Written Testimony of

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I am Dr. Lorenz R. Rhomberg, a Principal at Gradient Corporation, an environmental sciences consulting firm based in Cambridge, Massachusetts. Gradient Corporation provides scientific analysis and technical consulting services to a variety of clients in the public and private sectors, including municipal and state government, the federal government, trade associations, law firms, and industrial companies. I should disclose that I have had several contracts with the US Environmental Protection Agency over the years to conduct scientific research and analysis, and I have two current open contracts with that agency. Today, I am appearing at the invitation of the Subcommittee, and I am representing solely my own point of view.

Before joining Gradient Corporation, from 1994 to 1999, I was on the faculty of the Harvard School of Public Health, doing research and teaching regulatory toxicology and risk assessment. Before that, from 1984 to 1994, I was a scientist at the US Environmental Protection Agency, first in the Office of Toxic Substances and later in the Office of Research and Development (in EPA headquarters in Washington) where I worked on chemical risk assessments and on risk assessment methodology improvement issues. I hold a doctorate in biology from Stony Brook University.

I am currently a member of the National Research Council's Standing Committee on Risk Assessment Issues and Reviews, and in the past I have served on several other committees convened by the National Academy, including as chair of the Committee on Strategies to Protect the Health of Deployed U.S. Forces. I was commissioned by the Presidential/Congressional Commission on Risk Assessment and Risk Management (which was mandated under the Clean Air Act Amendments of 1990) to write a report on differences among federal agencies in how human health risk assessments are conducted, addressing how such differences relate to differences the mandates of the various authorizing statutes. On several

occasions I have served as an *ad hoc* member of the EPA Pesticides Office's Scientific Advisory Panels. I am a past President of the Society for Risk Analysis New England Chapter and a past councilor of the national Society for Risk Analysis. I am the author or editor of several books and monographs and have published over 60 scientific papers and book chapters on the analysis of human health risks from environmental chemicals.

Children's Risk

I understand that today's hearing is an oversight hearing and that the general topic is the EPA's use of science in its regulatory decisions, and specifically whether undue influences exist on how that science is presented, or how it is used or not used in coming to conclusions about regulatory standards that the agency is charged with making. More specifically, I have been asked to address the use of science in the development of guidance for conducting risk assessments of children's exposures. I should say that this is not my main area of scientific focus, and my participation in the process of developing guidance has been limited. I have one technical paper, published in 2002, that investigates how the faster pace of physiological processes in children vis-à-vis adults affects the internal tissue levels of a chemical for a given amount of daily exposure; this paper was produced without any funding and at no one's behest, simply as a contribution to the field by writing up for publication a talk that I was invited to give at a scientific meeting on risk assessment issues convened by the University of Medicine and Dentistry of New Jersey.

In 2003, EPA came out with its draft *Supplemental Guidance for Assessing Susceptibility from Early-Life Exposures to Carcinogens*, and made the draft available for public comment. I was commissioned by an industrial trade association to evaluate the scientific basis of the EPA's draft guidance and to make oral public comments during the public comment period of the EPA Science Advisory Board (SAB) meeting of May 13-14, 2003, at which the SAB reviewed the draft. My comments were supportive of the EPA draft on some items but also noted that what appeared to be technically inappropriate formulas were used in calculating the observed sensitivity differences to cancer induction in young experimental animals *versus* adults for the same chemical, especially when applied to bioassays that had exposure to young animals continued through adulthood. I suggested an alternative approach to this calculation. In the end, when the final revised document was published by EPA, my suggestions had substantially been applied, resulting (in my view) in a sounder scientific basis for the EPA's policy decisions on how to treat early-life exposures to potential carcinogens in the risk assessment process.

This is not to say that I agree with every use of science in the final Supplemental Guidance document, for there are parts of the analysis with which I would continue to take issue. Quite a few other commenters, from all quarters, also made comments and presented their scientific arguments for them, and there was debate among the members of the Science Advisory Board about the merits of the various arguments, with evidence and counter-evidence discussed publicly. There are several points about this process that bear comment.

First, each comment was not simply an urging on what the final policy decision should be; instead, each was a technical comment on how the available scientific information should interpreted and brought to bear. Each commenter supported his or her proposal by adducing scientific evidence and conducting analysis, and the discussion focused on the strengths and weaknesses of this support and the consideration of the scientific plausibility of alternative explanations for the same scientific data that would imply different policy consequences.

