Proposed Diagnostic Criteria for Alzheimer's Include PET

An international group of experts have proposed new criteria for the research diagnosis of Alzheimer's disease (AD), maintaining that the existing criteria have been rendered outdated by recent scientific discoveries about the disease, its etiology, and progression. The proposed criteria were outlined in a position paper in *The Lancet Neurology* (2007;6:734–746). The existing criteria, published in 1984 by the National Institute of Neurological Disorders and Stroke–Alzheimer Disease and Related Disorders working group, are reflected in DSM-IV-TR definitions.

Lead author Bruno Dubois, of the Salpêtrière Hospital (Paris, France) and colleagues noted that "These existing criteria are the prevailing diagnostic standards in research; however, they have now fallen behind the unprecedented growth of scientific knowledge. Distinctive and reliable biomarkers of AD are now available through structural MR imaging, molecular neuroimaging with PET, and cerebrospinal fluid analyses."

The authors' framework was developed to capture the earliest stages of disease (before full-blown dementia) as well as the full spectrum of the illness and focus on a clinical core of early and significant episodic memory impairment. The new criteria for a diagnosis of probable AD stipulate that the patient must show progressive memory loss over more than 6 months and have at least 1 abnormal biomarker as shown on structural neuroimaging with MR, molecular neuroimaging with PET, and/or cerebrospinal fluid analysis of amyloid β or τ proteins. The authors noted that "the timeliness of these criteria is highlighted by the many drugs in development that are directed at changing pathogenesis, particularly at the production and clearance of amyloid β as well as at the hyperphosphorylation state of β or τ." They concluded that, "When effective disease-modifying medications are available, the argument for such biologically based studies will be even more compelling. These proposed criteria move away from the traditional 2-step approach of first identifying dementia according to degree of functional disability, and then specifying its cause. Rather, they aim to define the clinical, biochemical, structural, and metabolic presence of AD."

In an accompanying commentary (*Lancet Neurol*. 2007;6:667–669), Norman Foster from the Center for Alzheimer's Care at the University of Utah (Salt Lake City), added: "We should seize this opportunity to reopen the discussion of AD diagnosis. The time is right to use the advanced technology at our disposal to improve the early, accurate diagnosis of dementia and develop more effective treatments."

The Lancet Neurology

FDA Nanotechnology Report

The U.S. Food and Drug Administration (FDA) Nanotechnology Task Force released a report on July 25 that recommends the agency consider developing guidance and taking other steps to address the benefits and risks of drugs and medical devices using nanotechnology. "Nanotechnology holds enormous potential for use in a vast array of products," said FDA Commissioner Andrew von Eschenbach, MD, who endorsed the Task Force Report and its recommendations on July 23. "Recognizing the emerging nature of this technology and its potential for rapid development, this report fosters the continued development of innovative, safe, and effective FDA-regulated products that use nanotechnology materials."

The report addressed regulatory and scientific issues and recommended that the FDA consider development of nanotechnology-associated guidance for manufacturers and researchers. The Task Force reported that the potential exists for nanoscale material applications in most product types regulated by FDA and that these materials present challenges similar to those posed by products using other emerging technologies. The challenges, however, may be complicated by the fact that properties relevant to product safety and effectiveness may change as size varies within the nanoscale. The report also noted that the emerging and uncertain nature of nanotechnology and the potentially rapid development of applications for FDA-regulated products highlight the need for ensuring transparent, consistent, and predictable regulatory pathways. The report recommended consideration of agency guidance that would clarify, for example, what information to give FDA about products and when the use of nanoscale materials may change the regulatory status of particular products. As with other FDA guidance, draft guidance documents would be made available for public comment before being finalized.

In addition, the report recommended that the FDA work to assess data needs to better regulate nanotechnology products, including biological effects and interactions of nanoscale materials. The agency also was advised to develop in-house expertise, ensure consideration of relevant new information on nanotechnology, and evaluate the adequacy of current testing approaches to assess safety, effectiveness and quality of nanoscale materials. The FDA and 22 other federal agencies are part of the National Nanotechnology Initiative, a federal research and development program established to coordinate multiagency efforts in nanoscale

science, engineering, and technology. The report is available at: www.fda.gov/nanotechnology/taskforce/report2007.html.

