---oOo---

BEFORE THE
SCIENTIFIC AND MEDICAL RESEARCH
FACILITIES WORKING GROUP
OF THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE
ORGANIZED PURSUANT TO THE
CALIFORNIA STEM CELL RESEARCH AND CURES ACT

---oOo---

REGULAR MEETING

---oOo---

---oOo---

DATE: March 9, 2009

TIME: 2:07 p.m.

LOCATION: CIRM
210 King Street
Third Floor
San Francisco, California

---oOo---

REPORTED BY: Peter D. Torreano, CSR, CRR
Certified Shorthand Reporter
License Number C-7623

San Francisco, California March 9, 2009

P R O C E E D I N G S

CHAIRMAN LICHTENGER: I'd like to welcome you to the 2009 CIRM Facilities Working Group.

Patty, if you'd please call the roll.

MS. BECKER: Okay. Marcy Feit?

Deborah Hysen?

Ed Kashian?

MR. KASHIAN: Yes.

MS. BECKER: Bob Klein?

Jeff Sheehy?

MR. SHEEHY: Here.

MS. BECKER: Stuart Laff?

MR. LAFF: Here.

MS. BECKER: David Lichtenger?

CHAIRMAN LICHTENGER: Here.

MS. BECKER: Joan Samuelson?

David Serrano Sewell?

VICE CHAIR SERRANO SEWELL: Here.

CHAIRMAN LICHTENGER: So I want to thank the Facilities Working Group members and the members of the public, if we have any returning today. Hopefully, most of you know today is an historic day in stem cell research.

I think everyone realizes today is an historic

day -- this is David Lichtenger again -- that the President has lifted the ban on doing research into the existing stem cell lines; is that correct, Alan?

Okay. Great. So since we last met there have been some dramatic changes in the health -- hello? Somebody just dialed in. We've lost the court reporter.

THE COURT REPORTER: No. I'm still here.

CHAIRMAN LICHTENGER: David Lichtenger, I am continuing.

There have been some dramatic changes in the financial health of the California state government and the world financial markets and some of the projects that were funded by CIRM have been affected by these events, but most have progressed quite well.

So the purpose of this meeting is to provide update on these projects and we'll cover several topics.

John Robson, the vice-president of operations with CIRM, will provide us with a general update on the status of the shared labs and nature facilities projects that were recommended for funding by the ICOC. And then we'll discuss a request from the University of California Merced to modify its major facilities project. John has visited the site last

Friday accompanied by CIRM staff and outside consultants to evaluate the request.

I know I'm going to get your last name wrong. "Csete"? Okay. Dr. Marie Csete, chief scientific officer, will then lead a discussion of the report and recommendations that you received about GMP facilities and service role supporting that.

So I'd like to go to agenda item number 4, status report on the major facilities boards, but first Don Gibbons, CIRM's chief communications officer, will present a video presentation of the CIRM major facility speed science and create jobs video.

(VIDEO PRESENTATION, NOT REPORTED.)

MR. GIBBONS: Any questions? Okay. Time for us to go out and handle a few more of those tough media comments.

CHAIRMAN LICHTENGER: Thank you, Don.

Now I'd like to have John Robson, vice-president of operations, review the update for the major facilities awards. Please note there will not be a vote on anything. It's just an update.

MR. ROBSON: Okay? Thank you very much, David.

This is John Robson.

So since you last met, a lot of things have

happened around here. One, I arrived. This is the first meeting I've been to. Nice to meet all of you.

And Rick Keller who had been shepherding through the shared labs projects and the major facilities projects, he retired last August. We had hoped to bring him back on a part-time basis to continue to follow these things through to their completion, but he took an interim position with the UC president's office. So he wasn't able to do that.

We have since engaged Ray Groom who worked closely on the shared facilities project and also with some of the major facilities. He's been sort of taking over for Rick and he's been a big help with us following these various projects along.

What I'd first like to do is talk to you about the shared labs. I'm just going to give you kind of a brief update as to where these stand.

So if I could have the next slide. Thanks, Pat.

MR. SHEEHY: Do you have a handout on this, John?

MR. ROBSON: I think it's in your packet right there on the top.

MS. BECKER: Seeing that there is no public here, we could actually move the -- because they are

going to have to look at you and it might be more convenient if you stand here.

MR. ROBSON: I'm just afraid Peter won't be able to hear me.

MS. BECKER: Well, I'm going to move that.

MR. ROBSON: Okay.

MS. BECKER: Does that make sense?

MR. ROBSON: Sure.

MS. BECKER: We are playing tennis here.

MR. ROBSON: If I could get out.

MS. BECKER: If you could show us the sheet.

MR. ROBSON: Okay. So I'm on this PowerPoint presentation and it's just the first one. That's right here. Is everybody with me?

MR. LAFF: Now I am.

MR. ROBSON: Okay. All right.

MR. SERRANO SEWELL: Special GMP, there's another one in here.

MR. ROBSON: There should be another one. Okay. Is everybody with me here?

So let's just briefly go down these shared labs. These projects are -- almost all of them are on schedule. Several of them are already finished. So I can just give you them very quickly. The Buck Institute one is still in process. It's on schedule.

Burnham Institute is just waiting for its -- we're waiting for a request for disbursement on equipment and that one will be complete.

Children's Hospital in Los Angeles, same thing. We're waiting for equipment receipts.

Gladstone Institute, it's just in the last phases of review.

Salk Institute is done.

Scripps Institute is done, although we have a site visit pending on that one.

