



June 14, 2007

### **The Endocrine Society Unveils Recommendations for Increasing Minority Participation in Clinical Research**

The Endocrine Society has engaged in a continuing project to improve the participation of racial and ethnic minorities in clinical research. The Society's recommendations, developed by a task force of thought leaders on the topic, were released during a special program during ENDO 07. The task force comprised Society members and non-member representatives from each of the stakeholder groups that have a vested interest in the problem, including researchers, community leaders, the pharmaceutical industry, and government agencies. The project is an initiative of the Government Relations Committee (GRC) and is funded in part by a grant from the Robert Wood Johnson Foundation. Dr. Maria Alexander-Bridges, a member of the GRC, spearheads the effort.

The full white paper has not yet been published, but the recommendations can be viewed at <http://www.endo-society.org/publicpolicy/insider/loader.cfm?url=/commonspot/security/getfile.cfm&pageid=26919>. The Society will use the paper and its conclusions in advocacy efforts with policymakers and regulators and in outreach to organizations that may help implement the proposed changes.

Some examples of the recommendations include:

- Congress should pass legislation requiring FDA to adhere to inclusion policies similar to legislation requiring NIH-funded trials to adhere to such policies.
- FDA should consider adopting NIH guidelines on the inclusion of women and minority populations.
- FDA should require rather than recommend adherence to its guidelines.
- NIH and academia should establish and maintain an infrastructure of minority patient populations from which individual investigators can easily and efficiently recruit volunteers.

Research and the assembly of the paper represent the first phase of the project. The next phase is to disseminate the information and to advocate for change.

ENDO 07 featured two programs resulting from the project. The above-mentioned special program featured a panel-led discussion of the issues and the Society's recommendations. Panel members included members of the Society's task force and other interested parties. Additionally, there was an official ENDO 07 symposium featuring presentations by key

members of the task force. Each presentation addressed the issues from a unique perspective.

### **The Endocrine Society Responds to NEJM Article on Avandia**

A *New England Journal of Medicine* article (published online at [www.nejm.org](http://www.nejm.org) on May 21, 2007, and scheduled for print in the June 14 issue) on the prescription drug Avandia (rosiglitazone maleate) sparked a media frenzy regarding the safety of the drug. The article, which was based on meta-analysis of several studies, outlined potential cardiovascular risks associated with taking the drug. The results of the meta-analysis are controversial, resulting in debate among members of the scientific and medical communities.

In response to the media coverage, the Society's Clinical Affairs Committee generated a statement aimed at health care providers recommending a course of action for individual providers and for the biomedical community as a whole. The Society's statement may be viewed here:

<http://www.endo-society.org/publicpolicy/policy/avandia.cfm>.

In addition, ENDO 07 featured a Late-Breaking Hot Topic Symposium on the subject. The symposium, titled "Thiazolidinediones and Cardiovascular Risk: A Rational Perspective," was moderated by then-President Leonard Wartofsky, MD. The session featured the following presentations and speakers:

- A Methodologic Perspective. Hertz C. Gerstein MD, MSc, FRCPC, McMaster University
- A Clinical Perspective. John B. Buse, MD, PhD, University of North Carolina

### **The Endocrine Society Partners with Research!America on Congressional Survey**

The Endocrine Society has partnered with Research!America and the Albert and Mary Lasker Foundation on *Your Congress-Your Health*, a new initiative creating a dialogue on health and research between Congress and the public. A goal of the *Your Congress-Your Health* initiative is to provide a database that outlines the positions of individual members of Congress on research policy issues and, over time, align members' voting records with this information. *PARADE* magazine launched the initiative in its March 11 issue, asking readers what they would like to ask Congress about health and research issues. The response was overwhelming, and the article received more online comments than any *PARADE* story to date. This feedback shaped a questionnaire recently sent to all members of Congress to learn about their positions on a range of health related topics.

The Society encourages you to write to your members of Congress and ask them to respond to the *Your Congress-Your Health* questionnaire so that you may track where they stand on medical research and other health-related issues. A sample letter is available on the Research!America website through the following link:

<http://capwiz.com/ram/issues/alert/?alertid=9425906>

Visit [www.yourcongressyourhealth.org](http://www.yourcongressyourhealth.org) now to see what questions are being asked of members of Congress, and return in June to see how they respond.

