A. Bergman, M.D., 70 FR 33,193 (DEA 2005) (denying respondent's request for temporary suspension and granting motion for summary disposition where respondent lacked state authority); *see also Roy Chi Lung,* 74 FR 20,346, 20,346 (DEA 2009) ("Respondent * * * lack[s] authority to handle controlled substances in California * * * Respondent is therefore *not entitled* to maintain his DEA registration.") (emphasis supplied); *Sheran Arden Yeates, M.D.,* 71 FR 39,130, 39,131 (DEA 2006) ("DEA does not have statutory authority under the Controlled Substances Act to maintain a registration if the registrant is without state authority to handle controlled substances in the state in which he practices."). *See generally* 21 CFR 1301.01(17) (2010) (defining "individual practitioner" as a person, other than a pharmacist, pharmacy or institutional practitioner, possessing state authority to dispense a controlled substance in the course of a professional practice). Under the circumstances discussed above, I conclude that further delay in ruling on the Government's Motion for Summary Disposition is not warranted.

Recommended Decision

I grant the Government's motion for summary disposition and recommend that Respondent's DEA COR BS5109889 be revoked and any pending applications denied.

Dated: November 2, 2010

Timothy D. Wing,

Administrative Law Judge.

[FR Doc. 2011–7016 Filed 3–24–11; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 09–35]

Robert L. Dougherty, M.D.; Denial of Application

On March 16, 2009, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Robert L. Dougherty, M.D. (Respondent), of Poway, California. ALJ Ex. 1. The Show Cause Order proposed the denial of Respondent's pending application for a DEA Certificate of Registration as a practitioner, on the ground that his "registration would be inconsistent with the public interest, as that term is used in 21 U.S.C. 823(f)." *Id.* at 1.

The Show Cause Order alleged that on October 27, 1995, the DEA Deputy Administrator (DA) issued a Final Order revoking Respondent's registration based on his prescribing of controlled substances to three patients. *Id.* (citing 60 FR 55047). More specifically, the Show Cause Order alleged that the DA had "found that [Respondent's] prescribing of controlled substances to Patient #1 'on demand,' 'virtually upon request,' with 'virtually no scrutiny' and with 'virtually no records or monitoring' demonstrated a gross lack of judgment and showed that some of the prescriptions issued were outside the course of professional practice." *Id.*

With regard to Patient #2, the Show Cause Order alleged that the DA "found that * * * Respondent's prescribing of controlled substances to an admitted drug abuser showed a disregard of the requirements for detailed attention to individual patient behavior necessary for the dispensing of controlled substances." *Id.* With regard to Patient #3, the Show Cause Order alleged that the DA found that Respondent's "prescribing of an excessive number of refills of controlled substances over a six month period, without requiring a clinical examination or visit, demonstrated a reckless disregard for medical standards in dispensing controlled substances and violations of Federal regulations and state law[,]" and that he "had violated Federal and state record-keeping requirements for controlled substances." *Id.*

Finally, the Show Cause Order alleged that on June 25, 1997, the Medical Board of California (MBC) issued a decision which "severely criticized [Respondent's] treatment of [P]atient #1." *Id.* The Order alleged that the MBC had found that Respondent "had engaged in repeated negligent acts and had demonstrated incompetence in [his] treatment of the patient[,]" and that "[t]his misconduct included prescribing controlled substances to an obvious drug addict." *Id.* at 1–2.

Respondent requested a hearing on the allegations, and the matter was placed on the docket of the Agency's Administrative Law Judges (ALJ). Following pre-hearing procedures, on March 10, 2010, an ALJ conducted a hearing on the matter in San Diego, California, at which both parties called witnesses to testify and the Government introduced documentary evidence. Thereafter, both parties filed briefs containing their proposed findings of fact, conclusions of law, and argument.

On June 9, 2010, the ALJ issued her recommended decision (also ALJ). Therein, the ALJ found that the Government had "met its prima facie burden." ALJ at 22. However, the ALJ reasoned that all of the facts and circumstances should be considered including that Respondent's "mistakes" involved only "a very small portion of his patients," that one of the patients was a relative who has since died and that this "decreases the likelihood that similar circumstances would reoccur," and that Respondent's "mis-judgments were well intentioned." *Id.* at 22–24. Next, the ALJ reasoned that "there was controversy in the medical community with regards to his prescribing practices, and that his methods have since been adopted by the FDA, though not necessarily DEA," and that his prescribing methods, while "found to be objectionable over ten years ago * * * may, according to the record, arguably not be objectionable now." *Id.* at 24. The ALJ thus concluded that "the circumstances surrounding his prescribing practices have changed." *Id.*

Finally, the ALJ noted that in the 1995 Final Order, the Agency had made four summarized findings.[1] *Id.* at 25. While the ALJ noted that Respondent did not "completely acknowledge his past problems with refill practices with regards to Patient #2," she found it relevant that the ALJ who conducted the earlier hearing had "recognized discrepancies in the Government's evidence relating to how many refills were actually authorized." *Id.* With respect to the Agency's finding that Respondent failed "to act in a timely manner upon, and to take responsibility for, receipt of information given to him or to his staff concerning the forged prescriptions of Patient #3," the ALJ reasoned that "the record demonstrates that [he] received information about possibly forged prescriptions, made inquiries, questioned the patient, was deceived, and ultimately stopped prescribing to the patient." *Id.* at 26. Finally, with respect to Patient #1, the ALJ characterized the Agency's finding as that he had maintained an "inadequate treatment record." *Id.* at 26. Reasoning that "[t]here is no question that the Respondent demonstrated remorse with regards to his record-keeping," and that the "DA's summarized findings focused on record-keeping," the ALJ concluded that

[1] As the basis for rejecting the ALJ's recommended sanction of a one-year suspension and revoking Respondent's registration, the DA cited four findings: (1) Respondent's "failure to acknowledge the need for adequate recordkeeping to insure [sic] that controlled substances are not diverted"; (2) his "lack of remorse concerning his * * * unlawful recordkeeping and refill practices"; (3) his "failure to act in a timely manner upon, and to take responsibility for, receipt of information given him or to his staff concerning the forged prescriptions of Patient #3"; and (4) his "lack of acknowledgement that the inadequate treatment record of Patient #1 could have ultimately jeopardized that patient's welfare." 60 FR at 55051.

Respondent had generally accepted responsibility.[2] *Id.*

The ALJ thus concluded that while she did not "condone or minimize the seriousness of * * * Respondent's prior misconduct[,] * * * the circumstances, which existed at the time of the prior proceeding, have changed sufficiently to support a conclusion that Respondent's registration would be in the public interest." *Id.* at 28. While acknowledging that "Respondent failed to express remorse for the entirety of his prescribing practices," she recommended that I grant him a restricted registration. *Id.*

Thereafter, the Government filed Exceptions to the ALJ's recommended decisions. The record was then forwarded to me for Final Agency Action.

Having considered the record as a whole (including the ALJ's recommended decision), I agree with the ALJ's finding that the Government established a *prima facie* case to deny Respondent's application. However, I reject the ALJ's finding that Respondent has successfully rebutted the Government's *prima facie* case and will deny his application. As ultimate fact finder, I make the following findings of fact.

Findings

Respondent is a physician licensed by the Medical Board of California, GX 1, at 2. Respondent, who has been licensed since 1957, is board certified in Family Practice. Tr. 89. Respondent has taught pain management to Army hospital corpsmen as well as to U.S. Park Rangers, and served at two MASH hospitals in Korea. *Id.* at 90–91, 97.

The First DEA Proceeding

Respondent previously held a DEA Certificate of Registration as a practitioner. *Robert L. Dougherty, Jr., M.D.,* 60 FR 55047 (1995) (GX 7). However, on July 29, 1993, the Deputy Assistant Administrator, Office of Diversion Control, issued an Order to Show Cause which proposed the revocation of the registration he then held based on five separate allegations. *Id.* Respondent requested a hearing, and in July 1994, an Agency ALJ conducted a four-day hearing at which Respondent was represented by counsel and at which he testified and introduced documentary evidence. *Id.* Following the hearing, Respondent (and the Government) submitted briefs containing proposed findings of fact, conclusions of law, and argument. *Id.* Thereafter, the ALJ issued his decision, which found most of the allegations proved and recommended that Respondent's registration be suspended for a period of one year. *Id.* The Government filed Exceptions and Respondent filed a Response to the Government's Exceptions. *Id.* The record was then forwarded to the DA, who, on October 27, 1995, issued the Agency's Decision and Final Order which contained extensive factual findings. *Id.*

With respect to Patient #1, the DA credited the testimony of an expert in pain management who concluded that while Respondent's initial treatment of the patient was medically appropriate, "after Patient #1 moved into the Respondent's home in early 1990, the notations in his chart became sporadic, ending on December 3, 1991." 60 FR at 55048. Based on the Expert's testimony, the DA further found that "Respondent's standard of care as to Patient #1, to include a lack of a medical record showing [his] treatment, and the excessive amounts of prescribed medication between January 1990 and February 1992, 'fell below community standards for the average physician.'" *Id.* However, the DA also found "that the evidence 'does not support that the doctor was prescribing for an illegitimate purpose,' or that 'he was doing something dishonest,' but rather that such prescribing was not 'appropriate treatment' in this case." *Id.*

With respect to Patient #1, the DA further noted Respondent's testimony that "he altered his patient record practices in the case of Patient #1 after he moved into his home because he now saw him regularly and was able to closely observe him on a daily basis." *Id.* Respondent also conceded that he had provided samples of Xanax to Patient #1, but did not record doing so in his chart. *Id.* Respondent further admitted that he had prescribed schedule II drugs between April 1991 and March 1992, but generally did not record this in his chart. *Id.*

Finally, the DA found "that from mid-December 1991 to April 1992, Patient #1" would visit Respondent's office "to pick up prescriptions" but "'rarely ever' went into an examination room," and that "he would often call the Respondent's office and leave a message telling the Respondent what controlled substances to bring home." *Id.* The DA again credited the Expert's testimony that "such patient and physician behavior concerned him, because the patient's demands seemed to replace the physician's judgment." *Id.*

Concluding that Respondent dispensed to Patient #1 "on demand, virtually upon request, with virtually no security, and with virtually no records or monitoring in the early 1990s," as well as that it was his "practice of giving Patient #1 Xanax samples without documenting" this in his chart, the DA adopted the ALJ's conclusion that "Respondent's prescribing and dispensing to Patient #1 was 'outside the context of the Respondent's usual professional practice.'" *Id.* at 55049.

