

BEFORE THE  
APPLICATION REVIEW SUBCOMMITTEE OF THE  
INDEPENDENT CITIZENS' OVERSIGHT COMMITTEE  
TO THE  
CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE  
ORGANIZED PURSUANT TO THE  
CALIFORNIA STEM CELL RESEARCH AND CURES ACT  
REGULAR MEETING

LOCATION: HILTON SFO BAYFRONT HOTEL  
600 AIRPORT BOULEVARD  
BURLINGAME, CALIFORNIA

DATE: MARCH 19, 2013

REPORTER: BETH C. DRAIN, CSR  
CSR. NO. 7152

BRS FILE NO.: 92751B

**BARRISTERS' REPORTING SERVICE**

**I N D E X**

<b>ITEM DESCRIPTION</b>	<b>PAGE NO.</b>
<b>8. CONSIDERATION OF APPLICATIONS FOR RFAS 12-02, 12-03 AND 12-04: CIRM HUMAN INDUCED PLURIPOTENT STEM CELL INITIATIVE.</b>	<b>3</b>
12-02: CIRM TISSUE COLLECTION FOR DISEASE MODELING AWARDS	
12-03: CIRM HIPSC DERIVATION AWARD	
12-04: CIRM HPSC REPOSITORY AWARD	
<b>EXTRAODINARY PETITION</b>	
•APPLICATION ID1 06560	
•APPLICATION IR1 06564	
•APPLICATION IT1 06584	
•APPLICATION ID1 06617 AND IR1 06595	
<b>13. CONSIDERATION OF RECOMMENDATION REGARDING AN EXTRAORDINARY SUPPLEMENT AWARD TO RFA 09-01: DISEASE TEAM RESEARCH AWARD - DR1-01444, UNIVERSITY OF SOUTHERN CALIFORNIA.</b>	

**BARRISTERS' REPORTING SERVICE**

1 BURLINGAME, CALIFORNIA; TUESDAY, MARCH 19, 2013

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(THE APPLICATION REVIEW SUBCOMMITTEE

WAS THEN CONVENED AND HEARD AS FOLLOWS:)

MR. HARRISON: WITH RESPECT TO THE TISSUE  
COLLECTION APPLICATIONS, YOU ALL SHOULD HAVE A SHEET  
IN FRONT OF YOU THAT IDENTIFIES THOSE APPLICATIONS  
IN WHICH YOU HAVE A CONFLICT. WHETHER YOU'RE ONE OF  
THE 13 MEMBERS FROM AN INSTITUTION OR A PATIENT  
ADVOCATE OR LIFE SCIENCE MEMBER, YOU SHOULDN'T  
PARTICIPATE IN THE BOARD DISCUSSION REGARDING ANY  
APPLICATION WITH WHICH YOU HAVE A CONFLICT AS  
IDENTIFIED IN THE SHEET IN FRONT OF YOU.

CHAIRMAN THOMAS: OKAY. SO WE HAVE ONE  
PUBLIC COMMENT ON THE TISSUE COLLECTION APPLICATION?  
DOESN'T APPEAR WE HAVE ANY.

MR. SHESTACK: THERE WAS AN EXTRAORDINARY  
PETITION, BUT NO COMMENT?

MS. BONNEVILLE: YES.

MS. SAMUELSON: THERE IS AN EXTRAORDINARY  
PETITION. I DON'T THINK IT WAS COLLECTION. IT WAS  
DERIVATION.

CHAIRMAN THOMAS: WE'RE ON TISSUE  
COLLECTION RIGHT NOW.

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1 DR. GRIESHAMMER: I THINK IT'S  
2 THEORETICALLY POSSIBLE THAT A PERSON MIGHT BE ON THE  
3 PHONE FOR THIS.

4 CHAIRMAN THOMAS: IS THERE ANYBODY ON THE  
5 PHONE WHO WOULD LIKE TO SPEAK TO THE EXTRAORDINARY  
6 PETITION ON THE TISSUE COLLECTION RFA? OKAY.  
7 HEARING NONE, I WOULD SUGGEST THAT WE ENTERTAIN A  
8 MOTION TO APPROVE, CORRECT, MR. HARRISON?

9 MR. HARRISON: YES, FROM A MEMBER WHO HAS  
10 NO CONFLICTS WITH RESPECT TO ANY OF THE APPLICATIONS  
11 AND IS AMONG THE 15 MEMBERS WHO ARE NOT FROM  
12 RESEARCH INSTITUTIONS AND UNIVERSITIES.

13 CHAIRMAN THOMAS: OKAY. SOMEBODY LIKE TO  
14 MAKE SUCH A MOTION?

15 DR. JUELSGAARD: I SO MOVE.

16 MR. TORRES: SECOND.

17 CHAIRMAN THOMAS: MOVED BY MR. JUELSGAARD,  
18 SECONDED BY SENATOR TORRES. FURTHER DISCUSSION BY  
19 MEMBERS OF THE BOARD?

20 DR. LEVIN: SO I'LL APOLOGIZE THAT I'M NOT  
21 ENTIRELY FAMILIAR WITH THIS RFA. IT'S A LITTLE  
22 OUTSIDE OF MY SCOPE. BUT IN READING THE  
23 EXTRAORDINARY PETITIONS, THERE WERE SOME THINGS THAT  
24 WERE CONCERNING IN TERMS OF THE PROCESS OF THE  
25 REVIEW. SOME ISSUES WERE BROUGHT UP ABOUT REVIEW

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1 CRITERION NOT BEING LISTED IN THE RFA; FOR EXAMPLE,  
2 THE PAIRING THAT WENT ON AT THE END OF THE GRANTS  
3 WORKING GROUP HAVING TO DO WITH THE SCORE OR  
4 EVALUATING ADDITIONAL COMMITMENT OF PI ABOVE THE 25  
5 PERCENT THAT WAS STIPULATED IN THE RFA. SO I'M JUST  
6 WONDERING IF SOMEBODY WHO WAS AT THE REVIEW CAN  
7 SPEAK TO HOW THAT WENT ON.

8 DR. GRIESHAMMER: I TRIED ALREADY TO  
9 MENTION ACTUALLY THAT WE DID ANTICIPATE THAT THERE  
10 WOULD BE A NEED FOR A LOT OF COORDINATION AMONGST  
11 THESE AWARDS. SO WE DID HAVE INDIVIDUAL REVIEW  
12 CRITERIA FOR EACH RFA. AND THE SCORE YOU SEE IS  
13 BASED ON DELIBERATIONS AMONGST THE REVIEWERS AT THE  
14 GRANTS WORKING GROUP INDIVIDUALLY SCORING EACH  
15 APPLICATION BASED ON THOSE REVIEW CRITERIA. IN  
16 ADDITION, WE CONTEMPLATED AND ANTICIPATED THAT, FOR  
17 THE PROGRAMMATIC CONSIDERATIONS, WE WOULD LOOK AT  
18 HOW THE APPLICATIONS WOULD POTENTIALLY WORK TOGETHER  
19 TO BRING THIS INITIATIVE INTO LIFE HERE AT CIRM.  
20 AND WE DID MENTION IN THE RFA THAT AT PROGRAMMATIC  
21 CONSIDERATION THIS WOULD BE TAKEN INTO  
22 CONSIDERATION.

23 DOES THAT ANSWER YOUR QUESTION?

24 DR. LEVIN: I JUST REREAD THE RFA HERE,  
25 AND IT SEEMED PRETTY CLEAR TO ME THAT ALL THE GRANTS

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1 WORKING GROUP WAS ASKED TO DO AT THE END OF  
2 EVERYTHING WAS MAKE RECOMMENDATIONS FOR PAIRINGS,  
3 THAT ALL OF THAT SORT OF POST COORDINATION WAS GOING  
4 TO BE DONE BY CIRM STAFF AFTER AWARDS WERE MADE.  
5 AND SO IT WASN'T CLEAR TO ME FROM THE RFA THAT IT  
6 WOULD AFFECT THE SCORE IN ANY WAY.

7 DR. GRIESHAMMER: SO IT ACTUALLY DID NOT  
8 AFFECT THE SCORE. IT AFFECTED THE RECOMMENDATIONS,  
9 AS PROGRAMMATIC REVIEW ALWAYS DOES.

10 DR. TROUNSON: IT WAS BASICALLY  
11 PROGRAMMATICALLY HOW WELL DID THEY FIT TOGETHER. SO  
12 PROGRAMMATIC ASSESSMENT. SO THE SCORES REMAIN  
13 INDEPENDENT FOR THE INDIVIDUAL ONES.

14 INCIDENTALLY, THAT DOESN'T INVOLVE --  
15 THERE WAS NO PAIRING ASSOCIATED WITH THE TISSUE  
16 COLLECTING. IT'S A LITTLE OUTSIDE THE CURRENT ONE.  
17 I THOUGHT WE WERE DEALING WITH THE TISSUE COLLECTION  
18 ONE FIRST.

19 CHAIRMAN THOMAS: CORRECT.

20 DR. TROUNSON: THAT'S ACTUALLY OUT OF THIS  
21 SCOPE.

22 DR. GRIESHAMMER: I HAVEN'T FORGOTTEN  
23 ABOUT YOUR OTHER QUESTION WHICH I WILL ADDRESS WHEN  
24 WE GET TO THE OTHER SET.

25 CHAIRMAN THOMAS: ANY OTHER COMMENTS BY

**BARRISTERS' REPORTING SERVICE**

1 MEMBERS OF THE BOARD?

2 DR. TROUNSON: MAYBE ONE, CHAIR. FOR THAT  
3 EXTRAORDINARY PETITION, IT WAS A MUCH LOWER MARK  
4 ONE. IT WAS COLLECTION MATERIAL FROM BRAIN DEAD  
5 PATIENTS. SO IT WAS MUCH LOWER THAN ALL THE REST.  
6 I JUST WANTED TO LET YOU KNOW.

7 CHAIRMAN THOMAS: THANK YOU, DR. TROUNSON.  
8 DO WE NEED VOICE ON THIS ONE?

9 MR. HARRISON: NO. WE'LL DO A ROLL CALL  
10 VOTE OF THE 15 MEMBERS. AND IF YOU HAVE A CONFLICT  
11 WITH RESPECT TO AN APPLICATION, VOTE YES OR NO  
12 EXCEPT WITH RESPECT TO THOSE WITH WHICH YOU HAVE A  
13 CONFLICT.

14 MS. SAMUELSON: QUESTION, POINT OF ORDER.  
15 COULD YOU RESTATE WHICH GRANT NUMBERS APPLY TO THIS  
16 VOTE?

17 MR. HARRISON: THIS IS TO APPROVE FUNDING  
18 THE TISSUE COLLECTION APPLICATIONS IN TIER I, WHICH  
19 ARE 6611, 6596, 6589, 6571, 6601, 6563, AND 6570,  
20 AND NOT TO FUND THOSE IN TIER III.

21 CHAIRMAN THOMAS: MARIA.

22 MS. BONNEVILLE: ANNE-MARIE DULIEGE.  
23 MARCY FEIT.

24 MS. FEIT: YES, EXCEPT FOR THOSE WITH  
25 WHICH I HAVE A CONFLICT.

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1 MS. BONNEVILLE: MICHAEL GOLDBERG.  
2 STEPHEN JUELSGAARD.

3 MR. JUELSGAARD: YES.

4 MS. BONNEVILLE: SHERRY LANSING.  
5 FRANCISCO PRIETO. ROBERT QUINT.

6 DR. QUINT: YES.

7 MS. BONNEVILLE: DUANE ROTH.

8 MR. ROTH: YES.

9 MS. BONNEVILLE: JOAN SAMUELSON.

10 MS. SAMUELSON: YES.

11 MR. HARRISON: I BELIEVE YOUR VOTE WAS YES  
12 EXCEPT WITH RESPECT TO THOSE APPLICATIONS FOR WHICH  
13 YOU HAVE A CONFLICT.

14 MR. ROTH: ME?

15 MR. HARRISON: YES.

16 MR. ROTH: I COULDN'T FIND ONE ON HERE.  
17 SO YES, EXCEPT FOR THOSE WITH WHICH I HAVE A  
18 CONFLICT.

19 MS. BONNEVILLE: JEFF SHEEHY.

20 MR. SHEEHY: YES, EXCEPT FOR THOSE WITH  
21 WHICH I HAVE A CONFLICT.

22 MS. BONNEVILLE: JONATHAN SHESTACK.

23 MR. SHESTACK: YES.

24 MS. BONNEVILLE: OSWALD STEWARD.

25 DR. STEWARD: I'M GOING TO ABSTAIN ON THIS



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1 ONE. AN ABSTENTION DOESN'T HURT THE QUORUM, RIGHT?

2 MR. HARRISON: WE'LL HAVE TO EVALUATE THAT  
3 ON AN APPLICATION-BY-APPLICATION BASIS.

4 MS. BONNEVILLE: JONATHAN THOMAS.

5 CHAIRMAN THOMAS: YES.

6 MS. BONNEVILLE: ART TORRES.

7 MR. TORRES: AYE.

8 MS. BONNEVILLE: DIANE WINOKUR.

9 MS. WINOKUR: YES.

10 MR. GOLDBERG: YES, EXCEPT FOR THOSE WITH  
11 WHICH I HAVE A CONFLICT.

12 MS. BONNEVILLE: THANK YOU.

13 MS. SAMUELSON: I'M JUST CURIOUS, DR.  
14 STEWARD, THE BASIS FOR YOUR ABSTENTION IF YOU'RE  
15 COMFORTABLE OR IT'S APPROPRIATE TO ASK THAT  
16 QUESTION.

