Virginia 22152. All request for a hearing should also be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.34(a), this is notice that on December 7, 2021, Mylan Pharmaceuticals Inc., 2898 Manufacturers Road, Greensboro, North Carolina 27406–4600, applied to be registered as an importer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Remifentanil	9739	II

The company plans to import the above controlled substance as a Federal Drug Administration-approved drug product in finished dosage form for commercial distribution to its customers.

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).

Brian S. Besser,

Acting Assistant Administrator.

[FR Doc. 2022–01817 Filed 1–28–22; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 21–11]

Michael E. Smith, D.V.M.; Decision and Order

On December 3, 2020, a former Assistant Administrator, Diversion Control Division, of the Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause (hereinafter, OSC) to Michael E. Smith, D.V.M. (hereinafter, Respondent) of Zanesville, Ohio. Administrative Law Judge Exhibit (hereinafter, ALJX) 1 (OSC), at 1 and 5. The OSC proposed the denial of Respondent's application for DEA Certificate of Registration No. W20010614C (hereinafter, COR or registration) and the denial of any applications for any other DEA registrations pursuant to 21 U.S.C. 824(a)(2) and 824(a)(4) because Respondent was convicted of a felony related to controlled substances and because ''[Respondent's] registration would be inconsistent with the public interest, as that term is defined in 21 U.S.C. 823(f).'' *Id.* at 1.

On January 1, 2021, the Respondent timely requested a hearing, which commenced (and ended) on April 19, 2021, at the DEA Hearing Facility in Arlington, Virginia with the parties, counsel, and witnesses participating via video teleconference (VTC). On June 30, 2021, Administrative Law Judge Paul E. Soeffing (hereinafter, the ALJ) issued his Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge (hereinafter, Recommended Decision or RD).

By letter dated August 5, 2021, the ALJ certified and transmitted the record to me for final Agency action. In the letter, the ALJ advised that the Respondent filed untimely exceptions to the Recommend Decision on July 26, 2021. The ALJ stated that the Respondent had received an extension of time to file his exceptions by 2:00 p.m. ET on July 26, but did not file them until 2:58 p.m. ET. The ALJ also advised that the Government filed its Response to the Respondent's Exceptions on August 5, 2021.

Having reviewed the entire record, I find Respondent's Exceptions without merit and I adopt the ALJ's rulings, findings of fact as modified, conclusions of law and recommended sanction with minor modifications, where noted herein.*[A] Although Respondent's Exceptions were untimely, in this case, I decided to nonetheless consider and address each of Respondent's Exceptions, and issue my final Order in this case following the Recommended Decision.

Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge

Paul E. Soeffing

U.S. Administrative Law Judge

June 30, 2021

*[B] The issue in this case is whether the record as a whole establishes by a preponderance of the evidence that the Respondent's application for a DEA COR, Control No. W20010614C, should be denied, and any other pending applications for additional registrations should be denied, pursuant to 21 U.S.C. 824(a)(2) and (a)(4), because the Respondent has been convicted of a felony relating to controlled substances, and because his registration would be inconsistent with the public interest, as that term is defined in 21 U.S.C. 823(f).

After carefully considering the testimony elicited at the hearing, the admitted exhibits, the arguments of counsel, and the record as a whole, I have set forth my recommended findings of fact and conclusions of law below.

I. Findings of Fact

A. Allegations

The Government alleges that the Respondent's application for a DEA COR, Control No. W20010614C, should be denied and any applications by the Respondent for any other DEA registrations should be denied, pursuant to 21 U.S.C. 824, because (1) Respondent has been convicted of a felony relating to controlled substances; and (2) that registration would be inconsistent with the public interest, as that term is defined in 21 U.S.C. 823(f).

B. Stipulations

The Government and the Respondent agreed to fourteen stipulations, which I recommend be accepted as fact in these proceedings:

1. Respondent was previously registered with the DEA to handle controlled substances in Schedules II through V under DEA COR No. FS1126146 at 100 Sally Road, Zanesville, Ohio 43701.

2. Respondent surrendered DEA COR No. FS1126146 for cause on or about July 20, 2015, pursuant to his plea agreement in Case CR2015–0052, *State of Ohio* v. *Michael E. Smith.*

3. Respondent submitted an electronic application for a new DEA COR on or about February 3, 2020.

4. Government Exhibit No. 1 is a true and correct copy of Respondent's February 3, 2020 application for a DEA COR.

5. Government Exhibit No. 2 is a true and correct copy of the Certification of Registration History showing Respondent's answers to the liability questions from his February 3, 2020 application for a DEA COR.

6. Government Exhibit No. 3 is a true and correct copy of the docket sheet in Case CR2015–0052, *State of Ohio* v. *Michael E. Smith.*

7. Government Exhibit No. 4 is a true and correct copy of Respondent's signed plea agreement, dated July 20, 2015, in Case CR2015–0052, *State of Ohio* v. *Michael E. Smith.*

8. Government Exhibit No. 5 is a true and correct copy of the court's entry of Respondent's plea agreement, dated July 23,

*[A] I have made minor, nonsubstantive, grammatical changes to the RD and nonsubstantive conforming edits. Where I have made substantive changes, omitted language for brevity or relevance, or where I have added to or modified the Chief ALJ's opinion, I have noted the edits in brackets, and I have included specific descriptions of the modifications in brackets or in footnotes marked with an asterisk and a letter. Within those brackets and footnotes, the use of the personal pronoun ''I'' refers to myself—the Administrator.

*[B] I have omitted the RD's discussion of the procedural history to avoid repetition with my introduction.

2015, in Case CR2015–0052, *State of Ohio* v. *Michael E. Smith.*

9. Government Exhibit No. 6 is a true and correct copy of the court's entry of Respondent's sentence, dated October 7, 2015, in Case CR2015–0052, *State of Ohio* v. *Michael E. Smith.*

10. Government Exhibit No. 7 is a true and correct copy of the transcript of Respondent's plea hearing, dated July 20, 2015, in Case CR2015–0052, *State of Ohio* v. *Michael E. Smith.*

11. Government Exhibit No. 8 is a true and correct copy of the transcript of Respondent's sentencing hearing, dated October 5, 2015, in Case CR2015–0052, *State of Ohio* v. *Michael E. Smith.*

12. DEA lists Dilaudid (hydromorphone) as a Schedule II controlled substance under 21 CFR 1308.12(b)(1)(vii).

13. DEA lists oxycodone as a Schedule II controlled substance under 21 CFR 1308.12(b)(1)(xiii).

14. Dr. Smith currently holds an unrestricted license to practice veterinary medicine and surgery in the State of Ohio.

C. Government's Case-in-Chief

The Government presented its case in chief through the testimony of a single witness, Diversion Investigator (DI) K.P.

K.P. has worked for the DEA as a DI in Columbus, Ohio since May 2019. Tr. 14. She has been a DI since January 2019. Tr. 14–15. Her mission is to prevent, detect, and investigate diversion of controlled substances. Tr. 15. She conducts inspections, schedules investigations, and ensures registrants are in compliance with applicable laws. Tr. 15. If an applicant answers ''yes'' to a liability question [1] on the application, it will get flagged and assigned to a DI. Tr. 15–16. Once K.P. is assigned a new application for review, she will first read through the application and will then run a criminal history check. Tr. 16–17.

K.P. was assigned the Respondent's case because Respondent answered ''yes'' to three of the liability questions on the DEA Form 224, Application for Registration (''application'').[2] Tr. 17–19; Gov't Ex. 1 at 1. To the best of K.P.'s knowledge, the Respondent answered these questions correctly on his application. Tr. 38. After being assigned the case, K.P. called the Respondent. Tr. 17. She then reviewed the Ohio Veterinary Medical Licensing Board (''the Board'') action on his previous state license and realized he had a new Ohio state license. Tr. 18. She then ran his criminal history and submitted a request to Muskingum County for documents relating to the Respondent's criminal history. Tr. 18, 25–37; *See* Gov't Exs. 3–8. Throughout the investigation, K.P. spoke to the Respondent two or three times on the phone. Tr. 39. Otherwise, she was in contact with his counsel, Mr. I. Tr. 39. K.P. never met with the Respondent in person. Tr. 39.

In his answer to the first liability question, the Respondent stated that he pled guilty to ten counts of Illegal Processing of Drug Documents, had surrendered his vet license and his DEA registration, and served seventeen months of incarceration. Tr. 24; Gov't Ex. 2.[3] K.P. was concerned because the Respondent indicated he was addicted to opiates and had written prescriptions under his COR for dogs, but took them for his own personal use. Tr. 23–24; Gov't Ex. 2. K.P. asserted that the DEA's concern with granting the Respondent's application for registration is that the Respondent would not be able to responsibly handle a DEA registration because he has a proven history of misusing it. Tr. 40. The Respondent's guilty plea to ten counts of Illegal Processing of Drug Documents was significant to her because she believed it showed that the Respondent was not responsible with his registration. Tr. 24, 40.

K.P. did not believe that the Respondent had provided her with proof that he had been working on his addiction. Tr. 40. Although he provided her with certificates of the programs he completed, none were more recent than 2017. Tr. 40–41. She did not have an opinion on how often the Respondent should be attending a rehabilitation program or attending meetings. Tr. 41–42.

