appropriately consider whether Respondent had accepted responsibility such that I could entrust her with this responsibility, I would be minimizing Registrant's violations of state and federal law, undermining the public interest by not attempting to address those violations, and then placing the burden on the Agency whose trust she broke to monitor her compliance. Although such measures may be appropriate in some cases, here, Respondent has not given me a reason to extend them to her.

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 BK9710939 issued to Kaniz F. Khan-Jaffery, M.D. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(f), I hereby deny any pending application of Kaniz F. Khan-Jaffery, M.D., to renew or modify this registration, as well as any other applications of Kaniz F. Khan-Jaffery, M.D. for additional registration in New Jersey. This Order is effective August 28, 2020.

Timothy J. Shea,

Acting Administrator.

[FR Doc. 2020–16387 Filed 7–28–20; 8:45 am]

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punctuation that it was his frustration with the Government's case that led him to recommend a sanction less than revocation. *See id.* at 155. However, I cannot exclude from a final determination on this case consideration of the issue of trust in the face of violations, even where there are fewer violations found than initially alleged.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 17–41]

Hamada Makarita, D.D.S.; Denial of Application

I. Introduction

On June 29, 2017, the Acting Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause to Hamada Makarita, D.D.S. (hereinafter, Applicant), of McLean, Virginia. Administrative Law Judge Exhibit (hereinafter, ALJX) 1 (Order to Show Cause (hereinafter, OSC)), at 1. The OSC proposes the denial of Applicant's application for a DEA certificate of registration (hereinafter, registration) alleging that he does not have authority to handle Schedule II to IV controlled substances in Virginia, he has been convicted of felony counts related to controlled substances, and his registration would be inconsistent with the public interest.[1] *Id.* (citing 21 U.S.C. 823(f) and 824(a)).

The substantive grounds at issue in this proceeding, as more specifically alleged in the OSC, include that Applicant, ''[o]n April 12, 2013, . . . [was] convicted of eight felony counts in the United States District Court for the Eastern District of Virginia, Alexandria Division, six of which were related to controlled substances,'' one of which was for health care fraud, and one of which was for aggravated identity theft. OSC, at 2–3 (citing 21 U.S.C. 823(f)(3) and 824(a)(2) and (a)(4)). The OSC also alleges that Applicant ''fail[ed] to accept responsibility for . . . [his] convictions.'' OSC, at 3.

Regarding the allegation that Applicant's registration would be inconsistent with the public interest, the OSC alleges twelve findings of fact by the Virginia Board of Dentistry (hereinafter, VBD) concerning Applicant's prescribing controlled substances without or beyond a legitimate dental purpose. *Id.* at 4–5 (citing 21 U.S.C. 841(a) and 842(a), 21 CFR 1306.04(a), and Virginia Code secs. 54.1–2706, 54.1–3303(A), and 54.1–3408(A)). The OSC also alleges that Applicant ''refused to accept responsibility for . . . [his] unlawful prescriptions.'' OSC, at 5.

The OSC notified Applicant of his right to request a hearing on the allegations or to submit a written statement while waiving his right to a hearing, the procedures for electing each option, and the consequences for failing to elect either option. *Id.* at 5–6 (citing 21 CFR 1301.43). The OSC also notified Applicant of the opportunity to file a corrective action plan. OSC, at 6 (citing 21 U.S.C. 824(c)(2)(C)).

The matter was placed on the docket of the Office of Administrative Law Judges and assigned to Chief Administrative Law Judge (hereinafter, ALJ) John J. Mulrooney, II. The parties initially submitted seven stipulations.[2] RD, at 3; ALJX 8, at 1–2 (original).

The hearing in this matter lasted one day and took place in Arlington, Virginia on October 10, 2017. The Chief ALJ filed his RD on January 19, 2018. Neither party filed exceptions to the RD and the time for filing exceptions has expired. Letter of the Chief ALJ to the Acting Administrator, dated Feb. 14, 2018, at 1.

Having examined and considered the record in its entirety, I agree with the Chief ALJ that substantial record evidence establishes Applicant's six federal felony convictions relating to the dispensing of controlled substances, the Fourth Circuit's affirmance of those felony convictions, and Applicant's completion of his appeals of those convictions. I find substantial record evidence of the VBD's finding that Applicant illegally prescribed over 2,700 dosage units of Schedule II through IV controlled substances. I find that Applicant did not unequivocally accept responsibility for all of this proven controlled substance-related wrongdoing. Accordingly, I conclude that granting Applicant's request for a

[1] According to Applicant's request for a hearing, ALJX 2, Applicant's original registration application only concerned Schedule V controlled substances. ALJX 2, at 1. Applicant subsequently revised that application, the hearing request states, to include Schedule II through IV controlled substances. *Id.* ''In light of his inability to prescribe Schedule II through IV substances due to the findings and ruling of the Board of Dentistry of Virginia,'' Applicant's hearing request continues, he ''hereby withdraws his amended request for permission to prescribe Schedule II through IV substances'' and ''now requests only to have authority to prescribe Schedule V substances.'' *Id.; see also* ALJX 8 (Prehearing Ruling dated Aug. 31, 2017), at 2 (Stipulation No. 4), *infra* n.2.

The Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge in this matter (hereinafter, RD) states that Applicant's hearing request was ''timely filed.'' RD, at 2; *see also* Transcript page (hereinafter, Tr.) 5 (noting that Applicant filed a hearing request on July 31, 2017).

[2] In the stipulations, Applicant is referred to as ''Respondent.''

''1. On September 20, 2016, the Respondent filed an application for a DEA COR, Control No. W16093263C, seeking registration as a practitioner in Schedule V with a registered address of 4103 Chain Bridge Road, Suite LL 100, Fairfax, Virginia 22030.

''2. The Respondent currently possesses Dental License number 0401007149 from the Commonwealth of Virginia. His dental license expires on its own terms on March 31, 2018.

''3. The Respondent lacks authority in the Commonwealth of Virginia to handle Schedule II, III, or IV Controlled Substances.

''4. In the Respondent's Request for Hearing, he withdrew a prior request for Schedule II–IV authority.

''5. On April 12, 2013, the Respondent was convicted of eight felony counts in the United States District Court for the Eastern District of Virginia, Alexandria Division.

''6. The Respondent applied for reinstatement of his state dental license in 2016. The Virginia Board of Dentistry made a number of findings on September 22, 2016, regarding the Respondent's treatment of a number of patients.

''7. Following the hearing, the Board reinstated the Respondent's state dental license with conditions on September 22, 2016.''

On September 20, 2017, the parties filed additional Joint Stipulations, ALJX 10, agreeing to the authenticity of four of the seven Government Exhibits (hereinafter, GX) and five Applicant Exhibits (hereinafter, RX). ALJX 10, at 1–2.

Schedule V registration would be ''inconsistent with the public interest.'' [3] I make the following findings.

II. Findings of Fact

A. Applicant's State Dental License and Controlled Substance Authorization

Applicant is licensed as a dentist in the Commonwealth of Virginia. *See, e.g.,* RX 6 (Letter from the Commonwealth of Virginia, Department of Health Professionals to Applicant referencing ''Case No.: 178272—Inspection Report/Records Audit'' dated September 29, 2017), at 1. According to the online records of the Commonwealth of Virginia, of which I take official notice, Applicant's dental license is currently active. It expires on March 31, 2021.[4] Virginia Department of Health Professions License Lookup, *https://dhp.virginiainteractive.org/Lookup/* Index (last visited July 21, 2020).

After Applicant served his sentence and was released from federal custody, the VBD limited Applicant's authorization to issue controlled substance prescriptions to Schedule V. GX 3 (Order Before the Virginia Board of Dentistry In Re Hamada R. Makarita, D.D.S., License Number: 0401–007149, Case Number: 86781, 136371, 143367, 152192, dated, entered, and mailed on September 22, 2016 (hereinafter, VBD Order)), at 11; *see also* Tr. 51. According to the VBD Order, this limitation on Applicant's prescribing and dispensing authority was to last for two years from the date of the VBD Order, September 22, 2016. GX 3, at 12.

