



April 20, 2005

Society Members Engage Congress

On April 6th The Endocrine Society's Government Relations Committee took to Capitol Hill for its first visit of the 109th Congress. Members of the Committee met with a wide range of Congressional representatives to discuss issues important to the Society's legislative agenda. The themes that wove their way through each meeting were the issues of stem cell research and federal funding for biomedical research. Congress has committed to allowing a vote on the Stem Cell Research Enhancement Act (H.R. 810) before the July recess period. Committee members met with both of the bill's sponsors, Congresswomen Diana DeGette (D-CO) and Congressman Mike Castle (R-DE), to discuss the bill and offer the Society's support in the effort to get the legislation passed by the House of Representatives.

In addition to the DeGette and Castle meetings the group met with Senator Wayne Allard (R-CO), member of the both the Senate Budget and Appropriations Committees; Senator Olympia Snowe (R-ME); and Senator Dianne Feinstein (D-CA). While visiting offices in the House of Representatives the group met with Congresswomen Stephanie Tubbs Jones (D-OH), Congressman Russ Carnahan (D-MO), Congresswoman Rosa DeLauro (D-CT), Congresswomen Eleanor Holmes Norton (D-DC), Congressman Michael Capuano (D-MA), and Congressman Chris Van Hollen (D-MD).

Each office was lobbied on the importance of fully funding the National Institutes of Health (NIH) and other federally funded research agencies. Society members urged Congress to make research funding a priority for government spending. The Society's message was simple: Congress must consider federal spending on research as an investment and not an expense.

Look for a more in-depth account of the Society's April Hill visits in the June issue of *Endocrine News*. The June issue will include a feature story on the Society's day on Capitol Hill.

NIH COI Rules Suspended for 90 Days

Days after the Society's Government Relations Committee met with Rep. Chris Van Hollen (D-Md.) and expressed a need to re-evaluate the NIH conflict of interest rules, Reps. Van Hollen and Tom Davis (R-Va.) wrote a letter to NIH Director Elias Zerhouni, MD urging suspension of the regulations for 90 days, effective immediately.

In the April 14 letter, Van Hollen and Davis praise Zerhouni for his recent extension of the filing period for financial disclosure forms but maintain that the action does not address the central problems with the new interim rules. In March, NIH granted a blanket 90-day extension for submitting financial disclosure forms and exempted clinical research fellows from stock divestment requirements.

Van Hollen and Davis express particular concern that the rules will impact recruitment and retention of scientists. “We believe that the proposed regulations are overbroad and, unless refined, could dangerously undermine the mission of NIH,” the congressmen stated.

The letter asks Zerhouni to suspend the rules immediately to “review and carefully consider the proposals offered by the Assembly of Scientists and other comments submitted in response to these regulations.” The Assembly of Scientists released alternative conflict of interest rules in March.

The NIH campus is located in Rep. Van Hollen’s district. Van Hollen staffers have received several letters from scientists and non-scientists overwhelmingly opposing the rules.

On April 6, Zerhouni told the Senate Appropriations/Labor-HHS Subcommittee that the stock divestiture rules may have a “deleterious impact” and are being reevaluated.

Judge Strikes FDA Ban on Ephedra

On April 14, a federal judge struck down the Food and Drug Administration’s (FDA) ban on the supplement ephedra. Judge Tena Campbell's order prevents the FDA from stopping the manufacturer Nutraceutical from selling its product and sent the case back to the FDA to re-examine what should be considered safe and dangerous levels of ephedrine. Judge Campbell ruled that the FDA had not proved that its arbitrarily set dosages of 10 milligrams (mg) or less of ephedrine-alkaloid dietary supplements (EDS) were dangerous. The ruling stated that the FDA had not met the appropriate level of burden of proof to justify the ban. It was not immediately clear how the ruling will affect sales of ephedra. Officials with the Department of Health and Human Services stated that they are examining the impact of the ruling and will take the appropriate action to comply after evaluation is completed.

Society Joins Stakeholders Meeting on Future of Federal Research Funding

On April 14, the Ad Hoc Group for Medical Research Funding gathered more than 50 organizations to discuss future advocacy activities regarding biomedical federal research funding. The group acknowledged the challenges that lie ahead in the post-doubling period era. Participants also cautioned that competing federal spending issues and rising federal deficits have caused Administration and Congressional leaders to reduce their commitment to all federal research activities that falls outside of defense and homeland security.