17 DR. STEWARD: ON THIS ONE I WAS ACTUALLY  
18 OUT OF THE ROOM WHEN THE MOTION WAS MADE.

19 MS. SAMUELSON: THANK YOU.

20 CHAIRMAN THOMAS: THANK YOU FOR YOUR  
21 HONESTY, DR. STEWARD. DULY NOTED AND APPRECIATED.

22 MR. HARRISON: THAT MOTION CARRIES.

23 CHAIRMAN THOMAS: THANK YOU. NOW WITH  
24 RESPECT TO RFA'S 03 AND 04, WE DO HAVE PUBLIC  
25 COMMENT. OR, DR. SAMBRANO, DO YOU WANT TO SPEAK ANY

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1 FURTHER BEFORE WE HAVE PUBLIC COMMENT? NO. OKAY.  
2 SO, UTA, WOULD YOU LIKE TO ORCHESTRATE THIS, PLEASE.

3 DR. GRIESHAMMER: I CAN CERTAINLY START BY  
4 ADDRESSING THE OTHER QUESTION THAT DR. LEVIN WAS  
5 ASKING ABOUT, THE 25-PERCENT EFFORT THAT WE REQUIRED  
6 AS A MINIMUM FOR THE PROGRAM DIRECTOR FOR THE  
7 DERIVATION RFA. AND I BELIEVE THE EXTRAORDINARY  
8 PETITION SAYS THAT THE GRANTS WORKING GROUP DECIDED  
9 THAT THAT WAS NOT ENOUGH FOR A PARTICULAR APPLICANT.

10 AND I WANT TO CLARIFY WHAT WAS ACTUALLY  
11 MEANT AND INTENDED BY THAT CRITICISM WAS THAT  
12 ALTHOUGH 25 PERCENT, AS CIRM SUGGESTED AS A MINIMUM,  
13 WOULD BE ENOUGH, THERE WERE DOUBTS AS TO WHETHER  
14 THAT PROGRAM DIRECTOR WOULD INDEED HAVE THAT TIME  
15 FOR THIS PROJECT.

16 IF THERE'S NO MORE BOARD COMMENT --

17 CHAIRMAN THOMAS: CAN WE PROCEED TO  
18 MEMBERS OF THE PUBLIC WHO WOULD LIKE TO COMMENT.

19 MR. SHESTACK: CAN WE KEEP IT  
20 DERIVER/DERIVER, REPOSITORY/REPOSITORY?

21 CHAIRMAN THOMAS: GOOD SUGGESTION, MR.  
22 SHESTACK. LET'S START WITH THE DERIVER PUBLIC  
23 COMMENTS, AND PLEASE REMEMBER YOU HAVE THREE MINUTES  
24 EACH. PLEASE STATE YOUR NAME FOR THE RECORD.

25 MS. SOLOMON: HI. I'M SUSAN SOLOMON, AND

**BARRISTERS' REPORTING SERVICE**

1 I'M THE CO-FOUNDER -- I'M SUSAN SOLOMON, AND I'M THE  
2 CO-FOUNDER AND CEO OF THE NEW YORK STEM CELL  
3 FOUNDATION. AND I WANT TO THANK YOU, CHAIRMAN  
4 THOMAS, AND MEMBERS OF THE COMMITTEE, FOR THE  
5 OPPORTUNITY TO SPEAK TO YOU TODAY.

6 I WAS VERY HAPPY TO LEARN THAT THE GRANTS  
7 WORKING GROUP PROVISIONALLY RECOMMENDED BOTH OF OUR  
8 GRANT APPLICATIONS FOR FUNDING. FOR A LITTLE BIT OF  
9 BACKGROUND, WE'RE A NONPROFIT ORGANIZATION THAT I  
10 CO-FOUNDED WITH A NUMBER OF OTHER PATIENT ADVOCATES  
11 IN 2005. I'VE BEEN INVOLVED IN THE PATIENT ADVOCACY  
12 COMMUNITY FOR ABOUT 20 YEARS SINCE MY SON WAS  
13 DIAGNOSED WITH TYPE 1 DIABETES. AND A COUPLE OF  
14 YEARS, I THINK ABOUT 2004, AFTER I LOST MY PARENTS  
15 TO CANCER AND HEART DISEASE, A NUMBER OF US DECIDED,  
16 LOOKING AT THE VARIOUS CONDITIONS THAT WE WERE ALL  
17 LIVING THROUGH IN OUR LIVES, THAT IT WAS TIME TO DO  
18 SOMETHING ABOUT IT. AND SO WE STARTED NYSCF.

19 LIKE CIRM, OUR SOLE MISSION IS TO  
20 ACCELERATE CURES FOR THE MAJOR DISEASES OF OUR TIME  
21 THROUGH STEM CELL RESEARCH. IN 2006, WE OPENED THE  
22 FIRST PRIVATELY FUNDED STEM CELL LABORATORY IN NEW  
23 YORK THAT HAS NOW BECOME ONE OF THE LARGEST STEM  
24 CELL LABS IN THE COUNTRY. OUR SCIENTISTS ARE AMONG  
25 THE ACKNOWLEDGED WORLD LEADERS IN STEM CELL

## BARRISTERS' REPORTING SERVICE

1 PRODUCTION, AND WE'VE BEEN AT THE FOREFRONT OF THIS  
2 FIELD FROM THE START. OUR SCIENTISTS GENERATED THE  
3 FIRST-EVER PATIENT-SPECIFIC STEM CELL LINE IN 2008,  
4 THE FIRST-EVER PATIENT-SPECIFIC HUMAN EMBRYONIC STEM  
5 CELL LINE IN 2011, AND LAST DECEMBER, USING OUR STEM  
6 CELL EXPERTISE, DEVELOPED A METHOD FOR PREVENTING  
7 MATERNALLY INHERITED MITOCHONDRIAL DISORDERS.

8 OVER THE PAST FOUR YEARS, WE HAVE INVESTED  
9 OVER \$20 MILLION TO DEVELOP A SYSTEM THAT IS NOW UP  
10 AND RUNNING THAT DERIVES AND CHARACTERIZES STEM CELL  
11 LINES IN A FULLY AUTOMATED PROCESS. BECAUSE OF THIS  
12 PROCESS, WE'RE ABLE TO SIGNIFICANTLY REDUCE THE COST  
13 WITHOUT LOSING THE QUALITY OF THE STEM CELL LINES  
14 WHILE ALSO REMAINING SUSTAINABLE AFTER THE END OF  
15 THIS AWARD.

16 DR. STEPHEN CHANG, OUR VICE PRESIDENT FOR  
17 RESEARCH AND DEVELOPMENT AND PRINCIPAL INVESTIGATOR  
18 ON OUR APPLICATIONS, IS HERE TO ADDRESS SPECIFIC  
19 QUESTIONS. AND ALSO HERE TODAY IS DR. SCOTT NOGGLE,  
20 WHO IS OUR LABORATORY DIRECTOR AND HEADS UP OUR  
21 DERIVATION EFFORTS IF THERE ARE ANY SPECIFIC  
22 QUESTIONS ON DERIVATION.

23 WE CURRENTLY SUPPORT AND COLLABORATE WITH  
24 MANY CALIFORNIA SCIENTISTS, INCLUDING THOSE AT UCSD,  
25 USC, UCSF, STANFORD, UC SANTA BARBARA, THE BUCK

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1 INSTITUTE, AND MANY OTHER SCIENTISTS FROM AROUND THE  
2 WORLD WHO UTILIZE OUR STEM CELLS.

3 I UNDERSTAND THAT MANY OF THESE  
4 COLLABORATORS HAVE WRITTEN DIRECTLY TO YOU AND TO  
5 THE BOARD IN SUPPORT OF OUR PROPOSAL. AND I REALLY  
6 THANK YOU FOR THE OPPORTUNITY TO SPEAK TO YOU, AND  
7 I'M HOPING THAT I HAVE MANY OPPORTUNITIES TO VISIT  
8 WITH ALL OF OUR COLLABORATORS AS WELL AS MY CHILDREN  
9 AND GRANDCHILDREN IN CALIFORNIA. THANK YOU.

10 CHAIRMAN THOMAS: THANK YOU. DR. CHANG.

11 DR. CHANG: THANK YOU, CHAIRMAN THOMAS,  
12 MEMBERS OF THE INDEPENDENT CITIZENS OVERSIGHT  
13 COMMITTEE. THANK YOU FOR THE OPPORTUNITY TO SPEAK  
14 TODAY. I'M STEPHEN CHANG, A CALIFORNIAN, THE  
15 PRINCIPAL INVESTIGATOR OF THE NEW YORK STEM CELL  
16 FOUNDATION'S APPLICATION FOR THE CIRM HUMAN INDUCED  
17 PLURIPOTENT STEM CELL DERIVATION AND REPOSITORY  
18 AWARDS.

19 I'M VERY PLEASED THAT THE WORKING GROUP  
20 PROVISIONALLY RECOMMENDED BOTH OUR GRANTS FOR  
21 FUNDING. THIS IS THE FIRST POINT THAT WAS MADE IN  
22 THE CRITIQUES. LIKE CIRM, OUR MISSION IS TO  
23 ACCELERATE CURES THROUGH STEM CELL RESEARCH. OUR  
24 SOLE FOCUS ON STEM CELL RESEARCH HAS CULMINATED IN  
25 THE DEVELOPMENT AND OPERATIONS OF THE FIRST FULLY

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1 AUTOMATED STEM CELL SYSTEM FOR HIGH THROUGHPUT  
2 DERIVATION OF HUMAN INDUCED PLURIPOTENT STEM CELLS.  
3 THIS IS THE RESULT OF OUR \$20 MILLION INVESTMENT AND  
4 OUR FOUR YEARS OF HARD WORK. AND IT'S THE ONLY  
5 FULLY AUTOMATED SYSTEM THAT ISOLATES FIBROBLASTS,  
6 ISOLATION ALL THE WAY THROUGH TO STEM CELL  
7 PRODUCTION AND FULL CHARACTERIZATION.

8 ONE UNEXPECTED ADVANTAGE OF THIS  
9 CUTTING-EDGE TECHNOLOGY AND THE AUTOMATED SYSTEM IS  
10 THAT IT TAKES UP A MUCH SMALLER FOOTPRINT THAN THE  
11 CONVENTIONAL STEM CELL DERIVATION FACILITIES. THIS  
12 MAY NOT HAVE BEEN APPRECIATED BY THE REVIEW  
13 COMMITTEE. AND WE DID NOT ACTUALLY ASK FOR ANY MORE  
14 SPACE BECAUSE CURRENTLY WHAT WE ASKED FOR WAS DOUBLE  
15 THE SPACE WE HAVE AT OUR CURRENT FACILITY IN NEW  
16 YORK. AND WHAT WE ALSO HAD IN THIS APPLICATION IS  
17 IF WE COULD ASK FOR MORE SPACE. SO THE BUILDING  
18 PEOPLE ARE CERTAINLY WILLING TO GIVE US MORE SPACE.

19 ANOTHER CONCERN BY THE REVIEWERS WAS THAT  
20 OUR PROCESS IS NOT YET FULLY ROUTINE. WE ARE HAPPY  
21 TO REPORT THAT OUR SYSTEM IS CURRENTLY FULLY  
22 OPERATIONAL AND PRODUCING STEM CELL LINES AT A RATE  
23 OF APPROXIMATELY 200 FULLY CHARACTERIZED LINES A  
24 MONTH. THE AUTOMATION REMOVES ANY MANUAL  
25 MANIPULATION THAT MAY CAUSE CELL LINES TO DIFFER

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1 FROM ONE LINE TO ANOTHER, AT THE SAME TIME MAINTAIN  
2 THE HIGHEST LEVELS OF CHARACTERIZATION.

3 OUR MAIN CONCERN OF OUR DERIVATION PROCESS  
4 WAS OUR METHOD OF SELECTING CLONES AND THAT IT MAY  
5 NOT WORK. WE HAVE GENERATED SEVERAL HUNDRED IPS  
6 CELL LINES WITH THIS METHOD, AND THE PROCESS AND  
7 CHARACTERIZATION OF THESE CELL LINES WAS RECENTLY  
8 PEER REVIEWED AND ACCEPTED INTO THE JOURNAL *PLOS*  
9 *ONE*. THIS PAPER WHICH SHOULD HAVE BEEN PRESENTED TO  
10 YOU SHOWS THIS PROCESS NOT ONLY WORKS, IS SUPERIOR  
11 TO OTHER METHODS THAT OFTEN FAIL TO SELECT HIGH  
12 QUALITY COLONIES EARLY IN THE DERIVATION PROCESS,  
13 RESULTING IN CELL LINES THAT MAY REQUIRE INCREASED  
14 MAINTENANCE AND UNRELIABLE EXPERIMENTAL OUTCOMES.

15 WITH ME HERE TODAY IS DR. SCOTT NOGGLE,  
16 WHO HEADS OUR EXISTING DERIVATION OPERATIONS AND WAS  
17 THE LEAD AUTHOR OF THAT STUDY. HE WOULD BE COMING  
18 TO CALIFORNIA WITH OTHER MEMBERS OF OUR TEAM TO  
19 HIRE, TRAIN, AND RAMP UP PRODUCTION, BRINGING THEIR  
20 EXPERTISE TO LEAD THE NEW CALIFORNIA STAFF. DR.  
21 NOGGLE AND OUR TEAM ARE HERE TO ANSWER ANY  
22 QUESTIONS. THANK YOU VERY MUCH.

23 CHAIRMAN THOMAS: THANK YOU, DR. CHANG.  
24 DR. NOGGLE.

25 DR. NOGGLE: THANK YOU, CHAIRMAN THOMAS

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1 AND MEMBERS OF THE ICOC. MY NAME IS SCOTT NOGGLE.  
2 I'M THE DIRECTOR OF THE NYSCF LABORATORY, AND I LEAD  
3 THE DERIVATION EFFORTS AT THE LABORATORY.

