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Congress of the United States
House of Representatives
Washington, DC 20515

January 3, 1989

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Mr. Kenneth Carr
Chairman
U.S. Nuclear Regulatory Commission
1717 H Street
Washington, DC 20555

Dear Mr. Carr:

Attached is correspondence I have received from the my constituent, Shannon Anderson, concerning your agency's 10 CFR 35 regulations pertaining to the medical use of by-product material.

It would be greatly appreciated if you could respond to Ms. Anderson's concerns in a format suitable for forwarding to her. It would also be appreciated if you could provide my office with any background information you believe pertinent to the 10 CFR 35 regulations and the Petition for Rulemaking.

Thank you again for your assistance in this matter.

With kindest regards, I am

Yours truly,

JOHN J. DUNCAN, JR.
Member of Congress

JJD:jd

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December 4, 1989

DEC 1 1 1989

The Honorable John J. Duncan, Jr.
United States House of Representatives
506 Cannon House Office Building
Washington, DC 20515

Dear Representative Duncan:

I wish to express my strong support of the American College of Nuclear Physicians and the Society of Nuclear Medicine in their Petition for Rulemaking. I am very concerned over the revised 10 CFR 35 regulations (effecti e April, 1987) which govern the medical use of byproduct material. These regulations significantly impact my ability to provide quality radiopharmaceuticals and optimum patient care.

For example, if expiration times are to be strictly followed, crucial emergency studies may be delayed thus jeopardizing patient care.

The FDA allows and often encourages other clinical uses of approved durgs. The FDA also openly discourages the submission of physician sponsored INDs that describe new indications for approved pharmaceuticals. The NRC should recognize this approach. Package inserts were never intended to prohibit medical practitioners from using drugs for other indications. In fact, such deviation is necessary for growth and development of new therapeutic and diagnostic practices. The FDA does not require package insert revisions to reflect new indications. Because it is not required and is, in fact very costly, many manufacturers never revise package inserts.

Currently, the regulatory provisions in Part 35 (35.100, 35.200, 35.300 and 33.17(a)(4)) conflict with practices which are legitimate and legal under state pharmacy laws, state medical laws, and FDA regulations. 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 the 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-optional, 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, 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 misadminstrations from Nuclear Medicine diagnostic and therapeutic procedures. 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.

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

Sincerely,

Shannon Kelly Anderson, Pharm.D.

Shannon Kelly Anderson, Pharm.D.
Nuclear Pharmacist
Syncor International Corporation

SKA/pm