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DAUBERT AND JUDICIAL REVIEW

**DAUBERT AND JUDICIAL REVIEW: HOW DOES AN ADMINISTRATIVE AGENCY  
DISTINGUISH VALID SCIENCE FROM JUNK SCIENCE?**

by

D. Hiep Truong\*

I. INTRODUCTION

In regulating the nation's health, regulatory agencies must often make risk assessments based on scientific paradigms that are incomplete at best and questionable at worst. Substantive review of agency decision making is the only assurance that agencies are basing their decisions on valid and legitimate scientific evidence.<sup>1</sup> The rebuttal to this argument is that although regulatory agencies make educated predictions based on the best available scientific resources and evidence, these predictions are naturally going to be incomplete as agencies are given general grants of authority to fulfill their broad statutory mandates.

Furthermore, it is far better to preempt any harms that underregulation would present to the public's health, and err on the side of overregulation. While this is certainly true and equally valid, the move away from a harm-based to a risk-based standard for regulatory action greatly expanded the agencies' decision making authority. The agencies' mandate to assess risk has greatly

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<sup>1</sup> Judge Learned Hand, in his opinion in *N.L.R.B. v. Standard Oil Co.*, 138 F.2d 885, 887 (2d Cir. 1943), noted that:

That there can be issues of fact which courts would be altogether incompetent to decide, is plain. If the question were, for example, as to the chemical reaction between a number of elements, it would be idle to give power to a court to pass upon whether there was 'substantial' evidence to support the decision of a board of qualified chemists. The court might undertake to review their finding so far as they had decided what reagents had actually been present in the experiment, for that presumably would demand no specialized skill. But it would be obliged to stop there, for it would not have the background which alone would enable it to decide questions of chemistry; and indeed it could undertake to pass upon them only at the cost of abandoning the accumulated store of experience upon the subject.

expanded the available sources of evidence from which administrators could base their decision making and with which they could characterize as dangerous, or presenting a level of risk that is unacceptable. These sources of evidence, however, may either be from scientific or nonscientific sources.

This broad authority to assess risk, however, leaves too much discretion to administrative agencies. Even more disturbing is the fact that different agencies assess the same risks differently, which leads to inconsistent results. The Environmental Protection Agency (EPA), for example, in determining the cancer risks from pesticides on food, produced an estimated risk of cancer mortality ten times greater than the Food and Drug Administration (FDA).<sup>2</sup> To use a law and economics model, valuing equivalent (or identical) risks differently leaves open the possibility of economic misallocation.<sup>3</sup> For example, if one agency has determined the proper level of risk, and assuming that both agencies must regulate the risk to reduce it to its optimal level, the second agency is either over- or under-regulating.<sup>4</sup>

If an agency over-regulates, the agency is merely addressing a threat whose benefits are so marginal that the spending no longer justifies the cost of the additional regulation.<sup>5</sup> But if an agency under-regulates, potential lives may be lost that could have been saved by more regulation.<sup>6</sup> Unless agencies recognize that inconsistencies may occur if they fail to examine their regulations in a broader context, an agencies' regulation of one environmental risk may actually increase the danger posed by a collateral risk.<sup>7</sup> For example, if an agency decides to close a nuclear power plant to reduce the risk of radiation poisoning, there may actually be an increase in the potential damage from acid rain as people burn more fossil fuels to compensate for the nuclear power plant closing.<sup>8</sup>

Agencies have certainly proved to be more susceptible to political influences than the judiciary.<sup>9</sup> Furthermore, members from the various

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<sup>2</sup> Michael Gough, *How much Cancer Can the EPA Regulate Away?* 10 Risk Analysis 1, 4 at table 2. The EPA's estimation of total cancer risks (3,000 cancer deaths from an incidence of 6,000 cancer cases) still exceeded the FDA's (only 300 cancer deaths) by 13-30 percent.

<sup>3</sup> See, e.g., Cass R. Sunstein, *Health-Health Tradeoffs*, 63 U.CHI.L.REV. 1533, 1543-49 (1996).

<sup>4</sup> *Id.*

<sup>5</sup> *Id.*

<sup>6</sup> *Id.*

<sup>7</sup> *Id.* at 1540.

<sup>8</sup> *Id.*

<sup>9</sup> See, e.g. National Coalition Against the Misuse of Pesticides v. Environmental Protection Agency, 809 F.2d 875 (D.C. Cir. 1987) (When the EPA set a zero tolerance level for EDB (Ethylene dibromide), a chemical that has been shown to increase the risks of cancer, on September 1, 1985, the EPA immediately "received entreaties from the State Department and

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regulatory agencies are appointed for limited terms and serve at the pleasure of the Executive. Often based on methods of data collection which are untried or novel, and often based on a cross-disciplinary interpretive judgments, agency risk assessments generally lacked the institutional credibility of normal science. To industries which are subject to oversight by various administrative agencies—such as the Environmental Protection Agency (EPA), the Occupational Safety and Health Administration (OSHA), and the Consumer Product Safety Commission (CPSC) to name only a few—these interpretations of scientific evidence are not trivial, as their determinations of risk usually entail costly restructuring of industry standards in order to comply with the new regulations that are based on the agency’s interpretation of risk.

But, proponents of independent agency decision making argue judges should only be restricted to review agency decision making if it is based on pure questions of law. As Judge Bazelon has noted, judges are on firmer ground when reviewing issues of administrative law involving issues of individual rights and liberty when undertaking a substantive review of agency action, but are on shakier grounds when reviewing the technical merits of an agency’s decision making.<sup>10</sup> Moreover, judges are ill-equipped to review the agencies’ expertise, and therefore, should defer to an administrative agencies’ decision making.<sup>11</sup> However, given the over two decades of the federal “Hard Look” at agency rule making, if there really was a threat of judicial substitution of judgment, there would have been evidence of it.<sup>12</sup> Moreover, at the federal

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the Department of Agriculture to reconsider its newly imposed ban. Among the importunings were letters from John Whitehead, Deputy Secretary of State, and James Michel, Acting Assistant Secretary for Inter-American Affairs. The Whitehead-Michel communications reiterated the adverse economic impact on friendly countries occasioned by EPA’s ban on EDB-fumigated mangoes . . . On November 27, 1985, EPA did an about-face. The agency proposed to abandon the zero tolerance and revive the expired 30 ppb tolerance through at least September 30, 1986.” *Id.* at 876-77. Based on this, Starr, Circuit Judge, concluded that the EPA acted “arbitrarily and capriciously in reinstating the 30 parts per billion tolerance for ethylene dibromide in imported mangoes.” *Id.* at 880).

<sup>10</sup> See *International Harvester Co. v. Ruckelshaus*, 478 F.2d 615, 652 (D.C. Cir. 1973).

<sup>11</sup> See SHEILA JASANOFF, *SCIENCE AT THE BAR: LAW, SCIENCE, AND TECHNOLOGY IN AMERICA* 43 (1995), at 43. (“[L]egal institutions and procedures for dealing with technical evidence have remained remarkably static. Most U.S. judges are still generalists, without any special schooling in the sciences, and practices such as random assignment of cases prevent judicial specialization in areas requiring technical knowledge.”).

