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**THE SCIENTIFIC FACTS  
ABOUT BIOIDENTICAL HORMONES**

CLEVELAND, Ohio (January 15, 2007)—There has been much media attention recently focused on the debate regarding efficacy and safety of so-called bioidentical hormone therapy to treat menopause-related symptoms including hot flashes and vaginal dryness. “Bioidentical hormones” is a term typically used to describe custom-mixed (“custom-compounded”) recipes containing one or more hormones such as estrogen in differing amounts, depending on an individual prescriber’s order.

A recent editorial in the scientific publication *Menopause Management* entitled “*Feminine Forever, Round 2: The Bioidentical Cult*” provides important background information and insightful comments for the debate. A PDF of the editorial, written by Wulf H. Utian, MD, PhD, Executive Director of The North American Menopause Society (NAMS), is attached for your reference.

The Mission of NAMS, a nonprofit scientific organization, is to promote the health and quality of life of women through an understanding of menopause. The Society’s membership of 2,000 professionals representing a variety of disciplines—including clinical and basic science experts from medicine, nursing, pharmacy, anthropology, sociology, psychology, and complementary/alternative medicine—makes NAMS uniquely qualified to serve as the definitive resource for health professionals and the public for accurate, unbiased information about menopause. ([www.menopause.org](http://www.menopause.org))

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# From the EDITOR



**Dr. Wulf H. Utian**, consultant in women's health and reproductive endocrinology, has served as Editor-in-Chief of *Menopause Management* since its inception in 1988. The Arthur H. Bill Professor Emeritus of Reproductive Biology and Obstetrics and Gynecology, Case Western Reserve University School of Medicine, he is also Consultant in Women's Health to the Cleveland Clinic Foundation, and Executive Director of The North American Menopause Society (NAMS). He is Chairman of the Advisory Board of Rapid Medical Research, Cleveland. He received his medical degree from the University of Witwatersrand, Johannesburg, South Africa, and his PhD from the University of Cape Town, South Africa, and is a Fellow of the Royal and American Colleges of Obstetricians and Gynecologists, as well as the International College of Surgeons.

A pioneer in women's health issues and menopause research, in 1967 he established the Groote Schuur Menopause Research Clinic in Cape Town, the world's first such clinic. He was one of the three original founders of the International Menopause Society in 1976, of which he is Honorary Past President, and founded The North American Menopause Society in 1989.

He is the recipient of numerous national and international awards and research grants, and is still an active investigator with multiple grants. Dr. Utian has written over 200 papers related to the reproductive system in women and has authored five books on menopause and its effects on women. He is editor of *Menopause: The Journal of The North American Menopause Society*.

## Feminine Forever, Round 2: The Bioidentical Cult

George Santayana's admonition that "those who cannot remember history are condemned to repeat it" is a warning and not a cliché. *Feminine Forever – the Amazing New Breakthrough in the Sex Life of Women*, by Robert A. Wilson, MD, was published in 1966. In that book he claimed that "for the first time, a leading doctor in the field of menopause prevention explains why no woman—no matter what her age—need ever feel a day over forty."<sup>1</sup> He asserted that "as a simple statement of clinical fact every woman alive today has the option of remaining feminine forever. No longer need she fret about the cruel irony of women aging faster than men." He went on to state that "Your body's health and your soul's contentment may hinge on just one decision: to have your estrogen level checked." Then he promised that "these (natural estrogen) preparations are entirely free of side effects."<sup>1</sup>

The book caused a sensation. Women worldwide demanded hormones and physicians took sides for and against the concept. The euphoria was jolted in December 1975 when two papers were published in *The New England Journal of Medicine*<sup>2,3</sup> linking continuous unopposed estrogen with an increase in uterine cancer, something not unexpected by those of us already involved in menopause research. The addition of progestogen to the mix rescued hormone treatment, and it was off to the races again. Hormone sales boomed as women anticipated the prevention of Alzheimer's disease, heart disease and osteoporosis, as well as longer lives and other potential benefits.

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## From the Editor

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### So-called “Natural” Therapies

With this background, the 2002 termination of the estrogen-progestogen therapy (EPT) arm of the Women’s Health Initiative (WHI) was a major speed bump on the road of menopause history. But the subsequent massive backlash against the use of FDA-approved hormonal therapies has had an unanticipated and unfortunate outcome: a shot in the arm for a new school of “natural” therapies.

We are now in the era of *Ageless: The Naked Truth about Bioidentical Hormones*. Written and mega-marketed by former actress Suzanne Somers, who has no medical training or college degree, the book claims a foundation of “16 interviews from cutting-edge doctors on how to slow the aging process for women and men.”<sup>24</sup> The “cutting edgers,” doubtlessly so described to imply expert status or leading research credentials, were obviously selected to confirm a set of pseudoscientific principles, the bottom line of which is no different from that of Robert Wilson decades ago. Interestingly, a PubMed (Library of Congress) search of the medical literature failed to reveal one original publication on menopause-related research attributed to any of the 16 “cutting-edge” physicians listed in Somers’ book. This is quite remarkable—using 16 so-called “cutting-edge doctors” without portfolio, when there were literally dozens of real experts available worldwide, each with more than 50 peer-reviewed scientific publications to their names.

