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.

[FR Doc. 2011–8536 Filed 4–8–11; 8:45 am]

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[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.

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

application for a DEA registration on October 9, 2008. *Id.* The Order further alleged that on "June 28, 2007, July 19, 2007, and August 1, 2007," Applicant was subjected to random urine drug tests and tested positive for fentanyl, a Schedule II controlled substance,[1] although the drug had never been prescribed to him. *Id.* Relatedly, the Order alleged that on November 7, 2008, Applicant told DEA Investigators that he "obtained the fentanyl from patients who returned unused fentanyl to [him], because [he] was collecting pain medication to give as a donation to the Oakpointe Church's missionary project in Zambia, Africa." *Id.* The Order further alleged that DEA Investigators were subsequently "informed by Oakpointe Church executives that the church did not conduct any Zambian missionary projects in 2007, that the Zambian missionary projects of previous years did not collect donated controlled substances, and that [Applicant] did not participate in any of the Zambian missionary projects." *Id.* at 1–2. The Order then alleged that Applicant's "false statements to DEA investigators constituted both conduct which may threaten the public health and safety pursuant to 21 U.S.C. § 823(f)(5) and criminal acts pursuant to 18 U.S.C. 1001. *Id.* at 2.

Next, the Show Cause Order alleged that Applicant had previously held a DEA Certificate of Registration, BK4918528, which he "surrendered for cause on March 7, 2008." *Id.* The Order then alleged that "[b]etween March 7, 2008 and November 1, 2008," Applicant "issued approximately 435 prescriptions for controlled substances despite not having a valid DEA Certificate of Registration, in violation of 21 U.S.C. § 841(a)." *Id.* Finally, the Order alleged that Applicant's "violation[s] of Federal laws and regulations are inconsistent with the public interest." *Id.* (citing 21 U.S.C. 823(f) and 824(a)(4)).

The Show Cause Order also explained that Respondent had the right to request a hearing on the allegations or to submit a written statement in lieu of a hearing, the procedures for doing either, and the consequences for failing do so. *Id.* (citing 21 CFR 1301.43(c), (d), & (e)). On or about September 2, 2009, the Government attempted to serve Applicant with the Order by certified mail addressed to him at the address he provided in his application for a new registration. However, on or about September 11, 2009, the Post Office returned the Order as "not deliverable as addressed."

[1] *See* 21 CFR 1308.12(c)(9).

On or about September 25, 2009, DEA made a second attempt to serve Applicant with the Order by certified mail addressed to him at the address given on his application. Again, however, the Post Office returned the mailing as "not deliverable as addressed."

On or about September 16, 2009, DEA mailed a copy of the Show Cause Order to Applicant's counsel.[2] As evidenced by a signed return receipt card, Applicant's counsel received the letter on September 18, 2009.

On February 2, 2010, the Office of Administrative Law Judges received a letter from Applicant (dated Jan. 28, 2010). Therein, Applicant stated that "[a]round mid-October 2009, I received a letter from my attorney * * * that was supposed to contain a complete copy of the letter he received only a few days earlier. Due to several different miscommunications and difficulty with traveling due to expenses, I did not appear for the scheduled show cause on December 1, 2009. In spite of my absence, I am very interested in scheduling a show cause."

Upon receipt of this letter, the ALJ ordered that the Government provide evidence of the date of service of the Show Cause Order upon Applicant by February 19, 2010 and to file any motion to terminate based on his failure to timely request a hearing by the same date. Order Granting the Government's Motion to Terminate Proceedings, at 1. The Order further directed Applicant to file a responsive pleading by February 26, 2010. *Id.*

Thereafter, the Government timely filed a Motion to Terminate. Therein, it asserted that it "effected service of the OSC on Respondent's counsel via certified mail on or around September 18, 2009," that the Show Cause Order clearly set forth the procedures for requesting a hearing and the consequences for failing to do so, and that he did not request a hearing within 30 days of receiving the Order as required by DEA regulations. *Id.* at 2. Applicant did not file a response to the Government's motion.

