Congress Begins Support of the National Biomedical Tracer Facility

THE U.S. CONGRESS HAS taken a decisive step toward establishing a large-scale particle accelerator dedicated to biomedical radioisotope production. In September the House and Senate agreed on legislation that directs the Department of Energy to begin preliminary funding for the proposed National Biomedical Tracer Facility (NBTF).

The Society of Nuclear Medicine and the American College of Nuclear Physicians have backed the NBTF as a means to solve the mounting radioisotope supply problems that are hampering biomedical and other researchers. (An SNM task force carried out a feasibility study for the project with funding from the DOE in 1991.)

Citing the "lack of available domestically produced radioisotopes," Congress is directing the DOE to "address the situation by providing adequate funds to begin the one-year National Biomedical Tracer Facility Project Definition Phase." Rather than specify a sum, Congress refers to the 1991 feasibility study, which calls for a \$2 million appropriation to support the development of competing proposals for building the NBTF. The measure is part of a larger appropriations bill for DOE-sponsored research, which the President was expected to sign as Newsline went to press in early October.

"It think it's a smashing success," says Richard C. Reba, MD, of the University of Chicago, the presidentelect of SNM who has been involved in the effort to establish the NBTF. "It will be very difficult for the DOE not to go forward with this," he adds, alluding to earlier decisions by the DOE to exclude the project.

While the measure's passage is a great boon to the NBTF project, Dr. Reba says significant hurdles remain.

Although Congress asked the Energy Department for a status report on the NBTF by February, the legislation gives DOE the leeway to put off doing anything substantial until next October when fiscal year 1994 begins. And so far, no money has been set aside for the actual construction of the NBTF. When the DOE completes the project definition phase, and a winning proposal is selected, "Then the real work begins," says Dr. Reba.

Pressing Need

The NBTF would include research and teaching laboratories and an 100 MeV accelerator for producing a wide range of radioisotopes. Many radioisotopes with promising medical applications, particularly as agents for cancer therapy, are currently produced in extremely limited amounts by accelerators used primarily for physics research. These accelerators, the Los Alamos Meson Physics Facility (LAMPF) and the Brookhaven Linac Isotope Production Facility (BLIP), operate intermittently throughout the year, leaving gaps in production that have made it difficult if not impossible for clinical trials of new therapies for cancer to proceed.

Scientific panels have repeatedly concurred on the pressing need for a large-scale dedicated accelerator facility since at least 1988, but the DOE consistently excluded the project from serious consideration. Congress showed little interest in the project until now.

Washington's Wake-Up Call

A string of events over the summer helped bring the severity of isotope supply problems to the attention of lawmakers. The threatened strike by the near-monopoly supplier of molybdenum-99, Nordion International, caused a stir soon followed by the release of dire warnings from Congress's General Accounting Office about the near bankruptcy of the DOE's isotope production and distribution office.

A congressional hearing convened in August by Rep. Mike Synar of Oklahoma made much ado about the threatened strike and focused considerable attention on the need for the NBTF (even though the NBTF would not be used to produce molybdenum-99 and is not conceived as an answer to the problem of dependence on a single supplier of molybdenum-99). Rep. Synar and members of his subcommittee criticized DOE officials for failing to include funds for the NBTF in the 1993 budget.

Concerted efforts by the SNM and ACNP Office of Government Relations helped kindle Congressional interest. Accompanied by physicians and scientists, government relations staff met with congressional staffers and Administration officials to explain the need for the NBTF. The government relations office also coordinated a letter-writing campaign from SNM and ACNP members to Congress. "We played every front," says Kristen D.W. Morris, director of government relations for SNM and ACNP.

The efforts achieved strong support for the project from both the House and Senate. In July, eight senators (Democrats Lloyd Bentsen of Texas, Jeff Bingaman of New Mexico, and Paul Simon and Alan Dixon of Illinois, and Republicans Alfonse D'Amato of New York, John Seymour of California, and Richard Lugar and Dan Coats of Indiana) signed a letter to a Senate appropriations committee urging a \$900,000 commitment to begin the competitive siting process (continued on page 46N)



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showed that SPECT meets insurers' technology assessment criteria, efforts could be made to educate insurers. Gaps in research that might be identified could be filled in by targeted studies. If reimbursement for SPECT procedures appears low compared to planar studies, future research could be conducted to establish accurate cost information. A related project would revise Medicare relative value units (RVUs) to achieve higher reimbursement rates for SPECT procedures, which nuclear medicine physicians believe are undervalued. Revisions would be based on surveys of physicians and existing RVU data.

