

## A HARD LOOK AT FEDERAL REGULATION OF FORMALDEHYDE: A DEPARTURE FROM REASONED DECISIONMAKING\*

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Formaldehyde, one of the most widely used chemicals in modern industry, has recently become one of the most controversial as well.<sup>1</sup> A plethora of lawsuits, congressional hearings, and scholarly analyses have centered on formaldehyde, and more particularly on federal agency responses to new data indicating that it may be a carcinogen (cancer-causing substance). These developments were sparked by an October 1979 report from the Chemical Industry Institute of Toxicology (CIIT) that formaldehyde causes cancer in rats.<sup>2</sup>

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1. Formaldehyde, a simple organic molecule composed of one carbon atom, one oxygen atom, and two hydrogen atoms, is used in paper, plywood, cosmetics, fertilizers, particleboard, insulation, and explosives, and in a variety of manufacturing and other industrial processes. National Institute for Occupational Safety and Health, *Formaldehyde: Evidence of Carcinogenicity*, Current Intelligence Bulletin No. 34 at 2 (April 15, 1981). According to producers, formaldehyde is "used in products that account for about eight percent of the United States' three-trillion dollar Gross National Product." Formaldehyde Institute, *Formaldehyde: A Building Block of Our Society* (1983) (available from the Formaldehyde Institute).

2. Chemical Industry Institute of Toxicology, *Statement Concerning Research Findings*, Docket No. 11109 (Oct. 8, 1979).

Because of the chemical's widespread use and distribution — domestic production exceeds seven billion pounds per year,<sup>3</sup> and at least five million people are exposed to the chemical at greater than ambient atmospheric levels<sup>4</sup> — federal agencies responsible for toxic chemical control became concerned about its potential carcinogenicity in humans. Since 1979, a number of federal agencies have considered regulatory action. The controversy over formaldehyde has been intensified by the inconsistent treatment it has received at the hands of the various federal agencies.

This article examines the formaldehyde deliberations of three of those agencies: the Environmental Protection Agency (EPA), the Occupational Safety and Health Administration (OSHA), and the Consumer Product Safety Commission (CPSC). Part I provides an overview of the formaldehyde controversy, summarizing the actions taken by EPA, OSHA, and CPSC. Part II sets forth an analytic framework for evaluating those actions. Specifically, we address the legal standard of "reasoned decisionmaking" that has developed through judicial review of administrative decisions, the distinction between hard science and science policy issues, and the technical criteria for assessing health risks. Part III reviews the bioassay<sup>5</sup> and epidemiologic<sup>6</sup> evidence indicating that formaldehyde is carcinogenic, and then examines the data on human exposure. Parts IV through VI examine in turn EPA's, OSHA's, and CPSC's formaldehyde deliberations. The article concludes that CPSC acted well within its statutory authority in its evaluation of formaldehyde's cancer risk, but that EPA and OSHA may have violated their procedural and substantive mandates in refusing to take regulatory action.

## I. AN OVERVIEW OF THE FORMALDEHYDE DETERMINATIONS

### A. *The Federal Panel on Formaldehyde*

Upon receiving the CIIT findings, EPA, OSHA, CPSC, and other agencies undertook several joint actions, the most important of which was to form the Federal Panel on Formaldehyde.<sup>7</sup> The panel was composed of top scientists from the federal government and was directed to evaluate all available information on the long-term effects of exposure to

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3. STANFORD RESEARCH INSTITUTE, CHEMICAL ECONOMICS HANDBOOK 68.50310 (1979).

4. Those people exposed include workers and consumers of formaldehyde-based products. OFFICE OF TOXIC SUBSTANCES, U.S. ENVIRONMENTAL PROTECTION AGENCY, TECHNICAL DOCUMENT ON FORMALDEHYDE 59-62 Table 7 (Nov. 1981) [hereinafter cited as TECHNICAL DOCUMENT].

5. See *infra* note 86 and accompanying text.

6. See *infra* note 89.

7. See generally *Report of the Federal Panel on Formaldehyde*, 43 ENVTL. HEALTH PERSP. 139 (1982) [hereinafter cited as *Federal Panel Report*].

formaldehyde and to assess the human health risks.<sup>8</sup> In November 1980, the Panel presented its report to the agencies.<sup>9</sup> Based on its review of the available data, the Panel concluded that "formaldehyde should be presumed to pose a carcinogenic risk to humans."<sup>10</sup>

### B. Agency Responses

In March 1981, the Deputy Assistant Administrator for Toxic Substances and other officials of EPA, an executive branch regulatory agency, reviewed the existing evidence of the cancer risks to the U.S. population from exposures to formaldehyde.<sup>11</sup> They determined that the evidence was sufficient to require EPA to consider the chemical under section 4(f) of the Toxic Substances Control Act<sup>12</sup> and prepared a draft Federal Register notice to that effect. When Anne Gorsuch, the incoming EPA Administrator, and John Hernandez, the incoming Deputy Administrator, assumed office in May 1981, formal publication of the notice was delayed.<sup>13</sup> Ultimately, EPA declined to designate formaldehyde a section 4(f) chemical.

In December 1980, OSHA, also an executive branch regulatory agency, acting in conjunction with the National Institute for Occupational Safety and Health (NIOSH) and under the authority of the Occupational Safety and Health Act (OSHAct), released a Current Intelligence Bulletin for formaldehyde.<sup>14</sup> The bulletin recommended that formaldehyde be considered a potential carcinogen, and that appropriate controls be implemented to reduce worker exposure to the chemical. In March 1981, Thorne Auchter, the newly confirmed Assistant Secretary of Labor for OSHA, took charge of the agency. Shortly thereafter he rescinded OSHA's sponsorship of the Bulletin. In January 1982, OSHA denied a petition by labor unions for an emergency temporary standard to reduce formaldehyde levels in the workplace.

In February 1981, CPSC, an independent regulatory commission, proposed a ban on urea-formaldehyde foam insulation.<sup>15</sup> In February 1982, CPSC voted to impose the ban.<sup>16</sup>

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8. *Id.*

9. *Id.*

10. *Id.*

11. *See infra* notes 155-80 and accompanying text (discussing EPA's formaldehyde deliberations).

12. 15 U.S.C. § 2603(f) (1976).

13. Anne (Gorsuch) Burford resigned as EPA Administrator on March 9, 1983. [13 *Curr. Dev.*] *ENV'T REP.* (BNA) 2027 (Mar. 11, 1983). John Hernandez, Jr., assumed the position of Acting Administrator until March 25, 1983, when he also resigned. *Id.* at 2179 (Apr. 1, 1983).

14. *See infra* notes 325-48 and accompanying text (discussing OSHA's formaldehyde deliberations).

15. *See infra* notes 409-26 and accompanying text (discussing CPSC's formaldehyde deliberations).

16. On April 7, 1983, the U.S. Circuit Court of Appeals for the Fifth Circuit vacated

Not surprisingly, the disparities in federal agencies' treatment of formaldehyde have attracted considerable attention. Numerous articles have been written about one or all of the agencies' decisions,<sup>17</sup> and several congressional hearings have been held to examine various aspects of these decisions.<sup>18</sup> Though the agencies have defended their formaldehyde decisions as well-grounded in scientific evidence,<sup>19</sup> public interest groups and several Congressmen have charged that EPA and OSHA were unduly influenced by industry,<sup>20</sup> while industry representatives have claimed that CPSC was biased in its handling of formaldehyde data.<sup>21</sup>

### C. Departures from Federal Cancer Policy

One major ground on which EPA and OSHA have been criticized is that in their formaldehyde deliberations both agencies departed from the federal cancer risk assessment policies that they had developed over the last decade.<sup>22</sup> Federal control of human exposure to carcinogens is largely

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the ban. *Gulf South Insulation v. CPSC*, 701 F.2d 1137. See *infra* text accompanying notes 451-74.

17. See, e.g., Perera & Petito, *Formaldehyde: A Question of Cancer Policy?*, 216 SCIENCE 1285 (1982); Hileman, *Formaldehyde: How Did EPA Develop Its Formaldehyde Policy?*, 16 ENVTL. SCI. & TECH. 543 (1982); Sandler, *EPA's Secret Science Courts*, 24 ENVIRONMENT 4 (1982); Sun, *Agencies in Dispute Over Cancer Policy*, 217 SCIENCE 233 (1982); *Letup in the Drive to Regulate Formaldehyde*, BUS. WEEK, Oct. 12, 1981, at 80.

18. Various aspects of the EPA and OSHA formaldehyde deliberations were discussed during at least five House of Representatives hearings. See *The Proposed Firing of Dr. Peter Infante by OSHA: A Case Study in Science and Regulation: Hearings Before the Subcomm. on Investigations and Oversight of the House Comm. on Science and Technology*, 97th Cong., 1st Sess. 60 (1981) (chaired by Rep. Gore) [hereinafter cited as *Gore OSHA Hearings*]; *The Environmental Protection Agency--Private Meetings and Water Protection Programs: Hearings Before the Subcomm. on Environment, Energy and Natural Resources of the House Comm. on Government Operations*, 97th Cong., 1st Sess. (1981) (chaired by Rep. Moffett) [hereinafter cited as *Moffett Hearings*]; *Environmental Protection Agency Research and Development Posture Hearing: Hearing Before the Subcomm. on Natural Resources, Agriculture Research, and Environment of the House Comm. on Science and Technology*, 97th Cong., 1st Sess. (1981) (chaired by Rep. Scheuer) [hereinafter cited as *Scheuer Hearings*]; *Hearings to Review the Scientific Basis of the Environmental Protection Agency's Carcinogenic Risk Assessment on Formaldehyde Before the Subcomm. on Investigations and Oversight of the House Comm. on Science and Technology*, 97th Cong., 2d Sess. (1982) (chaired by Rep. Gore) (currently in press, so hereafter no page numbers can be cited except in reference to prepared testimony) [hereinafter cited as *Gore EPA Hearings*]; *EPA's Failure to Regulate Asbestos Exposure: Hearings Before the Subcomm. on Commerce, Transportation, and Tourism of the House Comm. on Energy and Commerce*, 97th Cong., 2d Sess. (1982) (chaired by Rep. Florio) [hereinafter cited as *Florio Hearings*].

19. See, e.g., *Gore EPA Hearings*, *supra* note 18 (testimony by John Todhunter); *Gore OSHA Hearings*, *supra* note 18, at 57-83 (testimony by Thorne Auchter).

20. See, e.g., *Moffett Hearings*, *supra* note 18, at 162-96 (statement by Jacqueline Warren, Attorney, Natural Resources Defense Council); *Gore EPA Hearings*, *supra* note 18 (statements by Rep. Gore); *Gore OSHA Hearings*, *supra* note 18, at 1-2 (statement by Rep. Gore).

21. See *infra* text accompanying note 418.

22. See *supra* sources cited at note 17.

exercised through statutes administered by EPA, OSHA, CPSC, and the Food and Drug Administration (FDA).<sup>23</sup> Although the various statutory mandates differ with respect to the degree of protection to be provided<sup>24</sup> and the criteria by which social costs and benefits are to be balanced,<sup>25</sup> a rather uniform approach towards the assessment of carcinogenic risk did evolve in the 1970's and early 1980's.

The key issues that had to be resolved in developing this approach were the nature and quality of the evidence required to designate a particular substance a human carcinogen for regulatory purposes. In addressing these issues, the agencies necessarily made a number of policy choices in areas where existing scientific evidence does not permit a purely technical determination.<sup>26</sup> The federal courts generally have endorsed such choices, noting that issues of this nature are "on the frontiers of scientific knowledge"<sup>27</sup> and that regulatory agencies may be compelled by their statutory mandates to make determinations of policy in the face of scientific uncertainty.<sup>28</sup>

OSHA has been responsible for a major part of the regulatory activity on carcinogens. In January 1980, after successfully defending a number of its carcinogen exposure standards in court,<sup>29</sup> OSHA codified the evolving policies by promulgating a generic cancer standard.<sup>30</sup> The major goal

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23. See generally Ashford, *Legal Implications of Working with Carcinogens*, in *CARCINOGENS IN INDUSTRY AND THE ENVIRONMENT* 47 (J. Sontag ed. 1981).

24. See generally Ashford, *Federal Control of Toxic Substances in the Environment and Workplace: Legal, Regulatory and Scientific Complexities*, 329 *ANNALS N.Y. ACAD. SCI.* 246 (1979).

25. See generally M. BARAM, *COST-BENEFIT ANALYSIS: AN INADEQUATE BASIS FOR HEALTH, SAFETY, AND ENVIRONMENTAL DECISIONMAKING*, (report to the Administrative Conference of the United States) (1979); Rodgers, *Benefits, Costs, and Risks: Oversight of Health and Environmental Decisionmaking*, 4 *HARV. ENVTL. L. REV.* 191 (1980).

26. See generally *infra* text accompanying notes 70-103.

27. *Industrial Union Dep't v. Hodgson*, 499 F.2d 467, 474 (D.C. Cir. 1974) (reviewing OSHA standards for worker exposure to asbestos).

28. See *Industrial Union Dep't v. American Petroleum Inst.*, 448 U.S. 607, 658 (1980); *United Steelworkers v. Marshall*, 647 F.2d 1189, 1206-07 (D.C. Cir. 1980), *cert. denied*, 453 U.S. 913 (1981); *Environmental Defense Fund v. EPA*, 636 F.2d 1267, 1277-78 (D.C. Cir. 1980); *Ethyl Corp. v. EPA*, 541 F.2d 1, 27 (D.C. Cir.) (en banc), *cert. denied*, 426 U.S. 941 (1976); *Reserve Mining Co. v. EPA*, 514 F.2d 492, 507 n.20 (8th. Cir. 1975) (en banc); *Society of Plastics Indus. v. OSHA*, 509 F.2d 1301, 1308 (2d Cir.), *cert. denied*, 421 U.S. 992 (1975); *Amoco Oil v. EPA*, 501 F.2d 722, 740 (D.C. Cir. 1974).

29. See *Synthetic Organic Chem. Mfrs. Ass'n v. Brennan*, 503 F.2d 1155 (3d Cir. 1974), *cert. denied*, 420 U.S. 973 (1975) (permanent standard for ethyleneimine) [hereinafter cited as *SOCMA I*]; *Synthetic Organic Chem. Mfrs. Ass'n v. Brennan*, 506 F.2d 385 (3d Cir. 1974), *cert. denied*, 423 U.S. 830 (1975) (permanent standards for three carcinogens) [hereinafter cited as *SOCMA II*]; *Industrial Union Dep't v. Hodgson*, 499 F.2d 467 (D.C. Cir. 1974) (asbestos standard) (note however that OSHA regulated asbestos as a lung toxin, not as a carcinogen); *Society of Plastics Indus. v. OSHA*, 509 F.2d 1301 (2d Cir.), *cert. denied*, 421 U.S. 992 (1975) (vinyl chloride standard); *American Iron and Steel Inst. v. OSHA*, 577 F.2d 825 (3d Cir. 1978), *cert. dismissed*, 448 U.S. 917 (1980) (coke oven emissions standard).

30. This standard was first proposed in 1977, 42 *Fed. Reg.* 54,148 (1977) (advance

of the standard was to expedite the lengthy process involved in setting standards for suspected carcinogens on a substance-by-substance basis. By resolving certain policy issues and standardizing carcinogen regulation, OSHA hoped to develop a more efficient, effective, and predictable rulemaking process.<sup>31</sup>

CPSC also developed a generic cancer policy,<sup>32</sup> but withdrew it<sup>33</sup> in favor of a "statement" on regulation of chemical carcinogens developed by the Regulatory Council.<sup>34</sup> That statement was published in October 1979 to "inform the public of the practices and principles the participating Federal regulatory agencies will follow in initiating regulatory actions relating to chemical carcinogens."<sup>35</sup> The Council based its policy in part on scientific work by the Interagency Regulatory Liaison Group (IRLG), which was then made up of OSHA, EPA, CPSC, and FDA. IRLG presented its work in a report published in a peer-reviewed scientific journal in July 1979.<sup>36</sup> It described the report as incorporating the best judgment of senior scientists at the National Cancer Institute (NCI) and the National Institute of Environmental Health Sciences (NIEHS), as well as the agency scientists, "on scientific concepts and methods currently in use to identify and evaluate substances that may pose a risk of cancer to humans."<sup>37</sup>

In October 1979, the same month that the Regulatory Council published its statement, the CIIT released its formaldehyde findings. The federal cancer policy expressed in the Council statement and in the OSHA generic standard would have been expected to guide agency deliberations on formaldehyde. CPSC apparently followed that policy. As will be discussed in Parts IV and V of this article, however, both EPA and OSHA departed from that policy in several respects, and adopted positions far less protective of public health. Perhaps more importantly,

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notice of proposed rulemaking) and was later promulgated under the title "Identification, Classification and Regulation of Potential Occupational Carcinogens," 45 Fed. Reg. 5002 (1980) (codified at 29 C.F.R. § 1990) (1982).

31. See generally McGarity, *OSHA's Generic Carcinogen Policy: Rule Making Under Scientific and Legal Uncertainty*, in *LAW AND SCIENCE IN COLLABORATION: RESOLVING REGULATORY ISSUES OF SCIENCE AND TECHNOLOGY* 55 (J. Nyhart & M. Carrow eds. 1983).

32. 43 Fed. Reg. 26,558 (1978). For a discussion of CPSC's cancer policy deliberations, see generally Merrill, *CPSC Regulation of Cancer Risks in Consumer Products: 1972-81*, 67 VA. L. REV. 1261, 1297-1304 (1981).

33. 44 Fed. Reg. 23,821 (1979).

34. Regulatory Council, Statement on Regulation of Chemical Carcinogens Policy and Request for Public Comment, 44 Fed. Reg. 60,038 (1979) [hereinafter cited as Regulatory Council Statement]. The Regulatory Council, composed of 35 federal agencies and departments, was established by President Carter in October 1978 to coordinate and streamline federal regulatory activities. See 44 Fed. Reg. 11,388 (1979).

35. 44 Fed. Reg. 60,038 (1979).

36. Interagency Regulatory Liaison Group, *Scientific Bases for Identification of Potential Carcinogens and Estimation of Risks*, 63 J. NAT'L CANCER INST. 241 (1979) [hereinafter cited as *IRLG Risk Assessment Document*], reprinted in 44 Fed. Reg. 39,858 (1979).

37. *IRLG Risk Assessment Document*, supra note 36, at 245.

they failed to acknowledge their departures as such. In Part II, we offer a framework to facilitate the identification of such policy shifts in the field of health risk assessment.

## II. A FRAMEWORK FOR EVALUATING THE FORMALDEHYDE DECISIONS

The great weight of authority suggests that the appropriate legal standard by which to evaluate agency decisions is whether the agency engaged in "reasoned decisionmaking."<sup>38</sup> As recently articulated by the

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38. The phrase "reasoned decisionmaking" was apparently first used in this context in *Greater Boston Television Corporation v. Federal Trade Comm'n*, 444 F.2d 841, 852 (D.C. Cir. 1970), *cert. denied*, 403 U.S. 923 (1971), where the D.C. Circuit stated: "Generally . . . the applicable doctrine that has evolved with the enormous growth and significance of administrative determination in the past forty or fifty years has insisted on reasoned decision-making."

Thereafter, without specifically referring to reasoned decisionmaking, the Supreme Court outlined a three-step review process in *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402 (1971). The Court noted that reviewing courts applying the "arbitrary and capricious" standard must engage in "a substantial inquiry . . . a thorough, probing, in-depth review." *Id.* at 415. It directed reviewing courts to determine: (1) whether the agency acted within the scope of its statutory authority; (2) whether the agency's decision "was based on a consideration of the relevant factors and whether there has been a clear error of judgment"; and (3) whether the agency "followed the necessary procedural requirements." *Id.* at 416-17. The D.C. Circuit further refined the reasoned decisionmaking concept on the basis of *Overton Park*. See, e.g., *International Harvester Co. v. Ruckelshaus*, 478 F.2d 615 (D.C. Cir. 1973) (Bazelon, J., concurring) (an agency must establish "a decision-making process which assures a reasoned decision"); *ASG Indus. v. CPSC*, 593 F.2d 1323, 1373 (D.C. Cir. 1979); *State Farm Mutual Auto. Ins. v. Department of Transp.*, 680 F.2d 206 (D.C. Cir.), *cert. granted*, 103 S. Ct. 340 (1982). The Fifth Circuit recently adopted the phrase "reasoned decisionmaking." See *City of Houston v. Federal Aviation Admin.*, 679 F.2d 1184, 1190 (1982). Other circuits, while not referring specifically to "reasoned decisionmaking," have applied the principles laid down by the Supreme Court in *Overton Park*. See, e.g., *Kerr-McGee Nuclear Corp. v. Nuclear Regulatory Comm'n*, 673 F.2d 1124 (10th Cir. 1982); see generally Verkuil, *Judicial Review of Informal Rulemaking*, 60 VA L. REV. 185 (1974).

The viability of *Overton Park*, and thus of the reasoned decisionmaking standard, may have been thrown into question by *Vermont Yankee Power Corp. v. Natural Resources Defense Council*, 435 U.S. 519 (1978), where the Supreme Court overturned the D.C. Circuit's reversal of a Nuclear Regulatory Commission (NRC) decision to grant licenses for two nuclear power plants. The lower court had, in effect, required the NRC to provide an opportunity for cross-examination in its informal rulemaking process. See 435 U.S. at 541-42. As the relevant statutes contain no such requirement, the Supreme Court reversed, cautioning reviewing courts "against engrafting their own notions of proper procedures upon agencies entrusted with substantive functions by Congress." *Id.* at 525.

Some commentators have read the case as a retreat from the "substantial inquiry" standard enunciated in *Overton Park*. Others, however, have argued that the case actually confirms the earlier doctrine. Although Justice Rehnquist's opinion focuses narrowly on the impropriety of requiring agencies to adopt rulemaking procedures beyond those required by statute, it does reaffirm both "the importance of a record supporting the decision and the reviewing court's authority to require additional justification for the agency decision." Delong, *Informal Rulemaking and the Integration of Law and Policy*, 65 VA. L. REV. 257 (1979). Indeed, the Court's ultimate description of the appropriate standard of judicial review under the National Environmental Policy Act (NEPA) appears consistent with the

D.C. Circuit, an agency practices reasoned decisionmaking when it: (1) takes a "hard look . . . at the relevant issues"; (2) deliberates "in a manner calculated to negate the danger of arbitrariness and irrationality"; (3) violates "no law"; and (4) provides an "articulated justification" that makes a "rational connection between the facts found and the choice made."<sup>39</sup>

Applying the concepts of reasoned decisionmaking as an analytical tool requires a clear understanding of what a particular agency has and has not done. With health risk determinations, this understanding often requires a technical knowledge of the underlying data and methodologies. Further, it requires an ability to distinguish between purely technical determinations and those based on the more subjective, science policy determinations.

In this part of the article, we discuss the applicability of the reasoned decisionmaking standard to the formaldehyde decisions, explore the science policy issues surrounding human health risk assessment, and, finally, offer an analytical framework for evaluating agency decisionmaking in this field of regulatory activity. This framework forms the basis for our discussion of the formaldehyde decisions.

In developing a general analytical framework, we are not unmindful of the judicial deference traditionally afforded agency decisions not to act.<sup>40</sup> In the past, legal challenges to agency decisions on health and safety have come primarily in response to specific regulatory *actions*. An agency's implementation of a statutory provision was challenged as either too zealous<sup>41</sup> or insufficiently protective.<sup>42</sup> In the present antiregulatory

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general concept of reasoned decisionmaking. Agencies operating under NEPA, said the Court, must arrive at a "fully informed and well-considered decision." 435 U.S. at 558.

The Supreme Court remanded *Vermont Yankee* to the Court of Appeals for a determination whether the NRC decision "finds sufficient justification in the administrative proceedings that it should be upheld by the reviewing court." 435 U.S. at 549. On remand, the D.C. Circuit decided that it did not. 685 F.2d 459 (1982). The Supreme Court has accepted this decision for review. 103 S. Ct. 443 (1982). Thus, further refinement of the *Overton Park* doctrine may be forthcoming.

39. *WWHT, Inc. v. FCC*, 656 F.2d 807, 817 (D.C. Cir. 1981) (citing *Action for Children's Television v. FCC*, 564 F.2d 458, 472 n.24, 479 (D.C. Cir. 1977)).

40. *See infra* note 66.

41. *See, e.g.*, *American Textile Mfrs. Inst. v. Donovan*, 449 U.S. 809 (1981) (OSHA cotton dust standard); *Industrial Union Dep't v. American Petroleum Inst.*, 448 U.S. 607 (1980) (OSHA benzene standard); *ASG Indus. v. CPSC*, 593 F.2d 1323 (CPSC safety standard for architectural glazing materials); *Aqua Slide 'n' Dive Corp. v. CPSC*, 569 F.2d 831 (5th Cir. 1978) (CPSC water slide standards); *American Iron and Steel Inst. v. OSHA*, 577 F.2d 825 (3d Cir. 1978) (OSHA coke oven emissions standard); *Ethyl Corp. v. EPA*, 541 F.2d 1 (D.C. Cir. 1976) (EPA gasoline lead additive regulation).

42. *See, e.g.*, *Vermont Yankee Power Corp. v. Natural Resources Defense Council*, 435 U.S. 519 (1978) (Nuclear Regulatory Commission's decision to grant nuclear power plant licenses); *Natural Resources Defense Council v. EPA*, 655 F.2d 318 (D.C. Cir. 1981) (EPA's standards for particulates from diesel vehicles); *Environmental Defense Fund v. EPA*, 636 F.2d 1267 (D.C. Cir. 1980) (EPA's PCB standards); *Industrial Union Dep't v. Hodgson*, 499 F.2d 467 (D.C. Cir. 1974) (OSHA asbestos standard).



climate, challenges to agency decisions *not to act* may assume greater significance.<sup>43</sup>

Judicial deference to agency discretion in such situations is based largely on respect for agency expertise in matters of resource allocation and technical evaluation.<sup>44</sup> Such deference is misplaced, however, where an agency uses the cloak of expertise to disguise inadequate technical analysis, improper decisionmaking procedures, or statutory misinterpretation. An analysis of the formaldehyde decisions demonstrates why, before deferring to an agency's decision not to take regulatory action to protect human health, the courts should first take a "hard look" at the agency's decision to determine whether such deference is, in fact, warranted.<sup>45</sup>

#### A. Applying the Reasoned Decisionmaking Standard

EPA, OSHA, and CPSC each approached the formaldehyde issue from a different statutory perspective. Nonetheless, all must meet the reasoned decisionmaking standard.

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43. Recent cases involving agency decisions not to act on health and safety matters include *Public Citizen Health Research Group v. Auchter*, No. 83-1071, slip op. (D.C. Cir. Mar. 15, 1983) (challenge to OSHA denial of emergency temporary standard for ethylene oxide) and *State Farm Mutual Auto. Ins. v. Department of Transp.*, 680 F.2d 206 (D.C. Cir. 1982) (challenge to National Highway Traffic Safety Administration rescission of automatic crash protection regulations).

