

Statement of James A. Brink, MD, FACR Chair, Board of Chancellors, American College of Radiology

Before the Committee on Science, Space and Technology Subcommittee on Energy

DOE Funding of Basic Research on Low Dose Radiation

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Chairman Weber, Ranking Member Veasey, and distinguished members of this subcommittee -I want to thank you for holding this hearing and for inviting me to testify. I am honored to be here today and welcome the opportunity to present the views of the American College of Radiology on the importance of Department of Energy-supported research on low-dose radiation.

My name is Dr. James Brink. I am Radiologist-in-Chief at Massachusetts General Hospital and the Juan M. Taveras Professor of Radiology, at Harvard Medical School. My professional career reflects a long- held interest in issues related to the monitoring and control of medical radiation exposure. As such, I currently serve as Vice Chair of the Nuclear and Radiation Studies Board (NRSB) of the National Academy of Sciences, Engineering and Medicine. I am also scientific vice-president for radiation protection in medicine on the National Council for Radiation Protection and Measurements (NCRP), having chaired the NCRP scientific committee that defined diagnostic reference levels for medical imaging in the United States (NCRP Report No. 172, 2012).

I am testifying today on behalf of the American College of Radiology (ACR) as the current chair of ACR's Board of Chancellors. ACR represents more than 36,000 radiologists, radiation oncologists, medical physicists, and nuclear medicine physicians whose patients benefit from diagnostic and therapeutic uses of radiation in medicine.

Sources of radiation exposure and beneficial uses of man-made radiation

In simple terms, "radiation" is energy that is emitted from a source as electromagnetic waves or as moving subatomic particles. "Ionizing radiation" is radiation with energy sufficient to strip electrons from atoms causing them to become charged. This displacement of electrons in a human cell has the potential to damage its DNA.

Although to some the term "radiation" may elicit extremely negative connotations, in truth radiation is a natural part of our universe. Humans are exposed constantly to radiation from natural sources including cosmic radiation from outer space and terrestrial radiation from soil and rocks. There is radiation in the air we breathe, the food and water we consume, the buildings in which we live and work, and even in our own bodies.

In addition to naturally occurring radiation, we are also exposed to man-made sources of radiation while enjoying the many benefits that come from medical uses, industrial activities, and commercial products. Consumer products such as fertilizer, welding rods, and smoke detectors, may contribute to our radiation exposure. Security systems such as those used at airports and for entry to Congressional office buildings and other federal buildings use low dose x-ray beams to visualize the contents of packages and baggage; this creates an extremely small amount of radiation exposure. Much higher doses of radiation are used to preemptively destroy biological agents such as anthrax although the irradiated mail does not itself expose the recipient to radiation.

Without doubt, the most significant source of exposure to manmade radiation in humans is that associated with medical diagnostic and therapeutic procedures. Such exposures include imaging tests that use low doses of radiation to allow radiologists to visualize the internal structure and function of the body as well as radiation therapy procedures that use high doses of radiation from radioactive material or external beams to destroy cancerous cells. A report by the National Council on Radiation Protection and Measurements (NCRP) calculates the average annual radiation dose per person in the U.S. at 620 <u>millirem</u> (6.2 millisieverts)(data reported for 2006). Approximately half of this exposure is naturally occurring radiation. A little less than half (48%) is associated with medical exposure (excluding radiation therapy) and includes Computed Tomography (24%), Nuclear Medicine (12%), Interventional Fluoroscopy (7%) and Conventional Radiography/Fluoroscopy (5%). I cannot overemphasize, however, the enormous benefits associated with the controlled use of radiation in medicine.

To be clear: the use of radiation in medicine saves lives, improves the quality of care, and the quality of life for millions of patients each year. Advances in medical imaging have rendered exploratory surgery virtually obsolete. Disease can be identified earlier and treatments monitored more readily to allow for optimal patient care. Additionally, image-guided procedures frequently replace more invasive surgical options, improving outcomes while reducing hospitalization and recovery times. Moreover, one million patients each year receive the benefits of radiation therapy for the treatment of cancer and other disorders; clinical trials and clinical experience have demonstrated the benefits of radiation therapy in curing cancer, extending life, and relieving pain and suffering.

Biological Effects of Radiation

The effects of high-level radiation exposure on the human body are relatively well-understood — learned from decades of atomic bomb survivor data as well as the experiences of first responders to the Chernobyl disaster. We know that high and extremely high radiation doses received over short periods of time can damage, modify, or kill cells—causing skin "burns," nausea, bone marrow depression, rapid onset of cancer, gastrointestinal issues, cerebrovascular issues, cardiovascular issues, and even death.

Likewise, the data establishing a relationship between radiation exposure and cancer are primarily based on populations that have received high level exposures including survivors of atomic bombs in Japan and patients who have received high dose radiation therapy for the treatment of cancer. Exposures to high doses of radiation have been associated with several types of cancer including leukemia, multiple myeloma, and cancers of the breast, bladder, colon, liver, lung, esophagus, ovary, and stomach.

