

# CURRENT NAVIGATION POINTS IN DRUG DIVERSION LAW: HIDDEN ROCKS IN SHALLOW, MURKY, DRUG-INFESTED WATERS<sup>†</sup>

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## I. INTRODUCTION

Drug diversion litigation continues to grow and evolve by leaps and bounds. While the practice has seen an increase in complexity over the years, the speed and scope of some recent developments have been striking, and in some respects confounding. Since the publication of the 2015 article about diversion practice in the *Albany Law Review*,<sup>1</sup> diversion practice under the Administrative

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Procedure Act (APA)<sup>2</sup> has been buffeted by the accounts in the press,<sup>3</sup> Congress,<sup>4</sup> and swerves in legal interpretation in the published final orders issued by the Drug Enforcement Administration (the DEA or the Agency).<sup>5</sup> Whether viewed as clarifications, enhancements, or afflictions, the modifications visited on diversion enforcement by Congress and the DEA itself will require some significant course adjustments by the practicing bar on both sides of the litigation equation.

This update is divided into three sections: Part II will address diversion law alterations crafted by Congress and signed by President Barack Obama; Part III will analyze new legal interpretations by the Agency in its final orders; and Part IV will parse the legal landscape for a current location check, some possible clues for what lies over the horizon for the enforcers, the regulated community, and the attorneys on both sides of the aisle, as well as some thoughts about why where we are now seems so different from where we were previously headed. Even without legal sonar or a crystal ball, there is merit to engaging in a measured level of informed reckoning about where rocks and hazards are likely to linger below the surface of the murky, drug-infested waters of diversion litigation.

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1. John J. Mulrooney, II & Andrew J. Hull, *Drug Diversion Administrative Revocation and Application Hearings for Medical and Pharmacy Practitioners: A Primer for Navigating Murky, Drug-Infested Waters*, 78 ALB. L. REV. 327 (2015).

2. Administrative Procedure Act, 5 U.S.C. §§ 551–59 (2012).

3. See, e.g., Lenny Bernstein & Scott Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, WASH. POST, Oct. 23, 2016, at A1; Editorial Board, *Locating Blame in the Opioid Epidemic*, WASH. POST: THE POST’S VIEW (Oct. 30, 2016), <https://www.washingtonpost.com/opinions/is-the-dea-partly-to-blame-for-the-opioid-epidemic/2016/10/30/> (insert URL into Google.com search engine; then follow “Locating blame in the opioid epidemic – The Washington Post” hyperlink) [hereinafter, THE POST’S VIEW].

4. See *infra* Part II.

5. See *infra* Part III.

## II. CONGRESS AND THE PRESIDENT

On April 19, 2016, President Obama signed the Ensuring Patient Access and Effective Drug Enforcement Act of 2016 (EPAEDEA) into law.<sup>6</sup> The co-sponsors of the EPAEDEA touted the amendment as a measure to “bring much-needed clarity to several key provisions of the Controlled Substances Act” and to “facilitate greater collaboration between registrants and relevant federal actors in combatting prescription drug abuse.”<sup>7</sup>

The EPAEDEA amends the Controlled Substances Act (CSA) in three respects: (1) any registrant served with an order to show cause (OSC) may now submit a corrective action plan (CAP) to the Agency, which the Agency must consider in order to determine whether it justifies the discontinuance or deferral of administrative proceedings; (2) the term “imminent danger to the public health or safety,”<sup>8</sup> a prerequisite finding to justify the issuance of an immediate suspension order, has been defined, or some would say, born; and (3) the phrase “factors as may be relevant to and consistent with the public health and safety,” which is the language used in the catch-all public interest factors to be considered by the Agency in determining whether to register or maintain registration for manufacturers<sup>9</sup> and distributors<sup>10</sup> of controlled substances, has been defined.<sup>11</sup>

### A. *The Corrective Action Plan (CAP)*

#### 1. The EPAEDEA’s CAP Provision’s Additions, Justifications, and Problems

Previously, the OSC to be served on the applicant or registrant was only required to “contain a statement of the basis” for the Agency’s proposed denial, revocation, or suspension of registration, and to provide a time and place for the applicant or registrant to appear.<sup>12</sup> The EPAEDEA added the requirement that every OSC issued by the DEA must “notify the applicant or registrant of the opportunity to submit a corrective action plan on or before the date of

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6. Ensuring Patient Access and Effective Drug Enforcement Act of 2016, Pub. L. No. 114-145, 130 Stat. 353 (to be codified at 21 U.S.C. §§ 823(j), 824(c), (d)).

7. 162 CONG. REC. S954 (daily ed. Feb. 23, 2016) (statement of Sen. Hatch).

8. Ensuring Patient Access and Effective Drug Enforcement Act of 2016 § 2 (to be codified at 21 U.S.C. § 824(d)(1)).

9. 21 U.S.C. § 823(a)(6), (d)(6) (2012).

10. *Id.* § 823(b)(5), (e)(5). The language is also similar to the catch-all factor for distributors of List I chemicals, but is not exactly the same. *Id.* § 823(h)(5) (“[S]uch other factors as *are* relevant to and consistent with the public health and safety.”) (emphasis added).

11. Ensuring Patient Access and Effective Drug Enforcement Act of 2016 § 2 (to be codified at 21 U.S.C. §§ 823(j), 824(c), (d)).

12. 21 U.S.C. § 824(c).

appearance.”<sup>13</sup> The EPAEDEA also added the requirement that, if a CAP is timely filed by a registrant, the Agency is required to consider it to “determine whether denial, revocation, or suspension proceedings should be discontinued or deferred for the purposes of modification, amendment, or clarification to such plan.”<sup>14</sup> Stated differently, before the DEA can proceed to secure an administrative sanction against a registration holder or deny an application for registration, it must now consider a written improvement plan, filed by the registrant or applicant, which outlines that registrant or applicant’s intentions to correct the regulatory transgressions alleged in the OSC.<sup>15</sup>

Co-sponsors of the EPAEDEA promoted the CAP provisions as “provid[ing] the DEA with the clarity to collaborate with the very people responsible for ensuring that [controlled substances] get to the patients who need them without hurting and harming th[e] distribution chain and while clamping down on diversions and abuse.”<sup>16</sup> It was touted as “a mechanism for companies<sup>17</sup> who inadvertently violate the Controlled Substances Act . . . to remediate the violation before their registration is suspended and the supply of drugs to patients is interrupted.”<sup>18</sup> It was explained that the EPAEDEA would “encourage greater self-reporting of violations,” while helping to “ensure that supply chains remain intact for legitimate uses such as the alleviation of pain and illness.”<sup>19</sup> One co-sponsor described the CAP as “a mechanism for companies that violate the Controlled Substances Act to correct their practices” before their registration is suspended or revoked, noting that “[e]ven inadvertent violations may lead to suspension or revocation, disrupting the supply chain for the company’s prescription drugs[, which] in turn can cause hardship for patients who rely on the company’s drugs for treatment and cure.”<sup>20</sup> In sum, the CAP was touted primarily as a method to ensure that patients continue to retain access (hence the “ensuring patient access” feature of the bill’s cumbersome title) to controlled substances in the event of

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13. Ensuring Patient Access and Effective Drug Enforcement Act of 2016 § 2 (to be codified at 21 U.S.C. § 824(c)(2)(C)).

14. *Id.* (to be codified at 21 U.S.C. § 824(c)(3)).

15. *Id.*

16. 161 CONG. REC. H2330 (daily ed. Apr. 21, 2015) (statement of Rep. Blackburn).

17. While the co-sponsors repeatedly emphasized the benefits of the CAP for “companies,” the bill does not limit the classes of registrants or applicants who can submit a CAP, and thus all registrants and applicants—individual practitioners, pharmacies, distributors, and manufacturers—can submit a CAP to the Agency.

18. 162 CONG. REC. S954-02 (daily ed. Feb. 23, 2016) (statement of Sen. Hatch).

19. *Id.*

20. 162 CONG. REC. S2006 (daily ed. Apr. 13, 2016) (statement of Sen. McConnell).

“inadvertent violations”<sup>21</sup> of the Controlled Substances Act by “companies”<sup>22</sup> in the distribution supply chain.<sup>23</sup>

The stated justification for the CAP is significantly undermined, however, by an absence of evidence in the Congressional Record or elsewhere to support the position that pending administrative proceedings in any way limit even a single patient’s access to medication, the purported reason the bill was introduced in the first place.<sup>24</sup> By the terms of the statute, the CAP provisions do not apply to the Administrator’s determination regarding an immediate suspension pending resolution,<sup>25</sup> and in every other adjudication, registrants retain their authority to conduct regulated activities until the Agency issues its final order.<sup>26</sup> Stated differently, if a registrant or applicant is served with an OSC but believes that it has made sufficient improvements to its operating procedures to ensure that the transgressions charged do not re-occur (or if it believes that the transgressions charged did not actually occur), it has—and had before the EPAEDEA—the right to request an administrative hearing and present evidence on its own behalf before any sanction can be imposed upon it.<sup>27</sup> Registrants and applicants have always been afforded the opportunity to present evidence of any corrective actions they have taken to ensure that the charged conduct does not continue, including plans to avoid future

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21. *Id.*; 162 CONG. REC. S954 (daily ed. Feb. 23, 2016) (statement of Sen. Hatch).

22. 162 CONG. REC. S2006 (daily ed. Apr. 13, 2016) (statement of Sen. McConnell); *see* 162 CONG. REC. S954 (daily ed. Feb. 23, 2016) (statement of Sen. Hatch).

23. 162 CONG. REC. S2006 (daily ed. Apr. 13, 2016) (statement of Sen. McConnell); *see* 162 CONG. REC. S954 (daily ed. Feb. 23, 2016) (statement of Sen. Hatch).

24. *See generally* 162 CONG. REC. S2006 (daily ed. Apr. 13, 2016) (statement of Sen. McConnell); 162 CONG. REC. S954 (daily ed. Feb. 23, 2016) (statement of Sen. Hatch).

25. Ensuring Patient Access and Effective Drug Enforcement Act of 2016, Pub. L. No. 114-145, § 2, 130 Stat. 353 (to be codified at 21 U.S.C. § 824(c)(5)). When served on a registrant, an Immediate Suspension Order (ISO/OSC) is accompanied by an OSC, affording the opportunity for post-deprivation due process. *See* Mulrooney & Hull, *supra* note 1, at 364–65 (describing Immediate Suspension proceedings). The decision to immediately suspend a registration is a final decision by the Agency, and while a registrant could potentially submit a CAP in response to the accompanying OSC, a determination on that CAP could in no way affect the already-final decision to immediately suspend the registration. However, inasmuch as every ISO/OSC has an accompanying OSC, the CAP provisions are available to respondents in all administrative proceedings, whether commenced with an ISO/OSC or an OSC. It would, thus, be inaccurate to broadly state that the CAP provisions do not apply to immediate suspension cases.

26. Ensuring Patient Access and Effective Drug Enforcement Act of 2016 § 2 (to be codified at 21 U.S.C. § 824(c)(1)) (“*Before taking action pursuant to this section, or pursuant to a denial of registration under [21 U.S.C. § 823], the Attorney General shall serve upon the applicant or registrant an order to show cause why registration should not be denied, revoked, or suspended.*”) (emphasis added). *See also* 21 U.S.C. § 824(c) (2012).

27. Ensuring Patient Access and Effective Drug Enforcement Act of 2016 § 2 (to be codified at 21 U.S.C. § 824(c)(1)); *see also* 21 U.S.C. § 824(c).

transgressions, and the Agency has always considered such evidence in making its final determination on whether to preclude or curtail the applicant or registrant's regulated activities.<sup>28</sup> Similarly, the parties have always been able to discuss the merits of the case amongst themselves, either before a request for a hearing is made or during the pendency of the administrative proceedings, and if an applicant or registrant offers a proposed plan of corrective action and the Agency (through counsel representing it in the administrative proceeding) determines that it is no longer prudent to continue administrative proceedings, then the Agency (the party which initiated proceedings in the first place) is free to seek termination of the case, which the DEA Administrative Law Judge (ALJ) will grant. Inasmuch as DEA administrative proceedings are remedial<sup>29</sup> and non-punitive in nature,<sup>30</sup> a written proposal to correct alleged deficiencies should, of course, merit special consideration by the Agency in its evaluation of the prudence and expense of continuing to seek preclusion or curtailment of regulated activity, but there was no apparent reason for the EPAEDEA to direct that such a proposal be considered and ruled upon in isolation, outside of an ongoing administrative proceeding. If, in the Agency's view, a proposed plan of action merits discontinuation or deferral of proceedings, it is (and has always been) free to seek termination of administrative proceedings at any time, or it can decide by final order that no sanction is appropriate based on all of the facts, including any remedial actions taken and plans put in place. Thus, the EPAEDEA's CAP provisions present as a solution to a problem that did not (and does not) seem to exist.

Furthermore, the CAP provisions create no incentive (and potentially create a disincentive) for regulated companies or individuals to "self-report[] . . . violations,"<sup>31</sup> to correct wrongdoing before an OSC is filed, or even to follow or continue following whatever plan is deemed sufficient to discontinue or defer proceedings once the proceedings are discontinued or deferred. Instead, the EPAEDEA is akin to a state legislature mandating that law enforcement authorities allow shoplifting suspects caught in the act to

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28. See, e.g., *Farmacia Yani*, 80 Fed. Reg. 29053, 29066 (Drug Enf't Admin. May 20, 2015); *Terese, Inc.*, 76 Fed. Reg. 46843, 46848 (Drug Enf't Admin. Aug. 3, 2011). While the Agency only considers evidence of remedial measures if a registrant accepts responsibility for past transgressions, *Jayam Krishna-Iyer*, 74 Fed. Reg. 459, 464 (Drug Enf't Admin. Jan. 6, 2009) ("Because of the grave and increasing harm to public health and safety caused by the diversion of prescription controlled substances, even where the Agency's proof establishes that a practitioner has committed only a few acts of diversion, this Agency will not grant or continue the practitioner's registration unless he accepts responsibility for his misconduct."), a registrant who submits a *corrective* action plan is necessarily admitting that there is something to be corrected.

29. *Farmacia Yani*, 80 Fed. Reg. at 29066.

30. Samuel S. Jackson, D.D.S., 72 Fed. Reg. 23848, 23853 (Drug Enf't Admin. Apr. 24, 2007).

31. 162 CONG. REC. S954 (daily ed. Feb. 23, 2016) (statement from Sen. Hatch).

outline how they intend to replace purloined items on store shelves; allow intoxicated drivers to pull to the side of the road and park their previously swerving vehicles; or perhaps allow bank robbers to round up and return ink-stained money and agree not to rob any more banks—all before any of those wrongdoers actually admit fault and without any consequence that might deter such behavior in the future. Such mandates sound absurd because they would be absurd. The ability to submit a written plan for improvement may provide incentive for registrants to step up their compliance once charges are filed—or at least, outline a plan and promise to do so—but before that time, they can act freely knowing that they can always come up with a convincing plan to fix their problems later and avoid sanction.<sup>32</sup> And, even in cases where the Agency does elect to discontinue proceedings based on a CAP, the statutory mechanism designed by Congress in the EPAEDEA provides no guarantee that the promises made in the CAP will be fulfilled, or for how long.<sup>33</sup> Assurances by the CAP filers are not required, and the EPAEDEA provides no consequences to unfulfilled CAP representations—even in cases where those representations result in the discontinuation of proceedings.<sup>34</sup> The only thing assured by the Agency’s discontinuance of proceedings through the acceptance of a CAP is that administrative proceedings will be discontinued.<sup>35</sup> The benefits for industry are plain, but for the public, the benefits are not as clear.

To the extent the legislation was driven by the hypothetical potential that the flow of painkillers could be interrupted due to improvident Agency revocations supported only by inadvertent, even minor, isolated violations, the law could have been crafted to achieve that objective. For example, the focus of the bill could have been directed to imbuing the CSA with a sanctions

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32. One co-sponsor explained that “the best example of why [the EPAEDEA] is needed is a story that comes from home,” going on to detail an account of a constituent who tried to obtain seizure medications for her son in anticipation of an ice storm (lamenting that it was one of many that winter, which “seemed as if [they] would never stop”), but—although the pharmacist was sympathetic—the pharmacy would not fill the prescription because “it was too early” and “there would be problems with the DEA and other agencies” if it were filled. 161 CONG. REC. H2330 (daily ed. Apr. 21, 2015) (statement of Rep. Blackburn). It is unclear exactly how such a registrant (if an OSC was filed for filling such prescriptions) would propose any convincing corrective action for that violation, other than maybe the pharmacist would feel less sympathetic next time and would refuse to fill the prescription. A considered reflection of the story reveals it to be a sort of advocacy for an after-the-fact forgiveness for actions founded in sympathy which ultimately result in “ensur[ing] that patients who have a legitimate need for medications can receive them,” even if those actions are clear, intentional violations of the CSA. *Id.* Whatever heart strings are pulled by the story of the reluctantly compliant pharmacist, it would be challenging to fashion the morale of the tale into any objectives supported by the provisions of the EPAEDEA as it was enacted.

33. *See generally* Ensuring Patient Access and Effective Drug Enforcement Act of 2016, Pub. L. No. 114-145, 130 Stat. 353 (to be codified at 21 U.S.C. §§ 823(j), 824(c), (d)).

34. *Id.*

35. *Id.*



framework founded in Congress's assessment of the seriousness of specific violations. Congress could have supplied guidance to the exercise of Agency discretion in particular types of cases or where conduct rose to a certain level. Likewise, the Agency could have been directed to give additional weight to remedial evidence in weighing the sanction decision, or Congress could have otherwise modified the CSA to address concerns regarding medication availability when a registration is ultimately revoked or limited by the Agency. The list of possible methods to address patient access to controlled substances under these limited circumstances is potentially limitless, but the path chosen instead was to enact legislation that created new rights for industry, and left the Agency without guidance as to how to implement the new laws.

## 2. The Agency's Treatment of the CAP Provisions

The new legislation provides only that, "[u]pon review of any [CAP] submitted by an applicant or registrant . . . the Attorney General shall determine whether denial, revocation, or suspension proceedings should be discontinued, or deferred for the purposes of modification, amendment, or clarification to such plan."<sup>36</sup> It does not specify what date is meant by the filing deadline of "on or before the date of appearance,"<sup>37</sup> and it provides neither a procedure for the filing of a CAP, nor the standards to be applied to adjudicate it. The EPAEDEA likewise does not provide guidance to the Agency about the supervisory level within the organization at which the CAP should be evaluated, and it does not provide an indication of the criteria by which the Agency is to evaluate filed CAPs, or the procedure or timeline for the Agency to follow once it determines whether (or not) to discontinue or defer proceedings. The CAP legislation provides for no review of the plan by a DEA ALJ in the event that proceedings are not discontinued or deferred, and it is silent on whether administrative proceedings should be abrogated or delayed in the event of a CAP filing, or if they should continue to proceed concurrently with whatever timeline on which the CAP review proceeds.

Enabling regulations have not yet been promulgated. In the absence of regulations, the Agency has supplied instructions regarding EPAEDEA CAP rights (CAP advisals) on OSCs it has issued since EPAEDEA became effective.<sup>38</sup> However, at least in one case, the manner in which the Agency has adjudicated a CAP raises an interesting issue.

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36. *Id.* (to be codified at 21 U.S.C. § 824(c)(3)).

37. *Id.* (to be codified at 21 U.S.C. § 824(c)(2)(C)).

38. *See generally, e.g.*, Marcus W. Anderson, M.D., 82 Fed. Reg. 42117, 42118–19 (Drug Enf't Admin. Sept. 6, 2017); Binh M. Chung, M.D., 82 Fed. Reg. 40601, 40602 (Drug Enf't Admin. Aug. 25, 2017); Arnold E. Feldman, M.D., 82 Fed. Reg., 39614, 39616 (Drug Enf't Admin. Aug. 21, 2017).

In *Thomas Horiagon, M.D.*, the Agency explained that its OSC “notified [r]espondent of his right under 21 U.S.C. § 824(c)(2)(C) to submit a [CAP] to the Deputy Assistant Administrator and [provided] the procedure for doing so.”<sup>39</sup> This is a strong indicator of the Agency’s intent to avoid the creation of an appealable final order by having the CAP issue decided by the Deputy Assistant Administrator, rather than the Administrator. The *Horiagon* final order noted that the Deputy Assistant Administrator did issue a CAP decision, but it also included a CAP determination by the Administrator that was based on an alternate legal theory.<sup>40</sup> Thus, the CAP determination was ultimately rendered by the Agency head.

The APA provides that:

[a]gency action made reviewable by statute and final agency action for which there is no other adequate remedy in a court are subject to judicial review. A preliminary, procedural, or intermediate agency action or ruling not directly reviewable is subject to review on the review of the final agency action.<sup>41</sup>

Apart from interlocutory appeals considered and decided by the Administrator,<sup>42</sup> administrative decisions rendered by its ALJs<sup>43</sup> and program heads<sup>44</sup> have historically been considered preliminary, procedural, or intermediate—and thus, are not directly reviewable. If the Agency elected to leave a decision regarding the CAP up to the Deputy Assistant Administrator (or some other subordinate official)—rather than the Administrator—it would

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39. *Thomas Horiagon, M.D.*, 81 Fed. Reg. 79051, 79051 (Drug Enf’t Admin. Nov. 10, 2016).

40. *Id.* at 79052 (concluding “that there [were] adequate grounds for denying [the CAP]” and that Administrator therefore “reject[ed] [the r]espondent’s CAP.”).

41. 5 U.S.C. § 704 (2012).

42. 21 C.F.R. § 1316.62 (2017).

43. *E.g.*, *id.* § 1316.47(b) (giving ALJ discretion to rule upon a request to enlarge the time granted to a respondent to answer an OSC); *id.* § 1316.50 (giving ALJ discretion to require notarized power of attorney from representative regarding scope of authority); *id.* § 1316.52 (providing non-exhaustive list of discretionary determinations entrusted to ALJs during DEA administrative proceedings); *id.* § 1316.57 (giving ALJ discretion to exclude, or upon good cause, admit evidence not timely disclosed by a party); *id.* § 1316.58 (giving ALJ discretion to direct pre-hearing summaries of proposed witness testimony); *id.* § 1316.62 (giving ALJ discretion to rule upon a motion seeking leave to file an interlocutory appeal).

44. *E.g.*, *id.* § 1301.16 (requiring permission from the Agency for certificate of registration application withdrawals after the issuance of an OSC); *Matthew Valentine/Liar Catchers*, 80 Fed. Reg. 50042, 50043 (Drug Enf’t Admin. Aug. 18, 2015) (noting that DEA Administrator had previously remanded case involving application withdrawal denial issued by the Deputy Assistant Administrator for Diversion Control (DAADC) for additional detail, reviewed and disregarded the discretionary decision issued by the DAADC, granted the applicant’s withdrawal application, and determined that the entire case was moot); *see also* Bobby D. Reynolds, N.P., 80 Fed. Reg. 28643, 28643 n.2 (Drug Enf’t Admin. May 19, 2015) (reviewing application withdrawal request that had been filed exclusively with the DAADC sua sponte, DEA Administrator acted absent any request by either party to do so).

likely avoid the unintentional issuance of an appealable final order. However, to the extent the Agency has already issued written CAP denials signed by the Agency head (in addition to ruling on a CAP in a final order dispositive of a whole case), it may have inadvertently created a path for ready review by the federal courts. If a CAP denial issued by the DEA Administrator constitutes a final order of the Agency, a denial of the requested relief (discontinuance or deferral of proceedings) could be subject to potential review in the courts. Congress has authorized “any person aggrieved by a final decision of the [DEA Administrator]” under the CSA to seek review “in the United States Court of Appeals for the District of Columbia or for the circuit in which his principal place of business is located . . . .”<sup>45</sup>

If an order issued by the Administrator is not a final action, under the APA, then it must be “preliminary, procedural, or intermediate action” that is “subject to review on the review of the final agency action.”<sup>46</sup> However, the final agency action in DEA administrative cases is the ultimate determination by the Administrator regarding the disposition of administrative sanction action.<sup>47</sup> The final action may be informed by a recommended decision by a DEA ALJ where a hearing was requested and held.<sup>48</sup> Because the CAP is filed separately from a request for hearing (or waiver),<sup>49</sup> it is not automatically part of the administrative record to be reviewed by the Agency—and neither is any decision issued regarding the CAP. In order for the CAP and the Agency’s decision to continue proceedings despite a filed CAP to even be considered in the Agency’s final order, the aggrieved party would need to somehow appeal the “preliminary” decision made to continue proceedings<sup>50</sup> to the Administrator through the process of the administrative hearing. In the instance where the Administrator signed a decision wherein the Agency declined to discontinue or defer proceedings at some point prior to consideration of the administrative record, this would place the parties in the position of appealing the Administrator’s own determination to the same Administrator to determine whether to affirm his previous decision, or would at least create the anomalous result of having the DEA Administrator review his own decision at the time a final order is issued—with no warrant for doing so in the EPAEDEA or the regulations. While the APA affords an agency head authority to issue a final

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45. 21 U.S.C. § 877 (2012).

46. 5 U.S.C. § 704.

47. 21 C.F.R. §§ 1301.46, 1316.67.

48. *Id.* §§ 1301.43, 1316.47, 1316.65(a).

49. *See id.* § 1301.43 (authorizing responses to an OSC); Thomas Horiagon, M.D., 81 Fed. Reg. 79051, 79051 (Drug Enf’t Admin. Nov. 10, 2016) (referencing the OSC instruction to “submit a [CAP] to the Deputy Assistant Administrator and the procedure for doing so.”).

50. *See* 21 C.F.R. § 1301.43; *Horiagon*, 81 Fed. Reg. at 79051.

order in administrative proceedings, the specter of having an appeal of the Administrator's decision to himself risks an imprudent buffeting of the Supreme Court's admonition that "no man can be a judge in his own case."<sup>51</sup>

The CAP is a new phenomenon, and it is reasonable to assume that the Agency's approach will benefit from some level of evolution. That said, to the extent that the DEA elects to have its Administrator review CAP submissions in the first instance, it enhances the opportunity for judicial review of any decision declining to discontinue or defer proceedings.

In view of the highly-regulated and technical nature of the registrants who engage in controlled substance regulated activity, the determination by Congress that the regulating agency is required (not merely permitted) to consider a remedial plan that is submitted to it,<sup>52</sup> by even the most egregious violators of standards that have been static and in place for decades, before proceeding with administrative proceedings, is a remarkable step. The CAP decision to discontinue or defer proceedings—a decision entirely separate from the formal administrative process that affords pre- or post-deprivation due process to all registrants and potential registrants of the Agency<sup>53</sup>—is undoubtedly now an important one for the Agency. If, as may well be the case, CAP submissions and the Agency's decision of whether to discontinue or defer proceedings based upon those submitted CAPs are ultimately subject to review by the courts, the regulated community may eventually enjoy the benefits of an evolving body of case law that mandates the discontinuation or deferral of administrative proceedings where various levels of remediation are convincingly proposed. To the extent it blossoms, judicial review of CAP determinations will likely provide decades of fertile litigation opportunities for the regulated community and will add an additional litigation burden on DEA regulators.

*B. Imminent Danger to Public Health and Safety for Immediate Suspension Orders*

Under the CSA, the DEA Administrator has authority<sup>54</sup> to immediately suspend a registration, and to keep that registration suspended during the pendency of administrative revocation proceedings, in any case "where he finds

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51. *In re Murchison*, 349 U.S. 133, 136 (1955).

52. Ensuring Patient Access and Effective Drug Enforcement Act of 2016, Pub. L. No. 114-145, § 2, 130 Stat. 353 (to be codified at 21 U.S.C. § 824(c)(2)(c)).

53. *Id.*

54. The statute assigns this authority to the Attorney General, who has delegated it to the DEA Administrator. 28 C.F.R. § 0.100(b), 0.103(a) (2017).

that there is an imminent danger to the public health or safety.”<sup>55</sup> The EPAEDEA created, for the first time, a statutory definition for the phrase “imminent danger to public health and safety.”<sup>56</sup>

The Administrator has always been required to determine that an “imminent danger to the public health or safety” exists before immediately suspending a registration.<sup>57</sup> However, before the EPAEDEA, that language was not specifically defined in the statute,<sup>58</sup> and was broad enough to afford the Agency head with latitude to make a determination as to whether, informed by the Agency’s expertise and experience, particular conduct or circumstances posed such a threat.<sup>59</sup> In fact, given that this extraordinary measure depends on post-deprivation due process, it is remarkable that during the more than four decades that a long line of Administrators had been determining whether there was an “imminent danger to the public health and safety” to justify immediately suspending a registration before that phrase was defined in the EPAEDEA, apart from a forty-year-old case from the Fifth Circuit Court of Appeals,<sup>60</sup> and a small handful of isolated unpublished exceptions from the district courts,<sup>61</sup> the courts have historically sustained the Administrators’ pre-EPAEDEA determinations of an imminent threat to public health and safety.<sup>62</sup> It is equally remarkable that, notwithstanding the dearth of court review of this public-safety tool, or any other readily apparent reason, Congress determined that the “imminent danger to public health and safety” standard required a statutory definition that imposed a dramatic diminution of the Agency’s authority to issue

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55. 21 U.S.C. § 824(d) (2012); *see* 21 C.F.R. § 1301.36(e) (2017).

56. Ensuring Patient Access and Effective Drug Enforcement Act of 2016 § 2 (to be codified at 21 U.S.C. 824(d)).

57. Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, 84 Stat. 1256 (codified at 2 U.S.C. § 304).

58. *See* 21 U.S.C. § 824(d) (2012).

59. The regulations provide that the immediate suspension order “shall contain a statement of [the Administrator’s] findings regarding the danger to the public health or safety.” 21 C.F.R. § 1301.36(e) (2017).

60. *Norman Bridge Drug Co. v. Banner*, 529 F.2d 822, 824–25, 828 (5th Cir. 1976) (finding that the Administrator’s ISO was unsupported due to staleness based on a seven-month delay in its issuance).

61. *See, e.g., Bates Drug Stores, Inc. v. Holder*, 2011 WL 1750066 \*3 (E.D. Wash. 2011); *Apothecary Arts Pharmacy, Inc. v. Gonzales*, Civ. No. 06-119 (D.D.C. Feb. 3, 2006), ECF No. 5; *MacKay v. Bolman*, No. 2:09cv285 (D. Utah Apr. 7, 2009), ECF No. 13.

62. *See, e.g., Novelty Distribs. v. Leonhart*, 562 F. Supp. 2d 20, 27–28 (D.D.C. 2008); *Neil Laboratories, Inc., v. Ashcroft*, 217 F. Supp. 2d 80, 87 (D.D.C. 2002).

Immediate Suspension Orders (ISOs)<sup>63</sup> at a time when, by all accounts, opioid abuse, addiction, and deaths were increasing markedly.<sup>64</sup>

In an effort to supply additional definition to the phrase “imminent danger to public health and safety,” EPAEDEA enhanced the required showing to secure an ISO with the following language:

[T]he phrase “imminent danger to public health or safety” means that, due to the failure of the registrant to maintain effective controls against diversion or otherwise comply with the obligations of a registrant under [the CSA], there is a substantial likelihood of an immediate threat that death, serious bodily harm, or abuse of a controlled substance will occur in the absence of an immediate suspension of the registration.<sup>65</sup>

In the post-EPAEDEA era, for the Agency to support the Administrator’s determination that the public health and safety is imperiled without a cessation of regulated activity while (often lengthy) administrative revocation proceedings are conducted, the Agency now bears the high burden of establishing that there is a “substantial likelihood” that a registrant’s failure “to maintain effective controls against diversion,” or non-compliance with the CSA, will result in an “immediate threat” of specific, enumerated harms, *to wit*: “death, serious bodily harm, or abuse of a controlled substance.”<sup>66</sup>

Even apart from the onerous task of demonstrating a link between a registrant’s alleged transgressions and an impending death, serious bodily harm, or abuse, the Agency now must shoulder the burden of showing that the “likelihood” of those evils, based on the purported transgressions, is “substantial.”<sup>67</sup> The courts have concluded in other contexts that “substantial likelihood” means that the referenced event or circumstance is “considerably more likely.”<sup>68</sup> Thus, before a single witness is produced or any piece of evidence admitted at a hearing, to sustain its ISO, the DEA is now required to establish by substantial evidence that the transgression(s) or violation(s) it has encountered will render death, serious bodily harm, or abuse considerably and imminently more likely.<sup>69</sup> However unlikely the Agency is to successfully bear

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63. See Ensuring Patient Access and Effective Drug Enforcement Act of 2016, Pub. L. No. 114-145, § 2, 130 Stat. 353 (to be codified at 21 U.S.C. § 824(d)(2)).

64. See, e.g., Centers for Disease Control and Prevention, <https://www.cdc.gov/drugoverdose/epidemic> (last visited Sept. 21, 2017).

65. Ensuring Patient Access and Effective Drug Enforcement Act of 2016 § 2 (to be codified at 21 U.S.C. § 824(d)(2)).

66. *Id.*

67. *Id.*

68. See, e.g., *United States v. Thorn*, 317 F.3d 107, 117 (2d Cir. 2003), *aff’d* 446 F.3d 378, 383 (2d Cir. 2006) (considering the term “substantial likelihood” in the context of the U.S. Sentencing Guidelines); *United States v. Mathis*, 738 F.3d 719, 740 (6th Cir. 2013) (same).

69. *Mathis*, 738 F.3d at 740.

this heavy burden in the case of individual practitioners or pharmacies, it is all but logically impossible, due to the obvious attenuation between the distributor or manufacturer registrant and the potential victims, to make the requisite showing up the production chain, in the case of a distributor or manufacturer. Stated differently, there are simply too many levels between distributors and manufacturers to logically establish any causation of death, serious bodily harm, or abuse to a specific patient down the chain to support an immediate suspension after the EPAEDEA. If it had been the intent of Congress to completely eliminate the DEA's ability to ever impose an immediate suspension on distributors or manufacturers, it would be difficult to conceive of a more effective vehicle for achieving that goal.

*C. Defining "Factors As May Be Relevant to and Consistent with the Public Health and Safety"*

The new definition of "imminent danger to the public health and safety" and the CAP provisions received the most attention when the EPAEDEA was signed by President Obama on April 19, 2016.<sup>70</sup> In fact, even the White House Statement that issued on the day that the EPAEDEA was signed by President Obama fails to mention the third change that the EPAEDEA made to the CSA.<sup>71</sup> Although it received scant attention when compared with the other two changes, the EPAEDEA's addition of a definition for "factors as may be relevant to and consistent with the public health and safety," which is the language used in the catch-all public interest factor to be considered by the Agency in determining whether to register or maintain registration<sup>72</sup> for manufacturers<sup>73</sup> and distributors<sup>74</sup> (but not prescribers, pharmacies, and researchers)<sup>75</sup> of controlled substances, is worth examining.

Under the CSA, the Agency "shall register an applicant" to manufacture controlled substances in schedule I or II "if [it] determines that such registration is consistent with the public interest and with [the country's] obligations under international [agreements],"<sup>76</sup> and "shall register an applicant" to distribute a

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70. See Harriet Ryan and Kim Christensen, *Amid Opioid Epidemic, Rules for Drug Companies are Loosened*, L.A. TIMES, July 27, 2016 at A1; Gardiner Harris and Emmarie Huetteman, *Actions by Congress on Opioids Haven't Included Limiting Them*, N.Y. TIMES, May 18, 2016 at A1.

71. Statement by the Press Secretary on S. 192, S. 483, S.2512, 2016 WL 1567506 (White House) (Apr. 19, 2016).

72. Ensuring Patient Access and Effective Drug Enforcement Act of 2016 § 2 (to be codified at 21 U.S.C. §§ 823(j)), 824(c), (d)); 21 U.S.C. § 823(a)–(f) (2012).

73. 21 U.S.C. § 823(a)–(a)(6), (d)–(d)(6) (2012).

74. *Id.* § 823(b)–(b)(5), (e)–(e)(5).

75. *Id.* § 823(f)(5).

76. *Id.* § 823(a).

controlled substance in schedules I–IV or manufacture controlled substances in schedules III–V “unless [it] determines that the issuance of such registration is inconsistent with the public interest.”<sup>77</sup> The CSA provides six factors that “shall be considered” in determining the public interest with regard to manufacturers,<sup>78</sup> and five factors that “shall be considered” in determining the public interest with regard to distributors.<sup>79</sup> For both manufacturers and distributors, one of the factors to be considered is a catch-all factor that encompasses “such other factors as may be relevant to and consistent with the public health and safety.”<sup>80</sup> The separate section of the CSA addressing suspension and revocation of existing registrations lists, as one of the grounds for suspension or denial, “a finding that the registrant . . . has committed such acts as would render his registration under section 823 . . . inconsistent with the public interest as determined under such section,”<sup>81</sup> and thus the public interest factors in Title 21, Section 823 are relevant to the inquiry of whether applicants shall be registered as well as the inquiry regarding whether current registrations should be suspended or revoked. Therefore, for both (and only) manufacturer and distributor applicants and registrants, the Agency can consider “factors as may be relevant to and consistent with the public health and safety,”<sup>82</sup> in addition to other enumerated factors, when reviewing whether to grant an application or sanction a registration.<sup>83</sup>

Before EPAEDEA, “factors as may be relevant to and consistent with the public health and safety” was not statutorily defined.<sup>84</sup> EPAEDEA adds the following: “In this section, the phrase ‘factors as may be relevant to and consistent with the public health and safety’ means factors that are relevant to and consistent with the findings contained in [21 U.S.C. § 801].”<sup>85</sup>

Co-sponsors of the EPAEDEA, like the media and the White House in its press release, did not emphasize the new definition to the extent they did the other two changes. One co-sponsor, apparently referencing this new definition,

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77. *Id.* § 823(b), (d), (e).

78. *Id.* § 823(a), (d).

79. *Id.* § 823(b), (e).

80. *Id.* § 823(a)(6), (b)(5), (d)(6), (e)(5). There are similar catch-all factors for practitioner (doctor and pharmacy) registrants and List I distributor registrants, but they do not contain the same language that was defined by the EPAEDEA. *See id.* § 823(f)(5) (“Such other *conduct* which may threaten the public health and safety.”); *id.* § 823(h)(5) (“[S]uch other factors as *are* relevant to and consistent with the public health and safety.”) (emphasis added).

81. *Id.* § 824(a)(4).

82. *Id.* § 823(a)(6), (b)(5), (d)(6), (e)(5).

83. *Id.* § 823(a).

84. *See id.* § 823.