DOE, Biotech Firm Developing Labeled Antibodies

The Los Alamos National Laboratory and RhoMed Inc. announced in September their plans to study potential uses for copper radioisotopes under a recently signed Cooperative Research and Development Agreement (CRADA). The U.S. Department of Energy is promoting CRADAs as a means for national labs and U.S. companies to bring new technologies to market quickly, while protecting patents and other intellectual property.

Scientists at Los Alamos labs in New Mexico, operated by the University of California for the U.S. Department of Energy, and at RhoMed have reported initial studies showing that copper-67 can be bound easily and efficiently to antibodies using methods developed for technetium-99m, many of them patented or in the process of being patented by Rhomed, a privately held biotechnology company based in Albuquerque, New Mexico.

By extending the labeling techniques to copper radioisotopes, researchers at the two institutions hope to develop antibodies and proteins for cancer therapy. The isotope ⁶⁷Cu can be used for imaging with standard gamma-ray cameras and isotopes such as ⁶²Cu and ⁶⁴Cu are compatible with positron emission tomography (PET).

Under the CRADA, RhoMed scien-

tists will conduct labeling studies and laboratory analyses of radioisotopes supplied by the Los Alamos Meson Physics Facility (LAMPF), a high-energy particle accelerator. The national lab will also supply expertise in the chemistry of labeling biomolecules with radioisotopes. Los Alamos and RhoMed considered the joint research venture for more than two years. The National Cancer Institute recently awarded a grant to RhoMed to support its research on ⁶⁷Cu compounds.

RhoMed has developed a series of ^{99m}Tc-labeled antibodies for detecting infectious diseases and cancer. The company's first product in the series, called LeukoScan, is undergoing preliminary human clinical trials and awaits approval for marketing from the Food and Drug Administration.

Election Results Revisited

Mickey T. Clarke, CNMT of St. Louis, Missouri, newly elected treasurer of The Society of Nuclear Medicine Technologist Section, was inadvertantly omitted from the Tech Section election results printed in *Newsline* in September.

NBTF

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for the NBTF. Rep. John Myers, an Illinois Republican, sponsored the measure for the NBTF that was ultimately accepted in conference by the House and Senate. Rep. Myers is interested in the NBTF as a "needed commodity for the nation," according to aide Doug Wasitis. Rep. Myers, who is ranking minority member of the House Energy and Water Appropriations Subcommittee, sent a personal letter to DOE Secretary James Watkins in August urging him to fund the NBTF.

Rep. Myers and fellow Indianans Senators Lugar and Coats have a vested interest in the NBTF-Purdue University and Indiana University are making plans for jointly developing the accelerator facility. Purdue held a workshop in April 1992 to work out a proposed mission for the NBTF with nuclear medicine researchers and representatives of the radiopharmaceutical industry. Purdue has estimated that the NBTF could be constructed for \$100 million dollars, according to a statement submitted to Rep. Synar's subcommittee by Kenneth Kliewer, PhD, Purdue's assistant vice president for research.

Competing Proposals

The congressional patronage won't qualify as pork-barrel support if all goes as planned and proposals for the NBTF are peer-reviewed. A competitive field is shaping up, with contenders from Los Alamos National Laboratory in New Mexico, Brookhaven National Laboratory in New York, the University of North Texas, and the University of California with Lawrence Livermore National Laboratory.

Given the growing momentum behind the NBTF, there is an outside chance that the Energy Department could find money in the current budget to go ahead with the competitive siting phase. Ms. Morris says one reason she urged lawmakers not to specify any particular appropriation was to give the DOE flexibility to act sooner. Says Ms. Morris, "The ball is in their court now."

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