

and his registration is currently “in a renewal pending status.” *Id.*

Registrant’s Exclusion

The evidence in the record demonstrates that, on September 25, 2018, Judgment was entered against Registrant in E.D. La. “based on [Registrant’s] conviction on one count of ‘Conspiracy to Commit Health Care Fraud,’ in violation of 18 U.S.C. 1349, one count of ‘Conspiracy to Pay and Receive Illegal Health Care Kickbacks,’ in violation of 18 U.S.C. 371, fifteen counts of ‘Health Care Fraud,’ in violation of 18 U.S.C. 1347 and 2, and one count of ‘Obstruction of a Federal Audit,’ in violation of 18 U.S.C. 1516 and 2.” RFAA EX 3 (Judgment in a Criminal Case at 1, *United States v. Barnes*, No. 2:15-cr-61-SM-JCW (E.D. La. September 28, 2018).

By letter dated March 29, 2019, HHS OIG notified Registrant of his exclusion from Medicare, Medicaid, and all federal health care programs under 42 U.S.C. 1320a-7(a) for a minimum period of twenty-five years based on Registrant’s felony convictions in E.D. La. RFAA, EX 4 (hereinafter, Exclusion Letter), at 1. The Exclusion Letter stated that the period of exclusion was greater than the minimum of five years, because the acts resulting in conviction “caused a financial loss to a government agency or program or to one or more entities of \$50,000 or more,” and specifically, the court ordered Registrant “to pay approximately \$10,850,200 in restitution.” *Id.* at 2. Further, the HHS OIG reasoned that “the acts were committed over a period of one year or more,” and specifically, that “the acts occurred from November 2008 to about May 2014.” *Id.* Finally, the HHS OIG considered whether the Registrant was incarcerated and found that the “court sentenced [Registrant] to 60 months of incarceration.” *Id.* Per the Exclusion Letter, the exclusion became effective twenty days from the date of the letter, or April 18, 2019. *Id.* at 1. The Exclusion Letter notified Registrant of his appeal rights. *Id.* at 2–4.

Accordingly, I find that the HHS OIG excluded Registrant from Medicare, Medicaid, and all federal health care programs under 42 U.S.C. 1320a-7(a) for twenty-five years, effective April 18, 2019, based on Registrant’s convictions in the E.D. La.

Discussion

Under Section 824(a) of the Controlled Substances Act (hereinafter, CSA), a registration may be suspended or revoked upon a finding of one or more of five grounds. Each subsection of Section 824(a) provides an independent

ground to impose a sanction on a registrant. *Arnold E. Feldman, M.D.*, 82 FR 39614, 39617 (2017); *see also Gilbert L. Franklin, D.D.S.*, 57 FR 3441 (1992) (“[M]andatory exclusion from participation in the Medicare program constitutes an independent ground for revocation pursuant to 21 U.S.C. [§] 824(a)(5).”). The ground in 21 U.S.C. 824(a)(5) requires that the registrant “has been excluded (or directed to be excluded) from participation in a program pursuant to section 1320a-7(a) of Title 42.” 42 U.S.C. 1320a-7(a) provides a list of four predicate offenses for which exclusion from Medicare, Medicaid, and other federal health care programs is mandatory and sets out mandatory timeframes for such exclusion. *Id.*

When a registrant facing a sanction under 21 U.S.C. 824(a)(5) offers no mitigating evidence for the Administrator to consider, “it is reasonable that the Administrator might revoke or suspend.” *Jeffrey Stein, M.D.*, 84 FR 46968, 46971 (2019); *see, e.g.*, *Narciso A. Reyes, M.D.*, 83 FR 61678, 61681 (2018); *Richard Hauser, M.D.*, 83 FR 26308, 26310 (2018). Further, “[t]here does not need to be a nexus to controlled substances to make a connection between the activity that caused the mandatory exclusion and the potential for abuse of a DEA registration.” *Jeffrey Stein, M.D.*, 84 FR at 46972; *Narciso Reyes, M.D.*, 83 FR at 61681; *KKK Pharmacy*, 64 FR 49507, 49510 (1999) (collecting cases); *Melvin N. Seglin, M.D.*, 63 Red. Reg. 70431, 70433 (1998); *Stanley Dubin, D.D.S.*, 61 FR 60727, 60728 (1996).

Here, there is no dispute in the record that Registrant is mandatorily excluded pursuant to Section 1320a-7(a) of Title 42 and, therefore, that a ground for the revocation or suspension of Registrant’s registration exists. 21 U.S.C. 824(a)(5). Indeed, Registrant was convicted of multiple counts involving fraud, kickbacks, and obstruction of a federal audit. The HHS OIG estimated that Registrant’s criminality spanned six years and resulted in a financial loss of approximately \$10,850,200. RFAA, EX 4, at 2.

