DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 11–73]

Jeffery J. Becker, D.D.S., and Jeffery J. Becker, D.D.S., Affordable Care Decision and Order

On December 22, 2011, Chief Administrative Law Judge John J. Mulrooney, II, (hereinafter, ALJ), issued the attached Recommended Decision.[1] Respondent filed Exceptions to the ALJ's Decision, and the Government filed a Response to Respondent's Exceptions.

Having reviewed the record in its entirety, including Respondent's Exceptions, I have decided to adopt the ALJ's recommended rulings, factual findings, legal conclusions and decision except as discussed below. A discussion of Respondent's Exceptions follows.

Respondent's Exceptions

In his Exceptions, Respondent raises five main contentions. Having considered his Exceptions, and finding one of them to be of merit, I nonetheless conclude that the record supports the ALJ's recommended order of revocation.

Exception 1—Respondent's Violation of the Separate Registration Requirement Does Not Support the Revocation of His Registration

The evidence shows that Respondent maintains a dental practice at two offices, which are located in Norwalk and Avon, Ohio, each of which is open two days a week. However, Respondent holds a registration only for the Norwalk office, even though the evidence shows that he routinely performs procedures, which require that he administer controlled substances to his patients, at both offices.

Under 21 U.S.C. 822(e), ''[a] separate registration shall be required at each principal place of business or professional practice where the applicant manufactures, distributes, or dispenses controlled substances or list I chemicals.'' *See also* 21 CFR 1301.12(a). While, by regulation, DEA has exempted several categories of locations from the registration requirement, with respect to practitioners, the exemption is limited to ''[a]n office used by a practitioner * * * where controlled substances are prescribed but neither administered nor otherwise dispensed as a regular part of the professional practice of the practitioner at such office, *and* where no supplies of controlled substances are maintained.'' 21 CFR 1301.12(b)(3) (emphasis added).

Respondent does not dispute that ''he dispensed controlled substances at his unregistered Avon office,'' Resp. Exc. at 11, and he admitted in his testimony that he had continued to do so up until the date of the hearing. Tr. 764–65. Respondent maintains, however, that upon being informed during the December 2009 DEA inspection that he could not store controlled substances at the Avon office, he discontinued storing controlled substances there. Resp. Exc. at 11. As for why he did not cease administering controlled substances at his Avon office, Respondent contends that he ''believed that the critical issue was where the controlled substances were 'stored' as opposed to 'administered.' '' *Id.* (quoting Tr. 764–65).

To buttress the latter contention, Respondent cites the testimony of the Government's Expert witness, a D.D.S., whose practice is limited to providing intravenous (IV) sedation services for the patients of other dentists ''throughout the Dayton-Cincinnati area,'' as well as at a local hospital. GX 14; Tr. 23–24. In particular, Respondent notes that the Government's Expert testified that he has only one registration, and that he does not obtain registrations for the numerous offices of other dentists at which he provides anesthesia to patients. Tr. 103. Citing the Government's Expert testimony that he is an expert on the state and federal regulations pertaining to controlled substances, as well as that he also teaches IV sedation and the standards of the dental profession to other dental practitioners in Ohio, Respondent asserts that revoking his registration cannot be reconciled with the Expert's testimony that a registration is only necessary ''where you order your drugs, store your drugs and keep the records of disposal and usage.'' Tr. 103; Resp. Exc. at 13.

While Respondent now concedes that both his belief and that of the Expert were mistaken, he contends that the Expert's testimony ''support[s] the reasonableness of [his] mistake in fact relating to the regulatory requirements.'' [2] Resp. Exc. at 13. According to Respondent, his violations of the CSA were the ''result of his confusion and apparent misunderstanding of the law.'' *Id.* However, Respondent then contends that ''it is difficult to comprehend a situation that would be more confusing to a respondent than to sit in a courtroom and hear testimony of the Government's expert advocating the very position for which [his] registration is in jeopardy.'' *Id.* at 13–14. Thus, Respondent argues that the ALJ's findings that he ''flagrantly'' violated the law and that he has failed to acknowledge wrongdoing and establish his future compliance are unsupported by the record and that the recommended sanction of revocation is unwarranted. *Id.* at 14.

The argument is not persuasive because the determination of the meaning of the CSA and Agency regulations is not within the proper role of expert witnesses. Rather, it is a function vested in the Agency and the Federal Courts. *See Chevron* v. *NRDC,* 467 U.S. 837 (1984). Most importantly, Respondent cannot credibly claim to have been confused as to the requirement that he obtain a separate registration for his Avon practice as both the Act itself and its implementing regulations provide clear notice as to what is required. *See United States* v. *Clinical Leasing Serv., Inc.,* 925 F.2d 120, 123 (5th Cir. 1991) (''A physician of ordinary means and intelligence would understand that the federal registration provisions apply to *each* important or consequential place of business where the physician distribute controlled substances. It is sufficiently clear that the application of the provisions is not limited to *a single* important or consequential place of business where controlled substances are distributed.'').

As set forth above, the CSA's registration provision states in relevant part that ''[a] separate registration shall be required *at each principal place* of business or professional practice where the applicant manufactures, distributes, or *dispenses* controlled substances.'' 21 U.S.C. 822(e) (emphasis added). Likewise, the CSA defines the term dispense to ''mean[] to deliver a controlled substances to an ultimate user * * * by * * * a practitioner, including the * * * administering of a controlled substance.'' *Id.* § 802(10). Thus, the statute provides clear notice that it is the activity of *dispensing,* which includes the administration of controlled substances, itself, which triggers the requirement, in the case of a practitioner, of obtaining a separate registration for a principal place of professional practice. *See* 21 U.S.C. 822(e). And to similar effect, the text of 21 CFR 1301.12(b)(3), which uses the conjunction ''and,'' makes clear that the exemption from registration for a practitioner's office obtains only when

[1] All citations to the ALJ's Recommended Decision are to the slip opinion as originally issued.

[2] Of course, this is not a mistake of fact at all as Respondent then states that his violations were caused in part by his ''apparent misunderstanding of the law.'' Resp. Exc. 13.

two conditions are met: (1) That the practitioner only engages in the prescribing of controlled substances and ''neither administer[s] nor otherwise dispense[s]'' at the office, and (2) that the practitioner does not maintain any supplies of controlled substances at the office.

To the extent Respondent suggests that the Expert's testimony establishes that there is widespread confusion among practitioners as to the scope of the registration requirements, the argument is unavailing. The clarity of the Act and the Agency's regulations is not determined by whether there are even a substantial number of members of the dental profession in Ohio who are confused as to the scope of the registration requirements. Rather, it is determined by assessing whether the text of the Act and regulations provide fair notice such that a person of ordinary intelligence can understand when a separate registration is required. *See FCC* v. *Fox Television Stations, Inc.,* 132 S.Ct. 2307, 2310 (2012) (quoting *United States* v. *Williams,* 553 U.S. 285, 304 (2008)). The Act and regulations pass this test with flying colors.

There is likewise no merit to Respondent's contention that the Government's position is ''irreconcilable'' with the Expert's acknowledgement that he does not hold registrations at each of the numerous offices where he administers controlled substances. Resp. Exc. at 12–13. The CSA's registration requirement applies only to ''each *principal* place of * * * professional practice * * * where controlled substances are * * * dispensed by a person.'' 21 CFR 1301.12(a) (emphasis added). While the record establishes that the Government's Expert travels to numerous offices of other dentists to provide anesthesia services for their patients, he does so on an apparently as-needed and random basis, and there is no evidence that he maintains a place of professional practice, let alone a principal one, at any of these locations. Nor is there any evidence as to whether the dentists who call on him to provide anesthesia to their patients themselves have DEA registrations. *See* 21 CFR 1301.22(b).

By contrast, the evidence shows that Respondent maintains two offices, at which he regularly both sees and administers controlled substances in the course of treating patients. Notwithstanding that the word ''principal'' ordinarily means the ''most important, consequential, or influential,'' *Webster's Third New International Dictionary* 1802 (1993), or the ''main, prominent'' or ''leading,'' *see Hertz Corp.* v. *Friend,* 130 S.Ct. 1181, 1192 (2010) (quoting 12 Oxford English Dictionary 495 (2d ed. 1989)), by inserting the word ''each'' into the statutory text, Congress clearly was aware that practitioners frequently maintain multiple places of professional practice and manifested its intent that such an office be registered if the practitioner administers controlled substances at the location. Any other interpretation would undermine Congress' purpose of requiring registration to ensure that those locations at which controlled substance activities take place have adequate security and procedures in place to prevent the diversion of drugs from their legitimate use.

Nor is there any merit to Respondent's contention that the ALJ erred in finding that he ''flagrantly'' violated the registration provision. Resp. Exc. at 14. Even if at the time of the December 2009 inspection, the Agency's Investigator told him only that he could not store controlled substances at his Avon office and did not mention that he was also prohibited from administering drugs at this location because it was not registered, subsequently, the Show Cause Order specifically cited 21 CFR 1301.12, the provision which makes plain that he was required to hold a registration at this Office. ALJ Ex. 1, at 2. Moreover, in its Pre-Hearing Statement, the Government provided notice that it intended to establish that Respondent's Avon office ''is not registered with DEA to handle controlled substances[,]'' and that ''DEA learned that Respondent administered controlled substances to patients from his Avon dental practice.'' ALJ Ex. 5, at 7. Yet even after being provided with notice that the Government was alleging that he was in violation of the registration provision, Respondent acknowledged that he had administered controlled substances at his Avon office as recently as the week before the hearing. Tr. 764–65. This is more than enough to establish that Respondent flagrantly violated the statute, and in the absence of mitigating evidence, it is sufficiently egregious to support the revocation of his registration.

Exception 2—Respondent's Violation of 21 CFR 1301.75(b) Does Not Support the Revocation of His Registration

Respondent also argues that the evidence pertaining to the storage of controlled substances at his Avon location in violation of 21 CFR 1301.75 does not ''reflect an intentional disregard for security,'' and that the ALJ ignored evidence of steps he took to comply when the adequacy of security was questioned by a State Board Inspector. Resp. Exc. at 17. However, while the ALJ found that Respondent violated 21 CFR 1301.75(b) by leaving controlled substances (unattended) in open storage bins in the sterilization room at the Avon office (rather than keeping them in a securely-locked and substantially-constructed cabinet), there is also credible evidence that Respondent had changed his storage practices at the time of the December 2009 DEA inspection and that he was then in compliance with the above regulation. *See* Tr. 595. The ALJ did not, however, discuss this evidence in his decision. Had Respondent's violations of 21 CFR 1301.75 been the only allegations sustained on the record, they would not support the sanction recommended by the ALJ. However, as explained above, they are not the only violations proved.

Exception 3—The Provisions of 21 CFR 1307.21(a) Are Not Mandatory, Are Void for Vagueness, and Are Inapplicable in Light of State Regulation

As noted above, the record shows that Respondent administered controlled substances intravenously to patients and that he disposed of the excess drug by squirting it down the sink. Respondent did not, however, notify the Agency of this practice and did not complete DEA Form 41 for these disposals.[3] The Government thus alleges that Respondent violated 21 CFR 1307.21(a), because he ''did not provide prior notification to DEA of such disposal as required by'' this regulation. ALJ Ex. 1, at 2.

[3] Other evidence of record relevant to the issue includes an affidavit of Dr. Joel Weaver, a dentist anesthesiologist and Professor Emeritus at The Ohio State University Medical Center, who has practiced for thirty-five years. RX J, at 1. In his affidavit, Dr. Weaver stated that ''[t]he standard practice among dentists in Ohio and most likely in most states is for the dentist to log the dose of the drug taken from his inventory, record the dose given to the patient in the patient sedation/anesthesia record and record any 'wasted' dose in either the drug log, the patient's record or both as soon as the case is concluded.'' *Id.* at 2. He also explained that ''[t]he 'wasted' drug is typically squirted into the sink * * *, into the trash or sharps container, or into the soil of potted plants as a source of nitrogen-containing fertilizer.'' *Id.*

According to Dr. Weaver, in titrating the dose of sedation for each patient, ''there is often some amount of drug remaining in syringes since the dose is individualized for each patient and [the] length of the operation[,] and cannot be predicted.'' *Id.* He then explained that ''[t]he safest and most convenient method of disposing of these drugs is immediate disposal and then placing the contaminated syringes in a sharps container.'' *Id.* Dr. Weaver further stated that in Ohio alone, there are approximately 500 dentists who are licensed to perform intravenous sedation and that each of these physicians could perform twenty sedation procedures each day for a total of 10,000 procedures each day. *Id.*

While Respondent admits that he disposed of controlled substances in this manner, he argues that the regulation does not set forth mandatory procedures for disposing of controlled substances. Resp. Exc. at 18–19. Alternatively, he argues that the regulation ''is void for vagueness,'' *id.* at 19, and that the regulation, when coupled with the instructions provided on DEA Form 41, create ''an alarming morass of confusion'' as to what it requires. *Id.* at 21. As support for his contention, Respondent points to the testimony of the Government's Expert that, he too, disposes of a drug, in excess of what he administered to a patient, by squirting it down the sink, and does so without obtaining permission from the Agency. *Id.* at 22–23. Respondent further points to the testimony of an Agency Investigator that ''a large portion'' of the practices he has inspected dispose of excess drugs by squirting them into either the sink or toilet.[4] *Id.* at 24 (quoting Tr. 631).

Responding to Respondent's contention that the regulation does not provide fair notice, the Government argues that the various cases he relies on ''are applicable to criminal or civil proceeding[s], but inapplicable to regulated persons subject to the licensing requirement set forth by an administrative agency or provision of the Administrative Procedures [sic] Act.'' Gov. Resp. to Exceptions, at 6–7. However, contrary to the Government's understanding, just last term the Supreme Court invalidated an FCC order finding various broadcasters liable for violating that Agency's indecency policy, because the FCC failed to provide fair notice that their conduct would be deemed a violation. *FCC* v. *Fox Television Stations, Inc.,* 132 S.Ct. 2307 (2012). In *FCC* v. *Fox,* the Court reiterated that the ''requirement of clarity in regulation is essential to the protections provided by the Due Process Clause,'' and that a ''punishment fails to comply with due process if the statute or regulation under which it is obtained 'fails to provide a person of ordinary intelligence fair notice of what is prohibited, or is so standardless that it authorizes or encourages seriously discriminatory enforcement.' '' *Id.* (quoting *United States* v. *Williams,* 553 U.S. 285, 304 (2008)).

While *FCC* v. *Fox* involved the imposition of a monetary penalty, it hardly broke new ground. *See General Electric Co.* v. *EPA,* 53 F.3d 1324, 1328–29 (D.C. Cir. 1995); *Diamond Roofing Co.* v. *OSHRC,* 528 F.2d 645, 649 (5th Cir. 1976) Nor is there any no doubt that the Government's obligation to provide ''fair notice'' of what conduct is prohibited applies to licensing proceedings as well. Indeed, this has been the law for more than forty years. *See Trinity Broadcasting of Florida, Inc.,* v. *FCC,* 211 F.3d 618, 628 (D.C. Cir. 2000); *Radio Athens, Inc.,* v. *FCC,* 401 F.2d 398, 404 (D.C. Cir. 1968). Thus, in *Trinity Broadcasting,* the D.C. Circuit recognized that the denial of an application to renew a license is ''a severe penalty,'' and ''held that 'in the absence of notice—for example, where the regulation is not sufficiently clear to warn a party about what is expected of it—an agency may not deprive a party of property by imposing civil or criminal liability.' '' *Id.* (quoting *G.E.* v. *EPA,* 53 F.3d at 1328–29). Accordingly, if the regulation (or other pronouncements interpreting it) do not provide ''fair notice'' of what is required, Respondent cannot be deemed to have violated it.

The starting point for resolving these contentions is, of course, the language of the regulation. The regulation, which was one of the original regulations promulgated by DEA's predecessor, the Bureau of Narcotics and Dangerous Drugs, *see* 36 FR 7802 (1971) (then codified at 21 CFR 307.21), provides, in relevant part, that:

> (a) Any person in possession of any controlled substance and desiring or required to dispose of such substance *may request assistance* from the Special Agent in Charge of the Administration in the area in which the person is located *for authority* and instructions to dispose of such substance. The request should be made as follows:
>
> (1) If the person is a registrant, he/she shall list the controlled substance or substances which he/she desires to dispose of on DEA Form 41, and submit three copies of that form to the Special Agent in Charge in his/her area[.]

21 CFR 1307.21(a) (emphasis added).[5]

The ALJ rejected Respondent's contention that the regulation does not impose a mandatory requirement of notification, reasoning that its language ''[n]ecessarily * * * implies that a person who does not request assistance to dispose of a controlled substance does not have authority to dispose of such substance. This is a classic example of permissive language which 'plainly carr[ies] a restrictive meaning.' '' Order Regarding Respondent's Multiple Motions For Appropriate Relief (ALJ Ex. 25), at 10 (quoting *Forest Grove School Dist.* v. *T.A.,* 557 U.S. 230, 254 n.1 (2009) (Souter, J., dissenting)). The ALJ further reasoned that ''[u]nder a plain reading of the regulation, a registrant is not required to dispose of controlled substances, but once he or she elects to do so, such disposal may not be made without authorization from the specified DEA official.'' *Id.* at 11.

I conclude, however, that the regulation's text does not provide sufficient clarity to conclude that it provides a mandatory procedure which must be followed in all instances in which a person seeks to dispose of a controlled substance rather than simply a mechanism by which a person who requires assistance to dispose of a controlled substance can obtain such assistance. Moreover, while the ALJ's interpretation might be permissible, it rests on the unsupported premise that authority must always be obtained to lawfully dispose of a controlled substance. However, neither the Government, nor the ALJ, undertook to analyze the CSA and explain why this conclusion is required.

Significantly, unlike most (if not all) other DEA regulations which are indisputably mandatory, the relevant text uses the word ''may'' rather than ''shall'' to modify the words ''request assistance.'' As the Supreme Court has explained, ''[t]he word 'may' customarily connotes discretion,'' and this is particularly true where, as here, an enactment also uses the word ''shall.'' *Jama* v. *ICE,* 543 U.S. 335, 346 (2005). Likewise, the phrase's use of the words ''request assistance'' rather than ''request authority,'' notwithstanding that obtaining authority may well be the ultimate purpose of the procedure provided in the regulation (at least in

[4] Respondent also contends that the regulation ''is inapplicable in light of'' an Ohio Board of Pharmacy regulation governing the disposal of controlled substances. *Id.* at 24–25. In light of my disposition of this Exception, I conclude that it is not necessary to address this contention.

