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Secretary of the Commission
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Attn: Docketing and Service Branch

Comments for Rulemaking Docket Number PRM-35-9 (Federal Register Notice Volume 54, Number 178 of 15 September, 1989.)

Dear Mr. Secretary:

I write in support of the petition for rulemaking filed by the American College of Nuclear Physicians and the Society of Nuclear Medicine.

The care for and service to individual patients is the primary duty and responsibility of physicians. These are legally assigned solely to physicians by society and the states. Before assuming this responsibility a physician must take extensive training and testing to receive a license to practice. The practice of medicine is carefully regulated by the states and when errors are made the courts serve as the remedy to compensate injured patients.

For physicians utilizing radioactive materials for diagnosis and therapy this duty and responsibility means providing the patient and his referring physician the most accurate and rapid diagnosis available. For diagnosis this may include using radiopharmaceuticals in ways not originally envisioned by the manufacturer. There is a direct parallel between using radiopharmaceuticals in this manner and the use of non-radioactive pharmaceuticals by physicians in the treatment of disease. The indications for use developed for a drug to gain NDA approval from the FDA are the simplest to prove the drug is effective. Typically additional indications are found, investigated, published and put into general use for care of sick people. These may never appear in the manufacturer's instructions.

This is common, legal, and approved practice as there is little reason for a manufacturer to pay to revise package inserts. When known effective it is unconscionable not to use either type of pharmaceutical because the specific indication is not listed by the manufacturer.

This is especially true of radiopharmaceuticals for diagnostic use. They have extremely small potential to produce harm. If safe Nuclear Medicine procedures are forbidden, there are alternative methods of gaining the same diagnostic information. These frequently are: 1. dangerous, 2. expensive, 3. painful, 4. slower, 5. less effective

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or have a higher radiation dose or a combination. It is difficult to believe that one can be prevented from helping sick people by regulations suited to nuclear applications with more potential to produce harm.

As a physician, I can direct a pharmacist to compound a medication to dispense to a patient. The pharmacist must recognize potential errors and question me if he does. Compounding and dispensing are part of the practice of Pharmacy and is well regulated by state and federal law and regulations. The selection of the prescription is my responsibility. As long as I follow state and federal laws and regulations I am free to prescribe what I decide is necessary. The addition of a radioactive tracer in itself should not add regulatory difficulties when the prescribing physician is licensed to use these materials.

The present NRC regulations do not recognize the protection provided patients by state licensing boards and the courts. Should a physician be "doing wrong" he likely will be disciplined by the board. If he harms patients, he is punished by the tort system.

Regulatory efforts should be made to ensure that users of byproduct materials are appropriately trained and use the materials in a prudent and safe manner. Carrying these regulations into the examining room and to patient care is interference into medical practice. The patient is well protected by other means. The NRC has judged me suitable as a user on the basis of training (3 specialized years), testing (American Board of Nuclear Medicine) and experience (17 years). You don't believe that I am competent to prescribe and use these radiopharmaceuticals in an appropriate and safe manner without more regulation. The carrier providing my insurance does not agree and judges on economic grounds that I am so unlikely to produce injury that my premiums are among the lowest.

I believe the Commission adopt the petition for Rulemaking as quickly as possible.

Yours truly,

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