With respect to Patient #2, the DA found that "[o]n October 24, 1990, the Respondent issued [her] an original prescription for 30 dosage units of Vicodin, [that] he saw this patient again on November 14, 1990, and although [he] did not see this patient again until May 1, 1991, he authorized more than twenty refills from the October 24, 1990, prescription for Vicodin," the latter being a schedule III controlled substance. *Id.* at 55048. The DA also found that on October 24, 1990, Respondent "issued Patient #2 an original prescription for Darvocet-N 100 * * * and between that date and May 1, 1991, he authorized more than twenty refills of Darvocet, a medication containing propoxyphene napsylate, a Schedule IV controlled substance." *Id.*

The DA thus concluded that "the excessive number of refills [Respondent] provided Patient #2 over a six-month period of time without requiring a clinical examination or visit, demonstrates a reckless disregard for medical standards in dispensing controlled substances." *Id.* at 55049. Based on his finding that between October 24, 1990 and May 1, 1991, Respondent had authorized original prescriptions for both Vicodin and Darvocet-N, as well as more than twenty refills for each drug, the DA also concluded that Respondent had violated 21 CFR 1306.22(a), which prohibited (then as now) both the filling or refilling of a prescription for a schedule III or IV controlled substance "more than six months after the date on which such prescription was issued," as well as the refilling of a prescription "more than five times" during this period, after which a new prescription must be issued. *Id.* at 55050. The DA also concluded that Respondent violated Cal. Health and Safety Code § 11200, which provided that "[n]o person shall dispense or refill a controlled substance prescription more than six months after the date thereof or cause a prescription for a Schedule III or IV substance to be refilled in an amount in excess of a 120 day supply, unless renewed by the prescriber." *Id.*

As for Patient #3, the DA found that Respondent and the Government had stipulated that Patient #3 had forged prescriptions under Respondent's name on seven different dates between February 3 and April 21, 1992, resulting

in "a total of 396 dosage units of Lortab," a schedule III controlled substance, being dispensed to Patient #3. *Id.* at 55049. The DA also found that Respondent was notified that Patient #3 was forging prescriptions on at least three occasions between January 1990 and April 1992. *Id.* These included: (1) A January 1990 incident in which "a pharmacist contacted the Respondent's office about a forged prescription from Patient #3," (2) a February 6, 1992 letter "written to * * * Respondent informing him of a suspicious prescription written to Patient #3 despite Respondent's office's verification of the prescriptions which the pharmacist had filled," and (3) another pharmacist notifying Respondent in April 1992 "about forged prescriptions for a controlled substance for Patient #3." *Id.* The DA found that notwithstanding that Respondent had received this information, he "authorized the refills and continued to prescribe Lortab for Patient #3." *Id.*

The DA also found that Patient #3 had stated during an interview that "he had been a patient of the Respondent's from July 1990 to about June 1992, that he had told the Respondent of his past drug addiction problems, but that the Respondent continued to prescribe Lortab" to him. *Id.* Patient #3 "also stated that the Respondent talked to him about forged prescriptions, that he had denied forging the prescriptions, but that the Respondent had told him that he did not believe his denial. However, the Respondent continued prescribing Lortab even after this conversation." *Id.* Patient #3 further "stated that in June 1992 he stopped receiving treatment from the Respondent and that he went into a rehabilitation treatment center for 90 days to overcome his addiction to Lortab." *Id.*

The DA noted Respondent's testimony that "he believed Patient #3 had valid complaints of pain stemming from a history of back pain, that he never received a copy of a forged prescription regarding Patient #3, [and] that he did not see such a copy until June 1992, when he then realized Patient #3 had been deceiving him." *Id.* The DA also noted the Expert's opinion that "Respondent's prescribing practices were excessive with poor documentation of the need for those narcotics, [and] demonstrate[d] a lack of usual care and precaution in dealing with these kinds of prescriptions." *Id.*

The DA concluded that "the dispensing of a controlled substance in the quantities prescribed to Patient #3, a patient known to the Respondent as an admitted drug abuser, even after receiving warnings of forged prescriptions, demonstrates at least a lack of precaution, and more probably a disregard of the requirements for detailed attention to individual patient behavior necessary for the dispensing of controlled substances." *Id.* The DA further observed that this "create[d] grave doubt as to * * * Respondent's prescription practices to known drug abusers," and that while Respondent had been warned about Patient #3's conduct, there was no evidence that he had "ceased prescribing controlled substances to this patient until he obtained and documented accurate information about the amounts of such substances actually received by Patient #3 through the use of these forged prescriptions." *Id.* at 55051.

In addition, the DA found that Respondent had violated various recordkeeping requirements of both Federal and State law. *Id.* at 55050. These included 21 U.S.C. 827(a)(3), which requires that "every registrant * * * dispensing a controlled substance or substances shall maintain, on a current basis, a complete and accurate record of each substance * * * received, sold, delivered, or otherwise disposed of by him"; and subsection 827(b), which requires that records "contain such relevant information as may be required by, regulations of the Attorney General," that the records for narcotics "be maintained separately from all other records of the registrant" and those for non-narcotic controlled substances "be in such form that information required by the Attorney General is readily retrievable from the ordinary business records of the registrant"; and that records "be available for at least two years, for inspection and copying by officers or employees of the United States authorized by the Attorney General." 21 U.S.C. 827(b) (quoted at 60 FR 55050) (also citing 21 CFR 1304.04(a) and 1304.24; Cal. Health and Safety Code §§ 11190–92).[3] In addition, the DA found that between April 16 and July 23, 1990, Respondent had ordered Demerol and morphine on ten occasions, which are schedule II controlled substances, from a local pharmacy, but on April 24, 1992, he "was unable or unwilling to produce" the DEA Order Forms, even though under Federal regulations he was required to maintain these forms "separately from all other records" and to keep them "available for inspection for a period of 2 years." 60 FR at 55050. Summarizing his findings, the DA concluded that Respondent had shown "a blatant disregard for statutory provisions" which exist "to prevent the diversion of controlled substances to unauthorized individuals." *Id.*

Finally, the DA found (again based on the Expert's testimony) that Respondent had failed "to maintain accurate, current, and complete patient treatment records" for all three patients. *Id.* This was deemed actionable as "such other conduct which may threaten the public health or safety" (factor five), because if "Respondent suddenly fell ill, [the] treatment [of his patients by another physician] could be seriously impaired by * * * Respondent's shoddy documentation." *Id.* at 55050–51 (citation omitted).

The Medical Board Proceeding

On dates not established in the record, the MBC filed an Accusation, as well two Supplemental Accusations against Respondent. GX 8, at 3. The Accusation charged, *inter alia,* that he had violated California law by engaging in "repeated acts of clearly excessive prescribing," as well as that he had "dispen[sed] or furnish[ed] * * * dangerous drugs without a good-faith prior examination and medical indication therefor." *Id.* at 3 (citing Cal. Bus. & Prof. Code §§ 725, 4211). The Accusation also charged Respondent with violating state record-keeping requirements for schedule II controlled substances, *id.* (citing Cal. Health & Safety Code § 11190), as well having violated "various sections of Federal law, contained in the Code of Federal Regulations (CFR) relating to dispensing controlled substances." *Id.* All of the charges involved Respondent's "administration of certain drugs" to Patient #1. *Id.* at 4.

In May 1997, a State ALJ conducted a hearing, which lasted seven days. *Id.* at 2. In his Decision, the State ALJ made extensive findings regarding Respondent's prescribing practices between November 1991 and September 1995, which he characterized as "a graphic illustration of a practice without a plan" and as "a pattern of excess." *Id.* at 14–15. For example, the State ALJ found that "[d]uring January 1992, [R]espondent prescribed 360 Demerol 100 mg tablets, 200 Valium 10 mg tablets, 500 Percocet tablets, and 220 Xanax 2 mg tablets" to Patient #1. *Id.* at 15.

As other examples, the State ALJ found that between January and March

[3] The ALJ also observed that the MBC's decision, which found that Respondent's prescribing to Patient #1 showed "a 'pattern of excess' resulting in 'irrational polypharmacy,' * * * also states [that]: '[t]he most powerful tool in reducing polypharmacy is an accurate medical record. It is thus easy to see why the out of control polypharmacy [] existed.'" ALJ at 26 (citation omitted). The ALJ thus reasoned that these statements "reflect primarily on the Respondent's past-poor record-keeping[,]" for which he had demonstrated remorse. *Id.*

1994, Respondent prescribed to Patient #1: 672 Lorcet 10/650, 240 diazepam 10 mg, 56 Xanax 2 mg, 360 amitriptyline 50 mg, and 56 alprazolam 2 mg; and that between January and March 1995, he prescribed to Patient #1: 672 Lorcet 10/650, 240 diazepam 10 mg, 720 amitriptyline 50 mg, 240 alprazolam 2 mg, and 90 Prelu-2 105 mg (phendimetrazine). *Id.* The ALJ further found that between July and September 1995, Respondent prescribed to Patient #1: 784 Lorcet 10/650, 360 diazepam 10 mg, 720 amitriptyline 50 mg, 120 alprazolam 2 mg, and 90 Prelu-2 105 mg. *Id.* The ALJ also found that Respondent maintained no medical records on Patient #1 during 1993, and that he had a total of ten chart notes on him for the years 1994 through 1996.[4] *Id.*

The State ALJ characterized Respondent's prescribing practices "as irrational pharmacy," further explaining that "[p]olypharmacy is the prescription, administration or use of more medications than are clinically indicated." *Id.* at 16. While acknowledging that Respondent "prescribed pain pills and the patient had pain," as well as that "the patient was anxious and received anxiolytics," the State ALJ observed that Patient #1 "really ceased being treated in a fully engaged professional manner long ago" as Respondent had "prescribed a mixture of narcotic, anti-depressant, anti-anxiety and anti-inflammatory medications without any serious attempt to discern efficacy, side effects or synergy." *Id.* at 15–16.