[5] The regulation also provides that:

> (b) The Special Agent in Charge shall authorize and instruct the applicant to dispose of the controlled substance in one of the following manners:
>
> (1) By transfer to person registered under the Act and authorized to possess the substance;
>
> (2) By delivery to an agent of the Administration or to the nearest office of the Administration;
>
> (3) By destruction in the presence of an agent of the Administration or other authorized person; or
>
> (4) By such other means as the Special Agent in Charge may determine to assure that the substance does not become available to unauthorized persons.

21 CFR 1307.21(b). In addition, subsection c of the regulation provides that:

> [i]n the event that a registrant is regularly required to dispose of controlled substances, the Special Agent in Charge may authorize the registrant to dispose of such substances, in accordance with paragraph (b) of this section, without prior approval of the Administration in each instance, on the condition that the registrant keep records of such disposals and file periodic reports with the Special Agent In Charge summarizing the disposals made by the registrant.

Id. § 1307.21(c).

some cases), is hardly the language of a mandatory requirement or command.

Thus, while on its face, section 1307.21(a) is broad in scope as it applies to all persons (and not only registrants) as well as all means of disposal, it is far from clear why a person, like Respondent, who disposes of a controlled substance by squirting or flushing it down the drain, would necessarily need any assistance to do so. Nor, even assuming that there are circumstances in which a person is required to obtain authority from DEA to dispose of a controlled substance (*i.e.,* because the person lacks authority to distribute the drug to another), is it clear why a person, who disposes of a controlled substance in the manner Respondent did, requires authority from DEA to do so. Thus, while it is clearly reasonable to construe the regulation as providing a mandatory procedure for disposing of controlled substances where a person must distribute the controlled substances to another person—because other provisions of the CSA make clear that a person cannot lawfully distribute a controlled substance without the required registration—that does not mean that the regulation provides fair notice that it is mandatory when applied to other circumstances.

Indeed, the regulation's use of the word ''may'' rather than ''shall'' itself suggests that there are circumstances in which authority from DEA is not required to dispose of a controlled substance.[6] So too, that the regulation ''shall not be construed as affecting or altering in any way the disposal of controlled substances through procedures provided in laws and regulations adopted by any State,'' 21 CFR 1307.21(d), raises the question of whether its procedures are still mandatory if one disposes of controlled substance in compliance with state law (and thus has authority) without engaging in a distribution.

In its pleadings, the Government acknowledges that ''the administrative case law is relatively silent on the requirements of a registrant under 21 CFR 1307.21.'' Gov. Resp. to Respondent's Motion to Exclude Paragraph 7 of the Order to Show Cause (ALJ Ex. 17), at 2. Indeed, while this regulation has been in existence for more than forty years, the Government points to no case in which a person, whether a practitioner or ultimate user, has been either criminally or administratively prosecuted for destroying a controlled substance, without notifying the Agency, which he/she lawfully possessed and retained possession of during the destruction process.[7] Nor does the Government cite to either an interpretive rule or guidance document it has issued explaining that this regulation requires all persons, including practitioners, to first obtain authority from the Agency before they destroy a controlled substance of which they retain possession.[8] Finally, even in this litigation, the Government does not explain why a person, who destroys controlled substances which they lawfully possess and which they do not distribute to another, nonetheless requires either ''assistance'' or ''authority'' to do so.

Notably, the CSA itself contains no provision explicitly prohibiting or regulating (other than through recordkeeping) the destruction of controlled substances. Moreover, in enacting the Secure and Responsible Drug Disposal Act of 2010, which amended the CSA, Congress found that ''take-back programs often cannot dispose of the * * * controlled substance medications * * * because Federal law does not permit take-back programs to accept controlled substances unless they get specific permission from [DEA] and arrange for full-time law enforcement officers to receive the controlled substances directly from the member of the public who seeks to dispose of them.'' Secure and Responsible Drug Disposal Act of 2010, Public Law 111–273, § 2(4)(B), 124 Stat. 2858, 2859 (2010). Yet Congress further found that:

> Individuals seeking to reduce the amount of unwanted controlled substances in their household consequently have few disposal options beyond discarding or flushing the substances which may not be appropriate means of disposing of such substances. Drug take-back programs are also a convenient and effective means for individuals in various communities to reduce the introduction of some potentially harmful substances into the environment, particularly into water.

Id. § 2(4)(C). Of significance, while Congress noted the lack of legal authority for take-back programs to accept controlled substances without Agency permission, it made no similar observation that those individuals who dispose of their controlled substances by discarding or flushing them also lack legal authority to do so.[9]

To be sure, because of their role in the closed system of distribution, the CSA imposes requirements on registrants which are not imposed on ultimate users, and the Act generally limits the authorized activities of practitioners to the dispensing of controlled substances and prohibits them from distributing a controlled substance. Yet the Government offers no argument that squirting the small amount of excess medication, which has been drawn into a syringe but not administered to a patient, into a sink or toilet and flushing it, constitutes a distribution within the

[6] The regulation's use of the permissive word ''may'' cannot be reasonably attributed to the fact that the regulation provides a procedure that applies whether a person is merely ''*desiring* * * * to dispose of a controlled substance,'' or is ''*required* to dispose of a controlled substance.'' 21 CFR 1307.21(a) (emphasis added). Surely, no one ''desiring * * * to dispose of a controlled substance'' would object if the regulation stated that he ''shall request assistance'' to do so. *Id.*

[7] The only case cited by the Government involved an entity, which was ''in the business of receiving salvage or undeliverable merchandise from common carriers,'' and which sought a DEA registration as a distributor. *Associated Pharmaceutical Group, Inc.,* 58 FR 58181 (1993). Notably, the entity was unregistered and could not lawfully possess controlled substances. *Id.* at 58183. The Order's brief discussion of 21 CFR 1307.21 simply recounted the advice given the entity by a DEA Investigator that the regulation ''requires that it seek DEA authorization for disposal or destruction of controlled substances that it was retaining in its possession,'' *id.* at 58181, as well as in a letter which advised it ''that all unclaimed controlled substances in [its] possession would have to be disposed of according to 21 CFR 1307.21.'' *Id.* at 58182.

[8] At the time of the regulation's promulgation, DEA did not recognize reverse distributors as a category of registrant and the regulations only authorized a person to distribute (without being registered to distribute) ''that substance to the person from whom he obtained it or to the manufacturer of the substance.'' 21 CFR 307.12 (1971).

[9] Consistent with this understanding, in several other pronouncements, including guidelines developed by the FDA in conjunction with the Office of National Drug Control Policy (ONDCP), which discuss the proper method of disposing of prescription drugs including controlled substances, not once has the Federal Government explained that a person must first obtain permission from DEA to dispose of a controlled substance if he destroys it himself. *See* ONDCP, *Epidemic: Responding to America's Prescription Drug Abuse Crisis* 7–8 (2011). Moreover, while the Guidelines instruct that drugs should be flushed ''down the toilet only if the accompanying patient information specifically instructs it is safe to do so,'' ONDCP, Press Release, *Federal Government Issues New Guidelines For Proper Disposal of Prescription Drugs* (Feb. 20, 2007), the FDA has determined, with respect to a number of controlled substances, that flushing them down the toilet or sink is appropriate and that ''any potential risk to people and the environment from flushing [these drugs] is outweighed by the real possibility of life-threatening risks from accidental ingestion of these medicines.'' U.S. Food and Drug Administration, *Disposal of Unused Medicines: What You Should Know* 1 (Jan. 2012). *See also* U.S. Food and Drug Administration, *How to Dispose of Unused Medicines* 2 (April 2011) (noting that the disposal instructions on some drugs may contain ''instructions to flush down the toilet, * * * because FDA * * * has determined this method to be the most appropriate route of disposal that presents the least risk to safety'' and that ''[d]rugs such as powerful narcotic pain relievers and other controlled substances carry instruction for flushing to reduce the danger of unintentional use or overdose and illegal abuse'').

To make clear, whether flushing the drugs which Respondent used in the procedures he performed creates environmental harms is an issue for other agencies.

meaning of the CSA, or is otherwise prohibited by the Act.[10] Indeed, disposing of the excess amount of a controlled substance, pursuant to the administration of the drug to a patient in the course of professional practice and in this manner, would seem to be a necessary incident of administering the drug and within the scope of a practitioner's authorized activities.

I therefore conclude that the use of the phrase ''may request assistance'' in the relevant language of the regulation creates an ambiguity as to whether it is permissive or mandatory in all instances in which a person disposes of a controlled substance. Because the Government points to no provision of the CSA which prohibits this method of disposal or otherwise requires that a practitioner obtain authority to dispose of controlled substances in all circumstances, and because notwithstanding that the regulation has been in existence for more than forty years, the Government has not published any administrative interpretation holding that disposal in this manner violates the Act or requires authority from the Agency, I hold that the Government has not provided fair notice that Respondent's conduct was prohibited.[11] Accordingly, this conduct cannot be used as a basis for finding a violation of the CSA.[12]

[10] To further demonstrate the lack of clear notice provided by the Government's proposed reading of the regulations, apparently even if a registrant wants to distribute a controlled substance to a reverse distributor, it must request authority to do so under 21 CFR 1307.21(a). Yet under a separate regulation, a practitioner is authorized to ''distribute (without being registered to distribute)'' a controlled substance to ''[a] reverse distributor who is registered to receive such controlled substances.'' 21 CFR 1307.11(a). Thus, this provision would seem to grant authority to a practitioner to dispose of his excess controlled substances by shipping them to a reverse distributor who destroys them. However, no guidance from the Agency explains whether a practitioner who disposes of his controlled substances in this manner (and who seemingly has been granted authority by this regulation to do so) is nonetheless required to comply with section 1307.21.

[11] My holding that the regulation is ambiguous as applied to practitioners engaged in this manner of disposal does not preclude the Agency from issuing an interpretative rule clearly explaining the scope of the regulation and attempting to provide a reasoned basis for applying the regulation to this conduct.

[12] The ALJ also noted that even after Respondent was advised by the Agency's Investigator that he was in violation of 21 CFR 1307.21, he continued to engage in the same conduct. While this conduct is disturbing, I do not rely on it given the absence of any published order, interpretive rule, or guidance document holding or explaining that the Agency deems such conduct to be a violation. In any event, given the evidence that Respondent continued to violate the registration requirement and did so even after being served with the Show Cause Order, this conduct is, by itself, sufficiently egregious to support the revocation of his registration.

Exception 4—The ALJ's Recommended Decision Is Arbitrary and Capricious and Unsupported By Law

Respondent also takes exception to the ALJ's factual findings, legal conclusions, and recommended sanction, contending that they are ''arbitrary, capricious and unsupported by law.'' Resp. Exc. at 27. However, with the exception of the ALJ's legal conclusions pertaining to the alleged violations of 21 CFR 1307.21, I find that the ALJ's findings of fact and legal conclusions are supported by substantial evidence. Based on the ALJ's findings that: (1) Respondent violated the separate registration requirement by failing to register his Avon practice, notwithstanding that he regularly administered controlled substances at this office, *see* ALJ at 37; (2) even after he was on notice that he was in violation of this provision, he continued to violate the Act and was still doing so the week before the hearing, *see id.* (citing Tr. 660 & 764); (3) Respondent failed to maintain proper records in that he was missing purchase records as well as order forms (DEA 222) for the schedule II controlled substances he purchased, *see id.* at 39–40; and (4) Respondent failed to properly secure the controlled substance he took to his Avon office, *see id.* at 38–39; I conclude that the ALJ's finding that Respondent has committed acts which render his registration inconsistent with the public interest is supported by substantial evidence and that the Government has satisfied its *prima facie* burden. *See id.*

While I acknowledge that Respondent produced evidence that he has changed his storage practices at his Avon office, he has offered no evidence that he has applied for a registration for the Avon office, nor provided any evidence to support a finding that he has addressed the serious recordkeeping violations proven on this record. Moreover, even to this day, Respondent does not accept responsibility for his violations of the registration requirement; instead, he argues—notwithstanding that the Agency's regulation is clear on its face—that because others violate the same regulation, his violations should be excused. Exacerbating this violation, Respondent continued to administer controlled substance at his Avon office in violation of the registration requirement even after being told by the DI that he was in violation and even after being served with the Show Cause Order. Accordingly, I agree with the ALJ's conclusion that Respondent has not rebutted the Government's *prima facie* case and will order that Respondent's registration be revoked and that any pending applications be denied.[13]

The Government also argues that Respondent's contention that the regulation does not provide fair notice should be rejected because he did not seek ''agency guidance regarding the issue.'' Gov. Resp. to Exceptions at 7. Contrary to the Government's understanding, the Due Process Clause places the burden on the Government to provide fair notice of what its regulation requires and not on Respondent to seek clarification of the regulation's ambiguity.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) and 824(a), as well as 28 CFR 0.100(b), I order that DEA Certificates of Registration Numbers FB2238865 and BB0569775, issued to Jeffery J. Becker, D.D.S., be, and they hereby are, revoked. I further order that any pending application of Jeffery J. Becker, D.D.S., to renew or modify any of the above registrations, be, and it hereby is, denied. This Order is effective January 4, 2013.

Dated: November 16, 2012.

Michele M. Leonhart,

Administrator.

Robert Walker, Esq., for the Government
Frank Recker, Esq., & *Todd Newkirk, Esq.,* for the Respondent

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

Chief Administrative Law Judge John J. Mulrooney, II. On July 28, 2011, the Deputy Assistant Administrator of the Drug Enforcement Administration (DEA or Government), issued an Order to Show Cause (OSC) seeking the revocation of DEA Certificates of

[13] I have considered Respondent's contention that the recommended sanction ''is a significant departure from prior agency decisions and * * * is without justification in fact.'' Resp. Exc. at 29. However, as the ALJ explained, in *Daniel Koller,* 71 FR 66975 (2006), I revoked the registration of a practitioner who engaged in similar misconduct. ALJ at 44. In his Exceptions, Respondent totally ignores *Koller.* Accordingly, I reject Respondent's Exception.

Respondent also contends that because an Agency Investigator approved his application for a Milwaukee registration when she knew that another Agency Investigator had requested the issuance of an Order to Show Cause, the Agency has ''voluntarily and intentionally'' waived its right to revoke his Milwaukee registration. Resp. Exc., at 25–26. Respondent, however, produced no evidence that he entered into an agreement with the Agency pursuant to which the Agency agreed that it would not seek to revoke this registration. In addition, even if the Investigator's decision to approve his registration was deemed to constitute a voluntary and intentional act of waiver (itself a dubious conclusion), DEA has not delegated the authority to waive prosecution to field investigators. *See* 28 CFR 0.104. Rather, that authority remains vested in the Deputy Assistant Administrator of the Office of Diversion Control. I thus reject the contention. It is further noted that Respondent does not claim that the Government is estopped from proceeding against his Milwaukee registration.

Registration (COR), Number BB0569775,[1] and Number FB2238865,[2] of Jeffrey J. Becker, D.D.S. (Respondent), as a practitioner, pursuant to 21 U.S.C. 824(a) (2006 & Supp. III 2010), and denial of a pending application for renewal of Respondent's DEA COR, Number BB0569775, pursuant to 21 U.S.C. 823(f) (2006). The OSC alleges that the Respondent's continued enjoyment of the privileges vested in his COR registrations is inconsistent with the public interest, as that term is used in 21 U.S.C. 823(f). On August 25, 2011, the Respondent, through counsel, timely requested a hearing, which was conducted in Arlington, Virginia on November 8–9, 2011.

The issue ultimately to be adjudicated by the Administrator, with the assistance of this recommended decision, is whether the record as a whole establishes, by substantial evidence, that the Respondent's CORs should be revoked [3] as inconsistent with the public interest, as that term is used in 21 U.S.C. 823(f) and 824(a).

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

The Allegations

The OSC issued by the Government contends that revocation of the Respondent's CORs is appropriate because: (1) The Respondent has practiced dentistry from a location in Avon, Ohio without obtaining a DEA COR to handle controlled substances at that location; [4] (2) the Respondent ''maintained * * * controlled substances at an unregistered [location] in violation [of] 21 U.S.C. 822(e);'' (3) the Respondent ''maintained controlled substances in an unsecured area in violation of 21 CFR § 1301.75(b);'' (4) ''sometime in 2009 [the Respondent] distributed controlled substances * * * to an unregistered location in violation of 21 CFR § 1307.11;'' (5) an accountability audit of the Respondent's ''handling of fentanyl, diazepam and midazolam * * * revealed shortages of fentanyl and midazolam and an overage of diazepam;'' and (6) the Respondent disposed of controlled substances but ''did not provide prior notification to DEA of such disposal as required by 21 CFR § 1307.21(a).'' ALJ Ex. 1 at 1–2.

The Stipulations of Fact

The Government and the Respondent, through counsel, have entered into stipulations regarding the following matters:

(1) The Respondent is registered with DEA as a practitioner in Schedules II–V under DEA registration number BB0569775 at 282 Benedict Avenue, Suite C, Box 22, Norwalk, Ohio 44857. While this registration reflects an expiration date of July 31, 2011, the Respondent timely submitted an application for renewal of registration on June 3, 2011.

(2) The Respondent is also registered with DEA as a practitioner in Schedules II–V under DEA registration number FB2238865 at Affordable Care, 6015 West Forest Home Avenue, Milwaukee, Wisconsin 53220. This registration expires by its terms on July 31, 2013.[5]

(3) Fentanyl is a Schedule II controlled substance pursuant to 21 CFR 1308.12(c)(9) (2011).

(4) Diazepam is a Schedule IV controlled substance pursuant to 21 CFR 1308.14(c)(14) (2011).

(5) Lorazepam is a Schedule IV controlled substance pursuant to 21 CFR 1308.14(c)(28) (2011).

(6) Versed is a brand name for a product containing midazolam, a Schedule IV controlled substance pursuant to 21 CFR 1308.14(c)(35) (2011).

The Evidence

The Government presented the testimony of Diversion Investigator (DI) Scott Brinks. Tr 428. DI Brinks testified that he has been employed as a DI in the Cleveland, Ohio, field office for just over ten years, Tr. 429, and that, during this time, he has been a part of at least a hundred investigations relating to practitioners. Tr. 431.

