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

DOCKETED
USNRC

'89 NOV 17 A8:23

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UNIVERSITY of PENNSYLVANIA

DIVISION OF NUCLEAR MEDICINE
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November 6, 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:

The purpose of this letter is 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 Professor of Radiology, Neurology and Psychiatry, and Chief of the Division of Nuclear Medicine at the Hospital of the University of Pennsylvania in Philadelphia, Pa. 19104. I am concerned over the revised 10CFR 35 regulations (effective April, 1987) governing the medical use of byproduct material as they significantly impact my ability to practice high-quality Nuclear Medicine and these regulations also prevent me from providing optimized care to Individual patients.

The NRC should recognize that the FDA does allow, in fact, 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.

Presently, the regulatory provisions in Part 35 (35,100, 35,200 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, innappropriately interfere with the practice of medicine, which directly contradicts the NRVC's Medical Policy statement against such interference.

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Finally, I would like to point out that highly restrictive NRC regulations will only jeopardize public health and safety by:

(1) restructing access to appropriate Nuclear Medicine procedures,
(2) exposing patients to higher radiation absorbed doses from alternative legal, but non-optimal, studies;
(3) 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 medicine, nor should it attempt to regulate radiopharmaceutical use. Rather, we would hope that the NRC would 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 Quality Assurance review procedures, and perhaps the most important, the professional judgment of physicians and pharmacists who have been well-trained to administer and prepare these materials.

The NRC's primary regulatory focus appears to be based on the unsubstantiated assumption that misadministrations, especially those involving diagnostic radiopharmaceuticals and pose a serious threat to the public health and safety, therefore, I strongly suggest the NRC request a comprehensive study study be made by a reputable scientific panel, (e.g. the National Academy of Sciences, or the NCRP) which would assess the radiobiological effects of misadministrations from Nuclear Medicine diagnostic and therapeutic studies. I feel confident that such a study will demonstrate that the NRC's efforts to impose more and more stringent regulations are unnecessary and would not be cost-effective in relation to the extremely low health risks of these studies.

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

Sincerely,

Abass Alavi

Abass Alavi, M.D.

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