B. The Investigation of Applicant

A DEA field investigation of Applicant began because he responded ''yes'' to ''a few liability questions on an application.'' [5] Tr. 15; *see also id.* at 15–17 (describing the internal DEA processes that ensue when an applicant provides a ''no'' answer and a ''yes'' answer to a liability question). Applicant answered ''yes'' to three questions. The first question to which Applicant answered ''yes'' asks, in pertinent part, ''Has the applicant ever been convicted of a crime in connection with controlled substance(s) under state or federal law?'' GX 7, at 3; *see also* Tr. 21–22. Under ''nature of incident'' regarding his ''yes'' answer to the first liability question, Applicant wrote:

> I found out my office manager was using my DEA license to call in rx to herself and friends and I called the FBI and she convinced the FBI agent I was the on [sic] who told her to. This was a lie. The judge said I was responsible for my ploys [sic] actions so I was convicted of conspiracy to distribute narcotics. She said I gave her permission which is not true at all or why would i [sic] have called the authorities and go to a lawyer and fire her?

GX 1, at 2. Concerning ''result,'' in connection with the first liability question, Applicant wrote:

> I voluntarily surrendered my DEA license and also I am applying only for schedule 5 drugs so I can treat my patients with NSAids [sic] for pain and antibiotics. I had my hearing with the board of Dentistry last week and my license was reinstated. It was a mandatory suspension because of the conviction. I will be pressing charges against this office manager again! I only wish to have permission for schedule 5 for now as it is a must to teat [sic] infections etc with antibiotics as well as NSAIDS for pain.

Id.

The second question to which Applicant answered ''yes'' asks, ''Has the applicant ever surrendered (for cause) or had a federal controlled substance registration revoked, suspended, restricted or denied, or is any such action pending?'' GX 7, at 3. For ''nature of incident'' regarding his ''yes'' answer to the second liability question, Applicant's submission was the same as his submission for the first liability question. GX 1, at 2. Likewise, Applicant wrote the same ''result'' concerning the second liability question as he wrote for the first liability question. *Id.*

The third question to which Applicant answered ''yes'' asks, ''Has the applicant ever surrendered (for cause) or had a state professional license or controlled substance registration revoked, suspended, denied, restricted, or placed on probation, or is any such action pending?'' GX 7, at 3. Concerning ''nature of incident'' regarding his ''yes'' answer to the third liability question, Applicant wrote:

> Due to conviction, the state dental board had to suspend (not revoke) my license because it is in the statutes. Although they had not hear [sic] day case until last week in full, and once they did and were presented with proofs of who was the culprit, they reinstated my license with no fines at all.

GX 1, at 3. For the ''result'' concerning the third liability question, Response wrote, ''License was suspended April 36, [sic] 2013 and reinstated Sep 15, 2016.'' *Id.*

C. The Felony Criminal Convictions and VBD Findings

According to Government counsel, the ''basis of the Government's *prima facie* case'' is that Applicant was convicted in federal court of dispensing controlled substances in violation of the Controlled Substances Act (hereinafter, CSA) and that the VBD ''found that he committed those unlawful actions.'' [6] Tr. 10. In his opening statement, counsel for Applicant stated that ''[w]e don't deny that . . . [Applicant] was convicted and there are Board findings against him.'' [7] *Id.* at 11. The uncontested criminal convictions and VBD findings are set out in Government Exhibits (hereinafter, GX) 2, 3, and 5, discussed *infra* section II.D.

There is factual agreement among the witnesses on a number of matters. When there is factual disagreement, I apply my credibility determinations and the credibility recommendations of the Chief ALJ.

D. The Government's Case

The Government called one witness, the DEA Diversion Investigator case agent (hereinafter, DI). The

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[3] I reviewed, and agree with, the Chief ALJ's pre-hearing, hearing, and post-hearing rulings and orders.

[4] Under the Administrative Procedure Act, an agency ''may take official notice of facts at any stage in a proceeding—even in the final decision.'' United States Department of Justice, Attorney General's Manual on the Administrative Procedure Act 80 (1947) (Wm. W. Gaunt & Sons, Inc., Reprint 1979). Pursuant to 5 U.S.C. 556(e), ''[w]hen an agency decision rests on official notice of a material fact not appearing in the evidence in the record, a party is entitled, on timely request, to an opportunity to show the contrary.'' Accordingly, Applicant may dispute my finding by filing a properly supported motion for reconsideration of finding of fact within fifteen calendar days of the date of this Order. Any such motion shall be filed with the Office of the Administrator and a copy shall be served on the Government. In the event Applicant files a motion, the Government shall have fifteen calendar days to file a response. Any such motion and response shall be filed and served by email on the other party at the email address the party submitted for receipt of communications related to this administrative proceeding, and on the Office of the Administrator, Drug Enforcement Administration at *dea.addo.attorneys@dea.usdoj.gov.*

[5] Application liability questions ask about ''past history'' such as a felony criminal conviction, an action against a state license, and an action against a registration. Tr. 15–16.

[6] Government counsel argued in his opening statement that Applicant ''has not accepted responsibility for his actions'' as evidenced by ''his application to the DEA and his pre-hearing statements and his conversations with the original Investigator.'' Tr. 10.

[7] Applicant's Counsel continued by stating that the federal convictions and VBD findings stemmed from Schedule II and III ''related issues,'' that Applicant has ''never been accused of or found guilty of or had any adverse . . . [VBD] findings concerning Schedule . . . [V] substances,'' that Schedule V ''substances typically are not the types of drugs that are sought out by addicts and people of that type, nor are those the types of drugs that lead to great financial wealth or anything of that nature,'' and, therefore, ''given the circumstances and given the work that . . . [Applicant] has done . . . , we believe it is consistent with the public interest to allow him to now dispense Schedule . . . [V] substances.'' Tr. 11–12.

Government's case included seven exhibits, all of which were accepted into the record.[8]

DI's testimony addressed Applicant's application, the process of referring that application for investigation, and her investigation of the application, including her obtaining documents relevant to the application and her communicating with Applicant. *Id.* at 14–33.

DI testified that she had email and telephonic contact with Applicant. *Id.* at 28–33. According to DI, Applicant told her that ''he did want to go before the judge,'' and that the judge told him that ''he was responsible, so he was convicted.'' *Id.* at 31. She testified that Applicant told her that ''he never abused, sold drugs or anything like that'' and that ''he wanted to present his case to the [administrative law] judge and not just apply for Schedule 5, but for 2 through 4 as well.'' *Id.; see also* GX 4 (Feb. 7, 2107 Letter from Applicant amending his September 20, 2016 Registration Application ''to all schedules . . . as opposed to just schedule V''), at 1; GX 6 (Nov. 20, 2016 Email from Applicant to DI stating that ''I have never abused, sold drugs, or anything like that'' and ''I wish . . . also not just [sic] apply for schedule 5 but for all of it''), at 1.

On cross examination, as clarified on redirect, DI recounted her recollection that Applicant admitted, in his application for a DEA registration, to having been criminally convicted.[9] Tr. 34, 42. She testified that she did not find ''any inconsistencies or issues'' about Applicant's background on his application. *Id.* at 34–35. She stated that she did not recall the involvement of a Schedule V controlled substance in Applicant's criminal convictions or in the VBD findings. *Id.* at 35. In her experience, she testified, Schedule II through V controlled substances are diverted by doctors, and ''pill mill-style doctors'' prescribe more Schedule II through IV controlled substances than Schedule V controlled substances. *Id.* at 35–37. She testified that she did not check whether Applicant uses or was ever prescribed a controlled substance, and that she did not recall whether the federal indictment or the VBD charges alleged that Applicant abused a controlled substance.[10] *Id.* at 37–38.