DI Brinks testified that, sometime prior to December of 2009, he was contacted by Investigator Flugge of the Ohio Dental Board (Board), who informed DI Brinks that ''he had some drug related problems with [Respondent].'' Tr. 433. After the conversation with Investigator Flugge, DI Brinks ran a query on the Respondent in the ARCOS [6] and RICS [7] databases. Tr. 433–436. Although Brinks ascertained from the Internet that the Respondent maintained a practice in Avon, Ohio, the RICS database query did not indicate that the Respondent had a COR for the Avon location. Tr. 435–36.

On the morning of December 21, 2009, DI Brinks met Investigator Flugge at a McDonalds across the street from the Respondent's practice in Norwalk, Ohio. Tr. 432. At this meeting, Investigator Flugge gave DI Brinks the Board's investigative file on the Respondent, including ''an anonymous complaint [and] a complaint by Rebecca Crockett.'' Tr. 433. Investigator Flugge also ''gave * * * a brief overview of the [the Board's] investigation and why he was referring [the matter].'' Tr. 433. However, ''Investigator Flugge said he did not want to come along because of [the Respondent's] relationship with the [B]oard.'' Tr. 438. When asked to clarify this remark, DI Brinks explained Investigator Flugge's reluctance to join the investigation ''had to do with some hearing that [the] Respondent had went to.'' Tr. 438–40.[8]

After meeting with Investigator Flugge, DI Brinks and a second DI drove across the street to the Respondent's office. Tr. 438. Upon entering the office, the DIs identified themselves, and presented the Respondent with a DEA Form 82, Notice of Inspection of Controlled Premises, which the

[1] The registered address under this registration is in Norwalk, Ohio. Gov't Ex. 1.

[2] The registered address under this registration is in Milwaukee, Wisconsin. Gov't Ex. 2.

[3] The Respondent has timely submitted an application for renewal of COR #BB0569775 (Norwalk) which was scheduled to expire under its own terms on July 31, 2011. Thus, by operation of law, this COR has been extended and remains in full force and effect until a final Agency order is issued in this case. 5 U.S.C. 558(c); 21 CFR 1301.36(i).

[4] This allegation does not aver that controlled substances are maintained, administered or dispensed at the Avon office. *See* 21 CFR 1301.12.

[5] The Respondent makes much of the granting of the Milwaukee registration, arguing that ''[i]f the DEA felt that the Respondent's continued registration was inconsistent with the public interest, they could have * * * at least denied the Respondent's application for his Wisconsin registration.'' Resp't Posth'g Brf., at 18. It is unclear on what legal authority this contention rests, but the DEA has considered the application of waiver in situations where, as here, the agency granted and then sought to revoke a license based on information available at the time the license was granted. *James Dell Potter, M.D.,* 49 FR 9970, 9971 (1984). In *Potter,* the DEA granted a license to the Respondent, notwithstanding information on the application referencing a felony conviction. Sometime later, the Agency rejected the respondent's argument that the granting of the application waived the Agency's right to seek revocation, holding that the doctrine of waiver requires a ''voluntary and intentional abandonment of known right.'' Thus, where the granting of a license is ''inadvertent and * * * unintentional[,]'' there can be no waiver. Here, as in *Potter,* there is no evidence that would support an election by the Agency to voluntarily and intentionally abandon a known right. Accordingly, application of waiver is unwarranted.

[6] The Automation of Reports and Consolidated Orders System (ARCOS) database tracks the course of distributions of controlled substances ''from the manufacturer down to the final seller.'' Tr. 434.

[7] DI Brinks explained the RICS system maintains a wide variety of information on DEA registrants. Tr. 436.

[8] DI Brinks reasonably explained that the motivation for the referral by Investigator Flugge did not matter to him because he ''ha[d] an allegation of a controlled-substance-related problem, so [he was] required to investigate that.'' Tr. 439.

Respondent reviewed and signed.[9] Tr. 438; Gov't Ex. 7. DI Brinks also requested that the Respondent provide ''all DEA Form 222s for the purchases of Schedule II controlled Substances, his purchase records for Schedule III–V [controlled substances, and] his dispensing records for Schedules II–V [controlled substances.]'' Tr. 442. DI Brinks also requested ''any DEA form 41s * * * Destruction of Controlled Substances, and any DEA Form 106, the Theft and Losses of Controlled Substances, and then [Respondent's biennial] inventory.'' Tr. 443. DI Brinks testified that, during their conversations,[10] he found the Respondent to be ''very nervous and his hands were shaking.'' [11] Tr. 442, 624.

The Respondent was able to produce only three controlled substance order forms (DEA Form 222) that related to a two-year period of practice, but even that modest number had one that did not contain all the information required. Tr. 444, 446–48, 639–40. When he realized he was unable to supply more than three Form 222s, the Respondent contacted his controlled substance supplier and had company purchase records faxed to his office for Brinks to review. Tr. 444, 638. The Respondent did provide his dispensing logs, Tr. 563, but no controlled substance destruction forms (DEA Form 41) or controlled substance theft/loss reports (DEA Form 106).[12] Tr. 443, 448–49.

After using the forms provided to conduct an audit that Brinks characterized as ''extremely short on * * * midazolam and * * * fentanyl,'' the DIs asked the Respondent if he had a way of justifying the shortages. Tr. 451. The Respondent responded that he had records and controlled substances at an office in Avon. Tr. 451. After completing their inspection of the Norwalk Office, the DIs traveled to the Respondent's (unregistered) office at Avon, where they found additional files and three-fourths of a bottle of fentanyl.[13] Tr. 452.

During the inspection of the Respondent's dispensing logs, DI Brinks ''observed * * * that [Respondent] had provided large quantities of midazolam.'' Tr. 455.[14] DI Brinks testified that he became concerned ''as soon as I started seeing 70 and * * * 100 [miligrams administered].'' [15] Tr. 457. DI Brinks asked Peg Herner, a dental assistant at Respondent's office, about doses of the medication that the DI divined were excessive, and was told that ''I just write down what [the Respondent] tells me to write down.'' Tr. 456. After consulting with Ms. Herner, DI Brinks asked the Respondent about the midazolam prescribing, and the Respondent told him that the patients ''build up a tolerance.'' Tr. 457–58. At some point during this conversation, DI Brinks questioned the Respondent about whether he was abusing controlled substances, and the Respondent twice volunteered to show the DIs his arms. Tr. 460, 621. When the Respondent pulled up the sleeves of his lab coat, DI Brinks observed three or four small ''poke marks'' on the left arm, but no bruising or scarring. Tr. 460–62. Respondent said that the marks were caused by dental students he allowed to practice IV techniques in a sedation class he taught at Case Western Reserve School of Dentistry on Fridays. Tr. 462. The following day, the DIs went to Case Western Reserve. Tr. 596. During their visit the DIs encountered the Respondent and, at the request of officials at the university,[16] he invoked his right to an attorney. Tr. 596.

As a result of his visit to the Respondent's practice, DI Brinks concluded that Respondent violated the DEA's regulations by failing to have a registration for his Avon Office. Tr. 640. DI Brinks also concluded that Respondent had violated DEA regulations by failing to maintain purchase records, and by failing to maintain accurate dispensing records. Tr. 639–40. It was Brinks' recollection that he informed the Respondent of ''some of the record keeping issues [and] the storing controlled substances at an unregistered location.'' Tr. 597–598. Brinks characterized the Respondent as ''cooperative'' during the investigation. Tr. 603, 637.

Brinks also discovered evidence that unused controlled substances that were left over in hypodermic needles at the conclusion of dental procedures conducted at the Respondent's practice were being disposed of by squirting them down the sink. Brinks explained that practitioners are not routinely provided with written guidance by the local DEA office on the issue of waste procedures authorized by the regulations,[17] and although there are options for compliance (utilization of DEA-registered reverse distributors, Ohio Pharmacy Board assistance, and providing medications directly to DEA),[18] ''a large portion'' of the practitioners he has inspected over the course of his career dispose of residual controlled substance medication from hypodermic needles by squirting it ''either down the sink or the toilet.'' Tr. 631.

During his testimony, DI Brinks attempted to explain the results of his drug audit. Apart from individual doses of medications reflected in the medication logs which, based on his experience, he concluded were high, Brinks' testimony regarding his audit was confusing, inconsistent, and unreliable. Brinks was unable to explain the data that he had collected and compiled. Brinks had processed his findings into a multicolor chart which he designed to compare the Respondent's levels of midazolam dispensing at his private practices with levels he dispensed at Case Western University School of Dentistry and the U.S. Food and Drug Administration (FDA) recommended maximum dosages. Tr. 464–77. When the numbers on his proposed chart could not be reconciled with the raw data he claimed to have based it on, the witness acknowledged that he really had no idea what the chart (he created) signified.[19] Tr. 475. The data in Brink's audit computation chart suffered from like blunders and was similarly excluded. Gov't Ex. 8 (ID); Tr. 478–90. An overnight break in the proceedings afforded the DI the opportunity to make revisions on his initial, ill-fated computation chart,[20] but there were issues with the revised version as well. Gov't Ex. 16; Tr. 583–

[9] Inexplicably, despite the details he provided about his visit to the Respondent's office, when asked about his recollection of the event, DI Brinks stated that he could ''vaguely recall walking in there * * *.'' Tr. 590.

[10] DI Brinks indicated that no recording devices were employed during the inspection. Tr. 442, 594. The Respondent testified that he believed that his conversation with Brinks was recorded. Tr. 781–82.

[11] On cross-examination DI Brinks conceded that, while other practitioners have appeared nervous during his investigations, he had ''not seen somebody shake like that in my experience.'' Tr. 624–25.

[12] The Government's theory on noting the absence of theft/loss forms was rooted in its concept that its audit demonstrated losses that should have been noted by such documentation. As discussed in some detail, *infra,* the quality of the audit results presented by the Government in these proceedings renders the presence or absence of theft/loss forms largely irrelevant here.

[13] Brinks testified that the Avon practice is not a location that is registered as a COR address that would be subject to an inspection, and accordingly, the DIs remained in the Respondent's waiting area, and were presented with the fentanyl and records by the Respondent after he went into the practice portion of the office by himself. Tr. 452–53.

[14] DI Brinks clarified that ''I know from experience * * * what midazolam should be, what should be given before surgery.'' Tr. 455.

[15] In his experience, DI Brinks had never ''seen anything close to 70 milligrams [administered] in one visit in one patient.'' Tr. 456–57.

[16] Tr. 707.

[17] Tr. 630.

[18] Tr. 630–33.

[19] Inasmuch as a sufficient foundation for admission could not be established, the proposed exhibit was excluded from the record upon a timely, cogent and correct objection. Gov't Ex. 9 (ID).

[20] Tr. 488–90.

89, 610, 612–17. The DI's initial computation chart was ultimately received into evidence at the behest of the Respondent. Resp't Ex. M. Given the confusing nature of the Government's presentation and the surprise nature of its revised audit results (generated during the proceedings) the revised document, Gov't Ex. 16, was not considered to establish its purported results in these proceedings.

DI Brinks presented testimony that was detailed, plausible, and generally credible. Ironically, the candor with which this witness addressed some profound preparation errors actually enhanced his credibility, even to the extent that it compromised his testimony's effectiveness. The errata that marred the Government's evidence regarding the audit of the Respondent's practice, although certainly the product of self-inflicted wounds, did not bear the indicia of any form of intentional malice toward the Respondent. Interestingly however, they were clearly also not the result of a rush to justice. DI Brinks testified that, after completing his investigation sometime in March 2010, the investigation (and the collected data) lay dormant for sixteen (16) months until approximately July of 2011, when this matter was initiated.[21] Tr. 599. During this time of investigative inaction, the Respondent applied for, and on September 14, 2010 received, the COR for his dental office in Milwaukee, Wisconsin. Tr. 601; Gov't Exs. 2,3. That registration is also the subject of these proceedings. ALJ Ex. 1.

The Government also presented the testimony of Lili C. Reitz, the Executive Director of the Ohio State Dental Board, the agency who referred this matter to DEA. Ms. Reitz holds a law degree from the Cleveland Marshall College of Law and formerly worked as an Assistant Attorney General with the Ohio Attorney General's Office.[22] During her testimony, Ms. Reitz explained the permitting requirements for conscious sedation versus general anesthesia for dentists in Ohio, and testified that a records check she conducted informed that the Respondent possesses the former permit, but not the latter. Tr. 374–83, 421.

Ms. Reitz also provided some background regarding the manner in which the Ohio Dental Board executes its mandate to investigate complaints of wrongdoing related to its licensed dentists. Tr. 384–85, 388. Ms. Reitz testified that she supervises a 15-person office that investigates 500 to 1,000 complaints per year against the state's 7,000 dentists. *Id.* Furthermore, Reitz discussed her agency's practice of sharing information with other law enforcement and regulatory authorities, including DEA. Tr. 390–91.

Regarding the Respondent, Ms. Reitz testified to the results of the Ohio Dental Board's investigation into Respondent's practice that commenced upon the receipt of an anonymous complaint alleging that the Respondent was using controlled substances from his practice at home.[23] Tr. 397–399. As a result of the complaint, the Ohio Dental Board sent two of its investigators to the Respondent's practice to conduct an infection control evaluation.[24] Tr. 400. The Respondent was not at the Norwalk office, so the Board investigators met him at his Avon location. Tr. 401. The report of the Board's investigators (which Reitz read from with no apparent knowledge beyond the four corners of the document) indicated, *inter alia,* that they found an unsecured plastic bin in the Respondent's office containing medications, including fentanyl and Valium. Tr. 401–03. According to Ms. Reitz, a complaint was subsequently filed by Ms. Crockett that strongly resembled the anonymous complaint previously received regarding the Respondent's alleged drug use. Tr. 405–06. Based on the information they had at the time, the investigators interviewed Ms. Crockett, and the matter remains under investigation. Tr. 408–12.

Ms. Reitz's testimony was sufficiently detailed, consistent, and plausible to be afforded credibility,[25] but the weight of her testimony regarding the Board's investigation of the Respondent is diminished by the reality that she was doing no more than relating the results of a report prepared by her subordinates, and admitted that she knew nothing more than (and could provide no insight beyond) the words on the page of her investigators' report. Tr. 401–03. Thus, it would be unreasonable to afford her testimony in this regard greater weight than if the report upon which she so heavily depended (and which was her constant companion on the stand) was admitted and considered without her appearance.[26]

The Government also presented affidavits and testimony from three individuals who were employed at the Respondent's dental practice during the events that form the basis of its current revocation actions. The first of these former employees was Rebecca Crockett.[27] Ms. Crockett testified that at the outset of her employment at the Respondent's practice she was charged with the responsibility of maintaining drug logs completed on patients during procedures, and with alerting the Respondent when sedation medication stocks were dwindling to a level where more needed to be ordered. Tr. 154, 182, 196; *see also* Gov't Ex. 12 at 2. Crockett recalled no occasion during her tenure as the drug-log custodian when controlled substances were missing or unaccounted for,[28] but did recall that Rebecca Tetzloff, an employee who subsequently assumed responsibility for the drug log, approached her with concerns about missing medication. *Id.* Crockett testified that the Respondent maintained two Ohio offices; one at Norwalk and another at Avon, and that she worked at both locations (which were each open two days per week) and observed the Respondent transport controlled substances to and from both practice locations. Tr. 154–58. The controlled substances (lorazepam, diazepam, and fentanyl) were transported on a cart that was loaded at the Norwalk office and driven to the Avon office. Tr. 157, 186–88, 197. According to Crockett, controlled substances were routinely stored in both the Norwalk and the Avon offices. Tr. 156–57, 186–88, 197–98. Crockett stated that because the daily preparations in the Avon office were frequently done in a hurry, controlled substances were routinely left unsecured on top of a sterilization room counter. Tr. 158. The sterilization room at the Avon office although not locked, was located in an inner, treatment area of the practice, to the rear of front reception desk, and was separated from the patient waiting room

[21] Brinks testified that he was working on another investigation. Tr. 633–35.

[22] Ms. Reitz's resume was received into evidence. Gov't Ex. 5.

[23] There was also testimony that in November of 2008 the Board and the Respondent entered into a consent agreement related to an issue that has no logical nexus to any issue germane to these proceedings. Tr. 391–92, 394–96.

[24] Reitz testified that an infection control evaluation examines issues related to sterilization, infection control, and licensing. Tr. 400.

[25] The Respondent's theory that the Board's investigation was the result of bad blood that had its genesis in Reitz's disagreement in the Respondent's support for state legislation regarding the conduct of Board proceedings and a potential lawsuit was not sufficiently developed on this record to affect Ms. Reitz credibility. Tr. 414–17.

[26] Although the Respondent, through counsel, noticed his intention to call the Ohio Dental Board's case investigator as a witness (ALJ Exs. 10, 12), the unrefuted testimony of record establishes that he refused to tender the required witness fee to the investigator. Tr. 417–21; 21 U.S.C. 876; Fed. R. Civ. P. 45; 28 CFR 76.25. Thus, the decision by the Respondent's counsel to forego the opportunity to cross-examine the investigator bears the hallmarks of a tactical election.

[27] Ms. Crockett's affidavit was received into evidence. Gov't Ex. 12.

[28] Gov't Ex. 12 at 2.

by some form of controlled-access door.[29] Tr. 158–60, 210.

Crockett testified that she and other employees noticed marks on the Respondent's upper extremities that they feared may have indicated IV drug use on his part, and observed behavior on the part of the Respondent that they communally deemed to be overly erratic, moody, and emotional. Tr, 164–67. After discussing these observations amongst themselves, they met with him as a group (in what some of their number termed an ''intervention'') and received his assurance that he was ''getting help'' for what ailed him. Tr. 164–67, 181, 202–03; Gov't Ex. 12 at 2–3. The Respondent did not share with the group what help he was getting or what it was for. *Id.* Crockett related a 2009 incident where she believed that the Respondent appeared to be intoxicated and/or disoriented at the outset of a procedure [30] and raised the issue with the office manager, Christina Painley. Tr. 172–73, 202.

