May 23, 2005 ICOC Meeting Minutes

The Tech Museum of Innovation
201 South Market Street
San Jose, CA

David Baltimore	Present
Robert Birgeneau	Present
Keith L. Black	Absent
Susan V. Bryant	Present
Michael A. Friedman	Absent
Michael Goldberg	Present
Brian E. Henderson	Present
Edward W. Holmes	Present
David A. Kessler	Present
Robert Klein	Present
Sherry Lansing	Absent
Gerald S. Levey	Present
Ted W. Love	Present
Richard A. Dr. Murphy	Present
Tina S. Nova	Present
Ed Penhoet	Present
Philip A. Pizzo	Present
Claire Pomeroy	Present
Phyllis Preciado	Absent
Francisco J. Prieto	Present
John C. Reed **Surrogate: Jeanne Fontana**	Present
Joan Samuelson	Present
David Serrano Sewell	Present
Jeff Sheehy	Present
Jonathan Shestack	Present
Oswald Steward	Absent
Leon J. Thal	Absent
Gayle Wilson	Present
Janet S. Wright	Present

PUBLIC COMMENT

Don Reed: We will never surrender

Agenda Item # 4
Approval of minutes from May 6, 2005 ICOC meeting.

Motion

- Mr. Serrano-Sewell moved we approve the minutes from the 5/6/05 ICOC meeting.
- Dr. Holmes seconded the motion.

Vote

- All in favor
- No opposition
- Motion Carries

Agenda Item #5
Consideration of adoption of NAS Medical and Ethical Standards as CIRM Interim Standards.

Following a presentation by CIRM Interim President Zach Hall on the NAS Guidelines, the board discussed the guidelines and whether to put them in place as the CIRM Interim Guidelines.

- With the current funding policy at the NIH for human embryonic stem cell research – read: limited – there has been just a patchwork of local guidelines developed by different institutions in different places.
- There has been an absence of generally agreed upon guidelines and national consensus.
- In order to address this issue and promote responsible stem cell research, the NAS took on the project of developing guidelines.
- Their appointed committee, chaired by Dr. Richard Hynes of MIT and Dr. Jonathan Moreno of UVA, held a two day workshop on the issues.
    - They also used the internet and other means to get public opinion, and invited several speakers to appear before the committee.
    - They then drafted the guidelines, which were reviewed by 14 expert reviewers, leading up to the announcement of the guidelines on April 26th.
- Our Standards Working Group will go through a similar process over the next six to nine months to adopt our long-term standards. In the meantime, we would like to adopt these interim standards for human embryonic stem cell work.
- The issues the NAS committee addresses are:
    - The donation of blastocysts, gametes and somatic cells
    - The characterization of stem cells
    - Safe handling and storage of blastocysts and stem cell material
    - The prerequisites to human embryonic stem cell research
    - Appropriate uses of human embryonic stem cell lines and limitations on their use
    - Safeguards against misuse
- One suggestion the NAS made is that research institutions should establish Embryonic Stem Cell Research Oversight Committees, to have oversight of all embryonic stem cell research at a particular institution.

- Oversight committees would perform several functions, including:
    - Ensuring the provenance of human embryonic stem cells is documented – know where each line came from and under what conditions it was created.
    - Ensure there is no research in which human embryonic stem cells are introduced into a nonhuman primate blastocyst or in which any kind of embryonic stem cell is introduced into a human blastocyst.
    - Ensure that no animal in which human embryonic stem cells have been introduced should be allowed to breed.
    - Other functions of the Committees include maintaining a registry and ensuring suitable standards for work to be done at international collaborations where guidelines may be different.

- The NAS also suggests there be a national body that continues the assessment and discussion of these guidelines. They didn't suggest who the body might be. A number of us feel they are the logical body to do this – the NIH can't do it and we don't want a vacuum there for people rushing in to do it.
    - With the ICOC's permission, Dr. Hall would send a letter to the National Academy on behalf of the CIRM recommending the National Academies provide this national oversight body.

- Korean paper published last Friday in "Science" had one American author who is at the University of Pittsburgh. He made the comment that if he did this research in his home state, he would be a felon, but at any rate, we anticipate international collaborations.

Chairman Klein: Thank you Dr. Hall. I'd like to point out the National Academies, in their report, cite Proposition 71 as the model for the highest standard for prohibiting compensation for egg donors to make certain that this donation is motivated by the moral desire to advance medical research to reduce suffering.

