

BEFORE THE  
SCIENCE 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 TELEPHONIC MEETING

LOCATION: AS INDICATED ON THE AGENDA

DATE: MONDAY, OCTOBER 5, 2015  
4 P.M.

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

BRS FILE NO.: 97987

BARRISTERS' REPORTING SERVICE

I N D E X

ITEM DESCRIPTION	PAGE NO.
1. CALL TO ORDER	3
2. ROLL CALL	3
3. CONSIDERATION OF ADOPTION OF THE GRANTS ADMINISTRATION POLICY FOR CLINICAL STAGE PROGRAMS, INCLUDING LOAN ELECTION POLICY.	4

BARRISTERS' REPORTING SERVICE

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25

OCTOBER 5, 2015; 4 P.M.

CHAIRMAN SHEEHY: I THINK THE FIRST ORDER OF BUSINESS IS TO CALL THE ROLL, PLEASE.

MS. BONNEVILLE: SURE. JEFF SHEEHY.

CHAIRMAN SHEEHY: HERE.

MS. BONNEVILLE: OS STEWARD.

DR. STEWARD: HERE.

MS. BONNEVILLE: MICHAEL FRIEDMAN. DAVID HIGGINS.

DR. HIGGINS: HERE.

MS. BONNEVILLE: BERT LUBIN. SHLOMO MELMED. ART TORRES.

MR. TORRES: HERE.

MS. BONNEVILLE: JONATHAN THOMAS.

CHAIRMAN THOMAS: HERE.

MS. BONNEVILLE: KRISTINA VUORI.

DR. VUORI: HERE.

MS. BONNEVILLE: THANK YOU. JEFF, WE HAVE A QUORUM.

CHAIRMAN SHEEHY: AND WE HAVE STEVE JUELSGAARD, CHAIR OF THE IP AND INDUSTRY SUBCOMMITTEE, ON THE PHONE AS WELL. YES?

DR. JUELSGAARD: YES, I'M HERE, JEFF.

CHAIRMAN SHEEHY: THANKS. SO I THINK WE

BARRISTERS' REPORTING SERVICE

1 HAVE ONE ITEM OF BUSINESS TODAY, CONSIDERATION OF  
2 ADOPTION OF THE GRANTS ADMINISTRATION POLICY FOR  
3 CLINICAL STAGE PROGRAMS, INCLUDING LOAN ELECTION  
4 POLICY. I THINK MR. JUELSGAARD IS ON TO TALK ABOUT  
5 THE SECOND PART OF THIS, THE LOAN ELECTION POLICY,  
6 WHICH HAS BEEN PULLED TOGETHER.

7 DO WE HAVE A PRESENTATION FROM THE TEAM ON  
8 THIS?

9 MR. HARRISON: YES. GABE THOMPSON, JEFF,  
10 WILL BE PRESENTING ON THE AMENDMENTS TO THE CLINICAL  
11 GAP, AND THEN I WILL SPEAK TO THE LOAN ELECTION  
12 POLICY. THIS IS JAMES HARRISON.

13 CHAIRMAN SHEEHY: GREAT. MAYBE WE SHOULD  
14 BREAK IT UP INTO TWO PARTS. AND I'LL SEE IF THERE  
15 ARE ANY QUESTIONS FROM COMMITTEE MEMBERS AFTER THE  
16 GAP, AND THEN WE'LL DO ANOTHER ROUND OF QUESTIONS  
17 AFTER THE LOAN ELECTION POLICY IF THAT'S OKAY WITH  
18 EVERYONE.

19 NOW, DO WE HAVE PUBLIC AT ANY OF THE  
20 SITES?

21 CHAIRMAN THOMAS: NOBODY HERE IN SAN  
22 FRANCISCO, JEFF.

23 CHAIRMAN SHEEHY: THANKS, J.T. OKAY.  
24 GABE, IF YOU WANT TO GO AHEAD, THAT WOULD BE GREAT.

25 MR. THOMPSON: THIS IS GABE THOMPSON,

BARRISTERS' REPORTING SERVICE

1 DIRECTOR OF GRANTS MANAGEMENT. WE'VE GOT THE  
2 MEMORANDUM THAT WE SENT AROUND, SO WE'LL GO THROUGH  
3 THIS AND SKIP OVER THE LOAN ELECTION POLICY FOR THE  
4 END. BUT BASICALLY WHAT WE HAVE TODAY IS THE FINAL  
5 EDITS TO THE GRANTS ADMINISTRATION POLICY FOR  
6 CLINICAL STAGE PROGRAMS.

7 AS YOU RECALL, WE USED OUR AUTHORITY TO  
8 INTRODUCE INTERIM REGULATIONS TO SUPPORT THE NEW  
9 CLINICAL STAGE PROGRAMS EARLIER THIS YEAR. AND THAT  
10 INTERIM AUTHORITY LASTS THROUGH DECEMBER. SO NOW  
11 WE'RE COMING WITH FINAL EDITS TO THE POLICY THAT  
12 WILL THEN GO TO THE OFFICE OF ADMINISTRATIVE LAW FOR  
13 FINAL ADOPTION.

