Appeals dismissed the Respondent's appeal of the Alabama Board Order on procedural grounds. *Cressman* v. *Ala. Bd. of Med. Exam'rs,* 72 So. 3d 679 (Ala. Civ. App. 2011). Moreover, as discussed, *supra,* in his Request for Hearing, the Respondent has already conceded that his Alabama controlled substance privileges were ''revoked in Feb[ruary] 2012.'' Resp't Req. for Hrng at 1. Therefore, the Respondent's letter notwithstanding, it is beyond argument that the Respondent does not currently possess authority to handle controlled substances in the State of Alabama, the state of his DEA COR.

In order to revoke a registrant's DEA registration, the DEA has the burden of proving that the requirements for revocation are satisfied. 21 CFR 1301.44(e). Once DEA has made its *prima facie* case for revocation of the registrant's DEA COR, the burden of production then shifts to the Respondent to show that, given the totality of the facts and circumstances in the record, revoking the registrant's registration would not be appropriate. *Morall* v. *DEA,* 412 F.3d 165, 174 (D.C. Cir. 2005); *Humphreys* v. *DEA,* 96 F.3d 658, 661 (3d Cir. 1996); *Shatz* v. *U.S. Dept. of Justice,* 873 F.2d 1089, 1091 (8th Cir. 1989); *Thomas E. Johnston,* 45 FR 72311 (1980).

The Controlled Substances Act (CSA) requires that, in order to maintain a DEA registration, a practitioner must be authorized to handle controlled substances in ''the jurisdiction in which he practices.'' *See* 21 U.S.C. 802(21) (''[t]he term 'practitioner' means a physician * * * licensed, registered, or otherwise permitted, by * * * the jurisdiction in which he practices * * * to distribute, dispense, [or] administer * * * a controlled substance in the course of professional practice''); *see also id.* § 823(f) (''The Attorney General shall register practitioners * * * if the applicant is authorized to dispense * * * controlled substances under the laws of the State in which he practices.''). DEA has long held that possession of authority under state law to dispense controlled substances is an essential condition for obtaining and maintaining a DEA registration. *Serenity Café,* 77 FR 35027, 35028 (2012); *David W. Wang,* 72 FR 54297, 54298 (2007); *Sheran Arden Yeates,* 71 FR 39130, 39131 (2006); *Dominick A. Ricci, M.D.,* 58 FR 51104 (1993); *Bobby Watts, M.D.,* 53 FR 11919 (1988). Because ''possessing authority under state law to handle controlled substances is an essential condition for holding a DEA registration,'' this Agency has consistently held that ''the CSA requires the revocation of a registration issued to a practitioner who lacks [such authority].'' *Roy Chi Lung,* 74 FR 20346, 20347 (2009); *see also Scott Sandarg, D.M.D.,* 74 FR 17528, 174529 (2009); *John B. Freitas, D.O.,* 74 ed. Reg. 17524, 17525 (2009); *Roger A. Rodriguez, M.D.,* 70 FR 33206, 33207 (2005); *Stephen J. Graham, M.D.,* 69 FR 11661 (2004); *Abraham A. Chaplan, M.D.,* 57 FR 55280 (1992); *see also Harrell E. Robinson,* 74 FR 61370, 61375 (2009).[1] ''[R]evocation is warranted even where a practitioner's state authority has been summarily suspended and the State has yet to provide the practitioner with a hearing to challenge the State's action at which he may ultimately prevail.'' *Kamal Tiwari, M.D.,* 76 FR 71604, 71606, (2011); *see also Bourne Pharmacy, Inc.,* 72 Fed Reg. 18273, 18274 (2007); *Anne Lazar Thorn,* 62 FR 12847 (1997).

Congress does not intend for administrative agencies to perform meaningless tasks. *See Philip E. Kirk, M.D.,* 48 FR 32887 (1983), *aff'd sub nom. Kirk* v. *Mullen,* 749 F.2d 297 (6th Cir. 1984); *see also Puerto Rico Aqueduct & Sewer Auth.* v. *EPA,* 35 F.3d 600, 605 (1st Cir. 1994); *NLRB* v. *Int'l Assoc. of Bridge, Structural & Ornamental Ironworkers, AFL–CIO,* 549 F.2d 634 (9th Cir. 1977); *United States* v. *Consol. Mines & Smelting Co.,* 455 F.2d 432, 453 (9th Cir. 1971). Thus, it is well-settled that, where no genuine question of fact is involved, or when the material facts are agreed upon, a plenary, adversarial administrative proceeding is not required. *See Jesus R. Juarez, M.D.,* 62 FR 14945 (1997); *Dominick A. Ricci, M.D.,* 58 FR 51104 (1993). Here, both parties agree, and the supplied Alabama Board Order and other documentation establish, that the Respondent is without authorization to handle controlled substances in Alabama,[2] the jurisdiction where the Respondent holds the DEA COR that is the subject of this litigation.

Summary disposition of an administrative case is warranted where, as here, ''there is no factual dispute of substance.'' *See Veg-Mix, Inc.,* 832 F.2d 601, 607 (D.C. Cir. 1987) (''an agency may ordinarily dispense with a hearing when no genuine dispute exists'').[3] At this juncture, no genuine dispute exists over the fact that the Respondent lacks state authority to handle controlled substances in the State of Alabama. Because the Respondent lacks such state authority, both the plain language of applicable federal statutory provisions and Agency interpretive precedent dictate that the Respondent is not entitled to maintain his DEA registration. Simply put, there is no contested factual matter adducible at a hearing that would provide DEA with the authority to allow the Respondent to continue to hold his COR. In view of this determination, it is unnecessary to address the remaining allegations contained in the OSC/ISO.

Accordingly, I hereby

Grant the Government's Motion for Summary Disposition; and *recommend* that the Respondent's DEA registration be *revoked* forthwith and any pending applications for renewal be *denied.*

Dated: December 5, 2012.

John J. Mulrooney, II,

Chief Administrative Law Judge.

[FR Doc. 2013–03878 Filed 2–20–13; 8:45 am]

BILLING CODE 4410–09–P

[1] *But see* 21 U.S.C. 824(a)(3) (''A registration pursuant to section 823 of this title to manufacture, distribute, or dispense a controlled substance *may* be suspended or revoked by the Attorney General upon a finding that the registrant * * * has had his State license or registration suspended, revoked, or denied by competent State authority. * * *'') (emphasis added).

[2] The Respondent's representation that he has secured employment in Texas is of no moment here. *See Shahid Musud Siddiqui,* M.D., 61 FR 14818 (1996) (a registrant's controlled substance privileges in a state outside the state of his DEA registration is irrelevant).

[3] Even assuming *arguendo* the possibility that the Respondent's state controlled substances privileges could be reinstated, summary disposition would still be warranted because ''revocation is also appropriate when a state license has been suspended, but with the possibility of future reinstatement,'' *Rodriguez,* 70 FR at 33207 (citations omitted), and even where there is a judicial challenge to the state medical board action actively pending in the state courts. *Michael G. Dolin, M.D.,* 65 FR 5661, 5662 (2000).

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 11–10]

John V. Scalera; Decision and Order

On November 17, 2010, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to John V. Scalera, M.D. (hereinafter, Respondent), of Northfield, New Jersey. The Show Cause Order proposed the denial of Respondent's application for a DEA Certificate of Registration as a practitioner, on the ground that his ''registration would be inconsistent with the public interest.'' ALJ Ex. 1, at 1.