K.P.'s testimony was primarily focused on the non-controversial introduction of documentary evidence and her contact with this case.[4] Her testimony was generally consistent and genuine and there was no indication she harbors any animosity towards the Respondent. As a public servant, K.P. has no personal stake in the DEA's action on the Respondent's application for registration. I therefore find her testimony to be entirely credible and it will be afforded considerable weight.

D. Respondent's Case

The Respondent presented his case in chief through the testimony of four witnesses: himself and three character witnesses A.B., R.W., and G.G.

Respondent

The Respondent graduated from Ohio State University and obtained his degree in 1994. Tr. 44–45; Gov't Ex. 1 at 1.[5] He worked with his father in a private practice, where they saw over 10,000 clients, including over thirty-seven species of animals from seven counties. Tr. 45. He is prepared to handle situations in internal medicine, emergency medicine, preventive care, and surgical procedures. Tr. 46. The Respondent currently has a veterinary practice, Smith Veterinary Services, in Muskingum County, Zanesville, Ohio, which is mainly a rural area. Tr. 44–46.

Within a few years of graduating, the Respondent's veterinary license was disciplined for the first time. Tr. 46–47. One night, sometime in the 1990's, a client offered him cocaine, he took it, and ultimately became addicted to cocaine.[6] Tr. 47, 122. He was arrested with a possession charge and reprimanded by the Board with a two-year suspension of his license. Tr. 48, 110. When he was first arrested, he was put on probation, but he violated that probation and served a sentence. Tr. 128. He was incarcerated for eight months total for this drug conviction.[7] Tr. 129. The Board set conditions on the reinstatement of his license in a settlement agreement in 2000, including the requirement that he complete a rehabilitation program and demonstrate that he was capable of operating in a proper manner.[8] Tr. 48–49; 131–33.

[1] This includes whether an applicant had prior issues with controlled substances, convictions, or any disciplinary action on a state or federal controlled substance license. Tr. 16.

[2] The Respondent submitted this application in February 2020. Stip. 3; Tr. 19; Gov't Exs. 1, 2.

[3] The Government presented evidence indicating that the Respondent pled guilty in *State of Ohio* v. *Michael E. Smith*, No. CR2015–0052 to ten counts of ''Illegal Processing of Drug Documents,'' in violation of Ohio Revised Code (''ORC'') § 2925.23(B)(1), which is a fourth-degree felony. Gov't Ex. 4. The Respondent also pled guilty to ''Having a Weapon While Under Disability'' in violation of ORC § 2923.13(A)(3), a third-degree felony. *Id.*

[4] Although the Government called K.P. as a rebuttal witness to introduce into evidence additional documentary evidence, the tribunal sustained the Respondent's objection to proposed Government Exhibit 9 being admitted into evidence. Tr. 163–67.

[5] Although not specified in the testimony, this appears to be when the Respondent graduated from Veterinary school. *See* Gov't Ex. 1 at 1.

[6] When questioned by the tribunal as to the year he first started abusing drugs, the Respondent stated that he ''may have had casual use throughout my youth'' which would presumably predate this cocaine use after he became a licensed veterinarian and was ''well into [his] 30's.'' Tr. 119–20.

[7] Respondent's first drug conviction, for cocaine, was in 1997. Tr. 129; Gov't Ex. 7 at 14:21–22. In the sentencing transcript for the Respondent's 2015 conviction, his defense attorney indicates the Respondent served a six-month sentence for the 1997 conviction. Gov't Ex. 8 at 6:4–5.

[8] During the testimony, there was some confusion as the Respondent's Prehearing Statement indicated there was a settlement agreement with the Board in 2005. ALJ Ex. 8 at 2. The Respondent's counsel also referenced a 2005 settlement agreement with the Board, but the Respondent clarified that the settlement agreement was in 2000. Tr. 48. According to the Respondent and his counsel, the

Continued

When his license was reinstated, he went back to working with his father. Tr. 49. His father died in 2010, but he continued to work in the office with his half-sister, who was also a veterinarian. Tr. 50. They ultimately ''parted ways'' in the fall of 2011. Tr. 50–51. At this point, the Respondent had been sober for approximately thirteen years. Tr. 120.

In October of 2011, he learned that he had avascular necrosis of both of his hips, which he found to be quite painful. Tr. 51. He was prescribed opiates by the emergency room doctor, likely Percocet, after this diagnosis, and continued receiving opiate prescriptions after having hernias repaired in November 2011. Tr. 51, 52, 120. He had hip replacement surgery in January 2012. Tr. 52. He continued to receive opiate prescriptions from various doctors until a doctor indicated that he would no longer prescribe him opiates. Tr. 52–53. He then reached out to a surgeon who prescribed him opiates after the Respondent ''used an argument of professional courtesy,'' but this doctor ultimately stopped prescribing opiates to him. Tr. 53. The Respondent then started doing illegal activities [9] to acquire his own drugs for about three or four months. Tr. 53 (''went on for maybe three months''); Tr. 83 (''over a four-month period''). A pharmacist friend called and asked about one of the prescriptions the Respondent wrote and he lied and told the pharmacist that the prescription was ''okay.'' [10] Tr. 53. This incident prompted him to seek help. He started going to meetings and took part in a faith-based rehabilitative program, Alcohol Chemical Tobacco Symposium (''ACTS'') prior to his incarceration.[11] Tr. 53–55, 62; Resp't Ex. C.

The Respondent was ultimately served with a warrant in September 2012. Tr. 56. After receiving the warrant, he went to church, attended Alcoholics Anonymous (''AA'') and Narcotics Anonymous (''NA'') meetings, and continued to practice as a vet.[12] Tr. 57. Criminal charges were filed against him in 2015, and he was arrested. Tr. 58. The Respondent pleaded guilty to ten counts of Illegal Processing of Drug Documents. Tr. 58–59. The Respondent admitted that he pleaded guilty to ten counts of Illegal Processing of Drug Documents based on a scheme whereby he would write false prescriptions for dogs that he did not examine, and would either fill those prescriptions and take the pills for his own use or would sell the prescriptions to others.[13] Tr. 101–02. He also admitted that by issuing those prescriptions, in most cases, he did so without a legitimate medical purpose and outside the usual course of professional practice. Tr. 103.

He denied using marijuana or smoking crack in 2011 or 2012. Tr. 122. *But see* Gov't Ex. 8 at 21:1–11, 22:7–14 (During the 2015 sentencing hearing, the Respondent testified that prior to his arrest he was smoking marijuana almost daily and started smoking crack again in 2011). He testified that he did not recall making the statement to the trial judge in 2015 that he was smoking crack, although he may have used powdered cocaine in early 2012. Tr. 124. He also did not recall making the statement in 2015 to the trial judge that he was smoking marijuana, and he did not recall smoking marijuana in 2011 or 2012. Tr. 125. However, he later testified he probably last smoked marijuana during his opiate addiction in 2011 or 2012. Tr. 125–26. He also did not recall a period when he was smoking marijuana almost daily. Tr. 126–27. He stated that he did not ''recall all that was going on'' during the time of his opiate addiction and his ''mind was horribly confused . . . and everything is a daze.'' Tr. 126.

The Respondent was also given a twenty-four-month sentence for a gun violation.[14] Tr. 127; Gov't Ex. 6 at 2; Gov't Ex. 8 at 19–20. He served a seventeen-month prison sentence for his drug-related crimes from late 2015 until spring 2017, and received about thirty days off his sentence for good behavior. Tr. 59, 64. *But see* Tr. 127 (The Respondent testified that he served a concurrent twenty-four-month sentence for his gun-related crime with about thirty days off his sentence for good behavior.). While incarcerated, he surrendered his veterinary license to the Board. Tr. 63.

While he was incarcerated, he applied to the Seeking a New Direction (''SAND'') program, which had limited seating, attended NA and AA meetings weekly to bi-weekly, and chaired some NA meetings. Tr. 59–61, 103; Resp't Ex. B.[15] Also while incarcerated, he applied to and was accepted into the Kairos Inside Weekend Program, which is a faith-based organization where a group of men take part in ''a complete weekend of spirituality,'' learning to love themselves and forgive others. Tr. 60, 103; Resp't Ex. D.

After being released from jail, he thanked God, took care of his wife, found employment, and took part in the ACTS program. Tr. 62, 64; Resp't Ex. C. This program focused him on maintaining his sobriety. Tr. 96. He also got a job at Winland's Complete Landscaping as a laborer, then advanced to head mower and trained others. Tr. 64, 66–67. Despite pain from his hip, he never used opiates or other illegal substances while employed there, and ''will never touch another one.'' Tr. 65. Instead, he took over-the-counter Ibuprofen and Tylenol and was prescribed Meloxicam and Flexeril, a muscle relaxant. Tr. 65, 99.

Post-release, he attended AA and NA meetings. Tr. 65. He ''used to go a lot,'' but he has ''pulled back some'' and now goes when he feels ''a little stressed'' to hear other addicts, including ''ones that are newly trying to recover,'' so he can ''recall the pain, the discomfort, the dysfunction.'' Tr. 66.

