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Resisting Regulation with Blue Ribbon Panels

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I. INTRODUCTION

Modern health, safety, and environmental regulations rely heavily on scientific information. Consequently, disputes over the reliability of scientific studies, the proper interpretation of scientific data, and the inferences that may appropriately be drawn from an existing body of scientific information arise with great regularity as agencies like the Environmental Protection Agency (EPA), the Occupational Safety and Health Administration (OSHA), and the Food and Drug Administration (FDA) go about their day-to-day business of implementing protective regulatory statutes.[1] These disputes typically raise issues of such mind-numbing complexity that they are virtually incomprehensible to agency decision makers who generally lack scientific training in the specific areas of scientific knowledge that those disputes invoke. Decision makers must therefore rely upon scientists who are familiar with the relevant research to assess the quality of the scientific studies, interpret the scientific data, and define the range of proper conclusions that can be drawn from the data. At the same time, however, the existing body of scientific information is rarely sufficient, by itself, to dictate a "scientifically correct" resolution of such disputes, and regulatory decisions necessarily turn on both scientific information and regulatory policy.[2] Regulatory decision makers therefore face the daunting task of resolving scientific disputes, defining where the science stops and where the policymaking begins, and determining the content of the policy that must necessarily fill the gaps left by incomplete

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1. *See* SHEILA JASANOFF, THE FIFTH BRANCH: SCIENCE ADVISERS AS POLICYMAKERS 207 (1990); WENDY WAGNER, RESCUING SCIENCE FROM POLITICS (forthcoming 2006); Wendy E. Wagner, *The Science Charade In Toxic Risk Regulation*, 95 COLUM. L. REV. 1613, 1639-40 (1995).

2. Thomas O. McGarity, *Substantive and Procedural Discretion in Administrative Resolution of Science Policy Questions: Regulating Carcinogens in EPA and OSHA*, 67 GEO. L.J. 729, 732-49 (1979); Wagner, *supra* note 1, at 1619.

or inadequate scientific information.

One tried and true decision-making aid in this context is the "blue ribbon panel," which is composed of neutral experts charged with answering specific questions that have been carefully crafted to limiting the panel's input to scientific issues while leaving the policymaking to agency decision makers.[3] The relevant agency can either appoint the blue ribbon panel on its own or contract with an outside body, like the National Research Council of the National Academies of Sciences (NAS), to assemble the panel and oversee its deliberations. In fact, Congress frequently requires agencies to enter into such contracts with NAS to address especially controversial scientific issues.[4] When such panels can achieve consensus, their reports can be very useful to the agency, both for the information that they provide, and for the legitimacy that they can lend to the agency's ultimate decision. Because the "blue ribbon panel" approach is time-consuming and expensive, it is not appropriate for every regulatory action involving science, but it is ideal for especially contentious scientific disputes that otherwise tend to paralyze regulatory decision-making.

Because science plays such a prominent role in the regulatory process, and because the science is invariably contestable, the entities that regularly participate in that process have a strong incentive to present the existing body of scientific information to the agency in a way that advances their preferred regulatory outcomes. One way for a regulated entity to accomplish this result is to assemble its own "blue ribbon panel," populate it with scientists who are likely to resolve disputes consistently with the regulated entity's preferred policies, charge the panel with questions that encompass both science and policy, and subtly attempt to influence the outcome of the panel's deliberations.[5] The panel members are paid generous honoraria or are hired as consultants, and they are flown, all expenses paid, to commodious locations for their periodic meetings.[6] The staff support that the regulated entity provides to the panel creates a built-in mechanism by which it can shape the panel's deliberations. Scientists from

3. *See* ENVTL. PROT. AGENCY, ACHIEVING CLEAN AIR AND CLEAN WATER: THE REPORT OF THE BLUE RIBBON PANEL ON OXEGENATES IN GASOLINE (1999), *available at* http://www.epa.gov/oms/consumer/fuels/oxypanel/r99021.pdf.

4. *See* 7 U.S.C. § 136d(d) (2000) (providing for referral of "questions of scientific fact" by the hearing examiner to a committee of the National Academy of Sciences).

5. Although public interest groups have the same incentive to assemble blue ribbon panels, they generally lack the resources to pay the scientists for their time and travel and to provide staff support to such panels. Therefore, the technique has generally been employed by regulated entities, rather than representatives of the beneficiaries of regulation.

6. *See, e.g.*, ALICIA MUNDY, DISPENSING WITH THE TRUTH 109-10, 119 (2001) (noting that an expert panelist for manufacturer of Fen-phen was paid $5000 per day plus expenses).

the regulated entities are made available to offer input and advice, but the meetings are otherwise typically private affairs.[7]

This Article will explore the use and abuse of "blue ribbon panels" by regulated entities in regulatory decision-making involving contested scientific issues. Part II of the Article will present a case study of one company's use of such a panel to avoid more stringent regulation of the manufacture of the metal beryllium. Drawing on the beryllium case study and other examples gleaned from news reports and the literature, Part III will explore the implications of widespread use of this technique for fair and effective health, safety, and environmental decision-making. Finally, Part IV will offer some suggestions for how regulatory agencies should approach industry-sponsored blue ribbon panels.

II. THE BERYLLIUM BLUE RIBBON PANEL

Beryllium is an extremely light, but exceedingly strong metal that is used in a variety of consumer goods ranging from cell phones and golf clubs to dental fixtures.[8] Because the primary use for beryllium in its early years was in the nuclear weapons industry, the history of its adverse effects on human beings is clouded in secrecy.[9] For decades, the primary producer of beryllium, the Brush Wellman Corporation, and the primary user of beryllium, the federal defense agencies, attempted to belittle the health risks that beryllium posed to workers and neighbors of beryllium plants.[10] In their efforts to prevent OSHA and EPA from promulgating protective regulations limiting human exposure to beryllium, they took every opportunity to "manufacture uncertainty" about the science documenting the fact that exposure to beryllium caused lung cancer and a debilitating and usually fatal disease called chronic beryllium disease (CBD), or berylliosis.[11] The primary vehicle that Brush Wellman employed for this purpose was a blue ribbon panel called the Beryllium Industry Scientific

7. *See, e.g.*, Neil Pearce, *Adverse Reactions, Social Responses: A Tale of Two Asthma Mortality Epidemics*, *in* CONTESTED GROUND 57 (Peter Davis, ed. 1996) (noting that members of expert panel hired by manufacturer of fenoterol assembled at Beverly Wilshire Hotel in Beverly Hills for meeting).

8. U.S. Dep't of Labor, Occupational Safety & Health Admin., Safety and Health Topics: Beryllium, http://www.osha.gov/SLTC/beryllium/.

9. Sam Roe, *Decades of Risk: U.S. Knowingly Allowed Workers to be Overexposed to Toxic Dust*, PITTSBURGH POST-GAZETTE, Mar. 30, 1999, at A1 [hereinafter Roe, *Decades of Risk*].

10. Sam Roe, *Lethal Exposure: Brush Mislead Workers, Regulators about Dangers*, PITTSBURGH POST-GAZETTE, Apr. 1, 1999, at A1 [hereinafter Roe, *Lethal Exposure*].

11. David Michaels, *Doubt Is Their Product*, SCI. AM., June 2005, at 96; Roe, *Decades of Risk*, *supra* note 9, at A1.

Advisory Committee (BISAC).

A. Beryllium Manufacture During the Cold War

During World War II, the federal government entered into contracts with Brush's predecessor and other companies to provide beryllium to several government-run laboratories associated with the Manhattan Project.[12] As this massive effort proceeded ahead in complete secrecy, it became clear to government health officials that some small proportion of the workers who were exposed to beryllium dust in laboratories and fabrication plants were suffering from a debilitating lung disease that resulted in shortness of breath and ultimately death.[13] When the officials recommended that the government take measures to reduce workplace exposures to beryllium, the federal facilities and some of their private contractors began to supply respirators to workers, but they took little additional action in the press to develop the atomic bomb for the war effort.[14]

Soon after the war ended, however, a secret report circulating within the newly created Atomic Energy Commission (AEC) noted that the federal government was "acutely interested in maintaining and expanding production of beryllium."[15] The report cautioned that if the incidence of berylliosis in workers became known outside the defense establishment, the outbreak "might be headlined, particularly in non-friendly papers, for weeks and months," and this might in turn "seriously embarrass the AEC and reduce public confidence in the organization."[16] Rather than risk that embarrassment and a potential reduction in beryllium supplies, the AEC and its contractors decided to keep the incidence of berylliosis under wraps.[17]

After a 1943 outbreak of berylliosis among workers and neighbors of a beryllium plant in Lorain, Ohio threatened precisely the public relations fiasco that the AEC feared, it took steps to reduce exposures to beryllium at beryllium processing and weapons manufacturing plants throughout the country.[18] AEC scientists determined that neighbors should be exposed to no more than 0.01 micrograms per cubic meter (μg/m3) in the ambient air, a number that became the very first federal ambient air quality standard

12. Roe, *Decades of Risk*, *supra* note 9, at A1.
13. *Id.*
14. *Id.*
15. *Id.*
16. *Id.*
17. *Id.*
18. *Id.*

years before the enactment of the Clean Air Act in 1970.[19] A workplace exposure standard was more difficult to promulgate, because it would have been impossible to limit exposures in some workplaces to 0.01 µg/m3 at a cost that government and industry officials were willing to pay at the time.[20] The federal workplace limit of 2.0 µg/m3, established in 1949, grew out of a taxicab conversation between an AEC scientist and a medical consultant.[21] That standard remains in place to this day.[22]

For the next twenty-five years, the original standards were enforced not through regulations backed up by civil and criminal penalties, but through clauses in the contracts between AEC and its successor agency, the Department of Energy (DOE), and the private government contractors.[23] This posed a clear institutional conflict of interest, because the AEC and DOE were also responsible for ensuring a continuing supply of beryllium for the nuclear weapons arsenal.[24] Indeed, the very same official was in charge of purchasing beryllium for the AEC and for enforcing the safety provisions in the purchase contracts.[25] While this official faced very little pressure from uninformed workers and neighbors to ensure that the standards were not exceeded, he faced enormous pressure from the military to keep the beryllium supplies flowing. When the AEC threatened during the 1960s to cancel one contract because of safety violations, a general called the relevant agency official to ask: "What are you, out of your goddamn-picking mind? I've got submarines out there. We need missiles."[26] The official soon left the agency to become a top executive at Brush Wellman.[27]

B. Beryllium Risks to Workers

Although the government had established a 2.0 µg/m3 limit for worker exposure to beryllium, workers were routinely exposed to levels exceeding 100 µg/m3 during the 1950s.[28] The owner of the primary manufacturing plant at the time, the Brush Beryllium Company, recognized that the

19. *Id.*
20. *See id.*
21. Michaels, *supra* note 11, at 98; Roe, *Decades of Risk*, *supra* note 9, at A1.
22. The DOE issued a new role, reducing the acceptable workplace exposure level by a factor of ten. Michaels, *supra* note 11, at 98.
23. Roe, *Decades of Risk*, *supra* note 9, at A1.
24. *Id.*
25. *Id.*
26. *Id.*
27. *Id.*
28. *Id.*

company was imposing health risks on its workers and that this could give rise to legal liability if the workers ever learned of those risks.[29] A government document from the 1950s noted that Brush Beryllium Company attorneys were "in agreement that should negligence suits be brought against Brush in the future, the company would be in a very vulnerable position because it could be pointed out that evidence of overexposure was available and no direct action was taken to lower the exposures."[30]

As the old beryllium plants were closed and replaced during the 1960s, the newer plants were designed to keep workplace exposures below the 2.0 µg/m3 level, though this was not always accomplished.[31] By the mid-1970s, however, evidence began to accumulate that beryllium causes lung cancer in human beings.[32] Since there is no safe level of exposure to a carcinogen, the most effective way to protect workers is to set the standard as low as possible to reduce the cancer risk. Additional controls, however, would have entailed large costs, and the industry therefore strongly resisted both the characterization of beryllium as a human carcinogen and attempts by OSHA and DOE to reduce allowable exposure levels.