4 PRIOR TO JOINING NYSCF, I WAS THE MANAGER  
5 OF THE TRI-INSTITUTIONAL STEM CELLS INITIATIVES  
6 DERIVATION CORE FACILITY AT ROCKEFELLER UNIVERSITY  
7 AND IN ASSOCIATION WITH MEMORIAL SLOAN KETTERING  
8 CANCER CENTER AND WEILL CORNELL MEDICAL COLLEGE.

9 I'VE WORKED AT NYSCF FOR ABOUT FIVE YEARS  
10 NOW. AND DURING THIS TIME, WE'VE SEEN A NEED FOR  
11 MORE QUANTITATIVE, STANDARDIZED METHODS FOR DERIVING  
12 STEM CELLS. WE SET OUT TO DEVELOP A NEW  
13 STANDARDIZED AND HIGH THROUGHPUT METHOD FOR MAKING  
14 STEM CELLS. AND TO MEET THIS NEED, WE'VE SUCCEEDED  
15 IN AUTOMATING THE SYSTEM.

16 DURING THIS TIME, WE'VE HAD MANY  
17 OPPORTUNITIES TO WORK WITH A LARGE NUMBER OF  
18 COLLABORATORS. AND TO THAT DR. ARNOLD KRIEGSTEIN OF  
19 UCSF HAD HOPED TO BE HERE TODAY, BUT WAS UNABLE AND  
20 ASKED THAT I READ A FOLLOWING LETTER. HE STATES,  
21 "AS THE DIRECTOR OF THE ELI AND EDITH BROAD CENTER  
22 FOR REGENERATION MEDICINE AND STEM CELL RESEARCH AT  
23 THE UNIVERSITY OF CALIFORNIA SAN FRANCISCO, I'M  
24 ENTHUSIASTIC ABOUT THE NEW YORK STEM CELL  
25 FOUNDATION'S PROPOSAL TO ESTABLISH AN IPS DERIVATION



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1 FACILITY IN CALIFORNIA.

2 NYSCF HAS A STRONG TRACK RECORD IN THE  
3 ADVANCED DERIVATION OF STEM CELL LINES. AND AS THIS  
4 AWARD WILL ENSURE THE STANDARDIZED PRODUCTION OF IPS  
5 CELL LINES OF THE HIGHEST QUALITY, I AM CONVINCED  
6 NYSCF PROPOSES THE BEST OPTION FOR GENERATING THE  
7 LARGE NUMBER OF CELL LINES REQUESTED BY CIRM. NYSCF  
8 HAS BUILT INTO THEIR AUTOMATED SYSTEM A LEVEL OF  
9 QUALITY CONTROL THAT'S NOT POSSIBLE USING STANDARD  
10 MANUAL METHODS. AND THEIR METHOD FOR  
11 CHARACTERIZATION WOULD ENSURE THAT CONSISTENT AND  
12 HIGH QUALITY IPS CELL LINES ARE AVAILABLE TO  
13 INVESTIGATORS HERE IN CALIFORNIA.

14 "IN THE PAST A NUMBER OF MY COLLEAGUES AT  
15 UCSF HAVE RECEIVED IPS CELLS AND IPS CELL-DERIVED  
16 CELLS FROM NYSCF FOR USE IN THEIR OWN STUDIES AND  
17 SUBMITTED PROPOSALS AND PROPOSED NYSCF AS A PARTNER  
18 IN DERIVING HUMAN IPS CELLS FOR THEIR  
19 INVESTIGATIONS. THIS IS AN ENDORSEMENT OF THE  
20 QUALITY OF THE LINES PRODUCED.

21 "AN ADDITIONAL IMPORTANT CONSIDERATION, IN  
22 MY VIEW, IS THE PROXIMITY OF THE CIRM DERIVATION  
23 FACILITY TO CLINICIANS, CLINICIAN SCIENTISTS, AND TO  
24 HOSPITALS. THE NYSCF FACILITY WILL BE ADJACENT TO  
25 THE RICH STEM CELL COMMUNITIES AT UCSF AND

**BARRISTERS' REPORTING SERVICE**

1 GLADSTONE, MAJOR CENTERS OF CIRM-FUNDED IPS  
2 DISCOVERY RESEARCH, THAT PROVIDE LOCAL EXPERTISE IN  
3 STEM CELL DERIVATION, QUALITY CONTROL, CULTURE, AND  
4 DIFFERENTIATION.

5 THE UCSF HOSPITALS, INCLUDING THE NEW  
6 WOMEN, CHILDREN, AND CANCER CENTERS WHICH SERVE AS  
7 CONDUITS FOR TISSUE COLLECTION, THE FIELD IS STILL  
8 YOUNG, THE TECHNOLOGY IS EVOLVING, AND SITING THE  
9 IPS LABORATORY IN A NEIGHBORHOOD TEEMING WITH  
10 CREATIVE ACADEMIC AND BIOTECH LEADERS MAKES THE MOST  
11 SENSE.

12 "THIS IS EXACTLY THE ATTRACTION THAT HAS  
13 CREATED THE BIOTECH BOOM CURRENTLY UNDER WAY IN  
14 MISSION BAY AND IS WHY LOCATING THE CIRM IPS  
15 DERIVATION FACILITY IN THIS UNIQUE ENVIRONMENT IS SO  
16 COMPELLING.

17 "IF AWARDED, NYSCF COMBINED WITH CIRM'S  
18 EXISTING EFFORTS WILL HELP ENSURE CALIFORNIA REMAINS  
19 AT THE FOREFRONT OF ACADEMIC AND TRANSLATIONAL STEM  
20 CELL RESEARCH. IT IS WITHOUT HESITATION AND IN THE  
21 STRONGEST TERMS THAT I SUPPORT NYSCF'S PROPOSAL.  
22 SINCERELY, DR. ARNOLD KRIEGSTEIN."

23 THANK YOU VERY MUCH.

24 CHAIRMAN THOMAS: THANK YOU, DR. NOGGLE.

25 DR. GRIESHAMMER: I JUST WANTED TO, FOR

**BARRISTERS' REPORTING SERVICE**

1 CLARITY FOR THE BOARD, POINT OUT THAT THE NYSCF  
2 APPLICATIONS THAT WERE JUST BEING REFERRED TO ARE  
3 NUMBER I.D. 6617 THAT HAS THE PAIRED RANKING OF TWO  
4 AND THREE. SO THEY WERE PART OF THE SECOND AND  
5 THIRD CHOICE PAIR. AND FOR THE REPOSITORY, IT'S  
6 I.R. 6595, AND THEY WERE PART OF THE THIRD PAIR  
7 CHOICE. JUST SO YOU KNOW.

8 CHAIRMAN THOMAS: THANK YOU. DO WE HAVE  
9 ADDITIONAL TESTIMONY, PUBLIC COMMENT ON A  
10 DERIVER-RELATED MATTER? PLEASE STATE YOUR NAME.

11 DR. SNYDER: I'M EVAN SNYDER, DIRECTOR OF  
12 THE STEM CELL CORE AT THE SANFORD BURNHAM. OUR  
13 PROPOSAL TO BECOME THE STATE'S IPS DERIVATION CENTER  
14 CAME IN SECOND PLACE, JUST FOUR POINTS BELOW THE  
15 LEADING CANDIDATE. AND, THEREFORE, IN A RACE THIS  
16 CLOSE, EVEN MINOR ERRORS OR MISCONCEPTIONS CAN HAVE  
17 SIGNIFICANT ADVERSE IMPACT. AND WHILE I DO HAVE  
18 SOME QUIBBLES REGARDING ERRORS IN OUR ASSESSMENT, I  
19 AM NOT GOING TO FOCUS IN MY THREE MINUTES ON THOSE,  
20 BUT RATHER ON SOME LARGER ISSUES THAT I BELIEVE THE  
21 ICOC SHOULD BE TAKING INTO CONSIDERATION.

22 THERE ARE MAJOR PROBLEMS THAT I WISH TO  
23 ADDRESS VERY BRIEFLY AND THEN OFFER WHAT I HOPE WILL  
24 BE A SOLOMONIC SOLUTION. FIRST, THERE'S AN  
25 EXPLICITLY STATED BIAS ON THE RECORD FROM CIRM

**BARRISTERS' REPORTING SERVICE**

1 AGAINST ACADEMIC INSTITUTIONS THAT WAS NOT ONLY  
2 DISAPPOINTING, BUT ALSO UNFAIR AND INACCURATE, YET  
3 WAS CITED AS DAMPENING ENTHUSIASM FOR PROPOSALS.

4 THE INACCURACIES SURROUNDED THE FATE OF  
5 INDIRECT COSTS THAT WERE SAID NOT TO CONTRIBUTE  
6 DIRECTLY TO THE PROJECT. IN FACT, ACADEMIC  
7 INSTITUTIONS ARE SIMPLY ABOVEBOARD IN TALLYING THE  
8 ACTUAL COSTS OF PRODUCING A PRODUCT. INDIRECT COSTS  
9 COVER SUCH NECESSARY SERVICES TO CELL LINE  
10 PRODUCTION AS DATA STORAGE AND PROCESSING AND  
11 TRACKING, BIOINFORMATICS, REGULATORY,  
12 ADMINISTRATIVE, LEGAL, IP, I.T. SUPPORT, CORE  
13 SERVICES SUCH AS MICROSCOPY, SECURITY, AND CUSTODIAL  
14 SERVICES, ETHICAL, AND HUMAN SUBJECTS TRAINING. SO  
15 COMMERCIAL ENTITIES SIMPLY ADD THESE COSTS TO THE  
16 DIRECT COST OF THEIR CELL LINE. HENCE, THE ISSUE OF  
17 BEING AN ACADEMIC INSTITUTION IS A RED HERRING, YET  
18 BLOCKED OUR EVEN BEING CONSIDERED AS BEING PAIRED  
19 WITH A REPOSITORY. AND INDEED WE WERE LEAP-FROGGED  
20 OVER TO MAKE SUCH A PAIRING TO A LOWER RANKING  
21 DERIVER.

22 BUT HERE'S THE MORE IMPORTANT ISSUE, THAT  
23 THERE MAY BE, IN FACT, SOME MISPLACED AND  
24 SHORTSIGHTED EMPHASIS AND BELIEF THAT HAVING THE  
25 DERIVER AND THE REPOSITORY IN THE SAME BUILDING IS

**BARRISTERS' REPORTING SERVICE**

1 CRITICAL. FIRST, THE RFA DID NOT REQUIRE OR SAY  
2 THAT IT WOULD VIEW FAVORABLY SUCH A PAIRING IN THE  
3 SAME BUILDING. OF COURSE, THE IMPACT MEANS THAT YOU  
4 COULD BE LEAP-FROGGING OVER A MERITORIOUS  
5 APPLICATION OR LOOKING, FOR EXAMPLE, AS IF YOU'RE  
6 BYPASSING SOUTHERN CALIFORNIA.

7 BUT MORE TO THE POINT, SCIENTIFICALLY THIS  
8 IS ALSO SHORTSIGHTED BECAUSE IN REALITY TRANSPORTING  
9 FROZEN CELLS WITHIN THE STATE IS NOT A SIGNIFICANT  
10 LIMITATION. CIRM WAS CORRECT IN NOT DEMANDING  
11 CO-LOCATION OF THOSE. IT IS MUCH MORE CRUCIAL THAT  
12 THE DERIVER BE NEAR THE TISSUE COLLECTORS WHICH ARE  
13 LOCATED THROUGHOUT THE STATE. THAT MATERIAL IS  
14 IDEALLY SENT TO THE DERIVERS AS FRESH AS POSSIBLE,  
15 UNFROZEN IF THEY'RE FIBROBLASTS, LIVING AND MEANT TO  
16 BE PROCESSED WITHOUT DELAY. IN OTHER WORDS, MUCH  
17 GREATER SCIENTIFIC JUSTIFICATION IS HAVING THE  
18 COLLECTORS AND THE DERIVERS BE NEAR EACH OTHER THAN  
19 THE DERIVERS AND THE BANKERS BE NEAR EACH OTHER.

20 SO I WOULD LIKE TO SUGGEST A SOLUTION THAT  
21 WOULD BE SCIENTIFICALLY SENSIBLE AND ENSURE EVEN  
22 DISTRIBUTION OF FUNCTIONS THROUGHOUT THE STATE. AND  
23 THAT WOULD BE FOR THE ICOC TO ENDORSE THE CREATION  
24 OF A NORTHERN CALIFORNIA DERIVER AND REPOSITORY AND  
25 A SOUTHERN CALIFORNIA DERIVER AND REPOSITORY,

**BARRISTERS' REPORTING SERVICE**

1 PERHAPS SPLITTING THE TASK EQUALLY BETWEEN THE 3,000  
2 PATIENTS AS WELL AS SPLITTING EQUALLY THE EARMARKED  
3 FUNDS. THE TWO GROUPS CAN THEN COORDINATE THEIR  
4 SOP'S.

5 THANK YOU VERY MUCH. I THINK THAT WOULD  
6 BE A VERY QUICK, EASY, AND EQUITABLE SOLUTION THAT  
7 IS VERY SCIENTIFICALLY VALID.

8 CHAIRMAN THOMAS: THANK YOU, DR. SNYDER.  
9 NEXT COMMENT ON THE DERIVER-RELATED RFA.

10 MR. SHESTACK: CAN WE ASK QUESTIONS?

11 CHAIRMAN THOMAS: YES.

12 MR. SHESTACK: YOUR SOLOMONIC SOLUTION WAS  
13 JUST PRESENTED SO QUICKLY. I KNOW YOU HAVE THREE  
14 MINUTES. I'M SORRY. YOUR PROPOSAL, SAY THAT AGAIN.

