E. PODOLAK

SCHOOL OF PHARMACY

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


Gerald L. Hatton
Division of Rules and Records
Office of Administration
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Dear Sir:

Reference is made to the Federal Register 44, 89, p. 26817, May 7, 1979, Docket No. PRM-35-1, in which comments are invited in relation to the petition of Dr. George V. Taplin who requested that the Commission reconsider and rescind the requirement that physicians must use an approved radiopharmaceutical strictly in accord with the manufacturers' package insert.

I wholly concur with the intent of this petition. Radiopharmaceuticals that have been approved by the FDA have been determined to be safe, non-toxic, and effective for the procedure approved.

The petitioner wishes that responsible and qualified physicians in nuclear medicine be allowed to use such agents at dosages and by routes of administration other than those listed on the package insert. While the use of an approved drug for a non-approved use requires, according to the rules, that we go back to square one, there is a mechanism that the FDA has instituted that might prove equally useful for the NRC in this consideration.

The Radioactive Drug Research Committees (RDRC's) have been set up by the FDA in order to allow approval, at the local level, of radioactive drug studies that are limited in number and scope, and hence need not be reviewed by the FDA itself.

It is proposed that the NRC authorize the RDRC's to grant such authority for radiopharmaceutical usage as Dr. Taplin proposes, subject to review of an appropriate protocol, and with no changes in the additional approvals that are required by the Radiation Safety Committees and the IRB's (Institutional Review Boards) of each institution.

This expanded use of the RDRC's would be in consonance with the philosophy of delegating review and control authority to responsible local specialists and committees. In at least one institution (the LAC-USC Medical Center) the RDRC has already become the Hospital Drug Committee for Radioactive Drugs, reviewing all their research use in its drug related aspects.

I hope the above concepts, supporting Dr. Taplin's proposal, will assist the Commission in reaching a decision.

Sincerely,

Acknowledged by card.....alh 7/2

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