



Department of Justice

FOR IMMEDIATE RELEASE
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**JUSTICE DEPARTMENT APPROVES SURVEY OF COST EFFECTIVENESS
OF CLINICAL TRIALS INVOLVING BREAST CANCER PATIENTS**

WASHINGTON, D.C. -- A group of cancer institutes will be allowed to collect data comparing the resource utilization and cost effectiveness of various treatments used in a study of breast cancer patients in order to demonstrate the effectiveness of the treatments in comparison to standard care under a proposal approved today by the Department of Justice's Antitrust Division.

In its first such project, The Southwest Oncology Group and its Clinical Practices Committee will be permitted to collect data from institutions in Washington, Florida, California, Missouri, Kansas and Michigan. The results of the study will be shared with other researchers, insurance companies and physicians through publications, at meetings and in medical journals. This will allow them to judge for themselves the cost effectiveness of various treatment regimens.

The Department said the proposed activities are unlikely to be anticompetitive since there is no agreement among the group's members to approach or negotiate with insurance companies collectively or to attempt to coerce concessions from them by taking a unified position in separate negotiations.

In addition, the Department said the study promises to benefit consumers by controlling health care costs and ensuring the most effective use of health care resources.

The Department approved a proposal to analyze the cost effectiveness of various treatments used in a study of breast cancer patients with a high risk of recurrence. The patients will be randomly treated with one of six different medication combinations using the drugs cyclophosphamide, adriamycin, Taxol and Tamoxifen. The oncology group's statistical center in Seattle will collect and analyze the data, which will be more than three-months-old at the time of analysis. The committee also plans to develop a data base for application to other clinical trials.

The Department's position was stated in a business review letter from Anne K. Bingaman, Assistant Attorney General in charge of the Antitrust Division, to counsel for The Southwest Oncology Group.

The Southwest Oncology Group is an association headquartered in San Antonio, Texas, whose members include universities, hospitals and other health care institutions and providers. It currently has 35 primary member institutions and more than 60 additional affiliated members located throughout the U.S.

Under the Department's Business Review Procedure, an organization may submit a proposed action to the Antitrust Division and receive a statement as to whether the Division will challenge the action under the antitrust laws.

A file containing the business review request, and the Department's response may be examined in the Legal Procedure

Unite of the Antitrust Division, Room 3235, Department of Justice, Washington, D.C. 20530. After a 30-day waiting period, the documents supporting the business review will be added to the file.

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