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

Dear Mr. Secretary:

I am a practicing Nuclear Medicine physician at the Albert Einstein College of Medicine and Bronx Municipal Hospital Center in New York City. I am disturbed over revisions in the 10 CFR 35 regulations (of April '87) which restrict the medical use of nuclear byproduct material. The restrictions are deleterious to the optimal performance of nuclear medicine diagnostic studies for patients in our hospital.

I must, therefore, express strong support for the Petition for Rule-making filed by the American College of Nuclear Physicians and the Society of Nuclear Medicine.

To clarify: An FDA approved radioactive tracer, such as technetium-99m DTPA, is approved in the package insert for intravenous injection and for aerosol inhalation. However, nowhere does it state within the package insert that this agent could be administered by mouth. Nonetheless, there certainly are occasions where oral administration of a technetium based agent such as technetium DTPA would have great value: For example, to clearly identify whether an organ is in fact the stomach. The stomach would be easily outlined by oral administration of a technetium based agent. Nonetheless, the wording of revised 10 CFR 35 regulations would prohibit such use by qualified physicians and radionuclide pharmacists. The availability of an orally approved technetium kit such as technetium sulfur colloid would certainly be a reasonable alternative and this would, indeed, be legal. However, in a busy nuclear medicine department we run out of kits and there is absolutely no reason not to substitute one technetium agent for another for such an indication when the patient's needs require it; especially since the substitution is a trivial one from a radiobiological perspective.

Similar limitations of the use of radionuclides for appropriate therapeutic indicators are also proposed by the above 10 CFR 35 regulation. For example, P-32 is used in the treatment of pleural effusions, as per package inserts. The 10 CFR regulation would implicitly prohibit the use of P-32 for therapy of pericardial effusions, because such an indication is not explicitly mentioned in the package insert. Yet there is literature to support this application of P-32.

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Bureaucratic restrictions on the judgement of qualified physicians and radiopharmacists belies the regulations already in place to certify the efficacy of their training. We must understand that our physicians, radiochemists, and radiopharmacists have the qualifications, when properly certified, to administer and tailor the use of radiotracers appropriately to the individual patient. If we overregulate this avenue of diagnosis, in fact we destroy it.

A similar example would be to restrict the use by an Internal Medicine physician of FDA approved medications by limiting use to package insert regulations. It would be akin to suggesting that the indications for ibuprofen include headache, fever, and arthritis. A patient presenting with arm pain, i.e. not falling within the above 3 categories, would not be eligible for treatment with ibuprofen if one restricted the use to the above categories dogmatically.

There appears to be a fear that the misadministration of diagnostic radiotracers poses a serious threat to public health and safety. In my personal experience of 11 years as a Nuclear Medicine physician, including my 2 years of training, I have indeed witnessed a handfull of misadministrations (approximately 5 or 6 in this period of time) of diagnostic tracers. Not one misinjection resulted in any patient reaction whatsoever. In general, this is characteristic of nuclear medicine studies. Virtually none of them produced reactions over either the short term or the long term. Therapeutic interventions of course have greater potential for unwanted side effects. The appropriate attention to care and detail required by the administration, however, is expected of nuclear physicians entirely analogously to that expected of any other trained medical specialist.

I would like to summarize by saying that I strongly urge that the Nuclear Regulatory Commission adopt the Society of Nuclear Medicine and the American College of Nuclear Physicians Petition for Rulemaking as soon as possible.

Yours truly,

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