



Bioidentical Hormones Lack Evidence for Safety and Effectiveness, According to New Statement by The Endocrine Society

Chevy Chase, MD; October 21, 2006 - The Endocrine Society issued a position statement calling for increased regulatory oversight of bioidentical hormones, which have been touted as safer and more effective than traditional hormone therapies.

Recently, there has been a barrage of misinformation in the popular press about bioidentical hormones. Much of this publicity is due to actress Suzanne Somers' latest book, which claims that bioidentical hormones are better and safer than traditional hormones.

These claims are highly misleading, and have no scientific or medical evidence to support them.

"No comprehensive study has ever been done to establish that bioidentical hormones are safer or more effective than traditional hormone therapies," said Dr. Leonard Wartofsky, president of The Endocrine Society. "The decision to undergo any hormone therapy should be carefully weighed, and the dearth of information on bioidentical hormones makes that decision even harder as patients and doctors work together to find the best treatment."

Bioidentical hormones have the same chemical and molecular structure as hormones that are produced in the human body. Any hormone can be made to be bioidentical. The term, however, has frequently been misused by the public and in the popular press to describe formulations containing estrogens, progesterone, and androgens that are customized by compounding pharmacies based on the results of saliva tests for hormone levels. Such tests are inaccurate and should not be considered reliable measures of hormones in the body.

Like traditional hormones, patients can obtain bioidentical hormones as FDA-approved preparations that are formulated with strict oversight and dispensed by retail pharmacies. The concern comes when bioidentical hormones are customized by compounding pharmacies.

Since the final hormone formulations of most compounding pharmacies are not subject to FDA monitoring for dose, purity, safety, or efficacy there may be additional, and at this

-more-

point unknown, risks associated with them. Therefore, the Society is advocating for FDA regulation and oversight of all hormones--bioidentical and traditional--regardless of their chemical structure or method of manufacture. This oversight should include, but not be limited to:

- Surveys for purity and dosage accuracy
- Mandatory reporting by drug manufacturers of adverse events
- A registry of adverse events related to the use of hormone preparations
- Inclusion of uniform information for patients, such as warnings and precautions, in packaging of hormone products

"The Endocrine Society believes it is vital that patients, doctors, and the public receive accurate, science-based information to make educated healthcare decisions," said Wartofsky. "Medical advice from celebrities and others outside the healthcare profession should be treated with a high degree of skepticism."

Complete text of the newly adopted position statement is available here:

<http://www.endo-society.org/publicpolicy/policy/index.cfm>

###

*Founded in 1916, **The Endocrine Society** is the world's oldest, largest, and most active organization devoted to research on hormones and the clinical practice of endocrinology. Today, The Endocrine Society's membership consists of over 13,000 scientists, physicians, educators, nurses and students in more than 80 countries. Together, these members represent all basic, applied, and clinical interests in endocrinology. The Endocrine Society is based in Chevy Chase, Md. To learn more about the Society, and the field of endocrinology, visit our web site at www.endo-society.org*