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PLANT CITY

William H. Anderson
Administrator/CEO

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OFFICE OF SECRETARY DOCKETING & SERVICE BRANCH

December 11, 1989

Secretary of the Commission
U.S. Nuclear Regulatory Commission
Docketing and Service Branch, Docket #PRM-35-9
Washington, DC 20555

Re: ACNP/SNM PETITION FOR RULEMAKING

Dear Mr. Secretary,

I am a practicing Nuclear Medicine/Diagnostic Radiology Physician, practicing in Plant City, Florida at South Florida Baptist Hospital. I am very concerned over the revised 10 CFR 35 regulations governing the medical use of byproduct material. 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.

The FDA allows, and often encourages, other clinical uses of approved drugs. In the past it has been clear that the package insert was never intended to prohibit physicians from deviating from it for other indications. Such deviation in the past has resulted in the development of new diagnostic and therapeutic procedures. Practicing physicians will not attempt careless or unreasonable use of isotopes, especially in the current litigious environment, if it does not have an excellent chance of improving the care of their patients. 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 inappropriately interfere with the practice of medicine, which directly contradicts the NRC's Medical Policy statement against such interference.

It is my feeling that highly restrictive NRC regulations will only jeopardize public health and safety by restricting access to appropriate Nuclear Medicine procedures.

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It is always difficult to achieve a proper balance between under and over regulation. However we must have that balance; a risk free society or environment is also a stagnant society or environment. The NRC should 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 the professional judgement of physicians and pharmacists who have been trained to administer and prepare these materials.

Since the NRC's primary regulatory focus appears to be based on the apparently unsubstantiated assumption that misadministrations, particularly those involving diagnostic radiopharmaceuticals, pose a serious threat to the public health and safety, I strongly urge the NRC to pursue a comprehensive study by a reputable scientific panel, such as the National Academy of Sciences or the NCRP, to assess the radiobiological effects of misadministrations from Nuclear Medicine diagnostic and therapeutic studies. I firmly believe that the results of such a study will demonstrate that the NRC's efforts to impose more and more stringent regulations are unnecessary and not cost-effective in relation to the extremely low health risk of these studies.

I strongly urge the NRC to consider and adopt the ACNP/SNM Petition for Rulemaking.

Yours truly,

A. John Elliott, M.D.

A. John Elliott, M. D.

AJE/clw