Methodist Hospital OF INDIANA, INC.

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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 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 Methodist Hospital in 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. These rules make it very difficult to provide optimized care to individual patients.

A good example would be ^{99m}Tc-sulfur colloid. The package insert allows this material to be constituted and injected only intravenously up to 6 hours after kit formulation. Strict adherence to the requirements under the revised 10 CFR 35 would preclude the following clinically efficacious studies from being performed on my patients: 1) this agent is useful in locating sites of acute gastrointestinal bleeding (I.V.), 2) use in determining rates of gastric emptying in vomiting disorders (oral), 3) for evaluations of tearing disorders by lacrimal imaging (topical on the eye), 4) lymphatic drainage patterns in certain malignancies such as melanoma (subcutaneous).

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.

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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.

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 are not cost-effective. In closing, I strongly urge the NRC to adopt the ACNP/SNM Petition for Rulemaking as expeditiously as possible.

Sincerely,

Larry L Heck, MD

Larry L. Heck, M.D.
Department of Nuclear Medicine

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