DOE/NIH Study to Evaluate Nuclear Medicine Effectiveness

Details of a $700,000 Department of Energy (DOE)/National Institutes of Health (NIH) study to determine the importance of nuclear medicine research came to light during a press briefing on "The Future of Medical Imaging: Transforming Health Care," held in Washington, DC, on January 31. In the question-and-answer period, SNM President Peter S. Conti, MD, PhD, queried Elias Zerhouni, MD, NIH director, about the $23 million cut in funding in the DOE fiscal year 2006 budget, a cut that effectively eliminated all money for basic nuclear medicine and molecular imaging research. Zerhouni responded by revealing plans for a planned National Academies study that will perform a "state-of-the-science" review of nuclear medicine.

"I was able to publicly raise the issue of nuclear medicine research funding directly with the NIH director, and the proposed study will provide the opportunity to validate the importance of basic nuclear medicine research," said Conti, a professor of radiology, clinical pharmacy and biomedical engineering at the University of Southern California, Los Angeles.

According to a summary published on February 2 in *Diagnostic Imaging* online, 15 experts will be appointed to carry out the review over a 1-year period. Project officer for the initiative is Belinda Seto, deputy director of the National Institute of Biomedical Imaging and Bioengineering at NIH. DOE and NIH plan to contract with the National Academies' Nuclear and Radiation Studies Board (NSRB) and the Board of Health Science Policy to conduct the investigation. The NRSB has agreed in principle to participate, board director Kevin Crowley told *Diagnostic Imaging*. Implementation will proceed after the DOE and NIH resolve final details concerning funding. DOE is set to spend $496,000 on the study, and NIH will contribute $248,000. The final report should be ready for publication about 14 months after organizing efforts begin.

The report will provide findings and recommendations on: future needs for radiopharmaceutical development for the diagnosis and treatment of disease; future needs for computational and instrument development for more precise localization of radiotracers in normal and aberrant cell physiologies; national impediments to the efficient entry of promising new radiopharmaceutical compounds into clinical feasibility studies and strategies to overcome these problems; and effects of shortages of isotopes and highly trained radiochemists on nuclear medicine research and short- and long-term strategies to alleviate such shortages.

Although Conti was encouraged by this news, he noted that SNM will continue to fight to restore funding for basic research in the DOE FY 2007 budget and will explore ways to continue existing programs through supplemental funding, reprogramming, or other mechanisms to cover the gap created by these cuts.

Society of Nuclear Medicine

Diagnostic Imaging Magazine

2007 DOE Budget Requests Presented

On February 2, U.S. Secretary of Energy Samuel W. Bodman announced President Bush's fiscal year (FY) 2007 budget for the Department of Energy (DOE), requesting $23.6 billion, a $124 million increase over the FY 2006 request. "This budget signifies an investment in our future," Bodman said. "Continued support for scientific discovery and the development of alternative energy sources is vital to America's energy and economic security. From new global threats of the 21st century, to recognizing the importance of providing our next generation of scientists, teachers, and engineers with a strong educational foundation, DOE's FY 2007 budget represents a comprehensive approach to addressing both the near- and long-term challenges America faces."

Despite these positive words, the proposed budget does not include renewed funding for Office of Science nuclear medicine–related programs that suffered severe cuts and, in some cases, were terminated under the 2006 budget. As a part of the American Competitiveness Initiative, the Office of Science FY 2007 budget requests $4.1 billion, a $505 million (14%) increase over FY 2006, to support funding for basic scientific research. Funding will pursue new technologies in cutting-edge scientific fields such as nanotechnology, material science, biotechnology, and high-speed computing. "The American Competitiveness Initiative will continue America's preeminence in science, and will ignite innovation to keep America competitive," said Dr. Raymond Orbach, Director of the Office of Science. "This funding will be coupled with efforts to make much more effective use of our national laboratories for research and development leadership in the physical sciences."

Among the Office of Science programs with increased funding are the Basic Energy Sciences Program ($286.4 million increase); Biological and Environmental Research ($54.6 million increase); High Energy Physics Program ($58.4 million increase); Nuclear Physics Program ($87 million increase); Fusion Energy Sciences Program ($31.3 million increase); Advanced Scientific Computing Research Program ($84.0 million increase), and the Workforce Development for Teachers and Scientists Program ($3.8 million increase).

