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Redirection of the Energy-Related Health Effects Research Program: Health Effects of Criteria and Non-Criteria Pollutants from Fossil-Fuel Combustion (Theme 1)

A Report of the Subcommittee on
Energy-Related Health Effects Research

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Science Advisory Board
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BACKGROUND

In September 1979 the Energy Effects Division of the Office of Research and Development (ORD) requested Science Advisory Board (SAB) assistance in a program planning effort to redirect portions of the Interagency Energy/Environment Program for fiscal years 1980 - 1984. One of these portions is the theme "The Health Effects of Criteria and Non-Criteria Pollutants from Fossil Fuel Combustion." The redirection of this group of projects was initiated by ORD's Energy Effects Division and is consistent with a request from the Office of Air Quality Planning and Standards (OAQPS) for more information on human health effects in geographic areas where criteria pollutant standards are routinely being exceeded.

Specifically, OAQPS and the Energy Effects Division requested advice about the proper balance among epidemiologic, clinical, and animal toxicologic studies; how such studies should relate to each other; how the program should be integrated; and how the projects which are ongoing should be modified.

In planning the second five-year period of the Interagency Program, the Energy Effects Division assigned approximately $3.1 million for animal toxicology projects, most of them inherited from the Department of Energy National Laboratory transfer; $650,000 was assigned to clinical studies, most of which were carried over from the first five-year period; and $2.8 million was assigned to new epidemiology studies. This effort is approximately 40% of the total interagency energy-health research program.

PROCEDURE

To provide informed advice on redirecting portions of the energy-related health effects research, the Subcommittee had to have the fullest understanding possible of the needs of OAQPS, as well as the content of both the current interagency-funded health effects research and the current "base program," that is, the health effects research on criteria and non-criteria pollutants funded through legislative mandates other than the Interagency Program (nevertheless related to energy). It was also considered advantageous to have EPA-recommended changes in the Program as a basis for SAB discussion.

Substantial progress was made toward these objectives in meetings held in Washington, D.C. on November 13 and 14 and December 18 and 19, 1979, and at a workshop in Raleigh, North Carolina on January 28-30, 1980. The workshop provided a much needed vehicle for communication among all interested parties--scientists from the Department of Energy (DOE), National Laboratories and EPA laboratories, representatives from air program offices, ORD headquarters, the SAB, and others. It was

especially valuable as a forum in which National Laboratory scientists and administrators could learn about and interact with EPA staff regarding the research needs of EPA as a regulatory agency.

After the workshop and follow-up communication between EPA and research project directors, there was a final meeting of the Subcommittee on April 11, 1980 to review the revised protocols and the recommendations of EPA staff.

FINDINGS and COMMENTS

The Subcommittee was very favorably impressed by the efforts of Mr. Frietsch and his staff and by the scientists at the Health Effects Research Laboratory in Research Triangle Park, North Carolina (HERL-RTP) who reviewed the projects, made recommendations of changes to improve relevance, and helped develop the communication with scientists outside EPA, which is essential to future success of the endeavor. The HERL-RTP scientists included Drs. Graham, Hayes, Hazuka, Miller and Riggan, with Drs. Miller and Graham playing leadership roles.

The Subcommittee agrees with most of the recommendations of the HERL-RTP group. These EPA staff reports and related papers, as presented at the December 1979 and April 1980 meetings of the Subcommittee, are a matter of record and will not be extensively quoted at this time. A few highlights will suggest the flavor of the EPA staff reports.

In general, most of the unmodified projects were considered to have only limited relevance to EPA. Even when modified, some of the projects will have only moderate relevance. To improve relevance, interaction between research planners and principal investigators will be needed over the next few years and continuing dialogue thereafter. Such interaction would be promoted by research planning workshops and the involvement of laboratory representatives in research planning activities.

The HERL-RTP scientists also noted the serious management problem inherent in improving coordination between EPA and scientists outside of EPA. In some cases EPA will have project officers who are thoroughly knowledgeable of regulatory needs and the content of the "base program" and who can interact effectively with project scientists. However, the number of HERL-RTP scientists actually available to serve as project officers could not possibly meet the need, given the number of projects involved.

Another suggestion of HERL-RTP scientists, with which the Subcommittee strongly concurs, is that research protocols be submitted for all studies. These would provide the basis for review of scientific merit, as well as relevance to EPA needs, and would include details of study design, statistical analysis, and quality control, particularly for exposure regimens and methodology.

Subcommittee members usually perceived their role as a dual one. They were asked to offer scientific judgments on individual projects and to assess the research in terms of relevance, cohesion, and balance. Scientific judgments had to be made in the context of project descriptions that were often vague and imcomplete. Of necessity, judgments were made on general approaches rather than on detail. Further, limited information was available on the current status of research progress. Thus, the usual role of reviewing and commenting on scientific merit was severely restricted.

The role of assessing the research program in terms of relevance to the missions of EPA was made especially difficult because principal investigators often had erroneous impressions of the requirements of the Agency. Insufficient guidance had been provided for preparing the project abstracts. Many investigators focused on final applications of their work rather than on a realistic presentation of current status of results achieved to date. Also, little attention was given to alternative plans in case original goals could not be realized.

