Ionizing Radiation Classed as Official Carcinogen

The U.S. Department of Health and Human Services (HHS) released the 11th edition of the *Report on Carcinogens* on January 31, adding ionizing radiation and several viruses to a growing list of cancer-causing agents, bringing the total to 246. The report, referred to as the *RoC*, lists cancer-causing agents in 2 categories: "known to be human carcinogens" (58) and "reasonably anticipated to be human carcinogens" (188). Federal law requires HHS to update the report every 2 years.

X-radiation and gamma-radiation are listed in the report as "known human carcinogens," because "human studies show that exposure to these kinds of radiation causes many types of cancer including leukemia and cancers of the thyroid, breast, and lung." The report summarizes the risk from exposure:

> The risk of developing cancers due to these forms of ionizing radiation depends to some extent on age at the time of exposure. Childhood exposure is linked to an increased risk for leukemia and thyroid cancer. Exposure during reproductive years increases the risk for breast cancer, and exposure later in life increases risk for lung cancer. Exposure to X-radiation and gamma radiation has also been shown to cause cancer of the salivary glands, stomach, colon, bladder, ovaries, central nervous system and skin.

Of the total worldwide exposure to X-radiation and gamma-radiation, 55% is from low-dose medical diagnosis such as bone, chest, and dental X-rays, and 43% is from natural sources like radon. Other sources, such as industry, scientific research, military weapons testing, nuclear accidents, and nuclear power generation, account for about 2%.

Neutrons are also listed in the report as a "known human carcinogen."

The announcement received wide coverage in the press, leading to some speculation about the generation of unwarranted fears about routine imaging and therapeutic procedures. In a press release issued on February 3, the SNM advised the public that "the benefits patients receive from appropriately indicated, appropriately performed diagnostic imaging greatly outweigh potential risks stemming from the radiation exposure." SNM Past President Henry D. Royal, MD, said, "SNM remains concerned about patients' safety and works to prevent unnecessary radiation exposure of patients through the development of procedure guidelines designed to optimize the diagnostic information obtained from nuclear medicine tests."

The *RoC* is prepared by the National Toxicology Program, an interagency group coordinated by HHS. The full report is available at: http://ntp.niehs.nih.gov.

Department of Health and Human Services

^{99m}Tc Vials Tied to Hepatitis C Outbreak

After a patient died on December 25 in Baltimore, MD, of complications from hepatitis C acquired from tainted ^{99m}Tc administered for stress testing, state officials stepped up their inquiries into a cluster of related infections. The implicated radiopharmaceutical batch was shipped from a Cardinal Health facility in Timonium, MD. Twelve people were infected with the disease from tests administered on October 15, according to Gordon Troup, president of Cardinal Health Nuclear Pharmacy Services. No more than 16 patients were injected with the infected material, he said, and only 1 had died. "Our thoughts and condolences go out to the family of that individual, and we're going to continue to support the investigation to quickly resolve and find out the cause of the infection," said Jim Mazolla, a Cardinal Health spokesman.

In an Internet statement released on January 13, Cardinal Health reported that it had voluntarily closed the Timonium pharmacy on December 6, immediately after learning the facility might be involved and that the Maryland Board of Pharmacy had also formally suspended operations there. The state's investigation is currently focusing on cross-contamination from a blood sample to the vial of ^{99m}Tc. Both the state and Cardinal Health have emphasized that this is regarded as a unique event rather than an ongoing public health risk.

Maryland Board of Pharmacy
Cardinal Health, Inc.

NIH Asks for Early Release of Scientific Articles

The National Institutes of Health (NIH) announced on February 3 a new policy designed to accelerate the public's access to published journal articles resulting from NIH-funded research. The policy, which is set to go into effect on May 2, calls on scientists to release to the public manuscripts from research supported by NIH as soon as possible and within 12 months of final publication. These peer-reviewed publications will be available in a Web-based archive to be managed by the NIH National Library of Medicine (NLM). "With the rapid growth in the public's use of the Internet, NIH must take a leadership role in making available to the public the research that we support," said NIH Director Elias A. Zerhouni, MD.

