Government Relations Update

FDA Holds Public Workshop on Radiopharmaceutical Approval Regulations

The Food and Drug Administration (FDA), complying with the FDA reform bill passed last year, held a workshop on the approval process for radiopharmaceuticals on February 27, 1998. The workshop was moderated by George Mills, MD, of the FDA Office of Biologics, and the staff panel was headed by Patricia Love, MD, Jane A. Axelrad, JD, and David Lee. There were four questions posed by the FDA:

1. How should the proposed use of a radiopharmaceutical in the practice of medicine determine the nature and extent of safety and effectiveness evaluations?
2. What general characteristics should be considered in the preclinical and clinical pharmacological and toxicological evaluations of a radiopharmaceutical (including the radionuclide as well as the ligand and carrier components; i.e., nonradioactive components)?
3. How should the estimated absorbed dose in humans be determined and considered?
4. Under what circumstances might an approved indication for marketing refer to manifestations of disease (biochemical, physiological, anatomic or pathological processes) common to, or present in, one or more disease states?

Presentations addressing these questions were made by representatives of several organizations, including the Council on Radionuclides and Radiopharmaceuticals (CORAR). Mark Tulchinsky, MD, represented the American College of Nuclear Physicians and the Society of Nuclear Medicine (ACNP/SNM). Radiation dosimetry was addressed by Barry Wessels, PhD, a radiation biologist from George Washington University, Washington, DC, and a member of SNM's MIRD committee, and Richard E. Toohey, PhD, CHP. Richard L. Wahl, MD, spoke on behalf of the American College of Radiology.

The panel's initial tone was skeptical and inquisitive. As the presentations progressed, however, the tone became interested and collaborative. At the end of the meeting, the FDA panel and the participants were comfortable discussants, and there was a positive atmosphere. The workshop discussions led to tentative agreements with the FDA regarding the approval of radiopharmaceuticals. The following are the major agreements attained in negotiations with the FDA regarding regulation of diagnostic radiopharmaceuticals:

- The FDA agreed to acknowledge the concept of "Class 1 radiopharmaceuticals" (i.e., tracers) and, further, that flexible safety requirements would apply.
- The FDA agreed to further define "Class 1 radiopharmaceuticals" in the preamble to the forthcoming regulation and in a guidance document to accompany the regulation.
- The FDA assured workshop participants that a guidance document would be proposed soon after the regulation (approximately May 20, 1998).
- The FDA agreed to include language in the preamble of the regulation making it clear that the Nuclear Regulatory Commission's occupational radiation limits (5 rem) are not an appropriate benchmark for establishing the radiation dose of a radiopharmaceutical.
- The FDA stated that the proposed regulation language would be similar to the position taken by CORAR and ACNP/SNM regarding both indications for diagnostic radiopharmaceuticals (multiple indications) and the evaluation of effectiveness.
- The FDA also agreed to the concept of granting early meetings with sponsors both before and during the preclinical phase of a trial to determine the level of safety studies required.

According to Tulchinsky's comments on the workshop, it appears that ACNP/SNM and CORAR achieved major gains in the FDA's approach to the regulation of radiopharmaceuticals. While the outcome of the process will not be determined until the release of the proposed rule, ACNP/SNM representatives feel confident about the content of the rule. Under Tulchinsky's direction, ACNP/SNM and CORAR will comment on the proposed rule when it is published.

—David Nichols is the director of the ACNP/SNM government relations office.

Nuclear Medicine Pioneer

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Cassen was the author of numerous journal articles and book chapters, including, as coauthor with Drs. Blahd and Bauer, the highly regarded 1958 text, *The Practice of Nuclear Medicine*. He also served for many years as a trustee of SNM, from which he received its first Distinguished Scientist Award in 1970. He was honored again by SNM in 1978 when he was cited as a Nuclear Medicine Pioneer.

Nuclear Medicine's Prestigious Cassen Prize

In 1982, Cassen's widow, Mary Wylie Cassen, made a bequest to the ERF to establish a major scientific award to honor the contributions of a living scientist or physician-scientist to nuclear medicine. As a tribute to the man who dedicated his life to research, the Cassen Prize, which is referred to as the " Nobel Prize of nuclear medicine," is a testament to Cassen's contributions to nuclear medicine and to his enduring legacy.

—Eleanore Tapscott