

ALABAMA State Board of Medical Examiners Medical Licensure Commission

Newsletter and Report

www.albme.org

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Treating androgen deficiency in the aging male: a urologist perspective

Matthew R. Thom, MD, Tuscaloosa urologist Introduction

Normal aging in men is accompanied by a decline in testosterone (T) production and function that may contribute to detrimental changes to overall male health. Hypogonadism displays numerous clinical manifestations and the degree and timing of onset is variable and not universal for all men. This can lead to difficulty in diagnosis and treatment. A typical man with low T may be between the age of 40 to 69 and present with signs and symptoms of fatigue, low energy, depressed mood and low sexual drive.



Matthew R. Thom, MD

What is Low T and what causes it?

Low T or symptomatic late-onset hypogonadism is a clinical and biochemical syndrome characterized by deficiency in androgen activity which may affect the function

of multiple organ systems and result in significant detriment in quality of life. More than 500,000 new cases may be diagnosed each year but remains under diagnosed and treated. Numerous theories to its cause are present with a combination of factors contributing to the problem. These include aging hypothalamus with decrease production of gonadotropins, primary testicular failure, changes in androgen receptor activity/function, and effects on T metabolism that lead to decrease function regardless of T levels.

What are the effects of androgen deficiency?

Presentation of the hypogonadal patient is variable which can make diagnosis difficult. Common signs and symptoms include low energy, depressed mood, sleep disturbances, depressed cognition, impotence, and low libido. But low T may also unknowingly contribute to systemic disease including metabolic syndrome, increased cardiovascular risk, and osteoporosis.

How is low T diagnosed?

Clinical diagnosis is problematic because neither low T nor symptoms are truly diagnostic. The most common symptoms – tiredness, depressed sexual drive, and

dysphoria – should tip the physician to further evaluate for hypogonadism. Several screening questionnaires are available to aid in the diagnosis, but unfortunately are not specific. Initial testing should include T levels obtained between 8 a.m. and 11 a.m., with total T being sufficient. Any low level should be confirmed and may include LH, prolactin if clinically warranted. Unfortunately, there is much variability in T level reporting and the parameters for hypogonadism. This is currently under scrutiny by medical groups and societies with hope to standardized reporting to ensure better research, trials and patient care.

See Androgen deficiency, page 4

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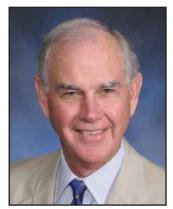
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A Message from the Executive Director Annual report of the Alabama BME

by Larry Dixon, Executive Director

In 2011, there was another increase in the number of newly licensed physicians in Alabama, with 769 approved applicants by endorsement and 66 approved applicants by examination, 40 more approved applicants than in 2010. This was the second year to report Qualified Alabama Controlled Substances Certificates (QACSCs), with 42 issued in 2011. The QACSC is for use by physician assistants. The Board of Medical Examiners and its staff have compiled the following Annual Report for your information.



Larry Dixon

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see BME Report, page 3

Schedule II controlled substances

Under DEA regulations, paper prescriptions for Schedule II controlled substances issued on the same sheet of paper as prescriptions for other schedules of controlled substances and non-controlled drugs cannot be filled by pharmacies without the pharmacy first separating the Schedule II controlled substances prescribed from the other drugs listed. This can lengthen the amount of time it takes for patients to receive their medications. **It is advisable that any paper prescription order for Schedule II controlled substances be written on a separate sheet of paper from any other prescriptions.** This should reduce any confusion for patients and speed in the filling of prescriptions.

BME Report, cont.

H. DISCIPLINARY / CONFIDENTIAL ACTIONS

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DEA announcement concerning carisoprodol (soma)

On December 12, 2011, DEA published a Final Rule (76 FR 77330) in the *Federal Register* making carisoprodol a schedule IV controlled substance. The Final Rule states that effective January 11, 2012, all prescriptions for drugs containing carisoprodol shall comply with 21 C.F.R. §§ 1306.03–1306.06, 1306.21, and 1306.22–1306.27.