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The announcement came after months of debate and sometimes acrimonious exchanges between NIH and the publishers of peer-reviewed scientific journals. The much anticipated formal policy is less stringent than anticipated, but left observers on both sides of the issue with questions about whether and how the new requirements will be encouraged and enforced. Proponents of "open access" to articles based on NIH-funded research had expected mandatory submission to the database and a 6-month deadline. Journal publishers and many of the professional societies that depend on journal revenues had lobbied against open access, arguing that such a requirement could cut subscriptions, produce reports of questionable quality, and ultimately work against the overall status and growth of scientific literature. They also maintained that the proposed NLM database would be wasteful and duplicate material already available in electronic archives.

In the days following the announcement, neither side seemed to know exactly how scientific authors should respond or what each journal's responsibility would be in notifying authors of this new policy. Beginning May 2, the policy requests that NIH-funded scientists submit an electronic version of final manuscripts upon acceptance for publication. The author's final manuscript is defined as the "final version accepted for journal publication" and includes all modifications from the publishing peer-review process. At submission, the author will be asked to select a specific time frame for public release—ranging from immediate public access after final publication to a 12-month delay. Articles will be available on PubMed Central (www.pubmedcentral.nih.gov), a part of the NLM digital repository of full-text biomedical, behavioral, and clinical research journals.

"While this new policy is voluntary, we are strongly encouraging all NIH-supported researchers to release their published manuscripts as soon as possible for the benefit of the public. Scientists have a right to see the results of their work disseminated as quickly and broadly as possible, and NIH is committed to helping our scientists exercise this right. We urge publishers to work closely with authors in implementing this policy. . .NIH recognizes the importance of preserving quality peer review and the viability of a diversity of publishing models. Nevertheless, we expect that only in limited cases will authors deem it necessary to select the longest delay period."

Heinrich Schelbert, MD, PhD, editor-in-chief of *The Journal of Nuclear Medicine,* said, "JNM's editorial board recognizes the importance of the wide dissemination of significant scientific information such as that regularly published in our journal. Like many other medical and science publishers, we continue to investigate ways to do this that ensure both the continued reliability and quality of published materials and the long-term future and growth of the journal itself."

Details of the new policy can be seen at: www.nih.gov/about/publicaccess/publicaccess_imp.pdf.

National Institutes of Health

Stringent NIH Ethics Reform Announced

The National Institutes of Health (NIH) announced on January 1 a new supplemental ethics regulation that addressed concerns raised about employees who perform outside consulting with pharmaceutical and biotechnology industries and went a step further to impose strict guidelines and new restrictions on the private financial dealings of employees and their families as well as on awards that employees may accept. The regulation was developed by the Department of Health and Human Services (HHS), with the concurrence of the Office of Government Ethics, the federal agency that prescribes executive branch-wide ethics standards.

"Nothing is more important to me than preserving the trust of the public in NIH. It is unfortunate that the activities of a few employees have tainted the stellar reputation of the many thousands of NIH scientists who have never compromised their integrity and have selflessly served the nation with great distinction through their discoveries. I am confident that these new rules will prevent the recurrence of past abuses and will go a long way in preserving the historic role of NIH as the primary source of unbiased scientific health information for the country," said NIH Director Elias A. Zerhouni, MD.

Under the new rules, all NIH employees are prohibited from engaging in certain outside employment with: (1) substantially affected organizations, including pharmaceutical and biotechnology companies; (2) supported research institutions, including NIH grantees; (3) health care providers and insurers; and (4) related trade, professional, or similar associations. Investments in organizations substantially affected by the NIH, such as the biotechnology and pharmaceutical industries, are also not allowed for those employees who are required to file public and confidential financial disclosure reports and are restricted for other staff.

At a town hall-style meeting on February 2, Zerhouni faced a hostile audience in which representatives of the agency's 18,000 employees expressed their distress over the new rules. Several speakers questioned the reasons for singling out NIH employees among federal employees and among others in the health care fields. "If we really want to reassure the public," asked one speaker, "why don't we apply these to everyone who gets an NIH grant?"

The rules will go into effect in 90 days. Over the next year, HHS will evaluate the effects of this regulation. NIH scientists will continue to be able to conduct academic activities, such as teaching courses at universities, writing general textbooks, per-

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forming scientific journal reviews, participating in scientific meetings, and providing general lectures to physicians and scientists at continuing professional education and similar events, as well as practicing medicine as appropriate, provided that the activities are otherwise in accordance with existing regulations and adhere strictly to the conditions specified in the new rules.

