manufactured finished dosage forms to foreign markets. No other activity for this drug code is 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.

Brian S. Besser,

Acting Assistant Administrator.

[FR Doc. 2021–23285 Filed 10–25–21; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 20–22]

Nicholas P. Roussis, M.D.; Decision and Order

On May 27, 2020, the Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause to Nicholas P. Roussis, M.D. (hereinafter, Respondent), of Staten Island, New York. Order to Show Cause (hereinafter, OSC), at 1. The OSC proposed the denial of Respondent's application for DEA Certificate of Registration, Control No. W19115227C, because Respondent was mandatorily excluded from '''participation in Medicare, Medicaid, and all federal health care programs for a minimum period of 10 years' pursuant to 42 U.S.C. 1320a–7(a)'' and such exclusion ''warrants denial of [Respondent's] application for a [registration] pursuant to 21 U.S.C. 824(a)(5).'' *Id.* at 1–2 (citing *Richard Hauser, M.D.,* 83 FR 26308 (2018)).

Specifically, the OSC alleged that, on October 16, 2017, the United States District Court for the District of New Jersey issued a judgment against Respondent ''based on [Respondent's] plea of guilty to the charge of Racketeering-Transporting in Aid of Travel Act-Acceptance of Bribes, in violation of 18 U.S.C. 1952(a)(3) & 18 U.S.C. 2, a felony.'' *Id.* at 2 (citing *U.S.* v. *Nicholas P. Roussis,* No. 2:17–cr–00231–SRC (D.N.J.)). The OSC further alleged that ''[b]ased on [Respondent's] conviction, the U.S. Department of Health and Human Services, Office of the Inspector General (''HHS/OIG''), by letter dated April 30, 2018, mandatorily excluded [Respondent] from 'participation in Medicare, Medicaid, and all federal health care programs for a minimum period of 10 years' pursuant to 42 U.S.C. 1320a–7(a), effective May 20, 2018.'' *Id.*

The OSC notified Respondent of the right to request a hearing on the allegations or to submit a written statement, while waiving the right to a hearing, the procedures for electing each option, and the consequences for failing to elect either option. *Id.* at 3 (citing 21 CFR 1301.43). The OSC also notified Respondent of the opportunity to submit a corrective action plan. *Id.* at 3–4 (citing 21 U.S.C. 824(c)(2)(C)).

By letter dated June 30, 2020, Respondent timely requested a hearing. Administrative Law Judge Exhibit (hereinafter, ALJX) 2. The matter was placed on the docket of the Office of Administrative Law Judges and was assigned to Administrative Law Judge Mark M. Dowd (hereinafter, the ALJ). On July 1, 2020, the ALJ issued an Order for Prehearing Statements. ALJX 3. The Government timely filed its prehearing statement (hereinafter, Govt Prehearing) on July 13, 2020. ALJX 4. Respondent timely filed his prehearing statement (hereinafter, Resp Prehearing) on July 22, 2020. ALJX 5. On July 28, 2020, the ALJ issued a prehearing ruling that, among other things, established the schedules and procedures for the remaining prehearing activities and for the hearing. ALJX 6 (Prehearing Ruling, at 1–11).

On September 8, 2020, the Government filed ''Objections Pursuant to 21 CFR 1316.59'' (hereinafter, Govt Objections), which objected to the admission of certain evidence submitted by Respondent on the grounds of authenticity. ALJX 8 (Govt Objections), at 2. The evidence in question consisted of ''Respondent's Exhibit 1, a 38-page document containing approximately 18 letters'' that Respondent had submitted on August 3, 2020. Govt Objections, at 1. According to the Govt Objections, ''[m]ost of the letters [appeared] to have been drafted . . . nearly three years before the Government served its [OSC].'' *Id.* Further, the Government alleged that, ''[a]ll but two of the letters [were] unsigned and four [were] undated.'' *Id.* Finally, the Government claimed that, ''[although] all but one of the letters [appeared] to be directed toward a Federal District Court Judge in connection with *U.S.* v. *Nicholas P. Roussis* . . . the letters [did] not seem to be available for inspection as part of the publically [sic] assessable electronic court file.'' *Id.* at 2. The Government concluded that because ''all but two of the letters [were] unsworn and no witness [was] disclosed to authenticate and/or lay a foundation for the documents' admissibility'' the letters should not be admitted. *Id.* On September 9, 2020, Respondent filed a Reply to Government's Objections (hereinafter, Reply to Objections). In the Reply to Objections, Respondent attached an affirmation from one of the attorneys who represented him in his criminal case. Reply to Objections, at 1. The affirmation stated that all 18 letters had been submitted as exhibits to the District of New Jersey as part of Respondent's sentencing submission during his criminal case. Reply to Objections, Attachment (Affirmation of Angela D. Lipsman), at 1–3. In the Reply to Objections, Respondent stated, ''[p]lease consider that affirmation as a response to the Government's objections.'' Reply to Objections, at 1. At the hearing in this matter, which took place on September 14, 2020, the Government further objected to the admission of the letters on the grounds of relevance. Tr. 41. The Government argued that in context, the letters related only to the sentencing of the Respondent in his criminal case and not to Respondent's prescribing practices or whether he could be entrusted with a DEA registration. Tr. 41–42. The ALJ ultimately overruled the Government's objections on both grounds of authenticity and relevance and admitted the letters into the record. Tr. 42–43.

