

From: <LelandRoge@aol.com>
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January 31, 2006
 Secretary
 U.S. Nuclear Regulatory Commission
 Washington, DC 20555
 Attn: Rulemaking and Adjudications Staff

January 31, 2006 (4:24pm)

OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

Dear Secretary,

Included below, and separately attached as a Microsoft Word document, are my comments concerning the use of I-131 for thyroid cancer patients, and my opposition to the recent petition for rulemaking filed by a former employee of the NRC'S Office of the General Counsel, Peter G. Crane (Docket No. PRM-25-18). Please feel free to contact me if any further information is needed. I can be reached at (801) 350-8400, or via email at Leland@GammaWest.com. Following are my comments:

I am in receipt of Federal Register Vol. 70, No. 244 (Wednesday, December 21, 2005) regarding a petition by Peter C. Crane (petitioner). This requests that the NRC amend regulations governing the medical use of radiopharmaceuticals, and not allow the release of patients who have received more than the equivalent of 30mCi of I-131.

I have 13 years experience with hundreds of patients whom I have treated with I-131, and hereby express my strong opposition to this petition, which requests that the rules revert to a prior, outmoded standard. Ratification of this petition would increase the cost of care substantially, and would improve neither patient nor public safety.

The former standard was to admit all patients receiving greater than or equal to 30mCi of I-131. Doses in excess of this are commonplace, and are standard in the treatment of patients with thyroid cancer. The regulations were updated in 1997, permitting patients to receive higher doses (e.g. 150-200mCi) on an outpatient basis, provided that patients consented to simple radiation precautions for a finite period, largely of about a week, after treatment.

By keeping patients out of the hospital, outpatient therapy has greatly reduced the cost of care. It has also improved patient comfort and safety. Almost every patient prefers home over hospitalization, and the risks of nosocomial infection and other adverse sequelae of hospitalization are well known. Furthermore, outpatient radiation precautions are straightforward. The vast majority of patients can follow them without difficulty. Those who cannot may, of course, be admitted, but compelling the admission of all patients is expensive and onerous.

Realize that the requirement for hospital admission assures frequent radiation exposure for a wide range of hospital staff and employees including physicians, nurses, food service and janitorial employees. On the other hand, outpatient therapy adhering with the required radiation precautions ensures either no or miniscule radiation exposure to anyone other than the patient. The majority of thyroid cancer patients are young and robust, can readily follow these safe and simple guidelines, and have no "trouble comprehending and remembering the guidance they are given," as suggested in the petition.

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SECY-02

Mention is made in the petition regarding radiation exposure for children. The precautions given to every patient are explicit in that regard, and my patients with young children have not had difficulty with this. I have instructed them to arrange with family or close friends to have children remain in one home while the patient remains in another for a few days after I-131 administration. If this cannot be arranged, the patient may be admitted to the hospital. Recall, however, that hospital admissions for radioiodine have almost always been for only a day or two. Radiation precautions for children are required beyond that time point. It can thus not be argued that hospitalization can obviate good patient education and compliance with radiation precautions.

The petitioner additionally invokes the "likelihood of vomiting" as a reason for disallowing outpatient therapy. This is an exaggeration. Although vomiting has occurred, this has been exceedingly rare. In my extensive personal experience, it has never occurred. I have traditionally given each patient an anti-emetic before I-131 administration, but this is likely unnecessary. Moreover, I have kept the patient in the shielded treatment room for 1 hour after treatment to observe for any nausea. Should nausea develop, the patient would be observed for a longer interval and might even be admitted to the hospital. However, this is manifestly rare, and is readily addressed by good, basic medical care and by careful patient education.

The current rules allow for the treating physician to make the appropriate choice for each patient, and even to admit an occasional patient for whom hospitalization might improve patient and/or public safety. However, changing the rules to re-impose old-fashioned and obsolete standards upon every patient is not a step forward. I strongly recommend that the rules, as currently established and with years of documented safety and effectiveness, be left in force to the benefit of patients, the public, and the overall cost of care.

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