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STAMFORD MEMORIAL HOSPITAL

PHONE 773-2725
AREA CODE 915

HIGHWAY 6 EAST -- BOX 911 STAMFORD, TEXAS 79553

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Secretary of the Commission
U.S. Nuclear Regulatory Commission
Docketing and Service Branch,Docket
Washington,DC 20555

OFFICE OF SECRETARY
DOCKETING & SERVICE
BRANCH

Dear Mr. Secretary:

I am writing to express my strong support for the Petition for Rulemaking filed by the American College of Nuclear Physicians and the Society of Nuclear Medicine. I am a practing Family Practice Physican at Stamford Hospital in Stamford,Texas. Iam deeply conerned over the revised 10 CFR 35 regulations (effective April,1987) governing the medical use of byproduct material as they significantly impact my abi to practice high-quality Nuclear Medicine/Nuclear Pharmacy and are preventing me fr providing optimized care to individual patients.
For diagnostic services, I am forced to strictly follow the manufacturer's instruct ions for kit preparation and expiration times.
The NRC should recognize that the FDA does allow, and often encourages, other clini uses of approved drugs, and actively discourages the submission of physican-sponsor IND's that describe new indications for approved drugs. The package insert was never intended to prohibit physicians form deviating from it for other indications; on th contrary such deviation is necessary for growth in developing new diagnostic and therapeutic procedures. In many sases, manufactureres will never go back to the FDA to revise a package insert to include a new indication because it is not required b FDA and there is simply no economic incertive to do so.

Currently, the regulatory provisions in Part 35 (35.100, 35.200, 35.300 and 33.17(a (4) do not allow practices which are legitimate and legal under FDA regulations and State Medicine and pharmacy laws. These regulations therefore inappropriately interfer with the practice of medicine, which directly contradicts the NRC's Medica Policy statement against such interference.

Finally, I would like to point out that highly restrictive NRC regulations will onl jeopardize public health and safety by: restricting access to appropriate Nuclear Medicine procedures; exposing patients to higher radiation absorbed doses from alternative legal, but non-optimal,studies; and exposing hospital personnel to high radiation absorbed doses because of unwarranted, repetitive procedures. The NRC should not strive to construct proscriptive regulations to cover all aspects of medicine, nor should it attempt to regulate radiopharmaceutical use. Instead, the N should rely on the expertise of the FDA, State Boards of Pharmacy, State Boards of Medical Quality Assurance, the Joint Commission on Accreditation of Healthcare Organizations, radiation safety committees.institutional Q/A review procedures, and most importantly, the professional judgement of physicians and pharmacists who have been well-trained to administer and prepare these materials.

Since the NRC's primary regulatory focus appears to be based on the unsubstantiated assumption that misadministrations,particularly those involving diagnostic radio-pharmaceuticals, psoe a serious threat to the public health and safety, I strongly the NRC to pursue a comprehensive study by a reputable scientific panel, such as th National Academy of Sciences orthe NCRP, to assess the radiobiological effects of m administrations form Nuclear Medicine diagnostic and therapeutic studies. I firmly believe that the results of such a study will demonstrate that the NRC's efforts to impose more and more strong regulations are unnecessary and not cost-effective in relation to the extremely low health risks of these studies.

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In closing, I strongly urge the NRC to adopt the ACNP/SNM Petition for Rulemaking e expeditiously as possible.

Sincerely,

D. Mark Pratt, M.D.

Stamford Hospital