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PROPOSED RULE PR 35-9
(54 FR 38239)

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USNRC

'89 NOV -7 P4:10

OFFICE OF SECRETARY
DOCKETING & SERVICE
BRANCH

Humana Hospital
South Broward

October 18, 1989

Nuclear Commission Secretary
U.S. Nuclear Regulatory Commission
Docketing and Service Branch
Docket Number PRM 35-9
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 Humana Hospital South Broward in Hollywood, Florida. I am deeply concerned over the revised 10 CFR 35 regulations effective April 1977 governing the medical use of byproduct material as it significantly impacts my ability to practice high-quality nuclear medicine and prevents me from providing optimal care to individual patients.

The NRC should recognize that the FDA does allow and often encourages, other clinical uses of approved drugs and actively discourages the submission of physician sponsored INDs that describe new indications for approved drugs. The package insert was never intended to prohibit the physicians from deviating from it for other indications; on the contrary, such deviation is necessary for growth and developing new diagnostic and therapeutic procedures. 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 insentive 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 medicine, which directly contradicts the NRC's medical policy statement against such an interference.

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Finally, I would like to point out that hihgly restrictive NRC regulations will only jeopardize public health and safety by; restricting access to appropriate nuclear medicine procedures, exposing patients to higher radiation absorb doses from alternative legal, but not optimal, studies and exposing hospital personnel to higher radiation absorb doses because of unwanted, repetitive procedures. The NRC should not strive to construct prescriptive regulations to cover all aspects of medicine, nor should it attempt to regulate radiopharmaceutical use. Instead, the NRC should rely on the expertise of the FDA, State Board of Pharmacy, State Board of Medical Quality Assurance, the Joint Commission on Accreditation of Health Care Organizations, Radiation Safety Committees, Institutional QA Review Procedures and most importantly, the professional judgement of physicians who have been well trained to administer and prepare these materials.

Since the NRC's primary regulatory focus appears to be based on the unsubstantiated assumption that this administration, 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 reputible scientific panel, such as the National Academy of Sciences or the NCRP to assess the radiobiological affects of this administration from nuclear medicine diagnostic and therapeutic studies. I firmly believe that the results of such a study will demonstrate that the NRVC'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 AC and P-SNM petition for law making as expeditiously as possible.

Sincerely,

Ferdinand L. Manlio, D.O.
Chief of the Department of Nuclear Medicine and Radiology,
Humana Hospital South Broward

FLM/cjp