that the case was not moot, he should specifically address why he failed to file a renewal application and what collateral consequences attach as a result of the suspension order.

On June 5, the Government filed its brief. As relevant here, the Government maintains that this proceeding is now moot and that the matter should now be dismissed. *See* Brief in Response to the Order of the Deputy Administrator at 10. As of this date, Respondent has not filed a brief.

In light of Respondent's failure to comply with the briefing order, his failure to file a renewal application, and his failure to provide any evidence of his intent to remain in professional practice or of other collateral consequences that attached with the issuance of the suspension order, I conclude that this case is now moot. Accordingly, the Order to Show Cause will be dismissed.

Order

Pursuant to the authority vested in me by 21 U.S.C. 824, as well as 21 CFR 0.100(b) and 0.104, I hereby order that the Order to Show Cause issued to Elmer P. Manalo, M.D., be, and it hereby is, dismissed. This Order is effective immediately.

Dated: August 18, 2008.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. E8–19773 Filed 8–25–08; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Janet L. Thornton, D.O.; Dismissal of Proceeding

On December 17, 2007, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Janet L. Thornton, D.O. (Respondent), of Monument, Colorado. The Show Cause Order sought the revocation of Respondent's DEA Certificate of Registration, AT2730984, as a practitioner, and the denial of any pending applications to renew or modify her registration, on two separate grounds.

First, it alleged that Respondent had entered into a series of stipulations with the Colorado Board of Medical Examiners under which she agreed that she ''will not practice medicine in the State of Colorado.'' Show Cause Order at 2. Relatedly, the Show Cause Order alleged that Respondent's ''Colorado medical license expired on May 31, 2007, and has not been renewed,'' and that therefore Respondent lacks state authority to handle controlled substances, which is a prerequisite for holding a DEA registration. *Id.*

Second, the Show Cause Order alleged that on December 3, 2005, the Colorado Board suspended Respondent's state medical license thus resulting in her lacking authority to handle controlled substances. *Id.* at 1. The Show Cause Order alleged that while her state license was suspended, Respondent issued two prescriptions to her neighbors: one in January 2006, for Tussionex, a schedule III controlled substance, and one in June 2006, for a schedule III drug containing hydrocodone. *Id.* at 1–2. Relatedly, the Show Cause Order also alleged that in 2005, Respondent issued a prescription for morphine to B.V., and that B.V. had ''later informed investigators that he had no knowledge of the * * * prescription and was never dispensed the drug.'' *Id.* at 2.

On February 12, 2008, the Show Cause Order was served on Respondent by First Class Mail at her registered location. On March 3, 2008, Respondent filed a written statement in lieu of a request for a hearing and expressly waived her right to a hearing. *See* 21 CFR 1301.43(c). Thereafter, the investigative file was forwarded to me for final agency action.

Having considered the entire record in this matter, including Respondent's statement, I hereby issue this Decision and Final Order. I conclude that the Government has not proved by substantial evidence the allegations regarding the prescriptions to B.V. or that Respondent currently lacks state authority to handle controlled substances. While I find that Respondent violated the Controlled Substances Act by issuing prescriptions for controlled substances following the suspension of her Colorado license, I further conclude that because the violations were limited to two instances and there is no evidence establishing that Respondent had not previously entered into a doctor-patient relationship with the two persons who received the prescriptions, the Government's proposed sanction of revocation would be excessive. Because the Government has not proposed an alternative sanction, the Show Cause Order will be dismissed.

Findings of Fact

Respondent holds DEA Certificate of Registration, AT2730984, which authorizes her to handle controlled substances as a practitioner at her registered location in Monument, Colorado. Respondent's registration was last renewed on October 18, 2005, and does not expire until November 30, 2008.

In May 2005, an Inquiry Panel of the Colorado State Board of Medical Examiners ordered that Respondent be evaluated by the Colorado Physician Health Program. *In re Janet L. Thornton,* Stipulation and Final Agency Order (Col. St. Bd. Med. Exam'rs 2007). Thereafter, on December 15, 2005, the Board suspended Respondent's state medical license. Respondent's state license remained suspended until May 17, 2007, the date when Respondent entered into a stipulation for the interim cessation of practice, under which she agreed to cease the practice of medicine. Respondent subsequently agreed to two additional amendments of the stipulation which extended the initial stipulation.

