CONUNDRUMS IN BIO-IDENTICAL HRT

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Who needs them, anyway?
They say menopause makes women do strange things ...

**LIKE SWALLOW HORSE URINE!**

**PREMARIN CONTAINS HORSE URINE**

What would you do if your doctor told you to swallow horse urine every day for the rest of your life? You’d recommend him or her to the funny farm, right? But what if your doctor handed you a bottle of pills called “Premarin”? If you were like 8 million other menopausal or post-hysterectomy women, you’d smile trustingly and take your medicine.

But Premarin, the most commonly prescribed drug in the U.S., has a nasty secret ingredient: pregnant mares’ urine.

To produce Premarin, pregnant mares are hooked up to rubber urine-collection bags and tethered in stalls so small they can’t even turn around or lie down comfortably. They are forced to stay there for six months, while their bodies are producing the most estrogen. Within days of giving birth in the spring, the mares are reimpregnated. Fertile mares may go through this same grueling cycle year after year.

The foals—all but a few kept for stud or to replace worn-out mares—will be sold at auction. From there, most go to feedlots to be fattened for slaughter. Mares, too, are slaughtered when they become lame or infertile. Look carefully at the label on a can of dog food and you may see them mentioned: meat byproducts.

The good news is that Premarin is the ONLY menopause drug made with animal-derived estrogen. Safe, effective alternatives include Cenestin, Estratab, Estraderm, Estrace, Ortho-Est, and Remifemin.

For more information and a list of alternatives, call 1-800-KNOW PMU.

People for the Ethical Treatment of Animals
501 Front St., Norfolk, VA 23510
757-622-PETA • www.MenopauseOnline.org

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Figure 7. Central Energy Pathway

STAGE I
Digestion and Assimilation
Fats
Carbohydrates
Proteins

Stage II
Intermediary Metabolism
Acetyl CoA
β-Hydroxybutyrate

Stage III
Electron Transport and Oxidative Phosphorylation

Note: Vitamin & mineral requirements for cofactors are shown in light blue box.
Elevations of metabolites before these steps indicate functional deficit of the nutrients.

Compounds Reported in ION® Profile are Printed in Red

Energy for muscle and nerve function and for building new tissue.
The study of the connectedness of mind, body, emotions and spirit.

The expansion of current concepts to include the human energy field.

The basis of Chinese, Indian, Hebrew and other world medicine systems.

The human energy field interacts with all the energy fields, beginning with the pineal gland.

Quantum physics is the basis of this study.
WHERE HAVE ALL THE HORMONES GONE?

- Dec. by OC’s
- Dec by tubal ligation
- Dec by hysterectomy
- Dec by oophorectomy
- Dec by vasectomy
- Dec by multiple pregnancies
- Dec by harmful EMF exposure
- Menopause & andropause

- Dec by miscarriages & terminated pregnancies
- Dec by stress adaptation
- Dec by medications
- Dec by physical anomalies
- Dec by lack of exercise
- Dec by nutritional deficiencies
- Dec by xenobiotics
CONCERNS IN TODAY’S WORLD OF HRT

- Media reported over & over on 3 studies done on foreign substances, Premarin & Provera
- This is not new information
- Used term “estrogen”---a class of related analogues not a single substance
- Unnecessary step back in time
- Negative press does not negate cellular & biological studies from the early 1900’s on the roles of endocrine molecules in human physiology or cat physiology or cantaloupe physiology!
HEALTH AND HORMONES

- Hormones as they relate to whole body functioning
- Misinterpretations of literature by media & health care professionals
- The need for HRT created by the effects of xenobiotics
- The difference of impact of bio-identical endocrine molecules and synthetic analogs on physiology
- Righting the mistakes in HRT over the years
- Appropriate monitoring
FUNCTIONS OF BIO-IDENTICAL PROGESTERONE

- Antioxidant
- Prepares breast for lactation
- Prepares uterus for implantation
- Saves pregnancies
- Natural Anti-depressant
- Decreases number of estrogen receptor sites
- Non Carcinogenic, induces apoptosis of cells
- Inhibits human cancer cell growth & invasiveness

