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DEPARTMENT OF RADIOLOGY

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

Dear Mr. Secretary:

I am writing to express my strong support for Rulemaking filed by the American College of Nuclear Physicians and the Society of Nuclear Medicine. I am a practicing physician at the New England Deaconess Hospital, Boston, MA. I am deeply concerned over the revised 10 CFR 35 regulations (effective April 1987) governing the medical use of byproduct material as they significantly impact my ability to practice high-quality Nuclear Medicine and are preventing me from providing optimized care to individual patients.

Over the years I have worked closely with both industry and FDA in designing IND protocols for radiopharmaceuticals. Dr. Palmer from the FDA has stressed upon us to limit the indications for new drug applications to aide in the approval process. It has been his contention and ours that once the pharmaceuticals are approved, they may be used for nonapproved indications under the practice of medicine. This therefore speeds up the approval process and limits the expenses incurred by the sponsoring company. Those of us who have been suggesting protocols had some difficulty coming around to the FDA's way of thinking on this matter and had preferred to go for broad sweeping indications for these new products. However, now that we have followed the FDA's advice, these new regulations would certainly hamper if not limit that approach that has been so long in coming. Nuclear medicine physicians have an enormous background in diagnostic and therapeutic usage of radionuclides and are constantly using that knowledge to benefit patients with those available pharmaceuticals that have been approved. These regulations therefore would severely inhibit ones ability to practice medicine as outlined.

In addition, strictly following of manufacturers instruction for kit preparation would unduly raise the cost during patient procedures. This is because the manufacturers have no economic interest in making a kit that can be used for more than one diagnostic study. Our radiopharmacist and physicians have soon realized that with only slight modifications, a kit can be used for multiple studies. This does keep the cost of health care down and is a beneficial cost saving measure in a time when hospitals are under extreme budgetary restrictions. A manufacturer would have no interest in

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changing the package insert that would allow for this type of commonly used preparation since it would be against their economic interest to do so. Therefore this restriction would be very anticonsumer who ultimately pays for these increased unnecessary costs.

The NRC should recognize that the FDA does allow, and often encourages, other clinical uses of approved drugs, and actively discourages the submission of physician-sponsored IND's that describe new indications for approved drugs. 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.

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 interfere with the practice of medicine, which directly contradicts the NRC's Medical Policy statement against such interference.

Finally, I would like to point out that highly restrictive NRC regulations will only 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 higher 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 NRC should rely on the expertise of the FDA, State Boards of Pharmacy, State Boards of Medical Quality Assurance, the Joint Commission of Accreditation of Healthcare Organizations, radiation safety committees, institutional Q/A review procedures, and most importanly, 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 radiopharmaceuticals, pose a serious threat to the public health and safety, I strongly urge the NRC to pursue a comprehensive study by a reputable scientific panel, such as the National Academy of Sciences or the NCRP, to assess the radiobiological effects of misadministrations from 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 stringent regulations are necessary and not cost-effective in relation to the extremely low health risks of these studies.

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

Sincerely,

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TCH/ed