15 CHAIRMAN THOMAS: MR. SHESTACK, POINT OF  
16 ORDER FOR MR. HARRISON.

17 MR. SHESTACK: ARE WE ALLOWED? HE'S  
18 TALKING ABOUT SPLITTING --

19 MR. HARRISON: AT YOUR DISCRETION.

20 CHAIRMAN THOMAS: MR. SHESTACK.

21 MR. SHESTACK: I'LL JUST ASK IT MORE  
22 PRECISELY THEN. YOUR PROPOSAL WOULD BE TO HAVE TWO  
23 DIFFERENT FACILITIES IN THE NORTH AND SOUTH THAT  
24 BOTH DID REPOSITORY AND DERIVATION TASKS?

25 DR. SNYDER: YEAH. WHAT I'M SIMPLY SAYING

## BARRISTERS' REPORTING SERVICE

1 IS THAT SINCE THE COLLECTORS WHO GET THIS FRESH  
2 TISSUE ARE DISTRIBUTED THROUGHOUT THE STATE, IT  
3 MAKES AN ENORMOUS AMOUNT OF SENSE TO HAVE A NORTHERN  
4 DERIVER AND A SOUTHERN DERIVER SO THAT TRANSPORTING  
5 THIS TISSUE CAN BE PROCESSED IMMEDIATELY. AND SINCE  
6 IT WOULD NOT COST ANY EXTRA MONEY, ONE CAN SIMPLY  
7 SAY, WELL, WE WANTED 3,000 PATIENTS, SO 1500, 1500.  
8 WE WANTED TO BE ALLOCATED 16 MILLION, EIGHT MILLION,  
9 EIGHT MILLION. AND NOW YOU HAVE THE DERIVERS NEAR  
10 THE COLLECTORS, AND THIS WOULD ALSO GIVE -- REWARD  
11 ALL THE MERITORIOUS DERIVERS IF ONE WANTED THE  
12 REPOSITORY ALSO TO BE NEAR THE DERIVERS. SO LET'S  
13 NOT SECOND-GUESS THE CIRM PROGRAM. AND, OF COURSE,  
14 YOU COULD HAVE A BANK ALSO SOUTHERN AND NORTHERN.

15 BUT I THINK THIS MAKES A LOT MORE SENSE  
16 THAN SOMEBODY IN SAN DIEGO DOING A SKIN BIOPSY AND  
17 HOPING THAT IT MAKES IT UP TO THE BAY AREA IN THE  
18 NEXT 48 HOURS WHEN WHAT YOU REALLY WANT TO DO IS  
19 PROCESS THE MATERIAL AS QUICKLY AS POSSIBLE.

20 DR. TROUNSON: CHAIR, THERE ARE A LOT OF  
21 ECONOMIC ISSUES ASSOCIATED WITH DUPLICATION OF  
22 FACILITIES, ETC. I THINK WE WOULD HAVE TO DO QUITE  
23 A BIT OF INVESTIGATION ABOUT WHETHER IT WAS  
24 ECONOMICALLY FEASIBLE. AND IT'S PROBABLY UNLIKELY  
25 TO BE SUPPORTED BY THE OTHERS.

**BARRISTERS' REPORTING SERVICE**

1 CHAIRMAN THOMAS: THANK YOU. THANK YOU,  
2 DR. SNYDER. LET'S MOVE ON NOW. NEXT, PLEASE.

3 MR. PALAY: GOOD AFTERNOON. I'M BOB  
4 PALAY. I'M CHAIRMAN AND CEO OF CELLULAR DYNAMICS  
5 INTERNATIONAL. IT'S AN HONOR TO SPEAK HERE TO YOU  
6 TODAY. CIRM HAS DONE SO MUCH FOR THIS FIELD. AND  
7 THOSE OF US WHO REALLY CARE AND LOVE STEM CELLS AND  
8 ITS POTENTIAL JUST WANT TO SAY THANK YOU. YOU'VE  
9 KEPT THIS FIELD GOING AT A TIME WHEN IT WAS IN  
10 TROUBLE. SO FROM CDI'S POINT OF VIEW, WE JUST WANT  
11 TO THANK YOU.

12 WE WANT TO TELL YOU THAT WE FEEL HONORED  
13 TO LEARN THAT OUR PROPOSAL FOR RFA 12-03 RECEIVED  
14 THE HIGHEST SCORE FROM THE GRANTS WORKING GROUP AND  
15 WAS RECOMMENDED FOR FUNDING. WE'RE ALSO HONORED TO  
16 LEARN THAT OUR PAIRED PROPOSAL WITH CORIELL FOR  
17 12-04 WAS RECOMMENDED FOR FUNDING, AND THE  
18 COMBINATION WAS SELECTED AS THE FIRST PAIR  
19 COMBINATION BY GRANTS WORKING GROUP. JUST TO BE  
20 CLEAR, WE RECRUITED CORIELL TO COME TO CALIFORNIA  
21 WITH US TO BE PART OF THIS BID.

22 CIRM LEADS THE WORLD IN TRANSLATING THE  
23 PROMISE OF STEM CELLS INTO REAL THERAPIES FOR THE  
24 BENEFITS OF PATIENTS. AT CDI WE'VE WORKED HARD TO  
25 BUILD OUR INDUSTRIAL CAPABILITIES FOR IPS DERIVATION



**BARRISTERS' REPORTING SERVICE**

1 AND MANUFACTURE, AND WE SEE THE RECOMMENDATIONS AS  
2 VALIDATION BY THE SCIENTIFIC LEADERS OF THE GWG  
3 RECOGNIZING THE PROGRESS CDI HAS MADE IN THIS AREA.

4 WE WERE BUILT TO ENABLE THE TRANSLATION OF  
5 THIS PROMISE OF STEM CELLS INTO THE CLINIC. WE  
6 BELIEVE THAT -- AND WE'VE SPENT -- RAISED OVER \$120  
7 MILLION IN OUR COMPANY TO DATE. WE BELIEVE THAT THE  
8 WAY TO MOVE THE FIELD FORWARD IS BY MANUFACTURING  
9 THE HIGHEST QUALITY STEM CELL LINES AND DOWNSTREAM  
10 DIFFERENTIATED CELLS TO TIGHT INDUSTRIAL  
11 SPECIFICATIONS. I THINK THE GRANT REVIEW REFLECTED  
12 OUR PROGRESS IN THAT.

13 WE BELIEVE THAT TRANSLATION INTO THE  
14 CLINIC IS GOING TO REQUIRE VERY LARGE VOLUMES OF  
15 HUMAN CELLS MANUFACTURED TO VERY TIGHT  
16 SPECIFICATIONS. AND ONE OF THE THINGS THAT'S BEEN  
17 HOLDING THE FIELD BACK TO DATE IS THE FACT THAT,  
18 FRANKLY, IT HASN'T HAPPENED. ACADEMICS, THIS ISN'T  
19 WHAT THEY FOCUS ON AND STRIVE FOR. SIMPLY STATED,  
20 OUR GOAL IS TO MANUFACTURE GREAT STEM CELLS AND  
21 TISSUE CELLS SO GREAT SCIENTISTS LIKE EVAN SNYDER,  
22 JEAN LORING, EVEN STEPHEN CHANG CAN CURE DISEASE  
23 BECAUSE THIS IS ALL ABOUT CURING DISEASE. ALL WE  
24 ARE IS MAKING THAT BASIC UNDERLYING TOOL SO THAT  
25 OTHER PEOPLE, THE GREAT SCIENTISTS, DON'T HAVE TO

**BARRISTERS' REPORTING SERVICE**

1 MAKE THEIR OWN CELLS, THAT SOMEBODY WILL MAKE THEM  
2 FOR THEM.

3 OKAY. NOW, ACCOMPLISHING THIS GOAL OF  
4 GREAT CELLS ISN'T GLAMOROUS. IT REQUIRES HIRING  
5 PEOPLE FOR THINGS LIKE PROCESS SCIENCE, QUALITY  
6 ASSURANCE, QUALITY CONTROL. IT MEANS SPENDING HOURS  
7 WORKING ON BORING THINGS LIKE PRODUCT SPECIFICATIONS  
8 AND STANDARD OPERATING PROCEDURES, BUT THAT'S WHAT  
9 CDI HAS BEEN DOING. OKAY. WE BELIEVE THAT IT TAKES  
10 THIS TYPE OF ROLL-UP-YOUR-SLEEVES WORK TO  
11 CONSISTENTLY PRODUCE THE CELLS OF THE HIGHEST  
12 POSSIBLE QUALITY IN THE QUANTITIES THAT GREAT  
13 RESEARCHERS NEED IN ORDER TO MAKE THAT TRANSLATIONAL  
14 LEAP.

15 WE CURRENTLY HAVE AT OUR COMPANY 116  
16 PEOPLE, WE HAVE OVER 450 YEARS OF STEM CELL  
17 EXPERIENCE. WE WERE -- IN 2006 WE STARTED  
18 ROBOTICALLY CULTURING. WE HAVE 70 BILLION HUMAN  
19 INDUCED PLURIPOTENT STEM CELLS PER MONTH, 128  
20 CUSTOMERS LAST YEAR, 18 OF THE TOP 20 BIOPHARMA, 50  
21 DIFFERENT ACADEMIC INSTITUTIONS. JUST TO TELL YOU  
22 THAT WHAT WE REALLY WANT TO DO HERE IS WE WANT TO  
23 HELP CIRM, THE WORLD LEADER IN TRANSLATING THE  
24 PROMISE OF STEM CELLS INTO REAL THERAPIES, BY  
25 PRODUCING THE CELLS THAT YOU NEED, THAT THAT BANK

**BARRISTERS' REPORTING SERVICE**

1 NEEDS, SO THAT RESEARCHERS AROUND THE WORLD CAN HAVE  
2 ACCESS TO THAT HIGH -- THOSE CONSISTENT, RELIABLE,  
3 HIGH QUALITY CELLS IN THE QUANTITIES --

4 CHAIRMAN THOMAS: BOB, WE NEED TO WRAP UP.

5 MR. PALAY: I APOLOGIZE. I JUST WANT TO  
6 TAKE ONE SECOND TO SAY THAT EMILE NUWAYSIR AND OUR  
7 PI TOM NOVAK ARE HERE TO ANSWER ANY TECHNICAL  
8 QUESTIONS. SORRY I RAN OVER.

9 CHAIRMAN THOMAS: THANK YOU. OKAY. NOW,  
10 DOES THAT CONCLUDE THE PUBLIC COMMENT ON THE DERIVER  
11 APPLICATION? YES. OKAY. NOW, ARE THERE ANY  
12 ADDITIONAL PUBLIC COMMENTS ON THE REPOSITORY  
13 APPLICATIONS, OR DID YOU SORT OF SPEAK TO BOTH?  
14 ANYBODY WHO'D LIKE TO SPEAK, PLEASE COME UP NOW.  
15 AGAIN, THREE MINUTES. PLEASE IDENTIFY YOURSELF.

16 MR. MOORE: I'M AARON MOORE. I'M WITH  
17 SANGUINE BIOSCIENCES. AND I GOT A LITTLE TIP  
18 EARLIER FROM SOMEBODY FROM THE COMMITTEE THAT SAID  
19 BE QUICK, BE GOOD, BE GONE. SO MY COMMENTS WILL BE  
20 VERY QUICK, HOPEFULLY. AND HOPEFULLY THEY'LL BE  
21 GOOD AND I'LL BE GONE.

22 CHAIRMAN THOMAS: MR. HARRISON, WILL YOU  
23 WRITE THAT DOWN? THAT WAS VERY CATCHY.

24 MR. MOORE: SO WE ARE APPLICANT FOR THE  
25 REPOSITORY, AND I THINK THAT THERE ARE JUST THREE

**BARRISTERS' REPORTING SERVICE**

1 THINGS THAT I'D LIKE TO HAVE IN YOUR EAR AS YOU GO  
2 INTO THE CLOSED SESSION.

3 THE FIRST IS THAT WE ARE AN ACTIVELY  
4 OPERATING COMPANY WITHIN CALIFORNIA. WE ARE LOCATED  
5 IN SOUTHERN CALIFORNIA IN VALENCIA, HAVE A GROWING  
6 LAB, AND WE PRESENT LESS OF A LOGISTICAL CHALLENGE  
7 OF HAVING TO GET A LAB RAMPED UP, BUT WE HAVE A LAB  
8 THAT'S ACTUALLY ACTIVE.

9 THE SECOND THING WAS THAT IN OUR  
10 EXTRAORDINARY PETITION WE RESPONDED THAT WE HAD NOT  
11 PARTNERED WITH A DERIVER, AND SO THAT WE WERE A LONE  
12 REPOSITORY. AND WE FILED IN THE EXTRAORDINARY  
13 PETITION THAT WE HAVE PARTNERED WITH THE SANFORD  
14 BURNHAM INSTITUTE SO AS TO POTENTIALLY DIMINISH SOME  
15 OF THE NEGATIVE IMPLICATIONS OF NOT HAVING A  
16 PARTNERSHIP AS A DERIVER REPOSITORY.

17 AND THEN THIRD, AS A REPOSITORY, WE ARE  
18 SOMEWHAT UNIQUE IN THAT WE WERE FOUNDED BY AN MS  
19 PATIENT. AND WE ARE A BIOBANK, BUT WE HAVE ACTIVE  
20 RELATIONSHIPS WITH PATIENT POPULATIONS. WHAT WE  
21 DEVELOPED IS A TECHNOLOGY THAT ALLOWS PATIENTS TO BE  
22 ENGAGED AND EMPOWERED IN THE PROCESS BY SEEING  
23 THROUGH A PORTAL HOW THEIR BIOSPECIMENS ARE BEING  
24 USED FOR RESEARCH. WHAT WE'RE TRYING TO DO IS  
25 ACTIVELY ENGAGE THE PATIENT, EMPOWER THE PATIENT

**BARRISTERS' REPORTING SERVICE**

1 THROUGH TRANSPARENCY AND COMMUNICATION AS TO WHAT  
2 THEY'RE DOING.

3 WHAT'S HAPPENED IS THAT WE'VE CREATED  
4 SOMEWHAT OF AN EXCITEMENT WITHIN THE SOUTHERN  
5 CALIFORNIA PATIENT ADVOCACY COMMUNITY THAT IS  
6 ALLOWING PATIENTS TO PARTICIPATE AND WORK WITH  
7 SANGUINE AND SEE WHAT THEY'RE DOING AND HOW -- WHAT  
8 AN IMPACT THEY'RE MAKING. AND SO WE HAVE RIGHT NOW  
9 ON OUR PATIENT PORTAL OVER A THOUSAND PATIENTS PER  
10 MONTH COMING AND LEARNING MORE ABOUT HOW THEY'RE  
11 ENABLING RESEARCH AND HOW THEY'RE FURTHERING,  
12 HOPEFULLY, A CURE.

