Introduction to Horomone Replacement

Hormone Myths vs. Scientific Evidence

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Objectives

1. Review the AMA Position Paper on Bioidentical Hormone Replacement
2. Present the Scientific Evidence for BHRT
3. Review the latest FDA Approved Bioidentical Medications

AMA, 2009: "No Credible Evidence Exists on the Value of Bioidentical Hormones."

1. Current evidence does not support the use of testosterone in older men with low testosterone levels.
2. Evidence of the value of testosterone as an antiaging therapy does not exist.
3. Current evidence fails to support the efficacy of hGH as an anti aging therapy
4. The long term use of estrogens with or without progestins cause more risks than benefits.
5. The long term use of estrogens for the prevention of chronic conditions in postmenopausal women is not recommended
6. DHEA as an antiaging supplement shows neither meaningful benefit nor serious adverse effects
7. No evidence of long term changes in therapeutic doses of "anti aging hormones"

Executive Summary of the AMA House of Delegates 2009 Annual Meeting: Council on Science and Public Health Report. The use of hormones for "anti aging": A review of efficacy and safety. *Report 5 of council on science and public health (A-09).* 2009:1-17.

AMA, 2016: "No Credible Evidence Exists on the Value of Bioidentical Hormones."

1. Current AMA policy supports the clinical decision-making authority of a physician to use an FDA-approved product off-label when such use is based upon sound scientific evidence or sound medical opinion
2. However, to date the use of compounded hormone therapies is not supported by such evidence.
3. Additionally, traditional compounding is recognized as a legal and important therapeutic approach when an FDA-approved drug product is not available or does not meet the clinical needs of individual patients.
4. However, in the case of many of the uses for compounded hormones, comparable FDA-approved therapies are available.
5. Further concern is prompted by the fact that compounding pharmacies are exempt from including specific and important safety information on labeled instructions. That lack of information may put some patients at risk.

AMA, 2016: "No Credible Evidence Exists on the Value of Bioidentical Hormones."

Patients receiving off-label therapies not backed by scientific evidence are more likely to experience adverse drug events. (15)

(15) Eguale T, Buckeridge DL, Verma A, et al. Association of off-label drug use and adverse drug events in an adult population. JAMA Inter(n Med. 2016;176(1):55-63.

Read the Study!

Design Setting: A cohort of 46,021 patients who received 151,305 incident prescribed drugs assembled from primary care clinics in Quebec, Canada.

Results: Off-label use lacking strong scientific evidence had a higher ADE rate (21.7 per 10,000 person-months) compared with on-label use (AHR, 1.54; 95% CI, 1.37-1.72).

However, off-label use with strong scientific evidence had the same risk for ADEs as on-label use The risks for ADEs were higher for drugs approved from 1981 to 1995, patients receiving 5 to 7 drugs and patients receiving cardiovascular drugs.

NO MENTION OF HORMONES IN STUDY AT ALL!

Bioidentical 'Natural' Hormone Evaluation in Early Menopause

Drisko, J., University of Kansas, 2006-2018
https://clinicaltrials.gov/ct2/show/results/NCT00302731?term=bioidentical+hormones&rank=2&sect=X430126

Study Arm 1

Prempro, premarin .45mg, provera 1.5mg

Study Arm 2

Estradiol .5mg, estriol 210mg, progesterone 100mg

Study Arm 3

estriol 2.5mg, progesterone 100mg

Study Arm 4

Estradiol 0.5 mg, progesterone 100 mg

Bioidentical 'Natural' Hormone Evaluation in Early Menopause

Drisko, J., University of Kansas, 2006-2018
https://clinicaltrials.gov/ct2/show/results/NCT00302731?term=bioidentical+hormones&rank=2&sect=X430126

	Chol	EM Prolif	Mammogram	Bone Denisty	Adverse React
Study Arm 1 Prempro, .45mg/ provera 1.5mg	221.5	13	0	0	0
Study Arm 2 Bi-est 2.6 mg Prog. 100mg	221.5	10	0	0	0
Study Arm 3 estriol 2.5mg, progesterone 100mg	223.0	2.5	0	0	0
Study Arm 4 Estradiol 0.5 mg, progesterone 100	165.5	3.1	0	0	0

October 29, 2018 FDA Approved Bioidentical Capsule

- **Company X Announces FDA Approval of TX-001HR:**

  (Estradiol and Progesterone) Capsules for the Treatment of Moderate to Severe Vasomotor Symptoms Due to Menopause

- **Brand Name is the First and Only FDA-Approved Hormone Therapy of Bio-Identical Estradiol in Combination with Bio-Identical Progesterone**

- **Fixed Doses: Estradiol 0.5 mg/Progesterone 100 mg**
  - **Estradiol 1.0 mg/Progesterone 100 mg**

Mayo Clinic

No evidence currently suggests that BHRT formulations offer clinically relevant benefits.

Julia A. Files, MD, Marcia G. Ko, MD, and Sandhya Pruthi, MD, Bioidentical Hormone Therapy, *Mayo Clin Proc. 2011* Jul; 86(7): 673–680.

PMCID: PMC3127562

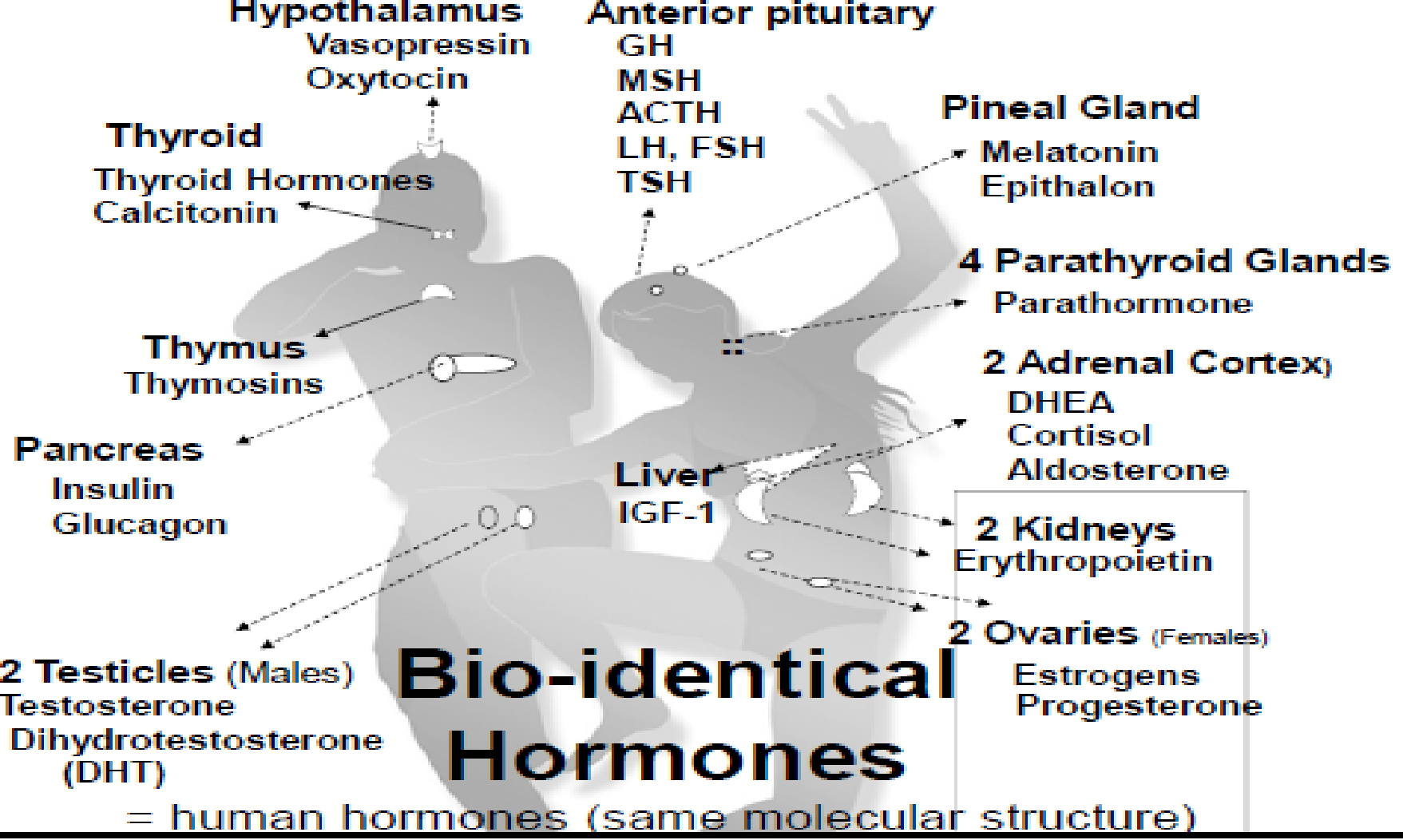
American Association of Clinical Endocrinologists

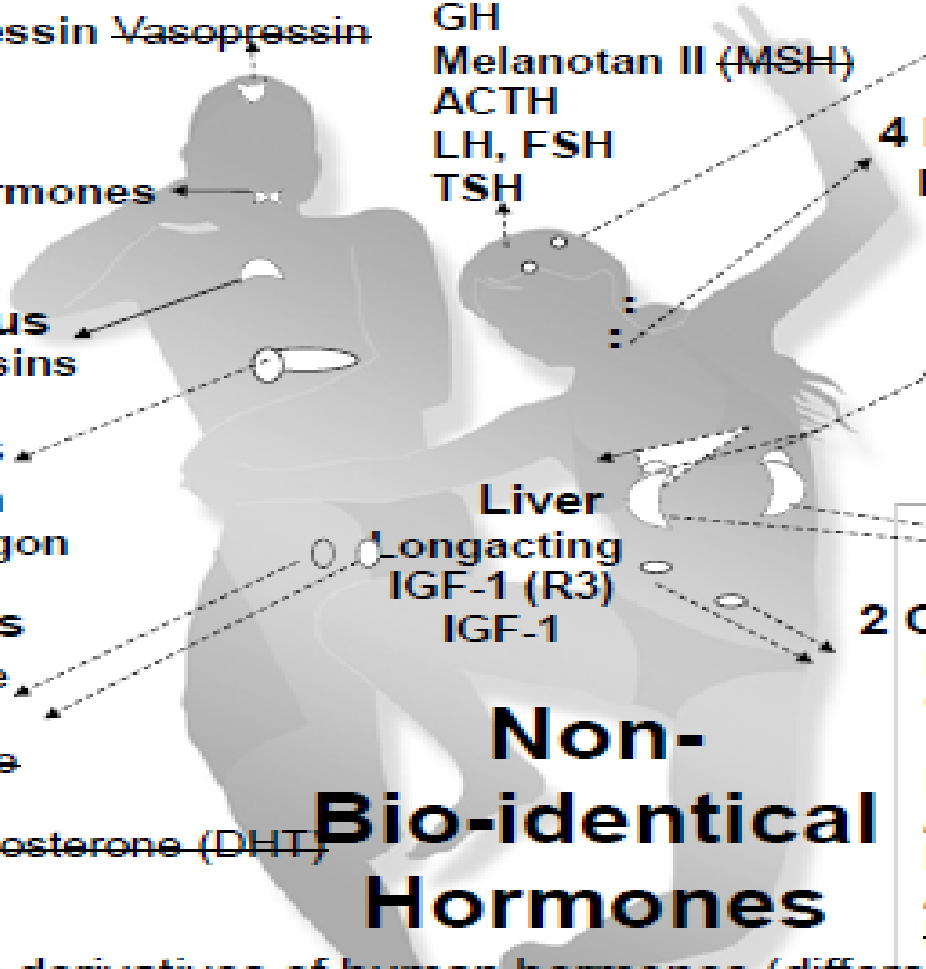
For women who cannot control severe vasomotor symptoms, lifestyle changes should be implemented first.

Pharmacologic therapy:

a. Antidepressants-Venlafaxine **(Effexor)**
b. Antidepressants intolerant
    i. **Clonidine (Catapress)**
    ii. **Megestrol (Synthetic Progesterone)**
    iii. **Gabapentin**

Neil F. Goodman, MD, FACE; Rhoda H. Cobin, MD, MACE; Samara Beth Ginzburg, MD; Ira A. Katz, MD, FACE; Dwain E. Woode, MD, American Association of Clinical Endocrinologists Medical Guidelines for Clinical Practice, *Endocrine Pract.,;2011*(17)Supplement 6; 1-25


Hypothalamus
Vasopressin
Oxytocin
Anterior pituitary
GH
MSH
ACTH
LH, FSH
TSH
Thyroid
Thyroid Hormones
Calcitonin
Pineal Gland
Melatonin
Epithalon
4 Parathyroid Glands
Parathormone
Thymus
Thymosins
2 Adrenal Cortex)
DHEA
Cortisol
Aldosterone
Pancreas
Insulin
Glucagon
Liver
IGF-1
2 Kidneys
Erythropoietin
2 Ovaries (Females)
Estrogens
Progesterone
2 Testicles (Males)
Testosterone
Dihydrotestosterone
(DHT)
Bio-identical Hormones
= human hormones (same molecular structure)



Hypothalamus
Desmopressin ~~Vasopressin~~
Oxytocin

Thyroid
Thyroid hormones
Calcitonin

Thymus
Thymosins

Pancreas
Insulin
Glucagon

2 Testicles
Nandrolone
Stanozolol
~~Testosterone~~
Mesterolon
~~Dihydrotestosterone (DHT)~~

Anterior pituitary
GH
Melanotan II ~~(MSH)~~
ACTH
LH, FSH
TSH

Liver
Longacting
IGF-1 (R3)
IGF-1

Pineal Gland
Melatonin
Epithalon

4 Parathyroid glands
Parathormone

2 Adrenal cortex
DHEA
Methyl/prednisolone
Dexamethasone
~~(Cortisol)~~
Fludrocortisone
~~Aldosterone~~

2 Kidneys
Erythropoietin

2 Ovaries
Ethinylestradiol
Conjugated estrogens
~~Estrogens~~
Medroxyprogesterone
/Cyproterone
Norethisterone
/Levonorgestrel
~~Progesterone~~

Non-Bio-identical Hormones

= synthetic derivatives of human hormones (different molecular structure)

"FDA Approved"

Who Amongst Us Never Strays from the FDA's Orthodoxy?