- Increases libido
- Diuretic - Tells the kidney to rid body of excess sodium and water
- Prevents & reverses fibrocystic breast disease
- Helps regulate blood sugar levels
- Anti-convulsive
- Thermogenic
- Thickens vag secretions
FUNCTIONS OF PROGESTERONE, (CON’T)

- Normalizes zinc & copper levels
- Escorts T3 across mitochondrial membrane
- Increases SHBG levels
- Skeletal Muscle Relaxant
- REM Sleep

- Vasodilation via inc. Nitrous Oxide release
- Adds to estrogen protection of glutamate toxicity
- Normalizes blood clotting
- Lowers blood pressure
- Decreases Vascular Proliferative and Inflammatory Responses
- Decreases Sympathetic Activity
- Immunosuppressant
Functions of Progesterone, (con’t)

- Helps the lining of the uterus mature in the second half of the cycle
- Modulates estrogen distribution across the tissues
- GABA receptor agonist (neuroinhibitory)
- Stimulates osteoblastic and inhibits osteoclastic function (bone trophic)


Functions of Progesterone, (con’t)

– protects arterial linings

– Protects hippocampus

Progesterone: Indications

- PMS
- Peri-menopause
- Preeclampsia / Toxemia
- Migraine Headaches
- Hysterectomy
- Luteal phase defect
- Multiple Sclerosis
Progesterone: Indications, (con’t)

- Anxiety Disorders (especially cyclic)
- Adrenal insufficiency
- Euthyroid Disorders
- PCOS
- Libido
- Infertility
- Mood disorders
- Premature ovarian failure
- Seizures
FUNCTIONS OF BIO-
IDENTICAL E₁,E₂,E₃

- Sex Characteristics
- Proliferates endometrium
- Thins cervical mucus
- Prevents & treats cervical dysplasia
- Libido and Orgasm
- Primes testosterone receptor site
- Dec. risk of CVD
- Promotes normal Heart rhythms
- Dec plasma renin substrate
- Improves lipid profile
- Dec triglycerides
- Stimulates reverse cholesterol transport
- Lowers blood pressure
- Normalizes blood clotting
- Strengthens heart valves and venous valves
- Inc. stroke volume
- Inc flow acceleration

ERα and ERβ (estrogen receptors) influence cytosolic signaling

- Anti-athrogenic (1)

GPR30 or GPER1 mediates estrogenic response to cardiovascular and metabolic regulation

- Vasorelaxation (1)

- Smooth muscle cell proliferation (1)

- Protection of myocardium against ischemia (1)

Estrogen impacts intracellular calcium to lower blood pressure (1)

MORE FUNCTIONS OF E₁, E₂, E₃

- Promotes neural cell growth
- Improves cerebral glucose utilization
- Improves synaptic activity
- Improves cerebral blood flow
- Protects brain from glutamate toxicity
- Improves cognitive function

- Reduces risk of senility/Alzheimer’s
- Natural antidepressant
- Maintains REM sleep
- Decrease in symptoms of Parkinson’s Disease
- Promotes emotional stability
- Increases desire to compete in life
- Prevents morbidity
- Protects the pancreas

Folding of amyloid beta protein is the pathogenic event in Alzheimer’s

- Estrogens inhibit the oligomer formation, with estriol being the strongest inhibitor
- Physiologic levels of hormones delay progression of disease

• Estradiol, progesterone, and androgens

– Estrogen
• Activation of signaling molecules and interactions with growth factors
• Effects dopamine signaling pathway
– Women with low estrogen often have low dopamine and serotonin levels when urine is tested
Telomeres

Biomarkers for cellular aging –
Telomere length
– Telomerase activity
– HRT for 1 year or longer

– Longer endogenous exposure associated with greater telomere length and lower telomerase activity

EVEN MORE FUNCTIONS OF E₁, E₂, E₃

- Antioxidant
- Increases energy production
- Blocks receptor sites from Xenoestrogens Dec. risk of colon cancer
- Slows calcium loss from bones
- Prevents macular degeneration, dry eye syndrome, cataracts, & most ocular diseases
- Improves fat to muscle ratio