When the Respondent applied for his veterinary license to be reinstated in Ohio, the Board initially denied his application. Tr. 68. The Board then held a hearing and decided ''the same day'' to reinstate his license. Tr. 69; Resp't Ex. A. His veterinary license was reactivated in January 2020. Tr. 67, 70, 87. Despite the fact that the Board's decision stated that it was issuing him a license ''with a reprimand letter,'' the Respondent asserts that he did not receive such a letter. Tr. 107, 109; Resp't Ex. A at 3. The Respondent further testified that there are no restrictions on his veterinary license and there was no discipline or reprimand. Tr. 69. The Board did not require any particular

2005 date listed in the Respondent's Prehearing Statement is a typographical error and the year should actually be 2000. Tr. 130–32.

[9] This appears to be a reference to the Respondent's criminal activity of writing prescriptions in the names of dogs that he or others would then fill so that the Respondent could use the drugs to satisfy his addiction.

[10] The Respondent later testified that this was a turning point for him where he realized that ''[n]ot only was I destroying myself, now I put him in a position of where he shouldn't have been and I came to the realization that what I was doing to myself, I may have been contributing this to happening to others as well.'' Tr. 97.

[11] The Respondent later testified that he took part in the program post-incarceration. Tr. 62. Furthermore, the certificate of completion for this ACTS program is dated August 16, 2017. Resp't Ex. C.

[12] The Respondent did not provide documentation of his attendance when he went to these meetings since he ''went on [his] own accord'' and ''the only time [he] signed was when [he] was incarcerated'' or ''back in the 90s when [the Courts] wanted [him] to have a paper signed.'' Tr. 57.

[13] The Respondent qualified his answer by saying ''[a] few of the prescriptions were actually for dogs that were damaged horribly.'' Tr. 102.

[14] The Respondent was a convicted felon in possession of a firearm, which he had used after his felony conviction. Gov't Ex. 8 at 19–20. At the hearing for the instant case, the Respondent admitted to having ''a deer shotgun and a .22 rifle here for protection for [his] office and family.'' Tr. 127.

[15] The Respondent testified that the Certificate of Completion for the Intensive Outpatient Program of Hocking County that was admitted into evidence as Respondent's Exhibit B is the same program as the SAND program. Tr. 60–61, 103.

rehabilitation or monitoring by the Board for his current license. Tr. 110–11. In its Finding and Order, the Board did suggest that the Respondent ''operate his practice under direct supervision by a licensed veterinarian.'' Tr. 107–08, 135–36; Gov't Ex. A at 3. The Respondent is not doing that. Tr. 107–08, 135. The Board's Finding and Order also suggested that he attend Ohio Physicians' Health Plan counseling for five years. Tr. 108, 134–35; Gov't Ex. A at 3. Respondent is also not doing this because when he previously looked into it—back in the 1990's—it was quite expensive and he would have to commute to Columbus, Ohio.[16] Tr. 108, 134–35. The Board has not checked in on the Respondent since reinstating his license. Tr. 69–70.

The Respondent built up his practice and set up an office in his house as a sole practitioner with his wife as his secretary and assistant. Tr. 70, 93–94, 106. He has seen approximately 1,000 patients since his license was reinstated. Tr. 70. The Respondent is specifically seeking the use of Schedule III, IV, and V drugs including Ketamine, which he would use as an anesthetic. Tr. 71–72, 90. He is also requesting Diazepam and Phenobarbital, which are used on animals having seizures. Tr. 73, 90. He is also seeking the use of testosterone and estrogen, which can be used on dogs with prostatitis. Tr. 74, 90. He is also seeking use of Nandrolene, an anabolic steroid, and Telazol, a short-acting narcotic. Tr. 75–76, 90. The Respondent would only administer these controlled substances, except for Phenobarbital, which he would prescribe to epileptic dogs. Tr. 91, 92. The Respondent is aware that Ketamine and Diazepam are controlled substances that are diverted. Tr. 94–95.

Every day, he prays, and he has learned many concepts and tools through NA and his rehabilitation programs. Tr. 79, 137–38. He has learned that addiction is ''a lifelong condition and it needs proper maintenance'' and that sobriety ''takes work, it takes maintenance.'' Tr. 80, 111. He would describe himself as ''a grateful recovered addict.'' Tr. 112. He also believes that addiction is ''part of [his] personality.'' Tr. 121. He testified that he appreciates that the Board reinstated his license and ''can guarantee [he] would never, ever, ever abuse that authority again.'' Tr. 81.[17]

Since his incarceration, the Respondent has not taken any classes or continuing education regarding his responsibilities and duties as someone with the authority to prescribe and administer controlled substances, but he did review regulations for the storage of controlled substances and record-keeping. Tr. 85, 116. The Respondent testified that he was ''not aware of any classes'' regarding responsibilities and duties of those with the authority to prescribe and administer controlled substances. Tr. 116. The last time the Respondent used an illegal controlled substance or any properly prescribed controlled substance was in 2012. Tr. 56, 96–98. He has been drug tested ''[m]any times'' since 2012 and has never had a positive result.[18] Tr. 56.

The Respondent stated that what is currently different as it relates to his prescribing or administering of controlled substances is the fact that he is no longer addicted to opiates. Tr. 111–12. He also does not continue to associate with any of the people he provided false prescriptions to in 2012. Tr. 112. The Respondent asserts that he did not provide drugs to his son (or any other relatives), either by prescribing or diverting them. Tr. 113, 115–16, 117–18. *But see* Gov't Ex. 8 at 16:17–18 (The Respondent stated that he ''became addicted [himself] and [his] son as well . . . .''); Gov't Ex. 8 at 18:15–19 (At the sentencing hearing, the trial judge stated ''you probably don't even know who all the victims are that got those drugs, do you?'' to which the Respondent replied ''One was my son, one was myself, I know that.'').

The Respondent believes a DEA COR would allow him to ''practice at a higher level'' and would provide for a ''better outcome or safety.'' Tr. 71, 76–77. The State of Ohio has never taken an action against his veterinary license due to the care he provided or failed to provide to an animal.[19] Tr. 77. The Respondent stated that he does not plan on writing prescriptions and trading them for drugs and he takes responsibility for his actions. Tr. 77, 137.

Regarding the Respondent's credibility, I note several areas of his testimony where there were inconsistencies or where his testimony was in direct opposition to previous testimony or established facts. First, the Respondent's testimony in this hearing that he never provided drugs to his son is in direct conflict with testimony he provided in his 2015 criminal proceedings as reflected in the sentencing transcript. Second, the Respondent's testimony in this hearing that he was not abusing other drugs, specifically crack and marijuana, at the time that he developed his addiction to opiates conflicts with testimony he provided, as reflected in the transcript, to the court during his 2015 sentencing. Third, the Respondent first testified that the Ohio Physicians' Health Plan counseling was too expensive for him to afford and also too far away for him to attend the in-person sessions. However, upon further examination by the tribunal, Respondent admitted he did not make any inquiries into the program after receiving the Board's Finding and Order and that his testimony was based on an inquiry he made back in the 1990's. Based on these inconsistencies in the Respondent's statements, and Respondent's uninformed (to be charitable) initial testimony regarding the Ohio Physicians' Health Plan counseling, I cannot fully credit the Respondent's testimony.

A.B.

A.B. has known the Respondent since 1995 and has taken her pets to him as her veterinarian since that time, except when he was not able to practice. Tr. 142–43. She is not a veterinarian and has never prescribed or administered controlled substances. Tr. 147–48. She knows that the Respondent was unable

[16] Upon further questioning by the tribunal, the Respondent admitted that he did not know if the Ohio Physicians' Health Plan counseling is currently an in-person program, nor did he know if financial assistance or a lower fee arrangement might be available to him. Tr. 134–35. The Respondent further admitted that ''I don't know what the program actually consists of or how they run it, at this time.'' Tr. 134. It therefore appears that the Respondent rejected out of hand any consideration of participating in the program based on his understanding of the program as it existed over twenty years ago, without making any inquiry as to how he might take part in or benefit from the program as it exists today. There did not seem to be any inquiry or investigation by the Respondent since the 1990's to justify his testimony that ''[i]t's very expensive'' and ''something [he] could not afford.'' Tr. 108.

[17] At the conclusion of his direct examination, the Respondent read a prepared statement to the tribunal. Tr. 81–86. He explained that he does not ''make light of the abuse of the trust given to my profession.'' Tr. 83. He admitted that he was convicted of the Illegal Processing of Drug Documents and has not lied or denied any of that. Tr. 83. He stated that he realized his actions harmed himself and potentially others and he regrets that. Tr. 83–84. He has also reviewed the standards for record-keeping for controlled substances, purchased key locks and a key lockbox, and will comply with all necessary regulations. Tr. 85, 116.

[18] The Respondent did not offer into evidence any documentation of any drug test results he may have had over the years. Nor did the Respondent testify regarding what drugs he was tested for or when he last submitted to a drug test.

