

ARTICLES

DRUG DIVERSION ADMINISTRATIVE REVOCATION AND APPLICATION HEARINGS FOR MEDICAL AND PHARMACY PRACTITIONERS: A PRIMER FOR NAVIGATING MURKY, DRUG-INFESTED WATERS

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I. INTRODUCTION

The prevalence of prescription controlled substance abuse has grown exponentially over the past decade.¹ State and federal regulatory agencies have struggled to adjust to the changing realities of a new challenge and a new dynamic between the regulators and the regulated community. State boards and federal regulators that have operated for decades on well-founded principles of mutual collegiality have been forced to revisit old

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¹ DRUG ENFORCEMENT ADMIN., NATIONAL DRUG THREAT ASSESSMENT SUMMARY 2013, at 2-5 (2013), available at <http://www.dea.gov/resource-center/DIR-017-13%20NDTA%20Summary%20final.pdf>.

methods with often mixed results. While enforcement efforts that have lurched forward in fits and starts at multiple levels of government have resulted in justifiable sanctions imposed upon law breakers, these efforts have also left many responsible professionals in the regulated community scrambling to understand new realities.

One inexorable result of federal efforts to react reasonably to an immense growth in prescription medication dependence is an increasingly complex and nuanced practice of administrative law before the Drug Enforcement Administration (DEA or Agency). The practice has morphed into a more contested and complicated dynamic that now requires litigation and academic skills that far exceed those previously demanded. Without an established manual or research resource currently available for this practice, even seasoned administrative practitioners can find themselves overwhelmed by well-trained and seasoned agency trial counsel, experts, and regulators. Hardened litigators unprepared for the technical nuances of this sophisticated regulatory scheme can unwittingly blunder their clients into irreparable and draconian results. This is a practice that now requires both skillful litigation and thoughtful study into the statutes, regulations, and precedents from both the agency and the courts of appeal that circumscribe the exercise of powerful discretionary authority that can wreak career-ending consequences on the members of the regulated community. This Article is designed to serve as a starting point to counsel undertaking the litigation of a DEA administrative enforcement action on either side of the aisle.

The Article is divided into multiple parts. Part II provides a general overview of the proceedings and the body of law pertinent to administrative proceedings against medical and pharmacy practitioners. Part III discusses the various bases for revocation or suspension of a DEA license, while Part IV examines the bases for denial of an application for a DEA license. Part V summarizes the process surrounding immediate suspension cases, and Part VI discusses the burdens on the parties and the DEA's exercise of discretion in sanctioning a party. Finally, Parts VII, VIII, and IX provide an examination of various pre-hearing, hearing, and post-hearing procedures, respectively.

II. OVERVIEW OF PROCEEDINGS

Administrative revocation and application proceedings conducted under the Controlled Substances Act (CSA) before the DEA

Administrative Law Judges (ALJs) are formal hearings controlled by:

- The Administrative Procedure Act (APA) (5 U.S.C. § 551, et seq.);²
- The Controlled Substances Act (21 U.S.C. § 801, et seq.);³
- The CSA Implementing Regulations (21 C.F.R. § 1300, et seq.);⁴
- Precedential decisions issued by the United States Courts of Appeals;⁵ and
- Final orders issued by the Drug Enforcement Administration and published in the Federal Register.⁶

DEA utilizes a recommended decision structure,⁷ and its administrative enforcement proceedings⁸ are initiated by the service of an Order to Show Cause (OSC) on a DEA Certificate of Registration (COR) holder (registrant) or one seeking such a registration (applicant) and by serving a copy of the OSC on the Hearing Clerk at the DEA Office of Administrative Law Judges (OALJ). Jurisdiction to conduct a hearing vests in the DEA ALJs upon the timely filing of a request for hearing upon the OALJ Hearing Clerk.⁹ Upon the filing of a timely request for hearing or petition for extension for time to respond to the OSC,¹⁰ the DEA Chief ALJ will assign the matter to an ALJ, and a docket number will be given to the case.¹¹ DEA is represented in every action by

² 5 U.S.C. § 551 (2012).

³ 21 U.S.C. § 801 (2012).

⁴ 21 C.F.R. § 1300 (2013).

⁵ See 21 U.S.C. § 877.

⁶ The Agency has held that “[o]nce the [A]gency has ruled on a given matter . . . it is not open to reargument by the administrative law judge.” Clair L. Pettinger, M.D., 78 Fed. Reg. 61592, 61600 n.13 (Drug Enforcement Admin. Oct. 3, 2013) (quoting *Kugelman*, 996 F.2d at 1260) (internal quotation marks omitted). Thus, the Agency’s published precedent regarding its interpretation of legal principles is binding on the administrative law judge presiding over the litigation.

⁷ 5 U.S.C. § 557(b).

⁸ Other proceedings, such as controlled substance scheduling, importation, and manufacturing cases are initiated by the publication of a Federal Register notice by DEA.

⁹ 21 C.F.R. § 1316.52 (“The functions of the presiding officer shall commence upon his designation and terminate upon the certification of the record to the Administrator.”).

¹⁰ *Id.* § 1316.47.

¹¹ The regulations also provide a vehicle for a respondent to waive hearing rights and submit a written statement of position, which “if admissible, shall be made a part of the record and shall be considered in light of the lack of opportunity for cross-examination in determining the weight to be attached to the matters of fact asserted therein.” *Id.* § 1316.49. DEA ALJs only have jurisdiction over cases where a timely hearing request has been filed by a party entitled to seek a hearing. See *id.* § 1316.52 (explaining the conditions to jurisdiction). All other matters that become ripe for a final Agency determination by the

Trial Attorneys from the DEA Office of the Chief Counsel, and the respondent may be represented by an attorney or an employee of the respondent.¹² The DEA ALJs are vested with authority to conduct prehearing and hearing procedures,¹³ and to either issue a recommended decision to the DEA Administrator¹⁴ or terminate proceedings upon case settlement or other appropriate good cause.¹⁵

The administrative sanction options provided to DEA by the CSA include the authority to revoke or suspend an existing COR,¹⁶ and to deny the application of a practitioner who seeks to obtain a COR.¹⁷ The CSA also specifically provides that the Agency can limit a revocation or suspension to a specific controlled substance or List I chemical authority where a supported sanction basis exists relative to that substance.¹⁸ Although not specifically authorized in the CSA or regulations, an established, lengthy body of Agency precedent has also endorsed the authority of the Agency to impose conditions on a registration.¹⁹ Before imposing any of these sanctions, the Agency must serve the proposed target of a sanction with an OSC and permit the utilization of formal hearing procedures.²⁰

III. BASES FOR REVOCATION OR SUSPENSION OF A REGISTRATION

The CSA provides five bases upon which the revocation,

Administrator are forwarded for consideration through other appropriate Agency channels.

¹² *Id.* § 1316.50. For a detailed discussion of representation issues, see discussion *infra* Part VII.N.

¹³ 21 C.F.R. § 1316.52.

¹⁴ *Id.* § 1316.65.

¹⁵ Although this authority has consistently been exercised by ALJs in DEA administrative proceedings (e.g., upon settlement or withdrawal of a hearing request) and is consistent with current practice, the existing DEA hearing regulations omit any reference to them.

¹⁶ 21 U.S.C. § 824(a) (2012).

¹⁷ *Id.* § 823(f).

¹⁸ *Id.* § 824(b).

¹⁹ *E.g.*, Kenneth Harold Bull, M.D., 78 Fed. Reg. 62666, 62676 (Drug Enforcement Admin. Oct. 22, 2013); Tyson D. Quy, M.D., 78 Fed. Reg. 47412, 47412 (Drug Enforcement Admin. Aug. 5, 2013); Perry T. Dobyms, M.D., 77 Fed. Reg. 45656, 45656 (Drug Enforcement Admin. Aug. 1, 2012); Kimberly Maloney, N.P., 76 Fed. Reg. 60922, 60923 (Drug Enforcement Admin. Sept. 30, 2011); Paul Weir Battershell, N.P., 76 Fed. Reg. 44359, 44369 (Drug Enforcement Admin. July 25, 2011); Robert M. Golden, M.D., 65 Fed. Reg. 5663, 5665 (Drug Enforcement Admin. Feb. 4, 2000); Merritt Matthews, M.D., 63 Fed. Reg. 44278, 44283 (Drug Enforcement Admin. Aug. 18, 1998); Donald P. Tecca, M.D., 62 Fed. Reg. 12842, 12847 (Drug Enforcement Admin. Mar. 18, 1997); Larry L. Kompus, M.D., 55 Fed. Reg. 30990, 30992 (Drug Enforcement Admin. July 30, 1990); Joseph A. Greco, M.D., 50 Fed. Reg. 47634, 47635 (Drug Enforcement Admin. Nov. 19, 1985).

²⁰ 21 U.S.C. § 824(c).

suspension, or other sanction upon a controlled substance registration may be based.²¹ All are discretionary,²² and all encumber the government with the burden of proof.²³ The Agency may seek sanction against a registration based upon: (1) material falsification in a registration application; (2) a conviction relating to a violation of state or federal controlled substance law; (3) state action against state controlled substance authority; (4) exclusion from participation in a federal health care program; and (5) the commission of an action that would render enjoyment of the registration inconsistent with the public interest.²⁴

A. Sanction Based on Material Falsification

The CSA authorizes DEA to sanction a registration “upon a finding that the registrant . . . has materially falsified any application filed [for a controlled substance registration].”²⁵ The Agency has reasoned that “[s]ince DEA must rely on the truthfulness of information supplied by applicants in registering them to handle controlled substances, falsification cannot be tolerated,”²⁶ and that a “cavalier attitude toward the importance of accurately executing [a registration] application suggests a lack of concern for the responsibilities inherent in a DEA registration.”²⁷

To serve as a basis for an adverse application determination, it is incumbent upon the government to establish that an applicant has provided false information in his/her/its application, and that the false information provided is material.²⁸ DEA adopted the well-settled definition of material falsification that requires that such a statement be one that “has a natural tendency to influence, or was capable of influencing, the decision of the decisionmaking [sic] body to which it was addressed.”²⁹ Proof that any government decision,

²¹ *Id.* § 824(a).

²² *Id.* (stating that a registration “may” be suspended or revoked).

²³ 21 C.F.R. § 1301.44(e) (2013).

²⁴ 21 U.S.C. § 824(a)(1)–(5).

²⁵ *Id.* § 824(a)(1).

²⁶ Bobby Watts, M.D., 58 Fed. Reg. 46995, 46995 (Drug Enforcement Admin. Sept. 3, 1993).

²⁷ Kuen H. Chen, M.D., 58 Fed. Reg. 65401, 65402 (Drug Enforcement Admin. Dec. 14, 1993).

²⁸ 21 U.S.C. § 824(a)(1).

²⁹ *The Lawsons, Inc.*, 72 Fed. Reg. 74334, 74338 (Drug Enforcement Admin. Dec. 31, 2007) (internal quotation marks omitted) (citing *Kungys v. United States*, 485 U.S. 759, 770 (1988)); *see also Robles v. United States*, 279 F.2d 401, 404 (9th Cir. 1960) (defining “materiality”).

including the one over the registration application, was actually influenced is not required.³⁰ The touchstone is whether the statement had the *capacity* to influence.³¹ Since a materiality determination turns on an analysis of the relevant substantive law,³² the allegedly false statement must be analyzed in the context of the application requirements sought by DEA and information provided by the applicant. The falsification must relate to a ground that could affect the decision, not merely a basis upon which an investigation could be initiated.³³ The entire application will be examined to determine whether there was an intention to deceive the agency.³⁴ Furthermore, the correct analysis hinges on whether the applicant knew or should have known that he or she submitted a false application.³⁵ Although even an unintentional falsification can serve as a basis for adverse action regarding a registration, lack of intent to deceive and evidence that the falsification was not intentional or negligent are all relevant considerations on the issue of sanction.³⁶

B. Sanction Based on “Conviction Relating To”

The CSA also authorizes a discretionary sanction to be imposed upon a registrant convicted of a federal or state felony relating to controlled substances or precursor chemicals.³⁷ A conviction alone is sufficient to support a sanction.³⁸ A conviction obtained pursuant

³⁰ *Lawsons*, 72 Fed. Reg. at 74339.

³¹ Hoi Y. Kam, M.D., 78 Fed. Reg. 62694, 62697 (Drug Enforcement Admin. Oct. 22, 2013); Alvin Darby, M.D., 75 Fed. Reg. 26993, 26998 (Drug Enforcement Admin. May 13, 2010); see *United States v. Alemany Rivera*, 781 F.2d 229, 234 (1st Cir. 1985) (quoting *United States v. Lopez*, 728 F.2d 1359, 1362 (11th Cir. 1984) (per curiam).

³² *Kungys*, 485 U.S. at 772.

³³ See Darryl J. Mohr, M.D., 77 Fed. Reg. 34998, 34998 n.2 (Drug Enforcement Admin. June 12, 2012); Harold Edward Smith, M.D., 76 Fed. Reg. 53961, 53964 (Drug Enforcement Admin. Aug. 30, 2011); Scott C. Bickman, M.D., 76 Fed. Reg. 17694, 17701 (Drug Enforcement Admin. Mar. 30, 2011).

³⁴ See Samuel S. Jackson, D.D.S., 72 Fed. Reg. 23848, 23852 (Drug Enforcement Admin. May 1, 2007).

³⁵ *Darby*, 75 Fed. Reg. at 26999; Dan E. Hale, D.O., 69 Fed. Reg. 69402, 69406 (Drug Enforcement Admin. Nov. 29, 2004); *The Drugstore*, 61 Fed. Reg. 5031, 5032 (Drug Enforcement Admin. Feb. 9, 1996); see Bobby Watts, M.D., 58 Fed. Reg. 46995, 46995 (Drug Enforcement Admin. Sept. 3, 1993).

³⁶ Anthony D. Funches, 64 Fed. Reg. 14267, 14268 (Drug Enforcement Admin. Mar. 24, 1999); see *Martha Hernandez*, M.D., 62 Fed. Reg. 61145, 61148 (Drug Enforcement Admin. Nov. 14, 1997).

³⁷ 21 U.S.C. § 824(a)(2) (2012).

³⁸ *Pearce v. DEA*, 867 F.2d 253, 255 (6th Cir. 1988); *Fitzhugh v. DEA*, 813 F.2d 1248, 1252 (D.C. Cir. 1987).

to a nolo contendere plea, or even one where adjudication is withheld or even subsequently dismissed, constitutes a conviction under this provision.³⁹ A corporate registrant's registration "may be revoked upon a finding that a natural person who is an owner, officer, key employee, or an individual who has some responsibility for the operation of the registrant's controlled substance business, has been convicted of a felony offense relating to controlled substances."⁴⁰

C. Sanction Based on Loss of State Controlled Substance Privileges

A discretionary sanction is also available to the Agency where a registrant has had state controlled substance authority "suspended, revoked, or denied by competent State authority and is no longer authorized by [s]tate law to engage" in the activity permitted by his DEA registration.⁴¹ Although there is little doubt that the language of this provision is discretionary on its face, the Agency has a long line of consistent precedent in support of the proposition that the absence of state authority in the case of a practitioner, once conclusively established, mandates revocation of DEA registration privileges.⁴² The Agency has "held that revocation is warranted even where a practitioner's state authority has been summarily suspended and the State has yet to provide the practitioner with a hearing to challenge the State's action . . . at which he . . . may

³⁹ *Pearce*, 867 F.2d at 255; *Noell v. Bensinger*, 586 F.2d 554, 556–57 (5th Cir. 1978); *Sokoloff v. Saxbe*, 501 F.2d 571, 574 (2d Cir. 1974); *Tyson D. Quy, M.D.*, 78 Fed. Reg. 47412, 47412 n.1 (Drug Enforcement Admin. Aug. 5, 2013); *Vincent J. Scolaro, D.O.*, 67 Fed. Reg. 42060, 42065 (Drug Enforcement Admin. June 20, 2002); *Edson W. Redard, M.D.*, 65 Fed. Reg. 30616, 30618 (Drug Enforcement Admin. May 12, 2000); *Stanley Alan Azen, M.D.*, 61 Fed. Reg. 57893, 57895 (Drug Enforcement Admin. Nov. 8, 1996).

⁴⁰ *Syncon Pharm., Inc.*, 53 Fed. Reg. 15155, 15156 (Drug Enforcement Admin. Apr. 27, 1988); *see also Neil Labs., Inc. v. Ashcroft*, 217 F. Supp. 2d 80, 87–88 (D.C. Cir. 2002); *Top RX Pharmacy*, 78 Fed. Reg. 26069, 26081–82 (Drug Enforcement Admin. May 3, 2013); *EZR, LLC*, 69 Fed. Reg. 63178, 63181 (Drug Enforcement Admin. Oct. 29, 2004); *Plaza Pharmacy*, 53 Fed. Reg. 36910, 36910 (Drug Enforcement Admin. Sept. 22, 1988).

⁴¹ 21 U.S.C. § 824(a)(3).

⁴² *Stephanie A. Tarapchak, M.D.*, 77 Fed. Reg. 73677, 73677 (Drug Enforcement Admin. Dec. 11, 2012); *Roy Chi Lung*, 74 Fed. Reg. 20346, 20347 (Drug Enforcement Admin. May 1, 2009); *Scott Sandarg, D.M.D.*, 74 Fed. Reg. 17528, 17529 (Drug Enforcement Admin. Apr. 15, 2009); *John B. Freitas, D.O.*, 74 Fed. Reg. 17524, 17525 (Drug Enforcement Admin. Apr. 15, 2009); *Roger A. Rodriguez, M.D.*, 70 Fed. Reg. 33206, 33207 (Drug Enforcement Admin. June 7, 2005); *Stephen J. Graham, M.D.*, 69 Fed. Reg. 11661, 11662 (Drug Enforcement Admin. Mar. 11, 2004); *Abraham A. Chaplan, M.D.*, 57 Fed. Reg. 55280, 55280 (Drug Enforcement Admin. Nov. 24, 1992); *see also Harrell E. Robinson, M.D.*, 74 Fed. Reg. 61370, 61375 (Drug Enforcement Admin. Nov. 24, 2009) (discussing lack of state authority under Factor One of the public interest factors).

ultimately prevail.”⁴³

D. Sanction Based on Exclusion from Federal Health Care Programs

The CSA also provides the Agency with the discretion to revoke or suspend a registrant’s license if the registrant “has been excluded (or directed to be excluded) from participation in a program pursuant to [42 U.S.C. § 1320a-7(a)].”⁴⁴ Section 1320a-7 covers the exclusion of individuals or entities, by the Secretary of the Department of Health and Human Services (HHS), from participating in federal health care programs.⁴⁵ Specifically, subsection (a), the part of the statute referenced by 21 U.S.C. § 824(a)(5), dictates when HHS *must* exclude individuals or entities.⁴⁶ There are four instances requiring *mandatory* exclusion: (1) conviction of a criminal offense “related to the delivery of an item or services under [42 U.S.C. §§ 1395 et seq.] or under any [s]tate health care program”; (2) conviction, “under [f]ederal or [s]tate law,” related to patient “neglect or abuse” connected “with the delivery of a health care item or service[;] (3) [f]elony conviction related to health care fraud”; and “(4) [f]elony conviction related to . . . the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance.”⁴⁷ In contrast to subsection (a), subsection (b) of 42 U.S.C. § 1320a-7 provides sixteen *discretionary* grounds of exclusion from federal health care programs.⁴⁸ Historically, the federal health care programs most frequently referenced in revocation cases of this sort have involved Medicare and Medicaid.⁴⁹

⁴³ Kamal Tiwari, M.D., 76 Fed. Reg. 71604, 71606 (Drug Enforcement Admin. Nov. 18, 2011); *see* Bourne Pharmacy, Inc., 72 Fed. Reg. 18273, 18274 (Drug Enforcement Admin. Apr. 11, 2007); Anne Lazar Thorn, M.D., 62 Fed. Reg. 12847, 12847 (Drug Enforcement Admin. Mar. 18, 1997).

⁴⁴ 21 U.S.C. § 824(a)(5).

⁴⁵ 42 U.S.C. § 1320a-7 (2012). A federal health care program is (1) a plan or program providing health benefits and is funded in some way by the U.S. government; or (2) a state health care program or plan receiving certain approval or funding from the U.S. government. *Id.* § 1320a-7b(f); *id.* § 1320a-7(h).

⁴⁶ *Id.* § 1320a-7(a) (“The Secretary shall exclude the following individuals and entities from participation in any [f]ederal health care program . . .”).

⁴⁷ *Id.*

⁴⁸ *Id.* § 1320a-7(b).

⁴⁹ *E.g.*, Daniel Ortiz-Vargas, M.D., 69 Fed. Reg. 62095, 62095–96 (Drug Enforcement Admin. Oct. 22, 2004); Joseph M. Piacentile, M.D., 62 Fed. Reg. 35527, 35527–28 (Drug Enforcement Admin. July 1, 1997); Anibal P. Herrera, M.D., 61 Fed. Reg. 65075, 65077 (Drug Enforcement Admin. Dec. 10, 1996); Suresh Gandotra, M.D., 58 Fed. Reg. 64781, 64782 (Drug Enforcement Admin. Dec. 9, 1993); George D. Osafo, M.D., 58 Fed. Reg. 37508, 37509 (Drug

The unambiguous words of 21 U.S.C. § 824(a)(5) provide that a practitioner's registration "may be suspended or revoked" if the registrant "has been excluded" from participating in a program pursuant to 42 U.S.C. § 1320a-7(a).⁵⁰ Agency precedent has strictly interpreted this provision and acknowledged that DEA has discretionary power to suspend or revoke a registration only when the registrant has been mandatorily excluded from a federal health care program under subsection (a) of 42 U.S.C. § 1320a-7.⁵¹ The Agency has specified that permissive exclusion under subsection (b) of 42 U.S.C. § 1320a-7 is not a basis for the discretionary suspension or revocation of a registrant's license under 21 U.S.C. § 824(a)(5).⁵² Likewise, as specified by the CSA, the misconduct mandating exclusion does not need to relate to controlled substances in order to provide the Administrator with the power to suspend or revoke a COR.⁵³ Additionally, the Agency has held that the Administrator should not consider the impact of revocation or suspension on the community when exercising the discretionary authority under this provision of the CSA.⁵⁴

When DEA alleges that a respondent has been mandatorily excluded from a federal health care program under 42 U.S.C. § 1320a-7(a) and, thus, seeks to impose a COR sanction, the government bears the burden to prove that such an exclusion occurred.⁵⁵ Once the government has met its burden, however, the burden shifts, and a respondent must show that a registration would be consistent with the public interest by establishing that he/she/it has accepted responsibility for the misconduct that formed the basis of the exclusion and by adequately demonstrating remedial measures to ensure against repetition.⁵⁶

The Agency has held that the consideration under 21 U.S.C. §

Enforcement Admin. July 12, 1993).

⁵⁰ 21 U.S.C. § 824(a)(5) (2012).

⁵¹ *Terese, Inc.*, 76 Fed. Reg. 46843, 46847 (Drug Enforcement Admin. Aug. 3, 2011); *Herrera*, 61 Fed. Reg. at 65077; *Gandotra*, 58 Fed. Reg. at 64782; *Nelson Ramirez-Gonzalez, M.D.*, 58 Fed. Reg. 52787, 52788 (Drug Enforcement Admin. Oct. 12, 1993).

⁵² *Alan R. Schankman, M.D.*, 63 Fed. Reg. 45260, 45260–61 (Drug Enforcement Admin. Aug. 25, 1998).

⁵³ *Ortiz-Vargas*, 69 Fed. Reg. at 62095–96; *Melvin N. Seglin, M.D.*, 63 Fed. Reg. 70431, 70433 (Drug Enforcement Admin. Dec. 21, 1998); *Osafo*, 58 Fed. Reg. at 37509.

⁵⁴ *Linda Sue Cheek, M.D.*, 76 Fed. Reg. 66972, 66972 (Drug Enforcement Admin. Oct. 28, 2011).

⁵⁵ *Kwan Bo Jin, M.D.*, 77 Fed. Reg. 35021, 35023 (Drug Enforcement Admin. June 12, 2012).

