



April 21, 2006

Zerhouni Defends NIH Investment Before Congress

NIH Director, Dr. Elias Zerhouni, testified before the House Appropriations Labor/HHS/Education Subcommittee on April 6. Dr. Zerhouni focused his remarks on the return on investment during the NIH budget-doubling period of 1998-2003.

Dr. Zerhouni specifically mentioned the advancements made in treating cardiovascular disease that have resulted in nearly one million fewer deaths from heart attacks each year. He stressed that Americans are now living twenty years longer than they used to after experiencing a heart attack. Dr. Zerhouni brought to the hearing a product now used to treat heart disease, a drug-coated stent, the discovery of which was made possible through research conducted by the National Institute of Aging. He also pointed out that NIH invests \$3.70 per year per American in cardiovascular research and stated that the cumulative investment in cardiovascular research is about \$110 per U.S. citizen over the last 30 years.

With regard to diabetes, the Director recounted that nearly 21 million Americans have diabetes, which can cause damage to multiple organs and lead to death. He mentioned that, without NIH research, the improvements during the past two decades in therapies for diabetes would not have occurred. Through large prospective trials, made possible by the doubling of the budget, NIH has assessed the relative value of drug based approaches versus weight loss and physical activity, and showed it is possible to reduce the risk of type 2 diabetes by 58 percent with lifestyle modifications alone.

The other diabetes-related example the Director mentioned was recent NIH research on end-stage renal disease (ESRD). This diabetes complication results in direct federal expenditures of approximately \$20 billion per year. He pointed out that, through the 1980s and 1990s, the incidence of ESRD nearly doubled each decade, but in the last five years overall rates have stabilized — and even declined in certain population groups. This improvement has been driven by monitoring for proteins in urine to prevent kidney disease or detect it in its early stages. Dr. Zerhouni stated that, when compared to earlier projections, the savings in federal health care expenditures are approximately \$1 billion per year due to these advancements.

Dr. Zerhouni also spoke to the positive impact that the agency has had on the economy. He stated that, from 1994-2004, the NIH has helped bring 3,114 new technologies to the market and influenced the formation of 4,543 new companies.

Finally, the Director addressed the future of NIH. He stated that health care costs will be impossible to manage unless we transform medicine from curative to preemptive care. NIH is investing in research to further understanding of the fundamental causes of diseases at their earliest stages so that scientists can reliably predict how and when a disease will develop and in whom.

CMS Creates Medically Unbelievable Edits

The Centers for Medicare and Medicaid Services (CMS) has quietly created a group of new edits applicable to claims. Termed “Medically Unbelievable Edits” (MUEs), they would apply to a unit-of-service limit per patient/per provider/per day to nearly every CPT code and be administered like CCI edits with no option to override with a modifier.

According to CMS in a letter to specialty medical societies, the purpose of the edits is to “prevent overpayments resulting from the reporting of excess units of service due to entry errors, incorrect interpretations of HCPCS/CPT codes, etc.” The list of proposed MUEs includes more than 10,800 codes; MUEs are based on anatomic considerations, CPT code descriptors, CPT coding instructions, and medical reasonableness. The edits would only apply to claims for physician and hospital outpatient services.

An example of how MUEs would work is as follows:

A MUE for code 99213 (mid-level office/outpatient visit for established patient, \$52.68, nat.) is set for two units of service. If a provider billed three units of that code (same patient, same day, same provider), the third unit would be denied. The provider would be paid for the other two units, if medically necessary.

The program was supposed to be implemented beginning July 1, 2006. However, this date has been delayed to no earlier than January 1, 2007. On April 10, 2006, the American Medical Association, along with more than 90 other medical and specialty societies, sent a letter to CMS addressing concerns about the MUE program. The letter stresses the belief of the medical community that CMS has underestimated the scope of review [of new and revised CPT codes]. Additionally, serious concerns exist regarding the continued lack of transparency in developing the program because rationale and frequency data used in developing the prospective units of service still have not been disclosed to most stakeholders. Finally, there is concern that there is no system in place for using modifiers or for appealing an edit.

The Endocrine Society endorsed the letter that was sent to CMS, and will continue to keep its members informed on the issue. To view the letter click on <http://www.endo-society.org/publicpolicy/legislative/letters/upload/Sign%20on%20MUE%20letter%20to%20CMS.pdf>.