The Show Cause Order specifically alleged that Respondent had previously held a DEA registration, which, on February 23, 2009, he voluntarily surrendered for cause. *Id.* The Order alleged that Respondent had written

prescriptions in the name of his deceased mother-in-law for oxycodone and Percocet, both of which are schedule II controlled substances, which he personally filled ''at numerous pharmacies.'' *Id.* The Order further alleged that this conduct had occurred since March 4, 2003, and was in violation of 21 U.S.C. 841(a) and state law. *Id.*

Next, the Show Cause Order alleged that ''[f]rom June 3 * * * through July 11, 2009,'' Respondent had written ''at least nine prescriptions for [t]ramadol, or its trade name Ultram, in the name of [his] daughter,'' and that he ''did not conduct an examination which was properly documented in her patient record in violation of'' the New Jersey Administrative Code. *Id.* at 2. The Order further alleged that he had ''personally filled these prescriptions at * * * five different pharmacies'' and had written ''most, if not all, of [them] to support [his] drug habit.'' *Id.* The Order then alleged that this conduct violated various provisions of New Jersey law. *Id.*

Finally, the Show Cause Order alleged that ''[o]n June 16, 2009, an employee of [Respondent's] office called in a prescription for [t]emazepam, a [s]chedule IV controlled substance, in the name of [his] daughter using'' the DEA number he had previously surrendered. *Id.* The Order further alleged that this prescription ''was refilled on July 14, 2009[,]'' and that Respondent's ''prescribing of this controlled substance'' violated 21 U.S.C. 822 and 841(a) and 21 CFR 1301.11 and 1301.13. *Id.*

Respondent requested a hearing on the allegations and the matter was placed on the docket of the Office of Administrative Law Judges (ALJ). Thereafter, an ALJ proceeded to conduct pre-hearing procedures, during which the Government raised additional allegations that following the voluntary surrender of his registration, Respondent issued prescriptions and hospital orders for controlled substances. More specifically, the Government alleged that Respondent: (1) Issued four prescriptions for diazepam, a schedule IV controlled substance, in the name of his wife, ''which were filled from March 11 * * * through June 17, 2009''; (2) issued at least nine prescriptions for Androgel (testosterone), a schedule III controlled substance, in both his own name and that of another person, which ''were filled from July 16, 2009 through April 19, 2010''; 3) issued ''[a]t least ten prescriptions for [t]emazepam * * * in the names of [his] daughter and [his former] son-in law, [which] were filled from March 18 * * * through May 24, 2009''; and 4) ''continued to issue orders for controlled substances [including morphine, hydromorphone, oxycodone, hydrocodone, meperidine, alprazolam, clonazepam, and zolpidem] for patients he was treating at AtlantiCare Regional Medical Center.'' ALJ Ex. 7, at 1–2. The Government further alleged that Respondent's conduct violated 21 U.S.C. 841(a)(1) and 843(a)(2) & (3). *Id.* at 2.

On May 3–5, 2011, the ALJ conducted a hearing at which both parties called witnesses to testify and submitted various exhibits into the record. Following the hearing, both parties submitted briefs containing their proposed findings of fact and conclusions of law.

Thereafter, the ALJ issued her recommended decision. Therein, the ALJ applied the five public interest factors and found that while the ''[d]enial of the Respondent's application can be justified by this record,'' recommended that ''a less severe action be taken in this case'' and that Respondent be granted a new registration subject to various conditions. ALJ at 28.

With respect to factor one—the recommendation of the State licensing board—the ALJ noted that the board had elected not to take ''adverse action'' against Respondent upon learning that he was writing tramadol prescriptions for both himself and his daughter and had ordered him ''to cease all self-prescribing and prescribing for his daughter's pain issues'' but had otherwise placed no restrictions on his medical practice. *Id.* at 23. The ALJ further noted that the Board was actively monitoring Respondent's recovery from drug addiction, that Respondent was required to participate in drug screening and that if Respondent had an ''illegitimate positive urine test result,'' his license was subject to suspension. *Id.* The ALJ thus concluded ''that the Board's recommendation, in light of the overlapping facts it considered, weighs in favor of the Respondent's registration.[1]'' ALJ at 23–24.

Next, the ALJ considered factors two and four—the applicant's experience in dispensing controlled substances and compliance with applicable laws related to controlled substances. *Id.* at 24–26. Here, the ALJ found that prior to surrendering his registration in February 2009, Respondent wrote prescriptions for controlled substances in the name of his deceased mother-in-law for his own use. *Id.* at 24. Moreover, the ALJ found that following the surrender of his registration, Respondent prescribed testosterone to both himself and one of his patients. *Id.*

The ALJ further found that following the surrender of his registration, Respondent wrote hospital orders for controlled substances for inpatients that he was treating. *Id.* Regarding these violations, the ALJ further noted that ''[w]hen asked if he had consciously violated his lack of DEA registration, unfortunately the Respondent denied that violation * * * explain[ing] that he thought he was acting under the auspices of the hospital.'' *Id.* at 24–25.

Finally, the ALJ found that ''Respondent failed to adequately supervise his staff and their placement of phone-in and fax-in prescriptions for controlled substances.'' *Id.* at 25. While the ALJ found that ''[t]he majority of these prescriptions were initially phoned in while the Respondent was receiving inpatient treatment'' and ''it credible that [he] did not place phone-in orders for controlled substances during that time,'' she further found that he ''left his prescription pads with his controlled substances registration number at the office during his absence.'' *Id.* Noting that Respondent's failure to safeguard his registration ''is not conduct indicative of a responsible registrant,'' as well as Agency precedent that ''[w]rongful conduct by the registrant's agent is imputed to the registrant,'' the ALJ concluded that he was responsible for the phoned and faxed-in prescriptions. *Id.* The ALJ thus held that factors two and four provided grounds to deny Respondent's application.

As for factor five—such other conduct which may threaten public health and safety—the ALJ cited several findings. More specifically, the ALJ noted Respondent's history of drug addiction which included two relapses, ''his pattern of prescribing medications for family members and then consuming them himself [which] continued with [his] prescribing of [t]ramadol for his daughter and then consuming some of the medication himself,'' and his having lied to a DEA agent when he denied that he was consuming the tramadol which he prescribed for his daughter. *Id.* at 26. The ALJ concluded that this conduct ''is not consistent with the responsibilities of a DEA registrant.'' *Id.*

However, the ALJ then noted Respondent had presented evidence of mitigating circumstances. This evidence included that he was actively participating in his recovery, and that a

[1] The ALJ also found that Respondent has not been convicted of any offense related to the handling of controlled substances (factor three). ALJ at 25–26.

treating professional with the State's Professional Assistance Program (PAP), who has worked with him for two years, had credibly testified that Respondent is in ''sustained full remission.'' *Id.* at 27.

In addition, the ALJ found that Respondent acknowledged his wrongdoing in prescribing testosterone. *Id.* Finally, the ALJ found that Respondent had provided various assurances of his future compliance including that ''he would no longer allow his staff to phone in or fax in prescriptions for controlled substances'' and that ''his daughter would no longer work in his office.'' *Id.* Also, Respondent acknowledged that DEA ''might want to obtain more oversight of the Respondent's handling of controlled substances.'' *Id.*

The ALJ thus recommended that Respondent be granted a restricted registration. The Government filed exceptions to the ALJ's decision and Respondent filed a response to the exceptions. Thereafter, the record was forwarded to my office for Final Agency Action.

Having considered the entire record including the parties' submissions and the ALJ's recommended decision, I agree with the ALJ's conclusion that grounds exist to deny Respondent's application. However, I disagree with the ALJ's recommendation that I grant Respondent's application because he has failed to acknowledge his misconduct with respect to most of the violations proved on this record and failed to demonstrate that he can be entrusted with a new registration. I make the following findings of fact.

Findings

Respondent is a medical doctor who is board certified in urology. RX 3, at 2. Respondent has been licensed by the New Jersey State Board of Medical Examiners since 1981; Respondent currently holds an active license. *Id.*

Respondent formerly held a DEA Certificate of Registration, which authorized him to dispense controlled substances as a practitioner. GX 9. However, on February 20, 2009, DEA Diversion Investigators (DIs) interviewed Respondent regarding information that he was writing prescriptions in the name of his deceased mother-in-law (who had died in May 2002) for Percocet and Roxicodone, both of which are schedule II narcotic controlled substances which contain oxycodone. GX 18, at 2; GXs 4 and 8. According to the evidence, Respondent began writing these prescriptions on approximately March 4, 2003 and continued doing so until shortly before the interview. GX 18, at 2; GX 4. During the interview, Respondent admitted that he wrote the prescriptions to obtain the narcotics for his own use. GX 18, at 2. Respondent denied selling or giving the drugs to anyone else. *Id.*

During the interview, Respondent executed a voluntary surrender form (DEA–104) for his DEA registration. *Id.; see also* GX 9. Among other things, the form stated: ''I understand that I will not be permitted to order, manufacture, distribute, possess, dispense, administer, prescribe, or engage in any other controlled substances activities whatever, until such time as I am again properly registered.'' GX 9. On or about June 3, 2009, Respondent submitted an application for a new registration. GX 18, at 2.