### Is It 1966 or 2006?

It is, therefore, not surprising if the following excerpts remind you of 1966.

*“This book introduces you to the most forward approaches of maintaining quality of life without drugs. Don’t you want to live a long, healthy life without illness and disability?”*

*“Ageless, that’s the promise.”*

*“I found the solution—a cutting-edge endocrinologist/anti-aging doctor, who prescribed a treatment of bioidentical hormones... This became and remains a huge passion for me: to let women know*

*there is a safe, effective treatment that is not based on drugs.”*

*“Bioidentical hormone replacement is the only answer to ward off illness, weight gain, and other symptoms associated with hormone decline.”*

What utter nonsense! We have come full circle in 40 years. Many women believe the concept, some healthcare providers are feeding the frenzy, and compounding pharmacies have hit the jackpot.

How on earth has modern medicine gotten into a situation in which the public believes the snake-oil salesman instead of the research and science? It would seem that contemporary women are merely confirming Santayana’s warning.

### Corruption and Collusion

Personally, I am concerned that the national disease of “acquire the dollar/garner the publicity,” irrespective of the integrity or outcome of the greedy chase, has now corrupted a significant number of healthcare practitioners. Women read their books, listen to them on radio and

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TV talk shows, and see their seductive Web sites with come-on photos and enticing promises. Sell, sell, sell, sell—their products, their books, a potentially dangerous therapy, and their enticing but misleading Web sites. Many of the latter hint at a medical conspiracy against women’s health!

Those of you who were fortunate enough to be at the NAMS 17th Annual Meeting (the proceedings are available on CD at [www.menopause.org](http://www.menopause.org)) in Nashville last fall would have heard how impotent the FDA is to police the situation in which physicians and compounding pharmacies collude to mix new and untested

concoctions, claiming that they carry the benefits of sex steroids without any of the risks because they are “bioidentical,” and not drugs. Fortunately for the public, the government is now acting to put the brakes on physicians promoting unapproved products and off-label uses of active hormones. The US Justice Department is using the False Label Protection Act to arrest and indict physicians responsible for these actions.

As the Wilson era ended in thousands of currently ongoing lawsuits, so too will this new cult-like phenomenon of compounding bioidentical hormones end in the courtroom. Moreover, do not anticipate supporting evidence from the real experts. Many of the most significant national medical associations and societies are now coming out with statements of reservation about the bioidentical cult. For example, the largest U.S. doctors’ group, the American Medical Association, voted in November 2006 to seek stricter FDA oversight and regulation of these so-called bioidentical hormone compounds. The Endocrine Society, which advocates FDA regulation and oversight of all hormones—bioidentical and traditional—has recommended the same thing.

### This is a Warning

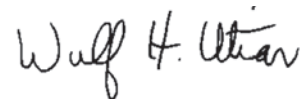
The purpose of this editorial is to caution those of you who are not questioning the results of “saliva” and other useless hormone tests brought to you by patients, and who then go on to “compound” the error by rubber-stamping a prescription for a concoction about which you know little but which has been recommended by a distant “compounding pharmacy” or for which you have obtained a so-called license or franchise from a nonmedical source to prescribe one of these protocols.

NAMS’s position on this matter has been clear for years. The organization has stated succinctly that “Another area of confusion in clinical practice is the utilization of ‘bioidentical hormones.’ As a result of concerns about safety issues with use of traditional HT, there is escalating utilization of alternatives to pharmaceutical dosage forms of estrogens and/or progestogens, including hormonal substances prepared in unique individualized dosage forms as gels, supposito-

ries, sublingual tablets, oral tablets, etc. The scientific evidence for these forms of usage was also reviewed and it was concluded that the same proviso applies; namely, that in the absence of specific safety and efficacy data for any specific product, the generalized risk and benefit data will apply.

“The NAMS HT Panel recognized that specific compounds, dose, and route of administration may have different outcomes. Nonetheless, in the absence of clinical trial data for each specific product, the clinical trial results for one agent should be generalized to all agents within the same family. This proviso also applies to the so-called bioidentical products.”<sup>4</sup>

There should be an explanatory patient package insert in all hormone prescriptions, whether commercial or compounded, that clearly explains to women the benefits and risks associated with the product. Nonetheless, you are the advocate for your patients and for safe and effective women’s health care. The responsibility to counsel women about risks and benefits of *all* pharmacotherapies is yours. You sign the prescription, you carry the liability. It is time to tell women, “Buyers beware!”



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