On October 25, 2007, Respondent and the Board entered into a Stipulation and Final Agency Order, which became effective on November 16, 2007, upon the Board's approval. *Id.* at 7. According to the Board's Final Order, Respondent has ''continuously'' held her state license since April 10, 1986. *Id.* at 1.

In the Order, the Board imposed certain practice restrictions on Respondent. The first of these was that ''Respondent shall not engage in any act constituting the practice of medicine in the state of Colorado unless such practice occurs within a clinical setting approved in advance by the Panel or unless such practice occurs in a hospital.'' *Id.* at 5. The second restriction was that ''Respondent shall order, dispense, administer or prescribe any controlled substance or other prescription medications only for persons with whom Respondent has a bona fide physician-patient relationship and only within the context of Respondent's practice in a clinical setting approved in advance by the Panel or a hospital.'' *Id.* Based on the above, I find that contrary to the Government's contention, Respondent retains authority to handle controlled substances in Colorado.

As relevant to the Show Cause Order's allegations regarding her improper prescribing, Respondent admitted in the stipulation that she:

> issued prescriptions and ordered medications while her license was suspended. Respondent had consulted with an out-of-state attorney who stated that he consulted Colorado attorneys and advised her that she was authorized to issue prescriptions and order medications in the state of Colorado while her Colorado license was suspended under the authority of out-of-state licenses. The Panel finds that the out-

of-state attorney's interpretation of Colorado's Medical Practice Act was erroneous.

Id. at 3.

The record establishes that on January 23, 2006, while her Colorado license was suspended, Respondent issued a prescription with one refill to D.V., her neighbor in Colorado, for Tussionex Extended Release, a schedule III controlled substance which contains hydrocodone. On June 6, 2006, Respondent issued an additional prescription to B.V., who was also her neighbor, for thirty tablets of hydrocodone/apap (10/500mg.) which was to last five days.[1] At the time she issued both prescriptions, Respondent was practicing in Texas, where she also holds a medical license. While DEA Investigators interviewed both D.V. and B.V., there is no evidence establishing that Respondent had not previously entered into a legitimate doctor-patient relationship with either person or that the prescriptions were issued for other than a legitimate medical purpose.

In support of her Response to the Show Cause Order, Respondent submitted a copy of a February 20, 2007 letter from Jeff Martin, a lawyer in Tulsa, Oklahoma. This letter states that Respondent:

> asked me about writing occasional prescriptions infrequently for Colorado residents who were her neighbors using her Texas and/or Oklahoma license even though her Colorado license was summarily suspended. I told her, as long as her Texas and/or Oklahoma licenses were still valid that she could still occasionally consult with her neighbors and prescribe medicine. I still believe this is accurate.
>
> Later when I tried to help her find a lawyer in Colorado, I asked two Colorado lawyers who are knowledgeable in this area about this and they believed she could continue occasionally prescribing medicine also. I'm sorry, but I no longer have the names and phone numbers of the lawyers I spoke to.

Exhibit C to Respondent's Response To Order To Show Cause.

Respondent also attached to her Response a copy of Col. Stat. § 12–36–106, which defines the practice of medicine under Colorado law and provides for certain exemptions from the licensing requirements. This statute states that:

> Nothing in this section shall be construed to prohibit, or to require a license * * * under this article with respect to, any of the following acts:
>
> * * *
>
> (b) The rendering of services in this state by a physician lawfully practicing medicine in another state or territory, whether or not such physician is in Colorado, but if any such physician does not limit such services to an occasional consultation or cases * * * such physician shall possess a license to practice medicine in this state.

Colo. Stat. § 12–36–106(3)(b).

