
The Growth Hormone Craze

Prepared testimony for the
Oversight Committee, The
United States House of
Representatives.

Hon. Henry Waxman,
Chairman
110th Congress

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Table of Contents

5 Minute Oral Testimony

- **Cited References**
 - **Supporting Documents**
-

Oral Testimony

What is growth hormone?

Human growth hormone or hGH is produced by a pea-sized endocrine gland near the base of the brain called the pituitary gland. Its primary utility relates to growth in the height of children.

Deficiency in adults

HGH levels gradually decline in adults with minimal or no negative health consequences for the vast majority of the population. The anti-aging industry, the primary pusher and seller of hGH in this country, advertizes that normal declines in hGH cause decreases in strength, muscle mass, sleep, and sexual performance. They go on to claim that replenishing growth hormone to levels present at younger ages stops or reverses these problems as well as aging itself.^{1, 2} This is a ruse.^{3, 4}

There are a few medical conditions in adults that merit the use of growth hormone.

The medically appropriate and legal indications for hGH distribution

Recognizing the potential for growth hormone abuse, Congress amended the Food Drug and Cosmetic Act in the late 1980s and early 1990's⁵ stipulating that hGH can be distributed to adults for only three specific indications approved by the Secretary of Health and Human Services.^{6, 7}

1. AIDS Wasting Syndrome
2. Short bowel syndrome, and
3. Growth Hormone Deficiency (GHD)

GHD is very rare, occurring at a rate of about 1 adult out of 10,000⁸ and the legal diagnosis requires documentation of disease, such as a cancer, or trauma to the pituitary gland and a failed stimulation test.⁹ Often times, GHD is accompanied by deficiencies of other pituitary gland-produced hormones.

In January, 2007, the FDA released an alert reminding those that distribute growth hormone for anti-aging, body-building and athletic enhancement that they are doing so illegally.¹⁰ [see supporting document A]

Use of hGH supplementation in healthy adults and potential risks

A recent Stanford University review of 31 clinical studies of hGH use among healthy, normally aging individuals found the only benefit to be a slight increase in muscle mass. The documented negative side effects included soft tissue swelling, joint pains, carpal tunnel-like syndrome, breast enlargement, and diabetes.¹¹ Other side effects include liver and heart enlargement, increased pressure around the brain and high blood pressure. In a 2002 Johns Hopkins study published in JAMA, about 50% of subjects experienced side effects, primarily joint pains. 13% developed elevated blood sugars or diabetes.¹²

Recent studies demonstrate strong associations between hGH and prostate, colon and breast cancers.^{13, 14} In another study, investigators found that hGH enhances the ability of cancer to spread.¹⁵ It is theoretically possible that normal declines in hGH with age may actually be protective against cancer.

Ironically, there is no credible scientific evidence that hGH substantively increases muscle strength or aerobic exercise capacity in normal individuals.^{12, 16-18}

Illegal and medically inappropriate distribution of hGH

Since 1990, a growing network of compounding pharmacies, anti-aging clinics, and physicians have created what some within the industry estimate is a 2 billion dollar-a-year business for distributing hGH¹⁹— a distribution network involving hundreds of thousands²⁰ of weight training enthusiasts, practitioners and promoters of anti-aging medicine, and those who have fallen victim to growth hormone replacement scams.

I personally have found websites of 279 anti-aging clinics that advertise hGH treatment and 26 pharmacies that distribute the drug to these clinics or sometimes directly to users. I have certainly discovered only a fraction of what exists out there.

Of the seized anti-aging clinic records I have reviewed for the DEA, the average patient that first presents to the clinic is not a person in their 60s or 70s seeking alleviation of their age-related problems, but rather, a male in his late 20's to mid 40's, weight training nearly daily, in otherwise excellent health, clearly seeking anabolic steroids and hGH.

In summary:

1. Experts in the care of patients with hGH related problems clearly state that giving hGH for anti-aging or age-management is not medically appropriate particularly when weighing the potential benefits and risks.²¹⁻²³
2. In his modern day and age, we have witnessed the reemergence of the health and longevity salesman. Many members of the public have been misled to believe in the magical powers of growth hormone and because of the associated risks and other drugs typically sold along with growth hormone, this is a major public health problem. The cash-only business of websites or clinics working closely together with compounding pharmacies to turn huge profits, the national and international organizations promoting the illegal use of the drug, and drug companies turning a blind eye to how and to whom their product is distributed bear similarity to what some investigative reporters have likened to a narcotics trafficking ring.^{24, 25}