Accordingly, as of January 11, 2012, a pharmacy may only fill or refill a prescription for a drug containing carisoprodol if all of the following requirements are met: the prescription was issued for a legitimate medical purpose by a DEA-registered practitioner acting in the usual course of professional practice (21 C.F.R. § 1306.04); the prescription contains all the information required by 21 C.F.R. § 1306.05; and the number of refills authorized by the prescribing practitioner is five or less (21 U.S.C. § 829(b)).

Practitioners and pharmacists are responsible for ensuring the prescription conforms to all requirements of the law and regulations, both federal and state. As 21 C.F.R. § 1306.04 states, "The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription."

The Controlled Substances Act (CSA) also provides that a prescription for a schedule IV controlled substance may not be filled or refilled more than six months after the date the prescription was issued. 21 U.S.C. § 829(b). Therefore, if a prescription for a drug containing carisoprodol was issued before January 11, 2012, and *see DEA, page 4*

Androgen deficiency, cont.

How is T replaced?

Intramuscular injections reliably increase T levels for hypogonadal men but T levels may reach supraphysiologic levels and the normal circadian rhythm is absent. This will make patients complain of a "roller coaster effect". Also, current preparations available require repeat injections typically every 2-3 weeks. Oral preparations are rarely used in US due to erratic effects on T levels and problems with liver toxicity and hyperlipidemia. Transdermal patches and gels are popular yet require daily administration with definite risk for transference to others. One of the newer formulations available is T pellets implanted subcutaneously every 3-6 months. It has benefits with fewer administrations and no risk of transference. But T pellet implantation requires a procedure and there is risk of extrusion of pellets, poor absorption and other procedure site side-effects.

What are the adverse effects of T replacement?

A prior history of prostate or breast cancer is considered an absolute contraindication for hormone replacement. This "truth" has been questioned particularly in light of current treatment of low risk prostate cancer. Hormone replacement in hypogonadal men with clinically cured or untreated low risk disease has been studied showing no significant increase risk of recurrence or progression. However, most practicing urologists discourage T replacement for these men. Neither an increased prostate size nor an increased PSA, with associated lower urinary tract symptoms or increased risk of prostate cancer, has been demonstrated in several short-term studies. Long term effects of T replacement are not well known at this time. T replacement may also lead to increase red blood cell mass and hemoglobin. Side effects from

excessive supplementation of T and other rare problems include infertility, testicular atrophy, priapism, fluid retention, liver toxicity (uncommon with current preparations), hepatitis and hepatic tumors, sleep apnea and gynecomastia. Infertility caused by T supplementation may require treatment with gonadotropins to increase testosterone and attempt to restore normal spermatogenesis. Side-effects from the route of administration may also occur.

Conclusion

Hypogonadism is a common yet under recognized problem in aging men. Not only will low T level lead to sexual side effects it may also effect psychological, physical and overall well-being of older men. Replacement is indicated for men who have signs and symptoms of hypogonadism accompanied by subnormal serum T levels. T supplementation can provide important health benefits to these hypogonadal men. T supplementation requires medical surveillance in order to identify early signs of possible adverse effects. Although the benefits and risks of long-term T supplementation have not been definitely established, the weight of current evidence does not suggest an increased risk of heart disease or prostate cancer with long-term use of T.

References

1. Bhasin S, Cunningham GR, Hayes FJ, et al. Testosterone therapy in men with androgen deficiency syndromes: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab. 2010; 95:2536-59

2. Morales A, Morley J and Heaton JPW. Androgen deficiency in the aging male. Campbell Walsh-Urology, 9th Edition. Philadelphia, WB Saunders Elsevier; 2007: vol. 1, 850

3. Morgentaler A, Lipshultz LI, Bennett R, et al. Testosterone therapy in men with untreated prostate cancer. J Urol. 2011; Apr: 185(4): 1256-61

4. Rhoden EL and Morgentaler A. Risks of testosterone replacement therapy and recommendations for monitoring. N Engl J. 2004; 350: 482-92

5. Traish AM, Guay A, Feeley R, et al. The dark side of testosterone deficiency: Metabolic syndrome and erectile dysfunction. J Androl. 2009; 30: 10-22

DEA, cont.

refills were authorized, as of January 11, 2012 those refills (no more than five) must be dispensed no later than six months after the date the prescription was issued.

