

**Testimony to the
Committee on Energy and Commerce
Subcommittee on Environment and the Economy
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“Chemical Risk Assessment: What Works for Jobs and the Economy”

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Introduction: Good morning, my name is Harvey Clewell, and I’m Director of the Center for Human Health Assessment at the Hamner Institutes for Health Sciences in Research Triangle Park, North Carolina. The Hamner, which was previously known as the Chemical Industry Institute of Toxicology, has now become an independent research institute with a diverse funding portfolio. I have more than thirty five years of experience in environmental quality research, toxicology research, chemical risk assessment, and hazardous materials management. I played a major role in the first uses of physiologically based pharmacokinetic modeling in cancer and non-cancer risk assessments by EPA, ATSDR, OSHA, and FDA, for such chemicals as methylene chloride, trichloroethylene, vinyl chloride, and retinoic acid. I received a Masters Degree in Chemistry from Washington University, St. Louis, MO, and a PhD in Toxicology from the University of Utrecht, the Netherlands. I served for 20 years as an officer in the U.S. Air Force; my positions included Deputy Director of the Air Force Toxic Hazards Research Unit, Director of Hazardous Materials Safety for the Air Force Aeronautical Systems Center, and consultant to the Air Force Surgeon General on Chemical Risk Assessment. After retiring from the Air Force I worked as a consultant in risk assessment at ICF and later Environ, before coming to The Hamner. In 2007 I received the Society of Toxicology’s Arnold J. Lehman award for major contributions to chemical safety and risk assessment.

In my position at the Hamner, as well as in my previous consulting positions, I have performed research and consulting for a large number of government and industry clients, including the EPA. I am here today at the request of Mr. Couri to present my professional opinions. I am not representing The Hamner or any other organization.

I am very familiar with EPA risk assessment practices. Over the last 30 years I have assisted EPA on risk assessments for a number of compounds, including methylene chloride, cadmium, styrene, vinyl chloride, trichloroethylene, chloroform, and perchlorate. I have served on the EPA's FIFRA Scientific Advisory Panel and the recent EPA SAB on the IRIS assessment for dioxin. I have also served as a peer reviewer for a number of recent EPA guidelines, including those for cancer risk assessment and risk characterization. I consider EPA to be a leader in advancing risk assessment methods and have been favorably impressed by a number of recent IRIS assessments for which I was a peer reviewer, including those for dioxane and acrylamide. Nevertheless, I am concerned that the lack of objectivity and transparency in some recent IRIS assessments will impair the ability of decisionmakers to make informed risk management decisions.

Comments on IRIS risk assessment practice: I am particularly concerned that in some recent IRIS assessments, such as the assessments for inorganic arsenic, formaldehyde and dioxin, only a single cancer risk assessment approach has been presented: a low-dose-linear default that assumes these chemicals are carcinogenic at any concentration. However, there is strong evidence for each of these chemicals that the true dose-response is nonlinear, and that the default greatly overestimates the actual risk at current human exposure levels. This IRIS practice of presenting only a single approach disregards the recommendation in OMB memorandum M-07-24, "Updated Principles for Risk Analysis" (Sep 19, 2007), to provide a characterization of the dispersion of risk estimates associated with different models, assumptions, and decisions. The OMB principles provide valuable guidance for assuring that risk assessments adequately inform decisionmakers faced with complex risk management options. Following the OMB recommendations should be a key objective of all IRIS assessments. The failure to objectively describe the evidence for alternative risk assessment approaches and to provide risk estimates other than the default has been a major deficiency in the IRIS risk assessment process. Even in the case of IRIS cancer assessments where alternative low-dose extrapolation options are discussed, there has been a clear bias towards presenting evidence that supports the selection of the default linear approach, even in cases where there is strong support for a nonlinear approach in the scientific community. Decisionmakers would be better informed by a balanced and objective discussion of both alternatives and the presentation of analyses based on both alternative approaches in the risk characterization section of the assessment.

As a justification for presenting only the default low-dose-linear risk assessment approach, the IRIS assessments have cited uncertainty in the evidence for alternative approaches. However, EPA guidance states that in the face of uncertainty, multiple approaches can be presented (Guidelines for Carcinogen Risk Assessment, EPA/630/P-03/001B, March 2005, p.3-23/24):

“Nonlinear extrapolation having a significant biological support may be presented in addition to a linear approach when the available data and a weight of evidence evaluation support a nonlinear approach, but the data are not strong enough to ascertain the mode of action applying the Agency’s mode of action framework.”

“In the absence of data supporting a biologically based model for extrapolation outside of the observed range, the choice of approach is based on the view of mode of action of the agent arrived at in the hazard assessment. If more than one approach (e.g., both a nonlinear and linear approach) are supported by the data, they should be used and presented to the decisionmaker.”

In a number of cases, NAS and EPA SAB peer reviews have requested that the IRIS assessment be modified to objectively present multiple risk assessment options, but the agency has not complied. I believe that the repeated refusal of the EPA to implement recommendations from NAS and SAB peer reviews to objectively present alternative risk assessment options has greatly delayed the completion of the IRIS assessments for a number of important chemicals, in some cases for more than a decade. In addition to being inconsistent with agency guidance, presentation of only a conservative default approach when there is a viable alternative provides the decisionmaker with an inaccurate characterization of risk that compromises his ability to make informed risk management decisions.

In my opinion, IRIS assessments currently do not provide an objective and transparent characterization of the potential risks associated with chemical exposure. The inadequacy of the risk characterization in IRIS assessments, coupled with the sole use of conservative default approaches, hampers the ability of decisionmakers to make informed risk management decisions and gives the public an inaccurate impression of their potential risks from chemical exposure. I believe that this deficiency could to a large extent be addressed by assuring that IRIS assessments adhere to the risk assessment principles elaborated in OMB memorandum M-07-24.