The hearing in this matter took place via video teleconference on September 14, 2020. Following the hearing, both the Government and the Respondent filed their post-hearing briefs on October 21, 2020. On November 5, 2020, the ALJ issued the Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision (hereinafter, RD). Neither party filed exceptions to the RD. *See generally* Transmittal Letter. I have reviewed and agree with the procedural rulings of the ALJ during the administration of the hearing.

Having considered the record in its entirety, I agree with the ALJ and find that that the record established by substantial evidence a *prima facie* case supporting the denial of Respondent's application. RD, at 37. I also agree with the ALJ that the Respondent failed to fully accept responsibility for his misconduct, failed to demonstrate that the Agency can entrust him to maintain his registration, and therefore, that denial of his application is the appropriate sanction. *Id.* I make the following findings of fact.

I. Findings of Fact

A. Respondent's Application for DEA Registration

Respondent previously held DEA registration No. BR8697940 as a practitioner authorized to handle controlled substances in Schedules II–V at the registered location of 2627B Hylan Blvd., Staten Island, NY 10306. RD, at 11 (Stipulation 1). Respondent's previous DEA registration expired by its terms on April 30, 2019. *Id.* On October 4, 2019, Respondent applied for a DEA registration, which was assigned Control No. W19115227C, in Schedules II–V at 4735 Hylan Blvd., Staten Island, New York 10312. GX 1, at 1; *see also* RD, at 12–13 (Stipulation 8).[1]

B. Respondent's Criminal Conviction

The evidence in the record demonstrates that on June 21, 2017, an Information was filed in the United States District Court for the District of New Jersey against Respondent. GX 3; RD, at 13. The Information charged that from October 2010 through April 2013, Respondent engaged in commercial bribery in violation of N.J.S.A. § 2C:21–10, 18 U.S.C. 1952(a)(3). *Id.* at 4. The Information charged that from October 2010 through April 2013, Biodiagnostic Laboratory Services, LLC (hereinafter, BLS), a clinical blood laboratory, paid Respondent and his brother bribes of approximately $175,000 in the aggregate to refer patient blood specimens to BLS. *Id.* at 1, 4–5; *see also* RD, at 12 (Stipulations 3–4). The Information charged that BLS used the patient blood specimens from Respondent to submit claims to Medicare, Tricare, and private insurers to collect approximately $250,000. *Id.* at 5. Further, the Information charged that between October 2010 and April 2013, ''in addition to cash payments'' BLS paid bribes to Respondent and his brother in the form of trips to strip clubs where ''BLS paid for women to perform lap dances on, and engage in sex acts with [Respondent] and [Respondent's brother].'' *Id.; see also* RD, at 12 (Stipulation 4). On June 21, 2017, Respondent pled guilty to the charge of Racketeering-Transporting in Aid of Travel Act-Acceptance of Bribes in violation of 18 U.S.C. 1952(a)(3) & 18 U.S.C. 2. GX 4, at 3. Respondent was found guilty on October 16, 2017. GX 4, at 3; *see also* RD, at 12 (Stipulation 2). Respondent was sentenced to serve 24 months in prison, pay a fine of $5,000, and forfeit $175,000. GX 3, at 7; GX 4, at 4, 8, and 9; *see also* RD, at 12 (Stipulation 5).

C. Respondent's Exclusion

Based on Respondent's conviction, on April 30, 2018, HHS/OIG excluded Respondent from participation in Medicare, Medicaid, and all federal health care programs for a minimum period of 10 years pursuant to 42 U.S.C. 1320a–7(a). GX 2, at 1; *see also* RD, at 12 (Stipulation 6).

D. Respondent's State Medical License

Respondent was authorized to practice medicine in the State of New York by issuance of license number 231555. GX 7, at 1. Following Respondent's guilty plea and conviction, Respondent's New York medical license was suspended during the period of his incarceration after a charge of professional misconduct was sustained. *Id.* Respondent's state medical license was to be reinstated on August 16, 2019, subject to probation for five years and other conditions. *Id.* According to the State of New York's online records, the status of Respondent's state medical license is currently listed as ''Registered.'' *http://www.op.nysed.gov/opsearches.htm* (last visited date of signature of this Order). Following his conviction, Respondent was also excluded from participation in the New York State Medicaid program, effective August 30, 2017. GX 5; *see also* RD, at 12 (Stipulation 7).

E. The Parties' Positions

1. Government's Position

The OSC's sole allegation is that Respondent's exclusion from federal health care programs pursuant to 42 U.S.C. 1320a –7(a) warrants denying his application under 21 U.S.C. 824(a)(5). OSC, at 2; Govt Prehearing. The Government alleges that Respondent's exclusion was based on his guilty plea to the charge of Racketeering-Transporting in Aid of Travel Act-Acceptance of Bribes, in violation of 18 U.S.C. 1952(a)(3) & 18 U.S.C. 2. *Id.* The Government further alleges that Respondent's exclusion from Medicare, Medicaid, and all federal health care programs warrants denial of his application notwithstanding the fact that the underlying conduct that led to his exclusion did not have a nexus to controlled substances. *Id.*

The Government's documentary evidence includes a copy of Respondent's application for DEA registration No. W19115227C as well as a copy of Respondent's exclusion letter from HHS/OIG. *See* GX 1 and 2. The Government's documentary evidence also includes a copy of the Information filed in the United States District Court for the District of New Jersey against Respondent and the Terms of Probation and Order of Judgment following Respondent's conviction. *See* GX 3 and 4. Finally, the Government's documentary evidence includes various New York State documents pertaining to Respondent's exclusion from the New York State Medicaid program, the status of Respondent's New York State medical license, and Respondent's disciplinary proceedings with the New York State Department of Health following his conviction. *See* GX 5–7.

