Alabama Board of Medical Examiners
Newsletter and Report
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Inside:

Board discourages use of HCG for treatment of obesity

*by George C. Smith Jr., MD**

The Board has expressed concern about the use of human chorionic gonadotropin (also sometimes referred to as gonadotrophin) hormone (HCG) for weight loss and wants to inform physicians of its current view concerning this practice.

HCG became of interest to the bariatric community after a study was published in 1954 by Dr. Albert T. Simeons[1]. He gave obese subjects a total dose of 5,000 IU of the hormone in daily injections of 125 IU. He reported significant decreases in measurements around the hips and waists of the subjects within ten days, loss of appetite and very few side effects. Male and female patients on a 500 calorie diet who received daily injections of HCG for 40 days lost significant amounts of weight. This study created quite a sensation, and over the next several years, there were multiple attempts by scientists to reproduce these results using double blind studies. The overwhelming evidence has been that there is no statistical difference in a control group receiving placebo and the group receiving HCG. The following table[2] summarizes six of these clinical trials. Note that five of them show no benefit, and the Asher and Harper study has been criticized for its statistical and treatment methods.

George C. Smith Jr., MD

**Dr. Smith practices family and emergency medicine in Lineville and Anniston. He is board certified in family medicine and has been a member of the Board of Medical Examiners since 2005.*

Clinical trials of human chorionic gonadotropin (HCG) in the management of obesity

Investigators, year of report, no. of patients	Study protocol	Results
Asher and Harper[3], 1973, n = 40	Randomized, double-blind*	Improvement, but HCG-treated patients were given more doses
Young and colleagues[4], 1976, n = 202	Randomized, double-blind, crossover*	No benefit
Stein and associates[5], 1976, n = 51	Randomized, double-blind*	No benefit
Shetty and Kalkhoff[6], 1977, n = 6	Randomized, double-blind; in hospital†	No benefit
Miller and Schneiderman[7], 1977, n = 19	Prospective, double-blind, cross-over*	No benefit
Greenway and Bray[8], 1977, n = 20	Randomized, double-blind*	No benefit

*Deep intramuscular injections, 125 IU/d for 6 days a week for 6 weeks, combined with a diet supplying 500 to 550 Cal (2100 to 2310 kJ) daily.
†Deep intramuscular injections, 125 IU/d for 30 days, combined with a diet supplying 500 Cal daily.

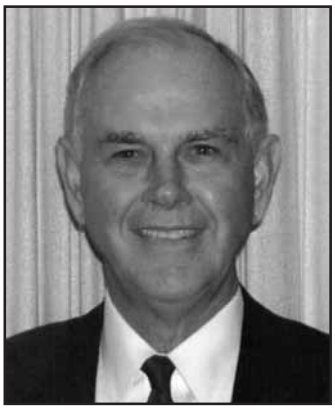
see HCG treatment, page 3

A Message from the Executive Director

Annual report of the Alabama BME

by Larry Dixon

In 2009 there was a small decrease in the number of newly licensed physicians in Alabama, with 594 approved applicants by endorsement and 136 approved applicants by examination, 49 fewer approved applicants than in 2008. We experienced an increase in collaborations with advanced practice nurses, with 734 collaborations approved, an increase over 2008 of 80. The Board of Medical Examiners and its staff have compiled the following Annual Report for your information.



Larry Dixon

A. APPLICANTS CERTIFIED TO MEDICAL LICENSURE COMMISSION
1. Applicants by endorsement 594
   a. Non-disciplinary Citation with Administrative Charge 13
2. Applicants by examination 136

B. APPLICANTS CERTIFIED FOR LIMITED LICENSE 94

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2. Applicants failing examinations 3

D. APPLICANTS FOR OUT OF STATE ENDORSEMENT 2

E. ADVANCED PRACTICE NURSES (CRNP/CNM)
1. Certified Registered Nurse Practitioner Collaborations Approved 731
2. Certified Nurse Midwife Collaborations Approved 3

F. PHYSICIAN ASSISTANTS
1. Physician Assistants Licensed 44
2. Physician Assistants Registered to Physicians (new applications) 194
3. Physician Assistants Granted Temporary Licensure 23
4. Temporary Licensure Converted to Full Licensure (after passing exam)... 23
5. Temporary Licensees Granted Registration..... 21
6. Anesthesiologist Assistants Licensed 1
7. Anesthesiologist Assistants Granted Temporary License 0
8. Anesthesia Assistants Registered to Physicians (new applications) 1

