

MUSC

MEDICAL UNIVERSITY
OF SOUTH CAROLINA

GENERAL PEDIATRICS
165 CANNON ST • STE 503
PO BOX 250853
CHARLESTON • SC 29425

(843) 792-9457
FAX (843) 792-2588

J. Routh Reigart, MD
Director

William T. Basco, MD
Paul M. Darden, MD
Walton L. Ector, MD
Kelly Hevig-Lipke, MD
Melissa Howard Henshaw, MD
Sherron Jackson, MD
Michelle Lally, MD
Colleen Moran, MD
James R. Roberts, MD
Sara E. Schuh, MD
Hazel M. Webb, MD

Patient Appointments
General Pediatrics Clinic
(843) 953-8444
Primary Care Clinic
(843) 792-3955

December 9, 1999

Ms. Carol M. Browner
Administrator
Environmental Protection Agency
401 M Street, SW (1101)
Washington, DC 20460

Dear Administrator Browner:

This report provides consensus recommendations from the Children's Health Protection Advisory Committee for improvement to the EPA's *Rule Writers Guidance for Considering Risks to Children* (the Guidance). These recommendations, with explanation and justification, are provided in Attachment 1.

The Guidance was distributed in late 1998 to facilitate preparation of clear, well-documented, and comprehensive rules and regulations, in response to EPA's October 1995 *Children's Health Protection Policy Evaluating Health Risks to Children* (the Policy) and Executive Order 13045, April 1997. When issued, the Guidance was intended to be modified to reflect agency experience in actual rulemaking. Input from the CHPAC was requested, and in response, the Regulatory Improvements Work Group was chartered to develop recommendations for CHPAC endorsement and submittal to EPA. A fundamental objective of the Work Group has been to analyze whether or not the Guidance "has led, or will lead, to institutional change within EPA" regarding the rule writing process and the characterization of children's risk. During 1999, the Work Group engaged in a data gathering and analysis process, including case studies, which is summarized in Attachment 2. These activities proved to be very helpful in understanding the regulatory process and how the Guidance can/should apply.

As a general observation, the Agency's efforts to strengthen the rulemaking process with initiatives such as the "Rule Writer's Guidance" are important in improving the effectiveness with which children's health issues are handled. As such, the CHPAC endorses use of the Guidance and encourages comprehensive application throughout the Agency. Furthermore, it is recommended that the Guidance be clear in its application to all rulemaking, not just for economically significant health rules. For this tool to realize its full potential, there must be strong support from each program office, accompanied by the requisite buy-in throughout the Agency at all levels of

the organization. The Agency must a) continue to demonstrate leadership commitment to children's health; b) take ownership at all levels of EPA to reinforce the importance of children's health protection in principle, priorities and efforts; and c) direct EPA employees as to the importance of implementing the relevant policies and Executive Order 13045.

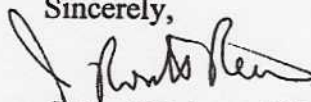
The specific recommendations cover a number of areas intended to improve the rulemaking process relative to children's health protection. They suggest ways to clarify the Guidance, improve its effectiveness, and promote its widespread use within the Agency. While all recommendations are meritorious, the following areas are highlighted:

- **Institutional Change:** Greater emphasis from Agency leadership is needed to "institutionalize" use of the Guidance. This may be accomplished through a) promoting the use of the Guidance; b) increased user training, c) implementing incentives and rewards for its effective use.
- **Closing Data Gaps:** Numerous gaps and voids exist in both toxicity and exposure data for children and in scientific understanding of children's health impacts. For example, one obstacle to creating regulations more protective of children's health is the lack of data regarding children's susceptibility to toxicants. As these gaps are identified during the rule writing process, it is essential that they be highlighted and brought forward for consideration and prioritization in future research. EPA must establish a mechanism such as a feedback loop to the appropriate program offices and the Office of Research and Development (ORD) when program offices identify gaps in knowledge and research. In this regard, the CHPAC commends the Agency for its effort to complete the *Children's Exposure Factors Handbook*, which will be a useful tool in risk assessment activities.