The ALJ granted the Government's motion noting that Applicant did not contest the Government's representation that the Show Cause Order had been served on his legal counsel/agent on or about September 18, 2009, and that, in his letter requesting a hearing, Applicant had acknowledged that in mid-October 2009, he had received a document from his attorney "related to this proceeding and 'did not appear for the scheduled show cause hearing on December 1, 2009,'" which information was contained on the front page of the Show Cause Order. *Id.* at 2–3. Because Applicant did not request a hearing until "several months after effective service of the" Order, and did not offer good cause for his failure to do so, the ALJ concluded that he had waived his right to a hearing and terminated the proceeding. *Id.* at 3 (citing 21 CFR 1301.43). I adopt this finding.[3]

Thereafter, the investigative record was forwarded to me for final agency action. Based on relevant evidence contained in the record, I conclude that granting Respondent's application would be "inconsistent with the public interest." 21 U.S.C. 823(f). Accordingly, his application will be denied. I make the following findings of fact.

Findings

On October 9, 2008, Applicant filed an application for a DEA Certificate of Registration through DEA's Web site. The application is the subject of this proceeding.

Applicant previously held DEA Certificate of Registration BK4918528. On March 7, 2008, Respondent voluntarily surrendered this registration and executed a DEA Form 104, Voluntary Surrender of Controlled Substances Privileges (which his counsel signed as a witness). The form clearly stated that it provided "authority for the Administrator * * * to terminate and revoke my registration without an order to show cause, a hearing, or any other proceedings." In addition, the form stated: "I understand that I will not be permitted to * * * prescribe, or engage in any other controlled substance activities whatsoever, until such time as I am again properly registered."

According to a report obtained by an Agency Investigator from the Michigan

[2] Applicant's counsel had represented him during an interview with DEA Investigators on November 7, 2008.

[3] Respondent did not challenge whether the Government's mailing of the Show Cause Order to the lawyer who previously represented him constituted sufficient service. *See* 21 U.S.C. 824(c) ("Before taking action pursuant * * * to a denial of registration under section 823 of this title, the Attorney General shall serve upon the applicant * * * an order to show cause. * * * ."); *see also United States* v. *Ziegler Boat and Parts Co.,* 111 F.3d 878, 881 (Fed. Cir. 1997) ("The mere relationship between a defendant and his attorney does not, in itself, convey authority to accept service. * * * Even where an attorney exercises broad powers to represent a client in litigation, these powers of representation alone do not create a specific authority to receive service.") (citing numerous authorities). However, a challenge to the sufficiency of service is deemed waived if it is not raised in a party's first responsive pleading. *See Hemisphere X Biopharma, Inc.,* v. *Johannesburg Consol. Investments,* 553 F.3d 1351, 1360 (11th Cir. 2008). Accordingly, I hold that Respondent has waived any challenge to the sufficiency of service.

Automated Prescription System (MAPS), within less than three weeks of the surrender, Applicant issued prescriptions to two patients for 60 and 90 tablets of OxyContin 80 mg. The report further showed that by the end of July, Applicant had resumed prescribing controlled substances full-bore.

The investigative record establishes that Applicant voluntarily surrendered his registration in connection with an Administrative Complaint ("Complaint") filed by the Michigan State Bureau of Health Professionals (BHP) on December 20, 2007. The Complaint alleged two counts. Administrative Complaint, *In re Glenn D. Krieger, M.D.,* No. 43–07–106420.

First, the Complaint alleged that Applicant had self-reported that he was abusing fentanyl, a schedule II controlled substance, to the Michigan Health Professional Recovery Program (HPRP) and had undergone a substance abuse evaluation and been diagnosed as abusing opioids. *Id.* at 5–6. The Complaint alleged that he had tested positive for fentanyl during urine drug screens conducted on June 28, July 19, and August 1, 2007, and that thereafter, HPRP advised him that "he was not safe to practice" medicine and recommended that he admit himself into an inpatient rehabilitation program. *Id.* at 6. The Complaint further alleged that he had failed to enter an inpatient drug rehabilitation program or enter into a monitoring agreement with HPRP. The BHP charged that his conduct "constitute[d] a mental or physical inability reasonably related to and adversely affecting Respondent's ability to practice in a safe and competent manner," "constitute[d] a conduct that impairs or may impair his ability to safely and skillfully practice medicine," and "constitute[d] substance abuse," all in violation of state law. *Id.* at 6–7.