SUMMARY and CONCLUSIONS

Animal Toxicology

The revised protocols are, almost without exception, much improved and more relevant to EPA needs than were the original submissions. This improvement is no doubt due to the clear communication of EPA needs by Drs. Graham and Miller and the forceful administration of Mr. Frietsch. This improvement illustrates that a more relevant program is possible and that the present program can be improved further. Eventually, EPA will have to provide more staff and more detailed direction to achieve an acceptable level of performance in terms of EPA's needs.

Since most of the projects request support for four years or longer, approval of these protocols represents a long-term commitment of research support. One must question the basic

tenet under which the compromise protocols have been drawn up. EPA staff in its general comments states, as given, "the objective of increasing relevance without major dislocations within the involved National Laboratories...." If it is presumed that National Laboratories are invariably the best place to carry out this work, the Subcommittee would seriously question such presumption.

The total budget committed to this segment of energy-environment research is not inconsequential. Every proposal's budget requests more funds than originally allocated because the work is being reoriented. This may, among other things, indicate a deficient level of scientific expertise, in the laboratories, in toxicology and especially in air pollution toxicology.

A very thorough review will be necessary to upgrade the scientific content of the projects. There is a point, however, where reviewers cannot help except by writing protocols. Then one must ask, is this group capable of carrying out the experiments even given acceptable protocols? The present federal support of research is, by necessity, a highly competitive endeavor, and those who cannot compete will not be supported. Should not the same standard of quality be applied here as elsewhere?

The Subcommittee favors application of the highest standards of quality, the most detailed review possible, and giving priority to the most relevant proposals. Undoubtedly such reviews, to be impartial, require a great deal of effort by reviewers, grantees, and administrators. If the program is to be reoriented to EPA's needs and kept on track to meet these needs, then EPA review is and will be essential.

There is still a lack of cohesiveness in the overall goals of these proposals. Eventually a further redirection, review, and winnowing will be needed to accomplish an integrated and well conceived program.

Clinical Studies

The Subcommittee, in general, endorses the quality and direction of the program in controlled human exposure to air pollutants. Because information obtained from such studies can be immediately relevant to setting air quality standards, even further expansion of effort in this area should be encouraged.

Close coordination among human exposure studies, already underway, should be strongly encouraged. This should include exchange of protocols, regular meetings of cooperating scientists, and workshops on such topics as development of methods of quantitative aerosol exposure and methods for pharmacologic evaluation of airway reactivity. In this field of applied research, scientific breakthroughs by individual laboratories are not the main goal, so proprietary considerations are secondary. Exposure atmospheres to be studied will be extremely sensitive to trace background contamination. Therefore, a careful investigation should be conducted to determine that the best possible air purification and exposure monitoring techniques are available.

Epidemiologic Studies

The Subcommittee supports the aim to increase the number of epidemiologic studies of air pollution, provided that projects of high scientific merit and relevance can be identified. Well conducted epidemiologic studies can provide the evidence needed to decide on appropriate standards which may be unobtainable in any other way. Unfortunately, such studies become increasingly difficult the lower the pollutant concentration and the more subtle the deterioration in health and functional capacity. Consequently, meticulous attention to details, both of monitoring exposures and measuring health indices, is crucial to success.

We support the actions taken on specific new proposals considered in this planning exercise.

General Observations

Overall, we believe an excellent start has been made in improving the balance among animal toxicology, clinical, and epidemiologic studies; in improving relevance in individual projects; and in developing effective communication with scientists in the National Laboratories. However, there is still a long way to go. Several requirements must be met before the projects reviewed in this planning effort will meet EPA's needs in terms of scientific merit and relevance.

First, all projects must be subjected to rigorous peer review of the sort practiced by NIH study sections and apparently being practiced by the review panels of ORD's new central grants administration. The latter mechanism would be a desirable one to use for these energy-environment projects.*/

Peer review requires a much more detailed project description than we have seen for any of the proposals we reviewed. The NIH grant proposal model may not be ideal, but we

*/ The Subcommittee has been advised and is pleased to note that steps are already underway to implement this recommendation.

suggest that EPA consider it seriously before adopting a less demanding proposal form. A detailed progress reporting system is also essential--something that we have not seen in this review but which is an inherent part of NIH grant review.

We would not accept an in-house peer review system either by EPA or by a National Laboratory as an adequate substitute for external peer review for scientific merit.

Finally, EPA must find resources to strengthen its management of this program. The Subcommittee has already commented that Mr. Frietsch and his staff have done an excellent job, but this is a multimillion dollar program and needs more than two or three people to manage it effectively in the complex environment in which it has to operate. As also mentioned before, HERL-RTP scientists have done an excellent job in this planning effort. They would make superb project officers, but they have other full-time activities without adding this special assignment. The Subcommittee is not in a position to make specific suggestions about personnel assignments and management, but we are concerned that the promising start made in this planning activity will be lost if more people cannot be involved in the management of this program.