Ms. Crockett testified that she voluntarily elected not to return to her position at the Respondent's practice at the conclusion of a period of maternity leave,[31] due to her concerns regarding her safety brought about by the Respondent's animated, angry outbursts, as well as concerns she had for the Respondent's patients, based on her suspicion that the Respondent was abusing sedation controlled substances maintained in the office. Gov't Ex. 12 at 3; Tr. 167–69, 174, 190. Crockett related that subsequent to her departure from the Respondent's employment she filed for unemployment benefits and sent a letter to the Ohio Dental Board outlining her suspicions regarding the Respondent's drug abuse. Tr. 177, 206–07. Ms. Crockett testified that her letter to the Dental Board was motivated by her concern for the safety of both the Respondent and his patients. Tr. 177–79.

Ms. Crockett's testimony was sufficiently detailed, internally consistent, and plausible to be relied upon as credible in this recommended decision. No persuasive reason for her to fabricate evidence against the Respondent has been offered into, or is supported by, the current record.

The Government also presented the testimony and affidavit [32] of former employee Rebecca Tetzloff, who worked on the Respondent's staff from March 2008 through October 2009. Gov't Ex. 10 at 1. Like Ms. Crockett, Ms. Tetzloff testified that she worked at both the Norwalk and Avon offices of the Respondent's practice, transported controlled substances to the Avon office, and that the Respondent routinely administered and stored controlled substances at the Avon office. Tr. 221, 223–27; Gov't Ex. 10 at 2. In fact, Ms. Tetzloff testified that she actually maintained a log recording controlled substances stored at Avon. Tr. 225–26. According to Tetzloff, before the Ohio Dental Board insisted on the installation of a safe, controlled substances were routinely kept at Avon in an intermittently-locked filing cabinet in an arrangement that frequently yielded ready access to the keys that could lock (or unlock) it. Tr. 227–32.

Consistent with Crockett's testimony, Tetzloff recollected that when controlled substances were unpacked at the Avon office, they were left unsecured in the ''rush, rush, rush'' of setting up equipment at the outset of the day. Tr. 233. According to Tetzloff, the controlled substances (midazolam, diazepam, and fentanyl) would be transported to Avon in a bin on a cart and left on a counter in the sterilization room. Tr. 233–36.

At some point during her employment at the Respondent's practice, Tetzloff was charged with the responsibility of accounting for the controlled substances used and on-hand in the practice. Gov't Ex. 10 at 2. In the discharge of these duties, Ms. Tetzloff became concerned about an apparent spike in the level at which office supplies were requiring replacement, and began having trouble reconciling the quantities of medications on hand. Tr. 237; Gov't Ex. 10 at 2. Ms. Tetzloff tacitly acknowledged that this was a rather unscientific process where, by the mere act of counting vials of medication, she would somehow divine whether too many vials had been used based on her expectation of how many vials should have been present, with no appreciable expertise to appraise how many vials were used on the procedures performed. Tr. 282–84, 291, 295, 307, 314–15. Tetzloff recalled that on one occasion when she called the Respondent while he was at his teaching position at Case Western Reserve University and asked him about a particular controlled substance deficit, he informed her that he had taken the medication with him. Tr. 237–38; Gov't Ex. 10 at 2–3. On another occasion, upon her arrival at the Norwalk office one morning, Tetzloff discovered a vial of diazepam sitting unsecured on top of the office safe. Tr. 241. When queried on the issue of why a controlled substance was left out in the open in that fashion, the Respondent's answer was merely to acknowledge what Tetzloff perceived with her own eyes, without any attempt at explanation. Tr. 241–42. When Tetzloff's suspicions grew, and she became increasingly concerned that medications were not being effectively locked up in the Norwalk office, she sought the advice of an attorney, who assisted her in drafting a letter raising her concerns to the Respondent and seeking discharge from her duties related to the accounting of office controlled subsances. Tr. 238, 243–47, 296–97. Tetzloff credibly testified that she presented the letter [33] to the Respondent and a member of his staff. Tr. 247–48; Gov't Ex. 10 at 3–4.

Tetzloff also related her recollection of marks on the Respondent's upper extremities which she felt were suspiciously reminiscent of track marks,[34] as well as bouts of animated anger bursts, ''irritability,'' [35] and essentially eratic behavior [36] during the work day on the Respondent's part,[37] all of which culminated in a staff meeting on a Friday when no patient appointments were scheduled (''the intervention''), wherein the Respondent

[29] Notwithstanding some initial confusion on this issue, Tr. 160, 199, the witness ultimately and credibly testified that the patients waiting to be seen were maintained on the other side of a door that led to the waiting room. Tr. 200–01, 208–09.

[30] Of particular concern to Crockett during this episode was the Respondent's action in removing a hypodermic needle cap with his mouth. Tr. 173, 201–02.

[31] Although the witness's affidavit fixes her resignation in June 2009, Gov't Ex. 12 at 3, Crockett credibly testified that her decision in this regard was made in September 2009, while still out on maternity leave following the birth of her son. Tr. 191, 194–95.

[32] Gov't Ex. 10.

[33] Gov't Ex. 11.

[34] Ms. Tetzloff did not deem the Respondent's explanation that his large dogs caused the marks by scratching his arms to be particularly credible. Tr. 253–55.

[35] Tr. 276–77.

[36] Tetzloff also related an incident wherein, on some date that she was unable to recall, she observed an uncapped hypodermic needle on the floor of the van used by the Respondent and other employees to transport medications and supplies between the Norwalk and Avon offices. Tr. 268–272, 308–10. The evidence of record indicates that the van routinely carried practice supplies, including hypodermic needles, and also supports the proposition that there were routinely multiple operators of the van. Tr. 269, 795–99. Accordingly, the evidence does not impact upon any issue that must be decided in these proceedings and was not considered in this recommended decision. The same can be said of an alleged episode of what Tetzloff perceived as erratic driving on the Respondent's part. Tr. 272–74, 625–26, 799–801. These incidents, at least to the extent they have been developed in the current record, simply have no bearing on any issues properly before this tribunal.

[37] Ms. Tetzloff acknowledged that although the Respondent was ''a demanding employer,'' that he is not the only dentist she knows of who possesses that trait. Tr. 288.

assured all present that he was seeking (unspecified) help that was related, Tetzloff thought, to a depression condition. Tr. 223, 249–32, 255–60, 263, 285, 298; Gov't Ex. 10 at 4. According to Tetzloff, the Respondent took a week-long vacation immediately after the meeting. Tr. 252.

On the issue of disposal, Tetzloff recalled routinely squirting controlled substances remaining in hypodermic needles at the conclusion of procedures into the sink. Tr. 305.

Ms. Tetzloff, like Ms. Crockett, testified that she cared about the Respondent, describing him as ''a good surgeon'' and ''a very good boss.'' Tr. 278. Ms. Tetzloff's testimony was sufficiently detailed, internally consistent, and plausible to be relied upon as credible in this recommended decision. No persuasive reason for her to fabricate evidence against the Respondent has been offered into, or is supported by, the current record.

The final former employee presented by the Government in its case-in-chief was Dr. Brian Toth, D.D.S.[38] Like the Respondent, Dr Toth, is a DEA registrant and a licensed Ohio dentist in good standing. Gov't Exs. 4, 13; Tr. 320–21, 337, 344. Although Dr. Toth's affidavit states that he ''worked at [Respondent's] Norwalk and Avon dental offices from January 2009 through January 2010,'' Gov't Ex. 13, at ¶ 2, during his testimony he agreed that the period of his employment could have been from April 2009 through February 2010. Tr. 336.

Also in his affidavit, Dr. Toth asserts that, ''[f]rom my observations, I believe that [Respondent] has injected himself with fentanyl and Versed (midazolam). I base my belief on my training as well as my observations of [Respondent's] erratic and aggressive behavior, red eyes, mood swings, anger, frustration, and lack of care while treating patients.'' Gov't Ex. 13, at ¶ 2. The affidavit also identifies the following as alleged indices of drug abuse: (1) Respondent's physical assault of Christina Painley; (2) track marks on Respondent's arms; [39] (3) ''meth bugs,'' described as ''scratching, and sores about the wrists, arms, and head;'' [40] (4) an incident on a undated Friday [41] morning where Dr. Toth observed Respondent enter the Norwalk dental office, appearing ''[d]isheveled, out of sorts, [and] wobbly,'' [42] in ''pajamas and flip flops,'' and walk in the general direction of the office drug safe stating that he needed antibiotics for a cold.[43] Gov't Ex. 13, at ¶¶ 3–4; Tr. 327–28. Toth, like other witnesses, testified that the Respondent was prone to ''drastic mood swings'' and ''erratic behavior.'' Tr. 332.

Toth's affidavit also described a post-DEA inspection restaurant interaction wherein the Respondent purportedly confessed to Toth that he was taking Valium [44] as a sleep aid, and subsequently told him that adjustments were being made to office controlled substance records to shield the losses from DEA scrutiny. Gov't Ex. 13 at 3. When pressed on the issue, however, Dr. Toth was not at all clear on whether the incident happened before or after DEA's involvement in the case. Tr. 353–56.

Dr. Toth testified that he is a recovering alcoholic and cocaine addict, and that he has been ''clean and sober'' since 2006. Tr. 322–23. Notwithstanding the witness's unambiguous assurance of his uninterrupted recovery and sobriety, when confronted with documentation concerning his April 2011 convictions for disorderly conduct/intoxication and marijuana possession,[45] Dr. Toth conceded that he had been arrested and pled guilty to those offenses. Tr. 337–44, 346.

The issue of Dr. Toth's success at his substance abuse recovery efforts (at least on the present record) is, without question, a collateral issue. However, when Dr. Toth volunteered, under oath, that he had been clean and sober since 2006, and then grudgingly acknowledged marijuana and alcohol-related convictions seven months prior to the commencement of the hearing, he deprived his own testimony of any measure of credibility in these proceedings.[46] Simply stated, Dr. Toth is not a person who is willing to provide candid and truthful testimony under oath, and in those instances where his account conflicts with other credible evidence of record it cannot be believed. Thus, his testimony cannot be afforded weight in supporting a substantial-evidence finding by this recommended decision and ultimately, by the Agency. Furthermore, inasmuch as he was unable to supply virtually any temporal details of the factual events he described, and his purported observation of a ''disheveled'' and ''wobbly'' Respondent standing in his own office, on some unspecified date, headed in the general direction in his office where controlled substances were stored, would (even if deemed credible) shed no light on anything that must be decided in this case, the absence of his testimony here will be of no moment.

The Government also presented the testimony and written report,[47] of Daniel Becker, D.D.S. Dr. Becker,[48] currently serves as an Associate Director of Education in the General Dental Practice Department at Miami Valley Hospital, in Dayton, Ohio, is an Associate Editor of Anesthesia Progress for the American Dental Society of Anesthesiology, and also serves as an Adjunct Professor of Life and Health Sciences at Sinclair Community College in Dayton, Ohio. Gov't Ex. 14. Additionally, Dr. Becker is the Chairman of the Human Patient Simulation Training Subcommittee at the American Dental Society of Anesthesiology. *Id.* Dr. Becker also testified that he teaches intravenous sedation techniques to dental residents, and is actively engaged in the practice of IV sedation to patients at numerous dental practices in Ohio. Tr. 32. Dr. Becker was received without objection as an expert in the practice of general dentistry in regards to pharmacology, sedation, and anesthesia. Tr. 29–30.

In his testimony, Dr. Becker (like Ms. Reitz) explained that in Ohio there are two varieties of dental sedation that are sanctioned by state law, with separate practitioner permits specified for each type. A ''conscious sedation permit,'' is required to sedate a patient to a depth where the patient is capable of being aroused, that is capable of responding to verbal commands. Tr. 41, 71. A ''deep

[38] An affidavit executed by Dr. Toth was received into evidence. Gov't Ex. 13.

[39] In his testimony, Dr. Toth opined that the marks on the Respondent's arm bore the appearance of IV drug abuse, not the marks of a teacher allowing students to practice IV insertion techniques. Tr. 326. In view of the absence of any foundation for Dr. Toth's expertise in this area, this testimony has been afforded no weight in this recommended decision.

[40] Dr. Toth testified that he has never tried methamphetamine. Tr. 347–48. In view of the absence of any foundation for Dr. Toth's expertise in this area beyond spending time at a rehabilitation clinic related to other substances, Tr. 326–27, this testimony has been afforded no weight in this recommended decision.

[41] Though Dr. Toth's identified the incident as occurring on a Saturday morning, during the administrative hearing he clarified that the incident occurred on a Friday. Tr. 327, 361–62.

[42] Tr. 330.

[43] Dr. Toth found this explanation implausible because ''antibiotics are not used to treat colds,'' and because ''the Norwalk office did not store antibiotics in the drug safe.'' Gov't Ex. 13, at ¶ 4.

[44] Valium is a brand of diazepam tablets. *See* 6–V Attorneys' Dictionary of Medicine V–121686.

[45] Resp't Exs. K, L.

[46] In like fashion, when cross-examined about (mostly irrelevant) statements he purportedly placed on a Facebook page, Dr. Toth initially denied having such a page during the relevant period, and then conceded that he did. Tr. 347–50. In this manner, Toth once again managed to morph irrelevant matter (the arguably unsavory comments he posted on his Facebook page) into a relevant issue (his disinclination to provide accurate testimony under oath).

[47] Gov't Ex. 15.

[48] This Dr. Becker is not related to the Respondent.

sedation/general anesthesia permit,'' in contrast, is required to sedate a patient to unconsciousness. Tr. 42. A conscious sedation permit may be obtained by a dentist after the completion of a course on the subject, while a deep sedation/general anesthesia permit requires the successful completion of a year-long residency. Tr. 41–42, 44–45. Becker testified that where general anesthesia is utilized,[49] additional personnel and monitoring equipment normally will be required. Gov't Ex. 15 at 1; Tr. 62–64, 85–86.

At the Government's request, Dr. Becker reviewed forty-three records of IV sedation [50] that had been administered by the Respondent and found all but one of the records were below ''the standard of practice'' because they did not reflect current vital signs or actual time at the time the medications were administered. Gov't Ex. 15 at 1. Dr. Becker's report further identified 17 patient charts which he found to be ''egregious.'' *Id.* The report also sets forth Becker's expert opinion that the doses recorded in the charts he reviewed were sufficiently high that, at least in his view, monitoring, staff, equipment, and general anesthesia training beyond what was apparent in the reviewed documents would have been required. *Id.* Becker noted that despite what he characterized as ''staggering doses,'' the records he evaluated reflected only four occasions where reversal drugs were administered, and that the records reflected none of the complications such as hypotension or respiratory arrest that he would have expected to encounter with doses at those levels. *Id.* At 2. In Becker's opinion, ''[t]his raises a question as to whether these doses were actually administered [because] [f]ollowing these dosages, serious complications would most surely have been encountered.'' *Id.*

According to Dr. Becker, in most cases where midazolam is used for conscious sedation, the required level of sedation could be obtained by 10 mgs or less, but that more midazolam might be needed for a longer appointment.[51] Tr. 58–60. Dr. Becker further testified that a patient's resistance to midazolam could alter the amount of drug necessary to achieve the desired sedation. For example, Dr. Becker opined that for a ''fairly resistant'' patient, twenty to thirty milligrams of midazolam might be necessary for a 3–4 hour procedure, and that there are some patients who are simply not sedatable with this medication.[52] In Becker's opinion, however, those cases that require the higher doses and demonstrate resistance are rare. Tr. 60–61. Midazolam, according to Dr. Becker, is administered in one-to-two milligram increments to achieve the desired level of sedation. Tr. 62. A five-miligram increment would cause a patient to lose consciousness, which in turn risks throat obstruction and breathing impairment. Tr. 62. Becker explained that it is for these reasons that procedures where general anesthesia is employed require additional staffing (of at least one additional person) during the procedures to monitor the patient breathing and EKG [53] via precordial stethoscope or capnography. Gov't Ex. 15 at 1; Tr. 62–64, 85–86.

Dr. Becker identified seventeen records of Respondent's sedation dispensing that he characterized as egregiously below the expected standard of care. Gov't Ex. 15 at 1. Among these seventeen records are instances where: (1) A patient was administered 55 mgs of midazolam and 200 micrograms of Fentanyl over a span of 15 minutes; (2) a patient was administered 40 mgs of midazolam, 40 mgs of Diazepam and 100 mcgs of fentanyl over a span of approximately 15 minutes; (3) a patient was administered 30 mgs of midazolam, 10 mgs of diazepam and 100 mcgs of fentanyl over a span of approximately a minute; and (3) a patient was administered 100 mgs of midazolam, 70 mgs of diazepam and 200 mcgs of fentanyl over a time span of approximately 90 minutes. *Id.* In his report and his testimony, Becker affirms that the medications in these doses would have rendered the patients unconscious. *Id.* at 1; Tr. 79, 84–85, 87–89. Becker's view is that sedation to unconsciousness was not an intent supported by the records he reviewed, as evidenced by the lack of additional professional monitoring staff, and would have required the deep sedation/general anesthesia permit that the Respondent does not possess. Tr. 85–86; Gov't Ex. 15 at 1.

Dr. Becker testified that, absent some type of resistance to midazolam, the doses identified in his expert report would ''predictably'' produce unconsciousness.'' Tr. 84. However, Dr. Becker noted that such resistance, while possible, is ''rare,'' and that over thirty years of practice he had not seen as many resistant patients as Respondent's patient records appeared to contain during a relatively brief period. Gov't Ex. 15 at Tr. 84–85. Assuming that not all the patients in the charts analyzed were resistant, Dr. Becker testified that the sedation records reflected a treatment regime below the standard of care for moderate sedation. Becker opined that there were simply too many patients receiving deep-sedation levels of medication during the time he analyzed Respondent's records to attribute that number to medication resistance. Tr. 84–85. Although Becker identified four occasions where medication reversal drugs were administered by the Respondent, the records shed no light on whether that was done pursuant to persistent somnolence or some other complication. Tr. 112–13. Finally, Dr. Becker provided his conclusion that based on the likelihood of widespread unconsciousness among the patients, the Respondent's lack of training and certification in general anesthesia, the lack of complications documented in the record regarding breathing obstruction, he entertains serious questions as to whether the amounts of controlled substances documented in the sedation reports were actually administered to the enumerated patients. Tr. 90–92. In Becker's view, since these high levels of medications were unlikely to have been administered to this number of patients without evidence of adverse effect, either the sedation records he reviewed were simply erroneous, or the medications listed in those records were not administered as documented and something else became of them. Tr. 93. Dr. Becker testified that the ''staggering'' doses of controlled substances reflected as administered in the sedation records he reviewed support his conclusion that the Respondent's handling of controlled substances was ''below the standard of practice.'' Tr. 94–95.

