## *NYT* Opinion Piece on Medical Overimaging

In an article titled "We Are Giving Ourselves Cancer," published in the opinion pages of *The New York Times* on January 30, authors Rita F. Redberg, MD, MSc, and Rebecca Smith-Bindman, MD, offered their viewpoint that in the United States "we are silently irradiating ourselves to death" through the overuse of advanced medical imaging. Redberg is a professor of medicine in the Division of Cardiology at the University of California, San Francisco (UCSF). Smith-Bindman is a professor in residence of radiology, epidemiology and biostatistics, obstetrics, and gynecology and reproductive medicine at UCSF. The article received almost 250 online comments, many of which criticized the "scare tactics" used in describing the dangers of CT overuse as well as the authors' contention that many emergency department physicians fail to consider each patient's true needs before ordering imaging studies. Several respondents took issue with the authors' statement that "according to our calculations, unless we change our current practices, 3 percent to 5 percent of all future cancers may result from exposure to medical imaging."

On February 11, Frederic Grannis, Jr., MD, clinical professor of thoracic surgery and immediate past president of the medical staff of City of Hope National Medical Center (Duarte, CA), published an editorial response to Redberg and Smith-Bindman in the online news resource AuntMinnie.com. Noting that the article "sensationalized the risks of medical radiation and demonstrated a poor understanding of what's definitively known about the risks of radiation at the very low doses used in medical imaging," Grannis focused his criticisms on the lack of randomized, controlled trials to provide definitive evidence about the risk of future cancer from CT imaging. He noted that most projections about future cancer rates resulting from medical radiation are based on the linear–no threshold theory and, with no direct study evidence, extrapolate conclusions about low serial doses of radiation from available studies of individuals who have experienced very high single radiation exposures.

*The New York Times*
*AuntMinnie.com*

## FDA and EMA Collaborate on Pharmacovigilance

The U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) announced on February 18 the establishment of a new "cluster" on pharmacovigilance (medicine safety) topics. Clusters are regular collaborative meetings between the EMA and regulators outside of the European Union, which focus on specific topic areas that have been identified as requiring an intensified exchange of information and collaboration. Building on the experience of previous regular videoconferences between the FDA and the EMA in this area and on the recent creation of the EMA Pharmacovigilance Risk Assessment Committee, this cluster will provide a forum for a more systematic and focused exchange of information on the safety of medicines.

The FDA and the EMA have already set up such clusters to discuss issues related to biosimilars, medicines to treat cancer, orphan medicines, medicines for children, blood-based products, and other topics. Health Canada and the Japanese Pharmaceuticals and Medical Devices Agency are also involved in some of these discussions and will participate as observers in this cluster. "The work of protecting the health and safety of the American people cannot be done in isolation," said Janet Woodcock, MD, director of the FDA Center for Drug Evaluation and Research. "It is part of a larger collaborative global effort between the FDA and its international regulatory partners to ensure the health and safety of all our citizens."

As part of the new cluster, discussions on shared pharmacovigilance issues will take place by teleconference between the agencies on a monthly basis. This increased degree of interaction will allow the agencies to work swiftly in the area of medicine safety and to coordinate communication activities. "In an increasingly globalized pharmaceutical market, collaboration between medicines' regulators is essential," explained Guido Rasi, MD, EMA executive director. "Medicines' regulators are interdependent: any action taken in one territory has repercussions on the rest of the world. International cooperation is a key area of work for the agency."

*U.S. Food and Drug Administration*

## PET and Dream Recall

In an article e-published on January 16 ahead of print in *Neuropsychopharmacology*, Eichenlaub et al. from the Center Hospitalier Le Vinatier and CERMEP–Imagerie du Vivant (both in Lyon, France) reported on a study assessing the relevance of the "forebrain dream-on hypothesis," which is based on neuropsychological studies that have shown that lesions in the temporoparietal junction and/or the white matter of the medial prefrontal cortex lead to global cessation of dream reports, suggesting that these regions of the default mode network have key roles in the dreaming process. The researchers used $^{15}O$-$H_2O$ PET to measure regional cerebral blood flow in 41 healthy individuals with records of high and low dream recall frequency ($5.2 \pm 1.4$ and $0.5 \pm 0.3$ dreams recalled per week, respectively) during wakefulness (rest) and sleep (rapid eye movement sleep [REM] and stage N2 and N3 sleep). High recallers were found to have higher regional cerebral blood flow in the temporoparietal junction during REM sleep, N3, and wakefulness and in the medial prefrontal cortex during

REM sleep and wakefulness. The resting states of high and low recallers differed during sleep and wakefulness, and these states correlated with specific functional organization of the brain. The authors concluded that these results "support the forebrain 'dream-on' hypothesis and suggest that the temporoparietal junction and medial prefrontal cortex are not only involved in dream recall during wakefulness but also have a role in dreaming during sleep (production and/or encoding)."

