



Newsletter and Report

www.albme.org

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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.

Use of non FDA approved hormones

by Richard E. Blackwell, PhD, MD, FACOG, FACS

Following the misinterpretation and misrepresentation of the results of the Women’s Health Initiative that appeared in *JAMA* July 2002, the use of FDA regulated hormone replacement therapy (HRT and ERT) for the treatment of menopausal symptoms rapidly declined. Subsequently, desperate women responding to aggressive advertising by the compounding pharmacy industry began to try “bioidentical hormones.” These agents were being recommended by physicians, nurse practitioners and compounders with varying levels of training in endocrinology and women’s health. Some of these treatments were administered without adequate hospital privileges, call coverage, availability of ultrasound, adequate lab support, in office or outpatient surgery. This now represents a billion dollar industry and is of concern to the FDA and the major organizations that deal with hormone therapy. There is no FDA oversight of these preparations, dosage is not monitored and may be inconsistent, purity is not tested, safety is unknown, efficacy is unproven, and scientific evidence for the use of these agents is insufficient.

Patients consistently present with misin-

formation about these products. They are told that they are natural and not synthetic, will not cause breast cancer and are safe. The major compounders were taken to task about this false advertising and other issues in 1997. This resulted in litigation and the compounders arguing that this abridged their first amendment rights (Western Case). Patients are told they need biestrogens or triestrogens, with testosterone, and progesterone whether they have undergone hysterectomy or not. This consistently results in little or no circulating progesterone and estradiol and male levels of testosterone.

All of the HRT/ERT products are made from soy with the exception of the
see Hormones, page 2



Richard E. Blackwell PhD, MD, FACOG, FACS

**Dr. Blackwell is Professor of Reproductive Endocrine Department of Obstetrics and Gynecology Women’s and Infants Center University of Alabama at Birmingham.*

NOTICE:

Changes to Office Based Surgery Rules

The Board is in the process of amending rules in Chapter 540-X-10, Office Based Surgery, to add special requirements for physicians performing tumescent liposuction using minimal sedation or local anesthesia. The Board is also considering modifications to the registration requirements for physicians performing office-based procedures. Developments will be posted at the Board’s website (www.albme.org) under “What’s New.”

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A Message from the Executive Director Mobile health screening

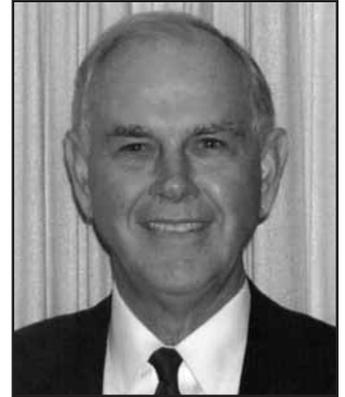
by Larry Dixon

You may have seen advertisements for mobile health screening units that travel to community centers, churches or other public places and offer to perform various tests, such as echocardiogram, carotid artery ultrasound or bone density tests. These units are officially termed “Independent Physiological Laboratories” and are regulated by the Alabama Department of Public Health (ADPH).

You may also have had patients ask you about obtaining one or more of these tests, or you may have had patients bring you test results or even DVD images of their ultrasound tests. If you find yourself in this situation, you should be aware that ADPH has rules governing mobile screening units, including a requirement to have an Alabama licensed medical director and having the medical director or other licensed physician interpret the diagnostic physiological testing results. These rules also include certain consulting and follow up requirements for carotid artery, abdominal aorta, ankle brachial vascular, or any other testing utilizing Doppler technology and ultrasonography.

If you are interested in reading the text of the rules, visit the ADPH website www.adph.org/providers/assets/ICL&IPLRulesAmended01202006.pdf.

If a patient provides you with a report of results that seems inaccurate, incomplete or otherwise suspicious, you should report the independent physiological laboratory to the Bureau of Health Provider Standards, CLIA Lab Unit, (334) 206-5120.