[19] Although the Board may not have ever taken action against his license, this certainly does not mean that the Respondent has at all times provided proper care. The Respondent testified that one of the illegal prescriptions he wrote drew the attention of the filling pharmacist who questioned the legitimacy of the prescription. Tr. 53, 97. Though this prescription was diverted for illegal human use, the medical records of the animal patient would presumably falsely reflect that the animal had been prescribed the drug.

to practice because he lost his license due to ''some mistakes with drugs.'' Tr. 143. She has chronically ill animals—puppy mill survivors—that she takes to the Respondent for care because their severe illnesses require someone who will take the time to ''keep these dogs going.'' Tr. 143–45. The Respondent has always taken time to sit down and order lab tests. Tr. 144. She has never seen the Respondent appear to be under the influence of drugs or alcohol during any of her visits. Tr. 146–47. She trusts the Respondent. Tr. 147.

A.B. was called as a character witness,[20] and although the depth of her knowledge of the Respondent's suitability to act as a responsible DEA registrant is extremely limited, she presented testimony that was sufficiently cogent, detailed, plausible, and internally consistent to be considered generally creditable. Although A.B. has known the Respondent for over twenty-five years, her interactions with him have been limited to the times over the years when she has brought her animals to him for care. Nevertheless, I credit her testimony that the Respondent has rendered compassionate care to her animals and has never appeared to be under the influence of alcohol or drugs.

R.W.

The Respondent was employed by R.W.'s landscaping [21] company about three and a half years ago. Tr. 150. R.W. is not a veterinarian and has never prescribed or administered controlled substances. Tr. 153. Although the Respondent had felony convictions, R.W. needed employees and the Respondent was ''up front and honest'' with him about his situation, so R.W. gave him a chance. Tr. 150. The Respondent passed the initial drug test and never appeared to be under the influence of drugs or alcohol while he worked for R.W. Tr. 150–51. He was a hard worker and R.W. trusts him. Tr. 151. R.W. takes all of his pets to the Respondent for veterinary care. Tr. 151–52. The Respondent has never appeared to be under the influence of drugs or alcohol when R.W. brought his animals to the clinic. Tr. 152.

R.W. was called as a character witness [22] and, like the first character witness, although the depth of his knowledge of the Respondent's suitability to act as a responsible DEA registrant is extremely limited, he presented testimony that was sufficiently cogent, detailed, plausible, and internally consistent to be considered generally creditable. As a past employer, R.W. had more opportunities to observe the Respondent's condition on a day-to-day basis and he also had a stake in the Respondent remaining sober while employed. I therefore credit his testimony that the Respondent passed an initial drug test and maintained sobriety during the course of his employment.

G.G.

The Respondent and the Respondent's father had taken care of G.G.'s cats in 1990.[23] Tr. 156. G.G. ran an animal shelter, which he took over in 1992, until he retired in 2005. Tr. 156–57. G.G. does not keep in contact with anybody from the shelter. Tr. 159. The Respondent's father and the Respondent worked with this shelter, taking care of animals. Tr. 156. G.G. is not a veterinarian and he does not have a DEA COR. Tr. 160–61. G.G. believed that the Respondent was very knowledgeable in pet care and would explain to his clients how to care for their pets. Tr. 158. G.G. currently takes his dog to the Respondent. Tr. 158. Despite the fact that the Respondent is a convicted felon, it has never come up in conversation because he believes the Respondent's concern is what he can do for the pets. Tr. 158–59. G.G. has never seen the Respondent appear to be under the influence of drugs or alcohol. Tr. 159. While G.G. worked at the shelter, he never heard any complaints about the Respondent's care. Tr. 159–60.

G.G. was called as a character witness [24] and, like the other two character witnesses, although the depth of his knowledge of the Respondent's suitability to act as a responsible DEA registrant is extremely limited, he presented testimony that was sufficiently cogent, detailed, plausible, and internally consistent to be considered generally creditable. Because G.G. retired from the animal shelter in 2005, well before the Respondent's most recent drug violations, and because he has not kept in touch with people at the animal shelter, I find that the substance of his testimony is more relevant as a client who takes his dog to the Respondent for care. I therefore credit his testimony that the Respondent has rendered compassionate care to his dog and has never appeared to be under the influence of alcohol or drugs.

Other facts necessary for a disposition of this case are set forth in the balance of this Recommended Decision.

II. Discussion

The burden of proof at this administrative hearing is a preponderance-of-the-evidence standard. *Steadman* v. *SEC,* 450 U.S. 91, 100–01 (1981). The Administrator's factual findings will be sustained on review to the extent they are supported by ''substantial evidence.'' *Hoxie* v. *DEA,* 419 F.3d 477, 482 (6th Cir. 2005). The Supreme Court has defined ''substantial evidence'' as such ''relevant evidence as a reasonable mind might accept as adequate to support a conclusion.'' *Consolidated Edison Co.* v. *NLRB,* 305 U.S. 197, 229 (1938). While ''the possibility of drawing two inconsistent conclusions from the evidence'' does not limit the Administrator's ability to find facts on either side of the contested issues in the case, *Shatz* v. *U.S. Dep't of Justice,* 873 F.2d 1089, 1092 (8th Cir. 1989), all ''important aspect[s] of the problem,'' such as a respondent's defense or explanation that runs counter to the Government's evidence must be considered. *Wedgewood Vill. Pharmacy* v. *DEA,* 509 F.3d 541, 549 (D.C. Cir. 2007). The ultimate disposition of the case must ''be in accordance with the weight of the evidence, not simply supported by enough evidence to justify, if the trial were to a jury, a refusal to direct a verdict when the conclusion sought to be drawn from it is one of fact for the jury.'' *Steadman,* 450 U.S. at 99 (internal quotation marks omitted).

Regarding the exercise of discretionary authority, the courts have recognized that gross deviations from past agency precedent must be adequately supported, *Morall* v. *DEA,* 412 F.3d 165, 183 (D.C. Cir. 2005), but ''mere unevenness'' in application does not, standing alone, render a particular discretionary action unwarranted. *Chein* v. *DEA,* 533 F.3d 828, 835 (D.C. Cir. 2008) (citing *Butz* v. *Glover Livestock Comm'n Co.,* 411 U.S. 182, 188 (1973)). It is well-settled that because the Administrative Law Judge has had the opportunity to observe the demeanor and conduct of hearing witnesses, the factual findings set forth in this

[20] Tr. 140.

[21] Although R.W. did not testify as to the type of business he operates, he did describe the Respondent's responsibilities as ''mowing'' and being ''in charge of the mowing crew.'' Tr. 151. The Respondent also previously testified that he worked for W.'s Complete Landscaping, a landscaping service. Tr. 64.

[22] Tr. 140.

[23] The Respondent testified he did not graduate from veterinary school until 1994 and he then went into private practice with his father. Tr. 44–45. While G.G. may have been mistaken as to whether the Respondent had personally cared for his cats as early as 1990, the Respondent also testified that he had ''managed dogs and horses and cats'' since he was six, (Tr. 68), so it is plausible that the Respondent was assisting in his father's practice in 1990 in some capacity.

[24] Tr. 140.

Recommended Decision are entitled to significant deference, *Universal Camera Corp.* v. *NLRB,* 340 U.S. 474, 496 (1951), and that this Recommended Decision constitutes an important part of the record that must be considered in the Administrator's decision. *Morall,* 412 F.3d at 179. However, any recommendations set forth herein regarding the exercise of discretion are by no means binding on the Administrator and do not limit the exercise of that discretion. 5 U.S.C. 557(b); *River Forest Pharmacy, Inc.* v. *DEA,* 501 F.2d 1202, 1206 (7th Cir. 1974); Attorney General's Manual on the Administrative Procedure Act § 8 (1947).

In the adjudication of a denial of a DEA registration, the DEA has the burden of proving that the requirements for such registration are not satisfied. 21 CFR 1301.44(d). Where the Government has sustained its burden and made its *prima facie* case, a respondent must both accept responsibly for his actions and demonstrate that he will not engage in future misconduct. *Patrick W. Stodola, M.D.,* 74 FR 20,727, 20,734 (2009). Acceptance of responsibility and remedial measures are assessed in the context of the ''egregiousness of the violations and the [DEA's] interest in deterring similar misconduct by [the] Respondent in the future as well as on the part of others.'' *David A. Ruben, M.D.,* 78 FR 38,363, 38,364 (2013).

A. 21 U.S.C. 824(a)(2): Felony Related to Controlled Substances

The Government alleges that the Respondent's COR application should be denied because he has been convicted of a felony related to controlled substances, pursuant to 21 U.S.C. 824(a)(2). Under this provision, the Attorney General *may* deny,*[C] revoke, or suspend a registration issued under 21 U.S.C. 823 ''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, or of any State, relating to any substance defined in this subchapter as a controlled substance or a list I chemical.'' 21 U.S.C. 824(a)(2)(emphasis added). Under 21 U.S.C. 824(a)(2), a felony conviction related to controlled substances is a lawful basis to revoke a COR, but the question of whether the registration is revoked is a matter of discretion. *Alexander Drug Co., Inc.,* 66 FR 18,299, 18,302 (2001).

The Government alleges that on July 20, 2015, the Respondent pleaded guilty to ten counts of Illegal Processing of Drug Documents in violation of Ohio Rev. Code. Ann. § 2925.23(B)(1),[25] and that the Respondent was sentenced to seventeen months of imprisonment to be served concurrently with a twenty-four-month prison sentence for a weapons charge.*[D] ALJ Ex. 1 at 2 ¶ 7. The Government further alleges that these ten convictions were based on a scheme in which the Respondent prepared false prescriptions for opioid medications, including hydromorphone and oxycodone/acetaminophen, for canines that did not exist or that the Respondent did not examine, and that the Respondent would either fill these prescriptions for his personal use or sell the prescriptions to others in exchange for cash or other controlled substances. ALJ Ex. 1 at 2–3 ¶ 8.

