

# Comments

## OSHA AT THE THRESHOLD: SETTING PERMISSIBLE EXPOSURE LEVELS FOR KNOWN CARCINOGENS AFTER *AMERICAN PETROLEUM INSTITUTE*

*How can a regulatory body determine the level at which exposure to a carcinogen is no longer healthful without reliable scientific data? OSHA's policy of refusing to recognize a safe exposure level in the absence of data has been recently scrutinized by the United States Supreme Court in its decision rejecting a new benzene standard. This Comment defends zero level exposure as something more than an ad hoc agency policy determination. In fact, OSHA's experience regulating carcinogens demonstrates that an understanding of what it is that is not known can serve as a valuable basis for sound policy making.*

### INTRODUCTION

Responding to the growing national concern about cancer,<sup>1</sup> the 1970 Occupational Safety and Health Act<sup>2</sup> (OSH Act) grants the Secretary of Labor and the Occupational Safety and Health Administration (OSHA) authority to control workplace carcinogens.<sup>3</sup>

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1. For a description of Americans' "exceptional fear" of cancer see Occupational Safety and Health Administration, Identification, Classification and Regulation of Potential Occupational Carcinogens, 45 Fed. Reg. 5001, 5016 (1980) (codified in C.F.R. § 1990) [hereinafter cited as OSHA Cancer Standard].

2. Pub. L. No. 91-596, 84 Stat. 1590 (1970) (codified at 29 U.S.C. §§ 651-678).

3. OSH Act § 6(b)(5), 29 U.S.C. § 655(b)(5) (1970) requires the Secretary to promulgate permanent standards to protect employees from "toxic materials or harmful physical agents".

Identification and assessment of the risks caused by various carcinogens, however, have presented problems in the application of the statute.<sup>4</sup> One area of difficulty has been OSHA's attempts to promulgate standards that establish safe or permissible exposure levels for known carcinogenic substances.<sup>5</sup> Complex questions of scientific and quantitative analysis necessarily involved in setting safe exposure levels have challenged OSHA and, eventually, reviewing courts.<sup>6</sup>

The determination whether or not the Secretary has satisfactorily performed his scientific homework within the dictates of the statute has been hindered by legal disagreement over the statute's meaning<sup>7</sup> and, even more perplexing, by the non-existence of the data needed to formulate standards. The lack of scientific certainty surrounding OSHA's attempts to set permissible exposure levels for a known carcinogen is traceable to three major sources. Foremost, the void in the scientific understanding of cancer mechanisms frustrates most meaningful evaluation of risk, especially in the causation context.<sup>8</sup> As a result of this limited comprehension, attempts to predict effects at low level exposure from data of high level exposure are usually unreliable.<sup>9</sup> Finally,

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4. The Secretary infers his statutory obligation to consider available scientific data on the effects of a workplace carcinogen at various dosage levels from several subsections of the OSH Act. Section 6(b)(5), limits the authorization to regulate substances "to the extent feasible, on the basis of best available evidence." Another provision requires the Secretary to determine the priority for the establishment of standards according to "the urgency of the need for mandatory safety and health standards" in endangered occupational settings. OSH Act § (6)(g), 29 U.S.C. § 655(g) (1970). Additionally, the Supreme Court's interpretation that OSH Act § (3)(8), 29 U.S.C. § 652(8) (1970) applies to § 6(b)(5) requires the Secretary to use quantitative analysis in making a threshold finding that standards are "reasonably necessary or appropriate" to control significant risks to employees. *Industrial Union Dep't, AFL-CIO v. American Petroleum Inst.*, 100 S. Ct. 2844, 2864 (1980) (plurality opinion) [hereinafter cited as *American Petroleum Inst.*].

5. Substances may play many different roles in the evolution of a cancer and OSHA has adopted a broad definition of the term carcinogen to include both direct and secondary causal substances. OSHA Cancer Standard, *supra* note 1, at 5022 (1980).

6. For a summary of how disputes on these questions have delayed the completion of regulations for selected agents see OSHA Cancer Standard, *supra* note 1, at 5011-12.

7. The Secretary is assigned the demanding task of applying scientific data to a statute whose key quantifiers are "adequately," "extent," "best available" and "material," OSH Act § 6(b)(5), 29 U.S.C. 655(b)(5) (1970). The interpretation of each of these terms has been central to judicial review of OSHA standards. *E.g.* *United Steelworkers of America v. Marshall* (D.C. Cir. No. 78-1562, *decided* August 15, 1980), *published in* 3 EMPLOYMENT SAFETY AND HEALTH GUIDE (CCH) § 24, 717, at 30, 371 (1980) (discussion of "material impairment"); *American Petroleum Inst. v. OSHA*, 581 F.2d 493, 502 (5th Cir. 1978) (interpretation of "most adequately assures" and "best available evidence"); *Industrial Union Dep't, AFL-CIO v. Hodgson*, 499 F.2d 467, 477 (D.C. Cir. 1974) (interpretation of "to the extent feasible").

8. OSHA Cancer Standard, *supra* note 1, at 5016-29.

9. *Id.* at 5178-200.

the fact that carcinogenic risks will only manifest themselves in the distant future inspires widespread disagreement in the scientific community about the accuracy and usefulness of various research techniques.<sup>10</sup> Few prospective studies exist to guide standard promulgations.<sup>11</sup>

In response to this scientific uncertainty, OSHA has settled on the theory that where available scientific data cannot establish a safe level of exposure for an occupational carcinogen, no safe level should be recognized at all.<sup>12</sup> Accordingly, OSHA has pursued a regulatory policy that strives for zero-level exposure,<sup>13</sup> limited only by considerations of feasibility.<sup>14</sup> This policy was at the heart of OSHA's defense of its benzene standard challenged in *Industrial Union Department, AFL-CIO v. American Petroleum Institute*.<sup>15</sup> A sharply divided Supreme Court rejected the benzene

10. *Id.* at 5035-78.

11. *Id.* at 5036.

12. *Id.* at 5137.

13. OSHA did not immediately endorse zero-level exposure policy. In promulgating standards for exposure to asbestos dust in 1972 and fourteen related carcinogens in 1974, OSHA found that no safe level of exposure could be determined. Nevertheless, it set the asbestos dust level with great sensitivity to industry cost and time necessary for technical compliance. 29 C.F.R. § 1910.1001; OSHA, Standard for Exposure to Asbestos Dust, 37 Fed. Reg. 11,318 (1972). See *Industrial Union Dep't v. Hodgson*, 499 F.2d 467, 477-78 (D.C. Cir. 1974). In the case of the fourteen related carcinogens, OSHA sought a standard that would avoid eliminating the use of materials and production techniques that OSHA considered invaluable to industry. OSHA ordered controls to generally reduce the fourteen carcinogens' exposure levels "to the maximum extent practicable consistent with continued use". 29 C.F.R. §§ 1910.1003-1006 (1977); OSHA, Standard for Carcinogens, 39 Fed. Reg. 3756 (1974). See *Synthetic Organic Mfgs. Assn. v. Brennan*, 506 F.2d 385, 390 (3d Cir. 1974). Beginning with the vinyl chloride standard set in 1974, OSHA more aggressively pursued its no safe level exposure policy. See *Berger and Riskin, Economic and Technological Feasibility in Regulating Toxic Substances Under the Occupational Safety and Health Act*, 7 *ECOL. L.Q.* 285, 311-18 (1978).

14. To interpret feasibility, OSHA looks to language in § 6(b)(5) bidding the Secretary consider "the attainment of the highest degree of health and safety protection for the employee," a legislative history implying Congressional understanding of the adverse costs to industry involved, and judicial precedent. See *Industrial Union Dep't, AFL-CIO v. Hodgson*, 499 F.2d 467, 478 (D.C. Cir. 1974) (costs feasible even though economically burdensome). According to these sources, the feasibility limitation emphasizes the status of technology available to help industry to comply with the new permissible exposure level. See *American Iron & Steel Inst. v. OSHA*, 577 F.2d 825, 832-35 (3d Cir. 1978), *cert. granted*, 100 S. Ct. 3054, *dismissal granted*, 101 S. Ct. 38 (1980) (discussion of technological feasibility). Economic burdens to industry are to be measured only by whether the level set would impose "massive economic dislocation" of the industry as a whole. *American Federation of Labor v. Brennan*, 530 F.2d 109, 123 (3d Cir. 1975).

15. 100 S. Ct. 2844 (1980).

standard. A four member plurality held that OSHA's present approach to setting permissible exposure levels needed to be reconsidered in light of OSH Act section 3(8)'s requirement that OSHA demonstrate that any standard it promulgates is reasonably necessary and appropriate to curtail significant health risks to employees. The issue remains, however, whether there are circumstances where OSHA can still enforce a no safe level of exposure standard in the absence of meaningful scientific data.

This Comment will examine the nature of the scientific uncertainty that complicates precision in setting permissible exposure levels for carcinogens under the OSH Act. OSHA's policy for dealing with these uncertainties, as represented by its Cancer Standard, will then be compared to the legal factual findings required by the plurality opinion in *American Petroleum Institute* as a prerequisite to standard promulgation. The future of OSHA's attempts to set exposure levels depends on the partnership the courts and the agency create to confront scientific issues. This Comment will encourage reviewing courts to yield to OSHA's expertise in analyzing, interpreting, and applying complex scientific data, thereby enhancing OSHA's efficiency.