Larry Dixon

Hormones

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Premarin family. The parent cyclic structure is modified to form estradiol (E2), estrone (E1), estriol (E3), progesterone (P4), testosterone, and DHEA. Only E2, P4 and testosterone play a physiological role. E1 is a weak metabolite of E2, and E3 is made by the placenta during pregnancy to dilate the uterine arteries. DHEA has no direct biological activity but is changed into estrogens or androgens at the tissue level. Oral delivery of DHEA lowers HDL by 17 percent in three months.

Therapy and doses are often based on salivary assays. These assays are inaccurate save for cortisol obtained at very specific times. There is great cycle to cycle variation. Ranges for

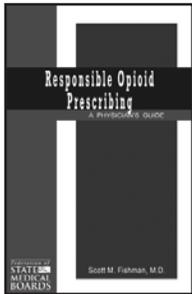
menopause don't exist. In fact, blood levels of testosterone and estradiol are inaccurate in the lower range. The lab should be used to assess safety, not dosage.

The Endocrine Society, North American Menopausal Society, ACOG, FDA, and American Society of Reproductive Medicine have issued position papers and guidelines regarding the use of bioidentical hormones. A summary follows:

- Women with a uterus need P4 therapy to protect the endometrium. P4 should be given orally as topical delivery produces very inconsistent blood levels and does not protect against adenocarcinoma. If unopposed E2 is

see *Hormones*, page 3

Responsible Opioid Prescribing: A Physician's Guide available for online purchase



Responsible Opioid Prescribing: A Physician's Guide offers physicians effective strategies for reducing the risk of addiction, abuse and diversion of opioids that they pre-

scribe for their patients in pain. This concise, 150-page book offers pragmatic steps for risk reduction and improved patient care, including:

- Patient evaluation, including risk assessment
- Treatment plans that incorporate functional goals
- Informed consent and prescribing agreements
- Periodic review and monitoring of patients
- Referral and patient management
- Documentation
- Compliance with state and federal law

Written by pain medicine specialist Scott M. Fishman, MD, chief of the Division of Pain Medicine at the University of California, Davis, the book translates the Federation of State Medical Boards' (FSMB) consensus model policy on pain management into practical, office-based pain management guidelines. FSMB's model was also used when the Alabama Board of Medical Examiners adopted its administrative rule, Guidelines for the Use of Controlled Substances for the Treatment of Pain. *Responsible Opioid Prescribing: A Physicians Guide* is available at www.fsmb.org for \$12.95.

The Alliance of State Pain Initiatives sponsors a *Responsible Opioid Prescribing* CME activity designated for a maximum of 7.25 *AMA PRA Category 1 Credits*[™]. To receive credit, participants purchase and read the book, register and pay for the activity (currently \$30), and complete

an online post-test and evaluation. For more information, please see the link below.

On the Net:

Order *Responsible Opioid Prescribing* online: www.fsmb.org *Responsible Opioid Prescribing* CME activity:

<http://www.aspi.wisc.edu/rop.html> FSMB's Model Policy for the Use of Controlled Substances for the Treatment of Pain:

http://www.fsmb.org/pdf/2004_grp_of_Controlled_Substances.pdf

Alabama Board of Medical Examiners' Rule 540-X-4-.07, Guidelines for the Use of Controlled Substances for the Treatment of Pain (scroll down to section .07):

<http://www.alabamaadministrativecode.state.al.us/docs/mexam/MicrftWrd4MEXAM.pdf>

Hormones

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used with few exceptions, ultrasound, biopsy, hysteroscopy, and D&C should be used to assess the endometrium.

- Women without a uterus don't need P4. Even during reproductive life the levels peak at 5-10ng/ml at mid luteal phase and is nearly immeasurable any other time. Its use may increase breast cancer risk.

