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"Gatekeeping" Agency Reliance on Scientific and Technical Materials After Daubert: Ensuring Relevance and Reliability in the Administrative Process

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"Gatekeeping" Agency Reliance on Scientific and Technical Materials After *Daubert:* Ensuring Relevance and Reliability in the Administrative Process

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I. Introduction

The continued reduction in federal economic regulation has been more than offset by the growth of federal environmental, health and safety regulation through federal agencies such as the Environmental Protection Agency, Occupational Safety and Health Administration, Consumer Product Safety Commission, or the Food and Drug Administration. These agencies engage in a constant stream of administrative decisions which assess the health and safety consequences of private economic activity and the costs and benefits of regulatory interventions intended to alleviate the allegedly adverse consequences of that activity on human health and/or the natural environment.[1] Scientific and technical analysis is critical to the rational conduct of this regulatory process, and agencies premise their actions on scientific and technical information, relying both on agency expertise and expert submissions from interested private parties.[2] Courts reviewing

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[1] *See, e.g.,* Consumer Product Safety Act, 15 U.S.C. § 2058 (2000) (authorizing CPSC to promulgate consumer product safety rules); Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 371(a) (2000) (providing FDA authority to promulgate regulations); Occupational Safety and Health Act, 29 U.S.C. § 655(b)(5) (2000) (authorizing OSHA to set standards for "toxic materials or harmful physical agents" in the workplace); Clean Air Act, 42 § 7409(b) (2000) (authorizing EPA to establish national ambient air quality standards).

[2] *See, e.g.*, Final Rule To Amend the Final Water Quality Guidance for the Great Lakes System To Prohibit Mixing Zones for Bioaccumulative Chemicals of Concern, 40 C.F.R. § 132 (Nov. 13, 2000); Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body, 21 C.F.R. § 101 (Jan. 6, 2000); Regional Haze Standards, 40 C.F.R. § 51 (July 1, 1999); Identification of Dangerous Levels of Lead, 66 Fed. Reg. 1206, 1233-1234 (Jan. 5, 2001) (to be codified at 40 C.F.R. pt. 745); EPA, *Drinking Water Standard for Arsenic*, Fact Sheet EPA 815-F-00-015

these agency actions often defer to agency expertise on scientific and technical issues and affirm the agency so long as the administrative record contains some support for the agency's conclusions and reflects some consideration of all opposing points raised in the agency process.[3]

We believe that such an overly deferential standard of judicial review cannot survive analysis under the principles laid down by the Supreme Court in *Daubert*[4] and its progeny and now codified in Federal Rule of Evidence 702. In our view, those principles require federal courts reviewing administrative actions to enforce the same "gatekeeper" standards as those courts now require when reviewing a trial court's treatment of scientific and technical evidence. Judicial enforcement of "gatekeeper" responsibilities in the administrative process should properly discipline both agency decisionmaking and the processes by which administrative agencies address scientific and technical issues.

There are some early encouraging indications, as discussed below, that reviewing courts eventually will subject agencies to *Daubert* discipline. As the administrative bar becomes better acquainted with *Daubert*, we believe this judicial trend will accelerate. However, the process of accommodation could and should be further accelerated by a prompt and definitive Presidential action revising scientific and technical decision standards and processes for all Executive branch agencies through an appropriate Executive Order. We present an illustrative draft of such an Order at the conclusion of this article.

(January 2001) *available at* < http://www.epa.gov/safewater/ars/ars_rule_factsheet.html >.

[3] *E.g.*, Int'l Fabricare Inst. v. EPA, 972 F.2d 382,389 (D.C. Cir. 1992) (upholding drinking water standards for levels of pesticide DBCP and solvent "perc"); Trinity American Corp. v. EPA, 150 F.3d 389, 395 (4th Cir. 1998) (upholding emergency order requiring monitoring of foam plant); Hells Canyon Preservation Council v. Jacoby, 9 F.Supp.2d 1216, 1239-1240 (D. Or. 1998) (rejecting conservation group's challenge to categorical exclusion finding under the National Environmental Policy Act).

[4] Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993).

II. The Supreme Court's *Daubert* Cases - Critical Discipline For Scientific And Technical Decisions

A. The New Expert-Evidence Review Process - Ensuring Scientific And Technical "Relevance" And "Reliability"

The Supreme Court's *Daubert, Joiner, Kumho* and *Weisgram* decisions firmly established and substantially defined the role of federal judges as substantive "gatekeepers" when parties attempt to use expert scientific and technical evidence to prove their cases in court.[5] *Daubert* initiated the concept of a gatekeeper role for the trial judge in respect to "scientific" expert testimony offered under the old Federal Rule of Evidence 702, requiring the judge to determine whether a proffered expert opinion is both "reliable" and "relevant" to the issue at bar.

Proposed expert evidence that is not both reliable and relevant must be excluded from consideration by the finder of fact as being "speculation," rather than "knowledge." Justice Blackmun's opinion for the Court in *Daubert* began with Rule 702 language providing that, "If scientific, technical, or other specialized knowledge will assist the trial of fact," an expert "may testify thereto,"[6] and reasoned that "the word 'knowledge' connotes more than subjective belief or unsupported speculation."[7] Qualifying scientific knowledge is "derived by the scientific method" and expert opinion "testimony must be supported by appropriate validation - i.e. 'good grounds,' based on what is known."[8]

The Supreme Court's 1999 *Kumho* decision subsequently made express that the obligation to "ensure that any and all scientific testimony is not only relevant, but reliable" equally "applies to all expert testimony."[9] Where called into question, the

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[5] *See* Dauber v. Merrill Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993), 113 S. Ct. 2786; General Electric Co. v. Joiner, 522 U.S. 136, 118 S. Ct. 512 (1997); and Kumho Tire Co., Ltd. v. Carmichael, 526 U.S. 137, 119 S. Ct. 1167 (1999); Weisgram v. Marlay Co., 528 U.S. 440, 120 S. Ct. 1011 (2000).

[6] 509 U.S. at 589.

[7] *Id.* at 590.

[8] *Id.*

[9] 526 U.S. at 147.

trial "judge must determine whether the testimony has 'a reliable basis in the knowledge and experience of [the relevant] discipline.'"[10] Thus, *Kumho* expanded the gatekeeper function to encompass at least all scientific and technical expert testimony offered under Rule 702. Additionally, *Kumho* clarified that in exercising the gatekeeper function, the trial judge must analyze not only the general reliability of an expert's methodology but also the application of that methodology to the specific issue and facts of the case at bar.[11]

Joiner specified an "abuse of discretion" standard for appellate courts to apply in reviewing the trial judge's performance of the gatekeeper function.[12] *Weisgram* further strengthened the authority of both appellate and trial judges to terminate litigation (rather than authorizing a new trial) where essential expert testimony was found to have been erroneously admitted.[13] In this context, the trial court's discretion includes "broad latitude when it decides *how* to determine reliability,"[14] but it "is not discretion to abandon the gatekeeping function" and "it is not discretion to perform the function inadequately."[15] Neither "the difficulty of the task nor any comparative lack of expertise can excuse the 'gatekeeping' duties that the Federal Rules of Evidence impose."[16]

The Supreme Court has stressed that "judges have increasingly found in the Rules of Evidence and Civil Procedure

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[10] 526 U.S. at 149, quoting *Daubert*, 509 U.S. at 592.

[11] The "issue before the court" is not the "*reasonableness in general of*" an "expert's use" of a given methodology; rather it is "the reasonableness of using such an approach," along with the expert's "particular method of analyzing the data thereby obtained to draw a conclusion regarding *the particular matter to which the expert testimony was directly relevant.*" 526 U.S. at 153-54.

[12] 522 U.S. at 143.

[13] Justice Ginsburg, writing for a unanimous Court, made unmistakably clear that a Court of Appeals "may instruct the entry of judgment as a matter of law for defendant" under Federal Rule of Civil Procedure 50. The Court rejected the plaintiff's contention that when expert testimony is "excised" on appeal for failure to meet the *Daubert* reliability standards, the appellate tribunal must "remand the case, leaving to the district court's discretion the choice between final judgment for defendant or a new trial of the plaintiff's case." 528 U.S. at 443.

[14] *Kumho*, 526 U.S. at 142.

[15] 526 U.S. at 158-59 (Justice Scalia, concurring).

[16] *Joiner*, 522 U.S. at 148 (Justice Breyer, concurring).

ways to help them overcome the inherent difficulty of making determinations about complicated scientific or otherwise technical evidence."[17] On review, the appellate court's role is to examine the trial court's analysis and determine whether the assessments of relevance and reliability were conducted adequately. This includes examination of the trial judge's evaluation of whether there is "too great an analytical gap between the data and the opinion proffered."[18] That process requires the appellate court itself to become substantially immersed in the application of the particular discipline of the proposed expert to the facts and theories incorporated in the specific opinion offered.[19]

The long-term institutional impact of these Supreme Court decisions has been further strengthened by the adoption of amendments to Federal Rule of Evidence 702 codifying the Court-defined rules requiring that expert evidence be found relevant and reliable before it may be used by the factfinder. These amendments were approved by the Judicial Conference's Advisory Committee on Evidence Rules in May, 1999,[20] by the Judicial Conference in September, 1999,[21] and by the Supreme Court on April 17, 2000.[22] Following the period allowed for review by Congress, which ran without legislative intervention, these amendments became effective on December 1, 2000.[23] Thus, the

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[17] *Id.* at 149. Examples of these techniques include "an increased use of Rule 16's pretrial conference authority to narrow the scientific issues in dispute, pretrial hearings where potential experts are subject to examination by the court, and the appointment of special masters and specially trained law clerks." *Id.*

[18] 522 U.S. at 146.