Second, the Complaint alleged that, in treating S.S. for chronic back pain, TMJ,[4] fibromyalgia and depression, Applicant's "chart for S.S. [was] devoid of physical exams or clinical findings to support his long term prescribing of high doses of opioids, benzodiazepines, and stimulants" and that he had "failed to recognize that his prescribing of escalating doses of opioids was detrimental to S.S.'s overall functioning and quality of life." *Id.* at 10. The BHP charged that his conduct "constitute[d] negligence," "incompetence," and the "prescribing, giving away or administering [of] drugs for other than lawful diagnostic or therapeutic purposes," all in violation of Michigan law. *Id.*

The investigative file contains copies of the results from the urine drop assessments of June 28, July 19, and August 1, 2007. These documents establish that Applicant tested positive for fentanyl on each occasion.

On December 28, 2007, the BHP's Board of Medicine's Disciplinary Subcommittee (DS) summarily suspended Applicant's state medical license effective on service of the order. Order of Summary Suspension, at 1. On May 30, 2008, Applicant entered into a Consent Order with the State. Consent Order, at 6. The Consent Order provided that the DS found "that the allegations of fact contained in the complaint are true" and that Applicant had violated sections 16221(a),[5] (b)(i),[6] (b)(ii),[7] (b)(iii),[8] and (c)(iv)[9] of the Michigan Public Health Code. *Id.* at 2. The DS thus ordered that Applicant's license be "LIMITED for a minimum period of two years" such that he "shall not obtain, possess, dispense, administer, or have access to any drug designated as a controlled substance under the Public Health Code or its counterpart in federal law unless the controlled substance is prescribed or dispensed by a licensed physician for [Applicant] as a patient." *Id.* The Consent Order also placed him "on PROBATION for a period of two years." *Id.*

As one of the probationary conditions, the State ordered that Applicant "shall comply with the terms of the monitoring agreement" which he had entered into with the HPRP on May 15, 2008. *Id.* at 3. The Monitoring Agreement provided, *inter alia,* that he "will not obtain, possess, dispense, or administer controlled substances," that he "will practice total abstention from alcohol, controlled substances, and other mood-altering substances," and that he "will submit to drug screens as requested by HPRP." Monitoring Agreement, at 1–2. In the Consent Order, the parties stipulated that Applicant "does not contest the allegations of fact and law contained in the complaint" but that "by pleading no contest * * * does not admit the truth of the allegations [and] agrees that the Disciplinary Subcommittee may treat the allegations as true for the resolution of the complaint." Consent Order, at 4–5.[10]

On September 26, 2008, a Diversion Investigator (DI) with the DEA Detroit Division Office received information that Applicant was issuing prescriptions using the DEA registration number which he had previously surrendered. That day he contacted Applicant's attorney and left a phone message advising him that Applicant could not issue controlled substance prescriptions without a valid DEA registration.

On October 3, 2008, a pharmacist phoned the DI and told him that Applicant had issued a prescription for Vicotussin, a controlled substance. The pharmacist further stated that he had determined that Applicant did not have a valid registration, and therefore, did not fill the prescription. The DI again left a phone message with Applicant's attorney advising that Applicant could not issue controlled substance prescriptions without a valid registration. The DI also attempted to contact Applicant directly; the DI left a phone message advising him that he was not legally authorized to write controlled substance prescriptions unless and until he obtained a new registration.

The same day, Applicant's attorney contacted the DI and informed him that Applicant's Michigan medical license had been reinstated; the attorney further stated that he had advised Applicant that all of his licensure had been restored upon the reinstatement of his medical license such that Applicant had issued controlled substance

[4] Temporo-mandibular joint dysfunction.