The now famous Bazelon-Leventhal debate on the propriety of "procedural" versus "substantive" review may be revitalized if review of decisions not to act becomes more commonplace. See Bazelon, *Science and Uncertainty: A Jurist's View*, 5 HARV. ENVTL. L. REV. 209 (1981). When reviewing agency actions, courts can arguably arrive at the same result whether they use a "procedural" or "substantive" standard of review. Here the theoretical distinction between the two standards may well have little practical significance. For decisions *not to act*, however, the remedy may well depend on the standard of review. If the court engages in substantive review, it will be free to order the agency to reverse its decision and to take the regulatory action that it had determined to avoid. But if the court limits itself to a purely procedural review, it may be unable to do more than direct the agency to reconsider the decision not to act, at least absent a finding that procedural irregularities have so tainted the agency's deliberations that a substantive review is necessary. The formaldehyde decisions are probably not an appropriate vehicle for resolving this issue, however, as both the EPA and OSHA determinations were plagued by significant substantive irregularities as well as by procedural flaws.

44. See *infra* note 66.

45. Indeed, in *Public Citizen v. Auchter*, the D.C. Circuit specifically inquired into "the status of all other ongoing rulemakings" within OSHA as part of its review of the agency's failure to issue an emergency temporary standard for ethylene oxide (EtO). Although OSHA asserted that it was "currently engaged in three proceedings that . . . would be disturbed by speedier EtO rulemaking," the court concluded that these other proceedings did not so tax agency resources or health priorities as to justify delaying further EtO regulation. *Public Citizen Health Research Group v. Auchter*, No. 83-1071, slip op. at 15 (D.C. Cir. Mar. 15, 1983). Thus, apparently reaching the substantive conclusion that "some workers . . . currently encounter a potentially grave danger" from EtO, *id.* at 14, the court ordered OSHA to expedite the section 6(b) rulemaking procedure that it had already instituted for EtO. For a more detailed discussion of specific aspects of this case, see *infra* text accompanying notes 58-60 & 401-08.

### 1. The Environmental Protection Agency

The Toxic Substances Control Act (TSCA) grants EPA broad authority to regulate toxic chemicals.<sup>46</sup> EPA's formaldehyde decision involved section 4(f) of the Act, which provides that upon receiving test data or other information

which indicates to the Administrator that there may be a reasonable basis to conclude that a chemical substance or mixture presents or will present a significant risk of serious or widespread harm to human beings from cancer, gene mutations, or birth defects, the Administrator shall . . . initiate appropriate action . . . to prevent or reduce to a sufficient extent such risk or publish in the Federal Register a finding that such risk is not unreasonable.<sup>47</sup>

EPA's ultimate decision to take no action on formaldehyde was thus a determination that there was no information from which the Administrator could find that there may be a reasonable basis to conclude that formaldehyde poses a significant risk of human cancer.

To date, the courts have not had occasion to consider the proper standard of review for a failure to make the threshold determination that would trigger section 4(f), nor does the Act specifically set forth an applicable standard of review.<sup>48</sup> Nonetheless, it appears clear that judicial review is available, and that "reasoned decisionmaking" is the appropriate standard of review.

The Administrative Procedure Act (APA) provides the most obvious avenue of review.<sup>49</sup> Because the agency's formaldehyde decision was in

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46. 15 U.S.C. §§ 2601-2629 (1976 & Supp. V 1981).

47. 15 U.S.C. § 2603(f) (1976).

48. Section 19, 15 U.S.C. § 2618 (1976), provides for direct review at the circuit court level of certain determinations made under sections 4, 5, 6, or 8, *id.* §§ 2603, 2604, 2605, & 2607.

Section 4(f), *id.* § 2603(f), provides for review under the Administrative Procedure Act (APA) of an EPA decision that the risk posed by a particular chemical is "not unreasonable." Because such a finding is not required to be made by formal hearing, the applicable standard of review under the APA is the "arbitrary and capricious" standard. 5 U.S.C. § 706(2)(A) (1976). TSCA prescribes no standard of review, however, for the agency's failure to make the section 4(f) threshold finding that there may be a reasonable basis to conclude that a chemical poses a significant risk of serious or widespread harm from cancer. 15 U.S.C. § 2603(f).

49. 5 U.S.C. §§ 701-706 (1976). An Administrator's failure to make a threshold finding under section 4(f) will often be a "final agency action" for the purpose of Section 704 of the APA. The formaldehyde decision appears to be such an action, because the agency not only reversed its previous decision that section 4(f) had been triggered, but also considered the data on formaldehyde at length and released a detailed written explanation of its position. *See supra* notes 66-67 and *infra* notes 181-89 and accompanying text.

Furthermore, even though Congress specifically provided for review of a determination that a chemical does not present an unreasonable risk under section 4(f), its failure to provide for review of a refusal to make a section 4(f) threshold determination should not preclude review, especially in light of the strong presumption of reviewability inherent in the APA. *See* *Natural Resources Defense Council v. SEC*, 606 F.2d 1031, 1043 (D.C. Cir.

the nature of an informal rulemaking procedure, review would proceed under the familiar "arbitrary and capricious" standard.<sup>50</sup> As the D.C. Circuit has recently emphasized, this standard demands an inquiry into whether the agency has practiced reasoned decisionmaking, even when applied to decisions not to act.<sup>51</sup>

Review may also be available under section 20 of TSCA, the "citizen suit" provision, which authorizes civil actions "to compel the Administrator to perform any act or duty under this Act which is not discretionary."<sup>52</sup> EPA's failure to make a threshold finding of a possibility of significant cancer risk does not, in itself, constitute a failure to perform a mandatory act. Once EPA makes that threshold determination, however, it must act in accordance with section 4(f): it must either take remedial action or publish in the Federal Register its rationale for declining to take such action. For formaldehyde, considerable evidence indicates that EPA initially made, but later rescinded, the necessary threshold

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1979). The legislative history of TSCA indicates that Congress was particularly concerned that the Act's strong public health mandate might be frustrated by EPA's hesitancy or unwillingness to act. When discussing the Act's citizen suit provision, for example, the Senate Report noted that "responsiveness of government is a critical concern," and indicated its desire to "protect against lax administration of the bill." S. REP. NO. 698, 94th Cong., 2d Sess. 13 (1976).

50. 5 U.S.C. § 706(2)(A) (1976).

51. The D.C. Circuit recently reviewed an FCC decision not to grant a petition to amend the Commission's mandatory cable carriage rules to include subscription television signals. *WWHT, Inc. v. FCC*, 656 F.2d 807 (D.C. Cir. 1981). Though the court noted that the scope of review "should be *extremely limited*" in such a situation, *id.* at 817 (emphasis in original), it nonetheless applied the four general principles of reasoned decisionmaking.

A year later, the same court reviewed the National Highway Traffic Safety Administration's decision to rescind passive restraint standards ten months before they were to take effect. *State Farm Mutual Auto. Ins. v. Department of Transp.*, 680 F.2d 206, 229 (D.C. Cir. 1982). The court noted that "rescission more resembles agency refusal to act than an agency decision to act, and the distinction has significance for the degree of judicial deference paid to the agency." *Id.* at 218. Citing *NLRB v. Brown*, 380 U.S. 278, 291 (1965), however, it also noted that "courts are 'not obliged to stand aside and rubber-stamp their affirmance of administrative decisions that they deem inconsistent with a statutory mandate or that frustrate the congressional policy underlying a statute,'" and specifically applied the concepts of reasoned decisionmaking. 680 F.2d at 229. Focusing on substantive rather than procedural aspects of the Administration's decision, the court defined the scope of review in different language than it had used in *WWHT*, but with similar significance for the substantive aspects of the review process:

We . . . review . . . whether the agency has engaged in reasoned decisionmaking, making actual judgments concerning the significance of the evidence in the record and supporting its decision with "reasoned analysis." We must ascertain the facts on which [the agency] relied, determine whether those facts have some basis in the record, and judge whether a reasonable decisionmaker could respond to those facts as the agency did. The court must also assure itself that [the agency's decision] is "based on consideration of the relevant factors."

680 F.2d at 229 (citations omitted); *see also* *Natural Resources Defense Council v. SEC*, 606 F.2d at 1053 (articulating similar standard). Thus, although the appropriate scope of review may vary with the particular agency decision and the relevant statutory mandate, the D.C. Circuit has repeatedly stressed its concern for ensuring that the agency made a *reasoned* decision.

52. 15 U.S.C. § 2619(a)(2) (1976).

determination.<sup>53</sup> If so, review under TSCA's citizen suit provision may well be appropriate. Furthermore, the D.C. Circuit has indicated that it will treat a normally discretionary threshold action as a mandatory action where the decision to act has been "arbitrarily withheld."<sup>54</sup> Because many aspects of EPA's formaldehyde decision were arguably arbitrary,<sup>55</sup> section 20 review may be appropriate under this doctrine as well.<sup>56</sup>

## 2. *The Occupational Safety and Health Administration*

OSHA reviewed formaldehyde following a request from several unions that the agency set an emergency temporary standard (ETS) for that substance under section 6 of the OSHAct. Section 6(c)(1) states:

The Secretary shall provide . . . for an emergency temporary standard . . . if he determines (A) that employees are exposed to grave danger from exposure to substances or agents determined to be toxic or physically harmful or from new hazards, and (B) that such emergency standard is necessary to protect employees from such danger.<sup>57</sup>

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53. See *infra* notes 155-75 and accompanying text.

54. *Environmental Defense Fund v. Ruckelshaus*, 439 F.2d 584 (D.C. Cir. 1971). There, the court reviewed a decision by the Secretary of Agriculture to delay the issuance, under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), of an order granting or denying a request for the suspension and cancellation of pesticides containing DDT. The Secretary argued that a decision to delay such a determination was within the discretion delegated to him by Congress, and was therefore not subject to review. The court disagreed:

The FIFRA gives the court jurisdiction to review any order granting or denying the cancellation of a pesticide registration. The Secretary could defeat that jurisdiction, however, by delaying his determination indefinitely. Petitioners contend that the Secretary's own findings with respect to DDT compel him to issue cancellation notices, and hence that his action is "unlawfully withheld or unreasonably delayed" within the meaning of the Administrative Procedure Act. In order to protect our appellate jurisdiction, this court has jurisdiction to entertain a request for relief in the form of an order directing the secretary to act in accordance with the FIFRA.

439 F.2d at 593.

Although the analogy is not perfect, this case parallels EPA's failure to make the threshold determination for formaldehyde under section 4(f) of TSCA. That section grants jurisdiction under the APA for review of an agency determination that a suspected human carcinogen does not pose an unreasonable risk to human health. EPA "could defeat that jurisdiction," however, by refusing to make the threshold finding that there may be a reasonable basis to conclude that the chemical poses a significant risk. Where, as for formaldehyde, the agency has substantial evidence that a chemical is an animal carcinogen — which raises in most reasonable minds the possibility of significant human risk — a section 20 action to compel the Administrator to determine whether the risk is unreasonable would appear appropriate. Such action would seem consistent with the expressed purpose of section 20 to "protect against lax administration of the bill." S. REP. NO. 698, *supra* note 49, at 13; see *supra* note 49.

55. See generally *infra* text accompanying notes 155-324.

56. See *supra* note 54.

57. 29 U.S.C. § 655(c)(1) (1970).

OSHA, like EPA, decided to take no action. For OSHA, however, the courts have spoken on the proper standard of review for such situations. Prior to denying the labor unions' request, OSHA denied a similar request for ethylene oxide.<sup>58</sup> The D.C. Circuit reviewed that denial and, although it did not order OSHA to promulgate an emergency standard, it did order OSHA to expedite permanent rulemaking procedures for ethylene oxide.<sup>59</sup> As the OSHA Act provides no specific standard of review for such a denial, the court applied traditional APA criteria and characterized its review as "'thorough' and 'probing'."<sup>60</sup> The standard of review for the denial of section 6(c)(1) petitions is thus the "arbitrary and capricious" standard, in which the concept of reasoned decisionmaking is inherent.

### 3. The Consumer Product Safety Commission

CPSC issued its ban on urea-formaldehyde foam insulation under the CPS Act.<sup>61</sup> Section 8 of the Act authorizes the Commission to ban a "hazardous" product upon a three-tiered finding: (1) that the product "is being, or will be, distributed in commerce"; (2) that it "presents an unreasonable risk of injury"; and (3) that "no feasible consumer product safety standard . . . would adequately protect the public from the unreasonable risk of injury associated with such product."<sup>62</sup> Judicial review of such a ban is specifically authorized by the CPS Act,<sup>63</sup> which directs the reviewing court to determine whether the action is supported by "substantial evidence in the record taken as a whole."<sup>64</sup> In reviewing CPSC actions taken under section 8, the D.C. Circuit has applied a reasoned decisionmaking standard.<sup>65</sup>

### 4. Summary

Reasoned decisionmaking would appear to be the appropriate standard for reviewing each of the three formaldehyde decisions. Courts have been somewhat more deferential to agency decisions *not* to take action, like EPA's and OSHA's, than to decisions to take a particular action,

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58. See *OSHA Denies Request for Emergency Rule, Pledges Rulemaking to Reach Lower Limit*, [11 Curr. Dev.] O.S.H. REP. (BNA) No. 18, at 341 (Oct. 1, 1981).

59. *Public Citizen Health Group v. Aucther*, No. 83-1071, slip op. (D.C. Cir. Mar. 15, 1983).

60. *Id.* at 13-14 (citing *Overton Park*, 401 U.S. 402, 415). The court makes no specific mention of the "arbitrary and capricious" standard, but its reliance on *Overton Park* and the nature of its inquiries indicate that it followed the traditional concepts of reasoned decisionmaking.

61. 15 U.S.C. §§ 2051-2083 (1976 & Supp. V 1981).

62. *Id.* § 2057.

63. *Id.* § 2060.

64. *Id.* § 2060(c).

65. See *ASG Indus., Inc. v. CPSC*, 593 F.2d 1323, 1331 & 1335 (D.C. Cir. 1979).

like CPSC's.<sup>66</sup> Such deference is unwarranted here<sup>67</sup> in light both of the significant procedural irregularities in the EPA and OSHA deliberations<sup>68</sup> and of the potentially significant consequences of these decisions for human health.<sup>69</sup> Whatever standard of review the courts may ultimately apply to the EPA and OSHA decisions, however, the rubric of reasoned decisionmaking provides an excellent framework for understanding and evaluating each agency's decision.

### B. Science Policy Issues and the Assessment of Cancer Risk

The term "science policy" denotes issues that are grounded in scientific analysis but for which technical data are insufficient to support an

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66. See *supra* note 51. The D.C. Circuit summarized six principal reasons for such deference in *National Resources Defense Council v. SEC*: (1) that the issues involved turn on "factors not inherently susceptible to judicial resolution," such as the management of budget and personnel and the balancing of competing policies within a broad statutory framework; (2) that there may be "such rapid technological development that regulations would be outdated by the time they could become effective"; (3) that there may be inadequate data currently available on which to base regulations; (4) that "[t]he circumstances in the regulated industry may be evolving in a way that could vitiate the need for regulation"; (5) that the agency may not yet possess "the expertise necessary for effective regulation"; and (6) that the record on review would be "of little use to a reviewing court unless [it is] narrowly focused on the particular rule advocated by plaintiff." 606 F.2d 1031, 1046 (D.C. Cir. 1979) (citations omitted).

67. The D.C. Circuit's six reasons for deference, see *supra* note 66, are largely inapplicable here. First, EPA's and OSHA's decisions can not truly be said to be discretionary decisions *not* to regulate. Rather, they are failures, or refusals, to make certain findings that trigger mandatory action under section 4(f) of TSCA and section 6(c) of the OSHAct. Further, as both of these sections explicitly anticipate imminent actions to protect public health, neither EPA nor OSHA has the authority to engage in the kind of discretionary delay implicit in reasons two through five.

Even if the agencies had such authority, none of the specific factors that concerned the D.C. Circuit, see *id.*, is present here. There is no "rapid technological development" in the use of formaldehyde, or in the detection of carcinogenicity, such that formaldehyde regulations "would be outdated by the time they could become effective"; similarly, nothing indicates that circumstances in formaldehyde industries are "evolving in a way that could vitiate the need for further regulation." The courts have indicated that information of the type here available to EPA and OSHA, given the present state of the art in carcinogenic risk assessment, is an acceptable basis upon which to premise regulations. *Industrial Union Dep't v. Hodgson*, 499 F.2d 467, 474-75 (D.C. Cir. 1974). Finally, both agencies have sufficient expertise to assess carcinogenic risk. The sixth reason for deference is also inapplicable. Both EPA and OSHA deliberated for over two years and made "narrowly focused" technical and policy determinations. Indeed, the record of EPA's deliberations is especially well developed, as many aspects of the agency's decision have been outlined at congressional hearings.

68. See *infra* text accompanying notes 228-302 & 367-86.

In *NRDC v. SEC*, the court noted that "more exacting scrutiny" of decisions not to act will be appropriate "when for some reason the presumption of agency regularity is rebutted." 606 F.2d at 1049 n.23 (citation omitted). It enumerated four examples of situations in which that presumption will be overcome. Two of them are relevant here: "where the agency has demonstrated undue bias towards particular private interests"; and "when an agency has departed from its consistent and longstanding precedents or policies." *Id.* at 1049 n.23 (citations omitted).

69. See *infra* text accompanying notes 104-29.

unequivocal scientific conclusion.<sup>70</sup> The ultimate resolution of these issues depends on determinations of social policy.<sup>71</sup>

Distinguishing science policy determinations from those of a truly technical nature is a central step in evaluating the adequacy of an agency's assessment of human health risks.<sup>72</sup> Simply deferring to agency expertise on all determinations that appear to be "scientific" overlooks the subjective determinations at the heart of the agency's decisions. Such an approach frustrates any effort to measure agency decisions against the reasoned decisionmaking standard.

Professor Thomas McGarity has noted that science policy issues can be divided into distinct conceptual categories.<sup>73</sup> Understanding these major categories can be useful in analyzing the extent to which agencies practice reasoned decisionmaking.

### 1. *Trans-Scientific Issues*

Some science policy issues, called "trans-scientific"<sup>74</sup> issues, raise scientific questions, but are not amenable to scientific study because of methodological constraints.<sup>75</sup> These issues are said to "transcend science."<sup>76</sup>

The recent controversy over the impact of chlorofluorocarbons (CFCs) on the upper atmosphere provides a familiar example.<sup>77</sup> In the last decade, the aerosol spray can was used to package household products ranging from deodorants to whipped toppings. Such cans contained small quantities of chlorofluorocarbons as a pressurizing agent. When the cans were used CFCs were released into the environment. In the early 1970's, researchers reported that the CFCs might be depleting the ozone

70. See generally McGarity, *Substantive and Procedural Discretion in Administrative Resolution of Science Policy Questions: Regulating Carcinogens in EPA and OSHA*, 67 GEO. L.J. 729 (1979).

71. Although they do not use the term "science policy," a number of other authors have also recognized the extreme technical uncertainty inherent in certain types of "scientific" decisions. See, e.g., Bazelon, *supra* note 43; Jasanoff & Nelkin, *Science, Technology, and the Limits of Judicial Competence*, 68 A.B.A. J. 1094 (1982); Kantrowitz, *Controlling Technology Democratically*, 63 AMERICAN SCIENTIST 505 (1975); Mazur, *Science Courts*, 15 MINERVA 1 (1977); Mazur, *Disputes Between Experts*, 11 MINERVA 243 (1973); Weinberg, *Science and Trans-Science*, 10 MINERVA 209 (1972).

72. See *infra* note 95 (discussing the several science policy determinations an agency must make in assessing carcinogenic risk).

73. McGarity, *supra* note 70, at 732-47. Professor McGarity classifies science policy issues into four categories: trans-scientific issues, decisionmaking based on insufficient data, varying scientific interpretations, and disagreement over inferences. Although we find his classification useful, we feel that his fourth category only describes the first two in another way, and we have structured our discussion accordingly.

74. Scientist Alvin M. Weinberg coined the term "trans-scientific" in 1972. See Weinberg, *supra* note 71, at 209.

75. See McGarity, *supra* note 70, at 733-36.

76. Weinberg, *supra* note 71, at 209.

77. See generally Rowland & Molina, Cairns & Jesson, *The Ozone Question*, 190 SCIENCE 1038 (1975) (exchange of correspondence); NATIONAL RESEARCH COUNCIL, NATIONAL ACADEMY OF SCIENCES, CAUSES AND EFFECTS OF STRATOSPHERIC OZONE REDUCTION: AN UPDATE (1982).

layer in the upper atmosphere, which acts as a natural radiation shield, and thus might pose a threat to the public health.<sup>78</sup> Reputable scientists disagreed, and credible hypotheses supported each side of the issue.<sup>79</sup>

Given existing scientific methodology, those hypotheses could be meaningfully tested only through direct experimentation in the upper atmosphere.<sup>80</sup> Sufficient experimentation was impractical, however, because it was both prohibitively expensive and exceedingly difficult.<sup>81</sup> CPSC nevertheless decided to regulate the pressurized can.<sup>82</sup> This decision was not, and could not have been, based on scientific "fact." It was based instead on the agency's assessment of a trans-scientific policy issue in light of a statutory mandate to protect the public health.<sup>83</sup>

Trans-scientific issues arise regularly in human health risk assessment. For example, suppose that an agency wishes to evaluate the human carcinogenic risk of a new chemical substance.<sup>84</sup> To do so, it must determine the probable human response at relevant — and often very low — exposure levels.<sup>85</sup> Direct human testing would be morally objectionable, and epidemiologic evidence is not available because the chemical is not yet in use. Consequently, the agency must rely on the results of other tests, principally animal bioassays.<sup>86</sup> In such bioassays, 100 or more

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78. Molina & Rowland, *Stratospheric Sink for Chlorofluoromethanes: Chlorine Atom-Catalyzed Destruction of Ozone*, 249 NATURE 810 (1974). The ozone layer helps screen out harmful radiation that would otherwise reach the earth's surface from the sun.

79. See Rowland & Molina, Cairns & Jesson, *supra* note 77; Molina & Rowland, *supra* note 78; Lovelock, *Atmospheric Halocarbons and Stratospheric Ozone*, 252 NATURE 292 (1974).

80. See NATIONAL RESEARCH COUNCIL, NATIONAL ACADEMY OF SCIENCES, PROTECTION AGAINST DEPLETION OF STRATOSPHERIC OZONE BY CHLOROFLUOROCARBONS, 31-57 (1979); NATIONAL RESEARCH COUNCIL, NATIONAL ACADEMY OF SCIENCES, HALOCARBONS: ENVIRONMENTAL EFFECTS OF CHLOROFLUOROMETHANE RELEASE, 11-13, 21-24, 51-53 (1976).

81. See references cited *supra* note 80.

82. For a discussion of CPSC's regulatory efforts, see Merrill, *supra* note 32, at 1318-23.

83. See *id.* EPA also took regulatory action against chlorofluorocarbons under TSCA. See *id.*

84. For a general discussion of the procedures and tests involved in assessing carcinogenic risk, see Office of Technology Assessment, *Assessment of Technologies for Determining Cancer Risks from the Environment* (June 1981) (U.S. G.P.O. #OTA-H-138); R. Merrill, *Federal Regulation of Cancer-Causing Chemicals*, Draft Report to the Administrative Conference of the United States, Part I (April 1982) (available from the Administrative Conference); Leape, *Quantitative Risk Assessment in the Regulation of Environmental Carcinogens*, 4 HARV. ENVTL. L. REV. 86 (1980).

85. See IRLG *Risk Assessment Document*, *supra* note 36, at 259.

86. Bioassays involve exposing test animals — commonly rats or mice — to various doses of the substance in question, observing those animals and "control" animals over a period of time, and comparing tumor growth in the test and control groups.

In addition to bioassays, various tests may be used to assess the mutagenicity of a chemical substance. Such tests provide useful data for evaluating carcinogenicity because available evidence indicates that carcinogenesis may proceed by primary genetic mechanisms. In brief, it is known that most cancers originate in single cells, that many carcinogens are mutagenic and react directly or indirectly with DNA, and that well-characterized genetic



animals are commonly tested at a high dose level, because directly measuring the effects of low-dose exposures would require testing tens of thousands of animals.<sup>87</sup> Thus arise two classic issues of trans-science: how does the agency interpolate high-dose data to lower exposure levels? and how does it extrapolate animal data to humans? Existing scientific knowledge cannot supply a definitive answer.

From a regulatory perspective, the important feature of trans-scientific issues is that, without a significant improvement in scientific methodology, delaying a decision to await their resolution will *not* permit the development of a "better" scientific answer. As Professor McGarity comments, "correct answers to these questions may exist as a philosophical matter, but the 'truth' is ultimately unascertainable in either the scientific or the legal forum."<sup>88</sup>

## 2. *Insufficient, but Obtainable, Scientific Data*

Many science policy issues conceivably could be resolved through current methodology without moral objection. Drawing from our previous example, suppose that an agency seeks to evaluate the human carcinogenic risk of a chemical that has long been in use. Here, science might well be able to provide an answer or at least be able to narrow the question. An epidemiologic study perhaps could isolate the nature and extent of the human carcinogenic risk.<sup>89</sup> The relevant science policy issue, then, is the propriety of delaying a risk determination until such a study has been concluded. Depending on the available data base, a study may take from two to forty years to complete.<sup>90</sup> When is such a delay

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impairments in DNA repair processes increase the risks of specific kinds of tumors. See F. VOGEL & A. MOTULSKY, *HUMAN GENETICS — PROBLEMS AND APPROACHES*, 326–29 (1979); Hattis, Ashford, & Hollomon, *Regulation of Cancer-Causing Substances: Another Point of View*, *CHEM. & ENG'G NEWS*, Dec. 13, 1982, at 35. Positive mutagenicity results are often considered as supporting evidence of a chemical's carcinogenicity. See, e.g., *IRLG Risk Assessment Document*, *supra* note 36, at 25–57.

For a more detailed discussion of the various tests, see Weisberger & Williams, *Chemical Carcinogens*, in CASARETT AND DOULL'S *TOXICOLOGY* 124–33 (J. Doull, C. Klassen, & M. Amdur 2d ed. 1980).

87. Humans are generally exposed to carcinogens at low levels in the environment or workplace. Common risks of concern at such levels range from 1 cancer case per 1000 persons exposed to 1 per 1,000,000. In bioassays, the test animals are essentially surrogates for people. Thus, in order to detect a risk of 1 per 1000 at a low exposure level, many more than 1000 animals would have to be tested to assure significant results. Testing at high exposure levels involves higher risks (e.g., 1 per 10 or 1 per 100) and thus fewer animals need be used. Such results then must be interpolated to lower exposure levels. For a discussion of this testing problem, see National Center for Toxicological Research, *Innovations in Cancer Risk Assessment (ED01 Study)*, 3 *J. ENVTL. PATHOLOGY & TOXICOLOGY* 1 (1980) (24,000 mouse experiment designed to detect 1 cancer per 100 mice).

88. McGarity, *supra* note 70, at 734.

89. Epidemiology is the statistical study of disease in human populations. G. FRIEDMAN, *PRIMER OF EPIDEMIOLOGY* 1 (2d ed. 1980). For general discussions of the benefits, and limits, of epidemiologic studies, see R. MONSON, *OCCUPATIONAL EPIDEMIOLOGY* (1980); B. MACMAHON & T. PUGH, *EPIDEMIOLOGY: PRINCIPLES AND METHODS* (1970).

90. A suitable "retrospective" cancer study, in which investigators examine existing

appropriate and when not? This is a question of social, not scientific, policy. The agency must look to its statutory mandate, rather than to science, for direction.<sup>91</sup> In the many situations where a delay will be inappropriate, the agency will have to treat the question of carcinogenic risk as if it were a trans-scientific issue.