[19] Justice Breyer's example of such a review in *Kumho*, which involved opinions on the cause of an automobile tire blow out, even included a cutaway drawing of a tire to illustrate "Radial-Ply Tire Construction." 526 U.S. at 143.

[20] Report of the Advisory Committee on Evidence Rules to the Standing Committee on Rules of Practice and Procedure at 5-7 (May 1, 1999).

[21] "Judicial Conference Proposes Changes to Rules of Evidence," BNA Criminal Law Reporter 612 (September 22, 1999).

[22] 68 U.S.L.W. 4303 (Apr. 25, 2000).

[23] As amended by the addition of the underlined language, the Rule reads as follows:

Rule 702. Testimony by Experts

If scientific, technical, or other specialized knowledge will assist the trier of fact to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the

principle that expert scientific and technical information not shown to be relevant and reliable must be excluded from the decisional process has been endorsed by the Supreme Court, as well as the Congress.[24] That principle fairly may be described as fundamental to the concept of due process in government actions affecting liberty and property interests.[25]

B. The Daubert Process - Transcending Rule 702's Limits

The Supreme Court developed the *Daubert* principles in interpreting and amending Rule 702, a rule governing the

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testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

[24] Even prior to these recent actions, a number of courts had read *Daubert* and *Joiner* to require a vigorous approach to assessing the reliability of opinions in a number of different litigation contexts. *See e.g.,* Blue Dane Simmental Corp. v American Simmental Assoc., 178 F.3d 1035 (8th Cir. 1999) (agricultural economist's expert opinion excluded); Target Market Publishing, Inc. v ADVO, Inc., 136 F.3d 1139 (7th Cir. 1998) (business appraiser's lost profits opinion excluded); U.S. v. $141,700 in U.S. Currency, 157 F.3d 600 (8th Cir. 1998) (chemist's opinion based on drug testing residue on currency excluded); Burns Philip Food, Inc. v. Cavalea Continental Freight, Inc., 135 F.3d 526 (7th Cir. 1998) (environmental consultant's land runoff opinion excluded); Black v. Food Lion, 171 F.3d 308 (5th Cir. 1999) (opinion on fibromyalgia excluded); Michigan Millers Mut. Ins. Corp. v. Benfield, 140 F. 3d 915 (11th Cir. 1998) (opinion of arson expert excluded); Kirsten v. Parks Corp., 159 F. 3d 1065 (7th Cir. 1998) (opinion of industrial safety expert excluded for doing no testing on the products at issue); Ancho v. Pentek Corp., 157 F.3d 512 (7th Cir. 1998) (mechanical engineer's opinion on design of factory excluded); Tanner v. Westbrook, 174 F.3d 128 (5th Cir. 1999) (neonatology expert's opinion on birth asphyxia/cerebral palsy excluded); Robertson v. Norton Co., 148 F.3d 905 (8th Cir. 1998) (product warnings expert excluded); Ruffin v. Shaw Industries, 149 F.3d 294 (4th Cir. 1998) (opinion on toxic exposure to carpet chemicals excluded); Moore v. Ashland Chemical, Inc., 151 F.3d 269 (5th Cir. 1998) (clinical medicine expert's opinion on toxic fume exposure and reactive airway disease excluded); Huey v. United Parcel Service, Inc., 165 F.3d 1084 (7th Cir. 1999) (vocational expert's opinion on retaliatory discharge excluded).

[25] The probable enduring nature of the *Daubert* process is signaled by the fact that there is a broad supporting consensus within the Supreme Court that cuts across the ideological lines that produce close, bitterly divided decisions in certain other areas. Thus, *Daubert* was a 7-2 decision, *Joiner* 8-1, *Kumho* 8-1, and *Weisgram* 9-0. The Justices who authored the opinion of the Court in these cases represented a range of judicial philosophies: Blackmun (*Daubert*), Rehnquist (*Joiner*), Breyer (*Kumho*), and Ginsburg (*Weisgram*).

admission of expert evidence at trial. For that reason, the full scope of the *Daubert* transformation, which goes far beyond refining an evidence-admissibility rule, is not always appreciated fully. The *Daubert* paradigm involves both fundamental changes in the decisional process and the role of judges in dealing with expert scientific and technical evidence or decisions that turn on such evidence. *Daubert* requires judges to understand and to explain both the general discipline involved and the logic of the particular expert opinion that is offered. Judges at all levels must now become immersed in, and appropriately conversant with, the wide range of scientific, technical or other types of specialized knowledge arising in a wide variety of cases. No longer may a federal judge simply "defer" to a proposed expert on the ground that he or she has good credentials in a field that is unusual or difficult.

An equally important change in the judicial process involves creation and use of a record relating to expert testimony. The parties and the trial court have duties to create a record showing the bases and logic of the expert opinion offered, as well as the reasoning that is found to support the opinion's admission or exclusion.[26] District Judges increasingly have concluded that preparing a Rule 702 record that can withstand judicial review requires preparation of a written opinion that includes a statement of specific findings,[27] and recent appellate decisions support that view. [28] As required by *Joiner* and *Weisgram*, appellate courts must analyze the record relied on to conclude that expert evidence

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[26] On the case-management implications of the *Daubert* process, *see* Paul S. Miller et al., *Weisgram v. Marley Co.: Strengthened Powers and Duties in Gatekeeping under Daubert*, 2 Science in the Courtroom Review 1, 11-18 (2000).

[27] *See, e.g.*, Hon. Janice Kessler (U.S. District Court for the District of Columbia), "View from the Bench: One Federal Judge's Approach to *Daubert* issues," presented as part of the D.C. Bar Continuing Legal Education program entitled, "Expert Witnesses in Federal Court: Kumho Tire in the Next Millennium," Oct. 4, 1999.

[28] Goebel v. Denver and Rio Grande Western Railroad Company, 215 F.3d 1083, 1088 (10th Cir. 2000) (We "specifically hold that a district court when faced with a party's objection, must adequately demonstrate by specific findings on the record that it has performed its duty as gatekeeper.").

is (or is not) relevant and reliable, in the manner illustrated by Justice Breyer's *Kumho* opinion.[29]

In summary, the *Daubert/Kumho* mandate requires judges preparing civil or criminal cases for trial to assess the relevance and reliability of expert evidence by personally evaluating the bases and logic of each opinion and creating a record that will permit reviewing courts meaningfully to evaluate that decisional process. While the *Daubert* process is relatively new – the Supreme Court's key decision in *Kumho* was announced in March, 1999[30] – it may fairly be anticipated that federal judges will increasingly become skilled "gatekeepers" both in developing and analyzing a *Daubert* record.

As federal judges become fully acclimated to the *Daubert* process, [31] they understandably will be driven to question why those same principles of relevance and reliability should not apply

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[29] See part III of the opinion, 526 U.S. at 153-158.

[30] Prior to *Kumho*, development of the *Daubert* process was hindered by conflicts among the circuits as to the scope of opinion covered by *Daubert* and *Joiner*. Specifically, the Second, Ninth and Tenth Circuits had taken the position that the *Daubert* decision was inapplicable altogether to admissibility decisions on non-science expert opinions. (*See, e.g.,* Iacobellii Construction, Inc. v .County of Monroe, 32 F.3d 119 (2d Cir. 1994); McKendall v. Crown Control Corp., 122 F.2d 803 (9th Cir. 1997); Compton v. Subaruu of America, Inc., 82 F.3d 1513 (10th Cir. 1966), *cert. Denied*, 519 U.S. 1042, 117 S. Ct. 611 (1996)). The First, Fourth and Eleventh (where *Kumho* arose) Circuits developed some gatekeeper role for non-science opinions, but it was not the same as the role described by *Daubert* (*See, e.g.,* Bogosian v. Mercedes-Benz of North America, Inc., 104 F.3d (1st Cir. 1997); Talkington v. Atria Reclamelucifers Fabrieken BV (Cricket BV*)*, 152 F.3d 254 (4th Cir. 1998); Carmichael v. Samyang Tire, Inc., 131 F.3d 1433 (11th Cir. 1997)). The Fifth, Sixth, Seventh and Eighth Circuits tended to apply *Daubert* to all expert testimony and their reliability doctrines would have more current validity. (*See, e.g.,* Watkins v. Telsmith, Inc., 1121 F.3d 984 (5th Cir. 1997); United States v. Jones, 107 F.2d 1147 (6th Cir. 1997); Deimer v. Cincinnati Sub-Zero Products, Inc., 58 F.3d 341 (7th Cir. 1995); Pestel v. Vermeer Manufacturing Co., 64 F.3d 382 (8th Cir. 1995)).