The article received significant media attention in the United States and Europe. On February 24, *The Washington Post* reviewed the results and focused on relevance to the ability to recall dreams. Reporter Meeri Kim described the "arousal–retrieval" phenomenon previously reported by the same authors, in which it was speculated that enhanced temporoparietal junction activity may make sleepers more sensitive to environmental noises and cause them to awaken more frequently, a process that may allow "encoding" of dream memories for later recall.

*Neuropsychopharmacology*

## HHS and Patient Access to Lab Results

The U.S. Department of Health and Human Services (HHS) announced on February 3 a final rule amending the Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations to allow laboratories to give a patient or designated representative on-request access to completed test reports. "The right to access personal health information is a cornerstone of the Health Insurance Portability and Accountability Act [HIPAA] Privacy Rule," said HHS Secretary Kathleen Sebelius. "Information like lab results can empower patients to track their health progress, make decisions with their health care professionals, and adhere to important treatment plans."

The final rule eliminated the exception under the HIPAA Privacy Rule that limited an individual's right to access his or her protected health information held by a CLIA-certified or CLIA-exempt laboratory. Although patients can continue to access their laboratory test reports from their physicians, these changes give patients a new option to obtain test reports directly from the laboratory while maintaining strong protections for information privacy.

The final rule was issued jointly by 3 agencies within HHS: the Centers for Medicare & Medicaid Services, which are generally responsible for laboratory regulation under CLIA; the Centers for Disease Control and Prevention, which provide scientific and technical advice; and the Office for Civil Rights, which is responsible for enforcing the HIPAA Privacy Rule. Under the HIPAA Privacy Rule, patients, patient's designees, and patient's personal representatives can see or be given a copy of protected health information, including an electronic copy, with limited exceptions. In doing so, the patient or personal representative may have to put requests in writing and pay for the cost of copying, mailing, or electronic media on which the information is provided, such as a CD or flash drive. In most cases, copies must be given to the patient within 30 d of such a request.

*U.S. Department of Health and Human Services*

## DOE and NIH to Fund Nuclear Medicine Research

On Thursday, February 6, the U.S. Department of Energy (DOE) Office of Science Office of Biological and Environmental Research and the National Institutes of Health (NIH) National Institute of Biomedical Imaging and Bioengineering released a large-scale funding opportunity announcement for "Targeted Radiochemistry and Associated Technology Development for Integrated Nuclear Medicine Research and Training with Human Application." Projects solicited for this announcement would fulfill 2 goals: (1) to develop clinically relevant radionuclide imaging biomarkers to individualize and optimize medical care through new, improved diagnostic and theranostic approaches; and (2) to enhance training opportunities of young scientists and clinicians in translational nuclear medicine. The announcement indicated that multiple awards would be available with funding of approximately $1 million each. The publication of this opportunity came with what is known in research funding as a short "string": preapplications were due on March 7, invitations for full application were scheduled for March 14, and completed applications are due on April 18.

In outlining the intent of the projected funding, DOE/NIH noted that currently few combined radiochemistry and imaging programs can meet the challenges of developing and evaluating radiotracers and following through to beneficial clinical applications. To meet these challenges, "translational programs are needed to focus the efforts of basic and clinical scientists with the goal of developing and validating molecular imaging probes and methodologies that can provide meaningful improvements to patient care and treatment outcomes." As a result, the funding targets both science and scientific training. Among the areas of research need cited in the announcement were: (1) identifying clinically relevant targets for the application of imaging techniques; (2) developing and applying better predictive tools; (3) efforts to enhance and identify molecular targets (including imaging gene expression in real time in living biological systems; proteins critical to epigenetic modifications; in vivo metabolomics; in vivo imaging of neurotransmitter chemistry and brain function for novel molecular targets in neurologic and psychiatric diseases; in vivo imaging targeted at understanding metabolic diseases, such as diabetes and obesity, and their complications; and in vivo imaging of diseases with discrete inflammatory components); (4) identifying and validating clinically relevant biomarkers for fluorine and radiometals; and (5) exploring applications of molecular radiotheranostics.

*U.S. Department of Energy*
*National Institutes of Health*

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