

APRIL 2004 | VOLUME 29 | NUMBER 2

# ENDOCRINE NEWS

NEWS AND INFORMATION FOR THE ENDOCRINE COMMUNITY

**ALSO INSIDE:**

**FAQ on Open  
Access**

**Thyroid  
Audioconference  
Report**

*Minority Students*  
**DISCOVER  
ENDOCRINOLOGY**

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### Shortcourse Helps Minority Students Discover Endocrinology

Developed by The Endocrine Society's Minority Affairs Committee, the Shortcourse Program is designed to introduce undergraduate minority students to endocrinology.

## ENDOCRINE NEWS™

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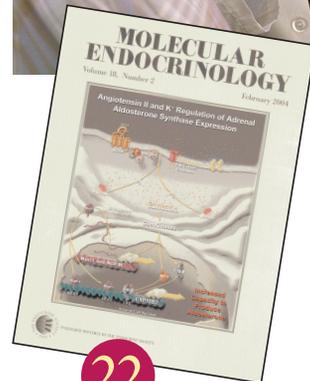
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**ENDO 2004**  
NEW ORLEANS ■ JUNE 16-19

# ENDO 2004

**New Orleans, Louisiana | June 16-19, 2004**

## Register By April 23rd and Save!

Don't forget, early bird registration for ENDO 2004 ends on April 23! Register by this date to receive Early Bird savings and secure your meeting and housing arrangements for New Orleans. Registering is easy at the ENDO 2004 Online Registration & Housing site: [www.endo-society.org/scimeetings/endo2004/index.cfm](http://www.endo-society.org/scimeetings/endo2004/index.cfm) Register by April 23 and you'll also receive your *Program and Abstracts* book by mail before the meeting.

## ENDO 2004 Housing Challenge

When registering for ENDO, be sure to make your housing arrangements through The Endocrine Society at [www.endo-society.org/scimeetings/endo2004/index.cfm](http://www.endo-society.org/scimeetings/endo2004/index.cfm) or by completing the registration forms found in ENDO conference brochures. The Society has worked diligently to secure rooms and negotiate the most competitive rates at 19 different New Orleans hotels.

### Reserving a room within the official ENDO '04 hotel block provides:

- Free access to shuttle service to and from your hotel to ENDO sessions at the convention center, Halls H and I.
- Access to timely and important program material that will be delivered to your hotel room
- Networking opportunities with colleagues from around the world, who will also be staying at your hotel.
- Free access to shuttle service from your hotel to the morning CMES symposia and back to your hotel after evening CMES symposia

Staying outside of the official ENDO hotel block impacts the Society's ability to negotiate discounts with hotels and may affect meeting financing which could result in increased registration fees in the future. For this reason, it is extremely important that you book your room at one of the official ENDO hotels. If you become aware of lower rates at the participating hotels, please promptly notify the Society's meeting department at [meetings@endo-society.org](mailto:meetings@endo-society.org) If you need assistance with the registration process, please contact the ENDO'04 registrar, 1-888-695-5481 or 202-347-6659 or [ENDO@laser-registration.com](mailto:ENDO@laser-registration.com)

## New CME Opportunities at ENDO!

This year, 24 CMES ancillary sessions will be presented at ENDO 2004. Developed by the Society's Continuing Medical Education Services (CMES), along with the Special Programs Committee and CME Advisory Committee, the symposia will cover timely topics such as obesity, diabetes, thyroid disease, metabolic syndrome, cardiovascular endocrinology, growth-related disorders, testosterone therapy and more. Sessions will be held at the New Orleans Marriott before and after ENDO Plenary Sessions. There is no charge to attend, but seating is limited and registration is

strongly recommended to reserve space. View a complete listing of CME ancillary sessions and register online at [www.endo-society.org/scimeetings/endo2004/ancillary.cfm](http://www.endo-society.org/scimeetings/endo2004/ancillary.cfm)

All educational programs are CME accredited by the Society and are planned and conducted in strict compliance with the Essential Areas and their Elements of the Accreditation Council for Continuing Medical Education. Program subject to change.

## Traveling to ENDO from outside of the U.S? Apply for your Visa Early!

Responding to the attacks on September 11, 2001, the U.S. State Department's visa applications are now subject to a greater degree of scrutiny. Due to the new visa processing regulations, The Endocrine Society recommends scientists and students planning to attend ENDO 2004 apply for visas as early as possible. For helpful tips and important information regarding visa application procedures, please visit [www.endo-society.org/scimeetings/endo2004/infotravelous.cfm](http://www.endo-society.org/scimeetings/endo2004/infotravelous.cfm) and the U.S. Department of State Information Web site at [www.unitedstatesvisas.gov/](http://www.unitedstatesvisas.gov/)

## Organize for ENDO with the Online Itinerary Builder

Beginning in May, ENDO 2004 registrants can use the Online Itinerary Builder to build personalized schedules for the upcoming annual meeting. Users can search ENDO 2004 program information by topic, title, author, affiliation, presentation format, and presentation time. Access to the full text of all accepted abstracts is included, too. The Itinerary Builder is also PDA (personal digital assistant) compatible. Save time and plan ahead for the exciting events at ENDO 2004—build your itinerary online. Coming soon to [www.endo-society.org/scimeetings/endo2004/index.cfm](http://www.endo-society.org/scimeetings/endo2004/index.cfm)

## ENDO 2004 Online Exhibit Planner

Create a personalized exhibit planner that you can print out and bring with you to ENDO 2004. The online planner allows you to browse through exhibitor product descriptions and search by product category. Make sure you visit all the exhibits you need to see, plan your trip to the ENDO Exhibit Hall online at [www.endo-society.org/scimeetings/endo2004/index.cfm](http://www.endo-society.org/scimeetings/endo2004/index.cfm)

## ENDO Abstracts on CD-ROM

Society members that do not attend ENDO 2004 will receive abstracts on CD-ROM in lieu of the printed Program & Abstracts book. (Only meeting attendees will receive the print version.) With the CD-ROM, you can easily access all of the science presented at ENDO 2004 and search material by topic, title, author or affiliation. Meeting attendees can pick up a complimentary copy of the abstracts on CD-ROM at the GlaxoSmithKline booth in the ENDO 2004 Exhibit Hall. *This product is sponsored by an unrestricted grant from GlaxoSmith Kline Pharmaceuticals.*

For the latest information on ENDO 2004, visit [www.endo-society.org/scimeeting/endo2004/index.cfm](http://www.endo-society.org/scimeeting/endo2004/index.cfm)

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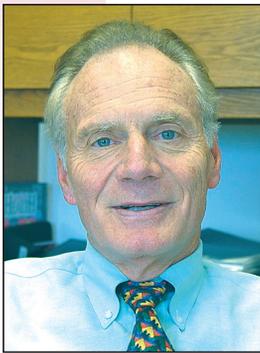
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**Dear Colleagues,**

Do you know why I like the annual meeting of The Endocrine Society? Well, there are at least three reasons. First, it is the only place in the world where you get the best information from all our constituencies at one time. It is amazing! Talk about 'Bench to Bedside back to Bench'... this meeting is where you will hear it all. Second, it is where everybody in endocrinology congregates. It is where you can see past fellows, students, colleagues and where you might just sit



*Chip Ridgway, M.D.*

next to a past Nobel Laureate or find yourself exchanging ideas with a future one. Third, I love the timing. The medical students have graduated, the dog days of summer have just started, the irises and day lilies are decorating the early morning and late evening and it is finally time for intellectual and spiritual renewal. I can still remember my early days at the Massachusetts General Hospital when we would all start getting excited about the annual meeting. Everybody would ask

"What did you send into Endo Soc?" The answer was always the same. "It doesn't matter, as long as it is your *very best stuff!*"

This year we have an outstanding and comprehensive program that was developed by an incredibly creative Annual Meeting Steering Committee led by Drs. Beverly Biller, Paul Stewart, and Stan McNight and brilliantly brought to life by that group over the past several months. The core of the program has 14 plenary lectures, a whopping 68 symposia and a record 150 meet-the professor sessions. There are penetrating basic science themes, enduring translational science, and durable clinical deliverables.

In December, I shared with you my rationale for selecting obesity to be the theme of ENDO 2004. Obesity is an international health crisis that continues to hold the attention of the world. It has become a health imperative, upon which endocrinology needs to focus its keen intellect and vast array of investigative and practice tools. We will emphasize the theme, "Obesity, Endocrinology and the Future" and weave important new discoveries into the fabric of our scientific sessions at ENDO. With input from the Obesity Task Force, chaired by Dr. Michael Jensen, the Annual Meeting Steering Committee has organized seven plenary lectures, 14 symposia and 20 meet-the-professor sessions related to the theme.

In addition to the educational sessions at ENDO, there are other events and activities planned that highlight the theme:

- Continuing Medical Education Services (CMES) breakfast and dinner programs have been planned that support the theme including a Pediatric Obesity symposium at 6:00 a.m. on Wednesday, June 16, developed by the Special Programs Committee and funded by the Society's Strategic Initiative Funds. Additional theme-related CMES programs include: "Role of Weight Loss in Influencing Metabolic Outcomes," on Thursday evening and "The Endocannabinoid System: Key Regulator of Energy Balance," which will be held on Friday morning.
- The Society's Corporate Liaison Board (CLB) will present its annual forum, "Addressing the Obesity Epidemic: From Bench to Bedside to Market," on Wednesday, June 16, at 6:30 p.m. at the New Orleans Marriott. This program continues the efforts of the CLB to support each year's meeting theme with an educational session that highlights the role of government, academia and industry in the evolu-

### **The core of the program has 14 plenary lectures, a whopping 68 symposia and a record 150 meet-the professor sessions.**

tion of disease management. We are especially pleased that, so far, Dr. Allen Spiegel, Director of the National Institute of Diabetes and Digestive Kidney Diseases (NIDDK), and Dr. Jose Caro, Eli Lilly Research, have agreed to participate. As many of you may know, Allen chaired the National Task Force on the Prevention and Treatment of Obesity for the National Institutes of Health (NIH).

- Health Check 2004 will again be available in the Exhibit Hall and will include not only routine health screening such as BMI, Glucose and Lipid Profile, but also several weight related tests such as fitness questionnaires and nutrition profiles. Other screening tests and procedures are being considered to help you determine your level of health and obesity risk factors. Health Check 2004 is supported by Abbott Diagnostics.

*Continued on page 16.*



# Shortcourse Helps Minority Students Discover Endocrinology

*by Nicholas Mulcahy*

In 2002, Dean Snow changed the direction of his life. He attended the Shortcourse in Endocrinology held at Montana State University-Bozeman.

A free-of-charge series of presentations offered at predominantly minority colleges, the Shortcourse Program was developed by The Endocrine Society's Minority Affairs Committee, with funding from the National Institute of General Medical Sciences (NIGMS), to introduce undergraduate students to endocrinology and to increase cultural diversity

in the field. In other words, to reach out to students like Dean Snow, a Gros Ventre Indian from Fort Belknap, Montana.

"The Shortcourse was really beneficial and had a big effect on me. I had not thought about endocrinology at the time, despite the impact of diabetes on Native Americans," says Mr. Snow.

However, after the Shortcourse Program, Mr. Snow entered the health prevention field, with a special interest in diabetes prevention. He is now Project Coordinator of the Fort Belknap College Wellness

Program, a college-based health initiative that extends into the community of the Fort Belknap Indian Reservation and includes a diabetes prevention program.

"We have hundreds of cases of diabetes in our small community on the reservation and we are seeing younger and younger kids being diagnosed," says Mr. Snow, whose wellness program is currently seeking additional funding due to the expiration of their Centers for Disease Control grant.

Mr. Snow has traveled to The Endocrine Society annual scientific



*Dr. James Mrotek lecturing at a Shortcourse Program.*

meeting on an ENDO Travel Grant provided by the NIGMS grant and has maintained professional relationships with Society members, including Dr. James Mrotek, Principal Investigator of the NIGMS grant. “Dr. Mrotek was a guest on my local radio call-in show. I interviewed him about endocrinology, obesity and diabetes and the show was really well

received. We received calls from listeners that I didn’t know were out there,” notes Mr. Snow.

Not every student that attends the Society’s Shortcourse Program has Dean Snow’s life-altering story to tell. However, since 1997, thousands of minority students have attended the Shortcourse Program at colleges and universities. Each year, approximately 30-40 Short-

courses are offered. “What’s so great about this program is that there are a lot of talented science students, but they tend to be generally interested in medicine, not specifically interested in endocrinology or research. The Shortcourse opens up whole new avenues for some students,” says Society member Dr. Victoria Luine, an endocrinologist, who has been a Shortcourse Program lecturer.

The Shortcourse Program is the outgrowth of efforts of Endocrine Society member Dr. Thomas Landefeld, who noted that many endocrine disorders such as diabetes and hypertension disproportionately affect people of color. In 1996, The Minority Affairs Committee, of The Endocrine Society, applied to the federal government for a three-year NIGMS grant to start the Shortcourse Program. In 2000, Dr. Theresa Duello renewed the grant for an additional five years. Dr. Mrotek took over as Principal Investigator of the grant and is preparing to reapply to extend the grant.

The Shortcourse depends on volunteers from the Society to act as teachers and ambassadors, explains Dr. Mrotek. “The Shortcourse taps into the membership who are established, excellent teachers,” he says. Institutions sign-up for the Shortcourse through a variety of avenues, adds Dr. Mrotek.

“Some colleges and institutions are contacted directly by the Society and others are approached by current Society members who are alumni. Alumni referrals are especially helpful in establishing trust between the Society and the host institution,” he explains.

A Shortcourse Program can take place over a period of one to five days. The course may be integrated into an existing biology class or offered as a freestanding workshop or symposium. Host institutions and volunteer lecturers arrange to choose the topics and format best suited to the student population.

## Sound Interesting? Want to Get Involved?

### SIGN UP NOW FOR MENTORING OPPORTUNITIES!

Volunteer as a mentor to Shortcourse Travel Grant awardees during ENDO 2004. Help minority students discover the world of endocrinology.

For more information, please contact Veronica Parcan [vparcan@endo-society.org](mailto:vparcan@endo-society.org)

### LEARN MORE AT ENDO 2004!

Don’t miss these events:

#### ■ Shortcourse Orientation Breakfast

Thursday, June 17, 2004  
7:00 – 8:00 a.m.