The Government called one witness to testify at the hearing, a Group Supervisor (hereinafter, GS) who works for the DEA New York Field Division. The GS testified about her investigation-related actions, including obtaining the Government's documentary evidence and confirming that Respondent's exclusion from federal health care programs was still in effect. Tr. 16–30; *see also* RD, at 5–6. The GS also authenticated the Government's documentary evidence through her testimony. *Id.*

Having read and analyzed all of the record evidence, I agree with the RD that the GS was ''consistent, genuine and credible,'' in her testimony and that the GS ''effectively explained how the investigation of the Respondent began and how she verified the Respondent's exclusion from federal [health care] programs.'' RD, at 22. I also agree with the RD that although she was the Government's witness, there was ''no indication from her testimony that any partiality interfered with her reliable testimony.'' *Id.*

2. Respondent's Position

Respondent requested a hearing in response to the Government's OSC, asserting that although his medical license had been restored, without a DEA registration, he was not able to effectively practice. Request for a Hearing (hereinafter, Hearing Request).

The Respondent's documentary evidence includes a collection of support letters from patients, colleagues, family, and friends that had been previously submitted to the District of New Jersey as part of Respondent's sentencing submission during his criminal case. *See* RX 1. Respondent was the sole witness to testify for his case.

Respondent testified that he has a wife, three children, and an elderly mother with medical problems who lives with him and his family. Tr. 31–32. Respondent became involved with

[1] The parties stipulated that the application was submitted on October 7, 2019, based on the Government's prehearing statement, but it appears that the application submission date was a scrivener's error.

BLS when a friend, who was a pharmaceutical representative for another company, started working for BLS as a salesman. *Id.* at 53. Respondent's friend asked him if he would ''send business his way'' just as he was sending it to other laboratories. *Id.* at 54. Respondent was ''very financially pressed'' at the time and when his friend and BLS offered to help him with some of his bills, ''at that point, [he] accepted.'' *Id.* Respondent and his co-defendant, his brother, received a combined $175,000 from BLS. *Id.* at 60–61. The bribes were periodic monthly payments of approximately $2,000 to $3,000 and not based on specific referrals. *Id.* at 69–70. BLS also paid for Respondent and his brother to go to strip clubs and to receive lap dances. *Id.* at 61–62. Respondent received payments from approximately October or November 2010 until January or February 2013. *Id.* at 70–71.

Respondent testified that he never prescribed any medication that was not necessary, never performed any unnecessary tests, and was never charged with performing any unnecessary tests. *Id.* at 32–33. Further, he claimed that the Government did not lose any money because Respondent used BLS and the payments made to BLS were the same as would be made to any other laboratory. *Id.* at 33–34. Additionally, Respondent testified that BLS was a ''credible laboratory'' [2] that provided legitimate, accurate, and verified [3] results and never did any improper testing. *Id.* at 33. He stated that BLS results were consistent, BLS was faster than other laboratories, and BLS never charged the patients any copay. *Id.* at 54–55; *see also id.* at 33 (''their turnaround time was quicker than the other laboratories, which was also another reason why I used them, as well.''). Respondent testified that ''from a testing aspect and a laboratory aspect'' he was satisfied with BLS. *Id.* at 55. Respondent testified that ''no patients were harmed in any way'' and that his actions did not cost the patients any money. *Id.* at 59. Nonetheless, Respondent testified that his actions were not a victimless crime and that his patients were the victims. *Id.* at 60. Respondent admitted to pleading guilty to the charges against him and when prompted for an explanation, said he did not have an explanation for it. *Id.* at 32. Respondent stated, ''It was the wrong thing to do, it was a wrong decision on my part, and I regret it every day, to this day.'' *Id.*

Respondent was incarcerated and his medical license was suspended while he was incarcerated. *Id.* at 34. Respondent's medical license has since been restored subject to probation with a practice monitor for two years. *Id.* at 32. Respondent testified that even though his medical license was restored, without a DEA license, he cannot effectively practice. *Id.* at 48. Respondent testified that he was ''totally guilty'' and ''totally [took] responsibility for what [he] did.'' *Id.* Respondent testified that he made a very bad decision that negatively affected his life as well as his family and patients. *Id.* at 48–49. There was a hearing regarding Respondent's medical license and the hearing committee determined that Respondent's medical license should be suspended, not revoked. *Id.* at 34–37. The hearing committee made their recommendation based on Respondent's acknowledgement of his poor judgment, Respondent's personal statement expressing remorse, the testimony of other doctors, letters from patients, and Respondent's remedial efforts in lecturing about his misconduct. *Id.* at 37–38. Respondent also wrote a letter to the Department of Health and Human Services ''trying to find out, and to speak with the judge . . . as to why [he] would have a ten year exclusion being the fact that [his actions were] nothing having to do with [billing].'' *Id.* at 51. Respondent testified that he ''had no part of the billing at all with Medicare and Medicaid, or the TRICARE federal services'' and ''[a]ll [he] did was [he] accepted the bribes.'' *Id.* Respondent also requested if he could have a decrease in his mandatory restriction, but the ten-year restriction was upheld. *Id.* at 51–52.

