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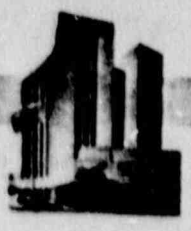

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October 25, 1989

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 to 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 Nassau County Medical Center in East Meadow, NY. I am deeply concerned over the revised 10 CFR 35 regulations (effective April, 1987) governing the medical us of byproduct material as they signficantly impact my ability to practice high-quality Nuclear Medicine/Nuclear Pharmacy and are preventing me from providing optimized care to individual patients.

For example, if I am forced to follow the package insert for Therapeutic Iodine-131 (I-131) from the CIS corporation, I would have to adhere to the usual recommended dose range of 4-10 millicuries (mCi) of Iodine-131. This dosage range would be inappropriate for the many hyperthyroid patients I see who have Plummer's Syndrome or Toxic Multinodular Goiter. Such patients usually require therapeutic dose ranges of 12-30 mCi of Iodine-131 for effective radioablation.

The CIS package insert also states that the usual dose of Iodine-131 for ablation of residual thyroid cancer is 50 millicuries and the usual dose for treatment of thyroid metastases is 100-150 millicuries. This is not necessarily true.

Many Nuclear Medicine physicians including myself prefer to use doses of 75 millicuries of Iodine-131 for ablation of residual thyroid cancer. I also prefer to individualize the therapy of patients with thyroid metastases depending on factors such as the size and location of the metastases and the biological half-life of Iodine-131 in the patients body. These factors may dictate that I use dosage ranges of 150-350 millicuries of Iodine-131 for radioablation.

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The NRC should recognize that the FDA does allow, and often encourages, other clinical uses of approved drugs, and actively discourages the submission of physician-sponsored IND's that describe new indications for approved drugs. The package insert was never intended to prohibit physicians from deviating from it for other indications; on the contrary, such deviation is necessary for growth in developing new diagnostic and therapeutic procedures. In many cases, manufacturers will never go back to the FDA to revise a package insert to include a new indication because it is not required by the FDA and there is simply no economic incentive to do so.

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's Medical Policy statement against such interference.

Finally, I would like to point out that highly restrictive NRC regulations will only jeopardize public health and safety by: restricting access to appropriate Nuclear Medicine procedures; exposing patients to higher radiation absorbed doses from alternative legal, but non-optimal, studies; and exposing hospital personnel to higher radiation absorbed doses because of unwarranted, repetive procedures. The NRC should not strive to construct proscriptive regulations to cover all aspects of medicine, nor should it attempt to regulate radiopharmaceutical use. Instead, 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 Q/A review procedures, and most importantly, the professional judgement of physicians and pharmacists who have been well-trained to administer and prepare these materials.

Since the NRC's primary regulatory focus appears to be based on the 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 risks of thes studies.

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In closing, I strongly urge the NRC to adopt the ACNP/SNM Petition for Rulemaking as expeditiously as possible.

Sincerely,

Philip A. Bardfeld, M.D.
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Nassau County Medical Center
Professor of Clinical Radiology
State University of New York
Health Science Center at Stony Brook

PB/pc