- Biotrogens and triestrogens contain E3, which according to FDA may not be used in humans without an Investigational New Drug application. This requires a research protocol and Institutional Review Board review and approval.

- The hormone pellets developed by Robert Greenblatt, MD, four decades ago have no place in current

therapy. Patients are being seen daily with bleeding, dysphoria, hirsutism, voice pitch change, aggression, clitromegaly, hyperplasias and cancers of the uterus. Patients have been seen in my office with E2 levels of 7000pg/ml (<40pg/ml in menopause) and testosterone levels of 1700ng/dl (male range 250-900ng/dl). Some of these pellets have taken two years to clear from the system. This puts patients at great risk as well as those who insert and make them.

- Custom made preparations using FDA regulated drugs can be used provided that physicians and patients



understand their risks, limitations and appropriate monitoring.

Practitioners are referred to the websites of the previously mentioned organizations. There appear numerous position papers, guidelines and articles with hundreds of references at the sites. One should understand that the use of these hormone

preparations, despite oversight by the State Board of Pharmacy, DEA, OSHA, EPA, and NRC, falls below the standards set by the national organizations representing women's health and should be discouraged.

DEA Policy Change: Prescriber's 'Authorized Agent'

On Oct. 6, 2010, the U.S. Drug Enforcement Administration (DEA) issued a statement concerning the role of authorized agents in communicating controlled substance prescriptions to pharmacies. An "agent" is defined as "an authorized person who acts on behalf of or at the direction of a ... dispenser." The term "dispense" includes "prescribing."

DEA summarizes the acts that an agent may take in connection with controlled substance prescriptions as follows:

- An authorized agent of an individual practitioner may prepare a written prescription for the signature of the practitioner, provided that the practitioner, in the usual course of professional practice, has determined that there is a legitimate medical purpose for the prescription and has specified to the agent the required elements of the prescription.
- Where a DEA-registered individual practitioner has made a valid oral prescription for a controlled substance in Schedules III-V by conveying all the required prescription information to the practitioner's authorized agent, that agent may telephone the pharmacy and convey the prescription information to the pharmacist.
- In those situations in which an individual practitioner has issued a valid written prescription for a controlled substance, and the regulations permit the prescription to be transmitted by fax to a pharmacy, the practitioner's agent may transmit the **practitioner signed (not a reproduced signature)** prescription to the pharmacy by fax.



DEA stresses that agents should be clearly identified as such, and their activities should be subject to evaluation. The practitioner is responsible for ensuring that all prescriptions comply with all regulations and therefore should decide who may act as an agent. DEA suggests considering the degree of control that the registrant may exercise over the proposed agent, the proposed agent's licensure, level of training and experience, and other such factors to determine

whether the person would be an appropriate agent.

DEA believes it is in the best interests of the practitioner, the agent and the dispensing pharmacist that the agent designation be reduced to writing, and DEA provides an example of such a written agreement. Individual practitioners may choose to authorize one or more persons at one or more locations within or outside their practice to act as their agent. Likewise, an individual may act as an authorized agent for multiple individual practitioners, depending upon the circumstances. The agreement should be clear that the agent may not further delegate the outlined responsibilities.

A signed copy of the agreement should be provided to the agent, the agent's employer (if other than the practitioner), and any pharmacies that regularly receive communications from the agent pursuant to the agreement. This may assist pharmacies with their responsibilities regarding the dispensing of controlled substances. Keep in mind that even where the pharmacist has a copy of an agency agreement, the pharmacist may also have a duty to inquire fur-

ther depending upon the particular circumstances. If the agency agreement is terminated, the practitioner should notify those pharmacies that were originally made aware of the agency agreement of the termination of that agreement. In most circumstances where an agent changes employment, the agreement should be revoked.

