DOCKET NUMBER
PETITION RULE PRM 35-9
(54 FR 38239)

(82)

MICHIGAN STATE UNIVERSITY

DEPARTMENT OF RADIOLOGY
B220 CLINICAL CENTER
TELEPHONE (517) 355-0120

EAST LANSING · MICHIGAN · 48824-1315

'89 OCT 26 P3:12

OFFICE OF SECRETARY
DOCKETING & SERVICE
BRANCH

October 20, 1989

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 currently here at Michigan State University doing a sabbatical. I normally reside at Yale, where I am Professor and Vice Chairman of the Department of Radiology. I have been actively practicing Nuclear Medicine full-time for the past 25 years, and am a past President of the Society of Nuclear Medicine. I think it is extremely important that the Petition for Rulemaking filed by the American College of Nuclear Physicians and the Society of Nuclear Medicine be approved. I have been most fortunate in my own practice to be in a tertiary care center where I have always been able to optimize patient care with minimum interference from rules like the current 10 CFR 35 regulations. For example, I recall routinely using one gram of perchloride prior to pertechnetate brain scans when the dose finally approved was 250 milligrams. I settled on one gram after evaluating the effect of the drug to block the perotids which interfered with my ability to diagnose a cerebello-pontine angle tumor. Two-hundred-fifty milligrams—the approved dose—is simply not enough to do this. Similarly, at Yale we currently utilize ten millicuries of gallium—67 citrate for patients with tumor. We have been doing this for over ten years, beginning at a time when most people were constrained to use three millicuries of gallium, at most, because of the package inserts. As a result of this, a gallium in most institutions is an occasional examination. In our institution, gallium scanning for recurrent gallium avid tumors is extremely common and people are referred to us for this study from all over southern Connecticut. We do approximately 800 gallium examinations a year, because we can give a dose appropriate to the problem. I sight the above two examples as instances of a general concept that instructions on a package insert and other types of restrictive regulations such as those now currently in effect are completely inflexible. Medical indications change over time. The type of patient involved and the need for differing diagnostic information requires modifications in this inflexibility. It seems to me the proposed petition for rule making accomplishes this by providing the flexibility necessary to achieve good patient care now **and in the future**. It is my understanding that the package insert was never intended to prohibit the development of new uses for any particular drug. And as you know full well, once approved, no drug company will go back to the FDA to change its package insert because of the cost and the time and the aggrevation involved.

D510

It is my belief that your current provisions in Part 35 are so inflexible that they do not even allow practices considered ligitimate and appropriate by current FDA regulations. Consequently, they are inappropriately interfering with the practice of medicine. It was my understanding that the NRC specifically stated that its medical policies never would do this.

If the purpose of the current regulations are to provide health and safety, then it is clear that minimizing appropriate indications and sanctioning inappropriate doses that do not provide optimum diagnoses can only be detrimental to both public health and safety. Finally, I assume that the NRC's principle focus seems to be an extension of the commission's concern for misadministration of radioisotope doses. It is my personal belief generated by 25 years of observation that the number of misadministrations is incredibly small in nuclear medicine. In fact, I would challenge you to find an area where there is a significantly better record in this area. Furthermore, the doses we give in diagnoses are almost always from among a group of tracers that are the safest drugs patients ever get. Consequently misadministrations--though not desirable--pose relatively little serious health risk. In short, it is my firm belief that you cannot legislate a better system than currently exists. You are clearly in the process of making it worse. At the very least, you will make it more expensive.

Because of the above, I strongly urge the NRC to adopt the Petition for Rulemaking proposed by the ACNP and the SNN in an expeditious fashion.

Sincerely,

Alexander Gottschalk, M.D.
Visiting Professor of Radiology and
Past President of the Society of Nuclear Medicine

AG/dd