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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:

I am writing on behalf of my colleagues and myself to express our support for the Petition for Rulemaking filed by the American College of Nuclear Physicians and the Society of Nuclear Medicine. We believe that the revised 10 CFR 35 regulations (effective April 1987) represent a thoroughly unjustified and inappropriate expansion of NRC authority over the practices of medicine and pharmacy with deleterious consequences for the health and well-being of patients.

It is the mandate of the NRC to be sure that radioactive materials are handled safely by personnel trained in their use, so that the radioactivity does not endanger the patient. It is not the NRC's mandate to impose limitations on uses of FDA-approved pharmaceuticals, radioactive or not, stricter than those imposed by the FDA itself. Adherence, for example to the 6-hour limitation for administration of a reconstituted kit preparation included in the package insert would deprive many patients of having their life-saving tests on a particular day, and would inexorably drive up the cost of what are now readily available tests. Such a restriction shows a thorough misunderstanding of the way pharmacies and medical facilities, unlike factories, operate. While there are specific preparations that may deteriorate once prepared, such as 99mTc-DMSA, this is not true for the majority of commonly used diagnostic agents. The physicians and pharmacists using these agents, regulated by their respective state agencies, are better able flexibly to determine to which preparations such a restriction need apply. There is no demonstrable or potential hazard sufficient for you to hamstring the daily practice of nuclear medicine in this manner.

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The FDA has long recognized that medical science progresses faster than its own ability to keep up with package insert changes, and that manufacturers have little economic incentive to return for frequent revisions. Therefore physicians have been able to expand the uses of approved pharmaceuticals into areas not envisioned when the drug was first developed. Yet the NRC would, for example, prevent a patient with life-threatening malignant pericardial effusion from receiving intrapericardial P-32 because a package insert developed decades ago includes only intracavitary indications recognized at the time. Many non-radioactive anti-cancer drugs were originally approved for use against only one particular malignancy; had the FDA pursued a course like the NRC's many successful chemotherapeutic protocols would never have been developed and many patients would have died sooner. We are on the threshold of a new era in radiotherapy with monoclonal antibodies, a very similar situation in which initial efficacy studies are performed in patients with one type of tumor, in order to obtain FDA approval within a finite time. Your rule will deprive patients with other lesions from receiving these agents even after clinical investigations show them effective.

There are more examples that can be offered but I am sure you will receive many from other of colleagues concerned about this unnecessary and dangerous infringement on medical practice. Its existence and enforcement pose a far greater health threat than any risk imagined by the NRC to exist from nuclear medicine diagnostic or therapeutic misadministrations. That risk has never been substantiated by the NRC, which we urge to study the subject before imposing unreasonable and unwise restrictions on the practice of trained professionals.

In closing, we urge the expeditious adoption of the ACNP/SUM Petition for Rulemaking.

Yours truly,

Letty G. Lutzker, M.D.
Chief, Nuclear Medicine