Ngai named Director of NIH BRAIN Initiative

National Institutes of Health (NIH) Director Francis S. Collins, MD, PhD, announced on January 29 the selection of John J. Ngai, PhD, as director of the NIH Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative. Until joining NIH in March, Ngai was the Coates Family Professor of Neuroscience at the University of California, Berkeley.

The NIH BRAIN Initiative is a large-scale effort to accelerate neuroscience. Since its launch in 2013, the initiative has funded hundreds of research projects that have led to breakthroughs, including creation of a self-tuning brain implant that could help treat Parkinson disease, development of a computer program that can mimic natural speech from brain signals, and construction of a brain cell inventory. BRAIN-funded researchers have also shown the ability to make high-speed, high-resolution, 3D films of functional nervous system activity.

"Recent technological and scientific advances are transforming our understanding of the brain," said Ngai. "I am deeply inspired by these advances and look forward to my new role in enabling BRAIN Initiative investigators to unlock the secrets of the brain and lay new foundations for treating human brain disorders." He will oversee the long-term strategy and day-to-day operations of the initiative as it takes on the challenges of the next 5-year plan, announced in fall 2019. Congress has consistently supported BRAIN through the appropriations process and the 21st Century Cures Act.

"Dr. Ngai's appointment marks a new chapter in the BRAIN Initiative," said Walter J. Koroshetz, MD, director of NIH's National Institute of Neurological Disorders and Stroke. "He will provide the initiative and the clear vision the project needs to navigate through this critical period."

National Institutes of Health

IAEA and Dose Projection for Radiologic Emergencies

In a press release issued on February 13, the International Atomic Energy Agency (IAEA) reviewed presentations and discussions for its first research coordination meeting on using dose projection tools in nuclear or radiologic emergencies. Participants in the meeting, held at the IAEA in Vienna, Austria, from January 20 to 24, came from 21 countries and 25 institutes to share their experience and knowledge about using dose projection tools when preparing for and responding to such emergencies. "The goal of this coordinated research project [CRP] is to outline the plans and details, which will be implemented over the next 3 years, to help improve the performance of dose projection tools in the preparedness and response to nuclear or radiological emergencies," said Phillip Vilar Welter, IAEA Emergency Preparedness Officer.

Researchers, technical experts, and observers attended the course organized by the IAEA Incident and Emergency Centre and IAEA Division of Radiation, Transport, and Waste Safety. Attendees represented a broad range of organizations, including national laboratories, public health organizations, and nuclear safety institutions.

IAEA noted the importance of dose projection tools in ensuring effective emergency preparedness and response. In the preparedness phase, tools such as the Real-time On-line Decision Support system (RODOS) or the MELCOR Accident Consequence Code System (MACCS) are used to assess the potential radiologic consequences of an event. These projections can help authorities develop emergency plans that specifically address the expected consequences. For example, these tools can be used to determine the size of emergency planning zones needed for protective actions, prioritize locations for radiation monitoring, estimate the location and type of contamination on the ground, or project the dose received by the public, among many other projections.

The CRP will use findings from these discussions to help IAEA Member States better understand the advantages and limitations of using dose projection tools, including uncertainties associated with modeling and variations in implementation of different models by different sites. At the meeting, experts considered reported experience from the use of dose projection tools and approaches in improving them. Their analysis will inform CRP recommendations to improve the tools' effectiveness in supporting emergency preparedness and response.

International Atomic Energy Agency

WHO Reports on Global Cancer Burden

The World Health Organization (WHO) on February 4 released its International Agency for Research on Cancer World Cancer Report: Cancer Research for Cancer Prevention. In addition to a separate report issued on the same day on current statistics and findings on cancer, this report emphasized the need to enhance cancer services in low- and middle-income countries. WHO warned that, if current trends continue, the world will see a 60% increase in cancer cases over the next 2 decades, with the global cancer burden expected to reach 29 million new cancer cases per year by 2040. The greatest increase (an estimated 81%) in new cases will occur in low- and middleincome countries, where survival rates are currently lowest, with severely limited resources focused on urgent needs in combating infectious diseases and improving maternal and child health. In 2019, more than 90% of high-income countries reported that comprehensive treatment services for cancer were available in the public health system compared to less than 15% of low-income countries.

