IMPROVING THE GOVERNMENT'S ENVIRONMENTAL SCIENCE

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Credible science is a critical foundation for sound and effective environmental regulation and remediation. It ensures achievement of regulatory objectives and builds confidence in the public and interested parties in regulatory decisions. Since the beginning of the modern environmental legal framework in the early 1970s, the credibility of government science has been the focus of constant scrutiny and controversy, and arguably such concerns have never been more pronounced than they are today.

This article examines the role of science in environmental regulatory decisions, and sets forth the goals of sound science, trusted science, timely science, comprehensive science, and transparent science. It identifies some persistent problems and recent controversies over the role of science in regulatory decisions and then proposes two new alternative institutional innovations for improving the science on which the government's environmental decisions rest: a Scientific and Engineering Investigation Board and an Institute for Scientific Assessments.

I. THE ROLE OF SCIENCE IN ENVIRONMENTAL REGULATORY DECISIONS

Environmental law is built on twin foundations of science, including engineering, and societal values. This is reflected in each of our major environmental laws:

- Under the Clean Air Act, the Administrator of the Environmental Protection Agency (EPA) is to issue air quality criteria for air pollutants which "shall accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence

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of such pollutant in the ambient air."[1] Identification of the problem is to be accompanied by identification of the engineering response. The Administrator is to issue "information on air pollution control techniques . . . [including] data relating to the cost of installation and operation, energy requirements, emission reduction benefits, and environmental impact of the emission control technology."[2]

- The Clean Water Act sets as its central objective restoring and maintaining the "chemical, physical, and biological integrity of the Nation's waters."[3] In order to achieve this objective, the Administrator of EPA is to publish water quality criteria "accurately reflecting the latest scientific knowledge (A) on the kind and extent of all identifiable effects on health and welfare including . . . plankton, fish, shellfish wild life, plant life, shorelines, beaches, aesthetics, and recreation which may be expected from the presence of pollutants . . . and (C) on the effects of pollutants on biological community diversity, productivity, and stability. . . ."[4] The Administrator is then to identify and implement, through a system of permits, the best available technology and the best management practices to control the discharges which have adverse effects on health and welfare.[5]
- Under the Superfund statute, whenever there is "a release or substantial threat of release into the environment of any pollutant or contaminant which may present an imminent and substantial danger to the public health or welfare, the President is authorized to . . . provide for remedial action relating to such hazardous substance, pollutant, or contaminant . . . ,"[6] which "shall attain a degree of cleanup of hazardous substances, pollutants, and contaminants released into the environment and of control of further release at a minimum which assures protection of human

[1] 42 U.S.C. § 7408(a)(2) (2000).
[2] 42 U.S.C. § 7408(b)(1).
[3] 33 U.S.C. § 1251(a).
[4] 33 U.S.C. § 1314(a)(1).
[5] 33 U.S.C. §§ 1314, 1342.
[6] 42 U.S.C. § 9604(a)(1).

health and the environment."[7] The President has delegated this responsibility to the Administrator of EPA.

- The Safe Drinking Water Act directs EPA to promulgate drinking water standards that are based on "the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices. . . ."[8]
- Under the Toxic Substances Control Act, the manufacturing, processing and use of polychlorinated biphenyls (PCBs) is banned, except that the Administrator of EPA may authorize manufacture, processing, or use that "will not present an unreasonable risk of injury to health or the environment."[9]

Examples can be multiplied. The sweep of EPA's responsibility—to assess the present state of scientific and engineering knowledge, to conduct scientific investigations on questions of human health, protection of the environment including flora, fish, and wildlife, and to develop engineering responses to the risks and adverse effects it finds through this work—is comprehensive and enormous.

These scientific and engineering analyses and investigations must routinely be coupled to societal values before they are expressed as regulations or administrative decisions. How are costs to be weighed when identifying the "best technology" under the Clean Water Act? What does it mean to protect public health under Superfund—cleaning up so that the remaining risk to a normally exposed adult is a chance of 1 in 100,000 that cancer will result? One in a million? For that matter, what is "normal exposure"? Is it right to protect the average adult or should protection be provided to sensitive subpopulations? In dealing with PCBs, for example, when does a risk to health become unreasonable—when there is a modest risk of contracting chloracne, or a very small risk of cancer, or both, or neither? In this country, the choice of societal values is primarily a political function. Congress may identify the value with some precision as with the Delaney Amendment which

[7] 42 U.S.C. § 9621(d)(1).
[8] 42 U.S.C. § 300g-1(b)(3)(A)(i).
[9] 15 U.S.C. § 2605(e)(2)(B).

banned carcinogens from food additives,[10] or it may place broad discretion in the hands of the Administrator of EPA, who presumably is grounded in the applicable societal values and reflects a greater degree of insight and sensitivity to environmental issues that comes from his life experience as well as from repeated and prolonged exposure to and consideration of the issues while serving as Administrator.

The distinction between science and societal values is a major theme in environmental law and regulation. In the late 1970s and early 1980s, a number of proposals were put forward by Congress and some industry groups to create a new stand-alone federal risk assessment institution to focus on the scientific side of the equation.[11] Congress commissioned the National Academy of Sciences (NAS) to consider a proposal to centralize all federal risk assessment activities into a single organization that was separate from existing regulatory agencies.[12] In 1983, the NAS released its influential report *Risk Assessment in the Federal Government*,[13] known colloquially as the "Red Book," that set forth a framework for regulatory risk analysis that has generally been followed by

[10] 21 U.S.C. § 348(c)(3)(A).

[11] *See* Richard A. Merrill, *The Red Book in Historical Context*, 9 HUM. & ECOLOGICAL RISK ASSESSMENT 1119 (2003). More recently, Justice Stephen Breyer, prior to being elevated to the U.S. Supreme Court, proposed the creation of a separate risk decision-making institution in the Executive Branch. STEPHEN BREYER, BREAKING THE VICIOUS CIRCLE: TOWARD EFFECTIVE RISK REGULATION (1993). Unlike the proposal in the present article, Justice Breyer's new institution would include risk management as well as risk assessment. His proposal was criticized for attempting to isolate risk decisions from political and interest group influences. *See, e.g.*, David A. Dana, *Setting Environmental Priorities: The Promise of a Bureaucratic Solution*, 74 B.U. L. REV. 365 (1994). As elaborated below, there is a stronger argument for political insulation of risk assessment, which is primarily a scientific undertaking, than for risk management, which appropriately does incorporate political, policy, ethical and social inputs. A proposal was put forward in the early 1990s, which garnered substantial support, including the endorsement of three former EPA Administrators, to create a National Institute of the Environment which would conduct independent risk assessments and fund environmental research that could be used by regulatory agencies. *See* NATIONAL COUNCIL FOR SCIENCE AND THE ENVIRONMENT, HISTORY, http://ncseonline.org/01about/cms.cfm?id=1139 (last visited Sept. 20, 2008).

[12] Joseph V. Rodricks, *What Happened to the Red Book's Second Most Important Recommendation?*, 9 HUM. & ECOLOGICAL RISK ASSESSMENT 1169, 1170 (2003).

[13] NAT'L RESEARCH COUNCIL, RISK ASSESSMENT IN THE FED. GOV'T: MANAGING THE PROCESS (1983).

U.S. and many foreign regulatory agencies since then. A central premise was the separation within an organization of risk assessment, a primarily scientific undertaking, from risk management, a more policy-related undertaking. The Red Book found that "[a]t least some of the controversy surrounding regulatory actions has resulted from a blurring of the distinction between risk assessment policy and risk management policy,"[14] and accordingly recommended that "regulatory agencies take steps to establish and maintain a clear conceptual distinction between assessment of risks and consideration of risk management alternatives."[15]

At the same time that the NAS recommended separating risk assessment from risk management within a regulatory agency, the report strongly recommended against dividing risk assessment and risk management into separate institutions because of the detrimental impact of such a separation on the communication and cooperation between scientists and policymakers.

In the twenty-five years since publication of the Red Book, the recommendation to separate risk assessment from risk management has come under increasingly sharp attacks from many scholars who argue that risk assessment inevitably involves policy assumptions (which the Red Book acknowledged) and should be more closely integrated with rather than distanced from risk management. Indeed, today's conventional wisdom is that it is inappropriate and ineffective to try to separate risk assessment from risk management.[16]

Our proposals run counter to both the Red Book and the current conventional wisdom by proposing institutional

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[14] *Id.* at 3.

[15] *Id.* at 7.

