



May 25, 2006

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### **Society Members Meet With Members of Congress**

On May 10, 2006 members of the Society's Government Relations Committee (GRC) took to the halls of Congress to advance the Society's advocacy agenda. The Committee members focused on three main issues: federal funding for biomedical research, obesity legislation, and physician reimbursement issues.

Perhaps the most daunting challenge the Society's membership faces is the declining federal support for biomedical research. Society members met with key congressional appropriations staff to convey the message that federal support for biomedical research must be sustained. The President has proposed providing the National Institutes of Health (NIH) with a flat budget for FY 2007, funding the agency at the same level as FY 2006. This scenario would result in budget decreases, when adjusted for inflation, and would be a major blow to current and future research.

Members of the GRC met with both the majority and minority chiefs of staff for the Senate Labor/HHS/Education Appropriations Subcommittee, who have jurisdiction over NIH funding. These senior staffers, from the offices of Senator Arlen Specter (R-PA) and Senator Tom Harkin (D-IA), were optimistic that Congress would authorize additional spending above the President's request. However, they did caution that the scientific community should not expect more than a two to three percent increase over FY 2006. In addition, both offices thanked the Society for its grassroots support of Sens. Specter's and Harkin's amendment in March to the FY 2007 Budget Resolution. This amendment added \$7 billion to fund health and education programs and was passed overwhelmingly in the Senate. Both offices said this strong support in the Senate was due to the grassroots efforts of the scientific community and patient groups who sent droves of letters to their representatives in the Senate urging them to support the Specter/Harkin amendment.

It was also important to meet with congressional offices that have been actively pursuing public policy solutions to the obesity epidemic. The offices that GRC members met with included Senate Majority Leader Bill Frist (R-TN), Senator Hillary Clinton (D-NY), Senator Pete Sessions (R-AL), and Representative Barbara Lee (D-CA). Senator Frist's staff thanked the Society for sponsoring the recent Senate Congressional staff briefing, "Obesity 101." The office expressed interest in hosting a follow-up briefing with the Society in the future. All offices were pessimistic about the chances that Congress would take any major action on pending obesity legislation before the November elections.

Members of the GRC also met with both Reps. Diana DeGette (D-CO) and Russ Carnahan (D-MO) to discuss stem cell research legislation. Both House members are sponsors of the Stem Cell Research Enhancement Act. They urged the Society to contact Senate Majority Bill Frist to encourage Senate action on the legislation—which the House passed last year.

Finally, Society members met with key congressional staff to discuss Medicare payment issues. Physicians again face a five percent payment cut in Medicare reimbursement if Congress does not act by the end of the year. This annual payment cut is due to the flawed Sustainable Growth Rate (SGR) formula that is used to calculate reimbursement rates. The SGR ties reimbursement rates to the Gross Domestic Product (GDP) rather than economic health care indicators. Staff with the House Ways & Means Health Subcommittee, which has jurisdiction over Medicare, remained optimistic that another short-term correction would be passed by Congress in 2006, but stated that a long-term correction of the SGR was not likely at this time.

### **House Passes Budget Resolution – Hope for Research Funding Restored**

On May 18, 2006 the House of Representatives passed their version of the FY 2007 Budget Resolution by a vote of 218-210. This measure sets congressional spending caps for the coming fiscal year and is used as a blueprint for congressional appropriators when determining spending levels for government agencies. The Senate passed its version of the budget resolution in March.

The Senate version of the budget resolution included the Specter/Harkin amendment to add \$7 billion in health and education spending. In the House, Republican moderates were working hard to ensure that the House version also included additional spending for health and education spending above the President's request. In particular Rep. Mike Castle (R-PA) and Rep. Nancy Johnson (R-CT) led the effort to secure additional funding for these important programs in the House.

As a result of the efforts of Reps. Castle and Johnson—and threats to not support the budget resolution unless it included additional health and education spending—the final version of the House budget resolution was amended to create a \$3.1 billion reserve fund for health, education, and other domestic priorities, but only if these funds are offset by savings from other discretionary or mandatory programs. Under an amendment by Rep. Curt Weldon (R-PA), at least \$1 billion of the offset for any increases for the Labor/HHS/Education bill would come from unobligated funds for Iraq reconstruction. Furthermore, the moderates were assured that the additional spending would not come at the expense of Medicare or Medicaid spending.

A few weeks ago the House Appropriations Committee agreed to transfer more than \$6 billion from the defense and foreign operations accounts to domestic programs, including allocations for the Labor/HHS/Education Subcommittee of \$4.1 billion above the President's budget. Adding the \$3.1 billion reserve fund budget allocation to the \$4.1 billion already allocated by the House Appropriations Committee provides a total of approximately \$7.2 billion of additional funding that was approved by the House, which matched the Senate version passed in March. Specifically, the House version states, "The House of Representatives recognizes the need to increase the President's fiscal year 2007 request for

the Departments of Labor, Health and Human Services, Education, and Related Agencies Appropriation bill by not less than \$7,158,000,000.”

The Endocrine Society will continue to push to see that this additional spending is indeed allocated appropriately during the appropriations process. In addition, the Society plans to thank those in the House who made this accomplishment possible.

