

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 MEETING

LOCATION: AS INDICATED ON THE AGENDA

DATE: MONDAY, OCTOBER 8, 2012  
1 P.M.

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

BRS FILE NO.: 93131

## BARRISTERS' REPORTING SERVICE

### I N D E X

ITEM DESCRIPTION	PAGE NO.
1. CALL TO ORDER.	3
2. ROLL CALL.	3
3. CONSIDERATION OF DISEASE TEAM III CONCEPT PLAN.	4
4. CONSIDERATION OF STRATEGIC PARTNERSHIP II CONCEPT PLAN.	27
5. CONSIDERATION OF INCLUDING BUDGET AS A FORMAL CRITERION FOR APPLICATION REVIEWS.	36
6. CONSIDERATION OF A DISCRETIONARY FUND FOR SUPPLEMENTS TO EXISTING GRANTS.	NOT HEARD
7. PUBLIC COMMENT.	NONE

**BARRISTERS' REPORTING SERVICE**

1 MONDAY, OCTOBER 8, 2012; 1 P.M.

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CHAIRMAN SHEEHY: OKAY. SO I'M GOING TO GO AHEAD AND LET MARIA DO AN INITIAL ROLL CALL SO THAT WE CAN GET A SENSE OF HOW CLOSE WE ARE TO QUORUM, AND I WANT TO LET YOU KNOW WHO'S HERE. STAFF, DR. FEIGAL, DR. TROUNSON, DR. OLSON, DR. STEFFEN, DR. CARAS, DR. SAMBRANO. DID I MISS ANYBODY? AND THEN JAMES HARRISON, SCOTT TOCHER, IAN, AND ELONA. AND WE HAVE A GUEST TODAY, DAVID JENSEN. AND J.T. IS HERE. SO WE'RE GOING TO TAKE AN INITIAL PASS AT THE ROLL.

MS. BONNEVILLE: AND IF YOU COULD PLEASE LET ME KNOW IF THERE ARE ANY MEMBERS OF THE PUBLIC AT YOUR LOCATION SO WE CAN MAKE SURE TO CALL ON THEM IF NEED BE.

SUE BRYANT.

DR. BRYANT: HERE.

MS. BONNEVILLE: MARCY FEIT. MICHAEL FRIEDMAN.

DR. FRIEDMAN: HERE. AND THERE'S NOBODY AT THIS LOCATION.

MS. BONNEVILLE: BERT LUBIN. SHLOMO MELMED. PHIL PIZZO.

DR. PIZZO: HERE. AND ALONE AGAIN.

**BARRISTERS' REPORTING SERVICE**

1 MS. BONNEVILLE: DUANE ROTH.  
2 MR. ROTH: HERE. AND I'VE GOT GUESTS.  
3 MS. BONNEVILLE: JOAN SAMUELSON.  
4 MS. SAMUELSON: HERE AND NO GUESTS.  
5 MS. BONNEVILLE: JEFF SHEEHY.  
6 CHAIRMAN SHEEHY: HERE.  
7 MS. BONNEVILLE: JON SHESTACK. OS  
8 STEWARD.  
9 DR. STEWARD: HERE.  
10 MS. BONNEVILLE: ART TORRES. JONATHAN  
11 THOMAS.  
12 CHAIRMAN THOMAS: HERE.  
13 MS. BONNEVILLE: CHRISTINA VUORI.  
14 DR. VUORI: HERE. NO MEMBERS OF THE  
15 PUBLIC.  
16 CHAIRMAN SHEEHY: OKAY. WE'RE ONE SHORT  
17 OF A QUORUM, BUT I THINK WE'RE GOING TO GO AHEAD AND  
18 START WITH THE FIRST ITEM AND HOPEFULLY WE'RE  
19 EXPECTING PEOPLE TO COME IN. SO THE FIRST ITEM ON  
20 THE AGENDA IS CONSIDERATION OF THE DISEASE TEAM III  
21 CONCEPT PLAN. AND I THINK DR. FEIGAL WILL LEAD US  
22 THROUGH THE STAFF'S PROPOSAL FOR THIS.  
23 DR. FEIGAL: YES. THANK YOU VERY MUCH.  
24 AND WHAT WE'RE GOING TO PROPOSE TODAY IS REALLY A  
25 MODIFICATION TO THE MOST RECENT DISEASE TEAM THERAPY

## BARRISTERS' REPORTING SERVICE

1 DEVELOPMENT CONCEPT. AND THAT'S TO HAVE A SINGLE  
2 REVIEW OF THE RESEARCH APPLICATION BY THE GRANTS  
3 WORKING GROUP WITH NARROWING OF INCLUSION CRITERIA,  
4 AND WE'RE PROPOSING NOT INCLUDING A PLANNING AWARD  
5 PROCESS.

