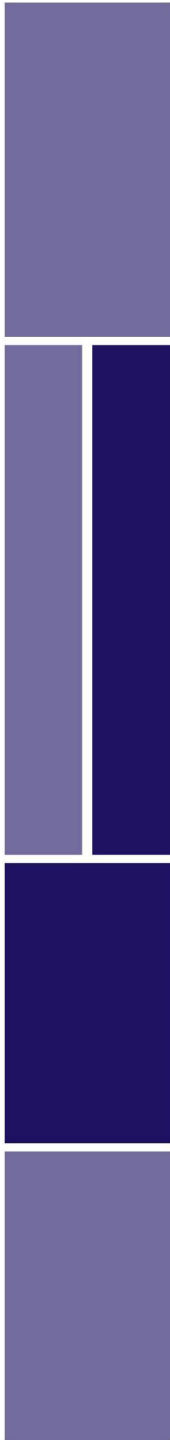




Update on HCG and hGH

February 7, 2006
FAAFM

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Andropause
Interpretation and Initial Treatment
Human Chorionic Gonadotropin

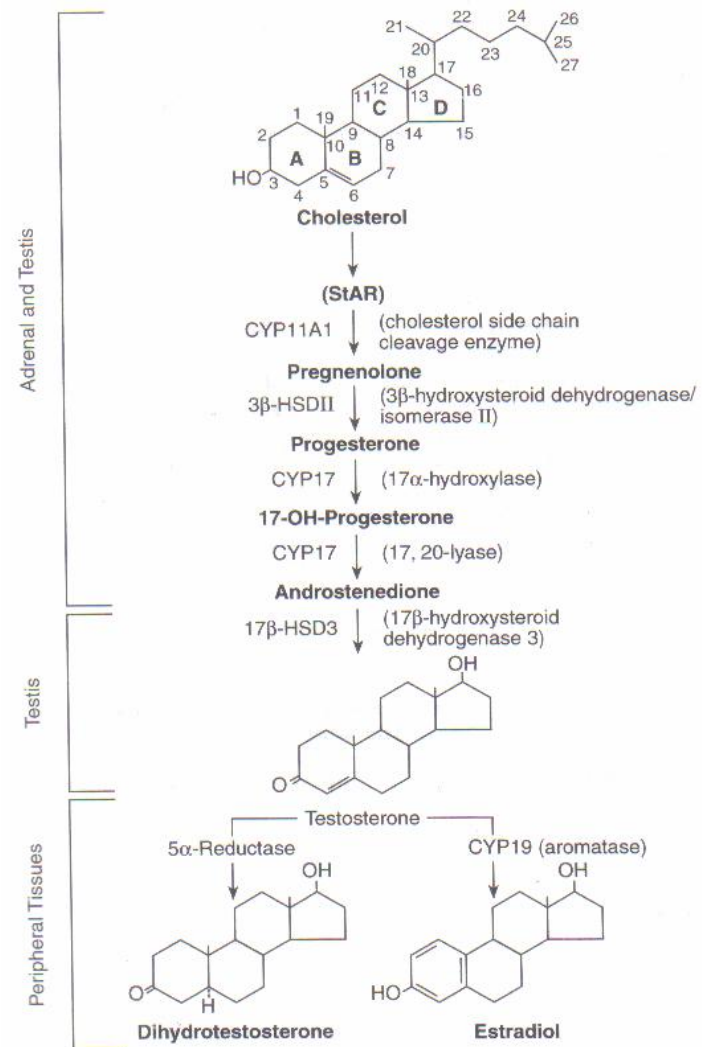
An alternative to Testosterone Replacement therapy

“Augmenting the positive”

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Synthesis of Testosterone

- Rate limiting step in synthesis of testosterone is the transport of cholesterol to the inner mitochondrial membrane
- Lutenizing Hormone (LH) enhances the delivery of cholesterol to the mitochondria
- Average production of 5-6 mg of testosterone per day



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Human Chorionic Gonadotropin - What is it?

