LLOYD BENTSEN
TEXAS

COMMITTEES
FINANCE
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JOINT ECONOMIC
JOINT COMMITTEE ON TAXATION

United States Senate

WASHINGTON, D.C. 20510

December 15, 1989

Mr. Dennis Rathbun, Director
Office of Congressional Affairs
The United States Nuclear Regulatory
Commission
1717 H Street, N.W.
Washington, D.C. 20555

Dear Mr. Rathbun:

I recently received the enclosed constituent inquiry, and I would very much appreciate your providing me with any pertinent information you might have regarding the matter.

Your kind assistance is greatly appreciated.

Sincerely,

Lloyd Bentsen

Lloyd Bentsen

Enclosure

PLEASE REPLY TO:

961 Federal Building
Austin, Texas 78701
ATTN: [redacted]

12/20...To EDO for Direct Reply....Suspense: Jan 5..OCA to Ack, DSB...89-1351

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November 22, 1989

Senator Lloyd Bentsen
House of Senates
Washington, D.C. 20515

Dear Senator:

This letter is in support of the American College of Nuclear Physicians and the Society of Nuclear Medicine' Petition for Rulemaking. This Petition for Rulemaking is necessary to clarify the ability of pharmacists and physicians to practice pharmacy and medicine.

Nuclear pharmacists compound and dispense radiopharmaceuticals upon the order of a licensed nuclear physician. Both nuclear pharmacists and physicians are trained professionals. The physician has the clinical expertise to decide what study a particular patient needs and what radiopharmaceutical should be used. The nuclear pharmacist has the expertise to compound the radiopharmaceutical the physician orders. The practice of medicine and pharmacy is clearly governed by the States regardless of specialty. NRC regulation of the practice of these professionals must be avoided since it will hamper the physicians and pharmacists ability to deliver quality patient care.

Of particular interest is the NRC's recent reinterpretation of license conditions for nuclear pharmacies and regulations for nuclear medicine licensees. At issue is a requirement to strictly follow the manufacturer's instructions for preparation of radiopharmaceuticals as printed in the manufacturer's package inserts. The package insert information should be used as a guideline in the preparation and use of any product, but pharmacists must have the ability to use professional judgement in compounding to assure the prescribing physician receives the most efficacious product for his/her patient.

[illegible] patients. The quality of medical care for these patients could be greatly increased if their diagnoses were supplemented with nuclear medicine studies.

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This Petition for Rulemaking is necessary to clarify that physicians and pharmacists have the flexibility to use radiopharmaceutical products as necessary and appropriate in the diagnosis and treatment of patients. Death, injury or inappropriate treatment of patients may result from any mandated, verbatim following of the package insert instructions.

I urge you to strongly consider the ACNP/SNM's Petition for Rulemaking. Its adoption would clarify the ability of Nuclear Medicine Physicians and Nuclear Pharmacists to give the best patient care.

Sincerely,

B. Nguyen RPh.
Nuclear Pharmacist

BAO NGUYEN, R.Ph.
Nuclear Pharmacist

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Washington, D.C. 20515

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Of particular interest is the NRC's recent reinterpretation of license conditions for nuclear pharmacies and regulations for nuclear medicine licensees. At issue is a requirement to strictly follow the manufacturer's instructions for preparation of radiopharmaceuticals as stated in the manufacturer's package insert. The package insert information should be considered as guideline in the preparation and use of any product , but pharmacists must have the ability to use professional judgement in compounding to assure the prescribing physician receives the most efficacious product for his/her patient.

Physicians must also prescribe products which are most appropriate for their individual patients. A strict following of the package insert could delay or prevent diagnosis of illness in some patients. The quality of medical care for these patients could be greatly increased if their physicians were allowed to perform more nuclear medicine studies.

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I urge you to strongly consider the ACNP/SNM's Petition for Rulemaking. Its adoption would clarify the ability of Nuclear Medicine Physicians and Nuclear Pharmacists to give the best patient care.