For additional information see www.nih.gov/about/ethics_COI.htm.

National Institutes of Health

HHS Releases Report on Medical Innovation

On January 13, Department of Health and Human Services (HHS) Secretary Tommy G. Thompson announced steps the agency plans to take "to advance medical innovations and move products more quickly from the lab bench to the bedside." The recommendations were outlined in *Moving Medical Innovations Forward: New Initiatives from HHS*. The report suggests ways to eliminate barriers so that "safe, effective medical technologies will be more readily available to Americans who could benefit from them." The task force that prepared the report examined internal procedures at agencies across the department, including the Centers for Disease Control and Prevention, the Centers for Medicare & Medicaid Services (CMS), the Food and Drug Administration (FDA), and the National Institutes of Health.

The report recommended that HHS should:

- Enter into new or expanded Memoranda of Understanding to improve cooperation with other federal agencies that play an important role in medical technology development.
- Streamline its involvement in medical technology by creating a forum, based on the Interagency Council on Biomedical Imaging in Oncology model from the National Cancer Institute, to serve as a sounding board for investigators and manufacturers to communicate with HHS agencies.
- Support the ongoing development of standard formats for electronic clinical trial data.
- Improve collaboration between CMS and FDA.
- Support new interagency scientific education and cross-training efforts to identify knowledge gaps among those serving in technology transfer functions in HHS.

The report is available at http://www.hhs.gov/reference/medicalinnovations.shtml.

Department of Health and Human Services

Health Care Spending Slows

According to a report in the January/February issue of *Health Affairs*, the rate of health care spending growth slowed in 2003, marking the first such drop in 7 years. In making the report, the Office of the Actuary of the the Centers for Medicare & Medicaid Services was careful to note the distinction between spending being reduced and a reduction in the rate of increase. Health expenditures in the United States grew 7.7% in 2003 to $1.7 trillion, down from a 9.3% growth rate in the previous year. On a per capita basis, health spending increased from $5,317 to $5,670. Despite the slowed growth rate, health spending accounted for 15.3% of the gross domestic product in 2003 and outpaced the growth rate of the overall economy by 3%.

Private payers (private health insurance and payments by individuals for copays, deductibles, and services not covered by insurance) funded more than half of national health expenditures ($913.2 billion). The public sector funded $766 billion (Medicaid program, $267 billion; Medicare, $283 billion).

Detailed national health spending estimates are available at www.cms.hhs.gov/statistics/nhe/default.asp.

Centers for Medicare & Medicaid Services

NIBIB Strategic Plan

The National Institute of Biomedical Imaging and Bioengineering (NIBIB) has developed a draft 5-year strategic plan, including goals, strategies, and objectives designed to maximize the institute's impact on human health. When finalized, the plan will provide the framework and action plan for the institute's direction over the coming years and will help determine how the NIBIB will allocate resources to support and enhance scientific research and research training. The complete draft plan can be viewed at: www.nibib.nih.gov.

National Institute of Biomedical Imaging and Bioengineering

Commerce and Brain Imaging

In an article in the online magazine *Slate*, posted on January 25, author David Dobbs posed a series of interesting questions about the future of nonmedical applications in brain-imaging technology, including PET and functional MRI. He surveyed the routine applications of these modalities and then noted: "Perhaps the most intriguing progress, most of which has come in the past 5 years, has been researchers' increasing ability to identify patterns distinctive to many of our more complex mental processes." The article went on to survey a number of proposed uses of functional imaging, including as lie detection and for screening job and school applicants. He also reported on the activities of groups such as those at the University of Pennsylvania's Center for Cognitive Neuroscience and the Stanford Center for Biomedical Ethics, who are working to predict and respond to the ethical issues such applications will raise.

Members of the nuclear medical community will be interested in reading Dobbs' description of the emerging neuromarketing industy, in which at least 1 marketing research firm is scanning volunteers to learn more about how the brain reacts to specific stimuli and advertising strategies. The complete article is available at: www.slate.com/id/2112653.

Slate