Research Advocacy Network
Advancing Patient-Focused Research

6505 W Park Blvd, Suite 305, PMB 220, Plano, TX 75093 Phone: 877.276.2187 FAX: 888.466.8803 www.researchadvocacy.org

January 18, 2011

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. FDA-2010-N-0621

The Research Advocacy Network requests the FDA to hold two open meetings: one to discuss the appeal of the withdrawal of Avastin for metastatic breast cancer and one to discuss the state of the science amongst all researchers currently involved in studying this question. The outcome of the state of the science meeting would be a strategy and timeline for answering these questions.

We would also respectfully ask that the public be allowed to speak at the appeal meeting. The people most affected by this decision are current and future breast cancer patients. They and their advocates should be heard. In addition to current and future breast cancer patients, patients diagnosed and being treated for other cancers with Avastin also may be impacted by this decision.

We are encouraged and applaud FDA for efforts to set standards for agents approved with PFS (Progression Free Survival) as an endpoint. We also ask for standards and consistent processes for agents approved with accelerated approval. What is the level of benefit and level of toxicity that must be met for accelerated approval? Are the criteria and or levels of benefit and toxicity different for targeted therapies than for chemotherapeutic agents? Is the level of benefit and toxicity used in primary cancer vs. metastatic cancer considered consistently? Many metastatic patients are willing to deal with greater toxicities than those in earlier treatment stages. We also ask for an understanding and full disclosure of the process for full approval when an agent is approved and/or removed after accelerated approval. The decisions from the agency related to the Avastin indication for breast cancer do not provide these for the public.

Clinicians state that they have patients who are or have benefited from taking Avastin. The level of benefit these patients have experienced is greater than the median 5.9 months found in E2100 – the trial that merited accelerated approval by the FDA. Removing the metastatic breast cancer indication for Avastin will mean current and future patients who could benefit from this agent will not have access without third party payer reimbursement.

Dr. Pazdur stated in a teleconference with advocates in December that we all want to find out which patients benefit from taking this agent. We will only find that out through research. There is research ongoing to find biomarkers for both benefit and toxicity. The state of the science meeting discussed above would allow researchers an opportunity to share what they have learned.

In conclusion, we strongly request the FDA withhold a decision until the research is completed and the results are made public.

Sincerely,

Mary Lou Smith
Co-Founders

Elda Railey