PET in Ontario

Members of the Ontario Association of Nuclear Medicine (OANM) and a coalition of interested citizens pooled their efforts in September to speak out against the province's official stance regarding PET as an experimental technology. This policy not only means that PET studies are not reimbursed but that access to PET units outside the research setting is challenging if not impossible for most patients and their physicians. Under headlines such as "Ontario Government Failing Cancer Patients" and "Got Cancer? Leave Ontario!" the nuclear medicine organization and the Ontario Citizens Cancer Coalition (OCCC) launched a grassroots campaign to raise public awareness.

"From British Columbia to Nova Scotia, Canadians can get a PET scan, but here in Ontario we continue to deny cancer patients access to this vital diagnostic tool," said Christopher O'Brien, MD, president of the OANM and chair of the Ontario Medical Association's Nuclear Medicine Section.

The Canadian government has approved the use of ^{18}F-FDG for PET in breast, colorectal, and lung cancer assessment. The OANM pointed out that this (as well as supportive data from other countries) suggests an endorsement of PET as safe and effective. "Yet the Ontario government continues to claim that PET is 'experimental' and to support research programs that are unlikely to produce any valuable information," said O'Brien. "Instead of allowing access to PET, the government insists on wasting time and lives with fruitless research projects that are underfunded, underrecruited, and that will merely duplicate work already done elsewhere."

More than 24,000 Ontarians are diagnosed with lung, colorectal, and breast cancer each year, and 12,000 die from these causes. The OANM pointed out in press releases that PET's ability to beneficially alter management in 25% of such patients is a clear indication of the benefits that could be conferred by its wider use. The OANM formally called on the government of Ontario to: immediately stop all PET research projects; direct funding to clinical applications of PET for lung, colorectal, and breast cancer assessment; and ensure that Ontarians have the same access to PET as the rest of Canada.

Citizens groups were equally strong in their indictment of the current situation. Canada's Association for the 50 Plus (CARP) joined forces with the OCCC in a campaign demanding that Ontario politicians commit to providing better access to cancer drugs and PET and vowing to exercise their dissatisfaction at the ballot box. CARP and the OCCC sent letters to the major candidates for new office asking for firm commitments to their demands. The 2 groups vowed to "fight to defeat vulnerable candidates belonging to the party(ies) that do not make a clear commitment to bringing in the necessary changes in Ontario's cancer policy if elected."

"Ontario ranks as one of the worst provinces in the country in terms of providing funding for access to newer intravenous cancer drugs and PET scans," said Antonia Codispoti, cofounder, OCCC. "Currently in Ontario, only 4 from a list of 24 newer intravenous cancer drugs are fully funded for all citizens compared to 20 in British Columbia. Similarly, only 6 PET scans are fully funded in Ontario for every 100,000 people, while Quebec funds 209 per 100,000 people."

Ontario Association of Nuclear Medicine

SNM Tops *RT Image*'s Annual List

RT Image announced its 2007 list of the "most influential" people, institutions, and organizations in imaging in its September 3 issue. Based on results from a reader poll and other assessments of drive, character, and integrity, the magazine announced that SNM topped the list of all nominees.

In describing its choice, *RT Image* noted, "By planning strategically, SNM continues to grow and adapt to meet the changing needs of patients, health care, its members, and the profession. For more than 50 years, SNM and its 16,000 physician, technologist, and scientist members have been well known for excellence in the nuclear medicine profession. Their work has expanded into the rapidly emerging—potentially revolutionizing—field of molecular imaging. Nuclear medicine imaging has always contributed functional assessment to the anatomical definition of the presence or absence of disease. The new tools made available through molecular imaging and PET have great potential to contribute to the personalized medicine revolution—and SNM is leading the way."

Additional text contributed by SNM President Alexander J. McEwan, MD, highlighted SNM efforts in translating multimodality breakthroughs from the lab into practical tools for physicians through the "Bench-to-Bedside" campaign and the SNM Molecular Imaging Center of Excellence.

The entire list of 25 "most influential" individuals and institutions in imaging can be accessed at www.rt-image.com/090307MostInfluential.

