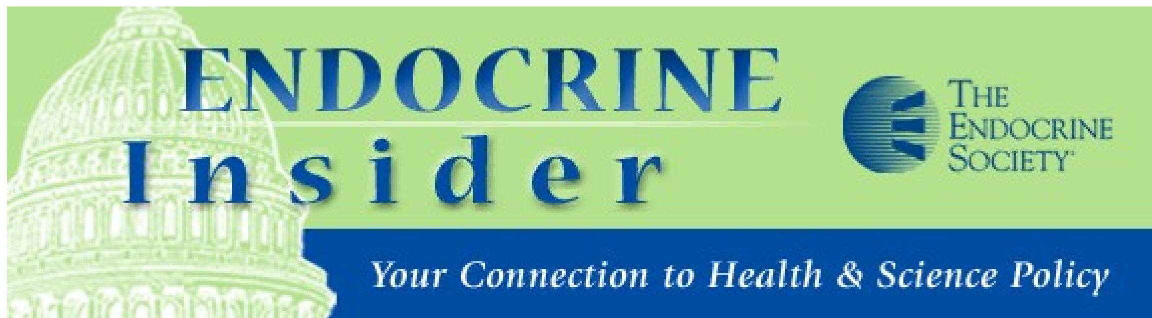

November 9, 2006

Democratic Control of Congress Means Changes in Research and Health Care Agendas

Decision 2006 brought change to Washington, D.C. in the form of Democratic control of the House of Representatives and the Senate. For the first time since 1994, Democrats will control the agenda in both houses of Congress. The shift in control will almost certainly bring changes in healthcare and budget policy.

House of Representatives

Democrats will control all House committee and leadership positions and will establish the legislative agenda. Here's a look at how Democratic House leadership and relevant House committees will likely be structured:

- **Speaker of the House** –Congresswoman Nancy Pelosi (D-CA)
- **Majority Leader** - Congressman John Murtha (D-PA) or Congressman Steny Hoyer (D-MD)
- **Committee on House Ways and Means** - Congressman Charlie Rangel (D-NY), Chairman
    - ***Subcommittee on Health*** - Congressman Pete Stark (D-CA), Chairman
- **Committee on Appropriations** – Congressman Dave Obey (D-WI), Chairman
    - ***Subcommittee on Labor/HHS/ED*** – Chairman undecided
- **Committee on Energy and Commerce** – Congressman John Dingell (D-MI), Chairman
    - ***Subcommittee on Health*** - Congressman Frank Pallone (D-NJ), Chairman
- **Committee on Science** – Congressman Bart Gordon (D-TN), Chairman

These key leadership changes will be determined by a vote of the House Democratic Caucus prior to the 110th Congress.

Senate

The fate of the Senate came down to a battle between incumbent Senator George Allen (R) and challenger Jim Webb (D). The AP has declared Webb the winner by about 7,200 votes. In the absence of a concession from Allen, the result may not become final until November 27, the date by which the Virginia State Board of Elections is required to certify the result. Nonetheless, all signs point toward Democratic control of the Senate.

A change in the Senate majority means a change in leadership and committee chairmanships. Here's a look at how a new Democratic Senate might be organized:

- **Majority Leader** – Senator Harry Reid (D-NV)
- **Majority Whip** – Senator Dick Durbin (D-IL)
- **Committee on Appropriations** – Senator Robert Byrd (D-WV), Chairman
    - ***Subcommittee on Labor/HHS/Ed*** – Senator Tom Harkin (D-IA), Chairman
- **Committee on Health, Education, Labor, and Pensions** – Senator Ted Kennedy (D-MA), Chairman
    - ***Subcommittee on Health*** – Senator Christopher Dodd (D-CT), Chairman
- **Committee on Commerce, Science, and Transportation** – Senator Daniel Inouye (D-HI), Chairman

Budget Issues

While a Democratic Congress may focus more on domestic discretionary programs, such as health, education, and social programs, funding for these must be considered in the context of the current environment, in which funding for homeland security and defense programs will remain a priority. A Democratic Congress and the Republican Administration will have to work together to reach agreements on funding for biomedical research and the myriad other programs for which tax dollars are appropriated.

Prior to the election, the House passed legislation that would reauthorize the National Institutes of Health (NIH) through 2009. There is widespread speculation – but no facts – regarding the future of the reauthorization bill now that Congress has changed hands. The Senate has not acted on the legislation this year and would have to do so in a lame duck session prior to January in order for it to become law. Should the Senate not act, new legislation would have to be drafted and introduced for the 110th Congress to consider.

Health Care

While the Bush Administration and the Republican Congress have been pushing to implement pay-for-performance (P4P) measures in Medicare reimbursement for physicians, a Democratic Congress will likely focus their efforts elsewhere in the realm of health policy. P4P issues will most likely be relegated to the backseat during congressional Medicare reform discussions, as Democrats focus more on Medicare prescription benefits and health information technology (IT). Throughout the P4P debate, Democrats have expressed concern that the type of reform sought in P4P measures is not attainable unless preceded by significant advancements in health IT. However, it is likely that CMS will continue implementing its voluntary reporting programs.