The Government provided a copy of the Respondent's signed guilty plea in which the Respondent pleaded guilty to ten counts of Illegal Processing of Drug Documents and one count of Having a Weapon While Under Disability.[26] Gov't Ex. 4. The Respondent also admitted that he pleaded guilty to ten counts of Illegal Processing of Drug Documents in his Application for Registration, Form DEA 224 (''application''). Gov't Ex. 2 at 1–2. Specifically, in response to background question one on the application, which asks whether the applicant has ''ever been convicted of a crime in connection with controlled substance(s) under state or federal law,'' the Respondent responded ''Yes'' and indicated the following:

> Incident Date: 10/05/2015 Incident Location: MUSKINGUM COUNTY OHIO Incident Nature: IN 2012 I BECAME ADDICTED TO OPIATES AFTER 5 STRAIGHT MONS OF DR. PRESCRIBED OPIATES FOR 2 MAJOR SURGERIES. WHEN THE DRS. FINALLY STOPPED THEM I WROTE OPIATE PRESCRIPTIONS FOR DOGS AND TOOK SOME FOR MY OWN USE. I DID THIS OVER A THREE MONTH PERIOD UNTIL I CAME TO MY SENSES AND SOUGHT HELP FOR MY ADDICTION. Incident Result: IN 2015 AFTER BEING CHARGED I PLEAD GUILTY TO 10 COUNTS OF ILLEGAL PROCESSING OF DRUG DOCUMENTS AND SURRENDERED MY VET. LICENSE AND MY DEA REGISTRATION. I SERVED 17 MONS. INCARCERATED AND COMPLETED 2 REHABILITATION/RECOVERY PROGRAMS . . . .

Gov't Ex. 1 at 1–2 (emphasis in original).

The Respondent also testified at the April 19, 2021 hearing that he had pleaded guilty to ''10 counts . . . of illegal processing of drug documents'' and that he received a seventeen-month sentence for these charges and served all seventeen months, except ''possibly 30 days off the sentence for good behavior.'' Tr. 58–59, 101.

During cross-examination, the Government referenced ALJ Exhibit 1, the Order to Show Cause for the instant case. Tr. 100.[27] The Government read through Paragraphs 7 and 8, and the Respondent agreed he pleaded guilty to these ten counts of Illegal Processing of Drug Documents. Tr. 101. The Government also asked the Respondent whether these false prescriptions were based on a scheme whereby he would write false prescriptions for dogs the Respondent did not examine and would then fill those prescriptions for his own use or would sell the prescriptions to others. Tr. 102; ALJ Ex. 1 at 3 ¶ 11. The Respondent indicated that although a ''few of the prescriptions were actually for dogs that were damaged horribly,'' he ''did write prescriptions that should not have been written so [he] could acquire these drugs to feed [his] addiction. [He] fully admit[s] . . . freely admit[s] that.'' Tr. 102. The Respondent also testified that he knew ''some people did acquire'' these false prescriptions. Tr. 102. Although the Respondent did not testify at the April 19, 2021 hearing that the specific controlled substances included hydromorphone and oxycodone, the transcript from his guilty plea, which was stipulated to by the parties, indicates that this scheme indeed included prescriptions for hydromorphone/Dilaudid, and oxycodone/APAP, which are both Schedule II controlled substances. Gov't Ex. 7 at 14; *See* Stip. 10, 12, 13.

Therefore, through the Respondent's testimony, the exhibits, and the stipulations, there is no controversy that the Respondent has pleaded guilty to ten counts of Illegal Processing of Drug Documents in violation of Ohio Rev.

*[C] A provision of section 824 may be the basis for the denial of a practitioner registration application and allegations related to section 823 remain relevant to the adjudication of a practitioner registration application when a provision of section 824 is involved. *See Robert Wayne Locklear, M.D.,* 86 FR 33,738, 33,744–45.

[25] Ohio Rev. Code. Ann. § 2925.23(B)(1) states that ''[n]o person shall intentionally make, utter, or sell, or knowingly possess any of the following that is false or forged: (1) Prescription.''

*[D] Although discussed herein as background, I am not considering the weapons charge under 21 U.S.C. 824(a)(2).

[26] The Government provided a copy of the signed plea agreement from the Muskingum County Court of Common Pleas. Gov't Ex. 4. The parties stipulated that this document is a true and correct copy of Respondent's signed plea agreement, dated July 20, 2015, in Case CR2015–0052, *State of Ohio* v. *Michael E. Smith.* Stip. 7.

[27] The Government ''shared'' this document on the screen so the Respondent, who was attending the hearing from a different physical location from his counsel, (Tr. 6), and did not have copies of the ALJ exhibits, was able to follow along with this line of questioning. Tr. 100.

Code Ann. § 2925.23(B)(1), was sentenced to seventeen months imprisonment to be served concurrently with a twenty-four month prison sentence for a weapons charge, and that these counts were based on a scheme by which the Respondent prepared false prescriptions for canines that did not exist or that he did not examine, and that he either filled the prescriptions for his own use or sold the false prescriptions to others in exchange for cash or other controlled substances.

Therefore, the allegations set forth in the OSC Allegations 7 and 8 are *Sustained*.

B. 21 U.S.C. 823(f): Public Interest Determination

Pursuant to 21 U.S.C. 823(f), the Administrator may deny an application for a registration if persuaded that maintaining such registration would be inconsistent with the public interest. The following factors shall be considered in determining the public interest:

(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).

''These factors are . . . considered in the disjunctive.'' *Robert A. Leslie, M.D.,* 68 FR 15,227, 15,230 (2003). Any one or a combination of factors may be relied upon, and when exercising authority as an impartial adjudicator, the Agency may properly give each factor whatever weight it deems appropriate in determining whether a registrant's registration should be revoked. *Id.; David H. Gillis, M.D.,* 58 FR 37,507, 37,508 (1993); *see also Morall,* 412 F.3d at 173–74 (D.C. Cir. 2005); *Henry J. Schwarz, Jr., M.D.,* 54 FR 16,422, 16,424 (1989).

Moreover, the Agency is ''not required to make findings as to all of the factors,'' *Hoxie,* 419 F.3d at 482; *see also Morall,* 412 F.3d at 173, and is not required to discuss consideration of each factor in equal detail, or even every factor in any detail. *Trawick* v. *DEA,* 861 F.2d 72, 76 (4th Cir. 1988) (holding that the Administrator's obligation to explain the decision rationale may be satisfied even if only minimal consideration is given to the relevant factors, and that remand is required only when it is unclear whether the relevant factors were considered at all). The balancing of the public interest factors ''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 . . . .'' *Jayam Krishna-Iyer, M.D.,* 74 FR 459, 462 (2009).

Factors Two, Three, and Four

The Government contends that granting the Respondent's application for registration would be inconsistent with the public interest based on Factors Two, Three, and Four.[28] ALJ Ex. 1 at 3 ¶ 10. Under Factor Two, the DEA analyzes a registrant's ''experience in dispensing . . . controlled substances.'' 21 U.S.C. 823(f)(2). This analysis focuses on the registrant's acts that are inconsistent with the public interest, rather than on a registrant's neutral or positive acts and experience. *Kansky J. Delisma, M.D.,* 85 FR 23,845, 23,852 (2020) (citing *Randall L. Wolff, M.D.,* 77 FR 5106, 5121 n.25 (2012)). Likewise, under Factor Four, the DEA analyzes an applicant's compliance with Federal and state laws, with the analysis focusing on violations of state and Federal laws and regulations concerning controlled substances. 21 U.S.C. 823(f)(4); *Kansky J. Delisma, M.D.,* 85 FR 23,852 (citing *Volkman* v. *DEA,* 567 F.3d 215, 223–24 (6th Cir. 2009). Under Factor Three, the tribunal may consider a registrant's ''conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.'' 21 U.S.C. 823(f)(3). A guilty plea may be considered under the third factor of the public interest standard. *Mark P. Koch, D.O.,* 79 FR 18,714, 18,734 n.121 (2014).

Regarding Factor Two, the Respondent has approximately seven years of experience[29] with dispensing controlled substances as a veterinarian. Gov't Ex. 2 at 1. In 2015, after pleading guilty to ten counts of Illegal Processing of Drug Documents, the Respondent surrendered his registration. As discussed *supra,* the Respondent admitted that he wrote false prescriptions ''that should not have been written so [he] could acquire these drugs to feed [his] addiction.'' Tr. 102. He also admitted that ''some people did acquire'' some of these false prescriptions. Tr. 102, 112. These prescriptions included hydromorphone/Dilaudid, a Schedule II controlled substance, and oxycodone/APAP, also a Schedule II controlled substance. Gov't Ex. 7 at 14; Stips. 12, 13.