#### THE NATURE OF THE SCIENTIFIC UNCERTAINTY

##### *Cancer Mechanisms and Causation*

However incomplete scientific understanding of cancer might be, OSHA in its proceedings to set standards has heard much expert testimony that keeps the agency up to date with the current state of cancer research and knowledge.<sup>16</sup> Cancer is a general term used to describe a proliferation of abnormal cells that invade normal tissue in the human body.<sup>17</sup> A brief summary of the current theories about the origins of cancer will reveal why it is so difficult to apply quantitative risk assessment or legal causation principles.

Cancer appears to result from a cell or cells which have been transformed by changes in or damage to DNA or other genetic material.<sup>18</sup> Cell self-replication causes an irreversible growth pattern of aberrant cells that sometimes are capable of invading normal tissue. The cancerous cell growth has three characteristics: cell multiplication, invasiveness, and autonomy.<sup>19</sup> Invasiveness can be a matter of the abnormal cells destroying solid tissue, or a

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16. OSHA Cancer Standard, *supra* note 1, at 5005-08 (description of the rule-making procedure).

17. *Id.* at 5016.

18. *Id.*

19. *Id.* at 5017 (testimony of Dr. Francis C.J. Roe).

condition in which the accelerated growth rate of new cells so exceeds the destruction of old ones that an invasive state exists. Whereas a particular body organism normally oversees the development and growth of its member cells, the cancerous cell multiplication displays autonomy in defying that control mechanism.

OSHA has endorsed the common theory "that most cancers have multiple 'causes' and that it therefore would be simplistic to assign to each a single causative agent."<sup>20</sup> In fact, scientists are looking at three separate roles an individual substance might perform in the cancer mechanism.<sup>21</sup> The agent might directly initiate neoplastic (tumorous) cell transformation by acting on the DNA or other genetic structure of a normal cell. Other substances might participate as "promoters" or "co-carcinogens" by, for example, activating a latent virus. Lastly, a third group of agents might enhance the metabolic activation of an existing carcinogen, accelerating the development of cancer cell lines by modifying hormone levels or suppressing the immune mechanism.<sup>22</sup> Consequently, the evaluation of a particular carcinogen's contribution to the causation of cancer is likely to resemble the most intricate proximate cause problem. The pathological development of cancer to a point of clinical recognition is an evolutionary process. At each evolutionary stage, different substances can play a significant role in furthering the cancer's development. This role may also be played by environmental factors surrounding the condition of the host (affected) cell.<sup>23</sup>

A corollary of the multiple cause theory is the great probability that a combination of substances, if not factors, cause cancer.<sup>24</sup> Some poignant examples are found in prospective studies that have compared the occurrence of lung cancer in smoking and non-smoking workers exposed to asbestos for long periods. One study showed no reported deaths from lung cancer among the eighty-seven non-smokers as compared to twenty-four deaths for the two hundred eighty-three men with a smoking history.<sup>25</sup> Causal factors appear to be able to interact either: additively, as

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20. *Id.* at 5017.

21. *Id.* at 5018 (testimony of Dr. Arthur Upton).

22. *Id.*

23. *Id.*

24. *Id.* at 5020.

25. *Id.* at 5020-21 (based on 1967 study of New York metropolitan area asbestos workers).

the sum of the individual risks; synergistically, as in the asbestos-smoking example where the additional causes have multiplying effect upon the risk; or even antagonistically, with individual causal factors cancelling one another out.<sup>26</sup> There is little use or accuracy in an assessment of an individual carcinogen's risk potential outside the context of these other potential contributing factors.<sup>27</sup> Thus, the basic features of carcinogenesis defy quantitative risk assessment.

The theory of single-cell origin or the initiation of the cancer from the interaction of a single molecule of the carcinogen with the DNA or genetic material in a single cell seriously challenges the idea that there are any safe levels of exposure.<sup>28</sup> Accordingly, OSHA concludes in its Cancer Standard: "This (concept) is of profound importance for the concept of threshold dose."<sup>29</sup> Irreversibility theory suggests that the final cell transformation is caused by a series of related steps. A dose of one carcinogenic agent causes a partial and irreversible change in the cell structure which only results in a cancer through subsequent changes caused by exposure to another agent or several more agents.<sup>30</sup> This theory leads OSHA to opine: "The importance of these findings for the regulation of carcinogens is that even brief exposures early in life may be assumed to have irreversible effects which may be manifested as cancers late in life."<sup>31</sup> One explanation for the greater incidence of cancer in the elderly is that the individuals have had a longer time to go through all the steps necessary for a complex cell transformation.<sup>32</sup> Again, such unpredictable and delayed manifestation complicates the regulation of occupational carcinogens.

Finally, latency periods frustrate causation analysis of cancer. Latency is defined as the time between exposure to the carcinogen and the manifestation of the cancerous effect.<sup>33</sup> Such latency periods are suspected to last between five and fifty years.<sup>34</sup> This basic characteristic of cancer, the fact that in trying to control it

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26. *Id.* at 5020.

27. *Id.* at 5022. This is a basic deficiency in the use of animal studies to establish permissible exposure levels.

28. *Id.* at 5023-24. There is great disagreement in the scientific community about the validity of the single-cell theory. See American Petroleum Inst., 100 S. Ct. 2844, 2861 n.41 (1980).

29. OSHA Cancer Standard, *supra* note 1, at 5023, 5024.

30. OSHA Cancer Standard, *supra* note 1, at 5024 (testimony of Dr. Stewart).

31. *Id.* at 5025.

32. Alternatively, some experts argued that cancer is a disease of old age because natural selection has only led to the evolution of defense mechanisms for early ages. OSHA Cancer Standard, *supra* note 1, at 5026.

33. *Id.* at 5026.

34. *Id.* at 5040 (testimony of Dr. Hoover).

we are grappling with some future, unknown risk, is a most apt demonstration of why carcinogen regulation by definition is a hit or miss proposition.

### *Cancer Study Techniques and Exposure Levels*

Whatever the difficulties in cancer risk assessment, cancer policy-making under the OSH Act must be based on "the best available evidence."<sup>35</sup> To meet this requirement, OSHA has utilized three kinds of studies: epidemiological studies that review histories of human reactions to carcinogens, laboratory experiments on animals called animal bioassays, and a variety of short-term tests done on isolated single cells.<sup>36</sup>

Although properly conducted epidemiological studies provide the most reliable indicator of whether a substance is a carcinogen, they are inadequate measures of potency.<sup>37</sup> Analyses of the histories of occupational groups exposed to the carcinogen in question necessarily occur in uncontrolled circumstances, and consequently are fraught with confounding variables and uncertainty.<sup>38</sup> Because scientists cannot control or understand outside causation factors affecting both those employees exposed to a particular carcinogen and those who are not, these studies are poor indicators of lower level risks.<sup>39</sup> Likewise, latent manifestation of effects make epidemiological studies that describe recent exposures inconclusive. Moreover, there is an obvious limit to the specificity with which histories report the levels and circumstances of the occupational exposures.<sup>40</sup> Oftentimes the data contains errors or is simply unobtainable. Finally, because they cannot regulate exposure to carcinogens from the onset, scientists cannot control and study relevant risk factors. These include worker socio-economic status, age at exposure, smoking histories,

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35. OSH Act § 6(b)(5), 29 U.S.C. 655(b)(5) (1970).

36. See Leape, *Quantitative Risk Assessment in Regulation of Environmental Carcinogens*, 4 HARV. ENV'T'L L. REV. 86, 91 (1980). The technology of short term or in vitro tests has only recently emerged and their reliability is as yet questionable. OSHA Cancer Standard, *supra* note 1, at 5173.

37. Leape, *supra* note 36, at 96.

38. *Id.* at 92.

39. OSHA Cancer Standard, *supra* note 1, at 5040 (testimony of Dr. Hoover).

40. *E.g.*, American Petroleum Inst., 100 S. Ct. at 2854 (1980) (validity of key epidemiological study supporting benzene standard challenged for errors in specificity of exposure of subject group).

reporting errors, and other workplace and domestic influences.<sup>41</sup>

Animal bioassays avoid many of the weaknesses in epidemiological studies, providing the controlled experimentation essential to a focus upon the isolated effects of a single carcinogen.<sup>42</sup> If multiple cause, irreversibility, and synergistic interaction theories are valid, however, the precise advantages of animal studies raise complex questions as to their accuracy when extrapolated to humans. An employee's exposure to a particular level of carcinogen is not in isolation; other causal factors should not be discounted. Oftentimes, because the concern is to produce qualitative data quickly and cheaply, animal test-subjects are injected with the maximum dose tolerated by OSHA, making the tests of limited value in assessing permissible exposure levels.<sup>43</sup>

Similarly, there is uncertainty about the validity of analogies between different organisms. The test animals might differ from man in how they absorb chemicals through their gastrointestinal tracts, the length of time they store absorbed compounds, their rates of body metabolism, their rates and routes of excretion, and in the quality of the cellular and inter-cellular membranes that interact with the carcinogen initiating the cancer growth.<sup>44</sup> Combining these factors with the environmental differences in exposure, the inbred aspect of most animal test populations, and the relatively small size of animal test samples, creates uncertainties that must be carefully considered for proper quantitative risk assessment.<sup>45</sup>

### *Dose Response Curves*

The final uncertainty plaguing OSHA's attempts to set permissible exposure levels concerns the use of available statistical data to predict a safe level. The impetus for setting the new permissible exposure level (p.e.l.) might come from recent outbreaks of cancer in workers exposed to a carcinogen, or from scientific research determining a substance is carcinogenic and needs regulation, or from new scientific data or beliefs that an existing p.e.l. standard poses a risk to employee health.<sup>46</sup> In all cases, the car-

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41. Some scientists believe that epidemiological studies could be used to check whether incidences of cancer have in fact occurred at low level exposures and, consequently, to determine no effect levels. See OSHA Cancer Standard, *supra* note 1, at 5047.