6 THE USE OF A PLANNING AWARD WOULD LENGTHEN  
7 THE TIME TO RESEARCH AWARD BY ONE YEAR. AN  
8 ALTERNATIVE TO A PLANNING AWARD WOULD BE THE USE OF  
9 A PREAPPLICATION PROCESS WHICH WOULD ALSO LENGTHEN  
10 THE TIME TO RESEARCH AWARD MINIMALLY BY ONE YEAR.  
11 WHAT WE'RE PROPOSING ACTUALLY IS TO JUST POST A  
12 SOLICITATION FOR THE DISEASE TEAM THERAPY RESEARCH  
13 AWARD. AND BY A LETTER OF INTENT INCLUSION  
14 CRITERIA, WE ACTUALLY ARE PROPOSING NOT TO USE  
15 EITHER A PREAPPLICATION OR A PLANNING AWARD, BUT  
16 ACTUALLY HAVE ALL THE APPLICATIONS THAT GET  
17 SUBMITTED BE REVIEWED BY THE GRANTS WORKING GROUP  
18 UNLESS THEY'RE OTHERWISE EXCLUDED BY THE LETTER OF  
19 INTENT.

20 SPECIFICALLY, THE CONCEPT INCLUDES THE  
21 CONTINUATION OF CIRM'S DISEASE TEAM THERAPY  
22 DEVELOPMENT INITIATIVE AND PROVIDES FUNDING FOR  
23 PRECLINICAL DEVELOPMENT AND EARLY CLINICAL TRIALS  
24 AND TARGETS CIRM'S KEY CLINICAL GOALS THAT ARE  
25 ARTICULATED IN THE SCIENTIFIC STRATEGIC PLAN. THE

## BARRISTERS' REPORTING SERVICE

1 DISEASE TEAM INITIATIVE WAS CREATED TO ENCOURAGE  
2 RESEARCHERS TO WORK IN MULTIDISCIPLINARY TEAMS,  
3 ASSEMBLING THE SKILLS NECESSARY TO COMPLETE THE KEY  
4 PRECLINICAL RESEARCH AND DEVELOPMENT ACTIVITIES.

5 WE'VE AWARDED TWO PRIOR DISEASE TEAM  
6 ROUNDS, RFA 0901 IN OCTOBER OF THE 2009 IN WHICH 14  
7 TEAMS WERE FUNDED AND FUNDING INITIATED IN 2010 FOR  
8 THAT FIRST COHORT, AND MOST RECENTLY RFA 1005 IN  
9 SEPTEMBER OF 2012 IN WHICH 11 DISEASE TEAMS WERE  
10 FUNDED IN MULTIPLE THERAPEUTIC AREAS.

11 WITH ADVANCING SCIENCE IN THE FIELD, SUBSEQUENT  
12 ROUNDS OF THE DISEASE TEAM AWARDS HAVE ADDRESSED  
13 ACTIVITIES AT A MORE MATURE STAGE IN THE THERAPY  
14 DEVELOPMENT PROCESS. FOR EXAMPLE, THE FIRST ROUND  
15 OF DISEASE TEAMS HAD AS THEIR GOAL FILING AN  
16 APPROVABLE IND WITH THE U.S. FOOD AND DRUG  
17 ADMINISTRATION TO ENTER FIRST-IN-HUMAN CLINICAL  
18 TRIALS. THE SECOND ROUND OF DISEASE TEAMS, WHICH  
19 WERE AWARDED IN JULY AND SEPTEMBER OF THIS YEAR,  
20 ADDED THE AIM OF COMPLETING EARLY PHASE CLINICAL  
21 TRIALS.

22 THIS THIRD ROUND OF DISEASE TEAMS IS  
23 ENVISIONED TO FOCUS ON MATURE PRODUCTS THAT CAN  
24 COMPLETE EARLY PHASE CLINICAL TRIALS WITHIN THE  
25 PLANNED FOUR-YEAR PROJECT PERIOD.

## BARRISTERS' REPORTING SERVICE

1           IN YOUR PREREAD YOU SEE A LITTLE BIT OF  
2 BACKGROUND ABOUT WHERE WE ARE WITH THESE DISEASE  
3 TEAMS, THAT WE ACTIVELY HAVE MANAGED THESE  
4 MILESTONE-DRIVEN DISEASE TEAM PROJECTS, INCLUDING  
5 EVALUATION BY AN EXTERNAL CLINICAL DEVELOPMENT  
6 ADVISORS PANEL. OUTCOMES FROM THE FIRST COHORT OF  
7 14 TEAMS TO DATE INCLUDE ONE TEAM HAS ACHIEVED AN  
8 IND FILING WITH THE FDA AND HAS SUCCESSFULLY  
9 COMPETED FOR FUNDING FOR CLINICAL TRIALS. ONE  
10 PROJECT OF THE 14 WAS TERMINATED AS IT WAS NOT ABLE  
11 TO MEET THE MUTUALLY AGREED MILESTONES, AND THE  
12 REMAINING 12 PROJECTS ARE COMPLETING THEIR CDAP  
13 ASSESSMENT FROM NOW THROUGH THE END OF THIS YEAR.

14           PROJECTS IN THE SECOND ROUND ARE JUST  
15 GETTING UNDER WAY LATE IN 2012 AND EARLY 2013. SO  
16 THE MAIN ISSUE UNDER DISCUSSION TODAY IS THAT WE'D  
17 LIKE TO DO THE THIRD ROUND OF DISEASE TEAMS, PUT  
18 TOGETHER THE SOLICITATION, AND HAVE JUST A LETTER OF  
19 INTENT, AS WE DO WITH ALL OF OUR SOLICITATIONS, BUT  
20 NOT HAVE A PLANNING AWARD PROCESS NOR A  
21 PREAPPLICATION PROCESS.