[5] Section 16221(a) "provides the [DS] with the authority to take disciplinary action against [Applicant] for a violation of general duty, consisting of negligence or failure to exercise due care . . . or any conduct, practice, or condition which impairs or may impair, the ability to safely and skillfully practice medicine." Administrative Complaint, at 2.

[6] Section 16221(b)(i) provides the DS with authority to take disciplinary action against a licensee for "incompetence," defined as "[a] departure from, or failure to conform to, minimal standards of acceptable and prevailing practice for a health profession whether or not actual injury to an individual occurs." Administrative Complaint, at 2.

[7] Section 16221(b)(ii) provides the DS with authority to take disciplinary action against a licensee for "substance abuse," defined as "the taking of alcohol or other drugs at dosages that place an individual's social, economic, psychological, and physical welfare in potential hazard or to the extent that an individual loses the power of self-control as a result of the use of alcohol or drugs, or while habitually under the influence of alcohol or drugs, endangers public health, morals, safety, or welfare, or a combination thereof." Administrative Complaint, at 2.

[8] Section 16221(b)(iii) provides the DS with authority to take disciplinary action against a licensee "for a mental or physical inability reasonably related to and adversely affecting the licensee's ability to practice in a safe and competent manner." Administrative Complaint, at 2.

[9] Section 16221(c)(iv) provides the DS with authority to take disciplinary action against a licensee for "obtaining, possessing, or attempting to obtain or possess a controlled substance[] * * * without lawful authority; or selling, prescribing, giving away, or administering drugs for other than lawful diagnostic or therapeutic purposes." Administrative Complaint, at 3.

[10] On June 4, 2008, a State ALJ dissolved the summary suspension of his medical license. Order Dissolving Suspension, at 1.

prescriptions based on the attorney's erroneous advice. The DI informed the attorney that Applicant would have to apply for a new registration in order to prescribe controlled substances.

On October 5, 2008, the DI received a letter from Applicant's attorney, dated October 1, 2008. The letter requested the reinstatement of Applicant's controlled substances privileges, based on the reinstatement of his medical license.

The following day, on October 6, 2008, the DI received a telephone call from a second pharmacist regarding a controlled substance prescription (for 120 tablets of Oxycontin 80 mg.) issued by Applicant on September 10, 2008. The pharmacist had also checked Applicant's registration, found that he lacked a valid registration, and did not fill the prescription.

On October 9, 2008, Applicant filed an application for a new registration. Six days later, the DI received a telephone call from a third pharmacist. The pharmacist reported that the day before, a person had presented to him controlled substance prescriptions (for OxyContin, Roxicodone, Norco and Xanax) issued by Applicant on October 3, 2008. However, the pharmacy had experienced a delay in ordering the prescribed medications.[11]

On October 15, the pharmacist called the customer to advise her of the delay. Within fifteen minutes, he received a phone call from Applicant about the delay. Finding this suspicious, the pharmacist contacted the DI, who advised him that Applicant did not have a valid registration.

On November 7, 2008, the DI and his Group Supervisor interviewed Applicant in the presence of his attorney. During the interview, Applicant's attorney stated that he had "fumbled the ball" by advising Applicant that he could resume his customary practice, including prescribing controlled substances, upon the reinstatement of his medical license.[12] During the interview, Applicant stated that he had stopped issuing controlled substance prescriptions on October 3, 2008, when the DI had notified him that he could not do so without first obtaining a new registration. He further acknowledged that he had previously executed a Voluntary Surrender Form.

The DI also questioned Applicant about his abuse of fentanyl. Noting that he had obtained a report from the Michigan Automated Prescription System (MAPS)[13] showing the prescriptions Applicant had received as a patient and that no fentanyl prescriptions were listed, the DI asked Applicant how he had obtained the fentanyl. Applicant stated that he obtained the fentanyl by collecting unused pain medication from his patients, which he was collecting to give as a donation to his church's missionary project in Zambia. He further denied that he had issued fentanyl prescriptions to patients in order to have them fill the prescriptions and return the drugs to him for his personal use.

