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May 11, 2016

Annette Vietti-Cook
Office of the Secretary
Secretary of the Commission
U.S. Nuclear Regulatory Commission
ATTN: Rulemaking and Adjudications Staff
Washington, DC 20555-0001

Re: Docket ID NRC-2008-0175
Medical Use of Byproduct Material—Medical Event Definitions, Training and Experience, and Clarifying Amendments; Proposed Rule

Dear Secretary Vietti-Cook:

The Lymphoma Research Foundation (LRF) appreciates the opportunity to again submit comments to the Commission on this very important issue. As you are aware, LRF has participated in the comment process for this proposed rule for several years and we fully support the NRC's efforts to update its regulations to reflect changes in the clinical practice and advances in medical technology. Our primary concern remains the impact of any regulation which proves too burdensome for practitioners or results in limited access to safe and effective treatments for individuals diagnosed with lymphoma.

In its March 16, 2016 Final Report (Report), The Advisory Committee on the Medical Uses of Isotopes (ACMUI) Sub-Committee on Training & Experience for Authorized Users of Alpha and Beta Emitters recommended against the reduction in the number of training and experience (T&E) required for 10 CFR 35.390 use. The Sub-Committee was unable to conclude that the current regulatory framework was the "only, or even the principal, cause of the decreased use of radiopharmaceuticals…" It should be noted that the ACMUI Patients' Rights Advocate, Laura Weil, expressed a differing opinion with respect to the barriers to access. LRF shares some of these same concerns.

A lymphoma patient faces a difficult and complex process as it relates to their diagnosis and treatment. Lymphoma is unique in that there are more than 67 subtypes of the disease, each considered to be a rare and complex diagnosis which is notorious for recurrence. A lymphoma patient needs access to every tool in the arsenal for the management of their disease. The ACMUI Sub-Committee noted that there "is no shortage of clinicians available and authorized to administer these radiopharmaceuticals…", however as stated by Ms. Weil, this may not be true for patients who are treated in the community setting. The T&E requirement means that AUs are basically limited to those medical specialties that cover the requirements in residency training. Those specialties are not regularly available in the community setting which can cause a barrier to access for many lymphoma patients.

Every patient should have access to the treatments recommended by their doctor regardless where they receive treatment. LRF believes that the Commission must find balance between ensuring public safety during the administration of radiopharmaceuticals while not hindering access to potentially lifesaving treatment to all patients.

We agree with the ACUMI Sub-Committee recommendation that the educational paradigm has changed and it has come time to reevaluate the educational approach to T&E. Additionally, we fully support the notion that once the T&E requirements are established they will require regular review to ensure that they are current. As stated in the Report this is a complicated undertaking and cannot be properly completed in weeks or months and will require input from many stakeholders, therefore we further recommend that the Commission include additional studies to include issues related to access and safety.

We commend the Commission on its efforts and appreciate the opportunity to again submit comments on this issue.

Sincerely,

Robin Roland Levy
Director, Public Policy and Advocacy

NRCExecSec Resource

From: Robin Roland Levy <Rlevy@lymphoma.org>
Sent: Wednesday, May 11, 2016 3:31 PM
To: NRCExecSec Resource
Subject: [External_Sender] Additional Comments by the Lymphoma Research Foundation
Attachments: LRF NRC Comments on Medical Use of Byproduct 5_11_16.pdf

Ms. Vietti-Cook:

Attached please find additional comments of the Lymphoma Research Foundation for your review. I realize that we are unable to submit them online. If you should require additional information or if someone else should receive this letter please feel free to contact me.

Regards,.
Robin Levy

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