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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 12-15]

Belinda R. Mori, N.P.
Decision And Order

On November 17, 2011, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Belinda R. Mori, N.P. (Respondent), of Santa Fe, New Mexico. The Show Cause Order proposed the denial of Respondent's pending application for a DEA Certificate of Registration, on the ground that her "registration would be inconsistent with the public interest." ALJ Ex. 1, at 1.

The Show Cause Order specifically alleged that on March 18, 2011, Respondent applied for a Certificate of Registration as a mid-level practitioner, seeking authority to dispense controlled substances in schedules II through V. *Id*. The Order further alleged that Respondent had previously held a registration, which authorized her to dispense controlled substances in schedules II through V as a mid-level practitioner but that "this registration expired on January 31, 2011." *Id*.

Next, the Show Cause Order alleged that "[b]etween August 29, 2009 and March 15, 2011, [Respondent] issued approximately thirty-three purported prescriptions for alprazolam (a [s]chedule IV controlled substance) to [her] daughter without conducting a medical examination and without creating a patient record," and that these prescriptions "were issued outside the usual course of professional practice, in violation of Federal and . . . state law." *Id*. (citing 21 CFR 1306.04(a); N.M Admin. Code tit. 16, §§ 12.2.7(V) and 12.2.13(N)(5)(g)). The Order further

alleged that "[o]n or about March 15, 2011, [Respondent] issued a purported prescription for alprazolam . . . to [her] daughter . . . while [she was] without a valid DEA Certificate of Registration, in violation of Federal and . . . state law." *Id*. at 2 (citing 21 U.S.C. § 841(a)(1); N.M. Admin. Code tit. 16, § 12.2.13(N)(5)(a)).

On December 5, 2011, Respondent, through her counsel, requested a hearing on the allegations. ALJ Ex. 2. The matter was placed on the docket of the Office of Administrative Law Judges (ALJ), and assigned to an ALJ who proceeded to conduct pre-hearing procedures.

On December 20, 2011, the Government filed its pre-hearing statement. Therein, the Government provided notice that it intended to elicit the testimony of an Agency Diversion Investigator (DI) that "on or about April 14, 2011, she spoke with Respondent about her application for a DEA Certificate of Registration" and "asked Respondent whether [she] used her previous DEA Certificate of Registration after it expired, and Respondent stated that she had not." Gov't Prehr'g Statement, at 3. The Government also provided notice that it intended to show that "[o]n this same day, [the DI] ran a prescription monitoring report with the New Mexico Board of Pharmacy for the period of February 1, 2011, through April 14, 2011, and that the report showed that Respondent issued one prescription for controlled substances (alprazolam) after her previous DEA Certificate of Registration expired," and that the prescription was for her daughter and issued "on or about March 15, 2011." *Id*. Finally, the Government provided notice that the DI would "testify that on or about May 3, 2011, she interviewed Respondent about the alprazolam prescription that was issued after her previous DEA Certificate of Registration expired," and that "Respondent informed [the DI] that she issued the alprazolam prescription to her daughter because [she] did not have health insurance and therefore could not see her treating physician." *Id*.

On May 1, 2012, the ALJ conducted a hearing in Albuquerque, New Mexico. At the hearing, the Government elicited the testimony of the DI and introduced various documents into the record; Respondent testified on her own behalf and also introduced various documents into the record. Following the hearing, both parties submitted briefs containing their proposed findings of fact, conclusions of law, and argument.

On July 30, 2012, the ALJ issued her Recommended Decision (R.D.). Therein, the ALJ found that the Government had proved that Respondent violated federal law because she issued thirty-three prescriptions to her daughter and "did not establish a good faith practitioner-patient relationship with [her] prior to issuing controlled substance prescriptions to her." R.D. at 16. Moreover, the ALJ found that Respondent "violated federal law by issuing a prescription after the expiration of her DEA Certificate of Registration." *Id*. (citing 21 U.S.C. § 843(a)(2)). The ALJ thus concluded that "in light of Respondent's serious and undisputed violations of the CSA and New Mexico law, . . . the Government has presented a *prima facie* case that supports the denial of Respondent's application." *Id*. at 16-17.

The ALJ then addressed whether Respondent had rebutted the Government's *prima facie* case. R.D. at 17. The ALJ found that "Respondent has both taken responsibility for her actions and shown remorse for her unlawful conduct," noting that "she demonstrated visible remorse for her misconduct" and "testified credibly and candidly about the circumstances surrounding the misconduct." *Id*. She also explained that Respondent's testimony regarding her "health problems," the "death of her son in a motorcycle accident, and her daughter's subsequent struggle with mental illness after losing her health insurance" were "appropriate mitigating factors" which should be considered. *Id*. at 17-18.

The ALJ further found that although Respondent had made a false statement to the DI in an April 2011 phone call when she denied writing any prescriptions after her registration had expired, the ALJ rejected the Government's contention that she did so deliberately. *Id*. at 18. Instead, the ALJ found "that it is quite plausible that [Respondent] unintentionally made the false statement," reasoning that "the Government's argument regarding [her] lack of candor is undercut by the extensive and voluntary disclosures [she] made to [the DI] during that April 2011 telephone conversation, namely that she had not prepared or maintained any treatment records regarding these prescriptions." *Id*. The ALJ thus reasoned that "[i]n light of the totality of [her] interaction with [the DI] and her credible testimony at the hearing, . . . her statement, while admittedly false, does not negatively outweigh her overall candor with the Agency." *Id*.

Next, the ALJ found "that Respondent has demonstrated specific remedial measures which she has undertaken to prevent the reoccurrence of her unlawful conduct," including her completion of "a continuing medical education class on prescribing for family members" and that she "has pledged to cease writing prescriptions for her daughter or any other family member." *Id*. at 19. The ALJ further noted that Respondent had discussed her daughter's treatment with her psychiatrist and confirmed that all of her daughter's prescriptions would henceforth be issued by him. *Id*.

The ALJ thus concluded that the Government's proposed sanction of denial would be "too severe." *Id*. While finding that Respondent's "misconduct was . . . serious," the ALJ recommended that Respondent be granted a restricted registration, concluding that she "has now demonstrated that she understands the responsibilities and requirements of a DEA registrant." *Id*. at 19-20.

Having considered the record in its entirety, I adopt the ALJ's findings of fact and conclusions of law except as discussed below. While I reject the ALJ's finding that Respondent violated the CSA's prescription requirement when she prescribed to her daughter as unsupported by substantial evidence, I adopt her finding that Respondent violated DEA regulations when she prescribed a controlled substance after the expiration of her registration. I further reject the ALJ's finding that Respondent unintentionally made a false statement to the DI when she denied having written any controlled substance prescriptions after the expiration of her DEA registration. Because Respondent has failed to accept responsibility for her misconduct, I reject the ALJ's recommended sanction and will order that Respondent's application be denied.