Diabetes

• ERRα
  – Improves insulin sensitivity

• Newest evidence that estrogen is functional metabolically

Pancreas

- Stabilizes blood glucose
- Supports survival of pancreatic B cells
  - Stimulates insulin release
  - Protects against pancreatic B cell apoptosis

Metabolic

• Perimenopause
  – Increased abdominal fat – Loss of skeletal muscle

• HRT reverses or reduces menopausal changes in body composition

• Endothelial dysfunction
  ◦ Aging causes decreased Endothelium dependent dilation in response to stimuli
  ◦ Reduced bioavailability of NO as a result of oxidative stress
  ◦ Aging leads to increased oxidative stress without increase in antioxidant status
  ◦ Increased activity of endothelin 1 reduces productions of dilatory prostaglandins
    ▪ Development of vascular inflammation
    ▪ Formation of advanced glycation end products
    ▪ Increased endothelial apoptosis
    ▪ Reduced expression of estrogen receptor alpha
    ▪ Impaired endothelium dependent dilation
ENDOTHELIAL FUNCTION

• Moderation of vascular endothelial function
  ◦ Body weight
  ◦ Vitamin D status
  ◦ Estrogen status
  ◦ Exercise
  ◦ Diet high in antioxidants
THE ROLE OF E1, E2, AND E3 IN HEALING

- Increases energy production
- Decreases osteooblastic function
- Increases osteoclastic function
- Necessary for rapid bone turnover, but not great for rebuilding lost bones
- Slows bone loss by mediating mineral content of the bone, both in bone matrix & kidneys
- Increases collagen mass—ligaments, tendons, muscle, connective tissue
- Normalizes blood clotting
- Maintains REM Sleep/reduces stress

- Helps with osteocalcin formation
- Inc. stroke volume
- Inc. strength of cardiac valves & muscle
- Promotes neural cell growth
- Improves cerebral & other tissue glucose utilization
- Improves synaptic activity
- Increases cerebral and total body blood flow
- Protects from glutamate toxicity
- Lowers blood pressure
- Improves lipid profile
ESTRIOL

- Has been used successfully in western Europe for over 60 years
- 80 times weaker than beta-17 estradiol
- Is not metabolized backwards to estrone or estradiol
- Is an adaptogen
- Prevents bone loss in post menopausal women
- Oral use was not associated with a risk of breast cancer
- Is safe for use in post menopausal women previously treated for breast cancer
At 10 times the concentration of estradiol it is antagonistic to the effects of E2

Effective in the treatment of MS

Is useful as alternative in post menopausal women with UG tract disturbance

Decreases total cholesterol and LDL’s

Up-regulates LDL receptor activity

Raises HDL’s
The Structure of Hormones

Cholesterol
Progesterone
Testosterone
Estrogen
Cortisone
Natural (bio-identical) vs. Synthetic
Figure 63-3. Principal pathways for biosynthesis of adrenocorticosteroids and adrenal androgens.
Figure 61-1. The biosynthetic pathway for the estrogens. Additional details and structures are shown in Figure 63-3 (page 1472).
**Cholesterol-5-en-3\beta-ol-1\alpha-Hydroxycholesterol-6-one (Cholesterol)**

**Progesterone USP**
Pregna-4-ene-3,20-dione; Proluton (Schering)

**Testosterone NF**
Androst-4-ene-3-one, 17-hydroxy, (17\beta)-; Androloy (Lincoln);
Bio-Hemisabol (Organon); Oralet-F (Scherering); Synandrol (Pfizer)

**Hydrocortisone USP**
Pregna-4-ene-3,20-dione, 11,17,21-trihydroxy-, (11\beta)-; Cortisol; Compound \textit{F}; Reichstein’s "Substance M"; Cortef (Upjohn); Cortril (Pfizer);
Hydrocortisone (MSD)

**Medroxyprogesterone Acetate USP**
Pregna-4-ene-3,20-dione, 17-(acetoxy)-4-methyl-, (17\beta)-;
Provera, Depo-Provera (Upjohn)

