

Respondent did not accept any responsibility for his failure to physically examine those seven patients within ninety-six hours of admission. The ALJ also found that four of the seven patients were admitted for treatment at RIM and received controlled substance prescriptions while the Respondent was out of the country and there was no other physician coverage provided. RD, at 94; *see also supra* II.F. Respondent not only failed to accept responsibility for his failures here, he seemed to pass blame for his lack of coverage onto another physician who left the practice shortly before Respondent's trip abroad. Tr. 74; RD, at 94. Additionally, the ALJ found, and I agree, that Respondent's testimony regarding the work he did perform while in Europe lacked credibility.⁵¹ RD, at 38, 95.

In all, Respondent failed to explain why, in spite of his misconduct, he can be entrusted with a registration. "The degree of acceptance of responsibility that is required does not hinge on the respondent uttering "magic words" of repentance, but rather on whether the respondent has credibly and candidly demonstrated that he will not repeat the same behavior and endanger the public in a manner that instills confidence in the Administrator." *Jeffrey Stein, M.D.*, 84 FR 46,968, 49,973.

The Agency also looks to the egregiousness and extent of the misconduct which are significant factors in determining the appropriate sanction. *Garrett Howard Smith, M.D.*, 83 FR at 18910 (collecting cases). Here, the ALJ found, and I agree, that the evidence suggests that Respondent's "offending practices had been ongoing and patterned behavior." RD, at 89. The ALJ found that Respondent's care for four patients while he was in Europe was a "particularly aggravating circumstance." RD, at 94. I agree with the ALJ that Respondent's conduct was egregious, particularly in the prescriptions issued while in Europe and those where he delayed seeing the patients for long periods of time. Additionally, I have found many more instances of misconduct than the ALJ, who nonetheless recommended revocation.

The Government argued that the Respondent was on notice, by virtue of the 2010 MOA, that he could not prescribe controlled substances prior to personally examining his patients. Tr. 12; RD, at 69. The MOA stated that "Respondent must conduct an initial examination validating the necessity to

prescribe Suboxone or Subutex to each [new] OBOT patient." I agree with the ALJ that the MOA does not clearly indicate that the examination was required by existing law and that Respondent could have read it to be merely an enhanced requirement placed on Respondent only for the length of the agreement. RD, at 69–70. As such, I will agree with the ALJ and find that the MOA, in and of itself, does not put Respondent on notice that his conduct was illegal per se, even though state law on this matter certainly should have. However, I find the fact that DEA previously gave Respondent an opportunity to correct his behavior and Respondent reverted back to his prior practices upon the expiration of the MOA to be relevant to whether I can entrust the Respondent with a registration. As Respondent did not seem to learn from his prior experience and, as discussed, made no efforts to accept responsibility, I do not trust that a sanction less than revocation will deter Respondent from engaging in this behavior again in the future.

In sanction determinations, the Agency has historically considered its interest in deterring similar acts, both with respect to the respondent in a particular case and the community of registrants. *See Joseph Gaudio, M.D.*, 74 FR 10083, 10095 (2009); *Singh*, 81 FR at 8248. I find that considerations of both specific and general deterrence weigh in favor of revocation in this case. There is simply no evidence that Respondent's egregious behavior is not likely to recur in the future such that I can entrust him with a CSA registration; in other words, the factors weigh in favor of revocation as a sanction.

I will therefore order that Respondent's registration be revoked as contained in the Order below.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a), I hereby revoke DEA Certificate of Registration No. BC3579969 issued to Michael W. Carlton, M.D. This Order is effective March 22, 2021.

D. Christopher Evans,

Acting Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–788]

Bulk Manufacturer of Controlled Substances Application: Patheon API Manufacturing, Inc.

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Patheon API Manufacturing, Inc., has applied to be registered as a bulk manufacturer of basic class(es) of controlled substance(s). Refer to Supplemental Information listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before April 20, 2021. Such persons may also file a written request for a hearing on the application on or before April 20, 2021.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 8701 Morrisette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.33(a), this is notice that on November 12, 2020, Patheon API Manufacturing, Inc., 309 Delaware Street, Greenville, South Carolina 29605, applied to be registered as an bulk manufacturer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Tetrahydrocannabinols ...	7370	I
5-Methoxy-N-N-Dimethyltryptamine.	7431	I
Psilocybin	7437	I
Oxymorphone	9652	II

The company plans to bulk manufacture the listed controlled substances as an Active Pharmaceutical Ingredient (API) for distribution to its customers. In reference to drug code 7370 (Tetrahydrocannabinols), the company plans to bulk manufacture these drugs as synthetic. No other activities for these drug codes are authorized for this registration.

William T. McDermott,

Assistant Administrator.

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⁵¹ Generally, Respondent described his failures as being an "[o]versight." Tr. 122; *see also* Tr. 123; RD, at 36.