Statement of Leonard Wartofsky, M.D.
On Behalf of The Endocrine Society
Before the Senate Special Committee on Aging

April 19, 2007

Mr. Chairman, I would like to thank you, as well as the distinguished Ranking Member, Senator Smith, and the members of the committee, for the opportunity to testify today. My name is Leonard Wartofsky. I am the Chairman of the Department of Medicine at the Washington Hospital Center. I previously served as Director of the Endocrinology Division and the Endocrinology Fellowship Training Program, and Chief of the Department of Medicine and Program Director of the Internal Medicine Residency at Walter Reed Army Medical Center. I am an elected a Master of the American College of Physicians, Professor of Medicine at Georgetown University School of Medicine and Professor of Medicine and Physiology at the Uniformed Services University of Health Sciences. In my professional capacity as a physician, I treat patients suffering from a variety of endocrine disorders, such as thyroid disease, pituitary disease, diabetes, and obesity.

I am here today, however, as President of The Endocrine Society, the world's largest and most active professional organization of endocrinologists representing more than 14,000 members worldwide. Our organization is dedicated to promoting excellence in research, education, and clinical practice in the field of endocrinology. Appropriate clinical use of hormone therapy of all kinds falls under the purview of endocrinology and the Endocrine Society. My testimony will address The Endocrine Society's concerns regarding the compounding of what are commonly known as "bioidentical hormones." Specifically, The Endocrine Society believes it is critical that the federal government increase the regulatory oversight of bioidentical hormones, which have been inaccurately touted as safer and more effective than traditional hormone therapies.

Claims such as these, which are propagated by the popular media, are leading women to request bioidentical hormones from their doctors. As the leading experts in hormone treatments, endocrinologists are constantly approached by patients who are convinced that bioidentical

hormone therapy will cure their ills without risk of side effects such as those reported in the Womens Health Initiative (WHI). Despite their expertise, our doctors often find it extremely difficult to reverse the misinformation held by their patients who hope to find relief of their symptoms without the adverse effects reported in the WHI Study.

Initial analysis of The Women's Health Initiative—a large, long-term, prospective study of menopausal and post-menopausal women taking traditional hormone therapy for a period of several years—has raised concerns among some patients and physicians regarding long-term use of hormone replacement therapy. The study was cut short due to evidence of increased risk of cardiovascular disease in women taking estrogen or a combination hormone replacement therapy, and increased risk of breast cancer in women taking combination hormone therapy. Although further analysis of this study shows that the risks vary by age cohort and at what age hormone therapy began, the recent reports of these findings appeared too late to stop women from searching for alternative methods to treat the symptoms of menopause. This has created an environment for the proliferation in the lay media of the scientifically unproven idea that "bioidentical hormones" are somehow safer and more effective than traditional hormone therapies.

It is important at this point to identify some confusing aspects of this topic and to clarify definitions. Much of the public demand for "bioidentical hormone" therapy has arisen as a result of coverage in the media and popular press that encourages women to aggressively seek out and utilize "bioidentical hormones" that are supposedly customized or individualized for a particular woman's needs. This is misleading in a number of ways. First, women are led to believe that the terms "bioidentical" and "customized" are interchangeable. In fact, the word "bioidentical" simply describes a compound that has exactly the same structure as one produced in the body.

Under this appropriate and precise definition, there are bioidentical hormones that exist as FDA-approved drugs that have been available to the public for years. While we do not oppose the use or prescribing of FDA-approved bioidentical hormones, we caution physicians and patients alike against the presumption that they are safer or more effective than those hormones studied

in the WHI. In fact, no study as comprehensive as the WHI has been performed to assess FDA-approved bioidentical hormones. Therefore, it is impossible to directly compare the safety and efficacy of bioidentical hormones with that of the drugs used in the WHI. In order to ensure patient safety, then, we must begin with the assumption that "bioidentical hormones" would perform similarly to their counterparts if tested in a similar study.

Second, women are led to believe that compounded hormones are all bioidentical and are provided in a dose and form that is precisely formulated for their bodies. In reality, compounding does not by default make a hormone bioidentical; non-bioidentical hormones can also be manipulated by compounding pharmacies. The purported customization, while perhaps theoretically logical, is very difficult, if not impossible, to achieve.