<sup>12</sup> Frank E. Cooper, *Administrative Law: The Substantial Evidence Rule*, 44 A.B.A.J. 945, 947 (1958). The author notes that: “The cases studied [188 federal court of appeals cases between 1951 and 1958] vindicate the rule-of-thumb test commonly employed by practicing attorneys, *viz.*: if the appellant can convince the appellate court that the administrative findings of facts is obviously just plain wrong, and if the appellant can at the same time

level, there is a significant body of scholarship which rigorously examines the effect of judicial review of agency rule making.<sup>13</sup>

The need for more rigorous review of risk assessment determinations by an agency simply boils down to this: cost. If an agency is allowed to rely on various sources of information, both scientific and nonscientific, risk-assessment based regulations run the risk of spinning out of control and wreaking havoc on the economy. Without fear of having to justify its sources of “scientific” evidence, an agency has virtual carte-blanche powers with respect to its determinations of risk. Without any substantive criteria for assessing the validity of the scientific sources used by agencies, agencies may naturally succumb to pressures that they “err on the side of overprotection”<sup>14</sup> and, moreover, “[e]specially at the margin, where costs skyrocket in relation to benefits, the United States had misdirected or inefficiently expended many hundreds of billions of dollars in pursuit of environmental, health and safety protection.”<sup>15</sup> As Justice Breyer has accurately noted:

Tunnel vision, a classic administrative disease, arises when an agency . . . effectively carries single-minded pursuit of a single goal too far, to the point where it brings about more harm than good . . . The regulating agency considers a substance that poses serious risks, at least through long exposure to high doses. It then promulgates standards so stringent—insisting, for example, upon rigidly strict site cleanup requirements—that the regulatory action ultimately imposes high costs without achieving significant additional safety benefits. A former EPA

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arouse the court with a zealous desire to correct the error, the court can always find means to do so, whatever labels must be applied.” However, as the authors of the case book accurately note, courts are reluctant to review an agency’s findings because “[a]gencies specialize and develop expertise in the areas they regulate. Their fact-finding process reflects that expertise, and thus their findings should receive only limited judicial scrutiny.” See MICHAEL ASIMOW ET AL., STATE AND ADMINISTRATIVE LAW 546 (2d ed. 1998), at 546.

<sup>13</sup> See, e.g., Cass R. Sunstein, *On the Costs and Benefits of Aggressive Judicial Review of Agency Action*, 1989 DUKE L.J. 522; Peter H. Schuck & E. Donald Elliott, *To the Chevron Station: An Empirical Study of Federal Administrative Law*, 1990 DUKE L.J. 984, 986; Richard J. Pierce, Jr., *Two Problems in Administrative Law: Political Polarity on the District of Columbia Circuit and Judicial Deterrence of Agency Rulemaking*, 1988 DUKE L.J. 300, 301; Peter L. Strauss, *Considering Political Alternatives to “Hard Look” Review*, 1989 DUKE L.J. 538, 539; R. MELNICK, REGULATION AND THE COURTS: THE CASE OF THE CLEAN AIR ACT (1983); M. SHAPIRO, WHO GUARDS THE GUARDIANS? JUDICIAL CONTROL OF ADMINISTRATION (1988).

<sup>14</sup> R. SHEP MELNICK, REGULATION AND THE COURTS 295 (1983).

<sup>15</sup> See Edward W. Warren & Gary M. Marchant, “*More Good Than Harm*”: A First Principle for Environmental Agencies and Reviewing Courts, 20 ECOLOGY L.Q. 379, 380-81 (1993).

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administrator put the problem succinctly when he noted that about 95 percent of the toxic material could be removed from waste sites within a few months, but years are spent trying to remove the last little bit. Removing that last little bit can involve limited technological choice, high costs, devotion of considerable agency resources, large legal fees, and endless argument.<sup>16</sup>

Upon judicial review, the Administrative Procedure Act (APA) provides that courts shall “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>17</sup> In fact, as it stands today, a federal litigant<sup>18</sup> is subjected to a more rigorous standard if he or she wants to introduce novel scientific evidence into court, insofar as the trial court is bound by the court’s ruling in *Daubert*.<sup>19</sup>

Risk assessment is used by agencies to lay a foundation for the decisions that they reach. Risk assessment, then, operates in a manner that is similar to expert testimony: ie. helping the factfinder to make an appropriate determination of fact. In the words of Federal Rules of Evidence 702, risk assessment is there to “assist the trier of fact to understand the evidence or determine the fact in issue.”<sup>20</sup> *Daubert* provides the judiciary with a check on agency decision making, while at the same time increasing the agency’s credibility, consistency, and accuracy with respect to its reliance on scientific evidence.

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<sup>16</sup> See STEPHEN BREYER, *BREAKING THE VICIOUS CIRCLE: TOWARD EFFECTIVE RISK REGULATION*, 11 (1993).

<sup>17</sup> 5 U.S.C. 701 et seq. (1994); 5 U.S.C. 706(2)(A)(1994).

<sup>18</sup> See Alfred A. Brenner et al., *Technical Knockout: On the Difference Between Valid Scientific Evidence and “Junk,”* LOS ANGELES DAILY JOURNAL, March 31, 1999 at 6. (The authors accurately note the current state of affairs in the federal courts: “It is essential that attorneys have the capability to determine what evidence is based on sound science and what is “junk” science—and to explain the difference to a jury . . . Counsel must question whether opinions are based on sound scientific evidence. Experts should supply references, published in a respected, peer-reviewed journal, corroborating their opinions.”).

<sup>19</sup> *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993). (“*Daubert* exists because the justice system cannot take on faith that when experts say the evidence supports their conclusions, it must be true. Very often, through statistical manipulation, selective analysis of results or just plain faulty data, conclusions are reached that may be inaccurate or a stretch. This method of manipulating data to support a hypothesis is sometimes kindly referred to in the business as ‘hand-waving.’” See Alfred A. Brenner et al., *supra* note 18, at 6.).

<sup>20</sup> FED. R. EVID. 702.

This Comment, then, examines the possibility of using the *Daubert* standard to effectuate a more meaningful judicial review of an agency's determination of risk. By using the *Daubert* standards, a reviewing court is simply treating an agency like a testifying expert. When an agency is justifying its determination of the level of risk to courts, they must offer evidence from the record from which a reviewing court can examine the nexus between the evidence that is relied upon and the ultimate decision reached by the agency.

## II. BACKGROUND

### A. *The Origin of the Substantive Administrative Review Debate: The Leventhal-Bazelon Debate*

The judiciary's dilemma, whether to defer to an administrative agency's expertise, or to subject such agency decision making to more rigorous review, can best be illustrated by the lively exchange between Judge Leventhal and Judge Bazelon in *International Harvester v. Ruckelshaus*.<sup>21</sup> At issue in the case was whether the EPA had erred in rejecting a request by the auto industry to suspend the one-year tailpipe emission standards set by Congress to control smog.<sup>22</sup> In reversing the Administrator's decision to deny the auto industry's request for the one-year tailpipe suspension, the Court, per Leventhal, concluded that it was "troubled by arguments advanced by [the auto industry] that the methodology used by the Administrator in reaching his conclusions . . . was inconsistent with that of the [National Academy of Sciences]. It was our view that if and to the extent that such differences existed they should be explained by EPA, in order to aid us in determining whether the Administrator's conclusion . . . rested on a reasoned basis."<sup>23</sup>

Concurring in the result, Chief Judge Bazelon disagreed with the judiciary's role in reviewing such complex agency decision making, noting that he could not "believe that Congress intended this court to delve into the substance of the mechanical, statistical, and technological disputes in this case."<sup>24</sup> Bazelon would have clearly deferred to the administrative agency's

<sup>21</sup> *International Harvester Co. v. Ruckelshaus*, 478 F.2d 615 (D.C. Cir. 1973).

