ADDRESSES: The Drug Enforcement Administration requires that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to *https://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon submission of your comment, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on *https://www.regulations.gov.* If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.33(a), this is notice that on July 24, 2024, Cambridge Isotope Laboratories, Inc., 50 Frontage Road, Andover, Massachusetts 01810–5413, applied to be registered as a bulk manufacturer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Tetrahydrocannabinols	7370	I

The company plans to synthetically bulk manufacture the controlled substance Tetrahydrocannabinols to produce analytical standards for distribution to its customers. No other activity for this drug code is authorized for this registration.

Marsha L. Ikner,

Acting Deputy Assistant Administrator.

[FR Doc. 2024–19788 Filed 9–3–24; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–1422]

Importer of Controlled Substances Application: Fisher Clinical Services, Inc.

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Fisher Clinical Services, Inc. has applied to be registered as an importer of basic class(es) of controlled substance(s). Refer to Supplementary Information listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants, therefore, may submit electronic comments on or objections to the issuance of the proposed registration on or before October 4, 2024. Such persons may also file a written request for a hearing on the application on or before October 4, 2024.

ADDRESSES: The Drug Enforcement Administration requires that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to *https://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon submission of your comment, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on *https://www.regulations.gov.* If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment. All requests for a hearing must be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for a hearing should also be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.34(a), this is notice that on July 10, 2024, Fisher Clinical Services, Inc., 700A–C Nestle Way, Breinigsville, Pennsylvania 18031–1522, applied to be registered as an importer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Marihuana Extract	7350	I
Dimethyltryptamine	7435	I
Psilocybin	7437	I
Methylphenidate	1724	II
Levorphanol	9220	II
Noroxymorphone	9668	II
Tapentadol	9780	II

The company plans to import the listed controlled substances for use in clinical trials only. No other activities for these drug codes are authorized for this registration.

Approval of permit applications will occur only when the registrant's business activity is consistent with what is authorized under 21 U.S.C. 952(a)(2). Authorization will not extend to the import of Food and Drug Administration-approved or non-approved finished dosage forms for commercial sale.

Marsha L. Ikner,

Acting Deputy Assistant Administrator.

[FR Doc. 2024–19791 Filed 9–3–24; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 23–15]

Samirkumar Shah, M.D.; Decision and Order

On November 28, 2022, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause (OSC) to Samirkumar Shah, M.D., (Applicant) of Pittsburgh, Pennsylvania.

OSC, at 1, 3. The OSC proposed the denial of Applicant's application for a DEA Certificate of Registration, Control No. W21057811C, alleging that Applicant has been excluded from participation in Medicare, Medicaid, and all federal health care programs pursuant to 42 U.S.C. 1320a–7(a). *Id.* at 1 (citing 21 U.S.C. 824(a)(5)).[1]

A hearing was held before DEA Chief Administrative Law Judge John J. Mulrooney, II (the Chief ALJ), who, on November 16, 2023, issued his Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision (Recommended Decision or RD), which recommended denial of Applicant's application. RD, at 19. Following the issuance of the RD, Applicant filed Exceptions.[2] Having reviewed the entire record, the Agency adopts and hereby incorporates by reference the entirety of the Chief ALJ's rulings, credibility findings,[3] findings of fact, conclusions of law, sanctions analysis, and recommended sanction as found in the RD.

[1] In its OSC, the Government relies upon 21 U.S.C. 824(a), grounds which Congress provided to support revocation or suspension, not denial of an application. Prior Agency decisions have repeatedly determined that it is appropriate to consider a provision of 21 U.S.C. 824(a) when determining whether to grant a practitioner registration application. *Robert Wayne Locklear, M.D.,* 86 FR 33,738, 33,744–33,745 (2021) (collecting cases); *see also Dinorah Drug Store, Inc.,* 61 FR 15,972, 15,973–15,974 (1996).

[2] In Applicant's Exceptions document, dated November 22, 2023, Applicant does not put forward any particular arguments contesting the Chief ALJ's Recommended Decision, but simply requests an appeal of the Decision. Applicant's Exceptions, at 1–2.