U.S. Food and Drug Administration

Orbach Named as DOE Technology Transfer Coordinator

On June 29, U.S. Secretary of Energy Samuel W. Bodman named Under Secretary for Science, Raymond Orbach, PhD, as Technology Transfer Coordinator, a new position that will oversee efforts to transfer energy technologies from Department of Energy (DOE) National Laboratories and facilities to the global marketplace. Bodman also established a Technology Transfer Policy Board, chaired by the Under Secretary for Science, to assist in coordinating and implementing policies for DOE technology transfer activities. The coordinator and the policy board will undertake a comprehensive review of DOE technology transfer policies, with the goal of deploying energy technologies to the marketplace at an accelerated rate. "The Under Secretary for Science is uniquely positioned to expand and enhance the Department's coordination of world-class scientific research to further the deployment of technologies that are ripe for commercialization," said Secretary Bodman.

To establish a framework for continuity and uniformity of technology transfer activities throughout the DOE complex, the Policy Board will include DOE officials from relevant offices and will meet to review the technology transfer activities of the DOE National Laboratories and other DOE facilities. The Policy Board will advise Orbach on funding for technology transfer activities, efforts to engage the private sector, and review of contract and other legal mechanisms governing access to DOE facilities by state and local governments, universities, and industry. The coordinator and policy board will develop a technology transfer execution plan and will establish and oversee the activities of the Technology Transfer Working Group, which will include representatives from DOE National Laboratories and other DOE facilities authorized to conduct technology transfer activities.

U.S. Department of Energy

New Resource for Technology Commercialization

The National Institutes of Health (NIH) on July 11 launched a Web-based resource called NIH Pipeline to Partnerships (P2P), aimed at advancing the development of NIH's licensed technologies and technologies funded through the NIH Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs. This initiative, developed jointly between the NIH Office of Technology Transfer (OTT) and the NIH SBIR and STTR Program Office, provides a virtual space where NIH licensees and NIH SBIR/STTR awardees can showcase their technologies and product development for an audience of potential strategic partners, investors, and licensees.

"In the last decade, many successful biomedical products have come from pharmaceutical and biotechnology companies that licensed early-stage technologies from NIH," said Mark Rohrbaugh, PhD, JD, Director of the NIH OTT. "Faced with less demand for early-stage technologies, this pipeline provides an avenue for potential partners to find NIH licensees along the spectrum of product development to share costs, infrastructure, and expertise as the research and development progresses to later-stage clinical trials."

The P2P initiative can also help NIH SBIR/STTR awardees who face similar challenges in moving their innovations along the development pipeline. "These small companies simply can't go it alone," said Jo Anne Goodnight, Coordinator of the NIH SBIR/STTR programs. "Given the expensive preclinical and clinical studies necessary to bring novel products to the market and the patient, many of these projects need additional financing, licensing deals, or strategic partnerships. We see the P2P database as an important resource to help small businesses make a successful leap from discovery to commercialization of products resulting from innovative biomedical and behavioral research."

A pipeline of technologies available for partnering is now available on the OTT Web site at www.ott.nih.gov/P2P as an index searchable by category of technology and stage of development. Once a technology of interest is identified, the interested party is directed to the licensee/awardee developing the technology. All submissions to the site by the licensees and grantees will be voluntary. Although NIH will approve all postings, NIH will not be involved directly in the partnering activities. Additional information is available at www.nih.gov/icd/od/.

National Institutes of Health

Cancer Health Disparities Summit 2007

The annual National Institutes of Health (NIH) Cancer Health Disparities Summit was held July 16–18 in Bethesda, MD, and brought together U.S. researchers in the field of cancer health disparities under the theme of "Catalyzing Transdisciplinary Regional Partnerships to Eliminate Cancer Health Disparities." NIH grantees, health professionals, and community advocates from across the country gathered to discuss their research, successful program strategies, challenges, and accomplishments. This year's program was cosponsored by the National Cancer Institute, the National Center for Research Resources, and the National Center on Minority Health and Health Disparities. The summit program highlighted grantee activities in 4 geographical regions and focused on collaborations and partnerships, communications and bioinformatics, community engagement, managing and sustaining programs, and training and education. A full report based on the proceedings of the summit will be released later this year.