Who Never, Ever, Ever Prescribes Anything "Off-Label"

Just For Fun: "FDA Approved Treatment With "Credible Evidence" of Therapeutic Efficacy

1. **Rofecoxib (Vioxx)**

- Maker: Merck
- Recalled: 2004 (after five years on the market)
- Financial damage: nearly $6 billion in litigation-related expenses alone
- 140,000 incidents of premature cornary artery disease

2. **Cerivastatin (Baycol)**

- Maker: Bayer
- Hyperlipidemia
- Recalled: 2001 (after four years on the market)
- Financial damage: Litigation-related damages totaled $1.2 billion
- 100,000 Deaths Due to Rhabdomyalysis

Just For Fun: "FDA Approved Treatment With "Credible Evidence" of Therapeutic Efficacy

3. **Oxycontin-Pain Relief**

   a. **Side Effects**-Highly Addictive, Easy Accommodation. Patients quickly need larger and larger doses to achieve same level of relief. Leading drug of abuse from 2004 on. 29,600 drug related fatalities due to overdose
   b. **Costs-**$38.5 Billion for abuse treatment, medical complications, productivity loss (minus mortality), and criminal justice. **Premature Death Cost** $63 B **Life Years Lost** 29
   c. **Sales- $36 B** **Fine-**$600 million

August 14, 2015: FDA Approves Oxycontin for Children as Young as 11

OxyContin sales put Purdue's Sackler family on Forbes rich list

Ravi Katari and Dean Baker, Patent Monopolies and the Costs of Mismarketing Drugs;*Cen ter for Economic and Policy Research,* April 2015; 1-18.

10 Most Common Off Label Use Drugs in USA

SSRIs	Premature ejaculation, hot flashes, tinnitus (ringing in the ears)
Prazosin	Post Traumatic Stress Disorder
Amitriptyline	Fibromyalgia, migraines, eating disorders, pain after shingles infection
Statins	Rheumatoid arthritis
Clonidine	Smoking cessation, hot flashes, attention deficit/hyperactivity disorder (ADHD), Tourette's Syndrome, RLS
Aripiprazole	Dementia, Alzheimer's Dx.
Gabapentin, anti seizure	Peripheral Neuropathy esp. DM, Migraine H.A. Hot Flashes
Topiramate-anti seizure	Bipolar disorder, depression, weight, alcohol dependence
Risperidone	Alzheimer's disease, dementia, eating disorders, PTSD
Trazodone	Insomnia, anxiety, bipolar dx.
Propranol	Stage Fright

"Ed Begley, Jr. Rule”

“ Don't get your information from me, folks, or any newscaster. Get it from people with PhD’s after their names."

The AMA vs. Testosterone

- **Current evidence does not support the use of testosterone in older men with low testosterone levels.**

- **Evidence of the value of testosterone as an antiaging therapy does not exist.**

Executive Summary of the AMA House of Delegates 2009 Annual Meeting: Council on Science and Public Health Report. The use of hormones for “anti aging”: A review of efficacy and safety. *Report 5 of council on science and public health (A-09).* 2009:1-17.

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The Opinion Pages | OP-ED CONTRIBUTOR

Don't Ask Your Doctor About 'Low T'

By JOHN LA PUMA FEB. 3, 2014

SANTA BARBARA, Calif. — A FUNNY thing has happened in the United States over the last few decades. Men's average testosterone levels have

U.S. Department of Health & Human Services

FDA U.S. Food and Drug Administration
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Drugs

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Drug Safety and Availability

FDA evaluating risk of stroke, heart attack and death with FDA-approved testosterone products

En Español

View and print full Drug Safety Communication (PDF - 36KB)

Safety Announcement | References

Safety Announcement

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CBS EVENING NEWS w/ SCOTT PELLEY

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By JONATHAN LAPOOK / CBS NEWS / January 29, 2014, 7:16 PM

Testosterone supplements linked to heart attacks in new study

TESTOSTERONE SUPPLEMENTS

AUTOPLAY ON SHARE CC

FROM CBS NEWS

Senate takes... extending... benefits

Subway to... found in yo...

Jay Leno... Tonight...

Leonard... lung dis...

Snipe... transf... attack...

60 MINUTES

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FDA Evaluating Safety Of Testosterone Products

1 comments, 1 called-out + Comment Now + Follow Comments

The FDA said today that it was evaluating the cardiovascular safety of testosterone products. The investigation is prompted by two recent published studies that found a significant increase in cardiovascular events in men who received testosterone therapy.

The FDA said it had not concluded that testosterone is unsafe but recommended that "health care professionals should consider whether the benefits of FDA-approved testosterone treatment is likely to exceed the potential risks of treatment." Testosterone is approved for use only in men who lack or have low testosterone levels in conjunction with an associated medical condition.

Larry Husten
Contributor
+ Follow

I cover cardiology news for CardioExchange, a social media website for cardiologists published by the New England Journal of Medicine. I was the editor of TheHeart.Org from its inception in 1999 until December 2008. Following the purchase of TheHeart.Org by WebMD in 2005, I became the editorial director of WebMD

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Link To Prostate Cancer Brings More Bad News For Fish Oil Story

MORE FROM LARRY HUSTEN

Current Evidence does not Support the Use of Testosterone in Older Men with Low Testosterone levels.

- **Risk of non-fatal MI greater in the 3 months after testosterone Rx.**
- **ICD-9 study, patients not seen or interviewed**
- **No information on preparation, dose or interval of usage or if even used**
- **No info on fatal MI or cardiovascular mortality or all cause mortality**
- **No information on testosterone serum levels before or after therapy**

Vigen R et al. Association of testosterone therapy with mortality, myocardial infarction, and stroke in men with low testosterone levels. JAMA. 2013 Nov 6;310(17):1829-36

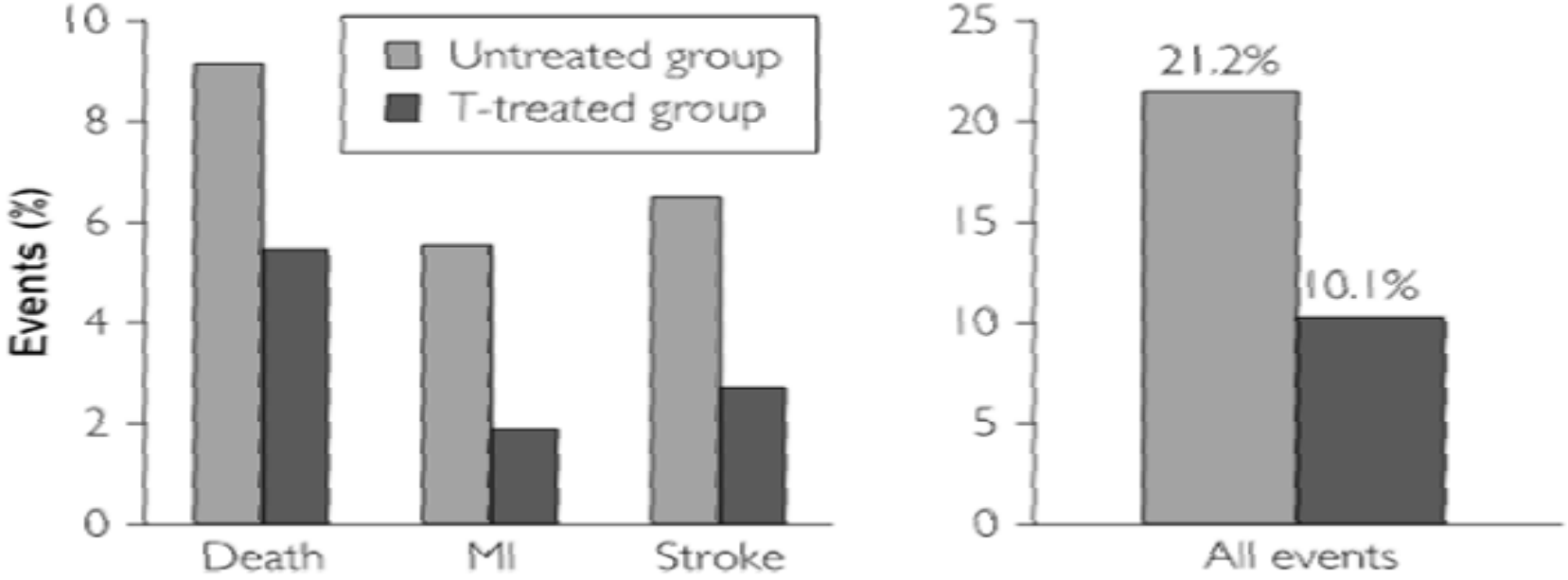
Facts: Testosterone and Heart Disease

- **Low testosterone levels are associated with increased mortality, atherosclerosis, and incident coronary artery disease;**

- **Mortality is reduced by one half in testosterone-deficient men treated with testosterone therapy compared with untreated men;**

Morgantaler, A et al. Testosterone Therapy and Cardiovascular Risk:Advances and Controversies. Mayo Clin Proc. February 2015;90(2):224-251 18

Morgantaler vs Vigen



Morgantaler, A et al. Testosterone Therapy and Cardiovascular Risk:Advances and Controversies. *Mayo Clin Proc*. February 2015;90(2):224-251

Conclusional: Delusional?

A Predetermined Outcome?

With T 10% w Event vs. Without T 21% Events = T Caused Events?

With T 5% Deaths vs. Without T 9% Deaths= T Caused Deaths?

Testosterone and Heart Disease-Study Retracted

1. Authors improperly excluded 1132 men from analysis. Corrected to 128 subsequently.
    a. (Error rate 89%)
2. **100 women were identified among the study group.**
3. Original group of 1132 individuals, meaning that one out of eleven “men” in the study were actually women.
4. More than 160 leading testosterone researchers and 29 medical societies from around the world joined ASG called for retraction of the study following revelation of the data errors, asserting that the magnitude and quality of the errors rendered the study "no longer credible."

Myth: Testosterone Causes Prostate Cancer

Based on one report from 1941

- **No relationship of T, DHT, E2 to prostate Ca**
- **No reports of PC in men treated with T after radical prostatectomy**
- **Benefits from head to toe when hypogonadism treated**

- **Morgentaler A. Testosterone and Prostate Cancer: An Historical Perspective on a Modern AMA. Eur Urol. 2006 Jul 26**

Myth: Testosterone Causes Prostate Cancer

- **3886 men with prostate cancer, 6438 controls**

No associations were found between the risk of prostate cancer, Testosterone, calculated free testosterone, dehydroepiandrosterone sulfate, androstenedione, androstanediol, estradiol, calculated free estradiol

Endogenous Sex Hormones and Prostate Cancer: A Collaborative Analysis of 18 Prospective Studies Endogenous Hormones and Prostate Cancer Collaborative Group . **J Natl Cancer Inst 2008 100: 170-183 51**

- Conclusion- **Testosterone therapy in hypogonadal men does not increase the risk of prostate cancer.**

Myth: Testosterone Causes Prostate Cancer

- “**No compelling evidence at present suggests that men with higher testosterone levels are at greater risk of prostate cancer or that treating men who have hypogonadism with exogenous androgens increases this risk.**

- **In fact it should be recognized that prostate cancer becomes more prevalent exactly at the time in a man's life when testosterone levels decline.**”

Rhoden E et al. “Medical Progress: Risks of Testosterone Replacement Therapy and Recommendations for Monitoring.” **N Engl J Med** 2004; Jan 29; 350:482-492

• Bassil et al, “The benefits and risks of testosterone replacement therapy: a review,” **Therapeutics and Clinical Risk Management** 2009: 5 427-448

•Morgentaler A Testosterone therapy and prostate risks: where’s the beef**? Can J Urol.** 2006 Feb;13 Suppl 1:40-43

Testosterone and Depression

T has Antidepressant effect in Depressed Patients, esp. those w Hypogonadism.

Zarrouf, FA, Artz S., F=Griffith J, et al. Testosterone and Depression:Systematic review and meta-analysis. J. *Psychiatric Pract.* 2009 Jul;15(4):289-305.