FINDINGS OF FACT

Respondent is a Certified Nurse Practitioner licensed by the Board of Nursing for the State of New Mexico. GX 3, at 3. On June 23, 2010, the Executive Director of the Board of Nursing (Board) notified Respondent that she had reviewed evidence suggesting that Respondent had practiced on an expired license (and thus practiced without a license). GX 4, at 1. While the Executive Director noted that "there is sufficient evidence for the Board to consider disciplinary actions against [Respondent's] nursing license," the Board offered Respondent a "voluntary reprimand and fine." *Id*., *see also* GX 4, at 3. On July 2, 2010, Respondent accepted the reprimand, *id*. at 2, and in December 2010, the Board issued her a Voluntary Letter of Reprimand. GX 5.

Respondent also previously held a DEA Certificate of Registration, which authorized her to dispense controlled substances in schedules II through V, as a mid-level practitioner, at the registered address of 3715 Southern Blvd., Rio Rancho, New Mexico. GX 2, at 1. On January 31, 2011, the registration expired. *Id*. Thereafter, "no controlled substances could be obtained,

stored, administered, prescribed, or dispensed under" the registration. *Id*. Respondent did not submit a renewal application until March 18, 2011. *Id*.

At some point not clear on the record, but after Respondent submitted her renewal application, Respondent called the DEA Office in Albuquerque regarding the status of her application. Tr. 16. The DI who was assigned the weekly duty of taking phone calls subsequently returned her call and explained that her application had yet to be assigned to an investigator, but that it would be and that an investigator would contact her for further information. *Id*.

The DI testified that before she returned Respondent's phone call, she had determined that Respondent had previously held a DEA registration.[1] *Id*. at 17. The DI also testified that before she returned Respondent's call, she had queried the Board of Nursing's website and noted that Respondent had been reprimanded by the Board. *Id*.

During the phone call, the DI verified with Respondent that she had previously held a registration. *Id*. The DI also told Respondent that as part of the pre-registration investigation, she would be contacting the Board for more information regarding the basis of the reprimand. *Id*. She then discussed with Respondent the reason for having to submit a new application. Respondent told the DI that her registration had expired because she had failed to renew it. *Id.* at 22.

The DI asked Respondent if she had written any prescriptions past the expiration date*;* Respondent "stated she had not." *Id.* The DI then told Respondent that she "would be running a prescription monitoring program report [PMP]" and "explained to [her] what the PMP was and

[1] According to the DI, at the time of her first phone call with Respondent, the matter had yet to be assigned to an Investigator. However, the matter was eventually assigned to the DI. The record is less than transparent regarding whether at the time of the DI's initial phone call with Respondent she had queried the State Board's website as well as determined that Respondent had previously been registered or whether she made these inquiries prior to a second phone conversation.

what it would show me." *Id*. The DI told Respondent that the PMP "would show the prescriptions that were filled pursuant to her DEA number for a certain time period," *id*, and "explained that [she] would be querying that to verify the information she had provided of not writing any prescriptions with an expired DEA number." *Id.* at 23.

Subsequently, the DI ran the PMP from August 1, 2009 through August 5, 2011. *Id*. at 23; GX 6. The DI testified that "the document shows… that Ms. Mori had self-prescribed a controlled substance in August of 2009, and also that there was a patient by the name of Mia Mori who had a prescription written and filled on March 15 of 2011." *Id.*; GX 6, at 1. The DI testified that the report listed additional prescriptions written by Respondent for Mia Mori, which were for two schedule IV controlled substances, alprazolam and zolpidem, and which were written between August 29, 2009 through March 15, 2011. *Id.* at 24-25; GX 6, at 1-3. The PMP report also shows that on August 12, 2009, Respondent self-prescribed thirty tablets of zaleplon 10 mg, a schedule IV controlled substance. GX 6, at 1; 21 CFR 1308.14(c)(51).

The DI then testified that Respondent's DEA registration had expired on January 31, 2011. *Id.* at 25. She also reiterated that Respondent had not told her about the March prescription when she spoke to her in April 2011. *Id.*

Next, the DI testified regarding the process for renewing a registration and the procedures used by the Agency to notify a registrant regarding an impending expiration. More specifically, the DI explained that a DEA registration does not renew automatically, and that a "renewal application . . . has to be submitted by the registrant, asking for a renewal of the number." *Id.* The DI further explained that the expiration date is printed on the face of the registration certificate, and that "the [Agency's] registration unit … automatically generates two notices before the expiration, advising [the registrant that] you're coming close to the expiration date."

Id. at 25-26. According to the DI, if a registration "actually does expire before it is renewed… a delinquency notice is mailed out to the registered address of the registrant." *Id*. at 26.

The DI testified that after she discovered the March 15, 2011 prescription, she spoke again with Respondent by telephone. The DI explained to Respondent that she had run the PMP report and that there were three prescriptions filled after the expiration date which were written prior to the expiration date, and one prescription that was written after the expiration date that was also filled. *Id*. at 26. Regarding these prescriptions, the DI testified that Respondent told her "that Mia Mori was her daughter and that she had written the prescription after her daughter had lost her health insurance, and that she had forgotten to advise me of that." *Id*. at 26-27. Respondent told the DI "that her daughter had seen a psychiatrist" and that she was "treating her daughter's anxiety and that was why she had prescribed the alprazolam to her." *Id*. at 27.

The DI then asked Respondent to meet her and bring her daughter's patient chart for review. *Id*. Respondent told the DI that she had not created a patient chart for her daughter, and that she did not maintain any records regarding periodic evaluations of her daughter to determine whether her treatment was proceeding as it should. *Id.* at 27-28. Moreover, when asked by the Government's counsel if she knew if Respondent "was conducting a medical examination of any sort," the DI answered that she did "not know." *Id*. at 28.

The DI ran another PMP report using Mia Mori's name; the report covered the period from January 2006 through December 8, 2011. GX 7. The report shows that Respondent first began prescribing to her daughter in April 2007; the first prescription was for hydrocodone with acetaminophen, a schedule III controlled substance. Tr. 29; GX 7, at 2.

The report also shows that Respondent wrote multiple prescriptions for her daughter for both zolpidem and alprazolam. These include prescriptions for 90 tablets of zolpidem 10 mg on

July 28 and October 17, 2007, as well a prescription for 30 tablets of zolpidem 10 mg on August 29, 2009, which was refilled on September 26, 2009. GX 7, at 2.

