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

DOCKETING & SERVICE BRANCH

December 12, 1989 DOCKET NUMBER
PETITION RULE PRM 35-9

Dear Mr. Secretary: (54 FR 38239)

I am writing on behalf of the Regulatory Affairs Committee, Greater New York Chapter of the Society of Nuclear Medicine. Our committee is in strong support of the Petition for Rulemaking filed by the American College of Nuclear Physicians and the Society of Nuclear Medicine. We are deeply concerned over the revised 10 CFR 35 regulations (effective April, 1987) governing the medical use of byproduct material as they severely impact the ability of professionals to practice high-quality Nuclear Medicine/Nuclear Pharmacy and prevents us from providing the optimal care of individual patients.

Our committee represents several Nuclear Medicine specialties and has experienced the interference caused by these regulations in several diagnostic and therapeutic aspects, in particular the strict adherence to instructions for kit preparations, FDA approved indications, route of administration, activity levels, kit preparation, and expiration times.

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 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; on the contrary, such deviation is necessary for growth in 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 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 medicine, which directly contradicts the NRC's Medical Policy statement against such interference.

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These highly restrictive 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 health care personnel to higher radiation absorbed doses because of unwarranted, repetitive procedures. The NRC should not strive to construct proscriptive 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 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 well trained to administer and prepare these materials.

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, we 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 radiobiologic effects of misadministrations from Nuclear Medicine diagnostic and therapeutic studies. We firmly believe that the results of such a study will demonstrate that the NRC's efforts to impose more stringent regulations are unnecessary and not cost-effective in relation to the extremely low health risks of these studies.

In closing, the Regulatory Affairs Committee, Greater New York Chapter of the Society of Nuclear Medicine strongly urges the NRC to adopt the ACNP/SNM Petition for Rulemaking as expeditiously as possible.

Sincerely,

John M. Gochoco

John M. Gochoco, Chairman
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