### 3. Disagreement Over Scientific Interpretation

The final category of science policy issues involves differences in scientific judgment. Even when dealing with a scientific issue rather than a trans-scientific one, scientists may disagree on the proper scientific interpretation of the data. Different interpretations of the same data do not stem from differences in social or political philosophy; instead, "scientific judgment has more to do with scientists' views, growing out of long years of study, on how things operate in the physical world with which they are familiar."<sup>92</sup> The science policy issue is the choice between the different scientific interpretations. For these issues, as for trans-scientific issues, science cannot now provide an answer.<sup>93</sup>

### C. Evaluating Agency Decisionmaking in Health Risk Assessment

Acknowledging that science policy will often play a major role in agency assessments of human health risks, we now consider how to determine whether an agency has abided by the principles of reasoned decisionmaking. These principles impose three primary responsibilities on an agency assessing health risks: (1) it must adequately evaluate the technical data; (2) it must follow proper administrative procedures; and (3) it must correctly carry out its statutory mandate.<sup>94</sup> In practice, these functions overlap. An agency's interpretation of its statutory mandate, for example, can influence both the nature of the technical data it examines and the manner in which it makes that examination. In analyzing completed agency decisions, however, the three elements are separable and provide a logical framework.

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health records, might be conducted within a relatively short period provided that sufficient data exist on exposure and outcome for the study population. A "prospective" study, in which the investigators identify people currently exposed to a suspect chemical, takes much longer to complete because the study must last as long as the latency period for cancer, which can be up to 40 years. *See generally* MONSON, *supra* note 89, at 35-64.

91. In evaluating agency inaction under statutes designed to reduce human exposure to toxic substances, courts must necessarily determine whether and to what extent Congress intended the agency to act in the face of uncertainty. *See Industrial Union Dep't v. Hodgson*, 499 F.2d 467 (D.C. Cir. 1974).

92. McGarity, *supra* note 70, at 742.

93. *See generally id.* at 740-53.

94. This scheme, of course, is not unfamiliar. It reflects the framework that the Supreme Court laid in *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402 (1971), structured to accommodate science policy decisions. *See supra* note 38.

### 1. Treatment of Technical Data

In evaluating the technical data relevant to determining the health risk, an agency must delve deeply into scientific issues. The agency will ordinarily engage in two levels of scientific analysis. On one level, it will address "hard" scientific issues that can be resolved with currently available methodologies. On a second level, the agency will confront various science policy issues, which cannot be answered solely on a technical basis.<sup>95</sup> Thus, a meaningful critique of an agency's treatment of technical data requires both an understanding of the relevant technical methodology and an ability to distinguish between "hard science" and "science policy" determinations.

For example, most reputable toxicologists agree that an animal carcinogenesis bioassay will produce misleading results unless it allows sufficient time — about two years — for the development of tumors.<sup>96</sup> An agency that concluded that a substance was not carcinogenic on the basis of a negative three-month bioassay would commit an identifiable methodological error.

In contrast, there is considerable disagreement among toxicologists on the proper interpretation of benign tumors in bioassays;<sup>97</sup> current scientific understanding is simply insufficient to permit a conclusive assessment of the significance of benign tumors in cancer risk assessment.<sup>98</sup> When an agency makes a determination based on benign tumor data, it operates outside the realm of hard science.

Scientific opinion on some science policy issues, such as the issue of extrapolating animal data to humans,<sup>99</sup> is much more uniform. Here the analytical question is whether the agency has adhered to prevailing scientific opinion. In appropriate circumstances, of course, the agency may depart from scientific opinion on these issues. They do, after all,

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95. The science policy determinations that agencies must make in assessing carcinogenic risk include: (1) the extrapolation of animal data to humans; (2) the interpolation of high-dose data to project low-dose risk; (3) the usefulness of short-term *in vitro* tests for assessing carcinogenicity; (4) the usefulness of chemical structure for predicting carcinogenicity; (5) the reversibility of cell transformation induced by carcinogens; (6) the distinction between benign and malignant tumors; and (7) the importance of negative human epidemiologic data and negative animal experimental data.

96. See Weisberger & Williams, *supra* note 86, at 130 (exposures of two years for rats, 21–24 months for mice and hamsters).

97. Benign tumors, unlike malignant ones, do not divide, become dislodged from their original site, or invade surrounding tissues or organs. See Office of Technology Assessment, *supra* note 84, at 127.

98. Compare AD HOC COMMITTEE ON THE EVALUATION OF LOW LEVELS OF ENVIRONMENTAL CHEMICAL CARCINOGENESIS, EVALUATION OF ENVIRONMENTAL CARCINOGENS: REPORT TO THE SURGEON GENERAL 180 (1970) (benign tumors should be counted as significant in assessing carcinogenicity) with Plant, *A Dangerous Definition*, CHEMICAL & ENGINEERING NEWS, Oct. 20, 1975, at 4 (opposite conclusion). Further experimentation will undoubtedly generate more data on the relationship between benign and malignant tumors, but an ultimate answer does not seem immediately forthcoming.

99. See, e.g., IRLG Risk Assessment Document, *supra* note 36, at 248.

involve *policy* determinations, and accordingly should be made by the governmental entity charged with reflecting the will of the people through the execution of a congressional mandate. Nonetheless, they are also determinations that should be properly based on a sufficient understanding of the underlying scientific evidence. When a majority position on a science policy issue has evolved within the scientific community, then, the agency should not depart from that position without acknowledging and justifying the departure.

## 2. Adherence to Procedural Requirements

Science policy issues may also arise in the context of procedural matters. Agencies often develop general policy guidelines for their regulatory actions, in the form of either formal generic standards, such as OSHA's,<sup>100</sup> or informal statements of procedure, such as the Regulatory Council's.<sup>101</sup> These guidelines not only promote regulatory continuity, but also provide notice to affected industries and interested members of the general public. As a matter of administrative procedure, an agency must either adhere to its policy guidelines or identify and explain any change in, or departure from, those guidelines.<sup>102</sup> To develop policy guidelines in the area of health risk assessment, the agency must adopt positions on science policy issues. Absent formal announcements of changes in these positions, recognizing policy departures will require that one first identify and understand the underlying science policy issues.

In addition, the agency must conform with a number of other procedural requisites. Of particular importance in evaluating health risk determinations is the agency's use of outside technical experts, whose opinions will often influence the agency's decision. Here, proper scrutiny of agency procedures will entail an examination of the agency's duties under the Federal Advisory Committee Act,<sup>103</sup> which limits the solicitation of advice from sources outside the agency.

## 3. Execution of Statutory Mandates

Finally, the agency must act in accordance with its statutory mandate. This responsibility has two elements. The agency must carry out the specific duties of the particular statutory provisions under which it is considering regulatory action. At the same time, it must faithfully adhere to the more general aspects of the congressional mandate underlying its enabling legislation.

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100. See *supra* text accompanying notes 29-31.

101. See *supra* text accompanying notes 34-35.

102. See, e.g., *State Farm Mutual Auto. Ins. v. Department of Transp.*, 680 F.2d 206, 220 (D.C. Cir. 1982) ("an agency changing its course must supply a reasoned analysis indicating that prior policies and standards are being deliberately changed, not casually ignored") (citing *Greater Boston Television Corp. v. FTC*, 444 F.2d 841, 852 (D.C. Cir. 1970)).

103. 5 U.S.C. app. I (1976).

Any analysis of agency decisionmaking must carefully consider both of these elements. In evaluating health risk determinations, particular attention must be given to the ways in which assessments of science policy issues reflect an agency's interpretation of its statutory mandate. In close cases, for example, should the agency tip the balance in favor of finding a human health risk, or in favor of deferring such a finding until additional data are available?

### III. FORMALDEHYDE CANCER RISK: AVAILABLE SCIENTIFIC EVIDENCE

#### A. Evidence on Formaldehyde Carcinogenicity

##### 1. Bioassay Evidence

The most important and conclusive evidence on formaldehyde carcinogenicity came from a two-year bioassay sponsored by the Chemical Industry Institute of Toxicology (CIIT), an independent laboratory supported by chemical corporations.<sup>104</sup> Groups of rats and groups of mice were exposed to nominal levels of zero, two, six, and fifteen parts per million (ppm) of formaldehyde gas for six hours per day, five days per week. Actual average exposure levels were measured at 0.0, 2.0, 5.6, and 14.3 ppm. Each group consisted of 240 animals, half males and half females, some of which died for reasons unrelated to formaldehyde exposure and were excluded from the study.<sup>105</sup> Final study results for the rats showed the following:<sup>106</sup>

Exposure level	# of rats examined	# of malignant nasal tumors <sup>107</sup>	# of benign nasal tumors <sup>108</sup>
14.3	232	106	7
5.6	235	2	6
2.0	236	0	8
0	232	1	1

104. See Chemical Industry Institute of Toxicology, *Final Report on a Chronic Inhalation Toxicology Study in Rats and Mice Exposed to Formaldehyde*, CIIT Docket No. 10922 (1981).

105. Some animals from each group were sacrificed and examined after twelve, eighteen, and twenty-four months. *Id.*

106. Chemical Industry Institute of Toxicology, Data Released to the International Agency for Research on Cancer Working Group (Oct. 19, 1981) (Appendix A of Memorandum from John A. Todhunter to Anne M. Gorsuch (Feb. 10, 1982)).

107. Of the 106 rats that developed cancer following exposure at 14.3 ppm, 103 developed squamous cell carcinomas. One of those rats also developed a nasal carcinoma and another an undifferentiated carcinoma or sarcoma. The remaining three rats developed a nasal carcinoma, an undifferentiated carcinoma or sarcoma, and a carcinosarcoma, respectively. Of the two rats that developed cancer following exposure at 5.6 ppm, both developed squamous cell carcinomas. One rat in the 0 ppm group developed an osteochondroma.

108. All of the benign tumors were polypoid adenomas.

Two of the mice exposed at 14.3 ppm developed nasal tumors;<sup>109</sup> these results were not statistically significant.<sup>110</sup> There was considerable early mortality among the mice due to miscellaneous causes, including fighting among the males.<sup>111</sup>

Also important were two inhalation bioassays conducted at New York University (NYU). The first study exposed a group of 100 male rats to a mixture of gaseous formaldehyde at 14.7 ppm and hydrogen chloride at 10.6 ppm for six hours per day, five days per week, for life.<sup>112</sup> Another group exposed to neither substance served as a control. Twenty-seven exposed rats developed malignant nasal tumors, but no malignant tumors were found among the control rats. The researchers were unable to determine, however, whether the tumors were induced by formaldehyde, by bis(chloromethyl) ether (BCME), a product of the chemical reaction of formaldehyde and hydrogen chloride, or by the interaction of all three chemicals. Based on previous experience with BCME,<sup>113</sup> the researchers suggested that formaldehyde was probably the causal agent.

A later NYU study,<sup>114</sup> the preliminary results of which were provided to the agencies in 1981,<sup>115</sup> shed further light on this issue. This study used the same methodology as the earlier NYU bioassay, but it added three groups of 100 rats. The first group was exposed to a slightly different mixture of formaldehyde and hydrochloric acid, the second was exposed only to 14.6 ppm formaldehyde, and the third only to 10.6 ppm hydrochloric acid. By eighteen months, ten rats in the group exposed only to formaldehyde had died and were found to have developed malignant tumors, whereas a total of eighteen rats in the two groups exposed to a mixture of formaldehyde and hydrochloric acid had developed such tumors. Based on these preliminary results, the researchers tentatively concluded that formaldehyde was the causal agent. Final results are not yet available.

The results available from a number of other animal carcinogenesis studies using a variety of experimental techniques were generally inconclusive.<sup>116</sup>

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109. Both were squamous cell carcinomas.

110. The term "statistically significant" indicates that the probability that the observed effect (here, nasal tumors), might have occurred by chance is below a certain predefined level, generally five percent. See Office of Technology Assessment, *supra* note 84, at 123.

111. Chemical Industry Institute for Toxicology, *Summary of Final Report on Formaldehyde Study*, 2 CIIT ACTIVITIES, Mar. 1982, at 9.

112. See Albert, *et al.*, *Nasal Cancer in the Rat Induced by Gaseous Formaldehyde and Hydrogen Chloride*, 4 J. NAT'L CANCER INST. 597 (1982).

113. Kuschner, Laskin, Drew, Capiello, & Nelson, *The Inhalation Carcinogenicity of Alpha Halo Ethers* (pt. 3: *Lifetime and Limited Period Inhalation Studies with Bis(chloromethyl) Ether at 0.1 ppm*), 30 ARCHIVES ENVTL. HEALTH 73 (1975).

114. See Albert, *et al.*, *supra* note 112.

115. Letter from Dr. Arthur Upton, Chairman, New York University Medical Center, to Representatives of the NCI, NIOSH, OSHA, EPA, NIEHS, CPSC, AFL-CIO, and Chemical Manufacturers' Association (Aug. 17, 1981).

116. *Compare Federal Panel Report*, *supra* note 7, at 151-54 (concluding that studies

## 2. Epidemiologic Evidence

The most important available epidemiologic evidence came from studies by Walrath and Fraumeni,<sup>117</sup> Wong,<sup>118</sup> and Marsh.<sup>119</sup> The largest of these three studies was Walrath and Fraumeni's study of embalmers in New York state, which was based on 1106 deaths. Although Walrath and Fraumeni found no deaths due to nasal cancer and no apparent excess of deaths from respiratory system cancer, they did find suggestive increases in the frequency of deaths from skin, kidney, and central nervous system cancer.

Evidence available from Wong's study of 2000 workers employed by a formaldehyde manufacturer showed no nasal cancers or excesses of other cancers in those that had died. As of the date of the study, however, only 146 workers had yet died from any cause.

Marsh considered 592 deaths among workers at a plant that began making formaldehyde-based products in 1938. Only 136 of the workers, however, had more than one month of "exposure" to formaldehyde. Marsh observed no nasal or other noteworthy cancer excesses during the study period, 1938 to 1976.<sup>120</sup>

## 3. Scientific Panel Evaluations

Before the agencies made their decisions, at least four scientific panels had evaluated the available evidence on formaldehyde's carcinogenicity.<sup>121</sup> Those four panels were the Federal Panel on Formaldehyde,<sup>122</sup>

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provide suggestive evidence of carcinogenicity) with INTERNATIONAL AGENCY FOR RESEARCH ON CANCER, FINAL DRAFT EVALUATION OF FORMALDEHYDE (1981) (studies considered inadequate for evaluation) [hereinafter cited as IARC REPORT]; see also CPSC, Ban of Urea-Formaldehyde Foam Insulation, 47 Fed. Reg. 14,365, 14,370, 14,375-76, 14,380 (1982) [hereinafter cited as CPSC Ban Notice].

117. Walrath & Fraumeni, *Proportionate Mortality among New York Embalmers*, in THE THIRD CHEMICAL INDUSTRY INSTITUTE OF TOXICOLOGY CONFERENCE OF TOXICOLOGY: FORMALDEHYDE TOXICITY (J. Gibson ed.) (in press) [hereinafter cited as THIRD CIIT CONFERENCE].

118. Wong, *An Epidemiologic Mortality Study of a Cohort of Chemical Workers Potentially Exposed to Formaldehyde, with a Discussion on PMR and SMR*, in THIRD CIIT CONFERENCE, *supra* note 117.

119. Marsh, *Proportional Mortality Among Chemical Workers Exposed to Formaldehyde*, in THIRD CIIT CONFERENCE, *supra* note 117.

120. Two of the workers, however, died of nasal cancer in 1979. Memorandum from Peter F. Infante, Director, Office of Carcinogen Classification and Identification, OSHA to Thorne G. Auchter (Jan. 19, 1982). See also Memorandum from John Martonik to Thorne Auchter (Feb. 4, 1982) (formaldehyde exposure data lacking for cases reported by Infante).

121. In addition to the animal bioassay and epidemiologic studies described above, mutagenicity tests provide secondary evidence of formaldehyde's carcinogenicity. Formaldehyde has been found to produce mutations in insects, bacteria, and mammalian cells. See *Federal Panel Report*, *supra* note 7, at 148-49; CPSC Ban Notice, *supra* note 116, at 14,373. Test results generally indicate that formaldehyde is a weak mutagen.

122. *Federal Panel Report*, *supra* note 7.

the Environmental Cancer Information Unit of the Environmental Sciences Laboratory at the Mount Sinai School of Medicine,<sup>123</sup> the National Research Council Committee on Aldehydes,<sup>124</sup> and the International Agency for Research on Cancer (IARC).<sup>125</sup>

The Federal Panel report was completed before the final CIIT data, the second NYU study, or the epidemiologic studies were available. The Panel concluded that "formaldehyde should be presumed to pose a carcinogenic risk to humans," and recommended future studies.<sup>126</sup> The Mt. Sinai and National Research Council reports also preceded the final results of the CIIT study and the results of the second NYU study. The Mt. Sinai scientists concluded that formaldehyde should be considered a human carcinogen.<sup>127</sup> The National Research Council committee declined to draw any conclusion because it judged the available data inadequate.<sup>128</sup> In October 1981, an IARC working group considered all of the evidence summarized above and concluded:

There is *sufficient evidence* that formaldehyde gas is carcinogenic to rats.

The epidemiological studies provide inadequate evidence to assess the carcinogenicity of formaldehyde to man.

In the absence of adequate epidemiological data, formaldehyde gas should be considered, for practical purposes, as if it represented a carcinogenic risk to man.<sup>129</sup>

### *B. Evidence of Human Exposure to Formaldehyde*

#### *I. Worker Exposures*

Three estimates of worker exposure to formaldehyde have been prepared. The first, by the Snell Division of Booz, Allen, and Hamilton, Inc. ("Snell"),<sup>130</sup> and the second, by MIT's Center for Policy Alternatives

123. I. SELIKOFF & E. HAMMOND, MT. SINAI SCHOOL OF MEDICINE, CARCINOGENICITY OF FORMALDEHYDE — FINAL REPORT (1981) (prepared for the American Cancer Society) [hereinafter cited as MT. SINAI REPORT].

124. NATIONAL RESEARCH COUNCIL, NATIONAL ACADEMY OF SCIENCES, FORMALDEHYDE AND OTHER ALDEHYDES (1981).

125. IARC REPORT, *supra* note 116.

126. *Federal Panel Report*, *supra* note 7, at 1.

127. MT. SINAI REPORT, *supra* note 123.

128. NATIONAL RESEARCH COUNCIL, NATIONAL ACADEMY OF SCIENCES, *supra* note 124.

129. IARC REPORT, *supra* note 116, at 2-3. The IARC categorizes data from positive animal studies as either "inadequate," "limited," or "sufficient," with "sufficient" evidence defined as "increased incidence of malignant tumors: (a) in multiple species or strains, or (b) in multiple experiments (preferably with different routes of administration or using different levels), or (c) to an unusual degree with regard to incidence, site or type of tumour, or age at onset." IARC MONOGRAPHS ON THE EVALUATION OF THE CARCINOGENIC RISK OF CHEMICALS TO HUMANS, SUPPLEMENT I (1979).

130. Foster D. Snell Division, Booz, Allen, & Hamilton, Inc., Preliminary Study of the Costs of Increased Regulation of Formaldehyde Exposure in the U.S. Workplace (Apr. 1979) (prepared for the Formaldehyde Institute, Scarsdale, N.Y.) [hereinafter cited as Snell



("MIT"),<sup>131</sup> provided estimates only for occupations within the purview of the OSHAct, and thus excluded education.<sup>132</sup> A third study, by EPA's Office of Toxic Substances,<sup>133</sup> included education-related exposures.

Snell prepared its report in 1978 and 1979 for the Formaldehyde Task Force of the Synthetic Organic Chemical Manufacturers Association. In estimating the costs of industry compliance with stricter formaldehyde regulations, Snell assessed exposures in seventeen industries based on company responses to questionnaires.<sup>134</sup> The questionnaires requested information on formaldehyde use, numbers of employees exposed, and exposure levels. Employers were asked to judge workers' exposure levels qualitatively on a scale of observed odor strength and eye irritation, and to provide quantitative measurements if available. Snell extrapolated the responses to develop industry-wide exposure profiles.

Snell estimated that a total of 1.4 million full- and part-time workers were exposed to formaldehyde.<sup>135</sup> Based on the odor strength scale,<sup>136</sup> Snell's qualitative estimates were that formaldehyde exposure probably exceeded 1.8 ppm five percent of the time in over 1.1 million workplaces, twenty per cent of the time in over 120,000 workplaces, forty-five percent of the time in over 7500 workplaces, and seventy percent of the time in over 6000 workplaces.<sup>137</sup> In addition, Snell indicated that formaldehyde exposure exceeded 3.0 ppm about one percent of the time in at least 70,000 workplaces.<sup>138</sup>

MIT completed its report for the Department of Labor in early 1981. MIT rejected the Snell exposure level estimates as methodologically deficient,<sup>139</sup> but relied in part on Snell's estimates of the numbers of

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Report]. This report was published in a final form, entitled COSTS OF INCREASED REGULATION OF FORMALDEHYDE EXPOSURE IN THE U.S. WORKPLACE (1980).

131. D. Hattis, C. Mitchell, J. McCleary-Jones, & N. Gorelick, Control of Occupational Exposures to Formaldehyde: A Case Study of Methodology for Assessing the Health and Economic Impacts of OSHA Health Standards (Apr. 1981) (available as CPA-81-17 from MIT's Center for Policy Alternatives) [hereinafter cited as MIT Report].

Although all three authors of this article are currently affiliated with the Center for Policy Alternatives and although the MIT study is sometimes referred to as "the Ashford report," none of us participated in that study. In any event, the evidence of impropriety in OSHA's formaldehyde deliberations appears strong regardless of the validity of the MIT study.

132. Most educational institutions are controlled by state and local government and are therefore excluded from OSHAct coverage. See 29 U.S.C. §§ 652(5), (7) (1976); 29 C.F.R. § 1975.5 (1982). Private institutions, however, are subject to OSHAct requirements.

133. OFFICE OF TOXIC SUBSTANCES, EPA, DRAFT PRIORITY REVIEW LEVEL 1: FORMALDEHYDE (1981) [hereinafter cited as PRL-1]. In preparing this document, EPA relied primarily on information from the IRLG Workgroup on Formaldehyde.

134. See Snell Report, *supra* note 130, at 53-70 (describing study methodology).

135. Snell Report, *supra* note 130, at 12.

136. *Id.* at 10.

137. Figures derived using data presented in Snell Report, *supra* note 130, at 9, 10, 89, 110, 128, 145, 158, 181, 207, 238, 256, 283, 294, 308, 318.

138. *Id.*

139. MIT Report, *supra* note 131, at 2-42 to -53.

workers exposed.<sup>140</sup> To estimate exposure levels, MIT relied on quantitative workplace and worker measurements drawn primarily from National Institute for Occupational Safety and Health (NIOSH) surveys and OSHA inspections.<sup>141</sup> These data were extrapolated to estimate industry-wide exposure.<sup>142</sup> High, midrange, and low exposure estimates were provided.

The data used by MIT indicated that of 640 measurements taken in various industries, seventeen percent exceeded 1.0 ppm, seven percent exceeded 2.0 ppm, and three percent exceeded 4.0 ppm.<sup>143</sup> Extrapolating from this data, MIT estimated that the equivalent of between 0.6 and 2 million full-time workers were exposed to formaldehyde at levels above 0.03 ppm in 1979.<sup>144</sup> Exposures were estimated to exceed 1.0 ppm for the equivalent of between 67 and 500 thousand workers;<sup>145</sup> to exceed 2.0 ppm for the equivalent of between 27 and 200 thousand workers; and to exceed 4.0 ppm for the equivalent of between 7 and 80 thousand workers.

EPA prepared its exposure estimates in 1980 and early 1981 as part of the IRLG formaldehyde study effort, and included figures for worker, consumer, and ambient exposures. To estimate the numbers of exposed workers, EPA relied in part on the results of NIOSH's National Occupational Hazard Survey and in part on its own estimates derived from a variety of sources.<sup>146</sup> For exposure level estimates, EPA relied primarily on the NIOSH results.<sup>147</sup>

Excluding education-related exposures, the estimates indicated that between 188,000 and 408,000 workers within these industries were exposed to formaldehyde. EPA exposure level estimates generally range from minimal to 2, 3, or 4 ppm, with associated average values generally ranging from 0.25 to 1.5 ppm.<sup>148</sup> Estimates for education-related exposure

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140. *Id.* at 3-12 to -14.

141. *Id.* at 2-32 to -42.

142. The methodology is described in the MIT Report, *supra* note 131, at 3-3 to -18.

143. MIT Report, *supra* note 131, at 2-37 to -39 (Table 2.11).

144. *Id.* at 3-15, -17. Workplace exposure levels vary greatly from hour to hour and day to day. In the course of a year, individual workers will spend portions of their time at a wide range of exposure levels. It is therefore not strictly accurate to represent exposures in terms of "X workers at level A and Y workers at level B." The MIT Report essentially estimated the total *worker time* spent at various exposure levels and reported the results as "full-time equivalents" at specific levels.

145. These and the following estimates were calculated from data presented in the MIT Report, *supra* note 131, at 3-10, -15, -17 (Tables 3.1-3.3).

146. PRL-1, *supra* note 133, at 54-63. Both Snell and MIT criticized the NIOSH data. See Snell Report, *supra* note 130, at 53-56; MIT Report, *supra* note 131, at 2-54. The EPA study covered formaldehyde producers and fifty-nine user groups, although data were not available for all of the groups. PRL-1, *supra* note 133, at 65-68 (Table 8). For each industry group for which data were available, EPA presented a range of expected exposure levels, as well as average or median values, and a range of numbers of workers exposed. *Id.*

147. *Id.* at 36-45.

148. Industries with particularly high exposure levels include furniture production, embalming/funeral services, pathology labs, and mushroom farms. *Id.* at 65-70, Table 8.

indicated that 35,000 college/university and high school biology instructors, 1.2 million college students, and an unknown number of high school students were exposed to formaldehyde levels ranging from 0.1 to 14.8 ppm with an average value of 8.3 ppm.

At present, though they certainly indicate substantial exposure near the current 3.0 ppm OSHA standard,<sup>149</sup> estimates of worker exposure are somewhat uncertain and tentative. The Snell estimates are extrapolations from qualitative survey responses. The MIT estimates, though based on 640 total measurements, were not based on a large number of measurements in a number of specific industry groups. Moreover, the available measurements were not from deliberately randomized samples. MIT attempted to limit the uncertainty arising from the possible unrepresentativeness of the available data base by providing "high" and "low" estimates, but it called its procedures for doing so "highly speculative."<sup>150</sup> Similarly, the EPA estimates were based on a small number of measurements.<sup>151</sup>

## 2. Consumer Exposures

Data for consumer exposures came primarily from EPA estimates<sup>152</sup> and from CPSC studies.<sup>153</sup> EPA surveyed data for residents of mobile homes and residents of conventional homes. It estimated that 2.2 million mobile home residents were exposed to formaldehyde released from particleboard or plywood at levels ranging from 0.01 to 2.54 ppm with a mean value of 0.4 ppm, and an unknown number of conventional home residents was exposed to formaldehyde from this source at levels ranging from 0.08 to 2.24 ppm with a mean of 0.5 to 0.6 ppm. EPA also estimated that 1.3 to 1.6 million residents of homes with urea-formaldehyde foam insulation (UFFI) were exposed at levels ranging from 0.05 to 3.40 ppm with a mean of 0.72 ppm.

