



February 9, 2006

Society and Senate Majority Leader Co-Host Briefing on Obesity

On February 7, members of The Endocrine Society briefed Congressional health policy staff about the prevention and treatment of obesity and engaged in discussions about possible legislative solutions to the problem. The briefing, “Childhood Obesity 101—Combating a National Epidemic,” included presentations from James O. Hill, Ph.D., Director of the Center for Human Nutrition and Michael D. Jensen, M.D., Chair/Director of the Obesity Treatment Clinic at Mayo Clinic. Society President-elect Leonard Wartofsky, M.D., kicked off the briefing, and health care staff from Senate Majority Leader Frist’s office discussed pending obesity legislation.

During the briefing, Dr. Hill offered his perspective as an obesity expert, emphasizing the importance of improved nutrition and physical activity. He stressed that there is no single solution to the obesity epidemic, rather there are several. Dr. Hill explained that this is precisely why obesity is such a difficult issue to solve because crafting solutions must address incremental changes in several different areas including: lifestyle, environment, government programs (including school and local communities), translation of research findings out into the community, and public awareness. He added that currently there is no clear and concise message to the public about how to lose weight and how to maintain a healthy lifestyle.

Dr. Jensen spoke about the science behind obesity and illustrated why this disease can be caused by more than just eating poorly and not exercising. He outlined genetic and physiological barriers some people have that make it difficult for them to lose weight and maintain a healthy weight. His presentation also outlined the need for further education of the physician community. Currently, physicians are not being trained to evaluate or treat obese patients, and he stressed that new programs are needed to address this training void.

In June 2005, Senator Frist introduced two pieces of legislation, the Improved Nutrition and Physical Activity (IMPACT) Act (S. 1325) and the Childhood Obesity Reduction Act (S. 1324). Both measures contain multifaceted approaches to tackle the obesity epidemic. Senator Frist’s office is hopeful that the briefing will spark renewed interest in the legislation and that the measure can be passed by Congress this year. The legislation aims to address several of the concerns brought forth by the presenters by authorizing funding for community-based preventive block grants for activities and community education programs designed to address and prevent obesity. In addition, the legislation expands an existing grant program for the training of health professionals and students to include the treatment of overweight and obesity. It also awards grants for the training of primary care physicians and other health professionals on how to identify, treat, and prevent obesity.

Dr. Wartofsky provided an overview of how endocrinology and obesity were linked and offered insight into the work endocrinologists do, from bench to bedside, to combat the obesity epidemic.

The briefing illustrates the value the Society's investments in advocacy and public awareness around the issue of obesity. The Society was approached by Sen. Frist to co-host the briefing and comment on his obesity bills because the organization has become a recognized, credible source for information on the subject. For the last several years, the Society has been working to educate Congress, the media, and the public about the role of endocrinology and in fighting and treating obesity. Further, Society efforts have focused on advancing public policy solutions to the obesity epidemic that meets the needs of Society members and patients.

Advocacy Efforts Avert Physician Medicare Pay Cuts

The House on February 1, 2006, approved the fiscal year 2006 budget reconciliation bill (S. 1932) by a narrow 216 - 214 votes. The budget bill averts the 4.4 percent across-the-board cut in Medicare physician payments by freezing payments at 2005 rates. The "Deficit Reduction Act" does contain more than \$39 billion in cuts, with approximately \$6.4 billion from Medicare and \$4.8 billion from Medicaid. The bill carried over from 2005 after the House, on December 19, voted 212 - 206 to approve the bill, but a procedural move forced the bill from the Senate back to the House after a 51-50 vote.

Due to a flawed payment structure based on the sustainable growth rate, reimbursement rates have been outpaced by practice costs for the past several years. As a result, through its regulatory authority, CMS has cut physician pay for Medicare patients each year. Every year, Congress has stepped in at the eleventh hour to enact a temporary "fix," although there are several members of Congress interested in enacting a long-term solution.

The Endocrine Society worked with the American Medical Association (AMA) and medical specialty societies to lobby Congress to act on behalf of physicians to avert the cut. Society members sent 145 messages to their Congressional representatives following a call to action issued by the Society.

The cost of the physician reimbursement fix is offset by a reduction in payments to Medicare Advantage managed care plans. Other changes to Medicare include increased premiums for beneficiaries (with greater increases for higher-income beneficiaries) and a freeze in payments for home health care providers.