As it relates to Factor Four, the record establishes multiple instances in which the Respondent failed to comply with applicable Federal and State laws. The Government alleges that the Respondent violated 21 U.S.C. 841(a), 842(a), and Ohio Admin. Code 4729:5–30.[30] ALJ Ex. 1 at 3 ¶ 11. The Controlled Substances Act's (''CSA'') general criminal provision is contained in 21 U.S.C. 841(a), and in relevant part states: ''[e]xcept as authorized by this subchapter, it shall be unlawful for any person knowingly or intentionally . . . to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled

[28] The record contains no recommendation from any state licensing board or professional disciplinary authority (Factor One), but, aside from cases establishing a complete lack of state authority, the presence or absence of such a recommendation has not historically been a case-dispositive issue under the Agency's precedent. *Stodola, M.D.,* 74 FR 20,730 n.16; *Krishna-Iyer,* 74 FR 461. Two different forms of recommendations have appeared in Agency decisions: (1) An explicit recommendation regarding the DEA's decision to issue or sanction a COR; and (2) the action of the relevant state authority regarding state licensure under its jurisdiction on the same matter that is the basis for the OSC. *Mark A. Wimbley,* 86 FR 20,713, 20,725 (2021); *see also, Jennifer L. St. Croix,* M.D., 86 FR 19,010, 19,022 (2021) (Agency affords minimal weight to a state board reprimand due to differences in evidence considered by the state in issuing its order.); *Jeanne E. Germeil, M.D.,* 85 FR 73,786, 73,799 (2020) (Agency recognizes that its prior final orders have considered this dichotomy of sources for Factor One consideration). In the instant case, the Board did reinstate the Respondent's veterinary license in a Finding and Order dated November 14, 2019, after he surrendered it in 2015. *See* Resp't Ex. A; ALJ Ex. 20 at 10 (''There is approval from the Ohio Veterinary Medical Board. They granted Dr. Smith an unrestricted veterinary license, knowing his history of drug use and addiction.''). The Respondent currently has an Ohio veterinary license. Therefore, although not determinative in this proceeding, Factor One tends to lean in favor of the Respondent. As the Government's allegations and evidence fit squarely within the parameters of Factors Two, Three, and Four and do not raise ''other conduct which may threaten the public health and safety,'' 21 U.S.C. 823(f)(5), Factor Five militates neither for nor against the sanction sought by the Government in this case.

[29] The Respondent's first and only DEA registration, COR No. FS1126146, was assigned to the Respondent on October 22, 2008, and was surrendered for cause on July 27, 2015. Gov't Ex. 2 at 1.

[30] While OSC Allegation 11 charges the Respondent with violating Ohio Admin. Code 4729:5–30, the Government did not present any evidence on this issue during the hearing and did not address the issue in its post-hearing brief. Therefore, the Government has apparently abandoned this particular portion of OSC Allegation 11. *See George Pursley, M.D.,* 85 FR 80,162, 80,181–82, 80,185 (2020) (finding the Government abandoned allegation by not addressing it within its post-hearing brief). I also take official notice that this particular administrative code section was rescinded, effective March 15, 2021. Ohio Admin. Code 4729:5–30 (LexisNexis 2021).

substance.'' 21 U.S.C. 841(a)(1). ''Congress devised a closed regulatory system making it unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the CSA'' to prevent abuse and diversion of controlled substances. *Gonzales* v. *Raich,* 545 U.S. 1, 13 (2005). DEA regulations require that for a prescription for a controlled substance to be effective it must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice. 21 CFR 1306.04(a).

Under the CSA, a veterinarian falls within the definition of a practitioner, and upon obtaining a registration, a veterinarian has legal authority to prescribe, administer or distribute a controlled substance to an ''ultimate user,'' who is a person who has lawfully obtained a controlled substance ''for an animal owned by him or a member of his household.'' *Daniel Koller, D.V.M.,* 71 FR 66,975, 66,981 (2006) (citing 21 U.S.C. 802(21), (27)).

As discussed *supra,* the Government referenced ALJ Exhibit 1 and read through OSC Allegations 10 and 11. Tr. 101–03. The Respondent indicated that he understood the allegations and that he was guilty of the alleged conduct. Tr. 101–03.

Regarding Factor Three, as discussed at length throughout this Recommended Decision, the Respondent's guilty plea, which may be considered under the third factor of the public interest standard,[31] included ten counts of Illegal Processing of Drug Documents, which related to a scheme by which the Respondent would write fraudulent prescriptions which he would either fill himself, taking the pills for his own use, or would sell to others. Tr. 101–02. The Respondent began doing these ''illegal activities'' to acquire drugs for himself after he was unable to obtain further valid opioid prescriptions from other practitioners. Tr. 53, 83.

Therefore, OSC Allegation 10 is *Sustained* and OSC Allegation 11 is *Sustained in Part* to the extent that the Respondent unlawfully issued prescriptions for controlled substances in violation of 21 U.S.C. 841(a) and 842(a), specifically, by issuing fraudulent prescriptions and then converting those prescriptions to his own use or selling them, and that the Respondent issued prescriptions for controlled substances outside the usual course of professional practice and not for a legitimate medical purpose, (21 CFR 1306.04(a)). OSC Allegation 11 is *Not Sustained in Part* to the extent that the Respondent violated Ohio Admin. Code 4729:5–30.

As it relates to the Respondent's experience in dispensing controlled substances, the Respondent's compliance with applicable State and Federal laws relating to controlled substances, and the Respondent's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances, Factors Two, Three, and Four militate strongly in favor of the Government's position that granting the Respondent a DEA registration is inconsistent with the public interest.

Based upon my review of the allegations by the Government, it is necessary to determine if it has met its *prima facie* burden of proving the requirements for a sanction pursuant to 21 U.S.C. 824(a).

It is clear from the stipulations, the Government's evidence, and the Respondent's position in this matter that there is no controversy between the parties that the Respondent was convicted of the underlying criminal charges. The Government's evidence clearly demonstrates the necessary elements of proof under 21 U.S.C. 824 and I find that the Government has established a *prima facie* case for denial of the Respondent's application for registration.

III. Sanction

A. Acceptance of Responsibility and Rehabilitative Measures

With the Government's *prima facie* burden having been met, an unequivocal acceptance of responsibility stands as a condition precedent for the Respondent to prevail. *Jones Total Health Care Pharmacy, L.L.C. & SND Health Care, L.L.C.,* 81 FR 79,188, 79,201 (2016). This feature of the Agency's interpretation of its statutory mandate on the exercise of its discretionary function under the CSA has been sustained on review. *MacKay* v. *DEA,* 664 F.3d 808, 819–20 (10th Cir. 2011). Accordingly, the Respondent must ''present[ ] sufficient mitigating evidence to assure the Administrator that [he] can be entrusted with the responsibility carried by such a registration.'' *Medicine Shoppe-Jonesborough,* 73 FR 363, 387 (2008) (quoting *Samuel S. Jackson,* 72 FR 23,848, 23,853 (2007)). As past performance is the best predictor of future performance, the DEA has repeatedly held that where an applicant has committed acts inconsistent with the public interest, the applicant must accept responsibility for its actions and demonstrate that it will not engage in future misconduct. *ALRA Labs, Inc.* v. *DEA,* 54 F.3d 450, 452 (7th Cir. 1995).

Although the Respondent ''freely admit[s] [he] did wrong,'' his language was conditional, and as opposed to taking unequivocal responsibility, the record is replete with examples of the Respondent placing the blame of his addiction on others, including a former client and his doctors. Tr. 112. For example, when he discussed using cocaine a few years after graduating from veterinary school, he prefaced this by explaining that a lot his previous friends from high school ''were using illicit drugs including cocaine'' and that he did not ''know much about'' cocaine until he ''had a client one night offer'' him some. Tr. 47. When the Respondent was prescribed opiates in October 2011 and ultimately became addicted to them, he blamed a string of doctors who treated him for various ailments. He testified that he was ''not aware of the force of opiate addiction'' (Tr. 121) and that he ''had no idea what it was like until I found out myself.'' Tr. 84. He explained that he ''trusted the doctors to help'' him, (Tr. 121), and ''maybe [he] should have told the doctors, please don't give me these opiates.'' Tr. 122. With this detached approach, the Respondent appears to have abdicated his responsibility to participate in the proper management of his pain by accounting for his history of drug addiction. Even in his application, which is the subject of these proceedings, he stated that he ''BECAME ADDICTED TO OPIATES AFTER 5 STRAIGHT MONS OF DR. PRESCRIBED OPIATES FOR 2 MAJOR SURGERIES. WHEN THE DRS. FINALLY STOPPED THEM I WROTE OPIATE PRESCRIPTIONS FOR DOGS AND TOOK SOME FOR MY OWN USE.'' Gov't Ex. 2 at 1 (emphasis in original). Essentially, the Respondent, despite his status as a medical professional and onetime DEA registrant, claimed ignorance of the potential for addiction of cocaine and opiates and instead blamed others for his addiction.