## **Society Continues Bridge Grant Program in 2008, Modifies Eligibility Criteria**

The Endocrine Society's Council has approved the continuation of the pilot Bridge Grant Program for an additional year in 2008. During its pilot year, the program provided \$50K grants for seven outstanding research projects, and as many as ten will be awarded in 2008. Interest in the program has been strong, and Society members have made suggestions regarding the eligibility requirements. In response to these suggestions, and upon evaluation of the first year, two of the eligibility requirements have been adjusted.

During the pilot year, the funding was restricted to competing renewal applications of established investigators with established projects that had recently been denied renewal funding by a national granting agency. In 2008, such investigators are eligible, and the program is open also to individuals who have been funded under mentored or semi-independent mechanisms and are seeking their first independent research grant to continue their work. For example, an individual who has held an NIH K award and now seeks an NIH R award would be eligible to apply. Established independent investigators who seek funding for a new project are not eligible.

In 2007, the non-funded research grant upon which the bridge grant application was based must have ranked within the top quartile to be considered for Society funding. Society members made the case for relaxing this restriction, as increasing numbers of meritorious grants are being denied funding, thereby making each successive round of grant submission more competitive than the last. In response to this argument, the Society has relaxed the ranking requirement to include any non-funded grant that ranked within the top 40<sup>th</sup> percentile.

Bridge Grant funds are approved for direct research costs and are expected to provide investigators the ability to continue working on promising projects and to retain key personnel while seeking outside funds. Bridge funding should provide researchers the means with which to strengthen their research proposals for resubmission to national agencies or major foundations, thus improving the chances of the proposal being re-funded.

More details on the revised 2008 program will be available soon on the Society's Web site at <http://www.endo-society.org/publicpolicy/bridge-grants/index.cfm>.

## **Some ENDO 07 Highlights**

### ***Advocacy***

In order to increase awareness of issues important to the Society's membership, Government & Public Affairs staff provided ENDO attendees with an opportunity to participate in grassroots advocacy by writing to their senators and representatives about two critical issues: increasing funding for NIH in FY 2008 and halting payment cuts for medical imaging procedures performed in the physician's office. Strong interest from the membership on these two issues resulted in approximately 250 letters being sent to Congress.

### ***Media***

DISCOVER Magazine, in partnership with The Endocrine Society, sponsored a unique public roundtable discussion at ENDO 07. "Redefining Aging: the Impact of Endocrine Research" engaged a select panel of Society members\* to discuss the potential opportunities

and risks surrounding the use of hormones in an attempt to forestall the effects of aging. Held June 3 at the Metro Toronto Convention Centre, the roundtable forms the foundation of a strong editorial outreach on hormones and aging by DISCOVER. The contents of this roundtable will be published as a feature article in an upcoming issue of the magazine, and the video from the event will be posted on the DISCOVER website ([www.discovermagazine.com](http://www.discovermagazine.com)). Considered the world's largest circulation general science publication, DISCOVER Magazine has been a prominent feature on newsstands for more than 25 years.

\*Panelists included Dr. Marc Blackman, National Institutes of Health; Dr. Ginger Constantine, Wyeth Research; Dr. Adrian Sandra Dobs, Johns Hopkins School of Medicine; Dr. Andrea Dunaif, Northwestern University; Dr. M. Sara Rosenthal, University of Kentucky School of Medicine; and Dr. Michael Thorner, University of Virginia Health Systems.

### ***Clinical Practice Guidelines***

ENDO 07 featured scientific sessions on three clinical practice guidelines—*Prevention and Treatment of Pediatric Obesity*, *Management of Thyroid Dysfunction during Pregnancy and Postpartum*, and *Androgen Therapy in Women*. Each session included an overview of the guideline from the chair of the task force that developed it, including highlights, recommendations, and challenges, and an open discussion led by an independent moderator. The moderator began each session by using a new Audience Response System to poll audience members on how they would handle a clinical scenario. The clinical vignettes were used to highlight controversial issues within the guideline topic and to measure the effectiveness of the guideline for the clinical endocrinologist.