I agree with the Chief ALJ that DI ''presented testimony that was detailed, plausible, internally consistent, and devoid of any indication of any cognizable motive to fabricate. She gave every appearance of an impartial investigator/regulator, was forthcoming and candid in her responses to questions, and her testimony is accepted here as fully credible.'' RD, at 13.

The Government's admitted documentary evidence consists of documents detailing the disposition of the felony criminal charges brought against Applicant, the Circuit Court's affirmance of the charges of which Applicant was convicted, and the VBD's findings of fact, conclusions of law, and Order concerning Applicant's medical license and controlled substance prescribing authority. GX 2, 3, and 5, respectively. The Government also put in the record Applicant's correspondence with DEA and DI related to his registration application and background information to help contextualize that correspondence. GX 1, 4, 6, and 7.

GX 2 consists of six sheets concerning Applicant's eight felony convictions in the Eastern District of Virginia. GX 2 (Judgment, *United States* v. *Makarita,* No. 1:12cr00223–001 (E.D. Va. Apr. 12, 2013) (hereinafter, Eight Felony Conviction Trial)). The first sheet is the ''Judgment in a Criminal Case.'' *Id.* at 1. It shows that Applicant was ''found guilty as to Count(s) 1, 2, 3, 10, 12, 13, 14, and 15 of the Indictment,'' all of which are felonies. *Id.* The second sheet shows that Applicant was sentenced to twenty-five months of imprisonment. *Id.* at 2. The third sheet shows that Applicant was put on supervised release for three years. *Id.* at 3.

The first count listed on the Judgment of the Eight Felony Conviction Trial is conspiracy to distribute and dispense controlled substances in violation of 21 U.S.C. 846. *Id.* at 1. Applicant appealed his conviction on this count arguing that ''there was insufficient evidence to support his conviction . . . because the evidence failed to demonstrate any agreement to illegally distribute controlled substances between him and any other individual.'' 576 F. App'x at 262–63 (GX 5, at 9). According to the Fourth Circuit Conviction Affirmance, however, Applicant's ''conviction for conspiracy is supported by substantial evidence.'' 576 F. App'x at 263 (GX 5, at 9). The Eight Felony Conviction Trial testimony of two of Applicant's former employees, his former office manager and his former dental assistant, ''established that . . . [Applicant] entered into an agreement with each of them to pick up prescriptions in their own names and deliver them to . . . [Applicant], either for him to illicitly deliver to others, or for his own personal use.'' [11] *Id.* In the face of the conflicting testimony of Applicant, ''the jury elected to credit . . . [the two former employees'] testimony'' over Applicant's. *Id.*

[8] The parties agreed to the authenticity of four of the Government's Exhibits. ALJX 10; *see also supra* n.2.

[9] On re-direct, DI clarified that Applicant's application accurately admitted to the existence of criminal convictions, and that she had not addressed the accuracy of Applicant's description of the facts underlying those convictions. Tr. 42.

[10] Regarding whether Applicant abused drugs in Schedules II, III, or IV, the Fourth Circuit's *per curiam* decision upholding Applicant's criminal convictions describes Count 10 as charging Applicant with illegally distributing or dispensing a controlled substance to his former office manager. *United States* v. *Makarita,* 576 F. App'x 252, 256 (4th Cir. 2014) (hereinafter, Fourth Circuit Conviction Affirmance) (GX 5, at 4). The Fourth Circuit Conviction Affirmance describes evidence that Applicant wrote a prescription for ''several boxes of [f]entanyl patches'' for his former office manager to fill and deliver to him, and that Applicant applied one of the patches to his body in the former office manager's presence. *Id.* Also according to the Fourth Circuit Conviction Affirmance, Applicant ''corroborated'' this evidence, testifying that ''I was hoping this was something I could use as a treatment modality to use for any oral pain. That's why I used it on myself. I said, 'I want to see if it helps my back.' '' *Id.*

According to the prosecution's expert witness in the criminal case, Dr. Lawrence Singer, fentanyl is ''outside the scope of dentistry or oral surgery and 'is only appropriate for a chronic pain patient who has cancer pain or . . . something extremely debilitating and may be chronically ill.' '' 576 F. App'x at 257 (GX 5, at 5). Based on Dr. Singer's testimony, Applicant's admission that he used the fentanyl patch on his back to see if it might relieve oral pain implicates illegal prescribing, dispensing, and use of a Schedule II controlled substance. *See* Tr. 11 (''I will tell the court that you will hear testimony today from . . . [Applicant] regarding . . . his own needs or lack of needs for medication.''). It also evidences Applicant's lack of candor during the DEA investigation and administrative hearing about his history of controlled substance use. *Id.* at 31 (DI testimony) and 111 (Applicant's testimonial denial); GX 6, at 1 (Applicant's written denial); 576 F. App'x at 255 (GX 5, at 4) (recounting testimony of former dental assistant at Eight Felony Conviction Trial).

[11] As already discussed, testimony the United States elicited about the conspiracy count was presented by Applicant's former office manager. She testified that she filled prescriptions Applicant wrote for boxes of fentanyl patches, delivered them to Applicant, and witnessed Applicant apply one patch to his body at the dental office. 576 F. App'x at 255 (GX 5, at 3). The former office manager also testified that Applicant had her print ''multiple prescriptions for controlled substances from the office computer for . . . [his] various family members, patients, and friends.'' *Id.*

Applicant's former dental assistant similarly testified that Applicant wrote a Valium prescription in her name and instructed her to fill it so that he could give it to his girlfriend. 576 F. App'x at 255 (GX 5, at 4). The former dental assistant also testified that Applicant wrote a Vicodin prescription in her name and instructed her to fill it so that he could use it himself. *Id.* She also testified that she learned during the federal investigation of Applicant that he had ''written several other prescriptions in her name which were filled at various pharmacies.'' *Id.*

The Eight Felony Conviction Trial ''Judgment in a Criminal Case'' sheet shows that the second, third, tenth, twelfth, and thirteenth counts are for dispensing controlled substances in violation of 21 U.S.C. 841(a)(1). GX 2, at 1. Applicant also appealed his conviction on these counts arguing that there was ''insufficient evidence to support his distribution offenses.'' 576 F. App'x at 263 (GX 5, at 10). The Fourth Circuit Conviction Affirmance found Applicant's argument to be ''without merit,'' stating ''after a careful review of the record, we conclude substantial evidence clearly supports that . . . [Applicant] distributed and dispensed a variety of controlled substances for recreational purposes and not for a legitimate medical and dental purpose.'' [12] *Id.*

The fourteenth felony count in the indictment of Applicant is health care fraud, a violation of 18 U.S.C. 1347. *Id.* The fifteenth felony count is aggravated identity theft under 18 U.S.C. 1028A. These counts charged Applicant with submitting dental service reimbursement requests under the name of a dentist previously affiliated with the practice to circumvent the health insurance plan's exclusion of services provided to family members. 576 F. App'x at 258 (GX 5, at 5–6). The corroborated testimony received during the Eight Felony Conviction Trial included that Applicant would forge the dentist's signature on the reimbursement checks, sign the checks to himself, and deposit the checks in his personal or business bank account. 576 F. App'x at 258, 264 (GX 5, at 6, 10). The Fourth Circuit Conviction Affirmance concluded that the ''evidence was more than sufficient to show that . . . [Applicant] made the false representations . . . knowingly and willfully, in order to receive money to which he was otherwise not entitled.'' 576 F. App'x at 264 (GX 5, at 10). The restitution ordered upon Applicant's conviction was $91,629.38. GX 2, at 6.

