



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

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OFFICE OF  
RESEARCH AND DEVELOPMENT

Melanie A. Marty, Ph.D.  
Chair, Children's Health Protection Advisory Committee  
Cal/EPA, Office of Environmental Health Hazard Assessment  
1515 Clay Street, 16<sup>th</sup> Floor  
Oakland, CA 94612

Dear Dr. Marty:

Thank you for your June 8, 2004, letter to Administrator Michael Leavitt, U.S. Environmental Protection Agency, regarding the Children's Health Protection Advisory Committee's comments regarding EPA's *Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens*. While you may have been focusing on this Supplemental Guidance, I think you will be pleased to know that our *Draft Final Guidelines for Carcinogen Risk Assessment* also emphasizes the importance of evaluating potentially sensitive lifestages.

As you know, EPA's Science Advisory Board also expressed an interest in prenatal and peri-pubertal exposures. EPA is interested in identifying all lifestages that may be particularly sensitive for carcinogenesis, and believes that the mode of action framework as described by the Guidelines is an appropriate mechanism for elucidating these lifestages. Puberty, and the associated biological changes that occur during ages 9 - 15, clearly include many biological processes that could lead to changes in the sensitivity to the effects of some carcinogens. The National Toxicology Program has ongoing multigeneration studies with genistein, nonylphenol, and ethinyl estradiol; we anticipate that the results of these studies will provide valuable insights on these issues. While the SAB also expressed concerns about prenatal exposures, it concluded that it "cannot recommend at this time a feasible method for incorporating transplacental or in utero exposure data."

To date, the Guidelines and Guidance have proceeded in a manner that is most likely to result in their concurrent release. It is my expectation that they will continue to progress through the finalization process together.

Sincerely,

A handwritten signature in black ink that reads "Paul Gilman".

Paul Gilman, Ph.D.  
Assistant Administrator



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