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## THE DANGERS OF *DAUBERT* CREEP IN THE REGULATORY REALM

*Claire R. Kelly*\*

### INTRODUCTION

*Daubert v. Merrell Dow Pharmaceuticals, Inc.*<sup>1</sup> threatens to trigger an ambiguous paradigm shift in administrative law. In 1993, the Supreme Court decided *Daubert* and established judges as gatekeepers for expert testimony in both civil and criminal trials. The case has had enormous impact on the use of experts in litigation. Some have called for agencies and/or courts to adopt some form of “regulatory *Daubert*,” essentially requesting a standard to examine, test, or question evidence relied upon by federal agencies. *Daubert* proponents have offered various means to adopt this heightened scrutiny of agencies. Critics have explained why agencies should not be subjected to *Daubert* as a normative matter. My concern in this essay is the effect any form of regulatory *Daubert* could have on administrative law. There is a danger that *Daubert* can undermine administrative law by fostering an attitude of skepticism of agency action based upon science and creating a rhetorical weapon with which to attack agency policy-making.

Those who follow administrative law recall the power of paradigm shifts by referencing *Chevron U.S.A. v. Natural*

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\* Associate Professor of Law, Brooklyn Law School. I am grateful for the research assistance of Lynsey Heffernan Murphy (BLS '06) and William J. Leahey, III (BLS '07). This work was supported by a generous grant from the Brooklyn Law School Summer Research Stipend Program. I also would like to thank Margaret Berger, Neil Cohen, Dana Brakman Reiser, John J. Emslie and Heidi Kitrosser for their helpful comments and suggestions.

<sup>1</sup> 509 U.S. 579 (1993).

*Resources Defense Council, Inc.*<sup>2</sup> *Chevron* established that courts will defer to reasonable agency interpretations of its own organic statute where the statute is vague or ambiguous.<sup>3</sup> *Chevron* sought to improve administrative law functioning; although some may argue about whether its goals were desirable, its goals were administrative law goals. Agencies' relative specialization and political accountability, as compared to courts, supported the *Chevron* shift to a more deferential judicial framework. Nonetheless, *Chevron* was a somewhat murky standard that caused and continues to cause problems in administrative law. Sometimes known as the counter-*Marbury*, because it directs agencies to, under certain circumstances, "say what the law is,"<sup>4</sup> *Chevron* spawned issues regarding its applicability, its scope, and its application. *Chevron* also became a rhetorical tool, as it turned into a rallying cry of deference. The rhetorical effect of *Chevron* was perhaps unavoidable but nevertheless disruptive.

A *Daubert* shift threatens agency functioning and lacks *Chevron*'s administrative law agenda. As an enigmatic paradigm shift in the administrative law context, *Daubert* will likely engender many of the same problems associated with the *Chevron* shift, while also creating additional problems. A regulatory *Daubert* standard is even less clear than *Chevron*. Further, regulatory *Daubert* lacks the normative administrative law goal found in *Chevron*. *Chevron* sought to improve administrative law functioning. *Daubert* aims more at substantive law areas that rely upon science. This *Daubert* Trojan horse threatens sound administrative law doctrine by devolving into a rhetorical tool and a generic standard. To the extent that agency decision-making often blends factual and policy issues, regulatory *Daubert* will

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<sup>2</sup> 467 U.S. 837 (1984).

<sup>3</sup> *See id.* at 843.

<sup>4</sup> *Chevron* became known as the counter-*Marbury* because *Marbury v. Madison* stood for the proposition that it was the courts that were to "say what the law is" while *Chevron* empowered agencies to do so. Cass R. Sunstein, *Law & Administration After Chevron*, 90 COLUM. L. REV. 2071, 2074-75 (1990) (explaining *Chevron*'s relationship to *Marbury v. Madison*, 5 U.W. (1 Cranch) 137 (1803)).

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inevitably impede the policy function given to the agencies by *Chevron* and place it in the hands of the judiciary. In this regard, regulatory *Daubert* is the counter-*Chevron*.<sup>5</sup> There also seems to be little need for *Daubert* in the agency setting. Although no one would argue that agencies should use “junk science,” agencies already have the means and an obligation to avoid doing so.<sup>6</sup>

Part I of this essay briefly recounts the current debates over *Daubert* in both the civil and administrative contexts. These debates focus on *Daubert*'s normative appeal. Part II explains the means by which agencies might adopt or have thrust upon them some sort of *Daubert* criteria. These means include more vigorous review using already established administrative law doctrine, statutory directives requiring agencies to evaluate scientific or expert data more rigorously, wholesale adoption of a regulatory *Daubert* framework by agencies or courts, and judicial invocation of *Daubert* principles more generally.

Part III argues that any framework that extends beyond already established administrative law doctrine risks an unclear and unhelpful paradigm shift toward less deference and greater judicial scrutiny of both data and policy decisions by agencies, causing confusion and instability. Part III uses the *Chevron* doctrine as a model paradigmatic event in administrative law in order to illustrate the inherent difficulties in paradigm shifts. The *Chevron* shift, normatively aimed at improving administrative functioning, was unfortunately less than crystal clear and thus spawned thirty years of confusion and missteps. Although I would contend that *Chevron* ultimately benefited administrative functioning, I do not

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<sup>5</sup> The call for regulatory *Daubert* is essentially a call for courts to be less deferential to agency decisions. See Alan Charles Raul & Julie Zampa Dwyer, *Regulatory Daubert: A Proposal to Enhance Judicial Review of Agency Science by Incorporating Daubert Principles into Administrative Law*, 66 LAW & CONTEMP. PROBS. 7, 8 (2003). But see *id.* at 32 (explaining that “*Daubert* principles could easily and properly inform *Chevron* analysis without eliminating *Chevron* deference”).

<sup>6</sup> Wendy Wagner, *Importing Daubert to Administrative Agencies Through the Information Quality Act*, 12 J.L. & POL'Y 589, 591-94 (2004) (comparing agency expertise to that of courts) [hereinafter Wagner, *Importing Daubert*]. See Administrative Procedure Act, 5 U.S.C. §§ 556(d), 553(c), 706 (2000).

believe that a *Daubert* shift would hold the same promise. Adapting *Daubert* to the regulatory realm promises a standard even more unclear than *Chevron*. Regulatory *Daubert* is not aimed at administrative functioning but rather at substantive areas of administrative law that use and make policy decisions involving scientific evidence.

### I. THE *DAUBERT* DEBATES

*Daubert* established federal judges as gatekeepers, requiring them to evaluate proffered expert testimony and consider several factors before admitting it.<sup>7</sup> Assigning the role of gatekeeper to the judge changed how courts received and reviewed expert evidence. Previous courts generally deferred to expert communities.<sup>8</sup> *Daubert* mandated that the trial judge evaluate the evidence for herself based upon a non-exclusive list of factors.<sup>9</sup> *General Electric Co. v. Joiner*<sup>10</sup> followed *Daubert* and added that a trial judge's exclusion of evidence under *Daubert* would only be

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<sup>7</sup> *Daubert*, 509 U.S. at 592-94.

The specific factors explicated by the *Daubert* Court are (1) whether the expert's technique or theory can be or has been tested—that is, whether the expert's theory can be challenged in some objective sense, or whether it is instead simply a subjective, conclusory approach that cannot reasonably be assessed for reliability; (2) whether the technique or theory has been subject to peer review and publication; (3) the known or potential rate of error of the technique or theory when applied; (4) the existence and maintenance of standards and controls; and (5) whether the technique or theory has been generally accepted in the scientific community.

FED. R. EVID. 702 advisory committee's note (2000 amendment). *Daubert* shifted away from the *Frye* general acceptance standard where courts generally deferred to scientific communities. David G. Owen, *A Decade of Daubert*, 80 DENV. U. L. REV. 345, 372 (2002) (commenting that the change, on balance, "appears to make good sense").

<sup>8</sup> Margaret A. Berger, *What Has a Decade of Daubert Wrought?*, AMER. J. OF PUB. HEALTH, July 2005, at S60.

<sup>9</sup> *Daubert*, 509 U.S. at 592-94.

<sup>10</sup> 522 U.S. 136 (1997).

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reversed for abuse of discretion.<sup>11</sup> Subsequently, in *Weisgram v. Marley*,<sup>12</sup> the Supreme Court further indicated that since parties were on notice to present their best evidence in light of *Daubert*, appellate courts could enter a verdict against a party whose evidence was excluded by a *Daubert* challenge on appeal.<sup>13</sup>

*Daubert* generated significant commentary and debate.<sup>14</sup> Some have argued that courts' new gatekeeping role may distort the appropriate use of science in the court room.<sup>15</sup> For example, by testing each scientific assertion separately and excluding any evidence that does not conform to *Daubert*, courts may inappropriately exclude evidence that is probative when combined with other evidence.<sup>16</sup> Professor McGarity distinguished this new corpuscular approach from the weight-of-the-evidence approach:

The weight-of-the-evidence approach focuses upon the totality of the scientific information and asks whether a

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<sup>11</sup> *Id.* Subsequently, *Kumho Tire v. Carmichael*, 526 U.S. 137, 152 (1999), established that *Daubert* applied to all expert testimony, not just scientific testimony, and also reinforced the abuse of discretion standard.

<sup>12</sup> 528 U.S. 440 (2000).

<sup>13</sup> *Id.* at 455-56. *See also* FED. R. CIV. P. (50)(a)(1).

<sup>14</sup> Compare Thomas O. McGarity, *On the Prospect of "Daubertizing" Judicial Review of Risk Assessment*, 66 LAW & CONTEMP. PROBS. 155, 156 (2003) (noting that "assigning a *Daubert*-like gatekeeper role to courts engaged in judicial review of agency risk assessments is a profoundly bad idea") [hereinafter McGarity, "*Daubertizing*" *Judicial Review*], and Neil B. Cohen, *The Gatekeeping Role in Civil Litigation and the Abdication of Legal Values in Favor of Scientific Values*, 33 SETON HALL L. REV. 943, 963 (2003) (explaining how "*Daubert* gatekeeping" risks exclusion of relevant and helpful evidence in civil litigation), and Berger, *supra* note 8, at S59, with Owen, *supra* note 7, at 373 (concluding that "the reliability and relevancy principles of *Daubert*, used properly, provide a firm foundation for the fair and rational resolution of the scientific and technological issues which lie at the heart of products liability adjudication").

<sup>15</sup> *See, e.g.*, Cohen, *supra* note 14, at 961-63. *But see* Thomas Michael Spitaletto, *The Frye Standard Finally Fries: Has Daubert v. Merrell Dow Furthered the Use of Scientific Evidence in our Legal System?*, 14 REV. LITIG. 315, 320 (1994) (noting the positive effect *Daubert* has had on the distorting effect of junk science in the court room).

<sup>16</sup> Berger, *supra* note 8, at S60.

cause-effect conclusion seems warranted. Given the inevitability of flaws in individual studies and the fact that some of the studies were not undertaken with the litigative or regulatory process in mind, this necessarily involves the exercise of scientific judgment grounded in scientific expertise. The corpuscular approach focuses upon the inevitable flaws in individual studies and asks whether a sufficient number of unflawed studies that are sufficiently relevant to the causation issue remain to support a conclusion that is in itself relevant and reliable. Under the corpuscular approach, a study is either valid or invalid, and it is either relevant or irrelevant. A conclusion based upon invalid or irrelevant studies cannot be relevant and reliable and must therefore be rejected.<sup>17</sup>

Additionally, courts may be confusing similar but distinct legal and scientific terms.<sup>18</sup> For example, where both courts and scientists may speak of probabilities, scientists may be comfortable with inferences that are suggested but cannot be proven.<sup>19</sup> The legal system, uncomfortable with uncertainties, requires that something be either proven or not proven, and will translate merely suggested inferences into unproven evidence.<sup>20</sup> Therefore it is

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<sup>17</sup> Thomas O. McGarity, *Our Science is Good Science and Their Science is Junk Science: Science-Based Strategies for Avoiding Accountability and Responsibilities for Risk Producing Products and Activities*, 52 U. KAN. L. REV. 897, 924 (2004) [hereinafter McGarity, *Our Science*]. See also McGarity, "Daubertizing" Judicial Review, *supra* note 14, at 166, 178-221 (discussing Flue Cured Tobacco Cooperative Stabilization Corp. v. EPA, 4 F. Supp. 2d 435 (M.D.N.C. 1998), *vac'd & rem'd* 313 F.3d 852 (4th Cir. 2002), as an example of the corpuscular approach); Berger, *supra* note 8, at S60.

