TP 102-3

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(2)

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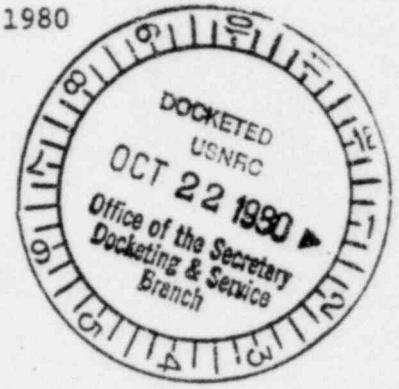
September 26, 1980



Mr. John F. Ahearne
Chairman
U. S. Nuclear Regulatory Commission
1717 "H" Street, N.W.
Washington, D. C. 20555

Dear Mr. Ahearne:

At the recent Annual Meeting of the American Medical Association, there were two resolutions passed that are relevant to the activities of your agency. I would like to deal with these separately in the following paragraphs.

In connection with the decision to require mandatory reporting to the U.S. Nuclear Regulatory Commission of all radiopharmaceutical mis-administrations, even though more than 90% of the comments on the proposed rules were in opposition to this, such rules do represent an unprecedented and unwarranted intrusion by the Federal government in the patient/physician relationship and may well increase professional liability insurance premiums which will ultimately increase the cost of this care to the patients. Therefore, the House of Delegates:

> RESOLVED, That the American Medical Association oppose the implementation of the Nuclear Regulatory Commission's rules requiring reporting and recording of mis-administration of radiopharmaceuticals as not being in the best interests of the physician/patient relationship.

Our membership was also concerned about the Nuclear Regulatory Commission's regulation on "human use of by-product material" 10 CFT part 35, published in the Federal Register 44 F.R. 10358, February 20, 1979). This ruling requires that physicians must use an FDA approved drug (radiopharmaceutical) strictly in accord with the manufacturer's package insert. They felt that this restriction is an unprecedented intrusion into the patient/physician relationship and is in direct opposition to the previously stated position of the FDA that physicians may use approved drugs according to their best knowledge and judgement, when in the interests of the patient. The House of Delegates thus resolved:

> RESOLVED, That the American Medical Association request the Nuclear Regulatory Commission to rescind the regulation requiring the physician to use an approved drug (radiopharmaceutical) in accordance with the manufacturer's package insert as regards chemical and physical form, route of administration and dosage range; and be it further,

L-4-1, Pt. 35

10/15...To EDO to Prepare Reply for EDO's Signature. Suspense: Oct 31
Cpys to: Chm,Cmrs,OPE,OGC...80-1869 (NOTE: comm would like EDO to develop either a paper for the comm or response to be cleared by the comm)

RESOLVED, That the American Medical Association immediately send this policy statement to the five Commissioners of the Nuclear Regulatory Commission and to the Radiation Policy Council, newly appointed by the Executive Office of the President, composed of 13 agencies of the Federal government.

If you have any further question about our feelings in these matters, I will be happy to eleaborate further upon them should you so desire. If there is any way in which we may be of assistance in helping to remedy these regulations, please know that we stand ready to assist.

Sincerely yours,

James H. Sammons, M. D.

JHS/bl