13 SO AS A RESULT OF THIS KIND OF ACTIVE  
14 PATIENT RELATIONSHIP, WE FEEL THAT WE HAVE A REALLY  
15 EXCITING, SUSTAINABLE BUSINESS GOING FORWARD. AND  
16 WE THINK THAT THIS IS A FUNDAMENTAL PART OF WHAT  
17 CIRM BELIEVES IN, AND WE HOPE THAT WE'RE KIND OF A  
18 MODEL OF WHAT THE FUTURE WILL HOLD. SO THANK YOU  
19 VERY MUCH.

20 CHAIRMAN THOMAS: THANK YOU. ANY OTHER  
21 PUBLIC COMMENT ON THE REPOSITORY RFA? SEEING NONE,  
22 MR. HARRISON, HOW SHALL WE PROCEED?

23 MR. HARRISON: I THINK AT THIS POINT IN  
24 TIME IT WOULD BE APPROPRIATE FOR THE APPLICATION  
25 REVIEW SUBCOMMITTEE, INCLUDING EX OFFICIO MEMBERS,

**BARRISTERS' REPORTING SERVICE**

1 TO CONVENE IN CLOSED SESSION TO CONSIDER ANY  
2 CONFIDENTIAL OR PROPRIETARY INFORMATION RELATED TO  
3 APPLICATIONS FOR REPOSITORY RFA OR THE DERIVER RFA.

4 CHAIRMAN THOMAS: THANK YOU. AND THAT  
5 MEETING SHALL NOW TAKE PLACE IN THIS ROOM. SO IF  
6 ALL THOSE NOT INVOLVED IN THIS CLOSED SESSION, IF  
7 YOU COULD PLEASE STEP OUT FOR A FEW MINUTES, WE'LL  
8 NOTIFY YOU WHEN WE'VE COMPLETED CLOSED SESSION.

9 MR. SHESTACK: I JUST WOULD LIKE TO THANK  
10 ALL THE PEOPLE WHO MADE THE TREK TO SPEAK TO US,  
11 SOME OF THEM FROM FAR AWAY. AND ALL OF THEM ARE  
12 EXCELLENT COMPANIES.

13 CHAIRMAN THOMAS: GOOD POINT, MR.  
14 SHESTACK. THANK YOU FOR MAKING IT.

15 MR. HARRISON: JUST FOR THE RECORD, THE  
16 SUBCOMMITTEE IS CONVENING IN CLOSED SESSION PURSUANT  
17 TO HEALTH AND SAFETY CODE SECTION 125290.30(F)(3)(B)  
18 AND (C).

19 CHAIRMAN THOMAS: THANK YOU, MR. HARRISON.

20 (THE APPLICATION REVIEW SUBCOMMITTEE  
21 THEN CONVENED IN CLOSED SESSION, NOT REPORTED NOR  
22 HEREIN TRANSCRIBED. AT THE CONCLUSION OF THE CLOSED  
23 SESSION, THE SUBCOMMITTEE RECONVENED IN OPEN SESSION  
24 AND WAS HEARD AS FOLLOWS:)

25 CHAIRMAN THOMAS: OKAY, EVERYBODY. TAKE

**BARRISTERS' REPORTING SERVICE**

1 YOUR SEAT, PLEASE. WE'VE COMPLETED OUR CLOSED  
2 SESSION REVIEW OF CERTAIN MATTERS PERTAINING TO THE  
3 APPLICANTS. THIS IS OBVIOUSLY A FAIRLY COMPLEX RFA  
4 WITH CRITERIA APPLYING INDIVIDUALLY AND JOINTLY IN A  
5 PAIRING CONTEXT. AND WE'VE HAD A CHANCE TO EVALUATE  
6 BOTH OF THOSE WAYS. AND I'D LIKE TO ASK DR.  
7 TROUNSON FOR A SUMMARY OF WHERE HE BELIEVES WE STAND  
8 AND HIS RECOMMENDATION OF HOW WE SHOULD PROCEED.

9 DR. TROUNSON: THANK YOU, CHAIR. AND CAN  
10 I SAY THAT I DON'T NECESSARILY HAVE COMPLETE  
11 CONCORDANCE WITH EVERYBODY IN THE ROOM BECAUSE IT'S  
12 ONE OF THESE REALLY TRICKY ISSUES. I THINK THE  
13 REVIEWERS WERE VERY CLEAR ABOUT THE STAND-OUT  
14 PAIRINGS OF CDI AND CORIELL. I ALSO THINK THAT THE  
15 NEW YORK STEM CELL FOUNDATION HAVE PUBLISHED A PAPER  
16 WHICH MAKES A VERY IMPORTANT AND SIGNIFICANT STEP,  
17 AND I WOULD HOPE THAT EVERYBODY WOULD BE ABLE TO USE  
18 THAT TECHNOLOGY IN DUE COURSE. SO THAT MIGHT -- IT  
19 MAY WELL IN MY VIEW IMPROVE THEIR INDIVIDUAL MARK AS  
20 A DERIVER. I'M LESS SURE THAT IT WOULD ACTUALLY  
21 CHANGE THE OPTION FROM THE GRANTS WORKING GROUP OF  
22 SAYING THAT THAT LEAP-FROGS THEM OVER THE FRONT LINE  
23 PAIRING OF CDI AND CORIELL BECAUSE I THINK WE HAVE  
24 TO THINK ABOUT NEW YORK STEM CELL FOUNDATION WITH  
25 NEW YORK STEM CELL FOUNDATION.

**BARRISTERS' REPORTING SERVICE**

1                   SO MY VIEW IS I DON'T THINK IT WOULD  
2           CHANGE THE PAIRING ALTHOUGH IN MY OWN VIEW I THINK  
3           IT ANSWERS ONE OF THE CRITICAL QUESTIONS THAT THE  
4           REVIEWERS HAD ABOUT THE DERIVATION.  SO I'M IN A  
5           KIND OF STRANGE SITUATION WHERE I'M TRYING TO  
6           SECOND-GUESS WHETHER THIS IS REALLY GOING TO HAVE AN  
7           IMPACT.  AND MY VIEW WOULD BE THAT I THINK WE CAN  
8           MAKE A DECISION HERE, AND THAT PROBABLY WOULD BE A  
9           VERY GOOD DECISION.  I THINK SENDING IT BACK WILL  
10          PROBABLY END UP WITH THE SAME DECISION, BUT JUST  
11          TAKE A LONGER TIME.  AND SO I KIND OF ERR IN SAYING  
12          YOU'VE GOT THE INFORMATION YOURSELVES, AND I THINK  
13          IT'S A PROGRAMMATIC ISSUE PRINCIPALLY.  AND YOU CAN,  
14          FROM MY POINT OF VIEW -- I WOULD SAY THAT THE NEW  
15          YORK STEM CELL FOUNDATION PROBABLY WOULD GET SOME  
16          EXTRA MARKS FOR SURE FOR THIS DEVELOPMENT BECAUSE I  
17          THINK IT'S A VERY USEFUL DEVELOPMENT THAT THEY'VE  
18          GOT.  AND MAYBE THEY'LL BE ABLE TO SHOW IN THE  
19          FUTURE THAT THEY ARE THE TEAM TO ALWAYS GO TO.  BUT  
20          I THINK AT THIS POINT IN TIME, YOU'VE GOT AS MUCH  
21          REALLY INFORMATION AS I HAVE, AND I THINK YOU CAN  
22          MAKE THE DECISION JUST PROBABLY AS WELL AS I CAN AND  
23          PROBABLY AS WELL AS THE GRANTS WORKING GROUP WOULD  
24          IN THAT KIND OF SITUATION.

25                   SO IF I THOUGHT IT WOULD REALLY, REALLY



## BARRISTERS' REPORTING SERVICE

1 CHANGE EVERYTHING DRAMATICALLY, I'D RECOMMEND IT.  
2 BUT MY RECOMMENDATION TO YOU, CHAIR, IS I THINK THE  
3 ORIGINAL PAIRING AS RECOMMENDED BY THE GRANTS  
4 WORKING GROUP IS PROBABLY A GOOD DECISION, BUT ANY  
5 OTHER DECISION WITH THE NEW YORK STEM CELL  
6 FOUNDATION PROBABLY WOULDN'T BE BAD EITHER. CAN I  
7 LEAVE IT THAT, THAT MY RECOMMENDATION IS YOU COULD  
8 MAKE THAT DECISION HERE JUST AS WELL AS WE MIGHT  
9 MAKE IT BACK AT THE GRANTS WORKING GROUP.

10 CHAIRMAN THOMAS: I WOULD JUST POINT OUT  
11 THE GRANTS WORKING GROUP AND YOU AND STAFF EVALUATE  
12 THINGS ON STRICT SCIENTIFIC MERIT, WHICH YOUR  
13 CAPABILITIES ARE MUCH GREATER THAN MEMBERS OF THE  
14 BOARD HERE THAT ARE GOING TO BE ENTERTAINING THIS  
15 VOTE. SO WE DO RELY HEAVILY ON YOUR RECOMMENDATION  
16 AS TO WHAT WE SHOULD BE DOING IN THIS INSTANCE.

17 DR. TROUNSON: YES, BUT -- OKAY. WHAT  
18 I'VE SAID IS I DO THINK THE INFORMATION THAT WE  
19 RECEIVED IN THE *PLOS ONE* PAPER IS REALLY GOOD  
20 QUALITY INFORMATION. LET ME SAY THAT. AND I THINK  
21 IT DOES MAKE A DIFFERENCE IN THE SENSE OF THE  
22 CRITICISM OF THEM IN THAT DERIVER STUDY, BUT I'M NOT  
23 SURE THAT WOULD CHANGE THE PAIRING. THAT'S WHAT I'M  
24 SAYING TO YOU.

25 CHAIRMAN THOMAS: SO YOUR RECOMMENDATION

**BARRISTERS' REPORTING SERVICE**

1 IS TO PROCEED WITH THE PAIRING AS RECOMMENDED?

2 DR. TROUNSON: YEAH. YEAH. I THINK IF  
3 YOU WANTED ANOTHER DECISION, THAT WOULD BE ALSO ALL  
4 RIGHT. BUT I THINK IT'S A REASONABLE OUTCOME. I  
5 THINK IT'S A REASONABLE OUTCOME. AND IF YOU SENT IT  
6 BACK, I THINK THAT'S THE SAME -- I THINK YOU'D GET  
7 THE SAME RECOMMENDATION. THAT'S MY FEELING.

8 CHAIRMAN THOMAS: THERE WERE SOME OTHER  
9 QUESTIONS.

10 DR. KRONIRIS: SO I WAS CURIOUS AS TO THE  
11 STAFF RESPONSE TO THE ASSERTION BY DR. SNYDER THAT  
12 THE SCIENTIFICALLY DEFENSIBLE PAIRING WAS BETWEEN  
13 COLLECTORS AND DERIVERS, NOT DERIVERS AND BANKERS.  
14 SO DO YOU HAVE ANY COMMENT ON THAT?

15 DR. TROUNSON: WELL, MAYBE UTA WANTS TO  
16 ANSWER THAT. YOU COULD SAY THEY'D ALL BE BETTER OFF  
17 IN THE SAME PLACE. YOU WOULDN'T HAVE ANY ISSUES.  
18 MOVING MATERIALS AROUND IN A RELATIVELY QUICK WAY IN  
19 A SHORT DISTANCE IS WHAT WE OFTEN DO WITH HUMAN  
20 SAMPLES. SO I THINK THEY'VE GOT TO HAVE A  
21 WELL-WORKING PROCEDURE TO MOVE THE SAMPLES AROUND.

22 YOU DON'T NECESSARILY HAVE TO HAVE THE  
23 DERIVER AND THE BANK IN THE SAME PLACE. THAT'S TRUE  
24 ENOUGH. IT WOULD BE GOOD IF THEY WERE TALKING TO  
25 ONE ANOTHER AND INTERACTING, THAT'S TRUE, BECAUSE IT

**BARRISTERS' REPORTING SERVICE**

1 WOULD MAKE THINGS A LITTLE MORE EFFICIENT, BUT WE'RE  
2 GOING TO HAVE SOMEBODY THAT WOULD HELP THAT. SO  
3 WHETHER IT WAS ARTIFICIAL OR NOT, I THINK YOU CAN  
4 HAVE ALL OF THEM IN A DIFFERENT PLACE IF YOU REALLY  
5 THOUGHT THAT THEY'RE ALL THAT REALLY SPECIAL, AND  
6 YOU WOULDN'T NECESSARILY HAVE TO HAVE THOSE PAIRINGS  
7 TOGETHER.

8 BUT I THINK IN THIS CASE CORIELL WAS  
9 OUTSTANDING AND GOT TO THE TOP, AND SO THEY WERE THE  
10 ONES THAT GOT THE HIGHEST MARK THERE. AND CDI WAS  
11 THE HIGHEST MARK ON THE OTHER, AND THEY HAPPEN TO BE  
12 THE PAIR THAT CAME FORWARD AS NO. 1. WHEREAS, THE  
13 OTHERS WERE A LITTLE FURTHER DOWN THE TRACK, AND  
14 THERE WAS NO INDICATION THAT CORIELL WANTED TO WORK  
15 WITH EVAN. SO THAT REALLY DIDN'T COME INTO ANY  
16 DISCUSSION ABOUT PAIRING THEM UP IN ANOTHER WAY.