Noting that "[t]he most powerful tool in reducing polypharmacy is an accurate medical record," the State ALJ reasoned that it was "easy to see why the out of control polypharmacy of the 1990's existed." *Id.* at 16. The ALJ further found that "[t]otally absent from [Respondent's] care and treatment of [Patient #1] was control, monitoring and periodic assessment," and that "[f]rom 1990 to 1996, almost all of [his] prescribing to [Patient #1] took place in the absence of a legitimate physical examination." *Id.*

The State ALJ made additional findings based on the expert testimony of a practitioner in pain management as to the standard of care in treating a chronic pain patient. *Id.* at 20–21. While the State's Expert testified "that it is not necessarily a breach of the standard of care to prescribe potent narcotic analgesics to an addict," he further explained that "[h]ow a physician goes about this and how such a plan is monitored is the key to whether the patient is engaged in improper drug seeking behavior or properly receiving medications for a medical condition." *Id.* at 21.

The State's Expert testified and the ALJ found that "if a patient with serious and legitimate back pain admits to addiction to opioids," the "treating physician should always have a psychiatrist or psychologist working with him for adjunctive evaluation and necessary treatment." *Id.* at 21. Moreover, "[t]he patient should be required to sign a narcotic contract that specifically spells out the terms and conditions under which the physician agrees to provide pain medication to the patient and what is expected from the patient in return." *Id.* The ALJ further found that "[t]he physician should explore other [treatment] modalities besides narcotics" to see if they will "lessen the need for narcotics." *Id.* While acknowledging that narcotics may still be necessary after trying other treatment modalities, the Expert testified that "the prescribing must be monitored extremely closely [and] [t]here must be very strict limitations placed on the patient to discourage drug seeking behavior." *Id.*

The State ALJ found that the Expert "established that [R]espondent was guilty of excessive prescribing to [P]atient [#1] based on the extremely large quantity of drugs prescribed, the toxicity of the medications and the absence of good faith examinations."[5] Id. The State ALJ further found that while Patient #1 "lived in pain," "[t]he evidence is overwhelming that [Patient #1] abused prescription medication over an extended period of time, that his abuse was manifest and apparent to those around him and that [R]espondent could not have been ignorant of this." *Id.* at 24. The State ALJ then noted that while "[i]t appears that [R]espondent was motivated by a desire to alleviate [Patient #1's] suffering," Respondent "fail[ed] to acknowledge any errors." *Id.; see also id.* at 33 (Respondent "fails to acknowledge any responsibility for any of his actions. He blames others or completely excuses his actions.").

The State ALJ thus found that Respondent had violated numerous provisions of both state and Federal law including, *inter alia,* that "[h]e prescribed medication without a good faith examination and medical indication," that "he excessively prescribed controlled substances," and that he had violated 21 CFR 1306.04(a), which requires that "a prescription for a controlled substance 'must be [issued] for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.'"[6] *Id.* at 27–28 (citing Cal. Bus. & Prof. Code § 2242, Cal. Health & Safety Code § 11153, and 21 CFR 1306.04(a)). The State ALJ further found that Respondent had violated DEA regulations requiring that he maintain a biennial inventory of controlled substances, that "he failed to maintain all required DEA 222 order forms" for schedule II controlled substances, and that "he failed to maintain all required controlled substances records." *Id.* (citing 21 CFR 1304.11–1304.13; 1305.03; 1305.13; 1304.21; 1304.24).

Thereafter, the MBC adopted the ALJ's decision. *Id.* at 1. Respondent's license was revoked, but the revocation was stayed and he was placed on probation for ten years. *Id.* at 35. In addition, Respondent's license was suspended "for 180 days" and he was ordered to take a course in prescribing practices; he was also ordered to take an additional Continuing Medical Education course for each year of his probation. *Id.*

Respondent testified that he completed the probationary period imposed by the MBC and did not have any violations. Tr. 117–18. He further maintained that he had "substantially" improved his charting practices. *Id.* at 118.

The Current Proceeding

At the hearing in this matter, Respondent testified as both a witness for the Government and himself. The Government asked him a series of questions regarding the findings of both the 1995 DEA Final Order and the MBC.

With respect to Patient #1, the Government asked Respondent whether he agreed with the DA's finding that his dispensing of controlled substances "between January 1990 and February 1992, was highly irregular in the medical profession and was excessive?"

[4] The State ALJ also made findings regarding Respondent's prescriptions to Patient #1 during the months of November and December 1991, as well as January through March 1993. *See* GX 8, at 14–15.

[5] The State's Expert also identified five "examples of gross negligence by [R]espondent" in his prescribing to Patient #1." *Id.* at 20–21. These included that "the dose of [D]emerol * * * was dangerous and potentially toxic," "the dose of acetaminophen," which is contained in Lorcet, "was very excessive and toxic to the patient's liver," "the lack of record-keeping is virtually unheard of in terms of this degree of prescribing," "the lack of monitoring given the patient's condition and history of substance abuse," and "the lack of use of other modalities besides narcotics to treat the patient's pain." *Id.*

[6] The State ALJ also found that Respondent had committed unprofessional conduct under several provisions of California law. GX 8, at 26–27.

Tr. 15. Respondent answered: "No, I do not." *Id.*

Next, the Government asked Respondent whether he agreed with the DA's finding that his management of Patient #1 "demonstrated behavior such that the patient's demands seemed to replace your judgment." Tr. 15. Respondent answered: "No, I do not."

The Government then asked Respondent whether he agreed with the DA's finding that he "dispensed controlled substances to Patient Number 1 basically on demand?" Tr. 16. Respondent again answered: "No, I do not." *Id.* at 16.

Next, the Government asked Respondent whether he agreed with the DA's finding that, during "the early 1990's," he had "dispensed controlled substances to Patient Number 1 * * * with virtually no records or monitoring?" *Id.* at 17. Respondent answered: "My records were far less thorough than they should have been. I know that now and in the future will be much more cautious." *Id.*

With respect to Patient #3, the Government asked Respondent whether he agreed with the DA's finding that his "conduct in continuing to prescribe to [him], despite his use of forged prescriptions, showed a carelessness inappropriate for continued registration?" *Id.* at 17. Respondent answered:

> In the first place, this was not what I would call a forgery although it was close. What happened was the patient got a reasonable prescription from me, ran it through a copy machine, took both prescriptions to pharmacies so that both prescriptions looked extremely genuine, and yet I know I'd only written one. I don't know if that is legally a forgery or not, but it's very similar to that. * * * I did not think that it was a forgery. Forgeries are usually very obvious to pharmacists who are familiar with my prescriptions and signature. So I was blindsided on that. And I did subsequently dismiss that patient from my practice when there were increasing questions about what was going on.

Id. at 17–18.

The Government then asked Respondent if he agreed with the DA's "finding that [he was] careless in continuing to prescribe to * * * Patient Number 3?" *Id.* at 18. Respondent answered: "No, I do not, but I had not seen the prescription that is now being called a forgery until much later." *Id.*

As a follow-up, the Government asked Respondent if he agreed with the finding that his "continued prescribing to this patient showed more probably a disregard of the requirements for detailed attention to individual patient behavior necessary for the dispensing of controlled substances?" *Id.* at 19. Respondent answered:

> I find that rather strange. I don't know what behavior is being referred to or conduct at that point. Quite simply, the patient came to me complaining of severe headaches, appeared to be having severe headaches, and was prescribed, but there became increasing questions about some things that were going on. And finally, I just terminated his treatment.

Id.

With respect to Patient #2, the Government noted the DA's finding that "over a six-month period of time, [Respondent's] prescribed [an] excessive number of refills [and] showed a reckless disregard for medical standards in dispensing controlled substances." *Id.* The Government then asked Respondent whether he agreed that he "showed a reckless disregard for medical standards in dispensing controlled substances with regard to Patient Number 2?" *Id.* at 19–20. Respondent answered: "No, I do not." *Id.* at 20.

Testifying on his own behalf regarding Patient #2, Respondent stated that he understood that he could not "legally write on the prescription itself more than five refills." *Id.* at 121. He then testified: "I don't think I ever did write more than five [refills] on Ms. [J.]" *Id.*

The Government then objected that Respondent's counsel was trying to re-litigate the findings as to Patient #2. *Id.* Respondent's counsel acknowledged that this was "true," stating that "I am pointing out the discrepancy in the ALJ's findings versus the final revocation order," and that "[t]here are discrepancies that I think that need to be illuminated." *Id.* at 121–22.

While the ALJ initially expressed the opinion that Respondent was "trying to revisit these facts which are facts that have already been adjudicated," *id.* at 122, Respondent's counsel replied that "the conclusions [of the 1995 Order] aren't support by the facts, and the facts are in the record," and that his line of questioning was only being done to show that when Respondent answered the Government's questions by stating "that he disagreed with the conclusion," this was "in fact, supported by the record." *Id.* The ALJ then agreed to allow Respondent's counsel to ask him questions to clarify "why he disagree[d] with the final order." *Id.* at 123.

Next, Respondent's counsel read a portion of the prior DEA ALJ's recommended decision which noted that there was "arguably * * * conflicting evidence" as to whether Respondent had issued more than five refills to Patient #2 between November 14, 1990 and May 1, 1991. *Id.* at 125. Respondent's counsel then asked Respondent whether he "agree[d] that the evidence that was presented and, in fact, the footnote here that the judge found conflicted with the conclusion that you had violated the prescription refill limits?" *Id.* at 126. After the Government again objected that Respondent's counsel was trying to re-litigate the findings of the earlier proceeding, and before the ALJ ruled on the objection, Respondent's counsel rephrased his question "as simply asking is that the reason for your disagreement with [the Government counsel's] question earlier?" *Id.* Respondent answered:

> The word 'refill' is perhaps ambiguous. When I write a prescription for a patient with an ongoing problem, * * * I would write in the number of refills, if any, and that's a refill. On the other hand, if the patient calls me back a month later and says I need this medicine again, and I'm confident the patient still has that symptom, that problem, I call the pharmacy and say give Ms. Doe another 30 tablets or whatever. Legally, I think it's a new prescription. Some people would call it a refill, but I don't think that the refill thing was intended to necessarily refer to situations in which a doctor phones in what the pharmacy considers a new prescription at that point[.] * * * [W]hether I use the word refill or say give the patient another 30 tablets, basically, it means I've considered what to do, have hopefully a reason to do it, and go on from there. And it's technically, I believe a new prescription. * * * Basically, * * * I did not believe I was violating any refill laws on this.

Id. at 127.