[3] The Agency adopts the Chief ALJ's summary of each of the witnesses' testimonies as well as the Chief ALJ's assessment of each of the witnesses' credibility. *See* RD, at 3–10. The Agency agrees with the Chief ALJ that the testimony from the DEA Diversion Investigator (DI), which was primarily focused on the non-controversial introduction of documentary evidence and the DI's contact with the case, was sufficiently detailed, plausible, and internally consistent without indication of any motive to fabricate or exaggerate and thus warranted full credibility. *Id.* at 4. The Agency also agrees with the Chief ALJ that the testimony from Applicant, which was focused on Applicant's criminal conviction, the underlying facts of Applicant's criminal conviction, and the mandatory exclusion resulting from Applicant's criminal conviction, was ''ubiquitously inconsistent, frequently lacking in detail, and commonly bereft of even a modest level of basic plausibility.'' *Id.* at 9. The Chief ALJ also noted, and the Agency agrees, that Applicant was ''unwilling to acknowledge his own misconduct on any level.'' *Id.* Based on these factors, the Chief ALJ found, and the Agency agrees, that Applicant's testimony was lacking in credibility and warranted reduced weight. *Id.* at 9–10.

I. Findings of Fact

1. Applicant's Criminal Conviction and Exclusion

In 2021, Applicant was convicted of two felony counts of healthcare fraud in violation of 18 U.S.C. 1347. RD, at 4; Government Exhibit (GX) 3. As a result of Applicant's conviction, the U.S. Department of Health and Human Services, Office of Inspector General (HHS/OIG) excluded Applicant, effective July 20, 2022, from participation in Medicare, Medicaid, and all federal health care programs pursuant to 42 U.S.C. 1320a–7(a) for a period of twenty-seven years. RD, at 4; GX 4; Tr. 26–28.

2. Applicant's Argument

Regarding the allegations underlying his criminal conviction, Applicant testified that he started implementing in his practice a cardiovascular therapy called ''external counter pulsation therapy'' (ECP) designed to help patients with heart failure. Tr. 59. Applicant testified that he offered this therapy with 25 certified physicians in Pennsylvania. *Id.* According to Applicant, ''[t]he mistake was the billing of this therapy.'' RD; at 7; Tr. 59–60. Applicant testified that he is ''not trained as a biller'' and he ''had a private company who prepared all the codes and billing forms.'' RD, at 7; Tr. at 60. Applicant asserted that he ''did not realize that the billing was not done correctly,'' but also that he ''did everything by the book and the law.'' RD, at 7; Tr. 60, 90. Nonetheless, Applicant stated, ''the biller is responsible for what happened . . . my name was used, but he's liable.'' RD, at 7; Tr. 104.

Notably, when Applicant appealed his criminal conviction, the United States Court of Appeals for the Third Circuit (Court of Appeals) found that the ECP therapy that Applicant was prescribing and billing for was unnecessary. RD, at 7 (citing *United States* v. *Shah,* 43 F.4th 356, 366–367 (3d Cir. 2022)). Even so, Applicant testified that every patient to whom he prescribed ECP therapy needed it. RD, at 7; Tr. 77, 85–86. The Court of Appeals also found that Applicant had advertised his ECP therapy to accomplish unrealistic goals, such as that it would make patients ''younger and smarter'' and could help with a plethora of conditions including obesity, erectile disfunction, restless leg syndrome, and blood pressure issues. RD, at 7 (citing *United States* v. *Shah,* 43 F.4th at 361). According to Applicant, ''[t]hose comments were made by a couple of [his] office employees without [his] knowledge.'' RD, at 7; Tr. 89. As for the finding by the Court of Appeals that Applicant was often not present to supervise the ECP treatments, *see United States* v. *Shah,* 43 F.4th at 361, Applicant testified that this finding was ''bogus'' because other physicians were present. RD, at 7; Tr. 89–90.

As highlighted by the Chief ALJ, Applicant also repeatedly emphasized that he had ''hired a very awful attorney in Western Pennsylvania as [his] attorney to defend [his] case.'' RD, at 7–8; Tr. 60. Specifically, Applicant took issue with his attorney's legal strategy (which led to the attorney firing Applicant as a client) as well as the fact that the attorney went on to accept an appointment as a federal prosecutor, which Applicant characterized as creating a conflict of interest regarding his case. RD, at 8; Tr. 61. As noted by the Chief ALJ, Applicant's latter complaint was raised with the Court of Appeals and found to be without merit. RD, at 8 (citing *United States* v. *Shah,* 43 F.4th at 363–365). Furthermore, Applicant claimed he was forced to go to trial without access to relevant medical files and also was unable to have these files reviewed by a potential expert witness. RD, at 8; Tr. 77, 81–82, 84. Again, the Court of Appeals found this contention to be without merit. RD, at 8 (citing *United States* v. *Shah,* 43 F.4th at 364–365). Finally, Applicant made claims as to the Court of Appeals itself. Specifically, Applicant claimed incorrectly that the panel of the Court of Appeals that affirmed his conviction was split. RD, at 8 (citing *United States* v. *Shah,* 43 F.4th at 360); Tr. 83. Applicant also claimed that his request for an *en banc* reconsideration of his case was denied ''because they're busy, they're on vacations and everything, they denied my ten-judge panel appeal.'' RD, at 8; Tr. 83. Overall, Applicant characterized his conviction as a ''complete miscarriage of justice.'' RD, at 8; Tr. 88. Regarding the findings of HHS/OIG, Applicant testified that HHS/OIG ''just had a summary judgment'' without providing Applicant with a trial or hearing. RD, at 9; Tr. 93.