[31] Further support for recognizing the general applicability of the *Daubert* principles may arise from state court practice. The state court systems of a majority of states have adopted a copy of Rule 702 or have adopted doctrines similar to the *Daubert* relevance and reliability doctrines through interpreting their somewhat different rules governing expert opinion testimony. See Sorett, "Junk Science in the States -- The Battle Lines," 2 Science in the Courtroom Review 29 (2000).

to the use of expert materials in agency rulemaking and other administrative actions that are not governed by the Federal Rules of Evidence.[32] Although the Supreme Court's *Daubert*-line opinions reason in terms of the language of Rule 702, the principle that "subjective belief or unsupported speculation" is not an appropriate basis for government decisionmaking has been broadly recognized, including at the constitutional Due Process level.[33] Consequently, where agency rulemaking or similar decisionmaking purports to be based on scientific, technical or other specialized information, *Daubert*-trained judges instinctively and appropriately will recognize that the scientific or technical expertise relied upon by agencies ought not to be mere speculation or subjective belief.[34] Thus, we anticipate increasingly frequent

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[32] The thesis developed here is not that administrative agencies should be required to follow the Federal Rules of Evidence in general. Indeed, such a requirement clearly would be counterproductive in many scenarios. 2 Kenneth Culp Davis & Richard J. Pierce, Jr., Administrative Law Treatise § 10.1, p. 117 (3d ed. 1994). What we do contend is that the *Daubert* process should be applied generally by administrative agencies, notwithstanding the fact that this process was developed through cases construing FRE 702.

[33] Blue Cross & Blue Shield of New Jersey, Inc. v. Philip Morris, Inc., 113 F.Supp.2d 345, 375 (E.D.NY 2000) ("the use of statistical evidence (subject to satisfaction of the *Daubert* criteria) ... does not violate due process strictures"); *United States v. Perrone*, 936 F.2d 1403, 1419 (2d Cir. 1991) (using facts about quantity of drug production premised on "speculation violates the commitment to due process where, as here, difference in quantity can have enormous impact on the sentence to be imposed.")

[34] Imposing the *Daubert* principles on agency decisionmaking also has found support in legal literature. *See, e.g.*, Charles D. Weller & David B. Graham, *New Approaches to Environmental Law and Agency Regulation: The Daubert Litigation Approach*, 30 Envtl. L. Rep. 10557 (July 2000) ("As a matter of policy and statutory interpretation, the *Daubert* reliability standard should apply to federal environmental agencies in rulemaking and adjudication."); D. HiepTruong, *Daubert and Judicial Review: How Does an Administrative Agency Distinguish Valid Science from Junk Science?*, 33 Akron L. Rev. 365 (2000) ("by using Daubert standards, the Court is not second-guessing the agency's decisionmaking, but is simply ensuring ... that the evidence relied upon by the agency meets the same threshold requirements that a federal litigant is already subjected to."); Andrew Trask, *Daubert and the EPA: An Evidentiary Approach To Reviewing Agency Determinations of Risk*, 1997 U. Chi. Legal F. 569 (1997) ("Applying the *Daubert* gatekeeping function thereby allows courts to check the validity of the agency's reasoning while maintaining the proper amount of deference to the agency's rulemaking and adjudicative powers.");

use of the *Daubert* principle in reviewing agency action, particularly if counsel are alert to this opportunity. In fact, the beginning of such a trend has become visible.

III. Courts Are Beginning To "*Daubertize*" Review Of Agency Action

There are many categories of agency action, ranging from individual adjudications that are very much like civil litigation to notice and comment rulemakings that can be almost legislative in breadth. We see no reason why "junk science" or unreliable technical information should provide legally adequate support for an agency's decision in any type of administrative action, and recent decisions show increasing judicial support for that position.

A. The Daubert Process Applied To Benefits Adjudication.

Some of what agencies do is "adjudicative" in nature, such as determining whether an individual claim for benefits under the federal Black Lung Benefits Act warrants payment. Black lung contested claims are heard and resolved in the first instance by an Administrative Law Judge ("ALJ"), subject to review by the Benefits Review Board and then by the U.S. Courts of Appeals. The courts have found no difficulty in requiring that opinions of experts on cause of death in black lung adjudications be subjected to the *Daubert* process, as illustrated by the Court of Appeals decision in *United States Steel Mining Co. v. Director, Office of Workers' Compensation Programs, U.S. Department of Labor.*[35] The Fourth Circuit, in discussing the review process, first explained that the governing provision of the Administrative

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Mary Christina Wood, *Reclaiming the Natural Rivers: The Endangered Species Act as Applied to Endangered River Ecosystems,* 40 Ariz. L. Rev. 197, 259-262 (Spring 1998) (arguing that "*Daubert* has, albeit indirectly, deflated the driving rationale behind agency deference" because in a post-*Daubert* world judges have to make decisions about scientific evidence through admissibility gatekeeping).

[35] 187 F. 3d 384, 390 (4th Cir. 1999) (reversing award where the "only evidence in the record [on causation] is Dr. Rasmussen's speculative statement").

Procedure Act, 5 U.S.C. § 556(d), makes the exclusion required by FRD 702 inapplicable and requires a *Daubert* adaptation:

> Section 556(d) of the Act recognizes the reality that rigorous exclusionary rules for the admission of evidence make little sense in hearings before an administrative agency where the ALJ acts as both judge and factfinder. When the judge is also factfinder, he is equally exposed to evidence whether he admits it or excludes it.
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> In that context, the courts have required the ALJ to admit "all relevant evidence, erring on the side of inclusion."[36] The gatekeeping begins after admission, as explained in *U.S. Steel Mining Co.*:
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> But even though the more stringent exclusionary rules of evidence, which are generally applicable to jury trials, are not justified in agency proceedings, the agency process nonetheless requires that the ALJ perform a gate keeping function while assessing evidence to decide the merits of a claim. To assure both fairness in the process and an outcome consistent with the underlying statutory scheme, the ALJ has, under § 556(d) of the Administrative Procedure Act, the affirmative duty to qualify evidence as "reliable, probative, and substantial" before relying upon it to grant or deny a claim.[37]

Thus, the *Daubert* process becomes decisional rather than focused on admissibility. As summarized by the Fourth Circuit:

> in an agency proceeding the gate keeping function to evaluate evidence occurs when the evidence is considered in decisionmaking rather than when the evidence is admitted. Even though it arises later in the administrative process than it does in jury trials, the ALJ's duty to screen evidence for reliability, probativeness, and substantiality similarly ensures that final agency decisions will be based on evidence of requisite quality and quantity.[38]

In short, the *U.S. Steel Mining* Court made unmistakably clear that the agency factfinder has a duty to "screen evidence for

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[36] Underwood v. Elkay Mining, Inc., 105 F. 3d 946, 951 (4th Cir. 1997).
[37] 187 F.3d at 388-89.
[38] *Id.* at 389.

reliability" to ensure that the final agency decision is "based on evidence of requisite quality and quantity" and that a reviewing court must enforce that duty.

B. Tariff Classification And Other Agency Actions Scrutinized Using Daubert Principles

The utility of applying *Daubert* principles in review of agency action also is exemplified by the import tariff classification decision in *Libas, Ltd. v. United States.*[39] Libas sought to import fabric into the United States under the tariff rules applicable to "hand-loomed" fabric, but the U.S. Customs Service classified the fabric as "power-loomed" based on "a new test developed by the Los Angeles Customs Laboratory."[40] The result was to subject the fabric to a higher tariff rate and a quota. Libas sought review of the classification before the Court of International Trade, which affirmed based on the results of the Customs test.[41] On appeal to the Federal Circuit, Libas contended that the trial court erred "because the methodology involved in the Customs test was not shown to be reliable or properly validated by scientific or other appropriate technical means,"[42] relying on *Daubert* and *Kumho.*

The Federal Circuit properly first acknowledged that "*Daubert* and Kumho were decided in the context of determining standards for the admissibility of expert testimony under the Federal Rules of Evidence, which are not at issue here,"[43] because the Customs test was not "admitted" but, instead, was "part of the record" supporting the Customs determination that was transferred to the Court of International Trade pursuant to the statutory procedure governing judicial review.[44] The Federal Circuit, nevertheless, recognized the importance of *Daubert* and *Kumho*, reasoning as follows:[45]

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[39] 193 F.3d 1361 (Fed. Cir. 1999).
[40] 193 F.3d at 1363.
[41] Libas Ltd. v. U.S., 944 F. Supp. 938 (1996).
[42] 193 F.3d at 1365.
[43] *Id.* at 1366 n.2.
[44] *Id.* at 1366.
[45] *Id.* at 1366.

We agree with Libas, however, that the proposition for which they stand, that expert testimony must be reliable, goes to the weight that evidence is to be accorded as well as to its admissibility. Neither the plain language of the relevant Supreme Court opinions nor the underlying principles requiring reliability for expert testimony are narrowly confined in application to questions of admissibility.

