



October 20, 2005

Endocrine Society VP Testifies in NY; Helps Avert Potentially Harmful Change in Medicaid Policy

On October 14, Society Vice President Carolyn Becker, MD, testified before the New York State Medicaid Pharmacy and Therapeutics Committee, and her testimony helped make the case that a change in Medicaid policy regarding thyroid treatments could potentially harm patients and create confusion for physicians.

The Committee heard Dr. Becker's testimony as it was considering a proposal that would have removed levothyroxine sodium oral products from the list of drugs exempted from prior-authorization requirements for brand-name drugs dispensed in New York under its Mandatory Generic Program for Medicaid patients. If approved, this change in policy would have required that physicians apply for prior-authorization each time a branded levothyroxine sodium product was prescribed for a Medicaid patient, including each time a levothyroxine sodium dose was changed because of titration or other treatment considerations. Furthermore, prior-authorizations would have to be renewed after each six months of therapy and for each patient prescribed a branded levothyroxine sodium product.

In her testimony, Dr. Becker asked the Committee to continue the current policy and keep levothyroxine sodium products exempted from the Mandated Generic drug program. She explained, "If NY State removes levothyroxine sodium products from the list of drugs exempted from the Mandatory Generic program, this will cause great confusion and consternation for doctors and patients alike." She added, "In addition to taking up valuable physician or staff time that could be better spent caring for patients, this regulation will lead to inadvertent substitution of product formulations that are not equivalent. Moreover, since patients and physicians may not even be aware of the change in formulation, they may fail to recognize that symptoms that occur are due to the change in medication and not to some new disease state. This may lead to unnecessary testing, expensive work-ups, and in some cases, hospitalization."

Thanks to Dr. Becker and others who testified before the Pharmacy and Therapeutics Committee, the Committee voted unanimously to recommend that levothyroxine sodium products remain exempt from the state's Mandatory Generic Program and be kept off the list of drugs requiring pre-authorization for Medicaid patients. The full text of Dr. Becker's testimony can be found at http://www.endo-society.org/publicpolicy/insider/upload/CBecker_Levothyroxine_Testimony.pdf.

Society Members Lobby Capitol Hill

On October 7, the Government Relations Committee (GRC) took to Capitol Hill for its second visit of 2005. Members of the Committee met with 14 Congressional offices on items important to the Society's legislative agenda. A few of the more important meetings included a meeting with the Staff Director of the House Ways and Means Committee and Congresswoman Nancy Johnson (R-CT). Congresswoman Johnson is the sponsor of legislation that would repeal the Sustainable Growth Rate (SGR) to fix the flawed Medicare reimbursement system and implement pay-for-performance (P4P) measure for physicians. The Staff Director indicated that it was unlikely that P4P would be implemented this year and that it was more likely Congress would pass a one-or two-year fix in the Medicare reimbursement system to avoid the impending cuts.

The Committee also met with Cheryl Jaeger, who is Senior Health Policy Advisor to House Majority Leader Roy Blunt (R-MO) and the lead staffer in charge of NIH reauthorization. Ms. Jaeger informed the Committee that Congress is committed to seeing NIH reauthorized because Congress does not have a good understanding of how money is being utilized at NIH. Furthermore, she indicated that Congress feels the current system of pro-rata increase for each institute and center is inefficient. Ms. Jaeger indicated that the reauthorization process would not move forward without the input of the scientific community and encouraged the Society to prepare written questions and comments on reauthorization to share with her and members of Congress.

One other meeting of note was the Committee's meeting with the office of Senate Majority Leader Bill Frist (R-TN). The focus of the Frist meeting was on stem cell and obesity legislation. Senator Frist has hired a Health Care Fellow to help shepherd meaningful stem cell reform legislation through the Senate following passage of the Stem Cell Research Enhancement Act in the House. Senator Frist's Health Care Fellow was very engaged in the discussion of the science behind stem cell research and, in particular, its possibilities to treat diabetes. Senator Frist's office also indicated they are committed to passing meaningful legislation in the future designed to develop a federal response to the growing obesity epidemic and promised to work with the Society in this venture.

The Endocrine Society Joins 56 Other Groups on New Open Access Proposal

On October 17, The Endocrine Society joined with 56 other scientific and medical organizations on a letter proposing revisions to NIH's open access policy that was sent to Dr. Elias Zerhouni at the National Institutes of Health (NIH). The letter asks that NIH provide public access to final articles through the existing system of NIH links from the abstracts that are indexed in the Medline/PubMed database rather than hosting author manuscripts on the PubMed Central (PMC) website.