Next, Respondent's counsel asked him if he "remember[ed] what the * * * main issue [was that] the Government * * * had with Patient Number 3?" *Id.* at 127–28. Respondent answered: "[t]he problem with Patient Number 3 was that there was a great deal of confusion from a lot of parties. It was * * * not until much later that I realized the problem." *Id.* at 128. Following the Government's objection (again, on the ground that Respondent was trying to re-litigate the findings of the first proceeding), which was overruled by the ALJ, Respondent testified that:

> There was a question about a pharmacy that called me and said, 'We've got a prescription here, we think something is wrong with it.' And I of course, they knew my signature and my handwriting, and I said, 'Well, you know, I did give the patient a prescription for this, I guess you might as well fill it.' What actually happened and what * * * no one notices was that the patient had taken my prescriptions, run it through a copying machine, then used scissors and cut it to size, * * * took it to pharmacies, and each of them had what looked like a genuine prescription. And eventually, I got copies of both and sure

enough, it was a photocopy so that I think I was acting in innocence, and the pharmacist was right when he thought something was wrong with it, but it was not a prescription that the patient forged. He simply illegally copied a prescription.

Id. at 128–29.

Respondent was then asked whether at some point, he had ceased his relationship with Patient Number 3. *Id.* at 129–30. Respondent answered:

Yes. There were too many suspicious things. I can't remember the details, but not uncommonly a patient will say something like 'my dog ate my pills' or whatever, rather phony-sounding reason for wanting an [sic] new prescription. And believe me, if somebody drops a bottle in the bathroom, the pills always fall in the toilet. I mean it's just, as a doctor, I've heard all these reasons, and I am extremely suspicious, especially now. I often, in fact, have the patient come into the office so I can eyeball the squirming when I start asking the embarrassing questions, so that when these things started happening with Mr. [F.], I finally said enough is enough, no more, no more medical care.

Id. at 130.

Respondent's counsel then asked him "[h]ow much time passed between * * * this issue with regard to the forgery and your ceasing the relationship?" *Id.* Respondent answered that he could not "remember the exact dates" and that he had "no memory of * * * what that time was." *Id.* at 130–31.

Respondent was then asked if "in any way, shape, or form do you take responsibility for * * * Patient Number 3 regarding the forged prescriptions?" *Id.* at 131. Respondent answered:

I wrote a prescription, patient apparently went to two pharmacies, and one of them * * * they was [sic] alert enough to notice that a ballpoint pen hadn't indented it or anything and simply called and said, "I think I have a forged prescription." And I simply said * * * yes * * * "That's what I wrote, the quantity." "You know my signature." "You might as well fill it, cause I did write that prescription for the patient." I didn't realize the patient had photocopied it and * * * had taken it, presumably, [to] two different places.

Id. at 132. Respondent then maintained that if he had known the prescription had been forged, he "would not have done that," but did not specify what "that" was. *Id.*

Respondent further conceded that he did not have the required bi-annual inventory on hand because when he first started practicing in 1959, he had to take an inventory every year and mail it in, but that after "the doctors of the country were notified that they no longer needed to mail the DEA an inventory every two years, * * * we mistakenly believed that we didn't need to do the inventory either, because no one would ever see it except ourselves or an investigator. So I stopped making an inventory. It was, I think, good faith." *Id.* at 134–35. Respondent, however, acknowledged that he had to keep an inventory, receipts for any controlled substances he obtained from drug company representatives, and dispensing records. *Id.* at 135–37.

The Government also asked Respondent a series of questions regarding the MBC's Order. First, it asked Respondent whether he agreed with the Board's finding that he was "guilty of unprofessional conduct in [his] care and treatment of [Patient #1] both in terms of [his] prescribing practice and in terms of [his] recordkeeping?" Tr. 21. Respondent answered that he "agree[d] with the part on recordkeeping," but that "[o]n the other things, I do not agree." *Id.* Respondent then explained that "[t]his patient received textbook treatment in accordance with standards of the American Medical Association, and shortly after, the FDA adopted policies which indicated that [it] agreed with the AMA." *Id.* at 21–22.

The Government then asked Respondent whether he agreed with the Board's finding that Patient #1 "was making the only therapeutic decision and that the patient was determining his need for drugs?" *Id.* at 22. Respondent answered: "No." *Id.* Next, the Government asked Respondent whether he agreed with the Board's finding that "serious monitoring [of Patient #1] was non-existent?" *Id.* at 22–23. Respondent answered: "I was obviously in a position to observe him, that he was showing no evidence of drug overdose or problems. He was monitored but my recordkeeping was inadequate, to say the least." *Id.* at 23.

Next, the Government asked Respondent whether he agreed with the Board's finding that his prescribing practices with respect Patient #1 "could be characterized as irrational polypharmacy?" *Id.* at 23. Respondent answered: "No, I do not, and the reason is that polypharmacy is, by definition, irrational." *Id.* Continuing, Respondent explained "[t]o give more than one drug to a patient when there is a reasonably good reason for doing that is not considered polypharmacy in the medical profession, but it must be rational and there must be a good reason for using more than one drug in a class." *Id.* at 24.

The Government then asked Respondent whether he agreed with the Board's finding that his "prescribing practices to [Patient #1] * * * made little sense?" *Id.* Respondent answered: "Again, this patient needed more than one specific drug in his treatment depending on whether the problem was being awake and alert and reasonably pain free during the daytime and also something additional at night so that he could sleep as well. I do not consider that irrational or unreasonable." *Id.* at 24–25.

Next, the Government asked whether Respondent agreed with the Board's finding that "even though the drugs were given for conditions that [Patient #1] had, their manner of dispensing was totally irrational?" *Id.* at 25. Respondent answered: "No, I do not." *Id.*

The Government then asked whether he agreed with the Board's finding that he "committed acts of clearly excessive prescribing or administering of drugs to" Patient #1? *Id.* at 26–27. Respondent answered: "No." *Id.* at 27; *see also id.* at 50.

The Government also asked Respondent whether he agreed with the Board's finding that he "had violated federal statutes and regulations regulating dangerous drugs or controlled substances?" *Id.* Respondent answered: "In terms of recordkeeping, there's some truth in it. In terms of following accepted guidelines, including those of the American Medical Association, and they're still the guidelines of the Food and Drug Administration, although they were adopted after that, indicate that the treatment I gave was within national standards." *Id.*

Respondent further challenged the State Expert's finding that the doses of Demerol he prescribed to Patient #1 were potentially toxic, contending that there was uncertainty in medical texts as to whether metabolites of the drug accumulate and whether "they cause any significant harm." *Id.* at 36. He testified that even today, there is still controversy over the appropriate dosing of Demerol, although not "as much * * * as there used to be" because most doctors are using oxycodone or morphine to treat patients with severe pain. *Id.* at 38.

Respondent also maintained that Patient #1 had been "treated with all sorts of things other than controlled substances early in his course," and that "the more potent medications and narcotics were used only when the other modalities failed." *Id.* at 32. Respondent asserted that he had tried anti-inflammatories such as Aleve and Naproxen with Patient #1 to no avail, and that he had referred him to "a so-called pain clinic * * * at which they tried everything," including "extensive physical therapy" but this "did not give him any relief." *Id.* at 52. While Respondent admitted that he did not

obtain any of the charts that the pain clinic maintained on Patient #1, he maintained that he was aware of what modalities the clinic had tried because "they're pretty much standard." *Id.* at 53.

Respondent further testified that he "frequently" would not document the use of non-prescription medicines "because it's over-the-counter," and thus a physician reviewing his charts "could not have seen necessarily everything else that was tried." *Id.* at 32. While Respondent agreed that he needed to closely monitor a patient, he admitted that he did not write down every time he saw Patient #1. *Id.* at 40. Respondent testified that Patient #1 had lived with him for a two-year period and that he had observed him on a daily basis. *Id.* at 42.

Respondent's counsel also asked him whether "a reasonable doctor looking at [Patient #1's] history wouldn't have enough information to * * * form a strong opinion except to the extent that the lack of information indicates that perhaps he wasn't treated correct[ly], right?" *Id.* at 40. Respondent answered that he did not "agree quite with that because a person reviewing it with inadequate records would not know * * * [and] probably would not even [be able] to formulate a guess unless there was other evidence pointing in one particular direction." *Id.* Respondent then testified that the Board's decision used "strong language," and that in his "opinion, there were not multiple violations or even violations of [the] standard of care, although there were in recordkeeping." *Id.* at 40–41.

Next, Respondent asserted that it was not true—as found by the State ALJ—that he had ceased treating Patient #1 "in a fully engaged professional manner long ago" and noted that he had refused to provide him with medication that he "did not consider indicated." *Id.* at 43. He then testified that the situation with Patient #1 was not likely to happen again because Patient #1 "was [a] slightly distant cousin," whose family was close to his father's relatives. *Id.*

Respondent testified that while he agreed with the State ALJ statements that he "had a desire to alleviate [Patient #1's] suffering," he did not think that he had "lost sight * * * of [his] duty as a physician." *Id.* at 47. He then testified that he did not think that the prescriptions "were in error," and "other physicians also agreed that [Patient #1] needed relatively heavy medication." *Id.* Respondent then stated that in his "opinion, [Patient #1] was never an addict, and I certainly never gave him medications along those lines." *Id.* at 48.

Respondent then maintained that at some point "in the 1990's, * * * the AMA recommended major changes in dosage as did the FDA * * *. [B]ut the FDA regulations were postponed at the request of the DEA, which felt that they were too high." *Id.* at 51. Continuing, Respondent claimed that "[a]fter a year of discussion, the FDA decided that their proposal was correct, that the[y] * * * did not agree with the DEA, did agree with the American Medical Association and adopted those things, I would guess [in the] early 1990's." *Id.*

Subsequently, Respondent testified that "[s]hortly after [his] Medical Board case," the FDA changed its position and "approved the higher dosage." *Id.* at 55. Clarifying his testimony, Respondent stated that prior to the FDA action, "the highest number of milligrams in a tablet of oxycodone was 5 milligrams," and that "after my Medical Board hearing, the FDA approved a * * * 20 milligram and 40 milligram tablet, [and] about a year and a half later, an 80 milligram tablet." *Id.* at 55–56. In Respondent's view, the FDA was "simply saying many patients need [a] higher dosage than doctors have necessarily been using and that * * * rather than have a patient take 4 or 8 tablets at a time or even eventually 16, a larger size tablet is relevant." *Id.* at 56. Respondent then maintained that these "changes" were "[e]xactly in line with the American Medical Association." *Id.*

Respondent then testified that as early 1958, the AMA had published guidelines which "made it clear that much larger doses of oxycodone were relevant," that the "milligram dosage and timing [of oxycodone] should be identical with [that of] morphine," and that "morphine should be given, based on body weight, on the order of 15 milligrams every 4 to 6 hours, which would be a whole lot of oxycodone tablets in a day." *Id.* at 57. He then maintained that "[t]he FDA and DEA are taking opposite positions on oxycodone dosage * * * and the AMA is on the same side as the FDA." *Id.*

Later, Respondent's counsel asked him if he was "remorseful at all for any of the problems that occurred?" *Id.* at 138. Respondent answered:

> Remorseful, no, because in terms of the treatment I actually gave, I believed it was good treatment. And I can't think of any patient who was damaged by my treatment. At the same time, of course, I certainly am sorry that this relative died while under the care of another physician. Basically, who was giving him narcotics and many other things. So remorse, no, but obviously, I regret many things that happened.