**Estradiol NF**
Estron-1,3,5(10)-triene-3,17-diol, (17\beta)-; 17-Beta-estradiol; Dihydrotheicin;
(Merrell-National); Progynon (Scherering)

**Fludrocortisone Acetate USP**
Pregna-4-ene-3,20-dione, 21-(acetoxy)-9-fluoro-11,17-dihydroxy-, (11\beta)-;
Florinef Acetate (Squibb)
SIDE EFFECTS OF PROGESTINS

- Increases sodium and water retention
- Causes depression
- Cannot maintain pregnancy
- Increases appetite and weight gain
- Carcinogenic
- Blood clots lungs, periphery, brain
- Hair loss

- Masculinizes the female fetus
- Can be estrogenic or androgenic
- Cannot be synthesized into other compounds
- Cannot raise basal temperature
- Acne & facial hair growth
- Impaired glucose tolerance
MORE SIDE EFFECTS OF PROGESTINS

- Breakthrough bleeding
- Fibrocystic breasts
- Headaches & migraines
- Cardiac arrest
- Nausea
- Cholestatic jaundice
- Diarrhea
- Irritability/moodiness
- Seizures
- Lethargy
- Anxiety/panic/ anger
- Insomnia
- Dysrhythmias
- Poor lipid profile
- Elevated BP
- Skeletal muscle spasms
  overall tightness
- Dec immune function & stress adaptation
ADDITIONAL OBSERVATIONS IN OC USERS

- Altered Immune Factors
- Altered Inflammatory Factors
- Vitamin Deficiency
- Magnesium, Folic Acid, B2, B6, B12, Vitamin C and Zinc
- Increased Insulin resistance and Glucose Intolerance
- Elevated Cholesterol and Triglycerides
- Increased C-Reactive Protein
- 3-6 fold increase risk of venus thrombosis
- 2-5 fold increase of Mi’s and Stroke
- Increased Hepatocytes CRP synthesis
 REFERENCES FOR PREVIOUS SLIDE


The presence of serum immune complexes such as antiethinylestradiol and anti progestogen antibodies cause vascular lesions and other inflammatory cytotoxic conditions including thrombosis. These form in as little as 3 weeks.

Researchers confirmed that the immune complexes are not formed against non synthetic hormones.
World Health Organization. Improving access to quality care in family planning. Published 1996. Revised 2001


- Increased risk of lupus, Rheumatoid Arthritis, Crohn’s and Ulcerative Colitis

- Increased incidence of severe periodontitis, periodontal pockets and gingival inflammation

- Increased inflammatory immune cytokines


Elevated WBC’s in OC users

Increased hospitalization for inflammatory diseases of the respiratory, digestive, urogenital and musculoskeletal system of women under age 40 that use OC’s

ESTROGEN DISTRIBUTION (ENDOGENOUS)

- Secreted directly to the blood stream
- Travels directly to tissues via the inferior venacava
- Returned to the liver after exerting its affect on tissue receptor sites for methylation and conjugation
ESTROGEN DISTRIBUTION
(TRANSDERMAL/TRANSMUCOSAL)

- Transmucosal- Same as exogenous

- Transdermal- Same as exogenous except when applied to abdominal skin

- Transformation in subcutaneous adipose to other molecules

- Subcutaneous adipose deposition for later release

- TD/TmM does not have the same impact on liver, clotting factors

Ref 17-19
ESTROGEN DISTRIBUTION (ORAL)

- Significant processing through gut lumen and in gut endothelial cells
- Travels to the portal circulation
- Liver transformation and metabolism
- Only 10% of dose is bio-available
- 90% is converted into bioactive, untoward metabolites before absorption

Ref - #6 and 7
METABOLISM OF ESTROGENS

- After oral and intravenous administration of E2 - 50% is converted to E1

- CYP450 phase 1 oxidation - 16-alpha hydroxylation (estrogen dependant diseases- lupus and breast cancer), 2 - alpha hydroxylation, (protective) 4 hydroxylation- (DNA damaging quinone)

- Phase 2 conjugation - sulfation, methylation, glucuronidation of 2-, 4-, 16-hydroxylated compounds