Stanford is in process, on schedule.

Final payments are being issued at Berkeley.

The University of California at Davis is slightly behind schedule, but it seems to be moving along towards completion.

Final payments are in process for Irvine.

UCLA is slightly behind schedule again.

Riverside, the construction component is just about complete, but, again, it still seems to be pretty much on schedule.

San Diego is in process.

We're just about closing out at UCSF.

And the last two are also -- Santa Barbara and Santa Cruz are also near completion.

So there don't seem to be any problems with

any of these. Ray Groom has been doing a great job tracking them and I think we'll be, you know, finished on schedule on almost everything.

CHAIRMAN LICHTENGER: John, can we get some kind of a document showing all -- you know, what you just told us, and if there are any numbers behind it, you know --

MR. ROBSON: Sure.

CHAIRMAN LICHTENGER: -- you know, distributed to the Facilities Working Group, you know, I mean, if they are on budget and the schedule. Just because a lot of the members here were involved in the award -- you know, the shared labs and we'd like to see kind of exactly where they are.

MR. ROBSON: Okay. We can do the same. We can do the same for major facilities. I have -- again, I think for the major facilities -- well, that's just a summary of what I just told you.

For the major facilities I'd really like to focus our competition primarily on three and that's the Stanford consortium, that's the San Diego consortium, the Buck Institute and then UCSF. Those are the three where we've had some delays and some difficulties. And so I'd like to talk to you and then we can have a more elaborate conversation about those.

The others again are all doing quite well. Some of them are already under construction. That's Stanford, UC Davis, UC Irvine, UCLA --

CHAIRMAN LICHTENGER: Excuse me, John.

Hi. It's Dave Lichtenger. I guess you've now officially joined the call. Thanks for joining.

MS. FEIT: Yes, thank you.

CHAIRMAN LICHTENGER: Marcy Feit just joined. So she's now on this call.

Sorry, John. Go ahead.

MR. ROBSON: That's all right. So I was just running through the major facilities, ones where the construction has begun, and that's Stanford, UC Davis, US Irvine, UCLA, UCSF and University of Southern California. So construction is ongoing there. The Stanford consortium at the top. I'd say we'll talk about that in a minute separately. The same with the Buck Institute.

Now, the three -- three of the UC campuses that are listed below there, Berkeley, Santa Barbara and Santa Cruz, none of them were expected to start their -- scheduled to start their construction until this spring. They are all ready to go, but what we're hearing now is they are going to be delayed because of the financial crisis in the state and the freezing of

the pool money investment account.

So this is information I got from Rick Keller who is still overseeing these projects and many others from the president's office. So those are likely to be delayed, unfortunately. They are ready to go.

I think you know that Santa Cruz had some delays due to ecological issues. Those things have all been resolved, again, and so they are all pretty much on track.

So, again, that's what I just sort of went through there on that list.

CHAIRMAN LICHTENGER: John, I have a question before we get into the specifics.

Have you gotten any feedback -- this is David Lichtenger again.

Have you gotten any feedback from the institutions about construction costs coming down? Because I'm seeing some significant reductions in costs out there and I would expect that some of these projects should -- the costs should go down, not up.

MR. ROBSON: Yeah. Well, that will come up a bit when we talk about Merced, but I haven't seen it. Not that I'm aware of so much with these, but certainly with the shared labs that's been the case where the construction has been complete and when the actual cost

requests came in they were below what has been estimated. And so we're sort of expecting it at this point they'd have to be, but I think it's a little too early to see that.

CHAIRMAN LICHTENGER: Okay.

MR. ROBSON: Okay. So let's talk a little bit about the Stanford consortium. They had some delays due to zoning issues and they had -- there was a hearing of the Coastal Commission in January. And those objections were taken care of and they have approval to go forward. Of course, in the interim there's been some financial issues that have come up in the state and nationally and they need to secure a bank loan in order to get the project going at this point.

There's some difficulty. The bank wants an up-front payment from CIRM so that they can be assured that CIRM's contribution to the -- to the total cost is secure, but we're not in a position to make that up-front payment right now because of our cash flow situation. Even though we are -- we are fully authorized to raise $3 million -- $3 billion over, you know, the course of ten years and we have full authority to do this, we're just not able to -- the state has not been able to sell bonds to this point.

And now, as I think you know, and James

Harrison can talk to you about it in more detail, the process of preparing a private placement with general obligation bonds. So when that goes through hopefully that's going to ease our situation relatively quickly.

But in the meantime, James and Bob Klein have been working with the lawyers at the Stanford consortium to create a collateral pledge agreement which will satisfy the banks and will secure their money and allow them to go ahead and make the loan that Stanford needs so that their project can move forward.

I know there's been some conversations, a couple of conversations back and forth about that. James, if you want to -- you know, comment on where that is.

MR. HARRISON: Sure.

CHAIRMAN LICHTENGER: Just a quick update for those of us who are not as up to date.

MR. HARRISON: Sure. Let me just quickly describe the situation. As John said, one of the primary issues facing both the Stanford consortium and the Buck Institute is the concern on the part of financial institutions that they're relying on that the state funds will ultimately be there when they are called upon.

As you know, both Buck and the consortium are

slated to receive dollars on a last dollar bid basis, and the financial institutions are concerned given our current financial situation in the State of California and the state's recent inability to access the bond market that the financial institutions could put up their funds, the institutions could send their leverage dollars, they have ability that's two-thirds complete, and the state wouldn't be in a position to make those final payments to push the building to completion and the financial institutions would be stuck with a building that's two-thirds complete, which is not much coverage now.