The group discussed new options to gain public and Congressional support for increased federal funding. Most participants agreed that the scientific community has had great success by putting a human face on disease and the need to cure disease by funding research and that we needed to continue this type of campaign. However, most felt that this patient outreach strategy must be coupled with stronger arguments that prove investment in research is in the best economic interest of the country.

The group decided that the immediate goal should be to focus on the near future of the National Institutes of Health (NIH) and to increase short term funding to create a “soft” landing in the post-doubling period. In addition, this immediate advocacy should join an incremental strategy to construct an econometric model that would show that increased levels of investment would optimize federal revenue returns.

Possible immediate outcomes from the meeting included creation of a working group to explore the economic messages further. In addition, it was suggested that the group create a master advocacy calendar where all groups could share information on dates of Congressional hearings, forums and meetings relevant to research funding. The master calendar will also serve as a forum to share information relevant to the community’s arguments for increased federal funding.

The April 14 meeting served as a planning session for future activities which the Society will continue to play an active role in. Please look for future stories and information in coming editions of *Endocrine Insider* as the group’s activities increase.

NIH to Fall Behind in Stem Cell Research

NIH institute directors have expressed concern over new Bush Administration policy governing federal funding for research involving human embryonic stem cells. New Bush policies will limit the number of hESC lines available for research funded with government dollars therefore hindering the research capabilities of NIH.

Letters presented in an April 6 testimony to Senate Appropriations Labor/HHS Subcommittee quoted National Institute on Deafness and Other Communication Disorders Director James Battery, MD, PhD. Battery stated, “It is clear that the state of the science is evolving very rapidly and limitations of the President’s policy become more apparent.” National Heart Lung and Blood Institute Director, Elizabeth Nabel, MD, maintains that scientific “progress has been delayed by the limited number of cell lines.” National Institute of Child Health and Human Development Director Duane Alexander, MD, notes, “Scientists have complained about working with federally approved stem cell lines. Inadequate quantity and quality as well as cumbersome procedures and long waiting lines complicate the process.”

Senator Arlen Specter (R-Penn) chairs the Senate Appropriations Labor/HHS Subcommittee, questioned NIH Director Elias Zerhouni, MD on the use of frozen embryos from in vitro fertilization clinics. Zerhouni responded, “Clearly, when you look at the scientific evolution of this field...from a purely scientific standpoint, there’s no doubt that access to more cells is seen by scientists as very important to their progress. There are also issues of contamination and genetic instability with the 22 cell lines approved for federal support. The issue is not scientific; the policy is based on a moral and ethical line.”

Representative Diana DeGette (D-Colo.) who co-sponsored legislation with Representative Michael Castle (R-Del.) that would extend government funds to research involving stem cells from discarded IVF embryos stated, “The nation’s top stem cell researchers are migrating to countries with more supportive policies. Simply put the President’s stem cell policy is handcuffing our nation’s top scientists.”

The Stem Cell Research Enhancement Act of 2005 (HR 4682) is expected to go to the House floor for a vote during the summer.

CIRM Models COI after NIH

On April 7, 2005, the California Institute of Regenerative Medicine (CIRM) announced the adoption of a set of conflict of interest policies closely modeled on those established by the National Institutes of Health, the California Breast Cancer Research Program and the National Academies.

The CIRM established in 2004 and responsible for the distribution of \$3 billion for stem cell research to California Universities and research institutions, told members of the Independent Citizens Oversight Committee (ICOC) that the rules were crafted to, “ensure the success of the institute’s research program.”

Consistent with the California Political Reform Act, members of the ICOC are required to report all financial interests and to recuse themselves from voting on matters in which there may be a financial interest for the member. ICOC members also cannot participate in any review of grant applications in which there is the potential for financial benefit and barred from owning property or a financial interest in any organization the applies for CIRM funding. Members are also required to disclose all financial, professional, and personal conflicts of interest.

The ICOC is established as a governing board of the CIRM and therefore required to comply by medical and ethical standards established by California’s conflict of interest disclosure policies. CIRM Interim President Zach Hall, PhD, also stated that the rules were crafted to “maintain public confidence.” The policies were adopted after hearing extensive public comment and after thoughtful consideration by ICOC members according to Robert Klein, chair of ICOC.

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:

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

Chris Rorick, Associate Director
301-941-0254
crorick@endo-society.org

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