On March 2, 2009, Respondent re-entered the ARP [2] with a diagnosis of opiate dependence.[3] RX 8, at 5. According to a follow-up report, Respondent had previously been in the ARP but ''had relapsed into the use of Oxycodone and has been unable to discontinue use.'' *Id.* Respondent ''was advised to stop practice[ing] immediately'' and was ''referred to inpatient treatment at Behavioral Health of the Palm Beaches.'' *Id.*

Respondent was an in-patient at Behavioral Health of the Palm Beaches ''from 3/2/09 till 4/3/09.'' RX 11, at 1. During the initial phase of this treatment, Respondent was unable to make telephone calls. Tr. 385. Moreover, while thereafter Respondent was allowed to make phone calls, any calls would have been monitored. *Id.*

Respondent successfully completed the inpatient treatment and was discharged. Tr. 255, RX 11, at 1. Thereafter, Respondent has been involved in weekly 12-step recovery meetings, sessions with a psychologist, meetings with both a Professional Assistance Program (PAP) monitor (every other month) and the program's chairman (once a quarter), and random urine drug screens (UDSs). RX 11, at 1; RX 8, at 3. For the first year following the completion of his inpatient treatment, Respondent was subject to twice weekly UDSs, followed by weekly UDSs for the second year, and is now subject to twice-monthly screening. RX 11, at 1. Respondent has not tested positive for any non-prescribed drug, but has tested positive for tramadol. RX 13. Moreover, according to the Assistant Director of the PAP, Respondent is in ''sustained full remission.'' Tr. 388.

Following the receipt of Respondent's application, DEA DIs received information from a pharmacist that Respondent was writing prescriptions for tramadol [4] in the name of his daughter; however, Respondent brought the prescriptions to the pharmacy and filled them. GX 18, at 3. Making inquiries to other area pharmacies, the DIs determined that in one six-week period during June and July 2009, Respondent had written ten tramadol prescriptions in his daughter's name for a total of 810 dosage units; the prescriptions were filled at six different pharmacies. *Id.* at 3; *see also* GX 11.[5]

On July 21, 2009, two DIs and a State Investigator met with Respondent at his office and questioned him about the tramadol prescriptions. *Id.* at 4. During the interview, Respondent admitted that he had written the prescriptions for his daughter claiming they were for an injury; but while Respondent had a patient file for his daughter, the file ''did not show his prescribing of any tramadol to her.'' *Id.* Respondent further admitted that he had picked up the prescriptions at the pharmacies but said he did so routinely. *Id.*

While she was still at Respondent's office, the DI called Respondent's daughter who stated that she had received only a single tramadol prescription from her father which she had refilled two times. *Id.* Upon being told by the DI that his daughter had ''only confirmed receipt of one of the numerous [t]ramadol prescriptions in question,'' Respondent ''stated that his daughter must be mistaken and that she

[2] The ''ARP'' or ''Alternative Resolution Program'' is a program established ''for those subject to Board jurisdiction who are suffering from chemical dependencies and other impairments which shall permit such licensees to disclose their status to an entity which would allow for confidential oversight.'' N.J. Admin. Code 13:35–11–1.

[3] Respondent had previously entered the ARP on May 21, 1997 as ''a self-referral * * * because of [his] intermittent use of codeine-containing cough syrups over the course of approximately eight years and [his] consuming approximately a pint a day.'' RX 8, at 13. Respondent also testified that he had been enrolled in the Professional Assistance Program from 1978 to either 1983 or 1985. Tr. 253. After giving this testimony, Respondent was asked ''[w]ere there other times that you were enrolled as well?'' *Id.* Respondent answered ''no,'' *id.,* notwithstanding the other documentary evidence establishing that he enrolled in the program in May 1997.

[4] While tramadol (ULTRAM) is not a controlled substance, the FDA now requires that its label include the following statement:

ULTRAM may induce psychic and physical dependence of the morphine-type (μ-opioid). Dependence and abuse, including drug-seeking behavior and taking illicit actions to obtain the drug are not limited to those patients with prior history of opioid dependence. The risk in patients with substance abuse has been observed to be higher. ULTRAM is associated with craving and tolerance development. Withdrawal symptoms may occur if ULTRAM is discontinued abruptly.

GX 16, at 1.

[5] Many of the prescriptions include the notation ''PRN Pain.'' GX 11.

received all of the prescriptions he wrote for her.'' *Id.* at 5. Respondent further maintained that ''he did not ingest any of the [t]ramadol himself.'' *Id.* Respondent ''stated that he would not write any more [t]ramadol prescriptions for his family members'' and reiterated that he was not diverting the drug for himself. *Id.*

Thereafter, the DI notified Dr. Baxter, the PAP's Executive Medical Director regarding Respondent's use of tramadol. *Id.* The Executive Director told the DI that Respondent needed to get permission from the PAP to be prescribed tramadol and that he would speak with Respondent. *Id.* In a subsequent phone conversation, the Executive Director told the DI that Respondent had ''admitted that he had used the [t]ramadol that he obtained by writing prescriptions in his daughter's name.'' *Id.* However, at the hearing, Respondent testified that while he picked up some of the tramadol prescriptions he issued for his daughter, he ''never used [t]ramadol written in [his] daughter's name.'' Tr. 323.

On July 31, 2009, Dr. Baxter wrote a letter to the Executive Director of the State Board of Medical Examiners. RX 8, at 16. Therein, Dr. Baxter reported that he had confronted Respondent about his writing tramadol prescriptions in his daughter's name and his positive UDSs for tramadol. *Id.* Dr. Baxter wrote that Respondent had stated ''that he 'did not know that he could not use [t]ramadol since it was not a controlled substance.''' *Id.* Dr. Baxter further wrote that Respondent's daughter had ''initially confirmed that he had written her one prescription and later said that there were more'' and that Respondent ''dispute[s] the number of prescriptions that the DEA reported.'' *Id.* Dr. Baxter also wrote that he ''admonished [Respondent] for self-prescribing'' and that Respondent was told ''to get his treating physician . . . to write any future prescriptions.'' *Id.* Finally, Dr. Baxter wrote that Respondent had yet to start therapy with a psychologist and that he was instructed to do so ''immediately.'' *Id.*

Several weeks later, the DI received information from a pharmacy that Respondent was receiving tramadol prescriptions from two different physicians (Dr. M. & Dr. C.).[6] GX 18, at 5–6. In his testimony, Respondent acknowledged that he had received tramadol prescriptions from both Dr. C. and Dr. M. Tr. 259–64. According to Respondent, Dr. C. is an orthopedic surgeon who treated him for a back injury he suffered in a January 2008 motor vehicle accident and who had prescribed the tramadol to him to treat his back pain. *Id.* at 259–60, 262, 316. Respondent also testified that eight months after the accident, he was walking with a cane and tripped, breaking his hip, thus requiring hip replacement surgery. *Id.* at 317; RX 11, at 1. Respondent testified that Dr. M. was treating him for his hip and prescribed the tramadol for that purpose.[7] *Id.* at 263–64.

On September 23, 2009, the DIs went to Respondent's office to ask him to withdraw his application. GX 18, at 6. Respondent declined to do so and again stated that he had not used any of the tramadol he prescribed for his daughter. *Id.* Respondent's daughter was also present and stated that she was now receiving tramadol from another physician, and that she was ''trying to get off of Percocet.'' *Id.*

On December 14, 2009, the DIs, accompanied by the Resident Agent in Charge, again met with Respondent at the local DEA office. *Id.* During this interview, Respondent was asked ''if the Percocet he previously diverted under [his late mother-in-law's name] was for himself or his daughter?'' *Id.* at 7. Respondent stated ''that 60 percent was for him, and 30 percent was for his daughter, but * * * then recanted and said that all of the Percocet he diverted was for himself.'' *Id.* Respondent then stated that he had misunderstood the question and that the above percentages referred to the tramadol prescriptions he had written. *Id.* As found above, in the July 21 as well as September 23 interviews, Respondent had denied ingesting any of the tramadol. *Id.* at 5–6. Moreover, at the hearing, Respondent testified that when the DI asked him whether he had diverted the tramadol prescriptions issued in his daughter's name, his ''answer was why would I divert something like that when I get it from my own doctor.'' Tr. 304. And when asked if he had admitted to Dr. Baxter (the PAP Medical Director) that he had used some of the tramadol obtained from the prescriptions he issued in his daughter's name, Respondent testified: ''I never used [t]ramadol written in my daughter's name.'' *Id.* at 323. However, as did the ALJ, I find that Respondent wrote prescriptions in his daughter's name for tramadol to obtain the drug for his personal use. ALJ at 10.

