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

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Dear Mr. Secretary:

OFFICE OF THE SECRETARY
DOCKETING & SERVICE
BRANCH

I am writing to express my support for the Petition for Rulemaking filed by the American College of Nuclear Physicians and the Society of Nuclear Medicine. I am a full time Nuclear Medicine Physician at Albert Einstein Medical Center in Philadelphia, Pa. I am deeply concerned over the revised 10 CFR 35 regulations (effective April, 1987) governing the medical use of byproduct material as the significantly impact on my ability to practice high-quality Nuclear Medicine and are preventing me from providing optimized care to individual patients.

At our hospital we do about 40 studies per day (in about 25 patients). Several times a week the clinical situation of a patient causes us to need to adjust the administered dosage of a tracer so that diagnostic information can be obtained in unusual clinical circumstances. Entire classes of clinical studies (such as Gastric Emptying studies and Gastro-Esophageal Reflux studies) involve usage of standard tracers in manners not described by the package insert. The package insert was never intended to prohibit physicians from deviating from it for other indications: on the contrary, such deviation is necessary for growth in developing new diagnostic and therapeutic procedures. In many cases, manufacturers will never go back to the FDA to revise a package insert to include a new indication because it is not required by the FDA, and there is simply no economic incentive to do so. In fact the entire area of the expansion of the usage of diagnostic tracers is a manifestation of the 'orphan drug' problem.

If we as physicians are limited in our ability to use our trained judgement as to how to best render clinical care - the losers will be the people who do not have these diagnostic techniques available to them. This does not have an economic impact on me - because the patients will have to have a study (e.g. if they don't have test A they will have test B - and I get paid either way). Medical care is affected if test A is more accurate/safer/easier. Limiting my ability to use my medical judgement will raise the cost of medical care and lower it's quality in exchange for rather nebulous benefits.

For these reasons I strongly urge the NRC to adopt the ACNP/SNM petition for rulemaking.

Sincerely,

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