17 DR. GRIESHAMMER: IF I CAN JUST MAKE ONE  
18 OTHER COMMENT. ALTHOUGH THE REVIEWERS DID COMMENT  
19 ON PROXIMITY BEING POTENTIALLY AN ADVANTAGE, I WILL  
20 SAY THAT IT WAS NOT THE DECIDING FACTOR. EACH OF  
21 THESE DELIBERATIONS AND SCORES AND RECOMMENDATIONS  
22 ARE A COMBINATION OF MANY ISSUES THAT ARE BEING  
23 CONSIDERED. IT WAS ONE OF THE THINGS CONSIDERED. I  
24 DON'T THINK IT WAS THE MOST IMPORTANT ONE.

25 CHAIRMAN THOMAS: OTHER QUESTIONS BY

**BARRISTERS' REPORTING SERVICE**

1 MEMBERS OF THE BOARD? DO WE HAVE A MOTION?

2 MR. SHESTACK: I'M SORRY. I JUST WOULD  
3 LIKE TO SAY ONE THING, THAT THERE SEEMS TO BE A  
4 CONSENSUS FROM REVIEWERS, FROM STAFF EVEN THOUGH  
5 THERE'S QUESTIONS. I JUST WANT TO POINT OUT THAT AS  
6 WE ARE ASKED TO LOOK MORE AT INDUSTRY, THAT WE  
7 NOTICED THAT THERE WERE MANY INTERESTING CALIFORNIA  
8 COMPANIES AND FACILITIES THAT MIGHT NOT HAVE MADE  
9 THE CUT, BUT THAT WE MIGHT BE ABLE TO WORK WITH IN  
10 THE FUTURE TO PROVIDE IMPORTANT SERVICES. I THINK  
11 IT MIGHT NOT HAPPEN THIS TIME, BUT I URGE US TO  
12 SERIOUSLY LOOK AT THIS BENCH OF PEOPLE OF INDUSTRY  
13 IN CALIFORNIA IN THE FUTURE FOR PARTICIPATION WITH  
14 US.

15 MR. TORRES: MR. CHAIRMAN AND MEMBERS,  
16 JOAN SAMUELSON HAD TO LEAVE FOR A MOMENT DUE TO HER  
17 VERY SENSITIVE ISSUES, BUT I OFFERED TO OFFER A  
18 MOTION ON HER BEHALF, WHICH I THINK MR. HARRISON  
19 WILL HELP EXPLAIN. AND THAT IS HER CONCERN AS SHE  
20 EXPRESSED TO US IN THE EXECUTIVE SESSION WAS THAT  
21 SHE WOULD LIKE TO ENDORSE DR. SNYDER'S APPROACH,  
22 WHICH ENDORSES THE CREATION OF A NORTHERN CALIFORNIA  
23 AND A SOUTHERN CALIFORNIA REPOSITORY AND DERIVER.

24 IS THAT A CORRECT ASSESSMENT OF WHAT SHE  
25 REQUESTED? SO I OFFER TO MAKE THAT MOTION ON HER

**BARRISTERS' REPORTING SERVICE**

1 BEHALF.

2 CHAIRMAN THOMAS: MOTION ON THE FLOOR. IS  
3 THERE A SECOND?

4 MR. TORRES: I AM NOT OFFENDED.

5 MS. WINOKUR: SECOND.

6 CHAIRMAN THOMAS: THERE IS A SECOND BY  
7 MS. WINOKUR. MR. HARRISON.

8 MR. HARRISON: IF I COULD JUST MAKE ONE  
9 POINT. AND THAT IS THAT THE REQUEST FOR APPLICATION  
10 SPECIFIED THAT THERE WOULD BE ONE AWARD FOR A  
11 DERIVER AND ONE AWARD FOR A REPOSITORY. AND THE  
12 MOTION WOULD, IF APPROVED, CREATE A VERY DIFFERENT  
13 OUTCOME WHERE YOU WOULD HAVE TWO AWARDS FOR EACH,  
14 WHICH REALLY WOULD AMOUNT TO A VERY DIFFERENT RFA.  
15 IN OTHER WORDS, IF THE BOARD HAD INTENDED TO HAVE A  
16 SOUTHERN CALIFORNIA REPOSITORY AND DERIVER AND A  
17 NORTHERN CALIFORNIA REPOSITORY AND DERIVER AND HAD  
18 FRAMED AN RFA IN THAT MANNER, IT MAY HAVE RECEIVED  
19 APPLICATIONS THAT WERE GEARED TOWARDS THAT OUTCOME.  
20 AND INTRODUCING THE CONCEPT AT THIS POINT IN THE  
21 PROCESS DOES RAISE A QUESTION OF FAIRNESS BECAUSE  
22 THAT WASN'T WHAT THE RFA SPECIFIED.

23 CHAIRMAN THOMAS: THANK YOU, MR. HARRISON.  
24 I BELIEVE, DR. TROUNSON, YOU HAD SOME COMMENTS ON  
25 THE ECONOMICS OF THIS IDEA.

**BARRISTERS' REPORTING SERVICE**

1 DR. TROUNSON: USUALLY IF YOU HAVE A DUAL  
2 FACILITY, YOU'RE DUPLICATING EQUIPMENT AND PEOPLE  
3 AND PROCESSES, AND THAT'S GOING TO COST A LOT MORE.  
4 BUT I WOULD DRAW YOUR ATTENTION, CHAIR, TO THE NEW  
5 YORK STEM CELL FOUNDATION SUGGESTING THAT THEY  
6 WANTED TO WORK IN NORTHERN AND SOUTHERN CALIFORNIA,  
7 AND THEY ARE A SINGLE ENTITY. BUT I CAN'T REALLY --  
8 THEY DIDN'T REALLY PUT THAT IN ANY FORM OF AN  
9 APPLICATION. AND I DON'T KNOW IF THEY WANT TO SPEAK  
10 TO THAT, BUT I WOULD HAVE THOUGHT THAT WAS DIFFICULT  
11 EVEN FOR THEM TO DUPLICATE MATERIALS AND FACILITIES  
12 IN SUCH A WAY.

13 SO IF THE BOARD WISHED US TO LOOK AT THAT,  
14 WE WOULD LOOK AT THE ECONOMICS OF IT; BUT I'M KIND  
15 OUT OF DOUBTFUL WHETHER IT WOULD STAND UP TO  
16 ECONOMIC GOOD SENSE IN THIS CASE TO HAVE A DUAL  
17 NORTH AND SOUTH FACILITY IN MY OWN MIND. I THINK IT  
18 DOESN'T SOUND LIKE THE SMARTEST THING TO DO BECAUSE  
19 OF THE DUPLICATIONS. BUT IF THE BOARD WISHED US TO  
20 LOOK AT THAT, WE COULD TAKE A LOOK AT IT.

21 CHAIRMAN THOMAS: ANY MORE MEMBERS WITH  
22 COMMENTS? COMMENTS FROM MEMBERS OF THE BOARD?  
23 HEARING NONE, ANY PUBLIC COMMENT ON THIS MOTION?

24 DR. CHANG: STEVE CHANG AGAIN FROM THE NEW  
25 YORK STEM CELL FOUNDATION. REMEMBER, WE BUILT THE

**BARRISTERS' REPORTING SERVICE**

1 SYSTEM ALREADY IN NEW YORK, AND IT WORKS, AND IT'S  
2 THE HARDWARE, OUR UNDERSTANDING THE SOFTWARE, SO  
3 IT'S A CLONE. SO WE CAN CLONE. THE COST OF CLONING  
4 BECOMES AN ECONOMIC ANALYSIS. WE HAVE NOT THOUGHT  
5 ABOUT THIS BECAUSE, AS MR. HARRISON SAID, THE RFA  
6 WAS ORIGINALLY DESIGNED FOR ONE FACILITY. BUT  
7 BECAUSE WE'VE GOT THIS THING UP AND RUNNING, WE JUST  
8 HAVE TO LOOK AT ECONOMICS WITH THIS AND THE NUMBER  
9 OF LINES.

10 I ACTUALLY LOOKED AT THE 3500 LINES. I  
11 SAID THAT'S EASY. THAT'S A FEW MONTHS FOR US, A  
12 YEAR. BECAUSE YOU HAVE THREE YEARS TO DO THIS. SO  
13 WHILE THERE'S ECONOMIC COSTS OF SUPPLIES AND  
14 MATERIALS, WE JUST HAVE TO FACTOR IT INTO DOING  
15 THIS. THIS IS REALLY THE TECHNOLOGY. IT IS THE  
16 OUTSTANDING TECHNOLOGY. IN MANY WAYS I KIND OF  
17 THINK OF THIS AS THE SATELLITE PHONE VERSUS THE  
18 SMART PHONE. AND WE'VE MADE IT A SMART PHONE, AND  
19 I'D LIKE TO BRING THIS TECHNOLOGY FURTHER.

20 PART OF THE THING IS WE CAN ACTUALLY DO  
21 SOME OF THE WORK IN NEW YORK; BUT BECAUSE OF THE  
22 RULES OF PROP 71 IN TERMS OF MONEY GOING  
23 OUT-OF-STATE, WE HAVE TO PUT THE SYSTEM HERE.  
24 AGAIN, BECAUSE COLLABORATIVELY WE WORK. IT'S  
25 SEAMLESS. AS WE KNOW, WITH THE INFORMATION AGE OF

**BARRISTERS' REPORTING SERVICE**

1 TECHNOLOGY AND COMMUNICATION, WE CAN BE ALMOST  
2 ANYWHERE AND WE WORK ALL THE TIME. AND SO IT'S  
3 GREAT. SO MANY WAYS IT'S A VERY SIMPLE EXERCISE FOR  
4 US, BUT IT'S AN ECONOMIC EXERCISE.

5 DR. SNYDER: I JUST WANTED TO SAY THAT WE  
6 TOO HAVE PAPERS THAT HAVE BEEN GENERATED AT OUR  
7 INSTITUTE AS A RESULT OF OUR TECHNOLOGY AND SOME  
8 GROUNDBREAKING WORK IN *SCIENCE* AND OTHER JOURNALS.

9 I THINK THAT ALSO WITHIN CALIFORNIA  
10 INSTITUTIONS, EVEN THOUGH WE'RE AN ACADEMIC  
11 INSTITUTION, WE ACTUALLY CAN PRODUCE THE LINES MORE  
12 EFFICIENTLY AND MORE INEXPENSIVELY THAN ANYONE IN  
13 THE STATE. WE'VE DONE THAT AND PROBABLY HAVE MADE  
14 MORE IPS LINES THAN ANYBODY IN CALIFORNIA.

15 AND I THINK THAT WE CAN MAKE IT VERY  
16 ECONOMICALLY ADVANTAGEOUS, FOR EXAMPLE, IF WE WERE  
17 TO DO THIS FOR SOUTHERN CALIFORNIA. WE WOULD  
18 CERTAINLY MERGE OUR SOP'S. STEVE AND I, IN FACT,  
19 HAVE TALKED ABOUT PERHAPS MARRYING OUR TWO  
20 DERIVATION ENTITIES TOGETHER SO THAT IT WOULD BE  
21 ECONOMICALLY ADVANTAGEOUS, AND IT'D PROBABLY BE A  
22 WIN-WIN FOR THE STATE AND NO WAY A DISADVANTAGE.

23 CHAIRMAN THOMAS: MR. PALAY.

24 MR. PALAY: I'M BOB PALAY, CHAIRMAN AND  
25 CEO OF CELLULAR DYNAMICS. WE HAVEN'T HAD AN



**BARRISTERS' REPORTING SERVICE**

1 OPPORTUNITY TO ANALYZE THE DUAL LOCATIONS WITH  
2 CORIELL, OUR PARTNER IN THIS. SO IT WOULD BE HARD  
3 FOR US OFF THE CUFF TO JUST ANSWER THE QUESTION.  
4 AND WE THINK THAT IF THIS IS WHAT THE BOARD WANTS TO  
5 DO, WE WOULD LIKE AN OPPORTUNITY TO REANALYZE AND  
6 LOOK AT IT. CERTAINLY TO JUST SAY THAT -- WE ALSO  
7 HAVE EXPERTISE IN ROBOTICS AND STANDARD OPERATING  
8 PROCEDURES AND ALL THE THINGS. THANK YOU.

9 CHAIRMAN THOMAS: THANK YOU. I THINK MR.  
10 HARRISON DID IDENTIFY THERE'S ANOTHER ISSUE WHICH IS  
11 THAT THIS CONCEPT IS NOT REALLY PART OF WHAT WAS  
12 CONTEMPLATED BY THE RFA. SO THIS IS, I THINK, VERY  
13 INTERESTING; BUT IF WE WERE TO CONSIDER IT, YOU NEED  
14 A LARGE SCOPE.

15 SO BEFORE WE VOTE ON THIS, DR. TROUNSON,  
16 HEARING ALL THE PUBLIC COMMENT, ETC., DOES THIS  
17 MATERIALLY AFFECT YOUR RECOMMENDATION ON HOW WE  
18 SHOULD PROCEED?

