



November 9, 2005

Council Approves Society's Second Clinical Guideline

At its October 22 meeting, The Endocrine Society's Council unanimously and enthusiastically approved the organization's second clinical guideline, *The Use of Testosterone Therapy in Adult Men with Androgen Deficiency Syndromes*. This guideline was written by a task force led by Shalender Bhasin, MD, and is now 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. Bhasin and the members of his task force for their hard work and dedication. Several Council members commented on the high quality of the guideline and applauded the work of the task force.

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 forces, followed by a review of the literature, grading of evidence, and then by the actual writing of the guideline. Once drafted by the task forces, the guidelines go through a series of revisions and are edited and refined by a medical writer. The guidelines then go through another series of reviews by the CGS, Clinical Affairs Committee, and then Council. Following those steps, each of the guidelines is posted on the Society's Web site for member comment. Finally, after the member-comment period closes and any necessary revisions are made, the guidelines are then submitted for publication in *JCE&M*, where they undergo peer review.

Other guidelines currently in development and expected in 2006 are: *Thyroid Disease in Pregnant and Postpartum Women*, *Pediatric Obesity*, *Metabolic Syndrome*, and *Use of Androgens in Women*. Council will also consider three new topics for Society guidelines at its January meeting.

TES Stresses Importance of Healthy Children for Clinical Controls

On October 25, The Endocrine Society submitted comments to the Food and Drug Administration (FDA) in response to a *Federal Register* notice soliciting comments on a research protocol, "Gonadotropin-releasing Hormone Agonist Test in Disorders of Puberty." The Society's comments have been submitted for consideration to the Pediatric Ethics Subcommittee of FDA's Pediatric Advisory Committee in advance of the Subcommittee's November 15 meeting, when this particular protocol will be addressed.

At issue is the "407 Review" process. Recently, research institutions in the U.S. have begun strict enforcement of the Department of Health and Human Services' (HHS) regulations protecting children involved in clinical research studies. These regulations, known as 407 Review, call on an institution's Institutional Review Board (IRB) to "consider the potential benefits, risks, and discomforts of the research to children to assess the justification for their inclusion in the research" before approving research. This additional level of review follows the normal regulatory IRB requirements associated with study review. If an IRB finds that a study involving children might not meet these "standards," the study is sent to the Office for Human Research Protection (OHRP) for a

407 panel review. These panels, composed primarily of ethicists, review the study, solicit public comments regarding the proposed study's appropriateness, and then make a recommendation to HHS to approve or deny the study.

The above-referenced protocol, authored by Robert L. Rosenfield, MD, a pediatric endocrinologist and Society member, has been referred for 407 Review by the University of Chicago IRB. On November 15, FDA's Pediatric Ethics Subcommittee and OHRP will discuss the protocol and make a recommendation as to whether it should proceed.

The Endocrine Society's comments focus on the importance of studying healthy children to obtain normative data in studies such as this one. In the comment letter, the Society calls for the rational use of the 407 Review process, with a system in place to provide greater guidance to IRBs for determining "minor increase over minimal risk" that is based on scientific and ethical expertise and is consistent at a national level. The Society argues in its comments to FDA that the regulations stipulating 407 Review may substantially constrain the enrollment of normal children as control subjects in clinical research. An excerpt from 'TES' comments to FDA reads, "Without carefully performed studies in normal children, research to advance the treatment of disease in children will suffer. Studies in normal children may in some circumstances be the only basis for determining safety and efficacy of medications and medical tests that are critical for the diagnosis and treatment of diseases in children." The full text of the Society's comments may be viewed at http://www.endo-society.org/publicpolicy/legislative/letters/upload/407_Review_Comments.pdf.