RT Image

Collaborative Research on Existing Radioligands

The National Institute on Drug Abuse, the National Institute on Aging, the National Institute of Neurological Disorders and Stroke, and the National Institute of Mental Health have issued a request for application (RFA) for proposals that would lead to broader

uses of established PET/SPECT radioligands. The sponsoring institutions seek to "encourage collaborations between sites that develop and use PET and/or SPECT radioligands for the purpose of expanding the range of ligand applications as well as sharing the ligands themselves or the procedures used in their development/synthesis."

The overall goal of the solicitation is to optimize the utility of PET/SPECT radiotracers across organ systems and diseases and between and among sites in human subjects. Applications for this RFA are advised to demonstrate a high degree of risk, innovation, and novelty with regard to new uses for existing radioligands and unique and innovative collaborations across disciplines, fields, and diseases. The primary focus of the proposal must be on human studies. Animal studies are allowable only if required to obtain regulatory approval for the ligands.

The deadline for applying for this funding is January 28, 2008. The complete RFA is available at http://grants.nih.gov/grants/guide/rfa-files/RFA-DA-08-001.html.

National Institutes of Health

Safety of Resident On-Call Reads

Results of a study published in the September issue of the *American Journal of Roentgenology* (2007;189: 523–526) suggest that well-trained residents, regardless of their year of training, can interpret imaging studies while on overnight call safely and with minimal discrepancy rates. Richard B. Ruchman, MD, and colleagues from Monmouth Medical Center (Long Branch, NJ) reviewed approximately 12,000 emergency diagnostic imaging exams that were interpreted after hours by residents.

"In the midst of our research, a vigorous national debate began concerning the appropriate stage of radiology resident training prior to independent call," said Rutman. "Specifically, the Accreditation Council for Graduate Medical Education [ACGME] proposed and subsequently approved a new requirement that would mandate 1 year of residency training prior to independent call. Our study examined the discrepancy rate by year of training, and attempted to answer the question whether it was safe for first-year residents to take independent call with faculty back up."

The study indicated that the major discrepancy rate (those interpretations by residents after hours that disagreed with the attending physicians' final interpretation and in which the difference in diagnosis had some negative effect on patient care) was 2.6%. A significant negative clinical effect resulting from discrepancies was found in only 0.3% of total exams. "This discrepancy rate is comparable to the discrepancy rates of the attending radiologists in our program," Ruchman noted. Most major discrepancies involved abdominal or chest examinations, with the most frequently missed or corrected diagnosis being acute appendicitis. The second most commonly missed diagnosis was pulmonary embolism.

"The results of our study demonstrate that well-trained and supervised residents at all levels can interpret imaging studies safely," said Ruchman. "The rate of significant adverse consequences was miniscule and, in fact, was not greater for residents in the early years of training. This should give a sense of confidence to referring physicians and patients that off-hour imaging studies are being interpreted accurately. It also suggests a re-examination of the ACGME's recent revision of the rule regarding resident independent on-call duties."

American Journal of Roentgenology

FDA Oversight of Clinical Trials Criticized

The Office of Inspector General (OIG) for the U.S. Department of Health and Human Services (HHS) released a report on September 28 that identified specific weaknesses in Food and Drug Administration (FDA) information systems and management processes, resulting in flaws in the agency's ability to oversee clinical trial inspections. FDA inspects clinical trials to determine whether sponsors, clinical investigators, and institutional review boards responsible for conducting or overseeing clinical trials for investigational products are complying with relevant regulations. FDA oversees clinical trials through a variety of mechanisms that include protocol reviews and onsite inspections through its Bioresearch Monitoring (BiMo) Program.

The OIG report focused exclusively on BiMo inspections, an important mechanism for protecting human subjects once a clinical trial is underway. The OIG concluded that the FDA does not have a mechanism to identify all clinical trials and institutional review boards (IRBs) that approve, monitor, and review research involving human subjects. Moreover, it lacks a comprehensive database for tracking its inspections of clinical trials. "Data limitations hinder the FDA's ability to ensure that participants are protected from unreasonable risks," said Daniel R. Levinson, HHS inspector general. "Accurate record-keeping is critical to maintaining the safety of clinical trial patients."

The OIG found that the FDA inspected only about 1% of clinical trial sites from fiscal year (FY) 2000 to FY 2005. Of this small group, 75% were surveillance inspections, which generally target completed trials and most often focus on verifying the quality of trial data. The FDA also inspected few IRBs. These findings were particularly troubling in light of past OIG studies. In 1998, a series of OIG reports concluded that most IRBs lacked the time and expertise to sufficiently monitor research. A 2000 report found that data integrity concerns, rather than human subject protection, drove FDA oversight of clinical investigators.