- Phase 3 excretion in bile or urine

  - Review

STEROID HORMONE METABOLISM

ENZYMES
1. Cholesterol side chain cleavage (CSCC)
2. 3β-Hydroxysteroid Dehydrogenase (3β-OHSD) AND Δ5,4 Isomerase (reside on same protein)
3. 17α-Hydroxylase **
4. C17,20 - Lysase **
5. 17β-Hydroxysteroid Dehydrogenase (17β-OHSD)
6. Aromatase
7. 5α-Reductase AND NADPH
8. 21-Hydrolase
9. 11β-Hydroxylase
10. 18 - Hydroxylase AND 18 - Hydroxydehydrogenase
11. 16α-Hydroxylase
(A) Inhibited by Chrysin
(B) Increased by cruciferous vegetables (Indole-3-Carbinol) and flaxseed
(C) Decreased by cruciferous vegetables (Indole-3-Carbinol) and flaxseed

** NOTE: 17α-Hydroxylase and C17,20 - Lysase activities reside on a single protein (designated P450s)
SIDE EFFECTS OF ORALLY ADMINISTERED ESTROGEN

- Migraine headaches
- Increases Estrone, not Estradiol levels
- Increases triglycerides
- Increases blood pressure
- Carcinogenic
- Cholelithiasis
- Sat of Cytochrome P450
- Gallbladder Disease
- Bloating
- Depression
- Thromboembolism
- Increase in Fibrocystic Breast Disease
- Competes with hepatic conversion of HGH to IGF-1 (Dec 1GF-1)
Changes in Hepatic Protein Synthesis with Oral Estrogens

- Prothrombotic
- Inc fibrinogen I&II
- Dec TFPI (Tissue Factor Pathway Inhibitor)
- Inc CRP (X2)
- Inc Factor VII
- Inc D-Dimer
- Dec Plasminogen Activator Inhibitor Type I

- Dec circulating Antithrombin III
- Inc Renin
- Inc IGF-1 clearance & induction of GH resistance
- Promotes insulin resistance
- 16-alpha hydroxyestrone & other psycho hormones
- Inc triglycerides
- Inc lipid per oxidation, inc fat mass
IS THERE SAFE & EFFECTIVE ENDOCRINE SUPPLEMENTATION?

I believe there is if we learn from our mistakes and follow a few integral principles...
PRINCIPLES OF NATURAL HORMONE REPLACEMENT

- Use only bio-identical hormones (natural human hormones)
- Use the safest route of administration (buccal)
- Preserve the delicate balance
- Individualize the dose
- Eat a Diet void of Xenobiotics & rich in fruits and vegetables
- Supplement with MVM, antioxidants, EFA’s
TESTOSTERONE

- Necessary for emotions of confidence, joy, affection, friendliness
- Is lowered by OC’s
- Is protective of autoimmune diseases
- Is inc’d by weight training & exercise
- Is dec’d by menopause & oophorectomies
- Restores ability to achieve & sustain erections

- Prevents platelet aggregation
- Lowers blood pressure
- Is lower in Andropause and BPH
- Lowered by environmental toxicities
- Physiologic levels protect against prostatic hyperplasia

FUNCTIONS OF TESTOSTERONE

- Produced in adrenals and testicles in men
- Produced in adrenals, skin, adipose tissue, muscles, brain, and ovaries in women
- Male secondary sex characteristics
- Anabolic: increases MM and bone mass and all collagen
- Increases libido in both men and women
- Improves memory and cognitive function
- Reduces body fat
- Desire to compete in game of life
- Necessary for energy and sense of well-being
- Antidepressant
- Decreases drinking
FUNCTIONS OF TESTOSTERONE

- Antioxidant
- Necessary for collagen formation
- Improves neural cell formation
- Positive lipid profile, stroke prevention
- Required for optimal transport of excess cholesterol from tissues and blood vessels back to the liver
- Enhances HDL-induced reverse cholesterol transport from arterial walls
- Decreases platelet aggregation
- Improves all tissue stamina
- Decreases SHBG
- Levels are decreased by 250 drugs
- Elevates hepatic lypase necessary for the liver to safely clear the body of excess cholesterol
HORMONE
STATUS