Testosterone and Growth Hormone Improve Body Composition and Muscle Performance in Older Men

Supplemental T produced significant gains in lean mass, strength and aerobic endurance with significant reductions in whole body and trunk fat. GH further enhances outcome

Sattler FR, Castaneda-Sceppa C, Binder EF, et al. Testosterone Growth Hormone Improve Body Composition and Muscle Performance in Older Men. *J. Clin Endocrinol Metabol.* 2009 Jun;94(6):1991-2001.

Testosterone and Depression

Testosterone Levels Inversely Proportional to Degree of Depression

- **Free testosterone in lowest quartile=highest incidence of depression**

Male

–At Risk: *295* ng/dL Free T *6.0* ng/ml (Median 12-14 ng/ml)
–Depression: *147.5* ng/dL Free T *3.0* pg/ml

Female

–At Risk: *22* ng/dL (median 44 ng/dL) ; Free T 1.0 ng/dL (median 2-4 ng/dL)
–Depression: *11* ng/dL ; Free *0.5* ng/dL

T Modulates Anorexia Nervosa

Craft, S; et. al. Androgen Effects on Cognitive Function, William Brenner Geriatric Research, Education and Clinical Center, VA Puget Sound Health Care System, Seattle, Washington, 2007

Testosterone and Alzheimer's Disease

Dementia, Tremor and Gait Dysfunction Attributed to Low T

Plasma testosterone levels in Alzheimer's and Parkinson Diseases Neurology. 2004; (62(3):411-3 Okun, MS;, Delong, MR, Hanfelt, J. et al. Gainesville, Fl.

↑ Free & Total Testo => ↓ Alzheimer's D.

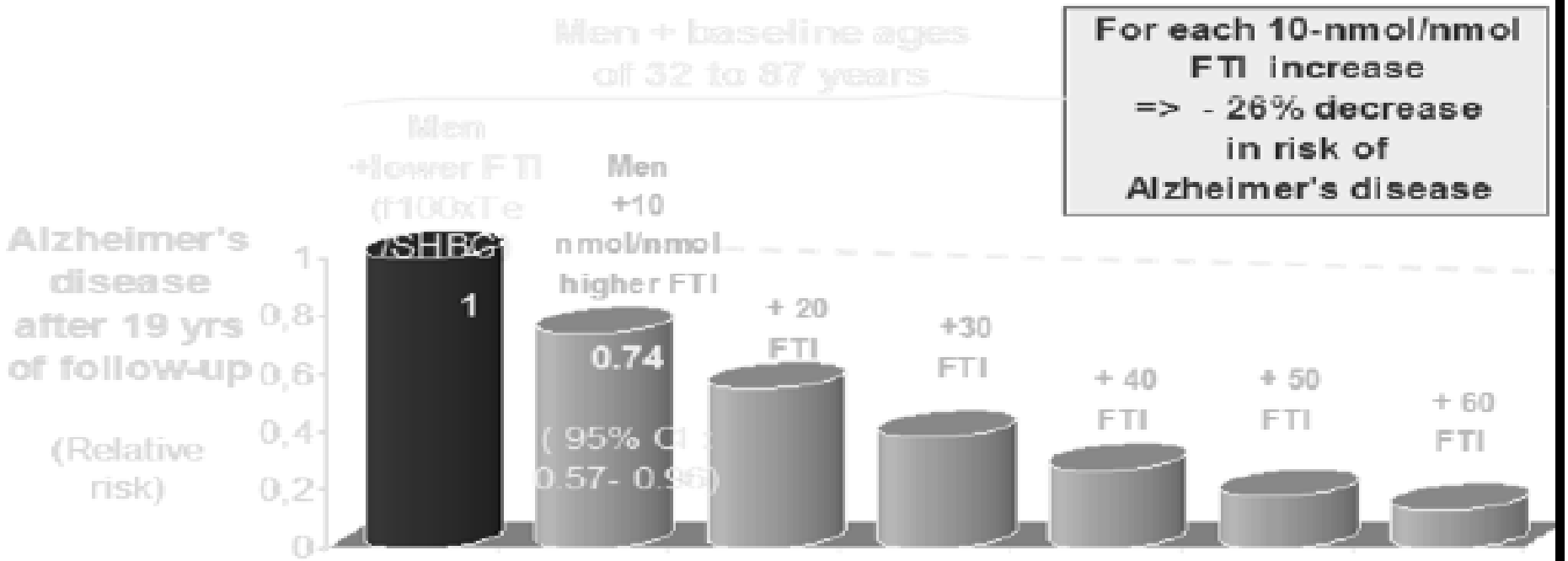
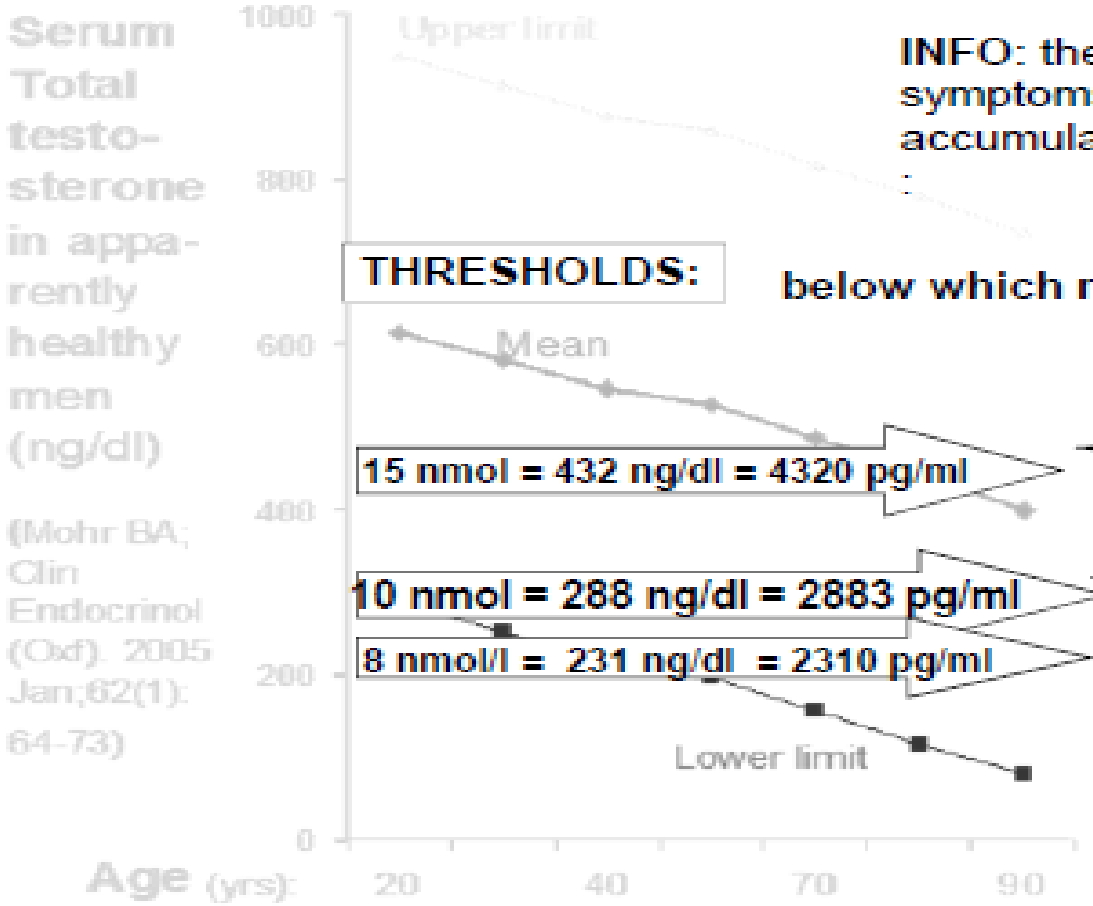


Figure: Increases in the FTI were assoc. w/ a decreased risk of Alzheimmer's disease Calculated free testosterone conc. were lower in men who developed Alzheimer disease, & this difference occurred before diagnosis

n = 574 men followed for a mean of 19.1 years (range, 4 - 37 years)

Moffat SD, Zonderman AB, Metter EJ, Kawas C, Blackman MR, Harman SM, Resnick SM. Free testosterone and risk for Alzheimer disease in older men. : Neurology. 2004 Jan 27;62(2):188-93

↓ Serum Testost. within ref. range => ↓ vigor, libido, depression, type 2 diabetes, erectile dysfunction



INFO: the prevalence of psychosomatic symptoms & metabolic risk factors accumulated with ↓ androgen levels

THRESHOLDS: below which risk factors sign. increased

15 nmol = 432 ng/dl = 4320 pg/ml → Loss of vigor, Loss of libido

10 nmol = 288 ng/dl = 2883 pg/ml → Depression & Diabetes mellitus type 2 (also in nonobese men)

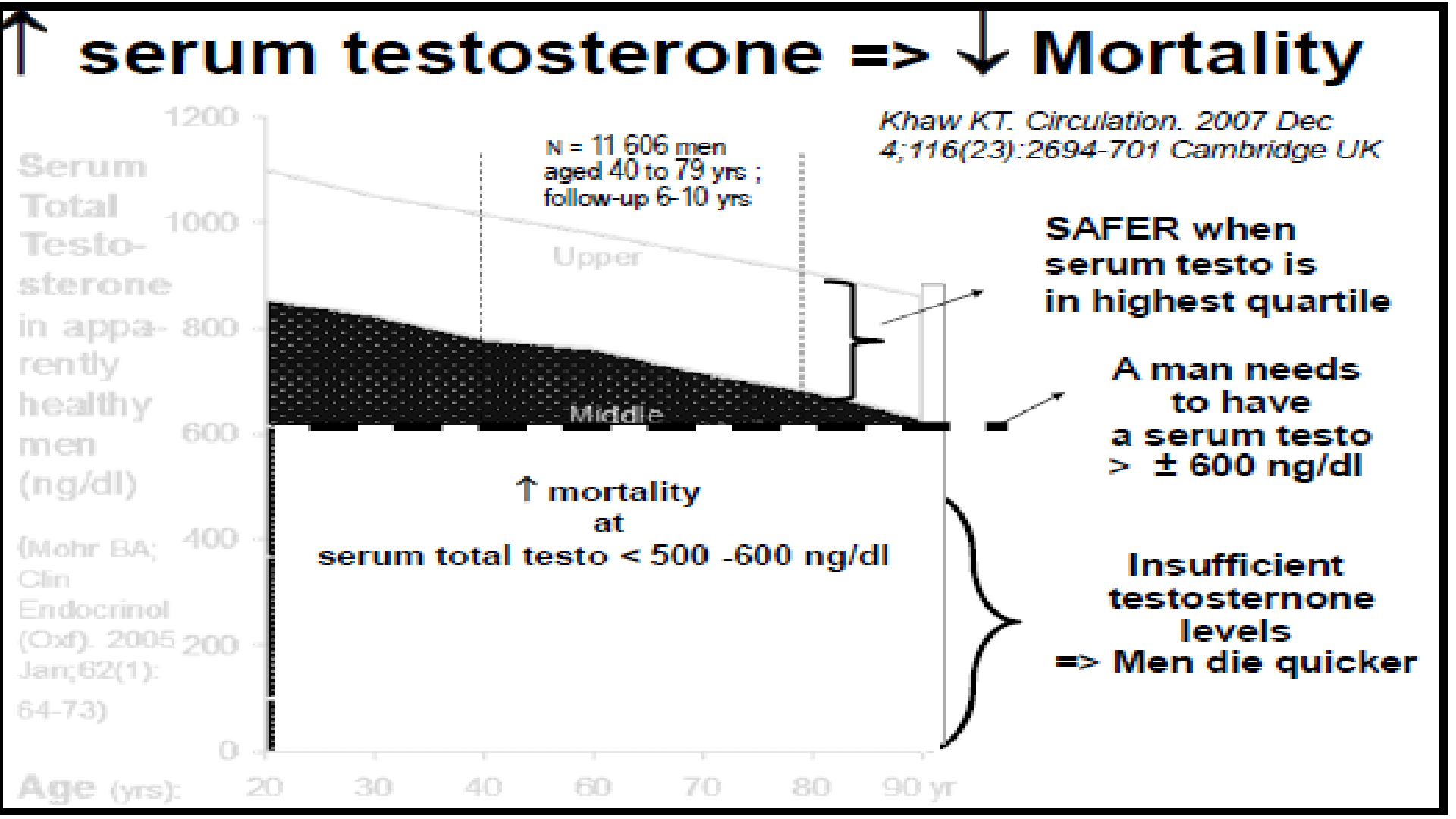
8 nmol/l = 231 ng/dl = 2310 pg/ml → Erectile dysfunction

Many levels within the ref. range

N = 434 consecutive male patients aged 50-86 yr

Zitzmann M, et al. J Clin Endocrinol Metab. 2006 Nov;91(11):4335-43

↑ serum testosterone => ↓ Mortality



TBI → Low T → Depression → Suicide

- 10th leading cause of death in US

  (37,000 successful, 1 million attempts in 2009)

- Direct Relationship between Depression and Suicide

- Men Have 4X Suicide Risk of Women

- Suicide Attempts are Inversely Related to Testo Levels

- Peak Years Men 80-90, Women 50-65
  - (UCSF-Attributed to Loss of Estrogen)

Testosterone Novelties

1. **Dry Eye Disease-**0.3% Testosterone with 0.5% Progesterone in cyclodextrin base. Dawson, T.L., Testosterone eye drops: “A novel treatment for dry eye disease,” *Opthalmology Times,* November 15, 2015

1. **Chronic Pain in Fibromyalgia-**White, H.,Robinson T.; “A novel use for testosterone to treat central sensitization of chronic pain in fibromyalgia patients,” *International Immunopharmacology*, Volume 27, Issue 2, August 2015, Pages 244–248

1. **Chronic Non Radicular Low Back Pain-**Dubick MN, Ravin TH, Michel Y, Morrisette DC; Use of localized human growth hormone and testosterone injections in addition to manual therapy and exercise for lower back pain: a case series with 12-month follow-up, *Dove Press*, 23 June 2015 Volume 2015:8 Pages 295—302

Testosterone and Anxiety

- **Testosterone reduces anxiety, enhances cognition.**
- **Analgesic, anxiolytic, and cognitive effects**
  - **due to action on 5 alpha reductase metabolites in hippocampus effect**

Edinger, KL; Frye, CA, *Testosterone's analgesic, anxiolytic and cognitive-enhancing effect may be due in part to actions of its' 5 alpha-reduced metabolites in the hippocampus;* Behav Neuroscie; 2004 Dec;118(6):1352-64. Albany, NY

The presence of a LOW Prolactin level can be a tip-off in a patient with treatment resistant anxiety. Having a high dopamine (Prolactin inhibiting factor) will suppress the production of Prolactin from the Anterior Pituitary.