Consequently, the Federal Circuit, as contemplated by *Joiner*, went on to scrutinize the administrative record, seeking evidence establishing that the Customs test was valid, and focused its analysis on the four factors related to reliability identified in *Daubert*.[46]

The Court of Appeals found that "the Customs test fails to satisfy any of [the *Daubert*] factors except – possibly – general acceptance, and it offers no other assurances of reliability based on factors not mentioned in *Daubert* to make up for those defects."[47] The Court concluded, "therefore, it was clearly erroneous for the trial court to credit the testimony of Customs' witnesses that the test could distinguish between power-loomed and hand-loomed fabric."[48] It then remanded the case to the Court of International Trade "for further findings because the trial court was not on notice that in circumstances like those presented here, it was obliged to make an assessment of reliability based on the sort of analysis we have described."[49]

Following remand, the Court of International Trade "conducted a hearing to assess the reliability of Customs' test"[50] and found, based on analysis of the resulting record, that Customs "failed to establish that its test satisfied any of the *Daubert*

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[46] As described by the Federal Circuit:
The Supreme Court, in Daubert, cited four such factors: (1) the testability of the hypothesis; (2) whether the theory or technique has been subject to peer review and publication; (3) the known or potential rate of error; and (4) whether the technique is generally accepted. 509 U.S. at 593-94, 113 S.Ct. 2786.
193 F. 3d at 1366-67.

[47] 193 F.3d at 1369.

[48] *Id.*

[49] *Id. Libas* was decided before *Weisgram*, which made clear that where there has been fair notice, the Court of Appeals properly may terminate the litigation by order favorable to the party not relying on the unreliable expert proof.

[50] *Libas Ltd. v. U.S.*, 118 F. Supp. 2d 1233, 1235 (Ct. Int. Trade 2000).

standards cited by the Federal Circuit" or "any other indicia of reliability."[51] The Court then concluded that, without reliable evidence, Customs "fails to prove that the fabric at issue was power-loomed,"[52] and ordered the fabric reclassified as hand-loomed.[53]

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.[54] 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. As set forth by the Justice Department in a recent FDA review case:

Courts "review scientific judgments of the agency 'not as the chemist, biologist, or statistician that we are qualified neither by training nor experience to be, but as a reviewing court exercising our narrowly defined duty of holding agencies to certain minimal standards of rationality.' "*Troy Corp. v. Browner,* 120 F.3d 277, 283 (D.C. Cir. 1997) (quoting in part *Ethyl Corp. v. EPA,* 541 F.2d 1, 36 (D.C. Cir. 1976)). *See also New York v. Reilly*, 969 F.2d 1147, 1152 (D.C. Cir. 1992).[55]

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[51] *Id.* Both the Court of Appeals and the Court of International Trade clearly were troubled by the failure of Customs to attempt to validate its test by running the test in circumstances where a number of pieces of fabric actually known to be hand-loomed or power-loomed were tested by testers who did not know in advance whether the tested samples were hand-loomed or power-loomed.

[52] 118 F. Supp. 2d at 1237.

[53] *Id.* at 1238.

[54] The *Libas* treatment of *Daubert* doctrines has been endorsed by other appellate courts. *Elliott v. CTFC*, 202 F.3d 926, 934 (7th Cir. 2000) ("Daubert and Kumho were decided in the context of admissibility, but the principle for which they stand - that all expert testimony must be reliable - should apply with equal force to the weight a factfinder accords expert testimony"); *Rucker v. Brown*, 10 Vet.App.67, 73 (Ct. Vet. App. 1997) (In Veterans Appeal Board Action on benefits claims, "reference to the criteria found in *Daubert* ... would more thoroughly elucidate the necessary 'reason and bases' for the Board's decision").

[55] Brief for Appellees Donna E. Shalala, et al. in *Pfizer Inc. v. Donna E. Shalala*, D.C. Cir. No. 98-5151, filed Nov. 4, 1998, at 17-18. The quoted language from *Troy* was dictum related to an issue of construing ambiguous statutory language (governed by *Chevron U.S.A. Inc. v. National Resources Defense Council,* 467 U.S. 837 (1984)), where the Court of Appeals "would have to conclude that [EPA's] interpretation either ran athwart a clear mandate of Congress, or was an

We would hope that the government would rethink this position in light of *Daubert* and accelerate the *Libas* trend, but revision may be a slow process absent Presidential direction. In addition, judicial review of agency action takes place under a variety of statutory provisions, as well as the Administrative Procedure Act, and a comprehensive *Daubert* review jurisprudence will take years to develop. Finally, as we now discuss, the courts have not yet come to grips with the application of *Daubert* principles to informal rulemaking.

IV. The *Daubert* Process Properly Applies To Agency Rulemaking

We have found no case applying *Daubert/Kumho* principles to the review of a regulation arising from informal rulemaking under the Administrative Procedure Act. We believe that void partly reflects that novelty of the *Daubert* process and partly the fact that neither agencies nor advocates have had time to digest fully its relevant implications.

A. The Nature And Uses Of Informal Rulemaking

Health and safety agencies generally use informal rulemaking as a vehicle for promulgating regulations incorporating scientific and technical conclusions. In informal notice and comment rulemaking, the agency publishes notice of a proposed rulemaking in the *Federal Register*, after which interested persons have a fixed period of time (specified by each agency or by executive order) to make submissions concerning the proposed rule.[56] After the comment period expires, the agency must consider the public comments before promulgating a final rule. In

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unreasonable one." 120 F.3d at 284. When it came to considering EPA's classification of specific chemicals, the Court scrutinized very carefully what EPA had done, and where the Court found inconsistencies, it vacated the EPA action, stating that absent "further explanation of its different approaches in the two cases, the agency has acted arbitrarily and capriciously in listing Bronopol as a chronic toxicant." 120 F.3d at 291.

[56] Administrative Procedure Act, 5 U.S.C. § 553 (2000).

their final rulemaking decisions, agencies are required to explain the basis and purpose of their actions including the scientific and technical analyses which support them.[57]

Examples of informal rulemakings include the EPA's issuance of air quality standards under the Clean Air Act[58] and CPSC requirements for child resistant packaging under the Poison Prevention Packaging Act.[59] In addition, OSHA promulgates workplace safety and health regulations using an informal notice and comment procedure.[60] Even where a health and safety agency such as FDA focuses on a specific type of product (*e.g.*, breast implants), it is likely to employ an informal process rather than a formal adjudicatory proceeding.[61]

Under informal rulemaking procedures, agencies typically do not develop a controlled administrative record equivalent to the record that would be produced in a trial court.[62] Unlike judicial fora which are responding to cases initiated by public or private parties, agencies are most often the initiators of the regulatory proceedings on which scientific and technical analysis is brought to bear.[63] Agencies initiate these proceedings with proposals based

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[57] 5 U.S.C. § 553(c) (2000) ("After consideration of the relevant matter presented, the agency shall incorporate in the rules adopted a concise statement of their basis and purpose.").

[58] 42 U.S.C. § 7409(a) (2000).

[59] 15 U.S.C. § 1471-1476 (2000).

[60] However, the OSH Act sets forth a procedure that provides an opportunity for a public hearing in some circumstances. 29 U.S.C. § 655(b)(2)-(4) (2000).

[61] *E.g.*, Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360e(b) (2000) (provides informal procedure when FDA issues regulations requiring pre-market approval of medical devices); Silicone Gel-filled Breast Prosthesis, 21 C.F.R. § 878.3540 (Apr. 10, 1991) (regulation requiring pre-market approval of breast implants).

[62] Agencies vary in the extent to which they develop their administrative records in informal rulemakings. CPSC is mandated by the Consumer Product Safety Act to include certain items. 15 U.S.C. § 2060 (2000) ("For purposes of this section, the term 'record' means such consumer product safety rule; any notice or proposal published pursuant to section 2056, 2057, or 2058 of this title; the transcript required by section 2058(d)(2) of this title of any oral presentation; any written submission of interested parties; and any other information which the Commission considers relevant to such rule.").

[63] *See, e.g.*, Household Products Containing Hydrocarbons, 65 Fed. Reg. 93 (Notice of proposed rulemaking) (Jan. 3, 2000) (to be codified at 16 C.F.R. pt. 1700) (CPSC initiated proposal to request information and comments about a

on their own evaluations and may or may not disclose in a complete or timely manner the scientific and technical materials upon which they rely or the analytical process they follow. Moreover, the Administrative Procedure Act permits public participation in the rulemaking process without regard to the quality of public submissions.[64] Thus, the agency record may provide little useful guidance on the scientific and technical materials or conclusions relied upon by the agency to reach the rulemaking conclusions.

B. The Daubert Principles - A Natural Fit Within The Typical Standard For Judicial Review Of Agency Action

The first line of defense against allowing this amorphous process to open the door to agency reliance on bad science or misleading technical assessments is for advocates to invoke *Daubert* principles in rulemaking and to vigorously challenge scientific and technical submissions which are not relevant and reliable. In litigation, failure timely to raise issues of *Daubert* relevance and reliability can waive the right to challenge.[65] Waiver

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rule which would require child-resistant packaging for consumer products containing low viscosity hydrocarbons); NMFS, *Commerce Secretary Mineta Acts to Protect Horseshoe Crabs*, Press Release NOAA 2000-149 (Oct. 12, 2000) *available at* <http://www.publicaffairs.noaa.gov/releases2000/oct00/noaa00r149.html > as of Jan. 12, 2001; NMFS, *NOAA Fisheries Closes Area on the Grand Banks to Longline Fishermen under Emergency Rule to Protect Sea Turtles*, Press Release NOAA 2000-148 (Oct. 6, 2000) *available at* < *http://www.publicaffairs.noaa.gov/releases2000/oct00/noaa00r148.html* > as of Jan. 13, 2001.

