



888 16th Street NW
Suite 150
Washington DC 20006
202-463-2080
lungcanceralliance.org

February 11, 2011

Margaret A. Hamburg, M.D.
Commissioner
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Dear Ms. Hamburg,

Lung Cancer Alliance is concerned with the Food and Drug Administration's (FDA) decision to pull the metastatic breast cancer indication from the Avastin label as this decision could have a ripple effect among a broader cancer community – including lung cancer that impacts access, cost, and coverage.

Avastin is a drug used in the treatment of lung cancer. It has been shown to slow or halt growth of tumors and thus prolong life in many cases and improve the quality of life in many others. While we acknowledge FDA's thorough investigation and subsequent concerns about side effects from this treatment, the decision by FDA to remove Avastin from approved treatments for advanced breast cancer applies a "one size fits all" standard that denies doctors and patients access to Avastin as a treatment option – an option that has shown benefit of use in some women.

Today the decision affects the breast cancer community – but tomorrow it could be the lung cancer community. This is a slippery slope that not only compromises doctor-patient decision making but has far reaching implications on insurance coverage and out of pocket costs for patients. We feel it is important that the FDA has agreed to hold another public hearing to further evaluate these considerations and that Genetech will be providing additional data and analysis.

Lung Cancer Alliance remains committed to furthering our understanding of and support for more targeted therapies in the metastatic setting and in the development of biomarkers.

Sincerely,

Laurie Fenton Ambrose
President & CEO