authority to dispense controlled substances in Utah, the State in which he holds his DEA registration.

The Controlled Substances Act defines the "[t]he term 'practitioner' [to] mean[] a physician * * * licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practice * * * to distribute, dispense, [or] administer * * * a controlled substance in the course of professional practice or research." 21 U.S.C. 802(21). Moreover, under 21 U.S.C. 823(f), "[t]he Attorney General shall register practitioners * * * to dispense * * * controlled substances * * * if the applicant is authorized to dispense * * * controlled substances under the laws of the State in which he practices." DEA has therefore repeatedly held that holding state authority is an essential requirement for obtaining a registration and maintaining an existing one. *See David W. Wang,* 72 FR 54297, 54298 (2007); *Sheran Arden Yeates,* 71 FR 39130, 39131 (2006); *Dominick A. Ricci,* 58 FR 51104, 51105 (1993); *Bobby Watts,* 53 FR 11919, 11920 (1988); *see also* 21 U.S.C. 824(a)(3) (authorizing revocation "upon a finding that the registrant * * * has had his State license or registration suspended, revoked, or denied by competent State authority and is no longer authorized by State law to engage in the * * * dispensing of controlled substances").

As the Final Order of the Utah DOPL makes clear, Respondent does not possess authority under Utah law to dispense controlled substances. Because he does not meet this requirement, his application will be denied. *See* 21 U.S.C. 823(f).

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 Layfe Robert Anthony, M.D., for a DEA Certificate of Registration as a practitioner be, and it hereby is, denied. This Order is effective May 11, 2011.

Dated: April 1, 2011.

Michele M. Leonhart,

Administrator.

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issuing controlled substance prescriptions "on forms which falsely identified his address." *Id.* at 21 & 24.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 07–20]

Mark De La Lama, P.A.; Denial of Application

On January 16, 2007, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Mark De La Lama (Respondent), of Phoenix, Arizona. The Show Cause Order proposed the denial of Respondent's application for a DEA Certificate of Registration as a mid-level practitioner (*i.e.,* physician assistant) on various grounds.

Specifically, the Show Cause Order made four major allegations against Respondent. First, the Order alleged that Respondent's former DEA registration had expired on June 30, 2003, but that Respondent had continued writing prescriptions for controlled substances after that date. ALJ Ex. 1, at 1 & 3. Next, noting that as a condition of his initial registration Respondent had entered into a Memorandum of Agreement (MOA) with the Agency, the Order alleged that Respondent had violated the MOA in two ways: First, by failing to produce the log of his controlled substance prescriptions which he was required to maintain when DEA Diversion Investigators (DIs) visited his practice premises on April 13, 2005, and; second, by failing to report two changes of his practice location. *Id.* at 1, 2–3. Finally, the Order alleged that on November 21, 2004, Respondent submitted a new application for a registration which he falsified by failing to disclose his April 1992 and October 1994 felony convictions for offenses related to controlled substances, as well as the existence of the MOA. *Id.* at 3.

Respondent, through his counsel, requested a hearing. The matter was assigned to a DEA Administrative Law Judge (ALJ), who conducted a hearing on January 16, 2008, in Phoenix, Arizona. ALJ at 2. Both parties called witnesses to testify and introduced documentary evidence into the record. Following the hearing, both parties filed briefs containing their proposed findings of fact, conclusions of law and argument. *Id.*

On April 2, 2009, the ALJ issued her Recommended Decision. Therein, the ALJ concluded that Respondent "knowingly issued prescriptions for controlled substances using an expired DEA registration number over a span of nearly two years" but that the "lack of evidence that Respondent issued prescriptions for other than a legitimate purpose * * * weigh[s] in favor of a finding that Respondent's registration would not be inconsistent with the public interest." *Id.* at 26.

The ALJ also found that Respondent's conviction record for two felonies under Arizona law involving controlled substances weighed "in favor of a finding that Respondent's registration would be inconsistent with the public interest." *Id.* at 27. Based on his failure to disclose these two felonies on his November 21, 2004 application, the ALJ further found that Respondent materially falsified his application but concluded that his conduct was only negligent because an office manager had completed the form for him. *Id.* at 28–29. The ALJ credited "Respondent's testimony and * * * his expressions of regret and recognition of his wrongdoing on this specific point, and * * * therefore conclude[d] that his material falsification in the 2004 application [did] not warrant denying his application." *Id.* at 30.

Next, the ALJ found "that Respondent failed to adhere to certain requirements contained" in a Memorandum of Agreement (MOA) which he was required to enter into with the Agency as a condition of obtaining a registration. *Id.* More specifically, Respondent "failed to maintain a log of all controlled substances that he prescribed as of the date of the April 2005 site visit" and he failed to notify the Agency of his changes in the location of his practice address. *Id.* 30–31. The ALJ also found, however, that Respondent "equally accepts responsibility for what went wrong[ ] and has demonstrated a commitment to cooperate with DEA in the future." *Id.* at 32. Moreover, while the ALJ noted that Respondent had been convicted (in 1985) in Thailand of possession and attempted smuggling of marijuana, as well as a more recent conviction for driving under the influence, the ALJ also noted that Respondent was then practicing "at a clinic that serves a primarily underserved and underinsured population" and that this is "an appropriate consideration in determining whether [his] application * * * should be granted." *Id.* at 33.

Based on his multiple convictions for controlled substances offenses and his "considerable difficulty [in] adhering to some of the requirements of the" MOA, the ALJ concluded that the Agency had "made out a prima facie case for denying [Respondent's] application." *Id.* The ALJ reasoned, however, that "[d]espite his criminal convictions involving controlled substances in the 1990s, Respondent appears to have put that period of his life behind him." *Id.* at 34.

In the ALJ's view, Respondent's "most recent conviction involving controlled substances occurred more than fifteen years ago [and] [s]ince that time, he has neither been implicated in nor been convicted of any other crime involving controlled substances [and] [t]he Government presented no evidence that the future would hold any differently." *Id.* Based on his "expression of remorse and his expressed willingness to comply with restrictions on his registration," the ALJ "conclude[d] that the public interest would best be served by granting Respondent a restricted registration" subject to four conditions. *Id.* These were that: (1) Respondent must comply with all Federal, State and local laws and regulations relating to controlled substances; (2) Respondent may not personally use controlled substances in any form or for any reason without a prescription issued by a duly licensed physician who possesses a valid DEA Certificate of Registration; (3) Respondent must permit DEA personnel to enter his practice location at any time during normal business hours, without prior notice, to verify compliance with all applicable laws and regulations relating to controlled substances, as well as with any or all restrictions imposed on Respondent as a condition of his registration with the DEA; and (4) Respondent must notify the DEA Phoenix Division, in writing, of any change of business address or employer. *Id.* at 34–35.

Neither party filed exceptions to the ALJ's decision. On May 7, 2009, the ALJ forwarded the record to me for a final agency action.

During the initial review of the record, it was noted that the Government had introduced into evidence—over Respondent's objection—a printout of a data compilation prepared by SearchPoint, a private entity, which purportedly listed the prescriptions Respondent issued between October 8, 2003 and May 23, 2005. The Government introduced this document, which is not a record required to be maintained under either federal or state law, to prove the allegations that Respondent had issued controlled substance prescriptions even after he knew his registration had expired and had done so even after being told to stop by DEA Investigators. Because Respondent's objection went to the foundation for admitting the compilation and the reliability of the information it contains, and the Government did not establish that the methods used to compile the data were sufficiently trustworthy, I remanded the case to the ALJ for further proceedings and specifically instructed the Government to address various questions as set forth in the remand order.[1] Following additional proceedings, the ALJ forwarded the record back to me for final agency action.

