



February 10, 2005

Welcome from Society President Means

It is my pleasure to introduce *Endocrine Insider* to those of you who are receiving it for the first time. For the last few months, *Endocrine Insider* has been distributed as a pilot to a few Society committees. The response has been so favorable that we decided to broaden its distribution to a wider audience.

Endocrine Insider is a semi-monthly newsletter with a focus on health and science policy uniquely affecting the endocrinologist. It is designed to provide you with timely updates on policy matters that are important to you and to highlight Society advocacy efforts—all in one place. Each issue contains up-to-date news about the Society's legislative and regulatory activities, the latest NIH policies, research funding updates, developments at FDA, new grant opportunities, changes in Medicare policy, and more. *Endocrine Insider* captures the policy news important to basic researchers, clinical scientists, and clinicians in practice and packages it in an easy-to-read format that will ensure that you're informed about key policy issues.

I hope that you will find this new communication tool as useful and informative as I do. Please feel free to contact me or the Programs & Policy Affairs staff, and let us know what you think about *Endocrine Insider*. Also, don't hesitate to forward a copy to your colleagues who share your interest in these issues.

Anthony R. Means, PhD
President
means001@mc.duke.edu

NIH Issues Final Public Access Policy

On February 3, NIH issued its final public access publication policy calling for study authors to post their research manuscripts on the PubMed Central database as soon as possible after publication but within 12 months. As reported in previous issues of *Endocrine Insider*, the Society has been actively engaged in advocacy around this issue and submitted comments to NIH Director Elias Zerhouni asking him to alter his original proposal—which would have required the publisher to submit the manuscripts six months after publication.

According to the new policy published in the *Federal Register*, beginning May 2, NIH-funded researchers, not publishers, are requested to submit an electronic version of their final

manuscript upon acceptance for publication, which is defined as “the final version accepted for journal publication [that] includes all modifications from the publishing peer review process.”

Society staff participated in a February 3rd telebriefing with Dr. Zerhouni, where he explained his rationale for the new policy and acknowledged that it was revised from a proposed six-month timeframe for posting on PMC. “We do want to encourage publication as soon as possible after the date of publication by the publisher, but we do recognize that flexibility will maximize participation, and that was the intent of the change. It wasn’t to go from a six-month ‘date-certain’ to a 12-month ‘date-certain’ and nothing before that,” he said. “The spirit is maximum flexibility for maximum participation, recognizing that one size does not fit all.”

Norka Ruiz Bravo, PhD, NIH Deputy Director for Extramural Research, emphasized that the policy is a “request” and not a “requirement,” and will not result in penalties for researchers who choose not to participate. The policy aims to create a “stable archive of peer-reviewed publications” to ensure their preservation, to improve searchable efficiency of these peer-reviewed publications to better monitor scientific publications, and to make NIH-funded research more readily accessible to the public, according to the agency.

In response to a question posed by Society staff, Dr. Zerhouni said the policy directs that links from PMC to the journal of origin be provided in order to offer the most comprehensive database possible. “We’re going to use all the indexing tools that the National Library of Medicine uses,” he said. “We’re going to also link these papers to their original publisher, their original site, and make it all cross-referenced so that the retrieval is as easy as possible and that the search process will be as comprehensive as possible.” Dr. Zerhouni said, however, that PMC would not publish links to publisher Web sites in lieu of posting the author manuscript.

In order to assess the economic impact of the policy on journal publishers, NIH will create a Public Access Advisory Working Group, composed of members of the National Library of Medicine’s Board of Regents, to monitor the progress of the policy’s implementation and assess the need for future modifications and enhancements. Guidance also will be provided to assist NIH grantees in navigating the mechanics of the policy. Look for updates and guidance in future issues of *Endocrine Insider*.

NIH Announces New Conflict of Interest Policy for its Employees

On February 1st, the National Institutes of Health (NIH) announced a new supplemental ethics regulation that addresses outside consulting activities by NIH employees. The regulation was developed by the Department of Health and Human Services (HHS), with the concurrence of the Office of Government Ethics, the federal agency that prescribes executive branch-wide ethics standards. The new regulation focuses on outside activities, financial holdings, and awards for all NIH employees. It raises many questions about interactions between NIH employees and non-profit professional societies such as The Endocrine Society.