The DI subsequently interviewed several individuals associated with the church's missionary project. The church's senior pastor stated that while he knew Applicant through the church, he was not a member of it, and that while the church did conduct missionary projects in Zambia, Applicant had not participated in any of them. Subsequently, the DI interviewed a physician, who had run the project in 2003 and 2008, and a physician assistant, who had run the project in 2004 and 2005. Both individuals stated that there had been no missionary projects in 2006 and 2007, when Respondent tested positive for fentanyl. Moreover, the physician had never met Applicant and the physician assistant had not spoken to him since 2005. Finally, according to the church's Executive Pastor, the 2008 project did not use controlled substances and any drugs that were used had been bought and not donated.

On November 19, 2008, the DI ran another MAPS inquiry, this time for controlled substance prescriptions written by Applicant between March 1 and November 1, 2008. The report shows that between March 7, the date on which he surrendered his registration, and November 1, Applicant issued approximately 438 controlled substance prescriptions. The report also shows that he issued three controlled substance prescriptions prior to June 4, the date on which his Michigan medical license was reinstated,[14] and that he issued eight controlled substance prescriptions after October 3, 2008,[15] the date he received the DI's phone message to stop writing prescriptions and the date he claimed that he had ceased doing so.

Discussion

Section 303(f) of the Controlled Substances Act (CSA) provides that the Attorney General "shall register practitioners * * * to dispense * * * controlled substances in schedule II, III, IV, or V, if the applicant is authorized to dispense * * * controlled substances under the laws of the State in which he practices." 21 U.S.C. 823(f). However, the statute also provides that the Attorney General "may deny an application for such registration if he determines that the issuance of such a registration is inconsistent with the public interest." *Id.* In determining the public interest, Congress directed 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.*

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

In this matter, I have considered all of the factors. While Applicant's state medical license has been re-instated (factor one) and there is no evidence

[11] The record contains copies of various controlled substance prescriptions issued by Applicant on which he used the DEA registration number he had previously surrendered.

[12] The attorney also stated that he was unaware that Applicant was required to apply for a new registration, despite his having witnessed the Voluntary Surrender Form previously executed by Applicant which had clearly stated that "I will not be permitted to * * * dispense, administer, prescribe, or engage in any other controlled substance activities * * * until such time as I am again properly registered." DEA Form 104.

[13] MAPS is part of a mandatory system in Michigan through which pharmacies and dispensing physicians report their controlled substance dispensings twice a month.

[14] Two of the prescriptions, dated March 19 and April 11, 2008, were issued to patient A.F. and were for first 60 tablets and then 90 tablets of OxyContin 80 mg. The third prescription, issued March 26, 2008, was for patient D.P. and was for 90 tablets of OxyContin 80 mg.

[15] On October 4, 2008, Applicant issued two prescriptions to patient L.V.: One for hydrocodone/APAP 10 mg./325 mg. (90 tablets) and one for OxyContin 40 mg. (180 tablets). On October 8, 2008, Applicant wrote five prescriptions for patient K.B.: For clonazepam 1 mg. (30 tablets), for Endocet 325 mg./10 mg. (90 tablets), for Methadone Hcl 10 mg. (90 tablets), for Methylin 20 mg. (90 tablets), and for OxyContin 80 mg. (75 tablets). On October 9, 2008, he issued a prescription to patient D.P. for alprazolam 1 mg. (75 tablets).

that he has been convicted of an offense related to the distribution or dispensing of controlled substances,[16] I conclude that the evidence relevant to Respondent's experience in dispensing controlled substances (factor two) and his compliance with applicable laws related to controlled substances (factor four), conclusively establishes that granting his application would be "inconsistent with the public interest." 21 U.S.C. 823(f).

