

DATES: February 5, 2024.

FOR FURTHER INFORMATION CONTACT:

Alexis Yim (202–708–1446), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (<https://www.usitc.gov>). The public record for this proceeding may be viewed on the Commission's electronic docket (EDIS) at <https://edis.usitc.gov>.

SUPPLEMENTARY INFORMATION:

Background.—On February 5, 2024, the Commission determined that the domestic interested party group response to its notice of institution (88 FR 75026, November 1, 2023) of the subject five-year review was adequate and that the respondent interested party group response was inadequate. The Commission did not find any other circumstances that would warrant conducting a full review.¹ Accordingly, the Commission determined that it would conduct an expedited review pursuant to section 751(c)(3) of the Act (19 U.S.C. 1675(c)(3)).

For further information concerning the conduct of this review and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A and B (19 CFR part 201), and part 207, subparts A, D, E, and F (19 CFR part 207).

Staff report.—A staff report containing information concerning the subject matter of the review has been placed in the nonpublic record, and will be made available to persons on the Administrative Protective Order service list for this review on March 11, 2024. A public version will be issued thereafter, pursuant to § 207.62(d)(4) of the Commission's rules.

Written submissions.—As provided in § 207.62(d) of the Commission's rules, interested parties that are parties to the review and that have provided individually adequate responses to the notice of institution,² and any party

other than an interested party to the review may file written comments with the Secretary on what determination the Commission should reach in the review. Comments are due on or before 5:15 p.m. on March 14, 2024 and may not contain new factual information. Any person that is neither a party to the five-year review nor an interested party may submit a brief written statement (which shall not contain any new factual information) pertinent to the review by March 14, 2024. However, should the Department of Commerce ("Commerce") extend the time limit for its completion of the final results of its review, the deadline for comments (which may not contain new factual information) on Commerce's final results is three business days after the issuance of Commerce's results. If comments contain business proprietary information (BPI), they must conform with the requirements of §§ 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's *Handbook on Filing Procedures*, available on the Commission's website at https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf, elaborates upon the Commission's procedures with respect to filings.

In accordance with §§ 201.16(c) and 207.3 of the rules, each document filed by a party to the review must be served on all other parties to the review (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Determination.—The Commission has determined this review is extraordinarily complicated and therefore has determined to exercise its authority to extend the review period by up to 90 days pursuant to 19 U.S.C. 1675(c)(5)(B).

Authority: This review is being conducted under authority of title VII of the Act; this notice is published pursuant to § 207.62 of the Commission's rules.

By order of the Commission.

Issued: February 15, 2024.

Lisa Barton,

Secretary to the Commission.

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adequate. Comments from other interested parties will not be accepted (*see* 19 CFR 207.62(d)(2)).

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Henry Manning Pickett, M.D.; Default Decision and Order

On July 10, 2023, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause and Immediate Suspension of Registration (OSC/ISO) to Henry Manning Pickett, M.D., (Respondent) of Lakewood, Colorado. Request for Final Agency Action (RFAA), Exhibit (RFAAX) 1, at 1. The OSC/ISO informed Respondent of the immediate suspension of his DEA Certificate of Registration, Control No. AP1388948, pursuant to 21 U.S.C. 824(d), alleging that Respondent's continued registration constitutes "an imminent danger to the public health or safety." *Id.* (quoting 21 U.S.C. 824(d)). The OSC/ISO also proposed the revocation of Respondent's registration, alleging that Respondent's continued registration is inconsistent with the public interest. *Id.* (citing 21 U.S.C. 823(g)(1), 824(a)(4)).

The OSC/ISO notified Respondent of his right to file with DEA a written request for hearing within 30 days after the date of receipt of the OSC/ISO; the OSC/ISO also notified Respondent that if he failed to file such a request, he would be deemed to have waived his right to a hearing and be in default. *Id.* at 8–9 (citing 21 CFR 1301.43). Here, Respondent filed an untimely request for hearing on August 17, 2023,¹ and within his request for hearing, failed to answer the allegations contained in the OSC/ISO as required by 21 CFR 1301.43. *See* RFAAX 3. On August 17, 2023, Chief Administrative Law Judge John J. Mulrooney, II, (the Chief ALJ) issued an Order requiring Respondent to, among other things, answer the allegations by August 23, 2023. *See* RFAAX 4. Respondent failed to file answers to the allegations or to otherwise respond to the order. Ultimately, the Chief ALJ determined that Respondent was in default, and on August 28, 2023, issued an Order Terminating Proceedings. *See* RFAAX 5. "A default, unless excused, shall be deemed to constitute a waiver of the registrant's/applicant's right to a hearing