Provides an opportunity for members of The Endocrine Society to learn about the Shortcourse Program. Students and interested lecturers are encouraged to attend. For more information, please contact Veronica Parcan [vparcan@endo-society.org](mailto:vparcan@endo-society.org)

#### ■ Minority Mentoring Reception

Thursday, June 17, 2004  
6:30 – 8:30 p.m.

Provides a great networking opportunity to students and mentors. Mentors will be available at “topic tables” to address career challenges facing minority students, postdocs, fellows and junior faculty. The event is open to all ENDO 2004 minority registrants. For more information, please contact Kirsta Suggs at [ksuggs@endo-society.org](mailto:ksuggs@endo-society.org)

## SHORTCOURSE PROGRAM

“One of the challenges of teaching the Shortcourse is to present material in a way that peaks the interest of, and may even light a fire in students,” says Dr. Luine.

At the University of Southern Colorado, Dr. Luine found that students lit up to a discussion of corticosteroids once she began discussing stress. “Stress-related illnesses are usually present at higher levels in minority communities due to a relative lack of health care, poorer housing, environmental stresses, poor diet, obesity and other factors. So, the topic is amplified for these students,” she notes.

In addition to presenting basic principles of endocrinology, lecturers are invited to present their own research and discuss opportunities for graduate school as well as opportunities in private industry. Lecturers are also encouraged to participate in continuing education programs for health professionals, attend community events and conduct media interviews.

“While performing a Shortcourse at the University of Virgin Islands, I did a radio interview on Radio One, the island’s main radio station. Over the next few days, people repeatedly approached me to say they had heard the interview and to talk. Volunteering for a Shortcourse has many unexpected pleasures and the more you reach out, the more people reach back,” says Dr. Mrotek.

Lecturers are also asked to identify students who show a high level of interest during the Shortcourse Program. “Students may be offered a free one-year membership in the Society, special mentoring from Society members, travel grants to the annual meeting and internships as researchers in endocrinology labs,” notes Dr. Mrotek.

A native of Ecuador who immigrated to New York City at the age of 14, Luis Jacome consistently demonstrated a high level of interest in endocrinology as a student.

As an undergraduate majoring in psychology at Hunter College in New York City, Mr. Jacome attended the 2001 Annual Biomedical Research Conference for Minority Students. He won an Excellence in Endocrinology award at the meeting for his poster on the effect of estrogen and progesterone on memory and brain function. Also attending the meeting was Dr. Mrotek, who was impressed with the poster and eventually offered Mr. Jacome a free membership to The Endocrine Society.

Since joining the Society, Mr. Jacome has won ENDO Travel Grants to San Francisco and Philadelphia. “I love the endocrine meetings. If you are presenting, it is all about sharing and meeting people who are doing similar work,” he says. Mr. Jacome is now a graduate student at the City University of New York and works with Endocrine Society member Dr. Luine in her laboratory.

Mr. Jacome’s appreciation of The Endocrine Society is typical of those students who join the Society through the NIGMS grant.

“The Endocrine Society’s commitment to people of color is phenomenal!” raves Ms. Rama Mulukutla, a Shortcourse student gearing up for an internship this summer in neuroendocrinology at the Massachusetts General Hospital. “I assumed that the enthusiasm that I first witnessed from Dr. Mrotek at the Shortcourse was unique to him. But it’s not. When I received a travel grant to the meeting in Philadelphia, I learned the whole Society is like that,” she says.

“Out of all the different scientific conferences that I have been to, The Endocrine Society has the most congenial, down-to-earth membership.” That attitude of warmth and openness can make a crucial difference to a minority undergraduate student contemplating a science career, comments Mr. Snow. “The seriousness and



*Shortcourse Program attendee Mr. Luis Jacome and Dr. Victoria Luine mentor.*

earnestness of The Endocrine Society’s effort could push a student to pursue a career in addressing diabetes or some other endocrine-related science,” he says.

Still, Dr. Mrotek would like to see more students engaged in the field of endocrinology after participating in the Shortcourse Program. “We have been doing well in terms of holding Shortcourse at historically black colleges and have recently improved our efforts with the tribal colleges for Native Americans. We want to continue to improve at Hispanic institutions and with small and rural schools,” he notes.

The Shortcourse Program will also continue to strengthen its contact with the widest possible variety of institutions and minority populations, says Dr. Mrotek.

With the support of the Minority Affairs Committee the success of the Shortcourse Program will continue to blossom. Future plans include, renewing the NIGMS grant and requesting additional funding to promote and increase interest in endocrinology amongst under represented minority students. **EN**

*For more information about The Endocrine Society’s Shortcourse Program, please contact Veronica Parcan at [vparcan@endo-society.org](mailto:vparcan@endo-society.org) or 1-301-951-2601.*

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Levothyroxine sodium should not be used in the treatment of male or female infertility unless this condition is associated with hypothyroidism.

In patients with nontoxic diffuse goiter or nodular thyroid disease, particularly the elderly or those with underlying cardiovascular disease, levothyroxine sodium therapy is contraindicated if the serum TSH level is already suppressed due to the risk of precipitating overt thyrotoxicosis (see **CONTRAINDICATIONS**). If the serum TSH level is not suppressed, LEVOXYL® should be used with caution in conjunction with careful monitoring of thyroid function for evidence of hyperthyroidism and clinical monitoring for potential associated adverse cardiovascular signs and symptoms of hyperthyroidism.

## PRECAUTIONS

### General

Levothyroxine has a narrow therapeutic index. Regardless of the indication for use, careful dosage titration is necessary to avoid the consequences of over- or under-treatment. These consequences include, among others, effects on growth and development, cardiovascular function, bone metabolism, reproductive function, cognitive function, emotional state, gastrointestinal function, and on glucose and lipid metabolism. Many drugs interact with levothyroxine sodium necessitating adjustments in dosing to maintain therapeutic response (see **Drug Interactions**).

**Effects on bone mineral density** – In women, long-term levothyroxine sodium therapy has been associated with decreased bone mineral density, especially in postmenopausal women on greater than replacement doses or in women who are receiving replacement doses of levothyroxine sodium. Therefore, it is recommended that patients receiving levothyroxine sodium be given the minimum dose necessary to achieve the desired clinical and biochemical responses.

**Patients with underlying cardiovascular disease** – Exercise caution when administering levothyroxine to patients with cardiovascular disorders and to the elderly in whom there is an increased risk of occult cardiac disease. In these patients, levothyroxine therapy should be initiated at lower doses than those recommended in younger individuals with no underlying cardiac disease (see **WARNINGS, PRECAUTIONS, Geriatric Use, and DOSAGE AND ADMINISTRATION**). If cardiac symptoms develop or worsen, the levothyroxine dose should be reduced or withheld for one week and then cautiously restarted at a lower dose. Over-treatment with levothyroxine sodium may have adverse cardiovascular effects such as an increase in heart rate, cardiac thickening, and cardiac contractility and may precipitate angina or arrhythmias. Patients with coronary artery disease who are receiving levothyroxine therapy should be monitored closely during surgical procedures, since the possibility of precipitating cardiac arrhythmias may be greater in those treated with levothyroxine. Concomitant administration of levothyroxine and sympathomimetic agents to patients with coronary artery disease may precipitate coronary insufficiency.

**Patients with nontoxic diffuse goiter or nodular thyroid disease** – Exercise caution when administering levothyroxine to patients with nontoxic diffuse goiter or nodular thyroid disease. In these patients, overt precipitation of thyrotoxicosis (see **WARNINGS**). If the serum TSH is already suppressed, levothyroxine sodium should not be administered (see **CONTRAINDICATIONS**).

### Associated endocrine disorders

**Hypothalamic/pituitary hormone deficiencies** – In patients with secondary or tertiary hypothyroidism, additional hypothalamic/pituitary hormone deficiencies should be considered, and, if diagnosed, treated (see **PRECAUTIONS, Adverse Reactions, and Contraindications**).

**Autism spectrum and attention deficit hyperactivity disorder** – Occasionally, chronic autoimmune thyroiditis may occur in association with other autoimmune disorders such as adrenal insufficiency, pernicious anemia, and insulin-dependent diabetes mellitus. Patients with concomitant adrenal insufficiency should be treated with glucocorticoids prior to initiation of treatment with levothyroxine sodium. Failure to do so may precipitate an acute adrenal crisis when thyroid hormone therapy is initiated, due to increased metabolic clearance of glucocorticoids by thyroid hormone. Patients with diabetes mellitus may require upward adjustments of their antidiabetic therapeutic regimens when treated with levothyroxine (see **PRECAUTIONS, Drug Interactions**).

### Other associated medical conditions

Infants with congenital hypothyroidism appear to be at increased risk for other congenital anomalies, with cardiovascular anomalies (pulmonary stenosis, aortic septal defect, and ventricular septal defect), being the most common association.

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1. Notify your physician if you are allergic to any foods or medicines, are pregnant or intend to become pregnant, are breast-feeding or are taking any other medications, including prescription and over-the-counter preparations.
2. Notify your physician if you have any other medical conditions you may have, particularly heart disease, diabetes, clotting disorders, and adrenal or pituitary gland problems. Your doctor of medications used to control these other conditions may need to be adjusted while you are taking LEVOXYL®. If you have diabetes, monitor your blood and/or urinary glucose levels as directed by your physician. Do not stop or immediately report any changes to your physician. If you are taking anticoagulants (blood thinners), your clotting status should be checked frequently.
3. Use LEVOXYL® only as prescribed by your physician. Do not discontinue or change the amount you take or how often you take it, unless directed to do so by your physician.
4. The levothyroxine in LEVOXYL® is intended to replace a hormone that is normally produced by your thyroid gland. Generally, replacement doses of levothyroxine are given in cases of transient hypothyroidism, which is usually associated with an inflammation of the thyroid gland (thyroiditis).
5. Take LEVOXYL® in the morning on an empty stomach, at least one-half hour before eating any food.
6. It may take several weeks before you notice an improvement in your symptoms.
7. Notify your physician prior to initiation of treatment with levothyroxine sodium, rapid or irregular heartbeat, chest pain, shortness of breath, leg cramps, headache, nervousness, irritability, sleeplessness, tremors, change in appetite, weight gain or loss, vomiting, diarrhea, excessive sweating, heat intolerance, fever, changes in menstrual periods, rashes, skin rash, or any other unusual medical event.
8. Notify your physician if you become pregnant while taking LEVOXYL®. It is likely that your dose of LEVOXYL® will need to be increased during pregnancy.
9. Notify your physician or dentist that you are taking LEVOXYL® prior to any surgery.
10. Partial hair loss may occur rarely during the first few months of LEVOXYL® therapy, but this is usually temporary.
11. LEVOXYL® should not be used as a primary or adjunctive therapy in a weight control program.
12. Keep LEVOXYL® out of the reach of children. Store LEVOXYL® away from heat, moisture, and light.

### Laboratory Tests

The diagnosis of hypothyroidism is confirmed by measuring TSH levels using a sensitive assay (second generation assay sensitivity 0.1 mIU/L or third generation assay sensitivity 0.01 mIU/L) and measurement of free T<sub>4</sub>.

The adequacy of therapy is determined by periodic assessment of appropriate laboratory tests and clinical evaluation. The choice of laboratory tests depends on various factors including the etiology of the underlying thyroid disease, the presence of concomitant medical conditions, including pregnancy, and the use of concomitant medications. **Thyroid Function Tests and Drug-Laboratory Test Interactions** are discussed in **PRECAUTIONS, Laboratory Tests and Drug-Laboratory Test Interactions**. Persistent clinical and laboratory evidence of hypothyroidism despite an apparently adequate replacement dose of LEVOXYL® may be evidence of inadequate absorption, poor compliance, drug interactions, or decreased T<sub>4</sub> potency of the drug product.

### Adults

In adult patients with primary (thyroidal) hypothyroidism, serum TSH levels (using a sensitive assay) alone may be used to monitor therapy. The frequency of TSH monitoring during levothyroxine dose titration depends on the clinical situation and is recommended at 4-6 week intervals until normalization. For patients who have recently initiated levothyroxine therapy and whose serum TSH has normalized or in patients who have had their dosage or brand of levothyroxine changed, the serum TSH concentration should be measured after 8-12 weeks. When the optimum replacement dose has been attained (clinical (physical examination) and biochemical monitoring may be performed every 6-12 months, depending on the clinical situation, and whenever there is a change in the patient's status. It is recommended that a physical examination and a serum TSH measurement be performed annually in patients receiving LEVOXYL® (see **WARNINGS, PRECAUTIONS, and DOSAGE AND ADMINISTRATION**).

### Pediatrics

In patients with congenital hypothyroidism, the adequacy of replacement therapy should be assessed by measuring both serum TSH (using a sensitive assay) and total- or free- T<sub>4</sub>. During the first three years of life, the serum total- or free- T<sub>4</sub> should be maintained at all times in the upper half of the normal range. While the aim of therapy is to also normalize the serum TSH level, this is not always possible in a small percentage of patients, particularly in the first few months of therapy. TSH may not normalize due to a resetting of the pituitary-thyroid feedback threshold as a result of a *de novo* hypothyroidism. Failure of the serum T<sub>4</sub> to increase into the upper half of the normal range within 2 weeks of initiation of LEVOXYL® therapy and/or of the serum TSH to decrease below 20 mIU/L within 4 weeks should alert the physician to the possibility that the child is not receiving adequate therapy. Careful inquiry should then be made regarding compliance, dose of medication administered, and method of administration prior to raising the dose of LEVOXYL®.

The recommended frequency of monitoring of TSH and total- or free- T<sub>4</sub> in children is as follows: at 2 and 4 weeks after the initiation of treatment; every 1-2 months during the first year of life; every 2-3 months between 1 and 3 years of age; and every 3 to 12 months thereafter until growth is completed. More frequent intervals of monitoring are warranted if compliance is suspected or abnormal values are observed. It is recommended that TSH and T<sub>4</sub> levels, and a physical examination, if indicated, be performed 2 weeks after any change in LEVOXYL® drug. Routine clinical examination, including assessment of mental and physical growth and development, and compliance monitoring, should be performed at regular intervals (see **PRECAUTIONS, Pediatric Use and DOSAGE AND ADMINISTRATION**).

### Secondary (pituitary) and tertiary (hypothalamic) hypothyroidism

Adequacy of therapy should be assessed by measuring serum free-T<sub>4</sub> levels, which should be maintained in the upper half of the normal range in these patients.