⁵⁶ *See id.*

824(a)(5) of a respondent's mandatory exclusion under 42 U.S.C. § 1320a-7(a) is distinct from Factor Five of the public interest test set forth in 21 U.S.C. § 823(f)(5).⁵⁷ Most recently, the Agency held that the grounds for discretionary exclusion under subsection (b) cannot be considered as "[s]uch other conduct which may threaten the public health and safety"⁵⁸ (Factor Five) in determining the public interest.⁵⁹ The Agency determined that this blanket rule is in keeping with congressional intent because (1) Congress specifically stated in 21 U.S.C. § 824(a)(5) that the Agency should only consider mandatory exclusion under subsection (a) as a discretionary basis for revocation and suspension, and (2) reading Factor Five to encompass permissive exclusion under subsection (b) would render the entirety of 21 U.S.C. § 824(a)(5) superfluous.⁶⁰

E. Sanction Based on Acts Inconsistent with the Public Interest

The CSA also authorizes a discretionary sanction where the government's evidence establishes that a registrant "has committed such acts as would render his registration under [21 U.S.C. § 823(f)] inconsistent with the public interest as determined under such section."⁶¹ This is the newest sanction basis in the CSA, and it is the basis most commonly utilized in DEA administrative sanction actions. Congress provided five factors that "shall be considered" in determining the public interest:

- (1) The recommendation of the appropriate [s]tate licensing

⁵⁷ See Joseph M. Piacentile, M.D., 62 Fed. Reg. 35527, 35528 (Drug Enforcement Admin. July 1, 1997). For a discussion of Factor Five of the public interest test, see *infra* Part III.E.5.

⁵⁸ 21 U.S.C. § 823(f)(5) (2012).

⁵⁹ Grider Drug #1 & Grider Drug #2, 77 Fed. Reg. 44070, 44102-03 (Drug Enforcement Admin. July 26, 2012); Terese, Inc., 76 Fed. Reg. 46843, 46848 (Drug Enforcement Admin. Aug. 3, 2011).

⁶⁰ *Grider Drug #1 & Grider Drug #2*, 77 Fed. Reg. at 44103 ("In short, were an allegation that a Registrant has committed Medicaid fraud actionable under [F]actor [F]ive of the public interest standard as 'such other conduct which may threaten public health and safety,' then Congress did not need to amend section 824 by adding subsection (a)(5). Yet not only did Congress amend the statute, it then limited the Agency's revocation authority to those instances in which a registrant has been convicted of a felony enumerated in [42 U.S.C. § 1320a-7(a)]."); *Terese*, 76 Fed. Reg. at 46847-48 ("[I]n subsection 824(a)(5), Congress specifically addressed the circumstances in which an exclusion by the Secretary [under 42 U.S.C. § 1320a-7] is grounds for the revocation of a DEA registration. . . . Were the [g]overnment's interpretation correct that the Attorney General's authority under the public interest standard encompasses the allegations against respondent, then Congress had no need to enact subparagraph (a)(5). Statutes, however, are not to be construed in a manner that renders their texts superfluous.")

⁶¹ 21 U.S.C. § 824(a)(4).

- board or professional disciplinary authority [Factor One;]
- (2) The [registrant]’s experience in dispensing, or conducting research with respect to controlled substances [Factor Two;]
- (3) The [registrant]’s conviction record under [f]ederal or [s]tate laws relating to the manufacture, distribution, or dispensing of controlled substances [Factor Three;]
- (4) Compliance with applicable [s]tate, [f]ederal, or local laws relating to controlled substances [Factor Four; and]
- (5) Such other conduct which may threaten the public health and safety [Factor Five].⁶²

Although the CSA is clear that these factors “shall” be considered in determining the public interest, the Agency has long taken the position that the factors are properly “considered in the disjunctive.”⁶³ The courts have not required the Agency to make findings on every public interest factor⁶⁴ and have sustained its sanctions where all factors were not discussed.⁶⁵ The courts have also given deference to the Agency’s determination as to the appropriate weight to be assigned to the factors that were considered.⁶⁶

1. Public Interest Factor One: Recommendation of Appropriate State Licensing Board or Professional Disciplinary Authority

The first public interest factor requires the Administrator to consider “[t]he recommendation of the appropriate⁶⁷ [s]tate licensing

⁶² *Id.* § 823(f). The definition of “dispensing” includes “the prescribing and administering of a controlled substance and the packaging, labeling, or compounding necessary to prepare the substance for . . . delivery.” *Id.* § 802(10).

⁶³ Robert A. Leslie, M.D., 68 Fed. Reg. 15227, 15230 (Drug Enforcement Admin. Mar. 28, 2003); *accord* Ralph J. Chambers, M.D., 79 Fed. Reg. 4962, 4969 (Drug Enforcement Admin. Jan. 30, 2014).

⁶⁴ *See, e.g.*, *MacKay v. DEA*, 664 F.3d 808, 816 (10th Cir. 2011) (quoting *Volkman v. DEA*, 567 F.3d 215, 222 (6th Cir. 2009)); *Hoxie v. DEA*, 419 F.3d 477, 482 (6th Cir. 2005) (citing *Morall v. DEA*, 412 F.3d 165, 173–74 (D.C. Cir. 2005)); *Morall*, 412 F.3d at 173–74 (quoting Henry J. Schwarz, Jr., M.D., 54 Fed. Reg. 16422, 16424 (Drug Enforcement Admin. Apr. 24, 1989)); *Trawick v. DEA*, 861 F.2d 72, 76 (4th Cir. 1988).

⁶⁵ *See, e.g.*, *Trawick*, 861 F.2d at 76.

⁶⁶ *See, e.g.*, *MacKay*, 664 F.3d at 816; *Volkman*, 567 F.3d at 222 (quoting *Hoxie*, 419 F.3d at 482); *Morall*, 412 F.3d at 173–74 (quoting *Schwarz*, 54 Fed. Reg. at 16424).

⁶⁷ In *Zizhuang Li, M.D.*, the Agency held that in an application case, “the appropriate” state licensing board is limited to the board located in the state where the applicant seeks registration, and that this is true even where the applicant had been licensed and disciplined for controlled substance violations elsewhere. *Zizhuang Li, M.D.*, 78 Fed. Reg. 71660, 71663 (Drug Enforcement Admin. Nov. 29, 2013). The *Li* decision did not indicate which factor (if

board or professional disciplinary authority.”⁶⁸ Despite the seeming simplicity of this factor, the Agency precedent is greatly divided over the proper understanding of what constitutes a “recommendation.” As described below, the interpretations can be placed in one of two camps. The first (broad) approach interprets the meaning of “recommendation” liberally by finding various forms of state action relevant under Factor One. The second (plain language) approach interprets the meaning of “recommendation” narrowly, only giving credence under a Factor One analysis to express statements by state authorities to the DEA.

Notwithstanding the seeming lack of apparent ambiguity in the language employed by Congress in specifying that a “recommendation”⁶⁹ is the operative requirement for consideration under this factor,⁷⁰ the Agency has acknowledged that “DEA precedents have typically taken a broader view as to the scope of [Factor One].”⁷¹ Under this (broad) interpretation, the Agency has found that various forms of disciplinary action, such as revoking a state license,⁷² placing a license on probation,⁷³ suspending a license,⁷⁴ and subjecting a license to a consent order,⁷⁵ provide

any) the recommendation of a different state board (even a detailed and well-supported recommendation) could be considered under.

⁶⁸ 21 U.S.C. § 823(f)(1) (2012) (footnote added).

⁶⁹ 21 U.S.C. § 823(f)(1).

⁷⁰ See *Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837 (1984), for the two-step process constructed by the United States Supreme Court regarding the deference afforded to an agency in interpreting a statute it is charged to administer.

First . . . [i]f the intent of Congress is clear, that is the end of the matter; for the . . . agency[] must give effect to the unambiguously expressed intent of Congress. . . . [I]f the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency’s answer is based on a permissible construction of the statute.

Chevron, 467 U.S. at 842–43.

⁷¹ Ralph J. Chambers, M.D., 79 Fed. Reg. 4962, 4969 (Drug Enforcement Admin. Jan. 30, 2014) (quoting Tony T. Bui, M.D., 75 Fed. Reg. 49979, 49986 (Drug Enforcement Admin. Aug. 16, 2010)) (internal quotation marks omitted).

⁷² *E.g.*, Saihb S. Halil, M.D., 64 Fed. Reg. 33319, 33320–21 (Drug Enforcement Admin. June 22, 1999); John Porter Richards, D.O., 61 Fed. Reg. 13878, 13878 (Drug Enforcement Admin. Mar. 28, 1996); Myrtle L. Miller, D.O., 58 Fed. Reg. 64005, 64006 (Drug Enforcement Admin. Dec. 3, 1993).

⁷³ *E.g.*, Tyson D. Quy, M.D., 78 Fed. Reg. 47412, 47417 (Drug Enforcement Admin. Aug. 5, 2013); Gregory D. Owens, D.D.S., 67 Fed. Reg. 50461, 50463 (Drug Enforcement Admin. Aug. 2, 2002); Jude R. Hayes, M.D., 59 Fed. Reg. 41785, 41786 (Drug Enforcement Admin. Aug. 15, 1994).

⁷⁴ *E.g.*, Daniel Koller, D.V.M., 71 Fed. Reg. 66975, 66981 (Drug Enforcement Admin. Nov. 17, 2006); Wilbert McClay, Jr., M.D., 59 Fed. Reg. 30612, 30614 (Drug Enforcement Admin. June 14, 1994).

⁷⁵ *E.g.*, Robert M. Golden, M.D., 65 Fed. Reg. 5663, 5664 (Drug Enforcement Admin. Feb. 4, 2000).

evidence from which a “recommendation” may somehow be deduced/extrapolated and then considered under a Factor One analysis.⁷⁶ Similarly, under this broad approach, the Agency has held that the restoration of a respondent’s license can be interpreted as a significant recommendation.⁷⁷ The Agency has even held that the mere fact that a respondent holds a license under state authority can constitute a relevant Factor One recommendation.⁷⁸

Under the plain language approach, other Agency decisions have declined the invitation of the parties to find a Factor One recommendation in the absence of an express recommendation from the state regarding the status of a DEA COR.⁷⁹ While the plain language approach has, over the years, gained less support in Agency decisions, it is arguably the view most easily defended under the law. There are at least two features that militate in favor of the plain language view: (1) it is more aligned with the plain meaning of the statute; and, (2) it is more consistent with noted rules of statutory interpretation.

Turning to the first feature (plain meaning of the statute), basic administrative law principles constrain agencies to adhere to the plain meaning of a statute.⁸⁰ Every federal agency “must give effect to the unambiguously expressed intent of Congress.”⁸¹ Under 21 U.S.C. § 823(f)(1) (Factor One), the Agency must consider “[t]he recommendation of the appropriate [s]tate licensing board or professional disciplinary authority.”⁸² The word “recommendation” has been defined as “the act of recommending” or “something (as a procedure) recommended.”⁸³ A recommendation, thus, is an express act of communication to an outside party regarding how that party

⁷⁶ Kenneth Harold Bull, M.D., 78 Fed. Reg. 62666, 62672 (Drug Enforcement Admin. Oct. 22, 2013) (“DEA has interpreted [F]actor [O]ne more broadly and thus considers disciplinary actions taken by a state board as relevant in the public interest determination . . .”).

⁷⁷ *E.g.*, *Quy*, 78 Fed. Reg. at 47417; Vincent J. Scolaro, D.O., 67 Fed. Reg. 42060, 42064–65 (Drug Enforcement Admin. June 20, 2002); William E. Brown, D.O., 58 Fed. Reg. 64004, 64005 (Drug Enforcement Admin. Dec. 3, 1993).

⁷⁸ Margy Temponeras, M.D., 77 Fed. Reg. 45675, 45684 (Drug Enforcement Admin. Aug. 1, 2012); Saihb S. Halil, M.D., 64 Fed. Reg. 33319, 33320 (Drug Enforcement Admin. June 22, 1999); Dinorah Drug Store, Inc., 61 Fed. Reg. 15972, 15973 (Drug Enforcement Admin. Apr. 10, 1996).

⁷⁹ *E.g.*, Scott D. Fedosky, M.D., 76 Fed. Reg. 71375, 71377 (Drug Enforcement Admin. Nov. 17, 2011); Gilbert Eugene Johnson, M.D., 75 Fed. Reg. 65663, 65666 n.3 (Drug Enforcement Admin. Oct. 26, 2010).

⁸⁰ *Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 842–43 (1984).

⁸¹ *Id.* at 843.

⁸² 21 U.S.C. § 823(f)(1) (2012).

⁸³ MERRIAM-WEBSTER’S COLLEGIATE DICTIONARY 1039 (11th ed. 2003).

should decide or act in a particular situation. Under the framework provided in the CSA, the Agency is the outside party authorized and required to consider the “recommendation” of a state board on the issue of whether a DEA registration should be revoked or continued. Under the CSA, where a state board makes such a recommendation on a DEA COR, DEA must consider that recommendation in assessing a registrant’s fitness to hold a registration.⁸⁴ While state-licensing actions taken by state boards can speak to a state’s confidence in a practitioner’s ability to handle controlled substances (and, where a license is revoked, can even preclude the DEA from issuing or continuing a registration)⁸⁵, the fact remains, that these adjudications are not recommendations of any kind to the DEA. It is the DEA (not entities within state government) that bears the independent and exclusive responsibility to determine whether a registration is in the public interest.⁸⁶ The recognition that state authorities and the DEA have independent missions supports the proposition that when a state licensing board issues an order regarding a professional license (or even controlled substance authority), it is operating within the framework and authority of its own authority and mandate, and nothing more. Interpreting a state board order as a sort of *sub rosa* recommendation to the DEA on how to best exercise its authority arguably extends the reach of the order beyond the intended limits of the CSA and state laws related to professional licensing.

The second feature that supports a plain language approach to Factor One is the reality that broadening the term “recommendation” to include activities by state authorities that fall short of an express recommendation to the DEA would necessarily violate one of two noted rules of statutory interpretation—the “whole act rule” and the “rule to avoid surplusage”—in relation to an adjoining section of the Act, § 824(a)(3). As discussed in greater detail *supra*, Congress has equipped the Agency with a

⁸⁴ 21 U.S.C. § 824(a)(4) (2012) (placing the responsibility of determining whether a registrant’s license should be revoked under the discretion of the Attorney General). This authority has been delegated to the Administrator. 28 C.F.R. § 0.100(b) (2013). The Administrator, in turn, may delegate this authority to the Deputy Administrator. *Id.* § 0.104.

⁸⁵ 21 U.S.C. § 824(a)(3) (“A registration . . . may be suspended or revoked . . . upon a finding that a registrant . . . has had his [s]tate license or registration suspended, revoked, or denied by competent [s]tate authority . . .”).

⁸⁶ Patrick W. Stodola, M.D., 74 Fed. Reg. 20727, 20735 n.31 (Drug Enforcement Admin. May 5, 2009); Edmund Chein, M.D., 72 Fed. Reg. 6580, 6590 (Drug Enforcement Admin. Feb. 12, 2007), *aff’d*, Chein v. Drug Enforcement Admin., 533 F.3d 828 (D.C. Cir. 2008); Mortimer B. Levin, D.O., 55 Fed. Reg. 8209, 8210 (Drug Enforcement Admin. Mar. 7, 1990).

discretionary ground for sanction where a registrant has lost state authority to handle controlled substances (Loss of State Authority Revocation).⁸⁷ This provision permits a sanction against a registration where a registrant:

[H]as had his [s]tate license or registration suspended, revoked, or denied by competent [s]tate authority and is no longer authorized by [s]tate law to engage in the manufacturing, distribution, or dispensing of controlled substances or list I chemicals or has had the suspension, revocation, or denial of his registration recommended by competent [s]tate authority.⁸⁸

This subsection authorizes revocation or suspension where a registrant's state license or state controlled substance registration has been the subject of adverse action or a recommendation for adverse action. Thus, a state's action against its own state authorization for a practitioner to handle controlled substances (or a recommendation by competent state authority to do so) constitutes a discretionary basis for the DEA to impose a sanction on a DEA registration.

Even a cursory review of the language employed demonstrates that Congress discerned a difference between adverse state action against state controlled substance authority (§ 824(a)(3)) and a (Factor One) recommendation to the DEA regarding the status of the DEA controlled substance registration (§ 824(a)(4) and § 823(f)). Stated differently, if a state licensing action is synonymous with a Factor One recommendation by the state regarding a DEA registration, the CSA would be authorizing the same instrument (the recommendation) to have different impacts within the same regulatory scheme. Under this strained interpretation, the language in Factor One (recommendation) and the Loss of State Authority sanction would be identical, rendering one of them as surplusage. The rule to avoid surplusage supports a contrary result. Under the rule to avoid surplusage, the courts will not read a statute to say one thing if the reading would render some words redundant.⁸⁹ However, by construing the word "recommendation" to mean sanctions against state controlled substance authority, the

⁸⁷ 21 U.S.C. § 824(a)(3). For a more detailed discussion of this basis for sanction, see *supra* Part III.C.

⁸⁸ 21 U.S.C. § 824(a)(3).

⁸⁹ *E.g.*, *United States v. Alaska*, 521 U.S. 1, 59 (1997); *Gustafson v. Alloyd Co.*, 513 U.S. 561, 574 (1995); *see, e.g.*, *United States v. Menasche*, 348 U.S. 528, 538–39 (1955).

broad approach provides two procedures for considering the same state board action without any rational reason for doing so.

The broad approach may also run afoul of the “whole act rule.” The “whole act rule” requires that when the same word is used in multiple provisions of the same act, the words should generally be given the same meaning.⁹⁰ In authorizing the Loss of State Authority sanction basis, Congress distinguished between action taken by a state against a practitioner’s controlled substance privileges and action “recommended by competent state authority.”⁹¹ If an action was synonymous with a recommendation, there would have been no need to parse out the former from the latter. Congress, however, deliberately chose to differentiate between a state action and a state recommendation. While Factor One specifies consideration of “[t]he recommendation of the appropriate [s]tate licensing board or professional disciplinary authority,”⁹² the broad approach forces, in effect, a separate definition for the word “recommendation” under the Loss of State Authority sanction basis and under Factor One, thus violating the whole act rule. However, Congress’s intentional election to distinguish action from recommendation in the Loss of State Authority sanction provision presents at least some evidence that state action was not designed to serve as an authority to attempt to divine a recommendation essence from state action. Stated differently, Agency precedent to the contrary notwithstanding, Factor One was likely crafted to require the presence of an explicit state recommendation to the DEA on the subject of a practitioner’s DEA registration or application therefor. In short, Congress spoke plainly on Factor One and meant what it said.

The literal approach avoids this pitfall. By interpreting the word “recommendation” under Factor One to mean an express communication from state authorities to the DEA, the approach prevents a definitional ambiguity in the word “recommend” in § 824(a)(3) that is necessarily implied by the broad approach. Also, the literal approach prevents there from being a redundancy of language within the Loss of State Authority sanction⁹³ because it recognizes that Congress would not have distinguished state action

⁹⁰ *Taniguchi v. Kan Pac. Saipan, Ltd.*, 132 S. Ct. 1997, 2004–05 (2012); *Gustafson*, 513 U.S. at 570; *Dep’t of Revenue v. ACF Indus., Inc.*, 510 U.S. 332, 342 (1994).

⁹¹ 21 U.S.C. § 824(a)(3).

⁹² *Id.* § 823(f)(1).

⁹³ *Id.* § 824(a)(3).

from state recommendation if there was no basis to do so.

Agency precedent has not been marked with homogeneity on this issue. While the majority of Agency decisions follow the broad approach, some recent decisions have also embraced a plain language approach. For example, the Agency has held that the mere existence of a state board investigation or proceeding is not relevant under Factor One,⁹⁴ that suspending a respondent's state license or placing it on probation is not a recommendation,⁹⁵ and that, in the absence of an express recommendation by state authorities to the DEA, Factor One is irrelevant.⁹⁶ Thus, there is some (albeit minor) support amidst Agency precedent for a plain language approach to this issue.

Regardless of the approach taken, the Agency has been consistent in its view that evidence considered under Factor One is rarely the dispositive element in the Agency's final determination on sanction.⁹⁷

2. Public Interest Factor Two: Experience in Dispensing, or Conducting Research with Respect to, Controlled Substances

In requiring an examination of a registrant's experience in dispensing controlled substances in Factor Two, Congress manifested an acknowledgement that the qualitative manner and the quantitative volume in which a registrant has engaged in the dispensing of controlled substances may be significant factors to be evaluated in reaching a determination as to whether a registrant should continue to be entrusted with a DEA registration.

⁹⁴ See, e.g., Jeffery J. Becker, D.D.S., 77 Fed. Reg. 72387, 72403 (Drug Enforcement Admin. Dec. 5, 2012); Morris W. Cochran, M.D., 77 Fed. Reg. 17505, 17517 (Drug Enforcement Admin. Mar. 26, 2012).

⁹⁵ See, e.g., Paul Weir Battershell, N.P., 76 Fed. Reg. 44359, 44365 (Drug Enforcement Admin. July 25, 2011); Robert L. Dougherty, M.D., 76 Fed. Reg. 16823, 16833 n.13 (Drug Enforcement Admin. Mar. 25, 2011); Gilbert Eugene Johnson, M.D., 75 Fed. Reg. 65663, 65666 n.3 (Drug Enforcement Admin. Oct. 26, 2010).

⁹⁶ See, e.g., Mark G. Medinnus, D.D.S., 78 Fed. Reg. 62683, 62692 (Drug Enforcement Admin. Oct. 22, 2013); George R. Smith, M.D., 78 Fed. Reg. 44972, 44979 (Drug Enforcement Admin. July 25, 2013); Robert M. Brodtkin, D.P.M., 77 Fed. Reg. 73678, 73681 n.5 (Drug Enforcement Admin. Dec. 11, 2012); *Becker*, 77 Fed. Reg. at 72403; Scott D. Fedosky, M.D., 76 Fed. Reg. 71375, 71377 (Drug Enforcement Admin. Nov. 17, 2011); *Battershell*, 76 Fed. Reg. at 44365; *Dougherty*, 76 Fed. Reg. at 16833 n.13; *Johnson*, 75 Fed. Reg. at 65666 n.3.

⁹⁷ See, e.g., Tyson D. Quy, M.D., 78 Fed. Reg. 47412, 47417 (Drug Enforcement Admin. Aug. 5, 2013); Jose G. Zavaleta, M.D., 78 Fed. Reg. 27431, 27440 (Drug Enforcement Admin. May 10, 2013); *Becker*, 77 Fed. Reg. at 72403; Scott H. Nearing, D.D.S., 70 Fed. Reg. 33200, 33202 (Drug Enforcement Admin. June 7, 2005); Anant N. Mauskar, M.D., 63 Fed. Reg. 13687, 13688 (Drug Enforcement Admin. Mar. 20, 1998).

The (modest) legislative history associated with the enactment of this provision signals that its purpose is to evaluate the level of experience that a registrant or applicant brings to the public interest equation. One House of Representatives committee hearing report clarifies that this experience factor “shall not, of course, be construed in [any way] to hinder registration of recent graduates of professional schools who may have no professional experience dispensing or conducting research with controlled substances.”⁹⁸ In addressing a public interest factor with similar “experience” language in the List I chemical context, the Agency has held that experience within the scope of the registration sheds light on a registrant’s knowledge of applicable rules and regulations.⁹⁹ Similarly, the Agency has utilized the same analysis in the context of adjudicating an application for a researcher’s DEA registration under 21 U.S.C. § 823(f).¹⁰⁰ However, the Agency has made it clear that it has no intention of applying this reasoning to practitioner cases where intentional diversion¹⁰¹ has been preponderantly established.¹⁰²

⁹⁸ H.R. REP. NO. 98-835, pt. 1, at 14 (1984). This statement in the legislative history of Factor Two appears to be the result of the lobbying efforts of the American Pharmaceutical Association (APhA), which expressed its concern that an applicant’s lack of experience (such as in the case of a recent graduate) would be held against the applicant. *Diversion of Prescription Drugs to Illegal Channels and Dangerous Drug Diversion Control Act: Hearing on H.R. 4698 Before the Subcomm. on Crime of the H. Comm. on the Judiciary*, 98th Cong. 326, 334 (1984) (statement of Maurice Q. Bectel, Interim President, American Pharmaceutical Association). The APhA specifically requested that some statement be placed in the record to ensure that the mere lack of opportunity would not prevent recent graduates from obtaining a COR. *Id.* The American Veterinary Medical Association (AVMA) also expressed its concern with Factor Two, arguing that it was duplicative of the conduct covered under Factors Three and Four (a view similar to the Agency’s current view of Factor Two’s relation with Factor Four). *Id.* at 425 (post-hearing statement of the American Veterinary Medical Association). Despite the AVMA’s interpretation of Factor Two, Congress retained the factor in the final bill.