Having considered the entire record, I hereby issue this Decision and Final Order. I agree with the ALJ's conclusions that: (1) Respondent materially falsified his application, (2) that he has a significant history of convictions relating to controlled substances; (3) that he failed to meet the MOA's requirements with respect to both his proper keeping of a log and his obligation to notify the Agency of any changes in his practice location.[2] As the ALJ recognized, these findings establish a *prima facie* case for the denial of his application.

However, I reject the ALJ's conclusion that Respondent's employment at a clinic that serves an underserved population is "an appropriate consideration in determining whether [his] application * * * should be granted." ALJ at 33; *see also Gregory D. Owens,* 74 FR 36751, 36756–57 (2009) (rejecting consideration of socioeconomic status of practitioner's patients as appropriate consideration under the CSA). Moreover, while I do not reject the ALJ's findings that Respondent has accepted responsibility for his misconduct, I reject her proposed sanction because it clearly rests on a fundamental misunderstanding as to the scope of permissible sanctions under the CSA. Given the circumstances of this matter, I conclude that Respondent's application should be denied at this time.

The Reliability of the SearchPoint Data Compilation

Before proceeding to make factual findings, it is necessary to resolve the issue of whether the ALJ properly admitted—over Respondent's objection that the Government had not laid a proper foundation—Government Exhibit 8, which it represents to be a data compilation listing the prescriptions Respondent issued between October 8, 2003 and May 23, 2005.[3] The Government argues that this exhibit showed that Respondent had issued controlled substance prescriptions not only following the expiration of his registration, but also after he knew it had expired and even after he was told by DEA Investigators to stop doing so.[4] Gov. Proposed Findings at 7–8, 10–11. The ALJ relied on this evidence, in part, in her decision.

Under the Administrative Procedure Act (APA), an Order must be "supported by and in accordance with the reliable, probative and substantial evidence." 5 U.S.C. 556(d). While the Agency's decision may be based on hearsay evidence, *see Richardson* v. *Perales,* 402 U.S. 389, 410 (1971), such evidence must still be reliable.

The compilation is not, however, a record maintained by a government agency. Nor is it a record which is required to be maintained under either federal or state law. Moreover, on reviewing the compilation, there appeared to be various discrepancies which called into question the data's reliability. As I noted in the remand order, this Office is unaware of any judicial decisions either admitting or excluding similar data compilations prepared by SearchPoint.

At the hearing, a DI testified that prescription information is entered by a pharmacy into a computer which is then collected and sent to SearchPoint. Tr. 43. The DI did not, however, explain the basis of his knowledge. Moreover, the record did not establish the procedures or methods used by the pharmacies in entering the information, when the information is entered, whether either the pharmacies or SearchPoint have any procedures to verify the accuracy of the information, whether the data is properly secured, and whether there are procedures to protect the data from manipulation. *Cf. McCormick on Evidence* § 314, at 886 (3d ed. 1984).

[1] To make clear, I remanded the case because there was no prior Agency decision addressing the admissibility of data compilations prepared by private entities.

[2] Under the express terms of the MOA, Respondent agreed to surrender his registration without issuance of an Order to Show Cause in the event that he failed to comply with the MOA. GX 3, at 3. Also, a violation of the MOA's terms would "result in the initiation of proceedings to revoke" Respondent's registration. *Id.*

[3] The ALJ overruled the objection after determining that the Exhibit had been provided to Respondent in advance of the hearing even though Respondent's counsel had objected on grounds of lack of foundation and that "we have no way of determining the accuracy of the information as set forth herein." Tr. 66. While under the Agency's regulation, "[t]he authenticity of all documents submitted in advance [is] deemed admitted unless written objection thereto is filed with the presiding officer," 21 CFR 1316.59(c), there is no such rule applicable to objections based on a lack of foundation. The ALJ apparently confused these two independent grounds for objecting to the admission of evidence.

[4] Notably, the Government did not introduce into evidence either copies of any prescriptions Respondent wrote during this period, or pharmacy dispensing logs, even though such evidence should have been readily obtainable (as a pharmacy is required to keep such records for two years, *see* 21 CFR1304.04(a) and 1304.22(c)), and is what the Government customarily uses in these proceedings to establish that a practitioner wrote unlawful prescriptions.

The record also did not establish whether a prescription that was signed by both Respondent and a supervising physician (which was one of Respondent's defenses to the allegation that he continued to prescribe even after he realized his registration had expired) would be attributed to Respondent or the physician. Nor did the record establish why, where refills were authorized by a single prescription, the printout provided the same date for the date the prescription was written and the date it was dispensed.

Because the record did not adequately establish the procedures or methods used to compile this database and that the compilation is sufficiently trustworthy so as to satisfy the APA's requirement that the evidence be reliable, I remanded the case to the ALJ with instructions to address these various concerns. I also expressly ordered that the questions "must be addressed by a witness who has personal knowledge of the procedures and methods used by Searchpoint." Remand Order at 3.

On remand, the Government submitted an affidavit of the same Diversion Investigator whose testimony I previously found to be inadequate for establishing that the SearchPoint data is reliable. From his affidavit, it is clear that the DI lacks personal knowledge of the procedures and methods used by SearchPoint. *See* Affidavit of Miguel Rodriguez.

This, by itself, is reason to conclude that the Government has failed to comply with the remand order. However, even in his affidavit, the DI offered no evidence which establishes that the SearchPoint data is reliable. To the contrary, the DI explained that:

> [t]he accuracy and authenticity of the data was only as good as the accuracy of the pharmacy reporting. It was stipulated to all DEA investigators, that SearchPoint was only *a pointing tool* and the data provided by SearchPoint *was to be verified against actual records that the pharmacy,* distributor, [or] practitioner was required to maintain by current regulations and laws."

Id. at 4 (emphasis added).

The DI further acknowledged that he "did not verify the information found during the query of the SearchPoint database prior to meeting with [Respondent] on April 13, 2005." *Id.* at 4–5. (Indeed, it is apparent that the DIs did not verify the information even after meeting with Respondent as there are no "actual records" in evidence.) The DI's statement that the SearchPoint data was only to be used as a "pointing tool" begs the question of why the actual pharmacy (or Respondent's patient) records were never obtained.

Based on the DI's assertion that the SearchPoint database was "a valuable tool in DEA's investigative efforts," *id.* at 5, "the Government respectfully request[ed] an additional finding that the SearchPoint data proved useful in DEA's investigation of Respondent, and helped further the objectives of DEA's investigation." Gov't Memorandum on Remand at 2. Contrary to the Government's understanding, whether the SearchPoint data proved useful in its investigation is not material to the resolution of any issue in this proceeding.

As the Government's brief makes clear, determining the extent of Respondent's issuance of prescriptions after his registration expired and assessing his culpability in doing so is one of the central issues in this matter. Given that there was no clear agency precedent addressing the admissibility of similar data compilations, this proceeding was remanded to determine whether the SearchPoint data was sufficiently reliable to prove that Respondent had continued to issue controlled substance prescriptions not only after he became aware that his registration had expired, but also after he was told by a DI to stop doing so.

Notwithstanding that the remand order clearly stated what the Government was required to show to establish that this evidence is reliable, it failed to do so. Because the Government failed to comply with the remand order and offers no valid excuse for its failure to do so, I conclude that the SearchPoint compilation is not competent evidence and should have been excluded. *See* 21 CFR 1316.59(a) ("The presiding officer shall admit only evidence that is competent, relevant, material and not unduly repetitious."). Accordingly, as ultimate factfinder, I do not base any of my findings on it.

