

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

LOCATION: AS INDICATED ON THE AGENDA

DATE: MAY 19, 2016  
11 A.M.

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

BRS FILE NO.: 98579

BARRISTERS' REPORTING SERVICE

I N D E X

ITEM DESCRIPTION	PAGE NO.
ACTION ITEMS:	
1. CONSIDERATION OF REAPPOINTMENT AND NEW APPOINTMENT OF SCIENTIFIC MEMBERS TO THE GRANTS WORKING GROUP.	
2. CONSIDERATION OF AMENDMENTS TO THE TRANSLATIONAL RESEARCH PROJECTS CONCEPT PLAN.	
3. CONSIDERATION OF AMENDMENTS TO THE GRANTS WORKING GROUP BYLAWS.	
4. CONSIDERATION OF TRANSLATIONAL RESEARCH PROJECTS APPLICATION TRAN1-08522.	
5. CONSIDERATION OF DISCOVERY STAGE RESEARCH PROJECTS: THE INCEPTION AWARDS (DISC 1) APPLICATIONS.	
6. CLOSED SESSION	NONE
7. PUBLIC COMMENT	NONE

BARRISTERS' REPORTING SERVICE

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MAY 19, 2016; 11 A.M.

CHAIRMAN THOMAS: GOOD MORNING. THANK YOU, MARIA. EVERYBODY, WELCOME TO THE MAY MEETING OF THE BOARD AND APPLICATION REVIEW SUBCOMMITTEE. MARIA, WILL YOU PLEASE TAKE THE ROLL.

MS. BONNEVILLE: DAVID BRENNER. LINDA BOXER. LARS BERGLUND. ANNE-MARIE DULIEGE.

DR. DULIEGE: HERE.

MS. BONNEVILLE: ELIZABETH FINI.

DR. FINI: HERE.

MS: BONNEVILLE: MICHAEL FRIEDMAN. JUDY GASSON.

DR. GASSON: HERE.

MS. BONNEVILLE: DAVID HIGGINS.

MR. HIGGINS: HERE.

MS. BONNEVILLE: STEPHEN JUELSGAARD.

DR. JUELSGAARD: YES.

MS. BONNEVILLE: SHERRY LANSING. KATHY LAPORTE.

MS. LAPORTE: HERE.

MS. BONNEVILLE: BERT LUBIN. SHLOMO MELMED. LAUREN MILLER. ADRIANA PADILLA.

DR. PADILLA: HERE.

MS. BONNEVILLE: JOE PANETTA.

BARRISTERS' REPORTING SERVICE

1 MR. PANETTA: HERE.  
2 MS. BONNEVILLE: ROBERT PRICE.  
3 DR. PRICE: HERE.  
4 MS. BONNEVILLE: FRANCISCO PRIETO.  
5 DR. PRIETO: HERE.  
6 MS. BONNEVILLE: ROBERT QUINT.  
7 DR. QUINT: HERE. PRESENT.  
8 MS. BONNEVILLE: AL ROWLETT. JEFF SHEEHY.  
9 MR. SHEEHY: HERE.  
10 MS. BONNEVILLE: OS STEWARD.  
11 DR. STEWARD: HERE.  
12 MS. BONNEVILLE: JONATHAN THOMAS.  
13 CHAIRMAN THOMAS: HERE.  
14 MS. BONNEVILLE: ART TORRES.  
15 MR. TORRES: HERE.  
16 MS. BONNEVILLE: KRISTINA VUORI.  
17 DR. VUORI: HERE.  
18 MS. BONNEVILLE: BRUCE WINTRAUB.  
19 MR. WINTRAUB: HERE.  
20 MS. BONNEVILLE: DIANE WINOKUR.  
21 DR. BRENNER: THEY JUST TOLD ME I'M BACK  
22 ON. I'M HERE.  
23 MS. BONNEVILLE: THANKS, DAVID. I'M JUST  
24 GOING TO CALL A COUPLE NAMES AGAIN.  
25 LINDA BOXER. LARS BERGLUND. OKAY. THANK

BARRISTERS' REPORTING SERVICE

1 YOU.

2 CHAIRMAN THOMAS: OKAY. THANK YOU VERY  
3 MUCH, MARIA.

4 MEMBERS OF THE BOARD, WE HAVE FIVE ACTION  
5 ITEMS ON TODAY'S AGENDA. YOU HAVE THE MATERIALS.  
6 THE FIRST THREE ITEMS ARE FOR CONSIDERATION BY THE  
7 ENTIRE BOARD, THE LATTER TWO BY THE APPLICATION  
8 REVIEW SUBCOMMITTEE. SO LET'S PROCEED.

9 ITEM 1, CONSIDERATION OF REAPPOINTMENT AND  
10 NEW APPOINTMENT OF SCIENTIFIC MEMBERS TO THE GRANTS  
11 WORKING GROUP. WE HAVE NO PRESENTATION ON THIS.  
12 YOU HAVE THE MATERIALS. DO I HEAR A MOTION TO  
13 APPROVE?

14 MR. SHEEHY: SO MOVED.

15 MR. TORRES: SECOND.

16 DR. BRENNER: SECOND.

17 CHAIRMAN THOMAS: THANK YOU. AND JUST FOR  
18 EVERYBODY'S EDIFICATION, THOSE MOVING AND SECONDING  
19 COULD SAY WHO THAT IS BECAUSE SOMETIMES IT'S A BIT  
20 HARD TO TELL OVER THE LINE THERE.

21 MR. TORRES: T. E. TORRES.

22 CHAIRMAN THOMAS: THANK YOU. ANY PUBLIC  
23 COMMENT ON THIS ITEM? HEARING NONE, ALL THOSE IN  
24 FAVOR PLEASE SAY AYE.

25 MS. BONNEVILLE: WE HAVE TO TAKE A ROLL

BARRISTERS' REPORTING SERVICE

1 CALL VOTE.

2 CHAIRMAN THOMAS: FOR THIS ITEM AS WELL.

3 OKAY.

4 MS. BONNEVILLE: EVERYONE IS ON THE PHONE.

5 CHAIRMAN THOMAS: I THOUGHT THIS WAS  
6 SUFFICIENTLY MINISTERIAL THAT WE COULD -- OKAY.

7 MARIA, PLEASE TAKE THE ROLL.

8 MS. BONNEVILLE: DAVID BRENNER.

9 DR. BRENNER: YES.

10 MS. BONNEVILLE: LINDA BOXER.

11 DR. BOXER: YES.

12 MS. BONNEVILLE: LARS BERGLUND.

13 DR. BERGLUND: YES.

14 MS. BONNEVILLE: ANNE-MARIE DULIEGE.

15 DR. DULIEGE: YES.

16 MS. BONNEVILLE: HOWARD FEDEROFF.

17 ELIZABETH FINI.

18 DR. FINI: YES.

19 MS. BONNEVILLE: MICHAEL FRIEDMAN. JUDY  
20 GASSON.

21 DR. GASSON: YES.

22 MS. BONNEVILLE: DAVID HIGGINS.

23 MR. HIGGINS: YES.

24 MS. BONNEVILLE: STEVE JUELSGAARD.

25 DR. JUELSGAARD: YES.

BARRISTERS' REPORTING SERVICE

1 MS. BONNEVILLE: SHERRY LANSING. KATHY  
2 LAPORTE.  
3 MS. LAPORTE: YES.  
4 MS. BONNEVILLE: BERT LUBIN. SHLOMO  
5 MELMED. LAUREN MILLER. ADRIANA PADILLA.  
6 DR. PADILLA: YES.  
7 MS. BONNEVILLE: JOE PANETTA.  
8 MR. PANETTA: YES.  
9 MS. BONNEVILLE: ROBERT PRICE.  
10 DR. PRICE: YES.  
11 MS. BONNEVILLE: FRANCISCO PRIETO.  
12 DR. PRIETO: AYE.  
13 MS. BONNEVILLE: ROBERT QUINT.  
14 DR. QUINT: YES.  
15 MS. BONNEVILLE: AL ROWLETT.  
16 MR. ROWLETT: YES.  
17 MS. BONNEVILLE: JEFF SHEEHY.  
18 MR. SHEEHY: YES.  
19 MS. BONNEVILLE: OS STEWARD.  
20 DR. STEWARD: YES.  
21 MS. BONNEVILLE: JONATHAN THOMAS.  
22 CHAIRMAN THOMAS: YES.  
23 MS. BONNEVILLE: ART TORRES.  
24 MR. TORRES: AYE.  
25 MS. BONNEVILLE: KRISTINA VUORI.

BARRISTERS' REPORTING SERVICE

1 DR. VUORI: YES.

2 MS. BONNEVILLE: BRUCE WINTRAUB.

3 MR. WINTRAUB: YES.

4 MS. BONNEVILLE: DIANE WINOKUR.

5 THANK YOU. MOTION CARRIES.

6 CHAIRMAN THOMAS: THANK YOU, MARIA. ONTO  
7 ITEM 2, CONSIDERATION OF AMENDMENTS TO THE  
8 TRANSLATIONAL RESEARCH PROJECTS CONCEPT PLAN. PAT  
9 WILL BE PRESENTING. DR. OLSON.

10 DR. OLSON: THANK YOU. CHAIRMAN THOMAS,  
11 MEMBERS OF THE BOARD, MEMBERS OF THE CIRM TEAM, AND  
12 THE PUBLIC, IN JULY OF LAST YEAR THIS BOARD APPROVED  
13 THE CONCEPT PLAN FOR TRANSLATIONAL STAGE PROJECTS.  
14 SINCE THAT TIME, WE HAVE CONDUCTED THE FIRST OF TWO  
15 APPROVED ROUNDS IN 2016 FOR THIS FUNDING PROGRAM.

16 AS A RESULT OF OUR EXPERIENCE IN THE FIRST  
17 ROUND AND IN ANTICIPATION OF THE NEXT ROUND, WE'RE  
18 BRINGING TO YOU AMENDMENTS TO THE CONCEPT PLAN FOR  
19 THE TRANSLATIONAL RESEARCH PROJECTS.

20 SO IN THE FIRST ROUND THESE PROJECTS  
21 TOTALING 39.7 MILLION WERE RECOMMENDED FOR FUNDING  
22 BY THE GRANTS WORKING GROUP. AROUND 36 MILLION HAS  
23 BEEN APPROVED BY THIS BOARD AT, I BELIEVE, THE APRIL  
24 MEETING OR PERHAPS MARCH, AND THE OTHER ONE IS  
25 COMING UP FOR APPROVAL AT THIS ONE.



BARRISTERS' REPORTING SERVICE

1           THIS REFLECTED THE QUALITY OF THE PROJECTS  
2           THAT WERE AVAILABLE TO US AND POSSIBLY THE PENT UP  
3           DEMAND. SO WHAT WE'D LIKE TO DO FOR THE NEXT CYCLE  
4           IS, GIVEN THAT THE BOARD APPROVED 40 MILLION FOR TWO  
5           AWARD CYCLES OVER 12 MONTHS IN THE CONCEPT PLAN,  
6           WE'D LIKE TO ASK YOU FOR AN ADDITIONAL ALLOCATION  
7           FOR 2016 TO THE TRANSLATIONAL RESEARCH PROGRAMS.  
8           WE'RE PROPOSING AN ADDITIONAL ALLOCATION OF 15  
9           MILLION FOR THE PLAN'S SECOND ROUND.