85. Ensuring Patient Access and Effective Drug Enforcement Act of 2016, Pub. L. No. 114-145, § 2, 130 Stat. 353, 354 (to be codified at 21 U.S.C. § 823(j)).



stated that the EPAEDEA “will better delineate the standards a company must satisfy in order to obtain a [CSA] registration,”<sup>86</sup> although he did not explain why such delineation was needed. A few months later, at another session, he more explicitly explained that the EPAEDEA “makes three important changes to the [CSA],” and, as relevant to this definition, explained that “it clarifies the factors that the Attorney General is required to consider when deciding whether to register an applicant to manufacture or distribute controlled substances.”<sup>87</sup> He continued:

The current text of the [CSA] instructs the Attorney General to consider factors that ‘may be relevant to and consistent with the public health and safety,’ but it does not provide any guidance as to what those factors might be. This vague language creates uncertainty among advocates regarding the standards they must meet to obtain a registration. [The EPAEDEA] reduces this uncertainty by tying those standards to Congress’s findings in [21 U.S.C. § 801] regarding the benefits, harms, and commercial impact of controlled substances. This change will bring clarity to the registration process and provide better guidance to regulators as they consider applications to manufacture or distribute controlled substances.<sup>88</sup>

Therefore, the single basis of support offered for the addition of this definition was that it would purportedly make the factors to be considered in that catch-all factor clearer for potential registrants.<sup>89</sup>

To the extent that this portion of the EPAEDEA was aimed at providing a supplemental definition because the catch-all factors used by the Agency were too vague, it is not altogether clear why the insertion of a definition that extends only to manufacturers and distributors was adequate to achieve that goal. It might seem that if the catch-all language for manufacturers and distributors created such “uncertainty among advocates”<sup>90</sup> for those registrants that it required a more specific definition linking it to certain congressional findings, then it is likely that advocates for pharmacies, physicians, and List I distributors would also be uncertain about the catch-all language in the equivalent factors applicable to those applicants/registrants, as the language is remarkably similar, but Congress elected to leave the existing catch-all language for practitioners<sup>91</sup>

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86. 162 CONG. REC. S954 (daily ed. Feb. 23, 2016) (statement of Sen. Hatch).

87. 162 CONG. REC. S2006 (daily ed. Apr. 13, 2016) (statement of Sen. McConnell).

88. *Id.* at S2006-07.

89. *Id.*

90. *Id.*

91. 21 U.S.C. § 823(f)(5) (2012).

and List I distributors<sup>92</sup> in place—and to leave it undefined. Thus, the EPAEDEA either created an enhanced definition for two types of applicants/registrants that was not truly necessary, or it created an enhanced definition only for those types of registrants, while failing to address the same problem for the remaining applicants and registrants covered by the CSA. Additionally, to the extent that Congress had perceived a need to do so, it certainly had the ability to supplement the public interest factors with specific, enumerated sub-factors.

While it has yet to be tested, this newly-defined factor should be watched closely in the years to come. Time will tell if the CSA enhancements supplied by Congress in the EPAEDEA achieved its espoused beneficial objectives, or whether the entire effort proves to have been a solution in search of a problem. Whether the new language serves as a helpful clarifier or creates wide potential for manufacturers and distributors—but, notably, not other types of registrants—to dramatically constrict the range of evidence available for regulators to properly consider within the confines of § 801 (or whether it will do both or neither) will only be discernible after all sides take the new statute for a test drive.

### III. AGENCY PRECEDENT

Agency legal thinking, as expressed through the final orders it has issued recently, has taken dramatic swings and detours that are certain to affect diversion litigation, the options chosen by prosecutors, and the advice given to clients. Both sides of the litigation equation should be familiar with other nuanced details, set forth only in Agency final orders, that may affect the parties' relative positions.

The most tectonic shifts in recent Agency legal interpretation arguably occurred in the field of practitioners in general, and pharmacies in particular. In a relatively brief period of time, the DEA, through its final order precedent, has modified numerous legal standards, the bulk of which may ultimately increase the challenges faced by its own agents and prosecutors to prevail in its enforcement efforts.

#### A. *The Public Interest Factors for Practitioners*

In the course of supplying a framework for the granting and sanctioning of DEA controlled substance registrations for practitioners, Congress directed that

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92. *Id.* § 823(h)(5).

the Attorney General<sup>93</sup> must consider and balance five factors (the Public Interest Factors).<sup>94</sup> The Public Interest Factors regarding practitioners are as follows:

- (1)The recommendation of the appropriate State licensing board or professional disciplinary authority;
- (2)The applicant's [or registrant's] experience in dispensing, or conducting research with respect to controlled substances;
- (3)The applicant's [or registrant's] conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances;
- (4)Compliance with applicable State, Federal, or local laws relating to controlled substances; and
- (5)Such other conduct which may threaten the public health and safety.<sup>95</sup>

While the text of the CSA relating to the Public Interest Factors has not been changed, the Agency's interpretation of the public interest standard for practitioners generally, and certain aspects of Public Interest Factors One and Two<sup>96</sup> in particular, have been evolving.

#### 1. The Re-Re-Tweaking of Public Interest Factor One

In *Wesley Pope, M.D.*, the Agency directed some attention to explaining how it intends to handle evidence under Public Interest Factor One in the future.<sup>97</sup> Public Interest Factor One requires the Agency to consider, in determining the public interest, "[t]he recommendation of the appropriate State licensing board or professional disciplinary authority."<sup>98</sup> Inasmuch as the ultimate responsibility to determine whether a registration is consistent with the public interest has been delegated exclusively to the DEA and not to entities within a state government,<sup>99</sup> it is not surprising that the actions of state licensing and disciplinary authorities have not historically played a case-dispositive role in diversion cases under Factor One.<sup>100</sup> Notwithstanding the seeming simplicity

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93. This authority has been delegated to the Administrator. 28 C.F.R. § 0.100(b), 0.103(a) (2017). The Administrator, in turn, may delegate this authority to the Deputy Administrator. *Id.* § 0.104.

94. 21 U.S.C. §§ 823(f), 824(a)(4).

95. *Id.* § 823(f)(1)–(5).

96. *Id.* § 823(f)(1)–(2).

97. Wesley Pope, M.D., 82 Fed. Reg. 14944, 14965 n.36 (Drug Enf't Admin. Mar. 23, 2017).

98. 21 U.S.C. § 823(f)(1).

99. Edmund Chein, M.D., 72 Fed. Reg. 6580, 6590 (Drug Enf't Admin. Feb. 12, 2007), *aff'd*, Chein v. DEA, 533 F.3d 828, 835 (D.C. Cir. 2008), *cert. denied*, 555 U.S. 1139 (2009).

100. See, e.g., George Mathew, M.D., 75 Fed. Reg. 66138, 66145 (Drug Enf't Admin. Oct. 27, 2010) (declining to adopt as dispositive under Factor One the state medical board's sanction of

of the language utilized by Congress in this straightforward provision, final orders from the Agency regarding this factor have presented a surprising level of inconsistency.<sup>101</sup>

The plain language of Public Interest Factor One reflects that Congress made the existence of a “*recommendation* of the appropriate State licensing board or professional disciplinary authority”<sup>102</sup> the clear condition precedent for consideration of evidence under this factor. Where a “recommendation” by one of those bodies exists and is part of the record,<sup>103</sup> it is to be considered in the Agency’s determination of whether granting or continuing a registration is in the public interest, and where the record does not contain a recommendation from a state licensing authority or disciplinary board, no evidence may be considered under Factor One.<sup>104</sup> The plain language of the statute thus renders a binding, binary choice based on whether or not the appropriate state agency has made a recommendation.<sup>105</sup>

Notwithstanding the apparent clarity of congressional intent, over time some, but not all, agency precedent progressively morphed into a broader view

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suspending respondent’s medical license, the Agency then stayed the suspension, in a case where respondent was prescribing controlled substances without physically examining patients or maintaining medical records); Patrick W. Stodola, M.D., 74 Fed. Reg. 20727, 20730 (Drug Enf’t Admin. May 5, 2009) (considering the Agency’s acknowledgement that “the record contain[ed] no evidence that the [state] ha[d] taken action against [r]espondent’s medical license” as a Factor One consideration and dismissing the issue without analysis). This is not to say that state licensing and disciplinary actions do not ever play a case-dispositive role. In situations where a registrant or applicant lacks the requisite authority to handle controlled substances in his or her state, the Agency has determined that revocation or denial is mandatory. *E.g.*, Rezik A. Saqer, M.D., 81 Fed. Reg. 22122, 22126 (Drug Enf’t Admin. Apr. 14, 2016); *see* Mulrooney & Hull, *supra* note 1, at 333–34.

101. *See* Mulrooney & Hull, *supra* note 1, at 338–43.

102. 21 U.S.C. § 823(f)(1) (emphasis added).

103. *See, e.g.*, John Porter Richards, D.O., 61 Fed. Reg. 13878, 13878 (Drug Enf’t Admin. Mar. 28, 1996) (relying upon a recommendation from the Ohio State Board of Medicine).

104. *See* 21 U.S.C. § 823(f)(1).

105. Even if the straightforward language used by Congress did not render resort to legislative history regarding Factor One superfluous, a review of the legislative history does not alter the result. An isolated reference to a House Committee hearing notes that the inclusion of the state recommendation among the mandatory factors to be considered by the DEA, and the placement of it first among the Factors, was designed to ensure that “deference would continue to be given to the opinions of the state licensing authorities.” *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. 122–23 (1984) (statement of Gene R. Haslip, Director, Office of Diversion Control, Drug Enforcement Administration). This testimony supports the obvious intent of the language to incorporate the “recommendation” of state authorities regarding the disposition of DEA application and revocation decisions.

of the term “recommendation.”<sup>106</sup> This broader view embraced the principle that, through an analysis of the actions of state licensing authorities, the Agency may be able to divine what the state *would have* recommended to the DEA regarding the disposition of a registration application or revocation *if* it had actually made a recommendation, in cases where it did not actually make such a recommendation.<sup>107</sup> Under the broader interpretation, the Agency has, at times, found that various forms of disciplinary action<sup>108</sup> provide evidence from which a ‘recommendation’ against registration or continued registration may somehow be extrapolated and then considered under a Factor One analysis.<sup>109</sup> Similarly, under this broad approach, the Agency has held that the restoration of a respondent’s state license,<sup>110</sup> or the mere fact that a respondent holds a state medical license,<sup>111</sup> can be interpreted as a recommendation in favor of registration or continued registration.

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106. Compare Ralph J. Chambers, M.D., 79 Fed. Reg. 4962, 4969 (Drug Enf’t Admin. Jan. 30, 2014) (quoting Tony T. Bui, M.D., 75 Fed. Reg. 49979, 49986 (Drug Enf’t Admin. Aug. 16, 2010)) (internal quotation marks omitted), with Scott D. Fedosky, M.D., 76 Fed. Reg. 71375, 71377 (Drug Enf’t Admin. Nov. 17, 2011) and Gilbert Eugene Johnson, M.D., 75 Fed. Reg. 65663, 65666 n.3 (Drug Enf’t Admin. Oct. 26, 2010).

107. Johnson, 75 Fed. Reg. at 65666 n.3.

108. E.g., Saihb S. Halil, M.D., 64 Fed. Reg. 33319, 33320–21 (Drug Enf’t Admin. June 22, 1999) (state license revoked); Myrtle L. Miller, D.O., 58 Fed. Reg. 64005, 64006 (Drug Enf’t Admin. Dec. 3, 1993) (state license revoked); Tyson D. Quy, M.D., 78 Fed. Reg. 47412, 47417 (Drug Enf’t Admin. Aug. 5, 2013) (state license placed on probation); Gregory D. Owens, D.D.S., 67 Fed. Reg. 50461, 50463 (Drug Enf’t Admin. Aug. 2, 2002) (state license placed on probation); Jude R. Hayes, M.D., 59 Fed. Reg. 41785, 41786 (Drug Enf’t Admin. Aug. 15, 1994) (state license placed on probation); Daniel Koller, D.V.M., 71 Fed. Reg. 66975, 66981 (Drug Enf’t Admin. Nov. 17, 2006) (state license suspended); Wilbert McClay, Jr., M.D., 59 Fed. Reg. 30612, 30614 (Drug Enf’t Admin. June 14, 1994) (state license suspended); Robert M. Golden, M.D., 65 Fed. Reg. 5663, 5664 (Drug Enf’t Admin. Feb. 4, 2000) (state license subjected to consent order).

109. Chambers, 79 Fed. Reg. at 4969 (quoting Bui, 75 Fed. Reg. at 49986) (“DEA precedents have typically taken a broader view as to the scope of [Factor One].”) (internal quotation marks omitted); Kenneth Harold Bull, M.D., 78 Fed. Reg. 62666, 62672 (Drug Enf’t 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 . . .”).

110. E.g., Quy, 78 Fed. Reg. at 47417; Vincent J. Scolaro, D.O., 67 Fed. Reg. 42060, 42064–65 (Drug Enf’t Admin. June 20, 2002); William E. Brown, D.O., 58 Fed. Reg. 64004, 64005 (Drug Enf’t Admin. Dec. 3, 1993).

111. E.g., Margy Temponeras, M.D., 77 Fed. Reg. 45675, 45684 (Drug Enf’t Admin. Aug. 1, 2012) (“Although not dispositive, [r]espondent’s possession of a valid unrestricted medical license . . . weighs against a finding that [r]espondent’s registration would be inconsistent with the public interest.”); but see Farmacia Yani, 80 Fed. Reg. 29053, 29058 n.13 (Drug Enf’t Admin. May 20, 2015) (ruling by Agency where it “considered” evidence that the respondent pharmacy was registered with the state and that the state board took no action against the pharmacist license of its owner and pharmacist-in-charge, but stated that the evidence does not “constitute a recommendation . . . as to whether the DEA should grant the [pharmacy’s] application” for a DEA registration).

In *Pope*, the Agency included a footnote that may signal about how it will consider state actions that do not constitute recommendations to the DEA,<sup>112</sup> at least insofar as those actions ultimately result in the registrant or applicant retaining state authority.<sup>113</sup> Citing two cases decided by the Agency in 2002,<sup>114</sup> the Agency explained that “[t]o be sure, the Agency’s case law contains some older decisions which can be read as giving more than nominal weight in the public interest determination to a [s]tate [b]oard’s decision (not involving a recommendation to the DEA) either restoring or maintaining a practitioner’s state authority to dispense controlled substances,”<sup>115</sup> but noted that “these cases cannot be squared with the Agency’s longstanding holding” that the Administrator must make a determination independent from any state determination as to whether controlled substance privileges would be in the public interest.<sup>116</sup> In the same footnote, the Agency, referencing several more recent cases, acknowledged that “in other cases [it] has given some weight to a [state board’s] action in allowing a practitioner to retain his state authority even in the absence of an express recommendation,”<sup>117</sup> but noted that “the Agency has repeatedly held that a practitioner’s retention of his state authority is not dispositive of the public interest inquiry.”<sup>118</sup>

Based on its language in the footnote in *Pope*, the Agency appears to be signaling that it may be willing to consider evidence that a state license has reinstated (or not acted upon) a registrant or applicant’s state license under Factor One, but that it may give such evidence no more than “nominal weight,”<sup>119</sup> and, in any event, such evidence will not be dispositive. Inasmuch as the Agency has long held that retention of state authority is a threshold

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112. Wesley Pope, M.D., 82 Fed. Reg. 14944, 14965 n.36 (Drug Enf’t Admin. Mar. 23, 2017).

113. *Id.* While *Pope* only explicitly addressed how a state authority’s reinstatement of a state license (or inaction as to a state license) would be considered, if the state board revokes or suspends the practitioner’s ability to handle controlled substances in the state in which the practitioner is registered with the DEA, the Agency routinely holds that such practitioner “does not meet the CSA’s essential requirement for maintaining a practitioner’s registration,” e.g., Steven Bernhard, D.O., 82 Fed. Reg. 23298, 23300 (Drug Enf’t Admin. May 22, 2017), and thus no consideration under Factor One is necessary to the disposition of the case.

114. *Pope*, 82 Fed. Reg. at 14965 n.36 (citing Gregory D. Owens, 67 Fed. Reg. 50461, 50463 (Drug Enf’t Admin. Aug. 2, 2002) and *Scolaro*, 67 Fed. Reg. at 42065 (Drug Enf’t Admin. June 20, 2002)).

115. *Pope*, 82 Fed. Reg. at 14965 n.36 (citing *Owens*, 67 Fed. Reg. at 50463).

116. *Id.* (citing Mortimer Levin, 57 Fed. Reg. 8680, 8681 (Drug Enf’t Admin. Mar. 11, 1992)).

117. *Id.* (citing Paul Weir Battershell, N.P., 76 Fed. Reg. 44359, 44366 (Drug Enf’t Admin. July 25, 2011)).

118. *Id.* (citing *Battershell*, 76 Fed. Reg. at 44366.)

119. *Id.* (citing *Owens*, 67 Fed. Reg. at 50463 (Drug Enf’t Admin. Aug. 2, 2002) and *Scolaro*, 67 Fed. Reg. at 42065 (Drug Enf’t Admin. June 20, 2002)).

statutory requirement for entitlement to hold a DEA registration,<sup>120</sup> this analysis may result in more confusion than clarity, because the line between assessing threshold state controlled substance authority and evidence to be considered under Factor One is arguably somewhat blurred. If this footnote signals a deliberate navigation to a more consistent application of how evidence will be considered (or not considered) under Factor One, this aspect of *Pope* would likely be welcomed by the practicing bar and the regulated community. After many years and no small amount of vacillation, it now appears that the Agency may be considering a swerve back to the plain language provided by Congress relative to Factor One, meaning that for a state action to be considered with any measurable weight under Factor One, it must constitute a recommendation from a state licensing or disciplinary board, not merely some action related to state licensure. The Factor One language in *Pope* does specifically note that the respondent's state board "has not made a recommendation to the Agency with respect to whether his [DEA registration] application should be granted,"<sup>121</sup> which sounds like some movement towards a plain-language Factor One approach, but the decision stopped short of settling the matter. However, a subsequent final order, *David D. Moon, D.O.*, does provide some reason to believe that the Agency is moving in a cognizable direction back towards a plain-language requirement for an actual state recommendation, with less reliance on trying to distill intent from non-recommendations.<sup>122</sup> For all sides of the litigation aisle, less dependence on legal alchemy is likely welcome.

Another interesting Factor One question addressed by the Agency is whether an adverse action taken or recommendation given by a state authority other than the state in which the applicant seeks to be registered or the registrant seeks to maintain his registration could ever be considered by the Agency and, if so, what weight it would be given. In *Zizhuang Li, M.D.*, the Agency rejected the Government's argument that revocation of the practitioner's state license in Mississippi should be considered in determining whether to grant an application for licensure in California,<sup>123</sup> holding that the Mississippi Medical Board was not the "appropriate" state licensing board.<sup>124</sup> *Li* thus appears to foreclose consideration of adverse actions taken in states other than the state in which a respondent seeks a new or continued registration under Factor One. The practicing bar on both sides will likely wonder why the Agency's interpretation

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120. James L. Hooper, M.D., 76 Fed. Reg. 71371, 71372 (Drug Enf't Admin. Nov. 17, 2011), *pet. for rev. denied*, Hooper v. Holder, 481 F. App'x 826 (4th Cir. 2012).

121. *Pope*, 82 Fed. Reg. at 14965 n.36.

122. See, e.g., *David D. Moon, D.O.*, 82 Fed. Reg. 19385, 19387 n.5 (Drug Enf't Admin. Apr. 27, 2017).

123. *Zizhuang Li, M.D.*, 78 Fed. Reg. 71660, 71663 (Drug Enf't Admin. Nov. 29, 2013).

124. *Id.*

seems to preclude any consideration of an adverse action taken by a state, merely because it is a different state than the one in which the registrant seeks to hold a DEA registration. However, it is still unclear whether the Agency would extend *Li* so far as to ignore such evidence if it were in the format of an actual recommendation made to the DEA regarding a registration by a different state's licensing authority.

Although rarely pursued by litigants on either side, a recommendation garnered from a state tribunal for or against a DEA sanction, depending on the facts of the case and the strength of the recommendation, could potentially constitute powerful evidence for the Government or a respondent, and *Pope* at least suggests that from now on, such a recommendation may be the only evidence that will be considered with any weight under Factor One. The takeaway here is that, in a post-*Pope* world, both sides should be looking harder at Factor One.

## 2. Is Public Interest Factor Two Shrinking, Melding, Both, or Neither?

The *Pope* case also presented a fascinating next chapter in what could arguably be characterized as the Agency's progressive constricting of evidence properly considered "experience" under Public Interest Factor Two in practitioner cases.<sup>125</sup> Factor Two compels consideration of "[t]he applicant's experience in dispensing, or conducting research with respect to controlled substances."<sup>126</sup> Inasmuch as the statutory definition of "dispense" includes "prescribing" and "administering,"<sup>127</sup> this section addresses experience regarding those regulated activities as well.<sup>128</sup>

Before discussing the Factor Two aspects of *Pope*, a consideration of the language and history of Factor Two is pertinent. It is axiomatic that the interpretation of any statute begins and ends with an examination of clear, directive language.<sup>129</sup> "Unless otherwise defined, words will be interpreted as

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125. 21 U.S.C. § 823(f)(2); *Pope*, 82 Fed. Reg. at 14965.

126. 21 U.S.C. § 823(f)(2).

127. *Id.* § 802(10).

128. For general background regarding the language and reach of Factor Two, see Mulrooney & Hull, *supra* note 1, at 343–46.

129. See *Consumer Prod. Safety Comm'n v. GTE Sylvania, Inc.*, 447 U.S. 102, 108 (1980) ("We begin with the familiar canon of statutory construction that the starting point for interpreting a statute is the language of the statute itself. Absent a clearly expressed legislative intention to the contrary, that language must ordinarily be regarded as conclusive."); see also *Woods v. Standard Ins. Co.*, 771 F.3d 1257, 1265 (10th Cir. 2014) (stating that if a court finds statutory language clear, its inquiry ends; only if language is "ambiguous" does court turn to legislative history); *Falvo v. Owasso Indep. Sch. Dist. No. I-011*, 233 F.3d 1201, 1203 n.2 (10th Cir. 2000) (same). It is well-settled that "words [should be given] their ordinary meaning," *Moskal v. United States*, 498 U.S. 103, 108 (1990) (internal quotations omitted), and that "[w]here the language is clear and unambiguous, it must be followed



taking their ordinary, contemporary, common meaning,”<sup>130</sup> and “where language is clear and unambiguous, it must be followed, except in the most extraordinary situation where the language leads to an absurd result contrary to clear legislative intent.”<sup>131</sup> The plain language of Factor Two supplies a mandate by Congress for the Agency, in determining the public interest, to consider “[t]he applicant’s experience in dispensing, or conducting research with respect to controlled substances.”<sup>132</sup> The simplicity of the language directs no more than a mandatory evaluation of the experience that an applicant brings to the regulated activity the applicant seeks to conduct within the scope of a DEA certificate of registration. Congress did not limit or qualify the experience that the Agency is required to consider under this factor, nor did Congress authorize the Agency to ignore offered evidence on the subject by caprice. If a party to an administrative registration adjudication offers relevant evidence regarding the applicant or registrant’s experience that is not otherwise inadmissible, the language selected by Congress appears to unequivocally require its admission and consideration under Factor Two.

It could be persuasively argued that the precision of the language employed by Congress in Factor Two all but precludes resort to any source beyond the statute itself, but even if it were not so, a review of the legislative history specific to this provision reveals no intention to impose limitations on the evidence to be considered under this Factor. The single reservation evident in the legislative history was a clarification that an absence of any prior experience, at least in the case of a recently-graduated practitioner, should not be considered negatively against such a practitioner.<sup>133</sup>

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except in the most extraordinary situation where the language leads to an absurd result contrary to clear legislative intent.” *United States v. Plotts*, 347 F.3d 873, 876 (10th Cir. 2003) (citing *United States v. Tagore*, 158 F.3d 1124, 1128 (10th Cir. 1998)); see *Griffin v. Oceanic Contractors*, 458 U.S. 564, 572 (1982); *Comm’r v. Brown*, 380 U.S. 563, 571 (1965).

130. *Perrin v. United States*, 444 U.S. 37, 42 (1979).

131. *Plotts*, 347 F.3d at 876 (citing *Tagore*, 158 F.3d at 1128); see *Griffin*, 458 U.S. at 572; *Brown*, 380 U.S. at 571.

132. 21 U.S.C. § 823(f)(2).

133. Specifically, a House of Representatives committee hearing report clarifies that Factor Two “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.” H.R. REP. NO. 98-835, pt. 1, at 14 (1984). This brief statement resulted from input by the American Pharmaceutical Association (APhA), stemming from its concern that the absence of experience would bar the registration of recent pharmacy school graduates. *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). Thus, it is clear that the Factor Two language signified to the APhA that, unless its concerns on the point were addressed, the draft language chosen (and ultimately adopted) by Congress would require the Agency to consider the

Some context regarding the Agency's and the courts' treatment of Factor Two is also helpful in navigating the Agency's current course. Historically, Agency final orders placed evidence of an applicant's past experience engaging in the regulated activity under its Factor Two discussion, but eventually reasoned that a robust level of benign, or even commendable, experience could be easily outweighed by other evidence demonstrating that granting a registration application was inconsistent with the public interest.<sup>134</sup> Even though the Agency has considered the experience of List 1 applicants<sup>135</sup> on the issue of whether they possess the level of experience and subject area knowledge to discharge effectively the obligations of a registrant,<sup>136</sup> it has dismissed the notion of applying this rationale to practitioner cases.<sup>137</sup>

In 2006, in its discussion of Factor Two in *Krishna-Iyer, M.D.*, the Agency discussed only the established transgressions, and did not mention evidence in the record regarding other experience or weigh the wrongdoings against such

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applicant's prior experience in the regulated field—or lack thereof—in order to gauge applicant suitability. During the legislative hearing process, the American Veterinary Medical Association (AVMA) also expressed a reservation that the draft Factor Two language (ultimately retained by Congress) would address conduct also covered by Factor Three (conviction of a felony related to controlled substances) and Factor Four (compliance with laws relating to controlled substances), thus rendering consideration of evidence under this factor duplicative. *Id.* at 425. As discussed later in this section, the interpretive evolution currently embraced by the Agency regarding the application of the Public Interest Factors to all evidence of record has rendered the AVMA prescient in this regard. *See* discussion *infra* pp. 31–33.

134. *See, e.g.*, Paul J. Caragine, Jr., 63 Fed. Reg. 51592, 51600 (Drug Enf't Admin. Sept. 28, 1998) (acknowledging, in its discussion of Factor Two, that during twenty years of practice, the respondent saw over 15,000 patients, but noting that, “even though the patients at issue are only a small portion of [r]espondent's patient population, his prescribing of controlled substances to [the patients at issue] raises serious concerns regarding [his] ability to responsibly handle controlled substances in the future”); Med. Shoppe–Jonesborough, 73 Fed. Reg. 364, 386 (Drug Enf't Admin. Jan. 2, 2008) (acknowledging, under its discussion of Factor Two, that the respondent had 17,000 patients, but finding that established misconduct, which related to only a relatively small portion of the respondent's patient population, outweighed any other conduct); *see also* Ivan D. Garcia-Ramirez, M.D., 69 Fed. Reg. 62092, 62093 (Drug Enf't Admin. Oct. 22, 2004) (finding Factor Two irrelevant to public interest determination because “there is no information in the investigative file relative to [r]espondent's lawful handling of controlled substances in his professional practice” where practitioner pled guilty to one felony count of possession with intent to import heroin).

135. 21 U.S.C. § 823(h).

136. TNT Distribs., Inc., 70 Fed. Reg. 12729, 12731 (Drug Enf't Admin. Mar. 15, 2005); Volusia Wholesale, 69 Fed. Reg. 69409, 69410 (Drug Enf't Admin. Nov. 29, 2004); K & Z Enters., Inc., 69 Fed. Reg. 51475, 51476 (Drug Enf't Admin. Aug. 19, 2004); Island Wholesale, Inc., 68 Fed. Reg. 17406, 17407 (Drug Enf't Admin. Apr. 9, 2003).

137. *See, e.g.*, Cynthia M. Cadet, M.D., 76 Fed. Reg. 19450, 19450 n.3 (Drug Enf't Admin. Apr. 7, 2011) (noting only that List 1 distributors are “a different category of registrant[s],” the Agency dismissed the comparative rationale).

evidence.<sup>138</sup> On appeal, in *Krishna-Iyer v. DEA*,<sup>139</sup> the United States Court of Appeals for the Eleventh Circuit (in an unpublished *per curiam* decision) noted that “the DEA is required to consider the [Public Interest Factors] to determine if continued certification is against the public interest,”<sup>140</sup> and criticized the Agency for failing to adequately consider evidence admitted to the record of proceedings under Factor Two.<sup>141</sup> In its decision, the Eleventh Circuit held:

In considering Petitioner’s experience in dispensing controlled substances under [F]actor 2, the DEA identified only four visits by three undercover “patients,” who were all attempting to make a case against her. The DEA failed to consider Petitioner’s experience with twelve patients whose medical charts were seized by the DEA, or with thousands of other patients. In short, the DEA did not consider any of Petitioner’s positive experience in dispensing controlled substances. This is an arbitrary and unfair analysis of the Petitioner’s experience. We vacate the order of the [Agency] and remand the case for reconsideration of this factor, where the DEA should pay particular attention to the entire corpus of Petitioner’s record in dispensing controlled substances, not only the experience of the undercover officers. The five factors should accordingly be rebalanced.<sup>142</sup>

The court’s directive to the Agency seemed clear enough: on remand, rebalance the evidence considered under Factor Two in light of the entire corpus of the prescriber’s experience, and rebalance the five factors accordingly.<sup>143</sup> The Agency could have easily done what it had historically done: briefly discuss the evidence under Factor Two, but ultimately find that the established misconduct outweighed the positive or benign conduct,<sup>144</sup> but instead, the Agency pushed back somewhat on the Eleventh Circuit’s analysis, stating, *inter alia*, that:

[E]vidence that a practitioner has treated thousands of patients does not negate a *prima facie* showing that the practitioner has committed acts inconsistent with the public interest. While

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138. Jayam Krishna-Iyer, M.D., 71 Fed. Reg. 52148, 52158 (Drug Enf’t Admin. Sept. 1, 2006). In its findings of fact, the Agency noted that the practitioner testified that she had around 800 to 1000 recurring patients and saw around 3,000 patients per year. *Id.* at 52149. It also made findings regarding her education, training, and experience at various hospitals. *Id.*

139. 249 F. App’x 159 (11th Cir. 2007).

140. *Id.* at 159.

141. *Id.* at 160.

142. *Id.*

143. *Id.*

144. Paul J. Caragine, Jr., 63 Fed. Reg. 51592 (Drug Enf’t Admin. Sept. 28, 1998).

such evidence may be of some weight in assessing whether a practitioner has credibly shown that she has reformed her practices, where a practitioner commits intentional acts of diversion and insists she did nothing wrong, *such evidence is entitled to no weight*.<sup>145</sup>

Thus, the Agency's reply to the Circuit Court of Appeals was essentially that it would obey its directive to consider positive experience, but that it would only do so as a matter of sanction discretion in cases where the respondent accepts responsibility for the transgressions alleged against it, not under Factor Two when determining whether the Government has met its *prima facie* burden that registration is not in the public interest.<sup>146</sup> The Agency emphasized its qualified acceptance of the court's mandate with this additional statement:

[E]ven where the Agency's proof establishes that a practitioner has committed only a few acts of diversion, this Agency will not grant or continue the practitioner's registration unless he accepts responsibility for his misconduct. Put another way, even where the Government proves only a few instances of illegal prescribing in the "entire corpus" of a practitioner's experience, the Government has nonetheless made out a *prima facie* case and thus shifted the burden to the registrant to show why he should be entrusted with a new registration.<sup>147</sup>

Thus, in its second order, the Agency essentially adhered to its previous (pre-remand) analysis, with the additional wrinkle that, in a case where the Government had established acts of intentional misconduct, the Agency would not consider the entire corpus of a practitioner's experience in its analysis of Factor Two, nor would it consider experience at all unless the respondent has manifested an unconditional acceptance of responsibility.<sup>148</sup> While true that, if writing upon a clean slate, it may not have been unreasonable for the Agency to insist upon an acceptance of responsibility to render evidence of benign or commendable conduct more probative to a registrant's defense that established misconduct was an aberration and he should be entrusted with a registration, the analysis is remarkable in that it risks the appearance of the Agency substituting its own structure of analysis for that created by Congress (the body that required consideration of this evidence without qualification in Factor Two) and for the legal interpretation set forth in the decision of the Eleventh Circuit.

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145. Jayam Krishna-Iyer, M.D., 74 Fed. Reg. 459, 463 (Drug Enf't Admin. Jan. 6, 2009) (emphasis added).

146. *See id.*

147. *Id.* at 464 (footnotes omitted).

148. *See id.*; 21 U.S.C. § 823(f)(2) (2012).

Inasmuch as the Agency's second final order in *Krishna-Iyer* granted the doctor in that case a registration with conditions,<sup>149</sup> the case was never re-appealed to the Eleventh Circuit, and the final order was maintained as a recurrent bedrock of Agency precedent.<sup>150</sup> In *MacKay v. DEA*, the Tenth Circuit upheld an Agency final order that included the Agency-created *Krishna-Iyer* analysis, but the Agency's failure to consider experience evidence under Factor Two was not a significant focus of the court's affirmance opinion;<sup>151</sup> instead, the Tenth Circuit found that the Agency "considered the entire record" to include the hypothetical situation that the doctor "had provided proper medical care to all of his other patients" and found that it did not outweigh the evidence of negative experience.<sup>152</sup> Likewise, in *McNichol v. DEA*<sup>153</sup> the Eleventh Circuit found that the Agency's decision, which had included the *Krishna-Iyer* analysis, was supported by substantial evidence and was not arbitrary and capricious.<sup>154</sup> However, the Eleventh Circuit did not mention the *Krishna-Iyer* analysis, or even Factor Two specifically, in its unpublished decision.<sup>155</sup>

After *Krishna-Iyer*, the Agency's reliance upon its own interpretation of Factor Two has become increasingly restrictive, and the Agency has become increasingly critical of any ALJ who recommends a different analysis of it to the Administrator when considering the facts of a particular case.<sup>156</sup> In *JM*

149. *Krishna-Iyer*, 74 Fed. Reg. at 464.

150. See, e.g., Dewey C. Mackay, M.D., 75 Fed. Reg. 49956, 49973–78 (Drug Enf't Admin. Aug. 16, 2010); Beau Boshers, M.D., 76 Fed. Reg. 19401, 19402–13 (Drug Enf't Admin. Apr. 7, 2011); Wesley Pope, M.D., 82 Fed. Reg. 14944, 14982–85 (Drug Enf't Admin. Mar. 23, 2017); T.J. McNichol, M.D., 77 Fed. Reg. 57133, 57144–49 (Drug Enf't Admin. Sept. 17, 2012).

151. See *MacKay v. DEA*, 664 F.3d 808, 819 (10th Cir. 2011).

152. *Id.*

153. 537 F. App'x 905 (11th Cir. 2013).

154. *McNichol*, 77 Fed. Reg. at 57144–46.

155. See *McNichol*, 537 F. App'x at 906. In *Pope*, the Agency discussed another case, *Lynch v. DEA*, which it said also rejected an alternative view of the Agency's *Krishna-Iyer* analysis. *Pope*, 82 Fed. Reg. at 14983. While the Agency discussed arguments raised by the practitioner in his briefs before the Eleventh Circuit in that case, neither the Agency's decision nor the Eleventh Circuit's unpublished decision mentions *Krishna-Iyer* or discusses the Agency's decision to not consider evidence of positive experience under Factor Two. See Ronald Lynch, M.D., 75 Fed. Reg. 78745 (Drug Enf't Admin. Dec. 16, 2010); *Lynch v. DEA*, 480 F. App'x 946 (11th Cir. 2012).

156. See, e.g., Syed Jawed Akhtar-Zaidi, M.D., 80 Fed. Reg. 42962, 42962 n.2 (Drug Enforcement Admin. July 20, 2015) (scolding of ALJ by Agency, saying that "every Administrator and Deputy Administrator who has exercised [Agency authority] has rejected the ALJ's view"); Clair L. Pettinger, M.D., 78 Fed. Reg. 61591, 61597 (Drug Enf't Admin. Oct. 3, 2013) (describing ALJ's reasoning as "illogical" for analyzing Factor Two in terms of "both the qualitative and quantitative volume of the [r]espondent's experience"); Randall L. Wolff, M.D., 77 Fed. Reg. 5106, 5121 (Drug Enf't Admin. Feb. 1, 2012) (rejecting respondent's contention that he was prejudiced by the denial of his ability to access his own seized medical charts to establish his experience under Factor Two in light

*Pharmacy*, the Agency held that it was error for the DEA ALJ to find in a recommended decision that Factor Two calls for the Agency to analyze “the qualitative manner and the *quantitative volume* in which an applicant has engaged” in regulated activity.<sup>157</sup> By placing italics on the “quantitative volume” aspect of the recommended decision, the Agency presumably signaled that, under Factor Two, it only wishes to receive and consider evidence regarding the “qualitative manner” in which regulated activity has been conducted, and exclude any consideration relative to the “quantitative volume.”<sup>158</sup> Based on that language, it now seems apparent that a registrant seeking to demonstrate that the established non-compliance was an anomaly can no longer introduce evidence that the misconduct represented only a small percentage of the registrant’s body of compliant regulated activity that Congress mandated be considered under Factor Two.

In *Pope*, the Agency vehemently rejected the suggestion that the Agency had narrowed Factor Two beyond its plain meaning and in contravention of Congress and the Eleventh Circuit’s directives.<sup>159</sup> In doing so, the Agency cited multiple definitions of the word “experience” from two dictionaries,<sup>160</sup> and distilled no obligation to consider the quantity of benign regulated activity to any extent.<sup>161</sup> Confusingly, in addressing Congress’s reservation regarding new registration applicants in the legislative history, the Agency posited that “if Factor Two’s meaning was so plain,” there would have been “no need to express that it should not be construed to deny registrations to newly-licensed practitioners, most of whom can point to no volume of dispensing other than by

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of the purported irrelevance of such evidence under *Krishna-Iyer*); *McNichol*, 77 Fed. Reg. at 57144 (excoriating ALJ publicly throughout the Agency final order for legal and factual analysis, to include the ALJ’s attempt to follow the directives of the Eleventh Circuit in *Krishna-Iyer v. DEA*, 249 Fed. App’x at 160), *aff’d*, T.J. McNichol v. DEA, No. 12-15292, slip op. at 3 (11th Cir. Oct. 17, 2013) (per curiam) (lacking discussion in affirmance regarding Factor Two analysis); Jeri Hassman, M.D., 75 Fed. Reg. 8194, 8235 (Drug Enf’t Admin. Feb. 23, 2010) (characterizing ALJ’s analysis as “erroneous” for including a comparison between the two acts of substandard prescribing with the over nine-hundred presumably benign prescribing events).