42. See Leape, *supra* note 36, at 95.

43. OSHA Cancer Standard, *supra* note 1, at 5142 (testimony of Dr. Harold Stewart).

44. *Id.* at 5190-91 (citing 1977a The Safe Drinking Water Commission, National Academy of the Sciences, 32-36, 41-42).

45. *Id.* at 5189.

46. In the case of the benzene standard, for example, the National Institute of



cinogen regulator must use data of risks at higher exposure levels to predict what lower level of exposure is the threshold of safety from the occurrence of cancer. The common tool for statistical analysis of this sort is the dose response curve.<sup>47</sup> Unfortunately, keen disagreement exists over the proper method for making a reliable dose response curve.<sup>48</sup> The vast discrepancy in the results coming from the varying statistical techniques has spawned speculation whether dose response curves can predict threshold levels at all.<sup>49</sup> This has been reinforced by current causation theory that even low level exposure is adequate to initiate cell transformation.<sup>50</sup> The respected scientific support for this position has had a profound impact in the formation of OSHA's present policy that without adequate data on low level exposures, there is no determinable safe level of exposure at all.<sup>51</sup>

#### OSHA'S P.E.L. POLICY-MAKING AND JUDICIAL REVIEW

Among those agencies concerned with environmental and occupational carcinogens, considerable differences have arisen in the policy devised for use of quantitative data.<sup>52</sup> Some of these differences are attributable to the different statutory language and respective legislative histories authorizing each agency's powers. For example, although OSHA's obligation to regulate carcinogens "to the extent feasible" forces it to consider technological and economic feasibility, the Food and Drug Administration is told to consider health effects alone.<sup>53</sup> Other differences in use of quantitative data are attributable to the varying nature of the regulatory

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Occupational Health and Safety (NIOSH) discovered a new study of low level exposure related leukemia deaths that it felt justified a change in the permissible exposure level. See 43 Fed. Reg. 5,918 (1978).

47. OSHA Cancer Standard, *supra* note 1, at 5184, 5197.

48. Three common mathematical extrapolation models are: the *probit*, that assumes each member in society has a threshold tolerance level to the given agent; the *single hit*, that calculates the random chances of the inter-action of the molecule and lost cell; and the *multi-stage*, that calculates the likelihood of the suspect molecule playing a role in some cancer forming process. Expected response rates at low doses for the same tested agent vary according to the model from 1 in a billion responses to 7 in a thousand. See OSHA Cancer Standard, *supra* note 1, at 5185, Table 3.7.

49. *Id.*

50. See note 40 *supra*.

51. OSHA Cancer Standard, *supra* note 1, at 5118-37.

52. See OSHA Cancer Standard, *supra* note 1, at 5195-97; Leape, *supra* note 36, at 109-13.

53. 21 U.S.C. §§ 301-92 (1976).

tasks. The magnitude of the Environmental Protection Agency's job of overseeing numerous low level exposures makes even crude quantitative risk assessments imperative for setting regulatory priorities.<sup>54</sup>

Part of the difference appears to be philosophical. Among the agencies, OSHA is the most aggressive supporter of the no safe level of exposure policy for known carcinogens.<sup>55</sup> Whatever scientific bases underly OSHA's endorsement of no safe level policy, the economic burdens of such a policy have placed OSHA in the forefront of the political battle on regulation.<sup>56</sup> OSHA has dug in and chosen to defend its policy based on authority delegated to it by the 1970 legislation and by scientific data.

On January 22, 1980, OSHA published its Cancer Standard.<sup>57</sup> Noting the history of the agency's prolonged and frustrated attempts to regulate potential occupational carcinogens, the standard represents OSHA's determination to settle policy questions repeatedly disputed in substance regulation proceedings.<sup>58</sup> The advantages of an overall cancer policy are obvious. The Supreme Court has encouraged agencies to promulgate general rules that will guide agency discretion in individual cases.<sup>59</sup> By establishing the procedures and grounds for carcinogen regulations, and the bases upon which those regulations may be challenged, the agency avoids the waste of time, money and human resources in-

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54. "The extrapolation of cancer risks to very low levels of exposure is undoubtedly more useful to EPA than OSHA. In the general environment, exposure to carcinogens can commonly be very low and involve large populations. In the occupational setting the potential for exposure is always high." Testimony of Dr. Albert of the Environmental Protection Agency. OSHA Cancer Standard, *supra* note 1, at 5198.

55. See TOXIC SUBSTANCES STRATEGY COMMITTEE, TOXIC CHEMICALS AND PUBLIC PROTECTION 135 (Report to the President, May, 1980).

56. See De Long, *Benzene Exposes Workers to Unresolved Issues*, LEGAL TIMES WASH. D.C. Sept. 8, 1980, at 40, 44; Ross, *Time to Regulate the Regulators—And Place the Blame on Congress*, NAT'L L.J., May 12, 1980, at 24, col. 1; Zerner, *Cancer Policy: Extreme Regulatory Philosophy*, LEGAL TIMES WASH. D.C., Feb. 4, 1980, at 10, 11. See also Statement on Executive Order No. 12,044, Improving Government Regulations, 14 WEEKLY COMP. OF PRES. DOC. 562 (Mar. 23, 1978) (President Carter ordered agencies to make regulations that limit economic burdens on the private sector).

57. Identification, Classification and Regulation of Potential Occupational Carcinogens, OSHA Cancer Standard, *supra* note 1.

58. The National Institute of Occupational Safety and Health has identified over 2,400 agents as "suspect carcinogens" and projected that 271 of those are likely to meet the Cancer Standard's Category 1 criteria for regulation. Yet since its creation in 1971 OSHA has only completed regulatory action on twenty agents. See OSHA Cancer Standard, *supra* note 1, at 5029. For a summary of the delays and time involved in completing regulations of selected agents see OSHA Cancer Standard, *supra* note 1, at 5011-12.

59. See *Vermont Yankee Nuclear Power Corp. v. Natural Resources Defense Council, Inc.*, 435 U.S. 519, 548 (1978).

herent in repetitious litigation. Likewise, it avoids the risk of inconsistent interpretations and determinations on the same facts by different courts. From OSHA's point of view, such a policy is essential to improve the efficiency of carcinogen regulations.<sup>60</sup>

OSHA used notice and comment rule-making procedure to collect extensive and conflicting expert testimony on major issues surrounding quantitative risk assessment.<sup>61</sup> This record provided the support for three types of policy determinations OSHA made to govern future carcinogen regulation proceedings. First, OSHA determined the degree of reliability it was going to attribute to various kinds of human, animal, and cellular studies of exposure levels.<sup>62</sup> Parties could thereafter know in advance how useful a particular study would be as evidence supporting or opposing a proposed exposure level. Second, OSHA specified the statistical methods it found most useful for determinations of low level effects.<sup>63</sup> These methodological preferences were dependent upon the quality of data to be analyzed and OSHA's decision that it is obligated by statute to estimate conservatively on behalf of employee protection.<sup>64</sup> Third, the Cancer Standard established how data and statistical interpretations would be used in the regulatory process. OSHA concluded that "the uncertainties involved in extrapolating from high-dose animal experiments to predict low-dose risks to humans are far too large at present to justify using the estimates as the basis of quantitative risk/benefit analysis."<sup>65</sup>

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60. In her speech to the Construction Advisory Committee at its December 16-17, 1980 meeting in Washington D.C., outgoing Assistant Secretary of Labor, Director of OSHA, Eula Bingham said her greatest disappointment during her tenure was the seeming impossibility of streamlining standards promulgation procedure. *Reported in EMPLOYMENT SAFETY AND HEALTH GUIDE (CCH) No. 503, Dec. 30, 1980, at 2.*

61. *See* note 17 *supra*.

62. For example, OSHA considered the reliability of comparisons between mutagenic and carcinogenic potencies. Since data on the former is more easily obtained, an established correlation to carcinogenic potency might make better predictions available on level exposure risks to humans. Since the correlation has not yet been confirmed, OSHA determined it would be premature to consider mutagenic studies in setting p.e.l. *See* OSHA Cancer Standard, *supra* note 1, at 5199-200.