Sincerely,

Richard Sheriff

Richard Sheriff RPh.
Nuclear Pharmacist

RICHARD SHERIFF, R.Ph.
Pharmacy Manager

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Proposed Rules

Federal Register
Vol. 54, No. 178
Friday, September 15, 1989

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 30, 33, and 35

[Docket No. PRM-35-9]

American College of Nuclear Physicians and the Society of Nuclear Medicine; Receipt of Petition for Rulemaking

AGENCY: Nuclear Regulatory Commission.

ACTION: Petition for rulemaking; notice of receipt.

SUMMARY: The Commission is publishing for public comment a notice of receipt of a petition for rulemaking dated June 5, 1989, which was filed with the Commission by the American College of Nuclear Physicians and the Society of Nuclear Medicine. The petition was docketed by the Commission on June 8, 1989, and has been assigned Docket No. PRM-35-9. The petitioners request that the Commission revise its regulations to give cognizance to the appropriate scope of their practice of medicine and pharmacy and thereby allow nuclear physicians and nuclear pharmacists to reconstitute non-radioactive kits differently from the method recommended by the manufacturer; allow nuclear physicians and nuclear pharmacists to prepare radiopharmaceuticals whose manufacture and distribution are not regulated by FDA; and permit nuclear physicians to determine appropriate diagnostic and therapeutic applications of radiopharmaceuticals.

DATES: Submit comments by December 14, 1989.

Comments received after this date will be considered if it is practical to do so, but the Commission is able to assure consideration only for comments received on or before this date.

ADDRESSES: All persons who desire to submit written comments concerning the petition for rulemaking should send their comments to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Service Branch.

Deliver comments to the One White Flint North Building, 11555 Rockville Pike, Rockville, Maryland between 7:30 a.m. and 4:15 p.m., Federal workdays.

For a copy of the petition, write the Regulatory Publications Branch, Division of Freedom of Information and Publications Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555.

The petition and copies of comments received may be inspected and copied for a fee at the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC.

FOR FURTHER INFORMATION CONTACT: Michael T. Lesar, Acting Chief, Rules Review Section, Regulatory Publications Branch, Division of Freedom of Information and Publications Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Telephone: 301-492-7758 or Toll Free: 800-368-5642.

SUPPLEMENTARY INFORMATION:

Petitioners

The American College of Nuclear Physicians (ACNP) and the Society of Nuclear Medicine (SNM) are comprised of over 12,000 individuals who participate in the medical use of byproduct material. Members include physicians, technologists and nuclear pharmacists. The physicians supervise the preparation and administration of radiopharmaceuticals to diagnose and treat patients. Technologists administer radiopharmaceuticals and perform clinical procedures under the direction and supervision of an authorized user physician. Nuclear pharmacists reconstitute radiopharmaceutical kits, compound radiopharmaceuticals, and dispense radiopharmaceuticals for medical purposes.

Petitioner's Interest

The petitioners are interested in the requested action because under current NRC regulations, members of the petitioning organizations believe they cannot appropriately practice their professions. The petitioners state that authorized user physicians cannot prescribe certain radiopharmaceuticals or routes of administration for optimal patient care, even though they are permitted to do so by the Food and Drug Administration (FDA) and by their state medical licenses. According to the petitioners, nuclear pharmacists have been disenfranchized as a professional entity because activities that are permitted by the FDA and the states are not allowed under NRC regulations. The petitioners state that although a nuclear pharmacist is authorized by state license to prepare radiopharmaceuticals for patient administration upon receipt of a prescription by an authorized user physician, current NRC regulations severely restrict their activity to rigid reconstitution of standard kits and to dispensing doses of radiopharmaceuticals distributed by manufacturers. Nuclear medicine technologists reconstitute radiopharmaceuticals and perform clinical procedures under the supervision of an authorized user physician. The petitioners believe that their professional activities are curtailed by the limitations imposed on nuclear physicians and pharmacists.

Background

The petitioners begin the petition with a recitation of the following:

At the time the Atomic Energy Act of 1954 was passed, the FDA did not regulate radioactive drugs (although they had the mandate to do so). FDA began regulating accelerator-produced radiopharmaceuticals in 1968 and began regulating byproduct radiopharmaceuticals in 1974. Until that time, the preparation and use of radiopharmaceuticals made from byproduct material had been regulated solely by the Atomic Energy Commission (now the Nuclear Regulatory Commission). As years passed, FDA continued to refine its role in reviewing, approving, and regulating radiopharmaceuticals for research and clinical purposes.