C. OSHA Attempts to Set A Protective Standard.

On October 14, 1975, OSHA proposed to promulgate a federal occupational health standard for beryllium that would reduce the existing standard of 2.0 µg/m3 to 1.0 µg/m3.[33] OSHA based the proposal on its determinations that at least a dozen workers per year were being diagnosed with berylliosis and that beryllium had been shown to cause cancer in laboratory animals.[34] It also relied on three controversial studies concluding that beryllium exposures caused cancer in workers at beryllium production plants.[35] A criteria document prepared by OSHA's sister agency, the National Institute for Occupational Safety and Health (NIOSH), provided scientific support for OSHA's rulemaking.[36]

The proposed rule took Brush Wellman officials completely by surprise,

29. *Id.*

30. *Id.*

31. *Id.*

32. Occupational Exposure to Beryllium; Notice of Proposed Rulemaking, 40 Fed. Reg. 48,814, 48,817 (Oct. 17, 1975) (to be codified at 29 C.F.R. pt. 1910).

33. *Id.* at 48,814.

34. *Id.* at 48,816, 48,818.

35. *Id.*; *see also* Testimony of Edward U. Baier, Deputy Dir., Nat'l Inst. for Occupational Safety & Health, Ctr. for Disease Control, before the Occupational Safety & Health Admin. 3-4 (Aug. 19, 1977) (on file with author) [hereinafter Baier Testimony].

36. Baier Testimony, *supra* note 35, at 3-4.

and they were not pleased. Given the company's close relationship with the Department of Energy (the entity now responsible for managing nuclear weapons contractors), they expected more advance notice. The CEO of Brush Wellman told his lawyers that he was determined to fight the rule "with every weapon we had," and he expected it to be the top priority both for his company and for the law firm that it hired.[37] The company and its lawyers would challenge the legal basis for the proposal, but it would also attack the science underlying the agency's conclusions and apply other "informal pressures" through its allies in Congress and the Administration.[38]

The rulemaking process culminated in a three-week formal hearing before a panel of OSHA officials in which attorneys from the agency, the company, and labor unions presented experts to testify and be cross-examined on relevant scientific and engineering issues.[39] A witness for NIOSH testified that the evidence of beryllium's carcinogenicity justified increasing the stringency of the standard to ensure that workers received the lowest feasible exposures.[40] In the witness's opinion, "[p]robably no compounds known to man give so consistent a carcinogenic response in so many animal species as do the compounds of beryllium."[41] Moreover, the fact that beryllium caused cancer at relatively low exposure levels in laboratory animals meant that beryllium compounds were "considered to be among the most potent carcinogens that have ever been tested in animals.[42] The NIOSH witness also relied upon human epidemiological studies conducted over several years by Dr. Thomas Mancuso and his colleagues and on a very recently completed study undertaken for NIOSH by David L. Bayliss and Joseph K. Wagoner, a special assistant to the Director of NIOSH.[43] Relying on "the cumulative evidence presented," NIOSH recommended that "beryllium be classified as a carcinogen."[44] Since "no safe level has yet been demonstrated for a carcinogen," NIOSH recommended that "beryllium be controlled as low as possible in the industrial setting so as to materially reduce the risk of cancer."[45]

To make its case on the scientific issues, Brush Wellman hired an

37. Sam Roe, *Death of a Safety Plan*, PITTSBURGH POST-GAZETTE, Mar. 31, 1999, at A1.

38. *Id.*

39. *Id.*

40. *See* Baier Testimony, *supra* note 35, at 3-4.

41. *Id.* at 3.

42. Deborah Shapley, *Occupational Cancer: Government Challenged in Beryllium Proceeding*, 198 SCIENCE 898, 898 (1977); Baier Testimony, *supra* note 35, at 3.

43. Baier Testimony, *supra* note 35, at 3-4.

44. *Id.* at 4.

45. *Id.*

impressive array of witnesses, including Dr. Merril Eisenbud, a professor at New York University School of Medicine, and Dr. Brian MacMahon, a well-known epidemiologist at the Harvard School of Public Health. They argued that the animal studies were by and large irrelevant, because they did not use the form of beryllium (beryllium copper) to which seventy percent of the workers were exposed.[46] They were extremely critical of the epidemiological studies because an earlier version of the Bayliss and Wagoner study had found no increase in the incidence of lung cancer and because the more recent version of the study suffered from what they believed to be several serious flaws.[47]

A careful examination of the underlying data undertaken by industry consultants did reveal some information that tended to undermine the NIOSH authors' conclusions. In particular, thirty of the forty-six employees who died of lung cancer had been working at the beryllium plant for less than one year. In the minds of the industry consultants, this was too brief an exposure to yield a credible conclusion concerning the capacity of beryllium to cause cancer in humans.[48] This was particularly evident in one of the lung cancer victims who was hired and terminated on the same day.[49] They also criticized the authors' failure to correct for age and smoking habits, two potentially serious confounding factors.[50]

D. The Industry Reacts

Concluding that it was unlikely to prevail on the merits in the formal regulatory proceedings, Brush Wellman decided "that the only chance we had was to indict the government for bad faith."[51] A Brush spokesperson therefore charged that NIOSH had concealed information, abused its power, and generally treated the industry like "the enemy."[52] Through its public relations company, Brush convened a panel of eight scientists, six of whom were past or present company consultants,[53] at the Cosmos Club in Washington, D.C. and asked them to draft a critique of the cancer studies upon which NIOSH and OSHA were relying.[54] In an open letter to the

46. Shapley, *supra* note 42, at 898.
47. *Id.*
48. *Id.* at 899.
49. *Id.* at 901.
50. *Id.* at 899.
51. Roe, *Death of a Safety Plan*, *supra* note 37, at A1.
52. *Id.*
53. Letter from Joseph Odorcich, Vice President, Safety & Health Dep't, et al. to Joseph A. Califano, Jr., Sec'y of Health, Educ., & Welfare and Hon. F. Ray Marshall, Sec'y of Labor 1 (Mar. 20, 1978) (on file with author).
54. Roe, *Death of a Safety Plan*, *supra* note 37, at A1.

Secretaries of Labor and Health Education and Welfare (HEW), the scientists characterized the studies as "shocking examples of the shoddy scholarship and questionable objectivity utilized in making important national regulatory decisions."[55] The letter, which the public relations firm also sent to reporters and members of Congress, did not identify any of the authors as consultants for the beryllium industry and therefore did nothing to dispel the impression that it had been spontaneously generated by the outraged scientists.[56]

Two weeks after the scientists' letter went out, Brush Wellman attached it to a letter to the Associate Director for Regulatory Policy and Management at the Office of Management and Budget (OMB) urging him to "take appropriate action to correct this shocking exhibition of misconduct on the part of Federal regulators" and demanding that OMB "prevent any precipitous action by OSHA until this matter has been thoroughly reviewed and resolved."[57] At roughly the same time, OSHA received letters from prominent senators and congresspersons demanding, among other things, a "truly independent review" of the science underlying OSHA's position on beryllium's carcinogenicity.[58]

The public relations assault had its intended effect. Although the rulemaking record was complete, the Assistant Secretary of Labor for OSHA, Eula Bingham, wrote to HEW's Assistant Secretary for Health, Donald Millar, to request that he convene a "group of senior governmental scientists to review all the epidemiological, clinical, and experimental data and provide us with an assessment that will help us resolve the issues" that the industry consultants had raised.[59] In her response to the letter written by the Cosmos Club group of scientists, she promised to "hold in abeyance the issuance of a final beryllium standard until we have received" comments from the government scientists.[60]

Thus, the government responded to the industry-appointed blue ribbon

55. Letter from Dr. Merril Eisenbud, Prof. of Envtl. Med., New York Univ. Med. Ctr., et al. to Joseph A. Califano, Jr., Sec'y of Health, Educ., & Welfare and Hon. F. Ray Marshall, Sec'y of Labor 1 (Feb. 10, 1978) (on file with author).

56. Roe, *Death of a Safety Plan*, *supra* note 37, at A1.

57. Letter from Martin B. Powers, Vice President, Brush Wellman, Inc. to Wayne Grandquist, Assoc. Dir. for Regulatory Policy & Mgmt., Office of Mgmt. & Budget 2 (Feb. 24, 1978) (on file with author).

58. Roe, *Death of a Safety Plan*, *supra* note 37, at A1; Letter from Orrin G. Hatch, United States Senate to Hon. F. Ray Marshall, Sec'y of Labor 1 (Mar. 21, 1978) (on file with author).

59. Letter from Eula Bingham, Assistant Sec'y, Occupational Safety & Health Admin. to Julius Richmond, Assistant Sec'y for Health, Dep't of Health, Educ., & Welfare 1 (Mar. 8, 1978) (on file with author).

60. *Id.*

panel of private sector scientists by proposing to empanel a blue ribbon panel of government scientists. This solution was totally unacceptable to the industry, which objected to any "review being conducted by governmental scientists at the direction of the Department within which the studies were originally conducted."[61] The industry was understandably concerned that a blue ribbon panel composed of government scientists would lack sufficient objectivity. It did not comment on the objectivity of the blue ribbon panel that it had convened at the Cosmos Club.

With matters at an impasse, the leader of the Cosmos Club group, Dr. Merril Eisenbud, met with Dr. Millar to urge him to take the issue of beryllium's carcinogenicity away from government officials and lawyers and give it to the scientists from both government and industry. Dr. Eisenbud suggested that "the main issues could be resolved during a one-day conference if the lawyers would stay on the sidelines."[62] He argued that "[t]he decisions should be reached by the scientific and technical representatives and the role of the lawyers should be limited to translating the decisions into the simplest possible memorandum of understanding that could serve as the basis for the OSHA standard."[63] He urged Millar to meet with a Brush Wellman vice-president to discuss co-sponsoring such a scientific meeting.[64]

Although the Department of Defense (DOD) had not played a significant role in the OSHA hearings, it became very interested in the outcome of the OSHA effort when DOD officials learned that one of the two national suppliers of beryllium, Brush Wellman's competitor Kawecki Berylco Industries, might quit making beryllium, rather than comply with stringent OSHA standards.[65] A special DOD task force concluded that a decision by both companies to cease beryllium production would have serious national security implications.[66] The government could, of course, pay for the improvements necessary to meet the OSHA standards through its contracts with the companies, but that would cost tens of millions of dollars, and the Department of Defense did not want to include that expense in its budget.[67]

61. Letter from Patrick F. McCartan, Cousel for Brush Wellman, Inc. to Eula Bingham, Assistant Sec'y, Occupational Safety & Health Admin. 1 (Mar. 22, 1978) (on file with author).