Myth: “No Credible Evidence Exists on the Value of Bioidentical Hormones.”

- **Current evidence fails to support the efficacy of hGH as an anti aging therapy.**

Executive Summary of the AMA House of Delegates 2009 Annual Meeting: Council on Science and Public Health Report. The use of hormones for “anti aging”: A review of efficacy and safety. *Report 5 of council on science and public health (A-09).* 2009:1-17.

Yet: **Rudman D**, Feller AG, Nagraj HS, Gergans GA, Lalitha PY, Goldberg AF, Schlenker RA, Cohn L, Rudman IW, Mattson DE. Effects of human growth hormone in men over 60 years old. N Engl J Med. 1990 Jul5;323(1):1-6

- **8.8 percent increase in lean body mass**
- **14.4 percent decrease in adipose-tissue mass**
- **1.6 percent increase in average lumbar vertebral bone density (P less than 0.05 in each instance).**
- **Skin thickness increased 7.1 percent.**

Myth: GH Deficiency is Only Seen in Patients with Severe Multiple Pituitary Deficiencies since Childhood

Patients treated with GH experience significant improvements in concentration, memory, depression, anxiety and fatigue.

Pituitary failure can occur even in minor head injuries and is poorly recognized.

Rothman MS, The neuroendocrine effects of traumatic brain injury. J Neuropsychiatry Clin Neurosci. 2007 Fall;19(4):363-72.

Behan LA et al. Neuroendocrine disorders after traumatic brain injury. J Neurol Neurosurg Psychiatry. 2008 Jul;79(7):753-9

AGHD is common and often not recognized after TBI and other brain insults.

- Evaluate all TBI, CVA patients within a year for AGHD. Treat if deficiency disease exists.

GH replacement therapy improves cognition and QoL in TBI patients with GHD, especially in those with severe disabilities.

Kozlowski O et al. Growth hormone replacement therapy in patients with traumatic brain injury. Neurotrauma. 2013 Jan 16.

“Current evidence fails to support the efficacy of hGH as an anti aging therapy.”

1. GH-therapy of GH-deficient men **reverses early atherosclerotic changes**, namely the increased thickness of the intima media of the common carotid artery & the carotid bifurcation in 11 GH-deficient men (24-49 yr old) (Pfeifer M et al, J Clin Endocrinol Metab, 1999, 84 : 453-457)
2. **Decrease in Oxidative Stress** (free radical formation) **by 50%** Evans LM, Davies JS, Anderson RA, Ellis GR, Jackson SK, Lewis MJ, Frenneaux MP, Rees A, Scanlon MF. The effect of GH replacement therapy on endothelial function and oxidative stress in adult growth hormone deficiency. Eur J Endocrinol. 2000 Mar;142(3):254-62. Section of Endocrinology,Diabetes and Metabolism, University Hospital of Wales, Cardiff, UK.
3. **Increases thyroid & androgen** activities, but **decreases cortisol.** 1) Vierhapper H, Nowotny P, Waldhausl W. Treatment with growth hormone suppresses cortisol production in man. Metabolism 1998 Nov;47(11):1376-8 ; 2) Rodriguez-Arnao J, Perry L, Besser GM, Ross RJ. Growth hormone treatment in hypopituitary GH deficient adults reduces circulating cortisol levels during hydrocortisone replacement therapy. Clin Endocrinol (Oxf) 1996 Jul;45(1):33-7 ; 3) Weaver JU, Thaventhiran L, Noonan K, Burrin JM, Taylor NF, Norman MR, Monson JP. The effect of growth hormone replacement on cortisol metabolism and glucocorticoid sensitivity in hypopituitary adults. Clin Endocrinol (Oxf) 1994 Nov;41(5):639-48 ; 4) Carani C, Granata AR, De Rosa M, Garau C, Zarrilli S, Paesano L, Colao A, Marrama P, Lombardi G.The effect of chronic treatment with GH on gonadal function in men with isolated GH deficiency. Eur J Endocrinol 1999 Mar;140(3):224-30 ; 5) Belgorosky A, Martinez A, Domene H, Heinrich JJ, Bergada C, Rivarola MA .High serum sex hormone-binding globulin (SHBG) and low serum non-SHBG-bound testosterone in boys with idiopathic hypopituitarism: effect of recombinant

All Mortality with GH Use Decreased Post MI by Minimum 300%

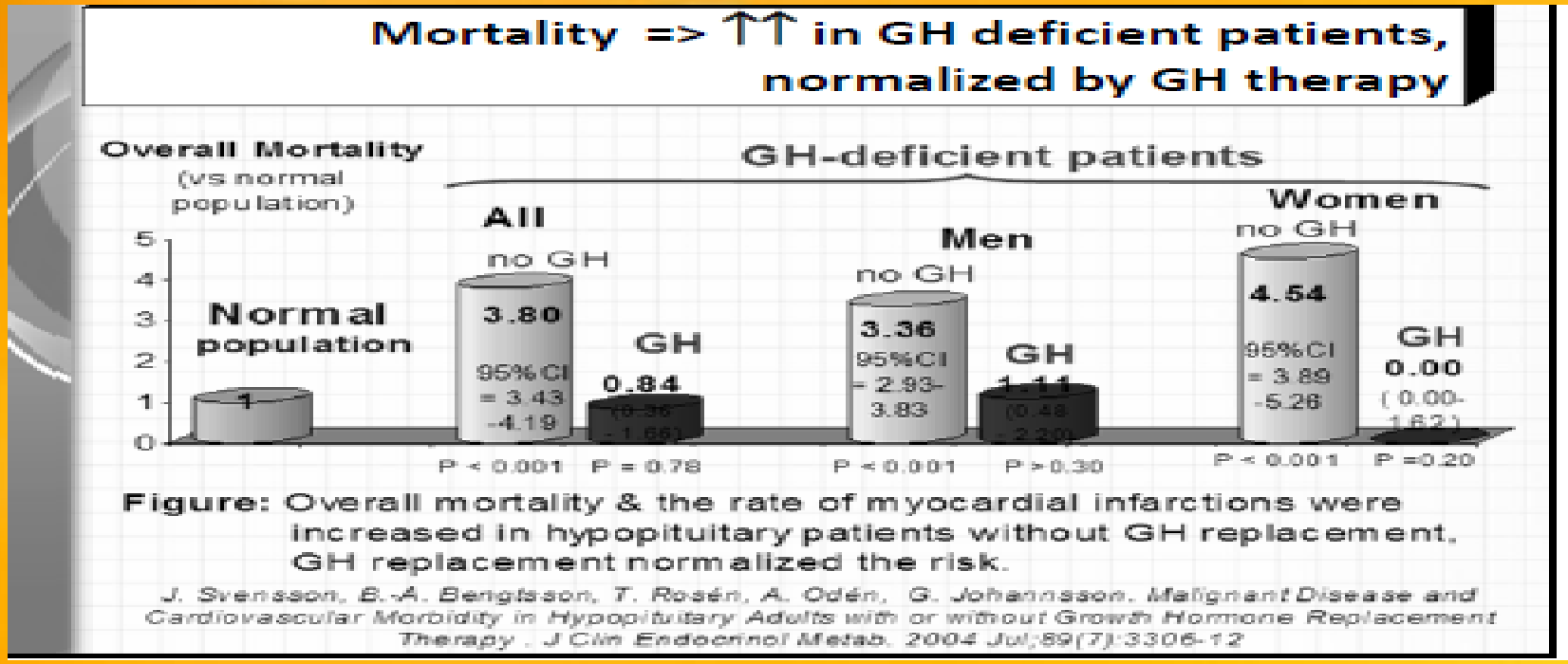


Figure: Overall mortality & the rate of myocardial infarctions were increased in hypopituitary patients without GH replacement. GH replacement normalized the risk.

J. Svensson, B.-A. Bengtsson, T. Rosén, A. Odén, G. Johannsson. Malignant Disease and Cardiovascular Morbidity in Hypopituitary Adults with or without Growth Hormone Replacement Therapy . J Clin Endocrinol Metab. 2004 Jul;89(7):3306-12

"Current evidence fails to support the efficacy of hGH as an anti aging therapy."

GH Improves Nutrition, QOL and CV Risk

Feldt-Rasmussen B, Lange M, Sulowicz W, Gafter U, Lai KN, Wiedemann J, Christiansen JS, El Nahas M; APCD Study Group. Growth hormone treatment during hemodialysis in a randomized trial improves nutrition, quality of life, and cardiovascular risk. J Am Soc Nephrol. 2007 Jul;18(7):2161-71

Rudman D, Feller AG, Nagraj HS, Gergans GA, Lalitha PY, Goldberg AF, Schlenker RA, Cohn L, Rudman IW, Mattson DE. Effects of human growth hormone in men over 60 years old. N Engl J Med. 1990 Jul5;323(1):1-6

Colao A, Di Somma C, Spiezia S, Savastano S, Rota F, Savanelli MC, Lombardi G. Growth hormone treatment on atherosclerosis: results of a 5-year open, prospective, controlled study in male patients with severe growth hormone deficiency. J Clin Endocrinol Metab. 2008 Sep;93(9):3416-24

GH, Longevity, and Efficacy of hGH as an Anti Aging Therapy

1. **Increases albumin and prolongs survival in patients with chronic liver failure**
2. **Reduces neoplastic disease, modifies age-related pathology, increases life span**
3. **HGH is not associated with any increase in mortality**.

Li N, Zhou L, Zhang B, Dong P, Lin W, Wang H, Xu R, Ding H. Recombinant human growth hormone **increases albumin and prolongs survival in patients with chronic liver failure:** a pilot open, randomized, and controlled clinical trial. Dig Liver Dis. 2008 Jul;40(7):554-9

Sonntag WE, Carter CS, Ikeno Y, Ekenstedt K, Carlson CS, Loeser RF, Chakrabarty S, Lee S, Bennett C, Ingram R, Moore T, Ramsey M. Adult-onset growth hormone and insulin-like growth factor I deficiency **reduces neoplastic disease,** modifies age-related pathology, and **increases life span.** Endocrinology. 2005;146(7):2920-32

Khansari DN, Gustad T. Effects of long-term, low-dose growth hormone therapy on immune function and life expectancy of mice. Mech Ageing Dev. 1991 Jan;57(1):87-100

Bengtsson BA, Koppeschaar HP, Abs R, Bennmarker H, Hernberg-Stahl E, Westberg B, Wilton P, Monson P, Feldt-Rasmussen U, Wuster C. **Growth hormone replacement therapy is not associated with any increase in mortality**. KIMS Study Group. J Clin Endocrinol Metab. 1999;84(11):4291-2

Myth: GH Deficiency is Only Seen in Patients with Severe Multiple Pituitary Deficiencies since Childhood

1. **Some degree of hypopituitarism is found in 35-40% of TBI patients.**

1. **Untreated TBI induced hypopituitarism contributes to the chronic neurobehavioral problems seen in many head-injured patients**

Popovic C et al. Hypopituitarism following traumatic brain injury. Growth Horm IGF Res. 2005 Jun;15(3):177-84.