### **Society Co-sponsors NICHD Congressional Obesity Briefing**

The Friends of the National Institute of Child Health and Human Development (NICHD) hosted a congressional briefing on May 22, 2006 to highlight the Institute’s work in the area of childhood obesity research and prevention. Twelve patient and physician groups, including The Endocrine Society, co-sponsored the briefing. The speakers at the briefing were: Gilman D. Grave, MD, Chief, Endocrinology, Nutrition, and Growth Branch at NICHD; Jack Yanovski, MD, PhD, Head, Unit on Growth and Obesity at NICHD; and Jill Center, MPH, Public Health Advisor for NICHD.

The first two speakers focused on current research being conducted at the Institute regarding childhood obesity. Dr. Grave spoke about research the Institute is conducting on the childhood origins of adult diseases, specifically type 2 diabetes and metabolic syndrome. He stated that both diseases have seen significant increase in childhood onset over the past decade and that recent research at the Institute has identified trends that might help researchers prevent the childhood onset of these diseases. Studies sponsored by NICHD have captured trend data that shows the age at which male and female children first begin to show signs of metabolic syndrome; this data will help to target prevention programs. Dr. Yanovski spoke of ongoing clinical research studies at NICHD related to the evaluation and treatment of obesity in children and adults. The research is helping to evaluate medications designed to treat obesity and also to study the genetic and biological causes of obesity.

Ms. Center highlighted a recently released obesity public relations campaign from the Department of Health and Human Services (HHS) targeted to children. The campaign, called Media-Smart Youth, is an interactive after-school education program for young people ages 11 to 13. It is designed to help teach them about the complex media world around them, and how it can affect their health—especially in the areas of nutrition and physical activity. NICHD created Media-Smart Youth to empower young people to think critically about media and make thoughtful decisions about nutrition and physical activity.

More information on the program can be found at <http://www.nichd.nih.gov/msy/>.

### **ACP Council of Subspecialty Societies (CSS) Holds Spring Meeting**

Representatives from The Endocrine Society attended the spring meeting on May 8, 2006 of the American College of Physicians (ACP) Council of Subspecialty Societies (CSS). The CSS meeting, which occurs twice a year, represents a unique opportunity for the internal medicine specialties to discuss important issues. The Council comprises 21 subspecialty groups, and has the following functions as its core mission:

- To develop a close working relationship among the subspecialty societies and ACP.
- To initiate and influence policy proposals of ACP.

- To identify issues germane to internal medicine and its subspecialties that, through actions of the Council, will improve health, the quality of medical care, and enhance the practice of medicine.
- To generate, exchange, and disseminate information and ideas related to internal medicine.
- To function as a forum to discuss education and scientific research issues, as well as legislative and regulatory activities that affect internal medicine and the member subspecialty societies.

The meeting featured reports from several ACP representatives that described policy papers that are being developed as well as 2006 enhancements to the American Board of Internal Medicine (ABIM) Maintenance of Certification program. Representatives from ACP also reported the College's legislative priorities for 2006. Reform of the dysfunctional Medicare physician payment system was at the top of the list, followed by a redesign of internal medicine, quality improvement in health care (through pay-for-performance or pay-for-reporting initiatives), and support of health information technology initiatives. These issues are among the legislative priorities for The Endocrine Society as well, and the Society will continue working with CSS and similar coalitions to advocate for our members.

Perhaps the most favorable news for the subspecialties came from a representative from the Subspecialty Advisory Group on Socioeconomic Affairs (SAGSA). Many of the member organizations in SAGSA, including The Endocrine Society, have been working to increase payments for Evaluation and Management (E/M) services as part of the Medicare Five-Year Review. Due to the efforts of the group, internal medicine, internal medicine subspecialties, and other cognitive specialties will likely see a substantial increase in payment for E/M services beginning in 2007.

### **FDA Officials Comment on the Latest Clinical Trials Requirements and Safeguards for Patients**

Food and Drug Administration (FDA) Officials recently reported on the latest clinical trials requirements, strategies, and safeguards. The report, aimed at patients and trial participants, contains information that patients should consider before becoming involved in studies. The FDA has authority over clinical trials for drug, biologic, and medical device products regulated by the agency. This authority includes studies that are funded by the Department of Health and Human Services (HHS) and studies that are funded by industry or private parties.

The report explains the purpose of a clinical trial—to test potential treatments in human volunteers to assess whether these treatments should be approved by the FDA for use in the general population. Officials reiterate that while participation in clinical trials by human volunteers is vital to advancing medical knowledge, participants should have a full understanding of the study process, and be aware that there may be inherent, unforeseen risks to the treatment being tested.

The report also contains detail on the informed consent process by which researchers and patients exchange information so that patients may be given complete information about the study, including potential benefits or risks. The report gives a complete list of what the

FDA requires for informed consent in clinical trials, such as disclosing the purpose of research, possible risks or benefits to the participants, and whether other procedures or treatments are available that might be advantageous to participants.

FDA officials explain in the report the clinical trial process, beginning with a description of “protocol maps” that plan what study procedures will be done, by whom, and for what purpose. The report also defines Phase 1, 2, 3, and 4 trials, and highlights the benefits of study randomization and blinding in study design that can avert bias in trial conduction or results interpretation.

FDA officials urge patients to consult physician and patient advocacy groups, newspapers, or relevant departments at local university medical centers for information on how to participate in new or ongoing clinical trials. The report directs patients and health care professionals to a Clinical Trials website developed by the National Institutes of Health (NIH), which contains information on clinical studies sponsored by the NIH, other federal agencies, and the pharmaceutical industry primarily in the United States and Canada.

For further information, refer to <http://www.clinicaltrials.gov/>.

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

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