National Institutes of Health

National Minority Institution Research Network

The National Center for Research Resources (NCRR), a part of the National Institutes of Health, announced on July 24 that it will initially provide $9.5 million over 3 years to launch a Translational Research Network designed to increase opportunities for multisite clinical and translational research among minority and other collaborating institutions throughout the United States. Investigators at these institutions are focused on diseases that disproportionately affect minority populations. Translational research conducted in the network will range from studies focused on applying discoveries generated during research in the laboratory to clinical trials, and then to developing and implementing best practices in disease prevention and intervention in local community settings. By providing computer-based tools for analyzing and managing clinical research data, recruiting for clinical trials, and sharing information with patients, the network will enable clinical and translational researchers to collaborate more efficiently with each other and their communities.

The principal investigator leading the network is Keith Norris, MD, an expert in kidney disease at Charles Drew University (Los Angeles, CA). Other participating institutions include Morehouse School of Medicine (Atlanta, GA), the University of Hawaii (Honolulu), Hunter College (New York, NY), the University of Puerto Rico (San Juan), Meharry Medical College (Nashville, TN), Howard University (Washington, DC), and Jackson State University (MS). The Data Technology and Coordinating Center for the network will be located at Jackson State University. The center will provide a secure Web site, data management and data sharing tools, staff, hardware, and software for collection, analysis, storage, and exchange of clinical data for the multisite studies. Institutions participating in the network are part of the Research Centers in Minority Institutions Program (RCMI). Funded by NCRR since 1985, the RCMI program enhances the research capacity and infrastructure at minority colleges and universities that award doctorates in the health sciences.

The National Center for Research Resources

New International Health Regulations in Force

U.S. Department of Health and Human Services (HHS) Secretary Mike Leavitt announced on July 18 that revised International Health Regulations (IHR) were now in force in the United States. The updated rules are designed to prevent and protect against the international spread of diseases, as well as emerging bioterror threats, while minimizing interference with world travel and trade. Participating countries will work together to identify, respond to, and share information about public health emergencies of international concern. The U.S. government formally accepted the IHR in December 2006 and began the process of implementing these new international rules. "Today's world of rapid air travel, international migration, emerging diseases, threats of terrorism, and the potential threat of an influenza pandemic, underscores the importance of the IHR," Leavitt said. "The improved global cooperation that will come from implementing these revised regulations represents a major step forward for global public health."

The IHR constitute an international legal instrument that governs the roles of the World Health Organization (WHO) and its member countries in relation to disease outbreaks and other public health events. They establish a framework for countries that are party to the regulations to promptly and transparently report on and respond effectively to health events that present a risk of spread to other countries and potentially require coordinated international response. Many of the provisions in the new regulations are based on the experience of the global community over the past 30 years, including experience with the emergence of severe acute respiratory syndrome (SARS) and H5N1 avian influenza.

The previous version of the IHR, adopted in 1969, applied to only 4 diseases: cholera, yellow fever, smallpox, and plague. However, increases in international travel and trade, along with marked developments in communication technology, have led to new challenges in the control of emerging and re-emerging infectious diseases. In addition, new challenges are posed by the threat of natural, accidental, or deliberate release of chemical, biologic, or radiologic materials. Under these regulations, countries that have accepted the IHR have a much broader responsibility to take preventive measures against, as well as detect, report on, and respond to public health emergencies. The regulations give the WHO clearer authority to recommend to its member countries measures that will help contain the international spread of disease, including public health actions at ports, airports, land borders, and on means of transport that involve international travel.

The revised regulations include a list of 4 diseases—smallpox, polio, SARS, and cases of new strains of human influenza—that member countries must immediately report to the WHO. The regulations provide an algorithm to determine whether other incidents, including those of unknown causes or sources, may constitute public health events of international concern and as such must be reported to the WHO. The rules also provide specific procedures and timelines for assessing, reporting, and responding to public health events. To meet the requirements of the IHR, the U.S. government will rely on state and local reporting networks to relay information about public health events of concern. In addition, actions taken by state and local governments to respond to public health events within their jurisdictions will facilitate U.S. fulfillment of the objectives of the IHR. More information about the IHR is available at www.globalhealth.gov/ihr.