Dr. Baltimore: These are a terrific set of guidelines to go forward with. I have no particular problem with any of them – very thoughtfully put together. One nit: they require all institutions conducting research should establish an escro committee, an embryonic stem cell research oversight committee. Dr. Henderson and I think it might be preferable to have one committee that dealt with a number of institutions because it is very hard to find people who are involved in assisted reproduction and the other particular expertise indicated in the outline for the committee.

The guidelines don't prohibit that. I just want to put on the record the understanding that a committee could represent more than one institution.

Chairman Klein: My understanding is that there is nothing in the guidelines that would prohibit having a much higher quality benefit of inter-institutional committees, and such inter-institutional committees would fill the role and be appropriate.

Dr. Hall: I think so. I don't think the guidelines speak to this in an explicit way. But I see no prohibition against this.

Ms. Samuelson: We might have the necessity of approving these guidelines to have something in place, but I wonder if we have the opportunity of having our own Standards Working Group review these guidelines and give us their evaluation before we do.

Dr. Kessler: I think the feeling is that the Standards WG will have an opportunity to review these, but with training grants to initiate process, would be unfair to the Standards Working Group if we required them to do this with any haste. We want to have something in place – the thoughtful and deliberate thinking of the NAS – and do exactly what you're asking, but to give them time.

Dr. Hall: Harriet Rabb strongly supports the guidelines. She foresaw the Working Group would start with this. Our intent is to have something in place to move forward with. Rather than having the Standards Working Group have to approve something quickly, better to have this in place and then have the Working Group go forward with an in-depth investigation.

Chairman Klein: The Initiative spells out that the process is one where public and institutions have the benefit of immediate clarity on the guidelines because we adopt interim guidelines, then have an extraordinary long public hearing and review process to bring in public comments. The Administrative Procedures Act requires that we publish contemplated changes, get comments on those and then adopt final guidelines.

The public gets the advantage of understanding we have a national group with tremendous credentials which drew up guidelines, which will then be reviewed over our 270-day period. It will have a complete vetting in the public forum.

Dr. Hall: If we are to get Training Grants out in fall, they can't set the ESCRO committees up in a day. Passing this now gives notice to institutions this is what they will be expected to do.

Dr. Prieto: Do guidelines go into how institutions should go about appointing their ESCRO committees, or do we want to provide some guidance?

Dr. Hall: It does not. It does list the kinds of personnel that might be there, members of the lay public, experts in reproductive medicine, molecular biologists, developmental biologists, ethicists.

Mr. Shestack: Is there any reason why the Standards Working Group might not decide to recommend that the state of California form one ESCRO committee to make things move faster rather than having every institution do it?

Chairman Klein: During the public hearing process, that is clearly an option.

Dr. Hall: It is very important for institutional collaboration that one institution be able to accept approval by other institution. If we have these NAS guidelines, process is much easier. It's in our interest to want to have that happen in California – in the interest of the CIRM.

Dr. Kessler: I was watching the Sunday shows yesterday, the nation is focused on stem cell, especially this week. One of our jobs is to help educate the American public so they have confidence in where the lines are here. Using words like primitive streak is not

great for the average citizen. Can you help, talk for a minute or two: what does the public need to know about the guidelines?

Dr. Hall: Nobody believes in reproductive cloning. There is no agenda to produce an organism here. There's the intent to produce a cell line for therapies. So we're not cloning human beings.

Dr. Kessler: There is confusion in the public around the word cloning. We're not cloning human beings, correct?

Dr. Hall: Yes, that's the distinction you are driving at. We are cloning cells. We're not cloning organisms, without a doubt.

Dr. Prieto: A more direct way to phrase this in what we say to the public. The use of word cloning is unfortunate. These are cells that have never seen and will never see the inside of a uterus.

Motion

- **Dr. Henderson**: Move approval of the guidelines as interim guidelines for this organization.

- Second: **Dr. Bryant**

BOARD COMMENT

Ms. Samuelson: I recommend we issue a statement along with adoption of these guidelines, saying we're not in the business of cloning, very clear and in plain language.

Chairman Klein: An affirmative statement, yes, saying we are moving this recommendation and emphasizing that California has put a prohibition of reproductive cloning in the constitution. We'll make sure for the public it's a very clean line drawn in this doc.

PUBLIC COMMENT

Don Reed: I agree with Joan Samuelson – you really need to make it clear – no sperm, no uterus, no pregnancy, no baby at all - overkill that, it must be crystal clear.

