such drugs and that he be prohibited from prescribing controlled substances to himself or any family member. Further, I recommend that the Respondent be ordered to comply with the terms of his DBC probation and promptly notify the DEA if the DBC takes any action against his dental license. Lastly, I recommend that he maintain and provide quarterly prescription logs for all controlled substances prescriptions he authorizes to the local DEA office for monitoring. I recommend these restrictions apply for three years from the date of the final order so directing this result. In this way, the Respondent may safely continue his return to the full practice of dentistry, and the DEA can assure itself of the Respondent's compliance with DEA regulations as well as the protection of the public interest.

Dated: October 17, 2012.

Gail A. Randall,

Administrative Law Judge.

[FR Doc. 2013–24697 Filed 10–21–13; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Hoi Y. Kam, M.D.; Decision and Order

On August 29, 2012, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Hoi Y. Kam, M.D. (Respondent), of Fresh Meadows, New York. The Show Cause Order proposed the revocation of Respondent's DEA Certificate of Registration, which authorizes him to dispense controlled substances as a practitioner, as well as the denial of any pending applications to renew or modify his registration, on the grounds that he: (1) Materially falsified a renewal application, and (2) committed acts which render his registration inconsistent with the public interest. Show Cause Order at 1 (citing 21 U.S.C. 824(a)(1) & (4)).

More specifically, the Show Cause Order alleged that Respondent materially falsified his December 1, 2011 renewal application, by falsely answering the application question which asked if he had ''ever surrendered for cause or had a state professional license or controlled substance registration revoked, suspended, denied, restricted, or placed on probation or is any such action pending?'' *Id.* at 2. The Government alleged that Respondent gave a negative answer to this question, notwithstanding that on July 12, 2011, the New York State Department of Health, Office of Professional Misconduct and Discipline, had revoked his medical license, based on a finding that he had billed for Medicaid services which he did not perform and ''created false entries in [his patient] charts to conceal that fact.'' *Id.* at 1–2. However, the Government then alleged that Respondent's ''medical license was reinstated on October 27, 2011.'' *Id.* at 1.

The Government further alleged that between July 21 and October 4, 2011, Respondent violated federal law and regulations by ''issu[ing] at least six (6) prescriptions for controlled substances, despite lacking legal authority to do so.'' *Id.* (citing 21 U.S.C. 841(a)(1) & 21 CFR 1306.03). Specifically, the Government alleged that Respondent had issued a July 21, 2011 prescription for 240 dosage units of oxycodone 30mg; a September 16, 2011 prescription for 30 dosage units of alprazolam 2mg; two October 4, 2011 prescriptions for 30 dosage units of zolpidem tartrate 10mg; an October 4, 2011 prescription for 60 dosage units of alprazolam .25mg; and an October 4, 2011 prescription for 90 dosage units of oxycodone/acetaminophen 7.5/500mg. *Id.* at 2.

On August 31, 2012, a DEA Diversion Investigator (DI) ''attempted to personally serve the Order to Show Cause on Respondent at his registered address.'' GX 2, at 3. According to the DI, ''[s]ince no one appeared to be at the registered location, I left a copy of the Order to Show Cause in Respondent's mailbox.'' *Id.* Subsequently, on September 10, 2012, Respondent wrote a letter to DEA Counsel in which he denied the allegations of the Show Cause Order. GX 7.