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- [5] In 1988 and again in 1990, Congress amended the Food, Drug, and Cosmetic Act (FDCA) to enact more stringent controls with higher penalties for offenses involving the distribution of anabolic steroids and HGH [codified at 21 USC §333(e)(1)].²¹ In 1993, the provisions outlawing the distribution of specifically growth hormone were recodified as 21 USC §333(f) (pursuant to PL No. 103-80, §3(e), 107 Stat 775). .
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- [10] FDA Alert, IA #66-71, 1/23/07, "IMPORT ALERT #66-71, "DETENTION WITHOUT PHYSICAL EXAMINATION OF HUMAN GROWTH HORMONE (HGH), ALSO KNOWN AS SOMATROPIN". URL: http://www.fda.gov/ora/fiars/ora_import_ia6671.html. *Section 303(e) (1) of the FDCA, 21 USC 333(e) (1), prohibits knowingly distributing, or possessing with the intent to distribute, HGH for any use in humans other than the treatment of a disease or other recognized medical condition, where such use has been authorized by the Secretary of Health and Human Services (HHS) under section 505 of the FDCA (21 USC 355) and pursuant to the order of a physician The Secretary of HHS has not authorized, for example, any HGH use for anti-aging, bodybuilding, or athletic enhancement Thus, distributing, or possessing with the intent to distribute, HGH for these uses or any other unapproved use violates section 303(e) (1) of the FDCA A violation of section 303(e)(1) carries up to 5 years imprisonment and fines and, if the offense involves an individual under the age of 18 years of age, up to 10 years imprisonment and fines.*
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SUPPORTING DOCUMENTS

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A. *FDA document clearly stating the distribution laws regarding growth hormone. See especially highlights in yellow.*

FDA Alert, IA #66-71, 1/23/07, "IMPORT ALERT #66-71, "DETENTION WITHOUT PHYSICAL EXAMINATION OF HUMAN GROWTH HORMONE (HGH), ALSO KNOWN AS SOMATROPIN". URL: http://www.fda.gov/ora/fiars/ora_import_ia6671.html.

B. *A press release by a Beverly Hills clinic asserting the utility of replacing growth hormone and multiple other hormones to "youthful levels".*

URL: http://www.myhealthcollection.com/hormone_replacement_therapy_2.htm

C. *A compounding pharmacy sponsored meeting with talks about growth hormone for anti-aging and how to establish an anti-aging practice that distributes hormones.*

D. *United States map indicating, by State, a sampling of the number of compounding pharmacies and anti-aging, wellness and other clinics that advertise growth hormone replacement. The true numbers of each are likely much larger. The top 4: California, Florida, Texas and Arizona.*

IA #66-71, 1/23/07, "IMPORT ALERT #66-71, "DETENTION WITHOUT PHYSICAL EXAMINATION OF HUMAN GROWTH HORMONE (HGH), ALSO KNOWN AS SOMATROPIN"

TYPE OF ALERT: Detention Without Physical Examination (DWPE)

NOTE: This import alert contains the Agency's current guidance to FDA field personnel regarding the manufacturer(s) and/or product(s) at issue. It does not create or confer any rights for or on any person and it does not operate to bind FDA or the public.

PRODUCT: Human Growth Hormone (HGH); Somatropin

PRODUCT CODE: 64R[][]18 Human Growth Hormone (Hormone)
64R[][]20 Somatrem (Hormone)
64R[][]21 Somatropin (Hormone), Serostim, Nutropin,
Humatrope
64R[][]22 Somatropin (RDNA Origin) (Hormone)
64R[][]23 Somatropin, Biosynthetic (Hormone)

PROBLEM: Unapproved new drugs; Misbranded drugs

PAC: 56008H

PAF: AAP-Approval

COUNTRIES: All

MANUFACTURER/
SHIPPER:

All. Please see guidance for exceptions.

CHARGES: For finished drug products: "The article is subject to refusal of admission pursuant to Section 801(a)(3) in that it appears to be a new drug within the meaning of Section 201(p) without an effective new drug application (NDA)[Unapproved New Drug, Section 505(a)]."

and/or

"The article is subject to refusal of admission pursuant to section 801(a)(3) in that it appears to be misbranded in that it lacks adequate directions for its intended use. [Misbranding, Section 502(f)(1)]."

For all active pharmaceutical ingredients (APIs), including

those APIs intended for use in pharmaceutical compounding:
"The article is subject to refusal of admission pursuant to section 801(a)(3) of the FDCA because it appears to be misbranded in that it lacks adequate directions for its intended use and it is not exempt from this requirement. (Misbranding, section 502(f)(1) of the FDCA) OASIS CHARGE CODE: UNAPPROVED; DRUGS DIRECTIONS

RECOMMENDING

OFFICE: CDER, OC, Division of New Drugs and Labeling Compliance (HFD-310)

REASON FOR

ALERT: Human Growth Hormone (HGH) is the active ingredient in a number of human prescription drugs approved for marketing in the U.S. under new drug applications (NDAs). FDA-approved HGH can be legally prescribed for a limited number of conditions including:

- * hormonal deficiency that causes short stature in children;
- * long-term treatment of growth failure due to lack of exogenous GH secretion;
- * long-term treatment of short stature associated with Turner syndrome;
- * adult short bowel syndrome;
- * adult deficiency due to rare pituitary tumors or their treatment; and
- * muscle-wasting disease associated with HIV/AIDS.