[16] *See, e.g.*, SHEILA JASANOFF, THE FIFTH BRANCH: SCIENCE ADVISERS AS POLICYMAKERS (1990); ROGER PIELKE, JR., THE HONEST BROKER: MAKING SENSE OF SCIENCE IN POLICY AND POLITICS (2007); Bernard D. Goldstein, *Risk Characterization and the Red Book*, 9 HUM. & ECOLOGICAL RISK ASSESSMENT 1283, 1287 (2003); Ellen Silbergeld, *Risk Assessment and Risk Management: An Uneasy Divorce*, *in* ACCEPTABLE EVIDENCE: SCIENCE AND VALUES IN RISK MANAGEMENT 102 (Deborah G. Mayo & Rachelle D. Hollander, eds., 1991); Bailus Walker Jr., *Impacts of the Red Book*, 9 HUM. & ECOLOGICAL RISK ASSESSMENT 1373, 1380 (2003). *But see* William D. Ruckelshaus, *Science, Risk, and Public Policy*, 221 SCIENCE 1026, 1027 (1983) (calling for risk assessment and risk management to 'be separated as much as possible within a regulatory agency").

arrangements that would more effectively separate science and risk assessment from societal values and risk management. We do not deny that risk assessment inherently involves assumptions and inputs that go beyond science.[17] We argue that the separation can help immunize scientific input into environmental decision-making from the most corrosive political influences, and can help provide regulators, interested parties, courts, and the public a clearer picture of what science can and cannot tell us about the particular environmental problem at issue.

II. TYPES OF SCIENTIFIC AND ENGINEERING INQUIRY

Our focus is on how the science side of the government's environmental responsibilities should be discharged so that an effective job is done in what will inevitably be a highly contentious and difficult field. We start with a sketch of what the environmental science in the government is aimed at doing, then we sketch out the elements of how we think those ends may best be attained.

We identify three types of scientific inquiry that are significant. These are not rigid categories and the borders between them are no doubt fuzzy, but the division is an aid to analysis. First, there is the task of basic research which establishes a relationship between a pollutant and an effect on public health or some aspect of the environment. This is the basis for the scientific analysis that underlies a great deal of environmental regulation. But federal agencies rarely undertake this basic research themselves. This work is typically carried out by investigators at universities or research institutes or by corporate interests, for instance, in pharmaceuticals or pesticides.

Secondly, environmental agencies employ basic science directly in developing regulations. They marshal the scientific data and knowledge relevant to the issue at hand, and then marry the science to the societal values by judging which investigations should be relied on and to what extent, what the relevant uncertainties are, and how the uncertainties and knowledge gaps are to be dealt with.

The third area is the technological and remedial, broadly

[17] Kristin S. Shrader-Frechette, *Evaluating the Expertise of Experts*, 6 RISK: HEALTH, SAFETY & ENV'T 115, 119 (1995).

defined to encompass not only major Superfund clean-ups but also the regulations developed on the basis of technological feasibility. This area relies much more heavily on engineering and is less focused on expressing basic scientific relationships and much more focused on the innovation and invention that will produce better and more efficient pollution control and clean up over time.

Each of these last two areas has its own dynamic that will be explored further to understand the approach that is likely to produce the best and most efficient results.

A. *Translating Basic Science into Regulations*

The work of translating statutory standards that protect health or environmental amenities into regulatory requirements covers a wide range of complexity. Some of these determinations are not difficult: inhalation of carbon monoxide in excessive amounts will lead to rapid death. Other determinations are far more difficult: that inhalation of airborne particulate matter can result in adverse health effects is probably generally accepted by scientists, but it is far from settled as to which sizes of particles and of what chemical composition result in which adverse health effects. Obviously if, say, illness could be traced to sulfate particles but not to wood smoke particles, regulations protective of human health should be aimed at sulfate production but not at the burning of wood. As these basic questions vary in their complexity, they also vary in the time and effort necessary to resolve them. In fact, frequently, it is not possible to make accurate estimates of the time needed to answer the issues presented because the initial round of investigation may raise unforeseen questions that must be answered in another round of data collection and analysis.

A useful example of the unfolding of new questions as a scientific investigation progresses can be found in the views expressed by EPA's Science Advisory Board (SAB) on the issue of what level of arsenic in drinking water will be protective of human health. In the late 1990s, the SAB reviewed the studies on the effects of arsenic, particularly one study from Taiwan indicating increased cancer where drinking water contained naturally occurring arsenic, and another with similar exposures in Utah that showed no such increase.[18] The SAB found that the

[18] U.S. ENVTL. PROT. AGENCY SCI. ADVISORY BD., ARSENIC PROPOSED

Taiwan arsenic data had "serious limitations" for use in a quantitative assessment of risk in the United States, noting that the Taiwan study population was rural, very poor, and had varying degrees of nutritional deficiencies that could have enhanced the effects of arsenic. For instance, the Taiwan study population was estimated to have selenium intakes that were only 25 percent of the recommended dietary intake, and the SAB noted that several studies have documented substantial effects of smaller selenium decrements on bladder and lung cancer. The SAB also suggested that the Utah study, which found no evidence of either bladder or lung cancer where mean drinking water concentrations of arsenic approached 200 µg/L, cast further doubt on the applicability of the Taiwan results to the U.S. population. Although the SAB recognized shortcomings associated with the Utah study (the study population was limited in size and was largely Mormon and, therefore, the analysis might have been confounded by the lifestyle differences between the study population and the general American population), the SAB concluded that transferring the dose response curves describing the cancer risk from Taiwan to the U.S. was likely to bias U.S. risk estimates towards overestimates. If one really wanted to understand the effect of arsenic in drinking water, the only realistic course would have been to undertake another epidemiological study which had adequate numbers in a study group that consumed alcohol and caffeine but drank water with "high" concentrations of naturally occurring arsenic, and had no dietary deficiencies of selenium. This would, of course, take time and money but might very well show that removal of low concentrations of arsenic from drinking water is not necessary to protect public health in the United States.

The importance of comprehensive science in reducing uncertainty—and frequently relaxing regulatory requirements which assume that the area of uncertainty is an area of risk—is illustrated by the rat feeding studies which have been the basis for the regulatory cancer slope factor for PCBs. The cancer slope factor was initially developed from a number of limited studies which tested one or another commercial mixture or "Aroclor" of PCBs at various doses. A subsequent comprehensive feeding

DRINKING WATER REGULATION: A SCIENCE ADVISORY BOARD REVIEW OF CERTAIN ELEMENTS OF THE PROPOSAL (2000).

study using all of the Aroclors at a number of doses filled gaps in the knowledge and data on PCBs from the more limited studies; this in turn reduced the uncertainty surrounding the carcinogenicity of PCBs and resulted in a significant lowering of the cancer slope factor.[19]

An obvious need of the environmental agencies is to have the ability to do the type of investigation suggested by the cases of airborne particulates, arsenic in drinking water, and PCBs: examination of a field shows that existing investigations have limitations which raise questions about extrapolating a study to a broad general conclusion, typically with considerable uncertainty associated with the generalized finding. Since the societal values to which those scientific findings are married are typically aimed at avoiding risk, the result is frequently to regulate more stringently than might be required if knowledge were more complete and uncertainty much narrower. Greater knowledge in this area should help make regulation more a scalpel than a blunt instrument.

B. *Science Focused on Regulation*

Generally speaking, the environmental statutes set timetables for the promulgation of regulations so that, if the statutory schedule is to be adhered to, there is not time for much research. This is the result of the societal value expressed in the regulatory schedules: it is better to take action now with partial knowledge than to delay action until one has comprehensive if not perfect knowledge. This results in some judgments that spring more from empirical experience than scientific analysis. The designation of hazardous wastes under the Resource Conservation and Recovery Act (RCRA) has a large element of this: many of these wastes are identified by their history rather than their chemistry. More than one hundred listed wastes are described as the by-products or residues or wastewaters that result from particular industrial processes rather than by their chemical composition or some other

[19] EPA did not take on this comprehensive work; it was conducted by an independent laboratory with funds provided by General Electric, one of the few companies that still have a major stake in the toxicology of PCBs. *See* B.A. Mayes et al., *Comparative Carcinogenicity in Sprague-Dawley Rats of the Polychlorinated Biphenyl Mixtures Aroclors 1016, 1242, 1254, and 1260*, TOXICOL. SCI, 62 (1998).

hazardous characteristic such as flammability.[20] This method of identification makes it easier to identify the waste when it is first produced but does little to make clear what it is about the waste that makes it hazardous and at what concentration or volume.

It should also be noted that once the regulatory system is established it is usually very difficult to make fundamental changes in its organizational framework. For instance, when PCB use was banned in the 1970s, EPA had to decide the point at which PCBs no longer presented an unreasonable risk of injury to health.[21] By rule, the agency cut off regulation of PCBs at 50 ppm.[22] This aspect of the rule was not supported by the administrative record and was vacated by the Court of Appeals for the District of Columbia Circuit.[23] Nevertheless, residual elements of the 50 ppm standard remain in the rule today; at a more fundamental level, EPA has never shifted from its focus on PCB concentrations as the measurement of risk despite the fact that it is exposure to the quantity of PCBs which results in risk, not the concentration of PCBs.[24]

Two lessons can be drawn from the writing of regulations under the pressure of time and with only partial knowledge of scientific facts that govern the field. First, the promulgating agency should think through the framework of the regulation with great care so that it matches the correct aspect of the substance that is being regulated; if risk comes from quantity, regulate exposure to quantity. Second, write the regulations being explicit that the science they are based on is still being developed and that the regulations may therefore need to be changed or amended in the future. If possible, the focus of on-going or future investigations

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[20] 40 C.F.R. § 261.32 (2007).