Regarding the allegation that he had written six prescriptions between July 10 and October 27, 2011, Respondent denied writing them with the exception of ''the prescription dated July 21, 2011,'' which it was ''possible'' he ''predated.'' *Id.* Respondent contended that he was ''so sure someone stole my prescription pads without my knowledge'' and that he was ''the victim of prescription fraud.'' *Id.* He also urged the Government to check the handwriting on the prescriptions. *Id.*

As for the material falsification allegation, Respondent wrote that ''I probably did not pay attention to the box. I marked on the wrong box. I apologize for the mistake.'' *Id.* And regarding the basis for the action taken by the State against his medical license, Respondent wrote that he ''never billed for the Medicaid services,'' that ''[t]he Medicaid provider number is not mine,'' and that he ''did render the services.'' *Id.*[1]

However, while the Show Cause Order notified Respondent that he had a right to request a hearing and the procedure for doing so, Respondent did not request a hearing. Consistent with 21 CFR 1301.43(c), I deem Respondent's September 10, 2012 letter to be a statement of his ''position on the matters of fact and law'' asserted by the Show Cause Order.

On September 23, 2012, Respondent submitted a further letter to DEA counsel, which he titled as his ''response to'' a ''phone conversation'' he had with the DI. GX 8, at 1. Therein, Respondent asserted that the DI ''admitted there are false accusations of the prescriptions written.'' *Id.* Respondent also again admitted that he ''predated the prescription for a patient in June,'' [2] and explained that he ''could not foresee my license revoked in early July and I had only seventy-two hours [sic] notice.'' *Id.* Respondent further wrote that there was ''[n]o way [the] patient was aware of what happened'' and that the ''patient is willing to testify for me.'' *Id.* Respondent included an unsworn letter of the patient (N.I.), who stated that he ''got the prescription on 6/28/12 and I had no time in July 2011,'' and that he ''requested[ ] Respondent to predate [sic] on July 28, 11.'' *Id.* at 2. The patient also wrote that he ''did not know [that] something happened to'' Respondent. *Id.*

Regarding the prescription, Respondent explained that ''pharmacist should call and verify each controlled substances [sic] prescription'' but that ''[n]o one called me.'' *Id.* at 1. Continuing, Respondent wrote that ''[s]ince July 11, 2011, no pharmacies accepted my prescriptions anymore. Why this pharmacy dispensed the medication without following the routine[?]'' *Id.* Respondent then asserted that the name of the drug was misspelled on the prescription, and that he ''had the intention to misspell to make sure the pharmacy . . . call[ed], then I know what happens to the prescriptions. Unfortunately, no pharmacies called regarding to the selling [sic] mistakes.'' *Id.* Here again, however, Respondent did not request a hearing and ended the letter by stating

[1] Respondent also disputed the findings of the State Board, but then noted that his ''[l]awyer told [him] to forget about it,'' that ''[t]he appeal will not change,'' and that he ''refused to beg [the State board] because I believed I did not do anything wrong.'' GX 7.

[2] If the prescription was written in June, it was actually post-dated.

that he did not ''think it is necessary to show cause or [sic] hearing[3].''

Based on Respondent's failure to request a hearing in either his September 10 or September 23 letter, I find that Respondent has waived his right to a hearing on the allegations of the Show Cause Order. 21 CFR 1301.43(c) & (d). Having reviewed the investigative record submitted by the Government, including Respondent's letters, I make the following findings of fact.

Findings

Respondent is the holder of a DEA Certificate of Registration, which authorizes him to dispense controlled substances in schedules II through V as a practitioner. GX 1. On December 1, 2011, Respondent submitted a renewal application, and on April 3, 2012, DEA issued Respondent a new registration, which does not expire until December 31, 2014. *Id.*

Respondent is also the holder of a medical license issued by the New York Department of Health (hereinafter, the Department). On February 10, 2011, the Department's Bureau of Professional Medical Conduct (hereinafter, BPMC) issued a Statement of Charges to Respondent, which alleged that on or about November 10, 2006, the Department had, following a hearing, ''sustained a decision to exclude Respondent from participation in the Medicaid program for five (5) years'' based on his violation of several state regulations. GX 3, at 6 (citations omitted). The BPMC alleged that these violations ''would constitute professional misconduct under the laws of New York State.'' *Id.*

