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DIPLOMATE AMERICAN BOARD OF NUCLEAR MEDICINE
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December 7, 1989

Secretary of Commission
U.S. Nuclear Regulatory Commission
Docketing and Service Branch, Docket #PRM-35-9
Washington, DC 205555

Dear Mr. Secretary,

I am a practicing Nuclear Medicine Physician at the Florida Medical Center in Ft. Lauderdale, Florida. The proposed revision of 10 CFR 35 regulations governing the medical use of byproduct material will have a significant negative impact on my ability to practice Nuclear Medicine and Nuclear Pharmacy in the appropriate way.

As you may recognize, the practice of Nuclear Medicine is a distinct specialty providing direct patient care for a broad spectrum of disease entities with cardiovascular, oncological, renal, orthopedic, endocrine and gastrointestinal disorders among the most common. The nature of Nuclear Medicine practice requires individual judgements for each patient with respect to appropriate individualized diagnostic and therapeutic decisions.

It is my strong belief that the regulatory provisions in Part 35 (35.100, 35.200, 35.300 and 35.17 (a)(4) do not allow practices which are legitimate and legal under FDA regulations and the Florida State Medicine and Pharmacy Laws. Therefore, these regulations interfere with my practice of medicine and my best medical judgement. It is clear that these directly contradict the NRC medical policy statement against that interference.

The FDA currently does allow and often encourages individual judgements with respect to the clinical uses of approved drugs. Package inserts primarily serve as a guideline, but they were never intended to prohibit physicians from deviating from it for other appropriate and subsequently established indications. While some regulations are well intended and do serve a means to protect the public, regulations should not be used to totally inhibit clinical and medical judgement when necessary and appropriate.

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An additional level of regulation by the NRC in the presence of current FDA regulations is unnecessary, even though well intended, and will have no beneficial effect or additional protection for the public. There is no significant evidence that the current state of affairs under the FDA regulations and the Medicine and Pharmacy Laws at the state level require adjustment. In other words, "if it ain't broke, don't fix it." Anything that restricts the utilization of Nuclear Medicine procedures can have the consequence of exposing patients actually to higher radiation observed doses, resulting from alternative and ionizing radiation even less optimal study. It appears that the NRC is attempting to control the practice of medicine in every detail when it relates to radiopharmaceuticals. Furthermore, the proposed additional regulation will have an impact on and compete with State Boards of Pharmacy and other organizations, including the Joint Commission on Accreditation of Hospitals and Institutional Peer Review and Quality Assurance review procedures. There is no evidence that misadministration of diagnostic radiopharmaceuticals poses any serious threat to public health and safety. The frequency is miniscule. The impact is nil. If additional regulations are needed, they should be based on demonstrated need and not on misguided attempts to further hamstring the practice of medicine.

I strongly urge the NRC to adopt the Petition for Rulemaking filed by the American College of Nuclear Physicians and the Society of Nuclear Medicine.

Sincerely yours,

August Miale, Jr., M.D.

AM/jmc