[21] 15 U.S.C. § 2605(e)(2)(B) (2000) ("The administrator may by rule authorize the manufacture, processing, distribution in commerce or use . . . of any polychlorinated biphenyl . . . if the administrator finds that such manufacture, processing, distribution in commerce or use . . . will not present any unreasonable risk of injury to health or the environment.").

[22] EDF v. EPA 636 F.2d 1267, 1279–80, (D.C. Cir. 1980).

[23] *Id*.

[24] *See* 40 C.F.R. 761.2 (2007), *available at* http://edocket.access.gpo.gov/cfr_2007/julqtr/pdf/40cfr761.2.pdf; U.S. ENVTL. PROT. AGENCY, INTEGRATED RISK INFORMATION SYSTEM, POLYCHLORINATED BIPHENYLS (PCBS), http://www.epa.gov/ncea/iris/subst/0294.htm (last visited Sept. 20, 2008).

should be pointed out so that the public and regulated entities have the best sense of what the future may hold and can plan accordingly in the way they use the chemical or substance.

C. *Technological and Remedial Science*

This area covers both regulations that lay out requirements for controlling emissions or discharges based on what is technologically feasible and the techniques and approaches used in clean-ups of hazardous substances and wastes under Superfund and RCRA. This area is dominated by engineering. It differs from the regulatory areas predominantly based on science in that it can be and usually is improved on from year to year. American manufacturing methods are in a constant state of change as companies push to find more efficient and less expensive methods to manufacture goods that the public wants. This change is driven by the search to reduce costs, to introduce new products or versions of products, and to retire or replace old products that no longer have a market. In those areas of the market where there is a clear price tag on the disposal of wastes, these improvements will be driven in part by trying to avoid such costs. An example is the response of American industry in the mid-1980s when the RCRA hazardous waste regulations went into place. As any lawyer can attest who has had the opportunity to review a company's environmental records for that period, the normal course was that, not too long after the regulations were proposed that would govern the disposal of a company's hazardous waste, someone in the company did a calculation of what it was likely to cost to get rid of the waste. If the cost of disposal was anything more than de minimus, there followed an analysis of how to reduce the cost. Were there non-hazardous substitutes for the process? Could the product be made using less of the hazardous material? Could some or all of the waste be reclaimed or recycled or used to make another product?

The lesson to be learned from this is that the profit motive can, when incentives are appropriately structured, be a very useful tool to foster the reduction of environmental emissions and discharges. The additional lesson is that this aspect of the science and engineering that is used in the government's environmental programs is continually changing, usually at a slow pace as one modest improvement after another is discovered and thought out

and put into production, but sometimes at a fast pace when new technologies, problems, or findings create a sufficiently strong incentive for ingenious solutions. The scientific product that will best serve the development and advancement of "remedial engineering" is the analytical collection and review of industrial practices, particularly innovative practices.

III. CRITERIA FOR QUALITY REGULATORY SCIENCE

Before proposing alternative schemes that would improve the quality, timeliness, and focus of the government's environmental science, we will start by setting out some propositions that we trust are not too controversial.

First, settling a scientific controversy through litigation should be a last resort, not the normal course of business. The first reason for this is that most of the actual science, as opposed to the question of whether the societal values have been properly applied to the science, is time-consuming and expensive to research. If the arsenic in drinking water decision were contested and the government was defeated on the grounds that the record had to be supplemented by a comprehensive epidemiological study to avoid being arbitrary or capricious in choosing between the Taiwan study and the Utah study, at least two to three years are likely to be spent in briefing the case, arguing it, waiting for the Court of Appeals to decide it, and then having the Agency decide whether it will seek Supreme Court review or go back to the drawing board. At the conclusion of that process, the work of designing and carrying out another epidemiological study is likely to begin. Several more years would pass before an appropriate study population could be found and the data could be collected and analyzed. It is reasonable to estimate that a minimum of seven or eight years are likely to be consumed before a second final decision would be ready for promulgation. That is a lot of time. A process that avoided such extensive delays should be favored.

Second, few lay judges bring to scientific controversy the background and ability to decide competently and consistently what weight to give to differing pieces and views of the scientific puzzle. The deference that the courts show to expert agencies is rooted in large measure in the fact that it takes an expert to understand the pros and cons of the more complex decisions that are faced in specialized inquiries. As a result, the courts provide

rough justice: if an agency's errors are of a type or magnitude that a well-educated layman can confidently identify and pass judgment on, the courts should be able to correct them, but if the errors are more subtle or obscure or counter-intuitive, the courts will not upset the views of the agency experts. There is a better chance of getting the best scientific result if the highly complex issues are resolved between knowledgeable scientists rather than between skilled lawyers.[25]

Finally, the adversary process of litigation runs counter to the culture of science. Every litigator recognizes that victory in trial depends not only on the inherent factual strength of one's case, but to a significant measure on one's skill in advocacy. The scientist, in contrast, sees himself in a quest for the truth where persuasion should lie in the power of the tests to which he subjects a hypothesis, not in his personal persuasive powers. These precepts counsel for a science regime in which the range of controversy over a scientific investigation is reduced by reaching agreement among the interested parties on exactly what questions should be asked and what data should be collected and how it should be analyzed at an early stage of the investigation. This should be done very largely by scientists; lawyers may be helpful in adding clarity and articulation and assuring that the scientists have asked the appropriate self-critical questions, but the basic formulation of the investigation and its conduct is for

[25] This should not be taken as an argument that litigation and the courts have no place in the controversies of environmental science. For instance, in our view, the Data Quality Act, codified in a note to 44 U.S.C. § 3516 (2000), which is aimed at strengthening the "quality, objectivity, utility, and integrity of information" disseminated by the government and, hence, government-sponsored science, has a flaw in that determinations under the statute are not judicially reviewable, and thus may not be taken as seriously as they should by some agency decision-makers. Pub.L. 106-554, § 1(a)(3), 114 Stat. 2763, 2763A-153 (2000). Although the Act and the guidelines published under it provide for administrative mechanisms for private parties to seek the correction of government data that they claim is false or inaccurate, the statutory language does not directly provide for judicial review of agency action and the courts have held that there is no private right of action under the statute, with the result that judicial review of agency action is not available. *See* Salt Inst. v. Leavitt, 440 F.3d 156 (4th Cir. 2006); *In re* Operation of Missouri River System Litig., 03-MD-1555 (PAM) (D. Mont. 2004). Without the right to court review, the Act loses much of its force as a constraint on wayward agencies. The problem is not to get federal agencies to promise to put out accurate data; it is having an effective method of enforcing that promise when it appears to have been ignored.

scientists, not lawyers.

Environmental regulatory decision-making will benefit from scientific inputs that are developed, debated, and decided through a process and culture that emphasizes consensus and objectivity. The scientific output from this system should have several desired characteristics. First, one wants *sound science*: science that has the respect of experts in the field; science that will withstand the close scrutiny of outsiders. Unfortunately, there are many examples where the scientific foundation of EPA's regulatory decisions does not meet that standard. This failing is frequently uncovered and "corrected" in the context of litigation, as the following examples show. Our point is not that litigation should be abandoned but that mechanisms should be employed that make resort to litigation much less frequent:

- In 1994, the D.C. Circuit over-turned an EPA decision to list methylene diphenyl diisocyanate (MDI) as a "high risk" air pollutant based on a generic air dispersion model.[26] The problem was that EPA's determination was scientifically implausible because MDI was a solid at the relevant temperatures, a fact with which EPA was confronted but refused to consider.[27] The court held "EPA has not pointed to any record evidence that shows a rational relationship between the generic air dispersion model and the physical properties of MDI, even in the face of the specific scientific evidence to the contrary adduced by [the Chemical Manufacturers Association]."[28]
- In 2000, the D.C. Circuit overturned another EPA regulation setting a drinking water standard for chloroform based on a linear no-threshold risk model, even though the Agency itself, and its own SAB, had concluded that the scientific evidence demonstrated that chloroform did not conform to the linear, no threshold dose-response model.[29]

The criticism of EPA's scientific determinations is not limited to the courts and rulemaking commentators. A former General Counsel of EPA gave a dark summary of the Agency's science:

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[26] Chemical Mfrs. Ass'n v. EPA, 28 F.3d 1259 (D.C. Cir. 1994).

[27] *Id.* at 1265–66.

[28] *Id.* at 1265.

[29] Chlorine Chemistry Council v. EPA, 206 F.3d 1286, 1288–89 (D.C. Cir. 2000).