¹ Based on the Government's submissions in its RFAA dated August 29, 2023, the Agency finds that service of the OSC/ISO on Registrant was adequate and rendered on July 11, 2023. Specifically, on August 23, 2023, the Government filed a Notice of Service and Motion to Dismiss Request for Hearing as Untimely and to Terminate Proceedings, which included as an attachment the Declaration of a DEA Diversion Investigator asserting that on July 11, 2023, Registrant was personally served with the OSC/ISO at his registered address. RFAAX 2, at 1, 3, 13.

¹ A record of the Commissioners' votes, the Commission's statement on adequacy, and any individual Commissioner's statements will be available from the Office of the Secretary and at the Commission's website.

² The Commission has found the response submitted on behalf of NobelClad to be individually

and an admission of the factual allegations of the [OSC].” 21 CFR 1301.43(e).

Further, “[i]n the event that a registrant . . . is deemed to be in default . . . DEA may then file a request for final agency action with the Administrator, along with a record to support its request. In such circumstances, the Administrator may enter a default final order pursuant to [21 CFR] § 1316.67.” *Id.* § 1301.43(f)(1). Here, the Government has requested final agency action based on Respondent’s default pursuant to 21 CFR 1301.43(c), (f). *See also id.* § 1316.67.

I. Findings of Fact

The Agency finds that, in light of Respondent’s default, the factual allegations in the OSC/ISO are admitted.

Colorado Standard of Care

Respondent is deemed to have admitted that the applicable standard of care for the practice of medicine in Colorado indicates that prior to prescribing opioid medication, a physician must, among other things: (1) establish a bona fide provider-patient relationship; (2) establish a diagnosis and legitimate medical purpose through performing a history, physical exam, laboratory imaging, and other studies; (3) assess the risk of opioid therapy, including identifying patient and family history and medication history through review of Prescription Drug Monitoring Program (PDMP) data; (4) assess the patient’s pain for its nature, intensity, type, frequency, duration, and impact on function; (5) assess the patient’s functional ability during treatment and prior to change in medications; (6) consider referrals to other providers for mental health assessments if necessary; and (7) review the PDMP patient profile. RFAAX 1, at 2. Further, Respondent admits that the applicable standard of care provides that clinicians should continue opioid therapy only if there is a clinically meaningful improvement in pain and function that outweighs the risk to patient safety and should practice particular caution when co-prescribing opioid pain medication with benzodiazepines or muscle relaxants and/or sedative hypnotics. *Id.* at 2–3.

Patient N.B.

According to the OSC/ISO, between June 2021 and October 2022, Respondent issued prescriptions for controlled substances to Patient N.B. on an approximately monthly basis; these prescriptions included prescriptions for fentanyl 50 mg (a schedule II opioid), zolpidem tartrate 10 mg (a schedule IV

sedative), oxycodone/acetaminophen 10/325 mg (a schedule II opioid), alprazolam 2 mg (a schedule IV benzodiazepine), and tramadol 50 mg (a schedule V opioid). RFAAX 1, at 3. Respondent has admitted that he issued these prescriptions without conducting an appropriate evaluation, without appropriately establishing a medical justification, without proper medical records, and without conducting proper ongoing monitoring of the patient. *Id.* Respondent has also admitted that he did not issue the above-referenced controlled substance prescriptions for a legitimate medical purpose in the usual course of professional practice. *Id.* at 4.

Patient K.C.

According to the OSC/ISO, between June 2021 and February 2023, Respondent issued prescriptions for controlled substances to Patient K.C. on an approximately monthly basis; these prescriptions included prescriptions for oxycodone 30 mg (a schedule II opioid), carisoprodol 350 mg (a schedule IV muscle relaxant) and pregabalin 300 mg (a schedule V anti-convulsant). *Id.* at 4. Respondent has admitted that he issued these prescriptions without conducting an appropriate evaluation, without appropriately establishing a medical justification, without proper medical records, and without conducting proper ongoing monitoring of the patient. *Id.* Respondent has also admitted that he did not issue the above-referenced controlled substance prescriptions for a legitimate medical purpose in the usual course of professional practice. *Id.*

Patient B.M.

