

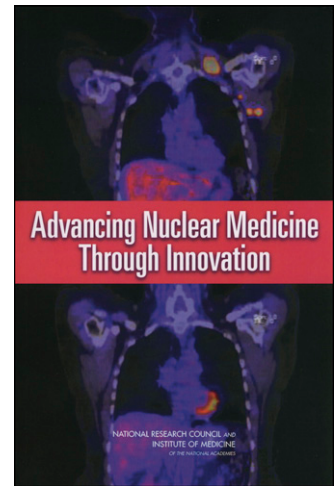
NAS Study Supports Enhanced Funding for Nuclear Medicine Research

On September 20, the National Academy of Sciences (NAS) released a final state-of-the-science report on nuclear medicine, titled *Advancing Nuclear Medicine Through Innovation*. The report offers both a positive look at the future and a series of recommendations that strongly endorse the restoration of lost funding and the creation of new means of federal support for the field. Funded by the Department of Energy (DOE) and the National Institutes of Health (NIH), the report is the result of a 13-month, \$700,000 research, compilation, and consensus effort prompted by a \$23 million reduction in DOE Office of Sciences funding in fiscal year 2006. This unexpected and drastic cut effectively eliminated most support for basic nuclear medicine and molecular imaging research and ended more than a half century of sustained DOE funding of biomedical research with radioisotopes.

The sponsoring agencies, with additional expressions of concerns from professional scientific organizations, asked the NAS to mobilize its widely respected consensus reporting program to assess areas of need in nuclear medicine research, examine the DOE Office of Science program, and make recommendations to improve its impact on nuclear medicine research and isotope production. In response, the National Research Council (NRC) of the National Academies of Science appointed a committee of 14 experts to carry out this study. The committee, which was chaired by Hedvig Hricak, MD, gathered information from members of the public, experts on nuclear medicine, scientific and medical societies,

and federal agencies. In summarizing its findings, the committee chose to describe needs in nuclear medicine research primarily in terms of future opportunities in the field.

The report provides an exhaustive review of the benefits and broadening range and scope of nuclear and molecular medicine but concludes, "In spite of these exciting possibilities, deteriorating infrastructure and loss of federal research support are jeopardizing the advancement of nuclear medicine. It is critical to revitalize the field to realize its potential."



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Key Points from the NAS Report

The report described key challenges to nuclear medicine research and makes broad recommendations for meeting these challenges. The following text is taken directly from the report summary of these challenges:

- Loss of Federal Commitment:** Historically, the bulk of the support for nuclear medicine research in the United States has come from the DOE, which focuses on supporting research and development of next-generation technology and radiopharmaceuticals, and the NIH, which focuses on applying nuclear technologies to medical applications. However, the report concludes that nuclear medicine research is not currently sufficiently supported, particularly in the physical sciences. Funding for nuclear medicine research has been dramatically reduced in recent years: DOE funding for nuclear medicine research dropped 85% from 2005 to 2006 and remained low in 2007. There is currently no specific programmatic long-term commitment by any federal agency for maintaining high-technology infrastructure or centers.
- Recommendation:** Federal commitment to nuclear medicine research should be enhanced. To this end, DOE and NIH should coordinate a national nuclear medicine research program.
- Shortage of Trained Nuclear Medicine Scientists:** There is a critical shortage of clinical and research

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SNM Calls for Grassroots Support

SNM is urging its members and others in the medical community to reinforce the impact of the publication of the NAS study by contacting members of Congress to ask for restored and enhanced support for basic nuclear medicine research. E-mails can be sent to representatives through the SNM/American College of Nuclear Physicians (ACNP) legislative action center (<http://capwiz.com/snm/issues/alert/?alertid=10333326>). The center also provides text that can be used in letters or for direct calls to Congressional representatives (capitol switchboard: 202-224-3121). For guidance, technical assistance, or answers to questions, contact the SNM/ACNP Health Policy and Regulatory Affairs staff at 703-708-9000 or hpra@snm.org.

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personnel in all nuclear medicine disciplines. Training, particularly of radiopharmaceutical chemists, has not kept up with current demands at universities, medical institutions, and industry, a problem that is exacerbated by a shortage of university faculty in nuclear chemistry and radiochemistry. There is a pressing need for additional training programs with the proper infrastructure to support interdisciplinary science, more doctoral students, and postdoctoral fellowship opportunities.