"EPA is truly bipartisan in its tendency to run roughshod over science to follow the political winds."[30] In its own 1992 self-assessment of its scientific practices, EPA concluded that it "has not always assured that contrasting, reputable scientific views are well explored and well documented from the beginning to the end of the regulatory process . . . EPA science is *perceived* by many people, both inside and outside the Agency, to be adjusted to fit policy."[31] Each of the examples listed above, and no doubt countless others, involves regulatory decisions that one or another affected interest perceived was not made on the basis of sound, credible, transparent science. An institutional regime which promotes sound science should clearly improve the quality of EPA's decision-making.

Equally important to *sound science* (an objective quality), one also wants *trusted science* (a subjective quality). There are a great many scientific findings that educated laymen do not have the background to critique or judge. Moreover, every scientific study involves choices and analyses that could be subject to conscious or unconscious bias, and which may not be apparent to even the trained observer who only has access to the final published scientific paper. In these circumstances, those who distrust the findings are often quick to move from a judgment of the science to a judgment of the people who produced it. Work paid for by an industrial interest that reached results that favor the financial interests of the industry are suspect. A common response would likely be something like: "Of course a study paid for by the timber industry will favor the forest management practices of the industry." Conversely, a study by a scientist who is an outspoken activist on environmental issues will be viewed as suspect by many scientists and industry representatives. If the science is trusted, the controversy can, as it should, focus on the scientific merits of its findings.

Science must also be *timely*. Regulatory agencies such as EPA are often under statutory or court-imposed deadlines to make

[30] E. Donald Elliot, *Strengthening Science's Voice at EPA*, 66 LAW & CONTEMP. PROBS. 45, 45 (2003).

[31] U.S. ENVTL. PROT. AGENCY, SAFEGUARDING THE FUTURE: CREDIBLE SCIENCE, CREDIBLE DECISIONS, THE REPORT OF THE EXPERT PANEL ON THE ROLE OF SCIENCE AT EPA TO ADMINISTRATOR WILLIAM REILLY 36–37 (1992).

regulatory decisions, and it is critical that the science these agencies need to make their determinations is available at the time the decisions must be made. Industry is often accused of seeking to delay regulatory requirements by arguing for more study; there often is, beyond this strategic ploy, a real need for more timely science. An example of the importance (and lack) of timeliness of regulatory science is the National Acid Precipitation Assessment Program, a $500 million research program created by Congress in 1980 to evaluate the causes and risks of acid rain, which had not been completed in time for the enactment of a national regulatory program to address acid rain in 1990.[32]

It is also important, where possible, to have *comprehensive science.* That is part of the lesson to be learned from both the example of the arsenic in drinking water controversy and the development of the cancer slope factor for PCBs. In both those cases, the degree of risk could not be determined from the existing partial studies with any accuracy. In both cases this uncertainty led to assessment and regulation that was designed to guard against the zone of uncertainty actually being a zone of risk. In the case of the PCBs, comprehensive feeding studies led to an assessment that concluded that much of the zone of uncertainty was not a zone of risk. With arsenic, the question is still open. Of course, partial analysis may also lead to a false sense that there is no risk. Tests only done at low dosages will miss dangers present at higher, perhaps unusual, dosages or present only when suspect chemicals are fed to the correct animal: mink, for instance, are markedly more likely to suffer adverse reproductive results from PCB exposure than are other animals.[33]

Another important aspect of comprehensive science is to consider fairly all the relevant studies as part of the review: those that showed, say, that a chemical had an effect on a child's neurodevelopment and those that did not show such an effect. One clear reason for this is that at the 95 percent confidence level, if a

[32] *See* Edward S. Rubin et al., *Keeping Climate Research Relevant*, 8 ISSUES SCI. & TECH., Winter 1991–92, at 47, 48–50; *see also* Steve Russell, *Potential Fall Out From the National Acid Precipitation Assessment Program*, 6 BYU J. Pub. L. 423, 425–26 (1992).

[33] Isaac I Wirgin & John Waldman, *Bioaccumulation and Toxicities of Aromatic Hydrocarbon Contaminants at Different Trophic Levels of the Hudson River Ecosystem*, *in* ENVIRONMENTAL AND OCCUPATIONAL MEDICINE 1552, 1563 (William N. Rom & Steven B. Markowit eds., 4th ed. 2006).

chemical exposure is measured against twenty endpoints, it is likely that random chance alone will produce one statistically significant "positive" result. If that investigation is written up focusing only on the positive result and not reporting the nineteen negative results, a misleading impression is created. Worse, if random positive results from a number of studies are reported out of context, a deeply misleading conclusion is likely to be drawn, one that would be refuted if it were clearly stated that the results were not replicated in succeeding similar cohorts.[34]

Finally, *transparent science* should be favored. The easier it is for both experts and laymen to understand the data and the analytical reasoning and scientific precepts that an investigator employs, the greater the confidence there is likely to be in a well-supported result. In the long run, transparency should reduce controversy and aid in the acceptance of scientific results.

Sound science, trusted science, timely science, comprehensive science, transparent science—this constellation of characteristics is the ideal. Attaining the ideal is not easy and will not be consistently achieved, but a system that builds in incentives to achieve these goals and constrains interested parties from straying from them will be a major stride in the right direction.[35]

IV. ACHIEVING BETTER REGULATORY SCIENCE

A great deal of the government's environmental science is

[34] *See, e.g.*, D.V. Cicchetti, A. S. Kaufman & S. S. Sparrow, *The Relationship Between Prenatal and Postnatal Exposure to Polychlorinated Biphenyls (PCBs) and Cognitive, Neuropsychological and Behavioral Deficits: A Critical Appraisal*, 41 PSYCHOLOGY IN THE SCHOOLS 589, 597 (2004).

[35] Implicitly, these characteristics require an open system where opinions and information are fully shared and impartially weighed. Knowledge that one's judgments and decisions are subject to impartial and intelligent review is a valuable constraint for promoting sound decision-making both on scientific and other issues. The Administrative Procedure Act embodies this view in its standards for agency action. A real weakness of the Superfund remedial program is that EPA's scientific and engineering judgments are shielded from such review. The bar on district court review of remedy selection removes the courts from this traditional role. 42 U.S.C. § 9613(h) (2000). EPA has not instituted an independent and impartial scientific review in its place. The result has been a deep lack of confidence in EPA's decision-making in numerous Superfund cases which do not involve clean ups that demand a fast response, but will cost tens of millions of dollars. This approach is also destructive of trusted science. We recommend reform of this system to bring it into line with the principles we set out in this article.

controversial and generates adversarial conflicts. Exploring an example can help make these dynamics clearer. Many species of fish spawn enormous numbers of eggs per female. A very low number of the eggs produce adults and the mortality rate is highest in the early life stages. A robust fish population that is limited, say, by the available food in the second year of life will not be increased by doubling the numbers of fish that survive for the first year. Moreover, if the population in the first year suffers mortality from anthropogenic causes that do not drive the numbers of fish below the limitation attributable to food availability in the second year, the mortality caused by humans in the first year will not affect the adult population. On the other hand, if the population has been driven very low by overfishing or environmental catastrophe, so that food is no longer a limitation, then further mortality in the first year may very well be reflected in lower adult numbers. This density dependence of the population is not difficult to accept when described in these bland and clinical terms. This view is also supported by the common knowledge that one can consume a large number of fish from a river or ocean population with the confident belief that the population can replenish itself but also with the knowledge that overfishing can be destructive when it reaches a tipping point.

But when this abstract proposition is set out with the number of early life forms of fish killed in large scale water withdrawals for power plant cooling, there will be far more controversy and emotion brought to the subject. Estimated counts of early life forms of fish killed by entrainment, the passage through the plant's cooling water system, have been made at a number of power plants on the Hudson River. At six of those plants the numbers of early life forms of five species of fish combined killed in 1985, a year picked at random, was approximately 568,000,000.[36] It is counter-intuitive, *very* counter-intuitive, for a layman to conclude that numbers of that magnitude, repeated year after year, will not have a profound effect on the fish stocks. But these plants have been operating for more than thirty years and there has been no crash of the stocks to date. Many stocks are doing very well. Given the simple fact of these numbers, it is not hard to understand that

[36] DRAFT EIS FOR SPDES PERMITS FOR BOWLINE POINT, INDIAN POINT 2 & 3, AND ROSETON STEAM ELECTRIC GENERATING STATIONS, APP. VI-1-D-1, ESTIMATED NUMBERS OF FISH KILLED DUE TO ENTRAINMENT (1999).

environmental groups interested in fish protection will be deeply antagonistic to the power plants' once-through cooling water systems. Given the continuing healthy fish stocks in the river, it is not hard to understand that the power generation interests will be deeply antagonistic to a very costly retrofit of a closed cycle cooling system which is done in the name of protecting fish.