On May 19, 2011, a committee of the BPMC held a hearing, after which it determined that Respondent's medical license should be revoked. *Id.* at 3, 9. On July 1, 2011, the BPMC committee issued its decision, which provided that it was effective upon service. *Id.* at 10. Therein, the BPMC explained that:

> This is a case about Medicaid fraud for which the Respondent has been excluded from the Medicaid program. The five-year exclusion was sustained by a decision after a hearing in 2006. The panel weighed all the facts and circumstances in this case and recognized that this was primarily a case of greed and dishonesty.[4]

Id. at 9. The BPMC further explained that while it had considered lesser sanctions than revocation, it concluded that revocation was appropriate because it ''was troubled and concerned by the Respondent's patent lack of respect for the truth.'' *Id.*

On July 5, 2011, the Department served the Determination and Order on Respondent and his attorney in that proceeding, by certified mail. *Id.* at 1. The letter specifically stated that the order was ''deemed effective upon [its] receipt or seven (7) days after mailing by certified mail.'' *Id.* (citation omitted). The letter also explained that a ''[r]equest for review of the . . . determination by the Administrative Review Board stays penalties *other than suspension or revocation* until final determination by that Board.'' *Id.* at 2.

Respondent sought review by the State's Administrative Review Board (ARB). On or about October 14, 2011, the ARB issued its Determination and Order. GX 2, at 2. Therein, the ARB vacated the revocation of Respondent's medical license, noting, *inter alia,* ''that the conduct at issue under the Medicaid Exclusion occurred between 2001 and 2004'' and that the State ''has offered no evidence that [he] has engaged in additional misconduct since and the Respondent has remained in practice during that time.'' GX 4, at 8. However, the ARB voted unanimously to suspend Respondent's license for five years, but ''to stay the suspension in full and to place [him] on probation,'' subject to various terms and conditions.

On October 27, 2011, the New York Diversion Program Manager sent a letter to Respondent by certified mail; the letter stated that the Government had been advised that his medical license had been revoked (even though it no longer was).[5] GX 5. After quoting the Agency's authority under section 824(a)(3) to revoke a registration where a registrant ''is no longer authorized by State law'' to dispense controlled substances, the letter stated that ''[i]n lieu of undergoing an Order to Show Cause proceeding against your DEA registration, we are providing you an opportunity to surrender your DEA registration by signing the enclosed DEA Voluntary Surrender of Controlled Substances Privileges form (DEA Form 104) for cause.'' *Id.* Respondent did not, however, claim the letter. GX 2, at 2.

As found above, on December 1, 2011, Respondent submitted an application to renew his DEA registration. GX 2, at 3. In completing the application, Respondent was required to answer several questions, including question three, which asked: ''Has the applicant ever surrendered for cause or had a state professional license or controlled substance registration revoked, suspended, denied, restricted, or placed on probation or is any such action pending?'' *Id.; see also* GX 1, at 4. Respondent answered no. GX 1, at 4.

On or about April 12, 2012, a DI issued a subpoena to the N.Y. Department of Health, requesting a summary of all controlled substance prescriptions issued by Respondent between July 12 and October 27, 2011. GX 2, at 3. On April 16, 2012, the State provided the DI with a report which listed six prescriptions as having been issued by Respondent during the above period. *Id.*

On September 14, 2012, the DI contacted the pharmacies which had filled the prescriptions listed on the report and obtained copies of the prescriptions. *Id.* Upon reviewing the prescriptions, the DI determined that only one of the six prescriptions had been issued by Respondent. *Id.* at 4. This prescription, which was dated July 28, 2011, was for 240 oxycodone 30mg and was issued to N.I.

As noted above, in his letter, Respondent denied writing the prescription after his state license was revoked. However, he did admit to pre-signing the prescription, and submitted an unsworn statement from N.I. which corroborates Respondent's story.

Discussion

Under the Controlled Substances Act, ''[a] registration pursuant to section 823 of this title to . . . dispense a controlled

[3] However, I have also deemed this letter to be a written statement of position on the matters of fact and law asserted in the Show Cause Order.

