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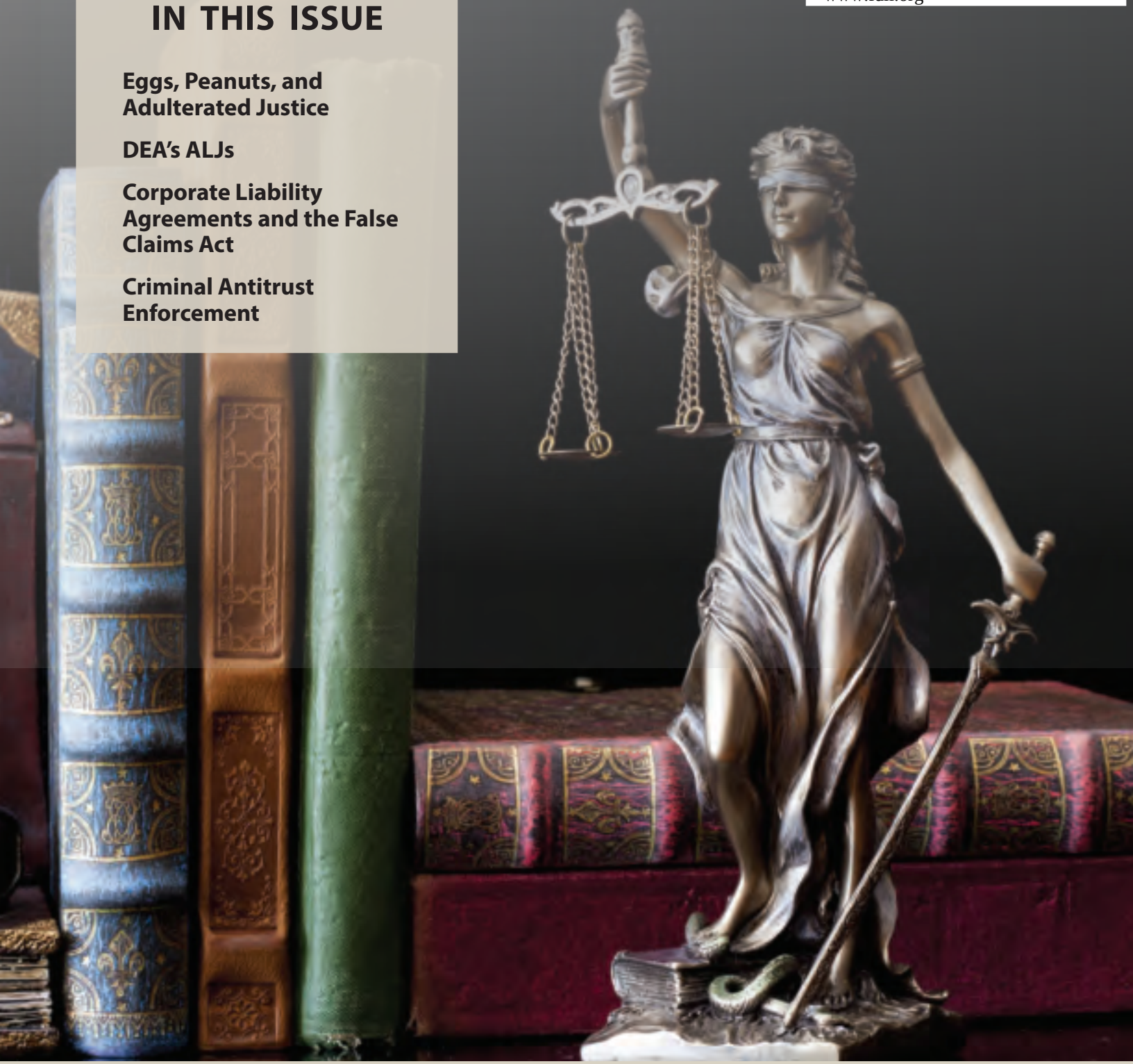