63. For example, OSHA considered and rejected the use of time-to-event models in statistical risk assessments. These studies sought to understand the effects of a dose by looking at the period of time between exposure and manifestation of the cancer. OSHA Cancer Standard, *supra* note 1, at 5187-88.

64. *Id.* at 5010-11.

65. *Id.* at 5200. For an argument that the OSHA Cancer Standard is defective in that it makes no attempt to quantify the risks see Caruso, *Industry Responsibility*

Assuming adequate data exists, risk assessment might be used for two purposes: to predict relative risks in establishing priorities, and to estimate reduction in risks from agency action.<sup>66</sup>

OSHA likewise reviewed in great detail evidence whether "safe," "no-effect," or "threshold levels" could be established for an identified carcinogenic substance.<sup>67</sup> The issue is not merely whether quantification of a threshold level is possible, but also whether a threshold level of exposure to carcinogens below which no harm will occur even exists.<sup>68</sup> OSHA's conclusion that "even if thresholds for specific carcinogens could be demonstrated for certain human individuals, no reliable method is known today for establishing a threshold that could apply to a group of workers" was bitterly disputed by some experts.<sup>69</sup>

OSHA frequently points out that its analysis and conclusions are based on careful consideration of the record and supportable by substantial evidence therefrom.<sup>70</sup> Nonetheless, the standard has been challenged by industry and labor alike in four circuit courts and one district court.<sup>71</sup> Those actions have been consolidated in the Fifth Circuit Court of Appeals.<sup>72</sup>

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*ity for Environmentally Caused Cancer Under The Toxic Substances Control Act*, 7 RUTGERS J. COMPUTERS, TECH. & L. 213, 229 (1979).

66. OSHA Cancer Standard, *supra* note 1, at 5201.

67. See generally OSHA Cancer Standard, *supra* note 1, at 5118-37.

68. The principle that a dose must exist below which a toxic agent is ineffective comes from toxicology. OSHA Cancer Standard, *supra* note 1, at 5124.

69. OSHA supported its conclusion based on its interpretation of the evidence on six points: (1) The mechanisms of carcinogenesis are distinct for other toxicological processes where thresholds have been determined. If the single carcinogenic molecule's interaction with a single cell initiates the cancer process, the threshold must be determined at the cellular levels. Given the differences in cell environments in individuals, thresholds for a population become even more difficult to determine. (2) Not enough is known about protective mechanisms (immunities, DNA repair, metabolism rates, hormone levels) to assure us that threshold data is conclusive. (3) The existence of certain bionutrient chemicals essential to human existence at low levels but carcinogenic to animals at high doses does not prove thresholds exist. (4) The current attempts to demonstrate thresholds for specific carcinogens are few and inconclusive. (5) Models based on the inverse relationship between dose levels and time of latency manifestation are not at present developed sufficiently to be applicable to humans. (6) Interaction of carcinogenic and environmental factors in causation nullifies the validity of threshold tests of one carcinogen carried out on animals. OSHA Cancer Standard, *supra* note 1, at 5124-37. Some experts argued that although single-cell origin theory might be plausible, there must still be a minimum number of molecules present at the host cell before there is a chance of initiation occurring. *Id.* at 5131 (summary of expert testimony).

70. OSHA Cancer Standard, *supra* note 1, at 5137.

71. Challenges to the Cancer Standard in the Third, Fifth, Seventh, and District of Columbia Circuit Courts of Appeals were consolidated in the Fifth Circuit along with an appeal of a district court decision affirming the Cancer Standard as a standard within the meaning of the OSH Act. See note 72 *infra*.

72. American Petroleum Inst. v. OSHA, *appeal docketed*, Nos. 80-3018, 3040,

One issue on appeal is whether the Cancer Standard is a standard within OSH Act's meaning, or instead a regulation or a general policy governing OSHA's performance.<sup>73</sup> Industry will question whether OSHA's general standards on quantitative risk assessment and no safe exposure levels are supported by substantial evidence and allowable in light of the Supreme Court's decision on the benzene standard in *American Petroleum Institute*.<sup>74</sup>

### *American Petroleum Institute*

Alongside the promulgation of and challenge to the OSHA Cancer Standard has been the troubled history of the agency's standard altering permissible exposure levels for airborne benzene.<sup>75</sup> The Fifth Circuit of Appeals rejected the standard in 1978.<sup>76</sup> Two years later, the Supreme Court affirmed the appellate court's decision, but on a variety of grounds, none of which garnered the express support of five Justices.<sup>77</sup> *American Petroleum Institute*

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3042, 3057 (5th Cir., Sept. 15, 1980); *American Indus. Health Council v. Marshall*, 494 F. Supp. 941 (S.D. Tex. 1980), *appeal docketed* (5th Cir., Sept. 15, 1980).

73. Letter from George H. Cohen, counsel for AFL-CIO, (December 30, 1980).

74. Conversation with Diane E. Burkley, Dep't of Labor Attorney, January 9, 1981.

75. Standard for Exposure to Airborne Benzene, 43 Fed. Reg. 5918 (codified in 29 C.F.R. 1910.1028) (1978) [hereinafter cited as OSHA Benzene Standard]. Long recognized for producing chronic effects in workers, benzene is a liquid that evaporates rapidly under ordinary atmospheric conditions. Workers are exposed to it in its production, in its use as an intermediate for the production of other chemicals, as a solvent in a variety of chemical and production industries, and as a reactant in chemical laboratories. The American National Consensus Institute adopted a benzene exposure standard that set a 10 ppm eight hour averaged exposure limit, with 25 ppm ceiling concentration and 50 ppm excursions for ten-minute periods. All of the National Consensus standards were adopted as the federal standards pursuant to OSH Act § 6(a). Benzene was recognized as a potential cause of non-malignant blood disorders, chromosome damage, and leukemia.

In 1974 NIOSH recommended the peak concentration limit period be lowered to 25 ppm. On the basis of a 1976 epidemiological study of workers thought to have been exposed to 0-15 ppm benzene at two Pliofilm plants between 1940-1949, NIOSH recommended a new standard be set for 1 ppm, with 5 ppm ten minute ceilings and 25 ppm peak concentrations. An emergency standard adopted on NIOSH's advice was stayed by the Fifth Circuit on May 27, 1977. A similar permanent standard was the subject of industry challenge and eventually the Supreme Court's first attempt to review an OSHA carcinogen standard. See *American Petroleum Inst.*, 100 S. Ct. 2844 (1980); EMPLOYMENT SAFETY AND HEALTH GUIDE (CCH) ¶ 12,305-306 (1978) for a history of benzene regulation.

76. 581 F.2d 493 (5th Cir. 1978), *cert. granted*, 440 U.S. 906 (1979).

77. *American Petroleum Inst.*, 100 S. Ct. 2844 (1980). Justice Powell joined Justice Steven's plurality opinion except for the section that dealt with the burden of

discusses in the context of an individual substance many of the issues raised and resolved generally in the Cancer Standard. Justice Rehnquist's opinion striking down the standard, however, failed to address any of these grounds. His call for the resurrection of the unlawful delegation doctrine seems to indicate a disinclination to support legislative-like policy decisions, such as those made in OSHA's Cancer Standard, until clearer Congressional authority is expressed.<sup>78</sup> Consequently, any four Justices agreeing OSHA has erred in setting permissible exposure levels are likely to prevail. Although *American Petroleum Institute* leaves much unresolved and the extent of its general applicability is uncertain, the case cannot be ignored in future standard promulgation.

### The Lack of Appropriate Findings

The four member Supreme Court minority flatly rejected the Fifth Circuit's holding that the Secretary must determine whether the benefits of the new standard were reasonably related to its costs.<sup>79</sup> Justice Powell's concurrence endorsed an interpretation of "feasibility" requiring justification of costs by a determination of benefits as indispensable to "any rational system of regulation."<sup>80</sup> The plurality opinion of Justice Stevens, however, deferred the issue of cost/benefit analysis.<sup>81</sup> Something more basic was wrong with the findings underlying the change in the benzene standard.

OSHA was alerted to the need to change the standard by an alarming epidemiological study from NIOSH. Although OSHA

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proof question, which he discussed in his concurring opinion. He also opined that OSHA should be held to cost/benefit justification of its standards under the feasibility language. Chief Justice Burger joined the plurality opinion completely, but wrote a concurring opinion saying the Court's detailed scrutiny should not be construed as meaning the Court was going to stop giving OSHA great leeway in making essentially legislative judgments. Justice Rehnquist provided the fifth vote for the judgment, but on the grounds that the pertinent OSH Act section feasibility language was an unconstitutionally broad and ambiguous grant of legislative authority. Justice Marshall filed the opinion on behalf of the four dissenters, arguing that OSHA's new benzene standard was supportable with substantial evidence.

78. Justice Rehnquist states:

In the case of a hazardous substance for which a "safe" level is either unknown or impractical, the language of § 6(b)(5) gives the Secretary absolutely no indication where on the continuum of relative safety he should draw his line. Especially in light of the importance of the interests at stake, I have no doubt that the provision at issue, standing alone, would violate the doctrine against uncanalized delegations of legislative power.

100 S. Ct. at 2881. *See also*, *Schechter Poultry Corp. v. United States*, 295 U.S. 495 (1935); *Panama Refining Co. v. Ryan*, 293 U.S. 388 (1935).

