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Humana Hospital Audubon

October 20, 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:

This letter is to express my strong support for the petition for rule making filed by the Americal College of Nuclear Physicians and the Society of Nuclear Medicine. I am a board certified Nuclear Medicine Physician at Humana Hospital Audubon in Louisville, Kentucky. The revised regulation 10 CFR 35 (effective April, 1989) governing the medical use of byproduct material has a significant impact on delivering high quality Nuclear Medicine/Nuclear Pharmacy.

Had this change been in effect in the early 80's we would probably not be able to do gastric emptying and gastroesophageal reflux studies to this date. We would also not be able to do isotope cystograms and reflux studies. These are only two examples of studies that formerly required a hundred times greater radiation dose to the patient than what they are now receiving for better quality studies.

If your proposed regulation goes into effect you are in essence governing the practice of medicine by the individual phyisician--even the FDA does not do this. I therefore believe that it is not in the expertise of the NRC to take upon itself the practice of medicine when the FDA, which may be somewhat more competent in this field does not dare do so.

In the 12 years that I have been chairman of the Institutional Review Board here at Audubon I've had numerous contacts with the FDA and appeared before their advisory committee and found that they were not adverse to clinical uses and routes of administration that differed from the package insert.

It is an extremely expensive process for pharmaceutical houses to supply the necessary information to the FDA to make changes on the package inserts. There is no financial reward nor is there always the possibility of even recouping expenses for the suppliers of our isotopes or kits to add indications to the package insert. If the proposed regulation goes into effect advances in Nuclear Medicine will certainly be stiffled and only the patient will suffer. As has been pointed out repeatedly the regulatory provisions in part 35 (35.100, 35.200, 35.300, and 33.17 (a)(4)) do not allow

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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 statment 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, and I strongly urge the NRC to pursue a comprehensive study by a reputable scientific panel, such as a National Academy of Sciences or the NCRP, to assess the radiobiological effects of misadministration from Nuclear Medicine diagnostic and therapeutic studies. I firmly believe that the results of such a study will demonstrate that he 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.

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

Sincerely,

George H Zenger

George H. Zenger, M.D.
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GHZ/mm