



November 13, 2008

### **Society Takes Leadership Role in Easing Burden of Clinical Research Regulation**

Last week, The Endocrine Society undertook a major initiative in support of its clinical researcher members and established itself as a leading organization in the clinical research policy arena when it hosted a workshop titled “Regulation of Clinical Research—Improving the Balance: A Consensus Conference.” Clinical researchers face difficulties gaining approval for their research protocols because of inconsistent protocol review by Institutional Review Boards (IRBs) and other regulatory hurdles associated with research involving human subjects.

The two day conference, jointly hosted by the Society and Lawson Wilkins Pediatric Endocrine Society (LWPES), focused on regulatory burdens associated with multisite trials and with pediatric research. Lynnette K. Nieman, MD, Vice President-Clinical Science, co-chaired the organizing committee with Robert L. Rosenfield, MD, Past-President of LWPES. The discussion focused on risk-benefit analyses related to human subjects research, issues and models related to multisite projects, problems in the study of healthy childhood controls, and efforts to define a “condition.” The conference included presentations by experts in the field, panel discussions, and small group discussions to identify solutions to the problems raised by the panelists. The discussions will inform a consensus paper to be published in a peer-reviewed journal and a set of recommendations to regulatory agencies, members of Congress, IRBs, and institutions to streamline and facilitate human subjects research.

The conference brought together prominent members of the clinical research community, including representatives from government, industry, and academia. The inclusive format allowed representatives from government agencies including the Office of Human Research Protections (OHRP) and the US Food and Drug Administration (FDA) to hear first-hand the difficulties faced by investigators as a result of federal regulations and inconsistent interpretation of those regulations. Such understanding among agency staff has laid the groundwork for future discussions with the agencies to work toward policy changes.

The conference was co-sponsored by 15 non-profit organizations and pharmaceutical manufacturers, including the American Society for Bone and Mineral Research, American Thyroid Association, and The Obesity Society—all Sister Societies—and the American Society of Clinical Oncology, Astra Zeneca, Bristol-Myers Squibb, Burroughs Wellcome Fund, Infectious Diseases Society of America, Genentech, Gate, Juvenile Diabetes Research Foundation, Novo Nordisk, Pfizer, Pharmaceutical Researchers and Manufacturers of America, and Wyeth.

The regulatory burden associated with conducting research on human subjects may be the most limiting factor, besides funding difficulties, in the clinical research process. If a streamlined, standardized set of criteria were to be accepted by all organizations that monitor and support clinical research, researchers would be freed to concentrate on the research rather than the administrative work associated with IRB approval. The Endocrine Society is dedicated to easing the regulatory burden for its clinical researcher members. With consensus recommendations from the recent conference, the Society will have a strong advocacy tool to use in its future efforts in this area.



Lynnette Nieman, Vice President-Clinical Science, with co-organizer Robert Rosenfield, Past-President of LWPES.



President Robert M. Carey, MD MACP, welcoming the audience on the first day of the conference



Lynnette Nieman addressing the participants



Conference participants



Julie Kaneshiro of OHRP answering a question from the audience.

## **Health Care Reform near Top of Agenda for President-Elect Obama and Congress**

The recent election of Barack Obama to the office of President of the United States and the increased Democratic majority may mean many changes in health care and research that could positively impact endocrinologists.

President-elect Obama has laid out an aggressive plan for his first days in office and has placed the economic issues facing the country at the top of his agenda. Obama has indicated that a second stimulus package should be passed shortly after his inauguration, which may present an opportunity to increase funding for the National Institutes of Health in fiscal year 2009. As reported in the October 1, 2008 edition of *Endocrine Insider*, Senate Majority Leader Harry Reid (D-NV) and Senate Appropriations Committee Chair Robert Byrd (D-WV) introduced a \$56.2 billion economic stimulus package in September that included \$1.2 billion for the NIH. Portions of this stimulus package may be included in the stimulus package now being discussed by House and Senate leaders. President-elect Obama has stated that the budgets for physical and life sciences should be doubled over the next decade.

Another high priority for Obama after his swearing-in on January 20, 2009 will be to repeal some of President Bush's more controversial executive orders, including the order which restricts federal money for research on stem cell lines created after August 9, 2001. President-elect Obama would allow all scientists to participate in stem cell research in accordance with the ethical guidelines proposed by the National Research Council.

Throughout his campaign for president, Obama expressed his desire to see comprehensive health care reform during his first term. Democrats in Congress have already begun working on a single, comprehensive bill to revamp the health care system and will likely follow many of the tenets of Obama's plan. Senator Edward Kennedy (D-MA) is developing a plan that will overhaul the current health care system, with a focus on coverage, cost, and quality. Preventive care will be an important tenet of Senator Kennedy's bill, opening the door to a possible fix for the DXA payment cuts in order to increase screenings for osteoporosis. Kennedy's bill may also address the physician payment cuts scheduled to go into effect on January 1, 2010, although whether it will be a long-term fix or a one-year fix is unclear. Senator Max Baucus (D-MT) will also be releasing his health care policy proposal this week, and it is expected that many of his proposals will closely follow Obama's plan. Both plans may include components of the Patient-Centered Medical Home and continue the Physician Quality Reporting Initiative. Prominent committee chairs in the House have also expressed their intent to address health care reform in the 111<sup>th</sup> Congress.