157. JM Pharmacy Grp, Inc., 80 Fed. Reg. 28667, 28667 n.2 (Drug Enf’t Admin. May 19, 2015).

158. *Id.*

159. *Pope*, 82 Fed. Reg. at 14982.

160. *Id.* at 14982 n.54. The definitions provided by the Agency as “those most relevant in assessing” the meaning of “experience” in the context of Factor Two are: “(1) The ‘direct observation of or participation in events as a basis for knowledge,’ (2) ‘the fact or state of having been affected by or gained knowledge through direct observation or participation,’ (3) ‘practical knowledge, skill, . . . or participation in events or in a particular activity,’ and (4) ‘the length of such participation.’” *Id.* (citing *Merriam-Webster’s Collegiate Dictionary* 409 (10th ed. 1998)).

161. *Id.* at 14982.

observing a physician during clinical rotations.”<sup>162</sup> Additionally, the Agency bristled at the notion that the Agency failed to follow the Eleventh Circuit’s direction in *Krishna-Iyer*, proposing instead that “the Administrator carefully reviewed” the additional files in evidence and assumed that the rest of the prescriptions the practitioner had issued were lawful, but that “they did not negate the Government’s *prima facie* showing that the physician had knowingly diverted drugs to others.”<sup>163</sup>

By adjusting the analysis through its adjudications, the Agency has, in essence, decided that its examination of a registrant’s experience under Factor Two will be generally limited to the Government’s established allegations regarding the quality of an applicant’s activities.<sup>164</sup> Stated differently, the only experience to be considered will be the transgressions supported by the preponderant evidence of record.<sup>165</sup> Further, to the extent the universe of experience is further constricted, Factor Two analysis, in the majority of Agency cases, consists largely of a reprise of adverse evidence also considered under Factor Four (compliance with laws pertaining to controlled substances),<sup>166</sup> *to wit*: experience that shows proven misconduct in violation of state and federal laws. The Agency’s affinity for the merging of Public Interest Factors Two and Four was signaled in *Syed Jawed Akhtar-Zaidi, M.D.*, a recent case where the Agency held that “[p]roof that a physician knowingly diverted controlled substances is the best evidence for assessing his experience in dispensing controlled substances, although it is also relevant in assessing his compliance with applicable laws related to controlled substances.”<sup>167</sup> Thus, the Agency’s precedent has, in effect, morphed Factor Two into a consideration where the only evidence to be considered is evaluated once under Factor Two, and then again under Factor Four.

By framing its analysis in terms of whether the registrant or applicant can “negate the Government’s *prima facie* showing”<sup>168</sup> with evidence of positive dispensing experience, the Agency has signaled that evidence of positive experience will not be considered in the Public Interest Factor analysis—the analysis which determines whether the Government has met its *prima facie* burden—but will instead be considered at some later point, once the Agency

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162. *Id.* at 14982 n.55. It is difficult to understand what the Agency intended to convey by this statement.

163. *Id.* at 14982–83.

164. *See id.* at 14982.

165. *See id.*

166. 21 U.S.C. § 823(f) (2012).

167. *Syed Jawed Akhtar-Zaidi, M.D.*, 80 Fed. Reg. 42962, 42962 n.2 (Drug Enf’t Admin. July 20, 2015).

168. *Pope*, 82 Fed.Reg. at 14983.

has shifted the burden to the respondent.<sup>169</sup> In *Pope*, the Agency noted that, “[a]s in past cases, the parties may continue to introduce evidence as to the extent of both a practitioner’s lawful or unlawful dispensing activities,”<sup>170</sup> but also reminded litigants that, “in past cases, [the] Agency has given no more than nominal weight to a practitioner’s evidence that he has dispensed controlled substances to thousands of patients in circumstances which did not involve diversion.”<sup>171</sup> A practitioner may understandably be left to wonder whether to seek the introduction of evidence of positive experience at all and, if so, how to demonstrate the extent of such lawful dispensing to the ALJ when the Agency has previously declared such evidence to be essentially irrelevant. If, as *JM Pharmacy* concluded, analysis of the “quantitative volume” of benign, compliant conduct is per se irrelevant,<sup>172</sup> then it may not be altogether clear how to establish admissibility for the evidence such that the Agency would be able to consider it in its sanction determination. Additionally, if the volume of benign, compliant conduct is not relevant to the Agency’s analysis, then a practitioner who seeks to juxtapose several acts that fall below the applicable standard with evidence of an expansive otherwise-compliant history stands in the same position no matter whether the registrant has practiced for decades or for less than a month.

While not altogether clear how the Agency intends to consider evidence of a history of benign conduct outside of Factor Two, the Agency has provided some clues. In *Roy S. Schwartz*, the Agency, in discussing the issue of sanction in a non-hearing case, utilized language that was eerily similar to Factor Two analysis language and found that “the Government produced no evidence that the Registrant has engaged in any other misconduct related to controlled substances during the course of his professional career, which has spanned more than fifty years.”<sup>173</sup> In *Pope*, the Agency more explicitly stated that “in these proceedings, the Agency will assume, without requiring the production of any evidence by a respondent, that the practitioner has lawfully issued every prescription other than those alleged by the Government to be unlawful.”<sup>174</sup> In *Roberto Zayas, M.D.*, the Agency stated that the Public Interest Factors simply shape the scope of the relevant evidence in the proceeding, and given the nature of this inquiry, the Agency properly considers a respondent’s evidence of a lengthy history of compliance after the Government makes out its *prima facie*

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169. *See id.*

170. *Id.* at 14982.

171. *Id.*

172. *JM Pharmacy Grp, Inc.*, 80 Fed. Reg. 28667, 28667 n.2 (Drug Enf’t Admin. May 19, 2015).

173. *Roy S. Schwartz*, 79 Fed. Reg. 34360, 34363 (Drug Enf’t Admin. June 16, 2014).

174. *Pope*, 82 Fed. Reg. at 14984.



case, as determining what sanction is necessary to protect the public interest is the ultimate purpose of these provisions.<sup>175</sup>

Thus, the Agency has signaled to the regulated community that, where the Government produces no evidence of other misconduct over the course of a lengthy career as a registrant, the Agency, in its final order, may be willing to assume it to be benign and may be willing to consider it as a matter of sanction discretion.<sup>176</sup> Both sides of the litigation equation should thus be prepared to make their case for the Agency to exercise its discretion—apparently outside the bounds of the Public Interest Factors—in their favor.

### 3. The Blurring of the Factors

Perhaps foreshadowed by the blurring of the line between Factor Two and Factor Four over time,<sup>177</sup> in *Zayas*, the Agency announced what many experienced practitioners may have quietly feared: that it does not matter to the Agency which factor or factors evidence is considered under, and the Agency believes that it has no obligation to parse out which evidence is considered under what factor.<sup>178</sup> This is so, the Agency posits, because “misconduct is misconduct whether it is relevant under Factor Two, Factor Four, or Factor Five, or multiple factors,” and because “the inquiry focuses on protecting the public interest; what matters is the seriousness of the registrant’s or applicant’s misconduct.”<sup>179</sup> Regarding the danger that, under such an interpretation, the Agency could consider the same evidence multiple times under multiple factors, the *Zayas* order tenders the Agency’s assurance that, because its own prior final orders “ha[ve] repeatedly explained that it does not mechanically count up the [Public Interest F]actors and determine how many favor the Government versus how many favor the respondent,” there is no danger to the regulated community that their transgressions will be given additional weight if considered multiple times under multiple factors.<sup>180</sup> A representation that the Agency is disinclined to “mechanically count up the [Public Interest F]actors,”<sup>181</sup> even if accepted at its face value, is not a phrase that is readily

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175. Roberto Zayas, M.D., 82 Fed. Reg. 21410, 21422 n.27 (Drug Enf’t Admin. May 8, 2017).

176. *See id.*

177. *E.g.*, Randall L. Wolff, M.D., 77 Fed. Reg. 5106, 5121 n.26 (Drug Enf’t Admin. Feb. 1, 2012) (“[W]hether conduct is considered under [F]actor [T]wo—the experience factor, or [F]actor [F]our—the compliance factor, or both factors, is of no legal consequence because the fundamental question is whether the registrant ‘has committed such acts as would render [his] registration . . . inconsistent with the public interest.’”).

178. *Zayas*, 82 Fed. Reg. at 21420.

179. *Id.* at 21422.

180. *Id.*

181. *Id.*

understandable in the context of a legislative format that requires the balancing of public interest factors. It is challenging to perceive why this phrase would supply comfort to litigants and courts concerned about the risk that the same evidence will be or has been considered more than once under multiple factors, yielding results that militate in favor of the sanction sought by the enforcement arm of the Agency. For example, in a hypothetical case where the same evidence is considered under both Factors Two and Four, and the Agency final order explains that both of these factors weigh in favor of a sanction, legal and evidentiary analysis on appeal can become obfuscated, and assurances by the Agency that it “does not mechanically count up the [Public Interest F]actors”<sup>182</sup> or that “misconduct is misconduct”<sup>183</sup> will bring little to the analysis.

The *Zayas* analysis is potentially nettlesome in several respects. Congress, obviously recognizing the potential that the term “public interest” could be viewed as sufficiently amorphous as to unfairly deprive the regulated community of fair notice, or unfairly empower the regulators with too broad a role in interpretation, supplied a specific definitional framework to the term as it is used in determining whether to register (or continue the registration of) practitioners under the CSA.<sup>184</sup> At least at first blush, it is difficult to perceive where blurring the lines cast by Congress would be helpful in guiding either regulators or the regulated community in discerning the limits of acceptable activity conducted under the authority of a DEA registration. There is a potentially huge divide between consideration of evidence in specific categories supplied by the statute,<sup>185</sup> and a blanket pronouncement that “misconduct is misconduct”<sup>186</sup> could conceivably authorize a level of after-the-fact Agency discretion that well exceeds congressional intent. Further, in terms of defending adjudications on appeal, a past willingness by the courts to affirm sanctions based on evidence considered under any one or more of the Public Interest Factors,<sup>187</sup> which is the rationale tendered by the Agency in its analysis of why it need not specify what evidence is being considered under which factors,<sup>188</sup>

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182. *Id.*

183. *Id.*

184. 21 U.S.C. § 823(f) (2012). Similar frameworks are used in determining whether to register or sanction manufacturers, distributors of controlled substances, as well as distributors of List I chemicals. *See generally id.* § 823. It is not altogether clear whether the Agency would follow the same path that it has taken with practitioners if faced with similar cases regarding the other types of registrants.

185. *See* Mulrooney & Hull, *supra* note 1, at 336–37.

186. *Zayas*, 82 Fed. Reg. at 21422.

187. *See, e.g.,* Trawick v. DEA, 861 F.2d 72, 76 (4th Cir. 1988); Hoxie v. DEA, 419 F.3d 477, 482 (6th Cir. 2005); Morall v. DEA, 412 F.3d 165, 173–74 (D.C. Cir. 2005).

188. *Zayas*, 82 Fed. Reg. at 21422.

may not translate into a willingness by the courts to embrace a “misconduct is misconduct” approach to determining whether granting or maintaining registration status is “inconsistent with the public interest.”<sup>189</sup> Additionally, despite the Agency’s assurance that it does not count up the factors to determine which weigh in favor of or against the respondent, where Congress has declared that the public interest is defined by consideration of record evidence under specific factors,<sup>190</sup> those factors must inescapably be weighed and balanced against each other. The assurance that the Agency “does not mechanically count up the [Public Interest F]actors”<sup>191</sup> may provide scant comfort to the regulated community, and even less guidance to regulators and the diversion bar, about how misconduct will be considered against them.

#### 4. The X Factor?

While *Zayas* suggested that the Agency is moving away from differentiating between the factors when considering evidence of misconduct, the *Pope* decision also contained a statement that was brief in terms of verbiage, but potentially extremely consequential. In the same footnote where the Agency discussed Factors One and Three, which it found to be insignificant to its determination that the Government satisfied its *prima facie* burden, the Administrator included the following statement: “While I have considered [F]actor [F]ive, I deem it unnecessary to make any findings.”<sup>192</sup> The Administrator’s choice of words signals that the Agency apparently considered evidence under Factor Five but “deem[ed] it unnecessary”<sup>193</sup> to explain what evidence was considered or in what manner it was analyzed, because it ultimately concluded that “the Government’s evidence with respect to Factors Two and Four satisfies its *prima facie* burden.”<sup>194</sup> While the failure to consider all Public Interest Factors has not garnered negative attention from the courts on review,<sup>195</sup> and the absence of any evidence offered or considered under a particular factor is not uncommon, the declaration that the factor *was* considered but its significance is not explained raises a potential analytical red flag. The Supreme Court has made it clear that, in reviewing administrative determinations rendered by federal agencies, “[t]he grounds upon which an administrative order must be judged are those upon which the record discloses

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189. 21 U.S.C. § 823(f).

190. *Id.* (“In determining the public interest, the following factors shall be considered . . . .”)

191. *Zayas*, 82 Fed. Reg. at 21422.

192. Wesley Pope, M.D., 82 Fed. Reg. 14944, 14965 n.36 (Drug Enf’t Admin. Mar. 23, 2017).

193. *Id.*

194. *Id.* at 14965.

195. See, e.g., *Trawick v. DEA*, 861 F.2d 72, 76 (4th Cir. 1988); *Hoxie v. DEA*, 419 F.3d 477, 482 (6th Cir. 2005); *Morall v. DEA*, 412 F.2d 165, 173–74 (D.C. Cir. 2005).

that its action was based,” and that review in the courts will be “confin[ed] . . . to a judgment upon the validity of the grounds upon which [an agency] itself based its action.”<sup>196</sup> If no consideration was given to Factor Five, or if no evidence was offered or considered under Factor Five, then no review would be necessary. But with the chosen language, it may be analytically impossible to determine the total body of considerations upon which the sanction was based. This language, or similar language that omits or obscures the bases upon which an Agency sanction is based, is particularly unhelpful in reviewing its legal sufficiency, and renders its defense in the courts potentially unwieldy. Stated differently, there is no analytical flaw in a final Agency order that determines that no evidence is relevant under a given Public Interest Factor, but where an Agency has indicated that evidence has been considered under a Factor, it must explain what evidence was considered and how it was analyzed under that Factor.<sup>197</sup>

*B. The Pharmacy’s Corresponding Responsibility and Willful Blindness*

The DEA regulations have long explained that the responsibility required of a pharmacy registrant in ensuring that controlled substance prescriptions are legitimately issued is not identical to the responsibility of prescribers, but is instead a “corresponding responsibility.”<sup>198</sup> Recent final orders issued by the Agency have increased the quantum and nature of evidence that now must be demonstrated to establish a violation of a pharmacy registrant’s corresponding responsibility.<sup>199</sup> In *JM Pharmacy*, the Agency set forth that it must establish “willful blindness” in order to meet its (own) burden to demonstrate a violation of a pharmacy’s corresponding responsibility.<sup>200</sup> This is a higher standard than it required of itself in prior cases.<sup>201</sup> The willful blindness standard requires that, at the time of the alleged transgression(s), the pharmacy registrant (generally through its pharmacists) subjectively believed that there was a high probability that a particular fact existed, and took deliberate actions to avoid learning that fact.<sup>202</sup> The Agency’s adoption of the higher standard in

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196. *SEC v. Chenery Corp.*, 318 U.S. 80, 87–88 (1943).

197. *See id.*

198. 21 C.F.R. § 1306.04(a) (2017).

199. *E.g.*, *JM Pharmacy Grp., Inc.*, 80 Fed. Reg. 28667, 28672 (Drug Enf’t Admin. May 19, 2015).

200. *Id.* at 28670.

201. *See* *Holiday CVS, L.L.C.*, 77 Fed. Reg. 62316 (Drug Enf’t Admin. Oct. 12, 2012); *see also* *Mulrooney & Hull*, *supra* note 1, at 354–56 (discussing the corresponding responsibility of pharmacy registrants).

202. *JM Pharmacy*, 80 Fed. Reg. at 28672 (citing *Global-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 769 (2011)).

administrative pharmacy enforcement cases was unexpected, particularly given that in *Global-Tech*,<sup>203</sup> the single authority cited by the Agency to support this increased standard,<sup>204</sup> the court dealt exclusively with the doctrine to be applied in civil lawsuits for induced patent infringement under 35 U.S.C. § 271(b), a statute that bears no readily-apparent relation to the Controlled Substances Act<sup>205</sup> or the corresponding responsibility regulation.<sup>206</sup> In fact, the corresponding responsibility regulation and the patent infringement statute do not share common elements, structure, or language.<sup>207</sup>

This was a considerable, voluntary step up from the Agency's previous interpretation, which required only a demonstration that a pharmacy's controlled substance dispensing fell below the standard of care for dispensing in the particular state.<sup>208</sup> This higher standard may make it less burdensome for pharmacy registrants to defend enforcement actions brought against them, and harder for the Agency enforcers to bring and prevail in actions based on a violation of the corresponding responsibility. Litigants representing members of the regulated community who are careless or sloppy (even very sloppy) with required paperwork obligations under the regulations will doubtless find comfort in *JM Pharmacy* and the Agency's interpretation that it is no longer sufficient for the Government to merely demonstrate practice below the prevailing state standard, but that it instead must demonstrate willful blindness.

### 1. Red Flags and Willful Indifference

The Agency has long held that a pharmacy can violate its corresponding responsibility by ignoring red flags raised by prescriptions and the circumstances in which they are presented.<sup>209</sup> However, in *Superior Pharmacy I and Superior Pharmacy II*, again citing *Global-Tech*, the Agency held that, to satisfy its new willful indifference standard for corresponding responsibility violations, it is not enough to show that a pharmacist dispensed a controlled

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203. *Global-Tech*, 563 U.S. at 760 (discussing 35 U.S.C. § 271(b)).

204. *JM Pharmacy*, 80 Fed. Reg. at 28672.

205. Controlled Substances Act of 1970, Pub. L. No. 91-513, 84 Stat. 1236 (codified as amended at 21 U.S.C. §§ 801-904 (2012)).

206. 21 C.F.R. § 1306.04(a) (2017).

207. Compare 21 C.F.R. § 1306.04(a), with 35 U.S.C. § 271(b) (2012).

208. See, e.g., *Holiday CVS, L.L.C.*, 77 Fed. Reg. 62316 (Drug Enf't Admin. Oct. 12, 2012).

209. The Agency has defined a "red flag" to mean "a circumstance that does or should raise a reasonable suspicion as to the validity of a prescription." *Superior Pharmacy I and Superior Pharmacy II*, 81 Fed. Reg. 31310, 31335 (Drug Enf't Admin. May 18, 2016) (citing discussion in Government's brief of *Holiday CVS*, 77 Fed. Reg. at 62341).

substance prescription in the face of a red flag.<sup>210</sup> This is because, according to the Agency, “[a]ll red flags do not have the same hue,”<sup>211</sup> and although some red flags may create only a “reasonable suspicion” that a prescription lacks legitimate medical purpose—which is less than what is required to show willful blindness<sup>212</sup>—“where there are multiple red flags, none of which alone would establish the requisite scienter, the combination of red flags may well create a subjective belief that there is a high probability that a prescription lacks a legitimate medical purpose.”<sup>213</sup> *Hills Pharmacy L.L.C.*, citing liberally to *Superior I & II*, likewise held that “establishing the requisite scienter for a violation requires more than simply showing that a [controlled substance] prescription presented a[n unresolved] red flag.”<sup>214</sup> Thus, to meet the new requisite scienter, the Agency has decided that it will now impose upon its prosecutors the requirement to demonstrate more than pharmacy registrants were doling out controlled substances below the state standard; DEA prosecutors must now show that the medications were dispensed in the face of willful indifference on the part of the registrant.<sup>215</sup>

## 2. Willful Indifference and Evidence/Absence of Red Flag Resolution

The evidence required by the Agency regarding willful indifference is also undergoing some measure of evolution. In *Superior I & II*, notwithstanding the unrefuted testimony of the Government’s expert that, “in the practice of pharmacy, a red flag which is resolved must be documented and that the documentation should be placed on the prescription itself,”<sup>216</sup> the Agency held that the failure to document red flags on prescriptions is not alone sufficient to establish that the pharmacists failed to resolve the red flags, and thus, that they deliberately failed to avoid learning that the prescriptions lacked a legitimate medical purpose.<sup>217</sup> The Agency stated that, “while evidence of a custom certainly has probative value, it is not conclusive proof,”<sup>218</sup> and that

[w]hile it would be reasonable to draw an adverse inference that a pharmacist failed to resolve a red flag (or flags) from the

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210. *Superior I & II*, 81 Fed. Reg. at 31335 n.5 (citing *Global-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754 (2011)).

211. *Id.*

212. *Id.* (“[A]s the Supreme Court’s decision in *Global-Tech* makes plain . . . a ‘reasonable suspicion’ . . . is not enough to establish that a pharmacist acted with the requisite scienter.”).

213. *Id.*

214. *Hills Pharmacy, L.L.C.*, 81 Fed. Reg. 49816, 49839 (Drug Enf’t Admin. July 28, 2016).

215. *See Superior I & II*, 81 Fed. Reg. at 31335; *Hills Pharmacy*, 81 Fed. Reg. at 49839.

216. *Superior I & II*, 81 Fed. Reg. at 31335.

217. *Id.*

218. *Id.* at 31335 n.55.

failure to document the resolution in any manner, the Government offered no evidence that the [investigators] *even asked* the pharmacists . . . if they documented their resolution of red flags, and if so, where they did so.<sup>219</sup>

Thus, although the Government's expert provided unmet evidence that the failure to document red flag resolution on the back of prescriptions meant that those red flags were not resolved, the Agency announced that it is incumbent upon Agency investigators to query pharmacy employees about where else the information could be documented, essentially calling upon them to prove the negative.<sup>220</sup> No witness testified that red flag resolution was or should be documented elsewhere, but because the prosecution's case did not eliminate other potential repositories at the pharmacy, its evidence came up short.<sup>221</sup>

In *Hills Pharmacy*, the Agency held to its position that a lack of documentation alone is insufficient to establish that the pharmacy failed to fulfill its corresponding responsibility by resolving red flags, again despite the Government's expert's testimony that any resolution should have been documented on the prescriptions themselves.<sup>222</sup> Unlike in *Superior I & II*, however, the Agency went on to discuss "additional evidence, which establishes by a preponderance of the evidence" the requisite scienter—evidence that included a pharmacist's testimony, which was offered by the respondent and partial medical records, also supplied by the respondent.<sup>223</sup> The Agency acknowledged that it rejected similar allegations in *Superior I & II*, where the evidence only included absence of documentation, noting that "in that matter, neither party called any of the pharmacists who dispensed the prescriptions" and that the respondent "had the option of not putting forward evidence on the dispensing allegations [but] nonetheless chose to present [the pharmacist's] testimony and submit the partial medical records."<sup>224</sup> Thus, the Agency held that documents submitted as part of the respondent's case, as well as the testimony of a pharmacist—put on the stand by the respondent pharmacy—can be used to shore up the Government's case when it otherwise relies upon a lack of documentation.<sup>225</sup>

What made the Agency's announcement that it would use evidence presented in the respondent's case in *Hills Pharmacy* particularly poignant, and particularly painful for the respondent, is that at the hearing, the respondent's

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219. *Id.* at 31335.

220. *Id.* at 31337 n.60.

221. *Id.* at 31336–37.

222. *Hills Pharmacy*, L.L.C., 81 Fed. Reg. 49816, 49835–36 (Drug Enf't Admin. July 28, 2016).

223. *Id.* at 49836.

224. *Id.* at 49840 n.41.

225. *Id.* at 49836.

counsel, in an exercise of caution, moved for a partial summary disposition based on its (ultimately vindicated) position that the Government had not established its case because there was no evidence that red flags had not been resolved.<sup>226</sup> The ALJ denied the motion, not because it was devoid of merit, but because the ALJ was unable to identify a basis in the hearing regulations to grant the requested relief.<sup>227</sup> Notwithstanding the cautious manner in which the respondent's counsel proceeded, the Agency was at once unsympathetic and ambiguous as to the availability of a summary disposition motion in similar circumstances in the future. The following analysis was set forth by the Administrator in his final order:

Even if the ALJ committed error when she denied [r]espondent's motion, [r]espondent had the option of not putting forward evidence on the dispensing allegations. [r]espondent nonetheless chose to present . . . testimony and submit [exhibits]. Cf. *United States v. Sherod*, 960 F.2d 1075, 1076 (1992) ("It is the universal rule in the federal circuits that 'a criminal defendant who, after denial of a motion for judgment of acquittal at the close of the government's case-in-chief, proceeds to the presentation of his own case, waives his objection to the denial.'") (quoting *United States v. Foster*, 783 F.2d 1082, 1085 (D.C. Cir. 1986) (en banc)). Thus, I am not required to ignore this evidence in adjudicating the dispensing allegations.<sup>228</sup>

This analysis is of particular significance in light of the fact that the Agency, as already discussed, has previously created an evidentiary framework in enforcement cases wherein the respondent is precluded from avoiding a sanction if the Government has established its *prima facie* case and the evidence is not met with an acceptance of responsibility and a demonstration of remedial steps aimed at the avoidance of future transgressions.<sup>229</sup> The Agency has also embraced the viability of adverse inferences borne of missing evidence, even where a respondent declines to testify based on self-incrimination concerns at the advice of counsel.<sup>230</sup> Thus, the respondent faces the unpleasant specter of a three-option choice: (1) presenting no evidence on a given charge and having a *prima facie* case established with the assistance of an adverse inference; (2)

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226. *Id.* at 49840 n.41.

227. *Id.*

228. *Id.*

229. Jeri Hassman, M.D., 75 Fed. Reg. 8194, 8236 (Drug Enf't Admin. Feb. 23, 2010); *See supra* Part III.A.2.

230. Joseph Baumstarck, M.D., 74 Fed. Reg. 17525, 17528 n.3 (Drug Enf't Admin. Apr. 15, 2009).



presenting no evidence and having an established *prima facie* case stand un rebutted by an absence of any demonstration of acceptance of responsibility or remedial steps; or (3) presenting evidence, only to have it used to potentially shore up a deficient Government presentation.<sup>231</sup> In an environment (more fully discussed elsewhere in this Article)<sup>232</sup> where virtually all factual and legal determinations rendered by the ALJ are increasingly supplanted by the Agency, it would seem that some measure of clairvoyance has become a required skill for the registrants' bar in evaluating whether and how to meet the Government's case. Even if a conscientious respondent's counsel were to procure a ruling on a timely-rendered motion for a partial summary disposition, there is no present guarantee that such a motion is authorized, or even that counsel possesses the luxury of assuming that the Agency would uphold the ALJ's determination. The only two fixed points of certainty seem to be that the respondent cannot prevail if the Agency finds that the Government has met its *prima facie* burden without the respondent meeting the evidence, and that the Agency will supplement the Government's *prima facie* case with the respondent's evidence if any is presented.<sup>233</sup>

The approach for both parties to the litigation equation must shift along with this new Agency precedent. For its part, the Government can no longer rely on an expert's testimony regarding where the resolution of red flags should be documented under applicable state standards. Instead, to prevail now, it must insure that its agents and investigators scour through all documentation that exists in a pharmacy and, if its case is based upon an absence of evidence that red flags—or at least those which, in combination, can establish the requisite scienter—the Government must be prepared to show proof that the red flags were not resolved and documented anywhere in the pharmacy operation, paper files, or computer databases. The respondent, on the other hand, must be prepared to counsel his client and determine whether offering the testimony of any pharmacists or staff members could potentially backfire in support of the Government's case. Whether the availability of a motion for a summary disposition based on the Government's failure to meet its burden exists in DEA administrative proceedings remains an open question.

The new willful indifference standard embraced by the DEA in its pharmacy final orders is positive news for pharmacy registrants and those who represent them, but the Agency's newly expressed willingness to shore up its case with the respondents' evidence, coupled with its unwillingness to provide a reliable framework for summary disposition motions made at administrative

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231. See *id.*; *Hassman*, 75 Fed. Reg. at 8236; Jayam Krishna-Iyer, M.D., 74 Fed. Reg. 459, 463 (Drug Enf't Admin. Jan. 6, 2009).

232. See *infra* Part III.L–M.

233. *Hills Pharmacy*, L.L.C., 81 Fed. Reg. 49817, 49818 (Drug Enf't Admin. July 28, 2016).

hearings, presents new perils for the regulated community. Government counsel should expect to defend the higher patent-infringement/*Global-Tech* standard of willful blindness, and registrant's counsel should be seeking to demonstrate that the higher burden has not been met—before calling its first witness.

### 3. Verification of a Prescriber's Registration

In a further tightening of the standards applied to its own enforcement efforts, the Agency has announced that it will no longer rely on a pharmacy registrant's failure to verify that a prescriber possessed a valid DEA registration prior to dispensing in finding a violation of the pharmacy's corresponding responsibility.<sup>234</sup>

About a decade ago, in *United Prescription Services*, the Agency called the testimony of an expert “nonsense”<sup>235</sup> when that expert testified “that it was ‘probably’ not inappropriate to fill a prescription for controlled substances issued by a practitioner whose DEA registration had expired even if the pharmacy had a copy of the expired registration on file.”<sup>236</sup> The Agency opined that “filling a prescription issued by a practitioner whose registration has recently expired might be excusable,” but admonished the pharmacy respondent for filling prescriptions “long after the expiration” of the practitioner's registration, stating that it “clearly was not appropriate and was unlawful.”<sup>237</sup> This statement, that the Agency might excuse a pharmacy's failure to refuse prescriptions when a registration issue arose “recently,” but not “long after” it arose, suggested that the Agency expected pharmacies to verify registrations at least somewhat regularly.

Shortly thereafter, in *Medicine Shoppe—Jonesborough*, the Agency stated unequivocally that “[a] pharmacy has a duty to periodically check to see that a practitioner retains the authority to practice medicine and dispense a controlled substance.”<sup>238</sup> Four years later in *Holiday CVS*, without referencing *Medicine Shoppe—Jonesborough*, the Agency stated that “[i]t would be difficult to imagine a duty of a pharmacy registrant that is more fundamental to the law and spirit of the CSA than the obligation to ensure that controlled substance prescriptions are issued only on the authority of those empowered to prescribe

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234. See *JM Pharmacy Grp, Inc.*, 80 Fed. Reg. 28667, 28671 (Drug Enf't Admin. May 19, 2015).

235. *United Prescription Services, Inc.*, 72 Fed. Reg. 50397, 50408 (Drug Enf't Admin. Aug. 31, 2007).

236. *Id.* at 50406.

237. *Id.* at 50408–09.

238. *Med. Shoppe—Jonesborough*, 73 Fed. Reg. 363, 381 n.45 (Drug Enf't Admin. Jan. 2, 2008).

by the DEA.”<sup>239</sup> However, the Agency went on to explain that “the expiration of a COR is a clear red flag that a prescription issued pursuant to that COR is invalid,” and stated that “the question becomes whether the expirations of the CORs were recognized, or should have been recognized, by the [pharmacies].”<sup>240</sup> After finding that the pharmacies “knew or should have known of the relevant registration statuses,” the Agency addressed the “third prong of the inquiry—resolution,” and determined that the pharmacies did not conclusively resolve the red flag prior to dispensing.<sup>241</sup> Thus, the Agency concluded that the pharmacies dispensed controlled substances in the face of red flags “that put them on notice that the controlled substance prescriptions were not issued in the usual course of a professional practice,” and held that “[s]uch acts are sufficient for the Government to sustain its burden in establishing its prima facie case for revocation.”<sup>242</sup> The Agency’s statement that the “obligation to ensure that controlled substance prescriptions are issued only on the authority of those empowered to prescribe by the DEA” is “fundamental” seemed to contrast with its three-prong approach in determining whether a violation occurred, because a registrant that never attempted to verify a prescriber’s registration could seemingly shield itself by arguing that it did not know—and had no reason to know—that the registration had expired.<sup>243</sup> *Holiday CVS* therefore left the regulated pharmacy community with the conflicting impressions that the duty to determine that a prescriber is appropriately registered is “fundamental,” but that a pharmacy registrant with no knowledge or reason to know of a problem with the prescriber’s registration status can seemingly escape liability for filling prescriptions from that prescriber.<sup>244</sup>

Two and a half years later, the DEA explicitly stated in *JM Pharmacy* that “a pharmacist is not obligated to verify whether every prescription he fills has been issued by a practitioner who holds a valid DEA registration.”<sup>245</sup> The *JM Pharmacy* decision specifically acknowledged the Agency’s statement in *Medicine Shoppe–Jonesborough* requiring pharmacy registrants to “periodically” check the dispensing authority of prescribing practitioners,<sup>246</sup> and even held that a failure to verify a controlled substance prescriber’s

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239. *Holiday CVS, L.L.C.*, 77 Fed. Reg. 62316, 62341 (Drug Enf’t Admin. Oct. 12, 2012).

240. *Id.* at 62342.

241. *Id.*

242. *Id.* (citing 21 C.F.R. § 1306.04(a) (2017)) (emphasis added).

243. *Id.* at 62341.

244. *See generally id.*

245. *JM Pharmacy Grp., Inc.*, 80 Fed. Reg. 28667, 28671 (Drug Enf’t Admin. May 19, 2015).

246. *Id.* at 28671 n.18 (citing *Med. Shoppe–Jonesborough*, 73 Fed. Reg. 363, 381 n.45 (Drug Enf’t Admin. Jan. 2, 2008)).

registration at any time during a three-year period (where prescriber's prescriptions were dispensed pursuant thereto) is a breach of that duty,<sup>247</sup> but rejected the Government's allegations that such failure constituted a violation of federal law or regulations.<sup>248</sup> In coming to that conclusion, the Agency stated that, just because there is no duty to verify the prescriber's status on every prescription, the pharmacy still must meet its corresponding responsibility obligation to fill only those prescriptions that conform to the requirements of the CSA and DEA regulations, including the requirement that the prescribing practitioner be appropriately registered,<sup>249</sup> but faulted the Government's case because it "did not prove that [the pharmacy's] misconduct was intentional or knowing."<sup>250</sup> In discussing the duty to verify a prescriber's registration, the Agency stated that it would "place only nominal weight on this aspect of the [pharmacies'] misconduct" in part because "the lack of specific guidance as to what steps are necessary to comply with this duty diminished its egregiousness to some degree."<sup>251</sup> It then lectured (itself) that, "if the Agency intends to enforce this duty in other cases, it must provide the regulated community with guidance as to its scope," but declined to offer any guidance in the decision.<sup>252</sup>

In *Farmacia Yani*, a decision released the day after *JM Pharmacy*, the Agency reemphasized that "no Agency regulation requires that a pharmacist ascertain that each prescription presented to [him or her] has been issued by a practitioner who possesses a valid DEA registration,"<sup>253</sup> and again noted that the Agency has not "published any guidance to the regulated community setting forth the parameters of [the] duty."<sup>254</sup> The Agency then explicitly stated that "the corresponding responsibility does not impose strict liability on pharmacists but rather requires proof that a pharmacist filled a controlled-substance prescription either knowing that it was unlawful or with willful blindness or deliberate ignorance of the fact that the prescription was unlawful."<sup>255</sup> It also noted, in a footnote, that liability may potentially arise if the pharmacy acted

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247. *Id.* at 28673.

248. *Id.*

249. *Id.* at 28671.

250. *Id.* at 28673.

251. *Id.*

252. *Id.*

253. *Farmacia Yani*, 80 Fed. Reg. 29053, 29063 (Drug Enf't Admin. May 20, 2015).

254. *Id.* at 29063 n.26.

255. *Id.* at 29063. It then rejected the Government's allegations that a pharmacy that filled more than two hundred controlled substance prescriptions issued by a practitioner whose registration had been expired for more than seven months violated its corresponding responsibility because there was no evidence that the pharmacist who filled the prescriptions "either knew or was willfully blind to the fact that [the prescriber] was no longer registered." *Id.*

outside the usual course of professional practice in failing to verify a prescriber's registration, but dismissed that possibility because the Government did not rely on that theory.<sup>256</sup>

Inasmuch as the Agency has not yet published a standard for the intervals at which prescribing authority must be checked, actual knowledge (or willful blindness) appears to be the applicable standard for demonstrating a breach of corresponding responsibility based on dispensing controlled substances on a prescription signed by a prescriber who is no longer authorized to prescribe.<sup>257</sup> The Agency's suggestion in *Farmacia Yani* that failure to verify the prescriber's registration might potentially render dispensing "outside the usual course of professional practice,"<sup>258</sup> leaves some opportunity for the Government to rely on that theory, but it will need to establish, likely through expert testimony, that there is an applicable standard for how often a prescriber's registration must be verified. In light of the Agency's intriguing pronouncement in *JM Pharmacy* that "while [prescriber license check frequency] guidance can be announced in an adjudicatory proceeding, the process of adjudication is not well suited for doing so,"<sup>259</sup> it appears that the enforcement of this issue must wait for duly promulgated regulations following APA notice and comment proceedings.<sup>260</sup> Until then, Government counsel should come prepared to argue the patent unreasonableness of long periods of unlicensed conduct or other factors that show that the pharmacy's pharmacists knew or were willfully blind to the prescriber's registration issue. Pharmacy

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256. *Id.* at 29063 n.26.

257. In *Jones Total Health Care Pharmacy, L.L.C.*, the Agency offered the observation that [w]hile it is true that in *Holiday CVS* the Agency found that pharmacies knowingly filled prescriptions issued by two physicians who were no longer registered and did so well after the pharmacies should have known that the physicians were no longer registered, that was only a small part of the case.

*Jones Total Health Care Pharmacy, L.L.C.*, 81 Fed. Reg. 79188, 79198 (Drug Enf't Admin. Nov. 10, 2016) (referencing *Holiday CVS, L.L.C.*, 77 Fed. Reg. 62315, 62316–17 (Drug Enf't Admin. Oct. 12, 2012)). Interestingly, it would be challenging to tease that nuance from the actual language in the cited portion of the *Holiday CVS* decision, which states that "[i]t is manifest that [r]espondent's conduct in filling prescriptions issued by a practitioner whose registration had been revoked undermines the Congressional [comprehensive and closed system for regulating the distribution of . . . controlled substances]." *Holiday CVS*, 77 Fed. Reg. at 62317.