62. Letter from Dr. Merril Eisenbud, Prof. of Envtl. Med., New York Univ. to Dr. J. Donald Millar, Dir., Bureau of State Servs., Ctr. for Disease Control 1 (May 26, 1978) (on file with author).

63. *Id.*

64. *Id.*

65. Roe, *Death of a Safety Plan*, *supra* note 37, at A1.

66. *Id.*

67. *Id.*

Instead, the task force asked the Secretary of Energy to attempt to "moderate" the OSHA proposal.[68]

Secretary of Energy James Schlesinger then wrote to Secretary of Labor Ray Marshall and Secretary of Health, Education and Welfare Joseph Califano to bring to their attention the fact that, "[t]he loss of beryllium production capability would seriously impact our ability to develop and produce weapons for the nuclear stockpile and, consequently, adversely affect our national security."[69] Because "significant questions have been raised within the scientific community concerning the quality and adequacy of the data on which change of the standard is presently based," DOE demanded an "independent peer review" of all available data on the effects of beryllium to address the adequacy of the present standard before issuing the proposed new standard."[70] Secretary of Defense Harold Brown sent a similar letter to Marshall.[71]

Accepting Schlesinger's recommendation, Secretary Califano then wrote the head of the Cosmos Club group, Dr. Merril Eisenbud, to tell him that that HEW would appoint "an outside group of scientists to review the experimental and epidemiological evidence."[72] One of the other members of the Cosmos Club group wrote to Brush Wellman's vice-president to congratulate him on this coup, noting that "Califano's letter does [make it] look as if you have indeed stirred up a proper re-approach to the subject, especially with the appointment of an outside group of scientists to review things."[73]

To Brush Wellman's chagrin, the panel, which was chaired by University of North Carolina epidemiologist Dr. Carl Shy, found the science underlying the proposal to be of sufficient quality to justify regulatory action.[74] The panel found that the existing animal studies were "credible in showing carcinogenicity of beryllium in at least two species" and that "the epidemiological evidence is suggestive that beryllium is a

68. *Id.*

69. Letter from James R. Schlesinger, Sec'y, Dep't of Energy to Hon. F. Ray Marshall, Sec'y of Labor 1 (Aug. 30, 1978) (on file with author).

70. *Id.*

71. Roe, *Death of a Safety Plan*, *supra* note 37, at A1.

72. Letter from Joseph A. Califano, Jr., Sec'y of Health, Educ., & Welfare to Dr. Merril Eisenbud, Prof. of Envtl. Med., New York Univ. 1 (Aug. 30, 1978) (on file with author).

73. Letter from Dr. H.S. VanOrdstrand, Dep't of Pulmonary Disease to Martin B. Powers, Vice President, Brush Wellman, Inc. 1 (Sept. 6, 1978) (on file with author).

74. Letter from Dr. Carl M. Shy, Prof. of Epidemiology, Univ. of North Carolina Med. Sch. to Dr. William H. Foege, Dir., Ctr. for Disease Control 1 (Oct. 12, 1978) (on file with author).

carcinogen in man."[75] The evidence was only "suggestive" because "alternative explanations for the positive findings" had not been definitively excluded and because the three recent papers that most indicated carcinogenicity still required "some revisions after journal peer review prior to publication."[76] Nevertheless, "it would be imprudent from a public health perspective to delay our judgment about beryllium exposure of current workers, until these studies were completed."[77]

The letter precipitated a flurry of responses from members of the Cosmos Club group. To a letter from Merril Eisenbud, Shy was deferential, but unrepentant.[78] Like Eisenbud, Shy was troubled by the fact that workers exposed for less than a year appeared to suffer cancer at a greater frequency than those who had been exposed for four years or more.[79] Eisenbud's letter had, however, helped clarify the matter by pointing out that many of the short-term exposure cancer victims had been exposed to the highest levels of beryllium during the uncontrolled period of the 1940's.[80] Some or all of these workers may have worked for only short periods because the high exposures made them acutely ill.[81]

In his letter to Dr. Shy, Cosmos Club group member Brian MacMahon was charitable toward the committee's report, but warned that the committee may have been duped by the Bayliss-Wagoner paper.[82] Dr. MacMahon wrote that Shy's comments on the paper "were reasonable enough but if you had any concept of the skullduggery that has gone on in the historical development of this paper I do not believe that you would have any confidence that the findings as now presented are reasonably error-free or that they result from an objective effort to ascertain the facts."[83]

Dr. MacMahon's innuendo was at least partially validated more than a year later when a dispute erupted between the authors of the Bayliss-

75. *Id.* at 1-2.

76. *Id.* at 2.

77. *Id.* at 4.

78. Letter from Dr Dr. Carl M. Shy, Prof. of Epidemiology, Univ. of North Carolina Med. Sch. to Dr. Merril Eisenbud, Prof. of Envtl. Med., New York Univ. 1 (Nov. 17, 1978) (on file with author).

79. *Id.*

80. *Id.*

81. *Id.*

82. Letter from Dr. Brian MacMahon, Prof. of Epidemiology, Harv. Univ. to Dr. Carl M. Shy, Prof. of Epidemiology, Univ. of North Carolina Med. Sch. 1 (Feb. 13, 1979) (on file with author).

83. *Id.*

Wagoner paper.[84] By the time that the study was published in the *Journal of Environmental Research*, its preparation had effectively been taken over by Wagoner and OSHA scientist Dr. Peter Infante.[85] David Bayliss, who had worked on the study as a NIOSH employee but was by that time employed by the EPA, wrote to the head of the Centers for Disease Control on November 12, 1980, to complain that the final version of the study had been published without his approval or permission, despite the fact that he was listed as a co-author.[86] Bayliss complained that the paper contained "several serious shortcomings" that other scientists had called to the authors' attention but had not been corrected.[87] Bayliss alleged that as Dr. Wagoner (his superior at NIOSH) became more involved in the preparation of the paper, it seemed increasingly "motivated . . . by a desire to provide evidence in support of the proposed OSHA standard and of the position advanced by OSHA that beryllium should be treated as a human carcinogen."[88] Bayliss believed that "there is now in the public domain a report attributed in part to me and bearing the apparent imprimatur of agencies of the United States government, which is at best misleading and by even the lowest common denominator of scientific standards should not be permitted to stand unchallenged in its present form."[89]

The beryllium industry was delighted to hear that Bayliss had disassociated himself from the paper, and it made sure that the Bayliss letter was heavily publicized.[90] NIOSH officials, however, stood by the study as published and noted that it remained validated by the positive animal studies.[91] In a letter to noted British epidemiologist Sir Richard Doll, New York University epidemiologist Norton Nelson said he believed some of Bayliss' allegations, but had concluded that "the basic findings survive, leading to (generally) a conclusion of significant increases in lung cancer."[92]

As the scientific controversy was brewing, the new owner of Kawecki

84. Letter from David L. Bayliss, Carcinogen Assessment Group, Envtl. Prot. Agency to Dr. William H. Foege, Dir., Ctr. for Disease Control 1 (Nov. 12, 1980) (on file with author).

85. *Id.* at 1-2.

86. *Id.* at 2.

87. *Id.*

88. *Id.* at 3.

89. *Id.* at 5.

90. R. Jeffrey Smith, *Beryllium Report Disputed by Listed Author*, 211 SCIENCE 556, 556-57 (1981).

91. *Id.* at 556.

92. Letter from Norton Nelson, Prof., New York Univ. Med. Ctr. to Sir Richard Doll, M.D., Prof., Green College (Jan. 12, 1981) (on file with author).

> Berylco decided to get out of the beryllium production business even without the impetus of a new OSHA standard.[93] This left Brush Wellman as the government's only domestic supplier of beryllium.[94] Operating from this very strong negotiating position, Brush Wellman entered into an agreement with the DOE under which it received a thirty-five percent increase in the price that it charged for beryllium. The DOE agreed not to work with other companies to develop an alternative supply of beryllium, and it promised to "exert its best efforts to convince OSHA to revise its proposed beryllium standard."[95]

Although the negotiations took place at very high levels in the government, Dr. Bingham (the OSHA director) later recalled that the Department of Labor "got the message that the Department of Defense and Energy indicated that what was going forward caused a problem with national defense."[96] To Bingham's great disappointment, the Department of Labor in 1979 acceded to pressure from DOE and DOD and put the beryllium proposal on the back burner,[97] where it has remained until this day. Brush Wellman continued to produce beryllium at its aging plant where workers were frequently exposed to levels of beryllium that exceeded even the less stringent 2.0 µg/m3 OSHA standard.[98]

E. The Oxford Conference

Although the OSHA threat disappeared, the scientific controversy did not. The industry still faced the serious possibility that private and international standard-setting agencies would act on the accumulating scientific studies indicating that beryllium was a human carcinogen and that the aging 2.0 µg/m3 standard was not preventing workers from contracting berylliosis. Not all of the processes that Brush Wellman employed were capable of meeting the 2 µg/m3 standard on a continuing basis, and scientists were increasingly expressing their doubts that the standard was stringent enough in any event.[99] If beryllium caused cancer, then a 2.0 µg/m3 standard was clearly not adequate to protect workers, and

93. Roe, *Death of a Safety Plan*, *supra* note 37, at A1.

94. *Id.*

95. Proposal of Brush Wellman Inc. for Upgrading of Beryllium Metal Plant at Elmore, Ohio (1981) (on file with author); Roe, *Death of a Safety Plan*, *supra* note 37, at A1.

96. Enric Volante & Rhonda Bodfield Sander, *Protection for Workers Stymied by Firm, Allies*, ARIZ. DAILY STAR, May 9, 1999, at A1.

97. *Id.*; Roe, *Death of a Safety Plan*, *supra* note 37, at A1.

98. Roe, *Death of a Safety Safety Plan*, *supra* note 37, at A1.

99. Memorandum from Hugh D. Hanes, Vice President, Brush Wellman, Inc. to Jere Brophy et al., Beryllium Supply to the Government 1 (Mar. 12, 1992) (on file with author).

the neighbors of beryllium plants were also at risk of contracting lung cancer. Worst of all, once former workers, neighbors, and consumers of beryllium-containing products got wind of the fact that beryllium caused cancer, the company could expect "widespread litigation," that would, in the words of a company attorney, lead to "a modern day gold rush."[100]

Brush Wellman consultants therefore continued to closely monitor scientific developments involving beryllium. In mid-1983, Dr. Brian MacMahon attended a conference at Oxford University hosted by preeminent epidemiologist Dr. Richard Doll. Dr. MacMahon related to Brush Wellman that Gary Flamm of the FDA presented a paper on the animal evidence of beryllium carcinogenicity that, in MacMahon's view, indicated "[w]ithout a doubt [that] it is the most powerful metallic cause of cancer."[101] Dr. MacMahon further reported that a scientist from the International Agency for Research on Cancer (IARC), an international standard-setting body associated with the World Health Organization, delivered a paper on the epidemiology of beryllium in which he concluded that "the single most likely explanation of the observations was that beryllium is carcinogenic in man," though there were, of course, "other explanations."[102] MacMahon himself provided background on the Wagoner study (no longer associated with Bayliss), and he told the conference that NIOSH had concluded that the studies should be redone.[103] This almost produced an agreement to take beryllium off the meeting agenda altogether, but Dr. Doll "did not wish to go so far."[104] Instead, the participants agreed that any statement about beryllium would be "followed by a statement that because of the uncertainty as to the reliability of the epidemiologic data, the symposium did not wish to take a position relating to the epidemiologic evidence on beryllium."[105] Although the proceedings were supposed to be kept confidential until the formal papers were published, Dr. MacMahon could "see no particular reason" not to relate them to Brush Wellman's vice-president, "[j]ust so [he didn't] write to Richard Doll about it!"[106] Brush Wellman's interests were thus well served by Dr. MacMahon's presence at the meeting.