Dr. Paul Berg: A very useful term to defray the concern about the general public is to keep referring to what we're doing as "patient specific stem cells" and 'disease specific stem cells". The Australians and now the South Koreans are using these terms.

Mr. Shestack: If we start internally working to change our vocabulary on this, perhaps the world will follow.

Dr. Pomeroy: One additional point to clarify motion: the implication of adopting these as Interim Standards is that we will have an extensive public hearing process about these, and that if there is anything not appropriate to the state of California, that's something

the Standards Working Group will make recommendations to the ICOC about. It's important to make sure the process is clear.

Chairman Klein: Right, these would be referred to Standards Working Group and that group will begin process of public hearing with oversight by the board. Is the maker of the motion amendable to having that understanding?

Dr. Henderson: Certainly. Also, Dr. Hall's suggestion about directly contacting the Academy about its continued leadership in this area is an important thing to do as well.

PUBLIC COMMENT

Mike Clayes: The CIRM and the ICOC are leading the country. There is a tremendous opportunity and responsibility to lead in educating the public and commentators.

Chairman Klein: I recognize you as someone who's done a lot of work with the Michael J. Fox Foundation nationally.

Vote

- All in favor, no opposition
- Motion carries passes

Agenda Item # 6
Chairman's Report

Dr. Paul Berg: re. State legislation – SCA 13 - its provisions would cripple the CIRM. Ortiz was one of the initial people involved with Prop 71 and knew full well the text of it. Strange she's pushing through SCA 13. Peer review must be done confidentially. Grant apps will be unwilling to have ideas, experiments and unpublished results discussed. Turning to another provision: current NIH guidelines have drawn ire and ridicule of scientific community. They are making revisions to soften impact of original published guidelines. What logic can be imposed on individuals…ICOC could not exist in present form if had to follow NIH policy. ICOC should adopt NAS COI policy – members of these advisory bodies declare all matters of COI. Not time to comment on all provisions. Same can be said re. patent applications etc.

The presupposition that there will be substantial royalty streams from the CIRM's patented research discoveries is counting chickens long before they've even been conceived.

Agenda Item #8
Consideration of State legislation- ACR 1 (Negrete McCleod): ACR 24 (Mullin): SB 18 (Ortiz/Runner); SCA 13 (Ortiz/Runner)

Chairman Klein: Mr. Berg's suggestion SCA 13 would cripple the CIRM is appropriate. Language is extraordinarily important, must be clear. I have asked Senator Ortiz to meet with me and several groups; she declined. We invited her to the NAS Workshop in Dec.; she chose not to attend those meetings. She decided to go a different direction without working with the best minds in the country.

The ability to fund the best and brightest science in this state is being impeded.

We are not being given an adequate opportunity to bring forth the experts in the state to get heard on these items.

We're hopeful this Thursday we'll have opportunity to participate in the Appropriations Committee Hearing.

We understand the Appropriations Committee is focused on financial issues. We wanted to be able to address thoroughly with experts. Senator Migden, the chair of the Appropriations committee, is insisting we have an opportunity to make a presentation.

On the other side, I have great faith in the legislative process, that there will be opportunities. The assembly has been thoughtful in its approach, setting up the California Council on Science and Technology and its task force to look Intellectual Property policy. Dr. Susan Bryant and Michael Goldberg from this board serve on the task force.

We don't understand this rush to judgment on the Ortiz bill, attempting to put in place an entire policy on Intellectual Property without even hearing the Assembly's Task Force input.

BOARD DISCUSSION

Ms. Samuelson: I'd like to take it up a level, speaking as a patient and a voter. Being a member of this committee is an honor, but I'm also a patient and a voter. And I voted for Proposition 71, and I can't overstate the immense hope its passage gave me. I know this initiative well, and I believe it promises me breakthrough therapies for the cure of Parkinson's disease far sooner than otherwise, it will make a difference for many and will perhaps save my life.

And so I take this very seriously. I looks at the series of provisions covered in SCA 13. Every one of these very issues were tasked to us by the voters. We have been working as hard as we possibly can. I learned in two days in Irvine at the NAS workshop that that issue is intertwined whether and how fast we would get cures. It is intertwined with incentives given to scientists and with the issue of delivering revenue back to California. It is immensely complicated. We need experts from around the world to do this and do this right away. The thought that this task being lifted off our plate is wrong. It undermines this process and what Prop 71 gave us. It could very well lead to extra suffering and deaths. This might sound inflammatory, but I believe it.

