February 24, 2016

## Re: Administration of Ibritumomab tiuxetan (Zevalin) by Physicians other than Radiation Oncologists and Nuclear Medicine Physicians

## Members of the Board of ACMUI:

In late 2002 I was diagnosed with non-Hodgkin's lymphoma (later deemed to be related to my Agent Orange exposure in Vietnam) and, rather quickly, was given the unnerving news that I had Stage IV, incurable disease.

Based upon my background and creed I would not accept standard therapy if standard therapy had no chance of curing me. Therefore, I sought something new, an experimental clinical trial that might offer me a better prognosis.

It was my good fortune that my son is a physician; together, we searched and found a National Cancer Institute-sponsored clinical trial in which Zevalin would be administered after a very short course of CHOP chemotherapy and rituximab. I learned much about Zevalin from professors who were leading figures in the emerging and exciting discipline of radioimmunotherapy.

I was, particularly, impressed with what I like to call the specificity and punch of Zevalin, as its tagged antibodies attack the antigens on my tumor cells without killing my normal tissues. I applied for this clinical trial and was pleased to have been accepted as a patient. (I believe I was the 6<sup>th</sup> patient in the trial.)

In May 2003 I received a single dose of intravenous Zevalin in an examination room of a radiation oncologist. I was clearly aware that no special protective garments needed to be worn by myself or the administering clinician; no radioactive monitoring devices surrounded me; I was not enveloped within thickened walls in order to prevent radiation exposure to the unsuspecting public. The painless intravenous infusion, as I recall, took 2 or 3 minutes. A small adhesive bandage was applied. I shook everyone's hand and left with my wife. That evening I had dinner with my wife, my son, and my daughter-in-law.

My hematologic response to the Zevalin was superb and, to my delight, I did not miss a single day of work as a university professor. I did continue to communicate with professors who were experienced in radioimmunotherapy and I was terribly dismayed when they informed me that many prospective patients who could benefit from Zevalin were unable, for several reasons, to receive it.

I trust that the members of the Advisory Committee on Medical Uses of Isotopes (ADMUI) to be aware of this unfortunate situation. Patients who could receive a single dose of radioimmunotherapy are consigned to prolonged chemotherapy and multiple, serial infusions of monoclonal antibodies.

Respectfully,

Morton A. Diamond, MD