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KAISER PERMANENTE MEDICAL CENTER
DEPARTMENT OF NUCLEAR MEDICINE
280 WEST MACARTHUR BOULEVARD
OAKLAND, CALIFORNIA 94611

PAUL M. WEBER, M.D.
DANIEL A. NAVARRO, M.D.

(415) 596-6210

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October 26, 1989

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

Dear Mr. Chilk:

As a practicing Nuclear Medicine physician at Kaiser Permanente Medical Center in Oakland, California I want to add my strong support to the American College of Nuclear Physicians and Society of Nuclear Medicine Petition for Rule Making filed by those organizations. Revised 10 CFR 35 regulations (April 1987) prevent me from providing optimized care to individual patients by interfering negatively with my ability to practice high quality Nuclear Medicine.

Examples are legion and I'm sure have been documented by others. Fundamentally following the manufacturer's instructions for kit preparation essentially prevents the implementation of new studies well described, documented, and proven in medical literature until and unless the package insert is changed. The net effect is the inability to most cost-effectively and safely perform many diagnostic studies with the result that patients must undergo more expensive and riskier procedures. This is particularly galling since the FDA allows and at times encourages other clinical uses for approved drugs while at the same time actively discouraging submission of physician-sponsored INDs that describe new indications for approved drugs. Thus a "Catch 22" is created by the package insert which was never intended to prohibit physicians from practicing medicine but now is being used in just that fashion thereby preventing development of new diagnostic procedures. In the absence of such an FDA requirement and of any economic incentive the manufacturer rarely sees fit to revise the package insert.

The bottom line is that these highly restrictive NRC regulations jeopardize public health and safety in contradiction to the charge of that commission. This in turn restricts access to some of the most appropriate applications, results in increased radiation absorbed doses to patients from alternative procedures

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etc. The NRC should recognize that the practice of medicine is impacted upon not only by the FDA but by state boards of medicine, pharmacy, quality assurance, as well as by the Joint Commission on Accreditation of Health Care Organizations and local hospital committees. All of these appear better positioned to monitor the appropriate use of radiopharmaceuticals and I believe that the NRC should recognize the expertise of these agencies, boards, and committees. In the end it is the professional judgement of well-trained physicians and pharmacists that will assure the safe and effective use of diagnostic radiopharmaceuticals.

I therefore strongly urge the NRC to adopt the ACNP/SNM petition for rule making as expeditiously as possible. In addition, I support the position of those organizations and urge that the NRC pursue a comprehensive study by a reputable panel such as the National Academy of Sciences or the NCRP to assess the radiobiologic effects of misadministrations from Nuclear Medicine diagnostic and therapeutic studies. I firmly believe that these will demonstrate that more stringent NRC regulations are unnecessary and will not significantly reduce the extremely low health risks of these Nuclear Medicine procedures.

Sincerely yours,

Paul M. Weber, M.D., Chief
Department of Nuclear Medicine

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