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Bioidentical Hormones

In recent years, many women have become concerned about the safety of pharmaceutical replacement hormones for treatment of menopausal symptoms. “Bioidentical” hormone preparations, which are not approved by the FDA, are heavily promoted in popular books and on TV as alternatives; these are derivatives of soy or plant extracts, chemically modified to be structurally identical to endogenous hormones. Most FDAapproved single-entity hormones are also derivatives of soy or plant extracts and are structurally identical to hormones produced by the ovary.1

MANUFACTURING STANDARDS

Bioidentical hormones are generally prepared in compounding pharmacies, which are not regulated by the FDA.2 The FDA has reported sub-potency, super-potency and contamination of pharmacy-compounded drugs. In one 2006 survey, their potency ranged from 67.5% to 268.4% of the amount specified on the labeling, and both sub- and super-potent active ingredients were found within the same sample.3

DOSAGE

Typically, dosing of bioidentical hormones is individualized, based on measurements of endogenous hormone levels in saliva or blood. It has been proposed that since saliva is an ultrafiltrate of blood, hormone levels in saliva could reflect unbound or free hormone levels in blood. However, salivary hormone levels vary widely, and no correlation has been established between salivary and serum hormone levels.

ADVERSE EFFECTS

Bioidentical products that contain progesterone, testosterone and estrogen can be expected to have the same adverse effects that conventional preparations have. Most bioidentical hormone preparations contain estriol, which occurs in large quantities endogenously only during pregnancy. No drug product containing estriol has been approved by the FDA and the safety and effectiveness of supplemental estriol is unclear.4 Endometrial cancer associated with bioidentical hormone therapy has been reported.

DRUG INTERACTIONS

Bioidentical estrogen preparations, like conventional preparations, are metabolized partly by CYP3A4. Drugs that are strong inhibitors of CYP3A4, such as clarithromycin (*Biaxin*, and others), could increase serum concentrations of estrogen.

CONCLUSION

There is no acceptable evidence that "bioidentical" hormones are safe or effective. Patients should be discouraged from taking them.

Table 1. Some Preparations of Bioidentical Hormones

Drug	Source	Route of Delivery
Estriol 100% estriol	Soy	Oral, transdermal, sublingual, and vaginal
Biest (biestrogen) 20% estradiol 80% estriol	Soy	Oral, transdermal, sublingual, and vaginal
Triest (triestrogen) 10% estrone 10% estradiol 80% estriol	Soy	Oral, transdermal, sublingual, and vaginal
Progesterone injectable	Soy or Yams	Oral, transdermal, sublingual, vaginal and
Testosterone injectable	Soy	Oral, transdermal, sublingual, vagina and

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