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CENTER FOR THE HEALTH SCIENCES

Please Reply to: 691/W115
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LOS ANGELES, CALIFORNIA 90073

December 5, 1989

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

Dear Mr. Secretary:

I am writing to express my strong support for the Petition for Rulemaking filed by the American College of Nuclear Physicians and the Society of Nuclear Medicine. I am a Nuclear Medicine physician at Veterans Administration Medical Center West Los Angeles; and Professor of Medicine, UCLA School of Medicine, Los Angeles, California. I am deeply concerned over the revised CFR 35 regulations (eff April 1987) governing the medical use of byproduct material as they in many instances interfere with optimal patient care.

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 physicians from deviating from it for other indications; on the contrary, such deviation is necessary for growth in developing new diagnostic and therapeutic procedures.

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.

Finally, I would like to point out that highly restrictive NRC regulations will only jeopardize public health and safety by: Restricting access to appropriate Nuclear Medicine procedures; exposing patients to higher radiation absorbed doses from legal, but non-optimal studies; and exposing hospital personnel to higher radiation absorbed doses because of unwarranted, repetitive procedures. The NRC should not apply 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

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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 judgment 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, 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 radiobiological effects of misadministrations from Nuclear Medicine diagnostic 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.

Sincerely,

W. H. BLAHD, M. D.

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