22           THE MAIN REASON, WE FEEL, IS THAT WE'RE AT  
23 A MATURE STAGE OF THE FIELD IN TERMS OF HAVING A  
24 GOOD DENOMINATOR OF INVESTIGATORS WHO ARE  
25 WELL-VERSED IN PUTTING TOGETHER THEIR PROJECTS. WE

## BARRISTERS' REPORTING SERVICE

1 FEEL THAT THE 26-MONTH TIMELINE THAT WE HAD WITH  
2 PLANNING AWARDS IS JUST NOT ACCEPTABLE GIVEN THE  
3 TYPES OF -- THE WAY THAT RESEARCH IS MOVING FORWARD  
4 IN THIS FIELD. WE BELIEVE IT'S TOO LONG OF A LAG  
5 TIME TO MOVE FORWARD WITH A PLANNING AWARD. WE  
6 THINK THE PREAPPLICATION PROCESS WOULD ALSO ADD  
7 UNDUE AMOUNT OF TIME ON THIS INITIATIVE AND WOULD  
8 ALSO REALLY ONLY HAVE A SUBSET OF THE PROJECTS BE  
9 ABLE TO GO TO GRANTS REVIEW GROUP. BECAUSE OF THE  
10 DENOMINATOR OF WHAT WE RECEIVE, WE DON'T EXPECT A  
11 FLOOD OF PROPOSALS AS WE DO WITH SOME OF THE EARLIER  
12 STAGE PROJECTS, SO WE DON'T THINK THIS TRIAGING OR  
13 FILTERING PROCESS IS REALLY NECESSARY FOR THIS TYPE  
14 OF APPLICATION PROPOSAL.

15 CHAIRMAN SHEEHY: CAN I ASK WHO'S JOINED?

16 MS. FEIT: THIS IS MARCY.

17 MR. SHESTACK: JON SHESTACK.

18 CHAIRMAN SHEEHY: GREAT. THANK YOU.

19 SO LET ME ASK A QUICK QUESTION, AND THEN  
20 IF I CAN GET OTHERS ON THE PHONE WHO WOULD LIKE TO  
21 ASK QUESTIONS. SO IS HAVING AN IND GOING TO BE ONE  
22 OF THE CRITERIA FOR APPLYING FOR THIS GRANT?

23 DR. FEIGAL: WELL, I PROBABLY WON'T GO  
24 OVER THE ELIGIBILITY HERE, BUT WHAT WE'RE TALKING  
25 ABOUT DOING IS TO ACTUALLY HAVE THEM BE AT A MATURE



## BARRISTERS' REPORTING SERVICE

1 STAGE WHERE, SAY, THEY HAVE ALREADY HAD THEIR  
2 PRE-IND DISCUSSION OR AT LEAST BE WITHIN 12 TO 18  
3 MONTHS OF THEIR IND FILING AND/OR THEY CAN START  
4 WITH A CLINICAL TRIAL. BUT WE'RE HAVING IT BE A  
5 MORE MATURE STAGE OF WHERE THEY ARE.

6 CHAIRMAN SHEEHY: SO YOU THINK THE  
7 MATURITY WILL SCREEN OUT AND PREVENT US FROM HAVING  
8 AN EXCESSIVE NUMBER OF GRANTS?

9 DR. FEIGAL: YEAH. WHAT WE THINK IS THAT  
10 MAINLY BY ASKING FOR THE MORE MATURE PROJECTS, WE'RE  
11 GOING TO HAVE A MORE FINITE NUMBER OF APPLICATIONS  
12 COMING IN.

13 CHAIRMAN SHEEHY: SO ARE THERE QUESTIONS  
14 FROM OTHER MEMBERS OF THE BOARD ON THE PHONE?

15 MS. SAMUELSON: I'VE GOT A COUPLE. IT'S  
16 JOAN.

17 ELLEN, I'M CONFUSED BY THAT. MATURE MEANS  
18 THEY HAVE BEEN WORKING ON THAT TARGET FOR A LONGER  
19 PERIOD OF TIME?

20 DR. FEIGAL: MATURE IN TERMS OF WHERE THEY  
21 ARE IN THE PRODUCT DEVELOPMENT SPECTRUM. SO WE HAVE  
22 USUALLY -- AS YOU KNOW, AT CIRM WE FUND EVERYTHING  
23 FROM THE BASIC RESEARCH THROUGH TO EARLY PHASE  
24 CLINICAL TRIALS. AND THEN WE HAVE DIFFERENT PARTS  
25 OF THE RESEARCH AS IT ADVANCES WHERE WE HAVE

**BARRISTERS' REPORTING SERVICE**

1 DIFFERENT INITIATIVES. WHAT WE'RE SAYING IS IT'S  
2 THE MATURITY OF THE PROJECT. IT MAY OR MAY NOT BE  
3 RELATED TO THE LENGTH OF THE TIME AT WHICH THEY'VE  
4 DONE THE WORK, BUT THEY'VE REACHED THAT STAGE IN  
5 MATURITY OF THE RESEARCH WHERE THEY'RE WITHIN 12 TO  
6 18 MONTHS OF THEIR IND FILING.