During the December 2009 interview, the DI asked Respondent whether his daughter had a drug problem; Respondent stated '''yes''' but that ''she was doing better.'' GX 18, at 7. Respondent admitted that he had not previously told investigators about his daughter's drug problem and stated that ''he did not realize how bad his daughter's problem was until he got out of drug rehabilitation himself and became sober.'' *Id.* Respondent further stated that he had prescribed tramadol for his daughter to help her get off of Percocet. *Id.* However, previously, Respondent had stated that he had prescribed the tramadol to her for an injury. *Id.* One of the DIs then told Respondent that he was not authorized to prescribe controlled substances for addiction treatment.[8] *Id.*

Several days later, the DI and a Special Agent went to a Rite Aid pharmacy in Northfield, New Jersey and spoke with the pharmacist about two prescriptions for temazepam which were authorized for Respondent's daughter. *Id.* at 8. The pharmacist stated

[6] According to the DI's affidavit, she met with one of the physicians, Dr. M., who acknowledged writing a prescription for 200 dosage units because Respondent claimed he was having insurance issues; Dr. M. further stated that he did not know that Respondent was also seeing another physician. GX 18, at 6. *Id.* The DI then called Dr. C., who confirmed that Respondent was his patient and that he had written him a prescription for tramadol. *Id.* The DI's statement does not address whether she asked Dr. C. if he knew Respondent was being treated by Dr. M. *Id.*

While Dr. M.'s statement, which apparently was unsworn, that he had written a prescription for 200 dosage units is corroborated by other evidence, *see* GX 14, there is no evidence corroborating his statement that he did not know that Respondent was seeing another physician. Dr. C.'s statements that Respondent was his patient and that he had written him a tramadol prescription was corroborated by Respondent's testimony and documentary evidence. *See* GX 13; Tr. 259–60.

[7] Subsequently, Respondent appeared before the New Jersey Board's Preliminary Evaluation Committee to discuss his ''positive urine screens for Ultram [tramadol] and to discuss prescriptions issued in the name of his daughter.'' RX 8. Subsequently, the Board permitted Respondent ''to remain in the ARP'' and asked the Director of the PAP ''to enter into a new agreement with [Respondent] which makes clear that he must notify [the PAP] of all of his treating physicians, as well as any medications he ingests pursuant to prescription.'' *Id.* at 1.

The Committee also noted that it had discussed with Respondent ''the prescriptions written by him for his daughter'' and that it ''was troubled that [he] did not appear to keep routine medical records for family members.'' *Id.* at 8. However, ''[t]he Board accepted the Committee's representation that [Respondent] is now aware of the need to maintain such records.'' *Id.*

Moreover, according to the Assistant Director of the PAP, the Board and the PAP ''are in agreement that [the] monitoring protocol is an effective way of monitoring his recovery as well as protecting the public safety'' and ''[t]he Board has also determined not to restrict his prescribing privileges (other than for himself and family members).'' RX 11, at 2.

[8] One of the DIs interviewed Respondent's daughter, who had come with him to the DEA office. GX 18, at 7. She denied having previously told the DI that she had not received all of the tramadol prescriptions and asserted that she had taken all of the tramadol her father had prescribed. *Id.* at 8.

that on June 16, 2009, Linda, an employee in Respondent's office, had called in a temazepam prescription for his daughter with three refills. *Id.* This statement is corroborated by a Telephone Prescription Order dated ''6/16/09'' for 60 temazepam 30mg, with three refills, listing Respondent's daughter as the patient, Respondent as the prescriber, and noting that the prescription was ''phoned in by Linda.'' GX 33, at 3. According to a Physician's Activity Report compiled by the pharmacy, both the prescription and a refill of it were dispensed, the latter occurring on July 14, 2009. GX 33, at 1; *see also* GX 22, at 4.

In addition, another Physician's Activity Report for Respondent lists a prescription for 60 tablets of temazepam 15mg (#46128) issued for his daughter which was refilled on March 5 and 30, 2009, as well as a new prescription for 30 tablets of temazepam 30mg (#55132) which was issued on April 27 and refilled on May 24, 2009. GX 32, at 1. The latter prescription was phoned in and has the notation ''Linda'' written on top.[9] *Id.* at 2.

On March 9, 2011, a DI sought additional records from both CVS and Rite Aid for the period beginning on February 20, 2009, the date on which Respondent had surrendered his registration. GX 24. These records showed that on March 11, 2009, a prescription for Respondent's wife was called into a CVS Pharmacy (located in Somers Point, NJ) for 30 diazepam; this prescription was refilled on March 30, May 19, and June 17, 2009. *Id.* at 2. The records from Rite Aid also showed both the April 27 and June 16, 2009 prescriptions for temazepam for Respondent's daughter. *Id.* at 3–4.

The records further showed that on March 18, 2009, a prescription for Respondent's former son-in-law was called into a CVS (located in Ventnor, NJ) for 60 temazepam; this prescription was refilled on April 15, May 12, and June 9, 2009. *Id.* at 3. Also, on July 6, 2009, an additional prescription for 60 temazepam for Respondent's son-in-law was faxed in to the same pharmacy by R.M., an employee of Respondent; this prescription was refilled on August 30, 2009. *Id.* at 3; *see also* GX 26.

Next, various records show that Respondent issued prescriptions for Androgel (testosterone), a schedule III controlled substance, for both D.S., who was a patient, and for himself. GX 24, at 2. Respondent wrote the first prescription for D.S. on July 16, 2009; this prescription was refilled on August 10, 2009. *Id.* Respondent wrote the second prescription for D.S. on September 10, 2009; this prescription was refilled on October 17 and November 27. *Id.*

Respondent called in the first Androgel prescription for himself on July 12, 2009. *Id.* Respondent called in a refill of this prescription on December 6, 2009; however, there were no refills remaining. *Id.* at 3; GX 29. Respondent then authorized a second prescription for himself, which he refilled on January 25 and April 19, 2010. GX 24, at 3; GX 25; GX 29.

In addition, the Government subpoenaed pharmacy records from the AtlantiCare Health System, a hospital at which Respondent held privileges and treated patients. GX 35. These records, which covered the period from February 21, 2009 through April 13, 2011, showed that on numerous occasions following the surrender of his registration, Respondent issued orders for the administration of controlled substances to patients he was treating at the hospital. More specifically, during the year 2009 (and following the surrender of his registration), Respondent issued eight orders for controlled substances. *Id.* at 4–5. Moreover, during 2010, Respondent issued an additional twenty hospital orders for controlled substances, the last being issued on October 12th of that year.[10] *Id.* at 6–8. Finally, Respondent issued six additional hospital orders for controlled substances through April 2011. GX 36.

Regarding the post-surrender prescriptions and hospital orders, Respondent denied issuing the March 11, 2009 diazepam prescription for his wife, noting that this prescription was called in to the pharmacy during the period in which he was an inpatient at Behavioral Health of Palm Beach. Tr. 311–12. Respondent also denied issuing the March 18, 2009 prescription for temazepam for his former son-in-law (on which date he was still an inpatient in Palm Beach), as well as the July 6, 2009 authorization for an additional prescription which was faxed into the pharmacy. Tr. 272, 330–31. With respect to the July 6 prescription, which was faxed into the pharmacy, Respondent testified that R.M., the employee whose name is listed as having faxed in the request on behalf of Respondent, denied having sent in the prescription. *Id.* at 331. While Respondent ''ha[d] no idea'' why the prescription was faxed in and stated that he did not authorize it, he did not deny that it originated from his office. Tr. 272.

Respondent also denied authorizing all of the temazepam prescriptions for his daughter including the April 27 and June 16, 2009 prescriptions which were called in by Linda. Indeed, Respondent denied having issued any of the temazepam prescriptions. *Id.* at 315. He also testified that Linda had denied authorizing the prescriptions and stated that he believed her. *Id.* at 330–31. However, when asked if someone in his office had authorized the prescriptions, Respondent replied that he ''ha[d] no idea what happened'' and did not ''know anything about it.'' *Id.* at 270.