Individual budget requests for each of the DOE funding areas are available at: www.doe.gov/media/FY2007Budget/FY_2007_1pg_fact_sheets.PDF.

U.S. Department of Energy

NIH Launches Large-Scale Alzheimer's Neuroimaging Study

The National Institute on Aging (NIA) of the National Institutes of Health (NIH) announced on February 10 an initiative to recruit 800 older adults to participate in a study aimed to identify biological markers of memory decline and Alzheimer's disease (AD), as part of the Alzheimer's Disease Neuroimaging Initiative (ADNI). The $60 million, 5-year ADNI study is the most comprehensive effort to date to identify brain and other biological changes associated with memory decline. The project was begun by NIA and is supported by more than a dozen other federal agencies and private-sector companies and organizations. Investigators at 58 local study sites across the United States and Canada will be asking individuals ages 55–90 to become a part of this research.

"We encourage people to participate in this important study because it will help us to identify needed biological markers of memory decline and Alzheimer's disease. These biomarkers could become comparable to the cholesterol measures now used as biomarkers for heart disease," said Susan Molchan, MD, program director for the ADNI project at the NIA. "In addition, using what we learn from the brain scans and other tests, we hope to lessen the time and cost of testing drugs and to bring treatments to patients much sooner."

The ADNI researchers will employ serial MR imaging, PET, hematologic tests, and clinical and neuropsychological assessments to track mild cognitive impairment (MCI) and early AD progression. The study's principal investigator is Michael W. Weiner, MD, of the San Francisco Veterans Affairs Medical Center and the University of California, San Francisco. The Northern California Institute for Research and Education, a foundation affiliated with the U.S. Department of Veterans Affairs, has been awarded the multicenter ADNI grant. Three groups of individuals are being recruited for the study: approximately 200 cognitively normal older people, who will be followed for 3 years; 400 people with MCI, who will be followed for 3 years; and 200 people with early AD, who will be followed for 2 years. At the end of the study, the researchers will compare neuroimaging, biological, and clinical information from the participants, looking for correlations among the data to develop standards for tracking the progression of memory decline. A unique feature of the project is the development of an imaging and biomarker database that can be tapped by researchers in both the public and private sectors as they develop and test drugs for memory decline. "Our goal is to 'see' critical brain changes and to identify biochemical indicators that may be useful in evaluating treatments aimed at slowing memory decline and AD," explains Weiner.

ADNI is the largest public–private partnership on brain research underway at the NIH. In addition to the NIA, the federal ADNI partners include the National Institute of Biomedical Imaging and Bioengineering, also part of NIH, and the U.S. Food and Drug Administration. Partnership with private-sector funders is managed through the not-for-profit Foundation for the National Institutes of Health, established by the U.S. Congress to facilitate support of and involvement with NIH programs. Corporate and nonprofit participants are: Pfizer Inc; Wyeth Research; Bristol-Myers Squibb; Eli Lilly and Company; GlaxoSmithKline; Merck & Co., Inc.; AstraZeneca AB; Novartis Pharmaceuticals Corporation; Eisai Global Clinical Development; the Alzheimer's Association; Elan Corporation, plc; and the Institute for the Study of Aging. Siemens, Philips, and General Electric are providing software support for the imaging aspects of the project.

Other investigators for the project are Leon Thal, MD, University of California at San Diego, (Coordinating Center); Ronald Petersen, MD, PhD, of the Mayo Clinic, Rochester, MN (Clinical Aspects); Clifford Jack, MD, Mayo Clinic (Neuroimaging/MRI Core); William Jagust, MD, University of California, Berkeley (Neuroimaging/PET Core); John Q. Trojanowski, MD, PhD, University of Pennsylvania (Biomarker Core); Arthur W. Toga, PhD, University of California, Los Angeles (Bioinformatics Core); and Laurel Beckett, PhD, University of California, Davis (Biostatistics Core). Other investigators are at more than 60 participating sites in the United States and Canada.