As stated in the December 12, 2011, Final Rule, effective January 11, 2012, any person who engages in any activity involving carisoprodol is subject to the criminal, civil, and administrative provisions of the CSA and DEA regulations. This means, among other things, that as of January 11, 2012, persons who prescribe, administer, or dispense carisoprodol by means of the Internet are subject to all applicable provisions of the Ryan Haight Online Pharmacy Consumer Protection Act of 2008 (74 FR 15596), and the regulations issued thereunder.

On the net:

DEA web page on carisoprodol: http://www.deadiversion.usdoj. gov/drugs_concern/carisoprodol/ index.html_

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Dispensing physician registration

Board Rules require the registration with the Board of all physicians who dispense controlled substances from their office(s). Dispensing means ordering for and delivering a controlled substance to a patient and the patient consumes the medication off premises. It does not matter whether the patient pays for the medication or not. Medications labeled as samples and which are not for resale are excluded.

It is not dispensing and no registration is required for distributing

prepackaged samples and starter packs, administering oral or injectable controlled substances in the office, dispensing non-controlled

substances, and dispensing controlled substances purchased with a hospital's or clinic's DEA registration.

Every location where medications are dispensed must be registered and the separate DEA number listed. Physicians are responsible for updating address changes, additional sites, additional DEA numbers, and removal of sites. If a physician chooses to allow another individual to complete this registration, it is the physician's responsibility to ensure that accurate information is provided.

The Board is finding that in some cases, a service is used that registers all the dispensing physicians that work for a particular clinic, for example. Often, these forms are not filled out properly or they are completed for physicians who do not truly dispense. Sometimes it is not clear that the physician signed the form. Again, if you allow another individual to complete this registration for you, accurate information remains your responsibility. Additionally, these forms must be personally signed by the physician. If a clinic handled your dispensing registration but you have not signed a form, then there may be a problem with your registration.

It is important to have current, accurate information on dispensing physicians. It is especially important

If you allow another individual to complete this registration for you, accurate information remains your responsibility. **not** to have physicians registered who are not truly dispensing, because the list of

dispensing physicians is provided to the Alabama Department of Public Health, which in turn **reports** those physicians who are registered but have **not reported** to the Prescription Drug Monitoring Database as required.

Do not register as a dispensing physician "just in case" it applies to you; physicians should be certain that they are dispensing controlled substances within the meaning of the rules before registering. This is not a determination to be made by someone other than the physician.

On the net:

Board's web page for dispensing registration: <u>http://www.albme.org/</u> <u>dispphysregis.html</u> PDMP (AL Dept. of Public Health) web page: <u>http://www.adph.org/</u> <u>pdmp/</u>

MASA/BME Educational Opportunities for 2012



March 31-April 1

Prescribing and Pharmacology of Controlled Drugs: Critical Issues and Common Pitfalls

April 13

Ensuring Quality in the Collaborative Practice

April 13-14

MASA's Annual Session: Ready. Set. Lead.

August 10-12

Prescribing and Pharmacology of Controlled Drugs: Critical Issues and Common Pitfalls

November 17-18

Prescribing and Pharmacology of Controlled Drugs: Critical Issues and Common Pitfalls

November 29

Ensuring Quality in the Collaborative Practice

December 15 Ethics Education

Visit <u>www.masalink.org</u> for more information.