There is much greater uncertainty as to the link between exposure to low dose radiation and cancer. Lower doses occurring over a long period of time do not cause immediate health effects, and the biological effects of exposure to low dose radiation may be undetectable. While exposure to lower doses may damage or alter a cell's genetic code or DNA, such exposure does not necessarily result in negative health consequences. This is because of the body's innate ability to repair itself and recover from cellular damage. For example, human cells exposed to and damaged by low dose radiation can simply repair themselves or die off and be replaced by new and healthy cells. A problem can occur, however, when cells incorrectly repair themselves, causing a biophysical change that might eventually result in an adverse effect for the individual.

There are myriad variables that can influence whether exposure to low dose radiation might produce an adverse health effect, and because of the latency period between exposure and any resultant disease, researchers struggle to tease out the many confounding variables that might contribute to the disease. We know that there are numerous lifestyle factors (such as smoking, alcohol use, physical inactivity and obesity), as well as chemical exposures and physical hazards that can contribute to cancer risk. Moreover, we believe that certain factors such as age, gender, and life expectancy of the exposed individual can influence the level of risk associated with low dose radiation exposure to a particular individual. Additional research could add to our understanding in this area.

Theories Concerning the Health Effects of Low Dose Radiation – Policy Implications

In the absence of definitive data on the health effects of low dose radiation, those of us who use radiation in the practice of medicine, as well as those U.S. agencies charged with regulating the use of radiation and radiation exposure, have adopted the conservative approach of assuming that any amount of radiation exposure may pose some health risk. This theory is commonly referred to as the linear non-threshold model.

In keeping with the linear non-threshold theory, the medical community and regulators have adopted policies and practices to keep radiation doses "As Low as Reasonably Achievable"

(ALARA). As defined in regulatory schema of the Nuclear Regulatory Commission (Title 10, Section 20.1003, of the *Code of Federal Regulations* (10 CFR 20.1003), ALARA "means making every reasonable effort to maintain exposures to ionizing radiation as far below the dose limits as practical, consistent with the purpose for which the licensed activity is undertaken, taking into account the state of technology, the economics of improvements in relation to state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of nuclear energy and licensed materials in the public interest." A complementary concept in medicine is "dose optimization" which entails using only the amount of radiation that yields the image quality necessary for a diagnosis (or the conduct of a procedure).

Not everyone in the scientific community agrees with the validity of extrapolating cancer risk for low dose radiation exposure based on data from individuals who have received high doses of radiation. Some believe there is a threshold below which radiation exposure should not be a concern. A somewhat controversial school of thought, known as Radiation Hormesis, hypothesizes that there could even be beneficial health effects of low-dose exposure.

The Need for Additional Study on the Health Effects of Low Dose Radiation

Given the current state of scientific understanding of the health effects of low dose radiation, the radiology community is committed to the principles of ALARA and dose optimization. Nevertheless, we also believe there is a compelling need to improve science's direct understanding of low-level exposure and to apply new knowledge to radiation safety practices, professional guidelines, and regulatory policy.

The National Academies Board on Radiation Effects Research has played an integral role in the study of the biological effects of ionizing radiation over the last several decades, having published a series of reports (BEIR report series) that are frequently cited in professional literature, regulatory and policy- making venues. However, its most recent report was issued in 2006. Given the extensive volume of research that has occurred since the publication of the last BEIR report, there is a need for an update to the BEIR report series that critically looks at the research and provides a balanced perspective on the significance of research and knowledge in this field over the past decade.

Alongside its comprehensive risk assessments, the BEIR VII report identified a dozen needs for further research:

- 1. Determination of the level of various molecular markers of DNA damage as a function of low-dose ionizing radiation.
- 2. Determination of DNA repair fidelity, especially with regard to double and multiple strand breaks at low doses, and whether repair capacity is independent of dose.
- 3. Evaluation of the relevance of adaptation, low-dose hypersensitivity, bystander effect, hormesis, and genomic instability for radiation carcinogenesis.
- 4. Identification of molecular mechanisms for postulated hormetic effects at low doses.
- 5. Tumorigenic mechanisms.
- 6. Genetic factors in radiation cancer risk.

- 7. Heritable genetic effects of radiation.
- 8. Future medical radiation studies.
- 9. Future occupational radiation studies.
- 10. Future environmental radiation studies.
- 11. Japanese atomic bomb survivor studies.
- 12. Epidemiologic studies in general.

As medical providers who use ionizing radiation in the diagnosis and treatment of disease, we value the role the National Academies has played in distilling volumes of research related to ionizing radiation. The knowledge garnered from BEIR studies helps to guide our understanding and decision-making as we strive to optimize the care we provide our patients.

To that end, the American College of Radiology endorsed the Low-Dose Radiation Research Act of 2015 in the last Congress. As this subcommittee knows, the legislation would have required the Director of the Department of Energy (DOE) Office of Science to carry out a research program on low dose radiation for the purpose of enhancing the scientific understanding of and reduce uncertainties associated with the effects of exposure to low dose radiation. Further, it would have required the Director to enter into an agreement with the National Academies to conduct a study assessing the current status and development of a long-term strategy for low dose radiation research. We believe it is important for the National Academies to periodically assess the status and inform the development of a long-term strategy for low dose radiation research. We also believe the Department of Energy and other federal agencies must be adequately funded to support low dose radiation research activities. Accordingly, we urge that similar legislation be introduce and passed in the current Congress.

We hope to continue to be a resource to this subcommittee moving forward. Thank you again for the opportunity to testify today, and for holding this hearing on such an important topic.