



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

January 11, 1990

The Honorable Jon Kyl
United States House of Representatives
Washington, D. C. 20515

Dear Congressman Kyl:

This is to acknowledge receipt of your letters dated December 5 and December 23, 1989, transmitting correspondence from your constituents, Mr. James J. Burnis and Dr. Richard J. Peterson, in support of a petition for rulemaking to revise 10 CFR 35 Regulations.

The petition for rulemaking was submitted to the Nuclear Regulatory Commission (NRC) by the American College of Nuclear Physicians and the Society of Nuclear Medicine. The petitioners requested that the NRC modify current regulations to allow: (a) the use of radiopharmaceuticals for therapeutic indications not listed in the package insert (diagnostic indications are not restricted by current regulations), (b) deviations from the manufacturer's instructions in preparing radiopharmaceuticals, and (c) compounding radiopharmaceuticals from reagent chemicals.

The NRC published a Federal Register notice (54 FR 38239, September 15, 1989), announcing receipt of the petition and providing a 90-day public comment period. We have received more than 400 comment letters.

In light of the information submitted by the petitioners and the commenters, the NRC is currently reexamining its regulations governing the use of radiopharmaceuticals in nuclear medicine. The issues raised will be addressed in a rulemaking proceeding specifically designed to resolve the petition. During this rulemaking process, the NRC will consult with the Food and Drug Administration, which approves the package inserts and the manufacturer's instructions, and the State Boards of Pharmacy and invite their views regarding the resolution of this petition.

I want to assure you that the comments of your constituents will be considered along with the others in reexamining our regulations. However, it would be premature to predict the outcome of the reexamination before completion of the rulemaking proceeding.

I trust this information is responsive to your request.

Sincerely,

Dennis K. Rithbun, Director
Congressional Affairs
Office of Governmental and
Public Affairs

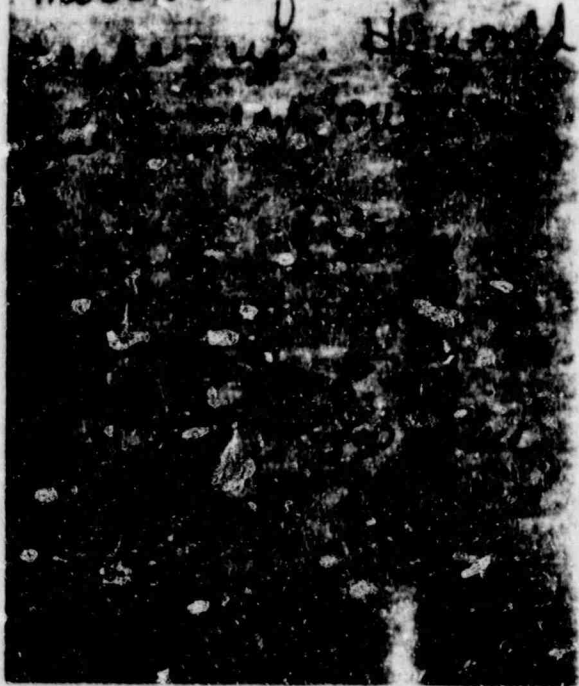
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Mr. Blaha

Dennis Rathbun brought
these over for OEDD's



Letter also verbally approved by Jim Blaha and Mike Weber
(per Dennis Rathbun/Betsy Keeling) ON 1-11-90.

HOUSE OF REPRESENTATIVES, U.S.
WASHINGTON, D.C.

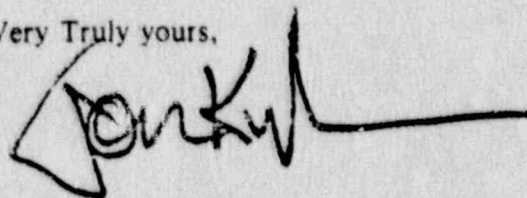
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Mr. Dennis Rathbun
Director of Congressional Affrs.
Nuclear Regulatory Commission
Washington, D.C. 20555

The attached communication is submitted for your consideration, and to ask that the request made therein be complied with, if possible.

If you will advise me of your action in this matter and have the letter returned to me with your reply, I will appreciate it.

Very Truly yours,



..... Jon Kyl
M.C.

..... Arizona, 4th. District.

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Lutheran Healthcare Network

Valley Lutheran Hospital
6644 Baywood Avenue
Mesa, Arizona 85206
(602) 981-2000

November 30, 1989

Congressman Jon Kyl
4250 E. Camelback Rd.
Phoenix, AZ

Dear Congressman Kyl:

I am writing 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 am a practicing Nuclear Medicine technologist at Valley Lutheran Hospital in Mesa, Arizona. I am deeply 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/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's 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 to do so.

Currently, the regulatory provisions in Part 35 (35.000, 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, 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 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 judgment of physicians and

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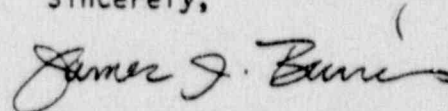
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pharmacists who have been well-trained to administer and prepare these materials.

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 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.

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

Sincerely,



James J. Burnis, CNMT
Valley Lutheran Hospital

JJB/bg

cc: Senator Dennis DeConcini
Senator John McCain
Congressman John J. Rhodes, III.
Congressman Robert Stump
Congressman Jon Kyl