Applicant challenged the health care fraud conviction on two grounds. First, he argued that he was not bound by the terms of the health insurance plan because he was not a party to the contract. 576 F. App'x at 263 (GX 5, at 10). The Fourth Circuit Conviction Affirmance rejected this argument, stating that being a party to an insurance contract ''is not relevant to whether . . . [Applicant] formed the specific intent to commit health care fraud.'' 576 F. App'x at 264 (GX 5, at 10). Second, Applicant claimed that the record evidence was insufficient to support a finding that the health insurance plan was a ''health care benefit program'' as defined by the criminal statute. *Id.* The Fourth Circuit Conviction Affirmance disagreed, concluding that Applicant's health care fraud conviction was supported by ''substantial evidence.'' [13] 576 F. App'x at 264 (GX 5, at 10–11).

In sum, the Fourth Circuit Conviction Affirmance found no reversible error and affirmed the results of the Eight Felony Conviction Trial. 576 F. App'x at 254 (GX 5, at 3).

GX 3 is the VBD Order regarding Applicant's state dental license. Applicant testified about his post-release preparations for, and his participation in, the ''14-hour [VBD] hearing nonstop . . . [that] lasted until 2:00 a.m.'' Tr. 50–51. The Order notes Applicant's appearance at the hearing ''not represented by legal counsel.'' GX 3, at 1. The VBD's post-hearing Order reinstated, indefinitely suspended, and then stayed the indefinite suspension of Applicant's dental license ''contingent upon continued compliance'' with specified terms and conditions. *Id.* at 10–11. As already discussed, those terms and conditions include ''not prescrib[ing] or dispens[ing] Schedule II, III, and IV controlled substances for a period of two (2) years from the date of this Order.'' *Id.* at 11. The terms and conditions also include timely completion of VBD Executive Director-approved, face-to-face, interactive continuing education programs in Principles of Pharmacology and Prescription Writing (seven hours), Treatment of Medically Compromised Patients (four hours), Diagnosis and Treatment Planning Protocol (ten hours), and Ethics for the Dental Professional (seven hours), and undergoing annual random audits of ten patient charts for two years.[14] *Id.*

The ''Findings of Fact'' section of the VBD Order spans eight pages. GX 3, at 1–8. It lists, among other things, eight categories of fact findings about Applicant's illegal actions related to controlled substances from 2006 through 2011.[15] The categories are (1) providing a Schedule III controlled substance to a patient outside of his dental office without a legitimate dental purpose on multiple occasions, (2) prescribing Schedule II through IV controlled substances to eight patients

[12] Testimony the United States elicited about the unlawful distribution and dispensing counts included testimony from a patient whose relationship with Applicant later became romantic. 576 F. App'x at 256 (GX 5, at 4). She testified that ''she would call . . . [Applicant] to get prescriptions for Vicodin and Valium for recreational use, and she would consume these controlled substances as well as alcohol while on dates'' with Applicant. *Id.* She testified that, to obtain these prescriptions, she had to ''hang out'' with Applicant. She stated that on at least one occasion, she combined Vicodin with alcohol and ''blacked out.'' *Id.* Shortly after one such occurrence, she testified, Applicant sent her photographs he had taken of her ''while she was incapacitated, which depicted her nude except for a jacket and a single boot, lying apparently unconscious on his bed.'' *Id.* She testified that she was using the controlled substances, with Applicant's knowledge, ''solely for recreational purposes.'' *Id.* Dr. Singer testified that Applicant performed ''minor dental procedures'' on this patient/girlfriend ''that would result in 'mild discomfort' at most.'' *Id.* The expert also testified that ''between 2007 and 2008 . . . [Applicant] prescribed . . . [for this patient/girlfriend] 'several hundred pills total' in prescriptions that 'were maybe a couple dozen,' '' and that the patient/girlfriend's ''patient record was devoid of any clinical notes to support this treatment.'' *Id.*

The fentanyl patch testimony of Applicant's former office manager was also relevant to these counts. Dr. Singer found that Applicant ''wrote prescriptions . . . [for her] for what [a]ll amounted to a few hundred—several hundred doses of narcotics.' '' 576 F. App'x at 257 (GX 5, at 5). According to the expert, a fentanyl patch is ''outside the scope of dentistry or oral surgery and 'is only appropriate for a chronic pain patient who has cancer pain or . . . something extremely debilitating and may be chronically ill.' '' *Id.*

Likewise, the testimony of Applicant's former dental assistant/patient was relevant to these counts. Dr. Singer opined that Applicant had no clinical notes to support the writing of Valium or Vicodin prescriptions for her. *Id.* The expert concluded that ''these prescriptions were not written within the bounds of dental practice for a legitimate dental purpose.'' *Id.*

[13] The Fourth Circuit Conviction Affirmance also addressed, and found meritless, Applicant's claims of error based on *Brady* v. *Maryland.* 576 F. App'x at 259–62 (GX 5, at 7–9). Its analysis of the error claims addressed, among other things, Applicant's former office manager and her testimony in the Eight Felony Conviction Trial. According to the Fourth Circuit Conviction Affirmance, Applicant's counsel ''conducted a thorough cross examination'' of the former office manager. 576 F. App'x at 260–61 (GX 5, at 7–8). The areas covered by the ''zealous'' cross examination included Applicant's having terminated her for making a false statement to an insurance company, her submitting a false résumé to a local doctor, her submitting a false bill to an insurance company and pocketing the reimbursement check, her forging Applicant's signature on prescriptions, her making inconsistent statements to the grand jury, her submission of fraudulent insurance claims for her sister, her conviction for writing false checks, and her embezzling from Applicant's 401(k) plan. 576 F. App'x at 261 (GX 5, at 8).

[14] The Order also imposed on Applicant administrative costs of $5,000.00. GX 3, at 12.

[15] The VBD Order also documents fact findings about Applicant's provision of care and treatment to a patient that was recorded in a fraudulently created patient record under an alias, fraudulent contracting of health insurance coverage for eleven individuals, and provision of dental treatment to a 92 year old patient without consulting and/or documenting any consultation with the patient's physician concerning the patient's heart defect or heart murmur and atrial fibrillation, without explaining the proposed treatment plan, providing an estimate, or obtaining consent, without appropriately documenting the patient's treatment records, without billing for the correct (lower cost) metal used, and without explaining deceptive or misleading abbreviations in correspondence to the patient. GX 3, at 2, 7–8.

and an individual on multiple occasions without a legitimate dental purpose, (3) prescribing Schedule II and IV controlled substances under the name of an office employee and asking that employee to pick up those prescriptions from the pharmacy for him, (4) instructing the office employee to lie to investigators about these pain medications by stating that Applicant had written them for the employee, (5) excessively prescribing Schedule II, III, and IV controlled substances to two patients beyond a legitimate dental purpose, (6) prescribing to two patients Schedule II controlled substances without a legitimate purpose around the time of office appointments at which x-rays were taken but neither treatment nor the prescriptions were noted in the patient's dental record, (7) prescribing Schedule II controlled substances to six patients without recording the prescriptions in the patient's dental record, and (8) accessing the Virginia Prescription Monitoring Program to obtain information about multiple patients without patient authorization and without a legitimate dental purpose.[16] *Id.* at 2–6. In sum, the VBD Order documents Applicant's unlawful dispensing of 2,711 dosage units of controlled substances in Schedule II (1,740 dosage units), Schedule III (290 dosage units), and Schedule IV (681 dosage units).

E. Applicant's Case

At the hearing, Applicant testified and called one other witness, his current assistant. Tr. 9, 55. He also introduced five exhibits concerning ''the circumstances and . . . the work that . . . [Applicant] has done.'' *Id.* at 12.

During his testimony, Applicant described his credentials and professional affiliations, the establishment and nature of his current dental practice, when he would prescribe Schedule V controlled substances in his current practice, and his ''feel[ing] like . . . [he is currently] helping . . . [patients] 80 percent of the way versus if they had muscle relaxants to take at night . . . which helps them not clench and grind and so forth from being in the wrong bite position. That would help them.'' [17] *Id.* at 44–45, 54–57, 45–46, 46–48, and 48, respectively.