14 SO WE HAVE MADE ABOUT FIVE KIND OF  
15 CLARIFYING STATEMENTS HERE TO HELP MAKE SURE THAT  
16 WE'RE CLARIFYING OUR REPORTING REQUIREMENTS,  
17 OPERATIONAL MILESTONES, THEN A SECTION ON PRIOR  
18 APPROVAL REQUESTS. SO I'M GOING TO GO THROUGH EACH  
19 ONE OF THESE, AND FEEL FREE TO STOP ME AT ANY TIME,  
20 BUT MAINLY TECHNICAL CLARIFICATIONS HERE.

21 SO FIRST OFF, WE'VE CLARIFIED THE CONFLICT  
22 OF INTEREST MANAGEMENT PLAN. THE GAP HAS ALWAYS  
23 REQUIRED OUR AWARDEES TO MAINTAIN A CONFLICT OF  
24 INTEREST PLAN TO JUST ESTABLISH SAFEGUARDS TO  
25 PREVENT CIRM-FUNDED INDIVIDUALS OR ORGANIZATIONS

BARRISTERS' REPORTING SERVICE

1 FROM USING THEIR POSITION TO INFLUENCE ACTIVITIES IN  
2 WHICH THEY ARE KNOWN TO HAVE A FINANCIAL INTEREST.

3 SO THE PROPOSED AMENDMENT HERE IS TO  
4 ACTUALLY REQUIRE THE AWARDEES TO DISCLOSE WHEN A  
5 FINANCIAL INTEREST FOR A PERSON OR ORGANIZATION  
6 WHO'S BEEN CIRM-FUNDED, WHEN THEY TAKE SUCH ACTION  
7 AND WHEN A CONFLICT OF INTEREST IS DISCOVERED, AND  
8 THEN TO ALSO PROVIDE CIRM WITH THE CONFLICT OF  
9 INTEREST MANAGEMENT PLAN AS SOON AS POSSIBLE. SO  
10 CLARIFYING THAT.

11 NEXT ONE ON OPERATIONAL MILESTONES, WE'RE  
12 CLARIFYING THAT, AS YOU MIGHT RECALL, OPERATIONAL  
13 MILESTONES ARE DEFINED AS OBJECTIVE MEASURES OF  
14 SUCCESS FOR A CLINICAL STAGE PROJECT, THINGS LIKE  
15 ENROLLMENT, 50 PERCENT OF ENROLLMENT IN A TRIAL,  
16 SUBMITTING THE FINAL CLINICAL STUDY REPORT FOR A  
17 TRIAL. WHAT WE'RE CLARIFYING HERE IS THAT FOR EVERY  
18 CLINICAL STAGE PROJECT THAT WE FUND, WE'RE GOING TO  
19 ESTABLISH A FINAL MILESTONE THAT DEFINES THE END  
20 DATE FOR THE AWARD. GIVEN THAT CLINICAL TRIALS CAN  
21 BE FAIRLY LENGTHY, WE WANT TO MAKE SURE IT'S CLEAR  
22 THAT WE ESTABLISH A FINAL OPERATIONAL MILESTONE THAT  
23 DEFINES THE END DATE BY WHICH THEY CAN SPEND CIRM  
24 FUNDING.

25 NEXT UP IS WE HAVE A NEW SECTION REGARDING

BARRISTERS' REPORTING SERVICE

1 USE OF A CIRM LOGO. SO WE'VE INDICATED HERE THAT  
2 WHEN CIRM IS DIRECTLY FUNDING A CLINICAL TRIAL, THE  
3 SPONSOR CAN USE CIRM'S LOGO; BUT THE SPONSOR OF A  
4 TRIAL THAT'S NOT FUNDED BY CIRM CANNOT USE CIRM'S  
5 LOGO. AND THIS CAME ABOUT MAINLY VIA THE CIRM ALPHA  
6 STEM CELL CLINICS WHO ARE ABLE TO USE CIRM'S LOGO TO  
7 SHOW CONNECTION TO THE ALPHA STEM CELL CLINIC, BUT  
8 THEY CAN'T USE THAT LOGO TO SHOW CIRM'S ENDORSEMENT  
9 OF A TRIAL THAT MIGHT BE RUNNING THROUGH THE ALPHA  
10 STEM CELLS CLINIC, BUT IS NOT DIRECTLY FUNDED BY  
11 CIRM.