On the other hand, stem cell research has seen recent bipartisan support, with Congress passing the Stem Cell Research Enhancement Act earlier this year. The bill was vetoed by President Bush, and Democrats will likely reintroduce stem cell legislation in 2007.

Endocrinology to Fare Better than Most in CMS' Final Rule

The Centers for Medicare and Medicaid Services (CMS) released the Final Rule on the Physician Fee Schedule on November 1, 2006. The final adjustment to overall physician payments will be -5%, a figure relatively unchanged from the -5.1% predicted in the August 2006 Proposed Rule. The Final Rule also includes positive adjustments to payments for certain evaluation and management (E/M) services that endocrinologists regularly perform, and changes to the geographic practice cost index (GPCI). All of these changes will go into effect January 1, 2007, unless Congress acts to stop the cuts during the lame duck session.

The Final Rule has two provisions that impact payments for imaging services. Payment for multiple imaging procedures performed on contiguous body areas will be reduced by 25%, rather than by 50% as originally proposed. The Final Rule also caps the payment for the technical component of imaging services performed in a physician office to the payment for the same procedure in a hospital outpatient department.

As reported in the October 26 issue of *Endocrine Insider*, the Society focused specifically on the proposed cuts to CPT code 76075 (CPT code 77080 for 2007)—DXA bone density, axial—in its comments to CMS on the Proposed Rule. Despite arguments that this reduction in payments would directly conflict with federal initiatives such as the 2004 Surgeon General's Report on Bone Health and Osteoporosis—which supports increasing bone density screening for at-risk groups including patients with fractures, women aged 65 and older, patients on glucocorticoids, and other high risk groups—CMS cut payments for this procedure by $26.91. The 2007 payment rate for CPT code 77080 will be $112.55. CMS has requested that the RVS Update Committee (RUC) review again the practice expense (PE) inputs for DXA services to ensure that the direct inputs associated with these services are accurately reflected in their PE database. The Society will follow this further review closely.

The DRA cuts further impact imaging payment rates, including rates for CPT code 76942 - ultrasonic fine needle aspiration guidance for biopsy - which will receive a payment of $160.29 in 2007, a reduction of approximately 30%. However, CPT code 76536 – ultrasound exam of head and neck and most nuclear endocrinology procedures (CPT codes 78000-78075) will receive a positive update.

The Final Rule also addresses the GPCI. The current floor of 1.00 on the GPCI will expire in 2007, and the Final Rule outlines geographic adjustments for 2007 which will further reduce physician payments in a large number of localities. The GPCI reductions are listed in Table 7 of the Final Rule, which may be accessed through the link below.
http://www.cms.hhs.gov/PhysicianFeeSched/PFSFRN/itemdetail.asp?filterType=none&filterByDID=0&sortByDID=4&sortOrder=descending&itemID=CMS1188377

Many specialties will experience double digit reductions in payments due to the overall cuts, imaging cuts, and geographic adjustments. However, four specialties, including endocrinology, will receive positive updates. Endocrinology will receive a 1% increase in payments in 2007, primarily due to the increases in payments for E/M services.

Congress has the opportunity to reduce the severity of the overall physician payment cut either during the lame duck session or in the new Congress, as they have done in past years.

Furthermore, House bill H.R. 5704 introduced by Representative Pitts (R-PA), calls for a two year delay in implementing the DRA imaging cuts in order to study the effects of the cuts on patients and access to services. However, sources predict that rather than address specific legislation during the lame duck session, Congress will choose to pass a Continuing Resolution (CR) to keep the government operating until the new Congress begins. Under a CR, Medicare payment cuts would go into effect. However, if the new Congress were to pass legislation to repeal the cut in 2007, CMS would retroactively pay claims made under the CR to reflect the higher payment rate. The Society has been proactively engaged in advocating for fair reimbursement for physicians—submitting comments to CMS on the Proposed Rule and sending alerts to members to make them aware of issues that need their attention—and will continue to take these and other steps to meet the needs of our members during these uncertain times.

The Endocrine Society Urges Appropriators to Fund the National Children's Study
As Congress enters the lame duck session, legislators will take up numerous FY 2007 appropriations bills, including the Labor-Health and Human Services-Education (L-HHS-E) spending bill. A component of both the Senate and House L-HHS-E bills focuses on the NIH's National Children's Study, though the two bills take different approaches to funding the study. In its current form, the House's L-HHS-E spending bill would instruct the NIH to continue with the study with no additional funding. The Senate L-HHS-E bill would require that the funding for the study come from the NIH Roadmap funds.

The Endocrine Society is one of 100 organizations, representing patients with dozens of diseases and genetic disorders that signed a letter to appropriators in the Senate and House urging their support for funding of the National Children's Study. The letter may be read at: http://www.endo-society.org/publicpolicy/legislative/letters/upload/Support_the_National_Childrens_Study.pdf

The study is designed to track 100,000 children from before birth until age 21 in order to identify preventable environmental causes of diseases such as asthma, obesity, diabetes, premature birth, autism, and attention deficit disorder.