Factors Two and Four—Respondent's Experience in Dispensing Controlled Substance and Compliance With Applicable Laws Related to Controlled Substances

Under Federal law, it is unlawful "for any person [to] knowingly or intentionally * * * dispense a controlled substance" "except as authorized by" the CSA. 21 U.S.C. 841(a)(1). It is "unlawful for any person knowingly or intentionally * * * to use in the course of the * * * dispensing of a controlled substance * * * a registration number which is * * * revoked." *Id.* § 843(a)(3). Moreover, "[e]very person who dispenses, or propose to dispense, any controlled substance, shall obtain from the Attorney General a registration issued in accordance with the rules and regulations promulgated by him." *Id.* § 822(a)(2); *see also* 21 CFR 1301.11(a) (same). Also relevant here is 21 CFR 1301.13(a), which provides that "[n]o person required to be registered shall engage in any activity for which registration is required until the application for registration is granted and a Certificate of Registration is issued by the Administrator to such person."

As found above, Applicant issued more than 400 controlled substance prescriptions even after he had surrendered his registration and had no authority to lawfully do so. Moreover, upon surrendering his registration, Respondent acknowledged his understanding that his registration was being revoked and that he could not engage in any controlled substance activities including the dispensing of drugs "until such time as I am again properly registered." Yet within three weeks of surrendering his registration, Applicant issued two prescriptions for OxyContin 80 mg. Moreover, in late July, he escalated his prescribing activities.

During the November 7, 2008 interview, Applicant's lawyer stated that he had erroneously advised Applicant that upon the restoration of his state medical license, he could resume prescribing controlled substances. However, both the Voluntary Surrender Form and Federal law clearly stated that he could not issue controlled substances prescriptions until he obtained a new DEA registration. Moreover, the evidence shows that Applicant issued controlled substance prescriptions two months before his medical license was reinstated [17] and that he issued controlled substances prescriptions even after he was told to stop doing so by the DI. Thus, it is clear that Applicant knowingly and intentionally issued prescriptions in violation of Federal law. *See* 21 U.S.C. 822(a)(2), 841(a)(1), 843(a)(3). These violations were extensive and provide reason alone to deny his application.

In addition, on at least three occasions during the summer of 2007, Respondent tested positive for fentanyl, a schedule II controlled substance. *See* 21 CFR 13087.12(c). According to a MAPS report obtained by the DI which listed the prescriptions Applicant had obtained between September 20, 2004 and November 20, 2007, Respondent was never prescribed fentanyl by any physician. Moreover, as found above, Respondent told the DI that he obtained unused fentanyl from his patients to donate to his church's missionary project.

At a minimum, the evidence establishes a violation of 21 U.S.C. 844(a), which makes it "unlawful for any person knowingly or intentionally to possess a controlled substance unless such substance was obtained directly, or pursuant to a valid prescription or order, from a practitioner acting in the usual course of his professional practice, or except as otherwise authorized by" the CSA or the Controlled Substances Import and Export Act. Moreover, while Applicant still held a practitioner's registration during the period in which he tested positive for fentanyl, such a registration authorizes its holder only to dispense, i.e., "to deliver a controlled substance to an ultimate user." 21 U.S.C. 802(10). A practitioner's obtaining of a controlled substance from a patient is not dispensing and thus is not an authorized activity under a practitioner's registration. *See* 21 CFR 1301.13(e). Thus, even if Applicant had not engaged in the self-abuse of fentanyl, he was not lawfully authorized to obtain possession of the drug in this manner.[18] This conduct further supports the conclusion that granting Respondent's application would be "inconsistent with the public interest." 21 U.S.C. 823(f).

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

The Government further alleged that Applicant made a false statement to an Agency Investigator when he stated that he had obtained the fentanyl he self-abused because he collected the drugs "to give as a donation to the Oakpointe Church's missionary project in Zambia." Show Cause Order at 1 (para.2) (citing 18 U.S.C. 1001). The evidence clearly shows that Applicant's statement to the DI was false in that he did not participate in the missionary project, let alone collect drugs for it.

