6/14/01, distributed 7/1/01

TO: Southwest Oncology Group

FROM: NCCTG

MEMORANDUM

The National Cancer Institute has requested that each cooperative group Data Monitoring Committee (DMC) provide DMC recommendations to institutional review boards. For intergroup studies coordinated by NCCTG, the Operations Office of each participating group will receive a report of the NCCTG DMC's recommendations. The cooperative group will be responsible for making the information available to its member institutions.

Below is SWOG's report:

#N9831 (Adjuvant AC + Paclitaxel +/- Trastuzumab in HER-2 Overexpressing Node-Positive Breast Cancer):

The DMC voted unanimously (6-0) to accept the report without discussion.
The adverse event data was reviewed, and no toxicity problems were found.

#93-46-53 (Laparoscopic-Assisted Colectomy vs. Open Colectomy for Colon Cancer):

Action: The DMC reviewed the adverse events information for this trial and found no problems. The DMC voted unanimously (6-0) to recommend that accrual to the study be terminated as of August 31, 2001, and that the study team make a concerted effort to ensure the accrual goal of 900 patients is achieved by that time point.

#N9741 (Phase III Randomized Trial of Two Different Regimens of CPT-11 + 5FU + CF, Two Different Regiments of OXAL + 5FU + CF, and One Regimen of OXAL + CPT-11 Compared to 5FU + CF as Initial Treatment of Patients with Advanced Adenocarcinoma of the Colon and Rectum):

Study Team recommendation: The study team presented updated data regarding the toxicity on the trial. As of 4/25/01 there had been 293 patients entered onto arm A of the trial with 9 treatment-related deaths (3.1%). This compares to rates of 0.7% on arm F and 1.5% on arm G. This difference is not statistically significant. The study team sought the advice of the DMC as to the appropriate course of action.

Action: The DMC sought external advice on this matter. The DMC was joined via conference call by Drs. Jack MacDonald, Daniel Haller, and Sam Wieand. Dr. Goldberg abstained from voting due to his role as study chair. The committee first denied by a 2-3 vote a motion to allow the external advisors to vote on the final recommendation for this study. The DMC subsequently recommended by a 3-2 vote that accrual to the trial be temporarily suspended, that the starting dose be modified on arm A to dose level -1, and that a dose-escalation step be added to arm A for patients who tolerate dose level -1 well. The committee also requested that the study team present to the DMC at the Fall 2001 meeting an assessment of the impact of this study change on the design, statistical power, and necessary accrual.

#N9841 (A Randomized Phase III Equivalence Trial of Irinotecan (CPT-11) vs Oxaliplatin (OXAL)/ 5-Fluorouracil (5-FU)/Leucovorin (CF) in Patients with Advanced Colorectal Carcinoma Previously Treated with 5-FU):

The DMC voted unanimously (6-0) to accept the report without discussion.
No toxicity problems were found.