Statement on Recommendations of the Consensus Development Panel on Breast Cancer Screening

The National Cancer Institute (NCI) has received the final conclusions and recommendations of a 16-member panel that examined the issues and state of the art of breast cancer screening. The panel, which met September 14-16, 1977, in Bethesda, Maryland, consisted of clinicians, scientists, and lay people. It was chaired by Samuel Thier, M.D., professor and chairman of the Department of Internal Medicine, Yale University, New Haven, Connecticut.

Much of the discussion centered on the use of mammography in routine breast cancer screening.

The panel concluded that scientific evidence of the benefit of X-ray mammography was provided in a study by the Health Insurance Plan (HIP) of Greater New York, conducted in the 1960's. They agreed that benefit, as measured by mortality, was established for women 50 years of age and older and that this benefit was provided through combined use of physical examination and mammography. No scientific evidence is available to determine the individual contribution of each method. No similar evidence of benefit to women under 50 years of age could be established.

Throughout the proceedings, the panel was careful to emphasize the difference between the use of mammography as a screening tool and as a diagnostic technique. The value of mammography as used in diagnosis for the evaluation of symptoms or clinical signs of breast cancer (such as the presence of a lump, swelling, discharge, dimpling, thickening, or other abnormality in the breast) has not been questioned.

Panel members acknowledged that mammography has improved markedly in recent years, detecting smaller and presumably earlier cancers, and that radiation dosage from the procedure has been reduced greatly. Nonetheless, they accepted the presumed risk of exposure to radiation from mammography that was outlined in a report submitted in March 1977 by Dr. Arthur C. Upton, then head of an ad hoc working group studying the risk of radiation exposure. That report stated that current evidence strongly suggests a direct linear relationship between the amount of radiation exposure and the risk of developing cancer. It placed the presumptive increased risk from exposure to the breast at less than 1% per rad. This implies that a mammogram with current low-dose techniques would increase a woman's presumed lifetime risk of breast cancer from an average natural level of about 7% to a level of less than 7.07% following mammography.

Panel members concluded that the BCDDP's may have an ethical obligation to continue to offer mammography to women under 50 years of age enrolled in the program, if it is made clear to them through informed consent that the benefit has not been proved, that there is presumed risk, and that the panel does not recommend its routine use for this age group.

NCI has made no final determination in this matter. A new informed consent form is being developed that will reflect these concerns. Until it is completed, the BCDDP's have been instructed to continue using mammography to screen only women designated by the panel or those whose personal physicians have submitted written requests for mammography. The new informed consent form also will include the radiation dosage received. This information will be supplied at each project and will be updated as appropriate. Inclu-
sion of dosage information was recommended by the panel.

Data on the breast cancer detection rates of the BCDDP's were provided in a report from the Working Group to Review the NCI/ACS BCDDP's, chaired by Dr. Oliver Beahrs of the Mayo Clinic, Rochester, Minnesota. The Pathology Review Committee of the Beahrs group had reviewed 506 cases of "minimal" cancers (< 1 cm in size or papillary or intraductal cellular proliferations). The committee concluded that 66 of these cases, previously interpreted as cancerous, should be reclassified as benign. (This figure later was revised to 64 cases.) The committee designated an additional 22 cases as "borderline," because agreement could not be reached on whether the lesions were benign or malignant. The panel recommended that in these instances the women involved should be notified that their cases had been reinterpreted.

To pursue these developments, NCI began an immediate review of the cases in question and found that the Pathology Review Committee may not have received consistently all the pathology slides used by the hospital pathologist in making his diagnosis. For example, when the entire tumor was removed during biopsy, tissue samples obtained following subsequent surgery contained no malignant tissue. In a number of cases, a two-stage procedure—biopsy during one operation and surgery as a later, separate procedure—was performed. In many such instances, the original pathologist considered the case to be borderline and consulted several other pathologists before treatment decisions were made. Often the woman was informed by the physician of the difficulty in making a pathologic assessment, and she was involved in the decision to go ahead with surgery. Therefore, it has become clear that in most instances the original pathologist recognized difficulty in assessing the lesion, that interpretation may have depended critically on the particular slide or slides examined, that differences of opinion about these lesions may not be uncommon, and that a final assessment may be fraught with considerable uncertainty.

The project directors have been asked to review the materials sent to the BCDDP Working Group (Beahrs group), to obtain additional slides not available to the Pathology Review Committee; to discuss the diagnosis, treatment, and other pertinent information (e.g., medical history) with the project pathologist, hospital pathologist, and personal physician; and to submit to the Beahrs group all information that might clarify the findings of the Pathology Review Committee. The entire Beahrs group has been asked to examine this additional information and will submit a final report on its findings in mid-November.

The number of cases in which reclassification as benign or borderline persists is expected to be lower than that first reported by the Beahrs group. A procedure for notification of the women whose cases may deserve to remain reclassified after further review is being developed by NCI, the project directors, and the collaborating physicians.

The group recommended that those women enrolled in the BCDDP's and in whom cancer has been detected be followed to provide valuable scientific information. Panelists could not reach a consensus on whether those women in whom no cancers have been found also should be followed after conclusion of the screening program.

NCI recognizes that follow-up studies on women with cancer, particularly the minimal type, can provide valuable insight into the progression of breast cancer. NCI will develop procedures to follow women whose cancers were diagnosed through BCDDP screening. Follow-up of "normal" screenees is under study.

The Panel concluded that quality control of the screening procedures, including physical examination, and quality control of the pathologic review are needed. The panel members recommended that concurrent pathologic review of minimal lesions be performed routinely by consulting pathologists before treatment is instituted (two-stage procedure).

NCI will work out details with BCDDP directors to implement this recommendation.

Before making its recommendations, the panel heard presentations on the benefits and risks of routine breast cancer screening of symptom-free women. The presentations were made by four groups of scientists who have studied the issue and by other professionals and concerned members of the public.