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FDA Advisory Committee Decision Consistent with Endocrine Society Comments: Recommends against Switching Lovastatin to OTC

On Friday, an FDA advisory committee voted against recommending that the Agency approve an industry application to sell Mevacor (lovastatin) without a prescription, *The Washington Post* and other news sources report.

The advisory panel said that the industry studies had not adequately shown that people could safely use the drug without the help of a doctor, the news sources report. Only 10 percent of patients who opted to take Mevacor in the trial met the “strict guidelines on the label,” as reported in *The Washington Post*.

“In Merck’s actual use study, the majority of participants said they needed more information to make a decision about whether to take Mevacor, but one third of all Mevacor users didn’t know their cholesterol levels and still took the drug,” said Daiva Shetty, who works with the FDA’s division of over-the-counter drug products, CBS MarketWatch reports. Shetty said that in the study, over half of those taking the drug had at least one contraindication to its use.

Shetty also noted that if Mevacor is available without a prescription, it is likely to be used by those who don't need the drug or by those who shouldn't take the drug, such as “women of child-bearing age, people with contraindications, and by people with low risk or no risk of heart disease”.

As reported in the last issue of *Endocrine Insider*, The Endocrine Society submitted written testimony to the FDA earlier this month. 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, and of assessing for the presence of co-morbid conditions that could affect management choices. The FDA advisory committee reviewed this testimony during its January 12 hearing on the matter.

Council Sets Society’s Policy Agenda for 2005

At its January meeting, in Phoenix, AZ, Council approved the Government Relations Committee recommendations for legislative priorities this year. Government Relations Committee Chair, Dan Spratt, MD, presented the recommendations, noting that this year’s agenda includes issues carried over from last year—Medical Research Funding, Obesity, Hormone Abuse/Misuse—as well as two new priorities—Physician Reimbursement and

Minority Health Disparities. More details on the specific bills and advocacy activities related to these issues will appear in future issues of *Endocrine Insider*.

Society Calls for Congressional Leaders to Fund New Anabolic Steroid Control Law

The Endocrine Society and The Hormone Foundation have worked diligently during the past session of Congress to ensure the passage of the “Anabolic Steroid Control Act of 2004.” Both individually and as a member of a broader coalition of stakeholder organizations (USOC, NCAA, NFL, etc.), the Society aggressively lobbied Capitol Hill to amend the Controlled Substances Act to: 1) clarify the definition of anabolic steroids; and 2) provide for research and education activities relating to steroids and steroid precursors.

Following many months of meetings with members of Congress and garnering key Capitol Hill support, the Anabolic Steroid Control Act of 2004 was signed into law on October 22, 2004 (shortly before Congress recessed for the November elections). Although this legislation was enacted into law, Congress failed to provide the appropriate funding to implement some of the important provisions contained in the new law, such as the research and educational activities relating to steroids and steroid precursors.

On January 13, less than two weeks after the new 109th Session of Congress was sworn into office, staff from the Society, The Hormone Foundation and our federal government relations consultant joined Society member Dr. Linn Goldberg and Dr. Diane Elliot for a day on Capitol Hill to urge Congressional leaders to fully fund the provisions included in the Anabolic Steroid Control Act.

Representatives from the Society met with House and Senate legislative sponsors, Congressman James Sensenbrenner (R-WI), Senator Joseph Biden (D-DE), several House and Senate legislators that co-sponsored the anabolic steroid bill and members of the Senate Appropriations Committee with jurisdiction over funds necessary to implement the new law in the FY 2006 appropriations cycle.

Coincidentally, Major League Baseball announced their new anabolic steroid reform policy shortly after Society representatives met with the Office of Senator John McCain (R-AZ), Chairman of the Senate Commerce Committee. In the past, Sen. McCain has been a vocal critic of steroids and steroid precursors and has mentioned the possibility of his Congressional Committee convening official hearings on the abuses of these substances. The Society offered to assist the Senator's office and/or provide expertise for any future Congressional hearings on this important issue.

At the conclusion of the day on Capitol Hill, more than a half dozen Congressional offices agreed to work with the Society and The Hormone Foundation to pursue federal funding to implement the Anabolic Steroid Control Act of 2004 and to continue to raise the visibility of this very important issue.

2005 NIH Director's Pioneer Award Program Opens

The National Institutes of Health announces the 2005 NIH Director's Pioneer Award, a key component of the NIH Roadmap for Medical Research.