Respondent testified that he suffered in prison because he was away from his family. *Id.* at 49. While he was in prison, he ''tried to stay proactive'' and read medical journals. *Id.* Since his release from prison, he has taken over 200 hours [4] in continuing medical education courses (CME), multiple courses and certifications in his field, medical ethics courses, and courses such as the DEA's opioid training program. *Id.* at 38–39. Respondent also mentioned that he had become a CPR instructor and performed CPR classes. *Id.* at 39. Respondent also spoke to the Medical Society of Staten Island and to the residents at Richmond University Medical Center to explain what he had done and to deter them from making the same mistake. *Id.* at 47. Respondent testified that he had destroyed his life, embarrassed himself and his family, and become an embarrassment to his patients, community and church. *Id.* He explained that he ''just became very proactive because [he] wanted [his] medical license.'' *Id.* Respondent testified that he paid back all his debts to society from his forfeiture, fines, prison, and supervised release. *Id.* at 50. Respondent testified that medicine is ''the only thing [he knows] how to do'' and ''the only thing [he wants] to do.'' *Id.* at 49. Respondent testified that he wants to get back to practicing medicine and become a good member of society again. *Id.* at 49–50.

Respondent stated that while previously working in obstetrics and gynecology, he did not prescribe oxycodone or opioids to patients and the most he ever prescribed was Tylenol with Codeine after delivery or a caesarian section.[5] *Id.* at 64. Respondent testified that he ''never really prescribed any controlled substances unless [he] had to.'' *Id.* Respondent currently has an aesthetics practice where ''[he] will be doing injectables, fillers, hormone therapy, and weight loss treatment'' and that it is the type of practice he intends to maintain. *Id.* at 52. Respondent testified that he would need Schedules II–V for his practice. *Id.* at 53. Finally, Respondent testified that the majority of the support letters that had been submitted during his criminal case had been sent directly to his attorney. *Id.* at 58–59. Respondent had spoken to patients and asked them if they would write character letters for him as well as provided his attorney's email for them to send the letters directly. *Id.* at 59.

Having read and analyzed all of the record evidence, I agree with the RD that Respondent was candid in discussing the details of his misconduct as well as the remedial efforts that he made following his conviction. RD, at 22–23. However, I also agree with the RD that Respondent's conflicting statements, particularly those regarding his characterization of BLS as a ''credible'' laboratory and his initial claim that he had verified all of the results from BLS, as well as the defensive bend to much of his testimony, reduce his credibility and the

[2] When prompted later during cross examination, Respondent clarified that he had meant that BLS was a ''credible'' laboratory in terms of their work, not in terms of their behavior. *Id.* at 53–55.

[3] Respondent initially testified that he had verified all of the results from all of the patients that he sent to BLS, approximately 500 patients. *Id.* at 55–56. When prompted for clarification, however, Respondent admitted that he did not actually verify every single patient that he had sent to BLS. *Id.* at 56–57.

[4] Respondent initially testified that he had taken over 200 ''courses'' but later clarified that he had meant 200 hours of courses. *Id.* at 38, 64.

[5] This was the only testimony Respondent gave pertaining to his work in obstetrics and gynecology.

weight the decision gives to his testimony. *Id.* at 23–24; Tr. 33 and 53–57.

II. Discussion

A. Government's Position

In its Proposed Findings of Fact and Conclusions of Law (hereinafter, Government's Post-Hearing Brief), the Government argues that ''[m]andatory exclusion pursuant to 42 U.S.C. 1320a–7(a) is a basis to revoke a DEA registration under 21 U.S.C. 824(a)(5)'' and that ''notwithstanding the fact that the underlying conduct for which Respondent was convicted had no nexus to controlled substances, Respondent's mandatory exclusion from Medicare, Medicaid and all Federal health care programs by HHS/OIG warrants revocation of his registration pursuant to 21 U.S.C. 824(a)(5).'' Government's Post-Hearing Brief, at 9. Additionally, the Government argues that Respondent's continued registration would be contrary to the public interest, specifically under factor five of 21 U.S.C. 823(f), ''such other conduct which may threaten the public health and safety.'' *Id.* at 10–11. Further, the Government argues that ''[Respondent's] crimes were not wholly unrelated to his practice as a practitioner'' and that ''[his] behavior [evinced] a severe lack of ethical judgment that, had it occurred in a clinical context, could have resulted in diversion or an adverse impact on patient care.'' *Id.* Finally, the Government expresses doubts as to Respondent's acceptance of responsibility for his actions and emphasizes the deterrent effects of revoking Respondent's registration. *Id.* at 12–13.

B. Respondent's Position

In Respondent's Post-Hearing Brief, Respondent highlighted the Determination and Order of the Hearing Committee on [New York State] Department of Health, State Board for Professional Medical Conduct (hereinafter, Hearing Board) that rejected revocation of Respondent's medical license and instead suspended Respondent's license. Respondent's Post-Hearing Brief, at 3. Respondent alleged that the Hearing Board based its judgment on ''Respondent's acknowledgement of his poor judgment in accepting bribes, his remorse for his criminal conduct, and the testimony of two doctors and patients' letters.'' *Id.* Respondent also highlighted how he had ''lectured to physician residents . . . about his misdeeds'' and that ''since [his] release from prison, [he had] taken over 200 hours of CME courses'' including DEA's opioid training program. *Id.* Further, Respondent argued that he was ''a true follower of the Hippocratic Oath'' and provided letters from patients, colleagues, family, and friends to ''[demonstrate] the type of care [he] provided to his patients and how they reflect his following the Hippocratic Oath.'' *Id.* at 3–4. In concluding his Post-Hearing Brief, Respondent emphasized that he had broken the law, made a mistake, and ''paid dearly for it.'' *Id.* at 6. Respondent also reiterated that without a DEA license, he would no longer be able to practice medicine and earn a living as a doctor. *Id.*

