



Endocrine Society Applauds FDA Actions Countering Misleading Claims on Compounded “Bioidentical” Hormones

Chevy Chase, MD—The Endocrine Society strongly supports recent action by the U.S. Food and Drug Administration (FDA) countering unfounded and misleading claims that compounded “bioidentical hormones” are safer and more effective than traditional hormone therapies. The Endocrine Society is deeply concerned about claims about safety and efficacy of these compounds and shares the FDA’s belief that patients and healthcare providers need accurate and reliable information to make informed medical decisions.

Public demand for "bioidentical hormones" has grown in recent years and many women have been lured into taking them by deceptive claims that they are more natural and somehow risk-free, even though there is no scientific evidence to support these claims.

To help ensure the public has valid and factual information, the FDA announced that it has begun enforcement action against seven compounding pharmacies making false and misleading claims about the safety and efficacy of "bioidentical hormones." The FDA also stated that the Agency considers the term "bioidentical" to be a marketing term and not one of scientific or medical merit.

The FDA also supports greater public outreach to inform women of the truths and untruths of "bioidentical" hormone replacement therapy. On its Consumer Health Information Page, the FDA has posted a new Consumer Update, titled “Bio-Identicals: Sorting Myths from Facts.”

The Endocrine Society and a number of medical professional organizations, including the American Medical Association (AMA), have published formal statements regarding compounded bioidentical hormones that are consistent with the FDA’s actions. In November 2006, the AMA unanimously and enthusiastically passed a resolution introduced by The Endocrine Society and other concerned organizations urging the FDA to increase its oversight and regulation of so-called bioidentical hormones.

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The Endocrine Society's statement is here:

http://www.endosociety.org/publicpolicy/policy/upload/BH_Position_Statement_final_10_25_06_w_Header.pdf.

The Society, along with its public education affiliate The Hormone Foundation, applaud the Agency's expanded efforts to arm patients and healthcare providers with valid and reliable information about all forms of hormone replacement therapy.

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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 14,000 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.

The Hormone Foundation is a leading source of hormone-related health information for the public, physicians, allied health professionals and the media. Its mission is to serve as a resource for the public by promoting the prevention, treatment and cure of hormone-related conditions through outreach and education. (www.hormone.org)