10                    SO THAT'S THE FIRST ONE.

11                    CHAIRMAN THOMAS: THANK YOU, DR. OLSON.

12                    DO I HEAR A MOTION --

13                    MS. BONNEVILLE: OH, NO. NO. THERE'S  
14                    MORE, J.T.

15                    DR. OLSON: THERE'S MORE. IN ADDITION, AS  
16                    A RESULT OF THE FIRST CYCLE, WE DID AN ANALYSIS OF  
17                    ALL THE TRAN1 APPLICATIONS THAT CAME IN, AND WE  
18                    LOOKED AT THE REQUESTED DIRECT PROJECT COSTS. AND  
19                    BASED ON THAT, WE'D LIKE TO ASK THE BOARD TO --  
20                    WE'RE REQUESTING A REDUCTION IN THE DIRECT PROJECT  
21                    COST ALLOCATION FOR THE TRAN1 IN THE CAP. SO A CELL  
22                    THERAPY OR A BIOLOGIC, WE HAD ALLOWED IN THE CONCEPT  
23                    PLAN UP TO FIVE MILLION IN DIRECT PROJECT COSTS.  
24                    WE'RE PROPOSING TO REDUCE THAT TO FOUR MILLION.

25                    THE SMALL MOLECULE, IF THE CANDIDATE WAS A

BARRISTERS' REPORTING SERVICE

1 SMALL MOLECULE, WE DID HAVE 2.5 MILLION AS THE UPPER  
2 LIMIT FOR DIRECT PROJECT COSTS. WE'RE PROPOSING TO  
3 REDUCE THAT TO TWO MILLION.

4 SO, AGAIN, WE'RE TRYING TO BE MORE  
5 REALISTIC, AND IT HAS PERHAPS THE ADDED BENEFIT OF  
6 POSSIBLY ALLOWING US TO FUND MORE QUALITY PROJECTS.  
7 SO THAT IS THE SECOND MODIFICATION WE HAVE PROPOSED  
8 FOR THE CONCEPT PLAN.

9 AND THEN --

10 MR. SHEEHY: SO THIS IS JEFF SHEEHY. SO,  
11 PAT, CAN YOU JUST KIND OF EXPLAIN? SO DOES THAT  
12 MEAN THAT THE FIRST ROUND WE DIDN'T SEE PROJECTS  
13 THAT WENT UP TO FIVE MILLION OR TWO AND A HALF  
14 MILLION OR THAT THE MAJORITY OR THE OVERWHELMING  
15 MAJORITY FELL BELOW THOSE LIMITS?

16 DR. OLSON: WE SAW BOTH. WE SAW CELL  
17 THERAPY PROJECTS, SOME WENT UP THERE AND WE SAW SOME  
18 THAT WERE LOWER. WE LOOKED AT IT BY CATEGORY AS  
19 WELL. AND SO WE DID HAVE A RANGE, BUT THE AVERAGE,  
20 EVEN WITHIN A CELL THERAPY TYPE OF PROJECT, WAS  
21 AROUND \$4 MILLION FOR DIRECT COST.

22 MR. SHEEHY: THANK YOU.

23 DR. OLSON: THE OTHER AMENDMENT WE WOULD  
24 LIKE TO PROPOSE IS IN THE TRAN4 PROGRAM ANNOUNCEMENT  
25 OR THE TRAN4 PROGRAM, WHICH IS TOOLS, DEVELOPMENT OF

BARRISTERS' REPORTING SERVICE

1 TOOLS. WE WOULD LIKE TO CLARIFY THE OBJECTIVES FROM  
2 DEVELOPING A NOVEL TOOL FOR BROAD USE TOWARD  
3 COMMERCIALIZATION TO DEVELOPING A NOVEL TOOL FOR  
4 COMMERCIALIZATION. BY ELIMINATING THE STATEMENT  
5 "BROAD USE," WE WANT TO CLARIFY THAT THIS IS CLEARLY  
6 A PRODUCT DEVELOPMENT STAGE AWARD WHERE THE EXPECTED  
7 OUTCOME IS TRANSFERRED TO MANUFACTURING FOR  
8 COMMERCIALIZATION. VIRTUALLY EVERY SINGLE TRAN4  
9 APPLICATION THAT WE SAW IN ROUND ONE WOULD BE MORE  
10 APPROPRIATELY DESIGNATED A QUEST TYPE OF AWARD.  
11 THEY WERE NOT DOING DEVELOPMENT TYPE OF ACTIVITIES.  
12 SO TO HELP CLARIFY THAT, WE ARE REQUESTING THIS  
13 CHANGE IN LANGUAGE.

14 SO FINALLY, THE REQUESTED ACTIONS OF THE  
15 BOARD ARE TO APPROVE THE PROPOSED AMENDMENTS TO THE  
16 TRAN CONCEPT PLAN, TWO OF WHICH I'VE OUTLINED TO  
17 YOU, THE REDUCTION IN DIRECT PROJECT COSTS, A  
18 CLARIFICATION OF THE TRAN4 LANGUAGE, I THINK THE  
19 OTHERS, WHICH WERE MORE MINOR, ARE INCLUDED IN THE  
20 LARGER DOCUMENT, AND TO REQUEST AN ALLOCATION OF AN  
21 ADDITIONAL 15 MILLION FOR THE SECOND PLANNED ROUND  
22 OF THE TRAN PROGRAM THIS YEAR.

23 IF YOU HAVE ANY QUESTIONS, I'D BE HAPPY TO  
24 ADDRESS THEM.

25 DR. JUELSGAARD: SO THIS IS STEVE

BARRISTERS' REPORTING SERVICE

1 JUELSGAARD. I DO HAVE A QUESTION.

2 SO GOING FORWARD, THERE ARE TWO WAYS OF  
3 APPROACHING THE ISSUE OF THE AMOUNT OF FUNDING FOR  
4 TRANSLATIONAL PROGRAMS. ONE IS THE ONE THAT WE'RE  
5 WORKING ON NOW, WHICH IS TO APPROVE AN INITIAL  
6 AMOUNT AND THEN, IF WE THINK IT'S NECESSARY, APPROVE  
7 ADDITIONAL MONIES. THE OTHER IS TO CREATE A BUDGET,  
8 AND THE BUDGET BASICALLY SPECIFIES THE AMOUNT OF  
9 MONEY THAT WE'RE GOING TO USE. AND ONCE WE HIT THAT  
10 BUDGETED AMOUNT, THEN WE'RE DONE FOR THAT YEAR NO  
11 MATTER WHAT COMES IN AFTER THAT.

12 SO WHAT'S -- HOW ARE WE THINKING ABOUT  
13 THIS GOING FORWARD?

14 DR. MILLS: STEVE, THANK YOU VERY MUCH FOR  
15 THE ACTUALLY VERY TOPICAL QUESTION. IN A COUPLE OF  
16 OTHER MEETINGS, AS WE WERE INTRODUCING THE STRATEGIC  
17 PLAN, WE TALKED ABOUT WHAT WE CALLED THE REBALANCING  
18 THAT WOULD NEED TO TAKE PLACE AS WE MOVE THROUGH THE  
19 FIVE YEARS OF THE STRATEGIC PLAN. AND WE ARE GOING  
20 TO BRING, I DON'T WANT TO SAY CONCEPT PLAN BECAUSE  
21 IT'S A TERM OF ART, BUT WE'RE GOING TO BRING A  
22 CONCEPT TO THE BOARD AT THE NEXT MEETING WHERE WE  
23 WILL BE DISCUSSING THIS SPECIFIC ISSUE. AND  
24 PARTICULARLY WE'LL BE PROPOSING THAT IN DECEMBER OF  
25 EACH YEAR THAT WE WILL TAKE A LOOK AT THE FUNDING

BARRISTERS' REPORTING SERVICE

1 FOR THE PRIOR YEAR AND THE PORTFOLIO ACROSS  
2 DISCOVERY, NOT JUST TRANSLATIONAL, BUT DISCOVERY,  
3 TRANSLATIONAL, AND CLINICAL, AND THEN HAVE THE BOARD  
4 VOTE ON AND SET THE NEXT YEAR'S FUNDING LIMITS FOR  
5 THE INDIVIDUAL PROGRAMS THAT MAKE UP DISCOVERY,  
6 TRANSLATIONAL, AND CLINICAL.

7 AND SO THE IDEA IS EVERY YEAR THE FULL  
8 BOARD WOULD PARTICIPATE IN SETTING THE BUDGET LIMITS  
9 FOR THE NEXT YEAR. SO THIS IS REALLY A STEP THAT  
10 WE'RE TAKING ESSENTIALLY TO GET US TO DECEMBER WHERE  
11 WE CAN INSTITUTE THAT NEW PARADIGM. BUT WE'LL BE  
12 TALKING -- WE'RE GOING TO BRING A MORE COMPREHENSIVE  
13 OBVIOUSLY DISCUSSION ABOUT THIS TO THE BOARD AT THE  
14 NEXT MEETING.

15 (TECHNICAL GLITCH, REPEAT OF PREVIOUS  
16 COMMENTS BY DR. MILLS.)

17 DR. JUELSGAARD: HELLO. IS EVERYBODY  
18 STILL THERE? I DON'T KNOW IF ANYBODY ELSE HEARD  
19 THIS, BUT, RANDY, YOU BASICALLY SAID THE SAME THING  
20 TWICE. I DON'T KNOW IF THAT WAS FOR MY BENEFIT  
21 BECAUSE YOU THINK I JUST DIDN'T HEAR YOU THE FIRST  
22 TIME OR EXACTLY WHAT. BUT ANYWAY, I DID HEAR YOU  
23 THE FIRST TIME. AND THANK YOU VERY MUCH, AND I LIKE  
24 THAT. AND SO I DON'T HAVE ANY OTHER QUESTIONS.

25 DR. MILLS: I GOT TO TELL YOU. I DIDN'T

BARRISTERS' REPORTING SERVICE

1 GET TO HEAR IT THE FIRST TIME, BUT THE SECOND TIME I  
2 SOUNDED FANTASTIC.

3 DR. JUELSGAARD: YOU SOUNDED FANTASTIC  
4 BOTH TIMES.

5 CHAIRMAN THOMAS: ARE THERE ANY OTHER  
6 QUESTIONS BY MEMBERS OF THE BOARD ON THIS  
7 PRESENTATION? DO WE HAVE A MOTION TO APPROVE THE  
8 AMENDMENTS TO THE CONCEPT PLAN?

9 DR. JUELSGAARD: THIS IS STEVE JUELSGAARD.  
10 I SO MOVE.

11 DR. PRIETO: SECOND. FRANCISCO PRIETO.

12 CHAIRMAN THOMAS: THANK YOU, GENTLEMEN.  
13 ANY FURTHER DISCUSSION BY MEMBERS OF THE BOARD?

14 MS. BONNEVILLE: I JUST WANT TO CLARIFY  
15 THAT THAT MOTION INCORPORATED BOTH THE REQUESTED  
16 ACTIONS.

17 DR. JUELSGAARD: YES. THE MOTION DID  
18 INCLUDE BOTH REQUESTED ACTIONS.

19 MS. BONNEVILLE: GREAT. THANK YOU.

20 CHAIRMAN THOMAS: HEARING NO FURTHER  
21 DISCUSSION BY MEMBERS OF THE BOARD, DO WE HAVE ANY  
22 COMMENTS BY MEMBERS OF THE PUBLIC? HEARING NONE,  
23 MARIA, PLEASE TAKE THE ROLL.

