



November 21, 2007

House Fails to Override Presidential Veto of L-HHS Funding Bill

On November 13, President Bush vetoed the Labor-Health and Human Services-Education (L-HHS) spending package that he received from Congress. Bush had vowed to veto any domestic spending bill that exceeded his proposed budget, and the L-HHS bill did so by nearly \$10 billion.

The House attempted an override on November 15 but fell two votes short of the required 2/3 majority of voting members. The only spending bill to be signed by the president to date—the Defense appropriations bill—contained a Continuing Resolution (CR) to keep the government in operation until December 14. It is unclear what approach Congress will take with L-HHS and the remaining spending measures when it reconvenes after the Thanksgiving recess.

Legislation Introduced to Halt DXA Payment Cuts; Study Shows Costs to Perform Tests Higher than 2007 Reimbursement

The Endocrine Society strongly endorses H.R. 4206, the Medicare Fracture Prevention and Osteoporosis Testing Act, introduced on November 15, 2007, by Representative Shelley Berkley (D-NV). If enacted, this legislation would restore physician payments for dual energy x-ray absorptiometry (DXA) and vertebral fracture assessment (VFA) services to their 2006 levels. It would also require the Institute of Medicine to study the ramifications of Medicare reimbursement reductions to patient access to DXA and VFA services.

Under the Deficit Reduction Act (DRA) of 2005, payments for DXA were reduced from approximately \$140 in 2006 to \$82 in 2007. By 2010, payments for DXA services are expected to be reduced to approximately \$35 under the DRA. The Endocrine Society is working with a coalition of other interested organizations to advocate for H.R. 4206, and Society members discussed it with members of Congress during recent Hill visits. In addition, many Endocrine Society members individually contacted their members of Congress, asking them to co-sponsor the legislation. As a result of those efforts and Representative Berkley's commitment to the legislation, more than 40 other members of the House of Representatives have signed on to become original co-sponsors of the bill.

The position that the payment cuts would decrease patient access to DXA tests is supported by a new study that was conducted by The Lewin Group and sponsored by The Endocrine Society and its coalition partners. The study shows that the cost of performing DXA in an office setting will continue to significantly diverge from reimbursement rates for the service as the DRA cuts are fully implemented in the next few years. According to the survey, the

median cost of performing DXA in an office setting was approximately \$135 in 2006, just \$5 less than the Medicare reimbursement rate for that year and much higher than the \$35 reimbursement that physicians are expected to receive in 2010. In fact, 93 percent of physicians queried for the Lewin study stated that they would stop providing the service to patients if the cuts are fully implemented. To read more details of this report, go to http://www.endo-society.org/publicpolicy/legislative/upload/DXA_Final_Report_from_The_Lewin_Group_Executive_Summary_3_2.pdf.

The results of the Lewin study make clear the vital importance of Representative Berkley's legislation. Sixty-one million people in the U.S. are projected to have osteoporosis and low bone mass by 2020, and it is critical that the nation maintain and preserve its capacity to treat this costly and debilitating disorder. The Medicare Fracture Prevention and Osteoporosis Testing Act is an important step forward to preserve patient access to cutting-edge life-saving technologies that save money in the overall treatment of osteoporosis.

You can still make a difference to the future of this legislation. If you have not previously done so, please contact your representative and ask him or her to co-sponsor the legislation by clicking the link below:

<http://capwiz.com/endocrine/issues/alert/?alertid=10473241>

Society Pushes AMA to Reduce Minority Health Disparities in Clinical Research

Last week, during the semi-annual meeting of the American Medical Association (AMA) House of Delegates (HOD) in Honolulu, HI, The Endocrine Society's delegation advocated strongly for a Society-sponsored resolution to increase minority participation in clinical trials.

The resolution, which was introduced by the Society and the American Society for Reproductive Medicine (ASRM), was based on the Society's white paper "Increasing Minority Participation in Clinical Research" and directed the AMA to support the Society's advocacy efforts to:

- Request that the FDA establish an Office of Minority Health to supervise the implementation of NIH-like guidelines on the inclusion of women and minority populations in clinical trials undertaken for FDA drug approvals.
- Encourage Congress to require that clinical trials for FDA approval of drugs include women and minorities.