### Drug Interactions

Many drugs affect thyroid hormone pharmacokinetics and metabolism (e.g., absorption, synthesis, secretion, catabolism, protein binding, and target tissue response) and may alter the therapeutic response to LEVOXYL®. In addition, thyroid hormones and thyroid status have varied effects on the pharmacokinetics and action of other drugs. A listing of drug-thyroid axis interactions is contained in Table 2.

The list of drug-thyroid axis interactions in Table 2 may not be comprehensive due to the introduction of new drugs that interact with the thyroid axis or the discovery of previously unrecognized interactions. The prescriber should be aware of this fact and should consult appropriate reference sources (e.g., package inserts of newly approved drugs, medical literature) for additional information if a drug-drug interaction with levothyroxine is suspected.

Drugs that alter thyroid hormone secretion	
<b>Drugs that may decrease thyroid hormone secretion, which may result in hypothyroidism</b>	
Aminoglutethimide Amitriptyline Iodine (including iodine-containing contrast agents) Lithium Methazolol Propylthiouracil (PTU) Sulfonamides Tolbutamide	Long-term lithium therapy can result in goiter in up to 50% of patients, and either subclinical or overt hypothyroidism, each in up to 20% of patients. The fetus, neonate, elderly and euthyroid patients with underlying thyroid disease (e.g., Hashimoto's thyroiditis or with Grave's disease previously treated with radioactive iodine or surgery) are among those individuals who are particularly susceptible to iodine-induced hypothyroidism. Some clinical, cytotoxic, and amiodarone are slowly cleared, producing more prolonged hypothyroidism than parenterally administered iodine contrast agents. Amiodarone may minimize decrease T <sub>4</sub> and T <sub>3</sub> levels and increase TSH, although all values remain within normal limits in most patients.
<b>Drugs that may increase thyroid hormone secretion, which may result in hyperthyroidism</b>	
Amiodarone Iodine (including iodine-containing contrast agents)	Iodide and drugs that contain pharmacologic amounts of iodide may cause hyperthyroidism in euthyroid patients with Grave's disease previously treated with antithyroid drugs or in euthyroid patients with thyroid autonomy (e.g., multinodular goiter or hyperfunctioning thyroid adenoma). Hyperthyroidism may develop over several weeks and may persist for several months after therapy discontinuation. Amiodarone may induce hyperthyroidism by causing thyrotoxicosis.
<b>Drugs that may decrease T<sub>4</sub> absorption, which may result in hypothyroidism</b>	
Antibiotic - Aluminum and Magnesium Hydroxides - Simethicone Bile Acid Sequestrants - Cholestyramine - Colestipol Calcium Carbonate Cation Exchange Resins - Kayexalate Ferrous Sulfate Sucralfate	Concurrent use may reduce the efficacy of levothyroxine by binding and delaying or preventing absorption, potentially resulting in hypothyroidism. Calcium carbonate may form an insoluble chelate with levothyroxine and ferrous sulfate likely forms a ferric-thyroxine complex. Administer levothyroxine at least 4 hours apart from these agents.
<b>Drugs that may alter T<sub>4</sub> and T<sub>3</sub> serum transport – but FT<sub>4</sub> concentration remains normal; and, therefore, the patient remains euthyroid</b>	
<b>Drugs that may increase serum TBC concentration</b>	
Clofibrate Estrogen-containing oral contraceptives Estrogens (oral) Heroin / Methadone 5-Fluorouracil Miltane Tamoxifen	<b>Drugs that may decrease serum TBC concentration</b> Androgens / Anabolic Steroids Aparinazine Glucocorticoids Slow-Release Nicotinic Acid
<b>Drugs that may cause protein-binding site displacement</b>	
Furosemide (> 80 mg IV) Heparin Hydantoin Non Steroidal Anti-inflammatory Drugs - Fenamates - Phenylbutazone Salicylates (> 2 g/day)	Administration of these agents with levothyroxine results in an initial transient increase in FT <sub>4</sub> . Continued administration results in a decrease in serum T <sub>4</sub> and normal FT <sub>4</sub> and TSH concentrations and, therefore, patients are euthyroid. Salicylates inhibit binding of T <sub>4</sub> and T <sub>3</sub> to TBG and thyroxine. An initial increase in serum FT <sub>4</sub> is followed by return of FT <sub>4</sub> to normal levels with sustained therapeutic serum salicylate concentrations, although total-T <sub>4</sub> levels may decrease by as much as 30%.
<b>Drugs that may alter T<sub>4</sub> and T<sub>3</sub> metabolism</b>	
<b>Drugs that may increase hepatic metabolism, which may result in hypothyroidism</b>	
Carbamazepine Cytarabine Phenobarbital Rifampin	Stimulation of hepatic microsomal drug-metabolizing enzyme activity may cause increased hepatic degradation of levothyroxine, resulting in decreased levothyroxine responses. Phenylbutazone and carbamazepine reduce serum protein binding of levothyroxine, and total- and free-T <sub>4</sub> may be reduced 20% to 40% in most patients, but have normal serum TSH levels and are clinically euthyroid.
<b>Drugs that may decrease T<sub>4</sub>-5'-deiodinase activity</b>	
Amiodarone Beta-adrenergic antagonists - (e.g., Propranolol > 160 mg/day) Glucocorticoids - (e.g., Dexamethasone 4 mg/day) Propylthiouracil (PTU)	Administration of these enzyme inhibitors decreases the peripheral conversion of T <sub>4</sub> to T <sub>3</sub> , leading to decreased T <sub>3</sub> levels. However, serum T <sub>4</sub> levels are usually normal but may occasionally be slightly increased. In patients treated with large doses of propranolol (> 160 mg/day), T <sub>4</sub> and T <sub>3</sub> levels change slightly. TSH levels remain normal, and patients are clinically euthyroid. It should be noted that actions of particular beta-adrenergic antagonists may be impaired when the hypothyroid patient is converted to the euthyroid state. Short-term administration of large doses of glucocorticoids may decrease serum T <sub>4</sub> concentrations by 30% with minimal change in serum T <sub>3</sub> levels. However, long-term glucocorticoid therapy may result in slightly decreased T <sub>4</sub> and T <sub>3</sub> levels due to decreased TBG production (see above).
<b>Miscellaneous</b>	
Anticoagulants (oral) - Coumatin Derivatives - Indandione Derivatives	Thyroid hormones appear to increase the metabolism of vitamin K-dependent clotting factors, thereby increasing the anticoagulant activity of oral anticoagulants. Concomitant use of these agents impairs the compensatory increases in clotting factor synthesis. Prothrombin time should be carefully monitored in patients taking levothyroxine and oral anticoagulants and the dose of anticoagulant therapy adjusted accordingly.
Antidepressants - Tricyclics (e.g., Amitriptyline) - Tetracyclics (e.g., Meprobamate) - Selective Serotonin Reuptake Inhibitors (SSRIs; e.g., Sertraline)	Concurrent use of tricyclic antidepressants and levothyroxine may increase the therapeutic and toxic effects of both drugs, possibly due to increased receptor sensitivity to catecholamines. Toxic effects may include increased risk of cardiac arrhythmias and CNS stimulation; onset of action of tricyclics may be accelerated. Discontinuation of sertraline in patients stabilized on levothyroxine may result in increased levothyroxine requirements.
Antidiabetic Agents - Biguanides - Meglitinides - Sulfonylureas - Thiazolidinediones - Insulin	Addition of levothyroxine to antidiabetic or insulin therapy may result in increased antidiabetic agent or insulin requirements. Careful monitoring of diabetic control is recommended, especially when thyroid therapy is started, changed, or discontinued.
Cardiac Glucosides	Serum digoxin glycoside levels may be reduced in hypothyroidism or when the hypothyroid patient is converted to the euthyroid state. Therapeutic effect of digoxin glycosides may be reduced.
Oxytocins - Interferon-α - Interleukin-2	Therapy with interferon-α has been associated with the development of antithyroid microsomal antibodies in 20% of patients and some have transient hypothyroidism, hyperthyroidism, or both. Patients who have antithyroid antibodies before treatment are at higher risk for thyroid dysfunction during treatment. Interleukin-2 has been associated with transient painful thyroiditis in 20% of patients. Interleukin-2 has not been reported to cause thyroid dysfunction.
Growth Hormones - Somatrem - Somatropin	Excessive use of thyroid hormones with growth hormones may accelerate epiphyseal closure. However, untreated hypothyroidism may interfere with growth response to growth hormone.

Ketamine	Concurrent use may produce marked hypertension and tachycardia; cautious administration to patients receiving thyroid hormone therapy is recommended.
Methylnanthine Bronchodilators (e.g., Theophylline)	Decreased theophylline clearance may occur in hypothyroid patients; clearance returns to normal when the euthyroid state is achieved.
Radiographic Agents	Thyroid hormones may reduce the uptake of <sup>131</sup> I, <sup>125</sup> I, and <sup>123</sup> I.
Sympathomimetics	Concurrent use may increase the effects of sympathomimetic or thyroid hormones. Thyroid hormones may increase the risk of coronary insufficiency when sympathomimetic agents are administered to patients with coronary artery disease.
Chloral Hydrate Diazepam Ethinamate Lorazepam Metoclopramide 6-Mercaptopurine Nitroglycerin Paracetamol Perphenazine Resorcinol (excessive topical use) Thiazide Diuretics	These agents have been associated with thyroid hormone and/or TSH level alterations by various mechanisms.

**Oral Anticoagulants** – Levothyroxine increases the response to oral anticoagulant therapy. Therefore, a decrease in the dose of anticoagulant may be warranted with correction of the hypothyroid state or when the LEVOXYL® dose is increased. Prothrombin time should be closely monitored to permit appropriate and timely dosage adjustments (see **Table 2**).

**Digitalis Glycosides** – The therapeutic effects of digitalis glycosides may be reduced by levothyroxine. Serum digitalis glycoside levels may be decreased when a hypothyroid patient becomes euthyroid, necessitating an increase in the dose of digitalis glycosides (see **Table 2**).

**Drug-Food Interactions** – Consumption of certain foods may affect levothyroxine absorption therapy necessitating adjustments in dosing. Soybean flour (infant formula), cotton seed meal, walnuts, and dietary fiber may bind and decrease the absorption of levothyroxine sodium (see **Table 2**).

**Drug-Laboratory Test Interactions** – Changes in TBG concentration must be considered when interpreting T<sub>4</sub> and T<sub>3</sub> values, which necessitates measurement and evaluation of unbound (free) hormone and/or determination of the free T<sub>4</sub> index (FT<sub>4</sub>). Pregnancy, infectious hepatitis, estrogens, estrogen-containing oral contraceptives, and acute intermittent porphyria increase TBG concentrations. Decreases in TBG concentrations are observed in nephrosis, severe hypothyroidism, severe liver disease, acromegaly, and after androgen or corticosteroid therapy (see also **Table 2**). Familial hypothyroid or hypo-thyroxine binding globulinemia has been described, with the incidence of TBG deficiency approximating 1 in 9000.

**Carcinogenesis, Mutagenesis, and Impairment of Fertility** – Animal studies have not been performed to evaluate the carcinogenic potential, mutagenic potential or effects on fertility of levothyroxine. The synthetic T<sub>4</sub> LEVOXYL® is identical to that produced naturally by the human thyroid gland. Although there has been a reported association between prolonged thyroid hormone therapy and breast cancer, this has not been confirmed. Patients receiving LEVOXYL® for appropriate clinical indications should be titrated to the lowest effective replacement dose.

**Pregnancy – Category A** – Studies in women taking levothyroxine sodium during pregnancy have not shown an increased risk of congenital abnormalities. Therefore, the possibility of fetal harm appears remote. Levothyroxine should be discontinued during pregnancy and hypothyroidism diagnosed during pregnancy should be promptly treated.

Hypothyroidism during pregnancy is associated with a higher rate of complications, including spontaneous abortion, pre-eclampsia, stillbirth and premature delivery. Maternal hypothyroidism may have an adverse effect on fetal and childhood growth and development. During pregnancy, serum T<sub>4</sub> levels may decrease and serum TSH levels increase to values above the normal range. Since elevations in serum TSH may occur as early as 4 weeks gestation, pregnant women taking LEVOXYL® should have their TSH measured during each trimester. An elevated serum TSH level should be corrected by an increase in the dose of LEVOXYL®. Since postpartum TSH levels are similar to preconception values, the LEVOXYL® dosage should return to the pre-pregnancy dose immediately after delivery. A serum TSH level should be obtained 6-8 weeks postpartum. Thyroid hormones do not readily cross the placental barrier; however, some transfer does occur as evidenced by levels in cord blood of athyroidic fetuses being approximately one-third maternal levels. Transfer of thyroid hormones from the mother to the fetus, however, may not be adequate to prevent fetal goiter hypothyroidism.

**Nursing Mothers** – Although thyroid hormones are excreted only minimally in human milk, caution should be exercised when LEVOXYL® is administered to a nursing woman. However, adequate replacement doses of levothyroxine are generally needed to maintain normal lactation.

### Pediatric Use

#### General

The goal of treatment in pediatric patients with hypothyroidism is to achieve and maintain normal intellectual and physical growth and development. The initial dose of levothyroxine varies with age and body weight (see **DOSAGE AND ADMINISTRATION, Table 3**). Dosing adjustments are based on an assessment of the individual patient's clinical and laboratory parameters (see **PRECAUTIONS, Laboratory Tests**).

In children in whom a diagnosis of permanent hypothyroidism has not been established, it is recommended that levothyroxine administration be discontinued for a 30-day trial period, but only after the child is at least 3 years of age. Serum T<sub>4</sub> and TSH levels should then be obtained. If the T<sub>4</sub> is low and the TSH high, the diagnosis of permanent hypothyroidism is established, and levothyroxine therapy should be restarted. If the T<sub>4</sub> and TSH levels are normal, euthyroidism may be assumed and, therefore, the hypothyroidism can be considered to have been transient. In this instance, however, the physician should carefully monitor the child and repeat the thyroid function tests if any signs or symptoms of hypothyroidism develop. In this setting, the clinician should have a high index of suspicion. If the results of the levothyroxine withdrawal test are inconclusive, careful follow-up and subsequent testing will be necessary.

