



## Bioidentical Hormones for Menopausal Symptoms

Many women want to deal with menopausal symptoms "naturally" and may turn away from prescribed traditional hormone therapy ("HRT") in favour of so-called "bioidentical" hormone treatments. These are often referred to as "bioequivalent" or "natural" hormone therapies. This pamphlet explains why the Australasian Menopause Society does not support their use.

### What are Bioidentical Hormones?

- Bioidentical hormones are mixtures of hormones supplied by compounding pharmacists, most commonly as lozenges or troches sucked and absorbed through the mouth, or as creams rubbed on the body.
- The products are claimed to be made from yams, the same source as most traditional HRT. The manufacturers claim their products are "natural" but the main active ingredient, oestradiol, is identical to that in most forms of HRT.
- The sales pitch may be that the bioidentical mixture is a unique mix of oestrogens called oestradiol, oestrone and oestriol but in reality, whatever forms of oestrogens are ingested are converted within the human body.
- The oestrogen mixtures are sometimes combined with testosterone, DHEA, growth hormone, thyroxine and melatonin. All of these substances are prescription medicines and supply of them without a prescription from an authorised prescriber is illegal both in Australia and New Zealand. In addition, some of these products contain abnormally high levels of hormones.
- DHEA is not included in any approved medicines in either Australia or New Zealand.
- The compounds may also be sold directly to the public via the Internet or through laboratories. Some doctors also prescribe them and may receive incentives in return for doing so.

### Disadvantages to Consumers

- Women can obtain bioidentical hormones without seeing or being examined by a doctor. If there is no medical consultation then safety issues may not be addressed. There is no opportunity for them to be offered a proven, prescribed therapy.
- The compounding pharmacists who make the products bypass the stringent quality standards required for prescribed drugs made by pharmaceutical companies. Bioidentical hormone ingredients have been produced outside Australia and New Zealand and the manufacture of these active ingredients may not have been audited by the Therapeutic Goods Administration (TGA) in Australia or MEDSAFE in New Zealand to see if they have met their guidelines for safe and proper manufacture.
- The mixtures have not been subjected to rigorous scientific trials required to produce reliable evidence that they work and are safe. Their ingredients can be made, imported and mixed without comprehensive government approval or quality control.
- The bioidentical products are claimed to be "tailored" to the needs of individual women based on hormonal measurements taken from their saliva. However there is inadequate scientific proof that salivary hormone levels relate well to blood hormone levels or to menopausal symptoms. HRT should be tailored to women's needs according to their symptoms, not to blood or salivary hormone levels.
- These products and unnecessary tests are costly.



### **Australasian Menopause Society Concerns re Bioidentical Hormones**

- There is inadequate high quality scientific evidence to show that bioidentical hormones are effective.
- There is inadequate scientific evidence that these compounded hormones are safe and free of adverse side-effects.
- There is inadequate scientific evidence that these compounds are pure and free from contamination.
- There is inadequate scientific evidence to demonstrate the "equivalent dose" of bioidentical hormones to conventional HRT.
- The risk of cancer of the uterus may be increased with the use of bioidentical hormones because there are no data on the amount of progestin or "natural progesterone" necessary to protect the uterus from the oestrogenic effect of these products. (See AMS HRT pamphlets)
- There is inadequate scientific evidence documented of the interactions between the compounded hormones themselves, or between these hormones and other drugs which may be taken at the same time.
- Unproven interpretations of salivary or blood hormone levels are being used to suggest abnormal ovarian, thyroid or adrenal function and as a basis to offer other hormone products for "treatment". This is potentially very dangerous.

#### **Remember:**

1. If the oestrogens used in the bioidentical mixtures reach similar oestrogen levels in the circulation as conventional HRT they are likely to have the same benefits but also the same risks. (see AMS pamphlets on risks and benefits of HRT) If, for example, the opposing progestin in the bioidentical hormone therapy does not have equal protective effect on the uterus, the treatment will be associated with a greater risk of cancer of the uterus than conventional HRT.
2. If a doctor elects to prescribe an unregistered complementary or alternative therapy the woman must be fully informed that this therapy is unproven. She should be told of any potential risks and must not be denied the option of a proven therapy.
3. In the absence of peer-reviewed scientific data, and for all the other reasons mentioned above, the Australasian Menopause Society cannot support the use of "bioidentical" hormone therapies.

#### **References:**

1. AMA Adopts Resolution Introduced by The Endocrine Society Calling for FDA Oversight of Bioidentical Hormones, 14th Nov 2006:  
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2. The Endocrine Society: Position Statement : Bioidentical Hormones, October 2006:  
[http://www.endosociety.org/publicpolicy/policy/upload/BH\\_Position\\_Statement\\_final\\_10\\_25\\_06\\_w\\_Header.pdf](http://www.endosociety.org/publicpolicy/policy/upload/BH_Position_Statement_final_10_25_06_w_Header.pdf)
3. MacLennan AH, Sturdee DW. The 'bioidentical/bioequivalent' hormone scam. *Climacteric* 2006 Feb;9(1):1-3.

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