Second, even with the scientific debate that occurred, there was no single evident "best" or "correct" scientific answer to the questions at hand (about relative sensitivity of young individuals and adults to carcinogenic chemicals). Extracting an unambiguous measure of relative sensitivity from the data that are available is not straightforward; many of the studies are ill suited to separate such sensitivity differences from the potential contribution of other factors, and in any case, data are available on a limited number of chemicals, with different chemicals showing different results. The SAB members – and later, the EPA policy formulators who drew on the SAB recommendations – had to arrive at a policy about relative sensitivity assumptions to be applied to *other* chemicals not among those with current data, and that policy had to be reasonably likely to be approximately correct and as well supported as possible by the scientific understanding of the data at hand – that is, a policy supported by science, but not (because to do so is not possible) identified by science.

Third, not all the alternative interpretations were equally supportable. Some proposals by commenters were rejected by the SAB as insufficiently supported, even though no single best answer was available. Deciding which interpretations are sufficiently supported is a matter of scientific judgment, which in this case was invested in the SAB and ultimately in the EPA policy formulators, acting on the SAB recommendations.

Fourth, individual participants in the debate, including the public commenters and the SAB members, had differing views on the relative bearing of different studies and the relative merits of the alternative

scientific arguments. I presume they were acting in good faith, and this shows that it is the *collective* scientific judgment of knowledgeable and appropriately trained people – the span of mainstream opinion of the field as a whole – and not any individual's scientific judgment (no matter how well qualified the individual scientist may be) that characterizes "what science has to say" on the issues. I would venture that no participant in the SAB meeting at which I commented, especially including the SAB members, would be entirely satisfied with the document that resulted, because each individual view of what constitutes the "best" scientific interpretation will vary in some regard. That is, every participant probably felt, to some smaller or larger degree, that his or her expertise was not sufficiently heeded and that the collective judgment was not the "best" one, defining "best" as the one that one would have made oneself.

General Thoughts on the Use of Science in Setting Environmental Standards

I would like to offer some general thoughts on the use of science in setting environmental standards. They stem from the above observation that science often cannot provide a definitive answer to the questions asked by the regulatory process. Because of this, scientific judgment is necessary, and so the question arises how to make a process that weighs the evidence and comes to those judgments in a way that evaluates the scientific uncertainties in good faith in a way that will be broadly acceptable and seen as legitimate.

Many of our environmental laws are cast using the implicit presumption that there are clear scientific answers to its key questions, and that any competent scientist, acting forthrightly and in good faith, will look at the evidence and come to essentially the same conclusion. This presumption leads to mandates that scientific "findings" by the Administrator of EPA (or other responsible official) that a chemical or exposure "may pose an unacceptable risk to human health or the environment" trigger some regulatory action "to protect the public health with an adequate margin of safety" (to use approximate language that many environmental statutes employ, with some variations). In such a setting, the agency scientists' evaluations serve as a surrogate for the opinions of the scientific world as a whole – presuming that any competent scientific investigation will yield a clear and rather definitive answer that all would agree upon. Under this view, the role of the Science Advisory Board or other high-level external peer review is mostly to provide due process and oversight to ensure that the investigations and findings are indeed made competently and in good faith.

The difficulty with this view is that, in fact, the scientific answers to the key questions are not that clear, and different interpretations – with very different risk management consequences – can be made of the available data. We should distinguish between the hard facts of science – the particular data items that can often (but not always) be measured with objectivity and precision – from the application of those facts to make the generalizations and conclusions that constitute our overall scientific understanding of a chemical's potential toxicity in exposures as people actually experience them. We can say that 5 of 40 rats given 100 milligrams of a chemical per kilogram of body mass every day for 2 years developed kidney tumors, but it is very different to conclude from such data that we know the daily dose that humans would need to have in order to have a lifetime cancer risk increase of one in a million. A large part of the problem is that, from a regulatory policy point of view, we are interested in knowing about very low risks from very low exposures, and we want to characterize the levels where adverse effects do *not* happen. We cannot generally find these things out by direct observation, and so we use inferences from animal data on relatively small numbers of subjects at what are generally very high doses. It is not just that we need to extrapolate; we routinely have data that are incomplete and that contain apparent contradictions (*e.g.*, tumors in rats but not mice – should we suppose that humans are like the rats or the mice?).