<sup>18</sup> Cohen, *supra* note 14, at 945 (explaining how the ability to express the burden of persuasion probabilistically in civil litigation "masks the important differences in the value systems that govern standards of legal proof and parallel standards of scientific and technical inquiry").

<sup>19</sup> *Id.* at 950-51.

<sup>20</sup> *Id.* Professor Cohen also comments on the confusion over *Daubert* noting, "some post-*Daubert* cases suggest that the deference to the methods of the world of scientific decision-making is already beginning to have the undesirable effect of confusing scientific and legal values, and the norms that

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tempting, but perhaps inappropriate, to map scientific terms directly onto legal proceedings.

On the other side of the debate, some see *Daubert* as a reasonable tool to screen evidence that reaches the jury. Judges are better suited to evaluate the validity of complex evidence than juries.<sup>21</sup> Scientific evidence tends to be complex, and therefore, a simple relevancy threshold may be inadequate to properly filter evidence.<sup>22</sup> And some would argue that it makes common sense that the party charged with deciding who wins the case—the jury—should not also be charged with determining whether evidence is valid.<sup>23</sup> Juries can be confused or overwhelmed by expert and particularly scientific testimony.<sup>24</sup> Thus, some argue that, appropriately employed, *Daubert* serves a useful purpose.<sup>25</sup>

As the debate over the appropriateness or the effects of *Daubert* continues, one must recognize that there is an entirely

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follow from them.” *Id.* at 958. See generally Margaret A. Berger, *The Supreme Court’s Trilogy on the Admissibility of Expert Testimony*, in FED. REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 32-38 (FED. JUDICIAL CTR. Ed., 2d ed. 2000) (discussing difficulties proving causation in toxic tort cases).

<sup>21</sup> Christopher B. Mueller, *Daubert Asks the Right Questions: Now Appellate Courts Should Help Find the Right Answers*, 33 SETON HALL L. REV. 987, 993-94 (2003).

<sup>22</sup> *Id.*

<sup>23</sup> *Id.*

<sup>24</sup> *Daubert*, 509 U.S. at 595 (discussing FED. R. EVID. 403).

<sup>25</sup> Owen, *supra* note 7, at 373. There is some indication that the courts applying the *Daubert* trilogy themselves are adopting the more conservative approach. Professor Margaret Berger notes:

Although nothing in the *Kumho* opinion is inconsistent with *Daubert*, the Court’s opinion does seem to set out a more flexible test. Instead of stressing factors that, although not definitive, are nevertheless suggested as guides for determining reliability, Justice Breyer in *Kumho* stressed the need to look at reliability in the context of the particular case and the testimony being offered. Courts, however, are citing and relying on *Daubert* more frequently than *Kumho*. (A Westlaw search on June 28, 2004, found 2708 citations in judicial opinions to *Daubert* since *Kumho* was decided and only 1454 citations to *Kumho*.)

Berger, *supra* note 8, at S61.

separate debate over its appropriateness and usefulness in the administrative law realm.<sup>26</sup> In *Science for Judges IV*, Professor Wagner outlined the risks of substantive errors and the process costs associated with the importation of *Daubert* by administrative agencies through the Information (or Data) Quality Act (IQA or DQA).<sup>27</sup> As Professor Wagner points out, agencies and courts play fundamentally different roles. Agencies are often experts themselves or can employ experts.<sup>28</sup> Agency processes, as well as external forces, cabin agency discretion and provide checks and

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<sup>26</sup> Wendy E. Wagner, *The "Bad Science" Fiction: Reclaiming the Debate Over the Role of Science in Public Health and Environmental Regulation*, 66 LAW & CONTEMP. PROBS. 63, 96-97 (2003) (challenging the good science reforms in the administrative realm) [hereinafter Wagner, "*Bad Science*" Fiction]; Wagner, *Importing Daubert*, *supra* note 6 (discussing the Information (or Data) Quality Act); David Michaels & Celeste Monforton, *Scientific Evidence in the Regulatory System: Manufacturing Uncertainty and the Demise of the Formal Regulatory System*, 13 J.L. & POL'Y 17, 39-41 (2005) (explaining *Daubert's* application to the scientific basis for public safety and health regulations as "both counterproductive and dangerous"). Cf., Paul S. Miller & Bert W. Rein, "*Gatekeeping*" *Agency Science and Technical Materials After Daubert: Ensuring Relevance and Ability in the Administrative Process*, 17 Touro L. Rev. 297 (2000) (advocating the use of *Daubert* by agencies through executive order to prevent restrictive overregulation); Raul & Dwyer, *supra* note 5, at 8 (arguing that *Daubert* principles "should apply to the review of agency rulemaking under the APA" and asserting that *Daubert*-style analysis would better document scientific decisions and "enhance the rigor and predictability of judicial review of agency action based on scientific evidence").

<sup>27</sup> Wagner, *Importing Daubert*, *supra* note 6, at 600-12. Professor Wagner notes in particular, the problems with the DQA given the "institutional differences between the agencies and the courts that could lead the [DQA] to be more damaging and potentially counterproductive as compared with the courts' use of *Daubert*." *Id.* at 598. Professor Wagner outlines the substantive errors and process costs that can arise from importing *Daubert* via the DQA into the administrative realm. Among these is the danger that a *Daubert* standard will infect policy decisions under the guise of challenging data, imposing a greater informational burden on agencies and slowing down the administrative process. *Id.* at 600-12.

<sup>28</sup> *Id.* at 592-93. See also Wendy Wagner, *The Perils of Relying on Interested Parties to Evaluate Scientific Quality*, 95 AM. J. OF PUB. HEALTH, July 2005, at S99-S100 [hereinafter Wagner, *The Perils of Relying on Interested Parties*].

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balances to deter agency reliance on “bad science.”<sup>29</sup> At the same time, Professor Wagner explains how the agency setting as a non-adversarial policy forum lacks institutional protections against *Daubert* abuses.<sup>30</sup> Finally, as Professor Wagner points out, the line between agency policy-making and scientific fact-finding can be blurred.<sup>31</sup> In a related vein, Professor McGarity notes that “‘Daubertizing’ judicial review of agency risk assessments will bestow upon courts a policymaking role that is entirely inappropriate for a politically unaccountable institution.”<sup>32</sup>

Conversely, others contend the evils of junk science that visit agency processes equally demand appropriate gatekeeping.<sup>33</sup> Courts imposing regulatory *Daubert* will force agencies to better explain themselves, better document their findings, and expose themselves to greater scrutiny.<sup>34</sup> Some would note that imposing *Daubert* principles upon agencies would enhance the “rigor and predictability of judicial review of agency action based on scientific evidence.”<sup>35</sup>

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<sup>29</sup> Wagner, “*Bad Science*” Fiction, *supra* note 26, at 79-80 (noting *inter alia* the effect of scientific advisory boards, judicial review, and Congressional oversight).

<sup>30</sup> Wagner, *Importing Daubert*, *supra* note 6, at 598. Wagner points out that “no attention has been given to tracing these proposals through the agencies to determine the types of unintended administrative reactions they are likely to produce.” Wagner, “*Bad Science*” Fiction, *supra* note 26, at 72.

<sup>31</sup> Wagner, *Importing Daubert*, *supra* note 6, at 601-02.

<sup>32</sup> McGarity, “*Daubertizing*” Judicial Review, *supra* note 14, at 156. See also Wagner, *The Perils of Relying on Interested Parties*, *supra* note 28, at S102-03 (discussing the danger of blurring the line between science and policy).

<sup>33</sup> While not advocating regulatory *Daubert*, Professor Elliott has noted that courts’ traditionally deferential attitude towards agency decision-making may be inappropriately exaggerated when agencies rely on technical or scientific rationales. E. Donald Elliott et al., *Science, Agencies, and the Courts: Is Three a Crowd?*, 31 ENVTL. L. REP. 10125, 10126 (2001).

<sup>34</sup> *Id.* at 10130.

<sup>35</sup> Raul & Dwyer, *supra* note 5, at 8. See also D. Hiep Truong, *Daubert and Judicial Review: How Does an Administrative Agency Distinguish Valid Science from Junk Science?*, 33 AKRON L. REV. 365, 369 (2000); Miller & Rein, *supra* note 26, at 298 (suggesting that courts reviewing agencies must perform some gatekeeping function).

I would like to raise a small but significant additional consideration for the regulatory *Daubert* debate, namely that regulatory *Daubert* may creep into judicial opinions via numerous routes and slowly impel a murky paradigm shift in the review of agency actions. My concerns are that: (i) the numerous routes by which *Daubert* can creep into agency functioning will trigger an unclear paradigm shift, reducing the amount of deference to agency decision-making and causing confusion and abuse, and (ii) the amorphous paradigm shift will have two uniquely destructive consequences in the administrative law realm, “rhetorical *Daubert*” and “generic *Daubert*.” To illustrate my concerns, Part II will explain how agencies might adopt some sort of regulatory *Daubert* and Part III details the problems with unclear or ambiguous paradigm shifts and how attempts to insert *Daubert* into the regulatory context are ill-conceived and ill-defined.

## II. HOW AGENCIES MIGHT ADOPT *DAUBERT*

Although agencies perform different functions than courts, and operate under constitutional doctrine and statutory laws specific to them, there have been several suggestions as to how agencies might adopt *Daubert* from the judicial model. First, agencies may apply their statutory directives more vigorously. Alternatively, Congress may impose *Daubert*-like mechanisms by statutorily requiring agencies to screen expert evidence upon which they base decisions. Additionally, agencies may explicitly adopt *Daubert* in either adjudication or rulemaking,<sup>36</sup> requiring decision makers to

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<sup>36</sup> A recent search of the Federal Register reveals three citations to *Daubert* in agency rulemaking. One involved the Department of Justice’s revision of the Rules of Evidence used in Courts Martial. Manual for Courts Martial; Proposed Amendments, Summary of Public Comment, 66 Fed. Reg. 63040, 63045 (Dec. 4, 2001); Manual for Courts Martial; Notice of Proposed Amendments, Summary of Public Comment, 66 Fed. Reg. 30431, 30435 (Jun. 6, 2001). The other two specifically rejected calls from industry for the agency to adopt *Daubert*. See Diesel Particulate Matter Exposure of Underground Coal Miners, Final Rule, 66 Fed. Reg. 5526, 5596-97 (Jan. 19, 2001) (to be codified at 30 C.F.R. pt. 72) [Re-asserted in Diesel Particulate Matter Exposure of Underground Coal Miners, Final Rule, 70 Fed. Reg. 32868, 32912 (June 6,

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act as agency gatekeepers. Further, agencies may reject a gatekeeper function but still adopt a *Daubert* standard when decision-makers *weigh* already admitted evidence. Most subtly, and perhaps most perniciously, agencies and the reviewing courts may adopt a *Daubert* attitude or as some have called it “the spirit of *Daubert*.”

