PATIENT SAFETY BLOG

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By Patrick A. Malone - **June 28, 2011**

Once Again, the FDA and Avastin Are Doing the Hokey Pokey

A couple of months ago we gave a shout-out to a physician who had written a commentary about Genentech's efforts to have the FDA bless the use of its drug Avastin for treatment of certain breast cancers. He had objected to the use of patient testimonials as compelling evidence to support such appeals because they're not science, they're marketing.

In what the company and its supporters probably consider honorable tenacity but thinking minds ascribe to naked greed and abuse of taxpayer resources, the FDA again this week is hearing the case for approving Avastin as a conditional treatment for certain breast cancers, never mind that studies have shown it to be neither life-prolonging nor markedly life-enhancing. In the face of life-threatening side effects, Genentech still champions the drug because it has helped some patients.

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Yes, Virginia, and some people make a living swallowing swords and eating fire, but such activity isn't, as they say in FDA-land, "generally recognized as safe."

Two editorials appearing this week in the New England Journal of Medicine speak in favor of science and respect for human life.

Genentech presented four arguments against the FDA's proposed withdrawal of Avastin for breast cancer: one, the move has no precedent; two, the possibility of some patients benefiting justifies continued approval; three, individual patient choice should prevail; and four, ruling against Avastin will make future drug development confusing and discourage innovation. And, like the kid who throws the ball over the fence because he doesn't like the ump's call, Genentech also took a shot at the FDA committee considering the matter, calling it biased and requesting different judges.

We won't dignify Genentech's hissy fit, but, in order, here's why Genentech's appeal is folly.

One: Precedent for removing a drug's indication for a specific disease is part and parcel of U.S. drug regulatory process.

Two: Just because some patients might benefit doesn't mean there is enough benefit to outweigh the harm to many other patients taking this highly toxic drug. Such lazy extrapolation ignores the absence of Avastin data identifying the patient characteristics that are associated with the benefit. That's incomplete science, and it's dangerous.

Three: Genentech's position that "conflicting interpretations of data should be resolved in favor of retaining access and choice" is a direct contradiction of the FDA's mandate. As the NEJM commentary stated, "In a democratic republic, access and choice represent two among many values. The FDA must also protect scientific rigor, the integrity and legitimacy of federal regulations and guidance, and the public's health. The agency's reputation for using science to guide regulatory decisions in the public interest is its most critical institutional asset."

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Four: FDA action to restrict a drug's use from some applications is common and practically perfunctory. Instead of chilling R&D, such a situation might effect more aggressive drug development--if Avastin offers little promise for patients with metastatic breast cancer, won't pharmaceutical companies be inspired to develop a better product? After all, that's where the money is, and we all know what motivates Big Pharma.

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