Information about participating in the research is available through NIA's Alzheimer's Disease Education and Referral (ADEAR) Center at 800-438-4380 or by visiting the ADNI section of the ADEAR Web site at www.alzheimers.org/imagine.

National Institute on Aging

The Cost of Developing Imaging Agents

AD Nunn, from Bracco Research USA (Princeton, NJ) reported in the March issue of *Investigative Radiology* (2006;41:206–212) on the financial cost of developing imaging agents for routine clinical use and on the potential effects of these costs on the future clinical imaging agent environment. Cost estimates were based on publicly available financial data from annual reports of major companies developing and selling imaging agents. These estimates were compared with more in-depth data and analyses available for the development costs of therapeutic drugs. The author estimated that the cost of developing a drug for diagnostic imaging is in the $100–$200 million range, and that "blockbuster" imaging drugs (those with wide utility and high numbers of procedures) have current sales of $200–$400 million. These blockbuster imaging drugs tend to be mainstays of routine imaging that have been on the market for some time and represent a segment of the market that changes slowly. Future agents, Rudd

noted, will most likely address smaller markets in the rapidly developing molecular imaging field—an area in which developmental costs are especially high. Small markets and high development costs usually result in extremely high per-dose costs. The authors concluded that cost must "either be greatly increased for new imaging agents, with a corresponding increase in the value of the information they provide, or the use of imaging agents must be widened and/or their development made less costly in time and money. Without addressing these issues, the commercialization of new imaging agents will continue to be slow and may get slower. This will impact the progress of imaging agents toward use as validated biomarkers."

Investigative Radiology

DOE Awards Supercomputing Time

On February 1, Secretary of Energy Samuel W. Bodman announced that the DOE Office of Science had awarded a total of 18.2 million hours of computing time on some of the world's most powerful supercomputers to help researchers in government labs, universities, and industry who are working on projects that range from designing more efficient engines to developing a better understanding of Parkinson's disease. The allocations of computing time are made under the DOE Innovative and Novel Computational Impact on Theory and Experiment (INCITE) program, now in its third year of providing resources to computationally intensive research projects in the national interest.

"Through the INCITE program, the department's scientific computing resources will continue to allow researchers to make discoveries that might otherwise not be possible," Bodman said in announcing the latest INCITE grants. "We live in an exciting time as researchers make advances that potentially can help us all." Funded projects range from aviation science to molecular physics to computer animation, with several projects requiring millions of supercomputing hours for completion.

One project of interest to the nuclear medicine community is "Simulation and modeling of synuclein-based 'protofibril structures' as a means of understanding the molecular basis of Parkinson's Disease." The University of California, San Diego, was awarded 16,000 processing hours at Argonne National Laboratory on the IBM Blue Gene supercomputer. This study will combine high-end computation with biochemical and NMR experiments to model the molecular basis for alpha synuclein aggregation. By combining the theoretical findings with experimental validation, the researchers hope to identify key amino acid interactions that favor amyloid pore formation and to use this information in new drug identification and development.

For the first time in the 3-year history of INCITE, proposals from private sector researchers were specifically encouraged. In return, much of the resulting knowledge will be made publicly available.

U.S. Department of Energy

BioShield Contract for Radiation Countermeasures

The Department of Health and Human Services (HHS) announced on February 13 the award of a $21.9 million BioShield program contract to Akorn, Inc. of Buffalo Grove, IL, for the manufacture and delivery of 2 medical countermeasures for radiological or nuclear incidents. Akorn, Inc. will deliver 390,000 doses of Ca-DTPA (pentetate calcium trisodium injection sterile solution) and 60,000 doses of Zn-DTPA (pentetate zinc trisodium injection sterile solution). The initial number of doses being purchased under the new contract is based on the Department of Homeland Security's threat assessment and the interagency Weapons of Mass Destruction Medical Countermeasures Subcommittee's evaluation of medical consequences of a radiological or nuclear incident. Under the terms of the 5-year contract HHS has the option to purchase up to 500,000 additional doses of Ca-DTPA and 500,000 additional doses of Zn-DTPA.