[4] As set forth in the Administrative Review Board's (ARB) discussion of the original exclusion proceeding:

> The Exclusion found that the Respondent's records failed to reflect accurately the examinations the Respondent performed on the Investigators. Such conduct amounted to misconduct under [N.Y. Educ. Law] § 6530(32) as failure to maintain accurate records. The Exclusion also concluded that the Respondent billed Medicaid for services the Respondent never provided. Such conduct amounted to fraud in practice under the misconduct definition at [N.Y. Educ. Law] § 6530(2). The Exclusion also found that the Respondent violated Title 18 NYCRR § 515.2(b)(12) by failing to furnish medical care according to professional recognized standards. The failure, on repeated occasions, to practice according to accepted medical standards amounted to practicing medicine with negligence on more than one occasion, a violation under [N.Y. Educ. Law] § 6530(3).

GX 4, at 7–8.

It is also noted that among the probationary terms imposed by the ARB was that ''Respondent shall maintain legible and complete medical records, which accurately reflect the evaluation and treatment of patients. The medical records shall contain all information required by State rules and regulations regarding controlled substances.'' *Id.* at 15.

[5] According to the DI's affidavit, shortly after the State revoked Respondent's medical license, she contacted Respondent's attorney and told him that because Respondent's ''medical license was revoked, he was required to surrender his DEA registration.'' GX 2, at 2. Several days later, the DI also sent a letter to Respondent's attorney, which included a Voluntary Surrender form. *Id.* However, ''[n]o response was received.'' *Id.*

substance . . . may be suspended or revoked by the Attorney General upon a finding that the registrant . . . has materially falsified any application filed pursuant to or required by'' the Act, or ''has committed such acts as would render his registration under section 823 of this title inconsistent with the public interest as determined under such section.'' 21 U.S.C. 824(a)(1) & (4). With respect to the latter provision, the CSA provides that the following factors are to be considered in the case of a practitioner:

(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.

The public interest ''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 a registration or to deny an application for a registration. *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).

Where the Government has met its *prima facie* burden of showing that grounds exist to revoke a registration, whether because a registrant (or applicant) materially falsified an application for registration or committed acts which render his registration inconsistent with the public interest, the burden of production shifts to the registrant 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 Tron Tran,* 63 FR 64280, 64283 (1998); *Prince George Daniels,* 60 FR 62884, 62887 (1995).

The Material Falsification Allegation

The Government contends that Respondent materially falsified his December 1, 2011 application to renew his registration when he answered ''no'' to the question of whether he had ''ever surrendered (for cause) or had a state professional license or controlled substance registration revoked, suspended, denied, restricted, or placed on probation, or is any such action pending?'' Respondent's answer was clearly false, because his State medical license had not only been revoked for approximately three months (even if the revocation was ultimately vacated), his license was then suspended by the ARB (albeit the suspension was stayed), and he was also placed on probation. However, that Respondent's answer was false does not end the inquiry, because his answer must also have been material.

''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.'' *Kungys* v. *United States,* 485 U.S. 759, 770 (1988) (quoting *Weinstock* v. *United States,* 231 F.2d 699, 701 (D.C. Cir. 1956) (other citation omitted)) (quoted in *Samuel S. Jackson,* 72 FR 23848, 23852 (2007)); *see also United States* v. *Wells,* 519 U.S. 482, 489 (1997) (quoting *Kungys,* 485 U.S. at 770). The Supreme Court has further explained that ''[i]t has never been the test of materiality that the misrepresentation or concealment would more likely than not have produced an erroneous decision, *or even that it would more likely than not have triggered an investigation.'' Kungys,* 485 U.S. at 771 (emphasis added). Rather, the test is ''whether the misrepresentation or concealment was predictably capable of affecting, *i.e.,* had a natural tendency to affect, the official decision.'' *Id.* '' '[T]he ultimate finding of materiality turns on an interpretation of substantive law,' '' *id.* at 772 (int. quotations and other citation omitted), and must be met ''by evidence that is clear, unequivocal, and convincing.'' [6] *Id.*