<sup>22</sup> *Id.* at 621 ("Congress was aware that these 1975 standards were 'drastic medicine,' designed to 'force the state of the art.' There was . . . concern whether the manufacturers would be able to achieve this goal. Therefore, Congress provided, in Senator Baker's phrase, a 'realistic escape hatch': the manufacturers could petition the Administrator of the EPA for a one-year suspension of the 1975 requirements, and Congress took the precaution of directing the National Academy of Sciences to undertake an ongoing study of the feasibility of compliance with the emission standards.") *Id.* at 623.).

<sup>23</sup> *Id.* at 627.

<sup>24</sup> *Id.* at 651.

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expertise, noting that the court's "proper role is to see to it that the agency provides 'a framework for principled decision-making.' . . . [b]ut in cases of great technological complexity, the best way for courts to guard against unreasonable or erroneous administrative decisions is not for the judges themselves to scrutinize the technical merits of each decision. Rather, it is to establish a reasoned decision that can be held up to the scrutiny of the scientific community and the public."<sup>25</sup>

Judge Bazelon strenuously argued against any sort of substantive review of an agency's decision making in matters of scientific complexity, noting that

where administrative decisions on scientific issues are concerned, it makes no sense to rely upon the courts to evaluate the agency's scientific and technological determinations; and there is perhaps even less reason for the courts to substitute their own value preferences for those of the agency, to which the legislature has presumably delegated the decisional power and responsibility . . . [t]he agencies themselves will usually be in the best position to determine which particular procedures, or combinations of procedures, are best suited to a particular issue.<sup>26</sup>

Three years after *International Harvester* was decided, the D.C. Circuit had another chance to review an agency's decision making, and this time, Judge Bazelon's position seemed to gain ground. In *Ethyl Corp. v. EPA*,<sup>27</sup> the Court upheld the EPA's lead-in-gasoline regulations. Once again, Chief Judge Bazelon argued, as in *International Harvester*, that "substantive review of mathematical and scientific evidence by technically illiterate judges is dangerously unreliable,"<sup>28</sup> and he believed that the judiciary's role is to "improve administrative decision making by concentrating our efforts on strengthening administrative procedures."<sup>29</sup> Judge Leventhal notes that Judge Bazelon's position is actually "no substantive review at all, whenever the substantive issues at stake involve technical matters that the judges involved consider beyond their individual technical competence."<sup>30</sup> Judge Leventhal noted that "[t]he aim of the judges is not to exercise expertise or decide

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<sup>25</sup> *Id.* at 652.

<sup>26</sup> David L. Bazelon, *Coping With Technology Through the Legal Process*, 62 CORNELL L. REV. 817, 822-823 (1977). (Judge Bazelon noted that judges are, for the most part, "technically illiterate," and includes himself in that category.).

<sup>27</sup> *Ethyl Corp. v. EPA*, 541 F.2d 1 (1976).

<sup>28</sup> *Id.* at 67.

<sup>29</sup> *Id.*

<sup>30</sup> *Id.* at 68.

technical questions, but simply to gain sufficient background information . . . individual judges have had to acquire the learning pertinent to complex technical questions in such fields as economics, science, technology and psychology.”<sup>31</sup> As it stands today, a court, upon review of an agency’s decisionmaking on matters of scientific expertise, is more likely to exhibit deference.<sup>32</sup> In order to understand the context from which an agency’s decisionmaking is structured, we must first examine the concept of risk assessment, as agencies rely heavily on this method when determining risk regulations.

### 1. What is Risk Assessment?

Risk regulation is comprised of two steps: risk assessment and risk-benefit analysis. Agencies, during risk assessment, make a determination of the level of danger a threat poses to the environment. Risk assessment is the “use of the factual base to define the health effects of exposure of individuals or populations to hazardous materials and situations . . . [and the] qualitative assessment or hazard identification part of risk assessment contains a review of the relevant biological and chemical information bearing on whether or not an agent may pose a carcinogenic hazard.”<sup>33</sup> According to the National Research Council, risk assessment includes several elements:

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<sup>31</sup> *Id.*

<sup>32</sup> *Vermont Yankee Nuclear Power Corp. v. National Resources Defense Council Inc.*, 435 U.S. 519 (1978) (rejecting Judge Bazelon’s suggestion of improving administrative agency decisionmaking by imposing procedural safeguards, noting that judicial imposition of procedures on the agency is contrary to the Administrative Procedures Act); *Baltimore Gas & Elec. Co. v. National Resources Defense Council Inc.*, 462 U.S. 87, 103 (1983) (noting that a reviewing court should be “at its most deferential” when an agency has made a decision on “the frontiers of science.” *Id.*); *Chevron U.S.A., Inc. v. National Resources Defense Council Inc.*, 467 U.S. 837, 843 (1984) (the court noted that if a “statute is silent or ambiguous with respect to the specific issue (the agency must decide), the question for the court is whether the agency’s answer is based on a permissible construction of the statute.”); *See also* 5 U.S.C. § 706(2)(A), which permits an agency’s action to be set aside by a reviewing court only if the action is “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law.” An “arbitrary and capricious decision exists where an agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of the agency expertise.” *Von Eye v. United States*, 92 F.3d 681, 685 (8<sup>th</sup> Cir. 1996).

<sup>33</sup> *See* National Resource Council (NRC), *RISK ASSESSMENT IN THE FEDERAL GOVERNMENT: MANAGING THE PROCESS* 3, 18 (1983) (cited in *Flue-Cured Tobacco Coop. Stabilization Corp. v. United States Environmental Protection Agency*, 4 F. Supp. 2d 435, 440 (M.D. N.C. 1998)).

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[D]escription of the potential adverse health effects based on an evaluation of results of epidemiologic, clinical, toxicologic, and environmental research; extrapolation from those results to predict the type and estimate the extent of health effects in humans under given conditions of exposure; judgements as to the number and characteristics of persons exposed at various intensities and durations; and summary judgments on the existence and overall magnitude of the public-health problem. Risks assessment also includes characterization of the uncertainties inherent in the process of inferring risk.<sup>34</sup>

Once the determination of risk assessment is made, agencies move onto risk-benefit analysis, which measures the benefits of regulation against the cost of imposing it.<sup>35</sup> Risk assessment is usually divided into four stages.<sup>36</sup>

First, the agency performs a hazard identification, which determines whether the exposure to a potentially toxic agent threatens human health. Second, the agency performs a dose-response assessment, which relates the dose of the toxin to its adverse health effects.<sup>37</sup> Third, the agency then performs an

<sup>34</sup> *Id.* at 18 (cited in *Flue-Cured Tobacco* at 4 F. Supp. 2d at 441).

<sup>35</sup> See MURRAY L. WEIDENBAUM, *BUSINESS AND GOVERNMENT IN THE GLOBAL MARKETPLACE* 215 (5<sup>TH</sup> ed. 1995). The need for a searching regulatory analysis of agency decisionmaking is aptly noted by Professor Weidenbaum:

The motive for incorporating benefit-cost analysis into public decision making is to lead to a more efficient allocation of government resources by subjecting the public sector to the same types of quantitative constraints as those in the private sector . . . [t]he government agency decision maker, however, usually does not face such constraints. If the costs to society of an action by an agency exceed the benefits, that situation has no immediate adverse impact on the agency, as would be the case if the private business executive makes a bad investment decision . . . [i]n requiring agencies to perform benefit-cost analysis, the aim is to make the government's decision-making process more effective, eliminating those regulatory actions for which net benefits are negative."