G. ACSC ISSUED / RENEWED 11,818

H. DISCIPLINARY / CONFIDENTIAL ACTIONS
1. ACSC Surrender / Revocation / Restriction / Reinstatement 6
2. Certificates of Qualification Denied / Surrendered..... 6

see BME Annual Report, page 4

HCG treatment

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HCG, marketed under the trade names A.P.L., Chorex, Pregnyl and Profasi, can be used for the treatment of prepubertal cryptocordism not due to anatomic obstruction and in selected cases of hypogonadotrophic hypogonadism secondary to pituitary deficiency in males. It is also occasionally used to induce ovulation. These are the only indications shown in the current FDA drug labeling. In fact, the FDA labeling states:

> *HCG has not been demonstrated to be effective adjunctive therapy in the treatment of obesity. There is no substantial evidence that it increases weight loss beyond that resulting from caloric restriction, that it causes a more attractive or "normal" distribution of fat, or that it decreases the hunger and discomfort associated with calorie-restricted diets.*

One non-label (and illegal) use of HCG is to stimulate the production of natural testosterone in subjects who have been using anabolic steroids for muscle building. In other words, it is often used to try to mask the side effects of exogenous steroids on the testosterone producing system.

HCG probably received its most widespread publicity from the infomercials of Kevin Trudeau. His 2007 book, *The Weight Loss Cure They Don't Want You to Know About*, claimed that "an absolute cure for obesity was discovered almost 50 years ago, but was 'suppressed' by the AMA, FDA, and 'other medical establishments throughout the world.'"[9] In September 2007, the FTC charged Kevin Trudeau with violating a court order by misrepresenting the contents of the book and infomercials. Trudeau falsely claimed that the book's weight loss plan was easy to do, can be done at home, and ultimately allowed readers to eat whatever they wanted. The use of HCG was the central tenet of that book.

In summary, the use of HCG is extremely controversial and perhaps even harmful. It is associated with illegal muscle-building steroid use and has never been proven in double-blind studies to be an effective weight loss adjunct. Considering that the injections cost from $36 to $45 for three ampules of 5,000 IU each plus $12 to $15 for 5,000 IU of the compounds that are mixed with the HCG powder, its only proven weight loss is to patients' wallets. The Alabama Board of Medical Examiners views this practice as dubious medicine bordering on quackery and will take a dim view of its continued use.

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[1]Simeons ATW. The action of chorionic gonadotrophin in the obese. Lancet 2:946-947, 1954.

[2]Birmingham CL, Smith, DC. Human chorionic gonadotropin is of no value in the management of obesity. *Can Med Assoc J* 1983; 128: 1156-1157.

[3]Asher WL, Harper H: Effect of human chorionic gonadotrophin on weight loss, hunger, and feeling of well-being. *Am J Clin Nutr* 1973; 26: 211-218.

[4]Young RL, Fuchs RJ, Woltjen MJ: Chorionic gonadotropin in weight control. A double-blind crossover study. *JAMA* 1976; 236: 2495-2497.

[5]Stein MR, Julis RE, Peck CC, Hinshaw W, Sawicki JE, Deller JJ: Ineffectiveness of human chorionic gonadotropin in weight reduction: a double-blind study. *Am J Clin Nutr* 1976; 29: 940-948.

[6]Shetty KR, Kalkhoff RK: Human chorionic gonadotropin (HCG) treatment of obesity. *Arch Intern Med* 1977: 137: 151-155.

[7]Miller, R, Schneiderman, LJ: A clinical study of the use of human chorionic gonadotrophin in weight reduction. *J Fam Pract* 1977; 4: 445-448.

[8]Greenway FL, Bray GA: Human chorionic gonadotropin (HCG) in the treatment of obesity; a critical assessment of the Simeons method. *West J Med* 1977; 127: 461-463.