CPSC estimated only exposure levels for residents of homes with urea-formaldehyde foam insulation. The Commission's final estimates were based on 1164 measurements in homes with formaldehyde insulation, and on the results of laboratory foam panel tests.<sup>154</sup> Calculations based on the former data set indicate that formaldehyde levels immediately after installation are approximately 3.0 ppm. They decline rapidly to 0.12 ppm after 40 weeks, and then more slowly to 0.04 ppm after 9 years. Calculations based on the latter data set yielded an average value of 0.07 ppm in a corner room for the first 464 days after installation, with

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149. See *infra* note 331.

150. See MIT Report, *supra* note 131, at 3-9.

151. See PRL-1, *supra* note 133, at 71-75.

152. See *id.* at 42-43, 58-59, 63-64, 69.

153. See CPSC, REVISED CARCINOGENIC RISK ASSESSMENT FOR UREA FORMALDEHYDE FOAM INSULATION: ESTIMATES OF CANCER RISK DUE TO INHALATION OF FORMALDEHYDE RELEASED BY UFFI (1981) [hereinafter cited as CPSC RISK ASSESSMENT].

154. See *id.* at 9-12. For a discussion of the major strengths and weaknesses of this data set, see *infra* text accompanying notes 455-64.

declining values thereafter. CPSC estimated that in 1981 there were 1.75 million residents of homes with formaldehyde insulation, and projected that future installation of UFFI in additional homes would expose another 262,500 residents each year.

#### IV. EPA'S DECISION NOT TO DESIGNATE FORMALDEHYDE A SECTION 4(F) CHEMICAL

##### A. Background

##### 1. Chronology of Events

EPA received the preliminary results of the CIIT bioassay in November 1979.<sup>155</sup> In response, the agency participated in efforts by the Interagency Regulatory Liaison Group (IRLG) to estimate formaldehyde exposures.<sup>156</sup> A year later, the agency's Office of Toxic Substances (OTS) received the Federal Panel on Formaldehyde report on the chemical's carcinogenicity, and, shortly thereafter, IRLG's exposure data.<sup>157</sup> Based on the available carcinogenicity and exposure information, OTS determined that formaldehyde might be a candidate for action under section 4(f) of TSCA.<sup>158</sup> In January 1981, OTS began to prepare a Priority Review Level 1 (PRL-1) document on formaldehyde.<sup>159</sup> A PRL-1 designation was an internal EPA mechanism for identifying items of highest priority within the agency. In March 1981, after estimating the potential formaldehyde cancer risk to the general population, EPA's Deputy Assistant Administrator for Toxic Substances, together with other EPA officials, determined that there "may be a reasonable basis to conclude" that formaldehyde poses a significant cancer risk and that the threshold requirement of section 4(f) had thus been met.<sup>160</sup> Accordingly, they drafted a Federal Register notice indicating that section 4(f) had been invoked, that additional information would be required before the agency could formulate

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155. See 7 PESTICIDE & TOXIC CHEMICAL NEWS 10 (1979).

156. *Gore EPA Hearings*, *supra* note 18 (statement by Richard Dailey, EPA Office of Toxic Substances). In December 1979 the IRLG established a work group on formaldehyde composed of representatives from the five member agencies — EPA, OSHA, CPSC, the Food and Drug Administration, and the Department of Agriculture — and from the Department of Housing and Urban Development and the Department of Energy. Richard Dailey represented EPA.

157. *Id.*

158. *Id.*

159. *Id.* See PRL-1, *supra* note 133. See also Office of Toxic Substances, EPA, Formaldehyde Designation as a Priority for Investigation Under the Toxic Substances Control Act, Draft Federal Register Notice 6 (May 1981) [hereinafter cited as Draft Federal Register Notice]. The PRL-1 was based largely on the Federal Panel report and the IRLG exposure data.

160. *Gore EPA Hearings*, *supra* note 18 (statement by Richard Dailey, EPA Office of Toxic Substances). See also 9 PESTICIDE & TOXIC CHEMICAL NEWS 27 (1981).

a proper response, and that an expedited investigation to obtain the necessary information would begin.<sup>161</sup>

When newly confirmed EPA Administrator Anne Gorsuch and Deputy Administrator John Hernandez assumed office in May 1981, the draft notice awaited them. Also awaiting them was a letter from John Byington, a lawyer representing the Formaldehyde Institute, who disputed the work of the EPA staff.<sup>162</sup> Byington argued that section 4(f) had not been "triggered" and that the available data was insufficient to support *any* immediate action. He urged that further studies be undertaken outside of official agency auspices.<sup>163</sup>

Hernandez delayed further EPA action on formaldehyde and met with representatives of the Formaldehyde Institute to review their position.<sup>164</sup> Thereafter, he determined that the available scientific information was insufficient to support a section 4(f) determination and called for further study.<sup>165</sup> During July and August 1981, he held a series of three closed meetings with EPA staff, industry representatives, and a few selected scientists from other institutions.<sup>166</sup> In testimony at subsequent congressional hearings, Hernandez characterized these meetings as "exclusively scientific," and described their purpose as having been to "shed some light" on the "scientific" issues.<sup>167</sup>

During the following months, EPA acted on several fronts. In a September 11 memorandum, Don Clay, the newly appointed OTS director, indicated to John Todhunter, the newly designated Assistant Administrator for Pesticides and Toxic Substances,<sup>168</sup> that consideration of

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161. Draft Federal Register Notice, *supra* note 159, at 1, 5, 23. The agency was most concerned about the limitations of the available exposure data, which it believed "suggest the potential for significant human exposure," *id.* at 1, but which it recognized were incomplete, *id.* at 15. Accordingly, EPA proposed to satisfy the section 4(f) requirement to "initiate appropriate action" by "investigat[ing] those exposures of greatest concern and determin[ing] whether they lead to unreasonable risks." *Id.* at 1.

162. Letter from John Byington to John Hernandez, Jr., (May 20, 1981).

163. *Id.* at 3. Byington wrote: "[W]e urge you not to proceed with a TSCA § 4(f) proceeding on formaldehyde at this time. Rather we suggest that a voluntary program aimed at the collection and analysis of additional scientific data be undertaken . . ." EPA eventually adopted Byington's approach. *Id.*; see OTS Formaldehyde Workplan, in Memorandum from John Todhunter to Anne Gorsuch, Attachment 1 (Feb. 10, 1982) [hereinafter cited as Todhunter Memorandum].

164. *Moffett Hearings*, *supra* note 18, at 15 (prepared statement by John Hernandez, Jr.). Hernandez met with seven Formaldehyde Institute representatives on May 27, 1981. *Id.* at 15-16.

165. *Id.* at 16; see also Memorandum from Anne Gorsuch to Edwin H. Clark, Acting Assistant Administrator for Pesticides and Toxic Substances (June 12, 1981), reprinted in *Moffett Hearings*, *supra* note 18, at 29.

166. See *Moffett Hearings*, *supra* note 18, at 1-100, 162-96; *Scheuer Hearings*, *supra* note 18, at 49-55, 88-96, 105-15.

167. *Moffett Hearings*, *supra* note 18, at 19 (statement by John Hernandez, Jr.).

168. John Todhunter resigned March 25, 1983. [13 Curr. Dev.] ENV'T REP. (BNA) No. 48, at 2179 (Apr. 1, 1983).

formaldehyde under section 4(f) was inappropriate.<sup>169</sup> Clay based his position on several factors, including his belief that section 4(f) should be reserved for "a crash effort to remedy a very serious hazard to public health."<sup>170</sup> Between August and November 1981, the OTS staff revised the original agency document on formaldehyde, reclassifying it from a "Priority Review" status to a "Technical Document" status.<sup>171</sup> During October and November 1981, Administrator Gorsuch repeatedly stated that the agency had yet to take a position on formaldehyde.<sup>172</sup>

EPA formally announced its position on February 12, 1982, by releasing a memorandum from Todhunter that embraced Clay's earlier position on formaldehyde.<sup>173</sup> Unlike Clay, Todhunter supported this position with an analysis of the "scientific" issues inherent in formaldehyde risk assessment. He also outlined a plan for further formaldehyde study.<sup>174</sup> EPA characterized the Todhunter memorandum as "concluding present agency action on the subject."<sup>175</sup>

Todhunter's analysis advanced theories that conflicted with prevalent scientific opinion in the field,<sup>176</sup> and that departed from prior cancer policies of EPA and other regulatory agencies.<sup>177</sup> The memorandum accordingly created considerable controversy, within both the scientific community and other agencies.<sup>178</sup> In response, congressional hearings were held in May 1982 to explore the scientific basis for EPA's formaldehyde determination.<sup>179</sup> Following those hearings, both EPA and industry have proceeded with further formaldehyde research.<sup>180</sup>

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169. Memorandum from Don Clay to John Todhunter (Sept. 11, 1981), *reprinted in Moffett Hearings, supra* note 18, at 193 [hereinafter cited as Clay Memorandum].

170. *Id.* at 3, *reprinted in Moffett Hearings, supra* note 18, at 195.

171. TECHNICAL DOCUMENT, *supra* note 4. For a discussion of the evolution of this document, see *Gore EPA Hearings, supra* note 18 (statements of John Todhunter and Richard Dailey).

172. See *Moffett Hearings, supra* note 18, at 77; *Scheuer Hearings, supra* note 18, at 230; 5 CHEM. REG. REP. (BNA) 950 (Nov. 20, 1981) (reporting that Gorsuch sent a letter to the Natural Resources Defense Council saying that "scientific review and toxicological interpretations of data" were nearly complete and that a decision would be released before December 5, 1981).

173. Todhunter Memorandum, *supra* note 163; EPA, *Notice of Availability*, EPA ENVTL. NEWS, Feb. 12, 1982 (accompanying press advisory).

174. Todhunter Memorandum, *supra* note 163, at 1.

175. EPA, *Notice of Availability*, EPA ENVTL. NEWS, Feb. 12, 1982.

176. See *infra* notes 195-227 and accompanying text. See also *Gore EPA Hearings, supra* note 18 (statements by Drs. Sidney Weinhouse, Norton Nelson, Roy Albert, Richard Griesemer, and Federica Perera); Perera & Petito, *supra* note 17.

177. See *infra* notes 278-295 and accompanying text.

178. See *supra* note 17. See also Marshall, *EPA's High-Risk Carcinogen Policy*, 218 SCIENCE 975 (1982).

179. *Gore EPA Hearings, supra* note 18.

180. For a listing of ongoing work, see Letter from James Ramey, Chairman, Formaldehyde Institute, to Thorne Auchter, Attachment 1 (Nov. 25, 1981). Probably the most important ongoing study is a joint National Cancer Institute-Formaldehyde Institute epidemiologic study of 20,000 workers. See 5 CHEM. REG. REP. (BNA) 1051 (Jan. 8, 1982); see also FORMALDEHYDE INSTITUTE, PROCEEDINGS OF A CONFERENCE ON FORMALDE-

## 2. The Agency's "Statement of Reasons"

The substantive basis for EPA's decision is reportedly contained in one, or both, of two documents: the four-page Clay memorandum and the sixteen-page Todhunter memorandum. The two memoranda both concluded that formaldehyde should not be designated a section 4(f) priority, but for different reasons. Todhunter claimed that Clay's memorandum represented the primary analysis and that his was simply an update and concurrence.<sup>181</sup>

Clay based his memorandum on the risk assessments set forth in the original PRL-1 document on formaldehyde and on an OTS "options memorandum" prepared after EPA's meetings with representatives of the formaldehyde industry.<sup>182</sup> He offered two principal reasons for his conclusion that section 4(f) was inapplicable. First, though acknowledging that formaldehyde was a "suspect human carcinogen," he argued that the available epidemiologic data was unpersuasive.<sup>183</sup> He recommended delaying agency action until an epidemiologic study being conducted by the National Cancer Institute was completed.<sup>184</sup> Second, he argued that the available exposure data did not support a finding of "serious" or "widespread" harm.<sup>185</sup>

Todhunter's memorandum was considerably more detailed. Characterized by its author as a compilation of his "professional conclusions and policy recommendations,"<sup>186</sup> it reviewed the available evidence on formaldehyde carcinogenicity and exposure. Todhunter concluded that there were "limited but suggestive" epidemiologic data supporting "the notion that any human problems with formaldehyde carcinogenicity may be of low incidence or undetectable."<sup>187</sup> He also examined the language of section 4(f), concluding that cancer risks estimated to fall in a range of 1 in 10,000 or less should not be considered "significant" under the terms of that section, and that formaldehyde fell within that range of risk.<sup>188</sup> He summarized his findings as follows:

- (a) formaldehyde is a carcinogen in the rat by the inhalation route; (b) its carcinogenic potential appears to vary significantly with species and route; (c) under certain exposure conditions it could present some carcinogenic risk to humans; and (d) given available data the risk estimates suggest that certain populations may experience a carcinogenic risk — albeit low —

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HYDE TOXICOLOGY: 1982 UPDATE (in press) (presenting the results of recent formaldehyde studies).

181. Todhunter Memorandum, *supra* note 163, at 1.

182. Clay Memorandum, *supra* note 169, at 1. See OFFICE OF TOXIC SUBSTANCES, EPA, OPTIONS PAPER ON FORMALDEHYDE (1981).

183. Clay Memorandum, *supra* note 169, at 2.

184. See *supra* note 180.

185. Clay Memorandum, *supra* note 169, at 2-3.

186. Todhunter Memorandum, *supra* note 163, at 1.

187. *Id.* at 5.

188. *Id.*

due to formaldehyde exposure. However, because of the nature of the toxicology data and the unreliability in the exposure data one cannot reasonably conclude, at this time, that formaldehyde poses a significant risk among the U.S. population.<sup>189</sup>

### B. The Decisionmaking Process

In a real sense, any discussion of EPA's decisionmaking process may be superfluous. Considerable evidence suggests that the incoming EPA officials had determined their policy on formaldehyde long before any "decisionmaking process" had been completed.

Some of this evidence is circumstantial. The *Chemical Regulation Reporter* (CRR) reported in October 1981 that not long after Reagan officials took over, EPA dropped formaldehyde as a priority consideration.<sup>190</sup> The CRR noted that in March 1981 OTS had cited a "Formaldehyde Notice of 4(f) Designation" as its fourteenth most pressing concern.<sup>191</sup> By July 1981, however, two months after Anne Gorsuch assumed office and seven months before Todhunter's memorandum, OTS had reshuffled its priorities. The new formaldehyde reference item was the "Formaldehyde Program," and it was not designated as a priority.<sup>192</sup>

Todhunter himself has provided more direct evidence. He testified at congressional hearings that, upon his arrival at EPA in July 1981, he was informed that the agency did not intend to take any action on formaldehyde other than to conduct a two-year exposure assessment.<sup>193</sup>

If Todhunter is correct, the agency's eventual "statement of reasons" was little more than an exercise in *post-hoc* rationalization, and its deliberations could scarcely be said to have met the criteria of reasoned decisionmaking.<sup>194</sup> Assuming, however, that the Todhunter memorandum does represent the culmination of a lengthy decisionmaking process, this process was nonetheless flawed in numerous respects.

#### 1. Analysis of Technical Data

An agency decision must evidence a "rational connection between the facts found and the choice made."<sup>195</sup> Health risk assessments thus

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189. *Id.* at 5-6.

190. 5 CHEM. REG. REP. (BNA) 789 (Oct. 16, 1981).

191. *Id.*

192. *Id.*

193. *Florio Hearings, supra* note 18, at 27. Todhunter testified: "When I arrived at the Agency, . . . I was . . . informed that the Agency at that time had no intention of regulating formaldehyde other than conducting an exposure assessment over a 2-year period." *Id.* See also 5 CHEM. REG. REP. (BNA) 1983 (Jan. 15, 1982) (citing Todhunter as the source of their information, BNA reported that EPA's original decision to regulate formaldehyde under section 4(f) was "scrapped at the suggestion of EPA legal counsel before the agency held controversial private meetings with industry").

194. *Post hoc* rationalizations "have traditionally been found to be an inadequate basis for review." *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 419 (1971).

195. *WWHT, Inc. v. FCC*, 656 F.2d 807, 817 (D.C. Cir. 1981) (citing *Action for*



require a careful analysis of the relevant technical data regarding both a substance's toxicity and the extent of human exposure. Unquestionably, an agency is properly accorded some discretion in its treatment of technical data.<sup>196</sup> Nonetheless, the agency's analysis must be free of overt errors in technical methodology or reasoning.<sup>197</sup> EPA's treatment of the formaldehyde data roused significant criticism.<sup>198</sup> A review of the agency's technical analysis reveals several examples of questionable scientific reasoning.

*a. Issues of "Hard" Science*

The Todhunter memorandum apparently contains the technical basis for the agency's decision. It also appears to contain significant lapses in scientific judgment and methodology.

*i. Analysis of Epidemiologic Data*

Perhaps the most troublesome aspect of Todhunter's memorandum is its reliance on the available epidemiologic studies. Todhunter seems to have used the results of these studies as a partial basis for his conclusion that formaldehyde does not pose a significant risk of human carcinogenicity.<sup>199</sup> Numerous factors, however, including small study population and poor exposure documentation, limited the "sensitivity" of each of the studies,<sup>200</sup> as Todhunter himself apparently recognized.<sup>201</sup> Given

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Children's Television v. FCC, 564 F.2d 458, 479 (D.C. Cir. 1977)). See *supra* text accompanying note 39.

196. As Judge Skelly Wright of the D.C. Circuit wrote in *Ethyl Corp. v. EPA*: "the court must give due deference to the agency's ability to rely on its own developed expertise. The immersion in the evidence is designed *solely* to enable the court to determine whether the agency decision was rational and based on consideration of the relevant factors." 541 F.2d 1, 36 (D.C. Cir. 1976) (citation omitted).

197. In *State Farm Mutual Auto. Ins. v. Department of Transp.*, 680 F.2d 206, 230 (D.C. Cir. 1982), the court noted that a reviewing court must "judge whether a reasonable decisionmaker could respond to those facts as the agency did." In *Overton Park*, the Supreme Court said that a reviewing court must determine whether there was a "clear error of judgment." 401 U.S. at 416.

198. See *Gore EPA Hearings*, *supra* note 18 (statements by Drs. Sidney Weinhouse, Norton Nelson, Roy Albert, Richard Griesemer, Federica Perera, and Sorell Schwartz).

199. Todhunter Memorandum, *supra* note 163, at 11-12. In his one-paragraph discussion of the epidemiologic data, Todhunter wrote:

A number of small scale retrospective epidemiology studies on groups occupationally exposed to formaldehyde have found no excess of cancers of any type, in particular nasal or oral, in these groups which can be attributed to formaldehyde exposure when corrected for smoking and drinking . . . . There does not appear to be any relationship, based on the existing data base on humans, between exposure and cancer.

*Id.*

200. See OFFICE OF TOXIC SUBSTANCES, *supra* note 182, at 17; IARC REPORT, *supra* note 116, at 2; CPSC Ban Notice, *supra* note 116, at 14,373; see also R. MONSON, *supra* note 89, at 37-43 (general discussion of sources of error in epidemiologic studies).

201. Todhunter Memorandum, *supra* note 163, at 11-12 ("While I recognize the limits of sensitivity inherent in epidemiology, such data are useful . . . .").

these methodological limitations, the studies would have been expected to produce largely negative results regardless of the true nature of the carcinogenic risk. For this reason, several other reviewers — including the International Agency for Research on Cancer (IARC), the CPSC, and even EPA's own Office of Toxic Substances — had declined to rely on these studies in their analyses.<sup>202</sup> Todhunter's interpretation of these studies as suggesting "that any human problems with formaldehyde carcinogenicity may be of low incidence or undetectable"<sup>203</sup> was unjustified.

## ii. Site Specificity

Todhunter also concluded that human carcinogenic risk from formaldehyde is likely limited to nasal and oral cancers.<sup>204</sup> This conclusion was likewise flawed. Todhunter correctly noted that the great majority of tumors in the rat bioassays did occur in the nasal or oral cavities,<sup>205</sup> and that IARC studies do indicate an eighty-percent concordance between sites at risk in humans and those at risk in animals.<sup>206</sup> He failed, however, to consider another equally important factor: unlike rats, which breathe only through the nose, humans breathe through both the nose and the mouth. Potential lung exposure to formaldehyde is, therefore, much greater for humans than for rats.<sup>207</sup> From a toxicological standpoint, strict body site extrapolation is inappropriate, at least in the absence of other supporting data. Todhunter's failure to consider this factor undermines his conclusion.

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202. See sources cited *supra* note 116. Indeed some reviewers feel that the available epidemiologic data gives positive indications of formaldehyde carcinogenicity. See, e.g., *Federal Panel Report*, *supra* note 7, at 159 (relying on study results available before October 1980).

203. See *supra* text accompanying note 187.

204. Todhunter Memorandum, *supra* note 122, at 11. Todhunter stated that CIIT radio-isotope studies suggest that only the nasal and oral cavities would be at risk. In those studies, radioactive tracers were used to ascertain how and where rats that inhale formaldehyde gas absorb it into their bodies. See Heck, Chin, & Schmitz, *Distribution of 14C Formaldehyde in Rats After Inhalation Exposure*, in THIRD CIIT CONFERENCE, *supra* note 117.

205. In the CIIT rat study, two of the carcinomas were found in the rats' tear ducts. The rest were found in the rats' nasal cavities. *Gore EPA Hearings*, *supra* note 18 (prepared testimony by Dr. Richard Griesemer, Former Chairman of the Federal Panel on Formaldehyde, at 4). Lesions attributable to formaldehyde exposure were found in the rats' trachea, bronchi, and bronchioles, suggesting that those sites were potentially at risk also. *Id.*

206. Tomatis, *et al.*, *Evaluation of the Carcinogenicity of Chemicals: A Review of the Monograph Program of the International Agency for Research on Cancer*, 38 *CANCER RESEARCH* 877 (1978).

207. *Gore EPA Hearings*, *supra* note 18, (prepared testimony by Dr. Richard Griesemer, at 4). At one point in his memorandum Todhunter did acknowledge the significance of differences in breathing patterns. Todhunter Memorandum, *supra* note 163, at 8. He failed to cite this factor, however, when he argued that the human sites at risk are limited.

*iii. Species Specificity*

On the basis of the statistically insignificant results of the CIIT mouse study and other generally negative rodent studies, Todhunter concluded that formaldehyde carcinogenicity is species specific to rats.<sup>208</sup> This specificity, he suggested, tempers concern about formaldehyde's human carcinogenic potential.<sup>209</sup>

The Federal Panel on Formaldehyde, IARC, and a number of other groups that have reviewed the formaldehyde data disagree.<sup>210</sup> Indeed, several factors contradict the species specificity finding. Dr. Richard Griesemer, chairman of the Federal Panel, has noted that the CIIT mouse study was marred by fighting among the mice.<sup>211</sup> When adjusted for the resulting early mortality, the mouse study indicates a significant increase in carcinomas at the 14.3 ppm dose level.<sup>212</sup> The director of the CIIT has noted that mice exposed at 14.3 ppm actually received approximately half of the dose received by rats at that level because of differences in the two species' breathing rates; thus, mouse results at 14.3 ppm are comparable to rat results at 5.6 ppm.<sup>213</sup> In fact, the number of carcinomas observed in mice at the 14.3 ppm level was identical to the number observed in rats at the 5.6 ppm level.<sup>214</sup>

None of the other negative rodent studies that Todhunter cited were designed to test the carcinogenicity of formaldehyde.<sup>215</sup> From a toxicological standpoint, then, they do not provide evidence of a lack of formaldehyde carcinogenicity.

*iv. Irritant Effects*

Todhunter argued that there is a "threshold" exposure level below which formaldehyde produces no carcinogenic effects.<sup>216</sup> He based this position, in part, on a finding that the irritant properties of formaldehyde are a necessary link in the causal chain of formaldehyde carcinogenicity.<sup>217</sup> Because such irritation does not occur at relatively low exposure

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208. Todhunter Memorandum, *supra* note 163, at 6-7.

209. *Id.* at 7.

210. For example, the Federal Panel examined the available bioassays and concluded "[t]here is suggestive evidence that formaldehyde might be carcinogenic in other species and tissues other than nasal." *Federal Panel Report*, *supra* note 7, at 152-54. The IARC considered the studies that Todhunter cited to be inadequate for evaluation. IARC REPORT, *supra* note 116, at 1. The Mt. Sinai report stated, "formaldehyde is a carcinogen in rats, and, data suggest, in mice." MT. SINAI REPORT, *supra* note 123.

211. *Gore EPA Hearings*, *supra* note 18 (prepared testimony by Dr. Richard Griesemer, at 3).

212. *Id.*

213. See CPSC Ban Notice, *supra* note 116, at 14,366, 14,370.

214. See *supra* notes 104-11 and accompanying text.

215. See *Gore EPA Hearings*, *supra* note 18, at 3-4 (prepared testimony by Dr. Richard Griesemer). See also *Federal Panel Report*, *supra* note 7, at 151.

216. Todhunter Memorandum, *supra* note 163, at 11.

217. *Id.* at 8-9.

levels, he concluded that carcinogenesis would not occur at those levels.<sup>218</sup>

In taking this position, Todhunter failed to note the NYU bioassays, which suggest that formaldehyde is a carcinogen independent of its irritant effects.<sup>219</sup> If the irritant properties of formaldehyde do play a significant role in carcinogenicity, the addition of hydrochloric acid, another irritant (though not by itself a carcinogen), should have heightened the carcinogenic effect. The number of tumors found in rats exposed to the combination of formaldehyde and hydrochloric acid, however, did not differ significantly from the number found in rats exposed only to formaldehyde.<sup>220</sup> Though these results are not conclusive, Todhunter's failure to discuss them reflects negatively on his scientific reasoning.

#### *v. Exposure Data*

Finally, Todhunter apparently based his conclusions on questionable assumptions regarding human exposure to formaldehyde. Without supporting evidence, Todhunter assumed that humans will avoid exposure to levels above 2 ppm because they do not adapt to levels above 5 ppm, and they find levels from 2 to 5 ppm unpleasant.<sup>221</sup> Thus, he downplayed reported exposure levels above 2 ppm, and generally considered only exposures at lower levels. In light of contrary observations by other scientists,<sup>222</sup> Todhunter's failure to support this assumption with reliable empirical data calls his conclusions into question. Furthermore, Todhunter stated that formaldehyde exposure levels in homes with urea-formaldehyde foam insulation have not been shown to exceed those in other homes.<sup>223</sup> He failed to note, however, that this statement holds true only for homes observed long after the insulation has been installed. Shortly after installation, significant differences have been measured.<sup>224</sup>

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218. *Id.* at 8-11.

219. See *supra* notes 112-15 and accompanying text. The NYU researchers stated that "[t]he [experimental] results . . . do not *decisively* disprove the notion that the carcinogenic response to HCHO [formaldehyde] is a nonspecific response to irritation, but they do not support it either." Albert, *supra* note 112, at 601 (emphasis added). The formaldehyde industry has argued that the concentrations of hydrochloric acid were not large enough to test the "irritant effects" hypothesis. See Reply Brief of Petitioners at 7 n.14, *Gulf South Insulation v. CPSC*, 701 F.2d 1137 (5th Cir. 1983).

220. Albert, *supra* note 112, at 599-600.

221. Todhunter Memorandum, *supra* note 163, at 12.

222. Based on his own experience as a pathologist, Dr. Richard Griesemer testified that some people develop partial tolerances to formaldehyde's irritant effects and continue to work even at high exposure levels. See *Gore EPA Hearings*, *supra* note 18 (prepared testimony by Dr. Richard Griesemer, at 8).