By linking to journal Web sites rather than hosting different manuscripts, NIH can provide access to more than a million articles that are available without cost to the government or to the reader. In detail, the proposal includes a public-private partnership with NIH that would take advantage of the fact that most not-for-profit publishers already make all their research articles—not just NIH supported ones—available for free to the public 12 months or less after publication. Instead of NIH/PMC undertaking a new publishing venture that involves formatting and publishing unfinished manuscripts of NIH-funded authors, the letter argues

that NIH should use existing links from NIH's highly respected PubMed (a venerable search engine of scientific literature) to the existing journals' Web sites. Using these links, readers can access the final, published articles already residing on journals' Web sites.

The Society remains concerned that strong advocates for the NIH open access policy are pushing for mandatory submissions of manuscripts rather than the current optional status of this "request." The Society maintains that mandatory submission of manuscripts, prior to its own 12-month open access policy, would be a violation of the copyright agreement between the Society and its authors.

Since the May 2 launch of its Enhanced Access policy, NIH has reported that only about three percent of the eligible articles have been voluntarily submitted to NIH to be placed in the PubMed Central database for public review. This latest proposal is an attempt to make the open access policy a success for both NIH and the publishing community. The letter asks that NIH meet with the signatories so we can create steps to implement this new proposal. To date, there has been no formal response from NIH.

The Endocrine Society Submits Comments on 2006 Physician Fee Schedule

The Society recently submitted comments in response to the 2006 Medicare Physician Fee Schedule released by the Centers for Medicare and Medicaid Services (CMS). The Fee Schedule's major component of interest for most medical groups is the scheduled across-the-board cut of approximately 4.4 percent in Medicare payments for physicians beginning January 1, 2006 (endocrinology faces a 4.6 percent cut.) Under the current formula for determining payment, annual spending targets are calculated using the sustainable growth rate (SGR) formula. However, these annual updates have not kept up with practice cost inflation, which has resulted in negative payments for several years. In fact, under the existing flawed formula, physicians face a cumulative cut of 26 percent over six years.

Organized medicine has advocated for a repeal of the SGR for several years. The clear message from Congress in 2005 has been that any repeal of the SGR formula is inexorably linked to the implementation of pay-for-performance components in Medicare. The only legislative vehicle for accomplishing both is Rep. Johnson's bill, H.R. 3617, which is unlikely to see action this year.

Congress has repeatedly stepped in at end of the year to enact a temporary "fix." It is still unclear whether physicians will see similar action before Congress adjourns for 2005. The buzz among Congressional sources has named a number of actions, including a zero percent update over one or two years, a freeze of this year's payment levels over one or two years, or a one percent increase for 2006. Most groups are lobbying for a two-year fix, since the midterm elections in 2006 will make it difficult to push through expensive legislation. Senator Charles Grassley (R-IA), Chairman of the Senate Finance Committee, recently commented on Medicare, stating that the budget reconciliation package would ensure that physician payments are not cut in 2006.

Another component of interest to endocrinology in the 2006 Physician Fee Schedule is Medicare Telehealth Services. CMS proposed not to include Diabetes Self Management Training to the list of Medicare telehealth services because of concerns regarding the merits of providing beneficiary training to administer insulin injections via telehealth. CMS also

proposed not to add group medical nutrition therapy (MNT) to the list of Medicare telehealth services, but to add individual MNT as a Medicare Telehealth Service. The Endocrine Society supports CMS' updates and proposals for Medicare telehealth coverages. While we remain supportive of the emerging technology of telehealth medicine and the benefits it can bring to patients, we share CMS' concerns for more conclusive data regarding the efficacy of certain expanded services.

To view The Endocrine Society's 2006 Physician Fee Schedule comments, click on the following, http://www.endo-society.org/publicpolicy/insider/upload/TES_Comments_2006PhysicianFeeSchedule.pdf

CISCRP Conducts Survey on Satisfaction of Clinical Trials Registry Data

A survey that included over 4,500 participants was conducted by The Center for Information & Study on Clinical Research Participation (CISCRP), to gauge the satisfaction of those who use online listings/clinical trial registries. Results from the survey show that 40 percent of respondents found the online listings easy to use and were satisfied with the quality and quantity of the information provided.

Ninety percent of the respondents were either patients or friends of the patients. The remaining 10 percent included health care professionals and clinical research professionals. Out of the most common types of information requested, 67 percent were detailed descriptions about the studies. In addition, respondents indicated that the hospital's or investigative site's reputation was important to them. The survey also indicated that 45 percent of the respondents visited nonspecific registries which were found either through a link from another Web site or by using a search engine.

"Most of the public locates information about clinical trials either through the media (44%) and/or clinical trail registries (25%). This is the first data that can paint a broad picture on users' satisfaction of registries and how information they receive is being used," said Roni Thaler, President and Co-founder of CISCRP.

For additional information regarding CISCRP, visit www.ciscrp.org. For complete survey results, log on to <http://www.ciscrp.org/programs/registriessurvey1.htm>.