As the above makes clear, the relevant decision for assessing whether a false statement is material is the Agency's decision as to whether an applicant is entitled to be registered (or in the case of a current registrant, remain registered). In this regard, the Government argues that ''Respondent is not 'entitled to be registered' based upon the revocation and subsequent suspension/probation of his medical license, as well as the fact that he issued a prescription for controlled substances during the period where he was not legally authorized to do so.'' Req. for Final Agency Action, at 7–8.

Because possessing authority to dispense controlled substances under the laws of the State in which a physician practices medicine is a requirement for holding a DEA registration, *see* 21 U.S.C. 802(21) & 823(f), a false answer to the state license question is material where an applicant no longer holds authority to practice medicine (regardless of the reason for the State's action) or authority to dispense controlled substances, as well as where the state has placed restrictions on a practitioner's authority to prescribe controlled substances. So too, because in determining whether an application should be granted, Congress directed the Agency to consider the five public interest factors, even where an applicant currently holds unrestricted state authority to dispense controlled substances, the failure to disclose state action against his medical license may be material if the action was based on conduct (or on the status arising from such conduct, *i.e.,* a conviction for a controlled substance offense or mandatory exclusion from federal health care programs) which is actionable under either the public interest factors or the grounds for denial, suspension, and revocation set forth in section 824. *See Scott C. Bickman,* 76 FR 17694, 17701 (2011).

Here, however, the Government's contention ignores that the BPMC's revocation order had been vacated prior to Respondent's filing of the application. Moreover, while the ARB suspended Respondent's license, the suspension was stayed. Thus, Respondent was ''authorized'' to dispense controlled substances at the time he submitted the application. DEA therefore could not have revoked his registration and denied his application on the basis that Respondent lacked

[6] While *Kungys* involved a denaturalization proceeding, in other civil proceedings, courts have required that a party establish that a falsification is material by ''clear, unequivocal, and convincing evidence'' and not simply by a ''preponderance of the evidence.'' *Driscoll* v. *Cebalo,* 731 F.2d 878, 884 (Fed. Cir. 1984). In any event, the Government's evidence on materiality does not even meet the preponderance standard.

state authority. *See* 21 U.S.C. 823(f); *id.* § 824(a)(3) (authorizing the suspension or revocation of a registration 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'').

In placing Respondent on probation, the ARB also noted the various findings of the order which had excluded him years earlier from the New York Medicaid program. However, because the exclusion order does not fall under the mandatory exclusion authority of 42 U.S.C. 1320a–7(a), but rather, the permissive exclusion authority of 42 U.S.C. 1320a–7(b), by itself, the exclusion does not fall within the Agency's authority to suspend or revoke a registration. *See* 21 U.S.C. 824(a)(5); *see also Terese, Inc., d/b/a Peach Orchard Drugs,* 76 FR 46843, 46848 (2011). Moreover, the Government offers no evidence that Respondent's Medicaid exclusion was based on findings that he committed acts, or had been convicted of criminal offenses, which provide actionable grounds to revoke his registration under either the public interest standard of sections 823(f) and 824(a)(4) or section 824(a)(2).

To be sure, the probationary terms imposed by the ARB included that Respondent maintain medical records that ''contain all information required by State rules and regulations regarding controlled substances.'' GX 4, at 15. The ARB's Order did not, however, discuss what evidence supported the imposition of this probationary term. *See generally* GX 14. And the Government offers no argument, let alone any evidence, that the truthful disclosure of the State's action against his medical license would have led it to evidence in the exclusion proceeding that Respondent violated any state rules or regulations regarding controlled substances and thus would have supported the denial of his application.[7] Indeed, in its Request for Final Agency Action, the Government concedes that ''the allegations underlying the disciplinary action did not involve controlled substances.'' Req. for Final Agency Action, at 8. I therefore conclude that the Government has failed to show that Respondent's false statement had the capacity to influence the Agency's decision to grant his application.

