258

Secretary of the Commission *November 17, 1989*
U.S. Nuclear Regulatory Commission
Docketing and Service Branch, Docket #PRM-35-9
Washington, D.C. 20555

'89 NOV 27 P3:28

Dear Mr. Secretary,

I strongly support the Petition for Rulemaking filed by the American College of Nuclear Physicians and the Society of Nuclear Medicine. As a practicing Nuclear Medicine physician at William Beaumont Hospital in Royal Oak, MI and a Clinical Associate Professor at the University of Michigan and Wayne State University Medical Schools, I remain opposed to revised 10 CFR 35 regulations effective 4/87 governing the medical use of byproduct material as they significantly affect my ability to render high quality Nuclear Medicine care to individual patients referred to me for diagnostic and therapeutic procedures.

Physicians involved in clinical practice have understood from the beginning the difference between FDA-approved indications for a given drug and using the particular drug in accordance with FDA regulations. For years, I used various beta-blockers such as propranolol to treat acutely-ill patients with hyperthyroidism in accordance with FDA regulations, yet this was not an FDA-approved indication for these agents. Similarly, radioiodine (I-131) is beneficial in reduction of goitrous tracheal or esophageal compressive symptomatology in selected patients in my practice, yet this is not an FDA-approved indication for its use.

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 INDs 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 for them 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 interfere with the practice of medicine, which directly contradicts the NRC's Medical Policy statement against such interference. Highly restrictive NRC regulations will only jeopardize public health and safety. Just last week, I was required to admit to our hospital an 80 year old woman living at home alone and participating in all activities of daily living just to administer 100 mCi of I-131 to treat her Plummer's Disease. The private room, the monitoring, the unnecessary radiation exposure to hospital personnel, and the $1500 expended by Medicare were required by 10 CFR 35 and without any benefit to the patient or the general public.

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

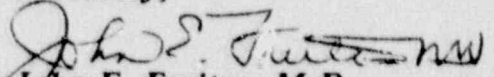
DS10

Boards of Parmacy, 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.

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 these studies.

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

Sincerely,



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