

STATEMENT OF RANKING MEMBER GORDON H. SMITH

U.S. Senate Special Committee on Aging
“Bioidentical Hormones: Sound Science or Bad Medicine?”
April 19, 2007

Good morning and welcome. Thank you for attending today’s hearing “Bioidentical Hormones: Sound Science or Bad Medicine.” As this title suggests, we are here today to closely examine the controversy surrounding the production and use of bioidentical hormones as an alternative to conventional hormone therapies. The intent of this hearing is not to endorse one therapy over another. Rather, it is to ensure that the federal government is providing the information and oversight necessary so that consumers, women specifically, are able to make safe and well-informed decisions about their individual health care needs.

From my review, it seems that the federal government and medical practitioners are playing a guessing game with women’s health in the prescribing of hormone therapies. Today’s hearing reflects my belief that women deserve better – and I hope to get some answers today regarding the state of the science and the federal government’s oversight role in this arena.

Over a decade ago, the National Institutes of Health set out to shed some light on the effect of hormone therapy on preventing heart disease in women through the largest research initiative ever undertaken of this kind—the Women’s Health Initiative. When evidence indicated that the health risks of the therapies studied in WHI exceeded the benefits, the study was prematurely ended, scaring thousands of women away from traditional hormone therapy. As an alternative, bioidentical hormones have become a popular and controversial option, not only for aging women, but for men and women of all ages seeking a route to the fountain of youth.

Sale of bioidentical hormone products are on the rise with promoters, such as actress Suzanne Somers, and major marketing campaigns in doctors’ offices, pharmacies and the internet – touting bioidenticals as a “natural” and thus “safer” alternative to traditional hormone therapies.

There has been much debate in the scientific community, however, as to whether the science exists to support these claims. By the end of this hearing, I hope to have a clear understanding of whether additional federally funded studies are needed to address concerns regarding the safety and efficacy of these products.

Today we will also address the regulatory issues relating to the manufacturing of these products, especially those that are “custom made” or compounded in pharmacies. I am particularly troubled that compounded medications are not routinely tested, and are not accompanied by the warning labels and risk indicators that are required for traditionally manufactured medications.

Further, there is a lack of information available to assist Congress in determining the proper roles of the federal government, the state governments and the industry in regulating pharmacy compounding. That is why I have asked the Congressional Research Service to conduct a 50-state survey that will help me determine the best course of action going forward.

Ultimately, the federal government must do a better job of empowering consumers to make informed decisions regarding hormone therapies and compounded medications. But the current regulatory framework is hazy and creating confusion between the Federal Trade Commission, the Food and Drug Administration, and state boards of pharmacy regarding who has the ultimate regulatory responsibility. I fear that lack of consistent and certain oversight has created an atmosphere ripe with opportunities for fraud and abuse. By the end of this hearing, I would like to have some confidence that the regulatory agencies are taking these issues seriously, and have a concrete plan of action to address the Committee's concerns.

On our first panel this morning, I am pleased that NIH will be testifying for the first time before Congress regarding the latest findings from the Women's Health Initiative study. Also on the first panel will be the FDA and FTC, who will speak about the agencies' enforcement efforts. Our second panel promises a lively discussion regarding the science of bioidentical hormones and the regulatory issues relating to pharmacy compounding. I look forward to that dialogue.

As we have several witnesses to hear from in a short timeframe, I will conclude my remarks and turn to my colleague Senator Kohl for his opening statement.