Dr. Birgeneau: Speaking as a leader as one of our premier public research and teaching universities. Our great research and teaching universities in the United States are the envy of world. One of the fundamental bases of that is the fact we are able to

make very strict judgments on who we hire and on the research they do, both done through the peer review process. In order to have a viable peer review process, we rely on peers being able to say exactly what they think – in a candid way without worry about their views being made public. We wouldn't get candid information if it was to be presented publicly. The only possibility is that the caliber of the research we'd be carrying out in the stem cell field on behalf of the people of California would inevitably be compromised because we could no longer have the kind of information needed to guarantee these dollars be spent in the best way possible.

Dr. Pomeroy: We're at a critical juncture, the decisions we make now will set a tone for how we do our work and how we're perceived by the public. I am a strong supporter of confidential peer review, it is essential to the academic process. We know that in academia because we've seen it. As a committee, we have a big responsibility to be inclusive in our discussion of these issues. As we consider a resolution here, we may want to modify it saying that SCA 13 in its current form is problematic but we'd like to work with the public and various constituencies to discuss and modify it.

Chairman Klein: The resolution is meant to be about current form. Ortiz was a strong supporter of Prop 71. We will continue to reach out to find ways to work with all constituencies and with Senator Ortiz. We do share goals. The issue is the current language.

Dr. Prieto: I appreciate the comments from Joan and Dr. Birgeneau. I'm a patient advocate and a physician who sees patients every day suffering from these chronic diseases. I think it's premature for us to take a position in opposition to this bill. I don't want to see us drawing lines in the sand that don't yet need to be drawn and may hurt us if they get drawn.

Dr. Henderson: Is there any other experience from anyone on this board or Dr. Hall related to this legislation? I'm uncomfortable taking confrontational posture unless absolutely necessary. It seems to me it is taking this committee away from our primary work. Dr. Hall, have you talked to her?

Dr. Hall: I have not spoken to Ortiz. I'm happy the language has changed somewhat. We're poised to move forward and are being weighted down with a struggle that is unnecessary and is very distracting from our real mission.

Request made to James Harrison to provide insight into some of the legal issues with the language and the risks it has.

Mr. Harrison: Looking at page 3 of 3, section 9 (a) (1), this is a provision that reads: notwithstanding Section 6, the contract, award, grant, loan or other arrangement does not result in a gift of public funds within the meaning of Section 6 of Article 16. The state constitution prohibits the state from making a gift of public funds. Proposition 71 declared that conducting stem cell research in California served a public purpose. The provision appears to require the ICOC to make a determination that each grant, loan or contract does not result in a gift of public funds, so it raises a question about what standard would apply. If the people in adopting Proposition 71 have already declared that conducting stem cell research serves a public purpose, what more would you need to demonstrate in order to satisfy this new constitutional standard?

The language is vague and ambiguous, and therefore raises the possibility of legal challenges. Something that will be added today: a provision prohibiting members of the board from having financial interest in grant applicants as well as entities that do a substantial amount of stem cell research. It is likely intended to mean investments, but might be vague enough to mean source of income of $500 or more. In other words, if you receive $500 or more from a grant applicant, you would be precluded from serving on the board.

Chairman Klein: That means any member from a research institution on this board would have to resign.

Mr. Harrison: Right. The language may not be intentional. The language creates creating uncertainty in these 2 areas.

Dr. Levey: The UC system gets continuously challenged with legislation that is antithetical to the mission of the UC System. The UC Government relations office puts out analyses and we put out our position, for and against. I don't think we need to be obsequious with Senator Ortiz. We happen to strongly disagree with what she's saying. I think we should take a strong and respectful stance here. I congratulate Mr. Klein – he's gone the full nine yards to work with her. We can respectfully disagree with her and oppose the legislation she is sponsoring.

Mr. Sheehy: I'm an appointee of the Senate. I've spoken with Peter Hansel, Senator Ortiz's aide, at length many times. I've met with him in Sacramento. I've offered to meet with Senator Ortiz and she has not taken me up on that offer, or offer to bring anything back to this board to negotiate.

We need to sit back and ask ourselves what we've done wrong. What have we done wrong? We've conducted all of our business thus far in public. And I'm proud of my service on this board. I'm proud of the service of the people I've been serving with. We need to say that to the people of California. People have been beating us up, and there's just no reason for this to happen.

