(19)

FOSTER G. McGAW HOSPITAL
LOYOLA UNIVERSITY OF CHICAGO
2160 South First Avenue, Maywood, Illinois 60153 312 531-3777

DEPARTMENT OF NUCLEAR MEDICINE

DOCKET NUMBER
PETITION RULE PRM 35-9
(54 FR 38239)

'89 OCT 23 P4:46

OFF. OF SECRETARY
DOCKETING & SERVICE BRANCH

October 10th, 1989

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

Dear Mr. Secretary,

I am a full time nuclear physician practicing at Loyola University in Maywood, Illinois. This letter is to express my support for the Petition for Rulemaking which was filed by the American College of Nuclear Physicians and the Society of Nuclear Medicine. The revised 10 CFR 35 regulations governing the medical use of byproduct material will severely impact our practice of high quality nuclear medicine.

This will affect our practice in several important ways. First, and foremost, as a leading institution in the development and enhancement of nuclear medicine procedures, we rely on our physicians to use radiopharmaceuticals in innovative ways to gather information about various pathologic processes that could not otherwise be obtained. Strict adherence to the package inserts for scan indications, dosages, and routes of administration would eliminate many of the new procedures described as so useful in recent medical literature. This would be a tremendous hindrance to the future advance of nuclear medicine. The overall quality of care of patients would be adversely affected and the usefulness of nuclear procedures diminished.

Our institution has a full time radiopharmacist on staff. His expert guidance is often sought out when research projects are planned. This however is not his only function. Using his skills in pharmacy and radiopharmacy, he can produce some of the more commonly used radiopharmaceuticals and save tremendous costs to the hospital, patient and health care system. The FDA recognizes this as a valid specialty with appropriate safety measures already in place for production of in house pharmaceuticals. The current provisions in part 35 (35.100, 35.200, 35.300 and 33.17(a)(4)) do not allow for this and are in direct conflict with practices that are allowed under FDA regulations and state pharmacy laws. In addition, this conflicts with the NRC's Medical Policy statement against interference with the practice of medicine.

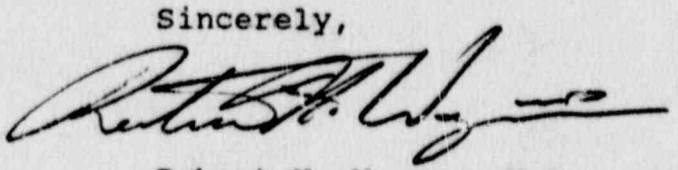
D510

Rather than try to further restrict the advancement of nuclear medicine and increase the overall cost of health care, the NRC should rely on the expertise of the numerous organizations already in place that oversee the quality of health care. In addition, it is the right of the physician to use any approved drug in any fashion they may see fit. This is the purpose behind the intensive training all physicians receive in pharmacology very early in their careers.

Finally, the NRC has been spending all too much effort on attempting to decrease the number of misadministrations. Available literature will show that the current number of misadministrations is several orders of magnitude below that seen on a typical nursing floor in a high quality hospital. Radiopharmaceuticals, by definition, have no physiologic effect. NCRP studies have shown that the radiation exposure from radiopharmaceuticals is completely safe and without side effects when used for diagnostic studies. The same cannot be said for the drugs used on a typical nursing floor. A misadministration of many of those drugs would be lethal. The strict regulation of relatively safe drugs in view of the nonregulated use of more dangerous drugs is an anachronism. To further pursue a lower number of misadministrations is a waste of resources and is against the original ALARA philosophy.

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

Sincerely,



Robert H. Wagner, M.D.