12 NEXT UP IS ALLOWABLE FACILITIES COSTS. WE  
13 HAVE SOME CLARIFYING LANGUAGE THAT BASICALLY STATES  
14 THAT CIRM WILL ACCEPT PROVISIONALLY APPROVED  
15 FACILITIES RATES AT THE TIME AN APPLICANT SUBMITS A  
16 BUDGET TO US. OFTENTIMES AN APPLICANT IS IN  
17 NEGOTIATIONS WITH THE FEDERAL GOVERNMENT REGARDING  
18 THEIR FINAL FACILITIES RATES AND ARE ALLOWED TO USE  
19 PROVISIONALLY APPROVED RATES. WHAT THIS SAYS IS  
20 THEY CAN GO AHEAD AND USE THOSE PROVISIONALLY  
21 APPROVED RATES AT THE TIME OF APPLICATION; AND ONCE  
22 THEIR FEDERALLY NEGOTIATED RATES ARE IN EFFECT, WE  
23 WILL THEN GO BACK AND RECONCILE THE AWARD TO ENSURE  
24 WE'RE NEVER PAYING MORE THAN THE FEDERALLY APPROVED  
25 FACILITIES RATES.

BARRISTERS' REPORTING SERVICE

1 AND THEN NEXT PART IS PRIOR APPROVAL  
2 REQUIREMENTS, AND SPECIFICALLY A CHANGE IN RESEARCH  
3 PLAN. THE PRIOR APPROVAL REQUIREMENTS ARE SCENARIOS  
4 IN WHICH AN AWARDEE IS REQUIRED TO REQUEST CIRM'S  
5 APPROVAL TO TAKE AN ACTION ON AN AWARD. AND ONE  
6 SUCH REQUEST WOULD BE A CHANGE OF RESEARCH PLAN.  
7 WE'VE NOW ADDED SOME ADDITIONAL SCENARIOS THAT WOULD  
8 CONSTITUTE A CHANGE OF RESEARCH PLAN AND, HENCE,  
9 WOULD REQUIRE CIRM'S PRIOR APPROVAL BEFORE THEY TAKE  
10 ACTION. AND THIS IS NOW INCLUDING A CHANGE IN THE  
11 PATIENT ENROLLMENT CRITERIA. SO THINGS LIKE PATIENT  
12 INCLUSION AND EXCLUSION CRITERIA FOR A TRIAL, A  
13 CHANGE IN THE AWARD'S TARGETED DISEASE INDICATION.  
14 SO IF THEY ARE GOING FROM ONE DISEASE INDICATION TO  
15 ANOTHER, THEY SHOULD RECEIVE CIRM'S PRIOR APPROVAL.

16 CHAIRMAN THOMAS: CAN I ASK A QUESTION ON  
17 THAT? HOW COULD THAT POSSIBLY ONLY REQUIRE AN  
18 APPROVAL? IF YOU'RE CHANGING THE DISEASE YOU'RE  
19 TALKING ABOUT, THAT WOULD SEEM TO ME TO  
20 FUNDAMENTALLY CHANGE THE WHOLE PROJECT. WHY ISN'T  
21 THAT SOMETHING THAT WOULD REQUIRE REAPPLICATION?

22 MR. THOMPSON: RIGHT. SO I THINK THERE  
23 MIGHT BE CASES WHERE A CHANGE IN DISEASE INDICATION  
24 MIGHT NOT TOTALLY CHANGE THE AWARDED PROJECT. SO  
25 THERE MIGHT BE A LOT OF SIMILAR ACTIVITIES THAT

BARRISTERS' REPORTING SERVICE

1 WOULD BE CONDUCTED, AND IT'S A PRETTY EASY CHANGE OF  
2 INDICATION. BUT AS WE'RE ACTUALLY SPELLING OUT  
3 HERE, THIS JUST STARTS THE PROCESS BY WHICH CIRM  
4 THEN CAN LOOK AT THAT REQUEST AND DETERMINE WHETHER  
5 WE CAN ACTUALLY MAKE A CHANGE.

6 DR. MILLS: SOME CLEAR EXAMPLES ARE THINGS  
7 LIKE IF YOU GO FROM -- WE HAVE A COUPLE OF CLINICAL  
8 PROGRAMS RIGHT NOW RUNNING A SOLID TUMOR PROGRAM.  
9 BECAUSE A SPECIFIC SOLID TUMOR HASN'T BEEN DEFINED,  
10 WHERE IT TURNS OUT THAT PANCREATIC CANCER IS A SOLID  
11 TUMOR OF INTEREST, THAT WOULD BE A CHANGE OF  
12 INDICATION FROM SOLID TUMORS TO PANCREATIC CANCER.  
13 BONE FRACTURES TO VERTEBRAL COMPRESSION FRACTURES IN  
14 A PARTICULAR PERSON VERSUS AVN OR SOMETHING LIKE  
15 THAT. I THINK THERE'S PLENTY OF TIME WHERE THE  
16 INDICATION CAN BE CHANGED OF RECORD AND HAVE IT BE  
17 NOT SOMETHING THAT WE WOULD -- SOMETHING WE WOULD  
18 ENCOURAGE AND EVIDENCE OF PROGRESS. WE'RE NOT  
19 TALKING ABOUT WE'RE GOING AFTER IND'S WITH THIS CELL  
20 AND NOW ALL OF A SUDDEN WE'RE GOING AFTER DILATED  
21 CARDIAC MYOPATHY.