C. Analysis of Respondent's Application for Registration

In this matter, the OSC calls for my adjudication of the application for registration based on the charge that Respondent was excluded from participation in a program pursuant to section 1320a–7(a) of Title 42, which is a basis for revocation or suspension under 21 U.S.C. 824(a)(2). OSC, at 1–2. The Government did not allege that Respondent's applications should be denied because his registration would be inconsistent with the public interest pursuant to section 823 in the OSC and did not advance any arguments or present any evidence under the public interest factors in its prehearing statement. *See generally* Govt Prehearing; OSC. The Government raised the public interest factors in its Post-hearing Brief; however, I find that they are unavailable as a basis of sanction due to the late stage at which they were raised. *See Robert Wayne Locklear, M.D.,* 85 FR 33738, 33745 (2021). Accordingly, the OSC's specific substantive basis for proposing the denial of Registrant's registration application is his mandatory exclusion under 21 U.S.C. 824(a)(5).

Prior Agency decisions have addressed whether it is appropriate to consider a provision of 21 U.S.C. 824(a) when determining whether or not to grant a practitioner registration application. For over forty-five years, Agency decisions have concluded that it is. *Robert Wayne Locklear, M.D.,* 86 FR 33744–45 (collecting cases); *see also, William Ralph Kincaid,* In the recent decision *Robert Wayne Locklear, M.D.,* the former Acting Administrator stated his agreement with the results of these past decisions and reaffirmed that a provision of section 824 may be the basis for the denial of a practitioner registration application. 86 FR 33745. He also clarified that allegations related to section 823 remain relevant to the adjudication of a practitioner registration application when a provision of section 824 is involved. *Id.*

Accordingly, when considering an application for a registration, I will consider any actionable allegations related to the grounds for denial of an application under 823 and will also consider any allegations that the applicant meets one of the five grounds for revocation or suspension of a registration under section 824. *Id. See also Dinorah Drug Store, Inc.,* 61 FR 15972, 15973–74 (1996).

1. 21 U.S.C. 823(f): The Five Public Interest Factors

Under Section 304 of the Controlled Substances Act, ''[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 by such section.'' 21 U.S.C. 824(a)(4). In the case of a ''practitioner,'' defined in 21 U.S.C. 802(21) to include a ''physician,'' Congress directed the Attorney General to consider the following factors in making the public interest determination:

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

(2) The applicant's experience in dispensing, or conducting research with respect to controlled substances.

(3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

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

(5) Such other conduct which may threaten the public health and safety. 21 U.S.C. 823(f).

In this case, it is undisputed that Respondent holds a valid state medical license and is authorized to dispense controlled substances in the State of New York where he practices. RD, at 13; *see also* GX 1.

Because the Government has not timely alleged that Respondent's registration is inconsistent with the public interest under section 823, I will not deny Respondent's application based on section 823, and although I have considered 823, I will not analyze Respondent's application under the public interest factors. Therefore, in accordance with prior agency decisions, I will move to assess whether the Government has proven by substantial evidence that a ground for revocation

exists under 21 U.S.C. 824(a). *Supra* II.C.

2. 21 U.S.C. 824(a)(5): Mandatory Exclusion From Federal Health Care Programs Pursuant to 42 U.S.C. 1320a–7(a)

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. 21 U.S.C. 824. 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.* Here, there is no dispute in the record that Registrant is mandatorily excluded from federal health care programs under 42 U.S.C. 1320a–7(a). The Government has presented substantial evidence of Respondent's exclusion and the underlying criminal conviction that led to that exclusion, and Respondent has admitted to the same. GX 2, at 1; GX 4, at 3; Respondent's Post-Hearing Brief, at 2. Accordingly, I will sustain the Government's allegation that Respondent 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).[6] Although the language of 21 U.S.C. 824(a)(5) discusses suspension and revocation of a registration, for the reasons discussed above, it may also serve as the basis for the denial of a DEA registration application. *Dinorah Drug Store, Inc.,* 61 FR 15973 (interpreting 21 U.S.C. 824(a)(5) to serve as a basis for the denial of a registration because it ''makes little sense . . . to grant the application for registration, only to possibly turn around and propose to revoke or suspend that registration based on the registrant's exclusion from a Medicare program''). Respondent'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).

Here, there is no dispute in the record that Respondent 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).

Where, as here, the Government has met its *prima facie* burden of showing that a ground for revocation exists, the burden shifts to the Respondent to show why he can be entrusted with a registration. *See Jeffrey Stein, M.D.,* 84 FR 46968, 46972 (2019).

III. Sanction

The Government has established grounds to deny a registration; therefore, I will review any evidence and argument the Respondent submitted to determine whether or not the Respondent has presented ''sufficient mitigating evidence to assure the Administrator that [he] can be trusted with the responsibility carried by such a registration.'' *Samuel S. Jackson, D.D.S.,* 72 FR 23848, 23853 (2007) (quoting *Leo R. Miller, M.D.,* 53 FR 21931, 21932 (1988)). '''Moreover, because ''past performance is the best predictor of future performance,'' *ALRA Labs, Inc.* v. *Drug Enf't Admin.,* 54 F.3d 450, 452 (7th Cir. 1995), [the Agency] has repeatedly held that where a registrant has committed acts inconsistent with the public interest, the registrant must accept responsibility for [the registrant's] actions and demonstrate that [registrant] will not engage in future misconduct.''' *Jayam Krishna-Iyer,* 74 FR 459, 463 (2009) (quoting *Medicine Shoppe,* 73 FR 364, 387 (2008)); *see also Samuel S. Jackson, D.D.S.,* 72 FR 23853; *John H. Kennnedy,* M.D., 71 FR 35705, 35709 (2006); *Prince George Daniels, D.D.S.,* 60 FR 62884, 62887 (1995). The issue of trust is necessarily a fact-dependent determination based on the circumstances presented by the individual respondent; therefore, the Agency looks at factors, such as the acceptance of responsibility and the credibility of that acceptance as it relates to the probability of repeat violations or behavior and the nature of the misconduct that forms the basis for sanction, while also considering the Agency's interest in deterring similar acts. *See Arvinder Singh, M.D.,* 81 FR 8247, 8248 (2016).