Findings

Respondent is a physician assistant, who is licensed by the Arizona Regulatory Board of Physicians Assistants (The Board). GXs 6 & 7. At the time of the hearing, Respondent was 49 years of age. Tr. 286.

Respondent obtained a Bachelor of Science degree in human biology in 1997 and a Master's degree in physician assistant studies in October 1999. *Id.* at 208. After obtaining his state license, Respondent commenced working as a physician assistant; his duties involve performing physical exams, making diagnoses, treating patients, interpreting test results, and ordering diagnostic tests and studies. *Id.*

On October 26, 2000, Respondent applied for a DEA registration to handle controlled substances in Schedules II through V as a mid-level practitioner. GX 2. On the application, Respondent was required to answer four "liability questions"; the questions included whether the applicant had ever been convicted of an offense related to controlled substances under either federal or state law. *Id.* at 2.

Respondent answered in the affirmative and provided an explanation of the circumstances surrounding a 1992 marijuana conviction. *Id.* Respondent wrote that in 1989 or 1990, a friend he met in karate class was involved in "selling dope" and that Respondent "made the horrible mistake of trying to make a 'fast buck.'" *Id.* Respondent also stated on the application that "I entered guilty pleas in 1992 and have never violated any of the terms of my probation." *Id.*

Respondent also stated on the application that his "criminal convictions were expunged by the Maricopa County Superior Court in 1999," based on the recommendation of his probation officer. *Id.* He also "regret[ted] this experience in [his] life" and that his "goal was to be the best P.A. and father I can be." *Id.*

On February 12, 2001, the Agency granted Respondent's application. GX 1. However, because of his prior conviction, the Agency issued him a restricted registration; as a condition of his registration, Respondent was required to enter into a Memorandum of Agreement (MOA), which imposed various conditions on his registration. Tr. 19; GX 3.

The MOA further detailed Respondent's drug-related offenses, which included two other drug convictions, one of which should clearly have been disclosed on his application, but was not. On May 3, 1985, Respondent was convicted in Bangkok, Thailand for "Possession and Attempted Smuggling" of approximately 145 grams of marijuana. GX 3, at 1. The court suspended the 21-month sentence, and Respondent paid a fine and completed two years of probation. *Id.*

On or about April 10, 1992, Respondent entered into a plea agreement in which he pled guilty to "Attempted[] Possession, Use, Production, Sale and Transportation" of approximately eight pounds of marijuana, a class 3 felony under Arizona law. *Id.* Respondent paid a fine, was jailed for two months, and was placed on five years' probation.[5] *Id.*

[5] On June 16, 1999, the Maricopa County Superior Court vacated the judgment of guilt and restored Respondent's civil rights. *Id.* at 2. This is the felony that he listed on his application in 2000.

With respect to this incident, Respondent maintained at the hearing that he "was approached by somebody" and ended up being "a fall guy." Tr. 284.

On October 24, 1994, Respondent was found guilty of "Conspiracy to Transfer, Sell or Possess" a narcotic drug, a class 2 felony under Arizona law, based on his involvement in a conspiracy to illegally import cocaine from Panama to the United States. GX 3, at 2. Respondent was fined and sentenced to seven years' probation, but the probation was subsequently reduced.[6] *Id.* With respect to this conviction, Respondent maintained at the hearing that he was not "directly involved" in the conspiracy because he only "had phone conversations with the particular individual," but he nevertheless pled guilty. *Id.* at 288–90.

Respondent did not disclose this conviction on his initial application. GX 2, at 2; Tr. 293. When questioned as to why, Respondent stated that he "suppose[d]" that it was because of "inadvertence" on his part and added that "[i]t was all at the same time," apparently referring to the marijuana distribution offense. Tr. 293.

As found above, as a condition of his registration, Respondent entered into an MOA, under which he agreed to comply with various conditions. The MOA was to remain in effect for five years from the date of signing, January 25, 2001, during which time the DEA would be able to monitor Respondent's handling of controlled substances. Tr. 115–16; GX 3, at 2.

As relevant to the allegations in this proceeding, Respondent agreed "to maintain a log for five years, which will list all controlled substances that he prescribes." GX 3, at 2. The log was "subject to inspection by DEA for five years from the date" the MOA was "fully executed," which was January 30, 2001. *Id.* at 2–3.

Second, Respondent agreed "that DEA personnel may enter his place of practice at any time during regular business hours, without prior notice, to verify compliance" with the MOA. *Id.* at 3. Finally, Respondent agreed "to notify the DEA Phoenix Division prior to transferring his DEA Certificate of Registration to another address within the state of Arizona or to another state." *Id.* In the MOA, Respondent indicated that he would be registered at the location of 3201 West Peoria Avenue, Suite A–202, Phoenix, Arizona. *Id.* at 1.

In October 2000, Respondent began working as a physician assistant under the supervision of a Dr. John Curtin, at the above address. Tr. 223. Sometime thereafter, Respondent contracted pneumonia and missed substantial time from work; upon his return, his hours were reduced. *Id.* at 224. Consequently, in 2001 or 2002, Respondent left this position and went to work for William Zachow, D.O., who owned 21st Century Family Medicine (21st Century), 6707 North 19th Ave., Suite 201, Phoenix, Arizona. *Id.* at 167–68, 224. Respondent did not notify DEA of this change of practice address, as required by the MOA.[7] Tr. 38–39.

As part of Respondent's employment agreement at 21st Century, the clinic was to handle matters related to his licensing fees, his malpractice coverage and his DEA registration. *Id.* at 224. Specifically, Sonia Zachow, Dr. Zachow's wife, "would take care of the fees and all the licensing and the DEA." *Id.* at 224–25. Respondent testified that this was a verbal agreement, as it had originally been with his first employer, Dr. John Curtin, and that he trusted Dr. Zachow to honor the agreement. *Id.* at 219. Respondent testified that "[f]rom my understanding, all my mail went to [Sonia Zachow] and through her. I didn't receive any." *Id.* at 225. In particular, Respondent testified that he never received a notification from DEA that his registration would expire after June 30, 2003. *Id.* Given that he had not notified the Agency of his new address, this is hardly surprising.

Shirley Reigle, a medical assistant at 21st Century, testified that she was employed at the clinic when Respondent was hired and that she worked with Respondent for four or five years. *Id.* at 168, 193. Ms. Reigle testified that she managed the "back office," coordinating the activities of the medical assistants, while Sonia Zachow managed the "front office," or business office. *Id.* at 169–71. Mrs. Zachow's responsibilities included the renewal of the licenses and DEA registrations held by the clinic's physicians and physician assistants, the renewal of insurance coverage and the billing of insurance claims. *Id.* at 171, 174, 176. According to Ms. Reigle, Mrs. Zachow's responsibilities further included notifying the DEA if a physician or physician assistant moved his or her location of practice. *Id.* at 188. However, in one instance prior to Respondent's employment at 21st Century, Ms. Reigle tried to induce Mrs. Zachow to give notice of a move but ended up having to provide the information to DEA herself. *Id.* at 204–05.

Respondent's DEA registration expired June 30, 2003. *Id.* at 42; GX 1. According to Ms. Reigle, sometime in late 2003, Mrs. Zachow entered the office that Ms. Reigle shared with Respondent and threw a bill from the DEA onto Respondent's desk, saying, "Why should I pay his DEA license when we're selling the practice." Tr. 176–77, 181. Ms. Reigle testified that she believed that Respondent "had gone for the day" and that, when she told Respondent about the incident later and he went to his desk to look, the bill was no longer on his desk. *Id.* at 177, 199. While Ms. Reigle testified that she told Respondent about the incident, he apparently took no action to determine whether he still held a valid registration.