*A. More Vigorous Administrative Procedure Act (APA) Review*

Agencies play a different role than courts. Agencies include any “authority of the government of the United States,” not including Congress, the courts and a few other limited exceptions.<sup>37</sup> Typically, when we think of agencies, we think of executive and independent agencies that have been given some relatively specific function in their enabling statutes and some range of powers.<sup>38</sup> That is, agencies target specific problems<sup>39</sup> and are limited by enabling statutes, the APA, and the Constitution.<sup>40</sup>

Generally speaking, the APA provides a framework within which agencies must operate. The APA defines agency functioning and procedure as well as judicial review.<sup>41</sup> Naturally, constitutional law, common law doctrine, and specific enabling acts supplement this framework. In terms of procedure, the APA

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2005)]; Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body, Final Rule, 65 Fed. Reg. 1000 (June 6, 2000) (to be codified at 21 C.F.R. pt. 101). There have been no meaningful cites to *Daubert* since *Diesel Particulate* in 2005, as of this article’s publication date.

<sup>37</sup> Administrative Procedure Act, 5 U.S.C. §§ 551 (2000).

<sup>38</sup> See, e.g., *In re Humphrey’s Executor*, 295 U.S. 602 (1935) (distinguishing between independent and executive agencies).

<sup>39</sup> See JERRY L. MASHAW ET AL., ADMINISTRATIVE LAW: THE AMERICAN PUBLIC LAW SYSTEM, CASES AND MATERIALS 5 (5th ed. 2003) (“[A]lthough each agency has its own distinctive social and political history, agencies typically are responses not only to the perception of social problems warranting government response, but also the perception that existing institutions are inadequate to the task.”).

<sup>40</sup> 5 U.S.C. § 706 (2000). See MASHAW ET AL., *supra* note 39, at 1-3.

<sup>41</sup> Administrative Procedure Act, 5 U.S.C. §§ 553-559, 701-706 (2000).

provides minimum standards to cabin agency action. APA sections 553, 554 and 556 provide a framework for formal and informal adjudication and rulemaking.<sup>42</sup> APA section 706 instructs courts to review agency action (whether formal or informal) to ensure that it is reasonable, based upon the record, and in accordance with the Constitution and all applicable laws and procedures.<sup>43</sup>

There are thus already administrative law provisions that promote reliability, reasonableness, and proper procedure. For example, APA section 556(d) requires evidence to be “supported by and in accordance with the reliable, probative, and substantial evidence.”<sup>44</sup> Admittedly, APA section 556(d) speaks more to the sufficiency of evidence rather than to its admissibility. However, the Federal Rules of Evidence (FRE), and specifically FRE 702 regarding admission of experts, from which *Daubert* evolved, do not apply to administrative agencies.<sup>45</sup> Courts conduct review of the agency record under the APA and, therefore, the Federal Rules of Evidence are not implicated.

Likewise, APA section 553 affords a reliability mechanism in the informal rulemaking context. Section 553 requires that interested parties be given notice of a proposed rule and its basis, as well as an opportunity to respond to the proposal with comments.<sup>46</sup> In *United States v. Nova Scotia Food Products*,<sup>47</sup> the Court of Appeals for the Second Circuit found that an agency’s

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<sup>42</sup> *Id.* at §§ 553, 554, 556.

<sup>43</sup> *Id.* at § 706.

<sup>44</sup> *Id.* at § 556(d).

<sup>45</sup> *Id.* at § 706.

<sup>46</sup> *Id.* at § 553(c) provides:

After notice required by this section, the agency shall give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments with or without opportunity for oral presentation. After consideration of the relevant matter presented, the agency shall incorporate in the rules adopted a concise general statement of their basis and purpose. When rules are required by statute to be made on the record after opportunity for an agency hearing, sections 556 and 557 of this title apply instead of this subsection.

<sup>47</sup> 568 F.2d 240 (2d Cir. 1977).

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“failure to disclose to interested persons the scientific data upon which the [Food and Drug Administration] relied was procedurally erroneous.”<sup>48</sup> The agency, in regulating the manufacturing processes for smoked whitefish, relied upon undisclosed outside studies. The requirement to disclose the scientific information was a function of judicial review and the court was charged under *Citizens to Preserve Overton Park v. Volpe*<sup>49</sup> to satisfy itself that the agency had considered all relevant factors.<sup>50</sup> Thus, one view of judicial review would require agencies engaged in rulemaking based upon scientific evidence to make the evidence available for comment. Further, courts should review whether the agency considered all relevant factors in making its decision, which would include responding to those comments.<sup>51</sup>

Finally, there is review pursuant to APA section 706. Courts will “hold unlawful and set aside agency action, findings, and conclusions found to be arbitrary, capricious, an abuse of discretion or otherwise not in accordance with law.”<sup>52</sup> Thus, courts can invalidate agency action based upon junk science as an abuse of agency discretion.

Some have drawn the connection between administrative law provisions and *Daubert*, arguing that these provisions are consistent with *Daubert* or indeed provide the foundation for its adoption.<sup>53</sup> Arguably, these provisions do the work of *Daubert* in the administrative setting. If they do, one might ask what *Daubert* may add and, if it adds nothing, then what harm will it do. *Daubert*'s potential harm is that it may add more rigor, more

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<sup>48</sup> *Id.* at 252.

<sup>49</sup> 401 U.S. 402 (1971).

<sup>50</sup> *Nova Scotia*, 568 F.2d at 251 (citing *Overton Park*, 401 U.S. at 415-16 and *Appalachian Power Co. v. EPA*, 477 F.2d 495, 507 (4th Cir. 1973)).

<sup>51</sup> In *Nova Scotia*, however, the court specifically noted that an agency may resort to its own expertise outside of the record. *Nova Scotia*, 568 F.2d at 251. The agency in that case did not have specific scientific expertise in the matter under consideration. *Id.*

<sup>52</sup> Administrative Procedure Act, 5 U.S.C. § 706(2)(A) (2000).

<sup>53</sup> See Miller & Rein, *supra* note 26, at 307 (explaining how *Daubert* under APA section 556(d) becomes a decisional standard rather than an admissibility standard).

rhetoric, and/or an attitude change signaling a distrust of agency science.

We can see that some courts have turned to *Daubert* even though they might have reached the same result relying upon the APA. In *Sec. of Labor v. Keystone Coal Mining Corp.*,<sup>54</sup> the court upheld the decisions of the Administrative Law Judge (ALJ) and the Federal Mine Safety Health and Review Commission, rejecting a claim by the Secretary of Labor that mine operators had intentionally tampered with coal samples. In doing so, the court invoked both *Joiner* and *Daubert* in affirming the ALJ's finding that the "Secretary's scientific evidence was inconclusive or otherwise could not be adequately evaluated."<sup>55</sup> The court noted "[a]ll of these issues involve conflicting expert testimony, and this Court must defer to the reasonable determination of the trier of fact regarding not only the relevance but the reliability of the expert testimony presented at trial."<sup>56</sup> It would seem there is an established basis in administrative law to defer to the "reasonable determination of the trier of fact."<sup>57</sup> This basis is the arbitrary and capricious review under APA section 706.<sup>58</sup> One could question

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<sup>54</sup> 151 F.3d 1096 (D.C. Cir. 1998).

<sup>55</sup> *Id.* at 1107.

<sup>56</sup> *Id.* (citing *Joiner*, 522 U.S. at 136; *Daubert*, 509 U.S. at 579).

<sup>57</sup> *Id.*

<sup>58</sup> Administrative Procedure Act, 5 U.S.C. § 706 (2000) provides:

To the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action. The reviewing court shall—

(1) compel agency action unlawfully withheld or unreasonably delayed; and

(2) hold unlawful and set aside agency action, findings, and conclusions found to be—

(A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;

(B) contrary to constitutional right, power, privilege, or immunity;

(C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right;

(D) without observance of procedure required by law;

(E) unsupported by substantial evidence in a case subject to

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whether *Daubert*'s invocation is harmful. After all, if the result is justified, why does the invocation of an arguably analogous doctrine undermine the court's ultimate reliance upon the APA and standard administrative law doctrine? It is harmful because it validates a shadow regime with vastly different objectives in which there is less deference to agencies and more power placed in the hands of courts. It validates this regime slowly, letting it creep into agency functioning without serious and probing consideration. It signals the existence of a standard by which agencies may be judged without delineating the contours of the standard. Indeed, because the reference to *Daubert* is merely dicta, courts do not have to explain their references to it in a meaningful way.

The turn to *Daubert* may stem from a desire for a more vigorous and more *Daubert*-like approach to agencies' use of science.<sup>59</sup> After all, APA sections 553 and 556 merely require relevant and probative evidence to be considered and, when not based upon agency expertise, to be available to all involved to view and challenge. These are still fairly deferential mechanisms. Some would call for *Daubert* to limit agency discretion to consider evidence further than that set out in the APA. One set of commentators has suggested that "as a matter of policy and statutory interpretation, the *Daubert* reliability standard should apply to federal environmental rulemaking and adjudication."<sup>60</sup> Perhaps, this could mean that agency decision-makers would be required either by Congress or the courts to measure proffered evidence according to the *Daubert* factors, either prior to

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sections 556 and 557 of this title or otherwise reviewed on the record of an agency hearing provided by statute; or

(F) unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing court.

In making the foregoing determinations, the court shall review the whole record or those parts of it cited by a party, and due account shall be taken of the rule of prejudicial error.

<sup>59</sup> Raul & Dwyer, *supra* note 5, at 7 (citing "the need for a mechanism to enable more rigorous, consistent review of agency science").

<sup>60</sup> Charles D. Weller & David B. Graham, *New Approaches to Environmental Law and Agency Regulation: The Daubert Litigation Approach*, 30 ENVTL. L. REP. 10557, 10568-69 (2000).

considering it or in determining what weight to assign to it.

*B. Statutorily Mandated Daubert Review*

Congress could require some form of *Daubert* analysis in agency decision making. To some extent, the DQA discussed in Science for Judges IV and V has already started the “Daubertization” process,<sup>61</sup> removing some agency discretion with respect to scientific evidence.<sup>62</sup> The DQA commands relevant agencies to “issue guidelines ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by the agency.”<sup>63</sup> The Office of Management and Budget (OMB) *Guidelines*,<sup>64</sup> in explicating the mechanisms individual agencies must create, envision specific agency guidelines that take a common sense approach and that do not impose undue burdens upon agency resources or inhibit the dissemination of information.<sup>65</sup> Lastly, under the *Guidelines*,

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<sup>61</sup> Wagner, *Importing Daubert*, *supra* note 6, at 590-91; Wagner, “*Bad Science*” *Fiction*, *supra* note 26, at 63. Professor McGarity has discussed Daubertizing more generally. See McGarity, “*Daubertizing*” *Judicial Review*, *supra* note 14.

<sup>62</sup> Information Quality Act, § 515(b)(2)(A), 44 U.S.C. § 3516 (2000).

<sup>63</sup> *Id.*

<sup>64</sup> Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies, 67 Fed. Reg. 8452 (Feb. 22, 2002) [hereinafter *Guidelines*].

<sup>65</sup> *Id.* In a general sense, the *Guidelines* try to tailor the correction process in a way that does not prevent the agencies from doing their respective jobs. Agencies “are required to undertake only the degree of correction that they conclude is appropriate for the nature and timeliness of the information involved.” *Id.* at 8458. Additionally, the *Guidelines* “stress the importance of having agencies apply these standards and develop their administrative mechanisms so they can be implemented in a common sense and workable manner.” *Id.* at 8453. The OMB *Guidelines* have some limits in that they apply only when “the agency represents the information as, or uses the information in support of, an official position of the agency.” *Id.* Although, the DQA governs information prepared by outside sources and endorsed by agencies. *Id.* at 8454 (“[T]hese guidelines govern an agency’s dissemination of information, but generally do not govern a third-party’s dissemination of information (the

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“influential” information (*i.e.*, information with an important impact on public policy or private sector interests) requires greater scrutiny.<sup>66</sup> The *Guidelines* leave the form and function of this greater scrutiny up to the individual agencies. The general trend of the DQA and the OMB *Guidelines*, however, is to establish a framework to limit agency discretion over scientific evidence. It requires agencies to establish a procedure by which parties can petition agencies to correct information disseminated by the agency.<sup>67</sup>

Professor Wagner has succinctly described the burden that may fall upon agencies:

This petition process places interested parties in the role of peer reviewer. They can allege, through a formal process, that a study should be excluded from regulatory decision-making because it is too unreliable to be useful . . . . Disgruntled complainants whose request for correction are denied can file an appeal with the agency. It is also expected that complaints and requests for correction will carry some weight if an agency action is challenged in court and that they might even be appealable in and of

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exception being where the agency is essentially using the third-party to disseminate information on the agency’s behalf”). In addition, information used by specific parties in adjudication is not subject to the DQA. *Id.* at 8454 (excluding adjudicatory materials from the term “disseminated,” thereby exempting those materials from the DQA because “[t]here are well-established procedural safeguards and rights to address the quality of adjudicatory decisions and to provide persons with an opportunity to contest decisions”).

