



July 6, 2005

### **Society Delegation Represent Society Interests in AMA Policy Discussions**

The Society's delegation to the American Medical Association's (AMA) House of Delegates concluded a five-day Annual Meeting on June 22<sup>nd</sup>. The AMA's House of Delegates is the policy-making body of the AMA and directs the lobbying and advocacy activities of the organization. The Society holds a one-vote seat in the House and is represented by Delegate Susan Sherman, MD, Alternate Delegate Robert Vigersky, MD, Government Relations Committee liaison Daniel Spratt, MD, and the Society's representative to the AMA's Young Physicians Section, Holly Wyatt, MD.

The issue of Pay-for-Performance (P4P) dominated the agenda at the 2005 Annual Meeting. The House debated the merits and flaws of the new proposal which is designed to produce a more efficient and effective Medicare system (see "**Medical Stakeholders and Legislators Continue to Discuss Pay-for-Performance Initiatives**" in this issue of *Endocrine Insider*). Congressional leaders are pushing for enactment of a P4P system, and AMA policy makers are determined to make sure that provisions in any such system take into account the physicians' point of view. The Society articulated its concerns with the potential changes during the meeting and will continue to work with the AMA and other societies to provide a voice for endocrinology in the debate over P4P.

Other issues of importance to the Society during the Annual Meeting included a resolution urging the AMA to become more actively engaged in the NIH open access issue. The Society spoke in support of the resolution, which urged the AMA to oppose mandatory submission of manuscripts and asks the NIH to link back to Society journals rather than hosting a separate archive of manuscripts. The resolution was referred back to the AMA Board of Trustees for further study. In addition, the Society successfully argued that the AMA examines the issue of endocrine disruptors. The AMA will now conduct a report to evaluate the impact of disruptors to determine if further action is necessary. The Society also provided input into a Board of Trustees report on obesity. Society members helped develop the obesity report, which stemmed from the AMA Summit on Obesity in October 2004.

During the meeting, Society member Melissa Thomas, MD was reelected to the AMA's Council on Medical Education. The Council formulates policy on medical education by recommending educational policies to the AMA House of Delegates. Look for a more detailed story on the events surrounding the AMA Annual Meeting in an upcoming feature article in *Endocrine News*.

### **Society's First Clinical Guideline Approved by Council**

At its June 2<sup>nd</sup> meeting, The Endocrine Society's Council enthusiastically approved the organization's first clinical guideline, *Evaluation and Treatment of Growth Hormone Deficiency in Adults*. The guideline, developed by a task force led by Mark Molitch, MD, will now be posted on the Society's Web site for a 30-day member comment period.

In his presentation of the guideline to Council, Robert Vigersky, MD, Chair of the Clinical Guidelines Subcommittee (CGS) commended Dr. Molitch and the members of his task force for their incredible work and dedication, noting that, as authors of The Endocrine Society's first guideline, "they are truly pioneers."

The Society's development process for this guideline and the others in the pipeline is a rigorous and thorough one, starting with the selection of content experts to serve on the writing task force, followed by a review of the literature and evidence, and then by the actual writing of the guideline. Once drafted by the task force, the growth hormone guideline went through a series of revisions and was then edited and refined by a medical writer. The guideline then went through another series of reviews by the CGS, Clinical Affairs Committee, and then Council. Finally, after the member-comment period closes and any necessary revisions are made, the guideline will be submitted for publication in *JCE&M*, where it will undergo peer review.

The next guideline to be completed will be *Use of Testosterone Therapy in Adult Men with Androgen Deficiency Syndrome*. Others soon to follow include: *Thyroid Disease in Pregnant and Postpartum Women*, *Pediatric Obesity*, *Metabolic Syndrome*, and *Use of Androgens in Women*.

### **House Approves Labor/HHS/Education Spending Bill— Includes .5 Percent Increase for NIH**

On June 22<sup>nd</sup>, the House Appropriations Committee approved a \$602 billion 2006 spending bill for the Departments of Labor, Health and Human Services, and Education. The bill would provide \$142.5 billion in discretionary spending, which is \$164 million less than in fiscal year 2005 – a 0.1 percent decrease – and \$924 million more than the President's budget request. The National Institutes of Health (NIH) would receive a \$142 million increase, for a total of \$28.5 billion – a 0.5 percent increase over 2005 and equal to the President's budget request. NIH's increase is the smallest increase the agency has received in 36 years. Observers suggest that the 0.5 percent increase would result in funding 505 fewer research grants in fiscal year 2006 than the agency funded in 2004.

During deliberations on the spending bill, the Appropriations Committee rejected, 29-36, an amendment offered by Rep. Dave Weldon, (R-FL) that would ban any state, local government or university from receiving NIH funding if they conducted embryonic stem cell research for either reproductive or therapeutic purposes. Opponents of the amendment said it would be too far-reaching and penalize states and universities with the loss of all NIH funding only because they wanted to conduct embryonic stem cell research to help find cures for diseases.

The Senate Appropriations Committee adopted its 302(b) allocation for fiscal year 2006. Sen. Thad Cochran (R-MS), Chairman of the Senate Appropriations Committee, has transferred \$7 billion from defense accounts and another \$1 billion from foreign aid to support increased spending in domestic programs. Appropriators saved money by funding the Labor/HHS/Education bill (which includes NIH) at the President's request (\$141.3 billion) – \$1 billion below the House bill. However, Senator Cochran is allowing the Labor/HHS/Ed Subcommittee to add at least \$3 billion to its L/HHS appropriations bill. If approved, the \$3 billion addition would provide for a \$2 billion discrepancy between the House and Senate bills which would need to be resolved in conference committee.