Akorn, Inc. has an exclusive marketing and distribution license agreement for the United States with Hameln Pharmaceuticals, Gmbh, of Hameln, Germany. Hameln Pharmaceuticals is the only manufacturer with Food and Drug Administration (FDA) approval for Ca-DTPA and Zn-DTPA to treat internal contamination from radioactive elements. FDA granted Hameln Pharmaceuticals orphan drug exclusivity until 2011. The Ca-DTPA and Zn-DTPA chelators are radiolabeled with plutonium, americium, or curium to treat internal radiation contamination. The HHS Office of Public Health Emergency Preparedness, which oversees the research and procurement efforts under the Project BioShield program through its Office of Research and Development Coordination, will manage the DTPA contract.

U.S. Department of Health and Human Services

Nuclear Medicine in Germany

In an article in the January issue of *Nuklearmedicine* (2006;45:1–9), Stamm-Meyer et al. reported on the frequency and collective effective doses of diagnostic nuclear medicine procedures in Germany between 1996 and 2002. The authors estimated the application frequencies for 10 groups of common nuclear medicine procedures by accessing official reimbursement data provided by German health insurance companies. Mean effective doses for these examinations were estimated from data on types of radiopharmaceuticals and administered activities at 14 clinics and 10 practices. These data led to the estimation that during the study period, a total of approximately 3.5 million nuclear medicine procedures were performed in an average year, corresponding to a mean annual application frequency of approximately 47 examinations per 1,000 inhabitants. More than 90% of the examinations were scintigraphies

of the thyroid (37%), skeleton (25%), myocardium (13%), lungs (8%), and kidneys (8%). The mean annual effective per capita effective dose was approximately 0.12 ± 0.02 mSv. Three types of procedures were responsible for about 80% of the total collective effective dose: scintigraphies of the myocardium (36%), skeleton (33%), and thyroid (10%). Averaged over all procedures, the mean effective dose per examination was 2.7 ± 0.8 mSv. The authors concluded that the average effective dose per inhabitant and year caused by nuclear medicine examinations is markedly lower than that resulting from medical X-ray procedures.

Nuklearmedicine

Reluctant Radiologists?

According to the results of a survey released in January, 29% of radiologists practicing in the United States in 2005 would not choose medicine if given the opportunity to go back in time and choose another career, an increase of 24% since the question was last asked in 1997. The survey results were reported by the physician-recruiting firm, LocumTenens.com, which asked similar questions of other medical specialists.

Compensation is not the key issue in dissatisfaction. "Compensation for radiologists has skyrocketed over the past decade because there aren't enough of them to meet demand," LocumTenens.com Vice President Katie Thill said. Respondents to LocumTenens.com reported average annual compensation for a radiologist in the United States at $354,260.) "However, most physicians choose medicine for reasons beyond a paycheck and many of them today are seeking better work/life balance," said Thill.

Although almost half (49%) of radiologists responding to the survey indicated they had no plans to make a job change, half said they planned to change jobs in the next 3 years (23% within 6 months). Fifty-three percent of those indicating an upcoming change cited lifestyle issues ("better community for self/family" or "better work environment") as their top reason for making the change.

In part, this reflects a competitive market for imaging services that allows flexibility. In the last decade U.S. health care facilities, particularly those in rural areas, have experienced a shortage of radiologists. The demand for radiology services is likely to outpace physician supply into the foreseeable future.

"Improving medical technology and aging baby boomers are increasing the number of imaging procedures, while the pool of radiologists remains fairly stable," Thill said. She referred to American Medical Association data indicating the number of residents entering radiology practice between 1990 and 2002 declined by 1%. Meanwhile, locum tenens industry sources indicate demand increased by 16% in a much shorter time frame (1997–2001). A recent study of demand by National Imaging Associates indicated patient use of imaging technology triples after age 65. According to the August 1 issue of *RT Image*, the number of imaging procedures will likely grow to nearly half a billion outpatient and 100-million inpatient scans annually by 2008.

Although the survey included some radiologists who include nuclear medicine techniques in their practices, results for nuclear medicine practitioners were not included separately in the study.

LocumTenens.com

(Continued from page 20N)

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