<sup>66</sup> *Id.* (noting that “[g]iven the differences in the many Federal agencies covered by these guidelines, and the differences in the nature of the information they disseminate, we [OMB] . . . believe it will be helpful if agencies elaborate this definition of ‘influential’ in the context of their missions and duties, with due consideration to the information they disseminate”).

<sup>67</sup> Treasury and General Government Appropriations Act for Fiscal Year 2001 § 515 (commanding agencies guided by the DQA to “establish administrative mechanisms allowing affected persons to seek and obtain correction of information maintained and disseminated by the agency that does not comply with the guidelines”).

themselves under limited circumstances.<sup>68</sup>

A recent visit to the Council on Regulatory Competitiveness<sup>69</sup> revealed 152 petitions and requests for corrections.<sup>70</sup> The very burden of responding to these inquiries may be enough to affect a *Daubert* shift by influencing internal agency functioning. Resources will be diverted to respond to these inquiries and one can imagine the chilling effect that these inquiries will have upon agency initiative.<sup>71</sup>

Likewise, the application of the DQA promises not just increased burdens but the potential for obfuscation and abuse. Professor Wagner described this amorphous problem with the DQA:

Also like *Daubert*, the criteria for “good” versus “bad” science or science related information is amorphous, but the inability to validate or replicate the study is one of the primary grounds for challenging the information. Finally, those filing the complaints generally do not limit their concerns to scientific quality or reliability, but also contest embedded judgments and policy choices in the agencies’ use of scientific research, even though the challenges are framed as if they concerned only technical information.<sup>72</sup>

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<sup>68</sup> Wagner, “*Bad Science*” Fiction, *supra* note 26, at 69 (citations omitted).

<sup>69</sup> See The Center for Regulatory Effectiveness Home Page, <http://www.thecre.com>.

<sup>70</sup> The Center for Regulatory Effectiveness, Federal Agency Data Quality Petitions by Agency, <http://thecre.com/quality/petitions.html>. We determined that 152 petitions and requests for corrections since the passing of the DQA by following each link to agency DQA websites and tabulating total petitions. *Id.* (last visited Feb. 16, 2006).

<sup>71</sup> Wagner, *Importing Daubert*, *supra* note 6, at 613 (noting the “[DQA] may cause agencies to think twice before disseminating information although it is difficult to locate concrete evidence of this effect”).

<sup>72</sup> *Id.* at 597.

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A wholly distinct means of limiting agencies' discretion over scientific evidence would be to subject any scientific evidence offered in administrative proceedings to a *Daubert* hearing. Thus, in an administrative adjudication, the agency decision-maker would be required to conduct a *Daubert* hearing to determine whether evidence could even be considered by the agency. Alternatively, a court could impose *Daubert* upon judicial review of the agency decisions; however, doing so would presumably force the agency to conduct some sort of initial *Daubert* inquiry in order to increase its chances of success upon review.<sup>73</sup>

No court has yet required an administrative agency to exclude expert testimony based upon *Daubert*, although one district court has countenanced *Daubert* and invoked its spirit by opining that it *could* be used as an admissibility rule by agencies.<sup>74</sup> In *Lobsters, Inc. v. Evans*,<sup>75</sup> after noting that the rules of evidence did not apply to a decision made by the National Oceanic and Atmospheric Administration that a vessel had entered prohibited waters, the court nevertheless invoked the spirit of *Daubert*.<sup>76</sup> The court pronounced, "[n]onetheless 'the spirit of *Daubert*' does apply to administrative proceedings because 'junk science has no more place in administrative proceedings than in judicial ones.'" <sup>77</sup> Why the court needed the spirit of *Daubert* is unclear, as it first recited the applicable regulations requiring that admissible evidence be "relevant, material, reliable, and probative and not unduly repetitious or cumulative."<sup>78</sup> It might have invoked *Daubert's* spirit to validate the *Daubert* hearing held by the ALJ. Nevertheless, the ALJ had limited his *Daubert* application to

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<sup>73</sup> For a list of regulatory *Daubert* proposals, see Wagner, "Bad Science" Fiction, *supra* note 26, at 70 n.29.

<sup>74</sup> *Lobsters, Inc. v. Evans*, 346 F. Supp. 2d 340 (D. Mass. 2004).

<sup>75</sup> *Id.*

<sup>76</sup> *Id.* at 344.

<sup>77</sup> *Id.* (citing *Niam v. Ashcroft*, 354 F.3d 652, 660 (7th Cir. 2004)).

<sup>78</sup> *Id.* at 344 (citing 15 C.F.R. § 904.251(b) (2004)).

assessing the weight of the evidence, whereas the court indicated that *Daubert* factors were not limited in function. They could be used not only for weighing the evidence but for admissibility as well.<sup>79</sup>

As *Lobsters, Inc.* illustrates, courts or agencies adopting *Daubert* could not only invoke *Daubert* to exclude evidence, they could also use it to assess the weight accorded to the evidence. Courts have suggested that although agencies are not bound by the FRE and can hear all evidence, they must still consider *Daubert* in weighing that evidence.<sup>80</sup> It is unclear what about *Daubert* they must consider. One possibility is that agencies should base their decisions on evidence that is reliable, probative, and substantial; however, agencies are already required by APA section 556(d) to do that in proceedings subject to APA section 556, and APA section 706 provides a general check on arbitrariness in all other cases by requiring judicial review.<sup>81</sup> Perhaps agencies (or the courts) should use the *Daubert* factors to assess the reliability or probity of the evidence. Given that agencies are specialized, in some cases experts themselves, and required to evaluate the worthiness of evidence as experts, it is unclear that adoption of such a standard would lead to anything less than some sort of distrust or heightened skepticism of scientific evidence by administrative agencies. Perhaps all that is meant is that agencies should be more skeptical of science. Proponents of regulatory

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<sup>79</sup> *Id.* at 345 (“The *Daubert* factors can, in fact, be used to exclude evidence from an administrative hearing if the ALJ finds the evidence to be unreliable; their function is not limited, as the ALJ in his Initial Decision suggested, to bearing upon the weight afforded to the evidence once admitted.”).

<sup>80</sup> One court, although explicitly rejecting *Daubert*, nevertheless seemed to express a view that agencies performed a *Daubert*-like function in weighing evidence. The court first stated that because of agency skill and expertise, “*Daubert* does not apply directly . . . because it is based on Fed. R. Evid. 702, which agencies need not follow.” *Peabody Coal Co. v. McCandless*, 255 F.3d 465, 469 (7th Cir. 2001). But thereafter, the court noted: “[Agencies] have a corresponding obligation to *use* that skill when evaluating technical evidence.” *Id.* (emphasis in original).

<sup>81</sup> *See supra* notes 41 to 52 and accompanying text.

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*Daubert* might say that agencies should be wary of junk science.<sup>82</sup> It would seem to me that agencies should have always been wary of junk science and that current administrative law doctrine should guard against it.

Nevertheless, courts still speak of the plague of junk science as a new worry for agencies exposed by the light of *Daubert*. In *Peabody Coal Company v. McCandless*,<sup>83</sup> the court invoked *Daubert* by stating that since *Daubert*, courts understood the importance of reliable scientific evidence.<sup>84</sup> It then recognized *Daubert*'s technical inapplicability in reviewing evidence in support of a Black Lung benefits case because "our dispute does not entail a contest of admissibility,"<sup>85</sup> but went on to morph *Daubert* into a weighing of the evidence standard. The court acknowledged that *Daubert* did not apply because the ALJ could use his skill to handle evidence that might mislead a jury.<sup>86</sup> The court stated the ALJ had "a corresponding obligation to use that skill when evaluating technical evidence."<sup>87</sup> It is unclear why the court referenced *Daubert*; as if now that we have *Daubert* we know the ALJ's decision was wrong. The ALJ's decision was based upon a non-medical rule that arbitrarily gave more credence to some physicians than others.<sup>88</sup> The case could have been

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<sup>82</sup> Raul & Dwyer, *supra* note 5, at 43 ("If agencies may justify their policy preferences based on junk science, government accountability, and perhaps even public health, might suffer gravely. Junk science can lead agencies to foist misleading remedial measures on the public, thereby diverting or misdirecting regulatory efforts from more effectively serving the public interest.").

<sup>83</sup> *Peabody Coal Co.*, 255 F.3d 465.

<sup>84</sup> *Id.* at 468.

<sup>85</sup> *Id.* at 469.

<sup>86</sup> *Id.* ("Agencies relax the rules of evidence because they believe that they have the skill needed to handle evidence that might mislead a jury.").

<sup>87</sup> *Id.*

<sup>88</sup> *Id.* The court stated:

[Agency decision makers] avoided the medical dispute by adopting a non-medical rule that physicians who work in white smocks are more reliable than physicians who do their work in the laboratory. As that preference has no apparent medical basis—and as it contradicts many decisions requiring agencies to resolve scientific controversies on the

resolved using standard administrative law doctrine. Again, the harm here is not that the court reached the wrong result. The harm is the way in which *Daubert* creeps into administrative functioning—either as a sloppy analogy or as a pernicious throw away reference that validates an entirely new framework.

Some commentators and courts have suggested what I would call a *Daubert*-light approach. In this approach, the agency must be mindful of the spirit of *Daubert*. I am not sure what the spirit of *Daubert* tells us, but the spiritual invocations thus far seem to warn against untested or unreliable science. *Lobsters Inc.* warned of unreliable science, and in *Niam v. Ashcroft*,<sup>89</sup> Judge Posner invoked *Daubert*'s spirit somewhat gratuitously in striking down an immigration judge's arbitrary refusal to hear from an expert. After noting that "the federal rules of evidence do not apply to the federal administrative agencies,"<sup>90</sup> the court noted "'[j]unk science' has no more place in administrative proceedings than in judicial ones."<sup>91</sup> The call upon the spirit was nevertheless unnecessary because, as the court pointed out, the immigration judge had arbitrarily imposed a higher standard than that required by *Daubert*.<sup>92</sup> It is not hard to imagine that *Daubert*'s spirit will be invoked to undermine an agency decision that would otherwise pass arbitrary and capricious or substantial evidence review.

Other cases have squarely rejected a *Daubert* incursion into administrative law.<sup>93</sup> In *Stewart v. Potts*,<sup>94</sup> the district court, reviewing a decision by the Army Corps of Engineers, stated *Daubert* "does not apply to APA review of agency action."<sup>95</sup> The

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merits rather than through legal legerdemain—the result cannot stand.

*Id.* at 469.

<sup>89</sup> 354 F.3d 652 (7th Cir. 2004).

<sup>90</sup> *Id.* at 660.

<sup>91</sup> *Id.*

<sup>92</sup> *Id.*

<sup>93</sup> *See, e.g., Stewart v. Potts*, 996 F. Supp. 668, 678 n.8 (S.D. Tex. 1998) ("The Court's task under the APA is to ensure that the agency's decisions are not arbitrary or capricious; it is not to evaluate their scientific methods.").

