



April 19, 2007

Endocrine Society President Testifies before U. S. Senate Special Committee on Aging

President Leonard Wartofsky, MD, was invited to testify as an expert witness on April 19, 2007, before the U.S. Senate Special Committee on Aging regarding the use and regulation of bioidentical hormones. The invitation was the result of the Society's strong leadership and ongoing advocacy efforts on this issue. President Wartofsky outlined the Society's position calling for greater oversight of compounded hormone preparations and for required uniform patient information in the packaging of all hormones. The Society's position statement (http://www.endo-society.org/publicpolicy/policy/upload/BH_Position_Statement_final_10_25_06_w_Headline.pdf), published in October 2006, placed the Society at the center of the debate on bioidentical hormones and formed the basis of recently adopted policy of the American Medical Association (AMA). The AMA's endorsement of the Society's position indicates support by the broader medical community.

The testimony of the majority of witnesses at the hearing reflected the medical community's support and also indicated the support of federal regulatory agencies. Of the seven witnesses to testify, only two dissented on the call for greater regulatory oversight of compounded hormones—T. S. Wiley, self-proclaimed theorist in the field of Darwinian Medicine and writer/researcher on the use of hormones; and Lloyd Allen, Jr., PhD, RPh, editor-in-chief of the *International Journal of Pharmaceutical Compounding*.

Both Wiley and Dr. Allen testified on the same panel as Dr. Wartofsky and JoAnn Manson, MD, DrPH, FACP, Society member and women's health expert. In addition to stressing the need for greater regulatory oversight, Dr. Wartofsky supported Dr. Manson's scientific arguments against the much promoted idea that bioidentical and/or compounded hormones are safer or more effective than FDA-approved hormone treatments. Both expressed concern that women were receiving scientifically unproven information or not receiving enough information to make informed decisions about their treatments.

Drs. Wartofsky and Manson also expressed concern over the lack of warning labels, contraindications, and risk information in the packaging of compounded hormones. This concern was shared by members of the other panel of witnesses—representatives of the National Institutes of Health (NIH), the US Food and Drug Administration (FDA), and the Federal Trade Commission (FTC).

FDA and FTC both have some jurisdiction in the oversight and regulation of compounding pharmacies. In his questioning of the agency officials, ranking member Senator Gordon Smith (R-OR), raised concerns about the agencies' performances in policing the activities of compounders. Senator Smith highlighted his concerns by displaying a progesterone cream with a label claiming protection from some types of cancer that his staff had purchased from an Internet compounding pharmacy site within the past week. The senator asked Eileen Harrington of the FTC how it is possible that his staff was able to purchase the product from the pharmacy, which the FTC had warned about its marketing practices in November 2005. The senator also pointed out that 19 of the 34 pharmacies cited by the agency at that time had not complied with the FTC's requests to re-evaluate their marketing strategies for veracity.

For his part, Jacques Rossouw, MD, Chief of the Women's Health Initiative Branch of NIH, emphasized that, while the data are still being gathered and analyzed on age-dependent effects of hormone treatment, the risks and benefits of all estrogens and all progestones are equivalent. As such, it is important for women taking all forms of hormone therapy to be fully informed. Dr. Rossouw also stated that in science and medicine, there is no distinction between "natural" and "synthetic" drugs, but that the distinction is between safe and effective drugs and those that aren't.

The Society met with FDA officials, including Kathleen Uhl, MD, Director of the Office of Women's Health, on April 9 on the issue of bioidenticals and will continue to work through the necessary legislative and regulatory channels to advance its policy goal of increased regulatory oversight of compounded hormone preparations. Future issues of *Endocrine Insider* will provide updates as advances occur. Senator Smith has requested a study and report by the Congressional Research Service on the practices and standards of the state boards of pharmacy in all fifty states. The senator hopes the information gained will help determine how equipped the states are to provide uniform regulatory oversight. While it is unclear at what point the report may be finished, Society staff will report on the findings as soon as they become available.

For more information on the April 19 hearing, including the written statements of all witnesses, go to: http://aging.senate.gov/hearing_detail.cfm?id=272538&.

Senate Passes Two Stem Cell Bills, Still Short of Veto Override

The Senate passed two stem cell research bills on April 11, 2007, both of which allow for expanded federal funding for human stem cell research. The first bill, the "Stem Cell Research Enhancement Act of 2007" (S. 5), was approved by a vote of 63-34 and is almost identical to a bill passed earlier in the year by the House (HR 3). Both the Senate and the House bills support expansion of the pool of stem cells on which federally funded research may be conducted. Additional sources of stem cells might include 1) embryos donated by in vitro fertilization clinics that would otherwise be destroyed or discarded or 2) new stem cell lines derived from alternative sources. Although the President vetoed a similar bill last year, Senate leaders hope to garner enough support to have the 67 votes necessary to override a veto that Bush has promised again this year. At the time of the vote, it appeared that the

Senate would be one vote short of the necessary margin (three senators that support expanded federal funded research were unable to vote).

A second bill, “Hope Offered Through Principled and Ethical Stem Cell Research Act of 2007” (S. 30), was passed by the Senate by a vote of 70-28. This bill encourages research on pluripotent stem cell lines without harming or destroying human embryos. The President has expressed strong support for this bill.