According to the OSC/ISO, between June 2021 and March 2023, Respondent issued prescriptions for controlled substances to Patient B.M. on an approximately monthly basis; these prescriptions included prescriptions for oxycodone 10 mg, alprazolam 2 mg, oxycodone/acetaminophen 10/325 mg, OxyContin 30 mg (a brand name drug containing an extended release formulation of oxycodone), and carisoprodol 350 mg. *Id.* at 5. Respondent has admitted that he issued these prescriptions without conducting an appropriate evaluation, without appropriately establishing a medical justification, without proper medical records, and without conducting proper ongoing monitoring of the patient. *Id.* Respondent has also admitted that he did not issue the above-referenced controlled substance prescriptions for a legitimate medical purpose in the usual course of professional practice. *Id.*

Patient R.M.

According to the OSC/ISO, between June 2021 and February 2023, Respondent issued prescriptions for controlled substances to Patient R.M. on an approximately monthly basis; these prescriptions included prescriptions for oxycodone 10 mg and 20 mg, zolpidem tartrate 10 mg, and lorazepam 0.5 mg (a schedule IV benzodiazepine). *Id.* Respondent has admitted that he issued these prescriptions without conducting an appropriate evaluation, without appropriately establishing a medical justification, without proper medical records, and without conducting proper ongoing monitoring of the patient. *Id.* Respondent has also admitted that he did not issue the above-referenced controlled substance prescriptions for a legitimate medical purpose in the usual course of professional practice. *Id.* at 6.

Patient S.S.

According to the OSC/ISO, between June 2021 and February 2023, Respondent issued prescriptions for controlled substances to Patient S.S. on an approximately monthly basis; these prescriptions included prescriptions for oxycodone 10 mg and 20 mg, alprazolam 0.5 mg and 1 mg, lorazepam 0.5 mg, and OxyContin 60 mg. *Id.* at 6. Respondent has admitted that he issued these prescriptions without conducting an appropriate evaluation, without appropriately establishing a medical justification, without proper medical records, and without conducting proper ongoing monitoring of the patient. *Id.* Respondent has also admitted that he did not issue the above-referenced controlled substance prescriptions for a legitimate medical purpose in the usual course of professional practice. *Id.*

Patient P.M.

According to the OSC/ISO, between June 2021 and March 2023, Respondent issued prescriptions for controlled substances to Patient P.M. on an approximately monthly basis; these prescriptions included prescriptions for oxycodone 30 mg, hydromorphone 4 mg and 8 mg (a schedule II opioid), alprazolam 2 mg, and testosterone 200 mg/ml (a schedule III steroid). *Id.* at 6–7. Respondent has admitted that he issued these prescriptions without conducting an appropriate evaluation, without appropriately establishing a medical justification, without proper medical records, and without conducting proper ongoing monitoring of the patient. *Id.* at 7. Respondent has also admitted that he did not issue the above-referenced controlled substance prescriptions for a legitimate medical

purpose in the usual course of professional practice. *Id.*

Patient D.J.

According to the OSC/ISO, between June 2021 and December 2022, Respondent issued prescriptions for controlled substances to Patient D.J. on an approximately monthly basis; these prescriptions included prescriptions for oxycodone 30 mg and lorazepam 2 mg. *Id.* Respondent has admitted that he issued these prescriptions without conducting an appropriate evaluation, without appropriately establishing a medical justification, without proper medical records, and without conducting proper ongoing monitoring of the patient. *Id.* Respondent has also admitted that he did not issue the above-referenced controlled substance prescriptions for a legitimate medical purpose in the usual course of professional practice. *Id.* at 8.

II. Discussion

A. The Five Public Interest Factors

Under the Controlled Substances Act (CSA), “[a] registration . . . to . . . dispense a controlled substance . . . may be suspended or revoked by the Attorney General 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.” 21 U.S.C. 824(a). In making the public interest determination, the CSA requires consideration of the following factors:

(A) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(B) The [registrant’s] experience in dispensing, or conducting research with respect to controlled substances.

(C) The [registrant’s] conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(D) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(E) Such other conduct which may threaten the public health and safety.

