



# BIOTE SUB-CUTANEOUS HORMONE PELLETT THERAPY



- 
- Bio-Identical vs Synthetic
  - Beginning look at the BioTE Method
  - History of Pellets
  - Regulatory or not?
  - Procedure requirements
  - Training process

## BIOTE HELPS BODY RETURN TO NORMAL HORMONAL BALANCE & PHYSIOLOGICAL STATE

Hormone replacement must be BASED ON

- ✓ Right Kind of Hormone (*Bio-Identical*)
- ✓ Right Amounts (*Individualized Dosing*)
  - ✓ Right Delivery System (*Pellets*)

## WHAT IS THE BIOTE METHOD OF HRT

- Learning advanced HRT in order to have an Alternative to “Bad Medicine”
- A journey of learning proper interpretation of lab work
- Applying it to the use of Bio-identical hormone implants
- Via delivery system that is 80+ years old
- IM+ patients treated successfully
- Whole Health Optimization

# WHAT IS THE BIOTE METHOD OF HRT?

- Advanced training and certification involving both didactic and clinical certification. Creating a standard of care for patients not achievable thru traditional medicine.
  - Advanced HRT is necessary to have and Alternative to “Bad Medicine” thru individualized dosing and patient care
  - A journey of learning proper interpretation of lab work
  - Applying this to the use of Bio-identical hormone implants
  - Via delivery system with 80+ years of research
  - IM+ patients treated successfully
  - Whole Health Optimization

## BIOTE METHOD

- Testosterone (with guidelines of less than 3% variance in every doses)
- Estradiol (with guidelines of less than 5% variance in every dose)
- Diet
- Thyroid
- HGH
- Vitamins and Minerals

## HOW DOES BIOTE'S MISSION ALIGN WITH A NATUROPATHIC PROVIDER?

- To address the fundamental causes of disease. To heal the whole person through **individualized** treatment. To teach the principles of healthy living and **preventive** medicine. I will conduct my life and the practice of Naturopathic health care with vigilance, integrity, and freedom from prejudice.

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- Widely used in Europe and Australia
  - Discussed the use of estradiol and testosterone pellets for the symptoms of menopause
    - Greenblatt, R. (1949). American Journal of OB/GYN 57,244-301
  - Developed in 1939 for women who had radical hysterectomies
    - Salmon, U., et al.:Use of estradiol subcutaneous pellets in humans. Science 1939, 90:162

## HISTORY OF PELLETS



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- “There is no magic hormone or combination of hormones that can be indiscriminately used by all men and women. Each is an individual and hormone balance must be the ultimate goal”

## “PHYSIOLOGIC” HRT

Need Bio-identical hormones

Biologically available- not in Depo form

Absorbed directly, not taken orally or transdermal

Effective- reproduces steady, consistent serum levels

Minimal side effects

Hassle- free

## BIO- AVAILABLE – HOW ARE PELLETS MADE

Pure testosterone and estradiol (less than 3% dose variance)

