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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 practicing Nuclear Medicine physician at the Morton Plant Hospital in Clearwater, Florida. The revised 10 CFR 35 regulations (effective April, 1987) are of great concern to me in view of their impact on patient care.

Over the years it has been recognized that the FDA package insert was never meant to prohibit physicians from using the pharmaceutical for other uses. In fact it has been clearly indicated that such deviation often led to new and valid uses. Regulatory provisions in Part 35 (35.100, 35.200, 35.300 and 33.17(a)(4) inappropriately interfere with the practice of medicine contrary to the NRC's policy against such interference.

Regulatory changes such as these are apparently based on the thought that misadministration of diagnostic radiopharmaceuticals is a serious threat to patients. I do not think such is the case and urge the NRC to pursue a comprehensive study by a reputable scientific panel.

I strongly recommend adoption of the ACNP/SNM Petition for Rulemaking.

Sincerely yours,

Ben I. Friedman M.D.
Medical Director, Department of Nuclear Medicine
Morton Plant Hospital

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