In closing, the CHPAC appreciates the EPA's efforts to improve the regulatory process, especially with regard to children. The *Rule Writer's Guidance for Considering Risks to Children* is a valuable tool for EPA rule writers and risk assessors and it will be further strengthened by incorporating these recommended improvements. Further, EPA is encouraged to share the Guidance within the President's Task Force On The Protection Of Children From Environmental Health Risks And Safety Risks so that other agencies will consider utilizing these concepts in their own jurisdictions.

Your consideration of the recommendations is appreciated, and the CHPAC stands ready to provide further assistance where needed.

Sincerely,



Orrout Reigart, MD
Chair, Children's Health
Protection Advisory Committee

GTT:bdb
Attachments

c - w/attachments:
Ms. P. Goode
Ms R. Trovato

Attachment 1

RECOMMENDED IMPROVEMENTS TO EPA'S "GUIDANCE FOR CONSIDERING RISKS TO CHILDREN DURING THE ESTABLISHMENT OF PUBLIC HEALTH-BASED AND RISK-BASED STANDARDS"

INTRODUCTION

EPA has taken actions to implement the Agency's 1995 National Children's Health Policy *Evaluating Health Risks to Children Risks* (referred to as the October 1995 Policy) and President Clinton's Executive Order 13045 *Protection of Children from Environmental Health Risks and Safety*. In recognition that public health decisions need to reflect data on children, *New Guidance for Rule Writer's on Considering Risks to Children* (hereafter referred to as *the Guidance*) was developed to establish a process for EPA programs to (1) consider children in public-health based and risk-based standard setting; (2) evaluate potential disproportionate risk to children during rule development; and (3) include this information during the Agency's decision-making process. We commend EPA's initiative in promoting the Guidance as a means to facilitate this mandated change. This Guidance seeks to consistently and explicitly establish a process, in which risks to infants and children are determined, and risk assessments are clear and transparent to the public and regulated community.

CHPAC chartered the Regulatory Process Improvement Work Group to provide EPA with evaluation and feedback on the Guidance. This Work Group undertook a number of tasks in reviewing the present Regulatory Process at the Agency. Such work is highlighted in Attachment 2.

This report identifies areas where the clarity context and application of the Guidance can be improved. At the heart of its review, the Work Group asked the fundamental question:

Has the Guidance led or will the Guidance lead to institutional change at the Agency with regard to the rule writing process and the characterization of children's risk?

RECOMMENDATIONS

I. FURTHER AGENCY INTEGRATION EFFORTS

A) Agency Policy: The Work Group believes it is critical to promote the Guidance for use in the Agency as an important step in implementation of the October 1995 Policy. CHPAC recommends that the revised Guidance be transmitted agency wide with a cover letter from Administrator Browner underscoring that the Guidance be used in all rulemaking.

B) Agency Procedures: The initial Rule Writer's Guidance was intended to be a stand-alone document for the review of children's health risks in rule development. CHPAC believes that children's health protection should be routinely considered in all aspects of rule development and be an integral part of the overall rulemaking sequences of activities. Progress toward institutionalizing these health protections could occur through the adoption and incorporation of concepts contained in the Guidance into an overall Analytical Blueprint and standard operating procedures (SOPs) for rule writers. However, it is critical that these SOPs specifically address and integrate decision points and processes around children's health issues to achieve the following goals:

- Improve children's health
- Change EPA culture to promote routine consideration of children's health in all risk assessments
- Impact the Office of Research and Development (ORD hereafter) budget and priorities in order to develop data specific to children's health
- Standardize consideration of children in rule writing
- Ensure that documentation for rules is complete, accessible, and written in plain English.

II. PROBLEMS IDENTIFIED BY USERS OF THE GUIDANCE

Responses to the protocol for assessing the Guidance through case studies indicate that further clarification will be necessary to eliminate the confusion that exists in a number of areas.