So we've been working with the Stanford consortium lawyers to try to devise a way to provide some sense of security to their lenders that CIRM will, in fact, be in a position to make good on its payments when the time comes.

And we are now examining a variety of different options, one of which is a collateral pledge agreement, which would essentially entail an agreement by CIRM to make payments on the grant directly to the financial institution if the grantee, in this case the consortium, were to pledge its grant agreement to the financial institution as security for the financial institution's participation in the construction.

We're also looking at the possibility of using the bonds, which, as John said, have now been authorized to sell, as another means of possibly providing security at the financial institution. One of the advantages of the bond is that under state law debt services payment on principal for bonds is entitled to the second highest priority on the state general fund. So second only to education funding, the state pays debt service and principal, which means that there's a good deal of security in holding the bonds because they know they will get payment on interest and eventually on principal as well.

So we're in the process of trying to find a way to use the tools that we have, either collateral pledge agreements, bonds or some combination of the two, to provide sufficient security to the financial institutions that they will be willing to put their own money in up front with the understanding that the state through CIRM will be there when the money is needed.

CHAIRMAN LICHTENGER: Thank you, James. Any questions?

MR. ROBSON: So as James mentioned, the Buck Institute has similar issues regarding finances and the plan has been for the last month or so to try to work out an arrangement with the Stanford consortium and

then whatever model we develop which seems to satisfy the bank in San Diego, we would just try to apply the similar sort of strategy to the Buck Institute when we're ready.

There's -- there's another issue with the Buck Institute that it has really -- has come up recently in a letter that we received from them last month which dealt in part with the finances but also with the fact that they are looking into using the building a little differently than originally anticipated. The original building was to house 12 PI, two floors, research labs on stem cells.

Now they would like to use some of the space to rent it out to private enterprises concerned with stem cells or stem cell research, perhaps as a way to attract research organizations that are outside California to set up a base here so that they could take advantage of the stem cell community here and some of the funding opportunities here.

So that said, it has not been brought to us in any kind of detail. It's not something that was included in the original application. So it's not -- I'm not quite sure how we are going to proceed with that and we might want to just discuss that a little bit.

CHAIRMAN LICHTENGER: Yeah. John, you know, do we know what percentage of the building they are thinking about renting out?

MR. ROBSON: No. We have no details on this at all. They just said that it would be replacement for some of the PI -- I mean, that's the implication in the letter. It doesn't say how much, how many.

MR. SERRANO SEWELL: This is David Serrano Sewell speaking.

John, are they looking for our approval or are they sort of notifying us and are requesting our opinion?

MR. ROBSON: At this point my reading of the letter -- I don't know if anybody else has read it -- it was sort of a heads up, this may be coming down the pike, but we haven't seen anything formal from them.

Marie?

DR. CSETE: Is it a modification of the scientific plan?

MR. ROBSON: It looks like it would be a modification of the scientific plan, yes. It looks like that.

CHAIRMAN LICHTENGER: Thank you, John.

DR. TROUNSON: This is Alan Trounson.

I think until we get the details of what they

are proposing -- I did visit them and they generally utilized the facilities in these kind of ways. So, you know, they do make space available for social entities, so should they be in that particular area.

I think we need to wait until we get, you know, some more complete details. I'm not overly concerned right at the moment, but I think if it was a major adjustment of the scientific focus, I would have some concerns, but I think we ought to wait until we've got more information on it.

MR. ROBSON: We really have very little information.

MR. SHEEHY: A final question for James. This is Jeff Sheehy.

I am concerned because the idea was that we were building this space. Our researchers would -- served by the researchers would do their work in this space. We actually were getting a return in a recalculation of the indirect costs.

And so it looks like what Buck is doing is now making money off the state's investment. It's a private entity and it's taken the state's investment and is turning it into their own revenue stream and I am very uncomfortable with this. And my sense is if that's going to happen, we should either not go forward

or get a return because we -- as everybody knows, California taxpayers money is very dear right now.

VICE CHAIR SERRANO SEWELL: This is David Serrano Sewell. So I had a question for James.

That has to do with the -- if you can refresh my memory as to the facilities FGAP and how did that -- how this may come into play if an application is modified to some degree. And we're dealing with that at some level, I think, for these three institutions that you're talking about, John.

At what point does it trigger the president's involvement? What discretionary authority do we have? Are they obligated to notify us and then we look at it and do what we're doing today? How might that play out?

MR. HARRISON: This is James Harrison. There are a couple of different provisions that are relevant here. With respect to -- well, first of all, when you have a situation where the estimates that have been presented, and the part 2 application are estimates only, not reflective of an actual construction contract, and then once a construction contract is entered, if there are cost savings as a result of the construction contract being entered, then CIRM under the FGAP has an opportunity to share in those savings.

There is an exception which implicates the president's authority and that is if the -- the applicant has been able to achieve cost savings equal to or less than the difference between the amount of the award they requested and what CIRM actually gave them, then the president has authority to, in essence, let them keep those savings.

Likewise, once the project is complete, if the costs -- going to your question, David Lichtenger -- are less than what was actually projected, then again CIRM has an opportunity to save and to share in those savings, again, with power to the president to make a determination that some of the changes that have been made further the -- provide further equipment or further square footage not identified in the application that served the mission of the facility. Then in that instance, CIRM would not share in those savings because they would be redirected towards the mission of the program.