Applicant testified that the criminal court had ordered $1.2 million in restitution and that he was paying $300 per month. RD, at 9; Tr. 70. As for any potential remedial measures, Applicant testified that when he restarts his practice, he will not need Medicare patients and he plans to focus on weight loss and cosmetic procedures for ''cash-paying patients.'' RD, at 9; Tr. 70–71.

II. Discussion

1. The Five Public Interest Factors

Pursuant to Section 303(g)(1) of the Controlled Substances Act (CSA), ''[t]he Attorney General shall register practitioners . . . to dispense . . . controlled substances . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices.'' 21 U.S.C. 823(g)(1). Section 303(g)(1) further provides that an application for a practitioner's registration may be denied upon a determination that ''the issuance of such registration . . . would be inconsistent with the public interest.'' *Id.* 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 applicant's experience in dispensing, or conducting research with respect to controlled substances.

(C) The applicant'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).

In the current matter, it is undisputed that Applicant holds a valid state medical license and is authorized to dispense controlled substances in the Commonwealth of Pennsylvania where he practices. Moreover, because the Government has not alleged that Applicant's registration is inconsistent with the public interest under section 823, and although the Agency has considered section 823, the Agency will not analyze Applicant's application under the public interest factors. Therefore, in accordance with prior agency decisions, the Agency will move to assess whether the Government has proven by substantial evidence that a ground for suspension exists under 21 U.S.C. 824(a). *See supra* n.1.

2. Mandatory Exclusion From Federal Health Care Programs

Under Section 824(a) of the CSA, a registration ''may be suspended or revoked'' upon a finding of one or more of five grounds. 21 U.S.C. 824(a). 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.'' *Id.* at § 824(a)(5). Here, there is no dispute in the record that Applicant is mandatorily excluded from federal health care programs under 42 U.S.C. 1320a–7(a). The Government has presented substantial evidence of Applicant's exclusion and the underlying criminal conviction that led to that exclusion, and Applicant has admitted to the same. GX 2–8; Applicant's Post-Hearing Brief, at 4–5. Accordingly, the Agency will sustain the Government's allegation that Applicant has been excluded from participation in a program pursuant to section 1320a–7(a) of Title 42 and find that the Government has established that a ground exists upon which a registration could be revoked pursuant to 21 U.S.C. 824(a)(5).

Further, although the language of 21 U.S.C. 824(a)(5) discusses suspension and revocation of a registration, for the reasons discussed above, *see supra* n.1, it may also serve as the basis for the denial of a DEA registration application. *Dinorah Drug Store, Inc.,* 61 FR at 15,973. Applicant's exclusion from participation in a program under 42 U.S.C. 1320a–7(a), therefore, serves as an independent basis for denying his application for DEA registration. 21 U.S.C. 824(a)(5).[4]

III. Sanction

Where, as here, the Government has established sufficient grounds for revocation or denial, the burden shifts to the registrant to show why he can be entrusted with the responsibility carried by a registration. *Garret Howard Smith, M.D.,* 83 FR 18,882, 18,910 (2018). To establish that he can be entrusted with registration, a registrant 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 62,316, 62,339 (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 33,738, 33,746 (2021).

Here, and as noted by the ALJ, ''[Applicant's] consistent minimization and flat out denial of his wrongdoing supports the proposition that he has not credibly and unequivocally accepted responsibility for his actions.'' RD, at 14. Further, Applicant repeatedly placed the blame on others, including his practice's third-party billers, his office employees, his attorney, the Court of Appeals, and HHS/OIG itself. *Id.* at 14–15. Ultimately, the ALJ concluded, and the Agency agrees, that Applicant has not demonstrated unequivocal acceptance of responsibility for his actions. *Id.* at 16.[5]

In addition to acceptance of responsibility, the Agency considers both specific and general deterrence when determining an appropriate sanction. *Daniel A. Glick, D.D.S.,* 80 FR at 74,810. In this case, the Agency agrees with the ALJ that, regarding specific deterrence, ''[w]ithout understanding the nature of his misconduct and his own culpability in it, there is no rational reason [to] believe that [Applicant] would make different choices in the face of the same circumstances in the future.'' RD, at 17. Further, the Agency agrees with the ALJ that the interests of general deterrence also support revocation, as a lack of sanction in the current matter would send a message to the registrant community that a registrant can commit similar misconduct without consequences. *Id.* at 18. The Agency also agrees with the ALJ that Applicant's actions were egregious, as '''defrauding federal health care programs is egregious.'' RD, at 18 (quoting *Gilbert Y. Kim, D.D.S.,* 87 FR 21,139, 21,145 (2022)). As noted by the ALJ, Applicant was convicted of two felony counts of healthcare fraud, with the Court of Appeals itself highlighting that Applicant ''billed insurers for millions of dollars in ECP treatments where they were either not medical necessary for the patient or delivered without the required physician supervision or both.'' RD, at 18 (quoting *United States* v. *Shah,* 43 F.4th at 367).