On the Net:

Read the entire policy at http://www.dea diversion.usdoj.gov/fed_regs/rules/2010/fr1006.htm

www.albme.org

The following forms are available on the BME's Website:

- Retired Senior Volunteer license application
- Request for waiver from CME due to retirement
- Address change form
- Application for replacement of lost or destroyed license
- Malpractice payment report form for insurance companies
- Dispensing physician registration form
- Office based surgery registration form
- Office based surgery adverse event reporting form
- Laser/pulsed light device procedures registration form
- Laser/pulsed light device procedure adverse event reporting form

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

MLC – September 2010

◆ On Sept. 9, the Commission entered an Order placing on indefinite probation the license to practice medicine in Alabama of **Christopher P. Gay, DO**, license number DO.687, Sheffield, AL, with certain restrictions.

◆ On Sept. 22, the Commission entered an Order revoking the license to practice medicine in Alabama of **Rangarao V. Gummadapu, MD**, license number MD.7800, Selma, AL.

◆ On Sept. 27, the Commission entered an Order lifting the suspension of the license to practice medicine in Alabama of **Robert H. Carlson, MD**, license number MD.8549, Birmingham, AL, to practice only under the supervision of a Commission approved physician with quarterly reports to the Commission.

◆ On Sept. 27, the Commission entered an Order that will lift the suspension of the license to practice medicine in Alabama of **Anthony Lessa, MD**, license number

MD.26315, Birmingham, AL, upon his successful completion of the Special Purpose Examination; thereafter, his practice is limited to employment with the Hale County Health Authority with monthly reports to the Commission.

MLC – October 2010

◆ On Oct. 27, the Commission entered an Order summarily suspending the license to practice medicine in Alabama of **John A. Kreisberg, MD**, license number MD.22819, Mobile, AL, until such time as the Administrative Complaint of the Board shall be heard by the Commission and a decision rendered thereon.

BME – October 2010

◆ On Oct. 15, **William R. Jordan, MD**, license number MD.13263, Smiths, AL, entered an Amended Voluntary Restriction on his certificate of qualification and license to practice medicine in Alabama.

MLC – November 2010

◆ On Nov. 5, the Commission entered an Order assessing an administrative fine against the license to practice medicine in Alabama of **Jose Juan Chung, MD**, license number MD.19309, Montgomery, AL.

◆ On Nov. 5, the Commission entered an Order assessing an administrative fine against the license to practice medicine in Alabama of **Dan Stephen Hollis, MD**, license number MD.8278, Auburn, AL.

BME – November 2010

◆ On Nov. 17, the Board accepted the voluntary surrender of the certificate of qualification and license to practice medicine in Alabama of **John P. Moore Jr., MD**, license number MD.9967, Dothan, AL.

◆ On Nov. 17, the Board accepted the voluntary surrender of the certificate of qualification and license to practice medicine in Alabama of **Joseph P. Thomas, MD**, license number MD.9744, Mobile, AL.

Meet the Staff - Burke Britton Savage

Ms. Savage joined the Board staff in November 2006 as receptionist and administrative assistant.

In addition to handling the busy switchboard, Ms. Savage acts as Verifications Coordinator, responding to requests for written license verifications and providing verbal public licensee information to requesting callers.

She is also responsible for address change requests and other administrative duties.

FDA Electronic Tools

The U.S. Food and Drug Administration (FDA) offers a growing number of electronic tools for accessing important safety information on medical products. You can subscribe to safety alerts for medical products and safety-related drug labeling changes; view the alerts at the FDA website and download audio broadcasts (podcasts). FDA makes updated prescription drug labels available to physicians free of charge through the National Library of Medicine's DailyMed website. Drug and device manufacturers are also turning to electronic methods to disseminate safety information in a timely, targeted and secure manner.

On the Net:

FDA MedWatch (medical product safety information):

<http://www.fda.gov/medwatch/safety.htm>

National Library of Medicine's DailyMed Web site:

<http://dailymed.nlm.nih.gov/dailymed/about.cfm>

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***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 masa@masalink.org.

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.