U.S. Department of Health and Human Services

Funds for Hospital Public Health Emergency Preparedness

U.S. Department of Health and Human Services (HHS) Secretary Mike Leavitt announced on June 28 a total of $430 million in awards to states, territories, and 4 major metropolitan areas to strengthen the ability of hospitals and other health care facilities to respond to bioterror attacks (including radiation threats), infectious diseases, and natural disasters that may cause mass casualties. "These grants are an important addition to national security, because our hospitals and other health care facilities play such a critical role in responding to a terrorist attack, an infectious disease outbreak, and natural disasters," Leavitt said. Health departments in the states, territories, and New York, NY; Chicago, IL; Los Angeles County, CA; and Washington, DC, received the funds and will use them to strengthen medical "surge" capabilities. Recipients will use the funds to develop or improve interoperable communications, systems to track available hospital beds, advance registration of volunteer health professionals, and planning for both fatality management and hospital evacuations. Congress transferred oversight of the grant program from the Health Resources and Services Administration to the new HHS Office of the Assistant Secretary for Preparedness and Response with passage of the Pandemic and All Hazards Preparedness Act of 2006.

Also new this year is the $15 million Healthcare Facilities Partnership Program, competitive grants or cooperative agreements to eligible health care partnerships to enhance community and hospital preparedness for public health emergencies. The $15 million will be awarded through a competitive process resulting in 6–30 cooperative agreement awards for regional partnerships that may range from $500,000 to $2.5 million. "The goal of the new program is to develop innovative and creative projects that can be replicated across the country," said HHS Assistant Secretary for Preparedness and Response Craig Vanderwagen, MD. "These partnerships will require close coordination among health officials from state, local, and private sectors."

U.S. Department of Health and Human Services

Proposed CMS Clinical Research Policy

The Centers for Medicare & Medicaid Services (CMS) announced on July 19 the reopening of its clinical trial policy national coverage determination and released a proposed decision memorandum for public comment. The public comment period closed on August 18, and it is anticipated that a final decision will be released by October 19. CMS published its final Clinical Trial Policy Decision Memorandum on July 9, 2007, with 2 changes to its previous policy: the addition of Coverage with Evidence Development and clarification of the situation when an item under investigation is considered a routine cost and therefore coverable by Medicare (if it would have been covered outside the trial). The proposed determination builds on input received while CMS was developing the policy. It clarifies the standards that CMS believes to be important in patient safety and good outcomes and allows study sponsors or principal investigators to certify that their studies have met these standards. "This proposed decision will address ambiguities about Medicare coverage in research studies and what items and services are reasonable and necessary for beneficiaries participating in clinical research studies," said CMS Acting Administrator Leslie V. Norwalk. Details of the proposed coverage policy are available at the CMS coverage Web site at www.cms.hhs.gov/mcd/viewdraftdecisionmemo.asp?id=210.

Centers for Medicare & Medicaid Services

Annual MEIR Scientific Update

Leading experts on worldwide nuclear and radiological response, radiobiology, and medical effects of exposure to ionizing radiation presented current findings during a course offered from July 30 through August 3 at the Uniformed Services University of the Health Sciences (USU) Armed Forces Radiobiology Research Institute (AFRRI) in Bethesda, MD. The presentations were part of the annual Medical Effects of Ionizing Radiation Course (MEIR) Scientific Update. The postgraduate-level meeting, with continuing education credits, was attended by military personnel, health care providers, senior disaster preparedness personnel, and operational planners. The event included a tour of the unique radiation facilities at AFRRI; a presentation by Albert Wiley, MD, director of the Radiation Emergency Assistance Center and Training Site (REAC/TS), on radiation accidents and triage; and a presentation by Evan Douple, PhD, scholar at the National Academies, on the late effects of exposure to ionizing radiation.

Presentations and other educational offerings in the course covered the biomedical consequences of radiation exposure, measures to reduce these effects, and medical management of radiation casualties.

AFRRI, a component of USU, conducts research in the field of radiobiology and related matters essential to the operational and medical support of the U.S. Department of Defense and the military services. AFRRI provides services and performs cooperative research with other federal and civilian agencies and institutions and responds to radiological crises and conducts consequence management missions. More information about the MEIR Course is available at www.afrri.usuhs.mil/www/outreach/meir/meir.htm.

Uniformed Services University of the Health Sciences