⁹⁹ *See, e.g.*, TNT Distribs., Inc., 70 Fed. Reg. 12729, 12731 (Drug Enforcement Admin. Mar. 15, 2005); Volusia Wholesale, 69 Fed. Reg. 69409, 69410 (Drug Enforcement Admin. Nov. 29, 2004); K & Z Enters., Inc., 69 Fed. Reg. 51475, 51476 (Drug Enforcement Admin. Aug. 19, 2004); Island Wholesale, Inc., 68 Fed. Reg. 17406, 17407 (Drug Enforcement Admin. Apr. 9, 2003).

¹⁰⁰ Moore Clinical Trials, LLC, 79 Fed. Reg. 40145, 40154–55 (Drug Enforcement Admin. July 11, 2014).

¹⁰¹ The Agency has sustained findings of intentional diversion based on circumstantial inferences. *See, e.g.*, The Medicine Shoppe, 79 Fed. Reg. 59504, 59507 (Drug Enforcement Admin. Oct. 2, 2014) (sustaining a finding of intentional diversion on the part of a pharmacy registrant based on large shortages of controlled substances coupled with multiple dispensing violations).

¹⁰² *See* Cynthia M. Cadet, M.D., 76 Fed. Reg. 19450, 19450 n.3 (Drug Enforcement Admin. Apr. 7, 2011).

The plain language of Factor Two appears to require an analysis of a registrant's actions even established transgressions against a backdrop of how regulated activities have been performed within the scope of a registration to provide a contextual lens to assist in a fair adjudication of whether registration is in the public interest. Stated differently, the inquiry is centered on whether established misconduct constitutes an aberration (or business as usual) when viewed in the light of the registrant's past history of performance under a registration. In its precedent, the Agency has sometimes placed minimal reliance on evidence presented under this factor, holding that evidence properly the subject of this factor can be easily outweighed by acts held to be inconsistent with the public interest, and that such evidence will be afforded scant or no weight in the face of proven allegations of intentional diversion.¹⁰³ The Agency has opined that because regulated activity among practitioners is limited to those with state authority to handle controlled substances, "every registrant can undoubtedly point to an extensive body of legitimate [controlled substance] prescribing over the course of [a] professional career."¹⁰⁴ The Agency's view is that since the principal issue regarding a public-interest-based revocation case is whether a registrant "has committed such acts as would render [continued] registration . . . inconsistent with the public interest,"¹⁰⁵ "[n]o amount of legitimate [controlled substance transactions] can render . . . flagrant violations [acts which are] consistent with the public interest."¹⁰⁶ It has thus been the view of the Agency that benign regulated activity, even in copious amounts

¹⁰³ Jayam Krishna-Iyer, M.D., 74 Fed. Reg. 459, 463 (Drug Enforcement Admin. Jan. 6, 2009); see also Jeri Hassman, M.D., 75 Fed. Reg. 8194, 8235 (Drug Enforcement Admin. Feb. 23, 2010) (acknowledging Agency precedential rejection of the concept that conduct inconsistent with the public interest is rendered less so by comparing it with a respondent's legitimate activities that occurred in substantially higher numbers); Paul J. Caragine, Jr., 63 Fed. Reg. 51592, 51600 (Drug Enforcement Admin. Sep. 28, 1998) ("[E]ven though the patients at issue are only a small portion of [r]espondent'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.").

¹⁰⁴ *Krishna-Iyer*, 74 Fed. Reg. at 463. *But see*, Roy S. Schwartz, 79 Fed. Reg. 34360, 34363 (June 16, 2014) (Agency final order placed weight on its finding that "the [g]overnment produced no evidence that [the r]egistrant has engaged in any other misconduct related to controlled substances during the course of his professional career, which has spanned more than fifty years.").

¹⁰⁵ 21 U.S.C. § 824(a)(4) (2012).

¹⁰⁶ Clair L. Pettinger, M.D., 78 Fed. Reg. 61592, 61597 (Drug Enforcement Admin. Oct. 3, 2013) (quoting *Medicine Shoppe—Jonesborough*, 73 Fed. Reg. 364, 386 n.56 (Drug Enforcement Admin. Jan. 2, 2008)) (internal quotation marks omitted).

over an extended career, cannot erase egregious conduct that constitutes “such acts as would render [a] registration . . . inconsistent with the public interest.”¹⁰⁷

The Agency has further reasoned that where the government has established a *prima facie* case that a registrant “has committed such acts as would render [a] registration . . . inconsistent with the public interest”¹⁰⁸ by acts manifesting intentional diversion, all evidence of benign regulated activity is “entitled to no weight” in the absence of an acknowledgment of responsibility.¹⁰⁹ Although the Agency’s decision to apply “no weight” to a public interest factor (experience) seems, on its face, to conflict with the directive language¹¹⁰ drafted into the CSA by Congress, a final order¹¹¹ utilizing this approach was reviewed by the Tenth Circuit Court of Appeals and survived unscathed.¹¹²

In practice, the manner in which the Agency has applied Factor Two has resulted in a significant level of factual overlap with Factor Four (compliance with applicable law relating to controlled substances).¹¹³ For example, the same evidence that establishes that a registrant has performed in a substandard (or malevolent) manner as a registrant may concomitantly establish that the same registrant has been violating one or more laws applicable to controlled substances. That said, although a consideration of the factual predicates of these two public interest factors may share common elements, the manner in which the evidence must be evaluated is significantly different.

¹⁰⁷ 21 U.S.C. § 824(a)(4).

¹⁰⁸ *Id.*

¹⁰⁹ Randall L. Wolff, M.D., 77 Fed. Reg. 5106, 5121 n.25 (Drug Enforcement Admin. Feb. 1, 2012).

¹¹⁰ 21 U.S.C. § 823(f) (“[T]he following factors *shall* be considered . . .” (emphasis added)).

¹¹¹ Dewey C. Mackay, M.D., 75 Fed. Reg. 49956, 49977 (Drug Enforcement Admin. Aug. 16, 2010).

¹¹² *MacKay v. Drug Enforcement Admin.*, 664 F.3d 808, 819 (10th Cir. 2011). However, that portion of the Agency final order that disregarded experience evidence offered under Factor Two was not the subject of specific discussion by the Tenth Circuit opinion. The *MacKay* Court did specifically endorse the DEA’s reliance on the fact that the respondent took no responsibility for his established misconduct. *Id.* at 820.

¹¹³ *E.g.*, Ralph J. Chambers, M.D., 79 Fed. Reg. 4962, 4970–73 (Drug Enforcement Admin. Jan. 30, 2014) (discussing Factors Two and Four); Zizhuang Li, M.D., 78 Fed. Reg. 71660, 71663–64 (Drug Enforcement Admin. Nov. 29, 2013) (considering Factors Two and Four).

3. Public Interest Factor Three: Conviction Record Under Federal or State Law Relating to the Manufacture, Distribution, or Dispensing of Controlled Substances

The third public interest factor requires the Agency to analyze a registrant's "conviction record under [f]ederal or [s]tate laws relating to the manufacture, distribution, or dispensing of controlled substances."¹¹⁴ While some older Agency decisions have interpreted this factor to include all convictions related, in some way, to controlled substances,¹¹⁵ the approach most in line with the statutory text accounts for only those convictions that specifically deal with the manufacture, distribution, or dispensing of controlled substances.¹¹⁶ In other words, for a conviction to apply under Factor Three, a registrant's conviction must pertain specifically to the *manufacturing, distributing, or dispensing* of controlled substances instead of just being somehow amorphously *related* to controlled substances.¹¹⁷

Thus, while the Agency has concluded that convictions for a controlled substances recordkeeping violation¹¹⁸ and for the unlawful distribution of a controlled substance¹¹⁹ were relevant under Factor Three, it has held that convictions for the transportation of controlled substances,¹²⁰ the possession of controlled substances,¹²¹ and the possession of drug

¹¹⁴ 21 U.S.C. § 823(f)(3).

¹¹⁵ See, e.g., Jeffrey Martin Ford, D.D.S., 68 Fed. Reg. 10750, 10753 (Drug Enforcement Admin. March 6, 2003) (finding that the respondent's guilty plea to various possession offences was relevant under Factor Three); Trudy J. Nelson, M.D., 66 Fed. Reg. 52941, 52943 (Drug Enforcement Admin. Oct. 18, 2001) (finding that a guilty plea for the attempted corrupting of another with drugs and theft of drugs was relevant under Factor Three); Stanley Alan Azen, M.D., 61 Fed. Reg. 57893, 57895 (Drug Enforcement Admin. Nov. 8, 1996) (holding that a nolo contendere plea for a state felony count of possession of a controlled substance was relevant under Factor Three).

¹¹⁶ Jeffery M. Freesemann, M.D., 76 Fed. Reg. 60873, 60886–87 (Drug Enforcement Admin. Sep. 30, 2011); Michael S. Moore, M.D., 76 Fed. Reg. 45867, 45875 (Drug Enforcement Admin. Aug. 1, 2011); Alvin Darby, M.D., 75 Fed. Reg. 26993, 27000 n.32 (Drug Enforcement Admin. May 13, 2010); Super-Rite Drugs, 56 Fed. Reg. 46014, 46014 (Drug Enforcement Admin. Sept. 9, 1991).

¹¹⁷ Tyson D. Quy, M.D., 78 Fed. Reg. 47412, 47412 n.1 (Drug Enforcement Admin. Aug. 5, 2013); Freesemann, 76 Fed. Reg. at 60887; Moore, 76 Fed. Reg. at 45875.

¹¹⁸ Hodayoun Hodayouni, M.D., 61 Fed. Reg. 1406, 1409 (Drug Enforcement Admin. Jan. 19, 1996).

¹¹⁹ David D. Miller, M.D., 60 Fed. Reg. 54511, 54512 (Drug Enforcement Admin. Oct. 24, 1995).

¹²⁰ Freesemann, 76 Fed. Reg. at 60887.

¹²¹ Super-Rite Drugs, 56 Fed. Reg. at 46015.

paraphernalia¹²² did not meet the criteria necessary to be applicable under Factor Three. The Agency has also held that a conviction for the forging of a prescription in order to obtain controlled substances constitutes a conviction relevant under Factor Three.¹²³

While a registrant's conviction of offenses related to controlled substances may not be relevant under Factor Three, the Agency has stated that such convictions may be relevant under Factor Five ("[s]uch other conduct which may threaten the public health and safety").¹²⁴

It is not necessary for a registrant to have been convicted by a jury or bench trial in order for the conviction to be relevant under Factor Three. Instead, the Agency has held that a deferred adjudication of guilt,¹²⁵ a nolo contendere plea,¹²⁶ or a guilty plea¹²⁷ can constitute convictions under Factor Three. The Agency has held, however, that an indictment is no more than an allegation of culpability and does not count as a conviction in terms of Factor Three applicability.¹²⁸

When the evidence establishes that a practitioner¹²⁹ has been convicted of an offense under federal or state law regarding the manufacturing, distributing, or dispensing of controlled substances, the Administrator may find that Factor Three weighs in favor of revoking a license or denying an application.¹³⁰ Indeed, such a

¹²² *Moore*, 76 Fed. Reg. at 45875.

¹²³ *Kimberly Maloney, N.P.*, 76 Fed. Reg. 60922, 60923 (Drug Enforcement Admin. Sept. 30 2011).

¹²⁴ 21 U.S.C. § 823(f)(5) (2012); *Maloney*, 76 Fed. Reg. at 60923 n.2; *Alvin Darby, M.D.*, 75 Fed. Reg. 26993, 27000 n.32 (Drug Enforcement Admin. May 13, 2010).

¹²⁵ *Maloney*, 76 Fed. Reg. at 60922; *Harlan J. Borcharding, D.O.*, 60 Fed. Reg. 28796, 28797 (Drug Enforcement Admin. June 2, 1995); *Mukand Lal Arora, M.D.*, 60 Fed. Reg. 4447, 4448 (Drug Enforcement Admin. Jan. 23, 1995).

¹²⁶ *David D. Miller, M.D.*, 60 Fed. Reg. 54511, 54512 (Drug Enforcement Admin. Oct. 24, 1995).

¹²⁷ *Homayoun Homayouni, M.D.*, 61 Fed. Reg. 1406, 1409 (Drug Enforcement Admin. Jan. 19, 1996).

¹²⁸ *Paul Weir Battershell, N.P.*, 76 Fed. Reg. 44359, 44359, 44364 n.17 (Drug Enforcement Admin. July 25, 2011).

¹²⁹ In the case of a pharmacy registrant, Agency precedent has consistently held that the registration of a pharmacy may be revoked as the result of the unlawful activity of the pharmacy's owners, majority shareholders, officers, managing pharmacist or other key employee. *Neil Labs., Inc. v. Ashcroft*, 217 F. Supp. 2d 80, 87 (D.C. Cir. 2002); *Top RX Pharmacy*, 78 Fed. Reg. 26069, 26081 (Drug Enforcement Admin. May 3, 2013); *EZRX, LLC*, 69 Fed. Reg. 63178, 63181 (Drug Enforcement Admin. Oct. 29, 2004); *Plaza Pharmacy*, 53 Fed. Reg. 36910, 36911 (Drug Enforcement Admin. Sept. 22, 1988); *Syncon Pharmaceuticals, Inc.*, 53 Fed. Reg. 15155, 15155 (Drug Enforcement Admin. Apr. 27, 1988).

¹³⁰ *E.g.*, *Michael S. Moore, M.D.*, 76 Fed. Reg. 45867, 45875 (Drug Enforcement Admin. Aug. 1, 2011).

conviction history is a “highly relevant consideration” in determining whether a registrant should be entrusted with the privileges and responsibilities of a registrant.¹³¹ Inasmuch as the plain language of Factor Three refers to a conviction record, not the absence of one, Agency precedent has followed the sensible approach that the absence of a conviction is not dispositive of whether a registrant’s registration would be in the public interest.¹³² Because there are numerous reasons why prosecution authorities may decide not to initiate, pursue, or dispose of criminal proceedings, the government’s failure to provide evidence of a conviction under Factor Three has not historically been a heavily controlling issue in reaching a final determination on revocation.¹³³

4. Public Interest Factor Four: Compliance with Applicable State, Federal, or Local Laws Relating to Controlled Substances

The fourth public interest factor requires the Administrator to consider a registrant’s “[c]ompliance with applicable [s]tate, [f]ederal, or local laws relating to controlled substances.”¹³⁴ This provision casts a wider net than the limited subset of convictions that can be properly considered under Factor Three.¹³⁵ Naturally, conduct that has formed the basis for a criminal conviction can be considered under this section, but the more common evidence considered under this factor in support of registrant sanctions relates to the failure of a practitioner to comply with controlled-substance related obligations imposed by the CSA, its implementing regulations, and state statutes and regulations.¹³⁶ Federal and (many) state statutes and regulations impose standards relating to prescribing, examining, and documenting regulated conduct related

¹³¹ Satinder Dang, M.D., 76 Fed. Reg. 51424, 51428 n.20 (Drug Enforcement Admin. Aug. 18, 2011); Dewey C. Mackay, M.D., 75 Fed. Reg. 49956, 49973 (Drug Enforcement Admin. Aug. 16, 2010).

¹³² *Dang*, 76 Fed. Reg. at 51428 n.20.

¹³³ *Top RX Pharmacy*, 78 Fed. Reg. at 26081; *Holiday CVS, LLC*, 77 Fed. Reg. 62316, 62340 (Drug Enforcement Admin. Oct. 12, 2012).

¹³⁴ 21 U.S.C. § 823(f)(4) (2012).

¹³⁵ *Compare id.* (requiring that compliance with three broad categories of law—state, federal, and local—be considered in determining whether the issuance or modification of registration would be contrary to the public interest), *with id.* § 823(f)(3) (requiring that only the registrant’s conviction record under federal and state laws relating specifically to the manufacture, distribution, or dispensing of controlled substances be considered).

¹³⁶ *See, e.g.*, *George C. Aycock, M.D.*, 74 Fed. Reg. 17529, 17529 (Drug Enforcement Admin. Apr. 15, 2009) (considering, in support of registrant sanctions, the practitioner’s failure to comply with state and federal law, including the CSA and its implementing regulations).

to controlled substances. A demonstrated inability or unwillingness to adhere to the requirements associated with controlled substances is frequently the most dispositive issue in an administrative sanction case. Notwithstanding the seeming facial simplicity of the language included in this factor that the violation of law be merely “relating to the manufacture, distribution, or dispensing of controlled substances,”¹³⁷ Agency precedent has self-limited the scope of this factor. It is not enough that the federal or state law transgressed *relate* to controlled substances, but the law violated must be “directed at preventing diversion.”¹³⁸ The provision violated must, according to the Agency’s own precedent, have “a sufficient nexus to the CSA’s core purpose of preventing the diversion and abuse of controlled substances.”¹³⁹

The overwhelming majority of administrative practitioner sanction cases relate to the prescribing or dispensing of controlled substances by practitioners. Under the CSA, the term “practitioners” includes:

physician[s], dentist[s], veterinarian[s], scientific investigator[s], pharmac[ies], hospital[s], or other person[s] licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.¹⁴⁰

Thus, pharmacies (not individual pharmacists) and individuals (e.g., physicians, dentists) authorized to handle controlled substances are included within the definition of “practitioner.” The CSA definition for “dispense” includes “prescribing and administering” controlled substances.¹⁴¹

To effectuate the dual goals of conquering drug abuse and

¹³⁷ 21 U.S.C. § 823(f)(3).

¹³⁸ Fred Samimi, M.D., 79 Fed. Reg. 18698, 18710 (Drug Enforcement Admin. Apr. 3, 2014) (holding that a violation of state law warning and labeling requirements aimed at protecting consumers, and which had application to all prescription medications, not just controlled substances, not to be within the purview of Factor Four, but holding that a violation of a state provision proscribing the unsupervised dispensing of prescription medications by unlicensed individuals to be sufficiently related to the core purposes of the CSA to be properly considered under Factor Four).

¹³⁹ *Id.*

¹⁴⁰ 21 U.S.C. § 802(21).

¹⁴¹ *Id.* § 802(10).

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.”¹⁴² Under the regulations, “[t]he responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription.”¹⁴³ While the overarching objective is the preservation of the closed regulatory system and the prevention of diversion, the responsibilities incumbent upon the prescribing practitioners are distinct from those shouldered by pharmacy registrants.¹⁴⁴

A controlled substance may only be dispensed upon a prescription issued by a practitioner.¹⁴⁵ Under the regulations, a prescription is unlawful unless it is “issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.”¹⁴⁶ The Agency has specifically outlined seven factual scenarios that, in its view, categorically compel the conclusion that a controlled substance prescriber lacked a legitimate medical purpose and acted outside the usual course of professional practice, therefore violating the CSA. These scenarios include (but presumably are not limited to) occasions where the controlled substance prescription was issued by the prescriber: (1) without performing an appropriate physical examination, (2) without utilizing appropriate diagnostic testing, (3) without devising and documenting a written treatment plan, (4) without periodically reassessing the effectiveness of the controlled substance treatment regimen, (5) in continuation of the prescribing of controlled substances without pursuing alternative treatment, (6) in the course of repeatedly and continually prescribing without referring the patient to appropriate specialists, and (7) without keeping and maintaining records which contain adequate findings to support a diagnosis and the need to prescribe one or more medications.¹⁴⁷

¹⁴² *Gonzales v. Raich*, 545 U.S. 1, 13 (2005).

¹⁴³ 21 C.F.R. § 1306.04(a) (2013).

¹⁴⁴ *See* *Holiday CVS, LLC*, 77 Fed. Reg. 62316, 62341 (Drug Enforcement Admin. Oct. 12, 2012) (stating that the corresponding responsibility of a pharmacy registrant relates to the dispensing (not prescribing) of controlled substances).

¹⁴⁵ *See* 21 U.S.C. § 829.

¹⁴⁶ 21 C.F.R. § 1306.04(a).

¹⁴⁷ *Jose Raul S. Villavicencio, M.D.*, 80 Fed. Reg. 3624, 3628 (Drug Enforcement Admin. Jan. 23, 2015).

The regulations also provide that “[a]n order purporting to be a prescription issued not in the usual course of professional treatment . . . is not a prescription within the meaning and intent of [21 U.S.C. § 829] and the person knowingly . . . issuing it[] shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.”¹⁴⁸ A prescription authorizes the dispensing of a controlled substance to an ultimate user (i.e., the patient) and cannot be used by a physician to stockpile in an office and dispense to patients.¹⁴⁹

A registered practitioner is authorized to dispense,¹⁵⁰ which the CSA defines as “to deliver a controlled substance to an ultimate user . . . by, or pursuant to the lawful order of, a practitioner.”¹⁵¹ The prescription requirement is designed to ensure that controlled substances are used under the supervision of a doctor as a bulwark against the risk of addiction and recreational abuse.¹⁵² The prescription requirement likewise stands as a proscription against doctors “peddling to patients who crave the drugs for those prohibited uses.”¹⁵³ The courts have sustained criminal convictions based on the issuing of illegitimate prescriptions where physicians conducted either no physical examinations or sham physical examinations.¹⁵⁴

The CSA provides the DEA with regulatory authority over practitioner registrants, but its authority is not without limits. While it is true that the CSA authorizes the “regulat[ion of the]

¹⁴⁸ 21 C.F.R. § 1306.04(a).

¹⁴⁹ *Id.* § 1306.04(b). Controlled substances procured for purposes other than being dispensed by a pharmacy to an ultimate consumer, such as office stock, or to be administered in an institutional setting, are obtained through the use of an order. *See id.* § 828(a); *id.* § 1300.01 (defining “prescription”); *id.* § 1306.11(c).

¹⁵⁰ 21 U.S.C. § 823(f).

¹⁵¹ *Id.* § 802(10); *see also* Rose Mary Jacinta Lewis, M.D., 72 Fed. Reg. 4035, 4040 (Drug Enforcement Admin. Jan. 29, 2007) (stating that the holder of a practitioner’s license may only use the license to obtain controlled substances in order to conduct research or dispense to an ultimate user). “Ultimate user” is defined as “a person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his household or for an animal owned by him or by a member of his household.” *Id.* § 802(27).

¹⁵² George C. Aycock, M.D., 74 Fed. Reg. 17529, 17541 (Drug Enforcement Admin. Apr. 15, 2009) (citing *Gonzales v. Oregon*, 546 U.S. 243, 274 (2006)); *see* *United States v. Moore*, 423 U.S. 122, 135, 142–43 (1975) (finding that a physician exceeded the bounds of professional practice by giving “inadequate examinations or none at all,” ignoring the results of the tests he did perform, and failing to take precautions against “misuse and diversion” of controlled substances).

¹⁵³ *Aycock*, 74 Fed. Reg. at 17541 (citing *Gonzales*, 546 U.S. at 274).

¹⁵⁴ *United States v. Alerre*, 430 F.3d 681, 685, 690–91 (4th Cir. 2005); *United States v. Norris*, 780 F.2d 1207, 1208–09 (5th Cir. 1986).

medical practice insofar as it bars doctors from using their prescription-writing powers as a means to engage in illicit drug dealing and trafficking as conventionally understood,¹⁵⁵ an evaluation of cognizant state standards has historically been seen as essential¹⁵⁶ to determine whether a controlled substance prescription was issued with a legitimate medical purpose in the usual course of a professional practice.¹⁵⁷ That said, some Agency precedent has held that national standards for practice do exist and can be applied, *Gonzales v. Oregon* notwithstanding, as a kind of national metric to evaluate whether a practitioner has exercised the requisite standard of required care.¹⁵⁸ The Agency has held that where a patient has presented a physician registrant with numerous behaviors reflecting red flags of potential diversion, the patient's claims (seemingly irrespective of the prevailing state standard) must be independently verified.¹⁵⁹ DEA's evaluation of a registrant's prescribing must be consistent with the CSA's recognition of state regulation of the medical profession and the CSA's bar on physicians from peddling to patients who crave drugs for prohibited uses.¹⁶⁰ The analysis must be "tethered securely" to state law and federal regulations in application of the public interest factors, and may not be based on a mere disagreement between experts as to the most efficacious way to prescribe controlled substances to treat pain.¹⁶¹

¹⁵⁵ *Gonzales*, 546 U.S. at 270.

