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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 08-1]

Elmer P. Manalo, M.D.; Dismissal of Proceeding

On August 30, 2007, I, the Deputy Administrator of the Drug Enforcement Administration, issued an Order to Show Cause and Immediate Suspension of Registration to Elmer P. Manalo, M.D. (Respondent), of Greensburg, Indiana. The immediate suspension of Respondent's registration was based on my preliminary finding that Respondent posed an "imminent danger to public health or safety" because he prescribed schedule II and IV controlled substances to undercover law enforcement personnel on numerous occasions without a legitimate medical purpose and outside the scope of his professional practice. Show Cause Order at 1. The Show Cause Order further alleged that Respondent continued to prescribe controlled substances to certain persons notwithstanding that he had been specifically informed that these persons "were illegitimate drug seekers and addicts," and that several of his patients had "died due to mixed drug intoxication or accidental drug overdose." *Id.* at 2.

Following service of the Show Cause Order, Respondent, through his attorney, requested a hearing on the allegations and the ALJ proceeded to conduct pre-hearing procedures. Meanwhile, on October 2, 2007, the Medical Licensing Board of Indiana summarily suspended Respondent's registration for ninety days effective September 27, 2007. The State Board

subsequently extended the suspension an additional ninety days.

Thereafter, the Government moved for summary disposition on the ground that because Respondent lacked authority under state law to handle controlled substances, he was not entitled to maintain his DEA registration. Gov. Mot. for Summ. Disp. at 1 (citing 21 U.S.C. 801(21); 823(f); & 824(a)(3)). Responding to the Government's motion, Respondent did not dispute that his state license had been suspended. Respondent's Reply to DEA's Motion, at 1. Respondent, however, sought a stay of the issuance of the final order in this matter pending the resolution of the state proceedings.

Based on the undisputed fact that Respondent lacked authority to practice medicine in Indiana, and that it was reasonable to infer that he was also without authority to handle controlled substances under state law, the ALJ granted the Government's motion, noting the settled rule that "DEA does not have statutory authority under the [CSA] to maintain a registration if the registrant is without state authority to dispense controlled substances in the State in which he practices medicine." ALJ Dec. at 3 (citing 21 U.S.C. 823(f) & 824(a)(3)). The ALJ further denied Respondent's request to stay the proceeding. The ALJ then ordered that the hearing be cancelled, recommended that Respondent's registration be revoked and any pending renewal applications be denied, and forwarded the record to me for final agency action.

In reviewing the record, I noted that neither the Show Cause Order nor any other document establishes the status of Respondent's registration or whether Respondent has filed a timely renewal application. I therefore took official notice of the Agency's record pertaining to Respondent's registration. That record indicated that Respondent's

registration expired on January 31, 2008, and that Respondent had not filed a renewal application. *See* 5 U.S.C. 558(c). Accordingly, I found that Respondent is not currently registered with the Agency.

Under DEA precedent, "if a registrant has not submitted a timely renewal application prior to the expiration date, then the registration expires and there is nothing to revoke." *Ronald J. Riegel*, 63 FR 67132, 67133 (1998). In other words, under ordinary circumstances the case is moot.

This case commenced, however, with the issuance of an Order of Immediate Suspension, and this Order was based on allegations that Respondent committed acts which rendered "his registration * * * inconsistent with the public interest." 21 U.S.C. 824(a)(4); *see also* Show Cause Order at 1-2. DEA has recognized a limited exception to the mootness rule in cases which commence with the issuance of an immediate suspension order because of the collateral consequences which may attach with the issuance of such a suspension. *See William R. Lockridge*, 71 FR 77791, 77797 (2006).

I also noted that in moving for summary disposition, the Government did not seek to litigate the allegations of the Order to Show Cause and Immediate Suspension. Rather, it relied on the different ground that Respondent no longer had authority under state law to handle controlled substances and thus was not entitled to be registered. *See* 21 U.S.C. 824(a)(3). I further observed that because Respondent did not file a renewal application, it is unclear whether he intended to remain in professional practice.

Accordingly, on May 6, 2008, I ordered that the parties brief the issue of whether this proceeding remains a live controversy. The Order further directed that if Respondent contended

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.

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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-