DEPARTMENT OF JUSTICE
Antitrust Division

ANNE K. BINGAMAN
Assistant Attorney General

Main Justice Building
10th & Constitution Ave., N.W.
Washington, D.C. 20530
(202) 514-2401 / (202) 616-2645 (f)
antitrust@justice.usdoj.gov (internet)
http://www.usdoj.gov (World Wide Web)

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A. Michael Ferrill, Esquire
Cox & Smith
112 East Pecan Street, Suite 1800
San Antonio, TX 78205-1521

Dear Mr. Ferrill:

This letter responds to your request on behalf of Southwest Oncology Group ("SWOG") and its Clinical Practices Committee ("the Committee") for a business review letter pursuant to the Department of Justice's Business Review Procedure, 28 C.F.R. § 50.6, concerning a project of the Committee to advance clinical research through resource utilization and cost effectiveness analysis.

As we understand from the information that you have provided, SWOG, which was formed in the late 1950s, is an unincorporated association of universities, hospitals and other health care institutions and providers. It currently has 35 primary member institutions and more than 60 additional affiliated institutional members throughout the United States. In pursuing its primary function, which is the conducting of clinical trials associated with cancer research, SWOG contracts with approximately 4,000 investigators at 523 institutions (both SWOG and non-SWOG members) in 44 states. Together, these investigating physicians treated 17,000 clinical trial participants in 1994.

The Committee is made up of the principal investigators from SWOG's member institutions,[1] and was officially formed about two years ago in response to some insurance

[1] SWOG's 35 primary member institutions include Boston University; Columbia University; Loyola University; University of Michigan; Ohio State University; UCLA; and University of California, Irvine. Current members of the Clinical Practices Committee "Working Group" are the Swedish Tumor Institute, Seattle; the Cleveland Clinic Florida; Springfield Clinic, Springfield, MO; St. Francis Hospital, Wichita, KS; Los Angeles Oncology Institute; Mount

companies' refusals to cover costs to patients for participation in clinical trials. Thus, among the Committee's stated goals are evaluating the effectiveness of trials in comparison to standard cancer care, and informing the public of the comparative value of clinical trials.[2]

Approximately 60 percent of SWOG's funding comes from grants awarded by the National Cancer Institute ("NCI"). Additional funding is provided through cost-sharing by the member institutions and arms-length contracts with various pharmaceutical companies.

SWOG and similar cooperative research groups enable their members to conduct clinical trials that would not be possible if each member attempted to conduct such trials unilaterally. Through the cooperative efforts of its members, SWOG is able to increase the number of patients participating in trials and improve the statistical significance of the results. Trial ideas are presented to SWOG administrators and NCI by SWOG's various committees and their scientific experts. Protocols are then developed, and sent by computer to the various participating investigators, who then obtain the consent of their institution to the protocols. The protocols, which must be strictly followed in conducting each trial, ensure patient homogeneity and uniform treatments so that all trials yield meaningful results. When results are tabulated, they are distributed to all institutional participants, are reported at SWOG meetings, may be published in medical journals, and are generally publicly available.

In order to demonstrate to insurance companies that clinical trials are a cost-effective alternative to standard cancer treatments, and to encourage the companies to extend insurance coverage to treatment provided in clinical trials, the Committee's Clinical Practices Working Group proposes to devise ancillary protocols to be used to study resource utilization and cost effectiveness. In order to do this, investigators will track numbers of physician visits, laboratory tests, x-rays, nurses' visits, primary and supportive drugs, hospitalizations, etc., provided to each patient in the course of the clinical trials. Costs will be assigned to all procedures and treatments based on standardized data bases such as Medicare's allowable reimbursements for medical services. These cost figures will then be analyzed in relation to treatment effectiveness to assess the cost effectiveness of each course of treatment studied by the Committee.

The first clinical trial under this program, SWOG-9410, will study patients who have a high risk of recurring breast cancer. Patients will randomly receive one of six different treatments that include various combinations and amounts of the drugs cyclophosphamide, adriamycin, Taxol and Tamoxifen. The purpose of the ancillary protocol will be to determine the relative effectiveness of the treatments based on their cost and also their toxicity. Data will

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Clemens General Hospital, Mount Clemens, MI; University of Washington Medical Center; and the National Coalition for Cancer Survivorship, Silver Spring, MD.

[2] Other stated goals of the Committee are to encourage and enhance the proper utilization of resources, and to emphasize the ethical questions posed by clinical trials.

be collected from at least five providers,[3] located in various regions of the United States. The data collected will be more than three months old at the time of analysis and the survey will be managed by SWOG's Statistical Center in Seattle, Washington. The information disseminated will be sufficiently aggregated so that it will not allow the recipients to identify the costs incurred by any particular provider. In addition, no individual provider's data will constitute more than 25% on a weighted basis of any statistic disseminated. Finally, results obtained will be presented in such a way as to allow physicians, researchers and others to draw their own conclusions about the cost effectiveness of any given treatment, and SWOG will not attempt in any way to influence its members to follow a particular treatment regimen to the exclusion of other types of treatment.

Statement 6 of the Statements of Enforcement Policy and Analytical Principles Relating to Health Care and Antitrust issued by the Department of Justice and the Federal Trade Commission on September 27, 1994 provides a safety zone for competing providers' participation in written surveys of costs or prices for health care services. While we have not determined the extent to which members of SWOG or its investigatory affiliates are competitors,[4] in any event SWOG's proposed activities involving the exchange of cost or price information would fall under the Statement 6 safety zone.

Other aspects of SWOG's proposed activities also appear unlikely to result in anticompetitive effects. While it is contemplated that the results of SWOG's cost-effectiveness study will be provided to insurance companies to persuade them to extend coverage to treatment provided during clinical trials, there is no agreement among SWOG members or affiliates 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 proposed cost-effectiveness study promises to benefit consumers by providing information that can be used to help control health care costs and ensure the most effective use of health care resources. Accordingly, the Department has no intention to challenge SWOG's proposed conduct described in this letter. In accordance with our normal practice, however, the Department remains free to bring whatever action or proceeding it subsequently comes to believe is required by the public interest if the proposed program proves to be anticompetitive in purpose or effect.

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[3] Swedish Tumor Institute, Seattle; Cleveland Clinic Florida; Cancer Institute of Los Angeles; Springfield Clinic (MO); St. Francis Hospital, Wichita; Mount Clemens General Hospital (MI).

[4] A number of those institutions participating in SWOG's activities compete with each other to some extent to attract patients, and SWOG participants may compete with each other to some degree to obtain research grants from NCI and other sources.

This statement is made in accordance with the Department of Justice Business Review Procedure, 28 C.F.R. § 50.6, a copy of which is enclosed. Pursuant to its terms, your business review request and this letter will be made publicly available immediately. In addition, any supporting data that you have not identified as confidential business information under paragraph 10(c) of the Business Review Procedure also will be made publicly available.

Sincerely,

/S/

Anne K. Bingaman
Assistant Attorney General