22 CHAIRMAN THOMAS: IS THERE ANY QUALIFYING  
23 LANGUAGE WE NEED TO PUT IN THAT MEMORIALIZES THAT?  
24 BECAUSE JUST READING THAT CLAUSE AS IT IS IS AWFULLY  
25 BROAD.

BARRISTERS' REPORTING SERVICE

1 MR. THOMPSON: RIGHT. WHAT WE ACTUALLY  
2 CLARIFIED IN THIS LANGUAGE, WHICH IS NEW LANGUAGE  
3 HERE, IS THAT WE ACTUALLY SAY THAT SOME PROPOSED  
4 CHANGES TO THE RESEARCH PLAN GO BEYOND CIRM'S  
5 AUTHORITY TO APPROVE GIVEN WHAT WAS ORIGINALLY  
6 RECOMMENDED BY THE GWG AND THE BOARD. AND THEN  
7 UNDER THOSE CIRCUMSTANCES, THE AWARDEES WILL HAVE TO  
8 REAPPLY TO CIRM AS A NEW PROJECT. AND WE GAVE AN  
9 EXAMPLE OF SUCH THAT WOULD BE A RESUBMISSION OF AN  
10 IND WITH THE FDA. SO IF THE PROJECT HAD TO -- FOR  
11 WHATEVER REASONS RETOOLING REQUIRED A FULL NEW IND  
12 SUBMISSION, THEN WE WOULD TELL THEM TO -- WE WOULD  
13 WIND DOWN THE CURRENT AWARD AND TELL THEM TO REAPPLY  
14 WITH THEIR NEW PROJECT.

15 CHAIRMAN THOMAS: YOU COULDN'T PUT IN SOME  
16 NONMATERIALITY TYPE WORDS.

17 MR. HARRISON: THAT LANGUAGE IS IN THERE  
18 ACTUALLY. THE PRESIDENT HAS THE AUTHORITY TO MAKE A  
19 DETERMINATION WHETHER THE CHANGE IN SCOPE SO  
20 MATERIALLY AFFECTS THE PURPOSE OF THE PROJECT OR ITS  
21 GOALS, THEN IT ESSENTIALLY WOULD CONSTITUTE A NEW  
22 PROJECT REQUIRING SUBMISSION OF A NEW APPLICATION.  
23 IF THE PRESIDENT MAKES THE DETERMINATION, AS WITH  
24 THE EXAMPLE OF THE AUTHOR, IT DOESN'T FUNDAMENTALLY  
25 CHANGE THE APPLICATION, THEN IT'S WITHIN CIRM'S

BARRISTERS' REPORTING SERVICE

1 ADMINISTRATIVE AUTHORITY TO APPROVE THE CHANGE IN  
2 SCOPE.

3 CHAIRMAN THOMAS: THAT WORKS.

4 MR. THOMPSON: ARE THERE ANY OTHER  
5 QUESTIONS ABOUT THIS?

6 THE ONLY OTHER SCENARIO WE ADDED TO CHANGE  
7 OF RESEARCH PLAN WAS A CHANGE IN THE TRIAL'S  
8 SPONSORSHIP.

9 SO MOVING ON, UNDER RELINQUISHMENT OF AN  
10 AWARD, WE'RE ACTUALLY CLARIFYING THAT AN AWARDEE'S  
11 DECISION TO RELINQUISH THE AWARD DOES NOT EXTINGUISH  
12 THEIR REQUIREMENTS UNDER THE INTELLECTUAL PROPERTY  
13 REGULATIONS. SO JUST A CLARIFYING STATEMENT THERE.

14 AND UNDER, THEN, FAILURE OF COMPLIANCE,  
15 WE'VE ADDED THAT IF CIRM TERMINATES AN AWARD, THAT  
16 THE AWARDEE MUST RETURN TO CIRM ALL UNEXPENDED FUNDS  
17 WITHIN 120 DAYS OF THE DATE OF TERMINATION. JUST  
18 CLEARING THAT LANGUAGE UP.

19 SO THOSE ARE ALL THE CHANGES WE'RE MAKING  
20 TO THE GRANT ADMINISTRATION POLICY MINUS THE LOAN  
21 ELECTION POLICY. SO THE LOAN ELECTION POLICY  
22 LANGUAGE WILL EXIST WITHIN THE GRANTS ADMINISTRATION  
23 POLICY, AND I'LL LET JAMES GO THROUGH THAT SECTION  
24 WHEN WE'RE READY.