*Id.* at 215. Otherwise known as Cost-Benefit Analysis (CBA), much has been written on the topic. See *also*, THOMAS O. MCGARITY, *REINVENTING RATIONALITY: THE ROLE OF REGULATORY ANALYSIS IN THE FEDERAL BUREAUCRACY* (1991); Richard H. Pildes & Cass R. Sunstein, *Reinventing the Regulatory State*, 62 U.CHI.L.REV. 1, 43-95 (1995).

<sup>36</sup> MARK BOROUSH, *UNDERSTANDING RISK ANALYSIS: A SHORT GUIDE FOR HEALTH, SAFETY, AND ENVIRONMENTAL POLICY MAKING* 18-19 (INTERNET ED 1998).

<sup>37</sup> *Id.* at 19. ("For example, an anesthetic may cause headaches at low doses, a medically advantageous sleep at higher doses, but is lethal at very high doses . . . [w]ith noncarcinogens . . . the normal working assumption . . . is that biological effects occur only after a threshold level of exposure has been exceeded. Various thresholds have come to be

exposure assessment, which estimates the possible intensity, frequency, and duration of human exposure to the toxin.<sup>38</sup> Finally, the agency generates a risk characterization, which estimates the incidence of adverse health effects under various exposure conditions.<sup>39</sup>

The sources of evidence with which an agency could theoretically base its decision making is vast, as the following non-exclusive list will make clear: epidemiologic studies, toxicological studies, structure-activity studies, exposure data and exposure modeling, as well as research on metabolism, pharmacokinetics, and the mechanisms of toxicity.<sup>40</sup> The problems associated with deferring to an agency's expertise on matters of risk assessment frequently involve "exceedingly complex analyses, with much judgmental weighing of diverse data; it is vulnerable to limitations in data and to uncertainties in scientific reasoning; and it requires a good many assumptions, at least some of which will be debatable."<sup>41</sup>

According to the National Resource Council, the uncertainties inherent in risk assessment can be grouped in two general categories: missing or ambiguous information on a particular substance and gaps in current scientific theory. When scientific uncertainty is encountered in the risk assessment process, inferential bridges are needed to allow the process to continue . . . The judgments made by the scientist/risk assessor for each component of risk assessment often entail a choice among several scientifically plausible options; the Committee has designated these inference options.<sup>42</sup>

Even those who otherwise advocate the use of risk assessment by agencies, acknowledge its shortcomings, noting that "[t]he current state of

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established; they include a *lowest observable effect level* (LOEL), the smallest dose that causes any detectable effect; a *no-observed-effect level* (NOEL), the dose at or below which no biological effects of any type are detected; and a *no-observed-adverse-effect level* (NOAEL), the dose at or below which no harmful effects are detected.") *Id.*

<sup>38</sup> *Id.* at 19-20.

<sup>39</sup> *Id.* at 20.

<sup>40</sup> *Id.* at 20-23.

<sup>41</sup> *Id.* at 23. (Borouh also points to other problems associated with risk assessment: "(1) The high (in terms of level or duration) exposures used in the standard animal test designs usually have no parallel in humans, thus creating the need for extrapolations to levels outside that verifiable by experimental data (a situation science shies from). (2) The high exposures may provide a misleading picture of the potential for health effects, because it is possible that the high doses induce effects that do not arise at lower doses. (3) Finally, some toxic mechanisms and pathways that occur in animals may not occur in humans.") *Id.*

<sup>42</sup> *See supra* note 33, at 28 (cited in *Flue-Cured Tobacco* at 4 F. Supp. 2d at 442).

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scientific understanding has often been found to be incomplete, indecisive, and controversial in attempting to resolve the important questions about the type and size of specific hazards . . . [and] considerations in risk management—issues of risk acceptability and how to balance trade-offs among competing interests—are beyond the technical/scientific debate.”<sup>43</sup>

*B. A More Meaningful Judicial Standard of Review: Daubert v. Merrell Dow Pharmaceuticals, Inc.*

1. The Majority Opinion

To understand how Daubert applies, we must first examine the controversy in Daubert. In *Daubert v. Merrell Dow Pharmaceuticals*,<sup>44</sup> two minor children and their parents sued Merrell Dow Pharmaceuticals, alleging that the severe birth defects resulted from their mother’s ingestion during pregnancy of Bendectin, a prescription anti-nausea drug marked by Merrell Dow.<sup>45</sup> Instead of contesting Merrell Dow’s characterization of the published record concerning Bendectin, Daubert responded to Merrell Dow’s summary judgment motion by marshaling eight experts of their own.<sup>46</sup> All these experts concluded that, on the basis of “in vitro” (test tube) and “in vivo” (live) animal studies, Bendectin can cause birth defects.<sup>47</sup> The district court granted Merrell Dow’s motion for summary judgment on the basis that Merrell Dow’s expert testimony found there was no scientific study that linked Bendectin to severe birth defects.<sup>48</sup>

The court stated that “scientific evidence is admissible only if the principle upon which it is based is ‘sufficiently established to have general acceptance in the field to which it belongs.’”<sup>49</sup> The court held that petitioners’

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<sup>43</sup> *Id.* at 7.

<sup>44</sup> *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993).

<sup>45</sup> *Id.* at 579-80.

<sup>46</sup> *Id.* at 583. (These experts had impressive degrees: one had a master’s degree in biostatistics from Columbia University and a doctorate in statistics from the University of California at Berkeley, and is chief of the section at the California Department of Health and Services that determines the causes of birth defects. The other experts had equally impressive degrees. *See Id.* at 583, n. 2).

<sup>47</sup> *Id.*

<sup>48</sup> *Id.* (Steven H. Lamm, a physician and an epidemiologist, stated that he had “reviewed all the literature on Bendectin and human birth defects—more than 30 published studies involving over 130,000 patients. No study had found Bendectin to be a human teratogen (ie., a substance capable of causing malformations in fetuses). On the basis of this review, Doctor Lamm concluded that maternal use of Bendectin during the first trimester of pregnancy has not been shown to be a risk factor for human birth defects.” *Id.* at 582.).

<sup>49</sup> *Id.* (After *Frye v. United States*, 293 F.2d 1013 (D.C. Cir. 1923), was decided in 1923, federal

evidence did not meet this standard. Given the “vast body of epidemiological data concerning Bendectin, the court held, expert opinion which is not based on epidemiological evidence is not admissible to establish causation.”<sup>50</sup> Petitioners’ epidemiological analyses, the court stated, were ruled to be “inadmissible because they had not been published to peer review.”<sup>51</sup>

The Ninth Circuit affirmed. The Court stated that “expert opinion based on a scientific technique is inadmissible unless the technique is ‘generally accepted’ as reliable in the relevant scientific community.”<sup>52</sup> The Court noted that other Courts of Appeals who had considered the risks of Bendectin had refused to admit “reanalyses of epidemiological studies that had been neither published nor subjected to peer review.”<sup>53</sup> Those courts that had considered the risks of Bendectin had found the unpublished reanalyses “particularly problematic in light of the massive weight of the original published studies supporting [Dow’s] position, all of which had undergone full scrutiny from the scientific community.”<sup>54</sup> The Ninth Circuit concluded that the evidence marshaled by petitioners “provided an insufficient foundation to allow admission of expert testimony that Bendectin caused their injuries, and accordingly, that petitioners could not satisfy their burden of proving causation at trial.”<sup>55</sup>

The Supreme Court granted certiorari. It thereafter vacated the lower court’s decision and held that the Frye “general acceptance” test had been superseded by the enactment of the Federal Rules of Evidence.<sup>56</sup> The Court noted that the Frye standard was “austere . . . [,] incompatible with . . . the Federal Rules of Evidence, [and] should not be applied in federal trials.”<sup>57</sup> The Court then articulated a new test for admissibility of scientific expert testimony and listed several nonexclusive factors that federal courts should consider when faced with a proffer of such testimony.<sup>58</sup>

## 2. The Daubert Standards

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courts required that the expert’s theory be generally accepted within the relevant scientific community. The Federal Rules of Evidence in 1975 called into question the viability of the “general acceptance” test. A literal reading of FRE 702 and its legislative history make no mention of the “general acceptance” test. Daubert finally laid to rest this issue by concluding that the Federal Rules of Evidence superseded the Frye “general acceptance” test.).