A) Clarity of Purpose: Administrator Browner's cover memo states that the Guidance implements both the 1995 October Policy and the April 1997 Executive Order. The Guidance must be consistent throughout and apply to all rules. The document notes several times that it is applicable to all rules and elsewhere only to economically significant rules. In order to make the intended purpose of the Guidance clear and consistent, and apply to all rules, the document should be restructured several ways:

- The title *Rule Writer's Guide To Executive Order 13045* on page 1 should be edited to include *And EPA's Policy on Evaluating Health Risks to Children* to be consistent with the title on page 4.
- We recommend that the Flow Chart be moved to become Attachment A (subsequent attachments should be appropriately re-lettered) in order to ensure that the important information in the background and Question and Answer sections is widely read within the Agency.

- B) Definition of Disproportionate Risk:** The Agency needs to ensure that there is a basic and uniform understanding by all EPA programs of the term “disproportionate risk to children.” The Guidance states that “disproportionate means that children’s exposure, uptake, and/or susceptibility is greater than that of adults.” Since this fundamental concept is critical to EPA decision points and processes, further elaboration is recommended for rule writers and risk assessors. This could occur through educational workshops on the scope of the definition and related concepts and applications.
- C) Flow Chart Organization:** The “Flow Chart for Determining if Your Action is Covered Under Executive Order 13045, and the Appropriate Template Language to Use in Attachment A” assigns templates for different rule categories. However, the flow chart is confusing. Reorganizing the flow chart is necessary to enhance presentation and comprehension. Omissions exist, e.g., question 4 and Template B. The flow can be discontinuous with boxes unconnected from one to another and on separate pages (such as question 3 to question 7 to question 8). Presenting the flow chart in the landscape orientation will illustrate multi-level decision making on one page. The flow arrows should be consistent with respect to yes and no actions.
- D) Format:** A question and answer format is used to develop and present the background information in the Guidance. While this format can be effective, care should be taken to ensure that answers are succinct and focused. Consideration should be given to inserting additional questions to segment the responses, such that questions and answers match up in a clear, succinct fashion. Alternatively, a format that utilizes descriptive headings and subheadings (e.g., purpose, scope) could be used instead of the question and answer format. Consideration should be given to which format would be most effective in this situation.

III. TECHNICAL SUPPORT FOR RISK ASSESSORS

The Guidance does not provide technical direction on how to conduct a risk assessment for children. However, a central consideration in the development of an EPA rule will be an assessment of risks to children’s health. Attachment C of the Guidance entitled *Technical Support for Risk Assessors* (hereafter referred to as Attachment C) offers suggestions for characterizing risks to children and provides clear information that helps risk assessors objectively characterize risks to children. However there are obstacles to incorporating consideration of children in risk assessment. These barriers have much more far reaching implications than the Guidance and its Attachment C.

- A) Data:** Regarding the availability of child specific data, Attachment C should clarify the need to describe the state of the data, the areas where data are lacking and where data are now available. We recommend that the answer to

question 5 ("What types of data would be helpful to characterizing risks to children") briefly address that some data on the toxicity of individual compounds to children may not be available and that research needs to be conducted to obtain the data. Further, a statement should be included that information gaps must be shared with the appropriate program offices and the ORD so that they are aware of the missing data and can ensure that the data gaps are filled.

In contrast, data used to assess children's exposure to toxicants are more readily available. In particular this document should specifically refer readers to EPA's *Children's Exposure Factors Handbook*, which is planned for release early in 2000 for data to assess children's exposure. Likewise the technical support under question 8 ("What data sources and health scientists should I consult") should specifically list the *Children's Exposure Factors Handbook*.

