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PEPI STUDY FINDINGS LEAD TO CHANGES IN WOMEN'S HEALTH INITIATIVE

The Women's Health Initiative (WHI), the largest prevention study ever funded by the National Institutes of Health, responded promptly to the findings from the Postmenopausal Estrogen/Progestin Interventions (PEPI) study. In this week's Journal of the American Medical Association, PEPI investigators report that a large proportion of women with a uterus who received estrogen developed adenomatous endometrial hyperplasia. If not treated, a small percentage of adenomatous hyperplasias may progress to cancer. Acting on preliminary data from PEPI, since December 16, 1994, the WHI investigators have not enrolled any WHI participant with a uterus to the estrogen arm of the study. Instead, women with a uterus could enroll in the arm receiving estrogen in combination with progestin or the arm receiving an inactive pill. As confirmed by the PEPI results, the progestin will prevent the development of endometrial hyperplasia. Women with a uterus who had previously been assigned to estrogen alone were switched to the combination therapy in the spring of 1995.

Early in 1995 PEPI had also reported that estrogen and estrogen with progestin improved some risk factors for heart disease. However, the hypothesis that hormones will actually reduce heart

disease remained unproven. The WHI is testing directly whether these hormones will reduce the rate of heart disease in postmenopausal women. Thus far, over 7,000 women have enrolled for the study in 40 WHI clinical centers nationwide. WHI needs a total of 27,500 women for the hormone trial, and women in their sixties and seventies are especially sought. For more information about participating in WHI, call 1-800-54-WOMEN.

In the WHI trial, women with a uterus will be placed in a group that receives estrogen and progestin or a group that receives a placebo (an inactive pill). Similarly, women without a uterus will be placed in a group that receives estrogen or a group that receives placebo. Participants are placed in groups by chance using a computer, thereby eliminating any possibility that differences in health characteristics of the groups will account for any subsequent differences in health outcomes. The participants will be followed for an average of 9 years. At the conclusion of this trial (first results are expected in 2005 or shortly thereafter) scientists will know with certainty whether estrogen lowers heart disease and bone fracture rates or increases breast cancer rates. The effects of adding progestin to estrogen will also be known. Then, for the first time armed with conclusive data, doctors will be able to counsel their postmenopausal patients on the benefits and risks of long term hormone replacement therapy.