Applicant admitted that he was convicted of eight federal felonies in the Eastern District of Virginia and, regarding fault, stated, ''The buck stops here. It's a hundred percent my fault.'' *Id.* at 48–49. He elaborated on why he was at fault by stating, ''I am responsible to guard my DEA number, to prescribe and document properly anything I prescribe that's controlled and I was perhaps a little bit lax about it.'' *Id.* at 49. Applicant admitted that ''it's easier before to blame others. But, you know, when I had a lot of time to reflect, it was 100 percent me because I'm the boss, I own the practice. Everything should be my responsibility.'' *Id.* at 49–50.

Applicant admitted that the VBD ''suspended . . . [his] license because of the convictions.'' *Id.* at 50. The VBD suspension was ''automatic'' and he ''had never met with them at the time,'' he stated. *Id.* After a ''14-hour [VBD] hearing nonstop . . . [that] lasted until 2:00 a.m.,'' the VBD reinstated his license, although only allowing him to prescribe Schedule V controlled substances. *Id.* at 50–51. In the course of his testimony about the requirements imposed on him by the VBD, Applicant described the one-on-one courses he paid $13,500 to take at Virginia Commonwealth University, recounted a pre-conviction experience he had with a drug-seeking ''soccer Mom,'' and detailed his reaction to patient push-back he received when he prescribed five Vicodin.[18] *Id.* at 57–88, 78–82, 76–77, respectively.

Applicant testified that he had just received a letter from the VBD about the unannounced inspection that was conducted pursuant to Term #3 of the VBD Order and the ensuing VBD review of the inspection report and patient records. *Id.* at 108–09. According to the letter, the VBD found Applicant ''to be in compliance with Term #3 of . . . [the] Order and no violations were noted. Case No. 178272 is CLOSED with no further action necessary.'' RX 6, at 1 [emphasis in original]. Although the VBD informed Applicant that he would be subject to another audit, one that would be announced, Applicant testified that he had paid the $5,000 VBD administrative fee and that there were no other VBD conditions with which he still had to comply. Tr. 110–11.

Applicant testified about other courses, such as in cosmetic dentistry, he has taken, stating that ''I do a lot of continuing education . . . . I'm constantly taking courses all over the country.'' *Id.* at 88; RX 3. He also discussed the post-conviction speeches he presented and articles he wrote. *Id.* at 90–97, 98–103, 124–130; RX 4; RX 5. Applicant testified that he ''just wanted to get that information out there,'' so that it would not ''happen to anyone else.'' Tr. 91. He stated that his ''whole point about it is, you are responsible. . . . [I]t doesn't matter if one of your employees does something, if you are lax about where you keep your prescription pad, it comes back to haunt you, it comes back to bite you, it's a privilege to have the DEA license.'' [19] *Id.* at 92. He also stated that his ''problem'' was that he did not ''properly document prescriptions.'' *Id.* at 94. ''[H]ow to properly document. . . . [Y]ou think it's a pain in the butt, try what I went through, that's a pain in the butt,'' he testified. *Id.*

Applicant specifically addressed what he had ''previously said in an email or on an application,'' presumably concerning his amending the DEA application he submitted from requesting only Schedule V authority to requesting Schedule II through V authority. *Id.* at 50. ''[P]art of it was I had just finished a grueling process . . .—when I was released, of preparing for the . . . [VBD] . . . for reinstatement because they suspended my license because of the convictions,'' he began. *Id.* ''[J]ust rehashing everything in my mind and going through everything with the . . . [VBD],'' he continued. *Id.* Applicant also stated that, ''when I went onto the application . . . and that was just fresh in my mind that it was, you know, there are some things that happen in the office that were still my responsibility.'' [20] *Id.* at 51. Prefacing his final points with the note that he was not represented by counsel at the time, he stated that ''the way I thought about it was I could apply for my DEA,

[16] Applicant admitted to a VBD investigator that, after writing eight prescriptions for a total of 150 dosage units of hydrocodone without recording them in the patient's dental record, he ''subsequently determined'' that the ''patient'' was ''exhibiting drug-seeking behaviors and that he did not write any prescriptions'' for the ''patient'' thereafter. GX 3, at 6.

[17] Applicant testified that his practice has ''around 300'' patients, ''a good 40 percent'' of whom he treated prior to being criminally convicted, and that ''the patients who are returning . . . still come'' even though he does not prescribe controlled substances. Tr. 56–57. He denied that he expects his ''income to change significantly or at all'' if DEA allows him to prescribe Schedule V controlled substances and represented that, prior to being criminally convicted, ''[z]ero . . . percent'' of his income ''was derived from Schedule 2 through 5 prescriptions.'' *Id.* at 113–14. Applicant stated that ''the only thing that would change is the patients would be more comfortable with the muscle relaxants, that's it.'' *Id.* at 113.

[18] ''I've had patients tell me if I give them five Vicodin, they say 'Five? My physician gives me 90.' I say, 'Well, yeah, I'm not your physician,' you know. So, I don't know who needs 90, but those kind of things can end up on the streets.'' Tr. 76.

[19] Applicant's article entitled ''Fraud and Embezzlement in the Dental Office—Part 2,'' for example, offers a variety of suggestions about how to prevent fraud, such as obtaining background checks before hiring employees, reviewing credit card statements, and using software application audit trails. RX 4, at 4.

[20] While not stated explicitly, this portion of Applicant's testimony appears to concern his DEA application.

because they said I could apply for my DEA license . . . [and] 'Okay, but I just won't prescribe Schedule anything but Schedule 5,' you know, I didn't really know at the time,'' he testified. *Id.* at 51–52.

Applicant listed the changes he made in his practice since his felony convictions. He stated that ''[e]verything is in a locked safe . . . , you need a key and a combination . . . [, and] [t]here's a camera on it.'' *Id.* at 97. He testified that ''you can't print prescriptions,'' ''[t]here's no prescriptions lying around anywhere,'' and ''I document like crazy.'' *Id.; see also id.* at 118–19.

Applicant testified that the only time he took a controlled substance was ''15 years ago or something . . . [when] the oral surgeon prescribed . . . [him] Tylenol #3 or something back then.'' *Id.* at 111. He stated that he has never been treated for addiction to any narcotics or any drugs, and that he has ''zero'' drug problem. *Id.* On cross examination, he testified that, before the criminal convictions, he only directed staff to pick up blood pressure and cholesterol prescriptions for him from the pharmacy; ''never, ever . . . any medication that was not prescribed to'' him. *Id.* at 115.

The Chief ALJ, who observed Applicant's demeanor during the hearing, assessed Applicant's credibility and included his observations and conclusions in the RD. According to the Chief ALJ, ''Even beyond the obvious reality that, as the applicant, the . . . [Applicant] has the most at stake regarding the outcome of the proceedings, his presentation conflicted with the incontrovertible evidence, was blatantly self-serving, and struck as inconsistent even with his own exhibits.'' RD, at 25. The Chief ALJ concluded that ''there was some testimony of the . . . [Applicant] that can certainly be credited in this recommended decision, such as biographical information . . . . Where his recitation of relevant facts conflicts with incontrovertible evidence, such as facts subsumed by his convictions and the findings rendered by the . . . [VBD], his testimony is not just legally incapable of belief; it is factually unworthy of credibility.'' *Id.*

My review and analysis of the record are consistent with the Chief ALJ's conclusions. For example, according to the record transcript, Applicant testified that the only time he took a controlled substance was ''15 years ago or something . . . [when] the oral surgeon prescribed . . . [him] Tylenol #3 or something back then.'' Tr. 111. According to the Fourth Circuit Conviction Affirmance, however, Applicant ''corroborated'' his former office manager's testimony that he applied a fentanyl patch to his body in her presence.[21] 576 F. App'x at 256 (GX 5, at 4).