258. *Farmacia Yani*, 80 Fed. Reg. at 29063 n.26; 21 C.F.R. § 1306.06 (2017).

259. *JM Pharmacy Grp., Inc.*, 80 Fed. Reg. 28667, 28673 (Drug Enf't Admin. May 19, 2015).

260. See Administrative Procedure Act, 5 U.S.C. § 553 (2012). While it is likely that such parameters likely could have been correctly issued through an adjudication with appropriate facts, the Agency's determination that regulations must precede enforcement would seem to foreclose adjudication as an appropriate vehicle. At the very least, notwithstanding the arguably cumbersome APA rulemaking process, in light of the strident manner in which the Agency addressed the issue in *JM Pharmacy*, sorting out the issue through an adjudication would, at the very least, be confusing.

registrant counsel should come equipped with a copy of *JM Pharmacy* and a motion to exclude evidence of dispensing on prescriptions issued by prescribers with expired registrations.

#### 4. Can Prescriber's Actions Immunize Pharmacy Registrants?

In continuing the torrent of seemingly heartening news for the pharmacy bar, in *Hills Pharmacy*, the Agency's final order contained the declaration that "it is true that a pharmacist [sic]<sup>261</sup> cannot violate his corresponding responsibility if a [controlled substance] prescription was nonetheless issued for a legitimate medical purpose . . . ."<sup>262</sup> This seemingly unequivocal proposition runs contrary to one of the central tenets that all parts of diversion regulation and litigation had understood: a pharmacy registrant's actions are judged by what he or she knew or should have known at the time a controlled substance was dispensed.<sup>263</sup> Because the training and execution of the duties of the pharmacist have historically controlled the question of whether the pharmacy registrant has complied with his or her obligations,<sup>264</sup> it was theoretically possible for a pharmacy registrant who dispensed a prescription issued by a doctor in good faith to be non-compliant by not identifying, addressing, resolving, and documenting red flags. Contrariwise, if all red flags encountered were resolved within the parameters of state standards, and a pharmacist otherwise complied with his or her obligations, even a bad prescription that was issued by a non-compliant prescriber should not result in a sanction on a pharmacy registrant. Prior to the *Hills Pharmacy* final order, the touchstone for assessing whether the regulatory corresponding responsibility<sup>265</sup> had been satisfied had always been an objective analysis of whether the pharmacy registrant (through pharmacists and other key employees) had acted within the standard of care based on the indicia presented or available.<sup>266</sup> Now, unless the Agency issues a clarification of the language it utilized in *Hills Pharmacy*, it appears that even a patently non-compliant, reckless pharmacy registrant could potentially be immunized by a validly-issued prescription, irrespective of what was done or not done prior to or at the

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261. DEA issues registrations to practitioners, which include pharmacies, not pharmacists. 21 U.S.C. §§ 802(21), 823(f) (2012).

262. *Hills Pharmacy*, L.L.C., 81 Fed. Reg. 49816, 49836–37 n.33 (Drug Enf't Admin. July 28, 2016).

263. *JM Pharmacy*, 80 Fed. Reg. at 28681.

264. *Id.* at 28681 n.24.

265. 21 C.F.R. § 1306.04(a) (2017).

266. *Holiday CVS, L.L.C.*, 77 Fed. Reg. 62316, 62322 (Drug Enf't Admin. Oct. 12, 2012) ("[I]t is clear that if the red flags presented by a prescription could not be resolved, then the Government satisfied the third element of its *prima facie* burden.").

moment controlled substances are dispensed.<sup>267</sup> Stated differently: if the prescriber issued a good prescription, dispensing it can bring no liability on the pharmacy registrant.

This sea change comes with a potentially powerful procedural ramification. It is currently routine practice for ALJs to deny sometimes copious subpoena requests for prescribing physicians and their patients.<sup>268</sup> Under the longstanding theory that it is the knowledge available to the pharmacy at the time of dispensing that controls the assessment of whether its corresponding responsibility has been breached, testimony regarding the actual medical purpose and legitimacy of a prescription was irrelevant, and patients are incompetent to offer opinions about whether dispensing was compliant with applicable regulations and standards.<sup>269</sup> However, this new language in *Hills Pharmacy* calls the current approach into serious question. If it is true that a pharmacy cannot, as a matter of law, violate its corresponding responsibility obligations whenever a controlled substance prescription was, in fact, issued for a legitimate medical purpose—no matter how illegitimate it appears to be at the time of dispensing—then the irrelevancy argument long-utilized by ALJs to eschew the issuance of *en masse* subpoena requests to compel the attendance of every prescriber and every patient whose prescriptions are at issue in the hearing by compulsory process to establish the legitimacy of those prescriptions is substantially undermined. If a witness can support a potential defense raised by a party in the proceeding, and the testimony is likely to elicit evidence that is “competent, relevant, material, and not unduly repetitious,” it would be manifest error to deny the subpoena request.<sup>270</sup> This may mean that in a post-*Hills Pharmacy* world, dozens or even hundreds of prescribers and patients are potentially subject to compulsory process.<sup>271</sup> Inasmuch as the Administrative Procedure Act (APA) affords every respondent at a hearing the right “to present his case or defense,”<sup>272</sup> it may be difficult for ALJs to justify denying registrants the ability to present the defense, suggested by the Agency for the first time in

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267. *Hills Pharmacy*, 81 Fed. Reg. at 49836–37 n.33.

268. *Id.* at 49817; *Superior Pharmacy I* and *Superior Pharmacy II*, 81 Fed. Reg. 31310, 31312–13, 31317 (Drug Enf’t Admin. May 18, 2016); *see* Administrative Procedure Act, 5 U.S.C. § 555(d) (2012).

269. *See* 21 C.F.R. § 1316.59(a).

270. *Humphreys v. DEA*, 96 F.3d 658, 663 (3d Cir. 1996); *See also* 21 C.F.R. § 1316.59(a); 5 U.S.C. § 555(d).

271. For example, in *Hills Pharmacy*, the respondent proposed calling 1,461 patients whose prescriptions had been seized by DEA as witnesses, along with more than 130 doctors. *Hills Pharmacy*, 81 Fed. Reg. at 49817. The respondent estimated that it would require 45 to 60 days to present its case-in-chief. *Id.*

272. 5 U.S.C. § 556(d).

*Hills Pharmacy*, that all of the prescriptions under scrutiny were, in fact, legitimately issued.

Government counsel should be prepared to distinguish *Hills Pharmacy*, or minimize its exposure by bearing down on those aspects of the hearing regulations that limit “unduly repetitious” evidence,<sup>273</sup> and be prepared to persuade the assigned ALJ to exercise his authority to “regulate the course of the hearing.”<sup>274</sup> Respondent’s counsel should spend their pre-hearing hours tracking down the names and addresses of all prescribers and patients that pertain to the allegations, and determining whether those otherwise-uninvolved persons might be able to supply a defense for the pharmacy client. The ALJs should prepare for longer hearings and an increased level of subpoena litigation.

### C. Medical Practice Standards

More than a decade ago, in *Gonzales v. Oregon*,<sup>275</sup> the Supreme Court categorically dictated that Congress and the CSA do not regulate the practice of medicine generally, noting the following:

The [Controlled Substances Act] and our case law amply support the conclusion that Congress regulates 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. Beyond this, however, the statute manifests no intent to regulate the practice of medicine generally. The silence is understandable given the structure and limitations of federalism, which allow the States great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons.<sup>276</sup>

Thus, in regulating its registrants, the DEA is required to apply medical practice standards that emanate from the states as part of their police powers.<sup>277</sup> This division of regulatory power is particularly important when the Agency seeks to rely on an allegation that a registrant or applicant fell below a state medical standard in its administrative enforcement proceedings.<sup>278</sup>

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273. 21 C.F.R. § 1316.59(a).

274. 5 U.S.C. § 556(c)(5).

275. 546 U.S. 243 (2006).

276. *Id.* at 269–70 (internal citations and quotation marks omitted) (emphasis added).

277. *Id.* at 270 (“The structure and operation of the CSA presume and rely upon a functioning medical profession regulated under the States’ police powers.”).

278. See 21 C.F.R. § 1306.04(a) (“A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner *acting in the usual course of his professional practice* . . .”) (emphasis added).



Where a sanction is sought by DEA's regulators based on a failure to comply with an applicable state standard, it is incumbent upon the Government to demonstrate both what the state standard is and that a registrant has committed acts or practiced in a manner that falls short of that standard.<sup>279</sup> This is typically, but not always, accomplished through the use of expert testimony.<sup>280</sup> However, expert testimony is not always required, and in *Jack A. Danton, D.O.* the Agency outlined the other ways in which cases without expert testimony can be proved:

[W]here the Government fails to provide expert testimony to support a finding that a practitioner acted outside of the usual course of professional practice and lacked a legitimate medical purpose, it can nonetheless prove a violation by: (1) providing evidence that a practitioner committed a violation of a state medical practice standard which is sufficiently tied to a state law finding of illegitimacy to support a similar finding under federal law[;] (2) providing evidence showing that [a registrant] knowingly diverted drugs[; or, (3) providing evidence that a registrant] violat[ed] a state medical practice standard which has a substantial relationship to the CSA's purpose of preventing substance abuse and diversion.<sup>281</sup>

In *Lawrence E. Stewart, M.D.*, the Agency recently reaffirmed that expert testimony is "typically necessary" to establish that a physician fell below the standard for writing controlled substance prescriptions when the physician made "some attempt to comply with various state medical practice standards and the adequacy of those efforts is at issue," but that "the facts and circumstances surrounding the issuance of the prescription" established on the record in that case could also support such a charge.<sup>282</sup> As discussed below, other recent Agency cases have added additional nuances to the area of medical practice standards in DEA proceedings that both sides should be aware of.

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279. T.J. McNichol, M.D., 77 Fed. Reg. 57133, 57147–48 (Drug Enf't Admin. Sept. 17, 2012).

280. *Id.* at 57147 ("[W]here a physician makes some attempt to comply with various state medical practice standards and the adequacy of those efforts is at issue, expert testimony is typically necessary to establish that a physician violated 21 C.F.R. § 1306.04(a).") (internal quotation and citation omitted).

281. Jack A. Danton, D.O., 76 Fed. Reg. 60900, 60901 (Drug Enf't Admin. Sept. 30, 2011); *see also* Joe W. Morgan, D.O., 78 Fed. Reg. 61961, 61978 (Drug Enf't Admin. Oct. 8, 2013) (reaffirming *Danton*).

282. Lawrence E. Stewart, M.D., 81 Fed. Reg. 54822, 54824 (Drug Enf't Admin. Aug. 17, 2016) (citing *McNichol*, 77 Fed. Reg. at 57147–48) (additional citation omitted).

### 1. Investigators as Experts?

In *Jones Total Health Care Pharmacy, L.L.C.*, the Government's expert testified regarding payment in cash as an indicator of diversion, specifically testifying that it is indicative of diversion when a patient asks the pharmacy not to bill his or her insurance and instead requests to pay cash.<sup>283</sup> Based on that testimony, the ALJ found that paying cash was a red flag, but the respondent pharmacy challenged that finding because there was no evidence that patients requested that the pharmacy not bill their insurance—a seemingly essential component of what the expert testified constitutes a red flag.<sup>284</sup> In the Agency's final order, with no apparent prior warning to the respondent, the Agency held that a diversion investigator, who, at the hearing, also "testified that 'paying cash' is a 'red flag of diversion,'" <sup>285</sup> possessed sufficient expert knowledge to supplement the expert's opinion in order to find that when a pharmacy customer pays cash it constitutes a red flag of diversion that should have been acknowledged and acted upon by the pharmacy registrant.<sup>286</sup> While, in *Jones Total Health*, the diversion investigator's testimony was used to bolster the expert's opinion,<sup>287</sup> the decision suggests that the Agency may be amenable to finding that its investigators possess sufficient knowledge and experience such that they may offer expert testimony on certain subjects in future cases. This is something for both sides of the litigation equation to consider as they prepare their cases.

### 2. When "Should" Means "Must"

While the Agency disagreed with the Government's expert and the findings of the ALJ that certain documentation should exist in a certain location in *Superior Pharmacy I & Superior Pharmacy II*,<sup>288</sup> in *Wesley Pope, M.D.*, the

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283. *Jones Total Health Care Pharmacy, L.L.C.*, 81 Fed. Reg. 79188, 79191 (Drug Enf't Admin. Nov. 10, 2016).

284. *Id.*

285. *Id.* (internal punctuation omitted).

286. *Id.*

287. *Id.*

288. As discussed, in *Superior I & II*, the Agency discounted the unchallenged testimony of the Government's expert witness (the only expert witness to testify at the hearing) that a pharmacy encountering circumstances that raise suspicion about the validity of a prescription must be resolved prior to dispensing, and that such resolution would customarily be documented on the prescription itself. See Part III.B.2.; *Superior Pharmacy I & Superior Pharmacy II*, 81 Fed. Reg. 31310 (Drug Enf't Admin. May 18, 2016). The Agency, while not outright rejecting the testimony, emphasized that the expert did not (and conceded that he could not) point to any statute or regulation requiring such documentation in any particular location, and held that just because documenting resolution of a red flag on the prescription is "customary in the profession . . . does not make it improper to document the resolution somewhere else." *Id.* at 31335 n.55.

Agency was willing to agree with the Government's expert—over the ALJ's findings—that certain documentation that state code provisions provided should exist was, in fact, mandatory.<sup>289</sup> In *Pope*, the Government's expert testified that the practitioner's documentation deficiencies placed him outside of the standard of care, as that standard is described in certain provisions of the Oklahoma Administrative Code.<sup>290</sup> The Oklahoma provisions at issue directed that "[a] medical history and physical examination must be obtained, evaluated and documented in the medical record," and went on to list specific areas that the "medical record should document,"<sup>291</sup> and further directed that "[r]ecords should remain current" and that "[t]he physician should keep accurate and complete records."<sup>292</sup> The Government's expert testified that all of the documentation requirements listed in the code provision are mandatory (and that such documentation was missing from the prescriber's records), despite the fact that the code provisions used the word "should," rather than "shall" or "must," in describing numerous aspects of the documentation to be kept.<sup>293</sup> While finding the expert credible, the ALJ declined to give weight to certain aspects of the expert's testimony interpreting the code provisions, instead finding that his testimony was based upon a mistaken understanding of the Oklahoma Board's documentation and recordkeeping standards in finding that "should" was mandatory, not permissive.<sup>294</sup>

The Agency disagreed with the ALJ's interpretation of the Oklahoma provisions, and held that "should" does not really mean "should," at least in those provisions, but actually means "must," and connoted a mandatory obligation in the context of the provisions at issue.<sup>295</sup> The Agency based its decision on its interpretation of cases from the Seventh Circuit, the D.C. Circuit, a federal district court in Florida, and a dictionary definition of "should," as well as an analysis of the Oklahoma Medical Practice Act and a Policy Statement.<sup>296</sup> Interestingly, a Tenth Circuit (which includes Oklahoma) case which held that "'should' indicates a recommended course of action, but does not itself imply the obligation associated with 'shall,'" received no mention in the Agency's decision in *Pope*.<sup>297</sup> Thus, contrary to the Agency's view, the

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289. Wesley Pope, M.D., 82 Fed. Reg. 14944, 14945 (Drug Enf't Admin. Mar. 23, 2017).

290. *Id.*

291. *Id.* (citing Okla. Admin. Code § 435:10-7-11(1) (2016)).

292. *Id.* (citing Okla. Admin. Code § 435:10-7-11(6)).

293. *Id.*

294. *Id.* at 14946.

295. *Id.*

296. *Id.* at 14945–46.

297. *Qwest Corp. v. FCC*, 258 F.3d 1191, 1200 (10th Cir. 2001). In *Qwest*, the Tenth Circuit considered an FCC statute which, like the Oklahoma Administrative Code provisions at issue in *Pope*,

pertinent Circuit Court of Appeals holds the view that the most reasonable interpretation of the word “should” is really “should”—a discretionary term.<sup>298</sup> The Agency did not discuss the fact that there is some level of conflict in the circuit courts about whether to treat “should” as mandatory or permissive,<sup>299</sup> but the Agency has apparently taken the position that, if the state law supplying the practice standard in a DEA case uses the word “should,” the Agency is likely to read that word as “must,” irrespective of federal circuit law on the issue.<sup>300</sup>

While *Pope* dealt with codified evidence of a standard which dictated that certain information “should” be documented and *Superior I & II* dealt with testimonial evidence of a standard which dictated that certain information “should” be documented in a certain location, the Agency found that one standard was mandatory, while the other was permissive.<sup>301</sup> On that backdrop, if the Government’s theory of a case is grounded in the absence of certain documentation, both parties will need to dedicate substantial energy to a thorough examination of the codified standards to determine what aspects are mandatory or merely permissive, and both parties will need to narrowly focus their expert witnesses—or the other party’s expert witnesses on cross examination—to the full extent of any given standard.

### 3. “General” Practice Standards?

Although, as previously discussed, the Supreme Court has unambiguously clarified that the authority to set medical standards rests exclusively with the states, and is nowhere within the purview of the DEA,<sup>302</sup> some recent Agency final orders have embraced the application of what the Agency has termed “general practice standards” in ascertaining whether a practitioner has acted in the course of a professional practice.<sup>303</sup> In one such case, *Fiaz Afzal, M.D.*, the Agency accepted the findings and legal conclusions of a state medical board, which, in a decision that occurred after the close of the DEA administrative

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began with an overarching “shall,” a mandatory instruction, followed by a subset of items that “should” be considered under that “shall” provision. *Id.* at 1199–1200.

298. *Id.* at 1200.

299. *E.g.*, *United States v. Maria*, 186 F.3d 65, 72–73 (2d Cir. 1999) (discussing circuit split and declining to follow decisions of the First, Fifth, and Ninth Circuits, which found that the use of the word “shall” in a sentencing guideline imposed a mandatory requirement).

300. *Pope*, 82 Fed. Reg. at 14945.

301. *Id.*; *Superior Pharmacy I and Superior Pharmacy II*, 81 Fed. Reg. 31310 (Drug Enf’t Admin. May 18, 2016).

302. *Gonzales v. Oregon*, 546 U.S. 243, 274 (2006).

303. *See, e.g.*, *Grider Drug #1 & Grider Drug, #2*, 77 Fed. Reg. 44070, 44093 n.73 (Drug Enf’t Admin. July 26, 2012); *Bienvenido Tan, M.D.*, 76 Fed. Reg. 17673, 17681 (Drug Enf’t Admin. Mar. 30, 2011).

hearing, suspended the respondent's state medical privileges.<sup>304</sup> In the course of its reliance on the state board, citing its own prior final orders and a criminal diversion case,<sup>305</sup> the Agency held that:

[T]he prescribing of a controlled substance (and the continued prescribing of a controlled substance) under the following circumstances establishes that a physician lacked a legitimate medical purpose and acted outside the usual course of professional practice and therefore violated the CSA:

- [w]ithout performing an appropriate physical examination,
- without utilizing appropriate diagnostic testing,
- failing to devise and document a written treatment plan,
- failing to periodically reassess the effectiveness of the treatment,
- continuing to prescribe controlled substances without pursuing alternative therapies,
- repeatedly and continually prescribing without referring the patient to appropriate specialists, and
- failing to keep and maintain records which contain adequate findings to support a diagnosis and the need to prescribe one or more medications.<sup>306</sup>

The Agency has also indicated a willingness to use its own prior final orders to establish that registrants should know that particular circumstances are suspicious, particularly in the area of establishing a pharmacy's corresponding responsibility in filling prescriptions with "red flags" of diversion. In *Jones Total Health Care Pharmacy, L.L.C.*, the Agency found that it was unnecessary to determine whether anyone had discussed with the pharmacists their duties and obligations under the Agency's corresponding responsibility rule, declaring that "the Agency's corresponding responsibility rule has been in force for decades and numerous decisions of both the courts and the Agency have provided ample guidance as to the scope of a pharmacist's duty under the rule."<sup>307</sup> Also, in *Jones Total Health*, the Agency, seemingly separate from those "red flags" outlined by the Government's expert,<sup>308</sup> found "additional

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304. Fiaz Afzal, M.D., 79 Fed. Reg. 61651, 61652 (Drug Enf't Admin. Oct. 14, 2014). The Government filed notice of the state board's action with the Administrator's office after the conclusion of hearing procedures before the Agency ALJ, and it was considered over the objection of the respondent. *Id.*

305. *Id.* at 61653 (citing *United States v. Moore*, 423 U.S. 122, 135, 142–43 (1975)).

306. *Id.* at 61654.

307. *Jones Total Health Care Pharmacy, L.L.C.*, 81 Fed. Reg. 79188, 79190 (Drug Enf't Admin. Nov. 10, 2016) (citations omitted).

308. *Id.* at 79218–19 (discussing expert's testimony regarding "red flags").

indicators of diversion,”<sup>309</sup> including a finding that “high prices and copious dispensing of controlled substances can be an indicator of possible diversion because it elucidates a customer base willing to pay exorbitant prices for a drug the customer could otherwise purchase at a nearby pharmacy for much less,” based on “federal court precedent” evidently cited by the Government in its brief.<sup>310</sup> In *Hills Pharmacy*, the Agency rejected testimony by a pharmacist that he was unfamiliar with the concept and significance of a “drug cocktail,” citing prior Agency orders where the “DEA had identified this combination of drugs . . . as being highly abused” before the pharmacist filled the prescriptions at issue.<sup>311</sup>

In *Pope*, the Agency further tested the limits of the Supreme Court’s holding in *Gonzales*<sup>312</sup> with the inclusion of the following language:

[W]hile [s]tates have the primary responsibility for the regulation of the medical profession, many of the profession’s norms were created by the profession itself. Thus, on such issues as the adequacy of a clinical evaluation for a particular pain complaint and the necessary documentation to support the prescribing of controlled substances, *the standard of medical practice would not seem to vary to any material degree between [s]tates, especially between [s]tates that border each other.*<sup>313</sup>

Read broadly, these cases may provide an indication that the Agency, *Gonzales* notwithstanding, is willing to draw from its own body of prior final orders and court precedents to establish “general practice standards” applicable to all DEA registrants. *Pope* is not a case where comparison of multiple state standards was in issue and litigated, but a case where the Agency drew a general conclusion, with no evidentiary support in the record of the pertinent proceeding, and included it as a sort of rumination. To the extent the Agency continues to test the waters of establishing a set of the DEA’s own medical standards, it risks confusion where its standards conflict with those of the states where misconduct is alleged to have occurred. While it is a safe bet that the courts will follow *Gonzales* and apply the state standard where it conflicts with any “general practice standards” created by the DEA,<sup>314</sup> not every case will make it to the courts, and litigants on both sides of the aisle will need to stay vigilant in discerning which standards are argued and supported by record evidence. If there is a take away from the recent Agency decisions regarding

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309. *Id.* at 79219.

310. *Id.* at 79219 & n.67.

311. *Hills Pharmacy, L.L.C.*, 81 Fed. Reg. 49816, 49837 (Drug Enf’t Admin. July 28, 2016).

312. *Gonzales v. Oregon*, 546 U.S. 243, 269–70 (2006).

313. *Wesley Pope, M.D.*, 82 Fed. Reg. 14944, 14976 (Drug Enf’t Admin. Mar. 23, 2017).

314. *See Gonzales*, 546 U.S. at 269–70.

state medical practice standards, it probably is that where state standards are in issue, both sides would be prudent to support their relative positions with identifiable state medical standards expressed in statute, regulation, state board opinions, and secure competent expert testimony.

*D. When “Legitimate Medical Purpose” Means “Outside the Usual Course of Professional Practice” and Vice Versa.*

Under longstanding regulations drafted by the Agency, “[a] prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.”<sup>315</sup> Among the more striking of the Agency’s recent final orders is its pronouncement in *Pope*,<sup>316</sup> that “legitimate medical purpose” and “outside the course of professional practice,” two terms listed separately as requirements under the regulations, and thus forming a conjunctive requirement in order for a prescription to be “effective,”<sup>317</sup> have the same meaning—not similar meanings, but the *same* meaning<sup>318</sup>—rendering them interchangeable and indistinct.

The dichotomy present in the regulatory definition of an “effective” controlled substance prescription is reasonably rooted in the reality that controlled-substance prescribing accomplished outside a prescriber’s professional practice is as potentially dangerous as controlled-substance prescribing accomplished within a prescriber’s professional practice where there is no legitimate purpose for the medication. While both features are required to render a prescription legitimate,<sup>319</sup> the components are distinct and are separately delineated for good reason. By way of example, a practitioner registrant who prescribes an opioid to someone who demonstrates an etiology consistent with a need for pain treatment (*e.g.*, a broken back, recent surgery, intractable pain) may have prescribed the medication for a legitimate medical purpose, but when it is done without the establishment of a bona fide doctor-patient relationship, without the creation of a chart, or without the requisite documentation, it is likely to have been issued outside the course of a professional practice. Conversely, a practitioner who has a bona fide doctor-patient relationship with a patient and who keeps meticulous and detailed notes

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315. 21 C.F.R. § 1306.04(a) (2017).

316. *Pope*, 82 Fed. Reg. at 14967 n.38.

317. *United States v. Nelson*, 383 F.3d 1227, 1233 (10th Cir. 2004) (“[A] practitioner is authorized to dispense controlled substances only if he acts with a legitimate medical purpose *and* in the usual course of professional practice. Conversely, a practitioner would be unauthorized to dispense a controlled substance if he acts without a legitimate medical purpose *or* outside the usual course of professional practice.”).

318. *Pope*, 82 Fed. Reg. at 14967 n.38.

319. *See* 21 C.F.R. § 1306.04(a).

about controlled pain medications that the practitioner prescribes where there is no apparent organic pain source, the potency and frequency of the medication are unwarranted, or the patient has manifested objective indications of addiction, may well be prescribing in the usual course of a professional practice, but not for a legitimate medical purpose. The two bases may be (and frequently are) co-morbidly present, but that does not support the proposition that the phrases are interchangeable.

In *Pope*, the Government noticed its case exclusively on the theory that the prescriptions in issue were issued outside the usual course of professional practice.<sup>320</sup> No allegation was tendered that the prescriptions were not for a legitimate medical purpose.<sup>321</sup> In essentially rolling over any notice issue, the Agency held that “there is no material difference between the phrases ‘usual course of a professional practice’ and ‘legitimate medical purpose,’”<sup>322</sup> relying on criminal cases where, it said, “the courts have sustained convictions for violating the regulation . . . notwithstanding that an indictment charged the defendant” with violating only one of the two elements, “as well as where the jury instructions only referenced” one of the two elements.<sup>323</sup> Ignoring the Tenth Circuit’s statement that it was “hesitant to say that [the distinction between the two phrases] never could make a difference,”<sup>324</sup> as well as the fact that the court in that case considered the argument rather than rejecting it outright and holding that the phrases mean the same thing,<sup>325</sup> the Agency quoted only the court’s statement that “it is difficult to imagine circumstances in which a practitioner could have prescribed controlled substances” in violation of one element, but not the other.<sup>326</sup> However, the cited cases may not reach as broadly as the Agency suggests, and importantly, the cited cases are not cases where the Government alleged only one theory, to the exclusion of the other, as was the situation in *Pope*.<sup>327</sup> The cases stand only for the irrefutable proposition that evidence under either theory will suffice to prove a violation of 21 C.F.R. § 1306.04(a).

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320. *Pope*, 82 Fed. Reg. at 14967 n.38.

321. *Id.*

322. *Id.*

323. *Id.* (citing *United States v. Fuchs*, 467 F.3d 889, 898–901 (5th Cir. 2006)).

324. *United States v. Nelson*, 383 F.3d 1227, 1231 (10th Cir. 2004).

325. *Id.* at 1231–33.

326. *Pope*, 82 Fed. Reg. at 14967 n.38 (quoting *Nelson*, 383 F.3d at 1231).

327. *Id.* (citing the ALJ’s recommended decision, which provided that “the Government noticed a theory based in the issuance of prescriptions outside the course of a professional practice . . . not that any prescriptions were not issued for a legitimate medical purpose,” wherein the ALJ held that a violation under the unnoticed theory, which was alleged for the first time in the Government’s post hearing brief, was unavailable to support a sanction).



Both elements—that a prescription was issued in a usual course of professional practice *and* for a legitimate medical purpose—are required for a prescription to be “effective.”<sup>328</sup> It is true that the Government only needs to prove that one of the elements was missing in order to support its prima facie case that the prescription was not “effective,”<sup>329</sup> but this is not the same as holding (as the Agency did) that a respondent had sufficient notice as to both theories if the Government only relies on one theory in its charging document and prehearing filings.<sup>330</sup> Courts have not been willing to extend *Chevron*<sup>331</sup> deference to the Agency’s view that certain words in phrases used in the CSA constitute mere surplusage,<sup>332</sup> but if the Agency’s interpretation of its prescription regulation is challenged, it will be interesting to see if the courts are more inclined to extend regulatory deference to the DEA in this regard under *Skidmore*.<sup>333</sup>

In view of the frequency with which both aspects of illegitimate prescriptions are alleged and established in practice, as a practical matter, there may be little risk to the Agency in electing to merge the terms—and using one phrase interchangeably to actually mean both phrases—even in the face of a clearly-drafted regulation which requires both elements to be present for a prescription to be legitimate. In terms of the practicing bar, both sides would do well to prepare theories in support of and against each aspect of the legitimate prescription equation. A practitioner whose prescriptions are only alleged to have been issued without a legitimate medical purpose may wish to defend himself quite differently than a practitioner whose prescriptions are only alleged to have been issued outside the usual course of professional practice, but *Pope* should serve as a warning for respondents’ counsel to prepare a defense to both theories, even if only one is charged. For the time being, the Agency has indicated its willingness to treat the dual components as an amalgam and support a sanction based on either, irrespective of which is alleged

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328. 21 C.F.R. § 1306.04(a)(2017); *Nelson*, 383 F.3d at 1233 (“[A] practitioner is authorized to dispense controlled substances only if he acts with a legitimate medical purpose *and* in the usual course of professional practice.”).

329. 21 C.F.R. § 1306.04(a); *Nelson*, 383 F.3d at 1233 (“[A] practitioner would be unauthorized to dispense a controlled substance if he acts without a legitimate medical purpose *or* outside the usual course of professional practice.”).

330. *Pope*, 82 Fed. Reg. at 14947.

331. See *SEC v. Chenery Corp.*, 332 U.S. 194, 200 (1947).

332. In *Novelty, Inc. v. DEA*, 571 F.3d 1176, 1187–88 (D.C. Cir. 2009) (Tatel, J., concurring), a majority of the D.C. Circuit was unwilling to extend *Chevron* deference so far as to assume that “principal” as used by Congress in the phrase “principal place of business” in 21 U.S.C. § 822(e) (2012), constituted surplusage.

333. *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944).

in the OSC.<sup>334</sup> But if the Government intends to proceed on a theory that a particular practitioner violated both or either of the elements, it may want to consider charging the elements in the disjunctive, in the event that its evidence only supports one of the theories.

*E. DEA-222s and the Absence of Delivery/Receipt Evidence*

To track the movement of schedule I and II controlled substances within the closed regulatory system, the DEA requires the use of a Controlled Substance Order Form (hereinafter DEA-222).<sup>335</sup> In keeping with its trend of requiring additional evidence to sustain allegations against pharmacy registrants regarding the exercise of their corresponding responsibility, the Agency has also recently imposed heightened requirements on its prosecutors for allegations relating to DEA-222s.<sup>336</sup>

A long and established body of Agency final orders held that evidence of DEA-222s maintained in a purchaser's files that were not completed in

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334. *Pope*, 82 Fed. Reg. at 14967 n.38.

335. 21 C.F.R. §§ 1305.03, 1305.12 (2017).

336. Upon request by an authorized registrant-purchaser, the DEA sends the registrant-purchaser DEA-222 forms with the purchaser's name, address, registration number, and authorized activity and schedule information pre-printed. *Id.* § 1305.11. Each individually-numbered order form comes in a three-copy stack—a brown copy (Copy 1), a green copy (Copy 2), and a blue copy (Copy 3)—with interleaved carbon sheets so that anything written on the top copy (Copy 1) transfers to the lower two copies. *Id.* §§ 1305.11, 1305.12. Aside from their color and copy number, Copies 1 and 2 are identical. Each of them contains two sections, one “to be filled in by purchaser” and another “to be filled in by supplier.” The information “to be filled in by supplier” on Copies 1 and 2 includes the supplier's DEA registration number, the National Drug Code, and “Packages Shipped” and “Date Shipped” information for each item that the supplier sends to the purchaser. The purchaser's copy, Copy 3, does not have an area “to be filled in by supplier.” Instead, in that section of the form where Copies 1 and 2 reflect that they are “to be filled in by supplier,” Copy 3 contains correspondingly-located National Drug Code, packages, and date columns, but on Copy 3, the packages and date columns, entitled “No. of Packages Received” and “Date Received,” indicate that they are “to be filled in by purchaser.” To order controlled substances, the purchaser fills in all portions of the form except the area designated “to be filled in by supplier” on Copy 1 and signs and dates the form. *Id.* § 1305.12. Because of the interleaved carbon sheets, all of the information written by the purchaser in those designated areas is also reflected on Copies 2 and 3. Pursuant to DEA regulations, the purchaser then separates the bottom copy, Copy 3, from the stack; retains that copy in the purchaser's files; and sends Copies 1 and 2 to the supplier, with the carbon sheets intact. *Id.* § 1305.13(a). When the supplier fills the order, it annotates both of its copies with details of the controlled substances that it shipped and the date on which each was shipped. *Id.* § 1305.12(b). The supplier then retains Copy 1 for its records and sends Copy 2 to the DEA. *Id.* § 1305.13(d). When the purchaser receives the shipment from the supplier, the purchaser is required to record the number of packages received and the date the packages were received on its copy, Copy 3, which was retained at the time of the order. *Id.* § 1305.13(e). When viewed together, the various copies should reflect that each package shipped by the supplier was received by the purchaser, which creates a record reflecting which controlled substances each registrant is accountable for.

accordance with the regulations could constitute a basis for a registration sanction.<sup>337</sup> However, in *Superior Pharmacy I & Superior Pharmacy II*, the Agency added an apparently new element to the mix. Reading the plain language of the regulation, the Agency divined that incomplete forms *alone* could not prove a regulatory violation; instead, it required additional proof that the purchaser actually had an obligation, triggered by the receipt of the ordered drugs, to complete the forms, but that it did not do so.<sup>338</sup> This interpretation was reaffirmed by the Agency in *Hills Pharmacy*.<sup>339</sup>

In *Superior I & II*, the Government presented evidence demonstrating that several DEA-222s on file at the pharmacies were missing information regarding the number of packages received and the date on which they were received.<sup>340</sup> There, the Agency declared the Government's case infirm because the "Government offered no evidence that any portion of the two orders listed on the form were filled."<sup>341</sup> The Agency was unpersuaded by the testimony presented by the Government that an absence of a shipment should have yielded an entry on the form of "a zero and the date they put the zero[] on the form" to indicate that nothing ever arrived; the Agency simply noted that the regulations do not require that step.<sup>342</sup> Thus, because the Government "did not identify a single instance in which a line item had actually been shipped to [the r]espondent and the entry had not been made," the Agency found that the Government had not proven that the forms were incorrectly filled out such that they would warrant a sanction.<sup>343</sup>

Shortly after *Superior I & II* was issued, the Agency issued its decision in *Hills Pharmacy*, reaffirming the requirement of additional proof that an order was actually filled, shipped, and received in order to sustain a finding that an incomplete DEA-222 was in violation of the regulations' requirements.<sup>344</sup> In

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337. *The Medicine Shoppe*, 79 Fed. Reg. 59504, 59516 (Drug Enf't Admin. Oct. 2, 2014); *Alexander Drug Co., Inc.*, 66 Fed. Reg. 18299, 18303 (Drug Enf't Admin. Apr. 6, 2001); *D-Tek Enters.*, 56 Fed. Reg. 28926, 28926 (Drug Enf't Admin. June 25, 1991); *Wayne Nichols, D.V.M.*, 54 Fed. Reg. 37167, 37167–68 (Drug Enf't Admin. Sept. 7, 1989); *York Pharmacy, Inc.*, 41 Fed. Reg. 10933, 10933 (Drug Enf't Admin. Mar. 15, 1976); *David M. Higgins*, 39 Fed. Reg. 26758, 26759 (Drug Enf't Admin. July 23, 1974).

338. *Superior Pharmacy I and Superior Pharmacy II*, 81 Fed. Reg. 31310, 31335, 31338 (Drug Enf't Admin. May 18, 2016).

339. *Hills Pharmacy, L.L.C.*, 81 Fed. Reg. 49816, 49842–43 (Drug Enf't Admin. July 28, 2016).

340. *Superior I & II*, 81 Fed. Reg. at 31338.

341. *Id.* Interestingly, there is no indication that the potential that the orders were not filled was even raised by the respondent in that case. *Id.*

342. *Id.* (internal punctuation and quotation marks omitted).

343. *Id.*

344. *Hills Pharmacy*, 81 Fed. Reg. at 49843. The Agency's decision in *Hills Pharmacy* does not cite the *Superior I & II* decision for its requirement that additional evidence be provided to show

*Hills Pharmacy*, the Agency again rejected a diversion investigator's testimony that, if the registrant did not "'receive a drug,' . . . it was required 'to write a zero' in the column for the number of packages received."<sup>345</sup> Like in its decision in *Superior I & II*, the Agency did not sustain the allegations regarding all of the DEA-222s in evidence which contained no entries whatsoever in the "No. of Packages Received" or "Date Received" columns.<sup>346</sup> However, unlike in *Superior I & II*, two of the DEA-222s in evidence in *Hills Pharmacy* contained a number in the "No. of Packages Received" column, but did not contain an entry for the date that the package(s) were received.<sup>347</sup> The Agency sustained those allegations, apparently accepting the registrant's notations in the "No. of Packages Received" column as sufficient evidence that the registrant actually received the drugs and, therefore, that it had the obligation to fill out the DEA-222s completely.<sup>348</sup> Thus, under the Agency's current interpretation of its regulations, the existence of an entirely incomplete form is superfluous in the absence of evidence that the controlled substance order was actually filled and shipped to the purchaser, while a partially complete DEA-222 may be sufficient to support the Government's allegation regarding the same.

