What The Experts are Saying Now: A Round-Up of International Opinion

By the Editors of *A Friend Indeed*,
the newsletter for women in menopause and midlife:
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With all the controversy about HRT, it is sometimes difficult to keep up with the most recent scientific information, since every few months brings a flurry of new data. So here's an update of the most significant recent practice guidelines and studies:

- **International Position Paper on Women's Health and Menopause:** An international team of experts in women's health have established new clinical guidelines for the treatment of patients going through menopause. At a recent symposium sponsored by the Office of Women's Health Research at the National Institutes of Health and the Giovanni Lorenzini Medical Science Foundation in Milan, 28 doctors and scientists evaluated the most current HRT research and collectively recommend that HRT should NOT be prescribed for heart disease, fractures, depression and urinary incontinence (National Heart, 2002; Vastag, 2002).

  The authors of the position paper note that most of the evidence in favor of HRT in the past had come from observational studies and clinical experience. New randomized, controlled clinical trials are causing many health specialists to reconsider their views on HRT and revise their clinical practice.

  The expert panel notes that:

  - There is no reliable evidence to suggest that HRT arrests or delays the onset of Alzheimer's disease, relieves depression, or aids urinary incontinence.

  - While studies indicate that HRT helps to prevent bone loss in postmenopausal women, there is no direct evidence to determine if HRT reduces the risk of fractures. And for HRT to be effective in maintaining bone mass, it must be taken continuously, and not just in the short term. Since long-term HRT use has several serious side effects, including blood clots, biliary disease and breast cancer, the panel recommends non-hormonal drug options, such as bisphosphonates, as well as dietary and lifestyle changes, to address bone mass in place of HRT.

- HRT has been shown to alleviate hot flashes and night sweats, but diet and lifestyle changes as well as SSRIs (selective serotonin reuptake inhibitors) are other viable options.

- The new evidence on HRT and coronary disease indicates that HRT does not reduce the risk for heart attack and stroke, but may, in fact, increase that risk. Diet and lifestyle changes, as well as non-hormonal drugs to lower cholesterol and blood pressure, may address coronary health in place of HRT.

The bottom line: HRT should not be prescribed to reduce the risks associated with Alzheimer's disease, heart disease, severe depression, urinary incontinence and fractures.

- **Journal of the American Medical Association Editorial:** A panel of experts examines the new data on HRT and notes that long-term HRT use has been linked to an increased risk of cardiovascular disease, breast cancer, venous thromboembolism and gallbladder disease. Given these significant risk factors, the authors recommend that caution should be employed before embarking on treatment. While studies have demonstrated that HRT may improve bone density, the authors note that there are other, non-hormonal means available for the prevention and treatment of osteoporosis (Rexrode, 2002).

- **Revised Guidelines for the American Heart Association and the Heart and Stroke Foundation of Canada:** Both the AHA and the HSF have recently issued new guidelines regarding hormone therapy.

    - Hormone therapy should not be prescribed to women who already have a history of heart disease.

    - Hormone therapy should not be prescribed solely in order to reduce the risk of developing heart disease.
    - Other non-medicinal measures can be undertaken to reduce the risk of heart disease, such as stopping smoking, becoming more active and reducing blood pressure and cholesterol levels.

The Evidence from Clinical Trials

The shift in expert opinion has been based on findings from a number of important recent clinical trials:

- **The Heart and Estrogen/Progestin Replacement Study (HERS):** This randomized, blinded, placebo-controlled trial of women *with* a history of heart disease found no overall benefit after four years of treatment with estrogen plus progestin. Participants in the first year of the study had more heart attacks and deaths (Haskell, 2001; National Institutes of Health, 1998; Tudiver, 1999).

- **The Women's Health Initiative (WHI):** Randomized trials of more than 27,000 *healthy* women. Based on the first 3 years of the Estrogen Plus

Progestin Study (16,608 postmenopausal women), researchers reported that estrogen and estrogen plus progestin were associated with an increased risk of heart attacks, blood clots and strokes compared to placebo. Study participants were updated about these findings and encouraged to continue in the trial. Final results were not expected before 2005, but the trial was stopped on July 9, 2002 due to increased risks of invasive breast cancer, coronary heart disease, stroke and pulmonary embolism in women taking active medication over placebo (Women's Health Initiative, 2002; Writing group, 2002).

- **The Estrogen Replacement in Atherosclerosis (ERA) trial:** This study finds that atherosclerosis (degeneration of the arteries due to fatty deposits) is not slowed by taking estrogen or estrogen plus progestin in women with pre-existing heart disease (Herrington, 2000).

- **The Women's Estrogen for Stroke Trial (WEST):** Finds no reduction in risk of stroke and death or coronary events among 664 postmenopausal women treated with estrogen or placebo for 2.8 years. Women in the hormone group have an increased risk of stroke in the first 6 months of treatment (National Cancer Institute, 2001).

- **HERS data:** Also shows that women who took hormones for a mean of 4.1 years do not have a lower risk of any type of fracture compared with those taking placebo. While hormone therapy reduces bone loss in postmenopausal women, no large randomized trial has been done to demonstrate that HRT reduces the risk of *fractures* (Cauley, 2001).

- **HRT, ERT and Breast Cancer:** Many types of research suggest a link between estrogen use and increased risk of breast cancer among long-term hormone users (i.e. over 5 years). Data from the National Cancer Institute suggests that HRT may increase the risk of breast cancer beyond that associated with estrogen alone (Grady, 2002; Tudiver, 2000). Recently, the Women's Health Initiative study reported an increased risk of breast cancer for those using HRT for more than 4 years (Women's Health Initiative, 2002; Writing group, 2002).

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