Respondent testified that he did not receive notice that his registration required renewal and that, had he known, he would not have continued to practice without it. *Id.* at 225. Respondent admitted, however, that at the time he received his registration he knew it was subject to renewal in three years. *Id.* at 301. He further asserted that he did not keep track of the time or display his registration certificate and that he expected the office manager to handle matters pertaining to his licenses, as that was done for all incoming health care providers. *Id.* Respondent did, however, acknowledge that he was ultimately responsible for renewing his registration. *Id.* at 220.

Respondent left 21st Century sometime between July and October 2004, when Dr. Zachow sold the clinic.[8] *Id.* at 217. Respondent began practicing at the 51st Avenue Clinic (51st Avenue), which is located at 4700 North 51st Street, Suite 6, in Phoenix. *Id.;* GX 4, at 1.[9]

When the clinic did not offer him adequate hours, Respondent resumed

[6] The Superior Court also apparently vacated this conviction in 1999, when it restored Respondent's civil rights. Tr. 210.

[7] Respondent also testified that the year 2001 was a difficult year: In May his father fell from a roof and was hospitalized for 21 days with a brain hemorrhage before he finally died; Respondent took in three more dependents into his household as a result of his father's death; later that year, Respondent developed pneumonia, and when he returned to work his employer noticed he was depressed and referred him to counseling; then the national crisis of September 11, 2001 happened. Tr. 220–221. Respondent testified that "there was a lot of stuff that happened in 2001 that I think I was a little bit confused, just overwhelm[ed]." *Id.* at 221. While this sequence of events may have overwhelmed Respondent, and provide some basis for excusing his failure to notify the Agency of his having changed his location, it is not a credible explanation for his failure to renew his registration, which did not expire until June 30, 2003.

[8] As was much of his testimony regarding the dates of various events, Respondent's testimony as to the date when he left 21st Century and commenced working at the 51st Avenue clinic was vague.

[9] Respondent used the address of this clinic on his 2004 application. GX 4.

working on a part-time base at 21st Century and split his time between the two clinics. Tr. 217–18. Sometime in October 2004, Respondent received a letter from the Arizona Physician's Assistants Board notifying him that his "license had lapsed [on] October 1, 2004." GX 9, at 4.

Respondent testified that during the period in which he moved to the new practice, pharmacies were not honoring the prescriptions he wrote at his new employer, and that his "office was getting calls for the prescriptions that [he] had been writing, and they were talking about a DEA number." Tr. 226–27. Notwithstanding the phone calls, Respondent maintained that he did not know that the registration had "lapsed" until three or four months later when, in November 2004 or early 2005, he was "contacted by DEA." *Id.* at 226–27. In November 2004, Ms. Muniz, the office manager at 51st Avenue, told Respondent that he needed to reapply for a DEA registration.[10] *Id.* at 228.

According to Respondent, Ms. Muniz filled out the application for him and showed him only the signature page, which he signed without reviewing. *Id.* at 228–29, 262–63, 309–10. As with his previous application, the form asked Respondent whether he had "ever been convicted of a crime in connection with controlled substances under state or federal law?" GX 4, at 1; ALJ Ex. 3, at 3. The "no" answer was circled on the application. GX 4, at 1. Moreover, Respondent left blank the box which the form provided for explaining a "yes" answer to this question, and which is on the same page as the signature block. *Id.* at 2. The application was then submitted.

As to why he did not disclose his convictions, Respondent testified: "I was busy. I was probably seeing 50 patients a day. I was trying to make an impression." Tr. 228. According to Respondent, had Ms. Muniz given him the entire application, he would have given a detailed explanation and an answer of "yes" to the liability question, just as he had done on his October 2000 application. *Id.* at 229.

[10] In a letter he faxed to a DI on April 24, 2005, Respondent indicated that in October of 2004, he "received a letter stating that my P.A. license had expired" and that after "doing some investigation, it turn[ed] out [that] my fees had not been paid." GX 9, at 1. Sometime around the time that he got his state license reinstated, he "got a call from the former office manager stating that I had better check up on my malpractice fees. It turn[ed] out those had not been paid in over a year." *Id.* Moreover, in the same October time period, his new clinic "was getting calls back from the pharmacy saying that my DEA license was no longer valid" but that he did not think too much about it at first as "I didn't know that the license could expire." *Id.* at 2.

The ALJ specifically credited Respondent's testimony that he would not have provided a "no" answer "had he personally filled out the form" and that "he would have detailed the explanation of his past conduct as he had done in 2000." ALJ at 29. The ALJ further credited Respondent's "expressions of regret and recognition of his wrongdoing" in submitting the application. *Id.* at 30. The Government did not except to these findings.

It is undisputed that after filing his application, Respondent continued to write prescriptions for controlled substances under his expired registration even though he then clearly knew that it had expired and did so through at least March 2005. *See* GX 9, at 4; *see also* Resp. Prop. Findings at 6–7. Respondent offered two main (and somewhat inconsistent) explanations for why he continued to write prescriptions during this period.

First, in a written statement he provided to an Agency investigator in April 2005, Respondent claimed that "after reapplying" there was "some confusion * * * as to what was going on at that time, some months went by and [he] was informed by the clinic's office manager that she had taken care of everything and it was okay to write again." GX 9, at 4. Continuing, Respondent explained that Ms. Muniz had contacted someone "at DEA headquarters and he had informed her that we had filled out the incorrect application and our money had been posted to the wrong account, he said he would fax over the correct application to be filled out immediately and faxed back." *Id.* Respondent maintained that employees had said that "the money would be posted to the correct account and this would make the license active at this point." *Id.* Respondent faxed in the new application on February 17, 2005. *Id.*

Respondent further asserted that he "wrote very few prescriptions during this time [when he] was waiting for a copy of the new license." *Id.* According to Respondent, "[a]fter several weeks of not receiving [the] paperwork[,] we called again and were informed that there was a problem." *Id.* Respondent added that "[a]t this time I discontinued completely and left the controlled substances, the few we do write up to the responsibility of my supervising physicians." *Id.* at 5. Finally, Respondent claimed that while he could not "recall the very last prescription I wrote, it probably was over a month or two ago and was some cough syrup with codeine as I wrote very little in the first place." *Id.*

Second, in his testimony, Respondent further claimed that he "was getting co-signatures on the prescriptions if I did need to write or just having them written altogether by a supervising physician." Tr. 230. Respondent explained that the co-signed prescriptions would be "[o]ne prescription, my name and the doctor's name, usually above mine." *Id.* at 231. Respondent also asserted that the pharmacy "might have run it [the prescription] as my DEA, but actually the doctor, the supervising physician, it was under his DEA as well if his signature" was on the prescription. *Id.* Respondent further asserted that he had "some copies" available that would show that his prescriptions were being co-signed. *Id.*

Respondent submitted a letter (which is unsworn) dated April 22, 2005 written by Ms. Muniz, Director of Operations for the 51st Ave. Family Clinic. RX 8. According to the letter, Respondent submitted a renewal application sometime around December 3, 2004, when the payment for the application fee cleared. *Id.* However, after several months, Respondent had still not gotten his registration. *Id.* According to Ms. Muniz, she then called DEA Headquarters and was told that Respondent had submitted the wrong form. *Id.* The employee at DEA Headquarters then faxed over the correct form which Respondent then submitted. *Id.* According to Ms. Muniz, the employee told her that he would post the previous payment to the correct account and this would activate Respondent's registration. *Id.* However, according to an affidavit of a DEA Diversion Investigator, "there is no record of" Respondent's having submitted an application after November 21, 2004. Affidavit of Miguel Rodriguez, at 6.