25 CHAIRMAN SHEEHY: DO WE HAVE ANY QUESTIONS

BARRISTERS' REPORTING SERVICE

1 ON THE GAP FROM MEMBERS OF THE COMMITTEE? COMMENTS?

2 CHAIRMAN THOMAS: ONE MORE, JEFF. GOING  
3 BACK TO THAT SAME SECTION WE WERE TALKING ABOUT  
4 EARLIER, CHANGE IN RESEARCH PLAN, WHEN YOU SAY  
5 CHANGE IN SPONSOR, GIVE AN EXAMPLE OF A NONMATERIAL  
6 EXAMPLE OF THAT.

7 MR. THOMPSON: SO THERE COULD BE EITHER  
8 INVESTIGATOR-INITIATED SPONSORS OR AN ORGANIZATION  
9 COULD BE SPONSORING THE TRIAL. AND SO IN EITHER  
10 CASE, IF THE PROJECT DECIDED TO REASSIGN  
11 SPONSORSHIP, FOR INSTANCE, FROM AN ACADEMIC SPONSOR  
12 TO A COMPANY SPONSOR, SO THAT WOULD BE AN EXAMPLE OF  
13 SOMETHING THEY NEED PRIOR APPROVAL.

14 UNIDENTIFIED SPEAKER: BUT YOU'RE RUNNING  
15 A PATIENT TRIAL UNDER AN IND AND YOU GET A NEW PI, A  
16 DIFFERENT PERSON MIGHT HAVE TO HAVE THE IND TO  
17 CONTINUE THE TRIAL. I THINK THE COMPANY THING IS  
18 MORE OR LESS ACADEMIC.

19 CHAIRMAN THOMAS: OBVIOUSLY IF IT WAS A  
20 CHANGE THAT INVOLVED A VERY MATERIAL DIFFERENCE IN  
21 TEAM MEMBERS, FOR EXAMPLE, WHAT WOULD YOU DO IN THAT  
22 INSTANCE? THAT OBVIOUSLY IS ONE OF THE THINGS  
23 HEAVILY FOCUSED ON BY THE GRANTS WORKING GROUP.

24 MR. THOMPSON: RIGHT. ONE SECTION OF  
25 CHANGE OF RESEARCH PLAN THAT ACTUALLY CAPTURES, I

BARRISTERS' REPORTING SERVICE

1 THINK, SOME OF THAT IS WE SAY UNDER CHANGE OF  
2 RESEARCH PLAN, ANY SUBSTANTIAL CHANGE OF FUNDED  
3 ACTIVITIES TO A THIRD PARTY WOULD CONSTITUTE A  
4 CHANGE OF RESEARCH PLAN. SO IF THEY WERE MOVING  
5 ACTIVITIES FROM IN-HOUSE TO A CONTRACTOR, FOR  
6 INSTANCE, THAT WOULD CONSTITUTE A CHANGE.

7 DR. MILLS: THE LANGUAGE IS CATCH-ALL. WE  
8 DETERMINE IT'S A MATERIAL CHANGE. JUST BECAUSE IT  
9 SAYS SOMEWHERE ELSE DOESN'T MEAN WE CAN'T DETERMINE  
10 THE CHANGE IS MATERIAL.

11 MR. HARRISON: THESE ARE EXAMPLES, AND  
12 OBVIOUSLY, AS THE CONVERSATION HAS ILLUSTRATED,  
13 THERE ARE SOME EXAMPLES WHERE THE CHANGE MAY BE  
14 MATERIAL AND THERE ARE OTHER EXAMPLES WHERE IT MAY  
15 NOT BE, AND IT'S THE SAME CATEGORY. SO THE  
16 PRESIDENT UNDER THIS POLICY IS VESTED WITH THE  
17 DISCRETION TO MAKE THE CALL AS TO WHETHER THE CHANGE  
18 IS MATERIAL, THAT IT'S SOMETHING THAT SHOULD GO BACK  
19 THE BOARD, OR WHETHER IT'S SOMETHING CIRM CAN  
20 APPROVE INTERNALLY.

21 DR. MILLS: BUT ANYTHING THAT'S THAT  
22 MATERIAL, DOESN'T MATTER HOW IT'S CALLED OUT IN  
23 OTHER SPOTS.

24 CHAIRMAN THOMAS: OKAY. THANKS.

25 CHAIRMAN SHEEHY: ANY OTHER COMMENTS OR

BARRISTERS' REPORTING SERVICE

1 QUESTIONS?

2 MR. TORRES: COMMENT ON SECTION 6, PART G.

3 CHAIRMAN SHEEHY: I DIDN'T HEAR THAT  
4 MYSELF.

5 MR. TORRES: 6 G. 6 G, WOMEN AND MEMBERS  
6 OF MINORITY GROUPS MUST BE INCLUDED IN ALL CIRM-  
7 FUNDED CLINICAL RESEARCH, UNLESS A CLEAR AND  
8 COMPELLING RATIONALE...ESTABLISHES TO THE  
9 SATISFACTION...THAT INCLUSION IS INAPPROPRIATE. HOW  
10 ARE WE MONITORING THAT?