79. *American Petroleum Inst.*, 100 S. Ct. at 2894, 2898 n.27, 2903 (1980) (dissenting opinion of Justice Marshall).

80. *Id.* at 2878 (concurring opinion of Justice Powell).

81. *Id.* at 2850.

later determined the statistical basis of the study was flawed as to the actual exposure levels of the subject group, the results confirmed what OSHA already believed<sup>82</sup>—no safe or threshold level is known to exist for benzene, and OSHA should therefore eliminate the risk to the extent feasible.

Conclusive, undisputed evidence indicated that benzene was a carcinogen.<sup>83</sup> The studies of benzene were all based on epidemiological studies.<sup>84</sup> OSHA found deficient the epidemiological studies offered by industry both as proof of “no effect” levels and as a basis for a determination of threshold; primarily because the studies failed to adequately define the composition of the “cohort” or studied groups.<sup>85</sup> The lack of careful definition of the exposed cohort was exacerbated by incomplete histories and followup of cohorts.<sup>86</sup> Furthermore, the study’s usefulness was diluted by failures to account for latency<sup>87</sup> or the variability of individual sensitivity. OSHA reiterated its policy that “no effect” studies had to be held to higher standards of accuracy; consequently, the methodological problems noted were amplified.<sup>88</sup>

Finally, OSHA reviewed all studies introduced in the proceeding in light of the fact that much is unknown about the relationship between benzene exposure and leukemia. Early evidence provided contradictory indications about the following issues in benzene’s causation mechanism: whether it participated as a primary, co-carcinogen or a pro-carcinogen;<sup>89</sup> the extent of special sensitivity demonstrated by specified age groups, individuals with prior benzene exposures, and individuals with a history of blood diseases;<sup>90</sup> and what kind of decline in incidences of leukemia re-

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82. See OSHA Benzene Standard, *supra* note 75, at 5921, 5932.

83. *Id.* at 5931.

84. *Id.* at 5927-29. For an unknown reason, animal bioassays have not uncovered any clear-cut occurrences of leukemia and, therefore, are inapplicable.

85. *Id.* at 5931.

86. *Id.*

87. *Id.* at 5930. Specific studies supported the finding that benzene has a considerable latency period between exposure and effects.

88. *Id.* at 5932.

89. *Id.* at 5929. One epidemiological study specifically found coke oven emissions and benzene synergistically interacted in increasing risks of leukemia.

90. *Id.* at 5929. Industry maintained that because the evidence of the occurrences of potential benzene related leukemia was tied with peculiar characteristics of individuals, the actual risk attributable to benzene was reduced. OSHA found the fact that benzene might act in the presence of these special sensitivities actually increased the need for the standard.

sult from cessation of worker exposure.<sup>91</sup> OSHA concluded that uncertainties about the actual number of expected benzene-related deaths and about the theories for extrapolating such data from existing studies placed quantitative risk assessment on the “frontiers of scientific knowledge.”<sup>92</sup> There, agency discretion and expertise should prevail.

In reviewing OSHA’s findings in support of the benzene standard, the plurality in *American Petroleum Institute* was non-plussed by OSHA’s discussion of the insufficiency of the data. By overemphasizing the unavailability of hard facts, OSHA neglected other approaches to the problem. The plurality criticized OSHA for not discussing the possibility of making “rough estimates” of risks at high-level exposures if more complete epidemiological and animal studies were made. These estimates could then be extrapolated to make other, rougher estimates of risks at low-level exposures.<sup>93</sup> The plurality implied that OSHA was underestimating science’s predictive powers.

The plurality took a fresh, independent look at the two studies OSHA primarily relied upon in deciding to promulgate the 1 p.p.m. level.<sup>94</sup> The Ohio Pliofilm plant studies which had initiated concern over the existing 10 ppm levels were discarded because there had been erroneous information about the population sample’s exposure.<sup>95</sup> OSHA merely concluded the lack of definitive data prohibited it from deriving any conclusions about excess risks at any specific exposure levels. Nevertheless, OSHA still felt the study raised valid suspicions about potential low-level exposure hazards.<sup>96</sup>

The plurality likewise took issue with OSHA’s interpretation of a Dow Chemical study of 2 to 9 ppm benzene exposures that showed three leukemia-related deaths versus 0.2 expected deaths in a sample of 594 workers.<sup>97</sup> Again, OSHA’s position was equivocal: the study was not conclusive evidence of increased risks below 10 ppm exposures, but one could not rule out the benzene exposure’s role as a causal factor in the three deaths.<sup>98</sup> The plurality conclusion on the study was:

[I]t could not be viewed as proof of a relationship between low-level exposure and leukemia because all three workers had probably been occupationally exposed to a number of potentially carcinogenic chemicals at

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91. *Id.* at 5930 (hereinafter cited as the Askoy Study).

92. *Id.* at 5940.

93. *American Petroleum Inst.*, 100 S. Ct. at 2859 n.33.

94. P.p.m. refers to parts of the toxic substance per million parts of air.

95. *See OSHA Benzene Standard*, *supra* note 75, at 5926, 5927.

96. *Id.* at 5927-29.

97. *American Petroleum Inst.*, 100 S. Ct. at 2860.

98. *Id.*; *OSHA Benzene Standard*, *supra* note 75, at 5928 n.8.



other points in their careers and because no leukemia deaths had been uncovered among workers who had been exposed to much higher levels of benzene.<sup>99</sup>

The plurality plunged right into the controversy over how to properly utilize inconclusive scientific data and when to reject data for uncertainty. Sometimes it is singularly unimpressed by OSHA's conclusions that uncertainties belie the value of a study. At other times, however, the plurality displays great dexterity in showing why uncertainties render studies inadequate proof. Dismissing the proof content of these studies, the plurality gets to the heart of its discontent with OSHA's finding:

In the end OSHA's rationale for lowering the permissible exposure limit to 1 ppm, was based not on any finding that leukemia has ever been caused by exposure to 10 ppm and that it will *not* be caused by exposure to 1 ppm, but rather a series of assumptions indicating that some leukemias might result from exposure to 10 ppm and that the number of cases might be reduced by reducing the exposure level to 1 ppm.<sup>100</sup>

OSHA had changed the benzene exposure standard from 10 ppm to 1 ppm using the following analysis: benzene is a known carcinogen; since the industry failed to prove any threshold level of safety and there was no other evidence available, the agency assumed any level above zero presents an increased risk of exposure. OSHA then applied a safety factor of 10/100 to the existing standard, assuming it was a known level of danger, thereby arriving at the 1 ppm figure. Finally OSHA ordered a study to see if industry compliance at 1 ppm was technologically and economically feasible.<sup>101</sup>

The dispute between the plurality and OSHA breaks down to two groups of issues: (1) what *is* a finding and whether OSHA made any in support of the benzene standard,<sup>102</sup> and (2) who is to determine whether the scientific data is adequate and accurate enough to be used as findings and how is the determination to be made. The plurality implies the findings it wants are studies and

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99. 100 S. Ct. at 2860.

100. *Id.*

101. *Id.*

102. Justice Powell thought the plurality's conclusion that OSHA had not even attempted to carry its burden of proof was too harsh. He saw the issue as whether substantial evidence supported OSHA's finding that quantification techniques are too imprecise to permit useful risk estimates, and stated the question was a close one. Because the plurality did not seem to consider the status of the evidence as relevant to the required findings, the implication was that there could be no regulation without quantification of the risks. 100 S. Ct. at 2876-77 (concurring opinion of Justice Powell).

quantitative risk estimates based on the studies. OSHA found in its rule-making, however, that all the studies were inadequate to assess risk at specific levels.<sup>103</sup> Likewise, OSHA believes its findings were based on analysis of expert testimony that no safe level of benzene exposure could be determined<sup>104</sup> and that dose-response curves could not be extrapolated from existing data to establish a threshold.<sup>105</sup> The Supreme Court called these determinations general policy "assumptions."<sup>106</sup>

Given the independent and detailed review of the scientific data made by the plurality, the issue of who should determine the adequacy and usefulness of such data looms even larger in future regulation. One searching and valuable study of science policy questions has made a useful attempt to distinguish the varieties of scientific questions as a preliminary step to determining the judicial and administrative decision-making role.<sup>107</sup> It identifies four categories of questions: (1) where there is an impossibility of reliable determination, the issue is trans-scientific and any decision is purely one of public policy; (2) where the data is insufficient, but eventually obtainable, and the issue is whether to postpone determination until complete data may be obtained; (3) where there are varying scientific interpretations of adequate data; (4) where there is agreement on the interpretation of the data, but differences exist as to the inferences or predictions to draw from such data.<sup>108</sup> Depending on the available data, these questions range from ones of pure policy to ones of pure scientific fact. One might expect the judiciary to give greater deference to agency policy setting.

The study classifies questions about no effect levels or the design of a dose-response curve as trans-scientific.<sup>109</sup> Because of the impossibility of obtaining adequate facts, agencies should be encouraged to make policies that ensure the consistent resolution of questions that arise repeatedly in litigation.<sup>110</sup> Nevertheless, the plurality in *American Petroleum Institute* is not easily convinced that issues of benzene's low-level effects are beyond the

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103. OSHA Benzene Standard, *supra* note 75, at 5941.