Recommendation: Train nuclear medicine scientists. NIH and DOE, in conjunction with specialty societies, should consider convening expert panels to identify the most critical national needs for training and determine how best to develop appropriate curricula to train the next generation of scientists and provide for their support.

- **Inadequate Domestic Supply of Medical Radionuclides for Research:** There is no domestic source for most of the medical radionuclides used in day-to-day nuclear medicine practice. The lack of a dedicated domestic accelerator and reactor facilities for year-round uninterrupted production of medical radionuclides for research is discouraging the development and evaluation of new radiopharmaceuticals.

Recommendation: Improve domestic medical radionuclide production. To alleviate the shortage of accelerator- and nuclear reactor-produced medical radionuclides available for research, a dedicated accelerator and an appropriate upgrade to an existing research nuclear reactor should be considered.

- **Cumbersome Regulatory Requirements:** The report identifies regulatory requirements that impede the efficiency with which new radiopharmaceuticals are brought into clinical feasibility studies. Complex U.S. Food and Drug Administration (FDA) toxicologic and other regulatory requirements, combined with a lack of guidelines on manufacturing nuclear imaging devices and radiopharmaceuticals, make translating nuclear medicine research into practical applications unnecessarily difficult. Additionally, there is a lack of consensus for standardized image acquisition in nuclear medicine imaging procedures, making it challenging to harmonize protocols for multi-institutional clinical trials.

Recommendation: Regulatory requirements should be clarified and simplified. FDA should provide clear guidelines specifically in the areas of toxicology (for evaluating when it is safe to conduct clinical trials on new radiopharmaceuticals) and good manufacturing practices. Members of the imaging community should work with federal agencies to develop standardized imaging protocols.

- **Need for Technology Development and Transfer:** Transfer of technological discoveries from the laboratory to the clinic is critical for advancing nuclear medicine. Improvements in detector technology, image reconstruction algorithms, and advanced data processing techniques, as well as development of lower cost radionuclide production technologies, are among the research areas that should be explored for effective translation into the clinic. **Recommendation:** Encourage interdisciplinary collaboration. DOE's Office of Biological & Environmental Research

should continue to facilitate collaborations between basic chemistry, physics, computer science, and imaging laboratories, as well as multi-disciplinary centers focused on nuclear medicine technology development and application.

The committee recommended that research be focused on the following areas to accelerate advances in the field:

- (1) The development of new radionuclide production facilities and technologies;
- (2) The synthesis of new radiotracers to improve understanding of the ways in which specific organs function;
- (3) The development of imaging instruments, enabling technologies, and multimodality imaging devices, such as PET/CT and PET/MRI, to improve disease diagnosis;
- (4) The development and use of targeted radionuclide therapeutics that will allow cancer treatments to be tailored for individual patients;
- (5) The use of nuclear medicine imaging as a tool in the discovery and development of new drugs; and
- (6) Translation of research from bench to bedside, including investment in training of clinician scientists in nuclear medicine techniques.

Each of these recommendations is discussed in detail in the report, with specific examples of research opportunities.

New Urgency

Nuclear medicine and molecular imaging scientists were encouraged by the NAS study, which came after another disappointing round of funding legislation. Earlier this summer, the Senate Energy and Water Development Appropriations Committee report for FY 2008 included \$34 million for the DOE Office of Science/Office of Biological and Environmental Research Medical Applications and Measurement Science program, with \$20 million explicitly dedicated to nuclear medicine research. The House, however, passed a version of the appropriations that did not address nuclear medicine research funding.

“The loss of funding for nuclear medicine research in the U.S. Department of Energy budget has been a tremendous blow to our current and future patients and our field,” said SNM President Alexander J. McEwan, MD. “The NAS study confirms the importance of basic nuclear medicine research, and the society—with this report in hand—intends to convince Congress to continue its funding. This is an exceptionally critical period for patients and medical imaging.” (See box, page 14N).