The Agency's own precedent in *Superior I & II* and *Hills Pharmacy* presents at least the potential for something of an evidentiary conundrum for the Government. Although the burden imposed by *Superior I & II* is couched in terms of whether the order was "filled"<sup>349</sup> or "shipped,"<sup>350</sup> the purchaser's obligation to complete the form only arises when it receives the order, as

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that the registrant "had actually received any of the drugs listed in the line items which were left blank." *Id.* at 49843 n.49. Instead, it references only the language of the regulation, 21 C.F.R. § 1305.13(e). *Id.* at 49843.

345. *Id.*

346. *Id.* at 49843 & n.49.

347. *Id.* at 49843.

348. *Id.* Although the Agency found that the two forms violated the regulations, it noted that they (along with one violation of the requirement that the registrant keep the original DEA-222 Copy 3, not a copy) were "of minor consequence." *Id.* It is unclear whether that statement, which arguably stands in some tension to its prior precedent regarding the importance of accurate recordkeeping, *see, e.g.,* *Satinder Dang, M.D.*, 76 Fed. Reg. 51424, 51429 (Drug Enf't Admin. Aug. 18, 2011); *Paul H. Volkman*, 73 Fed. Reg. 30630, 30644 (Drug Enf't Admin. May 28, 2008), reflects a determination on the part of the Agency that multiple violations of like nature are "of minor consequence" or that this type of violation of the DEA-222 recordkeeping requirement is "of minor consequence."

349. *Superior Pharmacy I and Superior Pharmacy II*, 81 Fed. Reg. 31310, 31338 (Drug Enf't Admin. May 18, 2016) ("[T]he Government points to no provision which requires, where no portion of a line entry has been filled . . . the purchaser to notate on the form that no portion of that entry was received.").

350. *Id.* ("[The investigator] did not identify a single instance in which a line item had actually been shipped to [the r]espondent and the entry had not been made.").

recognized in *Hills Pharmacy*.<sup>351</sup> While, in theory, the Government could provide the copy of the DEA-222 sent to it by the supplier that shows when the controlled substances order was filled,<sup>352</sup> that would not demonstrate when or whether controlled substances were *received* by the pharmacy, but only that the vendor shipped them. The best logical evidence for the Government to meet its burden under *Superior I & II* would be the purchaser's copy of the DEA-222.<sup>353</sup> However, when all of the receipt information is missing from the purchaser's forms, it will still remain incumbent upon the Government to present reliable evidence that the controlled substances described in the DEA-222 were actually received by the respondent pharmacy.<sup>354</sup> Under *Superior I & II*, where the only repository for product receipt information is the incomplete DEA-222, establishing a prima facie case for a violation of this obligation will not be without its challenges when the registrant leaves the forms entirely blank. The Agency's precedent could cynically be read to create something of a potential disincentive to fully complete the DEA-222 form, particularly where no other available paperwork maintained by a pharmacy registrant (or at least no paperwork shared with or available to the DEA) establishes the receipt of the controlled medication ordered on the DEA-222. If a pharmacy registrant declines to present testimony and presents no paperwork demonstrating delivery of the controlled substances, it creates the potential for a virtual absolution of culpability related to incomplete paperwork.<sup>355</sup> Contrariwise, the same purchaser who makes an inadvertent mistake on a DEA-222 (such as recording the "No. of Packages Received," but leaving off the "Date Received") but otherwise keeps meticulous records (such as a separate inventory document that reflects all controlled substances received and the date on which they were received) is arguably rendered more vulnerable to a potential sanction because the incomplete entries will facilitate the Government's ability to demonstrate receipt.<sup>356</sup> In the first scenario, there is simply no way to determine whether the

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351. *Hills Pharmacy*, 81 Fed. Reg. at 49843 n.49 ("The Government put forward no evidence . . . that [r]espondent had actually *received* any of the drugs listed in the line items which were left blank.") (emphasis added).

352. 21 C.F.R. § 1305.13(b) (2017) ("A supplier . . . must record on Copies 1 and 2 the number of commercial or bulk containers furnished on each item and the date on which the containers are shipped to the purchaser."); *id.* § 1305.13(d) ("The supplier must . . . forward Copy 2 to the Special Agent in Charge of the Drug Enforcement Administration in the area in which the supplier is located.");

353. *Id.* § 1305.13(e).

354. *Hills Pharmacy*, 81 Fed. Reg. at 49843.

355. See generally *Superior Pharmacy I* and *Superior Pharmacy II*, 81 Fed. Red. 31310 (Drug Enf't Admin. May 19, 2016).

356. *Hills Pharmacy*, 81 Fed. Reg. at 49843 ("Two of the order forms contain a notation that a number of packages were received but no entry for the date the package was received . . . thus violat[ing] 21 C.F.R. § 1305.13(e) by failing to notate the date these two packages were received.");

substances have stayed within the closed regulatory system; in the latter, at least the (albeit technically non-compliant) records can be put together to determine whether or not there is a leak in the system.

#### F. *The Rebirth of Community Impact Evidence*

Agency pharmacy precedent took another fascinating turn in *Perry County Food & Drug*, where the Agency's final order held that long-disfavored community impact evidence can potentially be used by a pharmacy registrant to defend against a sanction proposed by the Agency.<sup>357</sup> By way of background, the Agency was once willing to consider evidence of community impact in determining whether the public interest would best be served by revoking or maintaining a registration.<sup>358</sup> In 1999, in *Pettigrew Rexall Drugs*,<sup>359</sup> the Agency considered the pharmacy's value to an underserved area to the registrant's benefit.<sup>360</sup> Over time, however, the Agency developed a body of final orders that have consistently declined to consider community impact evidence offered by practitioners.<sup>361</sup> In *Gregory D. Owens, D.D.S.*, the Agency compellingly justified its decision to abandon the practice of considering community impact evidence.<sup>362</sup> The Agency set forth its rationale this way:

The diversion of prescription drugs has become an increasingly serious societal problem, which is particularly significant in poorer communities whether they are located in rural or urban areas. . . . The residents of the Nation's poorer areas are as deserving of protection from diverters as are the citizens of its wealthier communities, and there is no legitimate reason why practitioners should be treated any differently because of where they practice or the socioeconomic status of their

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*see* *Alexander Drug Co., Inc.*, 66 Fed. Reg. 18299, 18303 (Drug Enf't Admin. Apr. 6, 2001) (finding a violation of the regulations because, although the respondent kept records which "arguably detailed sufficient information to determine that the controlled substances were not diverted to an illicit purpose," it did not properly execute its DEA-222s).

357. *Perry County Food & Drug*, 80 Fed. Reg. 70084, 70091–92 (Drug Enf't Admin. Nov. 12, 2015).

358. *Marta I. Blesa, M.D.*, 60 Fed. Reg. 53434, 53436 (Drug Enf't Admin. Oct. 13, 1995) ("[T]estimony given which described the medical services provided by the [r]espondent to her community impacts upon the need for her continued medical contributions to that community.").

359. *Pettigrew Rexall Drugs*, 64 Fed. Reg. 8855, 8859–60 (Drug Enf't Admin. Feb. 23, 1999) (ameliorating a sanction based upon a finding by Agency that the respondent pharmacy was one of only two pharmacies "serving a poor, medically underserved population").

360. *Id.* at 8859–60.

361. *Kwan Bo Jin, M.D.*, 77 Fed. Reg. 35021, 35021 (Drug Enf't Admin. June 12, 2012); *Linda Sue Cheek, M.D.*, 76 Fed. Reg. 66972, 66972–73 (Drug Enf't Admin. Oct. 28, 2011); *Gregory D. Owens, D.D.S.*, 74 Fed. Reg. 36751, 36757 (Drug Enf't Admin. July 24, 2009).

362. *Owens*, 74 Fed. Reg. at 36757.

patients.<sup>363</sup>

Significantly, the CSA definition of “practitioners” includes both prescribers (e.g. physicians, dentists, veterinarians) and pharmacies,<sup>364</sup> and the justification for the abandonment of community impact evidence referenced practitioners.<sup>365</sup> It thus appeared that the Agency was no longer willing to consider community impact evidence when adjudicating any practitioner cases.

Two years after *Owens*, in *Linda Sue Cheek, M.D.*, the Agency reaffirmed its position that “community impact evidence is not relevant” in determining whether to grant or revoke “a prescribing practitioner’s” registration, and held that, “to the extent . . . any . . . case involving a prescribing practitioner[] suggests otherwise, it is overruled.”<sup>366</sup> In that decision, the Agency noted that “there are no workable standards for determining whether other doctors are reasonably available” and that it is “unworkable” to determine “what constitutes a patient with a limited income or finances and how many patients (or what percentage of patients) a [prescribing] practitioner must have” to claim an impact.<sup>367</sup>

*Cheek* neither stated that *Pettigrew* was being specifically overruled, nor carved out an exception for pharmacy registrants.<sup>368</sup> It just said that community impact evidence would no longer be considered on behalf of prescribing practitioners.<sup>369</sup> However, *Physicians Pharmacy, L.L.C.*, a pharmacy case published one year after *Cheek*, suggested that the Agency would not consider community impact relating to pharmacy registrants, for the same reasons provided in *Cheek* and *Owens*.<sup>370</sup> In that case, the Government urged the Agency to consider the “nature and amount of diversion of controlled substances in a geographical area when determining whether an applicant should be granted a DEA registration,” but the Agency held that such evidence “is simply the other side of the community impact coin,” evidence of which the “DEA has held . . . is not relevant to any of the public interest factors and [consideration of which] is completely unworkable.”<sup>371</sup> While the signals from the Agency were admittedly mixed, *Physician’s Pharmacy* provided a none-

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363. *Id.* (citations omitted).

364. 21 U.S.C. § 802(21) (2012).

365. *Owens*, 74 Fed. Reg. at 36757.

366. *Cheek*, 76 Fed. Reg. at 66972–73.

367. *Id.* at 66973 n.4.

368. *See id.* at 66972.

369. *Id.* at 66973.

370. *Physician’s Pharmacy, L.L.C.*, 77 Fed. Reg. 47096, 47096 n.2 (Drug Enf’t Admin. Aug. 7, 2012).

371. *Id.* (citing *Cheek*, 76 Fed. Reg. at 66973 n.4 (quoting Gregory D. Owens, D.D.S., 74 Fed. Reg. 36751, 36757 n.22 (Drug Enf’t Admin. July 24, 2009))).

too-subtle signal that the Agency was no longer interested in considering community impact evidence to meet a registration sanction sought by the Government against any practitioners.

Given this background, the Agency's recent decision re-embracing community impact for pharmacy practitioners is surprising. In *Perry County Food & Drug*, the Agency acknowledged that it had, "in multiple cases[,] rejected the contention that community impact is a relevant consideration" in prescriber practitioner cases, and noted that "the reasoning of these decisions calls into question the continuing vitality of [*Pettigrew*] even as applied to a pharmacy," but emphasized that, contrary to the ALJ's conclusion, the Agency "has not formally overruled the case."<sup>372</sup> The Agency, referring to its discussion of community impact in *Physicians Pharmacy* as dicta, points out that no reference was made to *Pettigrew* in that decision, and thus it "cannot be read as overruling" *Pettigrew*.<sup>373</sup> The Agency then explicitly stated that "the Agency's reasons for rejecting consideration of community impact evidence in cases involving prescribing practitioners apply with equal force to pharmacies,"<sup>374</sup> and discussed *Owens*, but faulted the Government for not addressing whether *Pettigrew* "remains viable as precedent," and ultimately considered the evidence but found it unpersuasive.<sup>375</sup>

The obvious contention between its statements that the reasons for rejecting consideration of community impact in prescribing practitioner cases "apply with equal force to pharmacies,"<sup>376</sup> but that *Pettigrew* "remains viable precedent,"<sup>377</sup> leaves significant ambiguity as to how community impact evidence will be considered by the Agency in future cases. Analytically, the Agency now appears to be sending the message that underserved communities are not better served by prescriber practitioners who commit acts inconsistent with the public interest, but are still benefitted by pharmacy practitioners who commit acts inconsistent with the public interest. If an inherent danger associated with all practitioners who commit acts that are inconsistent with the public interest is the potential for controlled substance diversion, it is challenging to distinguish why dangerous and powerful narcotics diverted due

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372. *Perry County Food & Drug*, 80 Fed. Reg. 70084, 70091 (Drug Enf't Admin. Nov. 12, 2015).

373. *Id.* at 70091 n.20. The Agency added, in another footnote, that while it "decline[d] to overrule" *Pettigrew*, it found the reasoning in that decision to be "problematic" due to the weight given to the community impact evidence, particularly given other evolving Agency case law since that decision was issued, including the addition of the requirement that the registrant/applicant acknowledge misconduct to rebut the Government's prima facie case and the Agency's emphasis on candor. *Id.* at 70092 n.23.

374. *Id.* at 70091.

375. *Id.* at 70092.

376. *Id.* at 70091.

377. *Id.* at 70092.



to pharmacies' conduct are somehow more beneficial to underserved communities than those same drugs diverted due to prescribing doctors' conduct. Counsel on both sides of pharmacy litigation (and, perhaps, litigation involving manufactures or distributors) should remain prepared to provide and address community impact evidence. By specifically declining to overrule *Pettigrew*, the Agency has left open the ability of pharmacy registrants to introduce community impact evidence and arguments, and conscientious Government counsel must now once again introduce evidence that the community impact of revoking (or not granting) registration is nominal when juxtaposed against the potential risks. In addition to affecting pharmacy litigation, *Perry County* has potentially reopened the door for counsel on both sides of prescriber-registrant cases as well. Counsel for prescribers should have their equal protection arguments at the ready, because the view that underserved communities are no more benefitted by drug-diverter-prescribers than those more affluent neighborhoods would seem to apply with equal analytical force to drug-diverter-pharmacies, and the Government should be prepared to defend the continuing vitality of *Owens* and its progeny in the face of *Perry County*.

### G. *The Sins of Our Relatives*

In *Cove Inc.*, the Agency re-affirmed its longstanding willingness to negatively consider CSA violations committed by relatives in denying an application for registration.<sup>378</sup> In *Cove*, the Agency denied a registration application because the applicant's husband had previously "violated his corresponding responsibility and the CSA,"<sup>379</sup> while employed by a formerly-registered pharmacy.<sup>380</sup> Interestingly, *Cove* represents another installment in an increasingly-expanding complement of cases where, notwithstanding the absence of exceptions filed by either side to the ALJ's recommended decision, the Agency issued its own, contrary factual findings and legal conclusions.<sup>381</sup> In its final order, the Administrator "reject[ed] the ALJ's conclusion that the

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378. *Cove Inc.*, 80 Fed. Reg. 29037, 29043 (Drug Enf't Admin. May 20, 2015); *see, e.g.*, *City Drug Co.*, 64 Fed. Reg. 59212, 59214 (Drug Enf't Admin. Nov. 2, 1999); *Monk's Pharmacy*, 52 Fed. Reg. 8988, 8989 (Drug Enf't Admin. Mar. 20, 1987); *Carriage Apothecary, Inc.*, 52 Fed. Reg. 27599, 27599 (Drug Enf't Admin. July 22, 1987); *Unarex of Plymouth Road and Unarex of Dearborn*, 50 Fed. Reg. 6077, 6079 (Drug Enf't Admin. Feb. 13, 1985); *Lawsons & Sons Pharmacy*, 48 Fed. Reg. 16140, 16141 (Drug Enf't Admin. Apr. 14, 1983); *see also Terese, Inc.*, 76 Fed. Reg. 46843, 46846-47 (Drug Enf't Admin. Aug. 3, 2011) (showing that the Agency emphasized that the only reason it did not revoke based on the misconduct of the applicant's husband was that the record did not adequately support violations of the CSA or state controlled substance laws on his part).

379. It is the pharmacy that is registered with the DEA, not the pharmacist. 21 U.S.C. §§ 802(21), 823(f) (2012).

380. *Cove*, 80 Fed. Reg. at 29041.

381. *See id.* at 29043.

links between the applicant and [her former registrant-employed husband] are sufficiently attenuated to conclude that he will exercise no influence or control over [r]espondent.”<sup>382</sup>

This area of familial imputation basis for sanction remains available to Agency prosecutors contemplating the opposition of registration applications, and is an important concept for the bar to consider when providing advice to prospective registration holders.

#### *H. Ninety-Day Prescription Rule Narrowed?*

In *Wesley Pope, M.D.*, the Agency addressed an argument made under one of its regulations that allows multiple controlled substance prescriptions to be issued simultaneously, and potentially narrowed the availability of that regulation as a defense for unwitting prescriber registrants.<sup>383</sup> Under longstanding DEA regulations, a prescriber registrant may issue multiple controlled substance prescriptions at one time that will provide controlled substances for up to a ninety-day period, provided that five conditions are met.<sup>384</sup> (1) “[e]ach separate prescription is issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice;” (2) the prescriber must provide written instructions on each prescription to indicate the earliest date on which a pharmacy may fill each prescription; (3) the prescriber must conclude that providing multiple prescriptions “does not create an undue risk of diversion or abuse;” (4) state law allows “[t]he issuance of multiple prescriptions as described in this section;” and (5) the prescriber “complies fully with all other applicable requirements” under the CSA, the regulations, and state law.<sup>385</sup>

In *Pope*, a prescriber registrant took over care of a patient in a practice and saw the patient for three visits, each about two weeks apart,<sup>386</sup> before the prescriber decided that the patient could “go into the three-month” schedule for his prescriptions.<sup>387</sup> For the two months following that visit,<sup>388</sup> the patient would request a new prescription when his prior 30-day-supply ran out, a PMP report would be obtained, the patient’s file would be pulled, and the prescription

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382. *Id.*

383. *Wesley Pope, M.D.*, 82 Fed. Reg. 14944, 14973 (Drug Enf’t Admin. Mar. 23, 2017).

384. 21 C.F.R. § 1306.12(b) (2017).

385. *Id.* § 1306.12(b)(i)–(v).

386. *Pope*, 82 Fed. Reg. at 14954 (September 22, 2011 visit), 14956 (October 6, 2011 visit), 14957 (October 20, 2011 visit).

387. *Id.* at 14973 (quoting the prescriber’s testimony).

388. *Id.* (November and December, 2011).

would be issued by the prescriber and left for the patient to pick up.<sup>389</sup> The prescriber registrant argued that, under the regulation, he did not need to see the patient every month, and he could issue up to a 90-day-supply based on the visit at the beginning of the three months (and those visits that occurred prior).<sup>390</sup>

The Agency held that the 90-day-supply regulation “does not provide a safe harbor”<sup>391</sup> for the registrant, in part because the provision “contemplates the issuance of multiple prescriptions at one time,”<sup>392</sup> so “it is not directly applicable” to the registrant’s situation,<sup>393</sup> and in part because the Administrator, contrary to the ALJ’s findings, concluded that all of “the prescriptions [r]espondent issued at the three previous office visits were issued outside of the usual course of professional practice and lacked a legitimate medical purpose.”<sup>394</sup> Thus, the Agency found that the regulation’s first condition—that each separate prescription is issued for a legitimate medical purpose by a prescriber acting in the usual course of professional practice<sup>395</sup>—was not met because the prescriber “acted outside the usual course of professional practice and lacked a legitimate medical purpose in issuing the [controlled substance] prescriptions without requiring an office visit.”<sup>396</sup> The Agency faulted the prescriber for not insisting upon an office visit, and for not considering two aberrant drug screens from several months prior to the prescriptions issued without an office visit, which the Agency said constituted a “fail[ure] to determine whether issuing the prescriptions created an undue risk of diversion.”<sup>397</sup>

During a subsequent ninety day time period, the prescriber registrant again saw the patient on day one of the ninety-day period, issued a thirty-day supply, and then issued new thirty-day-supply prescriptions for the two months that followed, without additional office visits.<sup>398</sup> The Agency again held that there should have been an office visit each month and faulted the prescriber for not considering the same aberrant drug screens from over six months prior, also crediting the Government’s expert testimony that the prescriber “needed to obtain a consultation with a specialist in addiction.”<sup>399</sup> In addition to the

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389. *Id.*

390. *Id.*

391. *Id.*

392. *Id.* at 14973 n.44.

393. *Id.* at 14973.

394. *Id.* at 14973.

395. 21 C.F.R. § 1306.12(b)(i) (2017).

396. *Pope*, 82 Fed. Reg. at 14973.

397. *Id.*

398. *Id.* at 14958–14961 (January, February, and March 2012 visits).

399. *Id.* at 14977.

conduct that it deemed deficient to establish legitimate medical purpose at the visit on day one, the Agency also noted that, by the two later dates where the respondent wrote new prescriptions without an office visit—based on the idea that the first visit justified the subsequent ninety days of prescribing—the prescriber “likely had the results” of a drug screen obtained at the first visit, which it found to be aberrant.<sup>400</sup> Had the prescriber issued all of the controlled substance prescriptions simultaneously at the initial visit, labeled appropriately to designate the earliest date on which each could be filled, and not seen the patient again for ninety days, the evidence of the aberrant drug screen that was used against him in regards to the two subsequent dates would not have been available to the Government to support a sanction.

The implications for attorneys advising prescriber clients are not yet altogether clear, and *Pope* may signal potential adverse consequences to a prescriber registrant regardless of the prescriber’s choice of how to proceed. One choice is for the prescriber to issue all three prescriptions at one single visit, as the Agency says 21 C.F.R. § 1306.12(b) contemplates, in which case only that visit (and presumably only the circumstances known to the prescriber on that visit date) would be properly considered when evaluating the legality of all three prescriptions covering the subsequent ninety-day period. While this choice seemingly insulates a prescriber from having negative circumstances that arise after the visit considered against him, if the Agency finds the first visit to be deficient then it will undoubtedly find all three prescriptions to be deficient. Another choice is for the prescriber to issue only one prescription at the first visit, then issue two additional prescriptions at thirty-day intervals, without seeing the patient again. But as the prescriber in *Pope* discovered, the Agency may find that an office visit should have occurred during the two latter months and will consider the lack of an office visit and any circumstances that arise between prescription issuances against the registrant.<sup>401</sup> The third choice is for the prescriber to simply not avail himself of the 90-day prescription option and write one prescription per visit per thirty days. His patients may not appreciate having to return (and pay for a visit) so frequently, but he may be better situated to justify prescribing with records that correspond with each prescribing event date, unless, of course, those records are found to be insufficient. If the prescriber chooses the last option and sees his patients every thirty days, it is unclear based on *Pope* whether the Agency might be amenable to his notes from visit day one potentially serving as a safety net for the subsequent two visits—such that the latter two visits are considered in the aggregate with visit one—since he could have issued all three prescriptions at visit one, anyway. Clients will likely be asking whether seeing their patients

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400. *Id.* at 14976.

401. *Id.*

and issuing prescriptions more frequently than once every ninety days demonstrates attention to their responsibilities, or whether it merely creates an enhanced source of adverse evidence available to the Government in enforcement proceedings, and they will almost certainly be asking why the DEA is in a superior position to dictate how frequently an office visit is required in connection with prescribing controlled substances.

### I. To Stay or Not to Stay

*Judson J. Somerville, M.D.*, a case involving no more than the relatively routine adjudication of a matter where the registrant lost his state authority, morphed into another interesting final order.<sup>402</sup> In *Somerville*, the Agency re-clarified its prior statement from *Grider Drug #1 & Grider Drug #2*,<sup>403</sup> where the Agency had indicated that “a stay in administrative enforcement proceedings is unlikely ever to be justified due to ancillary proceedings involving the [r]espondent,”<sup>404</sup> and sought to distinguish its prior precedent in *Odette L. Campbell*,<sup>405</sup> wherein it granted lengthy stays of proceedings based on an ancillary criminal matter and an ancillary state board matter involving the respondent.<sup>406</sup>

The respondent in *Somerville* sought a stay of DEA administrative proceedings because state board proceedings—which had resulted in the summary suspension of his state controlled substance privileges and, in turn, the commencement of the DEA revocation action—were ongoing.<sup>407</sup> The ALJ denied the respondent’s request for a stay of proceedings, citing the Agency’s prior statement in *Grider #1 & #2* that stays are “unlikely ever to be justified

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402. *Judson J. Somerville, M.D.*, 82 Fed. Reg. 21408, 21409 & n.3 (Drug Enf’t Admin. May 8, 2017).

403. *Grider Drug #1 & Grider Drug, #2*, 77 Fed. Reg. 44070, 44104 n.97 (Drug Enf’t Admin. July 26, 2012); see also *Lawrence E. Stewart, M.D.*, 81 Fed. Reg. 54822, 54827 (Drug Enf’t Admin. Aug. 17, 2016).

404. *Somerville*, 82 Fed. Reg. at 21409 n.3 (citation and internal punctuation omitted).

405. *Odette L. Campbell, M.D.*, 80 Fed. Reg. 41062, 41064 (Drug Enf’t Admin. July 14, 2015).

406. While the *Grider* final order contains no specific dates or other indications as to when the Administrator issued specific stays or abeyance orders in the proceedings, it is worthy of note that the ALJ’s (second) recommended decision was issued on October 26, 2010 and the final order was issued nearly five years later, on July 14, 2015. The only dates referenced in the final order are an August 27, 2010 date where the state medical board initiated administrative proceedings, a “new formal complaint against the [r]espondent” filed by the state medical board on September 19, 2014, and a March 27, 2013 pre-trial diversion agreement relating to the pending criminal matter. *Id.* at 41063–64.

407. *Somerville*, 82 Fed. Reg. at 21408.

due to ancillary proceedings,”<sup>408</sup> but also citing *Campbell* as contrary authority.<sup>409</sup>

The Agency did not dispute that it issued a lengthy stay for state administrative proceedings and federal criminal proceedings in *Campbell*, but explained that three features about the *Campbell* case made it “the rare case where withholding the issuance of a final decision was warranted:” (1) the *Campbell* case involved a DEA registration that had expired shortly after the evidentiary hearing, so it was an application case, rather than a revocation case; (2) the state criminal charges, which were brought shortly before the evidentiary hearing, could have resulted in an additional basis for sanction if the respondent had been convicted; and (3) the state administrative proceedings could have resulted in suspension or denial of her state license, and “denial of her application would have been required under the CSA.”<sup>410</sup>

However, upon objective, comparative analysis of *Campbell* and *Somerville*, it is challenging to reconcile the sua sponte granting of the lengthy stay by the Administrator in *Campbell* from the denial of the stay sought in *Somerville*. Under the Agency’s analysis in *Grider #1 & #2*,<sup>411</sup> there is nothing facially apparent about proceedings that involve only an application, as opposed to a revocation, that would render a long stay more appealing, particularly when a registrant is effectively unable to conduct any regulated activity under the registrant’s existing DEA registration due to limitations on practice imposed at the state level.<sup>412</sup> Similarly, the fact that the ancillary proceedings in *Campbell* could conceivably have raised additional grounds for sanction that had not been noticed in the present DEA proceedings, a potential that was not discussed but was also potentially present in *Somerville* and other cases where ancillary proceedings are ongoing, bears no readily apparent logical relationship to the wisdom of granting or denying a stay of proceedings. If the Agency can revoke based upon the grounds existing before a stay is requested, any additional grounds that ultimately arise will be superfluous; and alternatively, if additional grounds ultimately arise out of the ancillary matters, they can be charged against a respondent in future proceedings brought to revoke a registration or deny an application, if necessary. While *Somerville*’s discussion of *Campbell*

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408. *Id.* at 21409 n.3 (quoting *Grider #1 & #2*, 77 Fed. Reg. at 44014 n.97) (discussing ALJ decision) (internal punctuation omitted).

409. *Id.* (citing *Campbell*, 80 Fed. Reg. at 41062).

410. *Id.* (discussing *Campbell*, 80 Fed. Reg. at 41063).

411. *Grider #1 & #2*, 77 Fed. Reg. at 44104 n.97.

412. In *Campbell*, the Agency had issued an Immediate Suspension Order, so the practitioner could not have continued regulated activity during the pendency of administrative proceedings, even before her registration expired. *Campbell*, 80 Fed. Reg. at 41063 n.3. Thus, it cannot be that the Agency is worried about lengthy delays where the registrant maintains the ability to conduct authorized activity pursuant to his DEA registration.

provided little clarity as to the Agency's reasoning for granting stays in that case, it remains apparent that the Agency disfavors stays and is unlikely to grant lengthy stays as a matter of course.

*J. Summary Disposition and State Due Process*

In addition to the discussion regarding the imposition of a stay, another key aspect of *Campbell* also reared its head in the *Somerville* case. In *Campbell*, the ALJ initially granted summary disposition, but the Agency remanded the matter back to the ALJ because “[o]n review, the Administrator noted that it appeared that under Texas law and regulations, [r]espondent was not entitled to a hearing before [the state board that suspended her controlled substance privileges] to challenge [the board’s] suspension or the denial of her application for a new [state] registration.”<sup>413</sup> Under Texas state law, Dr. Campbell was unequivocally deprived of the state authority required to handle controlled substances, but the lack of state authority was due to the issuance of the DEA immediate suspension order, creating an apparent circular problem for the Agency.<sup>414</sup> The Agency sent the case back to the ALJ for a determination as to whether the state “would provide [the respondent] with a hearing on the allegations,” and ruled that she would only be subject to summary disposition based on her lack of state authority if the state afforded her the ability to challenge the state board action (of suspending her based on the DEA ISO) at a state board hearing.<sup>415</sup> Thus, the Administrator remanded the matter back to the ALJ to essentially conduct a due process analysis regarding Texas state law.<sup>416</sup>

In *Somerville*, in contrast, although the respondent made the argument that the state board was acting in violation of Texas law by failing to provide him with an informal settlement conference or formal administrative proceedings within the time frame required under Texas law, the Agency adopted the ALJ’s summary disposition recommendation and cited another previously-issued final order,<sup>417</sup> stating that the DEA “accepts as valid and lawful the actions of a state regulatory board unless that action is overturned by a state court . . . pursuant to state law.”<sup>418</sup> Thus, while the Agency has indicated that it will not generally entertain a respondent’s allegations related to purported infirmities in state law

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413. *Id.*

414. *Id.*

415. *Id.*

416. *Id.*

417. Judson J. *Somerville*, M.D., 82 Fed. Reg. 21408, 21409–10 (Drug Enf’t Admin. May 8, 2017) (citing Kamal Tiwari, M.D., 76 Fed. Reg. 71604, 71607 (Drug Enf’t Admin. Nov. 18, 2011)).

418. *Somerville*, 82 Fed. Reg. at 21409–10.

and board proceedings as bases to withhold summary disposition,<sup>419</sup> it has also signaled that, where the Agency believes that state proceedings do not measure up to some undefined DEA standard of due process, no summary disposition based on an absence of state authority will issue.<sup>420</sup>

Given the limited authority of the Agency in enforcement adjudications,<sup>421</sup> litigators on both sides of the aisle can likely assume that the Agency will not lightly re-travel into adjudications which evaluate the legality of state licensing schemes, but both sides should be vigilant to brief the issue where there is a possibility that state due process does not measure up to the DEA's standards with state law features similar to those Texas provisions that the DEA found violative of due process.

### *K. Notice This, Consent to That*

The issue of notice and the related issue of litigation by consent have received some level of attention in recent Agency final orders, but still exist in some level of flux. Admittedly, the Agency's handling of notice under the APA in the past has not been marked with unwavering consistency,<sup>422</sup> but more recent Agency precedent on the issue of notice bears a marked level of new potential dangers for practitioners on both sides of the litigation aisle.

#### 1. Notice Requirements

The level and specificity of notice that the Agency is required to furnish those it seeks to sanction has been the subject of a fair amount of recent attention in Agency final orders.<sup>423</sup> Inasmuch as the current state of what notice is required in DEA administrative proceedings is not entirely clear, a proper analysis is best commenced with an examination of the bedrock sources of authority that underpin the requirements. The notice requirements that Congress placed on agency administrative practice under the APA are actually relatively modest.<sup>424</sup> APA notice in this context requires only that "[p]ersons entitled to notice of an agency hearing shall be timely informed of—(1) the

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419. *Id.* at 21408.

420. *Id.*

421. *Gonzales v. Oregon*, 546 U.S. 243, 274 (2006).

422. *Compare, e.g., Jose Raul S. Villavicencio, M.D.*, 80 Fed. Reg. 3624, 3630 (Drug Enf't Admin. Jan. 23, 2015) (showing loss of state authority considered without notice) *and Fiaz Afzal*, 79 Fed. Reg. 61651, 61655 (Drug Enf't Admin. Oct. 14, 2014) (same), *with Ideal Pharmacy Care, Inc.*, 76 Fed. Reg. 51415, 51416 n.1 (Drug Enf't Admin. Aug. 18, 2011) (showing loss of state authority not considered due to lack of Government notice).

423. *See e.g. Farmacia Yani*, 80 Fed. Reg. 29053, 29064 (Drug Enf't Admin. May 20, 2015); *Jana Marjenhoff, D.O.*, 80 Fed. Reg. 29067, 29068 (Drug Enf't Admin. May 20, 2015).

424. *See Administrative Procedure Act*, 5 U.S.C. § 554(b) (2012).



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.”<sup>425</sup> The Attorney General’s Manual on the APA<sup>426</sup> provides that the APA notice requirement in this provision “is not required to set forth evidentiary facts or legal argument. All that is necessary is to advise the parties of the legal and factual issues involved.”<sup>427</sup>

The notice requirements included in the DEA’s longstanding implementing regulations are similarly modest, providing only that “[t]he [OSC] shall . . . contain a statement of the legal basis for such hearing and for the denial, revocation, or suspension of registration and a *summary* of the matters of fact and law asserted.”<sup>428</sup> In evaluating its obligations under the APA and its own regulations, the Agency, in some of its more vintage precedent, has long held that in DEA administrative proceedings, “the parameters of the hearing are determined by the prehearing statements.”<sup>429</sup> While the Agency has previously embraced the principle that “pleadings in administrative proceedings are not judged by the standards applied to an indictment at common law,”<sup>430</sup> and the rules governing DEA hearings do not require the formality of amending a show cause order to comply with the evidence,<sup>431</sup> some newer Agency precedent imposed what appears to be significantly tighter notice requirements on the Government.<sup>432</sup>

In *Farmacia Yani*, for example, the Agency scolded its prosecutors because the charging document and prehearing statement did not include a citation to a particular regulation subsection, and the Agency addressed the issue by parsing each subsection, finding that no evidence was put forth under one subsection, and another subsection did not apply to the facts of the case.<sup>433</sup> The Agency

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425. *Id.*

426. TOM CLARK, U.S. DEP’T OF JUSTICE, ATTORNEY GENERAL’S MANUAL ON THE ADMINISTRATIVE PROCEDURE ACT (1947) [hereinafter ATTORNEY GENERAL’S MANUAL].

427. *Id.* § 5(a)(3), at 47.

428. 21 C.F.R. § 1301.37(c) (2017) (emphasis added).

429. CBS Wholesale Distribs., 74 Fed. Reg. 36746, 36750 (Drug Enf’t Admin. July 24, 2009) (citing Darrell Risner, D.M.D., P.S.C., 61 Fed. Reg. 728, 730 (Drug Enf’t Admin. Jan. 10, 1996)).

430. Clair L. Pettinger, M.D., 78 Fed. Reg. 61591, 61596 (Drug Enf’t Admin. Oct. 3, 2013) (quoting Aloha Airlines, Inc. v. Civil Aeronautics Bd., 598 F.2d 250, 262 (D.C. Cir. 1979)).

431. *Id.*; Roy E. Berkowitz, M.D., 74 Fed. Reg. 36758, 36759–60 (Drug Enf’t Admin. July 24, 2009).

432. *Farmacia Yani*, 80 Fed. Reg. 29053, 29053 n.1 (Drug Enf’t Admin. May 20, 2015).

433. *Id.* at 29064 & n.28. To the extent that the Agency found that the evidence supported a successful Government theory under any subsection, the message to the parties from the Agency appears to be that an allegation that does not specify the specific subsection will be rejected based on lack of adequate notice. Discounting the improbable possibility that this aspect of the decision reflected some manner of gratuitous grousing at its prosecutors, where the Agency has determined that

then found that the conduct alleged violated an entirely different regulatory section, leaving the reader to ponder the purpose for the scolding.<sup>434</sup> In another final order, *Jana Marjenhoff, D.O.*, the Agency refused to allow the Government to rely on certain noticed conduct,<sup>435</sup> which it found was “clearly probative of [an] allegation [set forth in the OSC] that [the] [r]espondent engaged in obtaining controlled substances through fraud,”<sup>436</sup> because it failed to specify that the conduct would be specifically considered under Factor Five.<sup>437</sup> This was a somewhat eyebrow-raising development in view of *Clair L. Pettinger, M.D.*, a final order issued two years earlier, wherein the Agency had indicated that the Government was not required to specify which Public Interest Factor noticed misconduct was to be considered under.<sup>438</sup> Thus, without specifically saying as much, it appeared that the Agency was indicating either that it is not necessary to specify the public interest factor relied upon, unless it sought to rely on Factor Five, or saying (also without saying) that it was now increasing the notice requirements imposed on its prosecutors in administrative proceedings in general.

Although it appeared after *Marjenhoff* that evidence to be considered under Factor Five, if not the other factors also, required particularly detailed notice, the Agency then issued *Roberto Zayas, M.D.* In *Zayas*, upon its review of the respondent’s hearing testimony, the Agency determined that the respondent gave “false testimony” at his hearing in support of his actions (i.e., in presenting his defense) and held that “his provision of false testimony . . . constitutes actionable misconduct under Factor Five.”<sup>439</sup> No notice, no problem. So it thus appears that, under the Agency’s current precedent when considered as a whole, Factor Five allegations may require enhanced notice even when the conduct itself is alleged to be against the public interest generally, unless the Administrator decides, during the preparation of the final order, that the Agency does not believe the respondent’s explanation for his or her conduct, in which case the testimony—the provision of the respondent’s defense itself—will be deemed adverse conduct held against the respondent under Factor Five with no

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no subsection can be sustained as a factual matter, pointing out the absence of a specified subsection in the OSC would have little other utility in the final order.

434. *Id.*

435. *Jana Marjenhoff, D.O.*, 80 Fed. Reg. 29067, 29068–69 (Drug Enf’t Admin. May 20, 2015). The Agency found that the “Respondent clearly had notice that her conduct . . . would be at issue in the proceeding” because the Government provided the respondent with notice in its prehearing statement that it would elicit testimony from the pharmacist regarding the conduct. *Id.*

436. *Id.* at 29068.

437. *Id.* at 29068–69.