[64] 5 U.S.C. § 553(c) (2000) ("[T]he agency shall give interested persons an opportunity to participate in the rule making through the submission of written data, views, or arguments with or without opportunity for oral presentation.").

[65] Mascenti v. Becker, 237 F.3d 1223, 1231-32 (10th Cir. 2001) ("Daubert does not mandate an inquiry questioning and challenging the scientific proffer absent a timely request by an objecting party.") A "decision to admit expert opinion evidence will be reviewed only for plain error when objections under *Daubert/Kumho* are not timely made." *Id.* at 1232. Where a timely objection is made, the decision on admission is reviewed for "abuse of discretion," as specified in *Joiner* and illustrated in *Kumho*.

in the absence of objection was proper in those circumstances, because the party tendering the evidence was "deprived of the opportunity to offer other supporting proof" and the "trial judge was disadvantaged in that she was not alerted to the need of stating *Daubert/Kumho* findings and analysis."[66] While waiver may not apply directly in agency rulemaking, pre-comment disclosures by the agency of critical scientific/technical premises which can then be addressed in comments or opportunities for reply comment call for a targeted challenge to materials that could not be relied upon in a court proceeding. That substantive challenge would advisedly be coupled with a demand for particularized agency findings and any special procedures, (*e.g.*, supplemental scientific/technical comments or informal oral hearings) necessary to resolve the relevance and reliability issues. By laying this foundation, advocates can prompt reviewing courts to give agency scientific evidence decisions the close scrutiny they deserve.

1. Reliance On "Speculation" - A Violation Of Settled Review Standards

The standards used by courts in reviewing the results of informal agency rulemaking combine the particular requirements of the statute authorizing agency action,[67] the general standards set forth in the Administrative Procedure Act ("APA") (unless displaced by the enabling statute), and Constitutional limitations on the underlying legislative power. While statutory specific standards are not uncommon, certain general principles are almost universally applicable. Thus, under the terms of the APA, a reviewing court may set aside a regulation issued through informal rulemaking when it is determined to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law."[68] If

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[66] *Id.* at 1234.

[67] Merely as one illustration, the Safe Drinking Water Act, as amended in 1996, provides that "to the degree that an Agency action is based on science, the Administrator shall use ... the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices." Section 300g-1(b)(3)(A); 42 U.S.C. § 300g-1(b)(3)(A)(2000).

[68] This four-part standard often is referred to as the "arbitrary and capricious" test. 5 U.S.C. § 706(2)(A). Black Media Coalition v. FCC, 822 F.2d 277, 280 (2d Cir. 1987).

the agency's decision rests on factual premises, its "factual findings must be supported by substantial evidence."[69]

The *Daubert* principles of relevance and reliability are clearly compatible with these standards of review. If a court bound by *Daubert* erroneously allows consideration of excludable expert evidence, a reviewing court may set aside its verdict as an "abuse of discretion" under *Joiner*. If an agency bases a rulemaking decision on irrelevant or unreliable expert evidence, that reliance is an equally fundamental "abuse of discretion" under the APA and should require the agency's action to be set aside and remanded for further determination on a reliable record.

The "substantial" evidence requirement applicable to an agency's factual findings has both quantitative and qualitative dimensions which support this conclusion. Quantitatively, substantial evidence "has been construed to mean less than a preponderance, but more than a scintilla"[70] Thus, there must be some probative evidence in the agency record to support its findings. Specifically, there must be "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion."[71] *Daubert* and its progeny, as encapsulated in new Rule 702, teach that for expert evidence to be adequate to support a decision, it must be "knowledge," as distinguished from mere "speculation." The *Daubert* logic thus fits readily into the substantial evidence test. If an expert opinion is not shown to be both relevant and reliable, then it has not been shown to be more than speculation. As described by one Court of Appeals, "speculation is, of course, no substitute for evidence, and a decision based on speculation is not supported by substantial evidence."[72] Thus, were an agency to premise a rule solely on unreliable scientific or technical information, i.e. on speculation, a reviewing court has ample APA authority to vacate and remand it that rule.

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[69] Cellular Phone Taskforce v. FCC, 205 F.3d 82, 89 (2d Cir. 2000).

[70] Cellular Tel. Co. v. Town of Oyster Bay, 166 F.3d 490, 494 (2d Cir. 1999).

[71] Universal Camera Corp. v. NLRB, 340 U.S. 474, 477 (1951) (internal quotation marks omitted).

[72] White Ex Rel. Smith v. Apfel, 167 F.3d 369, 375 (7th Cir. 1999) (reversing Social Security Administration's denial of benefits).

2. Courts Are Already Applying A *Daubert* Review Model Implicitly

Although it lacks an express reference to *Daubert* standards, the recent District of Columbia Circuit Court of Appeals decision in *Cellular Phone Taskforce v. FCC*,[73] 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. That case involved review by the D.C. Circuit of Federal Communications Commission ("FCC") amendments to guidelines required under the National Environmental Policy Act.[74] Those guidelines specified levels of maximum permitted exposure to radio frequency radiation from facilities such as radio broadcast antennas or cellular phone towers. Where exposure would not exceed the guidelines, then the FCC would license without an environmental assessment and would preempt state authorities from regulating the operation of such facilities based on RF emissions.[75]

The health and safety issues involved in setting such radio frequency maximum exposure guidelines were outside the FCC's expertise. Thus, in reaching its decision, the FCC was required to rely on expert communications from other sources including the Environmental Protection Agency ("EPA"), the Occupational Safety and Health Administration ("OSHA"), the National Institute for Occupational Safety and Health ("NIOSH"), the Food and Drug Administration ("FDA") and standards setting bodies such as the American National Standards Institute ("ANSI"),[76] the National Council on Radiation Protection and Measurements ("NCRP"), and the International Radiation Protection Association.[77]

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[73] 205 F.3d 82 (D.C. Cir. 2000)

[74] 42 U.S.C. § § 4321 et seq. (2000).

[75] Guidelines for Evaluating the Environmental Effects of Radio frequency Radiation, 11 F.C.C. Red. 15123, 1996 WL 926565 (1996); Procedures for Reviewing Requests for Relief from State and Local Regulations Pursuant to Section 332(c)(7)(B)(v) of the Communications Act of 1934, 12 F.C.C. Rcd. 13494, 1997 WL 522796 (1997).

[76] In this area, ANSI standards reflect the standards development work of the Institute of Electrical and Electronic Engineering. 205 F.3d at 88 n.1.

[77] 205 F.3d at 88.

The issues in the rulemaking included whether the maximum permitted exposure standards properly could be based solely on the capacity of radio frequency radiation to cause tissue warming (referred to as "thermal effects") or whether they should be based on some lower exposure ceiling that would protect against alleged "non-thermal effects," most notably cancer.[78] The FCC's final guidelines, which "combined the NCRP standard with the ANSI standard,"[79] reflected only that radio frequency "radiation at excessive levels has thermal effects."[80] Petitioners' challenge was that the "Guidelines are arbitrary and capricious because they fail to account for non-thermal effects of RF radiation," in that "neither the ANSI nor the NCRP sufficiently considered evidence of non-thermal effects."[81]

The Court of Appeals, responding to the petitioners' argument, noted that when "an agency makes a decision in the face of disputed technical facts, '[a] court must be reluctant to reverse results supported by ...the weight of considered and carefully articulated expert opinion.'"[82] The court's reference to "considered and carefully articulated expert opinion" resonates the *Daubert* requirement that reviewing courts ensure decisions are based on reliable scientific evidence. Additionally, the Court stated that it "must be satisfied that the agency examined the relevant data and established a 'rational connection between the facts found and the choice made'."[83] This standard is analogous to the *Joiner* relevance requirement that even reliable scientific evidence can sustain a result only if there is no "analytical gap" between its conclusions and the issues to be resolved by the trier of fact.

The record before the Court of Appeals showed that "ANSI found that 'no reliable scientific data exist indicating that

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[78] *See generally*, Bruce L. McDonald, "FCC's Rulemaking Focuses On Issues Important To Litigation," Andrews Electromagnetic Field Litigation Reporter at 16-28 (April, 1994).

[79] 205 F.3d at 88.

[80] *Id.* at 90.

[81] *Id.*

[82] *Id.* at 89. (quoting Federal Power Commission v. Florida Power & Light Co., 404 U.S. 453, 463 (1972)).

[83] *Id.* (quoting Motor Vehicle Manufacturers Association v. State Farm Automobile Insurance Co., 463 U.S. 29, 43 (1983).