HGH has important benefits, but also serious, known risks. Among the possible long-term side effects of HGH is an increased risk of cancer, and other dangerous side effects have been reported, including nerve pain and elevated cholesterol and glucose levels. For this reason, HGH is carefully regulated in the U.S.

The cost of approved HGH products is high, averaging several hundred dollars per dose. Because of this high cost, HGH drugs have been counterfeited and unapproved HGH products

are offered for sale to U.S. consumers. For example, we have encountered HGH products imported as a lyophilized powder and declared as an active pharmaceutical ingredient (API) for pharmacy compounding. Some pharmacies promote compounded HGH for anti-aging purposes. It is sold as a "fountain of youth" in longevity clinics and to build body mass, weight loss, increase libido, and gain stamina. None of these indications are in the labeling of the FDA approved products.

The agency is aware of unapproved HGH finished dosage form products being imported into the U.S. and recently noted a large increase of HGH being offered for import for pharmacy compounding. If the drug is bought from foreign sources or over the Internet, safeguards built into the U.S. drug distribution system may be bypassed, placing consumers who use HGH at higher risk.

Section 303(e) (1) of the FDCA, 21 U.S.C. ¹ 333(e) (1), prohibits knowingly distributing, or possessing with the intent to distribute, HGH for any use in humans other than the treatment of a disease or other recognized medical condition, where such use has been authorized by the Secretary of Health and Human Services (HHS) under section 505 of the FDCA (21 U.S.C. ¹ 355) and pursuant to the order of a physician. The Secretary of HHS has not authorized, for example, any HGH use for anti-aging, bodybuilding, or athletic enhancement. Thus, distributing, or possessing with the intent to distribute, HGH for these uses or any other unapproved use violates section 303(e) (1) of the FDCA. A violation of section 303(e)(1) carries up to 5 years imprisonment and fines and, if the offense involves an individual under the age of 18 years of age, up to 10 years imprisonment and fines.

HGH products are new drugs and cannot be legally marketed in the U.S. without an approved application. The few HGH products that have been approved for sale by FDA are sold either in liquid form or as lyophilized powders that are labeled for reconstitution by the health care professionals who dispense them. Accordingly, FDA considers both imported HGH lyophilized powder products and liquid HGH products to be finished dosage form drugs, not APIs. Unless these products are the subject of approved new drug applications, they violate section 505 of the FDCA, 21 U.S.C. ¹ 355, and

may not be legally imported into the U.S.

Some HGH marketers may claim that their HGH drug products are intended for use in pharmaceutical compounding. These drugs should be evaluated on a case-by-case basis considering the factors in FDA Compliance Policy Guide, section 460.200, and the specific prohibitions set forth in section 303(e) of the FDCA, 21 U.S.C. ¹ 333(e). The use of HGH in pharmacy compounding is addressed in more detail, below.

Some HGH marketers may claim that their HGH products are dietary supplements. FDA first approved HGH as a new drug in 1940, and HGH was not marketed as a dietary supplement, or as a food, before then. Accordingly, HGH is excluded from the definition of a dietary supplement under section 201(ff) (1) of the FDCA (21 U.S.C. ¹ 321(ff) (3) (A)) because growth hormone was an article approved as a new drug under section 505 of the FDCA (21 U.S.C. ¹ 355) before its introduction as a dietary supplement.

GUIDANCE:

Districts may detain without physical examination all shipments of HGH finished drug products and all shipments of HGH APIs intended for the manufacture of a drug that is not subject to an approved new drug application (NDA). If field personnel are unsure of whether the HGH product at issue is an API or finished drug product, those personnel should contact CDER Compliance at the number listed below for further guidance.

Exceptions include:

- (1) Finished drug products that are covered by approved NDAs;

Note: Shipments should be intended for persons who can lawfully possess and/or distribute HGH;

- (2) APIs that are intended for use in the manufacture of finished drug products subject to approved or pending applications and where the approved/pending application covers the production and delivery of the API to the application holder by persons named in the application;

Note: Districts should contact the CDER Import-Export Team if they cannot confirm in CDER's databases that an HGH finished drug product is covered by an approved application or if an API is covered by an approved or pending application.

- (3) APIs that are intended solely for tests in vitro or in animals used only for laboratory research, and are labeled in accordance with 21 CFR ¹ 312.160(a)(1)(i);
- (4) APIs that will be used for non-clinical research and development, under the conditions set forth in 21 CFR ¹ 201.125;

Note: Importers of HGH API that claim to fall within exceptions (3) or (4) may obtain release of the detained substance only by providing documentation establishing that the substance meets the conditions set forth in 21 CFR ¹¹ 312.160 or 201.125.

