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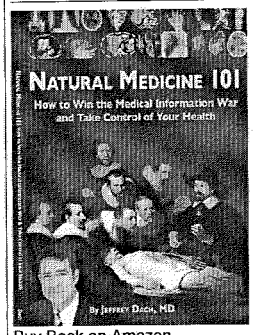

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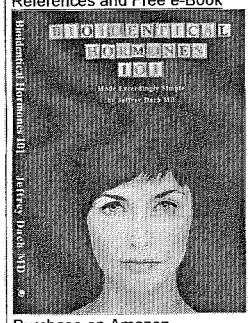

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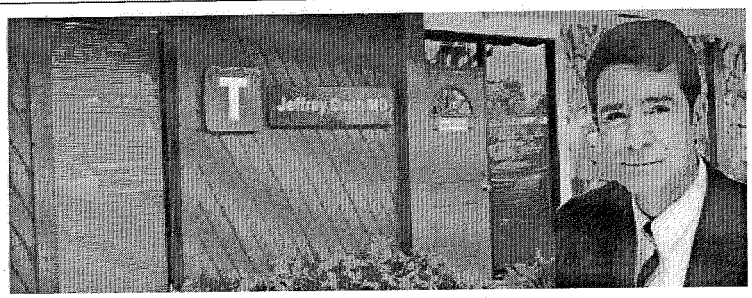

Inept FDA Declares Misguided War on Bio-Identical Hormones, and Promptly Shoots Own Foot

by Jeffrey Dach MD

FDA Tries to Protect Wyeth From Financial Losses

Acting as agent for drug maker Wyeth this week, a dysfunctional and inept FDA fired the opening salvo in a misguided war on bio-identical hormones. Using typical Orwellian DoubleSpeak, the FDA issued a series of nonsensical and contradictory statements intended to serve the financial interests Wyeth, maker of synthetic hormones Premarin and Prempro, found to cause cancer and heart disease in the 2002 NIH sponsored Women's Health Initiative Study. Since the study's release, millions of women have switched to the safe and more effective bio-identical hormones, currently prescribed by thousands of physicians, available as FDA approved products at local drug stores and compounding pharmacies. Wyeth has lost market share and suffered financial loss as synthetic hormone profits have declined from 4.4 to 1.2 billion annually from 2001 to 2006.

Wyeth Files a Citizen's Complaint with the FDA

October 2005, in a move to prevent further financial losses, Wyeth filed a Citizen's Complaint with the FDA, requesting the FDA take action against Wyeth's competition, prohibiting compounding pharmacies from providing bio-identical hormones to their patients. More than 66,000 doctors, patients, and pharmacists filed comments in favor of bioidentical hormones and against Wyeth. In spite of this public outcry, Wyeth continues to abuse the FDA to the harm and detriment of millions of women who use bio-identical hormones.

Analysis of the FDA Statements:

Here is an analysis of the recent FDA statements: a comedy of errors, omissions, contradictions, and Orwellian DoubleSpeak. The January 9, 2008 statements can be found at the FDA website.

FDA Takes Action Against Compounded Menopause Hormone Therapy (1)(2)

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Top Blogger Award

Astonishingly, the FDA does not recognize the term, "bio-identical" !

FDA says:

The term "bio-identical" has no defined meaning in any medical or conventional dictionary, and FDA does not recognize the term. Even different medical groups define the term differently. The Endocrine Society, for example, defines "bio-identical" hormones as "compounds that have the exact same chemical and molecular structure as hormones that are produced in the human body," while the American College of Obstetricians and Gynecologists (ACOG) defines "bio-identical" hormones as "plant-derived hormones that are biochemically similar or identical to those produced by the ovary or body."

My Reply:

The term bioidentical has a definite meaning and is widely used. The term, bioidentical, means a hormone chemical structure which is identical to that found in the human body. Both the Endocrine Society and ACOG define the term, "bioIdentical", exactly the same, even though the two definitions are worded differently. It is an embarrassment to medical science that the word BioIdentical has to be used at all. All Hormones should have been manufactured as bio-identical hormones. However, because of U.S. patent law which prevents patenting a bioidentical hormone, the drug industry created chemically altered hormones which could be patented and sold at higher profit margins.

Astonishingly, the FDA is UNAWARE of a basic fact of biochemistry !

Astonishingly, the FDA is UNAWARE that identical chemical structures have the same biological effects. This is the basis for all biochemistry. A water molecule, for example, will have the same biologic effect in the body regardless of how it is synthesized, and this is also true for any other chemical, including hormones.