The Public Interest Allegations

The Government also asserts that Respondent has committed acts which render his registration inconsistent with the public interest. More specifically, the Government argues that factors two (Respondent's experience in dispensing controlled substances) and four (Respondent's compliance with applicable laws related to controlled substances) support the revocation of his registration.[8] *Id.* at 9.

More specifically, the Government contends that ''[i]n order to maintain a registration with DEA, a practitioner must be currently authorized to handle controlled substances in the jurisdiction in which he practices.'' *Id.* (citing 21 U.S.C. 802(21); 823(f) (internal quotations omitted)). The Government then maintains that ''[n]otwithstanding having lost his state authority to practice medicine, Respondent did not surrender his DEA'' registration. *Id.*

While the Government is correct that a practitioner must be currently authorized under the laws of the State in which he practices in order to maintain a DEA registration, it cites no support for the suggestion that a registrant *must surrender* his registration upon the loss of his state authority. Indeed, as the title of DEA Form 104 makes plain, surrendering one's registration is a ''voluntary'' act. *See* GX 5, at 2 (form entitled: ''VOLUNTARY SURRENDER OF CONTROLLED SUBSTANCES PRIVILEGES''); *see also id.* (first paragraph of form: ''After being fully advised of my rights, and understanding that I am not required to surrender my controlled substance privileges, I freely execute this document and choose to take the actions described herein.''). Even where a registrant no longer possesses state authority, as long as he does not use that registration to acquire, distribute, or dispense a controlled substance, he neither commits a violation of federal law, nor an act inconsistent with the public interest, when he refuses to voluntarily surrender his registration. Rather, as the Voluntary Surrender form—which was given that title for a reason—makes clear, a registrant is entitled to insist that the Government pursue the revocation of his registration through a proceeding brought under 21 U.S.C. 824(a)(3).

On the other hand, where a registrant no longer possesses state authority, he cannot lawfully prescribe a controlled substance. *See* 21 CFR 1306.03(a) (''A prescription for a controlled substance may be issued only by an individual practitioner who is . . . [a]uthorized to prescribe controlled substances by the jurisdiction in which he is licensed to practice his profession.''); *see also* 21 U.S.C. 802(10) (''The term 'dispense' means to deliver a controlled substance to an ultimate user . . . by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance. . . .''). And ''[e]xcept as authorized by this subchapter [*i.e.,* the Controlled Substances Act], it is ''unlawful for any person knowingly or intentionally . . . to distribute or dispense . . . a controlled substance.'' 21 U.S.C. 841(a)(1).

As found above, Respondent disputes the Government's contention that he violated the CSA by issuing a controlled substance prescription for 240 oxycodone 30mg. on July 28, 2011, after the revocation by the BPMC of his New York medical license. Rather, Respondent maintains that he actually wrote the prescription in June 2011, prior to the BPMC's issuance of its order. Respondent also submitted an unsworn hearsay statement from the patient who received the prescription, which supports his assertion.

However, even accepting Respondent's explanation that he pre-signed (and post-dated) the prescription, I conclude that he still violated the CSA. Under DEA's regulations, ''[a]ll prescriptions for controlled substances shall be dated as of, and signed on, the