<sup>50</sup> *Daubert*, 509 U.S. at 583-84.

<sup>51</sup> *Id.* at 584.

<sup>52</sup> *Id.*

<sup>53</sup> *Id.*

<sup>54</sup> *Id.*

<sup>55</sup> *Id.* at 585.

<sup>56</sup> *Daubert*, 509 U.S. at 588-89 & n.6.

<sup>57</sup> *Id.* at 589.

<sup>58</sup> *Id.* at 592-594.

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In overruling the “general acceptance” test set forth in *Frye*, the Court noted that “[t]here is a specific Rule that speaks to the contested issue. Rule 702, governing expert testimony, provides:

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or 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.

Nothing in the text of this Rule establishes ‘general acceptance’ as an absolute prerequisite to admissibility. Nor does respondent present any clear indication that Rule 702 or the Rules as a whole were intended to incorporate a ‘general acceptance’ standard.”<sup>59</sup> The Court held that Rule 702, in conjunction with other Evidence Rules, assigned to the trial court the gate keeping function of “ensuring that an expert’s testimony both rests on a reliable foundation and is relevant to the task at hand.”<sup>60</sup>

The Court added that “[p]ertinent evidence based on scientifically valid principles” will satisfy these requirements.<sup>61</sup> The Daubert Court interpreted Rule 702 as entrusting a trial judge with the responsibility of ensuring that an expert is testifying to “(1) scientific knowledge that (2) will assist the trier of fact to understand or determine a fact in issue.”<sup>62</sup> The phrase “scientific knowledge” in Rule 702 requires that “the reasoning or methodology underlying the testimony [be] scientifically valid.”<sup>63</sup> The term “scientific” signifies “a grounding in the methods and procedures of science,” and “knowledge” is “more than subjective belief or unsupported speculation.”<sup>64</sup> The requirement of scientific knowledge “establishes a standard of evidentiary reliability.”<sup>65</sup>

However, the Daubert Court offered the District Court further guidance. The Court ventured several general observations as to how to determine “whether a theory or technique is scientific knowledge that will assist the trier of fact.”<sup>66</sup> In addition to determining whether the methodology underlying the testimony is scientifically valid, the Court enumerated four nonexclusive factors

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<sup>59</sup> *Id.* at 588.

<sup>60</sup> *Id.* at 597.

<sup>61</sup> *Id.*

<sup>62</sup> *Daubert*, 509 U.S. at 592.

<sup>63</sup> *Id.* at 592-593.

<sup>64</sup> *Id.* at 590.

<sup>65</sup> *Id.*

<sup>66</sup> *Id.* at 589.

that trial courts should consider: (1) whether a scientific theory can and has been tested; (2) whether it has been subjected to peer review; (3) its known or potential rate of error; and (4) its degree of general acceptance within the relevant scientific community.<sup>67</sup> Second, a judge must determine whether the proffered evidence “properly can be applied to the facts at issue,” a characteristic courts call “fit.”<sup>68</sup> When evaluating regulations, courts have considered reliability more important than fit, determining the question of fit as more appropriately categorized as a question of policy rather than science.<sup>69</sup>

### III. ANALYSIS

#### A. Review Under The Administrative Procedures Act

Under the Administrative Procedure Act (APA), courts shall “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>70</sup> Kenneth Davis and Richard Pierce, Jr. note in their Administrative Law Treatise that “to the extent that the FRE announce any policy relevant to the rules of evidence (governing administrative law), that policy is contained in Rule 703.”<sup>71</sup> In questioning whether the Federal Rules of Evidence should even be applied to an administrative agency, at least one Commentator has accurately noted the following:

Why treat agencies like testifying experts? Mainly because the analogy is extremely apt. When agencies justify their regulation of risk to courts, they must offer evidence from the record to justify their regulatory decisions. The evidence they offer in support of those regulations will contain, at least in part, the agency’s assessment of the risk regulated. Agencies must use risk assessments to lay a foundation for the ultimate decision they make. In that sense a risk assessment operates as expert testimony, designed to help the fact finder make the appropriate determinations of fact . . . [b]ecause “the party presenting the expert must show that the expert’s findings are based on sound science,” the agency must provide evidence from the record justifying its decision . . . [if the risk

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<sup>67</sup> *Id.* at 593-594.

<sup>68</sup> *Id.* at 591-92.

<sup>69</sup> *See, e.g.,* In re Paoli Railroad Yard, PCB Litigation, 35 F. 3d 717, 746; *see also* Cavallo v. Star Enter., 892 F. Supp. 756, 762 (E.D. Va. 1995) (declined to be followed by Heller v. Shaw Indus. 167 F. 3d 146 (3<sup>rd</sup> Cir. 1999)).

<sup>70</sup> 5 U.S.C. § 701 et seq. (1994); 5 U.S.C. § 706 (2)(A).

<sup>71</sup> KENNETH CULP DAVIS AND RICHARD J. PIERCE, JR., 2 ADMINISTRATIVE LAW TREATISE §§ 10.1-10.3 (Little, Brown 3d Ed. 1994).

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assessments represent factual judgments], then the court must determine their admissibility. If they are policy, then the court must defer to the agency's judgment.<sup>72</sup>

In order to fully understand how the *Daubert* standards might have resulted in more consistent results upon judicial review of agency decision making, we must first examine in detail an actual case where the reviewing court reversed an agency's decision making under the traditional "substantial evidence" standard of review. In *AFL-CIO v. OSHA*,<sup>73</sup> the Court held that:

(1) OSHA failed to establish that existing exposure limits in the workplace presented significant risk of material health impairment or that new standards eliminated or substantially lessened the risk; (2) OSHA did not meet its burden of establishing that its 428 new permissible exposure limits (PEL) were either economically or technologically feasible; and (3) there was insufficient explanation in the record to support across-the-board, four-year delay in implementation of the rule.<sup>74</sup>

The Occupational Safety and Health Administration (OSHA) in 1989 issued its Air Contaminants Standard, which is a set of permissible exposure limits for 428 toxic substances.<sup>75</sup> These Air Contaminants Standard were challenged by petitioners who represented various affected industries and the AFL-CIO on the grounds that the Standards were promulgated in violation of the procedural and substantive requirements of the Occupational Safety and Health Act of 1970.<sup>76</sup> The Act was adopted "to assure so far as possible every working man and woman in the Nation safe and healthful working conditions."<sup>77</sup>

The Act, to this end, authorized the Secretary to issue occupational health and safety standards with which each employer must comply.<sup>78</sup> OSHA, pursuant to that authority, in 1971 promulgated approximately 425 permissible exposure limits ("PELs") for air contaminants<sup>79</sup> derived primarily from federal standards applicable to government contractors under the Walsh-Healey Act.<sup>80</sup>

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<sup>72</sup> Andrew Trask, *Daubert and the EPA: An Evidentiary Approach to Reviewing Agency Determinations of Risk*, 1997 U.CHI.LEGAL.F. 569.

