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### **Society Advances AMA Policy to Address FDA Bioequivalence Standards**

The AMA held its 2005 Interim Meeting of the House of Delegates in Dallas, TX, in early November. The Society's delegation, led by Susan Sherman, Robert Vigersky, and Holly Wyatt, introduced and successfully passed a resolution instructing the AMA to contact the Food and Drug Administration (FDA) regarding its generic drug bioequivalence standards.

The Society developed the resolution because of the concern that current FDA policy allows patients to be switched from one levothyroxine formulation to another without their knowledge or the knowledge of their physicians. Specifically, the resolution requires the AMA to contact the FDA and urge the agency to reexamine its bioequivalence standards regarding levothyroxine. It also requires that the AMA ask the FDA to reinstate the warning labels for thyroxine manufacturers regarding dose retitration after switching brands.

The Society's delegation also closely monitored and offered Society input into the continuing debate on pay-for-performance and physician reimbursement issues. Of particular concern at the meeting was Congress' inaction regarding the impending cut in Medicare physician payment, which is scheduled to begin in 2006. If Congress does not update the payment schedule by the end of the year, physicians will experience a 4.4 percent payment reduction starting January 1, 2006.

An AMA survey found that 38 percent of physicians will be forced to limit the number of Medicare patients in their practices if these severe cuts go into effect. The AMA's House of Delegates orchestrated a call-to-Congress campaign at the meeting, which resulted in more than 1,700 phone calls to Congress demanding action on the impending cuts. Society members are encouraged to call as well. Please call 1-800-833-6354 to be connected to your representatives and urge Congress to fix the impending cut before January 1, 2006.

On the pay-for-performance front, the AMA voted to oppose Medicare pay-for-performance initiatives (such as "value-based purchasing programs") that do not meet the AMA's Principles and Guidelines for Pay-for-Performance. The five AMA principles for fair and ethical pay-for-performance programs make it clear that these programs must:

- ensure quality of care;
- foster the patient/physician relationship;
- offer voluntary physician participation;
- use accurate data and fair reporting; and,
- provide fair and equitable program incentives.

Twice a year the AMA's House of Delegates, the policy-making body of the AMA, meets to discuss important health care policy issues affecting patients and physicians. The body is composed of delegates representing all specialties of medicine and from all 50 states.

**Society Activates Grassroots during Final Days of Congress—600 Members Weigh In**  
Society President Andrea Dunaif, M.D. has called upon Society members several times in the past month to contact Congress and make their voices heard on important issues, such as federal funding for medical research and physician payment. Society members have recognized the urgency of these request and responded. In the past six weeks, Society members have sent approximately 600 messages to Congress, with a majority of messages from members urging an increase in federal funding for biomedical research. In addition, Society members sent almost 50 messages to Congress urging them to avert the impending Medicare physician reimbursement cut scheduled for January 1, 2006.

If you have not sent your message yet, please do so by using The Endocrine Society's advocacy Web site at <http://capwiz.com/endocrine/home/>. Simply click on the relevant action alert in the yellow box and fill out your contact information to make your voice heard.

### **House Energy and Commerce Health Subcommittee Holds Hearing to Discuss Medicare Physician Payment**

The House Energy and Commerce Health Subcommittee held a November 17 hearing entitled "Medicare Physician Payment: How to Build a More Efficient Payment System" to discuss Medicare physician payment issues. Committee chair Joe Barton (R-TX) called the hearing on the heels of the announcement by CMS of a new physician quality initiative, the Physician Voluntary Reporting Program. At the same time, physicians are slated to experience a 4.4 percent cut in Medicare reimbursement beginning January 1, 2006, under the current flawed sustainable growth rate (SGR) methodology that links physician payment updates to volume of physician services relative to growth in the gross domestic product.

Panel members expressed doubts about implementing a new Medicare physician payment system that would be based on pay-for-performance (P4P). Rep. Charles W. Norwood (R-GA), a dental surgeon, advocated for keeping a payment system separate from any P4P system, stating that experimentation with P4P could have "terrible consequences." He expressed concern that there is no clear understanding of how a P4P system would work, arguing that the concept has not been proven to save money or improve quality of care. Rep. John B. Shadegg (R-AZ) also expressed skepticism on P4P, fearing that "bureaucrats and not consumers would grade physicians."