So it really depends is the answer the president does have --

VICE CHAIR SERRANO SEWELL: But that's on the construction side. What about the --

MR. HARRISON: Well, if there is a divergence between the scientific proposal that was presented and

reviewed and what is currently being proposed, then that would be a time, I think, at which the Facilities Working Group would get involved and perhaps request, you know, a supplemental scientific review, conduct some rereview itself or develop another process for dealing with the proposed change because the FGAP itself doesn't really address that particular situation.

CHAIRMAN LICHTENGER: So there's -- David Lichtenger. So there's nothing in the FGAP that deals with any inconsistencies other than the financial ones that may develop?

MR. HARRISON: Yeah. I think the inconsistencies that the FGAP deals with deal with modification in the actual construction of the facility, you know, new materials, different sizing, changes to the actual construction specification as opposed to changes to the scientific plan itself.

CHAIRMAN LICHTENGER: Or the use of the facility.

MR. HARRISON: Or the use of the facility, right.

CHAIRMAN LICHTENGER: Thank you, James.

MR. HARRISON: Well, I think if the chairman agrees, we can move on. My final comment would be if

the president thinks it's wise not to do anything at this time, that's fine. However, I wouldn't want our silence to be read by Buck Institute as a tacit agreement that we think it's okay what they are doing. Obviously, as Alan said, we don't have enough information yet other than being made aware of the situation.

CHAIRMAN LICHTENGER: Thank you, James.

Are there any other questions?

VICE CHAIR SERRANO SEWELL: John, just to -- David Serrano Sewell on this point.

I think we're going to want to take a very close hard look at a comparison between the project previously in all aspects and the comparison to any proposed changes and, you know, use square footage, number of PIs, cost, you know, percentage of building for CIRM, you know, all the major areas where we get that information and distribute that to the facilities.

CHAIRMAN LICHTENGER: Absolutely. In fact, that's a perfect lead-in to the discussion for Merced. So essentially that's what we've been doing over the last three or four months. So if you're finished with this one, okay, we'll move on then.

So just as a little bit of background, we

began to hear -- if you recall on this project, the plan was to build what they called a stem cell instrumentation foundry, a microfabrication facility. It was going to be located at an old airport about seven or eight miles from campus in existing buildings on land owned by the county. There were some problems with the length of the lease we were struggling with, and they were struggling to meet CIRM's requirements.

But then we began to hear from them in the fall that perhaps that was not going to be the site of choice because there were -- in addition to these problems with the lease, there were also -- it looked like there were going to be some cost overruns over what they had estimated.

So they came in and came back to us because we've had some written exchanges, we've had some conference calls, some private conversations, and they came back with a new proposal which was to relocate the -- the stem cell foundry into their science and engineering building, which is the only science building that they have on their campus. It's a large new environmentally sensitive state building, and it's right in the heart of campus. It's the same building where the faculty members that would actually use the facility, their laboratory is located in the same

building. Students are around. So it had some attraction in that way.

I think for us we had concerns, but the main difference in the project is that the laboratory size was going to be shrunk by about 40 percent. The office space, conference room, administrative space was roughly the same in size, didn't look too problematic. A little bit distributed around the building, but the size of the lab was a concern. Could they get all the equipment in there, could they accommodate people from outside campus, could they achieve the scientific mission that was approved in the original application.

So we felt that -- we had some conversations with them about this. They tried to assure us that they could -- that they could meet those needs, but we decided that the most expeditious thing to do was to go visit this facility, see what they had in mind and take some experts with us so we could get a good clear picture. So we did that. Unfortunately, we weren't able to schedule the trip until last Friday on the 6th. And so there was a group of us who went. We can move on here.

So this is the group from CIRM who is Alan Trounson and myself, Marie Csete, Jeff Lomax, who's in the audience there. And then we had Ray Groom who has

been our consultant on many of these facilities projects. Ray is not a clean room expert. This is the clean room facility they were going to build. And Marie Csete was able to locate, identify a fellow at Berkeley, Bill Flounders, who is the manager of the microfabrication lab there. They just built a brand new facility that just opened about two weeks ago. And he agreed to come along as a very highly specialized clean room consultant.

So we went out and met with this group from -- from UC Merced from the provost -- the chancellor actually made a brief appearance at one point. So we had most of the people who were the administrators who would be involved in the project and we met many of the faculty members, I think most of the faculty members on campus who would make use of the facility. And, in fact, they spent some time talking with us about how they would use the facility.

We were there for about four hours and we spent -- about half of the time we spent really reviewing the details of their plan and we had alerted them what we were -- one of our main concerns, general concern was that they wouldn't be able to do the work that they had proposed in this new space.

We went into it quite in detail and Ray Groom

and Bill Flounders really kind of got into it with them. Bill Flounders I thought was really quite terrific -- both he and Ray were both terrific, but Bill was very good and focused on this thing.

He made the point that he had seen the original plans and thought that the facility they were proposing to build was much too large and being off campus, it was going to be unsustainable. It wouldn't be used enough. The overhead costs would be too high. It would never be successful. It would never really get going.

So he thought moving it onto campus was a terrific idea. And when he reviewed the detailed drawings that they had given us, and we walked through the building, he said this is perfect. They're going to be able to get all of their equipment in there. There's some room for expansion in that area.

Some of the ancillary facilities that they were -- adjacent facilities that they would use like a TEM, transmission electron microscopy imaging facility, which is currently located out at Castle, the off-campus site, well, they are installing a TEM and building it in a room that's two doors down from where this new foundry would be. So it really looked like they had -- the facility itself was going to be quite

fine.