¹⁵⁶ Joseph Gaudio, M.D., 74 Fed. Reg. 10083, 10090 (Drug Enforcement Admin. Mar. 9, 2009) ("The CSA, however, generally looks to state law to determine whether a doctor and patient have established a bonafide doctor-patient relationship."); Kamir Garces-Mejias, M.D., 72 Fed. Reg. 54931, 54935 (Drug Enforcement Admin. Sept. 27, 2007); United Prescription Servs., Inc., 72 Fed. Reg. 50397, 50407 (Drug Enforcement Admin. Aug. 31, 2007).

¹⁵⁷ 21 C.F.R. § 1306.04(a) (2013).

¹⁵⁸ See, e.g., Samuel Mintlow, M.D., 80 Fed. Reg. 3630, 3649 n.25, 3651 n.28 (Drug Enforcement Admin. Jan. 23, 2015) (holding that "numerous judicial decisions in both medical malpractice and criminal cases, medical board decisions involving allegations of unprofessional conduct, and Agency decisions involving allegations of unlawful prescribing" supply the "standard of care which governs the scope of an appropriate physical exam" and that a physician registrant is required to include "documentation of a patient's prior attempts to bribe a doctor and obtain drugs" in patient charts, whether required by standard within the state or not); Grider Drug #1 & Grider Drug #2, 77 Fed. Reg. 44070, 44093 (Drug Enforcement Admin. July 26, 2012) (holding that it was not improper to measure the usual course of professional practice under 21 U.S.C. § 841(a)(1) and 21 C.F.R. § 1306.04 with reference to generally recognized and accepted medical practices); Bienvenido Tan, M.D., 76 Fed. Reg. 17673, 17681 (Drug Enforcement Admin. Mar. 30, 2011) (same).

¹⁵⁹ *Mintlow*, 80 Fed. Reg. at 3650.

¹⁶⁰ See *Volkman v. DEA*, 567 F.3d 215, 223 (6th Cir. 2009).

¹⁶¹ *Id.*

“Under the CSA, it is fundamental that a practitioner must establish and maintain a *bona fide* doctor-patient relationship in order to act ‘in the usual course of . . . professional practice’ and to issue a prescription for a ‘legitimate medical purpose.’”¹⁶² The CSA has historically looked to state law to determine whether a bona fide doctor-patient relationship was established and maintained.¹⁶³

The applicable state medical standards to evaluate issues such as the bona fides of a doctor-patient relationship and other issues attendant on a determination of whether a prescription was issued for a legitimate medical purpose in the course of a professional practice¹⁶⁴ can be discerned from expert testimony, state statutes and regulations, or rulings by state disciplinary authorities. The Agency has held that expert testimony may be required to establish a violation in close cases where the evidence establishes that a registrant has attempted to comply with the regulations.¹⁶⁵ However, expert testimony is not always essential.¹⁶⁶ Expert testimony is not required where the evidence undermines any reasonable possibility that the prescribing was legitimate.¹⁶⁷ The qualification of the expert is a question for the trier of fact. There is some authority to support the proposition that a DEA diversion investigator can, with a sufficient foundation, be qualified to testify as an expert on the issue of red flags of diversion.¹⁶⁸

The “corresponding responsibility [that] rests with the pharmacist who fills the [controlled substance] prescription”¹⁶⁹ is by no means identical to the obligations of the individual practitioners who write

¹⁶² Dewey C. Mackay, M.D., 75 Fed. Reg. 49956, 49973 (Drug Enforcement Admin. Aug. 16, 2010) (quoting Laurence T. McKinney, 73 Fed. Reg. 43260, 43265 n.22 (Drug Enforcement Admin. July 24, 2008)); accord Patrick W. Stodola, M.D., 74 Fed. Reg. 20727, 20731 (Drug Enforcement Admin. May 5, 2009); Ladapo O. Shyngle, M.D., 74 Fed. Reg. 6056, 6057–58 (Drug Enforcement Admin. Feb. 4, 2009).

¹⁶³ *Stodola*, 74 Fed. Reg. at 20731; *Shyngle*, 74 Fed. Reg. at 6058; *Garces-Mejias*, 72 Fed. Reg. at 54935; *United Prescription Servs., Inc.*, 72 Fed. Reg. at 50407.

¹⁶⁴ 21 C.F.R. § 1306.04(a).

¹⁶⁵ Ralph J. Chambers, M.D., 79 Fed. Reg. 4962, 4971 (Drug Enforcement Admin. Jan. 30, 2014); David A. Ruben, M.D., 78 Fed. Reg. 38363, 38375 (Drug Enforcement Admin. June 26, 2013); Jack A. Danton, D.O., 76 Fed. Reg. 60900, 60900 (Drug Enforcement Admin. Sept. 30, 2011).

¹⁶⁶ T.J. McNichol, M.D., 77 Fed. Reg. 57133, 57147–48 (Drug Enforcement Admin. Sept. 17, 2012); *Danton*, 76 Fed. Reg. at 60900–01.

¹⁶⁷ Cynthia M. Cadet, M.D., 76 Fed. Reg. 19450, 19450 n.3 (Drug Enforcement Admin. Apr. 7, 2011) (“Where . . . the [g]overnment produces evidence of undercover visits showing that a physician knowingly engaged in outright drug deals, expert testimony adds little to the proof necessary to establish a violation of [f]ederal Law.”); *Danton*, 76 Fed. Reg. at 60915.

¹⁶⁸ *United States v. Lovern*, 590 F.3d 1095, 1102 (10th Cir. 2009).

¹⁶⁹ 21 C.F.R. § 1306.04(a).

those prescriptions. Under the regulations, a pharmacist has a duty “to fill only those prescriptions that conform in all respects with the requirements of the [CSA] and DEA regulations, including the requirement that the prescribing practitioner be properly registered.”¹⁷⁰ That is to say, a pharmacist has a “corresponding responsibility under [f]ederal law to dispense only lawful prescriptions,”¹⁷¹ and, under Agency precedent, this corresponding responsibility to guarantee “the dispensing of valid prescriptions extends to the pharmacy itself.”¹⁷² The Agency has interpreted this corresponding responsibility as prohibiting the filling of a prescription where the pharmacist or pharmacy “knows or has reason to know” that the prescription is invalid.¹⁷³ The pharmacy registrant’s responsibility under the regulations is not coextensive or identical to the duties imposed upon a prescriber, but it is a *corresponding* one.¹⁷⁴ The practice of medicine is not required of the pharmacist, but, rather, the pharmacist has the responsibility to decline to dispense based upon an order that purports to be a prescription but is not where the pharmacist knows or has reason to know that the practitioner issued it outside the scope of legitimate

¹⁷⁰ Elec. Prescriptions for Controlled Substances, 75 Fed. Reg. 16236, 16266 (Drug Enforcement Admin. Mar. 31, 2010).

¹⁷¹ Liddy’s Pharmacy, LLC, 76 Fed. Reg. 48887, 48895 (Drug Enforcement Admin. Aug. 9, 2011) (internal quotation marks omitted).

¹⁷² Holiday CVS, LLC, 77 Fed. Reg. 62316, 62341 (Drug Enforcement Admin. Oct. 12, 2012) (citing *Medicine Shoppe-Jonesborough*, 73 Fed. Reg. 364, 365, 383–84 (Drug Enforcement Admin. Jan. 2, 2008) (finding that respondent pharmacy was properly charged with violating corresponding responsibility); *United Prescription Servs., Inc.*, 72 Fed. Reg. 50397, 50408 (Drug Enforcement Admin. Aug. 31, 2007) (finding that respondent pharmacy violated the CSA when it had reason to know that prescriptions issued by certain physicians were unlawful and nevertheless filled them); see *EZRX, LLC*, 69 Fed. Reg. 63178, 63181 (Drug Enforcement Admin. Oct. 29, 2004) (“DEA has issued orders to show cause and subsequently revoked the DEA registrations of pharmacies which failed to fulfill *their* corresponding responsibility in Internet prescribing operations.” (emphasis added)); *Role of Authorized Agents in Communicating Controlled Substance Prescriptions to Pharmacies*, 75 Fed. Reg. 61613, 61617 (Drug Enforcement Admin. Oct. 6, 2010) (referring to a pharmacy’s “corresponding responsibility regarding the dispensing of controlled substances.”); *Issuance of Multiple Prescriptions for Schedule II Controlled Substances*, 72 Fed. Reg. 64921, 69424 (Drug Enforcement Admin. Nov. 19, 2007) (referring to a *pharmacy’s* corresponding responsibility).

¹⁷³ *E. Main St. Pharmacy*, 75 Fed. Reg. 66149, 66163 (Drug Enforcement Admin. Oct. 27, 2010) (quoting *Medicine Shoppe*, 73 Fed. Reg. at 381); *accord* *Bob’s Pharmacy & Diabetic Supplies*, 74 Fed. Reg. 19599, 19601 (Drug Enforcement Admin. Apr. 29, 2009); see also *United Prescription Servs., Inc.*, 72 Fed. Reg. at 50408 (finding a violation of corresponding responsibility where pharmacy “had ample reason to know” that the practitioner was not acting in the usual course of professional practice).

¹⁷⁴ 21 C.F.R. § 1306.04(a).

medical practice.¹⁷⁵ One court has aptly described the corresponding responsibility this way:

[T]he “corresponding responsibility” *is* corresponding. The physician’s responsibility is not to prescribe improperly while the pharmacist’s responsibility is not to dispense a controlled substance for non-medical reasons. The regulation does not place an unduly heavy burden on the pharmacist. Proof is required that the pharmacist had reason to believe that the prescription was not issued in the usual course of professional treatment.¹⁷⁶

DEA has interpreted the “legitimate medical purpose” feature of the corresponding responsibility duty “as prohibiting a pharmacist from filling a prescription for a controlled substance when he either knows or has reason to know that the prescription was not written for a legitimate medical purpose.”¹⁷⁷ DEA has been equally consistent in its admonishment that “[w]hen prescriptions are clearly not issued for legitimate medical purposes, a pharmacist may not intentionally close his eyes and thereby avoid [actual] knowledge of the real purpose of the prescription.”¹⁷⁸ The Agency does not require omniscience.¹⁷⁹ However, when the circumstances surrounding the presentation of a prescription would give rise to suspicion in a “reasonable professional[,]” there is a duty to “question the prescription[.]”¹⁸⁰ Though initially framed as a “reasonable professional” standard, the Agency has evaluated the duty to discharge the corresponding responsibility by looking at the circumstances in light of what would be considered suspicious by a “reasonable pharmacist.”¹⁸¹ Accordingly, a pharmacist or pharmacy may not dispense a prescription in the face of a red flag (i.e., a

¹⁷⁵ *E. Main St. Pharmacy*, 75 Fed. Reg. at 66157 & n.30 (citing *United States v. Hayes*, 595 F.2d 258, 261 (5th Cir. 1979)).

¹⁷⁶ *United States v. Henry*, 727 F.2d 1373, 1379 (5th Cir. 1984).

¹⁷⁷ *Sun & Lake Pharmacy, Inc.*, 76 Fed. Reg. 24523, 24530 (Drug Enforcement Admin. May 2, 2011) (quoting *Medicine Shoppe*, 73 Fed. Reg. at 381) (internal quotation marks omitted).

¹⁷⁸ *Ralph J. Bertolino*, 55 Fed. Reg. 4729, 4730 (Drug Enforcement Admin. Feb. 9, 1990); *accord Liddy’s Pharmacy, LLC*, 76 Fed. Reg. 48887, 48895 (Drug Enforcement Admin. Aug. 9, 2011); *E. Main St. Pharmacy*, 75 Fed. Reg. at 66163; *Lincoln Pharmacy*, 75 Fed. Reg. 65667, 65668 (Drug Enforcement Admin. Oct. 26, 2010); *Bob’s Pharmacy*, 74 Fed. Reg. at 19601.

¹⁷⁹ *Carlos Gonzalez, M.D.*, 76 Fed. Reg. 63118, 63142 (Drug Enforcement Admin. Oct. 11, 2011).

¹⁸⁰ *Bertolino*, 55 Fed. Reg. at 4730.

¹⁸¹ *E. Main St. Pharmacy*, 75 Fed. Reg. at 66164; *see also Winn’s Pharmacy*, 56 Fed. Reg. 52559, 52561 (Drug Enforcement Admin. Oct. 21, 1991) (finding that the volume of prescriptions issued by the physician would have indicated to a reasonable pharmacist that the prescriptions were not being issued for a legitimate medical purpose).

circumstance that does or should raise a reasonable suspicion as to the validity of a prescription, or an elevated likelihood of diversion or abuse) unless he/she/it takes steps to resolve the red flag and ensure that the prescription is valid.¹⁸² Agency precedent limits the corresponding responsibility of pharmacists to circumstances that are known or should have been known.¹⁸³ Because DEA registrations are issued to pharmacies (not pharmacists), when considering whether a pharmacy registrant has complied with its corresponding responsibility, the Agency considers whether the *entity*, not the pharmacist, can be charged with the requisite knowledge.¹⁸⁴

The Agency has held that:

to show a violation of a corresponding responsibility, the [g]overnment must establish that: (1) the [r]espondent dispensed a controlled substance; (2) a red flag was or should have been recognized at or before the time the controlled substance was dispensed; and (3) the question created by the red flag was not resolved conclusively prior to the dispensing of the controlled substance.¹⁸⁵

¹⁸² *E. Main St. Pharmacy*, 75 Fed. Reg. at 66164–65 (finding that the pharmacist failed to act as a reasonable pharmacist when he admittedly found certain prescriptions to be questionable but never verified their legitimacy); *see also Winn's Pharmacy*, 56 Fed. Reg. at 52561 (stating that the pharmacist disregarded clear signs that the prescriptions he filled had no legitimate medical purpose).

¹⁸³ *Sun & Lake Pharmacy, Inc.*, 76 Fed. Reg. 24523, 24530 (Drug Enforcement Admin. May 2, 2011).

¹⁸⁴ *See United Prescription Servs. Inc.*, 72 Fed. Reg. 50397, 50407 (Drug Enforcement Admin. Aug. 31, 2007) (“[A]n *entity*[, in this case a pharmacy,] which voluntarily engages in commerce . . . [to] other [s]tates is properly charged with knowledge of the laws regarding the practice of medicine in those [s]tates.” (emphasis added)); *see also Pharmboy Ventures Unlimited, Inc.*, 77 Fed. Reg. 33770, 33771 n.2 (Drug Enforcement Admin. June 7, 2012) (“DEA has long held that it can look behind a pharmacy’s ownership structure ‘to determine who makes the decisions concerning the controlled substance business of a pharmacy.’” (quoting *Carriage Apothecary*, 52 Fed. Reg. 27599, 27599 (Drug Enforcement Admin. July 22, 1987)); *S & S Pharmacy, Inc.*, 46 Fed. Reg. 13051, 13051 (Drug Enforcement Admin. Feb. 19, 1981) (“The corporate pharmacy acts through the agency of its . . . pharmacist in charge.”). Any knowledge that the pharmacists and their employees obtain while acting within the scope of their employment may be imputed to the pharmacy. *See United States v. 7326 Highway 45 N.*, 965 F.2d 311, 316 (7th Cir. 1992) (“Only knowledge obtained by corporate employees acting within the scope of their employment is imputed to the corporation.”); *see also Moore Clinical Trials, LLC*, 79 Fed. Reg. 40145, 40157 (Drug Enforcement Admin. July 11, 2014) (finding that actions of independent contractor in a researcher registration case imputed to the researcher applicant where the terms of employment included compliance with applicable laws and provided the researcher with authority to terminate the contract upon a breach).

¹⁸⁵ *Holiday CVS, LLC*, 77 Fed. Reg. 62316, 62341 (Drug Enforcement Admin. Oct. 12, 2012).

Naturally, the measures required to resolve the red flags are issue dependent and, thus, will often require expert testimony to minimize the risk that pharmacy practitioners would face sanctions based on fluctuating, amorphous expectations presented after the fact by administrative regulators and adjudicators. A standard, which requires that sanctions on pharmacy registrants based on unresolved red flags be supported by competent expert testimony, will best provide the regulated community with knowable, fixed, and defensible expectations and a fair adjudication that can be meaningfully reviewed by the courts. The Agency has taken the reasonable position that a pharmacy registrant who encounters a red flag is not absolved of all responsibility by merely reaching out to the prescriber who issued the scrip for verification.¹⁸⁶

Another common source of Factor Four misconduct is noncompliance with federal and state recordkeeping laws. The Agency has held that “[r]ecordkeeping is one of the central features of the CSA’s closed system of distribution. ‘[A] registrant’s accurate and diligent adherence to this obligation is absolutely essential to protect against the diversion of controlled substances.’”¹⁸⁷ The maintenance of accurate records by registrants has been deemed by the Agency to be a critical component of its ability to fulfill its statutory mandate to regulate controlled substances.¹⁸⁸ The obligation to maintain accurate records extends equally to individuals and corporations.¹⁸⁹ Thus, under Agency precedent, where established by reliable evidence, recordkeeping deficiencies may provide a reason—“which is sufficient by itself”—to find that the granting of a registration would be inconsistent with the public interest.¹⁹⁰ DEA has also held that noncompliance with recordkeeping obligations can lend “substantial credence” to allegations that a registrant is engaged in “massive diversion.”¹⁹¹ Thus, recordkeeping deficiencies that might, in other contexts, seem

¹⁸⁶ The Medicine Shoppe, 79 Fed. Reg. 59504, 59510 (Drug Enforcement Admin. Oct. 2, 2014).

¹⁸⁷ Satinder Dang, M.D., 76 Fed. Reg. 51424, 51429 (Drug Enforcement Admin. Aug. 18, 2011) (second alteration in original) (citations omitted) (quoting Paul H. Volkman, 73 Fed. Reg. 30630, 30644 (Drug Enforcement Admin. May 28, 2008)).

¹⁸⁸ See *Volkman*, 73 Fed. Reg. at 30644, (6th Cir. 2009) (specifically upholding the DEA Administrator’s reliance on recordkeeping violations in denying a COR application), *aff’d*, *Volkman v. DEA*, 567 F.3d 215, 224.

¹⁸⁹ *Moore Clinical Trials, LLC*, 79 Fed. Reg. at 40156.

¹⁹⁰ *Volkman*, 73 Fed. Reg. at 30644.

¹⁹¹ Grider Drug #1 & Grider Drug #2, 77 Fed. Reg. 44070, 44101 (Drug Enforcement Admin. July 26, 2012).

trivial or inconsequential, can result in the imposition of significant sanctions in a DEA administrative adjudication. That said, a harsh sanction is not compelled by every recordkeeping imperfection. The Agency has held that where non-egregious recordkeeping errors are acknowledged and remedied promptly, revocation may not always be required.¹⁹²

In *Terese, Inc.*, substantial evidence established that the registrant had failed to comply with three recordkeeping requirements.¹⁹³ In declining to revoke Terese's registration, the Agency, emphasizing that the registrant had accepted responsibility for its violations and had instituted corrective actions, determined that, under the circumstances, the three recordkeeping violations did not render its continued registration inconsistent with the public interest.¹⁹⁴ In *Ideal Pharmacy Care, Inc.*, an audit of the registrant's records showed a shortage of 150,000 dosage units of hydrocodone, 83,000 dosage units of alprazolam, and 1.6 million milliliters of promethazine with codeine.¹⁹⁵ However, in contrast to *Terese*, the Agency found that Ideal Pharmacy's failure to maintain accurate records constituted an act that rendered its continued registration inconsistent with the public interest.¹⁹⁶ Taken together, *Ideal* and *Terese* indicate that, when considering recordkeeping violations, the Agency has coupled consideration of the degree of severity of the noncompliance with an analysis of whether the registrant has both acknowledged culpability and demonstrated credible efforts aimed at correction.

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

The fifth factor relevant to determining whether a practitioner's license would be in the public interest requires the Agency to consider "[s]uch other conduct which may threaten the public health and safety."¹⁹⁷ In this final factor, Congress provided a catch-all provision in the Agency's determination of whether registration would be in the public interest. Despite its generic wording, Factor

¹⁹² *Terese, Inc.*, 76 Fed. Reg. 46843, 46848 (Drug Enforcement Admin. Aug. 3, 2011).

¹⁹³ *Id.*

¹⁹⁴ *Id.*

¹⁹⁵ *Ideal Pharmacy Care, Inc.*, 76 Fed. Reg. 51415, 51416 (Drug Enforcement Admin. Aug. 18, 2011).

¹⁹⁶ *Id.*

¹⁹⁷ 21 U.S.C. § 823(f)(5) (2012).

Five is limited by its own terms and Agency precedent.

In similar catch-all provisions found in § 823(d)(6) (regulation of controlled substance manufacturing) and § 823(h)(5) (regulation of List I chemical distribution), the CSA requires the Agency to consider “such other *factors*” relevant to the public interest.¹⁹⁸ In contrast, the practitioner Factor Five public interest factor examines “such other *conduct*.”¹⁹⁹ Congress has assigned specific parameters to the term “public interest” in the CSA context, and the Agency has recognized that it cannot look to, or invent, factors outside the five listed in the CSA to determine whether a practitioner’s registration is in the public interest.²⁰⁰ Instead, the Agency is constrained to look only to the practitioner’s actual conduct.²⁰¹ Likewise, because Factor Five speaks specifically and only to “such *other conduct*,” it follows that conduct relevant under Factors One through Four cannot be considered in Factor Five.²⁰²

Agency precedent has also established that only conduct that has “a nexus to controlled substances and the underlying purposes of the CSA” may be considered under Factor Five.²⁰³ Specifically, the Agency has held that conduct is only relevant under Factor Five if there is “a substantial relationship between the conduct and the CSA’s purposes of preventing drug abuse and diversion.”²⁰⁴ While

¹⁹⁸ *Id.* § 823(d)(6) (emphasis added); *accord id.* § 823(h)(5). Congress’s use of the word “conduct” instead of the word “factor” appears to be in response to input received on the bill from the American Medical Association and the American Pharmaceutical Association. *See Diversion of Prescription Drugs to Illegal Channels and Dangerous Drug Diversion Control Act: Hearing on H.R. 4698 Before the Subcomm. on Crime of the H. Comm. on the Judiciary, supra* note 98, at 334 (statements of P. John Seward, M.D., Council on Legislation, American Medical Association, and Maurice Q. Bectel, Interim President, American Pharmaceutical Association).

¹⁹⁹ 21 U.S.C. § 823(f)(5) (emphasis added).

²⁰⁰ *Top RX Pharmacy*, 78 Fed. Reg. 26069, 26085 (Drug Enforcement Admin. May 3, 2013); *Holiday CVS*, 77 Fed. Reg. at 62345.

²⁰¹ *See Top RX Pharmacy*, 78 Fed. Reg. at 26085; *Holiday CVS*, 77 Fed. Reg. at 62345.

²⁰² *See* Jeffery J. Becker, D.D.S., 77 Fed. Reg. 72387, 72407 (Drug Enforcement Admin. Dec. 5, 2012) (holding that the admitted evidence that the registrant disposed of controlled substances into public sewage system in violation of the regulations is not relevant under Factor 5 in the absence of evidence distinguishing the conduct already considered under Factor 4).

²⁰³ Joe W. Morgan, D.O., 78 Fed. Reg. 61961, 61977 (Drug Enforcement Admin. Oct. 8, 2013); *accord* *Holiday CVS*, 77 Fed. Reg. at 62345; *see also* *Terese, Inc.*, 76 Fed. Reg. 46843, 46848 n.11 (Drug Enforcement Admin. Aug. 3, 2011).

