

DOCKET NUMBER

PETITION RULE PRM 35-9

(54FR 38239) RICHARD S. BENUA M.D.

82 WILLOW AVENUE
LARCHMONT, NEW YORK 10538

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'89 NOV -8 A9:45

November 3, 1989

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

OFFICE OF THE SECRETARY
DOCKETING & SERVICE BRANCH

Dear Mr. Secretary:

I am writing to express my support of the Petition of the American College of Nuclear Physicians and the Society of Nuclear Medicine concerning the revisions to 10 CFR 35 (April, 1987). I am a member of both organizations and a practicing nuclear physician at the New York Hospital in New York City. I believe that the restrictions to which that petition is addressed are hampering my ability to practice quality nuclear medicine.

Specifically, following to the letter the packaging insert on therapeutic I-131 for the treatment of cancer would make it impossible to use the largest safe dose in many cases. See: Benua RS, Loeper, RD. A method and rationale for treating metastatic thyroid carcinoma with the largest safe dose of 131 I. In McGeiros-Neto, G. (ed), Frontiers in Thyroidology, Plenum Press, New York, 1986, Vol 2, pp1317-1321. This is but one example of the problems arising from strict compliance with package inserts about indications, expiration times, patient selection and routes of administration of both diagnostic and therapeutic radionuclides.

Manufacturers generally do not keep changing package inserts in line with the progression of medical knowledge. They have no incentive to do so. The FDA wisely permits physician (at their own peril) to use established drugs for non-standard indications and in non-standard ways. I believe that you also should follow such a policy.

I urge you to withdraw these restrictive rules according to the SNM/ACNP petition.

Very truly yours,

Richard A. Benua

Richard S. Benua, M.D.
Attending Radiologist
The New York Hospital

From: FRONTIERS IN THYROIDOLOGY, Vol. 2
Edited by Geraldo Medeiros-Neto, M.D.
and Eduardo Gaitan, M.D.
(Plenum Publishing Corporation, 1986)

**A METHOD AND RATIONALE FOR TREATING METASTATIC THYROID CARCINOMA WITH THE
LARGEST SAFE DOSE OF ^{131}I**

Richard S. Benus and Robert D. Leeper

**Nuclear Medicine Service
Memorial Sloan-Kettering Cancer Center
New York, NY, USA**