- (5) HGH intended for pharmacy compounding should be reviewed on a case-by-case basis. Consistent with its Compliance Policy Guide on human drug compounding and the prohibitions set forth in section 303(e) of the Act, 21 U.S.C. ¹ 333(e), FDA may exercise its enforcement discretion in certain instances to allow the importation of HGH for use in traditional pharmacy compounding. In general, FDA should exercise its enforcement discretion only in those instances where (1) the compounded product is intended for a use that has been authorized by FDA for HGH under section 505 of the FDCA; and (2) the drug will be compounded to meet the individual medical needs of a specific patient who cannot be treated with an FDA-approved HGH drug product (e.g., the patient is allergic to the commercially available FDA-approved HGH product. To this end, FDA should consider the following factors when making a determination about whether it is appropriate to exercise enforcement discretion to allow entry of a shipment:

- * the indication for which the HGH is being compounded;
- * information indicating the individual medical

need for a specific patient; e.g., letter from physician or prescription;

- * the volume of HGH imported and the appropriateness of the volume, based on considerations such as the amount of HGH used to compound a typical prescription;
- * the medical need for the compounded product;
- * the identity of the firms that will receive HGH from the shipment;
- * the identity of the firms that have received the HGH in the past;
- * the presence of statements on the HGH label, at the time that it is imported or offered for import, that the HGH is "For Prescription Compounding" and "Rx only";
- * whether the HGH meets official compendia requirements where applicable (for example, as shown on a certificate of analysis), and
- * whether the HGH comes from a firm that complies with drug registration and listing requirements

Additionally, the importer should affirm in writing that the HGH will be used solely for human drug compounding.

In order to facilitate FDA's case-by-case review, the information identified in points (1)-(5) above should be made available to FDA at the time the offer to import is made.

Discretionary release of these products under the Personal Importation guidance of Chapter 9 of the Regulatory Procedures Manual (RPM) is not appropriate.

If the District Offices have questions concerning the importation of Human Growth Hormone (HGH) they should contact CDER/OC/DNLC immediately.

Ada Irizarry 301-827-8967

PRIORITIZATION

GUIDANCE: N/A

FOI: No purging required

KEYWORDS: HGH, human growth hormone, somatropin; somatrem

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The Truth about Human Growth Hormones (HGH) and Hormone Replacement Therapy from a Trusted Physician

Recent publicity around human growth hormones (HGH) and its use by athletes and celebrities prompts the question: "Just what is hormone replacement therapy and human growth hormone and are there real medical benefits in its use?" A trusted Beverly Hills Physician speaks out.

“ *Just what is hormone replacement therapy and human growth hormone and are there real medical benefits in its use?* ”

Beverly Hills, CA (PRWEB) February 1, 2008 -- With the recent publicity and press around human growth hormones (HGH) and its use by athletes and celebrities one might ask, "Just what is hormone replacement therapy and human growth hormone and are there real medical benefits in its use?" A trusted Beverly Hills physician, founder of Rejuvalife Vitality Institute in Beverly Hills, offers his own opinion.

"The whole truth," says Dr. Berger, "is that prescribed advanced [human growth hormone therapy \(HGH\)](#) for the treatment of diagnosed adult growth hormone deficiencies has also helped thousands of men and women feel more energetic, and more vibrant."

What you haven't read in many news accounts is that healthy people naturally secrete growth hormone throughout their lifespan, as it is produced by the pituitary gland. We have the highest concentration coming during our adolescence, but HGH levels fall off as we get older. Depending on the person, starting somewhere between the ages of 21 to 30 they aggressively start declining, averaging around an average drop of around 14% per decade. A 60-year-old can make half as much growth hormone as they did in their 20s. Any one with a history of a head injury in the past, no matter how subtle or slight is very likely to experience a deficiency of human growth hormone as well as other essential hormones. In 1996, the FDA approved growth hormone as a

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replacement therapy for adults whose HGH secretions had fallen below their normal levels.

Dr. Andre Berger specializes in [anti-aging treatments](#) and non-surgical cosmetic procedures. As part of any treatment he offers, "We start by performing a comprehensive patient interview and examination and a series of diagnostic lab tests to determine if and where any hormonal deficiencies may be present, and then we correct any deficiencies. **The Rejuvalife personalized hormone replacement therapy program modulates hormonal and metabolic balance to optimal youthful levels, so our patients can live and function at a stronger, healthier, and more efficient level.**"

"We understand that everyone is an individual with different hormonal and supplementary needs," says Dr. Berger. Rejuvalife's personalized [hormone replacement therapy](#) involves a series of hormones, supplements and other treatments designed to support and balance individual deficient hormone levels. **The main types of hormones involved are estrogen, progesterone, testosterone, thyroid, DHEA, pregnenolone, and human growth hormone (HGH).**

Some of the medical benefits seen from prescribed human [growth hormone therapy \(HGH\)](#) have been improved quality of life measures, energy and psychological well being, decreased fat and increased lean muscle mass, decreased blood pressure and improved cholesterol profile, improved bone-mineral density and skin tone, and enhanced memory and brain responsiveness.