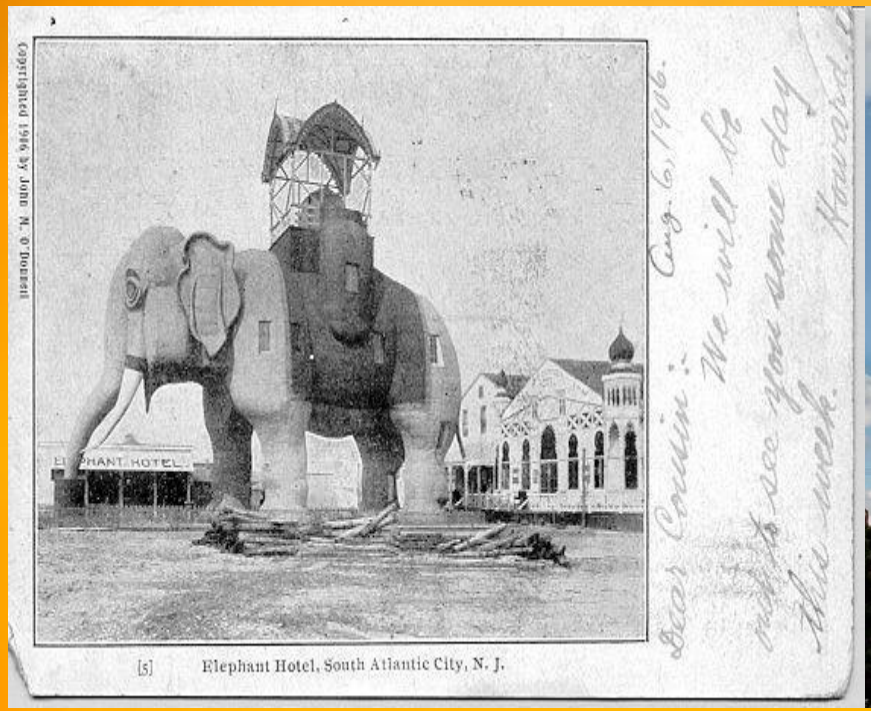
Myth: “No Credible Evidence Exists on the Value of Bioidentical Hormones.”

- **The long term use of estrogens with or without progestins cause more risks than benefits.**

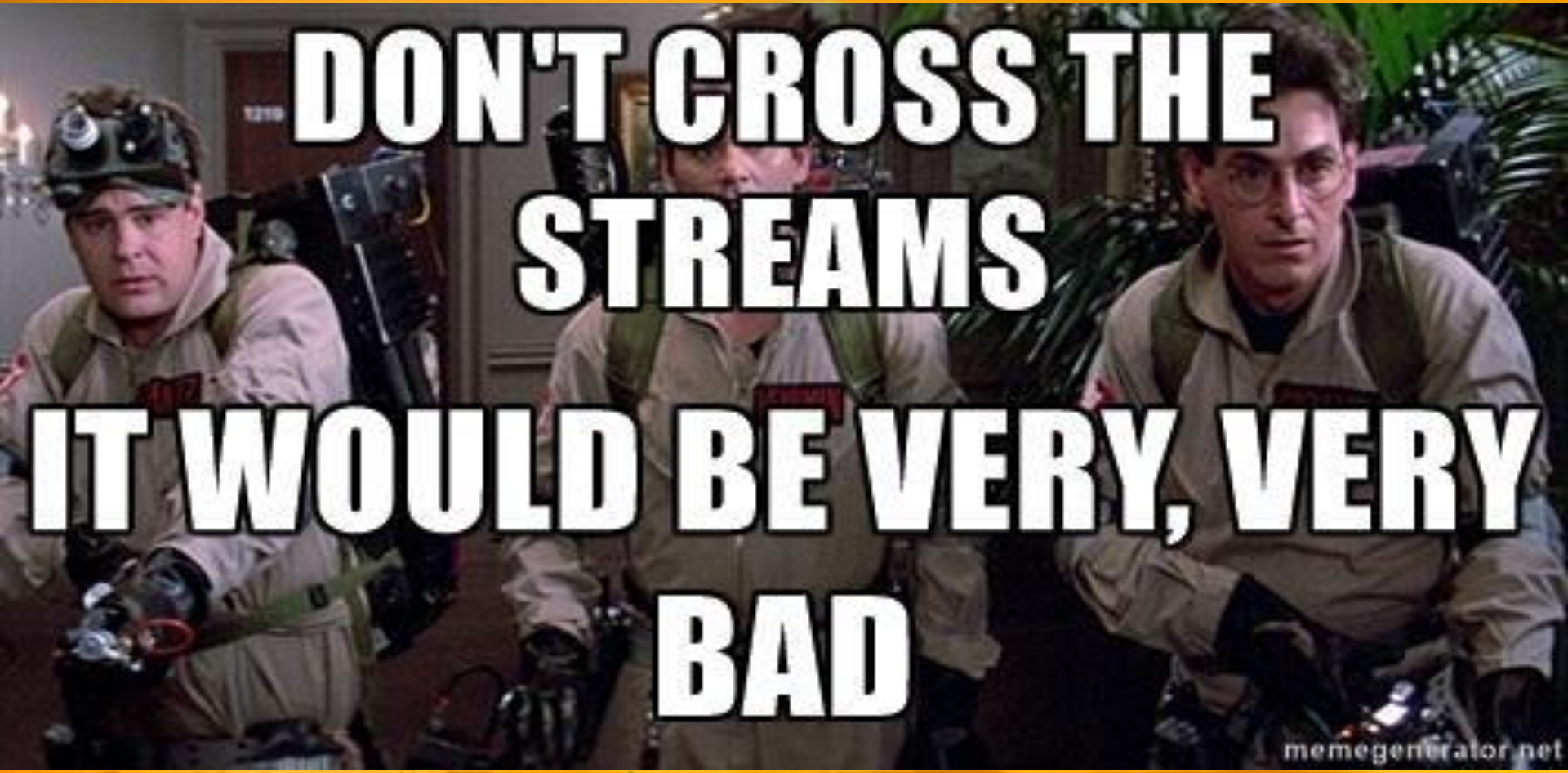
- **The long term use of estrogens for the prevention of chronic conditions in postmenopausal women is not recommended**

Executive Summary of the AMA House of Delegates 2009 Annual Meeting: Council on Science and Public Health Report. The use of hormones for “anti aging”: A review of efficacy and safety. *Report 5 of council on science and public health (A-09).* 2009:1-17.

The Elephant In The Room: Estrogen Causes Cancer



AMA: Estrogen Use in Postmenopusal Women=

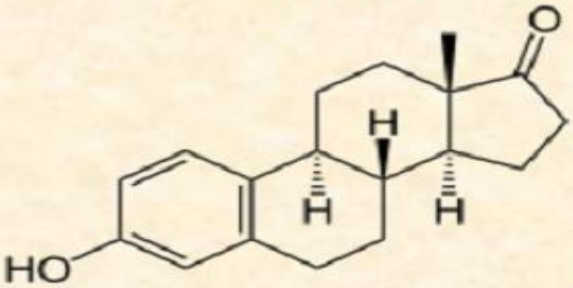


2002 WHI Study—"HRT" is Dangerous!

- Premarin® alone given to older postmenopausal women caused adverse effects in the **first year** (strokes, blood clots)
  - Oral estrogens cause blood clots, transdermal estradiol does not
- Adding Provera® (Prempro®) caused more adverse effects (breast cancers, heart attacks, dementia)
  - Provera increases breast cancer and vascular inflammation. Progesterone does neither.
- Thousands of lawsuits pending; drug companies running a legal-protection propaganda campaign to paint all "hormones" as equally dangerous!

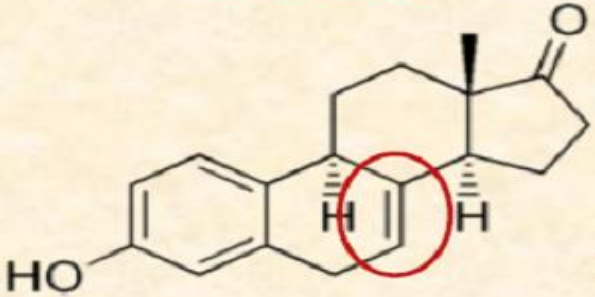
Premarin®
Conjugated Equine Estrogens

Human



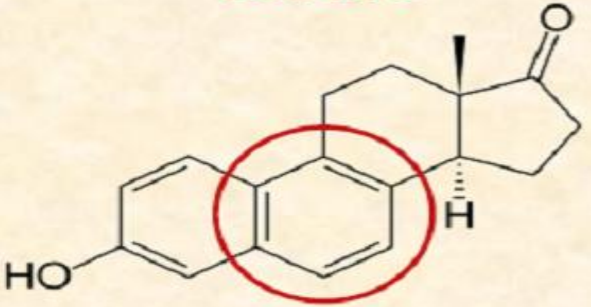
Estrone

Horse



Equilin

Horse



Equilenin

CEE contains at least 10 estrogens, only 3 are human; also contains horse androgens and progestins.

Klein R The Composition of Premarin. 1998 Int J Fertil 43:223

Women Killers and Hormones

- Cardiovascular disease (CVD), osteoporosis, dementia and breast cancer are all **rare** before menopause.
- The first 3 are clearly related to estradiol deficiency ; breast cancer is related to progesterone deficiency.
- Early removal of ovaries increases risk of heart disease, osteoporosis, and dementia.

  Parker WH, Womens Health (Lond Engl). 2009 Sep;5(5):565-76
- **Youthful hormone levels protect** women from these diseases.

Estradiol Restoration

- Protects against heart disease, dementia and osteoporosis.
- Improves insulin sensitivity—prevents diabetes
- Eliminates hot flashes, restores sleep
- Restores cognitive function and mood
- Maintains thickness, fullness of skin and hair
- Maintains genital/pelvic health-helps with vaginal lubrication, incontinence, bladder infections
- Protects against colon cancer and macular degeneration

Estradiol vs. Cardiovascular Disease

- Prevents the oxidation of LDL
- Improves lipid profile
- Reduces lipoprotein (a)
- Reduces blood pressure
- Improves endothelial function
- Reduces plaque formation
- Improves insulin sensitivity

Myth: E2 Replacement Increases Risk of Clots

Transdermal E2 does not increase risk of VTE like oral E2

FDA approved Estradiol-Progesterone pill DOES NOT ALTER COAGULATION FACTORS

- **Cardioprotective, decreased risk of AMI, Decreased risk of T2DM**

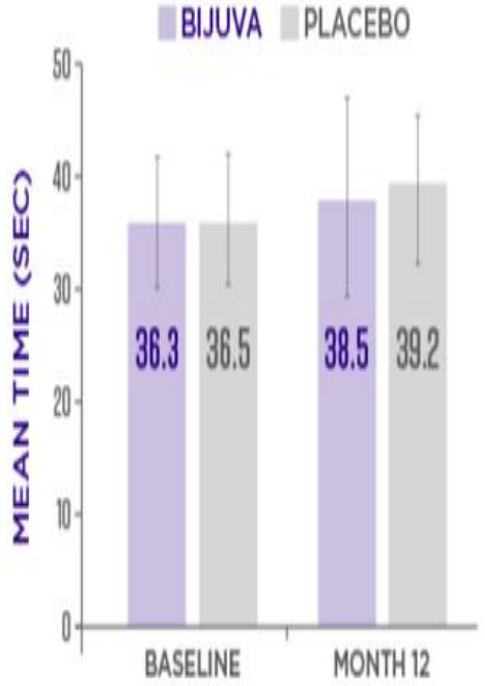
- **Internal Carotid Artery lumen widens by 224% when patient administered Estradiol > 6 months.**

(Jonas HA et al, Ann Epidemiol, 1996, 6 (4) : 314-23)

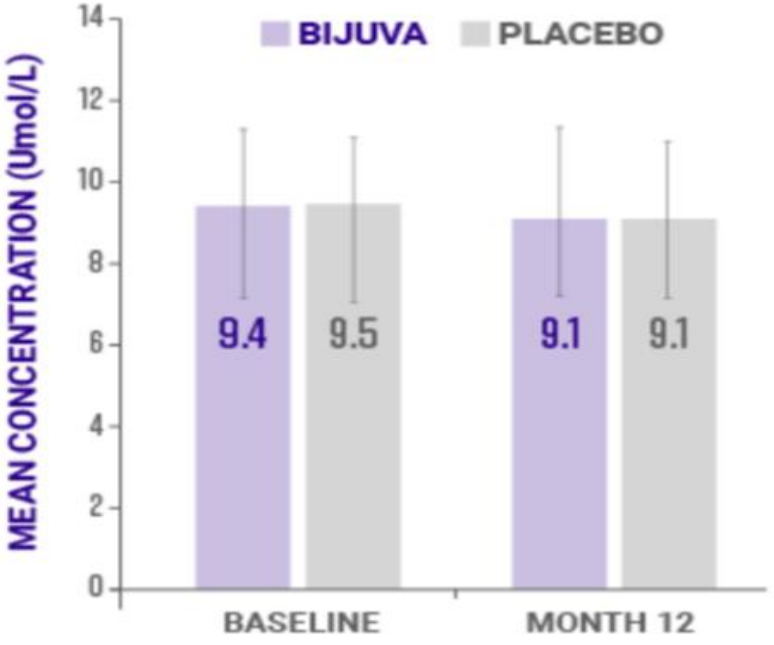
- Mueck AO. Et al. Postmenopausal hormone replacement therapy and cardiovascular disease: the value of transdermal estradiol and micronized progesterone. Climacteric. 2012 Apr;15 Suppl 1:11-7