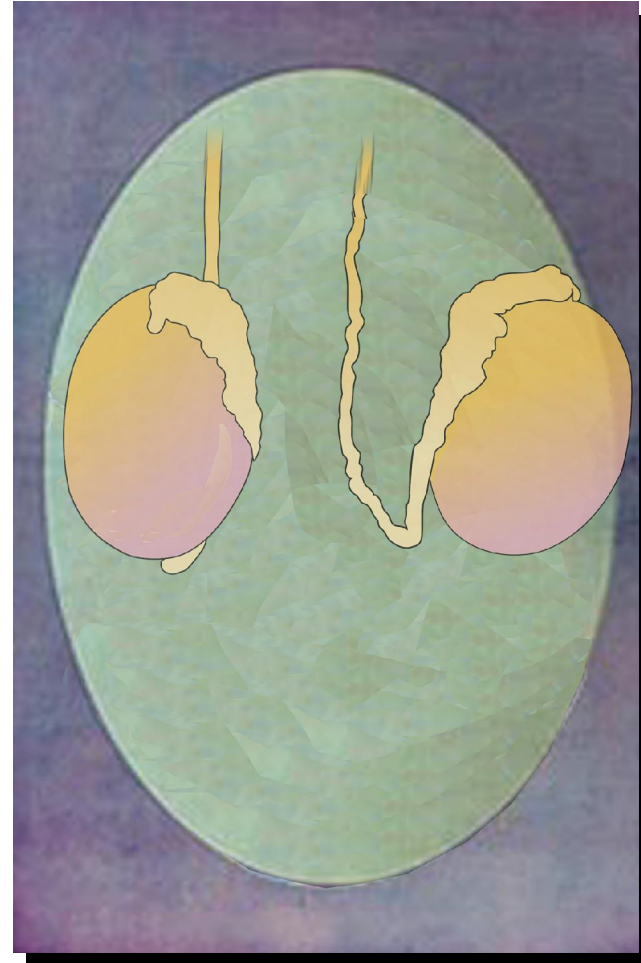


- A polypeptide produced by the human placenta (obtained from urine)
- Composed of an alpha and a beta subunit
- The alpha subunit is essentially identical to the alpha subunit of LH and FSH
- Vials contain 10000 IU HCG and Mannitol

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Human Chorionic Gonadotropin - How does it work?

- The action of hCG is virtually identical to that of pituitary LH (and has a small degree of FSH activity)
- hCG (LH analog) stimulate Leydig cells in the testes to produce testosterone
- FDA approved to treat hypogonadotropic hypogonadism (low testosterone due to low LH)



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Human Chorionic Gonadotropin - Studies

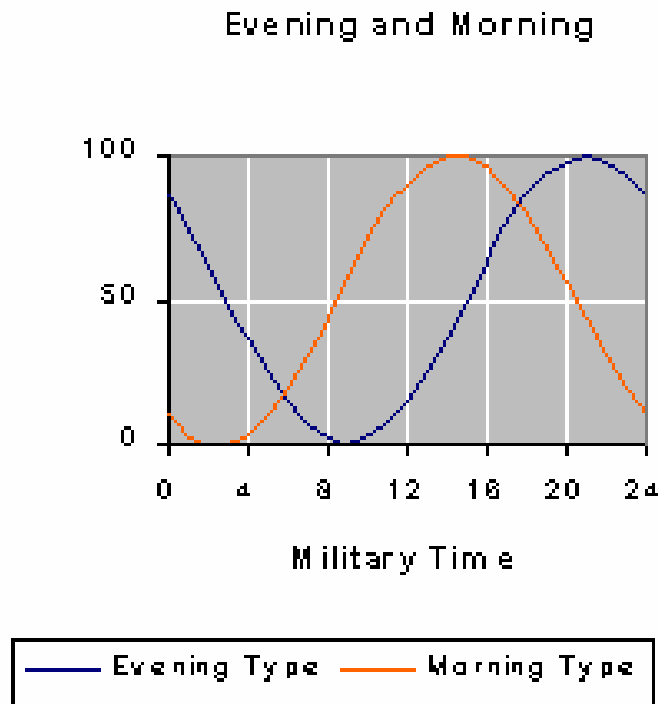
- Administration of hCG to men for long periods results in steady-state elevations of testosterone



Smals, AGH. Dissociated responses of plasma testosterone and progesterone to single or repeated HCG administration in normal men. J Clin Endocrinol Metab 1980; 50:190-193

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Human Chorionic Gonadotropin - Studies



- The increase in total plasma testosterone after hCG administration is greater in the morning than in the afternoon, in keeping with the normal circadian rhythm

Ahokoski, O. Biological day to day variation and daytime changes of testosterone in healthy men. Clin Chem Lab Med 1998; 36:485-491

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Human Chorionic Gonadotropin - Side effects

