



Headquarters Office:
919 18th Street, NW, Suite LL54, Washington, DC 20006
202.659.9709 Phone 202.659.9301 Fax 888.7939355 Toll Free

New York City Office:
48 Wall Street, 11th Floor, New York, NY 10005
917.305.1200 Phone 917.305.0549 Fax 888.445.3248 Toll Free

Research & Training Institute:
2020 Chamounix Drive, 2nd Floor, Fairmount Park, Philadelphia, PA 19131
215.878.0777 Phone 215.878.0853 Fax

January 7, 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:

I am writing today to urge the FDA's thoughtful consideration of women living with metastatic breast cancer and ensure that they continue to have access to a broad range of treatment options.

We have been informed that the manufacturer has requested a hearing and would encourage you to grant such a hearing so that the issues and concerns may be discussed and reviewed in greater detail.

We realize that FDA approval is not a requirement for a doctor to prescribe a drug, however it has the potential to have a tremendous impact on reimbursement. We feel strongly that treatment decisions should be a joint decision between a woman living with breast cancer and her treatment team. As with all medicines, we encourage a thoughtful discussion between a woman and her doctor that carefully considers the benefits and the risks. Each patient is different, with unique concerns, fears, and hopes for the future, and with different responses to medications and treatment protocols. Further limiting the already scarce range of treatment options for women with metastatic breast cancer could have a devastating impact.

We believe that the FDA has a great responsibility to act in the public interest. With an estimated 209,060 new diagnoses of breast cancer anticipated in 2010 in the United States, the public is in great need of improved treatment options and better access to those treatments - especially when a treatment promises improved outcomes (even modest improvements), manageable side effects and other positive results. At the

Cancer Support Community, we have learned a great deal from those we support, and we believe in the importance and value of an educated and empowered patient. Since people with cancer often feel stigmatized, alone, and overwhelmed with grief, they feel stronger and more hopeful when they have more treatment options available to them.

About the Cancer Support Community

Backed by evidence that the best cancer care includes emotional and social support, the Cancer Support Community offers these services to all people affected by cancer. Likely the largest professionally-led network of cancer support worldwide, the organization delivers a comprehensive menu of personalized and essential services. Because no cancer care plan is complete without emotional and social support, the Cancer Support Community has a vibrant network of community-based centers and online services run by trained and licensed professionals.

In July 2009, The Wellness Community and Gilda's Club Worldwide joined forces to become the Cancer Support Community. The combined organization provides high-quality psychological and social support through a network of nearly 50 local affiliates, more than 100 satellite locations and online.

Sincerely,



Kim Thiboldeaux
President and CEO
Cancer Support Community

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