Based on Respondent's "no" answer on his 2004 application to the liability question regarding whether he had any prior convictions for controlled substances offenses, a DI commenced an investigation. Tr. 93. The DI reviewed the records from the Agency's prior investigation, police reports and the MOA. *Id.* at 93–95. He also learned that, in September 2003, Respondent had been arrested in Florida for a hit-and-run incident while driving under the influence.[11] *Id.* at 103.

[11] There was no evidence presented that Respondent was under the influence of a controlled substance at the time of the incident. Tr. 256. Moreover, there is no evidence in this record that Respondent has recently abused controlled substances. I therefore conclude that the incident

Continued

Using Respondent's registration number, the DI also conducted a search of Respondent's controlled substance prescriptions using the SearchPoint database. *Id.* at 42–44, 76. The data indicated that Respondent had written controlled substance prescriptions after the expiration of his registration (June 30, 2003). *Id.* at 42–43. However, the DI testified that after reviewing the data, he did not have any concerns about Respondent's prescribing other than that he lacked a registration. Tr. 152.

On April 13, 2005, as part of his investigation of Respondent's application, the DI and his senior partner visited Respondent at the 51st Avenue clinic, which was the address Respondent had given on his application. Tr. 30–31. However, this address was different from Respondent's address of record on file with the Agency, as Respondent had not notified the Agency that he had changed his practice location and had therefore violated the MOA. *Id.* at 31.

According to the DI, Respondent was not authorized to handle controlled substances at the 51st Avenue clinic. *Id.* at 33. The DI testified that, although failing to notify DEA of a change of address is not typically the sole basis for revoking a DEA registration, Respondent's failure to comply with the address-change provision of the MOA gave cause for particular concern. *Id.* at 109. However, the Government produced no evidence that Respondent had done anything other than write prescriptions at this address.

During the visit, the DI did not observe Respondent working under the supervision of a physician, and Respondent did not inform him or his partner that he was working under physician supervision. *Id.* at 31–32. The DIs then asked to inspect the log which Respondent was required to maintain under the MOA. *Id.* at 33. Respondent left the room and returned with a box containing an assortment of papers and several folders in no particular order. *Id.* at 33–34. Respondent partially attributed the disorganization of his "log" to the fact that he was in the process of moving into a new practice while continuing to work part-time at the other such that each location had its own records. *Id.* at 327. Yet, at this point, he had been at 51st Avenue clinic for at least six months.

According to the DI, his partner examined the contents of the box and asked whether Respondent had records more recent than those for the year 2003. *Id.* at 35–36, 124–25, 160–61. Respondent answered that he could "put something together," thus indicating that he was not currently keeping a log. *Id.* at 36, 125. However, the DIs did not take the box to copy the contents and "never asked for a copy." *Id.* at 249, 251. Respondent later testified that "I had it together and I'd have produced—I even took a ledger and * * * copied them all down so I did have a log book of the individual entries."[12] *Id.* at 251.

In a subsequent conversation, Respondent offered the material to the DI to which the latter responded: "'No, I'll give [the letters] you have already provided to me to Washington and it will go from there.'" *Id.* The DI admitted that he and his partner did not ask for copies of the materials in the box and did not offer Respondent the option to submit later the materials that he would gather together. *Id.* at 128.

Respondent testified that he had photocopied his notes of "patient encounters," which contained "the patient's name, date of birth, everything that we're seeing about that patient on that day and the reasonable explanation of why you would write a controlled substance for that patient on that day" as well as the controlled substance prescriptions he had written and then placed the copies in a manila folder in a box. *Id.* at 216, 235, 239. Respondent testified that he thought this would be "even better than a logbook." *Id.* at 216, 235. As he explained:

> Now I thought that if there was ever a question about my writing abilities and what I was doing, that I could pull up the patient encounter and show my reasonable action on why I would write a prescription on that particular day for that particular patient. So I thought it was actually better than a logbook.

Id. at 236.[13]

The parties disputed whether what Respondent had presented to the DIs constituted a log. According to the DI, a log is "something that we could easily obtain and review to check and verify [Respondent's] prescription habits," which would normally be a "bound book with notations" or a "binder with prescriptions." Tr. 34–35. The DI testified that he did not consider the records in the box to be "easily reviewable." *Id.* at 36. However, he later conceded that the MOA did not specify what format the log was to be maintained in and that the information he sought could be obtained from the copies of the prescriptions. *Id.* at 36, 122.

Respondent testified that he "[p]robably" did not "completely" understand the MOA's requirement. *Id.* at 215. However, he also testified that "[a] log is actually a journal reading; it's a journal." *Id.* at 321. Respondent then testified that he thought "that a patient list was even better [and] was the same thing as a log book." *Id.* He also maintained that "there was nothing in the [MOA] that told me how * * * a patient log book should look," but then acknowledged that he never inquired of the Agency what the log should consist of "[b]ecause [he] thought that from what [he] had seen with other physicians, what they used was a photo-a three- or double—you know, the two-sided prescriptions where you just get a copy of it, that's what I'd seen." *Id.* at 322.

Respondent further testified that, while initially he kept the copies of prescriptions and patient encounters in a box in the office in chronological order, when he moved from 21st Century to 51st Avenue in October 2004, he placed the records from the new location in another box. *Id.* at 217, 237. Thus, at the meeting on April 13, 2005, he was only able to produce a portion of the prescriptions he had written as the remaining records were at 21st Century. *Id.* at 235–38.

The DIs discussed with Respondent the MOA's requirement that he notify the DEA before transferring his registration to another address. *Id.* at 37; GX 3, at 3. Respondent told them that he was not sure whether he had notified the Agency of his most recent move, and he acknowledged that he had moved to 51st Avenue approximately six months earlier. Tr. 38–39. He also told the DIs that he had worked at 21st Century for four years prior to the move to 51st Avenue and that this address was also different from the address at which he had originally been registered. *Id.* at 38–39, 154; RXs 6 & 8. Respondent provided the DIs with two changes of address: 4700 North 51st Avenue, Suite 6, Phoenix, Arizona, and 1526 West Glendale Avenue, Suite 109, Phoenix, Arizona. Tr. 38–39. Although he testified that it was ultimately his responsibility to advise the DEA that he had changed his practice address, Respondent maintained that it had been the responsibility of Mrs. Zachow to do so. *Id.* at 188 & 190.

The DIs also discussed with Respondent the fact that his DEA

has little relevance to the issues in this proceeding and deem it unnecessary to make further findings.

[12] Copies of this document were apparently offered as Respondent's Exhibit 2. However, the Government objected to the admission of the exhibit on the ground that it was not timely exchanged, and the ALJ sustained the objection.

[13] At the hearing, Respondent attempted to enter copies of this "log" into evidence as Respondent's Exhibit 1, but the Government objected on the ground that the documents had not been timely provided to the Government. *Id.* at 242–43, 248. The ALJ's sustained the objection and rejected the evidence. *Id.* at 248.

registration had expired. Tr. 59. Respondent told them that he had learned that the registration had expired several months before their meeting. *Id.* at 59, 113–14. Respondent further told the investigators that the office manager (Sonia Zachow) had been responsible for renewing the registration and had failed to do so. *Id.* at 112, 114–15.

During the April 13, 2005 meeting, the DI's senior partner instructed Respondent to desist from writing prescriptions for controlled substances; Respondent agreed that he would not write prescriptions for controlled substances. *Id.* at 62–63, 78.