Id. at 139–40. Respondent then explained that what he regretted was that he had "been unable to prescribe medications for people in severe pain." *Id.* at 140.

Respondent was then asked whether he felt that "a distinction [should] be drawn in [his] case" between his contention he had "performed and issued prescriptions that were medically necessary and the Government's contention that [he] didn't * * * properly keep track of [them] and follow the correct procedures in doing it?" *Id.* at 139. Respondent testified:

> I think it's a major distinction. I prescribed in good faith what I thought the patient needed and was appropriate. And partly from my ignorance and partly from maybe being very busy, I did not keep the detailed records I now know I should have taken. The other thing is that there were so many consultations on [Patient #1] especially, nine consultations saying yes * * * your treatment is correct * * * the patient is getting good care. In the practice of medicine, there are enough uncertainties so that if a large group of physicians are almost unanimous in a patient's need for a particular treatment, going back later and saying, well, maybe they were all or nearly all wrong is not very productive. In other words, there are enough uncertainties that going back [in] hindsight is 100 percent, but at the time, things look * * * like the right thing to do.

Id. at 140. Respondent then claimed that "two consultants testified for the Medical Board, but neither one of them, identified any problems in my care or with his medications. And they simply said, oh, if [Respondent] had only told me this or that, I would have decided differently." *Id.*

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 (DC 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 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 [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).

Where, as here, DEA has previously issued a Final Order which revoked an applicant's former registration, "the critical issue in th[e] proceeding is whether the circumstances, which existed at the time of the prior proceeding, have changed sufficiently to support [the] conclusion that" granting the application would be consistent with the public interest. *Ellis Turk, M.D.,* 62 FR 19603, 19604 (1997); *Stanley Alan Azen, M.D.,* 61 FR 57893, 57893–94 (1996). Contrary to the ALJ's apparent understanding, this is not an invitation to relitigate the findings of the prior proceeding. Rather, where, as here, an applicant has previously been the subject of an Agency Final Order, the doctrine of *res judicata* bars the relitigation of the factual findings and conclusions of law of the prior proceeding absent the applicant's establishing that he falls within one of the doctrine's recognized exceptions. *See City Drug Co.,* 69 FR 1304, 1306 (2004); *Turk,* 62 FR at 19604; *Azen,* 61 FR at 57894; *see also* Restatement (Second) of Judgments § 28 (2010). So too, the doctrine of *res judicata* bars the relitigation of the findings of the MBC's final order. *See Christopher Henry Lister, P.A.,* 75 FR 28068, 28069 (2010) (citing *University of Tenn.* v. *Elliot,* 478 U.S. 788, 798–99 (1986)); *Marie Y.* v. *General Star Indem. Co.,* 2 Cal. Rptr.3d 135, 155 (Cal. Ct. App. 2003) ("When an administrative agency acts in a judicial capacity to resolve disputed issues of fact properly before it which the parties have had an adequate opportunity to litigate, its decision will collaterally estop a party to the proceeding from relitigating those issues."); *see also Misischia* v. *Pirie,* 60 F.3d 626, 629–30 (9th Cir. 1995); Restatement (Second) of Judgments, § 29.

Accordingly, upon the Government's establishing that the Agency has previously issued a Final Order revoking an applicant's registration and absent the applicant's establishing that he falls within a recognized exception to the application of *res judicata,*[7] the Government has satisfied its *prima facie* burden of showing that granting the application would be inconsistent with the public interest. Moreover, the scope of the issues to be litigated is limited. As in any other proceeding, "an applicant must accept responsibility for [his] actions and demonstrate that [he] will not engage in future misconduct." *Medicine Shoppe,* 73 FR at 387 (int. quotations and citations omitted).

For example, in *Robert A. Leslie, M.D.,* DEA denied the application of a practitioner whose registration had been previously revoked following his state court convictions for unlawfully prescribing or furnishing controlled substances. 60 FR 14004, 14005 (1995). While the practitioner attempted to relitigate his convictions, the then-Deputy Administrator, agreeing with the ALJ, held that "the conviction is *res judicata,* and that [r]espondent should not be allowed to relitigate the matter." *Id.* Continuing, the Deputy Administrator noted that "although [r]espondent was free to offer new evidence that he would never again engage in the type of conduct that resulted in his conviction, he failed to do so. * * * [W]hile [r]espondent offered evidence and expended time arguing the invalidity of his criminal convictions, he offered no evidence of remorse for his prior conduct, that he has taken rehabilitative steps, or that he recognizes the severity of his actions." *Id.* The Deputy Administrator thus denied the practitioner's application.

Likewise, when, several years later, Dr. Leslie re-applied for a registration, the Deputy Administrator held that the 1995 Agency Order was *res judicata;* the Order specifically noted that the "[r]espondent continued to blame others for his criminal convictions," contending that his name had been forged on various prescriptions; that his criminal convictions had been affirmed because his counsel was ineffective; and that a Government witness in the earlier DEA proceeding had committed perjury. *Robert A. Leslie, M.D.,* 64 FR 25908, 25908–09 (1999). After again observing that both Dr. Leslie's criminal convictions and the 1995 Agency Order were *res judicata,* the Deputy Administrator denied his application, stating that "[r]espondent continues to fail to acknowledge wrongdoing or accept responsibility for his actions. Therefore, the Deputy Administrator is not convinced that [r]espondent has been rehabilitated and would properly handle controlled substances in the future, even on a restricted basis." *Id.* at 25910; *see also Robert A. Leslie, M.D.,* 68 FR 15227, 15231 (2003) (revoking registration obtained through administrative error, noting that "[i]n the face of DEA's repeated concerns regarding his lack of contrition, the [r]espondent remains steadfast in his insistence upon denying any previous wrongdoing. Despite previous findings that his criminal convictions were *res judicata,* the [r]espondent in his support of his most recent application * * * attempted yet again to re-litigate his criminal convictions").[8]

At the instant hearing, the Government objected to various questions asked of Respondent by his counsel on the ground that Respondent was attempting to relitigate the findings of the 1995 Agency Order. Tr. 121–22. Respondent's counsel admitted that this was "true," *id.,* but justified doing so to show purported discrepancies between the record (and the ALJ's decision) in the prior proceeding and the Agency's Final Order. *Id.* at 122. The ALJ overruled the Government's objection

[7] There is no dispute that neither the 1995 DEA Order, nor the 1997 MBC Order, was vacated by a court.

[8] *See also City Drug,* 69 FR at 1307 (denying application; noting that applicant had not "present[ed] any persuasive evidence of meaningful procedural changes * * * that would ensure that it will not again fail to account for controlled substances or dispense [them] without authorization," as well as its "lack of acknowledgement or explanation for previous shortages of large quantities of controlled substances"); *Turk,* 62 FR at 19606 (denying application, noting that "while [r]espondent has stated that he has changed his inventory practices, there is more than sufficient evidence in the record to indicate that [r]espondent has not accepted responsibility for his prior actions as a DEA registrant, [and] has not significantly changed his inventory practices").

and allowed Respondent to pursue this line of inquiry, *id.* at 123, 128; she also allowed Respondent to testify extensively as to why he disagreed with the MBC's findings. Moreover, in her decision, the ALJ ignored many of the findings of the 1995 Agency Order regarding Respondent's prescribing practices, and generally found proved only the various recordkeeping violations to which Respondent admitted. *See generally* ALJ. The ALJ also entirely ignored the MBC's findings that Respondent violated California law by "prescrib[ing] medication without a good faith examination and medical indication," that "he excessively prescribed controlled substances," and that he violated Federal law because he issued prescriptions which lacked "a legitimate medical purpose" and which were issued outside of the usual course of professional practice. *Compare* ALJ at 7–12, 19–27, *with* GX 8, at 27–28. Indeed, in her decision, the ALJ did not even acknowledge that DEA has long applied the doctrine of *res judicata,* let alone explain why the doctrine should not apply here.

Factors Two and Four—The Applicant's Experience in Dispensing Controlled Substances and Record of Compliance With Applicable Controlled Substance Laws

In her discussion of these two factors, the ALJ found only that "[t]he Government has proven and the Respondent has admitted to various record-keeping violations." ALJ at 19. Specifically, the ALJ found that Respondent did not keep receipts for the controlled substances he obtained, did not maintain the required biennial inventories, and that his records were not readily retrievable. *Id.* Noting that Respondent had "shown remorse for" these violations, the ALJ concluded "that this factor falls in favor of granting Respondent's application." *Id.*

It doesn't. As noted above, the ALJ ignored many of the most significant findings of both the 1995 Agency Order and the 1997 MBC Decision, which are relevant under these factors. With respect to Patient #1, the ALJ ignored the DA's findings that Respondent dispensed controlled substances to him "on demand [and] virtually upon request," with "virtually no records *or monitoring,*" and that the prescribing occurred "outside the context of the Respondent's usual professional practice." 60 FR at 55049 (emphasis added). These findings are *res judicata* and establish that Respondent violated the CSA in prescribing to Patient #1. *See* 21 CFR 1306.04(a).

Likewise, the MBC's Decision and Order found that Respondent had committed numerous violations of California law. In addition to his failure to keep required records, the MBC found that Respondent had prescribed controlled substances to Patient #1 "without a good faith examination and medical indication," in violation of Cal. Bus. & Prof. Code § 2242, and that "he excessively prescribed controlled substances," in violation of Cal. Health & Safety Code § 11153. The MBC also found that Respondent violated 21 CFR 1306.04 in that he issued prescriptions to Patient #1 outside of the usual course of professional practice and which lacked a legitimate medical purpose.

