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Society Members Advocate for Endocrinologists on Capitol Hill

Members of The Endocrine Society's Advocacy and Public Outreach Core Committee (APOCC) visited Capitol Hill on September 22, 2008 to discuss issues of concern to the Society's membership with key House and Senate offices. Committee members focused on four main issues: support for the Society's recently released white paper titled *Increasing Minority Participation in Clinical Research*, biomedical research funding, legislation to reverse cuts to physician reimbursement for dual energy x-ray absorptiometry (DXA), and the Society's new position statement on steroid abuse.

Society members discussed the Society's white paper on minority participation in clinical research with top staffers of Senators Biden (D-DE) and Dorgan (D-ND), and Representatives Cantor (R-VA), Camp (R-MI), Bilbray (R-CA), and DeGette (D-CO). While the National Institutes of Health (NIH) requires that women and minorities be included in the research it funds, the Food and Drug Administration (FDA) does not require the same of pharmaceutical companies' drug trials when bringing new drugs to market. Without inclusion of diverse populations in clinical trials of new drugs, the safety and efficacy of these drugs cannot be verified in all populations. In an effort to address the complex issue of participation by minorities, the Society's white paper makes recommendations for all stakeholder groups. Suggestions for Congress include the establishment of an office of minority health within the FDA to oversee the regulatory changes that the agency must implement to ensure adequate diversity in trials.

Congress was working on appropriations at the time of the Hill visits (see related story in this week's *Endocrine Insider*), enabling Society members to address the need for increased funding for biomedical research in the Fiscal Year 2009 Continuing Resolution with those offices listed above and with Representatives Pascrell (D-NJ), Murtha (D-PA), and Inslee (D-WA). Most were supportive of increased funding for biomedical research, but the sense was that Congress would pass a straightforward continuing resolution with little to no increase in program budgets.

Although action on the Medicare Fracture Prevention and Osteoporosis Testing Act (HR 4206 and S 2702) is unlikely in this Congress, Society members encouraged those members of Congress that they visited to support the legislation should it be introduced in the next Congress. Society members also met with Senator Salazar's (D-CO) staff, expressing the Society's appreciation for the Senator's efforts to introduce the bill in the Senate and to develop support among his colleagues. The legislation would return reimbursement for DXA and VFA scans back to their 2006 levels.

Finally, APOCC members mentioned the approval of a new Society position statement on steroid abuse. Anabolic steroids can have serious and potentially life-threatening side effects, and their abuse by athletes and others is evolving into a major health problem in the United States, especially for our nation's youth. The Endocrine Society strongly believes that anabolic steroids and all other hormones should be prescribed and administered only when medically necessary and only by doctors specializing in the diagnosis and treatment of hormonal disorders.

At CBC Legislative Conference, Society Recommends Measures to Improve Health Disparities

On September 26, 2008 The Endocrine Society presented its recommendations to the Congressional Black Caucus (CBC) Health Braintrust on measures to increase the participation of racial and ethnic minorities in clinical research. A Society Task Force led by Maria Alexander-Bridges, MD PhD, former member of the Government Relations Committee, developed detailed recommendations in the Society's white paper "[Increasing Minority Participation in Clinical Research.](#)"

The CBC Health Braintrust, chaired by Congresswoman Donna M. Christensen (D-VI), has worked tirelessly and collaboratively in Congress to improve the health of minorities in the US. For example, the CBC, the Congressional Hispanic Caucus (CHC), and the Congressional Asian Pacific American Caucus—collectively known as the Tri-Caucus—strongly support the Health Equity and Accountability Act of 2007 (HR 3014). The bill, introduced in July 2007 by Representative Hilda Solis (D-CA), chair of the CHC Task Force on Health and the Environment, contains many provisions for improving health disparities. The legislation has 114 co-sponsors.

Dr. Alexander-Bridges built upon discussions of the day and highlighted some of the Society's recommendations to Congresswoman Christensen during the CBC Legislative Conference in Washington, DC. The Society's recommendations are largely in line with provisions in HR 3014, and Dr. Alexander-Bridges expressed support for the bill's intent. Additionally, Dr. Alexander-Bridges presented some of the Society's novel recommendations that are not included in the bill but are complementary to approaches in the legislation. Rep. Christensen indicated her appreciation of the Society's work and of Dr. Alexander-Bridges' remarks and invited the Society to come to her office and discuss the recommendations.

Though HR 3014 is unlikely to move in the current Congress, the CBC and Congresswoman Christensen are committed to the bill's progress in the next Congress and to reducing health disparities through all means available. The Society will continue to work with legislators to advance important legislation to alleviate health disparities across the nation.

NIH Announces Implementation of New Policies to Enhance Peer Review

On September 30, NIH announced its first-stage priorities for enhancing peer review, with implementation set to begin early 2009. The priorities and initiatives were identified after a year-long review process in which stakeholders in the scientific community provided feedback and recommendations to NIH to improve the process of peer review. The Endocrine Society engaged in the community activities and joined the broader biomedical research community in recommending several enhancements. As previously reported in [Endocrine Insider](#), Society Past-President Shupnik presented the Society's recommendations to the NIH Peer Review Working

Group of the Advisory Committee to the Director at a stakeholder meeting in Washington, DC, in July 2007.

The current plans address three priority areas—engaging the best reviewers, improving the quality and transparency of review, and ensuring balanced and fair reviews across scientific fields and career stages while reducing administrative burden.

Plans to engage the best reviewers include providing reviewers with flexibility in their tour of duty and conducting pilots of virtual review methods.

To improve quality and transparency, the Agency proposes a new criterion-based scoring scale with structured critiques beginning in May 2009. Applications will be shortened, and streamlined applications will receive preliminary scores in 2009.

Efforts to ensure balanced and fair reviews will begin by clustering and reviewing separately applications from newly defined [Early Stage Investigators](#). NIH is considering similar clustering for clinical research applications and is also considering separate percentile rankings for new and resubmitted proposals.

For details about the effort to enhance peer review at NIH, [click here](#).

NIH Flat Funded in CR

In order to ensure that the government continued to operate after the fiscal year (FY) ended on September 30, 2008, Congress passed a continuing resolution (CR) that will fund government agencies through March 6, 2009. Under the CR, most agencies will operate with the same budget for FY 2009 that they received in FY 2008. As a result, the National Institutes of Health will receive no increase in funding for at least the first five months of the fiscal year. The President signed the legislation on September 30.

Although many appropriations subcommittees held mark-ups of their bills, no FY 2009 appropriations bill was debated or voted on by either the House of Representatives or the Senate before the end of the fiscal year. The leaders of the House and Senate Appropriations Committees made a conscious decision to forgo passage of the individual appropriations bills that fund government agencies because the President stated that he would veto any appropriations bill that exceeded his budget request. The hope of congressional leaders is that a new President will be more willing to sign appropriations bills that address priorities of both Congress and the President.

In an effort to provide additional funds for some programs, including the National Institutes of Health, Senate Majority Leader Harry Reid (D-NV) and Senate Appropriations Committee Chair Robert Byrd (D-WV) introduced a \$56.2 billion economic stimulus package on the afternoon of September 25, 2008. The package included \$1.2 billion to restore some of the purchasing power of NIH that was lost because of inflation in the past five years and the money would have allowed NIH to award at least 3,300 new research project grants. On September 26, the Senate voted 52-42 in favor of the measure, 8 votes short of the 60 needed for passage.

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