[n]onthermal exposure may be meaningfully related to human health"' and that "NCRP found that the existence of non-thermal effects is 'clouded by a host of conflicting reports and opinions'."[84] The record further showed that "the expert agencies consulted" by the FCC (i.e., FDA, EPA, OSHA and NIOSH) each "had been advised of such evidence of non-thermal health effects as may have existed and still found the FCC's approach to be satisfactory."[85] The Court also stressed that the "FCC satisfied itself that there was a mechanism in place for accommodating changes in scientific knowledge" within ANSI and NCRP, together with an FCC commitment to "consider amending [its] rules at any appropriate time if these groups conclude that such action is desirable."[86]

The Court of Appeals held that, where there were "no reliable scientific data" establishing the existence of non-thermal effects and when the agency's process accommodated" future "changes in scientific knowledge," the FCC's refusal to base its Guideline on non-thermal effects "was not arbitrary and capricious."[87] The Court's decision carried with it the implicit caution that if the agency had based its decision on unreliable science or had failed to establish a mechanism to accommodate future changes in knowledge that might invalidate the scientific basis of the rule, then the Court would have vacated the rule. An express application of *Daubert* principles, in our view, would have supported the same result.

C. *Daubert Review Of Administrative Agency Actions – Consistent With "Chevron Deference"*

The Supreme Court's decision in *Chevron U.S.A. Inc. v. Natural Resources Defense Council*,[88] is frequently cited as establishing a "principle of deference to administrative interpretations." Properly understood, however, that deference applies only to legal interpretations reflecting policy/political

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[84] 205 F.3d at 90.
[85] *Id.*
[86] *Id.* at 90-91.
[87] *Id.* at 90.
[88] 467 U.S. 837 (1984).

judgments delegated to the agencies by the Congress. It does not create an unreviewable mandate permitting an agency to proceed on the basis of scientific or technical speculation.

Chevron involved review of an Environmental Protection Agency ("EPA") regulation defining the term "stationary source" for purposes of the federal Clean Air Act. The challenged EPA regulation embodied a plantwide "stationary source" definition that would "allow all of the pollution-emitting devices within the same industrial grouping" to be treated "as though they were encased within a single 'bubble,'" thus permitting an "existing plant that contains several pollution-emitting devices [to] install or modify one piece of equipment" without meeting "several stringent conditions" that are applicable to permits for "new or modified major stationary sources," so long as the "alteration will not increase the total emissions from the plant."[89] The National Resources Defense Council ("NRDC") argued that each pollution-emitting device was a "stationary source" under the Act and could be modified only if it individually met the stringent conditions. The Court of Appeals sided with the NRDC, but the Supreme Court reversed that decision and reinstated the bubble regulation.

The Court first noted that when "Congress has addressed the precise question at issue," an agency "must give effect to the unambiguously expressed intent of Congress."[90] In the situation presented in *Chevron*, however, where "the statute is silent or ambiguous with respect to the specific issue," then "a court may not substitute its own construction of a statutory provision for a reasonable interpretation made by the administrator of an agency."[91] This "deference" principle – that the agency to which Congress has delegated authority, rather than its reviewing court, has final authority to choose between reasonable alternative constructions of statutory language – has now become settled jurisprudence. [92] Nothing in *Chevron,* however, justifies agencies

[89] 467 U.S. at 840.

[90] 467 U.S. at 842-43.

[91] 467 U.S. at 844.

[92] *See, e.g.,* Whitman v. American Trucking Association, 531 U.S. ___, Slip. Op. at 21 (2001) ("if the statute is 'silent or ambiguous' with respect to the issue, then we must defer to a 'reasonable interpretation of an agency'"). A corollary of the *Chevron* deference rule is that agencies may change their interpretations of ambiguous statutory language when a new political party or philosophy takes

in taking non-political, fact-based actions premised on speculation. In that area, Congress has unequivocally vested final arbitrary and capricious review authority in the courts.

V. The Case For A *Daubert* Executive Order

We believe that, given sufficient time and effective advocacy, the courts inevitably will impose *Daubert* discipline on the agency process. In the interim, however, agencies may continue to impose restrictions on personal freedoms and the use of private property based on scientific or technical information and conclusions that could not survive review in a federal court. In addition, agencies will continue to use disparate processes in evaluating scientific and technical submissions from interested parties, as well as in regulating review of their internally-generated scientific and technical premises.

Because of the increasing importance of scientific and technical issues in health and safety regulation, and the constitutional due process underpinnings of the *Daubert* cases, a compelling case may be made for accelerating and harmonizing *Daubert* application through an appropriate Executive Order. We thus turn to a brief consideration of the role of Executive Orders in regulating the agency process and discussion of a proposed order that would establish *Daubert* both in policy and process.

A. Executive Orders - Appropriate Vehicles For Agency Guidance

The President's authority to issue Executive Orders is said to arise in substantial part from Article II, Section 3 of the Constitution, which provides that the President "shall take care that

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control. An agency may, within the limits of a legislative ambiguity, that is, a Congressional delegation of authority, "properly rely upon the incumbent administration's views of wise policy to inform its judgments." 437 U.S. at 865. *See also,* Rust v. Sullivan, 500 U.S. 173, 186 (1991) ("An agency is not required to 'establish rules of conduct to last forever,' but rather 'must be given ample latitude to adapt [its] rules and policies to the demands of changing circumstances'" (quoting Motor Vehicle Mnfrs. Ass'n v. State Farm Mut. Automobile Ins. Co., 463 U.S. 29, 42 (1983)).

the laws be faithfully executed." Executive Orders first were given that label by President Lincoln,[93] and first were organized in numbered sequence by the State Department beginning in 1907.[94] They have been used with considerable frequency during the past 30 years, as the size and complexity of government has increased,[95] with the result that almost 13,200 had been issued prior to 2001.[96] Some Executive Orders rely solely on constitutional authority; others are issued pursuant to statute.[97] Executive Orders are used for many purposes, including to delegate authority from the President to department heads,[98] to create new government organizational entities,[99] to guide federal government agency relations with state governments,[100] and to

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[93] George Washington issued a neutrality proclamation of 1793 directing all U.S. citizens to refrain from engaging in conduct that could provoke a belligerent power. Frank B. Cross, Executive Orders 12,291 and 12,498: A Test Case in Presidential Control of Executive Agencies, 4 J. Law Pol. 483, 485 (1988).

[94] *Id.* at 486 n. 5. The Executive Orders issued during a given year are published in Title 3 of the Code of Federal Regulations issued the following year (*e.g.*, the 1999 Orders are in the CFR "Revised as of January 1, 2000") The Code of Federal Regulations publication is not cumulative; so in order to locate a given Executive Order, one must find the correct year of Title 3 of CFR. Executive Orders are also published in the Federal Register, typically several days after issuance by the President. Executive Orders may be found in the WESTLAW "PRES" online database.

[95] On limits of presidential power under the "take care" clause, see *Youngstown Sheet & Tube Co. v. Sawyer*, 343 U.S. 579, 587 (1952) (holding that President Truman lacked authority to seize and operate private property to ensure steel production).

[96] On Dec. 28, 2000, President Clinton issued Executive Order 13,185 ("To Strengthen the Federal Government-University Research Partnership"), 66 Fed. Reg. 701 (Jan. 3, 2001).

[97] For example, compare Executive Order 13045 (62 Fed.Reg. 19885, Apr. 23, 1997), which relies only on the "Constitution and the laws of the United States," with Executive Order 13132 (64 Fed.Reg. 43225, Aug. 10, 1999) which invokes the "Unfunded Mandates Reform Act," as well.

[98] *See, e.g.*, Executive Order 10250, Delegation of Functions to the Secretary of the Interior, 16 Fed. Reg. 5385 (June 5, 1951), as amended.

[99] *See, e.g.*, Executive Order 13,100, establishing the President's Council on Food Safety. 3 CFR 209 (1999).

[100] For example, President Reagan's Executive Order 12,612 limited federal agencies from attempting or purporting to preempt state law except where federal statutes clearly authorized such preemption. 3 CFR 253, 255 (1988). This Executive Order was revoked by President Clinton's Executive Order

prescribe rules and procedures so that diverse agency activities can be coordinated by the President and focused in terms of the President's priorities.[101]

Executive Orders may be directed to all "federal agencies" and will apply to any entity defined under 44 USC § 3502(1),[102] excluding entities considered to be "independent regulatory agencies" under 44 USC § 3502(5).[103] Frequently, however, Executive Orders include a provision declaring that each "independent regulatory agency is encouraged to participate in the

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13,083, which established different "Federalism" principles and included no such restriction on agency preemption attempts. 3 CFR 146 (1999).

[101] *See, e.g.*, Executive Order 13045 (62 Fed. Reg. 19885, Apr. 23, 1997) by which President Clinton directed agencies to have concern in rulemaking and other actions involving "a environmental health risk or safety risk that an agency has reason to believe may disproportionately affect children," and establishing related procedures.