Respondent acknowledged that his daughter had a drug abuse problem and had undergone treatment shortly before the hearing in this matter. *Id.* at 315. Respondent further testified that his daughter had worked at his office,

[9] On April 27, 2009, the same day, another prescription (for tramadol) was called in to a CVS Pharmacy by ''Linda'' for Respondent's daughter. GX 10, at 1.

[10] According to a representative of the hospital, the spreadsheets showed hospital orders that ''were placed into the system by a pharmacist and were assigned to [Respondent] as the attending physician.'' Tr. 30.

With respect to the hospital orders, Respondent contends that the reports provided by the hospital are unreliable because a patient may have had both an attending and an admitting physician, each of whom could have issued an order for a controlled substance. Resp. Br. 9. The hospital representative further testified that the practice of the pharmacy department was to list the attending physician as the prescriber unless the signature of the prescribing physician was legible. Tr. 77–79. In addition, the hospital representative testified that ''[r]esidents do not have independent prescribing authority at the hospital'' and that any orders placed by a resident had ''to be cosigned by the attending physician'' that the order is assigned to. *Id.* at 32–33.

While Respondent testified that ''there are times when I'll call in and there will be a resident or he'll call me and ask me what I think, and I'll tell him what to do'' and ''[t]here are various ways to order things,'' *id.* at 278, as found above, residents did not have independent prescribing authority at the hospital. Likewise, Respondent was required to approve any order called or faxed in by a nurse. *Id.* at 59. Moreover, Respondent offered no testimony that any of the hospital orders were authorized by another physician who had independent prescribing authority.

It is further noted that the hospital representative testified that he had ''one hundred percent confidence'' in the accuracy of the spreadsheets, *id.* 57–58; he also testified that he had retrieved the medical files for seven of the patients and confirmed that Respondent had actually signed the forms ordering controlled substances for them. *Id.* at 60–62. Six of these orders cover the period following the date on which Respondent surrendered his registration and included two orders from May and June 2010. *See* GX 36. Moreover, a further spreadsheet listed multiple orders that were issued in April 2011.

In her decision, the ALJ noted in a footnote that the ''[t]he parties dispute the number of hospital orders issued by Respondent.'' ALJ, at 13 & n.8. However, as ultimate factfinder, I reject Respondent's various contentions as to the reliability of the spreadsheet. As explained above, I find that Respondent issued thirty-four hospital orders for controlled substances following his surrendering of his registration.

including during the period in which he was an inpatient at Behavioral Health and that she was authorized to call in prescriptions. *Id.* at 316; 328–29. However, when asked if he thought it was ''a good idea'' to authorize his daughter to call in prescriptions ''when she had a drug problem,'' Respondent asserted that ''[n]obody was authorized to refill narcotic prescriptions at all.'' *Id.* at 329; *see also id.* at 335.

Moreover, when asked how he monitored his staff to ensure that this did not happen, Respondent replied: ''Well it's a matter of trust. How would you know?'' and added that ''[t]he only way you would know is if you get a fax that something was called in that I didn't authorize.'' *Id.* at 329. Respondent then acknowledged that his office staff had access to his DEA number, *id.* at 330, and that while he would ''absolutely'' fire an employee who was inappropriately using his DEA number, there was not enough evidence to convince him that any of his employees had actually called in the prescriptions with his surrendered number. *Id.* at 332. Respondent also testified that his daughter no longer works for him. *Id.* at 337.

Respondent did admit to having issued the Androgel prescriptions for both D.S. and himself. *Id.* at 273. Respondent claimed that he did not realize that Androgel is a controlled substance, but testified that he was wrong to have issued the prescriptions and said he was ''sorry.'' *Id.* at 274.

As for the hospital orders, Respondent asserted that he ''was a staff physician'' at AtlantiCare. *Id.* at 275. While Respondent then acknowledged that his status as ''a staff physician'' did not mean that he was an employee, he then claimed that ''when I'm on call, I'm considered an employee.'' *Id.* at 276. However, according to the letter submitted by AtlantiCare's Associate General Counsel in response to the Government's subpoena for the records of Respondent's patients and hospital orders, Respondent was not employed by AtlantiCare. GX 35, at 1. Indeed, Respondent testified that he was ''self-employed.'' Tr. 250.

Respondent also testified that he ''felt obliged to treat'' the hospital patients and that while ''looking back * * * it's kind of a silly thing to do * * * I had no else to ask to treat these people. I was responsible for them. That was my job.'' Tr. 309. Respondent's counsel then asked him if he was ''consciously violating [his] lack of a DEA license?'' *Id.* Respondent replied: ''Not really. I really felt I was acting under the auspices of the hospital and in the patient's best interest, and that's the way I was trained. The patients always come first.'' *Id.* at 309–10. However, an employee of AtlantiCare testified that it has physicians known as hospitalists who were available to order any controlled substances necessary to treat Respondent's patients. *Id.* at 81. Moreover, when asked whether the effect of his surrendering his registration was that he was ''not allowed to prescribe,'' Respondent acknowledged that this was ''correct'' and added that he did not think he was allowed to administer controlled substances. Tr. 251.

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,* 68 FR 15227, 15230 (2003). I may rely on any one or a combination of factors and may give each factor the weight I deem appropriate in determining whether to revoke an existing registration or to deny an application for a registration. *Id.* Moreover, I am ''not required to make findings as to all of the factors.'' *Hoxie* v. *DEA,* 419 F.3d 477, 482 (6th Cir. 2005); *see also Morall* v. *DEA,* 412 F.3d 165, 173–74 (D.C. Cir. 2005).

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, the burden then shifts to the applicant to ''present sufficient mitigating evidence'' to show why he can be entrusted with a 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 [his] actions and demonstrate that [he] 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).

Factor One—The Recommendation of the State Licensing Board

The ALJ found that this factor supported granting Respondent's application. More specifically, the ALJ noted that the PAP is actively monitoring Respondent's compliance with his aftercare plan and that he remains subject to UDSs. ALJ at 23. Moreover, in the event of a positive test result for a drug which has not been prescribed to him, his state license is subject to suspension.[11] Also, with respect to his writing of tramadol prescriptions in his daughter's name and his positive urine screens for tramadol, the ALJ noted that he had appeared in front of the State Board and that the Board had declined to ''taken any adverse action.'' *Id.* The ALJ thus concluded that the Board's action, ''although not dispositive, deserve[s] consideration in determining the public interest.'' *Id.* The ALJ thus concluded ''that the Board's recommendation, in light of the overlapping facts it considered, weighs in favor of the Respondent's registration.[12]'' ALJ at 23–24.

Were this case limited to Respondent's prescribing of tramadol (which is not a controlled substance), I would likely adopt the ALJ's conclusion

[11] Citing the testimony of a PAP professional, the ALJ found that ''[i]f an illegitimate positive urine test result is reported, the Board will suspend the Respondent's license.'' ALJ at 23. However, while ''[a]ny non-prescribed positive test would result in an immediate notification to the Board,'' RX 11, at 1; it seems likely that the Board retains discretion as to whether to suspend his license.

[12] It is noted that the Board itself has made no recommendation to DEA in this matter and there is no evidence that the Assistant Director of the PAP is authorized to make recommendations on behalf of the Board. In discussing this factor, I assume without deciding that the Board's continuation of Respondent's license constitutes a recommendation of the state licensing or disciplinary authority as contemplated by 21 U.S.C. 823(f)(1).

as to the weight to be given this factor. However, while Respondent's self-prescribing and fraudulent prescribing to his daughter of tramadol may have been considered by the Board, as explained below, the record here contains substantial evidence of multiple violations of the Controlled Substances Act. Thus, not only did the state board not consider the entire scope of Respondent's misconduct, DEA has held that it has separate oversight responsibility (apart from that which is vested in state authorities) with respect to the handling of controlled substances and a statutory obligation to make its independent determination as to whether granting a registration would be consistent with the public interest. *See Jayam Krishna-Iyer,* 74 FR 459, 461 (2009); *Mortimer B. Levin,* 55 FR 8209, 8210 (1990). Thus, while Respondent's continued licensure by the State renders him eligible to hold a DEA registration,[13] this factor neither supports nor weighs against a finding that granting his application would be consistent with the public interest.[14] *See* 21 U.S.C. 823(f).

