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OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

DOCKET NUMBER

PETITION FILE PRM 35-18
(70 FR 75752)

March 1, 2006

Ms. Annette Vietti-Cook
Secretary
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Re: PRM-35-18: Release of patients treated with radio pharmaceuticals
Support for the current Patient Release Rule, 10 CFR 35.75

Dear Ms. Vietti-Cook:

On behalf of The Endocrine Society, representing more than 11,000 physicians and scientists in the field of endocrinology, we strongly support the Nuclear Regulatory Commission's (NRC) leadership and mission to protect the public's health and safety from the effects of radiation. The Society shares the NRC's commitment to ensure only the safest and most effective use of radio pharmaceuticals utilized during patient care.

As a result, the Society has significant concerns regarding the recent petition seeking to amend the current regulation (10 CFR 35.75) governing the release of patients who have been treated with more than the equivalent of 30 millicuries of radioactive iodine (I-131). The Society supports the current regulation and believes it provides the most effective and efficient care for patients being treated for life threatening thyroid diseases. We are opposed to the petitioner's request (Docket No. PRM-35-18) to have the NRC prohibit the release of patients from radioactive isolation who have received the equivalent of 30 millicuries of radioactive iodine-131 (I-131).

In our review of the petition, The Endocrine Society believes there is no benefit to reversing or amending the present rule (10 CFR 35.75). In fact, our Society is concerned that changing the current rule will likely have a negative impact on patient care and significantly increase health care costs by mandating unnecessary hospitalizations for patients that pose no risk to the public health. With the full participation of radiation safety officers, it is the current practice of treating physicians to conduct careful evaluations of all patients exposed to radio pharmaceuticals and to make determinations for necessary hospitalizations when it is in the best interest of the patient, their household members, and/or the public.

The Society believes that there is no compelling evidence to support the modification of the current Patient Release Rule (10 CFR 35.75). In fact, available data published in the Journal of the American Medical Association¹ suggests that radiation exposure to household members of patients who received outpatient I-131 treatment ranged from ~75 to ~150 mCi of I-131 was low. These reported levels are well below the levels mandated by current NRC regulations.

¹ Grinsbt, P.W., Siegel, B.A. Baker, S., and Eichling, J.O. Radiation exposure from outpatient radioactive iodine (I-131) therapy for thyroid carcinoma. JAMA, 283:2272-2272, 2000.

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We respectfully request that the NRC support the current policy to provide the most effective patient protections and care in treating thyroid diseases. In addition, any change in current policy should be developed using evidence-based data and carefully performed studies, not anecdotal evidence, to prevent unintended negative consequences for both patients and the nation's health care system.

If you have any questions or require additional information, please do not hesitate to contact me directly or our Associate Director, Government & Professional Affairs, Christopher Rorick, at (301) 941-0254.

Sincerely,

A handwritten signature in black ink, appearing to read "Andrea Dunaif". The signature is fluid and cursive, with a large, stylized "D" at the end.

Andrea Dunaif, MD
President
The Endocrine Society

From: "Rorick, Chris" <CRORICK@ENDO-SOCIETY.ORG>
To: <SECY@nrc.gov>
Date: Mon, Mar 6, 2006 9:44 AM
Subject: PRM-35-18

Please find attached The Endocrine Society's comments regarding Docket No. PRM-35-18. Feel free to contact me with any questions.

Christopher C. Rorick

Associate Director, Government & Professional Affairs

The Endocrine Society

8401 Connecticut Ave. Ste. 900

Chevy Chase, MD 20815-5817

(301) 941-0254 w (301) 941-0259 f

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From: "Rorick, Chris" <CRORICK@ENDO-SOCIETY.ORG>

Created By: CRORICK@ENDO-SOCIETY.ORG

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