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May 31, 1995

Honorable Anne K. Bingaman
Assistant Attorney General
Antitrust Division
United States Department of Justice
Tenth Street & Constitution Avenue, N.W.
Washington, D.C. 20530

Re: Request for Business Review Letter
Southwest Oncology Group

Dear Ms. Bingaman:

Pursuant to 28 C.F.R. § 50.6, Southwest Oncology Group ("SWOG") requests that the Justice Department review and state its present enforcement intentions with respect to a project of SWOG's Clinical Practices Committee (the "Committee") to advance clinical research through cost analysis.

SWOG is an unincorporated association of health care institutions and providers. Its purpose is to conduct clinical trials associated with medical research. The Committee is composed of the principal investigators from SWOG's member institutions. The Committee's primary function is to encourage proper utilization of resources and evaluate the effectiveness of clinical trials in comparison to standard care. The Committee proposes to introduce ancillary protocols for clinical trials. The Committee will determine and compare the resource utilization of the various treatment arms of clinical trials and determine the cost effectiveness of each arm. The Committee will compare the results in the long term with the outcomes of overall survival and time-to-relapse, with the goals of encouraging the proper allocation of resources and establishing the cost effectiveness of clinical trials in comparison to standard care. Secondary to these goals is the Committee's plan to develop a database for application to other clinical trials.

Pursuant to the Department's September 27, 1994 Statements of Enforcement Policy and Analytical Principles Relating to the Health Care and Antitrust (the

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"Statements") issued by the Department and Federal Trade Commission, we understand that the Agencies will not challenge, absent extraordinary circumstances, provider participation in written surveys of (a) prices for health care services or (b) wages, salaries or benefits of health care personnel, if the following conditions are satisfied:

- (1) The survey is managed by a third party (e.g., a purchaser, government agency, health care consultant, academic institution or trade association);
- (2) The information provided by survey participants is based on data more than three months old; and
- (3) There are at least five providers reporting data upon which each disseminated statistic is based, no individual provider's data represents more than 25 percent on a weighted basis of that statistic, and any information disseminated is sufficiently aggregated such that it would not allow recipients to identify the prices charged or compensation paid by any particular provider.

In connection with the Project, the Committee proposes to collect aggregated data from at least five providers, 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. The information disseminated will be sufficiently aggregated such that it will not allow the recipients to identify the prices charged or compensation paid by any particular provider. In addition, no individual provider's data shall constitute more than 25% on a weighted basis of any statistic disseminated.

To facilitate the Department's review, we enclose a description of the first ancillary protocol under this program, SWOG 9410 - Doxorubicin Dose Escalation, With or Without Taxol, as Part of the CA-Adjuvant Chemotherapy Regimen for Node Positive Breast Cancer: A Phase III Intergroup Study ("Trial 9410"). This intergroup study is a randomized trial for patients who have a high risk of recurring breast cancer. Patients will be randomized to receive one of six possible different treatments. We would appreciate your expedited review of this matter and stand ready to cooperate fully with the Department and to provide such additional information as may be necessary.

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No part of the enclosed material is deemed confidential.

Thank you in advance for your attention to this matter. Please contact the undersigned at the address and telephone number given above with any inquiries you may have.

Very truly yours,

A handwritten signature in black ink, appearing to read "Michael Ferrill", written in a cursive style.

A. Michael Ferrill

AMF/hi/0077988.01
Enclosure