

Europe reviews primate rights rules

Proposed changes to laws governing the use of nonhuman primates in research moved one step closer to adoption when the European Parliament voted in favor of the revisions last May. The changes would allow studies involving monkeys but prohibit testing on great apes, except for experiments intended to help conserve these species or for investigating new outbreaks of life-threatening diseases. Now, in response to a complaint from animal rights lobbyists, European Ombudsman Nikiforos Diamandouros said in February that he will look into the drafting process behind the changes.

The complaint, filed last year by the London-based European Coalition to End Animal Experiments (ECEAE), alleges that a

European Commission scientific committee that presented data on primate research to lawmakers did not have sufficient expertise. The ECEAE also says that the committee ignored evidence supplied by advocacy groups and failed to adequately consider alternatives to animal use.

"They simply assumed that nonhuman primate research is valid—therefore, they approach the task planning to justify the research," says Michelle Thew, chief executive of ECEAE. "It's simply unforgivable that the Commission has come up with such a one-sided report."

But Simon Festing, chief executive of Understanding Animal Research, a pro-research advocacy group in London,

dismisses such criticisms. "It's a last desperate effort from an antivivisection group that has failed in all its arguments," he says. "Most people who read that report [by the Commission's scientific committee] find it scientifically compelling," adds Roger Lemon, a neuroscientist at University College London who studies motor control in monkeys.

The legislation is expected to be adopted before the end of the year, although it will probably take another 18 months before European countries put the laws into effect, according to an EU spokesperson. The Commission has until the end of April to respond to the ECEAE's allegations.

Elie Dolgin, New York

State stem cell agency to fund clinical trials

Stem cell therapies in the Golden State might soon see the light of day—and the clinic. The California Institute for Regenerative Medicine (CIRM) announced last month that it will contribute up to \$50 million toward early-stage clinical trials for cells derived from embryonic or induced pluripotent stem cells.

The state stem cell agency has already put more than \$1 billion toward basic research in human cell cultures and animal models, and CIRM made an initial foray into therapeutics last year with its early translational grant program. In this new initiative, however, "we want to complete the pipeline from discovery to phase 2 clinical trials," CIRM president Alan Trounson told *Nature Medicine*.

Deepak Srivastava, director of the Gladstone Institute of Cardiovascular Disease in San Francisco, says the CIRM

announcement is important for academic researchers who "have faced a major road block with venture capitalists and companies, who find these therapies too risky for their appetite."

"With CIRM, we can finally fund this high-risk, but necessary, step," he says.

The agency expects to select up to two awardees before the end of the year and provide each the lesser of \$25 million or 50% of program costs. The money will be provided as a grant for nonprofit institutions and as a loan to businesses. Recipients are also required to provide matching funds.

Trials must take place in the state to qualify, and only companies or researchers with an investigational new drug (IND) application on file with the US Food and Drug Administration (FDA) are eligible for funding. Currently, that leaves only two known projects in the running: a treatment for spinal cord

injury by Menlo Park-based Geron and a therapy for Stargardt's macular dystrophy, a retinal disease, by Santa Monica-based Advanced Cell Technology.

"This kind of funding has been a long time coming," notes William Caldwell, chief executive of Advanced Cell Technology, which is still awaiting a decision from the FDA on its IND application. Caldwell says that his company has not yet decided whether it will apply for the award. Geron, whose trial remains on hold by the FDA, did not respond to requests for comment.

Should these or other companies secure funding, CIRM expects to see results within three years of the trials' start dates. "If these projects are able to get going and we have the chance to see efficacy in these trials, then that will truly be an important step for the field," Trounson says.

Christian Torres, New York

A timeline of new CIRM funding initiatives