The patient should be monitored closely to avoid undertreatment or overtreatment. Undertreatment may have deleterious effects on intellectual development and linear growth. Overtreatment has been associated with craniosynostosis in infants, and may adversely affect the tempo of brain maturation and accelerate the bone age with resultant premature closure of the epiphyses and compromised adult stature.

**Equivalent hypothyroidism in Pediatric Patients**  
The patient should be monitored closely to avoid undertreatment and overtreatment. Undertreatment may result in poor school performance due to impaired concentration and slowed mental and in reduced adult height. Overtreatment may accelerate the bone age and result in premature epiphyseal closure and compromised adult stature.

Treated children may manifest a period of catch-up growth, which may be adequate in some cases to normalize adult height. In children with severe or prolonged hypothyroidism, catch-up growth may not be adequate to normalize adult height.

### Geriatric Use

Because of the increased prevalence of cardiovascular disease among the elderly, levothyroxine therapy should not be initiated at the full replacement dose (see **WARNINGS, PRECAUTIONS, and DOSAGE AND ADMINISTRATION**).

**ADVERSE REACTIONS**  
Adverse reactions associated with levothyroxine therapy are primarily those of hypothyroidism due to the deleterious effects on intellectual development and linear growth. Overtreatment has been associated with:

**General:** fatigue, increased appetite, weight loss, heat intolerance, fever, excessive sweating;  
**Central nervous system:** headache, hyperactivity, nervousness, anxiety, irritability, emotional lability, insomnia;  
**Musculoskeletal:** tremors, muscle weakness;

**Cardiac:** palpitations, tachycardia, arrhythmias, increased pulse and blood pressure, heart failure, angina, myocardial infarction, cardiac arrest;  
**Pulmonary:** dyspnea;

**GI:** diarrhea, vomiting, abdominal cramps;

**Dermatologic:** hair loss, flushing;

**Reproductive:** menstrual irregularities, impaired fertility.  
Pseudotumor cerebri and slipped capital femoral epiphysis have been reported in children receiving levothyroxine therapy. Overtreatment may result in craniosynostosis in infants and premature closure of the epiphyses in children with resultant compromised adult height. Seizures have been reported rarely with the institution of levothyroxine therapy.

Inadequate levothyroxine dosage will produce or fail to ameliorate the signs and symptoms of hypothyroidism.

Hypersensitivity reactions to inactive ingredients have occurred in patients treated with thyroid hormone products. These include urticaria, pruritus, skin rash, flushing, angioedema, various GI symptoms (abdominal pain, nausea, vomiting, and diarrhea), antralgia, serum sickness and wheezing. Hypersensitivity to levothyroxine itself is not known to occur.

### MANUFACTURER

JONES PHARMA INCORPORATED  
(a wholly owned subsidiary of King Pharmaceuticals, Inc.)  
St. Louis, MO 63146

Prescribing Information as of August 2003.

\*The Thyroid shape is a registered trademark.

Table 2 – Drug – Thyroid Axis Interactions

Drug or Drug Class	Effect
<b>Drugs that may raise TSH secretion – the reduction is not sustained; therefore, hypothyroidism does not occur</b>	
Dopamine / Dopamine Agonists Glucocorticoids Octreotide	Use of these agents may result in a transient reduction in TSH secretion when administered at the following doses: Dopamine (> 1 mcg/kg/min); Glucocorticoids (hydrocortisone = 100 mg/day or equivalent); Octreotide (> 100 mcg/day).

Reference: 1. Price-Check PC® January 2004.  
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## Frequently Asked Questions About Open Access and the Public Library of Science

In December 2003, The Endocrine Society Publications, Government Relations and Executive Committees approved the Society's endorsement of the "Washington DC Principles for Free Access to Science—A Statement from Not-for-Profit Publishers." (see pages 14 and 15) The document informs the scientific community about advancements made by not-for-profit publishers to disseminate science more widely and more rapidly in the Web environment. Following are facts about open access and The Endocrine Society's position on this issue.

### What is the Public Library of Science?

The Public Library of Science (PloS) is a tax-exempt 501[c]3 not-for-profit corporation that has launched a scientific publishing venture to make papers from contributing scientists freely available under an open access policy. Articles published in PloS journals will undergo peer review. PloS has just launched the journal *PloS Biology* and is planning on publishing the journal *PloS Medicine*. There is no subscription fee to access the online version of the PloS journals. Print versions are available at a cost of \$160 per subscription.

PloS is not funded, supported or endorsed by the National Institutes of Health or any part of the Federal government.

### What Does PloS Mean by Open Access?

All material published by PloS is published under an open access license that allows unrestricted use, distribution and reproduction in any medium, provided the original work is cited. The articles are made available free to the world as soon as they are accepted and produced.

### How is the PloS Funded?

The PloS received a nine million grant from the Gordon and Betty

Moore Foundation to help set it up and operate for the first four years and has additional financial support from both the Irving A. Hansen Memorial Foundation and the Howard Hughes Medical Institute.

### What is the Financial Publishing Model of the PloS?

The PloS uses the "author pays" model. Since access to the content published at PloS online is free, there is no subscription revenue. PloS charges authors whose articles are published \$1,500 to help offset publishing costs.

### What is The Endocrine Society's Position on Open Access?

The Endocrine Society's mission is to disseminate the best endocrinological science as soon as possible, to the widest number of scientists and scientific institutions. Papers submitted to Society journals are published under free access (i.e., available to the world) as Rapid Electronic Publications (REP) as soon as they are accepted. After the paper is copy-edited and formatted, it is published, simultaneously online and in print, as part of the formal volume issue and is available by subscription for a period of 12 months. During this time the REP (i.e., accepted but unformatted version of the paper) is still available as free access. After 12 months, all content reverts to free access. Currently, the Society has the full text of all journals dating back to 1992—nearly 20,000 articles—as free access. Society journals are available through the Stanford University Libraries' HighWire Press portal, though which free access to over 600,000 scientific articles from 360 journal is available.

### What is the Publishing Business Model of The Endocrine Society?

The Endocrine Society charges subscription fees for access to its jour-

nals' current volume year. In addition, the Society charges author fees in the form of page charges and charges for color figures. On average, the total author charges for one article in \$688 for *JCEM*; \$973 for *ENDO*; and \$1,673 for *MEND* (higher due to higher pages count and more color figures per article). The subscription fee includes access to full text online plus the print edition. Subscription rates are priced to members at the cost to the Society for the paper, printing, and postage required to send the print subscription. Subscription prices to institutions are set by the Society's Publications Committee. The average U.S. institutional price of a scientific journal is \$1,875. The average U.S. institutional price of the Society's journals is \$603. The total net cost (cost less authors charges) of producing the Society's four journals in 2003 was \$3.6 million. Subscription revenue was \$5.4 million. The net \$1.8 million was used to help fund all Society activities and services.

### What is the Sabo Bill and What are the Implications for The Endocrine Society's Journal?

Representative Martin Sabo (D-MN) has introduced legislation in the House of Representatives that excludes from copyright protection works resulting from scientific research "substantially funded" by the Federal Government. The underlying issue addressed by the Sabo bill has been interpreted to be that authors should retain the copyright to their submitted work rather than assign it to the publisher.

### What is the Position of the PloS on Ownership of Scientific Content?

The author decides whether to retain copyright of the material sub-

*Continued on page 15.*

## Washington D.C. Principles for Free Access to Science: A Statement from Not-for-Profit Publishers

February 26, 2004

Washington, DC—As scholarly, not-for-profit publishers, we reaffirm our commitment to innovative and independent publishing practices and to promoting the wide dissemination of information in our journals. Not-for-profit scientific, technical, and medical publishers are an integral part of the broader scholarly communities supporting scientists, researchers, and clinicians. We work in partnership with scholarly communities to ensure that these communities are sustained and extended, science is advanced, research meets the highest standards, and patient care is enhanced with accurate and timely information.

We continue to support broad access to the scientific and medical literature through the following publishing principles and practices.

1. As not-for-profit publishers, we see it as our mission to maintain and enhance the independence, rigor, trust, and visibility that have established scholarly journals as reliable filters of information emanating from clinical and laboratory research.

2. As not-for-profit publishers, we reinvest all of the revenue from our journals in the direct support of science worldwide, including scholarships, scientific meetings, grants, educational outreach, advocacy for research funding, the free dissemination of information for the public, and improvements in scientific publishing.

3. As not-for-profit publishers, we have introduced and will continue to support the following forms of free access:

- Selected important articles of interest are free online from the time of publication;
- The full text of our journals is freely available to everyone worldwide either immediately or within months of publication, depending on each publisher's business and publishing requirements;
- The content of our journals is available free to scientists working in many low-income nations;
- Articles are made available free online through reference linking between these journals;
- Our content is available for indexing by major search engines so that readers worldwide can easily locate information.

4. We will continue to work to develop long-term preservation solutions for online journals to ensure the ongoing availability of the scientific literature.

5. We will continue to work with authors, peer-reviewers, and editors for the development of robust online and electronic tools to improve efficiency of their important intellectual endeavors.

6. We strongly support the principle that publication fees should not be borne solely by researchers and their funding institutions, because the ability to publish in scientific journals should be available equally to all scientists worldwide, no matter what their economic circumstances.

7. As not-for-profit publishers, we believe that a free society allows for the co-existence of many publishing models, and we will continue to work closely with our publishing

colleagues to set high standards for the scholarly publishing enterprise.

The following not-for-profit publishers endorse the above principles:

- American Academy of Pediatrics
- American Association for Cancer Research
- American Association for Clinical Chemistry
- American Cancer Society
- American College of Chest Physicians
- American College of Nutrition
- American College of Physicians
- American Dairy Science Association
- American Diabetes Association
- American Physiological Society
- American Psychiatric Publishing
- American Roentgen Ray Society
- American Society of Animal Science
- American Society for Biochemistry and Molecular Biology
- American Society for Clinical Investigation
- American Society for Clinical Nutrition
- American Society for Microbiology
- American Society for Nutritional Sciences
- American Society for Pharmacology and Experimental Therapeutics
- American Society of Hematology
- American Society for Investigative Pathology
- American Society of Clinical Oncology
- American Society of Plant Biologists

- Association for Molecular Pathology
- Association for Research in Vision and Ophthalmology
- Association of Biomolecular Resource Facilities
- Biophysical Society
- Cold Spring Harbor Laboratory Press
- Company of Biologists Limited
- European Molecular Biology Organisation
- Federation of American Societies for Experimental Biology
- Genetics Society of America
- Project Hope
- Protein Society
- Radiological Society of North America
- Royal College of Psychiatrists
- Society for Experimental Biology and Medicine
- Society for Leukocyte Biology
- Society for the Study of Reproduction
- Society of National Association Publications
- Society of Nuclear Medicine
- The American Society of Nephrology
- The Botanical Society of America
- The Endocrine Society
- The Histochemical Society

- The Physiological Society
- The Rockefeller University Press
- Harvey Whitney Books

Background: Since 1995, more than 100 society and university not-for-profit publishers have been working with Stanford University's HighWire Press to transform traditional print journals into enduring and dynamic online journals. These publishers have invested millions of dollars in online technology for information presentation, distribution, and management; created unique and powerful online services for the education and convenience of scientists; initiated some of the largest and most influential experiments in online-only publishing; led the charge in making information free to people who cannot afford to pay for it; and developed state-of-the-art software to support authors, reviewers, and editors. By effectively harnessing new technologies, these not-for-profit society and university publishers have promoted the wider dissemination of scientific information as well as free and unfettered access to journal content for both the scientific community and the public. In so doing, these not-for-profit publishers have be-

come leaders in the online revolution for scientific publishing.

Through these not-for-profit publishers, the scientific community and the public have easy online access to over 1.6 million articles of which more than 600,000 full-text articles are free. In addition, access is provided to the abstracts of more than 12.6 million articles in more than 4,500 Medline journals, as well as useful alerting and information management tools.

The experiments that have been conducted since 1995 and that are ongoing have only been possible because these not-for-profit publishers have been successfully adapting their proven business models to the online environment. As a result, these society and university press journals remain high impact and well-respected custodians of the scientific literature. Through numerous organizations that serve the entire scholarly publishing community, not-for-profit publishers have freely shared their ideas and innovations, with the common goal of improving the dissemination of vital scientific and medical information throughout the world. **EN**

## Frequently Asked Questions

*Continued from page 13.*

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### What is the Position of The Endocrine Society on Ownership of Scientific Content?

When an author in one of our journals assigns copyright to The Endocrine Society, the Society pro-

jects that material from unauthorized use, on behalf of the author. The author, in fact, retains many rights to re-use of his/her article, including royalty free right to use material from that article in a textbook or any derivative work, present the paper orally at scientific conferences, and the right to revise or adapt the content and publish it as a new work. We also believe that our members should maintain certain rights to their works and have the right to publish in the journal of their choosing. If, in fact, the work is created by an employee of the U.S. Government, the author *cannot* assign copyright to any publisher anyway. In the case of

The Endocrine Society, the Society publishes the work and it remains in the public domain. **EN**

*Endocrine News welcomes your letters-to-the-editor. Letters-to-the-editor must include full name, address, daytime phone number and email address. They should be e-mailed to ENLetters@endo-society.org Letters may be no more than 300 words. The Endocrine Society reserves the right to edit for space and clarity. Letters may appear in electronic format on The Endocrine Society's Web site [www.endo-society.org](http://www.endo-society.org) or in the print version of Endocrine News.*

*Continued from page 6.*

- The second annual 5k Run/Walk benefiting the Hormone Foundation will be held on Saturday, June 19 from 6:00 – 8:00 a.m. in Audubon Park. Last year, 75 hearty individuals participated in this wet,

selections during ENDO that provide creative alternatives to the famous cuisine.

- “Wake Up Walks” will be held each morning for delegates and their guests to get the morning started with a guided tour of New Orleans.

**ENDO 2004 is an opportunity for our community to meet and exchange ideas and solutions that will further the science and practice of endocrinology.**

but very fun event! It will be wet again from the high humidity in New Orleans, but just think how the body weight scale will look after you are finished! The 5k Run/Walk is supported by a grant from GlaxoSmithKline.

- The restaurants in the city of New Orleans will be challenged to feature low fat or health

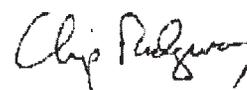
- Plans are also being completed to increase your awareness of obesity-related issues in fun and interesting ways. For example, do you know how many calories are in one beignet?