FDA approved Estradiol-Progesterone Pill
DOES NOT ALTER COAGULATION FACTORS

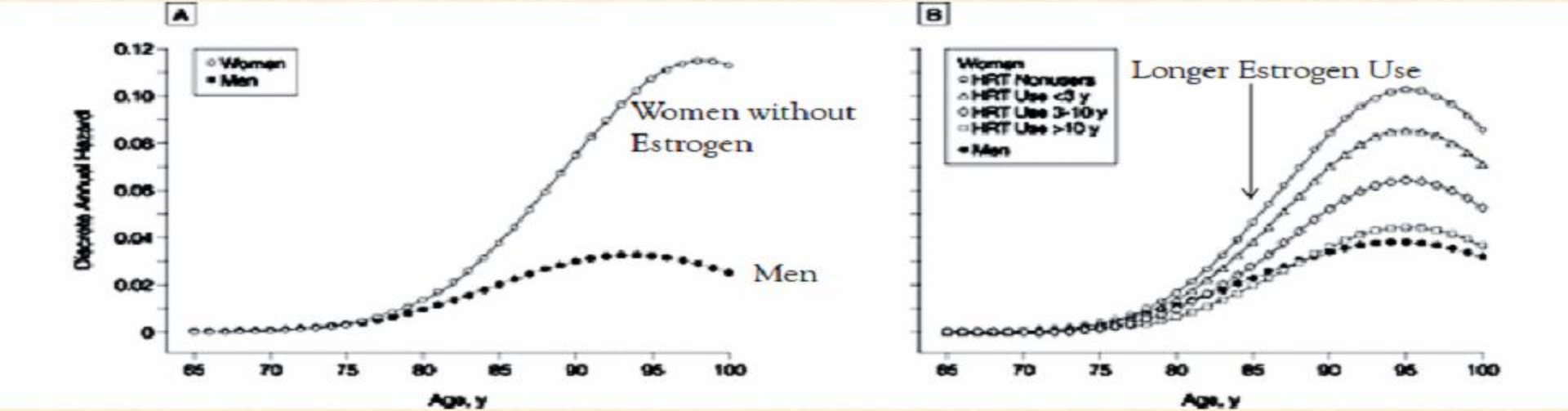
ACTIVATED PARTIAL THROMBOPLASTIN LEVELS WITH BIJUVA COMPARED WITH PLACEBO[5]



FIBRINOGEN LEVELS WITH BIJUVA COMPARED WITH PLACEBO[5]



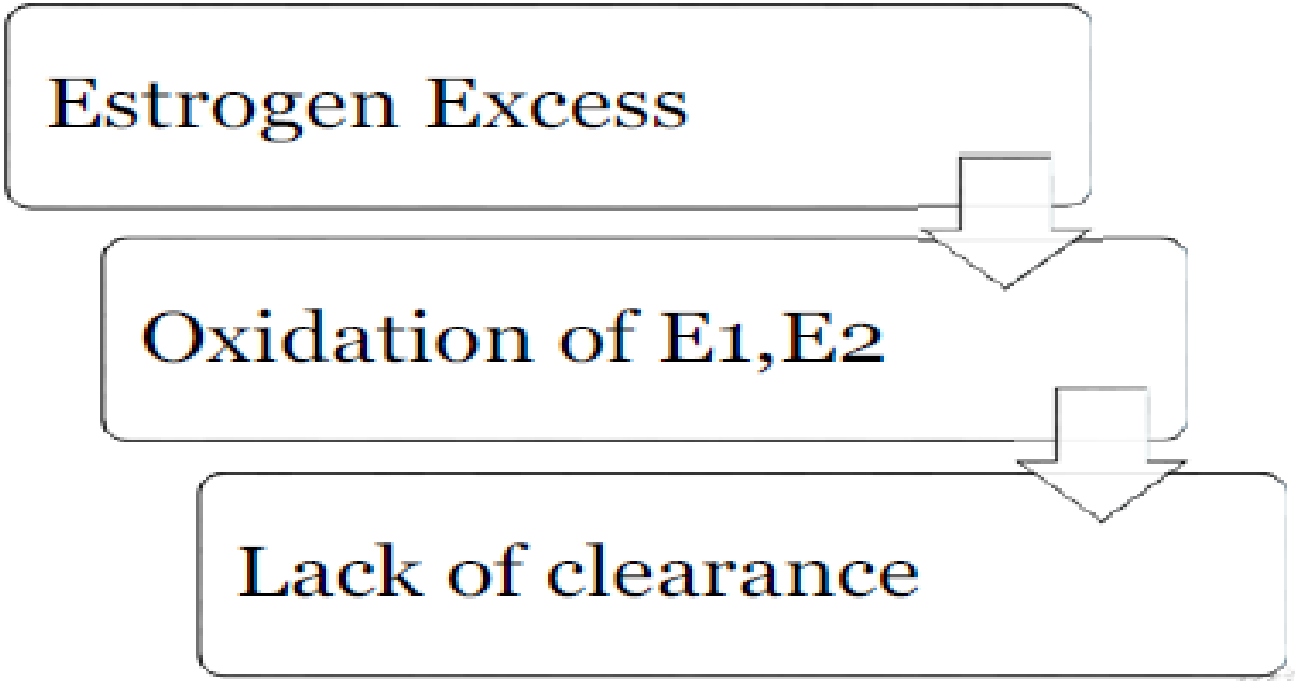
Estrogen Replacement Prevents Alzheimer's Disease



72% used Premarin® only

Zandi PP, et al., Cache County Study. JAMA. 2002 Nov 6;288(17):2123-9.
RR 0.46 in Kawas C, The Baltimore Longitudinal Study of Aging. Neurology 1997;48:1517-1521
RR 0.65 Paganini-Hill A, Arch Intern Med 1996;156:2213-2217.
RR 0.4, Tang M-X, Lancet 1996;348:429-432.

Hormonal Influence on Breast Cancer Risk



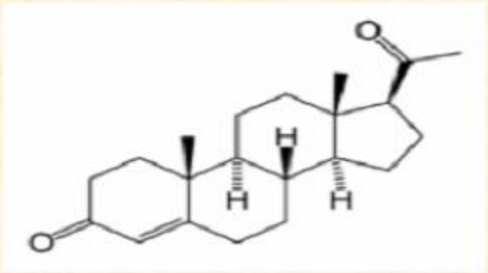
Estrogen Dominance

- Allergies
- Autoimmune diseases
- Anxiety, moodiness
- PMS
- Bloating, fluid retention
- Fibrocystic breasts
- Heavy periods
- Endometriosis
- Breast cancer
- Ovarian cancer
- Uterine cancer
- Gallstones

Progesterone is the only effective treatment for estrogen dominance

Progestins ≠ Progesterone

Progesterone ≠ Medroxyprogesterone Drospirenone



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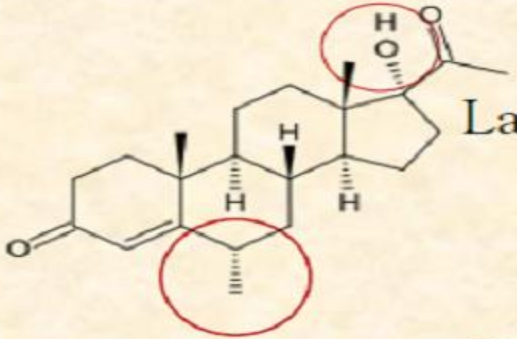
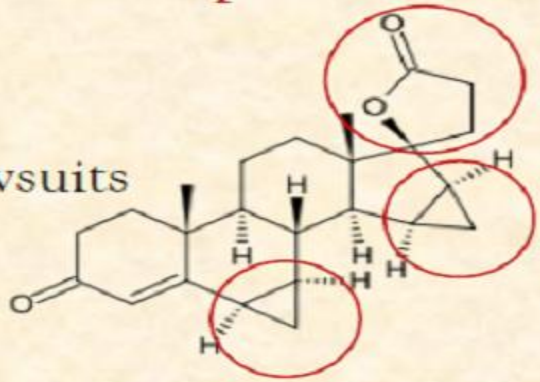


Provera® Prempro®

Lawsuits



Yasmin®

Confusion:

Progestins are often called "progesterone", in the media and in scientific papers!

Scientific studies show that:

Provera®	≠	Progesterone
• Causes birth defects		• Maintains pregnancy
• Can cause depression		• Improves mood
• Insomnia, irritability		• Improves sleep
• Fluid retention		• Diuretic
• Raises blood sugar		• No effect on blood sugar
• Counteracts estrogen-induced arterial dilation		• Maintains estrogen-induced arterial dilation
• Worsens lipid profile		• Improves lipid profile
• Causes heart attacks		• No evidence of ↑ CVD
• Increases estrogenic stimulation of breasts		• Reduces estrogenic stimulation of breasts
• **Causes breast cancer**		• **Prevents breast cancer**

Who Needs Progesterone Supplementation?

- Irregular menstrual cycles
- No periods—amenorrhea
- Heavy bleeding
- Fibrocystic breast disease
- Endometriosis/adenomyosis
- Every woman in menopause

Novel Use of Progesterone: CVA, DM, BP and TBI

1. **Progesterone inhibits ischemic brain injury**
2. **Progesterone reduces infarct volume and improves functional deficits following cerebral ischemic event.**
3. **Micronized P4 reduces risk of T2DM, does not increase risk of VTE, reduces BP**

4. **Dose: 8 mg/kg Progesterone best clinical results**

• Sayeed I et al. Progesterone inhibits ischemic brain injury in a rat model of permanent middle cerebral artery occlusion. Restor Neurol Neurosci. 2007;25(2):151-9

• Ishrat T et al. Effects of progesterone administration on infarct volume and functional deficits following permanent focal cerebral ischemia in rats. Brain Res. 2009 Feb 27;1257:94-101

Yousuf S et al. Progesterone in transient ischemic stroke: a dose response study. Psychopharmacology (Berl). 2014 Sep;231(17):3313-23

Does Estrogen Cause Breast Cancer?

Trick Question :

What is the LARGEST study ever done, exploring

hormone use and breast cancer occurrence?

What did it show?

Does Estrogen Cause Breast Cancer?

If you said “Women’s Health Initiative”

You Are Wrong!

E3N Vs. WHI

WHI – no Bioidentical hormone used

E3N – (+)Bioidentical and CEE + Progestins were used

# of women receiving “hormone” treatment

- **WHI = 13,816 E3N = 29,420**

Estrogen alone (CEE) both studies showed increase risk

Progestin’s in both studies showed GREATER risk

BHRT when used in balanced combo – no increased risk

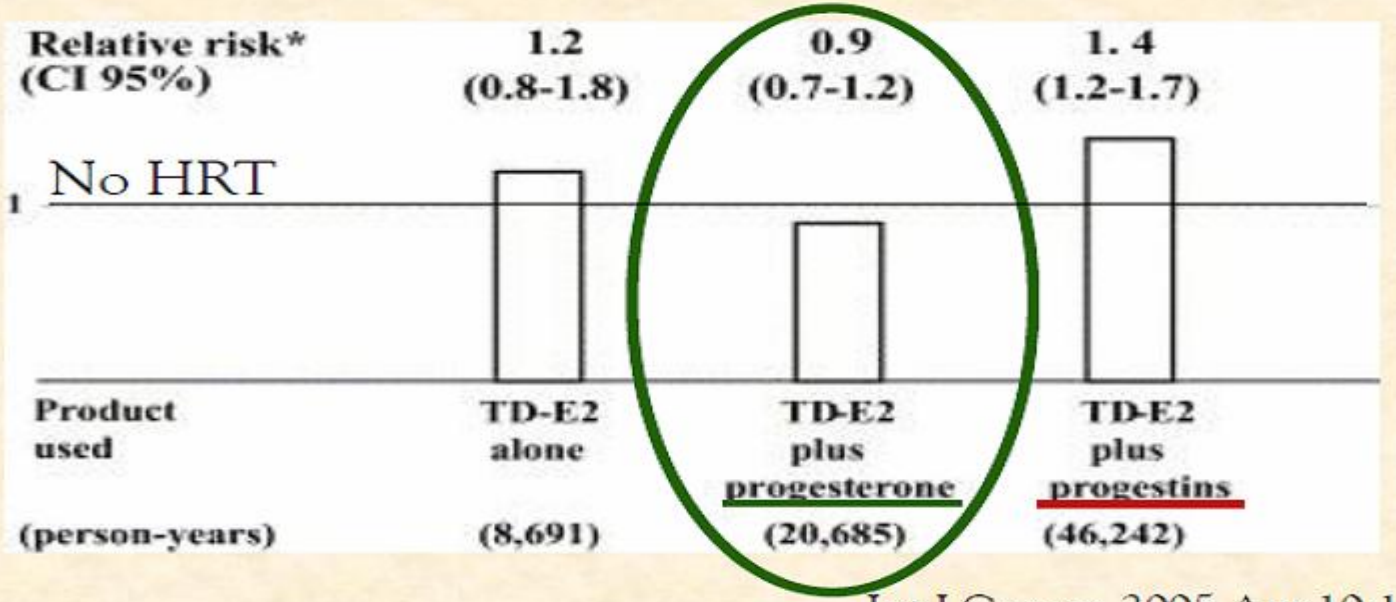
If You Said “WHI”CONCEPT

You Are Wrong!

E3N-EPIC Study

Cohort study
55,000 women
8 years f/u
c/w WHI--
16,000, 6 yr. f/u

TD-E2 = transdermal estradiol



Int J Cancer. 2005 Apr 10;114(3):448-54

E2 plus progesterone: no increased risk of breast cancer!