²⁰⁴ Tony T. Bui, M.D., 75 Fed. Reg. 49979, 49988 (Drug Enforcement Admin. Aug. 16, 2010); *see also* Paul Weir Battershell, N.P., 76 Fed. Reg. 44359, 44368 (Drug Enforcement Admin. July 25, 2011) (noting that although a registrant’s noncompliance with the Food, Drug, and Cosmetic Act is not relevant under Factor Five, consideration of such conduct may properly be considered on the narrow issue of assessing a respondent’s future compliance with the CSA).

this view of the breadth of Factor Five appears to be the current interpretation by the Agency, as will be discussed *infra*, past precedent is not altogether in accord.

Historically, the types of conduct considered by the Agency under a Factor Five analysis have been quite varied, but some recurring varieties are identifiable. Conduct that has been found germane to Factor Five in the past has included (but is not limited to): lack of candor to DEA investigators;²⁰⁵ lack of candor to state officials;²⁰⁶ deceptive practices to avoid detection by law enforcement;²⁰⁷ prior convictions;²⁰⁸ self-abuse of controlled substances and alcohol;²⁰⁹ failure to take steps to prevent against diversion of controlled substances;²¹⁰ persistence in diversion-related misconduct despite warnings to desist by federal or state regulators;²¹¹ material

²⁰⁵ George R. Smith, M.D., 78 Fed. Reg. 44972, 44979–80 (Drug Enforcement Admin. July 25, 2013); Glenn D. Krieger, M.D., 76 Fed. Reg. 20020, 20024 (Drug Enforcement Admin. Apr. 11, 2011); David A. Hoxie, M.D., 69 Fed. Reg. 51477, 51479 (Drug Enforcement Admin. Aug. 19, 2004); Maxicare Pharmacy, 61 Fed. Reg. 27368, 27369 (Drug Enforcement Admin. May 31, 1996). *But see* Roy S. Schwartz, D.D.S., 79 Fed. Reg. 34360, 34363 n.6 (Drug Enforcement Admin. June 16, 2014) (false statements made to DEA and state regulators not considered under Factor Five).

²⁰⁶ *Hoxie*, 69 Fed. Reg. at 51749; Thomas G. Easter II, M.D., 69 Fed. Reg. 5579, 5581 (Drug Enforcement Admin. Feb. 5, 2004); Cecil E. Oakes, Jr., M.D., 63 Fed. Reg. 11907, 11909 (Drug Enforcement Admin. Mar. 11, 1998). *But see* *Schwartz*, 79 Fed. Reg. at 34363 n.6 (false statements made to DEA and state regulators not considered under Factor Five).

²⁰⁷ Jerry Neil Rand, M.D., 61 Fed. Reg. 28895, 28897 (Drug Enforcement Admin. June 6, 1996); Richard M. Koenig, M.D., 60 Fed. Reg. 65069, 65071 (Drug Enforcement Admin. Dec. 18, 1995); Albert L. Pulliam, M.D., 60 Fed. Reg. 54513, 54514–15 (Drug Enforcement Admin. Oct. 24, 1995); Nelson A. Smith, D.D.S., 58 Fed. Reg. 65403, 65404 (Drug Enforcement Admin. Dec. 14, 1993).

²⁰⁸ Merlin E. Shuck, D.V.M., 69 Fed. Reg. 22566, 22568 (Drug Enforcement Admin. Apr. 26, 2004); Trudy J. Nelson, M.D., 66 Fed. Reg. 52941, 52943 (Drug Enforcement Admin. Oct. 18, 2001); G. Wayman Blakely, Jr., M.D., 63 Fed. Reg. 44277, 44278 (Drug Enforcement Admin. Aug. 18, 1998); Hugh I. Schade, M.D., 60 Fed. Reg. 56354, 56356 (Drug Enforcement Admin. Nov. 8, 1995). While the range of convictions found relevant by the Agency has been rather wide, the Agency recently pointed out that a conviction considered under Factor Five must be related to controlled substances. *See* Mark De La Lama, P.A., 76 Fed. Reg. 20011, 20020 n.20 (Drug Enforcement Admin. Apr. 11, 2011) (“I place no weight on [r]espondent’s DUI/Hit and Run conviction there being no evidence that he was under the influence of a controlled substance at the time.”).

²⁰⁹ Tyson D. Quy, M.D., 78 Fed. Reg. 47412, 47417 (Drug Enforcement Admin. Aug. 5, 2013); *Smith*, 78 Fed. Reg. at 44980; Michael W. Dietz, D.D.S., 66 Fed. Reg. 52937, 52938 (Drug Enforcement Admin. Oct. 18, 2001); Mary M. Miller, M.D., 63 Fed. Reg. 71157, 71159 (Drug Enforcement Admin. Dec. 23, 1998); Stanley Alan Azen, M.D., 61 Fed. Reg. 57893, 57896 (Drug Enforcement Admin. Nov. 8, 1996).

²¹⁰ Kevin Dennis, M.D., 78 Fed. Reg. 52787, 52800 (Drug Enforcement Admin. Aug. 26, 2013); Mireille Lalanne, M.D., 78 Fed. Reg. 47750, 47776 (Drug Enforcement Admin. Aug. 6, 2013); Earl A. Humphreys, M.D., 61 Fed. Reg. 2840, 2841 (Drug Enforcement Admin. Jan. 29, 1996).

²¹¹ Salvatore DeFrank, D.P.M., 70 Fed. Reg. 285575, 28578 (Drug Enforcement Admin. May 18, 2005); James E. Eaves, M.D., 67 Fed. Reg. 35586, 35587 (Drug Enforcement Admin. May

falsification of an application for DEA registration;²¹² failure to comply with state pharmacy rules and food and drug safety provisions;²¹³ harmful treating/prescribing practices;²¹⁴ and debilitating health.²¹⁵

More recent Agency precedent that closely links conduct reviewable under Factor Five with the CSA's anti-diversion focus²¹⁶ is more consonant with the Supreme Court's admonition that an Agency's statutory interpretation must "stay[] within the bounds of its statutory authority."²¹⁷

IV. APPLICATION CASES

Under 21 U.S.C. § 823(f), the Administrator may deny an applicant's request for a DEA registration if the granting of the registration "would be inconsistent with the public interest."²¹⁸ Just as with revocation cases, the government bears the burden of proof to show that it is not in the public interest to grant an application.²¹⁹ In order to determine the public interest, the CSA provides that the following five factors must be considered:

- (1) The recommendation of the appropriate [s]tate licensing board or professional disciplinary authority.
- (2) The applicant's experience in dispensing, or conducting research with respect to controlled substances.
- (3) The applicant's conviction record under [f]ederal or [s]tate

20, 2002); Lowell O. Kirk, M.D., 58 Fed. Reg. 15378, 15379 (Drug Enforcement Admin. Mar. 22, 1993).

²¹² Bernard C. Musselman, M.D., 64 Fed. Reg. 55965, 55967 (Drug Enforcement Admin. Oct. 15, 1999); Saihb S. Halil, M.D., 64 Fed. Reg. 33319, 33320 (Drug Enforcement Admin. June 22, 1999); Richard S. Wagner, M.D., 63 Fed. Reg. 6771, 6773 (Drug Enforcement Admin. Feb. 10, 1998); Village Drug, 59 Fed. Reg. 30038, 30039 (Drug Enforcement Admin. June 10, 1994); Robert L. Vogler, D.D.S., 58 Fed. Reg. 51385, 51386 (Drug Enforcement Admin. Oct. 1, 1993). Material falsification of an application for a DEA registration also stands as a separate ground for revocation. 21 U.S.C. § 824(a)(1) (2012).

²¹³ Sigrid Sanchez, M.D., 78 Fed. Reg. 39331, 39336 (Drug Enforcement Admin. July 1, 2013); Paul Weir Battershell, N.P., 76 Fed. Reg. 44359, 44368 (Drug Enforcement Admin. July 25, 2011).

²¹⁴ *Quy*, 78 Fed. Reg. at 47417–18; Michael J. Aruta, M.D., 76 Fed. Reg. 19420, 19434 (Drug Enforcement Admin. Apr. 7, 2011); Paul W. Saxton, 64 Fed. Reg. 25073, 25079 (Drug Enforcement Admin. May 10, 1999); Hugh I. Schade, M.D., 60 Fed. Reg. 56354, 56356 (Drug Enforcement Admin. Nov. 8, 1995).

²¹⁵ Edward L.C. Broomes, M.D., 61 Fed. Reg. 3946, 3948 (Drug Enforcement Admin. Feb. 2, 1996).

²¹⁶ *Gonzales v. Oregon*, 546 U.S. 243, 250 (2006).

²¹⁷ *City of Arlington v. F.C.C.*, 133 S. Ct. 1863, 1868 (2013).

²¹⁸ 21 U.S.C. § 823(f) (2012).

²¹⁹ *See* 21 C.F.R. § 1301.44(d) (2013).

laws relating to the manufacture, distribution, or dispensing of controlled substances.

(4) Compliance with applicable [s]tate, [f]ederal, or local laws relating to controlled substances.

(5) Such other conduct which may threaten the public health and safety.²²⁰

In practice, the interpretation and application of these five factors in application cases mirrors the application of those factors in revocation cases, discussed *supra* Part III.²²¹

Agency precedent has extended the CSA revocation grounds to also constitute bases for the denial of applications under the theory that the law would not require, from the beginning, the granting of a registration that should be revoked.²²² These other separate bases are (1) material falsification in a registration application; (2) conviction relating to a violation of state or federal controlled substance laws; (3) state action against state-issued controlled substance license (or recommendation); and (4) exclusion from participation in Medicare.²²³ The Agency has denied applications for registration based on these revocation factors.

Once an order to show cause has been issued regarding an application, it may only be withdrawn with the permission of the Administrator.²²⁴ Permission will only be granted upon a showing of good cause or if the withdrawal is in the public interest.²²⁵ While there is no requirement to do so, it is not uncommon for the ALJ to grant a continuance or even a stay of proceedings while the Agency is deliberating over a withdrawal request submitted by an

²²⁰ 21 U.S.C. § 823(f)(1)–(5).

²²¹ Although the language in Public Interest Factors Two and Four speaks to “applicants,” Agency precedent has interpreted the CSA public interest revocation ground (21 U.S.C. § 824(a)(4) (2012)) as incorporating all public interest factors to revocation adjudications in the same way those factors have been applied to applications. *See* Clair L. Pettinger, M.D., 78 Fed. Reg. 61592, 61599–600 (Drug Enforcement Admin. Oct. 3, 2013); Thomas H. McCarthy, D.O., 54 Fed. Reg. 20936, 20936 (Drug Enforcement Admin. May 15, 1989); *see also supra* Part III.E (discussing the public interest factors in detail).

²²² *The Lawsons, Inc.*, 72 Fed. Reg. 74334, 74337 (Drug Enforcement Admin. Dec. 31, 2007); Dan E. Hale, D.O., 69 Fed. Reg. 69402, 69406 (Drug Enforcement Admin. Nov. 29, 2004); Anthony D. Funches, 64 Fed. Reg. 14267, 14268 (Drug Enforcement Admin. Mar. 24, 1999); Alan R. Schankman, M.D., 63 Fed. Reg. 45260, 45260 (Drug Enforcement Admin. Aug. 25, 1998); Dinorah Drug Store, Inc., 61 Fed. Reg. 15972, 15973 (Drug Enforcement Admin. Apr. 10, 1996); Kuen H. Chen, M.D., 58 Fed. Reg. 65401, 65402 (Drug Enforcement Admin. Dec. 14, 1993).

²²³ 21 U.S.C. § 824(a); *see also supra* Part III (providing a more detailed analysis).

²²⁴ 21 C.F.R. § 1301.16(a).

²²⁵ *Id.*

applicant. Although the authority to approve an application withdrawal at DEA has historically been vested in the discretion of the Deputy Assistant Administrator for Diversion Control (DAA/OD), a recent Agency case reviewed and reversed a withdrawal denial issued by the DAA/OD, notwithstanding the regulatory absence of a basis for appeal on this ground.²²⁶ In its final order, the Agency created a new test by which it would evaluate the discretion exercised by the DAA/OD in accepting or rejecting an applicant's request to withdraw an application. In this new, Agency-created right of review, DEA will consider the following factors: (1) the egregiousness of the misconduct established by the record,²²⁷ (2) the extent of government resources that have been expended in the litigation and review of the case, and (3) any potential prejudice to the government's case regarding a registration application that could be filed subsequently on related facts.²²⁸

V. IMMEDIATE SUSPENSION CASES

The CSA authorizes the DEA Administrator, upon a finding of "imminent danger to the public health or safety," to immediately suspend a registration "simultaneously with the institution of [administrative] proceedings."²²⁹ The regulations provide that where the Administrator issues an immediate suspension order, that order will be issued contemporaneously with the service of an order to show cause on a registrant and "shall contain a statement of his findings regarding the danger to public health or safety."²³⁰

Unlike an order to show cause proceeding, an immediate suspension order issued by the Administrator is final when issued, is not reviewed by a DEA ALJ, and "continue[s] in effect until the conclusion of [formal administrative] proceedings, including judicial review thereof, unless sooner withdrawn by the [Administrator] or dissolved by a court of competent jurisdiction."²³¹ The immediate suspension order may be issued and executed without a pre-

²²⁶ Vincent G. Colosimo, D.M.D., 79 Fed. Reg. 20911, 20913 (Drug Enforcement Admin. Apr. 14, 2014).

²²⁷ In cases where the Agency is reviewing the acceptance of a withdrawal application, the extent of the "record" to be reviewed for this purpose is not clear.

²²⁸ *Colosimo*, 79 Fed. Reg. at 20913.

²²⁹ 21 U.S.C. § 824(d).

²³⁰ 21 C.F.R. § 1301.36(e).

²³¹ 21 U.S.C. § 824(d).

suspension hearing,²³² so long as post-deprivation proceedings are conducted in a prompt fashion.²³³

An immediate suspension order will not be sustained in the absence of a sustained finding of an imminent danger to public health and safety²³⁴ “supported by and in accordance with . . . reliable, probative, and substantial evidence.”²³⁵ A suspended registrant may seek relief through a petition for injunctive relief through the cognizant United States District Court²³⁶ or by petition for a review of the Agency’s (final) immediate suspension order “in [either] the United States Court of Appeals for the District of Columbia or for the circuit in which [the registrant’s] principal place of business is located.”²³⁷

Although the ALJ designated to preside at the administrative hearing is without authority over the immediate suspension order, it is worthy of note that any seizures of controlled substances that take place based on the immediate suspension order are forfeited upon the issuance of an Agency final revocation order.²³⁸ Indeed, DEA precedent has held this relationship between the forfeiture of seized controlled substances and a final order of revocation may present a collateral consequence of sufficient moment to preclude a finding of mootness where a registration has expired without timely application to renew.²³⁹

VI. THE PARTIES’ BURDENS AND THE EXERCISE OF DISCRETION

In all cases involving practitioner and pharmacy sanctions, the government enters the fray as the burdened party. Where the case involves a revocation/suspension, the government must establish

²³² See *Gilbert v. Homar*, 520 U.S. 924, 933–34 (1997) (holding that a state had no constitutional obligation to provide a campus police officer with a presuspension hearing); *FDIC v. Mallen*, 486 U.S. 230, 248 (1988) (holding that the FDIC’s post suspension procedure was not constitutionally infirm).

²³³ See *Barry v. Barchi*, 443 U.S. 55, 68 (1979) (holding that, although post-deprivation proceedings are not per se inadequate, state post-suspension proceedings can be infirm due to inadequate statutory assurances of a prompt post-suspension hearing).

²³⁴ *Norman Bridge Drug Co. v. Banner*, 529 F.2d 822, 828 (5th Cir. 1976).

²³⁵ 5 U.S.C. § 556(d) (2012).

²³⁶ *Norman Bridge Drug Co.*, 529 F.2d at 823–24.

²³⁷ 21 U.S.C. § 877 (2012).

²³⁸ See *id.* § 824(d), (f).

²³⁹ *Meetinghouse Cmty. Pharmacy, Inc.*, 74 Fed. Reg. 10073, 10074 n.5 (Drug Enforcement Admin. Mar. 9, 2009); *William R. Lockridge, M.D.*, 71 Fed. Reg. 77791, 77797 & n.7 (Drug Enforcement Admin. Dec. 27, 2006).

that the requirements for sanction are satisfied,²⁴⁰ and where the issue is an application, the government bears the burden to prove that an application should be denied.²⁴¹ The respondent may choose to contest the government's evidence, but the burden rests on the government in the first instance to demonstrate that the requirements for sanction that have been alleged have been satisfied.²⁴²

Under a long line of established Agency precedent, once the government has established a prima facie case for sanction, the burden shifts to the registrant/applicant to demonstrate that he/she/it should be (or continue to be) "entrusted with a DEA registration."²⁴³ To successfully rebut the government's prima facie case, the respondent must (1) accept responsibility for the proven misconduct, and (2) demonstrate corrective measures.²⁴⁴ Agency precedent has made it clear that, when the government meets its burden, the acceptance of responsibility and a demonstration of remedial action aimed at the avoidance of reoccurrence are hard and fast prerequisites to escape sanction.²⁴⁵ Further, these mandatory features must be demonstrated together for either to be relevant, and proffered evidence of one without the other has been held to be irrelevant.²⁴⁶ The reliance placed by the Agency on the importance of acceptance of responsibility and remedial action(s) has been sustained on review.²⁴⁷

The imposition of sanctions by the Agency is an act of discretion under the CSA.²⁴⁸ Thus, while the government may meet its prima facie case against a respondent, the Agency is still empowered and

²⁴⁰ 21 C.F.R. § 1301.44(e) (2013).

²⁴¹ See *id.* § 1301.44(d).

²⁴² *Id.* § 1301.44(e).

²⁴³ Joe W. Morgan, D.O., 78 Fed. Reg. 61961, 61980 (Drug Enforcement Admin. Oct. 8, 2013); e.g., Jeri Hassman, M.D., 75 Fed. Reg. 8194, 8235–36 (Drug Enforcement Admin. Feb. 23, 2010); Medicine Shoppe—Jonesborough, 73 Fed. Reg. 364, 387 (Drug Enforcement Admin. Jan. 2, 2008).

²⁴⁴ See, e.g., Mireille Lalanne, M.D., 78 Fed. Reg. 47750, 47777 (Drug Enforcement Admin. Aug. 6, 2013); Jeri Hassman, 75 Fed. Reg. at 8235–36; Jayam Krishna-Iyer, M.D., 74 Fed. Reg. 459, 463 (Drug Enforcement Admin. Jan. 6, 2009).

²⁴⁵ E.g., Lalanne, 78 Fed. Reg. at 47777; George Mathew, M.D., 75 Fed. Reg. 66138, 66148 (Drug Enforcement Admin. Oct. 27, 2010).

²⁴⁶ The Medicine Shoppe, 79 Fed. Reg. 59504, 59510 (Drug Enforcement Admin. Oct. 2, 2014) (finding that an equivocal, hence ineffective, acceptance of responsibility rendered evidence of remedial measures irrelevant).

²⁴⁷ MacKay v. DEA, 664 F.3d 808, 819–20 (10th Cir. 2011).

²⁴⁸ See 21 U.S.C. § 823(f) (2012) ("The Attorney General *may* deny an application for such registration" (emphasis added)); *id.* § 824(a) ("A registration . . . *may* be suspended or revoked by the Attorney General . . ." (emphasis added)).

required to determine whether/how much, sanction is appropriate. Accordingly, the Agency may choose to outright deny an application²⁴⁹ or revoke a registration,²⁵⁰ or it may allow a registrant/applicant to continue/commence regulated activity under conditions.²⁵¹ Where the Agency imposes conditions on a registration, those conditions “must be related to what the government has alleged and proved in any case.”²⁵² The Agency has held that in its assessment of whether/how much sanction is appropriate, it will always consider (1) “the egregiousness and extent of a registrant’s misconduct,” and (2) the Agency’s interest in both specific deterrence (on the registrant/applicant) as well as general deterrence (among members of the regulated community).²⁵³

VII. PREHEARING PROCEDURES

The authority of the Administrative Law Judge at DEA administrative hearings is authorized and circumscribed by the APA.²⁵⁴ The authority and enumerated powers vested by the APA in the ALJ flow “without the necessity of express agency delegation [and] an agency is without power to withhold such powers from [the ALJ].”²⁵⁵ The APA affords the presiding officer at an administrative hearing significant control over the course of the hearing and specified prehearing procedures,²⁵⁶ as well as authority to “take other action authorized by agency rule consistent with this

²⁴⁹ *E.g.*, *Lalanne*, 78 Fed. Reg. at 47753.

²⁵⁰ *E.g.*, *Top RX Pharmacy*, 78 Fed. Reg. 26069, 26069 (Drug Enforcement Admin. May 3, 2013).

²⁵¹ *See, e.g.*, *David A. Ruben, M.D.*, 78 Fed. Reg. 38363, 38387–88 (Drug Enforcement Admin. June 26, 2013) (granting an application with conditions and a preliminary suspension); *Martha Hernandez, M.D.*, 62 Fed. Reg. 61145, 61148 (Drug Enforcement Admin. Nov. 14, 1997) (continuing a registration upon condition).

²⁵² *Janet L. Thornton, D.O.*, 73 Fed. Reg. 50354, 50356 (Drug Enforcement Admin. Aug. 26, 2008).

²⁵³ *Fred Samimi, M.D.*, 79 Fed. Reg. 18698, 18714 (Drug Enforcement Admin. Apr. 3, 2014) (holding that the ALJ erred in failing “to consider the Agency’s need to deter similar misconduct on the part of other registrants” in the recommended decision). *Ruben*, 78 Fed. Reg. at 38385.

²⁵⁴ 5 U.S.C. § 556(c) (2012).

²⁵⁵ U.S. DEPT OF JUSTICE, ATTORNEY GENERAL’S MANUAL ON THE ADMINISTRATIVE PROCEDURE ACT § 7(b), at 74 (1947) [hereinafter ATTORNEY GENERAL’S MANUAL].

²⁵⁶ *See* 5 U.S.C. § 556(c). The Supreme Court, in reviewing the boundaries of immunity relative to an agency administrative law judge, has held that “[t]here can be little doubt that the role of the modern federal . . . administrative law judge within [the] framework [of the APA] is ‘functionally comparable’ to that of a [U.S. District Court] judge.” *Butz v. Economou*, 438 U.S. 478, 513 (1978).

subchapter.”²⁵⁷ The DEA regulations supply authority to the ALJ to, *inter alia*, direct and schedule litigation and conferences, direct the filing of prehearing statements, direct the exchange of proposed evidence, sign and issue subpoenas, handle witnesses, evidence and procedural matters that arise, and “[t]ake any action permitted . . . as authorized by [the regulations] or by the provisions of the [APA].”²⁵⁸

A. *Prehearing Statements*

As soon as practicable after an ALJ is designated, he/she will issue an order directing the parties to file prehearing statements²⁵⁹ and scheduling a telephonic or in-person prehearing conference. The respective theories of the parties, their proposed evidence, potential motions, areas of possible stipulation(s), respective positions as to hearing venue, and other issues specified by the ALJ in the order for prehearing statements will be addressed in the parties’ prehearing statements.²⁶⁰

B. *Prehearing Conference*

After receipt of the parties’ prehearing statements, the ALJ will conduct a prehearing conference.²⁶¹ The prehearing conference may be in person or via electronic means, and may or may not (at the option of the ALJ) be transcribed verbatim.²⁶² The regulations provide the following areas for potential discussion at the prehearing conference: (a) issue simplification; (b) stipulations and admissions; (c) expert witness limitation; (d) identification and scheduling of witnesses; (e) advance submission of noticed exhibits; and (f) “[s]uch other matters as may aid in the expeditious disposition of the hearing.”²⁶³

In practice, prehearing conferences are generally not transcribed, and they are often conducted telephonically.

²⁵⁷ 5 U.S.C. § 556(c)(11).

²⁵⁸ 21 C.F.R. § 1316.52 (2013).

²⁵⁹ *See id.* § 1316.52(c).

²⁶⁰ *See id.*

²⁶¹ *See id.* § 1316.54.

²⁶² *Id.* § 1316.55.

²⁶³ *Id.* § 1316.54.