24 MS. BONNEVILLE: DAVID BRENNER. LINDA  
25 BOXER.

BARRISTERS' REPORTING SERVICE

1 DR. BOXER: YES.  
2 MS. BONNEVILLE: LARS BERGLUND.  
3 DR. BERGLUND: YES.  
4 MS. BONNEVILLE: ANNE-MARIE DULIEGE.  
5 DR. DULIEGE: YES.  
6 MS. BONNEVILLE: ELIZABETH FINI.  
7 DR. FINI: YES.  
8 MS. BONNEVILLE: JUDY GASSON.  
9 DR. GASSON: YES.  
10 MS. BONNEVILLE: DAVID HIGGINS.  
11 MR. HIGGINS: YES.  
12 MS. BONNEVILLE: STEVE JUELSGAARD.  
13 DR. JUELSGAARD: YES.  
14 MS. BONNEVILLE: KATHY LAPORTE.  
15 MS. LAPORTE: YES.  
16 MS. BONNEVILLE: ADRIANA PADILLA.  
17 DR. PADILLA: YES.  
18 MS. BONNEVILLE: JOE PANETTA.  
19 MR. PANETTA: YES.  
20 MS. BONNEVILLE: ROBERT PRICE.  
21 DR. PRICE: YES.  
22 MS. BONNEVILLE: FRANCISCO PRIETO.  
23 DR. PRIETO: AYE.  
24 MS. BONNEVILLE: ROBERT QUINT.  
25 DR. QUINT: YES.

BARRISTERS' REPORTING SERVICE

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MS. BONNEVILLE: AL ROWLETT.  
MR. ROWLETT: YES.  
MS. BONNEVILLE: JEFF SHEEHY.  
MR. SHEEHY: YES.  
MS. BONNEVILLE: OS STEWARD.  
DR. STEWARD: YES.  
MS. BONNEVILLE: JONATHAN THOMAS.  
CHAIRMAN THOMAS: YES.  
MS. BONNEVILLE: ART TORRES.  
MR. TORRES: AYE.  
MS. BONNEVILLE: KRISTINA VUORI.  
DR. VUORI: YES.  
MS. BONNEVILLE: BRUCE WINTRAUB.  
MR. WINTRAUB: YES.  
MS. BONNEVILLE: MOTION CARRIES.  
CHAIRMAN THOMAS: THANK YOU, MARIA.  
ONTO ITEM 3, CONSIDERATION OF AMENDMENTS  
TO THE GRANTS WORKING GROUP BYLAWS. SCOTT WILL  
PRESENT. MR. TOCHER.  
MR. TOCHER: THANK YOU, J.T. AS PART OF  
OUR ONGOING EFFORT TO MONITOR AND CALIBRATE THE CIRM  
2.0 PROGRAMS, AND SPECIFICALLY WITH THIS ITEM, THE  
SCORING SYSTEMS, IN THE REVIEW OF THESE PROGRAMS,  
WE'VE IDENTIFIED THREE AREAS FOR IMPROVEMENT. TWO  
ARE IN THE CONTEXT OF OUR NONCLINICAL PROGRAM



BARRISTERS' REPORTING SERVICE

1 REVIEWS AND THE THIRD IS IN THE CONTEXT OF THE  
2 CLINICAL REVIEWS.

3 IF YOU LOOK ON PAGE 8 OF THE PROPOSED  
4 AMENDMENTS TO THE GRANTS WORKING GROUP BYLAWS, THE  
5 FIRST PROPOSED AMENDMENT REMOVES THE USE OF THE TERM  
6 "TIER" TO DESCRIBE THE FUNDING CATEGORIES THAT ARE  
7 USED FOR THESE TWO PROGRAMS. CURRENTLY SCORES OF 85  
8 OR ABOVE RECEIVE A TIER I RANKING AND BELOW 85 ARE  
9 RECEIVING TIER II RANKINGS. HOWEVER, THERE IS THE  
10 OPPORTUNITY FOR CONFUSION GIVEN THAT WE USE THAT  
11 TERM "TIERS" IN THE CONTEXT OF OUR CLINICAL PROGRAMS  
12 WHICH HAVE DIFFERENT DEFINITIONS.

13 SO IN A BID TO MAKE THINGS CLEAR, WE  
14 PROPOSE ACTUALLY ELIMINATING THE USE OF THE WORD  
15 "TIER" AND SIMPLY NAME THIS CATEGORY FOR WHAT THEY  
16 ARE, WHICH IS RECOMMENDED FOR FUNDING AND NOT  
17 RECOMMENDED FOR FUNDING.

18 THE SECOND PROPOSAL ADDRESSES THE CONTEXT  
19 OF SINGLE-AWARD PROGRAMS SUCH AS THE ACCELERATING  
20 CENTER, FOR INSTANCE. THERE ARE TWO CONTEXTS. ONE,  
21 WHERE THE CONTINGENCY WHERE NO APPLICATION RECEIVES  
22 A FUNDABLE SCORE, OR, SECOND, WHEN MORE THAN ONE  
23 APPLICATION RECEIVES A FUNDABLE SCORE, WE'D LIKE TO  
24 DRAW A LITTLE MORE DETAIL INTO THE BYLAWS TO ADDRESS  
25 THOSE SITUATIONS.

BARRISTERS' REPORTING SERVICE

1 SO WE PROPOSE THAT IF NO APPLICATION  
2 RECEIVES A FUNDABLE SCORE OF 85 OR GREATER, THE  
3 APPLICANTS MAY RESUBMIT A REFINED APPLICATION THAT  
4 IS BASED ON THE REVIEWER COMMENTS THEY RECEIVE FROM  
5 THE FIRST REVIEW WHICH WILL THEN BE REVIEWED AT A  
6 SUPPLEMENTAL MEETING OF THE GRANTS WORKING GROUP.

7 AND IN THE SITUATION IF MORE THAN ONE  
8 APPLICANT RECEIVES A FUNDABLE SCORE, THEN THE  
9 HIGHEST AVERAGE SCORE WILL BE DEEMED THE RECOMMENDED  
10 APPLICATION.

11 FINALLY, ON THE NEXT PAGE, PAGE 9 OF THE  
12 BYLAWS, WE PROPOSE TO REFINE THE DEFINITION OF THE  
13 TIER III TO PROVIDE GREATER FLEXIBILITY FOR NUISANCE  
14 APPLICATIONS WHILE ALLOWING SIGNIFICANTLY FLAWED  
15 APPLICATIONS THE OPPORTUNITY TO BE RECONSIDERED  
16 AFTER REMEDIATION AT A FUTURE DATE. CURRENTLY THE  
17 TIER III APPLICATION IS DEFINED AS ONE THAT IS  
18 SUFFICIENTLY FLAWED THAT IT DOES NOT WARRANT FUNDING  
19 AND SHOULD NOT BE RESUBMITTED. HOWEVER, OUR  
20 AMENDMENT PROPOSES THAT WE ACTUALLY ALLOW FOR  
21 RESUBMISSION AFTER A SIX-MONTH PERIOD IF AN  
22 APPLICATION RECEIVES A THREE. WE BELIEVE THAT THIS  
23 IS SUFFICIENT TO DISCOURAGE THE FRIVOLOUS OR  
24 NUISANCE APPLICATION WHILE SIMULTANEOUSLY PROVIDING  
25 AN OPPORTUNITY EVEN FOR SIGNIFICANTLY FLAWED

BARRISTERS' REPORTING SERVICE

1 APPLICATIONS TO COME BACK AT A LATER DATE.

2 AND THOSE ARE THE THREE PROPOSALS THAT WE  
3 HAVE, AND I'M HAPPY TO TAKE ANY QUESTIONS.

4 DR. JUELSGAARD: SO THIS IS STEVE  
5 JUELSGAARD. I GUESS I'M IN A QUESTIONING MODE  
6 TODAY. SO TELL ME WHAT DROVE YOU TO MAKE THESE  
7 CHANGES OR PROPOSED CHANGES. I'M SORRY. WHAT  
8 HAPPENED THAT YOU SAID, WELL, WAIT A MINUTE, WE  
9 SHOULD DO THINGS A LITTLE DIFFERENTLY?

10 MR. TOCHER: WELL, I THINK IT DEPENDS ON  
11 THE CIRCUMSTANCE. I CAN TAKE THEM IN ORDER. IN THE  
12 FIRST, IN TERMS OF THE USE OF TIERS, I THINK THAT  
13 THAT WAS JUST SOMETHING THAT WE NOTICED IN  
14 DISCUSSION OF THE RULES AND APPLICATIONS TO THE  
15 WORKING GROUP MEMBERS AND TO MEMBERS OF THE PUBLIC  
16 AND THE BOARD AS WELL.

17 IN THE SECOND CONTEXT THIS IS JUST SIMPLY  
18 A RECOGNITION THAT THERE IS IN THESE UPCOMING  
19 SINGLE-AWARD PROGRAMS THAT THERE IS A LACK OF DETAIL  
20 IN THE BYLAWS THAT SHOULD BE ADDRESSED.

21 AND IN THE CONTEXT OF THE CLINICAL  
22 PROGRAMS, WITH THE REDEFINITION OF TIER III, I  
23 BELIEVE RANDY ADDRESSED THAT IN PART AT A PRIOR  
24 BOARD MEETING WHERE HE WAS CONCERNED THAT THERE  
25 COULD BE A TENDENCY TO OVERUTILIZE THE RANKING OF A

BARRISTERS' REPORTING SERVICE

1 TIER III FOR AN APPLICATION THAT CONCEIVABLY AFTER  
2 SIGNIFICANT WORK COULD COME BACK FOR  
3 RECONSIDERATION.

4 DR. JUELSGAARD: OKAY. THANKS.

5 CHAIRMAN THOMAS: ANY OTHER QUESTIONS BY  
6 MEMBERS OF THE BOARD?

7 MR. SHEEHY: YES. THIS IS JEFF SHEEHY.

8 SO I JUST WANT TO -- SO FOR THE PART THAT  
9 HAS APPLICATIONS COME BACK, CAN WE REVISIT THAT  
10 POLICY AFTER WE DO THESE SINGLE-PROJECT ROUNDS? SO  
11 CAN WE HAVE A -- JUST TO SEE IF IT WORKS, IF IT  
12 HAPPENS? BECAUSE ONE WAY TO ADDRESS THIS ISSUE  
13 COULD BE JUST SIMPLY TO REOPEN THE ROUND, BUT I KNOW  
14 THAT THE THREE PROJECTS WE HAVE COMING UP ARE REALLY  
15 VITAL TO OUR STRATEGIC PLAN, AND THERE'S A TIME  
16 FRAME THAT WE NEED TO GET THESE -- IF WE CAN OBTAIN  
17 GOOD PROJECTS, THERE'S A TIME FRAME THAT WE WANT TO  
18 DO THIS EXPEDITIOUSLY.

19 SO I WOULD REQUEST THAT WHATEVER MOTION  
20 THAT IS MADE INCLUDES REVISITING THIS BECAUSE I CAN  
21 THINK OF CIRCUMSTANCES WHERE WE WOULD REOPEN THE  
22 ROUND TO ALL COMERS IF WE DIDN'T GET GOOD  
23 APPLICATIONS.

24 AND THEN THE SECOND ISSUE IS ON THE TIER  
25 III WHERE PEOPLE CAN COME BACK IN SIX MONTHS. SO

BARRISTERS' REPORTING SERVICE

1 DOES THIS INCLUDE PROJECTS THAT HAVE ALREADY  
2 BEEN -- IS THIS GRANDFATHERED TO INCLUDE PROJECTS  
3 THAT HAVE COME THROUGH OUR PROCESS ALREADY?

4 MR. TOCHER: YES.

5 MR. SHEEHY: GREAT. THANK YOU.

6 CHAIRMAN THOMAS: ANY OTHER COMMENTS,  
7 QUESTIONS BY MEMBERS OF THE BOARD?

8 DR. BERGLUND: THIS IS LARS BERGLUND. I  
9 WAS JUST WONDERING WHAT IS THE TIME DATE FOR WHICH  
10 THE SIX MONTHS IS COUNTING? IS THAT FROM THE  
11 ORIGINAL APPLICATION DATE OR FROM THE DATE WHERE THE  
12 DECISION IS RENDERED, OR DOES IT NEED TO BE  
13 CLARIFIED?