Compressed into pellets using thousands of pounds of pressure

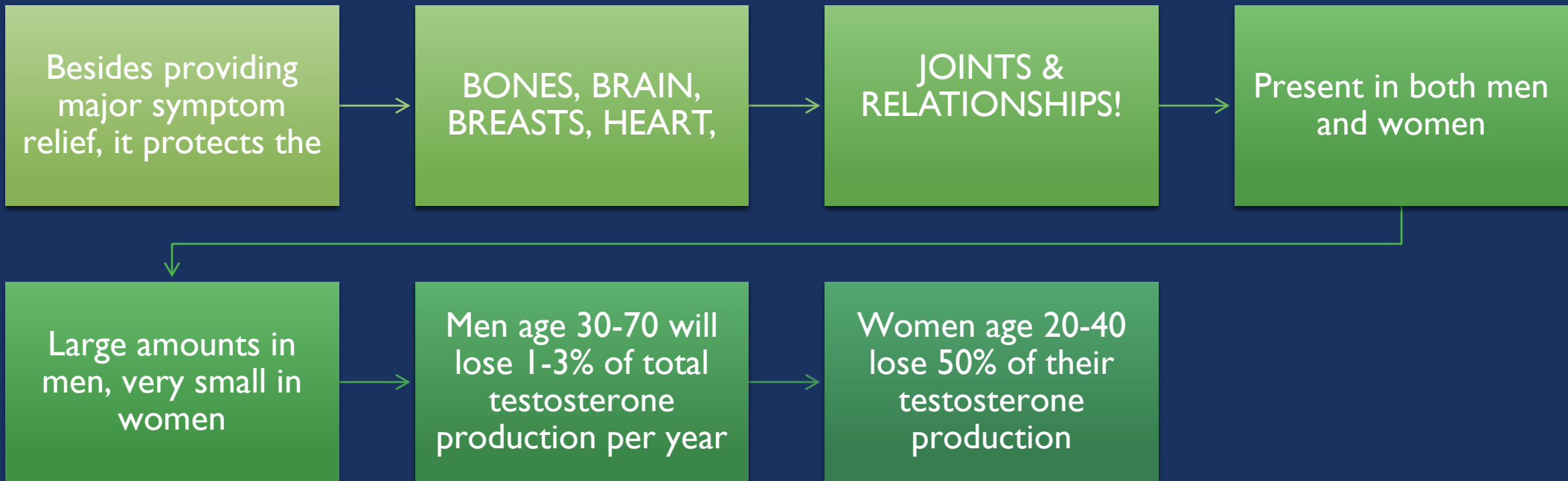
503B FDA monitored facility

E beam sterility

Absorbed based on Cardio vascular output NOT time released

## ONLY PELLETS DO THIS!

- In women and men “physiologic” androgen replacement therapy needs to have relatively constant blood levels without daily spikes.



# TESTOSTERONE

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- HRT in your post-menopausal women safe and effective tool :
  - Counteract climacteric symptoms
  - Prevent long-term degenerative diseases
    - Osteoporotic fractures
    - Cardiovascular disease
    - Diabetes mellitus
    - Cognitive impairment
- Non oral estrogens: No VTE and better BP
- Natural Progesterone – positive cognitive effects and no increase of breast cancer
- TD estrogen and Natural Progesterone significant advantages

# POTENTIAL & UNNECESSARY EFFECTS OF ORAL ESTROGEN THERAPY

- Breast Tenderness
- Increased Risk of Endometrial cancer & Breast Cancer (Oral, Synthetic, Chemical Methyl Testosterone Increased the Risk of Breast Cancer)
  - Estratest, Estratest HS, Syntest & Syntest DS
- Increase the Risk of Heart Disease
- Increase Risk of Alzheimer's Dementia
- Non-Oral, Testosterone (*Hormone*) Prevents the Stimulation of Breast Tissue and Lowers the Risk of Breast Cancer
- Weight Gain
- Vaginal Bleeding
- Headaches
- Nausea & Vomiting
- Fluid Retention
- Blood Clots
- Leg Cramps
- Non-Oral, Testosterone (*Hormone*) Prevents the Stimulation of Breast Tissue and Lowers the Risk of Breast Cancer

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## ORIGINAL INVESTIGATION

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### **Combined Estrogen and Testosterone Use and Risk of Breast Cancer in Postmenopausal Women**

*Rulla M. Tamimi, ScD; Susan E. Hankinson, ScD; Wendy Y. Chen, MD;  
Bernard Rosner, PhD; Graham A. Colditz, MD, DrPH*