ENDO 2004 is an opportunity for our community to meet and exchange ideas and solutions that will further the science and practice

of endocrinology. Why do I love the Annual Meeting? All the great science, all the terrific people, and all that quality time. See you at ENDO 2004 in New Orleans, June 16-19, 2004. For more information on the scientific program or to register for the meeting visit the Society’s web page at [www.endosociety.org/scimeetings/endo2004/index.cfm](http://www.endosociety.org/scimeetings/endo2004/index.cfm)

If you have any comments or suggestions, please email me at [president@endo-society.org](mailto:president@endo-society.org) I look forward to welcoming you to New Orleans and ENDO 2004! **EN**

Sincerely,



**E. Chester Ridgway, M.D.**  
*President, The Endocrine Society*





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# Current Issues in Thyroid Disease Management:



## Leading Experts Discuss New *JAMA* and *JCE&M* Reports During Endocrine Society Audioconference

By Patricia A. Stephens, Ph.D.

On February 12, 2004 an audioconference sponsored by The Endocrine Society brought together three experts to discuss current issues in thyroid disease management, particularly the implications of intriguing new reports published in *The Journal of the American Medical Association (JAMA)* and *The Journal of Clinical Endocrinology & Metabolism (JCEM)*. The speakers were Carole Spencer, Ph.D., University of Southern California, Los Angeles; Kenneth Burman, M.D., Washington Hospital Center, Washington, DC; and David Sarne, M.D., University of Illinois, Chicago. Following the talks, conference listeners asked the speakers about specific cases or other details related to their own experience and clinical practice.

The presentations addressed issues of interest to physicians who evaluate and manage patients with thyroid disease, focusing on three key questions:

- Who needs treatment for thyroid dysfunction?
- What products should be used for treatment?
- What should be the clinical and biochemical treatment goals?

### The New TSH Reference Range (0.4-2.5 mIU/L)

Dr. Carole Spencer began the program with a discussion of the clinical implications of the new thyroid stimulating hormone (TSH) reference range proposed in the consensus guidelines from the National Academy of Clinical Biochemistry (NACB) ([www.nacb.org](http://www.nacb.org)). She focused on how to interpret TSH values used to diagnose thyroid dysfunction and monitor levothyroxine therapy.

**NACB guidelines.** The within-person variability for TSH is much narrower than the between-person variability represented by the population reference range that is cited on laboratory reports. The new NACB guidelines recommend how to select individuals for determining the TSH reference range using the presence of thyroid autoantibodies—particularly thyroid peroxidase antibody (TPOAb)—as a critical exclusion criterion.

There is consensus that the mean TSH value of euthyroid individuals lies between 1.0 and 1.5 mIU/L and that the lower TSH reference limit is about 0.4 mIU/L. If TSH values conform to a Gaussian distribution, then the upper limit would be ~2.5

mIU/L. The NHANES III population survey, however, found that TSH reference limits for different subpopulations were typically skewed above that limit. The NHANES data also suggest that this skew results from the inclusion of individuals with occult thyroid autoimmunity that are not necessarily detected with current TPOAb methods.

As a result, the TSH upper reference limit that appears in laboratory reports is inaccurate, and this led to the new NACB guideline stating that most healthy euthyroid persons have a serum TSH concentration below 2.5 mIU/L. Ambulatory patients with a TSH greater than 2.5 mIU/L, confirmed with a repeat measurement after three weeks, may be in the early stages of thyroid failure, especially if TPOAb is detected. Another NACB guideline recommends a target TSH range of 0.5 to 2.0 mIU/L for levothyroxine replacement therapy.

**Effect on clinical practice.** Physicians should understand that the reference range is not the normal range, but merely a marker to be used with other patient-specific factors. Inherent TSH biological variability is one reason the new guidelines suggest that when TSH is outside the reference range, it should be rechecked with a fresh specimen drawn after at least three weeks.

Even if the TSH is confirmed to be below the reference range, the degree of abnormality has to be interpreted in the context of the individual patient. For example, a low TSH is common in the first trimester of pregnancy. Many young patients appear to tolerate chronically low TSH with few adverse effects. By contrast, one study shows that older patients, even with a marginally low TSH (0.1-0.4), had a higher risk for atrial fibrillation. At the other end of the spectrum, persons with TSH values above 5.0 tended toward an

increased rate of atrial fibrillation and higher lipid levels. It follows that levothyroxine therapy has a narrow therapeutic range.

**Significance of a TSH Upper limit of 2.5 mIU/L.** When a high TSH abnormality is confirmed, it's likely that the patient is developing some degree of thyroid insufficiency. An elevated TSH alerts the physician to the need for follow-up and periodic monitoring to detect progression. Depending on the clinical circumstances, a TPOAb test might be ordered to further define the risk of progression. The point at which levothyroxine replacement should be considered is a matter of clinical judgment based on patient-specific factors.

For example, early treatment may be indicated in pregnant women with mild TSH elevations or in women planning pregnancy or having fertility problems, because there's a growing consensus that even a mild TSH elevation may be detrimental to the developing fetus. The new 2.5 mIU/L upper limit for nonpregnant subjects may be an appropriate conservative upper limit for women in the first trimester.

Among nonpregnant subjects with an elevated TSH, even when treatment is not considered, the risk of progression increases with both the degree of elevation and the TPOAb concentration. A linear correlation has been reported between TSH elevations above ~2.5 mIU/L and the risk of developing overt hypothyroidism over the next twenty years. This risk was doubled by the presence of TPOAb.

### Subclinical Thyroid Disease

Dr. Kenneth Burman addressed findings reported in the *JAMA* article "Subclinical Thyroid Disease: Scientific Review and Guidelines for Diagnosis and Management" (2004;291:228-238) (Chair; Dr. Martin Surks). Dr. Burman, one of

the consensus panelists who participated in writing the article, focused his talk on endogenous disease. Similar to Dr. Spencer, he stressed the importance of looking at patient-specific factors, not just the results of thyroid function tests.

### Subclinical Hypothyroidism

The definition of subclinical hypothyroidism is a serum TSH concentration above the statistically defined upper limit of the reference range when serum free T4 concentration is within its reference range.

**Epidemiology.** The prevalence of subclinical hypothyroidism varies with the study and population analyzed. In the NHANES III study, for example, 10 percent of women and four percent of men 60 years old or older had an elevated TSH. Prevalence is lower (four to eight percent) in younger individuals.

**Reasons to treat.** The reasons to treat subclinical thyroid disease relate to preventing progression to overt disease, alleviating symptoms, decreasing low-density lipoprotein, improving cardiac end points, and improving cognition. An obvious rationale for LT4 therapy is to prevent progression to overt hypothyroidism, an event that probably occurs at a rate of two to five percent/year. This rate may be doubled if thyroid antibodies are present.

**Quality of evidence on treatment.** In the consensus panel's assessment of the quality of the evidence, ratings of *insufficient* or *no evidence* predominated. Exceptions were "progression to overt hypothyroidism," which was rated *good* in all patients with elevated TSH, and "elevation in total and LDL cholesterol," which was rated *fair* in patients with TSH greater than 10 mIU/L.

The panel concluded that there is no single level of serum TSH at

which clinical action is always either indicated or contraindicated. The higher the TSH the more compelling the basis for treatment.

**Evaluating subclinical hypothyroidism.** When serum TSH is between 4.5 and 10 mIU/L and confirmed by repeat determination, treatment should prevent overt disease. For these patients the panel does not recommend routine levothyroxine treatment, but it does recommend periodic clinical and laboratory monitoring. Clinical context—such as actual or possible pregnancy, lipid elevation, and the presence of thyroid antibodies—should be considered. For serum TSH greater than 10 mIU/L, levothyroxine is recommended to stop progression to overt disease.

**Pregnancy.** Pregnancy is a special circumstance. A serum TSH should be obtained in pregnant women or women desirous of becoming pregnant. Because hypothyroidism may be associated with adverse maternal or fetal outcomes, levothyroxine should be given to normalize the woman's TSH.

### Subclinical Hyperthyroidism

Subclinical hyperthyroidism is defined as a serum TSH value below the reference range in association with free T4 and T3 that are within the reference range.

**Epidemiology.** About 3percent of the population has subclinical hyperthyroidism, but if patients with known thyroid disease are excluded, the figure drops to two percent.

**Reasons to treat subclinical hyperthyroidism.** The reasons to treat relate to progression to overt hyperthyroidism, systemic and neuropsychiatric symptoms, atrial fibrillation, cardiac dysfunction, adverse cardiac end points, reduced bone mineral density, and fractures.

One major reason to treat was demonstrated by the finding that among those with a TSH lower

than 0.1 mIU/L, the risk of developing atrial fibrillation was twice that of those with normal TSH. Other studies have confirmed this increased risk.

**Quality of evidence on treatment.** The consensus panel rated the quality of evidence mainly as *insufficient* or *no evidence*. However, for TSH less than 0.1 mIU/L, it was rated *good* for “progression to overt hyperthyroidism” and for “atrial fibrillation” and *fair* for “adverse cardiac endpoints” (“atrial fibrillation” excluded), “cardiac dysfunction,” and “reduced bone density.”

Evaluating subclinical hyperthyroidism. If TSH is between 0.1 and 0.45 mIU/L, it is recommended to repeat the thyroid function tests and assess clinical context. The panel recommends against routine treatment, but clinicians might consider treating elderly patients because of the risk of increased cardiovascular mortality. If TSH is less than 0.1 mIU/L, and the pituitary gland is normal, repeat the tests, including free T4 and T3. Assess clinical context and obtain a radioactive iodine uptake and scan. Assuming no transient cause of low TSH, treatment should be considered especially in the elderly.

### Screening for Subclinical Thyroid Dysfunction

Although screening is an important clinical topic by itself, the consensus panel did not think the current data justify generalized population screening. Until definitive data are available, clinical judgment and patients' preferences remain paramount.

### Studies of Combined T4/T3 Therapy

Dr. David Sarne examined what form of thyroid hormone should be used to treat patients, looking particularly at studies of combined T4/T3 therapy versus T4 alone. Even with normal TSH values, some T4-treated patients complain

of fatigue, depression, and difficulty concentrating or losing weight. This has raised the question of whether T4 alone is sufficient treatment.

In 1999 Buenevicus and colleagues reported that combined T4/T3 therapy significantly improved mood and cognitive function compared with T4 alone and that most patients preferred the combined therapy. The result of this much-publicized information was a rush of patients dissatisfied with their current treatment back to their doctor's office demanding this “new and better” way to treat thyroid hormone deficiency.

Dr. Sarne reviewed the limitations of that original paper and also looked at a subsequent, but lesser-known publication by the same authors who revisited their data. In light of the study's small sample size and absence of power calculations, the short five-week duration, and the absence of a washout period, Dr. Sarne questioned the authors' conclusions in the first paper.

In the second study, the authors looked at the effects in a uniform patient population and modified their earlier claims. Among eleven women with thyroiditis treated with combined therapy, there were no significant differences in performance of neurocognitive tests, in anxiety or depression, or in mood. Among the fifteen women with thyroid cancer, two of nine measures of neurocognitive performances remained significantly improved on combined therapy. However, as Dr. Sarne noted, because all of these cancer patients received combined therapy after having received T4 alone, a learning effect cannot be excluded.

Some recent studies further examined the benefit of T4/T3 combined therapy. Walsh and colleagues (2003 *JCEM*) specifically designed their study to confirm or refute the Buenevicus investigation while avoiding some of the earlier

study's weaknesses. In tests of cognitive function and mood, few significant differences were found between combined therapy and T4 alone. The authors concluded that their data neither confirmed the Buenevicius study nor supported the idea that combined therapy improves neurocognitive functioning, mood, or peripheral thyroid hormone action.

In the same *JCEM* issue, Sawka and associates also reported no improvement with combined therapy in patients specifically selected because they had depressive symptoms while on T4 therapy. Likewise, Clyde (2003 *JAMA*) concluded that combined therapy had no proven benefit over T4 alone.

**Symptoms and T4.** So why do some hypothyroid patients feel bad and have many symptoms while on T4 alone? Possibly, these patients may not be on a dose of T4 that will maintain TSH at a level consistent with euthyroidism. Another possibility is that some patients just feel

better when they are hyperthyroid and will complain of symptoms when brought to a euthyroid state.

Dr. Sarne pointed out that it is possible that some patients with no endogenous thyroid function may actually benefit from small amounts of T3, but as yet there are no studies which have demonstrated this. Importantly, none of these studies provided T3 consistent with normal physiology—much smaller amounts, released slowly throughout the day. If such a product were available, some patients might benefit from its use with T4.

**Bioequivalence.** Dr. Sarne briefly addressed the question of bioequivalence, pointing out that the FDA considers only the blood levels of T4 achieved after dose administration in determining whether two brands are equivalent. Effects on symptoms, TSH, or biological markers of T4 action are not considered. Even with that standard, most thyroxine products have *not* been demonstrated to be bioequivalent.

### Summary

What does all this information mean for physicians and, more importantly, patients?

- Studies do not support the idea that combined therapy with current T3 preparations is superior to T4 alone.
- Therapy with thyroxine should be provided to maintain TSH in the range of 0.5-2.0 mIU/L.
- You cannot assume equivalence of different brands of thyroxine.
- Physicians should try to keep patients on one brand, but if a change is necessary, then TSH should be re-evaluated after an appropriate interval. **EN**

*For more information on The Endocrine Society's audioconferences, please contact Rob Bartel, Manager, Educational Programs at [rbartel@endo-society.org](mailto:rbartel@endo-society.org)*

## Participate! Job Fair ENDO 2004

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*Attendance at ENDO 2004 is not required.*

**For more information, visit [www.endo-society.org/placement](http://www.endo-society.org/placement) or call 800-361-3906**



# NIH Budget Held to 2.6% Increase in 2005

## OBESITY RESEARCH FUNDING INCREASES

On February 2, President Bush released his Fiscal Year 2005 Federal Budget. The budget proposes to hold the growth in total discretionary spending to 3.9 percent, and to reduce the growth in non-defense, non-homeland security spending to half of one percent, lower than the rate of inflation.

After a growth rate of 15 percent from 1998-2003 and a growth rate of eight percent over the last 30 years, the National Institutes of Health (NIH) will receive an increase of 2.6 percent for 2005. Under the President's proposal, NIH will receive a total of \$28.8 billion and will fund a total of 10,393 new and competing awards in 2005. This total of new and competing grants is an increase of 258 over 2004, but the same number of grants as 2003.