438. *Clair L. Pettinger, M.D.*, 78 Fed. Reg. 61591, 61596 (Drug Enf’t Admin. Oct. 3, 2013).

439. *Roberto Zayas, M.D.*, 82 Fed. Reg. 21410, 21428 (Drug Enf’t Admin. May 8, 2017).

opportunity to respond at all beyond petition to the courts.<sup>440</sup> Further confounding the issue, in *Peter F. Kelly, D.P.M.*, the Agency considered conduct under Factor Five that was not noticed by the Government, based on its assessment that “[n]otwithstanding that the Government did not cite Factor Five with reference to this allegation, [r]espondent clearly knew that his conduct . . . was at issue.”<sup>441</sup> So the rule presently appears to be that notice of the specific factor the evidence is to be offered under is not important—unless the evidence is offered under Factor Five—unless the Agency says notice is not important there either.<sup>442</sup>

Perhaps lending support to the old wisdom that continuously sawing off pieces of chair legs seldom leads to a more balanced chair, the Agency issued a lengthy final order in *Wesley Pope M.D.*, in which it sought, *inter alia*, to clarify its position on both the administrative notice requirements and, relatedly, litigation by consent.<sup>443</sup> In *Pope*, the Agency insisted that it has not tightened notice requirements, that it has not changed its litigation-by-consent requirements, and that any claims to the contrary are the unfortunate product of misreading its precedents.<sup>444</sup> With regards to its view of notice, the Agency focused on *Farmacia Yani* and *Marjenhoff*, declaring that “[a] review of these [two] decisions shows . . . that the Agency has not imposed an increased standard of notice but simply applied the extensive body of judicial precedent that addresses the adequacy of notice in administrative adjudication . . . .”<sup>445</sup> The presented explanation—that it has not increased notice standards, but has chosen to now apply what it describes as an “extensive body of judicial precedent”<sup>446</sup> on the issue of notice—presents at least a risk of some level of

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440. While the ALJ’s recommended decision regarding the same testimony concluded that “it is clear that he made it up” and the respondent could have filed exceptions relating to that finding, the ALJ only considered the respondent’s testimony incredible, not as actionable misconduct, and therefore the respondent had no notice that his testimony would be considered against him under Factor Five. *See id.* (discussing the ALJ’s characterization of the respondent’s testimony).

441. *Peter F. Kelly, D.P.M.*, 82 Fed. Reg. 28676, 28687 n.30 (Drug Enf’t Admin. June 23, 2017).

442. *Id.*

443. *Wesley Pope, M.D.*, 82 Fed. Reg. 14944, 14946-48 (Drug Enf’t Admin. Mar. 23, 2017).

444. *Id.* at 14946-47.

445. *Id.* (internal quotation marks and footnote omitted).

446. In *NLRB v. I.W.G., Inc.*, one of the two cases that comprise the Agency’s “extensive body of judicial precedent,” the Tenth Circuit, in discussing the bounds of acceptable notice and whether one of the parties could be sanctioned where an administrative charging document was at variance with the findings, reaffirmed its long-held view that, “variation between an unfair labor practice charged in the complaint and one found by the [NLRB] does not deprive a respondent of due process where it is clear that the respondent understood the issue and was afforded full opportunity to justify its actions. 144 F.3d 685, 687 (10th Cir. 1998) (internal punctuation and citations omitted). The court clarified that, “[t]he introduction of evidence relevant to an issue already in the case may not be used to show consent to trial of a new issue absent a clear indication that the party who introduced the evidence was

confusion. It could potentially be viewed as incongruous to maintain that Agency notice requirements were indeed remaining static, while simultaneously announcing a sudden reliance on a body of judicial precedent (extensive or otherwise) to justify them. Further, in contravention of the longstanding principle that “[t]he grounds upon which an administrative order must be judged are those upon which the record discloses that its action was based,”<sup>447</sup> the *Pope* final order cites internal procedural filings by the parties in those cases that the bar and regulated community have no reasonable ability to review.<sup>448</sup> Unavailable references cited in defense of otherwise-unexplainable shifts in Agency precedent risk the perception that the Agency is telling the practicing bar: ‘Move along, folks, nothing to see here.’

As already mentioned in greater detail,<sup>449</sup> the *Zayas* final order, which came after *Pope*, held that “misconduct is misconduct” and that because “the inquiry focuses on protecting the public interest[,] what matters is the seriousness of the registrant’s or applicant’s misconduct.”<sup>450</sup> Thus, it is unclear whether *Yani*, *Marjenhoff*, *Pope*, or some combination thereof currently represents the Agency’s view of required notice, as the Agency now appears to be of the view that it does not matter whether misconduct is considered under any, some, or all of the Public Interest Factors. If specificity is vital as to all Public Interest Factors, to only Factor Five, or to none of the Public Interest Factors because “misconduct is misconduct,”<sup>451</sup> it will be difficult to divine what the applicable notice requirements are in any reliable way. Even with the help of a scorecard, managing litigation under this evolving notice standard will likely present challenges on both sides of the litigation aisle, and it is difficult to know whether another Agency order seeking to “clarify” this issue will help or saw a little more off another chair leg.

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attempting to raise a new issue. *Id.* at 688 (internal punctuation and citations omitted). In *Pergament United Sales, Inc. v. NLRB*, the other half of the “extensive body of judicial precedent” relied upon by the Agency, the court sustained NLRB’s charge, notwithstanding a variation that it characterized as “a minor distinction without significant legal consequences on the facts of th[e] case.” 920 F.2d 130, 135 (2d Cir. 1990). Interestingly, the *Pergament* court focused on the second prong of the litigation-by-consent principle, *to wit*, whether the case had been fully and fairly litigated based on a review of the record. The court instructed that “whether a charge has been fully and fairly litigated is so peculiarly fact-bound as to make every case unique; a determination of whether there has been a full and fair litigation must therefore be made on the record in each case.” *Id.* at 136

447. *SEC v. Chenery Corp.*, 318 U.S. 80, 88 (1943).

448. *Pope*, 82 Fed. Reg. at 14946 n.4 (citing in final order to hearing briefs in final order filed by the parties before the ALJ).

449. *See supra* Part III.A.3.

450. Roberto Zayas, M.D., 82 Fed. Reg. 21410, 21422 (Drug Enf’t Admin. May 8, 2017).

451. *Id.*

Reliability in legal interpretation helps representatives on both sides of the aisle in providing advice and planning strategy. The very real risk of the Agency's current approach to notice is the inadvertent creation of a perception that the Agency may retroactively choose which Public Interest Factor(s) require increased notice scrutiny well after proceedings are completed. The absence of a consistently articulated approach carries the potential of complicating the business of formulating a coherent litigation strategy for both sides of the litigation equation. Further, the Agency's determination that a registrant's testimony that is not found credible by the Administrator will constitute adverse conduct considered under Factor Five<sup>452</sup> bears potentially serious consequences for members of the bar advising clients about the wisdom of testifying, and also for the Government in assessing the investment appropriately devoted to cross examination. Both sides of the litigation equation must be cognizant of these precedents in crafting hearing strategy, challenging and defending notice sufficiency, and presenting arguments in post-hearing submissions. The status of the level of notice required in DEA administrative enforcement proceedings will likely be the subject of litigation, adjustment, and additional clarification in the future.

## 2. Litigation by Consent

The notice-related issue of litigation by consent also saw some attention in recent Agency precedent. It has long been the case under Agency practice that a failure on the part of the Government to disclose an allegation in the OSC can be rectified if it discloses such allegation in its prehearing statements or "otherwise timely notifies a [r]espondent of its intent to litigate the issue."<sup>453</sup> Moving a step further, the Agency explicitly embraced the concept of litigation by consent in its own administrative enforcement proceedings a few years ago in *Grider Drug #1 & Grider Drug #2*.<sup>454</sup> There, the Agency announced that where the Government has failed to adequately notice its intent to litigate an issue, the parties, in the absence of objection, can be deemed to have litigated an unnoticed basis for sanction by consent where they fully litigate the issue.<sup>455</sup> Thus, the two basic elements required for the application of the concept are: (1) lack of objection to insufficiently noticed misconduct; and (2) a full litigation of the issue in question.<sup>456</sup>

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452. *Id.* at 21428.

453. CBS Wholesale Distribs., 74 Fed. Reg. 36746, 36750 (Drug Enf't Admin. July 24, 2009).

454. *Grider Drug #1 & Grider Drug #2*, 77 Fed. Reg. 44070, 44077 n.23 (Drug Enf't Admin. July 26, 2012).

455. *Id.*

456. *Id.*

In further refinement of its litigation-by-consent adoption, the Agency issued *Cove Inc.*, a case where the ALJ recommended that certain evidence be considered against the respondent as a materially false statement.<sup>457</sup> Notwithstanding the absence of any objection by the respondent to either the introduction of the evidence at the hearing or the ALJ's consideration of it as a materially false statement in his recommended decision, the Agency rejected the ALJ's recommendation, citing inadequate notice of the allegation, and further held that a litigation-by-consent theory was unavailable to the Government because it did not pursue that position in its closing brief or its exceptions to the ALJ's decision.<sup>458</sup> Shortly thereafter, in *Odette Campbell*, the ALJ declined to consider certain evidence because the Government did not provide notice of the evidence.<sup>459</sup> Even though, once again, there was no corresponding respondent objection to the ALJ's analysis of the evidence in *Campbell*, the Agency again held that the Government waived its ability to rely on litigation by consent because it did not raise the theory in exceptions to the ALJ's decision.<sup>460</sup> The Agency recently sought to clarify *Campbell* in *Pope*, noting that, in *Pope*, the day was saved for the Government by raising litigation by consent (not before the ALJ), but in its exceptions.<sup>461</sup>

*Cove* and *Campbell* were particularly remarkable notice cases in that the respondents in those cases did not interpose a claim of unfair surprise regarding the issues the Agency ultimately refused to consider based on lack of adequate notice.<sup>462</sup> Even where neither side interposed any objection or raised issues regarding surprise, prejudice, or even a mistake, the Agency took it upon itself to issue lengthy final orders in those cases, addressing self-identified legal topics<sup>463</sup>—a sort of law review article within an adjudication. These were cases where the Agency decided to hold the Government's level of notice to be inadequate, noted its own prior willingness to embrace litigation by consent, and then ruled out litigation by consent because the Government (who never

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457. *Cove Inc.*, 80 Fed. Reg. 29037, 29039 (Drug Enf't Admin. May 20, 2015).

458. *Id.*

459. *Odette L. Campbell*, 80 Fed. Reg. 41062, 41062 n.2 (Drug Enf't Admin. July 14, 2015).

460. *Id.*

461. *Wesley Pope, M.D.*, 82 Fed. Reg. 14944, 14947 n.5 (Drug Enf't Admin. Mar. 23, 2017). Interestingly, as a procedural matter, where both parties have filed exceptions and one side raises litigation by consent for the first time in filed exceptions, no means exists under the regulations for the opposing party to object or argue contrary law. 21 C.F.R. § 1316.66(c) (2017) (“[E]ach party shall be entitled to only one filing[:] that is, either a set of exceptions or a response thereto.”).

462. *Campbell*, 80 Fed. Reg. at 41063 (showing that only the Government filed an exception to the recommended decision); *Cove*, 80 Fed. Reg. at 29037 (showing that neither side filed any exceptions to the recommended decision).

463. *See Campbell*, 80 Fed. Reg. 41062 (Drug Enf't Admin. July 14, 2015); *Cove Inc.*, 80 Fed. Reg. 29037 (Drug Enf't Admin. May 20, 2015).

had the opportunity to field a notice objection from the respondents at the hearing) did not seek to pursue this theory (which it could not have known it would have needed) in its closing brief or exceptions.<sup>464</sup> Pursuit of unraised issues by the Agency is at some variance with the adjudicative approach embraced by the courts. While in reviewing trial court proceedings, the federal circuit courts of appeal are precluded, in the absence of plain and prejudicial error, from considering errors and defects;<sup>465</sup> the Agency's current approach to litigation by consent and other issues has expanded its reach to expound upon unraised issues of legal interest on a sua sponte basis.

Theoretically, escalation of notice requirements, coupled with a more robust application of litigation by consent, could result in something of a wash, although it does carry the prospect of some level of confusion for those engaged in the Agency's administrative litigation. It could be argued that the Agency's current approach places the primary analytical emphasis in litigation by consent cases on the absence of objection and mere introduction of evidence, rather than whether the record makes it "clear that the respondent understood the issue and was afforded full opportunity to justify its actions" and whether there was "a clear indication that the party who introduced the evidence was attempting to raise a new issue."<sup>466</sup> If subsequent final orders maintain the same trajectory, this approach could prove unwieldy to both sides of the litigation equation, and may be challenging for the Agency to defend on appeal.

### 3. Notice and Lack of State Authority

Supporters and detractors of the current Agency view on the issue likely found much to be surprised about regarding the Agency's handling of notice as it applies (or does not apply) to cases where a registrant lacks state controlled substance authority. All other Agency analysis tendered on the issue of notice metaphorically goes out the window with lack of state authority cases. Previous precedents of the Agency have sometimes considered lack of state authority against a registrant without prior notice<sup>467</sup> and at other times have declined to

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464. While the Government might have been able to pursue the litigation-by-consent theory in *Campbell* because the ALJ declined to consider the evidence, it would not have known of the need for a litigation-by-consent theory in *Cove* until after the Agency's final order.

465. Fed. R. Crim. P. 52; Fed R. Civ. P. 61; see *O'Neal v. McAninch*, 513 U.S. 432, 441 (1995) (suggesting that the civil and criminal harmless error standards are the same).

466. *NLRB v. I.W.G., Inc.*, 144 F.3d 685, 687–88 (10th Cir. 1998) (internal punctuation and citations omitted).

467. Jose Raul S. Villavicencio, M.D., 80 Fed. Reg. 3624, 3630 (Drug Enf't Admin. Jan. 23, 2015); Fiaz Afzal, 79 Fed. Reg. 61651, 61655 (Drug Enf't Admin. Oct. 14, 2014).

consider lack of state authority due to lack of notice.<sup>468</sup> It is on this backdrop that the Agency issued *Hatem Ataya, M.D.*, wherein, *over Government objection based on lack of notice to the registrant*,<sup>469</sup> the Agency definitively announced that “[b]ecause the possession of state authority is a prerequisite for obtaining a registration and for maintaining a registration, the issue [of no state authority] can be raised *sua sponte* even [during the preparation of the Agency final order].”<sup>470</sup> Thus, the Agency unequivocally declared that, not only did it possess the authority to issue conclusive findings and issue sanctions based on lack of state authority without any prior notice to either party, but it can (and presumably will continue to) do so on its own motion.<sup>471</sup>

The Agency’s approach in *Ataya* creates an intriguing dynamic and an engaging ethical decision point for Agency prosecutors. If an Agency prosecutor is aware that a respondent no longer possesses the state authority required to maintain a registration, but intentionally declines to include that ground among the bases for sanction charged in the OSC, the respondent will have no ability to challenge, meet, or even address that ground at a due process hearing. Thus, it now ironically stands as a basis for sanction that can theoretically be insulated from challenge by declining to charge it. ALJs’ authority in enforcement matters extends only to matters charged by the Agency that are the subject of a timely request for hearing,<sup>472</sup> and so, in cases where the Government has not alleged or introduced evidence on the issue of lack of state authority, evidence offered by the respondent regarding that issue at an administrative hearing could correctly be viewed as beyond the scope of the hearing, notwithstanding its conclusive post-hearing impact when the Agency renders its final order. Inasmuch as the Agency has indicated its amenability to taking up the matter *sua sponte*,<sup>473</sup> and, as discussed in greater detail below,<sup>474</sup> has increasingly engaged in the process of having the Administrator’s

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468. *Ideal Pharmacy Care, Inc.*, 76 Fed. Reg. 51415, 51416–17 n.1 (Drug Enf’t Admin. Aug. 18, 2011).

469. *Hatem M. Ataya, M.D.*, 81 Fed. Reg. 8221, 8244 (Drug Enf’t Admin. Feb. 18, 2016). In its opinion, the Agency specifically criticizes the DEA prosecutors’ notice position as being “fundamentally inconsistent with the position [the Government] ha[d] taken in [past] numerous cases” where OSCs had been issued. *Id.* The final order acknowledges that Agency prosecutors had argued that considering lack of state authority where it had not been noticed “could arguably upend basic protections afforded to DEA registrants and would surely diminish the perceived fairness of the administrative process.” *Id.* The Administrator was unconvinced by the due process arguments the prosecutor advanced on behalf of this respondent in particular and the regulated community in general.

470. *Id.*

471. *Id.*

472. 21 C.F.R. §§ 1301.42–43, 1316.47(a) (2017); *see id.* § 1301.52.

473. *Ataya*, 81 Fed. Reg. at 8244 n.55.

474. *See supra* Part III.L.6.



adjudication staff check state board websites to determine state licensure status,<sup>475</sup> from a purely tactical standpoint, there is little advantage for Government counsel to raise the issue during the respondent's due process administrative hearing. To the extent that the Agency increasingly relies on state board websites, the nuances of which Agency staff may not be familiar with, respondents lose the ability to defend against the legal and factual call that state authority has been compromised, or completely abrogated.<sup>476</sup> Thus, the Agency, through its precedent, has arguably created a situation that precludes a respondent who has timely requested a hearing from defending against a ground of sanction that the Agency has determined to be conclusive.

The litigation takeaway here is that, where lack of state authority is raised by the facts within their knowledge, Government prosecutors must decide whether, as a matter of fairness, to charge lack of state authority in the OSC. Where it is alleged as a basis for sanction, the respondent can challenge the law and evidence to defend against the charge. Even where it is not alleged as a basis for sanction, respondent's counsel may wish to introduce evidence on the matter if the status of a client's state authority is at all questionable, because the Agency has made it clear that its adjudicative staff will search applicable state websites, and accept post-hearing filings regarding a lack of state authority.

Beyond state authority, both parties should closely examine both noticed and unnoticed evidence at the conclusion of a hearing for possible use in pursuit of a sanction, and both counsel should evaluate multiple permutations of evidence (particularly those which were the subject of defective notice) for a potential post-hearing Government litigation-by-consent request. The failure to do so could well result in a surprise in the Agency's final order,<sup>477</sup> though it could be a welcome or unwelcome surprise, depending on where counsel sits in the litigation equation. Even in the absence of a hearing objection, assignment of error in a post hearing brief, or in the absence of exceptions filed by either side, both parties need to consider whether the Agency will potentially preclude admitted evidence or findings during the preparation of the final order. Contrariwise, if a registrant or applicant stands at any risk of an interruption of state controlled substance authority, the parties' election to brief or ignore evidence may have little impact on the outcome.

#### *L. Proceedings*

While much of the discussion regarding changes in Agency precedent has focused on the law to be applied by the ALJ and, ultimately, the Agency in its

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475. See, e.g., Steven Bernhard, D.O., 82 Fed. Reg. 23298, 23299 (Drug Enf't Admin. May 22, 2017); David D. Moon, D.O., 82 Fed. Reg. 19385, 19387 n.5 (Drug Enf't Admin. Apr. 27, 2017).

476. See *supra* Part III.L.6.

477. See, e.g., *Ataya*, 81 Fed. Reg. at 8221.

final orders, there have also been a host of developments related to the hearing proceedings themselves.

### 1. Regulation by Adjudication

The fact that the Agency's rudimentary hearing regulations exist today substantially as they did when first promulgated over four decades ago tends to magnify the significance of the increasingly ubiquitous procedural edicts that the Agency disseminates through adjudication final orders. To be sure, the concept of creating procedural and substantive rules through adjudication, in lieu of notice and comment regulation promulgation under the APA,<sup>478</sup> can present a dubious strategy where the regulated community, the bar, and the public are deprived of the ability to supply input. But even more fundamentally, the APA's adjudication apparatus was not designed by Congress to replace promulgated regulations, is not well suited for doing so, and carries the very real dangers of inconsistency and confusion. Adjudications are designed to resolve conflicts between two parties, not set policy and procedure for an agency and an enormous regulated community. Beyond the tension created between the Agency's practice in this regard and the APA, there are powerful practical considerations that militate against this approach.

It is well settled that "[w]hen Congress has not specified the level of specificity expected of [an] agency . . . the agency is entitled to broad deference in picking the suitable level."<sup>479</sup> The APA "does not require that all the specific applications of a rule evolve by further, more precise rules rather than by adjudication."<sup>480</sup> Federal agencies are "not precluded from announcing new principles in an adjudication proceeding . . . [r]ather, the choice between rulemaking and adjudication lies in the first instance within the agency's discretion."<sup>481</sup> That said, an agency's authority to issue principles through rulemaking is by no means absolute. An action that results in a substantive change to (or abandonment of) an existing rule must proceed through the APA's notice and comment procedure.<sup>482</sup> While agencies are not permitted to "slip by the notice and comment rule-making requirements needed to amend a rule by

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478. See Administrative Procedure Act, 5 U.S.C. § 553 (2012).

479. *Shays v. FEC*, 528 F.3d 914, 930 (D.C. Cir. 2008) (citing *Cement Kiln Recycling Coal. v. EPA*, 493 F.3d 207, 217 (D.C. Cir. 2007)).

480. *Shalala v. Guernsey Mem'l Hosp.*, 514 U.S. 87, 96 (1995).

481. *Cassell v. FCC*, 154 F.3d 478, 486 (D.C. Cir. 1998) (internal quotation marks and citations omitted); see also *Kansas Gas & Elec. Co. v. FERC*, 758 F.2d 713, 719 (D.C. Cir. 1985) ("[I]t is . . . beyond dispute that an agency may articulate its general policy in a particular proceeding . . . rather than in a rulemaking.").

482. *U.S. Telecom Ass'n. v. FCC*, 400 F.3d 29, 34 (D.C. Cir. 2005); *Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1028 (D.C. Cir. 2000).

merely adopting a *de facto* amendment to its regulation through adjudication,” where a genuine ambiguity exists, the courts will permit the resolution of the issue through an adjudication.<sup>483</sup> However, unless and until an existing regulation (irrespective of its value) is amended or repealed, it continues to carry the force of law, and may not be modified by an agency adjudication.<sup>484</sup> A critical factor in ascertaining whether an existing regulation binds the agency’s action will be whether the subsequent principle in question that has been delivered by the Agency “spells out a duty *fairly encompassed within the regulation* [that the interpretation] purports to construe.”<sup>485</sup>

Thus, it is beyond argument that where a regulation contains some level of ambiguity or flexibility, the courts will endure some level of agency clarification of its legal interpretation through an adjudication where warranted.<sup>486</sup> But the license to do so is hardly absolute. In *Peter F. Kelly, D.P.M.*, the Agency blatantly announced that it was creating several new duties upon prescribing registrants under very specific circumstances with precise obligations.<sup>487</sup> The language chosen by the Agency in its final order left no reasonable doubt that the intent was to create new duties upon registrants and anticipated sanctions for those who run afoul of those requirements in the future. In his final order, the Administrator stated:

I now hold that where a registrant is provided with credible information that his state prescribing authority is being used to divert a state-controlled (but not federally-controlled) drug, such information triggers the duty to investigate whether his DEA registration is also being used to divert federally controlled substances. However, *as this is a new and additional duty* beyond that which was announced in [a previous final order], which applies only to a practitioner’s receipt of information that his DEA registration is being misused, I conclude that it cannot be retroactively imposed on the [r]espondent.<sup>488</sup>

Regarding the Agency’s intention to impose a new, actionable standard upon the regulated community, the Administrator’s language that “this is a new

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483. *Marseilles Land and Water Co. v. FERC*, 345 F.3d 916, 920 (D.C. Cir. 2003).

484. *Tunik v. Merit Sys. Prot. Bd.*, 407 F.3d 1326, 1345 (Fed. Cir. 2005) (citing *United States v. Nixon*, 418 U.S. 683, 695–96 (1974)); *see also* *Nat’l Family Planning and Reprod. Health Ass’n v. Sullivan*, 979 F.2d 227, 234 (D.C. Cir. 1992) (to same effect).

485. *Air Transp. Ass’n of Am., Inc. v. FAA*, 291 F.3d 49, 55–56 (D.C. Cir. 2002) (citing *Paralyzed Veterans of Am. v. D.C. Arena, L.P.*, 117 F.3d 579, 588 (D.C. Cir. 1997)).

486. *See Marseilles Land and Water Co.*, 345 F.3d at 920.

487. *Peter F. Kelly, D.P.M.*, 82 Fed. Reg. 28676, 28685–86 (Drug Enf’t Admin. June 23, 2017).

488. *Id.* at 28686 (emphasis added).

and additional duty”<sup>489</sup> leaves precious little to the imagination. The Agency “now hold[s]” that it has created this new duty, and concedes (as it must) that based on the fact that this “new and additional duty”<sup>490</sup> has been spawned in an adjudication, due process precludes a sanction in this case.<sup>491</sup> The *Kelly* final order also creates other new obligations on the part of registrants. At another point in the final order, the Administrator renders the following announcement:

[W]here a practitioner receives credible information that fraudulent prescriptions under his name are being presented for state but not federally-controlled drugs, and the state [prescription monitoring program] permits a practitioner to obtain information as to his controlled substance prescribings [sic], that practitioner has a duty to obtain that information and to determine whether unlawful prescriptions for federally controlled substances are also being dispensed under his registration. Moreover, even if state law does not authorize a practitioner to obtain a [prescription monitoring program] report of the dispensings [sic] which have been attributed to him, a practitioner is obligated to obtain that information from a pharmacy that reports a fraudulent prescription to him. If information obtained from either the [prescription monitoring program] or a pharmacy shows that one’s registration is being misused, a registrant must report that information to the DEA (as well as local law enforcement authorities) even if the practitioner concludes that no employee or agent is involved in the misuse of his registration. A practitioner is not excused from this duty because others, who also have responsibilities to investigate, such as law enforcement officers and pharmacists, failed to carry out those responsibilities.<sup>492</sup>

By dropping new duties unceremoniously in the midst of an adjudication, the Agency is spared the laborious tasks of publishing its now-established new registrant duties in the Federal Register, explaining and defending its actions in annotated commentary, and having to address potentially disquieting comments from the public, including the regulated community. Likewise, the Agency is spared the arduous internal approval process attendant upon promulgation, including review of those in the executive branch charged with evaluating the possibility for potential responsive congressional action. Under this approach, those arduous undertakings are supplanted by the more efficient act of placing the Administrator’s signature on the adjudication. Just like that.

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489. *Id.*

490. *Id.*

491. *Id.*

492. *Id.* (internal footnote with yet an additional new duty omitted).

Although this streamlined approach to rulemaking may present obvious time and effort dividends for the Agency, it is likely that the view from the regulated community may not be as supportive. Even accepting the Agency's oft-quoted position that controlled substance registrants operate in a highly-regulated activity,<sup>493</sup> it strains credulity and every reasonable common-sense-based expectation to assume that busy practitioners will be regularly pouring over obscure (and increasingly lengthy and esoteric) Agency final orders to divine the latest outpouring of extra-regulatory obligations upon which continuation of their registration (and often their livelihood) depends. Busy practitioners possess neither the legal acumen to understand the Agency's increasingly legalistic and nuanced final orders, nor the resources to maintain a specialized cadre of regulatory attorneys devoted to perpetually scouring the Federal Register to locate and explain new duties conjured up by the latest Agency adjudication(s). To require knowledge of, and compliance with, the applicable regulations should be enough. Regulations require publication, notice, and comment from the public,<sup>494</sup> which is often a messy process. That said, there have arguably been more procedural and substantive developments effected by DEA final orders through adjudications in the last few years than at any other time during the Agency's existence.

These concerns notwithstanding, in *Masters Pharmaceutical, Inc. v. DEA*, the court was unpersuaded by the distributor respondent's contention that the Agency's imposition of a high volume of new duties imposed on distributors through adjudication was impermissible, holding that the extensive list of extra-regulatory obligations were not new duties at all, but merely an "explan[ation of] what a distributor in [the respondent's] position must do" when it elects to fill an order instead of declining to do so and filing a suspicious order report with the DEA.<sup>495</sup> The explicit nature in which the Agency unambiguously explained the creation of numerous new obligations in *Kelly* provides an enlightening window into the Agency's actual objectives in this approach and arguably stands in some tension with the *Masters* holding.<sup>496</sup>

## 2. Representations by Counsel

From the very outset of the most rudimentary litigation at common law, conventions have developed between the litigants that have given rise to expectations and the orderly development of issues in virtually every manner of forum where issues are contested. One of the most basic tenets of any

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493. See, e.g., Keith Ky Ly, D.O., 80 Fed. Reg. 29025, 29037 n.36 (Drug Enf't Admin. May 20, 2015).

494. Administrative Procedure Act, 5 U.S.C. § 553(b) (2012).

495. *Masters Pharm., Inc. v. DEA*, 861 F.3d 206, 222 (D.C. Cir. 2017).

496. *Id.* at 230.

litigation is the right of a party on either side to rely on the representations made by opposing counsel. The courts have long recognized the principle that the representatives of a party can render binding admissions in a forum. The principle has been succinctly articulated as follows:

A judicial admission is usually treated as absolutely binding, but such admissions go to matters of fact which, otherwise, would require evidentiary proof. They serve a highly useful purpose in dispensing with proof of formal matters and of facts about which there is no real dispute. Once made, the subject matter ought not to be reopened in the absence of a showing of exceptional circumstances, but a court, unquestionably, has the right to relieve a party of his judicial admission if it appears that the admitted fact is clearly untrue and that the party was laboring under a mistake when he made the admission.<sup>497</sup>

Despite the history and practice of both sides relying on concessions of counsel in contested litigation, the Agency recently indicated its unwillingness to find itself bound by the concessions of its own prosecutors. In *Perry County Food and Drug*, Government counsel conceded the timeliness of the respondent's registration renewal application, but the Administrator, in the Agency's final order, and without substantive analysis, disregarded that concession with the dismissive explanation, in a footnote, that "[i]n this matter, I am not bound by the Government's agreement not to contest the timeliness of the [r]espondent's renewal application."<sup>498</sup> The impact of this sua sponte ruling is magnified even further by the fact that at no time did the Government even ask to be relieved of its concession,<sup>499</sup> and at no time prior to the issuance of the final order did the respondent have any inkling that the once-settled factual issue was not only in play, but would be summarily decided to its detriment at a level where it had no notice or opportunity for input.<sup>500</sup> Irrespective of the relative merits of the Agency's apparent disregard of the time-honored litigation convention of honoring concessions made by the representatives of the parties, it is presently unclear whether any concession or stipulation tendered by DEA counsel can be afforded any weight by conscientious opposing counsel. The effect of this potentially significant procedural sea change is yet to be determined, but Government counsel must consider whether and to what extent they are authorized to concede any point, and respondents' counsel must be wary of accepting any proposed concession stipulation offered

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497. *New Amsterdam Cas. Co. v. Waller*, 323 F.2d 20, 24 (4th Cir. 1963).

498. *Perry County Food & Drug*, 80 Fed. Reg. 70084, 70089 n.17 (Drug Enf't Admin. Nov. 12, 2015).

499. *Id.*

500. *Id.*

by Agency counsel, lest the agreement be disregarded and found against their clients on review by the Administrator.

### 3. Requested Hearings, Subsequent Waivers, and Statements of Position

Among the more remarkable procedural cases recently issued by the Agency is *Edge Pharmacy*.<sup>501</sup> In *Edge*, the respondent pharmacy timely requested a hearing through counsel, but subsequent counsel agreed to waive a hearing so long as his client was afforded the ability to submit a statement of position.<sup>502</sup> As designed, everyone associated with the litigation equation appeared to benefit. By electing to proceed in that manner, the expenses associated with conducting a contested hearing could be avoided, the Agency would avoid the risks inherent in contested litigation and could seek a favorable final order based on evidence virtually impervious to objection, and the pharmacy would secure the modest ability to file its position on paper. While it may have appeared to even an experienced observer that nothing could possibly go wrong, what actually resulted was continued and protracted litigation, which was managed—not by the ALJ—but by the Administrator and his staff. In the course of its review, the Agency reversed the ALJ’s discretionary decision to allow the pharmacy respondent to file a statement of position along with its waiver of the hearing that it had previously requested.<sup>503</sup>

In *Edge*, the respondent pharmacy’s counsel sought,<sup>504</sup> and the ALJ granted, additional time to file a statement of position that was to accompany his client’s hearing waiver.<sup>505</sup> While the ALJ found that there was good cause to extend the respondent’s ability to respond to the OSC and accepted the statement on behalf of the Agency (along with the hearing waiver), the Agency’s final order held that the demonstration of good cause by the respondent’s counsel was insufficient.<sup>506</sup> Thus, the only part of the equation that the Agency deemed worthy of keeping intact was the waiver of the respondent-pharmacy’s hearing rights.<sup>507</sup> The Agency went further, and held that on these facts,

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501. *Edge Pharmacy*, 81 Fed. Reg. 72092 (Drug Enf’t Admin. Oct. 19, 2016).

502. *Id.* at 72094.

503. *Edge Pharmacy*, 81 Fed. Reg. at 72098 n.10 (noting that the respondent could have, but did not, seek an extension of time under 21 C.F.R. § 1316.47(b) (2017)); *but see* 21 C.F.R. §§ 1309.53(b), 1316.47(b).

504. While the Agency’s order states that the respondent “never requested an extension of time to file its written statement,” *Edge Pharmacy*, 81 Fed. Reg. at 72098, it also acknowledges that the respondent “filed a pleading in which [it] waived its right to a hearing while seeking leave to file a written statement.” *Id.* at 72094.

505. *Id.* at 72098.

506. *Id.* at 72097–98.

507. *Id.* at 72108.

notwithstanding the fact that the pharmacy was permitted by the ALJ to submit a statement of position, it had (contrary to what it believed it agreed to) “waived its right to submit any evidence in refutation of the Government’s case.”<sup>508</sup> The practical result here was that the respondent’s counsel (and perforce the hapless pharmacy respondent) was, in effect, the victim of a bait and switch; the respondent’s tactical decision to waive a hearing was no doubt informed by the ALJ’s ruling that its position would be contained in a statement of position available to the Agency to review in making its final determination, and only after it had done so was it informed that its position statement would not, in fact, be considered.<sup>509</sup> But the waiver of the pharmacy’s hearing rights stood firm.<sup>510</sup>

The Agency’s narrow reading<sup>511</sup> of the amount of discretion afforded to the ALJ in permitting the untimely filed position statement under the regulations<sup>512</sup> thus resulted in the Agency essentially refusing to engage in the arguably modest exercise of merely considering the respondent’s position in the preparation of the final order.<sup>513</sup> So, the respondent was at once without the ability to have affirmatively raised any and all issues,<sup>514</sup> at the same time it made a bona fides tender of its legal analysis to the Agency so that the final order could address any potential bases for appeal raised therein;<sup>515</sup> essentially a legal double whammy. To make matters worse, lending credibility to the old adage that “no good deed shall go unpunished,” this legal double whammy was inflicted upon the respondent based on its offer to save the Agency the expense and risks associated with proving its allegations at a hearing.<sup>516</sup>

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508. *Id.* at 72098.

509. *Id.* at 72094, 72113.

510. *Id.* at 72098.

511. Interestingly, the Agency’s restrictive interpretation of the ALJ’s authority under 21 C.F.R. § 1316.47(b) (2017) in this case arguably stands in some level of tension with a more broad interpretation of the ALJ’s authority in its recent holding in *John P. Moore, III, M.D.*, 82 Fed. Reg. 10398 (Drug Enf’t Admin. Feb. 10, 2017) (internal citation and punctuation omitted). In *Moore*, the Agency held that “where an ALJ receives an untimely hearing request it is within the ALJ’s authority to conduct such proceedings as are necessary to determine whether the respondent has established good cause” and that this authority (nowhere set forth in the text of the regulation) continues until “the Government submits a request for final agency action to [the Administrator].” *Id.* at 10399 n.2 (internal citation and punctuation omitted). Thus, at this juncture, it would be difficult to prognosticate whether the Agency is moving toward a more broad or more restrictive interpretation of the ALJ’s authority under § 1316.41(b).

512. 21 C.F.R. § 1316.47(b).

513. *Edge Pharmacy*, 81 Fed. Reg. at 72113–14.

514. *Id.* at 72099.

515. *Id.* at 72097.

516. *Id.* at 72094.



In an unprecedented procedural environment, the Agency, after refusing to consider the respondent pharmacy's statement of position, issued a series of orders directing briefings on various legal issues, including "whether . . . the ALJ had authority to admit [the pharmacy's] [s]tatement of [p]osition,"<sup>517</sup> and whether the Agency should allow the pharmacy to withdraw its renewal application;<sup>518</sup> both of which were (predictably) answered in the negative.<sup>519</sup> To put this in context, the registrant's counsel, who conveyed his client's hearing waiver, was directed to brief the issue of whether the condition that was accepted by the Agency's own ALJ was lawful, and whether it should be permitted to withdraw the renewal application it submitted as part of its hearing request on the revocation action.<sup>520</sup>

#### 4. Administrator's Staff as Pseudo-ALJs

The procedural dynamic in an increasing number of Agency final orders merits particular attention. The structure Congress crafted into the APA, coupled with the complimentary structure laced into the DEA's own regulations, provides a dichotomy of functions created to ensure a just result and an appearance of fairness.<sup>521</sup> The APA provides federal agencies with the authority to hire and assign cases to ALJs, but places unalterable duties and bright-line restrictions on the individuals who hold those positions.<sup>522</sup>

The APA provides ALJs presiding at hearings with the authority and responsibility over specified enumerated powers, *to wit*:

(1) [to] administer oaths and affirmations; (2) [to] issue subpoenas authorized by law; (3) [to] rule on offers of proof and receive relevant evidence; (4) [to] take depositions or have depositions taken when the ends of justice would be served; (5) [to] regulate the course of the hearing; (6) [to] hold conferences for the settlement or simplification of the issues by consent of the parties or by the use of alternative means of dispute resolution . . . ; (7) [to] inform the parties as to the availability of one or more alternative means of dispute resolution, and encourage the use of such methods; (8) [to] require the attendance at any conference held . . . ; (9) [to] dispose of procedural requests or similar matters; (10) [to]

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517. *Id.* at 72095.

518. *Id.* at 72102.

519. *Id.* at 72095, 72102.

520. *Id.* at 72102.

