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SCHOOL OF PHARMACY AND
PHARMACAL SCIENCES

December 5, 1989

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

Dear Mr. Secretary:

I wish to express my strong support for the Petition for Rulemaking filed by the American College of Nuclear Physicians and the Society of Nuclear Medicine. I have a seventeen year history in nuclear pharmacy as a practicing nuclear pharmacist in both commercial and university settings and as a pharmacy educator specializing in nuclear pharmacy education. I am currently teaching nuclear pharmacy to undergraduate and graduate students at Purdue University in West Lafayette, Indiana. I am deeply concerned over the revised 10 CFR 35 regulations, effective April 1987, governing the medical use of byproduct material. These regulations are being used to prevent nuclear pharmacists from providing the best patient care tailored to individual patient needs.

As a practicing nuclear pharmacist, I feel it is my professional obligation to provide the best quality product for the patient, and if that requires the occasional deviation from literal package insert instructions, I know that my years of training and continuing education in nuclear pharmacy have enabled me to make the correct decision. Preparing a kit according to package insert instructions will be acceptable for more than 97% of the patient population, but the 3% that have special requirements must be able to trust that the pharmacist can make necessary alterations in formulation to make the product safe for them and also confirm the quality of the product. As an educator, I spend a substantial portion of my class time teaching my pharmacy students how to solve the problems they will encounter in patient practice. For example, when I teach them how to reduce the number of particles in a macroaggregated human serum albumin kit so that the product may be safely used on a neonate or a patient with a moderate degree of pulmonary hypertension, I do so knowing that one day a patient's welfare may depend on that pharmacist being able to exercise good professional judgement. Pharmacists are trained to place patient welfare first, and I do not believe that the fact that the patient is scheduled for a nuclear medicine procedure is any reason to deprive the patient of the pharmacist's best care.

The NRC should recognize that the FDA allows, and often encourages , other clinical uses of approved drugs. When new uses are found for radiopharmaceuticals that are approved drugs, it is usually beneficial to some, if not all, patients. The FDA does not insist that a new use be beneficial to the majority of the patient population because it recognizes that the new uses are necessary for growth in developing new diagnostic and therapeutic procedures. The FDA does

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not require that the manufacturer go back to the FDA to revise package inserts as each new use of a pharmaceutical becomes known, and in reality, it would not be economically feasible for the manufacturer 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 individual states' laws governing medicine and pharmacy practice. These regulations inappropriately interfere with the practice of medicine, which is a direct contradiction of the NRC's Medical Policy statement against such interference. The NRC should be relying on the expertise of the FDA, State Boards of Pharmacy, State Boards of Medical Quality Assurance, the Joint Commission on Accreditation of Healthcare Organizations, radiation safety committees, institutional Q/A review procedures, and most importantly, the professional judgement of physicians and pharmacists who have been trained to prepare and administer these radiopharmaceuticals.

If the NRC believes that misadministrations, particularly those involving diagnostic radiopharmaceuticals, pose a serious threat to the public health and safety, I strongly urge that they pursue a comprehensive study by a reputable scientific panel, such as the National Academy of Sciences, to assess the radiobiological effects of misadministrations from nuclear medicine diagnostic and therapeutic studies. I also firmly believe that the perceived increase in misadministrations is actually the result of the more uniform and reliable reporting of those which do occur because of the checks and balances brought about by commercial nuclear pharmacies supplying nuclear medicine departments with prepackaged unit doses. If the NRC conducts studies into these areas, I am confident that such studies will demonstrate the the NRC's efforts to impose increasingly more stringent regulations are unnecessary and not cost effective in relation to the extremely low health risks involved in these nuclear medicine procedures.

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

Sincerely,

C. Anne Smith

C. Anne Smith, R.Ph., M.S., B.C.N.P.
Nuclear Pharmacy Program Director