Society Issues Position Statement on Stem Cell Research

At its October meeting, the Society's Council approved an Endocrine Society position statement on stem cell research. The Society has recently instituted a formal development and review process for official statements such as this one that are designed to support the Society's advocacy efforts. This particular statement on stem cell research originated in the Society's Research Affairs Committee and was developed in response to a need for the Society to have a clear, definitive statement on this issue for use with legislators and the media. The Government Relations and Ethics Advisory Committees also played important roles in its development. In summary, the statement supports the following positions for the Society:

- Increased federal funding and NIH support for stem cell research;
- Increased number of federally funded embryonic stem cell lines for human therapeutic research;
- Collection of stem cells through voluntary donation only, without monetary incentives, after thorough informed consent;
- Conclusions of the National Academies of Science report, which recommends that biomedical research using nuclear transplantation to produce stem cells be permitted and that a ban on reproductive cloning be imposed;
- Enforcement and adherence to strict embryonic stem cell research regulations to assure ethical standards are always met.

This statement will be the first in a series of Society position statements to be developed and managed through the Government Relations Committee. All will undergo a rigorous, multi-step review process before being referred to Council for approval. This particular position statement underwent extensive internal review by experts in stem cell research followed by review by three Society committees. After the committee review process was completed, the statement was posted on the Society's Web site for a 10-day member comment period. Every member of the Society was given the opportunity to review and comment on the statement, and the overwhelming majority of

members who participated in the process approved of the Society's position. The final step was the approval by Council at its October meeting.

President-Elect Leonard Wartofsky, MD, presented the draft statement, and Council approved it unanimously.

To view the stem cell statement in its entirety, please go to http://www.endo-society.org/publicpolicy/policy/upload/Stem_Cell_Research.pdf.

Senate Budget Reconciliation Package Proposes Several Changes to Medicare, May Avert Physician Pay Cut

On October 25, the Senate Finance Committee passed its budget reconciliation package with a vote of 11-9. The Committee package recommends a one percent increase in physician Medicare reimbursements for 2006. Without such a measure, most physicians will face a 4.4 percent decrease in Medicare reimbursements effective January 1, 2006.

The reconciliation package also recommends several changes to Medicare. First, it would implement a pay-for-performance (P4P) component to the program for provider groups including hospitals, physicians, Medicare Advantage (managed care) plans, end-stage renal disease providers, and home health agencies. Providers would receive a one percent bonus for reporting data on quality measures; this amount would increase to two percent over five years. The Congressional Budget Office (CBO) estimates that this proposal would have no effect on Medicare spending in 2006, and would reduce Medicare spending by \$4.5 billion from 2006-2010 and \$7.2 billion from 2010-2015.

A portion of the savings generated from the P4P component would come from reduced program spending for managed care plans; the budget package calls for \$11.8 billion in cuts to Medicare Advantage payments. The Senate Finance Package would reduce direct spending by \$10 billion between 2006 and 2010, and \$54.8 billion from 2006-2015. The Medicare Program would account for 57 percent of the package's savings for the first five years, and 74 percent of the savings over ten years.

The full Senate will likely deliberate on the Finance Committee proposals next week, with a close party-line vote expected. A House-Senate conference committee will then be responsible for reconciling any differences between the Senate and House reconciliation packages. This will be no easy task, since the House Energy and Commerce and Ways and Means Committees are not expected to include Medicare provisions in either of their packages.

CMS Announces Voluntary Quality Reporting System

The Centers for Medicare and Medicaid Services (CMS) has announced a new voluntary program intended to help the agency assess and improve quality of care for Medicare beneficiaries. The first phase of the "Physician Voluntary Reporting Program" (PVRP) will begin January 2006, and is based on a starter set of 36 evidence-based performance measures. Additional quality measures may be phased in throughout 2006. The starter set includes several measures of interest to endocrinology, including Types I and II diabetes mellitus and osteoporosis. CMS relied on several sources in developing measures, including the National Quality Forum (NQF), the Ambulatory Care Quality Alliance, the American Medical Association's Physician Consortium for Quality Improvement (Consortium), and the National Committee for Quality Assurance (NCQA). The Endocrine Society actively participates in the Consortium, which includes representatives from more than 60 national medical specialty and state medical societies. James Rosenzweig, MD, represents the Society on the Consortium.

