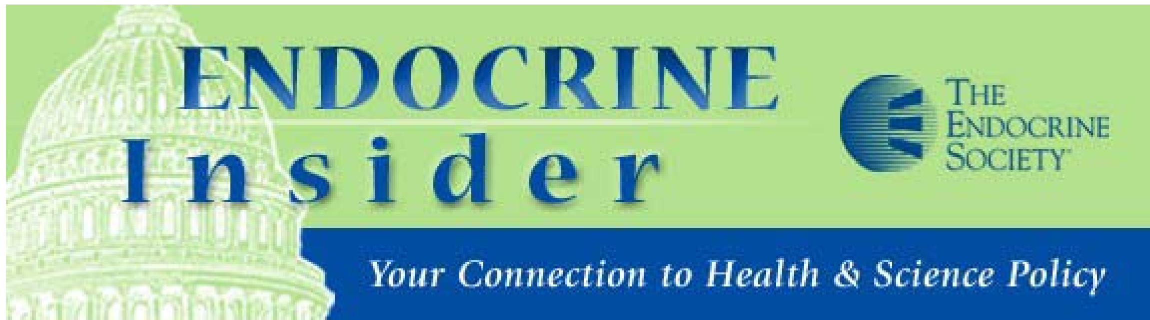

April 6, 2005

Society Voices Concern over NIH Conflict of Interest Rule

On behalf of the Society, President Tony Means submitted comments to the Department of Health and Human Services regarding the new conflict of interest regulations issued for employees of the National Institutes of Health (NIH). In the comments, the Society expresses its concern over how the new regulations will affect the relationship between NIH employees and the Society. According to the regulations, NIH employees are seemingly prohibited from participating in professional associations. The rule specifically prohibits NIH employees from engaging in employment and from being compensated for teaching, speaking, writing, or editing. The rule also precludes serving as an officer, director, or other fiduciary board member, serving on a scientific advisory board or committee, and consulting or providing professional services.

In the Society's comments, Dr. Means states that "NIH employee involvement in outside professional scientific organizations, such as The Endocrine Society, is essential for the professional growth of the scientific community. Existing NIH regulations already prohibit participation in fiduciary and advocacy activities by NIH employees within our organization. In our view, these regulations are sufficient to limit conflict of interest concerns for professional scientific societies." A copy of the Society's comments in their entirety can be found at http://www.endo-society.org/publicpolicy/legislative/letters/upload/NIH-CoI-Comments.pdf

Federation of American Societies for Experimental Biology (FASEB) President, Paul Kincade, PhD, recommended an agency-wide independently conducted evaluation of the impact of the NIH conflict of interest regulations. He was quoted in a recent Washington Fax article as saying, "The implementation of the rule without due process has had immediate negative effects on the agency and its scientists, the final regulations should be carefully considered and rigorously monitored to assess both negative and positive consequences."

FASEB comments to HHS can be viewed at:
http://www.faseb.org/opa/PDF/NIH%20CoI%203%2030%2005.pdf

New Institute Director Has Second Thoughts Following Conflict of Interest Proposal

In a letter to NIH Director Elias Zerhouni and Health and Human Services Secretary Mike Leavitt, David Schwartz indefinitely postponed his appointment to become the new Director

of the National Institute of Environmental Health Sciences. Schwartz cited his concerns over the recently announced conflict of interest restrictions as his reason for the delay.

Schwartz, director of pulmonary medicine and critical care at Duke University Medical Center, was announced as the new future director of the Institute in October, before the conflict of interest regulations had been announced. According to the Washington Post, following the announcement of the regulations Schwartz fears he will not be able to recruit or retain the personal needed to effectively carry out his duties.

Many current NIH employees have expressed frustration with the new regulations, which limit a broad range of outside consulting activities and require divesting biomedical stocks regardless of your position within the agency.

The public comment period on the Department of Health and Human Services final interim rule closed on April 4th. NIH and Department officials have stated that they will review the comments on the interim rule and retain the option of revising them based on the comments collected.

Congress Eyes Short and Long-Term Fixes for Physician Payment

Senate Majority Leader Bill Frist (R-TN) told a crowd at a recent American Medical Association (AMA) event that he is considering another one year fix to the projected cut in Medicare reimbursement but that a long-term fix to the overall payment formula could be delayed until next year. Physician payment rates are estimated to be cut 31% from 2006-2013, 4.3% in 2006, because of a flaw in the sustainable growth rate (SGR) formula that is used to determine pay rates. Congress and the Centers for Medicare and Medicaid (CMS) have yet to determine the best way to fix the payment methodology for the long term. Sen. Frist indicated that Congress will likely work to pass a 1.5% increase for 2006.

