California Radiation Law

On September 30, California Governor Arnold Schwarzenegger signed into law SB 1237, the first state regulation designed to protect patients from excessive radiation exposure in CT scans and in some radiation therapy treatments. The legislation was introduced in February by State Senator Alex Padilla after the discovery of a number of radiation overdoses during brain profusion CT imaging at Cedars–Sinai Medical Center (Los Angeles) and other excessive radiation exposures at other facilities. The bill will become effective in 2012.

In general, the bill will require hospitals and other facilities to document radiation exposure on each CT scan and to report overdoses to both patients and their referring physicians. The more detailed requirements of the bill and the ways in which these will be met in practice are topics of discussion among California practitioners and those outside the state. The delay of implementation until 2012 will provide an opportunity to resolve questions that now focus on compliance and reporting. Robert Achermann, executive director of the Sacramento-based California Radiological Society, told an AuntMinnie.com reporter that "Delayed implementation is going to allow the radiology community, the legislators, the regulatory agents, and the FDA to continue to explore the issues and look for the best solutions." He added, "I'm sure this will not be a static issue in terms of what are the best ways to reduce exposure. That's what cleanup legislation is for." Specifics now in the bill in addition to reporting of overdoses include recording of the CT dose on each scan, accreditation compliant with federal standards for all facilities that conduct CT scans beginning in 2013, and annual calibration and verification of all CT equipment. The text of the bill is available at: http://info.sen.ca.gov/cgi-bin/pagequery?type=sen_bilinfo&site=sen&title=Bill+Information by typing 1237 in the search engine.

AuntMinnie.com
California State Senate

FDA Final Rule on Clinical Trial Safety Info

The U.S. Food and Drug Administration (FDA) on September 28 issued a final rule designed to clarify what safety information must be reported during clinical trials of investigational drugs and biologics. "This final rule will expedite FDA's review of critical safety information and help the agency monitor the safety of investigational drugs and biologics," said Rachel Behrman, MD, associate director for medical policy in the FDA's Center for Drug Evaluation and Research. "These changes will better protect people who are enrolled in clinical trials."

The new rule requires that certain safety information that previously had not been required to be reported to the FDA be reported within 15 d of awareness of an occurrence. These reports include: findings from clinical or epidemiologic studies that suggest a significant risk to study participants; serious suspected adverse reactions that occur at a rate higher than expected; and/or serious adverse events from bioavailability and bioequivalence studies. The rule also provides examples of evidence that would suggest that an investigational product may be the cause of a safety problem. Under current regulations, drug sponsors often report all serious adverse events, even if there is little reason to believe the product caused the event. Such reporting complicates and delays the FDA's ability to detect a safety signal. The examples address when a single event should be reported or when it is appropriate to wait for more than a single occurrence.

The rule is also designed to harmonize definitions and reporting standards so that they are more consistent with those of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use and the World Health Organization's Council for International Organizations of Medical Sciences. The changes are designed to help ensure more standardized reporting of globally conducted clinical trials. Along with this final rule, the FDA also issued draft guidance for industry and investigators that provides information and advice about the new requirements.

U.S. Food and Drug Administration

UK-Wide PET Clinical Trials Network

In an article e-published on September 2 ahead of print in *Annals of Oncology*, Barrington et al. from Kings College London (UK) reported on the establishment of a national PET clinical trials network in the United Kingdom and the setup of a core laboratory to coordinate quality control and to interpret submitted scans. The network is currently focusing on trials in Hodgkin lymphoma and diffuse large B-cell lymphoma. The report detailed the qualification and standardization procedures required for scanner validation at each of 15 participating sites and the development of quality control protocols. The researchers were successful in achieving consistency and similar performance from all scanners, allowing central and standardized readouts at the core facility. The authors concluded that, going forward in this and other groups of trials, results "will be significantly strengthened by this system."

Annals of Oncology

NRC Seeks ACMUI Patients' Rights Advocate

The Nuclear Regulatory Commission (NRC) is requesting nominations for the position of patients' rights advocate on the Advisory Committee on the Medical Uses of Isotopes (ACMUI). Committee members currently serve 4-y terms and may be considered for reappointment to an additional term. The ACMUI advises NRC on policy and technical issues that arise in the regulation of the medical use of radioactive materials. Responsibilities include providing comments on changes to NRC rules, regulations, and guidance documents; evaluating certain nonroutine uses of radioactive material; providing technical assistance in licensing, inspection, and enforcement cases; and bringing key issues to the attention of NRC for appropriate action.

Nominees must be U.S. citizens and be able to devote approximately 160 h/y to committee business and have professional or personal experience with or knowledge about patient advocacy. Involvement or leadership with patient advocacy organizations is preferred. Interested candidates should submit an electronic copy of their resume or curriculum vitae, along with a cover letter, to Ashley Cockerham at Ashley.cockerham@nrc.gov. The cover letter should describe current involvement with patients' rights advocacy and express the candidate's interest in the position. Submittals should include the following information, if applicable: education; certification; professional association membership and committee membership activities; and number of years, recentness, and type of setting for patient advocacy. Nominations will be accepted until Nov. 15. For additional information about membership on the ACMUI, see www.nrc.gov/about-nrc/regulatory/advisory/acmui/membership.html.

