Dispatch: No More Avastin For Breast Cancer

By ACSH Staff — July 21, 2010

On Tuesday, an FDA advisory panel recommended that Avastin no longer be indicated for breast cancer after new studies failed to show that the drug could increase patients’ life expectancy. Avastin is currently approved for colon, lung, and other cancers, but physicians will have to prescribe it as an off-label breast cancer treatment if the FDA chooses to adopt the panel’s decision.

ACSH’s Jeff Stier believes this post-market evaluation process illustrates how difficult it is for pharmaceutical companies to thrive in the current regulatory climate. “They went through all of this testing and obtained approval for their drug, only for post-market studies to discount those findings and most likely lead the FDA to pull the drug indication.”

ACSH’s Dr. Gilbert Ross, however, emphasizes his support for such post-marketing drug studies. “I think it’s appropriate that drugs approved by the FDA, based on small clinical trials — phase I, II and III — be required to have post-marketing studies done to see if there’s a toxicity or adverse reaction in large populations of patients taking the drug that was not detected in the relatively small pre-market studies. In this case, Avastin was shown to lack efficacy for a large number of patients, but it could still benefit certain populations.”

“Then the FDA should feel more comfortable granting approval knowing that they can always reevaluate later,” Stier responds. “The more people you test these drugs on, the more likely you are to determine which patients will actually benefit from the drug.”

Source URL: https://www.acsh.org/news/2010/07/21/dispatch-no-more-avastin-for-breast-cancer

Links