100. Roe, *Lethal Exposure*, *supra* note 10, at A1.

101. Letter from Dr. Brian MacMahon, Prof. of Epidemiology, Harv. Univ. to Martin B. Powers, Vice President, Brush Wellman, Inc. (July 13, 1983) (on file with author).

102. *Id.*

103. *Id.*

104. *Id.*

105. *Id.*

106. *Id.*

F. Challenging EPA's Health Effects Document

In the mid-1980s, a new agency entered the regulatory fray. The Environmental Protection Agency prepared a health effects document for beryllium for the purpose of promulgating a hazardous emissions standard for companies, like Brush Wellman, that discharged beryllium compounds into the ambient air.[107] Brush Wellman hired Neil Roth of Roth Associates to help coordinate the company's response to EPA's beryllium risk assessment.[108] In early 1985, Roth reported that the document would be reviewed by a seven-member scientific panel assembled by EPA's Science Advisory Board (SAB), and that the company would have a "receptive ear" in one of the members, Ron Wyzga, who worked for the power industry-funded Electric Power Research Institute.[109]

In anticipation of a panel meeting in early June, Dr. MacMahon wrote to the Executive Secretary of the Environmental Health Committee of the SAB to express his views on the Draft Health Assessment Document.[110] He believed that the section was "comprehensive, clear, well written and generally accurate," except for the document's reliance on the Wagoner epidemiology study.[111] His problem was not that the data were "controversial," but rather that they were "clearly wrong."[112] A second epidemiological study by Dr. Thomas Mancuso was afflicted by the same errors and uncertainties, but had been "less fully explored because of the investigator's unwillingness to release [the underlying data]."[113] Dr. MacMahon concluded that, "[i]n light of these errors and uncertainties, to base a human risk assessment on either of these two sets of data is, in my view, scientific malpractice—in the sense in which that term is used in clinical medicine."[114] Nowhere in the letter did MacMahon mention that he was a long-time paid consultant for Brush Wellman.[115]

In June 1985, Roth reported on conversations that he had with several

107. U.S. ENVTL. PROTECTION AGENCY, HEALTH ASSESSMENT DOCUMENT FOR BERYLLIUM (1987).

108. *See* Memorandum from Neil Roth, Roth Associates, Inc. to Tom Concannon et al., Upcoming Beryllium Hearing 1 (Feb. 7, 1985) (on file with author).

109. *Id.*

110. Letter from Dr. Brian MacMahon, Prof. of Epidemiology, Harv. Univ. to Dr. Daniel M. Byrd III, Executive Sec'y, Envtl. Health Comm. Sci. Advisory Bd., U.S. Envtl. Prot. Agency 1 (May 22, 1985) (on file with author).

111. *Id.*

112. *Id.*

113. *Id.*

114. *Id.*

115. *Id.*

EPA employees subsequent to the SAB panel meeting.[116] David Bayliss, who now worked for EPA's carcinogen assessment group (CAG), reported to Roth that the panel had endorsed the document.[117] The CAG planned to perform some additional calculations using different latency periods and thereafter finalize the document.[118] It did not plan to address MacMahon's criticisms in any comprehensive way.[119] Ron Wyzga, the industry ally on the panel, was surprised to hear from Roth of CAG's response, and he agreed to submit "specific recommendations on what he expects from them."[120] Roth reported that as a result of his efforts, "[a]t a minimum Ron's comments will force them to obtain and process the latest NIOSH life table program or ask us to do it. Knowing Dave Bayliss, this will take him years to do."[121]

As Roth predicted, in September of 1985, the SAB advised the Administrator of EPA that "the draft document merits revision on several critical points."[122] The Committee agreed with CAG that beryllium was "a carcinogen for animal species," but asserted that the animal studies that were appropriate for quantitative risk assessment purposes "lead to estimates which are inconsistent with the expectations from human epidemiological studies."[123] As for the epidemiological studies, the document demonstrated a "thorough understanding of the problems and questions embedded in these data," but "[m]any of the confounding factors that the draft document discusses have quantitative implications that have not been made explicit in the risk calculations."[124] The agency staff should therefore "calculate the quantitative implications of these confounding factors."[125] This was, of course, exactly the reaction that Roth had predicted.[126]

By communicating his conversation with CAG member Bayliss to panel member Wyzga, industry consultant Roth ensured that CAG would not be

116. Memorandum from Neil Roth, Roth Associates, Inc. to J. Butler et al., Revisions to EPA Beryllium Document 1 (June 11, 1985) (on file with author).

117. *Id.*

118. *Id.*

119. *Id.*

120. *Id.*

121. *Id.*

122. Letter from Richard A. Griesemer, Chair, Envtl. Health Comm. and Norton Nelson, Prof., New York Univ. Med. Ctr. to Hon. Lee M. Thomas, Adm'r, U.S. Envtl. Prot. Agency 1 (Sept. 23, 1985) (on file with author).

123. *Id.*

124. *Id.*

125. *Id.*

126. *Id.*

able to disregard the critique of industry consultant MacMahon, thereby ensuring that a final version of the Health Assessment Document (and any subsequently promulgated regulatory requirements) would not be forthcoming for years.

G. The BISAC

At a two-day meeting in 1986, Brush Wellman officials hit upon a plan to shape the evolving science to fit the company's benign view of the hazards that beryllium posed to workers.[127] One critical component of that plan was to formalize the Cosmos Club group into an entity called the Beryllium Industry Scientific Advisory Committee (BISAC).[128] Like the Cosmos Club group, BISAC was chaired by Dr. Merril Eisenbud, and it included the most active members of the Cosmos Club, Dr. Brian MacMahon and Dr. Adrianne Rogers, a colleague of Dr. MacMahon at the Harvard School of Public Health.[129] The final scientist to join BISAC was Dr. Paul Kotin, a well-known toxicologist who had been the first director of the National Institute for Environmental Health Sciences and was later the senior medical officer for the Johns Manville Corporation, a prominent United States manufacturer of asbestos products.[130] Dr. Thomas Markham, Brush Wellman's medical director, rounded out the five-member committee. Its Executive Director was long-time Brush Wellman occupational health specialist Martin Powers.[131]

The reconstituted committee held its inaugural meeting on October 8, 1990 at the Cosmos Club,[132] and it met at least twice a year thereafter. The members were paid two thousand dollars each, plus travel expenses,[133] but individual members also served as consultants to Brush Wellman. Over the next decade Brush Wellmon contributed more than one million dollars to support BISAC's activities.[134] According to its charter, one of the purposes of the committee was to "develop and implement a strategy to address . . . the perception of beryllium as a human carcinogen."[135] An

127. Sam Roe, *Thought Control: Brush Devised Strategy to Shape Knowledge*, PITTSBURGH POST-GAZETTE, Apr. 2, 1999, at A1 [hereinafter Roe, *Thought Control*].

128. *Id.*

129. Letter from Martin B. Powers, Vice President, Brush Wellman, Inc. to Tom Hall, Consumer Affairs Office, Dep't of Labor 1 (Sept. 16, 1977) (on file with author).

130. Roe, *Thought Control*, *supra* note 127, at A1.

131. Minutes of Beryllium Industry Scientific Advisory Committee (BISAC) Meeting 1 (Oct. 8, 1990) (on file with author).

132. *Id.*

133. Roe, *Thought Control*, *supra* note 127, at A1.

134. *Id.*

135. *Id.*

internal company document suggested that the committee would "provide the scientific basis for our cancer strategy."[136] Two other issues also dominated BISAC's deliberations: (1) the curious resurgence of Chronic Beryllium Disease (CBD) at Brush Wellman plants years after Brush Wellman scientists had concluded that the 2.0 µg/m3 standard had all but eradicated the disease; and (2) the intriguing possibility of reducing the incidence of CBD by screening susceptible workers out of the workplace through genetic testing.

1. Testing for CBD

At its July 1991 meeting, BISAC agreed to convene a workshop aimed at standardizing protocols for a more sensitive probe for berylliosis called LTT testing.[137] Later that year, the committee met with representatives of the DOE and other beryllium users, and they agreed "that two meetings were in order."[138] The first would be a workshop "to quickly develop protocols for testing, analysis and follow-up," and the second would be "a more comprehensive conference . . . to assess the meaning of the data generated and the efficacy of the programs to that date."[139] The workshop, which was held in February of 1992 in Washington, D.C.,[140] was attended by representatives of the relevant government agencies, the beryllium industry, the United Steelworkers Union, and one nonprofit worker advocacy group.[141] Although the participants discussed the pros and cons of establishing a "national database for the consolidation of all beryllium LTT," the group did not reach a consensus on that question.[142] The industry representatives were concerned that DOE's screening efforts were "proceeding at a pace that could be summarized as 'too much, too fast,'" but the representatives of the labor unions disputed this characterization.[143] At the next BISAC meeting, the committee concluded that DOE was not likely to heed industry concerns that the LTT testing program was "too ambitious in both scope and speed of execution."[144]

Given that the LTT screening was likely to go forward despite its

136. *Id.*

137. Minutes of BISAC Meeting 1-2 (July 25, 1991) (on file with author).

138. Minutes of BISAC Meeting 2 (Oct. 16-17, 1991) (on file with author).

139. *Id.*

140. Minutes of Joint U.S. Dep't of Energy and Beryllium Industry Scientific Advisory Comm. Workshop Meeting on Lymphocyte Transformation Testing of Beryllium Workers 1 (Feb. 3-4, 1992) (on file with author).

141. *Id.* at Attachment II.

142. *Id.* at 4.

143. *Id.* at 5.

144. Minutes of BISAC Meeting 1 (Apr. 23, 1992) (on file with author).

reservations, BISAC provided its input on what information from the screening program should be communicated to Brush Wellman employees.[145] Early reports from one hundred seventy-two employees that had been tested at one of Brush Wellman's plant indicated that five of the tests were abnormal and four were considered "borderline."[146] At the other plant, eight of one hundred forty-four were abnormal and five were borderline.[147] Of the eight abnormal tests at the first plant, three cases had been confirmed and five were being re-tested.[148] Although the abnormal and borderline cases were of sufficient importance, the committee was interested in the breakdown, and the members agreed that "in order to avoid undue anxiety on the part of the employee, employee notification should be confined to confirmed cases."[149]

By July of 1992, the National Institute for Environmental and Health Science (NIEHS) had agreed to join BISAC and the DOE in sponsoring the suggested international conference, but it was not clear that it would be limited to CBD.[150] In a letter to his counterpart at DOE, the BISAC Chairman strongly recommended that the conference not take up the question of the carcinogenicity of beryllium.[151] By January of 1993, however, a tentative agenda for the meeting indicated that the entire second day would be devoted to carcinogenicity-related issues.[152] BISAC then concluded that it would not sponsor the meeting after all.[153]

2. The Genetics of CBD

BISAC understood that "[i]f techniques could be developed to determine whether an individual is predisposed to CBD it might be possible to prevent the disease by pre-employment screening."[154] The committee therefore supported the work of Italian scientist Cesare Saltini, who also did work at Johns Hopkins University. In early 1991, BISAC decided to devote fifty thousand dollars to Saltini's work.[155] Brush Wellman's 1991

145. Minutes of BISAC Meeting 2 (July 8, 1993) (on file with author).

146. *Id.*

147. *Id.*

148. *Id.*

149. *Id.*

150. Letter from Dr. Merril Eisenbud, Prof. of Envtl. Med., New York Univ. to Paul F. Wembach 1 (July 13, 1992) (on file with author).

