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DOCKET NUMBER
PETITION RULE PRM-35-1 (27)

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

Attention: Docketing and Service Branch

Dear Sir:

This concerns the filing of a petition by George V. Taplin, M.D. (Docket No. PRM-35-1 published in the Federal Registry, May 7, 1979, requesting the Commission to amend its regulation "Human Uses Of Byproduct Material," 10 CFR Part 35.

This amendment requires the physicians to follow the package insert regarding the chemical and physical form, route of administration and dosage range when they perform clinical procedures that have not been approved by FDA.

Dr. Taplin requests that the Commission reconsider and rescind the requirement that physicians must use an approved radiopharmaceutical strictly in accord with the manufacturers package insert. Dr. Taplin refers specifically to the use of Technetium99m DTPA as an aerosol by inhalation for lung imaging. TcDTPA has been approved by FDA for brain and kidney imaging using doses varying between 5 and 20 millicuries per examination and administered intravenously. Tc-DTPA is an ubiquitous radiopharmaceutical used for many years in Nuclear Medicine in several other applications within the dose range stated by FDA. Namely, among these applications the most important are: Tc-DTPA aerosol studies by inhalation for lung imaging, Tc-DTPA measurements of gastric emptying time using 500 microcuries to 1 millicurie, extremely useful studies such as cisternography for determination of CSF leaks where the dose is 1 millicurie.

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Aerosol studies are extremely useful for the differential diagnoses of perfusion defects in perfusion lung scans with Tc-macroaggregates in pulmonary embolism. Gastric emptying is quite in vogue and extremely useful for studies of esophgeal and pyloric regurgitation, and cisternography performed with Tc-DTPA is a very useful procedure for the demonstration of cerebrospinal fluid leaks.

For these reasons I coincide with Dr. George V. Taplin and respectfully request that the Commission reconsider and rescind the requirement that physicians must use an approved radiopharamceutical strictly in accord with the manufacturers package insert. In particular, when staying within the dosage approved by the Food and Drug Administration and the Nuclear Regulatory Commission. This will provide the latitude for nuclear physicians to work within the regulations of our institutional human use committees and radiationsafety committee and use our ingenuity in the task of "slaying the common dragon of disease."

Respectfully submitted,

Very sincerely yours,

Ismael Mena, M.D.
Professor, Radiological Sciences
Director, Nuclear Medicine Division

IM/aml
cc: George V. Taplin, M.D.