

January 19, 2011

Margaret Hamburg, M.D.  
Commissioner  
Food and Drug Administration  
Department of Health and Human Services  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

Dear Dr. Hamburg:

We appreciate the opportunity to share our perspective. I am writing today on behalf of Men's Health Network (MHN), a national non-profit organization whose mission is to reach men and their families where they live, work, play, and pray with health prevention messages and tools, screening programs, educational materials, advocacy opportunities, and patient navigation.

We urge FDA to carefully consider the well-being of women and their families affected by metastatic breast cancer to ensure that they continue to have access to a broad range of treatment options. Men's Health Network seeks to support and promote optimal care and access. It is well documented that access and reimbursement issues often affect underserved and minority patients. Efforts need to be taken to ensure that we aren't putting an undue burden on these individuals.

This issue does not affect women in isolation; it also impacts and has serious implications for husbands, loved ones, and families. Men and their families want the best care, management, and support for their wives and partners and visa versa. Also, even though breast cancer occurs mainly in women, men can get it, too.

We strongly believe that treatment decisions should be made between an individual and their healthcare provider. That decision should be made after a thoughtful discussion about the benefits and risks of any course of treatment or therapy.

Where possible, we should avoid action which would stifle medical research and innovation and limit access to life saving therapies for women, men, and their families. We stand here concerned about the long term implications of these decisions, three, five, and ten years down the road. We are worried that this issue with Avastin may set a bad precedent moving forward.

Finally, we've heard that the manufacturer has requested a hearing and would encourage you to grant a hearing so that the issues and concerns may be discussed and reviewed in greater detail.

Thank you for your time and consideration.

Best Regards,

Scott T. Williams  
Vice President  
Men's Health Network

cc: Joshua Sharfstein, M.D.  
Janet Woodcock, M.D.  
Richard Pazdur, M.D.