Your Medical License

As a physician, your license to practice medicine in the State of Alabama is one of your most important assets. It allows you to apply what you learned during years of school and post-graduate training to earn a livelihood to support your family. Exercise care to protect this asset.

A Call to Preceptors

One of the most important components of any physician assistant program is the education provided by volunteer clinical preceptors. Each clinical preceptor is greatly appreciated and is an unparalleled commodity. They serve as an integral part of the teaching program. By offering medical expertise and guidance to physician assistant students, clinical preceptors are able to make a genuine impact on the medical profession by ensuring that future clinicians are skilled, competent, and compassionate. The fundamental role for a preceptor is to serve as a bridge between didactic knowledge and the development of clinical decisionmaking skills. Preceptors serve as role models for physician assistant students and help them perfect skills in history taking, physical examination, effective communication, physical diagnosis, succinct recording and reporting, problem assessment, and plan development including a logical approach to further studies and therapy. Physician assistant students learn the art and science of medical care through this "hands on" experience. Providers can use their knowledge and experience to help pave the way for the next generation.

The University of Alabama at Birmingham and the University of South Alabama Physician Assistant Programs are soliciting providers to guide the next generation of certified, licensed physician assistants by becoming a preceptor. We believe that this can be rewarding and fulfilling for both staff and patients. If you are interested in becoming a preceptor for physician assistant students, please contact the following individuals:

Paul Harrelson or Stephanie McGilvray UAB Surgical Physician Assistant Program (205) 975-0342 or (205) 500-9647

Cheryl Click USA Physician Assistant Program (251) 445-9334

The Medical Association of the State of Alabama, the Alabama Board of Medical Examiners and the Alabama Board of Nursing present...

Ensuring Quality in the Collaborative Practice *Working together to deliver quality healthcare*



April 13, 2012 7:45 a.m. to 10:30 a.m. The Wynfrey Hotel, Birmingham

Registration Fee for MASA and AMASA Members: Free

Registration Fee for Guests of MASA and AMASA Members: \$100

November 29, 2012

4 p.m. to 7 p.m. Embassy Suites, Montgomery Registration Fee: **\$100**

Faculty

- Charlene Cotton, MSN, RN, Nurse Consultant for Advanced Practice Nursing of the Alabama Board of Nursing
- Pat Ward, RN, Collaborative Practice Inspector of the Alabama Board of Medical Examiners
- Ray Hudson, MD, Collaborative Practice Consultant to the Alabama Board of Exminers
- Cheryl Thomas, MSM, RN, Collaborative Practice Inspector of the Alabama Board of Medical Examiners

Learning Objectives

After attending this course, participants will be able to:

- Cite the application, approval and renewal requirements for CRNPs and CNMs in a collaborative practice relationship.
- List the credentials a CRNP or CNM is required to have to enter into a collaborative practice agreement.
- List the responsibilities of both physicians and nurses in a collaborative practice agreement.
- Describe common problems seen in a collaborative practice and the methods to apply to correct them.

• Cite the regulations for prescribing drugs, participating in a quality assurance review and practicing in various practice settings, including remote sites.

For more information about the course, call MASA's Education Department at (334) 954-2500 or visit <u>www.masalink.org/CollaborativePractice</u>.

Registration Fee: \$100

Report of Public Actions of the Medical Licensure Commission and Board of Medical Examiners

MLC – December 2011

◆ On Dec. 30, the Commission entered an Order reinstating to full, unrestricted status the license to practice medicine or osteopathy in Alabama of **Michael David Williams, DO**, license number DO.426, Tuscaloosa, AL.

◆ On Dec. 30, the Commission entered an Order reinstating the license to practice medicine in Alabama of **David G. Morrison, MD**, license number MD.20819, New Orleans LA, subject to certain conditions, including a practice limited to Northshore Oncology Associates in Covington, LA.

BME – January 2012

◆ On Jan. 18, the Board accepted the Voluntary Surrender of the Alabama Controlled Substances Certificate of Jose Gonzalo Zavaleta, MD, ACSC number ACSC.22305, Alexandria, LA.

