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DOCKETING & SERVICE
BRANCH

Secretary of the Commission
U.S. Nuclear Regulatory Commission
Docketing and Service Branch, Docket # PRM35-9
Washington, D.C. 20555

Dear Mr. Secretary:

I am writing to express my strong support for the Petition for Rule making filed by the American College of Nuclear Physicians and the Society of Nuclear Medicine. I am a practicing Nuclear Medicine physician at The Allentown Hospital-Lehigh Valley Hospital Center in Allentown, PA. I am deeply concerned over the revised 10 CFR 35 regulations (effective April, 1987) governing the medical use of byproduct material as they significantly impact my ability to practice high quality Nuclear Medicine and are preventing me from providing optimized care to individual patients.

The NRC should recognize that the FDA does allow other clinical uses of approved drugs and actively discourages the submission of physician-sponsored IND's that describe new indications for approved drugs. Nuclear Medicine is still an art which should not be strictly regulated by a manufacturer's package insert. The current NRC regulations inappropriately interfere with the practice of medicine, which directly contradicts the NRC's Medical Policy statement against such interference.

I also believe that highly restrictive NRC regulations will only jeopardize public health and safety by: restricting access to appropriate Nuclear Medicine procedures; exposing patients to higher radiation absorbed doses from non-optimal studies, and exposing hospital personnel to higher radiation absorbed doses because of unwarranted and repetitive procedures. The NRC should rely on the FDA, State Boards of Pharmacy, State Boards of Medical Quality Assurance, The JCAHO, radiation safety committees, institutional quality assurance review procedures, and most of all, the professional judgement of physicians and pharmacists who have been well trained to administer and prepare these materials.

The Nuclear Medicine community does not need more stringent regulations on studies that pose essentially no health risk to patients when used by competent professionals. I urge the NRC to adopt the ACNP/SNM Petition for Rulemaking as expeditiously as possible.

Sincerely,

Robert J. Rienzo, M.D.
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