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Nuclear Medicine Axed at Oak Ridge

Budget cutters at the Department of Energy (DOE) have jettisoned two of the three major nuclear medicine research projects underway at Oak Ridge Associated Universities (ORAU) in Tennessee, and severed funding for three of the five nuclear medicine researchers employed there.

The Medical Sciences Division of the multi-university consortium has lost over $500,000 from the nuclear medicine program's $860,000 total annual budget provided by the DOE's Office of Health and Environmental Research, which halts the development of an investigational new drug (IND) protocol for human trials of yttrium-90 (^{90}Y) in treating colon cancer and a study of radiolabeled monoclonal antibodies against colon cancers in tamarin monkeys. The Radiopharmaceutical Internal Dose Information Center (RIDIC) will continue as the sole nuclear medicine project operating in the Medical Sciences Division at Oak Ridge.

"The nuclear medicine program had a very rich heritage, and I think we were doing pretty exciting work when we got the rug pulled out from under us," says former Acting Program Director Lee Washburn, PhD, who received formal notice in January that his funding would be severed.

J. Glenn Davis, PhD, vice-president and chairman of the Medical Sciences Division, says the budget cutbacks eliminate "a good portion of our program." The DOE's Office of Health and Environment Research, which supports the Oak Ridge consortium, decided which programs to cut to meet DOE budget requirements, according to Dr. Davis, who adds that he hopes to recover some funding in subsequent years.

Dr. Washburn, now a research associate professor at the University of Cincinnati Medical Center in Ohio, plans to continue developing the IND proposal for clinical trials of ^{90}Y. The research is partially funded by the National Cancer Institute through ORAU, and Dr. Washburn, an 18-year veteran at Oak Ridge, will consult from Cincinnati until his grant runs out in August. Research associate Tan Tan Sun, Dr. Washburn's assistant for 17 years, will work temporarily at Oak Ridge until the grant ends, as will biochemist Yu Chen Lee, PhD, also a research associate.

Dr. Washburn says he will discontinue the project involving radiolabeled monoclonal antibodies in tamarins because he will no longer have access to the tamarin colony at Oak Ridge. These long-tailed new world monkeys are particularly effective as research models because they are the only species, other than homo sapiens, that spontaneously develops colorectal cancer.

The proposed clinical study follows success in animal models using the ^{90}Y labeled monoclonal antibody CO17-1A, which is specific to human colorectal carcinoma. Radioimmunotherapy using the antibody resulted in a 95% reduction in the size of tumors that had been transplanted into nude mice, according to Dr. Washburn. He estimates that the move from Oak Ridge will set him back at least a year.

"The delay in the clinical study is very difficult to take," Dr. Washburn says. "Major advances are being made every day in this field—being delayed a year really puts us at a disadvantage." ■

Pilot Research Grant Recipient to Develop Anti-Tumor, Anti-Viral Agents

A proposal for developing radiopharmaceuticals that hold promise for in vivo imaging of tumors and viral infections is the winner of the $5,000 Pilot Research Grant for 1991, sponsored by the Education and Research Foundation of The Society of Nuclear Medicine.

John R. Grierson, PhD, research assistant professor, department of radiology, University of Washington School of Medicine, Seattle, intends to demonstrate practical radiolabeling chemistries for the preparation of two nucleoside analogues that could act as quantitative imaging agents for DNA synthesis in tumors and viral infections, such as herpes simplex, CMV, and HIV.

Dr. Grierson proposes a novel method for labeling the nucleoside analogues FFUdR and FFaraU with high specific activity fluoride-18. The work to be undertaken is not part of any funded research in progress. Dr. Grierson notes that the Pilot Research Grant will strengthen a proposal for a five-year NIH grant that he is applying for as a co-investigator. ■

EPA Postpones NESHAPS Rule

The Environmental Protection Agency (EPA) has stayed its national standards for radionuclide emissions until November 15, 1992, to allow more time to decide if Nuclear Regulatory Commission (NRC) requirements for such emissions provide an "ample margin of safety" for public health. EPA announced the stay in the Federal Register on April 24.

The Clean Air Act established National Emissions Standards for Hazardous Air Pollutants (NESHAPS) in 1989 that would regulate radionuclide emissions from sources including NRC-regulated nuclear medicine research and treatment facilities. EPA stayed the enactment of the national standards several times following comments about dual EPA and NRC regulation, and the adverse impact on nuclear medicine. Last fall Congress exempted radionuclide emissions associated with medical research and treatment from NESHAPS until 1992.