A Matter of Substantial Discretion: A Recent Rift between DEA and Its ALJs Could Significantly Impact Registrants

By John A. Gilbert, Jr. and Andrew J. Hull

The federal Controlled Substances Act (CSA) and regulations promulgated by the Drug Enforcement Administration (DEA) provide for the adjudication of administrative actions involving entities registered to handle controlled substances. DEA annually adjudicates dozens of matters, the majority of which involve determining whether a party should be authorized to obtain or maintain a DEA registration for the handling of controlled substances.[1] The majority of DEA registrants are practitioners, such as physicians and pharmacies, but DEA also registers importers, exporters, manufacturers, wholesalers, hospitals, and veterinarians. When DEA, operating under its authority to enforce the CSA, proposes either to deny an application for registration or to revoke an existing registration, it must issue an Order to Show Cause (OSC), stating the factual allegations and legal basis supporting denial or revocation. The applicant or registrant then has a chance to respond to the proposed action, including the opportunity to request an administrative hearing on the merits.[2]

If the entity requests a hearing, the matter is brought before the DEA's Office of Administrative Law Judges (OALJ). An Administrative Law Judge (ALJ) is then assigned to conduct an administrative hearing. The ALJ will issue a Recommended Ruling and Findings of Fact and Conclusions of Law ("recommended decision"), which is transmitted to the DEA Administrator[3] who will issue a final order in the matter.

The ALJs have traditionally asserted in these recommended decisions that their findings and rulings are entitled to significant or substantial deference when the Administrator reviews their decisions and issues final orders. Registrants requesting hearings have been on notice of this fact. However, within the last year, several DEA final orders have expressed a distinct disagreement with the ALJs on the level of deference to be afforded the ALJ's recommended decision. Although this rift has been gradual and only noted in footnotes of final orders, it appears that the DEA Administrator may have modified his position in regard to whether the ALJs' opinions and rulings are entitled to significant or substantial deference when the agency issues a final order.

This article summarizes the significance of this disagreement, as well as the administrative law principles involved. Most importantly, it evaluates the potential impact the agency's evolving view of its own fact finding powers may have on a DEA registrant's decision to pursue administrative hearings.

DEA Recommended Decision Structure

For agency adjudication, the Administrative Procedure Act (APA) establishes an *initial decision* structure and a *recommended decision* structure.[4] Under an *initial decision* structure, an ALJ presides over a hearing and then issues a decision on the merits that becomes the decision of the

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agency unless it is appealed.[5] Appealed decisions are then heard by the agency head or an appointed board. The Food and Drug Administration (FDA) utilizes an initial decision structure when adjudicating the collection of civil penalties, with appeals directed to the Departmental Appeals Board.[6] Most Social Security disability hearings follow the same structure.[7]

Alternatively, a *recommended decision* structure is one in which the ALJ issues a decision providing a recommendation to the agency on how to rule in the matter.[8] While the ALJ still presides over a hearing on the merits, the ALJ must certify the "recommended" decision and record to the agency. The agency head or appointee must then review the ALJ's recommended decision, as well as the entire record, and issue a final decision of the agency. In essence, the final order either adopts, modifies, or rejects the ALJ's decision.

DEA follows the recommended decision structure. When a respondent requests a hearing on the merits of the allegations contained in an OSC, the matter is assigned to the DEA OALJ. The DEA is represented in the matter by staff attorneys from the DEA's Office of Chief Counsel. The DEA ALJs are vested with authority to conduct prehearing and hearing procedures,[9] and the ALJ maintains effective and independent jurisdiction over the matter until a recommended decision is issued or the matter is otherwise resolved, e.g., settlement, withdrawal of a hearing request, or termination for lack of jurisdiction. DEA ALJs have the power to, among other things, set the time and date of hearings, hold prehearing conferences, issue subpoenas, examine witnesses, and receive, rule on, exclude, or limit evidence.[10] DEA attorneys, representing the agency, have the burden of proof to present evidence demonstrating why an application should be denied or a registration revoked. A respondent requesting a hearing may choose to rebut DEA's case or to put on a case demonstrating acceptance of responsibility and corrective actions.