7 MS. SAMUELSON: OKAY. I THOUGHT OUR  
8 PREVIOUS RFA'S REQUIRED INCLUDING AN IND FILING.  
9 THAT SOUNDS MORE MATURE TO ME.

10 DR. FEIGAL: NO. NO. IT CAN STILL --  
11 EVEN WITH THIS ITERATION, WE'RE STILL ALLOWING IND  
12 FILING. WHAT I'M SAYING IS AS OPPOSED TO BEING  
13 WITHIN FOUR YEARS OF IND FILING, THEY'RE WITHIN 12  
14 TO 18 MONTHS OF IND FILING SO THAT THEY HAVE THE  
15 POSSIBILITY OF COMPLETING AN EARLY PHASE CLINICAL  
16 TRIAL.

17 MS. SAMUELSON: I SEE.

18 MR. ROTH: JEFF, IT'S DUANE. YOU KNOW, I  
19 THINK WHAT ELLEN JUST SAID IS -- THERE'S A  
20 DEFINITION USED IN THE VENTURE WORLD, CLINICAL TRIAL  
21 READY. THE DEFINITION TRANSLATES TO WITHIN 12  
22 MONTHS YOU WOULD BE IN A CLINICAL TRIAL. SO I THINK  
23 PEOPLE WILL UNDERSTAND THAT.

24 BUT I DO THINK WE SHOULD HIGHLY  
25 COMMUNICATE THAT THEY'RE NOT GOING TO MAKE IT IF

## BARRISTERS' REPORTING SERVICE

1 THEY AREN'T WITHIN WHATEVER PARAMETER THAT'S IN  
2 BECAUSE I WATCHED THAT LAST REVIEW. THEY'RE VERY  
3 GOOD ON THE REVIEWS TO PICK UP PEOPLE WHO ARE REALLY  
4 NOT THERE. SO HOPEFULLY WE'LL COMMUNICATE TO THE  
5 APPLICANTS DON'T TRY TO COME IN IF YOU'RE REALLY NOT  
6 IN THAT STAGE.

7 DR. FEIGAL: AND SOME OF THE FEEDBACK THAT  
8 WE DID RECEIVE -- AS YOU KNOW, WE'LL BE GOING  
9 FORWARD TO THE BOARD IN OCTOBER WITH THE  
10 RECOMMENDATIONS FROM THAT GRANT REVIEW GROUP. BUT  
11 WHAT WE FELT IS THAT WE NEEDED TO BE MORE PRECISE  
12 ABOUT WHEN PEOPLE WERE COMING IN. WE WERE VERY  
13 CLEAR ABOUT THE TARGET OF COMPLETING AN EARLY PHASE  
14 CLINICAL TRIAL, BUT WE NEEDED TO BE CLEARER ABOUT  
15 THE ENTRY CRITERIA. AND SO I THINK IF WE'RE CLEARER  
16 ABOUT HOW FAR AWAY FROM IND FILING THEY ARE, THAT  
17 WILL BE COMMUNICATED AS CLEAR AS WE CAN. SOMETIMES  
18 THAT'S DOCUMENTED BY THEY'VE HAD THEIR PRE-IND  
19 DISCUSSION WITH THE FDA, AND WE'VE HAD A CHANCE TO  
20 SEE WHAT TYPE OF INTERACTION THEY HAD AND WHETHER OR  
21 NOT THERE ARE ISSUES THAT ARE PRESUMABLY RESOLVABLE  
22 WITHIN THE 12- TO 18-MONTH PERIOD OF TIME OR WHETHER  
23 THERE'S SOMETHING MORE COMPLICATED AND COMPLEX THAT  
24 WOULD MAKE IT SEEM LIKE THE TIMELINE WOULD BE  
25 FURTHER AWAY THAN THAT.

## BARRISTERS' REPORTING SERVICE

1 SO WE'RE HOPING TO BE MORE PRECISE ABOUT  
2 THE LEVEL OF MATURITY OF THE PROJECT SO THAT THEY  
3 HAVE A CHANCE TO EITHER FILE THAT IND AND COMPLETE A  
4 CLINICAL TRIAL OR START AT THE CLINICAL TRIAL SITE.

5 MS. SAMUELSON: IN OUR CURRENT GRANT  
6 PORTFOLIO, WHAT YOU CAN SAY ABOUT HOW FAR THEY ARE,  
7 THE VARIOUS FUNDED ARE FROM THAT POINT?