[49] Dr. Becker testified that sedation in excess of conscious sedation is generally utilized in cases involving special needs, such as physically or mentally handicapped patients. Tr. 76.

[50] Dr. Becker testified that it was common practice among dentists to have these records completed by staff members during dental procedures. Tr. 146–47. This is consonant with the testimony of Ms. Crockett that office staff merely acted as a scrivener with regard the document, entering the numbers dictated by the Respondent. Tr. 183–85.

[51] Dr. Becker's difference of professional opinion with the Respondent's practice regarding the relative merits of combining midazolam and diazepam versus increasing the doses of those respective medications, Tr. 77–78, 731–32, 735; Gov't Ex. 15 at 1, does not provide any insight on the issue of diversion risk or whether the Respondent's continued DEA registration is inconsistent with the public interest, and has played no part in this recommended decision. *See Gonzales* v. *Oregon,* 546 U.S. 243, 274 (2006).

[52] Dr. Becker testified that the sedation logs reflect medication given, but ordinarily do not reflect any rationale for higher-than-normal doses of sedation medication or sufficient data from which that decision could be extrapolated. Tr. 66–67, 74, 76–77.

[53] During his testimony, the Respondent stated that his patients were routinely monitored by EKG and pulse oximeter. Tr. 736.

At one point during his testimony, Dr. Becker conceded that on one occasion medication was drawn for a patient [54] who did not appear for treatment, and the medication was disposed of. Tr. 115–17. In an unfortunate choice of words employed during his re-evaluation of whether the record relating to the drawn and discarded medication was comparable to the other records he characterized as ''egregious,'' Dr. Becker stated that although he still found the practice of drawing sedation medication prior to patient arrival ''strange,'' ''odd,'' and ''funny,'' he believed that he ''should be punished'' for his initial characterization. Tr. 117–23. Nonetheless, Dr. Becker stated that the practice of drawing medication prior to the arrival of a patient did not impact on documentation obligations, and did not fall below an acceptable level of practice. Tr. 145, 123.

On the issue of the ''track marks'' that were purportedly seen on the Respondent's arms by his staff, Dr. Becker acknowledged that, as part of his teaching responsibilities, he instructs students on establishing IV access. Tr. 33. Consistent with the position taken by the Respondent, Dr. Becker testified that he does allow patients to practice IV insertion on himself, including on the backs of his hands. Tr. 33–34, 135. Becker conceded that some days the practice attempts by his students have him resembling a ''pin cushion,'' [55] but he described the needle punctures routinely made on arms by the relatively small needles handled by students in his class, which in his view, ''generally [does not] leave much of a mark.'' Tr. 34. Dr. Becker also explained that a ''difficult attempt'' by a less skilled individual can result in a hematoma, or bruise. Tr. 34–35. Dr. Becker testified that the scars generally referred to as ''track marks'' are the product of repeated attempts into the same veins by habitual drug abusers. Tr. 37–38. According to Dr. Becker, those experienced teachers who allow their students to practice venipuncture on them in class minimize the risk of scarring by requiring their students to avoid repeated attempts at the same location. Tr. 37–38. It is Dr. Becker's opinion that poorly-done clinical attempts at IV insertions by students are more likely than drug use to produce bruising. Tr. 39. A bruise left by an improper IV insertion could last for ''several'' days. Tr. 40.

Notwithstanding the Government's posture that the Respondent has violated the regulations by squirting controlled substances remaining in the hypodermic needles after procedures into the sink, Becker (the Government's own expert) testified that this is his practice as well. Tr. 55–58, 100–01. Furthermore, Dr. Becker expressed agreement with the Respondent's expert that the DEA regulations on disposal are unclear. Tr. 105.

On the issue of whether the observations of the Respondent's moodiness, grouchiness, and erratic behavior support the concerns of his former employees that he was abusing the controlled substances acquired for procedures in his practice, Dr. Becker testified that an individual under the influence of midazolam would likely exhibit symptoms of lethargy or calming. Tr. 69, 71. Thus, none of the characteristics highlighted by the Respondent's former employees in their testimony or during the ''intervention'' conducted in his office support an inference that the Respondent was abusing the controlled-substance medications he employed to sedate his patients.

Dr. Becker was by no means an ideal expert witness. He was vague about the method that his ''most egregious'' list of cases were selected, and retreated from his designation of one case as egregious by the flip remark that he ''should be punished'' [56] for his initial opinion in this regard. Still, his testimony was sufficiently authoritative, consistent, and reasonable that it will be credited and afforded significant weight in this recommended decision.

The Respondent's case-in-chief consisted of his own testimony and an affidavit from Dr. Joel Weaver, D.D.S., Ph.D., an individual he previously noticed as an expert witness. The affidavit executed by Dr. Weaver was admitted on motion and without Government objection during the hearing. Resp't Ex. J.

According to his curriculum vitae, Dr. Weaver served from 1981–2006, as a professor in the Department of Anesthesiology at the Ohio State University. Resp't Ex. G, at 1. He holds a Bachelors of Science from Ohio Northern University and a D.D.S., from the Ohio State University College of Dentistry. Resp't Ex. G, at 1. Additionally, Dr. Weaver has completed residencies at the Ohio State University in both Anesthesiology and in Ambulatory General Anesthesia and Sedation. *Id.* Dr. Weaver also holds a Ph.D. in pharmacology from the Ohio State University, and has been previously certified as a pharmacist in Ohio.[57] Resp't Ex. G.

In his affidavit, Dr. Weaver described what he characterized as a ''concern * * * as to the proper procedure to dispose of injectable drugs remaining when perhaps 5 [milliliters' (ML)] is drawn into a syringe but only 4 ML is actually injected into the patient's [intravenous (IV)].'' Resp't Ex. J at ¶ 2. Although Dr. Weaver's report did not address a practitioner's obligation to comply with regulatory requirements under 21 CFR 1307.21,[58] after providing some anecdotal evidence relative to logistical concerns attendant upon disposal issues, his affidavit set forth his view that:

> [t]he standard practice among dentists in Ohio * * * is for the dentist to log the dose of the drug taken from his inventory, record the dose given to the patient in the patient sedation/anesthesia record and record any ''wasted'' doses in either the drug log, the patient's anesthesia record or both as soon as the case is concluded. The ''wasted'' drug is typically squirted into the sink (no longer politically correct because of community water trace contamination), into the trash or sharps container, or into the soil of potted plants as a source of nitrogen-containing

[54] The Respondent testified that this patient did not appear for her appointment. Tr. 784–85.

[55] Tr. 135.

[56] Tr. 117–23.

[57] Although initially noticed as an expert witness by the Respondent, Dr. Weaver was never called as a witness at the hearing. the Respondent's counsel, citing a logistical issue, represented that Dr. Weaver was unavailable, and that this information only became available to counsel on the eve of the commencement of the hearing. Tr. 9. Accepting counsel's representation of late notice of Dr. Weaver's availability, it is not insignificant that no continuance request or other accommodation (such as video teleconferencing) was requested by the Respondent to facilitate the witness's testimony. A perhaps unintended consequence of what may well have been a tactical decision on the part of the Respondent and his counsel, is that Dr. Weaver was never offered or accepted as an expert in anything during the proceedings. Confounding the issue further, the Government's expert, Dr. Becker, conceded that Dr. Weaver is ''well more experienced'' than he is in terms of both training and experience. Tr. 106. DEA's regulations comport with the generally reasonable notion that information received through affidavit must be weighted consistent with the opposing party's lack of cross examination ability. 21 CFR 1316.58 (''Affidavits admitted into evidence shall be considered in light of the lack of opportunity for cross-examination in determining the weight to be attached to the statements made therein.'') Accordingly, as the record now stands, the Government's expert testified that Dr. Weaver is a superior expert, but no one has offered him to the tribunal as such, and the Government, by surprise at the outset of the hearing, has not been afforded any manner of cross-examination. Still, the Government consented to the admission of Dr. Weaver's affidavit, and did not make any attempts to compel his appearance by process.

[58] The obligation to interpret the law and regulations falls squarely within the purview of this tribunal initially, and then secondarily with the Agency. Dr. Weaver's purported legal analysis of the regulations and DEA's interpretation of the applicable requirements has been accepted into evidence without objection as part of the affidavit he prepared, but cannot control the legal analysis employed by this recommended decision.

fertilizer. Some practitioners have a witness initial the record of ''wasted drug.''

Resp't Ex. J, at ¶ 5.

Dr. Weaver also provided his opinion regarding what he characterized as ''mobile sedation and anesthesia practitioners.'' Resp't Ex. J, at ¶ 9. In essence, the practice of mobile sedation and anesthesia is where a practitioner has ''one permanent office address where they do business and that is where they are registered for their DEA license. They order, receive, and securely store controlled substances at that single address and maintain all drugs logs and patient records at that one office location.'' Resp't Ex. J, at ¶ 10. The practitioner will then administer the drugs at various dental and medical offices where anesthesia or sedation might be required. *Id.* In any year, a mobile anesthesiologist ''may service more than 50–100 offices.'' *Id.* In light of the foregoing, Dr. Weaver opines that ''[i]t would be impractical if not impossible for the anesthesiologist or other healthcare worker to have a separate DEA license for every location they service so long as the drugs and records are not stored at those multiple locations but rather at their single office location.'' *Id.,* at ¶ 11. Inasmuch as the Government has not alleged that the Respondent was required to obtain a COR to take controlled substances to varying locations and return and store them as required, Dr. Weaver's endorsement of such a procedure adds nothing here. The Respondent is alleged to have administered and stored controlled substances at an unregistered permanent private practice, a scenario which Dr. Weaver, even if assumed competent to express a view on a this issue of law, did not address.

While Dr. Weaver's qualifications are doubtless impressive, even setting aside the absence of any foundational predicate for the presentation of expert opinion, his affidavit provides no expert opinion that sheds light on any issue that must be decided by this recommended decision. However, his *observation* that his experience that Ohio practitioners routinely dispose of small amounts of residual controlled substance by squirting into drains all over the state is consistent with the testimony provided by the Government's expert, its investigator, and its lay witnesses, and will be credited in these proceedings. Weaver's opinion concerning the wisdom or logistical practicalities of the relevant DEA regulations regarding the authorized manner of controlled substance disposal have been afforded no weight whatsoever.

The Respondent testified on his own behalf at the hearing. According to the Respondent, he holds a Bachelor of Arts from the University of Toledo and a D.D.S. from the Ohio State University.[59] The Respondent also holds a certificate in periodontics from the Case Western Reserve University School of Dentistry, a certificate in Zygoma Implant placement from the Northwestern School of Dentistry and a IV certification from the University of Southern California School of Dentistry, and from 1996 through the present he has maintained a private practice in Norwalk and Avon, Ohio.[60] *Id.* Respondent testified that he limits his dental practice to the field of periodontics, ''which involves bone grafting, dental implants [and] gum and bone surgery.'' Tr. 656. The Respondent testified that because many of his patients ''are very apprehensive in regards to that type of procedure,'' IV sedation is a ''critical component'' of his practice. TR. 660.

The Respondent testified that his practice is ''all referral-based,'' and he receives referrals of patients who require treatment ''that's a little bit more advanced'' and who sometimes present ''very difficult cases.'' Tr. 657–58. When asked to explain what he meant by ''very difficult cases'' and ''more advanced'' treatment, the Respondent clarified that he was referring to the fact that there was a limited number of periodontics specialists in the geographic area of his practice, and these were patients who required treatment in that specialty. Tr. 658. The Respondent stated that there was also a limited number of dentists in his geographic area who practiced conscious-sedation dentistry. Tr. 659. Thus, from the Respondent's testimony it is clear that it was not that periodontists were referring difficult patients to him who were difficult to anesthetize, but that dentists were referring patients his way who simply needed periodontic treatment or desired conscious sedation within the Respondent's geographic area. Tr. 749. Thus, the Respondent's assertion that higher doses are required because he is a specialist is a *non sequitur.*

The Respondent subsequently diminished his credibility even further on the issue of patient resistance. When asked about Dr. Becker's assertion that the sedation logs from the Respondent's practice that he examined had more allegedly sedation-resistant patients than he had encountered in his thirty years of practice, the Respondent stated that Becker's opinion was borne of the fact he is a ''general dentist,'' and not a specialist, such as the Respondent. Tr. 748–49. The problem here is that Dr. Becker (whom the Respondent acknowledges knowing on a professional basis even before the proceedings began),[61] testified that his entire practice is focused on the administration of conscious sedation to patients for other practitioners. Tr. 23. Again, the Respondent seeks to confuse the difference between the specialization required to perform periodontic dental work with some special expertise in hard-to-sedate patients.[62]

When queried on the issue of whether his doses were high compared to other practitioners, the Respondent acknowledged that his former instructor, and the author of the textbook he uses in connection with his teaching responsibilities, suggests that the range of acceptable midazolam doses of 2.5 to 7.5 milligrams. Tr. 732–33. The Respondent even acknowledged that one patient received 70 milligrams of the medication during a procedure, an amount that the even the Respondent characterized as ''a large amount.'' Tr. 743, 745. Another 100 milligram dosage was also acknowledged as ''high'' by the Respondent. Tr. 754. The Respondent also agreed with the Government's expert that his sedation records reflected ''a high proportion of [sedation-] resistant patients.'' Tr. 734. The explanation that the Respondent volunteered for this phenomenon served him worse than if he had remained silent on the point. The Respondent stated:

> *Like I had stated earlier,* I am a specialist, all right. I get cases sent to me that a lot of other people cannot handle, and so that is not unusual. I've got a lot of medically compromised patients that do come in the door for services, because other general practitioners are not comfortable handling those patients.

Tr. 734 (emphasis supplied). While it is unquestionably true (as acknowledged elsewhere in this recommended decision) that decisions regarding

[59] The Respondent's CV was received into evidence. Resp't Ex. E.

[60] The Respondent testified that he also owns a dental clinic at his registered location in Milwaukee, but does not practice IV sedation at that location. Tr. 661–64; *see also* Gov't Ex. 2.

[61] Tr. 747–48.

[62] Even temporarily suspending for a moment the undisputed reality that the Government's expert practices exclusively in the area of conscious sedation for dentists and sees all manner of patients, had the Respondent taken the view that the seemingly high doses were attributable to nothing more than a simple difference of opinion between professionals his position would have been likely more effective, and certainly less revealing on the issue of credibility than the analytical red herring of widespread resistance.

medical care which are unrelated to the issue of diversion are beyond the jurisdiction of DEA,[63] the Respondent attempted to explain the high (by his own admission) doses he administered by positing that *as he had explained earlier,* because he was a specialist he utilized higher levels of medication on his patients, which tended present more difficult cases. *Id.* Even a cursory review of what he had ''stated earlier'' in his testimony reveals that he gets periodontic referrals because there are not many periodontists near him, not that he gets unsedatable patients who must routinely be sedated with copious amounts of controlled substances. Tr. 749. His testimony in this regard was misleading. The Respondent was attempting to blur the line of his specialization in periodontics and conscious sedation with a hypothetical expert practitioner who is routinely sought by others in his field to consciously sedate patients who had been previously found difficult to sedate. This attempt to muddle the record did not enhance his credibility and has drawn attention to an issue that might otherwise have lived in benign, analytical obscurity.

The Respondent, the holder of an Ohio-issued conscious sedation permit, testified that he monitors his IV sedation patients ''under an EKG strip, as well as a pulse oximeter,'' and he unambiguously stated that among the sedation records reviewed by the Government's expert, Dr. Becker, all patients remained conscious during the sedation employed in the procedures. Tr. 736–37. In fact, the Respondent followed up this response with an unsolicited, detailed explanation of the reasons he is confident that all patients were conscious. Tr. 737–38. The Respondent declared that ''if you were to ask my staff, they'll tell you nobody has ever been out of consciousness in my office.'' Tr. 755. When pressed on the issue of the level of medication of one patient in particular, the Respondent replied:

> This patient, I can't tell you if this person was on a Fentanyl patch, which might require more medications. I can't tell you if this patient has had multiple IVs at other locations. Multiple occasions of having drugs such as benzodiazepines in your body, you develop a cellular adaption, all right. What happens is your metabolism becomes a tolerance to that, and so what happens, it takes more of the drug to get the same type of effect that you did maybe from the first time that you ever used that drug. So I have—based on not having the medical history from the patient's chart here, I can't answer anything else other than that. This patient is not dead.

Tr. 742. One problematic aspect of the Respondent's explanation is that as the custodian of his own patient charts, contrary to his testimony, he is the one person who actually could have authoritatively and conclusively divined all these factors about these patients, but chose not to do so. Tr. 746, 749–51, 807. Another possible explanation offered by the Respondent is that some of his patients were well-to-do, elective surgery veterans who may have had sedation for other elective surgeries in the past. Tr. 750–51. Yet another possible explanation offered by the Respondent is that some of his patients may have had histories of drug abuse that they were reluctant to share.[64] Tr. 758. The Respondent's election to spin all manner of hypothetical contingency to provide potential explanations for the dosing levels is a tacit acknowledgement that his dosing levels were so high that they actually did require additional explanation; a proposition that he eventually conceded. Tr. 750. The point is hammered home by the Respondent's terse conclusory assurance that the patient did not expire as a result of his sedation procedures. *Id.* If, as it seems from the Respondent's lengthy diatribe on the subject, the only possible explanation in the high dosage levels lies in extraordinary contingencies, it would seem reasonable that these contingencies would be at his disposal to produce. Another problematic issue is that the sedation logs associated with these high-dose patients note no current medications in the block designated for that purpose. Tr. 742, 747, 758. This is another example of the Respondent's answer raising the relative importance of an inquiry that easily could have remained in the shadows.

The Respondent's account of DI Brinks' May 2009 visit to his Norwalk office was generally consistent with Brinks' version. Tr. 671–79. It was the Respondent's recollection that when Brinks suggested his own drug use as a source for shortages,[65] he not only offered his arm for inspection, but also offered to submit to a urinalysis.[66] Tr. 676–79. Consistent with Brinks' testimony, the Respondent recalled volunteering during the visit that he also was operating a practice in the Avon, Ohio[67] where controlled substances were stored and dispensed. Tr. 677–78.