As for the alprazolam prescriptions, on October 23, 2009, Respondent wrote a prescription for 30 tablets of alprazolam 0.5 mg; this prescription was refilled on November 8, 18, and 29. *Id*. On December 9, 2009, Respondent wrote a prescription for her daughter for 60 tablets of alprazolam 0.5 mg; this prescription was refilled on December 28 and January 14, 2010. *Id*. This was followed by a February 3, 2010 prescription for 30 tablets of alprazolam 0.5 mg, which was refilled on February 12, 22, and March 3, 2010; as well as another prescription for 30 tablets of alprazolam 0.5 mg on March 14, 2010 (which was not filled until March 25, 2010). *Id*.

On April 15, 2010, Respondent wrote another prescription for 60 tablets of alprazolam 0.5 mg, which was refilled on May 20, June 15, and July 2, 2010. *Id*. This was followed by prescriptions for 30 tablets of alprazolam 0.5 mg on July 28, 2010 (which was refilled on August 9, 19, and 29), on September 8, 2010 (which was refilled on September 20, October 4, 15 and 27), and on January 14, 2011 (which was refilled four times through March 6, 2011). Respondent wrote a final prescription for 30 alprazolam 0.5 mg for her daughter on March 15, 2011, which was 43 days after her DEA registration had expired. *Id*.

The DI testified that the 2007 prescriptions were noteworthy because Respondent's daughter turned twenty-two in 2009, and the DI's understanding was that she had lost her health insurance upon reaching this age. Tr. 29. The DI stated that "based on the information that [Respondent] provided, her daughter would have had health insurance" in 2007. *Id.* at 29-30.

The DI continued her investigation by contacting the pharmacies listed as having filled the controlled substances and asking them to pull the original prescriptions, the signature log,

and the method of payment for those prescriptions. *Id*. at 31. Those documents indicated that each of those prescriptions was called in by Respondent for her daughter, and that Mia Mori had picked up the prescriptions. *Id.*

The DI testified that Respondent issued her daughter a total of thirty-three controlled substance prescriptions. *Id*. Of these, eleven were original prescriptions; the other twenty-two were refills. *Id*.

The DI testified that she provided a copy of her report to the New Mexico Board of Nursing, and that after the report was forwarded to the Board, it initiated a complaint and subsequently took action against Respondent's nursing license. *Id.* at 32. This resulted in a Settlement Agreement between the Board and Respondent in December 2011. *Id.* at 33-34; RX 4, at 2. Under the Settlement Agreement, Respondent received a letter of reprimand and was required to complete a continuing education course in patient/physician/family caregiver relationships. RX 4, at 2. Respondent completed the course in December 2011. *Id*. at 5.

Respondent testified that in 2004, after being released from active duty in the army, she had suffered a heart attack, and that about a year and a half later, her son was killed in a motorcycle accident. Tr. 53. Shortly thereafter, her daughter complained that "she was going crazy" and "needed to see a psychiatrist." *Id*. at 53-54. Respondent stated that she took her daughter to a psychiatrist, who diagnosed her with "severe anxiety disorder with an OCD component." *Id.* at 54. Subsequently, the psychiatrist recommended that Respondent's daughter see a specialist in OCD, and so she began treating with a Dr. Summers. *Id*.

When asked by her counsel as to why she had written her daughter prescriptions for Abilify (a non-controlled prescription drug) and alprazolam, Respondent testified that her

daughter's OCD causes thoughts of self-harm, and she wanted to ensure that her daughter was mentally stable. *Id.* Respondent testified that she "could not lose another child." *Id*.

Respondent then testified regarding several other prescriptions she had issued for her daughter. Specifically, Respondent testified that she prescribed Ambien (zolpidem) for her daughter on two occasions, including on August 29, 2009 (as well as on another date which she did not recall) because "she was unable to sleep at all." *Id*. at 55. *See also* GX 7, at 2 (zolpidem prescriptions issued on 7/28/07 and 10/16/07). Respondent testified that Ambien had been prescribed for her daughter by her treating physicians, but did not state when or by whom specifically.[2] *Id.* at 56. Respondent testified that she also wrote her daughter a prescription for Percodan on April 21, 2007, when she had inflamed tonsils. *Id.* at 58.

Respondent stated that one of the reasons she wrote the prescriptions for her daughter was because she "did not have insurance and the cost of the drugs," and "to maintain her sanity, so that she would not commit suicide." *Id.* However, when the Government asked Respondent if her daughter had been diagnosed as suicidal, she stated: "I have not read her records." *Id*. at 61. Moreover, Respondent's evidence shows that her daughter resumed treatment with her psychiatrist on January 13, 2011. RX 3, at 11. Yet the next day, Respondent issued to her daughter another prescription for thirty alprazolam with four refills. GX 8, at 40. Moreover, on March 15, 2011, Respondent issued another prescription for thirty alprazolam, which also authorized multiple refills. GX 8, at 45. Respondent offered no explanation as to why she issued these prescriptions when her daughter had resumed seeing her psychiatrist.

Respondent was also asked whether she looked into care alternatives when she knew her daughter would not be able to continue seeing her doctor. *Id*. at 62. Respondent first stated she

[2] Other evidence corroborates Respondent's testimony that Ambien had been prescribed to her daughter on multiple occasions by a Dr. D.R., beginning in May 2006. GX 7, at 2.

did not, but then changed her response to "yes." *Id.* Respondent then testified that there were neither free therapy services nor group therapy sessions available for her daughter, and that because she was stable, she decided to just continue her on the medication. *Id*. Respondent then admitted that when she informed the doctor that her daughter no longer had health insurance, he did not immediately cease all ties with her. *Id.* at 63. When asked whether she had developed a treatment plan with her daughter's psychiatrist for the period when her daughter did not have health insurance, Respondent replied that the psychiatrist had already created a treatment plan. *Id*.

Regarding the prescriptions she issued her daughter, Respondent also introduced several exhibits. The first of these is an affidavit by her daughter's psychiatrist, who stated that he had treated her daughter from April 2006 through 2011, and that he had diagnosed her with "an anxiety disorder and secondary depression due to obsessive compulsive neurosis." RX 1. The psychiatrist stated that he had prescribed Abilify and alprazolam to Respondent's daughter. *Id*. The psychiatrist further stated that it was his understanding that "due to insurance concerns," Respondent had "actually filled out prescriptions for her daughter from the time frame of August 2010 through March 2011[3]," and that "[s]uch prescriptions would have been in conformance with my desired treatment including drugs ordered, strength indicated, and number of pills to be given." *Id*. Finally, the psychiatrist expressed his belief that the "prescriptions were written in conformance with my treatment and do not indicate any prescription regime that was not recommended by me." *Id*. Yet, the psychiatrist did not address why Respondent had continued to prescribe alprazolam after her daughter had resumed treatment with him.