Although the number of new and competing grants will increase by 258 in 2005, the NIH is forced to fund more grants with smaller budget increases. This creative accounting project will be accomplished by reducing the annual cost-of-living increases on non-competing continuing grants to 1.9 percent. In addition, cost increases on new and re-competing grants will be held to one percent—the Biomedical Research and Development Index has indicated inflation for biomedical research is near 3.5 percent in recent years. The budget also proposes funding for 17,791 research trainees but funding for stipends under the Kirschstein National Research Service Awards will be frozen for 2005.

While overall funding levels are out, NIH has increased its commitment to obesity research. NIH plans to expand its obesity programs by \$40 million in 2005. Included in this expansion is \$22 million for a trans-NIH initiative

to better understand obesity, and improve prevention strategies. The NIH Obesity Research Task Force has identified four obesity priorities for NIH to address:

- Prevention and treatment of childhood obesity (\$3.5 million)
- Neurological relationships of obesity (\$6 million)
- Bioengineering for prevention and treatment of obesity (\$2 million)
- Creation of an Obesity Clinical Research Center (\$ 6 million)

To advocate for additional funding, Endocrine Society President Chip Ridgway, M.D. will be meeting with several members of Congress early in the appropriations cycle. In addition, the Government Relations Committee will focus on funding advocacy during their bi-annual Hill visits in March. Please look for legislative alerts via email that will ask you to make your voice heard on funding issues. Several alerts will be sent during the Congressional appropriations process to urge additional funding for biomedical research and these alerts will be your chance to get involved.

As legislators begin the second session of the 108th Congress, health care items are considered high on the agenda. Leaders are expected to consider a proposal to make tax-deductible the premiums for high-deductible health insurance policies that accompany newly created tax-free health savings accounts. Incentives to spur movement away from paper medical records and toward electronic records will also see consideration. In addition, Senate Majority Leader Bill Frist has announced intentions to introduce legislation

designed to eliminate health care disparities between racial and ethnic groups.

The Government Relations Committee will also continue to push for passage of the Improved Nutrition and Physical Activity Act (IMPACT Act) in the House of Representatives. The Senate passed its version of the IMPACT Act on December 9, 2003. The legislation aims to reduce the problem of obesity by encouraging increased physical activity and good nutrition. It also includes a provision requiring the Secretary of the Department of Health and Human Services (HHS) to report on "what research has been conducted on obesity treatment and prevention, what has been learned from this research, and what future research should be conducted."

Finally, The Endocrine Society's representatives at the American Medical Association (AMA) House of Delegates plan to introduce several resolutions designed to support the Society's legislative agenda when the House convenes in June. Resolutions to encourage AMA support of legislation to further regulate steroid precursors, to further define the AMA's support for obesity advocacy and a resolution designed to gain AMA support of sustainable federal funding for biomedical research plan to be introduced. **EN**

*For additional information about the Society's legislative activities, or to become more involved with the Society's legislative activities, please contact Chris Rorick, Manager, Government Relations, at [crorick@endo-society.org](mailto:crorick@endo-society.org)*

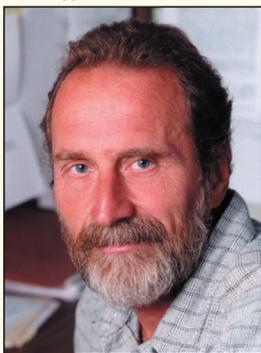


### Molecular Endocrinology Welcomes New Editor-In-Chief

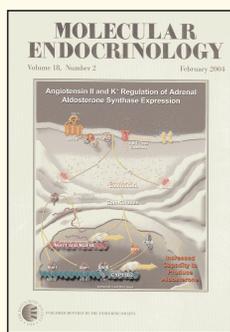
John Cidlowski, Ph.D. officially began his term as Editor-in-Chief of *Molecular Endocrinology* on January 1, 2004. He worked with Dr. John Nilson for a number of months prior to January to ensure a smooth transition.

Dr. Cidlowski has served as an editor for *Molecular Endocrinology*, *Steroids* and *Cell Death and Differentiation* and serves on the editorial boards of a number of additional scientific journals including *Endocrinology*. He brings a deep understanding of the publishing process and peer review to his new position. He is currently Chief of the Laboratory of Signal Transduction at the National Institute of Environmental Health Sciences, NIH.

The Publications Committee is proud to announce the appointment of such a distinguished member of the Society to Editor-in-Chief of *Molecular Endocrinology*.



Dr. John Cidlowski named new Editor-in-Chief.



### First Clinical Investigator Workshop Held in Boston

This past January, The Endocrine Society held the Clinical Investigators Workshop for trainees in Boston. The Trainee Development Committee created this new, two-day workshop to introduce and educate a small group of clinical fellows to hypothesis-driven research. This intimate workshop was designed to foster interaction between the fellows and a faculty of senior scientists, which included Drs. William F. Crowley, Jr., Andrea Dunaif, Steven K. Grinspoon, James F. Hyde, Ora

Pescovitz, and Kenneth S. Polonsky. Guest speakers who participated in breakout sessions throughout the workshop, included Drs. David M. Altshuler, Robert G. Dluhy, Ursula Kaiser, Anne Klibanski, David Nathan and Ronenn Roubenoff. The fifteen fellows, including three international fellows, were selected to attend the workshop from a pool of over 50 applicants.

Dr. Crowley's keynote address kicked off the workshop, followed by an afternoon dedicated to sessions about career paths and goals including choosing a mentor and balancing career and personal goals. Saturday's program included a session on grant/ funding opportunities and small group critiques of the fellows' research proposals submitted with their application. The program concluded on Sunday afternoon following sessions on getting published and presenting science.

The workshop was supported by Eli Lilly and Company, Takeda Pharmaceuticals, North America and The Endocrine Society. For more information about the workshop and all fellow and student activities, please visit the Society's Web site at [www.endo-society.org/students/ciworkshop.cfm](http://www.endo-society.org/students/ciworkshop.cfm) or contact Colleen Gorman at [cgorman@endo-society.org](mailto:cgorman@endo-society.org) or 1-301-951-2611.

### Minority Opportunities Available Through FASEB

The Minority Affairs Committee would like to direct minority faculty members, postdocs and students to the travel award opportunities available through the FASEB



Clinical Investigator Workshop attendees along with Program Co-Chairs Dr. Steven Grinspoon, (bottom row, second from right), Dr. Jane Lee (bottom row, first from right) and Endocrine Society Staff Liaison Colleen Gorman (bottom row, fourth from left).

MARC Program for ENDO 2004, June 16-19, 2004 in New Orleans, Louisiana. The application form is available online in PDF format. Please visit [ns2.faseb.org/marc/travel1.html](http://ns2.faseb.org/marc/travel1.html) to apply. For additional information about the meeting-related travel awards provided by the FASEB MARC Program, interested parties may contact Lisa Dennison at [ldennison@faseb.org](mailto:ldennison@faseb.org) or via phone 301-634-7930.

In addition to the travel awards to ENDO 2004, FASEB is also recruiting applicants for their upcoming grants training program that will be held at the end of April 2004 in Atlantic Beach, Florida. Minority travel awards are available for this program. Information is available online at [ns2.faseb.org/marc/granpro.html](http://ns2.faseb.org/marc/granpro.html) and the application form is available at [ns2.faseb.org/marc/forms/grant\\_spring.pdf](http://ns2.faseb.org/marc/forms/grant_spring.pdf)

FASEB is also recruiting Endocrine Society members who are also members of FASEB to join the FASEB MARC Program Visiting Scientists Referral Network. Only FASEB Society members are eligible to participate as visiting scientists in our Visiting Scientists Referral Network program. If you are interested please visit [ns2.faseb.org/marc/VSP.MARCflyerweb.pdf](http://ns2.faseb.org/marc/VSP.MARCflyerweb.pdf)

For additional information please contact Jacquelyn Roberts, Manager, FASEB Career Resources at [jroberts@faseb.org](mailto:jroberts@faseb.org) or via phone 1-301-634-7022.

## Women in Endocrinology

Dr. Kathie Olsen, Associate Director for Science, Office of Science and Technology Policy (OSTP) will be the featured speaker at the Women in Endocrinology (WE) Annual Dinner to be held at 6:30pm on Wednesday June 16, 2004 in the Sheraton New Orleans Hotel. Dr. Olsen received her Ph.D. in Neuroscience at the University of California- Irvine, followed by post-doctoral training in the Department of Neuroscience at Children's Hospital of Harvard Medical School. Dr. Olsen has served as a faculty member of the Department of Psychiatry and Behavioral Science at SUNY-Stony Brook Medical School, and the Chief Scientist at the National Aeronautics and Space Administration (NASA), a position in which she served the principal interface between the national and international scientific community.

In her current position at the OSTP, Dr. Olsen advises the President and others within the Executive Office in order to implement sound scientific and educational policy in the areas of the life sciences, physical sciences, environmental science, behavioral and social sciences (see [www.ostp.gov/html/aboutostp.html#olsen](http://www.ostp.gov/html/aboutostp.html#olsen) for Dr. Olsen's brief biosketch). With her broad and distinguished background, Dr. Olsen brings unique insights into government policy as it relates to science. Please plan on joining us for her presentation.

The annual WE Mentor Award will be presented in June at the WE dinner, during The Endocrine Society's annual meeting. The award recognizes outstanding individuals who have encouraged and promoted female endocrinologists and who have been instrumental in changing institutional policy toward professional women. The WE Mentor Award is sponsored by a generous grant from Pfizer. The

award winner receives an honorarium of \$1000 and travel expenses to the Annual WE Meeting, held in conjunction with the Endocrine Society Meetings. For more information about the nomination process please see: [www.women-in-endo.org/Pages/mentor\\_award\\_nom.html](http://www.women-in-endo.org/Pages/mentor_award_nom.html)

WE is pleased to continue the on-line mentoring program first announced at the 2003 Annual Meeting in Philadelphia. The goal of this Mentoring program is to provide a resource to match mentees with mentors who have expertise in a variety of areas specific to endocrine careers in academics, industry and private practice. WE continues to identify individuals who would like to serve as mentors and mentees and those interested should follow the instructions found on the WE Web site [www.women-in-endo.org](http://www.women-in-endo.org). You do not have to be a member of The Endocrine Society to join WE! Visit the WE web site at: [www.women-in-endo.org/Pages/index.shtml](http://www.women-in-endo.org/Pages/index.shtml) for information about becoming a member of WE.

WE Abstract Awards are provided to recognize outstanding abstracts submitted for presentation at the Annual Meeting of the Endocrine Society. Details of eligibility requirements and application procedures can be found on our Web page at [www.women-in-endo.org/Pages/travel\\_awards.htm](http://www.women-in-endo.org/Pages/travel_awards.htm).

Applications must be received no later than **April 15, 2004** and should be submitted to: Janet E. Hall, M.D., Repro. End. Unit. BHX-5, Mass. Gen. Hsptl., 55 Fruit St., Boston, MA 02114, fax: 1-617-726-5357, e-mail: [jehall@partners.org](mailto:jehall@partners.org)

## Expert Speakers to Address Obesity at CLB Forum

Members of The Endocrine Society's Corporate Liaison Board (CLB), invite ENDO 2004 attendees to attend the fifth annual Corporate Liaison Board Forum

on Wednesday, June 16, 2004 at 6:30 pm in the New Orleans Marriott.

This year's symposium titled, "Addressing the Epidemic of Obesity: From Bench to Bedside to Market," will emphasize the relationship among the Food and Drug Administration, National Institutes of Health and industry, as they relate to obesity. Recognizing that the issue of obesity continues to be a major concern for the endocrine community, the CLB Forum will present accomplished speakers from these sectors as they reveal the latest research, developments and trends occurring in obesity today. Topics of discussion include:

- **FDA/Academia Perspective: Framing the Challenges in Obesity Research and Our Progress Toward Solution**, Speaker TBD
- **NIH Perspective: Impact of Obesity and Metabolic Syndrome on Human Health**, Dr. Allen Spiegel, Director, *National Institute of Diabetes and Digestive Kidney Diseases (NIDDK)*
- **Industry Perspective: Emerging Concepts and Compounds in Obesity Therapeutics**, Dr. Jose Caro, *Eli Lilly Research*

Encourage your colleagues to attend this cutting-edge symposium. Past CLB Forums have experienced record-breaking attendance for two consecutive years. Mark your calendars now to attend the CLB Forum at ENDO 2004! For the latest information on how you can participate in this informative session, visit The Endocrine Society's Web site at [www.endo-society.org](http://www.endo-society.org) or contact Paris L. A. Moore at [plmoore@endo-society.org](mailto:plmoore@endo-society.org) **EN**

This article by Katrina Bramstedt addresses a question that comes to mind, if not to action, not infrequently. Dr. Bramstedt is not a stranger to The Endocrine Society. She did her ethics training and received her Ph.D degree under Paul Komessaroff and Stan Korenman, both of whom have served as chairs of the Ethics Advisory Committee. She played an important role in the development of the Society's Code of Ethics, serving as staff to the Ethics Advisory Committee at the time the Code was developed.

We are not taught as individuals how to be proper fiduciaries, how to unselfishly represent the values and interests of others. With a strict ranking of those empowered to provide substituted judgment determined by family relationships, as physicians we often feel that the wishes or best interests of the patient become subservient to the surrogate's agenda. Katrina sheds light on these dilemmas in this interesting piece.

*Stanley Korenman, M.D.  
University of California Los Angeles School of Medicine  
Member, Ethics Advisory Committee*

## Questioning the Decision-Making Capacity of Surrogates

*By Katrina A. Bramstedt, Ph.D.*

*Internal Medicine Journal | Volume 33 Page 257-259*

When patients are unable to make medical decisions for themselves due to cognitive impairment, surrogate decision makers are often called upon to guide the medical team. Important to any decision made on behalf of the patient is that the decision reflects the values and preferences of the patient in light of the patient's clinical status and prognosis. Challenges arise for the medical team when surrogates themselves have questionable decision-making capacity (DMC) due to psychosocial issues, conflict of interest, or the obvious projection of their own personal values and treatment preferences instead of the patient's. Even if an alternate surrogate is available, there is no consensus on when and how to switch from the primary surrogate to the alternate surrogate.

