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OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

27

AMERICAN
THYROID
ASSOCIATION
FOUNDED 1923

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

Attention: Rulemaking and Adjudication Staff

Subject: PRM-35-18

Dear Ms. Vietti-Cook:

Founded in 1923, the American Thyroid Association (ATA) is a professional society of about 900 U.S. and international physicians and scientists who specialize in the research and treatment of thyroid diseases. The Association is dedicated to promoting scientific and public understanding of the biology of the thyroid gland and its disorders, so as to improve methods for prevention, diagnosis, and management of thyroid disorders. The Association fosters excellence in research, patient care, and education of patients, the public, and the medical and scientific communities. The Association also guides public policy about the prevention and management of thyroid diseases. It is in this context that we emphatically respond to the Nuclear Regulatory Commission's (NRC) solicitation for public comment on the petition for rulemaking docket No. PRM-35-18.

Mr. Crane has requested that the NRC amend the regulation that governs the medical use of byproduct material concerning release of individuals who have been treated with radio pharmaceuticals. Specifically, he requests that the patient release rule (10 CFR 35.75) be partially revoked to prevent patients from being released from radioactive isolation with more than the equivalent of 30 millicuries of radioactive iodine (I-131) in their bodies. From a safety standpoint, the petitioner objects to the current patient release criteria rule stating that it creates unwarranted hazards with regard to the radioactive iodine treatment of thyroid patients. The petitioner expresses concern that while patients are to receive instructions on minimizing radiation exposure to others, they may have trouble comprehending and remembering the guidance they are given. Particular concern was expressed regarding potential exposure of children given their greater sensitivity to radiation, and of caregivers in the event that the patient vomits.

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SECY-02

After review of Mr. Crane's petition[1], and his January 30, 2006 response (1661-009)[2] the American Thyroid Association concludes that no compelling data or arguments have been made to warrant change. This petition should be denied.

In 1997 the NRC amended its patient release criteria in 10 CFR Part 35 to allow the release of patients from licensee control who had been administered unsealed byproduct material if the total dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv (0.5 rem). Prior to that time, NRC regulations required hospitalization of patients with the equivalent of 30 mCi or more of I-131 in their systems. To put 5 mSv in context, this is about double the total overall background ionizing radiation exposure per year that the average citizen receives.

Current data suggests no benefit to reversal of this amendment. First, there are no data to support harm to an individual in the public who receives a dose of 5 mSv from exposure to an I-131 treated patient. Second, contrary to Mr. Crane's concern, the available data suggests that most patients are able to limit radiation exposure to the public as witnessed by several publications. One study[3] of the current practice found that radiation exposure to household members of patients receiving outpatient I-131 therapy for thyroid carcinoma that ranged from ~75 to ~150 mCi of I-131 were well below the limit (5.0 mSv) mandated by current regulations. In fact, the mean dose to household members was 0.24 mSv with a maximum of 1.09 mSv (less than one-forth the allowable limit). Similar exposures to household pets were recorded. No levels of contamination were found in home surveys by Panzegrau et al[4] and patient satisfaction with outpatient therapy was high. Supporting the low potential for significant radiation exposure to the public are the data of Venencia et al[5] who treated 14 patients with 1110-8175 MBq (30-221 mCi) and monitored them with dosimeters placed on the pectoral muscle. The doses to the public at 1 meter from the patient were calculated. Assuming that a person was always 1 meter from the treated patient (100% occupancy factor), their exposure dose did not exceed 5.0 mSv when the treatment activity was $\leq$187 mCi.

A third argument against reversal of the current practice is that it is anticipated that an increasing percentage of I-131 treatments will be done with recombinant human TSH stimulation.[6,7] This will increasingly eliminate hypothyroidism during the treatment period so that Mr. Crane's concern of impaired mental faculties will be diminished. Further, treatment with I-131 in the euthyroid state will hasten elimination of I-131 from the non-thyroidal tissues of the patient's body and very likely further reduce the dose to the public.[6]

Fourth, while patient vomiting after I-131 treatment may occur, it typically happens after I-131 has left the proximal gastrointestinal system so that little of the treatment activity is present in the vomitus. People cleaning up this vomit would typically be exposed to little radiation and for just a short duration of time. This supposition of limited radiation exposure of caregivers is supported by the calculated low radiation exposure of a theoretical person that is constantly 1 meter from the treated patient as reported by Venencia[5] and described above.

