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Veterans Administration

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

In Reply Refer To:
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BRANCH

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 technologist at the VA Medical Center, Sepulveda, California. I am deeply concerned over the revised 10 CFR 35 regulations 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 effective care to patients.

The NRC should recognise 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. In many cases, manufacturers may 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) do not allow practices which are legitimate and legal under FDA regulations and State medicine and pharmacy laws. These regulations interfere with the practice of medicine, which directly contradicts the NRC's Medical Policy statement against such interference.

Finally, I feel that restrictive NRC regulations will jeopardize public health and safety. Exposing patients to higher radiation absorbed doses. Exposing hospital personnel to higher radiation absorbed doses because of unnecessary, repetitive procedures. The NRC should not strive to construct proscriptive regulations to cover all aspects of medicine, nor should it attempt to regulate radipharmaceutical 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 Accredition 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.

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

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

Sincerely,

Archie L. Brown NMT

Archie Brown, NMT
VA Medical Center, Sepulveda, California