



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D. C. 20460

August 12, 1986

Honorable Lee M. Thomas  
Administrator  
U. S. Environmental Protection Agency  
401 M Street, S. W.  
Washington, D. C. 20460

SAB-EC-86-027

OFFICE OF  
THE ADMINISTRATOR

Dear Mr. Thomas:

At its July 10-11 meeting the Science Advisory Board's (SAB) Executive Committee met with representatives of the Health Effects Institute (HEI) to discuss several issues of mutual interest, including ways in which both SAB and HEI can work together to further our common goal of improving the adequacy of scientific data used in Agency decision making. The discussion was preceded by a General Accounting Office (GAO) briefing that summarized that organization's recent review of HEI. GAO also encouraged greater cooperation between SAB and HEI.

Following these discussions, the Executive Committee reached consensus on the following issues:

- Is there a need for a more systematic and extensive SAB-HEI relationship? The Committee agreed that both of our independent organizational missions are complementary. While HEI's primary responsibility is to sponsor research and the SAB's role is to conduct scientific reviews, both bodies request the Agency to assess scientific data needs for its research programs before they independently carry out their respective functions. A key strength of both bodies is their independence from the Agency. The Executive Committee believes that there is a need for a more systematic relationship between the SAB and HEI, but that both ought to continue to maintain their independence from each other in the course of their mutual interaction.
- What specific mechanisms should SAB and HEI use to address their common needs? A reasonable balance between independence and interaction is for SAB to regularly invite HEI selected representatives as observers to its reviews of EPA research programs. This will enable HEI to receive EPA prepared research needs assessment documents, become more familiar with how the standard setting process influences the definition of research priorities and receive the results of SAB evaluations at an earlier stage. Reciprocally, HEI could periodically brief SAB committees on its ongoing research program. Both SAB and HEI committee chairs and staff can supplement these exchanges with periodic presentations on future activities and plans.

- Should the results of HEI studies be immediately utilized by EPA prior to their publication in refereed journals? The most common and authoritative form of acceptance of research results is publication in refereed journals. This kind of peer review not only serves a quality control function but also promotes the dissemination of information and stimulates wider thought and debate on scientific issues. HEI has always encouraged its research contract recipients to submit their research results for publication. In addition, HEI's internal peer review process is very thorough and, in many cases, is more methodical than the review process utilized by many scientific journals. There can be a significant delay between the preparation of HEI research reports (following internal peer review) and the ultimate publication of the research results in a journal. Since EPA will have a keen interest in HEI's research in its rulemaking activities, an important issue is whether to use such data before it appears in a refereed journal. The Science Advisory Board concludes that, as a general principle, journal publication is preferable prior to the use of scientific data in regulatory decision making. The research results HEI sponsors may play a significant role in EPA's decision making process. Recognizing the above, the SAB believes that such data should not be excluded from consideration. This belief, however, assumes that EPA will continue to conduct its own assessment of the data and make it widely available for public distribution and comment. The position is consistent with former Administrator Ruckelshaus' letter of November 6, 1984 to me in response to a SAB report on dichloromethane. Mr. Ruckelshaus stated that, "My belief is that it would not be feasible to exclude automatically all unpublished data since it may provide some insights in making health assessment/ risk management decisions."

I hope these views are useful to both the Agency and to the Health Effects Institute.

Sincerely,



Norton Nelson, Chairman  
Executive Committee  
Science Advisory Board

.cc: A. James Barnes  
Donald Ehreth  
Craig Potter  
Charles Powers  
Terry F. Yosie