The Respondent provided additional insights into potential distractors that existed at the time of the DEA inspection, such as his heavy patient traffic on the day of the visit and his high level of other professional commitments during that period in his career. Tr. 664–67, 676. Of even greater import, was the Respondent's account of his treatment for a mental health issue during this time. The Respondent initially sought treatment from his physician, progressed through a therapist, and ultimately sought the aid of a psychiatrist. Tr. 686–88, 726–28. The Respondent recounted various medications prescribed to address his mental health symptoms, and how, in March-April 2009, one attempted course of prescribed Lamictal landed him in the Cleveland Clinic to address a medication-caused decompensation. Tr. 686–89. This setback resulted in the Respondent taking a week off from work. Tr. 689–90. The Respondent also discussed the frustrations associated with the trials of psychiatric medication and side-effects that included concentration diminishment and mood lability. Tr. 689–92. The Respondent recalled the Friday morning meeting that his staff has euphemistically dubbed an ''intervention.'' Tr. 786. According to the Respondent, the term ''intervention'' was not utilized, suspicions of drug abuse on his part were never discussed, and the meeting was a vehicle to notify that staff that he would be out of the office for a week, a necessity precipitated by his adverse reaction to Lamictal. Tr. 786–87. The Respondent described how his professional commitments caused stress that, at least in his view, contributed to his mental health difficulties, and that some of this was ameliorated when he retreated from his teaching responsibilities at Case Western in 2010. Tr. 690–91.

The Respondent commendably took the evidence of what his former staff members considered erratic behavior head on, and acknowledged that he is ''a

[63] *See Gonzales* v. *Oregon,* 546 U.S. 243, 274 (2006).

[64] In response to a series of leading questions posed by his counsel, the Respondent also suggested that obesity, age, and past surgical history could also be contributing factors to the high dosage levels that the Respondent was routinely using on his patients. Tr. 805–06. The Respondent also mentioned diabetes and smoking. Tr. 806. Informative as this list may have been, the record contains no evidence that so much as a single patient described in the sedation logs was impacted by any of these factors.

[65] The Respondent also recalled that DI Brinks similarly accused his office manager of abusing controlled substances that were not accounted for in the paperwork presented. Tr. 679–80.

[66] The Respondent testified that he has been randomly drug tested about once a year by Fisher Titus Hospital without positive results. Tr. 709, 730, 761–62.

[67] The Respondent testified that separate controlled substance sedation logs were maintained at the Avon office. Tr. 694.

very hard person to work for,'' and that he has thrown surgical instruments in the past, and has yelled at more than one employee during his career as a dentist. Tr. 790–92. On the subject of his late morning arrival and puncture wounds on the tops of his hands on a day where he was not teaching at Case Western, the Respondent offered no explanation, other than his assertion that he is ''a picker,'' who picks at the skin on his head, and that he has a playful, large Newfoundland dog. Tr. 792–94.

Regarding the allegations that controlled substances were periodically unsecured at the Avon office, the Respondent testified that it was the practice of his office to transport controlled substances to the Avon Office in a bin about the size of a shoe box. Tr. 768–69. The bin was taken into the sterilization room of the Avon Office by a cart, and staff members were ''supposed to put [the controlled substances] on [the Respondent's] desk [where] they get locked.'' Tr. 768–69. Despite this policy, the Respondent did not dispute that controlled substances were left on the counter, or that they may have been left on the counter when the Ohio Dental Board investigators conducted their inspection. Tr. 770, 772–74. However, the Respondent claimed that ''at some point [the drugs] would have gotten to my office.'' Tr. 770.

Although the Respondent acknowledged that he teaches his students to simultaneously record amounts of controlled substances utilized during conscious sedation procedures on the form designed for that purpose, his own practice was to write the administered doses on a paper towel and transfer those numbers to the sedation logs later. Tr. 680–84. Curiously, the Respondent's testimony diverged from that of his testifying staff members to the extent that they were unambiguous and unanimous in their assertion that when completing sedation logs they acted as scriveners, merely recording the amounts of medication that the Respondent called out.[68] The Respondent, for his part, claims that the staff members independently divined the medication amounts by their own examination of the syringes while the procedures were in progress and entered those values onto the sedation logs without his input. Tr. 695–97, 743. But in earlier testimony, when describing his paper-towel procedure, he employed the word ''we'' when describing the manner in which the amounts were recorded. Tr. 680–84. If a staff member were the sole individual charged with monitoring and entering the amounts, it is unlikely that the Respondent would use the word ''we.'' Based on the Respondent's testimony that it was his practice to maintain a contemporaneous record of administered medication on a paper towel that was then routinely discarded, and the absence of any conceivable motivation on the part of the staff members to fabricate such a seemingly innocuous detail (at least to them) of standard operating procedure, coupled with what appeared to be genuine confusion (not defensiveness) in their demeanor when asked about the subject, the Respondent's account of this process is less credible than the account of his former employees. The Government's expert, Dr. Becker, testified that in an office setting, auxiliaries of the practitioner routinely make these entries in the sedation logs, but he did not indicate whether it was based exclusively on the word of the practitioner or on their own personal observations. Tr. 146–47. The credible evidence supports the testimony supplied by Crockett and Tetzloff that they were tasked with recording the amounts of medication dictated by the Respondent.

The sedation logs that were noticed and initially provided by the Respondent was another aspect of this case that did not reflect well on his credibility. The Respondent testified that separate logs were generated and maintained at Norwalk and Avon,[69] but a consolidated version was provided to the tribunal. Resp't Ex. A (ID). Whether the Respondent's account of who completed the sedation logs or the account provided by his former employees is credited, no one who testified at the hearing suggested that multiple pages of entries were simultaneously prepared or maintained, yet the version of the logs initially provided by the Respondent was so replete with duplication that a modified version with the duplications culled out was prepared by his counsel after the commencement of the hearing. Resp't Ex. A–1; Tr. 703–05, 713–14. Additionally, although the sedation log pages contained an internal capacity to designate them as belonging to Norwalk, Avon, or another office, the pages provided did not designate any location. Resp't Ex. A–1; Tr. 756–57. The Respondent testified that as a result of Brinks' visit, he took the sedation logs and the medication from Avon to Norwalk, but when pressed on why there were so many duplicates among the sedation log pages, the Respondent stated that his office staff (specifically, ''the front desk people'')[70] prepared the logs and that he ''rel[ied] on other people to help [him] me try to keep track of this.'' Tr. 697–700. Since DEA already knew the Respondent kept two sets of logs, consolidating them into one, disorganized version would accomplish no reasonable purpose. Puzzlingly, the Respondent's counsel then attempted to shift responsibility for the duplicates to staff at his law office. Tr. 701. It would simply make no sense that the clerical staff at counsel's office would spontaneously supplement the sedation logs provided by their client with multiple copies of randomly selected pages. Likewise, the fact that the version brought to the hearing had entries that were not initially presented to DI Brinks, and those additions are not readily apparent from the documents,[71] also casts doubt on their reliability. Paradoxically, the Respondent's version of who bears the responsibility of a plethora of duplicate records is the more plausible account, although it reflects poorly on his credibility, his recordkeeping, or both. In an acknowledgement of this reality, the Respondent ultimately conceded that the responsibility of the preparation of the logs as they were provided ''falls to [him].'' Tr. 703.

During his testimony, when the Respondent was asked to provide an account of what is required of a registrant ''[b]ased on what you've learned'' from DI Brinks' testimony, he replied as follows:

> I understand what [Brinks is] saying that every syringe I've got left over, I guess I've got to package it up and send it to either the Pharmacy Board or have the Pharmacy Board come or send it to [Brinks'] office in Cleveland, as I understand it now.''

Tr. 709. Thus, by the Respondent's account, he has first learned of his disposal obligations as a registrant as he sat at his own revocation hearing and *guesses* that he is required to send it to an appropriate place for disposal. *See also,* Tr. 776. Remarkably, although served in August 2010 with an OSC which alleges, *inter alia,* that he has been improperly disposing of controlled substance without notifying DEA, the Respondent testified that his practice has not altered the manner in which it has been disposing of residual controlled substances (*to wit,* by squirting it down the drain without DEA approval), and did so as recently as the

[68] In addition to the testimony of Tetzloff and Crockett, this version of events is consistent with the account provided by another employee, Peg Herner, in her conversation with DI Brinks. Tr. 456.

[69] Tr. 694.

[70] Tr. 703.

[71] Tr. 591–92.

week before the hearing. Tr. 762–64, 777–78. More remarkable still, is the Respondent's testimony that, although he has stopped storing controlled substances at Avon, he continues to administer controlled substances there, despite the fact that it has never been a registered COR location. Tr. 764–66. When asked why he has persisted in this conduct, notwithstanding the current charges, the Respondent explained that he finds proper disposal ''to be very laborious.'' Tr. 775–76. Respondent also testified that every dentist he knows disposes of substances in a similar way and that, therefore he ''didn't know if that [regulation] really pertained to me.'' Tr. 780–81.

The issue of the Respondent's credibility was a mixed bag. As discussed at length, supra, the Respondent's answers were intermittently inconsistent, implausible, and periodically lacking in detail. There were some issues, such as his background, education, and mental health issues, where his testimony had sufficient indicia of reliability to be credited, and there were other matters, several of which were in conflict with other evidence, where his version of events must be found to be less than completely credible.

Additional facts required for a resolution of the issues in this matter are set forth below.

The Analysis

Pursuant to 21 U.S.C. 824(a)(4) (2006), the Administrator[72] is permitted to revoke a COR if persuaded that the registrant ''has committed such acts as would render * * * registration under section 823 * * * inconsistent with the public interest * * *.'' The following factors have been provided by Congress in determining ''the public interest'':

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

(2) The [registrant's] experience in dispensing, or conducting research with respect to controlled substances.

(3) The [registrant's] conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(4) Compliance with applicable State, Federal or local laws relating to controlled substances.

(5) Such other conduct which may threaten the public health and safety. 21 U.S.C. 823(f) (2006 & Supp. III 2010).

''[T]hese factors are considered in the disjunctive.'' *Robert A. Leslie, M.D.,* 68 FR 15227, 15230 (2003). Any one or a combination of factors may be relied upon, and when exercising authority as an impartial adjudicator, the Administrator may properly give each factor whatever weight she deems appropriate in determining whether a registration should be rejected. *Morall* v. *DEA,* 412 F.3d 165, 173–74 (D.C. Cir. 2005); *JLB, Inc., d/b/a Boyd Drugs,* 53 FR 43945, 43947 (1988); *David E. Trawick, D.D.S.,* 53 FR 5326, 5327 (1988); *see also Joy's Ideas,* 70 FR 33195, 33197 (2005); *David H. Gillis, M.D.,* 58 FR 37507, 37508 (1993); *Henry J. Schwarz, Jr., M.D.,* 54 FR 16422, 16424 (1989). Moreover, the Administrator is ''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,* 412 F.3d at 173–74. The Administrator is not required to discuss consideration of each factor in equal detail, or even every factor in any given level of detail. *Trawick* v. *DEA,* 861 F.2d 72, 76 (4th Cir. 1988) (the Administrator's obligation to explain the decision rationale may be satisfied even if only minimal consideration is given to the relevant factors and remand is required only when it is unclear whether the relevant factors were considered at all). The balancing of the public interest factors ''is not a contest in which score is kept; the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the registrant. Rather, it is an inquiry which focuses on protecting the public interest * * *.'' *Jayam Krishna-Iyer, M.D.,* 74 FR 459, 462 (2009).

In an action to revoke a registrant's COR, the DEA has the burden of proving that the requirements for revocation are satisfied. 21 CFR 1301.44(e) (2011). The Government may sustain its burden by showing that the Respondent has committed acts inconsistent with the public interest.[73] *Jeri Hassman, M.D.,* 75 FR 8194, 8235–36 (2010). Once DEA has made its *prima facie* case for revocation of the registrant's COR, the burden of production then shifts to the Respondent to present sufficient mitigating evidence to assure the Administrator that he or she can be entrusted with the responsibility commensurate with such a registration and that revocation is not appropriate. *Steven M. Abbadessa, D.O.,* 74 FR 10077, 10078, 10081 (2009); *Medicine Shoppe-Jonesborough,* 73 FR 364, 387 (2008); *Samuel S. Jackson, D.D.S.,* 72 FR 23848, 23853 (2007); *Morall,* 412 F.3d at 174; *Humphreys* v. *DEA,* 96 F.3d 658, 661 (3d Cir. 1996); *Shatz* v. *U.S. Dept. of Justice,* 873 F.2d 1089, 1091 (8th Cir. 1989); *Thomas E. Johnston,* 45 FR 72311, 72312 (1980). Further, ''to rebut the Government's *prima facie* case, [the Respondent] is required not only to accept responsibility for [the established] misconduct, but also to demonstrate what corrective measures [have been] undertaken to prevent the reoccurrence of similar acts.'' *Jeri Hassman, M.D.,* 75 FR at 8236. Normal hardships to the practitioner and even to the surrounding community that are attendant upon the lack of registration are not relevant considerations. *Linda Sue Cheek, M.D.,* 76 FR 66972, 66973 (2011); *Abbadessa,* 74 FR at 10078; *see also Gregory D. Owens, D.D.S.,* 74 FR 36751, 36757 (2009).

While the burden of proof at this administrative hearing level is a preponderance-of-the-evidence standard, *see Steadman* v. *SEC,* 450 U.S. 91, 100–01 (1981), the Administrator's factual findings will be sustained on review to the extent they are supported by ''substantial evidence.'' *Hoxie,* 419 F.3d at 481. And while ''the possibility of drawing two inconsistent conclusions from the evidence'' does not limit the Administrator's ability to find facts on either side of the contested issues in the case. *Shatz,* 873 F.2d at 1092; *Trawick,* 861 F.2d at 77, all ''important aspect[s] of the problem,'' such as a Respondent's defense or explanation that runs counter to the Government's evidence, must be considered. *Wedgewood Vill. Pharmacy* v. *DEA,* 509 F.3d 541, 549 (D.C. Cir. 2007); *Humphreys,* 96 F.3d at 663. The ultimate disposition of the case must be in accordance with the weight of the evidence, not simply supported by enough evidence to justify, if the trial were to a jury, a refusal to direct a verdict when the conclusion sought to be drawn from it is one of fact for the jury. *Steadman,* 450 U.S. at 99 (internal quotation marks omitted).

Regarding the exercise of discretionary authority, the courts have recognized that gross deviations from past agency precedent must be adequately supported, *Morall,* 412 F.3d at 183, but mere unevenness in

[72] This authority has been delegated pursuant to 28 CFR 0.100(b) and 0.104 (2010).

[73] The Agency's conclusion that past performance is the best predictor of future performance has been sustained on review in the courts, *Alra Labs.* v. *DEA,* 54 F.3d 450, 452 (7th Cir. 1995), as has the Agency's consistent policy of strongly weighing whether a registrant who has committed acts inconsistent with the public interest has accepted responsibility and demonstrated that he or she will not engage in future misconduct. *Hoxie,* 419 F.3d at 483; *Ronald Lynch, M.D.,* 75 FR 78745, 78749 (2010) (Respondent's attempts to minimize misconduct held to undermine acceptance of responsibility); *George Mathew, M.D.,* 75 FR 66138, 66140, 66145, 66148 (2010); *East Main Street Pharmacy,* 75 FR 66149, 66165 (2010); *George C. Aycock, M.D.,* 74 FR 17529, 17543 (2009); *Abbadessa,* 74 FR at 10078; *Krishna-Iyer,* 74 FR at 463; *Medicine Shoppe,* 73 FR at 387.

application does not, standing alone, render a particular discretionary action unwarranted. *Chein* v. *DEA,* 533 F.3d 828, 835 (D.C. Cir. 2008) (citing *Butz* v. *Glover Livestock Comm. Co.,* 411 U.S. 182, 188 (1973)), *cert. denied,* __ U.S. __, 129 S. Ct. 1033, 1033 (2009). It is well-settled that since the Administrative Law Judge has had the opportunity to observe the demeanor and conduct of hearing witnesses, the factual findings set forth in this recommended decision are entitled to significant deference, *Universal Camera Corp.* v. *NLRB,* 340 U.S. 474, 496 (1951), and that this recommended decision constitutes an important part of the record that must be considered in the Administrator's decision, *Morall,* 412 F.3d at 179. However, any recommendations set forth herein regarding the exercise of discretion are by no means binding on the Administrator and do not limit the exercise of that discretion. 5 U.S.C. 557(b) (2006); *River Forest Pharmacy, Inc.* v. *DEA,* 501 F.2d 1202, 1206 (7th Cir. 1974); *Attorney General's Manual on the Administrative Procedure Act* 8 (1947).