When the Respondent was cross-examined by Government counsel regarding the ten prescriptions he wrote for which he was convicted of Illegal Processing of Drug Documents, the Respondent expressed ambivalence stating that a ''few of the prescriptions were actually for dogs that were damaged horribly.'' Tr. 102. During this same line of questioning regarding the ten prescriptions for which he was convicted, when asked if he issued the prescriptions ''without a legitimate medical purpose and outside the usual

[31] *Koch,* 79 FR 18,734 n.121.

course of professional practice,'' the Respondent would only allow that ''[i]n *most* cases that is exactly correct.'' Tr. 103 (emphasis added). The Respondent's answers to these pointed questions about the ten distinct prescriptions for which he was convicted do not exhibit an unequivocal acceptance of responsibility.

He also appears to have regret mostly for what his actions caused to his own life and it is evident the Respondent does not fully comprehend the repercussions of his actions and the effects it had on the community at large. During his testimony, he stated that his ''actions had harmed [himself] and *potentially* others.'' [32] Tr. 83–84; 102 (emphasis added). He also discussed the fact that he went through bankruptcy proceedings and ''lost everything that [he] ever worked for.'' Tr. 108. When questioned regarding the other people who obtained false prescriptions through him, the Respondent was only able to ''mainly recall two people [whose] prescriptions were improper,'' one of which he ''found out later . . . was a very big drug dealer in this area.'' Tr. 112–13. The Respondent's failure to fully grasp how his diversion adversely impacted his community is a failure to accept full responsibility for his actions.

Therefore, I do not find that the Respondent has demonstrated an ''unequivocal acceptance of responsibility'' for his actions. *Jones Total Health Care Pharmacy, L.L.C.,* 81 FR 79,201–02. Due to the fact that this is the Respondent's second episode of addiction and the fact that he used his DEA registration to divert controlled substances for a period spanning several months, I do not have confidence in the Respondent's statement that he ''can guarantee [he] would never, ever, ever abuse that authority again.'' Tr. 81.[33]

B. Egregiousness, Deterrence, and Lack of Candor

While a registrant must accept responsibility and demonstrate that he will not engage in future misconduct in order to establish that his continued registration is consistent with the public interest, DEA has repeatedly held these are not the only factors that are relevant in determining the appropriate sanction. *See, e.g., Joseph Gaudio,* 74 FR 10,083, 10,094 (2009); *Southwood Pharm., Inc.,* 72 FR 36,487, 36,502–04 (2007). The egregiousness and extent of a registrant's misconduct are significant factors in determining the appropriate sanction. *See Jacobo Dreszer,* 76 FR 19,386, 19,387–88 (2011) (explaining that a respondent can ''argue that even though the Government has made out a *prima facie* case, his conduct was not so egregious as to warrant revocation''); *Paul H. Volkman,* 73 FR 30,630, 30,644 n.45 (2008).

Further, in determining whether and to what extent imposing a sanction is appropriate, besides the egregiousness of the offenses established by the Government's evidence, consideration must also be given to the Agency's interest in both specific and general deterrence. *Ruben, M.D.,* 78 FR 38,385. Here, the egregiousness of the offense favors denial of the application. The Respondent was convicted of ten counts of Illegal Processing of Drug Documents. These ten illegal prescriptions were for Schedule II controlled substances: Eight were for hydromorphone/Dilaudid and two were for oxycodone/APAP. Gov't Ex. 7 at 14. The Respondent admitted that he diverted to numerous people, a few of whom he could recall and two of whom he specifically identified at the hearing. Tr. 112–13. The Respondent described one of these individuals as someone that he ''found out later . . . was a very big drug dealer.'' Tr. 112–13.

Considerations of specific and general deterrence in this case militate in favor of denial of the application.[34] As to specific deterrence, this is not the Respondent's first bout with drug addiction, having suffered from cocaine addiction in the 1990's and having served a term of incarceration for possession of that drug.[35] Thus, the Respondent has acknowledged his past history of drug addiction, even going so far as to state he believes his ability to become ''highly addicted'' is ''part of [his] personality.'' Tr. 121. Thus, the interests of specific deterrence, even standing alone, motivate powerfully in favor of the denial of the Respondent's application.

The interests of general deterrence compel a like result. As the regulator in this field, the Agency bears the responsibility to deter similar misconduct on the part of others for the protection of the public at large. *Ruben,* 78 FR 38,385. Where the record demonstrates that the Government has borne its burden and established that the Respondent was convicted of a felony related to controlled substances and abused his prescriptive privileges to actively divert controlled substances to himself and others by writing prescriptions in the names of purported

[32] It is startling that the Respondent couched his diversion of Schedule II controlled substances as ''potentially'' harming others when he also testified that he was diverting to a ''very big drug dealer,'' thereby implicitly acknowledging the widespread effect of his diversion. Tr. 112–13. Additionally, when testifying that, were he to obtain a new DEA registration, he would not divert drugs from his practice to his son, he also testified that he was ''almost thankful'' his son is ''in jail right now so I don't read in the morning paper that he's dead.'' Tr. 118. Thus, while the Respondent is intimately familiar with his own struggles with drug addiction and that of his son, the fact that he couches his own diversion as having ''potentially'' harmed others leads this tribunal to conclude that he has not yet come to terms with his own role in this country's opioid crisis.

[33] Where a registrant has not accepted responsibility, it is not necessary to consider evidence of the registrant's remedial measures. *Ajay S. Ahuja, M.D.,* 84 FR 5479, 5498 n.33 (2019) (citing *Jones Total Health Care Pharmacy, L.L.C. & SND Health Care, L.L.C.,* 81 FR 79,202–03 (2016)). [In this case, even if Respondent had accepted responsibility, his remedial measures were inadequate.] Although the Respondent stated he believes he is fully rehabilitated, the tribunal is not entirely convinced the Respondent is taking the necessary measures to maintain his sobriety long term. He attended a few programs while incarcerated and on an outpatient basis after his release from jail. Although he stated that he attends NA meetings, by his own admission, he only does so when he ''feel[s] maybe a little stressed.'' Tr. 66. Furthermore, although he has ''reviewed the standards for record keeping,'' ''purchased keyed locks, key lockbox,'' and ''will acquire controlled substance logbooks and keep meticulous records,'' he has not taken any classes that relate to prescribing controlled substances. Tr. 85, 94. Finally, the Respondent does not appear to have seriously considered the Board's suggestions, when he was relicensed, that he attend counseling and practice under the supervision of another veterinarian. *See supra* at 9 n.19. Although the Respondent asserts that he ''learned through education about addiction that it is a lifelong condition,'' he does not appear to have in place an adequate support system (such as participating in the Ohio Physicians' Health Plan counseling) or an oversight structure (such as operating his practice under direct supervision by a licensed veterinarian) such that the tribunal has confidence he can be entrusted with a registration. Tr. 80.

[34] I note that the Respondent did not include his 1997 conviction related to cocaine possession or his two-year veterinary license suspension in the late 1990's in his liability question responses. Gov't Ex. 2 at 1–2. However, because the Government did not make any allegations regarding a material falsification of the Respondent's application and also did not specifically rely on these events for denial of the instant application, I have not considered the previous conviction and license discipline except as historical information to put the Respondent's 2015 conviction and loss of his veterinary license into the proper context given his past experience. Presumably, the Agency was aware of these incidents when it granted the Respondent's previous application for registration in 2008—which the Respondent surrendered for cause in 2015. Gov't Ex. 2 at 1.

[35] In the Respondent's mind, his cocaine addiction in the 1990's and his opiate addiction years later are unconnected and he implies he could not have foreseen his later addiction to opiates because he was ''never addicted to opiates'' and ''didn't go looking for a new addiction.'' Tr. 121. The Respondent also took issue with the tribunal's characterization of his opiate addiction as ''a relapse.'' Tr. 122. The Respondent made similar statements to the judge at his criminal sentencing in 2015 when the judge stated he was concerned because the Respondent had a drug addiction earlier in life and the Respondent replied ''I never had a (sic) opiate problem.'' Gov't Ex. 8 at 16–17. The judge in the criminal proceeding did not appear to accept this rationale, stating ''[y]ou had an addictive problem'' and ''[y]ou know how addictive opiates are. And you're an addict. Were and are.'' Gov't Ex. 8 at 17.

animal patients, the unmistakable message to the regulated community would be that such conduct can be overlooked after a period of non-registration. Although the Respondent surrendered for cause his previous DEA registration in 2015,[36] he was not eligible to reapply for a new registration until January 2020, when he reacquired his state veterinary license. The following month, he submitted his application for a new DEA registration.[37] At this time, the Respondent has been without a DEA registration for nearly six years. I find that this is not an insignificant period of time. However, based on the egregiousness of the Respondent's behavior discussed above, I find that the interests of general deterrence support the denial sought by the Government.

Another factor that weighs significantly in favor of the denial sanction sought by the Government is lack of candor. In making the public interest determination, ''this Agency places great weight on [a respondent's] candor, both during an investigation and in [a] subsequent proceeding.'' *Fred Samimi, M.D.,* 79 FR 18,698, 18,713 (2014) (quoting *Robert F. Hunt, D.O.,* 75 FR 49,995, 50,004 (2010)).