MLC – February 2012

◆ On Feb. 10, the Commission entered an Order revoking the license to practice medicine in Alabama of **Venkatreddy Akkanti, MD**, license number MD.18594, Bastrop, TX.

◆ On Feb. 10, the Commission entered an Order denying the request to remove restrictions on the license to practice medicine in Alabama of **Scott H. Boswell, MD**, license number MD.16975, Jasper AL.

◆ On Feb. 10, the Commission entered an Order placing on indefinite probation the license to practice medicine in Alabama of **Morris Wayne Cochran, MD**, license number MD.14439, Birmingham, AL.

◆ On Feb. 10, the Commission entered an Order denying the request to terminate restrictions on the license to practice medicine in Alabama of **Oscar V. Fadul, MD**, license number MD.9585, Huntsville, AL, and providing for a plan of chart review.

♦ On Feb. 10, the Commission entered an Order lifting the suspension on the license to practice medicine in Alabama of Stephen Chalko Jacob, MD, license number MD.18772, Douglasville, GA, subject to certain conditions.

◆ On Feb. 10, the Commission entered an Order terminating all restrictions on the license to practice medicine in Alabama of **Benjamin H. Johnson, MD**, license number MD.9687, Birmingham, AL.

◆ On Feb. 10, the Commission entered an Order terminating all restrictions on the license to practice medicine in Alabama of **Anthony Lessa**, **MD**, license number MD.26315, Birmingham, AL.

 ♦ On Feb. 10, the Commission entered an Order indefinitely suspending the license to practice medicine in Alabama of Wade Anderson Young, MD, license number MD.14717, Tuscaloosa, AL.

◆ On Feb. 28, the Commission entered an Order denying the request to modify restrictions on the prescribing authority of **Scott H. Boswell, MD**, license number MD.16975, Jasper, AL.

◆ On Feb. 28, the Commission entered an Order approving the practice plan of **Allan C. Walls, MD**, license number MD.17151, Birmingham, AL.

BME – February 2012
♦ On Feb. 9, pursuant to the Order of the Montgomery County Cir-

cuit Court, the Alabama Controlled Substances Certificate of **Brian E. Cressman, MD**, ACSC number ACSC.19928, Jasper, AL, was revoked.

◆ On Feb. 15, the Board accepted the Voluntary Surrender of the Alabama Controlled Substances Certificate of William E. Feist, MD, ACSC number ACSC.19606, Birmingham, AL.

BME – March 2012

◆ On Mar. 21, the Board accepted the voluntary surrender of the certificate of qualification and license to practice medicine of **Eloise K.L. Alexander**, **MD**, license number MD.13907, Huntsville, AL.

Actions taken regarding failure to comply with 2010 CME requirements (fine, additional CME required):

• Frank S. Pair, MD, license number MD.17448, Huntsville, AL (reprimand, fine, additional CME required).

Non-accredited PALS/ACLS/ATLS/ BLS courses

Your provider may not be accredited to confer AMA PRA Category 1 CreditTM. Be sure to check before certifying that you have met the annual CME requirement of 25 AMA PRA Category 1 CreditsTM or equivalent.

See <u>http://www.albme.org/</u> <u>cme.html</u> for the Board's web page on CME.



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Receive alerts for new public actions, agendas, newsletters and rules.

Look inside for important news from the Board of Medical Examiners that pertains to your license to practice medicine in Alabama.

All current licensees receive the Board of Medical Examiners *Newsletter and Report* at their address of record at no charge. Licensees may also choose to receive the newsletter by e-mail. Non-licensee subscriptions to the newsletter are by e-mail only.

If you would like to receive the newsletter by e-mail, please send a request to <u>masa@masalink.org</u>.

Change of Address

Alabama law requires that every licensed physician notify the Board of Medical Examiners in writing within 15 days of a change of the physician's practice location address and/or mailing address.