



American
Pharmaceutical
Association

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The National Professional
Society of Pharmacists

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Charles R. Green
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September 13, 1988

VADM Lando W. Zeck, Jr.
Chairman, Nuclear Regulatory Commission
Matomic Building
1717 H Street, N.W.
Washington, D.C. 20555

Dear Chairman Zeck:

The American Pharmaceutical Association (APhA) is the national professional society of pharmacists representing the third largest health profession. We have a large and active contingent of nuclear pharmacists in our membership.

We are writing to bring your attention to a problem that nuclear pharmacists are facing due to the NRC regulation 10 CFR 35.100, 35.200, and 35.300, published in the October 16, 1986 Federal Register. This regulation allows for the administration of a radioactive drug only if the Food and Drug Administration (FDA) has accepted a "Notice of Claimed Investigational Exemption for a New Drug" (IND) or approved a "New Drug Application" (NDA) for the drug. In doing so, this regulation prohibits the compounding of radiopharmaceuticals by pharmacists using radiochemicals and/or other appropriate non-radioactive materials (upon receipt of a prescription order from a duly-licensed prescriber) unless an IND or NDA is submitted and accepted for the end-product.

While we understand that this regulation is intended to protect the public safety by providing only FDA approved drugs to the end-user, we feel it unnecessarily restricts nuclear pharmacists from fully carrying out their professional responsibilities. These responsibilities include the provision of extemporaneously compounded radiopharmaceutical products for critical diagnostic and therapeutic procedures.

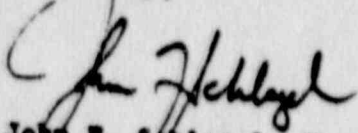
Like all pharmacists, nuclear pharmacists are trained to work with pharmaceutical chemicals. Nuclear pharmacists, and in particular those nuclear pharmacists who are certified by the Board of Pharmaceutical Specialties, have further extensive training in the safe and proper use of radiopharmaceutical materials and other radioactive compounds. We believe that these nuclear pharmacists, who are regulated by their respective state boards of pharmacy, should be allowed to use their professional judgment in this area. Physicians using radiopharmaceuticals will then be able to provide the best available diagnosis and treatment to their patients.

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In no other areas of pharmacy practice are there restrictions on the manner in which appropriate materials may be used in extemporaneous compounding. We believe that it is unreasonable to arbitrarily restrict nuclear pharmacists from exercising their professional prerogatives in the performance of their duties. We believe that a less stringent interpretation of the regulation would permit nuclear pharmacists to carry out their professional duties to the benefit of the end-user.

We, in turn, would be pleased to provide you with several names of nuclear pharmacists who would be able to meet with you to discuss this issue further. We urge you to consider working with us to seek a mutually agreeable solution to this problem.

Sincerely,



John F. Schlegel, Pharm.D.
President

JFS/efg