[3] In a letter written by the psychiatrist to Respondent's counsel approximately one week before he executed his affidavit, the psychiatrist stated that "[a]pparently, in 2009[,] she [Respondent's daughter] was unable to afford health insurance. She was lost to follow-up until January 2011." RX 2, at 1. In resolving the apparent conflict between the dates during which Respondent's daughter lacked insurance, I give no weight to the psychiatrist's letter (which is unsworn) and rely solely on the affidavit.

Regarding the prescribing class the Board required her to take, Respondent testified that "it's common practice that is not well established to not prescribe for your family members, and that this is a real issue." *Id*. at 59. She further testified that she understood that she can never again prescribe to a family member. *Id*. And when asked by the ALJ if she had issued any prescriptions to her daughter since taking the class on prescribing to family members, Respondent answered "absolutely not." *Id.* at 66.

Respondent also acknowledged that in December 2010, the State Board issued her a reprimand for not renewing her state license in a timely manner. *Id*. at 64-65. When the Government asked if it was correct that she then let her DEA registration lapse in January 2011, Respondent replied:

> Well, I didn't let it. I just was unaware of the expiration, and I didn't know this until I started refilling my New Mexico pharmacy license, where they require you to put in the expiration of your DEA. At that point, I called the DEA in El Paso, to ask them when that was, and that's how I found out. . . .

Id. at 64. Respondent admitted that notwithstanding having been reprimanded for not renewing her state license in a timely manner, she did not then check her DEA registration to determine if it was going to expire soon. *Id.* at 65. Indeed, she described herself as being "very much" scattered during the previous five years with regard to filing the renewals for her various licenses on time. *Id*. at 53. However, in response to a series of questions regarding whether she now understood the importance of keeping her licenses current, Respondent testified that she "understood the gravity" of the situation, *id*., and on cross-examination, she testified that she had recently renewed her pharmacy license and had "sent it in early." *Id*. at 66.

DISCUSSION

Section 303(f) of the Controlled Substances Act (CSA) provides that the Attorney General "may deny an application for [a practitioner's] registration if he determines that the

issuance of such a registration is inconsistent with the public interest." 21 U.S.C. § 823(f). In making the public interest determination, the CSA directs that the following factors be considered:

> (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.

"[T]hese factors are . . . considered in the disjunctive." *Robert A. Leslie, M.D.*, 68 FR 15227, 15230 (2003). It is well settled that I "may rely on any one or a combination of factors, and may give each factor the weight [I] deem[] appropriate in determining whether a registration should be revoked." *Id.*; *see also MacKay v. DEA*, 664 F.3d 808, 816 (10th Cir. 2011); *Volkman v. DEA*, 567 F.3d 215, 222 (6th Cir. 2009); *Hoxie v. DEA*, 419 F.3d 477, 482 (6th Cir. 2005). Moreover, while I am required to consider each of the factors, I "need not make explicit findings as to each one." *MacKay*, 664 F.3d at 816 (quoting *Volkman*, 567 F.3d at 222); *see also Hoxie*, 419 F.3d at 482.[4]

The Government has "the burden of proving that the requirements for . . . registration . . . are not satisfied." 21 CFR 1301.44(d). However, where the Government has met its *prima facie* burden of showing that issuing a new registration to the applicant would be inconsistent with the public interest, an applicant must then "present sufficient mitigating evidence" to show why she

[4] In short, this 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. *Jayam Krishna-Iyer*, 74 FR 459, 462 (2009). Accordingly, as the Tenth Circuit has recognized, findings under a single factor can support the revocation of a registration. *MacKay*, 664 F.3d at 821. Likewise, findings under a single factor can support the denial of an application.

can be entrusted with a new registration. *Medicine Shoppe-Jonesborough*, 73 FR 364, 387 (2008) (quoting *Samuel S. Jackson*, 72 FR 23848, 23853 (2007) (quoting *Leo R. Miller,* 53 FR 21931, 21932 (1988))).

In this matter, while I reject the ALJ's conclusion that Respondent violated 21 U.S.C. § 843(a)(2), I find Respondent violated DEA regulations when she issued a controlled substance prescription when she was not registered to do so. Accordingly, I agree with the ALJ's conclusion that factors two (Respondent's experience in dispensing controlled substances) and four (Respondent's compliance with applicable laws related to controlled substances) support the denial of Respondent's application. R.D. at 16-17. However, with respect to factor five, I reject the ALJ's conclusion that Respondent did not intentionally make a false statement to the DI when she denied having written any controlled substance prescriptions after her registration expired. Moreover, I reject the ALJ's conclusion that Respondent has "both taken responsibility for her actions and shown remorse for her misconduct." *Id*. at 17. Indeed, Respondent offered no remorse for her misconduct in prescribing to her daughter after her registration expired. Nor did she offer any testimony addressing the materially false statement she made to the DI when she denied writing controlled substance prescriptions after the expiration of her registration.[5]

[5] As for factor one, I acknowledge that Respondent holds the requisite New Mexico certified nurse practitioner and controlled substance licenses. However, there is no "recommendation" one way or the other from the various state authorities as to whether Respondent's application should be granted.

While the possession of state authority to dispense controlled substances is a prerequisite for obtaining and maintaining a DEA registration, the CSA vests this Agency with "a separate oversight responsibility [apart from that which exists in state authorities] with respect to the handling of controlled substances." *Mortimer B. Levin*, 55 FR 8209, 8210 (1990). DEA has therefore long recognized that it has "a statutory obligation to make its independent determination as to whether the granting of [a registration] would be in the public interest." *Id*. Thus, while Respondent satisfies this prerequisite for obtaining registration, this factor is not dispositive of the public interest inquiry. *Id*. (holding that practitioner's reinstatement by state board "is not dispositive" in public interest inquiry).

As for factor three, while a history of criminal convictions for offenses involving the distribution or dispensing of controlled substances is a highly relevant consideration in the public interest inquiry, there are any number of reasons why a registrant may not have been convicted of such an offense, and thus, the absence of such a conviction is of considerably less consequence. *Jayam Krishna-Iyer*, 74 FR 459, 461 (2009). Accordingly, that Respondent has

Factors Two and Four – Respondent's Experience in Dispensing Controlled Substances and Compliance with Applicable Laws Related to Controlled Substances

Under a longstanding Agency regulation, "[a] prescription for a controlled substance [is not] effective [unless it is] issued for a legitimate medical purpose by an individual practitioner acting in the usual course of [her] professional practice." 21 CFR 1306.04(a). This regulation further provides that "an order purporting to be a prescription issued not in the usual course of professional treatment . . . is not a prescription within the meaning and intent of [21 U.S.C. § 829] and . . . the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances." *Id.*; *see also* 21 U.S.C. § 802(10) (defining the term "dispense" as meaning "to deliver a controlled substance to an ultimate user by, or pursuant to *the lawful order of*, *a practitioner*, including the prescribing and administering of a controlled substance") (emphasis added).

