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Society Provides Comments to FDA in Opposition to Lovastatin Switch

Switching the drug Lovastatin from a prescription medication to an over-the-counter (OTC) drug could result in patients losing the benefits of physician supervision and decreased follow-up of side effects from fewer laboratory tests and doctor visits. This was the message from The Endocrine Society in written testimony to the FDA earlier this month. An FDA advisory committee reviewed this testimony during a January 12 hearing on the matter.

“While the Society recognizes there is an underutilization of statins to treat hypercholesterolemia in this country, we do not believe that moving a statin to OTC status is the solution,” said Tony Means, PhD, Society president, in a letter dated January 6. “Monitoring the drug’s therapeutic effects and side effects is one of the best ways to ensure medicine compliance and to work on the associated risk factors such as hypertension or diabetes mellitus that also need attention. OTC status would almost certainly result in a failure to monitor the good and bad effects of this statin.”

The testimony emphasized the importance of correct diagnosis of hypercholesterolemia by physicians, of properly counseling such patients about their disease and management program, of appropriately monitoring these patients during therapy for outcomes (good or bad), and of assessing for the presence of co-morbid conditions that could affect management choices.

The Society’s testimony concluded by urging committee members to consider the importance of physician counseling to encourage patients to institute lifestyle changes and to take their medications properly is a necessary part of a successful patient management program.

Members of the 109th Congress Sworn In

The 109th session of Congress began January 4th with members being sworn in and Congressional leaders addressing both the Senate and House chambers. Republican leaders outlined their agenda for the upcoming Congress which will include a package of reforms including Social Security, tort reform, immigration, and the tax code. All members who won election in 2004 were sworn in—this included 34 senators and all members of the House. The majority party re-elected Sen. Bill Frist (R-TN) and Rep. Dennis Hastert (R-IL) to leadership posts in their respective chambers and passed a rules package that will govern the body during the 109th session.

AAAS Predict Difficult Period for Science

During a recent Research!America science and technology forum, Alan Leshner, CEO of American Association for the Advancement of Science (AAAS), said “we in the science community are feeling very defensive.”

The Honorable John Edward Porter, Research!America chair-elect, and Bob Palmer, minority staff director, House Committee on Science, were both panelists on this post-election forum and both agreed that science has not been a high priority on the Hill. Palmer noted that Congress is currently going through political reshuffling that will leave science with few supporters. The budgets for research projects and grants have been overshadowed by a surging deficit and increased defense spending.

“In a polarized Congress, moderate legislators have lost a lot of power and are pressured to be team players,” said Porter. He named Sen. Arlen Specter (PA) as an example of a successful advocate. Specter was instrumental in doubling the National Institutes of Health (NIH) budget, which is an achievement demonstrative of the science community’s success with organized advocacy. Porter called for a return to the same strategy, urging science groups “to get on the same page, work from the same data, and have the same message.”

Porter called for increased advocacy within the science community. He encouraged researchers to reach out to Congress and build strong bridges. However, during an earlier AAAS election debate, The Honorable Bob Walker, former chair of the House Science Committee and Bush campaign representative, had warned that if scientists engaged in partisan politics it would “engender a push-back” from the Bush Administration.

Like the rest of the scientific community, The Endocrine Society recognizes the challenges we face in the coming years to bring science to the forefront of the political agenda. We will continue to work with our coalition partners to create new approaches for new challenges. As former Chairman Porter has stated, one of the biggest challenges we face is developing new Congressional “champions” to carry our message through the halls of Congress. Molding the next generation of Congressional leaders will be a focus of the Society’s advocacy agenda in the New Year.

CMS Conference Call Open to Physicians and Allied Health Professionals

The Physician, Nurses, and Allied Health Professionals Open Door Forum conference call will take place next **Wednesday, January 12, from 2:00 pm to 3:00 pm Eastern Standard Time (EST).**

As reported in the first issue of *Endocrine Insider*, the Centers for Medicare and Medicaid Services (CMS) offers Medicare physicians and other participating health care providers the opportunity to participate in monthly conference calls with agency staff and regional office representatives. These Open Door Forums provide a dialogue for the many individual service areas and beneficiary needs within CMS. Each forum is chaired by a senior-level agency official and co-chaired by a CMS Regional Administrator. Rich Lawlor, a senior level policy advisor in the Office of the Administrator, will serve as one of this month’s conference leaders. Callers may ask questions and provide comments during the hour-long call.

To participate on this call, dial 1-800-837-1935 and use reference conference identification number: 2865506.

If you are unable to participate in the call but would like to listen to a recording of it, use the CMS Encore service by dialing 1-800-642-1687 and using Conf. ID Number: 2865506. "Encore" is a recording of this call that can be accessed beginning two hours after the call has ended. The recording expires after three business days.

To sign up for e-mail reminders of monthly forums, schedule updates, Listserv registration, and Frequently Asked Questions, go to the CMS web site at www.cms.hhs.gov/opendoor/

Intelligence Reform Bill Tightens Visa Requirements

Before adjourning the 108th Congress in December lawmakers passed S 2845, the National Intelligence Reform Act of 2004. Included in the bill was a provision that bars the U.S. State Department from exempting more foreign students and scholars from a requirement that they have a personal interview with a consular officer before getting a visa. The language reaffirms current regulations, revised last year, that allow consular officers to waive visa interviews for diplomats, travelers on NATO business, and members of international organizations like the United Nations, but require interviews for most other visa applicants including students and scholars. In an attempt to reduce the ever increasing numbers of visa delays for scholars and students, groups have been urging the State Department to allow consular officers to waive the interview requirement for some students and scholars. The language in the intelligence reform bill makes this interview waiver request increasingly more difficult.

The Endocrine Society will continue to work with the scientific community to ease visa restrictions on students and scholars.

AHRQ to Spend \$15 Million on Research for 10 Priority Conditions

On December 15, the Agency for Healthcare Research & Quality (AHRQ) announced that it will begin research on 10 "priority conditions" in FY 2005. The project will be funded through the Medicare Modernization Act (MMA) and will study the comparative clinical effectiveness and appropriateness of treatments for each condition.

Diabetes mellitus, control of hypertension, and ischemic heart disease are three endocrine-related conditions slated for study. The conditions were chosen with input from a May 21 "listening session" and written comments submitted to the Department of Health and Human Services (HHS). The comments were compiled and reviewed by a steering committee made up of AHRQ, the Centers for Medicare & Medicaid Services (CMS), the Food and Drug Administration (FDA) and HHS Office of the Secretary personnel. Research will produce "state-of-the-art information about the effectiveness of interventions, including prescription drugs, for the 10 top conditions affecting Medicare beneficiaries," AHRQ said.

Existing AHRQ contractors will systematically review scientific literature to generate outcomes for various treatments, health service organizations, and management and delivery for each condition. Information from the research will be disseminated to Medicare,

Medicaid, and comprehensive health insurance plan beneficiaries, as well as health plans, prescription drug plans, and other health care providers and the public. MMA specifies that the data be presented in a form that is “easily understood by the individuals receiving health care items and services” under the plans and be available through “easily accessible and searchable electronic mechanisms” as well as hard copy formats. The law also requires that AHRQ make public all “scientific evidence relied upon and the methodologies employed” during the research.

MMA specifies that the studies “shall reflect the principle that clinicians and patients should have the best available evidence upon which to make choices in health care items and services, in providers, and in health care delivery systems recognizing that patient subpopulations and patient physician preferences may vary.” It further specifies that the law does not give the AHRQ “authority to mandate a national standard or require a specific approach to quality measurement and reporting.”

The studies should be completed by mid-2006.

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

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