We would argue that the crucial question in this example is whether injury to fish should be measured in terms of individual fish or in terms of fish populations. The interests that are aligned on either side of the question are obviously the power generators and the environmental fish protection groups with the position of the government likely unknown or even varying between the federal and state government. We would argue that the right time to try to resolve this crucial question is before a great deal of research or analysis is done. And that, so long as the statute in question, the Clean Water Act, does not provide the answer in terms of a societal value, which it does not, it should be resolved to the extent possible by scientists.

What is the rationale for this approach? First, reaching scientific consensus on whether one measures injury in terms of individual fish or fish populations is not the sort of question that requires research on the Hudson River; there is plenty of discussion in the literature as to what measurements matter. Moreover, if one concludes that the correct metric is individual fish, there really is little need for further digging—the annual destruction of 500 million early life forms of fish should be enough to conclude that, in the words of the Clean Water Act, there is an "adverse environmental impact." If the correct metric is fish populations, then the direction of future research is clearly set: what effect, if any, is entrainment mortality at the Hudson power plants having on Hudson fish stocks? This is not an easy question to answer in the short term and it is an expensive one to answer in the long term, but there is little point to posing it and investing in the research unless there is agreement on the correct metric.[37]

[37] In the 1980 Hudson River settlement agreement, the utilities committed at least $2 million a year in 1980 dollars to undertake studies designed both to determine the numbers of fish killed by impingement and entrainment at the Hudson River plants and studies to assess the adult fish stocks, but the agreement was silent as to which metric would be used in future regulatory analyses of the effects of impingement and entrainment. THE HUDSON RIVER POWER PLANT

Assuming that there is agreement that the metric for measuring impact on fish should be decided early and that it should be decided by scientists, how does one assure that all the stakeholders will have confidence in and be willing to abide by the scientific decision and the results of any research that follows from it? In other words, how do we get trusted science? First, all three classes of stakeholders (power companies, environmentalists, government) must be able to participate in the resolution of the metric question and be able to have the assistance of competent scientific help. The same is true with regard to any later research. One obvious and effective way for stakeholders to have a committed stake in the scientific work is to put up part of the money that pays for the work. The sharing of costs between the government and profit-making organizations, typically industry, is fully appropriate and should become a routine part of assuring trusted science to which diverse interests are committed.

The non-profit non-governmental organizations (NGOs) present a special problem. Making a meaningful financial contribution that assures a stakeholder's commitment is likely to be prohibitive for thinly stretched environmental groups with few resources for costly scientific advice. What mechanism would help to assure the NGOs' commitment to the scientific enterprise and acceptance of its outcome? One possibility would be for NGOs to form alliances with universities strong in relevant disciplines and to designate respected professors of their choosing to review and endorse scientific investigation on behalf of the NGO. In short, the NGO would be contributing the reputation of the scientist; it would be difficult for the NGO to attack its own endorsers if it simply did not like the outcome of the investigation and the NGO's ability to gain future endorsements would be likely to decline. Another alternative would be public funding for the NGO to spend on its chosen suite of joint scientific investigations of this sort. But if that route is followed it is important to find mechanisms that ensure that the choice by the NGO represents a commitment to joint and cooperative scientific investigation. It is not the method, but the end result, that matters here.

Next, one needs to consider the mechanisms that will promote

SETTLEMENT: MATERIALS PREPARED FOR A CONFERENCE SPONSORED BY NEW YORK UNIVERSITY SCHOOL OF LAW AND THE NATURAL RESOURCES DEFENSE COUNCIL (Ross Sandler and David Schoenbrod, eds. 1981).

impartial science. Given the difference in points of view that the fishery example assumes, the selection of researchers acceptable to all interests is one indicator of impartiality. As just discussed, the commitment of financial resources by a spectrum of interests is another. Another mechanism that could be employed would be competitive bidding to do the scientific work, with some form of committee with representatives from industry, environmental groups, and government reviewing and selecting the proposals submitted. This should assure that the selected scientists would clearly understand that they were not beholden to any single interest. Through the public notices seeking the scientific help, it might well broaden the field of investigators engaged in such work. It would reduce the ability of any party unhappy with the results to claim that the results simply reflect the money or interests behind the investigation.

We also recommend that peer review in a modified form be used to advance impartial and trusted science. In the typical scientific context, peer review takes place when the investigation is complete and ready for presentation to the public and it typically is done by a small number of peers. In the case of major, long term scientific work we argue that it would be better, first, to assure that all the major disciplines that contribute to the scientific product are represented on the peer review panel and that the panel meet periodically as the work progresses, both to consider whether the investigation has been conducted soundly to date and to advise with regard to unforeseen issues that arise in the course of the work. For instance, in a fish population study, changes in the legal fishing regime, say, establishing a catch and release regime for some or all of the popular sports fish in the study area, are likely to be beyond the control of the investigators, but will pose serious questions as to how it may affect the fish stock in terms of its age distribution as well as its total size. This sort of peer review panel would operate as a continuing monitor of the investigation with the aim of reducing or eliminating errors and missteps while seeking to assure impartiality in the work.

The interests of transparent science are best served in this example not only by assuring the production of full reports, but also by clear subscription to the resolution of the crucial question set out above. In fact, in the actual Hudson case this was not done, and this has produced results that put in question the value of the

entire research project.[38] The environmental groups settled their claims against the Hudson River power plants in 1980 with a program that included a number of measures such as scheduled outage periods and better fish return devices at the screens to the plants and with the power generators conducting a biological monitoring program on the Hudson. This program was, in fact, carried on with a thoroughness and at a scale that allowed a great deal to be learnt about the fish stocks of the river and the effects on them of the power plant cooling water systems. Implicitly the settlement and the monitoring program adopted the metric of fish populations. But nowhere was this openly affirmed. Perhaps it could not be agreed on and the settlement should be viewed more realistically as a truce in a Thirty Years War rather than as a Peace of Westphalia. In any case, the extensive data collection and analysis conducted by the power generators was met at the end of the program by the state analogue to EPA deciding without discussion that effects on individual fish were the proper measurement of adverse impacts.[39] It may be possible to defend either metric at the start of a controversy. It is not easy to defend changing metrics after the work is done. Transparency is more than stating results fully and fairly. It is spelling out in clear terms what one has agreed on as the measures by which a controversy can be resolved. Transparency binds participants just as much as it informs outsiders.

Finally, we touch on the issue of timely science in the Hudson River example. The blunt reality is that it takes many years to collect and analyze data on a large scale biological system influenced by a myriad of different elements. There is fresh water flow in the spring which determines where spawning takes place and hence the vulnerability of the fish eggs and larvae to the plants. There is water temperature which determines when the spawning takes place. There are plant outages, planned and not planned, that influence the loss of eggs and larvae. There is the management of fish stocks that in large measure determines the number of spawning fish from year to year. There is the slow, steady reduction of pollution and its stress on fish in the river; and

[38] *Id.*

[39] *In re* Entergy Nuclear Indian Point 2 LLC and Entergy Nuclear Indian Point 3 LLC, NYS DEC No. 3-5522-00011/00004 (Aug. 13, 2008).

so on. Sorting out these confounding factors takes time and cannot be done quickly. It is foolish to think one can speed this up. But one should at least make good use of the time needed for such work. In a few rivers and estuaries the thirty years following the passage of the Clean Water Act in 1972 were employed productively.[40] In a great many, the complex biological issues were ignored.[41] The result was that when, at the turn of the century, EPA was faced with having to promulgate regulations on minimizing adverse environmental impacts from cooling water intake structures at major power plants, it had very little systematic knowledge to work from and was unable to formulate rules that demonstrated a substantial advance over what the Agency would have been able to do in the 1970s.[42]

V. TWO PROPOSED MODELS FOR IMPROVING REGULATORY SCIENCE

As we hope the discussion above has demonstrated, achieving

[40] In the Federal Register preamble to its cooling water intake structure rule for existing power plants, EPA gives four examples of waterbodies which have been subject to careful data collection and analysis. The agency then goes on to look at the state of the data more broadly:

> Although numerous studies were conducted to determine the environmental impacts caused by impingement and entrainment at existing facilities, many of them are based on limited data that were collected as long as 25 years ago. EPA's review of available facility impingement and entrainment studies identified a substantial number of serious study design limitations, including data collections for only one to two years or limited to one season and for a subset of the species affected by cooling water intakes; limited taxonomic detail (i.e., many losses not identified to the species level); a general lack of statistical information such as inclusion of variance measures in impingement and entrainment estimates; and the lack of standard methods and metrics for quantifying impingement and entrainment, which limits the potential for evaluating cumulative impacts across multiple facilities. Further, in many cases it is likely that facility operating conditions and/or the state of the waterbody itself has changed since these studies were conducted. Finally, the methods for monitoring impingement and entrainment used in the 1970s and 1980s, when most section 316(b) evaluations were performed, were often inconsistent and incomplete, making quantification of impacts difficult in some cases.