Similar study: estradiol + progesterone 0.4; estradiol + synthetic progestin 0.94
Espié, Gynecol Endocrinol. 2007 Jul;23(7):391-7.

WHI Vs. E3N

# of women receiving “hormone” treatment

WHI = 13,816

WHI – no Bioidentical hormone used

•Estrogen alone (CEE) both studies showed increase risk

Progestin’s in both studies showed GREATER risk

# of women receiving “hormone” treatment

E3N = 29,420

E3N – Bioidentical and CEE + Progestins used

Estrogen alone (CEE) both studies showed increase risk

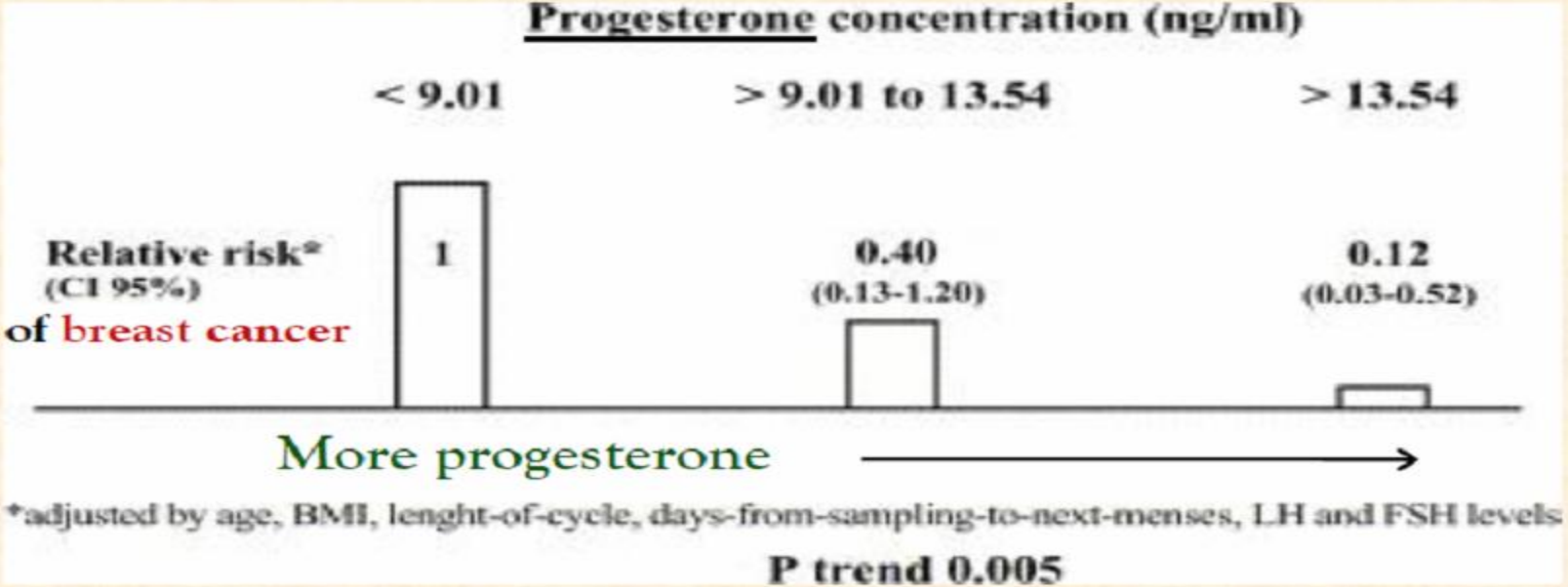
Progestin’s in both studies showed GREATER risk

BHRT When Used in Balanced Combo – no increased risk

Ordet Study: Int. J. Cancer **112** (2004) (2), pp. 312–318.

Progesterone vs. Breast Cancer in menstruating women

6,000 women
5 yr. F/U



Higher progesterone=lower risk of breast cancer

Estrogen, Progesterone and Breast Cancer

Never, Ever, Never, Ever Use Estrogen without Progesterone

•

Never, Ever

You All Have to Pinky Swear


PINKY
SWEAR

Myth: The Women's Health Initiative Saved Lives by Demonstrating the Dangers of HRT.

10 years of randomized treatment

- Oral HRT (estradiol, norethindrone) early after menopause

- Significantly reduced risk of mortality, heart failure, myocardial infarction

Without any apparent increase in risk of: Cancer, venous thromboembolism and stroke.

- Schierbeck et al Effect of hormone replacement therapy on cardiovascular events in recently postmenopausal women: randomised trial. BMJ 2012;345

HRT after breast cancer => ↓ mortality

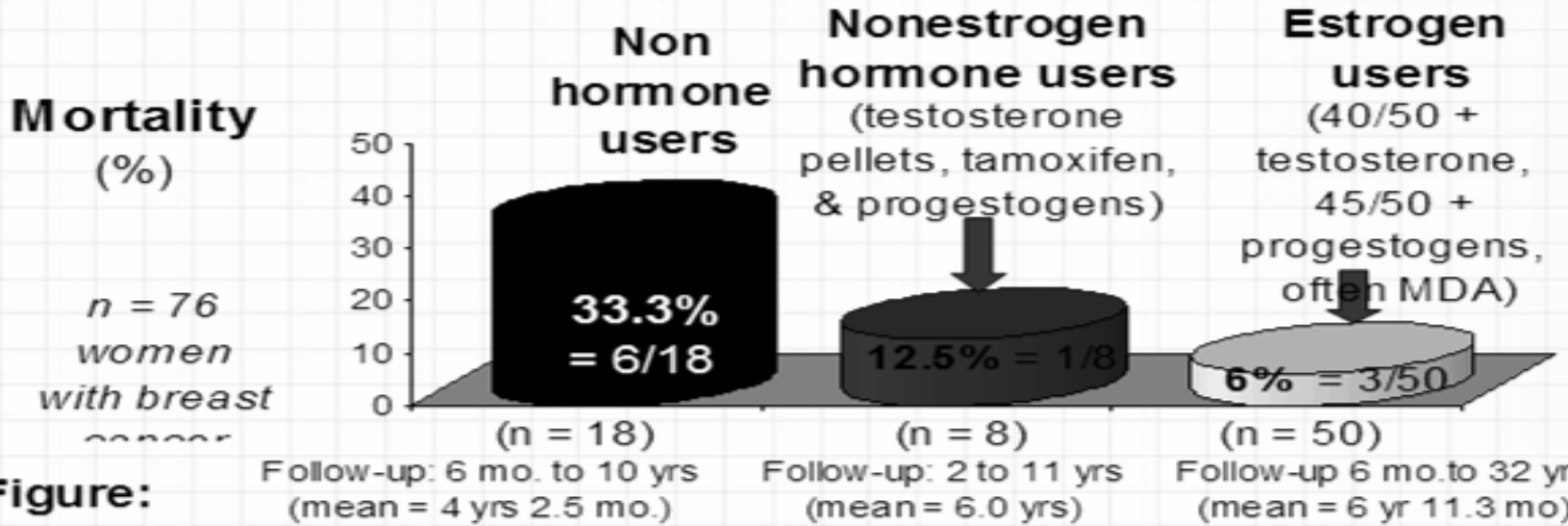


Figure:
Estrogen replacement does not seem to increase either recurrences or mortality rates. Adding progestogens may even reduce recurrences.
Women with early breast cancer should be offered hormone replacement after full explanation (risks, benef.,controv.)

Natrajan PK, Soumakis K, Gambrell RD Jr. Estrogen replacement therapy in women with previous breast cancer. Am J Obstet Gynecol. 1999;181(2):288-95. Georgia, USA

Case Hx.-Breast cancer in remission x 2 years

(+) Hormone Sx Do you give hormones? Other options?

- Black cohosh
- Siberian rhubarb extract

Swedish Sunflower Seeds

- Gabapentin, Clonidine, Paroxetine, Citalopram

Hormone options might include

- Vaginal DHEA to address dryness
- Progesterone to modulate estrogen receptors

Interventions to Improve Estrogen Balance

- Cruciferous vegetables = DIM & Allium (garlic, onion)
- Iodine – promotes Cyp-1A1 enzyme
- Flax seed meal – lignans (never OIL)
- High Protein DIet, Exercise
- Omega 3 fatty acids, NAC, ALA
- Folic acid, B6, B12 support pathway and promote COMT
- Soy – always organic, whole (not fractionated)
- Kudzu - isoflavone (daidzein)

Estrogen Use in the Presence of Breast Cancer

Estradiol is not completely contraindicated if Remission x2 years, (-) Mammo and clearance pathways have been evaluated

Durna, Wren, et al. Hormone replacement therapy after a diagnosis of breast cancer: cancer recurrence and mortality. MJA 2002; 177: 347–351

Peters, Fodera, et al. Estrogen replacement therapy after breast cancer: a 12-year follow-up. Ann Surg Oncol. 2001 Dec;8(10):828-32.

O'Meara, Rossing, et al. Hormone Replacement Therapy After a Diagnosis of Breast Cancer in Relation to Recurrence and Mortality. Journal of the National Cancer Institute, Vol. 93, No. 10, May 16, 2001

Testosterone: For Males Only?

Testosterone- T is the most abundant active sex steroid in women throughout the female lifespan.

- Helps maintain muscle and bone strength, restores sex drive and libido.
- Improves overall feeling of well being, reduces “bad” cholesterol.
- Testosterone replacement leads to increase bone and muscle mass.
- Testosterone Deficiency leads to dry eyes, pale faces, thinning of inner 1/3 of eyebrow.

C. Dimitrakakis, J. Zhou, C.A. Bondy, Androgens and mammary growth and neoplasia, Fertility and Sterility, 77 (2002), pp. 26–33

Myth: Testosterone's Only Role in Women is Sex Drive and Libido

Pre and post-menopausal women, and aging men, experience symptoms of androgen deficiency:

Dysphoric mood (anxiety, irritability, depression)

Lack of well being

Physical fatigue

Rheumatoid complaints, pain,

Bone loss and Muscle loss

Sexual dysfunction

Urinary complaints, incontinence

Hot flashes,

Breast pain

Changes in cognition, Memory loss, Insomnia

Fact: Testosterone is essential for women's physical and mental health and wellbeing.

K. Maclaran, N. Panay, The safety of postmenopausal testosterone therapy, Womens Health, 8 (2012), pp. 263–275

More Myths: Testosterone and Women

1. **Myth: Testosterone masculinizes females** **Fact:** T does not have a masculinizing effect on females.
2. **Myth: Testosterone causes hoarseness and voice changes.** **Fact:** There is no evidence that T causes hoarseness or irreversible vocal cord changes in women.
3. **Myth: Testosterone causes hair loss.** **Fact:** T increases scalp hair growth in women
4. **Myth: Testosterone causes liver damage. Fact:** Non-oral T does not adversely affect the liver or clotting factors.

5. C.J. Wolf, A. Hotchkiss, J.S. Ostby, G.A. LeBlanc, L.E. Gray, Effects of prenatal testosterone propionate on the sexual development of male and female rats: a dose–response study, Toxicological Sciences, 65 (2002), pp. 71–86
6. F. Nordenskjöld, S. Fex, Vocal effects of danazol therapy, Acta Obstetricia et Gynecologica Scandinavica, 63 (1984), pp. 131–132
7. V. Matilainen, M. Laakso, P. Hirsso, P. Koskela, U. Rajala, S. Keinänen-Kiukaanniemi, Hair loss, insulin resistance, and heredity in middle-aged women. A population-based study, European Journal of Cardiovascular Risk, 10 (2003), pp. 227–231
8. D.J. Handelsman, A.J. Conway, C.J. Howe, L. Turner, M.A. Mackey, Establishing the minimum effective dose and additive effects of depot progestin in suppression of human spermatogenesis by a testosterone depot, Journal of Clinical Endocrinology & Metabolism, 81 (1996), pp. 4113–4121

Myth: Testosterone Increases the Risk of Breast Cancer

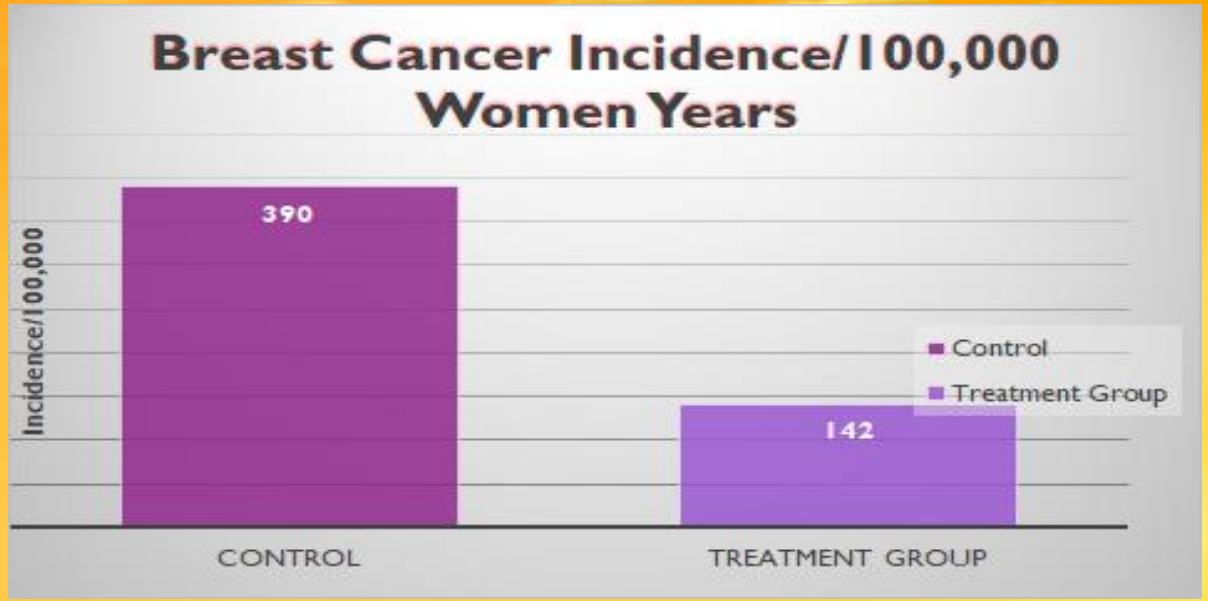
- **1268 pre and postmenopausal women**
- **142/100,000 treatment groups**
- **390/100,000 control groups**

