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The University of Iowa Hospitals and Clinics
Department of Radiology

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October 17, 1989

Secretary of the Commission
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555
Attention: Docketing and Service Branch

RE: Docket No. PRM-35-9
Petition for Rulemaking, Nuclear Regulatory Commission, 10 CFR Parts 30, 33, 35

Dear Sirs:

I am writing to express my total, unequivocal support for the entire petition for rulemaking referred to above.

I am a practicing nuclear pharmacist working in the nuclear medicine department of a university hospital. I am a registered pharmacist licensed by the State Board of Pharmacy in my state and am board certified in Nuclear Pharmacy by the Board of Pharmaceutical Specialties.

All of my pharmacist colleagues who work in other practice settings are allowed to use their professional judgement and expertise to optimize the delivery and use of drugs for individual patients. Much of pharmacy practice, generally speaking, extends beyond the simple regulatory case of using FDA-approved drugs (i.e., NDA or IND) within the confines of package insert recommendations. For example, community pharmacists routinely compound and dispense skin lotions, emulsions, suppositories, etc., for individual patient use upon the receipt of a valid prescription. Similarly, hospital pharmacists routinely compound and dispense drugs in I.V. solutions, complex parenteral nutrition I.V.'s (e.g., TPN's), and other drug dosages for individual patient use upon the receipt of a valid medical order. Moreover, both community and hospital pharmacists frequently depart from package insert directions for preparation of drugs in order to provide a more desirable concentration, etc., for a particular patient. All of these actions are performed pursuant to the receipt of a valid prescription, are subject to state laws governing the practice of pharmacy, and are the result of the pharmacist's best professional judgement in each specific case.

The fact that NRC has severely restricted my professional practice in nuclear pharmacy is, to say the least, extremely disturbing. The fact that NRC has essentially ignored or denied my professional existence is, frankly, insulting. The fact that I am not allowed to use my professional judgement in compounding and dispensing certain drugs pursuant to the receipt of a valid prescription is, in the eyes of my pharmacist colleagues, appalling.

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NRC's strict, narrow, and incomplete interpretation of FDA's role in drug approval and use as evidenced in current NRC regulations (viz. 10 CFR Part 35) is a severe impediment to optimal patient care. In my own practice, for example, I typically prepare and dispense NDA radiopharmaceuticals according to package insert instructions; on almost a daily basis, however, I am requested by one of my nuclear physician colleagues to prepare and dispense a "special" dose of radiopharmaceutical for a specific patient. As I stated earlier, I practice in a university hospital so we have an unusually high number of patients with unusual conditions. Thus to optimize the patient's medical care frequently requires a radiopharmaceutical that is specially prepared for that patient. Many of these special requests, however, are not allowed to be realized under current NRC regulations and a less desirable alternative is necessary by default. The inability to optimize individual patient studies using "customized" radiopharmaceuticals may result in the necessity of performing two or more alternate studies to get equivalent (or even inferior) information, more radiation dose to the patient, prolonged hospital stay, and other monetary or non-monetary costs.

The major concern surrounding extemporaneous compounding of drug doses or departing from package insert instructions is that it places a greater burden of liability on the pharmacist. The pharmacist must be willing to accept the professional and legal responsibility to assure that the "special" drug dose is safe and effective. This assurance may involve drug quality testing (e.g., purity, sterility, apyrogenicity), reference to reports in the scientific literature, and personal experience. Compliance with established drug standards (USP/NF) and drug use (USP-DI) monographs, if they exist, is generally recommended.

In summary, the FDA, in conjunction with State Boards of Pharmacy, allows several acceptable mechanisms for drug preparation and use, only two of which are NDA and IND designations. Furthermore, the philosophy of the FDA and State Boards of Pharmacy is that drugs should be safe and efficacious, and that drug use should be optimized for each patient. Thus the NRC should adopt the petition for rulemaking, thus allowing the delivery of optimal patient care; the appropriateness of radiopharmaceutical preparation and dispensing will be ensured by State Board of Pharmacy governance, profession-accepted standards of practice in nuclear pharmacy, competency recognition through certification and re-certification in nuclear pharmacy, and independent professional judgement.

Sincerely,

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JAP/pd