11 MR. THOMPSON: SO WE ACTUALLY JUST  
12 RELEASED IN JULY IN OUR GRANTS MANAGEMENT SYSTEM A  
13 WAY FOR TRIALS THAT ARE CURRENTLY ENROLLING TO  
14 REPORT ON THE GENDER AND ETHNICITY OF THE PATIENTS  
15 BEING ENROLLED. SO THEY DO THAT ON A QUARTERLY  
16 BASIS. SO WE'RE JUST STARTING TO CAPTURE THAT.

17 MR. TORRES: HOW ARE YOU MONITORING IT  
18 BECAUSE DIVERSITY IS GOING TO BE EXTREMELY IMPORTANT  
19 FOR THESE CLINICAL TRIALS GIVEN CALIFORNIA'S  
20 POPULATION. HOW ARE WE MEASURING THAT?

21 DR. MILLS: THIS IS THE REVIEW CRITERIA.  
22 SO THIS IS SOMETHING THAT IS IN THE DESIGN OF THE  
23 CLINICAL TRIAL (INAUDIBLE) THERE'S NOT A DISEASE  
24 THAT THERE'S NOT A CLEAR AND CONVINCING RATIONALE  
25 WHY A GROUP SHOULD BE EXCLUDED, BUT YET THEY ARE

BARRISTERS' REPORTING SERVICE

1 EXCLUDED. THAT WOULD BE ONE OF THE THINGS THAT  
2 WOULD FAIL THAT.

3 MR. TORRES: WHO ON OUR STAFF -- WILL THAT  
4 BE YOU MONITORING?

5 DR. MILLS: THE GWG LITERALLY WOULD REVIEW  
6 THAT.

7 MR. TORRES: OKAY. THANK YOU.

8 DR. MILLS: THIS IS ALSO VERY IMPORTANT TO  
9 FDA, VERY IMPORTANT TO A LOT OF PLACES. JUST LOOKED  
10 AT, THIS IS UNDER THE INCLUSION OF HUMAN SUBJECTS.  
11 THE REPRESENTATION ACROSS THE APPROPRIATE BORDER.

12 MR. TORRES: BUT IT'S AN ISSUE WE'RE GOING  
13 TO CONFRONT WITH THE STEM CELL BANK AS WELL.

14 CHAIRMAN SHEEHY: DO WE HAVE ADDITIONAL  
15 QUESTIONS OR COMMENTS? SO, JAMES, DO YOU WANT TO  
16 TAKE US INTO THE LOAN ELECTION POLICY.

17 MR. HARRISON: YES. JUST TO TAKE YOU  
18 BACK, EARLIER THIS YEAR IN MAY, THE BOARD APPROVED A  
19 POLICY FOR OUR CLINICAL AWARDS TO ALLOW FOR A  
20 RECIPIENT TO ELECT TO TREAT THEIR AWARD AS A LOAN  
21 RATHER THAN A GRANT. AND UNDER THE POLICY, THE  
22 AWARDEE WAS TO HAVE THE EARLIER OF SEVEN YEARS FROM  
23 THE DATE OF THE AWARD OR THE SUBMISSION OF AN  
24 APPLICATION FOR A MARKETING AUTHORIZATION TO THE  
25 FDA. AND THE BOARD DELEGATED TO THE IP AND INDUSTRY

BARRISTERS' REPORTING SERVICE

1 SUBCOMMITTEE THE AUTHORITY TO SET THE APPROPRIATE  
2 RATE OF RETURN.

3 THE CIRM TEAM BEGAN TO EXPLORE HOW TO SET  
4 A FAIR RATE OF RETURN AND QUICKLY CAME TO THE  
5 CONCLUSION THAT IT WAS VERY, VERY DIFFICULT IN LIGHT  
6 OF THE VARIABILITY COVERED BY THE POLICY BOTH IN  
7 TERMS OF THE THERAPEUTIC TYPE, WHETHER IT WAS CELL  
8 THERAPY OR SMALL MOLECULE OR ANTIBODY, THAT THE  
9 STAGE OF RESEARCH THAT WE WERE FUNDING AND THEN THE  
10 STAGE OF DEVELOPMENT AT WHICH THE ELECTION IS MADE.  
11 IN OTHER WORDS, IF SOMEONE ELECTED TO TREAT THEIR  
12 AWARD AS A LOAN BEFORE THE FIRST READOUT OF DATA IN  
13 A PHASE I TRIAL, OBVIOUSLY THAT AWARDEE WOULD BE  
14 ASSUMING SUBSTANTIALLY MORE RISK THAN ANOTHER  
15 AWARDEE WHO ELECTED TO TREAT ITS AWARD AS A LOAN  
16 JUST BEFORE SUBMISSION OF AN APPLICATION FOR  
17 MARKETING AUTHORIZATION TO THE FDA AFTER A  
18 SUCCESSFUL PHASE III CLINICAL TRIAL.

