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February 7, 2011

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

Dear Ms. Hamburg:

The Colon Cancer Alliance is the oldest and largest patient advocacy organization dedicated to colorectal cancer in America. We serve almost 500,000 people affected by the disease annually. I write to you in connection with the FDA's decision to withdraw Avastin for metastatic breast cancer.

As you know, colorectal cancer (CRC), also known as colon cancer, is one of the deadliest and most expensive diseases to treat. CRC is the second-leading cause of cancer deaths in the United States, but early detection and treatment can yield a 90 percent survival rate. Sadly, most are diagnosed with CRC at later stages when the disease is very difficult to treat. There are only a few treatment options for later stage patients, and most are not very effective and carry significant side effects.

While we understand the decision to withdraw Avastin for breast cancer does not directly affect CRC, we are concerned about the FDA processes in place and what we perceive as lack of consistent standards. We would like to see standards and consistent processes for approval and for review of approved therapies. What guidance does the FDA provide for what it considers a reasonable length of progression free survival? We understand some women taking Avastin may benefit from extended progression free survival thanks to the therapy, while other may not. We are concerned the FDA's decision takes away the doctor/patient decision making process. Metastatic patients often have few, if any, treatment options and it should be the decision of those patients and their doctors about what side effects and risks they choose to assume.

As the voice for the 1.2 million colorectal cancer survivors in the United States, we ask the FDA to consider the importance of a cancer patient's access to life extending treatment options as well as the individual preferences of the patient and their physicians.

Please feel free to contact me if you have any questions or wish to discuss this matter.

Very truly yours,

A handwritten signature in dark ink, appearing to read "Andrew Spiegel", is written over a light gray rectangular background.

Andrew R. Spiegel, Esquire

Chief Executive Officer