We spent an hour of the time visiting these proposed labs, discussing the nuts and bolts. That was mostly Ray and Bill were discussing it and crawling around the pipes and all that sort of stuff, and we went and visited the faculty members in their labs. They have very nice lab facilities in this building.

The new campus is a small campus, but they are really trying to find a niche where they can be successful, make a name for themselves and grow, and they seem to be doing a really good job. They've got energetic young faculty members for the most part who are quite eager to collaborate and quite eager to use this facility, and we heard from all of them about how they would take advantage of the facility.

So in the end we got a report which I got yesterday from Ray Groom. Hopefully, I think you got this, a summary of the visit. I wrote something up last night, a summary of our visit. I attached the report that I received from Ray Groom, which arrived last night.

(Pause in the proceedings.)

CHAIRMAN LICHTENGER: Dr. Trounson is speaking now.

DR. TROUNSON: So I'm talking about the

only -- the only negative component of the proposal as we saw was an underestimate of the costs of the specific tools that are needed in this specialized facility, and that they agreed that they had underestimated their costs.

They did ask if there was any way of -- of CIRM looking at making some adjustments on the savings to be able to accommodate that because the -- the tools are really critical for the functioning of this unit. And my view was to ask them to write to us all the details of it.

And so they just sent that and I've had a quick read of it. I think there's probably a sound case for doing that. I think it makes the facility more functional more quickly. I wouldn't have a particular problem with it unless any of the members of the Working Group do.

That was the only downside. Everything else was pretty much a very strong upside. So this is one of those times when you felt -- everyone felt that, you know, thank goodness, they had made a reassessment in reality.

So I think it could be -- you could feel comfortable, as John said, in endorsing this and no need for really a review. The science will be as it

is -- as it was stated and the facility is a bit smaller but much more likely to be sustainable and more used.

MS. FEIT: This is Marcy Feit. Do we know what that's going to cost CIRM?

DR. TROUNSON: You mean the additional -- there is a sign it's --

MR. HARRISON: It's about 1.3 million and the new equipment was about half of that.

DR. TROUNSON: About $600,000, about half of the savings that we were making. The cost of the building because it's -- it's -- it's -- it's a renovation really and it's within a very good building. And so what you've got to do is make some alteration -- to -- to the air inflows and so forth. There is a net saving to us and that we're talking about half of that net savings.

CHAIR LICHTENGER: Marcy, did you have something else to say?

MS. FEIT: No. I just wondered what, you know, the net cost to CIRM was going to be for the change.

CHAIR LICHTENGER: So, Marcy, I'm asking -- you probably don't have this document that we just got.

MR. HARRISON: I don't have it in front of me,

no. I think the figures are there for CIRM.

CHAIR LICHTENGER: But it appears that it's less costly to CIRM and less costly project and more efficient, but we'll try to get you copies of this.

MS. FEIT: I just had put on my desk a whole stack of copies for this meeting. So I'm looking through them as I'm talking to you.

CHAIR LICHTENGER: Yeah, I don't think -- we could try to e-mail it to you. Pat is going to try to send it to you right now.

MS. FEIT: I have it now. It's a thick document about the facility with a lot of numbers on it. Is that the document?

CHAIR LICHTENGER: No. There's an older one that -- there was one that we did include in the packet and then there's another letter that just came this afternoon.

MS. FEIT: Okay. I probably didn't --

CHAIR LICHTENGER: Pat is probably going to try to e-mail that one to you.

There's one other thing that I might mention, which is somewhat ancillary to this. We had been -- we had also been a bit concerned about whether or not they were going to be able to raise their matching funds. So we asked them about that, especially in the current

situation, and what we've been hearing about some of the other UC campuses.

And they assured us that they have the money. The money has been allocated. They have it in the bank and they're ready to go. So there don't seem to be any problems. They -- they think they -- if we get the go-ahead quickly, which we plan to do with them, that they can get the project started and the construction started in the summer and do the heavy demolition stuff when the students aren't there and be ready and have the thing about ready to go next summer.

MR. SERRANO SEWELL: So, John, I have a question. Are we going to be having a formal kind of document issued by the consultant?

MR. ROBSON: He said he would send me something, but he left Merced and headed off towards Yosemite, not back to Berkeley. So I'm not sure exactly when I'm going to get it.

CHAIR LICHTENGER: So I'd like to open this up to questions by the Facilities Working Group, but my gut reaction here is that if we can get a better facility for less money, and we've got, you know, the room consultant and Ray Groom and management of CIRM to agree that there's a better project, you know, unless there's something that comes up, you know, I would

assume that we would be supportive of this.

And I don't know if we need to have any kind of vote eventually, but I assume James will let us know. But any questions?

MS. FEIT: This is Marcy again. I appreciate the site visit. I think it's helpful to know that someone went out and actually look a look and talked to them. That's very helpful.

CHAIR LICHTENGER: Great. Thanks, Marcy.

So, James, you'll let us know, and we'll eventually have a vote on this.

MR. HARRISON: At this point no action by the Working Group is necessary. Once they have a construction contract signed the president can make a determination that the changes that are made don't compromise the scientific value of the facility. And he may determine that the cost savings, to the extent that it can be used to improve the facility, is something that Merced can be developing in the president's discretion based on the information received at that time.

MR. SERRANO SEWELL: What about the dollars on the equipment? I was talking to John Robson about this. How would that work?