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

The ALJ found that factors two and four support the denial of Respondent's application. *See* ALJ at 24–25. I agree noting that the record establishes that Respondent has committed numerous violations of the CSA and has only accepted responsibility for a small portion of them.

First, Respondent issued prescriptions for schedule II controlled substances including Roxicodone (oxycodone) 15 mg in the name of his deceased mother-in-law to obtain drugs which he personally abused. Moreover, Respondent engaged in this conduct for a period of approximately six years. In issuing these prescriptions, Respondent committed felony violations of federal law. *See* 21 U.S.C. 843(a)(3) (''It shall be unlawful for any person knowingly or intentionally * * * to acquire or obtain possession of a controlled substance by misrepresentation, fraud, forgery, deception, or subterfuge[.]'').[15]

Second, on February 20, 2009, Respondent voluntarily surrendered his registration, thereby relinquishing his authority to prescribe, dispense, and administer controlled substances. Respondent nonetheless proceeded to issue numerous prescriptions and/or hospital orders for controlled substances. Respondent's conduct in doing so also violated federal law.

Under federal law, ''[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). *See also* 21 CFR 1301.11(a) (''Every person who manufactures, distributes, [or] dispenses * * * any controlled substance * * * shall obtain a registration unless exempted by law or pursuant to [21 CFR] 1301.22 through 1301.26.''). In addition, ''[e]xcept as authorized by [the CSA], it [is] unlawful for any person knowingly or intentionally * * * to distribute [or] dispense a controlled substance.'' 21 U.S.C. 841(a)(1).

It is undisputed that following the surrender of his registration, Respondent issued prescriptions both to himself and a patient for Androgel (testosterone), an anabolic steroid and a schedule III controlled substance. In his testimony, Respondent maintained that he did not know that Androgel is a controlled substance. The ALJ was not, however, favorably impressed by this testimony, noting that ''even if true, such denial does not relieve the Respondent from his responsibility to know such facts in the practice of his profession.'' ALJ at 24. I agree with the ALJ. Indeed, given that Respondent testified that prescribing testosterone was his ''specialty'' and that ''[p]art of urology [his practice specialty] is to treat male hypogonadism,'' Respondent has no excuse for not knowing that testosterone is an anabolic steroid and a controlled substance. *See* 21 U.S.C. 802(41) (''The term 'anabolic steroid' means any drug or hormonal substance, chemically and pharmacologically related to testosterone[.]''); *id.* § 812(c) Schedule III(e). However, Respondent did acknowledge his wrongdoing in having issued these prescriptions.

The same cannot be said for his misconduct in issuing hospital orders for controlled substances. As found above, for more than two years after he surrendered his registration, Respondent issued hospital orders for controlled substances; this conduct was still occurring up until a month before the hearing in this matter. Moreover, while the Show Cause Order did not specifically refer to the hospital orders, it did allege that he had violated federal law and DEA regulations by authorizing prescriptions without a registration. ALJ Ex. 1, at 2 (citing 21 U.S.C. 822 and 841(a); 21 CFR 1301.11 and 1301.13). Yet for months after being served with the Show Cause Order, Respondent continued to issue hospital orders without a registration.

In defense of his actions, Respondent contends that there was no one else who could treat his patients and that he was acting in their best interests. While one would expect nothing less from a physician than to act in the best interest of his patients, this does not excuse his violations, and in any event, other record evidence establishes that AtlantiCare has physicians on staff who could have legally prescribed controlled substances to his patients.

Respondent also attempted to justify the violations contending that he believed that: (1) He acted as an employee of the hospital when he was on call, and (2) he was ''acting under the auspices of the hospital.'' Tr. 309–10. As to the first contention, Respondent conceded that he was self-employed and not an employee of the hospital.

As for the second contention, it is true that under federal law and DEA regulations, ''[a]n individual practitioner who is an agent * * * of a hospital, may, when acting in the normal course of business * * *, administer, dispense, or prescribe controlled substances under the registration of the hospital * * * which is registered in lieu of being registered himself * * * provided'' six conditions are met. 21 CFR 1301.22(c); *see also* 21 U.S.C. 822(c). While Respondent met some of these conditions (in that there is no evidence that he acted outside of

[13] *See* 21 U.S.C. 823(f) (''The Attorney General shall register practitioners * * * to dispense * * * controlled substances . . . if the applicant is authorized to dispense * * * controlled substances under the laws of the State in which he practices.''); *id.* § 802(21) (''The term 'practitioner' means a physician * * * licensed, registered, or otherwise permitted, by the * * * jurisdiction in which he practices * * * to distribute, dispense, [or] administer * * * a controlled substance in the course of professional practice or research.'').

[14] It is also noted that Respondent has not been convicted of an offense related to the distribution or dispensing of controlled substances (factor three). However, because there are multiple reasons why an applicant or registrant may not have been convicted or even prosecuted for such an offense, the absence of such a conviction ''is of considerably less consequence in the public interest inquiry.'' *Krishna-Iyer,* 74 FR at 461; *Edmund Chein,* 72 FR 6580, 6593 n.22 (2007), *pet. for rev. denied* 533 F.3d 828 (D.C. Cir. 2008). Accordingly, this factor is not dispositive.

[15] In his post-hearing brief, Respondent argues that his ''overwhelming positive experience, totaling over 30 years as a specialist in the field of urology * * * should be a significant consideration'' in his favor. Resp. Prop. Findings & Conclusions of Law, at 14. Contrary to Respondent's assertion, factor two does not provide for an inquiry into Respondent's experience as a physician (which is beyond the expertise of this Agency) but only his experience in dispensing controlled substances. On that count, as found above, Respondent's experience is marked by his extensive and egregious misconduct in writing fraudulent prescriptions and by issuing numerous prescriptions and hospital orders without a registration.

the usual course of professional practice in issuing the orders and that he was authorized to prescribe controlled substances by the State, *see id.* 1301.22(c) (1) & (2)), Respondent produced no evidence that AtlantiCare authorized him ''to administer, dispense or prescribe controlled substances under the hospital['s] registration.'' *Id.* 1301.22(c)(5). Respondent therefore cannot credibly claim that he acted as an agent of the hospital.

With respect to Respondent's testimony regarding the hospital orders, the ALJ noted that it was ''unfortunate[ ] [that] the Respondent denied these violations.'' ALJ at 24–25. Whether it is fortunate or unfortunate is neither here nor there. It is, however, a manifestation that Respondent does not accept responsibility for a significant part of the misconduct which was proved on this record.[16] Moreover, these violations were not limited in scope but continued for more than two years after Respondent surrendered his registration.

As for the various controlled substance prescriptions that were issued in the names of Respondent's wife, daughter, and former son-in-law following the surrender of his registration, the ALJ found ''it credible that [he] did not place phone-in orders for controlled substances during that time.'' ALJ at 25. However, the ALJ found that ''Respondent left his prescription pads with his controlled substances registration number at the office during his absence'' and that ''[s]omeone utilized that number to call in prescriptions for controlled substances.'' *Id.* Under DEA precedent, a practitioner is strictly liable for misuse of his registration by his employees. *Edmund Chein,* 72 FR 6580, 6593 (2007) (citing *Leonard Merkow,* 60 FR 22075, 22076 (1995)), *pet. for rev. denied* 533 F.3d 828 (D.C. Cir. 2008).

Moreover, even accepting the ALJ's credibility finding that Respondent did not call in the prescriptions during the period in which Respondent was an inpatient at Behavioral Health, as found above, additional controlled substance prescriptions were either called-in or faxed-in from his office (for his daughter and son-in-law) after he returned from rehab. In his testimony, Respondent denied having authorized these prescriptions. It is unclear, however, whether the ALJ found this testimony credible.[17] *See* ALJ at 10–11 (noting Respondent's denial of having authorized April 2009 temazepam prescription for his daughter yet not making credibility finding as she did with other findings of fact); *id.* at 12 (noting that Respondent denied authorizing the July 2009 temazepam prescription for his son-in-law but not making credibility finding).