By way of further example, the Chief ALJ asked Applicant whether it would be incorrect ''if someone said that . . . [he] intentionally wrote up prescriptions or gave them to people for other than a legitimate medical purpose.'' Tr. 121. Applicant agreed, ''That would be wrong.'' *Id.* As already discussed, however, both the Fourth Circuit Conviction Affirmance and the VBD Order conclusively found that Applicant intentionally wrote controlled substance prescriptions for other than a legitimate medical purpose. 576 F. App'x at 256–57 (GX 5, at 4–5); GX 3, at 2–5.

Applicant's lack of credibility is exhibited in ways in addition to blatant conflicts between his record testimony and the records of the Eight Felony Conviction Trial, the Fourth Circuit Conviction Affirmance, and the VBD Order. For example, Applicant could have sought access to, and potentially introduced into the record, Prescription Drug Monitoring files to support his answer to his own counsel's question about whether he ever took Schedule II or Schedule III controlled substances. Tr. 111. There are no such files in the record, however. Neither did Applicant submit any evidence explaining why he did not seek to obtain or offer any such corroborating evidence.

By way of further example, Applicant testified that the software used in his dental office, Dentrix, includes an audit trail, ''[s]o, everything that's put in there cannot be erased.'' *Id.* at 100. Applicant detailed that ''if somebody prints a prescription out and deletes it out of the system, . . . [Dentrix] documents that somebody, under their login, printed a prescription and deleted it. *Id.* at 100–01. Applicant even testified that he showed evidence from Dentrix to the VBD and the VBD stated ''why is this even an issue,'' whereas he ''told the FBI about those digital records and they just never did anything about it.'' *Id.* at 122. Yet, although Applicant suggested that Dentrix audit trails would exonerate him, the record in this matter does not contain a single Dentrix audit trail. The record also does not contain Applicant's explanation as to his failure to offer the exonerating evidence he claimed exists.

In sum, I agree with the Chief ALJ's credibility assessment of Applicant. Further, I afford no weight to Applicant's claims of innocence when he failed to produce the documentary evidence that he testified exists and supports those innocence claims.[22]

The second witness Applicant called was his current assistant, a certified dental assistant (hereinafter, CDA), whose employment with him began after his release from incarceration. *Id.* at 138. CDA testified about her job responsibilities and stated that Applicant gave her ''general information'' about ''what happened and that his license was suspended and he couldn't practice for some time.'' *Id.* at 137–38. She testified that Applicant keeps his prescription pads in a safe, that there is a camera trained on the safe, and that a key and a combination are needed to open the safe. *Id.* at 139. CDA stated that the dental office uses the ''Dentrix system,'' but that only Applicant knows the passwords to it. *Id.* at 140. She denied seeing Applicant prescribe a controlled substance or take a controlled substance, and seeing Applicant use anyone else's prescription pad or DEA number. *Id.* at 141–42. CDA testified that Applicant never asked her to ''phone in any sort of Schedule[d] substances.'' *Id.* at 142. She stated that she has heard patients ask Applicant to prescribe ''something stronger than ibuprofen or Motrin or Tylenol'' and that Applicant replied to ''just take Advil and Tylenol.'' *Id.* at 142–43.

I agree with the Chief ALJ's assessment that CDA's ''testimony presented no basis to conclude that she was not credible. She appeared candid and forthright, and her testimony was sufficiently detailed, internally consistent, and plausible to be fully credited.'' RD, at 27.

F. Allegation That Applicant Was Convicted of Felonies Related to Controlled Substances

As already discussed, the OSC charged that Applicant's application for a registration should be denied due to his having been convicted of six felonies related to controlled substances. OSC, at 1. Applicant does not dispute that he was criminally convicted of eight felonies in the Eastern District of

[21] Fentanyl is a Schedule II controlled substance.

[22] This Agency has applied, and I apply here, the ''adverse inference rule.'' As the D.C. Circuit explained, ''Simply stated, the rule provides that when a party has relevant evidence within his control which he fails to produce, that failure gives rise to an inference that the evidence is unfavorable to him.'' *Int'l Union, United Auto., Aerospace & Agric. Implement Workers of Am. (UAW)* v. *Nat'l Labor Relations Bd.,* 459 F.2d 1329, 1336 (D.C. Cir. 1972). The Court reiterated this rule in *Huthnance* v. *District of Columbia,* 722 F.3d 371, 378 (D.C. Cir. 2013). According to this legal principle, Applicant's decision not to provide evidence within his control gives rise to an inference that any such evidence is unfavorable to Applicant.

Virginia. Tr. 48–49. Based on the uncontroverted evidence in the record, I find that six of these undisputed felony convictions, Applicant's convictions for conspiracy to dispense controlled substances illegally under 21 U.S.C. 846 and for illegally distributing or dispensing controlled substances under 21 U.S.C. 841(a)(1), relate to controlled substances.[23] GX 2; GX 5; *see also* GX 3, at 1–2.

III. Discussion

A. The Controlled Substances Act and the Public Interest Factors

Pursuant to section 303(f) of the 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(f). Section 303(f) 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:

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

(2) The applicant's experience in dispensing . . . 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.

Id.

These factors are considered in the disjunctive. *Robert A. Leslie, M.D.,* 68 FR 15227, 15230 (2003). I ''may rely on any one or a combination of factors and may give each factor the weight [I] deem[ ] appropriate in determining whether . . . an application for registration [should be] denied.'' *Id.* Moreover, while I am required to consider each of the factors, I ''need not make explicit findings as to each one,'' and I ''can 'give each factor the weight . . . [I] determine[ ] is appropriate.' '' *MacKay* v. *Drug Enf't Admin.,* 664 F.3d 808, 816 (10th Cir. 2011) (quoting *Volkman* v. *Drug Enf't Admin.,* 567 F.3d 215, 222 (6th Cir. 2009) quoting *Hoxie* v. *Drug Enf't Admin.,* 419 F.3d 477, 482 (6th Cir. 2005)). In other words, the public interest determination ''is not a contest in which score is kept; the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the registrant. Rather, it is an inquiry which focuses on protecting the public interest; what matters is the seriousness of the registrant's misconduct.'' *Peter A. Ahles, M.D.,* 71 FR 50097, 50098–99 (2006).

Pursuant to section 304(a)(2), the Attorney General is authorized to suspend or revoke a registration ''upon a finding that the registrant . . . has been convicted of a felony under this subchapter or subchapter II of this chapter or any other law of the United States . . . relating to any substance defined in this subchapter as a controlled substance or a list I chemical.'' 21 U.S.C. 824(a)(2). It is well established that the various grounds for revocation or suspension of an existing registration that Congress enumerated in this section are also properly considered in deciding whether to grant or deny an application under section 303. *See Richard J. Settles, D.O.,* 81 FR 64940, 64945 (2016); *Arthur H. Bell, D.O.,* 80 FR 50035, 50037 (2015); *Mark P. Koch, D.O.,* 79 FR 18714, 18734–35 (2014); *The Lawsons, Inc., t/a The Medicine Shoppe Pharmacy,* 72 FR 74334, 74338 (2007); *Samuel S. Jackson, D.D.S.,* 72 FR 23848, 23852 (2007); *Alan R. Schankman, M.D.,* 63 FR 45260, 45260 (1998); *Kuen H. Chen, M.D.,* 58 FR 65401, 65402 (1993).

The Government has the burden of proof in this proceeding. 21 CFR 1301.44. Both parties submitted documentary evidence. All of the documentary evidence was admitted without objection. *See, e.g.,* ALJX 10, at 1–2 (stipulating to the authenticity of certain evidence). The admitted documentary evidence implicates Factors One, Two, Three, and Four. Of these relevant factors, the OSC first alleges Applicant's controlled substance felony convictions. OSC, at 2–3. Accordingly, Factor Three is discussed first, followed by Factor One, and then Factors Two and Four.

