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April 14, 2000

Carol Browner
Administrator
Environmental Protection Agency
401 M Street SW
Washington, D.C., 20460

Re: "Strategy for Research on Environmental Risks to Children"

Dear Administrator Browner,

The Children's Health Protection Advisory Committee met on March 29-30, 2000 to consider, among other topics, the proposed "Strategy for Research on Environmental Risks to Children" prepared by the Office of Research and Development. The Committee commented generally in a previous letter dated January 21, 2000.

The purpose of this letter is to convey the Committee's more specific comments about the priorities included in the draft strategy, along with additional suggestions about the overall process by which EPA sets research priorities on environmental risks to children.

Overall, the Committee's comments are based on the following general themes and concerns:

- EPA has insufficient resources to adequately fund all of the research that is widely considered to be a very high priority.
- The primary objective of this research strategy should be to improve *children's* health outcomes, although it may also address other objectives.
- EPA is a regulatory agency and must invest in research that will improve its regulatory decision making. However, such improvements are only possible if they rest on a solid understanding of the fundamental science on which regulatory decisions are based, as well as on improvements in methods and models for risk assessment.
- The central question is in what ways and to what degree children generically are more susceptible than adults to environmental exposures and risks, highlighted in the document (page two of the Executive Summary). This requires sustained research efforts, which must not be delayed and must remain a high priority even in the face of immediate regulatory decision making challenges.

Based on the Committee's underlying concerns, we are submitting the following specific comments about the relative priorities suggested by ORD and about improvements in priority setting processes for the future.

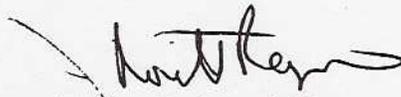
1. EPA must place the highest priority on conducting fundamental research on children's differential susceptibility and on adding new and improved data about exposures and risks to children *directly* which improves *actual data* about children, rather than relying on extrapolations from adults to children or on models that may seriously overestimate or underestimate actual exposures.
 - a) Specifically, the Committee believes that some research areas that ORD designated in its August 1999 draft as medium priorities are, in fact, high priorities that are critical to the improvements in the risk assessment methods designated as high priorities in the draft. These also are the research areas that provide the most direct benefit to children specifically and that constitute the most innovative, cutting edge items in the strategy document. High priority must be assigned to:
 - Methods for measuring exposures and effects in children and to aid in extrapolations between animals and humans.
 - Variation in human susceptibility
 - Mixtures/cumulative risk to children.
 - b) In addition, the Committee wishes to make special note of the high importance of epidemiological studies so that risk assessment and management decisions can be understood in the context of actual health outcomes in children.
 - c) The federal government has begun to explore the need for and design of a proposed longitudinal cohort study on children, encouraged by this Committee, and we believe it deserves a stronger emphasis than merely being subsumed within a research area that is only given a medium priority as it is in this document.
 - d) We would like to note two gaps at this time:
 - EPA should develop and validate improved developmental neurotoxicity testing protocols.

- There is no analysis in this strategy of disease patterns and how they vary geographically and by environmental exposures. EPA should collaborate with HHS to ensure that linkages are made between environmental and health data sets. A discussion of this should be added to the overall context for this research strategy document.
2. The Committee agrees with the high priority given to several of the research areas designated as such in the August 1999 draft.
- a) These include:
- Exposure field studies, and
 - Activity patterns and exposure factor studies.
- b) The Committee would suggest modifications to other high priorities as follows:
- Mode of action research should be expanded to include the entire life span, especially the prenatal and postnatal periods.
 - Reduction of exposure buildup of contaminants indoors must be done in the context of adequate evaluation of presumed benefits utilizing epidemiological methods, including randomized controlled trials.
 - Research on education and communication of risk and risk reduction techniques must be linked to the development of effective public policies and programs that are demonstrated to reduce exposure to unhealthy environments and reduce adverse health effects. As well, attention must be given to the diversity of communities in this country, including communities of color and low-income communities.
3. The process by which EPA sets research priorities on environmental risks to children would benefit from a broader, more proactive dialogue with others outside the agency to ensure that it is obtaining the benefit of the latest research, innovative ideas, and new ways of thinking. This is easier said than done and, thus, requires conscious effort. In the future, rather than taking the traditional approach of developing a strategy internally and then asking for reactions, EPA should:
- a) Consult with a broad range of individuals representing the full range of scientific disciplines outside the agency early in the process of developing a strategy.
- b) Make a deliberate effort to seek new ideas from new voices.
- c) Given the challenges that face any organization seeking to think "outside the box," look for creative processes of consultation and collaboration that go beyond the traditional peer review process.

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Finally, the Committee supports your efforts to seek additional resources from Congress for this critical activity of improving EPA's ability to more accurately reflect risks to children in its decision making. The Children's Health Protection Advisory Committee remains very committed to supporting EPA's efforts to better protect the health and safety of children, and thanks you for the opportunity to comment.

Sincerely,



J. Routh Reigart, MD
Chair, Children's Health Protection Advisory
Committee

cc. R. Trovato, P. Goode, N. Noonan