19 DR. TROUNSON: NO. I THINK -- LOOK, I  
20 THINK I'D GO OVER THE SAME THING. YEAH, THE  
21 METHODOLOGY IS IMPROVED, THE NEW YORK STEM CELL  
22 FOUNDATION, AND THAT PAPER MAKES A DIFFERENCE TO ME  
23 ABSOLUTELY. BUT I THINK IN TERMS OF THE DUALITY  
24 THERE THAT WAS RECOMMENDED BY THE BOARD IN  
25 PROGRAMMATIC REVIEW, I'M NOT SURE THAT I'VE GOT A

**BARRISTERS' REPORTING SERVICE**

1 GOOD ARGUMENT TO OVERRIDE IT. AND SO THAT'S  
2 ESSENTIALLY MY PROBLEM. SO I THINK I HAVE TO BE  
3 SUPPORTIVE OF THE REVIEWERS AT THIS POINT,  
4 ACKNOWLEDGING THAT I THINK THE NEW YORK STEM CELL  
5 FOUNDATION HAVE MADE A TREMENDOUS STEP FORWARD IN  
6 THEIR *PLOS* PAPER. AND I HOPE EVERYBODY WILL PICK UP  
7 THAT TECHNOLOGY AND USE IT.

8 I HAVEN'T CHANGED MY MIND, NO. BUT I  
9 THINK YOU SHOULD USE YOUR OWN PROGRAMMATIC ENDEAVORS  
10 TO SEE IF YOU CAN COME TO A SOLUTION IF IT'S AT ALL  
11 POSSIBLE. BUT IF YOU WANT US TO TAKE IT BACK, I'M  
12 NOT OPPOSED TO THAT IN THE END EITHER.

13 CHAIRMAN THOMAS: OKAY. SO WE HAVE A --  
14 WE HAVE A MOTION ON THE TABLE WHICH IS, MR.  
15 HARRISON, COULD YOU SAY PLEASE.

16 MR. HARRISON: THE MOTION IS TO ENDORSE  
17 THE PROPOSAL TO ESTABLISH A NORTHERN CALIFORNIA  
18 DERIVER AND REPOSITORY AND A SOUTHERN CALIFORNIA  
19 DERIVER AND REPOSITORY.

20 CHAIRMAN THOMAS: MARIA, DO YOU WANT TO  
21 TAKE THE ROLL ON THIS PLEASE. CAN WE DO A VOICE  
22 VOTE ON THIS, MR. HARRISON? NO.

23 MS. BONNEVILLE: ROBERT QUINT.

24 DR. QUINT: NO.

25 MS. BONNEVILLE: JOAN SAMUELSON. JONATHAN

**BARRISTERS' REPORTING SERVICE**

1 SHESTACK.

2 MR. SHESTACK: NO.

3 MS. BONNEVILLE: OSWALD STEWARD.

4 DR. STEWARD: NO.

5 MS. BONNEVILLE: JONATHAN THOMAS.

6 CHAIRMAN THOMAS: NO.

7 MS. BONNEVILLE: ART TORRES.

8 MR. TORRES: NO.

9 MS. BONNEVILLE: DIANE WINOKUR.

10 MS. WINOKUR: NO.

11 MR. HARRISON: THAT MOTION FAILS.

12 CHAIRMAN THOMAS: OKAY. DO I HEAR A  
13 MOTION ON THE MAIN ITEM HERE? SOMEBODY NEEDS TO  
14 MOVE SOMETHING, PEOPLE. MR. HARRISON, WERE YOU  
15 ABOUT TO COMMENT? THIS IS US STRUGGLING WITH THE  
16 NEW FORMAT OF WHO CAN MAKE MOTIONS. CAN WE PLEASE  
17 SOMEBODY MAKE A POSSESSION?

18 MR. TORRES: SO MOVED.

19 CHAIRMAN THOMAS: WHAT IS SO MOVED, MR.  
20 SENATOR?

21 MR. TORRES: WHATEVER MR. HARRISON SAID I  
22 MOVED.

23 CHAIRMAN THOMAS: I'M NOT SURE THAT'S  
24 SUFFICIENT. IS YOUR MOTION TO APPROVE THE TOP  
25 RECOMMENDED PAIRING?

**BARRISTERS' REPORTING SERVICE**

1 MR. TORRES: YES.

2 CHAIRMAN THOMAS: IT'S BEEN MOVED. IS  
3 THERE A SECOND ON THAT?

4 DR. QUINT: SECOND.

5 CHAIRMAN THOMAS: SECONDED BY DR. QUINT.  
6 FURTHER DISCUSSION BY MEMBERS OF THE BOARD?

7 MR. SHESTACK: MR. HARRISON, HOW MANY  
8 PEOPLE ARE PERMITTED TO VOTE ON THIS MOTION?

9 MR. HARRISON: THERE ARE 15 MEMBERS OF THE  
10 BOARD WHO ARE ELIGIBLE. LEEZA GIBBONS LEFT THE  
11 BOARD, SO THAT'S WHY IT'S 15, NOT 16. OF THOSE 15,  
12 SIX HAVE CONFLICTS, WHICH TAKES US DOWN TO NINE  
13 MEMBERS WHO ARE ELIGIBLE. OF THOSE NINE, ONLY SEVEN  
14 ARE HERE TODAY, AND JOAN SAMUELSON HAD TO LEAVE THE  
15 ROOM, WHICH LEAVES US WITH SIX.

16 MR. SHESTACK: SO A QUORUM IS BASED ON  
17 PERCENTAGE OF WHAT NUMBER?

18 MR. HARRISON: A QUORUM IS SIX, SO WE HAVE  
19 A QUORUM IN THE ROOM.

20 MR. SHESTACK: SIX OF 15.

21 MR. HARRISON: SIX OF NINE. IT'S 65  
22 PERCENT OF NINE. A QUORUM IS 65 PERCENT OF THOSE  
23 WHO ARE ELIGIBLE TO VOTE.

24 MR. SHESTACK: AND NINE IS -- I SEE.

25 CHAIRMAN THOMAS: FURTHER DISCUSSION BY

**BARRISTERS' REPORTING SERVICE**

1 MEMBERS OF THE BOARD? ANY FINAL PUBLIC COMMENT? I  
2 THINK WE'VE HEARD FROM EVERYBODY. WE HAVE A MOTION  
3 ON THE FLOOR. MR. HARRISON, PLEASE RESTATE.

4 MR. HARRISON: THE MOTION IS TO APPROVE  
5 THE GRANTS WORKING GROUP'S RECOMMENDATIONS FOR THE  
6 NO. 1 DERIVER AND REPOSITORY. SINCE THEY HAVE BEEN  
7 IDENTIFIED PUBLICLY, I'LL DO THAT HERE. CELLULAR  
8 DYNAMICS INTERNATIONAL FOR THE DERIVATION AWARD AND  
9 CORIELL INSTITUTE FOR MEDICAL RESEARCH FOR THE  
10 REPOSITORY AWARD.

11 CHAIRMAN THOMAS: MARIA, PLEASE TAKE THE  
12 ROLL.

13 MS. BONNEVILLE: ROBERT QUINT.

14 DR. QUINT: ABSTAIN.

15 MS. BONNEVILLE: JOAN SAMUELSON. JONATHAN  
16 SHESTACK.

17 MR. SHESTACK: YES.

18 MS. BONNEVILLE: OSWALD STEWARD.

19 DR. STEWARD: YES.

20 MS. BONNEVILLE: JONATHAN THOMAS.

21 CHAIRMAN THOMAS: YES.

22 MS. BONNEVILLE: ART TORRES.

23 MR. TORRES: AYE.

24 MS. BONNEVILLE: DIANE WINOKUR.

25 MS. WINOKUR: YES.

**BARRISTERS' REPORTING SERVICE**

1 MR. HARRISON: THE MOTION CARRIES.

2 DR. PRICE: FOR THE RECORD I'D LIKE TO  
3 NOTE HOW THE IOM HAS IMPROVED OUR PROCESSES.  
4 DEFINITELY WORTH THREE-QUARTERS OF A MILLION  
5 DOLLARS.

6 CHAIRMAN THOMAS: ALL RIGHT. WE HAVE A  
7 PASSED MOTION. I'D LIKE TO THANK EVERYBODY WHO CAME  
8 HERE. I KNOW THIS HAS BEEN A LONG PROCESS, AND WE  
9 APPRECIATE EVERYBODY'S INPUT, EVERYBODY'S INTEREST.  
10 AND WE LOOK FORWARD TO PROCEEDING HERE WITH  
11 IMPLEMENTING THIS RFA.

12 WE'RE NOW GOING TO MOVE ON TO ITEM NO. 13,  
13 CONSIDERATION OF RECOMMENDATIONS REGARDING AN  
14 EXTRAORDINARY SUPPLEMENT AWARD, RFA 9-01, DISEASE  
15 TEAM RESEARCH AWARD DR1-01444, USC. DR. FEIGAL, ARE  
16 YOU PRESENTING?

17 DR. FEIGAL: SO THIS IS A MEMO THAT  
18 DR. INGRID CARAS AND I SENT TO THE BOARD, AND LET ME  
19 GIVE YOU THE BACKGROUND FOR THIS. IN OCTOBER OF  
20 LAST YEAR, YOUR GROUP APPROVED THE CONCEPT PROPOSAL  
21 FOR EXTRAORDINARY SUPPLEMENTS TO EXISTING AWARDS.  
22 AND THIS CONCEPT PROVIDED FOR A LEVEL 1, MINOR  
23 SUPPLEMENT, AS WELL AS A LEVEL 2, MAJOR SUPPLEMENT.  
24 AND THE LEVEL 2, MAJOR SUPPLEMENTS, ARE INTENDED TO  
25 SUPPORT GRANTEES IN ORDER TO ENHANCE THE PROBABILITY

## BARRISTERS' REPORTING SERVICE

1 OF CONVERSION OF FUNDED PROJECTS TO UNEXPECTED AND  
2 TRANSFORMATIONAL BENEFITS AND TO RAISE PROJECTS TO A  
3 HIGH PROBABILITY OF CLINICAL BENEFIT.

4 THIS AWARD PROVIDES UP TO \$3 MILLION.  
5 WE'RE PROPOSING THAT A LEVEL 2, MAJOR SUPPLEMENT,  
6 AWARD IN THE AMOUNT OF \$3 MILLION BE AWARDED TO THE  
7 DR. HUMAYUN DISEASE TEAM DR1-01444.

8 IN 2010 THIS BOARD AWARDED DR. HUMAYUN AND  
9 HIS TEAM A DISEASE TEAM AWARD IN THE AMOUNT OF 15.9  
10 MILLION. THERE WAS A 20-MILLION CAP ON THAT AWARD  
11 AMOUNT, AND HE CAME IN WITH 15.9 TO DEVELOP A  
12 CELLULAR THERAPY FOR DRY AGE-RELATED MACULAR  
13 DEGENERATION. AND THIS IS A DISEASE THAT  
14 PARTICULARLY AFFECTS THE OLDER POPULATION AND IS A  
15 MAJOR CAUSE OF VISION LOSS.

16 HE'S USING A RETINAL PIGMENT EPITHELIAL  
17 DERIVED FROM HUMAN EMBRYONIC STEM CELLS. THIS FITS  
18 RIGHT INTO THE MIDDLE OF THE RADAR SCREEN OF WHAT  
19 THIS AGENCY WAS PUT INTO PLACE TO DO, TO LOOK AT THE  
20 POWER OF PLURIPOTENT STEM CELLS TO TRY AND ATTACK A  
21 SIGNIFICANT MAJOR MEDICAL ILLNESS.

22 AN IMPORTANT COMPONENT OF HIS APPROACH IS  
23 IMPLANTATION OF THESE CELLS. THEY'RE IMPLANTED INTO  
24 THE BACK OF THE EYE, THE BACK OF THE RETINA. AND  
25 THESE CELLS ARE GROWN ON A SYNTHETIC MEMBRANE THAT

**BARRISTERS' REPORTING SERVICE**

1 MIMICS THE NATURAL MEMBRANE AT THE BACK OF THE EYE.  
2 AND THIS IS IMPORTANT FOR THE ATTACHMENT, THE  
3 SURVIVAL, AND THE DIFFERENTIATION OF THESE CELLS.

4 THE PROGRESS ON THIS PROJECT HAS BEEN IN  
5 PLACE SINCE 2010, SINCE THEY WERE AWARDED. AND IT'S  
6 BEEN EVALUATED BY OUR SCIENTIFIC TEAM ON A QUARTERLY  
7 BASIS, BY ANNUAL PROGRESS REPORTS, AND ALSO BY OUR  
8 EXTERNAL PANEL, A CLINICAL DEVELOPMENT ADVISOR  
9 PANEL, AT LEAST ON A YEARLY BASIS. THEY WERE  
10 EVALUATED BY THIS EXTERNAL PANEL BASED UPON MUTUALLY  
11 AGREED UPON GO/NO-GO AND PROGRESS MILESTONES. THEY  
12 WERE EVALUATED IN JULY OF 2011 AND AGAIN IN JULY OF  
13 2012. AND THE PANEL MEMBERS WERE EXTREMELY  
14 IMPRESSED AT BOTH EVALUATIONS BY THE TEAM, THE  
15 QUALITY OF THE DATA PRESENTED, THE OUTSTANDING  
16 PROGRESS BEING MADE, AND THEY STRONGLY ENDORSED BOTH  
17 THE TEAM AND THE APPROACH.

18 THE TEAM IS NOW ENTERING THE FINAL STAGE  
19 OF THEIR FOUR-YEAR AWARD. THEY'RE IN THEIR THIRD  
20 YEAR RIGHT NOW, ENTERING THEIR FOURTH YEAR. AND  
21 THEY'RE ON TRACK TO FILE AN IND SO THAT THEY CAN  
22 ENTER HUMAN CLINICAL TRIALS IN PATIENTS BY THE END  
23 OF THE FOUR-YEAR PROJECT PERIOD FOLLOWING COMPLETION  
24 OF A SERIES OF FDA-MANDATED, PIVOTAL IND-ENABLING  
25 PRECLINICAL STUDIES.