FDA says:

Many compounding pharmacies use Bio-identical as a marketing term to imply that drugs are natural, or have effects identical to those from hormones made by the body. FDA is not aware of credible scientific evidence to support these claims.

My Reply:

Bio-identical hormones are (1) natural and (2) have effects identical to hormones made in the body. These are basic axioms of biochemistry, and accepted as basic truth by all of biochemistry, including the following medical textbooks Lehninger Principles of Biochemistry, Guyton Textbook of Medical Physiology, and Williams Textbook of Endocrinology.

It is astonishing that the FDA can be UNAWARE of the scientific evidence that is present in every medical textbook, and thousands of Medline references that state that bio-identical hormones ARE natural and DO produce the same effects as human hormones !!

The FDA Does Recognize this basic fact of biochemistry when looking at Synthetic Hormone Structures !

Astonishingly, for the FDA, when it comes to synthetic hormones, all of a sudden, chemical structures that are identical DO have the same biologic effects !!

FDA says:

Compounded products that have identical chemical structures to synthetic hormones can be

Jeffrey Dach

Genetics

Patient Handout Sheets

Menstrual Diary Log Sheet
MercOut Mercury Test Kit
Mercury Testing
SSRI's Taper Off
Acid-Alkali Food List

Bioidentical References

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Holt Schwartz 1Care Clinics
L'Hermite Safer
Hotze JP and S
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French Cohort Fournier
Teitelbaum Twnsend
Brownstein,Schw,Holt WSJ

Useful Medical Studies

Judith Walsh JAMA 2004
Frustaci JACC 1999

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Jeffrey Dach MD Bio

expected to have the same benefits—and risks— associated with FDA-approved hormone therapy.

My Reply:

This is Orwellian DoubleSpeak again. Compounded natural bio-identical hormones DO NOT have the same chemical structure as synthetic hormones. Compounded hormones are natural and bio-identical, and DO NOT increase risk of increased cancer and heart disease, as was demonstrated for the synthetic hormones in the WHI study. The Women's Health Initiative study published in JAMA July 2002 showed that Provera, a chemically altered form of progesterone causes increased risk of cancer and heart disease, while the natural, human bioidentical progesterone does not. (5) (6)

The following two studies show that bio-identical hormones are safe: One is the French Cohort Study which showed that Bio-identical hormone therapy does not cause increased risk of breast cancer.(3) The second is the June 2007 NEJM Calcium Score study which showed no increase in heart disease risk with estrogen. (4)

The FDA Attacks Saliva Hormone Testing !

FDA says :

Some compounding pharmacies and other promoters of "BHRT" claim that estrogen levels in a person's saliva can be tested by practitioners to help practitioners estimate the amount of hormone a person needs and purportedly to "customize" the hormone therapy for individual patients. There is no scientific basis for using saliva testing to adjust hormone levels. Instead, practitioners should adjust hormone therapy dosages based on a patient's symptoms.

My Reply:

Salivary hormone testing has been done by two large companies for many years, Diagnos-Techs and ZRT. Both Web Sites list plenty of scientific evidence validating saliva hormone testing. ZRT lists references supporting salivary hormone testing here and here.

Here is a comment on Saliva Testing by *Kenna Stephenson, MD, clinical professor at University of Texas at Tyler:* "**Saliva testing** has been used in clinical research, including studies conducted at the National Institutes of Health (NIH) for more than 30 years. Saliva testing has been available to practicing physicians for over a decade, and Medicare and many insurance companies provide reimbursement for its use. Over years of clinical practice, I have found that saliva testing is the most accurate measurement of the body's availability of the steroid hormones cortisol and DHEA and the sex steroid hormones estrogen, progesterone, and testosterone. Saliva testing correctly identifies the level of hormone at the cellular level (i.e. the biologically interactive form of the hormone), in contrast to a serum (blood) test, which measures the level of hormone circulating in the bloodstream."

In addition, salivary hormone testing for cortisol and melatonin is accepted and used by NASA on the astronauts on the space shuttle. (7)

A PubMed Medline search shows many research studies validating the use of salivary hormone testing.(8)

Key Word Search:

Salivary hormone 4075 articles
Salivary cortisol: 1478 articles
Salivary estradiol 177
Salivary progesterone 317
Salivary testosterone 428

The FDA Claims Ignorance of Its Own FDA Approvals !

FDA says:

Some pharmacies promote hormone therapy for men in the form of testosterone to treat a decline in the level of testosterone in older men, sometimes referred to as andropause. There are currently no FDA-approved products for the treatment of andropause. In addition, there are no FDA-approved testosterone drugs for women.