B. Factor Three—Applicant's Felony Convictions Relating to Controlled Substances

As already discussed, I found that Applicant's convictions for conspiracy to dispense controlled substances and for illegally distributing or dispensing controlled substances are six felony convictions relating to controlled substances. *Supra* section II.F. I further find that Applicant's convictions for conspiracy to dispense controlled substances and for illegally distributing or dispensing controlled substances are six felony convictions ''relating to'' controlled substances as those terms are defined in 21 U.S.C. 824(a)(2). 21 U.S.C. 846 and 841(a)(1); *William J. O'Brien, III, D.O.,* 82 FR 46527, 46529 (2017). In addition, with respect to the record evidence, I find that these six felony convictions constitute Applicant's ''conviction record under Federal . . . laws relating to the manufacture, distribution, or dispensing of controlled substances.''[24] 21 U.S.C. 823(f)(3). Accordingly, the CSA, under Factor Three, requires me to consider these six felony convictions in my determination of whether the issuance of a registration to Applicant would be ''inconsistent with the public interest.'' *Id.*

C. Factor One—Recommendation of the Appropriate State Licensing Board

Factor One calls for consideration of the ''recommendation of the appropriate state licensing board or professional disciplinary authority'' in the public interest determination. 21 U.S.C. 823(f)(1). Neither the VBD Order nor any other record evidence constitutes a direct recommendation to the Agency from the VBD about Applicant's registration application.

As already discussed, after suspending Applicant's dental license about ten days after entry of Judgment in the Eight Felony Conviction Trial, the VBD reinstated Applicant's dental license, placed it on indefinite suspension, and stayed that suspension ''contingent upon continued compliance'' with various terms and conditions. GX 3, at 10–11. One such term and condition was that Applicant was not to ''prescribe or dispense Schedule II, III, and IV controlled substances for a period of two (2) years from the date of this Order,'' September 22, 2016. GX 3, at 11–12. Both parties implicitly interpret this VBD term as authorizing Applicant to prescribe and dispense Schedule V controlled substances in Virginia. *See, e.g.,* OSC, at 2.

The record does not include a comparison of the evidence presented in the Eight Felony Conviction Trial and in the VBD hearing. Clearly, though, the Fourth Circuit Conviction Affirmance and the VBD Order do not discuss all of the same incidents or evidence.

[23] I agree with the Chief ALJ's conclusions that, in this case, the felony convictions for health care fraud and aggravated identity theft are not sufficiently related to controlled substances. RD, at 35.

[24] Just as a felony conviction relating to controlled substances provides a basis for revoking an existing registration without proof of any other misconduct, *see* 21 U.S.C. 824(a)(2), it also provides an independent and adequate ground for denying an application. *Mark P. Koch, D.O.,* 79 FR at 18734–35; *Alvin Darby, M.D.,* 75 FR 26993 n.30 (2010); *Brady Kortland Fleming, D.O.,* 46 FR 45841, 45842 (1981).

My predecessor recently addressed Factor One and its application in a matter when the state board granted a doctor limited controlled substance authority based on less evidence of misconduct than the Government had presented during the OSC proceeding. *John O. Dimowo, M.D.,* 85 FR 15800, 15810 (2020).[25] In that case, my predecessor concluded that the state board's input was not a ''direct recommendation'' for purposes of Factor One. *Id.* at 15810. Viewing the state's action as ''indicating a recommendation,'' though, and stating that the CSA clearly places on him the responsibility to conduct the public interest inquiry and analysis, he noted that the state board had ''severely limited'' the doctor's medical license, ''which does not indicate a substantial amount of trust'' in the doctor. *Id.* Pointing out that he had more evidence of misconduct before him than the state board had, he stated that he considered the state board's action in the doctor's favor even though it was based on a subset of the evidence before him. *Id.*

I apply the same analysis and reach the same conclusion here given the differences between the evidence set out in the VBD Order and the evidence before me, including the evidence addressed in the Fourth Circuit Conviction Affirmance. In sum, while the terms of the VBD Order are not dispositive of the public interest inquiry in this case and are minimized due to the differences in the evidence in the VBD Order and the uncontroverted record evidence in this matter, I consider the VBD's grant of Schedule V authority in Applicant's favor.

D. Factors Two and Four—Applicant's Experience Dispensing Controlled Substances and Compliance With Applicable Laws Related to Controlled Substances

Factors Two and Four call for consideration of Applicant's ''experience in dispensing . . . controlled substances'' and his ''[c]ompliance with applicable State, Federal, or local laws relating to controlled substances.'' 21 U.S.C. 823(f)(2) and (4), respectively. I reviewed all of the record evidence concerning Applicant's controlled substance dispensing experience and compliance with applicable laws relating to controlled substances, including the testimony received during the adjudication of this OSC, and Applicant's position on it. I evaluated the evidence using the credibility assessments already discussed. *Supra* section II.E.

Relevant, uncontroverted record evidence concerning Factors Two and Four is in the VBD Order documenting Applicant's unlawful 2,711 dosage unit dispensing of controlled substances in Schedule II (1,740 dosage units), Schedule III (290 dosage units), and Schedule IV (681 dosage units). GX 2, at 2–10; *see also supra* section II.D. The VBD Order also documents the multiple provisions of Virginia law about controlled substances that Applicant violated.[26] GX 3, at 2–10. Other relevant, uncontroverted record evidence concerning Factors Two and Four is in the Judgment of the Eight Felony Conviction Trial and in the Fourth Circuit Conviction Affirmance already discussed.[27] *Supra* section II.D. GX 2, at 1; 576 F. App'x at 254–64 (GX 5, at 3–11).

Other record evidence concerning Applicant's controlled substance experience and dispensing is Applicant's testimony and written communications. During the hearing, for example, Applicant admitted that he wrote prescriptions that he ''shouldn't have written and that was a mistake and that would never, ever happen again.'' Tr. 130. By way of further example, Applicant also admitted that he ''wrote prescriptions, a few prescriptions that were not medically necessary. . . . I made a mistake, stupidity, naiveté, not being responsible.'' *Id.* at 131. He also admitted that he ''authorized a prescription or called a prescription or wrote a prescription that . . . [he did not] really know if it was a legitimate dental purpose, because they didn't come in.'' *Id.* at 129; *see also id.* at 128. Going back to 2006 and 2007, and ''quite a long time ago,'' Applicant testified, he ''made mistakes as far as what I prescribed to certain people.'' *Id.* at 129.

While admitting he wrote controlled substance prescriptions that were not legitimate, Applicant also testified that ''as far as . . . [his] trying to get any kind of favors or money or anything like that, that is not the case.'' *Id.* at 130. Material in the Fourth Circuit Conviction Affirmance conflicts with this testimony. 576 F. App'x, at 256 (GX 5, at 4) (describing a total of several hundred pills that were ''devoid of any clinical notes to support this treatment'' that Applicant prescribed between 2007 and 2008 to a woman with whom he was romantically involved). By way of further example, in written communications with DI, Applicant stated that ''I have never abused, sold drugs or anything like that.'' GX 6, at 1. This is not true according to the Fourth Circuit Conviction Affirmance. 576 F. App'x, at 256–57 (GX 5, at 4–5) (finding it a ''reasonable determination'' for the jury to have credited other witnesses' testimony over Applicant's when Applicant corroborated the testimony of his former office manager that Applicant wrote a prescription for several boxes of fentanyl patches in her name and applied a patch to his body in her presence because he was ''hoping this was something . . . [he] could use as a treatment modality . . . for any oral pain . . . [and wanted] to see if it helps . . . [his] back,'' even though, according to Dr. Singer, a fentanyl patch is ''outside the scope of dentistry or oral surgery and 'is only appropriate for a chronic pain patient who has cancer pain or . . . something extremely debilitating and may be chronically ill''').

