



March 9, 2009

President Barack Obama
The White House
1600 Pennsylvania Ave.
Washington, DC
20500

Dear Mr. President:

Thank you for lifting the Bush era restrictions on federal funding of embryonic stem cell research and returning to using sound, scientific practice and evidence, instead of dogma to guide federal policy.

Your action will undoubtedly spur new gains in this vital area of medical research. Celebrating the change in policy is not enough, however. It is now necessary, more than ever, to examine the regulations governing the way federal funds are distributed to researchers. A change in those rules is needed and we call on you to work with Congress to implement reforms of the Bayh-Dole Act.

Most of the federal funding for biomedical research is funneled through the National Institutes of Health. Basic scientific research is usually done at universities and non-profit research institutions, most of it with federal funds. Under the Bayh-Dole Act discoveries that are made at these institutions can be patented by them. They then license the patents to industry. The royalties go only to the universities and research institutions. Nothing is returned to the taxpaying public who funded the research.

Under Bayh-Dole, the public pays twice for medical discoveries. First we fund the research; then we are faced with high drug prices protected by the monopoly guaranteed by a patent. We believe the Bayh-Dole Act must be amended to incorporate these principles:

First, when the public has funded a discovery, the public should share in any profits from that discovery.

Second, if the public has paid for key discoveries, then government policies should guarantee affordable access to cures and treatments resulting from those discoveries.

Third, if the government has funded an invention, but the patent holder does not commercialize it, the government should be able to license the invention to someone who will.

Fourth, the results of all federally funded research should be available to all U.S. researchers for further research without a licensing fee. Once taxpayers pay to develop a technology, all researchers should have free access to it for further non-commercial research.

When venture capitalists provide money to companies they require clearly spelled out conditions and expectations. There is no reason it should be any different when taxpayers put their hard-earned dollars on the line to fund research.

This equitable approach to government funding of research is not a theoretical construct that has not been applied in the real world. California is an example of how it works.

The California Institute for Regenerative Medicine (CIRM) was created by the voters of California under Proposition 71 to partially fill the void created when President Bush imposed the stem cell funding restrictions. Its \$6 billion program makes it the world's largest funder of stem cell research.

Key elements of its Intellectual Property Policy regulations are provisions for a payback to the state. For example, if there is revenue to a research institution as the result of publicly funded research, 25 percent goes back to the state's general fund. The IP policy also has provisions to help ensure affordability and access by uninsured people to cures and treatments that were developed with public money.

California's stem cell policies are a good model to start the necessary revisions to the Bayh-Dole Act. Here is a link to those regulations:

http://www.cirm.ca.gov/reg/pdf/consolidated_regulations_OAL_notice.pdf

In addition CIRM's ethical guidelines for stem cell research are a good model for federal policies. They are found here: <http://www.cirm.ca.gov/reg/default.asp> .

The premise of the policy we are suggesting is simple: The public should share equitably in the fruits of the research for which it paid. We call on you to take the necessary steps to make this goal a reality.

Sincerely,


John M. Simpson
Stem Cell Project Director