



September 30, 2009

President Obama Addresses NIH, Announces Awarding of \$5B in ARRA Grants

In a speech today at the National Institutes of Health, President Obama praised the work of the NIH and announced the funding of almost 12,000 grants through funds from the American Recovery and Reinvestment Act (ARRA). NIH was awarded \$10.2 billion under the stimulus plan, and \$5 billion of that money has been awarded. The President also compared the current allegations that government is trying to take over health care to similar allegations aimed at Franklin Roosevelt when he spoke at the dedication of NIH 70 years ago. President Obama concluded his speech by pledging to provide NIH the support it needs to continue its important work.

To view the President's address to NIH, please click [here](#). Information on the grants funded by ARRA funds may be found on the NIH [website](#).

Shorter Grant Applications to Be Implemented; Other NIH Peer Review News

As part of its effort to improve the peer-review process, the Center for Scientific Review (CSR) of the National Institutes of Health (NIH) has announced that it will implement a shortened and restructured application format for FY2011 grant submissions. NIH announced the impending changes in a notice to investigators, and CSR included a story about the changes, along with other items of interest, in its September issue of *Peer Review Notes*. The new application format will be required for grants submitted on or after the January 25, 2010, due date. Some of the changes include:

Shortened Page Limits:

- For grants with a current limit of less than 25 pages, the new limit will be 6 pages.
- For grants with a current limit of 25 pages, the new limit will be 12 pages.
- For grants with a current limit of greater than 25 pages, applicants should consult the individual Funding Opportunity Announcements (FOA).
- Page limits do not include Specific Aims or Introduction (where applicable).

Research Plan:

- Background and Significance, Preliminary Studies/Progress Report, and Research Design and Methods will be replaced by a new single section entitled Research Strategy, which will be sub-divided into three parts: Significance, Innovation, and Approach.

Other changes include new requirements under the Facilities and Other Resources section and the inclusion of a Personal Statement in the applicant's biosketch.

For detailed information on the restructured grant applications, please click [here](#).

September's *Peer Review Notes* also reports the adaptation of a new grant scoring system, pilot projects to examine other peer-review recommendations, and an approach to finding homes for "orphan" applications.

The full issue of *Peer Review Notes* is available [here](#).

DXA Payment Cut Fix Included In Senate Health Reform Package

Due to the efforts of Senator Blanche Lincoln (D-AR), sponsor of the "Medicare Fracture Prevention and Osteoporosis Testing Act" (S 769/HR 1894), the Chairman's Mark of the Senate Finance Committee health reform legislation includes an amendment to address the payment cuts to DXA services provided in a physician's office. The amendment, based on the language in S 769, would set the payment rate back to 70% of the 2006 level. It would also authorize the Institute of Medicine to study the effect of Medicare reimbursement reductions for DXA on beneficiary access to bone density tests.

Representative Shelley Berkley (D-NV), the sponsor of HR 1894, is working to include a DXA-related provision in the final health reform package that will be debated by the House.

The Endocrine Society has been working with Senator Lincoln and Representative Berkley and a group of coalition partners to address the DXA payment cuts. The cuts, if fully implemented in 2010, will reduce Medicare payment rates to physicians performing DXA scans in their offices by 68 percent in comparison to 2006 levels. The Endocrine Society will alert the membership of opportunities to advocate for the inclusion of DXA-related provisions in the final health reform package.

House Passes Continuing Resolution

Last week, the US House of Representatives passed a continuing resolution (CR) to fund some government agencies through October 31, and the Senate was expected to consider the measure before the end of the 2009 fiscal year (September 30, 2009). Because Congress has not cleared any of the FY 2010 appropriations bills, the CR will fund government agencies at FY 2009 levels. As reported by the Society in an alert last week, the House and Senate conferees are meeting to come to agreement on the differences between the two bills passed by the House and Senate Labor, Health and Human Services, Education and Related Agencies Appropriations Committees. The House approved a 3.1 percent increase for the NIH and the Senate approved a 1.4 percent increase.

HIPAA Breach Notification Rule Now In Effect for Physicians

Effective September 23, 2009, HIPAA-covered entities, including physicians and health care providers, health plans, and health care clearinghouses, are required to notify patients, the Secretary of the Department of Health and Human Services (HHS), and in some cases the media, if breaches of security involving personal health information (PHI) are discovered. Though the rule took effect on September 23, HHS has stated that it will not impose sanctions or financial penalties for breaches discovered before February 22, 2010.