After the hearing, which resembles a federal bench trial, the ALJ will allow the parties an opportunity to submit post-hearing briefs. The ALJ will then issue a recommended decision. Each party will have the opportunity to file exceptions to the ALJ recommended decision. The ALJ will then transmit to the DEA Administrator the entire administrative record, including the recommended decision, transcript, documentary evidence, post-hearing briefs, and any exceptions to the ALJ's recommended decision. The Administrator's final order may adopt, modify, or reject the ALJ's decision, and the Respondent may appeal the Administrator's decision to either the U.S. Court of Appeals for the D.C. Circuit or the U.S. Court of Appeals for the circuit in which the Respondent's principal place of business is located.[11]

Traditional DEA Deference to ALJ Recommended Decisions

A review of DEA final orders issued in recent years shows that DEA has typically afforded the recommended decisions of its ALJs a significant amount of deference. Rather than reject an ALJ's recommended decision, the agency typically will adopt or slightly modify the recommended decision absent a clear distortion of agency precedent or gross misinterpretation of the facts in the record. This is reasonable given that the ALJs are the adjudicators best able to examine and determine the credibility of the evidence and are most knowledgeable of the facts of the case. In recent years, the ALJs have demonstrably asserted in their recommended decisions that their rulings and opinions are entitled to "significant deference" by the agency.[12] Although the ALJs recognize that the agency is still the ultimate factfinder in all matters, these recommended decisions stress the importance of their role in the adjudicatory process as the factfinders most enmeshed with the facts of the case and of the significant amount of deference that the agency should attribute to their findings.

The significant deference standard asserted by DEA's ALJs is supported by a line of agency precedent. The agency itself has not only adopted and published recommended decisions setting forth this standard,[13] but it has also stressed the importance of and its adherence to this standard on multiple occasions. For example, in the matter of *Dewey C. Mackay, M.D.*, the agency held that, based on the ALJ having personally observed the testimony of a witness, the ALJ's findings were "entitled to *substantial deference*."[14] For the same reasons, the agency held that the ALJ's findings of fact in the matter of *Michael S. Moore, M.D.*, were entitled to "substantial deference."[15] Other DEA final orders have expressed a similar acceptance of this standard.[16]

Universal Camera and ALJ Deference

Until recently, DEA has adhered to the traditional substantial or significant deference standard rooted

in *Universal Camera Corp. v. N.L.R.B.* In that seminal administrative procedure case from 1951, the Supreme Court examined whether an agency's decision was supported by substantial evidence, as required by the APA, when the agency arrived at a different conclusion than the one issued in the initial decision of its ALJ (referred to in the decision as the hearing examiner).[17] The Court held that the substantiality of evidence in an agency decision rests on consideration of the "whole record," including evidence that detracts from the agency's conclusions.[18] Because the agency is the ultimate factfinder, however, the mere fact that its decision differs from that of an ALJ is not enough for a reviewing court to overturn a decision. Instead, the agency is free to reject the findings of its ALJs.

Despite finding for the agency in *Universal Camera*, the Court still stressed the importance of ALJs and the deference that agencies should give to their decisions. While disagreement between an agency and its ALJ does not leave an agency decision devoid of substantial evidence, the Court held that "evidence supporting a conclusion may be less substantial when an impartial, experienced [ALJ] who has observed the witnesses and lived with the case has drawn conclusions different from the [agency's] than when he has reached the same conclusion."[19] The Court noted, however, that the significance of the ALJ's decision "depends largely on the importance of credibility in the particular case."[20]

This standard—that evidence supporting an agency decision may be less substantial if an ALJ reached a differing conclusion based on the ALJ's observation of witnesses and "living" with the case—has become an established and recognized rule in administrative law.[21] The Court reaffirmed this standard a few years later in *F.C.C. v. Allentown Broadcasting Corp.*[22] DEA and its ALJs, while recognizing that the agency is the ultimate factfinder, have referenced *Universal Camera* in the numerous decisions regarding DEA deference to its ALJs.