8 DR. FEIGAL: SO WHAT I DID IN THIS PAST  
9 YEAR, I PROVIDED YOU AN UPDATE ON OUR DISEASE TEAMS.  
10 AND I JUST VERY BRIEFLY WENT OVER OUR FIRST COHORT  
11 OF DISEASE TEAMS, WHO'S FILED THE IND, WHO'S  
12 ENTERING IN CLINICAL TRIAL, WHO DID NOT MEET  
13 MILESTONES, THE 12 THAT ARE CONTINUING ON THEIR WAY.  
14 WHAT I PLAN TO DO IN MARCH EARLY NEXT YEAR IS TO  
15 GIVE YOU AN UPDATE OF WHERE THOSE TEAMS ARE BECAUSE  
16 RIGHT NOW THEY'RE GOING THROUGH THEIR ASSESSMENTS.  
17 AND I THINK IT WOULD MAKE MORE SENSE TO GIVE YOU AN  
18 UPDATE AFTER ALL THOSE ASSESSMENTS ARE COMPLETED.

19 MS. SAMUELSON: I CAN UNDERSTAND THAT, AND  
20 AT THE SAME TIME, HAVING NO CLEAR IDEA WHERE WE  
21 STAND WITH OUR PROGRESS TOWARDS TARGETS FOR GIVEN  
22 DISEASES --

23 DR. FEIGAL: WELL, WHAT I CAN SAY IS --

24 MS. SAMUELSON: I WOULD ASK WHAT NEXT WE  
25 SHOULD SPEND MONEY ON.

**BARRISTERS' REPORTING SERVICE**

1 DR. FEIGAL: YEAH. WELL, JOAN, WHAT I'M  
2 SAYING IS THAT WHEN THOSE WERE AWARDED AND THEY  
3 STARTED GETTING THEIR FUNDS IN 2010 AND THEY HAVE A  
4 WHOLE FOUR YEARS TO REACH THEIR IND FILING, SO IN  
5 2014, WHICH IS THE PREDICTED TIME WHEN MOST OF THEM  
6 WOULD BE ABLE TO FILE AN IND. WHAT I'VE ALREADY  
7 SAID IS AT LEAST ONE OF THOSE 14 HAS ALREADY FILED  
8 AND IS READY TO ENTER FIRST-IN-HUMAN CLINICAL TRIALS  
9 AND WILL START THIS YEAR. THE OTHER 12 OF THE 14  
10 ARE ON THEIR PATHWAY TO ENTER THE CLINICAL TRIAL  
11 SOMETIME IN 2014.

12 AND WHAT I CAN'T SHARE WITH YOU YET ARE  
13 THE ONES THAT WE REVIEWED RECENTLY THAT I'LL BE  
14 COMING TO THE BOARD IN OCTOBER. SO THAT ONE WAS  
15 REALLY GEARED ALSO AS COMPLETING CLINICAL TRIALS,  
16 AND I'LL BE ABLE TO SHARE THAT TO YOU.

17 SO WHAT I CAN SAY RIGHT NOW IS THAT ONE OF  
18 OUR DISEASE TEAMS IS READY TO START A CLINICAL  
19 TRIAL.

20 MS. SAMUELSON: HAVING THE JOB OF HAVING  
21 TO ACTUALLY BE THE PERSON WHO VOTES TO SPEND THE  
22 MONEY, I DON'T KNOW HOW I CAN DO IT WITH THAT LITTLE  
23 INFORMATION. IT SEEMS TO ME I NEED TO KNOW MORE  
24 ABOUT HOW WE'RE SPENDING OUR MONEY, HOW THEY'RE  
25 DOING. I MEAN THIS DOESN'T -- IS ON THE

## BARRISTERS' REPORTING SERVICE

1 CUTTING-EDGE OF THE BEST SCIENCE IN THE WORLD,  
2 RIGHT?

3 DR. FEIGAL: I GUESS I'M SAYING I WASN'T  
4 PLANNING ON GIVING AN UPDATE ON ALL THE DISEASE  
5 TEAMS AT THE SCIENCE SUBCOMMITTEE MEETING. I'M  
6 PLANNING TO DO THAT FOR THE FULL ICOC AFTER THE  
7 FIRST OF THE YEAR.

8 MS. SAMUELSON: BUT YOU'RE ASKING ME TO  
9 VOTE NOW.

10 CHAIRMAN SHEEHY: JOAN, MAYBE THIS WAS  
11 SOMETHING BECAUSE I GUESS -- DOES WHAT PROGRESS  
12 WE'VE MADE DETERMINE WHETHER OR NOT WE SHOULD PURSUE  
13 THIS OTHER DISEASE TEAM ROUND? IT'S NOT EVEN CLEAR  
14 THAT OUR FIRST ROUND OF GRANTS, FRANKLY, THE WAY IN  
15 WHICH WE SET IT UP, THE MAJORITY OF THEM WOULD EVEN  
16 NECESSARILY BE ELIGIBLE FOR THIS ROUND BECAUSE THEY  
17 STILL STAND, SOME OF THEM, QUITE A BIT A WAYS FROM  
18 THE CLINIC. IN FACT, THE FIRST DISEASE TEAM ROUND  
19 WAS ONLY SUPPOSED TO ACHIEVE AN IND IN FOUR YEARS.

