PATIENT SAFETY BLOG

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Posted On: May 25, 2011 by Patrick A. Malone

Does a Drug Really Work? Why Numbers, Not Testimonials, Matter

Testimonials from satisfied customers sell products. Every marketer knows that. But testimonials from patients are the wrong way to decide if a drug deserves an endorsement worth billions in sales from the Food and Drug Administration.

Why? Because, as a Virginia cancer doctor explains in a new article, the testimonials from happy cancer patients mask the fact that many other patients were not helped, or worse, were killed by the drug.

Patrick A. Malone Patrick Malone & Associates, P.C. 1331 H Street N.W. Suite 902 Washington, DC 20005 pmalone@patrickmalonelaw.com www.patrickmalonelaw.com 202-742-1500 202-742-1515 (fax) The drug now being pushed to the FDA by the testimonial technique is called Avastin.

It's been proven to help patients with some kinds of cancers: colon, brain, lung and

kidney cancers which have spread beyond their first site of discovery. It doesn't cure

the cancer, but it can strangle a tumor's blood supply and thus shrink a cancer.

Avastin was tried with advanced breast cancer, but rigorous studies found that it didn't

help quality of life for patients with breast cancer, and it didn't extend their lives, even

measured by months. Plus it comes with serious side effects, the most prominent being

the potential to cause a hole to suddenly develop in the stomach or intestines, which

can be fatal.

So the FDA said the manufacturer couldn't market it for breast cancer.

Now Genentech, the maker of Avastin, is taking another run at the FDA, using

testimonials from patients and treating doctors to try to get the agency to change its

mind.

Dr. Frederick C. Tucker Jr., an oncologist in Fredericksburg, Virginia, wrote an "op-ed"

piece in the New York Times commenting on this stratagem by the drug company:

[A]necdote is not science. Such testimonials may represent the human voices behind

the statistics, but the sad fact is that there are too many patients who have been

treated with Avastin but are not here to tell their stories.

Avastin will not disappear because of the F.D.A. decision. It remains available for

treating other cancers, and research to find its appropriate role in breast cancer

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treatment continues. In the meantime, the F.D.A., which is expected to make its decision in September, needs to resist Genentech's attempt to have it ignore scientific evidence.

Serious progress in the treatment of cancer will not be the result of polemics, lobbying or marketing. Genentech's money and efforts would be better spent on research for more meaningful treatments for breast cancer.

The Avastin website has photos of real patients who Genentech says have been helped by the drug. These photos tug at viewers powerfully. But they don't substitute for hard statistical analysis.

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