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NIH Enhanced Access Policy Goes Into Effect

The NIH's policy for making author manuscripts available for free to the public went into effect on May 2nd. The policy strongly encourages, but does not require, NIH-funded investigators to send their final, peer reviewed author manuscripts to the National Library of Medicine's PubMed Central (PMC) immediately after the date of publication. To help authors comply with the new regulations the Society has issued the following compliance guidelines:

- The manuscript provided by the authors must be the “pre-print” form of the manuscript. It is the accepted, unedited manuscript exactly like what The Endocrine Society publishes on-line and free of charge as a “Rapid Electronic Publication.”
- As the author-grantee principal investigator, you must submit your accepted manuscript at a secure Web site following the NIH file format requirements (a wide range of electronic word processing formats or PDF). For a full description of the submission procedures, please visit the PubMedCentral (PMC) Web site at <http://nihms.nih.gov>. After you submit the manuscript to PMC, PMC will reconfigure your manuscript to comply with a standard PMC format, (i.e., on PMC it will likely look different from your accepted manuscript on The Endocrine Society Rapid Electronic Publications site.)
- When you submit their manuscripts to PMC, the NIH requests that you (only the principal investigator may do this) designate when your accepted, un-edited, manuscript may be posted on PMC for public access. This designation will be in the form of a delay period from final publication by the publisher, for example, a delay of up to 12 months from print (final) publication of the article by the publisher. The Endocrine Society permits, and requests, that you designate no delay from the date of print (final) publication by the Endocrine Society, i.e., a delay of 0 (zero). Note that PMC will be able to determine the date of print (final) publication. The author need not do anything after submitting the pre-print manuscript.
- The Endocrine Society will be unable to submit manuscripts on the author's behalf. Therefore, the author must fulfill his/her reporting requirements with PMC. However, The Endocrine Society will be allowed, and may choose to replace later the author's un-edited manuscript in PMC with The Endocrine Society's final version of the article or, preferably a link back to the author's article on The Endocrine Society Web site. You, as the author, may not submit the final, copy edited article to PMC.

- Copyright remains with The Endocrine Society, which invests time and effort to review the accepted manuscript, print and post online the final edited version of the manuscript, and archive your research findings.

The Society will keep members apprised of any changes in the NIH policy or procedures. Further guidance can be found on the Society's Web site at http://www.endo-society.org/journalspublications/nih_author_policy.cfm. For questions regarding The Endocrine Society policies, please contact the editorial office of the journal to which you are submitting. If you have questions about the specific NIH submission requirements, please see <http://nihms.nih.gov>.

Senate Staff Say Pay Cut for Physicians Still Likely— Pay-for-Performance System on the Way

In a briefing hosted by the American Medical Association (AMA), Senate Finance Committee staff from both parties reported on the continuing struggle to fix the Medicare reimbursement system for physicians. Society staff joined representatives from other medical specialty groups to get the latest information on the projected 4.3 percent cut to physician Medicare reimbursement scheduled for 2006.

Staff from the Finance Committee stated that no long-term solution to resolve the Sustainable Growth Rate (SGR), the formula responsible to calculating reimbursement rates, is imminent. They expressed that Congress is demanding to see improved efficiency and delivery of care in any new evaluation of the reimbursement system. Specialty groups were asked to move forward with implementing new standards and measurement of quality care to use as pilot projects. Congress is also asking physicians to embrace new technology to improve delivery and efficiency in any new model. Other solutions included new pay-for-performance standards and possibly implementing provider profiling to publicly report on the performance of physicians.

In the near-term, the Committee was cautiously optimistic about another one-year update in reimbursement to reverse the impending 4.3 percent cut. However, they cautioned that following the passage of the budget resolution (see article, "Congress Approves FY 2006 Budget Resolution" in this issue), Congressional leadership is committed to maintaining the fiscal discipline outlined in the budget and is not likely to increase spending with an update in physician reimbursement.

Congress Approves FY 2006 Budget Resolution

On April 28th, Congress approved the Fiscal Year 2006 Budget Resolution. The budget includes an \$843 billion limit on discretionary spending for FY 2006; this is a 2.1 percent increase over FY 2005 and is in line with the Administration's request. Defense spending is increased by 4.1 percent over this year and spending for homeland security is increased by 3.9 percent. The budget also includes up to \$106 billion in new tax cuts over five years.

Amendments approved earlier in the budget process by the Senate to increase spending to function 550 (Health), including the National Institutes of Health were dropped in the conference committee and were not included in the final version of the budget. While the measure was being debated in the conference committee, the Society sent a targeted alert to

our members who are represented by those appointed to the conference committee urging them to retain the increased spending authorized by the Senate amendments.

The FY 2006 budget would also reduce by \$35 billion spending on entitlement programs, including Medicaid. This is the first budget since 1997 that reduces entitlement spending. Specifically, the budget includes a \$10 billion reduction in Medicaid funding over five years. In exchange for the Medicaid cuts, the budget calls for the creation a bipartisan commission to find ways to eliminate fraud and abuse in the state reimbursement component of Medicaid.

