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TEMPLE UNIVERSITY
A Commonwealth University

Department of Medicine
Cardiology Section

Broad & Ontario Streets
Philadelphia, Pennsylvania 19140
(215) 221-4733

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Secretary of the Commission
U.S. Nuclear Regulatory Commission
Docketing and Service Branch, Docket No.PRM-35-9
Washington, D.C. 20555

Dear Mr. Secretary:

I am writing this letter to express my strong support for the petition of the Rulemaking filed by the American College of Nuclear Physicians of the Society of Nuclear Medicine. I am a practicing nuclear cardiologist at Temple University Hospital in Philadelphia, Pa. I express my deep concern over the revised 10 CFR 35 regulations effective April 1987 governing the medical use of byproduct material as they significantly impact the ability to practice high quality nuclear cardiology, and which will therefor greatly affect on patient care.

Coronary artery disease remains the single greatest cause of mortality in western industrialized nations. With the improvement in techniques available now in coronary artery bypass grafting as well as the developing technology of percutaneous transluminal coronary angioplasty cardiologists now have an unprecedented ability to intervene in the natural history of this disease. As a result, the field of nuclear cardiology is also rapidly evolving. It is probably the single most important technique available for identifying patients that require and would most benefit from these interventions. Forcing a strict adherence to FDA approved indications and guidlines would severely hamper the optimal assessment of each individual patient and would have a deleterious effect on patient care and patient outcome.

It is important for the NRC to recognize that the FDA does allow other clinical uses of approved drugs. It actively discourages the admission of physician sponsored INDs that describe new indications for approved drugs. It is my understanding that the FDA feels it is not their position to tell physician how to practice medicine. Most manufacturers would find that the expense required to revise the package insert to include a new indication would be prohibitive. Furthermore, I

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do not think that the FDA would be capable of evaluating every new indication for every drug in a timely fashion and the resulting delays would markedly impede the progress in medicine.

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 medical policy statement against such interference. It seems the NRC's primary regulatory focus is predicated on the assumption that misadministrations of diagnostic radiopharmaceuticals pose a serious threat to the public health. I think if this issue were studied carefully either by the National Academy of Sciences or the NCRP, it would find that such regulations would cause considerably more harm than they would prevent.

In closing, I would strongly urge the NRC to adopt the ACNP/SNM petition for role making as quickly as possible.

Sincerely yours,

Christopher L. Hansen, M.D.
Asst. Professor of Medicine
and Diagnostic Imaging

CLH:jc