Regulatory Issues Are Primary Focus for Nuclear Medicine Groups

The following report highlights recent Government Relations Office activities: fast-tracking cancer diagnostics with the Food and Drug Administration (FDA) and Environmental Protection Agency (EPA) and Nuclear Regulatory Commission (NRC) agreement on radionuclide air emissions regulations.

On December 9, 1996, representatives of the Council on Radionuclides and Radiopharmaceuticals (CORAR), Institute for Clinical PET (ICP), SNM and ACNP met with Janet Woodcock, Director-Center for Drug Evaluation and Research (CDER), Murray Lumpkin, MD, Deputy Director, Robert Temple, Deputy Director and other FDA staff members to urge that FDA use accelerated approval for drugs that diagnose cancer. The FDA currently has a policy in place to fast-track therapeutic drugs for the treatment of cancer.

In the proposal the group recommended that accelerated approval be made available for imaging agents that are used to diagnose or provide other information that contributes to detection, treatment or monitoring of cancer. The proposal included reducing clinical trials from two to one, as well as using clinical endpoints other than effectiveness in diagnosing a particular disease. Following approval, the sponsor could be required to confirm the effectiveness of the agent by conducting studies of its effectiveness in: (a) detecting and localizing additional tumors in patients for whom marker lesions were detected in pre-approval studies or (b) diagnosing tumors in patients who have not been previously diagnosed with the disease.

The group also proposed that the accelerated procedures presented to the FDA be available not only for original applications but also for supplemental applications for new indications as well. This policy, the group contended, would encourage the submission of supplements so that the label of a diagnostic imaging agent accurately conveys information corresponding to the actual uses of the agent in clinical practice. Finally, the group proposed that the FDA implement, with regard to diagnostic imaging agents, a program similar to the one recently established to expand access to therapeutic cancer drugs. Where a diagnostic imaging agent under study in the U.S. for the detection, diagnosis or monitoring of cancer has been approved in a foreign country and there is no comparable drug or procedure commercially available in the U.S., the FDA would approve expanded access protocols regardless of the length of time the product has been studied in the U.S.

The FDA was receptive to the proposal and will continue to work with the professional organizations to develop such a plan.

On October 31, 1989, the EPA promulgated National Emission Standards for Hazardous Air Pollutants (NESHAPs) under Section 112 of the Clean Air Act to control radionuclide emissions to the ambient air from a number of different source categories. Subpart I of 40 CFR part 61 covers facilities licensed and regulated by the NRC and individual Agreement States. It limits radionuclide emissions to the ambient air to that amount which would cause any member of the public to receive in any year an effective dose equivalent (eDe) no greater than 10 mrem, of which no more than 3 mrem eDe may be from radioiodine.

When subpart I was originally promulgated in December 1989, the EPA simultaneously granted reconsideration of the subpart based on information received late in the rulemaking on the subject of duplicative regulation by the NRC and EPA on this issue. While collecting information on this topic, the EPA granted a stay from the regulations, but this order was overturned in court. As a result the EPA implemented subpart I regulations on November 16, 1992. In the Clean Air Act of 1990, however, there was a provision for the Administrator of the EPA to rescind regulations if a determination that NRCs program adequately protected public health and safety was made. The delay in rescission resulted in the NRC having a 50-mrem standard that was higher than the 10 mrem set by the EPA.

For several years, the ACNP and SNM worked with the EPA and NRC to develop a dose limit that would satisfy both agencies. The EPA, however, was insistent on the 10 mrem level originally set. Eventually, the NRC made changes to their regulations, including lowering the level to 10 mrem, and published a final rule effective January 1, 1997. Based on the implementation of these new regulations, the EPA has also published a final rule rescinding subpart I of 40 CFR part 61. This means that as of December 30, 1996, NRC licensees will have to comply only with NRC regulations and not with both EPA and NRC in this area.

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ACNP and SNM Join Appeal of Syncor Decision

Syncor International Corporation, the American College of Nuclear Physicians, (ACNP), the Society of Nuclear Medicine (SNM) and the American Pharmaceutical Association have asked the U.S. Court of Appeals for the District of Columbia Circuit to overturn the District Court decision that upheld the legality of the Food and Drug Administration's (FDA) new regulatory scheme for PET. The PET regulations were upheld in an October 18, 1996 decision by U.S. District Court Judge Emmet G. Sullivan.

The appellants challenged the FDA's PET regulatory scheme, announced in February 1995, on the grounds that is was adopted in violation of the Administrative Procedure Act, that it exceeded FDAs statutory authority, and that, in regulating the practices of medicine and pharmacy, it violated the Tenth Amendment to the U.S. Constitution. The appeal, filed on December 13, 1996, will argue that Judge Sullivan wrongly decided the case. A schedule for filing of briefs has not yet been established. A decision from the Court of Appeals should not be expected before September.

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