20 DR. FEIGAL: NO. SOME OF THEM WOULD BE IF  
21 THEY'RE WITHIN 12 TO 18 MONTHS OF THEIR IND FILING.

22 MR. SHESTACK: I GUESS THE QUESTION THAT  
23 MAYBE JEFF AND JOAN OR ACTUALLY I HAVE IS WHAT -- IS  
24 THERE A MECHANISM WHEREBY GRANTS THAT ARE PRETTY  
25 SUCCESSFUL BUT NOT NECESSARILY TIMING-WISE IN

## BARRISTERS' REPORTING SERVICE

1 DISEASE TEAM I AND MAYBE EVEN IN II WILL HAVE A  
2 MECHANISM BY WHICH THEY CAN GO FURTHER AND WE CAN  
3 FURTHER SUPPORT THEM, AND DOES IT HAVE TO BE ANOTHER  
4 DISEASE TEAM GRANT? IS THERE TIME FOR IT, OR IS  
5 THERE SOME OTHER MECHANISM THAT THEY CAN USE SO  
6 WE'RE NOT JUST WASTING PROGRESS THAT WAS FANTASTIC,  
7 BUT NOT SUPER FANTASTIC?

8 MS. SAMUELSON: SO POTENTIALLY WASTING  
9 MONEY TOO.

10 DR. FEIGAL: I GUESS WHAT WE'RE SAYING IS  
11 THAT WE NEED TO HAVE -- WHAT WE SAID WHEN WE  
12 STARTED -- FIRST OF ALL, WE HAVE A FIVE-YEAR  
13 STRATEGIC PLAN WHERE WE SAID WE'RE GOING TO HAVE A  
14 CERTAIN NUMBER -- WHICH YOU ALL REVIEWED AND AGREED  
15 UPON AT, I BELIEVE IT WAS, IN MAY ICOC BOARD MEETING  
16 WHERE WE TALKED ABOUT HAVING AT LEAST TEN CLINICAL  
17 TRIALS IN AT LEAST FIVE DIFFERENT THERAPEUTIC AREAS  
18 WITHIN A CERTAIN AMOUNT OF TIME FRAME, WITHIN FIVE  
19 YEARS.

20 IN ADDITION, WE SAID WITHIN FIVE YEARS WE  
21 WANTED TO HAVE CLINICAL PROOF OF CONCEPT IN AT LEAST  
22 ONE OF THESE STEM CELL-BASED THERAPY AREAS. SO  
23 WORKING BACKWARDS FROM A STRATEGIC PLAN THAT WE ALL  
24 WORKED TOGETHER ON AND REVIEWED AND AGREED UPON, WE  
25 HAVE THESE INITIATIVES TO TRY AND HELP US GET TO OUR

## BARRISTERS' REPORTING SERVICE

1 STRATEGIC GOALS.

2 AND IN ORDER TO GET TO OUR STRATEGIC  
3 GOALS, WE NEED TO HAVE THESE INITIATIVES IN PLACE SO  
4 WE CAN HAVE SOME OF THIS RESEARCH CONTINUE TO GO.

5 OUR DISEASE TEAM I STOPPED AT THE IND  
6 FILING. WE NEED TO HAVE A PATHWAY FORWARD SO THAT  
7 THEY CAN ADVANCE. SOME OF THEM WE ANTICIPATE WILL  
8 BE READY TO ADVANCE BY THE TIME THIS SOLICITATION  
9 COMES OUT. IN ADDITION, IT'S ALLOWING WHAT WE WERE  
10 ALSO TOLD BY AN EXTERNAL PANEL IS NOT JUST GO WITH  
11 OUR ENDOGENOUS PIPELINE, BUT CONTINUE TO BE  
12 RECEPTIVE TO OTHER PROPOSALS THAT CAN COME IN.

13 SO WHAT WE'RE TRYING TO DO IS HAVE A  
14 SEAMLESS PATHWAY FOR AN ENDOGENOUS PIPELINE AS WELL  
15 AS ALLOW PROMISING AND MATURE PROJECTS TO COME IN TO  
16 THIS INITIATIVE.

17 CHAIRMAN SHEEHY: DR. TROUNSON HAD A  
18 COMMENT.

19 DR. TROUNSON: WELL, JUST IN ADDING TO  
20 WHAT ELLEN HAS SAID, THERE'S REALLY ONLY ONE OF THE  
21 STUDIES AT THE MOMENT THAT'S ACTUALLY GOING INTO  
22 CLINICAL TRIAL. HASN'T ACTUALLY STARTED. SO, YOU  
23 KNOW, WE AREN'T VERY MATURE IN THESE PHASE I AND  
24 PHASE II STUDIES, AND WE'VE GOT TO ACTUALLY ACHIEVE  
25 SOME PROOF OF CONCEPT IF WE CAN. SO NOT ALL OF



## BARRISTERS' REPORTING SERVICE

1 THOSE -- UNFORTUNATELY NOT ALL OF THOSE STUDIES WILL  
2 GET TO THAT POINT. SO WHAT WE'VE GOT TO DO IS TRY  
3 AND PRODUCE SOME OF THESE MORE MATURE STUDIES, HELP  
4 THEM GET TO THAT POINT SO THAT WE'VE GOT  
5 DEMONSTRATION AT PHASE II OF PROOF OF CONCEPT IN A  
6 HUMAN.

