From the SNM

Mallinckrodt Issues ^{99m}Tc Generator Recall

On November 18 Mallinckrodt, Inc. (St. Louis, MO), a part of Tyco Healthcare, issued a voluntary product recall on its Ultra-TechneKow DTE generator, with a request for immediate discontinuation of use in the North American and Latin American markets. This recall came as the result of a routine sterility assurance process revalidation. The generator is prepared with fission-produced ^{99}Mo and provides a closed system for the production of sterile metastable ^{99m}Tc. Isotonic solutions of sodium pertechnetate ^{99m}Tc are obtained by periodic aseptic elution of the generator and are used in brain, thyroid, cardiac, blood pool, urinary bladder, and nasolacrimal drainage imaging. In the recall, Mallinckrodt indicated that patient doses should not be formulated from any of its generators, and that generator availability would be affected for at least 6 weeks. No adverse events related to the recall had been reported at Newsline press time.

Three days after the recall, the Council on Radionuclides and Radiopharmaceuticals (CORAR)—an association of U.S. and Canadian companies that manufacture and distribute radiopharmaceuticals, sealed sources, and radionuclides—released a statement to the medical imaging community. "The industry is cooperating, as appropriate, to meet the overall demand for ^{99m}Tc generators in North America and related patient unit doses, provided through radiopharmacy distributors, which use this critical isotope. This includes production scale-up for both ^{99m}Tc generators and ^{99}Mo," the release stated. CORAR predicted that market shortages would ease in December as additional supplies were produced. CORAR representatives added, however, that "the possibility exists for sporadic shortages to still occur over the next month or so, due to one company not being able to assure total supply of market demand. With only one manufacturing site, other influencing factors, such as winter weather, may affect availability of ^{99m}Tc generators and ^{99m}Tc unit doses."

On the same day, Bristol–Myers Squibb Medical Imaging, the only other North American manufacturer of the generators, issued a statement indicating that the company was "aggressively" implementing plans to meet the overall ^{99m}Tc generator demand in North America with their TechneLite product. They noted that the effort to scale up production might occasion temporary disruptions in generator supply but that the company expected to be able to sustain increased production as long as required.

On November 23 Mallinckrodt provided updated information and a document with frequently asked questions and answers on the recall. Mallinckrodt noted that despite the discovery of a gram-positive cocci contaminant in 1 of 800 product test cultures, there was "no reason to believe there is a significant health risk to patients." Health care professionals were advised to call Mallinckrodt corporate product monitoring (888-744-1414, option 2 then, option 1) if adverse reactions are noted.

Mallinckrodt confirmed that remedial actions including successful revalidation of the affected production process would take a minimum of 6 weeks to complete. At Newsline press time, the company was working with both SNM and the American Society of Nuclear Cardiology to identify appropriate alternative approaches to cardiac nuclear scans during the shortage.

Society of Nuclear Medicine

National Oncologic PET Registry Advances

SNM announced on November 18 that it had been notified by the Centers for Medicare & Medicaid Services (CMS) that clearance had been obtained for the filing of the National Oncology PET Registry (NOPR). In December, CMS was in the final clearance process for the contract with affiliated organizations. The SNM, Academy of Molecular Imaging, American College of Radiology (ACR), and American Society of Clinical Oncology are hopeful the process will be implemented later this month.

NOPR launched PET facility registration on November 27 in the ACR booth at the annual meeting of the Radiological Society of North America (RSNA) meeting in Chicago, IL. Physicians and administrators came in large numbers to complete preregistration forms. Additional registration materials were e-mailed to designated contacts at each facility in December. Registrants also signed up for regular NOPR updates and to preview the NOPR Web site.

NOPR was developed in response to the CMS proposal to expand coverage for ^{18}F-FDG PET imaging to include most cancers not currently eligible for Medicare reimbursement. Medicare reimbursement for these cancers will be available if the patient's referring physician and provider submit data to a clinical registry to assess the effect of PET on patient management. NOPR is implementing this registry for CMS. Any PET facility that is approved to bill CMS for either technical or global PET charges can apply to participate in NOPR. Sites are not required to have ACR or Intersocietal Commission for the Accreditation of Nuclear Medicine Laboratories accreditation to participate.

