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Secretary of the Commission
U.S. Nuclear Regulatory Commission
Docketing and Service Branch, Docket # PRM-35-9
Washington, DC 20555

October 26, 1989

Dear Mr. Secretary:

I am writing to express my support for the Petition for Rulemaking filed by the American College of Nuclear Medicine Physicians and the Society of Nuclear Medicine. I am a practicing nuclear pharmacist at Walter Reed Army Medical Center in Washington DC. I am deeply concerned over the revised 10 CFR 35 regulations governing the medical use of byproduct material as they significantly impact my ability to practice high quality nuclear pharmacy and are preventing me from providing optimum care.

An example of how the NRC has lessened my effectiveness is in the way NRC has chosen to interpret the FDA labeling which accompanies a drug. I believe the NRC would find me in violation of the labeling if I knowingly dispensed a pediatric dose of a radiopharmaceutical. After all, it is explicit within the package insert that the safety and effectiveness for most radiopharmaceuticals has not been proven for children and pregnant women. I am astounded that the NRC can cite pharmacies which compound radiopharmaceuticals for violating FDA labeling supplied by the manufacturer and intended as a guideline for the medical professional. The NRC should keep in mind that the labeling which comes with a drug is a very small part of the information submitted to the FDA by the drug manufacturer in pursuit of an approved NDA.

The decision for prescribing any NDA drug is the responsibility of the physician who is caring for the patient not a bureaucracy in Washington. My responsibility as the nuclear pharmacist is to review the physician's prescription, prepare and test the radiopharmaceutical, and dispense or administer the drug. As the physician's consultant on radioactive drugs he relies on my professional judgement on issues of formulation, quality control, and mechanisms of localization. I reserve the right to question his prescriptions and, in the extreme, refuse to fill a prescription. I believe there is a symbiotic relationship between physician and pharmacist which is beneficial to the patient and is implicit within the Food, Drug, and Cosmetic Act. I resent the meddling of the NRC which is still grappling with the concept of the professional practice of medicine and pharmacy.

The NRC should recognize that the FDA does allow, and often encourages, other clinical use of approved NDA drugs, and actively discourages the submission of physician-sponsored IND's that describe new indications for approved drugs. The package insert was never intended to prohibit physicians from deviating from it for other indications or pharmacists from compounding and dispensing these drugs. In many cases, manufacturers will never go back to the FDA to revise a package insert to include a new indication because it is not required by the FDA and there is simply no economic incentive to do so.

Currently, the regulatory provisions in Part 35 (35.100, 35.200, 35.300 and 33.17(a)(4)) do not allow practices which are legitimate and legal under FDA regulations and state medicine and pharmacy laws. These regulations therefore inappropriately interfere with the practice of

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medicine and pharmacy, which directly contradicts the NRC's Medical Policy Statement against such interference.

Finally, I would like to point out 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 alternative legal, but non-optimal, studies; and exposing hospital personnel to higher radiation absorbed doses because of unwarranted, repetitive procedures. The NRC should not strive to construct prescriptive regulations to cover all aspects of the practice of medicine and pharmacy, nor should it attempt to regulate radiopharmaceutical use. Instead, the NRC should rely on the expertise of the FDA, State Boards of Pharmacy, State Boards of Medical Quality Assurance, the Joint Commission of Accreditation of Healthcare Organizations, radiation safety committees, institutional Q/A review procedures, Institutional Review Boards, and most importantly, the professional judgement of physicians and pharmacist who have been well educated and trained to prepare and administer these drugs.

Since the NRC's primary regulatory focus appears to be based on the unsubstantiated assumption that misadministrations, particularly those involving diagnostic radiopharmaceuticals, pose a serious threat to the public health and safety, I strongly urge the NRC to pursue a comprehensive study by a reputable scientific panel, such as the National Academy of Sciences or the NCRP, to assess the radiobiological effects of misadministrations from nuclear medicine diagnostic and therapeutic studies. I believe that the results of such a study will demonstrate that the NRC's efforts to impose more and more stringent regulations are unnecessary and not cost-effective in relation to the extremely low health risk of these studies.

In closing, I strongly urge the NRC to adopt the ACNP/SNM Petition for Rulemaking as expeditiously as possible.

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