Other hormone therapies for conditions associated with menopause also yield benefits. Menopause hormone therapy using bioidentical hormones can provide relief from menopausal symptoms and can reduce the risk of osteopenia that can lead to osteoporosis. Younger women with hormone deficiencies, premature ovarian failure or surgical menopause may use hormone replacement therapy for many years.

Though men don't experience menopause the way women do, they do go through an age-related change called viropause or andropause or "man-o-pause". Gradually, the symptoms become more apparent, driving [male testosterone deficiency symptoms](#) or [andropause](#). They include increased fatigue both in the morning and at night, decreased interest in sex and increased irritability.

Unfortunately, many men are reluctant to seek hormone treatment which in the past has been cumbersome and time consuming. Thanks to scientific advancements, treatments are now available that are convenient, and offer an unobtrusive approach to hormone replacement therapy for men. It's been found that testosterone replacement in men improves libido, erectile dysfunction, mood, depression, memory, Alzheimer's, angina, heart disease, type 2 diabetes, muscle mass, fat, bone inflammation, and other quality of life issues.

If you have any questions or concerns about hormone replacement therapy treatments for women and men, or would like to find out more about Rejuvalife's treatments, please call (310) 276-4494 or go to www.rejuvalife.md.

About Rejuvalife Vitality Institute

The skilled and experienced physicians, nurses, nutritionists, exercise physiologists, dieticians, and estheticians at the Rejuvalife Vitality Institute are trained in the most cutting-edge scientific advances in less-invasive lipolysis procedures and anti-aging treatments. The Rejuvalife Vitality Institute is founded on an all-inclusive balanced approach to health and beauty with a special emphasis on customized patient care, education, and lifestyle changes.

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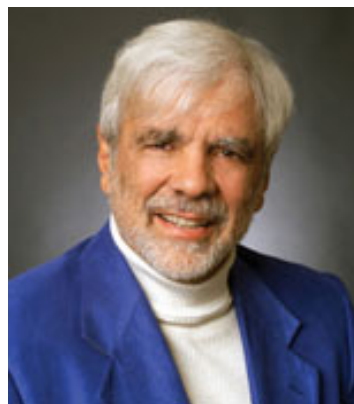
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 - Hormones for Women
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 - Erectile Dysfunction
 - Hormone Drug Information
 - Pain Management
 - Motion Sickness
 - Compounds for Children
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BIO-IDENTICAL HORMONE REPLACEMENT THERAPY SEMINAR

A Practical Application in Treating Adult Hormone and Nutritional Deficiencies
Utilizing Advanced Testing Protocols, Bio-Identical Hormones and Nutraceuticals.

Advanced Course with Basic Introduction.

February 28 - March 2, 2008

INTRODUCING THE FACULTY



Jonathan Wright, MD



Thierry Hertoghe, MD



David Brownstein, MD



Ron Rothenberg, MD, FACEP

Harrah's
LAS VEGAS CASINO & HOTEL



3475 LAS VEGAS BLVD SOUTH,
LAS VEGAS, NV 89109

\$599 until
January 25, 2008*

Early Bird SPECIAL!

*After January 25, registration is \$799. \$899 at the door.
A \$50 processing fee applies to all cancellations.

Add a **STAFF MEMBER**
for **ONLY**

\$400

4-DAY SEMINAR

- Thursday, February 28th
- Friday, February 29th
- Saturday, March 1st
- Sunday, March 2nd, 2008

This *approved 26 CME Course* will be held at:
HARRAH'S LAS VEGAS

- **To Register:**
CALL: 866-444-9475 or 619-398-2740
ONLINE: www.ucprx.com
- **Reserve Rooms by January 31, 2008**
Cost: \$145 per night
- **For Reservations and Group Hotel Rates**
CALL: 888-458-8471 Group Code SHIHS8

THIS COURSE WILL COVER THE FOLLOWING TOPICS!

- Introduction to Treating Adult Hormone Deficiencies
- Female Bio-Identical Hormone Replacement Therapy
- Lab Testing - Blood & Urine Testing
- The Laws & Hormone Replacement
- How to Prescribe - Algorithms for Hormone Optimization
- Andropause - Treating the Adult Male
- Treating Adult GH Deficiencies
- Iodine: Most Misunderstood Nutrient
- Nutraceuticals and Hormones
- Testosterone for Males and Females
- Oxytocin and Sexual Orgasms
- A Clinical Approach to Diagnosing and Treating Hypothyroidism
- The Importance of Hormones and the Cardiovascular System
- Case Studies on Female Hormone Replacement
- DHEA - Melatonin - Progesterone - Pregnenolone - Estradiol - Estriol - Testosterone - Cortisone
- Questions and Answers for Physicians
- Live Diagnosis of the Audience
- Physician Networking
- Bone Loss and Parathyroid

This course is approved by Medical Educators Consortium for a maximum of 26 CME credit hours toward category I AMA physician recognition award.