Evidence of a Change in DEA's Position on the ALJ Discretion Standard

The first signs of a possible disagreement between DEA and its ALJs on the issue of whether ALJ decisions are entitled to significant deference appeared in October 2014. In the matter of *Michael A. White, M.D.*, DEA, while agreeing with the ALJ's recommendation to deny the respondent's application, declined to publish the ALJ's discussion of the substantial evidence standard, stating that it "suffice[d] to say that . . . [DEA] adheres to the principles set forth in [*Universal Camera*]."[23] The agency, however, did not explain its reasons for deciding not to publish the ALJ's purported statement and whether there was in fact a difference between the ALJ's interpretation of the standard and the "principles" contained in *Universal Camera*.

Since then, while the ALJs have continued to include statements interpreting the deference owed to ALJs, DEA has appeared to continue to reject the significant discretion standard, typically by refusing to publish an ALJ's discussion of this standard.[24] The most noticeable example of this rift can be found in the matter of *JM Pharmacy Group, Inc.*, decided several months ago, in which the agency took issue with the ALJ's observation (citing *Universal Camera*) that his factual findings were "entitled to significant deference."[25] The agency retorted (in a footnote): "To make clear, the Agency is the ultimate factfinder and considers an ALJ's factual findings 'along with the consistency and inherent probability of testimony. The significance of [the ALJ's] report, of course, depends largely on the importance of credibility in the particular case.'"[26] Once again, the Administrator failed to explain whether and to what extent this statement indicated a difference between the ALJ's significant deference standard and the agency's view of the appropriate standard.

As a result of these recent decisions, DEA's view of the requisite standard of deference owed to its ALJs' recommended decisions is unsettled and lacks clarity. However, it seems clear that the agency is questioning the standard previously asserted by the ALJs and, more significantly, used by the agency to defend prior final orders. In doing so, DEA has failed to explain why it has changed its view and what is the appropriate standard for reviewing ALJ rulings and recommendations.

Line-Item Redactions and the Arbitrary and Capricious Standard

A curious bit of history regarding DEA's treatment of ALJ recommended decisions shines an interesting light on this current disagreement between the agency and its ALJs. Until recently, DEA rarely published the recommended decision of one of its ALJs. Instead, the agency would publish a final order in the *Federal*

Register that summarized the factual findings from the administrative hearing and reached a conclusion.[27] In these cases, the reader was often left without key information about the evidence presented that would inform the basis for the agency's decision.

This changed in 2011 when the agency routinely started to publish, along with its final order, the ALJ's recommended decision. If the agency decided to adopt the recommended decision, it would provide as its final order specific findings with reference to the ALJ's recommended decision. Any minor disagreements with the ALJ's recommended factual findings or legal conclusions were typically contained in the final order's footnotes. This practice not only provided greater public insight into the rationale for the agency's decision making, but it also signaled a significant amount of reliance on and discretion to the ALJs as agency factfinders and to their ability to make rulings on evidentiary matters.

Recently, the Administrator, while still publishing recommended decisions that it adopts, has started to redact certain parts of those decisions, such as the portions discussing agency discretion to its ALJs' recommended decisions. For example, the agency may choose to adopt an ALJ's decision recommending revocation of a registrant's registration, but it may disagree with the ALJ's interpretation of a particular legal standard. Under this new practice, the agency appears to be simply refusing to publish that particular sentence or paragraph by cutting it from the original recommended decision.

