

PRM-35-19
(71FR34285)



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May 16, 2007

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May 17, 2007 (3:09pm)

Secretary
United States Nuclear Regulatory Commission
Washington, D.C. 20555

OFFICE OF THE SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

Dear Sir:

Thank you for the opportunity to comment on the petition for rulemaking submitted by Dr. William Stein, Docket No. PRM-35-19.

Five years ago, my wife was rescued by Zevalin after all else failed, and so from a very personal standpoint, we know how effective radiolabeled antibody treatments are. But more important than our personal experience, scientific studies consistently show that Bexxar and Zevalin are the most effective single agents available for the treatment of some forms of lymphoma, yet estimates indicate that only 5% to 10% of patients eligible for radioimmunotherapy are actually receiving it.

The current licensing requirements and the reimbursement issues discourage oncologists from prescribing radioimmunotherapy, and thus 90% to 95% of the patients who might benefit from it are not receiving this treatment which has few side effects, is given in a period of one week, and enables patients to return to work almost immediately. Traditional treatments such as chemotherapy and transplants require much longer treatment time and have significantly more side effects which add to both the cost of treatment and the reduction of patient productivity.

I recognize and appreciate the need for regulatory oversight of all drugs, but I cannot understand why endocrinologists are required to take only 80 hours of training in order to be licensed to prescribe iodine for the treatment of thyroid disease in much higher doses than that which is found in Bexxar. As medicine expands and new treatments become available, regulatory oversight must be consistent and fair so that patients will have easy access to all treatments, old and new.

Until the training requirement for oncologists to prescribe Bexxar and Zevalin is adjusted to 80 hours, many patients will continue to have limited access to effective new treatments like Bexxar and Zevalin and will continue to suffer through months of treatments and unpleasant side effects. I urge you to change the licensing requirements for these drugs so that they may find their place in the array of treatment options.

Sincerely,

Alex de Parry
President

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Template = SECY-067

SECY-02

From: Carol Gallagher
To: SECY
Date: Thu, May 17, 2007 10:33 AM
Subject: Comment letter on PRM-35-19

Attached for docketing is a comment letter on the above noted PRM from Alex de Parry, that I received via the rulemaking website on 5/16/07.

Carol

Mail Envelope Properties (464C67AA.419 : 5 : 35764)

Subject: Comment letter on PRM-35-19
Creation Date Thu, May 17, 2007 10:33 AM
From: Carol Gallagher

Created By: CAG@nrc.gov

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