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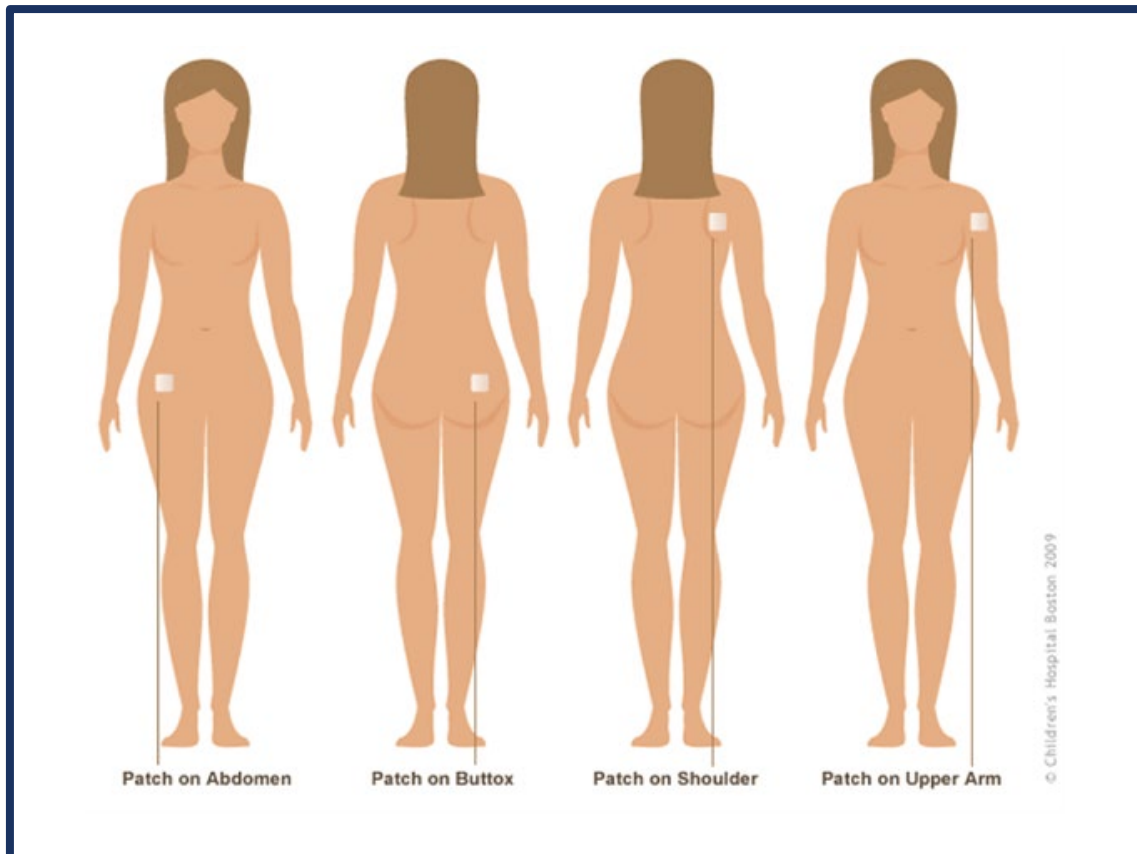
# Susan Davis, et al

*Menopause* Vol. 7, No. 6, pp.395-401

- CONCLUSION: Estrogen replacement with pellets has effects on body fat in post menopausal women that are associated with improved lipid parameters.
  - ✓ Decreased total cholesterol & LDL
  - ✓ Increased HDL
  - ✓ Decreased triglycerides
- Addition of testosterone does not negate the favorable effects of estrogen on LDL Cholesterol
  - *Marked reduction in fat mass was seen in the estrogen plus testosterone group after two years*
- Many studies concluding the beneficial effects of natural testosterone on the heart!  
(*primarily males have been studied*)



# PATCHES



- Estradiol levels better than pills, but not as good as pellets
- Adhesive problem
- Need to be changed throughout the week
  
- Some weight gain, but less fluid retention than being on synthetic or horse estrogen
- *45% of people do not absorb hormone through the skin!*
- Patches

# CREAMS / GELS



- Did You Apply Enough?
- Have to Remember to Rub it in Daily
- Short Half-Life; May Need Twice Daily Dosing
- Applied Topically Onto the Skin  
(Is It Even Absorbing?)
- Can Transfer to Others (Babies & Pets)
- Most Important Estriol (As in the Product BiEst)  
**DOES NOT** Have Bone, Heart, & Brain Protection  
– Proven in Studies!

# PELLET VS INJECTION

- Injection:
  - Uneven Absorption
  - Significant “Roller Coaster” Effect
  - 99% Synthetic Hormone
  - Significant Adverse Effects:
    - ✓ Liver Toxicity, Heart Disease
    - ✓ Elevate LDL, VLDL, Decrease HDL Cholesterols
  - ALWAYS Wears Off Before Time for Next Shot...*Makes Guys Really CRANKY!*
- Pellet:
  - Natural, Non Synthetic, Plant Derived Compounds
  - Same Molecular Structure As Human Hormones
  - Lasts Longer Than Other Treatments, 4-6 Months
  - Are the Most Widely Studied Form of Natural Hormone Therapy
  - Provides A Steady Stream of Hormone in Your Blood
  - Individualized Dosing
  - Injected Under The Skin
  - **DON'T EVEN KNOW IT'S THERE!**

