



February 21, 2007

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### **FDA Issues Warnings to Compounding Pharmacies on Distribution of Hormone Products**

Following the adoption by the American Medical Association (AMA) of the Society's bioidentical hormone position statement, the U.S. Food and Drug Administration (FDA) issued warning letters to three independent compounding pharmacies in December of last year. The letters warn the pharmacies to disengage from one or more of a number of violations, including producing hormone medications that are copies or essentially copies of FDA-approved versions, producing compounded hormones for mass sale rather than for individuals by prescription, or engaging in illegal interstate commerce by shipping products across state lines. The letters required that the pharmacies respond in writing within 15 days; only one pharmacy has issued a response to FDA.

The warning letters underscore the importance of Society's recent position statement on the use and regulation of bioidentical hormones. The position statement, which can be viewed in its entirety here [http://www.endo-society.org/publicpolicy/policy/upload/BH Position Statement final 10 25 06 w Header.pdf](http://www.endo-society.org/publicpolicy/policy/upload/BH_Position_Statement_final_10_25_06_w_Header.pdf), was published by the Society last October and adopted by the AMA last November and was recently endorsed by the North American Menopause Society.

The Society's position statement highlights the need for uniform patient safety information and surveys for safety and efficacy of all hormone preparations, regardless of the source of the formulation. This position asks that FDA exert more regulatory control than it has previously, even beyond the action recently taken with the warning letters.

The recent FDA warning letters and the single response may be viewed at:

<http://www.accessdata.fda.gov/scripts/wlcfm/resultswl.cfm>

<http://www.accessdata.fda.gov/scripts/wlcfm/resultswl.cfm>

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### **NIH FY 2007 Budget Finally Set; President Signs Joint Funding Resolution**

President Bush signed the Joint Funding Resolution developed by the House and Senate Appropriations Committees that laid out FY 2007 funding levels for the nine agencies operating under a continuing resolution, including the National Institutes of Health (NIH). The House passed the spending package by a vote of 286-140 on January 31, and the Senate passed the measure on February 14 by a vote of 81-15.

The funding resolution allocates an additional \$620 million to the NIH to reverse a projected decline in new NIH research project awards, instructing the agency to support an additional 500 research project grants and 1,500 first time investigators, and expanding funding for high risk and high impact research.

In addition to the FY 2007 increase for NIH, the National Science Foundation (NSF) received an increase of \$335 million and the Department of Energy, Office of Science (DOE-SC) received an increase of \$200 million.

With FY 2007 funding levels decided, Congress can now turn its attention to the President's FY 2008 budget. However, the new Democratic-controlled Congress will set its own funding priorities, which will likely differ significantly from the President's. Look for updates on the FY 2008 budget process and The Endocrine Society's advocacy efforts in future issue of *Endocrine Insider*.

### **2008 Federal Budget Proposes 10% Physician Payment Cut**

The proposed federal budget has projected a 10 percent cut to the physician payment rate in 2008. Much of the reason for the projected cut is based on CMS' assumption that the Sustainable Growth Rate (SGR), the formula that determines physician payments, will remain intact this year.

The SGR has been a controversial payment system for some time, as it uses the Gross Domestic Product (GDP) in combination with other formulae to determine physician payment rates. Physicians and some members of Congress have said that tying physician payment to medical inflation is a more suitable means to determine payment rates. Some lawmakers have called for an end to the use of the SGR, replacing it with a similar expenditure target policy to be applied to all health care providers and hospitals. Currently, the SGR is applied only to physicians.

The Medicare Payment Advisory Commission (MedPAC) has been tasked with advising Congress on Medicare payment policies and recommending a new physician payment formula. Most recently, MedPAC failed to endorse either of two proposed alternatives to reform the physician payment system. Instead, they reiterated their concern that the SGR needs to be revised, but did not recommend a specific model with which to fix the problem.

While the projected cuts are cause for concern, the proposed 2008 budget currently under consideration will go through months of debate and revisions before approval by Congress. The Endocrine Society will keep abreast of the situation and continue to work with Congress and CMS to advocate for fair physician payment rates.

### **Family Practice Organization Encourages Physicians to Participate in Quality Reporting Program**

Although many questions remain about the implementation of the quality measures reporting program, many in the field are encouraging physicians to participate when the program begins in July 2007. Not only will this allow physicians to be paid for something that they will likely be mandated to do in the future, it also allows physicians to smooth out the process in their own practices for reporting measures.

A question weighing on the minds of physicians is how much they can expect to receive for reporting quality metrics. The medical director for quality improvement of the American Academy of Family Physicians developed a back-of-the-envelope calculation to help physicians determine how much they could expect to receive by reporting quality measures under the new CMS program. An average, full-time, family physician bills about \$500,000 annually, 22 percent of which is billed to Medicare (approximately \$55,000 in Medicare charges during a 6 month period), which would result in a 1.5 percent bonus of \$825 for 6 months (*Part B News*, January 8, 2007). Other specialties may have a higher percentage of Medicare patients, but this formula could provide a ballpark figure of how much a physician could expect to receive for reporting quality measures from July to December 2007.

While reporting quality measures this year may not provide a significant financial boost to a practice, there could be benefits that outweigh the costs. For instance, Dr. Michael O'Dell, who heads a 27-physician family practice in Tupelo, Mississippi, found that patient care has improved as a result of tracking diabetes quality measures. Tracking foot exams for his 1,200 patients with diabetes has prevented amputations, and tracking Hemoglobin A1c and LDL cholesterol, both PVRP measures for diabetics, have resulted in global improvements (*Part B News*, January 8, 2007). He has also been able to develop tracking mechanisms to collect patient data before or during the visit, as well as phase in quality measure tracking into his electronic medical record.

Endocrine Society staff will continue to monitor CMS' progress toward implementation of the quality reporting system, and will report on future developments in *Endocrine Insider*.

### **Bill to Delay Imaging Cuts to be Introduced in House**

Representatives Carolyn McCarthy (D-NY), Joe Pitts (R-PA), and Gene Green (D-TX) plan to introduce the "Access to Medicare Imaging Act of 2007" during the week of February 26. The bill, identical to a bill introduced in the 109<sup>th</sup> Congress that was co-sponsored by 140 representatives on both sides of the aisle, calls for a two-year moratorium on the implementation of the imaging cuts and require a comprehensive GAO study on patient access and service issues. The Deficit Reduction Act of 2005 (DRA) imaging cuts reduces all physician office and clinic reimbursement rates for imaging services to the rates paid to hospital outpatient departments. As a result of these cuts and the change in practice expense methodology, DXA payments are expected to drop from \$140 in 2006 to approximately \$40 by 2010. These imaging cuts may seriously impact the ability of physicians to provide critical imaging services in their offices, placing millions of seniors at risk of losing access to these services. The sponsors of the bill have sent out a "Dear Colleague" letter to all cosponsors of HR 5704 from the 109<sup>th</sup> Congress in an effort to secure bipartisan support for the new legislation. The Endocrine Society has sent a letter of support for the legislation to Representative McCarthy's office, and will continue to be active in various coalitions focused on stopping the DRA imaging cuts.

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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