104. *Id.* at 5927-29.

105. *Id.* at 5932.

106. 100 S. Ct. at 2860 (OSHA benzene standard based on a "series of assumptions.") The plurality's opinion that these assumptions were not policies based on findings did not stop the plurality from later disputing and substituting its own findings on questions of scientific analysis and technique. See note 128 *infra*.

107. McGarity, *Substantive and Procedural Discretion in the Administrative Resolution of Science Policy Questions: Regulating Carcinogens in the EPA and OSHA*, 67 GEO. L. REV. 729 (1979).

108. *Id.* at 733-47.

109. *Id.* at 757.

110. *Id.*

possibility of reliable determination. The Court may not have felt that OSHA studied these possibilities with the thoroughness required by the statute to justify its decision that no safe threshold could be determined. If the latter interpretation is correct, then maybe a generic cancer policy can still survive *American Petroleum Institute*.

### The Requirement of a Threshold Determination of Significant Risk

The plurality determined that OSHA should have made "rough" risk estimates, at least as a part of a preliminary inquiry as to whether a new benzene standard was justified.<sup>111</sup> This does not mean, however, that the agency must use such an estimate in the final choice of a permissible exposure level. Such a conclusion could certainly be inferred from the plurality requirement that OSHA not only show a significant risk of harm at the existing 10 ppm level but also show the likelihood that the new 1 ppm level will lessen the risks.<sup>112</sup>

In its determination that section 3(8) must be incorporated into section 6(b)(5)—meaning that a promulgated standard must be "reasonably necessary" in the face of a significant risk—the plurality left open the possibility that it was discussing a proof requirement prior to and separate from the promulgation of a health standard.

Only after the Secretary had made the threshold determination that such a risk exists with respect to a toxic substance, would it be necessary to decide whether § 6(b)(5) requires him to select the most protective standard he can consistent with economic and technological feasibility, or whether, as respondents argue, the benefits of regulation must be commensurate with the costs of implementation.<sup>113</sup>

In support of its interpretation of section 3 (8), the plurality noted section 6(g)'s requirement that the Secretary establish priorities for his standards based on urgency,<sup>114</sup> and section 6(b)(8)'s requirement that the Secretary explain how changes in existing standards "better effectuate" the purposes of the Act.<sup>115</sup> Both

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111. 100 S. Ct. at 2859 n.33.

112. 100 S. Ct. at 2870.

113. 100 S. Ct. at 2863; *see also* 100 S. Ct. at 2864 (before promulgation the Secretary is required to find significant risks present and can be eliminated). The wording suggests there might be a distinction between the quantification required to justify promulgation and that required to determine the standard.

114. 29 U.S.C. § 655(g) (1970).

115. 29 U.S.C. § 655(b)(8) (1970).

these requirements address themselves to the determination whether the standard needs to be promulgated. This might be distinguished from a determination of how the final standard is selected, or what level of exposure is permissible. In the latter situations, the pressure on the Secretary to quantify risks might decrease.

Perhaps the plurality is not so convinced that OSHA clearly mishandled the quantitative data in the benzene proceedings as it is apprehensive about the potential consequences if OSHA's regulatory approach is generally applied. The plurality foresees OSHA gaining "unprecedented power over American industry" in regulating occupational carcinogens.<sup>116</sup> OSHA could easily conclude that a substance is probably a human carcinogen. It would then immediately conclude the substance poses some regulatable risk of harm no matter how small the level of exposure, without regard to contrary evidence. Given the enormous number of potential occupational carcinogens with minute levels of exposure, perverse regulatory policy would result, trying to eliminate all risks at outrageous costs.<sup>117</sup> This discussion bears ominously on the future of the OSHA Cancer Standard. At one point, the plurality even concludes that the generic cancer policy proves its doomsday scenario "is not merely hypothetical."<sup>118</sup> But the plurality's summary of the Cancer Standard is exaggerated on at least two points: (1) the ease with which the quantum of proof can be met to justify categorization of a substance as a priority carcinogen<sup>119</sup> and (2) the extent to which industry would be foreclosed from providing or OSHA itself would ignore reliable data on safe exposure levels. One hopes the Court will get a chance to examine the Cancer Standard in greater detail.<sup>120</sup>

### Burden of Proof

The OSHA Cancer Standard would place the burden of proof on industry to establish a safe level of exposure for a known carcino-

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116. 100 S. Ct. at 2865.

117. *Id.* at 2866.

118. *Id.* at 2866 n.51.

119. See OSHA Cancer Standard, *supra* note 1, at 5001-5296. The Cancer Standard goes to great lengths to analyze the kind of scientific data available and the extent of its reliability in making the qualitative determination of whether or not a substance is carcinogenic. Given the time and costs it takes to develop studies to satisfy the Standard's requirements, the plurality's connotation in the phrase "certain quantum" is simplistic.

120. See note 72 *supra*. It seems quite likely that the Supreme Court will eventually review the Cancer Standard. See De Long, *Benzene Exposes Workers to Unresolved Issues*, LEGAL TIMES WASH. D.C., Sept. 9, 1980, at 47, col. 3, n.3.

gen.<sup>121</sup> In *American Petroleum Institute*, however, the plurality assumed that OSHA, as the proponent of the new benzene standard, had the burden of supporting it with substantial evidence under the Administrative Procedure Act.<sup>122</sup> The problem is defining "the burden of proving significance of the risk in a case . . . where scientific knowledge is imperfect and the precise quantification of risks is therefore impossible."<sup>123</sup> Again the plurality's framing of the issue implies that OSHA refrains from quantitative analysis merely because "precise quantification is impossible." OSHA's claim is not merely that precision is impossible, but that the current level of sophistication in the quantitative analysis of most carcinogens is useless or useful only to the extent that the imprecisions and uncertainties are carefully accounted for.<sup>124</sup> Once this imprecision is demonstrated, OSHA switches the burden of proof on safe exposure levels to the opponents of the standard.<sup>125</sup> The plurality saw only that OSHA was unreasonable in its demand for precision and held that OSHA had not even attempted to meet its burden of showing the significant risk benzene posed.<sup>126</sup>

OSHA's grounds for rejecting an industry dose-response curve showing a risk of two deaths per 30,000 workers every six years

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121. 29 C.F.R. § 1990.111(h); Judge Leventhal's discussion of Congressional intent in allocating the burden of proof under the Federal Insecticide, Fungicide and Rodenticide Act in *Environmental Defense Fund, Inc. v. EPA*, 548 F.2d 998, 1012-18 (D.C. Cir. 1977) concluded that "burden of proof" is a general term applicable to all the nuances of burden. Therefore, the plurality's "more likely than not" standard is discussed as the burden of proof. *American Petroleum Inst.*, 100 S. Ct. at 2869.

122. Administrative Procedure Act, § 7(c), 5 U.S.C. § 556(d). This would be so unless the OSH Act provided otherwise. It is important to note that Justice Powell did not accept, and Justice Rehnquist did not discuss, the plurality's discussion on the burden of proof question. In fact, Justice Powell and the four minority members seem to agree OSHA does not always have to meet its burden by quantifying the risks involved. This would be so where OSHA demonstrated such quantification cannot be done reliably. Justice Powell, however, muddles the issue by requiring the Secretary to support with substantial evidence the finding that the existing exposure level poses a significant risk. Can that be done without quantitative risk assessment? Justice Powell's support of cost/benefit analysis also detracts from his discussion on the burden of proof question. *American Petroleum Inst.*, 100 S. Ct. at 2876-77.

123. 100 S. Ct. at 2869.

124. See OSHA Cancer Standard, *supra* note 1, at 5200, 5201 (OSHA's conclusions on the use of quantitative risk assessments).

125. See text accompanying notes 97-100 *supra*.

126. 100 S. Ct. at 2869-70.

were held inadequate.<sup>127</sup> The plurality's marked inconsistency in emphasizing uncertainties in order to discredit the studies suggesting low-exposure risks, while holding OSHA's emphasis on uncertainties unfounded in the case of industry's dose-response curve, is explained primarily by its preference for extrapolations from data of high exposure risks. In this instance, the plurality is susceptible to a charge that it has substituted its own judgment in an area where the agency would normally be thought to have greater expertise.<sup>128</sup>

The plurality, however, left the door open for a different interpretation of why OSHA's findings on the dose-response curves failed—OSHA had not adequately explained the reasons for rejection. OSHA's explanation did not make it clear whether it believed that the risk of low-level exposure was greater than the industry curve showed, that the low-level risks established were significant, or that it was compelled under the statute to establish the most protective standard feasible.<sup>129</sup> *American Petroleum Institute* invalidates only the third rationale. Furthermore, the plurality's discussion did not make clear if OSHA would be allowed to support with substantial evidence a fourth reason for rejection of the curve—that it was too unreliable to be used in setting a p.e.l.<sup>130</sup>

Finally, the plurality discussed more generally the impact of its holding upon OSHA's standard promulgation. Saying that the term "significant" was not a mathematical "straight-jacket," it placed upon the agency the initial responsibility and discretion to determine what "significant" risk means in this complicated area of science.<sup>131</sup> The plurality allowed that "one in a billion" odds were not significant, but one in a thousand might be.<sup>132</sup> Thus the plurality's main objective appears to be to force OSHA to become bolder in its use of imperfect data.