<sup>73</sup> *American Fed'n of Labor and Congress of Indus. Org. v. Occupational Safety and Health Admin.* U.S. Dept of Labor, 965 F.2d 962 (11<sup>th</sup> Cir. 1992).

<sup>74</sup> *Id.*

<sup>75</sup> *Id.* at 967.

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

<sup>77</sup> *Id.* at 968. (citing 29 U.S.C. §§ 651-71; *Id.* at 651(b)).

<sup>78</sup> *Id.* (citing 29 U.S.C. §§ 654, 655).

<sup>79</sup> *AFL-CIO*, 965 F.2d at 968 (citing 29 C.F.R. § 1910.1000 (1971)).

<sup>80</sup> *Id.* (citing 41 U.S.C. § 35 (1988)).

On June 7, 1988, OSHA had published a Notice of Proposed Rule making for its Air Contaminants Standard in which OSHA, in this single rule making, proposed to issue new or revised PELs for over 400 substances.<sup>81</sup> On January 19, 1989, OSHA then issued its revised Air Contaminants Standard for 428 toxic substances, and established a four-year period for which employers could come into compliance with the new standard using engineering and work practice controls.<sup>82</sup> Petitioners contend that “OSHA’s use of generic findings, the lumping together of so many substances in one rule making, and the short time provided for comment by interested parties, combine to create a record inadequate to support this massive new set of PELs.”<sup>83</sup>

#### 1. Substantial Evidence Standard of Review: the Traditional Test.

The Court cited Section 6(f) of the OSH Act which provides that “the determinations of the Secretary shall be conclusive if supported by substantial evidence in the record considered as a whole.”<sup>84</sup> “Substantial evidence,” the Court noted, “is such relevant evidence as a reasonable mind might accept as adequate to support a conclusion . . . [and under this test] . . . we must take a ‘harder look’ at OSHA’s action than we would if we were reviewing the action under the more deferential arbitrary and capricious standard applicable to agencies governed by the Administrative Procedure Act.”<sup>85</sup>

The substantial evidence test applies “to review of policy decisions as well as factual determinations<sup>86</sup> even though policy decisions are ‘not so susceptible to verification or refutation by the record.’”<sup>87</sup> Furthermore, the Court stated, “the validity of an agency’s determination must be judged on the basis of the agency’s stated reasons for making that determination.”<sup>88</sup> Section 6(e) of the OSH Act provides that “whenever the Secretary promulgates any standard . . . he shall include a statement of the reasons for such action, which shall be published in the Federal Register.”<sup>89</sup>

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<sup>81</sup> *Id.* at 969.

<sup>82</sup> *Id.*

<sup>83</sup> *Id.* at 971.

<sup>84</sup> *Id.* at 969 (citing 29 U.S.C. § 655(f) (1998)).

<sup>85</sup> *AFL-CIO*, 965 F.2d at 970. See *American Textile Mfrs. Inst. Inc., v. Donovan*, 452 U.S. 490, 522 (1981) (quoting *Universal Camera Corp. v. N.L.R.B.*, 340 U.S. 474, 477 (1951)).

<sup>86</sup> *Id.* (citing *Texas Indep. Ginners Ass’n v. Marshall*, 630 F.2d 398, 404 (5<sup>th</sup> Cir. 1980)).

<sup>87</sup> *Id.* (quoting *American Petroleum Inst. v. OSHA*, 581 F.2d 493, 497 (5<sup>th</sup> Cir. 1978)).

<sup>88</sup> *Id.* (citing *Industrial Union Dept., AFL-CIO v. American Petroleum Inst.*, 448 U.S. 607, 631 n.31 (1980) (hereinafter “Benzene” case)).

<sup>89</sup> *Id.* at 970 (citing 29 U.S.C. § 655(e) (1998)). (“In that statement of reasons, the agency must pinpoint the factual evidence and the policy considerations upon which it relied. This requires explication of the assumptions underlying predictions or extrapolations, and of the

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## 2. Significant Risk of Material Impairment of Health

Under this standard, the Court examined whether OSHA fulfilled its statutory mandate. Under Section 3(8) of the OSH Act, “occupational health and safety standard” is defined as “a standard which requires conditions, or the adoption or use of one or more practices, means, methods, operations, or processes, reasonably necessary or appropriate to provide safe or healthful employment and places of employment.”<sup>90</sup> The reviewing court noted that the Supreme Court has interpreted this provision “to require that, before the promulgation of any permanent health standard, OSHA make a threshold finding that a significant risk of material health impairment exists at the current levels of exposure to the toxic substances in question<sup>91</sup> and that a new, lower standard is therefore ‘reasonably necessary or appropriate to provide safe or healthful employment and places of employment.’”<sup>92</sup>

The Court also noted that “OSHA ultimately bears the burden of proving by substantial evidence that such a risk exists and that the proposed standard is necessary . . . [but that] . . . the agency has no duty to calculate the

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basis for its resolution of conflicts and ambiguities. In enforcing these requirements, the court does not reach out to resolve controversies over technical data. Instead, it seeks to ensure public accountability.” *Id.* at 970-71. *See* *AFL-CIO v. Marshall*, 617 F.2d at 651.).

<sup>90</sup> *Id.* at 972 (citing 29 U.S.C. § 652(8) (1998)).

<sup>91</sup> *Id.* (citing *Benzene*, 448 U.S. at 614-615.).

<sup>92</sup> *AFL-CIO*, 965 F.2d at 972-3 (citing *Benzene*, 448 U.S. at 615.) (“Once OSHA finds that a significant risk of material health impairment exists at current exposure levels for a given toxic substance, any standard promulgated to address that risk must then comply with the requirements of section 6(b)(5) of the OSH Act” which provides that the agency:

[i]n promulgating standards dealing with toxic materials or harmful physical agents under this subsection, shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life. Development of standards under this subsection shall be based upon research, demonstrations, experiments, and such other information as may be appropriate. In addition to the attainment of the highest degree of health and safety protection for the employee, other considerations shall be the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws. Whenever practicable, the standard promulgated shall be expressed in terms of objective criteria and of the performance desired.

*Id.* (emphasis added) (citing 29 U.S.C. § 655(b)(5) (1998)).

exact probability of harm or to support its finding that a significant risk exists with anything approaching scientific certainty.”<sup>93</sup> Although the Court found OSHA’s explanation with respect to its determination of what constitute “material impairments” as being “adequately explained and supported in the record,”<sup>94</sup> the Court had trouble with the agency’s determination of risk with respect to each individual substance.<sup>95</sup> The Court stated that “[n]o one could reasonably expect OSHA to adopt some precise estimate of fatalities likely from a given exposure level, and indeed the Supreme Court has said that the agency has ‘no duty to calculate the exact probability of harm.’”<sup>96</sup>

However, the Court continued, OSHA “has a responsibility to quantify or explain, at least to some reasonable degree, the risk posed by each toxic substance regulated.”<sup>97</sup> Without doing so, “OSHA has not demonstrated, and this court cannot evaluate, how serious the risk is for any particular substance, or whether any workers will in fact benefit from the new standard for any particular substance.”<sup>98</sup> Instead of attempting to estimate the risk of contracting the adverse health effects caused by the exposure at various levels of individual substances, OSHA “merely provided a conclusory statement that the new PEL will reduce the ‘significant’ risk of material health effects shown to be caused by that substance.”<sup>99</sup>

The Court concluded that “[i]n most cases, OSHA cited a few studies and then established a PEL without explaining why the studies mandated the particular PEL chosen. For example, the PEL for bismuth telluride appears to be based on a single study that showed almost no effects of any kind in animals at several times that concentration . . . [and] . . . [s]imilarly, the PEL for ferrovanadium dust was based on pulmonary changes at exposure levels many hundreds of times higher than OSHA’s new standard.”<sup>100</sup> In some cases, “OSHA merely repeated a boilerplate finding that the new limit would protect workers from significant risk of some material health impairment.”<sup>101</sup> The Court noted that while its deference to agency decisionmaking is at its peak when an agency’s choices “are among scientific predictions, we must still look for some

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<sup>93</sup> *Id.* (citing *Benzene*, 448 U.S. at 655-656).

