



March 19, 2002

TO: THE GASTROINTESTINAL DRUG ADVISORY COMMITTEE
RE: CHEMOPREVENTION OF COLORECTAL CANCER TRIAL DESIGN

The Colorectal Cancer Network is committed to clinical trials in general and is particularly interested in any prevention trials. We encourage the Food and Drug Administration to give this area particular focus and emphasis in order to reach a day when colorectal cancer can be prevented.

Our participation in today's advisory committee is to ensure that several items of importance to the patient community are kept in mind and considered in the design phase.

QUESTIONS:

Has the statistically significant number of trial participants been estimated so that all general population (those at risk for sporadic colorectal cancer) preventive trials will accurately reflect real world circumstances?

Will particular enforcement be taken in order to ensure that women, cultural, and ethnic groups are reliably represented in any trial that takes place?

ISSUES:

A study to prevent colorectal cancer will need to be a lengthy one with a large enrollment. Small studies and studies done over a short period of time will show little since colorectal cancer can take ten years or more to develop. However, in that ten year period polyps can be expected to develop in the tested population. It is important that any chemoprevention study for colorectal cancer be validated not just by the absence of cancer but also by the absence of the polyps that precede this cancer.

We are concerned with your use of the word "most" in your pre-committee meeting briefing with regards to polyps that do not become malignant. The term used more frequently is "many". We would be appreciative if you would please identify the documentation used that has led to your choice of the word 'most'.

Your pre-committee meeting briefing seems to indicate that short-term polyp suppressive effects do not have value. We ask you to reconsider this point. If true preventive measures are not available then any measure that lengthens the growth and development time of polyps

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would also lessen the incidence rate of colorectal cancer by increasing the window of early or pre-detection.

In your BACKGROUND statement you have noted that 6% of Americans will develop this cancer and that 2.6% of them will die from it. The 2.6% seems to be too low since the death rate of colorectal cancer patients is nearly 60%.

We do not believe that chemoprevention will replace colonoscopies. Rather it will ultimately increase the length of time that it is safe to go between getting colonoscopies.

Chemopreventions will be especially valuable in those people who are unable to undergo colonoscopies due to other health reasons.

There are a growing number of sporadic colorectal cancer incidences in the under-50 population. Any study that is conducted should not be limited to just those 50 and older.

Dietary causes of colorectal cancer have not been properly documented and studied and therefore need to be kept separate from these studies. However, co-existing studies documenting diet of the trial participants may prove to have value at a later date. Doing co-existing studies should be considered.

Thank you for this opportunity. The FDA's inclusion of the patient populations in this process is valuable and valued by CCNetwork and the thousands of patients that we represent.

Priscilla Savary
Executive Director