

April 18, 2005

Dr. Keith O. Hodgson
Chair, BERAC
Director, Stanford Synchrotron Radiation Laboratory
Department of Chemistry
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Dear Chairman Hodgson and Members of BERAC:

The Society of Nuclear Medicine (SNM) is deeply concerned with the near elimination of funding for the Department of Energy (DOE) Office of Science Biomedical and Environmental Research (BER) Medical Applications and Measurement Science program (merged in 2006) in the President's fiscal year (FY) 2006 budget request. Specifically, the President proposes reducing funding for these programs from approximately \$37 million in FY '05 to \$13.6 million in FY '06. Most of the remaining \$13.6 million in FY '06 will go to research in fields unrelated to nuclear/molecular medicine, essentially eliminating over eighty basic research projects fundamental to the continued development of the field.

The modern era of nuclear/molecular medicine is an outgrowth of the original charge of the Atomic Energy Commission (AEC), "to exploit nuclear energy to promote human health." The Medical Applications and Measurement Science program supports directed scientific research through radiopharmaceutical development and nuclear/molecular medicine activities to study uses of radioisotopes for non-invasive diagnosis and targeted, internal molecular radiotherapy. This practical nuclear/molecular medicine research is vital to industry, educational institutions, and other government agencies, such as the National Institutes of Health (NIH). In fact, the Director of the DOE Office of Science recognized that "the DOE, through BER supported research in universities and in the National Laboratories, occupies a critical and unique niche in the field of radiopharmaceutical research. The NIH relies on our basic research to enable them to initiate clinical trials."

The majority of major advances in nuclear/molecular medicine have historically been sponsored by the DOE, including:

- development of Positron Emission Tomography (PET) at Washington University, UCLA, Lawrence Berkeley Laboratory and the University of Pennsylvania (as well as the development of small animal imaging systems that was pioneered at UCLA, with advances also made at the University of Pennsylvania and University of California, Davis);
- use of PET to carry out accurate treatment planning prior to therapy with radionuclides (at many DOE-funded sites);
- development of the molybdenum-99m technetium-99m generator, the mainstay of nuclear medicine studies today, at Brookhaven National Laboratory, as well as radionuclide thallium-201, which is used in cardiac viability studies in the majority of hospitals throughout the world;
- development of NeutroSpect (recently approved by the FDA) for imaging infection at Thomas Jefferson University;
- synthesis of fluorine-18-labeled fluorodeoxyglucose at Brookhaven National Laboratory (this agent is utilized in more than 95% of all PET scans carried out today);
- the first imaging of tumor receptors (estrogen receptors were imaged through a collaboration of the University of Illinois and Washington University, St. Louis);
- development of a whole series of ligands to study brain function at many DOE-sponsored sites, and development of agents to study tumor and other organ hypoxia at Washington University, St. Louis;

- pioneering work in the study of brain function (both in normal brains and in the understanding of addiction), carried out largely at UCLA and Brookhaven National Laboratory;
- advances in the application of alpha-particle emitters for therapy (at Duke University and MSKCC); and,
- development of the Anger camera at Berkeley Lawrence Laboratory.

In April 2004, a subcommittee of the Biological and Environmental Research Advisory Committee (BERAC) released a report entitled "Radiopharmaceutical Development and the Office of Science." This report details DOE achievements in the area of nuclear/molecular medicine, and outlines recommendations for the enhancement of BER programs dealing with nuclear/molecular medicine. Among the subcommittee's official recommendations were to:

- Establish 5-6 regional centers of excellence, through freely competed peer review, whose purpose is to expand support for radiopharmaceutical development, by emphasizing new approaches to the molecular imaging probe discovery process.
- Expand training program support in radiopharmaceutical chemistry and allied chemical disciplines, including pharmaceutical chemistry, cyclotron (target) radiochemistry, organic chemistry, peptide and protein chemistry, and chemical biology, for those with interest in molecular targeting with radiotracers.
- Create a master plan to foster more optimal development of radiotracers for biologic research and medical care by working with sister governmental agencies.
- Lead an effort involving FDA, NIH, United States Pharmacopeia, professional societies and industry to create regulations and a process that recognizes the unique nature of radiotracers as "generally safe and effective" based on sound scientific principles.

Less than ten months later, with the FY '06 budget rollout in February 2005, the DOE stated "molecular nuclear medicine research, research and technology development activities in imaging gene expression, magnetoencephalography, biosensors, PET instrumentation for human clinical applications, MRI and neuroscience research, radiation dosimetry for therapeutic dose estimation, and targeted molecular radionuclide therapy are curtailed in FY 2005 and terminated in FY 2006" (pg 258, Department of Energy FY 2006 Congressional Budget Request). These cuts are in direct opposition to the official recommendations of the scientific advisory committee.

With DOE funding, essential nuclear/molecular medicine research continues at universities, research institutions, national laboratories and small businesses as well as the continuation of research with radiochemistry, genomic sciences and structural biology to usher in a new era of mapping the human brain and using specific radiotracers and instruments to more precisely diagnose neuropsychiatric illnesses and cancer. The future of life-saving therapies and cutting-edge research in nuclear/molecular medicine and imaging depends on funding for the DOE Medical Applications and Measurement Science Program. Without funding for this program, future innovations in nuclear/molecular medicine research may never be realized, and millions of patients with heart, cancer and brain diseases will potentially be adversely affected. Therefore, on behalf of SNM, I urge your support to ensure that this funding is continued without interruption. Should members of BERAC or DOE staff have any questions, please contact Hugh C. Cannon, SNM Director of Public Affairs, at 703.708.9000 ext. 1322, or by email at hcannon@snm.org.

Sincerely,



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