<sup>94</sup> *Id.* at 975.

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

<sup>96</sup> *Id.* at 975. (quoting *Benzene*, 448 U.S. at 655).

<sup>97</sup> *Id.*

<sup>98</sup> *AFL-CIO*, 965 F.2d at 975.

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

<sup>100</sup> *Id.* at 976. (the Court also noted that the same was true for iron pentacarbonyl; cesium hydroxide, iron salts; ethylene dichloride; and sulfur tetrafluoride.).

<sup>101</sup> *Id.*

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articulation of reasons for those choices.”<sup>102</sup> The Court made the following observation:

Explicit explanation for the basis of the agency’s decision not only facilitates proper judicial review but also provides the opportunity for effective peer review, legislative oversight, and public education. This requirement is in the best interest of everyone, including the decision-makers themselves. If the decision-making process is open and candid, it will inspire more confidence in those who are affected. Further, by opening the process to public scrutiny and criticism, we reduce the risk that important information will be overlooked or ignored.<sup>103</sup>

The Court continued by stating that “[m]ere conclusory statements, such as those made throughout the Air Contaminants Standard, are simply inadequate to support a finding of significant risk of material health impairment.”<sup>104</sup> In explaining why it set standards where a significant risk of material health impairment remains, OSHA reasoned “that the time and resource constraints of attempting to promulgate an air contaminants standard of this magnitude prevented detailed analysis of these substances.”<sup>105</sup> The Court noted that “[t]he agency’s response to this criticism [was] unpersuasive.”<sup>106</sup>

The Court found “OSHA’s use of safety factors in this rule making problematic” because “first, OSHA’s use of safety factors in this rule making is very similar to the approach criticized by the Supreme Court in *Benzene*.”<sup>107</sup>

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<sup>102</sup>*Id.* (citing *International Union United Auto, Aerospace and Agr. Implement Workers of America, UAW v. Pendergras*, 878 F.2d 389, 392 (1989)).

<sup>103</sup> *Id.* at 976 (citing *AFL-CIO v. Marshall*, 617 F.2d 636, 651-52 (D.C. Cir. 1979)).

<sup>104</sup> *AFL-CIO*, 965 F.2d at 976.

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

<sup>106</sup> *Id.* at 977. (The Court further pointed out that “[d]ose response models have often been used in the quantitative assessment of the risks associated with exposures to carcinogenic substances. However, less scientific effort has been devoted to models to be used with non-carcinogenic substances. Mathematically precise methods to establish the true no-effect level or to define the dose-response curves have not been developed for most of the more than 400 substances involved in this rule making. Most of the scientific work that has been done was designed to identify lowest observed effect or no-effect levels for a variety of acute effects . . . It is possible to use these data, combined with professional judgement and OSHA’s expertise and experience, to determine that significant risk exists at current levels of exposure and that a reduction in these levels will substantially reduce this risk of material impairment of health.” *Id.*).

<sup>107</sup> *Id.* at 978. (The Court made the following observation: “[f]rom OSHA’s description, safety factors are used to lower the standard below levels at which the available evidence shows no

Second, even assuming that the use of safety factors is permissible under the Act and *Benzene*, application of such factors without explaining the method by which they were determined, as was done in this case, is clearly not permitted.”<sup>108</sup> The Court observed that “[t]he Supreme Court in *Benzene* did recognize that absolute scientific certainty may be impossible when regulating on the edge of scientific knowledge, and that ‘so long as they are supported by a body of reputable scientific thought, the Agency is free to use conservative assumptions . . . , risking error on the side of overprotection rather than underprotection.’”<sup>109</sup>

However, the Court continued, “[t]he lesson of *Benzene* is clearly that OSHA may use assumptions, but only to the extent that those assumptions have some basis in reputable scientific evidence. If the agency is concerned that the standard should be more stringent than even a conservative interpretation of the existing evidence supports, monitoring and medical testing may be done to accumulate the additional evidence needed to support that more protective limit.”<sup>110</sup> Overall, the Court noted, “OSHA’s use of safety factors in this rule making was not adequately explained by this rule making record.”<sup>111</sup> The Court concluded that:

It is clear that the analytical approach used by OSHA in promulgating its revised Air Contaminants Standard is so flawed that it cannot stand . . . The result of this approach is a set of 428 inadequately supported standards. OSHA has lumped together substances and affected industries and provided such inadequate explanation that it is virtually impossible for a reviewing court to determine if sufficient evidence supports the agency’s conclusions.<sup>112</sup>

Therefore, the Court concluded, “although we find that the record adequately explains and supports OSHA’s determination that the health effects

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significant risk of material health impairment because of the possibility that the evidence is incorrect or incomplete; ie., OSHA essentially makes an assumption that the existing evidence does not adequately show the extent of the risk. That may be a correct assumption, but beyond a general statement that the use of safety factors is common in the scientific community, OSHA did not indicate how the existing evidence for individual substances was inadequate to show the extent of the risk from those substances. Such a rationale is very reminiscent of the ‘benefits are likely to be appreciable’ rationale rejected in *Benzene* as insufficient to satisfy the agency’s obligations under the OSH Act.” *Id.* (emphasis added).

<sup>108</sup> *Id.*

<sup>109</sup> *Id.* at 978-79. (citing *Benzene*, 448 U.S. at 656).

<sup>110</sup> *Id.*

<sup>111</sup> *Id.*

<sup>112</sup> *Id.* at 986.

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of exposure to these 428 substances are material impairments, we hold that OSHA has not sufficiently explained or supported its threshold determination that exposure to these substances at previous levels posed a significant risk of these material health impairments or that the new standard eliminates or reduces that risk to the extent feasible. OSHA's overall approach to this rulemaking is so flawed that we must vacate the whole revised Air Contaminants Standard."<sup>113</sup>

*B. Review Under the Daubert Standards.*

Currently, a reviewing court is required to determine whether the agencies' proposed admission of evidence into the record rests on "substantial evidence."<sup>114</sup> A reviewing court's subjective idea of what "substantial evidence" may or may not entail is the quintessential problem that *Daubert* addresses. By using the *Daubert* standards, the Court is not second-guessing the agency's decision making, but is simply ensuring, as it is already required to do under the "substantial evidence" test, that the evidence relied upon by the agency meets the same threshold requirements that a federal litigant is already subjected to. If the *Daubert* factors were not used by a reviewing court, the plaintiff is placed in the awkward position of challenging an agency decision to meet evidentiary standards that the agency itself could ignore.

