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BT-124

16 October, 1989

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

Dear Mr. Secretary:

Sir, did you know that there is no regulation of any specialty in medicine comparable to that of nuclear medicine! The Commission's revised 10 CFR 35 regulations which took effect in April, 1987, make much of what we do to help patients using the power of the atom a criminal activity! You can change that.

Please consider the Petition for Rulemaking filed by the American College of Nuclear Physicians and the Society of Nuclear Medicine very seriously. There is much at stake. I have no doubt that my patients and many others will be injured if the revised 10 CFR 35 is allowed to stand.

After their initial limited approval by the FDA, conventional pharmaceuticals assume a transcendent and ever changing texture of use. Indications change and expand. Routes of administration multiply. And doses become optimized for the original and new indications. If a new or better way of using a drug is found - the improvement is quickly incorporated into patient care. The FDA endorses this implicitly, without stipulations - as well they should.

Why are patients deprived of this vitally important evolution in care when it concerns radiopharmaceuticals? I will tell you why. It is because 10 CFR 35 (35.100, 35.200, 35.300, and 33.17(a)(4)) do not allow it. Does this not contradict the NRC's own policy of not interfering with the practice of medicine? I should say it does.

NRC

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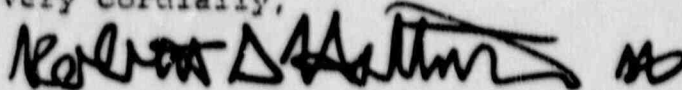
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Prescription and administration errors in the use of radiopharmaceuticals have repeatedly been shown to be far less frequent than those of conventional pharmaceuticals. And the risks? They are simply not comparable.

Radiopharmaceuticals have ineluctable risks compared to the potential lethal and morbid consequences of untoward responses to ordinary drugs. And, golly, the risks of not using a proven drug strategy are never apparent - except to an individual patient and his physician.

Let me make the best decision I know how to give my patients the care that they deserve! Please, adopt the ACNF/SNM Petition for Rulemaking now. Thanks.

Very cordially,

A handwritten signature in black ink, appearing to read "Robert S. Hattner" with a stylized flourish at the end.

Robert S. Hattner, M.D.
Associate Professor, Nuclear Medicine