Patients Against Lymphoma

Non-Profit | Independent | Evidence-based

Founded in 2002 by patients, for patients

EIN: 51-0426732

February 16, 2016

Advisory Committee on the Medical Use of Isotopes (ACMUI)
Subcommittee on Training and Experience for Alpha and Beta Emitters

Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission (NCR)
Washington, DC 20555-0001

Re: Radioimmunotherapy Training and Experience Requirements

To whom it may concern:

Patients Against Lymphoma (PAL) is a non-profit group founded by patients and loved ones who are afflicted by lymphoma. We are an evidence-based source of information on lymphoma that is independent of health industry funding and therefore our perspectives are not influenced by funding sources.

We are writing to urge the ACMUI and NCR to amend the ruling that substantially increases the required time needed to be certified to administer ibritumomab tiuxetan (Zevalin) a type of radioimmunotherapy (RIT). It's our understanding that the required time for training has increased **from 80 hours to 700 hours.** It is very difficult to understand the rationale of an 8-fold increase in the time needed to receive accreditation to administer RIT.

We have been informed that 700 hours of training is not required for similar therapeutics, such as for sodium iodide I-131, which is considered more complicated than the administration of RIT. It is also our understanding that RIT products are provided to oncologists in "patient-ready doses prepared at licensed radiopharmacies."

PAL agrees with the medical authorities such as the American Society of Hematology that have submitted letters opposing the additional time for training, specific to the administration of RIT. We urge the ACMUI and NCR to instead focus on the redesign of the course work so that it trains physicians in an efficient way -- in a time frame that makes it feasible for community oncologists and hematologist to take part and acquire the necessary skills to meet the needs of their patients.

Our major concern is an important one. The rule change will make it virtually impossible for oncologists in the community setting to receive the training needed to offer this important FDA-approved therapeutic to patients, a treatment that demands less of the patient in terms of time – taking about one week to administer, compared to months of treatment with cytotoxic chemotherapy.

RIT is an important class of treatment that can induce very durable remissions with side effects that can be easier for patients to tolerate. This aspect of RIT can be especially important to elderly patients or patients with a

preference to avoid the side effects of cytotoxic agents, such as nausea, hair loss, neuropathy, and gastric and oral complications.

We remind that many insurance policies do not support receiving therapies out of network; and that travel to nuclear medical facilities will not be feasible for many patients due to their age, secondary medical conditions, frailty, and their income status.

We appreciate the critical role of the ACMUI and NCR in protecting patient safety. We urge you to reconsider the rule change based on the anticipated and serious impact on patient access to RIT in the community setting. We urge the committees to focus on redesign of the course work so that the necessary skills can be delivered in a time frame that has been used previously – and so the training is applicable to the skills that are needed by hematologists and oncologists who treat lymphoma.

We thank you for your attention to this matter.

Sincerely,

Karl Schwartz
President, Patients Against Lymphoma
Approved by PAL's Board of Directors