In the September report, the OIG identified steps that FDA could take to improve its system for overseeing clinical trials, including: developing a comprehensive internal database of all clinical trials; creating a registry of IRBs; creating a cross-center database that allows complete tracking of FDA

inspections; seeking legal authority to provide oversight that reflects current clinical trial practices; and establishing a mechanism to provide feedback to FDA district office staff on their inspection reports and findings. The FDA's full response to the OIG's recommendations is included as an appendix to the report, which can be viewed at www.oig.hhs.gov/oei/reports/oei-01-06-00160.pdf.

U.S. Department of Health and Human Services

NIH Director Invests in Innovation, New Investigators

National Institutes of Health (NIH) Director Elias A. Zerhouni, MD, announced on September 19 a "major investment in the future of science" with 41 5-year grants totaling more than $105 million to a group of exceptionally innovative investigators, many of whom are in the early stages of their careers.

"Novel ideas and new investigators are essential ingredients for scientific progress, and the creative scientists we recognize with NIH Director's Pioneer Awards and NIH Director's New Innovator Awards are well-positioned to make significant and potentially transformative discoveries in a variety of areas," said Zerhouni. "The conceptual and technological breakthroughs that are likely to emerge from their highly innovative approaches to major research challenges could speed progress toward important medical advances."

This is the first group of New Innovator Awards and the fourth group of Pioneer Awards. Both programs are part of an NIH Roadmap for Medical Research initiative that tests new approaches to supporting research. Pioneer Awards support scientists at any career stage, and New Innovator Awards are reserved for new investigators who have not received an NIH regular research (R01) or similar grant.

The 12 new Pioneer Award recipients will each receive $2.5 million in direct costs over 5 years. The 29 New Innovator Award recipients will each receive $1.5 million in direct costs over the same period. NIH selected the award recipients through special application and evaluation processes that engaged 262 experts from the scientific community in identifying the most highly competitive individuals in each pool. The NIH Advisory Committee to the Director performed the final review and made recommendations to Zerhouni based on evaluations by the outside experts and programmatic considerations.

"We hope that these programs also help remind the scientific community, including its newest members, that we encourage investigators to be bold and 'swing for the fences' with their proposals," said Jeremy M. Berg, PhD, director of the National Institute of General Medical Sciences, which runs the Pioneer and New Innovator Award programs for NIH.

Biographical sketches of the 2007 NIH Director's Pioneer Award recipients are at http://nihroadmap.nih.gov/pioneer/Recipients07.aspx. More information on the Pioneer Award, including details on the 35 scientists who received awards in the first 3 years of the program, is at http://nihroadmap.nih.gov/pioneer. Information on the 2007 NIH Director's New Innovator Award is at http://grants.nih.gov/grants/new_investigators/innovator_award/index.htm.

National Institutes of Health

DOE Launches Online Patent Search Tool

The U.S. Department of Energy (DOE) announced on September 18 the launch of DO*epatents*, a Web site that allows search and retrieval of information from a collection of more than 20,000 patent records. The database represents a growing collection of patents resulting from research and development supported by DOE from the 1940s to the present.

"From helping the blind to see again to identifying hidden weapons through holographic computerized imaging technology, the U.S. DOE has supported and will continue to support research addressing some of the world's most pressing scientific challenges," said the DOE's under secretary for science Dr. Raymond L. Orbach. "Content within DO*epatents* represents a truly impressive demonstration of DOE research and development and technological innovation."

Highlighted on the Web site is a compilation of noteworthy DOE innovations from the past few decades. One such invention is the artificial retina, a collaborative research project between DOE national laboratories, universities, and the private sector. Another invention is the DOE National Renewable Energy Laboratory's pioneering multijunction solar cell. The database also includes inventions by Nobel laureates associated with DOE or its predecessors.

DO*epatents* citations include bibliographic records, with full text (where available) through either a PDF file or an HTML link to the record at the U.S. Patent and Trademark Office. The database will be updated regularly with new patent records, news, and information about significant and recent inventions. Resource links for inventors are included at the site, as well as pages on recent inventions and patent news. The site was developed by the DOE Office of Scientific and Technical Information and is available at www.osti.gov/doepatents.