As the Supreme Court recently explained, "the prescription requirement . . . ensures patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse. As a corollary, [it] also bars doctors from peddling to patients who crave the drugs for those prohibited uses." *Gonzales v. Oregon*, 546 U.S. 243, 274 (2006) (citing *United States v. Moore*, 423 U.S. 122, 135, 143 (1975)).

Under the Controlled Substances Act, "it is fundamental that a practitioner must establish a bona fide doctor-patient relationship in order to act 'in the usual course of professional practice' and to issue a prescription for a legitimate medical purpose." *Patrick W. Stodola*, 74 FR 20727, 20731 (2009) (citing *Moore*, 423 U.S. at 141-43). The CSA generally looks to state law and medical practice standards to determine whether a practitioner has

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not been convicted of an offense related to the distribution or dispensing of a controlled substance is also not dispositive of whether granting her application "is consistent with the public interest." 21 U.S.C. § 823(f); *Krishna-Iyer*, 74 FR at 461.

established a valid practitioner-patient relationship. *See United Prescription Services, Inc*., 72 FR 50397, 50407 (2007) (citation omitted); *but see* 21 U.S.C. § 829(e).

Under New Mexico regulations, a Certified Nurse Practitioner (CNP) who has "fulfilled the requirements for prescriptive authority may prescribe and distribute dangerous drugs including controlled substances. . . within [her] clinical specialty and practice setting." N.M. Code § 16.12.2.13N(5). These regulations further provide that a CNP "may prescribe, provide samples of and dispense any dangerous drug to a patient where there is a valid practitioner-patient relationship as defined in" N.M. Code § 16.12.2.7. The latter provision defines a "valid practitioner-patient relationship" as:

> a professional relationship between the practitioner and the patient for the purpose of maintaining the patient's well-being. At minimum, this relationship is an interactive encounter between the practitioner and patient involving an appropriate history and physical or mental examination, ordering labs or diagnostic tests sufficient to make a diagnosis and providing, prescribing or recommending treatment, or referring to other health care providers. A patient record must be generated by the encounter.

Id. § 16.12.2.7.V.

Based on this regulation, the Government argues that Respondent violated both federal and state law when she prescribed controlled substances such as alprazolam and Ambien (zolpidem) to her daughter because she "kept no prescription records, kept no patient charts, and performed no physical or mental examinations." Gov't Br. 8. It further argues that "[a] practitioner is not excused from establishing a valid [practitioner]-patient relationship simply because another practitioner has previously established a valid relationship and the course of prescribed controlled substances is the same as with the prior practitioner." *Id*. at 7 (citing *Randall L. Wolff*, 77 FR 5106 (2012)). With respect to the latter contention, the Government argues that the psychiatrist's "post-approval of the program, [in] an attempt to bring validity to

the prescriptions[,] instead reveals two New Mexico practitioners ignoring or unaware of the simple fact that a doctor-patient relationship is not transferrable." *Id*. at 8 (citations omitted).

As support for its contention that Respondent "performed no physical or mental examinations," the Government cites the DI's testimony. Gov't Br. 4 (citing Tr. 27-28). However, while the DI testified that Respondent indicated "that she had never made a patient chart for her daughter" or provided her "with any prescription records," *id*. (citing Tr. 27), on the issue of whether Respondent had examined her daughter, the DI's testimony lacked probative force.

More specifically, when asked if Respondent told her "about weekly, monthly sessions of meeting with her daughter to diagnose or to make sure the treatment was proceeding as it should," the DI testified: "No, she did not." Tr. 27. When the Government followed up by asking the DI if she knew "why [Respondent] didn't provide you with any of that information?" the DI testified: "Because she stated she had not maintained any of those documents." *Id*. And when asked "do you know if she [Respondent] was conducting a medical examination of any sort?," the DI testified: "No, I do not know." *Id*. at 28.

Significantly, at no point did the Government ask the DI if she had specifically asked Respondent whether she had examined her daughter or had performed periodic evaluations of her and been told that she had not. Nor, during Respondent's testimony, did the Government ask her if she had examined her daughter or performed periodic evaluations of her.[6]

To be sure, there are cases in which evidence that a practitioner failed to create medical records has given rise to the inference that the practitioner failed to perform those tasks (such as

[6]There is evidence that Respondent practiced at a med spa. *See* GX 1 (Respondent's application); Tr. 52 (Respondent's testimony that in 2006, she had "moved into the medical aesthetics industry"). However, while New Mexico's regulations limit a CNP's prescribing authority to "their clinical specialty and practice setting," N.M. Code § 16.12.2.13N(5), and it seems most unlikely that prescribing for psychiatric conditions was within Respondent's clinical specialty, the Government made no such contention.

taking the necessary history and performing an appropriate examination) which are essential for properly diagnosing and periodically re-evaluating her patient. Yet this case stands on a substantially different footing than those cases, because even if it is not within professional ethics for a Nurse Practitioner to prescribe to a family member,[7] the evidence is undisputed that Respondent was intimately involved in her daughter's wellbeing and the decision to seek psychiatric care. Thus, while Respondent may not have documented a history of her daughter's psychiatric condition, she was obviously well aware of her daughter's condition. So too, she was well aware of her daughter's diagnosis and her response to treatment. And significantly, upon resuming active treatment of Respondent's daughter, her psychiatrist made the same assessment of her condition and continued to prescribe alprazolam to her. *See* RX 3, at 9-10.

As noted above, the Government also cites the Agency decision in *Wolff*, to argue that a "doctor-patient relationship is not transferrable" and that Respondent "ignor[ed] clear laws that make such transference of the doctor-patient relationship a violation." Gov't Br. 8. The Government ignores that the decision in *Wolff* specifically cited the testimony of an expert

[7] It is noted that the State Board required Respondent to take a course in "patient/physician/family caregiver relationships." RX 4, at 2. While it seems unlikely that the Board would have required Respondent to take this course if prescribing to a family member was not a violation of professional standards, the Board's Order contains no reference to any such standard. *See generally* RX 4. Nor does the Government cite to any New Mexico statute, board regulation, policy statement, or decision (of either the Board or state courts) holding that prescribing to family members exceeds the bounds of professional practice. It also did not sponsor any expert testimony on the issue.

In her decision, the ALJ sidestepped the issue of the adequacy of the Government's proof, reasoning that "[t]he parties acknowledge that [Respondent] violated both federal and state law when she issued the thirty-three prescriptions to" her daughter. R.D. at 16 (citing, *inter alia*, Tr. 45). However, the cited portion of the transcript was simply the opening statement of Respondent's counsel and not testimony. Therein, Respondent's counsel stated: "Should she have written prescriptions for her daughter? The answer is, no, she shouldn't have." Tr. 45.

