Government Relations Update

Pharmacy Compounding: Background on the Latest Federal Initiatives

Pharmacy compounding language has been a topic of discussion in Congress for several years. Originally, language was supported by the nuclear medicine community as a means to seek relief from FDA regulation of PET, but following the introduction of language by Senator Ted Stevens (R-AK) particularly focusing on PET, the compounding provisions were no longer necessary to seek such relief. The American College of Nuclear Physicians (ACNP) and SNM continued to work with the pharmacy community, however, seeking a bill that would provide greater freedom for physicians and pharmacists to compound under state law. Senator Tim Hutchinson (R-AR) and Representative Richard Burr (R-NC) were instrumental in moving these provisions forward in the recently enacted FDA reform bill. (See "Congress Passes FDA Reform Act," page 15N.)

The Senate addressed FDA reform first, and much of the negotiation took place there. To gain the support of the FDA and of Senator Ted Kennedy (D-MA), compromise on the bill was necessary, and the pharmacy community joined together to work on changes. In the end, however, the provisions negotiated were determined to be too restrictive for radiopharmaceuticals, and an exemption was agreed upon following lobbying led by ACNP/SNM, joined by the rest of the pharmacy community.

Along with the exempted provisions (detailed below), negotiators agreed that regulation should be based on current law—in this case, a 1984 guideline released by the FDA on nuclear pharmacy compounding.

All of these restrictions on compounding—in addition to the additional power given to the FDA to determine some of the applicable situations in which compounding would be allowed—were of significant concern to the nuclear medicine community. The resulting exemption represented the only subset of drug products to be excluded in the provisions and governed under current law.

Consequently, except for radiopharmaceuticals and PET drugs, the following provisions apply if a drug product must be compounded for an individual patient based on an unsolicited receipt of a valid prescription. The product must be compounded by either (a) a licensed pharmacist in a state-licensed pharmacy or federal facility or (b) a licensed physician on the prescription order of a licensed physician. Alternatively, the compounding may be done by (a) a licensed pharmacist or physician in limited quantities before the receipt of a valid prescription order for an individual patient, which is (b) based on a history of receiving valid prescription orders.

The relief provided by the compounding act applies only under the following circumstances:

1. The product must be compounded using bulk drug substances, as defined in regulation by the FDA, that (a) comply with a U.S. Pharmacopeia (USP) monograph and the USP chapter on pharmacy compounding. (b) If such a monograph does not exist, then compounding must be done using drug substances that are components of drugs approved by the FDA. (c) If such a monograph does not exist and the drug substance is not a component of an FDA-approved drug, then the drug substance must be on a list developed by the FDA through regulation. (d) The bulk drug substances must be manufactured by an FDA-registered facility. (e) The bulk drug substances must be accompanied by valid certificates of analysis.

2. The compounding of a drug product using ingredients other than bulk drug substances must comply with the standards of an applicable USP monograph and the USP chapter on pharmacy compounding.

3. The individual doing the compounding must not compound a drug product that is on a list published by the FDA of products that have been withdrawn or removed from the market because such drug products or components thereof have been found to be unsafe or not effective.

4. The individual doing the compounding must not compound regularly or in inordinate amounts (as defined by the FDA) any drug products that are essentially copies of ones commercially available.

5. The compounded drug may not be a drug product that the FDA has determined will present demonstrable difficulties for compounding that will reasonably demonstrate an adverse effect on the safety or effectiveness of the product.

6. Relief will apply if the drug product is compounded in a state that has a Memorandum of Understanding (MOU) with the FDA addressing the distribution of inordinate amounts of compounded drugs interstate or is compounded in a facility in an state without an MOU but the product does not exceed 5 percent of the total prescription orders dispensed or distributed by the facility's pharmacy or physicians.

7. A drug may be compounded only if the pharmacy, licensed pharmacist or physician does not advertise or promote the compounding of any particular drug, class of drug or type of drug. However, the pharmacy, licensed pharmacist or licensed physician may advertise and promote the compounding service provided.

Justice Department Files Motion to Vacate Syncor Appeal

In October 1997 the U.S. Court of Appeals for the D.C. Circuit, ruling on a claim by Syncor International, the American Pharmaceutical Association (APhA) and ACNP/SNM, found that the February 25, 1995, notice issued by the FDA concerning PET failed to meet the requirements

of the Administrative Procedure Act.

In response to this decision, the Justice Department has filed a motion to vacate the ruling on the grounds that the passage of the PET provision in the Food and Drug Administration Modernization Act of 1997 (S. 830) renders the case moot. If the ruling is vacated, the following effects may be felt by the nuclear medicine community.

Because the decision by the appeals court validates the actions of PET facilities not complying with the FDA's policy statements and final rules from 1995 to 1997, removal of the appeals court decision makes those actions illegal and subject to potential liability lawsuits or action by the FDA. Observers consider this result unlikely.

Since the decision also indirectly protects the nuclear medicine community from facing internal change to the 1984 nuclear pharmacy guideline by the FDA without appropriate notice and comment, the result might be to lose the guiding document for FDA jurisdiction over radiopharmaceutical compounding.

ACNP/SNM, along with the APhA and Syncor, has filed opposition to the government's motion. Alvin J. Lorman of Mintz, Levin, Cohn, Ferris, Glovsky, and Popeo, PC, will continue to represent the group.

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

FFTF

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Future of FFTF

Restarting FFTF as an interim source is being considered by the DOE to supplement its longer-term dual-track strategy for producing tritium. As part of a dual-track strategy, the DOE is evaluating proposals to make tritium either by building a new accelerator at the Savannah River site in Aiken, SC, or by leasing or buying a commercial power reactor to provide irradiation services and electricity production.

The DOE announced on January 15, 1997, that it was maintaining FFTF in standby mode until it decided whether the reactor could play a role in the Department's tritium production strategy. In hot standby, Hanford is making sure that there is no degradation of key FFTF systems. The reactor is currently defueled, but the liquid sodium is still flowing through the cooling system, and essential systems, staffing and support services are being maintained.

Under the plan being evaluated by the DOE, three core positions would be made available for the production of medical isotopes. "What we've been doing is calculating the amount of 30 different isotopes that we could make using just those three assemblies of the high-flux region of the reactor," said Tenforde. "I was surprised. The production rates, even of isotopes that have relatively small cross-sections, is sufficiently high that it would certainly justify including a medical isotope mission along with a tritium mission."

Part of the technical situation being considered by the DOE is the fact that the ideal cycle for producing tritium is a fairly long 100 days, which is much too long for some short-lived medical isotopes of interest. PNNL and its engineering collaborators are working on a design for a rapid retrieval system that would allow operators to insert and remove short-lived medical isotope target assemblies with the reactor at full power. Under the plan being evaluated, FFTF could be restarted by mid-2002.

The FFTF Standby Project Office (SPO) finished an evaluation of the technical and economic feasibility of future FFTF operations and delivered it to the DOE's Office of Nuclear Energy, Science, and Technology in December 1997. According to the SPO, this report includes a technical information document covering environmental issues associated with restarting FFTF, a technical database and tritium production analysis, a life-cycle cost estimate and mode for FFTF restart and operation, a systems engineering document assessing critical interfaces and a feasibility report on medical isotope production. The NMRC and many of the professionals at Hanford believe strongly that FFTF can make an important contribution to medicine and medical research. They are working to convince the DOE of the value of such a contribution.

The DOE plans to select one of the dual-track options in December 1998 as the primary, long-term source of tritium, with the second option to be maintained as a backup.

—Allen Zeyher