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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

From the Office of Dr. Nicholas J. Sarlis

October 14, 1999

The Honorable Chairwoman Greta J. Dicus
U.S. Nuclear Regulatory Commission
Office of the Chairwoman
016C1
Washington
DC 20555

DOCKET NUMBER
PROPOSED RULE **PR** 20,32+35
(63FR43516)

Re.: Proposed rule changes to Part 35-Medical Use of Byproduct Material
October 21, 1999 Hearing

Dear Honorable Chairwoman,

As a clinical endocrinologist, and a principal investigator on active clinical research protocols relevant to the use of iodine-131 (131-I) for therapy of thyroid disorders (including thyroid cancer), I am writing to express my strong hope that you and the other Commissioners will concur with the NRC staff recommendations regarding the number of training and experience hours required for those physicians who treat patients with 131-I.

The proposal to maintain the current 80 hour training requirement is reasonable, and the exemplary 50-year safety record of endocrinologists and thyroid specialists using 131-I in the context of clinical care and clinical research under the current regime provides ample proof to ensure the safe administration of this radionuclide by such specialists.

I am well aware that certain groups of medical colleagues who belong to other specialties and sub-specialties of Medicine, as well as medical administrators, have vested interests in seeing the number of hours of training of endocrinologists in the administration of 131-I increased to 700 hours, a ninefold increase over the current mandates! If such an unreasonable and unnecessary increase is implemented, the excessive resultant regulatory burden would eliminate endocrinologists from treating their own patients.

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Furthermore, and most importantly, patients who have traditionally trusted their endocrinologists - expert medical sub-specialists in the field of thyroid-related disorders, for which 131-I is therapeutically administered - will be certainly forced to seek treatment elsewhere. This will undoubtedly prove detrimental for the health of these patients, especially in the domain of thyroid cancer, a disease which requires long-term reliable follow-up over many years (preferably by the same physician and/or the same institution). The continuity of this follow-up is of the utmost importance for more than 150,000 patients in the U.S..

Finally, recognizing myself the importance for a federal Institution to act as an advocate for patients in the arena of Public Health - especially within the current socio-financial environment in the private Health Care Industry - I strongly commend the NRC staff for taking a position that is rational, fair, and "pro-patient". I genuinely hope that the Commissioners will embrace their recommendation by leaving the current 80 hour rule in force.

Thank you in advance for giving my views your careful consideration and thought.

Most sincerely yours,



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