1. How Did OSHA Determine "Significant Risk" in *AFL-CIO*?

The Court concluded that "OSHA's discussions of individual substances generally contain no quantification or explanation of the risk from that individual substance."<sup>115</sup> The individual substances were simply summarized discussions of various studies and the concomitant health effects found at various levels of exposure to that substance.<sup>116</sup> If the *Daubert* standards were applied here, the reviewing court would have to ask: 1) Is the agency relying on scientific knowledge?, and 2) Will the scientific knowledge assist the reviewing court to understand or determine a fact in issue?<sup>117</sup> Again, according to the *Daubert* Court, the phrase "scientific knowledge" in Rule 702 requires that the reasoning or methodology underlying the testimony [be] scientifically valid."<sup>118</sup> The term "scientific" signifies "a grounding in the methods and procedures of

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<sup>113</sup> *Id.* at 986-87.

<sup>114</sup> 5 U.S.C. § 706(2)(E) (1994). *See also* National Coalition Against the Misuse of Pesticides v. EPA, 867 F.2d 636, 642 (D.C. Cir. 1989) ("[T]he Administrator satisfies his burden of production by proffering 'substantial evidence' of harm from respected scientific sources.").

<sup>115</sup> American Fed'n of Labor and Congress of Indus. Org. v. Occupational Safety and Health Admin. U.S. Dept of Labor, 965 F.2d 962,975 (11<sup>th</sup> Cir. 1992).

<sup>116</sup> *Id.*

<sup>117</sup> *See supra* note 44, Section II.B.1, and accompanying text.

<sup>118</sup> *See supra* note 63.

science,” and “knowledge” is “more than subjective belief or unsupported speculation.”<sup>119</sup> The requirement of scientific knowledge “establishes a standard of evidentiary reliability.”<sup>120</sup>

Whether a theory or technique is scientific knowledge that will assist a reviewing court will depend on four nonexclusive factors: 1) whether a scientific theory can and has been tested; 2) whether it has been subjected to peer review; 3) its potential rate of error; and 4) its degree of general acceptance within the relevant scientific community.<sup>121</sup>

In the case of *AFL-CIO*, the Court determined that “the individual substance discussions in the Air Contaminants Standard are virtually devoid of reasons for setting those individual standards [with respect to assessing the level at which significant risk of harm is eliminated or substantially reduced].”<sup>122</sup>

In most cases, the Court concluded, “OSHA cited a few studies and then established a PEL (permissible exposure limits) without explaining why the studies mandated the particular PEL chosen. For example, the PEL for bismuth telluride appears to be based on a single study that showed almost no effects of any kind in animals at several times that concentration.”<sup>123</sup> For some substances, the Court noted, “OSHA merely repeated a boilerplate finding that the new limit would protect workers from significant risk of some material health impairment. For example, OSHA did not cite any studies whatsoever for its aluminum welding fume standard or its vegetable oil standard.”<sup>124</sup>

In determining whether the agency has met its “substantial evidence” burden, the court simply concludes that “[m]ere conclusory statements, such as those made throughout the Air Contaminants Standard, are simply inadequate to support a finding of significant risk of material health impairment.”<sup>125</sup> Instead of noting the conclusory nature of the Administrator’s findings, the Court could have provided a more meaningful judicial review, and concurrently, provided the agency with guidance as to the requisite level of review for future challenges of its decision making. For instance, here, the Court could have asked if the single study that OSHA relied upon for bismuth telluride was subjected to peer review, whether it was tested and repeated, what its potential rate of error was, and whether it was generally accepted in the relevant scientific community (which may or may not include other agency scientists).

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<sup>119</sup> See *supra* note 64.

<sup>120</sup> See *supra* note 65.

<sup>121</sup> See *supra* note 67.

<sup>122</sup> *American Fed’n of Labor and Congress of Indus. Org. v. Occupational Safety and Health Admin.* U.S. Dept of Labor, 965 F.2d 962, 976 (11<sup>th</sup> Cir. 1992).

<sup>123</sup> *Id.* at 976.

<sup>124</sup> *Id.*

<sup>125</sup> *Id.*

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The same could be asked with respect to the agency's "boilerplate finding that the new (PEL) limit would protect workers from significant risk of some material health impairment."<sup>126</sup> From what were these "boilerplate findings" derived from? Could they reasonably be characterized as 1) scientific knowledge that 2) would assist the reviewing court to understand or determine a fact in issue (here, to what extent would the boilerplate findings be reasonably related to significant risk of some material health impairment)? Do these basic findings meet the requirement of scientific knowledge, insofar as it "establishes a standard of evidentiary reliability"?<sup>127</sup> In short, the court in *AFL-CIO* could have provided clearer guidance to the lower courts if it had followed the guidelines set forth by the U.S. Supreme Court in *Daubert*. Without strictly adhering to the standards of judicial review in *Daubert*,<sup>128</sup> reasoned judicial decision making was substituted for discretionary review.

## IV. PROPOSAL

Under the current law, a reviewing court may either reverse an agency's decision making under the "clearly erroneous" test if it "is left with the definite and firm conviction that a mistake has been committed."<sup>129</sup> However, under the "substantial evidence test," a reviewing court may not reverse if a "reasonable person could have reached the same conclusion as the agency. This is the standard used by a federal court of appeals in reviewing the findings of a jury (or by a trial court in taking a matter from the jury)."<sup>130</sup> Unfortunately, both these standards come up short when the agency decision makers are relying on complex, and technically difficult, scientific evidence. Courts are more likely to defer to an administrative agency's decision making when it deems that the scientific data is within the expertise of the administrative agency (read: beyond the scope of the judicial review).

Although most commentators would concede that some scientific issues are so complex that they should be left to the specific agencies whose task is to specifically examine the evidence and present their findings to the reviewing court,<sup>131</sup> this analysis misses the point. The issue is not whether the information is scientifically complex, because most of the times it is, indeed, complex. The real issue, however, and the real challenge with respect to a reasoned judicial decision making, is whether the agency's actions—regarding risk assessment,

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<sup>126</sup> *Id.* at 975.

<sup>127</sup> *See supra* note 65.

<sup>128</sup> *See supra* notes 62-67.

<sup>129</sup> *United States v. U.S. Gypsum Co.*, 333 U.S. 364, 395 (1948).

<sup>130</sup> *See supra* note 11, at 535 (citing *Allentown Mack Sales & Serv. Co. v. NLRB*, 118 S. Ct. 818 (1998)).

<sup>131</sup> *See supra* note 26.

interpretive judgments, or scientific paradigms—are defensible, appropriate, and scientifically valid. The *Daubert* standards enable a reviewing court to bring structure, validity, and reliability to the agency decision making process.

#### V. CONCLUSION

In order to avoid the inconsistencies that have developed when courts review agency decision making, and in order to decrease the costs of excessive health regulations by agencies, reviewing courts should subject the agency decision maker to the exact same standards a federal litigant is subjected to when he or she proposes to admit scientific testimony: namely, the *Daubert* standards. Only by holding the agency decision makers to a higher standard will the courts avoid being labeled a mere rubber stamp for environmental policy decision makers.

Environmental risk regulation remains a priority for the United States. Until a specialized federal judiciary is created with respect to scientific decision making, a sitting court must continue to establish clear guidelines in order to determine the validity of an agency's decision making process. Therefore, only by applying the *Daubert* standards in the agency review process will courts ensure that the environmental regulations are based on falsifiable, valid, and reliable scientific evidence. In keeping the regulatory decision making scientific, *Daubert* enables courts to make it more effective.