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March 28, 1980

JACKET NUMBER
PROPOSED RULE PR-20
(45 FR 18023)



Dr. John Aherne
Chairman
United States Regulatory Commission
1717 H Street
Washington, D.C. 20555

Dear Dr. Aherne:

I wish to express my extreme concern regarding the NRC's proposal regarding misadministration of radiation therapy. I understand that the NRC has taken the viewpoint that it is the patient's right to know when there has been any differing in the "prescribed therapeutic dose" by more than 10%. Whenever such "misadministration" occurs, the NRC is to be notified within 24 hours. Unfortunately, this regulation will create havoc in the field of therapeutic radiology and will not solve the basic concern to which it is directed. I feel it will only lead to prescribing dosages by a wider range, thereby circumventing the regulation. An error in dosage of 10% occurring during one treatment session would certainly not be significant in the overall outlook and clinical course of that patient and yet item #4 would imply that this would be a reportable event.

There is no doubt that small and insignificant "errors," for instance administering 3300 rads instead of 3000 rads for palliation of metastatic breast cancer to bone, if reported to the physician and the patient as required would lead to lawsuits without reasonable grounds.

Although I am certainly not an attorney, I would feel that this regulation could be fought on the basis of the fifth amendment, in that disclosing errors would be a direct infringement upon one's protection from self-incrimination. Also, the regulation is highly selective and prejudicial to one particular medical group in dealing with oncology. Is a cancer surgeon required to report to the patient if he leaves an instrument within the abdomen or accidentally ruptures the spleen while removing the colon? Is a medical oncologist required to tell the patient that he inadvertently gave the wrong chemotherapeutic agent or gave too much or too little? Is the internist required to tell the family that a patient died because of the side effects of a toxic drug or surgical misadventure? The answer to all these questions is clearly no. To single out the radiation therapist as the "fall guy" in the whole aspect of cancer management is grossly unfair, unreasonable, and will not benefit anyone.

If a radiation therapist makes an obvious error and realizes that he will be sued by admitting the error, then he will obviously ignore the regulation

Acknowledged by card.....

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Dr. John Aherne

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under the attitude "I'm damned if I do and I'm damned if I don't." I feel many will take the risk of not reporting, hoping that the error is never discovered. If that attitude sounds unprofessional, consider the attorney who misinterprets a regulation or law and his client suffers for his error. Will this attorney notify his client that he has made a mistake?

I would hope that you will not support this amendment to the NRC regulations and will defeat the effort to require the reporting procedure as outlined.

With warm regards,

A handwritten signature in cursive script, appearing to read "John T. Fazekas".

John T. Fazekas, M.D.
Associate Professor and Acting Chairman,
Department of Radiation Therapy

JTF:mep