

## Court Orders Halt to Research Appeals Court Halts Halt

In a ruling that stunned the U.S. National Institutes of Health (NIH) research community and many patient advocacy groups, a federal judge in Washington, DC, issued an injunction that ordered the NIH to stop funding human embryonic stem cell research.

The injunction was issued as part of a lawsuit that challenged the legality of NIH guidelines that implemented President Obama's March 2009 Executive Order lifting a prohibition on federal funding of research using human embryonic stem cells. The lawsuit argues that the NIH Guidelines for Human Stem Cell Research (NIH Guidelines) violate a provision of the annual U.S. Departments of Labor, Health & Human Services, and

Education Appropriations bills. The provision, known as the Dickey-Wicker provision, prohibits the use of federal funds to create human embryos for research purposes or for research in which embryos are destroyed, discarded, or knowingly subjected to risk.

The plaintiffs in the lawsuit are both adult stem cell researchers who claim that the increased number of cell lines available for federal funding will result in increased competition for federal funds; this will threaten their ability to obtain NIH funding, they argue. Only one has ever received an NIH grant. The plaintiffs also assert that the NIH Guidelines violate the Dickey-Wicker provision.

In his opinion ordering the injunction, the judge held that the NIH Guidelines imposed harm on the plaintiffs; in refusing to stay this injunction, he denied that the injunction would harm federally funded human embryonic researchers.

In response to the injunction, the NIH immediately removed 50 grants from the queue awaiting peer review, stopped 12 highly scored grants valued at \$15–\$20 million that were ready for Council approval, and halted 22 grants

worth \$54 million that were ready for annual review. Stem cell lines ready to be added to the NIH Human Embryonic Stem Cell Registry were also placed on hold. The impact on many

ASCB members—and others—was immediate and catastrophic, and ASCB's Public Policy Committee, staff, and leadership immediately focused efforts on their behalf.

### NIH, ASCB Respond Forcefully

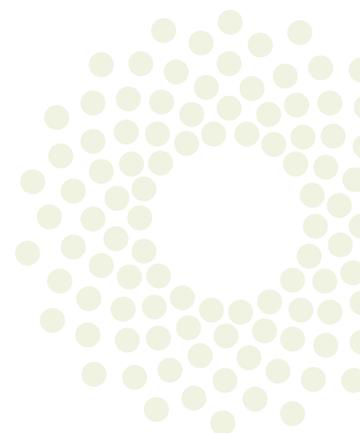
In a statement, NIH Director Francis Collins said, "The injunction threatens to stop progress in one of the most encouraging areas of biomedical research, just as scientists are gaining momentum—and squander the investment we have

already made. The possibility of using these cells to replace those that have been damaged by disease or injury is one of the most breathtaking advances we can envision. Human embryonic stem cells also represent a powerful new approach to the early stages of screening for new drugs, and may hold the secrets to creating entirely new, targeted clinical therapies. We must move forward—without delay—to sustain this field of research that provides so much hope for thousands of patients and their families."

The ASCB has been a strong supporter of federally funded research using both adult and embryonic stem cells for more than a decade. In a statement opposing the injunction posted on the ASCB website, the ASCB reiterates this support. The ASCB is continuing to work on both legal and legislative fronts to ensure that the NIH is able to fund the best science, free of ideologically based restrictions. ASCB is a founding member of the Coalition for the Advancement of Medical Research (CAMR), a coalition of almost 100 patient, university, and scientific groups that supports federally funded stem cell research. ASCB is working with CAMR and other groups, as well as contacts



*Left to right: ASCB members George Daley and Sean Morrison and U.S. National Institutes of Health Director Francis Collins were witnesses at a U.S. Senate Appropriations Subcommittee hearing on the state of human embryonic stem cell research on September 16, 2010. To view the hearing, go to <http://mytinyurl.net/095ca2>.*



in the Obama Administration and on Capitol Hill.

The U.S. Department of Justice (DoJ) filed a motion seeking a stay of the injunction. CAMR filed an amicus brief in support of the DoJ motion. ASCB members and staff contributed to the effort. In the brief, CAMR argued that the injunction “will halt—and in some cases, permanently impair—research projects that have been in progress for years, wasting millions of dollars invested in such research. It will preclude the funding and initiation of some 20 new research projects that have passed the rigorous, competitive peer review process operated by the National Institutes of Health (NIH). It will cause serious economic harm to research institutions and the researchers who have committed their professional careers to hESC [human embryonic stem cell] research. And, most critically, the resulting delay and disruption will inevitably mean that potential beneficiaries of hESC research risk losing the benefit of therapeutic treatments that would have been developed and deployed but for the injunction.”