- **High levels of DHEA, testosterone, and IGF-1**
- **Deficiency in one hormone** (DHEA, testosterone, or IGF-1)
- **Deficiency in two hormones** (DHEA, testosterone, or IGF-1)
- **Deficiency in all three hormones** (DHEA, testosterone, or IGF-1)

Three-Year Survival Rate

- 83%
- 74%
- 55%
- 27%

TESTOSTERONE BLOOD LEVELS AND SUBSEQUENT INCIDENCES OF DISEASE AND DEATH

<table>
<thead>
<tr>
<th></th>
<th>Highest Testosterone</th>
<th>Next to Highest Testosterone</th>
<th>Next to Lowest Testosterone</th>
<th>Lowest Testosterone</th>
</tr>
</thead>
<tbody>
<tr>
<td>All-Cause Mortality</td>
<td>41% Reduction</td>
<td>38% Reduction</td>
<td>25% Reduction</td>
<td>Highest rate of Death</td>
</tr>
<tr>
<td>Coronary Heart Disease</td>
<td>48% Reduction</td>
<td>41% Reduction</td>
<td>29% Reduction</td>
<td>Highest rate of Death</td>
</tr>
<tr>
<td>Cancer</td>
<td>29% Reduction</td>
<td>23% Reduction</td>
<td>26% Reduction</td>
<td>Highest rate of Death</td>
</tr>
</tbody>
</table>

DOSAGE FORMS

- Orally Ingested
  - In Oil Suspension
  - Sustained-Release
- Rectal/Vaginal
  - Suppositories
  - Pessaries
  - Emulsions
- Implants
DOSAGE FORMS (CONT’D)

- Injectable
- Topical
  - Enhanced Absorption Bases
  - Hydrophilic Creams
  - Ointments
- Buccal
  - Troches
  - Sprays
  - Drops
Evaluation of Patients

- Laboratory Studies
  - Saliva testing
  - Blood testing
  - Timing of the testing
  - Testing with creams vs. troches
HORMONAL MONITORING

- **Serum - bound fractions:**
  - Total estrogens, E2, DHEA, DHEA-S, Testosterone, etc.
  - Expensive, but insurance usually covers
  - Most accurate

- **Saliva - unbound (free-floating) fractions:**
  - Full panel of sex hormones, adrenal steroids
  - Least expensive
  - Least accurate

- **Urine - conjugated forms:**
  - E1, E2, E3, and other steroids; useful for metabolic errors
  - Most expensive
## Hormone Dosing and Monitoring (Progesterone)

<table>
<thead>
<tr>
<th>Dosing Route</th>
<th>Saliva Concentration</th>
<th>Serum Concentration</th>
<th>Capillary Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Luteal Phase</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Saliva</td>
<td>0.1-0.3 ng/ml</td>
<td>12-32 ng/ml</td>
<td>12-32 ng/ml</td>
</tr>
<tr>
<td>Buccal Troche 100mg</td>
<td><strong>Troche Saliva</strong></td>
<td><strong>Troche Serum</strong></td>
<td><strong>Troche Capillary</strong></td>
</tr>
<tr>
<td>1000 -3000 ng/ml</td>
<td>27-30 ng/ml</td>
<td>270-300 ng/ml</td>
<td></td>
</tr>
<tr>
<td>Transdermal Progesterone 20-30mg</td>
<td><strong>Transdermal Saliva</strong></td>
<td><strong>Transdermal Serum</strong></td>
<td><strong>Transdermal Capillary</strong></td>
</tr>
<tr>
<td>10-30 ng/ml</td>
<td>2-3 ng/ml</td>
<td>20-30 ng/ml</td>
<td></td>
</tr>
<tr>
<td>Capsules 100mg</td>
<td><strong>Capsule Saliva</strong></td>
<td><strong>Capsule Serum</strong></td>
<td><strong>Capsule Capillary</strong></td>
</tr>
<tr>
<td>0.02-0.04 ng/ml</td>
<td>2-4 ng/ml</td>
<td>2.4 ng/ml</td>
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</tbody>
</table>
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