However, even if it is true that Respondent did not authorize these prescriptions, he ''ha[d] no idea'' as to how the prescriptions were authorized and who had called or faxed them in to the respective pharmacies. Likewise, while Respondent testified that he would ''absolutely'' fire an employee who was inappropriately using his DEA number, he then asserted that there was not enough evidence to convince him that any of his employees had actually called in the prescriptions with his former number.[18]

Obviously, someone in his office called or faxed in the prescriptions. As noted above, under Agency precedent, Respondent is responsible for violations of the CSA committed by his employees and his practice's failure to comply with the Act. *Chein,* 72 FR at 6593. Having failed to explain why the temazepam prescriptions were called in, Respondent has offered no credible assurance that similar acts will not occur in the future.

Accordingly, as did the ALJ, I conclude that the Government's evidence pertaining to factors two and four makes out a *prima facie* case that granting Respondent's application would be inconsistent with the public interest. *See* ALJ at 25 (holding that ''grounds do exist for denying the Respondent's'' application).

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

With respect to factor five, the ALJ noted that ''Respondent has now had two relapses in his history of drug addiction'' and that ''[h]is pattern of prescribing medications for family members and then consuming them himself continued with [his] prescribing of [t]ramadol for his daughter and then consuming some of the medications himself.'' ALJ at 26. The ALJ further found that ''when first confronted with the information that DEA believed the Respondent had engaged in such conduct, the Respondent lied to the DEA agent and denied consuming such medication himself.'' *Id.* The ALJ thus noted that Respondent's ''conduct is not consistent with the responsibilities of a DEA registrant.'' *Id.* I agree with the ALJ that substantial evidence supports both the findings that he consumed some of the tramadol he prescribed in his daughter's name and then lied to DEA Investigators when he denied having done so.

However, the ALJ then noted that Respondent had presented ''mitigating evidence in the form of his active participation in his recovery'' and that the PAP's assistant director testified that Respondent is in ''sustained full remission.'' *Id.* at 26–27. The ALJ also noted that Respondent had acknowledged his wrongdoing in prescribing testosterone and had provided assurances of his future compliant behavior including that ''he would no longer allow his staff to phone in or fax in prescriptions for controlled substances and ''his daughter would no longer work in his office.'' [19] *Id.* at 27.

In his post-hearing brief, Respondent contends ''[t]hat DEA['s] argu[ment] that [his application] should be denied for being prescribed tramadol is by definition arbitrary and capricious.'' Resp. Prop. Findings of Fact, Conclusions of Law, and Argument, at

[16] To make clear, I acknowledge that there is no evidence that any of the hospital orders lacked a legitimate medical purpose. Nonetheless, federal law prohibits the dispensing of a controlled substance except as authorized by the CSA.

[17] For example, in her discussion of factors two and four, the ALJ wrote with respect to the prescriptions that were called in when he was at Behavioral Health, ''I find it credible that the Respondent did not place phone-in orders for controlled substances during that time.'' ALJ at 25. The ALJ did not explain whether she found credible Respondent's denials of having authorized the temazepam prescriptions that were issued for his daughter and ex son-in-law following his return from rehab. *Id.*

It is not entirely clear why the ALJ failed to address in her discussion of the public interest factors the prescriptions which were authorized following his return. However, her opinion suggests that she did not do so because ''[t]he majority of these prescriptions were initially phoned in while the Respondent was receiving inpatient treatment.'' ALJ at 25. Even so, the record shows that there were multiple prescriptions with refills issued following Respondent's return from inpatient treatment. Unlike the ALJ, I decline to ignore the evidence regarding these prescriptions and Respondent's explanation (or lack thereof) regarding why they were issued.

[18] As found above, in a December 2009 interview Respondent admitted that his daughter had a drug problem but that ''he did not realize how bad [her] problem was until he got out of drug rehabilitation * * * and became sober.'' GX 18, at 7. The Government did not, however, further clarify whether Respondent was aware of his daughter's drug problem before he went to rehab (even if he then did not realize ''how bad'' it was) nor the approximate date on which he finally realized ''how bad'' it was. Thus, I do not address the propriety of Respondent's having authorized his daughter to call in prescriptions.

[19] The ALJ did not, however, make a finding as to whether this factor supports or weighs against granting Respondent's application. ALJ at 27–28. However, in her conclusion and recommendation, the ALJ, while acknowledging that ''[d]enial of the Respondent's application can be justified by this record,'' recommended that ''a less severe action be taken.'' *Id.* at 28.

16. Respondent notes that ''tramadol is not even a controlled substance'' and that he ''is entitled to pain relief.'' *Id.* at 16–17.

It is undeniable that Respondent is entitled to be treated (and receive lawfully issued prescriptions) for a legitimate pain condition.[20] However, the evidence shows that Respondent wrote numerous prescriptions in his daughter's name to obtain the drugs for his own use and thereby committed prescription fraud. *See* N.J. Stat. Ann. § 2C:35–10.5(d). Moreover, as found above under factors two and four, Respondent had previously obtained controlled substances by writing fraudulent prescriptions in the name of his deceased mother-in-law and did so for years. Thus, even though tramadol is not a controlled substance, Respondent's continuing to write fraudulent prescriptions even after he was confronted by DEA personnel about the fraudulent prescriptions he wrote for controlled substances is properly considered in assessing the likelihood that he will comply with the CSA were he granted a new registration. *See Paul Weir Battershell,* 76 FR 44359, 44368 (2011) (holding that violation of Federal law for introducing a misbranded drug into interstate commerce was not dispositive but could be considered under factor five ''for the limited purpose of assessing the likelihood of Respondent's future compliance with the CSA''); *Wonderyears, Inc.,* 74 FR 457, 458 n.2. (2009) (noting that violations of federal and state laws in distributing and importing a non-controlled drug were ''relevant in assessing whether [pharmacy] would comply with the'' CSA). *See also Terese, Inc., D/B/A Peach Orchard Drugs,* 76 FR 46843, 46848 (2011) (noting that while agency case law interpreting factor five ''has generally recognized that the misconduct must be related to controlled substances * * * there may be other acts, which do not directly involve controlled substances, but which threaten public health and safety and create reason to conclude that a person will not faithfully adhere to [his] responsibilities under the CSA''). The commission of prescription fraud clearly has a sufficient nexus to a registrant's obligations under the CSA to warrant consideration under factor five. *See* 21 U.S.C. 843(a)(3).

As noted above, the ALJ also found that Respondent had lied to the DEA Investigators ''when first confronted'' by them about whether he was using the tramadol he obtained by issuing prescriptions in his daughter's name. ALJ at 26. It further follows that Respondent gave false testimony under oath in this proceeding when he denied having ever admitted to the PAP Director that he had used some of the tramadol obtained from these prescriptions and then added that: ''I never used [t]ramadol written in my daughter's name.'' Tr. 323. Respondent's lack of candor both during the investigation and at the hearing is an important factor in the public interest determination. *See Hoxie,* 419 F.3d at 483 (''DEA properly considers the candor of the physician and his forthrightness in assisting in the investigation and admitting fault important factors in determining whether the physician's registration'' is consistent with the public interest.'');[21] *see also Edmund Chein* v. *DEA,* 533 F.3d 828 (D.C. Cir. 2008) (affirming order revoking practitioner's registration and denying application noting physician's ''continued dispensing of controlled substances even after his DEA registration was suspended'' and failure to ''accept[ ] responsibility for his misconduct'').

To be sure, Respondent presented substantial evidence that he is currently in remission. If the proven misconduct was limited to Respondent's self-abuse of controlled substances, the ALJ's recommendation that I grant him a restricted registration might be well taken. But it is not. While Respondent acknowledged his wrongdoing with respect to his issuance of the testosterone prescriptions without a registration, he failed to do so with respect to his issuance of hospital orders notwithstanding that he issued them for more than two years following the surrender of his registration and continued doing so even after being served with the Show Cause Order which notified him that his issuance of controlled substances without a registration was a violation of federal law. *See Hoxie,* 419 F.3d at 483 (noting that ''DEA properly considers * * * admitting fault [to be an] important factor[ ]'' in public interest determination); *see also Medicine Shoppe,* 73 FR at 387; *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).

