Scientific Workshop
Menopausal Hormone Therapy
October 23-24, 2002

Statement by Elias A. Zerhouni, M.D.
Director, National Institutes of Health

As I stated at the outset, the purpose of this scientific workshop was to review the results of one arm of the NIH Women's Health Initiative (WHI) clinical trial and place these results in the context of other completed and ongoing research on menopausal combination hormone therapy. This study of the use of combination estrogen and progestin in postmenopausal women was halted in May due to an increased risk of invasive breast cancer and cardiovascular disease. The goal of the meeting was to assess what we know about the use of menopausal hormone therapy, particularly as a preventive agent, and what questions still need to be addressed through further research.

During the last two days, we heard from the world's leading experts on menopausal hormone therapy. The evidence is clear-- long-term use of the estrogen plus progestin combination–one of the most commonly prescribed hormone regimens–does not prevent cardiovascular diseases and other chronic conditions in postmenopausal women. In fact, the risks (increased breast cancer, heart attacks, strokes, and blood clots in the lungs and legs) outweigh the benefits (fewer hip fractures and colon cancers). We are still studying the risks and benefits of estrogen alone and those results will be forthcoming. Given these results, it is clear that this combination hormone therapy should not be generally used for prevention purposes of chronic diseases. Although these results may fly in the face of our intuition and expectations, they provide evidence instead of opinion. They are also an important piece of information for a postmenopausal woman as she considers her options.

There is not a simple, single answer for all women, however, the WHI results do help simplify and clarify–not complicate-- the decision making process. Women now have information from a randomized clinical trial–the gold standard for evidence-based medicine. Combined hormone therapy should no longer be considered the effective prevention strategy against chronic diseases.

Women who are considering whether to start or continue hormone therapy to relieve menopausal symptoms need to consider the findings from this and other studies discussed here at the workshop, and discuss with their health care provider their individual risk for specific chronic conditions and their personal preferences.

Although the Women's Health Initiative is a study of the highest caliber and provided us with clear evidence, it, like all studies, does not provide all the evidence for all situations. In fact, like all good studies, it leads to important new questions. Therefore, from this meeting, we will continue to address the research implications of what we have learned and move forward with a research agenda that was outlined this afternoon.

And now that we do have direct evidence from this study, the next step is how best to apply that knowledge. As I mentioned at the beginning of this workshop, evidence-based medicine does not stop with the generation of new knowledge. The evidence must then be communicated effectively to women and their health care providers to facilitate informed decisions. As Dr. Stefanick said yesterday, it is up to everyone who attended this workshop to make that happen. What we learned at this meeting will serve as the foundation upon which to build our information and education efforts over the coming months, working in partnership with other HHS agencies such as AHRQ, FDA, and CDC, as well as health professional organizations, advocacy groups, and women and their health care providers. We will begin by publishing the proceedings from this meeting as soon as possible.

We must work together toward the common goal of ensuring that a woman and her physician have the information and guidance they need to make informed decisions about the short-term and long-term use of hormone therapy.