- B) Prioritization:** Elevating consideration of children in risk assessments also requires EPA making it a top priority. The Agency should dedicate its efforts to increasing agency-wide awareness, acceptance and application of the issues presented in Attachment C. In particular, we recommend that Attachment C, with the revisions noted above, be returned to the Risk Assessment Forum and be the topic of a Forum meeting. Forum members should then be asked to take the document back to their respective offices and review it with their risk assessors. Likewise the Science Policy Council is preparing a series of risk characterization guides. This exercise may provide an opportunity to elevate the issues contained in Attachment C.
- C) Model for Risk Assessment:** The Agency should consider the Office of Water's *Health Risks to Fetuses, Infants, and Children – D/DBP Rule* (October, 1998) as a model for documentation of future risk assessments for children's health protection. This document communicates the basis for the regulatory decisions with appropriate references to supporting studies and analysis.

IV. DATA MANAGEMENT

The EPA presently develops rules with the best data available at that time. A research feedback loop will assure more accurate data relative to children are developed. The results of this research and new data should then be used to modify existing rules to assure the protection of children's health.

The following processes are recommended for inclusion in the Guidance to improve the identification and management of available data and data gaps:

- A) Data Search Protocols:** Research protocols should be established for well-organized, comprehensive data searches on children's health when incorporating the risk to children in rule writing. These protocols should be

mandated for use by both Agency personnel and all contractors.

- B) Identification of Data Gaps:** Based upon research protocols, data gaps should be identified and documented.
- C) Recommendations for Research:** All data gaps should be converted to appropriate research suggestions. These recommendations for research should be sent to ORD for review, prioritization, and action.

V. STRENGTHENING RULE WRITERS USE OF THE GUIDANCE

The following actions should be considered to improve the rule writer's knowledge and use of the Guidance:

- A) Training:** A section on children's health considerations should always be included in basic training and continuing education that is provided within the EPA related to risk assessment and rules development.
- B) Incentives:** The Agency should initiate an incentives awards program for rule writers who show exemplary consideration of children's health in their work on rule writing. Recognition could be done through various options; i.e., letter from the Administrator, spot awards, other incentives, recognition at an Agency awards ceremony, acknowledgement in a newsletter, etc. Implementation should occur at several levels in the Agency to encourage stewardship from the top levels on down throughout the Agency.

VI. ASSESSMENT TOOL

The Guidance, when applied comprehensively and effectively, can serve as an instrument for positive change in the manner in which the Agency addresses children's health protection issues. To monitor application of the Guidance, and to prompt continuous improvement, a formal process should be established within the Agency to assess Guidance status and effectiveness. The assessment process should address the following areas:

- How widely is the Guidance being used?
- If not applied, why not?
- What can be done to improve the Guidance?
- How effective is the Guidance, and how has it helped the rulemaking process?

Further, there is value in developing metrics that demonstrates application of Guidance, e.g. "% of New Rules that Applied Guidance," or "Number of Improvement Recommendations Received/Implemented." There may be others that Agency management will find useful in identifying improvements to the Guidance.

Beyond this, the Guidance can serve as an evaluation instrument for EPA management to advance continuing improvement in the rulemaking process relative to considering risks to children. For the long term, it would be appropriate for the Agency to develop an assessment tool to determine the impact and success of considering risks to children in rule development. The Assessment Tool should, among other things, examine the methods used by rule writers to:

- identify important decision points and processes;
- make timely and appropriate decisions;
- solicit constructive comments and feedback;
- ensure that communication is sensitive to the needs of diverse groups; and
- provide the relevant context and rationale for decision making.

This tool will assist the Agency in identifying and prioritizing issues relative to addressing children's health risks in the rulemaking process, developing appropriate clarifications and response strategies, and establishing action plans. Overall, this tool will be an evaluative instrument for upper level managers to assure continuing improvement in the rulemaking process relative to considering risks to children.

SUMMARY

CHPAC appreciates the efforts taken by EPA to improve the regulatory process, especially with regard to children. The Guidance is a valuable tool for EPA rule writers and risk assessors and it will be further strengthened by incorporating these recommended improvements. Further, EPA is encouraged to share the Guidance within the President's Task Force On The Protection Of Children From Environmental Health Risks And Safety Risks so that other agencies will consider utilizing these concepts in their own jurisdictions.