Society staff will continue to monitor congressional activity on these bills and will provide new information in future issues of *Endocrine Insider*.

CMS Delays Penalties for Failing to Use National Provider Identifier

Early last week, the Centers for Medicare and Medicaid Services (CMS) announced that it would delay the deadline requiring physicians and groups to begin using the National Provider Identifier (NPI) number on Medicare and private insurer claims reporting. Originally, all claims submitted to CMS and private payers were to use the NPI as of May 23, 2007. The Health Insurance Portability and Accountability Act (HIPAA) mandate that physicians submitting claims electronically use the new identifier. CMS made the decision that all claims, whether submitted electronically or via paper, must contain the NPI as of May 23. The reason for the delay, at least in part, is because much of the health care industry remains unprepared for the 2007 deadline.

CMS Acting Administrator Leslie Norwalk stated that penalties on physicians and groups will not be imposed between May 23, 2007 and May 23, 2008, for those that have made a “good faith effort” to act in accordance with the NPI requirements. CMS will allow providers and groups to continue to use existing legacy identification numbers such as the Medicare Provider Identification Number (PIN), the Unique Provider Identification Number (UPIN), and proprietary commercial identifiers without penalty. Though good faith effort has not been specifically identified, an example given by CMS includes providers acquiring an NPI that can be used on HIPAA transactions.

CMS would like to hear whether providers are having serious obstacles as they convert to NPI reporting. You can contact the Physician Regulatory Issue Team (PRIT) by e-mail at prit@cms.hhs.gov or by phone at 202-236-3338, with questions.

Information can be found on CMS’ Web site at:

http://www.cms.hhs.gov/NationalProvIdentStand/01_Overview.asp#TopOfPage and will continue to be reported in *Endocrine Insider* as it becomes available.

Robert Wood Johnson Foundation Commits \$500 Million to Community Efforts to Reverse Childhood Obesity

The Robert Wood Johnson Foundation (RWJF) announced that it will commit at least \$500 million to reversing the epidemic of childhood obesity in the United States. It is the largest commitment by any foundation in response to the growing issue. RWJF plans to implement

its commitment through school-based programs, state-level advocacy efforts and community coordination, and by encouraging a change in food marketing practices.

As the Society and Research!America poll indicates, obesity is the leading health concern facing American children (<http://www.endo-society.org/publicpolicy/insider/PublicOpinionPollRevealsNatlConcernArt1.cfm>); RWJF's research shows similar findings. According to RWJF, more than one-third of all children are considered overweight or obese. The chance of these children being overweight or obese as adults is substantial, and can lead to related diseases such as type 2 diabetes, heart disease, and cancer. Corresponding health costs are also on the rise; \$14 billion of the \$117 billion per year in direct healthcare costs for the obesity epidemic is spent to treat children.

The Foundation's president and CEO, Risa Lavizzo-Mourey, MD, MBA, said a major problem of obesity is that it affects low-income communities that are unable to afford fresh produce and have limited or no access to safe recreational areas where kids can engage in physical activity. "To reverse the obesity epidemic and create a culture of health, we must provide families with better access to healthy choices," Lavizzo-Mourey said.

For more information about RWJF's commitment to reverse childhood obesity, see the article at: <http://www.rwjf.org/newsroom/newsreleasesdetail.jsp?id=10483>

CMS Releases Physician Quality Reporting Initiative Specifications

Last week, CMS released detailed specifications on the 74 quality measures in the voluntary Physician Quality Reporting Initiative (PQRI). The PQRI program begins on July 1st and will allow providers to earn up to a 1.5 percent bonus if they meet reporting requirements.

It is important for participating providers to determine which of the 74 quality measures they intend to report. In order to earn the 1.5 percent bonus, providers will have to report quality codes for at least 80 percent of the cases in which a quality measure can be applied. Providers should report on at least three quality measures if there are three or more measures that relate to their area of practice. For providers with less than three applicable measures, all relevant quality measures should be reported.

Quality measures most likely to be used by endocrinologists include three measures for diabetes and five measures for osteoporosis. Individual clinicians may find that additional measures are also applicable. Examples include:

Hemoglobin A1c Poor Control in Type 1 or 2 Diabetes Mellitus—This measure should be reported a minimum of once per reporting period for patients seen during the reporting period (12 months). It is anticipated that clinicians who provide services for the primary management of diabetes mellitus will submit this measure.

Screening or Therapy for Osteoporosis for Women Aged 65 Years and Older—This measurement is to be reported a minimum of once during the reporting period for patients seen during the reporting period. Female patients aged 65 years and older should have a central dual energy X-ray absorptiometry (DXA) measurement ordered or performed at least

once since the time they turned 60 years or have pharmacologic therapy prescribed to prevent or treat osteoporosis. It is anticipated that clinicians who provide primary care or care for treatment of fracture or osteoporosis will submit this measure.

The list of all 74 measures, including detailed descriptions on how to appropriately report each measure, can be found on CMS' Web site at:

http://www.cms.hhs.gov/PQRI/Downloads/Specifications_2007-02-04.pdf.

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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