14 MR. TOCHER: THE DATE OF THE DECISION BY  
15 THE WORKING GROUP.

16 DR. BERGLUND: OKAY. DOES THAT NEED TO BE  
17 ADDED?

18 MR. TOCHER: WE CAN PUT THAT IN FOR  
19 CLARITY, SURE.

20 CHAIRMAN THOMAS: ANY OTHER COMMENTS OR  
21 QUESTIONS FROM MEMBERS OF THE BOARD?

22 DR. JUELSGAARD: THIS IS STEVE JUELSGAARD  
23 AGAIN. I GUESS THE ONLY COMMENT, AND THIS IS  
24 REGARDS THE THIRD OF THE THREE CONCEPTS, SO THE TIER  
25 III BEING ABLE TO COME BACK AGAIN. I JUST -- YOU

BARRISTERS' REPORTING SERVICE

1 KNOW, PERHAPS IT IN SOME WAYS DOESN'T INCENTIVIZE  
2 PEOPLE ENOUGH TO GIVE IT THEIR BEST SHOT THE FIRST  
3 TIME OUT KNOWING THAT THEY GET A SECOND BITE OF THE  
4 APPLE. AND FOR ME THERE'S SOME VALUE IN BASICALLY  
5 SAYING, YOU KNOW, PUT YOUR BEST FOOT FORWARD. IF  
6 IT'S GOOD ENOUGH, THAT'S GREAT. IF IT ISN'T GOOD  
7 ENOUGH, THAT'S TOO BAD. BUT THAT'S MY ONLY CONCERN.  
8 SO I'M JUST A LITTLE UP IN THE AIR ABOUT HOW GOOD  
9 THE IDEA IS.

10 DR. MILLS: STEVE, RANDY AGAIN. AND I'M  
11 GOING TO HOPEFULLY JUST SAY THIS ONCE THIS TIME. SO  
12 THIS IS FOR THREES. SO I WOULD SAY IF YOUR CONCERN  
13 WERE TO PLAY OUT, IT WOULDN'T PLAY OUT IN THE THREE.  
14 IT WOULD REALLY PLAY OUT IN THE TWO, WHICH IS KEEP  
15 IN MIND THE SCORING OF ONE IS APPROVE IT NOW, TWO IS  
16 IT'S INTERESTING, WE HAVE THESE QUESTIONS ABOUT IT  
17 OR WE THINK IT CAN BE IMPROVED, REVISE IT, WE CAN  
18 USUALLY DO THAT. THAT WHOLE REVISION CYCLE FOR THE  
19 MOST PART CAN BE DONE IN ABOUT A MONTH. AND THEN  
20 SOMETIMES THE GWG WILL DO THAT ONCE OR TWICE AND  
21 SAY, LOOK, BASED ON WHAT WE HAVE RIGHT NOW, WE'RE  
22 GOING TO GIVE THIS A THREE. AND THE THREE  
23 HISTORICALLY HAS BEEN A DEATH PENALTY.

24 SO IT HASN'T -- I DON'T VIEW THIS AS A WAY  
25 OF SORT OF NOT TAKING YOUR BEST SHOT. I THINK

BARRISTERS' REPORTING SERVICE

1 ANYONE THAT GOES THROUGH THE TIME AND EFFORT TO  
2 APPLY ISN'T GOING TO NOT GIVE IT THEIR ALL BECAUSE  
3 THEY KNOW NOW THEY CAN GET A THREE AND HAVE A  
4 SIX-MONTH DEFERRAL. THIS IS REALLY MORE TO ADDRESS  
5 THE ISSUE OF WE'VE NOTICED SOMETIMES GWG MEMBERS IN  
6 GIVING SOMETHING A THREE WILL SAY -- WILL MAKE A  
7 COMMENT ABOUT, WELL, UNLESS THE FDA DOES THIS OR  
8 UNLESS WE SEE THIS KIND OF DATA. AND THAT'S REALLY  
9 NOT WHAT A THREE IS FOR. IF IT'S REMEDIABLE, THEN  
10 WE SHOULDN'T BE GIVING IT A LIFETIME BAN. WE SHOULD  
11 JUST BE SAYING GO AND HERE ARE THE COMMENTS. THIS  
12 IS NOT SOMETHING THAT CAN BE REMEDIED WITHIN A  
13 MONTH. THIS IS SOMETHING THAT'S GOING TO TAKE  
14 CLEARLY LONGER THAN A MONTH. YOU HAVE SIX MONTHS TO  
15 GO TRY TO MAKE THIS APPLICATION BETTER AND COME  
16 BACK, BUT NOT GIVE IT THE DEATH PENALTY IN ALL  
17 CASES.

18 I WILL ALSO REMIND EVERYONE THAT THE  
19 REASON, AS WE WERE CONSTRUCTING THIS, THE REASON  
20 THAT WE PUT THREES IN PLACE WERE TO BASICALLY  
21 PREVENT NUISANCE APPLICATIONS WHERE SOMEBODY CAME  
22 IN, MAYBE THEY'RE INCLINED TO APPLY, THERE WOULD BE  
23 ACTUALLY NO MERIT WHATSOEVER TO IT, WE WOULD REJECT  
24 IT, AND THEY WOULD JUST COME BACK AND APPLY  
25 IMMEDIATELY. SO WE JUST HAVEN'T SEEN ANY OF THAT,

BARRISTERS' REPORTING SERVICE

1 AND WE THINK A SIX-MONTH DEFERRAL WILL SORT OF  
2 STRIKE A NICE BALANCE BETWEEN YOU HAVE SUBSTANTIAL  
3 EDITS TO MAKE ON THIS APPLICATION, YOU HAVE  
4 SIGNIFICANT NEW DATA YOU NEED TO GET, BUT YOU CAN  
5 GET IT WITHOUT OVERTAXING OUR SYSTEM WITH NUISANCE  
6 APPLICATIONS.

7 DR. JUELSGAARD: OKAY. AND SO THERE'S  
8 ONLY GOING TO BE ONE MORE BITE OF THE APPLE, THEN, I  
9 TAKE IT, SO THEY GET ONE MORE SHOT. AND IF IT JUST  
10 ISN'T GOOD ENOUGH, THAT IT ISN'T GOOD ENOUGH?

11 DR. MILLS: WELL, I MEAN IT WOULD COME  
12 BACK IN AND IT WILL GET RESCORED HOWEVER IT GETS  
13 RESCORED. I MEAN IT'S IN THE REALM OF POSSIBILITIES  
14 THAT THEY COME IN AND THEY GET A TWO AND THEN AFTER  
15 THAT THEY GET A THREE, THEY GET A SIX-MONTH  
16 DEFERRAL, THEY REAPPLY, AND THEY GET ANOTHER TWO  
17 AGAIN. THERE'S NOTHING ABOUT WHAT WE'RE DOING THAT  
18 BASICALLY PREJUDICES THE APPLICATION AFTER THE  
19 SIX-MONTH DEFERRAL.

20 DR. JUELSGAARD: ALL RIGHT. WELL, I GUESS  
21 JUST IN MY WORLD, YOU KNOW, THERE NEEDS TO BE AN  
22 ENDPOINT, AND YOU JUST DON'T KEEP GIVING PEOPLE  
23 REPEATED OPPORTUNITIES TO SEE IF THEY CAN DO BETTER.  
24 AT SOME POINT EITHER THEY ARE GOOD ENOUGH OR THEY  
25 AREN'T GOOD ENOUGH, THAT YOU JUST SAY GO WITH GOD



BARRISTERS' REPORTING SERVICE

1 AND THAT'S THE END OF IT.

2 DR. MILLS: SO I THINK IF WE SORT OF WATCH  
3 HOW THIS PLAYS OUT GOING FORWARD, WE CAN MAKE  
4 ADJUSTMENTS ON IT. BUT I THINK A SIX-MONTH DEFERRAL  
5 IS A PRETTY LONG DEFERRAL. AND SO OUR CONCERN WOULD  
6 BE HAVING THE SYSTEM, THE REVIEW SYSTEM, OVERTAXED  
7 WITH THINGS THAT ARE NEVER EVER, EVER GOING TO COME  
8 AND SEE THE LIGHT WHILE AT THE SAME TIME PRESERVING  
9 OPPORTUNITIES FOR SOME THINGS WHICH ARE JUST  
10 TECHNICALLY VERY, VERY DIFFICULT OR WHICH THE GWG IS  
11 SAYING WE JUST DON'T SEE HOW THEY CAN DO THIS, WHICH  
12 THEY MIGHT BE ABLE TO FIX. AND I GUESS I WOULDN'T  
13 WANT TO KILL ARBITRARILY A HIGH RISK PROJECT WHERE  
14 THEY WERE ABLE TO ULTIMATELY DELIVER THE GOODS,  
15 PARTICULARLY ON THINGS LIKE REGULATORY QUESTIONS.

16 DR. STEWARD: THIS IS OS. COULD I MAKE A  
17 COMMENT?

18 CHAIRMAN THOMAS: OF COURSE.

19 DR. STEWARD: SO I'M JUST LISTENING TO  
20 THIS, AND I GUESS I HADN'T THOUGHT ABOUT THIS DEEPLY  
21 BEFORE, BUT I GUESS WHAT I'M WONDERING IS WHETHER WE  
22 NEED SOMETHING A FOUR. AND LET ME UNPACK THAT JUST  
23 A LITTLE BIT.

24 EVERYTHING THAT RANDY IS TALKING ABOUT  
25 RIGHT NOW IS GREAT. YOU HAVE PROJECTS THAT ARE NOT

BARRISTERS' REPORTING SERVICE

1 QUITE READY FOR PRIME TIME AND NEED TO GO BACK AND  
2 RETHINK, AND MAYBE THAT'S A TWO. AND IT MAY NOT BE  
3 A MONTH; IT MAY BE SIX MONTHS, IN FACT, FOR A TWO.  
4 AND THEN THERE ARE PROJECTS THAT REALLY NEED A LOT  
5 OF WORK AND BASICALLY THE PROJECT NEEDS TO BE  
6 REWRITTEN, AND THAT IS PROBABLY A THREE.

7 I WONDER IF WE NEED A CATEGORY FOUR. AND  
8 BY THAT I MEAN A CATEGORY THAT IS FLAT OUT  
9 DISAPPROVAL. AND LET ME JUST KIND OF UNPACK THE  
10 SCENARIO HERE.

11 SO THERE MIGHT BE A SITUATION WHERE  
12 SOMEBODY IS PROPOSING SOMETHING THAT IS, FOR  
13 EXAMPLE, SIMPLY UNETHICAL. AND THAT WOULD BE A CASE  
14 WHERE I THINK IT WOULD BE APPROPRIATE AND NECESSARY  
15 TO JUST SAY NO. THIS IS SOMETHING WE NEVER WANT TO  
16 SEE AGAIN. IT'S JUST NOT SOMETHING THAT WE WILL  
17 CONSIDER. SO JUST TO THROW THAT OUT THERE FOR  
18 DISCUSSION. THIS ACTUALLY -- I HAVE TO SAY I WAS  
19 THINKING ABOUT THIS BASED ON STEVE'S COMMENTS AND  
20 THE IMPLICATIONS. IT MIGHT EVENTUALLY GET TO THE  
21 POINT THAT WE WOULD FUND IT. THANK YOU.

22 DR. MILLS: SO I WOULD JUST ASK WE WAIT  
23 AND SEE WHETHER OR NOT THAT HAPPENS, WHETHER OR NOT  
24 WE GET THOSE APPLICATIONS THAT ARE THAT FLAWED, AND  
25 I WOULD ALSO SAY THAT TAXING.