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Gilbert Ling
Gooz News
Greg Palast
Gwenn Olsen
Hank Barns
HD Foster
Healthy Scepticism
Healthy Skeptic
HeartScan
Honest Medicine
Howard Liebowitz MD

My Reply:

Testosterone insufficiency in older men is associated with increased risk of death over the next 20 years. (17) Testosterone has been FDA approved for both men and women for decades. FDA approved testosterone commercial products can be obtained at the corner drugstore. Androgel for example, is FDA approved and contains testosterone. Estra-test is an FDA approved hormone for women which contains testosterone.

The following is a list of FDA-approved bio-identical hormone commercial products available at the drugstore commonly used to treat menopause and andropause:

Alora (estradiol): FDA approved 1996 - Watson Labs
Climara (estradiol): FDA approved 1994 - Bayer
FemPatch : FDA approved 1997 - Parke Davis
Vivelle-Dot (estradiol): FDA approved 1994 - Novartis
Estraderm: FDA approved 1986 - Novartis
Esclim: FDA approved 1998 - Women's First Healthcare
Estrace (estradiol): FDA approved 1993 -Bristol Myers Squibb
Estring: FDA approved 1996 - Pharmacia UpJohn
Prometrium (natural progesterone): FDA approved 1998 - Solvay
Androgel (natural testosterone): FDA approved 2000 - Unimed Pharmaceuticals
Crinone: FDA approved 1997 - Columbia Labs

FDA approved Estradiol containing products:Estrace, Progynova, estrofem, Alora, Climara, Vivelle, Vivelle-Dot, Menostar, Estraderm TTS Estrasorb Topical, Estrogel, Elestrin, Lunelle Estring, Femring

FDA approved Progesterone products Prometrium, Utrogestan, Minagest, Microgest, CRINONE, PROCHIEVE, Cyclogest

FDA approved testosterone:Testoderm, Androderm, AndroGel

The FDA Tries to Ban Estriol !

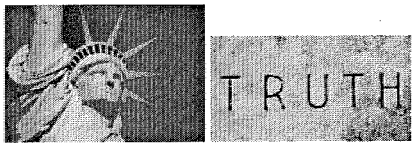
Astonishingly, the FDA wants to ban estriol, a popular component of natural hormone therapy for women.

FDA says:

Some compounded "BHRT" drugs contain an estrogen component called estriol. No drug containing estriol has been approved by FDA and the safety and effectiveness of estriol is unknown. Pharmacies may not compound drugs containing estriol unless they have an FDA-sanctioned investigational new drug application.

My Reply:

Like many commonly prescribed drugs (e.g. quinine, Phenobarbital, tinidazole), estriol has a monograph from the U.S. Pharmacopeia (USP). When Congress passed the FDA Modernization Act in 1997, it clearly indicated that drugs with a USP monograph could be compounded. 50,000 compounding pharmacists, 15,000 doctors and 2 million women have been prescribing, making and using estriol for decades. FDA approval is not required since this is regulated by the states, not the FDA.



Finally, the Truth About Bio-Identical Hormones !

And now, The Truth about Bioidentical Hormones-quoted from the IACP from the Compounding Pharmacists web site. (48)

Myth 1) Bioidentical hormone replacement therapy (BHRT) is unregulated.

Fact: Bioidentical hormones – like all compounded medications – are made from FDA- and USP-registered materials – the same used by pharmaceutical manufacturers – and their preparation is well regulated by state boards of pharmacy that have responsibility for overseeing

Hypertension Group
Int Medical Veritas Assoc
Iodine Group
ISIS
JAMA
Jenny's Diabetes Update
JeriLynn Prior MD
john lee md
Jonathan Wright Newsletter
JUNK Food Science
Kevin MD
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all pharmacy practice in each state. Pharmacies that compound medications, including bioidentical hormones, are regulated by state pharmacy boards – similar to the relationship doctors have with state medical boards. In addition, there are also national standards and guidelines for compounded medications. The ingredients and their suppliers are regulated at the federal level by the FDA, with additional oversight provided by the U.S. Pharmacopeia.

Myth 2) Compounded bioidentical hormones are unsafe because they aren't FDA-approved.

Fact: Compounded medications are regulated by state boards of pharmacy and are not subject to federal laws designed to regulate mass-produced drugs. This is because they are customized to meet the unique needs of patients based on the specific orders of a physician. The FDA approval process is designed for mass-produced manufactured drugs; it is universally recognized that holding compounded medications to these standards would completely eliminate their availability. Compounded medications are in a similar position as manufactured products prescribed for off-label use, which constitutes about a fifth of all prescriptions. They are not approved by the FDA for such use, and yet it is well accepted that physicians should be able to use their discretion to prescribe medications for off-label use.

