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September 3, 1999
(signatories updated December 20, 1999)

Richard R. Monson M.D., Chair
c/o Rick Jostes, Staff Officer
Committee on the Health Risks from Exposure to Low Levels of Ionizing Radiation (BEIR VII)
National Academy of Sciences
2101 Constitution Avenue, NW
Washington, D.C. 20418

Dear Dr. Monson,

We are writing in connection with your committee's work on assessing the effects of low-level radiation in the form of the Biological Effects of Ionizing Radiation (BEIR) VII review.

We are pleased that the BEIR VII Committee has set out to "consider a large amount of published data ... concerning the risks to humans of exposure to low levels of ionizing radiation" (BEIR VII Project Scope). We expect that, as part of this work, the Committee will examine conflicting evidence and interpretations in the process of identifying biological effects and risk factors. We look forward to following closely the Committee's deliberations throughout this important process and to participating in them.

The work of past BEIR Committees has been influential in setting the tone and terms of the scientific debate on the issue and in the radiation standard-setting process. Therefore, we believe it is crucial that the full range of information and issues regarding the health effects of ionizing radiation be considered. The BEIR V report considered only risks of cancer, some aspects of genetic damage (though it did not estimate risks of "diseases of complex genetic origin, which are thought to comprise the largest category of genetically-related diseases," p. 4) and mental retardation arising from in-utero exposure.

It is important that the BEIR VII process address the full range of risks that have not been conclusively evaluated so far. This should include risks that have come to light since the BEIR V report (such as the combined effects of radiation and hormonally-active agents, also called endocrine disrupters) as well as issues that could have been addressed in BEIR V, but were not. We have compiled a list of some of the most crucial issues that we believe you should address. These issues are as follows:

- **Effects of radionuclides that cross the placenta:** This should include consideration of the effects on the developing fetus itself (e.g. miscarriages, malformations, and developmental effects other than mental retardation) and the effects on relevant organs at

critical periods of fetal development. This study of health effects on the developing fetus should specifically include effects on development of specific organs, and the indirect effects of harm to organs such as the thyroid. We are especially concerned about radionuclides such as iodine-131, carbon-14, and tritium that could become part of the fetus in ways that could profoundly affect its well being. For instance, tritium, being a form of hydrogen, combines with oxygen to form water. Tritiated water behaves chemically like ordinary water. If ingested, a fraction of it becomes incorporated into the cells of the body, including genetic material. Such radioactive water also crosses the placenta. The potential for the resultant in-utero exposure to cause miscarriages, birth defects, and other health problems needs to be examined. The BEIR VII committee's evaluation of the risks of low-level radiation should include all such radionuclides and effects. If there are gaps in present knowledge, these should be identified clearly and their implications should be spelled out.

- **Effects of radiation on female fetuses:** Considering that ova are formed once per lifetime during females' fetal development, the Committee should evaluate the effects of radiation on the reproductive system of female fetuses and the possible effect of such radiation on the children of females irradiated in this way.
- **Effects of organically-bound radionuclides:** Radionuclides such as tritium or carbon-14 can become part of the DNA. Upon radioactive decay, they transmute into other elements. (Tritium becomes helium-3 and carbon-14 becomes nitrogen-14.) Such transmutation events could adversely affect the DNA. The potential health effects of such transmutations need to be evaluated.
- **Synergistic effects:** Exposure to radiation is sometimes coupled with exposure to other hazardous substances. The Committee should consider health effects caused by combined exposure to radioactive and non-radioactive substances. Special attention should be given to substances such as hormonally active agents that affect the hormonal system and the possibility that such disruption might increase the risk of cancer and other diseases arising from radiation exposure. Conversely, radiation exposure might damage the endocrine system, thereby increasing vulnerability to other disease-producing agents in the environment. The possibility of variability of such risks depending on age of exposure (and whether exposure takes place in-utero) should also be considered.
- **Data integrity and quality:** Worker dose records of the U.S. Department of Energy, and its predecessor agencies, are deeply flawed. The environmental contamination records are similarly deeply flawed. We know these things about the United States because much of the raw data record has become public through lawsuits, Freedom of Information Act requests, etc. Use of studies that accept official US worker or offsite dose estimates without evaluation of the raw data is highly questionable to say the least. Since the raw data in other countries are still largely secret, there is even less reason to accept them at face value. For instance, there is evidence that the health data in the former Soviet Union are questionable. The Committee should review these and related fundamental questions of data integrity and address whether any of this record is suitable at all for assessing the risks of low-level radiation, and if so how it should be used. The Committee should also address what criteria of data quality it will apply to the information contained in the studies it reviews. In this context, we do not believe that it will be enough to simply accept peer-reviewed studies as correct if they have not evaluated the soundness of the underlying official dose and health data. Finally the impact of misclassification of

radiation exposures and health outcomes and health-related selection factors, should be considered in interpreting all epidemiological studies, including studies of A-bomb survivors.

- **Effects on various populations:** The concept of "standard man" or "average" is often used to set radiation protection standards. Given the potential large variability of actual health effects of radiation in various populations, the Committee should assess the errors in risk estimates produced by the use of this concept. For instance, the age-dependence of the dose response relationship for various health effects should be explicitly spelled out, not only for children, but also for older age groups. Another example is the potential variation in sensitivity to low-level radiation among individuals who are otherwise of similar demographic make-up. In many of these areas, it may be that there is simply not enough knowledge to come to reliable scientific conclusions. In such cases, the Committee should clearly and frankly say so and recommend a research agenda. If possible, this should be accompanied by qualitative discussions of the mechanisms of potential health effects. It is of crucial importance to us that all areas where risk cannot be reliably calculated are clearly identified. If the types of risk can be qualitatively ascertained, the risks should be spelled out. If even the qualitative risks cannot be assessed, that conclusion would also be very material.

We have not discussed cancer-related issues above because we are presuming that the Committee will address the full range of relevant literature in regard to carcinogenic effects. It would be helpful if the committee published and updated frequently a list of the publications that it is reviewing, so that we may be able to follow the review and add to that list, should we feel that to be necessary or desirable.

We look forward to providing scientific input throughout the BEIR VII process and expect that the Committee will fully address the issues we have raised as seriously as it might were those same issues raised by a member of the Committee.

We appreciate the opportunity for public comment and ask that it be expanded as needed to fully accommodate the issues and evidence that we want to put forth. We look forward to your response. Do let us know if you have any questions or need more information. Please address your questions or responses to Lisa Ledwidge or Arjun Makhijani. Thank you very much.

Sincerely,

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