<sup>94</sup> *Id.*

<sup>95</sup> *Id.*

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court ruled that in light of its role, it must defer to the expert agency.<sup>96</sup> Likewise, in *Sierra Club v. Marita*,<sup>97</sup> petitioners challenged the Forest Service's consideration of ecological and biological evidence by suggesting *Daubert* as a means to evaluate whether the Forest Service's "scientific assertions are owed any deference."<sup>98</sup> The court rejected the idea by noting that although *Daubert*'s use might lead to better documentation, that was not the role of the Environmental Impact Statement (EIS) under review. "An EIS is designed to ensure open and honest debate of the environmental consequences of an agency action, not to prove admissibility of testimony in a court of law."<sup>99</sup>

*D. Daubert and Rulemaking*

One might expect *Daubert* and *Daubert*-like challenges to creep into the rulemaking realm and infect agency functioning even prior to any judicial review. A recent search of the Federal Register revealed two relevant references to *Daubert*.<sup>100</sup> In both cases the agency rejected the notion that *Daubert* applied to agency rulemaking. In one case, the agency dismissed a plea from the industry to employ *Daubert* by noting the differences between litigation and agency policy setting through rule-making:

[T]he purpose of this risk assessment is not to establish

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<sup>96</sup> *Id.*

<sup>97</sup> 46 F.3d 606 (7th Cir. 1995).

<sup>98</sup> *Id.* at 622.

<sup>99</sup> *Id.*

<sup>100</sup> See Diesel Particulate Matter Exposure of Underground Coal Miners, Final Rule, 66 Fed. Reg. 5526 (Jan. 19, 2001) (to be codified at 30 C.F.R. pt. 72); Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body, Final Rule, 65 Fed. Reg. 1000 (June 6, 2000) (to be codified at 21 C.F.R. pt. 101). The one other reference to *Daubert* in the *Federal Register* involved the Department of Justice's revision of the Rules of Evidence used in Courts Martial. Manual for Courts Martial; Proposed Amendments, Summary of Public Comment, 66 Fed. Reg. 63040, 63045 (Dec. 4, 2001); Manual for Courts Martial; Notice of Proposed Amendments, Summary of Public Comment, 66 Fed. Reg. 30431, 30435 (Jun. 6, 2001).

civil liabilities for personal injury. [The Mine Safety and Health Administration's] concern is with reducing the risk of lung cancer, not with establishing the specific cause of lung cancer for an individual miner. The excess risk of an outcome, given an excessive exposure, is not the same thing as the likelihood that an excessive exposure caused the outcome in a given case. To understand the difference, it may be helpful to consider two analogies: (1) the likelihood that a given death was caused by a lightning strike is relatively low, yet exposure to lightning is rather hazardous; (2) a specific smoker may not be able to prove that his or her lung cancer was "more likely than not" caused by radon exposure, yet radon exposure significantly increases the risk-especially for smokers. Lung cancer has a variety of alternative causes, but this fact does not reduce the risk associated with any one of them.<sup>101</sup>

One case specifically rejected a plea for *Daubert* in a rulemaking context. In *Edison Elec. Inst. v. Env'tl. Prot. Agency*,<sup>102</sup> the EPA issued new regulations pursuant to the Clean Water Act regarding the discharge of pollutants, which included compliance levels and permit procedures. The EPA decided upon the use of certain tests to determine toxicity compliance and industry organizations sued on the basis that the EPA test was not sufficiently valid. Upon review, the court determined the test was sufficiently reliable and the EPA's use of the test was not arbitrary and capricious.<sup>103</sup> In a footnote, the court addressed and dismissed any potential *Daubert* issue as follows:

Petitioners suggest, without supporting authority, that because the test results will be used as evidence in enforcement proceedings, EPA's rulemaking had to comply with the standard for scientific evidence articulated in Fed. R. Evid. 702, as interpreted in *Daubert* . . . . Evidentiary

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<sup>101</sup> Diesel Particulate Matter Exposure of Underground Coal Miners, 66 Fed. Reg. at 5596-97.

<sup>102</sup> 391 F.3d 1267 (D.C. Cir. 2004).

<sup>103</sup> *Id.* at 1270.

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rules govern the admissibility of evidence at trial, not the establishment of the processes whereby such evidence will be created. See Fed. R. Evid. 101 (“These rules govern proceedings in the courts of the United States . . .”).<sup>104</sup>

The court was not persuaded by the fact that enforcement proceedings could be based upon the scientific test that was being challenged, but the court did leave open the possibility that the test’s reliability could be challenged in an enforcement proceeding as lacking sufficient reliability.<sup>105</sup> The court also noted the EPA had fully explained its reasoning and rationales for using this particular test in the response to comments and in the Final Rule itself.<sup>106</sup>

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I think *Daubert*’s invocation in any matter other than simply requiring the vigorous application of already-established administrative law doctrines<sup>107</sup> threatens agencies with an unclear paradigm shift to a less deferential, more searching distrust of agency decisions based upon science. Adopting *Daubert* in agency rulemaking and adjudication would affect a “sea-change in federal agency law.”<sup>108</sup> A paradigm shift to a more skeptical approach is unwarranted, unclear, and unhelpful. More importantly for the purposes of this essay, it will bring confusion and instability. It also holds unique dangers because it is an attempt to manipulate administrative law doctrine, not to affect administrative law functioning, but to effectuate deregulatory goals in particular substantive areas of law.

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<sup>104</sup> *Id.* at 1269 n.2.

<sup>105</sup> *Id.* at 1272.

<sup>106</sup> *Id.* at 1269. As in the adjudication context, under the APA, rulemaking decisions must still be based upon reliable information. *See, e.g.*, *Cellular Phone Taskforce v. FCC*, 205 F.3d 82 (2d Cir. 2000) (refusing to find that the FCC had acted arbitrarily and capriciously by relying upon expert organization and federal agencies when enacting radiation Guidelines). *But see* Miller & Rein, *supra* note 26, at 316 (citing *Cellular Phone Taskforce v. FCC* for the proposition that courts are already implicitly applying *Daubert* to review of agency rulemaking even though the case does not mention *Daubert*).

<sup>107</sup> *See, e.g.*, *supra* note 58 and accompanying text.

<sup>108</sup> Weller & Graham, *supra* note 60, at 10569.

III. THE DANGER OF A *DAUBERT* SHIFT

A paradigm shift changing the way in which agencies or courts assess scientific evidence will be necessarily vague, causing endless confusion, subject to manipulation and abuse, and undermine administrative law. Part A of this section will illustrate the problem with unclear paradigm shifts using one of the most significant shifts in administrative law, the *Chevron* doctrine. The uncertainty, confusion and details of the *Chevron* shift have worked themselves out, but it has taken twenty years. In addition to the confusion and uncertainty surrounding *Chevron*, the doctrine was subject to manipulation and abuse.<sup>109</sup> Although, on the whole I would contend that *Chevron* was useful in that it sought to improve administrative law functioning by ushering in a new era of greater deference to agency decision-making,<sup>110</sup> it was not without costs.

A *Daubert* shift holds none of *Chevron*'s promise and will impose the same types of costs as *Chevron* as well as some additional costs. The normative shift that arises from "Daubertization" has little to do with administrative functioning and more to do with deregulation in specific areas of substantive law.<sup>111</sup> A *Daubert* shift would leave too many unanswered questions and would be particularly susceptible to abuse, leading parties to invoke *Daubert* either as a rhetorical tool or a generic standard. Finally, a *Daubert* shift would also be an anti-*Chevron* shift, repudiating *Chevron*'s progress towards a more flexible and pragmatic administrative state.

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<sup>109</sup> See *infra* note 139 and accompanying text.

<sup>110</sup> Cf. Ronald M. Levin, *The Anatomy of Chevron: Step Two Reconsidered*, 72 CHI. KENT L. REV. 1253, 1259 (1997) ("[T]oday reviewing courts regard *Chevron* as useful in providing a manageable framework, yet critical judicial scrutiny of administrative actions has continued . . . oriented around the *Chevron* terminology.").

<sup>111</sup> McGarity, "Daubertizing" Judicial Review, *supra* note 14, at 156 (referring to the "Daubertization" proponents' normative agenda).

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A. *The Chevron Shift*

*Chevron U.S.A. v. National Resources Defense Council, Inc.*<sup>112</sup> marks one of the most significant paradigm shifts in administrative law. As is often described, the case established the *Chevron* two-step.<sup>113</sup> First, a court would look to the statute to ascertain whether Congress had spoken to the issue.<sup>114</sup> If it had, the court would simply implement the will of Congress.<sup>115</sup> However, if Congress had not spoken to the matter, then the court would defer or, perhaps more accurately, accept a reasonable agency interpretation.<sup>116</sup>

Professor Donald Elliott has explained how *Chevron* effectuated a paradigm shift on several levels. *Chevron*, of course, had rhetorical power,<sup>117</sup> but more than that it “re-conceptualized the relative roles of courts and agencies when construing statutes over which agencies have been given interpretive rights.”<sup>118</sup> It changed the internal dynamics of agencies<sup>119</sup> and “power shifted

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<sup>112</sup> 467 U.S. 837 (1984).

<sup>113</sup> *Id.* at 843-44; Thomas W. Merrill, *Judicial Deference to Executive Precedent*, 101 YALE L.J. 969, 975-80 (1992) [hereinafter Merrill, *Judicial Deference*] (noting how lower courts took *Chevron* as a guide to reviewing agency decisions by first looking for specific intent of Congress; then, if the Congress has not spoken to the issue, to decide, in a deferential manner, whether the agency’s interpretation of a statute is reasonable).

<sup>114</sup> *Chevron*, 467 U.S. at 842 (“[F]irst, always, is the question whether Congress has directly spoken to the precise question at issue.”).

<sup>115</sup> *Id.* at 842-43 (“If the intent of the Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress.”).

<sup>116</sup> *Id.* at 842-44. The *Chevron* two-step first considers whether Congress has explicitly spoken to the issue. If not, then consider whether the agency’s interpretation of the guiding statute is reasonable. *Id.*

<sup>117</sup> E. Donald Elliott, *Chevron Matters: How the Chevron Doctrine Redefined the Roles of Congress, Courts and Agencies in Environmental Law*, 16 VILL. ENVTL. L.J. 1, 3 (2005) [hereinafter Elliott, *Chevron Matters*].

<sup>118</sup> *Id.* at 2.

<sup>119</sup> *Id.* at 11 (“*Chevron*’s importance is also demonstrated by the change it caused in the dynamics inside agencies.”).

from the judiciary to the Executive Branch.”<sup>120</sup> However, the parameters of the *Chevron* standard were not immediately clear. Three significant issues persisted over the years: (i) what tools could be used for step one of *Chevron* to determine whether Congress had spoken to the precise issue, (ii) what agency decisions were entitled to *Chevron* analysis, and (iii) what qualified as “reasonable” under *Chevron* step two. First, it was not certain to what length a court could go to ascertain whether Congress has spoken to the matter, *i.e.*, what means of statutory interpretation could be used. Courts and scholars invoked various approaches to ascertain what Congress meant,<sup>121</sup> with some invoking a textualist approach,<sup>122</sup> rejecting the use of legislative history and trying to ascertain Congress’s meaning from the text alone, and sometimes with the help of dictionaries.<sup>123</sup>

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<sup>120</sup> *Id.* at 4. Although some commented that perhaps *Chevron* did not have to be seen as a major change, after time, as Professor Elliott notes, “*Chevron* signified a fundamental paradigm shift.” *Id.* at 2. See also Sunstein, *supra* note 4, at 2088 (“*Chevron* reflects a salutary understanding that these judgments of policy and principle should be made by administrators rather than judges.”). Professor Elliott notes that he initially characterized *Chevron* as affecting a subtle change. Elliott, *Chevron Matters*, *supra* note 117, at 1. In short, *Chevron* signaled a new era of judicial deference to agency interpretation. Merrill, *Judicial Deference*, *supra* note 113, at 971-72 (“*Chevron* is widely understood to mark a significant transformation in the Supreme Court’s jurisprudence of deference.”). Professor Merrill went on to explain however that *Chevron* failed to “produce anything like a complete revolution in the Court’s jurisprudence.” *Id.* at 980.