MR. HARRISON: Well, again, if I have my

numbers correct, I believe the original request that Merced made was $7 million and the actual award was 6,304,000. So it's a differential of approximately 700,000.

So to the extent the president makes the determination that the proposed changes don't affect the specification facility and they don't compromise the scientific value of the facility, then he can make a determination that those savings can remain with the grantee. In other words, they could put that 700,000 towards the additional 600,000 or to the equipment.

MR. SERRANO SEWELL: So no change needs to be actually made on our part.

MR. HARRISON: At this time, that's correct.

CHAIRMAN LICHTENGER: Ed, go ahead.

MR. KASHIAN: Perhaps we had can upgrade the application and get more money.

MR. ROBSON: They haven't asked for that. So that's -- that's all I had in this report.

MR. SERRANO SEWELL: Yeah. I think, you know, I feel comfortable, I would like to obviously take some time to go through this report from Ray Groom in a little more detail. It's the first I'm seeing it.

MR. ROBSON: Yeah. I'm sorry we couldn't get this stuff to you ahead.

MR. SERRANO SEWELL: And then see the clean room expert. Assuming that it all reads through the way it seems to, I think this -- you know, this looks like a better project and more cost effective. So I would be wholeheartedly supporting it.

MR. ROBSON: Great.

CHAIRMAN LICHTENGER: So, John, you've gone through the Stanford location. We've gone through the Buck. Merced. So that's pretty much it.

MR. ROBSON: Those are the issues we wanted to cover.

CHAIRMAN LICHTENGER: Any other questions for John from members? No members of the public here. So thank you, John.

Ed?

MR. KASHIAN: It appears like the only problematic position is the Salk Institute.

DR. TROUNSON: I think that's right. I'd just like to see some more detail as to what they were proposing and it may be worth us to taking a site visit there as well, but I'm loathe to sort of be too definitive until I've seen much more about what they had in mind really, whether that was -- you know, that was stem cell related or not stem cell related. There's a number of issues that come in there.

So I think we'll get back to you on that when there is a lot more information rather than speculating about it.

CHAIR LICHTENGER: Great. Thank you, Dr. Trounson.

So at this point we can move on to agenda item 5, discussion of terms, GMP report recommendations. Dr. Marie Csete, CIRM's chief scientific officer, will now make a presentation.

DR. CSETE: So, as you know, we have been trying to put together workshops that anticipate down the road and bring in experts from around the country as well as from California to advise us on the best possible use of certain kinds of technologies and the best research agenda.

And a good manufacturing process is going to be an essential part of bringing cell therapy to the clinic. So I think that right now we're a little bit in the dark and so this workshop was really well timed.

Blood banks have a lot of regulations imposed by FDA in terms of their processes before those cells go into patients. Similarly, for solid organ transplantation there are a lot of recommendations that the FDA will be able to bring into recommendations for

GMP pluripotent stem cells, but to date the GMP recommendations out of the FDA do not deal with pluripotent stem cells. Nonetheless, the FDA has approved for clinical testing a human embryonic stem cell derived product.

The details of GMP and the scale-up of that master bank from Geron are not available to the pubic. So what we have to go with is what our advisors in this workshop brought to us as well as an extensive literature search that I did with help from Dr. Talib in the office and a summary report which we contracted after the meeting to just affirm really what we heard in the meeting.

CHAIRMAN LICHTENGER: Do we have that?

DR. CSETE: Yes. So our workshop was held in November and we brought together leaders from commercial contract GMP facilities, academic GMP facilities in the State of California, biotechnology experts who are using GMP in the development of their products, regulatory experts and members of the PACT which is a really wonderful NIH consortium of currently four GMP facilities to tell us how that was going.

And Darin Weber who did the consultation for us from the Biologics -- that should be BC Consulting Group was a former FDA regulator who's now consulting

on these issues.

So taking together a huge amount of material, this -- I will give you the recommendations that we walked away with after all of this material was digested.

We got a very clear message from the biotechnology industry and from the contract GMP organizations that they do not have educated people coming out of colleges and universities to field their technical needs, and our Bridges program we decided was a really good place to respond to this need.

So next year when we issue the Bridges program we'll try to get the universities to focus in on the kind of technical training that's needed to have people graduate directly from these programs and assume jobs in California's biotechnology industry.

So the Bridges timing was just perfect as a matter of fact. And I started to look around the country to see what kind of educational programs there are in GMP so that we can write the RSA with these best practices in mind.

The second major insight from the workshop is that there is significant expertise in California and capacity for GMP. So we heard from Progenitor, Lonza, and Cognate, which are the three biggest commercial GMP

facilities in the country. Two of them have major manufacturing presence in California right now. That's Progenitor and Cognate.

We also heard from other manufacturers after the workshop who found out about this through their contact and called me and said, "Hey, we have capacity, too. We need business and we're in California." So there's even more than what's identified in the workshop and by Darin Weber's report.

In terms of the intellectual structure around GMP, we also heard a clear recommendation that we should take advantage of what's out there already and try to get a patch facility in California. The four that are currently up and running and in their fifth year of operation are all outside California. The NIH has an RFA out now to which applications have been received to expand this by either one or two more programs.

We decided to -- I decided to call around to all the academic programs that would potentially be applicants to this programs, and there was really only one that was physically ready and intellectually ready to put in an application, and that was the City of Hope.