[102] As defined there:

(1) the term "agency" means an executive department, military department, Government corporation, Government controlled corporation, or other establishment in the executive branch of the Government (including the Executive Office of the President), or any independent regulatory agency, but does not include –

A) the General Accounting Office;

B) Federal Election Commission;

C) the governments of the District of Columbia and of the territories and possessions of the United States, and their various subdivisions; or

D) Government-owned contractor operated facilities, including laboratories engaged in national defense research and production activities.

[103] As defined there:

(5) the term "independent regulatory agency" means the Board of Governors of the Federal Reserve System, the Commodity Futures Trading Commission, the Consumer Product Safety Commission, the Federal Communications Commission, the Federal Deposit Insurance Corporation, the Federal Energy Regulatory Commission, the Federal Housing Finance Board, the Federal Maritime Commission, the Federal Trade Commission, the Interstate Commerce Commission, the Mine Enforcement Safety and Health Review Commission, the National Labor Relations Board, the Nuclear Regulatory Commission, the Occupational Safety and Health Review Commission, the Postal Rate Commission, the Securities and Exchange Commission, and any other similar agency designated by statute as a Federal independent regulatory agency or commission.

implementation of this order and comply with its provisions."[104] Thus, an Executive Order implementing *Daubert* principles could control most of the major rulemaking agencies and make the remainder subject to exhortative guidance that could prove highly influential in judicial review and congressional oversight.

B. Executive Order 12866 - A Bipartisan Foundation For A Daubert Executive Order.

The proposed *Daubert* order would fit easily into the process contemplated by Executive Order 12866, "Regulatory Planning and Review," issued by President Clinton on September 30, 1993.[105] This Executive Order declared that regulations should be "effective, consistent, sensible, and understandable" and began "a program to reform and make more efficient the regulatory process."[106] In that context, the Executive Order specifies a "regulatory philosophy" and states 12 "principles of regulation."[107] The Executive Order stresses that, "[b]ecause Federal agencies are the repositories of significant expertise and experience, they are responsible for developing regulations and assuring that the regulations are consistent with the applicable law, the President's priorities, and the principles set forth in this Executive Order."[108] The Order's principles include that each "agency shall base its decisions on the best reasonably obtainable scientific, technical, economic, and other information concerning the need for and consequences of, the intended regulation."[109] This commitment to use the best obtainable science and technical information is clearly compatible with *Daubert,* although it does leave open the possibility of proceeding on unreliable information if no better information is available.[110]

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[104] *See, e.g.*, subsection 1-102 of Executive Order 13045 (62 Fed.Reg. 19885, Apr. 23, 1997).

[105] 58 Fed. Reg. 51735 (Oct 4, 1993).

[106] Executive Order 12866, preamble.

[107] Executive Order 12866, at Section 1.

[108] *Id.* at Section 2(a).

[109] *Id.* at Section 1(b)(7).

[110] Some statutes, for example the Section 300g - 1(b)(3)(A) of the Safe Drinking Water Act, as amended in 1996 following *Daubert,* provide that "to the degree that an Agency action is based on science, the Administrator shall use

Executive Order 12866 also sets out a number of procedural requirements, many of which permit the Office of Information and Regulatory Affairs within the Office of Management and Budget to "provide meaningful guidance and oversight so that the agency's regulatory actions are consistent with applicable law, the President's priorities, and the principles," including the best-science principle.[111] The Executive Order also directs each agency to "provide the public with meaningful participation in the regulatory process," and to "afford the public a meaningful opportunity to comment on any proposed regulation."[112]

Because Executive Order 12866 was issued just four months after the *Daubert* decision was announced, and years before its meaning was refined and explained in *Joiner* and *Kumho*, it is unlikely that Executive Order 12866 was intended to impose *Daubert* standards. However, its compatibility with the *Daubert* decision provides a bipartisan basis for more detailed supplementation. An Executive Order specifying both substantive standards to satisfy the *Daubert* requirements and procedural steps to enforce *Daubert* analysis would provide a useful and properly noncontroversial supplement to Executive Order 12866.[113]

C. Content Of A Daubert Executive Order.

A *Daubert* Executive Order should establish conclusively that any scientific and technical information relied upon by

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... the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices." At least one reviewing court has perceived no difficulty in applying that standard of review to EPA rulemaking. *Chlorine Chemistry Council v. EPA*, 206 F.3d 1286, 1291 (D.C. Cir. 2000) (EPA failure to act "on the best available evidence, at the time of the rulemaking" was "arbitrary and capricious and in excess of statutory authority").

[111] *Id.* at Section 6(b).

[112] *Id.* at Section 6(a).

[113] It is commonplace for later Executive Orders expressly to supplement earlier ones. For example, President Clinton's Executive Order 12898 ("*Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations*") declared, "This Executive Order is intended to supplement but not supersede Executive Order No. 12250." 59 Fed. Reg. 7629, 7632 (Feb. 11, 1994).

agencies must be evaluated for reliability and relevance on a reviewable record specifying the scientific and/or technical basis for the agency's action and explaining the agency's detailed rationale for finding the relevance and reliability of that information.

Any agency proceedings forseeably raising scientific or technical issues should commence with a notice disclosing the anticipated issues and the content and source of information on which the agency intends to rely. Early notice is essential if public participants and their experts are to have a meaningful opportunity to address the issues and the reliability of any agency-asserted information. Disclosure could be made in the Federal Register publication of a proposed rulemaking or in the "technical support documents" already used by agencies and made available to the public on demand.[114] At least in the case of significant rulemakings, the agency's scientific and technical analysis, the factual bases that are key to the analysis, and resulting conclusions should be disclosed in their entirety.

The initial disclosure by an agency also should include a discussion of the agency's rationale for determining that any expert analysis relied on in the proposed action is scientifically or technically reliable. Testing the reliability of an expert's studies and opinions is both the heart of the *Daubert* process and one of its most complex dimensions. In *Daubert* itself, which involved opinions that exposure to the drug Bendectin had caused the plaintiffs' birth defects,[115] the Supreme Court did "not presume to set out a definitive checklist or text,"[116] but identified several factors thought to be relevant to evaluating scientific reliability:[117]

> a) whether a "theory or technique" "can be (and has been) tested" to see it if "can be falsified";
> b) "whether the theory or technique has been subjected to peer review and publication";

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[114] For an example of Technical Support Document use, see the Department of Energy's notice promulgating "Central Air Conditioners and Heat Pumps Energy Conservation Standards," 66 Fed.Reg. 7170 (Jan. 22, 2001).
[115] 509 U.S. at 582.
[116] 509 U.S. at 593.
[117] 509 U.S. at 593-94.

> c) "the known or potential rate or error" and the "existence and maintenance of standards controlling the technique's operation"; and
> d) "general acceptance," meaning "explicit identification of a relevant scientific community and an express determination of a particular degree of acceptance within that community."

Six years later, when the Supreme Court revisited reliability issues in *Kumho*, where the expert was an engineer specializing in automobile accident reconstruction and the expert opinion at issue asserted the cause of a tire blow-out, the Court recognized that different or additional factors were relevant to determining the reliability of technical information.[118] Thus, what constitutes a proper showing of the reliability of scientific and technical information and its proper application in a given rulemaking will vary widely with the discipline and type of opinion. While that reality means there is no single formula for specifying the reliability standard to be used and disclosed, a general disclosure requirement is essential.

A similar demonstration and disclosures are required for relevance. In the usual situation, there will be little doubt that proffered expert evidence is somehow generally relevant. As illustrated in *Joiner*, however, there often is an issue about whether admittedly reliable data or studies go far enough in what they prove to support the conclusion that an expert proposes to draw from them, or whether there is an "analytical gap" between the

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[118] Justice Bryer's *Kumho* reliability analysis teaches that types evidence of unreliability of an expert opinion include implausible inconsistency in the power of the method, reliance on subjective observations of the expert, casual or careless gathering of ostensibly key data, inconsistent application or changes in the method during the same factual assessment, and record-demonstrated data errors by the expert. In addition, other non-*Daubert* factors identified by the parties (or the absence of any), and evidence of use of the methodology of other experts (or the absence of that), articles or papers that validate the approach (or the absence of any) and use by the expert of the methodology in non-litigation business contexts (or the absence of any) all may bear on reliability. 526 U.S. at 154-57.

supporting data and the proposed scientific or technical conclusion.[119]

The Executive Order should make express that the demonstration and disclosure requirements apply not only when an agency relies on internal expertise but also when the agency relies on expert evidence or opinion submitted by others, such as other agencies or private parties. Agencies should make clear to commenters that they bear the burden of establishing that proffered scientific or technical information is relevant and reliable if they wish it to be considered as "knowledge" rather than "speculation." Absent such a demonstration, the commenter's information will remain in the rulemaking record but should be treated as argument.

In court proceedings, the record on reliability and relevance can be established by depositions and so-called *Daubert* hearings where experts can be confronted by counter-experts and cross-examined under oath.[120] While the APA does not require agencies to take these steps, the Executive Order should direct agencies, where authorized by law, to make available supplementary proceedings in which the agency on request or on its own initiative could explore the reliability and relevance of expert evidence in depth, including by examination of sponsoring witnesses.