[7] On October 27, 2011, more than a month prior to Respondent's submission of the application, the Government wrote Respondent, seeking the surrender of his registration. GX 5. Therein, the Government noted that on July 15, 2011, it had been informed that the BPMC had revoked his medical license ''pursuant to [his] exclusion from participating in the NYS Medical [sic] Program for five (5) years.'' *Id.* However, because the materiality of a statement is assessed based on ''the intrinsic capabilities of the false statement itself, rather than the possibility of the actual attainment of its end as measured by collateral circumstances,'' *United States* v. *Goldfine,* 538 F.2d 815, 820–21 (9th Cir. 1976) (internal quotations and citation omitted), it does not matter that certain employees of the Government already knew that the answer was false. That being said, the Government still bears the burden of showing, through evidence which is clear, convincing and unequivocal, that the false statement is material. As for its further contention that Respondent's false statement was material because ''he issued a prescription for controlled substances during the period where he was not legally authorized to do so,'' as explained below, the Government's evidence does not conclusively establish that the prescription was written after his state license was revoked, rather than written (as he maintains) before his license was revoked and post-dated.

[8] The Government correctly notes that there is no evidence that Respondent has been convicted of an offense under federal or state laws related to the manufacture, distribution, or dispensing of controlled substances. However, there are a number of reasons why even a person who has engaged in misconduct may never have been convicted of an offense under this factor, let alone prosecuted for one. *Dewey C. MacKay,* 75 FR 49956, 49973 (2010), *pet. for rev. denied MacKay* v. *DEA,* 664 F.3d 808 (10th Cir. 2011). The Agency has therefore held that ''the absence of such a conviction is of considerably less consequence in the public interest inquiry'' and is therefore not dispositive. *Id.*

day when issued.'' 21 CFR 1306.05(a). DEA has repeatedly held that the act of pre-signing a prescription violates the CSA. *See Alvin Darby,* 75 FR 26993, 26999 (2010) (collecting cases). Thus, whether I accept the Government's contention that Respondent issued a prescription when he lacked state authority to do so, or Respondent's assertion that he simply pre-signed a prescription, he still distributed a controlled substance in violation of 21 U.S.C. 841(a)(1). However, the record contains no evidence that Respondent acted outside of the usual course of professional practice and lacked a legitimate medical purpose in issuing the prescription.[9]

Sanction

The Government argues that it has ''establishe[d] by a preponderance of the evidence that Respondent's continued registration is inconsistent with the public interest'' and that Respondent has put on ''no evidence that could support a finding that [he] should be entrusted with a . . . registration.'' Req. for Final Agency Action, at 9–10 (citing cases). The Government thus seeks the revocation of Respondent's registration.[10]

Had the Government proved that Respondent materially falsified his application, I would grant the Government's request. The Government, however, has proved only that Respondent committed a single act of issuing a prescription in violation of DEA regulations (whether because he lacked state authority or pre-signed/post-dated the prescription). Moreover, the Government has produced no evidence that the prescription lacked a legitimate medical purpose. *See Dewey C. MacKay,* 75 FR 49956, 49977 (2010) (holding that DEA can revoke a practitioner's registration based on a single act of intentional diversion), *pet. for rev. denied MacKay* v. *DEA,* 664 F.3d 808 (10th Cir. 2011).

As I have previously held, in determining the appropriate sanction, DEA considers the egregiousness and the scope of the misconduct which has been proved on the record, as well as the need to deter similar misconduct on the part of others. *See Michael S. Moore,* 76 FR 45867, 45868 (2011); *Terese, Inc.,* 76 FR at 46848–49; *Janet L. Thornton,* 73 FR 50354, 50356 (2008).

In *Thornton,* the Government sought the revocation of a physician's registration, based on her having written two controlled substance prescriptions for former neighbors, when her license to practice in that State had been suspended. 73 FR at 50355. The physician, however, was practicing in another State, where she was licensed. *Id.* While the then-Deputy Administrator found that the prescriptions violated federal law because the physician engaged in the unlicensed practice of medicine and were thus issued outside of the usual course of professional practice (which the physician admitted in a state board proceeding), she declined to revoke the physician's registration, noting that there was no evidence that the physician had written the prescriptions ''for other than a legitimate medical purpose.'' *Id.* The Deputy Administrator also noted that a provision of state law created an exemption from the State's licensing requirements for ''occasional consultations or cases'' where a physician was ''lawfully practicing medicine in another state,'' and that while the State Board found that the physician violated the State's Medical Practice Act, the physician's case appeared to be one of first impression. *Id.* at 50356. Based on these circumstances, the Deputy Administrator concluded that the physician's violations did not warrant the revocation or suspension of her registration. *Id.*