521. Compare Administrative Procedure Act, 5 U.S.C. § 556 (2012), with 21 C.F.R. § 1316.52 (2017).

522. 5 U.S.C. §§ 556, 3105.

make or recommend decisions . . . ; (11) [to] take other action authorized by agency rule consistent with [the APA].<sup>523</sup>

A federal “agency is without power to withhold such powers from its [ALJ]s.”<sup>524</sup>

The DEA regulations unequivocally direct that DEA ALJs “shall have the duty to conduct a fair hearing, to take all necessary action to avoid delay, and to maintain order.”<sup>525</sup> The Agency regulations also supply DEA ALJs with their own set of exclusively-held, enumerated powers, some of which overlap with those of the APA.<sup>526</sup> The regulations provide that DEA ALJs

shall have all powers necessary to [avoid delay and maintain order], including (but not limited to) the power to: (a) [a]rrange and change the date, time, and place of hearings . . . ; (b) [h]old conferences to settle, simplify, or determine the issues in a hearing, or to consider other matters that may aid in the expeditious disposition of the hearing; (c) [r]equire parties to state their position in writing with respect to the various issues in the hearing and to exchange such statements with all other parties; (d) [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; (e) [e]xamine witnesses and direct witnesses to testify; (f) [r]eceive, rule on, exclude, or limit evidence; (g) [r]ule on procedural items pending before him; (h) [t]ake any action permitted to the [ALJ] as authorized by [the DEA regulations] or the provisions of the [APA].<sup>527</sup>

To protect their decisional independence, ALJs enjoy lifetime appointments and are only subject to removal for good cause.<sup>528</sup> ALJs “may not perform duties inconsistent with their duties and responsibilities as [ALJ]s,”<sup>529</sup> may not be arbitrarily replaced in the midst of commenced litigation,<sup>530</sup> are not subject to probation<sup>531</sup> or performance reviews by the agencies that employ them,<sup>532</sup>

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523. *Id.* § 556.

524. ATTORNEY GENERAL’S MANUAL, *supra* note 426, § 7(b) at 74.

525. 21 C.F.R. § 1316.52.

526. Compare 5 U.S.C. § 556, with 21 C.F.R. § 1316.52.

527. 21 C.F.R. § 1316.52.

528. 5 U.S.C. § 7521.

529. *Id.* § 3105.

530. *See id.* § 554(d).

531. 5 C.F.R. § 930.204(a).

532. 5 U.S.C. § 554(d)(2).

may not consider extra-record<sup>533</sup> or ex parte communications,<sup>534</sup> are statutorily ineligible to preside over any case where they have participated in any way in the investigative or prosecuting functions of the case,<sup>535</sup> and may disqualify themselves where appropriate.<sup>536</sup>

In providing a defined structure of adjudicatory duties and insulation, Congress provided litigants with a built-in assurance that, whatever the ultimate outcome of an enforcement action might be, the evidence will be amassed and evaluated by an impartial judge who has the freedom to operate without fear of reprisal, and, of equal importance, without undue interference by the agency.<sup>537</sup> The DEA regulations provide that, at the conclusion of hearing proceedings, the ALJ is required to assemble a record of proceedings and a recommended decision to the DEA Administrator, who is charged with the responsibility to, “[a]s soon as practicable,” prepare a “final order in the proceeding, which shall set forth the final rule and the findings of fact and conclusions of law upon which the rule is based.”<sup>538</sup>

It is thus beyond serious argument that both the APA and the DEA regulations have placed the control of the procedural aspects of administrative hearings within the exclusive control of the Agency ALJ presiding at the hearing, and charged the Agency with responsibility for the ultimate decision.<sup>539</sup> In an agency such as the DEA, where there is no formal board tasked with rendering the final Agency determination, the overwhelming likelihood is that orders are being managed, prepared, and issued at the final order level not by the agency head, who bears a myriad of other responsibilities, but by employees under the agency head’s supervision, who are unknown to the registrants and the practicing bar. Such agency employees assisting in the review and preparation of decisions for an agency head enjoy none of the protections, preclusions, or obligations, enjoyed by and levied on its ALJs.

Despite the defined structure and delineated responsibilities described previously, with increasing frequency in final orders issued by the Agency, every credibility, evidentiary, and procedural ruling, is being re-weighed, re-

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533. *Id.* § 556(e).

534. *Id.* § 557(d); *see also* 21 C.F.R. § 1316.51(c) (2017).

535. 5 U.S.C. § 554(d)(2).

536. *Id.* § 556(b).

537. *See generally* 21 C.F.R. § 1316.

538. *Id.* § 1316.67.

539. Even the standard of proof between the two functions is distinguishable. While the standard of proof at the hearing before the ALJ is a preponderance of the evidence, *Steadman v. SEC*, 450 U.S. 91, 100–01 (1981), the standard of review of the final agency action is whether the decision is “supported by and in accordance with the reliable, probative, and substantial evidence.” 5 U.S.C. § 556(d).

evaluated, and frequently reversed on final order review.<sup>540</sup> Additionally, the Agency has demonstrated an increasing proclivity for conducting active litigation outside the reach of the ALJ; it has become increasingly frequent practice for the Administrator's staff to direct the parties to submit evidence and brief legal issues that were not raised in front of the DEA ALJ. In so directing, the anonymous staff members step into the role of pseudo-ALJs and manage contested litigation—without offering any of the protections that the ALJ structure affords to litigants.

The DEA regulations provide no legal mechanism for administrative litigation to be managed by the Administrator or his staff. The Administrator's duties regarding adjudication are specifically enumerated in the regulations,<sup>541</sup> and are restricted to issuing an Agency final order “set[ting] forth the final rule and the findings of fact and conclusions of law upon which the rule is based,” publishing the final order in the Federal Register, and accomplishing these modest tasks “[a]s soon as practicable.”<sup>542</sup> In the APA, Congress has categorically limited the ability to conduct hearings<sup>543</sup> “in every case of an adjudication required by statute to be determined on the record after opportunity for an agency hearing,”<sup>544</sup> which specifically include DEA administrative hearings<sup>545</sup> to administrative law judges.<sup>546</sup> When the Administrator or his staff “preside” over contested administrative proceedings where the statute mandates on-the-record proceedings with an opportunity to request an agency hearing, the Agency risks a determination that the “proceedings” were ultra vires and per se violative of due process. The Administrator could no more delegate the enumerated powers in the APA to an Agency investigator or prosecutor than he could retain them to himself or task a legal advisor, special agent, or contract security guard, to act in the role of an ALJ.<sup>547</sup>

In *Edge*, the parties were directed to file briefs as part of the final order process,<sup>548</sup> which is ultra vires under both the APA and the Agency's

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540. See, e.g., Wesley Pope, M.D., 82 Fed. Reg. 14944, 14946–48 (Drug Enf't Admin. Mar. 23, 2017) (re-weighing, in the Agency final order, every credibility finding rendered by the hearing ALJ, including the testimony of the Government's expert witness); Superior Pharmacy I and Superior Pharmacy II, 81 Fed. Reg. 31310, 31320–25, 31332 (Drug Enf't Admin. May 18, 2016) (showing virtually every ruling on every objection ruled upon by the hearing ALJ scrutinized in detail and re-weighed and re-ruled upon in the final order without any perceptible deference).

541. 21 C.F.R. §§ 1301.46, 1316.67.

542. *Id.* § 1316.67.

543. See 5 U.S.C. § 556(c).

544. *Id.* § 554(a).

545. 21 U.S.C. § 824(c) (2012).

546. 5 U.S.C. § 554(a)(2).

547. See *id.* § 554(d).

548. *Edge Pharmacy*, 81 Fed. Reg. 72092, 72095 (Drug Enf't Admin. Oct. 19, 2016).

regulations,<sup>549</sup> and has little to commend it as a matter of trial practice or even common sense. Further, the manner in which the practice of conducting litigation at the final order level has expanded highlights some of the stronger arguments for expeditiously abandoning the illegal process. An ALJ “shall have the duty to conduct a fair hearing,”<sup>550</sup> but this is an obligation that is not imposed on other employees of the Agency. Lest it seem to be an unfounded concern that one party may have an advantage when litigation is conducted by those who think of themselves as pseudo-ALJs, the Agency’s order in *Edge* provides a striking example of the dangers that lurk in such a situation. In *Edge*, in vacating the ALJ’s finding of good cause for accepting an untimely statement of position, the Agency applied the rigorous “excusable neglect” standard against the registrant’s counsel.<sup>551</sup> But that was not the standard applied to both sides of the litigation equation. In its review of the Government’s submitted evidence, the Agency discovered that one of the declarations submitted by the Government was unsigned.<sup>552</sup> The Government was afforded the opportunity to resubmit a signed version, which was received into the record (apparently by the non-ALJ employee in his capacity as pseudo-ALJ) over the respondent’s objection.<sup>553</sup> The rigorous “excusable neglect” standard that had been wielded against the registrant was supplanted—for the Government only—by the gentler “simple inadvertence” standard,<sup>554</sup> and the evidence was successfully resubmitted by the Government and used against the respondent.<sup>555</sup> Another example of treatment that risks the perception of being preferential to the Government can be seen in *Robert Clark Maiocco, M.D.*, wherein, during the final order preparation process, the Agency sua sponte acted to correct the Government’s errant reliance on the wrong statutory provision in its charging document, without even a corresponding request to do so by the Government, with no more than a passing reference in a footnote.<sup>556</sup> Yet one week earlier, in *William H. Wytenbach, M.D.*, the Agency had entirely declined to consider a motion to reconsider a summary disposition order because it was filed beyond the authorized regulatory deadline for filing exceptions.<sup>557</sup> Indeed, at a time

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549. See 5 U.S.C. § 556(e); 21 U.S.C. § 1316.52.

550. 21 C.F.R. § 1316.52 (2017).

551. *Edge Pharmacy*, 81 Fed. Reg. at 72097–98.

552. *Id.* at 72100–72101.

553. *Id.* at 72101.

554. *Id.*

555. *Id.*

556. *Robert Clark Maiocco, M.D.*, 82 Fed. Reg. 19383, 19383 n.1 (Drug Enf’t Admin. Apr. 27, 2017).

557. *William H. Wytenbach, M.D.*, 82 Fed. Reg. 18777, 18777 (Drug Enf’t Admin. Apr. 21, 2017). See 21 C.F.R. § 1316.66(a) (2017).

when the Agency has been more actively engaged in creating an active litigation environment at the final order level, it has concomitantly demonstrated a markedly more aggressive posture in applying technical bases to disregard issues raised in exceptions filed by respondents.<sup>558</sup>

However well intentioned, even copious, highly-nuanced legal verbiage carefully set out in a final order could do little in dissipating the appearance that the potential for disparate treatment is exacerbated where evidentiary determinations and briefings are conducted by those not charged, qualified, or even permitted under the law to preside over litigation. While this article has striven to examine both sides of the issues raised by recent shifts in Agency procedures, it is difficult to perceive a silver lining in tasking non-ALJs with litigation management and expecting such employees to properly execute responsibilities where an ALJ is mandated. When acting in its role as neutral adjudicator, it is imperative for the Agency to be as mindful of optics as it is the ultimate adjudication. While not always as unambiguous as the disparate standards imposed on the parties' mistakes in *Edge*, the taking of sua sponte actions at the final order stage of adjudication always enhances the risk of appearing to favor one side—generally, at least in these cases, the enforcement side—of the litigation.

##### 5. Excluded by The ALJ Means Excluded

In the APA, Congress was unambiguous in extending to a party the right to “present his case or defense by oral or documentary evidence, to submit rebuttal evidence, and to conduct such cross-examination as may be required for a full and true disclosure of the facts.”<sup>559</sup> Simply stated, a respondent in APA proceedings must be afforded the opportunity to meet the evidence offered by the Government as a precondition to the Agency's ability to use that evidence

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558. See, e.g., *Jones Total Health Care Pharmacy, L.L.C.*, 81 Fed. Reg. 79188, 79189 n.5 (Drug Enf't Admin Nov. 10, 2016) (ruling that the legal issue in timely-filed exceptions was disregarded for failure to include “specific and complete citations of the pages of the transcript and exhibits” requirement in 21 C.F.R. § 1316.66(a)); *Superior Pharmacy I and Superior Pharmacy II*, 81 Fed. Reg. 31310, 31319 (Drug Enf't Admin. May 18, 2016) (ruling that filed exceptions received two days after transmission of the record to the Administrator and one year prior to the issuance of the final order disregarded because it was filed beyond the regulatory 20-day time limit in 21 C.F.R. § 1316.66(a)); *Perry County Food & Drug*, 80 Fed. Reg. 70084, 70084 (Drug Enf't Admin. Nov. 12, 2015) (ruling that filed exceptions received four months prior to the Agency final order were disregarded because filed beyond the regulatory 20-day time limit in 21 C.F.R. § 1316.66(a)); but see *Mark William Andrew Holder*, 80 Fed. Reg. 71618, 71618 (Drug Enf't Admin. Nov. 16, 2015) (showing that the respondent's counsel permitted to file a corrected copy of previously-filed exceptions where, based on a family emergency and a word processing system breakdown, she had secured prior leave to move to do so by the assigned ALJ).

559. Administrative Procedure Act, 5 U.S.C. § 556(d) (2012).

in support of a sanction. In *Lawrence E. Stewart, M.D.*, the Agency reversed its ALJ's evidentiary ruling which had excluded a Food and Drug Administration package insert.<sup>560</sup> Once the package insert had been excluded, the respondent had no need to challenge it or present evidence to contradict the document.<sup>561</sup> The Agency disregarded the ALJ's exclusion of the document and considered it in support of the sanction ultimately imposed.<sup>562</sup>

A similar practice was met with disapproval by the court in *Masters Pharmaceutical, Inc. v. DEA*, wherein the court found that the DEA committed error when, in issuing its final order, it considered evidence that had been excluded by the ALJ at the hearing.<sup>563</sup> The *Masters* court ultimately found the error harmless in light of the strength of other admitted evidence and the representation in the final order that the Administrator did not base his ruling on the re-included evidence, but the court, in no uncertain terms, held that the practice of holding ALJ-excluded evidence against a respondent in support of a sanction constitutes error.<sup>564</sup> The court acknowledged that the Agency had the authority to overrule the ALJ's evidentiary ruling, but held that

the Administrator could not proceed to rely on the excluded evidence of [the respondent's] misconduct [because] [d]oing so would be in derogation of [the respondent's] right to respond to it. Because the ALJ had excluded the evidence, however, [the respondent] had no need or opportunity during the administrative trial to exercise its right to respond.<sup>565</sup>

As discussed elsewhere in this article, the revisiting and refashioning of even the most pedestrian of procedural rulings by the impartial ALJ presents obvious risks to the perception of fairness that litigants can attach to the due process actually afforded by the DEA under the APA.<sup>566</sup> The concept that evidence excluded by the ALJ could only be available to the Agency for consideration following a remand where the respondent is afforded an opportunity to respond strikes as self-evident, but to the extent that judicial precedent was necessary to confirm this principle, it now exists.<sup>567</sup>

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560. *Lawrence E. Stewart, M.D.*, 81 Fed. Reg. 54822, 54822–23 (Drug Enf't Admin. Aug. 17, 2016).

561. *Id.*

562. *Id.* at 54823.

563. *Masters Pharm., Inc. v. DEA*, 861 F. 3d 206, 229 (D.C. Cir. 2017).

564. *Id.*

565. *Id.*

566. *See supra* Part III.K.1.

567. *Id.*

## 6. Official Notice in Final Agency Orders

Similar dangers lurk for both sides of the litigation equation due to the Agency's ever-increasing enamor for the prolific use of official notice. The taking of official notice (like judicial notice in courts of record) is authorized by the APA<sup>568</sup> and the DEA regulations.<sup>569</sup> In its explanatory commentary, the *Attorney General's Manual* explains that the Agency can take official notice in its final orders, and that official notice is designed to be broader than "the traditional matters of judicial notice [and to] extend[] properly to all matters as to which the agency by reason of its functions is presumed to be expert, such as technical or scientific facts within its specialized knowledge."<sup>570</sup> However, the manner in which official notice has been utilized in recent DEA final orders may be arguably broader than seemingly anticipated by that language, encompassing an ever-widening scope of matters, and—perhaps more significantly—it has been exclusively used for the benefit of the Government, and respondents are often not afforded a real opportunity to contest the facts before the Agency's final decision is published in the Federal Register.

On the more benign side of the spectrum, the Agency regularly takes official notice of its own records regarding a registrant's registration status. For example, the Agency has taken official notice of its own records to determine a registration's expiration date.<sup>571</sup> In cases where a respondent's registration expired by its terms while a case was pending and no renewal application or application for a new registration had been filed by the time the Agency decided the matter, the Agency has taken official notice of a registration's expiration

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568. Administrative Procedure Act, 5 U.S.C. § 556(e) (2012).

569. 21 C.F.R. § 1316.59(e) (2017).

570. ATTORNEY GENERAL'S MANUAL, *supra* note 426, § 7(d), at 80.

571. Karen S. Dunning, N.P., 80 Fed. Reg. 28640, 28641 n.1 (Drug Enf't Admin. May 19, 2015); Pedro E. Lopez, M.D., 80 Fed. Reg. 46324, 46324 n.1 (Drug Enf't Admin. Aug. 4, 2015); Adeline Davies Essien, M.D., 80 Fed. Reg. 46322, 46322 n.1 (Drug Enf't Admin. Aug. 4, 2015); Devra Hamilton, N.P., 80 Fed. Reg. 50034, 50034 (Drug Enf't Admin. Aug. 18, 2015); Christina B. Paylan, M.D., 80 Fed. Reg. 69979, 69979 n.1 (Drug Enf't Admin. Nov. 12, 2015); *but see* James Alvin Chaney, M.D., 80 Fed. Reg. 57391, 57391 n.1 (Drug Enf't Admin. Sept. 23, 2015) (taking official notice of the respondent's registration record with the Agency to find that his registration was not expired, but noting that "in the future, where a recommended decision lacks the requisite finding [that the Agency has jurisdiction to act because the registration is valid], [the Agency] will remand the matter" for the purpose of determining that the respondent "retains an active registration or has submitted an application for registration"); Robert Clark Maiocco, M.D., 82 Fed. Reg. 19383, 19384–85 & n.4 (Drug Enf't Admin. Apr. 27, 2017) (taking official notice of the respondent's registration record with the Agency, but noting that the Government has the burden of providing evidence establishing the Agency's jurisdiction as part of its motion and the ALJ is obligated to make findings as to the Agency's jurisdiction).



date in Agency databases.<sup>572</sup> Similarly, in cases where a respondent's license expired during the proceedings but he filed an application to renew the license, the Agency has taken official notice of its own database records to determine whether the renewal application was timely filed, thus extending the existing registration,<sup>573</sup> or whether it was untimely, in which case only the pending application remained before the Agency for determination.<sup>574</sup> The Agency has also taken official notice of its own records to determine that the Agency was not in possession of other documents that could be relevant to the issues, such as a power of attorney.<sup>575</sup>

On the other side of the spectrum, the Agency has shown an increasing willingness to widen the scope of facts that it is willing to find through the taking of official notice at the final, post-hearing stage, where it makes its final determination regarding a respondent's registration.<sup>576</sup> One prevalent example is the Agency's increasingly prolific use of state medical board websites to

572. Patricia A. Newton, M.D., 82 Fed. Reg. 26516, 26516 (Drug Enf't Admin. June 7, 2017); Rezik A. Saqer, M.D., 81 Fed. Reg. 22122, 22123 (Drug Enf't Admin. Apr. 14, 2016); Geoffrey D. Peterson, N.P., 81 Fed. Reg. 49266, 49266 n.1 (Drug Enf't Admin. July 27, 2016); Victor B. Williams, M.D., 80 Fed. Reg. 50029 (Drug Enf't Admin. Aug. 18, 2015); Tin T. Win, M.D., 78 Fed. Reg. 52802, 52803 (Drug Enf't Admin. Aug. 26, 2013); Donald Brooks Reece II, M.D., 77 Fed. Reg. 35054, 35054–55 (Drug Enf't Admin. June 12, 2012); James Edgar Lundeen, Sr., M.D., 77 Fed. Reg. 29696, 29696 (Drug Enf't Admin. May 18, 2012); Louisiana All Snax, Inc., 76 Fed. Reg. 20034, 20034 (Drug Enf't Admin. Apr. 11, 2011); Kermit B. Gosnell, M.D., 76 Fed. Reg. 4938, 4938 (Drug Enf't Admin. Jan. 27, 2011); Sylvester A. Nathan, 74 Fed. Reg. 17516, 17516–17 (Drug Enf't Admin. Apr. 15, 2009); Elmer P. Manalo, M.D., 73 Fed. Reg. 50353, 50353 (Drug Enf't Admin. Aug. 26, 2008); William W. Nucklos, M.D., 73 Fed. Reg. 34330, 34330 (Drug Enf't Admin. June 17, 2008); Benjamin Levine, M.D., 73 Fed. Reg. 34329, 34329–30 (Drug Enf't Admin. June 17, 2008); David L. Wood, M.D., 72 Fed. Reg. 54936, 54937 (Drug Enf't Admin. Sept. 27, 2007).

573. See 21 C.F.R. § 1301.36(i) ("In the event that an applicant for reregistration (who is doing business under a registration previously granted and not revoked or suspended) has applied for reregistration at least 45 days before the date on which the existing registration is due to expire, and the Administrator has issued no order on the application on the date on which the existing registration is due to expire, the existing registration of the applicant shall automatically be extended and continue in effect until the date on which the Administrator so issues his or her order.")

574. Jones Total Health Care Pharmacy, L.L.C., 81 Fed. Reg. 79188, 79188 n.3 (Drug Enf't Admin. Nov. 10, 2016); Perry County Food & Drug, 80 Fed. Reg. 70084, 70089 n.17 (Drug Enf't Admin. Nov. 12, 2015); Sharad C. Patel, M.D., 80 Fed. Reg. 28693, 28694 (Drug Enf't Admin. May 19, 2015); Ralph J. Chambers, M.D., 79 Fed. Reg. 4962, 4962 n.2 (Drug Enf't Admin. Jan. 30, 2014).

575. Glenn R. Unger, D.D.S., 79 Fed. Reg. 49339, 49340 (Drug Enf't Admin. Aug. 20, 2014) (taking official notice of the Agency's registration records to determine that the registrant had not submitted a power of attorney allowing any person other than himself to sign an application for a registration and consequently finding that the registration granted pursuant to an application signed by someone else was void *ab initio*).

576. See Steven Bernhard, D.O., 82 Fed. Reg. 23298 (Drug Enf't Admin. May 22, 2017); David D. Moon, D.O., 82 Fed. Reg. 19385, 19387 n.5 (Drug Enf't Admin. Apr. 27, 2017); William H. Wytenbach, M.D., 82 Fed. Reg. 18777, 18778 (Drug Enf't Admin. Apr. 21, 2017).

determine, through official notice, a registrant's current state licensure status.<sup>577</sup> This practice is of particular concern in view of the fact that there is no guarantee that the information contained on the various state board websites is accurate or current, and no transparent ability on the part of the regulated community to ascertain which DEA employee is making the queries and whether that employee is correctly interpreting the website entries. Additionally, even on the best of the state board websites, the information may be modified or deleted at any moment, making it all but impossible for a registrant (and, even more importantly, a reviewing court) to determine what the Agency decision-maker was looking at when he or she took official notice and whether the "fact" was accurate and interpreted correctly. The problem here is that, even assuming benign intention, in conducting a search to find a state board website, crafting and entering a query to the website, and interpreting the results reflected on the website in order to drop "facts" into a final order, some unnamed employee<sup>578</sup> is simultaneously conducting an investigatory function and participating and advising in the Agency adjudication.<sup>579</sup> When an Agency employee embarks upon an internet search

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577. Steven Bernhard, D.O., 82 Fed. Reg. 23298; *Moon*, 82 Fed. Reg. at 19387 n.5; *Wytenbach*, 82 Fed. Reg. at 18778; Robert Markman, M.D., 82 Fed. Reg. 11369, 11370 (Drug Enf't Admin. Feb. 22, 2017); Frank D. Li, M.D., 82 Fed. Reg. 11238, 11239 (Drug Enf't Admin. Feb. 21, 2017); Paul E. Pilgram, M.D., 82 Fed. Reg. 11058, 11059 (Drug Enf't Admin. Feb. 17, 2017); John P. Moore, III, M.D., 82 Fed. Reg. 10398, 10400 (Drug Enf't Admin. Feb. 10, 2017); Thomas Horiagon, M.D., 81 Fed. Reg. 79051, 79052 (Drug Enf't Admin. Nov. 10, 2016); Nicholas J. Nardacci, M.D., 81 Fed. Reg. 47409, 47410 (Drug Enf't Admin. July 21, 2016); Ibem R. Borges, M.D., 81 Fed. Reg. 23521, 23522 (Drug Enf't Admin. Apr. 21, 2016); William Mikaitis, M.D., 80 Fed. Reg. 73833, 73834 (Drug Enf't Admin. Nov. 25, 2015); *Chambers*, 79 Fed. Reg. at 4963 n.7; Kamal Tiwari, M.D., 76 Fed. Reg. 71604 (Drug Enf't Admin. Nov. 18, 2011); Pain Management and Surgery Center of Southern Indiana, 76 Fed. Reg. 71604, 71606 (Drug Enf't Admin. Nov. 18, 2011); Hicham K. Riba, D.D.S., 73 Fed. Reg. 75773, 75773 (Drug Enf't Admin. Dec. 12, 2008); Piyush V. Patel, M.D., 72 Fed. Reg. 18274, 18275 (Drug Enf't Admin. Apr. 11, 2007).

578. As discussed, there is no formal reviewing board at the DEA, and the likelihood of the DEA Administrator taking time from his massive Agency oversight and management responsibilities to conduct Internet searches to identify state board websites, query them, and craft the information he gleans in those sites into Agency final orders in a host of cases can safely be characterized as remote. Thus, the reality is that the employee tasked with preparing the draft final order is also conducting investigative functions and simultaneously providing the Administrator with advice and drafting final orders. Unless an employee on the investigative or Government counsel side is supplying the information (which is contrary to the apparent language in the decisions and would be *ex parte* in any event) this practice, where the same person is drafting and otherwise participating in the final adjudication, constitutes a violation of the unambiguous prohibition that is set forth in the APA. Administrative Procedure Act, 5 U.S.C. § 554(d) (2012).

579. In some cases, the Agency issues orders to the parties to provide information, but in others, it is apparently finding the information on its own. See Gregory White, M.D., 79 Fed. Reg. 24754, 24755 (Drug Enf't Admin. May 1, 2014) ("An internet search of the [state board's] public record actions webpage found . . ."); Franklyn Seabrooks, M.D., 79 Fed. Reg. 44196, 44197 (Drug Enf't

to identify state board websites for inclusion of his or her interpretation of that search into an Agency final order, it would take a highly-tortured definition to place that activity outside the realm of conducting an investigatory function. The *Attorney General's Manual* addresses the utilization of agency employees for the drafting of final orders as follows:

Nothing in the [APA] is intended to preclude agency heads from utilizing the services of agency employees as assistants for analysis and drafting. Of course, in adjudicatory cases subject to [5 U.S.C. § 557(c)], such assistants could not have performed investigative or prosecuting functions in the cases (or in factually related cases) in which they are so employed. Also, the agency heads are free to employ the [ALJ] who heard a particular case as the draftsman of their final decision and otherwise to assist in its formulation.<sup>580</sup>

To the extent that decision drafters in the Agency are regularly conducting internet searches to glean information that is seamlessly incorporated into Agency final orders, this may run in some tension with the restrictions of the APA.<sup>581</sup>

Even more tenuous than the Agency's practice of using state board websites in an attempt to essentially confirm facts supported in a record have not staled with time, is its use of official notice to actually add additional facts and materials to the record, and use those materials against respondents without providing a meaningful opportunity to challenge them.<sup>582</sup> In four cases where the Government alleged only that a registrant's state license had been suspended,<sup>583</sup> state board orders (and their contents) that were issued after the ALJ transmitted the records to the Administrator were held against the respondents where the Agency took official notice of the board orders—in one case even stating that it “made [the order] part of the record”<sup>584</sup>—and revoked

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Admin. July 30, 2014) (“An internet search of the [state board]’s public record actions Web page reveals . . .”); William G. Hamilton, Jr., M.D., 71 Fed. Reg. 39129, 39129 (Drug Enf’t Admin. July 11, 2006) (noting that since the time a state suspension order was issued (which was in the investigative file), Administrator “ha[d] become aware of further proceedings involving [r]espondent’s state medical license”).

580. ATTORNEY GENERAL’S MANUAL, *supra* note 427, § 8(b) at 87 (citing *Morgan v. United States*, 298 U.S. 468, 481 (1936)).

581. 5 U.S.C. § 554(d).

582. Geoffrey D. Peterson, N.P., 81 Fed. Reg. 49266, 49267 n.3 (Drug Enf’t Admin. July 27, 2016).

583. *Id.* at 49266; John R. Kregenow, D.D.S., 80 Fed. Reg. 50029, 50030 (Drug Enf’t Admin. Aug. 18, 2015); Roy Chi Lung, M.D., 74 Fed. Reg. 20346, 20346 (Drug Enf’t Admin. May 1, 2009); Sheran Arden Yeates, M.D., 71 Fed. Reg. 39130, 39130 (Drug Enf’t Admin. July 11, 2006).

584. *Peterson*, 81 Fed. Reg. at 49267 n.3.

the respondents' DEA registrations based on the later-issued board revocation orders.<sup>585</sup> On one occasion, the Agency limited its official notice of a state medical board order by only taking official notice of the order to the extent it established that the respondent was no longer authorized to practice medicine in the state, while declining to take official notice of the findings of fact and conclusions of law set forth in that order because, the Agency said, the Government could have—but did not—give the respondent notice that it intended to rely on prescribing events at issue in that order.<sup>586</sup> Even more recently, in responding to an argument *interposed by the Government* that doing so would be contrary to due process, the Agency found and took official notice of evidence of a state license revocation where lack of state authority was not alleged at any point during the proceeding.<sup>587</sup> The use of official notice to include information from state board websites can also prove confusing (and potentially unfairly prejudicial) when the Agency includes information about state suspensions or revocations that were not only not noticed, but are also unrelated to the licensure status of the respondent in the state at issue in the proceeding.<sup>588</sup>

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585. *Kregenow, D.D.S.*, 80 Fed. Reg. at 50030 n.3; *Lung*, 74 Fed. Reg. at 20347; *Yeates*, 71 Fed. Reg. at 39131.

586. Jose Raul S. Villavicencio, M.D., 80 Fed. Reg. 3624, 3627–28 n.5 (Drug Enf't Admin. Jan. 23, 2015). The Agency concluded that it could take notice of the board's action on the respondent's state medical license because "the Agency has long held that it lacks authority to continue a practitioner's registration where a practitioner no longer holds state authority to dispense controlled substances," noting that "the Agency has consistently taken official notice of state board decisions suspending or revoking a practitioner's state authority notwithstanding that the state did not take action until after the issuance of a[n OSC]." *Id.* The Agency added that "adequate notice is provided either by the Government's filing of a Motion for Summary Disposition (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)." *Id.* The circular nature of that statement—that taking official notice, by itself, provides adequate notice that the Agency intends to take official notice—only adds to the confusion surrounding what notice is adequate for an extra-record fact (or document) to be held against the respondent.

587. Hatem M. Ataya, M.D., 81 Fed. Reg. 8221, 8244 & n.55 (Drug Enf't Admin. Feb. 18, 2016) (taking official notice that a state medical board revoked a respondent's medical license during the course of proceedings and relying on that fact in revoking respondent's registrations and denying pending applications, despite the Government's argument that it did not allege lack of state authority in its OSC and relying on that fact would be contrary to due process because the issue was raised sua sponte by the Agency).

588. Zizhuang Li, M.D., 78 Fed. Reg. 71660, 71661 n.4 (Drug Enf't Admin. Nov. 29, 2013) (taking official notice that the Medical Board of California issued an accusation/petition to revoke a respondent's state medical license based on the results of an action taken by the Mississippi Board and taking official notice that the respondent voluntarily surrendered his Louisiana medical license, without stating where any of that information was found or why it took official notice of those facts in a case where the proposed denial of a respondent's application to be registered in California was based exclusively on findings made by the Mississippi Board).

In addition to state board licensure information, the Agency has also taken official notice of the following: facts and circumstances relating to ancillary criminal proceedings involving a respondent;<sup>589</sup> Food and Drug Administration National Drug Code (NDC) information;<sup>590</sup> zip code information;<sup>591</sup> post-hearing Mapquest queries, including determinations of how far patients reside from prescribing doctor's offices<sup>592</sup> and how many pharmacies exist in a certain geographic area;<sup>593</sup> supplementary information about doctor-prescribers in pharmacy cases, including whether the prescribers had action taken against

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589. Ibem R. Borges, M.D., 81 Fed. Reg. 23521, 23523 (Drug Enf't Admin. Apr. 21, 2016) (taking official notice of state court records to establish that the respondent was charged with committing particular crimes relating to controlled substances and had a jury trial scheduled but then declining to consider that information because it was not alleged as a basis for revocation in the order to show cause); Odette L. Campbell, M.D., 80 Fed. Reg. 41062, 41063 n.5 (Drug Enf't Admin. July 14, 2015) (taking official notice of "the Docket Sheet Entries in [the respondent's criminal case], as well as Document # 27 [from that case], which sets forth the disposition of . . . [a] hearing conducted by the district court on [r]espondent's violation of the conditions of her pretrial release, wherein the [district court] modified the conditions of her release to prohibit her from writing any controlled substance prescriptions," after the Government alerted the Agency to the indictment of the criminal case in a post-hearing filing after being directed by the Agency to address the status of state board proceedings against the respondent); Wayne E. Ellison, and North Stringtown Plaza, Inc., 42 Fed. Reg. 43136, 43136 n.1 (Drug Enf't Admin. Aug. 26, 1977) (revoking registration based on the respondent's conviction of a felony offense relating to controlled substances and taking official notice of the fact that the U.S. Court of Appeals for the Seventh Circuit affirmed the respondent's convictions after the record was certified and transmitted).

590. Jones Total Health Care Pharmacy, L.L.C., 81 Fed. Reg. 79188, 79189 n.7 (Drug Enf't Admin. Nov. 10, 2016) (taking official notice that, "according to the FDA's National Drug Code Directory website," a National Drug Code number on a prescription label in evidence is the drug code for a particular controlled substance).

591. Mark P. Koch, D.O., 79 Fed. Reg. 18714, 18719 n.15 (Drug Enf't Admin. Apr. 3, 2014) (taking official notice, "using the Web site of the U.S. Postal Service," that a particular zip code corresponds with Erie, Pennsylvania when the Certification of Registration history listed only "Erie" and the zip code).

592. *Jones Total Health*, 81 Fed. Reg. at 79194 n.18 (taking official notice of "a query conducted on Mapquest" to determine approximately how far a patient resided from a prescribing doctor's office).

593. Perry County Food & Drug, 80 Fed. Reg. 70084, 70092 (Drug Enf't Admin. Nov. 12, 2015) (taking official notice of "the results of a Mapquest search for pharmacies in the Perryville[, Arkansas] area[, which] show that there are six pharmacies located in Morrilton[, Arkansas], a town "which is only fourteen miles from Perryville," to reject the respondent pharmacy's claim that its closure will create a monopoly because there is only one other pharmacy in Perryville).

their licenses,<sup>594</sup> whether the doctors held any board certifications,<sup>595</sup> and even whether the doctors were still alive;<sup>596</sup> statistics “established” by prior agency orders;<sup>597</sup> and, most recently, “that morphine does not metabolize into oxymorphone” in the human body.<sup>598</sup>

Some of the facts the Agency now establishes through the use of official notice might be incontrovertible, such as NDC codes and zip code information. Some or even all of the information it currently pours into the record at the final order stage might be accurate, but the registrant that it was used against may not have had reason (or ability) to access the information, such as doctor-prescriber license information. Other information that the Agency has found as fact through official notice is potentially susceptible to reasonable dispute by experts, such as whether statistics set forth in a prior Agency order are relevant to the facts of a newer case, or whether particular controlled substances metabolize into particular chemicals.<sup>599</sup> And, of course, there is always the potential that the Agency could simply get the facts wrong when it takes official notice. The APA offers some ability to challenge the facts found through official notice, providing that “[w]hen an agency decision rests on official notice of a material fact not appearing in the evidence in the record, a party is entitled, on timely request, to an opportunity to show the contrary.”<sup>600</sup> However, a meaningful opportunity and procedure to challenge facts is not

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594. *Jones Total Health*, 81 Fed. Reg. at 79193 n.13 (revoking, through a prior Agency final order, a practitioner’s license for a doctor whose patients filled their prescriptions at the respondent pharmacy); *id.* at 79199 n.31 (suspending and later revoking licenses of several doctors whose patients filled their prescriptions at the respondent pharmacy); *Edge Pharmacy*, 81 Fed. Reg. 72092, 72103 n.28 (Drug Enf’t Admin. Oct. 19, 2016) (restricting doctor’s state license—on a date after the DEA’s inspection of the pharmacy—for cause and ultimately surrendered).

595. *Edge Pharmacy*, 81 Fed. Reg. at 72103 n.28 (taking official notice that “[a]ccording to the online records of the Florida Department of Health” a particular doctor whose prescriptions were filled at the respondent pharmacy was not board certified in pain medicine or anesthesiology).

596. *Hills Pharmacy, L.L.C.*, 81 Fed. Reg. 49816, 49830 (Drug Enf’t Admin. July 28, 2016) (taking official notice of the date of death of a doctor based on his “online obituary” in a pharmacy case where the pharmacist in charge testified that many of his customers visited a particular pain clinic because the (now deceased) doctor was famous).

597. *Vernor Prescription Center*, 59 Fed. Reg. 6305, 6306 (Drug Enf’t Admin. Feb. 10, 1994) (taking official notice of a statistic regarding average purchases of a certain drug by pharmacies in Michigan, which was “established” in a prior agency order issued three years prior, to determine that the respondent’s purchases remained excessive despite the ALJ’s finding that it was a mitigating factor that the respondent’s purchases if the drug were declining).

598. *Wesley Pope, M.D.*, 82 Fed. Reg. 14944, 14964 (Drug Enf’t Admin. Mar. 23, 2017) (citing Edward J. Cone, et al., *Evidence that Morphine is Metabolized to Hydromorphone But Not to Oxymorphone*, 32 J. ANALYTIC TOXICOLOGY 319, 319, 323 (2008) (“Pursuant to 5 U.S.C. § 556(e) (2012), I take official notice that morphine does not metabolize into oxymorphone.”)).