223. Todhunter Memorandum, *supra* note 163, at 11.

224. See *supra* text accompanying note 154; see also CPSC Ban Notice, *supra* note 116, at 14,377.

*b. Issues of Science Policy*

In a number of the technical areas discussed above, EPA adopted science policy positions inconsistent with prevailing scientific opinion. For instance, even if the available negative epidemiologic studies had been methodologically adequate, Todhunter would depart from prevailing opinion in concluding that such evidence suggested an absence of hazard. As noted by the scientific panel convened by the Interagency Regulatory Liaison Group (IRLG), “[a]bsence of a positive statistical correlation [in an epidemiologic study] does not by itself demonstrate absence of a hazard.”<sup>225</sup>

Similarly, Todhunter’s arguments for site specificity are inconsistent with scientific opinion on cancer risk assessment. The IRLG scientists also noted that “no direct analogy of morphologic response can be expected from a carcinogen in animals of different species and in humans.”<sup>226</sup> Furthermore, even if the negative rodent studies that Todhunter cited had been methodologically adequate, his assertion of species specificity would conflict with the IRLG’s conclusions: “the finding of negative results in some other species generally does not detract from the validity of a positive result as evidence of carcinogenicity for the test substance.”<sup>227</sup>

In sum, EPA’s formaldehyde deliberations reflected science policy positions that represent the views of a minority within the scientific community. While these positions may not be “wrong” in a purely technical sense, they demand justification. EPA neither acknowledged the need for such justification nor supplied any.

*2. The Procedural Aspects*

The principle of reasoned decisionmaking further requires that an agency deliberate “in a manner calculated to negate the dangers of arbitrariness and irrationality.”<sup>228</sup> Depending on the particular agency action under review, courts have enumerated various specific procedural requirements for reasoned decisionmaking. EPA’s treatment of formaldehyde raises several procedural questions.

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225. *IRLG Risk Assessment Document*, *supra* note 36, at 247. The IRLG document is a particularly good source of prevailing scientific opinion as it was written by scientists and published in the peer-reviewed and highly respected *Journal of the National Cancer Institute*.

226. *Id.* at 255.

227. *Id.* at 253.

228. *WWHT, Inc. v. FCC*, 656 F.2d 807, 817 (D.C. Cir. 1981) (citing *Action for Children’s Television v. FCC*, 564 F.2d 458, 472 n.24 (D.C. Cir. 1977)); *O’Donnell v. Shaffer*, 491 F.2d 59, 62 (D.C. Cir. 1974); *Friends of the Earth v. United States Atomic Energy Comm’n*, 485 F.2d 1031, 1033 (D.C. Cir. 1973); *EDF v. Ruckelshaus*, 439 F.2d 584, 598 (D.C. Cir. 1971); *see also supra* notes 38–39 and accompanying text.

a. *Industry Bias*

With the advent of the Gorsuch administration, EPA embarked upon a decisionmaking process for formaldehyde that appears to have been designed both to maximize input from the formaldehyde industry and to minimize input from other sectors. Regardless of the ultimate substantive validity of the agency's section 4(f) determination, the appearance of its decisionmaking process lends credence to claims of impropriety.

i. *"Science Meetings" with Industry*

In general, agencies are encouraged to seek input from interested parties before making regulatory decisions.<sup>229</sup> An agency is not free, however, to accept such input in any way it chooses; it must balance its approach.<sup>230</sup> EPA's three industry meetings in the summer of 1981 are troublesome in this regard, as they suggest that the agency based its decision on input from the representatives of only one point of view.

The initial impetus for the meetings apparently came from industry.<sup>231</sup> Though EPA has subsequently characterized these meetings as having been "exclusively scientific in nature,"<sup>232</sup> the rosters of those present reveal that the sessions were dominated by the perspectives of the formaldehyde industry. With the exception of one or two "neutral" scientists at each meeting,<sup>233</sup> the Formaldehyde Institute selected all of the non-EPA participants.<sup>234</sup>

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229. See Delong, *supra* note 38, at 302, 306.

230. The D.C. Circuit has indicated that "the presumption of agency regularity" will be refuted if "the agency has demonstrated undue bias toward particular private interests." *Natural Resources Defense Council v. SEC*, 606 F.2d 1031, 1049 n.23 (D.C. Cir. 1979).

231. *Moffett Hearings*, *supra* note 18, at 19 (statement of Deputy Administrator John W. Hernandez, Jr.). In prepared congressional testimony, Hernandez noted that the sessions "grew out of requests, made orally and in writing, by representatives of the Formaldehyde Institute . . . for an opportunity to meet with me to discuss the scientific issues pertaining to formaldehyde."

232. *Id.* at 18.

233. *Id.* at 57-59 (meeting participant lists). Of the 24 participants at the June 19 meeting, 14 were from EPA, nine represented industry, and one, Richard Griesemer, former chair of the Federal Panel, was not affiliated with either industry or EPA. At least two of the industry participants were lawyers, including John Byington, who later met privately with Todhunter, *see infra* text accompanying notes 250-260.

The roster of the July 28 meeting was similar. Of the 33 participants, 17 were from EPA, 14 represented industry, and Robert G. Tardiff attended on behalf of the National Academy of Sciences. Richard Griesemer was also present.

Finally, there were 35 participants at the August 14 meeting: 21 from EPA, 12 representing industry, and David Gaylor of the Food and Drug Administration. Again, at least three industry lawyers were present. The subject of the final meeting appears to have been risk assessment, certainly an area of science policy. See Memorandum from Joseph J. Merenda, Director, Assessment Division, EPA Office of Pesticides and Toxic Substances to Edwin H. Clark II, Acting Assistant Administrator for Pesticides and Toxic Substances (Aug. 12, 1981).

234. Hernandez described the selection process as follows:

Rather than solicit a variety of viewpoints, EPA closed the meetings to the public.<sup>235</sup> Conspicuous by their absence were scientists representing groups that might be expected to oppose the formaldehyde industry's position.<sup>236</sup> Also absent were representatives of other regulatory agencies and the Interagency Regulatory Liaison Group (IRLG). Indeed, the agency reportedly refused to admit two scientists who requested permission to attend: Andrew Ulsamer of CPSC and Han Kang of OSHA, both members of the IRLG formaldehyde group.<sup>237</sup>

Another objectionable characteristic of these three meetings was the agency's failure to maintain transcripts or detailed minutes. Although some of the participants prepared "points of agreement" memoranda, these memoranda provide little insight into the workings of these otherwise closed sessions.<sup>238</sup> As the D.C. Circuit has noted in a similar context,

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It was left to the Formaldehyde Institute to decide whom they wanted to bring. I asked the Acting Assistant Administrator for Pesticides and Toxic Substances to decide which Agency personnel — as well as outside scientists — should be invited. The only injunction I laid down to those doing the inviting was that participants in the discussion were to be those who could shed some light on the scientific issues.

*Moffett Hearings, supra* note 18, at 19.

235. The agency gave no public notice of any of the meetings. *Id.* at 23 (statement of Gorsuch). Indeed, the meetings came to public attention only after a House subcommittee staff member happened to hear about the last of three similar meetings on di-(ethyl-hexyl)phtalate (DEHP). *See id.* at 33.

236. Scientists from several environmental and consumer groups, such as the Natural Resources Defense Council, had a longstanding interest in toxic substance risk assessment. Other scientists, including the NYU bioassay team, had researched the carcinogenic risk from formaldehyde, and scientists at OSHA and CPSC also were assessing that risk. Finally, a number of prominent scientists had extensive experience in the broader topic of carcinogenic risk assessment. EPA was aware of the interests of all these scientists, yet asked none of them to attend.

237. *Gore EPA Hearings, supra* note 18 (testimony of Richard Dailey). We have confirmed this testimony with Dr. Ulsamer.

238. At least eight of these "points of agreement" memoranda were prepared: two by EPA staff members, five by members of the Formaldehyde Institute, and one by Professor Robert L. Sielken, Jr., of Texas A&M University, who was apparently employed by the Formaldehyde Institute as a consultant. The memoranda are largely conclusory, and reveal little about the process of deliberation, the points considered, or the arguments presented.

In general, the industry-prepared memoranda are the most detailed. Many of them are in the nature of proposed "findings of fact" — covering both science and science policy issues — for EPA use in preparing its statement of reasons. Several of the points proposed in the industry memoranda are quite similar to points that Todhunter made in his February 10 memorandum. Furthermore, these memoranda indicate that statutory interpretation and regulatory policy, in addition to science and science policy, were discussed at these meetings. The memorandum prepared by James Ramey, Chairman of the Formaldehyde Institute, for example, includes the following statement as its last "point of agreement":

There is no driving force to promulgate restrictive regulations on formaldehyde. There are no apparent health crises or *significant human health risks* associated with formaldehyde exposure.

Memorandum from James Ramey to John Hernandez, Jr. (Aug. 13, 1981), at 2 (emphasis added).

such documentation "hardly provides a substitute sufficient to allow for the 'searching and careful' judicial inquiry required."<sup>239</sup>

As other observers have suggested,<sup>240</sup> these meetings may also have violated the Federal Advisory Committee Act (FACA).<sup>241</sup> That statute recognizes that agencies have come to rely on technical "advisory committees" as an aid to decisionmaking, and establishes specific procedural requirements for such committees.<sup>242</sup> The Act requires that advisory committees be formally chartered, be composed of a "fair balance" among opposing viewpoints, give notice of their meetings and open them to the public, and maintain accurate and detailed minutes of those meetings.<sup>243</sup>

FACA covers "any committee, board, commission, council, conference, panel, task force, or other similar group . . . established or utilized by one or more agencies, in the interest of obtaining advice or recommendations."<sup>244</sup> Meetings with an interest group merely for the purpose of soliciting its position have been held to be outside the scope of the Act.<sup>245</sup> EPA's "science meetings," however, appear to have involved more than mere solicitation of position. EPA Deputy Administrator John Hernandez has written that the primary function of those sessions was to allow him to meet with "scientific and technical experts" to "discuss the scientific merits of the available information."<sup>246</sup> The meetings, he indicated, "were designed . . . to explore fully the scientific and technical issues."<sup>247</sup> He later testified that the purpose of the meetings was to "get all the scientific information pertaining to the exposure and toxicity of these substances out in the open."<sup>248</sup>

If this characterization is accurate, the meetings would probably fall within FACA's purview. Clearly, EPA departed from the Act's procedural requirements in numerous particulars. Certainly, the narrow range

239. *United States Lines, Inc. v. Federal Maritime Comm'n*, 584 F.2d 519, 541-42 (D.C. Cir. 1978).

240. See, e.g., R. MERRILL, *supra* note 84, Part III, at 153; see also Memorandum from Rep. Toby Moffett to the House Subcommittee on Environment, Energy, and Natural Resources, (Oct. 6, 1981) reprinted in *Moffett Hearings*, *supra* note 18, at 25.

241. 5 U.S.C. app. I (1976).

242. See generally Cardozo, *The Federal Advisory Committee Act in Operation*, 33 AD. L. REV. 1 (1981); C. Kaufman, *A Sociohistorical View of Advisory Committees* (June 1981) (unpublished paper presented at the Charles F. Kettering Foundation Conference on Federal Advisory Committees).

243. See 5 U.S.C. app. I, §§ 5, 9, 10 (1976).

244. *Id.* § 3(2).

245. See, e.g., *Consumers Union of United States, Inc. v. Dep't of Health, Educ., & Welfare*, 409 F. Supp. 473 (D.D.C. 1976), *aff'd*, 551 F.2d 466 (D.C. Cir. 1977); *Nader v. Baroody*, 396 F. Supp. 1231 (D.D.C. 1975).

246. Letter from John Hernandez, Jr. to Rep. Toby Moffett (Oct. 5, 1981) reprinted in *Moffett Hearings*, *supra* note 18, at 54-64.

247. *Id.* at 2, reprinted in *Moffett Hearings*, *supra* note 18, at 55.

248. *Moffett Hearings*, *supra* note 18, at 22.



of viewpoints represented at the industry meetings implicates the "fair balance" requirement of the Act.<sup>249</sup>

*ii. Todhunter's Informal Contacts with Representatives of the Formaldehyde Industry*

A substantial amount of evidence indicates that before releasing his February 10 memorandum, Todhunter met on several occasions with John Byington, attorney for the Formaldehyde Institute, and Len Guarraia, then a director of the American Industrial Health Council (AIHC) and Director for Governmental Relations for the Synthetic Organic Chemical Manufacturer's Association (SOCMA). Both AIHC and SOCMA have strong ties to the Formaldehyde Institute. AIHC is an industry research and lobbying group.<sup>250</sup> Until 1979, the Formaldehyde Institute was a part of SOCMA, where it was known as SOCMA's "Formaldehyde Task Force."<sup>251</sup> All three organizations maintain their offices in Scarsdale, New York, and all currently share the same phone number.<sup>252</sup>

Todhunter was questioned about his contacts with Byington and Guarraia at two congressional hearings, but his testimony was inconsistent.<sup>253</sup> The principal interrogator at the first hearing was Representative Toby Moffett (D-CT), who had obtained Todhunter's appointment calendar for the relevant time period.<sup>254</sup> Initially, Todhunter denied meeting

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249. 5 U.S.C. app. I, § 5(b)(2), (c) (1976). Although some commentators have expressed doubt about the meaning of this provision, *see, e.g.*, Cardozo, *supra* note 242, at 55, its plain language and its legislative history give a fairly clear indication of what Congress intended. Certainly, fairness demands more than a token representation of an opposing viewpoint; a good faith effort at parity is required. *See* National Nutritional Foods Ass'n v. Califano, 603 F.2d 327, 336 (2d Cir. 1979) (addresses Congress's concern "that agency action might be dominated by one particular viewpoint"); H.R. REP. NO. 1017, 92d Cong., 2d Sess. 6, reprinted in 1972 U.S. CODE CONG. & AD. NEWS 3491, 3496 (FACA intended to prohibit a "heavy representation of parties whose private interests could influence their recommendations").

*See generally* Ashford, *The Role of Advisory Committees in Resolving Regulatory Issues Involving Science and Technology: Experience from the Occupational Safety and Health Administration and the Environmental Protection Agency*, in LAW AND SCIENCE IN COLLABORATION: RESOLVING REGULATORY ISSUES OF SCIENCE AND TECHNOLOGY 165 (J. Nyhart & M. Carrow eds. 1983).

250. *See* AMERICAN INDUSTRIAL HEALTH COUNCIL, AMERICAN INDUSTRIAL HEALTH COUNCIL 2-3 (1983) (available from AIHC, Scarsdale, NY).

251. *See* FORMALDEHYDE INSTITUTE, *supra* note 1, at 4; Snell Report, *supra* note 130, at 3-4.

252. Directory Assistance, Scarsdale, N.Y. (Apr. 23, 1983).

253. *See Florio Hearings*, *supra* note 18, at 23-33; *Gore EPA Hearings*, *supra* note 18.

254. Reprinted in *Florio Hearings*, *supra* note 18, at 194. The calendar shows that between July 15, 1981, and November 13, 1981, Assistant Administrator designee Todhunter scheduled three meetings with Guarraia. Between November 13, 1981, his confirmation date, and February 10, 1982, the date of his memorandum, Todhunter scheduled seven meetings with Guarraia and two meetings with Byington.

with Byington.<sup>255</sup> When Moffett informed him that his calendar listed two meetings with Byington and six with Guarraia between November 1981 and February 1982, however, Todhunter admitted that he met with Byington on January 26, 1982, but claimed that another meeting scheduled for earlier in the month had been "snowed out."<sup>256</sup> He later confirmed that he had met with Byington once, and perhaps twice, during January.<sup>257</sup> He also admitted meeting with Guarraia, but he denied that they discussed formaldehyde.<sup>258</sup> At another hearing two months later, however, he denied having met with Byington prior to drafting the February 10 memorandum.<sup>259</sup> Upon further questioning, he acknowledged that he had talked briefly with Byington at one breakfast meeting.<sup>260</sup>

Although the precise nature and scope of these gatherings is difficult to deduce from the congressional testimony, it seems apparent that Todhunter did meet with formaldehyde interests before drafting EPA's position paper on the section 4(f) determination.<sup>261</sup> As the D.C. Circuit has noted, "[t]he inconsistency of *ex parte* contacts with reasoned decisionmaking and fairness to the public has been increasingly recognized in recent years . . . ."<sup>262</sup> The court added that such contacts "foreclose effective judicial review of the agency's final decision."<sup>263</sup> Accordingly, in the absence of substantial justification, the mere existence of *ex parte* communications may so taint an agency's informal decisionmaking process as to warrant reversal of the agency's decision.<sup>264</sup>

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255. *Florio Hearings*, *supra* note 12, at 26-27. Todhunter stated that he had attended one of the industry meetings with Byington. The participant lists for those meetings indicate that Todhunter attended two of them. *See Moffett Hearings*, *supra* note 18, at 58-59.

256. *Id.* at 28.

257. *Id.* at 29. At this point Todhunter said he was unsure if January 26, 1982, had been one of those occasions.

258. *Id.* at 28. Todhunter testified that he had known Guarraia socially for some time and that Guarraia had "no interest in formaldehyde one way or the other."

259. *See Gore EPA Hearings*, *supra* note 18.

260. *Id.* Todhunter said that on January 26, 1982, he was scheduled to have breakfast with Byington and others, but that he overslept. He said he arrived just in time to say hello and goodbye.

261. Even if the meetings with Byington never took place, one must wonder why they were scheduled.

262. *United States Lines, Inc. v. Federal Maritime Comm'n*, 584 F.2d 519, 540 n.8 (D.C. Cir. 1978) (emphasis added).

263. *Id.* at 541.

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[W]here, as here, an agency justifies its actions by reference only to information in the public file while failing to disclose the substance of other relevant information that has been presented to it, a reviewing court cannot presume that the agency has acted properly, but must treat the agency's justifications as a fictional account of the actual decisionmaking process and must perform find its actions arbitrary.

*Id.* at 541 (quoting from *Home Box Office, Inc. v. FCC*, 567 F.2d 9, 54-55 (D.C. Cir. 1977)) (citations omitted).

*iii. Insular Deliberations*

In addition to discouraging input from major segments of the public, the new EPA administrators ceased to cooperate with the other federal agencies that were assessing formaldehyde carcinogenicity. Consistent with its statutory mandate to consider *all* categories of human exposure to formaldehyde<sup>265</sup> and to coordinate its efforts with those of other federal agencies,<sup>266</sup> EPA had initially exchanged technical information and assessments with both OSHA and CPSC.<sup>267</sup> By September 1981, however, the Interagency Regulatory Liaison Group (IRLG) had been disbanded, and EPA had little or no further contact with either OSHA or CPSC regarding formaldehyde.<sup>268</sup> Indeed, EPA officials appear to have avoided such contact.<sup>269</sup>

EPA also isolated itself from its own Science Advisory Board. Congress created the Board, which by the terms of its charter is a "body of independent scientists and engineers of sufficient size and diversity to provide a range of expertise required to assess the scientific and technical aspects of environmental issues."<sup>270</sup> On October 29, 1981, the Board's Executive Committee recommended that EPA submit the formaldehyde issue to the National Academy of Sciences before it concluded its section 4(f) determination.<sup>271</sup> EPA instead permitted Todhunter to draft his technical memorandum on formaldehyde without such assistance.<sup>272</sup>

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265. Section 4(f), like the other operative provisions of TSCA, is not limited to certain classes of exposure. Congress clearly intended the generic regulation of suspect *chemicals*, not exposures, and directed other agencies to provide "such information, data, estimates, and statistics" to the Administrator as will further this purpose. 15 U.S.C. § 2625(a)(2) (1976). This appears to anticipate that other agencies — such as OSHA and CPSC — would be providing relevant exposure (and effect) information to EPA on suspect chemicals.

266. 15 U.S.C. §§ 2608(d), 2609(g) (1976).

267. Formal exchange occurred under the auspices of the IRLG Formaldehyde workgroup. See *supra* note 156. In addition, before Gorsuch and Hernandez took office, OTS had planned to coordinate its activities with those of other agencies once it designated formaldehyde a section 4(f) priority. Draft Federal Register Notice, *supra* note 159, at 19 & 25-27.

268. The IRLG was purportedly replaced by the Interagency Regulatory Working Group on Science and Technology, an informal group under the aegis of the White House Office of Science and Technology Policy. See 5 CHEM. REG. REP. (BNA) 592 (Oct. 2, 1981). We have seen no evidence that that group met to coordinate agency formaldehyde decisionmaking prior to Todhunter's February 10, 1982, memorandum.

269. *Gore EPA Hearings*, *supra* note 18 (testimony of Dr. John Todhunter). In addition, Dr. Peter Preuss, Associate Executive Director for Health Sciences at CPSC, testified that CPSC became aware of Todhunter's memorandum only after the Formaldehyde Institute submitted it to the Commission. *Id.*

270. USEPA, U.S. ENVIRONMENTAL PROTECTION AGENCY ADVISORY COMMITTEES: CHARTERS, ROSTERS, AND ACCOMPLISHMENTS 30-32 (Jan. 1980).

271. See 9 PESTICIDE & TOXIC CHEM. NEWS (Nov. 4, 1981).

272. See *infra* notes 296-300 and accompanying text.

*b. Inadequate Explanation of Decisionmaking Rationale*

The courts have long required agencies to "articulate with reasonable clarity their reasons for a decision."<sup>273</sup> In the words of an oft-cited opinion: "the orderly functioning of the process of review requires that the grounds upon which the administrative agency acted be clearly disclosed and adequately sustained."<sup>274</sup> EPA's formaldehyde deliberations fell far short of this standard.

The only articulated bases for the agency's decision appear in the Clay and Todhunter memoranda, the latter of which is considerably more comprehensive.<sup>275</sup> As discussed above, Todhunter's analysis contains several lapses in technical reasoning,<sup>276</sup> and relies heavily on determinations made in the realm of science policy rather than hard science.<sup>277</sup> To the extent that these defects stem from a failure to consider contrary empirical evidence, they call into question the procedural adequacy of the memorandum as a statement of reasons. The more troublesome procedural problem, however, lies in Todhunter's failure to acknowledge his departure from prior agency positions on many of the science policy issues involved. Where an agency has changed a previously articulated policy or departed from a relevant agency precedent, the courts have required the agency to provide a detailed rationale.<sup>278</sup> Although EPA never promulgated a formal cancer policy, it published informal cancer guidelines in 1976,<sup>279</sup> endorsed the Interagency Regulatory Liaison Group risk assessment document in 1979,<sup>280</sup> and participated in the Regulatory Council's September 1979 policy statement on regulation of chemical carcinogens.<sup>281</sup> Being most recent, the Regulatory Council's statement was the logical foundation for EPA's approach to formaldehyde.<sup>282</sup> Yet Todhunter's positions differ from the Council's in several areas.<sup>283</sup>

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273. *Greater Boston Television Corp. v. F.T.C.*, 444 F.2d 841, 851 (D.C. Cir. 1970).

274. *SEC v. Chenery Corp.*, 318 U.S. 80, 94 (1943). Since this case, the requirement of an adequate statement of reasons has become ensconced as a fundamental principle of administrative law. *See Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 420 (1971).

275. *See supra* text accompanying notes 181-189.

276. *See supra* text accompanying notes 195-224.

277. *See supra* text accompanying notes 225-27.

278. *See cases cited supra* note 102.

279. EPA, *Health Risk and Economic Impact of Suspected Carcinogens: Interim Procedures and Guidelines*, 41 Fed. Reg. 21,402 (1976).

280. *See IRLG Risk Assessment Document, supra* note 36.

281. *See Regulatory Council Statement, supra* note 34.

282. The summary of the Council statement read: "This policy is being published in the Federal Register to inform the public of the practices and principles the participating Federal regulatory agencies will follow in initiating regulatory actions relating to chemical carcinogens." 44 Fed. Reg. 60,038 (1979). EPA was a participating agency.

EPA subsequently published additional guidelines for carcinogen regulation under certain air and water programs, *see* 44 Fed. Reg. 58,642 (1979); 45 Fed. Reg. 79,318, 79,350 (1980), but not for TSCA activities.

283. The Clay memorandum also departs from a major position in the Council guide-

The guidelines specify that: (1) negative epidemiologic studies will not be presumed to indicate that a substance is not carcinogenic;<sup>284</sup> (2) sites exposed by routes other than those tested will be presumed to be at risk;<sup>285</sup> (3) negative bioassay results for some species, even in well-conducted tests, will not be said to detract from well-established positive evidence for other species;<sup>286</sup> and (4) a no-effect threshold level will not be assumed to exist for carcinogenic substances.<sup>287</sup> Todhunter adopted a contrary position on each of these points.

Todhunter also suggested that positive data in more than one species at more than one dose level should be a prerequisite to a determination of human risk.<sup>288</sup> The Council guidelines require only positive data in a single species at one dose level.<sup>289</sup> Similarly, Todhunter discounted findings of benign tumors in bioassay data and considered only verifiably malignant tumors,<sup>290</sup> while the Council concluded that benign tumors should be considered evidence of potential malignancy.<sup>291</sup> The Council statement also indicates that agencies will attempt to estimate the maximum risk that could reasonably be expected.<sup>292</sup> Todhunter consistently assumed policy positions that minimized estimated risks.<sup>293</sup>

In its failure to explain, or even acknowledge, these policy reversals,

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lines. Where Clay advised that EPA delay action until the National Cancer Institute epidemiologic study was complete, *see supra* note 169, the Council's policy is that agencies not wait for epidemiologic evidence, *see* Regulatory Council Statement, *supra* note 34, at 60,039.

284. Compare Regulatory Council Statement, *supra* note 34, at 60,039, with Todhunter Memorandum, *supra* note 163, at 11-12; *see also supra* note 199 and accompanying text.

285. Compare Regulatory Council Statement, *supra* note 34, at 60,040, with Todhunter Memorandum, *supra* note 163, at 11; *see also supra* note 204 and accompanying text.

286. Compare Regulatory Council Statement, *supra* note 34, at 60,040, with Todhunter Memorandum, *supra* note 163, at 6-7; *see also supra* notes 208-09 and accompanying text.

287. Compare Regulatory Council Statement, *supra* note 34, at 60,040-41, with Todhunter Memorandum, *supra* note 163, at 10; *see also supra* notes 216-18 and accompanying text.

288. Todhunter Memorandum, *supra* note 163, at 2. Todhunter's position is one that has generally been advanced only by industry groups. *See* Office of Technology Assessment, *supra* note 84, at 128-29.

289. Regulatory Council Statement, *supra* note 34, at 60,040.

290. Todhunter Memorandum, *supra* note 163, at 3. Todhunter stated: "Section 4(f) also draws a distinction between benign and malignant growths by use of the term 'cancer' rather than 'tumors.'" His distinction contradicts not only the Regulatory Council position, *see infra* note 291, but also previous agency interpretations of the meaning of "cancer" under TSCA. For example, section 4(b) of TSCA requires testing for "carcinogenicity," which literally refers only to malignant tumors. Yet in 1979, EPA proposed standards under section 4(b) which would have required testing for both benign and malignant tumors. *See* EPA, Proposed Health Effects Test Standards for Toxic Substances Control Act Test Rules, 44 Fed. Reg. 27,334, 27,335 (1979).

291. Regulatory Council Statement, *supra* note 34, at 60,040.

292. *Id.* at 60,041.

293. *See* Todhunter positions discussed *supra* at notes 279-88 & 290.