Moreover, even were I to treat this statement as evidence, there are many things that people do that they shouldn't do. But that does not necessarily make the particular act a violation of a law or regulation. Given that the State Board required Respondent to take a course in prescribing to family members, Respondent may well have recognized that doing so was unethical or constituted malpractice. While Respondent testified that prescribing to family members "is a real issue," Tr. 59, on cross-examination, the Government did not ask Respondent why she now recognized that doing so "is a real issue" or why she should not have written the prescriptions, and in any event, her acknowledgement does not constitute an admission that her "actions completely betrayed any semblance of legitimate medical treatment" and thus constituted drug dealing. *United States v. Feingold*, 454 F.3d 1001, 1010 (9th Cir. 2006).

witness that it was not "within the standard of care" in the State where Dr. Wolff practiced "for a physician to 'perpetuate[] the issuance of controlled substances ordered by another doctor without first establishing his own valid doctor-patient relationship.'" 77 FR at 5107 n.2. Contrary to the Government's understanding, neither the CSA, nor Agency regulations, address the issue of whether, and under what circumstances, a prescriber-patient relationship is transferable. Rather, this is an issue which can be decided only by reference to the standards adopted by the New Mexico authorities and the accepted standards of professional practice. Here, however, the Government cites to no state authority (whether a statute, regulation, administrative or judicial decision, or policy statement) to support its contention that Respondent violated "clear laws." Nor did it offer any expert testimony to this effect.

Thus, while Respondent's failure to create a patient record for her daughter provides some evidence that Respondent lacked a legitimate medical purpose in prescribing alprazolam to her daughter, I conclude that the record as a whole does not support a finding that she violated the CSA's prescription requirement.[8] As for whether her failure to create a patient record is, by itself, sufficient to establish that she prescribed without a valid practitioner-patient relationship under New Mexico law, I conclude that that was a matter for state authorities. In short, I conclude that the Government's evidence establishes only that Respondent did not create state-required medical records. *See* N.M. Code §§ 16.12.2.7.V, 16.12.2.13.N(5)(g).

The Government's evidence does, however, establish that Respondent's registration expired on January 31, 2011, GX 2, and that on March 15, 2011, Respondent issued her daughter another prescription for alprazolam. *See* GX 7, at 1; GX 8, at 45. Under federal law, it is "unlawful for any person knowingly or intentionally . . . to use in the course of the . . . dispensing

[8] It is also noted that the Government makes no claim that the drugs Respondent prescribed to her daughter were being abused or diverted to others.

of a controlled substance, . . . a registration number which is . . . expired." 21 U.S.C. § 843(a)(2).

Regarding this violation, the DI testified that the expiration date of a registration "is printed on the certificate" and that the Agency's registration unit "automatically generates two notices before the expiration" advising a registrant of the impending expiration. Tr. 25-26. The DI also testified that after the expiration of a registration, a delinquency notice is also mailed to the registrant. *Id*. at 26. Respondent's registration was not "retired from the DEA computer system [until] March 1, 2011." GX 2, at 1. However, the Government offered no evidence that these notices were actually mailed to Respondent, let alone evidence as to what address they were sent.[9]

At the hearing, Respondent asserted that she "was just unaware of the expiration" of her registration, and "didn't know this until [she] started refilling [sic] [her] New Mexico pharmacy license, where they require you to put in the expiration of your DEA." Tr. 64. She further asserted that notwithstanding the reprimand she had received in late December 2010 for practicing nursing without a license, she did not check her DEA registration to see if it was due to expire soon. *Id*. at 65. The Government did not, however, ask Respondent when she had filled out her pharmacy license application, or introduce any documentary evidence establishing the date on which she did this.

Notwithstanding Respondent's testimony (which the ALJ found to be credible) that she was unaware of the expiration of her registration, the ALJ found that Respondent "violated

[9] According to the Government's evidence, Respondent was registered at the address of PMG GI, 3715 Southern Blvd., Rio Rancho, New Mexico. GX 2, at 1. However, on her application, Respondent listed her proposed registered address as Eden Medspa, 405 Kiva Court, Santa Fe, New Mexico. GX 1, at 1. Under federal law, "[e]very registrant . . . shall be required to report any change of professional or business address in such manner as the Attorney General shall by regulation require." 21 U.S.C. § 827(g); *see also* 21 CFR 1301.51 (providing procedure for modifying address). While Respondent was required to inform the Agency that she had changed her address and modify her registration, no such allegation was raised by the Government. Moreover, no evidence was adduced as to whether her mail had been forwarded to her by the clinic listed on her expired registration.

federal law by issuing a prescription after the expiration of her" registration. R.D. at 16 (citing 21 U.S.C. § 843(a)(2)). However, as explained above, establishing a violation of section 843(a)(2) requires proof that Respondent knowingly issued the prescription after the expiration of her registration. As the D.C. Circuit has explained, to establish knowledge, the Government must either prove that when she wrote the March 15, 2011 prescription, Respondent had actual knowledge that her registration had expired or that she was willfully blind or deliberately indifferent to that fact that her registration had expired. *Cf. United States v. Alston-Graves*, 435 F.3d 331 (D.C. Cir. 2006). However, if Respondent "act[ed] through ignorance, mistake or accident," *id*. at 337, she did not act with the requisite knowledge.

Here, the ALJ found Respondent's testimony credible that she was unaware of the expiration of her registration at the time she issued the prescription and did not become aware of its expiration until she filed her application for her state pharmacy license and was required to provide the expiration date. Notably, the Government adduced no evidence sufficient to support the rejection of the ALJ's credibility finding. As explained above, the Government produced no evidence establishing the date on which she filed her pharmacy license application. Nor did it establish when Respondent had last looked at her DEA registration. And while there is evidence that various notices regarding the expiration of her registration were likely sent to Respondent, there is no evidence that the notices were mailed to her new address, or forwarded from her registered address to either her new registered address or her mailing address. *See* GX 1. Thus, the Government has failed to prove that Respondent either had actual knowledge of, or was willfully blind to, the fact that her registration had expired. Rather, the evidence supports the conclusion that Respondent was simply ignorant of the fact that her registration had expired.

Accordingly, the ALJ's conclusion that Respondent violated 21 U.S.C. § 843(a)(2) is not supported by substantial evidence.