The budget package also targets spending on pharmaceuticals, setting reimbursement rates for drugs based on the average manufacturers price (AMP). Beginning in 2007, the federal government will only pay up to 250 percent of the AMP of the lowest-cost version of a generic drug. The AMP will also be made publicly available, potentially reducing costs for patients and allowing private health plans to negotiate lower drugs prices.

Regarding Medicaid, the Congressional Budget Office (CBO) reported that the budget package contains funding to expand Medicaid services, such as expanded coverage for

disabled children from families whose incomes do not exceed 300 percent of the federal poverty level. Spending on Medicaid home- and community-based services will increase by approximately \$2.6 billion over ten years.

The budget reconciliation bill will now head to the White House for the President's signature.

President Releases Tight 2007 Budget Proposal

President Bush released his proposed budget for fiscal year (FY) 2007 on February 6. The lean budget proposal seeks to reduce government spending and trim the growing fiscal deficit. The \$2.77 trillion proposal would increase overall spending 2.3 percent from the projected total of \$2.71 trillion for FY 2006. The President contained most spending increases to only those agencies responsible for defense or homeland security. Most non-defense, non-homeland security agencies and programs will have their spending cut by an average of 0.5 percent. Among those, 141 government programs will be sharply reduced or eliminated. The largest spending increase would go to the military with a 6.9 percent increase to the Department of Defense. The Department of Homeland Security would also see an increase for 2007, while nine of the 15 Cabinet agencies would see outright cuts in their discretionary spending.

As proposed, the National Institutes of Health (NIH) would see its budget frozen at the FY 2006 number of \$28.8 billion. At the same time, the NIH announced its annual update of the Biomedical Research and Development Price Index (BRDPI). NIH projects the BRDPI will be 3.7 percent in FY 2006 and 3.5 percent in FY 2007. NIH estimates it will fund 642 less research project grants (RPG's) in 2007 if the President's budget number is approved. Despite the effective budget cut, NIH will direct \$443 million towards the Roadmap Initiatives, an increase of \$113 million over the FY 2006 appropriation. Of this amount, the NIH Director's Discretionary Fund will provide \$111 million, while the Institutes and Centers will contribute the remaining \$332 million.

NIH Budget at a Glance

		<u>Change</u>
FY 2005 Actual	\$28,644 M	
FY 2006 Appropriation	\$28,578 M	-0.2%
FY 2006 NIH Program Level	\$28,587 M	
FY 2007 President's Budget - Budget Authority	\$28,578 M	0.0%
FY 2007 NIH Program Level	\$28,587 M	0.0%
Number of Competing RPGs	9,337	+275 over FY 06
Total Number of RPGs	35,805	(642) under FY 06

Source: NIH Summary of Fiscal Year 2007 President's Budget

Among the winners in the budget proposal were those programs tied to the President's new American Competitiveness Initiative, which increases Federal investment in research to help ensure that the United States continues to lead the world in opportunity and innovation. The Department of Energy's (DOE) Office of Science received \$505 million, a 14.1 percent increase over FY 2006 funding. This budget puts DOE's Office of Science on the path to doubling its budget by 2016. The National Science Foundation received \$6.02 billion, a 7.9 percent increase over its FY 2006 budget. The Agency anticipates that it will be able to fund

around 500 additional research grants under the proposal. If Congress approves the budget increase, NSF will start its own path to doubling its budget by 2016.

Other programs and agencies of interest:

- **The Centers for Disease Control** – \$8.2 billion in FY 2007, a net decrease of \$179 million from FY 2006.
- **Health Resources and Services Administration** – \$6.4 billion in FY 2007, a net decrease of \$252 million from FY 2006.
- **Agency for Healthcare Research and Quality** – \$319 million for FY 2007, the same as FY 2006.
- **Department of Veterans Affairs** – The VA’s Health Care Program would see an increase of \$3.5 billion (or 11.3 percent) more than FY 2006. However, the VA Medical Research Program would have its budget cut by \$13 million.
- **United States Department of Agriculture** – The USDA’s National Research Initiative would see an increase of 37 percent over FY 2006; bringing total spending for the program to \$248 million.
- **Medicare** – The President’s budget would freeze Medicare payment rates for nursing homes, home health, and rehabilitation hospitals for 2007, decrease the payment updates for inpatient and outpatient hospital services by 0.45 percent, and decrease hospice and ambulance updates by 0.4 percent. The budget does not address the impending cut for physician’s services scheduled for 2007.