BIO-IDENTICAL HORMONE REPLACEMENT THERAPY SEMINAR

A Practical Application in Treating Adult Hormone and Nutritional Deficiencies Utilizing Advanced Testing Protocols, Bio-Identical Hormones and Nutraceuticals. Advanced Course with Basic Introduction.

Thursday, February 28

The Basics of BHRT

11:00-12:00	Registration
12:00-1:00	Overview of Hormone Replacement in Age Management - Testosterone, DHEA, Pregnenolone, Melatonin, Growth Hormone, Estriol, Estradiol – Ron Rothenberg, MD
1:00-3:00	Origins of BHRT—We haven't caught up yet! – Jonathan Wright, MD The importance of Copying Nature with BHRT – Jonathan Wright, MD Hormone Replacement for Women, Basics – Wendy Ellis, ND Lab Testing Considerations: Saliva, Serum, 24 Hour Urine – Wendy Ellis, ND
3:00-3:30	Break
3:30-5:00	How to prescribe - The nuts and bolts of using Bio-identical hormones in age management. You will learn what tests to prescribe, the hormones and their dosages and what to do as problems arise – Ron Rothenberg, MD
5:00-6:00	The laws you need to know! BHRT: What compounds are used? Governing laws relative to prescribing; safety in prescribing – John Grasela, Pharmacist

Friday, February 29

BHRT Advanced Course

7:00-8:00	Continental Breakfast. How to open a turn key weight management program – Kim Ruby, CN (No CME)
8:00-10:00	An in Depth review of the clinical signs of endocrine deficiencies. This will be Doctor Hertoghe's best lecture pointing out hormone deficiencies that he sees in his practice and how you now can easily find these problems.
10:00-10:30	Break
10:30-11:00	Lab Testing Considerations: The Serum testing done for the hormonally deficient patient – Thierry Hertoghe, MD
11:00-12:00	Treating Adult Growth Hormone Deficiencies In Your Practice – Ron Rothenberg, MD
12:00-1:30	Lunch on your own
1:30-2:00	Steroid "Treatment Failure" and Steroid Retention – Jonathan Wright, MD Estrogen Quotient & the Importance of Estriol – Jonathan Wright, MD
2:00-3:00	A clinical approach - Diagnosing and Treating Hypothyroidism – David Brownstein, MD Understand how to clinically diagnose hypothyroidism. How to recognize and treat Thyroid Hormone resistance? How to recognize and treat T4 to T3 conversion problems? – David Brownstein, MD
3:00-3:30	Break
3:30-5:00	The scientific data behind the clinical signs and symptoms of hypothyroidism Thyroid: the victories for improved diagnosis of hypothyroidism therapies The evidence for narrower reference ranges for the TSH is compelling. The population-based reference ranges for thyroid tests are too wide, individual reference ranges are much narrower: Thyroid test values within the reference values associated with pathology: the scientific data – Thierry Hertoghe, MD
5:00-6:00	Testosterone Therapeutics and its modulation – Jonathan Wright, MD

This course is designed for medical professionals and is particularly relevant to naturopathic doctors, general practitioners, endocrinologists, internists, geriatricians, psychiatrists, sports medicine doctors, dermatologists, and cardiologists. Additionally, other health professionals including physician assistants, nurse practitioners and others in this field will find this highly relevant.

Educational Goals: To provide physicians with the theoretical and applied knowledge concerning the impact of the age-related decline in hormones on the body and the occurrence of somatic age-related diseases. To provide, in a comprehensive manner, the skills required to diagnose and effectively treat hormone deficiencies in their patients.

Educational Objectives: At the end of this educational activity, the attendee will be able to • Discuss the complex interrelationships of many hormones • Know how to diagnose hormone deficiencies and dysfunctions • Know how to use laboratory tests to confirm diagnoses and monitor therapies • Know how to formulate customized balanced therapies for patients with hormone related diseases

Educational Formats: Lectures, question and answer sessions, audio/visual aids, extensive printed syllabus.

Accreditation: The Medical Educator Consortium, is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

Credit Hours: The Medical Educator Consortium, designates this educational activity for a maximum of 26 credit hours in category I towards the AMA Physician's Recognition award.

This activity has been planned and implemented in accordance with the Essential Areas and Policies of the Accreditation Council for Continuing Medical Education through the joint sponsorship of MEC and [University Compounding Pharmacy](#). MEC is accredited by the ACCME to provide continuing medical education for physicians.