The Society's AMA delegation, Drs. Robert Vigersky, Susan Sherman, and Vineeth Mohan, made a compelling case for AMA support of the measure and secured the backing of numerous other organizations at the HOD. Organizations speaking in support of the resolution included the American Academy of Pediatrics, the National Medical Association, the American Psychiatric Association, the Endocrine Section Council, several state medical societies, and the 130⁺-member Specialty and Service Society. The resolution was referred to the AMA Board of Trustees, which will study the proposal further and issue a report with its recommendation regarding AMA support in advance of the next AMA HOD meeting in June 2008.

In the meantime, the Society will continue to advocate for the recommendations within the white paper to improve the participation of racial and ethnic minorities in clinical research. The white paper will be available online at http://www.endo-society.org/publicpolicy/health_disparities/ on December 3.

To date, 11 of the Society's sister societies have endorsed the paper, including the American Association of Endocrine Surgeons, American Diabetes Association, American Society for Andrology, American Society for Bone and Mineral Research, ASRM, American Thyroid Association, Androgen Excess Society, Lawson Wilkins Pediatric Endocrine Society, Pediatric Endocrinology Nursing Society, Society for Gynecologic Investigation, and the Society for the Study of Reproduction.

Grant Opportunities

The Endocrine Society attempts to keep its members informed of opportunities for research grants from different sources. Four such opportunities are outlined below. More information on these and other award opportunities may be accessed on the Society's Web site at <http://www.endo-society.org/awards/other-fundig-resources.cfm>.

DoD Breast, Prostate, and Ovarian Cancer Grants

The recently passed Department of Defense FY 2008 Defense spending bill includes \$138 million in funding for peer-reviewed breast cancer research programs. This is a \$10.5 million increase over FY 2007's \$127.5 million appropriation.

The 2008 Defense bill will also provide \$80 million for prostate cancer research and \$10 million for ovarian cancer research.

Visit <http://cdmrp.army.mil/research.htm> for additional information on funding opportunities and research programs.

NIH Director's Pioneer Awards

NIH is seeking applications for its Pioneer Awards. The program is designed to fund scientists at any career stage who propose cutting-edge research with the potential to produce high impact rewards in a broad area of biomedical research. Introduced in 2005, the program is an initiative of the Roadmap for Biomedical Research. Pioneer Awards provide \$2.5 million in direct costs over five years, and NIH expects to award five to 10 of these grants in September 2008. The application period is December 16, 2007 through January 16, 2008.

For more information on NIH Director's Pioneer Awards, go to <http://grants.nih.gov/grants/guide/rfa-files/RFA-RM-08-013.html>.

NIH Director's New Innovator Awards

NIH also seeks applications for its New Innovator Awards, another Roadmap initiative. Created in 2007, the program is designed to support a small number of new investigators (those without prior R01 support) whose proposals hold the possibility of creating cross-cutting impact on a broad area of biomedical science. The research need not be in the biomedical field, but must support the NIH mission. New Innovator Awards provide \$1.5

million in direct costs over five years, and NIH expects to award up to 24 of these grants in September 2008. The application period is March 1 through 31, 2008.

For more information on the NIH Director's New Innovator Awards, go to <http://grants.nih.gov/grants/guide/rfa-files/RFA-RM-08-014.html>.

NOF Grants

The National Osteoporosis Foundation (NOF) invites Letters of Intent from qualified investigators for support of clinical or translational research related to osteoporosis. The program includes one-year grants of \$57,000 each.

Eligibility requirements:

- M.D., Ph.D. or equivalent degree
- Within four years post-completion of the postdoctoral training period
- U.S. citizenship or permanent resident status
- Affiliated with a U.S.-based not-for-profit academic or research institution

The deadline for Letters of Intent is December 1, 2007, and for complete proposals, February 20, 2008.

For additional information on NOF grant opportunities, visit www.nof.org/grants.

New ICD-9 Diagnosis Codes to Affect Endocrine Practices

The Centers for Disease Control and Prevention's (CDC) National Center for Health Statistics (NCHS) recently released its periodic list of new International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9) diagnosis codes. A number of these new codes specifically affect endocrinology, and practitioners should immediately alter their billing practices to reflect these changes. The modifications, effective October 1, 2007, have been approved by the Centers for Medicare and Medicaid Services (CMS), NCHS, the American Hospital Association, and the American Health Information Management Association.