National Pollutant Discharge Elimination System—Final Regulations to Establish Requirements for Cooling Water Intake Structures at Phase II Existing Facilities, 69 Fed. Reg. 41576, 41588 (July 9, 2004) (to be codified at 40 C.F.R. pts. 9, 122, 123, 124 & 125).

[41] *Id.* at 41624.

[42] *Id.*

sound and credible scientific bases for regulatory decisions is a challenging and difficult undertaking, and further progress and innovation are needed to address these challenges. We propose here two alternative innovative process-based approaches for strengthening the scientific input for environmental regulatory decisions.

Both proposals seek to minimize the influence of politics on science. An agency such as EPA that must make politically-charged regulatory decisions, such as the level at which to set national ambient air quality standards or the acceptable level of pesticide use or exposure, is increasingly seen (mostly accurately) as a political actor rather than a neutral arbitrator.[43] To take an extreme example, the Department of Interior's Office of Inspector General recently reported that a senior agency political appointee without any scientific training "bullied, insulted, and harassed the professional staff of the U.S. Fish and Wildlife Service (FWS) to change documents and alter biological reporting regarding the Endangered Species Program."[44] A recent survey found that over half of EPA's scientists reported experiencing political interference with their scientific decisions at the agency.[45] By institutionally separating scientific assessments from the political environment inherent to regulatory decisions, scientific results can be immunized to the extent possible from political interference and influence.[46]

[43] The National Academy of Sciences noted the inevitable quasi-political nature of EPA back in the 1970s: "Much of the process by which EPA makes regulatory decisions is adversarial, and often scientific information is provided by one of the principals. Similarly, the Agency itself is sometimes placed in an advocacy role." 2 NATIONAL RESEARCH COUNCIL, DECISION MAKING IN THE ENVIRONMENTAL PROTECTION AGENCY 48 (1977).

[44] J.B. Ruhl, *Reconstructing the Wall of Virtue: Maxims for the Co-Evolution of Environmental Law and Environmental Science*, 37 ENVTL. L. 1063, 1078 (2007) (quoting OFFICE OF INSPECTOR GEN., DEP'T OF THE INTERIOR, REPORT OF INVESTIGATION OF JULIE MACDONALD 2 (2007)).

[45] Christopher Lee, *Scientists Report Political Interference*, WASH. POST, Apr. 24, 2008, at A19.

[46] The potential benefits of such institutional separation are illustrated by EPA's previous decisions regarding formaldehyde and dioxin, two of the most highly-charged regulatory risk determinations EPA has made. As detailed by Sheila Jasanoff, EPA successfully handled these two controversial decisions by creating "a credible scientific forum . . . where the scientific questions critical to policy-making appeared to have been definitively, and impartially answered. In each case a collective decision among scientists with no apparent political stake

Separating scientific investigations and assessments from political influence can help reduce what Wendy Wagner has called the "science charade,"[47] the temptation and tendency of regulatory agencies to portray many regulatory decisions as purely scientific in order to immunize them from criticism from Congress, the courts, and interest groups.[48] Improperly characterizing regulatory decisions with significant normative dimensions as somehow being dictated by science is anti-democratic, as it misleads and limits the participation of non-scientific individuals and entities outside the agency.

A separate agency or system of scientific responsibility that reports not only what science does tell us about a particular problem, but, perhaps more importantly, what the science does not tell us, can help address the scientific charade. Once the independent and trusted scientific entity has weighed in with its scientific input, the policy and normative role of the regulatory agency in taking that science and integrating it with the applicable societal values in a regulatory decision will be clear. It will be readily apparent that the science cannot answer or dictate the ultimate regulatory decision, forcing the regulatory agency more expressly to acknowledge and explain the non-scientific factors and analysis that led to the final regulatory decision. An example of this dynamic is EPA's revision to its ozone air quality standard in 1997, which the EPA Administrator repeatedly characterized as a purely scientific determination.[49] However, this misimpression

in the matter at least temporarily 'black boxed' issues that had long vexed the agency." Sheila Jasanoff, *Science, Politics, and the Regulation of Expertise at EPA*, 7 OSIRIS 194, 216 (1992).

[47] Wendy E. Wagner, *The Science Charade in Toxic Risk Regulation*, 95 COLUM. L. REV. 1613 (1995).

[48] *See id.* at 1617; *see also* David L. Bazelon, *Risk and Responsibility*, 205 SCI. 277, 278 (1979); Cary Coglianese & Gary E. Marchant, *Shifting Sands: The Limits of Science in Setting Risk Standards*, 152 U. PA. L. REV. 1255 (2004); Giandomenico Majone, *Science and Trans-Science in Standard Setting*, 9 SCI., TECH., & HUM. VALUES 15 (1984); Mark E. Rushefsky, *The Misuse of Science in Governmental Decisionmaking*, 9 SCI., TECH., & HUM. VALUES 47 (1984); Eugene B. Skolnikoff, *The Role of Science in Policy*, ENV'T, June 1999, at 17, 19.

[49] *See* Coglianese & Marchant, *supra* note 48, at 1264–73. For example, Administrator Browner frequently told Congress that she "listened to the science." *Id.* (citing *Clean Air Act: Ozone and Particulate Matter Standards: Hearing Before the Subcomm. on Clean Air, Wetlands, Private Property and Nuclear Safety of the Senate Comm. on Env't and Pub. Works*, 105th Cong.

was undercut by the agency's own Clean Air Scientific Advisory Committee, which advised that "there is no 'bright line' which distinguishes any of the proposed standards (either the level or the number of allowable exceedences) as being significantly more protective of public health" and thus "the selection of a specific level and number of allowable exceedences is a policy judgment."[50] In the same way, a document from either of the bodies we recommend stating what science does and does not answer would force the regulatory agency more expressly and honestly to disclose the policy and normative bases for its decision.

Both of our proposals have their strengths and weaknesses. We present them in general terms to focus analysis and provoke discussion.

A. *Scientific and Engineering Investigation Board*

Our first proposal is for a new body at EPA that would be engaged in the development of the science that the agency will rely on at a much earlier stage than the present SAB. The SAB's charter states that "[t]he objective of the SAB is to provide independent advice and peer review to EPA's Administrator on the scientific and technical aspects of environmental issues."[51] It is also available to provide advice and views to the relevant Congressional committees. These are important and laudable functions. But the advice to the Administrator and the peer review generally take place very late in the development of the science; the SAB is to review and provide advice and recommendations on the adequacy and scientific basis of any "proposed criteria document, standard, limitation, or regulation."[52] This means that the SAB does its review of particular scientific products when the internal scientific work is complete, the marriage to societal values has taken place, and the documents are virtually ready for public

(1997) (testimony of Carol M. Browner, Administrator, EPA)).

[50] Letter from Dr. George T. Wolff, Chair, Clean Air Scientific Advisory Comm., to Administrator Carol M. Browner (Nov. 30, 1995), *available at* http://www.epa.gov/sab/pdf/casac02.pdf.

[51] U.S. ENVTL. PROT. AGENCY, CHARTER, EPA SCI. ADVISORY BD. (2008), *available at* http://yosemite.epa.gov/sab/sabproduct.nsf/WebBOARD/currentcharter?OpenDocument.

[52] *Id.*

comment and review. Moreover, the charter makes no reference to exchange or involvement with the stakeholders in the agency's decisions—the SAB's job is to advise the EPA, not to build and foster a framework in which the agency and its stakeholders join in a joint scientific enterprise. There is a sound basis for providing outside, respected scientists for the Administrator and Congress to consult with, but what we are proposing is a new framework for the development of EPA's science, starting much earlier in the process and for this we believe new institutional arrangements are necessary.

To achieve this objective, there should be a statutory instruction to the Administrator of EPA that he appoint a Scientific and Engineering Investigation Board (SEIB) of well-trained and respected scientists and engineers who would:

1. Receive from the Administrator on a periodic basis a list of the scientific investigations and literature reviews that need to be carried out by EPA and the timeframe within which the investigations should be completed;
2. Identify from the list the investigations that are likely to be controversial and for those investigations identify the major groups of stakeholders;
3. Convene the major groups of stakeholders for each controversial investigation and, where possible, work out with the stakeholders and the agency (represented not by the SEIB, but by the appropriate program official) an agreement as to the central questions to be answered in the investigation, a method of shared funding (or other commitment) for the investigation, and a process for the selection, preferably competitively, of impartial investigators to carry out the investigations;
4. Having solicited suggestions from the stakeholders and, perhaps the investigating scientists, select an appropriate peer review panel for the investigation;
5. Periodically obtain from the investigators, and the peer review panel, brief reports of the progress of the investigation and the date of its expected conclusion.