21 U.S.C. 823(g)(1).

The Agency considers these public interest factors in the disjunctive. *Robert A. Leslie, M.D.*, 68 FR 15227, 15230 (2003). Each factor is weighed on a case-by-case basis. *Morall v. Drug Enf’t Admin.*, 412 F.3d 165, 173–74 (D.C. Cir. 2005). Any one factor, or combination of factors, may be decisive. *David H. Gillis, M.D.*, 58 FR 37507, 37508 (1993).

While the Agency has considered all of the public interest factors in 21 U.S.C.

823(g)(1),² the Government’s evidence in support of its *prima facie* case for revocation of Respondent’s registration is confined to Factors B and D. See RFAAX 1, at 2–8. Moreover, the Government has the burden of proof in this proceeding. 21 CFR 1301.44.

Here, the Agency finds that the Government’s evidence satisfies its *prima facie* burden of showing that Respondent’s continued registration would be “inconsistent with the public interest.” 21 U.S.C. 824(a)(4).

B. Factors B and D

Evidence is considered under Public Interest Factors B and D when it reflects compliance (or non-compliance) with laws related to controlled substances and experience dispensing controlled substances. See *Sualeh Ashraf, M.D.*, 88 FR 1095, 1097 (2023); *Kareem Hubbard, M.D.*, 87 FR 21156, 21162 (2022). In the current matter, the Government has alleged that Respondent violated both federal and state law regulating controlled substances. RFAAX 1, at 2–8. Specifically, federal law states that “[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.” 21 CFR 1306.04(a). Further, Colorado state law defines “unprofessional conduct” as “[a]dministering, dispensing, or prescribing any habit-forming drug or any controlled substance . . . other than in the course of legitimate professional practice,” as well as “[a]ny act or omission that fails to meet generally accepted standards of medical practice.” Colo. Rev. Stat. section 12–240–121(1)(c), (j).

² As to Factor A, the record contains no evidence of a recommendation from any state licensing board or professional disciplinary authority. 21 U.S.C. 823(g)(1)(A). Nonetheless, an absence of such evidence “does not weigh for or against a determination as to whether continuation of the [registrant’s] DEA certification is consistent with the public interest.” *Roni Dreszer, M.D.*, 76 FR 19434, 19444 (2011). As to Factor C, there is no evidence in the record that Registrant has been convicted of an offense under either federal or state law “relating to the manufacture, distribution, or dispensing of controlled substances.” 21 U.S.C. 823(g)(1)(C). However, as Agency cases have noted, there are a number of reasons why a person who has engaged in criminal misconduct may never have been convicted of an offense under this factor. *Dewey C. MacKay, M.D.*, 75 FR 49956, 49973 (2010). Agency cases have therefore found that “the absence of such a conviction is of considerably less consequence in the public interest inquiry” and is therefore not dispositive. *Id.* Finally, as to Factor E, the Government’s evidence fits squarely within the parameters of Factors B and D and does not raise “other conduct which may threaten the public health and safety.” 21 U.S.C. 823(g)(1)(E). Accordingly, Factor E does not weigh for or against Registrant.

Here, Respondent has admitted that he repeatedly issued prescriptions for controlled substances without conducting appropriate evaluations, without appropriately establishing medical justifications, without taking and keeping proper medical records, and without conducting proper ongoing monitoring of his patients. Respondent further admitted that none of the above-referenced controlled substance prescriptions were issued for a legitimate medical purpose or in the usual course of professional practice. As such, the Agency finds that Respondent repeatedly violated 21 CFR 1306.04(a) and Colorado Revised Statutes section 12–240–121(1)(c).

Accordingly, the Agency finds that Factors B and D weigh in favor of revocation of Respondent’s registration and thus finds Respondent’s continued registration to be inconsistent with the public interest in balancing the factors of 21 U.S.C. 823(g)(1). The Agency further finds that Respondent failed to provide any evidence to rebut the Government’s *prima facie* case.

III. Sanction

Where, as here, the Government has established grounds to revoke Respondent’s registration, the burden shifts to Respondent to show why he can be entrusted with the responsibility carried by a registration. *Garret Howard Smith, M.D.*, 83 FR 18882, 18910 (2018). When a respondent has committed acts inconsistent with the public interest, he must both accept responsibility and demonstrate that he has undertaken corrective measures. *Holiday CVS, L.L.C., dba CVS Pharmacy Nos. 219 and 5195*, 77 FR 62316, 62339 (2012) (internal quotations omitted). Trust is necessarily a fact-dependent determination based on individual circumstances; therefore, the Agency looks at factors such as the acceptance of responsibility, the credibility of that acceptance as it relates to the probability of repeat violations or behavior, the nature of the misconduct that forms the basis for sanction, and the Agency’s interest in deterring similar acts. See, e.g., *Robert Wayne Locklear, M.D.*, 86 FR 33738, 33746 (2021).

