Gary C. Peters
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Congress of the United States

House of Representatives
Washington, DC 20515

March 1, 2011

Margaret A. Hamburg, M.D., Commissioner
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Dear Dr. Hamburg,

I am writing this letter to express my concern over the pending removal of the Food and Drug Administration's (FDA) breast cancer indication for the drug Avastin. I understand that the FDA has begun the removal process because of its belief that clinical studies have not shown significant effectiveness overall for metastatic breast cancer treatment and have concerns that the risks of the drug outweigh the benefits.

However, it has come to my attention from members of my community that Avastin has been used to successfully prolong the life of certain women with breast cancer, including a constituent in my district. I have concerns that withdrawing market approval of Avastin for the treatment of metastatic breast will result in limiting women's access to the drug, even in those patients who have shown signs of improvement or prolonged life because of the treatment.

Without FDA approval, public and private insurance plans will likely drop coverage of the drug making it next to impossible for many women to continue receiving this therapy. Additionally, the European Medicines Agency completed its own review of Avastin, and it continues to recommend Avastin coupled with paclitaxil as a viable treatment option for metastatic breast cancer. I am concerned that at a time when the United States has stepped to the forefront of innovation in searching for a cure on cancer, women in Europe could potentially have greater access to an American-made drug than my constituents.

The FDA had indicated its willingness to work with the manufacturer of Avastin, Genentech, to conduct additional studies of Avastin in patients with metastatic breast cancer to determine if there is a segment of patients in which the drugs benefits exceed the risks. I encourage you to pursue this research for the sake of my constituent and other women like her. Thank you for your time and consideration of this issue. If you should have any questions, please feel free to contact my office.

Sincerely,

Gary C. Peters
Member of Congress

CC: Secretary Kathleen Sebelius

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