Congress of the United States
Washington, DC 20515

July 28, 2010

Honorable Kathleen Sebelius
Secretary
Department of Health and Human Services
200 Independence Ave., SW
Washington, D.C. 20201

Dear Secretary Sebelius:

We are writing to express our concern about a pending FDA approval decision related to a July 20th recommendation by the Oncologic Drug Advisory Committee. The committee was tasked with evaluating Avastin's accelerated approval status for use in metastatic breast cancer patients, and recommended against continued approval by a vote of 12 to 1.

We respect the scientific integrity of the committee, and the need to carefully weigh the effectiveness of oncologic drugs for all of their indications. However, we are particularly concerned about the speed with which it appears FDA may be moving toward making a final approval decision for Avastin's breast cancer indication.

A truncated timeline may not allow for sufficient consideration of the science used to support the committee's decision, nor time to properly weigh dissenting views. As evidenced by the U.S. Preventative Services Task Force recommendations on mammography last year, the findings of government panels can run counter to the needs of patients and the opinions of medical providers. Understanding the emphasis that the federal government has placed upon comparative effectiveness research, we believe that the findings of government boards which could impact insurance coverage decisions for patients should allow time for public consideration before being implemented.

We have heard from concerned constituents who are taking Avastin for metastatic breast cancer, or have family members who are living with this condition. They have experienced longer survival times than expected, and many attribute this to Avastin's impact. In some cases, their survival time has extended considerably longer than the 5.5 month progression-free survival average indicated by the initial data that was considered by FDA in 2008.

Metastatic breast cancer patients often have limited options for treatment. This is largely due to the aggressive severity of their disease. Given the sincere concern of patients, families, and physicians who disagree with the recommendation of the ODAC, we would encourage you to allow an appropriate period of time for these concerns to be expressed to FDA before the agency makes a final decision on approval for this indication. If and when a final decision to remove Avastin's approval for the breast cancer indication is

made, we assume that the Centers for Medicare and Medicaid Services would follow suit with a National Coverage Decision to revoke reimbursement for the drug's use in these patients. Even if doctors continue to use the drug off-label, FDA's decision could quickly create significant coverage problems for patients and doctors who believe that the drug is beneficial.

Thank you for your consideration.

Sincerely,

Sue Myrick
Member of Congress

Phil Gingrey
Member of Congress

Cc: FDA Commissioner Margaret Hamburg, M.D.
Director Dr. Janet Woodcock, Center for Drug Evaluation and Research
Director Richard Pazdur, M.D., Office of Oncology Drug Products