EPA fell short of its procedural responsibility. Especially here, where the issues lie within the realm of "controversial, normative, or empirical determinations,"<sup>294</sup> and where the agency departed from its prior position on the specific carcinogenic risk, a detailed rationale is all the more necessary.<sup>295</sup>

EPA's formaldehyde deliberations powerfully illustrate the ease with which matters of policy may be confused with matters of science. The agency's technical analysis hides significant procedural deficiencies. Whether intentional or not, the result is an invidious one: the analysis purports to justify, in the name of science, a risk assessment policy far less protective of human health than the agency's prior policy.

In this regard, it is noteworthy that Todhunter's memorandum was not reviewed by his scientific peers either inside or outside the agency.<sup>296</sup> The failure to garner peer review, especially on matters so controversial, ran counter to the professed goal of the new EPA administrators to improve the scientific basis of the agency's regulatory decisions.<sup>297</sup> It may also have violated internal EPA procedures. In January 1982, EPA implemented a new internal policy governing the review of scientific, informational, and educational materials.<sup>298</sup> The policy, which applies to "any material prepared for distribution to anyone outside the agency,"<sup>299</sup>

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294. *Natural Resources Defense Council v. United States Nuclear Regulatory Comm'n*, 547 F.2d 633, 658 n.3 (D.C. Cir. 1976) (Tamm, J., concurring), *rev'd. sub. nom. Vermont Yankee Nuclear Power Corp. v. Natural Resources Defense Council*, 435 U.S. 519 (1978). In reversing the D.C. Circuit, the Supreme Court spoke favorably of Judge Tamm's approach. *See* 435 U.S. at 549.

295. *See, e.g., State Farm Mutual Auto. Ins. v. Department of Transp.*, 680 F.2d 206 (D.C. Cir. 1982). In vacating the National Highway Traffic Safety Administration's rescission of its automatic crash protection standards, the D.C. Circuit noted that the agency's explanations were "arbitrary in their failure to address obviously relevant considerations" and concluded that the agency had not provided "a reasoned or rational foundation" for reversing its course. *Id.* at 242.

296. *Gore EPA Hearings*, *supra* note 18 (statements by Dr. John Todhunter). Todhunter's testimony indicates that no other scientists, except perhaps Dr. John Hernandez, Jr., reviewed the memorandum before its release on February 12, 1982. Todhunter testified that in May 1982, three months after its release, he had telephone conversations with several scientists to whom he had sent the memorandum.

297. *See, e.g., Nominations of Anne M. Gorsuch and John W. Hernandez, Jr.: Hearings Before the Senate Comm. on Environment and Public Works*, 97th Cong., 1st Sess. 288 (May 1 & 4, 1981) (Hernandez testified: "I come to the agency with a single personal goal: that the agency attain a national and international reputation for quality and excellence in its development and use of science and technology in its decisionmaking process."); *Nominations of Matthew N. Novick and John A. Todhunter, Hearings Before the Senate Comm. on Environment and Public Works*, 97th Cong., 1st Sess. 10 (Sept. 22 & Oct. 16, 1981) (Todhunter testified: "I see my nomination as an opportunity to contribute to . . . the cultivation of sound science as a data base for regulatory decisionmaking.").

298. Memorandum from Anne Gorsuch to Associate, Assistant, and Regional Administrators and Staff Office Directors (Dec. 18, 1981) (*reprinted in Scheuer Hearings, supra* note 18, at 183). The memorandum was circulated on December 18, 1981, and the policy went into effect on January 18, 1982.

299. *Id.* at 1 (with exceptions not relevant here).

requires that at least two specialists review all such materials.<sup>300</sup> Nonetheless, the Todhunter memorandum was released to the public without prior peer review.

### 3. The Statutory Mandate

As noted, the courts have not yet interpreted section 4(f) of TSCA, nor is there any legislative history specifically pertinent to this section.<sup>301</sup> The plain language of the statute, however, lends itself to common-sense interpretation. Section 4(f) requires the agency to take action whenever the available information indicates

that there may be a reasonable basis to conclude that a chemical substance or mixture presents or will present a significant risk of serious or widespread harm to human beings from cancer, gene mutations, or birth defects . . . .<sup>302</sup>

Congress apparently designed section 4(f) as a mechanism for early identification and regulation of those chemicals that were of particular concern because they are likely carcinogens, mutagens, or teratogens. EPA's current interpretation of that section, however, will frustrate this scheme.

#### a. The Possibility of Harm

As noted, section 4(f) requires agency action if there "may be a reasonable basis" to conclude that a risk of harm exists.<sup>303</sup> In both common usage<sup>304</sup> and judicial interpretation,<sup>305</sup> the term "may" indicates the possibility of occurrence. Under the plain language of section 4(f), then, EPA cannot delay its threshold determination until a risk has become

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300. EPA, Order 2200: Review Process for Scientific, Informational, and Educational Documents, at 3 (undated) (*reprinted in Scheuer Hearings, supra* 18, at 188). The order also specifies that documents containing "significant scientific or technical uncertainties" are subject to review by the Science Advisor. *Id.* at 5.

301. EPA's Office of General Counsel has noted that there appears to be a "dearth of explicit Congressional discussion on the purposes of section 4(f)." Memorandum from D. Menotti and S. Atkinson to S. Jellinek 9 (Oct. 30, 1980) (subject: Primer on TSCA 4(f)) [hereinafter cited as Primer on 4(f)].

302. 15 U.S.C. § 2603(f) (1976).

303. *Id.* (emphasis added).

304. The common definition of "may" relevant here is "be in some degree likely to." WEBSTER'S NEW COLLEGIATE DICTIONARY 711 (1976).

305. *See, e.g.,* United States v. Lexington Mill & Elevator Co., 232 U.S. 399 (1914) ("may" equivalent to "might").

The legislative history of TSCA indicates that a similar meaning was intended to be ascribed to "may" in Section 4. In discussing Section 4(a), which provides for the treating of chemicals that "may present an unreasonable risk," the Conference Committee Report noted that testing is to occur when "there is a basis for concern," and that EPA "need not show that the substance does or will present a risk." H.R. REP. NO. 94-167a, 94th Cong., 2d Sess. 64 (1976).

certain or probable, but rather must take action upon learning of a credible possibility of such risk.

Presumably, EPA had made that threshold determination in early 1981, when it prepared its preliminary Federal Register notice on formaldehyde.<sup>306</sup> In subsequently reversing that determination, the agency offered a markedly different interpretation of the section 4(f) threshold. In essence, EPA redefined the word "may" in a manner inconsistent with both common usage and TSCA's statutory framework.

Todhunter's memorandum is particularly noteworthy in this respect. In summarizing the formaldehyde data, Todhunter noted that "there *may* be human exposure situations . . . which *may not* present carcinogenic risk which is of significance."<sup>307</sup> He thus stated the required statutory finding in the negative. The logical converse of this statement — that there may be human exposure situations that *do* present significant carcinogenic risk — is precisely the finding that requires EPA to proceed under section 4(f). The agency's failure to do so is simply a misinterpretation of statutory language.

EPA documents indicate that the agency continues to endorse this interpretation of section 4(f). EPA's Office of General Counsel has prepared a "Primer on TSCA 4(f),"<sup>308</sup> which details the agency's interpretation of its duties under that section. The Primer concludes that Congress must have intended "may" in this section to refer to a "reasonably high probability" of occurrence.<sup>309</sup> Given the agency's limited resources, the Primer argues, section 4(f) must be viewed as having been reserved for only a small number of highly probable risks.<sup>310</sup> In addition to being inconsistent with the plain language of section 4(f), this interpretation ignores that section's place in the overall scheme of TSCA. Section 7 of the Act specifically provides for expedited action on "imminent hazards,"<sup>311</sup> and section 6 details the actions to be taken against "unreason-

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306. See Draft Federal Register Notice, *supra* note 159. The notice stated:

EPA believes that formaldehyde has met the criteria of sec. 4(f) for the following reasons. First, the results of a recently reported bioassay study demonstrate that formaldehyde is carcinogenic in rats . . . . Second, review of the available information on the use of formaldehyde and resulting human exposure *suggests* that large numbers of people are potentially exposed to harmful concentrations of formaldehyde. Accordingly, the Agency finds that there *may* be a reasonable basis to conclude that formaldehyde presents a significant risk of widespread harm to humans from cancer.

*Id.* at 5-6 (emphasis added).

307. Todhunter memorandum, *supra* note 163, at 5 (emphasis added).

308. Primer on 4(f), *supra* note 301. This primer was prepared under the Carter Administration. EPA's Office of General Counsel reportedly prepared another 4(f) analysis in May 1982. 6 CHEM. REG. REP. (BNA) 315 (1982). EPA has not publicly released that document, and we therefore must assume that the Primer still represents EPA's views.

309. Primer on 4(f), *supra* note 301, at 21.

310. *Id.*

311. 15 U.S.C. § 2606 (1976).



able risks."<sup>312</sup> If EPA's interpretation were correct, section 4(f) would merely duplicate these other sections. As one commentator has noted, the agency's interpretation "effectively writes the [4(f)] provision out of TSCA."<sup>313</sup>

*b. The Nature and Extent of the Possible Harm*

The agency's assessment of the kind of risk that it is to consider under section 4(f) may also be inaccurate. The Clay memorandum, for example, argues that section 4(f) "should be reserved only for [carcinogens] of the most serious concern" and for "those situations that require a crash effort to remedy a very serious hazard to public health."<sup>314</sup>

Once again, the statute itself provides relatively clear guidelines, which point to a contrary interpretation. Congress dealt with both short-term and long-term risk in 4(f), which addresses chemical substances that either "present" or "will present" a significant risk of harm. The Act does not define the phrase "significant risk," but the context suggests that "significance" pertains to the likelihood of occurrence.<sup>315</sup> By providing that the risk that *may* exist must be *significant*, the Act seems to require only the *possibility* of a *probable* occurrence. Evidence indicating the possibility of a significant risk thus triggers the threshold determination that compels EPA to assess the risk more precisely.

In its risk assessment, the agency must consider *both* "serious" and "widespread" harm. By specifically distinguishing between these two categories of harm in section 4(f), Congress clearly indicated that either one will trigger a threshold determination. One element focuses on the extent to which the chemical may pose a risk of *serious* harm. Here the concern is not so much the number of people who may be affected, but how severely they may be affected. A low incidence of a debilitating cancer, then, would suffice. An alternate element is the extent to which the chemical may pose a risk of *widespread* harm. Here a higher incidence is required, but the harm need not be as severe.

*c. The Nature of the Required Action*

EPA's formaldehyde decision also reveals some confusion within the agency as to what it must do once it makes a section 4(f) threshold determination. Although Clay's reference to "a crash effort to remedy a

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312. *Id.* § 2605.

313. *Gore EPA Hearings*, *supra* note 18 (prepared testimony by Jacqueline Warren, NRDC, at 6).

314. Clay Memorandum, *supra* note 169, at 195.

315. In common usage, "significant" means "having or likely to have influence or effect." WEBSTER'S NEW COLLEGIATE DICTIONARY 1079 (1977). Although in a technical sense the term can mean *statistically* significant, nothing indicates that Congress intended this narrower meaning here.

very serious hazard to public health" may occasionally describe section 4(f) actions,<sup>316</sup> it more properly applies to actions under the "imminent hazard" provisions of section 7.<sup>317</sup>

After making a threshold determination of possible significant risk, EPA must decide, within a prescribed time period,<sup>318</sup> whether regulatory action is appropriate. If the agency determines that the risk is not unreasonable, it must subject this finding to public scrutiny by publishing it in the Federal Register.<sup>319</sup> If, on the other hand, the agency does *not* conclude that the potential risk is not unreasonable, it must "initiate appropriate action . . . to prevent or reduce to a sufficient extent such risk."<sup>320</sup>

Depending on the severity of the risk, various actions may be appropriate. The agency is free to exercise its reasoned discretion in selecting which of TSCA's other regulatory authorities to call into play, so long as it designs its action to reduce the risk sufficiently. In some cases, a chemical labeling requirement may be adequate.<sup>321</sup> In others,<sup>322</sup> the agency may have to limit the uses of the chemical,<sup>323</sup> or ban it outright.<sup>324</sup> While we express no opinion here as to the appropriate regulatory response to formaldehyde under TSCA, it appears that section 4(f) requires something more of EPA than the agency's actions to date.

## V. OSHA'S DECISION NOT TO ISSUE AN EMERGENCY TEMPORARY STANDARD

### A. Background

After receiving the results of the preliminary CIIT bioassay in late 1979, both OSHA and the National Institute for Occupational Safety and Health (NIOSH) joined ongoing formaldehyde studies by the Interagency Regulatory Liaison Group (IRLG) and Federal Panel on Formaldehyde. They also began preparing a joint Current Intelligence Bulletin (CIB) on formaldehyde.<sup>325</sup> A pre-publication version, co-signed by Eula Bingham,

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316. Clay Memorandum, *supra* note 169, at 195. Again, Clay's reference to "crash efforts" illustrates the agency's narrow reading of 4(f).

317. 15 U.S.C. § 2606 (1976).

318. Ordinarily, the Administrator has 180 days to decide upon an appropriate course of action. *Id.* § 2603(f). Section 4(f) also permits an additional period of up to 90 days for "good cause shown." *Id.*

319. *Id.* § 2603(f) (1976).

320. *Id.*

321. *See* § 6(a)(3), 15 U.S.C. § 2605(1)(3) (1976).

322. If a statement of reasons is published in the Federal Register as to why no *action* is being taken under sections 5, 6(a), or 7, 15 U.S.C. §§ 2304, 2305(a), 2306 (perhaps because there is convincing evidence that the public is being adequately protected through voluntary industry actions), then a monitored program of toxicological testing may suffice.

323. *See* § 6(a)(2), 15 U.S.C. § 2605(a)(2) (1976).

324. *See* § 6(a)(1), 15 U.S.C. § 2605(a)(1) (1976).

325. The formaldehyde CIB is the thirty-fourth in a series available from NIOSH;

then Assistant Secretary of Labor for OSHA, and Anthony Robbins, then Director of NIOSH, was made available to the public in December 1980.<sup>326</sup> The CIB contained information on formaldehyde uses, production, toxicity, and workplace exposures and recommended that "formaldehyde be handled as a potential occupational carcinogen and that appropriate controls be used to reduce worker exposure."<sup>327</sup>

In March 1981, Thorne Auchter assumed office as Assistant Secretary of Labor for OSHA. Soon thereafter, he withdrew OSHA's sponsorship of the CIB, explaining later that the agency "lacked confidence in the data" on which it was based.<sup>328</sup> In April 1981, NIOSH published the CIB without OSHA's sponsorship.<sup>329</sup>

Also in April, OSHA received a formaldehyde regulatory analysis that it had requested from a research team at MIT.<sup>330</sup> The report analyzed the cancer risks and economic impacts associated with several possible exposure levels. The authors estimated that under current OSHA standards,<sup>331</sup> between four and 5,700 workers contract cancer each year because of workplace exposure to formaldehyde.<sup>332</sup> After obtaining comments on the report from formaldehyde industry scientists,<sup>333</sup> and from a scientist whose theories on cancer risk assessment have been adopted

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the CIBs provide information on workplace health hazards. See *Gore OSHA Hearings*, *supra* note 18, at 51.

326. National Institute for Occupational Safety and Health, Formaldehyde; Evidence of Carcinogenicity, NIOSH Current Intelligence Bulletin #34 (Dec. 23, 1980).

327. *Id.* at 1.

328. See *Gore OSHA Hearings*, *supra* note 18, at 60 (statement by Thorne Auchter). The basis of Auchter's decision to withdraw sponsorship was discussed extensively at this hearing.

329. See 5 CHEM. REG. REP. (BNA) 91 (Apr. 24, 1981).

330. MIT Report, *supra* note 131.

331. The current OSHA formaldehyde standards limit the eight-hour time-weighted average concentration to 3 ppm, the ceiling concentration to 5 ppm, and the maximum peak above the ceiling concentration to 10 ppm for no more than a total of 30 minutes during an eight-hour shift. 29 C.F.R. § 1910.100, Table Z-2 (1981). In 1976, NIOSH recommended a new standard to limit concentrations to no more than 1 ppm for any 30-minute sampling period. This recommendation was based solely on formaldehyde's irritant effects, not on its carcinogenic potential.

332. MIT Report, *supra* note 131, at 3-65, Table 3.25. The authors emphasized the uncertainty inherent in such estimates and discussed the sources of that uncertainty. See *id.* at Chapter 3.

333. The industry scientists were Dr. Joel Bender and Linda S. Mullin of DuPont, a company whose annual formaldehyde production capacity of over one billion pounds is exceeded by that of only two other U.S. manufacturers. STANFORD RESEARCH INSTITUTE, *supra* note 3, at 658.5032K. Dr. Bender was also then Chairman of the Formaldehyde Institute's Medical Committee. See letter from Joel Bender to Thorne Auchter (Aug. 28, 1981).

For a copy of Bender's and Mullin's comments, see *Criticisms of Health Aspects of Ashford Document*, Appendix B to OSHA, PRELIMINARY COMMENTS ON SHORTCOMINGS OF ASHFORD'S ARGUMENTS FOR FURTHER OSHA REGULATION OF FORMALDEHYDE, AND OBSERVATIONS AS TO WHAT, IF ANYTHING, OSHA SHOULD DO WITH ASHFORD'S STUDY (May 28, 1981) [hereinafter cited as MIT REPORT REVIEW]. The author of the review appears to have relied heavily on Bender's and Mullin's comments.

by the industry,<sup>334</sup> OSHA determined that further action on formaldehyde was unnecessary.<sup>335</sup>

In July 1981, John Martonik, then chief of OSHA's Division of Health Compliance Programming, advised Han Kang, OSHA's representative to the IRLG formaldehyde workgroup, that OSHA no longer endorsed the IRLG formaldehyde risk assessment efforts.<sup>336</sup> Martonik stated that the preliminary CIIT bioassay did not "persuade OSHA that it needs to immediately regulate formaldehyde."<sup>337</sup>

In October of that year, the United Auto Workers and thirteen other major labor unions petitioned OSHA<sup>338</sup> to promulgate an emergency temporary standard (ETS) for formaldehyde under section 6(c) of the OSHAct.<sup>339</sup> In a letter dated January 29, 1982, Auchter denied the petition and gave the following rationale for this decision:<sup>340</sup>

Section 6(c) of the Occupational Safety and Health Act allows the Secretary to promulgate an emergency temporary standard without rulemaking only if he determines that (a) employees are exposed to a grave danger from exposure to toxic agents or from new hazards, and (b) that such emergency standard is necessary to protect employees from such danger. I believe that emergency temporary standards are appropriate only in response to extraordinary conditions which result in the exposure of employees to a grave danger during the course of their employment.<sup>341</sup>

Auchter dismissed the CIIT and NYU animal bioassays,<sup>342</sup> noting that the carcinogenic response was "statistically significant only at exposure levels of approximately 15 ppm, substantially above the current permissible exposure limit (PEL) for formaldehyde of 3 ppm."<sup>343</sup> He concluded that, at the 3 ppm level, exposure to formaldehyde was not a risk "suf-

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334. This scientist was Dr. Frank Carlborg. For a copy of his comments, see MIT REPORT REVIEW, *supra* note 333, at Appendix A. Carlborg favors high-dose to low-dose extrapolation models that estimate risks at low doses solely on the basis of observed risks at high doses. See Carlborg, *Multi-Stage Dose-Response Models in Carcinogenesis*, 19 FOOD COSMET. TOXICOLOGY 361 (1981). By contrast, the regulatory agencies generally endorse models that also assume that risks at low doses vary in linear proportion to dose. See, e.g., *IRLG Risk Assessment Document*, *supra* note 36, at 260-61; EPA, Notice of Water Quality Criteria Documents, 45 Fed. Reg. 79,318, 79,350 (1980). The former class of models generally produce lower risk estimates and have been adopted by industry. See, e.g., *Gore EPA Hearings*, *supra* note 18 (statements by Dr. Robert Sielken of the Formaldehyde Institute) (advocating use of such models).

335. MIT REPORT REVIEW, *supra* note 333, at 1-2.

336. Memorandum from John Martonik to File (July 29, 1981). From available documentation, it is unclear whether OSHA staff continued to participate in the IRLG efforts.

337. *Id.* at 1.

338. Letter from Howard Young, Director, Social Security Department, UAW to Thorne Auchter (Oct. 26, 1981).

339. 29 U.S.C. § 655(c) (1976).

340. Letter from Thorne Auchter to Howard Young (Jan. 29, 1982).

341. *Id.*

342. See *supra* text accompanying notes 104-16.

343. Letter from Thorne Auchter to Howard Young (Jan. 29, 1982).

ficient to warrant a finding of 'grave danger' and resulting emergency action."<sup>344</sup>

Auchter went on to say:

In all ETS situations, OSHA must not only sustain the burden of proving that the ETS is justified by a grave danger, which we do not believe exists here, but also that the emergency action is necessary to protect employees. [Available information] . . . indicates that exposure levels are generally below the current PEL of 3 ppm. This information is corroborated by OSHA inspection data. In addition, other OSHA standards . . . help provide additional protection to employees exposed to liquid formaldehyde.<sup>345</sup>

In light of these other standards and the existing 3 ppm exposure limit,<sup>346</sup> Auchter concluded that "the data . . . submitted would not enable us to make a showing that the emergency action . . . is necessary."<sup>347</sup>

On August 25, 1982, the United Auto Workers filed suit to compel OSHA to promulgate an ETS for formaldehyde.<sup>348</sup>

### B. The Decisionmaking Process

In many ways, OSHA's deliberations on formaldehyde mirror EPA's. Although OSHA's departures from sound technical reasoning and established administrative procedure were perhaps less blatant than EPA's, they were nonetheless significant. OSHA's treatment of science policy issues provides an excellent example of how such issues can cut across all three levels of an agency's administrative responsibility.<sup>349</sup>

#### 1. Analysis of Technical Data

The decision to deny the petition for an emergency temporary standard was apparently based on two evaluations performed by agency

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344. *Id.*

345. *Id.*

346. *Id.* Auchter cited standards requiring employees to use "protective equipment and eye and face protection when any chemical, including formaldehyde, is used in such a manner that it is capable of injuring or impairing employees." *Id.*

347. *Id.*

348. *United Auto Workers v. Donovan*, No. 82-2401 (D.D.C. filed Aug. 25, 1982).

349. This section of the article discusses some decisions made and actions taken before the agency received the ETS petition from the unions. Such intermediate actions are considered important by reviewing courts. As DeLong stated in his comprehensive review of informal rulemaking practices,

courts originally applied the [arbitrary and capricious] test only to the agency's final substantive decision. The process by which that decision was reached was immaterial. The recent cases require the agency to describe its decisionmaking processes in detail, and the court will examine the rationality of the processes as a part of its analysis of the final result. Phrased another way, final agency actions now are seen as the product of myriad intermediate choices. If the agency has made such choices irrationally, the taint is presumed to carry over into the final action, and the final action will be held arbitrary.

DeLong, *supra* note 38, at 285 (citations omitted).

personnel after Auchter took office. The first of these is a detailed and highly critical review of the MIT formaldehyde report.<sup>350</sup> Dated May 28, 1981, but unsigned, the review relies heavily on input from formaldehyde industry scientists,<sup>351</sup> and concludes that the available data warrant no additional agency regulation of formaldehyde.<sup>352</sup> The second evaluation, a preliminary risk assessment attributed to Mary Yurachek of the OSHA Health Standards staff, was apparently prepared after the ETS petition had been submitted to the agency.<sup>353</sup> Positions expressed in each of these documents found their way into Auchter's ultimate statement of rationale, although the extent to which they contributed to the ETS decision is not altogether clear.<sup>354</sup>

The review of the MIT study inappropriately relied on the formaldehyde epidemiologic studies, on arguments of species specificity, and on arguments of minimal exposure. As discussed above,<sup>355</sup> the epidemiologic studies are marred by a number of technical inadequacies, which render them far less sensitive than they would need to be in order to provide a reasonably accurate picture of potential human risk. Nonetheless, the OSHA review characterized the epidemiologic evidence as "quite reassuring," and argued that it "clearly justifies" the postponement of any further regulatory action.<sup>356</sup> Although several factors seriously undermine an argument of species specificity for formaldehyde,<sup>357</sup> the review placed great weight on the observation that different rodent species exhibit different reactions to formaldehyde.<sup>358</sup> The review also assumed that workers are exposed only to low levels of formaldehyde,

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350. MIT REPORT REVIEW, *supra* note 333.

351. *See supra* note 333 and accompanying text.

352. MIT Report Review, *supra* note 333, at 1-2.

353. M. Yurachek, OSHA, Preliminary Quantitative Risk Assessment for Formaldehyde (undated) (author not identified but believed to be Yurachek).

354. In addition, formaldehyde exposure risks were evaluated by Dr. Han Kang of OSHA's Office of Carcinogen Identification and Classification. Kang produced a quantitative risk assessment based on preliminary CIIT data. H. Kang, Preliminary Cancer Risk Assessment for Formaldehyde (undated) (attached to Memorandum from Peter Infante to John Martonik (Jan. 4, 1982)). The Yurachek analysis used a similar methodology and the final CIIT data and could be considered to have superceded Kang's analysis. Kang's risk estimates were approximately twice the magnitude of Yurachek's. Kang also reviewed the MIT formaldehyde report and found it "well-organized and scientifically defensible." (Memorandum from Han Kang to Peter Infante (Dec. 3, 1981)) (attached to Memorandum from Peter Infante to John Martonik (Jan. 4, 1982)). On the basis of Kang's evaluations, Dr. Peter Infante, Director of OSHA's Office of Carcinogen Identification and Classification, recommended that OSHA take action on formaldehyde. (Memorandum from Peter Infante to John Martonik (Jan. 4, 1982)).

355. *See supra* note 200 and accompanying text.

356. MIT REPORT REVIEW, *supra* note 333, at 10.

357. *See supra* notes 210-14 and accompanying text.

358. MIT REPORT REVIEW, *supra* note 333, at 7. ("In brief, there are no scientific data that demonstrate any risk of cancer to humans. Rodents produce extremely different responses to formaldehyde exposure. Whereas 1.5% of the rats developed nasal tumors at 6 ppm, it takes 15 ppm to produce tumors in 2.5% of mice, and hamsters apparently remain unaffected at even much higher exposures.")

avoiding exposures above 3 ppm because of their irritating effects.<sup>359</sup> Like the EPA Todhunter memorandum,<sup>360</sup> the OSHA review cited no empirical evidence for this assumption and apparently ignored data on exposures above the 3 ppm level.<sup>361</sup>

OSHA also departed from prevailing scientific opinion on science policy issues. Auchter's letter of denial stressed that the statistically significant cancer results in the rat data occurred at exposure levels well above the 3.0 ppm level of the current workplace standard. It thus implied that there is a threshold level for carcinogenesis or that it is inappropriate to interpolate high-dose data to low-dose exposures. Although the scientific community has not yet reached a consensus on the threshold issue,<sup>362</sup> the position of the Interagency Regulatory Liaison Group (IRLG) on high-dose interpolation is that "[t]esting should be done at doses and under experimental conditions likely to yield maximum tumor incidence."<sup>363</sup>

The review of the MIT study also departs from prevailing scientific opinion in a number of ways. As previously noted, the review presumes species specificity and relies on negative epidemiologic data. Neither position is consistent with current scientific opinion.<sup>364</sup> In an even more striking departure, the review does not merely question the way that the results of animal bioassays are extrapolated to humans, but rather argues that such extrapolation is meaningless: "Because of the vast uncertainties in extrapolating from experimental rodent studies to man, such experiments *do not* and *cannot* predict or measure human risks."<sup>365</sup> Accordingly, the review concludes that "there are *no* scientific data [on formaldehyde] that demonstrate *any* risk of cancer to humans."<sup>366</sup> At best, this sweeping denunciation of accepted science policy must be characterized as a controversial minority opinion.