Nuclear Regulatory Commission

New NIH Institute Introduced

The National Institutes of Health (NIH) announced on September 27 the transition of the National Center on Minority Health and Health Disparities (NCMHD) to the National Institute on Minority Health and Health Disparities (NIMHD). The transition gives the institute a more defined role in the NIH research agenda against health disparities, which it defines as "differences in the incidence, prevalence, mortality, and burden of diseases and other adverse health conditions that exist among specific population groups." The move authorizes the NIMHD to plan, coordinate, review, and evaluate all minority health and health disparities research activities conducted and supported by NIH institutes and centers, and it reaffirms the authority of the NIMHD director as the primary federal official with responsibility for coordinating such activities. Under its previous designation, the center coordinated the health disparities research activities of NIH's other institutes and centers.

"We have made some progress towards eliminating health disparities. Yet there is much unfinished business," said John Ruffin, PhD, NIMHD director. "We have to reexamine our strategy and accelerate the pace through innovative, sustainable and results-oriented approaches. Our goal is to establish an integrated research enterprise, building upon lessons learned and working with our many partners to address the complexity of health disparities." The law transfers all of the responsibilities of the NCMHD provided under the Minority Health and Health Disparities Research and Education Act to the new institute. This includes responsibility for coordinating the development of the NIH health disparities research agenda. In addition, it expands the eligibility criteria of the NIMHD Research Endowment program to include active NIMHD Centers of Excellence. For more information on the Institute's programs, see www.ncmhd.nih.gov.

National Institute on Minority Health and Health Disparities

NIDA Avant Garde Awards

National Institute on Drug Abuse (NIDA) officials announced on September 21 the recipients of the first Avant Garde Awards for Innovative Medication Development Research. The newly launched research competition is an extension of NIDA's successful Avant Garde Award for Innovative HIV/AIDS Research, now in its third year. "Science has clearly shown that drug addiction results from profound disruptions in brain structure and function, presenting numerous potential targets for medications development—yet, few medications have come to fruition," said NIDA Director Nora D. Volkow, MD. "The array of creative problem-solving approaches submitted by the awardees could help us quicken the pace to find urgently needed medications for addiction." Each recipient will receive $500,000/y for 5 y to support their research.

Awardees included Andrew Norman, PhD, from the University of Cincinnati (OH), whose project focuses on "A Human Antibody as an Immunotherapy for Cocaine Abuse"; William Brimijoin, PhD, from the Mayo Clinic (Rochester, MN), for "Cocaine Hydrolase Gene Therapy for Cocaine Abuse"; Jia Bei Wang, MD, PhD, University of Maryland at Baltimore, for "Development of l-THP as New Medication for Drug Addiction"; and Daniele Piomelli, PhD, University of California at Irvine, for "Optimization and Preclinical Development of FAAH Inhibitors for Smoking Cessation."

"The pharmaceutical industry has been reluctant to invest in medications development for addiction due to stigma and perceived financial disincentives," said Volkow. "These studies could lay the foundation to encourage greater pharmaceutical industry involvement, further helping to achieve our public health mandate to stop the devastation caused by drug abuse and addiction in this country." It is noteworthy that each of the awardees plan to incorporate some form of molecular imaging or related assessments into the validation studies associated with their research. For further information about the Avant Garde Award, please see http://drugabuse.gov/avgp.html. Information about applications for

the 2011 Avant Garde Awards will be posted on this site in the near future.

National Institute on Drug Abuse

NIH Expands Pharmacogenomics Resource

To help advance research on the ways in which genes affect responses to medicines, the National Institutes of Health (NIH) announced on September 7 that it will spend $15 million over 5 y to expand a key resource, the Pharmacogenomics Knowledge Base (PharmGKB). The goal of pharmacogenomics is to use information about a patient's genetic make-up to optimize his or her medical treatment. Begun in 2000 to catalog links between human genetic variation and drug responses, the PharmGKB Web site is now a centralized hub that collects, analyzes, and integrates data for national and international research consortia. All information in PharmGKB is carefully curated, meaning it is annotated and cross-referenced with related research data. "PharmGKB is a trusted source for curated knowledge about pharmacogenomics," said Jeremy M. Berg, director of the National Institute of General Medical Sciences, which administers the PharmGKB grant. "It plays a critical role in moving us closer to the goal of personalized prescriptions, meaning each patient receives a safe and effective drug dose based on his or her individual characteristics."

PharmGKB, which is freely available to the scientific community, identifies biochemical pathways influenced by specific drugs and provides detailed summaries of key genes that influence a person's response to a broad array of medicines. PharmGKB also includes 6 staff scientists and 6 software engineers who conduct research, collaborate with other investigators, and build the software infrastructure supporting PharmGKB.

