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Comprehensive Cancer Center

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The Honorable Debbie Stabenow
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Washington, D.C 20510
Phone: 202-224-4822
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November 20, 2007

Re: CMS 1392-FC, Final Ruling on Changes to the Hospital Prospective Payment System and CY 2008 Rates

Dear Senator Stabenow:

I am writing to you about a matter of the utmost urgency. Lives are at stake. On November 1, the Centers for Medicare and Medicaid Services (CMS) issued its "final ruling" on the reimbursement rate for two agents used for treating patients with lymphoma. These FDA-approved agents, I-131 tositumomab (Bexxar) and Ibritumomab Tiuxetan (Zevalin), are first-in-class representatives of a new form of treatment called radioimmunotherapy. In this treatment, cancer cell-seeking antibodies are tagged with a radioisotope, injected into the bloodstream, and the result is the targeting of radiation directly to tumor sites and minimizing exposure of normal tissues of the body. These agents have been shown to yield very high response rates (up to 95%), including complete remissions lasting many years even in patients whose lymphoma was no longer responding to chemotherapy. Remarkably, this treatment takes only one week to administer as opposed to multiple rounds of chemotherapy over several months. The CMS ruling cuts the reimbursement for these drugs to the point that the acquisition costs are close to double the reimbursement. Under these conditions, it is unlikely that hospitals will be willing to subsidize the remaining costs. What is all the more tragic is that CMS arrived at this ruling based on erroneous billing data and a misunderstanding and thus miscoding of the components of the treatment. The bottom line is this. If this ruling stands, it is quite likely that both of these valuable agents will no longer be available and patients will be denied a potential life-saving therapy.

To put my comments in perspective, I am one of the inventors of these radioimmunotherapy agents. I am a professor of Internal Medicine at the University of Michigan and a hematologist/oncologist specializing in lymphoma. I am Co-Director of the Leukemia/Lymphoma/Bone Marrow Transplant Program of the UM Comprehensive Cancer Center. I initiated the very first clinical studies of Bexxar in 1990 and was instrumental in formulating the methodology for the delivery of both agents. As an inventor I do receive royalty payments on these treatments through a licensing agreement.

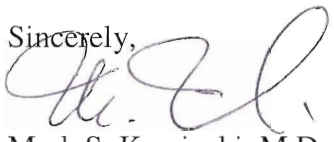
Over the years, our institution has treated more lymphoma patients with these radioimmunotherapy agents than any place in the world. With an experience in nearly 400 patients, I have seen first-hand the positive impact this treatment has made on lymphoma patients and their families. Many patients are in remission despite little or

no response to prior therapies, including bone marrow transplantation. Some of these patients still remain in complete remission at 10 to 14 years.

Senator Stabenow, I implore you to move forward in taking Congressional action to restore reimbursement for these two cancer therapies to 2007 rates through 2008. The goal in 2008 should be to obtain robust figures on actual costs to hospitals and actual billings so that proper rates can be set for 2009. Only in this way will this life-saving treatment remain an option for patients suffering from lymphoma.

Since I am acknowledged as one of the world's authorities on this treatment, I am happy to provide you and your staff any information you may need to make this happen.

Sincerely,



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