# PELLET VS INJECTABLE SYNTHETIC TESTOSTERONE

- Synthetic:
  - Absorption is time released
  - Allergies to cottonseed oil
  - DHT levels increase
  - High rate of aromatization (higher E2 levels)
  - Higher rate of erythrocytosis
- Bio-Identical Pellet form:
  - Absorption based on cardiovascular output
  - No allergies to hormones
  - Steady release in blood stream
  - Lower DHT conversion
  - Lower rate of aromatization
  - Very low risk of erythrocytosis

# ANABOLIC INJECTABLE TESTOSTERONE AND MYOCARDIAL EFFECTS

- Anabolic non-aromatizable androgens adversely affect the myocardium
- Anabolic androgens have been shown to increase vasoconstriction and vasospasm in experimental models
- Elevate LDL, VLDL, decrease HDL
- Aromatizable testosterone demonstrated antianginal effects
- High serum testosterone levels are associated with reduced risk of cardiovascular events in men
  - Hamm, L. Clin Endo 1942: 2: 325-328
  - Lesser, M.A., Clin Endo. 1946:6:549-557
  - Wu SZ, Weng XZ, Chin Med Sci 1193; 106: 415-418
  - J Am Coll Cardiol, 2011 Oct 11: 58 (16): 1674-81

# SYNTHETIC TESTOSTERONE INCREASE PLATELET THROMBOXANE A2 RECEPTORS AND PLATELET AGGREGATION

1

Testosterone  
Cypionate vs Saline

2

TXA2 is metabolite  
of platelets

3

Two significant  
activities

4

Inhibition of TXA2  
by aspirin  
decreases  
thrombotic  
cardiovascular  
events

# SYNTHETIC TESTOSTERONE INCREASES PLATELET THROMBOXANE A2 RECEPTORS AND PLATELET AGGREGATION (CONT.)

Platelets implicated in occlusive intracoronary thrombi

Patients with unstable angina and acute MI have increased TXA<sub>2</sub>

What about the receptors for TXA<sub>2</sub>?

4,468 sites per platelet in patients with acute events

2,206 sites in platelet control

What happens after the event?

The receptors go back to normal

# CYPIONATE INJECTIONS - HIGH AROMATIZATION, HIGH E2 LEVELS

## “ESTRADIOL AND CV DISEASE IN MEN, IT'S NOT JUST LOW T”

- Correct dosing, conversion and percentages are crucial in testosterone replacement!
- 501 men with chronic heart failure
- Men in the lowest estradiol quintile were 217% more likely to die during 3-year follow up
- Men in the highest estradiol quintile were 133% more likely to die
- Men in the balanced quintile – had the fewest deaths
- Excess estrogen contributes to development of atherosclerosis
- Men with low T and low E 96% increase overall mortality
  - JAMA 2009 may 13:301 (18): 1892-901
  - J Clin Endocrinol Metab. 2009 Jul; 94 (7): 2482-8



FDA approved dose (6-7 pellets, approximately 450 mg ) raises mean testosterone levels by 100-200 ng/dl

Many practitioners are using more than recommended dose (off label use)