So they hadn't planned on putting in an

application, but when we discussed the recommendations of the workshop and the City of Hope GMP director was at our workshop, he agreed that the timing was right for him to put in an application, and I wrote a letter of support for this application to the NIH.

So they -- their application was really focused on getting down to the details of the pluripotent cell GMP, making a unique niche for themselves within this PACT program, this PACT consortium. So we're working with them to try to hope that they get funded for this. And, you know, I think that the application will be competitive based on the long expertise of this program in this area.

The fourth workshop insight was that there's still significant amounts of research at every level that are required to optimize GMP for stem cell therapies. So we will continue to call for basic research under all of our core initiatives that cover this research need.

So, for example, derivation of cells under GMP conditions would be appropriate for basic biology research funding, for early translation, the methods to optimize the media, reduce costs, make SOPs for safe scale-up are all eligible parts for early translation, and we expect that our disease teams are going to have

to make clear-cut decisions about how their products will be developing the GMP as part of their translational program.

And, finally, the training ground programs -- the training programs, as you saw before, the Bridges is really quite perfectly suited for us to focus a little bit on the work force.

CHAIRMAN LICHTENGER: Thank you, Dr. Csete. Do we have any questions from members of the Facilities Working Group?

MR. SERRANO SEWELL: David Serrano Sewell speaking.

So this is a great report. It's interesting. I don't know. I haven't reached a conclusion one way or the other. So David asked this question about our previous report using Merced. Was there a difference -- were there any other opinions? Because the report is very strong, "the overwhelming opinion," "our overall recommendation."

Okay. So there was no voices out there "isn't it enough" or "maybe you should tweak it"? Which is fine. I'm just curious.

DR. CSETE: We hear occasionally from people that they think there's not enough, but whenever I confront that with, hey, have you called X, Y and Z,

then they just were unaware of the availability of agencies.

CHAIRMAN LICHTENGER: I have a couple more questions.

VICE CHAIR SERRANO SEWELL: So this goes to what -- what the remaining dollars are to work for facilities; right? It's like 30 million. Does that sound --

DR. CSETE: Yes, that sounds -- I think I understood there would be about $30 million that could potentially go for bricks and mortar. So we have options to consider. So, for example, we did not make a commitment to City of Hope that if they got into the PACT program that we would help them with their explanation of the GMP facility which is underway, but I think down the road that's a potential practice to consider. Yes, we have to do it by competition for sure.

But the other thing to consider is just to use that money in the research programs to facilitate our grantees having access to the best GMP facilities for their own use. So we would use it for research funds rather than for bricks and mortar.

MR. SERRANO SEWELL: That's a significant policy shift.

DR. CSETE: That would be a policy shift and I think we just have to see how the NIH application goes and what the options are for expanding.

So there are academic facilities around. UCLA's facility Alan and I saw, and we saw the GLP part of it, which CIRM is funding as part of the lab there. Davis's program was not quite yet up and running in a way that they could be applicable for the PACT program, but you could see that in a year from now they would be, and so that would be part of a competition.

City of Hope is certainly ready. Right here in town the blood systems program that's affiliated with UCSF is underused in terms of its space. So there would be competition, I think, for us to support space as well.

DR. TROUNSON: Alan Trounson. What I was going to say is there are a few people who might disagree with our strong recommendation. We've heard that, for example, at Geron. Yet Geron was a member of the workshop. They had their key person there. So we think that's a bit strange that, on the one hand, they were there and yet they disagree with us.

So we thought that we would -- it would be worthwhile to sort of go and try and source that particular divergence of views specifically, but it is

a very small cry in a large wilderness.

DR. CSETE: And not officially transmitted to us.

DR. TROUNSON: Maybe five years down the track everything would be very different and we may need to do something very specifically for a larger scale preliminary trial work. So I think keeping out how to drive at the moment still would be a worthwhile thing in my own view.

MR. SERRANO SEWELL: And I don't know, Alan, if a decision needs to be made anytime soon, but my point of that -- the ICOC will have to decide what to do with this remaining $30 million. It could very well decide, no, we're not going to dedicate it for a facility that's specified under the initiative, but we want to do it for something else. That's perfectly within their authority because I don't think we have to spend it on the 300 million.

They may also decide that the 300 million is something you do want to spend to total and let's find something else to do with this $30 million. It could be a project like you described, a limited focus RFA, or it could be something entirely different. At this point just what I'm hearing from Alan and you is we really don't know.

DR. CSETE: And probably also you're referring to the fact that at some point Mr. Klein wanted us to look at abandoned facilities in the state that were up for sale. And, you know, these are -- and we did. You know, these are $200 million purchases that cost a million dollars a year to run without any use and we have a much smaller budget in mind here for how we can optimize access to GMP for our grantees.

So I think one of the clear messages that I felt came out of the recommendations of the experts was that we not get into the business of purchasing and running a facility. Rather co-opt all the intellectual and structural capital that we can.

CHAIRMAN LICHTENGER: Any other comment?

MR. SHEEHY: This is Jeff Sheehy. Is it still true that the science isn't quiet there for that kind of scale in terms of -- there's lot of debate about what is the best way to do this, which is why you did mention further research.

DR. CSETE: Right, yeah. So it is now possible, of course, to expand undifferentiated human embryonic stem cells without any exposure to animal products, but that's very expensive. So in many ways that's not optimized.

Then the scale-up issues are constrained by

how much manipulation has to happen in your master bank before -- before you freeze down the cells as a master bank, and that's very dependent on the specific differentiation pathway you are going to.