Senate Measure Introduced Targeting School Junk Food

On April 6, Senator Tom Harkin (D-IA) introduced The Child Nutrition Promotion and School Lunch Protection Act (S.2592) in the U.S. Senate. The bill would update decades-old federal nutrition standards for snack foods sold in school cafeterias alongside regular school meals, and would apply those standards everywhere on school grounds, including vending machines and school stores.

Current regulations only allow the Agriculture Department to regulate foods sold in school cafeterias. The Department does not have the authority to regulate content at school a la carte lines in cafeterias, vending machines, or school stores. The Harkin proposal would require updated federal nutritional standards for all foods sold at school, and would apply those standards to all foods sold during the school day everywhere on schools grounds.

Senator Harkin, Ranking Member of the Senate Committee on Agriculture, Nutrition & Forestry, said of the legislation “Junk food sales in schools are out of control. It undercuts our investment in school meal programs, and steers kids toward a future of obesity and diet-related disease. Congress cannot stand idly by while our kids are preyed upon by junk food marketers.”

According to the Government Accountability Office, 99 percent of high schools, 97 percent of middle schools and 83 percent of elementary schools have vending machines, school stores, or snack bars. The most common items sold out of school vending machines, school stores, and snack bars include soda and sports drinks, salty snacks, candy, and high-fat baked goods.

Senators Arlen Specter (R-PA), Dick Durbin (D-IL), Lisa Murkowski (R-AK), Jeff Bingaman (D-NM), and Lincoln Chaffee (R-RI) cosponsored the Senate measure. Identical legislation (H.R. 5167) was also introduced April 6 by House Members Lynn Woolsey (D-CA) and Chris Shays (R-CT). The legislation has been endorsed by the American Medical Association and the Parent Teacher Association.

Society Enters Into Public Access Pilot Project

The Endocrine Society has joined with six other non-profit publishers and NIH on a pilot project that would increase public access to federally-funded research while protecting the rights of publishers. For the last year, NIH has been working under a voluntary author submission policy that suggests NIH-funded researchers submit copies of their research manuscripts to NIH. The agency would then compile the manuscripts and open them to free public access after a designated period of time. However, the voluntary program has suffered from very low compliance rates and is being re-evaluated.

The NIH Public Access Working Group met on April 10 to discuss the future of NIH’s public access policy. The majority of the Working Group, which includes all interested parties – publishers, patient groups, librarians, others – concluded at the meeting that policy should now be made mandatory, require deposition of final articles and release of articles six months after publication (12 months for quarterly journals). However, there was an increased awareness of the need to work with publishers in order to accomplish all these goals.

Just prior to the April 10 meeting of the Working Group, the Society joined with six other non-profit publishers in a meeting with NIH Director Elias Zerhouni to examine partnership opportunities for increasing public access. The Society has long held that mandatory author submissions and a six-month date of release after publication would be detrimental to publishers and scientific publishing in general. The experimental pilot project would shift the burden of submission of final articles to the publishers rather than the authors, which would allow for 100 percent compliance for participating journals. In turn,

NIH would not allow public access until 12 months after the publisher's date of publication. The project is still in its early stages and negotiations are continuing, but the Society is hopeful that the mutual goals of increased public access can be attained. Stay tuned to *Endocrine Insider* for further updates.

Society President Leads Study on PCOS

A recent study published in the *Proceedings of the National Academy of Science* journal, published results from a study on polycystic ovary syndrome (PCOS). The study was led by Society President Andrea Dunaif, MD. It stated that mothers of women with a common endocrine disorder, PCOS, provide evidence that menstrual irregularity and unhealthy metabolic traits associated with PCOS are inherited and persist with age.

To read a press release about this study, go to: <http://www.endo-society.org/news/press/2005/PCOSAprilRelease.cfm>.

MEDIA CORNER

The Society is actively seeking media spokespersons and is willing to provide media training for members who are interested. If you are interested and want more information, contact Tadu Yimam, Manager, Public Relations, at media@endo-society.org.

Share Your News with Colleagues

Endocrine News, The Endocrine Society's monthly magazine, accepts announcements from members regarding promotions, job changes and awards. These notices are published in "Smart Moves," a regular column in the magazine. Submit your news to endocrinenews@endo-society.org

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

Janet B. Kreizman, Director
301-941-0252
jkreizman@endo-society.org

Chris Rorick, Associate Director
301-941-0254
crorick@endo-society.org

Sarika Rane, Manager
301-951-2613
srane@endo-society.org

Lisa Marlow, Coordinator
240-482-1392
[lmarlow@endo-society.org](mailto:lmарlow@endo-society.org)