JOINT PRESS RELEASE

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PATIENT ADVOCATES FILE FOIA REQUEST TO FDA ON AVASTIN

Leaders in the battle with the U.S. Food and Drug Administration to retain metastatic breast cancer (mbc) as an indication for the drug Avastin today filed a Freedom of Information Act ("FOIA") request with the FDA.

The filers include noted attorney David Rivkin, partner at the law firm Baker Hostetler (www.bakerlaw.com/davidbrivkinjr/), Frank Burroughs and Steven Walker on behalf of the Abigail Alliance for Better Access to Developmental Drugs (www.abigail-alliance.org) campaigners for increased access to experimental drugs and Terrence Kalley on behalf of Freedom of Access to Medicines (www.fameds.org), an organization dedicated to the right of women to retain Avastin as a medical option for mbc.

The filers are troubled by many actions of the FDA in its review of the drug Avastin, a drug relied upon by an estimated 17,500 women with incurable mbc. Forty thousand American women die each year from metastatic breast cancer. Many woman and their oncologists report great success with the drug, yet the FDA will remove the indication for mbc, subject to a final appeal by the drug's manufacturer on June 28th & 29th at the FDA's headquarters in Silver Spring, Maryland.

The FOIA request includes documents regarding the nominations, appointment, actions and communications of the Oncologic Drugs Advisory Committee (ODAC) that will hear the appeal. Even though this panel will render a life and death decision at the June hearings, no patients or their advocates are allowed to speak and many may not be able to attend as the FDA claims space limitations.

The FOIA request also seeks documents regarding the processes by which the FDA reached its conclusions regarding Avastin, the communications between the FDA and various outside parties, any discussions related to the costs of Avastin in the FDA review process, conflicts of interest by those party to the Avastin decision, and other relevant issues.

The filers also seek the scientific basis for the FDA's decision with document requests related to risk and benefit evaluation of Avastin, comparison of the risk / benefit of Avastin versus current approved drugs, the use of progression free survival as a primary end point in cancer drug evaluation and the FDA's criteria for evaluation of toxicity under its Accelerated Approval Process.

The European Medicines Agency's advisory board recommended on April 15th, 2011 expanded use for Avastin for mbc. This follows the National Comprehensive Cancer Network's (an organization of leading U.S. cancer centers treating 160,000 patients per year) second vote to confirm retaining Avastin for use with mbc. The FOIA request includes documents related to how the FDA's decision-making process reached the opposite conclusion on Avastin from these bodies.