Impact of Stem Cell Reversal 'Limited' in Rheum

BY JOYCE FRIEDEN

President Barack Obama's executive order reversing the Bush administration's restrictions on government-funded stem cell research will probably not have a large effect on rheumatologic disease research, according to one expert.

Under the previous policy, government funding for embryonic stem cell research was limited to studies using only the few stem cell lines that were in existence in August 2001, when then-President George W. Bush announced the policy. President Obama's executive order, which he signed in March, lifts those restrictions and allows funded research to include embryonic stem cell lines created after that date. However, the order does not lift a current ban on using federal funds to create stem cell lines if the creation involves the destruction of human embryos. Federal policy does not affect privately funded stem cell research.

President Obama noted at the signing ceremony that "many thoughtful and decent people are conflicted about, or strongly oppose, [embryonic stem cell] research. I understand their concerns, and we must respect their point of view."

But he added that "in recent years, when it comes to stem cell research, rather than furthering discovery, our government has forced what I believe is a false choice between sound science and moral values. In this case, I believe the two are not inconsistent.

"After much discussion, debate and reflection, the proper course has become clear," he said. "The majority of Americans—from across the political spectrum, and of all backgrounds and beliefs—have come to a consensus that we should pursue this research. … That is a conclusion with which I agree. That is why I am signing this executive order and why I hope Congress will act on a bipartisan basis to provide further support for this research."

The president said that the government "will develop strict guidelines, which we will rigorously enforce, because we cannot ever tolerate misuse or abuse. And we will ensure that our government never opens the door to the use of cloning for human reproduction. It is dangerous, profoundly wrong, and has no place in our society, or any society."

The order refers to embryonic stem cell research, which is not being applied to rheumatic disorders.

DR. TYNDALL

Dr. Alan Tyndall, professor and head of the department of rheumatology at the University of Basel (Switzerland) said it is "not likely" that the executive order will advance stem cell research for rheumatologic diseases. "The order refers to [embryonic] stem cell research, which [is] not being applied to rheumatic disorders," he said.

Dr. Tyndall noted that much research is instead being done with adult stem cells. "In this way, you do not need to destroy an embryo, which in some religions and cultures is considered to be destroying an individual with a soul."

Rheumatologic diseases that are potential targets for stem cell research include "inflammatory disorders not responding to conventional treatment, since some adult stem cells—such as mesenchymal stem cells derived from fat, bone marrow, or placenta—exert anti-inflammatory and immunosuppressive effects on tissues without acute toxicity," said Dr. Tyndall. But despite recent attempts, the use of either embryonic cells or reprogrammed adult cells to replace damaged tissues "is a long way from reality," he added. "The problem is that the very plastic [embryonic] stem cells also form tumors called teratomas, and this has not yet been solved."

Lawrence Tabak, Ph.D., acting deputy director of the National Institutes of Health, expressed support for the executive order. "Researchers will now be able to pursue new knowledge about human development, regenerative medicine, and the origins of many of our most devastating diseases," he said in a teleconference. "This research promises to revolutionize how we predict, treat, and prevent many diseases, and will contribute to the development of lifesaving therapies. NIH will do its part to implement new policy and develop guidelines as expeditiously as possible to make sure the best science is funded and the research is conducted in a responsible manner."

The American Medical Association also applauded the change. "Stem cell research holds great promise to treat diseases that science has so far been unable to cure, and this change in policy will allow researchers to accelerate their efforts by applying for federal research funds," Dr. Joseph Heyman, chair of the AMA's board of directors, said in a statement.

"The AMA supports biomedical research on stem cells and has encouraged strong public support of federal funding for this research. [This] action by President Obama will help scientists realize the potential of stem cell research to benefit the many Americans living with diseases such as diabetes, Parkinson's, and Alzheimer's."

But Dr. David Stevens, CEO of the Christian Medical Association in Bristol, Tenn., cited problems with embryonic stem cell research. In addition to the moral issue, the prospects for embryonic stem cell research have been overblown, he said.