19 SO SETTING A SINGLE RATE OF RETURN THAT  
20 COVERED ALL THOSE VARIABLES PROVED TO BE IMPOSSIBLE.  
21 SO WE WENT BACK TO THE DRAWING BOARD AND DETERMINED  
22 THAT THE BEST APPROACH WOULD BE TO HAVE A VARIABLE  
23 RATE DETERMINED BY THE TYPE OF AWARD WE MADE, THE  
24 STAGE OF DEVELOPMENT AT WHICH THE ELECTION IS MADE,  
25 AND THE THERAPEUTIC CLASS, WHETHER THE THERAPEUTIC

BARRISTERS' REPORTING SERVICE

1 WAS A CELL THERAPY, WHICH IS INHERENTLY MORE RISKY,  
2 OR A SMALL MOLECULE. AND FROM THAT WHAT WE HAVE  
3 DONE IS DEVELOPED A CHART THAT SPECIFIES THE RATE OF  
4 RETURN DEPENDING UPON EACH OF THOSE VARIABLES.

5 SO, FOR EXAMPLE, IF WE WERE TO MAKE AN  
6 AWARD UNDER 15-01 FOR PRECLINICAL RESEARCH FOR A  
7 CELL THERAPY AND THE AWARDEE WAS TO ELECT  
8 IMMEDIATELY BEFORE THE FIRST READOUT OF DATA IN A  
9 PHASE I TRIAL TO TREAT ITS AWARD AS A LOAN, IT WOULD  
10 ONLY HAVE TO REPAY 60 PERCENT OF THE LOAN VALUE TO  
11 CIRM. AND THE REASON FOR THAT IS THAT AT THAT POINT  
12 IN TIME, THERE IS STILL AN INCREDIBLE AMOUNT OF RISK  
13 INVOLVED IN THE EVENTUAL COMMERCIALIZATION OF THE  
14 THERAPEUTIC AND YOU'VE GOT THE TIME VALUE OF MONEY.  
15 SO IF THEY REPAY CIRM EARLIER, WE GET A BENEFIT FROM  
16 THE NET PRESENT VALUE.

17 BY CONTRAST, IF YOU HAD AN AWARDEE TO WHOM  
18 WE HAD MADE AN AWARD UNDER 15-02 TO CONDUCT A PHASE  
19 II CLINICAL TRIAL INVOLVING A SMALL MOLECULE AND THE  
20 AWARDEE ELECTED TO TREAT ITS AWARD AS A LOAN WITHIN  
21 TEN DAYS AFTER SUBMISSION OF AN APPLICATION FOR  
22 MARKETING AUTHORIZATION TO THE FDA, THEN UNDER THOSE  
23 CIRCUMSTANCES, GIVEN BOTH THE PASSAGE OF TIME AND  
24 THE DERISKING OF THE PROJECT, THE AWARDEE WOULD HAVE  
25 TO PAY CIRM THE FULL PRINCIPAL OF THE LOAN PLUS

BARRISTERS' REPORTING SERVICE

1 INTEREST AT A RATE OF 30 PERCENT PLUS LIBOR. AND  
2 THOSE TWO SCENARIOS REALLY REFLECT THE SORT OF RANGE  
3 OF VARIABILITY UNDER THIS PROGRAM GIVEN THE FACT  
4 THAT IT APPLIES TO ALL AWARDS WE MAKE RANGING FROM  
5 AWARDS FOR PRECLINICAL DEVELOPMENT TO AN AWARD FOR A  
6 PHASE II OR PHASE III CLINICAL TRIAL.

7 THE TERMS, WE THINK NOW, ARE CLEARLY  
8 SPELLED OUT. WE'VE DEFINED WHAT CONSTITUTES THE  
9 ELECTION POINT, AND WE THINK THIS REFINEMENT  
10 PRESENTS AN OPPORTUNITY FOR US TO HAVE A MORE FINELY  
11 TUNED AND MORE FAIR RATE OF RETURN CONTINGENT ON  
12 THESE VARIABLES. SO WITH THAT, I'D BE HAPPY TO  
13 ANSWER ANY QUESTIONS, JEFF.

14 CHAIRMAN SHEEHY: ANY QUESTIONS FROM  
15 ANYONE?

16 I ACTUALLY HAVE A QUESTION. THE  
17 DEFINITION FOR CELL THERAPY, IS THAT COMPLETE? WHAT  
18 WAS THE THINKING ON THAT? IT SEEMS VERY SIMPLE AND  
19 FEW THINGS IN LIFE ARE THAT SIMPLE.