The public health sciences are not the only sciences that have this distinction between the firmness of the component facts and the more debatable interpretation of those facts. Every scientific endeavor has as its aim not just the accumulation of facts but the synthesis of those facts into an understanding of the fundamental causes of the phenomena that are measured and the broader general laws that allow the facts to be used to project understanding to other instances of those phenomena. And there is always debate about those inferences. When I was a graduate student studying evolutionary biology, there was a torrid debate in the field between two schools of thought – the pheneticists and the cladists – regarding how the classification system for all the species of animals and plants should be constructed. There were fierce rivalries, institutions that were hotbeds of one or another school of thought, sparring over research funding, accusations of underhandedness in peer review and research funding, and so on. And this is a field with virtually no public policy importance or really much at stake beside academic rivalry; there was no industry interest, no NGOs, no regulators. This illustrates that the scientific controversies and questions about whose judgment is being applied exist *before* the question of stakes in the outcome is introduced. It is not for nothing that furious debates about matters with little consequence are called "academic." But when there are stakes in the outcome, and different interested parties with different primary concerns, these pre-existing and fundamentally scientific debates get caught up with questions about the motivation of the debaters.

The debates are an inherent part of science and how it operates. They are not just a reflection of failure to get needed data or of personal pettiness or motivations of the participants. It is the method of science to be skeptical of conclusions, not accepting findings on the basis of the authority of the author but expecting to see the evidence and reasoning, and trying to pick apart that reasoning or find alternative explanations. The important point is that such actions should not automatically be ascribed to an attempt to manipulate the findings. Science depends on such skeptical inquiry to sort out the ideas that stand up to scrutiny from those that do not.

Science can and does suspend judgment on a question that is incompletely resolved, recognizing a range of tenable interpretations in view of what is known and what can be inferred. This is not to say that any alternative interpretation is equally accepted, but the array of possible interpretations, and the plausibilities assigned to them, can be maintained and continue to be addressed with further inquiry.

In sum, when the regulatory process expects science to produce clear or at least non-contentious "findings" that can be acted upon, findings that would be equally attested to by any trained investigator, and instead encounters factious debate about what the scientific data should be interpreted to mean, problems can ensue. Scientists who see the problems one way or the other tend to gravitate to the institutional places where their points of view are valued and where there is attention to seeing that certain parts of the spectrum of valid and tenable scientific opinion are not undervalued. In the resulting debate, then, arguments about the scientific status of different parts of the spectrum of interpretation – arguments that can be and ought to be legitimately scientific – can seem to be attempts to manipulate the outcome that would be triggered by the choice of which part of the spectrum of legitimate interpretation gets recognized as the "finding."

The question then is how can we structure the process of characterizing this more complex understanding of the findings of science in a way that informs the process of regulatory decision-making, exploring the varieties of legitimate scientific interpretation of the data at hand while preventing actual or perceived manipulation of the characterization or misrepresentation of the weight of scientific opinion.

One way to look at this is to ask who should have the ultimate say on how the span and thrust of legitimate scientific opinion is to be characterized? Should it be the individual agency scientist? No, since as I have argued, any single observer tends to have a view different than the collective opinion of the field as a whole, and it is that collective opinion that best characterizes what "science" has to say on

the matter. This is not to say that the individual scientist is not entitled to his or her view. I am in favor of publication policies that allow individual agency scientists to express their views, as long as those views are clearly characterized as personal and not official. Even though this can prove awkward and can be exploited by those who want to argue that the agency is "going against its own scientists," I think it is necessary to ensure against the formation of agency "orthodoxy" and to expose any attempt to narrow the range of opinions on a question. But while individual agency scientists should expect to be heard, they should not expect to be heeded. That is, no one person has dispositive power over scientific interpretation. Unfortunately, there have been scientists in parts of the agency who see themselves as arbiters of particular issues and expect their personal expert opinions to be the sole basis of the agency's finding. No one, at any level in the agency, should have that role, and failure of the agency exactly to follow any one scientist's views should not be constituted as ignoring or silencing that person, especially when the avenue of personal publication is open.