Therapeutic levels are achieved at 300 ng/dl per guidelines

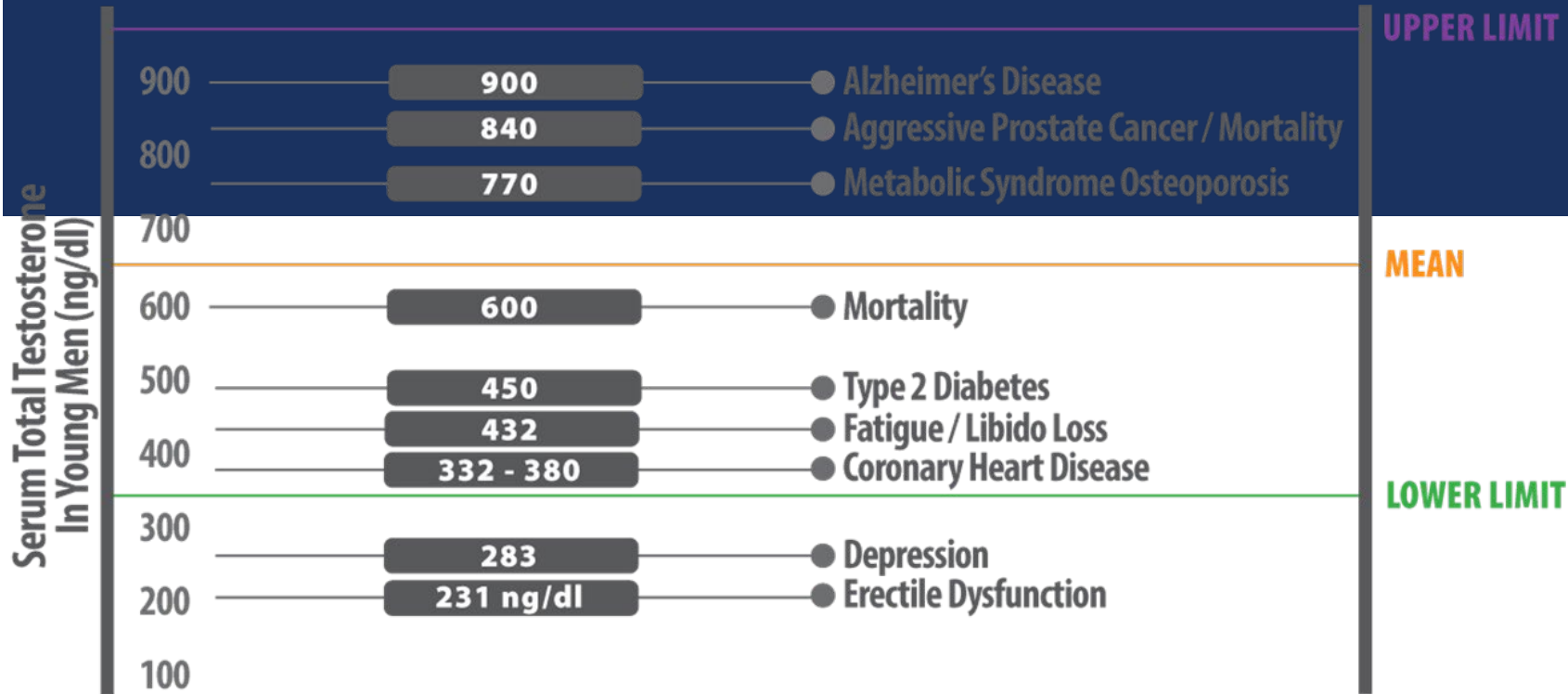
- Still at risk for heart disease
- Alzheimer's
- Prostate cancer
- Patients do not achieve symptom relief or long disease protection at this range

Synthetic hormone

TESTAPEL PELLETS

## HEART RHYTHM 2014

- 95 percent of all sudden cardiac arrests are fatal
- Cedar-Sinai Heart Institute Los Angeles analyzed blood hormone levels in 149 patients with sudden cardiac death
- The study showed that men with sudden cardiac arrest had lower testosterone levels – 440 ng/dl



## TESTOSTERONE THRESHOLDS

BELOW = > DISEASE, MORTALITY

DYSLIPIDEMIA • ATHEROSCLEROSIS, ARTERIAL STIFFNESS • ARTERIAL HYPERTENSION

ABDOMINAL OBESITY • SARCOPENIA • EXERCISE CAPACITY

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- Safe: Hundreds of Studies, 80yrs Experience, Long-Term Safety Record, Used in 5 Continents
  - Clinically Effective: Steady State of Hormones - *"NO Roller Coaster Effect"*
  - Convenience/Compliance: Implanted a Couple of Times A Year
  - Low Side-Effect Profile
  - The *BEST* Method to Increase Bone Density
  - No Evidence Increased Breast Cancer Risk, Does Not Stimulate Breast Tissue
  - No Increase in Blood Clots, Heart Attack or Stroke
  - Protective to the *Breast, Bones, Brains, Heart, & Relationships*

## BENEFITS OF PELLET THERAPY

# CONCLUSION

- In order to provide health optimization, we must use highly regulated methods and individualized dosing for patients. Our combined goal is healthy, happier aging and longevity. Disease prevention and whole body healing.
- The standards used must be consistent and practitioners must be educated and trained in order to protect the patient as well as them as practitioners.
- The procedure does not include stitching or invasive technique. Is less invasive than PRP therapy.
- Mentor physicians guide each practitioner and are an ongoing resource in clinical knowledge and education.
- No other modality provides consistent levels in the blood stream.