In his ruling rejecting the request for a stay of his injunction, the judge said that the DoJ was “incorrect about much of their ‘parade of horrors’ that will supposedly result from this Court’s preliminary injunction.”

### **Injunction Stayed, for Now**

The DoJ immediately appealed the judge’s rejection of a stay request. On September 9, 2010, the U.S. Court of Appeals granted a temporary Administrative Stay while it considered the request for a longer stay. In its order, the Appeals Court said that the temporary stay “should not be construed in any way as a ruling on the merits” of the request for a longer stay. In light of the stay order, NIH resumed the receipt, review, and awarding of applications and proposals that involve human embryonic stem cells. It also announced that the review of human embryonic stem cell lines for addition to the stem cell registry would also begin again.

At presstime, the plaintiffs and the DoJ were preparing their arguments for consideration by the Appeals Court regarding a longer stay of the injunction.

### **Action in Congress**

The ASCB is also supporting efforts on Capitol Hill to address the situation legislatively. (See photo caption on page 21.)

To advance ASCB’s legislative efforts, ASCB members can join Project 50 at [www.ascb.org/project-50.html](http://www.ascb.org/project-50.html) or the Congressional Liaison Committee at [www.coalitionforlifesciences.org/be-an-advocate/about-the-clc](http://www.coalitionforlifesciences.org/be-an-advocate/about-the-clc). ■

—Kevin M. Wilson

## **Coked-Up Stimulus Monkeys?**

Senators Tom Coburn (R-OK) and John McCain (R-AZ) issued a report highlighting what they consider to be wasteful spending of the American Reinvestment and Recovery Act (ARRA) dollars. Of the 100 programs highlighted in *Summertime Blues*, several are programs funded with National Institutes of Health and National Science Foundation monies.

Unless this misperception is corrected, the public and Congress will begin to believe the negative hype.

**If you have received ARRA funds, it is incumbent on you to tell Congress how the ARRA dollars are really being spent.**

Go to [www.ascb.org/ARRA](http://www.ascb.org/ARRA) to tell your story. ■

# Federal Agencies Begin to Plan for Next Budget

Many consider the annual State of the Union address by the President of the United States to be the official start of the federal budget process. Despite the pomp and circumstance of that event, the real kick-off of each budget cycle actually begins months earlier. It starts with the fanfare that only a government bureaucrat can appreciate.

Each year, the Office of Management and Budget (OMB) sends memos to the heads of federal agencies and departments issuing “guidance” on the preparation of the next year’s budget requests. During the Bush Administration, these OMB memos often included specific funding amounts for specific agencies.

Under President Obama, these memos have contained general guidelines federal agencies should follow when preparing their annual budget proposals. The OMB memos for FY12 have mixed news for the U.S. National Institutes of Health and the National Science Foundation. Overall, the OMB memo instructs federal agencies to submit budget requests that are 5% below the FY11 budget. OMB does not want the agencies to make across-the-board reductions. Instead, agencies are told to restructure their operations strategically by:

- Eliminating low-priority programs and activities

- Re-engineering staff plans
- Focusing management attention on high-priority performance goals

A follow-up memo from OMB Director Peter Orszag and John Holdren, director of the Office of Science and Technology Policy, hints that the science and technology portions of Obama’s FY12 budget request to Congress could fare better than other portions of the federal budget. The Orszag-Holdren memo does not contain any directives about budget cuts. Instead, it reminds agency heads of the President’s desire to have both private and federal research and development spending reach 3% of the U.S. gross domestic product. To reach that goal, agencies are urged to “pursue transformational solutions to the Nation’s practical challenges, and budget submissions should therefore explain how agencies will support long-term, visionary thinkers proposing high-risk, high-return (or ‘potentially transformative’) research.”

Agency heads were also told to develop outcome-oriented goals, establish timelines for evaluating performance of agency activities, and target investments toward high-performing programs.

To read the OMB memos, go to [www.whitehouse.gov/omb/memoranda\\_default](http://www.whitehouse.gov/omb/memoranda_default). ■

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