<sup>121</sup> See Richard J. Pierce, Jr., *The Supreme Court’s New Hypertextualism: An Invitation to Cacophony and Incoherence in the Administrative State*, 95 COLUM. L. REV. 749, 750 (1995) (discussing intentionalism and textualism).

<sup>122</sup> See, *e.g.*, *Immigration Naturalization Serv. v. Cardoza-Fonseca*, 480 U.S. 421, 452-53 (1987) (Scalia, J., concurring in judgment) (“Judges interpret laws rather than reconstruct legislators’ intentions.”).

<sup>123</sup> Gregory E. Maggs, *Reconciling Textualism and the Chevron Doctrine: In Defense of Justice Scalia*, 28 CONN. L. REV. 393, 398 (1996) (arguing that Justice Scalia, textualism’s Supreme Court provocateur, and textualism in general have been incorrectly labeled as hostile to the *Chevron* doctrine). Despite the growing emergence of textualism as the answer to *Chevron* step one, as recently as 2000 the Supreme Court arguably rejected the plain meaning of a statute in *Food and Drug Admin. v. Brown & Williamson Tobacco Corp.*, 529

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Second, for over twenty years after *Chevron* there was a debate over what “types” of agency decisions deserved *Chevron* analysis,<sup>124</sup> with some arguing that *Chevron* analysis should rely in part upon the format by which the agency issues an interpretation,<sup>125</sup> and others saying every authoritative agency interpretation deserves *Chevron*.<sup>126</sup> Finally in 2001, the Supreme Court in *United States v. Mead Corp.* addressed whether *Chevron* analysis would apply to customs classification rulings.<sup>127</sup> *Mead* rejected the government’s attempt to grab *Chevron* deference for rulings that could hardly be compared to regulations enacted pursuant to notice-and-comment procedures. Instead the Court fashioned a new mantra for the invocation of *Chevron*, namely whether “Congress intended such ruling to carry the force of law.”<sup>128</sup> However, even after *Mead*, questions regarding *Chevron*’s

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U.S. 120 (2000). At issue was the statutory meaning of the terms “drug” and “drug delivery devices.” Instead of limiting itself to the text, the Court considered prior legislative action and inaction in its *Chevron* analysis when discerning what Congress meant. *Id.* at 131-33.

<sup>124</sup> See Robert A. Anthony, *Which Agency Interpretations Should Bind Citizens and the Courts?*, 7 YALE J. ON REG. 1, 36-42 (1990) (discussing various formats for agency interpretations).

<sup>125</sup> *Id.*; Claire R. Kelly & Patrick C. Reed, *Once More Unto the Breach: Reconciling Chevron Analysis and De Novo Judicial Review After United States v. Haggart Apparel Company*, 49 AM. U. L. REV. 1167 (2000).

<sup>126</sup> *Christensen v. Harris County*, 529 U.S. 576, 590 (2000) (Scalia, J., concurring in judgment) (“Quite appropriately . . . we have accorded *Chevron* deference not only to agency regulations, but to authoritative agency positions set forth in a variety of other formats.”). For examples of authoritative agency decisions receiving *Chevron* deference, Justice Scalia cites *INS v. Aguirre-Aguirre*, 526 U.S. 415, 425 (1999) (adjudication); *NationsBank of N.C., N.A. v. Variable Annuity Life Ins. Co.*, 513 U.S. 251, 256-57 (1995) (letter of Comptroller of the Currency); *Pension Benefit Guaranty Corp. v. LTV Corp.*, 496 U.S. 633, 647-48 (1990) (evaluating the Pension Benefit Guaranty Corp. decision to restore pension benefit plan); *Young v. Cmty. Nutrition Inst.*, 476 U.S. 974, 978-79 (1986) (acknowledging the Food and Drug Administration’s “longstanding interpretation of the statute,” reflected in no-action notice published in the Federal Register”). *Christensen*, 529 U.S. at 590-91.

<sup>127</sup> 533 U.S. 218 (2001).

<sup>128</sup> *Id.* at 221. The Court stated:

[W]hen it appears that Congress delegated authority to the agency

application continued in *Barnhart v. Walton*.<sup>129</sup> As Robert Anthony points out, some unfortunate language in *Barnhart* mischaracterizes *Mead* and muddies the waters concerning to which types of agency interpretations *Chevron* applies.<sup>130</sup>

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generally to make rules carrying the force of law, and that the agency interpretation claiming deference was promulgated in the exercise of that authority. Delegation of such authority may be shown in a variety of ways, as by an agency's power to engage in adjudication or notice-and-comment rulemaking, or by some other indication of a comparable congressional intent.

*Id.* at 226-27.

<sup>129</sup> 535 U.S. 212 (2002). In *Barnhart*, the Court considered the Social Security Administration's interpretation of the word "disability." The Court had little problem finding the statute ambiguous and that *Chevron* analysis applied. Applying *Chevron*, the Court found that the agency's interpretation was a permissible one. *Id.* at 217-19.

<sup>130</sup> Robert Anthony, *Keeping Chevron Pure*, 5 GREEN BAG 2D 371 (2002). Professor Anthony quotes from *Barnhart*, "[*Mead*] indicated that whether a court should give such deference depends in significant part upon the interpretive method used and the nature of the question at issue." *Id.* at 372. Professor Anthony explains, "*Mead* said no such thing, either in the cited pages or elsewhere." *Id.* *Mead*, as explained by Professor Anthony, focused upon whether Congress had delegated to the agency the power to interpret with the "force of law." *Id.* In addition, Professor Anthony points out that the opinion also contains other language suggesting that a weighing of factors displaces the "force of law test established by *Mead*." *Id.* at 373.

In this case, the interstitial nature of the legal question, the related expertise of the Agency, the importance of the question to administration of the statute, the complexity of that administration, and the careful consideration the Agency has given the question over a long period of time all indicate that *Chevron* provides the appropriate legal lens through which to view the legality of the Agency interpretation at issue.

*Id.* at 373. Justice Scalia, in his concurrence in *Mead*, suggested that courts would struggle with its proscription for some time to come. *Mead*, 533 U.S. at 239. The Second Circuit has endorsed *Barnhart* in *Kruse v. Wells Fargo Home Mortgage*, 383 F.3d 49, 59 (2d Cir. 2004). See also *Cnty. Health Ctr. v. Wilson-Coker*, 311 F.3d 132, 137-38 (2d Cir. 2002).

Less formal interpretations may also be entitled to mandatory deference, depending upon to what extent the underlying statute suffers from exposed gaps in policies, especially if the statute itself is very

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Lastly, there is the question of what is a reasonable interpretation sufficient to satisfy step two of *Chevron*. Despite twenty years of cases and commentary, clarification of its breadth, scope, and meaning is still wanting.<sup>131</sup> Professor Levin has succinctly articulated the problem:

The vagueness of the step two standard was troubling enough, but more pertinent to my theme is the fact that the two-step test also seemed to verge on internal incoherence. Under the structure of the *Chevron* formula, a court should not reach step two unless it has already found during step one that the statute supports the government's interpretation or at least is ambiguous with respect to it. In other words, the agency's view is not clearly contrary to the meaning of the statute. If the court has made such a finding, one would think that the government's interpretation must be at least "reasonable" in the court's eyes. Why, then, is the second step not superfluous? Obviously, if it is to be meaningful, the step two inquiry has to involve *qualitatively different* considerations from those implicated during step one. Yet the Court's opinion did not identify those considerations. In this sense, *Chevron* left the very meaning of the second step ill-defined; further clarification was going to be necessary.<sup>132</sup>

In short, while *Chevron* shifted the balance between courts and agencies, it did so in a manner which was less than clear.<sup>133</sup>

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complex, as well as on the agency's expertise in making such policy decisions, the importance of the agency's decisions to the administration of the statute, and the degree of consideration the agency has given the relevant issues over time.

*Id.* at 137-38 (citing *Barnhart*, 535 U.S. 212 (2002)).

<sup>131</sup> William R. Andersen, *Against Chevron—A Modest Proposal*, 56 ADMIN L. REV. 957, 960-61 (2004). See Levin, *supra* note 110, at 1254 (noting that step two and arbitrary and capricious review are not just overlapping but identical).

<sup>132</sup> Levin, *supra* note 110, at 1260-61 (emphasis in original).

<sup>133</sup> As Professor Andersen points out, "other than litigation, there does not seem to be any practical way of predicting what a court will do with an agency legal interpretation." Andersen, *supra* note 131, at 961. See also Sunstein, *supra*

Perhaps, *Chevron*'s ambiguity stemmed from one of its positive attributes, namely that *Chevron* represented an attitude change.<sup>134</sup> It basically stood for the proposition that courts should and would be more deferential to agencies.<sup>135</sup> It is understandable that the specifics of that attitude would take time to evolve as the law needs to react to new contexts. Paradigm shifts are not intrinsically bad, but unclear or vague shifts are more subject to abuse and misapplication. Although paradigm shifts facilitate desirable legal evolution, ill-defined, or unclear shifts create a web of complex problems that take time to resolve.

Additionally, paradigm shifts change not only what happens in the courtroom but what happens elsewhere. The *Chevron* shift changed the way in which agencies operate. *Chevron* as a paradigm shift crept into the administrative psyche. Professor Donald Elliott has recently explained how *Chevron* affected internal agency functioning.<sup>136</sup>

Post-*Chevron*, statutes no longer possess a single prescriptive meaning on many questions; rather, they describe what I call a "policy space," a range of permissible interpretive discretion, within which a variety of decisions that the agency might make would be legally defensible to varying degrees. So the task of [the Office of the General Counsel] today is to define the boundaries of legal defensibility, and thereby to recognize that often there is

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note 4, at 2084 (noting the controversy *Chevron* spawned).

<sup>134</sup> Sunstein, *supra* note 4, at 2087. Professor Sunstein noted:

*Chevron* is best understood and defended as a frank recognition that sometimes interpretation is simply not a matter of uncovering legislative will, but also involves extra textual considerations of various kinds, including judgments about how a statute is best or most sensibly implemented. *Chevron* reflects a salutary understanding that their judgment of policy and principle should be made by administrators rather than judges.

*Id.* at 2087-88.

<sup>135</sup> Levin, *supra* note 110, at 1258 (noting that the courts and scholars "periodically speak of '*Chevron*' as shorthand for the principle of deference on questions of statutory interpretation").

<sup>136</sup> Elliott, *Chevron Matters*, *supra* note 117, at 1-2.

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more than one possible interpretation of the meaning of key statutory terms and concepts. The agency's policy-makers, not its lawyers, should decide which of several different but legally defensible interpretations to adopt.

*Chevron* opened up and validated a policy-making dialogue within agencies about what interpretation the agency should adopt for policy reasons, rather than what interpretation the agency must adopt for legal reasons. I believe that this expanded policy dialogue is productive and that it takes place more inside EPA today than it did pre-*Chevron*, and normatively, that is a good thing.<sup>137</sup>

Professor Elliott sees the *Chevron* change as "significant and positive."<sup>138</sup> Naturally, a *Daubert* shift would also affect how agencies function. One could argue whether the changes would be desirable, but the problem with *Daubert* creeping into the administrative state through an ill-defined standard is that it is difficult to assess what those changes might be and whether they would be desirable. Moreover, some agencies attempted to invoke *Chevron* for more than it was worth. *Mead* is one example of overreaching in the name of *Chevron*.<sup>139</sup> Naturally, that is what

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<sup>137</sup> *Id.* at 12-13.

<sup>138</sup> *Id.* at 13.