In sum, I carefully considered all of the record evidence relevant to Factors One, Two, Three, and Four and Applicant's arguments about that evidence. I applied my and the Chief ALJ's credibility assessments to that evidence. I conclude that the Government met its *prima facie* burden of showing that it would be ''inconsistent with the public interest'' for me to grant Applicant's registration application for Schedule V authority. 21 U.S.C. 823(f). I further find that Applicant did not rebut the Government's *prima facie* case.

IV. Sanction

Where, as here, the Government presented a *prima facie* case that it would be ''inconsistent with the public interest'' to grant Applicant's request for a Schedule V registration, and Applicant did not rebut the Government's *prima facie* case, Applicant must then ''present[ ] sufficient mitigating evidence'' to show why he can be entrusted with a registration. *Garrett Howard Smith, M.D.,* 83 FR 18882, 18910 (2018). Further, as past performance is the best predictor of future performance, Agency

[25] The *John O. Dimowo, M.D.* Agency decision stands for the proposition that ''[a]lthough statutory analysis [of the CSA] may not definitively settle . . . [the breadth of the cognizable state 'recommendation' referenced in Factor One], the most impartial and reasonable course of action is to continue to take into consideration all actions indicating a recommendation from an appropriate state.'' 85 FR at 15810.

[26] Va. Code Ann. sec. 54.1–3303 (West, current through End of the 2016 Reg. Sess.) (amended 2017, 2018, 2019); Va. Code Ann. sec. 54.1–3408 (West, current through End of the 2016 Reg. Sess.) (amended 2017, 2018, 2019). The seriousness and extent of these violations are sufficient bases for my decision in this matter and, therefore, I need not address the other VBD founded violations of Virginia law alleged in the OSC.

[27] 21 U.S.C. 841(a)(1) and 846.

decisions require Applicant's unequivocal acceptance of responsibility for his actions and a demonstration that he will not engage in future misconduct. *ALRA Labs, Inc.* v. *Drug Enf't Admin.,* 54 F.3d 450, 452 (7th Cir. 1995); *Jayam Krishna-Iyer, M.D.,* 74 FR 459, 463 (2009) (collecting cases); *Jeffrey Stein, M.D.,* 84 FR 46968, 46972–73 (2019). The Agency has decided that the egregiousness and extent of the misconduct are significant factors in determining the appropriate sanction. *Garrett Howard Smith, M.D.,* 83 FR at 18910 (collecting cases). The Agency has also considered the need to deter similar acts by Applicant and by the community of registrants. *Id.*

The extent of Applicant's misconduct proven by the record evidence is eight felonies, six of which relate to controlled substances and all of which were affirmed on appeal, and the unlawful dispensing of over 2,700 dosage units of controlled substances in Schedules II, III, and IV. In addition, as already discussed, Applicant's testimony was not always marked by candor. *Supra* sections II.E. and III.D; *see also* GX 3, at 3 (''Individual I stated that in or about 2011, . . . [Applicant] instructed her to tell investigators that he had written prescriptions for pain medications for her, although this was not true.'').

While Applicant took responsibility for some of his wrongdoing, he did not take unequivocal responsibility for all of it. First, despite the Fourth Circuit Conviction Affirmance, Applicant testified that he did not conspire to distribute and dispense controlled substances in violation of 21 U.S.C. 846. Tr. 115 (denying that he ever unlawfully directed employees to go to pharmacies to pick up prescriptions and return them to him); *see also id.* at 133–34. Instead, he blamed his conspiracy conviction on false testimony of his former office manager. *Id.* at 116–17. Second, concerning his convictions for unlawfully dispensing controlled substances, Applicant denied writing prescriptions that did not have a legitimate dental purpose. *Id.* at 116. Instead, he testified that the prescriptions were legitimate. He explained that his ''problem'' was that the prescriptions lacked proof of their legitimacy in the form of proper documentation. *Id.* at 117. Third, he testified that it ''would be wrong'' for someone to say that he intentionally wrote or gave people prescriptions ''for other than a legitimate medical purpose.'' *Id.* at 121. Instead, he attributed what courts and the VBD determined were unlawful prescriptions to his not being careful enough, his making a mistake, his stupidity, and his being lax. *Id.* at 127–31.

As the Chief ALJ stated, ''It would be illogical for the Agency to entrust . . . [Applicant] with the weighty responsibilities of a DEA registrant where he is unable to even accept the proposition that he has engaged in the misconduct that he was convicted of and which was sustained by the . . . [VBD].'' RD, at 42. ''[S]o long as . . . Applicant adheres to his (almost bizarre) state of denial regarding the actual facts subsumed in his convictions (and Board findings),'' the Chief ALJ continued, ''it would be unreasonable to believe that he will alter his conduct.'' *Id.* Thus, as past Agency decisions make clear that unequivocal acceptance of responsibility is a prerequisite for the forbearance of a sanction, Applicant's failure unequivocally to accept responsibility means that he is not eligible to avoid an unfavorable disposition of his application under the record facts in this case.[28]

Applicant testified that he is not currently prescribing controlled substances in his dental practice and that he does not expect the income he realizes from his practice to increase if he had that authority. Tr. 46–48,113–14. Instead, he stated, he would like authority to prescribe Schedule V controlled substances for the sake of his patients' comfort. *Id.* at 46–48; *cf. supra* n.17 (summarizing Applicant's testimony that his not having authorization to dispense controlled substances has not dissuaded patients from using his practice). Applicant does not cite, and I am unaware of, any past Agency decision that grants a registration for the sake of patient comfort when the applicant was convicted of eight felonies and the unlawful dispensing of over 2,700 controlled substance dosage units. I decline to suggest, let alone establish, such a path.

I agree with the Chief ALJ that ''consideration of the egregiousness of . . . [Applicant's] transgressions likewise does not support a sanction less than an outright denial of . . . [Applicant's] application.'' RD, at 43.

The record in this case paints a picture of a registrant out of control. He distributed and dispensed drugs to himself and others with no justifiable reason, tasked his employees with taking controlled substance scrips to pharmacies and filling them so that he could dole them out to himself, friends, and other non-patients, slapped a fentanyl patch on himself in front of his staff, handed out powerful controlled drugs to his love interests, and prescribed scores of controlled substances to multiple patients without a legitimate medical purpose.

Id. In this context, specific and general deterrence weigh in favor of denying the application. I agree with the Chief ALJ that ''[t]o issue a registration to this . . . [Applicant] would send a message to the regulated community that misconduct (even repeated serious, intentional misconduct) will bear no meaningful consequence, even after state board findings and convictions,'' if the Applicant ''deflects blame onto others.'' *Id.*

Given my decision that Applicant's application is not in the public interest, I conclude that Applicant's proposed Corrective Action Plan provides no basis for me to discontinue or defer this proceeding.

Accordingly, I shall order the denial of Applicant's application.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(f), I hereby deny the application submitted by Hamada Makarita, D.D.S., Control No. W16093263C, seeking registration in Virginia as a practitioner in Schedule V, and any other pending application submitted by Hamada Makarita, D.D.S. for a DEA registration in the Commonwealth of Virginia. This Order is effective August 28, 2020

Timothy J. Shea,

Acting Administrator.

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[28] Applicant testified about the changes he made to his dental practice after his felony convictions and the VBD Order. Those so-called ''remedial measures,'' however, ''bear no logical nexus to his established misconduct'' of misusing his controlled substance privileges, as the Chief ALJ observed. RD, at 41. While Applicant testified about the expensive educational courses he took and the ''measures calculated to protect his scripts and prescribing software from potential malfeasance of staff members and burglars,'' he introduced no remedial measure ''that might bear the capacity to protect these powerful tools from his own future malfeasance.'' *Id.*

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–684]

Bulk Manufacturer of Controlled Substances Application: Euticals Inc.

ACTION: Notice of application.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before September 28, 2020.