In order to obtain well-qualified scientists for the SEIB and reduce possible political bias, the terms of the members should be staggered and should be on the order of 5 to 7 years. Perhaps the

Administrator should be limited to making selections from lists drawn up by, say, the National Academy of Science or the National Academy of Engineering for each discipline. Respected scientists who work for one of the stakeholder interest groups should be eligible to serve on the SEIB, as is the case with the SAB, but not to deal with investigations directly involving the stakeholder group which employs them. This should maintain a healthy mix of participants from all parts of the profession while avoiding conflicts of interest.

One important part of the SEIB's work is to bring realism to the question of how much time is needed to investigate and resolve a question to which Congress or an agency wants an answer by a fixed time. The SEIB's job should be twofold: first, speaking plainly about how long it will take to answer the question, but, secondly, telling the Administrator what can be done within the statutory timetable—partial studies, studies with wide bands of uncertainty, no more than a comprehensive literature review—and then reaching agreement with the Administrator on how the matter should be handled.

An organization that has successfully employed many of the mechanisms that we recommend in the SEIB model is the Health Effects Institute (HEI): the HEI is a nonprofit corporation created in 1980 to provide independent research on air pollution issues. The HEI is equally co-funded by EPA and the automobile industry, and was established as an attempt to create a credible "neutral broker" between the EPA and the auto industry on highly controversial air pollution issues. The objective is for the HEI to provide "high-quality, impartial, and relevant science on the health effects of air pollution."[53] While initially chartered to be a research organization, it has subsequently evolved a secondary function of providing neutral scientific assessments of controversial issues. For example, after EPA promulgated its first national ambient air quality standards for fine particulate matter ($PM_{2.5}$) in 1997, the HEI was requested to conduct an independent, objective analysis of the available scientific data underlying that standard.[54] This detailed report produced by HEI, which generally

[53] HEALTH EFFECTS INSTITUTE, ABOUT HEI, http://www.healtheffects.org/about.htm (last visited Aug. 22, 2008).

[54] HEALTH EFFECTS INSTITUTE, REANALYSIS OF THE HARVARD SIX CITIES STUDY AND THE AMERICAN CANCER SOCIETY STUDY OF PARTICULATE AIR

upheld the key EPA conclusions from those studies, helped to quell the scientific controversy over the EPA standards. The HEI's commitment, implemented through both its organizational structure and procedures, to providing a neutral, objective scientific assessment has made it a highly-regarded and credible organization.[55] The HEI serves as a useful precedent for the type of independent, multi-stakeholder developer of scientific input that the SEIB model has the potential to expand.

B. *Institute for Scientific Assessments*

A second and somewhat more radical alternative would be to create an entirely new institution, perhaps named the Institute for Scientific Assessments (ISA or the Institute), to conduct scientific assessments for use in regulatory decisions. Such an institute could be in addition to and supplement the SEIB in situations where it has not been possible to reach agreement between stakeholders on the SEIB on how to proceed co-operatively. Alternatively, the Institute could replace the SEIB if one concluded that mechanisms on which the Board is built would not be effective in promoting better governmental science. The model we suggest is the creation of a separate, stand-alone agency to conduct scientific assessments and risk assessments to be used in regulatory decisions by EPA and other agencies. Unlike the roles of the National Institute of Environmental Health Sciences and the National Institute of Occupational Safety and Health, which are tasked with conducting basic scientific research that can ultimately inform the decisions of regulatory agencies such as EPA and the Occupational Safety and Health Administration, respectively, this new scientific assessment agency would not conduct its own research, but rather would gather, evaluate, and assess the existing data in a manner that could be used by a regulatory agency in making decisions. The regulatory agencies could identify questions on which they needed scientific assessments through an annual regulatory agenda, supplemented with ad hoc requests as they arise throughout the year (similar to EPA's occasional

POLLUTION AND MORTALITY (2000), *available at* http://pubs.healtheffects.org/view.php?id=6.

[55] *See* Terry J. Keating, *Lessons from the Recent History of the Health Effects Institute*, 26 SCI TECH. HUM. VALUES 409, 417 (2001); JASANOFF, *supra* note 16, at 209–16.

requests for scientific reviews by the National Research Council or its own SAB). In addition to requesting risk assessments for specific rulemakings, an agency may also request a scientific analysis from the ISA on a more general or cross-cutting issue. Congress could also request a scientific opinion from the ISA, helping to fill the gap in Congressional science advice since the demise of the Office of Technology Assessment in 1995.[56]

The Institute would then provide either a quantitative and/or qualitative assessment (depending on the matter and the available data) of the scientific data on the question presented, along with a clear identification of the uncertainties and assumptions on which such an assessment was based. The Institute's scientific assessments would be prepared by the scientific staff of the organization, and would seek to provide an objective estimate of the risks associated with the substance or activity at issue. To help ensure the objectivity of the organization, an external advisory board of representatives from industry, the public interest community, and academics would oversee and review the scientific assessments before they are released.[57] The requisitioning regulatory agency would then use that scientific assessment in making its regulatory decision, subject to all the statutory, policy, and political influences that go into such decisions.[58]

[56] Congress voted to withdraw funding for OTA in 1995 and the Office has not been revived. OFFICE OF TECHNOLOGY ASSESSMENT, http://www.gpo.gov/ota (last visited Sept. 20, 2008).

[57] The Institute would presumably be tasked with revising its report in response to the advisory board suggestions, much as the Health Effects Institute revises its reports before they are finalized in response to advice from its Health Research Committee and its Health Review Committee, which are scientific committees that oversee and review reports prepared by the HEI staff and researchers. *See* HEALTH EFFECTS INSTITUTE, ABOUT HEI, *supra* note 53.

[58] One complexity this proposal raises is how the public would have an opportunity to comment on, and perhaps challenge in court, the scientific assessments that the Institute prepares. One model would be similar to what EPA uses for its criteria documents for ambient air quality standards. The criteria documents, which are assessments of the available scientific data that are subsequently used to make a decision on whether to revise the air quality standard, are subject to a separate round of public comment before they are finalized and then used by EPA to make its regulatory decisions. There is no right of separate judicial review of the criteria documents. Alternatively, or perhaps in addition, the public could comment on the scientific assessment as part of its comments on the regulation based on the scientific assessment. Presumably, the Institute would respond to those comments directed to the merits

A separate institution to conduct such scientific assessments could provide several potential benefits. First, the stand-alone institutional structure would minimize the political influence and interference that are inherent to mission-driven regulatory agencies that must make politically-contested regulatory decisions. To be sure, the separate institution would itself be subject, like any governmental entity, to its own political biases and manipulations.[59] However, by deliberately structuring the agency to promote scientific credibility and balance, and avoiding the need to make regulatory decisions that necessarily bring political issues to the forefront, the actual and perceived scientific objectivity of the new organization could be maximized (while obviously never achieving complete objectivity). While the New Deal ideal of technocratic administrative neutrality and expertise is unachievable,[60] the design of an institution can make it more or less subject to political influence.

Accordingly, by inserting greater separation between risk assessment and the more politically-charged regulatory decisions, an independent scientific assessment organization can help enhance the credibility of both regulatory risk assessments and decision-making. When the two functions are combined in a single agency, there is always the perception, real or not, that the agency's regulatory preferences influence or bias its scientific assessments. Removing the risk assessment function into a separate institution not only eliminates this inherent built-in tension, but also allows the risk assessment entity to focus solely on structural and implementation approaches that maximize its actual and perceived scientific objectivity and credibility.

Second, an independent agency that separates risk assessment from risk management can help make regulatory decisions more transparent. Under the prevailing approach today, policy measures

of the scientific assessment, while EPA would respond to other comments on the proposed regulatory action. Judicial review would be available for both the regulation and the scientific assessment on which it was based once the regulation was finalized.

[59] *See* Nicholas A. Ashford, *Science and Values in the Regulatory Process*, 3 STAT. SCI. 377 (1988).

[60] *See* Daniel J. Gifford, *The New Deal Regulatory Model: A History of Criticisms and Refinements*, 68 MINN. L. REV. 299 (1983); Lars Noah, *Scientific "Republicanism": Expert Peer Review and the Quest for Regulatory Deliberation*, 49 EMORY L.J. 1033, 1037–39 (2000).

such as "erring on the side of safety" are embedded throughout the risk assessment and risk management phases, usually without explicit acknowledgement.[61] This makes it very difficult for anyone to really know or control how strongly (or poorly) we are erring on the side of safety. Anti-regulatory critics argue that "conservative" risk assessment assumptions during different steps of risk assessment stack-up in unintended and perhaps unreasonable ways, while proponents of the precautionary principle bemoan the absence of any explicit analysis of the application of precaution in regulatory decisions. Both sides have a point.

A separate stand-alone scientific assessment agency that is limited to describing what the science does and does not tell us, and the impact on risk estimates of the various plausible alternative assumptions, would clearly assign the role of policy goals or societal values such as erring on the side of safety and precaution to its appropriate locus in the decision by the regulatory agency. Removing these hidden and implicit policy factors from the scientific risk assessment stage will hopefully force regulatory agencies to address and incorporate normative factors such as precaution in a more deliberate and transparent manner.