During the next 5 y, PharmGKB plans to: develop tools that automatically extract information from the biomedical literature and key databases; intensify its focus on understanding the molecular basis for drug toxicity and multiple-drug interactions, information that may help improve the safety and efficacy of medicines; analyze the genomes of additional individuals, including a family who has volunteered to be studied; and develop guidelines for doctors about the use of genetic tests to customize dosages when prescribing certain medicines.

PharmGKB is part of a broader NIH pharmacogenomics initiative that includes individual research projects and a nationwide research consortium, the NIH Pharmacogenomics Research Network. To learn more about these groups, visit www.pharmgkb.org/ and www.nigms.nih.gov/Initiatives/PGRN/, respectively.

National Institute of General Medical Sciences

NRC Issues RSO RIS

On September 9 the Nuclear Regulatory Commission (NRC) released a regulatory issue summary (RIS) to address the issue of allowing only 1 radiation safety officer (RSO) for medical use licenses and the issue of the availability of RSOs to serve as preceptors for other individuals seeking RSO status on medical use licenses. The NRC provided this RIS to Agreement States for their information and for distribution to their medical licensees, as appropriate. In 10 CFR Part 35, "Medical Use of Byproduct Material," the NRC provides 4 methods that individuals can use to be recognized as RSOs at NRC-licensed medical use facilities. The regulations in 10 CFR 35.50 specify 3 of these methods. For all 3 methods, the proposed RSO must obtain a preceptor attestation and must complete training in the radiation safety, regulatory issues, and emergency procedures for the types of uses for which a licensee seeks approval. The provisions of 10 CFR 35.57 describe the fourth method. The RIS can be viewed at: www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/2010/.

Nuclear Regulatory Commission

CMS/FDA Request Comments on Parallel Review

The Centers for Medicare & Medicaid Services (CMS) and the U.S. Food and Drug Administration (FDA) requested in mid-September comments on the establishment of a process for overlapping evaluations of premarket, FDA-regulated medical products when the product sponsor and both agencies agree to such parallel review. This process is designed to serve the public interest by reducing the time between FDA marketing approval or clearance decisions and CMS national coverage determinations. The agencies have established a docket to receive information and comment from the public on what products would be appropriate for parallel review by the 2 agencies, what procedures should be developed, how a parallel review process should be implemented, and other issues related to the effective operation of the process. The agencies also announced their intent to create a pilot program for parallel review of medical devices. The pilot program will begin after both agencies have reviewed the public comments on this notice. A memorandum of understanding on the exchange of data and information between the 2 agencies was issued earlier in the year and can be viewed at www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/ucm217585.htm. Comments are due by December 16 and can be submitted at www.regulations.gov.

Centers for Medicare & Medicaid Services
U.S. Food and Drug Administration

IAEA Calls for New Cancer Agenda

Cancer experts gathered at the Scientific Forum of the 54th International Atomic Energy Agency (IAEA) General Conference in September to

address the issue of international cancer resources and the significant challenges to successful global strategies. Franco Cavalli, MD, chair of the Scientific Committee of the European School of Oncology, noted that many governments are reluctant to talk about cancer because, to be effective, cancer care and control require a health care system that is robust from the ground up. He added that efforts by nongovernmental, civil, and international organizations will never be successful unless national governments are interested and enthusiastic about curing cancer. Eduardo Cazap, MD, president of the International Union for Cancer Control, addressed the forum and called for "a wider perspective when combating cancer" to address universal problems in access to treatment.

Among the issues discussed in the forum were disparities in types of cancer common in high- and low-income countries. The patterns of these disparities are changing, especially with a rise in lung and breast cancers in areas where these diseases were once less common. Attendees cited the continued growth and aging of the world's population, in combination with exposure to cancer risks such as tobacco use, as factors that are likely to radically increase the future cancer burden. Projections suggest that by 2030 the world will see 21 million incident cases of cancer each year, with 13 million dying each year and more than 75 million living with the disease. The attendees discussed strategies for addressing these challenges.

International Atomic Energy Agency

OECD/NEA on Medical Radioisotope Supply

The Organisation for Economic Co-operation and Development (OECD) Nuclear Energy Agency (NEA) on September 27 released a report on medical isotope supplies. The interim report presented the findings of the OECD/NEA High-Level Group on the Security of Supply of Medical Radioisotopes (HLG-MR) and identified the main issues that affect the reliable supply of ^{99}Mo and ^{99m}Tc. The report discussed the current situation of supply challenges and issues, including reactor capacity limitations and constraints. Progress made in encouraging more reliable supply was detailed, including developing communication protocols, assessing transportation barriers, understanding the economic situation of the supply chain, and alternative production technologies.Moving into the last year of its mandate, the report highlighted the next steps of the HLG-MR in its efforts to support the long-term reliability of medical isotope supply. The full report can be accessed at www.nea.fr/med-radio/reports/HLG-MR-Interim-report.pdf.

Organisation for Economic Co-operation and Development