(294)

Nuclear Physicians Associates, P.A.

Clara Maass Medical Center
Nuclear Medicine Department
Belleville, New Jersey 07109
201.450.2229

Melvin H. Freundlich, M.D., FACNP
Diplomat, American Board of Nuclear Medicine
Clinical Professor of Radiology
UMDNJ, New Jersey Medical School

'89 DEC -1 P1:40

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

November 24, 1989

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

Dear Mr. Secretary:

I am writing to support the Petition for Rulemaking filed by the American College of Nuclear Physicians and the Society of Nuclear Medicine. I am Director of Nuclear Medicine at the Clara Maass Medical Center in Belleville, New Jersey and am Professor of Radiology, Division of Nuclear Medicine at the University of Medicine and Dentistry of New Jersey. The revised 10 CFR 35 regulations (effective April 1987), governing the medical use of byproduct material are very disturbing to me as they will restrict my ability to practice high quality Nuclear Medicine because they prevent me from providing an optimal care to each individual patient.

The most obvious example of this restriction would be that the package inserts states that these materials are not to be used in individuals under the age of 18 yrs. It is quite obvious that there are many indications for the use of these materials in extremely important tests in infants and children. In addition, it is well known that in patients who have certain types of pulmonary disease, it is necessary to make dilutions of the material in a different way from the package insert instructions.

It is well known that the FDA allows and encourages clinical uses of approved drugs, other than those that have been described by the package insert. The NRC should recognize that the package insert was never intended to prohibit physicians from deviating from it for other indications. It is obvious that such deviation is necessary for growth and developing of new diagnostic and therapeutic procedures. In many cases manufacturers do not go back to the FDA to revise the package insert to include a new indication, because it is not required by the FDA and there is no economic incentive to do so. Currently, the Regulatory provisions, in part, 35, 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 Medicine and it directly contradicts the NRC's medical policy statement against such interference. The NRC should not strive to construct proscriptive regulations to cover all aspects of medicine nor should it attempt to regulate radio-pharmaceutical use. Instead, the NRC should rely upon the expertise of the FDA, the State Boards of Pharmacy, the State Boards of Quality Medicine Assurance, the Joint Commission of Accreditation of Health Care Organizations and the various Radiation Safety Committees and Institutional Review Procedures. Most importantly, the judgement of physicians and pharmacists who have been well trained to administer and prepare these materials should be recognized.

DS10

Since the NRC's primary regulatory focus appears to be based upon the unsubstantiated assumption that misadministrations, particularly those involving diagnostic radiopharmaceuticals, poses 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 radio-biological effects of misadministrations from Nuclear Medicine Diagnostic and Therapeutic studies. I am convinced that the results from that study will demonstrate that the NRC's efforts to impose more and more stringent regulations are unnecessary and not cost-effective in the relationship to the extremely low health risks of these studies.

I express the opinions of my entire Staff in strongly urging the NRC to adopt the ACNP/SNM Petition for Rulemaking as expeditiously as possible.

Sincerely,

Melvin H. Freundlich, M. D.
Clinical Professor of Radiology UMDNJ
New Jersey Medical School

MHF/vc