EU OKs Avastin for breast cancer FDA behind the times?

By ACSH Staff — March 4, 2011

On Wednesday the European Commission approved the use of Avastin (bevacizumab) for treatment of advanced stage breast cancer. This decision [1], which follows from a recommendation of a European Union advisory panel, stands in marked contrast to the policies of the FDA. This past December the FDA announced that it planned to revoke its approval for the drug for breast cancer patients.

Avastin is still approved by the FDA as a treatment for lung, kidney and colon cancer and one form of brain cancer.

The European Commission based its decision on research showing that a combination therapy based on treatment with Avastin and Taxol (paclitaxel) stopped the spread of advanced stage breast cancer for five and a half months longer on average than a standard chemotherapy regimen alone. The FDA, however, has chosen not to focus on the length that a patient is in a state of disease-free progression (DFP) but on ultimate survival rates.

ACSH's Dr. Gilbert Ross notes that physicians can still prescribe Avastin for breast cancer “off-label.” “But,” he says, “if the FDA reversal is upheld after Roche’s appeal later this year, patients would have trouble getting private insurance or Medicare/Medicaid to pay for it. And paying for a prescription out of pocket can cost $80,000 per year.”

He adds: “Avastin has an assortment of side effects. Even so, if I had the choice of living an extra five and a half months without cancer progression, I think I’d want that. It appears that the FDA is increasingly taking a more restrictive approach to drug approvals even than the EU.”