151. *Id.* at 2.

152. Letter from Dr. Merril Eisenbud, Prof. of Envtl. Med., New York Univ. to BISAC, Attachment (Jan. 30, 1993) (on file with author).

153. Draft Minutes of October, 1993 BISAC Meeting 4 (Oct. 1993) (on file with author).

154. Merril Eisenbud, Summary BISAC Actions 1 (Oct. 14, 1991) (on file with author).

155. BISAC, Minutes of Meeting 2 (Apr. 18, 1991) (on file with author).

five-year strategic plan projected that the company would support Dr. Saltini's research at a level of thirty thousand dollars per year for the next three years.[156] In a letter soliciting monetary support for BISAC from other companies manufacturing and using beryllium, Brush Wellman's vice-president for environmental and governmental affairs noted BISAC's role in sponsoring Dr. Saltini's research and stressed that it "should lead to tests which will allow pre-screening of people who are sensitive to beryllium."[157]

As Dr. Saltini's work continued to show promising results, BISAC invited him to attend the committee's April 1993 meeting along with representatives from labor unions, DOE, EPA, OSHA, and other beryllium companies.[158] At the meeting, a labor representative expressed "concern about the confidentiality aspects of genetic information and the potential for abuse of the data generated."[159] Labor would "be cautious in agreeing to its use for screening purposes."[160] At a subsequent meeting, however, the BISAC members agreed that "attempts to stop scientific research for fear of its misuse at some later date were inappropriate as well as unrealistic."[161] The group congratulated itself for providing the "seed money" that stimulated research programs on this topic by Dr. Saltini and Dr. Rossman of the University of Pennsylvania Medical Center.[162]

Unfortunately, neither scientist succeeded in identifying a "magic bullet" gene indicating increased susceptibility to CBD, and by late 1996, Dr. Eisenbud urged Brush Wellman to abandon that line of work.[163] At a January 1999 meeting, BISAC concluded that "[e]thical and legal questions involving confidentiality versus medical consideration of disease prevention leave no clear course of action to be taken at this time."[164]

3. Attacking the Science on Carcinogenicity

A Health, Safety, and Environmental Strategic Plan presented to the

156. Robert Rozek, Brush Wellman Inc. Health, Safety and Environmental Strategic Plan 4, Tab 5(d), p. 4 (June 25, 1991) (on file with author).

157. Letter from Hugh D. Hanes, Vice President, Brush Wellman, Inc. to Unidentified Recipient (July 8, 1992) (on file with author).

158. Draft Minutes of BISAC Meeting, Attachment (April 7, 1993) (on file with author).

159. *Id.* at 3.

160. *Id.* at 3.

161. Draft Minutes of BISAC Meeting 2 (July 8, 1993) (on file with author).

162. *Id.* at 2.

163. Letter from Dr. Merril Eisenbud, Prof. of Envtl. Med., New York Univ. to Daniel A. Skoch, Vice President, Brush Wellman Inc. (Dec. 5, 1996) (on file with author).

164. Minutes of BISAC Meeting, Revised Draft 3 (Jan. 28-29, 1999) (on file with author).

Brush Wellman Board of Directors on June 25, 1991 outlined strategies for dealing with anticipated new scientific information on beryllium's toxicity, one of which was to "[c]hallenge unscientific or unreasonable regulations, studies or other government actions."[165] Among other things, Brush Wellman would dispute the upcoming revised NIOSH cancer study, challenge an anticipated air quality carcinogen standard by the Mine Safety and Health Administration, challenge EPA's upcoming drinking water standard for beryllium, and challenge an upcoming EPA quantitative risk assessment.[166]

The updated NIOSH study, now under the supervision of Dr. Elizabeth Ward and Dr. Andrea Okun, reaffirmed Dr. Wagoner's earlier conclusion that workplace exposure to beryllium caused cancer in human beings.[167] At its July 11, 1991 meeting, the BISAC reviewed the still unpublished Ward & Okun study and concluded that it "provided no basis for identifying beryllium as a carcinogen."[168] Dr. MacMahon agreed to prepare a statement to that effect.[169] The committee also suggested that the industry should suggest that "an international panel of beryllium experts be convened to address all pertinent beryllium health issues."[170]

A week later, Brush Wellman's President and CEO, Gordon D. Harnett, issued an ultimatum to Dr. J. Donald Millar, the head of NIOSH.[171] According to Harnett, Brush Wellman had reanalyzed the new Ward & Okun data and concluded that "when appropriately adjusted for smoking and geographic location," the results "retain no statistical significance."[172] Harnett demanded that NIOSH give the company "adequate advance notice of the publication journal" so that Brush Wellman could "contact the editor and request publication of our rebuttal in the same issue."[173] The CEO warned that the dispute over the revised study was "fast approaching a situation painfully reminiscent of that of the late 1970's with its acrimonious public debate over the scientific objectivity and competence of NIOSH studies,"[174] a debate, it will be recalled, that was generated

165. *See* Rozek, *supra* note 156, at 4, Tab 5(b).

166. *Id.*

167. Minutes of BISAC Meeting 2 (July 11, 1991) (on file with author).

168. *Id.*

169. *Id.*

170. *Id.*

171. Letter from Gordon H. Harnett, President, CEO, Brush Wellman, Inc. to Dr. J. Donald Millar, Dir., Nat'l Inst. for Occupational Safety & Health 1 (July 18, 1991) (on file with author).

172. *Id.*

173. *Id.* at 2.

174. *Id.*

primarily by Brush Wellman consultants now sitting on BISAC. Brush Wellman did not need to remind NIOSH that the outcome of that debate was that OSHA put aside its proposed workplace standard and that NIOSH backed away from the earlier conclusions of its scientists. Brush Wellman's CEO now warned NIOSH that publication of the Ward & Okun conclusions, "with no more scientific support than is in the study, would be difficult to explain short of a malicious effort to harm the industry."[175]

By October 1991, a study conducted by Dr. Kyle Steenland concluding that beryllium caused cancer in workers had been published in the *Journal of the National Cancer Institute*.[176] In an April 1992 communication to BISAC, Harnett stated that "the 'cancer cloud' that hung over the company was a very serious problem" and that he "hoped the Committee would soon see its way clear to address it."[177] This overture was consistent with the company's desire to "[d]evelop a long-term strategy through BISAC which will place the cancer issue in proper perspective."[178]

The "cancer cloud" darkened somewhat when Dr. Rogers reported to BISAC that a recent study showing that airborne beryllium caused lung cancer in rats had, in her view, been adequately conducted.[179] Although Brush Wellman had taken the position in the OSHA hearings and elsewhere that the older animal studies were of unacceptable quality, Dr. Rogers asserted that "these studies had to be seriously regarded."[180] By July, however, the committee had come up with a response to the animal studies. Rather than "debate whether beryllium is or is not an animal carcinogen," it was determined that the industry should demand that "the question be addressed on a material by material basis, i.e., ore, soluble salts, compounds, alloys, metal, etc., and examine the relevance of each to human cancer."[181] This strategy had the virtue of putting the burden on the government to test each of the materials in laboratory animals or explain why the results of tests of one form of beryllium were relevant to human exposures to a different form. The committee recommended that a seminar be convened to examine the relevance of animal tests to human beings and

175. *Id.*

176. Kyle Steenland & Elizabeth Ward, *Lung Cancer Incidence Among Patients with Beryllium Disease: A Cohort Morality Study*, 83 J. NAT'L CANCER INST. 1380, 1380-85 (1991).

177. Minutes of BISAC Meeting 2 (Apr. 23, 1992) (on file with the author).

178. Memorandum from Hugh D. Hanes, Vice President, Brush Wellman, Inc. to Bob Rozek, Vice President, Brush Wellman Inc., re: Environmental and Governmental Affairs 2 (June 19, 1992) (on file with author).

179. Minutes of BISAC Meeting 4 (Apr. 23, 1992) (on file with the author).

180. *Id.*

181. Minutes of BISAC Meeting 7 (Sept. 8, 1992) (on file with author).

related matters.[182]

Another discouraging development for the industry was the decision by the International Agency for Research on Cancer (IARC) to review its monograph on metals at its February 1993 meeting.[183] IARC was an agency of the World Health Organization (WHO), the primary health-oriented research arm of the United Nations, and its monographs were highly influential with regulatory bodies and private standard-setting agencies throughout the world.[184] Brush Wellman, however, considered IARC to be an "enemy" of industry.[185] The current monograph for metals characterized beryllium as a "Class IIA probable human carcinogen," but there was a significant likelihood that IARC would upgrade that classification to "Class I known human carcinogen,"[186] and this could spell disaster for the industry.

IARC had invited Euromateaux, a European trade association, to send a participant to the meeting, and Euromateaux had in turn agreed to allow Brush Wellman to select that participant.[187] Understanding that the IARC meeting was "extremely important to the beryllium industry" and that the focus of the meeting was likely to be on the epidemiological studies, BISAC concluded that it would be best to specify BISAC member Dr. Brian MacMahon as the industry representative.[188] Dr. MacMahon agreed to have his name put forward, "with the caveat that if health or other considerations dictated, he would withdraw from the commitment."[189] Euromateaux then recommended Dr. MacMahon for the position.[190]

As it happened, Dr. MacMahon could not make the IARC meeting, and Dr. Kotin attended in his stead.[191] As predicted, "the ultimate classification of beryllium was virtually entirely dependent on epidemiological considerations."[192] Dr. Kotin was incensed with what he believed to be

182. *Id.* at 7.

183. Memorandum from Linda Duffy to Joel Moskowitz et al., re: January 22 BCDA Meeting Trip Report 2-3 (Feb. 3, 1993) (on file with author).

184. International Agency for Research on Cancer, http://www.iarc.fr (last visited Apr. 12, 2006).

185. Memorandum from Linda Duffy to Joel Moskowitz et al., *supra* note 183, at 2.

186. *Id.* at 3.

187. Minutes of BISAC Meeting 7 (Sept. 8, 1992) (on file with the author).

188. *Id.*

189. *Id.* at 8.

190. Memorandum from Arlette Shagarofsky-Tummers to Members of the Dangerous Substances and Dangerous Preparations Coordination Groups et al. (Aug. 3, 1992) (on file with author).