[9]Trudeau K. The Weight Loss Cure They Don't Want You to Know About. Alliance Publishing, 2007.

www.albme.org

The following forms are available on the BME's Web site:

- Retired Senior Volunteer license application
- CME worksheet
- 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
- Notification of commencement or termination of collaborative practice
- Collaborative practice QA forms, chart review audits

Office-based surgical procedures

In 2003, the Board adopted rules governing surgical procedures performed in a physician's office or clinic (outside a hospital or outpatient facility licensed by the Department of Public Health). In this rule, "surgery" is defined as "the revision, destruction, incision or structural alteration of human tissue performed using a variety of methods and instruments." If you perform such procedures in your office or clinic, you should thoroughly read and comply with these administrative rules. See the Board's Web page concerning office-based surgery.

Physicians performing office-based surgery using moderate or deep sedation/analgesia (as defined in the rules) must meet the requirements of the rules, **including registration with the Board** and maintaining certain equipment and supplies, and physicians must be able to document satisfactory completion of training, such as being Board certified or being an active candidate for certification by a Board approved by the American Board of Medical Specialties or comparable formal training. **Alternative credentialing for procedures outside the physician's core curriculum must be approved by the Alabama Board of Medical Examiners after application to the Board.** The physician and at least one assistant must be trained in and current in Advanced Cardiac Life Support (ACLS).

On the Net:
Board's web page concerning office based surgery:
http://www.albme.org/index.cfm?fuseaction=app.displayPage&pageID=42

BME Annual Report

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H. DISCIPLINARY / CONFIDENTIAL ACTIONS, cont.

3. Certificates of Qualification with Agreements / Restrictions	2
Certificate of Qualification Restrictions Terminated	1
4. Letters of Concern	81
5. Complainant Inquiries Received	748
6. Complainant Inquiries Resolved	587
7. Complainant Inquiries Pending	49
8. Complainant Formal Investigations	112
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Formal Investigations Pending	21
9. Collaborative Practice Inspections	108
10. Collaborative Practice Compliance Seminars	1
11. Office Based Surgery Site Inspections	0
12. Interviews Conducted	68
13. Complaints filed with Medical Licensure Commission	32
14. Evaluations Ordered	9
15. Voluntary Agreements Entered Into	5
Voluntary Agreements Removed	1
16. Voluntary Restrictions Entered Into	0
Voluntary Restrictions Removed	0
17. Flag File for Reinstatement	3
18. Impaired Physician Coordinator Monitoring	71
Number monitored since 1990	890
19. Requested CME Course Attendance	12
20. Sent for Expert Review	7
21. Assessments (MLC/BME)	34
Administrative Fines	25
Administrative Costs	9
22. Summary Suspensions	4
Summary Suspension B Surrendered	1
Summary Suspension B Pending a Hearing before the MLC	3
23. Voluntary Surrender of Alabama Medical License	6

Meet the Staff

Kathy Burkett was employed by the Board in 2003 to provide assistance to the investigative division. Her administrative skills were quickly recognized, and soon her duties included assisting Mr. Ed Munson, Senior Investigator, with the complaints department, along with her responsibilities of records management and administrative support. Ms. Burkett is usually the first person encountered by complainants and may contact the physician for further information or clarification. Cooperation and responsiveness in these instances can often avert the instigation of a full investigation.

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.

Rules governing the use of lasers

In 2007, the Board adopted rules governing the use of lasers in a physician's office.

Who is affected

The rules affect physicians providing ablative and non-ablative treatments which utilize lasers/pulsed light devices or any energy source, chemical, or other modality that affects living tissue (when referring to the skin, anything below the statum corneum), whether applied for surgical, therapeutic or cosmetic purposes.

Registration requirement

Physicians who use or offer to use a laser/pulsed light device in any facility other than a hospital must register with the Board.

Who may perform what procedures

The use of lasers/pulsed light or other energy devices for **ablative** procedures may only be performed by a physician.

The use of lasers/pulsed light or other energy devices for **non-ablative** procedures may be delegated to a Level 1 Delegate[1] or a Level 2 Delegate[2], but these procedures cannot be delegated to Level 2 Delegates without the delegating/supervising physician being on-site and immediately available. Electrocautery may be used by a Level 1 or Level 2 Delegate under direct physician supervision[3]. Prior to any non-ablative initial treatment, the physician must examine the patient, establish a treatment plan, and sign the patient's chart.

Supervision

The rules state what will be considered adequate supervision, which includes (but is not limited to) the formulation or approval of a written protocol, evaluating the technical skills of the delegate and responding appropriately to complications and untoward effects of the procedures. All physicians subject to these rules should carefully read and comply with this (and every) section of the rules.

