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

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6 December, 1989

Secretary of the Commission
U.S. Nuclear Regulatory Commission
Docketing and Service Branch, Docket #
PRM-35-9
Washington, DC 20555

Dear Mr. Secretary:

I am writing to express my support for the Petition for Rulemaking filed by the American College of Nuclear Physicians and the Society of Nuclear Medicine. I am a retired executive of a radiopharmaceutical company and a long time supporter of the Nuclear Regulatory Commission. My concern is over the revised 10 CFR 35 regulations (effective April, 1987) governing the medical use of byproduct material. These rules will cause unnecessary delay in developing new radiopharmaceuticals without contributing to the safety and effectiveness of radiopharmaceuticals.

I was involved for many years in the original discussions and decisions concerning the FDA acceptance of regulatory concern for radiopharmaceuticals. The transfer of the regulatory power from NRC to FDA took much dialogue and compromise, but the result was a division of responsibility between FDA and NRC that has proven to be an aid to the safe use of radiopharmaceuticals and allowed reasonably timed development of new drugs for new uses.

The current rules of Part 35 do not allow practices which are legitimate and legal under FDA regulations and State medicine and pharmacy laws. They, therefore, act as a barrier to the proper practice of medicine and the development of new drugs under FDA regulations. Unnecessary differences between regulations cause unsafe practices and cause treatments and diagnostics to be withheld where patients needs are over-ridden by unclear rules.

If the reason for these rules is an increase in misadministrations of poor drugs or the wrong drugs, I have never seen any published studies that would support such a decision. At one time such a study was proposed and supported by the medical and business communities involved in nuclear medicine. If such a study showed that problems had occurred, it has never been made widely available.

I strongly recommend that NRC adopt the ACNP/SNM Petition for Rulemaking as soon as possible.

Sincerely,

J. Calvin Brantley

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