C. Prehearing Ruling

Shortly after the conclusion of the prehearing conference, the ALJ will issue a prehearing ruling, in which dates will be fixed for the exchanging of proposed exhibits, the filing of motions, and the commencement of the hearing. The regulations provide that the prehearing “ruling shall control the subsequent course of the hearing unless modified by a subsequent ruling.”²⁶⁴

D. ALJ Directives

The presiding ALJ possesses considerable discretion in the exercise of the enumerated authority to “regulate the course of the hearing.”²⁶⁵ The protections afforded the ALJ’s decisional independence have been reviewed and sustained by the courts.²⁶⁶ While neither the CSA, nor the enabling regulations, vest the ALJ with contempt powers, Agency precedent allows that the failure to file prehearing statements²⁶⁷ or follow other directives issued by the ALJ may result in an implied hearing waiver.²⁶⁸

The ALJ’s authority over pending litigation “commence[s] upon his designation and terminate[s] upon the certification of the record [of proceedings] to the Administrator.”²⁶⁹ Thus, once the record of proceedings has been transmitted to the Administrator for a final order, the ALJ no longer has authority over any aspect of the case.

²⁶⁴ *Id.* § 1316.55.

²⁶⁵ 5 U.S.C. § 556(c)(5) (2012).

²⁶⁶ *Harline v. DEA*, 148 F.3d 1199, 1205 (10th Cir. 1998) (citing *Ramspeck v. Fed. Trial Exam’rs Conference*, 345 U.S. 128, 134–43 (1953)).

²⁶⁷ *Kamir Garces-Mejias, M.D.*, 72 Fed. Reg. 54931, 54932 (Drug Enforcement Admin. Sept. 27, 2007); *Alan R. Schankman, M.D.*, 63 Fed. Reg. 45260, 45260 (Drug Enforcement Admin. Aug. 25, 1998); *Hampton Pharmacy*, 56 Fed. Reg. 12260, 12260 (Drug Enforcement Admin. Mar. 22, 1991).

²⁶⁸ *Robert M. Brodtkin, D.P.M.*, 77 Fed. Reg. 73678, 73679 (Drug Enforcement Admin. Dec. 11, 2012); *Brenton D. Glisson, M.D.*, 72 Fed. Reg. 54296, 54296 (Drug Enforcement Admin. Sept. 24, 2007); *Andrew Desonia, M.D.*, 72 Fed. Reg. 54293, 54293–94 (Drug Enforcement Admin. Sept. 24, 2007).

²⁶⁹ 21 C.F.R. § 1316.52. Although the regulations specify certification of the record to the Administrator, the authority to issue final Agency decisions has also been delegated to (and has historically been most commonly exercised by) the Deputy Administrator. See 28 C.F.R. §§ 0.100(b), 0.104; Joseph T. Rannazzisi, *Thawing the Chill: The U.S. Drug Enforcement Administration, Physicians and the Controlled Substances Act*, J. GLOBAL DRUG POL’Y & PRAC. (2008), <http://www.globaldrugpolicy.org/Issues/Vol%202%20Issue%201/JournalofGlobalDrugPolicyVol2Issue1.pdf>.

E. Notice and Hearing Scope

Unless “willfulness or . . . [where] public health, interest, or safety requires otherwise,” the Agency may only impose a sanction under the APA if it has provided legally sufficient notice.²⁷⁰ Sufficient notice under the APA must include: “(1) notice by the [A]gency in writing of the facts or conduct which may warrant the [sanction]; and (2) [the] opportunity to demonstrate or achieve compliance with all lawful requirements.”²⁷¹ “Those who are brought into contest with the [g]overnment in a quasi-judicial proceeding aimed at the control of their activities are entitled to be fairly advised of what the [g]overnment proposes and to be heard upon its proposals before [the government] issues its final command.”²⁷² The notice must specify both the adverse action proposed and the facts and evidence upon which the Agency seeks to rely.²⁷³

The APA provides that “[p]ersons entitled to notice of an agency hearing shall be timely informed of[:] (1) the time, place, and nature of the hearing; (2) the legal authority and jurisdiction under which the hearing is to be held; and (3) the matters of fact and law asserted.”²⁷⁴ Although DEA precedent has held that “[p]leadings in administrative proceedings are not judged by the standards applied to an indictment at common law,”²⁷⁵ and that a “bill of particulars [regarding] every allegation” is not required,²⁷⁶ the Agency has also recognized that where an order to show cause has not adequately apprised a respondent of the required information, a sanction will not lie.²⁷⁷ The Agency has also applied this principle to matters it adjudicates without a hearing, but not in an altogether consistent manner.²⁷⁸

²⁷⁰ 5 U.S.C. § 558(c).

²⁷¹ *Id.*

²⁷² *Gonzales v. United States*, 348 U.S. 407, 414 n.5 (1955) (quoting *Morgan v. United States*, 304 U.S. 1, 18–19 (1938)).

²⁷³ *Hess & Clark, Div. of Rhodia, Inc. v. FDA*, 495 F.2d 975, 983 (D.C. Cir. 1974).

²⁷⁴ 5 U.S.C. § 554(b).

²⁷⁵ *CBS Wholesale Distribs.*, 74 Fed. Reg. 36746, 36749–50 (Drug Enforcement Admin. July 24, 2009) (quoting *Citizens State Bank v. FDIC*, 751 F.2d 209, 213 (8th Cir. 1984)).

²⁷⁶ *Roy E. Berkowitz, M.D.*, 74 Fed. Reg. 36758, 36759 (Drug Enforcement Admin. July 24, 2009) (quoting *Boston Carrier, Inc. v. Interstate Commerce Comm’n*, 746 F.2d 1555, 1560 (D.C. Cir. 1984)).

²⁷⁷ *CBS Wholesale Distribs.*, 74 Fed. Reg. at 36750.

²⁷⁸ *Compare Ideal Pharmacy Care, Inc.*, 76 Fed. Reg. 51415, 51416 & n.1 (Drug Enforcement Admin. Aug. 18, 2011) (rejecting consideration of loss of state authority in the absence of a corresponding allegation), *with Peter A. Ahles, M.D.*, 71 Fed. Reg. 50097, 50099 n.3 (Drug Enforcement Admin. Aug. 24, 2006) (considering loss of state authority even in the

Agency precedent has consistently held that the parameters of its administrative hearings are determined by the allegations in the order to show cause and the prehearing statements filed by the parties.²⁷⁹ An exception to this otherwise stringently applied notice requirement has sprung up in the Agency precedent regarding lack of state authority, albeit unevenly. The Agency has demonstrated a willingness to absolve the proceedings of deficient notice where a sanction is sustained based on a lack of state authority to handle controlled substances,²⁸⁰ reasoning that “[i]n such cases, adequate notice is provided either by the Government’s filing of a [m]otion for [s]ummary [d]isposition (in a case where a hearing was requested) or by taking official notice and providing the applicant/registrant with the opportunity to refute the finding (when no hearing request was filed).”²⁸¹ The Agency has also embraced the concept of litigation by consent where there is no objection and the parties fully litigate a particular issue.²⁸²

F. Service

DEA precedent has devoted some attention to the requirements of adequate service of its charging documents in administrative proceedings. While proof of personal service, or “heroic efforts,”²⁸³ are not required, Agency precedent has acknowledged “that due process requires the government to provide notice reasonably calculated, under all the circumstances, to apprise interested parties of the pendency of the action and afford them an opportunity

absence of a corresponding allegation).

²⁷⁹ Liddy’s Pharmacy, LLC, 76 Fed. Reg. 48887, 48896 (Drug Enforcement Admin. Aug. 9, 2011); *CBS Wholesale Distribs.*, 74 Fed. Reg. at 36750; Darrell Risner, D.M.D., P.S.C., 61 Fed. Reg. 728, 730 (Drug Enforcement Admin. Jan. 10, 1996).

²⁸⁰ Fiaz Afzal, M.D., 79 Fed. Reg. 61651, 61654 (Drug Enforcement Admin. Oct. 14, 2014) (concluding that the loss of state authority formed basis of revocation, even though it occurred after the completion of DEA hearing proceedings, including the issuance of the recommended decision). *But see*, Ideal Pharmacy Care, Inc., 76 Fed. Reg. 51415, 51416 n.1 (Drug Enforcement Admin. Aug. 18, 2011) (noting that the loss of state authority was not considered in revocation because it “was not cited as a basis for Agency action in the [OSC] (as it occurred five days after the latter was issued) and there [were] no pleadings establishing that the Agency subsequently gave notice of its intent to rely on the [s]tate’s [action]”).

²⁸¹ Jose Raul S. Villavicencio, M.D., 80 Fed. Reg. 3624, 3628 n.5 (Drug Enforcement Admin. Jan. 23, 2015).

²⁸² Grider Drug #1 & Grider Drug #2, 77 Fed. Reg. 44070, 44077 n.23 (Drug Enforcement Admin. July 26, 2012) (citing *Citizens State Bank*, 751 F.2d at 213).

²⁸³ Nicholas J. Jerrard, M.D., 75 Fed. Reg. 49978, 49978 (Drug Enforcement Admin. Aug. 16, 2010) (quoting *Dusenbery v. United States*, 534 U.S. 161, 170 (2002)).

to present their objections.”²⁸⁴ The Agency has even sustained service via email where the circumstances warranted,²⁸⁵ and has indicated in its unpublished orders that service via first class mail to the address that is reasonably calculated to reach the respondent (even without a signature demonstrating receipt) will ordinarily be sufficient.

The Agency has also held that where an order to show cause fails to accurately notify a registrant that the consequences of failure to respond to the order to show cause will result in a waiver of hearing procedures, the service is not valid.²⁸⁶

G. Motions

Under the APA, “the proponent of a[n] . . . order has the burden of proof.”²⁸⁷ Motions for appropriate relief are filed in writing with the ALJ with service on all other parties to the litigation. Inasmuch as the DEA regulations currently provide no fixed motion response time, the ALJ will advise the parties on a standard response reply date.

In practice, the ALJ will set a motions due date and a response date in the prehearing ruling,²⁸⁸ and (in the absence of contrary direction by the ALJ) motions are filed via facsimile by the due date with a hard-copy follow up thereafter.

H. Continuances and Stays

Regarding the authority of the ALJ over scheduling issues,²⁸⁹ continuance determinations are sustained by the courts in the absence of a clear showing of abuse of discretion.²⁹⁰ In making a

²⁸⁴ See, e.g., Emilio Luna, M.D., 77 Fed. Reg. 4829, 4829 (Drug Enforcement Admin. Jan. 31, 2012) (quoting *Jones v. Flowers*, 547 U.S. 220, 226 (2006)) (internal quotation marks omitted); Robert Leigh Kale, M.D., 76 Fed. Reg. 48898, 48899 (Drug Enforcement Admin. Aug. 9, 2011) (quoting *Jones*, 547 U.S. at 226) (internal quotation marks omitted).

²⁸⁵ *Luna*, 77 Fed. Reg. at 4829–30.

²⁸⁶ James Clopton, M.D., 79 Fed. Reg. 2475, 2475–76 (Drug Enforcement Admin. Jan. 14, 2014).

²⁸⁷ 5 U.S.C. § 556(d) (2012); see also 21 C.F.R. § 1316.56 (2013) (“At any hearing, the proponent for the issuance, amendment, or repeal of any rule shall have the burden of proof.”). The APA definition of “order” includes “the whole or a part of a final disposition.” 5 U.S.C. § 551(6) (emphasis added).

²⁸⁸ 21 C.F.R. § 1316.55 (discussing the ALJ’s power to issue a prehearing ruling).

²⁸⁹ *Id.* § 1316.52(a).

²⁹⁰ *Fitzhugh v. DEA*, 813 F.2d 1248, 1252 (D.C. Cir. 1987) (quoting *Prof'l Air Traffic Controllers Org. v. Fed. Labor Relations Auth.*, 685 F.2d 547, 588 (D.C. Cir. 1982)).

determination as to whether to grant a continuance, the ALJ may factor: “(1) the length of the delay requested, (2) the potential adverse effects of the delay, (3) the possible prejudice to the moving party if denied a delay, and (4) the importance of the testimony that may be adduced if the delay is granted.”²⁹¹

While the regulations do not specifically provide authority to stay proceedings, in practice, the parties may seek a stay to pursue settlement negotiations. However, the Agency has held that parallel proceedings in state courts will not ordinarily justify a stay in DEA administrative proceedings.²⁹²

I. Venue

Although the DEA regulations dictate that “[t]he hearing will commence at the place and time designated”²⁹³ by the Agency and reflected either in the order to show cause²⁹⁴ or in the notice in the Federal Register,²⁹⁵ the APA mandates that “[i]n fixing the time and place for hearings, due regard shall be had for the convenience and necessity of the parties or their representatives.”²⁹⁶ Although, in theory, the Agency could apply the APA venue considerations in fixing the time and place of the hearing when it issues the order to show cause, in practice, “the convenience and necessity of the parties or their representatives”²⁹⁷ will not generally be elucidated until after the registrant has filed a hearing request and prehearing statement. The order to show cause issued by DEA customarily designates hearing commencement to occur at the DEA Hearing Facility in Arlington, Virginia, approximately sixty (60) days from the order to show cause issuance date. Upon a timely filed hearing request, the parties are directed to provide disclosure about the case to be heard, including input on the issue of venue.

In practice, although the regulations provide no specific grant of authority to the ALJ to change venue, the DEA generally notifies the parties that venue and the hearing commencement date are

²⁹¹ *Fitzhugh*, 813 F.2d at 1252 (citing *Prof'l Air Traffic Controllers Org.*, 685 F.2d at 588).

²⁹² See *Grider Drug #1 & Grider Drug #2*, 77 Fed. Reg. 44070, 44104 n.97 (Drug Enforcement Admin. July 26, 2012).

²⁹³ 21 C.F.R. § 1316.53.

²⁹⁴ *Id.* § 1301.37(d).

²⁹⁵ *Id.* § 1316.53; see also *id.* § 1301.37(d) (reflecting that an order to show cause, rather than a notice in the Federal Register, is used to provide notice to practitioners in revocation or denial of application cases).

²⁹⁶ 5 U.S.C. § 554(b)(3) (2012).

²⁹⁷ *Id.*

subject to the directives of the ALJ. Setting aside the issue of whether one party (the government) has the power to affect the authority of the ALJ by including a phrase purporting to do so in the charging document, it has long been the practice of the DEA ALJs to apply the terms of the APA and consider “the convenience and necessity of the parties or their representatives”²⁹⁸ in setting venue, irrespective of the language set forth in the order to show cause.²⁹⁹

An important consideration in fixing venue is the 500-mile geographical limitation incorporated into the DEA’s authority to subpoena witnesses.³⁰⁰ A hearing that is set at a location that deprives a party of its ability to secure witnesses by process risks the denial of that party’s APA right “to present his case or defense by oral . . . evidence.”³⁰¹ While the ALJ is without authority to entertain a challenge to controlling regulations, the ALJs have generally acted in accordance with the venue directives in the APA in setting hearing venue. However, the increasing availability of video conferencing (VTC) capacity has and will have a significant impact on venue options that are consistent with due process, the DEA regulations, and the APA.

J. Discovery

“The Administrative Procedure Act does not confer a right to discovery in federal administrative proceedings.”³⁰² Inasmuch as the authority over discovery is not among the specifically enumerated ALJ powers in the APA,³⁰³ it exists only to the extent “authorized by agency rule.”³⁰⁴ DEA hearing regulations supply a limited avenue of discovery in a section called “[i]nspection of record” wherein the primary focus is aimed at the designation of

²⁹⁸ *Id.*

²⁹⁹ *See, e.g.,* Cynthia M. Cadet, M.D., 76 Fed. Reg. 19450, 19451 (Drug Enforcement Admin. Apr. 7, 2011) (noting that ALJ granted registrant’s change of venue request to Florida, where registrant worked and was investigated).

³⁰⁰ 21 U.S.C. § 876(a) (2012).

³⁰¹ 5 U.S.C. § 556(d).

³⁰² *NLRB v. Valley Mold Co.*, 530 F.2d 693, 695 (6th Cir. 1976); *see also* *NLRB v. Interboro Contractors, Inc.*, 432 F.2d 854, 857–58 (2d Cir. 1970) (“It is well settled that parties to judicial or quasi-judicial proceedings are not entitled to pre-trial discovery as a matter of constitutional right.”).

³⁰³ *See* 5 U.S.C. § 556(c) (listing the powers of the ALJ over administrative proceedings).

³⁰⁴ *Id.* § 556(c)(11).

material *not* subject to inspection.³⁰⁵ The limitation of the scope of available discovery in the DEA regulations is hardly surprising in view of the DEA's coextensive law enforcement mission and its need to protect methods and sources, as well as the high level of proprietary information that registrants can be required to disclose during the licensing process. Agency precedent on the issue of discovery has been likewise restrictive³⁰⁶ and clear in its view that discovery rights that apply in a criminal context have no application in DEA administrative proceedings.³⁰⁷ However, Agency precedent has seen some level of subtle amelioration regarding its discovery position, at least where the issue implicates due process concerns. Where the government declined to honor a timely request for the data underlying an expert opinion offered against a respondent, the Agency has held that the expert opinion cannot constitute substantial evidence supporting a sanction.³⁰⁸ Agency precedent has likewise acknowledged that "[d]iscovery must be granted if in the particular situation a refusal to do so would so prejudice a party as to deny him due process."³⁰⁹ As is the case with a proponent of any motion for relief, the burden of demonstrating a potential due process violation attendant on a discovery denial is on the party seeking discovery.³¹⁰

It is worthy of note that, even in its evolving approach regarding discovery, Agency precedent has rendered some adjustments to what will be permitted to constitute substantial evidence, but it has not imbued the ALJs with enhanced authority to compel the government to turn over requested documents. Thus, it is not altogether clear what recourse (if any) is available to an administrative litigator seeking relief before the ALJ—even in the face of an established due process violation. One potential tool

³⁰⁵ 21 C.F.R. § 1316.46 (2013).

³⁰⁶ See Nicholas A. Sychak, 65 Fed. Reg. 75959, 75961 (Drug Enforcement Admin. Dec. 5, 2000) (holding that there is no right of discovery in DEA administrative cases); *accord* Beau Boshers, M.D., 76 Fed. Reg. 19401, 19403 (Drug Enforcement Admin. Apr. 7, 2011); Roy E. Berkowitz, M.D., 74 Fed. Reg. 36758, 36760 (Drug Enforcement Admin. July 24, 2009).

³⁰⁷ T.J. McNichol, M.D., 77 Fed. Reg. 57133, 57143 n.15 (Drug Enforcement Admin. Sept. 17, 2012).

³⁰⁸ See, e.g., CBS Wholesale Distribs., 74 Fed. Reg. 36746, 36747–49, (Drug Enforcement Admin. July 24, 2009).

³⁰⁹ Margy Temponeras, M.D., 77 Fed. Reg. 45675, 45676 n.4 (Drug Enforcement Admin. Aug. 1, 2012) (alteration in original) (quoting *McClellan v. Andrus*, 606 F.2d 1278, 1286 (D.C. Cir. 1979) (internal quotation marks omitted)).

³¹⁰ 5 U.S.C. § 556(d) (2012); see also 21 C.F.R. § 1316.56 ("At any hearing, the proponent for the issuance, amendment, or repeal of any rule shall have the burden of proof.").

available to the ALJ may lie in the ALJ's APA enumerated powers to "rule on offers of proof and receive relevant evidence"³¹¹ and to "regulate the course of the hearing,"³¹² as well as the authority supplied by the DEA regulations to "[r]eceive, rule on, exclude, or limit evidence."³¹³ The courts have recognized that an APA ALJ has the authority and duty to apply an adverse inference where warranted by the evidence (or lack thereof).³¹⁴ At a minimum, an ALJ presiding at a DEA administrative hearing has the authority to limit or even exclude evidence offered by a party who has refused to comply with an appropriate discovery directive supported by Agency precedent or due process.³¹⁵ The ability to control the admissibility and/or weight afforded to proffered evidence can constitute a powerful potential remedy to an aggrieved party.

K. Subpoenas

The ALJ's authority to issue agency subpoenas is an enumerated authority that flows "without the necessity of express agency delegation, [and] an agency is without power to withhold such power[] from [the ALJ]."³¹⁶ The APA couches the ALJ's duty regarding the issuance of subpoenas as a mandatory function, subject to the authority of federal agencies to promulgate procedural regulations requiring "a statement or showing of general relevance and reasonable scope of the evidence sought."³¹⁷ The DEA regulations contain procedural regulations relating to the issuance of subpoenas.³¹⁸ The regulations authorize the ALJ at DEA administrative hearings to "[s]ign and issue subpoenas to compel the attendance of witnesses and the production of documents and materials *to the extent necessary to conduct administrative hearings pending before him.*"³¹⁹ By thus circumscribing the scope of the subpoena issuance authority to extend only to those documents and

³¹¹ 5 U.S.C. § 556(c)(3).

³¹² *Id.* § 556(c)(5).

³¹³ 21 C.F.R. § 1316.52(f).

³¹⁴ *See Callahan v. Schultz*, 783 F.2d 1543, 1545 (11th Cir. 1986) (describing the adverse inference rule); *UAW v. NLRB*, 459 F.2d 1329, 1336–37 (D.C. Cir. 1972).

³¹⁵ Excluded evidence and offers of proof related thereto must be included in the record of proceedings so that the correctness of the ruling may be reviewed by the Administrator. *See* 21 C.F.R. § 1316.60.

³¹⁶ ATTORNEY GENERAL'S MANUAL, *supra* note 2555, § 7(b), at 74.

³¹⁷ 5 U.S.C. § 555(d).

³¹⁸ 21 C.F.R. § 1316.52(d).

³¹⁹ *Id.* (emphasis added).

materials necessary to conducting an administrative hearing, the language employed by the regulations inherently imposes requirements of relevance and materiality of the documents requested to the administrative proceedings pending before the presiding ALJ as conditions precedent to issuance.³²⁰

A request for a subpoena may be made *ex parte*,³²¹ but must be made in writing in the form designated by the DEA.³²² The ALJ's authority to issue a subpoena is naturally limited by the Agency's authority to do so. The DEA's subpoena authority extends to 500 miles from the hearing situs, and is enforceable in the courts of the United States.³²³ A witness compelled by process to attend a DEA administrative hearing "shall be paid the same fees and mileage that are paid witnesses in the courts of the United States."³²⁴ The party seeking to compel a witness through process bears the responsibility for adequate service, and a party other than the United States seeking enforcement of a subpoena must tender fees for one day and appropriate mileage to the witness prior to seeking enforcement.³²⁵

L. Right to Hearing and Summary Disposition

The DEA regulations afford thirty (30) days from the date of receipt of an order to show cause or federal register notice for one entitled to a hearing to file a timely request.³²⁶ The regulations authorize the ALJ, upon a demonstration of good cause, to "grant a reasonable *extension* of the time allowed for response to an Order to Show Cause."³²⁷ While the use of the term "extension" in the regulations lends support to the principle that the authority of the ALJ to enlarge the time to respond to an OSC ends at the time when the ALJ could no longer convene a hearing upon a request (i.e., day thirty-one), the Agency (at least in two unpublished decisions) may have signaled its intention to take a broader view.³²⁸

³²⁰ *See id.*

³²¹ ATTORNEY GENERAL'S MANUAL, *supra* note 2555, § 5(c), at 55.

³²² Subpoena forms have been placed on the DEA Office of Administrative Law Judges website. *Office of the Administrative Law Judges*, DRUG ENFORCEMENT ADMIN., http://www.justice.gov/dea/ops/oalj_documents/template-subpoena.pdf (last visited Feb. 23, 2015).

³²³ 21 U.S.C. § 876(a) (2012).

³²⁴ *Id.*

³²⁵ FED. R. CIV. P. 45(b)(1).

³²⁶ 21 C.F.R. §§ 1301.43(a)–(b), 1309.53(a) (2013).

³²⁷ *Id.* § 1316.47(b) (emphasis added).