Education requirements

The rules state particular education requirements for physicians, Level 1 and Level 2 Delegates. Physicians are responsible for ensuring they and any delegates meet these requirements prior to performing any of these procedures.

Quality assurance program

The Board requires that physicians ensure there is a quality assurance program for the facility where non-ablative procedures are performed. The rules further specify what should be included in a quality assurance program.

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[1]Level 1 Delegate - a mid-level practitioner (physician assistant or advanced practice nurse) who is authorized in a written job description or collaborative protocol to use a specific laser/pulsed light device or other energy source, chemical or other modality for non-ablative procedures, as designated in the written job description or collaborative protocol and who has met the educational requirements for a Level 1 Delegate stated in the rules.

[2]Level 2 Delegate - any person, other than a Level 1 Delegate, who has met the educational requirements for Level 2 Delegates stated in the rules.

[3]Direct supervision is defined as: "the physician is in the physical presence of the patient being treated and is directly observing the use of the modality by a delegate."

On the Net:
Board's web page about use of lasers (includes link to rules):
http://www.albme.org/index.cfm?fuseaction=app.displayPage&pageID=48

Collaborative Agreements in Alabama

Currently, there are more than 2,000 active collaborative agreements between physicians and Certified Registered Nurse Practitioners/ Certified Nurse Midwives. About 70 to 100 new agreements are approved on a bi-monthly basis.

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

Friday, April 9, 2010 – 9:00 a.m. until 12:15 p.m.
Von Braun Center – Huntsville, Alabama

Presented by:
The Medical Association of the State of Alabama, The Alabama Board of Medical Examiners, and The Alabama Board of Nursing

A Collaborative Practice Seminar will be presented during the Medical Association of the State of Alabama's Annual Session. The seminar is open to both members and non-members of MASA for a registration fee of $100.

For more information, contact the MASA Education Department at (334) 954-2500 or sfletcher@masalink.org.

Treating and prescribing to family members

The Board frequently receives inquiries from licensees, pharmacists and others concerning the Board's position on treating and prescribing to one's self or family members. The Board looks to the ethical opinion of the American Medical Association's Council on Ethical and Judicial Affairs when considering unprofessional conduct issues.

AMA opinion E-8.19, Self Treatment or Treatment of Immediate Family Members, states that physicians generally should not treat themselves or members of their immediate families except in emergency settings or isolated settings where there is no other qualified physician available and only until another physician becomes available. Except in emergencies, it is not appropriate for physicians to write prescriptions for controlled substances for themselves or immediate family members.

In addition, in Administrative Rule 545-X-4-.06, the Medical Licensure Commission includes in its definition of unprofessional conduct "**prescribing or dispensing a controlled substance to oneself or to one's spouse, child, or parent, unless such prescribing or dispensing is necessitated by emergency or other exceptional circumstances.**"

The Board has requested that pharmacists contact the Board if they experience physicians writing controlled substances to family members, or especially to themselves. It can avert future problems for the physician who is simply acting out of ignorance or be the catalyst for help for an impairment issue. Very few physicians lose their license on a first time impairment issue. Physicians should always interact with pharmacists with professionalism, particularly when a pharmacist questions or needs clarification on a prescription.

On the Net:
AMA web site: **http://www.ama-assn.org**
MLC Administrative Rules:
http://www.alabamaadministrativecode.state.al.us/docs/mlic/index.html

The Medical Association of the State of Alabama and The Alabama Board of Medical Examiners present:

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

The 2010 Series

Controlled substances are prescribed and dispensed today at an increasing rate to help patients cope with pain, insomnia, anxiety, depression, obesity and myriad other disorders. Studies show that most practitioners are rather conservative when prescribing controlled drugs while a small number are at times overly aggressive. In addition, controlled prescription medications are falling into the hands of increasing numbers of prescription drug abusers.

This Intensive Course in Prescribing Controlled Drugs is designed for physicians and physician assistants in all specialties who need or wish to increase their knowledge and ability to effectively prescribe and control medications without the potential for abuse.