"This is a wake-up call to all of us to tackle the unacceptable inequalities between cancer services in rich and poor countries," said Ren Minghui, MD, PhD, Assistant Director General, Universal Health Coverage/Communicable and Noncommunicable Diseases, WHO. "If people have access to primary care and referral systems then cancer can be detected early, treated effectively, and cured. Cancer should not be a death sentence for anyone, anywhere."

"At least 7 million lives could be saved over the next decade by identifying the most appropriate science for each country situation, by basing strong cancer responses on universal health coverage, and by mobilizing different stakeholders to work together," said Tedros Adhanom Ghebreyesus, PhD, MSc, Director General, WHO.

The WHO report highlighted a wide range of proven interventions to prevent new cancer cases. These include controlling tobacco use (responsible for 25% of cancer deaths), vaccinating against hepatitis B to prevent liver cancer, eliminating cervical cancer by vaccinating against human papilloma virus, enhancing screening and treatment, implementing high-impact cancer management interventions that bring value for money, and ensuring access to palliative care, including pain relief.

The complete report is available for download at https://shop.iarc.fr/products/world-cancer-report-cancer-research-for-cancer-prevention-pdf.

World Health Organization

Database Documents Loss of Radioactive Material

The International Atomic Energy Agency (IAEA; Vienna, Austria) in 2019 received notifications of nearly 190 incidents of nuclear and other radioactive material being out of regulatory control, including some cases of trafficking and other criminal activities. The data, submitted to the IAEA Incident and Trafficking Database (ITDB) by countries on a voluntary basis, was highlighted in an annual fact sheet published during the February IAEA ministerial conference on strengthening nuclear security and countering the threat of nuclear terrorism. With 140 participating States, the database fosters international cooperation and information sharing among countries. The data are shared with the IAEA, other Member States, and relevant international organizations supporting the retrieval of lost or stolen material and the prosecution of suspected criminals.

"As a unique asset in the IAEA's work to strengthen nuclear security, the ITDB allows us to identify threats and trends so that we can support our Member States in improving the implementation of their nuclear security commitments," said Raja Raja Adnan, Director of the IAEA Division of Nuclear Security.

In 2019, 189 incidents were reported by 36 States, indicating that unauthorized activities and events involving nuclear and other radioactive material, including incidents of trafficking and malicious use, continue to occur. Six of the incidents were related to trafficking or malicious use, continuing a slight downward trend since a peak of 20 such incidents around 2005. For the other 183 incidents, either insufficient information was available to determine any connection with trafficking or malicious use or sufficient information was available to rule out criminal activity.

Since 1993, 3,686 incidents have been reported to the ITDB, of which 290 involved a confirmed or likely act of trafficking or malicious use. Twelve of those incidents included high-enriched uranium and 2 included plutonium. Radioactive sources continue to be reported as stolen or missing, underscoring the need to improve security measures for such sources, especially during transport.

Attendees at the IAEA conference adopted a declaration to enhance global nuclear security, including a specific commitment "to combatting illicit trafficking of nuclear and other radioactive material and to ensure that the material cannot be used by non-State actors for malicious purposes." The related fact sheet is available at: https://www.iaea. org/sites/default/files/20/02/itdb-factsheet-2020.pdf

International Atomic Energy Agency

FDA Electronic Formats for Pharmaceutical Submissions

On February 24 the U.S. Food and Drug Administration (FDA) issued specifications for electronic formats for submissions to the agency. The document, titled Providing Regulatory Submissions in Electronic Format: Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications. Guidance for Industry, describes how sponsors and applicants must organize electronic content submitted to FDA for all submission types under section 745A(a) of the Food, Drug, and Cosmetic Act. The guidance also references several technical specification documents and the Electronic Common Technical Document Conformance (eCTD) Guide, which provide additional details about organization of content. The final document is available at https://www.fda.gov/media/ 135373/download.

FROM THE LITERATURE

Each month the editor of Newsline selects articles on diagnostic, therapeutic, research, and practice issues from a range of international publications. Most selections come from outside the standard canon of nuclear medicine

and radiology journals. These briefs are offered as a monthly window on the broad arena of medical and scientific endeavor in which nuclear medicine now plays an essential role. The lines between diagnosis and therapy are sometimes blurred, as radiolabels are increasingly used as adjuncts to therapy and/or as active agents in therapeutic regimens, and these shifting lines are reflected in the briefs presented here.