While non-binding, the Budget Resolution provides guidance for Congressional appropriations committees and finance committees that have jurisdiction over Congressional spending and tax issues. Passage of the budget also gives Republicans a tactical victory. Because Congress passed the Budget Resolution, the Senate cannot use the filibuster to stop policy provisions included in the budget such as Medicaid reductions and the implementation of permanent tax cuts. To implement these provisions later in the session, the Senate needs only 51 votes rather than the 60 votes needed to override a filibuster.

Society Helps Garner Support for Stem Cell Bill

At the request of House representatives Mike Castle (R-Del.) and Diana DeGette (D-Colo.), co-sponsors of the Stem Cell Research Enhancement Act, the Society recently circulated a member alert requesting that members encourage their congressperson to support this legislation. The alert was sent to more than 400 targeted members of the Society. The Castle-DeGette bill would allow for increased federal funding for research conducted on embryos produced *in vitro* fertilization.

Because of the bipartisan support of this legislation, the Castle-DeGette bill is likely to pass. The bill will be presented on the House floor for a vote this session. "At the moment we're focused on Castle-DeGette in the House because we expect a vote," said Sean Tipton of the Coalition for the Advancement of Medical Research (CAMR), a stem cell advocacy group. CAMR is also keeping an eye out for additional legislation that may come through the Senate as a result of the Stem Cell Research Enhancement Act. Tipton has stated that CAMR will support legislation that would also allow SCNT, also know as therapeutic cloning, and the use of embryos created by *in vitro* fertilization. "To fully realize the potential of the science you need both," Tipton said.

In related stem cell legislation, Senators Orrin Hatch (R-Utah) and Dianne Feinstein (D-Calif.) introduced a bill that would provide federal funding for somatic cell nuclear transplantation and ban human cloning. The bill, Human Cloning Ban and Stem Cell Research Protection Act, would put limits on SCNT and would limit research to unfertilized eggs. At the same time, Hatch has acknowledged that limiting federal funding for embryonic stem cell research only on *in vitro* embryos limits the science from progressing as far as it can.

Look for updates on these bills in future issues of *Endocrine Insider*.

Tufts Study Shows Decline in PIs

An investigation done by the Tufts Center for the Study of Drug Development (CSDD), reported that the number of principal investigators (PIs) conducting FDA-regulated clinical research has dropped 11 percent since 2001.

A decline in compensation is named as one of the factors reducing the number of PIs and clinical trials. "Investigators really receive compensation today that often times do not help them make ends meet. At the end of the day the studies do not generate a reasonable profit for them [researcher]," said Kenneth Getz, MS, MBA, a research fellow at the Tufts CSDD and lead author of the study. Research sponsors have been noted to compensate researchers 90-100 days after the work has been completed.

Countering the drop in the number of U.S. PIs is the increase of PIs outside of the U.S. Those numbers rose 8 percent between the years 2001-2003. A study from the Tufts CSDD *Impact Report* found that the value of trials and study grants declined in the 90s leading to doubling the turnover rate. "Higher turnover rates and a loss of capacity in the marketplace leads to a slowing down of innovation rates," said Getz. He continued to say that "A well-trained, informed investigator community would be an obvious counter to declining growth in the number of PIs and trials. The clinical landscape needs to be monitored to ensure that investigators are being well-trained and well-paid."

Staying positive, Getz points out that the study reports a steady growth of PIs up until 2001 and notes that receiving this information regarding the decline now, may assist in solving the problem at an earlier stage.

The center's study also touches on trends in gender disparity, noting that the proportion of female PIs to all PIs in 2003 was only 12 percent, and has been declining steadily since 1992. Getz revealed that his center will continue to monitor these trends, as well as trends in minority disparities and regional differences.

According to the center, the report is the first to assess the landscape of FDA-regulated PIs. Data was culled from extensive analyses of the database of 1572 forms received and maintained by FDA.

68 Senators Urge Increase in Science Funding

On April 28th, sixty-eight Senators signed a letter to Congressional appropriators asking that they reverse the Administration's proposal to cut funding for the Department of Energy's Office of Science and increase the office's budget by 3.2 percent over Fiscal Year 2005.

The Office of Science is the largest federal funding source for research in the physical sciences. According to the letter, the signatories are concerned that the Administration and Congress have become complacent with regard to the development of U.S. scientific strength and leadership.

The letter states "[if the budget is cut] America's physical sciences' research infrastructure, yet again, would be partially hard hit, coming at a time when our international competitors in

Asia and Europe are increasing their investments in these critical disciplines that underpin virtually every facet of our lives and economy.”

This letter indicates a strong acknowledgement from Congress about the importance of funding basic research, even in time of economic struggles. A link to the letter in its entirety can be found at http://www.aau.edu/budget/DOE_Office_of_Science_FY06.pdf

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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