“Our country needs to invest in the basic scientific research necessary to develop future breakthroughs in nuclear medicine imaging and therapy that will allow for earlier detection and treatment of cancer and other serious illnesses,” said Peter S. Conti, MD, PhD, chair of SNM's Government Relations Committee and a member of the committee that prepared the NAS report. “If funds are not restored, the

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devastating loss of money for research on diagnosing and treating diseases will be followed by a loss of funds to support the training of students and postdoctoral fellows to fill an expanding role of nuclear medicine in patient care.”

The committee of experts that prepared *Advancing Nuclear Medicine Through Innovation* reinforced these viewpoints with their conclusion:

...while history highlights the payoff and public benefit from government investments in science and technology for nuclear medicine, the competitive edge that the United States has held for the past 50 years is seriously challenged. . . . Thus, although the scientific opportunities have never been greater or more exciting, the infrastructure on which future innovations in nuclear medicine depend hangs in the balance. If the promise of the field is to be fulfilled, a federally supported infrastructure for basic and translational research in nuclear medicine should be considered.

Members of the Committee on the State of the Science of Nuclear Medicine included Hricak, Memo-

rial Sloan–Kettering Cancer Center (New York, NY); S. James Adelstein, MD, PhD, Harvard Medical School (Boston, MA); Conti, University of Southern California (Los Angeles); Joanna Fowler, PhD, Brookhaven National Laboratory (Upton, NY); Joe Gray, PhD, Lawrence Berkeley National Laboratory (CA); Lin-Wen Hu, PhD, Massachusetts Institute of Technology (Cambridge); Joel Karp, University of Pennsylvania (Philadelphia); Thomas Lewellen, PhD, University of Washington (Seattle); Roger Macklis, MD, Cleveland Clinic Foundation (OH); C. Douglas Maynard, MD, Wake Forest University School of Medicine (Winston-Salem, NC); Thomas J. Ruth, PhD, Tri-University Meson Facility (Vancouver, Canada); Heinrich Schelbert, MD, PhD, University of California, Los Angeles; Gustav Von Schulthess, MD, PhD, University Hospital of Zurich (Switzerland); Michael R. Zalutsky, PhD, Duke University (Durham, NC); and Naoko Ishibe, study director, NRC (Washington, DC).

Advancing Nuclear Medicine Through Innovation may be ordered, downloaded, or read online at the National Academies Press Web site, www.nap.edu>New Releases. ✧

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Tom has been an inspiration to others. He inspired his entire family to pursue advanced degrees. Karen Sue has a PhD in psychology; his daughter, Michelle, has her MD; and his son, Daniel, is pursuing a PhD in economics. No one would be surprised that Michelle has chosen a career in radiology and is now doing a neuroradiology fellowship at MIR. Tom was understandably proud of his family and frequently commented on how fortunate he was to spend so much time with them during the last year of his life.

In the Division of Nuclear Medicine, Tom was an inspiration to all of us—physicians, technologists, sci-

entists, and administrative staff—with his determined and optimistic approach to his serious illness. Few of us could handle similar adversity with Tom’s grace and equanimity. We will all miss Tom’s cheerful, optimistic, upbeat attitude toward life, a quality that he maintained until the very end. Tom will be remembered by his family, colleagues, and friends as a gentle, kind, and caring man. Our sincere condolences go out to Tom’s wife, daughter, and son.

Henry D. Royal, MD

Barry A. Siegel, MD

Mallinckrodt Institute of Radiology

Saint Louis, MO

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event based on topic areas and proximity and will arrange logistic details, payment, and honoraria.

We invite you to submit your name and area(s) of expertise to Zachary Hochstetler at molecularimaging@snm.org. An online speaker application form is available at www.molecularimagingcenter.org.

Funding is Available

Although the speaker database is currently being expanded, we are now accepting speaker proposals. Inside MI

will cover both travel expenses and honoraria for speakers. During this first year of operations, a limited budget will be available; therefore, we encourage you to apply early. Proposals will be evaluated based on topics proposed by the speakers and areas of interest expressed by requesters and defined by the MICoE Education Task Force. These criteria and the application form will continue to evolve. Speaker request forms are also available at www.molecularimagingcenter.org.

Marybeth Howlett, MEM

Director, MICoE, SNM