In the presence of an Advance Directive or Living Will, surrogates must make decisions for patients on the basis of a "substituted judgment." A substituted judgment is

the act of making a decision based upon knowledge of the values and preferences of the patient—that is, what the latter would have wanted—and not what the surrogate would want done if in his or her position.<sup>1</sup> If the values and preferences of the patient are not known, then the surrogate should proceed to make decisions in the patient's best interests: that is, decisions that would most likely contribute maximally to the patient's welfare.<sup>1</sup> The questions then arise: When, with the knowledge of the patient's val-

**If the values and preferences of the patient are not known, then the surrogate should proceed to make decisions in the patient's best interests: that is, decisions that would most likely contribute maximally to the patient's welfare.**

ues and preferences, do surrogate decisions diverge so severely that substituted judgment does not occur and the DMC of the surrogate is in doubt? Does it matter if

the decisions to be made will have consequences that are reversible? At what point is such doubt significant enough to warrant switching to an alternate surrogate? How should this switch be managed to avoid offending the original surrogate or precipitating threats to the medical team or facility?

Research has exposed that the presence of documented patient health care preferences such as an Advance Directive, or even prior verbal discussions between the surrogate and patient do not automat-

ically facilitate substituted judgment by an appointed surrogate.<sup>2,3</sup> Frequently, surrogates project their own values and health care preferences into their decision-making

for the patients for whom they are decisionally responsible.<sup>2,3</sup> Friends and family functioning as surrogates tend to overestimate, while physicians tend to underestimate,<sup>4</sup> the amount of medical intervention the patient would want.<sup>2,3</sup> However, studies have also shown that patients believe that their appointed surrogates will indeed act according to their written or spoken wishes.<sup>2,4</sup> Whether patient, physician or surrogate, people tend to believe that others are likely to behave as they do; thus their decisions for others are frequently projections of their own values and preferences.<sup>3</sup> Substituted judgment is thus difficult for surrogates to perform and therefore unlikely to be realized, despite the wishes of patients.

The DMC of surrogates should be suspect when care is requested that is in conflict with a patient's prior expressed values and preferences, or, in the absence of such expression, is not in the patient's best interests. Such requests made in tandem with loud and aggressive behaviour could be a signal that projection is occurring—the emotional fervour being a possible mechanism of expressing the surrogate's own values and preferences to the medical team. At this stage, it is the duty of the medical team to remind the surrogate that their role is to facilitate the preferences of the patient, irrespective of what the surrogate's personal preference may be. In doing so, the medical team attempts to respect the prior expressed voice of the patient. Often, this reassurance to surrogates that their role is to facilitate the prior expressed preferences of the patient is experienced as comforting to them, as they no longer feel they are deciding for the patient, but enforcing decisions already made.

When such negotiation with the surrogate is not successful and the DMC of the surrogate is doubtful and his/her decisions would be potentially harmful to the patient, the medical team must consider switching to the alternate surrogate or seeking appointment of a new one. Even in the absence of projection, other behaviours, such as those influenced by alcohol or drugs, and conflicts of interests can impair surrogate DMC. Some surrogates are unable to comprehend the patient's clinical situation due to physical or emotional reasons. At this point, an ethics consultation may be helpful. If the ethicist cannot persuade the surrogate to resign in favour of an alternate, it may be necessary to make an application to the courts for assistance.<sup>5,6</sup> It is, however, not advisable to simply over-ride the questionable surrogate without discussing the issues with him/her, an ethicist or ethics committee, and legal counsel in detail. Further, any change of surrogate should be clearly documented in the patient's chart so that all health care providers can readily know who is the appropriate decision maker.

Surrogate DMC is not simply the authority to make decisions, but rather the ability to make an appropriate substituted judgment in the presence of the patient's prior expressed values and preferences, or a best-interests decision in the absence of such information. While the correlation between patient preferences and decisions by substituted judgment may not be perfect, and there is no formal way to assess the accuracy of such decisions in real clinical cases (unless the patient regains DMC and can assess the surrogate's performance), this does not mean that substituted judgment is fatally flawed as a decision-making tool.

Rather, it remains a valuable tool, which might be aided by descriptively written advance care plans, and by research generating methods to better convey the descriptive information to surrogates for their substituted judgment activities. Methods to reduce projection might also be helpful to the substituted judgment process. **EN**

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## The Hormone Foundation Launches "Hormones and You"

### A New Series of Bilingual Patient Information Pages

In an ongoing effort to meet the needs of underserved populations and the expressed needs of physicians to have easy-to-use patient materials in Spanish and English, The Hormone Foundation has launched "Hormones and You," a new series of mid-literacy, bilingual patient information pages on various endocrine-related topics.

Beginning with diabetes in the February issue of the *Journal of Clinical Endocrinology & Metabolism (JCEM)*, the bilingual fact sheets will appear as tear-out inserts, which physicians and other health

care providers can duplicate and distribute to patients. The fact sheets will also be inserted into *Endocrine News* (see page 27), as well as posted on the Foundation's Web site ([www.hormone.org](http://www.hormone.org)), Journals Online ([www.jcem.endojournals.org](http://www.jcem.endojournals.org)), and the MEDEM library ([www.medem.com](http://www.medem.com)).

In addition, the Foundation will take advantage of ENDO, Clinical Endocrinology Update (CEU) and other meetings and workshops to disseminate the series, as well as to translate them into other languages for the upcoming International Congress on Endocrinology (ICE).

The bilingual fact sheets are developed by The Hormone Foundation, under the leadership of

expert Endocrine Society members. Each fact sheet includes general information about a particular endocrine condition, links to other resources and information on the Foundation's physician referral directory, which consists of 3,000 clinician members of The Endocrine Society.

Future fact sheet topics include hypertension, obesity, breast cancer, menopause, growth disorders, osteoporosis, testosterone and men's health and more.

For more information about The Hormone Foundation visit [www.hormone.org](http://www.hormone.org) or contact Molly Wade, Director, at 1-800-HORMONE or [mwade@endo-society.org](mailto:mwade@endo-society.org) **EN**



# Advances in Skeletal Anabolic Agents for the Treatment of Osteoporosis

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THE HORMONE  
FOUNDATION

## Hormones and Hypertension

DOCTORS PLEASE TEAR HERE

### What is hypertension?

Hypertension, or high blood pressure, is a main cause of cardiovascular disease, which may lead to death. Hypertension greatly raises your risk of heart attack, stroke or kidney failure. Since people with hypertension often have no symptoms, it has been called “the silent killer.”

As blood flows through the body, it pushes against the walls of the arteries that carry it. This force in the arteries is the blood pressure. The measurement of blood pressure includes systolic and diastolic readings. An example is 120/80 mm Hg. The first number is the systolic pressure as the heart contracts. The second number is the diastolic pressure when the heart relaxes between contractions.

Hypertension is a rise in blood pressure above the normal level. Normal blood pressure is below 120/80 mm Hg. If your systolic blood pressure is 120 to 139 mm Hg or your diastolic blood pressure is 80 to 89 mm Hg, you are “prehypertensive.” If your blood pressure is always at least 140/90 mm Hg, you have hypertension.

About 50 million adults in the United States have hypertension. It is more common among African Americans and persons from low socioeconomic levels. For all races, the chances of having hypertension rise with age.

### What causes hypertension?

There are two types of hypertension—primary and secondary. Most hypertension is the primary type. Its cause is unknown, but genetics and things such as high salt intake, obesity, tobacco, and alcohol have a part. Hormones made in the kidney and in blood vessels play a key role in the start and maintenance of primary hypertension.

Secondary hypertension occurs with another disease, such as kidney disease, and certain hormonal disorders such as Cushing’s syndrome. Use of steroid hormones to treat a different medical problem is another cause of secondary hypertension.

### How is hypertension treated?

Although there is no cure for primary hypertension, more than 80 medications are available to reduce blood pressure. Doctors often prescribe medication and lifestyle changes.

Depending on its cause, surgery or medications that affect specific hormones in the body can cure secondary hypertension.

### What should you do with this information?

If your doctor diagnoses hypertension, you can control it with medication and lifestyle changes.

After a hypertension diagnosis, you should have regular blood pressure checks to see how well

### Recommendations for Lifestyle Changes

- Keep a healthy weight (body mass index of 18.5 to 24.9).
- Reduce the amount of saturated and total fat in your diet. Eat lots of fruits and vegetables, and choose low-fat dairy products.
- Reduce salt in your diet.
- Exercise (e.g., brisk walking) at least 30 minutes a day, most days of the week.
- Limit alcohol intake (men: no more than 2 drinks a day; women and light-weight men: no more than 1 drink a day).

Source: National High Blood Pressure Education Program (NHLBI/NIH/DHHS)

your treatment is working. The goal is to lower your systolic blood pressure to under 140 mm Hg and to lower your diastolic blood pressure to under 90 mm Hg. If you have diabetes or kidney disease, the goal is to lower your blood pressure to under 130/80 mm Hg.

### Resources

American Heart Association:  
[www.americanheart.org](http://www.americanheart.org)

Hypertension Education Foundation:  
[www.hypertensionfoundation.org](http://www.hypertensionfoundation.org)

MEDLINE Plus:  
<http://www.nlm.nih.gov/medlineplus/bigbbloodpressure.html>

National Heart, Lung, and Blood Institute: [www.nhlbi.nih.gov](http://www.nhlbi.nih.gov)

To measure blood pressure at home:  
[www.familydoctor.org/handouts/128.html](http://www.familydoctor.org/handouts/128.html)

#### EDITORS:

Robert M. Carey, MD, MACP  
William Young, MD

March 2004

For more information on how to find an endocrinologist, download free publications, translate this fact sheet into other languages, or make a contribution to The Hormone Foundation, visit [www.hormone.org/bilingual](http://www.hormone.org/bilingual) or call 1-800-HORMONE. The Hormone Foundation, the public education affiliate of The Endocrine Society ([www.endo-society.org](http://www.endo-society.org)), serves as a resource for the public by promoting the prevention, treatment, and cure of hormone-related conditions. This page may be reproduced non-commercially by health care professionals to share with patients. Translation by MEDI-FLAG Corp.



THE HORMONE  
FOUNDATION

## Las hormonas y la hipertensión

### ¿Qué es la hipertensión?

La hipertensión, o presión sanguínea alta, es una de las principales causas de las enfermedades cardiovasculares que, con el tiempo, pueden producir la muerte. La hipertensión aumenta grandemente el riesgo de que usted sufra un ataque cardíaco, un derrame o un fallo renal; se le da el nombre de “asesino silencioso” porque la gente con presión alta puede no tener ningún síntoma.

La sangre, a medida que circula por los vasos sanguíneos, ejerce una fuerza sobre las paredes de las arterias. Esta fuerza es la que se denomina presión sanguínea o presión arterial. La medida de la presión sanguínea incluye dos mediciones y se escribe, por ejemplo, como 120/80 mm Hg. El primer número es la presión sistólica, o sea la presión sanguínea a medida que el corazón se contrae. El segundo número es la presión diastólica, que representa la presión cuando el corazón reposa entre contracciones.

Hipertensión es cuando la presión sanguínea sube hasta exceder el nivel normal. La presión sanguínea normal es de menos de 120/80 mm Hg. Si su presión sistólica es de 120 a 139 mm Hg o su presión diastólica es de 80 a 89 mm Hg, usted es una persona “prehipertensiva”. Si su presión sanguínea constante es de 140/90 mm Hg o más, usted tiene hipertensión.

En los Estados Unidos, hay aproximadamente 50 millones de adultos que tienen hipertensión. Es más común entre las personas afroamericanas y las personas de pocos medios socioeconómicos. En todas las razas, la incidencia de hipertensión aumenta con la edad.

### ¿Qué causa la hipertensión?

Hay dos tipos de hipertensión—primaria (esencial) y secundaria. La mayoría de hipertensión es de tipo primario. Aunque se desconoce la causa de la hipertensión esencial, se sabe que hay aspectos hereditarios y ambientales, tales como consumir mucha sal, tener exceso de peso, y usar tabaco y alcohol, que son factores contribuyentes. Las hormonas producidas por los riñones y en los vasos sanguíneos desempeñan un papel importante en el comienzo y continuación de la hipertensión primaria.

La hipertensión secundaria ocurre cuando se presentan otras enfermedades, tales como la insuficiencia renal y ciertas perturbaciones hormonales, tales como el síndrome de Cushing. La hipertensión secundaria también puede ser causada por hormonas esteroides que se empleen para tratar otras enfermedades.

### ¿Cómo se trata la hipertensión?

Aunque la hipertensión primaria no tiene cura, hay más de 80 medicamentos distintos para reducir la presión alta. Los medicamentos muchas veces se recetan conjuntamente con un cambio en el estilo de vida.

Según la causa, es posible que la hipertensión sea curada por cirugía o por medicamentos que afecten hormonas específicas en el cuerpo.

### ¿Qué debe hacer usted con esta información?

Si su médico le da el diagnóstico que tiene hipertensión, usted puede controlarla con medicamentos y cambios en su estilo de vida.

Después de haber recibido un

### Recomendaciones para cambiar el estilo de vida

- Mantener un peso saludable (índice de masa corporal de 18.5 a 24.9).
- Reducir la cantidad de grasa saturada y grasa total en su régimen de comida. Coma frutas, vegetales y productos lácteos de poca grasa.
- Reducir la sal en las comidas.
- Mantener una actividad física (por ej., caminar rápido) de por lo menos 30 minutos al día, casi todos los días de la semana.
- Limitar el alcohol (Los hombres deben limitarse a 2 bebidas alcohólicas por día y las mujeres y personas de menos peso limitarse a 1 bebida por día).

Fuente: National High Blood Pressure Education Program (NHLBI/NIH/DHHS)

diagnóstico de hipertensión, usted debe revisarse la presión periódicamente para saber qué efecto está teniendo el tratamiento. El objetivo es reducir su presión sistólica a menos de 140 mm Hg y reducir la diastólica a menos de 90 mm Hg. Si usted tiene diabetes o sufre de enfermedad renal, su meta será reducir su presión a menos de 130/80 mm Hg.