*Management of Thyroid Dysfunction during Pregnancy and Postpartum* is scheduled for publication in the August issue of the *Journal of Clinical Endocrinology & Metabolism (JCE&M)*. *Androgen Therapy in Women* is currently available at [http://www.endo-society.org/quickcontent/clinicalpractice/clinical-guidelines/CG\\_AndroWomen.cfm](http://www.endo-society.org/quickcontent/clinicalpractice/clinical-guidelines/CG_AndroWomen.cfm).

*Prevention & Treatment of Pediatric Obesity* is currently under peer review with *JCE&M*.

### ***New CDC Collaboration***

The Centers for Disease Control and Prevention (CDC) is collaborating with The Endocrine Society on a project to improve the accuracy and reliability of clinical testosterone (T) measurements. The initiative resulted from the Society's call for standardization of T assays, as detailed in the Society's position statement *Utility, Limitations, and Pitfalls in Measuring Testosterone* (*J Clin Endo Met* 92(2):405–413). The official public announcement of the collaboration occurred at ENDO 07 with a workshop describing the issue and outlining the steps to be taken to address the problem. The workshop was chaired by William Rosner, MD, and featured presentations from Hershel Raff, PhD, and CDC official Hubert Vesper, PhD.

### **ENDO 07 Generates Strong Media Attention**

Research presented at The Endocrine Society's annual meeting—ENDO 07, June 2-5, Toronto, Canada—drew considerable international media attention. More than 40 journalists from North America, Europe, and Asia were on site to report on the meeting, and more than 30 other journalists from around the globe were able to participate through an interactive webcast of media events.

Research of particular interest to the media came from Society member Dr. Anne Loucks of Ohio University on how calorie intake may affect bone health of young women. Loucks' research showed that formation of new bone depends on energy availability, which is the difference between calories eaten and calories burned during physical activity. This held true not just for adolescents but also for adults in their late 20s and early 30s. A *New York Times* report on this research is available here:

[http://www.nytimes.com/2007/06/12/health/nutrition/12nutr.html?\\_r=1&oref=slogin](http://www.nytimes.com/2007/06/12/health/nutrition/12nutr.html?_r=1&oref=slogin)

Dr. Alan Hirsch of Chicago's Smell and Taste Treatment and Research Foundation presented new research that implicates distraction as the main cause of overeating while watching TV. Hirsch measured potato chip consumption in 45 subjects during five-minute periods over three weeks. Subjects ate as much as they wanted while they viewed a monologue by David Letterman, while they watched a Jay Leno monologue, and while they did not watch TV. Subjects munched an average of 44 percent more chips while watching Letterman and 42 percent more of the snack food while viewing Leno than when they watched no television. Hirsch suggested that the more entertaining a television program, the more distracted a person becomes and the more food he or she consumes. Under this assumption, chip consumption during the study would suggest that participants found Letterman more entertaining than Leno. The study was well received by the popular press and covered extensively in Canada and the United States. A news report of this study in the *Toronto Star* is here: <http://www.thestar.com/entertainment/article/222000>

Dr. Gail Laughlin of the University of California at San Diego School of Medicine unveiled research on how men who have lower levels of testosterone may be at greater risk of dying. In the study, Laughlin and her co-investigators looked at death from any cause in nearly 800 men ages 50 to 91 years who participated in the Rancho Bernardo Study in the 1980s. The men with low T levels had a 33 percent greater risk of death than the men with higher T levels. This difference was not explained by smoking, alcohol intake, or level of physical activity, or by pre-existing diseases such as diabetes or heart disease. The *Washington Post* reported on this study: <http://www.washingtonpost.com/wp-dyn/content/article/2007/06/10/AR2007061000946.html>

During the meeting, the Society held six news conferences on various topics and a media roundtable on the current state of knowledge on endocrine disruptors. A video and audio archive of these press events is available here: <http://www.webcastcanada.ca/endo/>

Additional media coverage appeared in Reuters, ABC News, *U.S. News & World Report*, Web MD, and UPI, among many others. The Society also received local coverage in Toronto including the *Globe and Mail*, *Toronto Star*, *Toronto Sun*, and CBC World News.

For questions regarding articles listed in *Endocrine Insider* or information on advocacy and policy activities within The Endocrine Society, contact the Government & Public Affairs department:

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