



Important Notice About Your Study Pills

June 2002

Dear Ms. [*PERT participant's first and last name*]:

I am writing to tell you important news about the WHI Hormone Program you are in. You may recall that this is the study of estrogen plus progestin for women who *had not* had a hysterectomy before joining the WHI. At its most recent meeting, the WHI Data and Safety Monitoring Board (DSMB) recommended that women in the estrogen plus progestin study stop their study pills. In their judgment, it has become clear that the health risks of taking estrogen plus progestin now exceed the benefits.

The DSMB made this recommendation because of the following risks:

- The number of women who developed breast cancer was *higher* in women taking estrogen plus progestin pills than in women taking placebo pills.
- The numbers of women who developed heart attacks, strokes, and blood clots were *higher* in women taking estrogen plus progestin.

On the other hand, there were benefits of taking estrogen plus progestin:

- The numbers of women who had fractures or colorectal cancer were *lower* in women taking estrogen plus progestin.

What are we asking you to do? Please follow these instructions:

- Stop taking your study pills. **Most of you will probably have no effects from stopping your pills. Some of you may have some menopausal symptoms like hot flashes, or you may have mild spotting or bleeding. These symptoms should decrease over time. Please contact your clinic if you have concerns.**
- Complete the enclosed "Medical History Update" and return it to your clinic as soon as possible. **This update will help us to study all health events that have occurred.**
- Review and sign the enclosed "Signature Sheet" and return it with your "Medical History Update". **We want to be sure that you have received this information.**
- Do not throw away any left-over hormone study pills or bottles. **Your clinic staff will let you know how to return them at your next contact.**
- Continue your regularly scheduled clinic contacts. **For your safety, we want you to get yearly mammograms and your WHI clinic exams. We also have much more to learn from the Hormone Program even after you stop taking study pills.**
- Continue to participate in any other WHI programs you joined. **For example, if you are in the Calcium and Vitamin D Program, please continue to take those study pills as you have in the past. There are still many important questions to answer about women's health.**

I have asked the Clinical Coordinating Center to send you this letter. More information is available in the attached "WHI HRT Update" and on the World Wide Web at:

<http://www.whi.org>. Please share this information with your health care provider. Your local WHI clinic will be contacting you so you can hear more about these results and have your questions answered. You can also contact the [*clinic name*] clinic staff at [*clinic phone number*] if you have urgent questions.

These results are enormously important and will inform millions of women and their doctors worldwide about the risks and benefits of estrogen plus progestin. The findings from this study could not have been predicted when we began in 1993. You are a vital part of this historic study, which is expected to influence medical care for current and future generations.

Thank you for your dedication, both past and future, to the WHI Hormone Program.

Sincerely yours,

Claude Lenfant, MD
Director
National Heart, Lung, and Blood Institute

cc: Dr. [*PI first and last name*], Principal Investigator, [*clinic name*]