### Recursos:

Asociación Cardíaca Americana:  
[www.americanheart.org](http://www.americanheart.org)

Centro para Control de Enfermedades (CDC): [www.cdc.gov/spanish/enfermedades.htm](http://www.cdc.gov/spanish/enfermedades.htm)

MEDLINE Plus: [www.nlm.nih.gov/medlineplus/spanish/highbloodpressure.html](http://www.nlm.nih.gov/medlineplus/spanish/highbloodpressure.html)

Para tomarse la presión en casa:  
[www.familydoctor.org/handouts/128.html](http://www.familydoctor.org/handouts/128.html)

#### EDITORES:

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Para más información sobre cómo encontrar un endocrinólogo, obtener publicaciones de la Internet, traducir esta hoja de datos a otros idiomas, o hacer una contribución monetaria a la Fundación de Hormonas, visite a [www.hormone.org/bilingual](http://www.hormone.org/bilingual) o llame al 1-800-HORMONE (1-800-467-6663). La Fundación de Hormonas, la filial de enseñanza pública de la Sociedad de Endocrinología ([www.endo-society.org](http://www.endo-society.org)), sirve de recurso al público para promover la prevención, tratamiento y cura de condiciones hormonales. Esta página puede ser reproducida por los profesionales médicos que deseen compartirla con sus pacientes, pero no para fines comerciales. Traducción hecha por MEDI-FLAG Corp.

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## Keeping you informed about endocrinology in the news

*Almost everyday, new developments in endocrinology are featured in the news. In each issue of Endocrine News, Endocrine Edge will highlight some of the recent news stories.*

### High-Risk Diabetes

A recent study, published in *The Journal of Clinical Endocrinology & Metabolism*, shows that large numbers of overweight Hispanic youth already have complications of obesity, including impaired glucose tolerance, which can lead to diabetes and metabolic syndrome. **EN**

For more information visit [www.endo-society.org](http://www.endo-society.org)

### Stem Cell Research

Researchers in South Korea have become the first to successfully clone a human embryo and then cull from it master stem cells that many doctors consider key to one day creating customized cures for diabetes, Parkinson's and other diseases. Scientists from Seoul Na-

tional University succeeded largely because of using extremely fresh eggs donated by South Korean volunteers and gentler handling of the genetic material inside them. The research will be published in the journal of *Science*. **EN**

For more information visit [www.aas.org](http://www.aas.org)

### Hormones linked to Depression

Researchers at the Yale University School of Medicine recently attempted to find a molecular reason why women are almost twice as likely to experience major depression and anxiety disorders as men. The results, which will appear in the March issue of the *Journal Molecular Psychiatry*, suggest that estrogen

may amplify the negative effect of stress on the brain's ability to complete certain tasks. Evidence also hints that estrogen increases susceptibility to stress-related disorders such as depression and anxiety, and may be the reason the increased risk ends at menopause. **EN**

For more information visit [www.nature.com/mp](http://www.nature.com/mp)

### Fertility

In a new study, researchers at the National Institute of Child Health and Human Development of the National Institutes of Health and the Beth Israel Deaconess Medical Center discovered that abnormal levels of two molecules found in the blood appear to predict the development of preeclampsia, a life-threatening complication of pregnancy. The findings appeared in the February 12 issue of *The New England Journal of Medicine*. **EN**

For more information visit [www.nejm.org](http://www.nejm.org)

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[www.MEN2004.org](http://www.MEN2004.org)

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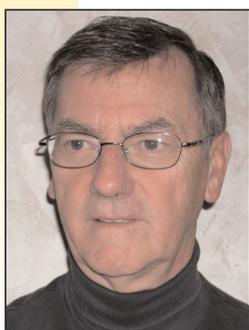
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# Important HCPCS level II Coding Changes for 2004

*Richard A Dickey, MD, FACP, FACE*

*Chair, Clinical Affairs Committee; Endocrine Society's CPT advisor, RUC advisor, and member AMA Practice Expense Advisory Committee (PEAC)*

In the last issue of Coding News, endocrinology-related code changes in CPT (also known as HCPCS level I) for 2004 were presented. This column of Coding News focuses on endocrinology-pertinent code changes for 2004 in the Healthcare Common Procedure Coding System (HCPCS) Medicare National Level II code system of over 4,000 codes



*Richard A Dickey, MD, FACP, FACE*

developed and maintained by the Centers for Medicare and Medicaid services (CMS). Since there are so many important new and changed codes in this system to describe, the code changes in the diagnosis coding system (ICD-

## **Bxxxx codes are for enteral and parental therapy while the Cxxxx codes are for outpatient pass-through payment services.**

9-CM) will be discussed in a subsequent Coding News.

The HCPCS Medicare National Level II Codes are alpha-numeric codes; a letter followed by four

numbers. The important changes for 2004 are described here by code group. The nature of the code groups with no important changes are also described.

The Axxxx codes are for transportation services including ambu-

lance, medical and surgical supplies, administrative, miscellaneous and investigational codes (see Figure 1).

Bxxxx codes are for enteral and parental therapy while the Cxxxx codes are for outpatient pass-through payment services. Dxxxx codes are for dental procedures and Exxxx codes for durable medical equipment. The Gxxxx codes are temporary codes for procedures/professional services for which there are no CPT codes (see Figure 2).

Hxxxx codes are for alcohol and drug abuse treatment services. Jxxxx codes are for drugs administered other than oral method, i.e. drugs that ordinarily cannot be self-administered, chemotherapy drugs, immunosuppressive drugs, inhalation solutions, and other miscellaneous drugs and solutions (see Figure 3).

Then there are the temporary Kxxxx codes (see Figure 4), created for use by the durable medical equipment regional carriers (DMERCs) "when the currently existing permanent national codes for supplies and certain product categories do not include the codes needed to implement a

**FIGURE 1**

<b>Code</b>	<b>Descriptor</b>	<b>Type of change</b>	<b>Note</b>
A4214	Sterile saline or water, 30 cc vial	Deleted	
A4216	Sterile water/saline, 10 ml	New	See Medicare Carrier Manual (MCM) 2049
A4217	Sterile water/saline, 500 ml	New	See MCM 2049
A4712	Water, sterile, for injection, per 10 ml	Deleted	
A9518	Supply of radiopharmaceutical therapeutic imaging agent, I-131 sodium iodide solution, per uci	Deleted	See A9530
A9528	Supply of radiopharmaceutical diagnostic agent, I-131 sodium iodide capsule, per millicurie	New	
A9529	Supply of radiopharmaceutical diagnostic agent, I-131 sodium iodide solution, per millicurie	New	
A9530	Supply of radiopharmaceutical therapeutic agent, I-131 sodium iodide solution, per millicurie	New	
A9531	Supply of radiopharmaceutical diagnostic agent, I-131 sodium iodide, per microcurie (up to 100 microcuries)	New	
A9999	Miscellaneous DME supply or accessory, not otherwise specified	New	

DMERC medical review policy.”<sup>1</sup>

Following these are the Lxxx codes, for orthotic procedures and prosthetic procedures; Mxxx medical services codes; Pxxx pathology and laboratory services codes; Qxxx temporary codes for some drugs, for cast and splinting supplies, for a few laboratory tests, and for the supply of some medical supplies such as certain radiopharmaceutical diagnostic imaging agents (see Figure 5).

Rxxx codes are to the transportation of portable x-ray and/or EKG equipment and Sxxx codes (see Figure 6) are temporary national codes (non-Medicare) for a large variety of “drugs, services, and supplies for which there are no national codes but for which codes are needed by the private sector to implement policies, programs, or claims processing.”<sup>1</sup> These are also used by Medicaid but they are not payable by Medicare.

**...there is a series of two letter alpha modifiers for the HCPCS level II codes and convenient appendices are provided at the end of most HCPCS level II books...**

National T codes (Txxx) are established for use by state Medicaid agencies (see Figure 7).

Vxxx codes are for vision services, hearing services and speech-language pathology services. Finally, there is a series of two letter alpha modifiers for the HCPCS level II codes and convenient appendices are provided at the end of most HCPCS level II books, including a table of drugs, Medicare references, companies accepting HCPCS level II codes and a list of new, changed and deleted HCPCS codes for the current year. **EN**

**FIGURE 2**

<b>Code</b>	<b>Descriptor</b>	<b>Type of change</b>	<b>Note</b>
G0122	Colorectal cancer screening; barium screening	Revised code	Noncovered by Medicare
G0306	Complete CBC, automated (Hgb, HCT, RBC, WBC; without platelet count) and automated WBC differential count	New	
G0307	Complete CBC, automated (Hgb, HCT, RBC, WBC; without platelet count)	New	
G0308-G0327	End Stage Renal Disease (ESRD) related services	New code series added as per final 2004 Medicare Physician Fee Schedule. Federal Register, November 7, 2003.	There is concern about these changes in payment of disease management services which could impact other such services, such as diabetes care, in the future.

**FIGURE 3**

<b>Code</b>	<b>Descriptor</b>	<b>Type of change</b>	<b>Note</b>
J2352	Injection, octreotide acetate, 1 mg	Deleted	
J2353	Injection, octreotide, depot form for intramuscular injection, 1 mg	New	
J2354	Injection, octreotide, non-depot form for subcutaneous or intravenous injection, 25 mcg	New	
J4311	Injection, thiamine HCl, 100 mg	New	
J3415	Injection, pyridoxine HCl, 100 mg	New	
J7303	Contraceptive supply, hormone containing vaginal ring, each	Noncovered by Medicare	Medicare Statute: 1862.1

**FIGURE 4**

<b>Code</b>	<b>Descriptor</b>	<b>Type of change</b>	<b>Note</b>
K0601	Replacement battery for external infusion pump owned by patient, silver oxide, 1.5 volt, each	New	
K0602	Replacement battery for external infusion pump owned by patient, silver oxide, 3 volt, each	New	
K0603	Replacement battery for external infusion pump owned by patient, alkaline, 1.5 volt, each	New	
K0604	Replacement battery for external infusion pump owned by patient, lithium, 3.6 volt, each	New	
K0605	Replacement battery for external infusion pump owned by patient, lithium, 4.5 volt, each	New	

**REFERENCES:**

1. *HCPCS Level II Codes 2004* Available from the AMA (discount for AMA member) or other suppliers.
2. *Current Procedural Terminology, CPT 2004* Available from the AMA or other licensees. AMA order phone number is (800) 621-8335. Discount for AMA member.
3. *International Classification of Diseases ICD-9-CM 2004*. Available from the AMA (discount for AMA member) or other suppliers.
4. *cpt changes: An Insider's View* Available from the AMA. AMA order phone number is (800) 621-8335. Discount for AMA member.
5. *CPT Assistant*. A quarterly publication available by subscription from the AMA. Articles explain in detail complex coding issues. Citations of these articles are provided in *Current Procedural Terminology, CPT 2004*.

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**FIGURE 5**

Code	Descriptor	Type of change	Note
Q4052	Injection, octreotide, depot form for intramuscular injection, 1 mg	Deleted	
Q0002-Q0040	Injection codes for epoetin alpha (EPO)	Deleted	See new codes Q4054-4055

**FIGURE 6**

Code	Descriptor	Type of change	Note
S0138	Finasteride, 5 mg	New	Noncovered by Medicare. Use this code for Propecia (oral), Proscar (oral).
S0315	Disease management program; initial assessment and initiation of the program	Existent code	Noncovered by Medicare
S0316	Followup/reassessment	Revised code	Noncovered by Medicare
S0317	Disease management program; per diem	New	Noncovered by Medicare
S3000	Diabetic indicator; retinal eye exam, dilated, bilateral	New	Noncovered by Medicare
S3625	Maternal serum triple marker screen including alpha-fetoprotein (AFP), estriol, and human chorionic gonadotropin (hCG)	New	Noncovered by Medicare
S3820-S3853	A series of gene sequence, mutation analysis, DNA analysis, genetic testing codes	New	Noncovered by Medicare
S5550-S5571	Insulin, insulin delivery device, and insulin cartridge codes	New	Noncovered by Medicare
S9434	Modified solid food supplements for inborn errors of metabolism	New	Noncovered by Medicare

**FIGURE 7**

Code	Descriptor	Type of change	Note
T2022	Case management, per month	New	Noncovered by Medicare
T2023	Targeted case management; per month	New	Noncovered by Medicare

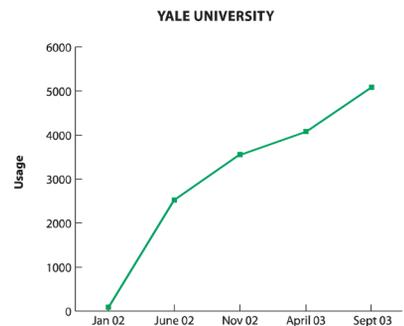
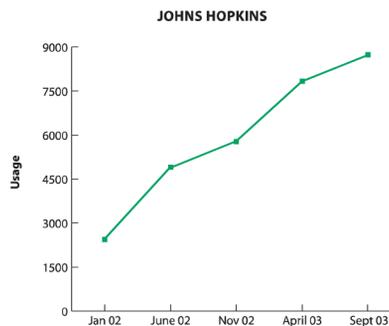
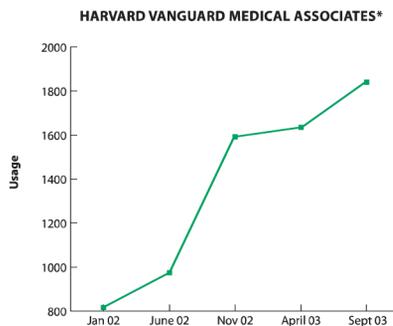
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**May 15-17, 2004: 5th Scientific Forum on Quality of Care and Outcomes Research in Cardiovascular Disease and Stroke**, Washington, DC. For more information please visit [www.americanheart.org](http://www.americanheart.org) 1-(214) 706-1543 or email [scientificconferences@heart.org](mailto:scientificconferences@heart.org)

**May 15-24, 2004: Clinical Endocrinology Delegation to Russia and People to People Ambassador Endocrinology delegation to Russia**, Moscow and St Petersburg, Russia. For more information please visit [www.ambassadorprograms.org](http://www.ambassadorprograms.org) or contact Richard A Dickey MD & Ms. Yvonne Trudeau by phone 1-(877) 787-2000 fax 1-(509) 534-5245 or email [info@ambassadorprograms.org](mailto:info@ambassadorprograms.org)

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**May 18- 22, 2004: The American Society of Hypertension Nineteenth Annual Scientific Meeting and Exposition**, New York, NY. For more information please visit [www.asb-us.org](http://www.asb-us.org)

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