<sup>139</sup> As discussed above, *Mead* was a customs classification ruling case. Forty-six customs ports issue thousands of short, stock, and almost "form" ruling letters each year. These classification letters by their very nature interpret tariff terms and determine whether a particular item should be called by one term or another. As in most classification cases, it was easy to find ambiguity. Classification rulings made at most ports considered no policy and contained little or no reasoning although headquarters rulings like the one in *Mead* could contain more analysis. *Mead*, 533 U.S. at 224. Not surprisingly, the government had not asserted *Chevron* deference in the CIT. After *United States v. Haggart Apparel*, 526 U.S. 380 (1999), holding that *Chevron* applied to classification regulations, the Court of Appeals for the Federal Circuit requested the parties to brief the impact of *Haggart* on customs rulings. *Id.* at 225-26. At this point, the government argued *Chevron* deference. In my view, the government overreached here. *Mead* doubted whether the agency practice evidenced any thought by the agency whether it was acting under a "lawmaking pretense" when issuing the ruling in question. *Id.* at 233. As the court in *Mead* discussed,

advocates do; they try to stretch the precedent to reach their case. But ill-defined or unclear standards are easier to stretch.

*B. The Dangers of Daubert Creep in the Regulatory Realm*

A *Daubert* shift threatens the same problems seen in *Chevron* and promises particular dangers because it would be even vaguer and lacks *Chevron*'s administrative law grounding. Regulatory *Daubert* will likely engender many of the same problems associated with the *Chevron* shift, such as confusion, uncertainty, and manipulation. Because *Daubert* lacks *Chevron*'s administrative law connection, it threatens sound administrative law doctrine and gives rise to particular dangers. Some of these dangers include that it will be seen as a general license to distrust agency experts altogether and it will be transformed into an amorphous and malleable mantra of distrust in order to fit into the administrative framework. Already, one can see that attempts to invoke regulatory *Daubert* are muddied, confused, and ill-defined. To force *Daubert* upon agencies, courts have invoked its spirit, morphed it into a weighing device, misapplied it, and ignored unique attributes of particular agencies while invoking it. Finally, to the extent agency decision-making often blends factual and policy issues, regulatory *Daubert* will inevitably impede upon the policy function given to the agencies by *Chevron* and place it in the hands of the judiciary. In this regard *Daubert* is the counter-*Chevron*.

As discussed above, courts have also already begun an *ad hoc* Daubertization of administrative law.<sup>140</sup> As Part II indicated, courts

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“the authorization for classification rulings, and Customs’s practice in making them, present a case far removed not only from notice-and-comment process, but from any other circumstances reasonably suggesting that Congress ever thought of classification rulings as deserving deference claimed for them here.” *Id.* at 231. The Court went on to note, “it is hard to imagine a congressional understanding more at odds with the *Chevron* regime.” *Id.* at 233.

<sup>140</sup> As one set of commentators who propose that *Daubert* should apply to administrative decisions and believe that courts have already started applying it note, “[a]s the administrative bar becomes better acquainted with *Daubert*, we believe this judicial trend will accelerate.” Miller & Rein, *supra* note 26, at 298.

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have taken at least five different *Daubert* approaches (some of which can be combined with others): (i) generally sanctioning *Daubert* in administrative review cases and invoking the spirit of *Daubert* or *Daubert* principles, (ii) admitting *Daubert* is inapposite but invoking the spirit of *Daubert* or *Daubert* principles nonetheless, (iii) adopting *Daubert*-like language to impose higher gatekeeping standards on agencies and courts, (iv) rejecting *Daubert* as an admissibility rule but applying it as a weighing of the evidence rule, and (v) rejecting *Daubert* altogether in the administrative context. The combination of these approaches leads to at least five deleterious results: an ill-defined standard, confusion regarding unique agency attributes, rhetorical *Daubert*, generic *Daubert*, and the usurpation of policy-making by courts.

*1. An Ill-Defined Standard*

The various regulatory *Daubert* approaches foreshadow a murky paradigm shift with all the concomitant problems of uncertainty and manipulation. These approaches raise many unanswered questions including: whether *Daubert* will be an admissibility standard or a weighing of the evidence standard; which *Daubert* factors will be used; whether *Daubert* will displace or complement already established agency reliability procedures. It is unclear who will apply *Daubert*, the courts or the agency, and if the agency fails to apply *Daubert*, will the court apply it anew or simply view the matter as waived? One can expect advocates to answer these questions in ways that suit their clients and courts to struggle with their own answers over a long period of time.

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Miller and Rein suggest courts are already adopting *Daubert*, without citing it. They use the case of *Cellular Phone Taskforce v. FCC*, 205 F.3d 82 (2d Cir. 2000), to argue courts are adopting the *Daubert* posture when reviewing agency decision-making. “Although it lacks an express reference to *Daubert* standards, [it] is an example of judicial review of agency reliance on expert evidence in rulemaking that implicitly invokes the *Daubert* principles under the ‘arbitrary and capricious’ standard of review.” Miller & Rein, *supra* note 26, at 316. The court speaks in general terms about reliability, but in the end it is quite deferential to the agency and does not really apply the *Daubert* factors. *Cellular Phone Taskforce*, 205 F.3d at 91.

The cases thus far foreshadow these questions. For example, in *Elliott v. Commodity Futures Trading Commission* (CTFC),<sup>141</sup> the court sanctioned *Daubert* as both an admissibility and weighing rule in administrative agencies. The court however refused to hear an admissibility challenge to the CFTC's expert because the challenge had not been preserved at the ALJ level, even though the court opined that had the challenge been made successfully below, the court would have been inclined to agree with it.<sup>142</sup> The court went on to approve of the ALJ's weighing of the expert's testimony as unreliable, as had also been concluded by the agency itself.<sup>143</sup>

## 2. The Problem of Unique Agencies

Another problem with *Daubert* in the regulatory realm is the number and variety of agencies. Some agencies are unique and have unique relationships with the courts that review them. How will *Daubert* be adapted for each agency? What precedential effect will such adaptations have? *Libas v. United States*<sup>144</sup> contains an early invocation of *Daubert* as a weighing of the evidence standard in a regulatory context, and has been cited for the proposition that courts can use *Daubert* when reviewing agency action.<sup>145</sup> The case should be distinguished from other cases because of the United States Court of International Trade's (CIT) unique standard of

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<sup>141</sup> 202 F.3d 926 (7th Cir. 2000).

<sup>142</sup> *Id.* at 933-34.

<sup>143</sup> *Id.* at 934-35.

<sup>144</sup> 193 F.3d 1361 (Fed. Cir. 1999).

<sup>145</sup> Miller & Rein, *supra* note 26, at 308.

*Libas* is the first, but not the only, decision in which a reviewing court has applied *Daubert* scrutiny to an agency action other than formal adjudication. This emerging jurisprudence also stands in stark contrast to the plea for expert deference generally advanced by the government in cases involving review of agency scientific and technical decisions.

*Id.* at 310 (citations omitted). See also *Niam*, 354 F.3d at 660 (citing *Libas* for the proposition that the spirit of *Daubert* applies to administrative agencies); Weller & Graham, *supra* note 60, at 10569.

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review of Customs rulings.<sup>146</sup> The CIT reviews Customs classification rulings *de novo*.<sup>147</sup> Although classification rulings are entitled to a presumption of correctness,<sup>148</sup> this presumption is not to be confused with deference.<sup>149</sup> The CIT looks at all evidence anew and makes its own decision. The United States Court of Appeals for the Federal Circuit (CAFC) reviews the CIT's factual determinations for clear error and its legal determinations *de novo*.<sup>150</sup>

In *Libas*, the CAFC reversed the CIT's classification of imported merchandise as power-loomed fabric because it found the evidence relied upon by the CIT, namely the Customs' fabric testing, to be unreliable under *Daubert*. The CAFC agreed with the importer that *Daubert* applied and that nothing in *Daubert* or its progeny limited it to exclusion issues, rather it could also inform the weight given to evidence by a trial court.<sup>151</sup> Because the

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<sup>146</sup> Ct. Int'l Trade, Rule 52; *Libas*, 193 F.3d at 1365 (noting that no deference attaches to Customs classification of merchandise, rather "the [CIT] must consider for itself whether the government's classification is correct, both independently and in comparison with the importer's alternative") (citations omitted).

<sup>147</sup> 28 U.S.C. § 2640(a).

<sup>148</sup> *Id.* at § 2639(a)(1).

<sup>149</sup> *Rollerblade, Inc. v. United States*, 112 F.3d 481, 483-84 (Fed. Cir. 1997).

<sup>150</sup> Ct. Int'l Trade, Rule 52(a). Thus, as the CAFC points out in its very first sentence in the opinion, the "case is centrally about the responsibilities of a trial court to ensure that its determinations based on expert testimony are founded upon reliable, scientifically trustworthy procedures." *Libas*, 193 F.3d at 1361. Given that the CIT is conducting *de novo* review, it is not relying upon the agency expertise, rather it is the trier of fact, just as a court would be in a non-agency case to which *Daubert* would clearly apply. *See id.* at 1366.

In any event, if a trial court relies upon expert testimony, it should determine that the expert testimony is reliable. It would make little sense to say that a trial court in its fact-finding role should accord much if any weight to expert testimony, the reliability of which is not established.

*Id.*

<sup>151</sup> *Libas*, 193 F.3d at 1366. The CAFC thereafter qualified the CIT's mandate concerning *Daubert*:

Customs test was already part of the administrative record required to be filed with the court, the evidence could not be excluded.<sup>152</sup> The court then invoked *Daubert* as the standard by which the court should assess reliability. Upon remand, the CIT conducted a *Daubert* hearing and found Customs' expert evidence unreliable.<sup>153</sup>

At least one court and several commentators have cited the case to support regulatory *Daubert*.<sup>154</sup> Given the CIT's unique role reviewing Customs decisions, this citation is probably not the best one. As a court that reviews agency action *de novo*, it is a trier of fact much like a court in a typical civil or criminal litigation subject to *Daubert*.

### 3. Rhetorical Regulatory *Daubert*

*Daubert* appears in some administrative law cases as a rhetorical device, a slogan, and an unnecessary prop thrown into a court's analysis to simulate authority for the court's proposition. The danger of *Daubert* as a rhetorical tool is that it will become detached from any meaningful standard and will simply serve as a signal to distrust agency science. In *Consolidation Coal Company v. Director, Office of Workers' Compensation Programs*,<sup>155</sup> the court reviewed the Department of Labor's decision on the Black

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There is no iron law that the *Daubert* factors be applied in Customs classification cases. The Court of International Trade obviously need not use them in every case, or even in most such cases. These factors are primarily applicable when the question involves a technical process where the reliability of a scientific or technical methodology has been raised as an issue.

*Id.* at 1367.

<sup>152</sup> *Id.* at 1366 n.2. See also *Zani v. United States*, 86 F. Supp. 2d 1334, 1336 (Ct. Int'l. Trade 2000).

<sup>153</sup> *Libas, Ltd. v. United States*, 118 F. Supp. 2d 1233, 1237 (Ct. Int'l Trade 2000).

<sup>154</sup> See *Niam*, 354 F.3d at 660 (citing *Libas*, 118 F. Supp. 2d 1233, for the proposition that the spirit of *Daubert* applies to administrative agencies). See also *Elliott*, 202 F.3d at 934; Miller & Rein, *supra* note 26, at 308; Weller & Graham, *supra* note 60, at 10569.

<sup>155</sup> 294 F.3d 885 (7th Cir. 2002).

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Lung Benefits Act. In doing so, it affirmed the ALJ, finding that she had appropriately weighed the evidence. The ALJ had listened to the petitioner's witness and later found that his testimony was "unreliable and unconvincing, as the record is bereft of any evidence reflecting that Dr. Bruce has any specialized knowledge, training, or experience in the field of radiology."<sup>156</sup> On appeal the coal company attempted to show that the ALJ's decision was irrational because it conflicted with the evidence put forth by the petitioner's witness.<sup>157</sup> In sustaining the ALJ's decision, the court first noted that "although agencies are not bound by the evidentiary strictures of *Daubert*, litigants must still satisfy the ALJ that their experts are qualified by knowledge, training, or experience . . . and have in fact applied recognized and accepted medical principles in a reliable way."<sup>158</sup> *Daubert*'s reference is unnecessary to the court's decision, but it serves a rhetorical function. *Daubert*'s invocation cues an intolerance of sloppy agency science. Unfortunately it is not attached to a meaningful standard to assess agency science; it simply signals that sloppy science is present.