BARRISTERS' REPORTING SERVICE

1 MR. SHEEHY: SO THIS IS JEFF SHEEHY. I  
2 WAS GOING TO ECHO KIND OF WHAT RANDY IS SAYING, THAT  
3 WE DON'T HAVE ANY EVIDENCE OF THAT SO FAR. AND THIS  
4 IS PRETTY LATE DOWN THE ROAD. THESE ARE CLINICAL  
5 TRIAL PROJECTS FOR THE MOST PART. SO FOR ME THIS  
6 KIND OF GETS TO SOME OF THE CONFLICTS THAT WE END UP  
7 HAVING BETWEEN REVIEWERS AND APPLICANTS WHERE THE  
8 REVIEWERS MAY SAY SOMETHING WHICH YOU'RE USING THE  
9 WRONG ANIMAL MODEL -- OR I'M JUST GETTING OUT  
10 SCENARIOS, NOT NECESSARILY ONES WE'VE SEEN -- OR YOU  
11 DON'T HAVE A STRONG ENOUGH PROOF OF CONCEPT STUDY,  
12 AND YOU CAN GO BACK AND FORTH ON THAT, AND THEN IT'S  
13 A THREE AND THEY'RE GONE. THEY MAY DECIDE TO  
14 ACTUALLY DO THOSE STUDIES. THESE PROJECTS COULD BE  
15 ACTUALLY VIABLE PROJECTS IF THEY JUST WOULD DECIDE  
16 TO DO THE STUDIES THAT THE REVIEW GROUP HAS ASKED  
17 THEM TO DO.

18 AND THAT'S WHERE I WORRY ABOUT MAYBE  
19 MISSING SOME OF THOSE ESPECIALLY SINCE IT'S  
20 EVOLVING, AS RANDY HAD MENTIONED EARLIER. THE  
21 REGULATORY ENVIRONMENT IS EVOLVING, THE SCIENCE IS  
22 EVOLVING. AND, FRANKLY, IF PEOPLE GET TWO THREES,  
23 YOU'RE TALKING ABOUT A YEAR DELAY FROM YOUR ORIGINAL  
24 SUBMISSION. SO THE APPLICANTS THEMSELVES HAVE TO  
25 HAVE RESOURCES AND STRONG FAITH IN THEIR PROJECT TO

BARRISTERS' REPORTING SERVICE

1 KEEP COMING BACK AFTER THAT.

2 SO I JUST FEEL LIKE THIS IS A MORE -- THIS  
3 IS AN EQUITY THING THAT ALLOWS PEOPLE WITH GOOD  
4 PROJECTS DOING DIFFICULT SCIENCE ANOTHER OPPORTUNITY  
5 TO COME IN IF THEY CAN ADDRESS SOME OF THE -- IF YOU  
6 HAVE TO DO A NEW PROOF OF CONCEPT STUDY, YOU'RE NOT  
7 GOING TO COME BACK IN TWO MONTHS. YOU'RE GOING TO  
8 TAKE SOME TIME BEFORE YOU COME BACK.

9 DR. MILLS: YEAH. I'D ALSO JUST SORT OF,  
10 AGAIN TO FOLLOW AND BUILD ON WHAT JEFF SAID, JUST  
11 CONCEPTUALLY, EVEN IF IT'S BURDENSOME TO US, I'D  
12 RATHER OVERWORK GIL IN REVIEW THAN MISS A GOOD THING  
13 THAT COULD GO ON AND HELP SOMEBODY. WE MIGHT BE  
14 FISHING IN VERY SPARSE WATERS, BUT I JUST THINK  
15 MISSING SOMETHING THAT COULD BE SAVED WOULD BE THE  
16 SORT OF BIGGEST TRAGEDY OF ALL. SO I JUST FEEL LIKE  
17 IF WE'RE GOING TO MAKE AN ERROR, LET'S MAKE AN ERROR  
18 ON THE SIDE OF INCLUSIVENESS.

19 DR. PRIETO: I JUST WOULD -- I'D LIKE TO  
20 COMMENT ON WHAT OS SAID. I THINK THAT THAT SORT OF  
21 AN APPLICATION, AND FORTUNATELY WE HAVEN'T HAD MUCH  
22 OF THAT, WOULD PROBABLY BE CAPTURED IN THE REVIEW  
23 CRITIQUES. SO I THINK IT WOULD BE FAIRLY CLEAR TO  
24 THE APPLICANT THAT THIS IS NOT SOMETHING WE'RE  
25 INTERESTED IN. THIS IS NOT SOMETHING WE WOULD EVER

BARRISTERS' REPORTING SERVICE

1 SERIOUSLY CONSIDER FUNDING. THANK YOU FOR YOUR  
2 INTEREST.

3 CHAIRMAN THOMAS: THANK YOU. ANY OTHER  
4 COMMENTS? SO DO I HEAR A MOTION TO APPROVE THESE  
5 AMENDMENTS?

6 MR. SHEEHY: SO COULD I MAKE THE MOTION,  
7 BUT WITH TWO AMENDMENTS? ONE IS TO NOTE THAT SIX  
8 MONTHS STARTS FROM THE DECISION AT THE GRANTS  
9 WORKING GROUP. THAT'S WHEN THE CLOCK STARTS. AND  
10 THE SECOND --

11 MR. HARRISON: JEFF, I JUST WANTED TO ASK  
12 FOR THE OPPORTUNITY FOR THE TEAM TO WRITE UP A  
13 PROCESS BECAUSE THERE ARE INSTANCES, FOR EXAMPLE,  
14 WHERE AN APPLICATION IS WITHDRAWN, SO THERE'S NOT A  
15 DECISION. SO IN TERMS OF DEFINING WHEN THE  
16 SIX-MONTH PERIOD STARTS, I'D JUST ASK FOR THE BOARD  
17 TO GIVE US SOME DISCRETION TO DEFINE THE PROCESS  
18 GIVEN THE VARIABLES INVOLVED.

19 MR. SHEEHY: THEY'RE NOT WITHDRAWN BEFORE  
20 GRANTS WORKING GROUP DECISIONS.

21 DR. JUELSGAARD: THIS IS STEVE JUELSGAARD.  
22 SO I TRIED THIS ONCE BEFORE UNSUCCESSFULLY. BUT  
23 THIS MOTION ISN'T READY FOR PRIME TIME BECAUSE WE  
24 STILL HAVE A COUPLE OF PIECES THAT ARE NOT FULLY  
25 DEVELOPED, AND MAYBE IT'S TIME TO TABLE THE MOTION

BARRISTERS' REPORTING SERVICE

1 AND BRING IT UP AT THE NEXT BOARD MEETING.

2 MR. HARRISON: STEVE, THERE'S ONE ITEM  
3 HERE WHICH RELATES TO THE SINGLE-AWARD APPLICATION  
4 PROCESS AND WHAT HAPPENS IF THERE IS NO APPLICATION  
5 THAT HAS A SCIENTIFIC SCORE OF 85 OR ABOVE WHICH  
6 WILL BE RELEVANT TO THE CONDUCT OF THE ACCELERATING  
7 CENTER REVIEW, WHICH TAKES PLACE NEXT WEEK. SO AT  
8 LEAST AS TO THAT PROPOSED CHANGE TO THE BYLAWS, WE'D  
9 LIKE TO MOVE FORWARD NOW.

10 I THINK IF WE DEFINE THE DATE AS THE DATE  
11 OF THE GWG DECISION AS OPPOSED TO THE BOARD  
12 DECISION, THAT THAT WOULD ADDRESS THE CONCERN ABOUT  
13 WITHDRAWAL BECAUSE JEFF IS CORRECT, THAT WITHDRAWAL  
14 HAPPENS AFTER A GWG TYPICALLY, NOT AFTER --

15 MR. SHEEHY: AND THERE IS NO BOARD  
16 DECISION ON THESE APPLICATIONS. SCOTT IN HIS  
17 ORIGINAL COMMENTS HAD SAID THE GWG, BUT THAT'S THE  
18 ONLY DECISION POINT.

19 RANDY, I DON'T THINK -- STEVE, I DON'T  
20 THINK THIS IS THAT COMPLEX. I MEAN I THINK IT  
21 REALLY IS JUST DEFINING THE SET POINT, WHICH IS  
22 EASY. I DON'T THINK THERE'S A LOT OF THOUGHT THAT  
23 NEEDS TO GO INTO THAT.

24 AND THE OTHER AMENDMENT I WAS GOING TO  
25 MAKE WAS TO REVISIT THE SUPPLEMENTAL REVIEW ISSUE

BARRISTERS' REPORTING SERVICE

1 AFTER WE FINISH WITH THESE THREE CRITICAL ELEMENTS  
2 OF OUR STRATEGIC PLAN JUST TO SEE IF WE WANT TO MAKE  
3 THIS A PERMANENT FEATURE OF OUR BYLAWS.

4 SO THOSE ARE MY TWO AMENDMENTS -- THE TWO  
5 SUPPLEMENTS TO THE MOTION THAT I WAS MAKING.

6 MR. TORRES: WHAT MOTION DID YOU MAKE?

7 MR. SHEEHY: TO APPROVE THIS WITH --

8 MR. TORRES: WITH THOSE AMENDMENTS.

9 MR. SHEEHY: -- WITH THOSE A AMENDMENTS.

10 DR. JUELSGAARD: WELL, I'M FINE WITH  
11 PROCEEDING. I WANT TO MAKE SURE WE'VE GOT THE I'S  
12 DOTTED AND THE T'S CROSSED AND THAT WE KNOW REALLY  
13 WHAT IT IS, HOW THIS IS GOING TO WORK.

14 MR. TORRES: TORRES SECONDS.

15 CHAIRMAN THOMAS: IT'S BEEN MOVED AND  
16 SECONDED. THANK YOU, GENTLEMEN. IS THERE ANY  
17 FURTHER BOARD DISCUSSION ON THE TOPIC? HEARING  
18 NONE, ANY PUBLIC COMMENT ON THIS TOPIC? MARIA,  
19 PLEASE CALL THE ROLL.

20 MS. BONNEVILLE: DAVID BRENNER. LINDA  
21 BOXER.

22 DR. BOXER: YES.

23 MS. BONNEVILLE: LARS BERGLUND.

24 DR. BERGLUND: YES.

25 MS. BONNEVILLE: ANNE-MARIE DULIEGE.

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1 DR. DULIEGE: YES.  
2 MS. BONNEVILLE: ELIZABETH FINI.  
3 DR. FINI: YES.  
4 MS. BONNEVILLE: JUDY GASSON.  
5 DR. GASSON: YES.  
6 MS. BONNEVILLE: DAVID HIGGINS.  
7 MR. HIGGINS: YES.  
8 MS. BONNEVILLE: STEVE JUELSGAARD.  
9 DR. JUELSGAARD: YES.  
10 MS. BONNEVILLE: KATHY LAPORTE.  
11 MS. LAPORTE: YES.  
12 MS. BONNEVILLE: ADRIANA PADILLA.  
13 DR. PADILLA: YES.  
14 MS. BONNEVILLE: JOE PANETTA. ROBERT  
15 PRICE.  
16 DR. PRICE: YES.  
17 MS. BONNEVILLE: FRANCISCO PRIETO.  
18 DR. PRIETO: AYE.  
19 MS. BONNEVILLE: ROBERT QUINT.  
20 DR. QUINT: YES.  
21 MS. BONNEVILLE: AL ROWLETT.  
22 MR. ROWLETT: YES.  
23 MS. BONNEVILLE: JEFF SHEEHY.  
24 MR. SHEEHY: YES.  
25 MS. BONNEVILLE: OS STEWARD.