A fifth argument against Mr. Crane's petition is that since enactment of the 1997 amendment, treating physicians have largely been able to admit their patients to the hospital for I-131 treatment if they believe that hospitalization is in the best interest of the patient, their household members, or the public. The ATA strongly believes that this treatment option needs to be vigorously defended. Sixth, Mr. Crane repeatedly comments on the current policy's trade off of decreased radiation exposure to the clergy for the increased exposure of the public and the family. The ATA has not considered the exposure of the clergy as a problem as they have not typically been allowed in the room of the isolated patient.

While the data suggest no benefit to reversal of the amendment, the ATA has substantial concern that amendment reversal may cause medical and financial harm to the patient. Some of these concerns include unnecessary pressure on the physician to treat their patient with an I-131 activity at a lower than desired amount just to avoid hospitalization and its associated inconvenience and cost[8]. Indeed, the ATA Guidelines on the treatment of thyroid cancer acknowledged that various activities at or above 30 mCi may be administered for proper patient care, and no treatment activities below 30 mCi were advised.[7] Mandatory patient hospitalization for all treatment activities of 30 mCi or more will undoubtedly increase cost as reported by Panzegrau et al.[4] Indeed, it is estimated that 26,690 people were diagnosed with thyroid cancer in 2005. If we assume that 95% of these people had differentiated thyroid cancer, and that 80% of these underwent thyroid remnant ablation then 21,352 hospitalizations would have been required. Add to this the additional 2,135 therapies that represent the 10% of patients that require multiple treatments. Thus, an estimated 23,487 hospitalizations would have been needed in 2005 at an estimated $1032/day for 2.5 days for a total of about 6 million dollars.

In summary, the American Thyroid Association finds no compelling evidence to endorse modification of the current Patient Release Rule (10 CFR 35.75). We feel strongly that this issue demands evidence-based data to drive rational policy and encourage additional properly conducted studies to optimize the health and well-being of our patients and the public. Finally, we request the affirmation of the NRC to support the legitimacy of elective hospitalizations for I-131 therapy whenever the treating physician believes it is in the best interest of the patient, their household members, or the public.

Respectfully,

Ernest L. Mazzaferri, MD
President, ATA

Gregory A. Brent, MD
Secretary, ATA

Reference List

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3. Grigsby, P. W., Siegel, B. A., Baker, S., and Eichling, J. O. Radiation exposure from outpatient radioactive iodine (^{131}I) therapy for thyroid carcinoma. JAMA, *283*: 2272-2274, 2000.

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6. Pacini, F., Ladenson, P. W., Schlumberger, M., Driedger, A., Luster, M., Kloos, R. T., Sherman, S., Haugen, B., Corone, C., Molinaro, E., Elisei, R., Ceccarelli, C., Pinchera, A., Wahl, R. L., Leboulleux, S., Ricard, M., Yoo, J., Busaidy, N. L., Delpassand, E., Hanscheid, H., Felbinger, R., Lassmann, M., and Reiners, C. Radioiodine Ablation of Thyroid Remnants after Preparation with Recombinant Human Thyrotropin in Differentiated Thyroid Carcinoma: Results of an International, Randomized, Controlled Study. J.Clin.Endocrinol.Metab, 2005.

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From: "Theresa Ronk" <tronk@thyroid.org>
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Date: Wed, Mar 1, 2006 10:48 AM
Subject: Docket No. PRM-35-18; Comments from the American Thyroid Association

Dear Ms. Vietti-Cook,

Please find attached comments submitted by the American Thyroid Association in regards to Docket No. PRM-35-18. Confirm receipt of these comments by reply email.

Thank you.

Theresa Ronk
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