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When a registered PET facility enters a patient on the NOPR, the patient's referring physician will be asked to complete both pre- and post-PET data collection forms that ask several questions about planned management. The PET facility will enter this information and a copy of the PET scan report into the NOPR database using a Web form. If the PET facility completes the data collection process in a timely fashion, the facility can bill Medicare for the procedure.

Although NOPR began the PET facility registration process at RSNA, PET centers cannot enter patients into the registry until final approval is received from CMS. Meanwhile, the NOPR Web site (www.cancerPETregistry.org) will provide access to facility registration forms, sample data collection forms, and information for clinicians.

Society of Nuclear Medicine

Nuclear Medicine Research Axed

On November 19 President George Bush signed the fiscal year (FY) 2006 Energy and Water Appropriations Bill. The bill had been approved by the Senate on November 14, with no member discussion on proposed cuts to the Department of Energy (DOE) Biological and Environmental Research (BER) Medical Applications and Measurement Science (MAMS) program during the final floor consideration. The net effect will be to reduce MAMS program funding from $37 million in FY 2005 to $14 million in FY 2006. Most of the remaining $14 million is designated for non-nuclear medicine–related DOE Office of Science BER activities. Most current MAMS researchers will be forced to search for nonfederal funding or to cease operations in 2006.

SNM and the American College of Nuclear Physicians (ACNP) lobbied jointly to prevent the cuts and indicated after passage that they would continue to seek funding for MAMS research projects in other appropriations bills. The 2 groups will also work with Congressional leaders to fully fund the program for FY2007 or, if necessary, identify a new base for basic nuclear medicine research programs other than the DOE Office of Science, which has been the home of this research for more than 50 years.

"The outcome is clear: Basic nuclear and molecular imaging research will decline beginning in 2006, and our professional community may have to fight a hard battle to maintain other federal research funding in 2007," said SNM President Peter S. Conti, MD, PhD, a professor of radiology, clinical pharmacy, and biomedical engineering at the University of Southern California, Los Angeles. "This budget cut pulls the plug on discoveries that could have translated into better disease management for millions of patients fighting oncological, neurological, and cardiovascular diseases each year. Although SNM acknowledges the budget constraints faced by federal appropriators, we cannot afford to sacrifice medical research that has a proven record of leading to transformational changes in the diagnosis and treatment of life-threatening cancer, heart and other diseases that affect millions every year."

Society of Nuclear Medicine

Additional Newsbriefs

Medicare and Voluntary Quality Reporting for MDs

The Centers for Medicare & Medicaid Services (CMS) announced on October 28 plans to "make it easier for physicians to participate in a voluntary program to report evidence-based, consensus quality measures." CMS Administrator Mark B. McClellan, MD, PhD, said, "Physicians are in the best position to know what can work best to improve their own practices and ultimately the quality of care available to all patients. Through these voluntary reports by physicians on evidence-based quality measures, we can take an important step together to help them improve care, and ultimately to help make sure that they are adequately compensated for that care."

The action created the Physician Voluntary Reporting Program. Beginning this month, Medicare will enable physicians to voluntarily report information to CMS about the quality of care they provide to Medicare beneficiaries. The 36 evidence-based measures to be reported in the first phase of the program are a result of collaborative efforts with physicians, physician organizations, and other experts involved in quality review. The new system comes as Medicare physicians face payment rate reductions for the next 7 years, triggered by a statutorily imposed payment formula.

"Medicare remains dedicated to preserving access to quality care and avoiding unnecessary costs, and that requires finding better ways to support quality care instead of simply adding more dollars into a system that focuses on volume," McClellan said.

To support better health outcomes for people with Medicare at a lower cost, CMS is working with medical professionals and Congress to consider changes to increase the effectiveness Medicare physician reimbursement while avoiding increases in overall Medicare costs.

