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NRC Ponders Regulations for Radiolabeled Monoclonal Antibodies

Brookhaven National Laboratory completed a report for the Nuclear Regulatory Commission (NRC) in March concluding that radiolabeled monoclonal antibodies "present new radiation safety issues" worthy of additional attention. The NRC plans to further review existing rules and to propose a new set of radiation safety guidelines for monoclonal antibodies by November 1992.

Among the radiation safety issues cited in the report: the use of alpha-emitters is new, it says, and no guidelines exist for prescribed doses, nor have studies been conducted exploring the possible occupational effects. The report suggests that patient confinement times for doses of radioiodinated antibodies for therapy can be higher than those commonly used in nuclear medicine.

Carol Marcus, MD, PhD, Director of the Nuclear Medicine Outpatient Clinic at the UCLA School of Medicine, scoffs at the document: "It rehashes very elementary immunology. . .The report indicates a profound lack of awareness of existing regulations and reports." Co-author of the report Donald E. Barber, PhD, a professor of environmental health at the University of Minnesota School of Public Health, counters that some aspects of the use of radiolabeled antibodies require different radiation safety procedures. The report, he says, only intended to identify those aspects.

Many in the nuclear medicine community question whether the NRC should be developing rules for radiobiologicals at all. Dr. Marcus says, "The NRC has no mandate for medical decision-making." She contends that use of radiolabeled antibodies is adequately guided by NRC standards for radiation protection, the National Council on Radiation Protection and Measurements, and the International Commission for Radiological Protection. "I do not believe that any new regulations are needed at all, by any regulatory agency," says Dr. Marcus.

Larry Camper, medical and academic section leader at the NRC, says his agency has the authority and responsibility under the Atomic Energy Act to regulate the medical use of antibodies containing radioactive byproduct material. He says that the NRC review of radiobiologicals was prompted by the petition submitted by SNM and the ACNP in 1989 requesting rule changes for the use of radiopharmaceuticals.

All radiolabeled antibodies are controlled by the FDA's investigational new drug (IND) process, except those labeled with byproduct material, which are regulated by the NRC. Barry Siegel, MD, chairman of the advisory committee to the NRC on the medical uses of isotopes (ACMUI), and professor of radiology and medicine at Mallincrodt Institute of Radiology, St. Louis, Missouri, says, "Radioimmunotherapy is being done by a small number of investigators on a very small basis, complying with current NRC safety limits." But inevitably, says Steve Larson, MD, chief of nuclear medicine at Sloan Kettering Hospital, use of radiolabeled antibodies will be considerable, "which is why the NRC is taking action now."

What influence radiation safety issues will have on the development of labeled antibodies in medicine remains to be seen. Dr. Siegel says that the radiobiologicals pose no public safety issues "that would require overwhelming response by the NRC." ■

Mallinckrodt Drops Party to Fund Education Efforts

Mallinckrodt Medical, Inc. gave $55,000 to The Society of Nuclear Medicine (SNM) and The Society of Nuclear Medicine Technologist Section (SNM-TS) at the society's June meeting in Cincinnati, and pledged continued funding for a variety of educational projects following a decision to discontinue the company's large-scale customer appreciation party — a ballyhooed event at SNM annual meetings.

"After taking a hard look we've decided the money would better be spent on education," says Richard Martin, director of marketing for Mallinckrodt's nuclear medicine division.

A sum of $30,000 will allow the Technologist Section to produce a continuing education video tape and to advance a project for the recruitment of minorities in nuclear medicine, says Bradley K. Pounds, CNMT, immediate past-president of SNM-TS and technical director of nuclear medicine at St. Luke's Episcopal Hospital, Houston, Texas.

The SNM share of $25,000 will help fund the new office of quality standards and practice policy.