Third, a stand-alone risk assessment agency can help ensure consistency of risk assessments both within and between regulatory agencies. Different federal agencies (or sometimes different offices or centers of the same agency) often undertake regulatory action on the same toxic substance, albeit in different contexts or applications.[62] The risk assessments underlying these different regulatory decisions often vary in important respects, frequently resulting from the use of different risk assessment assumptions or models.[63] A stand-alone scientific assessment

[61] *See* Albert L. Nichols & Richard J. Zeckhauser, *The Perils of Prudence: How Conservative Risk Assessments Distort Regulation*, 8 REG. TOXICOLOGY & PHARMACOLOGY 61, 67 (1988).

[62] *See, e.g.*, LORENZ R. RHOMBERG, A SURVEY OF METHODS FOR CHEMICAL HEALTH RISK ASSESSMENT AMONG FEDERAL REGULATORY AGENCIES: REPORT PREPARED FOR THE NATIONAL COMMISSION ON RISK ASSESSMENT AND RISK MANAGEMENT, *available at* http://www.riskworld.com/nreports/1996/risk_rpt/pdf/rhomberg.pdf; March Sadowitz & John D. Graham, *A Survey of Residual Cancer Risks Permitted by Health, Safety and Environmental Policy*, 6 RISK 17, 33–34 (1995).

[63] RHOMBERG, supra note 62, at 151–52.

entity could produce one risk assessment for a given substance that two or more agencies may then apply to problems within their jurisdiction, helping to promote greater inter-agency consistency.[64]

There are relevant recent precedents that demonstrate the potential value of such a stand-alone institute (in addition to the HEI discussed above):

Inter-Governmental Panel on Climate Change (IPCC): The IPCC was created by the World Meteorological Organization and by the United Nations Environment Programme in 1988 to provide periodic and objective scientific assessments of climate change. The IPCC assessments of climate change are made by hundreds of scientists nominated by national governments who work in a consensus-based approach to provide assessments of what science does and does not know about climate change. The IPCC does not seek to provide policy recommendations, rather it is strictly limited to objective assessments of scientific and other technical information that can then be used by policymakers to develop policies:

> The IPCC does not conduct any research nor does it monitor climate related data or parameters. Its role is to assess on a comprehensive, objective, open and transparent basis the latest scientific, technical and socio-economic literature produced worldwide relevant to the understanding of the risk of human-induced climate change, its observed and projected impacts and options for adaptation and mitigation. IPCC reports should be neutral with respect to policy, although they need to deal objectively with policy relevant scientific, technical and socio economic factors. They should be of high scientific and technical standards, and aim to reflect a range of views, expertise and wide geographical coverage.[65]

By limiting its work to scientific assessment and not policy,

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[64] As the two-time EPA Administrator William Ruckelshaus has written:

> The public interest is not served by two federal agencies taking diametrically opposed positions on the health risks of a toxic substance and then arguing about it in the press. We should be able to coordinate our risk assessment procedures across all federal agencies. The risk management strategies that flow from that assessment may indeed differ, depending on each agency's statutory mandate or the judgment of the ultimate decisionmaker.

Ruckelshaus, *supra* note 16, at 1028.

[65] INTERGOVERNMENTAL PANEL ON CLIMATE CHANGE, ABOUT IPCC, http://www.ipcc.ch/about/index.htm (last visited Aug. 22, 2008).

and adhering to high standards of scientific objectivity, the IPCC has been highly influential and effective in addressing the scientific underpinning and uncertainties of climate change.[66] The success of the IPCC model has led to suggestions for application of a similar model to other global environmental problems.[67]

European Food Safety Authority (EFSA): EFSA was created by the European Union and its member nations in 2002 after a series of food crises in the late 1990s, including the "mad cow" and dioxin in food scares, to serve as "an independent source of scientific advice and communication on risks associated with the food chain."[68] The structure of EFSA is explicitly based on separating risk assessment and risk management into separate institutions:

> In the European food safety system, risk assessment is done independently from risk management. As the risk assessor, EFSA produces scientific opinions and advice to provide a sound foundation for European policies and legislation and to support the European Commission, European Parliament and EU Member States in taking effective and timely risk management decisions. . . . EFSA's most critical commitment is to provide objective and independent science-based advice and clear communication grounded in the most up-to-date scientific information and knowledge.[69]

EFSA therefore provides scientific and risk assessments relating to food safety to the regulatory bodies of the European Union (i.e., the EU Commission and the EU Council of Ministers) as well as individual member nations, and issues such assessments in response to specific requests or "questions" from its "clients." While the EFSA has not been without some controversy, it has generally been perceived as responsible for restoring credibility and public trust to the European regulatory framework for food

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[66] Bruce Tonn, *The Intergovernmental Panel on Climate Change: A Global Scale Transformative Initiative*, 39 FUTURES 614, 615 (2007) (noting that "[t]he IPCC strives to be professional and non-partisan" and "has been widely praised for its efforts").

[67] *See, e.g.*, Mark Schrope, *Consensus Science, or Consensus Politics?*, NATURE, July 12, 2001, at 112, 114.

[68] EUROPEAN FOOD SAFETY AUTHORITY, ABOUT EFSA, http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_AboutEfsa.htm (last visited Aug. 22, 2008).

[69] *Id.*

safety, and is part of a trend in separating science from policy in EU institutions after the mad cow debacle.[70] Again, the secret of its success appears to be its deliberate focus only on science and not on policy, and its attempt to maximize its scientific objectivity and credibility through its structure and procedures. The Authority is expressly committed in its Mission statement "to the core standards of scientific excellence, openness, transparency, independence and responsiveness."[71]

These institutions have been largely successful in providing highly credible and respected scientific assessments on controversial environmental and safety issues. Although some communication and coordination is undoubtedly lost by separating the risk assessment function into a separate institution from the relevant risk management and relevant regulatory decision-making body, these examples demonstrate that such separation can result in more credible scientific assessments and regulatory decisions.

CONCLUSION

This article has presented two institutional alternatives for improving the credibility of regulatory science. While we understand that regulatory science will never achieve the ideals of purity and objectivity that early sociologists of science such as Robert Merton described,[72] the context and institutional structure in which science is considered can have a major impact on the credibility and objectivity of that science. In litigation, science presented by court-appointed neutral experts tends to be much more objective and balanced than the science presented by the parties' "hired gun" experts, who are often selected and counseled to give no credence to the opposing views. Agency science advisory committees that are composed of individual scientists

[70] Ragnar E. Lofstedt, *A European Perspective on the NRC "Red Book," Risk Assessment in the Federal Government: Managing the Process*, 9 HUM. & ECOLOGICAL RISK ASSESSMENT 1327, 1332 (2003).

[71] EUROPEAN FOOD SAFETY ADMINISTRATION, MANAGEMENT PLAN OF THE EUROPEAN FOOD SAFETY AUTHORITY FOR 2008 7 (2007), *available at* http://www.efsa.europa.eu/cs/BlobServer/DocumentSet/mb_managementplan2008-adopted,3.pdf?ssbinary=true.

[72] Robert K. Merton, *The Normative Structure of Science*, *in* THE SOCIOLOGY OF SCIENCE: THEORETICAL AND EMPIRICAL INVESTIGATIONS, 267 (Norman W. Storer, ed., 1973).

selected for their expertise and instructed to act as independent scientists, regardless of who they are employed by or affiliated with, tend to give much more balanced and useful scientific opinions than advisory committees made up of scientists from various interest groups who are selected to represent those constituencies. National Academy of Science committees established and operated on a consensus-seeking model provide much more balanced and objective scientific views than do a small cluster of individual scientists hand-picked by the two political parties to testify at a Congressional hearing. In short, context and institutional structure matter. Regulatory science as practiced today, which tends to become enmeshed in the political and interest group influences of regulatory decisions, often lacks the credibility and objectivity it needs to be effective and useful. The two proposals in this article are intended to address that problem by creating a bridge between scientific research and environmental regulation.

Although we believe that the models presented here should produce better environmental science for the government, we are keenly aware that we are developing human institutions and that they will be susceptible to human calculations and failings. Neither this system, nor any other we can think of, can prevent one stakeholder attempting and, from time to time, succeeding in settling scientific controversies in the legislature based on political influence rather than between scientists based on objective inquiry. Industry, government, and environmental advocates all from time to time have their idées fixes and are more interested in trying to get the public to adopt them than to explore and question the ideas through the lens of science. It is also obvious that sound science frequently takes a long time to develop and that often, for good reasons, regulators and the public have to make a decision in the short term. Some peer reviewers will be diligent, others will instinctively spend more time testing their own favorite hypotheses against the investigator's work rather than placing it in a larger context. In short, we trust that these models will frequently produce strong, useful, and timely science. They will not reform humankind. They will only be effective if the stakeholders really want to get the science right and the scientists diligently uphold their standards of impartiality and honesty.