That his statement was false does not, however, establish a violation by 18 U.S.C. 1001, because this provision requires that the statement be material to the matter being investigated by the Government. *See* 18 U.S.C. 1001(a) ("whoever, in any matter within the jurisdiction of the executive * * * branch of the Government of the United States, knowingly and willfully * * * (2) makes any materially false, fictitious, or fraudulent statement or representation * * * shall be fined under this title, imprisoned not more than five years * * * or both"). The Supreme Court has held that for a statement to be "material" for purposes of section 1001, it "must have a 'natural tendency to influence, or [be] capable of

[16] Putting aside that the State of Michigan has made no recommendation as to whether Respondent's application should be granted, this Agency has repeatedly held that the possession of a valid state license is not dispositive of the public interest inquiry. *See Patrick W. Stodola,* 74 FR 20727, 20730 n.16 (2009); *Robert A. Leslie,* 68 FR at 15230. As DEA has long recognized, "the Controlled Substances Act requires that the Administrator * * * make an independent determination as to whether the granting of controlled substances privileges would be in the public interest." *Mortimer Levin,* 57 FR 8680, 8681 (1992).

Nor is the lack of any criminal convictions related to the distribution or dispensing of controlled substances dispositive. *Edmund Chein,* 72 FR 6580, 6593 n.22 (2007), *aff'd, Chein* v. *DEA,* 533 F.3d 828 (D.C. Cir. 2008). Thus, the facts that Respondent holds a Michigan medical license (assuming that he is actually authorized to dispense controlled substances under the Consent Order) and has not been convicted of a relevant criminal offense are not dispositive.

[17] Given the terms of the Consent Order, which prohibited him from dispensing controlled substances, it also appears that his issuance of the prescriptions violated that order. However, the Government did not allege this in the Show Cause Order and thus I do not consider this conduct.

[18] The record does not conclusively establish whether he told this story to the persons from whom he obtained the fentanyl. Were this shown to be the case, Respondent would have violated 21 U.S.C. 843(a)(3), which renders it "unlawful for any person knowingly or intentionally * * * to acquire or obtain possession of a controlled substance by misrepresentation, fraud, * * * deception, or subterfuge[.]"

influencing, the decisionmaking body to which it is addressed.'" *United States* v. *Gaudin,* 515 U.S. 506, 509 (1995) (quoting *Kungys* v. *United States,* 485 U.S. 759, 770 (1988)). The Court has further explained:

> Deciding whether a statement is "material" requires the determination of at least two subsidiary questions: (a) "What statement was made?" and (b) "what decision was the agency trying to make?" The ultimate question: (c) "Whether the statement was material to the decision," requires applying the legal standard of materiality (quoted above) to these historical facts.

Gaudin, 515 U.S. at 512. The "evidence must be clear, unequivocal, and convincing." *Kungys,* 485 U.S. at 772.

While the DI's affidavit establishes the falsity of Applicant's statements, the Government does not explain what decision the statement had "the natural tendency" to influence or "was capable of influencing." *Gaudin,* 515 U.S. at 509 (quoting *Kungys,* 485 U.S. at 770). Among the possibilities are whether to grant or deny his application for registration, to pursue criminal charges against him, or to conduct further investigation to determine whether he had committed additional crimes or whether individuals (other than naïve patients [19]) were involved in supplying him with fentanyl. However, because the DI's affidavit does not offer any explanation as to why the false statement was "capable of influencing" any of the possible agency decisions, let alone identify which decision(s) the false statement was capable of influencing, I decline to address whether the statement was material.

In any event, given the extensive evidence under factors two and four establishing that Respondent knowingly wrote hundreds of controlled substance prescriptions even though he had surrendered his registration, that he wrote prescriptions within weeks of having surrendered his registration, that he wrote prescriptions even after being told to stop and that he could not do so until he obtained a new registration, as well as the evidence that he abused fentanyl, it is clear that issuing him a new registration would "be inconsistent with the public interest." 21 U.S.C. 823(f). 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 by 28 CFR 0.100(b) & 0.104, I order that the application of Glenn D. Krieger for a DEA Certificate of Registration as a practitioner be, and it hereby is, denied. This Order is effective immediately.

Dated: April 1, 2011.