While the MBC found that Patient #1 "lived in pain," it nonetheless concluded that "the evidence [wa]s overwhelming that [Patient #1] abused prescription medication over an extended period of time, that his abuse was manifest and apparent to those around him and that [R]espondent could not have been ignorant of this." GX 8, at 24. Of further significance, the MBC considered Respondent's dispensing practices in periods beyond those at issue in the first DEA proceeding including his practices during the periods following both the issuance of the Show Cause Order and the ALJ's recommended decision.

With respect to Patient #1, Respondent testified that in his "opinion, there were not multiple violations or even violations of [the] standard of care, although there were in recordkeeping." Tr. 40–41. He further suggested that the MBC's findings were flawed "because a person reviewing [his treatment of Patient #1] with inadequate records would not know" whether he was being treated appropriately, and "probably would not even [be able] to formulate a guess unless there was other evidence pointing in one particular direction." *Id.* at 40. Respondent also disagreed with the MBC's findings that he had ceased treating Patient #1 "in a fully engaged professional manner long ago;" he asserted that Patient #1 "was never an addict," that the prescriptions were not "in error," and that "other physicians also agreed that [Patient #1] needed relatively heavy medication." *Id.* at 43–48. He further claimed that "two consultants testified for the Medical Board, but neither one of them identified any problems in my care or with [Patient #1's] medications," and that these physicians said that if Respondent "had only told me this or that, I would have decided differently." *Id.* at 140.

All of Respondent's testimony could have been, and should have been presented in the MBC proceeding. Here again, it is clear that Respondent is simply trying to relitigate the findings of the MBC proceeding. Having failed to establish that the MBC proceeding did not provide him with a full and fair opportunity to litigate these issues, the doctrine of *res judicata* precludes Respondent from relitigating them in this proceeding. GX 8, at 26.

In her decision, the ALJ opined that "the record * * * contains evidence of changes in acceptable prescribing practices that make for changed circumstances." ALJ at 21. She noted that "at the previous [Agency] hearing, an expert witness testified to the controversy in the medical community at that time over prescribing practices for chronic pain." *Id.* The ALJ then explained that Respondent "credibly testified that the AMA standards he applied in the past have now been adopted by the FDA, though arguably, the DEA disagrees." *Id.* at 22.

Several pages later, the ALJ repeated this observation, noting that Respondent in this proceeding and a government witness in the first proceeding "stated that there was a controversy in the medical community with regards to his prescribing practices, and that his methods have since been adopted by the FDA, though not necessarily the DEA." *Id.* at 24. Observing that "[t]he Government did not rebut this testimony in any way," the ALJ suggested that "his standard of care, though not accepted universally then or even now, has yet become more established," and that his "methods of prescribing * * * may, according to the record, arguably not be objectionable now." *Id.* The ALJ thus opined that "the circumstances surrounding his prescribing practices have changed." *Id.*

Contrary to the ALJ's view, Respondent's evidence is manifestly insufficient to support a finding of changed circumstances regarding the legitimacy of his prescribing practices. Indeed, the ALJ's finding is quite strange given that for much of Respondent's testimony on this issue, he maintained that his prescribing practices with respect to Patient #1 were consistent with then-accepted medical practices.

For example, Respondent claimed that Patient #1 "received textbook treatment in accordance with standards of the AMA." Tr. 21–22. He maintained "that the treatment I gave was within national standards." *Id.* at 27. Respondent further testified that as "early as 1958," the AMA had published guidelines which "made it clear that much larger doses of oxycodone were relevant," that the "milligram dosage [of

oxycodone] should be identical with morphine," and that "morphine should be given * * * on the order of 15 milligrams every 4 to 6 hours, which would be a whole lot of oxycodone tablets in a day." *Id.* at 57.

Notably, Respondent did not enter into evidence the AMA guidelines he referred to. Nor did he introduce the guidelines of any other body of medical professionals with expertise in treating chronic pain, nor excerpts from any recognized medical treatise. Indeed, given that Respondent maintained that as early as 1958—more than thirty years before the events at issue in the first Agency and MBC proceeding—the AMA had issued guidelines on oxycodone dosage which were consistent with his prescribing practices; this evidence also could have been, and should have been, presented in the prior proceedings.[9] Indeed, it seems most unlikely that the MBC would have found that Respondent violated both State and Federal law if, as he contends, his prescribing practices with respect to Patient #1 had been consistent with the thirty-year old guidelines of one of, if not the largest, organization of physicians in the country, or if his dispensing practices constituted "textbook treatment," or treatment "within national standards."

Respondent further asserted that while at the time of the MBC proceedings, five milligram tablets were the strongest oxycodone available, thereafter, the FDA had "adopted" the AMA guidelines because it approved twenty, forty and then eighty milligram strength tablets for marketing. Respondent did not, however, produce any guidelines or regulation which the FDA has purportedly adopted.

Indeed, it appears that Respondent (and given her findings, the ALJ) fundamentally misunderstand the FDA's role. The FDA's approval of larger-strength tablets of oxycodone for marketing under the Food, Drug and Cosmetic Act does not mean that it is medically appropriate to prescribe those drugs to a particular patient. Rather, the daily dose of a controlled substance to be prescribed to any patient is a matter of a physician's clinical judgment based on his use of accepted medical practices (such as performing a good faith medical examination as California law explicitly requires, *see* Cal. Bus. & Prof. Code § 2242) to diagnose his patient and determine that the patient has a medical indication warranting the prescription, followed by proper monitoring and periodic assessment of the patient to determine both whether the treatment is effective (or causing harmful side effects) and to prevent drug abuse and diversion. *See* GX 8, at 8 (noting the MBC's "acknowledg[ment] that predetermined numerical limits on dosages or length of drug therapy cannot alone justify a claim of unprofessional conduct. Rather, the validity of a physician's prescribing is to be judged on the basis of the diagnosis and treatment of the patient and whether the drugs prescribed are appropriate for the condition. There is a requirement that good faith prescribing requires a good faith history, physical examinations and documentation.").

In short, the FDA does not regulate the practice of medicine; rather, it evaluates drugs to determine whether they are safe and effective for the treatment of particular medical conditions and illnesses. *See Bristol-Myers Squib Co.,* v. *Shalala,* 91 F.3d 1493, 1496 (DC Cir. 1996); *Weaver* v. *Reagen,* 886 F.2d 194,198 (8th Cir. 1989); 21 U.S.C. 396. The regulation of the practice of medicine is primarily a function performed by state medical boards such as the MBC.[10]

In sum, the ALJ's reasoning that "his [Respondent's] standard of care[11] may have become more universally accepted, and * * * his methods of prescribing may, according to the record, arguably not be objectionable now," ALJ at 24, has no credible support in the record. Indeed, it is flatly inconsistent with Respondent's testimony that he provided Patient #1 with treatment that was—even at the time—consistent with accepted standards of medical practice. However, the MBC found otherwise, and I conclude that evidence does not support a finding of changed circumstances.

As for Patient #2, the ALJ found it "relevant that the prior ALJ recognized discrepancies in the Government's evidence relating to how many refills were actually authorized (i.e., six or twenty)." ALJ at 25. The ALJ's view reflects a fundamental misunderstanding of the relationship between the ALJ and the Agency. Contrary to her understanding, the prior ALJ's findings are no longer relevant because the Agency—and not the ALJ—is the ultimate factfinder. *Morall* v. *DEA,* 412 F.3d at 177; 5 U.S.C. 557(b). While the prior ALJ's recommended decision was part of the record in that proceeding, and the Agency was required to consider it in making its findings in that proceeding, *Morall,* 412 F.3d at 177, the appropriate forum to challenge whether the Agency's 1995 finding was supported by substantial evidence was by filing a Petition for Review in a United States Court of Appeals within the time allowed for doing so. Because Respondent did not seek judicial review of the Agency's 1995 Order, the findings of fact and conclusions of law made therein are entitled to *res judicata* effect.

As for Patient #3, the ALJ likewise made no findings under factors two and four. Instead, she noted (under factor five) only that Respondent "received information about possibly forged prescriptions, made inquiries, questioned the patient, was deceived, and ultimately stopped prescribing." ALJ at 25–26.

The findings of the 1995 Agency Order regarding Patient #3 were, however, considerably more extensive than, and materially different from,

[9] Indeed, it appears that Respondent presented such evidence in the MBC proceeding as the State ALJ's decision noted that he argued that "unless dosages exceed the range recommended by the American Medical Association, *Drug Evaluations* (6th Edition), no evidence should be admitted about drug dosages." GX 8, at 26. The State ALJ rejected this argument, explaining that:

> [t]he text relied on by respondent is one small source of the standard of care for prescribing practices. * * * It provides information. The fact that respondent relied on [the AMA guidelines] to determine safe dosage does not establish compliance with the standard of care. Respondent fails to understand that his patient was not some representative abstraction. His patient was [L.S.] who presented over time with his own unique medical history. How respondent responded to the medical needs of this particular patient is what is relevant.

GX 8, at 26.

[10] I reject the ALJ's finding that "Respondent credibly testified that the AMA standards he applied in the past have now been adopted by the FDA." ALJ at 22. As noted above, Respondent did not submit a copy of the purported guidelines or regulation, and other than his testimony, which appears to equate the FDA's approval for marketing of greater strength tablets with that of a clinical guideline, there is no evidence that any such guidelines or regulation exist. Accordingly, the Government was not obligated to rebut this testimony.

Beyond this, the ALJ should have some understanding of the FDA's functions and should have carefully considered the inherent plausibility (or lack thereof) of an assertion regarding the scope of the FDA's activities. I further note that whether FDA has adopted such guidelines or a regulation is an issue of legislative (and not historic) fact. *See* II Richard J. Pierce, *Administrative Law Treatise* § 10.5, at 732 (4th ed. 2002). As such, I decline to defer to the ALJ's credibility finding. *See id.* (quoting *Concerned Citizens of So. Ohio, Inc.,* v. *Pine Creek Conservancy Dist.,* 429 U.S. 651, 657 (1977) ("As Mr. Justice Holmes recognized, the determination of legislative facts does not necessarily implicate the same considerations as does the determination of adjudicative facts.")).

