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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

Dear Mr. Secretary:

As a practicing nuclear medicine physician and a researcher in the use of radiopharmaceuticals for the benefit of mankind, I am writing to express my strong support for the Rulemaking Petition filed by the American College of Nuclear Physicians and the Society of Nuclear Medicine. My practice is at the University of Michigan Hospitals in Ann Arbor, where I am Director of General Nuclear Imaging. The revised 10 CFR 35 regulations (effective April, 1987) governing the medical use of byproduct material have a significant and negative impact on my ability to practice high quality nuclear medicine if strictly interpreted and are preventing me from delivering the radiopharmaceutical doses by the appropriate routes to provide the best care for individual patients.

As an example, only yesterday we had a patient with pulmonary hypertension who needed a lung scan. To spare the patient potential side-effects from this scan, which involves the injection of Tc-99m macroaggregated albumin (MAA), I prescribed a limited number of particles per dosage. To limit the number of particles and still have adequate photon flux for imaging, our nuclear pharmacist would ideally have reconstituted an MAA kit with quantities of Tc-99m that exceed the manufacturer's recommendations; otherwise, the patient is exposed to a potentially dangerous number of particles that could cause cardiac arrest and death. Naturally, I could not inject a dangerously large dose of particles. I seriously doubt that the intent of the authors of 10 CFR 35 was to subject patients to such risks from nuclear medicine procedures that should be safe.

This is but one of many examples. As another example, Tc-99m human serum albumin is approved as a blood pool imaging agent. In fact, it is an excellent agent for lymphoscintigraphy or the mapping of regional nodal anatomy to save people the surgical risks of removing lymph nodes that are not routes of potential drainage for tumors. Thus, strictly following 10 CFR 35, one cannot offer this safe and efficacious procedure, and therefore one may be delivering sub-optimal medical care and exposing the patient to greater health risk.

As a physician who uses radionuclides to diagnose and treat patients, I feel that by the individual review of the patient's history and physical examination I can best choose the route and radiopharmaceutical for an imaging or therapeutic procedure. This is the practice of medicine. The Nuclear Regulatory Commission should recognize that the FDA does allow, and often encourages, other clinical uses of approved drugs. It actively discourages the submission of physican-sponsored IND's that describe new indications for approved drugs. Package inserts are not intended to prohibit physicians from deviating from them for other indications, as I stated above. As indicated above, it is

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difficult for medicine to progress if we are allowed to do only what it says in on the package insert. For many nuclear applications ,it is simply not cost-effective for the manufacturers to go back to the FDA to revise a package insert, because it is not required by the FDA and there is not an economic incentive to do so. If the NRC regulations are strictly enforced, the practice of nuclear medicine will suffer greatly.

The current regulatory provisions in Part 35 (35.100, 35.200, 35.300 and 33.17(a)(4)) do not allow practices that 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. Thus, highly restrictive NRC regulations only jeopardize public health and safety by restricting access to appropriate nuclear medicine procedures, exposing patients to higher radiation doses from alternative legal, but not optimal, studies, and exposing hospital personnel to higher radiation absorbed doses because of unwarranted repetitive procedures. The examples I listed above specifically indicate how following the NRC regulations may harm patients. In my opinion, the Nuclear Regulatory Commission should not strive to construct proscriptive regulations to cover all aspects of medicine, nor should it attempt to regulate radiopharmaceutical use. It certainly would be difficult for me, despite my practicing nuclear medicine daily, to specify exactly how radiopharmaceuticals should be used in each patient in the U.S. without examining them, nor would I presume to do so. Instead, the NRC should rely on the experience of the FDA, State Boards of Pharmacy, State Boards of Medical Quality Assurance, the Joint Commission on Accreditation of Health Care Organizations, radiation safety committees, institutional quality assurance review procedures and, most importantly, the professional judgement of my colleagues, the physicians and pharmacists who have been well trained to administer and prepare these materials.

It is unclear to me why the NRC has attempted to regulate nuclear medicine to such an extent, but I am certain that the examples I point out above would indicate that such regulations, though well-intended, may inadvertently pose a serious threat to the public health and safety. Thus, I strongly urge the NRC to adopt the ACNP/SNM Petition for Rulemaking as soon as possible so that I may deliver the best possible medical care to my patients and comply with NRC regulations. Please do not hesitate to contact me if additional information is required.

Sincerely,

Richard L. Wahl, M.D.
Associate Professor of Internal Medicine and Radiology
Director of General Nuclear Imaging

cc: E. Willard Allen, M.D.
President, ACNP

Richard A. Holmes
President, SNM

Carl Levin
Senator
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