Also, in his own words, Respondent ''had no idea'' and ''did not know anything about'' why the temazepam prescriptions for his daughter and former son-in-law, which he denied issuing, continued to be called or faxed in to pharmacies after his return from inpatient treatment. Thus, even if it is true that Respondent did not authorize the prescriptions, he has failed to establish that this problem will not occur in the future. Respondent has therefore failed to ''present sufficient mitigating evidence'' to show why he can be entrusted with a new registration. *Medicine Shoppe-Jonesborough,* 73 FR at 387 (quoting *Jackson,* 72 FR at 23853 (quoting *Leo R. Miller,* 53 FR at 21932 (1988))). Respondent's conduct in issuing fraudulent prescriptions and giving less than truthful statements and testimony reinforces this conclusion.

Accordingly, I reject the ALJ's recommended sanction[22] and will deny Respondent's application.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) and 28 CFR 0.100(b),

[20] In its Exceptions, the Government notes that ''Respondent was concurrently receiving tramadol prescriptions from two different physicians.'' Exceptions at 2. While the Government notes that ''Respondent explained that he was being treated for a different medical condition by each physician,'' it then contends that ''Respondent did not contest the fact that neither doctor knew about the other or that Respondent was receiving the same medication from each doctor.'' *Id.* The Government then asserts that it ''does not believe that Respondent demonstrated the legitimacy of his prescriptions, because he failed to fully inform his treating physicians of his medical condition, of his treatment by the other physician and of his other prescriptions.'' *Id.* (citing GX 18, ¶ 11).

It is noted, however, that the Government called Respondent as a witness and yet never asked him whether he informed his treating physicians that he was receiving prescriptions from another physician. Moreover, the Government did not introduce any medical records maintained by the physicians on Respondent which may have shown that Respondent did not disclose that he was being treated by other doctors, and Dr. M.'s statements (which were related in GX 18) that he did not know that Respondent was seeing Dr. C. and receiving tramadol prescriptions were unsworn and not corroborated by any other evidence of record.

However, one of Respondent's Exhibits shows that on July 28, 2009 he was admonished by the Executive Medical Director of the PAP for ''his self-prescribing'' and told ''to get his treating physician, Dr. [B.], his orthopedic surgeon, to write any future prescriptions.'' RX 8, at 19; *see also id.* at 18. (Sept. 16, 2009 memo from Executive Medical Director, PAP, to State Board of Medical Examiners) (Respondent ''was instructed to have his orthopedic surgeon, Dr. [B.], write for any medication he needed for pain (7/28/09).''). Yet after that date, Respondent obtained prescriptions for tramadol from both Dr. C. (on Aug. 10) and Dr. M. (on Aug. 20). *See* GXs 13 & 14. While Respondent testified that Dr. M. and Dr. B. were in the same group, Tr. 260–61, he offered no evidence that Dr. C. was as well. This suggests that Respondent did not comply with the PAP Executive Director's instruction.

[21] I thus reject Respondent's contention that he has cooperated with DEA and ''exhibited'' candor ''throughout the process, including at the hearing.'' Resp. Prop. Findings at 16.

[22] As the ALJ herself recognized, the Government ''presented preponderating evidence of * * * Respondent's illegal conduct in handling controlled substances after the voluntary surrender of his DEA registration'' and the ''[d]enial of [his] application can be justified by this record.'' ALJ at 28.

I order that the application of John V. Scalera, M.D., for a DEA Certificate of Registration as a practitioner, be, and it hereby is, denied. This order is effective March 25, 2013.

Dated: February 12, 2013.

Michele M. Leonhart,

Administrator.

[FR Doc. 2013–03879 Filed 2–20–13; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances; Notice of Application; Meda Pharmaceuticals, Inc.

Pursuant to Title 21 Code of Federal Regulations 1301.34 (a), this is notice that on December 4, 2012, Meda Pharmaceuticals, Inc., 705 Eldorado Street, Decatur, Illinois 62523, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as an importer of Nabilone (7379), a basic class of controlled substance listed in schedule II.

The company plans to import the listed controlled substance as a finished drug product in dosage form for distribution to its customers.

Any bulk manufacturer who is presently, or is applying to be, registered with DEA to manufacture such basic classes of controlled substances listed in schedule II, which falls under the authority of section 1002(a)(2)(B) of the Act (21 U.S.C. 952(a)(2)(B)) may, in the circumstances set forth in 21 U.S.C. 958(i), file comments or objections to the issuance of the proposed registration and may, at the same time, file a written request for a hearing on such application pursuant to 21 CFR 1301.43 and in such form as prescribed by 21 CFR 1316.47.

Any such written comments or objections should be addressed, in quintuplicate, to the Drug Enforcement Administration, Office of Diversion Control, Federal Register Representative (ODL), 8701 Morrissette Drive, Springfield, Virginia 22152; and must be filed no later than March 25, 2013.

This procedure is to be conducted simultaneously with, and independent of, the procedures described in 21 CFR 1301.34(b), (c), (d), (e), and (f). As noted in a previous notice published in the **Federal Register** on September 23, 1975, 40 FR 43745–46, all applicants for registration to import a basic classes of any controlled substances in schedules I or II are, and will continue to be, required to demonstrate to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, that the requirements for such registration pursuant to 21 U.S.C. 958(a); 21 U.S.C. 823(a); and 21 CFR 1301.34(b), (c), (d), (e), and (f) are satisfied.

Dated: February 8, 2013.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 2013–03905 Filed 2–20–13; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances; Notice of Application; Mallinckrodt, LLC.

Pursuant to Title 21 Code of Federal Regulations 1301.34(a), this is notice that on November 30, 2012, Mallinckrodt, LLC., 3600 North Second Street, St. Louis, Missouri 63147, made application by renewal to the Drug Enforcement Administration (DEA) for registration as an importer of the following basic classes of controlled substances:

Drug	Schedule
Phenylacetone (8501)	II
Coca Leaves (9040)	II
Opium, raw (9600)	II
Poppy Straw Concentrate (9670)	II

The company plans to import the listed controlled substances for the manufacture of controlled substances in bulk for distribution to its customers.

No comments, objections, or requests for any hearings will be accepted on any application for registration or re-registration to import crude opium, poppy straw, concentrate of poppy straw or coca leaves. Comments and requests for hearings on applications to import narcotic raw material are not appropriate, in accordance with 72 FR 3417 (2007).

In reference to Phenylacetone (8501), the company plans to import the controlled substance for the bulk manufacture of amphetamine products for sale to its customers. Any bulk manufacturer who is presently, or is applying to be, registered with DEA to manufacture such basic classes of controlled substances listed in schedules I or II, which fall under the authority of section 1002(a)(2)(B) of the Act (21 U.S.C. 952(a)(2)(B)) may, in the circumstances set forth in 21 U.S.C. 958(i), file comments or objections to the issuance of the proposed registration and may, at the same time, file a written request for a hearing on such application pursuant to 21 CFR 1301.43 and in such form as prescribed by 21 CFR 1316.47.

Any such written comments or objections should be addressed, in quintuplicate, to the Drug Enforcement Administration, Office of Diversion Control, Federal Register Representative (ODL), 8701 Morrissette Drive, Springfield, Virginia 22152; and must be filed no later than March 25, 2013.

This procedure is to be conducted simultaneously with, and independent of, the procedures described in 21 CFR 1301.34(b), (c), (d), (e), and (f). As noted in a previous notice published in the **Federal Register** on September 23, 1975, 40 FR 43745, all applicants for registration to import a basic class of any controlled substance in schedule I or II are, and will continue to be, required to demonstrate to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, that the requirements for such registration pursuant to 21 U.S.C. 958(a); 21 U.S.C. 823(a); and 21 CFR 1301.34(b), (c), (d), (e), and (f) are satisfied.

Dated: February 8, 2013.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 2013–03898 Filed 2–20–13; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances; Notice of Application; Caraco Pharmaceutical Laboratories, LTD.

Pursuant to Title 21 Code of Federal Regulations 1301.34 (a), this is notice that on November 22, 2012, Caraco Pharmaceutical Laboratories, Ltd., 270 Prospect Plains Road, Cranbury, New Jersey 08512, made application to the Drug Enforcement Administration (DEA) to be registered as an importer of Fentanyl (9801), a basic class of controlled substance listed in schedule II.

The company plans to import the listed controlled substance in finished dosage form for clinical trials, and research.

The import of the above listed basic class of controlled substance is granted only for analytical testing and clinical trials. This authorization does not extend to the import of a finished FDA approved or non-approved dosage form