The Government also alleged that Respondent had issued a prescription to B.V. for morphine, but that B.V. denied ever receiving the prescription. This allegation is not, however, supported by substantial evidence as there is no evidence that Respondent ever issued a morphine prescription to an individual with these initials.[2]

Discussion

Under Section 304(a) of the Controlled Substances Act (CSA), the Attorney General may revoke or suspend a registration to dispense a controlled substance ''upon a finding that the registrant * * * has had [her] 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.'' 21 U.S.C. 824(a)(3). Section 304(a) further authorizes the Attorney General to suspend or revoke a registration ''upon a finding that the registrant * * * has committed such acts as would render his registration under section 823 of this title inconsistent with the public interest as determined under such section.'' *Id.* § 824(a)(4).

In section 303(f) of the CSA, Congress directed that the Attorney General consider five factors ''[i]n determining the public interest.'' 21 U.S.C. 823(f). The factors are:

> (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, M.D.,* 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 a registration should be revoked.'' *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). Having set forth the applicable law, I address each of the Government's contentions.

The Lack of State Authority

As found above, Respondent's Colorado medical license was suspended on December 15, 2005. Effective November 16, 2007—one month before the Show Cause Order was issued—the Colorado Board restored Respondent's license to practice medicine and her authority to prescribe controlled substances. While Respondent's authority to handle controlled substances limits her practice to a board-approved clinical setting or a hospital, the Board's Order make plain that Respondent currently has authority to handle controlled substances in Colorado. The Government's contention to the contrary is therefore rejected.

The Public Interest Allegations

In *United Prescription Services, Inc.*, 72 FR 50397, 50407 (2007), I held that ''a physician who engages in the unauthorized practice of medicine under state laws is not a ''practitioner acting in the usual course of * * * professional practice'' under the CSA. 21 CFR 1306.04(a).[3] As explained therein, this rule is supported by the plain meaning of the Act, which 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 practices * * * to * * * dispense * * * a controlled substance,'' 21 U.S.C. 802(21), and ''[t]he term 'dispense' [to] mean[] to deliver a controlled substance to an ultimate user * * * by, or pursuant to the lawful order of, a practitioner.'' *Id.* § 802(10). *See also id.* § 823(f) (''The Attorney General shall register practitioners * * * to dispense * * * if the applicant is authorized to dispense * * *

[1] While the record shows that Respondent issued several other prescriptions to B.V. and D.V., none of these were for controlled substances. These prescribings are not the concern of DEA.

[2] While there is evidence that Respondent issued a morphine prescription to D.H., even if this incident had been properly alleged, I would still reject it as unsupported by substantial evidence. While the record contains a summary of an interview in which D.H. stated that he did not recall receiving the morphine prescriptions, D.H. subsequently prepared a letter in which he retracted his earlier statement and acknowledged he ''had completely forgotten about the lower back and hip pain that prompted me to ask for pain medication.'' Exh. E to Respondent's Resp. to Order to Show Cause. The Government, which has the burden of proof even when a case does not go to a hearing, has not pointed to any additional evidence to support the conclusion that D.H.'s initial story to investigators is the more accurate version.

[3] Under 21 CFR 1306.04(a), ''[a] prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.''

controlled substances under the laws of the State in which he practices.'').

As I noted in *United Prescription Services*, shortly after the CSA's enactment, the Supreme Court explained that ''[i]n the case of a physician [the Act] contemplates that *he is authorized by the State to practice medicine* and to dispense drugs in connection with his professional practice.'' *United States* v. *Moore,* 423 U.S. 122, 140–41 (1975) (emphasis added) (quoted at 72 FR 50407). A controlled-substance prescription issued by a physician who lacks the license or other authority required to practice medicine within a State is therefore unlawful under the CSA. *See* 21 CFR 1306.04(a) (''An order purporting to be a prescription issued not in the usual course of professional treatment * * * is not a prescription within the meaning an intent of'' the CSA); *Cf.* 21 CFR 1306.03(a)(1) (''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[.]'').