[11] The ALJ's use of the phrase "his standard of care" suggests a degree of confusion on her part as to what a standard of care is. The concept of the standard of care refers to a standard of medical practice which is generally recognized and accepted by the medical community. *See Brown* v. *Colm,* 11 Cal.3d 639, 642–43 (1974) ("It is settled that a doctor is required to apply that degree of skill, knowledge and care ordinarily exercised by other members of his profession under similar circumstances."). It is not personal to a physician.

what the ALJ related. More specifically, the Order found that Respondent was notified that Patient #3 was forging prescriptions on three separate occasions, including one that occurred more than two years before the Patient forged seven additional prescriptions. The 1995 Order also found that Patient #3 had told Respondent of his past addiction problems, that Respondent had talked to Patient #3 about the latter's forging of prescriptions, that Patient #3 had denied doing so *but that Respondent did not believe his denial,* and that Respondent nonetheless continued to prescribe narcotics to him. *See* 60 FR at 55049. Moreover, the DA found it concerning that Respondent continued to prescribe controlled substances to a known drug abuser and that he did so even though he knew of Patient #3's criminal behavior.

Once again, Respondent attempted to relitigate the findings of the 1995 proceeding, Tr. 128–32, essentially contending that there was confusion, that the prescription was not forged but rather had actually been photocopied, and that he told the pharmacy to fill it because he had in fact issued Patient #3 such a prescription.[12] Here again, Respondent could have, and should have, presented this evidence in the first proceeding. I therefore conclude that the 1995 Order's findings and conclusions of law with respect to Patient #3 are *res judicata.*

I further reject the ALJ's characterization of Patient #3's prescriptions as "possibly forged" and her assertion that Respondent "questioned the Patient [and] was deceived." ALJ at 25–26. The findings of the 1995 Agency Order make clear that Respondent knew that Patient #3 had forged prescriptions and was abusing drugs, and yet Respondent continued to prescribe controlled substances to him. Here again, the ALJ erred in failing to give *res judicata* effect to the findings of the 1995 Order.

I therefore hold that the findings of the 1995 Agency Order, as well as the findings of the 1997 MBC Order, establish not only that Respondent committed numerous recordkeeping violations, but also that he violated both California law and the CSA by prescribing controlled substances without performing a good faith medical examination and without medical indication. *See* Cal.Bus.& Prof.Code § 2242; *see also* 21 CFR 1306.04(a) ("A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice."). I also find that Respondent violated California law by prescribing excessive quantities of controlled substances, Cal. Health & Safety Code § 11153; that he violated 21 CFR 1306.22(a) by prescribing excessive refills of both Vicodin and Darvocet-N; and that he prescribed Lortab to a known drug abuser and prescription forgerer. I thus conclude that Respondent's experience in dispensing controlled substances and record of compliance with Federal and State laws related to the dispensing of controlled substances establishes a *prima facie* showing that Respondent's registration would be "inconsistent with the public interest."[13] 21 U.S.C. 823(f).

Sanction

As explained above, Agency precedent establishes that "the critical issue in this proceeding is whether the circumstances, which existed at the time of the prior proceeding, have changed sufficiently to support [the] conclusion that" granting the application would be consistent with the public interest. *See Azen,* 61 FR at 57893–94. While the ALJ initially acknowledged this precedent, *see* ALJ at 17, 19–20, she then cited to a different line of cases, explaining that "[w]hen assessing the appropriate remedy in a particular case, the DA should consider all facts and circumstances at hand." *Id.* at 20 (citing *Martha Hernandez, M.D.,* 62 FR 61145, 61147 (1997)). The ALJ did not recognize the tension between these two precedents and proceeded to evaluate "the totality of the circumstances" rather than apply the *Azen* rule. She thus considered various circumstances which are no different today than they were at the time of the original proceeding such as his "overall track record" and the degree of Respondent's culpability.[14] *Id.* at 22–24.

Hernandez did not, however, involve a matter in which the Agency had previously issued a final order of revocation to an applicant; indeed, the decision did not even acknowledge the then-recent decisions in *Azen* and *Turk.* Moreover, subsequent to the issuance of the decision in *Hernandez,* this Agency continued to apply the *Azen* rule. *See Robert Golden,* 65 FR at 5663, 5664 (2000); *Leslie,* 64 FR at 25908. Thus, it is clear that the *Hernandez* decision did not overrule *Azen.* Moreover, Respondent had a meaningful opportunity to litigate such issues as the degree of his culpability and his "overall track record" in prescribing controlled substances in the first proceeding. Due Process does not require that he be given a second bite of the apple as to these issues. Rather, as explained above, to rebut the Government's *prima facie* case and demonstrate that his registration would be consistent with the public interest, Respondent must establish that he accepts responsibility for the full range of his misconduct and demonstrate that he will not engage in similar misconduct in the future. *Medicine Shoppe,* 73 FR at 387; *Leslie,* 60 FR at 14005.

The ALJ acknowledged that "Respondent failed to express remorse for the entirety of his prescribing practices." ALJ at 28. Indeed, what is clear is that Respondent does not acknowledge wrongdoing for anything other than his inadequate recordkeeping as he continues to dispute both the findings of this Agency and the MBC with respect to Patient #1, maintaining that this patient was not an addict (notwithstanding the MBC's finding that he was), that he provided this patient with "textbook treatment" and treatment in accordance with nationally accepted standards (again, notwithstanding the MBC's findings that Respondent's dispensings to him violated numerous provisions of State and Federal law), and that he properly monitored this patient (notwithstanding the MBC's finding that there was "overwhelming" evidence that the patient was abusing prescription medication, that "his abuse was manifest," and that "Respondent could not have been ignorant of this.").

[12] In fact, the 1995 Order makes clear that Patient #3 forged multiple prescriptions.

[13] I have also considered the other factors. With respect to factor one—the recommendation of the state medical board—while the MBC suspended his license for only six months and Respondent now holds a California medical license, the MBC has made no recommendation in this matter. Thus, while Respondent now meets a threshold requirement for obtaining a DEA registration, *see* 21 U.S.C. 823(f), DEA has long held that a practitioner's possession of state authority to handle controlled substances is not dispositive of the public interest inquiry. *See Patrick Stodola,* 74 FR 20727, 20730 (2009); *Leslie,* 68 FR at 15230.

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, 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 in the public interest inquiry." *Dewey C. Mackay, M.D.,* 75 FR 49956, 49973 (2010) (citing *Jayam Krishna-Iyer,* 74 FR 459, 461 (2009), and *Edmund Chein,* 72 FR 6580, 6593 n.22 (2007)). Accordingly, that Respondent has not been convicted of an offense within the purview of factor three "is not dispositive of whether * * * his registration [would be] consistent with the public interest." *Id.*

[14] Having explained above that the evidence does not support a finding of changed circumstances with respect to Respondent's prescribing practices so as to deny the application of *res judicata* to the findings of the earlier proceedings, I conclude that it is unnecessary to repeat that discussion here.

Nor, given the latter finding, am I persuaded that Respondent's violations with respect to Patient #1 are solely attributable to his inadequate recordkeeping.

Moreover, as the MBC found, Respondent "fails to acknowledge any responsibility for any of his actions. He blames others or completely excuses his actions." While Respondent now acknowledges that he failed to maintain proper records, it is disturbing that he continues to deny any wrongdoing with respect to his dispensing of controlled substances not only to Patient #1, but also to Patients #2 and 3.

While the ALJ acknowledged that "Respondent must demonstrate remorse to the full extent of his documented misconduct," ALJ at 24 (citing *Prince George Daniels,* 60 FR 62884, 62887 (1995)), and that Respondent had "failed to express remorse for the entirety of his prescribing practices," *id.* at 28, she nonetheless recommended that Respondent be granted a restricted registration to "afford[him] an opportunity to demonstrate that he can responsibly handle controlled substances." *Id.* Noting that fifteen years had passed since the first Agency decision, the ALJ rejected the Government's contention that "the passage of time is not dispositive, especially when coupled with a respondent's refusal to accept responsibility for [his] misconduct." ALJ at 20 (citing Gov. Br. 6). She further maintained that one of the cases cited in the Government's Brief, *John Porter Richards, D.O.,* 61 FR 13878 (1996), actually supported granting Respondent's application, stating that in that case, the "applicant 'continued to maintain that he had not committed the crimes for which he had been convicted.'" ALJ at 21 (quoting 61 FR at 13879); *see also* ALJ at 27. The ALJ then asserted that in *Richards,* "the DA *approved* the applicant's application *without restrictions* despite the fact that, at the hearing, the applicant accepted his conviction but did not completely admit to the crimes for which he was convicted." *Id.* at 21 (quoting 61 FR at 13879–80) (emphasis in ALJ's decision).

It is clear, however, that the ALJ took the quoted language out of context, ignoring that the language was merely a paraphrase of a question asked of the applicant by the Government's counsel. *See* 61 FR at 13879 ("When asked on cross-examination whether, consistent with his not guilty plea, he continued to maintain that he had not committed the crimes for which he had been convicted, the Respondent testified, 'I accept my conviction,' and when asked to what extent he did so, he replied, 'In its completeness.' "). Notably, the Agency did not find in *Richards* that the respondent "continued to maintain that he had not committed the crimes" of which he had been convicted. While in *Richards,* the applicant's answer to the Government's question may not have been entirely responsive, there is no indication in the decision that the Government followed up by asking him whether he denied having committed the crimes and the findings of the decision do not establish what testimony the applicant offered on his direct examination. Beyond this, most reasonable fact finders would, in the absence of testimony denying that one had committed the crime (thus demonstrating that one was talking out of both sides of his mouth), find that the statements referred to above established acceptance of responsibility.

By contrast, Respondent has continued to deny wrongdoing with respect to his dispensing practices. While it has been fifteen years since the first Agency order (which also found that he lacked remorse for both his unlawful recordkeeping and refill practices), and thirteen years since the MBC Order (which also found that he did not accept responsibility), Respondent continues to deny wrongdoing with respect to a significant portion of the misconduct which was found proved in the respective proceedings.[15]

The ALJ also cited *Paul J. Caragine, M.D.,* 63 FR 51592, 51601 (1998), noting that the Agency had granted the respondent in that case a restricted registration, notwithstanding that he "had not adequately demonstrated remorse for his mis-prescribing * * * to allow [him] to demonstrate that he can responsibly handle controlled substances in his medical practice." ALJ at 27. However, more than a year before the hearing in this case, I made clear that:

> [w]hile some isolated decisions of this Agency may suggest that a practitioner who [has] committed only a few acts of diversion was entitled to regain his registration even without having to accept responsibility for his misconduct, * * * the great weight of the Agency's decisions are to the contrary. In any event, the increase in the abuse of prescription controlled substances calls for a clarification of this Agency's policy. Because of the grave and increasing harm to public health and safety caused by the diversion of prescription controlled substances, even where the Agency's proof establishes that a practitioner has committed only a few acts of diversion, this Agency will not grant or continue the practitioner's registration unless he accepts responsibility for his misconduct.