As part of this effort, the Physician Voluntary Reporting Program will begin to phase in voluntary reporting of performance based on metrics established by a consortium of quality-focused organizations. CMS will begin to collect information through the use of a dedicated set of Healthcare Common Procedure Coding System codes that will supplement claims data that physicians currently submit to CMS with clinical data. These data will then be used to measure the quality of services provided to Medicare patients. CMS anticipates that these new codes will serve as an interim step until the submission of data through electronic health records replaces this process.

CMS will provide feedback to physicians who submit data by the summer of 2006 about the level of their performance. The goal is to use this feedback to assist physicians in improving data accuracy, reporting rates, and clinical care. CMS will also seek

input from participating physicians on ways to improve ease of reporting and usefulness of quality measures.

Although CMS officials note that the Physician Voluntary Reporting Program is similar to previous agency quality initiatives, such as the hospital voluntary reporting program, critics point to the new program as an opening wedge in creating more stringent pay-for-performance measures among physicians.

Centers for Medicare & Medicaid Services

Science.gov 3.0 Launched

The latest version of Science.gov was launched on November 15, allowing more refined queries for searches of federal science databases. "In these wonderful times for science, the tools by which we share science information must be extraordinary," said Dr. Raymond Orbach, Director of the Department of Energy Office of Science. "Science progresses when knowledge is shared, and Science.gov 3.0 provides researchers with a tool to hone their queries, resulting in more precise results."

Science.gov 3.0 introduces "MetaRank" which uses a sophisticated method for ranking science queries by searching metadata (bibliographic information such as title, author, date, abstract, or other keyword identifiers). This technology complements the relevancy-ranking capabilities of QuickRank, which was introduced in version 2.0 and is still deployed on every search. Science.gov 3.0 also offers enhanced Boolean search capability, improved fielded searching, intuitive site navigation, and early viewing of results while the database and Web site searches continue in real time.

Science.gov serves as the gateway to science and technology information from 17 organizations within 12 federal science agencies and leverages the power of a single query across 30 databases and 1,800 Web sites. Science.gov allows users to search the surface Web as well as the deep Web, where traditional search engines cannot go. The information is free, and no registration is required. See www.science.gov.

U.S. Department of Energy

UT-Battelle Gets $6.3-Billion ORNL Contract

U.S. Department of Energy Undersecretary David Garman announced on December 1 the award of a 5-year, $6.3-billion extension to its current management and operating contractor, UT-Battelle, LLC, for the continued operation of the Oak Ridge National Laboratory (ORNL) in Oak Ridge, TN. ORNL is one of the DOE's major, multiprogram national laboratories and an international leader in a range of scientific areas, including neutron science, energy, high-performance computing, complex biological systems, advanced materials, and national security. "This extension demonstrates the department's commitment to scientific research and also our confidence in the people of Oak Ridge National Laboratory," said Garman. The contract extension, signed earlier this fall, will run through March 31, 2010.

U.S. Department of Energy

Home-Based Cyclotron

The December 1 issue of online news source Wired.com carried a story about dissention brewing in an Alaska community over the plans of one citizen to operate a cyclotron in his residence. Writer Xeni Jardin detailed local reaction to the plans of Albert Swank, Jr., an Anchorage civil engineer, to install a nuclear particle accelerator in his home. Reaction was swift, as Anchorage assemblymen and -women introduced emergency rules to ban cyclotrons from home businesses and as state officials suspended Swank's preexisting permit to operate a cyclotron at his home business.

The cyclotron is a used unit from Johns Hopkins University, donated with the understanding that it was to benefit the citizens of Alaska with medical needs. Cyclotrons and PET units are scarce in Alaska, and Swank, whose father died of cancer, has indicated that he plans to produce PET radiopharmaceuticals for the benefit of his community and to use the device to interest young people in scientific careers. The unit is scheduled to ship from Baltimore, MD, later this month, and, if installed, would not be the first cyclotron in this home. Swank and his father built one there almost 40 years ago. The tone of rhetoric directed against the home installation of the unit has escalated, with one critic noting not only possible drains on available electrical power but also comparing potential damage from a cyclotron mishap to that from the Three Mile Island nuclear reactor accident. At Newsline press time, the Anchorage Assembly had scheduled a special session to consider a formal ban on home cyclotrons.

Wired.com