- Edema
 - Most common. If occurs, hold hCG until symptoms abate and restart at next lower level. Is not seen as often with low dose daily administration.
- Estradiol excess
 - May use Arimidex or lower dose of hCG. Is not seen as often with low dose daily administration.
- Testosterone excess
 - Uncommon. If occurs, Hold hCG until symptoms abate and restart at next lower level
- Site inflammation/infection
 - Rare

Andropause Interpretation and Initial Treatment Human Chorionic Gonadotropin

DOSING ** NEW GUIDELINES**

- hCG powder (10000 USP units) mixed with 4 ml sterile water
- hCG is given daily in the morning as an injection into the fat (subcutaneously)
- Maximum dose is 7000IU/week

IU of hCG	ml on syringe	units on insulin syringe
1000 IU	0.40 ml	40 units
750 IU	0.30 ml	30 units
500 IU	0.20 ml	20 units
250 IU	0.10 ml	10 units



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Andropause
Interpretation and Initial Treatment
Human Chorionic Gonadotropin

- If patient is symptomatic and bioavailable Testosterone is 250-500 ng/dL serum, first try:
 - Alcohol, caffeine, and drug avoidance
 - Increase exercise
 - Increase Protein and “Good fats” in diet
 - Decrease stress
 - If all else fails, give hCG 125 IU daily
- Bioavailable Testosterone is less than 150-250 ng/dL serum:
 - hCG 250 IU daily
- Adjustment: Increase by 125-250 IU daily, max dose 1000 IU daily

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Human Growth Hormone

- New GUIDELINES to dosing
- Treating symptoms versus Arginine Stimulation testing

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Growth Hormone Deficiency Syndrome

- Abnormal body composition
 - increased fat mass
 - decreased lean body mass
- Decreased extracellular water content
- Decreased bone mass
- Atherogenic lipid profile
- Reduced cardiac function
- Diminished muscle strength
- Decreased exercise performance

deBoar H Clinical aspects of growth hormone deficiency in adults. *Endocrine Review*, 16, 63-86.



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Somatopause Symptoms

MAJOR

- Reduced exercise capacity/increased recovery time
- Fatigue/exhaustion
- Inability to lose weight with diet and exercise

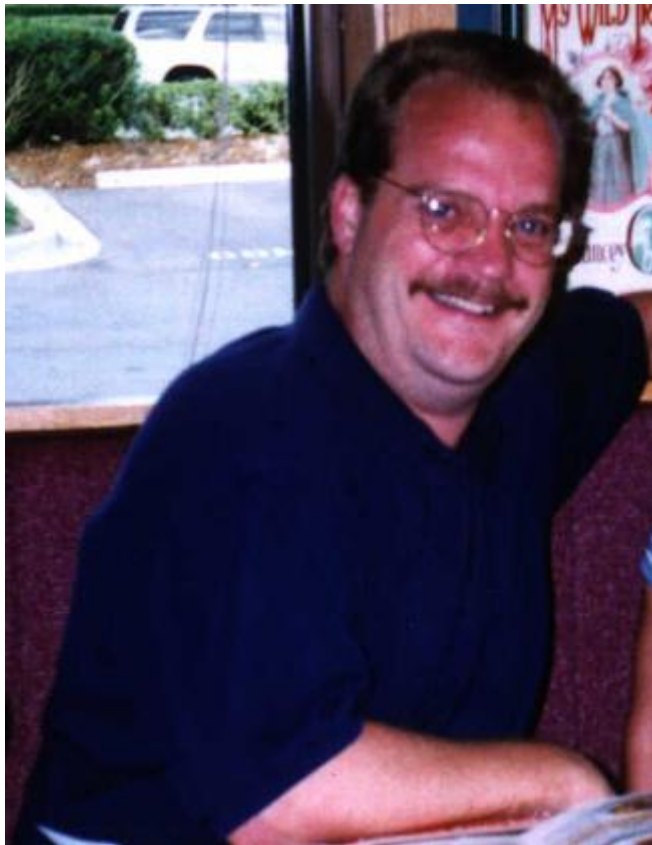
MINOR

- Loss of concentration
- Loss of self confidence/self esteem
- Tends to isolate self
- Decreased in quality of sleep



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Somatopause Physical Signs



MAJOR

- General muscle loss
- "Pot belly"
- Sagging cheeks
- Thinning lips
- Deep forehead lines
- Decreased facial tone
- Flabby muscles