U.S. Department of Energy

HHS Report on Personalized Health Care

The U.S. Department of Health and Human Services (HHS) on September 19 released the first department-wide report on the goal of personalized health care, noting that work in biomedical science, health information technology (IT), and health care delivery should be aligned to produce "the right treatment, at the right time" for each patient.

The report, *Personalized Health Care: Opportunities, Pathways, Resources,* presents a long-range plan for achieving more individualized treatment for patients, especially by using genetic

information and IT. "Health care professionals have always aimed at making medical care as individualized as possible. But in truth, our ability to deliver the right care for each person has been limited," HHS Secretary Mike Leavitt wrote in a foreword to the report.

The report describes how rapidly expanding knowledge of the human genome will increase the capacity to predict, detect, preempt, and treat disease by enabling physicians to "look beneath" visible symptoms and see signs and causes of disease at the molecular level. The report also outlines areas in which significant work and investment of resources are needed and provides the first inventory of 50 relevant programs underway throughout HHS. Among these are: genome-wide association studies, sponsored mainly by the National Institutes of Health, to identify genetic elements in disease; efforts by the Centers for Disease Control and Prevention to describe population-wide genomic characteristics and to lay the groundwork for the application of genomic elements in health care; programs under the National Cancer Institute to enhance understanding of the causes of cancer and improve treatment through scientific advances as well as new programs for sharing "best treatment" information; HHS-supported efforts in health IT to develop technical standards and provide for secure exchange of medical data; and new guidance and planning by the Food and Drug Administration to prepare for rapid development of useful new products and for integrating genomic information into drug prescribing and disease diagnosis.

The report is available on the HHS Web site at www.hhs.gov/myhealthcare/.

U.S. Department of Health and Human Services

Resource Guide on Corporate Responsibility for Quality

The Office of Inspector General (OIG) for the Department of Health and Human Services (HHS), in partnership with the American Health Lawyers Association (AHLA), released on September 10 a resource guide on quality of care titled, *Corporate Responsibility and Health Care Quality: A Resource for Health Care Boards of Directors.* As part of Inspector General Daniel R. Levinson's quality-of-care initiative, this resource guide seeks to assist directors of health care organizations in carrying out their important oversight responsibilities in the current challenging health care environment. It is the third in a series of documents on corporate responsibility cosponsored by OIG and the AHLA. The resource guide is designed to help health care organization boards ask appropriate questions related to health care quality requirements, measurement tools, and reporting requirements. Compliance with standards and regulations applicable to the quality of services delivered by health care organizations is essential for the lawful behavior and corporate success of these organizations. OIG and AHLA noted that this guide would be useful to health care organization directors in exercising their oversight responsibilities and in supporting their ongoing efforts to promote effective corporate compliance in health care quality.

As part of its efforts to promote the involvement of boards in the care delivered in their institutions, OIG will be hosting a series of roundtable discussions with industry leaders. The first of these meetings will focus on the boards' role in overseeing the quality of care provided in long-term care institutions. The roundtable, scheduled for December, will be cosponsored by the Health Care Compliance Association. The complete document is available at www.oig.hhs.gov.

U.S. Department of Health and Human Services

Iran to Develop Nuclear Medicine

The Atomic Energy Organization of Iran (AEOI) announced on September 11 that a special committee had been established to promote the development of nuclear medicine in that country. AEOI Director Gholamreza Aqazadeh told reporters that a 40-megawatt heavy water research reactor is being built in Iran for this purpose and that more than 15 tons of heavy water have been set aside. Aqazadeh's remarks came at a workshop during which the AEOI announced that mass production of ^{99}Mo/^{99m}Tc had already begun to supply Iranian hospitals and medical centers. Dr. Mohammad Ghannadi, chair of the AROI's research center for nuclear science and technology, told reporters that 10,000 patients per week in Iran undergo procedures using ^{99}Mo/^{99m}Tc in 120 medical centers. Ghannadi noted that "Production of this compound at home was important not only in terms of technical progress but also in terms of economic saving."

Atomic Energy Organization of Iran

(Continued from page 21N)

The ABNM expects that societies and accreditation groups will develop PPA modules on professional topics that are preapproved by the ABNM. Generic PPA modules related to patient safety and satisfaction surveys are also being developed. The advantage of these preapproved programs is that diplomates will be assured that these activities meet the requirements of the ABNM.

Henry D. Royal, MD
Executive Director, ABNM