



NUCLEAR MEDICINE WINS DECISION IN FDA PET CASE

In a suit brought jointly by the Society of Nuclear Medicine (SNM), Syncor International, the American College of Nuclear Physicians (ACNP) and the American Pharmaceutical Association, the U.S. Court of Appeals for the District of Columbia ruled in a 3-0 decision that an FDA regulation requiring new drug applications and abbreviated new drug applications for PET drugs was invalid. The U.S. District Court had ruled in favor of the FDA in *Synacor v. Shalala*, a five-part October 1996 decision. In that ruling, the court said that the FDA's regulation did not violate the Administrative Procedure Act and that in regulating PET drugs the agency did not exceed its statutory authority (by allegedly regulating interstate commerce), had not violated the Tenth Amendment by regulating pharmacies and had not been "arbitrary and capricious" in its denial of a May 1992 citizen petition by the nuclear medicine groups.

The appeals court ruling turned on a

procedural issue rather than on any of the other points earlier decided in favor of the FDA. The appeals court held that the FDA should have engaged in "notice-and-comment rulemaking" to adopt the challenged regulation. Such notice-and-comment process is required when the agency imposes "substantive" new requirements. The FDA had argued that it was simply issuing a policy statement or an "interpretive" rule, rather than imposing new requirements. The court rejected this argument. Although the court did not rule on this issue, it did evidence some skepticism toward the FDA's claim of regulating intrastate compounding.

The court decision now requires the FDA to use notice-and-comment rulemaking should the agency desire to change any of the existing regulations governing PET. The case sets a precedent that could potentially require a notice-and-comment process for any changes involving radiopharmaceuticals.

When this issue of *Newsline* went to press, the FDA had not made a decision whether to appeal. However, ACNP/SNM does not anticipate an appeal from the government.

While the victory was substantial in reversing the tide of what some observers term "overregulation" by the FDA, it may be superseded by negotiations in the FDA reform bill being discussed in Congress. The FDA reform legislation section on PET mandates a process over the next two to four years that would clarify which types of facilities using PET would be required to file with the FDA. This legislation sets up a construct that would place certain requirements on PET users, while recognizing some distinctions between academic and commercial facilities.

The nuclear medicine professional and industry groups were represented in the appeal by Alvin J. Lorman, of Mintz, Levin, Cohn, Ferris, Glovsky, and Popeo.

NRC WORKSHOPS

The NRC has conducted two workshops on 10 CFR Part 35 and is expected to begin putting together the text of the proposed rule for review by the nuclear medicine community and the NRC commissioners. Gathering input from professional societies, the NRC has been holding public meetings that included representation of nuclear medicine technologists, nuclear pharmacists and nuclear medicine physicians. Comments at the meetings ranged from issues identified by the NRC—such as the medical

policy statement, the quality management rule and training and experience criteria—to issues raised by the stakeholders, such as new patient release criteria.

The NRC is expected to forward a proposed rule to the Commission in May 1998, with public comment from June to September 1998. In addition to recommending members who are participating in the public workshops, SNM and ACNP have been in close contact with NRC staff to address other issues

not raised at the workshops. There will be an opportunity for SNM and ACNP members to review the material published by the agency and to provide additional comments.

The NRC information is located on a technical conference web page at <http://techconf.llnl.gov/noframe.html>. The NRC's home page is www.nrc.gov. Members are encouraged to review the information in the forum on 10 CFR Part 35 and to provide the agency with their perspectives.

FDA REFORM

The FDA Modernization and Accountability Act of 1997, commonly known as the 1997 FDA reform bill, remains under debate over differences between House and Senate versions. Both bills have sections that include different lan-

guage being debated in a conference committee that will be charged with making recommendations to the House and Senate regarding compromise between the bills. Two areas that are similar include provisions to revise the

approval process for radiopharmaceuticals and language that addresses PET regulation. One of the remaining issues of contention continues to be the pharmacy compounding provision.

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