



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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OFFICE OF
RESEARCH AND DEVELOPMENT

J. Routt Reigart M.D.
Chair, Children's Health Protection Advisory Committee
Medical University of South Carolina, General Pediatrics
165 Cannon St. - Suite 503, P.O. Box 250855
Charleston, SC 29425

Dear Dr. Reigart:

Thank you and the members of the Children's Health Protection Advisory Committee (CHPAC) for your comments on the draft *Strategy for Research on Environmental Risks to Children* developed by the U.S. Environmental Protection Agency's (EPA) Office of Research and Development (ORD). As the EPA Assistant Administrator responsible for the development of the strategy, I appreciate your support of ORD's Children's Health Program. I apologize for not answering this letter sooner.

In your letters of January 21 and April 14, 2000, to Administrator Browner, you remarked that the strategy should focus more on the basic science needed to better understand the unique environmental health issues affecting children. We agree with this view and have developed a strategy that examines the questions of when and why children are especially vulnerable to environmental agents. Although, as you point out in your comments, much of the strategy is directed toward generating information to support and improve EPA's risk assessment process, we also recognize the need for a strong body of fundamental research focusing on elucidating key physical, chemical, biological, sociological, and economic processes that are important in understanding and predicting the effects of human activities on human health and the environment. Approximately half of ORD's direct children's research comes from the Science to Achieve Results (STAR) grants program, covering such efforts as the Centers for Children's Environmental Health and Disease Prevention. Much of the effort under the children's centers focuses on basic science issues. Much of the remaining program is also directed toward answering the basic science questions, through projects such as the Interagency Longitudinal Cohort Study, which is described in the strategy and below.

We agree that the primary objective of our children's health research is to contribute to improving children's health outcomes through providing scientific knowledge about the impact of the environment on children's health. The objectives listed in the strategy refer to what the document itself is trying to accomplish rather than to the objectives of the research program.

The resources for the Children's Health Program, as listed in the draft strategy were somewhat misleading and have been removed from the final version because they did not reflect the entire ORD program of research on children's issues. The complete FY 1999 ORD direct Children's Health Program, including grants, amounted to \$7.5 million. In FY 2000, ORD increased its support of the Children's Health Program by dedicating an additional \$10.7 million

to the effort, raising the total FY 2000 program to \$18.2 million. In 1999, ORD did an analysis across all its programs to determine all significant levels of research support for children's issues, both directly as part of the Children's Health Program, and indirectly in other closely related efforts. We found that, in FY 1999, in addition to resources committed specifically to the Children's Health Program, ORD provided \$20.9 million in support to other research on children's issues. We estimate that about \$16 million in additional support was provided in FY 2000. This related research is supported through the STAR grants program and research conducted in other program areas, including the Air, Drinking Water, Pesticides and Toxics, Hazardous Waste, Endocrine Disruptors, and Human Health Risk Assessment Programs.

References to a 5-year plan have been removed from the strategy, and we have provided a more long-range plan that will lead to sustained research efforts in this important area. The remainder of this letter addresses your more specific comments as listed in the April 14 letter.

Comment 1. Research Priorities. In addition to the comments from the CHPAC, ORD received comments at a workshop for external reviewers organized by Eastern Research Group (Eastern Research Group. 2000. *Summary of the Peer Review Workshop of the ORD Strategy for Research on Environmental Risks to Children*. Nov. 9-10, 1999, Washington, DC).

The ORD Science Team members who wrote the strategy revised the draft report in response to comments from the peer review and the CHPAC, and the revised strategy was reviewed and cleared through the ORD management. As part of this process, the issue of prioritization of the research areas was revisited. As advised by the CHPAC and the external peer reviewers, a matrix was developed explaining how the team applied the ranking criteria to each research area. This matrix is Appendix F in the final version of the strategy.

The CHPAC recommended that the research areas described in the following sections be ranked as high:

- Section 4.3.3.2. Methods for Measuring Exposures and Effects in Infants and Children and to Aid in Extrapolations between Animals and Humans
- Section 4.3.5.1. Variation in Susceptibility and Exposure in Children
- Section 4.3.5.2. Cumulative Risks to Children

The external peer review panel, while noting that these were important research areas, agreed that they should rank below those research areas that were ranked high. A medium ranking as discussed in the strategy means that ORD will not establish a separate in-house research program in the research area.

The strategy specifies that in-house methods development should be carried out in the context of an ongoing study with objectives that meet one of the highly ranked research areas. For example, in 2000, ORD began pilot and feasibility studies to support the interagency longitudinal cohort study referred to in comment 1.c. These preliminary studies include methods of assessing neurobehavioral toxicity in human infants, optimization of low-cost exposure

measurements, and development and evaluation of biomarkers. A ranking of medium also does not preclude research supported under ORD's STAR grants program. In 2000, for example, STAR awarded grants for research on biomarkers for the assessment of exposure and toxicity in children, a topic that is covered in the research area described in section 4.3.3.2.

