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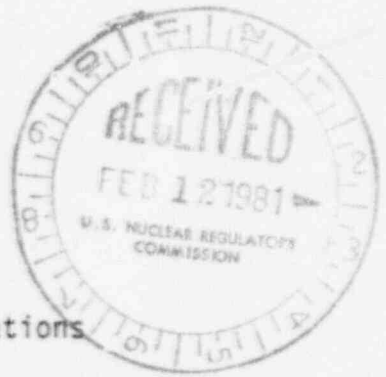
SECY-81-94



RULEMAKING ISSUE

(Affirmation)

For: The Commissioners

From: William J. Dircks, Executive Director for Operations

Subject: THERAPEUTIC TREATMENT OF CARDIAC DYSFUNCTION BY IODINE-131

Purpose: Approval of the publication of a Federal Register Notice, for public comment, indicating NRC's intent to unconditionally retain the therapeutic treatment of cardiac dysfunction by iodine-131 in the regulations.

Category: This paper covers a minor policy question.

Issue: Should NRC continue to allow physicians to use iodine-131 for the therapeutic treatment of cardiac dysfunction although the Food and Drug Administration (FDA) has reclassified this treatment as lacking substantial evidence of effectiveness?

Alternatives:

1. Publish for public comment in the Federal Register a notice of NRC's intent to delete the therapeutic treatment of cardiac dysfunction by iodine-131 from NRC regulations.

2. Publish for public comment in the Federal Register a notice of NRC's intent to uncorditionally retain the therapeutic treatment of cardiac dysfunction in the regulations.

3. Publish for public comment in the Federal Register a notice of NRC's intent to retain the therapeutic treatment of cardiac dysfunction in the regulations, but limit its application to such cases where it is the preferred treatment and patient benefit far exceeds the risk.

Discussion: In the Commission's February 21, 1980 action on SECY-79-542 (Therapeutic Treatment of Cardiac Dysfunction), the Commission deferred action on the staff's recommendation to publish a Federal Register Notice (FRN), for public comment, indicating NRC's intent to retain the therapeutic treatment of cardiac dysfunction in the regulations pending receipt of the following additional information:

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- A formal recommendation from NRC's Advisory Committee on the Medical Uses of Isotopes (ACMUI) on the subject.

- A reconsideration of this subject by FDA with cognizance of the ACMUI recommendation.

Upon receipt and analysis of the ACMUI and associated FDA comments, the staff was requested to recommend to the Commission the next appropriate step in the resolution of this matter.

A. Background

The key points presented in SECY-79-542 (Enclosure 1), the original Commission paper on the therapeutic treatment of cardiac dysfunction by iodine-131, are summarized as follows:

1. NRC's Medical Policy Statement specifies a regulatory policy which restricts the uses of therapeutic radioactive drugs to the clinical procedures that have been approved by the Food and Drug Administration.

2. In 1976, FDA reclassified the therapeutic treatment of cardiac dysfunction by iodine-131 as lacking substantial evidence of effectiveness. However, FDA's action, by itself, does not prevent physicians from using iodine-131 for the therapeutic treatment of cardiac dysfunction.

3. NRC currently authorizes the use of iodine-131 for treatment of both hyperthyroidism and cardiac dysfunction in Group IV of §35.100(d)(1) of 10 CFR Part 35. However, since FDA has removed this treatment from its list of approved procedures, retention of this treatment in the regulations appears to be inconsistent with NRC's Medical Policy Statement.

4. If NRC removes this authorization from the regulations, then it would be illegal for any physician to use iodine-131 for the therapeutic treatment of cardiac dysfunction.

5. NRC's Advisory Committee on the Medical Uses of Isotopes, the American College of Cardiology and several physicians have advised the staff that this treatment is the preferable therapy for a very limited subset of cardiac patients, and they have recommended that the therapeutic treatment of cardiac dysfunction by iodine-131 should not be removed from the regulations.

6. FDA regulates the manufacture and distribution of radioactive drugs and medical devices and not their routine use by physicians.

7. NRC is currently the only Federal agency authorized to regulate the physician's routine use of radioactive drugs for the purpose of reducing radiation exposure to patients.

B. The ACMUI Recommendation

At its August 18, 1980 meeting (see Enclosure 2-excerpt from meeting minutes), the ACMUI considered the following alternatives prior to submitting a formal recommendation on the subject of therapeutic treatment of cardiac dysfunction by iodine-131:

1. Delete the treatment from NRC regulations.

2. Unconditionally retain the treatment as it presently appears in the regulations (status quo).

3. Retain the treatment but limit its use to cases in which it is the preferred method of therapy and the potential patient benefits far exceed the risk.

