

From: Midthun, Karen
Sent: Friday, February 25, 2011 07:13 PM
To: [REDACTED]
Subject: Re: Avastin hearing exemption 6

Dear Ms. Howard:

Thank you for your message. Consistent with our regulations, I will place your message and this response in the docket for the Avastin hearing process.

The hearing is a legal proceeding involving the withdrawal of approval of an indication for Avastin. As I am sure you can appreciate, the FDA's decision on this matter must be based upon what the science shows. We believe that we must devote the time available at the hearing to presentations, by the sponsor, Genentech, and the FDA's Center for Drug Evaluation and Research, who will each present their side of the dispositive scientific issues.

We do understand the importance of this issue to you and to others who, like you, are battling this devastating condition. You, and they, will be given the opportunity to present your views in writing, and those views will be made part of the record of the hearing.

Sincerely,

Karen Midthun, M.D.

From: Patricia Howard [mailto:[REDACTED] exemption6]
Sent: Friday, February 25, 2011 11:31 AM
To: Midthun, Karen
Subject: Avastin hearing

Dear Ms. Midthun,

I just received the information regarding the Avastin public hearing in June.

I was the only metastatic breast cancer patient, representing thousands of women taking Avastin, that spoke in July at the FDA hearing for Avastin. My aim was to help you realize that there are so many of us surviving because of Avastin. And for many of us, we have no other treatment option. My latest scan, done at Sloan Kettering in New York, revealed no progression or evidence of disease. I was one of the original women selected for the clinical trial at Sloan Kettering testing Avastin in 2007, in combination with abraxane. I, to this day, continue to take Avastin with such positive results and minimal side effects.

I was upset to read that you do not want any speakers at the June hearing representing patients taking Avastin. I would like the opportunity, again, to speak in front of the committee. Please give us a chance to have our voices heard. The hearing is a discussion about a medicine for metastatic breast cancer, so those who have it and take Avastin should have the opportunity to speak.

Thank you.

Regards,
Pat Howard