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FDA ADVISORY COMMITTEE RECOMMENDS TAXOL FOR OVARIAN CANCER

We have had some media interest concerning the Nov. 16 recommendation by the FDA Oncology Drugs Advisory Committee that Taxol (paclitaxel) be approved for treatment of refractory ovarian cancer (cancer that is unresponsive to conventional therapy).

The committee, a group of outside experts, considered data presented by representatives of FDA, the National Cancer Institute (NCI) and Bristol-Myers Squibb Co., manufacturer of Taxol. The committee's recommendations were based on its conclusion that the data showed evidence of Taxol's effectiveness that is strong enough to allow its use in patients who have failed first line chemotherapy.

Clinical trials conducted by NCI at five centers around the country, plus multi-center trials in Europe sponsored by the manufacturer, were reported to have confirmed that Taxol shrinks tumors by at least one-half in 20 to 30 percent of patients with refractory ovarian cancer, for an average of five months. In these studies Taxol, like many other cancer drugs, was associated with serious side effects including a decrease in white blood cells (which may cause susceptibility to infections), hair loss and numbness of the fingers and toes.

FDA has completed its initial review of information on Taxol,

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the agency is awaiting further data relating to manufacture of the drug and completion of an environmental assessment, required by law. Because taxol is obtained from the Pacific yew tree, this involves an assessment of the effect of yew harvesting on U.S. forests. The environmental assessment is being prepared in cooperation with the U.S. Forest Service.

NCI and Bristol-Myers Squibb are also working under a collaborative agreement to find new sources of the active ingredient and to further develop Taxol as an anti-cancer drug.

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