**BARRISTERS' REPORTING SERVICE**

1           BECAUSE THIS APPROACH IS VERY NOVEL, IT'S  
2           A PLURIPOTENT STEM CELL, IT'S ON A SCAFFOLD, IT'S A  
3           COMBINATION PRODUCT, THE PRECISE REGULATORY  
4           REQUIREMENTS FOR THIS VERY NOVEL, PIONEERING TYPE OF  
5           THERAPY WERE NOT PREDICTABLE AT THE OUTSET. AND  
6           CONSEQUENTLY IT HAS BECOME APPARENT THAT THE  
7           ORIGINAL BUDGET OF 15.9, WHICH DETERMINED THE AMOUNT  
8           OF THE AWARD, IS NOT SUFFICIENT TO COVER ALL OF THE  
9           ACTIVITIES THAT HAVE BEEN REQUESTED BY THE FDA TO  
10          SUPPORT THE IND. AND THE TEAM WILL, THEREFORE, NEED  
11          SUPPLEMENTAL FUNDING TO ENABLE THEM TO CONTINUE  
12          THEIR ALREADY STRONG PROGRESS TOWARDS FILING THAT  
13          IND IN ORDER TO BE ABLE TO ENTER FIRST-IN-HUMAN  
14          CLINICAL TRIALS.

15                 THE TEAM IN JANUARY, AS PER OUR PROCESS,  
16                 SUBMITTED A REQUEST TO CIRM WITH INFORMATION AND  
17                 BACKGROUND DATA TO ENABLE THE COMPLETION OF  
18                 PRECLINICAL STUDIES THAT HAD BEEN REQUESTED BY THE  
19                 FDA.

20                 SO IN 2012, A LITTLE BIT OF BACKGROUND,  
21                 THE DISEASE TEAM WENT TO THE FDA TO HOLD A PRE-IND  
22                 MEETING. THIS IS PART OF A REGULATORY MILESTONE IN  
23                 WHICH THE TEAM TALKS WITH THE FDA ABOUT THE STUDIES  
24                 THEY'VE COMPLETED TO DATE AND THE PROPOSED STUDIES  
25                 SO THAT THEY CAN BE ON TRACK SUCCESSFULLY TO FILE AN

**BARRISTERS' REPORTING SERVICE**

1 APPROVABLE IND.

2 IN MEETING WITH THE FDA AND SUBSEQUENT  
3 FOLLOW-UP DISCUSSIONS, THE FDA HAD A NUMBER OF VERY  
4 SPECIFIC RECOMMENDATIONS REGARDING THE PRECLINICAL  
5 STUDIES TO BE CONDUCTED TO SUPPORT AN IND FILING.  
6 THIS RESULTED IN A MORE EXTENSIVE AND MORE EXPENSIVE  
7 PRECLINICAL PROGRAM THAN WHAT HAD ORIGINALLY BEEN  
8 BUDGETED FOR.

9 SO IN JANUARY THEY SUBMITTED TO US A  
10 FORMAL REQUEST FOR SUPPLEMENT FUNDING TO ENABLE THEM  
11 TO COMPLETE THE PRECLINICAL STUDIES REQUESTED BY THE  
12 FDA. THIS SUBMITTED REQUEST INCLUDED ALL COPIES OF  
13 FDA CORRESPONDENCE REGARDING THE IND-ENABLING  
14 PRECLINICAL PLAN AS WELL AS A DETAILED BUDGET AND  
15 BUDGET JUSTIFICATION. AND THIS REQUEST AND ALL THE  
16 MATERIALS WAS REVIEWED BY A CDAP THAT WE HELD IN  
17 FEBRUARY, LAST MONTH, TO JUST GO OVER THEIR PROJECT.

18 THE CDAP CONCLUDED THAT THERE IS A CLEAR  
19 PRECLINICAL PLAN THAT HAS BEEN VETTED BY THE FDA,  
20 THAT THERE IS A CLEAR PATH FORWARD TO AN IND, THAT  
21 THE BUDGET AND THE COSTS PROVIDED ARE REASONABLE,  
22 AND THAT THE TEAM HAS THE EXPERTISE TO CARRY OUT THE  
23 PRECLINICAL PLAN. THE CDAP, THEREFORE, RECOMMENDED  
24 THAT WE DO PROVIDE SUPPLEMENTAL FUNDING IN ORDER TO  
25 ENSURE THAT THE PROJECT STAYS ON THE CRITICAL PATH

**BARRISTERS' REPORTING SERVICE**

1 TO FILING AN IND BY THE END OF THE FOUR-YEAR PROJECT  
2 PERIOD.

3 SO OUR RECOMMENDATION TO YOU IS, FOLLOWING  
4 ENDORSEMENT BY CDAP EVALUATION, THAT WE ARE ASKING  
5 THAT A LEVEL 2 MAJOR SUPPLEMENT BE AWARDED IN THE  
6 AMOUNT OF THREE MILLION TO THE HUMAYUN DISEASE TEAM  
7 SO THAT IT MAY CONDUCT AND COMPLETE THE PIVOTAL  
8 PRECLINICAL STUDIES REQUIRED TO FILE AN APPROVABLE  
9 IND AS RECOMMENDED BY THE FDA IN THEIR PRE-IND  
10 MEETING AND IN SUBSEQUENT FOLLOW-UP DISCUSSIONS WITH  
11 THE AGENCY.

12 WE'D OBVIOUSLY BE HAPPY TO ANSWER ANY  
13 QUESTIONS. I THINK A MEMBER OF THE DISEASE TEAM IS  
14 ALSO HERE, BUT I WOULD ALSO LET YOU KNOW THAT A LOT  
15 OF THE INFORMATION THAT WE HAVE IS CONFIDENTIAL. SO  
16 WE MAY NEED TO GO INTO CONFIDENTIAL SESSION IF YOU  
17 HAVE QUESTIONS.

18 DR. JUELSGAARD: SO, DR. FEIGAL, GIVEN  
19 THAT THE FDA HAS APPARENTLY RAISED THE BAR IN TERMS  
20 OF WHAT IT WANTS BEFORE YOU GET INTO THE IND STAGE  
21 AND START CLINICAL TRIALS, PHASE I CLINICAL TRIALS,  
22 DOES THIS PORTEND ALSO LARGER HURDLES DURING THE  
23 CLINICAL TRIAL PERIOD?

24 DR. FEIGAL: WELL, JUST TO BE CLEAR, IT'S  
25 NOT THAT THEY RAISED THE BAR. THIS WAS THEIR FIRST

**BARRISTERS' REPORTING SERVICE**

1 PRE-IND MEETING WITH THE FDA. THERE IS NOT AN  
2 APPROVED PLURIPOTENT STEM CELL ON A SCAFFOLD BY  
3 WHICH TO LOOK AT A PRECEDENT OF HOW THIS WORKS. SO  
4 LOOKING AT GUIDANCES, HAVING PRE-PRE-IND DISCUSSIONS  
5 WITH THE AGENCY, THEY PROPOSED THE BEST PLAN THAT  
6 THEY COULD AT THAT POINT IN TIME. AND THERE ARE  
7 JUST SOME ADDITIONAL REQUIREMENTS THAT HAVE BEEN  
8 MANDATED BECAUSE THIS IS A COMBINATION PRODUCT.

9 DR. JUELSGAARD: I APPRECIATE THAT, BUT MY  
10 QUESTION IS IS DO YOU THINK OR DOES ANYBODY THINK  
11 THAT THIS ADDITIONAL WORK THAT THEY DIDN'T  
12 CONTEMPLATE IS GOING TO MEAN ADDITIONAL WORK AND  
13 ADDITIONAL EXPENSE AND ADDITIONAL TIME WHEN YOU GET  
14 INTO THE CLINICAL TRIAL PERIOD?

15 DR. FEIGAL: NO. I WOULD NOT SPECULATE TO  
16 THAT AT ALL.

17 CHAIRMAN THOMAS: MR. SHEEHY.

18 MR. SHEEHY: I'D LIKE TO MOVE TO ADOPT  
19 THIS. I THINK THIS IS A GREAT PROJECT, AND I THINK  
20 STAFF SHOWED ENORMOUS WISDOM IN HAVING US ADOPT THIS  
21 FUNDING MECHANISM LAST FALL BECAUSE I JUST THINK  
22 THAT'S THE WAY -- I WENT TO THE GRANTEE MEETING, AND  
23 WE HEARD A VERY INTERESTING PRESENTATION ON BONE  
24 MARROW TRANSPLANT AND I FORGET WHAT THE OTHER ONE  
25 WAS. AND ALL YOU HEARD ABOUT IS THAT WE TRIED THIS

## BARRISTERS' REPORTING SERVICE

1 AND WE HAD TO DO THAT AND WE HAD TO DO THIS. AND  
2 THAT STUFF COSTS MONEY. I THINK A LOT OF THIS  
3 SCIENCE AT THAT PARTICULAR STAGE ENDS UP RUNNING  
4 INTO THESE UNANTICIPATED COSTS.

5 AND THIS PROGRAM, I THINK, DR. FEIGAL, HAS  
6 BEEN HITTING THEIR MILESTONES. IT'S REALLY ONE OF  
7 OUR JEWELS. AND SO I THINK THIS IS A GREAT USE OF  
8 OUR MONEY. AND HOPEFULLY I THINK WE'RE GOING TO SEE  
9 A GREAT REWARD FOR HAVING THIS GO FORWARD. I  
10 COMMEND STAFF FOR HAVING GIVEN US THE METHODOLOGY IN  
11 ORDER TO KEEP THE SCIENCE FROM BEING INTERRUPTED BY  
12 GOING THROUGH ANOTHER RFA PROCESS.

13 MR. SHESTACK: SECOND.

14 CHAIRMAN THOMAS: MOVED BY MR. SHEEHY,  
15 SECONDED BY MR. SHESTACK. ADDITIONAL BOARD  
16 CONVERSATION? HEARING NONE, COMMENTS FROM MEMBERS  
17 OF THE PUBLIC? DR. CLEGG.

18 DR. CLEGG: I'M DENNIS CLEGG, AND I'M  
19 CO-PI ON THIS DISEASE TEAM, WHICH WE CALL THE  
20 CALIFORNIA PROJECT TO CURE BLINDNESS. AND ON BEHALF  
21 OF MARK HUMAYUN AND DAVID HINTON AND ALL OF THE TEAM  
22 MEMBERS AT USC, UC SANTA BARBARA, CITY OF HOPE,  
23 CALTECH, AND OUR PARTNERS AT UNIVERSITY COLLEGE  
24 LONDON, I JUST WANTED TO THANK THE BOARD FOR  
25 CONSIDERING THIS REQUEST WHICH WILL ALLOW US TO

**BARRISTERS' REPORTING SERVICE**

1 CARRY THIS PROJECT OVER THE GOAL LINE NEXT YEAR AND  
2 START CLINICAL TRIALS, AND HOPEFULLY BRING A  
3 TREATMENT TO MILLIONS OF CALIFORNIANS THAT CURRENTLY  
4 DON'T HAVE GOOD TREATMENT OPTIONS FOR DRY MACULAR  
5 DEGENERATION.

6 AND I'M HERE IF YOU HAVE ANY QUESTIONS FOR  
7 ME, I'D BE HAPPY TO ANSWER THEM. THANK YOU.

8 CHAIRMAN THOMAS: ANY QUESTIONS FOR DR.  
9 CLEGG? MARIA, PLEASE CALL THE ROLL.

10 MS. BONNEVILLE: MARCY FEIT.

11 MS. FEIT: YES.

12 MS. BONNEVILLE: STEVE JUELSGAARD.

13 MR. JUELSGAARD: YES.

14 MS. BONNEVILLE: ROBERT QUINT.

15 DR. QUINT: YES.

16 MS. BONNEVILLE: JEFF SHEEHY.

17 MR. SHEEHY: YES.

18 MS. BONNEVILLE: JONATHAN SHESTACK.

19 MR. SHESTACK: YES.

20 MS. BONNEVILLE: OSWALD STEWARD.

21 DR. STEWARD: ABSTAIN.

22 MS. BONNEVILLE: JONATHAN THOMAS.

23 CHAIRMAN THOMAS: YES.

24 MS. BONNEVILLE: ART TORRES.

25 MR. TORRES: AYE.

**BARRISTERS' REPORTING SERVICE**

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MS. BONNEVILLE: DIANE WINOKUR.

MS. WINOKUR: YES.

CHAIRMAN THOMAS: THANK YOU, DR. FEIGAL.

DR. FEIGAL: THANK YOU VERY MUCH.

MR. HARRISON: THE MOTION CARRIES.

(THE APPLICATION REVIEW SUBCOMMITTEE  
WAS THEN ADJOURNED.)

**BARRISTERS' REPORTING SERVICE**

REPORTER'S CERTIFICATE

I, BETH C. DRAIN, A CERTIFIED SHORTHAND REPORTER IN AND FOR THE STATE OF CALIFORNIA, HEREBY CERTIFY THAT THE FOREGOING TRANSCRIPT OF THE PROCEEDINGS BEFORE THE APPLICATION REVIEW SUBCOMMITTEE OF THE INDEPENDENT CITIZEN'S OVERSIGHT COMMITTEE OF THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE IN THE MATTER OF ITS REGULAR MEETING HELD AT THE LOCATION INDICATED BELOW

HILTON SFO BAYFRONT HOTEL  
600 AIRPORT BOULEVARD  
BURLINGAME, CALIFORNIA  
ON  
MARCH 19, 2013

WAS HELD AS HEREIN APPEARS AND THAT THIS IS THE ORIGINAL TRANSCRIPT THEREOF AND THAT THE STATEMENTS THAT APPEAR IN THIS TRANSCRIPT WERE REPORTED STENOGRAPHICALLY BY ME AND TRANSCRIBED BY ME. I ALSO CERTIFY THAT THIS TRANSCRIPT IS A TRUE AND ACCURATE RECORD OF THE PROCEEDING.

BETH C. DRAIN, CSR 7152  
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