This bill is a disaster. It's being rushed the ballot with haste that is irresponsible. It's poorly drafted. The measures in the bill, especially on Intellectual Property, do not belong in the California Constitution. She wants to amend the constitution of the state. This is highly inappropriate. Senator Ortiz may be well meaning, but to steal hope…cures won't be here tomorrow. How dare she steal hope from the patients of California?

Chairman Klein: Mr. Sheehy and Mr. Serrano-Sewell brought up the conceptual change to our working policies to have Standards Working Group meetings be open with modifications for patient privacy and other exceptions as appropriate. We are working with counsel to bring this back to the board. On agenda today, we have Facilities Working Group COI policy and recommendation for meetings to be open as much as possible. So this board has moved forward in a very thoughtful way, through 29 public meetings in the last 22 weeks. The NAS has portion of their hearings on standards that are open and rest are confidential. Senator Ortiz knew we were working toward open meetings on Standards.

Dr. Levey's position is well taken. It is part of the process. They need to know if we are in opposition based on its current position. We continue to make every overture possible because we have common goals.

Mr. Serrano Sewell: Jeff, Joan and I wrote an op ed that appeared in the Chronicle, "Give Patients a Chance". If enacted as presently drafted, SCA 13 will impair our efforts to fulfill our mandate to find cures and therapies. Every effort to communicate with Senator Ortiz' office has been made, want to work with her, she's our friend. We have to be able to say we disagree with her, we're opposed. The central tenets of SCA 13 haven't changed. We've got to move forward and communicate in a clear manner to the legislature where this committee stands.

Dr. Baltimore: If this was a piece of legislation at the national level that was counter to the scientific community, and we have friends in the legislature who will oppose things that don't make sense, we can bring muscle to bear to see this is carried out, why are we focused on Ortiz? Where are our friends? If we have none, the situation is a lot worse than just one person who's conceived of a misconceived bill.

Chairman Klein: There are people in the legislature such as Gene Mullin in the Assembly working constructively. He now has ACR 24, making it clear they are looking to the Science and Technology Council for intellectual property policy. There's also Negrete-McLeod which we support. We started on Ortiz legislation because Dr. Berg spoke about SCA 13. The issue has also been that the hearings are scheduled on days that we have full public hearings ourselves and we cannot get to those meetings with our representatives. We can't get our message out there with regard to why we are opposed. We have one Legislative/Government Relations staff member and that person has had other word as we've gone through 29 public meetings with our limited staff.

Dr. Pizzo: It's hard to imagine this group could have worked more diligently. Two things: we talk about public trust, but it has to be bilateral. We're seeking the trust of our community. We also should hope our community, including Senator Ortiz, have trust in us. We've given much evidence for that.

We have reached out and talked to people serving on these advisory groups. We've gotten support for all we're doing and recognition that the processes we've put in place are the right ones.

We need to have a broader, more open discourse with those legislators who have been persuaded Senator Ortiz is correct. Maybe our next visit should be to Sacramento, as a board, to meet with legislators.

Ms. Wilson: The reason they're in such a hurry is because they have a June 30 deadline to get this on the November ballot if there is a special election. They need a 2/3 vote in both the Senate and the Assembly, which is not easy. We are focusing just on Ortiz but we don't need to be. We each have senators and assembly members in our districts. We need to talk to them. They are being persuaded by people who don't have our best interests at heart.

Dr. Pizzo: Mr. Chairman, you should look into a trip to Sacramento for the board as a body, to meet with those who are voting, I think, not in the interests of the citizenry because they're not informed about what's happening. We should have a dialogue that

helps them to be better engaged in making an informed decision for the citizens of California.

Chairman Klein: I will take that suggestion and bring it back to the June 6 meeting. Perhaps we should push back our July business meeting so we can go to Sacramento

We should not be speaking to Sacramento with a single voice; everyone on this board has a powerful voice.

June 30 is their qualifying deadline. We will bring back to the 6/6 meeting.

Ms. Samuelson: can we afford to wait until July? Or should we commit our June meeting?

Dr. Wright: I agree with Joan. I think that's a great idea. Reflecting on the comments of this group, I hear three themes. The first I heard was trust – we want to build on or renew the trust we had. The second theme I hear is hope and optimism. And I speak not only for diseases that have affected my family, but as a cardiologist, every day I meet people who would benefit from this research. I am energized by the potential that we have to do good here and I don't want anything to step in the way of that.

The third theme was most beautifully stated by Jeff, and that is respect. It is respect for the voters of California, and subsequently respect for the work of the legislators. But also respect for this board and for the amount of time that these experts around the table have devoted to the project. Self-respect is very important. As a board, I think we need to go to Sacramento and help educate those who have not fully understood the impact of this proposed legislation.

