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November 8, 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 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 Wishard Memorial Hospital Indianapolis, Indiana. I am deeply concerned over the revised 10 CFR 35 regulations (effective April, 1987) governing the medical use of byproduct material as they significantly impact my ability to practice high-quality Nuclear Medicine/Nuclear Pharmacy and are preventing me from providing optimized care to individual patients.

The manufacturers' instructions for kit preparation may require modification for optimum patient care. An example would be the preparation of macroaggregated albumin for lung scanning to rule out pulmonary embolism in a patient with pulmonary hypertension. Since pulmonary angiography is contraindicated in these patients, the lung scan may be the only means of making the diagnosis of pulmonary embolism. Several articles have recommended decreasing the number of macroaggregated albumin particles administered, but increasing the activity per particle since these patients have so little pulmonary reserve. By reconstituting the kit only as the package insert recommends, some of these patients with pulmonary hypertension may die. In addition, most package inserts do not recommend their product for children; however, sometimes it is necessary clinically. For example, many surgeons request a bone scan in children with bone infection to determine where, precisely, they should operate. Failure to recognize all sites of infection could lead to the destruction of a joint and ultimately, a crippled child. Parading crippled children before congress would not serve the NRC or medicine's best interests.

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"Division of Hospitals . . .  
The Health and Hospital  
Corporation of Marion County"

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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 described 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 and 33.17(e)(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.

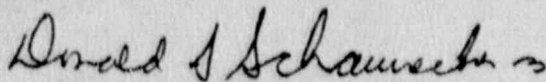
Finally, I would like to point out that highly restrictive NRC regulations will only jeopardize public health and safety by: restricting access to appropriate Nuclear Medicine procedures; exposing patients to higher radiation absorbed doses from alternative legal, but non-optimal, studies; and exposing hospital personnel to higher radiation absorbed doses because of unwarranted, repetitive 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 RBC 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 these 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,



Donald S. Schauwecker, Ph.D., M.D.  
Chief, Nuclear Medicine

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