Unlike other NIH grants, which support research projects, the Pioneer Award supports individual scientists. The award gives recipients the intellectual freedom to pursue new research directions and highly innovative ideas that have the potential for unusually great impact.

The program is open to scientists at all career levels. The scientists may currently be engaged in any field of research provided they are interested in exploring biomedically relevant topics and willing to commit the major portion of their effort to Pioneer Award research. Awardees must be U.S. citizens, non-citizen nationals, or permanent residents.

In September 2005, NIH expects to make five to ten new Pioneer Awards of up to \$500,000 in direct costs per year for five years. The first nine Pioneer Awards were made in September 2004 and support scientists working on a variety of challenging scientific problems.

“To maximize the diversity of those considered for Pioneer Awards, we encourage nominations from women, members of groups that are underrepresented in biomedical research, individuals in the early to middle stages of their careers, and scientists working in fields that have not traditionally been supported by NIH,” said Jeremy M. Berg, Ph.D., director of the National Institute of General Medical Sciences. Dr. Berg and Nora D. Volkow, M.D., director of the National Institute on Drug Abuse, are co- chairs of the NIH committee that oversees the Pioneer Award program.

The self-nomination process includes a three- to five-page essay, a biographical sketch, a list of current research support and the names of three references. Nominations may be submitted between March 1 and April 1, 2005, on the Pioneer Award Web site, <<http://nihroadmap.nih.gov/pioneer>>.

The complete Pioneer Award announcement is posted at <<http://grants1.nih.gov/grants/guide/notice-files/NOT-OD->

Survey to Society’s Clinicians in Practice Says Increase in Physician Work is Result of Increased Illnesses, More Rx Drugs

Increased/chronic illnesses, prevention counseling, accommodating formularies, and more prescription medications were recently cited by The Endocrine Society’s clinician members as indicators of the increase in physician work associated with providing evaluation and management (E/M) services to patients.

The Endocrine Society has been working with a coalition of cognitive (non-surgical) specialty organizations to obtain this data through a survey on physician work and E/M services.

These and other data were utilized to develop recommendations to the Centers for Medicare and Medicaid Services (CMS) that the physician work values of all E/M codes should be reviewed as part of the upcoming Five-Year Review of CPT codes. CMS is required to conduct the Five-Year Review every five years. The next Five-Year Review results will be implemented for the 2007 physician fee schedule.

A total of 118 Society members completed the survey, which was sent to approximately 2,000 clinician members of the Society, via e-mail, in November 2004. Respondents were asked to choose indicators from this list that best describe why their work has increased and is therefore in need of review.

Members also were asked to estimate how much they believed their work has increased in association with each code or family of codes in the past ten years. Physician work for the 99201 to 99205 office visits and 99214 was estimated to have increased by 28%. As for 99241 to 99245, the average increase in physician work was 27%, while physician work associated with 99213 was estimated to have increased by 20%.

Research Group Study Shows Health Care Spending up 7.7 Percent

The National Health Statistics Group, part of the Center for Medicare and Medicaid Services (CMS), released their annual report on health care spending last week. The report indicated that U.S. residents spent \$1.7 trillion in 2003 on health care, outpacing the overall economic growth by nearly 3 percent.

Although health care spending increased, spending on medicines, visits to doctors and other health care needs was reported at its lowest annual increase in seven years. The group reported that private payments for health insurance premiums, prescription drugs, doctors services, made up nearly two-thirds of the overall rise in 2003 health spending. States started to tighten their Medicaid budgets triggering a health care program spending deceleration.

The report indicated that patients spent nearly a quarter of their own health care dollars on medicine. Consumer out-of-pocket spending rose 7.6 percent compared to 6 percent in 2002. The increased patient spending accounted for Americans discontinuing their health insurance and employers increasing health care premium costs.

Overall the research showed that in 2004 US health care spending accounted for 15.3 percent of the gross domestic product.

MedPAC Recommends Increase in Physician Payments

Despite physician payment “experts” predictions that there will be no permanent fix this year to the formula that updates Medicare physician payments annually, the Medicare Payment Advisory Commission (MedPAC) an independent, federal body that advises Congress on Medicare physician payments last week voted to approve recommendations to Congress that include physician payment increases.

The recommendations will be part of a formal report to be submitted to Congress in March. They include a recommendation that physicians receive a pay raise of 2.7% in 2006.

Endocrine Insider will report more details of the report once it comes out in March.

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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