As reported in the February 23rd issue of *Endocrine Insider,* Congress is considering several pay-for-performance proposals. A pay-for-performance system would provide physicians “bonuses” for providing more efficient, high-quality care. One proposal being discussed is a phased-in system, which would provide incentives for physicians to report quality data. Staffers on the Hill, have indicated that such an initiative could be handled differently for different specialties. Currently, the Medicare system does not differentiate among providers when reimbursing them for a particular service. All heath care providers are paid the same regardless of the level of service performed. Critics worry that this system will create additional workloads for physicians, while supporters claim it will make the health care program more efficient.

The AMA and a large contingent of subspecialty organizations, including The Endocrine Society, are keeping an eye on Congress’ pay-for-performance proposals to ensure that any such system is appropriate relative to the needs of clinicians in practice. On March 2, the American Medical Association (AMA) released a new set of pay-for-performance Principles and Guidelines for the formation and implementation of pay-for-performance programs. The AMA has been cautiously optimistic about the future of pay-for-performance and believes the programs have the potential to have a positive impact on

improving quality of care. But, when applied with minimal regard to healthcare quality and patient safety, can be disruptive to the patient/physician relationship and cause overall quality to suffer.

While speaking about a potential pay-for-performance system, House Ways and Means Health Subcommittee Chair, Nancy Johnson (R-CT) said, "It's not something we can do right tomorrow." Rep. Johnson added that the need to reform the Medicare physician formula was forcing a move to replace it with a pay-for-performance system, but that the initiative was "two years ahead of the technology curve." She also expressed concern about imposing additional reporting requirements on physicians.

GAO Report Examines Diabetes Coverage

The Government Accountability Office (GAO) recently issued a report that examines health plan coverage of diabetes services and supplies. The GAO reviewed the extent to which (1) states require insurance policies to cover diabetes services and supplies, (2) health coverage not subject to state requirements includes diabetes services and supplies, and (3) individuals with diabetes ages 18 and older receive services and supplies.

The GAO contacted the health plans not subject to state insurance requirements that provide coverage—specifically, the three largest plans participating in Federal Employees Health Benefits Program (FEHBP) and 13 of the largest employers' self-funded plans—and found that they cover most of the diabetes services and supplies in most cases without limits on the coverage. Each of the three FEHBP plans and the 13 self-funded plans cover at least seven of the ten diabetes services, such as an annual blood glucose test, cholesterol and blood pressure monitoring, and influenza vaccinations. Services covered with less frequency include diabetes education, medical nutrition therapy, and smoking cessation therapy. All the plans cover at least five of the nine diabetes supplies, including insulin and insulin-administering supplies; most of these plans also coverblood glucose monitors, glucose control solutions, alcohol swabs, and therapeutic shoes.

According to the report, 47 states, including the District of Columbia, have laws or regulations related to coverage of diabetes services or supplies, although specific requirements vary by state. Services for which states most often require coverage were diabetes education (45 states) and medical nutrition therapy (27 states). In addition, all the reported states require coverage of diabetes supplies with some states being more specific about which supplies must be covered. A copy of the report in its entirety can be found at http://www.cq.com/flatfiles/editorialFiles/healthBeat/reference/20050328-28diabetes-report.pdf.

NSF Funding Rates Decline for FY 2004

Funding rates for National Science Foundation (NSF) grants declined in FY 2004, according to a merit review process report distributed to the National Science Board at its March 29 meeting.

In FY 2004, NSF funded 10,380 of 43,851 submitted proposals, yielding a funding rate of 24%. The average award amount for research grants was $139,522, an increase of 3% over FY 2003. The median award was $101,566, which reflects the effect of numerous small grants awarded by the agency. "Larger awards permit the participation of more students and allow scientists to devote a greater portion of their time to actual research rather than writing and reviewing proposals," the document states.

NSF Director Arden Bement, PhD, told the House Science/Research Subcommittee, on March 9, that the agency plans to improve its grant making process by issuing targeted grant solicitations intended to attract applications that are closest to the agency's core priorities.

While the number of submitted grant proposals has been rising – increasing by 16,344 from FY 2000 to FY 2004 – the number of awards has not increased at the same rate, increasing by 530 over the same five years. The disparity resulted in the funding rate declining 9% over the same period.

To increase efficiency of NSF's merit review process, the agency appointed an outside consultant to undertake a multi-year business analysis. In 2003, a similar report indicated that about 70% of NSF staff spent more than half of their time on merit research activities. Staff has noted that the increase in workload has made it difficult to perform merit reviews.

Director of NSF's human resource management division, Joseph Burt, has said that NSF may need to reduce the merit review workload, but further research needs to be done.

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:

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

Chris Rorick, Manager Government Relations
301-941-0254
crorick@endo-society.org

Lisa Marlow, Coordinator
240-482-1392
lmarlow@endo-society.org