Fact: More than double the Risk of Breast Cancer W/O Testosterone

- $P < 0.001$

- Glaser and Dimitrakakis. Reduced Breast cancer incidence in women treated with subcutaneous testosterone, or testosterone with anastrozole: a prospective, observational study. Maturitas 2013 Dec;76(4): 342-9

Testosterone and Breast Cancer Risk

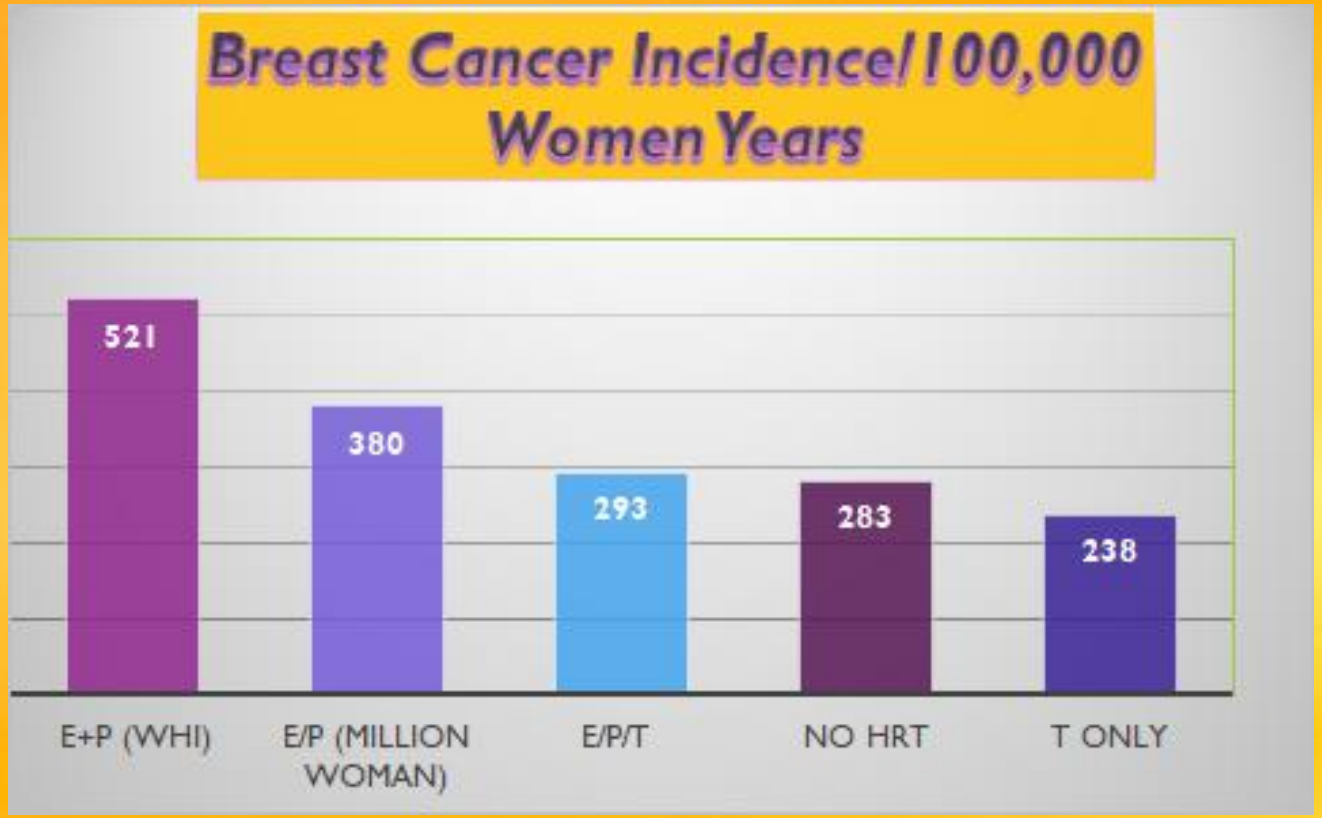


More than double the Risk of Breast Cancer Without Testosterone P < 0.00

Glaser and Dimitrakakis. Reduced Breast cancer incidence in women treated with subcutaneous testosterone, or testosterone with anastrozole: a prospective, observational study. Maturitas 2013 Dec;76(4): 342-9

Dimitrakakis C, Jones RA, Liu A, Bondy CA. Breast cancer incidence in postmenopausal women using testosterone in addition to usual hormone therapy. Menopause. 2004 Sep-Oct;11(5):531-535

Lowest Risk of Breast Cancer is in T Treated Patients



Myth: “No Credible Evidence Exists on the Value of Bioidentical Hormones.”

- **DHEA as an antiaging supplement shows neither meaningful benefit nor serious adverse effects**

Executive Summary of the AMA House of Delegates 2009 Annual Meeting: Council on Science and Public Health Report. The use of hormones for “anti aging”: A review of efficacy and safety. *Report 5 of council on science and public health (A-09).* 2009:1-17.

DHEA as an Antiaging Supplement shows Neither Meaningful Benefit nor Serious Adverse Effects

DHEA => **Builds and protects against cortisol catabolism.**

Decreases visceral & subcutaneous fat in elderly persons.

Reduces serum low density lipoprotein levels and body fat.

Improved Bone Density

Symptoms Relieved: Fatigue, Dry Eyes, Dry Skin

Regulates mood, Supports the immune system, Improves Insulin Sensitivity

Nestler JE, Barlascini CO, Clore JN, Blackard WG. Dehydroepiandrosterone reduces serum low density lipoprotein levels and body fat but does not alter insulin sensitivity in normal men. J Clin Endocrinol Metab. 1988;66(1):57-61

Jankowski CM, Gozansky WS, Kittelson JM, Van Pelt RE, Schwartz RS, Kohrt WM. Increases in bone mineral density in response to oral dehydroepiandrosterone replacement in older adults appear to be mediated by serum estrogens. J Clin Endocrinol Metab. 2008 Dec;93(12):4767-73

DHEA as an Antiaging Supplement shows Neither Meaningful Benefit nor Serious Adverse Effects

DHEA: Reduces of atherosclerotic plaques; Inhibits Platelet Aggregation (Similar to Aspirin)

Inhibits Free Radical Formation-inhibits nuclear factor-kappaB-dependent transcription

Improves Sexual Function

Improves Skin Tone, Reduce Vulvar Vaginal Atrophy Postmenopausal With No Systemic Side Effects

Gordon GB, Bush DE, Weisman HF. Reduction of atherosclerosis by administration of dehydroepiandrosterone. A study in the hypercholesterolemic New Zealand white rabbit with aortic intimal injury. J Clin Invest. 1988 Aug;82(2):712-20

Jesse RL, Eoesser K, Eich DM, Zhen Y, Hess M, Nestleer JE. Dehydroepiandrosterone Inhibits Human Platelet Aggregation in vitro and in vivo. Ann NY Acad Sci. 1995:774:281-90

Iwasaki Y, Asai M, Yoshida M, Nigawara T, Kambayashi M, Nakashima N. Dehydroepiandrosteronesulfate inhibits nuclear factor-kappaB-dependent transcription in hepatocytes, possibly through antioxidant effect. J Clin Endocrinol Metab. 2004 Jul;89(7):3449-54

Labrie, et al. Menopause, Sept-Oct 2009

DHEA as an Antiaging Supplement shows Neither Meaningful Benefit nor Serious Adverse Effects

Low levels associated with:

- **All cause mortality, Cardiovascular mortality, Obesity, Type 2 diabetes**
- **Immune dysfunction, Autoimmune disease, Cancer, Hypertension, CV Disease**
- **Depression and loss of well-being, Low libido, Erectile dysfunction, Osteoporosis**

Ohlsson C et al. Low Serum Levels of Dehydroepiandrosterone Sulfate Predict All-Cause and Cardiovascular Mortality in Elderly Swedish Men. J Clin Endocrinol Metab. 2010 Jul 7.

DHEA and Well-Ness (DAWN) Study.

Cognitive, life satisfaction and sexual function evaluated

- **Healthy, normal cognitive**
- **Double blind placebo controlled with 50 mg daily of DHEA**
- **Increased testosterone (60%) and estrogen (40%) in women, not men**
- **No adverse effects**

- Kritz-Silverstein, D et al. Effects of DHEA supplementation on cognitive Function and Quality of Life: The DHEA and Well- Ness (DAWN) Study. J Am Geriatric Soc. 2008 July; 56(7):

FDA Approved DHEA Vaginal Insert

Only INTRAROSA converts to androgens and estrogens in a woman's body with no restrictions on duration of use[1*]

- First and only FDA-approved, vaginal non–estrogen-based therapy[1,2*]
- Demonstrated efficacy[1-3]
- Once-daily treatment at bedtime[1]

*Prasterone, a synthetic version of endogenous dehydroepiandrosterone (DHEA), is an inactive precursor that is converted into active androgens and estrogens. The mechanism of action of INTRAROSA is not fully established.

DHEA Insert indicated for the treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause.

7 Keto DHEA

Weight loss without side effects (kalman)

- **Improves Immune function; Useful in Raynaud’s, Autoimmune Dx.**
- **Lowers Estrone Levels**
- **Improves lipids**
- **Improves memory in rats**
- **Dose: 50-200 mg in AM**

Ihler G et al. 7-oxo-DHEA and Raynaud's phenomenon. Med Hypotheses. 2003 Mar;60(3):391-7.

Myth: “No Credible Evidence Exists of the Value of Bioidentical Hormones.”

- **No evidence of long term cognitive changes in therapeutic doses of “anti aging hormones”**

Executive Summary of the AMA House of Delegates 2009 Annual Meeting: Council on Science and Public Health Report. The use of hormones for “anti aging”: A review of efficacy and safety. *Report 5 of council on science and public health (A-09).* 2009:1-17.

No Evidence of Long Term Changes with Therapeutic Doses of "Anti Aging Hormones"

1. **Vitamin D**-Infections Dx Protection, CV Disease Risk (<25=2.5x risk), IBS, Ovarian Cancer, Dementia, Keloids
2. **Melatonin**-Free Radical Scavenger, Delays Aging, Anti-inflammatory, inhibits Tumor Growth, Hypertension, Neuroprotective
3. **Telomeres-**Deterioration accelerates aging, Anti neoplastic, Can restore organ function with Telemerase
4. **Pregnenolone, Estrogen, Progesterone, Testosterone, DHEA, Thyroid**-Lessen and/or prevent Psychiatric Disorders including Schizophrenia
5. **Aldosterone**-Hearing Loss, Balance, Tinnitus

(References at end of slide presentation)

Do You Agree? There is No Credible Evidence Exists on the Value of Bioidentical Hormones.

- **Current evidence does not support the use of testosterone in older men with low testosterone levels.**
- **Evidence of the value of testosterone as an antiaging therapy does not exist.**
- **The long term use of estrogens with or without progestins cause more risks than benefits.**
- **The long term use of estrogens for the prevention of chronic conditions in postmenopausal women is not recommended**
- **Current evidence fails to support the efficacy of hGH as an anti aging therapy**
- **DHEA as an antiaging supplement shows neither meaningful benefit nor serious adverse effects**
- **No evidence of long term changes in therapeutic doses of “anti aging hormones”**

Executive Summary of the AMA House of Delegates 2009 Annual Meeting: Council on Science and Public Health Report. The use of hormones for “anti aging”: A review of efficacy and safety. *Report 5 of council on science and public health (A-09).* 2009:1-17.

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References Cited

In this Presentation 108 Peer Reviewed Studies Are Cited Refuting AMA Paper

In My Thyroid Module (available upon request) we cite 25 studies from peer reviewed medical journals.

A Grand Total of 133 “Non Credible” Evidence Published In Journals Endorsed by A Multitude of Mainstream Medical Societies

“Don't get your information from me, folks, or any newscaster. Get it from people with PhD after their names."

Do You Agree?

Myth: There are no studies on bioidentical hormones.

Reality: Do you have the Scientific Evidence for BHRT as the “Standard of Care?”

Reality: Do You Now Have A Succinct Reference Source to the Age Old Refrain “My Doctor Says BHRT is No Good For Anything.”

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Lucy and I Thank You For Inviting Us Today!

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