7 SO THAT'S THE REASON WHY I THINK WE'VE GOT  
8 TO PUSH ON THE MATURE SIDE AT THIS POINT IN TIME  
9 JUST TO BE ABLE -- AND I THINK THEY'RE THERE. JUST  
10 WE'VE GOT TO ACTUALLY ENCOURAGE THAT PART OF THE  
11 PIPELINE TO SORT OF BRING THOSE STUDIES FORWARD  
12 BECAUSE I THINK IN THE END, YOU KNOW, WE WILL BE  
13 JUDGED ON WHETHER WE'VE GOT SOME OF THEM TO GET TO  
14 THAT POINT IN TIME.

15 DR. FEIGAL: I THINK THIS IS A REAL  
16 NATURAL POINT IN TIME TO OFFER THIS KIND OF  
17 INITIATIVE BECAUSE, AS I SAID, WE FUNDED THE FIRST  
18 ONES IN 2009 AND STARTED FUNDING IT, AND THEY'RE  
19 WORKING ON THEIR WAY. EVEN POSTING THIS, THERE'S A  
20 YEAR GESTATION TIME IN TERMS OF POSTING THIS,  
21 GETTING THE PROPOSALS IN, REVIEWING IT, GETTING THE  
22 RECOMMENDATIONS BACK. SO WE'RE ENVISIONING THIS  
23 WILL COME OUT, THE FUNDING, IN JANUARY OF 2014. SO  
24 THAT'S A WHOLE YEAR DOWN THE ROAD FROM NOW. AND SO  
25 WE THINK THE TIMING IS ACTUALLY RIGHT TO BE PUTTING

## BARRISTERS' REPORTING SERVICE

1 THIS PROPOSAL TOGETHER TO ALLOW THAT PATHWAY TO BE  
2 ABLE TO BE CONTINUED.

3 MR. ROTH: JEFF, IT'S DUANE.

4 CHAIRMAN SHEEHY: OKAY. DUANE AND THEN I  
5 HAVE J.T. ARE THERE OTHERS WHO WANT TO TALK SO I  
6 CAN MAKE A LIST?

7 MS. SAMUELSON: I JUST NEED ONE MORE  
8 DEFINITIONAL QUESTION.

9 MR. ROTH: I WOULD LIKE TO PUT A MOTION ON  
10 THE TABLE THAT WE APPROVE THE CONCEPT WITH THE  
11 CONSIDERATION OF THE COMMENTS THAT HAVE BEEN MADE BY  
12 BOARD MEMBERS.

13 CHAIRMAN SHEEHY: AND DO I HAVE A SECOND  
14 FOR THAT?

15 DR. FRIEDMAN: I'LL SECOND IT.

16 CHAIRMAN SHEEHY: THANK YOU, DR. FRIEDMAN.  
17 OKAY, J.T.

18 CHAIRMAN THOMAS: I THINK IT MAKES PERFECT  
19 SENSE GIVEN THE STRATEGIC PLAN THAT WITH EACH  
20 PROGRESSIVE DISEASE TEAM OF A SET OF AWARDS THAT WE  
21 GO FURTHER DOWN THE LINE IN A CONTINUUM. AND SO TO  
22 ME I'M ENTIRELY IN FAVOR OF THAT CONCEPT. THE  
23 QUESTION IS REALLY ON THE DO YOU WANT A PREAP  
24 PLANNING AWARD OR NOT, JUST A LETTER OF INTENT.  
25 JUST A COUPLE OF QUESTIONS FOR ELLEN.

## BARRISTERS' REPORTING SERVICE

1 ON THE DISEASE TEAM II APPLICATIONS, WHICH  
2 WERE A CLOSER TIMELINE TO WHAT WE'RE RECOMMENDING  
3 HERE ON THIS, HOW MANY APPLICATIONS WERE THERE FOR  
4 PLANNING AWARDS?

5 DR. FEIGAL: THERE WERE 21 THAT WERE  
6 AWARDED IN TERMS OF PLANNING AWARDS.

7 CHAIRMAN THOMAS: SO HOW MANY APPLIED?

8 CHAIRMAN SHEEHY: CLOSE TO 40.

9 DR. FEIGAL: HOW MANY APPLIED FOR THE  
10 PLANNING AWARDS?

11 CHAIRMAN THOMAS: YES. THE ISSUE, WHAT  
12 YOU'RE SAYING HERE IS THAT YOU DON'T EXPECT A NUMBER  
13 SO STAGGERING TO WANT TO APPLY FOR THIS IN GENERAL.  
14 CLEARLY YOU WOULDN'T WANT TO HAVE 40 DISEASE TEAM  
15 AWARDS GOING TO GRANTS WORKING GROUP.

16 DR. FEIGAL: NO. WHAT WE --

17 CHAIRMAN THOMAS: SO WHAT, KNOWING KIND OF  
18 WHAT'S OUT THERE THESE DAYS, WHAT WOULD YOU  
19 ANTICIPATE AS A LIKELY BALLPARK NUMBER OF APPLICANTS  
20 FOR THIS ROUND?