Factors 1 and 3: The Recommendation of the Appropriate State Licensing Board or Professional Disciplinary Authority; and Any Conviction Record Under Federal or State Laws Relating to the Manufacture, Distribution, or Dispensing of Controlled Substances

In this case, it is undisputed that the Respondent holds a valid and current state license to practice medicine in Ohio. Although the Government introduced evidence that the Ohio Dental Board has previously placed the Respondent's state medical privileges on a period of suspension that was completed without complication, the matter was unrelated to the Respondent's obligations as a DEA registrant and not relevant here. Tr. 391–92, 394–96; *see Judulang* v. *Holder,* 132 S.Ct. 476, 556 U.S. ____ (2011) (invalidating Board of Immigration Appeals decision making practice where the ''rule [was] unmoored from the purposes and concerns of the immigration laws.''). Although Ms. Reitz, from the Ohio Dental Board, testified that there is an ongoing Board investigation into matters in common with these proceedings,[74] the record contains no evidence of a recommendation regarding the Respondent's medical privileges related to these issues by any cognizant state licensing board or professional disciplinary authority. The fact that an investigation by state authorities is pending is neither supportive of revocation nor antithetical to it. That a state has not acted against a registrant's medical license is not dispositive in this administrative determination as to whether continuation of a registration is consistent with the public interest. *Patrick W. Stodola, M.D.,* 74 FR 20727, 20730 (2009); *Jayam Krishna-Iyer,* 74 FR at 461. It is well-established Agency precedent that a ''state license is a necessary, but not a sufficient condition for registration.'' *Leslie,* 68 FR at 15230; *John H. Kennedy, M.D.,* 71 FR 35705, 35708 (2006). Even the reinstatement of a state medical license does not affect the DEA's independent responsibility to determine whether a registration is in the public interest. *Mortimer B. Levin, D.O.,* 55 FR 9209, 8210 (1990). The ultimate responsibility to determine whether a registration is consistent with the public interest has been delegated exclusively to the DEA, not to entities within state government. *Edmund Chein, M.D.,* 72 FR 6580, 6590 (2007), *aff'd, Chein* v. *DEA,* 533 F.3d 828 (D.C. Cir. 2008), *cert. denied,* __ U.S. __, 129 S. Ct. 1033 (2009). Congress vested authority to enforce the CSA in the Attorney General, not state officials. *Stodola,* 74 FR at 20375. While Respondent contends that the lack of board action weighs against revocation, Resp't Brief at 15, Agency precedent establishes that, where the record contains no evidence of a recommendation by a state licensing board, such absence does not weigh for or against a determination as to whether continuation of the Respondent's DEA certification is consistent with the public interest. *See Ronie Dreszer, M.D.,* 76 FR 19434, 19444 (2011) (''[T]he fact that the record contains no evidence of a recommendation by a state licensing board does not weigh for or against a determination as to whether continuation of the Respondent's DEA certification is consistent with the public interest.''). Accordingly, Factor One does not weigh for or against revocation in this matter. *Id.*

Regarding the third factor (convictions relating to the manufacture, distribution, or dispensing of controlled substances), the record in this case does not contain evidence that the Respondent has been convicted of a crime related to the manufacture, distribution, or dispensing of controlled substances. DEA administrative proceedings are non-punitive and ''a remedial measure, based upon the public interest and the necessity to protect the public from those individuals who have misused controlled substances or their DEA COR, and who have not presented sufficient mitigating evidence to assure the [Administrator] that they can be trusted with the responsibility carried by such a registration.'' *Jackson,* 72 FR at 23853; *Leo R. Miller, M.D.,* 53 FR 21931, 21932 (1988). Where evidence in a particular case reflects that the Respondent has acquired convictions relating to the manufacture, distribution, or dispensing of controlled substances, those convictions must be carefully examined and weighed in the adjudication of whether the issuance of a registration is in the public interest. 21 U.S.C. 823(f).

Although the standard of proof in a criminal case is more stringent than the standard required at an administrative proceeding, and the elements of both federal and state crimes relating to controlled substances are not always co-extensive with conduct that is relevant to a determination of whether registration is within the public interest, evidence that a registrant has been convicted of crimes related to controlled substances is a factor to be evaluated in reaching a determination as to whether he or she should be entrusted with a DEA certificate. While Respondent contends that the lack of convictions should weigh in his favor, Resp't Posth'g Brf. at 19, the probative value of an absence of any evidence of criminal prosecution, even if conceded as relevant *arguendo,* is perforce diminished by the myriad of considerations that are factored into a decision to initiate, pursue, and dispose of criminal proceedings by Federal, State, and local prosecution authorities. *See Robert L. Dougherty, M.D.,* 76 FR 16823, 16833 n.13 (2011); *Dewey C. Mackay, M.D.,* 75 FR 49956, 49973 (2010) (''[W]hile 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.'') (citing *Jayam Krishna-Iyer, M.D.,* 74 FR 459, 461 (2009); *Edmund Chein, M.D.,* 72 FR 6580, 6593 n.22 (2007), *aff'd, Chein v. DEA,* 533 F.3d 828 (D.C. Cir. 2008), *cert. denied,* __ U.S. __, 129 S. Ct. 1033 (2009)); *Ladapo O. Shyngle, M.D.,* 74 FR 6056, 6057 n.2 (2009).

Accordingly, consideration of the evidence of record under the first and third factors neither supports the Government's argument for revocation nor militates against it.

[74] Tr. 392–409, 412, 422–23.

Factors 2 and 4: Experience in Dispensing Controlled Substances and Compliance With Applicable State, Federal, or Local Laws Relating to Controlled Substances

In this case, the gravamen of the Government's case relates to the allegations that the Respondent: (1) Failed to comply with the CSA's registration requirements; (2) failed to adhere to the CSA's recordkeeping and security requirements and was unable to account for both shortages and overages of controlled substances; and (3) dispensed controlled substances to himself for illegitimate purposes.[75]

Regarding Factor 2, in requiring an examination of a registrant's experience in dispensing controlled substances, Congress manifested an acknowledgement that the qualitative manner and the quantitative volume in which a registrant has engaged in the dispensing of controlled substances, and how long he or she has been in the business of doing so, are significant factors to be evaluated in reaching a determination as to whether he or she should be entrusted with a DEA COR. In some cases, viewing a registrant's actions against a backdrop of how he has performed activity within the scope of the certificate can provide a contextual lens to assist in a fair adjudication of whether continued registration is in the public interest.

Evidence that a practitioner may have conducted a significant level of sustained activity within the scope of the registration for a sustained period can be a relevant and correct consideration, which may be accorded due weight. The registrant's knowledge and experience regarding the rules and regulations applicable to practitioners also may be considered. *See Volusia Wholesale,* 69 FR69409, 69410 (2004) (List I case).[76] However, the Agency has taken the reasonable position that this factor can be outweighed by acts held to be inconsistent with the public interest. *Jayam Krishna-Iyer,* 74 FR at 463; *see also Jeri Hassman, M.D.,* 75 FR 8194, 8235 (2010) (acknowledging Agency precedential rejection of the concept that conduct which is inconsistent with the public interest is rendered less so by comparing it with a respondent's legitimate activities which occurred in substantially higher numbers); *Paul J. Cargine, Jr.,* 63 FR 51592, 51560 (1998) (''[E]ven though the patients at issue are only a small portion of Respondent's patient population, his prescribing of controlled substances to these individuals raises serious concerns regarding [his] ability to responsibly handle controlled substances in the future.'').

Experience which occurred prior or subsequent to proven allegations of malfeasance may be relevant. Evidence that precedes proven misconduct may add support to the contention that, even acknowledging the gravity of a registrant's transgressions, they are sufficiently isolated and/or attenuated that adverse action against his registration is not compelled by public interest concerns. Likewise, evidence presented by the Government that the proven allegations are congruous with a consistent past pattern of poor behavior can enhance the Government's case.

In a similar vein, conduct which occurs after proven allegations can shed light on whether a registrant has taken steps to reform and/or conform his or her conduct to appropriate standards. Contrariwise, a registrant who has persisted in incorrect behavior, or made attempts to circumvent Agency directives, even after being put on notice, can diminish the strength of its case. *Novelty, Inc.,* 73 FR 52689, 52703 (2008), *aff'd,* 571 F.3d 1176 (D.C. Cir. 2009); *Southwood Pharm., Inc.,* 72 FR 36487, 36503 (2007); *John J. Fotinopoulous,* 72 FR 24602, 24606 (2007).

In *Jayam Krishna-Iyer,* 74 FR at 463, DEA acknowledged the reality that even a significant and sustained history of uneventful practice under a DEA certificate can be offset by proof that a registrant has committed acts inconsistent with the public interest. *Id.* Even, ''evidence that a practitioner has treated thousands of patients does not negate a prima facie showing that the practitioner has committed acts inconsistent with the public interest.'' *Id.* The Agency, in its administrative precedent, has further curtailed the scope of Factor 2. The Agency's current view regarding Factor 2 is that, while evidence of a registrant's experience handling controlled substances may be entitled to some weight in assessing whether errant practices have been reformed, where the evidence of record raises intentional or reckless actions on the part of the registrant, such evidence is entitled to no weight where a practitioner fails to acknowledge wrongdoing in the matters before the Agency. *Cynthia M. Cadet, M.D.,* 76 FR 19450 n.3 (2011); *Roni Dreszer, M.D.,* 76 FR 19434 n.3 (2011); *Michael J. Aruta, M.D.,* 76 FR 19420 n.3 (2011); *Jacobo Dreszer, M.D.,* 76 FR 19386–87 n.3 (2011). This reasonable approach accepts the unavoidable logic that a transgression can only be rationally styled as an aberration when it is acknowledged by the actor as a transgression for which remorse is demonstrated.

The Respondent argues that his professional experience supports favorable consideration under Factor 2. Resp't Posth'g Brf. at 16–19. Indeed, on the present record, it is undisputed that the Respondent has uneventfully practiced dentistry for over two decades, is a periodontic specialist, has published numerous scholarly articles in his field, and was sufficiently accomplished in his profession that he has served as a professor and clinical director Case Western Reserve School of Dental Medicine. Resp't Ex. E; Tr. 655–56. While the Respondent's level of professional achievement is undeniably impressive, he has offered no affirmative evidence regarding his experience dispensing controlled substances from peers, co-workers, or even himself. Still, his professional experience and contributions to his field have been considered in this recommended decision.

Regarding Factor 4, Sections 822(e) and 1301.12 require that a registrant maintain ''a separate registration * * * at each principal place of business or professional practice where the

[75] The present record is bereft of competent evidence to support this third factual allegation. The Respondent's erratic behavior was well-documented in the record, as were the IV marks on his hands and arms. The Respondent's explanation that the suspect marks were the product of some sort of hands-on IV experience by chronically untalented student dentists was more than just somewhat undermined by the blood and marks on the backs of his hands that were observed by his staff on a morning where he was inexplicably late for patients, and not teaching at Case Western Reserve. That the IV marks were the product of his large Newfoundland was about as unpersuasive as his ''I'm a picker'' theory. The evidence of record (enhanced by the Respondent's testimony) doubtless creates a suspicion that there was something more afoot than his offered explanations, but the Agency precedent on the subject has been commendably clear that ''under the substantial evidence test, the evidence must 'do more than create a suspicion of the existence of the fact to be established.' '' *Alvin Darby, M.D.,* 75 FR 26993, 26999, n.31 (2010) (citing *NLRB* v. *Columbian Enameling & Stamping Co.,* 306 U.S. 292, 300 (1939).

[76] In *Cynthia M. Cadet, M.D.,* 76 FR 19450, 19450 n.1 (2011), the Agency declined to adopt the List I experience analysis for practitioners charged with intentional diversion. Thus far, Agency precedent has left open the door to this form of evidence where intentional diversion has not been established. *Compare* 21 U.S.C. 823(h) (List I section mandating consideration of ''any past *experience* of the applicant in the manufacture and distribution of chemicals,'') (emphasis added) *with* 21 U.S.C. 823(f) (practitioner section mandating consideration of ''[t]he applicant's *experience* in dispensing, or conducting research with respect to controlled substances.); *see U.S.* v. *Tinklenberg,* 131 S.Ct. 2007, 2019–20 (2011) (''Identical words used in different parts of a statute are presumed to have the same meaning absent indication to the contrary.'').

applicant manufactures, distributes, or dispenses controlled substances or list I chemicals.'' This separate registration requirement has been called ''an essential requirement of DEA's diversion control program.'' *Preventing the Accumulation of Surplus Controlled Substances at Long Term Care Facilities,* 70 FR 25462, 25463 (2005) *(''Long Term Care'').* In its prehearing statement, the Government alleged that Respondent ''administered controlled substances to patients from his Avon dental practice,'' but did not obtain a registration for the Avon location. Gov't PHS, at 7. Paragraph 5 of the OSC also alleged that Respondent ''distributed controlled substances including fentanyl, diazepam and midazolam * * * to an unregistered location in violation of 21 CFR § 1307.11.'' [77] OSC, at ¶ 5.

The evidence of record establishes that Respondent maintained two dental offices: An office in Norwalk, where Respondent maintained his DEA registration; and an office in Avon, Ohio. Tr. 155–56, 221, 451–53. It appears that he practiced out of the Avon office once or twice per week. Tr. 156, 261. It is undisputed that controlled substances were, for a period of time, stored at Avon Office and that Respondent does not have a DEA registration for the Avon location. It is also undisputed that Respondent has regularly administered controlled substances for sedation at the Avon Office, and that he continues to do so. Tr. 764, Resp't Ex. M. Thus, it is clear that Respondent has administered controlled substances at a location that is unregistered, and has thus violated sections 822(e) and 1301.12.[78] Furthermore, insofar as the Respondent continues to administer controlled substances at the Avon Office, it appears that Respondent remains in flagrant violation of this regulation.[79] Even apart from the reality that the Respondent, as a DEA registrant is responsible for understanding his obligations under the clear language of the relevant regulations, he has been given direct notice that his Avon Office location must be registered, by the initiation of these proceedings and a full, contested hearing on the matter; yet the Respondent doggedly refuses to bring himself into compliance. He has not sought to obtain a registration for the Avon Office and has not stopped administering controlled substances there as a regular part of his professional practice. Hence, in the face of his refusal to obey the law, consideration of this factor, even standing alone, persuasively and conclusively balances in favor of revocation.

In addition to the registration violations, the Government also alleges that Respondent failed to secure controlled substances properly at the Avon Office, in violation of 21 CFR 1301.75(b). ALJ Ex. 1. With regard to security, 21 CFR 1301.71(a) provides, in relevant part, that ''[a]ll applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances. In order to determine whether a registrant has provided effective controls against diversion, the Administrator shall use the security requirements set forth in §§ 1301.72–1301.76 as standards for the physical security controls and operating procedures necessary to prevent diversion.'' While the security provisions of sections 1301.72 through 1301.76 are used as standards to determine compliance with section 1301.71(a), the language of each of these sections is phrased in mandatory terms. *See e.g.,* 21 CFR 1301.75(a) (''Controlled substances listed in Schedule I *shall* be stored in a securely, locked, substantially constructed cabinet.'') (emphasis added); 21 CFR 1301.76(a) (''The registrant *shall not* * * *'') (emphasis added). Thus, while compliance with the security provisions is a consideration under 21 CFR 1301.71(a), violation of any of the relevant security requirements in sections 1301.72–76 will be an independent consideration under Factor Four.

Section 1301.75(b) provides, in relevant part, that ''[c]ontrolled substances listed in Schedules II, III, IV, and V shall be stored in a securely locked, substantially constructed cabinet. However, pharmacies and institutional practitioners may disperse such substances throughout the stock of noncontrolled substances in such a manner as to obstruct the theft or diversion of the controlled substances.'' The security requirements of section 1301.75 are designed ''to prevent the unlawful diversion of * * * drugs.'' *Jerry Neil Rand, M.D.,* 61 FR 28895, 28897 (1996). Thus, a reasonable reading of the regulations would compel a registrant entrusted with the care of controlled substances to ensure that when the controlled substances are left unattended, they must be placed in a container meeting the requirements of section 1301.75. *See D-Tek Enterprises,* 56 FR 28926, 28926 (1991) (''21 CFR 1301.75 requires that all Schedule I and II controlled substances be *kept* in a securely locked, substantially constructed cabinet.'') (emphasis added); *see also* Merriam-Webster Dictionary (Defining ''kept'' as ''to cause to remain in a given place, situation or condition.'').

Here, the testimony establishes that, on numerous occasions, supplies of controlled substances were left in gray, shoebox-sized bins on the counters of the sterilization room in the Avon Office. Specifically, Ms. Tetzloff and Ms. Crockett testified that they would leave the gray bins in the open while preparing for patients in the morning. Tr. 157–58, 233–34. While true that the sterilization room was not readily accessible to patients standing by in the waiting room, a counter is not a locked cabinet. The regulations, which specify that controlled substances be stored in locked containers, are designed to provide both security and accountability

[77] The CSA provides that ''[t]he term 'distribute' means to deliver * * * a controlled substance or a listed chemical.'' 21 U.S.C. 802(a)(10). The term ''deliver,'' in turn, is defined as ''the actual, constructive, or attempted *transfer* of a controlled substance or a listed chemical, whether or not there exists an agency relationship.'' 21 U.S.C. 802(a)(8) (emphasis added). No authority has been cited which would stand for the proposition that a practitioner ''distributes'' controlled substances when he moves controlled substances from one of his offices to another. Rather, it seems that, under the CSA and its implementing regulations, controlled substances are distributed between persons, and not locations. *See* 21 CFR 1307.11–12 (Regulating distribution of controlled substances between parties without mention of location). Accordingly, the Government's charge brought under § 1307.11—that the Respondent distributed controlled substances improperly—is without merit.

[78] Through counsel in his Posthearing Brief, the Respondent acknowledges that dispensing in Avon without a valid COR was in violation of the law. Resp't Posth'g Brf. at 17, 20.

[79] As discussed, *supra,* through counsel in his Posthearing Brief, the Respondent acknowledges that dispensing in Avon without a valid COR was in violation of the law. Resp't Posthearing Brf. at 17, 20. Interestingly though, the Respondent's Posthearing Brief also contends that ''he discontinued storing drugs at his Avon location in order to be in compliance with the regulations.'' Resp't Posthearing Brf. at 3. This position, consistent as it may be with the posture the Respondent took on this matter during his testimony, is unsupported in the law. Tr. 765. DEA regulations clearly establish that *all* professional practices at which controlled substances are distributed must have their own DEA registration. 21 CFR 1301.12. A narrow exception to this requirement applies only insofar as: (1) The practitioner has a valid DEA registration in the same state as the second location; (2) the practitioner does not store controlled substances at the second location; and (3) the practitioner does not administer controlled substances as a regular part of the professional practice at the second location. 21 CFR 1301.12(b)(3). The Respondent testified that IV sedation is a ''critical component'' of his practice, and that he conducted procedures administering controlled substances up to the week prior to the hearing. Tr. 660, 764. Under these circumstances (even apart from the Respondent's through-counsel concession on this issue), the Respondent is clearly administering controlled substances is a regular part of his Avon practice, and therefore, must be separately registered under the regulations.

in the maintenance of a closed regulatory system for controlled substances. *Jerry Neil Rand, M.D.,* 61 FR at 28897. Where accountability is concerned, the system must be as concerned with the accountability of health professionals with access to office spaces as it is with potential access by the patients waiting for treatment. It is clear that the controlled substances were not left in securely locked, substantially constructed cabinets, as required by the regulations. 21 CFR 1301.75. Accordingly, substantial evidence supports the conclusion that Respondent violated the security requirement set forth in section 1301.75, and this factor militates in favor of revocation.