The latest EPA action extends a reprieve from NESHAPS to all NRC-

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licensed facilities, except nuclear power reactors, which the agency has already decided operate within an acceptable margin of safety. The EPA reports that radionuclide emissions from the other 12,000 NRC licensees, which include nuclear medicine facilities, "are not well characterized" for determining compliance with the Clean Air Act. The agency expects to have enough data to characterize such emissions by November 1992.

"The EPA is cooperating with us," says Kristen D. W. Morris, director of the Government Relations Office of The Society of Nuclear Medicine and the American College of Nuclear Physicians. "The stay confirms the EPAs intent to collect sound data on airborne emissions of radionuclides." ■

Industry Agrees to Join DOE Study of Domestic Moly-99 Production

Three American distributors of radiopharmaceuticals have agreed to fund a study proposed by the Department of Energy (DOE) that would pave the way, pending congressional budget approval, for the development of a secondary source of molybdenum-99 (^{99}Mo). The long sought agreement follows a brief disruption of the supply of ^{99}Mo that occurred for eight days in January when the sole source of the isotope, Nordion International of Kanata, Canada, shut down its primary medical radionuclide-producing reactor due to contamination in a reactor building.

DuPont-Merck Pharmaceuticals Co., Mallinckrodt Medical, Inc., and Medi-Physics, Inc., are fronting a total of about $250,000 for the DOE study to assess the feasibility of modifying one of the Department's existing reactors for the production of ^{99}Mo and related isotopes, company executives and a DOE official confirmed.

The agreement is based on the understanding that the DOE will sell ^{99}Mo at a price deemed competitive by the pharmaceutical distributors. The distributors, in turn, have agreed to buy a set percentage of their ^{99}Mo from the DOE. The costs of the feasibility study would be returned to the distributors in the form of discounts on initial purchases of the isotope. An estimated 80% of all nuclear medicine procedures depend on technetium-99 derived from ^{99}Mo generators.

The DOE has designated three promising sites that could be converted to produce ^{99}Mo: the Idaho National Engineering Laboratory (INEL), the Los Alamos National Laboratory (LANL), and Oak Ridge National Laboratory (ORNL).

Should the joint study find that conversion of a DOE reactor is economically possible, production of ^{99}Mo in the U.S. will still depend on Congress. The DOE's Office of Isotope Production and Distribution has requested from the Federal Government authority to borrow up to $8.5 million to pay for the modifications that would enable production of a number of medical and industrial isotopes at DOE sites.

"We're asking for the approval of borrowing authority. . .which ought to be infinitely easier to obtain than an outright appropriation," says Donald E. Erb, director of the Office of Isotope Production and Distribution. Mr. Erb proposed the joint study with industry in September 1990, and planned on completing the work within a year according to the study's original timetable. Commitment from industry came only after the Nordion shut-down.

Mallinckrodt's Lowell DePriest, materials manager, says the Nordion incident did not influence his company's decision to contribute to the DOE feasibility study. He says Mallinckrodt began looking for a domestic source of ^{99}Mo when the Cintichem reactor in Tuxedo, New York, was permanently shutdown in April 1990. "At that point, the entire industry was looking. . .we didn't want our molybdenum supply to be at the mercy of Nordion," he says. "We would certainly like to see the DOE in the business of making molybdenum."

"We are very supportive [of the DOE study] and have been for at least the past nine months," comments Al Herbert, president of Medi-Physics. "We've had a sense of urgency all along."

"We have been studying the issue for weeks," echoes Dupont-Merck Executive Director of Operations Roger Heiser. He maintains that Nordion has adequate capacity with its backup reactor to reliably supply ^{99}Mo, and says lack of competition is the reason his company is turning to DOE as a potential source for the isotope. "The loss of the reactor at Nordion," adds Mr. Heiser, "caused all of us a lot of anxiety."

Richard A. Holmes, MD, immediate past president of The Society of Nuclear Medicine (SNM), professor of medicine, radiology, and nuclear engineering, chief of nuclear medicine, University of Missouri Hospitals and Clinics, chief of nuclear medicine, Harry S. Truman Memorial Veterans Hospital, Columbia, Missouri, says: "Now that the agreement has been reached I hope this proceeds very rapidly because we're still sitting on the edge—should Nordion fail again, nuclear medicine will come to a screeching halt." ■

Erratum

A March *Newsline* story discussing the Nuclear Regulatory Commission's quality assurance rule misquoted the level of iodine-131 that the Advisory Committee on the Medical Uses of Isotopes recommended should be excluded from the requirements of the rule. The recommendation applies to levels below 30 milliCuries. ■