At the hearing, Respondent testified that he had complied with the DI's instruction. *Id.* at 345. More specifically, Respondent testified that "I've been compliant from the day when I said—when they told me you can't write controlled substances I've been—not written one." *Id.*

A DI testified that sometime after May 23, 2005, he conducted a second search of Respondent's DEA registration number on SearchPoint and found that Respondent had written controlled substance prescriptions after the April 13, 2005, meeting. Tr. 77. However, for reasons explained above, because the Government did not comply with the instructions in the remand order for establishing that the SearchPoint data is reliable, I conclude that the Government has not proved that Respondent violated the DI's order to stop writing prescriptions. I further find that the Government has failed to produce any reliable evidence rebutting Respondent's contention that he had his prescriptions co-signed by a supervising physician after he became aware that his registration had expired.[14]

At the hearing, Respondent testified that he was compliant with the MOA; that his work as a physicians assistant was difficult and stressful; that he had no training in office administration; and that he had learned how to be a "better professional" from this experience with his DEA registration expiring. Tr. 257–59.

Respondent testified that, although he currently works as a physicians assistant without writing controlled substance prescriptions, his lack of authority to do so significantly diminishes his employer clinic's ability to treat patients: he is the only health care provider at the current clinic and cannot prescribe drugs necessary to treat such common ailments as excessive weight, Attention Deficit Disorder/Attention Deficit-Hyperactivity Disorder, acute pain, acute anxiety attacks, and testosterone deficiencies. *Id.* at 267 & 278. If he cannot substitute a non-controlled substance, he must refer a patient who requires a controlled substance to a physician or another facility. *Id.* at 273.

According to Respondent, in around July 2005, his boss at the 51st Avenue clinic gave him two weeks to resolve the issues surrounding his DEA registration and told him he would lose his job if he did not do so because insurance companies use the DEA registration number as a tracking number for reimbursement. *Id.* at 259–60. Respondent subsequently lost his job at this clinic but subsequently gained employment at his current clinic. *Id.* at 260.

Respondent further testified that he had "made a lot of mistakes" and that he did not "plan on this happening again." *Id.* at 267. Respondent added that he could not "afford to make any mistakes in [his] life anymore," that he had "made plenty" and was "sorry" to have "made them" and was "remorseful." *Id.* at 268. He further stated that while "I made countless errors here * * * I've learned from them and I don't think I'll ever see a courtroom again." *Id.*

Discussion

Section 303(f) of the Controlled Substances Act (CSA) provides that an application for a practitioner's registration may be denied upon a determination "that the issuance of such registration would be inconsistent with the public interest." 21 U.S.C. 823(f). In making the public interest determination, the CSA requires that the following factors be considered:

(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.

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

Under DEA precedent, the various grounds for revocation or suspension of an existing registration which Congress enumerated in section 304(a), 21 U.S.C. 824(a), are also properly considered when deciding whether to grant or deny an application under section 303(f) because "'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.'" *Anthony D. Funches,* 64 FR 14267, 14268 (1999) (quoting *Kuen H. Chen,* 58 FR 65401, 65402 (1993)); *see also Alan R. Schankman,* 63 FR 45260 (1998). These include section 304(a)(1), which provides for the suspension or revocation of a registration in the event that the registrant "has materially falsified any application filed pursuant to or required by this subchapter." 21 U.S.C. 824(a)(1). Thus, the allegation that Respondent materially falsified his application is properly considered in this proceeding.

The Government bears the burden of proof in showing that the issuance of a registration is inconsistent with the public interest. 21 CFR 1301.44(d). However, where the Government has made out a *prima facie* case, the burden shifts to the applicant to "present[] sufficient mitigating evidence" to show why he can be entrusted with a new registration. *Medicine Shoppe-Jonesborough,* 73 FR 364, 387 (2008) (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 [his] actions and demonstrate that [he] 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); *Cuong Trong Tran,* 63 FR 64280, 62483 (1998); *Prince George Daniels,* 60 FR 62884, 62887 (1995).

Factor One—The Recommendation of the State Licensing Board

The Arizona Regulatory Board of Physician Assistants has made no recommendation in this matter as to whether Respondent's application should be granted. However, it is undisputed that Respondent holds a current Arizona Physician Assistant's license and possesses authority under

[14] The Government does not address whether this practice is even permissible under Arizona law.

State law to dispense controlled substances. While Respondent therefore meets an essential prerequisite for obtaining a registration under the CSA, 21 U.S.C. 823(f), DEA has held repeatedly that a practitioner's possession of State authority is not dispositive of the public interest determination. *See Mortimer B. Levin,* 55 FR 8209, 8210 (1990).

Factors Two, Three, and Four—Respondent's Experience in Dispensing Controlled Substances, Conviction Record Under Federal and State Laws for Offenses Related to the Manufacture, Distribution, or Dispensing of Controlled Substances, and Compliance With Applicable Laws Related to Controlled Substances

As found above, on two prior occasions, Respondent was convicted of offenses under Arizona law related to the distribution of both marijuana (in 1992) and cocaine (in 1994).[15] Subsequently, in 1999, both of these convictions were vacated upon his having successfully completed probation.

Given the obvious concerns raised by his prior criminal conduct, *see* GX 3, at 2; following Respondent's obtaining of his PA license, the Agency granted his application for a registration on the condition that he enter into the MOA, under which he agreed to comply with several conditions beyond those imposed by the CSA and DEA regulations. Of relevance here, Respondent agreed to maintain, for a period of five years, a log "list[ing] all controlled substances that he prescribes" which was also to "be subject to inspection * * * for five years." GX 3, at 3. In addition, Respondent "agree[d] to notify the DEA Phoenix Division prior to transferring his * * * [r]egistration to another address within the state of Arizona or to another state." *Id.*

As the ALJ found, Respondent did not comply with either condition. ALJ at 30–32. When asked to present his log, he provided a box which contained an assortment of papers and folders in no particular order, with some papers hanging out from the sides of the box. Moreover, the most recent records were for the year 2003.

While the meaning of the MOA provision seems clear, and Respondent eventually acknowledged that a log is "a journal," Tr. 321, even accepting Respondent's explanation that he was in compliance by compiling his notes of patient encounters and the controlled substance prescriptions, it undisputed that he did not have a complete record of his prescribing activities as he lacked records after the year 2003.[16] I therefore hold that he violated the MOA's log-keeping provision.

Moreover, while the MOA clearly stated that Respondent was required to notify the local DEA office prior to transferring his registration to another address, Respondent twice changed his practice location without notifying the Agency. Here again, Respondent violated the terms of the MOA. However, standing alone, Respondent's violations of the MOA would not warrant the denial of his application given his expression of remorse.

Alleged Violations of 21 U.S.C. 843(a)(2)

Under the CSA, it is "unlawful for any person knowingly or intentionally * * * to use in the * * * dispensing of a controlled substance * * * a registration number which is fictitious, revoked, suspended, *expired,* or issued to another person[.]" 21 U.S.C. 843(a)(2) (emphasis added). Doing so is a felony offense which is punishable by "a term of imprisonment of not more than 4 years, a fine under Title 18, or both." *Id.* at § 843(d)(1).

