

Article Summary: **“Not about rationing, why the FDA may reverse course on Avastin”**

The article “Not about rationing, why the FDA may reverse course on Avastin” by Sharon Begley in the October 2010 issue of Newsweek™ magazine discusses studies regarding the drug Avastin, a controversial cancer medication. Avastin is currently an FDA approved drug used to control metastatic cancers other than breast cancer. Given its potential Avastin received a “Fast-Track” approval to be used for the treatment of metastasized breast cancer. In July 2010 an FDA panel voted twelve to one to withdraw the approval of Avastin for MBC. The reason for this decision was the result of two large clinical trials, which found that Avastin did not keep woman alive any longer than chemotherapy alone. The article negates the idea that the decision to withdraw Avastin was some sort of political conspiracy associated with what the author refers to as “Obamacare”.

Some of the “Major Players” in this article are the drug company Genentech, the MBC patients, their physicians, and the researchers both at Genentech and associated with the FDA who are attempting to measure the effectiveness of Avastin for MBC. In addition to these major players, there are others involved in the entire story. They include the politicians on both sides of the aisle who are either for or against the new healthcare reform law, and the followers and pundits who develop and repeat the arguments about the drug Avastin and discuss its relationship, if any, to the new healthcare law.

One of the issues in testing the drug is that there are a tremendous amount of variation in the survival times of those who take the drug and those who do not. This variation requires a large sample size in the trial evaluation and a blind study to ensure there are no sample biases.

The author makes it clear that the politicians are trying to link the delisting of the drug to the Obama healthcare bill. The article quotes Sen. David Vitter accusing the FDA of “Assigning a value to a day of a persons life.” The article then quickly rebuts his assertion saying that Avastin has been shown to not only be ineffective in increasing one’s life but also has an extensive number of severe side effects. Those wanting to discredit the new health care reform law will ignore strong statistical evidence in order and use anecdotal information to build their case.

Success stories are anecdotal and are not indicative of the average likely effects of the drug. There is simply too much variation to base the effectiveness of the drug on a small number of anecdotal findings. Doctors and patients are sometimes influenced by their personal experiences as much as or more than actual statistical data.

One of the lessons that can be taken from this article is that no matter what large studies show or the FDA uses to prove the effectiveness of drugs, the patients and their physicians can be more influenced by their emotional attachment to the drug than by statistical data. In spite of good statistical analysis, politicians and pundits can distort facts by preying upon the fears and hopes of the public rather than their logic.