## 2. The Procedural Aspects

### a. Departure from the Generic Cancer Policy

Perhaps the most significant procedural deficiency in OSHA's deliberations was the agency's failure to adhere to its own policy on cancer risk assessment. Although that policy was promulgated as a formal

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359. *Id.* at 8.

360. *See supra* notes 221-22 and accompanying text.

361. MIT REPORT REVIEW, *supra* note 333, at 8.

362. IRLG Risk Assessment Document, *supra* note 36, at 259.

363. *Id.* at 250. The IRLG scientists offered several reasons for their position: (1) bioassays on even a few hundred animals have relatively low sensitivity; (2) people have varying degrees of sensitivity; and (3) high-dose testing provides a "safety margin" to guard against false negative results. *Id.*

364. *See supra* notes 225-26 and accompanying text.

365. MIT REPORT REVIEW, *supra* note 333, at 10 (emphasis added).

366. *Id.* at 7 (emphasis added).

agency regulation,<sup>367</sup> which is still in effect, Auchter's denial letter did not acknowledge it. Indeed, Auchter's treatment of the formaldehyde rat data and the agency's failure to consider benign tumor data conflict with the policy's plain language.<sup>368</sup> The OSHA review of the MIT report also departs significantly from the agency's cancer policy, again without acknowledging or explaining the departure.<sup>369</sup>

An agency has an affirmative obligation to explain adequately a substantial departure from prior agency policy.<sup>370</sup> Where that policy is embodied in a formal regulation, it is binding upon the agency as a matter of law; before the agency may deviate from the policy, it must amend the regulation.<sup>371</sup> A few weeks before denying the ETS formaldehyde petition, OSHA called for new comments on its generic cancer policy. It emphasized, however, in both the Federal Register notice<sup>372</sup> and its press release,<sup>373</sup> that the policy on cancer risk assessment remained in effect and unchanged.

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367. Identification, Classification, and Regulation of Potential Occupational Carcinogens, 29 C.F.R. § 1990 (1981). Section 1990.111(a) states that the policy "establishes the criteria and procedures under which substances will be regulated by OSHA as potential occupational carcinogens."

368. 29 C.F.R. § 1990.143(g) specifies, with exceptions not relevant here, that "[p]ositive results for carcinogenicity obtained in mammals exposed to high doses of a substance will be used to establish a qualitative inference of carcinogenic hazard to workers." A related provision, section 1990.143(h), specifies that "[n]o determination will be made that a 'threshold' or 'no effect' level of exposure can be established . . . ."

One other provision is particularly pertinent. Section 1990.143(i) provides that "[r]esults based on the induction of benign or malignant tumors, or both, will be used to establish a qualitative inference of carcinogenic hazard to workers." Auchter's statement that the CIIT results were statistically significant only at 15 ppm indicates that he did not consider the benign tumors found at the 2 and 6 ppm levels. If those tumors are considered, the CIIT results show statistically significant increases in tumors at 2 and 6 ppm. See Memorandum from Dr. Peter F. Infante to Dr. Richard Griesemer (April 2, 1982) (evaluation of polyploid adenomas attached); and letter from Dr. Richard Griesemer to Dr. Peter Infante (May 17, 1982). Although section 1990.143(i) requires the agency to consider benign tumor data only in qualitative risk assessments, section 1990.111(j), which specifies that "cautious and prudent assumptions will be utilized to perform risk assessments," would seem to require the agency to consider benign tumor data in quantitative risk assessments as well.

369. See 29 C.F.R. §§ 1990.143(c), 1990.144(a) (use of negative epidemiologic studies); § 1990.143(d) (species specificity); §§ 1990.143(b)–1990.143(c) (use of positive animal bioassays where human epidemiology is negative).

370. See *supra* note 102 and accompanying text.

371. An agency's failure to comply with its own regulations is grounds for judicial intervention. See 2 K. DAVIS, ADMINISTRATIVE LAW TREATISE § 7:21 (2d ed. 1979).

372. 47 Fed. Reg. 178, 188 (1982). The notice was termed an "[a]dvance notice of proposed rulemaking and proposal for partial stay pending completion of rulemaking proceedings." OSHA proposed to stay certain policy requirements not relevant here and stated that "[o]ther provisions of the Policy will continue in effect under the terms of this proposed stay." *Id.* at 188.

373. Office of Information, U.S. Dep't of Labor, *OSHA Asks for Public Comment on Carcinogen Policy*, News Dec. 31, 1981. The release stated that "during the comment period [length not defined] the carcinogen policy as well as OSHA's other individual rules on protection from carcinogens remain in effect."



*b. Other Deficiencies in Stated Rationale*

In addition to these policy reversals, the Auchter letter also may fail to meet the requirements of section 6 of the OSHAct.<sup>374</sup> Subsection (e) of that provision requires the Administrator to support "any rule, order, or decision" under the OSHAct with a written "statement of reasons," which must be published in the Federal Register.<sup>375</sup> The courts have applied this requirement to decisions to issue an ETS;<sup>376</sup> it would seem equally applicable to decisions *not* to issue an ETS, especially where, as here, that decision is made in response to a formal petition.<sup>377</sup> The courts have specified that the statement of reasons for an ETS "should indicate which data in the record is being principally relied on and why that data suffices."<sup>378</sup>

Although the Auchter letter contains a statement of rationale, that statement does not identify the agency "risk assessments" on which it says it relies.<sup>379</sup> Does it refer only to the OSHA assessment made after the ETS petition was filed, or does it refer also to the agency's earlier review of the MIT study? Indeed, the OSHA assessment appears to have been prepared in written form sometime *after* Auchter's letter was delivered to the unions.<sup>380</sup> This fact, along with the conclusory nature of Auchter's analysis, calls into question the letter's adequacy as a "statement of reasons." As one court has noted,

a conclusory statement of reasons places too great a burden on interested persons to determine and challenge the basis for the [decision], and makes possible in any subsequent judicial review the use of *post hoc* rationalizations that do not necessarily reflect the reasoning of the agency at the time

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The possibility of *post hoc* rationalization looms large here.

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374. 29 U.S.C. § 655(e) (1976).

375. *Id.*

376. *Dry Color Mfrs. Ass'n, Inc. v. Department of Labor*, 486 F.2d 98 (3d Cir. 1973); *Florida Peach Growers Ass'n v. U.S. Dep't of Labor*, 489 F.2d 120 (5th Cir. 1974).

377. Where there has been a formal petition, OSHA's failure to issue an ETS cannot be characterized as a mere discretionary determination regarding the proper allocation of agency resources. It is a determination to take a certain course of action on a narrowly defined issue in response to a public request. Even absent a specific statutory requirement, the principles of reasoned decisionmaking require an adequate statement of rationale. *See supra* note 274 and accompanying text.

378. *Dry Color Mfrs. Ass'n*, 486 F.2d at 106.

379. Letter from Thorne Auchter to Howard Young (Jan. 29, 1982).

380. On the last page of the copy we were able to obtain, Yurachek's name appears, along with the date February 26, 1982. Furthermore, Auchter's letter compares formaldehyde risks to "other occupational risks," but the only analysis of such other risks that has surfaced to date, also authored by Yurachek, is dated February 1, 1982. *See* Memorandum from Mary Yurachek to John Martonik (Feb. 1, 1982). Auchter's letter was dated January 29, 1982.

381. *Dry Color Mfrs. Ass'n*, 480 F.2d at 106.

*c. Disregard of Internal Science Advice*

A final procedural problem with OSHA's formaldehyde deliberations is that the agency disregarded and mischaracterized the advice of its own scientists. Although Auchter publicly stated that the agency withdrew its support of the formaldehyde Current Intelligence Bulletin (CIB) because it "lacked confidence in the data" on which the CIB was predicated,<sup>382</sup> all of the technical personnel within OSHA's carcinogenicity assessment group supported both the CIB and the underlying data.<sup>383</sup> Later, when Peter Infante, Director of OSHA's Office of Carcinogen Identification and Classification, wrote to the International Agency for Research on Cancer (IARC) recommending that formaldehyde be classified as an animal carcinogen, the agency took steps to have him dismissed.<sup>384</sup> The matter became the focus of a congressional hearing.<sup>385</sup> Subsequently, the dismissal proceedings were cancelled.<sup>386</sup>

*3. The Statutory Mandate*

The issuance of an ETS for a workplace chemical under section 6(c) depends upon a finding that "employees are exposed to grave danger from exposure" to that chemical.<sup>387</sup> Once the requisite danger has been established, OSHA must issue an ETS; no public hearing occurs.<sup>388</sup> As Auchter commented in denying the formaldehyde petition, the expedited section 6(c) process represents something of a departure from conventional administrative rulemaking procedures. The ETS is, as he noted, an "extraordinary" remedy.<sup>389</sup> Nonetheless, it is a remedy that must be imposed when appropriate circumstances arise. A review of OSHA's

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382. See *Gore OSHA Hearings*, *supra* note 18, at 60 (statement by Thorne Auchter). The same explanation was later given when the agency withdrew support from the IRLG formaldehyde risk assessment efforts. See *supra* notes 336-37 and accompanying text.

383. *Id.* at 8-9 (statement of Dr. Bailius Walker, then Director of Health Standards, OSHA). Dr. Walker testified that he was not aware of any scientist within OSHA who "lacked confidence" in the data upon which the CIB was based.

The only document made available to Gore subcommittee investigators that supported the withdrawal decision was a memorandum to Auchter from Mark Cowan, then Special Assistant for Regulatory Affairs and Director of Policy, U.S. Dep't of Labor. Memorandum from Mark Cowan to Thorne Auchter (undated), *reprinted in Gore OSHA Hearings*, *supra* note 18, at 13. Cowan, an attorney, wrote that the evidence upon which the CIB was based was "at best, conflicting, at worst, biased," and recommended that OSHA withdraw its sponsorship. He wrote the memorandum just after meeting with John Byington and another attorney representing the Formaldehyde Institute.

384. See Letter from Dr. Peter Infante to Dr. John Higginson, Director, IARC (May 12, 1981), *reprinted in Gore OSHA Hearings*, *supra* note 18, at 31; and Letter from Dr. Bailius Walker to Dr. Peter Infante (June 29, 1981) (proposing Infante's removal), *reprinted in Gore OSHA Hearings*, *supra* note 18, at 17.

385. *Gore OSHA Hearings*, *supra* note 18.

386. See 11 O.S.H. REP. (BNA) 205 (Aug. 13, 1981).

387. 29 U.S.C. § 655(c)(1) (1976); see *supra* text accompanying note 57.

388. Section 6(c)(1) allows the agency to promulgate a standard without regard to the informal rulemaking requirements of the APA. 5 U.S.C. § 553 (1976).

389. See *supra* text accompanying note 341.

formaldehyde decision indicates that the agency may have adopted a more limited interpretation of section 6(c) than the statute will permit.

Clearly, cancer is a "grave" illness.<sup>390</sup> The question is what degree of cancer risk constitutes a "grave danger" under section 6(c). Decisions from three courts provide considerable guidance.

*a. The Danger from Exposure*

The Fifth Circuit offered general remarks in a 1974 case that did not involve exposure to a potential carcinogen.<sup>391</sup> The court characterized section 6(c) as requiring a "determination of danger *from* exposure to harmful substances, not just a danger *of* exposure; and, not exposure to just a danger, but to a *grave* danger . . . ."<sup>392</sup> Thus, the danger must stem from current levels of worker exposure, not merely possible or probable levels of future exposure.

The Third Circuit provided more specific guidance in a 1973 opinion<sup>393</sup> that vacated ETSs for two substances regulated as carcinogens.<sup>394</sup> The agency had not set forth its grounds for concluding that the chemicals were carcinogenic.<sup>395</sup> Noting that an ETS cannot issue on a mere speculation of danger, the court stated that, "[w]hile the Act does not require an absolute certainty as to the deleterious effect of the substance on man, an emergency temporary standard must be supported by evidence that shows *more than some possibility* that a substance *may* cause cancer in man."<sup>396</sup>

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390. *Dry Color Mfrs. Ass'n, Inc. v. Department of Labor*, 486 F.2d 98, 104 (3d Cir. 1973).

391. *Florida Peach Growers Ass'n v. U.S. Dep't of Labor*, 489 F.2d 120 (5th Cir. 1974).

392. *Id.* at 130.

393. *Dry Color Mfrs. Ass'n*, 486 F.2d at 98 (challenging ETSs for 3,3'-dichlorobenzidine and ethyleneimine).

394. 38 Fed. Reg. 10,929 (1973). OSHA based its findings of potential carcinogenicity on rodent bioassays.

395. In the early 1970's, neither agencies nor scientists had reached general agreement that positive animal study results indicate potential human carcinogenicity. In promulgating the two ETS's, OSHA failed to cite available scientific papers supporting that approach. For this reason the court vacated the standards. Later, when OSHA properly cited such papers in promulgating a permanent standard for ethyleneimine, the court upheld that standard. *See SOCMA I*, 503 F.2d 1155. The court indicated that OSHA's decision was essentially a policy judgment to be supported by evidence sufficient to satisfy the OSHAct. *Id.* at 1158-60.

396. *Dry Color Mfrs. Ass'n*, 486 F.2d at 104 (emphasis added).

The evidentiary burden for a temporary standard under section 6(c) appears less than, nonetheless consistent with, the evidentiary burden that the Supreme Court more recently enunciated for permanent standards under section 6(b). *Industrial Union Dep't v. American Petroleum Inst.*, 448 U.S. 607 (1980). In reviewing OSHA's permanent standard for benzene, the Court interpreted section 3(8) of the OSHAct as requiring an indication that "it is at least more likely than not that long-term exposure . . . presents a *significant risk* of material health impairment." *Id.* at 653 (emphasis added). This language suggests that a permanent standard requires a semi-quantitative analysis indicating that some estimable number of workers are likely to contract cancer.

A review of OSHA records shows that such evidence was available during the formaldehyde deliberations. Extrapolating from the CIIT rat bioassay results, the agency's own risk analysis indicates that four formaldehyde-related cancer deaths per 1000 exposed workers would be expected at the currently permitted exposure level of 3 ppm.<sup>397</sup> Because OSHA estimated that the average occupational mortality rate for manufacturing workers, from *all* reported occupationally related causes, is also four per thousand, Auchter concluded that formaldehyde does not pose a grave risk of danger.<sup>398</sup> This comparison misses the mark. The question is not how the risk from formaldehyde compares with the aggregate of all other risks, but rather how many lives can be saved by regulating formaldehyde exposure. Furthermore, if the agency's estimate of average *aggregate* risk is valid, the fact that exposure to formaldehyde alone presents a risk of comparable magnitude should give rise to considerable concern.

This evidence of carcinogenic potency appears to be sufficient to warrant the issuance of an ETS, assuming that a determination of "grave danger" under section 6(c) may be made by extrapolating from animal data. Dicta from the Third Circuit again provide substantial guidance: "Extrapolation from animal experiments may in appropriate cases be used to establish a sufficient probability of harm to man."<sup>399</sup> Moreover, the courts have indicated that evidence of animal carcinogenicity is by itself sufficient to justify a permanent standard.<sup>400</sup> A greater burden would

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397. M. Yurachek, *supra* note 353, at Table 3. Yurachek used a multistage extrapolation model to derive a maximum likelihood risk estimate of 4.4 cancer cases per 1000 workers exposed at 3 ppm and a 95% upper confidence limit estimate of 7.3 cases per 1000 workers. If Yurachek had included benign tumor data, the risk estimates would have been substantially higher. *See supra* note 368. As a very rough indication of the difference, consider that in the CIIT study eight of the 236 rats exposed at 2 ppm developed benign tumors, as did one of the 232 rats at zero exposure. *See supra* notes 104-110 and accompanying text. After adjusting the observed 2 ppm figure to exclude the control group tumor, extrapolating the figure to humans yields a lifetime risk estimate of 30 cancer cases per 1000 workers at 2 ppm.

398. In his letter denying the ETS petition, Auchter noted that "the risk from formaldehyde exposure at the [present exposure level], when compared with other occupational risks, is not sufficient to warrant a finding of 'grave danger' and resulting emergency action." Letter from Thorne Auchter to Howard Young (Jan. 29, 1982), at 2. Auchter apparently was referring to an analysis prepared by Mary Yurachek. *See* Memorandum from Mary Yurachek to John Martonik (Feb. 1, 1982). Yurachek's estimates, derived from Bureau of Labor Statistics data, indicate that injury and illness risk rates in the manufacturing sector range from 0.3 to 6 deaths per 1000 workers with median and mean values of approximately 4 deaths per 1000 workers.

399. *Dry Color Mfrs. Ass'n*, 486 F.2d at 104.

400. The Third Circuit has upheld a permanent standard for ethyleneimine on the basis of extrapolations from rodent data "in the absence of evidence of carcinogenicity in humans." *SOCMA I*, 503 F.2d 1155, 1160 (3d Cir. 1974) and *SOCMA II*, 506 F.2d 385 (3d Cir. 1974). The Supreme Court gave implicit approval to this approach in the benzene decision, *Industrial Union Dep't v. American Petroleum Inst.*, 448 U.S. 607, 657 n.64 (1980).

hardly seem appropriate for a temporary standard. In addition to contravening both its own cancer policy and the Interagency Regulatory Liaison Group guidelines on this issue, OSHA contravened its section 6(c) mandate as well.

*b. Worker Exposure*

The remaining inquiry is whether the evidence of worker exposure to formaldehyde is sufficient to warrant the issuance of an ETS. In a recent decision involving ethylene oxide (EtO), the D.C. Circuit declined to compel OSHA to issue an ETS where the evidence indicated that only "some" workers are exposed to EtO at levels that present a "significant risk" of "grave danger."<sup>401</sup> On the basis of this finding, however, the court ordered OSHA to expedite ongoing procedures to set a permanent standard to reduce worker exposure to EtO.<sup>402</sup> Although the court's use of the term "significant risk" is somewhat confusing,<sup>403</sup> this decision indicates that OSHA may not be required to impose an ETS for a suspected human carcinogen unless (1) the substance is a probable animal carcinogen, and (2) a significant number of workers are exposed to the substance at levels that pose a risk of cancer.<sup>404</sup>

The formaldehyde exposure data appears stronger than the EtO data, both in the detail and reliability of the exposure information<sup>405</sup> and in the

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401. *Public Citizen Health Research Group v. Aucter*, No. 83-1071, slip op. (D.C. Cir. Mar. 15, 1983). The district court had ordered OSHA to issue the ETS within 20 days. *Public Citizen Health Group v. Aucter*, No. 81-02343, slip op. (D.D.C. Jan. 5, 1983). On expedited review, the court of appeals held that "[w]hile it is a close question, our review of the record indicates that, in ordering an emergency standard, the most drastic measure in the Agency's standard-setting arsenal, the district court impermissibly substituted its evaluation for that of OSHA." *Public Citizen*, No. 83-1071 (D.C. Cir.) at 6.

402. OSHA had issued an "Advance Notice of Proposed Rulemaking" for a permanent standard in January 1982 and had projected that it would promulgate a final regulation by the fall of 1984. Citing mandates for expedition in both the OSHAct and the APA, the court held that "a more than three-year span from [the ETS] petition to projected final regulation is not tolerable." *Id.* at 7.

403. In the OSHA context, the Supreme Court has used the term "significant risk" to refer to a serious risk to a sufficient number of workers. *See supra* note 396. In the EtO case, the D.C. Circuit appears to use the term to refer to the severity of the risk, regardless of the number of workers exposed to that risk.

404. The court apparently deferred to OSHA's determination that EtO exposures at 10 ppm and below do not pose a "grave danger," and it noted that it was "unable to venture even a guess as to existing exposure patterns over [10 ppm]." *Public Citizen*, No. 83-1071 (D.C. Cir.) at 13.

405. The court noted that "nothing offered to the district court" contradicted OSHA's estimates of a 10 ppm average exposure level to EtO and a statistically lower risk of harm at that level. *Id.* at 12. The current EtO eight-hour time-weighted average permissible level (PEL) is 50 ppm. By contrast, each of the three formaldehyde exposure studies indicates exposures at, near, and above the current PEL of 3 ppm, and OSHA's own risk estimate postulates a substantially higher risk at this level (4.4 deaths per 1000 at 3 ppm, compared to 0.16 per 1000 at 1 ppm). *See supra* text accompanying notes 397-98.

number of workers exposed.<sup>406</sup> As OSHA has not yet begun procedures to revise its permanent exposure standard for formaldehyde, and has not indicated that it intends to do so, an ETS presents the most likely possibility of expeditious regulation. Accordingly, formaldehyde may well meet the criteria that the D.C. Circuit enunciated in the EtO case. The evidence seems sufficient either to permit OSHA to issue an ETS on its own volition or for a court to compel it to do so.<sup>407</sup> Further, the EtO case seems to stand for the proposition that OSHA will not be allowed to delay affirmative regulatory action of some kind on substances such as EtO and formaldehyde.<sup>408</sup> Indeed, the D.C. Circuit's approach in the EtO case may also be appropriate for formaldehyde. An order to commence a procedure to set a permanent standard for formaldehyde would set the stage for an objective appraisal of the cancer risk from formaldehyde and of the need for further worker protection.

## VI. CPSC'S DECISION TO BAN UREA-FORMALDEHYDE FOAM INSULATION

### A. Background

#### 1. Chronology of Events

CPSC also received the results of the preliminary CIIT bioassay in late 1979. By this time, the Commission had already begun to study the health problems associated with the use of urea-formaldehyde foam insulation (UFFI).<sup>409</sup> As early as 1976, CPSC had received complaints from residents of UFFI-insulated homes who had suffered acute irritation

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406. NIOSH estimated that 75,000 workers were regularly exposed to EtO and another 25,000 were casually or intermittently exposed. *Public Citizen*, No. 83-1071 (D.C. Cir.) at 9. In contrast, the Snell study estimates that some 1.4 million workers are exposed to formaldehyde. See *supra* notes 134-51 and accompanying text.

407. In *Public Citizen*, the court hints broadly at the propriety of a voluntary ETS for EtO: "All we say today is that in the absence of a more complete record as to exposure levels, we are hesitant to *compel* the Assistant Secretary to grant extraordinary relief. We express no opinion as to whether the same record would support *voluntary* issuance by OSHA of an emergency standard." No. 83-1071 (D.C. Cir.) at 13 (emphasis in original).

408. The court's directive for expedited rulemaking does not appear to be dependent on OSHA's having already begun a section 6(b) procedure. Throughout the opinion, the court speaks the language of substantive review. It clearly examined the factual record in detail.

409. UFFI has been used to insulate existing structures, both residences and commercial buildings, rather than new ones. It is prepared on-site by mixing urea-formaldehyde resin and compressed gas to form a substance resembling shaving cream. This substance is pumped into the cavities in a wall, where it firms. Formaldehyde gas is released through the wall at rates that vary with conditions at the site. In general, the release rate is highest immediately after installation and diminishes with time. Releases may occur for several years after installation. See CPSC Ban Notice, *supra* note 116.

possibly attributable to formaldehyde exposure.<sup>410</sup> By March 1979, the Commission had decided to gather information on the issue.<sup>411</sup>

CPSC joined the Interagency Regulatory Liaison Group (IRLG) formaldehyde study efforts in late 1979.<sup>412</sup> In March 1980, when the need for further study became apparent, the Commission organized the Federal Panel on Formaldehyde.<sup>413</sup> In June 1980, the Commission proposed a rule requiring UFFI manufacturers to inform prospective buyers of UFFI health effects.<sup>414</sup> CPSC received the Federal Panel report in November 1980, and in February 1981 it proposed to ban UFFI altogether.<sup>415</sup>

The Commission set a 60-day notice and comment period, and held an informal public hearing on March 20, 1981.<sup>416</sup> CPSC subsequently gathered additional data, and in November 1981 solicited comment from industry, consumer groups, and other members of the public on issues related to that data.<sup>417</sup>

In January 1982, an industry group charged that the CPSC staff "had sought to substantiate a prejudgment on [UFFI] by using only selected and interpreted data — along with a host of hunches and assumptions — and knowingly provided false or misleading information" to Congress and the public, as well as to the CPSC Commissioners.<sup>418</sup> Five months later, the Commission promulgated a final rule banning UFFI as of August 1982.<sup>419</sup>

On April 12, 1982, the Formaldehyde Institute filed a suit to challenge the CPSC ban.<sup>420</sup> On August 10, 1982, a federal judge refused to issue a temporary injunction, and the ban took effect on that date.<sup>421</sup> The Fifth Circuit vacated the UFFI ban on April 7, 1983.<sup>422</sup>

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410. In October 1976, CPSC received a petition under section 10 of the CPS Act, 15 U.S.C. § 2059 (1976) (since repealed), from the Metropolitan Denver District Attorney's Consumer Office for regulation of certain insulation products, including UFFI. CPSC Ban Notice, *supra* note 116, at 14,367.

411. 44 Fed. Reg. 12,080 (1979) (denying petition for regulation of foam insulation).

412. CPSC Ban Notice, *supra* note 116, at 14,369.

413. *See id.*; *Federal Panel Report*, *supra* note 7, at 139; *Gore EPA Hearings*, *supra* note 18 (statement by Richard Dailey).

414. 45 Fed. Reg. 39,434 (1980). The proposed rule was based in part on a report prepared for CPSC by the National Academy of Sciences (NAS). The NAS concluded that there is no formaldehyde exposure level below which no person would experience irritant effects. *See* COMMITTEE ON TOXICOLOGY, NATIONAL ACADEMY OF SCIENCES, FORMALDEHYDE — AN ASSESSMENT OF ITS HEALTH EFFECTS, (1980) (NTIS Document No. ADA-087854).

415. 46 Fed. Reg. 11,188 (1981).

416. *Id.* at 11,188.

417. *See* 46 Fed. Reg. 49,140 (1981); 46 Fed. Reg. 56,762 (1981).

418. *See* TOXIC MATERIALS NEWS, Jan. 27, 1982, at 29 (quoting the National Insulation Certification Institute, whose members included manufacturers and installers of UFFI).

419. CPSC Ban Notice, *supra* note 116. The Commission had voted four to one in favor of the ban on February 22, 1982. *Id.*

420. 6 CHEM. REG. REP. (BNA) 113 (Apr. 23, 1982).

421. 6 CHEM. REG. REP. (BNA) 648 (Aug. 20, 1982).

422. *Gulf South Insulation v. CPSC*, 701 F.2d 1137 (5th Cir. 1983).

