DUKE UNIVERSITY MEDICAL CENTER
Department of Obstetrics and Gynecology
Office of the E.C. Hamblen Professor and Chairman Emeritus

September 30, 2003

Ms. Dornette Spell-LeSane
Center for Drug Evaluations and Research (HFD-21)
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

RE: EMDAC Meeting 10/7/03

Dear Ms. Spell-LeSane:

It is my understanding that the Endocrinologic and Metabolic Drugs Advisory Committee will meet October 7, 2003 to discuss the use of hormone therapy (estrogen, with or without progestin) for the primary prevention and treatment of postmenopausal osteoporosis in women. I wish to comment on that consideration.

For over 40 years I have practiced obstetrics and gynecology, and I have treated many women with hormone therapy (HT). While it has provided major control of symptoms (hot flushes and genital atrophy), I have also used it in women with osteopenia and osteoporosis. The treatment in this latter case has usually been quite effective, as documented by bone density determinations and fracture incidence. While there are certainly alternatives, none effectively also treat symptoms, and all have their own major side effects (bisphosphonates, raloxifine and synthetic parathyroid hormone) as well as cost factors. The Women's Health Initiative (WHI) trial and much more data conclusively demonstrate that HT is an effective way to treat the problem of bone loss in women.

To remove the primary indication for osteopenia and osteoporosis would, in my opinion, be more likely to be taken as a lack of effectiveness rather than its removal due to the concerns developed to date from the WHI data and will likely cause many physicians and their patients, appropriately informed, to give up HT in favor of other agents to their detriment in symptom control (where indicated). They thus might accrue protection from bone loss, but with the costs and side effects of the other therapy, and re-develop symptoms being controlled by HT. This is particularly true in the case of estrogen-only treatment where the concerns of the WHI trial to date have not yet been verified. I see no reason to "rush to judgement" until that part of the WHI trial is concluded and verified or rejected (2005). I certainly agree that risk-benefit must be evaluated, but I believe all data must be fully presented and verified before it is accepted.

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In summary, I believe it is far too soon to make any change in the labeling of these products as relates to bone loss in women and to give up a very effective and useful management tool in the health care of women.

Thank you for allowing me to express an opinion.

Yours truly,

Charles B. Hammond, M.D.

CBH/pcod