Although the Agency did not make any allegations regarding a lack of candor by the Respondent during the investigation, in making my credibility determination, as discussed above, I found discrepancies between the Respondent's prior testimony to the court at his sentencing hearing and statements made by the Respondent in this proceeding. During the instant proceeding, the Respondent downplayed the scope and extent of his drug use, contradicting statements he made at his sentencing hearing that he was doing crack around the same time he became addicted to opiates and disavowing his previously acknowledged ''almost daily'' use of marijuana by stating he was not using marijuana because he ''was after something for [his] pain, not marijuana.'' Tr. 126. Other statements at the hearing that his son was not the recipient of any of his diverted drugs again conflict with testimony he gave at his sentencing hearing that his son received drugs that he diverted from his false prescribing. Finally, I find that the Respondent's initial testimony that he was not participating in the Ohio Physicians' Health Plan counseling, due to its cost, exhibits a lack of candor where the basis for his statement regarding cost was from when he previously considered the program in the 1990's relating to his cocaine addiction. I find that the Respondent's statement that the program was too expensive for him to participate in demonstrated a lack of candor, inasmuch as he later admitted he had no idea how the program is run today and that he had not explored options regarding financial assistance or other accommodations regarding cost. Hence, the Respondent's lack of candor undermines the confidence that the Agency can have in the Respondent's ability to be a responsible DEA registrant.

For the above reasons, I find that the Respondent's misconduct is egregious and that deterrence considerations and the Respondent's lack of candor weigh in favor of revocation.

Considering the entire record before me, the conduct of the hearing, and observation of the testimony of the witnesses presented, I find that the Government has met its burden of proof and has established a *prima facie* case for denial of the Respondent's application for registration. Furthermore, I find that the Respondent has failed to meet his burden to overcome the Government's case. While the Respondent is to be commended for rebuilding his veterinary practice and while the testimony of his three character witnesses leads me to conclude that the Respondent is a caring and capable veterinarian, *[E] I cannot overlook the egregiousness of his offenses, his failure to unequivocally accept responsibility, and the need for specific and general deterrence in this case, each of which, even standing alone, provides a compelling reason for denial of the application.

Therefore, I recommend that the Respondent's application for a DEA registration, Control No. W20010614C, be *Denied* and any pending applications for other DEA registrations likewise be *Denied*.

Dated: June 30, 2021

Paul E. Soeffing

PAUL E. SOEFFING
U.S. Administrative Law Judge

Respondent's Exceptions

On July 26, 2021, Respondent filed his Exceptions to the Recommended Decision. DEA regulations require that Exceptions ''include a statement of supporting reasons for such exceptions, together with evidence of record (including specific and complete citations of the pages of the transcript and exhibits) and citations of the authorities relied upon.'' 21 CFR 1316.66. For the most part, Respondent's Exceptions not only fail to comply with this regulatory requirement, but also lack evidentiary support in the Administrative Record. Additionally, some of Respondent's Exceptions repeat arguments that were already raised throughout the proceedings and were adequately addressed in the adopted Recommended Decision. Therefore, I reject Respondent's Exceptions and adopt the Recommended Decision of the ALJ as amended above.

Exception 1

In his first Exception, Respondent argues that the ALJ failed to properly consider Factor One in the public interest analysis under 21 U.S.C. 823(f)(1). Respondent's Exceptions, at 1. Respondent argues that ''by granting [Respondent] a license to practice medicine and surgery in the State of Ohio after he surrendered it due to the criminal matter, the Ohio Veterinary Medical Licensing Board has given their stamp of approval for [Respondent] to

[36] Gov't Ex. 2 at 1.

[37] The Respondent's COR application was submitted on February 3, 2020. Gov't Ex. 2 at 1.

[E] *See Raymond A. Carlson,* 53 FR 7425 (1988) (finding that none of the character ''witnesses was in a position to make an adequate assessment of [r]espondent's ability to properly handle controlled substances.'').

use [sic] controlled substances in Ohio'' and that ''the Tribunal should have taken this into consideration.'' *Id.*

In determining the public interest under Factor One, the ''recommendation of the appropriate State licensing board or professional disciplinary authority . . . shall be considered.'' 21 U.S.C. 823(f)(1). ''Two forms of recommendations appear in Agency decisions: (1) A recommendation to DEA directly from a state licensing board or professional disciplinary authority (hereinafter, appropriate state entity), which explicitly addresses the granting or retention of a DEA COR; and (2) the appropriate state entity's action regarding the licensure under its jurisdiction on the same matter that is the basis for the DEA OSC.'' *John O. Dimowo, M.D.,* 85 FR 15,800, 15,809 (2020); see also *Vincent J. Scolaro, D.O.,* 67 FR 42,060, 42,065 (2002) (''While the State Board did not affirmatively state that the Respondent could apply for a DEA registration, [the ALJ] found that the State Board by implication acquiesced to the Respondent's application because the State Board has given state authority to the Respondent to prescribe controlled substances.''). It is the Administrator who makes a determination of whether granting a registration is in the public interest as defined by the CSA, and the Administrator's purview is focused on entrusting Respondent with a controlled substances registration. *See Ajay S. Ahuja, M.D.,* 84 FR 5479, 5490 (2019).

In Respondent's case, contrary to Respondent's Exception, the ALJ did consider in his Factor One analysis that the Board was aware of Respondent's history of drug use and addiction and nonetheless reinstated Respondent's Ohio veterinary license without restriction. RD, at 19 n.31. As such, the ALJ found that Factor One leaned in favor of Respondent. *Id.*

Ultimately, the ALJ found, and I agree, that Factors Two, Three, and Four militate strongly in favor of the Government's position that granting the Respondent a DEA registration is inconsistent with the public interest. Accordingly, I find Respondent's assertion that the ALJ did not take the unrestricted reinstatement of Respondent's veterinary license into consideration in the Factor One analysis to lack merit.

Exception 2

In his second Exception, Respondent argues that the ALJ improperly interpreted Respondent's nervous demeanor as a lack of remorse or a ''conditional remorse,'' citing the ALJ's analysis of Respondent's acceptance of responsibility. Respondent's Exceptions, at 1–2; *see* RD, at 23–25. However, in his analysis regarding Respondent's acceptance of responsibility, the ALJ made no reference whatsoever to Respondent's demeanor or nervousness. RD, at 23–25. Instead, the ALJ found that Respondent had not demonstrated an unequivocal acceptance of responsibility because Respondent's testimony itself demonstrated that he was ambivalent regarding the extent of his wrongdoing, consistently placed the blame of his addiction on others, and was primarily regretful for how his misconduct had affected his own life rather than the community at large. *Id.* Accordingly, I find Respondent's argument that the ALJ improperly interpreted Respondent's demeanor in the analysis of Respondent's acceptance of responsibility to lack merit. I credit Respondent's honest acknowledgment of his nerves during the proceeding. Tr. 81.

In spite of Respondent's commendable sobriety thus far, I have reason to doubt his claim that he would always be a compliant registrant. *See George R. Smith, M.D.,* 78 FR 44,972, 44,980 (2013). Particularly, I remain concerned that if he relapsed, which the record has demonstrated previously occurred, while entrusted with a controlled substances registration, he could harm himself and others too quickly for detection by this Agency or his monitoring. *See Robert Wayne Locklear, M.D.,* 86 FR 33,745. Ensuring that a registrant is trustworthy to comply with all relevant aspects of the CSA without constant oversight is crucial to the Agency's ability to complete its mission of preventing diversion within such a large regulated population. *Jeffrey Stein, M.D.,* 84 FR 46,974.

Exception 3

In his third Exception, Respondent argues that ''[t]he Tribunal gave too much weight to the DI [K.P.]'s opinions about [Respondent's] work on his addiction.'' Respondent's Exceptions, at 2. Respondent also argues that ''[t]here was no reason to include this as part of the Government's case'' and that ''there was no reason for the Tribunal to challenge [Respondent] about the Ohio Physicians' Health Plan.'' *Id.* However, where 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 46,968, 46,972 (2019). As such, because the Respondent presented evidence of his remedial measures in order to meet this burden, it was entirely relevant to the adjudication of this matter and appropriate for the Government to present its own evidence pertaining to Respondent's remedial measures, as well as for the ALJ to question Respondent regarding these remedial measures.

Moreover, in his third Exception, Respondent again argues the significance of the Board reinstating his license without restriction. Respondent's Exceptions, at 2. As already discussed *supra,* the ALJ adequately addressed this point in his public interest Factor One analysis. Accordingly, I find the claims made in Respondent's third Exception to lack merit.

Exception 4

In his fourth Exception, Respondent argues that rather than an unrestricted DEA registration, he should instead be granted a limited DEA registration ''to utilize a limited number of [S]chedule III or lower substances.'' Respondent's Exceptions, at 2. However, Respondent does not provide adequate substantiation as to why I should accept this proposal, nor is there sufficient evidence in the Administrative Record to support it. Moreover, Respondent has not adequately demonstrated that he can be entrusted with a controlled substance registration at any schedule. *See Larry C. Daniels, M.D.,* 86 FR 61,630, 61,664 n.30 (2021). Accordingly, I find Respondent's argument that he should be granted a limited DEA registration to lack merit.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a) and 21 U.S.C. 823(f), I hereby deny the pending application for a Certificate of Registration, Control Number W20010614C, submitted by Michael E. Smith, D.V.M., as well as any other pending application of Michael E. Smith, D.V.M., for additional registration in Ohio. This Order is effective March 2, 2022.

Anne Milgram,

Administrator.

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