CMS Administrator Mark B. McClellan spoke at the hearing in defense of P4P as a viable way to improve quality of care through better incentives and support for evidence-based care. Representatives from the Medicare Payment Advisory Commission (MedPAC) also attended the hearing and spoke in support of the development of evidence-based standards developed "by specialists for specialists." Earlier this year, MedPAC recommended that Congress adopt budget-neutral P4P programs.

Regarding the impending cut in Medicare physician reimbursement, members of both parties agreed that a physician reimbursement cut is unfair for physicians and that a negative

payment update could threaten beneficiary access to physicians and necessary health services. Chairman Joe Barton (R-TX) stated that he would not “support simply pouring more taxpayer dollars year after year into a system that is broken.” There was general agreement that Congress should step in during this session to halt the 4.4 percent cut, but acknowledged this as a short-term fix.

The Senate Finance Committee approved a budget reconciliation package that outlines an increase in physician Medicare payments by 1 percent in 2006. The plan would also add a P4P program to Medicare for several provider groups, including physicians. Providers would receive 1 percent bonus payments for reporting quality information during the first year of the program’s implementation, and 2 percent bonus payments over the subsequent five years. The House package does not contain language addressing either the impending cuts or pay-for-performance.

### **Health Care Spending Bill in Congressional Limbo**

Fast, furious, and unusual describe the action Congress took on the Labor/HHS appropriations bill prior to the Thanksgiving recess. On November 17, the House voted down the conference committee report on the FY 2006 Labor/HHS appropriations bill (H.R. 3010) by a vote of 224 - 209. All Democrats in the House voted against the legislation along with 22 Republicans. Included in the “No” column was Chairman of the House Ways and Means Committee Bill Thomas (R-CA), who was upset that the bill banned Medicare from funding erectile dysfunction drugs in 2006. Rep. Thomas claimed that the ban, which would have started in 2007 without this legislation, would result in a breach of contract for the government because beneficiaries have already signed up for drug coverage that included these medications. The actions of Rep. Thomas came as a surprise to the majority leadership, who had hoped to wrap up the appropriations bill before the Thanksgiving recess. Other Republicans refused to support the legislation because it did not cut enough spending, or because the bill cut funding to rural health care programs in their districts.

Following the defeat in the House, on November 18, the Senate voted to send the spending bill back to the conference committee for more negotiations. Included in the Senate vote was an instruction to the conferees to seek increased funding for the National Institutes of Health (NIH). The conference report that was rejected in the House included \$28.6 billion, an increase of \$253 million over the FY 2005 appropriation and \$107.7 million over the president's budget request, for the National Institutes of Health. The Senate agreed that its conferees insist on \$29.4 billion FY 2006 budget for NIH.

The conference committee will begin the next round of negotiations when it returns in mid-December. If the conference committee cannot agree on a final spending bill, or the measure is again rejected by one chamber of Congress, a few scenarios are possible. First, Congress could pass a year-long continuing resolution that would fund all agencies covered in the bill at the lowest of their funding levels in the House-passed version, the Senate-passed version, or the FY 2005 levels. In the case of NIH, this scenario would mean funding the agency at FY 2005 for all of FY 2006. Second, the Labor/HHS spending bill could be attached to other spending bills such as the defense spending package which would make voting against the measure more difficult and increase its chances for passage.

## NIH Announces Grant Commitment Reduction

On December 1, NIH announced that, as long as the NIH is funded under a continuing resolution from Congress, it will be forced to reduce their commitments to non-competing grants. The announcement from NIH reads “Until the final FY 2006 appropriation is enacted, NIH will be issuing non-competing research grant awards at a level below that indicated on the most recent Notice of Award (generally up to 80% of the previously committed level). NIH will consider upward adjustments to these levels after the final appropriation is enacted, but expects institutions to monitor their expenditures carefully during this period.” A link to the official NIH notice can be found at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-06-014.html>

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