Box 1 Plaudits and protests over stem cell reversal

Optimism spread among the biotech sector, only ten days after the 2010 budget was first announced, when the Obama White House lifted federal restrictions on hES cell research along with a strongly worded memorandum promising to "restore scientific integrity" in government decision-making.

On March 9, President Obama signed the executive order revoking President Bush's order that limited federal funding for hES cell research to those cell lines created before August 9, 2001.

Not surprisingly, the Obama change on hES cell research policy provoked a storm of protests mixed with high praise. For example, Senator Sam Brownback (R-KS), who refers to human embryos as "life," says, "no government has the right to sanction their destruction for research purposes."

But Representative Michael Castle (R-DE) says "Today begins the dawn of a new era in biomedical research in the United States, which holds so much promise for millions of Americans." Calling the Obama order "long overdue" and "only the first step," Representative Diana DeGette (D-CO) urges her congressional colleagues to "pass complementary legislation so that no future anti-science administration will be able to hinder progress."

Obama clarified his position on hES cell research later that day. "For embryos that are typically about to be discarded…to use those in order to find cures for Parkinson's or for Alzheimer's or all sorts of other debilitating diseases…that is the right thing to do," he says. "I believe that it is very important for us to have strong moral guidelines, ethical guidelines, when it comes to stem-cell research or anything that touches on…the issues of possible cloning…." The recently issued draft guidelines under development, he adds, "meet that ethical test."

exclusivity period falls short of PhRMA's call for at least 14 years, the timing in her proposal is much closer than the five years stipulated in the bills from Representative Waxman or Senator Schumer.

Other industry representatives see the Eshoo bill in a different light. It is a "pathway to biosimilars in name only," says Debra Barrett, senior vice president of government affairs at Teva Pharmaceuticals, of North Wales, Pennsylvania. Its call for 14 years of exclusivity would virtually "guarantee that a market had shifted to other products" by the time a particular biosimilar becomes available, says Barrett. One advantage of having such different bills before Congress, she adds, is that the sharp contrasts could prove "helpful for the discussion" now looming. "We're on the cusp of something happening in Congress, unlike a few years ago when opponents of biosimilars said that it 'couldn't be done and wouldn't be safe'."

Beyond the biogenerics issue, a striking feature of the 2010 budget issued in February is a shortage of figures specifying dollars for specific programs. Meanwhile, members of both the House of Representatives and Senate developed budgets of their own, although neither changes the thrust of the Obama Administration proposals regarding healthcare reform or other more specific biotech-related issues. By April 2, the House and Senate approved slightly different versions of fiscal year 2010 budget—the House passed a $3.6-trillion resolution, and the Senate voted for a $3.53-trillion plan. The two chambers will have to agree on not only the total budget but also the discretionary spending levels.

Two other major federal legislative spending packages will affect the biotech sector—the $787-billion American Recovery and Reinvestment Act of 2009, also called the stimulus package, which President Obama signed into law on February 17, and the $410-billion Omnibus Appropriations Act of fiscal year 2009, which was signed into law on 11 March and covers current federal spending programs through the end of the fiscal year, to September 30.

Some funding in the federal stimulus package is "available for industry and, although the amounts are low, everything helps," says Jenny Mather of Macrogenics of San Francisco. To obtain such funding, researchers at companies are required to submit proposals to the National Institutes of Health in Bethesda, Maryland, that compete with those from universities, meaning the funds lie outside the traditional Small Business Innovation Research program.

Meanwhile, the recently eased federal policy on human embryonic stem cell (hES) research (**Box 1**) could help to redirect some state-level resources to companies, Mather continues. For instance, the California

IN brief

Chugai reports Actemra deaths

Fifteen deaths links to Actemra (tocilizumab) have cast a cloud over Roche's first-in-class anti-inflammatory drug. Actemra, a monoclonal antibody targeting the interleukin-6 receptor, has been licensed as a rheumatoid arthritis treatment in Japan since early 2008 and touted as a potential blockbuster for the Basel-based Swiss company. Now, Roche's Tokyo-based partner, Chugai Pharmaceutical has reported that 221 patients among 4,915 taking the drug in Japan, in the year ending February, suffered serious side effects including pneumonia and severe fever, and 15 died. The company stressed that the death rate was at the same levels as in clinical trials and similar to competing medications. Chris Deighton, a consultant rheumatologist at Derbyshire Royal Infirmary, in Derby, UK says, "it's premature to be writing the obituary for Actemra," as severe rheumatoid arthritis is a disease with an intrinsically high mortality rate. Tumor necrosis factor blockers, such as Enbrel (etanercept) and Remicade (infliximab), although standard rheumatoid arthritis treatments, also have risks such as increased rates of tuberculosis and cancer and are not suitable for all patients. "We can't be complacent about these results," says Deighton about Actemra's side effects, "but we still need a lot more information." If Actemra is deemed unsafe, cautions Deighton, doctors will opt for other medications. Actemra was recently approved by the European Medicines Agency, but has not yet been licensed by the US Food and Drug Administration. In April, Genentech announced the voluntary withdrawal of its psoriasis drug Raptiva (efalizumab) from the US market because of confirmed links to brain infection. Raptiva has been associated with the rare and usually fatal progressive multifocal leukoencephalopathy. In Europe and Canada, where the drug is marketed by Geneva-based Merck Serono and Serono of Mississauga, Ontario, respectively, regulators had taken Raptiva off the market in February (*Nat. Biotechnol.* **27**, 303, 2009).

Asher Mullard

IN their words

"The most important next step is to secure the investment in Genentech and make sure that key scientists at Genentech don't jump off."

Swiss bank Vontobel's analyst Andrew Weiss provides Roche with some advice before completion of its merger with the US biotech. (*Dow Jones*, March 26, 2009)