Mallinckrodt plans to provide $30,000 a year for the technologist projects for three years, and will continue the $25,000 SNM donation each year for an indefinite length of time. ■

Specialties Unite Against RBRVS Rules

In a display of unity, more than 30 medical specialty societies, including The Society of Nuclear Medicine and the American College of Nuclear Physicians, joined an American Medical Association campaign against proposed rules that would cut Medicare payments by 16% in 1996. A joint letter, written by the AMA and signed by medical society leaders, denounces as "intolerable" the resource-based relative value scale (RBRVS) published in June. Sent to all members of Congress, the letter urges legislators to force the Health Care Financing Administration (HCFA) to rewrite the RBRVS.

The medical groups are united in opposition to the conversion factor proposed by HCFA for translating RBRVS values into actual Medicare dollars. HCFA claims that reducing the con-

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version factor by 16% is necessary to achieve budget neutrality in 1992. By 1996 when RBRVS is fully applied, however, physician payments could be as much as $8 billion less under the proposed conversion factor, according to Medicare figures cited by the AMA. Medicare payments for nuclear medicine procedures will decrease 32% over the next five years, according to Barbara Y. Croft, PhD, vice-chair of SNM's nomenclature and relative value scale committee.

HCFA reduced the conversion factor partly because the agency expects physicians to boost the volume of services performed to offset fee reductions under RBRVS. Nuclear physicians can't recoup decreases using this "behavioral offset" because they depend on referrals from other physicians, says Dr. Croft, associate professor of radiology at the University of Virginia in Charlottesville. Thus, she says, the proposed rules unfairly burden nuclear medicine.

"This is a double-hit against medical imaging," says Kenneth A. McKusick, MD, associate professor of radiology at Massachusetts General Hospital in Boston and chairman of the nomenclature and relative value scale committee. "Imaging has already been affected by a 20% reduction under the RVS fee schedule negotiated with Congress in 1988."

Congress mandated RBRVS-based Medicare payments in 1989 to replace charge-based physician payments. The medical profession supports efforts to revise physician payment, states the AMA letter, noting that the system is "unpredictable" and "often inequitable." The AMA and others contend, however, that the proposed system defies the intent of congress for budget neutrality. "HCFA is proposing a system that will be a budget slashing tool," the AMA letter says.

HCFA is accepting comments on the new RBRVS rules until August 5. A final rule will be published in October. ■

A Halt on Below Regulatory Concern

The Nuclear Regulatory Commission shelved its "below regulatory concern" policy until 1992 and approved a consensus-building effort to salvage the much-maligned BRC in a vote by the commissioners on July 1.

The decision means that NRC regulation will continue under the rules prior to the publication of the BRC policy statement. The NRC will defer consideration of petitions for rule-making under BRC that seek exemptions on a national scale for the disposal of radioactive wastes, distribution of consumer products, and other activities.

The NRC first published the policy on July 3, 1990 intending to define when radiation levels are so low that they do not need stringent regulation. The announcement ignited a firestorm of criticism from environmental, consumer, and public interest groups and resulted in a flurry of state and national legislation intent on thwarting the BRC policy.

The Society of Nuclear Medicine and the American College of Nuclear Physicians has taken a stand supportive of the concept of the BRC policy, but has urged refinements including strict criteria for disposal of radionuclides in landfills.

NRC officials declined to speculate on the fate of the BRC policy. Opponent Bill Magavern, staff attorney for the U.S. Public Interest Research Group, says, "The NRC has realized that they've put forth a terrible policy that the public and the Congress hate and they're beating a hasty retreat." U.S. PIRG, Greenpeace, Public Citizen, and other public-interest groups have shunned the consensus-building effort, saying their input in the past had no effect on the commissioner's rule-making. Many have joined the state of Maine and 16 other states in a lawsuit against the NRC aimed at suppressing the controversial policy.

The NRC's Francis Cameron, who's orchestrating the consensus process, says it's an opportunity "of great potential" for influencing the commission. "The groups that come to the table will set the agenda," he says. ■

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