Now, people can do it, but it's -- you know, purity issues and quality assurance issues are just not there perfectly yet. So there needs to be some basic research and I think that disease team is really going to encourage this because people are going to have to -- if they have a cell therapy that's first in man, in four years they are going to have a distinct plan for how they expand the cells and it's going to have to get run by the FDA.

MR. SHEEHY: I mean, aren't we years away from needing these facilities?

DR. CSETE: Well, you know, John had need to establish their master cell bank. Novacell independently established their master cell bank and I know of a number of biotechnology companies now in the state that are doing their own GMP just to do that.

So if we're wildly successful with these teams and all of the ones we fund are cell therapies, even under those circumstances I think the capacity in this state is there for the next five years. So, you know, if you calculate that all ten of them are going to

require GMP, I think our commercial entities would be very happy for that business.

And so we could reassess as we go along, but I can't imagine that in five years we're going to be ruing this decision.

CHAIR LICHTENGER: So, Marie, what do you think this committee, this Working Group and the ideals that you should take up at this policy discussion on what's new?

DR. CSETE: I think I would prefer that we wait until we see what the NIH's decision is on the PACT. I think they go to review at the end of this month. So probably by June we should have an idea. And that way we'll know what other capacity there is in this state for us to leverage.

MR. SHEEHY: This is Jeff Sheehy again. Would there be any other type of facility, specialized facility needs that lie on the horizon? This is just one particular type GMP.

DR. CSETE: Right, right. So the manufacturing facilities for specific kinds of biologics and drugs are something that we can envision our grantees needing depending on the nature of their research into these teams. And I haven't done the sort of wide literature review on those in the same way that

we did on the GMP facilities, but my sense is that for the manufacturing of antibody products and the manufacturing of drugs the state has ample facilities.

CHAIRMAN LICHTENGER: Just for some of the members, could you give an idea on a per-square-foot basis of some of these GMP facilities. They are very expensive.

DR. CSETE: Yeah, they are really expensive. And I don't know what the dollar amount is per square foot, but I can tell you that -- well, we looked -- I looked at the City of Hope one in detail. They have six small culture rooms basically and the other space that you need is anterooms for air and pressure control and gowning.

CHAIRMAN LICHTENGER: So $2,000 a foot, along that -- it's very expensive.

DR. CSETE: Something like that. It's insanely expensive, yeah.

And the sterilization issues in the rooms are unique to places that are expanding cells.

MR. SERRANO SEWELL: Marie, do you think anything really changed in the way we -- when Zack originally put together the scientific report, the one, you know, that is guiding us right now that Alan is revising, there was a call for GMP, and so was that

just because we had to put something in there that sounded like the right thing to do at the time?

DR. CSETE: I think that was far reaching.

MR. SERRANO SEWELL: It was far reaching at the time and now here we are five years later almost.

DR. CSETE: And, in fact, the field has sort of responded. So one of things that has grown Cognate and Progenitor --

MR. SHEEHY: They thought about it when Zack was putting it together.

DR. CSETE: He was smart. No, but seriously, one of the reasons that pushed Cognate and Progenitor to expand is the progress in the bankable stem cells. So they have really geared up, you know, to grow those in big abundance. And so that works in our favor, that that experience is something we can plug into as the pluripotent cell therapies come to fruition.

But I think Zack was wise to recognize that this was something where there wasn't -- well, there wasn't regulation established yet. You know, the adult stem cell work, you can pick and choose regulations, but there's nothing on pluripotent.

MR. SERRANO SEWELL: My point is our scientific plan called for funding of something, and now we're not or potentially may not.

DR. CSETE: Well, that's true. We potentially may not fund bricks and mortar, but we are funding research into scale-up and related issues.

CHAIR LICHTENGER: Any other questions for Dr. Csete?

Thank you.

So at this point I think we've covered everything we need to. John? So we don't have any members of the public, do we? Okay. Anyone else want to make any final comments before we adjourn the meeting?

MR. SHEEHY: This is Jeff Sheehy. I just want to commend staff on their thorough and very, very hard work. I mean, it makes you proud of the people we have working for this. You know, we've been able to recruit Merced, I mean, the thoroughness, and thank you so much. And the GMP issue, again, just very, very fine-grain detail about these issues and it makes it easy for us. So thank you again.

DR. CSETE: Merced was a happy day.

MR. SHEEHY: Yeah, that was a good day. Going to Merced was a good day.

CHAIR LICHTENGER: Okay. Great. Well, at this point the meeting will stand adjourned. Thank you very much.

(Whereupon, the meeting was adjourned at 3:17 p.m. on March 9, 2009.)

---oOo---

CERTIFICATE OF REPORTER

I, PETER TORREANO, a Certified Shorthand Reporter in and for the State of California, do hereby certify that the foregoing transcript of the proceedings before the Scientific and Medical Facilities Working Group of the Independent Citizens' Oversight Committee to the California Institute For Regenerative Medicine in the matter of its regular meeting on March 9, 2009 and held at the location indicated below

CIRM
210 King Street
Third Floor
San Francisco, California

was held as herein appears and that this is the original transcript thereof and that the statements that appear in this transcript were reported telephonically in stenotype by me and transcribed under my direction.

I certify that this transcript is a true and accurate record of the proceedings.

_____, 2009
DATE

_____
PETER TORREANO, CSR 7623
Torreano Shorthand Reporting
2959 Winchester Boulevard
Suite 200B
Campbell, California 95008
(408) 379-0900