

PRESS RELEASE – Climacteric (journal of the International Menopause Society)

Embargoed until 00.01 Thursday 5th July, 2012 (EDT – New York time)

BILLION DOLLAR NIH STUDY MAY HAVE HARMED WOMEN'S HEALTH – CALL FOR AN INDEPENDENT COMMISSION OF ENQUIRY

A one-billion dollar publicly-funded study into women's health may have harmed rather than helped the health of menopausal women. Founder and Executive Director Emeritus of the North American Menopause Society Professor Wulf Utian, writing in the peer-reviewed journal *Climacteric*, says that the analysis of the WHI study has been so compromised that an independent commission of enquiry is needed to establish whether the conclusions of the study can be justified by the data which the study produced. This call is supported by the International Menopause Society.

The results of the Women's Health Initiative (WHI) study in July 2002 caused a dramatic drop in Menopausal Hormone Therapy use following a controversial press announcement in July 2002 and subsequent WHI announcements. However, the WHI has come in for criticism over the way the results have been interpreted. Now, 10 years down the line, Professor Utian, calls for an independent review of the conclusions, to attempt to resolve the controversy.

Professor Utian says

“The WHI is a valuable study, but the way the results have been interpreted has caused real problems for most menopausal women, as well as giving US taxpayers poor value for their billion dollars.

To take just one example, the WHI developed its own methods of evaluating the relative importance of benefits and risks of MHT. But this method was never validated. In fact, the WHI ignored an entire science of ranking clinical outcomes using proven and validated tools.

This means that a project designed to be of benefit to women's health has boomeranged and instead may have resulted in significant impairment to both quality of life and physical health of women

If menopausal hormone therapy is given to women below the age of 60 or within 10 years of menopause, the risks are rare. Unfortunately, the way in which the WHI reported the halting of part of their investigation in July 2002 led millions of women to abruptly drop the therapy. Now it is estimated that this discontinuation may have resulted in over 43000 additional bone fractures per year in the USA, and most likely an even greater number of cardiovascular events, the leading cause of death in women in

the USA. The negative impact on quality of life, through recurrence of hot flashes and impaired sleep is immeasurable”.

Professor Utian, recognizing that this is a harsh indictment, calls for an urgent independent evaluation of the key WHI publications to determine whether the data reported justified the conclusions drawn, and the subsequent message delivered to women. If not, it is crucial that a clear updated message be delivered to women progressing currently through and beyond menopause so that further potential harm can be avoided.

He says

“We are 10 years on from the biggest study on post- menopausal women ever conducted, and in many ways we are back where we started. Women in the next 10 years need to be given the chances which mistakes over the WHI denied to women over the last 10 years”.

Dr Tobie de Villiers, President of the International Menopause Society said:

“The International Menopause Society supports Dr Utian’s call for an independent commission of enquiry; this call mirrors our own views. This is an important topic, and needs to be open to the widest possible scrutiny”.

ENDS

Notes for Editors

The full article: *A decade post WHI, menopausal hormone therapy comes full circle – need for independent commission*, by W. H. Utian, Consultant in Women’s Health, Executive Director Emeritus, The North American Menopause Society; Professor Emeritus, Reproductive Biology, Case Medical School, Cleveland, Ohio, USA, appears in the peer reviewed journal *CLIMACTERIC* 2012;15:320–325.

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Climacteric is the official (peer-reviewed) journal of the International Menopause Society. The International Menopause Society is the global body representing clinicians and scientists working with the menopause. Website: www.imsociety.org

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