"We know that embryonic stem cells are difficult to culture and to control. … Even people in this field say that if treatment is going to come out of this, it's probably 20 years away."

Instead of spending money on embryonic stem cell research, "we should put our money where we can get real cures real fast"—with adult stem cells, which already have shown promising preliminary results, Dr. Stevens said. "If we have one path we can go down which is cheaper, less complicated, and gets us to cures quickly, why would we go down another path?" ■

HIT Incentives in Stimulus Package Causing Controversy

BY JOYCE FRIEDEN

WASHINGTON — The health care provisions in the federal economic stimulus package continue to spark disagreement between Republicans and Democrats, as seen at a diabetes meeting sponsored by Avalere Health.

Wendell Primus, senior policy advisor to House Speaker Nancy Pelosi (D-Calif.), noted three provisions of interest in the Recovery Act (formally called the American Recovery and Reinvestment Act of 2009): $87 billion in Medicaid funding to states; a 65% subsidy to laid-off workers who are still receiving health coverage from their former employers through the Consolidated Omnibus Budget Reconciliation Act (COBRA) of 1986; and $19 billion to be invested in health information technology (HIT).

Under the HIT component of the law, the government must develop certain technology standards, he explained.

One important standard is interoperability. "We have an example [of noninteroperability] right here in town," Mr. Primus noted. "The George Washington [University] Hospital just recently bought an HIT system for its emergency department and one for its inpatient department, and unfortunately those two systems don't talk to one other. We're going to try to make sure that doesn't happen."

Functionality is another critical standard. "If I have a doctor-patient relationship, I may know what I think your situation is, but I may not know the four doctors that have seen you since your last visit to me," said Mr. Primus. "I want [the medical record] to quickly be able to tell the doctor that's currently visiting that patient what has happened, and what the other four doctors have prescribed. We also want the system to be able to do reminders and things like that." The government also must develop standards for data security and for privacy.

The Recovery Act includes incentives of $40,000-$60,0000 for providers to use toward the purchase of an HIT system. Over time, "those incentives turn into penalties" in the form of reduced reimbursement from government health care programs if physicians do not adopt an HIT system, he said. "We're using the sticks of Medicare and Medicaid to make sure we get all doctors' offices wired within 8-10 years."

From the Republican perspective, Dan Elling, minority staff director on the House Ways and Means subcommittee on health, said some of the HIT provisions were problematic.

"We were glad to see HIT move forward. Having hospitals and doctors be able to talk to one another and coordinate care …is going to improve our health care system," he said. However, "the incentive payments don't start until 2011. If this is part of the stimulus bill and we're not spending the money for another 3 years, what are we doing?"

In addition, "each physician would be able to qualify for up to $64,000 in incentive payments, independent of the actual cost of the system," said Mr. Elling, whose boss is Rep. Dave Camp (R-Mich.). "So if you're part of a 20-doctor practice that's able to use economies of scale …and purchase an HIT system that costs $20,000 per physician, that doctor is able to pocket the extra $44,000. That's taxpayer money. We'd [prefer] language that says, 'You only get what you pay [out]' " in terms of reimbursement by the government.

Another big chunk of Recovery Act funds is the $1.1 billion for comparative effectiveness research. CER is designed to "make doctors and [other] providers smarter" by letting them know which treatments are the most clinically effective and the most cost effective, according to Mr. Primus. He said that CER is not "cookbook medicine," but is aimed at producing "better public knowledge."

Mr. Elling agreed that "done effectively, there's a lot of promise in CER. Getting more information to patients and physicians is outstanding and we should be doing that." But he added that "this is the camel's nose under the tent on government control of your health care," especially since the consumer effectiveness board that's called for in the bill comprises only government employees, with no practicing clinicians or patient advocates as members.

Mr. Elling offered a cautionary tale about CER. "We've seen how they apply [CER] in other countries," he said.

For instance, the policy at the U.K. National Institute for Health and Clinical Excellence, the organization that determines which treatments the National Health Service will pay for, says that "if you want the expensive drug for macular degeneration, you have to go blind in one eye before they'll give it to you for the other eye. That's CER right there." ■