Faculty Disclosure Statement: The Medical Educator Consortium, in accordance with accreditation requirements, will disclose any significant financial interest or other relationship with the manufacturers of any commercial product(s) and/or provider(s) of commercial services discussed in an educational presentation and with any commercial supporters of the activity.



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A Practical Application of
Treating Adult Hormone
Deficiencies Using
Bio-identical Hormones

February 17 & 18, 2006

16 credit hour

San Diego

California

Ron Rothenberg M.D.

Pamela Smith M.D.

Suzie Schuder M.D.

John Grasela R.Ph.

Rod Comunale M.D.

Errol Korn M.D.

Jay Mead M.D.

Allan Broughton M.D.

Angelica Zaid M.D.

Steven Center M.D.

Kim Ruby

UNIVERSITY COMPOUNDING PHARMACY

SAN DIEGO – CALIFORNIA

619-683-2005

“A Practical Application of Treating Adult Hormone Deficiency”

Hormones control a lot more of our lives than we believe.

FRIDAY 8am-7pm

- 8:8:30 **The Unified Theory of Wellness – Ron Rothenberg M.D.**
How the prevention of chronic inflammation affects nutrition, exercise, vitamins, stress reduction and optimal hormones. How to measure inflammation. How to apply these principles to a primary care, preventive or an anti-aging practice.
- 8:30-9:15am **Patient Assessment.** Everything a doctor should do in assessing the patient from initial consultation, physical examination lab tests follow up lab tests , vitamin lab tests, starting doses and maintenance dose for the typical male and female patient. **Andrea Cole Raub D.O.**
- 9:15-10am **Lab testing** Urine spot testing used in hormone replacement . Latest advancements in GH testing IGF1, TSH, T-3, Lab assessment PSA ratios, estradiol levels in treating the Adult Hormone deficient patient.
Alan Brogton M.D.
- 10-10:30 Break
- 10:30-11:00 **Saliva Lab testing.** How to use them in your office to test hormone replacement levels. **Jay Mead M.D.**
- 11:00-12:00 **Growth Hormone Replacement Therapy- Ron Rothenberg M.D.**
Growth Hormone Replacement therapy of normal aging will be discussed in detail. Data on Cardiovascular, cognitive, immune system, body composition and quality of life benefits will be presented. Cancer risks and side effects will be analyzed. Differences between traditional endocrinology and anti-aging medicine approaches will be explained. Lab testing and treatment algorithms will be presented.
- 12:00-1:15 Lunch
- 1:15-3:15 **Bio-identical Estrogens and Progesterone Replacement Therapy. – Pam Smith** - Bio-identical hormone replacement therapy will be contrasted with traditional HRT with Premarin and Provera. The Women’s Health Initiative studies will be discussed. Cancer risks assessed. The importance of Estriol (E3). A Practical plan will be presented.
- 3:15-3:45 **Break – Compounding demonstrations – visit the booths**
- 3:45-5:15 Doctor Zaid a practicing gynecologist will be discussing case studies of common problems and follow up treatments a physician would encounter in her practice treating women. This will include dosing, PMS, heavy menstruation, peri-menopause dosing, breast tenderness and more. **Angelica Zaid M.D.**
- 5:15-6PM **“Compounds Used in Adult Hormone Deficiency”** present information on the most frequently used drugs used in the Bio-Identical Hormone Replacement Therapy along with cosmeceuticals that will improve your appearance.
John Grasela R.Ph.
- 6:00-7Pm **Social hour visit University Compounding Pharmacy - America’s Finest Compounding Pharmacy** located 5 minutes away in America’s Finest City. Complementary bus ride will take you to the pharmacy for cocktails and appetizers, only 5 minutes away and bring you back to the hotel.