FDA now regulates all radiopharmaceuticals, whether made by manufacturers, nuclear pharmacists or their designees in medical institutions or in centralized radiopharmacies, or nuclear physicians or their designees. FDA has the Federal authority to regulate all research and clinical use of radioactive drugs directly or indirectly. Because of the exemption from manufacturing and distribution requirements of the FDA for pharmaceuticals (including radiopharmaceuticals) prepared under State laws regulating the practice of

medicine and pharmacy, commercial New Drug Applications are not granted for these drug preparations. These drugs are still recognized and regulated by FDA.

The practices of medicine and pharmacy are exempt from FDA's manufacturing and distribution regulations by congressional mandate, but they are not exempt from FDA's regulations forbidding misbranding and adulteration. The FDA is the enforcement arm of the drug quality standards published in the United States Pharmacopoeia.

Petitioner's Proposal

The petitioners propose the following amendments.

1. Define "medical research use" in 10 CFR 30.4 as follows:

Medical Research Use means the intentional internal or external administration of byproduct material, or the radiation therefrom, to human subjects for research purposes.

2. Define "radiopharmaceutical" in 10 CFR 35.2 as follows:

Radiopharmaceutical means any drug or biologic that contains byproduct material.

3. Define "medical research use" in 10 CFR 35.2 as follows:

Medical Research Use means the intentional internal or external administration of byproduct material, or the radiation therefrom, to human subjects for research purposes.

4. Redefine "medical institution" in 10 CFR 35.2 as follows:

Medical Institution means a single health care facility or a health care organization which may physically exist in multiple separate locations but is integrated through economic and/or management agreements. Several medical disciplines may be practiced in a medical institution.

5. With regard to Practice of Pharmacy, Practice of Medicine, and Medical Research, the petitioners recommend the following amendments to §§ 35.100, 35.200, and 35.300:

Section 35.100

(a) A licensee may use for medical use any byproduct material in a radiopharmaceutical and for a diagnostic use involving measurements of uptake, dilution, or excretion in which:

(1) The radiopharmaceutical is manufactured and distributed in accordance with the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, or:

(2) The radiopharmaceutical is manufactured, prepared, propagated, compounded, or processed under an exempt category of section 510(g) of the Federal Food, Drug and Cosmetic Act.

(b) A medical institution licensee may use for medical research use any byproduct material in a radiopharmaceutical and for a use involving measurements of uptake, dilution, or excretion if its use has been approved by the Radiation Safety Committee (RSC) and the Institutional Review Board (IRB) chartered in accordance with 45 CFR part 46.

Section 35.200

(a) A licensee may use for medical use any byproduct material in a radiopharmaceutical and for a diagnostic use involving imaging in which:

(1) The radiopharmaceutical is manufactured and distributed in accordance with the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, or:

(2) The radiopharmaceutical is manufactured, prepared, propagated, compounded or processed under an exempt category of section 510(g) of the Federal Food, Drug, and Cosmetic Act.

(b) A medical institution licensee may use for medical research use any byproduct material in a radiopharmaceutical and for a use involving imaging if its use has been approved by the RSC and the IRB chartered in accordance with 45 CFR part 46.

Section 35.300

(a) A licensee may use for medical use any byproduct material in a radiopharmaceutical and for a therapeutic use in which:

(1) The radiopharmaceutical is manufactured and distributed in accordance with the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, or:

(2) The radiopharmaceutical is manufactured, prepared, propagated, compounded, or processed under an exempt category of Section 510(g) of the Federal Food, Drug, and Cosmetic Act.

(b) A medical institution licensee may use for medical research use any byproduct material in a radiopharmaceutical for a therapeutic use if its use has been approved by the RSC and the IRB chartered in accordance with 45 CFR part 46.

6. With regard to NRC licenses, the petitioners recommend the addition of a new paragraph to 10 CFR 35.11.

(a) Any medical institution licensed to use byproduct material for medical use as described in § 35.100, § 35.200 or § 35.300 may also use byproduct material for medical research use described in the sections for which it is licensed. This authorization supersedes any license condition issued before (insert effective date).