Congress Pushing for Additional Budget and Spending Cuts

House Republicans are moving forward with a budget-cutting plan that seeks to implement an across-the-board cut to discretionary spending and also would save money by cutting mandatory spending programs. Both House and Senate leaders are considering cuts to the FY 2006 budget to offset costs for Hurricane Katrina. House leaders hope to trim a total of \$50 billion from the budget over the next five years and have asked each budget authorizing committee to find cuts.

House Ways and Means Committee Chairman Bill Thomas (R-CA) has stated that his committee is planning to cut spending by \$3 billion to \$8 billion. Thomas revealed that all federal programs are being considered for cuts except Social Security because it cannot be altered in the budget reconciliation process.

The Education and the Workforce Committee, which authorizes NIH spending, has been asked to find a total of \$18 billion in savings. It is expected that a majority of that spending will come out of student loan programs. The Agriculture Committee will be tasked with reducing spending by \$4.5 billion, most of which will come from food stamp spending.

House Budget Chairman Jim Nussle (R-IA) has proposed a 2 percent across-the-board cut in discretionary spending, which will not exempt defense and homeland security spending. That cut would save \$17 billion, but has created controversy from fellow Republicans who fear cuts in defense spending, and worry that an across-the-board cut would halt the appropriations process altogether due to competing interests.

The Senate Finance Committee is also considering budget cuts. Chairman Charles Grassley (R-IA) is working on a plan for a net \$12 billion in savings. However, moderate Republicans on the panel are concerned that cuts are too deep and are urging that they be reduced.

Congressional leaders are leery to announce a timeline for the cuts but have stated they will move forward when they feel they have votes to support cuts in the budget.

Johns Hopkins University Survey Shows Increased Support for Stem Cell Research

Johns Hopkins University's Genetics and Public Policy Center (GPPC), released a survey recently, indicating that public attitude toward stem cell research is starting to relax.

The GPPC survey titled, "Values in Conflict: Public Attitudes on Embryonic Stem Cell Research," collected data from over 2,000 Americans in early September 2005. A little under half of the respondents supported federal funding for both the creation of new embryonic stem cell (ESC) lines and further research using them. The survey found wide spread support for ESC research including two-thirds either approving or strongly approving of human ESC research.

Respondents were given a choice of four ESC research policy options including gauging their support for the current policies and their thoughts of adding other congressional proposals. Twenty-two percent of respondents expressed support for the current policy while sixteen percent would ban ESC research altogether. Nineteen percent favored relaxing restrictions and forty percent believed the government should fund research to both create and study new lines.

David Prentice, Senior Fellow at the Family Research Council's Center for Human Life and Bioethics said that there was very little about the survey that was surprising or unexpected. Prentice, an opponent of ESC research, expressed concerns regarding the topics addressed in the survey. "Whereas embryonic [stem cell research] remains speculative and hypothetical, the reality is the adult stem cells are available, and this should have been one of the choices, one of the alternatives, in terms of what the respondents were asked to respond to," he said.

To read more about the survey click on <http://www.dnapolicy.org/jhtml/news/October132005.pdf>.

Frist Plans that Senate Will Adjourn by Thanksgiving, Despite Packed Schedule

Senate Majority Leader Bill Frist (R-TN) recently stated that he plans to adjourn the Senate *sine die* by Thanksgiving. This represents a lofty goal that gives senators and staff a mere five weeks to complete the full agenda slated in Congress. The government is currently running on continuing resolutions because 10 of the 12 appropriations bills remain unfinished, despite the start of the new budget year. Two massive spending and tax-cut packages are pending, and a budget reconciliation package still needs to be completed. These outstanding projects are complicated by the Hurricane Katrina recovery legislation that must also be passed.

GCRC Grants to be Phased out by 2010

A recent *Research Policy Alert* article noted that in 2006, institutions will be able to submit an M01 grant application or a Clinical and Translational Science Award (CTSA) planning grant application, but will not be able to submit applications for both project grants.

The National Center for Research Resources (NCRR) recently reported that NIH General Clinical Research Center grants will be phased out by 2010. In a recent notice published in the "NIH Guide to Grants and Contracts" the grants will cease to exist in its current form but instead will be transformed through the new CTSA.

The notice [NOT-RR-06-001] was published October 14 and outlines the transformation process for General Clinical Research Centers (GCRC), which are funded under the M01 mechanism. GCRC will relinquish their M01 grants so that the funds can be reconfigured to become part of the CTSA program. Unsuccessful CTSA grant applicants will retain their current GCRC grant for the award period.

In the meantime, GCRC applications for 2006 and beyond will continue to be accepted, and successful institutions will receive a three-year award. New and amended GCRC applications will be accepted through January 2007, and competing continuation GCRC applications will be accepted through June 1, 2007. GCRCs with a project period end date in 2008 may request a one-year extension of support for their M01 grant in lieu of a competing renewal application.

Source: Research Policy Alert, October 2005

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