

**Statement from the International Menopause Society  
in reply to the decision by the EMEA not to recommend  
hormone replacement therapy for the indication for  
prevention of osteoporosis**

**December 3, 2003**

*The International Menopause Society has issued the following statement in response to the decision of the EMEA not to recommend hormone replacement therapy as first-line therapy for the indication for prevention of osteoporosis.*

The International Menopause Society (IMS) is profoundly concerned that the European Medicines Evaluation Agency (EMA) has ignored important information in its decision to recommend that the risk/benefit balance of hormone replacement therapy (HRT) does not justify its use as first-line therapy for the indication for prevention of osteoporosis in women.

HRT is a most effective therapy for the prevention of osteoporosis and related fractures; indeed, the Women's Health Initiative (WHI) confirmed the fracture reduction at both the spine and hip. No other intervention has been shown to be so cost-effective in reducing hip and spine fractures.

In early postmenopausal women, there is no evidence that alternative treatments are as beneficial. Individual risk/benefit considerations should be left to the woman and her doctor.

Because of the age of the population studied in the WHI, safety concerns cannot be extrapolated to early postmenopausal women. The Million Women Study did not make any assessment of the risk/benefit ratio for osteoporosis and related fractures in postmenopausal women.

Therefore, the IMS considers that the EMA recommendations are unjustified and potentially harmful for the health of postmenopausal women.