³²⁸ Authority to conduct proceedings and/or enter findings on an untimely filed hearing

The DEA, in its regulations, placed the authority of its ALJs in subpart D of section 1316 (DEA Hearing Regulations).³²⁹ The DEA Hearing Regulations provide that the ALJ's authority over a case ripens upon designation and ends at the point the record (including the recommended decision) is certified to the Administrator for a final order.³³⁰ While the authority for the ALJ to conduct a hearing is conditioned upon a request filed "within the period permitted for filing,"³³¹ as is the ability to receive a hearing waiver,³³² there is no like limitation placed on the ALJ's ability to extend the time allotted to file a hearing request.³³³ Arguably, the drafters' decision to include the limiting language in two portions of subpart D addressing the authority over OSC responses and to omit the phrase from a provision providing authority to grant an extension provides at least some evidence that the temporal restriction imposed upon the authority of the ALJ to act on a timely hearing request³³⁴ or act on a timely hearing waiver³³⁵ was never intended to apply to the authority to grant an extension to reply to an OSC under 21 C.F.R. § 1316.47(b).

Supporting a contrary, more restrictive view of the ALJ's authority is the placement of the regulations permitting an untimely hearing requester to escape waiver upon a showing of "good cause for such failure"³³⁶ outside the DEA Hearing Regulations. A fair interpretation of this omission of the issue from the DEA Hearing Regulations reflects an intent on the part of the drafters to vest the good cause determination in the hands of the Administrator, not the ALJ.

In any event, with or without a recommendation from the ALJ, the Agency will find a waiver of the right to a hearing where an untimely hearing request is not supported by good cause for its

request is not among the powers enumerated in the APA or the DEA regulations.

³²⁹ 21 C.F.R. § 1316.41.

³³⁰ *See id.* § 1316.52.

³³¹ *Id.* § 1316.47(a).

³³² *Id.* § 1316.49.

³³³ *See id.* § 1316.47(b). *Compare id.* § 1316.47(a) (requiring filing of a request for a hearing within the permitted time period), *and id.* § 1316.49 (requiring waiver of a hearing within the time permitted to file a hearing request), *with id.* § 1316.47(b) (giving an ALJ the authority to extend the allowed time for a response to an OSC without any reference to when that authority must be exercised).

³³⁴ *See id.* § 1316.47(a).

³³⁵ *See id.* § 1316.49.

³³⁶ *Id.* § 1301.43(d).

tardiness.³³⁷ Still, since the Agency has not yet published a final decision on the limits of the ALJ's jurisdiction here, a prudent respondent's counsel seeking a hearing after day thirty should consider filing a petition for a hearing request extension (supported by good cause) with the ALJ, and prudent government counsel should likewise consider filing an opposition.

Even a timely request for a hearing may result in a summary disposition. Agency precedent has embraced the concept that a summary disposition may be appropriate where there is no dispute over facts that compel a decisional result.³³⁸ The proponent of a motion for summary disposition bears the burden to establish entitlement to that relief. "[A] party moving for summary disposition 'must show, with materials of appropriate evidentiary quality, that every state of facts is excluded save that which entitles [it] to relief.'"³³⁹ Where (but only where) the government has submitted evidence to establish the material fact(s) upon which summary disposition may be granted, a party opposing summary disposition must "show a genuine dispute over the material facts."³⁴⁰

Although the CSA provides that the absence of state authority to handle controlled substances constitutes merely a discretionary basis for revocation of a DEA registration,³⁴¹ the Agency has adjudicated cases through summary disposition where it is undisputed that a practitioner registrant or applicant does not possess or has lost (even temporarily) state authorization to handle controlled substances.³⁴²

The APA provides that "[w]hen [a] licensee has made timely and

³³⁷ Shannon L. Gallentine, D.P.M., 76 Fed. Reg. 45864, 45864 (Drug Enforcement Admin. Aug. 1, 2011); Gilbert Eugene Johnson, M.D., 75 Fed. Reg. 65663, 65664 (Drug Enforcement Admin. Oct. 26, 2010).

³³⁸ See, e.g., House of Med., 79 Fed. Reg. 4959, 4962 (Drug Enforcement Admin. Jan. 30, 2014); Stuart A. Bergman, M.D., 70 Fed. Reg. 33193, 33193 (Drug Enforcement Admin. June 7, 2005).

³³⁹ Bio Diagnostic Int'l, 78 Fed. Reg. 39327, 39328–29 (Drug Enforcement Admin. July 1, 2013) (quoting *Sword v. Fox*, 317 F. Supp. 1055, 1057 (W.D. Va. 1970)).

³⁴⁰ *Bio Diagnostic Int'l*, 78 Fed. Reg. at 39328 n.2.

³⁴¹ 21 U.S.C. § 824(a)(3) (2012).

³⁴² See, e.g., Serenity Café, 77 Fed. Reg. 35027, 35027–28 (Drug Enforcement Admin. June 12, 2012); James L. Hooper, M.D., 76 Fed. Reg. 71371, 71371–72 (Drug Enforcement Admin. Nov. 17, 2011); David W. Wang, M.D., 72 Fed. Reg. 54297, 54297–98 (Drug Enforcement Admin. Sept. 24, 2007); Sheran Arden Yeates, M.D., 71 Fed. Reg. 39130, 39130–31 (Drug Enforcement Admin. July 11, 2006); Dominick A. Ricci, M.D., 58 Fed. Reg. 51104, 51105 (Drug Enforcement Admin. Sept. 30, 1993); Bobby Watts, M.D., 53 Fed. Reg. 11919, 11920 (Drug Enforcement Admin. Apr. 11, 1988).

sufficient application for a renewal or a new license in accordance with agency rules, a license with reference to an activity of a continuing nature does not expire until the application has been finally determined by the agency.”³⁴³ Under the DEA regulations, a registrant seeking re-registration must submit the application at least forty-five days prior to the expiration date to maintain status during the pendency of proceedings.³⁴⁴ Where a registration subject to an order to show cause expires under its own terms and no timely application for renewal has been submitted, the Agency has ruled that the registration has expired, leaving nothing to revoke.³⁴⁵ Under these circumstances, the ALJ will terminate order to show cause proceedings, and (except in some immediate suspension cases) any pending case will be dismissed by the Agency as moot.

The Agency has not been as willing to find mootness where an immediate suspension is involved. Agency precedent holds that, even in the face of a registration that has expired without application for renewal, an immediate suspension case will not be deemed moot unless: (1) there are no collateral consequences attendant on the case; and (2) there is evidence that the registrant no longer seeks to engage in regulated activity.³⁴⁶

Regarding the first of these Immediate Suspension Order (ISO) mootness factors, Agency precedent has held that collateral consequences are present where the execution of an ISO has resulted in the seizure of controlled substances from a registrant, because, under the CSA,³⁴⁷ the seized controlled substances are forfeited upon the issuance of a final revocation order.³⁴⁸ The second ISO mootness requirement is grounded in the Agency’s view that an issue “where conduct is capable of repetition yet evading review” is not truly moot and should not be shielded from review by

³⁴³ 5 U.S.C. § 558(c) (2012).

³⁴⁴ 21 C.F.R. § 1301.36(i) (2013).

³⁴⁵ *See, e.g.*, Donald Brooks Reece II, M.D., 77 Fed. Reg. 35054, 35055 (Drug Enforcement Admin. June 12, 2012); Thomas E. Mitchell, M.D., 76 Fed. Reg. 20032, 20033 (Drug Enforcement Admin. Apr. 11, 2011); Ronald J. Riegel, D.V.M., 63 Fed. Reg. 67132, 67133 (Drug Enforcement Admin. Dec. 4, 1998).

³⁴⁶ *See, e.g.*, Meetinghouse Cmty. Pharmacy, Inc., 74 Fed. Reg. 10073, 10074 n.5 (Drug Enforcement Admin. Mar. 9, 2009); Nirmal Saran, M.D., 73 Fed. Reg. 78827, 78828–29 (Drug Enforcement Admin. Dec. 23, 2008); Elmer P. Manalo, M.D., 73 Fed. Reg. 50353, 50354 (Drug Enforcement Admin. Aug. 26, 2008); RX Direct Pharmacy, Inc., 72 Fed. Reg. 54070, 54071–72 (Drug Enforcement Admin. Sept. 21, 2007); CRJ Pharmacy, Inc., 72 Fed. Reg. 30846, 30847 (Drug Enforcement Admin. June 4, 2007); William R. Lockridge, M.D., 71 Fed. Reg. 77791, 77796–97 (Drug Enforcement Admin. Dec. 27, 2006).

³⁴⁷ 21 U.S.C. § 824(f) (2012).

³⁴⁸ *Meetinghouse Cmty. Pharmacy Inc.*, 74 Fed. Reg. at 10074 n.5.

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the invocation of that doctrine.³⁴⁹

M. Res Judicata / Collateral Estoppel

The DEA has acknowledged the Supreme Court's recognition of the applicability of both *res judicata* and collateral estoppel³⁵⁰ in Agency administrative proceedings.³⁵¹

1. Res Judicata (Claim Preclusion)

“Under the doctrine of *res judicata*, [or claim preclusion,] a judgment on the merits in a prior suit bars a second suit involving the same parties or their privies based on the same cause of action.”³⁵² Claim preclusion “encompasses the law of merger and bar,” under which a litigant is precluded from getting a proverbial second bite at the apple by attempting to litigate a new claim in a second suit that arose out of the same transaction or occurrence as the first suit.³⁵³

Claim preclusion is applicable if there was a prior DEA proceeding in which the respondent had a full and fair opportunity to litigate the claims.³⁵⁴ Thus, unless the respondent's case falls within one of the doctrine's recognized exceptions,³⁵⁵ evidence that the DEA has previously issued a final order in the matter will

³⁴⁹ *Id.*

³⁵⁰ The term “*res judicata*” can be used as an umbrella term that encompasses both doctrines of claim and issue preclusion. See *Burney v. Polk Cmty. Coll.*, 728 F.2d 1374, 1377 n.8 (11th Cir. 1984) (“[T]he term ‘*res judicata*’ is used generically to refer to both collateral estoppel, or issue preclusion, and *res judicata*, or claim preclusion.”).

³⁵¹ Christopher Henry Lister, P.A., 75 Fed. Reg. 28068, 28069 (Drug Enforcement Admin. May 19, 2010) (“When an administrative agency is acting in a judicial capacity and resolves disputed issues of fact properly before it which the parties have had an adequate opportunity to litigate, the courts have not hesitated to apply *res judicata*.” (quoting *Univ. of Tenn. v. Elliot*, 478 U.S. 788, 797–98 (1986))).

³⁵² *Semtek Int'l Inc. v. Lockheed Martin Corp.*, 531 U.S. 497, 502 (2001) (quoting *Parklane Hosiery Co. v. Shore*, 439 U.S. 322, 326 n.5 (1979)) (internal quotation marks omitted).

³⁵³ *Migra v. Warren City Sch. Dist. Bd. of Educ.*, 465 U.S. 75, 77 n.1 (1984) (“Claim preclusion refers to the effect of a judgment in foreclosing litigation of a matter that never has been litigated, because of a determination that it should have been advanced in an earlier suit.”).

³⁵⁴ Alan H. Olefsky, M.D., 76 Fed. Reg. 20025, 20031 (Drug Enforcement Admin. Apr. 11, 2011); Robert L. Dougherty, M.D., 76 Fed. Reg. 16823, 16830 (Drug Enforcement Admin. Mar. 25, 2011) (“[W]here, as here, an applicant has previously been the subject of an Agency Final Order, the doctrine of *res judicata* bars the relitigation of the factual findings and conclusions of law of the prior proceeding absent the applicant's establishing that he falls within one of the doctrine's recognized exceptions.”).

³⁵⁵ See RESTATEMENT (SECOND) OF JUDGMENTS § 28 (1982), cited with approval in *Dougherty*, 76 Fed. Reg. at 16830.

foreclose subsequent attempts to relitigate the case before the Agency.³⁵⁶

2. Collateral Estoppel (Issue Preclusion)

Collateral estoppel, or issue preclusion, prevents relitigation of a prior issue under a new claim if the prior claim was “actually litigated” and if the determination was “essential to the judgment.”³⁵⁷ Factual findings and legal conclusions based on state law reached by state administrative tribunals are given preclusive effect in DEA administrative proceedings.³⁵⁸ The Agency has acknowledged that state medical boards are presumed to be the expert agencies with authority to determine whether one of their practitioners “has engaged in unprofessional conduct or provided incompetent medical care,” and “[w]here . . . a state medical board has determined that a practitioner’s conduct violated the [state] standard of care, its findings of fact and conclusions of law are not subject to relitigation before the Agency.”³⁵⁹ The key inquiry is not whether a full evidentiary hearing was conducted in the prior proceedings, but whether the parties had a full and fair opportunity to litigate the issues prior to the Agency’s decision.³⁶⁰ Likewise, a criminal conviction under the CSA will preclude relitigation of the

³⁵⁶ *Dougherty*, 76 Fed. Reg. at 16830.

³⁵⁷ RESTATEMENT (SECOND) OF JUDGMENTS § 27.

³⁵⁸ See, e.g., Thomas Neuschatz, M.D., 78 Fed. Reg. 76322, 76325 (Drug Enforcement Admin. Dec. 17, 2013); David A. Ruben, M.D., 78 Fed. Reg. 38363, 38365–66 (Drug Enforcement Admin. June 26, 2013); *Dougherty*, 76 Fed. Reg. at 16830; Gilbert Eugene Johnson, M.D., 75 Fed. Reg. 65663, 65666 (Drug Enforcement Admin. Oct. 26, 2010); see also James William Eisenberg, M.D., 77 Fed. Reg. 45663, 45663 (Drug Enforcement Admin. Aug. 1, 2012) (taking official notice of findings in state medical board censure order with preclusive effect).

³⁵⁹ *Ruben*, 78 Fed. Reg. at 38368–69.

³⁶⁰ Fiaz Afzal, M.D., 79 Fed. Reg. 61651, 61654 (Drug Enforcement Admin. Oct. 14, 2014) (Agency actually evaluated the fairness and protections of state administrative proceedings); see also, Jose G. Zavaleta, M.D., 78 Fed. Reg. 27431, 27434 (Drug Enforcement Admin. May 10, 2013) (finding that collateral estoppel can apply even if the prior proceeding was uncontested or did not result in a hearing). Note, however, that “[a]n issue is not actually litigated . . . if it is the subject of a stipulation between the parties. A stipulation may, however, be binding in a subsequent action between the parties if the parties have manifested an intention to that effect.” RESTATEMENT (SECOND) OF JUDGMENTS § 27 cmt. e. In addition, [i]n the case of a judgment entered by . . . consent, . . . none of the issues is actually litigated. Therefore, the rule of [collateral estoppel] does not apply with respect to any issue in a subsequent action. The judgment may be conclusive, however, with respect to one or more issues, if the parties have entered an agreement manifesting such an intention.

Id.

findings integral to that conviction as those findings impact upon an administrative determination.³⁶¹

The Supreme Court broadened the scope of the issue preclusion doctrine contemplated by the common law “by abandoning the requirement of mutuality of parties,” and by approving the use of “offensive” non-mutual issue preclusion in certain cases.³⁶² The Court, however, has proscribed the application of the doctrine of offensive non-mutual issue preclusion (where a nonparty seeks to preclude a party to the original action from relitigating an issue from the original action) against the government.³⁶³ As such, the government can use the findings of fact or law from a state board order, despite not being a party to the original state action, against a litigant to substantiate the government’s burden of proof. The litigant, however, cannot use the findings of fact or law from the state board order against the government.³⁶⁴ Nonetheless, the litigant can still argue “whether those findings and legal conclusions . . . establish violations of federal laws and regulations, as well as whether those violations are sufficiently egregious to support the government’s proposed sanction.”³⁶⁵

There are several other considerations when determining the preclusive effect of a state board’s order. While the Agency recognizes the preclusive effect of findings and state law conclusions resulting from state administrative hearings, it has not extended, *carte blanche*, the same effect to settlement agreements (or consent agreements) entered between respondents and state boards. In *Ralph J. Chambers, M.D.*, the Agency held that a settlement agreement between the respondent and state medical board was not entitled to preclusive effect in the DEA proceedings because the

³⁶¹ See Roger A. Pellmann, M.D., 76 Fed. Reg. 17704, 17709 (Drug Enforcement Admin. Mar. 30, 2011) (citing *Taylor v. Sturgell*, 553 U.S. 880, 892 (2008)).

³⁶² *United States v. Mendoza*, 464 U.S. 154, 158–59 (1984).

³⁶³ *Id.* at 160 (“A rule allowing nonmutual collateral estoppel against the [g]overnment . . . would substantially thwart the development of important questions of law by freezing the first final decision rendered on a particular legal issue.”).

³⁶⁴ See Richard A. Herbert, M.D., 76 Fed. Reg. 53942, 53944 (Drug Enforcement Admin. Aug. 30, 2011).

³⁶⁵ *Ruben*, 78 Fed. Reg. at 38367 n.8. (“So too, even where the factual findings and legal conclusions of a state board order are entitled to preclusive effect, a respondent is still entitled to put on evidence as to his/her acceptance of responsibility and remedial measures.” (citing Robert L. Dougherty, M.D., 76 Fed. Reg. 16823, 16830 (Drug Enforcement Admin. Mar. 25, 2011))). *But see*, Fiaz Afzal, M.D., 79 Fed. Reg. 61651, 61655 n.5 (Drug Enforcement Admin. Oct. 14, 2014) (finding that although the Agency decision was based entirely on a state board order issued after the DEA hearing, it was “unnecessary to determine whether [r]espondent offered such evidence” at the state level).

settlement agreement “sa[id] nothing about whether [the respondent] would be estopped from challenging the findings in a subsequent proceeding brought by the Board (or . . . another state agency) against him.”³⁶⁶ While the respondent in *Chambers* had agreed not to seek judicial review of the settlement agreement, the Agency held that the government’s failure to cite state authority holding that such language was entitled to preclude the parties from relitigating the issues raised in the settlement agreement barred the settlement agreement from having any preclusive effect.³⁶⁷

A similar issue arose in *David A. Ruben, M.D.*, in which the Agency held that the findings memorialized in two orders based on consent agreements between a registrant and his state board were entitled to preclusive effect in the DEA proceedings because, in the consent agreements, the respondent (1) manifested an intent not to contest the validity of the orders in subsequent proceedings before the state board, (2) relinquished his right to judicial review of the matters alleged in the orders, and (3) waived his right to any further action related to the orders.³⁶⁸ Because state law allowed for a settlement agreement to have preclusive effect if the parties to the agreement had manifested such intent, the Agency held that the respondent in *Ruben* was precluded from relitigating the same findings at the DEA proceedings.³⁶⁹

While the complex facts in both *Chambers* and *Ruben* do not readily lend themselves to a discernable bright-line rule for when a settlement or consent agreement should be given preclusive effect, it is clear that Agency precedent dictates that the parties to the agreement must have manifested their intent that the findings and conclusions accompanying the agreement be non-challengeable and binding upon the parties.³⁷⁰ Also relevant to this determination is an analysis of whether state law recognizes the nature and wording of the agreement entered into by the parties as creating a preclusive effect upon the parties in subsequent litigation.³⁷¹

Also, when dealing with state board findings of law, in order to be

³⁶⁶ Ralph J. Chambers, M.D., 79 Fed. Reg. 4962, 4970 (Drug Enforcement Admin. Jan. 30, 2014).

³⁶⁷ *Id.*

³⁶⁸ *Ruben*, 78 Fed. Reg. at 38366–67.

³⁶⁹ *Id.*

³⁷⁰ *Chambers*, 79 Fed. Reg. at 4970; *Ruben*, 78 Fed. Reg. at 38366–67.

³⁷¹ *Chambers*, 79 Fed. Reg. at 4970; *Ruben*, 78 Fed. Reg. at 38366–67.

probative, the state board's standard must be substantially the same or equivalent to the standards imposed under federal law.³⁷² Similarly, regarding state board findings of fact, the Agency may "rel[y] on those findings of the Board which are relevant and material to the Agency's public interest determination."³⁷³

N. Representation

In DEA proceedings, the issue of representation is governed by 21 C.F.R. § 1316.50. The regulation provides, in pertinent part:

Any person entitled to appear in a hearing may appear in person or by a representative in any proceeding or hearing and may be heard with respect to matters relevant to the issues under consideration. A representative must either be an employee of the person or an attorney at law who is a member of the bar, in good standing, of any [s]tate, territory, or the District of Columbia, and admitted to practice before the highest court of that jurisdiction.³⁷⁴

Thus, a registrant appearing at a DEA administrative proceeding may represent him/herself, pro se, or may rely on the services of a representative.³⁷⁵ While a representative is typically an attorney, the regulations also authorize representation by an employee of the respondent.³⁷⁶ The decision by the drafters to allow representation by an employee is doubtless an acknowledgment of the reality that registrations are issued to pharmacies (not pharmacists), distributors, manufacturers, and other entities.

There is currently no Agency precedent regarding who constitutes an "employee" for purposes of this regulation. To ensure that an individual appearing on behalf of a registrant has the requisite authority to conduct litigation on behalf of the registrant, the regulations permit the ALJ to require a notarized power of attorney

³⁷² For instance, 21 C.F.R. § 1306.04(a) requires that "[a] prescription for a controlled substance . . . be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 C.F.R. § 1306.04(a) (2013). If the government intends to prove that a practitioner violated this regulation through issue preclusion, the state board standard must be equivalent or substantially similar to the federal regulation. See Kenneth Harold Bull, M.D., 78 Fed. Reg. 62666, 62674 (Drug Enforcement Admin. Oct. 22, 2013).

³⁷³ *Ruben*, 78 Fed. Reg. at 38366.

³⁷⁴ 21 C.F.R. § 1316.50.

³⁷⁵ *Id.*

³⁷⁶ *Id.*

attesting to that authority.³⁷⁷

The term “employee” finds no definition in the DEA regulations or the CSA other than in the specific interpretation of who constitutes an employee for the disposal and destruction of controlled substances.³⁷⁸ The Supreme Court, however, has provided some guidance in cases where terms relating to the employment relationship, such as “employee” or “employer,” are left undefined by federal law. The Supreme Court has held that “[w]here Congress uses terms that have accumulated settled meaning under . . . the common law, a court must infer, unless the statute otherwise dictates, that Congress means to incorporate the established meaning of these terms.”³⁷⁹ Applying this standard in its interpretation of the word “employee” in a federal copyright statute, the Court stated that, “[i]n the past, when Congress has used the term ‘employee’ without defining it, we have concluded that Congress intended to describe the conventional master-servant relationship as understood by common-law agency doctrine.”³⁸⁰ The Court further opined that “the general common law of agency, rather than . . . the law of any particular [s]tate,” is the appropriate source for interpreting these terms.³⁸¹ The Court then used the standard found in *Restatement (Second) of Agency* § 220.³⁸²

Using the terms “master” and “servant” to refer to “employer” and “employee,” respectively, section 220 states that “[a] servant [i.e., an employee] is a person employed to perform services in the affairs of another and who with respect to the physical conduct in the performance of the services is subject to the other’s control or right to control.”³⁸³ To aid the decision of whether an individual is a servant or merely an independent contractor, the Restatement provides the following relevant factors:

- (a) the extent of control which, by the agreement, the master may exercise over the details of the work;

³⁷⁷ *Id.*

³⁷⁸ *Id.* § 1300.05(b). This definition, however, generally corresponds with the common law agency approach described below. *Id.*

³⁷⁹ *Cnty. for Creative Non-Violence v. Reid*, 490 U.S. 730, 739 (1989) (quoting *NLRB v. Amax Coal Co.*, 453 U.S. 322, 329 (1981)).

³⁸⁰ *Reid*, 490 U.S. at 739–40.

³⁸¹ *Id.* at 740.

³⁸² *Id.* at 752 n.31 (“In determining whether a hired party is an employee under the general common law of agency, we have traditionally looked for guidance to the Restatement of Agency.”).

³⁸³ *RESTATEMENT (SECOND) OF AGENCY* § 220(1) (1958).