20 MR. HARRISON: OUR PRESIDENT ADMONISHES US  
21 CONSTANTLY TO LOOK FOR CLARITY. SO IN COMING UP  
22 WITH THIS DEFINITION, THAT'S PRECISELY WHAT WE WERE  
23 AIMING FOR. SO WE'VE DEFINED IT AS A THERAPY, THAT  
24 WHEN DELIVERED TO A PATIENT, HAS AT LEAST ONE  
25 COMPONENT THAT INCLUDES CELLS. AND WE'VE DEFINED

BARRISTERS' REPORTING SERVICE

1 EVERYTHING ELSE TO NOT BE CELL THERAPY, IN ESSENCE.

2 CHAIRMAN SHEEHY: SO JUST FOR MY OWN, SO  
3 IF IT'S SOMETHING THAT'S TARGETING A CERTAIN TYPE OF  
4 CELL, THAT WOULD NOT BE A CELL THERAPY, RIGHT? SO  
5 ACCORDING TO THIS DEFINITION, THERE HAS TO BE CELLS  
6 INVOLVED IN THE DELIVERY OF THE PRODUCT.

7 DR. MILLS: THAT'S CORRECT, JEFF. AND THE  
8 IDEA THERE IS THAT THE COMPLEXITY OF THE DRUG GOES  
9 UP SIGNIFICANTLY WHEN AT LEAST ONE COMPONENT OF THE  
10 THERAPY CONTAINS A CELL VERSUS A SMALL MOLECULE OR  
11 AN ANTIBODY THAT JUST TARGETS A CELL.

12 CHAIRMAN SHEEHY: THAT'S FINE. JUST  
13 WANTED TO BE CLEAR ON THAT.

14 ARE THERE OTHER QUESTIONS OR COMMENTS? DO  
15 WE HAVE A MOTION TO ADOPT?

16 MR. TORRES: SO MOVED.

17 CHAIRMAN SHEEHY: WHO WAS THE MOTION  
18 MAKER?

19 MR. TORRES: ART TORRES.

20 CHAIRMAN SHEEHY: MOTION MOVED BY SENATOR  
21 TORRES. DO WE HAVE A SECOND?

22 DR. HIGGINS: I'LL SECOND.

23 CHAIRMAN SHEEHY: SO DAVID HIGGINS IS THE  
24 SECOND. ANY ADDITIONAL BOARD COMMENT? NO PUBLIC  
25 COMMENT. MARIA, COULD YOU CALL THE ROLL.

BARRISTERS' REPORTING SERVICE

1 MS. BONNEVILLE: SURE. JEFF SHEEHY.  
2 CHAIRMAN SHEEHY: YES.  
3 MS. BONNEVILLE: OS STEWARD.  
4 DR. STEWARD: YES.  
5 MS. BONNEVILLE: MICHAEL FRIEDMAN. DAVID  
6 HIGGINS.  
7 DR. HIGGINS: YES.  
8 MS. BONNEVILLE: BERT LUBIN. SHLOMO  
9 MELMED. ART TORRES.  
10 MR. TORRES: AYE.  
11 MS. BONNEVILLE: JONATHAN THOMAS.  
12 CHAIRMAN THOMAS: YES.  
13 MS. BONNEVILLE: KRISTINA VUORI.  
14 DR. VUORI: YES.  
15 MS. BONNEVILLE: MOTION CARRIES.  
16 CHAIRMAN SHEEHY: GREAT. I THINK THAT  
17 CONCLUDES OUR BUSINESS. BUT BEFORE WE GO, I JUST  
18 WANT TO THANK MR. JUELSGAARD AND ANYONE ELSE WHO  
19 WORKED ON THE LOAN ELECTION POLICY. JUST FROM  
20 LOOKING AT THIS, I CAN TELL A LOT OF THOUGHT AND A  
21 LOT OF EFFORT WENT INTO THIS. AND THIS IS GREAT,  
22 AND THIS IS FANTASTIC THAT WE'VE BEEN ABLE TO MOVE  
23 THIS FORWARD. SO THANK YOU.  
24 DR. JUELSGAARD: JEFF, YOU'RE WELCOME.  
25 BUT ACTUALLY IT WAS AMAZINGLY SIMPLE TO DEAL WITH.

BARRISTERS' REPORTING SERVICE

1 AND THAT'S A JOKE.

2 CHAIRMAN SHEEHY: THAT'S WHAT I THOUGHT.

3 WELL, THAT CONCLUDES THE MEETING THEN, AND THANK

4 YOU, EVERYBODY.

5 (THE MEETING WAS THEN CONCLUDED AT

6 04:27 P.M.)

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25

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 SCIENCE SUBCOMMITTEE OF THE INDEPENDENT CITIZEN'S OVERSIGHT COMMITTEE OF THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE IN THE MATTER OF ITS REGULAR MEETING HELD ON OCTOBER 5, 2015, 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  
BARRISTERS' REPORTING SERVICE  
160 S. OLD SPRINGS ROAD  
SUITE 270  
ANAHEIM, CALIFORNIA  
(714) 444-4100