

## Holiday, Sophie

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**From:** Jan Waters <janwsyc@yahoo.com>  
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**To:** Holiday, Sophie  
**Subject:** [External\_Sender] Zevalin

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Advisory Committee on the Medical Use of Isotopes  
Subcommittee on Training and Experience for Alpha and Beta Emitters  
% Sophie Holiday  
Office of Nuclear Material Safety and Safeguards  
U.S.Nuclear Regulatory Commission  
Washington, DC 20555-0001  
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January 15,

Dear Members of the AGMUI:

My name is Jan Waters. I am 73 years old and I am alive today because of a treatment I had in 2004 with a drug named Zevalin. I was diagnosed with Small Cell Follicular Non Hodgkins Lymphoma in 1997 at age 55, just as I was looking forward to becoming a grandmother.

After a two year watch and wait program, I experienced pain and needed treatment. I was given CVP followed by Rituxin which had just been approved by the FDA. I was in remission a little over a year when I relapsed. I chose a clinical trial of Interleukin plus Rituxin. This treatment made me feel like I had the flu all the time and had no effect on my disease as evidenced by a CAT scan. In or about 2001 I was then given Fludarabine. I relapsed again in early 2004 and began reading about a treatment called Zevalin that looked good in clinical trials. My oncologist in Columbus said this treatment was new and hard on the bone marrow. I said, "Hasn't the chemo been hard on my bone marrow"? He replied, "Yes".

I read about Zevalin on an Internet support group where it posted the clinical trial showing the good results for Zevalin. I decided to get a second opinion from a doctor in Michigan who had given the drug. I had my records faxed to the second opinion doctor and went to see him. In the spring of 2004, the second opinion doctor said I was a good candidate for Zevalin. He didn't say why but I thought it was because I had relapsed several times and he had had good results with Zevalin at his hospital in Grand Rapids.

I took this information back to my oncologist, Dr. Eric Kraut, at the James Cancer Hospital in Columbus, Ohio and he said he could arrange for it to be given at the James. So in June of 2004 I had the treatment and in the following series of CAT scans I experienced the disease disappearing! I have been free of any observable disease since that time. I have my life back. I've watched my 8 grandchildren grow up. The baby that was born when I was diagnosed will graduate from high school this year. I was wearing out from chemotherapy. I would begin to get my strength back and would need another treatment again. The Zevalin treatment was much easier on me and was a one episode treatment.

Over the years I have been dealing with this disease. I have attended many workshops on Small Cell Follicular Lymphoma. I always ask the presenter, usually a doctor, why they aren't mentioning Zevalin as a treatment. The answers I have received always involve the fact that under current regulations, it takes two departments (oncology and nuclear medicine) to coordinate the treatment. Also many oncologists community practices do not have a nuclear medicine department and therefore cannot offer the therapy.

These reasons are unacceptable to me the patient. The primary focus should be whether the therapy is medically appropriate for the patient and is safe for the oncologist to administer it.

My hope is that all patients with my diagnosis will be told about Zevalin and have a chance to be treated with it. I think it would really help patients if the NCR would make it easier for doctors to obtain authorization to administer this drug,

Once I added up the cost of my three treatments before Zevalin I realized the total was more than the single Zevalin treatment. I wish my oncologist had been given the opportunity to start my treatment with Zevalin at the outset.

Thank you for reading this. Please forward to all commissioners.

Jan Waters