Jayam Krishna-Iyer, M.D., 74 FR 459, 464 (2009) (citation omitted). I further explained that to the extent any "decision of this Agency suggests otherwise, it is overruled."[16] *Id.* at n.9.

It is perplexing that the ALJ did not even acknowledge the holding of *Krishna-Iyer.* However, it is the law of this Agency. Moreover, the requirement that a practitioner accept responsibility for his misconduct applies regardless of whether the acts of diversion were done intentionally, recklessly or negligently. *See Dewey C. Mackay,* 75 FR at 49978 n.39 (noting disagreement with *Caragine*). This is so because the harm to the public is not dependent on the practitioner's mental state in committing the act of diversion, and recognizing one's misconduct is the first and an essential step in demonstrating that it will not happen again.[17] To make

[15] Speculating as to "why it is hard for the Respondent to 'admit errors in judgment,' " the ALJ observed that the MBC had "noted that the Respondent was vilified in the media by Agent Babcock of the California Bureau of Narcotic Enforcement, [and] that her statements hurt her credibility." ALJ at 27. The ALJ then noted that "[d]espite this poor treatment on the part of Agent Babcock, the Respondent has taken full responsibility for his record-keeping violations." *Id.*

The ALJ did not explain why Respondent's having been vilified by Agent Babcock would prevent him from taking responsibility for his prescribing violations but not his recordkeeping ones. In any event, it strains credulity to suggest that fifteen years later, Respondent's inability to accept responsibility for the full scope of his misconduct is because he was vilified in the media.

[16] In *Krishna-Iyer,* I noted that a study of the National Center on Addiction and Substances Abuse (CASA) had found that "[t]he number of people who admit abusing controlled prescription drugs increased from 7.8 million in 1992 to 15.1 million in 2003." National Center on Addiction and Substance Abuse, *Under the Counter: The Diversion and Abuse of Controlled Prescription Drugs in the U.S.* 3 (2005) (quoted at 74 FR at 463). Moreover, "[a]pproximately six percent of the U.S. population (15.1 million people) admitted abusing controlled prescription drugs in 2003, 23 percent more than the combined number abusing cocaine (5.9 million), hallucinogens (4.0 million), inhalants (2.1 million) and heroin (328,000)." *Id.* The study further found that "[b]etween 1992 and 2003, there has been a * * * 140.5 percent increase in the self-reported abuse of prescription opioids," and in the same period, the "abuse of controlled prescription drugs has been growing at a rate twice that of marijuana abuse, five times greater than cocaine abuse and 60 times greater than heroin abuse." *Id.* at 4.

[17] The ALJ further reasoned that "the majority of [Respondent's] issues emanated from his treatment of Patient #1 and only when Patient #1 was living in Respondent's home." ALJ at 23. She then asserted that "this Agency has considered the effect a relative's medical issues can have on a practitioner and recognized that when those stresses are taken out of the picture, it is less likely that the circumstances would ever be repeated." *Id.* (citing *Cecil M. Oakes, M.D.,* 63 FR 11907 (1998)).

While it is true that the Agency's factual findings in *Oakes* noted that the respondent had testified that at the time he altered his DEA registration, he was dealing "with the financial and emotional burdens that accompanied his son's having been diagnosed as having Attention Deficit Disorder," 63 FR at 11908, he further testified that he was "in no

clear, Respondent is not entitled to "an opportunity to demonstrate that he can responsibly handle controlled substances" through the issuance of even a restricted registration unless and until he accepts responsibility for his misconduct.[18]

It is acknowledged that fifteen years have passed since the first Agency Order. *See* ALJ at 20–21, 28. However, DEA has long held that "[t]he paramount issue is not how much time has elapsed since [his] unlawful conduct, but rather, whether during that time. * * * Respondent has learned from past mistakes and has demonstrated that he would handle controlled substances properly if entrusted with a new registration. *Leonardo* v. *Lopez,* 54 FR 36915 (1989); *see also Leslie,* 68 FR at 15227 (revoking registration issued through administrative error on ground that practitioner still refused to acknowledge misconduct which he committed seventeen years earlier notwithstanding that there was no evidence that he had mishandled controlled substances under the erroneously issued registration).

Moreover, it should be noted that neither the 1995 Order, nor any Agency rule, barred Respondent from re-applying at an earlier date. What does bar his obtaining of a new registration is his failure to fully acknowledge his misconduct. Absent Respondent's acknowledgment of the full scope of his misconduct, I am compelled to conclude that issuing him a new registration would be "inconsistent with the public interest." 21 U.S.C. 823(f). Accordingly, I reject the ALJ's recommended ruling and will deny Respondent's application.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f), as well as 28 CFR 0.100(b) and 0.104, I order that the pending application of Robert L. Dougherty, M.D., for a DEA Certificate of Registration as a practitioner, be, and it hereby is, denied. This Order is effective immediately.

Dated: March 11, 2011.

Michele M. Leonhart,

Administrator.

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way * * * using (his son's problems) as an excuse for bad behavior or to try to rationalize it away * * * as being justified." *Id.* Moreover, in discussing the public interest factors and whether the respondent had rebutted the Government's *prima facie* case, the decision made no reference to the medical issues of his son. *See* 63 FR at 11909–10. It is thus inaccurate to say that the Agency "considered the effect a relative's medical issues can have on a practitioner and recognized that when those stresses are taken out of the picture, it is less likely that the circumstances will ever be repeated." ALJ at 23.

Most significantly, the Agency's decision in *Oakes* noted in at least three different places that the respondent had expressed remorse and accepted responsibility for his misconduct. *See* 63 FR at 11909 (noting that "the evidence in favor of denial of Respondent's application is overcome by * * * his expressions of remorse and acceptance of responsibility for his actions"); *id.* at 11910 (noting that while the respondent's misrepresentation on a state application "is troublesome, it does not warrant the denial of Respondent's application in light of his expressions of remorse and acceptance of responsibility for his actions").

Thus, contrary to the ALJ's reasoning, *Oakes* provides no comfort to Respondent. Moreover, even giving weight to Respondent's testimony that he is not likely to again invite a patient to live with him, his testimony does not address his misconduct with respect to Patients #2 and 3.

[18] The ALJ also noted that since the revocation of his registration, "Respondent has had no further problems related to his practice of medicine." ALJ at 20. Given that DEA does not regulate the practice of medicine, it is an open question whether such evidence is even relevant in assessing whether an applicant's registration would be consistent with the public interest. *See Edmund Chein,* 72 FR 6580, 6590 (2007) (declining to decide "whether a registrant's unwillingness to comply with State rules that are unrelated to controlled substances can be considered [in a revocation proceeding] when the registrant maintains a valid State license").

What is noteworthy, however, are the State ALJ's extensive findings regarding Respondent's dispensing of controlled substances to Patient #1, not only during the period following the issuance of the first Order to Show Cause on July 29, 1993, but also after the DEA ALJ's issuance of his recommended decision on January 12, 1995. While the DEA ALJ's decision was not a final decision of the Agency, it found that Respondent dispensed controlled substances to Patient #1 "on demand," "virtually upon request," with "virtually no scrutiny," that his "prescribing and dispensing to [Patient #1] was outside of the context of the Respondent's usual professional practice" and thus violated 21 CFR 1306.04(a), and that the Government had "established a *prima facie* case under factor (2)." GX 6, at 20. Yet thereafter, Respondent continued to engage in what the State ALJ "characterized as irrational polypharmacy"; the State ALJ further noted that "[t]otally absent from his care and treatment of [Patient #1] was control, monitoring and periodic assessment" and that "[f]rom 1990 to 1996, almost all of respondent's prescribing to [Patient #1] took place in the absence of a legitimate physical examination." GX 8, at 15–16.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Erwin E. Feldman, D.O.; Revocation of Registration

On May 29, 2009, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Erwin E. Feldman, D.O. (Respondent), of Madison Heights, Michigan. The Show Cause Order proposed the revocation of Respondent's DEA Certificate of Registration, AF9086415, which authorizes him to dispense controlled substances as a practitioner, and the denial of any pending applications to renew his registration, on the ground that his "continued registration is inconsistent with the public interest." Show Cause Order at 1 (citing 21 U.S.C. 823(f) and 824(a)).

More specifically, the Show Cause Order alleged that on January 18, 2005, DEA issued an Order to Show Cause to Respondent, which alleged, *inter alia,* that between December 2001 and July 2004, he had prescribed controlled substances on ten occasions to undercover agents without performing a medical examination, and that he had issued prescriptions for Suboxone "to treat opiate addiction without having obtained" certification from the Michigan Center for Substance Abuse Treatment and a separate DEA registration to prescribe controlled substances for "maintenance and detoxification treatment of opiate addiction as required by 21 U.S.C. 823(g)." *Id.* at 1–2.

Next, the Show Cause Order alleged that on April 4, 2007, Respondent entered into a Memorandum of Agreement (MOA) with the Agency to resolve the allegations of the 2005 Show Cause Order, which was to remain in force through May 2010. *Id.* at 2. The Show Cause Order then alleged that under the MOA, Respondent agreed that he would prescribe controlled substances for only a thirty-day supply with one refill; that he would not prescribe controlled substances to persons who were not residents of the State of Michigan; that he would not prescribe controlled substances to family members; that he would maintain a log of all controlled substance prescriptions he issued; that he would maintain in patient charts, reports from the Michigan Automated Prescriptions System (MAPS) for all patients who received controlled substances from him for "in excess of six months"; and that he would notify DEA "in writing, within twenty days of the initiation of any proceedings which impacted [his] ability to handle controlled substances, including the initiation of any action by a state entity to restrict, deny, rescind, suspend, revoke or otherwise limit [his] authority to handle controlled substances." *Id.*

Finally, the Show Cause Order alleged that Respondent had violated the MOA. *Id.* The Order specifically alleged that "on several occasions," Respondent had issued controlled substance prescriptions "with as many as seven refills"; that he had prescribed controlled substances to residents of Florida and Colorado; that he had prescribed Phenobarbital, a schedule IV