"Breast Cancer Prevention Trial"

Department of Health & Human Services
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Statement of
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Good afternoon, Senator Specter and members of the subcommittee. I am Richard Klausner, Director of the National Cancer Institute (NCI). I am pleased to testify before you today on a remarkable advance in cancer prevention.

The goal of preventing cancer has long been a hope and a central focus of the National Cancer Program. Prevention can take many forms, from smoking cessation and other behavioral changes to vaccines or antimicrobial agents against cancer-causing infections to a new field in which medicines specifically interfere with the biologic processes of cancer development. For the past several years, the National Surgical Adjuvant Breast and Bowel Project (NSABP), an NCI-funded national clinical trials organization, has been carrying out a historic trial -- called the Breast Cancer Prevention Trial, or BCPT -- to determine whether women at increased risk of developing breast cancer can prevent the development of that cancer by taking a well-known medicine, tamoxifen. More than 13,000 women who participated in this study have been our partners in this work.

As with all of our clinical trials, an independent Endpoint Review, Safety Monitoring, and Advisory Committee regularly examines the data generated by the study to monitor whether either unacceptable or unexpected toxicities have arisen or whether the trial has succeeded in answering the questions it has been designed to answer. This committee met most recently on March 24. The committee concluded that the question of whether tamoxifen can significantly reduce the incidence of breast cancer in women at increased risk had been answered; and the answer is an unequivocal yes. Nevertheless, there were, as you have heard, adverse effects of tamoxifen which may make the very personal decision about taking tamoxifen complex. For all of these reasons, the committee recommended that the participants of the study be notified of these important results. It has been our commitment to the participants from the very start to notify them as soon as clear results had been achieved.

On March 26, the NSABP leadership presented these recommendations and the data behind them to the NCI and we -- NCI and NSABP -- agreed to accept the recommendations of the independent advisory committee. This afternoon, NCI and NSABP will share this information with you, describing the study, its results, and its

implications, and very importantly, place this study in the context of the larger march of science and research towards the control of this dread disease.

The results are remarkable. They tell us that breast cancer can be prevented. A forty-five percent decrease in the incidence of this disease represents one of the more dramatic findings we have seen. They represent the power of the Nation=s investment in research and the value of carefully conducted clinical trials. The insight that tamoxifen might prevent breast cancer came from another NSABP clinical trial for the treatment of breast cancer. That this drug does prevent breast cancer fits with our deep understanding of the role of estrogen and estrogen receptors in breast cancer and an enormous amount of science about this drug, which has been under study for over 25 years.

While it is tempting to generalize, our conclusions must adhere to the data available. For women whose predicted risks of breast cancer match those of the participants of this study, they have the option to take tamoxifen with confidence that it can lower the risk of developing breast cancer. This study provides the evidence for the magnitude of this reduction, as well as the extent of a variety of risks that women who take this drug could face. Women need to discuss with their physicians their own risks for breast cancer and the benefits and risks of taking tamoxifen. The NCI will provide information about this study to the public and health care providers through the Cancer Information Service (CIS) and through PDQ and the new NCI clinical trials web site. The data from this study will continue to be analyzed and the information will be made available through peer reviewed publications and via the different communication outlets of the NCI.

The NCI is committed to communicating the importance of research findings to women and their physicians in a clear and understandable manner. NCI has solicited feedback about the impact the Breast Cancer Prevention Trial announcement has had on those who counsel women regarding their decision to take tamoxifen for the prevention of breast cancer. The feedback concerning the handling of the announcement and the materials provided to date has been very positive. This feedback is being used to assist NCI and the NSABP to develop tools to help each woman, and her health care provider, when making a decision about whether use of tamoxifen is appropriate for her.

The preliminary findings from a survey of Cancer Center Directors, NCI=s Cancer Information Service, Principal Investigators of the NSABP, and the advocacy community indicate that it has been possible for them to respond to most inquiries and counseling requests using information already provided by NCI and NSABP. This information was disseminated through existing NCI and NSABP communication mechanisms before or at the time of the public announcement of the trial=s early results. A new mechanism was also used. NCI launched on the day of the announcement a new clinical trials web site, which included information about the benefits and risks of tamoxifen.

For women whose risks of developing breast cancer fall within the range of this study, tamoxifen can provide, for the first time, an option to reduce that risk, much as new cholesterol-lowering medication can reduce the risk of heart attacks. But that option must be weighed carefully and on an individual basis.

This emphasis on individual risk is important. Our ability to identify individuals at risk for disease and to begin to rationally intervene, based upon our knowledge of the disease process, is what medicine will become.

Great interest has been generated about genetic predisposition to breast cancer, and we know that some breast cancer is linked to certain mutations. It is likely that some of the women in this study, especially those with very strong family histories of breast cancer, carry such a genetic predisposition. While it is reasonable that such women would also experience a decreased risk of breast cancer with tamoxifen, no specific gene testing has been done. As further analyses of the data from this clinical trial are done, we hope to be able to provide more information over the next 6-12 months as to whether women with alterations in BRCA1 & 2, the two known genes whose alterations predispose to breast cancer, were protected from cancer in this trial. I would like to emphasize, however, that there are many important considerations as to how new knowledge about genetics can and should be made a part of medical decision-making that further complicate this process.

This study is not an end. It is rather a very propitious beginning. But it tells us that it is possible to prevent breast cancer. Tamoxifen is far from ideal. Its efficacy is only partial and it has significant risks. To move forward will require new agents and new clinical trials. Newer selective estrogen receptor modifiers are being developed and will be tested. The NCI hopes to be able to follow this study soon with additional clinical trials to find answers to the many questions that remain.

Thank you, Mr. Chairman, for your continued support for cancer research. I would be pleased to answer any questions the Subcommittee may have.