## 2. The Cancer Risk Assessment

CPSC summarized its analysis of the cancer risks of UFFI use in the final notice of the UFFI ban.<sup>423</sup> On the basis of the Federal Panel recommendations and the NYU bioassay results, the Commission concluded that formaldehyde is a carcinogen, and that the existing epidemiologic studies were "insufficient to assess the carcinogenic risk in humans."<sup>424</sup>

Noting the absence of any information demonstrating a threshold below which exposure poses no risk of cancer, the Commission then reviewed the exposure data:

Research conducted for the Commission has shown that U.F. foam insulation releases measurable amounts of formaldehyde in the laboratory even after installation under optimum conditions. In addition, increased levels of formaldehyde have been measured in residences where U.F. foam insulation has been installed. In some cases, the levels of formaldehyde in these homes are within an order of magnitude of the levels in the CIIT study that produced tumors in rats.<sup>425</sup>

The Commission also cited a risk assessment prepared by the CPSC staff on the basis of that data, which predicted "up to 1.8 additional cases of cancer from every 10,000 residences insulated."<sup>426</sup>

### B. The Decisionmaking Process

Especially when viewed in contrast to the EPA and OSHA deliberations, CPSC's formaldehyde deliberations might be considered a model of reasoned decisionmaking. The Commission was subject to more stringent statutory requirements than were EPA and OSHA.<sup>427</sup> However, CPSC not only met these requirements, but exceeded them.

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423. CPSC Ban Notice, *supra* note 116, at 14,369-73.

424. *Id.* at 14,371-72. The Commission enumerated four points leading to its conclusion:

1. Formaldehyde can interact with genetic material and cause irreversible changes in several cell systems,
2. Formaldehyde is carcinogenic in animals,
3. There are no significant qualitative differences in the manner in which formaldehyde is metabolized by animals and humans, and
4. All known human carcinogens except arsenic (which is thought to be a tumor promoter) are also animal carcinogens.

*Id.*

425. *Id.*

426. *Id.* That assessment was prepared using the model developed by the Federal Panel.

427. When CPSC develops a consumer product safety rule or ban under sections 7 or 8 of the CPS Act, it must follow procedures specified in section 9. 15 U.S.C. §§ 2056-2058 (1976), *amended by* 15 U.S.C. § 2057-2058 (Supp. V 1981).



### 1. Analysis of Technical Data

During the notice and comment rulemaking period for the UFFI ban, CPSC responded to many comments that specifically questioned its technical risk analysis. A search of the Commission's stated rationale,<sup>428</sup> background documents,<sup>429</sup> and comment responses<sup>430</sup> reveals no clear errors in scientific reasoning. In technical areas where EPA and OSHA used questionable reasoning, CPSC's analysis seems solid.

#### a. Issues of "Hard" Science

For example, where EPA and OSHA unduly relied on the inconclusive epidemiologic evidence,<sup>431</sup> CPSC explained the methodological inadequacies of that evidence, noting that "none of [the] studies included enough deaths among individuals potentially exposed to formaldehyde . . . for a meaningful evaluation."<sup>432</sup> CPSC also cited the similar conclusion reached by the International Agency for Research on Cancer (IARC).<sup>433</sup> Unlike EPA's Todhunter memorandum<sup>434</sup> and OSHA's review of the MIT report,<sup>435</sup> which declined to extrapolate from rat studies to humans because of species specificity, CPSC noted that apparent specificity may be explained by other factors such as differences in breathing rates.<sup>436</sup> Whereas Todhunter stated that formaldehyde's irritant properties are evidence of a threshold level for carcinogenesis,<sup>437</sup> CPSC noted that the second NYU bioassay results suggest otherwise.<sup>438</sup>

#### b. Issues of Science Policy

CPSC conformed to prevailing scientific opinion on science policy issues. For example, the Commission extrapolated animal results to humans, and high-dose results to low doses.<sup>439</sup>

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428. CPSC Ban Notice, *supra* note 116.

429. See M. Cohn, Risk Assessment for Formaldehyde Released from Urea-Formaldehyde Foam Insulation (Nov. 1980); and M. Cohn, Revised Carcinogenic Risk Assessment of Urea-Formaldehyde Foam Insulation: Estimates of Cancer Risk Due to Inhalation for Formaldehyde Released by UFFI (Oct. 26, 1981).

430. See CPSC Ban Notice, *supra* note 116, at 14,373-80; Memorandum from Harleigh P. Ewell, CPSC Attorney, to the Commission (Jan. 29, 1982) (Briefing Package on Urea-Formaldehyde Foam Insulation); Memorandum from K. Gupta and M. Cohn to Harry Cohen (Feb. 19, 1982) (discussing Health Sciences Analysis of Comments on the Proposed Ban of UFFI).

431. Regarding EPA, see *supra* text accompanying notes 199-203; regarding OSHA, see *supra* text accompanying notes 355-56.

432. CPSC Ban Notice, *supra* note 116, at 14,373.

433. *Id.*

434. See *supra* text accompanying notes 204-07.

435. See *supra* text accompanying notes 357-58.

436. CPSC Ban Notice, *supra* note 116, at 14,370.

437. See *supra* text accompanying notes 216-20.

438. CPSC Ban Notice, *supra* note 116, at 14,378.

439. *Id.* at 14,371-72.

## 2. The Procedural Aspects

In promulgating its UFFI ban, CPSC was subject to the procedural provisions of the CPS Act, which require an opportunity for notice and comment.<sup>440</sup> In addition, as a commission headed by a "collegial body," CPSC must comply with advance notice and open meeting requirements of the Government in the Sunshine Act.<sup>441</sup> CPSC appears to have conformed with these requirements<sup>442</sup> and to have comported with the principles of reasoned decisionmaking. It established and maintained a decisionmaking framework that allowed for input from all interested parties. Indeed, the Commission appears to have exceeded its procedural requirements in many ways. Its response to the initial CIIT findings is illustrative. Although EPA and OSHA initially joined the Interagency Regulatory Liaison Group and Federal Panel on Formaldehyde, CPSC led those efforts. CPSC's Dr. Andrew Ulsamer chaired the IRLG Formaldehyde Workgroup,<sup>443</sup> and CPSC initiated and coordinated the Federal Panel.<sup>444</sup>

CPSC's UFFI science policy decisions were consistent with the Regulatory Council policy on the regulation of carcinogens, which CPSC explicitly endorsed.<sup>445</sup> The Commission also provided a detailed statement of reasons for its decision to ban UFFI.<sup>446</sup> That statement explains the basis of the ban, cites specific sources of data, and responds to numerous comments.

## 3. The Statutory Mandate

The CPS Act requires the Commission to make certain findings before it promulgates a product rule.<sup>447</sup> The provision pertinent to cancer risk assessment states that CPSC must consider "the degree and nature of the risk of injury the rule is designed to eliminate or reduce."<sup>448</sup> For UFFI, CPSC specified that the nature of the injury is cancer, as well as acute effects, and estimated the risk to be "up to 1.8 additional cases of cancer from every 10,000 residences insulated."<sup>449</sup>

The Commission thus satisfied the statutory requirements for its assessment of UFFI cancer risks. Having made this risk estimate, CPSC

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440. 15 U.S.C. § 2058 (1976).

441. 5 U.S.C. § 552(b) (1976).

442. In fact, in its suit to overturn the UFFI ban, the Formaldehyde Institute alleged no procedural deficiencies on CPSC's part. See Brief for Respondent at 16, *Formaldehyde Institute v. CPSC*, No. 82-4135 (5th Cir. filed Apr. 12, 1982).

443. *Gore EPA Hearings*, *supra* note 18 (statement by Dr. Peter Preuss, CPSC).

444. See *supra* note 413 and accompanying text.

445. See CPSC, Proposed Methodology for Commission Consideration of Findings Under Section 9(c) of the Consumer Product Safety Act, 45 Fed. Reg. 85,772, 85,775 (1980).

446. CPSC Ban Notice, *supra* note 116.

447. See 15 U.S.C. §§ 2057, 2058(c) (1976), amended by 15 U.S.C. §§ 2057, 2058 (Supp. V 1981) (making minor wording changes in § 2057 and renumbering § 2058(c) as 2058(f)(1)(A)).

448. 15 U.S.C. § 2068(c)(1) (1976).

449. CPSC Ban Notice, *supra* note 116, at 14,372.

then had to consider the public need for the product, the alternatives to the proposed standard, and the reasonableness of the risk in light of various economic factors.<sup>450</sup> We express no opinion here as to the adequacy of the Commission's treatment of these issues.

### C. The Fifth Circuit Opinion Overturning the UFFI Ban

The Fifth Circuit does not share our sanguinity regarding the CPSC cancer risk assessment. Rather, the court has recently held that the Commission relied on an "inadequate" data base in making that assessment and, as noted, has vacated the UFFI ban.<sup>451</sup> We have no quarrel with the standard of review invoked by the court in reaching this decision, nor with the court's approach in applying that standard to the administrative record before it. Quite properly, the court employed the concepts of reasoned decisionmaking,<sup>452</sup> and examined the technical aspects of the record in some detail. Many of its conclusions regarding that record, however, do not appear appropriate. The court criticized two aspects of the Commission's cancer risk assessment: the manner in which homes were selected for measurements of in-home formaldehyde levels, and the use of the CIIT rat data to project levels of human carcinogenic risk from formaldehyde.<sup>453</sup> The court indicated that CPSC's handling of either of these factors would be sufficient to warrant reversal of the UFFI ban.<sup>454</sup> We disagree.

#### I. The Selection of UFFI Homes

As discussed previously,<sup>455</sup> CPSC based its estimate of likely formaldehyde exposure levels on 1164 measurements from homes insulated with UFFI, and on laboratory tests conducted on UFFI panels. Of the in-home measurements, 827 were conducted in residences whose occupants had complained about UFFI-related health problems, and 337 in

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450. 15 U.S.C. § 2058(c) (1976), amended by 15 U.S.C. § 2058 (Supp. V 1981) (re-numbering § 2058(c) as § 2058(f)(1)(A)).

451. *Gulf South Insulation v. CPSC*, 701 F.2d 1137, 1143 (5th Cir. 1983).

452. *Id.* at 3638 ("The ultimate question is whether the record contains 'such relevant evidence as a reasonable mind might accept to support a conclusion.'") (quoting *Aqua Slide 'N' Dive v. CPSC*, 569 F.2d 831, 838 (5th Cir. 1978), in turn quoting *Universal Camera v. NLRB*, 340 U.S. 474, 478 (1951) (emphasis added). The court further indicated, again citing *Aqua Slide*, 569 F.2d at 837, that it was taking a "harder look" at the administrative record. 701 F.2d at 1150.

453. The court also concluded that CPSC's findings on acute irritant effects were not supported by substantial evidence, and that CPSC erred by failing to proceed against formaldehyde under the Federal Hazardous Substances Act (15 U.S.C. §§ 1261-1276) rather than under the CPSAct. Our analysis of the court's decision does not extend to these aspects of the opinion.

454. Early in the opinion, the court indicates that it "need examine only [these two issues] in detail" in order to reach its decision. 701 F.2d at 1143. Later, however, the court indicates that its holding may be based solely on the perceived inadequacy of the in-home data. 701 F.2d at 1147.

455. See *supra* text accompanying note 154.

homes selected for other reasons. In concluding that these in-home measurements were an improper basis for the Commission's risk assessment, the court points to two "significant omissions:"

The Commission does not explain its reliance on a data base comprised largely of complainant houses. Nor does the agency justify its failure to conduct a study of randomly selected UFFI homes before issuing the product ban.<sup>456</sup>

In truth, however, the agency *did* explain its willingness to rely on the in-home data. According to the final risk assessment, all of the in-home measurements (for both "complaint" and "non-complaint" homes) were grouped according to the time that had elapsed between the date that UFFI had been installed in the home and the date that the measurement had been taken.<sup>457</sup> The groupings were by 10-week periods, over an overall period of nine years. Average measurements for complaint homes were compared with average measurements for non-complaint homes within *each* of these ten-week periods, but no statistically significant differences were found.<sup>458</sup> Thus, the agency concluded, there is no reason to believe that formaldehyde levels in the complaint homes were significantly higher than those in other homes insulated with UFFI. The court simply appears to have overlooked this evidence. While the statistical comparison employed by the agency does not rule out the possibility

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456. 701 F.2d at 1145.

457. CPSC RISK ASSESSMENT, *supra* note 153, at 9.

458. The widest gaps between the ten-week averages occur during the first four intervals; the average of the complaint home measurements is higher than the average of the non-complaint home measurements for each of those four intervals. Thereafter, the differences are generally much smaller, and in several of the intervals the non-complaint homes are higher than the complaint averages.

CPSC's risk assessment indicates that, in addition to the interval-by-interval comparisons, the agency examined the statistical significance of the difference between the *overall* averages of the complaint and non-complaint residences. This difference was found to lack statistical significance at the five percent level. (The term "statistical significance" is discussed at *supra* note 110.)

Two points need to be made about the statistical tests employed by the agency. One is that the number of measurements for some of the later intervals was not large enough to reveal a statistically significant difference, if indeed such a difference existed. In these cases, however, the range in the measurements was generally quite small. Second, the test used by the agency assumed that all of the samples examined were normally distributed, but in fact at least some of them were log-normally distributed. Strictly speaking, then, the agency's use of the normal "t-test" may have been inappropriate. As a practical matter, however, this error would probably make it *more* likely that any statistically significant difference would have been detected. CPSC's conclusion on the lack of statistical significance thus appears sound.

Regardless of this lack of strict statistical significance, the non-complaint home measurements *are* consistently lower over the first four intervals. For the reasons discussed at note 459 *infra*, however, we do not believe that this would appreciably affect the agency's cancer risk assessment.

that the use of complaint homes did influence the data to a certain degree, the data indicate that the effect of any such influence on the ultimate cancer risk projection would be relatively small.<sup>459</sup>

The failure to use a randomized sample is perhaps a closer question. Although selecting a study population through random sampling would be scientifically preferred, failing to do so does not necessarily vitiate the value of a study. The purpose of random sampling is to insure that the results of the study are not biased by the manner in which the study population is selected. Whether a lack of randomization invalidates a study thus depends on whether the results are in fact biased.

The obvious source of potential bias in the CPSC data — and the only one cited by the court — is the possibility that formaldehyde levels were appreciably higher in the complaint homes than in other homes.<sup>460</sup> If the higher levels had themselves triggered the complaints by consumers, then reliance on measurements from those homes would produce biased data. As noted, however, comparisons between complaint and non-complaint homes revealed no statistically significant differences in formaldehyde levels.

There remains a possibility that the lack of randomization allowed some other, presently unknown source of bias to influence the results. As the in-home measurements were largely consistent with the results of the laboratory tests, this possibility seems rather slight.<sup>461</sup> Nonetheless, some uncertainty remains. In choosing to take regulatory action in the face of this uncertainty, CPSC implicitly made a *policy* determination that the potential risk to human health from continued use of UFFI insulation did not permit it to delay action until a large randomized study of UFFI homes could be completed. In vacating the UFFI ban, the court has substituted its own policy judgment for that of the agency. As a matter of administrative law, a court may reverse an agency's policy determination only where that determination conflicts with the statutory mandate.<sup>462</sup>

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459. Overall, the difference appears to be something less than two-fold. Even if this difference were statistically significant, its effect would be small in comparison to the total level of uncertainty (generally at least two orders of magnitude) that prevails in any cancer risk assessment. Indeed, recalculating the CPSC risk assessment solely on the basis of the non-complaint measurements still projects a substantial cancer risk. CPSC's final projection was 51 additional deaths per million persons exposed. Based on the non-complaint data alone, the figure would be roughly 34 to 40 additional deaths per million.

460. As noted by the court, the formaldehyde industry argued that levels were higher in complaint homes because of faulty installation. 701 F.2d at 1144.

461. The court acknowledged this point, but concluded that it was immaterial. *Id.* at 1144-45. Though the fit between the data sets is not a perfect one, the general congruence between the in-home and laboratory results does serve to narrow the relevant range of uncertainty in the exposure data. Further, of the non-complaint homes, some were reported to have been randomly selected, others selected because the occupants requested measurement, and the remainder selected through a variety of other means. Thus, the overall data would not be likely to exhibit any consistent bias.

462. As the D.C. Circuit recently noted:

Does the CPSAct require the Commission to conduct a controlled test from a randomly selected study population before imposing a product ban? Clearly the statute itself contains no explicit direction in this regard. Rather, both the statutory language and the legislative history indicate that considerable discretion is to be afforded to the Commission in its choice of study designs, so long as it bases its conclusions on generally reliable data.<sup>463</sup> Furthermore, in a prior case interpreting the CPSAct the Fifth Circuit has held that the Commission is not required to conduct "an elaborate cost benefit analysis," but rather need only meet its burden of "producing substantial evidence" that "the relevant factors . . . weigh in favor" of the regulatory path chosen.<sup>464</sup> By rejecting the rigorously quantitative approach of a cost benefit analysis, the court's language appears to allow the agency a fair degree of discretion in choosing the manner in which that evidence is to be compiled.

The Fifth Circuit's formaldehyde decision is ambiguous. One could interpret it as a retreat from the court's earlier language and as an attempt to narrow the agency's discretion in employing technical methodology. If this reading is correct, the decision is ill-advised. Although random sampling might be required in order to obtain reliable evidence in certain situations it is not the only means of producing an adequate data base. Where, as here, the general reliability of the data can be shown by other means, the need for random sampling is far less pressing.

A more accurate reading, however, may be that the court would not require random sampling as a predicate to *all* CPSC product bans, but required such sampling here in order to overcome perceived bias that the court believed arose from CPSC's reliance on complaint home data. Because, as noted above, any such bias is probably insubstantial, the court's concern is largely unwarranted and does not justify a reversal of the agency's ban.

## 2. *The Use of the CIIT Data*

Declaring that "it is not good science to rely on a single experiment," the court found the Commission's "exclusive reliance" on the CIIT rat

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If the agency clearly articulates a reasonable basis for [its] action, we must defer to the policy judgments and expertise of the agency. By no means may we substitute the court's judgment, or fail to "guard against the danger of sliding unconsciously from the narrow confines of law into the more spacious domain of policy."

State Farm Mutual Auto. Ins. v. Department of Transp., 680 F.2d 206, 229 (D.C. Cir. 1982) (quoting Phelps Dodge Corp. v. NLRB, 313 U.S. 177, 194 (1941)).

463. See generally S. REP. NO. 835, 92d Cong., 2d Sess. (1972); H.R. REP. NO. 1153, 92d Cong., 2d Sess. (1972). The House Report states that a full cost-benefit analysis is not required, but cautions that the agency must provide "reasonable assurance that the frequency or severity of injuries or illness will be reduced." H.R. REP. NO. 1153, *supra*, at 33. As noted by Dean Richard A. Merrill of the University of Virginia School of Law, "[t]hese delphic instructions have left the agency a wide range of discretion." Merrill, *supra* note 32, at 1281.

464. Aqua Slide 'N' Dive v. CPSC, 569 F.2d 831, 840 (5th Cir. 1978).

bioassay in its projection of human cancer risk to be "unsupportable."<sup>465</sup> As discussed at the outset of this article,<sup>466</sup> the extrapolation of animal data to predict human cancer risk is ultimately an issue of policy; "good science" is simply unable to provide a precise calculation of formaldehyde's carcinogenicity in humans. Consistent with the federal cancer policy set forth in the Regulatory Council Statement,<sup>467</sup> CPSC based its projections on a single, well-conducted animal bioassay. Although the court makes no mention of the Council statement in its review of the Commission's action, its rejection of that action is an implicit repudiation of carefully established federal administrative policy. All indications are that the court did not base this position on its reading of the Commission's statutory mandate, but rather on its own understanding of scientific methodology. As such, the court has confused science with science policy, and has once again substituted its policy judgment for that of the agency.

The court's analysis of the CIIT bioassay also incorporates significant technical inaccuracies. It characterizes the 240-rat study as "small." If anything, however, the CIIT study was substantially larger than the average long-term bioassay, and was certainly large enough to produce statistically significant results.<sup>468</sup> The court also criticized the study's exposure protocol. That protocol has been evaluated and deemed acceptable by numerous scientists.<sup>469</sup> Finally, the court refers to a "wide gap" between the CIIT results and the results of the second NYU bioassay.<sup>470</sup> This is simply an inaccurate characterization of the data. Indeed, when the results of the two studies are properly compared they appear quite consistent. At the end of 18 months, 10% of the NYU rats at risk had died with malignant tumors, compared with 14.5% of the rats at risk at the 14.3 ppm level in the CIIT study.<sup>471</sup> This difference is hardly

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465. 701 F.2d at 1146.

466. See *supra* text accompanying notes 84-88.

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If a substance has been shown to be carcinogenic under the conditions of a single properly designed and conducted test, it should be considered as posing a risk of cancer to humans. Although the agencies should attempt to obtain additional data, they should not take the risk involved in waiting the two to four years required to complete an additional animal bioassay before initiating regulatory action.

Regulatory Council Statement, *supra* note 27, at 60,040.

468. The CIIT study used 240 rats at each of three dose levels, plus 240 "control" rats given no formaldehyde. The official National Cancer Institute guidelines recommend using at least 100 rats at each level. Sontag, Page & Saffiotti, *Guidelines for Carcinogenic Bioassay in Small Rodents* (1976).

469. The protocol was evaluated by the Federal Panel, the IRLG, and a group from the CIIT. *Federal Panel Report*, *supra* note 7, at 140, 150.

470. 701 F.2d at 1146 n.19.

471. Indeed, the results of the two studies have been termed "strikingly similar." Albert, *supra* note 112, at 601. At 18 months, 38 of the 100 rats exposed only to formaldehyde in the NYU study had died, and 10 of these had squamous cell carcinomas. At 18 months, 44 of the 240 CIIT 14.3 ppm rats had died; 28 had squamous cell carcinomas and one had a spindle cell carcinoma. As 40 rats of the original 240 had been sacrificed prior

striking, and may well be explained by the fact that the two studies used different strains of rats for their respective study populations.<sup>472</sup>

In sum, though we must again emphasize that we express no opinion as to the other aspects of the Commission's decision, nor of the court's review thereof,<sup>473</sup> we find the Fifth Circuit's analysis to be unpersuasive in its evaluation of CPSC's cancer risk assessment for formaldehyde.<sup>474</sup>

### CONCLUSION

Reasoned decisionmaking has evolved as a common standard for judicial review of agency action, and is a particularly appropriate criterion by which to evaluate the conduct of agencies responsible for protecting public health by regulating exposure to toxic substances. Although it was initially applied to decisions to *take* regulatory action, this standard has been increasingly applied to decisions *not* to act as well. This is a welcome development. In these anti-regulatory times, decisions not to act are becoming more numerous, and adequate review is needed to ensure that the agencies adhere to their statutory mandates.

This article has offered a logical framework for evaluating the extent to which agencies practice reasoned decisionmaking in human health risk assessments. This three-tiered framework involves an analysis of: 1) the

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to 18 months, only 200 of the CIIT rats were "at risk" at 18 months. (It is not clear from the reported data whether the spindle cell carcinoma was malignant. If not, the relevant malignant tumor percentage for the CIIT study would be 14% rather than 14.5%.)

472. The CIIT study used 7-week-old male and female Fischer 344 rats, while the NYU study used 9-week-old male SD rats (Charles River CD).

473. We should note, however, that "other contentions" regarding the cancer risk assessment that are cited, but not relied on, by the court are an equally insufficient basis for reversing the agency's action. The court characterizes the agency's assumptions concerning species specificity and threshold levels as "of questionable validity." 701 F.2d at 1147 n.20. As discussed previously, these are issues of science policy; the Commission's positions are consistent with the Regulatory Council guidelines. *See supra* text accompanying notes 282-87. Furthermore, the court's concern that the assumption of no threshold level for formaldehyde "leads inescapably to the conclusion that ambient air is carcinogenic," *id.*, is irrelevant. The fact that formaldehyde is generally compatible with human life at ambient levels does not necessarily mean that it does not cause cancer at those levels. Finally, industry also argued that the agency risk assessment is flawed because it predicts an upper limit of risk, rather than an estimate of average risk. 701 F.2d at 1143. As noted, however, cancer risk assessment is presently a very imperfect science. The use of upper limit estimates is consistent with the policy guidelines set forth in the Regulatory Council Statement. *See supra* text accompanying notes 282-87. It is also consistent with protecting those members of the population who may be more susceptible to formaldehyde. Protection of these people is well within the Commission's statutory authority.

474. Interestingly, the Supreme Judicial Court of Massachusetts has recently upheld the UFFI ban imposed in that state by the Commissioner of the Massachusetts Department of Public Health. *Borden, Inc. v. Commissioner of Public Health*, No. S-2849, slip op. (Mass. Apr. 12, 1983). Although the standard of judicial review applied there was less stringent than the reasoned decisionmaking standard imposed by federal courts, the Massachusetts court did note that the "evidence supports a rational determination that UFFI 'presents an imminent danger to the public health and safety'." *Id.* at 26 n.19.



agency's treatment of technical matters, including both hard science and science policy issues; 2) the agency's procedures; and 3) the agency's interpretation of its statutory mandate.

The case of formaldehyde presents an excellent opportunity to examine the principles of reasoned decisionmaking and to evaluate three separate regulatory responses to a human health problem. Applying the analytical framework developed in this article, we reach the following conclusions:

(1) CPSC assessed the available data on the carcinogenic risk from formaldehyde exposure in a manner free from significant technical error and in accordance with prevailing scientific opinion on science policy issues. In contrast, OSHA gave undue weight to questionable negative epidemiologic findings and to arguments of species specificity and limited exposure. Furthermore, OSHA departed from prevailing scientific opinion on science policy issues in discounting the value of interpolating high-dose animal data to low-dose human risk. EPA committed numerous technical errors: not only did it rely too heavily on the epidemiologic data, but it ignored empirical data contrary to its own conclusions and failed to substantiate a controversial assumption on exposure data. Like OSHA, EPA also departed from majority viewpoints on important science policy issues.

(2) CPSC conducted its deliberations in an open and fair manner, avoiding *ex parte* contacts and encouraging public participation at all stages. OSHA, on the other hand, departed without notice or justification from the carcinogen risk procedures set forth in its own generic cancer standard and in the Regulatory Council policy to which it had been party. Moreover, it ignored the advice of its own scientific experts and failed to provide an adequate statement of reasons. EPA likewise departed from the Regulatory Council policy guidelines, and it engaged in other procedural irregularities as well. Agency personnel had apparent *ex parte* contacts with industry, provided an inadequate statement of reasons, and may have made a decision before fully examining the data.

(3) In assessing the human cancer risk from urea-formaldehyde foam insulation, CPSC operated well within the discretion permitted it under the CPS Act. In light of its own data assessment, OSHA appears to have violated its statutory mandate in failing to take action to reduce worker exposure to formaldehyde. EPA made an indefensible interpretation of section 4(f) of TSCA and may have violated that provision in not taking regulatory action on the existing data.

This review of the OSHA and EPA actions demonstrates the need to examine scientific determinations carefully, lest social policy decisions be hidden in alleged assessments of technical or scientific fact. Science policy decisions based on sound, well-articulated technical grounds must be distinguished from politically motivated *post hoc* rationalizations.

Finally, the formaldehyde case raises important questions about the proper status for an environmental agency. Of the three agencies examined here, only the one structured as a Commission acted responsibly.

Recent concern over the political manipulation of environmental agencies has prompted proposals to convert EPA into a "hybrid commission."<sup>475</sup> Although structural changes can help insulate an agency from political influence, continued judicial and congressional scrutiny of executive branch agencies may — at least for the short term — provide the most practical check on agency impropriety. The courts and Congress thus must take a "hard look" in order to ensure that agencies exercise reasoned decisionmaking in their approach to toxic substance control.

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475. See 6 CHEM. REG. REP. (BNA) 1306 (Feb. 25, 1983) (bills introduced into the Senate by Sens. Moynihan and Mitchell and into the House by Rep. Scheuer).