Myth 3) Bioidentical hormones are just as risky as manufactured products like Premarin and Prempro.

Fact: There are no studies comparing the two types of therapies, so we cannot make any direct comparisons. The Women's Health Initiative study examined only Premarin and Prempro, which do not use the same ingredients that are used to compound bioidentical hormones. To date there have been no studies that show a link between BHRT and cancer/strokes/heart attack, however the pharmacy community supports and funds studies to better determine the risk profile of BHRT.

A physician is trained and licensed to diagnose disease and to determine appropriate therapy for patients. A physician uses clinical expertise to determine appropriate therapies for patients. Premarin and Prempro may be appropriate for some patients. Bioidentical hormones may be appropriate for others. It is up to doctors to make that determination.

Myth 4) Pharmacists are recklessly promoting BHRT as safe and effective.

Fact: Compounded medicines are a lot like off-label prescriptions: they are not subject to FDA approval and, as a result, cannot be marketed as safe or effective. In fact, the FTC Act, 15 U.S.C. § 41 et seq., prohibits unfair or deceptive acts and practices, including false and unsubstantiated advertising claims. It is already illegal for a pharmacy to make claims without substantiation or to overstate the health benefits of the products they promote.

Myth 5) Bioidentical is a misleading term.

Fact: The chemical structures of bioidentical hormones are identical to those produced by the human body. Because the chemical structure is identical, these hormones are often referred to as bioidentical.

Sign a Petition and Join a Boycott

Don't let the financial interests of the drug industry restrict your health freedom, call or email your senator today and voice your outrage at this blatant abuse of the FDA by special interest groups.

Write a protest letter your congressman with this easy **link**.

Sign this Petition opposing the recent FDA actions against bioidentical hormones, and send a message to Wyeth by boycotting their **product list**. Don't buy their products. Just say No to unethical manipulation of the FDA, or any government agency by drug companies.

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Jeffrey Dach, M.D. BLOG TrueMedMD

References and Links

List of medical textbooks stating that bio-identical hormones have the same chemical structure as those in the human body and have the same effect. (all of them):

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Textbook of Medical Physiology by Arthur C. Guyton
Williams Textbook of Endocrinology
Basic & Clinical Endocrinology by Francis S. Greenspan
Review of Medical Physiology by Ganong, William F. MD
Endocrinology (5th Edition) by Mac E. Hadley
Endocrine Physiology by Susan Porterfield

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(13) The Endocrine Society Position Statement Oct 2006 Bio-Identical Hormones

(14) The Endocrine Society Position Statement Oct 2006 Bio-Identical Hormones

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(20) Bioidentical Hormones are not snake oil: They are available commercially at your local drugstore with a prescription from your regular MD . Erika Schwartz blog, web site. Erika Schwartz, MD, Patients' Health Advocate and Leading Expert on Bioidentical Hormones

(21) FDA says alternative hormone claims unsupported Wed Jan 9, Reuters news service

(22) Listing of references in the Scientific Literature on validating use of bio-identical hormones, Erika Schwartz, MD, Patients' Health Advocate and Leading Expert on Bioidentical Hormones

(23) Wednesday, Jan. 09, 2008 FDA Asserts New Policy to Restrict Women's Access to Bioidentical Hormones International Academy of Compounding Pharmacists

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(26) Tell Congress: Don't Take Away My Compounded Medications! Send a letter to your congressman.

(27) Hot Flash: FDA Warns About BHRT Drugs,January 9th, 2008 2:51 pm By Ed Silverman Pharmalot

(28) E- Book on natural progesterone

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(31) About USP—An Overview Who We Are, The United States Pharmacopeia (USP) is the official public standards-setting authority for all prescription and over-the-counter medicines, dietary supplements

(32) Estriol listing in USP

(33) Pharmacies Warned About Compounding Estriol, Touting Mixture's Benefits Does the FDA have jurisdiction over these compounding pharmacies?There's a court battle going on right now to determine the answer to that question. Oral arguments are expected tomorrow in the U.S. 5th Circuit Court of Appeals in New Orleans. The fda is appealing a lower court ruling, which found that they do not have jurisdiction over drug preparations produced by compounding pharmacies.

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(48) The Truth about Bioidentical Hormones-IACP

(49) WomenInBalance.org NonProfit Advocacy Group for BioIdentical Hormones. They have compiled the currently available science references behind the use of bioidentical hormones for women.