Likewise, in *United States Steel Mining Co. v. Director, Office of Workers' Compensation Programs*,<sup>159</sup> the court did not invoke *Daubert* but instead used *Daubert*-like language noting that "[b]ecause the [ALJ] failed to perform the important gatekeeping function of qualifying evidence under the [APA] before relying upon it, he made an award that [was] untenable."<sup>160</sup> The court acknowledged that the federal evidentiary rules had no place in administrative functioning but that, in order to facilitate efficiency, fairness, and accuracy, ALJs needed to perform a "gatekeeping function while assessing evidence to decide the merits of a claim."<sup>161</sup> It is unclear what the court means by "gatekeeping" when it discusses assessing evidence. The term gatekeeping seems

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<sup>156</sup> *Id.* at 888.

<sup>157</sup> *Id.* at 890.

<sup>158</sup> *Id.* at 893 (citing *Peabody Coal Co. v. McCandless*, 255 F.3d 465, 468 (7th Cir. 2001) (internal citations to *Daubert* omitted)).

<sup>159</sup> 187 F.3d 384 (4th Cir. 1999).

<sup>160</sup> *Id.* at 386.

<sup>161</sup> *Id.* at 388-89.

to suggest entry of evidence, not weight. The court later notes, “[t]hus, in an agency proceeding the gatekeeping function to evaluate evidence occurs when the evidence is considered in decision-making rather than when the evidence is admitted.”<sup>162</sup> Although the court also couched its opinion in terms of the obligations imposed by the APA, it seems correct to say that the court has been influenced by *Daubert* rhetoric, specifically that agencies either need gatekeepers or must become gatekeepers for themselves (to keep shoddy science away from their decision-making).<sup>163</sup>

It may be that judges deciding cases involving agencies are also the same judges that hear non-agency cases and apply *Daubert* to those cases regularly. As a result, they may simply be tempted to add in an unnecessary reference to gatekeeping or *Daubert* for “good measure.” But as *Daubert* creeps its way into review of agency action, it starts to appear as a rhetorical rallying cry for distrust of agency expertise.<sup>164</sup> “‘Junk science’ has no more place

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<sup>162</sup> *Id.* at 389.

<sup>163</sup> As discussed above, the APA already provides means to ensure the use of sound science by agencies. For example section 556(d) provides, “Any oral or documentary evidence may be received, but the agency as a matter of policy shall provide for the exclusion of irrelevant, immaterial or unduly repetitious evidence.” Section 556(d) continues, “a sanction may not be imposed or a rule or an order issued except on consideration of the whole record or those parts cited by a party and supported by and in accordance with reliable, probative and substantial evidence.”

<sup>164</sup> An entirely distinct use of *Daubert* involving agencies arises when agency risk assessment arises in the context of civil litigation to which the agency is not a party. *See, e.g.,* Buchholz v. Dayton Int’l Airport, No. C-3-94-435 1995 U.S. Dist. LEXIS 9490, \*71 (S.D. Ohio 1995); Allen v. Penn. Eng’g Corp., 102 F.3d 194 (5th Cir. 1996).

Regulatory and advisory bodies such as IARC, OSHA and EPA utilize a ‘weight of the evidence’ method to assess the carcinogenicity of various substances in human beings and suggest or make prophylactic rules governing human exposure. This methodology results from the preventive perspective that the agencies adopt in order to reduce public exposure to harmful substances.

*Id.* at 198. Conversely in *In re Paoli Railroad PCB Litigation*, 35 F.3d 717, 781 (3d Cir. 1994), the court found that the EPA studies suggesting causation of

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in administrative proceedings than in judicial ones.”<sup>165</sup> Hopefully it had no place before *Daubert*, but now *Daubert*, its spirit, and its gatekeeping language provide a tempting tool for advocates. Unfortunately, it is hard to see a principled way in which it operates other than to say that agencies ought to make sure that the science they use is reliable and sufficient—a duty agencies already had.

#### 4. Generic *Daubert*

A related danger in the regulatory world to rhetorical *Daubert* is generic *Daubert*. The problem of generic *Daubert* arises because regulatory *Daubert* is so ill-suited for the administrative framework that it is hard to use it in any way but a generic manner. Generic *Daubert* is one-size-fits-all. It can be one size fits all because it has no form, no boundaries; it is a piece of putty that can be shaped and contorted to whatever the cause. Thus, we see in *Peabody Coal Company v. McCandless*,<sup>166</sup> discussed above, the court morphs *Daubert* into a weighing test because the court cannot use *Daubert* as an admissibility test when reviewing the administrative record. Likewise, in *Elliott v. Commodity Futures Trading Commission*,<sup>167</sup> the court said that it would have used *Daubert* as an admissibility test if only the challenge had been made below, but since no challenge had been made, the court would countenance *Daubert* as a weighing of the evidence test.<sup>168</sup> Finally, as the cases discussed illustrate, courts have revealed little about what regulatory *Daubert* actually requires agencies to do,

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cancer based upon animal studies were sufficiently reliable to be used in litigation. *Id.* at 781 (noting in particular that “[c]ertainly, the evidence meets the relevance requirements of Rule 402 and we think, after taking a hard look, that it also meets the reliability requirement of Rules 702, 703 and 403”). *Id.* In this case, the court admitted the expert testimony under the *Daubert* standards when the EPA classified the chemical as a carcinogen. *Id.*

<sup>165</sup> *Niam*, 354 F.3d at 660.

<sup>166</sup> 255 F.3d at 468-69.

<sup>167</sup> 202 F.3d 926, 933-34 (7th Cir. 2000).

<sup>168</sup> See *supra* notes 141 to 143 and accompanying text.

leaving courts reviewing agencies to do almost anything.

To be fair, regulatory *Daubert* does not have to be generic. There are some voices that issue a clearer statement both for and against *Daubert*. Some commentators have offered explicit proposals of how *Daubert* could work in a regulatory context. For example, Alan Charles Raul and Julie Zampa Dwyer articulate a list of factors for courts to consider when reviewing agency action involving science including:

[W]hether 1. the agency used methodologies and procedures that were reliable and scientifically valid; 2. the scientific evidence relied upon was relevant for the issues before the agency; 3. the agency has set forth the scientific assumptions underlying its policy decisions and exposed any uncertainties; 4. the evidence before the agency supports the conclusion reached; 5. the agency has considered all the important factors; and 6. the agency has engaged in reasoned decision making, which includes demonstrating that there is a rational connection between the facts and the choice made.<sup>169</sup>

The problem with these factors is that they are duplicative of what the APA and the case law applying the APA already provide.<sup>170</sup> By giving the courts a new checklist to review agency action again, we are validating a shadow regime with vastly different goals than the one that exists. Moreover, there is a real danger that the courts will not apply factors in a methodical checklist fashion but as a symbol of less deference. True, agencies may fail to fulfill their responsibilities under the APA's arbitrary and capricious, or substantial evidence review.<sup>171</sup> When they do, they should be called to task on it, but their task should not change.<sup>172</sup>

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<sup>169</sup> Raul & Dwyer, *supra* note 5, at 26.

<sup>170</sup> As others have already noted, *Daubert* and its offspring of the DQA really do not mesh with the function of administrative agencies and indeed agencies already have mechanisms to ward off "junk science." Wagner, *Importing Daubert*, *supra* note 6, at 592-94.

<sup>171</sup> Raul & Dwyer, *supra* note 5, at 22-23.

<sup>172</sup> One set of commentators invokes the *Daubert* principles on the ground that "federal courts routinely—though unpredictably—strike down agency

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## 5. Courts Adopting a Policy-Making Role

A judicial incursion via regulatory *Daubert* will impede agency policy-making as well as agency reliance upon factual data. Agency functions include collecting and analyzing information and pursuing policy objectives in light of statutory mandates.<sup>173</sup> *Chevron* itself is an example of these blended tasks.<sup>174</sup> The Clean Air Act authorized the EPA to establish a permit program for new or modified stationary sources of air pollution.<sup>175</sup> In adopting its permit program, the EPA necessarily had to consider factual data concerning whether its interpretation would lower air pollution as envisioned by the statute.<sup>176</sup> Blended into this factual analysis was a policy decision that the statute could allow for economic growth.<sup>177</sup> One could imagine as a factual matter that perhaps a different interpretation of the stationary source term would allow for greater pollution reduction, or perhaps it would not. But the EPA's decision necessarily contained both factual and policy considerations. If a court were to substitute its judgment for the agencies, it would necessarily usurp part of the agency's policy-making role. One could argue that the court would not be aggrandizing itself because it would simply be restraining the agency. But stopping the agency from making the policy choice can be the same as making the policy choice. Thus, regulatory *Daubert* would be a counter-*Chevron* doctrine, taking the policy-making role away from agencies and giving it to the courts.

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actions because of flawed science and methodologies, and in the course of doing so, remark upon the inadequacy of agency science.” Raul & Dwyer, *supra* note 5, at 19.

<sup>173</sup> *Cf.* Professor Wagner has explained how DQA petitions challenge not only “scientific quality or reliability, but also contest embedded judgments and policy choices in the agencies’ use of scientific research.” Wagner, *Importing Daubert*, *supra* note 6, at 597.

<sup>174</sup> *See Chevron*, 467 U.S. at 840.

<sup>175</sup> *Id.*

<sup>176</sup> *Id.* at 848 (discussing the Emissions Offset Interpretive Ruling). *See id.* at 858 (discussing EPA’s reasons for adopting the new regulation).

<sup>177</sup> *Id.* at 843.

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The cases that have arisen thus far, the attempted incursions into the rulemaking context, and the statutory advances towards a *Daubert* shift all indicate a *Daubert* shift will hold the same confusion, potential for abuse, and disruption the *Chevron* shift caused. Already one can imagine the unanswered questions that will be resolved differently throughout the circuits and throughout agencies. For example, how will *Daubert* affect *Chevron*? What will it mean for “hard look” review?<sup>178</sup> Can it ever relate to admissibility? If it relates to weighing the evidence, then how does it affect that weighing? How will policy decisions be extricated from factual decisions and vice versa? What does an administrative agency *Daubert* hearing look like? These are just the beginning.

At the same time, what does regulatory *Daubert* get us? Some would argue that junk science has no place in administrative agencies. Agreed, but that is not because of *Daubert*. Yes, agencies should police themselves and when they fail, judicial review should remind them. But we already have mechanisms for this within the existing administrative law framework. A *Daubert* shift is about substantive deregulation. It is about agencies doing less in substantive areas that involve science.<sup>179</sup> To get agencies to do less, a *Daubert* shift will require the judiciary to reign in agencies.

#### CONCLUSION

The debate about regulatory *Daubert* should include a debate on its effects on administrative agencies and the law under which they function. It is difficult to have that debate in a meaningful way if regulatory *Daubert* is allowed to creep into the law,

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<sup>178</sup> See, e.g., *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29 (1983).

<sup>179</sup> Regulatory *Daubert* might be part of a larger attack on the use of science. David Michaels has written on efforts by industry to combat government relation through casting doubt on scientific studies used by agencies. See David Michaels, *Doubt is Their Product*, 292 SCI. AM., 96-102, June 2005, available at [http://www.powerlinefacts.com/Sciam\\_article\\_on\\_lobbying.htm](http://www.powerlinefacts.com/Sciam_article_on_lobbying.htm).

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operating as shadow authority and installing a new framework. This new framework is less deferential to agencies than the current framework. Commentators can argue about whether that is a good thing. But as it stands now this framework is ill-defined and creates a host of predictable problems, including confusion and abuse. It also promises unique problems because it lacks any administrative law grounding. It is ill-suited to apply across the board to all agencies, it is likely to be used in a rhetorical and meaningless way, and it is likely to be overused, morphed, and stretched to fit any conceivable situation.