7. With regard to suppliers, the petitioners recommend inserting a new paragraph to 10 CFR 35.49 and rename paragraph (c) as paragraph (d).

(c) Byproduct material in radiopharmaceuticals compounded by or under the supervision of a state-licensed nuclear pharmacist or nuclear medicine physician if such radiopharmaceuticals are manufactured, prepared, propagated, compounded, or processed under an exempt category of section 510(g) of the Federal Food, Drug, and Cosmetic Act.

8. With regard to free-standing radiopharmacies the petitioners request that NRC revise the regulations to allow free-standing radiopharmacies licensed under 10 CFR 32.72 and 10 CFR 32.73 to also compound radiopharmaceuticals. The petitioners believe that this must be accomplished by licensing action because those licenses have a clause that states that if the license document is more restrictive than the regulation, the license document takes precedence. According to petitioners, those licenses should be amended by NRC, without charge to the licensee, to remove the requirement to reconstitute radiopharmaceuticals in accordance with the manufacturer's instruction. Petitioners believe that in the event of any disciplinary action by NRC, the applicable State Board of Pharmacy should be alerted.

9. With regard to specific licenses of broad scope for medical research use, the petitioners request 10 CFR 33.11(a) be amended as follows:

(a) A "Type A specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use, and transfer of any chemical or physical form of the byproduct material specified in the license, but not exceeding quantities specified in the license, for purposes authorized by the Act. The quantities specified are usually in the multicurie range. Applicants that are medical institutions may conduct medical research use in addition to conducting research and development as defined in 10 CFR 30.4.

10. The petitioners recommend that 10 CFR 33.13(c)(3) be amended by adding a new paragraph (iv) as follows:

(iv) Review, approval, and recording by the Radiation Safety Committee and the Institutional Review Board of the Safety and ethics of proposed uses involving medical research use prepared

in accordance with paragraph (c)(3)(iii) of this section prior to use of the byproduct material.

11. Finally, the petitioners recommend that 10 CFR 33.17(a)(4) be amended to read as follows:

(4) Add or cause the addition of byproduct material to any food, beverage, cosmetic, drug, or other product designed for ingestion or inhalation by, or application to, a human being unless permitted by the license document to conduct medical research use.

Grounds for Petition

The petitioners request that the NRC revise its regulations to give cognizance to the appropriate scope of the practice of medicine and pharmacy. The petitioners believe that 10 CFR part 35 should be revised to recognize all the mechanisms that FDA uses to authorize the use of radiopharmaceuticals. According to the petitioners, granting of this petition would allow nuclear physicians and nuclear pharmacists to reconstitute non-radioactive kits differently from the method recommended by the manufacturer; allow nuclear physicians and nuclear pharmacists to prepare radiopharmaceuticals whose manufacture and distribution are purposefully not regulated by FDA; and permit nuclear physicians to determine appropriate diagnostic and therapeutic applications of radiopharmaceuticals, as is their professional obligation.

Statement in Support

The petitioners state that NRC mentions only two FDA compliance mechanisms. The two mechanisms cited are the approved Investigational New Drug Application (IND) and the approved New Drug Application (NDA). Petitioners state that there are other mechanisms to achieve FDA compliance which the petitioners believe should be added to NRC's regulations. According to petitioners, mechanisms are approval via Product License Application (PLA), Radioactive Drug Research Committee approval (RDRC), Institutional Review Board approval (IRB).

The petitioners believe that 10 CFR part 35 directly conflicts with FDA's regulatory framework. The petitioners state that except for physician sponsored "Notice of Claimed Investigational Exemptions" (IND), 10 CFR part 35 only allows the use of radiopharmaceuticals prepared under the portion of FDA regulations devoted to manufacturers with nationwide distribution. The petitioners believe that regulatory incompatibility between NRC regulations, FDA regulations, and state pharmacy and medicine laws is causing serious problems in the optimal delivery of quality nuclear medicine care and the implementation of nuclear medicine research.

Dated at Rockville, Maryland, this 8th day of September, 1989.

For the Nuclear Regulatory Commission.

Samuel J. Chilk,

Secretary of the Commission.

[FR Doc. 89-21607 Filed 9-14-89; 8:45 am]

BILLING CODE 7590-01-M