

P.O. Box 35070
Louisville, KY 40232-5070
502-562-802C

DOCKET NUMBER PR 35-9
PROPOSED RULE
(54FR 38239)

167

'89 NOV -7 24:10

November 2, 1989

Secretary of the United States
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 rule-making filed by the American College of Nuclear Physicians and the Society of Nuclear Medicine. I am a practicing nuclear medicine physician at Norton Hospital in Louisville, Kentucky. I am deeply concerned over the revised ten 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, nuclear pharmacy, and are preventing me from providing optimized care to individual patients.

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 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 and developing new diagnostic and therapeutic procedures. In many cases, manufacturers will never go back to the FDA to revise the 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. For example, Technetium 99m sulfur colloid can be used to evaluate gastric emptying or can be used intraperitoneally to evaluate the peritoneal spaces prior to radiation therapy.

Currently the regulatory provisions in part 35 (35.100, 35.200, 35.300, and 33.17A4), 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.

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 nonoptimal studies; and

8911080496 891102
PDR PRM
35-9
PDR

Norton Hospital Kosair Children's Hospital Methodist Evangelical Hospital

2510

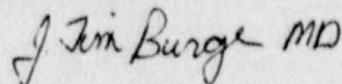
November 2, 1989

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 Health Care Organizations, radiation safety committees, institutional QA 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, 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 misadministration 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 risk of these studies.

In closing, I strongly urge the NRC to adopt the ACNP/SNN petition for rule-making as expeditiously as possible.

Sincerely,



J. Timothy Burger, M.D.
Department of Radiology
Norton Hospital

JTB/smc
6207V