

Terrence D. Kalley, Husband of Avastin patient Arlene Kalley, Founder, Freedom of Access to Medicines

Speech to FDA Avastin Hearing, July 28, 2011, Silver Spring, Maryland

President Officer Midthune, Distinguished members of ODAC, courageous patients, families, friends, ladies and gentlemen, and above all, my beloved wife Arlene,

Knowing that death will come early from an incurable disease is devastating. The FDA has compounded this anguish by its complete indifference to current Avastin patients. The FDA has treated these women as expendable; innocent statistics in the face of a regulatory machine on autopilot, a bureaucracy unencumbered by any ethical controls. Your callous indifference is terrifying patients, their anxiety is excruciating; your prolonged silence, deafening.

The FDA purports to base its actions on science, in defiance of evidence and common sense. The highly unscientific and unethical handling of this entire Avastin saga cries out for Congressional oversight and major FDA overhaul.

Let's turn to super-responders, those responding well to Avastin. Despite strong empirical and observed evidence, the FDA contemptuously ignores these women, dismissively calling them "anecdotal evidence". The FDA unscientifically only considers medians from its trials. However, the FDA approach misleadingly omits the details behind the medians. Those details are vital, changing the picture. Individual patients respond differently to treatments. Medians hide this. The super-responders, fall greatly above the median. The European Medicines Agency has approved Avastin. The practicing breast cancer oncologists of the NCCN are pro-Avastin. Can you say with certainty that all these medical experts and patients are wrong? If there is any doubt that Avastin is keeping some of these women alive, how can you in good conscience vote against Avastin?

As many issues regarding Avastin remain unresolved while research continues, justice and common sense dictate that you not sentence these women to premature deaths by depriving them of their life-saving Avastin. It should not be

for you but for my wife and her oncologist to make this life and death decision. Please just leave my dear wife Arlene alone to continue taking her medication without any interruption of existing insurance. Is this asking too much?

Make no mistake; this hearing is a death trial not of Avastin but of these women who rely on Avastin to stay alive. You are each personally responsible for the consequences of your own vote. If you vote against Avastin, do not count on insurance companies and Medicare to provide coverage for Avastin. A vote against Avastin by each of you is a vote against thousands of women.

It has fallen to organizations such as my own, Freedom of Access to Medicines, staffed and funded solely by patients, their families and friends to fight for these Avastin women, to file the Freedom of Information Act request of the FDA. We organized the protest outside the FDA today. Avastin will become a household word in America if heaven forbid just one patient dies after you deny them their Avastin.

As America watches you and the FDA, reversing your prior no votes on Avastin will take humanity, humility, wisdom and great courage. Let not history show that you abandoned these precious women in their moment of desperation by choosing regulatory opinions over humanity.

Thank you.

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