



October 11, 2007

Show Your Support for Increased NIH Funding – Contact Your Senators Now

As indicated in a recent Endocrine Society alert, the Senate is expected to vote next week on the Labor-Health and Human Services-Education appropriations bill, which contains proposed funding levels for the National Institutes of Health (NIH) and many other vital health programs for FY 2008. The President has already announced his intention to veto any appropriations bill that exceeds his spending targets, which includes the Labor-HHS bill. It is vitally important that you contact your Senators now and encourage them to vote in support of the Labor-HHS appropriations levels approved by the Senate Appropriations Committee, which would provide the NIH with \$29.9 billion in FY 2008. The scientific community needs to send a strong message to the President, and the best way to do this is to ensure that the Labor-HHS appropriations bill passes with a veto-proof majority.

Under the President's proposed FY 2008 budget, most NIH institutes and centers would see their budgets remain flat for the fourth year in a row. The President's proposed FY 2008 NIH budget of \$28.7 billion is \$230 million less than the FY 2007 budget. If the President's budget were passed, the NIH budget would fall 12 percent from 2004 to 2008 when adjusted for biomedical research inflation.

Please take a minute to e-mail your Senators by clicking on "Action Alert: Show Your Support for Increased NIH Funding – Contact Your Senator Now!" at the following link: <http://capwiz.com/endocrine/home/>. Let them know of the need to support an increase in research funding levels for FY 2008. A sample letter has been created for you; you may customize it if you wish.

FDA Tightens Requirements for L-T4 Potency but Does Not Address Bioequivalence

The U.S. Food and Drug Administration (FDA) announced on October 3 that it is tightening the potency specifications for levothyroxine sodium (L-T4). The decision results from an FDA study of potency throughout shelf life of L-T4 products, which the agency undertook after The Endocrine Society and other interested organizations raised concerns about adverse events related to switching L-T4 products in patients. The agency's decision is in line with the recommendations of a joint advisory committee that met last October to hear the study results. Society Past-President Leonard Wartofsky, MD, testified at the meeting, and the proceedings were reported in the October 6, 2006 issue of Endocrine Insider (link to story <http://www.endo->

[society.org/publicpolicy/insider/2006/Pres_Testifies_before_FDA_LevothyroxineArt1.cfm](http://www.endo-society.org/publicpolicy/insider/2006/Pres_Testifies_before_FDA_LevothyroxineArt1.cfm)).

The ruling means FDA will soon mandate that L-T4 products must fall within 95-105 percent of the expected potency throughout the entire shelf life. The current allowable range is 90-110 percent. Manufacturers will have up to two years to comply with the new restriction.

The FDA's recent efforts are a reasonable step to ensuring the safety of patients taking L-T4. However, the Society urges the agency to do more. Since 2005, The Endocrine Society, the American Association of Clinical Endocrinologists (AACE), and the American Thyroid Association (ATA) have been requesting that FDA reconsider its current system for determining bioequivalence of L-T4 products. Tightening of potency specifications will alleviate some, but not all, of the measured variability among L-T4 products, and it does nothing to address the flawed method by which FDA determines bioequivalence of the drugs. (For more information, see the joint statement by the Society, AACE, and ATA http://www.endo-society.org/publicpolicy/policy/upload/Joint_Statement_Levothyroxine-Thyroxine.pdf.)

The Society is encouraged by FDA's attention to L-T4 products and will continue to advocate with FDA for the safety of patients taking levothyroxine.

Click here for more information from the FDA on its recent ruling:
<http://www.fda.gov/cder/drug/infopage/levothyroxine/default.htm>.

NIH Details Funding for Non-Competing Awards under Continuing Resolution

On Friday, October 1, the National Institutes of Health (NIH) issued a release describing how it would fund non-competing grants under the current FY 2008 continuing resolution (CR). Consistent with its policy during the CRs of FY 2006 and 2007, NIH will fund non-competing grants at a level lower than the committed level, typically at around 80 percent. Once the FY 2008 budget is determined, the agency will consider adjusting the funding level upward to an amount allowed by the budget. In FY 2007, most grants were adjusted to a final funding level of about 97 percent of the committed level.

For specific questions regarding individual adjustments, investigators should contact their Grants Management Specialist (identified on the award notice).

The NIH announcement may be read here:
<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-001.html>.

Society Participates in Discussions on Patient-Centered Medical Home Model

During a recent meeting of the American College of Physicians - Council of Subspecialty Societies (ACP-CSS) in Washington, D.C., the major topic was the patient-centered medical home (PCMH). The concept, developed by ACP, the American Academy of Family Physicians (AAFP), the American Academy of Pediatrics (AAP), and the American Osteopathic Association (AOA), is intended to ensure continuity of care for patients by

allowing patients to select a “medical home” where their care will be coordinated. Subspecialists meeting certain criteria could become a medical home if they so choose.

Carol Greenlee, MD, member of the Society’s Clinical Affairs Core Committee (CACC) and CSS representative, attended the meeting on behalf of The Endocrine Society. The Society is generally in support of the concept, but has concerns that it is an untested model at this point, and more work needs to be done before it can be determined if it presents any unintended consequences for the endocrinology community.

Dr. Greenlee and Pamela Hartzband, MD, another CACC member, have also represented the Society over the course of several months in a small group of subspecialties that are looking deeper at the PCMH concept and its effect on referrals and the patient mix seen by endocrinologists and other subspecialists.

A second area of discussion at the CSS meeting focused on ACP’s development of clinical guidelines. Since many of the guidelines that ACP develops encompass the expertise of various subspecialties, the College asked that societies recommend representatives with specific expertise to participate in the development of guidelines of interest to their society. The Endocrine Society has expressed its interest in having Society members join guideline development committees and will provide expert representatives to appropriate committees.

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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