Here, although Respondent initially requested a hearing, he repeatedly failed to answer the allegations contained in the OSC/ISO, failed to file any other responses as directed by the Chief ALJ, and did not otherwise avail himself of the opportunity to refute the Government’s case. As such, Respondent has made no representations as to his future compliance with the CSA nor made any demonstration that he can be entrusted

with registration. Moreover, the evidence presented by the Government shows that Respondent violated the CSA, further indicating that Respondent cannot be entrusted.

Accordingly, the Agency will order the revocation of Respondent's registration.

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. AP1388948 issued to Henry Manning Pickett, M.D. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(g)(1), I hereby deny any pending applications of Henry Manning Pickett, M.D., to renew or modify this registration, as well as any other pending application of Henry Manning Pickett, M.D., for additional registration in Colorado. This Order is effective March 25, 2024.

Signing Authority

This document of the Drug Enforcement Administration was signed on February 14, 2024, by Administrator Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the Federal Register.

Heather Achbach,

Federal Register Liaison Officer, Drug Enforcement Administration.

[FR Doc. 2024-03548 Filed 2-21-24; 8:45 am]

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DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Under the Comprehensive Environmental Response, Compensation, and Liability Act

On February 13, 2024, the Department of Justice lodged a proposed Consent Decree with the United States District Court for the Southern District of Indiana in the case entitled *United States v. Navistar, Inc. et al.*, Civil Action No. 1:24-cv-00285.

In this action the United States is seeking reimbursement of response costs and future costs incurred from

Defendants Arconic Corporation, Navistar, Inc., and Ford Motor Company for alleged violations of the Comprehensive Environmental Response, Compensation, and Liability Act, 42 U.S.C. 9601 *et seq.* Under the proposed Consent Decree, the Defendants are required to reimburse the United States for costs incurred for response activities undertaken in response to the release and threatened release of hazardous substances at or from the A.A. Oil Site, a former waste oil collection, storage, and transfer facility located in Indianapolis, Indiana. The proposed Consent Decree also seeks a declaratory judgment that the Defendants are liable for future response costs that the United States may incur in connection with response actions that may be performed at the A.A. Oil Site.

The publication of this notice opens a period for public comment on the proposed Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States v. Navistar, Inc. et al.*, D.J. Ref. No. 90-11-3-12580. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail:

<i>To submit comments:</i>	<i>Send them to:</i>
By email	<i>pubcomment-ees.enrd@usdoj.gov.</i>
By mail	Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044-7611.

Any comments submitted in writing may be filed by the United States in whole or in part on the public court docket without notice to the commenter.

During the public comment period, the proposed Consent Decree may be examined and downloaded at this Justice Department website: <http://www.justice.gov/enrd/consent-decrees>. If you require assistance accessing the proposed Consent Decree, you may request assistance by email or by mail to the addresses provided above for submitting comments.

Patricia McKenna,

Deputy Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2024-03564 Filed 2-21-24; 8:45 am]

BILLING CODE 4410-15-P

DEPARTMENT OF LABOR

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Delinquent Filer Voluntary Compliance Program

ACTION: Notice of availability; request for comments.

SUMMARY: The Department of Labor (DOL) is submitting this Employee Benefits Security Administration (EBSA)-sponsored information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that the agency receives on or before March 25, 2024.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function.

Comments are invited on: (1) whether the collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (2) the accuracy of the agency's estimates of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: Michael Howell by telephone at 202-693-6782, or by email at DOL_PRA_PUBLIC@dol.gov.

SUPPLEMENTARY INFORMATION: Under title I of ERISA, the administrator of each welfare plan and each pension plan, unless otherwise exempt, is required to file an annual report with the Secretary containing the information set forth in section 103 of ERISA. The statutory annual reporting requirements under titles I and IV of ERISA, as well as the Internal Revenue Code (the Code), are satisfied generally by filing the appropriate annual return/report (the Form 5500).

On April 27, 1995, the Department implemented the Delinquent Filer