Planning for the study is complete and all study sites are selected, but in order for the program to move forward, appropriators must allocate $69 million to the initiative for FY 2007. Due to budget constraints, the President's budget did not contain funding for the study, leaving its fate in the hands of Congress.

More information regarding the fate of the National Children's Study in the absence of appropriated funding may be found at:
http://www.nationalchildrensstudy.gov/about/funding/index.cfm

NIH Director Reassures Young Scientists
In the fall 2006 issue of *From the Desk of the NIH Director*, Elias A. Zerhouni, MD, Director of NIH, describes several new initiatives at NIH that will address the needs of young researchers. Zerhouni summarizes the concerns and needs of emerging scientists and the ways in which NIH is reaching out to help them become established investigators.

One new initiative is the NIH Pathway to Independence (PI) Awards. Announced in January 2006, these awards are intended to provide funding for the final two years of postdoctoral research and the initial three years of an investigator's independent career. As such, a PI award will assist young investigators during the very difficult and critical transition from mentored to independent science and provide research funding while the investigator tries to secure an R01. During the first year of funding, 2007, NIH will award between 150 and 200 grants under this program and expects to fund the same number in each of the following five years.

NIH has instructed each of the individual Institutes and Centers (ICs) to develop their own initiatives to assist young investigators. Examples of these include separate pools of R01 funds for new investigators, higher paylines for new investigators, or review criteria for new investigator R01 applications that focus more on experience than on preliminary data. Additionally, the Center for Scientific Review has developed a pilot program that provides review results to young investigators quickly, so that they may resubmit grant applications during the first subsequent cycle, rather than having to wait for the second cycle as they have in the past. This will shorten the resubmission turnaround time from 9 months to 5, allowing the researcher more frequent R01 application opportunities during the initial stages of his or her career.

In addition to steps being taken to assist young scientists, Zerhouni uses the desk-to-desk newsletter to describe the agency's programs to retain women in scientific careers and to discuss the NIH Director's Pioneer Award Program.

The fall issue of *From the Desk of the NIH Director* can be viewed in its entirety at: http://grants1.nih.gov/grants/new_investigators/index.htm

2007 NIH Pioneer Award Competition to Begin December 1

On October 12, National Institutes of Health (NIH) Director Elias A. Zerhouni, M.D., announced a new round of competition for the NIH Director's Pioneer Award. Applications will be accepted Friday, December 1, 2006, through Tuesday, January 16, 2007.

The NIH Director's Pioneer Award (NDPA) Program—initiated in 2004 as part of the NIH Roadmap for Medical Research—funds investigators with highly innovative, and potentially transformative, research proposals addressing areas of major challenge in biomedical research.

Scientists at all career levels are eligible for the Pioneer Award, provided they have an interest in exploring biomedical or behavioral research, defined broadly in this program as investigations in the biological, behavioral, clinical, social, physical, chemical, computational, engineering, and mathematical sciences.

NIH's Jeremy M. Berg, PhD, director of the National Institute of General Medical Sciences and a leader of the Pioneer Award program was quoted as saying, "We hope to see a diverse applicant pool again this year. Toward that end, we continue to encourage applications from women, members of groups that are underrepresented in biomedical research and individuals in the early to middle stages of their careers."

Each Pioneer Award provides $2.5 million in direct costs over five years. NIH awarded nine Pioneer Awards in 2004, 13 in each 2005 and 2006, and expects to fund between five and ten additional scientists in 2007.

The application process for 2007 is electronic and features an essay on the applicant's vision for addressing a biomedical challenge, the importance of the problem, and the investigator's qualifications to engage in groundbreaking research.

Application instructions may be found at: http://grants.nih.gov/grants/guide/rfa-files/RFA-RM-07-005.html.

Evaluation criteria for applications are defined as:

- *The scientific problem to be addressed:* The biomedical or behavioral significance/importance of the problem, the likelihood that, if successful, the project will have a significant impact on a biomedical or behavioral problem, and the innovativeness of the project.
- *The investigator:* Evidence for the investigator's claim of innovativeness/creativity (innovation density), and the demonstrated ability of the investigator to devote 51% or more effort on NDPA project.
- *The suitability for NDPA mechanism:* Evidence that the proposed project is of sufficient risk/impact to make it more suitable for the NDPA than for the traditional NIH grant mechanism and that it is distinct from other research previously or currently conducted by the investigator.

For more information on the Pioneer Awards, please visit:
http://nihroadmap.nih.gov/pioneer.

Members in the News

A recent article by Society member Thomas Travison, PhD, in the *Journal of Clinical Endocrinology and Metabolism,* "A population-level decline in serum testosterone levels in American men," has received considerable media attention, including *Reuters*, *Forbes*, and *Newsweek*. Travison's results indicate that – after accounting for age and additional factors such as obesity, smoking, and medications – the total and bioavailable testosterone levels of American men have been on a two-decade decline, annually decreasing an average of 1.2 and 1.3 percent, respectively. The *Newsweek* article also quoted Society members Drs. Marc Blackman, S. Michael Harman, and Shalender Bhasin.

This story can be viewed at: http://msnbc.msn.com/id/15552184/site/newsweek/

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