BARRISTERS' REPORTING SERVICE

1 DR. STEWARD: YES.  
2 MS. BONNEVILLE: JONATHAN THOMAS.  
3 CHAIRMAN THOMAS: YES.  
4 MS. BONNEVILLE: ART TORRES.  
5 MR. TORRES: AYE.  
6 MS. BONNEVILLE: KRISTINA VUORI.  
7 DR. VUORI: YES.  
8 MS. BONNEVILLE: BRUCE WINTRAUB.  
9 MR. WINTRAUB: YES.  
10 DR. BRENNER: DAVE BRENNER. I WAS MUTED.  
11 I'M A YES TOO. I'M SORRY. I APOLOGIZE.  
12 MS. BONNEVILLE: THANK YOU. MOTION  
13 CARRIES.  
14 CHAIRMAN THOMAS: THANK YOU, MARIA.  
15 WE NOW MOVE TO THE PORTION OF THE AGENDA  
16 FOR THE APPLICATION REVIEW SUBCOMMITTEE. WE HAVE  
17 ITEMS 4 AND 5 AND FOR THOSE, I WILL NOW TURN THE  
18 MEETING OVER TO MR. SHEEHY.  
19 (THE BOARD THEN RECONVENED AS THE  
20 APPLICATION REVIEW SUBCOMMITTEE AND WAS HEARD AS  
21 FOLLOWS:)  
22 MR. SHEEHY: THANK YOU, J.T. SO I THINK  
23 WE'RE GOING TO START OFF WITH A PRESENTATION ABOUT  
24 THE DISCOVERY STAGE REVIEW: THE INCEPTION AWARDS.  
25 OH, FIRST WE HAVE THE TRANSLATION PROJECTS. I'M

BARRISTERS' REPORTING SERVICE

1 SORRY. I'M SO OLD, I CAN'T READ ANYMORE.

2 MR. TORRES: CHRONOLOGICALLY GIFTED.

3 MR. SHEEHY: ANYWAY, SO DR. SAMBRANO, ARE  
4 YOU GOING TO CONDUCT THIS? SO THIS ONE IS -- THE  
5 FIRST PROJECT IS ONE FROM THE TRANSLATION ROUND THAT  
6 THE TEAM THOUGHT NEEDED ANOTHER LOOK BEFORE WE CAME  
7 TO A DECISION POINT ON IT.

8 DR. SAMBRANO: SO THANK YOU, MR. CHAIRMAN,  
9 MEMBERS OF THE SUBCOMMITTEE. SO AT THE MARCH 15TH  
10 MEETING OF THE ICOC, THERE WERE TWO APPLICATIONS  
11 THAT YOU PROBABLY REMEMBER FROM THE TRANSLATION  
12 PROGRAM REVIEW THAT WERE DEFERRED AND FOR SLIGHTLY  
13 DIFFERENT REASONS.

14 THE FIRST ONE, WHICH IS NOT BEING  
15 CONSIDERED HERE, BUT JUST TO UPDATE YOU, IS  
16 TRAN1-08468, WAS NOT RECOMMENDED FOR FUNDING. AND  
17 THE BOARD HAD REQUESTED THAT WE REASSEMBLE A GRANTS  
18 WORKING GROUP PANEL TO ASSESS NEW INFORMATION  
19 PROVIDED BY THE APPLICANT. AND SO WE DID THAT. THE  
20 GRANTS WORKING GROUP'S RECOMMENDATION REMAINED  
21 UNCHANGED FOLLOWING THAT REVIEW, AND THE APPLICANT  
22 WITHDREW THE APPLICATION. AND SO, THEREFORE, WE'RE  
23 NOT TAKING ANY FURTHER ACTION ON THIS APPLICATION.  
24 THAT'S WHY IT IS NOT BEING CONSIDERED TODAY.

25 THE SECOND ONE, WHICH IS THE TRAN1-08522,

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1 IS ONE THAT WAS RECOMMENDED FOR FUNDING BY THE  
2 GRANTS WORKING GROUP WITH A SCORE OF 87. HOWEVER,  
3 CIRM LEARNED OF CIRCUMSTANCES THAT WE THOUGHT COULD  
4 MATERIALLY IMPACT ON THE POTENTIAL SUCCESS OR  
5 FAILURE OF THE PROPOSED PRODUCT.

6 AND SO WHAT HAPPENED WAS IN EARLY MARCH,  
7 JUST BEFORE THAT BOARD MEETING TOOK PLACE, THE  
8 COMPANY SPONSOR OF THE PHASE III CLINICAL TRIAL  
9 PUBLISHED A PRESS RELEASE THAT INDICATED THAT ITS  
10 CLINICAL TRIAL IN NEWLY DIAGNOSED GLIOBLASTOMA  
11 PATIENTS HAD BEEN DISCONTINUED BECAUSE INTERIM  
12 ANALYSIS REVEALED IT UNLIKELY TO MEET THE PRIMARY  
13 ENDPOINT OF OVERALL SURVIVAL. AND THE PRODUCT UNDER  
14 INVESTIGATION UNDER THAT PHASE III, IT IS THE FIRST  
15 GENERATION VERSION OF THE PRODUCT THAT IS PROPOSED  
16 FOR APPLICATION TRAN1-08522. SO OUR QUESTION REALLY  
17 WAS DOES THE RELATEDNESS OF THIS PRODUCT, THE SECOND  
18 GENERATION PRODUCT TO THE FIRST AND THE FAILURE OF  
19 THAT TRIAL, DOES IT CREATE A SITUATION WHERE IT'S  
20 UNLIKELY TO BE DEVELOPED IF WE FUND IT.

21 SO WHAT WE DID IS WE CONTACTED THE  
22 APPLICANT, AND THE APPLICANT AGREED TO POSTPONE THE  
23 ICOC CONSIDERATION SO THAT WE COULD CONFER WITH THE  
24 GRANTS WORKING GROUP. SO WE ASSEMBLED THE WHOLE  
25 PANEL, THE SAME PANEL THAT REVIEWED IT THE FIRST

BARRISTERS' REPORTING SERVICE

1 TIME, RECEIVED THE PRESS RELEASE, THEY RECEIVED A  
2 RESPONSE FROM THE APPLICANT ALONG WITH A COUPLE OF  
3 LETTERS PROVIDED FROM THE COMPANY SPONSOR AS WELL AS  
4 A LARGE PHARMACEUTICAL ENTITY IN SUPPORT OF ONGOING  
5 DEVELOPMENT OF THIS SECOND GENERATION PRODUCT. AND  
6 SO WE PROVIDED THIS TO THE WORKING GROUP, AND ON  
7 APRIL 26TH THEY DISCUSSED (INAUDIBLE)...AS INDICATED  
8 IN THE MEMO, THE REVIEWERS AGREED THAT THE REPORT OF  
9 THE FAILURE OF THE PHASE III TRIAL DID NOT AFFECT  
10 THEIR REVIEW AND RECOMMENDATION OF THE PRODUCT AND  
11 FELT THAT, YES, INDEED, THIS IS A RISKY PROPOSAL DUE  
12 TO THE NATURE OF THE IMMUNOTHERAPY APPROACH.  
13 HOWEVER, THEY FELT IT'S CRITICALLY IMPORTANT TO  
14 SUPPORT CONTINUED DEVELOPMENT TO BETTER OPTIMIZE A  
15 SECOND GENERATION PRODUCT LIKE THIS ONE, BUT THE  
16 TARGET IS STILL QUITE VALID. IT IS SUPPORTED BY  
17 BOTH THE PARENT COMPANY OF THE TRIAL AS WELL AS THE  
18 PHARMACEUTICAL COMPANY WHO HAD EXPRESSED INTEREST IN  
19 THAT SECOND GENERATION PRODUCT AND ALSO BECAUSE  
20 THERE IS A GREAT UNMET NEED FOR PATIENTS WITH  
21 GLIOBLASTOMA.

22 SO THE OTHER THING THAT WAS POINTED OUT  
23 WAS THAT THE CONTROL ARM OF THE STUDY PERFORMED MUCH  
24 BETTER THAN IN MOST TRIALS AND IT WAS AT LEAST AT  
25 THIS TIME DIFFICULT TO INTERPRET WHAT THE OUTCOMES

BARRISTERS' REPORTING SERVICE

1 FROM THE PHASE III TRIAL EXACTLY WERE. SO THE  
2 RECOMMENDATION FROM THE GRANTS WORKING GROUP REMAINS  
3 THE SAME TO FUND FOR 2.9 MILLION THIS TRAN1 AWARD.  
4 AND THE CIRM TEAM CONCURS WITH THAT OF THE GRANTS  
5 WORKING GROUP.

6 MR. SHEEHY: THANK YOU, DR. SAMBRANO.

7 JUST AS A POINT OF CLARIFICATION, CAN WE  
8 TALK ABOUT WHAT ACTUALLY HAPPENED AT THE SECOND  
9 GRANTS WORKING GROUP? SO DID THEY SCORE OR DID THEY  
10 JUST VOTE ON A RECOMMENDATION TO KEEP THE SCORE  
11 WHERE IT WAS?

12 DR. SAMBRANO: SO THEY DID NOT SCORE. SO  
13 THE PROCESS WAS THAT THEY -- WE WANTED ADVICE FROM  
14 THE PANEL. SO THEY ALL PARTICIPATED IN PROVIDING US  
15 THEIR OPINION ON WHETHER THIS MADE A DIFFERENCE IN  
16 THEIR RECOMMENDATION. AND THAT IS ALL THAT WE  
17 COLLECTED. AND SO THEY GAVE US THEIR OPINION, AND  
18 THE COMMENTS THAT I MADE REFLECT THE OPINION THAT  
19 WAS SOUGHT BY THESE MEMBERS, BUT THERE WAS NO  
20 RESCORING.

21 MR. SHEEHY: AND NO MOTIONS?

22 SO FIRST WE HAVE A MOTION -- SO FIRST I  
23 THINK THE PROCESS HERE WOULD BE TO GET A MOTION TO  
24 APPROVE OR NOT APPROVE THE RECOMMENDATION AND THEN  
25 TO HAVE A DISCUSSION SO THAT WE HAVE A MOTION TO

BARRISTERS' REPORTING SERVICE

1 START WITH.

2 MR. TORRES: SO MOVED. TORRES.

3 MR. SHEEHY: AND A SECOND?

4 DR. JUELSGAARD: STEVE JUELSGAARD. I

5 SECOND.

6 MR. SHEEHY: IS THERE ANY DISCUSSION? ANY  
7 PUBLIC COMMENT? COULD WE GET THE ROLL CALL PLEASE.

8 MS. BONNEVILLE: ANNE-MARIE DULIEGE.

9 DR. DULIEGE: AYE.

10 MS. BONNEVILLE: DAVID HIGGINS.

11 MR. HIGGINS: YES.

12 MS. BONNEVILLE: STEVE JUELSGAARD.

13 DR. JUELSGAARD: YES.

14 MS. BONNEVILLE: KATHY LAPORTE.

15 MS. LAPORTE: YES.

16 MS. BONNEVILLE: ADRIANA PADILLA.

17 DR. PADILLA: YES.

18 MS. BONNEVILLE: JOE PANETTA. FRANCISCO  
19 PRIETO.

20 DR. PRIETO: AYE.

21 MS. BONNEVILLE: ROBERT QUINT.

22 DR. QUINT: YES.

23 MS. BONNEVILLE: AL ROWLETT.

24 MR. ROWLETT: YES.

25 MS. BONNEVILLE: JEFF SHEEHY.

BARRISTERS' REPORTING SERVICE

1 MR. SHEEHY: YES.

2 MS. BONNEVILLE: OS STEWARD.

3 DR. STEWARD: YES.

4 MS. BONNEVILLE: JONATHAN THOMAS.

5 CHAIRMAN THOMAS: YES.

6 MS. BONNEVILLE: ART TORRES.

7 MR. TORRES: AYE.

8 MS. BONNEVILLE: MOTION CARRIES.

9 MR. SHEEHY: THANK YOU.

10 SO THE NEXT ITEM ON THE AGENDA IS THE  
11 INCEPTION AWARD APPLICATIONS. SO DR. SAMBRANO WILL  
12 LEAD US THROUGH A LOOK AT THAT, AND THEN WE'LL TAKE  
13 MOTIONS ON THE APPLICATIONS.

