

Date: January 19, 2005

Subject: DRC Recommendations to DCC and DHS

To: DHS, DCC, Dean's Office

From: Henry F. Simmons, Jr., MD, Ph.D.
Chairman DRC

At its 01/19/06 meeting, the Drug Review Committee considered the potential toxicity and therapeutic roles of selected estrogens for use by women with the indications listed below.

Estrogens under consideration for use in perimenopausal women and in women with natural or surgical menopause

17-beta estradiol: oral, transdermal, cream, vaginal ring

Estradiol valerate: oral

Conjugated equine estrogen: oral, cream

Synthetic conjugated estrogen: oral

Esterified estrogen: oral

Estropipate: oral

Indications under consideration

Hot flashes/flushes

Sleep disturbance/night sweats

Mood changes

Urogenital symptoms/sexual dysfunction

Quality of life issues

Prevention of osteoporosis and its complications

Based upon the bulk of the best available evidence pertaining to the aforementioned agents the Committee concluded the following:

The agents do not differ in terms of either safety considerations or frequency of adverse events during either short or long term use to the extent that one or more should be excluded from consideration.

The agents do not differ significantly in efficacy when used in equipotent doses.

At least one topical and one oral preparation should be available.

None of the agents appear to be associated with either special benefits or special risks on the basis of demographics.