After discussion of these alternatives, the ACMUI recommended that the therapeutic treatment of cardiac dysfunction should be unconditionally retained in NRC's regulations and supplied the following five points as its underlying rationale:

a. Use of iodine-131 for treatment of cardiac dysfunction has been in existence for a number of years.

b. This use is very limited today, but, nevertheless, some physicians will want to use this treatment in certain circumstances.

c. Physicians should have the option of using this treatment if they feel it is in the best interest of the patient.

d. Currently, the physician has the option of using iodine-131 for this patient treatment without violating FDA's rules, although FDA had reclassified the use of iodine-131 for cardiac dysfunction therapy as lacking substantial evidence of effectiveness. However, if NRC were to delete this from the regulations, it would, in fact, remove the option of the physician to use this treatment. The physician would either have to obtain a special license amendment from NRC or file an Investigational New Drug Application with FDA. These two courses of action introduce a time element which could be critical in treating a patient *in extremis*.

e. The Committee believes that the use of iodine-131 for treatment of cardiac dysfunction is safe and that there may be instances where its use might benefit the patient more than any alternatives.

C. FDA Comments on the ACMUI Recommendation

On September 30, 1980, FDA reiterated that none of the alternatives considered by NRC on the therapeutic treatment of cardiac dysfunction by iodine-131 would conflict with basic FDA policy.

Under FDA rules, a physician may still opt to therapeutically treat a patient with iodine-131 for cardiac dysfunction without violating any FDA rules, although this treatment was reclassified by FDA in 1976 as lacking substantial evidence of effectiveness. FDA regulates the manufacture and distribution of radioactive drugs and medical devices and not their routine use by physicians. NRC is the only Federal agency which is currently authorized to regulate the routine use of radioactive drugs by physicians for the purpose of reducing radiation exposure to patients.

D. Relevance to the Medical Policy Statement

Support for deletion of this treatment from the regulations (Alternative 1) is found principally in that part of the Medical Policy Statement which states that: "NRC will continue to restrict the uses of therapeutic and certain diagnostic radioactive drugs to the indicated procedures that have been approved by FDA."

However, other parts of the Medical Policy Statement provide a basis for retention of this treatment in the regulations (Alternatives 2 and 3) by permitting a certain flexibility to exist between the physician's practice of medicine and governmental regulatory authority as follows:

- "The NRC will minimize intrusion into medical judgments affecting patients and into other areas traditionally considered to be part of the practice of medicine."

- "The Commission recognizes that physicians have the primary responsibility for the protection of their patients. The Commission believes that basic decisions concerning the diagnosis and treatment of disease are a part of the physician-patient realtionship and are traditionally considered to be a part of the practice

of medicine. NRC regulations are predicated on the assumption that properly trained and adequately informed physicians will make decisions in the best interest of their patients."

E. NRC Staff Comments

Upon further consideration of this subject, the staff reaffirms its original recommendation stated in SECY-79-542, that the Commission unconditionally retain the therapeutic treatment of cardiac dysfunction by iodine-131 in the regulations (Alternative 2). In the staff's view, the points summarized in the Background section of this paper (these are detailed in SECY-79-542) and the consistent recommendation for unconditional retention by the ACMUI overwhelmingly support keeping this treatment in the regulations. Indeed, the staff believes that deletion of this treatment would have both a detrimental effect on a physician's professional prerogatives and be inhumane to certain patients. In fact, members of the ACMUI felt that the physician's access to this treatment should not be tied down only to cases of patients in extremis. This prerogative of the physician is directly related to the practice of medicine rather than to the sphere of regulatory control.

The staff thus believes that its position on the unconditional retention in the regulations of the use of iodine-131 for the therapeutic treatment of cardiac dysfunction is consonant with the expressed intent of the Medical Policy Statement. This Statement was formulated to establish a proper balance between governmental regulation and the physician's practice of medicine so that the best interests of the patient would not be compromised. The staff believes that its recommendation on this issue exemplifies and accentuates the proper balance which was originally established in the Policy Statement and that the Policy Statement is sufficiently flexible to accommodate special cases such as exist with this therapeutic treatment.

Recommendation: That the Commission:

1. Approve the publication, for public comment, of a Federal Register Notice indicating NRC's intent to unconditionally retain the therapeutic treatment of cardiac dysfunction in the regulations (Alternative 2). A Federal Register Notice detailing this intention is provided in Enclosure 3.

2. Note that, because the Federal Register Notice supports the status quo, the retention of the therapeutic treatment of cardiac dysfunction by iodine-131 in §35.100(d)(1) of 10 CFR Part 35, the Congressional Committees need not be informed of this Commission

action; however, we will mail a copy of the Federal Register notice to all interested byproduct material licensees and other interested persons.

3. Note that, unless there are significant adverse comments on this notice of intent, there will be no further Commission action necessary on this matter. The staff will place an analysis of the public comments in the Public Document Room.

William J. Dircks
Executive Director for Operations

Enclosures:
1. SECY-79-542 Therapeutic Treatment of Cardiac Dysfunction
2. pp 129-136 - excerpt from minutes of ACMUI 8/18/80 meeting
3. Federal Register Notice

Commissioners' comments or consent should be provided directly to the Office of the Secretary by c.o.b. Monday, February 23, 1981.

Commission Staff Office comments, if any, should be submitted to the Commissioners NLT Friday, February 13, 1981, with an information copy to the Office of the Secretary. If the paper is of such a nature that it requires additional time for analytical review and comment, the Commissioners and the Secretariat should be apprised of when comments may be expected.

This paper is tentatively scheduled for affirmation at an open meeting during the week of March 2, 1981. Please refer to the appropriate Weekly Commission Schedule, when published, for a specific date and time.

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