14 DR. SAMBRANO: OKAY. THANK YOU, MR.  
15 CHAIRMAN. SO WE'RE PUTTING UP THE POWERPOINT  
16 PRESENTATION WHICH WAS DISTRIBUTED TO YOU AND POSTED  
17 AS WELL. AND I'M GOING TO JUST GO OVER WHAT THE  
18 GRANTS WORKING GROUP RECOMMENDATIONS FOR THE  
19 INCEPTION PROJECTS WERE. THIS WAS A MEETING OF THE  
20 GWG THAT HAPPENED ON APRIL 11TH AND 12TH.

21 SO I'M GOING TO START WITH A SLIDE THAT  
22 HAS THE LITTLE CHOO-CHOO TRAINS ON IT JUST TO GIVE  
23 YOU THE OVERVIEW. THERE IT IS. ALL RIGHT. WE  
24 HAVE -- WE SET UP OPPORTUNITIES THAT ARE GOING TO  
25 SUPPORT PROJECTS ALONG THE ENTIRE PATH FROM

BARRISTERS' REPORTING SERVICE

1 DISCOVERY TO CLINICAL. AND YOU'VE SEEN THIS KIND OF  
2 ILLUSTRATION BEFORE, BUT MOSTLY HERE TO POINT YOU TO  
3 WHERE INCEPTION IS.

4 SO THE TRANSITION FROM DISCOVERY TO  
5 TRANSLATION AND TRANSLATION TO CLINICAL, WE TRY TO  
6 MAKE IT AS EASY AS POSSIBLE BY HAVING THE OUTCOME OF  
7 EACH BE THE ENTRY CRITERIA FOR THE NEXT.

8 INCEPTION IS REALLY AT THE VERY START AT  
9 THE BEGINNING OF DISCOVERY; AND THE WHOLE IDEA OF  
10 THIS INCEPTION PROGRAM, TO GO TO THE NEXT SLIDE, IS  
11 TO PROVIDE SEED FUNDING FOR GREAT IDEAS THAT EMBARK  
12 ON THE PATH, IF FUNDED, ALONG THIS JOURNEY AND THAT  
13 ULTIMATELY MAY IMPACT THE FIELD OF HUMAN STEM CELL  
14 RESEARCH.

15 ON THE NEXT SLIDE YOU WILL SEE THAT THE  
16 EMPHASIS THAT WE HAD AND THE INSTRUCTIONS TO THE  
17 GRANTS WORKING GROUP PANEL FOCUS THEM ON IDENTIFYING  
18 FOR US WHAT THEY BELIEVE TO BE GREAT NEW IDEAS WITH  
19 A POTENTIAL TO ULTIMATELY RESULT IN A TRANSLATABLE  
20 HUMAN STEM/PROGENITOR CELL-BASED PRODUCT OR  
21 TECHNOLOGY, SOMETHING THAT IF WE GIVE IT ENOUGH SEED  
22 FUNDING AND BASICALLY HOP ON THE TRAIN AND  
23 ULTIMATELY GET TO PATIENTS IN SOME WAY.

24 WE EMPHASIZE THE FACT THAT A SOUND  
25 SCIENTIFIC RATIONALE IS IMPORTANT, MEANING IT HAS TO



BARRISTERS' REPORTING SERVICE

1 MAKE SENSE. ON THE OTHER HAND, PRELIMINARY DATA IS  
2 NOT REQUIRED OR EXPECTED, AND THAT'S IMPORTANT  
3 BECAUSE THIS IS A SEED PROGRAM WE'RE TRYING TO START  
4 THEM OFF. IF THEY HAVE A GREAT IDEA, WE WANT TO  
5 SUPPORT THEM. IT IS A HIGH RISK, HIGH REWARD  
6 PROGRAM. AND WE'RE SIMPLY PROVIDING JUST 150 K.  
7 THERE'S NO -- THIS IS NOT A PER YEAR. IT'S JUST  
8 FLAT FOR AS LONG AS IT TAKES, USUALLY FROM SIX  
9 MONTHS TO TWO YEARS, TO TEST THE IDEA AND THEN  
10 GENERATE ENOUGH DATA TO THEN COMPETE FOR A LARGER,  
11 MORE SUBSTANTIAL FUNDING OPPORTUNITY THROUGH THE  
12 CIRM QUEST AWARD.

13 SO ON THE NEXT SLIDE I JUST WANT TO POINT  
14 OUT THAT WE USED A POSITIVE SELECTION PROCESS FOR  
15 THIS. WE STARTED OUT WITH A TOTAL OF 101 PROPOSALS.  
16 AND THROUGH THE POSITIVE SELECTION PROCESS, WE  
17 NARROWED IT DOWN TO 60 PROPOSALS.

18 AND THE WAY, JUST VERY BRIEFLY, THIS  
19 PROCESS WORKS IS THE GRANTS WORKING GROUP SCIENTISTS  
20 AND PATIENT ADVOCATE MEMBERS, SO 22 MEMBERS, DO AND  
21 HAVE ACCESS TO ALL 101 PROPOSALS, AND THEY SELECT  
22 THOSE IS THAT THEY FEEL ARE MOST LIKELY TO MEET THE  
23 OBJECTIVE OF THE INCEPTION PROGRAM AND SELECT THOSE  
24 FOR THEN FURTHER REVIEW. AND SELECTION BY ANY ONE  
25 MEMBER OF THE GRANTS WORKING GROUP IS SUFFICIENT TO

BARRISTERS' REPORTING SERVICE

1 MOVE THE APPLICATION FORWARD.

2 WHAT IT ALSO DOES, THOUGH, IS IT ALLOWS US  
3 TO NARROW THE NUMBER OF APPLICATIONS SO THAT THE  
4 GRANTS WORKING GROUP, WHEN THEY HAVE THEIR MEETING,  
5 HAVE A REASONABLE NUMBER TO GO THROUGH AND DISCUSS  
6 MORE FULLY AND THEN GO THROUGH THE SCORING PROCESS.

7 SO I WILL THEN NOW GO THROUGH THE  
8 RECOMMENDATIONS AND JUST SIMPLY REMIND YOU OF THE  
9 SCORING SYSTEM ON THE NEXT SLIDE. I USED TIERS  
10 HERE, BUT THIS IS WHAT WAS JUST RECENTLY APPROVED.  
11 A SCORE OF 85 TO 100 MEANS THAT IT HAS EXCEPTIONAL  
12 MERIT AND WARRANTS FUNDING. A SCORE OF 1 TO 84  
13 MEANS IT'S NOT RECOMMENDED FOR FUNDING.

14 AND SO ON THE NEXT SLIDE YOU WILL SEE THAT  
15 WHEN THE GRANTS WORKING GROUP PANEL WENT THROUGH ALL  
16 THE APPLICATIONS, 18 FELL INTO THE RECOMMENDED FOR  
17 FUNDING CATEGORY AND 42 DID NOT. SO THAT GAVE US AN  
18 APPROXIMATE FUNDING OF ABOUT 4 MILLION FOR ALL OF  
19 THESE.

20 AND THEN ON THE NEXT SLIDE, I JUST WANT TO  
21 NOTE THIS IS SOMETHING THAT WAS PRESENTED TO YOU, AT  
22 THE CONCLUSION OF EACH GRANTS WORKING GROUP REVIEW,  
23 WHICH WE HAVE ALL MEMBERS AND PATIENT ADVOCATE  
24 MEMBERS OF THE GRANTS WORKING GROUP VOTE ON THESE  
25 TWO STATEMENTS. ONE, THAT THE REVIEW WAS

BARRISTERS' REPORTING SERVICE

1 SCIENTIFICALLY VIGOROUS AND ENOUGH TIME WAS GIVEN  
2 FOR ALL VIEWPOINTS TO BE HEARD, AND THE SCORES  
3 REFLECT THE RECOMMENDATION OF THE WORKING GROUP.  
4 THAT'S BY ALL MEMBERS. AND THEN THAT THE REVIEW WAS  
5 CARRIED OUT IN A FAIR MANNER AND WAS FREE FROM UNDUE  
6 BIAS. SO IN BOTH CASES THE VOTE WAS UNANIMOUS.

7 AND THE LAST SLIDE JUST AGAIN SHOWS 18  
8 PROPOSALS THAT TOTAL UP TO ABOUT 4 MILLION ALLOCATED  
9 BASED ON THE CONCEPT OF 5 MILLION FOR THIS PROGRAM,  
10 SO WELL UNDER THE AMOUNT THAT WAS ALLOCATED FOR THIS  
11 PROGRAM.

12 THAT'S IT FOR THE PRESENTATION. THE LIST  
13 OF APPLICATIONS WHICH WAS ALSO PROVIDED TO YOU IN  
14 YOUR MATERIALS.

15 MR. SHEEHY: THANK YOU, DR. SAMBRANO.  
16 SENATOR TORRES.

17 MR. TORRES: YES. THANK YOU, MR.  
18 CHAIRMAN. I WOULD LIKE TO MOVE ITEM NO. 0643, WHICH  
19 RECEIVED A SCORE OF 84, TO BE MOVED INTO THE FUNDING  
20 AREA. I REALLY DO BELIEVE THAT WE NEED TO DO AS  
21 MUCH AS WE CAN IN CARDIAC AND HEART DISEASE. AND  
22 THIS PARTICULAR PROPOSAL SEEKS TO MOVE IN THAT  
23 DIRECTION. 25 PERCENT OF CALIFORNIANS DIE FROM  
24 HEART DISEASE EVERY YEAR IN THIS STATE, 6 PERCENT  
25 FROM STROKES. CLEARLY THE HEART DISEASE IS A MAJOR

BARRISTERS' REPORTING SERVICE

1 FACTOR FOR CALIFORNIA, AND I THINK THAT PARTICULAR  
2 PROJECT, ALTHOUGH IT'S NOT THAT EXPENSIVE, PROVIDES  
3 US AN OPPORTUNITY TO MOVE INTO AN AREA THAT MIGHT  
4 PROVIDE SOME HELP.

5 MR. SHEEHY: DO WE HAVE A SECOND?

6 DR. QUINT: SECOND. ROBERT QUINT.

7 MR. SHEEHY: OKAY. SO DO WE HAVE  
8 DISCUSSION? IS THERE A WISH FOR ANY INFORMATION  
9 FROM ANY TEAM MEMBERS, OR SHOULD WE JUST HAVE A  
10 DISCUSSION AMONGST OURSELVES?

11 DR. JUELGAARD: I'M SORRY. DID WE HAVE  
12 A -- WAS THERE A SECOND, JEFF? I DIDN'T HEAR.

13 MR. SHEEHY: YES. DR. QUINT.

14 DR. DULIEGE: I'M VERY COMFORTABLE WITH  
15 THE CONCEPT AND THE PROPOSAL. I DON'T HAVE ANY  
16 QUESTIONS. THAT IS ANNE-MARIE.