## **Medical Stakeholders and Legislators**

### **Continue to Discuss Pay-for-Performance Initiatives**

Pay-for-performance (P4P) is being monitored by many groups in the medical community, including The Endocrine Society, as Congress continues to push linking it to any potential fixes in the Sustainable Growth Rate (SGR) - the flawed payment mechanism that will result in a projected 4.3 percent payment cut for providers in 2006, and a cumulative fee reduction of approximately 26 percent by 2011. Congressional staff members have expressed interest in working with specialty groups to re-evaluate the payment system and implement P4P programs. Two pieces of legislation (H.R. 2356 and S. 1081) are aimed at reforming the physician payment update system; The Endocrine Society is currently supporting both measures. Regarding P4P legislation, the Senate Finance Committee is drafting a bill, which is expected to be introduced this summer. *Endocrine Insider* will provide an analysis of the legislation at that time.

The Centers for Medicare and Medicaid Services (CMS) undertook several P4P initiatives in such settings as physicians' offices and ambulatory care facilities, hospitals, nursing homes, home health care agencies, and dialysis facilities. CMS is collaborating with various public and private organizations on these pilot programs to bring efficient care and quality improvement to Medicare beneficiaries.

There are still many issues to resolve before P4P can be effectively integrated into the current health care system. Standard quality measures must be developed through consensus between providers and other medical entities, which will ensure accurate and objective measurement and reporting. Many providers are also concerned that P4P initiatives will impose additional costs on the physicians. This concern is heightened by the challenge of implementing health information technology systems to collect data and enhance the delivery of health care services to patients. The American Medical Association (AMA) has hosted several congressional briefings and meetings in which these issues arose. The most recent was the Annual Meeting of the House of Delegates, in which the advantages and disadvantages to incorporating P4P into the Medicare system were extensively debated (see "**Society Delegation Represent Society Interests in AMA Policy Discussions**" in this issue of *Endocrine Insider*). The Endocrine Society staff participated in these meetings, offering insight on behalf of our members' interests. In addition Society member, Sanford Mallin, M.D., holds a seat on the American College of Physician's Council of Subspecialty Societies (CSS), which also hosted discussions regarding P4P on meetings agendas. The Endocrine Society will continue to be involved in such discussions as the issue further

develops, and take action at the grassroots level to increase awareness among patients and members.

### **House Appropriations Bill Includes New Open Access Language— TES Lobbying Efforts Continue**

Report language included in the fiscal year 2006 spending package for Labor/HHS/Education urges the NIH to examine its open access policy. The language implies the policy may not be reaching its intended goals. It states that “The Committee is pleased that NIH is moving forward to implement in its public access policy...endorses NIH's expressed goals for the policy, namely to create an archive of NIH-funded research to provide an opportunity to better manage the NIH research portfolio, and to provide enhanced public access to NIH research results.” It goes on to say “The Committee is concerned, however, that the final policy may not achieve these goals.” The Committee also directs NIH “to submit to the Committee by March 1, 2006 a comprehensive report on the progress achieved during the first eight months following the implementation of the new policy.

Specifically, the Committee requests that the report provide: 1) the total number of applicable peer-reviewed articles deposited in PubMed Central since the May 2, 2005 implementation date; 2) the embargo period requested by the author for each deposited work; and 3) NIH's best estimate of the total number of applicable peer-reviewed articles available for deposit during this time frame, together with an explanation of the mechanisms relied upon to determine this estimate.”

The Society is concerned with the continued Congressional involvement in the issue of open access, particularly since this most recent assessment is based on a policy that has been in place for only eight weeks. TES remains concerned that strong advocates for the NIH open access policy are pushing for mandatory submissions of manuscripts rather than the current optional status of this “request.” The Society maintains that mandatory submission of manuscripts, prior to its own 12-month open access policy, would be a violation of the copyright agreement between the Society and its authors. The Society continues to work with all the relevant stakeholders, including Congress and the NIH, to create an open access system that works for both publishers and the public.

### **FASEB Conference Addresses Conflicts of Interest**

The Federation of American Societies for Experimental Biology (FASEB) held a conference on June 14-15 entitled “Shared responsibility, individual integrity: Scientists addressing conflicts of interest in biomedical research.” The Endocrine Society's FASEB board member, Wylie Vale, PhD, and Society staff participated in the conference. The conference was intended to facilitate a dialogue among researchers to address challenges faced when dealing with conflicts of interest, as well as relationships among academic institutions, private industries, and government. The issue has remained contentious since the National Institutes of Health (NIH) issued regulations regarding the outside consulting activities of NIH employees. The regulations were of particular concern to The Endocrine Society because they seem to prohibit employees from participating in professional associations.

The conference featured several notable speakers, including a keynote address by Dr. Elias Zerhouni, NIH Director. The bulk of the conference focused on the scope of relationships between academia and private industry. Dr. Louis Sherwood, a former Senior Vice President with Merck & Co. and a member of The Endocrine Society, presented comments on how scientists can minimize risks in academic-industry relationships while maximizing benefits.

The conference speakers shared the view that addressing and establishing protocols for conflicts-of-interest will involve much work and collaboration between academia, industry, and government. However, doing so is vital to maintaining integrity in medical research.

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