Some of the research described in the sections on variation in susceptibility (section 4.3.5.1) and cumulative risks (section 4.3.5.2) will be conducted under other research areas, including the studies described in section 4.1. These sections have been revised to clarify how this research will be conducted. In addition, ORD has separate research programs that study variation in susceptibility to environmental contaminants and cumulative risks, where some, but not all of the research is directed toward children's issues. ORD decided that these issues should be of a medium priority for children until such time as we learn more about how to study these complex issues. The peer reviewers at the November 1999 workshop agreed with this ranking. Therefore, ORD maintained the ranking of medium, but revised the sections to better describe the rationale.

The ranking of the research areas described in section 4.3.1.2, *Relationship between Exposure to Environmental Agents and Adverse Health Effects in Human Populations*, which includes epidemiology studies, has been changed to high, as advised by the CHPAC and the peer review workshop report. This is the research area containing the Longitudinal Cohort Study. The section has been rewritten to give more prominence to the study. As described above, ORD has already started pilot and feasibility studies for the interagency cohort study.

Development of testing methods is covered under Section 4.3.3.1, *In vivo/in vitro Methods for Hazard Identification*. The Science Team, during its deliberations on the priorities of the research areas, decided to raise the ranking of this research area to high in consideration of the recommendations in the recent National Research Council report that was released after the comments were received (National Research Council. 2000. *Scientific Frontiers in Developmental Toxicity*. Washington, DC: National Research Council). All relevant endpoints are covered by Section 4.3.3.1. Development of improved methods for developmental neurotoxicity testing is part of our strategy. ORD has an active program to identify key cellular and molecular processes that could serve as indicators of chemical-induced alterations in the development of the nervous system. The objective of this research is to develop sensitive and specific measures of developmental neurotoxicity that can be used as adjuncts to or possible replacements for current testing guidelines.

Section 4.3.1.2, *Relationship between Exposure to Environmental Agents and Adverse Health Effects in Human Populations*, includes both collection of data and analysis of data from epidemiology and exposure studies. The final version of the strategy specifies the use of existing databases, such as the National Health and Nutrition Examination Survey (NHANES), to study the relationship between exposure and effects. For example, EPA/ORD is currently studying the geographical variation in respiratory effects in children, using data from NHANES, and environmental emissions using data from EPA's Toxic Release Inventory.

Comment 2. Suggested Modifications to Research Areas. Section 1.1, *Scope and Definitions*, has been revised to specifically include both the prenatal period and effects that do not appear until later in life.

The study of reduction of indoor contaminants is a relatively modest research program conducted in the laboratory and a test house. As with all of ORD's risk management research, ORD will evaluate performance, cost, effectiveness, and improvements in environmental and public health that result from these activities (USEPA. 1997. *1997 Update to ORD's Strategic Plan*. Washington, DC: U.S. Environmental Protection Agency. EPA/600/R97/015). These evaluations generally take place in the context of using data from other studies to assess the benefits of reduced exposures and risks. ORD does not envision a controlled epidemiology study for the purpose of evaluating the benefits of these risk reduction studies. However, such an evaluation might take place in the context of some other ORD research effort, such as the interagency Longitudinal Cohort Study.

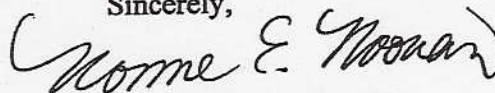
ORD's research on education and communication of risk and risk reduction techniques will support programs and policies implemented in EPA Program and Regional Offices. Current programs are directed at control and reduction of asthma in children and reduction of exposure to air toxics and unsafe drinking water. These programs are being implemented in diverse communities including Native American and inner city communities. The Children's Environmental Health and Safety Inventory of Research (www.epa.gov/chehsir) contains a listing of these programs. The strategy specifically calls for research dealing with a range of diverse communities. In the current ORD research program, the EPA/NIEHS supported Centers for Children's Environmental Health and Disease Prevention are conducting studies of community based risk reduction methods in inner city and agricultural communities.

Comment 3. A broad and proactive dialogue with those outside the agency is important to the success of our research programs. We will continue our efforts to ensure that our research planning receives the benefit of consultation.

Since 1996, ORD has significantly expanded its research into children's risk and plans to continue its research on this important topic. Your support and the continued participation and support of the research community are vital to our program.

Finally, enclosed is an advance copy of the recently finalized *Strategy for Research on Environmental Risks to Children* (the document will be released on October 26). Printed copies will be available in the near future.

Sincerely,



Norine E. Noonan, Ph.D.
Assistant Administrator

Enclosure