While the agency is, of course, free to adopt and publish all, none, or part of a recommended decision in the public record (registrants always get entire copies of the original recommended decision), this practice may raise issues for the agency on appeal. In the 2005 case of *Morall v. Drug Enforcement Administration*, the D.C. Circuit held that DEA's decision to revoke a registration was arbitrary and capricious based, in part, on the agency's failure to consider "relevant contradictory evidence" that had led the ALJ to reach a contrary finding.[28] The court emphasized the significance of an ALJ's findings and that an "'agency's departures from the [ALJ's] findings are vulnerable if they fail to reflect attentive consideration to the [ALJ's] decision.'"[29] Thus, under *Morall*, it is essential for DEA to articulate not only *how* its final order is different from an ALJ's recommended decision, but also *why* it is different. Failure to do so will likely constitute an arbitrary and capricious decision that cannot withstand judicial scrutiny.

The agency's recent trend to redact certain portions of the recommended decisions, when coupled with a failure to explain the rationale for the agency's difference of opinion, raises the same arbitrary and capricious concerns discussed in *Morall*. Thus, DEA's current handling of the discretion standard applied to ALJ recommended decisions will likely attract judicial scrutiny. DEA seems to have announced a departure from the discretion standard asserted by its ALJs and pronounced in its own final orders. Yet it has neglected to clarify what the appropriate standard is, and it has failed to explain its rationale for departing from the traditional standard.

Impact on Registrants

The appropriate standard of discretion DEA will afford to its ALJs' decisions could significantly impact registrants. First, there is now a lack of certainty (that is unexplained by DEA) as to the level of discretion that will be applied to ALJ rulings and decisions. This information is critical for registrants who are deciding whether to request a hearing before an ALJ. Given the precedent established by DEA's recent decisions, a registrant who requests a hearing before an ALJ will not know the significance of the ALJ's factual findings and conclusions. For registrants seeking their "day in court" and hoping to persuade the factfinder of their position, this uncertainty is problematic.

Second, while DEA has always been recognized as the "ultimate factfinder," DEA's ALJs have served as the primary audience to whom agency counsel and registrants make their case. The less significance the agency gives to its ALJs' recommended decisions (the apparent trajectory), the more a registrant will have to consider whether an administrative hearing provides the best opportunity to make its case to obtain or continue a registration.

Instead of choosing to take on the expense of presenting a case before an ALJ, registrants may find that it is more advantageous to waive their opportunity for a hearing and, instead, submit a written statement to the agency pursuant to 21 C.F.R. § 1316.49. A written statement may contain the registrant's "position on the matters of fact and law" involved in the matter, and it goes directly to the agency, bypassing the ALJ.[30] While many registrants depend on the chance to present evidence at an oral

hearing before an ALJ, a registrant may reach the decision that, based on a lack of discretion given to an ALJ's recommended decision, it is more efficient and effective to submit its evidence and arguments in writing directly to the agency.

Third, DEA's position may affect the manner in which its ALJs perceive their role in the process; specifically, they have acted as fact-gatherers whose role is to create a complete administrative record. While the traditional rules of evidence do not strictly apply in administrative hearings, DEA's regulations restrict admissibility to evidence that is "competent, relevant, material and not unduly repetitious."[31] In recent years, ALJs, with the backing of the agency, have become more active in restricting evidence and have more heavily relied on the Federal Rules of Evidence for guidance.[32] This was a departure from prior decisions and DEA Final Orders in which the agency as a whole appeared to encourage "broader" evidentiary rulings so that the agency could choose the appropriate evidence in its final orders.[33] Under a system where the ALJ evidentiary and credibility rulings are not granted significant deference, the administrative hearing process could become more about building a record rather than persuading the agency.

Conclusion

The end result of this shifting dereference remains to be seen. However, the lack of clarity could adversely impact registrants attempting to make their case to obtain or maintain a DEA registration, which dramatically affects the registrants' livelihoods. The regulated community relies on clarity from the agency in order to comply with the CSA and its implementing regulations. Clarity is necessary in order to ensure due process in the face of agency administrative enforcement action. Given that DEA has established a hearing process intended to provide due process to registrants facing a loss of livelihood, it is incumbent on the agency to justify what appears to be a weakening of the ALJ authority.

