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PETITION RULE PRM 35-9

Secretary of the Chairman
U.S. Nuclear Regulatory Commission
Docketing and Service Branch, Docket #PRM-35-9 (54FR38239)
Washington, D.C. 20555

(314)

Dear Mr. Secretary:

'89 DEC -5 A11:01

I am writing to express my strong support for the Petetion for Rulemaking filed by the American College of Nuclear Physicains and the Society of Nuclear Medicine. I am a practicing nuclear medicine technologist at St. Joseph Hospital in Flint, Michigan. I am deeply concerned over the revised 10 CFR 35 regulations (effective 4/87) governing the medical use of byproduct material as they significantly impact my ability to practice high-quality Nuclear Medicine and are preventing me from providing optimized 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 IND's that described 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 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 stated against such interference.

Finally, I would like to point out that restrictive NRC regulations will only jeopardize public health and safety by: restricting access to appropriate Nuclear Medicine procedures; exposing patients to high radiation absorbed doses from alternative legal, but non-optimal studies; and exposing hospital 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 midicine, nor should it attempt to regulate radiopharmaceutical use. Instead they should rely on the expertise of the FDA, State Borads, the Joint Commission on Accreditatoin of Healthcare Organizations, radiation safety committees, institutional Q/A review procedures, and 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 pose a 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 NCRP, to to assess the radiobiological effects of misadministrations from Nuclear Medicine diagnostic and therapeutic studies. I firmly believe that the results of such a study will demonstrate that the NRC's efforts to impose more and more stringent regulations are unnecessary and not cost-effective in relation to the extremely low health risks of these studies.

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

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