To effectuate the dual goals of conquering drug abuse and controlling both legitimate and illegitimate traffic in controlled substances, ''Congress devised a closed regulatory system making it unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the CSA.'' *Gonzales* v. *Raich,* 545 U.S. 1, 13 (2005). Consistent with the maintenance of that closed regulatory system, accurate and reliable records are an obvious bedrock safeguard that is essential to ensure the integrity of the closed regulatory system. A truly closed system requires not only that certain records and inventories be kept by all those registrants who either generate or take custody of controlled substances in any phase of the distribution chain until they reach the ultimate user, but that those documents be subject to periodic inspection and ready retrieval for that purpose. Registrants, such as the Respondent, who are authorized to dispense controlled substances are required to keep such records, and to maintain those records in a manner that is ''readily retrievable,'' upon demand of those DEA officials charged with conducting inspections. *See* 21 CFR 1304.04(g) & (f)(2) (2011); *see* 21 CFR 1304.03 (requiring recordkeeping set forth in § 1304.04 for dispensing physicians). Readily retrievable is defined in the regulations as ''records kept * * * in such a manner that they can be separated out from all other records in a reasonable time * * *'' 21 CFR 1300.01(b)(38).

The Government alleged that DI Brinks conducted a regulatory inspection on the Respondent's practice on December 21, 2009 and found multiple regulatory violations. ALJ Ex. 5 at 6. It need hardly be restated that the audit computation results as offered by DI Brinks at the hearing were profoundly problematic to say the least, and cannot be used to support a finding of substantial evidence of anything. However, the record does credibly establish that the Respondent, for his part, produced no purchase records, and was able to furnish Brinks with only three Form 222s over the course of a two-year period, which, even based on a cursory examination of the sedation logs,[80] was a fraction of what should have been available. Tr. 444, 446–48, 639–40. Of that paltry number, one was incomplete. Tr. 451. Notwithstanding the Respondent's regular practice of ''wasting'' residual medication, he was unable to produce any Form 41s. Tr. 443, 449–50.

In the present record, every health professional who provided evidence on the topic, including the Respondent, himself, is of the opinion that the amounts of controlled-substance medication administered by the Respondent to the patients depicted in the sedation logs is high. It was the view of the Government's expert, Dr. Becker, that the amounts administered would have resulted in unconsciousness and other complications, and that to the extent that the higher amounts were based on addressing sedation-resistant patients, that this temporally-limited sample contained more such resistant patients than he has encountered in a lifetime of practice. Interestingly, in his testimony, the Respondent did not dispute that the amounts were high, but offered that he is a specialist who deals in difficult cases, and that it could have been that the patients (even though there were quite a few in a small window of time) could have been medication resistant for reasons that he hypothesized could have been present. The Respondent's argument that he is a specialist and gets complicated cases is unpersuasive because his specialty is in periodontics, not sedation-resistant patients. His argument that these patients could all have been medication resistant is undermined by any efforts on the Respondent's part to introduce evidence to establish medication resistance based on any patient in issue, even though he is in possession of the patient charts. As discussed, *supra,* a scholarly discussion among health professionals as to what choices, levels and combinations of medication(s) achieve optimum results is a discussion for a different forum and beyond the proper jurisdiction of DEA and this forum to evaluate. *Gonzales* v. *Oregon,* 546 U.S. 243, 274 (2006). The issue here is diversion, and this tribunal (and this Agency) can have no reasonable view as to whether reasonable minds can, should, or do differ on the issue of whether the administered doses were out of line with accepted medical practice. That said, the Government's expert, Dr. Becker, provided credible, persuasive, and unrefuted testimony that the amounts of medication employed by the Respondent as reflected in the sedation logs he supplied would likely have resulted in unconsciousness. The Respondent's testimony that none of his sedated patients were ever unconscious is likewise credible. With the poor state of the Respondent's controlled substance records, it is not possible to conclusively determine whether the high levels of controlled substance medications were administered as noted. The results of the audit conducted by DEA regarding the Respondent's recordkeeping demonstrated sufficient inattention to maintaining required documentation that his records were not reliable. The accountability concerns credibly conveyed by Crockett and Tetzloff in their testimony were borne of this same unreliability in the state of the records. Reliable records are a key aspect of maintaining a closed system, and this aspect of the Respondent's practice impacts negatively on consideration of Factor 4.

Finally, it is noteworthy that Respondent concedes that he regularly disposed of controlled substances without notifying the DEA, in violation of the governing regulations. *See* 21 CFR 1307.21(a) (Registrants must notify regional Special Agent in Charge before disposing of controlled substances). Respondent also testified that, notwithstanding the DEA administrative proceedings pending against his COR, he continues to follow this practice, essentially because he feels that other professionals in his field do it as well.[81] Tr. 709, 762–64, 776–78. A defense of ''other people are doing it too'' is generally no more persuasive in administrative enforcement proceedings than it is in the defense of a traffic violation, however, this case contains the arguably different wrinkle that every witness who presented evidence on the issue from each party is in agreement that squirting or ''wasting'' residual, unused amounts of controlled substances into the drain is common practice among registrants. Tr. 55–58,

[80] As discussed at length, *supra,* the sedation logs that were provided to DI Brinks differed with those provided at the hearing. Those records provided at the hearing were replete with multiple duplications and transpositions of the quantities counted.

[81] This posture is likewise assumed by the Respondent in his Posthearing Brief. Resp't Post H'ring Brf. at 10.

100–01, 105, 631; Resp't Ex. J. This forum is without jurisdiction (or inclination) to question the wisdom of the prior-notification requirements applicable to controlled substance disposal. While the issue of a common practice which may be knowingly and routinely ignored by the Agency [82] may present an interesting legal issue in another case where an adequate record on the subject has been developed, under the circumstances presented here, the Respondent's unwillingness to cease this disposal practice in the face of actual notice by the Agency militates against entrusting him with a DEA registration under Factor 4.

Accordingly, consideration of Factors 2 and 4 militate in favor of the revocation of the Respondent's COR.

Factor 5: Such Other Conduct Which May Threaten the Public Health and Safety

The fifth statutory public interest factor directs consideration of ''[s]uch *other conduct* which may threaten the public health and safety.'' 21 U.S.C. 823(f)(5) (emphasis supplied). Existing Agency precedent has long held that this factor encompasses ''conduct which creates a probable or possible threat (and not only an actual [threat]) to public health and safety.'' *Dreszer,* 76 FR at 19434 n.3; *Aruta,* 76 FR at 19420 n.3; *Boshers,* 76 FR 19403 n.4; *Dreszer,* 76 FR at 19386–87 n.3. Agency precedent has generally embraced the principle that any conduct that is properly the subject of Factor Five must have a nexus to controlled substances and the underlying purposes of the CSA. *Terese, Inc., d/b/a/Peach Orchard Drugs,* 76 FR 46843, 46848 (2011); *Tony T. Bui, M.D.,* 75 FR 49979, 49989 (2010) (prescribing practices related to a non-controlled substance such as human growth hormone may not provide an independent basis for concluding that a registrant has engaged in conduct which may threaten public health and safety); *but see Paul Weir Battershell, N.P.,* 76 FR 44359, 44368 n.27 (2011) (a registrant's non-compliance with the Food, Drug, and Cosmetic Act may be considered on the narrow issue of assessing a respondent's future compliance with the CSA).

Similar ''catch all'' language is employed by Congress in the CSA related to the Agency's authorization to regulate controlled substance manufacturing and List I chemical distribution, but the language is by no means identical. 21 U.S.C. 823(d)(6), (h)(5). Under the language utilized by Congress in those provisions, the Agency may consider ''such *other factors* as are relevant to and consistent with the public health and safety.'' *Id.* (emphasis supplied). In *Holloway Distributors,* 72 FR 42118, 42126 (2007), the Agency held this catch all language to be broader than the language directed at practitioners under ''other conduct which may threaten the public health and safety'' utilized in 21 U.S.C. 823(f)(5). In *Holloway,* the Agency stated that regarding the List I catch all:

> [T]he Government is not required to prove that the [r]espondent's conduct poses a threat to public health and safety to obtain an adverse finding under factor five. See *T. Young,* 71 [FR] at 60572 n.13. Rather, the statutory text directs the consideration of ''such other factors as are relevant to and consistent with the public health and safety.'' 21 U.S.C. § 823(h)(5). This standard thus grants the Attorney General broader discretion than that which applies in the case of other registrants such as practitioners. See id. § 823(f)(5) (directing consideration of ''[s]uch other conduct which may threaten the public health and safety'').

72 FR at 42126.[83] Thus, the Agency has recognized that, while the factor five applicable to List I chemical distributors—21 U.S.C. 823(h)(5)—encompasses all ''factors,'' the factor five applied to practitioners—21 U.S.C. 823(f)(5)—considers only ''conduct.'' Furthermore, because section 823(f)(5) only implicates ''such *other* conduct,'' it necessarily follows that conduct considered in factors one through four may not be considered at factor five.

As discussed, *supra,* the Government has alleged and established that the Respondent disposed of controlled substances without procuring the prior DEA approval required in the regulations. The manner of disposal here, *to wit,* squirting the controlled substances into the drain, and thus, the sewage and water treatment system is *conduct* that could arguably have public safety implications. Because the public safety aspect of this conduct was not factually developed at the hearing, it is not necessary to reach this issue, or the issue as to whether the ultimate destination of the ''wasted'' controlled substances constitutes *other conduct* separate and apart from the act of disposing without prior DEA authorization. Accordingly, there being no other conduct alleged (or proven) which may threaten the public health and safety, Factor Five weighs neither for nor against revocation.

Recommendation

All relevant acts alleged by the Government and established in the record relate to the Respondent's registered location in Norwalk and his unregistered office in Avon. Although no misconduct related to the Respondent's registered location in Milwaukee have been alleged or proved, these proceedings relate to whether he ''has committed such acts as would render his registration under [21 U.S.C. 823] inconsistent with the public interest,'' (a question answered in the affirmative here) and whether, as a matter of discretion, the Respondent should continue to be entrusted by the Agency with responsibilities as a DEA registrant in all locations that are the subject of the OSC.

As set forth above, Factors 1, 3 and 5 do not weigh for against revocation. Under Factor Four, substantial evidence supports a finding that Respondent: (1) maintained an unregistered professional practice, in violation of 21 U.S.C. 822(e) and 21 CFR 1301.12; (2) failed to secure controlled substances properly, in violation of 21 CFR 1301.75(b); and (3) failed to dispose of controlled substances properly, in violation of 21 CFR 1307.21(a). These acts bear some resemblance to those found in *Daniel Koller, D.V.M.,* 71 FR 66975, 66982–83 (2006).

In *Koller,* the Agency found that the respondent had: (1) Not stored controlled substances in a securely locked, substantially constructed cabinet, in violation of 21 CFR 1301.75(b); (2) failed to maintain proper DEA Form 222s, in violation of 21 CFR 1304.22(c); (3) distributed controlled substances to an unregistered practitioner, in violation of 21 CFR 1307.11(a); and (4) maintained an unregistered professional practice, in violation of 21 U.S.C. 822(e) and 21 CFR 1301.12(a). 71 FR at 66982–83. The Agency was unimpressed with Koller's testimony that in his view it was 'an absurdity' to claim that he violated the law by taking controlled substances [from a registered location to an unregistered location] because he had a DEA registration for his San Diego Residence [and] could 'take those drugs anywhere he wanted.'' *Id.* at 66982. In denying Respondent's application for registration, the Agency held that ''Respondent's repeated violations of the CSA provide ample grounds to deny his application. Moreover, Respondent's attitude leaves [the Agency] with the firm impression that, if given the

[82] This issue was not sufficiently developed on the present record to support a finding that DEA has made a determination to eschew enforcement of this provision. Indeed the charges in the present OSC counter such a position in the strongest terms possible.

[83] In *Bui,* the Agency clarified that ''an adverse finding under [Factor Five did not require a] showing that the relevant conduct actually constituted a threat to public safety.'' 75 FR 49888 n.12.

opportunity, he will violate the Act again.'' *Koller,* 71 FR at 66983.

Like the registrant in *Koller,* the Respondent's repeated and continuing violations in the face of—and even motivated by—his disagreement with his obligations as a registrant, undermine the confidence that can be placed in him to execute his responsibilities in compliance with the law. *See Koller, D.V.M.,* 71 FR at 66983 (''Respondent's repeated violations of the CSA provide ample grounds to deny his application.'').

Following the guidance of *Koller,* it is clear that the Government has sustained its burden of showing that Respondent committed acts inconsistent with the public interest. Accordingly, the burden shifts to the Respondent to show that he can be entrusted with a DEA registration. As discussed above, ''to rebut the Government's *prima facie* case, [the Respondent] is required not only to accept responsibility for [the established] misconduct, but also to demonstrate what corrective measures [have been] undertaken to prevent the reoccurrence of similar acts.'' *Jeri Hassman, M.D.,* 75 FR at 8236. The present record does not present transgressions on a level that could not have been overcome by a credible and persuasive acceptance of responsibility coupled with a cogent plan for coming into compliance and avoiding future violations; but inasmuch as neither demonstration was convincingly offered by the Respondent, under current Agency precedent, he cannot prevail.

Here, while Respondent has nominally [84] acknowledged that his conduct was wrongful, Tr. 763, 765, he has failed to outline any steps he has taken to prevent the reoccurrence of the infractions. Generally, actions speak louder than words, and the Respondent's actions speak volumes about his level of responsibility acceptance. By his own admission, the Respondent continues to dispose of controlled substances down his office drains without DEA authorization, and continues to administer drugs at his unregistered Avon location. Tr. 764. The Respondent has also failed to outline any steps which he has taken (or even intends to take) that would tend to prevent controlled substances from being left unsecured during mornings at the *unregistered* Avon Office. Clear on the evidence presented here, is that far from demonstrating acceptance and contrition, the Respondent has violated the law, disagrees with the law, and has continued to violate the law even after the Agency served him with an OSC. Thus, in this case, the Respondent has failed to sustain his burden of showing that he can be entrusted with the responsibilities incumbent upon a DEA registrant. *Koller,* 71 FR at 66983; *Jeri Hassman, M.D.,* 75 FR at 8236.[85]

Where, as here, the Government has made out a *prima facie* case that the Respondent has committed acts that render registration inconsistent with the public interest, Agency precedent has firmly placed acknowledgement of guilt and acceptance of responsibility as conditions precedent to merit the granting or continuation of status as a registrant. *Hoxie* v. *DEA,* 419 F.3d 477, 483 (6th Cir. 2005); *Ronald Lynch, M.D.,* 75 FR 78745, 78749 (Respondent's attempts to minimize misconduct held to undermine acceptance of responsibility); *George Mathew, M.D.,* 75 FR 66138, 66140, 66145, 66148 (2010); *George C. Aycock, M.D.,* 74 FR 17529, 17543 (2009); *Steven M. Abbadessa, D.O.,* 74 FR 10077, 10078 (2009); *Jayam Krishna-Iyer, M.D.,* 74 FR 459, 463 (2009); *Medicine Shoppe-Jonesborough,* 73 FR 364, 387 (2008). As explained above, Respondent has not rebutted the Government's prima facie case to the extent that he can avoid the sanction of a revocation of his registrations. Accordingly, the Respondent's Certificate of Registrations should be *revoked,* and any pending renewal applications should be *denied.*

Dated: December 21, 2011.

John J. Mulrooney II,
Chief Administrative Law Judge.

[FR Doc. 2012–29333 Filed 12–4–12; 8:45 am]

BILLING CODE 4410–09–P

[84] Though the Respondent acknowledged wrong doing, he also testified, in essence, that ''everybody does it.'' These ministrations echo the righteous protests put forth in *Koller;* and are no more compelling here. Accordingly, the evidence here, as in *Koller,* leaves ''the firm impression that, if given the opportunity, [Respondent] will violate the [CSA] again.'' *Koller,* 71 FR at 66983.

[85] In its Posthearing Brief the Government contends that ''the agency has recently admitted and considered testimony with regard to community impact [of revocation].'' Gov't Posth'g Brf. at 33. However, the Agency has recently once again re-affirmed its view that ''community impact evidence is not relevant in determining whether to * * * revoke an existing registration under the various authorities provided in 21 U.S.C. 824(a).'' *Cheek, M.D.,* 76 FR at 66972. Accordingly, community impact has not played a role in this recommended decision. *Id.*

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Amy S. Benjamin, N.P.; Decision and Order

On April 20, 2012, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Amy S. Benjamin, N.P. (Respondent), of Wheeler, Mississippi. The Show Cause Order proposed the revocation of Respondent's DEA Certificate of Registration MB1536171, and the denial of any pending applications to renew or modify the registration, on the ground that Respondent lacks authority to handle controlled substances in Mississippi, the State in which she is registered with the Agency. Show Cause Order, at 1 (citing 21 U.S.C. 824(a)(3)). Specifically, the Show Cause Order alleged that on June 10, 2011, the State of Mississippi Board of Nursing issued a final order, which suspended her nursing license, to include her authority to handle controlled substances in the State. *Id.*

The Show Cause Order notified Registrant of her right to request a hearing on the allegations, or in lieu of a hearing, to submit a written statement regarding the matters of fact and law asserted therein; the procedures for doing either; and the consequences for failing to do either. *Id.* at 2 (citing 21 CFR 1301.43(a), (c), (d), & (e)). The Show Cause Order was personally served on Registrant by members of the DEA New Orleans Field Division-Oxford Resident Office on April 23, 2012. GX 2, at 2; GX 6. Since the date of service of the Show Cause Order, thirty days have now passed and neither Registrant, nor anyone purporting to represent her, has requested a hearing or submitted a written statement in lieu of a hearing. I therefore find that Registrant has waived her right to a hearing or to submit a written statement in lieu of a hearing. 21 CFR 1301.43(d).

I further find that Registrant's DEA registration was due to expire on July 31, 2012, and that Registrant has failed to submit a renewal application. *See* Gov. Notification of Registration Expiration, at Ex. B. Therefore, I find that Registrant's registration expired on July 31, 2012.

It is well settled that ''[i]f a registrant has not submitted a timely renewal application prior to the expiration date, then the registration expires and there is nothing to revoke.'' *Ronald J. Riegel,* 63 FR 67132, 67133 (1998); *see also William W. Nucklos,* 73 FR 34330 (2008). Moreover, in the absence of an application (whether timely filed or not), there is nothing to act upon. *See Donald Brooks Reece II, M.D.,* 77 FR 35054 (2012). Because Registrant's registration has expired and there is no pending application to act upon, I conclude that this case is now moot and will be dismissed.