The release of the President’s budget is the first step in the lengthy, and likely contentious, budget process. Congress must now review the budget proposal and make its own recommendations. Some members of Congress have already voiced their concerns over some of the President’s proposals, including the President’s recommendation for NIH. Senator Arlen Specter (R-PA), Chairman of the Senate Labor/HHS/Education Appropriations Subcommittee, called the health and education budget recommendations “scandalous” and indicated he would not support any budget resolution that did not adequately fund programs under his jurisdiction. His counterpart on the Committee, Senator Tom Harkin (D-IA) has expressed similar views and suggested the President “shortchanged vital medical research initiatives.”

NIH Creates New Office to Support Future Research Initiatives

The new Office of Portfolio Analysis and Strategic Initiatives (OPASI) at the National Institutes of Health (NIH) opened its doors on January 1, 2006. Society staff attended a briefing with Dr. Raynard Kington, Deputy Director at NIH, where he described the functions of OPASI. The office was borne from a recent effort in Congress to evaluate research and funding priorities, as well as the movement toward NIH reauthorization that gained momentum in 2005, but slowed later in the year. Several aspects of the NIH research portfolio have also been questioned, including the process by which the agency codes its funded portfolio related to specific disease and conditions and the process by which the agency assesses public health needs and integrates those needs into funding priorities.

OPASI’s mission includes the following goals:

- Provide all components of NIH with the methods and information necessary to manage their scientific portfolios;

- identify important areas of emerging scientific opportunity or rising public health challenges;
- assist in accelerating investments in these areas; and
- coordinate and make more effective use of the NIH-wide evaluation process.

The new office of approximately 13 staff members falls directly under the purview of the NIH Director and is divided into three divisions—Resource Development and Analysis, Strategic Coordination, and Evaluation and Systematic Assessments. A unique aspect of the office is that a variety of stakeholders, including the scientific and advocacy communities within and outside the NIH may submit suggestions for potential research projects to OPASI. Initiatives would largely be focused on areas that fall under the missions of multiple Institutes and Centers (IC). For example, obesity was recognized as a “trans-NIH” issue for which a coordinated agency-wide strategic plan has been slow to develop, even though individual ICs are conducting work on obesity. The aim is that OPASI would effectively identify such public health threats, assess current efforts at the NIH, and coordinate the efforts of multiple ICs to address the problem.

Initiative proposals will first be reviewed by OPASI staff and IC staff; more developed proposals will then be reviewed by the OPASI leadership, IC Directors, the Advisory Committee to the Director (ACD), the “council of councils,” and the NIH Director. The “council of councils” is a new committee formed comprising representatives from all advisory councils of the ICs. Once the initiatives are approved for funding, one or more ICs would be assigned administrative oversight.

The initial budget of OPASI is nearly \$2.5 million (about 1.1 percent of the NIH budget) and could grow up to five percent of the NIH budget. Initiatives will be funded for five-year cycles through the Common Fund, which is an allotted percentage of the NIH ICs’ annual budgets. Projects will also undergo annual reviews as well as major reviews at year 3-4 of the cycles. No initiative would be funded for more than ten years; at the conclusion of two five-year cycles, projects would either be vetted to a particular IC permanently, or ended.

NIH Establishes Multiple PI Research Awards

The National Institutes of Health announced on February 7, the implementation of a new policy to allow multiple Principal Investigators (PI) on individual research awards. The traditional NIH research grant structure awards a single PI, often working with other colleagues or subordinates, on an independent research project. The multiple PI model is intended to recognize that research often involves complex and multidisciplinary teams, and will supplement the traditional single PI model.

The NIH submitted a Request for Information (RFI) to garner feedback on the issue from the research community. Specific procedures for implementation of this policy are still in the early stages, although a small number of applications submitted with one or more PIs relative to single PI applications are expected. Applications submitted in response to a small group of Requests for Applications (RFAs) and Program Announcements (PAs) with May-June 1006 receipt dates will have the multiple PI option available. Additional pilot initiatives

will be selected in the fall. The multiple PI option will be available for most investigator-initiated research grants submitted for January 2007 and later.

For further information on Multiple Principal Investigator Awards, please visit the multiple PI website at the Office of Extramural Research (http://grants.nih.gov/grants/multi_pi/index.htm).

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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