191. Memorandum from Dr. Paul Kotin to Martin B. Powers, Executive Sec'y, BISAC 1 (Mar. 1, 1993) (on file with author).

192. *Id.*

"the obvious 'a priori' commitment of Dr. Carl Shy, as Chairman of the Epidemiology Subgroup to use whatever methods necessary that would result in beryllium being placed in IARC Group I."[193] Kotin believed that "Dr. Shy behaved egregiously as chairman by his obvious partiality to Group I status for beryllium in both his comments and meeting deportment."[194] Dr. Shy had written the first draft of the IARC epidemiology document with the help of Dr. Steenland, his colleague at the University of North Carolina, and author of the most recent epidemiological study, and he defended it throughout. Dr. Kotin later admitted that his own input had "an element of industry advocacy,"[195] but it was to no avail. A majority of the IARC group voted to elevate beryllium to Class I status.[196]

Concerned that the Ward & Okun and Steenland papers might soon be used for regulatory purposes, Dr. MacMahon told BISAC that he would redouble his efforts to prepare a review article critiquing those studies and the earlier NIOSH studies.[197] He completed his paper five months later, and it was accepted for publication in the *Journal of Occupational Medicine*.[198] The article concluded that "the small and inconsistent excess of lung cancer deaths in employees of one or two plants seen in [the Ward & Okun and Steenland] studies are compatible with a number of explanations other than that they are attributable to occupational exposure to beryllium."[199] Indeed, it stated that "confounding by cigarette smoking is a more likely explanation of the lung cancer excess than is occupational exposure to beryllium compounds."[200] Dr. Kotin wrote a lead editorial for the issue strongly supporting Dr. MacMahon's assessment.[201] Dr. Kotin complained that government agencies had in the past used "unconfirmed or noncritically reviewed data" in promulgating regulations, and he argued

193. *Id.*

194. *Id.* at 2.

195. Roe, *Thought Control*, *supra* note 127, at A1.

196. Memorandum from Dr. Paul Kotin to Martin B. Powers, Executive Sec'y, BISAC, *supra* note 191, at 3.

197. Minutes of BISAC Meeting 1 (Apr. 8, 1993) (on file with author).

198. Letter to Elizabeth Popper from Dr. Brian MacMahon, Prof. of Epidemiology, Harv. Univ. (Sept. 23, 1993) (on file with author). The paper acknowledged that it had been written at the request, and through funding from BISAC, which he characterized as "an independent committee supported by the Brush Wellman and NGK Metals Companies." Brian MacMahon, *The Epidemiologic Evidence on the Carcinogenicity of Beryllium in Humans*, 36 J. OCCUPATIONAL MED. 15, 15 (1994).

199. MacMahon, *supra* note 198, at 15.

200. *Id.*

201. Paul Kotin, *Re: The Epidemiological Evidence on the Carcinogenicity of Beryllium, by MacMahon*, 36 J. OCCUPATIONAL MED. 25, 25 (1994).

that the statutory "prudence" requirement that ordinarily applied to regulatory agencies did "not eliminate the requirement for validity of the data on which actions are based."[202] Despite the fact that the IARC panel and the peer reviewers for the journals in which they were published had accepted the Ward & Okun and Steenland studies, the unspoken implication of Dr. Kotin's editorial was that it would be inappropriate for OSHA or EPA to rely on those studies in light of Dr. MacMahon's conclusion that they were flawed.

As discussed in connection with BISAC's consideration of LTT screening, the international conference that BISAC envisioned for that issue had by January 1993 been co-opted to some extent by the NIEHS, which had insisted that the second day of the conference be devoted to beryllium's carcinogenicity.[203] Although BISAC had decided not to co-sponsor the conference, it remained very concerned with the content of the second day's presentations.[204] In a November 1, 1993 letter to NIOSH, BISAC committee chairman Merril Eisenbud complained that NIEHS had "not budged from its plan to include only two interrelated papers" (the Ward & Okun and Steenland papers) in the session devoted to the cancer epidemiological studies.[205] In particular, the session would apparently not include an independent presentation of Dr. MacMahon's article.[206] Eisenbud accused NIOSH of attempting to "perpetuate the adversarial positions on the subject of the human carcinogenicity of beryllium that have existed for many years, and with which the conference would have been in a position to deal in a constructive way."[207]

In 1994, Brush Wellman decided to undertake some empirical work of its own, not on the cancer histories of its workers, but on the history of the Lorain, Ohio plant from which Drs. Ward and Okun and Steenland had gathered their data.[208] Dr. Dimitrious Trichopoulos, a Harvard School of Public Health epidemiologist who replaced Dr. MacMahon on BISAC in January of 1994, suggested that the excess cancers at the Loraine plant might be explained by some factor unique to the processes that were employed at that plant.[209] This would be good news for Brush Wellman,

202. *Id.*

203. Letter from Dr. Merril Eisenbud, Chairman, BIASC to Dr. C.W. Jameson, Nat'l Inst. of Envtl. Health Sci. 1 (Nov. 1, 1993) (on file with author).

204. *Id.*

205. *Id.*

206. *Id.* at 2.

207. *Id.*

208. Letter from Dr. Dimitrios Trichopoulos, Prof., Harvard Sch. of Public Health to Mark Kolanz, Director EH&S, Brush Wellman, Inc. 4 (June 24, 1999) (on file with author).

209. *Id.*

because the Lorain plant had operated only from 1936 to 1948, when it was destroyed by fire.[210] If the cause of the cancer was uniquely related to a process employed at the abandoned Lorain plant, and if more recently constructed plants did not employ that process, then Brush might still be subject to a few workers compensation claims, but it would not have to worry about tightening exposure standards beyond the historical 2.0 µg/m3 standard at its current plants.[211] It could also avoid future liability to workers at plants using Brush Wellman's finished beryllium and to consumers claiming that they had contracted cancer from products containing beryllium.[212]

Brush Wellman asked a retired engineer and a retired metallurgist, both of whom had helped design and run the Lorain plant, to examine the possibility that the workers at the Lorain plant were exposed to some substance that was unique to that plant.[213] They soon reported back that the gas-fired rotary kiln used at the Lorain plant would have emitted sulfuric acid mists and that one of them had spoken to a friend who believed that the kiln would have been "a perfect acid-mist generator."[214] This was useful to Brush Wellman for two reasons: (1) sulfuric acid mist exposures had been associated with lung cancer in past epidemiological studies, and (2) none of the other more recently constructed beryllium plants used acid-fired rotary kilns.[215] In other words, this seemed to be precisely the sort of unique process that Dr. Trichopoulos had hoped to find.

In a memo to the BISAC, Brush Wellman's vice-president for governmental and environmental affairs suggested three projects.[216] First, Dr. Trichopoulos should provide a preliminary opinion as to whether the sulfuric acid mist theory was "plausible."[217] Second, the committee should review the IARC monograph on magenta, which had employed a process theory similar to Dr. Trichopoulos' suggestion, to "look for clues as to how the arguments were framed."[218] Third, BISAC should "have a

210. *Id.*

211. *Id.*

212. *Id.*

213. Memorandum from Hugh D. Hanes, Vice President, Brush Wellman, Inc. to Dr. Merril Eisenbud, Prof. of Envtl. Med., New York Univ. et al., re: What Was Unique About the Processing of Beryllium Materials in the Brush-Lorain Plant? 1 (Jan. 31, 1994) (on file with author).

214. *Id.* at 2.

215 *Id.*

216. *Id.* at 3.

217. *Id.*

218. *Id.*

knowledgeable chemical engineer model and analyze the Lorain calcinations process, looking for support of the opinion" of the two retired employees.[219] Brush Wellman hoped that this preliminary work could be completed and conveyed to a NIOSH group at a March meeting that was to be devoted to discussing whether workers at beryllium plants should be notified about the cancer risks they faced.[220] Although Brush Wellman did not "expect to change [the NIOSH group's] minds on their study results, it will hopefully create some doubt."[221]

At the NIOSH meeting, Drs. Kotin and Trichopoulos placed the new theory front and center, stressing that the "[t]he data clearly pointed to the uniqueness of the Lorain Plant" and that the "excess of cancer" detected in the Ward & Okun and Steenland studies "clearly had the fingerprint of cancer caused by acid mist."[222] Consequently, any notification to workers concerning cancer risks "should be directed only to that population."[223] Not surprisingly, representatives of NIOSH and organized labor disagreed. NIOSH "rejected the notion that acid mists were a plausible explanation of the cancer excess," and it stressed that the absence of excess cancer at the more recently constructed facilities was more likely attributable to the long latency period between exposure and onset of cancer.[224] In the end, however, the participants "reached a compromise that was probably better than [the industry representatives] expected."[225] The notification letter to employees would include specific information about individual facilities and "note the disagreement among scientists about the carcinogenicity of beryllium."[226] Thus, the uncertainty that BISAC manufactured found its way into the NIOSH communication to the workers at Brush Wellman's plants.

The Brush Wellman effort to focus attention on acid mists continued in 1995 when it assembled a team of engineers to "reconstruct the Lorain Plant, the processes, the products, the throughput, and the conditions that existed in that plant during its life."[227] This paper exercise was completed

219. *Id.*

220. *Id.*

221. *Id.*

222. Memorandum from Hugh D. Hanes, Vice President, Brush Wellman, Inc. to Bob Rozek, Brush Wellman, Inc., re: NIOSH worker Notification Meeting 1 (Mar. 14, 1994) (on file with author).

223. *Id.*

224. *Id.* at 2.

225. *Id.*

226. *Id.*

227. Letter from Hugh D. Hanes, Vice President, Brush Wellman, Inc. to Dr. Dimitrious Trichopoulos, Chairman, Harvard Sch. of Public Med. 1 (Apr. 18, 1995).

in April, and it "paint[ed] a picture of a plant that had ventilation that was barely adequate to control the acid fumes to the level of tolerance of the employees, but sufficiently inadequate to cause the employees to avoid the sulfating mill, if at all possible."[228] Brush Wellman then sought guidance from Dr. Trichopoulos "as to the information you feel would be necessary to back up your story."[229] Brush's vice-president for governmental and environmental affairs believed that there was "ample evidence to differentiate the processes in the Lorain Plant," and he hoped that Dr. Trichopoulos would "find this information as exciting as we do."[230]

At a subsequent BISAC meeting, Dr. Trichopoulos reported that he had evaluated the engineering report and concluded that the sulfuric acid levels suggested in the report were too high for human endurance.[231] He made some slightly different assumptions and "drafted a summary for Brush review and concurrence."[232] At BISAC's January 1996 meeting, Dr. Trichopoulos noted that the conclusions of IARC and NIOSH would be "extremely difficult to change, given the normal human tendency to perpetuate error rather than admit to it."[233] The acid mist paper, however, would give "everyone a chance to correct the error without losing face if they were willing to do so."[234] The committee agreed that the paper was of sufficient importance that it should be sent to the *Journal of Occupational and Environmental Medicine* "with the entire BISAC listed as authors."[235]

Things progressed precisely as planned, and the acid mist paper was published in the March 1997 issue of that publication.[236] The article began with a description of the IARC program for evaluating carcinogenicity in humans and the 1992 IARC evaluation of beryllium.[237] It then related Dr. MacMahon's earlier review article citing "serious defects in the methodology of the early epidemiologic studies" and questioning "the interpretation of the more recent, and generally better grounded, epidemiologic studies."[238] Noting that "[s]ulfuric acid mist and vapors are

228. *Id.* at 2.

229. *Id.*

230. *Id.*

231. Minutes of BISAC Meeting 4 (Oct. 9-10, 1995) (on file with author).

232. *Id.*

233. Minutes of BISAC Meeting 5 (May 20, 1996) (on file with author).

234. *Id.*

235. *Id.*

236. Haberman & Pratt et al., *Is Beryllium Carcinogenic in Humans?*, 39 J OCCUP. ENVTL. MED. 205, 205-08 (1997) (written by the members of BISAC).