A. Acceptance of Responsibility

In evaluating the degree required of a respondent's acceptance of responsibility to entrust him with a registration, in *Mohammed Asgar, M.D.,* the Agency looked for ''unequivocal acceptance of responsibility when a respondent has committed knowing or intentional misconduct.'' 83 FR 29569, 29572 (2018) (citing *Lon F. Alexander, M.D.,* 82 FR 49704, 49728). Here, Respondent has not alleged that he committed the misconduct in question unknowingly or unintentionally. I will, therefore, look for a clear acceptance of responsibility from Respondent.

Respondent is clearly remorseful for his conduct, testifying that it was ''the wrong thing to do'' and that he ''regret[s] it every day, to this day.'' Tr. 32. However, remorse and acceptance of responsibility are not the same thing, and I agree with the ALJ's conclusion that Respondent's consistent focus on his own suffering does not suggest an unequivocal acceptance of responsibility, but rather, suggests regret for the negative consequences that he has personally faced. RD, at 34. As the ALJ found, ''Respondent was more remorseful of the impact that his decisions had on his own life, rather than the effects his actions posed to his patients.'' *Id.* Additionally, I, too, am ''not convinced that [Respondent] would not take part in such a scheme in the future, if the monetary need were to arise.'' *Id.* at 36. Throughout his testimony, Respondent highlighted his own suffering above all else, emphasizing that he had ''destroyed [his] whole life'' and lamenting how he had ''embarrassed [himself], [his] family, [and] became an embarrassment to [his] patients, to [his] community, [and] to [his] church . . . .'' Tr. 47. Though Respondent did acknowledge that his actions had affected his patients, his testimony quickly shifted focus to what he had personally suffered, particularly that he had gone to prison ''away from [his] family, [and] [his] young children, for two years.'' *Id.* at 49. Even when Respondent stated that his actions were not ''a victimless crime'' and that ''[his] patients were the victims'' his explanation for *why* his patients were victims was that ''[t]hey lost [him], [he] lost them.''[7] *Id.* at 60. Further, according to Respondent's testimony, when Respondent spoke to

[6] The Government correctly argues, and Respondent did not rebut, that 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 46968, 46971–72 (2019); *see also Narciso Reyes, M.D.,* 83 FR 61,678, 61,681 (2018); *KK Pharmacy,* 64 FR 49507, 49510 (1999) (collecting cases); *Melvin N. Seglin, M.D.,* 63 FR 70,431, 70,433 (1998); *Stanley Dubin, D.D.S.,* 61 FR 60727, 60728 (1996).

[7] I also find it troubling that Respondent has clearly not attempted to fully understand the impact of his actions on others. His naïve belief that his patients were only victims because they lost him demonstrates that he has failed to even question whether there were greater impacts on his patients, potentially related to insurance claims or increases in pricing, or impacts on the laboratories that were legitimately conducting their business. I weigh Respondent's inability to perceive the full impact of his wrongdoing against a finding that Respondent has accepted responsibility. *See Robert Wayne Locklear, M.D.,* 86 FR 33738, 33747 (2021) (finding it ''significant in evaluating [the applicant's] acceptance of responsibility that he did not seem to be aware of the full extent of the harm that he caused.'').

the Medical Society of Staten Island and to the resident physicians at the Richmond University Medical Center, he ''tried to deter them from it, not to make [the same] mistake because . . . [he] destroyed his whole life.'' *Id.* at 47.

Additionally, there are points of Respondent's testimony and actions in the record that suggest attempts to downplay his mistakes, further demonstrating a lack of clear acceptance of responsibility and a lack of full appreciation for the severity of his misconduct. As the ALJ found, I too find it particularly alarming that despite everything that has happened, Respondent testified at the hearing that BLS was a ''credible laboratory, actually'' and did not clarify his characterization until later prompted to do so. *Id.* at 33, 53–55. I am also troubled by the letter that Respondent wrote to the Department of Health and Human Services in which, according to his testimony, he had questioned his ten-year exclusion and requested a decrease (which was ultimately rejected) because his misconduct had nothing to do with billing and ''all [he] did was [he] accepted the bribes.'' *Id.* at 51–52. On direct examination, Respondent defended his characterization of BLS as a ''credible laboratory'' and claimed ''[t]hey never had any issues with performing the laboratory tests or [for] obtaining results. They were legitimate results, they were accurate results, and they were verified,[8] as well. They never did any improper testing. Their turnaround time was quicker than the other laboratories, which was also another reason why [he] used them, as well.'' *Id.* at 33. As the ALJ noted, ''[Respondent's] consistent bolstering of [BLS's] credentials tends to serve as a validation of his behavior.'' RD, at 36. Regarding himself, Respondent emphasized that he never prescribed unnecessary medication, never performed any unnecessary tests, was never charged with performing any unnecessary tests, that the government did not lose any money because of him, and that the payments made to BLS were not any higher than they would be to another laboratory. *Id.* at 32–34. Overall, Respondent's focus on himself and his minimization of his wrongdoings suggests that he has not unequivocally accepted responsibility for his actions and the harm that he caused. *See Stein,* 84 FR 46972 (finding that a registrant's attempts to minimize his misconduct weigh against a finding of unequivocal acceptance of responsibility).