Passage of many of Obama's policy proposals will be made easier by the increased Democratic majorities in the House and Senate. Although there are races yet to be decided in both the Senate and the House, the Senate now has a 57-40 Democratic majority, and the House Democratic majority is 255-174. Committee appointments have not yet been determined, but there will be some shuffling of committee chairmanship with the election of Senator Joe Biden (D-DE) to Vice President, and Senator Robert Byrd (D-WV) announcing his intention to step down as chair of the Senate Appropriations Committee.

Although the election brought many changes to Washington, The Endocrine Society is well positioned to push its advocacy agenda forward with strong ties to members on both sides of

the aisle of the House and Senate. Look for updates on the Society's activities in future issues of *Endocrine Insider*.

### **Physicians Can Earn Additional Payment Increases in 2009**

Physicians looking to increase payment for their services have a few options available to them in 2009. The Centers for Medicare and Medicaid Services (CMS) recently released information on physician payment for next year. In addition to the 1.1 percent payment increase passed by Congress under the Medicare Improvements for Patients and Providers Act (MIPPA) in late summer, physicians can also earn an additional 2 percent payment for participation in a new electronic prescribing, or e-prescribing, initiative. Physicians and other medical professionals who adopt e-prescribing systems to submit prescriptions to pharmacies can earn this increased payment beginning January 1. Physicians also choosing to participate in the Physician Quality Reporting Initiative (PQRI) can earn an additional 2 percent in incentive payments from CMS for reporting quality measures.

All Medicare-participating physicians will automatically receive the 1.1 percent payment update from MIPPA. To participate in the e-prescribing program, physicians must use qualified e-prescribing capabilities, and must report one of three codes for the e-prescribing measure when submitting medical claims. Additional details on the e-prescribing program and how to participate can be found [here](#).

CMS has also increased its physician incentive payments for the PQRI from 1.5 percent in 2007 and 2008 to 2 percent in 2009 and 2010. The PQRI program was launched in July 2007 and has grown to include more than 150 quality measures on a variety of health issues including diabetes, osteoporosis, high blood pressure, and others. More information on the PQRI program and how to participate can be found [here](#).

### **Society Member David Allen on NBC's *Today***

Prompted by a news release written and distributed by the Society's media relations team announcing the publication of a Swedish study on growth hormone treatment for children, NBC *Today* producers sought out and contacted Society Member David Bruce Allen, M.D. to comment on the research. Dr. Allen is the Director of Endocrinology and Professor of Pediatrics at the University of Wisconsin Children's Hospital and served on the editorial board of the *Journal of Clinical Endocrinology & Metabolism (JCEM)* from 1997 through 2000.

The Swedish study, "Dose-Dependent Effect on Growth Hormone on Final Height in Children with Short Stature without Growth Hormone Deficiency," led by Kestin Albertsson-Wikland, MD, PhD, professor at the Goteborg Pediatric Growth Research Center at the University of Gothenburg, appeared in the November 8 issue of *JCEM*. Society members co-authoring the study were Jan Gustaffson, MD, PhD, Sten Ivarsson, MD, PhD, and Karl Olof Nilsson, MD, PhD,

The three-minute health segment featuring Dr. Allen and one of his patients aired on November 6. Since airing on NBC *Today*, the story has been run by a number of media outlets throughout the country.

### **Endocrine Society Members Asked to Submit Nominations for ASP Award**

The Association of Specialty Professors (ASP) has announced its call for nominations for the 2009 ASP Eric G. Neilson, MD Distinguished Professor Award. Nominations will be accepted until Friday, November 21, 2008, 5:00 pm EST. Named after ASP's founder, the Neilson Award recognizes an individual's outstanding contributions to specialty internal medicine.

The Endocrine Society and other associations that sit on the ASP Council have been invited to inform their members of the opportunity to nominate leaders who have made tremendous strides to promote academic and internal medicine. A nominee must be a current or former member of the ASP and a chair of an internal medicine department or a leader in another area of academic American medicine. Special attention will be given to nominees who have assisted ASP in achieving its mission.

When submitting nomination material, you must include:

- A completed nomination form.
- One nomination letter.
- Additional letters supporting the nomination. Please note that only three letters of support in addition to the first nominator's letter will be considered. Self-nominations are welcome.
- The nominee's curriculum vitae.

For more information on the award, please review the award brochure located [here](#)

For more information on ASP, [click here](#).

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

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