The plurality opinion briefly refers to appellate decisions in the 1970's that held OSHA could not be required to support its findings and standards with anything approaching scientific certainty.<sup>133</sup> Although one might debate whether the plurality opinion gave OSHA leeway on findings made "on the frontiers of

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127. *Id.*

128. *See* 100 S. Ct. at 2890 (minority opinion of Justice Marshall discussing plurality's arrogance in making its own factual findings).

129. 100 S. Ct. at 2870.

130. *But see* 100 S. Ct. at 2876-77 (concurring opinion by Justice Powell) (even where Secretary finds it impossible to precisely quantify, he may still find there is a significant health hazard).

131. 100 S. Ct. at 2871.

132. *Id.*

133. *Id.* at 2871; *Industrial Union Dep't, AFL-CIO v. Hodgson* 499 F.2d 467, 476

science" or in fact mandates exploration, the passing approval of *Industrial Union Dept., AFL-CIO v. Hodgson* and *Society of Plastics Industry, Inc. v. OSHA* is crucial to future attempts to regulate carcinogens.<sup>134</sup> The agency remains free to use conservative assumptions in interpretation of scientific data and to err on behalf of worker protection so long as such assumptions are "supported by a body of reputable scientific thought."<sup>135</sup>

In conclusion, the plurality urged OSHA to use its own experience and judgment in quantitative risk assessment to make decisions about significant risks associated with exposures to carcinogens.<sup>136</sup> It suggested that where the agency was faced with less than reliable data, OSHA should proceed more cautiously in reducing the p.e.l. In the meantime, the agency could do more monitoring and medical testing to determine if further reductions were justified. In support of these ideas,<sup>137</sup> the plurality cited as a model OSHA's experience in the regulation of coke oven emissions, which like the benzene standard, was supported primarily on the basis of epidemiological studies.<sup>138</sup>

#### AFTER AMERICAN PETROLEUM INSTITUTE

##### *American Iron and Steel*

Those who anticipated *American Petroleum Institute* would resolve the controversial question whether OSHA must base its regulation of carcinogens on some type of cost/benefit analysis were disappointed by the decision.<sup>139</sup> Disappointment gave way to renewed anticipation, however, when the Supreme Court granted certiorari to review OSHA's coke oven emission standard in *American Iron and Steel Institute v. OSHA*<sup>140</sup> on the same day it announced *American Petroleum Institute*. Since *American Petro-*

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(D.C. Cir. 1974); *Society of the Plastics Industry, Inc. v. OSHA*, 509 F.2d 1301, 1308 (2d Cir.), *cert. denied*, 421 U.S. 962 (1975).

134. 100 S. Ct. at 2871.

135. *Id.*

136. *Id.* at 2872.

137. *Id.*

138. See 41 Fed. Reg. 46742 (1976); *American Iron & Steel Inst. v. OSHA*, 577 F.2d 825 (3d Cir. 1978), *cert. granted*, 100 S. Ct. 3054, *dismissal granted*, 101 S. Ct. 38 (1980).

139. *E.g., Benzene Case Avoids Cost-Benefit Issue*, LEGAL TIMES WASH. D.C., July 7, 1980, at 2, col. 2.

140. *American Iron & Steel Inst. v. OSHA*, 577 F.2d 825, 825; see note 122 *infra* at 825.

leum Institute seemed to approve of OSHA's use of scientific findings in promulgation of the coke oven standard, the Court was expected to address the cost/benefit issue directly.<sup>141</sup> This expectation never materialized, however, because the industries involved found they had already substantially complied with the standard.<sup>142</sup> The Supreme Court granted industry's petition for dismissal soon after the grant of certiorari.<sup>143</sup>

*American Iron and Steel Institute* still offers a useful contrast to *American Petroleum Institute*.<sup>144</sup> Not bound by *American Petroleum Institute's* requirement there be a threshold finding of significant risk by the Secretary, the Third Circuit framed the question as whether there was substantial evidence supporting the Secretary's conclusion that the ambient atmosphere of a coke oven maintains particulate matter for which there is no safe exposure level. With remarkable brevity the court determined that the Secretary offered substantial evidence in the form of expert testimony that present knowledge could not establish safe levels.<sup>145</sup> The court's focus remained on the legitimacy of the agency's assertion that uncertainties precluded predictions; it did not feel its proper role was to push the Secretary to make quantitative predictions where he found the data insufficient. Although legal doctrine in *American Iron and Steel* is now suspect, its example of judicial review of science policy making remains available.

Whether the factual underpinnings of the coke oven emissions

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141. 100 S. Ct. at 2871-72 n.64.

142. Conversation with Diane E. Burkley, Labor Dep't Attorney, Jan. 9, 1981.

143. 101 S. Ct. 38 (1980). The Supreme Court has subsequently agreed to review challenges to OSHA's cotton dust exposure standard and it is again expected to confront the cost/benefit issue. Among questions presented are: (1) Should the Court resolve the conflict between the District of Columbia Circuit and the Fifth, Sixth and Seventh Circuits as to the showing OSHA must make to demonstrate its standards are economically feasible? (2) Can the statutory requirement that compliance with the OSHA standard is "economically feasible" be satisfied by the agency's conclusion that the standard will not put affected industry out of business? (3) Should the Court resolve the conflict between the District of Columbia Circuit and the Fifth Circuit as to whether the Act, construed as a whole, requires OSHA to demonstrate that the standard is reasonably necessary and that there is some reasonable relationship between the benefit sought to be secured from standards and the cost of obtaining them? *AFL-CIO v. Marshall*, 617 F.2d 636 (D.C. Cir. 1979), cert. granted sub. nom., *American Textile Manufacturers Institute, Inc. v. Marshall*, 48 U.S.L.W. 3626 (1980) (argued January 21, 1981).

144. As with benzene, the OSHA standard proposed to change the National Consensus standard for the p.e.l. adopted in 1971. As it is authorized to do by statute, OSHA established a Standards Advisory Committee on Coke Oven Emissions to prepare recommendations for a new standard to protect employees. After a review of the Advisory Committee's May 1975 report, the Secretary determined that there was no safe level of exposure and moved on to a consideration of feasibility in arriving at the final p.e.l. See *American Iron & Steel Inst. v. OSHA*, 577 F.2d at 829, 830.

145. *Id.* at 832.



should serve as a model for future carcinogen regulation by OSHA is likewise disputable.<sup>146</sup> The standard was supported by an unusually careful prospective epidemiological study that had reviewed exposures among workers for approximately twenty years. Based on that and other studies, OSHA was able to make what it considered a reliable dose-response curve to assess low level risks. Industry experience while awaiting the court challenge proved the feasibility of the standard.<sup>147</sup> Little basis remained to challenge the p.e.l., even under cost/benefit analysis.

The availability of such reliable scientific data is rare in OSHA's experience. To condition the decision to regulate upon the existence of evidence like that in the coke oven emissions proceedings would seriously impair efforts to reduce occupational cancers. Regulatory decisions must be made in advance of understanding of cancer causation mechanisms and risks. As OSHA states in the Cancer Standard, "the regulation of carcinogens must be anticipatory in nature: it is not justifiable to wait until manifestations of toxicity are observed, because by then a whole generation of workers may have been exposed."<sup>148</sup>

### *United Steelworkers*

Almost one month after *American Petroleum Institute* was decided, the Court of Appeals for the District of Columbia, in *United Steelworkers v. Marshall*, made the first attempt to apply the Supreme Court's opinion to a review of an OSHA standard.<sup>149</sup> The court made a lengthy review of numerous procedural and substantive challenges to OSHA's promulgation of a new lead standard.<sup>150</sup> It recognized that the Supreme Court's divisiveness in *American Petroleum Institute*, combined with a certain lack of clarity in the plurality's discussion of OSHA's approach to the benzene standard, left many doctrinal matters unresolved.<sup>151</sup>

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146. See note 142 *supra*.

147. See note 142 *supra*.

148. OSHA Cancer Standard, *supra* note 1, at 5001, 5026.

149. *United Steelworkers v. Marshall* [1980] 3 EMPLOYMENT SAFETY AND HEALTH GUIDE (CCH) § 24,717 (D.C. Cir. No. 78-1562, *decided* Aug. 15, 1980) [hereinafter *United Steelworkers*]. The Supreme Court has since granted a stay for the OSHA lead standard pending filing and disposition of petitions for certiorari. 49 U.S.L.W. 3424 (1980).

150. Judge Wright's opinion plus Judge McKinnon's dissent covered well over 100 pages.

151. See *United Steelworkers*, *supra* note 149, at 30,368 n.87.

Therefore, *American Petroleum Institute's* factual underpinnings were used as a touchstone for the pre-enforcement review of lead. It was easier to determine what the plurality found clearly unacceptable about the benzene standard than to interpret what the decision required as adequate support for a standard.