237. *Id.* at 205.

238. Haberman & Pratt, et al., *Is Beyrillium Carcinogenic In Humans?*, *supra* note 236, at 205.

established lung carcinogens in humans," the paper concluded that "*the process and circumstances* at the Lorain plant were probably carcinogenic to humans" and that the "apparent effect of 'beryllium and beryllium compounds' was the result of exposure to sulfuric acid mist and vapors that acted as typical confounding variables."[239]

H. The Government Takes a Modest Step

One of the goals of Brush Wellman's 1991 five-year plan was to "insure that the Company is protected, through competent defense, from unwarranted legal and regulatory actions related to [environmental health and safety] issues."[240] To meet that goal in the regulatory arena, the company would "[e]mploy legal means to defeat unreasonably restrictive occupational and emission standards and to challenge rulemaking and other regulatory activities that seek to impose unreasonable or unwarranted changes."[241] Apparently any change from the existing forty year-old occupational standard of 2.0 µg/m3 was deemed by the company to be "unreasonable" because another 1991 goal was to "[r]esist an attempt to make the existing occupational exposure standard of 2 micrograms/cubic meter, as measured and calculated by Brush, more restrictive."[242] With the help of BISAC, the company succeeded in forestalling regulation for the better part of a decade.

During the latter half of the Clinton Administration, however, the DOE decided that it had an obligation to protect workers at DOE-related facilities even if there were some scientific uncertainties about the need to take any particular action.[243] On December 8, 1999, DOE issued a rule applicable to workers at facilities managed by DOE and its contractors mandating a ten-fold reduction in the acceptable workplace exposure to beryllium.[244] In 1998, OSHA added to its regulatory agenda a new project under which it would consider whether to require that companies in the private sector implement the same protections,[245] but the project was not completed during the remainder of the Clinton Administration.[246] In 2002,

239. *Id.* at 207-08 (emphasis added).

240. Rozek, *supra* note 156, at 1, Tab 5(f).

241. *Id.* at 2, Tab 5(f).

242. *Id.*

243. Michaels, *supra* note 11, at 98.

244. Chronic Beryllium Disease Prevention Program, 64 Fed. Reg. 68,854, 68,862 (Dec. 8, 1999).

245. Occupational Exposure to Beryllium; Request for Information, 67 Fed. Reg. 70,707, 70,709 (Nov. 26, 2002).

246. Michaels, *supra* note 11, at 98.

the Bush Administration announced that OSHA would not propose a beryllium standard until further research had been completed, and it requested public comment on fifty-two questions that it thought would be relevant to its decision whether or not to go forward with a rulemaking effort.[247] The agency has taken no formal action since that time.

III. BLUE RIBBON PANELS AND SOUND REGULATORY DECISION MAKING.

Brush Wellmon's decision to appoint a "blue ribbon panel" of carefully chosen experts is a frequently relied upon industry response to the publication of an adverse scientific report or a worrisome regulatory development. If there was an unusual aspect to BISAC, it was its longevity. Because it is expensive to assemble several busy experts at a commodious location, pay them consultant fees or honoraria for their efforts, and provide staffing for the meetings and reports, most blue ribbon panels are assembled for a specific regulatory need and dismissed as soon as that task has been completed. If, however, an industry's products or activities are likely to prove controversial on a continuing basis, it can assemble a permanent panel of experts to provide advice to the industry and relevant regulatory agencies as the beryllium industry did with BISAC.

The cosmetics industry in 1976 created a similar quasi-permanent panel of seven experts called the Expert Panel for Cosmetic Ingredient Review (CIR) to address post-market studies indicating that cosmetics might be dangerous. CIR was then available to address a controversy that erupted in 2002 over the use of phthalates in nail polishes, shampoos, fragrances and similar products after laboratory animal research suggested that many phthalates can cause birth defects.[248] The CIR unanimously concluded that phthalates were "safe for use in cosmetic products in present practices of use and concentration."[249] Coming just twelve days after the European Commission (EU) ordered companies to remove two phthalates from cosmetics sold in EU countries,[250] an industry spokesperson declared the CIR finding to be a "triumph for science-based evidence over scare tactics."[251]

247. Occupational Exposure to Beyryllium; Request for Information, 67 Fed. Reg. at 70, 709.

248. Jim Morris, *FDA Scrutinizing Family of Chemicals*, DALLAS MORNING NEWS, June 17, 2002, at A1; Brian Reid, *Beauty Coverage?*, WASH. POST, Nov. 24, 2002, at F1.

249. Glenn Hess, *CIR Panel Finds Phthalates Safe for Cosmetics Applications*, 262 CHEMICAL MARKET REP. 1, 1 (2002).

250. *Id.*

251. *Id.*

The primary advantage of the blue ribbon panel to the government is its capacity to bring scientific expertise to bear on policy-relevant scientific issues. As discussed above, government agencies often find the considered judgment of a group of prominent scientists helpful in determining the reliability and quality of scientific studies. Blue ribbon panels also perform the perhaps less legitimate function of deflecting public criticism from agencies that are forced to make tough decisions. As Professor Wendy Wagner has demonstrated, agencies are all too willing in such situations to engage in a "science charade," through which they mask controversial policy decisions in the veneer of science and thereby avoid accountability for their policy choices.[252] Privately arranged blue ribbon panels can provide the same scientific input and political cover at no cost to the government.

The usefulness of a privately assembled blue ribbon panel to the government is less clear when the relevant agency has already initiated a scientific review procedure. For example, while EPA's Science Advisory Board was reviewing a draft of a staff-prepared assessment of the health risks posed by exposure to the Teflon precursor PFOA,[253] the industry-funded American Council on Science and Health (ACSH) hastily assembled a blue ribbon panel composed of an entirely different group of scientists. That panel produced a booklet and accompanying press release, based upon an industry-prepared position paper that was "peer reviewed" by scientists likewise chosen by ACSH.[254] The ACSH panel concluded that PFOA posed "no likely risk" to humans in the "trace amounts" found in human blood.[255] The resort to a press release, however, suggests that the panel's purpose had less to do with providing an objective scientific assessment to the agency than with preempting the contribution of the experts that the agency had already assembled.

From the perspective of a regulated entity, the blue ribbon panel has the great virtue of lending scientific legitimacy to what would otherwise be viewed as mere advocacy. The views of company scientists will predictably be dismissed as biased by participants who disagree with the company's position on the regulatory issues, and they are likely to be

252. Wagner, *The Science Charade in Toxic Risk Regulation*, *supra* note 1, at 1640.

253. *See* EPA, OFFICE OF POLLUTION PREVENTION & TOXICS, DRAFT RISK ASSESSMENT OF THE POTENTIAL HUMAN HEALTH EFFECTS ASSOCIATED WITH EXPOSURE TO PERFLUOROOCTANOIC ACID AND ITS SALTS (2005), *available at* http://www.epa.gov/oppt/pfoa/pfoaex.pdf.

254. *Teflon-Production Chemical Does Not Pose Health Risk to General Population, Science Panel Finds*, MED. NEWS TODAY, Mar. 19, 2005, *available at* http://www.medicalnewstoday.com/medicalnews.php?newsid=21512.

255. *Id.*

discounted by the agency for the same reason. Agency officials may legitimately suspect that company scientists are not entirely free to express their scientific judgment when it leads to conclusions that run counter to the company's economic well-being. The views of the distinguished scientists that make up a blue ribbon panel are less easily dismissed, because they typically have a degree of financial independence and are presumably less likely to risk damage to their reputations in the pursuit of a single company's economic interests.

As the BISAC and CIR examples suggest, the privately sponsored blue ribbon panel is an especially useful device for "deconstructing" one or more scientific studies that could, if relied upon by regulatory authorities, threaten the economic well-being of a company or industry. If, as is typically the case, the blue ribbon panel includes prominent scientists with established reputations in the relevant field, their criticisms of work undertaken by government scientists or less well-established scientists can carry a great deal of weight both in the scientific community and, more importantly, among high level regulatory decision makers. For example, in the mid-1990s, a consultant to the chlorine industry assembled a group of eighteen scientists at a commodious location to evaluate a nine-volume draft EPA assessment of the human health risks of dioxin.[256] The meeting resulted in a letter signed by all of the assembled scientists and published in *Science* expressing serious reservations about the quality of the science underlying the risk assessment.[257] Although one of the participants later acknowledged that the consulting company may not have been "unbiased in the choice of individuals it . . . brought together" to evaluate the risk assessment,[258] high level agency officials sent the draft back to the drawing board where it remained for another six years until the agency issued a "revised draft" for review.

The blue ribbon panel can also prove useful in an industry's broader attempts to influence pubic opinion. An effective public relations campaign may generate pressure on a regulatory agency against taking "precipitous" action, and it may also be necessary for more mundane marketing purposes when a company's product comes under attack. As the phthalates example suggests, a rapid scientific rebuttal to a study indicating that a product poses risks to human health may be required to restore

256. *Dioxin and the EPA: The Science and Politics of Regulation*, ENVTL. REV. NEWSLETTER (Envtl. Rev., Seattle, WA), May 1995, *available at* http://www.environmentalreview.org/vol02/mattison.html; Richard Stone, *Dioxin Report Faces Scientific Gauntlet*, 265 SCIENCE 1650, 1650 (1994).

257. *Dioxin and the EPA: The Science and Politics of Regulation*, *supra* note 256.

258. *Id.*

shaken consumer confidence in the product. It is therefore not surprising that public relations firms are frequently involved in assembling and managing blue ribbon panels. The public relations people use the blue ribbon panel to "manufacture uncertainty" about the validity of the damaging studies. In the messy world of regulatory science where perfection is impossible, the scientists on the blue ribbon panel can be relied upon to identify one or more aspects of virtually any study that could stand improvement. The public relations professionals then take over to characterize the study as "fatally flawed" and therefore unworthy of serious consideration by consumers, agencies and courts.

For example, in the early 1990s, the EPA prepared a risk assessment on environmental tobacco smoke (ETS) and presented it to the agency's Science Advisory Board for review.[259] Although EPA lacked any regulatory authority on its own to regulate indoor air quality, the tobacco industry recognized that the document posed a serious threat to the vitality of the industry if the public became convinced that secondhand smoke caused lung cancer.[260] RJR Tobacco Company therefore hired a consultant to assemble a "shadow committee" of "independent scientists," formally called the "EPA Health Assessment Review Committee," to evaluate EPA's risk assessment and be available at the behest of the company's public relations department to discuss relevant issues at regulatory, administrative, legislative, and other public forums.[261] The committee prepared a lengthy critique of the EPA document, concluding that, "EPA's classification of ETS as a Group A carcinogen is scientifically not justifiable."[262]

Professor Neil Pierce notes that a company's selection "of a few scientists who are hypercritical of others' work can result in massive pressure on public health decision makers" that is "particularly effective since it apparently comes from independent scientists."[263] Thus, the industry-funded Marshall Institute convened a panel of experts, drawn

259. EPA, OFFICE OF HEALTH & ENVTL. ASSESSMENT, RESPIRATORY HEALTH EFFECTS OF PASSIVE SMOKING: LUNG CANCER AND OTHER DISORDERS (1992), *available at* http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=2835.

260. Thomas O. McGarity, *On the Prospect of "Daubertizing" Judicial Review of Risk Assessment*, 66 L. & CONTEMP. PROBS. 155, 200 (2003).