Should the agency scientific apparatus as a whole be entrusted with the ultimate say on the characterization of science? This would entail some mechanism of internal debate and deliberation among many agency scientists and the forging of some kind of consensus that is then reported. Some such process is necessary, but in view of the hierarchical nature of the institution it would be hard not to have such a process perceived as a product of the agency's scientific management. Moreover, the span of opinion and perspective within the agency is still incomplete vis-à-vis the field as a whole. The agency has a natural set of interests and concerns, and it tends to put a big premium on precedent and consistency, which can tend to ossify its approaches to risk questions into a kind of orthodoxy. As toxicology gains more and more insight into modes of toxic action and increasingly depends on new experimental technologies, the agency's internal resources alone may have difficulty giving newer approaches their due.

There is value in getting input from the wider scientific community early on in the assessment process. Various ways to do this have been explored, such as special scientific meetings, peer-consultations, and in the case of the trichloroethylene carcinogenicity reassessment, an "external involvement group" that included academics and industry scientists discussing advances in the science and their interpretation before the agency undertook its synthesis and characterization of the science. One need not be too afraid of including interested parties in such processes, because the purpose is to put relevant data on the table and debate it scientifically, not to come to any findings. Indeed, there is value in assuring that all points of view that will be of special concern to the various interested parties at the end of the process get put on the table for examination early on.

I would favor such an approach, with the further proviso that the agency explicitly takes on the goal of creating a characterization of the view of the scientific issues that spans the range of scientifically supportable views of the field as a whole. That is, rather than the agency scientists being presumed to embody the judgment of the large scientific world in its own internal deliberation (the model used now), the agency's task would be to anticipate how a larger deliberation of the whole of scientific opinion would characterize the science. Whether the agency has succeeded in this attempt would be judged in the first step of the peer review (as expanded upon below).

One could also assign the ultimate judgment about what science has to say on a topic to the Science Advisory Board or to another group constituted of outside experts. Currently, such groups serve mostly to review and advise, not to create. Sometimes, on particularly thorny issues, the matter has been entrusted to a committee convened by the National Research Council. But this is an inefficient and expensive process, and it raises the further issue of how such a group is to be constituted. It may be better to have a process in which the SAB has as its initial charge the process of evaluating whether the science characterization assembled by the agency is indeed a thorough and comprehensive assessment of the scientific judgments of the field as a whole. Only after this is established would the agency go back and consider how to apply this characterization of the science to the assessment of the potential hazards in question. The model here is like the one in which a separate staff paper on the scientific issues is prepared for criteria air pollutants, and the deliberation of possible regulatory actions is an explicitly separate step.

Finally, assessment of risks and consideration of potential regulatory actions that could be taken in the face of the scientific uncertainties previously characterized can then be examined. There is no getting around the fact that developing regulatory options and making decisions is more difficult when the full complexity and variety of the viable scientific interpretations are considered. But this would avoid the problem of pretending that science has dictated the specific actions when in fact it is usually insufficiently precise in its answers to do so. It would be important for transparency and legitimacy of the decisions that the reasoning for the assessment approach and regulatory options chosen be thoroughly laid out, not just in a formulaic way, but fully attending to the possible impacts of alternative choices and the specific interpretations of evidence that support each possibility. These assessments and regulatory choices would then also be subject to SAB review.

The overarching theme of the approach I outline above is that it is good fully and transparently to lay out the entire complexity of the scientific questions that are driving a regulatory effort, and to do so before the regulatory analysis itself is conducted, so that one can avoid the tendency to narrow the view of the scientific interpretation to include only what corresponds to and (artificially) appears to point to a particular regulatory option. The guard against manipulation or undue influence in such a process is in its openness not only about the data and the process, but especially in its requirement that the reasoning and justification behind judgments be explicitly laid out for scrutiny and debate by all. Whenever a party can simply declare its judgment and expect to have the final say, there is opportunity for actual or perceived manipulation behind the scenes. An open process that is continually scrutinized and subject to criticism derives its legitimacy from the cogency of its arguments, and any misrepresentation or selective use of science to support a position is evident for all to see and hence ineffective.

There are those who would protect the integrity of the scientific deliberation by isolating it from outside influences and entrusting it only to those deemed to have pure motives and no biases. But such ideal judges do not really exist and the isolation itself leads to a narrow and unrepresentative set of interpretations. It is better to let interested parties contribute to the debate and have the ultimate review focus on whether the full complexity of the science and its alternative interpretations has been well represented in the public process.