In the court's assessment, the *American Petroleum Institute* plurality found three major flaws in OSHA's promulgation of the benzene standard: (1) OSHA insisted on relying on rigid and categorical assumptions about benzene's health risks, rather than at least attempting to interpret the available specific evidence or hard facts to assess benzene's harm at different exposures;<sup>152</sup> (2) the burden OSHA placed on industry to rebut the presumption that no safe level of exposure for benzene existed was virtually impossible to meet;<sup>153</sup> and (3) OSHA relied on data of high level exposures to show qualitatively that benzene was a carcinogen, but refused to use the data to predict the significance of risk because it had too many uncertainties.<sup>154</sup> OSHA merely assumed that lowering the p.e.l. to as near zero as possible would likely produce "appreciable" benefits.

With an eye for these flaws, the court had no difficulty finding that the p.e.l. in the lead standard was supportable by substantial evidence. The lead standard was not merely concerned with preventing deaths attributable to leukemia, but with a wide variety of malignant and non-malignant, clinical and sub-clinical harms that OSHA could consider significant.<sup>155</sup> This meant the categorical assumptions of the Cancer Standard did not even apply. OSHA found evidence of significant harms that were scientifically observable at specific blood-lead levels.<sup>156</sup> The dispute between OSHA and industry was not over the availability or adequacy of the data, but over how to interpret the data on sub-clinical effects—high blood-lead levels—for the potential for clinical health effects.<sup>157</sup> The court afforded OSHA great discretion in assessing the significance of those sub-clinical effects. Finding that the criteria of *American Petroleum Institute* had been met, the court next considered the feasibility question.<sup>158</sup>

One key distinction between the benzene standard and the lead standard is that the latter is based on observable scientific evidence. This lends credence to the belief that *American Petroleum*

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152. *Id.* at 30,367.

153. *Id.* at 30,368.

154. *Id.*

155. *Id.* at 30,369.

156. *Id.* at 30,369-71.

157. *Id.*

158. *Id.* at 30,380-417.

*Institute* demonstrates a judicial unwillingness to tolerate regulation founded upon unquantified and uncertain scientific evidence. Nevertheless, the *United Steelworkers'* court correctly deferred to OSHA's interpretation of the meaning of observable sub-clinical effects, in terms of potential health danger. It demonstrated a style of judicial review characterized by reluctance to tamper with OSHA's assessment of the risks involved.

#### CONCLUSION

OSHA has fought an uphill battle in gaining approval for its Cancer Standard.<sup>159</sup> *American Petroleum Institute* imposes the additional burden of a threshold finding of significant risk as a prerequisite to standard promulgation.<sup>160</sup> Furthermore, OSHA must at least reconsider its burden of proof allocation in those situations where it would determine that the unavailability of reliable scientific data warrants application of OSHA general policy conclusions.<sup>161</sup> The section on quantitative risk assessment must likewise be altered to allow appropriately designed dose-response curves to be used to determine significant risks.<sup>162</sup> Finally, so long as courts reserve the right to freely substitute their own determination whether or not the scientific data is uncertain enough to justify the agency's reliance upon the Cancer Standard's poli-

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159. OSHA offered the first form of the Cancer Standard for notice and comment on January 17, 1977. *American Petroleum Institute* has already had an impact on the OSHA Cancer Standard. OSHA has proposed deletions and additions to the final standard to make it conform to the plurality opinion. President Reagan's Executive Order of January 29, 1981 froze these changes for sixty days, allowing the President's Task Force of Regulatory Relief opportunity to review them. The Task Force approved the deletions and withdrew the additions. Executive Order No. 516, [1981] EMPLOYMENT SAFETY AND HEALTH GUIDE (CCH) 1. The main thrust of the deletions was to eliminate the binding requirement that the exposure level for Category I (or identified) carcinogens be set at the "lowest feasible level" achievable through engineering and work practice controls. Exposure levels would once again be set on a substance-by-substance basis, without a general policy. 29 C.F.R. §§ 1990.111 (h), (j), 1990.142 (a)(2)(iii), *as amended by* 46 Fed. Reg. 4892 (1981). The proposed additions, which would have required notice and comment rulemaking procedure, would have inserted a requirement that Category I carcinogen exposure levels be set at the "lowest feasible level which is reasonably necessary or appropriate to eliminate significant risk." Proposed amendment to 29 C.F.R. § 1990.111 (h), 46 Fed. Reg. 7403 (1981). If the Supreme Court should determine the cost/benefit issue against OSHA, still another change will delay the court challenge to the Cancer Standard.

160. Conversation with Diane E. Burkley, Dep't of Labor Attorney, Jan. 9, 1981.

161. But see the discussion of how the Court member's votes now seem to stand on the burden of proof issue in note 132 *supra*.

162. See note 169 *infra*.

cies, the present regulatory defect of ponderous substance-by-substance promulgation of standards will persist. Parties opposed to the standards supported by the policies of the Cancer Standard will flood the courts with arguments that there is indeed adequate quantitative data to base "rough" risk estimates.

The resistance to OSHA's Cancer Standard seems to be based in part upon a misconceived notion of its purposes.<sup>163</sup> Opponents look at the benzene standard's costs, and shudder at the prospect of those costs multiplied by the two hundred and seventy-one occupational carcinogens presently on OSHA's "suspect" list.<sup>164</sup> As pointed out by the minority in *American Petroleum Institute*, however, such a "draconian" portrayal of the Cancer Standard is unfounded.<sup>165</sup>

OSHA is trying to address itself to a crippling process of identification, administrative and scientific investigation, standard promulgation utilizing extensive notice and comment procedure, and finally, bitter, drawn-out judicial review that might or might not uphold the regulation. If the standards impose terrible economic costs on the national economy, the costs imposed by the present system of regulation tax the economy in still another, demoralizing way. As it presently stands, a massive and expensive federal agency clumsily pursues its statutory responsibility accomplishing relatively little. The costs of OSHA's inactivity are exacerbated by its failure to control the increasing number of occupationally caused cancers that drain our economy for the cost of medical care.

Even with a Generic Cancer Standard, there are safeguards available to protect industry. Current proposals for a system of regulatory budgets would force an agency like OSHA to make priority determinations.<sup>166</sup> An agency's success would depend to a great extent on how efficiently it performed its regulatory tasks. Moreover, the regulatory budget would work well in conjunction

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163. *E.g.* *American Petroleum Inst. v. OSHA*, 48 U.S.L.W. 5022, 5032, n.51 (1980); see text accompanying notes 116-120 *supra*.

164. De Long, *Benzene Exposes Workers to Unresolved Issues*, LEGAL TIMES WASH. D.C., Sept. 8, 1980, at 44, col. 3:

If our society spends \$500 million to control benzene, this money is not available to replenish the nation's capital stock, for example, or to purchase goods that people may value more than risk avoidance. If one multiplies this amount by the almost infinite number of risks in the world, the zero-risk approach translates into compulsory pauperization.

165. *American Petroleum Inst.*, 100 S. Ct. at 2891 (Marshall, J., dissenting): "Contrary to the plurality's suggestion, the Secretary did not rely blindly on some draconian carcinogen policy."

166. *E.g.*, Moss, *Time to Regulate the Regulators—And Place the Blame on Congress*, NAT'L L.J., May 12, 1980, at 25 (Discussion by Sen. Lloyd Bentsen, D-Texas, of S. 51, (1980), a bill to introduce a regulatory budget).

with a Cancer Standard. OSHA could move quickly through the process of identifying all the occupational health and safety risks it confronts and has authority to regulate, and then address its limited resources to the risks on a priority basis. The agency would not find it useful to waste resources on insignificant risks where greater ones exist. Furthermore, where the agency can know in advance the range of substances it can regulate, it might save industry and the economy money by developing comprehensive plans for regulation of multiple carcinogens.

It should also be remembered that section 6(b)(5) standards are not permanent fixtures. They are based on "the best available evidence" and can be amended as new, more accurate information is discovered.<sup>167</sup> The OSH Act also provides for a system of variances, that delay individual compliance for good cause.<sup>168</sup> Likewise, enforcement proceedings before the Occupational Health and Safety Review Commission, an independent commission, provide industry with additional procedural protections.<sup>169</sup>

Finally, the Cancer Standard might offer some stability to the reviewing courts' participation in standard promulgation. The judicial struggles that have centered around permissible exposure levels during OSHA's history have been misguided. Complex questions of science have been tangled up in the adversarial system and have thwarted systematic agency response to health dangers. Employees have paid most dearly for this by risking their physical welfare. The people and the nation have paid by funding an inefficient agency, and industry has suffered from inconsistent decisions and policies that make their development and growth unpredictable. Unfortunately, *American Petroleum Institute* only clouds the future of OSHA's regulatory approach to carcinogens.

GEORGE B. BLACKMAR

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167. See 29 C.F.R. § 1990.111(i).

168. OSH Act § 6(b)(6), (d), 29 U.S.C. § 655(b)(6), (d) (1970).

169. OSH Act § 10(a), (b), 29 U.S.C. § 659(a), (b). See Berger & Riskin, *Economic and Technological Feasibility in Regulating Toxic Substances Under the Occupational Safety and Health Act*, 7 *Ecol. L.Q.* 285, 301-11 for a general discussion of OSHRC's review of OSHA's enforcement of standards.