The ALJ found that that "is undisputed that Respondent issued prescriptions for controlled substances after his DEA registration expired in June 2003, and that he continued to do so even after submitting an application for a new registration." ALJ at 24. While apparently crediting Respondent's testimony that he was not aware that his registration expired "until late 2004," the ALJ concluded that "there is no doubt that he was aware of its expiration after that time, and that he therefore knowingly used an expired registration in violation of the statute when he continued to write prescriptions after late 2004." *Id.* (citing 21 U.S.C. 843(a)(2)). However, the ALJ rejected the Government's contention that Respondent issued prescriptions even after the April 2005 meeting during which a DI told him to stop. *Id.*

The Government apparently accepts Respondent's contention that he did not know that his registration had expired until sometime in the fall of 2004 when he applied for a new registration. *See* Gov. Br. 6 (Proposed Finding 11) ("Respondent testified that he was unaware that his DEA registration had expired and wasn't notified in writing or otherwise of the expiration.").[17] The Government's contention that Respondent violated 21 U.S.C. 843(a)(2) is therefore based on his having issued prescriptions even after he submitted his application and clearly knew that his registration had expired. *Id.* at 10. The Government further argues that "exacerbat[ing] his unlawful conduct, Respondent continued issuing prescriptions under his expired * * * registration after DEA investigators advised him against doing so during the * * * April 2005 inspection." *Id.* at 10–11.

To prove these allegations, the Government relied on a data compilation of his purported prescriptions, the reliability of which it failed to establish. As the DI candidly explained, this data "was only a pointing tool" and "was to be verified against the actual records that" a pharmacy or practitioner is "required to maintain" under the CSA and DEA's regulations. Inexplicably, the Government did not produce any reliable evidence showing the controlled substances prescriptions he authorized such as patient medical records, copies of the actual prescriptions, or pharmacy dispensing logs. In sum, the Government did not produce reliable evidence establishing the extent to which Respondent continued to prescribe controlled substances following the expiration of his registration.

It acknowledged that in a letter to one of the DIs, Respondent stated that he had resumed prescribing at some point following the submission of his application. Moreover, there is a degree of inconsistency between Respondent's contentions that: (1) His office manager had contacted someone at DEA Headquarters and been told that he could write again; and (2) that he had a supervising physician co-sign the prescriptions. Nonetheless, because there is no reliable proof establishing the specific prescriptions which Respondent wrote following his becoming aware that his registration had expired, and the Government does not dispute either the factual basis of his contention that he had his prescriptions co-signed or the legality of this practice, there is insufficient evidence to show that Respondent violated 21 U.S.C. 843(a)(2). I therefore reject the

[15] It is also noted that in 1985, Respondent was convicted in Thailand of the offense of Possession and Attempted Smuggling" of marijuana. While this conviction is not encompassed within factor three, it is properly considered under factor five.

[16] Respondent did not dispute that he prescribed after 2003.

[17] While the Government established that Respondent's registration expired on June 30, 2003, GX 1, it did not introduce into evidence a copy of the Certificate of Registration which was issued to him. Such certificates typically include the expiration date. Nor does the Government argue that proof of actual knowledge is not required to sustain a violation of 21 U.S.C. 843(a)(2).

Government's contention (and the ALJ's conclusion) that Respondent violated 21 U.S.C. 843(a)(2).

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

Under this factor, the ALJ considered the allegations that Respondent materially falsified his 2004 application and that he had been convicted of driving under the influence. ALJ at 27–33. She also deemed it appropriate to consider Respondent's "employment at a clinic that serves a primarily underserved and underinsured population." *Id.* at 33.[18]

The Material Falsification Allegation

As found above, on his 2004 application, Respondent answered "no" to the question: "Has the applicant ever been convicted of a crime in connection with controlled substances under state or federal law?" GX 4, at 1. Moreover, Respondent left blank the box which the application provided for explaining a "yes" answer. *Id.* at 2. By signing the application, Respondent "certif[ied] that the forgoing information furnished on [the] application [wa]s true and correct." *Id.*

Respondent does not dispute that he should have disclosed the two Arizona convictions on his application. Resp. Br. at 13 ("It seems obvious that the 2004 application should have included the same information regarding felony convictions that [the] 2000 application had."). Indeed, it cannot be disputed that his answer was false and materially so given that under the public interest standard, the Agency is required to consider, *inter alia,* both an "applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances," 21 U.S.C. 823(f)(3), and his "[c]ompliance with applicable State, Federal, or local laws relating to controlled substances." *Id.* § 823(f)(4). Given the statutory factors, it is clear that Respondent's false answer was "capable of influencing" the decision as to whether his application should be granted. *See Jackson,* 72 FR at 23852 (" 'The most common formulation' of the concept of materiality is that 'a concealment or misrepresentation is material if it "has a natural tendency to influence, or was capable of influencing, the decision of" the decisionmaking body to which it was addressed.' " (quoting *Kungys* v. *United States,* 485 U.S. 759, 770 (1988) (quoting *Weinstock* v. *United States,* 231 F.2d 699, 701 (DC Cir. 1956))).

That the Agency did not rely on Respondent's false statement and grant his application does not make the statement immaterial. *The Lawsons, Inc.,* 72 FR 74334, 74339 (2007) (quoting *United States* v. *Alemany Rivera,* 781 F.2d 229, 234 (1st Cir. 1985) ("It makes no difference that a specific falsification did not exert influence so long as it had the *capacity* to do so."); *United States* v. *Norris,* 749 F.2d 1116, 1121 (4th Cir. 1984) ("There is no requirement that the false statement influence or effect the decision making process of a department of the United States Government."). Nor does it matter that some employees of the Agency were previously aware of Respondent's criminal history. *See The Lawsons,* 72 FR at 74339 n.7.

Respondent nonetheless contends that he did not intentionally falsify the application, Resp. Br. at 13–14, and the ALJ credited his testimony that the office manager at the clinic, where he was then working, filled out the application for him and that he signed it in haste without carefully reviewing it. ALJ at 8. The ALJ also credited his testimony that if he had "personally filled out the form * * * he would have detailed the explanation of his past conduct as he had done in 2000." *Id.* at 29.

While I accept the ALJ's credibility findings, I reject her conclusion that Respondent was merely "negligent." *Id.* Notably, between the form's blocks for signing and printing one's name, the form stated: "I hereby certify that the forgoing information furnished on this application is true and correct." GX 4, at 2. Given the certification's location on the application, Respondent cannot credibly claim that he did not read it. Respondent's testimony simply begs the question of what information he thought he was certifying as being "true."

Likewise, the form's block for explaining his answers to the liability questions was on the same side as the signature and certification blocks. In addition, Respondent had previously completed an application in which he disclosed his criminal convictions; he likewise knew, based on the detailed recitation of his various drug-related offenses in the MOA (although he apparently rarely, if ever, reviewed the MOA), that these offenses were of particular concern to DEA. Respondent clearly had reason to know that he was required to disclose his criminal convictions to the Agency.

Finally, the ALJ gave insufficient consideration to the circumstances surrounding the 2004 renewal. Notably, this was not a routine renewal. Rather, at the time it was submitted, Respondent clearly knew that his registration had long since expired. And, notwithstanding his claim that he was a harried practitioner who was trying to make an impression with his employer by seeing numerous patients, reviewing the form for completeness would have taken no more than a few minutes.

I therefore conclude that Respondent deliberately failed to read the front of the form. As several courts have noted, deliberate avoidance is generally not a defense to an allegation of material misrepresentation. *United States* v. *Puente,* 982 F.2d 156, 159 (5th Cir. 1993) ("[A] defendant who deliberately avoids reading the form he is signing cannot avoid criminal sanctions for any false statements contained therein."); *Hanna* v. *Gonzales,* 128 Fed. Appx. 478, 480 (6th Cir. 2005) (rejecting alien's claim that he did not willfully misrepresent material fact because friend filled out application for him; having signed the application under oath, his "failure to apprise himself of the contents of this important document constituted deliberate avoidance—an act the law generally does not recognize as a defense to misrepresentation").