CMS will collect information through the Healthcare Common Procedure Coding System codes (G-codes), which will supplement the claims data that physicians submit. CMS officials expect that electronic submission of information through electronic health records will eventually replace the use of G-codes. CMS will provide feedback to participating physicians by summer of 2006 based on submitted data, with the goal of improving reporting rates, data accuracy, and clinical care.

Congress has not appropriated funding for the PVRP. In fact, participating physicians would not receive any additional Medicare compensation through the program. In contrast, legislation in the House that is widely supported by the medical community, H.R. 3617, calls for a Medicare payment increase for physicians who meet or exceed quality measures.

For further information, visit the PVRP's web page at <http://www.cms.hhs.gov/providers/p4p/> on the CMS website.

Senate Passes Labor/HHS/Education Appropriations Bill

On October 27, the Senate approved a \$612 billion spending package for the departments of Labor, Health and Human Services, and Education. The bill, which is the largest of the spending measures considered by Congress each year, includes \$146 billion for no entitlement programs and about \$458 billion for mandatory spending programs, including Medicare and Medicaid. The National Institutes of Health was allotted \$29.4 billion for Fiscal Year 2006; this is \$1 billion more than the Fiscal Year 2005 appropriation and \$908 million above the House-passed appropriation earlier this year. During deliberations in the Senate, legislators approved an amendment offered by Senator Tom Harkin (D-IA) that provides nearly \$8 billion for the development and production of an avian flu vaccine.

House and Senate negotiators must now meet in a conference committee to work out the differences between the two pieces of legislation. One item likely to be contested during the conference committee is a move by the Senate to shift \$3 million in mandatory Supplemental Security Income spending into Fiscal Year 2007. This accounting shift frees up Fiscal Year 2006 spending and allows the Senate to allocate more money to entitlement programs and still stay within the budget caps. The Senate tried the same maneuver last year, but the provision was removed by House negotiators in the conference committee.

Diagnostic Imaging Proposal Not Included in Senate Budget Package

Despite a heated lobbying campaign by the American College of Radiology (ACR), the Senate Finance Committee's Budget Reconciliation Package, which was approved October 25, did not include a proposal intended to place limits on the types of specialties that would be allowed to perform diagnostic imaging services. ACR had also requested that Congress mandate physician certification and office equipment accreditation for imaging services.

Several groups, including the Coalition for Patient-Centered Imaging, made up of 22 specialty societies, worked to lobby against ACR's efforts, arguing that they are equally qualified to perform diagnostic imaging tests in an appropriate manner.

The issue of diagnostic imaging services stems from an ongoing debate about whether a rise in utilization of medical imaging services and associated costs is tied to "inappropriate" use of tests. The Medicare Advisory Commission earlier this year recommended that the Department of Health and Human Services (HHS) develop standards for medical imaging providers and facilities.

Akaka Amendment Removed In Conference

As reported in the October 5 issue of *Endocrine Insider*, the Senate had recently adopted an amendment to the Agriculture, Rural Development, Food and Drug Administration Appropriations Act of 2006 that would have prohibited funding to biomedical research facilities that lawfully purchase animals from Class B dealers.

As a result of an intense education campaign mounted by The Endocrine Society, FASEB, the National Association for Biomedical Research (NABR), and others in the scientific community, this amendment was removed during deliberation of the conference committee. The amendment's sponsor Senator Daniel Akaka (D-HI) agreed after meeting with the scientific community that the amendment might have had unintended consequences and a broader impact than originally intended.

The original intent of the amendment was to prevent the theft of pets that are subsequently sold to Class B dealers. However, regulations provided under the Animal Welfare Act already prohibit Class B dealers from obtaining stolen pets.

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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