However, the Controlled Substances Act requires that "[e]very person who dispenses . . . any controlled substance, shall obtain from the Attorney General a registration issued in accordance with the rules and regulations promulgated by him." 21 U.S.C. § 822(a)(2). Agency regulations further provide that "[a] prescription for a controlled substance may be issued only by an individual practitioner who is . . . [e]ither registered or exempted from registration . . . ."[10] 21 CFR 1306.03(a). *Cf. id*. § 1301.13(a) ("No person required to be registered shall engage in any activity for which registration is required until the application for registration is granted . . . ."). To establish a violation of 21 CFR 1306.03(a), the Government is required to prove only that Respondent issued a prescription for a controlled substance when she was not registered to do so; it is not required to prove that Respondent knew that she lacked a valid registration when she issued the prescription. Accordingly, I find that Respondent violated DEA regulations when she issued the March 15, 2011 alprazolam prescription.[11]

Factor Five – Such Other Conduct Which May Threaten Public Health and Safety

In making the public interest determination, "this Agency also places great weight on a registrant's candor, both during an investigation and in any subsequent proceeding." *Robert H. Hunt*, 75 FR 49995, 50004 (2010); *see also*, *e.g.*, *The Lawsons, Inc*., *t/a The Medicine Shoppe Pharmacy*, 72 FR 74334, 74338 (2007); *Rose Mary Jacinta Lewis*, 72 FR 4035, 4042 (2007) (holding that lying under oath in proceeding to downplay responsibility supports conclusion that physician "cannot be entrusted with a registration"). As the Sixth Circuit has recognized,

[10] Respondent makes no claim that she was exempt from registration.

[11] While there was also evidence that Respondent self-prescribed thirty tablets of zaleplon, *see* GX 6, at 1, the Government offered no further evidence or argument regarding the lawfulness of this prescription. I therefore do not consider it.

"[c]andor during DEA investigations properly is considered by the DEA to be an important factor when assessing whether a . . . registration is consistent with the public interest." *Hoxie*, 419 F.3d at 483.

The Government argues that Respondent knowingly made a false statement to the DI when the DI asked her if she had written any prescriptions after the expiration of her registration and Respondent denied doing so. Gov't Br. 11. The ALJ rejected the Government's contention, explaining that she found it "quite plausible that [Respondent] unintentionally made the false statement to" the DI. R.D. at 18. As support for her conclusion, the ALJ reasoned that "the Government's argument regarding [Respondent's] lack of candor is undercut by the extensive and voluntary disclosures which [Respondent] made to [the DI] *during that April 2011 telephone conversation*, namely that she had not prepared or maintained any treatment records regarding these prescriptions." *Id*. (emphasis added). The ALJ thus concluded that "[i]n light of the totality of [Respondent's] interaction with [the DI] and her credible testimony at the hearing, . . . her statement, while admittedly false, does not negatively outweigh her overall candor with the Agency." *Id*.

I reject the ALJ's finding that Respondent unintentionally made the false statement. Indeed, the ALJ's conclusion clearly rests on a misreading of the record, which while not a model of clarity, nonetheless establishes that Respondent made the false statement in a phone call which occurred before the DI had run the PMP, and in fact, during this phone call, the DI specifically discussed with Respondent that her registration had expired and told her that she would be running a PMP report "to verify the information [Respondent] had provided of not writing any prescriptions with an expired DEA number." Tr. 22-23. Moreover, the evidence clearly shows that what the ALJ characterized as Respondent's "extensive and voluntary

disclosures" (regarding her failure to create and maintain treatment records for her daughter's prescriptions), were not made until a subsequent phone call which occurred after the DI had run the PMP report. Thus, contrary to the ALJ's understanding, it was only after Respondent was confronted with the evidence of her misconduct that she made the admissions regarding her failure to create records. And even then, she maintained that she had forgotten that she had written the March 15 prescription.

Of further note, Respondent submitted her application three days after she wrote the prescription and clearly knew then that her registration had expired. Moreover, the phone call in which she denied having written any prescriptions after the expiration of her registration occurred in April 2011, approximately a month (more or less) after she had written the prescription.[12] It simply defies credulity to suggest that Respondent did not remember having written the prescription in the preceding month, especially given that the prescription was written for her daughter.[13]

I therefore conclude that Respondent knowingly made the false statement to the investigator. I further conclude that the false statement was material in that it had "'a natural tendency to influence, or was capable of influencing, the decision of' the decisionmaking body to which it was addressed." *Kungys v. United States*, 485 U.S. 759, 770 (1988) (quoting *Weinstock v. United States*, 231 F.2d 699, 701 (D.C. Cir. 1956) (other citation omitted)) (quoted in *Samuel S. Jackson*, 72 FR 23848, 23852 (2007)); *see also United States v. Wells*, 519 U.S. 482, 489

[12] In its brief, the Government asserts that the conversation occurred on April 14, 2011. Gov. Br. 11. Yet the record does not establish anything more than that it occurred in April 2011. *See* Tr. 21 (testimony of DI: "I had a phone conversation with [Respondent] in April, and we discussed the licensing information, and at that point, I also asked [her] if she had prescribed controlled substances to anyone after the expiration date of her prior registration."); *see also id*. (Government counsel: "And do you know the date of this phone call or approximate date?" DI: "It was in April . . . of 2011.").

[13] In support of her contention that Respondent did not deliberately make the false statement, the ALJ also cited Respondent's "credible testimony at the hearing." R.D. at 18. Yet, Respondent offered no testimony regarding the circumstances surrounding her statement. Thus, the ALJ's finding does not rest on a credibility determination.

(1997) (quoting *Kungys*, 485 U.S. at 770). Most significantly for this proceeding, the Supreme Court has explained that "[i]t has never been the test of materiality that the misrepresentation or concealment would *more likely than not* have produced an erroneous decision." *Kungys*, 485 U.S. at 771 (emphasis in original). Rather, the test is "whether the misrepresentation or concealment was predictably capable of affecting, *i.e.*, had a natural tendency to affect, the official decision." *Id*.

"'[T]he ultimate finding of materiality turns on an interpretation of substantive law,'" *id*. at 772 (int. quotations and other citation omitted), and must be met "by evidence that is clear, unequivocal, and convincing." *Id*. That standard is met here. As explained above, under federal law, a practitioner cannot lawfully dispense a controlled substance unless she possesses a registration or is otherwise exempt from registration.[14] 21 U.S.C. § 822(a)(2); 21 CFR 1306.03(a). So too, it is a violation of federal law for a practitioner to knowingly use an expired registration to dispense a controlled substance.[15] 21 U.S.C. § 843(a)(2). Respondent's false statement denying that she had issued any controlled substance prescriptions after her registration expired was clearly material under the public interest standard, because the standard clearly directs the Agency to consider an applicant's "[c]ompliance with applicable . . . Federal . . . laws relating to controlled substances." *Id*. § 823(f)(4).

That the DI made clear that she intended to obtain a PMP report and verify the validity of Respondent's statement does not make her statement immaterial. As the First Circuit has noted with respect to the material falsification requirement under 18 U.S.C. §1001, "[i]t makes no difference that a specific falsification did not exert influence so long as it had the *capacity* to do

[14] Respondent makes no argument that she was exempt from registration at the time she issued the prescription to her daughter.