The ALJ failed to acknowledge this line of authority. Instead, she relied on several Agency decisions and reasoned that the "lack of intent to deceive is a relevant consideration in determining whether a registrant or applicant should possess a DEA registration." ALJ at 30 (quoting *Rosalind A. Cropper,* 66 FR 41040, 41048 (2001)). However, the cases cited by the ALJ are readily distinguishable. *See id.* (citing *Samuel Arnold,* 63 FR 8687 (1998); *Martha Hernandez,* 62 FR 61145 (1997)).

For instance, in *Cropper,* the physician was completely unaware of the underlying agency action which she had failed to disclose on her application. 66 FR at 41048. That is a far cry from this case as Respondent clearly knew that he had been previously convicted of two felony drug offenses in the Arizona courts.

In *Samuel Arnold,* a physician failed to disclose on his application a prior suspension of his state medical license based on misconduct which was not related to controlled substances. 63 FR at 8687. However, the Deputy Administrator found credible the testimony of two witnesses that Respondent had called a DEA Office on

[18] She also considered Respondent's violations of the MOA under this factor. I conclude, however that these violations are properly considered in assessing his experience in dispensing controlled substances. Moreover, as noted above, Respondent's 1985 conviction in the Thai courts for possession and attempting to smuggle marijuana is properly considered under this factor. However, it is noted that this conviction is now twenty-five years old.

a speaker phone to inquire as to whether he was required to disclose the suspension and was told by an Agency employee that he did not have to because his "license was no longer suspended." *Id.* at 8687–88. Here, however, Respondent makes no claim that in filling out the application he relied on erroneous advice from an Agency employee as to what he was required to disclose.

Of the cases cited by the ALJ, only *Martha Hernandez,* 62 FR 61145 (1997), and *Theodore Neujahr,* 65 FR 5680 (2000), provide any comfort to Respondent. In *Hernandez,* while my predecessor concluded that the practitioner's material falsifications in failing to disclose the suspension by two States of her medical licenses (for failing to pay her student loans, which she believed was not within the intent of the liability question) "indicate a careless disregard for attention to detail," he imposed only a reprimand and conditions on her registration. *Id.* at 61148. While my predecessor agreed that "this lack of connection to controlled substances [wa]s not dispositive of the matter," he concluded that it was "relevant in determining the appropriate remedy." *Id.* Here, by contrast, Respondent's falsifications involve his failure to disclose his convictions for controlled substances offenses and are clearly relevant in determining the appropriate sanction.[19] *See* 21 U.S.C. 823(f)(3).

The ALJ also relied on *Neujahr,* a case in which the Agency granted the application of practitioner, notwithstanding that he had he had materially falsified it, because he "acknowledged that he falsified his applications, he apparently regretted that conduct, and [the ALJ] believe[d] that he will not repeat it." ALJ at 30 & n.86 (quoting 65 FR at 5682). Subsequently in her decision, the ALJ reasoned that while the Government had "made out a *prima face* case for denying his application, * * * it is important to note that the [Agency's] decision whether to grant or deny an application for registration is a prospective, rather than a retrospective, determination." *Id.* at 34.

It is true that proceedings under section 303 and 304 of the CSA are remedial and not punitive. *See, e. g., Jackson,* 72 FR at 23853. However, contrary to the ALJ's understanding, the remedial nature of this proceeding does not preclude the Agency from considering the deterrent value of a sanction with respect to both the Respondent and others in setting the remedy. *See Southwood Pharmaceuticals, Inc.,* 72 FR 36487, 36504 (2007). As *Southwood* makes clear, "even when a proceeding serves a remedial purpose, an administrative agency can properly consider the need to deter others from engaging in similar acts." *Id.* (citing *Butz* v. *Glover Livestock Commission Co., Inc.,* 411 U.S. 182, 187–188 (1973) (upholding Agency's authority "to employ that sanction as in [its] judgment best serves to deter violations and achieve the objectives of [the] statute")). The ALJ, however, did not even acknowledge *Southwood*.

Contrary to the ALJ's conclusion that Respondent will conduct himself henceforth in a responsible fashion, *see* ALJ at 34, Respondent made a similar promise in the MOA when he agreed to "abide by its contents in good faith." GX 3, at 3. *See also ALRA Laboratories, Inc.* v. *DEA,* 54 F.3d 450, 452 (7th Cir. 1995) ("An agency rationally may conclude that past performance is the best predictor of future performance."). Respondent, however, then proceeded to ignore his obligations under the MOA.

Under these circumstances, granting Respondent's application subject to the restrictions proposed by the ALJ, which do no more than replicate the conditions imposed by the MOA, amounts to no sanction at all. In short, adopting the ALJ's proposed sanction would send the wrong message to both Respondent, who has demonstrated a disturbing lack of attention to the requirements of being a registrant, as well as other applicants/registrants, especially those who would submit an application without carefully reviewing it for completeness and truthfulness.

Accordingly, I conclude that Respondent's application should be denied. However, given Respondent's expression of remorse, I conclude that Respondent can re-apply for a new registration six months from the effective date of this Order. Provided that his application is not materially false and that he has committed no other acts which would warrant the denial of his application, the Agency will expeditiously grant his renewal application and issue him a new registration subject to the conditions of the 2001 MOA.[20]

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f), as well as 28 CFR 0.100(b) and 0.104, I order that the application of Mark De La Lama for a DEA Certificate of Registration as a mid-level practitioner be, and it hereby is, denied. This order is effective May 11, 2011.

Dated: April 1, 2011.

Michele M. Leonhart,

Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Glenn D. Krieger, M.D.; Denial of Application

On August 31, 2009, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Glenn D. Krieger, M.D. ("Applicant"), of West Bloomfield, Michigan. The Show Cause Order proposed the denial of Applicant's application for a DEA Certificate of Registration on the ground that his "registration would be inconsistent with the public interest as defined by 21 U.S.C. §§ 823(f) and 824(a)(4)." Show Cause Order, at 1.

More specifically, the Show Cause Order alleged that Applicant filed an

[19] Having reviewed the Agency's decision in *Neujahr,* I conclude that the case was wrongly decided because the respondent there did not fully address his misconduct, which included not only his failure to disclose his having surrendered his authority under Federal law to write prescriptions for schedule II controlled substances, but also his failure to disclose a State proceeding which placed his veterinary license on probation; at his DEA hearing, the respondent offered no explanation as to this separate act of material falsification. 65 FR at 5681. In *Neujahr,* the ALJ concluded that the respondent "apparently regretted that conduct." *Id.* at 5682. To make clear, the Agency should not have to guess as to whether one has accepted responsibility for his misconduct. A registrant/applicant's acceptance of responsibility must be clear and manifest.

[20] I place no weight on Respondent's DUI/Hit and Run conviction there being no evidence that he was under the influence of a controlled substance at the time. *See David E. Trawick,* 53 FR 5326, 5327 (1988) (noting that factor five encompasses "wrongful acts relating to controlled substances committed by a registrant outside of his professional practice but which relate to controlled substances").

The ALJ also opined that it is appropriate to consider Respondent's employment at a clinic that serves an "underserved and underinsured populations." ALJ at 33. However, I have previously rejected this reasoning noting that "[t]he public interest standard of 21 U.S.C. 823(f) is not a freewheeling inquiry but is guided by the five specific factors which Congress directed the Attorney General to consider [and that] consideration of the socioeconomic status of a practitioner's patient population is not mandated by the text of either 21 U.S.C. 823(f) or 824(a)(4), which focus primarily on the acts committed by a practitioner." *Gregory D. Owens,* 74 FR 36751, 36757 (2009). I further noted that such a rule is "unworkable," and "would inject a new level of complexity into already complex proceedings and take the Agency far afield of the purpose of the CSA's registration provisions, which is to prevent diversion." *Id.* at n.22. I therefore do not consider the issue.