Mr. Shestack: Gayle Wilson gave us a very specific message, which was that we have to be working with our representatives in our districts. It is not the best use of our time to try and change Senator Ortiz's mind. It is a complicated process and not so easy for her to win. Gayle gave us specific political advice on how to handle this situation, how to reach out. I feel motivated to ask the families in the mental health community – not to go to Sacramento but to go to their district and meet with their representatives, meet their Senators and Assembly members and explain it.

Gayle Wilson: All politics is local. We'd like to think people are looking at what's best for the state, but if they see a letter of a phone call coming from someone in their district, not some other district, that means something. I hope there is also a bigger view than that, but having people from their district weigh in on this issue will get their attention.

Chairman Klein: The other area we haven't yet touched on deeply are the Intellectual Property provisions, suggesting we set royalties and patent revenue at a level that would recoup 100% of the cost of the research for the state.

I don't know of any precedent in the nation for assuming you can set royalties at a level they would have 100% payback of the scientific costs.

It will also create problems for bonds, making them taxable, which would actually increase the cost to the state.

The legislature has the ability to set aside part of IP revenues for compassionate care. That's in their domain.

Another issue is that she's approaching all diseases as if they are the same. It would be a disservice to the patients and the state. We need to address affordability for patients of lower income, and that can happen through IP revenue. The other approach to this same goal may disable the whole ability to develop therapies at all. I think some of the members of this committee have been exposed to that background in terms of what happens if you take the approach outlined in SCA 13 with price fixing. Does anyone want to comment on that?

Dr. Bryant: In working with the CCST to develop an IP policy suitable for grants, and particularly for the CIRM, many issues have been discussed, including many of the ones you mentioned.

The Bayh-Dole Act has been successful in allowing research to go forth and encouraging products of research to be picked up by industry. In the biomedical area, there is a huge gap in time between when something is developed in a university and when that product is ready to be applied to people. Bayh-Dole has captured it and allows for it to happen successfully.

There was an experiment done at NIH where they tried to enforce reasonable pricing on products coming out of the internal NIH program. What it did was reduce to zero number of companies who would come in and take on some of the inventions because they were not willing to put up a huge investment without knowing ahead of time what their obligations would be and whether they would even be able to cover their costs.

It's complicated with lots of things that can unbalance situation. Also, down the line, federal and state funds may be able to mix. If we do have that, in order to handle funds at an institutional level, it would be important that our policies are consistent with federal policies.

Dr. Love: I'm angry and disappointed. I think as a group we should feel comfortable expressing that. This is a very serious initiative we've all engaged in. The people up here have taken it seriously, we're focused on doing something to help patients in CA and throughout the world. This effort (SCA 13) is really a problem for us, and I think we need to be very clear about being against it – not to be adversarial, but to be clear this is a serious initiative.
Just last week I met with a group of venture capitalists in the Bay area. To tack a burden on to VCs, with the length of time to getting any return, is wrong. It will cripple the whole process of what we're trying to generate here in terms of making therapies available for patients. It takes $750 million to $1 billion to make one successful company in biotechnology. $3 billion is a lot of money, but it is nowhere near the kind of money that will be required to make therapies actually available.

Dr. Nova: That was well summarized by Dr. Love. Coming from industry, we have a different perception about IP. If we don't follow guidelines like what Dr. Love just said, we will kill the industry because without the venture capital support in the end, this will not become a reality. I think we should be very strong on this issue.

Dr. Levey: Bob, you have your network of supporters from Prop 71, many in LA, we can ask them to write letters if they are in agreement with our position.

We need some advice from government relations experts. When we go to Sacramento it, must be well planned out.

Chairman Klein: We are working with research institutions and patient groups and their government relations groups. I'm going to Sacramento to meet with Senator Ortiz to make clear we're opposed based on the current language, but want to try to get language that does work.

Dr. Holmes: I'm supportive of this discussion. I'm supportive of approaching wide range of individuals. There are 5 of us from UCs. There are prohibitions of employees of the UC system with regard to lobbying particular pieces of legislation. Wouldn't want my voice to be muted. I support the board's position.

PUBLIC COMMENT

Don Reed: This is being proposed as a tinkering in something that's wonderful, minor tinkerings to make it run right. If she thinks it's that way, the only thing that will stop her is a strong opposition. Legislators like power and oversight; it's in their nature to control. Their first instinct is going to be to go with her.

