

DEPARTMENT OF RADIOLOGY

*DePaul Hospital*

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Norfolk, Virginia 23501

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

Re: 10 CFR 35 (effective April 1987)

Dear Mr. Secretary:

I am a practicing nuclear medicine physician at DePaul Medical Center and the Eastern Virginia Medical School in Norfolk, Virginia. I am very interested in your actions with regard to the revised 10 CFR 35 regulations (April 1987), and their impact on the practice of high quality nuclear medicine. As a result of these rules, the physician's medical practice and collaboration with pharmacists or other qualified persons in the compounding of radioactive diagnostic materials is seriously impaired, to an extent unique in the United States compared to the rest of the civilized world.

Throughout the medical world, various drugs and other therapeutic modalities are frequently used without explicit approval of the Food and Drug Administration. The drugs are used within a medical practice and not advertised for sale to others. The Food and Drug Administration has stated on many occasions that it is not their intent to inhibit physicians in the practice of medicine. Rather, their regulations should affect the applications for which a drug or modality may be advertised by the manufacturer. Because of the economics involved, it will never pay the manufacturer to exhaustively investigate and document every conceivable application of their product

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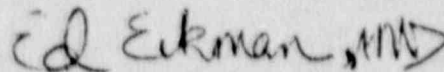
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and derivatives thereof, since there will be no incremental profit that would allow anything like recovery of the costs of such activities.

The use of nuclear radiopharmaceuticals is governed by knowledge of the basic underlying physiologic, pathophysiologic, and chemical principles involved. This is the practice of nuclear medicine, for which we are trained and certified.

I strongly urge the NRC to adopt the ACNP/SNM Petition for Rulemaking in order to clarify this and other aspects of the use of pharmaceutical agents.

Sincerely,



Edward A. Eikman, M.D.  
Section Chief of Nuclear Medicine  
DePaul Medical Center

Associate Professor of Radiology  
Eastern Virginia Medical School

EAE/nld