17 MR. SHEEHY: OKAY. WELL, UNLESS SOMEONE  
18 HAS A COMMENT, I SUPPOSE WE SHOULD JUST GO STRAIGHT  
19 TO OUR VOTE.

20 DR. JUELGAARD: CAN I MAKE A COMMENT? SO  
21 LET ME ASK OUR STAFF. WE ALREADY HAVE CLINICAL  
22 PROJECTS GOING ON IN THIS AREA. AND IF I REMEMBER  
23 RIGHT, THERE ARE AT LEAST THREE OF CARDIOMYOPATHY IF  
24 I REMEMBER RIGHT. IS THAT CORRECT?

25 DR. SAMBRANO: SO WE DO HAVE CLINICAL

BARRISTERS' REPORTING SERVICE

1 PROGRAMS THAT WOULD RELATE TO THIS APPLICATION; IN  
2 OTHER WORDS, THE STUDIES THAT ARE PROPOSED WOULD  
3 INFORM ON CLINICAL GRANTS THAT WE HAVE.

4 DR. JUELSGAARD: NO, THAT WASN'T MY  
5 QUESTION. MY QUESTION IS HOW MANY SEPARATE CLINICAL  
6 STUDIES ARE WE FUNDING RIGHT NOW IN THE AREA OF  
7 CARDIOMYOPATHY?

8 DR. MILLS: CLINICAL STAGE?

9 DR. JUELSGAARD: YEAH. BECAUSE I KNOW  
10 THERE'S AT LEAST ONE AT USC WITH DR. MARBAN, RIGHT?  
11 BUT THERE ARE A COUPLE OF OTHERS I BELIEVE AS WELL.

12 MR. SHEEHY: YEAH. WE HAVE TWO THAT I'M  
13 AWARE OF, TWO CLINICAL TRIALS.

14 DR. MILLS: DID YOU HEAR THAT, STEVE?

15 DR. JUELSGAARD: YEAH. SO THE NUMBER IS  
16 TWO AND NOT THREE.

17 DR. MILLS: IN CLINIC. IN THE CLINIC.

18 DR. JUELSGAARD: RIGHT. SO FAIRLY FAR  
19 ALONG. SO THE QUESTION IN MY MIND IS THIS MONEY  
20 WELL SPENT GIVEN WHAT WE ALREADY HAVE GOING, WHICH  
21 ARE CLINICAL TRIALS THAT ARE MUCH FURTHER AHEAD OF  
22 WHERE THIS PARTICULAR PROJECT IS. WHAT'S DIFFERENT  
23 ABOUT THIS PROJECT THAT MIGHT MAKE IT MORE  
24 OUTSTANDING THAN WHAT WE'VE ALREADY GOT GOING?

25 MR. TORRES: I THINK WE HAVE SOMEONE AT

BARRISTERS' REPORTING SERVICE

1 UCLA WHO MIGHT BE ABLE TO ANSWER THAT QUESTION.

2 DR. CAMBIER: HI. MY NAME IS LINDA  
3 CAMBIER. AND WHAT THIS PROJECT, I THINK WHAT IS  
4 NEW, SO THIS PROBABLY HAS (UNINTELLIGIBLE). AND  
5 HERE WE ARE TALKING ABOUT EXOSOME AND ABOUT HOW TO  
6 MODULATE THE CONTENT OF EXOSOME, WHICH CAN GIVE DATA  
7 CORRECTLY. THAT'S WHAT IT SAYS.

8 DR. JUELSGAARD: OKAY. SO IT'S A WHOLLY  
9 SEPARATE APPROACH TO DEVELOPING NEW CARDIAC CELLS?

10 DR. CAMBIER: YES. YES. NOW, WE ARE NOT  
11 TALKING ABOUT THE (UNINTELLIGIBLE) ANYMORE. WE ARE  
12 TALKING ABOUT EXOSOME AND HOW TO MAKE THEM MORE  
13 POTENT.

14 DR. JUELSGAARD: OKAY. THANK YOU.

15 MR. SHEEHY: SO IT HAS NO RELATIONSHIP TO  
16 THE CLINICAL TRIALS WE'RE DOING NOW, RIGHT?

17 DR. CAMBIER: IT'S ANOTHER ASPECT.

18 MR. SHEEHY: OKAY. SO DO WE HAVE  
19 ADDITIONAL BOARD DISCUSSION OR QUESTIONS? DO WE  
20 HAVE ADDITIONAL PUBLIC COMMENT ANYWHERE? SO WILL  
21 YOU CALL THE ROLL THEN PLEASE.

22 MS. BONNEVILLE: ANNE-MARIE DULIEGE.

23 DR. DULIEGE: YES.

24 MS. BONNEVILLE: DAVID HIGGINS.

25 DR. HIGGINS: YES.

BARRISTERS' REPORTING SERVICE

1 DR. STEWARD: I'M SORRY. THIS IS OS. CAN  
2 I JUST ASK WHAT WE'RE VOTING ON HERE? ARE WE VOTING  
3 ON SENATOR TORRES' MOTION ONLY OR ON THE WHOLE  
4 PACKAGE?

5 MR. TORRES: JUST MY MOTION ONLY TO MOVE  
6 THIS ITEM TO THE FUNDING CATEGORY.

7 DR. STEWARD: THANK YOU.

8 MS. BONNEVILLE: STEVE JUELSGAARD.

9 DR. JUELSGAARD: YES.

10 MS. BONNEVILLE: KATHY LAPORTE.

11 MS. LAPORTE: YES.

12 MS. BONNEVILLE: ADRIANA PADILLA.

13 DR. PADILLA: YES.

14 MS. BONNEVILLE: FRANCISCO PRIETO.

15 DR. PRIETO: AYE.

16 MS. BONNEVILLE: ROBERT QUINT.

17 DR. QUINT: YES.

18 MS. BONNEVILLE: AL ROWLETT.

19 MR. ROWLETT: YES.

20 MS. BONNEVILLE: JEFF SHEEHY.

21 MR. SHEEHY: NO.

22 MS. BONNEVILLE: OS STEWARD.

23 DR. STEWARD: NO.

24 MS. BONNEVILLE: JONATHAN THOMAS.

25 CHAIRMAN THOMAS: YES.

BARRISTERS' REPORTING SERVICE

1 MS. BONNEVILLE: ART TORRES.

2 MR. TORRES: AYE.

3 MS. BONNEVILLE: MOTION CARRIES.

4 MR. SHEEHY: THANK YOU. SO AT THIS TIME I  
5 WILL -- ARE THERE ANY OTHER MOTIONS TO MOVE THE  
6 PROJECT FROM THE NOT RECOMMENDED FOR FUNDING  
7 CATEGORY INTO THE RECOMMENDED FOR FUNDING CATEGORY?  
8 HEARING NONE, ARE THERE ANY MOTIONS TO MOVE ANYTHING  
9 FROM THE RECOMMENDED FOR FUNDING CATEGORY INTO THE  
10 NOT RECOMMENDED FOR FUNDING CATEGORY? HEARING NONE,  
11 IS THERE AN OMNIBUS MOTION? WHICH FORM SHOULD IT  
12 TAKE?

13 MR. HARRISON: THE MOTION SHOULD BE TO  
14 APPROVE THE APPLICATIONS THAT ARE IN THE RECOMMENDED  
15 FOR FUNDING CATEGORY AND NOT TO APPROVE THOSE THAT  
16 ARE IN THE NOT RECOMMENDED FOR FUNDING CATEGORY.  
17 AND A REMINDER FOR THOSE MEMBERS WHO HAVE A CONFLICT  
18 WITH RESPECT TO A PARTICULAR APPLICATION TO VOTE YES  
19 OR NO EXCEPT FOR THOSE APPLICATIONS FOR WHICH YOU  
20 HAVE A CONFLICT.

21 MR. SHEEHY: AND THE MOTION SHOULD COME  
22 FROM A MEMBER WITHOUT A CONFLICT. SO DO I HAVE A  
23 MOTION?

24 MR. TORRES: TORRES. I MOVE.

25 MR. SHEEHY: DO I HAVE A SECOND?



BARRISTERS' REPORTING SERVICE

1 MS. LAPORTE: KATHY. YES, SECOND.  
2 MR. SHEEHY: THANK YOU. SO ANY PUBLIC  
3 COMMENT? MARIA, COULD YOU CALL THE ROLL PLEASE.  
4 MS. BONNEVILLE: ANNE-MARIE DULIEGE.  
5 DR. DULIEGE: AYE.  
6 MS. BONNEVILLE: DAVID HIGGINS.  
7 MR. HIGGINS: YES.  
8 MS. BONNEVILLE: STEVE JUELSGAARD.  
9 DR. JUELSGAARD: YES.  
10 MS. BONNEVILLE: KATHY LAPORTE.  
11 MS. LAPORTE: YES.  
12 MS. BONNEVILLE: ADRIANA PADILLA.  
13 DR. PADILLA: YES.  
14 MS. BONNEVILLE: FRANCISCO PRIETO.  
15 DR. PRIETO: AYE.  
16 MS. BONNEVILLE: ROBERT QUINT.  
17 DR. QUINT: YES.  
18 MS. BONNEVILLE: AL ROWLETT.  
19 MR. ROWLETT: YES.  
20 MS. BONNEVILLE: JEFF SHEEHY.  
21 MR. SHEEHY: YES.  
22 MS. BONNEVILLE: OS STEWARD.  
23 DR. STEWARD: YES EXCEPT FOR THOSE WITH  
24 WHICH I HAVE A CONFLICT.  
25 MR. SHEEHY: OH, YEAH. FOR ME TOO. YES,

BARRISTERS' REPORTING SERVICE

1 EXCEPT FOR THOSE WITH WHICH I HAVE A CONFLICT.

2 MS. BONNEVILLE: JONATHAN THOMAS.

3 CHAIRMAN THOMAS: YES.

4 MS. BONNEVILLE: ART TORRES.

5 MR. TORRES: AYE.

6 MS. BONNEVILLE: MOTION CARRIES.

7 MR. SHEEHY: GREAT. THANK YOU. THAT  
8 CONCLUDES THE BUSINESS OF THE APPLICATION REVIEW  
9 SUBCOMMITTEE.

10 MR. TORRES: THANK YOU, MR. CHAIRMAN.

11 CHAIRMAN THOMAS: THANK YOU, MR. SHEEHY.

12 WE HAVE NO CLOSED SESSION ITEM. SO WE MOVE NOW --  
13 ARE THERE ANY COMMENTS BY MEMBERS OF THE PUBLIC ON  
14 ANYTHING THEY WOULD WISH TO SPEAK ABOUT? HEARING  
15 NONE, THAT CONCLUDES --

16 MS. CHEUNG: I JUST WANT TO REMIND THE  
17 BOARD MEMBERS OUR NEXT MEETING IS IN JUNE, AND  
18 THAT'S AN IN-PERSON MEETING, AND I'LL BE SENDING YOU  
19 AN E-MAIL SHORTLY AFTER THIS MEETING.

20 CHAIRMAN THOMAS: THANK YOU, AMY. AND  
21 THAT MEETING IS AT THE CLAREMONT. SO WE WILL SEE  
22 EVERYBODY THERE HOPEFULLY ON JUNE 15TH. SO THAT  
23 CONCLUDES OUR AGENDA TODAY. THANK YOU, EVERYBODY,  
24 VERY MUCH FOR YOUR PARTICIPATION AND WE WILL SEE YOU  
25 IN JUNE.

BARRISTERS' REPORTING SERVICE

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MS. BONNEVILLE: THANK YOU, EVERYONE.  
(THE MEETING WAS THEN CONCLUDED.)

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 TELEPHONIC PROCEEDINGS BEFORE THE INDEPENDENT CITIZEN'S OVERSIGHT COMMITTEE AND THE APPLICATION REVIEW SUBCOMMITTEE OF THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE IN THE MATTER OF ITS REGULAR MEETING HELD ON MAY 19, 2016, 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.



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