Michele M. Leonhart,

Administrator.

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[19] During the interview, Applicant also denied that he had ever issued prescriptions to patients to have them obtain drugs for himself. There is, however, no evidence that this statement was false.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 09–2]

Alan H. Olefsky, M.D.; Denial of Application

On August 22, 2008, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Alan H. Olefsky, M.D. (Respondent), of Chicago, Illinois. The Show Cause Order proposed the denial of Respondent's application for a DEA Certificate of Registration as a practitioner, "for reason that [Respondent's] registration would be inconsistent with the public interest, as that term is used in 21 U.S.C. 823(f)." ALJ Ex. 1, at 1 (citing 21 U.S.C. 823(f) & 824(a)(4)).

The Show Cause Order specifically alleged that in 1989, Respondent issued "two false prescriptions for [the] controlled substances [Percocet and Halcion (triazolam), schedule II and schedule IV drugs, respectively] in the names of others and attempted to have them filled at a pharmacy in Florida." *Id.* The Show Cause Order alleged that on January 9, 1992, and after a hearing, the Administrator revoked Respondent's then-existing DEA registration having found the allegations proved and that Respondent had lied during the hearing regarding "the circumstances surrounding [his] misconduct." *Id.*

Next, the Show Cause Order alleged that "[f]rom at least December 2002, through October 2004," Respondent "again issued false prescriptions for various controlled substances in the names of [M.G., V.G., and T.C.]" and that "[t]hese prescriptions were for [Respondent's] personal use." *Id.* The Show Cause Order then alleged that on May 25, 2005, "DEA issued an Order proposing to revoke [Respondent's] DEA registration * * * based upon [his] issuing false prescriptions," and that on July 20, 2007, the Deputy Administrator issued a final order denying Respondent's application (his registration having expired), having found that he "had issued the prescriptions for [his] personal use and that such conduct violated federal law." *Id.* at 1–2 (citing 21 U.S.C. 843(a)(3)). Finally, the Order alleged that Respondent has "also exhibited a pattern of abusing alcohol" that includes a June 2004 arrest for driving under the influence and a January 2007 hospitalization "with a blood alcohol level of .327," and that his "history of abusing controlled substances and alcohol shows that granting [his] application for a DEA registration would be inconsistent with the public interest." *Id.* at 2.

By letter of October 6, 2008, counsel for Respondent requested a hearing on the allegations, ALJ Ex. 2, and the matter was placed on the docket of the Agency's Administrative Law Judges (ALJs). Following prehearing procedures, an ALJ conducted a hearing on June 2–3, 2009, in Chicago, Illinois. Both parties called witnesses to testify and introduced documentary evidence. After the hearing, both parties filed proposed findings of fact, conclusions of law, and argument.

On February 22, 2010, the ALJ issued her Opinion and Recommended Ruling, Findings of Fact, Conclusions of Law and Decision (also ALJ or Recommended Decision). Therein, the ALJ considered the evidence pertinent to the five public interest factors and concluded that granting Respondent's application "would be inconsistent with the public interest." ALJ at 43.

As to the first factor—the recommendation of the appropriate State licensing board—the ALJ noted that Respondent's State licenses as a physician and as a handler of controlled substances "remain on indefinite probation and are subject to the restrictions stated in the May 22, 2007, consent order." ALJ at 35. Noting that Respondent is "currently authorized to handle controlled substances in Illinois," the ALJ concluded that "this factor weighs in favor of a finding that Respondent's registration would not be inconsistent with the public interest." *Id.* at 35–36. However, because "state licensure is a necessary but not sufficient condition for DEA registration," the ALJ concluded that "this factor is not dispositive." *Id.* at 36.

As to the second and fourth factors—Respondent's experience in handling controlled substances and his compliance with applicable Federal, State or local laws—the ALJ first noted that Respondent testified "in the instant proceeding that the explanation he offered in the 1991 hearing" about the Halcion and Percocet prescriptions "was true." *Id.* The ALJ did not, however, find his "explanation credible." *Id.*