Here, while the proven misconduct is limited to a single prescription, I conclude that a period of outright suspension is warranted. In contrast to *Thornton,* where the state law defining what constituted the unauthorized practice of medicine was arguably unclear, the applicable DEA regulations are clear, whether Respondent issued the prescription after his state license was revoked, *see* 21 CFR 1306.03(a), or whether he pre-signed (and post-dated) the prescription. *Id.* 1306.05(a). In either case, the evidence supports a finding that Respondent knowingly dispensed a controlled substance in violation of the Controlled Substances Act. *See* 21 U.S.C. 841(a)(1). Accordingly, I will order that Respondent's registration be suspended outright for a period of six months.

Order

Pursuant to the authority vested in me by 21 U.S.C. 824(a)(4), as well as 28 CFR 0.100(b), I order that the DEA Certificate of Registration issued to Hoi Y. Kam, M.D., be, and it hereby is, suspended for a period of six months. This Order is effective November 21, 2013.

Dated: October 9, 2013.

Thomas M. Harrigan,

Deputy Administrator.

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BILLING CODE 4410–09–P

[9] The Government also argues that factor one—the recommendation of the state licensing board—supports its proposed sanction of revocation. According to the Government, ''[t]hough his medical license is not revoked, and the allegations underlying action did not involve controlled substances, such action still weighs in favor of revocation.'' Req. for Final Agency Action, at 8 (citing *George Mathew,* 75 FR 66138, 66145 (2010)).

While my decision in *Mathew* noted that the respondent there had been subject to two disciplinary proceedings by the state board, one of the proceedings (which resulted in a summary suspension) was based on the respondent's failure to properly treat emergency room patients and did not involve his prescribing of controlled substances. 75 FR at 66,145. However, at the time of this Agency's proceeding, the State had reinstated Respondent's medical license. *Id.* Accordingly, I placed no weight on that proceeding and relied only on the other proceeding, which sanctioned the respondent for prescribing controlled substances to patients he never physically examined. *Id.* Thus, the Government's reliance on *Mathew* is misplaced.

[10] The Government also argues that Respondent's renewal application should be denied. Req. for Final Agency Action, at 1. However, it is too late for that, as the Government renewed Respondent's registration on April 3, 2012. GX 1.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 08–6]

Lannett Company, Inc.; Grant of Registration To Import Schedule I Substance

On November 15, 2012, I, the Administrator of the Drug Enforcement Administration, issued a Declaratory Order in the above-captioned matter.[1] Therein, I held that Lannett Company, Incorporated's (hereinafter, Lannett) proposed importation of synthetic dronabinol (THC) in finished dosage form, a schedule I controlled substance, for the purpose of conducting stability and bioequivalency studies to support an Abbreviated New Drug Application (ANDA), constitutes ''scientific, analytical, or research uses'' and is therefore a permissible importation under 21 U.S.C. 952(a)(2)(C). Declaratory Order, at 36. However, I further held that Lannett had not justified that the quantities of the proposed importations (300,000 dosage units) were ''limited quantities'' as required by section 952(a)(2)(C). *Id.* at 35–36. I therefore ordered Lannett to provide justification for the quantities it sought to import. *Id.* at 40. I also held that upon Lannett's ''providing adequate justification for the quantit[ies] of the [proposed] importation[s],'' its ''registration would be consistent with

[1] All citations to the Declaratory Order are to the slip opinion and not to the Order as published here in the Appendix.