Why Has Avastin Been Disapproved as a Treatment for Breast Cancer?

The recent decision by a Food and Drug Administration panel to reverse its past approval of Avastin as a treatment for breast cancer has received a lot of publicity and caused a significant amount of controversy. The final decision will be up to the FDA commissioner, Margaret A. Hamburg but if she chooses to follow the unanimous recommendation of her medical panel, Avastin will no longer have official sanction as a legitimate treatment option for breast cancer patients.

During the recent public hearings held to debate this issue, breast cancer victims who believe that Avastin has helped to prolong their lives gave emotional and impassioned testimony opposing the FDA's plans – but to no avail. Members of the general public, as well as many breast cancer sufferers who have used Avastin in the past or may have been considering using it in the future, may be confused as to why the FDA is planning to withdraw its approval for a drug that appears to be making a positive impact on the lives of many. To understand why this decision was reached, it is necessary to look a little closer at how Avastin has been used, what has been discovered, and why the FDA has chosen to change its policy at this particular time.

A Brief History of Avastin and Breast Cancer

Avastin has been used for a while to treat cancers of the lung, colon, brain, and kidney. It was only in 2008, however, that is was given tentative approval for use in the treatment of breast cancer and even then it was only to be used in combination with the chemotherapy drug Taxol. The pharmaceutical giant Roche, who manufactures Avastin, had performed preliminary studies that indicated the drug could be effective in extending lifespan and keeping breast cancer symptoms in remission. However, under this accelerated approval program the FDA required Roche Industries to perform further studies to verify that the drug really worked.

By 2010, it had become clear to researchers that the findings of the original study were not going to be confirmed. Subsequent studies have shown that Avastin does not increase survival rates, usually has only temporary benefits, and causes terrible side effects such as heart failure, dangerously high blood pressure, and gastrointestinal perforations (holes in the stomach). In approximately 2.5% of cases examined, the side effects of the Avastin/Taxol therapy regime were serious enough to lead to the death of the patient. Based on these later results, in December of 2010 the FDA announced its decision to withdraw its earlier, tentative approval of Avastin for use against breast cancer, and then reconfirmed that intention after the public hearings that were held in June.

The Future of Avastin

While there has been negative reaction from some breast cancer patients and advocacy organizations, others have expressed their approval of the FDA's change in policy. At this point, the only evidence in favor of Avastin is anecdotal, which has led many to speculate that the drug may be useful only for a small subset of breast cancer patients. Others have pointed out that because Avastin has only been given in combination with chemotherapy, it is possible that women who have apparently been helped would have had the same results if they had taken chemo alone. Oncologists and other cancer experts have called on Roche Industries to concentrate their future research efforts on trying to find out more about that subset of women who could perhaps be helped by Avastin, assuming that some breast cancer patients have indeed been helped by taking it in the past. In the meantime, however, medical personnel are not going to continue widely prescribing a drug that appears to cause terrible side

effects more frequently than it actually helps women with breast cancer.

Even though the FDA will apparently withdraw its support for Avastin as a treatment for breast cancer, that does not mean the drug will no longer be available for women who would like to continue using it. Because the drug is used for other cancers it will still be in production, and patients who want to take it for breast cancer will be able to have it prescribed “off-label” as long as doctors agree. Medicare officials also have announced that this government program will continue to cover Avastin for breast cancer patients regardless of any FDA action. The main difficulty for potential patients is that insurance companies seldom pay for off-label treatments, and since Avastin can cost as much as $8,000 a month, few breast cancer sufferers are likely to be able to afford to pay for it on their own.

The Only Possible Decision

While those who truly believe Avastin has helped them are understandably disappointed and upset about the FDA's decision, it is clear that the science simply does not support the use of Avastin for breast cancer at this time. The experiences of those who have become extremely sick or died as a result of taking this powerful drug are just as important to the equation as the experiences of those who believe they have been helped by Avastin. Until researchers can find a way to isolate those breast cancer victims who might be helped by Avastin from the larger group of patients, it does not make sense for doctors to continue widely prescribing this drug.