- (b) whether or not the one employed is engaged in a distinct occupation or business;
- (c) the kind of occupation, with reference to whether, in the locality, the work is usually done under the direction of the employer or by a specialist without supervision;
- (d) the skill required in the particular occupation;
- (e) whether the employer or the workman supplies the instrumentalities, tools, and the place of work for the person doing the work;
- (f) the length of time for which the person is employed;
- (g) the method of payment, whether by the time or by the job;
- (h) whether or not the work is a part of the regular business of the employer;
- (i) whether or not the parties believe they are creating the relation of master and servant; and
- (j) whether the principal is or is not in business.³⁸⁴

Applying these factors, the Supreme Court has explained that “[n]o one of these factors is determinative.”³⁸⁵ Whatever the precise parameters are regarding “employee” status for purposes of the DEA regulations, it is safe to say that the drafters of the regulation contemplated that the relationship between the registrant and the putative (non-attorney) advocate must be more than that of an independent contractor hired to engage in the unauthorized practice of law behind a fig leaf of a concocted employee status. The bottom line is that if a registrant seeks to pay a stranger for representation, the stranger better be an attorney.

It need hardly be said that the fact that the regulations authorize registrant representation by a non-attorney employee does not make it a good idea. Employee representation was a risky proposition for a registrant back when the regulations were drafted. Today, where DEA administrative litigation has evolved into an infinitely more sophisticated and complex practice, non-attorney representation is even more hazardous.

VIII. HEARING PROCEDURES

A DEA formal administrative hearing, in most respects,

³⁸⁴ *Id.* § 220(2); *see also Reid*, 490 U.S. at 752–53 (applying the factors found in § 220(2)).

³⁸⁵ *Reid*, 490 U.S. at 752 (citing *Ward v. Atlantic Coast Line R.R. Co.*, 362 U.S. 396, 400 (1960)).

resembles a bench trial conducted before the United States District Courts.³⁸⁶ The parties are afforded the opportunity to present opening statements, brief legal issues, submit motions for appropriate relief, call, cross-examine, and have witnesses produced by process, present and object to offered evidence, and present closing arguments. The hearings are conducted at the DEA Hearing Facility in Arlington, Virginia, or at state and federal courthouses in locations across the United States.

A. Evidence and Burdens at the Hearing

While the Federal Rules of Evidence are not strictly applied to DEA administrative hearings,³⁸⁷ the evidence that can be considered is by no means unlimited. The APA provides that “[a] sanction may not be imposed or rule or order issued except on consideration of the whole record or those parts thereof cited by a party and supported by and in accordance with the reliable, probative, and substantial evidence.”³⁸⁸ Consistent with the APA’s directive to agencies to “provide for the exclusion of irrelevant, immaterial, or unduly repetitious evidence,”³⁸⁹ the DEA regulations restrict admissibility to “only evidence that is competent, relevant, material and not unduly repetitious.”³⁹⁰ Agency precedent binds the rulings of its ALJs, and the Agency has interpreted this regulation as constraining the ALJ to preclude evidence that has been found by the Agency to lie beyond these parameters.³⁹¹

The Agency has held that while it is true that the Federal Rules of Evidence and Federal Rules of Civil Procedure do not control admissibility at DEA administrative hearings, these rules should be consulted for guidance “where they do not conflict with agency

³⁸⁶ See *Butz v. Economou*, 438 U.S. 478, 512–13 (1978) (holding that in the context of the ALJ immunity, “there can be little doubt that the role of the modern federal hearing examiner or administrative law judge within [the framework of the APA] is ‘functionally comparable’ to that of a [U.S. District Court] judge”); MORELL E. MULLINS, ADMIN. CONFERENCE OF THE U.S., MANUAL FOR ADMINISTRATIVE LAW JUDGES 34 (3d ed. 1993) [hereinafter MANUAL FOR ADMINISTRATIVE LAW JUDGES] (“The formal administrative hearing is quite similar to a trial before a judge sitting without a jury.”).

³⁸⁷ See *In re Rosalind A. Cropper, M.D.*, 66 Fed. Reg. 41040, 41041 (Drug Enforcement Admin. Aug. 6, 2001) (finding that the Federal Rules of Evidence are not directly applied to DEA administrative hearings).

³⁸⁸ 5 U.S.C. § 556(d) (2012).

³⁸⁹ *Id.*

³⁹⁰ 21 C.F.R. § 1316.59(a) (2013).

³⁹¹ *David A. Ruben, M.D.*, 78 Fed. Reg. 38363, 38365 n.3 (Drug Enforcement Admin. June 26, 2013).

regulations.”³⁹² The APA guarantees each party to an administrative hearing the right “to present his case or defense by oral or *documentary evidence*.”³⁹³ The language employed by Congress makes it clear that the intent was not to open the floodgates to allow every manner of affidavit and hearsay paper into the record,³⁹⁴ but to allow for documents “as would be admissible in judicial proceedings, such as writings and records made in [the] regular course of business.”³⁹⁵ A contrary interpretation (that is, an interpretation that would allow either side to flood the record with otherwise inadmissible written statements) would unduly inhibit the right of a party “to conduct such cross-examination as may be required for a full and true disclosure of the facts,”³⁹⁶ or burden “them [with] assum[ing] the expense of calling the affiants for cross-examination.”³⁹⁷

It is, however, beyond argument that some hearsay evidence will be properly admitted and considered at federal administrative hearings.³⁹⁸ However, the weight afforded such testimony and, a fortiori, whether that testimony can support substantial evidence, is an entirely different matter. There are clearly due process limitations on the extent to which an adverse administrative determination can be founded in hearsay evidence.³⁹⁹ “[H]earsay may constitute substantial evidence in administrative proceedings as long as factors that assure the ‘underlying reliability and probative value’ of the evidence are present.”⁴⁰⁰ The Agency has

³⁹² *In re Cropper*, 66 Fed. Reg. at 41041 (citing *Sinatra v. Heckler*, 566 F. Supp. 1354, 1359 (E.D.N.Y. 1983)); *accord* Roy E. Berkowitz, M.D., 74 Fed. Reg. 36758, 36759 (Drug Enforcement Admin. July 24, 2009).

³⁹³ 5 U.S.C. § 556(d) (emphasis added).

³⁹⁴ MANUAL FOR ADMINISTRATIVE LAW JUDGES, *supra* note 3866, at 67 (“Relaxed rules of evidence may lull counsel into sloppiness, or deliberate tactics aimed at clouding the record with chaff.”).

³⁹⁵ ATTORNEY GENERAL’S MANUAL, *supra* note 2555, § 7(c), at 77.

³⁹⁶ 5 U.S.C. § 556(d).

³⁹⁷ ATTORNEY GENERAL’S MANUAL, *supra* note 2555, § 7(c) at 77 (citing *Powhatan Mining Co. v. Ickes*, 118 F.2d 105, 109 (6th Cir. 1941)).

³⁹⁸ *See* *Richardson v. Perales*, 402 U.S. 389, 402 (1971) (holding that signed reports prepared by licensed physicians were correctly admitted at a Social Security disability hearing); *Keller v. Sullivan*, 928 F.2d 227, 230 (7th Cir. 1991) (holding that an insurance company’s investigative reports were correctly admitted in a Social Security disability hearing where sufficient indicia of reliability was established); *Calhoun v. Bailar*, 626 F.2d 145, 148–49 (9th Cir. 1980) (holding that hearsay affidavits were correctly admitted where indicia of reliability was established).

³⁹⁹ *Basco v. Machin*, 514 F.3d 1177, 1182 (11th Cir. 2008).

⁴⁰⁰ *U.S. Pipe & Foundry Co. v. Webb*, 595 F.2d 264, 270 (5th Cir. 1979) (quoting *Richardson*, 402 U.S. at 402).

acknowledged that “[w]hile hearsay statements are admissible in administrative proceedings, and can even constitute substantial evidence under certain circumstances, to do so, the statements must bear sufficient indicia of reliability.”⁴⁰¹ Thus, the utility of hearsay evidence before an administrative tribunal is limited by its reliability and credibility,⁴⁰² and the Agency has not hesitated to disregard hearsay evidence found lacking in those respects.⁴⁰³ In practice, the Agency will look to the law of the appropriate circuit in order to determine whether hearsay is reliable and probative.⁴⁰⁴

In practice, the presiding ALJ will require that all proposed exhibits be marked and furnished to the ALJ in advance of hearing commencement. The proponent of each proposed exhibit will be required to lay an adequate foundation in support of admission, but the regulations provide that, in the discretion of the ALJ, authenticity objections not registered in advance of hearing commencement may be deemed waived.⁴⁰⁵

Expert opinion testimony may be received at the hearing, but the burden rests with the proponent of the testimony to establish the expert’s qualifications.⁴⁰⁶

Although the Agency’s final order is reviewed in the Circuit Courts based on whether it is supported by “reliable, probative, and

⁴⁰¹ Fred Samimi, M.D., 79 Fed. Reg. 18698, 18712 (Drug Enforcement Admin. Apr. 3, 2014).

⁴⁰² See *J.A.M. Builders, Inc. v. Herman*, 233 F.3d 1350, 1354 (11th Cir. 2000) (applying reliability and credibility factors to hearsay evidence admitted at an administrative hearing).

⁴⁰³ See *James William Eisenberg, M.D.*, 77 Fed. Reg. 45663, 45663 & n.3 (Drug Enforcement Admin. Aug. 1, 2012) (excluding double hearsay from consideration as insufficiently reliable); *Cleveland J. Enmon, Jr., M.D.*, 77 Fed. Reg. 57116, 57116 n.1 (Drug Enforcement Admin. Sept. 17, 2012) (excluding hearsay witness statements of clinic employees from consideration as insufficiently reliable); *Henri Wetselaar, M.D.*, 77 Fed. Reg. 57126, 57130 (Drug Enforcement Admin. Sept. 17, 2012) (excluding affidavits of purported interviews of physicians from consideration as insufficiently reliable); *Carlos Gonzales, M.D.*, 76 Fed. Reg. 63118, 63119 (Drug Enforcement Admin. Oct. 11, 2011) (excluding unsworn statements from consideration as insufficiently reliable). *But see* *Ralph J. Chambers, M.D.*, 79 Fed. Reg. 4962, 4971 (Drug Enforcement Admin. Jan. 20, 2014) (“Notwithstanding that the CS’s [confidential source] statements are hearsay and unsworn, [the Agency found] that they are reliable and entitled to weight given that several *other* of the CS’s hearsay statements were corroborated by other evidence.” (emphasis added)).

⁴⁰⁴ See, e.g., *Mireille Lalanne, M.D.*, 78 Fed. Reg. 47750, 44752 & n. 4 (Drug Enforcement Admin. Aug. 6, 2013).

⁴⁰⁵ 21 C.F.R. § 1316.59(c) (2013).

⁴⁰⁶ 5 U.S.C. § 556(d) (2012); see also 21 C.F.R. § 1316.56 (“At any hearing, the proponent for the issuance, amendment, or repeal of any rule shall have the burden of proof.”); *Allison v. McGhan Med. Corp.*, 184 F.3d 1300, 1306 (11th Cir. 1999) (“The burden of laying the proper foundation for the admission of the expert testimony is on the party offering the expert, and admissibility must be shown by a preponderance of the evidence.” (citing *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 592 n.10 (1993))).

substantial evidence,”⁴⁰⁷ the standard of proof applied at a DEA administrative hearing is whether the facts are established by a preponderance of the evidence.⁴⁰⁸ The proponent of any order⁴⁰⁹ at a DEA administrative hearing bears the burden of proof.⁴¹⁰

In most practitioner sanction hearings litigated at DEA administrative hearings, the government bears the burden of proof. The DEA regulations provide that where DEA seeks to revoke or suspend a controlled substance practitioner registration, it bears the burden of establishing the elements required in support.⁴¹¹ Where the Agency seeks to deny an application for a controlled substance registration for a practitioner, it bears the burden of proving that the applicant has not satisfied the requirements for registration.⁴¹²

B. Failure to Testify and Negative Inferences

Because many of the respondents in the cases brought before the DEA may also be involved in related criminal matters, it is not uncommon for a registrant to invoke his/her Fifth Amendment right against self-incrimination.⁴¹³ Where the evidentiary record is supportive, an adverse inference may correctly be drawn from a registrant’s silence.⁴¹⁴ The Supreme Court has upheld the taking of adverse inferences in civil proceedings where a party refuses to testify,⁴¹⁵ and it has noted that “[s]ilence gains more probative weight where it persists in the face of accusation, since it is

⁴⁰⁷ 5 U.S.C. § 556(d).

⁴⁰⁸ *Steadman v. SEC*, 450 U.S. 91, 100–01 (1981).

⁴⁰⁹ The APA definition of “order” includes “the whole *or a part* of a final disposition.” 5 U.S.C. § 551(6) (2012) (emphasis added).

⁴¹⁰ 5 U.S.C. § 556(d); *see* 21 C.F.R. § 1316.56 (“At any hearing, the proponent for the issuance, amendment, or repeal of any rule shall have the burden of proof.”).

⁴¹¹ 21 C.F.R. § 1301.44(e).

⁴¹² *Id.* § 1301.44(d). There are applications for other types of registrations where the applicant bears the burden of proof. *Id.* § 1301.44 (a)–(c).

⁴¹³ *See, e.g., Hoxie v. DEA*, 419 F.3d 477, 478–79 (6th Cir. 2005) (discussing a case where a physician chose not to testify at his administrative hearing when he faced charges for violating California’s controlled substance law and materially falsifying registration applications).

⁴¹⁴ *Id.* at 483; *MacKay v. DEA*, 664 F.3d 808, 819 (10th Cir. 2011); *Beau Boshers, M.D.*, 76 Fed. Reg. 19401, 19404 (Drug Enforcement Admin. Apr. 7, 2011); *Joseph Baumstarck, M.D.*, 74 Fed. Reg. 17525, 17528 & n.3 (Drug Enforcement Admin. Apr. 15, 2009). This adverse inference may be applied even when the government has not called the respondent as a witness and the respondent simply chooses not to testify. *Grider Drug #1 & Grider Drug #2*, 77 Fed. Reg. 44070, 44104 (Drug Enforcement Admin. Jul. 26, 2012).

⁴¹⁵ *Baxter v. Palmigiano*, 425 U.S. 308, 318 (1976).

assumed in such circumstances that the accused would be more likely than not to dispute an untrue accusation.”⁴¹⁶ Accordingly, the Agency has used a respondent’s silence to infer, inter alia, that the analysis and conclusions of the government’s expert witness are correct,⁴¹⁷ that the government’s allegations of misconduct are true,⁴¹⁸ and that a respondent has failed to accept responsibility for his/her misconduct (thus, failing to rebut the government’s prima facie case).⁴¹⁹ The government cannot, however, use a negative inference to establish an element upon which it has not presented any evidence.⁴²⁰

The availability of an adverse inference in DEA administrative proceedings is particularly significant in light of the burden structure created by Agency precedent. As discussed in detail, *supra*, where the government has established a prima facie case for the imposition of a sanction, the registrant is virtually unable to prevail without an acceptance of responsibility and a demonstration of remedial steps taken to ensure against future transgressions.⁴²¹ Thus, where the government has met its initial burden of production, it is not uncommon for a registrant (and his counsel) to face the Hobson’s choice of balancing the risk of an administrative sanction against the risk of potential self-incrimination.

C. *Interlocutory Appeals*

The regulations authorize the interlocutory review of an ALJ ruling by the Administrator prior to the issuance of a recommended decision, but only on a restricted basis.⁴²² Any interlocutory appeal must be made with the leave of the presiding ALJ and, even then, is only permitted upon the ALJ’s certification “on the record or in writing that the allowance of an interlocutory appeal is clearly

⁴¹⁶ *United States v. Hale*, 422 U.S. 171, 176 (1975).

⁴¹⁷ *See, e.g.*, Michael J. Aruta, M.D., 76 Fed. Reg. 19420, 19433 (Drug Enforcement Admin. Apr. 7, 2011); Beau Boshers, M.D., 76 Fed. Reg. 19401, 19404 (Drug Enforcement Admin. Apr. 7, 2011).

⁴¹⁸ *See, e.g.*, *Boshers*, 76 Fed. Reg. at 19404.

⁴¹⁹ *See, e.g.*, Sun & Lake Pharmacy, Inc., 76 Fed. Reg. 24523, 24533 (Drug Enforcement Admin. May 2, 2011); Dewey C. Mackay, M.D., 75 Fed. Reg. 49956, 49977 (Drug Enforcement Admin. Aug. 16, 2010).

⁴²⁰ Carlos Gonzalez, M.D., 76 Fed. Reg. 63118, 63118–19 (Drug Enforcement Admin. Oct. 11, 2011).

⁴²¹ Jeri Hassman, M.D., 75 Fed. Reg. 8194, 8236 (Drug Enforcement Admin. Feb. 23, 2010).

⁴²² 21 C.F.R. § 1316.62 (2013).

necessary to prevent exceptional delay, expense, or prejudice to any party or substantial detriment to the public interest.”⁴²³

If the presiding ALJ permits an interlocutory appeal, he/she will fix a briefing schedule to allow the parties to file briefs (in quintuplicate) in support of their relative positions.⁴²⁴ In theory, the regulations grant the Administrator authority to entertain oral argument on the merits of the interlocutory appeal,⁴²⁵ but, in practice, there is no mechanism for this to be accommodated.

Depending on the issue, and the extent to which the issue bears upon the conduct of the litigation, the proceedings may be (but are not required to be) stayed pending the resolution of the interlocutory appeal.

IX. POST-HEARING PROCEDURES

Following a hearing, the ALJ will provide the parties with the opportunity to file post-hearing briefs setting forth the parties’ proposed findings of fact and conclusions of law.⁴²⁶ The DEA regulations state that the ALJ must issue a recommended decision “[a]s soon as practicable after the time [allotted] for the parties to file” their post-hearing briefs.⁴²⁷ The recommended decision must include: “(1) [the ALJ’s] recommended rulings on the [parties’] proposed findings of fact and conclusions of law; (2) [the ALJ’s] recommended findings of fact and conclusions of law,” accompanied by the rationale behind such findings and conclusions; “and (3) [the ALJ’s] recommended decision” in the matter.⁴²⁸

Within twenty days of the service upon the parties of the recommended decision, the parties may file exceptions to the ALJ’s recommended decision (or file a response to an opposing party’s exceptions).⁴²⁹ No sooner than twenty-five (25) days after the issuance of the recommended decision, the ALJ must forward the recommended decision (along with the case file) to the

⁴²³ *Id.*

⁴²⁴ *Id.*

⁴²⁵ *Id.*

⁴²⁶ *Id.* § 1316.64. Generally, at the hearing, the parties will also be permitted to present oral argument in addition to, or in lieu of a post-hearing brief.

⁴²⁷ *Id.* § 1316.65(a).

⁴²⁸ *Id.* § 1316.65(a)(1)–(3).

⁴²⁹ *Id.* § 1316.66(a). To accommodate a party’s request to file a response, the ALJ may extend the time allowed for filing. *Id.* § 1316.66(c). However, each party is only allowed one filing. *Id.* A party on the prevailing side of an ALJ’s recommended decision may, as a matter of tactics, defer filing until the opposing party files exceptions.

Administrator for final review.⁴³⁰ The regulations direct the Administrator to issue a final order as soon as practicable after receipt of the ALJ's recommended decision.⁴³¹ The Administrator's final order will adopt, modify, or reject the recommended decision.⁴³² The final order must be published in the Federal Register and, absent a finding by the Administrator "that the public interest in the matter necessitates an earlier effective date," will not take effect less than thirty (30) days from the publication date.⁴³³ In reviewing the record and issuing a final order, the Administrator is not free to ignore the ALJ's recommended decision (particularly the ALJ's credibility findings).⁴³⁴ It is well settled that since the ALJ 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,⁴³⁵ and that the ALJ's recommended decision constitutes an important part of the record that must be considered in the Administrator's decision.⁴³⁶ That said, recommendations set forth in the ALJ's recommended decision regarding the exercise of discretion are not binding on the Administrator.⁴³⁷

The Agency may deviate from its previously issued precedential decisions, but to the extent it does so, it must "supply a reasoned analysis for the change."⁴³⁸

An aggrieved registrant⁴³⁹ may appeal the Agency final order issued by the Administrator "in the United States Court of Appeals

⁴³⁰ *Id.* § 1316.65(c).

⁴³¹ *Id.* § 1316.67.

⁴³² *See id.*

⁴³³ *Id.*

⁴³⁴ *See Morall v. DEA*, 412 F.3d 165, 177 (D.C. Cir. 2005); *Novelty, Inc. v. DEA*, 571 F.3d 1176, 1180–81 (D.C. Cir. 2009) (Henderson, J., concurring).

⁴³⁵ *Universal Camera Corp. v. NLRB*, 340 U.S. 474, 496 (1951).

⁴³⁶ *Morall*, 412 F.3d at 177, 179.

⁴³⁷ *See* 5 U.S.C. § 557(b) (2012); *River Forest Pharmacy, Inc. v. DEA*, 501 F.2d 1202, 1206 (7th Cir. 1974); ATTORNEY GENERAL'S MANUAL, *supra* note 2555, § 8(a), at 83 ("In making its decision, whether following an initial or recommended decision, the agency is in no way bound by the decision of its subordinate officer; it retains complete freedom of decision—as though it had heard the evidence itself. This follows from the fact that a recommended decision is advisory in nature.")

⁴³⁸ *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 42 (1983) ("Accordingly, an agency changing its course by rescinding a rule is obligated to supply a reasoned analysis for the change beyond that which may be required when an agency does not act in the first instance."); *accord Republic Airline Inc. v. U.S. DOT*, 669 F.3d 296, 300 (D.C. Cir. 2012) ("But where, as here, 'a party makes a significant showing that analogous cases have been decided differently, the agency must do more than simply ignore that argument.'" (quoting *LeMoyne-Owen Coll. v. NLRB*, 357 F.3d 55, 61 (D.C. Cir. 2004))).

⁴³⁹ The government is, of course, bound by the final order issued by the Administrator.

for the District of Columbia or for the circuit in which [the registrant's] principal place of business is located."⁴⁴⁰ A registrant seeking to appeal the Agency's decision must file the petition with the court "within thirty days after notice of the [final order]."⁴⁴¹ Copies of the petition must also be served upon the Administrator, who will certify the record and file it with the appropriate court.⁴⁴² On appeal, the factual findings of the Agency are conclusive if they are supported by "substantial evidence."⁴⁴³ In reviewing the Agency's reasoning, the court of appeals will set aside a final order if the order is "arbitrary, capricious, an abuse of discretion or otherwise not in accordance with the law."⁴⁴⁴

X. CONCLUSION

As administrative litigation regarding practitioner sanctions has become increasingly complex and nuanced, a greater degree of specialized knowledge of the practice and advance preparation are required to avoid unintended, adverse results. An unprepared or unschooled counsel can unwittingly choose a tactic or make a concession that can result in the loss of a medical or pharmaceutical practitioner's livelihood. Gone are the days when an able litigator can step in at the last minute with a plan no more complex than testing the other side's evidence and realistically anticipate a good result. The stakes are simply too high, and many of the tried and true tactical allies of the experienced trial lawyer operate in a different dimension in these proceedings. An ill-advised concession can be as disastrous as an across-the-board demurer.

⁴⁴⁰ 21 U.S.C. § 877 (2012).

⁴⁴¹ *Id.*

⁴⁴² 21 C.F.R. § 1316.68 (2013).

⁴⁴³ 21 U.S.C. § 877. In *Morall v. DEA*, the D.C. Circuit defined "substantial evidence" as "evidence which is substantial, that is, affording a substantial basis of fact from which the fact in issue can be reasonably inferred. Substantial evidence is more than a scintilla, and must do more than create a suspicion of the existence of the fact to be established." *Morall v. DEA*, 412 F.3d 165, 176 (D.C. Cir. 2005) (quoting *NLRB v. Columbian Enameling & Stamping Co.*, 306 U.S. 292, 299–300 (1939)) (internal quotation marks omitted).

⁴⁴⁴ *Humphreys v. DEA*, 96 F.3d 658, 660 (3d Cir. 1996) (citing 5 U.S.C. § 706(2)(A) (2012)); *Trawick v. DEA*, 861 F.2d 72, 77 (4th Cir. 1988); *accord Craker v. DEA*, 714 F.3d 17, 26 (1st Cir. 2013) ("[An agency] decision is arbitrary and capricious 'if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.'" (quoting *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983))); *Morall*, 412 F.3d at 178.

Representation in this forum requires a skillful trial attorney who, at a minimum, has acquired an understanding of the CSA, its attendant regulations, and the circuit and Agency precedents that serve as the navigation points through the murky, drug-infested waters of diversion litigation.