In sum, Applicant has not offered any credible evidence on the record to rebut the Government's case for denial of his

[4] The underlying conviction forming the basis for a registrant's mandatory exclusion from participation in federal health care programs need not involve controlled substances to provide the grounds for revocation or denial pursuant to section 824(a)(5). *Jeffrey Stein, M.D.,* 84 FR 46,968, 46,971–46,972 (2019); *see also Narciso Reyes, M.D.,* 83 FR 61,678, 61,681 (2018); *KK Pharmacy,* 64 FR 49,507, 49,510 (1999) (collecting cases); *Melvin N. Seglin, M.D.,* 63 FR 70,431, 70,433 (1998); *Stanley Dubin, D.D.S.,* 61 FR 60,727, 60,728 (1996).

[5] When a registrant fails to make the threshold showing of acceptance of responsibility, the Agency need not address the registrant's remedial measures. *Ajay S. Ahuja, M.D.,* 84 FR 5,479, 5,498 n.33 (2019) (citing *Jones Total Health Care Pharmacy, L.L.C. & SND Health Care, L.L.C.,* 81 FR 79,188, 79,202–03 (2016)); *Daniel A. Glick, D.D.S.,* 80 FR 74,800, 74,801, 74,810 (2015). Even so, in the current matter, the Agency has considered Applicant's testimony that when he restarts his practice, he intends to avoid Medicare patients and instead focus on weight loss and cosmetic procedures for ''cash-paying patients.'' Tr. 70–71.

application and Applicant has not demonstrated that he can be entrusted with the responsibility of registration. *Id.* at 19. Accordingly, the Agency will order that Applicant's application be denied.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823, I hereby deny the pending application for a DEA Certificate of Registration, Control No. W21057811C, submitted by Samirkumar Shah, M.D., as well as any other pending application of Samirkumar Shah, M.D., for additional registration in Pennsylvania. This Order is effective October 4, 2024.

Signing Authority

This document of the Drug Enforcement Administration was signed on August 19, 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. 2024–19731 Filed 9–3–24; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–1419]

Importer of Controlled Substances Application: Caligor Coghlan Pharma Services

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Caligor Coghlan Pharma Services has applied to be registered as an importer of basic class(es) of controlled substance(s). Refer to Supplementary Information listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants, therefore, may submit electronic comments on or objections to the issuance of the proposed registration on or before October 4, 2024. Such persons may also file a written request for a hearing on the application on or before October 4, 2024.

ADDRESSES: The Drug Enforcement Administration requires that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to *https://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon submission of your comment, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on *https://www.regulations.gov.* If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment. All requests for a hearing must be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for a hearing should also be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.34(a), this is notice that on July 19, 2024, Caligor Coghlan Pharma Services, 1500 Business Park Drive, Unit B, Bastrop, Texas 78602, applied to be registered as an importer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Lysergic acid diethylamide	7315	I
5-Methoxy-N-N-dimethyltryptamine	7431	I
Dimethyltryptamine	7435	I
Psilocyn	7438	I

The company plans to import the listed controlled substances as finished dosage units for use in clinical trials. No other activities for these drug codes are authorized for this registration.

Approval of permit applications will occur only when the registrant's business activity is consistent with what is authorized under 21 U.S.C. 952(a)(2). Authorization will not extend to the import of Food and Drug Administration-approved or non-approved finished dosage forms for commercial sale.

Marsha L. Ikner,

Acting Deputy Assistant Administrator.

[FR Doc. 2024–19785 Filed 9–3–24; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–1421]

Bulk Manufacturer of Controlled Substances Application: Cambrex High Point, Inc

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Cambrex High Point, Inc has applied to be registered as a bulk manufacturer of basic class(es) of controlled substance(s). Refer to Supplementary Information listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants, therefore, may submit electronic comments on or objections to the issuance of the proposed registration on or before November 4, 2024. Such persons may also file a written request for a hearing on the application on or before November 4, 2024.

ADDRESSES: The Drug Enforcement Administration requires that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to *https://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon submission