Established under the American Recovery and Reinvestment Act of 2009, a breach is defined as the acquisition, access, use, or disclosure of unsecured PHI not permitted by HIPAA Privacy Rules and which compromises the security or privacy of the PHI. HIPAA covered entities are required to notify the affected individuals without unreasonable delay and not later than 60 calendar days after the discovery of a breach. In cases involving the breach of more than 500 individuals' PHI, the media must also be notified.

The American Medical Association has created a helpful document outlining what physicians need to know regarding the new HIPAA breach notification rule, which is available by clicking [here](#).

New Society Guideline on Treatment of Transsexual Persons Covered by LA Times

The Endocrine Society recently published its 11th clinical practice guideline titled *Endocrine Treatment of Transsexual Persons*. A task force chaired by Wylie Hembree, MD, developed the evidence-based clinical practice guideline, which was vetted through a rigorous multi-step peer review process. The guideline addresses several areas of interest in the field of treating transsexual persons, including diagnostic procedures, treatment of adolescents, hormonal therapies, and surgery for sex reassignment.

Originally published in the September issue of the *Journal of Clinical Endocrinology and Metabolism*, the *Endocrine Treatment of Transsexual Persons* clinical practice guideline is now available for free download and purchase at: <http://www.endo-society.org/guidelines/Current-Clinical-Practice-Guidelines.cfm>.

The Society issued a press release regarding the publication of the new guideline and saw immediate coverage highlighted by Melissa Healy's article, "[Treating transsexual kids: wait for, then delay puberty to treat](#)," which was published in the September 19, 2009 issue of *The Los Angeles Times*' health blog, "Booster Shots."

For questions regarding this and other Endocrine Society clinical practice guidelines please contact Lisa Marlow at lmарlow@endo-society.org.

NIH Now Considering Stem Cell Lines for Approval

The National Institutes of Health (NIH) has begun accepting requests for human embryonic stem cell (hESC) lines to be approved for use in NIH-funded research. In response to Executive Order 13505: *Removing Barriers to Responsible Scientific Research Involving Human Stem Cells*, NIH developed guidelines earlier this year describing requirements for hESC to be eligible for federal funding. The guidelines state that a working group of the Advisory Committee to the NIH Director (ACD) will review requests for approval and will make recommendations to the ACD. Final eligibility decisions will be made by the NIH director.

Members of the Working Group for Human Embryonic Stem Cell Eligibility Review of the ACD are Jeffery R Botkin, MD MPH (Chair), Dena S Davis, JD PhD, Pamela B Davis, MD PhD, David A Grainger, MD MPH, Richard P Lifton, MD PhD, Bernard Lo, MD, Terry Magnuson, PhD, Jeffery C. Murray, MD and Carlos Pavao, MPA.

For more information on NIH's stem cell policy, or to submit a cell line for consideration, click [here](#).

Pancreatitis Reported with Use of Sitagliptin and Sitagliptin/Metformin; FDA Recommends Careful Monitoring

Late last week, the U.S. Food and Drug Administration (FDA) released information for healthcare providers detailing new information on reported cases of acute pancreatitis in patients using sitagliptin (Januvia) and sitagliptin/metformin (Janumet). Sitagliptin is prescribed as an addition to diet and exercise to improve glycemic control in adults with type 2 diabetes.

According to the FDA, eighty-eight post-marketing cases of acute pancreatitis in patients using sitagliptin, including two cases of hemorrhagic or necrotizing pancreatitis, were reported between October 16, 2006 and February 9, 2009. Based on this information, FDA began working with the drugs' manufacturer to revise the prescribing information to include the following:

- Information regarding post-marketing reports of acute pancreatitis, including the severe forms, hemorrhagic or necrotizing pancreatitis.
- A recommendation that healthcare professionals monitor patients carefully for the development of pancreatitis after initiation or dose increases of sitagliptin or sitagliptin/metformin, and to discontinue treatment with the drugs if pancreatitis is suspected.
- Information noting that sitagliptin and sitagliptin/metformin have not been studied in patients with a history of pancreatitis and should be used with caution and with appropriate monitoring in these patients.

For additional details on the FDA statement, including considerations for health care professionals and important information for patients, please click [here](#).

PCC Seeks Pre-Applications for Anti-Doping Research

The Partnership for Clean Competition (PCC) is now accepting pre-applications for its grant program, which funds research with a high likelihood to advance the anti-doping field and ensure integrity in sports. The PCC was founded by the United States Olympic Committee, United States Anti-Doping Agency, Major League Baseball, and the National Football League with the aim of ensuring integrity in sport by supporting high-quality, high-impact, novel research. The National Basketball Association, National Hockey League, and PGA TOUR also participate.

Pre-application deadline is December 1. More information about the grant opportunity is available on the PCC's website at <http://www.cleancompetition.org/>.

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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