Even if Respondent's acceptance of responsibility for his wrongdoing had been sufficient such that I would reach the matter of remedial measures, Respondent has not offered adequate remedial measures to assure me that I can entrust him with a registration. *See Carol Hippenmeyer, M.D.,* 86 FR 33748, 33773 (2021). While in prison, he kept up with medical journals, has taken a wide variety of courses—including over 200 hours in continuing medical educations courses (CME) [9]—has become a CPR instructor, has taken certifications in ''areas of medicine that [he wants] to practice,'' and after his release, he spoke to the Medical Society of Staten Island and to the residents at Richmond University Medical Center about his crime.[10] *Id.* at 38–39, 49, and 64. In concluding his testimony regarding his remediation efforts, Respondent said, ''[medicine is] the only thing I know how to do, it's the only thing I want to do, and it's my passion . . . I just want to get back to practicing medicine, and get back to society.'' *Id.* at 49. From Respondent's testimony, it seems that the purpose of his remediation efforts was not as much about righting his wrongs and deterring others from similar acts as it was about saving Respondent's career. In fact, he even admitted to as much when he stated that after his release from prison, he ''just became very proactive because [he] wanted [his] medical license.'' *Id.* at 47. Accordingly, I find that, again, Respondent's consistent focus on how his own life has been impacted by his misconduct does not suggest that he can be entrusted with a DEA registration.

B. Specific and General Deterrence

In addition to acceptance of responsibility, the Agency gives consideration to both specific and general deterrence when determining an appropriate sanction. *Daniel A. Glick, D.D.S.,* 80 FR 74800, 74810 (2015). Specific deterrence is the DEA's interest in ensuring that a registrant complies with the laws and regulations governing controlled substances in the future. *Id.* General deterrence concerns the DEA's responsibility to deter conduct similar to the proven allegations against the respondent for the protection of the public at large. *Id.* Where a respondent has committed a crime with no nexus to controlled substances, it is sometimes difficult to demonstrate that a sanction will have a useful deterrent effect. In this case, I believe a sanction of denial of the application would deter Respondent and the general registrant community from unethical behavior and deceit, particularly involving the acceptance of money for unlawful and unethical acts. It is not difficult to imagine, as the Agency has repeatedly encountered, this situation repeating itself in the context of receiving money for controlled substance prescriptions. ''Deterring such deceit and knowing criminal behavior both in Respondent and the general registrant community is relevant to ensuring compliance with the CSA.'' *Ibrahim Al-Qawaqneh, D.D.S.,* 86 FR 10354, 10357 (2021).

C. Egregiousness

The Agency also looks to the egregiousness and the extent of the misconduct as significant factors in determining the appropriate sanction. *Garrett Howard Smith, M.D.,* 83 FR 18910 (collecting cases). In this case, Respondent knew that his arrangement with BLS was wrong but accepted the arrangement anyway and kept it going for a long period of time because, ''at that time, he was financially pressed.'' Tr. at 54. The arrangement was a blatant kick back scheme involving substantial monetary payments.[11] In addition, the

[8] As the ALJ noted, Respondent initially claimed that he verified all of the BLS lab results, but then conceded that he had not actually verified the results of every single patient he sent to BLS. *Id.* at 55–58.

[9] Though Respondent testified to completing CME courses, he did not provide evidence to the record confirming the completion of the courses.

[10] I commend Respondent on his attempts to have a deterrent effect on his colleagues and community. In *Martinho,* the former Acting Administrator considered this type of engagement in determining that a respondent who had been excluded from federal healthcare programs for accepting similar kickbacks for laboratory referrals could be entrusted with a registration; however, the facts of *Martinho* are very distinct from the facts on the present record. *Michele L. Martinho, M.D.,* 86 FR 24012, 24019 (2021). The respondent in that case had dedicated herself to self-described ''restorative justice'' well beyond what was required by her probation—engaging in sixty-nine speaking engagements, which were featured in major news outlets. *Id.* Although her misconduct occurred for a similar amount of time and money, HHS penalized her with the minimum timeframe for exclusion, she engaged in a methodological survey to verify for her own conscience that she did not increase her blood draws and did not overstate that survey's value, she admitted that the lab had created insurance problems for her patients and tried to correct it, and importantly, she also fully, sincerely and credibly accepted responsibility for her actions, such that the prosecutor at her criminal sentencing stated that she '''had demonstrated a level of contrition that has been unique among the many, many doctors that we've dealt with in this case.' '' *Id.*

[11] Also, I am concerned about repeat behavior in this case because the wrongdoing appears to be influenced by social interactions. The fact that Respondent was first approached about the bribes by a ''friend of [his and his brother's],'' Tr. 53, participated in the arrangement with his brother, and they all engaged in social activities together during which payments were received, does not inspire confidence that Respondent will take his responsibility to his patients and his ethical obligations seriously in the future.

arrangement was both periodic and ongoing for multiple years, giving Respondent plenty of opportunity to correct course, but there is nothing in the record to indicate that he had any intention of ending the arrangement. After receiving 2 to 3 thousand dollars per month, *Id.* at 70, there must have been a point at which he was no longer ''financially pressed,'' and yet he continued.

