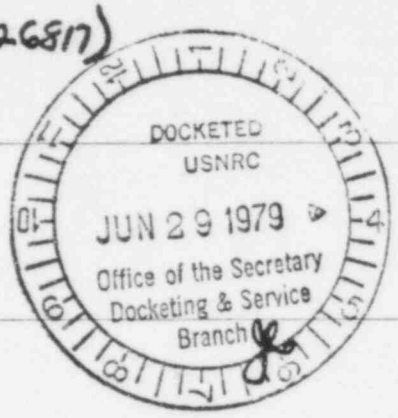
E. PODOLAK

the children's memorial hospital

DOCKET NUMBER (35)
PETITION RULE PRM-35-1 (44FR 26817)



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chicago, illinois 60614
312 649-4000

June 22, 1979

Secretary of The Commission
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Attn: Docketing and Service Branch

Dear Sirs:

I wish to respond to docket number PRM-35-1. I am in support of George V. Taplin's M.D. petition to amend the recent regulation published in the Federal register, volume 44, number 35 on Tuesday, February 20, 1979, which states "The Commission believes that the use of diagnostic radiopharmaceuticals listed in groups I, II, and III for clinical procedures not yet approved by FDA entails low risk to the patient, provided the chemical and physical form, route of administration, and the dosage range remain the same as specified in the radiopharmaceutical labeling.

My objection to this ruling is that it infringes upon the physicians right to practice medicine and that the Nuclear Regulatory Commission is assuming the physician's responsibility by this regulation.

I read with great interest and approval The Nuclear Regulatory Commission's policy statement, published in the Federal register, volume 44, number 29 on Friday, February 9, 1979 in which the statement is given that "NRC will not control physician's prerogatives on patient selection, instrument selection, procedure selection, drug selection, and dose level for most diagnostic uses of radioisotopes". I presumed that this position was adopted because of the acknowledged low risk involved with these radiopharmaceuticals. It would seem that the Nuclear Regulatory Commission's confidence in the qualified practitioners of Nuclear Medicine to use these low risk agents would apply also to the route of administration, particularly when the dosimetry calculations support their use.

Acknowledged by card... dlh 7/2

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In addition, it is my understanding, as a member of the FDA radiopharmaceutical drug advisory panel, that labels which accompany products are intended as guidelines and not as regulations. Labeling often lags behind scientific data accumulated on drug products, and therefore should be used as a guideline at the discretion of the prescribing physician. The new NRC regulation prempts the intention of labeling to serve as a guideline in the case of these low risk radiopharmaceuticals, and as a consequence The Nuclear Regulatory Commission is infringing upon the qualified physician's responsibilities in practicing medicine. It is requested that the regulation be amended to permit the route of administration of these agents at the discretion of the qualified physician.

Sincerely yours,

James J. Conway, M.D.

JJC:cw

cc: George V. Taplin, M.D.