What she's attempting to do with peer review is radical. It goes completely against the present set up for peer review.

The attempt to make this affordable has been tried before. The NIH tried it. It was a disaster. Before we have affordable computers, we must have computers. The greater good is the benefit of this, not the small tinkering, which will slow the whole thing down. We have to fight. Can't sit back and watch and wait for others. You are individuals and are the experts. If you don't speak up for us, we're going to lose.

Chairman Klein: It is still my hope Ortiz is for the same goals, and the language can be changed, but think it should be communicated the current language in SCA 13 is a mess.

Motion

- ***Vote on opposition position on SCA 13:***

- ***Moved: DSS***
- ***Seconded: Levey***

We are opposed to the current language of this bill. We are opposed to it passing with the current language.

Dr. Kessler: Our job as state officials, with regard to taking positions on certain bills, can we do this?

Mr. Harrison: You as a board can take a position on this legislation. Particular members' lobbying I will look into.

Dr. Baltimore: I think this legislation will make it impossible for CA scientists to play a constructive role in the development of knowledge or therapies that can come from stem cell research.

We should say it is our opinion that this legislation will make it impossible.

Mr. Serrano Sewell: I accept that amendment: "will make it impossible for scientists to do job".

Add "and delay critically needed research, etc.

Dr. Pomeroy: I have concerns about voting on a motion that is nebulous. We have to be careful about making a simplistic motion that includes notion we believe in COI rules, etc. This language is problematic. The motion doesn't capture full spectrum of discussion.

Chairman Klein: There will be a later discussion in greater detail. We're just addressing SCA 13 right now.

With regard to the exact motion we're voting on, we will have staff and legal counsel write something out during lunch and bring it back.

Dr. Kessler: Anything we say needs to be done thoughtfully, explaining why we're doing what we're doing. We just had an excellent 2 hour discussion of the issues here.

Chairman Klein: Our desire is to take a preliminary position.

Dr. Henderson: There was a letter sent to Senator Ortiz and others about SCA 13, from Presidents of top California institutions. If we endorsed that letter, would that take care of this?

Dr. Hall: 2 jobs need to be done – we need to address in a substantive, thoughtful way the things addressed in the bill. The second thing we need to do is to say clearly that the consequences of passing this legislation as written will cripple us, stop us in our tracks. Let's just say "here are the consequences."

Dr. Baltimore: That's right. We need to tell Legislature that they need to take time to think about these things. We have to tell them the way its written will stop us from doing our work. We are opposed to it.

BREAK

Adjourn for CLOSED SESSION

Back to Agenda Item #8
Consideration of State legislation- ACR 1 (Negrete McCleod); ACR 24 (Mullin); SB 18 (Ortiz/Runner); SCA 13 (Ortiz/Runner)

The drafted proposed language was presented on the screen.

BOARD DISCUSSION

Dr. Bryant: how about extremely difficult if not impossible?

Change to language made.

Chairman Klein: can we take public comment on this language as well? Is there any public comment?

PUBLIC COMMENT

Don Reed: As a former reporter I would like to see the first sentence as a purpose. I would like to see the first sentence saying "do not support.

Motion

- **Motion by David Serrano Sewell and**
- **Second by Dr. Levey**

Vote

- **All in favor**
- **No opposition**
- **Language approved**

Agenda Item # 10
Consideration of Conflict of Interest Policy for Facilities Working Group

Dr. Hall: I think you all have in from of you agenda item #10. This is a policy that was drawn up really to be an adaptation of the policy that we used for our Grants Working Group to make it appropriate for Facilities Working Group members.

Motion

- Dr. Henderson moved approval of the COI policy for the Facilities Working Group
- Ms. Samuelson seconded

PUBLIC COMMENT

Jesse Reynolds: I feel this policy captures some of the inadequacies of COI policies for other 2 working groups. It's a self-recusal policy. There's no real substance to such a conflicts policy. My question is: is it still the case these COI policies and the meeting policies for the Working Groups are interim and there will be public hearings to revise them?

Chairman Klein: Yes, that's correct. We need something in place as a good starting point. Your point regarding disclosure in advance is a good one. The disclosure point is included in Grant WG COI policy. It will be covered in public hearings.

Dr. Hall: It is the responsibility of CIRM staff to make sure reviews are done completely free of conflicts of interest. We will get this information and use to alert them they may have conflicts of interest. We will not make these documents/this info. public – they're not on the board or staff, but are an advisory committee.