In the Stipulation and Final Agency Order, Respondent admitted that the prescribings to B.V. and D.V. constituted ''prescribing * * * other than in the course of legitimate professional practice'' under Colorado law. *See In re Thornton*, Stipulation and Final Agency Order, at 3. Accordingly, I conclude that the prescriptions Respondent issued to D.V. and B.V. were issued outside of the course of professional practice and thus also violated Federal law. *See* 21 CFR 1306.04(a); *Moore*, 423 U.S. at 140–41; *United Prescription Services*, 72 FR at 50407. The prescribings thus constituted acts which render her registration ''inconsistent with the public interest.'' 21 U.S.C. 824(a)(4); *see also id.* § 823(f)(2) & (4) (directing consideration of registrant's ''experience in dispensing controlled substances'' and compliance with applicable federal and state laws).

I nonetheless conclude that it would be inappropriate to revoke Respondent's registration. With respect to the allegations, the record establishes only two instances in which Respondent unlawfully prescribed controlled substances. Moreover, while ordinarily a practitioner cannot credibly claim ignorance of state laws prohibiting the unlicensed practice of medicine, *United Prescription Services*, 72 FR at 50407; the Colorado Board's interpretation that Respondent was not within the exemption provided in Colo. Stat. § 12–36–106(b)(3), and that she thus violated the State's Medical Practice Act, appears to have been a case of first impression.[4]

Moreover, the Government has failed to show the absence of a legitimate doctor-patient relationship between Respondent and either person. Relatedly, there is no evidence that the prescriptions were written for other than a legitimate medical purpose. In short, the evidence does not remotely suggest that Respondent was using her prescription writing authority to deal drugs. *See Gonzales* v. *Oregon*, 546 U.S. 243, 270 (2006).

Furthermore, the Colorado Board has considered Respondent's state law violations and concluded that they do not warrant the revocation of her medical license. Under agency precedent, I am not bound by the State Board's recommendation. Nonetheless, because the only proven violations of the CSA are based on her having violated the Colorado Medical Practice Act's licensing provision and were limited to two instances, I conclude that Respondent's violations do not warrant the revocation or suspension of her registration.

While in some instances, this Agency has placed restrictions on a practitioner's registration, such restrictions must be related to what the Government has alleged and proved in any case. Notably, in this matter the Government has proposed no alternative sanction to revocation. Accordingly, the Order to Show Cause will be dismissed.

Order

Pursuant to the authority vested in me by 21 U.S.C. 824(a), as well as 28 CFR 0.100(b) and 0.104, I hereby order that the Order to Show Cause issued to Janet L. Thornton, D.O., be, and it hereby is, dismissed.

Dated: August 18, 2008.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. E8–19763 Filed 8–25–08; 8:45 am]

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[4] While the Colorado Board found that Respondent's attorney's interpretation of the Medical Practice Act ''was erroneous,'' the Board's Order did not cite any prior decision holding that Respondent's conduct was illegal.

NUCLEAR REGULATORY COMMISSION

Biweekly Notice; Applications and Amendments to Facility Operating Licenses Involving No Significant Hazards Considerations

I. Background

Pursuant to section 189a. (2) of the Atomic Energy Act of 1954, as amended (the Act), the U.S. Nuclear Regulatory Commission (the Commission or NRC staff) is publishing this regular biweekly notice. The Act requires the Commission publish notice of any amendments issued, or proposed to be issued and grants the Commission the authority to issue and make immediately effective any amendment to an operating license upon a determination by the Commission that such amendment involves no significant hazards consideration, notwithstanding the pendency before the Commission of a request for a hearing from any person.

This biweekly notice includes all notices of amendments issued, or proposed to be issued from July 31, 2008 to August 13, 2008. The last biweekly notice was published on August 12, 2008 (73 FR 46926).

Notice of Consideration of Issuance of Amendments to Facility Operating Licenses, Proposed No Significant Hazards Consideration Determination, and Opportunity for a Hearing

The Commission has made a proposed determination that the following amendment requests involve no significant hazards consideration. Under the Commission's regulations in 10 CFR 50.92, this means that operation of the facility in accordance with the proposed amendment would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. The basis for this proposed determination for each amendment request is shown below.

The Commission is seeking public comments on this proposed determination. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determination.

Normally, the Commission will not issue the amendment until the expiration of 60 days after the date of publication of this notice. The Commission may issue the license amendment before expiration of the 60-