



**Statement of the American Medical Women's Association before the
Endocrinologic and Metabolic Drugs Advisory Committee**

October 7, 2003

**Women's Health Initiative Study Results: Implications for the use of
hormone therapy with estrogen/progestin, as a second-line drug, in the
prevention and treatment of postmenopausal osteoporosis in women**

I am Dr. Omega Logan Silva, an endocrinologist and Past President of the American Medical Women's Association (AMWA). I appreciate the opportunity to present AMWA's views on the implications of the Women's Health Initiative (WHI) for the use of hormone therapy with estrogen/progestin as a second-line drug in the prevention and treatment of postmenopausal osteoporosis in women. Founded in 1915, AMWA is an organization of 10,000 women physicians and medical students dedicated to serving as the unique voice for women's health and the advancement of women in medicine.

AMWA supports the current FDA-approved indications for hormone therapy. Hormone therapy is the most effective FDA-approved treatment for menopausal symptoms such as hot flashes, night sweats, and vulvar and vaginal atrophy. Hormone therapy is also indicated for the prevention of postmenopausal osteoporosis.

AMWA is proud to be a partner in FDA's Menopause & Hormones Information Campaign, which provides women with important information about hormone therapy. As physicians, our role is to review a patient's family and medical history, and assess the risks and benefits of hormone therapy for that individual. We can help our patients by putting the risks into proper perspective. While hormone therapy may not be appropriate for one woman, it may be entirely appropriate for another.

With regard to osteoporosis, AMWA recognizes the enormous impact of this disease on the health of Americans, particularly women. The disease causes over 1.5 million fractures yearly at a cost of \$17 billion. Following osteoporotic hip fracture, there is an excess mortality of 12-20%. Hip fracture is the second leading cause of admission to nursing homes for women. Osteoporosis causes severe and unremitting bone pain. It is one of the major debilitating disorders that contributes to the loss of functional independence and quality of life in older women, as noted in AMWA's Position Statement on Osteoporosis.

To prevent osteoporosis, AMWA members recommend weight bearing exercise, adequate calcium and vitamin D intake, and the maintenance of a healthy lifestyle. In addition, medications to prevent further bone loss may be indicated. Women who think they are at risk of developing osteoporosis should consult their physicians. Treatment plans should be initiated as early as possible, because once bone is lost, it is difficult to replace, as noted in AMWA's Osteoporosis Q&A Fact Sheet.

The recent study in the October 1, 2003 issue of the *Journal of the American Medical Association* demonstrated that estrogen plus progestin increases bone mineral density and reduces the risk of all fractures in healthy postmenopausal women. This decreased risk of fracture appeared to be present in all subgroups of women examined. When considering the effects of hormone therapy on other important disease outcomes in a "global index" developed by the WHI investigators, the study authors concluded that there was no net benefit of hormone therapy, even in women considered to be at high risk of fracture. On this point, AMWA notes that this "global index" is based on selected risks and selected benefits and not on all risks and all benefits. For example, it includes hip fractures but not vertebral fractures or menopausal symptoms, the primary reason women take hormone therapy. For some women, the risk-benefit equation might change when relief from menopausal symptoms and prevention of vertebral fractures are taken into account.

AMWA agrees with the current FDA-approved labeling for hormone therapy (Prempro), which states that "when prescribing solely for the prevention of postmenopausal osteoporosis, therapy should only be considered for women at significant risk of osteoporosis and non-estrogen medications should be carefully considered." If hormone therapy is prescribed, it should be taken at the lowest possible dose for the shortest duration of time to meet treatment goals.

The WHI results have reinforced what physicians have known all along – that treatment decisions need to be individualized. For this reason, it is extremely important for FDA to preserve physician and patient choice of therapeutic agents to prevent and treat osteoporosis. Hormone therapy remains an important option for those women at significant risk of osteoporosis who are unable to take non-estrogen medications.

On behalf of AMWA, I thank you for the opportunity to testify before the Committee today.