Mr. Harrison: The act provides in section 125290.65 (a) (2) that members of the Facilities Working Group shall be prohibited from receiving compensation from any construction or development entity providing specialized services for medial research facilities.

Chairman Klein: When we agendize this, Mr. Reynolds, we'll point that out.

Vote

- All in favor
- No opposition
- COI Policy approved.

Agenda Item #15
Consideration of Status report from Facilities Working Group Subcommittee

Chairman Klein: Dr. Friedman is not here wants to be part of presenting candidates, so we'll do that 6/6.

Do we feel confident that we can move forward with Facilities Working Group meetings with the plan that they will be open with the exception of discussing topics that would compromise someone if not done publicly?

Chairman Klein to Dr. Love: was this consensus at Subcommittee?

Dr. Love: Yes, and Don Reed made public comments regarding what to hold in public, what to hold in private.

ACTION ITEM: CIRM staff and legal counsel will work on this meeting policy and bring it back to the ICOC at a future meeting, just like we're doing with the Standards Working Group meeting policy.

Agenda Item #13
Consideration of Standards Working Group members' ability to apply for CIRM grants and direction to Subcommittee on Alternates

Dr. Hall: The issue was whether members of the Standards Working Group could apply for a grant or not. The argument for including them – they are not involved in grant review, don't have same COI. The opposing view is that there may be perception of Conflict of Interest.

Motion

- Dr. Penhoet moves we adopt the intermediate proposal which is they cannot be a PI, nor benefit financially directly, but can be a member of a grant.
- Second: Dr. Pizzo

Vote

- All in favor
- No opposition

Agenda Item #7
Consideration of Federal legislation-HR 810 (Castle/DeGette) and S 471 (Specter/Harkin); HR 1822 (Bono) and S 876 (Hatch /Feinstein); HR 1357 (Weldon) and S 658 (Brownback)

Chairman Klein: To get on the record, is there a motion we can make to support the Castle/DeGette bill?

Motion

- Motion made by several members
- Second: Dr. Prieto

Ms. Samuelson: We've all studied this very carefully, and it's important we take a position.

Vote

- All in favor
- No opposition
- Motion carries

Ms. Wilson: Can we have Kirk tell us about the voting from California members of Congress?

Mr. Kleinschmidt: The members from California that I've been told are important people to communicate with are Congressmen Lewis, Cunningham, Dreyer, McKeon and Issa. I've been told they're getting a lot of pressure so it's important to communicate with them.

Dr. Pizzo: I spoke with Issa's office on the way here, and he has not yet made up his mind. Radanovich is against it on religious grounds so I'm not sure what we can do there.

Chairman Klein: The vote count in house was 230 before President Bush threatened to veto The individuals on the fence need to know we're very strongly supportive of them and will back them up.

PUBLIC COMMENT

Anne Meade: I've been listening to the update on legislation. You have a huge popular base of support in this state, but people don't know what the issues are. Put the analysis on your web site for starters. Is there any other way to reach out to the public? There is a need to help people understand the issues and interpret them.

Mr. Harrison: The CIRM can put analysis of this legislation on its web site in an effort to educate the public as well as make it clear to the public the positions it has taken today on legislation. The line tends to be drawn at efforts directed at the grass roots level, to voters, to have them then in contact with their legislators.

Jessie Reynolds: regardless of the fate of SC 18, I encourage board to think about long term effects on women of hyper-ovulation drugs. There is not consensus on these issues. I'd be happy to get together some data.

Michael Shuppenhauer: Just a comment on the cancer impact of using hormones out of the IVF set, that scientific discussion has been fairly contentious. Go back to the research from the mid-90's. The major point I wanted to make is that one of the key reasons Prop 71 is important for California is an economic reason. I'm really missing the economic impact of $3 billion being spent, what that means for California on a global scale. We're talking about ethical values and other things, but it is very important for the public to understand the U.S. is already behind in terms of stem cell research.

Agenda Item # 14
Presentation on Per Diem and Travel Policies by Walter Barnes

Walter Barnes:
Per Diem and updated Travel Policy: we sent you the Per Diem information via email. See in your binder for new Travel Policy

Agenda Item #9
President's Report

Dr. Hall gave a brief report on CIRM progress, including reminding everyone that the first CIRM RFA had been issued the previous Friday. This was met with applause.

Other issues on which the board was updated included personnel and the interviews taking place with potential scientific review officers, and the scientific priorities meeting being planned for the early fall.