MINOR

- Older than stated age
- Thinning hair
- Thinning skin
- Receding gums
- Atrophied jaw angle
- Tension in upper back/kyphosis

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Somatopause Initial tests

INITIAL TESTS (blood draw in morning, fasting for 12 hours)

- IGF-1
- IGFBP-3
- Fasting glucose
- Fasting insulin
- HgbA1C
- Other useful tests
 - TSH
 - Testosterone
 - Estradiol
 - Cortisol
 - DHEA-S



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Somatopause

Interpretation of Tests

– GOALS

- IGF-1 Men 270-350 ng/ml
- IGF-1 Women 220-300 ng/ml
- IGFBP-3 ~3000 ng/ml
 - If IGFBP3 >4000, (IGF1/IGFBP3 ratio <0.1) reflects an overall deficiency of IGF-1 available. Conditions which raise IGFBP-3 include elevated estrogens. Conditions which lower IGFBP-3 include hyperthyroidism, nephritis, and hepatitis.
 - IGF1/IGFBP3 > 1/10 may be significant in leading to cancer development

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Somatopause Dose Chart

<u>LEVEL</u>	<u>DOSE</u>	<u>Compounded</u>	<u>Genotropin MQ</u>	<u>Nortropin</u>
		(units on insulin syringe)		
FIVE	0.8 mg	40 units	0.8mg MQ syringe	0.8 mg
FOUR	0.6 mg	30 units	0.6mg MQ syringe	0.6 mg
THREE	0.5 mg	20 units	0.4mg MQ syringe	0.5 mg
TWO	0.3 mg	15 units	0.4mg MQ syringe	0.3 mg
ONE	0.2 mg	10 units	0.2 mg MQ syringe	0.2 mg

- SAIZON: Off the market
- Compounded hGH 6mg/vial: Mix 3 cc water gives you 1 mg per ½ cc of fluid
- Genotropin: dosed by syringe
- Nortropin: dial up dose on Nortropin Pen

- Conversion: 1mg = 3 IU

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Somatopause Treatment

- If patient has IGF-1 level over 120 ng/ml, would not recommend starting hGH. Encourage heavy lifting, good sleep, and balanced nutritional program of high quality proteins and carbohydrates, and retest in 6 weeks.
- **If patient has:**
 - Osteoarthritis OR Edema OR
 - HgbA1C >6.5 but < 7.1
 - Start on hGH at level ONE for 5 out of 7 mornings
- **IGF1 < 200 ng/ml**
 - Start hGH level ONE but move to LEVEL TWO within a few weeks, 6 out of 7 mornings

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Compounded hGH

- Due diligence:
 - Tested by FDA
 - Tested by Pharmacy
 - Quality of product
 - Free of pyrogens and contamination
 - Remember “tryptophan”



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MEDICOLEGAL HIGH ISSUES

- **DISCLAIMER: Dr. Paul Savage's Opinion**
 - Not a lawyer
 - Each physician must make his own decision
 - This is Dr. Paul Savage's Opinion
- Worry and confusion
- What is being investigated
- Who is being investigated
- How to protect yourself as a physician

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MEDICOLEGAL HGH ISSUES JAMA

- October 26, 2005
 - Dr. Thomas Perls et. al.
 - “Provision or Distribution of Growth Hormone for “anti-aging”: Clinical and Legal Issues

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MEDICOLEGAL ASPECTS of hGH

- FDA
 - Served 17 letters to website owners regarding sale of hGH and other hormones online
- FTC
 - Served 34 letters to website owners making unsubstantiated claims about product

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History

- 1988: Steroid Trafficking Act
 - Developed in response to Olympian use of steroids
- 1988: Testosterone moved to DEA, leaving STA empty
- 1990: hGH placed in STA (and not DEA) to limit its “abuse”

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MEDICOLEGAL HGH ISSUES

- hGH is not Federally controlled

» But it's CLOSE

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State Controlled

- State controlled hGH
 - CO
 - ID
 - IL
 - MN
 - OR
 - RI
 - WV

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Proper Diagnosis

- 1) Some component of “disease”, ex. Adult Growth Hormone Deficiency
- 2) Some other recognized medical condition and an FDA approved use
 - Ex. Pituitary failure due to trauma or radiation

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Improper Diagnosis

- Anti-aging
- Reversing the clock
- Weight loss
- Body Building
- Improve Athletic Performance

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