The newly approved ICD-9 diagnosis codes affecting endocrinology include:

255.41 – Glucocorticoid deficiency

255.42 – Mineralocorticoid deficiency

733.45 – Aseptic necrosis of bone, jaw

V18.11 – Family history of multiple endocrine neoplasia (MEN) syndrome

V18.19 – Family history of other endocrine and metabolic diseases

V84.81 – Genetic susceptibility to multiple endocrine neoplasia (MED)

In addition, three ICD-9 codes affecting endocrinology were recently categorized as invalid, and should no longer be used. These include:

255.4 – INVALID – Corticoadrenal insufficiency

258.0 – INVALID – Polyglandular activity in multiple endocrine adenomatosis

V18.1 – INVALID – Family history of other endocrine and metabolic diseases

For additional information on changes to ICD-9 diagnosis codes, please see <http://www.cdc.gov/nchs/icd9.htm>.

New Requirements for Registering Clinical Trials; HHS Provides Information to Researchers

The Protocol Registration System (PRS) of ClinicalTrials.gov has information online regarding new registration and reporting requirements. The information is intended to help those who conduct clinical trials to navigate the requirements set forth in the Food and Drug Administration Amendments Act of 2007, which was signed into law by the president earlier this year (U.S. Public Law 110-85).

The Web page <http://prsinfo.clinicaltrials.gov/fdaaa.html> includes instructions to investigators who are currently registered with PRS and those who anticipate needing to register, as well as links to:

- Required data elements—high level list of the required elements and whether the requirement is new relative to previous law
- New requirements for interventional clinical trial registration—a detailed description of the data elements
- NIH fact sheet—description of general requirements, timing of registration, and penalties for failure to register
- Guidance document from the NIH Office of Extramural Research—detailed analysis of the new law (including links to the text of the law) and instructions for obtaining help from NIH

The Endocrine Society's Executive Director Honored by American Medical Association

The American Medical Association (AMA) honored Scott Hunt, executive director and chief executive officer of The Endocrine Society, with the 2007 Medical Executive Meritorious Achievement Award. The award is given to a medical association executive who has demonstrated exceptional service and contributions to the goals and ideals of the medical profession. Mr. Hunt received the award at the AMA's semi-annual policymaking meeting.

A graduate of Harvard Business School, Mr. Hunt has served as executive director and CEO of The Endocrine Society since 1988 and has led the tremendous growth in both size and quality that the Society has enjoyed during that time. Under his leadership, the Society has expanded from a mostly academic society into one representing practicing physicians, clinical scientists, basic scientists, and academics. It is now one of the 50 largest associations in Washington, D.C., according to the *Washington Business Journal*.

Mr. Hunt was also instrumental in establishing the Hormone Foundation—the public education affiliate of The Endocrine Society—to meet patient needs and advance public awareness of endocrinology. He also helped establish the Society’s robust advocacy program, which provides the Society a highly effective voice in communicating the needs of endocrinologists to Congress and the Administration.

Mr. Hunt has served as president of the Council of Engineering and Scientific Society Executives and is active in the Professional Convention Management Association and the American Association for Clinical Chemistry. He is a frequent speaker and consultant to other professional societies on association management issues.

The Endocrine Society appreciates the AMA’s recognition of Mr. Hunt’s accomplishments and looks forward to continued growth and success under his leadership.

Revised Warning Label on Avandia Reflects Potential Heart-Related Risk, Inconclusive Data

The U.S. Food and Drug Administration (FDA) and GlaxoSmithKline (GSK) have agreed that the black box warning on Avandia (rosiglitazone) should be revised to include results from a meta-analysis of 42 clinical studies. The revised warning will indicate that the meta-analysis revealed an increased risk of myocardial ischemic events in patients taking Avandia when compared to placebo. The label will also reveal, however, that three other studies neither confirmed nor excluded that Avandia increased such risks when compared with other drugs, therefore rendering all available evidence on the cardiovascular risks of Avandia inconclusive.

The Endocrine Society promptly responded to the initial release of the meta-analysis through a statement to healthcare providers. The statement urged the continuation of ongoing studies on the safety of rosiglitazone and encouraged providers to counsel each of their Avandia patients to determine the risks and benefits of changing therapies. Furthermore, the Society stressed the need for strict and transparent post-marketing surveillance of all new drugs. To read the entire statement, go to <http://www.endo-society.org/publicpolicy/policy/avandia.cfm>.

As it stands, FDA has concluded that evidence is lacking in regard to whether the cardiovascular risks of Avandia are different from those of other type 2 diabetes oral treatments. GSK has agreed to conduct a long-term study comparing the cardiovascular risks of Avandia with other diabetes drugs. The FDA news release can be viewed at <http://www.fda.gov/bbs/topics/NEWS/2007/NEW01743.html>.

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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