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DOCKET NUMBER
PETITION RULE PRM 35-9
(54 FR 38239)
16 Nov 89

240

TO: Sec of the Commission
USNRC
Docketing and Service Branch, Docket # PRM-35-9
Washington, DC 20555

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OFFICE OF THE SECRETARY
DOCKETING & SERVICE
BRANCH

Dear Mr. Secretary:

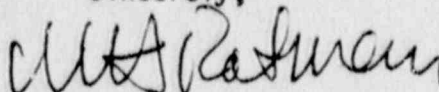
I am a licensed pharmacist and a **Board Certified Nuclear Pharmacist** and I strongly urge you to consider the petition from the SNM and ACNP that will change Part 35 on Medical Use regulations. These changes allow practitioners to practice their respective health care specialties. As it exists now, the NRC is liable from several points of view, and quite possibly could end up defending itself in a court of law.

Suppose a modification of a package insert were to be developed that allowed an existing Radiopharmaceutical to be used in a new way, previously unknown and therefore not part of the "approved" use. Suppose this new use might very well enable earlier detection of cancer, and perhaps with a reduced radiation exposure to both patient and medical personnel. If you prohibit this use, are you not a) interfering with patient care?, b) increasing radiation exposure to both patient and staff, c) inviting legal action by the patient for perhaps denying them the best medical care, and by staff for increasing their exposure?

Since these improvements are often published in reputable journals the entire Nuclear Medicine Community is quickly aware of them. Since modifications to NDA's often take a great deal of time to prepare and get approved, it is possible that a window of several years could occur? This NRC induced window of delay between discovery and FDA approval and thus NRC approval could amount to significant delays in the advancement of patient care.

Let us not forget the whole point of Medical Use of Radioactive Material is for the benefit of the patient, after all it is called Nuclear Medicine. I urge the NRC to allow the Nuclear Medicine community to take care of the patients. I realize that the purpose of the NRC is to protect from needless exposure, and I think that by carefully watching and inspecting the NRC can insure needless exposure is prevented whenever possible. Thorough investigation and publication of documented needless exposures can alert others to potential hazards, and hopefully prevent them from happening elsewhere. I feel the best role for the NRC is a "watchdog" for the Nuclear Medicine community, not as a "Lord and Master" to tell us exactly how to treat patients.

Sincerely,



Mark Rotman

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