261. C.R. Green, ETS Division Weekly Highlights 1 (Jan. 29, 1991) (on file with author); C.R. Green, ETS Division Weekly Highlights 2 (Jan. 22, 1991) (on file with author); Letter from G. Robert DiMarco to Alfred T. Wehner 1 (Nov. 9, 1990) (on file with author); RJR, ETS 1 (Draft, Jan. 24, 1991) (on file with author).

262. Biomedical & Envtl. Consultants, Inc., Critiques of EPA External Review Draft 600/6/90/006A, May 1990: Health Effects of Passive Smoking: Assessment of Lung Cancer in Adults and Respiratory Disorders in Children xv (Feb. 1991) (on file with author).

263. PEARCE, *supra* note 7, at 71.

almost exclusively from the diminishing ranks of climate change critics, to evaluate a report by the 2,500 member International Panel on Climate Change (IPCC). The Marshall Institute panel's report, which predictably criticized the IPCC for "failing to convey the underlying uncertainties that are important in policy considerations,"[264] was then relied upon by Senator James Inhofe to support his intense criticism of scientists who advocate taking action to reduce greenhouse gasses.[265]

As Professor Pierce suggests, the primary danger of the industry-appointed blue ribbon panel to the integrity of the regulatory decision-making process is it obvious potential for bias. The company that convenes the panel can choose its members, and it is likely to consider past statements, publications and other indicia of a member's policy predilections in going about that task. Even if every invited scientist is not dependably in the sponsor's camp, the sponsor knows that, as a practical matter, "whoever drafts the original document effectively controls the message."[266] The important thing, therefore, is to ensure that the chairperson and a solid majority of the members of the committee are likely to support the sponsor's position.

There is certainly evidence that blue ribbon panels do not always adopt a wholly neutral approach to the scientific evidence. For example, when the reproductive toxicity of low-level exposures to the ubiquitous plasticizer Bisphenol A (BPA) threatened its continued use, the plastics industry hired the Harvard Center for Risk Analysis to assemble a scientific panel to address that question.[267] While acknowledging that several studies had reported adverse reproductive effects in laboratory animals, the panel found no "consistent affirmative evidence of low-dose BPA effects."[268] Critics pointed out, however, that the panel reviewed seven of the nine industry-funded studies (all of which found no adverse effects) and only twelve of the thirty-eight available government-funded studies (nearly all of which identified some adverse effect at low levels).[269] Similarly, in response to the publication of the first paper detailing the serious side effects of the sleeping pill Halcion in *The Lancet*, the pill's manufacturer convened a

264. *Report Questions Role of Greenhouse Gases, Criticizes Conclusions of International Panel*, BNA ENV'T REP., Mar. 8, 2002, at 531.

265. ROSS GELBSPAN, BOILING POINT 55 (2004).

266. DAVID HEALY, LET THEM EAT PROZAC 115 (2004).

267. Kara Sissel, *Study Dismisses Bisphenol-A as Endocrine Discruper*, CHEMICAL WEEK, Sept. 8, 2004, at 28.

268. *Id.*

269. Frederick S. vom Saal & Claude Hughes, *An Extensive New Literature Concerning Low-Dose Effects of Bisphenol-A Shows the Need for a New Risk Assessment*, 113 ENV. HEALTH PERSPECTIVES 926, 928 (2005).

group of sleep researchers who sent a letter to the journal denouncing the study.[270] The chairperson of the group later acknowledged that he and the other researchers had been mislead by company representatives.[271]

After the manufacturer of the asthma drug fenoterol sharply criticized an epidemiological study published in *The Lancet* concluding that the drug caused increased mortality in asthmatics, the author conducted a second study to meet the manufacturer's objections.[272] When the second study reached the same conclusion, the manufacturer convened a group of carefully chosen experts at the Beverly Wilshire Hotel in Beverly Hills, California to evaluate the second study's conclusions.[273] Working "under some pressure" from the company's public relations representative, the group concluded that the second study avoided only one of the methodologic problems of the first study, but had "retained others and introduced new methodologic problems."[274] An independent review of the second study convened by the FDA, however, concluded that both studies supported the conclusion that fenoterol caused increased mortality, and the agency ultimately took steps to minimize the use of the drug.[275]

An industry can deflect allegations that a blue ribbon panel was "hand picked" by contracting with an outside organization that will reliably assemble a group that is dominated by scientists of the right persuasion. For example, after EPA proposed the establishment of a stringent standard for chloroform in drinking water, the chlorine industry arranged with the International Life Science's Institute, an industry-supported think tank, to assemble a blue ribbon panel to evaluate the carcinogenic risks of chloroform.[276] The panel disagreed with EPA's zero parts per billion maximum contaminant level goal for chloroform in drinking water and suggested a much less stringent goal of three hundred parts per billion.[277] Similarly, the American Council for Science and Health, at the behest of the plastics industry, convened a "blue ribbon panel" headed by former Surgeon General C. Everett Koop to evaluate the health risks and benefits of the plasticizer DEHP, a common component of medical devices.[278] The

270. Gina Kolata, *Maker of Sleeping Pill Hid Data On Side Effects, Researchers Say*, N.Y. TIMES, Jan. 20, 1992, at 1.

271. *Id.*

272. PEARCE, *supra* note 7, at 68.

273. *Id.* at 69.

274. *Id.* at 68-69.

275. *Id.* at 69.

276. Glenn Hess, *Chlorine Industry Challenges Chloroform Rule*, CHEMICAL MARKET REP., Feb. 8, 1999, at 6.

277. *Id.*

278. Jim Motavalli, *Science for Sale?*, E-MAGAZINE, Mar. 1, 2000, at 23.

panel concluded that DEHP was not harmful to human health and that banning it from medical devices would pose a significant health risk to people in need of those devices.[279]

IV. CONCLUSION

The numerous examples of privately commissioned blue ribbon panels reaching conclusions consistent with the sponsoring entity's position, and the dearth of examples of such panels reaching conclusions that undermine the sponsoring entity's position (the author has not located a single one, though it is entirely possible that one or more examples do exist), probably explains why regulated industries find these panels to be an effective, if expensive way to influence regulatory decision making and public perceptions about potentially risky products and activities. From the perspective of sound public policy, however, the critical question is whether the value to the decision-making process of the additional expertise and information that the blue ribbon panel makes available is outweighed by its potential to bias regulatory decisions in the direction of the positions of the sponsoring entities.

The easiest way for regulatory agencies to prevent bias from intruding into the process is to ignore the output of such panels altogether. Agencies could simply let it be known that reports from privately commissioned blue ribbon panels are so unreliable that they are not appropriate for citation in comments to the agency or in any agency support document. This extreme solution, however, is unworkable as a practical matter, and generally inconsistent with sound regulatory decision making. As a practical matter, sponsoring entities will still assemble blue ribbon panels to influence consumers and legislators, and an agency that adamantly refuses to acknowledge their reports is an easy target for severe public criticism by the sponsoring and their entities allies in think tanks and legislatures. As a scientific matter, a wholesale "exclusionary rule" is inconsistent with the "weight of the evidence" approach that scientists normally take toward evaluating the reliability of scientific information.[280]

The better solution is for the agency itself to take a "weight of the evidence" approach toward blue ribbon panel reports, and to discount them sufficiently to avoid bias. Sometimes this will merely require agency decision makers to take the blue ribbon panel's report "with a grain of salt." Sometimes, as with the case of blue ribbon panels dominated by scientists known to be on the extreme fringe of the relevant scientific issue

279. *Id.*

280. McGarity, *supra* note 260, at 165.

(e.g., the Marshall Institute's global warming panel), this will require the agency to discount the panel's predictable conclusions quite deeply. Furthermore, when an agency cites in support of a regulatory decision the conclusions of an outside blue ribbon panel that was supported by an entity with an interest in the outcome of the proceedings, it should provide its reasons for concluding that the panel's conclusions were objective and otherwise reliable.

Since the origin of and support for an outside blue ribbon panel will not always be obvious to the agency (or members of the general public), the agency should attempt to ascertain the identity of any sponsoring entity prior to relying upon the conclusions of such panels. In the case of some panels, like BISAC, the sponsoring entity is readily apparent. For others, like panels convened by intermediate entities such as the International Life Sciences Institute, identifying the real source of the panel's support may be difficult. In either case, full disclosure of the source of support is critical to the agency's evaluation of the panel's conclusions and to the public's ultimate acceptance of the agency's decisions.

Although it should be reasonably easy for a regulatory agency to identify and discount biased input from privately sponsored blue ribbon scientific panels, the general public may be mislead by the sophisticated public relations campaigns that sponsoring entities and their public relations consultants initiated. An agency may be hard-pressed to explain to the public why it is reaching a regulatory decision that appears to depart from the advice of a panel composed of scientists with prestigious pedigrees. A relatively expensive way to fend off public pressure generated by a blue ribbon panel is for the agency to appoint its own panel. As we have seen, the regulated industries are not above generating "dueling panels" when the stakes are sufficiently high. This solution, however, invites the agency to engage in the same kind of biased cherry-picking exercise in assembling the agency's panel that the private entity no doubt used to assembling its panel, thus inviting deserved criticism of the decision-making process for lack of objectivity.

One might hope that the scientific community would rally in defense of an agency that has become the target a well-financed campaign by a regulated entity to "manufacture uncertainty" through biased blue ribbon panels, but that is likely a vain hope. Scientists are cautious by nature and therefore not inclined to wade into public controversies.[281] While the scientific community has on some fairly rare occasions weighed in heavily

281. Saad Z. Nagi & Ronald G. Corwin, *The Research Enterprise: An Overview, in* THE SOCIAL CONTEXTS OF RESEARCH 24 (Saad Z. Nagi & Ronald G. Corwin, eds. 1972).

on an issue of profound public importance like global warming, agencies should not depend upon independent scientists to come to their defense in run-of-the-mill disputes over the quality of scientific studies, and the proper inferences to be drawn from those studies. The relatively mundane field of "regulatory science" is not likely to inspire many scientists to abandon their laboratories for the talk radio circuits.

At the end of the day, the agency may be forced to rely upon its own ability to influence public perception and on the willingness of the beneficiaries of the regulatory statutes it implements to come to its defense in the public relations wars. Unlike the scientific community generally, scientists employed by advocacy groups are willing and able to speak out on scientific issues that arise in regulatory contexts, and they are usually adept at attracting the attention of the news media. Although public interest groups lack the resources to assemble blue ribbon panels to deliberate at length and write reports, they can generate letters to agencies and congresspersons and ask prominent scientists to sign them. While this may not be an adequate substitute for the reasoned deliberation of a blue ribbon panel in the scientific community, it may prove quite persuasive in the realm of public relations.

Blue ribbon panels assembled by governmental bodies have contributed greatly to sound regulatory decision making. Like any policymaking tool, however, the blue ribbon panel has both virtues and limitations. It can, among other things, be misused by regulatory agencies to mask policymaking behind the veneer of scientific objectivity. In the hands of private entities with their own agendas, the blue ribbon panel concept has fewer virtues and more limitations. Because they are expensive, private entities will rely upon them when they feel most threatened by a scientific development or regulatory initiative. The motivation is self-defense, and not the advancement of scientific knowledge. Because they have such a high potential for mischief, agencies should not encourage their use and should view their products with a highly skeptical eye.