599. *Id.*

600. Administrative Procedure Act, 5 U.S.C. § 556(e) (2012).

consistently offered by the Agency,<sup>601</sup> is sometimes not offered at all,<sup>602</sup> and has been offered only in words but not in substance in the Agency's more recent decisions, because the final orders have already been published in the Federal Register before the time offered to the respondent to challenge the facts has elapsed.<sup>603</sup>

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601. See, e.g., *Pope*, 82 Fed. Reg. at 14964 n.33 (affording "[twenty] calendar days" from the date of the order to file "properly supported motion for reconsideration" and affording the Government twenty days to respond to such a motion); Robert Markman, M.D., 82 Fed. Reg. 11369, 11370 n.1 (Drug Enf't Admin. Feb. 22, 2017) (affording "[fifteen] calendar days [from] the date of service" to "file a motion for reconsideration"); *Hills Pharmacy*, 81 Fed. Reg. at 49823 n.11 (affording fifteen calendar days from the mailing of the order to "fil[e] a properly supported motion"); Jones Total Health Care Pharmacy, L.L.C., 81 Fed. Reg. 79188, 79188 n.3 (Drug Enf't Admin. Nov. 10, 2016) (affording "ten days" from the date of the order to "fil[e] a properly supported motion"); Piyush V. Patel, M.D., 72 Fed. Reg. 18274, 18275 n.1 (Drug Enf't Admin. Apr. 11, 2007) (affording fifteen days after "receipt of th[e] order" to "fil[e] a request for reconsideration which includes supporting documentation"); Edmund Chein, M.D., 72 Fed. Reg. 6580, 6583 n.4 (Drug Enf't Admin. Feb. 12, 2007) (citing 5 U.S.C. § 556(e)) (noting that "publication of [the] order will be withheld for a fifteen day period in order to provide [r]espondent with 'an opportunity to show to the contrary'").

602. David D. Moon, D.O., 82 Fed. Reg. 19385, 19387 n.5 (Drug Enf't Admin. Apr. 27, 2017) (taking official notice of the online records of two state medical boards to find that the respondent does not currently possess a license in either jurisdiction, but providing no opportunity to refute that fact); Edge Pharmacy, 81 Fed. Reg. 72092, 72103 n.58 (Drug Enf't Admin. Oct. 19, 2016) (citing 5 U.S.C. § 557(c)) (taking official notice of the Florida Department of Health "online records," which provides that parties are entitled to submit arguments and things to "employees participating in the decision[] [on agency review]," but which does not provide an opportunity for parties to challenge facts found through official notice in a final agency decision); Richard J. Settles, D.O., 81 Fed. Reg. 64940, 64944 n. 13 (Drug Enf't Admin. Sept. 21, 2016) (citing to the New Mexico Board of Osteopathic Medical Examiners website to state that certain state licenses were expired, but not stating that the Agency is taking official notice of the expiration dates or offering any opportunity to the respondent to challenge whether the licenses were, in fact, expired); Gregory White, M.D., 79 Fed. Reg. 24754, 24755 (Drug Enf't Admin. May 1, 2014) (citing an "internet search" to establish the respondent's state licensure status, but providing no opportunity for the respondent to challenge the finding).

603. See *Pope*, 82 Fed. Reg. at 14964 n.33 (purporting, in the Agency's decision signed on March 16, 2017, to afford the respondent 20 calendar days after that date to "fil[e] a properly supported motion for reconsideration" with the Office of the Administrator, while affording the Government 20 days to respond to such a motion, if filed, but the final order was published in the Federal Register only seven days after it was signed, on March 23, 2017.); Frank D. Li, M.D., 82 Fed. Reg. 11238, 11239 & n.2 (Drug Enf't Admin. Feb. 21, 2017) (purporting, in the Agency's decision, which was signed on February 13, 2017, to afford the respondent 15 calendar days from the date the order was mailed to "file a motion for reconsideration," but the final order was published in the Federal Register only eight days after it was signed, on February 21, 2017.); *Hills Pharmacy*, 81 Fed. Reg. at 49817, 49823 n.11 (purporting, in the Agency's decision, which was signed on July 19, 2016, to afford the respondent 15 calendar days from the mailing of the order to dispute the fact found by official notice "by filing a properly supported motion," but the final order was published in the Federal Register only nine days after it was signed, on July 28, 2016.); *Jones Total Health*, 81 Fed. Reg. at 79188 n.3, 79203 (purporting, in the Agency's decision, which was signed on October 31, 2016, to afford the respondent ten days to "dispute . . . any [] finding[s] which [are] the subject of official notice[]" by filing a properly supported motion," but the final order was published in the Federal Register exactly ten days later, on

Even when a respondent is provided with an opportunity to rebut the information found through official notice, Federal Register publication puts the information in the public domain for the respondent's patients, customers, peers, colleagues, and families to see that order before any dispute is resolved unless the Agency delays publication in order to resolve the dispute. In practice, the Agency's final order is published long before a respondent is able to refute the facts found through official notice.<sup>604</sup> On one occasion where the Administrator took official notice of numerous documents that were not included in the administrative record<sup>605</sup> the Agency published its final Agency order seven days after it was signed and eight days before the time afforded to the respondent to file a motion for reconsideration expired.<sup>606</sup> In that case, the respondent objected to the inclusion of the extra-hearing documents and requested an opportunity to respond to that evidence.<sup>607</sup> Even then, the Administrator did not remand the case to the ALJ to allow the respondent to introduce new documents in order to refute those documents that were included via official notice.<sup>608</sup> Instead, the Administrator ordered that the parties litigate the issue via filings—with the Administrator<sup>609</sup>—and ultimately took official

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November 10, 2016). That the orders sometimes reflect a delayed effective date changes nothing about the potential injury to fragile professional reputations resulting from this practice.

604. See cases cited *supra* note 603.

605. Lyle E. Craker, 74 Fed. Reg. 2101, 2108 n.24 (Drug Enf't Admin. January 14, 2009) (taking official notice of National Institute on Drug Abuse (NIDA) letter, "which appears on [the Multidisciplinary Association for Psychedelic Studies (MAPS)]'s website," to find the bases upon which NIDA denied a doctor's application to use marijuana in a research study); *id.* at 2109 n.30 (taking official notice of two reports available on the MAPS website); *id.* at 2111 n.41 (taking official notice "of the FDA's Guideline for Drug Master Files," and providing website link); *id.* at 2115 n.56 (taking official notice of a report authored by the International Narcotics Control Board (INCB)); *id.* at 2116 n.57 (taking official notice of a press release issued by the INCB).

606. *Craker*, 74 Fed. Reg. at 2133 (order signed on January 7, 2009); *id.* at 2108 n. 24 ("To allow [r]espondent the opportunity to refute the facts of which I take official notice, [r]espondent may file a motion for reconsideration within fifteen days of service of this order which shall commence with the mailing of this order.").

607. See Lyle E. Craker, PhD, 76 Fed. Reg. 51403, 51404 (Drug Enf't Admin. Aug. 18, 2011) (describing the post-Final Order filings that resulted from the 2009 Agency final order).

608. *Id.* (filing a motion for reconsideration, respondent including a request "that the administrative hearing be reopened so that he may call additional witnesses in view of certain documents of which [the Administrator] took official notice in the final order," but the Administrator denied that request).

609. *Id.* (directing the respondent, in Administrator's "interim order," "to submit a list of all witnesses he would call if his request to reopen the administrative hearing were granted[,] to provide a summary of the proposed testimony for each witness[,] and to "indicate precisely which documents he sought to introduce for purposes of his motion for reconsideration" and whether he was requesting official notice be taken of the documents or whether they would be introduced through witnesses if his request to reopen the hearing were granted); *id.* ("[h]aving ruled on which new documents would be considered part of the record (through [her] taking official notice thereof)," the Administrator afforded



notice of several documents submitted by the respondent.<sup>610</sup> The entire process took more than two years, and during that time the Agency's final order with the officially-noticed documents—which was already published—remained unchallenged, at least in the public's view.<sup>611</sup> Even if a registrant were ultimately to prevail on an official notice issue, the effects on the registrant's patient or customer base would be catastrophic and irreparable.

Also, whether the officially-noticed facts prove to be incontrovertibly true, probably true, arguably true, sort of true, or not true at all, the ever-escalating use of official notice still raises the unattractive specter of an unidentified Government employee sitting at a computer terminal somewhere in the office of the final adjudicator, performing investigative research into state board websites, other agency websites, and even biology reference materials and other sources. This phenomenon runs the risk of violating the APA's unambiguous provision that, subject to exceptions not relevant here:

An employee or agent engaged in the performance of investigative or prosecuting functions for an agency in a case may not, in that or a factually related case, participate or advise in the decision, recommended decision, or agency review [of initial decisions], except as a witness or counsel in public proceedings.<sup>612</sup>

The Agency's decision drafter certainly is not "a witness or counsel in the public proceedings," and he or she certainly is "participat[ing] or advis[ing]" the final Agency decision maker by drafting what will ultimately become the final decision of the Agency.<sup>613</sup> Therefore, the APA provision unequivocally prohibits him or her from "engag[ing] in the performance of investigative or prosecuting functions" for the Agency.<sup>614</sup> But the language of the Agency's final orders gives at least the appearance that this dynamic has become standard operating procedure through the increasingly aggressive use of official notice.<sup>615</sup>

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the respondent "an additional opportunity to file a final brief" and afforded the Government time to respond to that brief).

610. *Id.* (taking official notice of four documents and declining to take official notice of seven documents, noting that those seven documents "will not be considered part of the administrative record considered by the agency in this adjudication," which indicates that the other four *were* considered to be part of the record).

611. The first *Craker* final order was published on January 14, 2009, *Craker*, 74 Fed. Reg. at 2101, and the second was published on August 18, 2011, *Craker*, 76 Fed. Reg. at 51403.

612. Administrative Procedure Act, 5 U.S.C. § 554(d) (2012).

613. *Id.*

614. *Id.* § 554(d)(2).

615. *E.g.*, Gregory White, M.D., 79 Fed. Reg. 24754, 24755 (Drug Enf't Admin. May 1, 2014) ("An internet search of the [state board]'s public record actions Web page found the following . . .");

While official notice is certainly authorized in administrative enforcement proceedings, the essential question is whether the Agency's decision makers (and decision drafters), in their roles as impartial adjudicators, will be able to resist the temptation to shore up the Government's case through the use of official notice in preparing the Agency's final orders. Even if the bar representing the regulated community is actually afforded the opportunity (and instructions for how) to confront officially noticed facts, it does little to dispel the inescapable sense that the purportedly-neutral Agency final order adjudicator is being placed in the role of minding that the Government has dotted its "i's" and crossed its "t's," assisting in filling in gaps at the last moment where needed. With the current practice, the Government could be perceived by the regulated community and the public as essentially working with a safety net in the event that one of its prosecutors misses an important detail, forgets a declaration signature, or has its evidence staled through the passage of adjudication time. Respondents, on the other hand, are afforded little more than a passing moment, if anything, to refute the new evidence used against them and—even if they did manage to challenge the facts found through official notice before the final order was published—the Agency has rendered no hint that it would be willing to defer Federal Register publication in order to resolve the dispute (which it would presumably need to do by remanding the matter back to the impartial adjudicator), before the respondents would need to appeal the entire final order, rather than merely challenging an officially-noticed fact found within it.

*M. Is the Agency Marginalizing its ALJs, and its Due Process Hearings?*

1. Restraining (and Overruling) Decisional Independence

There is little doubt that the Agency's more recent final orders could be read as conveying an increasing discomfiture with the decisional independence of its own independent ALJs.<sup>616</sup> In one recent line of final orders, the Agency accepted and published the recommended decisions of its ALJs, but deleted those portions of the ALJ's recommended decisions which cited *Universal Camera Corp. v. NLRB*,<sup>617</sup> a decision wherein the Supreme Court set forth the level of deference properly accorded to the factual determinations rendered by

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Franklyn Seabrooks, M.D., 79 Fed. Reg. 44196, 44197 (Drug Enf't Admin. July 30, 2014) ("An internet search of the [state board]'s public record actions Web page reveals . . .").

616. See generally, John A. Gilbert and Andrew J. Hull, *A Matter of Substantial Discretion: A Recent Rift Between DEA and Its ALJs Could Significantly Impact Registrants*, FOOD AND DRUG LAW INSTITUTE MAGAZINE, November/December 2015.

617. 340 U.S. 474, 496 (1951).

federal agency ALJs.<sup>618</sup> In *JM Pharmacy*, the Agency adopted most of the ALJ's findings of fact and conclusions of law but, citing the ALJ's discussion of *Universal Camera*, included the statement that "[t]o make clear, the Agency is the ultimate factfinder . . . ."<sup>619</sup> Even setting aside the fact that the Agency, by its regulations, has qualified its own authority over aspects of the adjudication,<sup>620</sup> it is not so much the accuracy of the statement that presents an issue, but the Agency's election to include the seemingly confrontational declaration in its final order. Setting aside considerations regarding the wisdom of supplanting and qualifying clear Supreme Court precedent with pronouncements ensconced in prior Agency final orders, the Agency's decisions risk the appearance of an increasing willingness on the part of the Agency to disregard facts found by impartial ALJs and substitute its own, different facts.

There can also be little doubt that the Agency's precedents have demonstrated an increasing aggressiveness in publicly scolding its ALJs in final orders published in the Federal Register.<sup>621</sup> The Agency has also, in a published

618. See, e.g., Trenton F. Horst, D.O., 80 Fed. Reg. 41079, 41079 n.2 (Drug Enf't Admin. July 14, 2015); Jana Marjenhoff, D.O., 80 Fed. Reg. 29067, 29070 n.9 (Drug Enf't Admin. May 20, 2015).

619. *JM Pharmacy Grp., Inc.*, 80 Fed. Reg. 28667, 28667 n.2 (Drug Enf't Admin. May 19, 2015).

620. Administrative Procedure Act, 5 U.S.C. § 557(b) (2012) ("On appeal from or review of the initial decision, the agency has all the powers which it would have had in making the initial decision *except as it may limit the issues on notice or by rule.*") (emphasis added); 21 C.F.R. § 1316.52, 67 (2017)) (regarding the respective duties of the ALJ and the Administrator as limited by Agency regulations).

621. See, e.g., Syed Jawed Akhtar-Zaidi, M.D., 80 Fed. Reg. 42962, 42962 n.2 (Drug Enf't Admin. July 20, 2015) (criticising the ALJ including the pointed observation that "every Administrator and Deputy Administrator who has exercised [Agency authority] has rejected the ALJ's view"); *Farmacia Yani*, 80 Fed. Reg. 29053, 29063 (Drug Enf't Admin. May 20, 2015) (stinging in an Agency final order that the correct legal analysis was "[c]ontrary to the ALJ's understanding"); *Moore Clinical Trials, L.L.C.*, 79 Fed. Reg. 40145, 40157, 40155 (Drug Enf't Admin. July 11, 2014) (stating that "[n]ot only is the ALJ's reasoning counterfactual, it reflects a stunning misunderstanding of the [Controlled Substances Act]," and, while addressing another portion of the ALJ's analysis, stating "I reject the ALJ'S rumination as totally irrelevant"); *Clair L. Pettinger, M.D.*, 78 Fed. Reg. 61591, 61596-61600 (Drug Enf't Admin. Oct. 3, 2013) (reasoning by ALJ dismissed as "illogical," that the correct legal analysis was "[c]ontrary to the ALJ's understanding," and that "in future cases [the ALJ] should rest assured" that the Agency's legal analysis is the correct one); *T.J. McNichol, M.D.*, 77 Fed. Reg. 57133, 57144-49 (Drug Enf't Admin. Sept. 17, 2012) (excoriating ALJ throughout the Agency final order for legal and factual analysis, with characterizations such as "reflects a stunning disregard for Federal law," "[c]ontrary to the ALJ's ludicrous suggestion," "absurd," "ignor[ing] numerous decisions of both federal and state courts in criminal cases," and other phrases evincing disdain for the ALJ's ability and judgment), *aff'd*, *T.J. McNichol v. DEA*, No. 12-15292, slip op. at 3 (11th Cir. Oct. 17, 2013); *Grider Drug #1 & Grider Drug #2*, 77 Fed. Reg. 44070, 44070, 44082 n.40 (Drug Enf't Admin. July 26, 2012) (mocking openly, in Agency's final order, ALJ by equating the proceedings conducted by the ALJ to a portion of "Justice Douglas's dissenting opinion in *Sierra Club v. Morton*" wherein he analyzed whether a tree or other inanimate object should be accorded legal standing in

decision, recently reminded its ALJs that “[o]nce the [A]gency has ruled on a given matter[,] it is not open to reargument by the [ALJ].”<sup>622</sup> The effect on the level of decisional accuracy or fairness resulting from chastising independent Agency ALJs is not altogether clear, and neither is the purpose for doing so in published decisions readily apparent. The extent to which a federal agency head differs in legal analysis from one of the agency’s ALJs seemingly presents as a concept capable of dispassionate expression without gratuitous vitriol. Further, an analysis included by an ALJ that differs in some respect from prior final orders could prove to be more legally correct, and could persuade the current or future DEA Administrators to engage a legal issue in a different light. This is particularly so in the recommended decision structure of the APA<sup>623</sup> that is utilized by the Agency in its decisional structure.<sup>624</sup> It is hardly hyperbole to observe that the fostering of an environment where the Agency’s final orders communicate hostility towards recommendations not to its liking by its own ALJs does not further the purposes of Congress in creating a recommended decisional structure. The obvious concern in the gratuitous chastisement of ALJs by their employing agency is that intemperate language set forth in published Agency final orders risks the perception that the Agency is seeking an improper means to impact future hearing decisions.

In fact, in *Superior Pharmacy I & Superior Pharmacy II*, the Agency was forced to address the respondent’s contention that the Agency’s “public scolding” of the assigned ALJ in a prior case caused the ALJ to have a general bias against respondents.<sup>625</sup> The Agency did not deny the fact or severity of its prior reprobation aimed at the ALJ in that case, but dismissed the assignment of error based on the “extensive protections provided to ALJs under federal law to ensure their decisional independence, including that they are not subject to

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court proceedings, declared that “the ALJ’s sole function is to make findings that are relevant and material to the allegations raised by the Government,” and accused the ALJ of “fail[ing] to exercise anything more than minimal control over the parties’ respective presentations”); Randall L. Wolff, M.D., 77 Fed. Reg. 5106, 5112 n.15 (Drug Enf’t Admin. Feb. 1, 2012) (dismissing ALJ’s legal analysis as a “rumination”); George Mathew, M.D., 75 Fed. Reg. 66138, 66140 (Drug Enf’t Admin. Oct. 27, 2010) (accusing ALJ of “ignor[ing] extensive Agency precedent,” and dismissed her legal analysis, stating that the correct legal analysis is “[c]ontrary to the ALJ’s understanding”); East Main Street Pharmacy, 75 Fed. Reg. 66149, 66150 n.2 (Drug Enf’t Admin. Oct. 27, 2010) (dismissing ALJ’s analysis as “reflect[ing] a clear misunderstanding of her role,” and characterized her procedural ruling and case time management as “disturbing”); Jeri Hassman, M.D., 75 Fed. Reg. 8194, 8235 (Drug Enf’t Admin. Feb. 23, 2010) (dismissing ALJ’s legal analysis as “erroneous”). These examples, which are not intended to constitute an exhaustive list, involve the work of multiple ALJs.

622. *Pettinger*, 78 Fed. Reg. at 61600 n.13 (internal punctuation omitted).

623. 5 U.S.C. § 557(b).

624. 21 U.S.C. § 824(c) (2012); 21 C.F.R. § 1316.65(a).

625. *Superior Pharmacy I & Superior Pharmacy II*, 81 Fed. Reg. 31310, 31339 n.66 (Drug Enf’t Admin. May 18, 2016).

performance appraisals,[ ]their pay is set . . . independent of any evaluation by the Agency,[ ]and they are subject to discipline only upon a showing of good cause by the MSPB.”<sup>626</sup> The arguably dismissive attention devoted to this issue by the Agency misses the point that, although ALJs are endowed with statutory protections and their own personal integrity, subjecting impartial Agency judges to gratuitous personal criticism in decisions published in the Federal Register risks eroding the confidence that the public places in the fairness of adjudications by the Agency under the APA. In conjunction with the more recent practice of the Agency revisiting all of the evidence and making findings without regard to the findings of the ALJ, such practice conveys the message (accurate or not) that the underlying purpose could be to bully the ALJs into issuing recommended decisions more in line with the wishes of the Agency and its Administrator.

## 2. Summary Disposition Without Motion or ALJ Recommendation

It has long been the practice of the Agency, even in the face of a timely hearing request, to grant its prosecutors summary disposition against a respondent where the Government has alleged that the respondent does not possess the state authority required to issue or maintain a DEA registration.<sup>627</sup> This practice, while authorized nowhere in statute or regulation, is ostensibly founded in the notion that the CSA authorizes the Agency to issue registrations to “practitioners,” and that by definition under the CSA,<sup>628</sup> a practitioner must possess authority under state law to handle controlled substances.<sup>629</sup> Although in the revocation section of the CSA, Congress provided that the abridgement of state authority is a discretionary basis for sanction,<sup>630</sup> the Agency has taken the position that its view of the other provisions essentially renders the discretionary revocation provisions related to state authority as meaningless surplusage.<sup>631</sup>

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626. *Id.* (citations omitted).

627. *See, e.g.*, Emmanuel O. Nwaokocha, M.D., 82 Fed. Reg. 26516, 26518 (Drug Enf’t Admin. June 7, 2017); Frederick Marsh Blanton, M.D., 43 Fed. Reg. 27616, 27617 (Drug Enf’t Admin. June 26, 1978).

628. 21 U.S.C. § 802(21).

629. James L. Hooper, M.D., 76 Fed. Reg. 71371, 71372 (Drug Enf’t Admin. Nov. 17, 2011), *pet. for rev. denied*, Hooper v. Holder, 481 F. App’x 826, 828 (4th Cir. 2012).

630. 21 U.S.C. § 824(a)(3).

631. Rezik A. Saqer, M.D., 81 Fed. Reg. 22122, 22126 (Drug Enf’t Admin. Apr. 14, 2016) (stating that “[i]t is not clear . . . why using the word ‘shall’ rather than ‘may’ would make any difference, as [21 U.S.C. §] 824(a) grants the Agency authority to either revoke or suspend,” thus essentially holding that it was free to use its discretion to revoke in every case—without any exercise of discretion).

While summary disposition has been used historically by the Agency's prosecutors, the Agency recently confirmed in *Phong Tran, M.D.* that summary disposition is also available to respondents.<sup>632</sup> In that case, the Agency alleged that the respondent lacked the state authority to handle controlled substances required to maintain his multiple certificates of registration in the state of California.<sup>633</sup> Specifically, the Government alleged that, in response to state criminal charges relating to unlawful billing which had been levied against the registrant, the Medical Board of California petitioned the court handling the criminal charges for an order suspending the registrant's state medical license during the pendency of the criminal proceedings, and the court imposed a condition of bail which prohibited the registrant from practicing medicine during the pendency of his criminal matter.<sup>634</sup> The Government filed for summary disposition, but the motion was denied because the prohibition on practice was uncontrovertibly a condition of bail release, not a suspension or encumbrance of the medical license itself.<sup>635</sup> In other words, the ALJ concluded that "[the] [r]espondent (albeit at the peril of his release conditions) maintains the state authority requisite to retain his DEA registrations," despite the Government's argument to the contrary.<sup>636</sup> After the Government's motion was denied, the respondent was granted leave to file, and did file, a motion for summary disposition of his own, which was granted by the ALJ.<sup>637</sup> In its final decision, the Agency likewise concluded that the registrant's state medical license was neither suspended nor revoked.<sup>638</sup>

While the Agency's confirmation of the availability of summary disposition to respondents seemed to somewhat balance the playing field for respondents, in the case of *Richard J. Blackburn, D.O.*, the Agency took an even more aggressive stance regarding its ability to find facts without a due process hearing despite a timely request for such a hearing.<sup>639</sup> In response to a doctor's registration application, DEA prosecutors filed an OSC alleging that he lacked

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632. *Phong Tran, M.D.*, 82 Fed. Reg. 31070 (Drug Enf't Admin. July 5, 2017).

633. *Id.*

634. *Id.*

635. *Id.* at 31074.

636. *Id.* at 31071 (internal punctuation and quotation marks omitted).

637. *Id.* at 31072.

638. *Id.* The Agency declined to adopt the decision of the ALJ, *id.* at 31072 n.10, instead issuing its own decision with different analysis. The Agency's decision that the registrant maintained the requisite state authority despite the bail condition prohibiting practice was based, in part, on the Government's concession in its opposition to the respondent's motion for summary disposition that the respondent maintained such authority. *Id.* at 31075.

639. *Richard Jay Blackburn, D.O.*, 82 Fed. Reg. 18669, 18669 (Drug Enf't Admin. Apr. 20, 2017).

the requisite state authority and that he had made a materially false statement.<sup>640</sup> The respondent timely requested a hearing on both counts.<sup>641</sup> The ALJ granted a summary disposition motion filed by the Government regarding lack of state authority, but, finding the state authority issue case dispositive, declined to decide the issue of the material false statement allegation and forwarded the case to the Administrator for a final order.<sup>642</sup> Notwithstanding the fact that the Government never made a summary disposition motion regarding the material false statement allegation before the ALJ,<sup>643</sup> and the fact that the ALJ declined to make findings or recommendations on that allegation, the Agency sustained both the lack of state authority and material false statement allegations.<sup>644</sup> In support of its factual determinations, the Agency cited “attachments” filed by the Government in its no-state-authority motion, and referred to the material in the “attachments” as “reliable and probative evidence.”<sup>645</sup>

The ALJ assigned to hear the case had determined that the respondent had raised a triable issue of fact by asserting that any irregularities were mistakes, and not intentional false statements.<sup>646</sup> The Agency dismissed the ALJ’s determination, considered the “attachments” filed by the Government as evidence in support of its no-state-authority summary disposition motion on the issue of material false statement, and found against the respondent without conducting the hearing he had requested.<sup>647</sup> Although the Agency acknowledged that, in ruling upon summary judgment motions, “the usual rule is that all doubts are resolved against the moving party,”<sup>648</sup> it was unfettered by that convention in *Blackburn*.<sup>649</sup> Even though there was *not even a motion filed for summary disposition of the material falsification allegation*, the Agency

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640. *Id.*

641. *Id.*

642. *Id.* at 18670.

643. The Government styled its request for relief before the ALJ as a “Motion for Partial Summary Disposition,” and sought merely to press its right to prove up the material false statement charge at a contested hearing. *Id.* at 18669. It was not until it filed exceptions to the ALJ’s refusal to grant a hearing on the material false statement charge that the Government broadened the scope of relief to include both a remand for the hearing it had requested before the ALJ or a ruling in its favor as a matter of law. *Id.* The Agency found that this portion of the Government’s exceptions constituted sufficient notice to the respondent of the summary disposition issue and ruled in the Government’s favor. *Id.* at 18673 n.6.

644. *Id.* at 18673.

645. *Id.* at 18672–73. One of the “attachments” relied upon by the Agency was actually a printout from a state medical board webpage. *Id.* at 18670.

646. *Id.* at 18672.

647. *Id.*

648. *Id.* at 18673 n.7.

649. *Id.* at 18673 n.6.

reasoned that summary disposition on the material falsification issue was appropriate because the respondent did not “offer counter-affidavits or other evidentiary material supporting the opposing contention that an issue of fact remains, [and did not] show a good reason why he [was] unable to present facts justifying opposition to the motion.”<sup>650</sup> Thus, the respondent and his counsel were unable to challenge any of the evidence offered against him, despite having timely requested an evidentiary hearing.<sup>651</sup>

Even more concerning than the Agency’s troublesome reliance on “attachments,” is language in numerous final orders placing conclusive factual reliance on something even less. In several cases, the Agency found a hearing waiver based exclusively on the representations by the Government that no hearing request had been filed.<sup>652</sup>

The Agency’s decision to embrace a more robust view of its ability to find facts without a hearing, like its increasing inclination to disregard the factual and legal findings of its ALJs, may significantly impact the manner in which both sides litigate administrative enforcement cases before the Agency in the future. All parties will need to consider whether *Blackburn* stands for the proposition that, by merely “attaching” any manner of documents to charging documents, requests for hearing, or motions, evidentiary challenges as to reliability, authenticity, or other objections available at a contested hearing, can be avoided. Further, on this current trajectory, if the Agency is willing to find a hearing waiver based on no more than a “Government[] representation,”<sup>653</sup> it will be interesting to see if a more robust level of representations are permitted to play a larger role in the Agency’s factfinding. The registrants’ bar in particular will now need to consider whether a request for hearing under the regulations could potentially result in summary disposition of the matter on grounds other than lack of state authority, even in cases where the Government has not made a motion for summary disposition on such other allegations.

#### IV. GOING FORWARD

It would be difficult to conceive of a world where diversion law would be in a greater state of flux. The various components that have acted (Congress, the Agency, and the diversion bar) have not acted as experience might have predicted. In the face of expressed concern at rising opioid addiction and death,

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650. *Id.* at 18673 n.7 (internal punctuation omitted).

651. *Id.* at 18672, 18673 n.7.

652. Gentry Reeves Dunlop, M.D., 82 Fed. Reg. 8432, 8432 (Drug Enf’t Admin. Jan. 25, 2017); Lee B. Drake, M.D., 82 Fed. Reg. 11057, 11057 (Drug Enf’t Admin. Feb. 17, 2017); John Warren Cox, M.D., 82 Fed. Reg. 29329, 29329 (Drug Enf’t Admin. June 28, 2017).

653. *Cox*, 82 Fed. Reg. at 29329.



Congress has imbued the regulated community with the right to submit CAPs, and imposed upon the Agency the duty to consider those plans.<sup>654</sup> Regarding manufacturers and distributor registrants—but, notably, not practitioner registrants—Congress has surgically pared back the evidence that may be considered by the Agency in Public Interest Factor Five by narrowly redefining “factors as may be relevant to and consistent with the public health and safety,”<sup>655</sup> and created a definition of “immediate danger to the public health and safety”<sup>656</sup> in a manner that renders Agency utilization of an immediate suspension order against those types of registrants all but impossible to defend in the federal courts. Whatever the relative merits of the Ensuring Patient Access and Effective Drug Enforcement Act of 2016, there is little that can be distilled from the legislation that either ensures patients enhanced access to controlled medication or makes drug enforcement more effective. Access to medication will likely remain largely unimpeded by federal enforcement efforts, and law enforcement efforts aimed at curbing diversion may actually be hampered by the loss of the DEA’s authority to effectively utilize immediate suspension orders in cases involving manufacturers and distributors. Further, if the Agency elects to delay proceedings while it adjudicates corrective action plans submitted by respondents in administrative proceedings, the process of enforcing anything could be substantially elongated.

The Agency’s approach has also evolved in a manner that arguably ran contrary to what many may have expected, and it has seemingly attempted to effect change through a robust utilization of adjudication in place of rulemaking. While some news accounts have reported that the Agency’s administrative enforcement levels have decreased,<sup>657</sup> as discussed throughout this article, it also appears that the notice and burden standards it places on its own prosecutors may have increased. That said, once a case has been filed and reaches the final order stage, the Agency has not been shy about holding the respondents to strict procedural rules, and in the last few years, has rarely ruled against the sanctions sought by its regulators.<sup>658</sup> It could be persuasively argued

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654. See *supra* Part II.A.

655. See *supra* Part II.C.

656. See *supra* Part II.B.

657. See, e.g., Bernstein & Higham, *supra* note 3, at A1; THE POST’S VIEW, *supra* note 3.

658. Of the twenty-eight final orders issued in 2016, all but three resulted in the respondent’s application being denied or registration being revoked, and the other three were hardly positive for the applicant/registrants. In one case, the registration at issue had expired and thus no decision was made on whether the Agency could have revoked based on the facts. *Turning Tide, Inc.*, 81 Fed. Reg. 47411 (Drug Enf’t Admin. July 21, 2016). In the other two non-revocation/denial cases, the Agency restricted the respondents’ licenses to certain schedules because the relevant state authority had so restricted those respondents’ state licenses. *Ibem R. Borges, M.D.*, 81 Fed. Reg. 23521 (Drug Enf’t Admin. Apr. 21, 2016); *Abolghasem Rezaei, M.D.*, 81 Fed. Reg. 25425 (Drug Enf’t Admin. Apr. 28, 2016). In both

that the Agency's aggressive expansion of the reach of its adjudications may have extended to a level far beyond the legal or practical limits of that tool. Agency final orders have more aggressively utilized official notice, summary disposition, and litigation by consent, and have arguably demonstrated a voracious appetite for supplanting the facts and law recommended by its impartial ALJs with the Agency's own facts and law based on its review of the record.<sup>659</sup> The Agency has even experimented with conducting contested proceedings outside the reach of its ALJs during the preparation of its final orders.<sup>660</sup> Left on its current trajectory of robust dependence on final orders over formal APA rulemaking, the future could produce continued struggles with consistency, temperance, and clarity in the guidance the Agency transmits to the practicing bar and the regulated community.

The diversion bar has likewise responded in a surprising fashion. In the face of arguably expansive Agency adjudications, one may argue that the registrants' bar has collectively exhibited an almost sheepish complicity in its pursuit of redress in the courts.<sup>661</sup> Likewise, Government counsel has not

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of those cases, the Agency took note that, had allegations been made other than lack of state authority, the Government would have made a *prima facie* case for full revocation. *Rezaei*, 81 Fed. Reg. at 25426 n.2 (finding that the facts "clearly would have supported a *prima facie* case for revocation under the public interest standard"); *Borges*, 81 Fed. Reg. at 23523 ("The conduct . . . could serve as the basis for a request for total revocation based on public interest grounds . . . [or] conviction of a felony related to controlled substances.")). In 2015, thirty-seven cases were published, and only ten of those did not result in denial of an application or revocation of a registration. Two cases were dismissed because the applications were withdrawn. *Chung-Kuang Chen*, M.D., 80 Fed. Reg. 57020 (Drug Enf't Admin. Sept. 21, 2015); *Matthew Valentine/Liar Catchers*, 80 Fed. Reg. 50042 (Drug Enf't Admin. Aug. 18, 2015). One application was granted pursuant to an earlier order setting forth conditions the applicant had to meet in order to be granted a registration. *Abbas E. Sina*, M.D., 80 Fed. Reg. 53191 (Drug Enf't Admin. Sept. 2, 2015). Two cases were dismissed because the respondents' registrations expired and they filed no renewal application or new application. *Victor B. Williams*, M.D., 80 Fed. Reg. 50029 (Drug Enf't Admin. Aug. 18, 2015); *AIM Pharmacy & Surgical S. Corp.*, 80 Fed. Reg. 46326 (Drug Enf't Admin. Aug. 4, 2015). Two cases were dismissed because the respondents regained state authority, lack of which was the only allegation in those cases. *Nicholas Nardacci*, M.D., 80 Fed. Reg. 50032 (Drug Enf't Admin. Aug. 18, 2015); *Jeffrey S. Holverson*, M.D., 80 Fed. Reg. 50033 (Drug Enf't Admin. Aug. 18, 2015). Two applications for registration were granted with conditions and an initial suspension. *Odette L. Campbell*, M.D., 80 Fed. Reg. 41062 (Drug Enf't Admin. July 14, 2015); *Trenton F. Horst*, D.O., 80 Fed. Reg. 41079 (Drug Enf't Admin. July 14, 2015). One application case was held in abeyance and the Agency ordered that the application be granted or denied based on certain conditions. *Farmacia Yani*, 80 Fed. Reg. 29053 (Drug Enf't Admin. May 20, 2015).

659. See *supra* Part III.G–M.

660. See *supra* Part III.L.4.

661. Since 2015, only five cases (six, if *Superior I & II* are counted separately) have been appealed to a federal court of appeals. Of those, two remain pending as of the date of this article: *Peter F. Kelly*, D.P.M., No. 17-1175 (D.C. Cir.); *Jones Total Health Care Pharmacy L.L.C.*, No. 16-17346 (11th Cir.); three were dismissed because the petitions for review were withdrawn: *Stipulation of Dismissal, Superior Pharmacy I & Superior Pharmacy II v. DEA*, No. 16-1167 (D.C. Cir.), ECF No.

sought adjustments to edicts announced in final orders that run contrary to or otherwise cause detriment to their litigation positions, and sometimes even their sense of fairness. Mark Twain once famously quoted his close friend, Charles Dudley Warner, in observing that “Everyone complains about the weather, but nobody does anything about it.”<sup>662</sup> Changes in diversion practice have been largely treated by the practicing bar with a similar sense of fatalistic inevitability.

The many changes recently inflicted on diversion litigation present like dangerous rocks hidden beneath the surface of shallow, murky, drug-infested waters. Like ship captains negotiating uncharted, shallow waters, litigators on both sides of the aisle would be wise to navigate slowly and cautiously based on a study of what we know so far. That said, there are no guarantees that those with legislating and adjudicating authority will not be adding more perilous boulders beneath the waterline, and faulting the helmsmen for failing to deduce their existence and location prior to impact.

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1636080; Stipulation of Dismissal, *Hills Pharmacy v. DEA*, No. 16-1295 (D.C. Cir.), ECF No. 1636081; and one petition was denied in a published *per curiam* order, *Syed Jawed Akhtar-Zaidi v. DEA*, 841 F.3d 707 (6th Cir. 2016). Of those cases that were pending at the federal courts in 2015, one was affirmed and four petitions were denied. Memorandum On Petition for Review of a Final Order of the Drug Enf’t Admin. at 3; *Fred Samimi, M.D., DEA*, No.14-71315 (9th Cir. 2017); On Petition for Review of an Order of the Drug Enf’t Admin. at 6, *Michael A. White, M.D. v. DEA*, No. 14-60832 (5th Cir. 2015); Memorandum On Petition for Review of an Order of the Drug Enf’t Admin. at 4, *David A. Ruben, M.D. v. DEA*, No. 13-72577 (9th Cir. 2015); On Petition for Review of a Final Order of the Drug Enf’t Admin., *The Medicine Shoppe v. Loretta E. Lynch*, No. 14-1223 (D.C. Cir. 2015); On Petition for Review of a Final Order of the Drug Enf’t Admin. at 38, *Masters Pharmaceutical Inc. v. DEA*, No. 15-1335 (D.C. Cir. 2017).

662. Tim Chuey, *Everyone Complains About The Weather, But Nobody Does Anything About It*, EUGENE DAILY NEWS (Apr. 3, 2016), <http://eugenedailynews.com/2016/04/everyone-complains-weather-nobody-anything/>.