DOCKET NUMBER
PETITION RULE PRM 35-9
(54 FR 38239)

(93)

Beaumont

William Beaumont Hospital
Royal Oak

Nuclear Medicine
Howard J. Dworkin, M.D.
Director

'89 OCT 27 P4:23

October 23, 1989

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

Dear Mr. Secretary:

I write at this time 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 practice nuclear medicine at William Beaumont Hospital in Royal Oak, Michigan. I am 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 and have in several instances prevented me from providing optimized care to individual patients.

If manufacturers' instructions as presented in the package insert were followed strictly, I would no longer be able to perform gastric emptying studies with a sulfur colloid meal, would no longer be able to use macroaggregated albumin for the detection of patency of a Levine shunt, and I would no longer be able to use white blood cells labeled with HMPAO technetium-99m. In addition, high specific activity MAA is required for the performance of right-to-left cardiac shunt studies, and if the manufacturers' instructions are strictly adhered to, large amounts of technetium-99m could not be placed on the MAA, thus causing some hazard to the patient.

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 in my opinion was never intended to prohibit physicians from deviating from it for other indications when these other indications are in the patient's best interest. Such deviations are necessary for growth in developing new diagnostic and therapeutic agents. In many cases, manufacturers will not go back to the FDA to revise their package insert to include new indications because it is not required by the FDA, and there is simply no economic incentive to do so. This latter point is extremely important in the radiopharmaceutical field.

continued...

DS10

3601 West Thirteen Mile Road Royal Oak, Michigan 48072 (313) 551-4128

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 as I practice it, which directly contradicts the NRC's medical policy statement against such interference.

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 alternate legal, but non-optimal, studies; and exposing hospital personnel to higher radiation absorbed doses because of unwarranted repetition of 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 Health Care Organizations, radiation safety committees, institutional Q/A review procedures, and most importantly, 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 procedures. I firmly believe that the results of such a study will demonstrate that the NRC's effort 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 thes ACNP/SNM Petition for Rulemaking as expeditiously as is possible.

Sincerely,

Howard J. Dworkin, M.D.
Director, Department of Nuclear Medicine

HJD:cg
(Oc2389.L1)