Furthermore, the exclusion letter notes that HHS/OIG deemed Respondent's criminal misconduct egregious enough to warrant an exclusion period in excess of the statutory minimum. GX 2, at 2. The exclusion letter explains that HHS/OIG excluded Respondent for ten years instead of the statutory minimum of five years because (1) Respondent's misconduct caused or was intended to cause financial loss of more than $50,000 to a government agency or program; (2) Respondent committed the misconduct over a period of at least a year; and (3) Respondent's sentence included incarceration. *Id. See Michael Jones, M.D.,* 86 FR 20728, 20732 (2021) (considering the length of the HHS exclusion in assessing egregiousness).

D. Letters of Support

My final item of consideration is the collection of eighteen letters that Respondent submitted from patients, colleagues, friends, and family to demonstrate his high level of care as a physician and his commitment to the Hippocratic Oath. Respondent's Post-Hearing Brief, at 3–4;RX 1. Although I find the letters to be sincere, they can only be of limited weight in this proceeding because of the limited ability to assess the credibility of the letters given their written form. *See Michael S. Moore, M.D.,* 76 FR 45867, 45873 (2011) (evaluating the weight to be attached to letters provided by the respondent's hospital administrators and peers in light of the fact that the authors were not subjected to the rigors of cross examination). Furthermore, these letters were not written for the purposes of recommending that Respondent be granted a controlled substances registration and therefore offer little value in assessing the Respondent's suitability to discharge the duties of a DEA registrant. *William Ralph Kinkaid, M.D.,* 86 FR 40636, 40641 (2021). Instead, Respondent's letters were used by his criminal defense counsel prior to his sentencing, with most of the letters dated back to 2017. RX 1;Tr. 41. Additionally, almost all of the letters are unsigned, four are undated, and none of the letters are addressed to anyone at DEA. RX 1.

Finally, because Respondent has not demonstrated an unequivocal acceptance of responsibility, any value that the letters may have offered in evaluating my ability to trust Respondent with a DEA registration is nullified by the fact that he, himself, has not shown that he can be so entrusted. *Kinkaid, M.D.,* 86 FR 40641.

As discussed above, to receive a registration when grounds for denial exist, a respondent must convince the Administrator that his acceptance of responsibility is sufficiently credible to demonstrate that the misconduct will not occur and that he can be entrusted with a registration. Having reviewed the record in its entirety, I find that Respondent has not met this burden. Although Respondent expressed remorse and took some responsibility for his actions through his guilty plea and his efforts at remediation, his acceptance of responsibility was not unequivocal. Respondent's consistent focus on his own suffering and his minimization of his wrongdoings both raise concerns that he does not truly understand the severity of his misconduct. Further, Respondent's remediation efforts, though genuine, suggest to me that Respondent views the negative consequences he has faced as obstacles to overcome in restoring his career rather than the result of a serious lapse in ethics that calls for self-reflection. As such, I am not convinced that Respondent would not commit similar misconduct again in the future if he believed that it would not result in negative consequences, if he found himself in difficult financial times, or if he was persuaded by a friend or family member. Accordingly, I will order the denial of Respondent's application for a certificate of registration.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823, I hereby order that the pending application for a Certificate of Registration, Control Number W19115227C, submitted by Nicholas P. Roussis, M.D., is denied. This Order is effective November 26, 2021.

Anne Milgram,

Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Maura Tuso, D.M.D.' Decision and Order

I. Procedural Background

On August 20, 2018, the Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause (hereinafter, OSC) to Maura Tuso, D.M.D. (hereinafter, Applicant) of San Diego, California. OSC, at 1. The OSC proposed the denial of Applicant's application for DEA Certificate of Registration, Application Control No. W18011889C, because Applicant has ''been convicted of a felony relating to controlled substances and because [she has] committed acts which render [her] registration inconsistent with the public interest.'' *Id.* (citing 21 U.S.C. 824(a)(2) & (a)(4)).

Specifically, the OSC alleged that on August 25, 2015, Applicant entered a guilty plea to ''four felony counts related to unlawfully issuing controlled substance prescriptions in violation of California Health and Safety Code Section 11153(a), and related counts of conspiracy, prescription fraud, and insurance fraud. This guilty plea was accepted in the Superior Court of California, County of San Diego, as part of the Court's Finding and Order.'' *Id.* at 2.

The OSC also alleged that, ''[p]ursuant to a July 6, 2016 Stipulated Settlement and Disciplinary Order between [Applicant] and the Dental Board of California (the ''Board''), which was effective on September 16, 2016, [Applicant was] ordered to surrender a DEA Registration which [she] previously held and ordered not to reapply for a new DEA Registration without approval from the Board.'' *Id.*

Further, the OSC stated that, ''[o]n April 12, 2018 and April 13, 2018, the [DEA San Diego Field Division (hereinafter, SDFD)] attempted to provide'' Applicant with a proposed Memorandum of Agreement with conditions in order to grant her application. *Id.* During Applicant's visits to the SDFD, the OSC alleged that she used ''vulgar language and obscenities in an uncivilized display.'' *Id.*

The OSC continued to allege that since this encounter, Applicant has ''engaged in a pattern of sending many dozens of emails to various DEA personnel, including emails of a harassing nature.'' *Id.* It alleged that Applicant's actions constitute ''conduct