According to the regulation “subject to certain exceptions, all NIH employees are also prohibited from engaging in employment (which includes serving as an officer, director, or

other fiduciary board member, serving on a scientific advisory board or committee, and consulting or providing professional services) and compensated teaching, speaking, writing, or editing with a substantially affected organization; a hospital, clinic, health maintenance organization, or other health care provider (defined comprehensively to include the types of entities that are eligible to receive payments under the Medicare program for the provision of health care items or services); a health insurer; a health, science, or health research-related trade, professional, consumer, or advocacy association; or a supported research institution.”

This regulation could be interpreted to mean that NIH employees would be prohibited from serving on Society committees or Council. However, the rule does not appear to cover those who serve on NIH advisory panels. Participants on advisory panels are considered Special Government Employees and are not affected by this regulation according to the NIH Web site.

Additionally, the rule prohibits NIH employees, who file public (SF 278) or confidential (OGE 450) financial disclosure reports, from acquiring or holding financial interests, such as stock, in biotechnology, pharmaceutical, and medical device companies and others involved in the research, development, or manufacture of medical devices, equipment, preparations, treatments, or products. All other employees (that is, those who do not file either of these reports) are subject to a \$15,000 cap on holdings in such companies. There is an exception from both rules for a financial interest, such as a pension or other employee benefit, arising from employment with a substantially affected organization and widely diversified, publicly traded mutual funds.

NIH employees can still receive compensation for speaking at Continuing Medical Education (CME) programs, or other CME-like events, pending prior approval. As long as the teaching, speaking, writing or editing is on a broad, general topic within the employee’s area of expertise. The activity has to be part of an accredited CME or CME-like program, and may be permissible even if funded by a pharmaceutical or biotechnology company but only if such funding is through an unrestricted educational grant. Other provisions in the rule restrict the value of gifts and awards that NIH employees may accept.

NIH has provided a webpage dedicated to FAQ’s and a summary of the regulation, which can be found at http://www.nih.gov/about/ethics_COL.htm. This rule is an interim final regulation, which means that it goes into effect once it is published in the *Federal Register* and remains in effect unless changed, by subsequent regulations. HHS intends to evaluate certain provisions in the rule, including those regarding outside activities and financial holdings, within the next year. HHS will consider public comments about the regulation — which will be accepted for 60 days once the *Federal Register* notice is published — and the knowledge gained from the first year of implementation when deciding, which, if any, provisions to revise. The Endocrine Society is working with NIH to provide clarity to some of the unanswered questions raised by the NIH rule. The Society will provide additional information and guidance to its membership once these questions are answered.

Bush Proposes 2006 Budget

On February 7th President Bush released his proposed Fiscal Year 2006 budget for federal spending. The major theme of the President’s 2006 budget was spending restraint, as noted in Table 1. Under the proposed budget, overall discretionary spending (non mandatory

spending set by annual appropriation levels) rises by just 2.1 percent, lower than the rate of expected inflation. Non-security discretionary spending falls by nearly 1 percent.

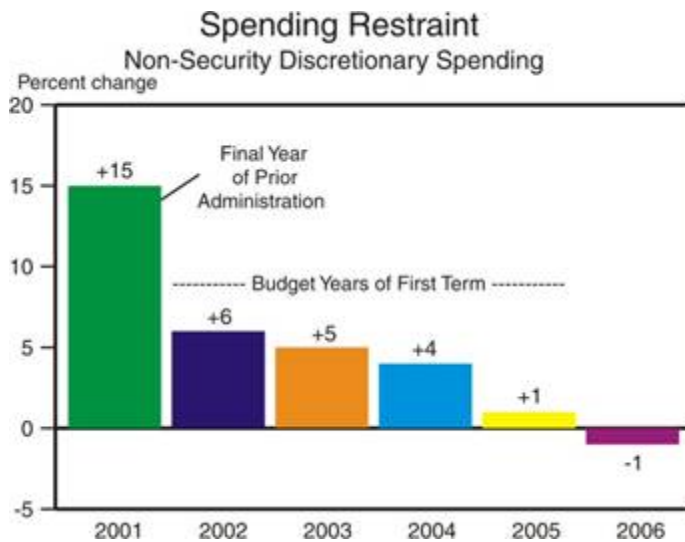


Table 1

Some of the major science and research funding agencies were funded at the following levels:

- The Department of Health and Human Services (HHS) is allocated \$67.2 billion, a decrease of 1 percent from 2005.
- The National Institutes of Health (NIH) will receive \$28.5 billion, an increase of \$145 million or 0.5 percent over the 2005 level.
- The Department of Veterans Affairs (VA) will be funded at \$33.4 billion, or a 3 percent increase from 2005.
- Total medical research programs at the VA will grow from \$784 million in 2005 to \$786 million in 2006, or .3 percent increase. However, the proposal request includes only \$393 million for the VA Research and Development Program, a cut of \$9 million from 2005.
- The National Science Foundation will receive \$5.6 billion, or a 2 percent increase from 2005.

For NIH, the total number of RPG's is 38,746 or 402 less than 2005. In the budget proposal, the President notes that "overall, NIH's research program has rated well in its Program Assessment Rating Tool (PART) performance assessments and is an effective mechanism for promoting biomedical breakthroughs. To better integrate research across its 27 Institutes and Centers, NIH is developing additional decision support tools to improve the management of its large and complex scientific portfolio. This will allow NIH to more efficiently address important areas of emerging scientific opportunities and public health challenges. The Administration is committed to this new effort, which will stimulate accelerated investments in research involving multiple Institutes and Centers, thereby helping improve the Nation's health." More detailed information about the FY 2006 NIH budget can be found at <http://www.nih.gov/news/budget/FY2006presbudget.pdf>

The Society will continue to study the 2006 budget to gauge the impact on the research community and make additional information and analysis of the 2006 budget as it becomes available. In addition, the Society will work with Congress to see that scientific research funding is protected during the appropriations process.

Society President Announces Help for Steroid Abuse in *Newsweek*

The January 17, 2005 issue of *Newsweek* magazine includes a letter to the editor from Society President Anthony Means, Ph.D. In the letter Dr. Means addressed a December 20 cover story by Newsweek titled, "Steroids and Kids." He stated that, "Although the article brought attention to the widespread use of steroids among youth...it failed to point out that help is now on the way to stem the growing tide of steroid use." He identified two science-based programs: Athletes Training and Learning to Avoid Steroids (ATLAS) and Athletes Targeting Health Exercise and Nutrition Alternatives (ATHENA).

To view a copy of the letter in its entirety, click onto the following link <http://www.endo-society.org/news/steroidslte.cfm>

Specter to Remain Appropriations Subcommittee Chair

In a letter to the Washington Post on February 8th, Senator Arlen Specter (R-PA) indicated that he would be remaining as the Appropriations Subcommittee Chairman for Labor/HHS/Education. As you may recall, the Society and the entire scientific community launched a grassroots effort encouraging Senator Specter to remain as chair of the subcommittee given his past commitment to scientific research funding. The following is the open letter that Senator Specter sent to the Post:

Staying Put for Social Spending
By Arlen Specter

Tuesday, February 8, 2005; Page A23

Strong advocacy for education, health care and worker safety will be indispensable if they are to get their fair share of President Bush's austere budget for the next fiscal year. I had been considering moving over to the newly created appropriations subcommittee on intelligence, but with tough fights looming on social spending, I have decided to stay with my chairmanship of the subcommittee on labor, health and human services and education.

There is no doubt that our nation's security and defeating terrorism trump all other priorities. Important work needs to be done immediately on the implementation of legislation creating the national intelligence director and prospective modification on appropriations for the intelligence community. I have had a keen interest in these subjects since chairing the Senate Select Committee on Intelligence in the 104th Congress and co-authoring the Homeland Security Act. But with the delay in appointing the new director, and with emerging doubts about the new appropriations subcommittee on intelligence, I believe I can make a greater contribution by staying put.

The president's budget puts at risk critical funding for the National Institutes of Health and other important priorities of the subcommittee. For more than a decade, Sen. Tom Harkin

(D-Iowa) and I have alternated on the subcommittee chairmanship with a seamless transfer of the gavel. We have more than doubled funding for NIH, which has made enormous progress on working toward cures for Parkinson's, Alzheimer's, cancer, heart disease and other deadly or debilitating diseases. Those gains may be nullified unless increases in funding continue.

Funding for Pell Grants, which has received considerable public attention, is only one of many worthy education programs deserving continued support. The president's support for increased money for Pell Grants is commendable, but there is no net gain to education if those increases come from cutting or eliminating other important programs. The tight budget will make it difficult to provide adequate funding for Head Start, special education, No Child Left Behind and mentoring at-risk students.

