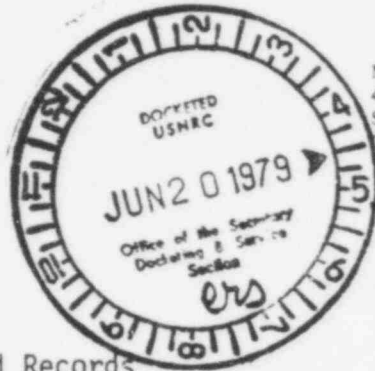




SCHOOL OF MEDICINE
DIVISION OF MEDICAL SCIENCES
DEPARTMENT OF RADIOLOGY

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June 8, 1979

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PETITION RULE PRM-35-1

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Gerald L. Hutton
Division of Rules and Records
Office of Administration
US Nuclear Regulatory Commission
Washington, D.C. 20555

Dear Mr. Hutton:

I wish to support the petition for rule making by George V. Taplin, M.D. which requests that use of diagnostic radiopharmaceuticals not be restricted to FDA authorized clinical procedures. NRC has responsibility to encourage minimum appropriate radiation exposure to the general populace, to radiation handlers and to the patient. In fulfilling this responsibility, it also must not deny patients procedures whose benefit exceeds real or theoretical radiation risks, nor societal benefits of legitimate biomedical investigations. Radiation exposure is determined by the amount and type of radiopharmaceutical and not by the purpose of the administration or the portion of the anatomy imaged or otherwise studied. To delve into the latter considerations is to deny the patient or society the benefits of the judgement of the physician scientist. Indeed it is unrealistic to attempt to do so since there is no practical way to control the process. By way of example, if one uses a radiopharmaceutical approved by the FDA for liver imaging and then moves the detector so that the lungs are visualized, is one in violation? A negative answer seems obvious to us workers in the field. To be more ridiculous, in the same set of circumstances, a large field of view camera allows one to visualize the kidneys simultaneously with the liver, and this obviously cannot be a violation. Indeed, the physician may be providing additional benefit to the patient. Historical precedent clearly indicates that the physician is to be the judge of the benefits of approved drugs within the bounds of peer review and medical malpractice.

Thank you for your consideration.

Sincerely,

Gerald DeNardo
Gerald L. DeNardo, M.D.
Director, Nuclear Medicine

POOR ORIGINAL

GLD/ct

- cc: George Taplin, M.D.
- Lawrence Muroff, M.D.
- Douglas Maynard, M.D.
- Leonard Freeman, M.D.
- William Briner, M.D.

Acknowledged by card... 6-21-79... wsh

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