Where, as here, the Government has met its *prima facie* burden of showing that a ground for revocation exists, the burden shifts to the Registrant to show why he can be entrusted with a registration. *See Jeffrey Stein, M.D.*, 84 FR at 46972. Registrant, as already discussed, failed to respond in any way to the OSC. *See* RFAA, at 6. Therefore, among other things, Registrant has not accepted responsibility for his criminality, shown any remorse for it, or provided any assurance that he would

not repeat it. *See Jeffrey Stein, M.D.*, 84 FR at 46972–74. Such silence weighs against the Registrant’s continued registration. *Zvi H. Perper, M.D.*, 77 FR 64131, 64142 (2012) (citing *Medicine Shoppe-Jonesborough*, 73 FR 264, 387 (2008); *Samuel S. Jackson*, 72 FR 23848, 23853 (2007)); *see also Jones Total Health Care Pharmacy, LLC v. Drug Enf’t Admin.*, 881 F.3d 823, 831 (11th Cir. 2018) (“‘An agency rationally may conclude that past performance is the best predictor of future performance.’” (quoting *Alra Laboratories, Inc. v. Drug Enf’t Admin.*, 54 F.3d 450, 452 (7th Cir. 1995))).

Based on the record before me, I conclude that Registrant’s founded criminality involving dishonesty and obstruction, resulting in his exclusion from Medicare, Medicaid, and all federal health care programs, makes him ineligible for a DEA registration at this time. Accordingly, I shall order the sanctions the Government requested, 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. BB1040269 issued to Shelton W. Barnes, M.D. Further, I hereby deny any pending application of Shelton W. Barnes, M.D., to renew or modify this registration, as well as any pending application of Shelton W. Barnes, M.D., for registration in Louisiana. This Order is effective March 4, 2020.

Dated: January 3, 2020.

Uttam Dhillon,
Acting Administrator.

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BILLING CODE 4410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-576]

Bulk Manufacturer of Controlled Substances Application: Noramco Inc.

ACTION: Notice of application.

DATES: Registered bulk manufacturers of the affected basic classes, and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before April 3, 2020.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 8701

Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.33(a), this is notice that on July 17, 2019, Noramco Inc., 1550 Olympic Drive, Athens,

Georgia 30601 applied to be registered as a bulk manufacturer of the following basic classes of controlled substances:

Controlled substance	Drug code	Schedule
Cathinone	1235	
Gamma Hydroxybutyric Acid	2010	
Marihuana Extract	7350	
Marihuana	7360	
Tetrahydrocannabinols	7370	
Codeine-N-oxide	9053	
Dihydromorphine	9145	
Hydromorphone	9301	
Morphine-N-oxide	9307	
Normorphine	9313	
Amphetamine	1100	II
Lisdexamfetamine	1205	II
Methylphenidate	1724	II
Nabilone	7379	II
Codeine	9050	II
Dihydrocodeine	9120	II
Oxycodone	9143	II
Hydromorphone	9150	II
Hydrocodone	9193	II
Levorphanol	9220	II
Morphine	9300	II
Oripavine	9330	II
Thebaine	9333	II
Oxymorphone	9652	II
Noroxyphorphone	9668	II
Alfentanil	9737	II
Sufentanil	9740	II
Carfentanil	9743	II
Tapentadol	9780	II
Fentanyl	9801	II

The company plans to manufacture bulk active pharmaceutical ingredients (APIs) and reference standards for distribution to their customers.

In reference to drug codes 7350 (marihuana extract), 7360 (marihuana), and 7370 (tetrahydrocannabinols), the company plans to bulk manufacture these drugs as synthetics. No other activities for these drugs are authorized for this registration.

Dated: January 24, 2020.

William T. McDermott,
Assistant Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-567]

Bulk Manufacturer of Controlled Substances Application: Bulk Manufacturers of Marihuana: Spocannabis LLC

ACTION: Notice of application.

SUMMARY: The Drug Enforcement Administration (DEA) is providing

notice of an application it has received from an entity applying to be registered to manufacture in bulk basic classes of controlled substances listed in schedule I. Prior to making decisions on this and other pending applications, DEA intends to promulgate regulations that govern the program of growing marihuana for scientific and medical research under DEA registration.

DATES: Registered bulk manufacturers of the affected basic classes, and applicants therefor, may file written comments on or objections to the issuance of the proposed registration on or before April 3, 2020.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW 8701 Morrissette Drive, Springfield, Virginia 22152. To ensure proper handling of comments, please reference "Docket No. DEA-567" in all correspondence, including attachments.

SUPPLEMENTARY INFORMATION: The Controlled Substances Act (CSA) prohibits the cultivation and distribution of marihuana except by persons who are registered under the CSA to do so for lawful purposes. In accordance with the purposes specified

in 21 CFR 1301.33(a), DEA is providing notice that the entity identified below has applied for registration as a bulk manufacturer of schedule I controlled substances. In response, registered bulk manufacturers of the affected basic classes, and applicants therefor, may file written comments on or objections of the requested registration, as provided in this notice. This notice does not constitute any evaluation or determination of the merits of the application submitted.

The applicant plans to manufacture bulk active pharmaceutical ingredients (APIs) for product development and distribution to DEA registered researchers. If its application for registration is granted, the registrant would not be authorized to conduct other activity under this registration aside from those coincident activities specifically authorized by DEA regulations. DEA will evaluate the application for registration as a bulk manufacturer for compliance with all applicable laws, treaties, and regulations and to ensure adequate safeguards against diversion are in place.

As this applicant has applied to become registered as a Bulk