Some compounding pharmacies are taking things even further by directly marketing their products to the public. Clearly, such activities are outside the scope of compounding pharmacies, which are intended to serve the special needs of patients on an individual basis.

The overall result of the activities I've just described has been one of confusion regarding the definition of "bioidentical hormones."

A further effect of this confusion is that women have been led to believe that bioidentical hormones are more natural than those studied in the Women's Health Initiative. Given this perception, it is easy to understand why women are drawn to these medications. In truth, bioidentical hormones are produced in labs, just as many other drugs are. Furthermore, compounded hormone preparations are not required to include any black box warning that reflects the findings of the Women's Health Initiative, as is required for FDA-approved estrogens and progesterones, which may also be bioidentical. The lack of patient information in these formulations highlights the reason that the Society is here testifying before your committee today. We are concerned that patients are not receiving accurate information regarding the safety and efficacy of compounded hormones.

Because compounding pharmacies are regulated by state boards of pharmacy, they are not required to adhere to the strict manufacturing processes that govern FDA-monitored facilities. Nor are they required to follow the same rigorous testing process for either safety or efficacy that FDA requires for FDA-approved drugs. This raises questions regarding the purity, potency, and quality of compounded drugs, that reflects in turn upon their safety and efficacy. In fact, the FDA performed a post-market analysis of 29 product samples from 12 compounding pharmacies in 2001. This revealed that 34 percent failed one or more standard quality tests. In contrast, the testing failure rate for FDA-approved drugs is less than 2 percent. Nine of the ten failing products, four of which were compounded hormones, failed assays for potency, in that they contained less of the active ingredient than expected. These results raise great concern about the inconsistencies and unknown risks of compounded bioidentical hormones. Without proper oversight and control of these products, the public has no way of knowing precisely what they are getting or what effect the drugs will have.

These concerns, as well as the Endocrine Society's call for greater oversight of bioidentical hormones, are outlined in the Society's 2006 position statement on the topic. This policy is supported by many organizations that represent the interests of female patients, including the American College of Obstetricians and Gynecologists, which issued their own Committee Opinion in November 2005 on the use of bioidentical hormones, and by the North American Menopause Society, which endorses The Endocrine Society's 2006 position statement.

The broader medical community also shares the Society's views, as the position statement was the basis for an overwhelmingly supported new policy of the American Medical Association. This new policy calls for greater oversight of compounded bioidentical hormones, tracking of adverse events, and inclusion of uniform patient information with each prescription.

In summary, the Endocrine Society is concerned that patients are receiving potentially misleading information about the risks and benefits associated with "bioidentical hormones." The Society supports FDA regulation and oversight of all hormone therapies—including both traditional and bioidentical hormones—regardless of chemical structure or method of manufacture. However, legislative action must be taken in order to give the FDA the authority to regulate these hormone therapies. Regulations should include requirements for:

1. Surveys for purity and dosage accuracy;
2. Mandatory reporting by drug manufacturers or compounding pharmacies of all adverse events;
3. A registry of adverse events related to the use of hormone preparations, including those that come from compounding pharmacies;
4. Inclusion of uniform information for patients, such as warnings and precautions, in packaging of all hormone products, compounded or commercial; and
5. According to the AMA's policy, use of the term "bioidentical hormones" should be prohibited unless the preparation is approved by the FDA.

Scientific evidence is lacking at this time that either negates or supports the claims that bioidentical hormones are safer and more effective than those hormones commonly prescribed. This would require controlled studies directly comparing bioidentical hormones to other hormone treatments. Even though the WHI was halted more than four years ago, its results have not been adequately analyzed to draw conclusions for all treatment groups. It is likely to take years for the scientific community to definitively determine whether bioidentical hormones are indeed safer than hormones that are not naturally produced in the human body. Until such time as these conclusions are reached, the federal government must ensure that patients receive safe and effective drugs, and accurate information about drugs they are taking. We believe that a regulatory mechanism is the only way to ensure patient safety.

This concludes my prepared remarks. Thank you again, Mr. Chairman, for the opportunity to testify before you today. I would be pleased to answer any questions that you or other members of the committee may have.