The Executive Order should provide that an agency's final rulemaking notice must include a clear and record-supported statement detailing and demonstrating the relevance and reliability rationales for all (i) supporting agency-supplied scientific and technical information that has been placed in dispute and (ii) any outside expert scientific and technical information that is relied upon to support some part of the final agency action. This statement of scientific and technical basis would provide the primary guide to judicial review.

Appendix A to this article is a draft Executive Order supplementing Executive Order 12866 to achieve these goals. We believe that the OMB Office of Information and Regulatory Affairs should give prompt and favorable consideration to a proposed Order along these lines.

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[119] *Joiner*, 522 U.S. at 146.

[120] Such proceedings are authorized respectively by Federal Rule of Civil Procedure 26 and Federal Rule of Evidence 102.

VI. Conclusion

Administrative agencies play a useful role in protecting the public-health and safety, but for too long they have been allowed to make decisions based on loosely scrutinized expert evidence concerning the nature, causes and remedies for environmental, health and safety problems. Now that the judiciary has strengthened its resolve to ensure rational scientific and technical decisionmaking by admitting only expert evidence that meets the standards of relevance and reliability, administrative agencies similarly must ensure that agency decisions affecting critical liberty and property interests do not rely on the sort of unreliable, speculative science that the Supreme Court rejected in 1993, 1997, 1999, and 2000.

The tide has turned against scientific and technical speculation and the unfair and costly consequences it leaves in its wake. The standards for treatment of scientific and technical evidence embodied in the *Daubert* decision and Federal Rule of Evidence 702 must be fully incorporated into agency decisionmaking in order to provide a rational and sustainable system of agency governance. The basic legal framework governing agency action is consistent with the achievement of that objective, and an insistence on *Daubert* discipline is beginning to be seen in the judicial review of agency actions. To speed the inevitable and put supporting procedures in place expeditiously, we urge President Bush to issue an Executive Order along the lines of Appendix A to implement the *Daubert* principles at the agency level.

APPENDIX A - Illustrative *Daubert* Executive Order

Executive Order _____

Ensuring That Rulemaking And Other Regulatory Actions Are Premised On Reliable And Relevant Scientific and Technical Information

[Date Issued], 2001

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

Section 1. Policy

1-101. The American people rely on Federal regulatory decision-making to protect and improve their health, safety, environment, and well-being and to improve the performance of the economy, without imposing unacceptable, unreasonable or excessive costs on society. Because Federal agencies are depositories of significant expertise and experience, they are responsible for developing regulations and taking other regulatory actions in a manner that is consistent with applicable law, the President's priorities and principles set forth by Executive Order, including Executive Order 12866's directive that Federal agencies base their decisions on the best obtainable science, technical, economic and other information concerning the need for and consequences of their intended actions.

1-102. The Supreme Court's recent decisions in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), *General Electric Co. v. Joiner*, 522 U.S. 136 (1997), and *Kumho Tire Co. v. Carmichael*, 526 U.S. 137 (1999) established and developed the principles that expert opinion testimony on scientific and technical matters and similar expert evidence must be shown on the record to be both reliable and relevant before it may be considered in civil or criminal proceedings governed by the Federal Rules of Evidence. Federal Rule of Evidence 702

subsequently has been amended to codify the Supreme Court's decisions.

1-103. This Executive Order establishes the principles that (a) Federal agencies must base regulations and other regulatory actions only on scientific and technical information that is both reliable and relevant, and (b) Federal agencies must structure their internal and public procedures so that the scientific and technical information used in such decision-making and the basis for determining its relevance and reliability are identified, described and made available for timely public scrutiny and comment. The Order also establishes obligations and assigns responsibilities related to the achievement of these goals.

1-104. Each independent regulatory agency is encouraged to participate in the implementation of this Executive Order and comply with its provisions.

Section 2. The following definitions shall apply to this Executive Order.

2-201. "Expert evidence" means opinion or other evidence that purports to be based on scientific, technical or other specialized knowledge offered by a person qualified as an expert by knowledge, skill, experience, training or education.

2-202. "Federal agency" means any authority of the United States that is an agency under 44 U.S.C. 3502(1) other than those considered to be independent regulatory agencies under 44 U.S.C. 3502(5). For purposes of this Executive Order, "military departments," as defined in 5 U.S.C. 102, are covered under the auspices of the Department of Defense.

2-203. "OIRA" means the Office of Information and Regulatory Affairs within the Office of Management and Budget.

2-204. "Regulation" or "rule" means an agency statement of general applicability and future effect, which the agency intends to have the force and effect of law, that is designed to implement, interpret, or prescribe law or policy or to describe the procedure or practice requirements of an agency. It does not, however, include:

Regulations or rules that pertain to a military or foreign affairs function of the United States, other than procurement

regulations and regulations involving the import or export of non-defense articles and services;

Regulations or rules that are limited to agency organization, management, or personnel matters; or

Any other category of regulations exempted by the Administrator of OIRA.

2-205. "Regulatory action" means any substantive action by an agency (normally published in the Federal Register) that promulgates or is expected to lead to the promulgation of a final rule or regulation, including notices of inquiry, advance notices of proposed rulemaking, and notices of proposed rulemaking.

2-206. "Relevant" scientific and technical information means information which is "reliable" within the meaning of Section 2-207 of this Executive Order and otherwise meets the standards of Section 3-301 of this Executive Order and which directly supports the conclusion which the agency proposes to draw from it.

2-207. "Reliability," with respect to scientific and technical information, means an expert opinion or similar body of information that meets the standards of Section 3-301. There is no mechanical test for determining whether principles and methods are reliable, and the appropriate analysis may vary with the type of scientific, technical or other specialized knowledge being considered. Factors bearing on a methodology's reliability may, in appropriate instances, include (1) whether the theory or technique can be tested to see if it can be falsified, (2) whether the theory or technique has been subjected to peer review and publication, (3) the known or potential rate of error and the existence and maintenance of standards controlling the technique's operation, and (4) general acceptance, meaning explicit identification of a relevant professional community and an express determination of a particular degree of acceptance within that community.

Section 3. Implementation and Coordination

3-301. Standards. Each Federal agency shall take the steps necessary to ensure that in promulgating, amending or otherwise modifying regulations as defined in Section 2-204, all scientific and technical information on which the agency relies:

(1) is based upon sufficient facts or data, (2) is the product of reliable principles and methods, and (3) reflects application of such principles and methods reliably to the facts or data. This standard is intended to ensure that scientific and technical information relied upon to support a rule or other regulatory action constitutes relevant and reliable knowledge, as distinct from mere speculation or subjective belief. This rule applies equally to information generated within an agency and to information submitted by other agencies or private parties.

3-302. Procedures. To the extent that such action is not inconsistent with an agency's authorizing statutes, the Administrative Procedure Act, and other governing law, each agency shall, not later than 180 days following the date of this Executive Order, amend its relevant procedures to incorporate the following requirements, steps, and features:

Public materials defining procedures applicable to agency rulemaking and similar decision-making processes shall declare expressly the agency's policy to follow the principles specified in this Order.

Federal Register notices and similar written notices of proposed agency action that involve an opportunity for public participation prior to a final decision shall include a separately identified section describing any scientific or technical information upon which the agency proposes to rely. This section shall include a detailed written explanation of why the agency believes such information meets the standards set forth in Section 3-301 of this Order.

Agency rules or notices shall make express that scientific or technical information submitted in response to the notice required by subsection (2) shall be accompanied by a demonstration establishing that such information meets the standards set forth in Section 3-301 and that failure to present such a demonstration will preclude the agency from relying upon the submission in taking final agency action.

Where public comments or similar responses to an agency proposal fairly call into question whether proposed scientific or technical information upon which the agency proposes to rely meets the standards set forth in Section 3-301 of this Order, the agency, to the extent permitted by law, shall employ oral hearings

or appropriate written procedures to develop a record as to whether the subject information meets the Section 3-301 standards.

Federal Register notices and similar written notices of final agency rulemaking action or similar final agency action shall include in their statement of basis and purpose a separately captioned discussion of any issues raised during the related proceedings as to compliance with the terms of this Executive Order and shall include an explanation of the agency's record bases and rationale for resolving each such issue. Where the final action relies on scientific or technical information not addressed by the agency proposal(s), the discussion required by this subsection shall include a detailed description of the agency's basis for concluding that such information meets the standards set forth in Section 3-301.

3-303. Coordination and Supervision.

OIRA Responsibilities. The Administrator of OIRA shall provide meaningful guidance and oversight so that each agency's regulatory procedures and actions are consistent with the principles and requirements set forth in this Executive Order.

3.304. Applicability. This Executive Order applies to any rulemaking or similar regulatory action that is initiated, or for which a Notice of Proposed Rulemaking is published, six months after the date of this Order.

Section 4. General

4-401. Judicial Review. Nothing in this Executive Order shall affect any otherwise available judicial review of agency action. This Executive Order is intended only to improve the internal management of the Federal Government and does not create any right or benefit, substantive or procedural, enforceable at law or equity by a party against the United States, its agencies or instrumentalities, its officers or employees, or any other person.

4-402. This Executive Order is intended to supplement but not supersede Executive Order 12866.

GEORGE W. BUSH
THE WHITE HOUSE
[Date signed], 2001

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