[15] That in this matter, the Government did not ultimately prove Respondent knew that her registration had expired does not make her statement immaterial. Moreover, at the time of the statement, Respondent knew her registration had expired, and that when she issued the prescription, she did not have authority to do so. 21 CFR 1306.03(a).

so." *United States v. Alemany Rivera*, 781 F.2d 229, 234 (1st Cir. 1985); *see also United States v. Norris*, 749 F.2d 1116, 1121 (4th Cir. 1984) ("There is no requirement that the false statement influence or effect the decision making process of a department of the United States Government.").

To the extent the ALJ's opinion suggests that because Respondent, in a subsequent conversation, admitted to various other acts (but not to writing a prescription after her registration expired), and thus her overall candor excuses her false statement, I reject it. Indeed, adopting the ALJ's reasoning would create a perverse incentive to falsely deny the commission of acts which could result in the denial of one's application, in the hope that the Agency's investigator would simply take one at her word. Contrary to the ALJ's understanding, there is no free pass for those who make a false statement during the course of an Agency investigation, and those who seek registration from the Agency have an obligation to provide truthful answers to all material questions asked by Agency personnel, no matter the stage of the investigation. I therefore conclude that Respondent's false statement provides additional grounds to conclude that her registration would be inconsistent with the public interest.[16]

SANCTION

As found above, while I reject the Government's contention that Respondent lacked a legitimate medical purpose and acted outside of the usual course of professional practice in violation of federal and state law when she prescribed to her daughter, I nonetheless find that Respondent violated federal law when she issued a controlled substance prescription after the expiration of her registration and then made a materially false statement to the DI when she denied having issued any such prescriptions after the expiration of her registration. Had the

[16] Respondent's false statement has generally been considered under factor five, as other conduct which may threaten public health or safety.

proven violations been limited to Respondent's issuance of a controlled substance prescription after the expiration of her registration, I would likely have concluded that denial of her application would be unwarranted. *See Jacobo Dreszer*, 76 FR 19386, 19387-88 (2011) (holding that even where the Government has made out a *prima facie* case under the public interest standard, a respondent can argue that "his conduct was not so egregious as to warrant revocation"); *Gregory D. Owens*, 74 FR 36751, 36757 n.22 (2009) ("in assessing what sanction to impose, the Agency . . . considers the extent and egregiousness of a practitioner's misconduct.").

However, I find that Respondent's act in making a materially false statement to the Investigator constitutes sufficiently egregious misconduct to support the denial of her application. I therefore hold that the Government has satisfied its *prima facie* burden of showing that issuing a new registration to the applicant would be inconsistent with the public interest.

As DEA has repeatedly held, upon this showing, the applicant must then "present sufficient mitigating evidence" to show why she can be entrusted with a new registration. *Medicine Shoppe-Jonesborough*, 73 FR 364, 387 (2008) (quoting *Samuel S. Jackson*, 72 FR 23848, 23853 (2007) (quoting *Leo R. Miller,* 53 FR 21931, 21932 (1988))). "Moreover, because 'past performance is the best predictor of future performance,' *ALRA Labs. Inc. v. DEA*, 54 F.3d 450, 452 (7th Cir. 1995), [DEA] has repeatedly held that where a registrant has committed acts inconsistent with the public interest, the registrant must accept responsibility for [her] actions and demonstrate that [she] will not engage in future misconduct." *Medicine Shoppe,* 73 FR at 387; *see also Jackson,* 72 FR at 23853; *John H. Kennedy*, 71 FR 35705, 35709 (2006); *Cuong Tron Tran*, 63 FR 64280, 64283 (1998); *Prince George Daniels*, 60 FR 62884, 62887 (1995); *Hoxie v. DEA*, 419 F.3d at 483 ("admitting fault" is "properly consider[ed]" by DEA to be an

"important factor[]" in the public interest determination). So too, in determining the appropriate sanction, the Agency has a substantial interest in deterring future acts of misconduct, both on the part of a respondent in a particular case and the community of registrants. *See Joseph Gaudio*, 74 FR 10083, 10094 (2009) (quoting *Southwood Pharmaceuticals*, *Inc*., 72 FR 36487, 36504 (2007)); *see also Butz v. Glover Livestock Commission Co*., *Inc.*, 411 U.S. 182, 187-88 (1973); *Michael S.* Moore, 76 FR 45867, 45868 (2011).

Here, the ALJ found that "Respondent has both taken responsibility for her actions and shown remorse for her unlawful conduct." R.D. at 17 (citing Tr. 53, 59). As to the first citation, Respondent testified regarding her having been reprimanded, for – in the words of her counsel – "not filling out things in a timely basis." Tr. 53. In this regard, Respondent testified that she was "very much scattered" and that she now "absolutely understand[s] the gravity of this." *Id*. The issue, however, is not whether Respondent timely completed a renewal application but why she issued a prescription when she lacked legal authority to do so and then falsely denied doing so to the DI.[17] Respondent simply offered no testimony acknowledging that she had violated federal law when she issued a prescription after her registration expired. Nor did Respondent even address the circumstances surrounding the false statement she made to the DI. Accordingly, I reject the ALJ's finding that Respondent has accepted responsibility for her misconduct.

In recommending that I grant Respondent's application, the ALJ also cited various mitigating factors which I should consider including Respondent's health problems (a 2004 heart attack), her son's death in a motorcycle accident (in 2006), and her daughter's struggle with mental illness after losing her health insurance. R.D. at 17. While the first two events are indisputably tragic, they do not mitigate Respondent's misconduct, which occurred years later.

[17] At Tr. 59, Respondent testified regarding what she had learned in the class about prescribing for family members. Respondent is not, however, required to acknowledge wrongdoing for unproven misconduct.

As for her daughter's struggle with mental illness after losing her insurance, because I find the allegation that Respondent acted outside of the usual course of professional practice in issuing prescriptions to her daughter to be unsupported by substantial evidence, I need not decide whether this mitigates her conduct. However, it clearly does not mitigate her misconduct in issuing the prescription after the expiration of her registration, as the evidence shows that Respondent's daughter had resumed treatment with her psychiatrist prior to the issuance of the prescription.

Most significantly, it does not excuse her deliberate and material false statement to the Investigator. Because Respondent has failed to acknowledge her misconduct in making the statement, I conclude that her application should be denied. However, in the event Respondent is willing to acknowledge her misconduct in making this statement, favorable consideration should be granted to a new application made no earlier than six months from the date of this Order.

ORDER

Pursuant to the authority vested in me by 21 U.S.C. § 823(f), as well as 28 CFR 0.100(b), I order that the application of Belinda R. Mori, N.P., for a DEA Certificate of Registration as a Mid-Level Practitioner, be, and it hereby is, denied. This Order is effective immediately.

Dated: June 9, 2013

Michele M. Leonhart
Administrator

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