APRIL 10 - 11
Embassy Suites, Huntsville
Registration: $250
Registration Deadline: March 22
The April Prescribing Seminar WILL NOT include the 4-hour Pharmacology Class.
Accommodations:
Call (800) EMBASSY or visit
www.embassysuiteshuntsville.com
Room Code: MAS

JULY 30 - AUGUST 1
Sandestin Golf and Beach Resort, Destin, Florida
Registration: $375
Registration Deadline: July 12
Accommodations:
Call (800) 320-8115 or visit
www.sandestin.com
Group Code: 22E65S
Room Block Cutoff: June 13

NOVEMBER 20 - 21, 2010
Renaissance Hotel & Spa at the Convention Center, Montgomery
Registration: $375
Registration Deadline: Nov. 1
Accommodations:
Call the Embassy Suites Montgomery at (334) 269-5055 or visit
www.embassysuitesmontgomery.com
Group Code: MED
Room Block Cutoff: October 20

Registration forms and agenda are posted in the Education section of MASA's Web site, www.masalink.org.

For more information, contact the MASA Education Department at (334) 954-2500.

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

MLC – December 2009

◆ On Dec. 7, 2009, the Commission entered an Order reprimanding the license to practice medicine in Alabama of **Dan S. Hollis, MD**, license number **MD.8278**, Auburn, AL, and assessing an administrative fine.

◆ On Dec. 29, 2009, the Commission entered an Order placing on indefinite probation the license to practice medicine in Alabama of **Oliver Wilson Crawford Jr., MD**, license number **MD.28100**, Ozark, AL.

MLC – January 2010

◆ Upon the stipulation of the parties, on Jan. 27, the Commission entered an Order reprimanding the license to practice medicine in Alabama of **JuDonn T. Adams, MD**, license number MD.14027, Fayeteville, GA, assessing an administrative fine, and requiring compliance with the provisions of the Consent Order entered into with the state of Georgia on May 20, 2009.

BME – January 2010

◆ On Jan. 20, the Board accepted the Voluntary Restriction on the certificate of qualification and license to practice medicine of **Adolfo Robledo, MD**, license number MD.13102, Troy, AL.

◆ On Jan. 20, the Board accepted the voluntary surrender of the certificate of qualification and license to practice medicine in Alabama of **Jason M. Hunt, MD**, license number MD.29076, Guntersville, AL.

MLC – February 2010

◆ On Feb. 4, the Commission entered an Order denying the request of **Bryant H. Hudson III, MD**, license number MD.4228, Montgomery, AL, for reinstatement of his Alabama Controlled Substances Certificate.

◆ On Feb. 4, the Commission entered an Order suspending the license to practice medicine in Alabama of **Gilberto Sanchez, MD**, license number **MD.17969**, Montgomery, AL, for a period of six months.

BME – February 2010

◆ On Feb. 17, the Board revoked the Alabama Controlled Substances Certificate of **Eldred Mattatha Brunson, MD**, ACSC number ACSC.11237, Pelham, AL. Dr. Brunson is no longer authorized to write prescriptions for controlled substances.

◆ Upon the stipulation of the parties, on Feb. 17, the Board assessed an administrative fine against **Bret L. Fisher, MD**, license number MD.25887, Panama City, FL, for issuing controlled substances prescriptions without having obtained an Alabama Controlled Substances Certificate.

◆ On Feb. 22, the Board issued an Order deferring consideration of the application for reinstatement of certificate of qualification of **Ricky Joe Nelson, MD**, license number MD.12557, Hanceville, AL, until he sits for and passes the Special Purpose Examination, at which time the Board will again consider the matter.

MLC – March 2010

◆ On March 10, the Commisison entered an Order indefinitely suspending the license to practice medicine in Alabama of **Oscar V. Fadul, MD**, license number MD.9585, Huntsville, AL.

◆ On March 10, the Commission entered an Order denying the application of **Pascual Herrera, Jr., MD**, license number MD.13663, Leesburg, AL, to lift the probationary status of his license to practice medicine in Alabama.

◆ On March 10, the Commission entered an Order granting the application for a license to practice medicine in Alabama of **Rock Navarkal, MD**, license number MD.30114, Birmingham, AL, subject to indefinite probation.

◆ On March 10, the Commission entered an Order approving the practice plan filed by **Ervin Wells, MD**, license number MD.28241, Calera, AL, for his practice of medicine in Alabama.

◆ On March 10, the Commission entered an Order denying the application for reinstatement of the license to practice medicine in Alabama of **Michael David Williams, DO**, license number DO.426, Riverview, FL.

BME – March 2010

None to date.

Alabama State Board of Medical Examiners
Newsletter and Report

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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.