1. Other matters that may be adjudicated through DEA's administrative process include drug scheduling, appeals of quota requests, and issues related to denial of import and export permits.
2. 21 C.F.R. § 1316.47.
3. The DEA Administrator has delegated this authority to the agency's Deputy Administrator. At the time of the writing of this article, however, the agency does not have a Deputy Administrator, and there is currently a new Acting Administrator who is reviewing the recommended decisions and issuing the final orders.
4. 5 U.S.C. § 557.
5. *See id.*
6. 21 C.F.R. §§ 17.45, 17.47.
7. 20 C.F.R. § 405.372.
8. *See* 5 U.S.C. § 557.
9. 21 C.F.R. § 1316.52.
10. *Id.*
11. For a more in-depth review of DEA administrative hearings, see 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).

12. *E.g.*, *Mark P. Koch, D.O.*, 79 Fed. Reg. 18,714, 18,731 (Drug Enforcement Admin. Apr. 3, 2014); *Top RX Pharmacy*, 78 Fed. Reg. 26,069, 26,080 (Drug Enforcement Admin. May 3, 2013); *Roni Dreszer, M.D.*, 76 Fed. Reg. 19,434, 19,444 (Drug Enforcement Admin. Apr. 7, 2011).
13. *See, e.g.*, *Koch*, 79 Fed. Reg. at 18,731; *Jeffrey M. Freesemann, M.D.* 76 Fed. Reg. 60,873, 60,886 (Drug Enforcement Admin. Sept. 30, 2011).
14. 75 Fed. Reg. 49,956, 49,963 (Drug Enforcement Admin. Aug. 16, 2010) (emphasis added).
15. 76 Fed. Reg. 45,867, 45,868 n.5 (Drug Enforcement Admin. Aug. 1, 2011).
16. *See Grider Drug #1 & Grider Drug #2*, 77 Fed. Reg. 44,070, 44,081 n.37 (Drug Enforcement Admin. July 26, 2012); *Linda Sue Cheek, M.D.*, 76 Fed. Reg. 66,972, 66,974 (Drug Enforcement Admin. Oct. 28, 2011) (citing *Mackay*).
17. 340 U.S. 474 (1951).
18. *Id.* at 488.
19. *Id.* at 496.
20. *Id.*
21. 2 RICHARD J. PIERCE, Jr., ADMINISTRATIVE LAW TREATISE 989-92 (5th ed. 2010).
22. 349 U.S. 358 (1955).
23. 79 Fed. Reg. 62,957, 62,957 n.2 (Drug Enforcement Admin. Oct. 21, 2014).
24. *See Trenton F. Horst, D.O.*, 80 Fed. Reg. 41,079, 41,079 n.2 (July 14, 2015); *Jana Marjenhoff, D.O.*, 80 Fed. Reg. 29,067, 29,070 n.9 (May 20, 2015).
25. 80 Fed. Reg. 28,667, 28,667 n.2 (Drug Enforcement Admin. May 19, 2015).
26. *Id.* (citing *Universal Camera*, 340 U.S. at 496).
27. *See, e.g.*, *William F. Skinner, M.D.*, 60 Fed. Reg. 62,887 (Drug Enforcement Admin. Dec. 7, 1995).
28. 412 F.3d 165, 180 (D.C. Cir. 2005).
29. *Id.* (quoting *Greater Boston Television Corp. v. FCC*, 444 F.2d 841, 853 (D.C. Cir. 1970)).
30. 21 C.F.R. § 1316.49.
31. *Id.* § 1316.59(a).
32. *See* Mulrooney & Hull, *supra* note 11, at 388-91.
33. *See, e.g.*, *Rosalind A. Cropper, M.D.*, 66 Fed. Reg. 41,040, 41,041 (Aug. 6, 2001).