Straight talk from... **Robert Klein**

After a two-year struggle, the California Institute for Regenerative Medicine (CIRM) has distributed $121 million for embryonic stem cell research. Erika Check speaks with Robert Klein, who played a major role in writing and financing the ballot initiative that led to CIRM's creation and now chairs the institute's Independent Citizens Oversight Committee.

How did you award the grants?

We have a three-stage process.

The applications first go to the scientific and medical grants working group, which is composed of 15 scientists and physician scientists and 7 patient advocates. Following peer review by the scientists, we come back on a second day and go through a programmatic review.

Those recommendations go to the board. There is a [closed] executive session during which board members may go through the full grant applications without compromising the confidentiality of proprietary information. Anyone with a conflict is barred from discussion. After that, we go into a public session and cast our final votes on the allocation of funds. If 35% of the [grant review] group feels strongly about an emerging technology or a position, they can also file a minority report that goes to the board to permit the rise of brilliant new ideas.

Why don't you want certain kinds of information about the review process to be public, such as financial information about the reviewers?

At the scientific working group level, we have extensive conflict provisions. The public knows they are all [from outside California] and can research their backgrounds.

Second, we have very deep conflict provisions so you cannot have a financial conflict, you cannot have published with someone in the past three years, you cannot have been their mentor and you cannot have a family relationship. Anyone who does not meet those requirements leaves the room during discussion and cannot vote. Legislative auditors can also audit our provisions to make certain we are monitoring conflicts.

When I wrote the initiative I looked at practices throughout the country—at patient advocacy groups, grant-making organizations and the National Institutes of Health (NIH)—and came to the conclusion that if we are going to attract the best and brightest minds, we have to give them confidentiality for their brilliant new ideas.

Those wanting more financial disclosure fall into two categories: people that legitimately want as much public disclosure as possible and those who are ideologically opposed to the research and make unreasonable demands for public disclosure as a way to undermine the research. This is a dynamic balance and we will provide as much disclosure as possible.

How do you respond to criticism of CIRM's patenting policy, that it's too strict and sets a bad precedent for other states?

I doubt that industry or public interest groups or patient groups will be completely pleased. But I would point out that the patient advocates on the board are highly focused on getting therapies to patients and it is critical to them that these patents be reasonable. The consensus on the board is that we have a reasonable balance and we will continue to adjust that balance if we find it's unreasonable.

People say the popular funding model should be tried in other areas of science. What do you think?

It was critical to create Proposition 71 to provide a legal sanctuary for this research against the uncertainty created in 2001 and 2002. Other areas of research don't have the same ideological pressures and don't need the same legal sanctuary and long-term funding stability.

Nevertheless, I think the new Speaker Nancy Pelosi has said it's a national disgrace that the NIH budget has been allowed to decline in a period of critical need. It's going to be vital that there is a paradigm change in funding of general science research, whether in climate change or medicine or any other area. We need to look at these areas of scientific research as investments in the intellectual property of the nation. They're not operating expenses that should be appropriated on a one- or two-year cycle.

How long can you stay in the job?

My term is six years, starting from 17 December 2004.

What will you do when it's over?

Take a vacation.

I hope I will have contributed the maximum amount possible by then. There are significant financial, legal and development objectives where I think I can make a special contribution. For example, to date we've focused on the grant-making authority but we have a capacity to provide a loan program which I think will be extremely important in the for-profit sector, particularly because it gives the public more predictability on payback through the public agency.

"We could potentially have $1 billion coming back to the agency as loan repayments."

That means that in years 8, 9, 10 and 11, we could potentially have $800 million or $1 billion coming back to the agency as loan repayments that could then fund another round of grants and loans. That is a particularly important time period because we may well be in early stage clinical trials or preclinical trials that would require substantial funding.

Do you personally believe that cures will come from CIRM?

We need to be conservative in what we project as achievable to keep expectations reasonable. On the other hand I tend to be optimistic and I intend to aggressively try to move the program forward to develop scientific tools.

You became involved in this research because of your son, correct?

Yes, my youngest son, Jordan, was diagnosed with diabetes at age 11 on 20 December, 2001. I immediately as a father wanted to make sure he didn't have to struggle with the fear of this disease for his entire life.

Since taking on such an active role, do you see your son much?

Yes, Jordan lives with me. We sometimes have to get up early in the morning and sometimes share discussions late at night but I try to create a priority for his schoolwork, movies and just being together. It's obviously challenging—but we are very close.