By retaining my subcommittee chairmanship, I can maintain special standing on oversight on proposed legislation calling for the Labor Department to administer an asbestos compensation program. The prospects are good this year that Congress will create a trust fund to compensate people injured by exposure to asbestos and whose employers have gone bankrupt. The labor appropriations subcommittee will set funding for the administrative process and could play a key role in implementing the legislation.

As the United States faces enormous deficits, discretionary spending has taken hits year after year. Congressional budgeteers and appropriators have not sufficiently recognized that education and health care are capital investments. Harkin and I, putting partisanship aside, have successfully fought for more funding for our subcommittee. Fiscal 2006 looks like an especially tough year, so I've decided to stay and fight rather than switch.

The writer is a Republican senator from Pennsylvania.

Society and FASEB Staff Meet with Moderate Republican Group

On January 28th, staff from The Endocrine Society and FASEB met with the office of Rep. Charlie Bass (R-NH). Rep. Bass is the Co-Chair of the Tuesday Group, a collection of moderate House Republicans who meet once a month to discuss various issues. Issues of interest to the Tuesday Group include pro-science legislation and stem cell research.

According to Bass' staff, the Tuesday Group's main science-related agenda item is expanding the number of stem cell lines available for federal research. The main vehicle for achieving this goal will be legislation to be introduced in the coming weeks sponsored by Rep. Michael Castle (R-DE). Bass' staff also indicated interest in gaining additional information about the science involved in stem cell research and were looking for resources that could help non-scientists understand this issue better. Society and FASEB staff offered to serve as resources on the issue and promised to provide talking points and other educational materials. Further indications were that the Tuesday Group was also considering hosting a briefing on stem cell research with Congressman Castle.

In addition, the Society and FASEB voiced concern about the future of federal funding for science and provided Rep. Bass' office with the FY 2006 FASEB funding report. Unfortunately, the Tuesday Group is unlikely to push for increased science spending this

year, as it is committed to reducing the deficit. One of the Society's and FASEB's advocacy goals this year is to create Hill champions who understand the value of increased NIH investment.

Bush Addresses Medical Research & Health Care Deliverables in State of the Union Address

On February 3rd, President Bush addressed Congress for this first State of Union address of his second term. The wide-ranging speech that outlined the President's objectives for the coming year and his final term included several issues relevant to Society members. First, the President stressed the need to exercise budget restraint in the coming years by stating that "America's prosperity requires restraining the spending appetite of the federal government. I welcome the bipartisan enthusiasm for spending discipline. I will send you a budget that holds the growth of discretionary spending below inflation, makes tax relief permanent, and stays on track to cut the deficit in half by 2009. My budget substantially reduces or eliminates more than 150 government programs that are not getting results, or duplicate current efforts, or do not fulfill essential priorities. The principle here is clear: a taxpayer dollar must be spent wisely, or not at all." (See related story, "Bush Proposes 2006 Budget.")

Second, the President stressed the important role that medical research plays in the Nation's future. Bush highlighted Congress' past commitment to the NIH doubling and urged ethical restraint for future medical research. Last, President Bush pushed for reforms in health care deliverables. He encouraged Congress to take measures to reduce the cost and increase access to health care. In his speech the President stated "to make our economy stronger and more productive, we must make health care more affordable, and give families greater access to good coverage, and more control over their health decisions. I ask Congress to move forward on a comprehensive health care agenda — with tax credits to help low-income workers buy insurance, a community health center in every poor county, improved information technology to prevent medical errors and needless costs, association health plans for small businesses and their employees, expanded health savings accounts, and medical liability reform that will reduce health care costs, and make sure patients have the doctors and care they need."

For questions regarding articles listed in *Endocrine Insider* or information on advocacy and policy activities within The Endocrine Society, contact the Programs & Policy Affairs department:

Janet B. Kreizman, Director
301-941-0252
jkreizman@endo-society.org

Meg LaPorte, Associate Director
301-951-2613
mlaporte@endo-society.org

Chris Rorick, Manager
Government Relations
301-941-0254
crorick@endo-society.org

Lisa Marlow, Coordinator
240-482-1392
lmарlow@endo-society.org