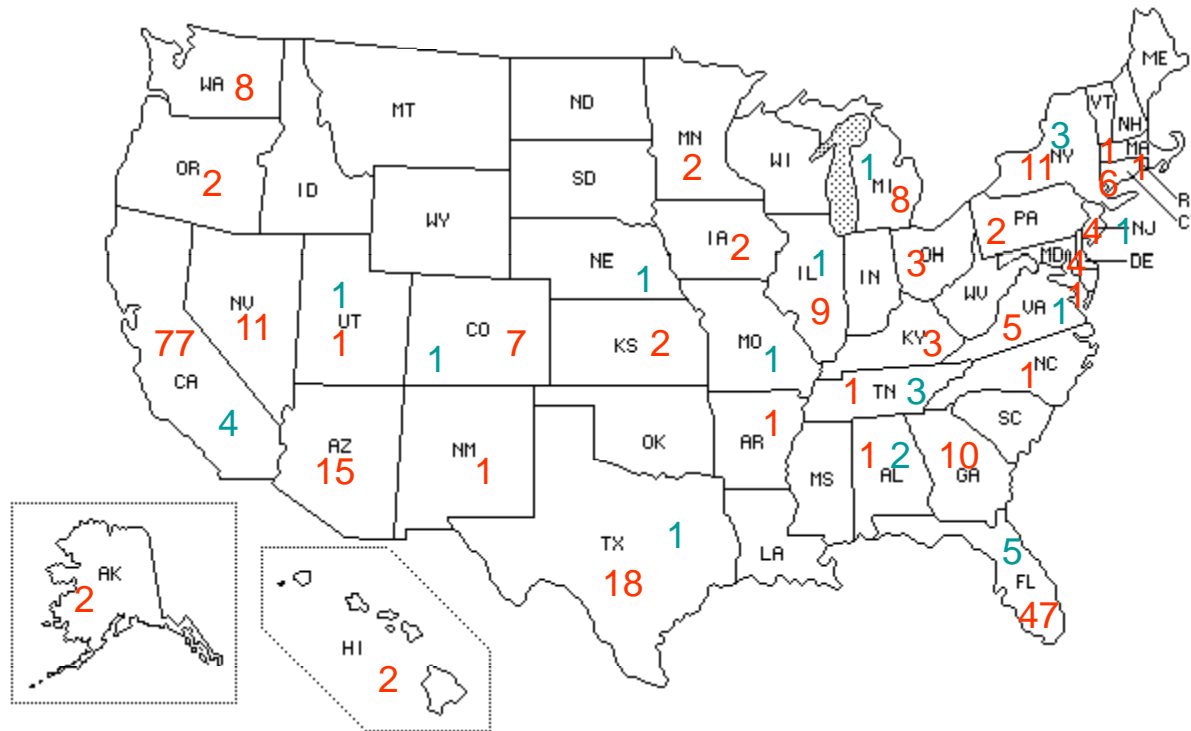
SATURDAY 8:00am-6pm

- 8:00-8:30 **DHEA Replacement therapy- Ron Rothenberg M.D.** -DHEA replacement therapy for normal aging in men and women will be presented. DHEA and testosterone, cognitive function, immune system, body composition and inflammation will be discussed. .
- 8:30-9:00pm **Melatonin** and the importance of Sleep & **Pregnenolone** and memory. **Ron Rothenberg M.D.**
- 9:00-9:45 **Testosterone Replacement therapy in men and women. Steven Center M.D.**
Testosterone replacement and cardiovascular function, cognitive function, body composition, sexual function and inflammation. Cancer risks? Methods of delivery, lab testing & treatment Testosterone
- 9:45-10:15 **BREAK**
- 10:15-11:15 **“Vitamins: Hype or Hope?”** will teach the importance of taking **Vitamins, Minerals, Essential Fatty Acids and Protein supplementation.** You will learn the importance of nutraceutical in the hormone deficient patient such as Indol 3- Carbinal, Co- Enzyme Q, Vitamins and Minerals used as part of the age management process. **Pam Smith M.D**
- 11:15-12:00 **Comparison of weight management programs** for your obese patient- Zone Diet, Atkins Diet, Medi-Fast Diet programs A nutritionalist view of the best way to treat your obese patients and provide you with the knowledge to treat your motivated patients. **Kim Ruby Nutritionalist.**
- 12:00-1:15PM **Lunch**
- 1:00pm 1:15 **Medifast weight loss program** and profit center for your office - **Kim Ruby Nutritionalist.**
- 1:15 -2:15pm **Hormones: The Body-Mind Connection** –The effect of hormone insufficiencies on mood, memory and the ability to think will be presented for each hormone: thyroid hormone, testosterone, estrogen, progesterone, cortisol, and growth hormone. Reversing depressed or anxious mood and slowed mentation with bioequivalent hormone replacement therapy **Suzie Schuder, M.D.**
- 2:15pm-3:15 **Stress Management** - is an important part of preventing the aging process that a patient can do at home that works. How stress effects hormone levels by **Rod Comunale, M.D. & Errol Korn, M.D.**
- 3:15-3:45 Break
- 3:45-4:30 Safe use of cortisol –How cortisol effects cortisol levels and aging. Replacement cortisol therapy will be discussed. **Susie Schudder M.D.**
- 4:30-5pm **Optimal Thyroid Replacement Therapy – Ron Rothenberg M.D.**
Optimal Thyroid Replacement will be contrasted with traditional thyroid replacement with just T4 (synthroid). The problems with just looking at the TSH will be stressed. The prevalence of sub-clinical hypothyroidism. Optimal, (not just normal) Free T3 and T4 and treatment algorithms with T3 and T4 will be presented

5:00-6:00

How to open a successful anti-aging practice. Questions and answers. - **Pam Smith & Ron Rothenberg M.D.**

Sample of
 Compounding pharmacies n=26 &
 Anti-aging, age-management, longevity, rejuvenation or wellness clinics n=276
 advertising on the internet that they provide growth hormone



Researched and constructed by Thomas Perls MD, MPH for the Oversight Committee, House of Representatives. February, 2008