21 DR. FEIGAL: WE THINK ACTUALLY THERE WILL  
22 BE BETWEEN ANYWHERE FROM 10 TO 15 IS WHAT WE  
23 ANTICIPATE BECAUSE WHAT -- WE THOUGHT ABOUT THE  
24 DIFFERENT WAYS THAT WE COULD TRY AND HAVE A FINITE  
25 DENOMINATOR COMING IN BECAUSE WE AGREE WE DON'T WANT

## BARRISTERS' REPORTING SERVICE

1 TO BE FLOODED WITH APPLICATIONS BECAUSE THESE ARE  
2 VERY COMPLEX AWARDS TO DO.

3 CHAIRMAN THOMAS: TWO WEEKS OF GRANTS  
4 WORKING GROUP MEETINGS.

5 DR. FEIGAL: SO WHAT WE SAID --

6 CHAIRMAN THOMAS: GIL WOULD PASS OUT.

7 DR. FEIGAL: WE'RE GOING TO REFINE IT ON  
8 THE BASIS OF THE MATURITY OF THE PROJECT. AND I  
9 TRULY BELIEVE, IF WE LOOK AT THE MATURITY OF THE  
10 PROJECT, THAT'S GOING TO GIVE US A FINITE  
11 DENOMINATOR OF WHO WOULD BE ELIGIBLE TO COME IN.

12 CHAIRMAN THOMAS: TEN TO 15, YOU THINK,  
13 BECAUSE THAT'S A MANAGEABLE NUMBER.

14 DR. TROUNSON: DON'T FORGET THAT WE HAVE  
15 THE STRATEGIC PLANNING AWARDS WHICH WILL HOPEFULLY  
16 DRAW A LOT OF THE INDUSTRIAL BUSINESS SECTOR IN  
17 THERE. THEY WON'T ALL GO THERE, BUT I THINK THE  
18 MAJORITY WILL. IT IS A BETTER FORMAT. SO I THINK  
19 IT WILL BE AROUND THAT NUMBER. THERE MAY BE MORE,  
20 BUT I THINK A FEW OF THEM WON'T FIT. THEY'LL APPLY,  
21 BUT THEY ACTUALLY WON'T FIT WHATEVER CRITERIA. IF  
22 YOU HAD 15, 12 TO 15, IT WOULD BE IDEAL.

23 DR. FEIGAL: I MEAN WE THOUGHT -- THERE'S  
24 ONLY SO MANY VARIABLES WE CAN REFINE. WE CAN REFINE  
25 THE MATURITY OF THE PROJECT, WE CAN REFINE THE

## BARRISTERS' REPORTING SERVICE

1 INCLUSION CRITERIA IN TERMS OF THE CELL THERAPY  
2 TYPE, WE COULD REFINE IN TERMS OF THERAPEUTIC AREA  
3 INDICATION. SO THERE'S A VARIETY OF THINGS WE CAN  
4 DO TO HAVE A MORE FINITE NUMBER. WE THOUGHT THE  
5 MOST REASONABLE AND APPROPRIATE WOULD BE REALLY TO  
6 LOOK AT THE MATURATION OF THE PRODUCT DEVELOPMENT.

7 CHAIRMAN THOMAS: ONE LAST QUESTION. SO  
8 WHEN THESE COME IN, I ASSUME THAT THERE'S AT LEAST A  
9 FIRST CUT TO EVALUATE WHETHER AN APPLICATION MEETS  
10 THE CRITERIA OR NOT.

11 DR. FEIGAL: THAT WOULD BE THROUGH THE  
12 LETTER OF INTENT. AND SO WE'LL HAVE SOME OBJECTIVE  
13 CRITERIA THAT WE CAN USE. THERE MAY BE SOME  
14 SUBJECTIVE, BUT THEY'LL HAVE TO PROVIDE EITHER A  
15 LETTER OR SOME SORT OF CORRESPONDENCE TO GIVE US  
16 SOME LEVEL OF COMFORT THAT THEY'RE ACTUALLY AT THE  
17 RIGHT STAGE OF DEVELOPMENT.

18 CHAIRMAN THOMAS: AND IF THEY'RE NOT, YOU  
19 CAN KNOCK THEM OUT AT THAT POINT.

20 DR. FEIGAL: YEAH. I MEAN WHAT WE WILL DO  
21 IS PICK UP THE PHONE. HOPEFULLY WHAT WE'D LIKE TO  
22 DO IS WHAT WE DID LAST TIME. WE'LL PUT OUT A  
23 WEBINAR. WE'LL TALK TO THE POTENTIAL APPLICANTS  
24 ABOUT WHAT WE'RE THINKING. AND WE'LL GET ON THE  
25 PHONE WITH PEOPLE WHO HAVE QUESTIONS. AND HOPEFULLY

## BARRISTERS' REPORTING SERVICE

1 PEOPLE WHO INTEND TO APPLY WILL PICK UP THE PHONE  
2 AND CALL US. SO WE'LL TRY AND REACH OUT TO PEOPLE  
3 WE THINK MIGHT BE INTERESTED. AND HAVE A  
4 CONVERSATION WITH THEM BECAUSE, YOU KNOW, AS ALAN  
5 SAID, FOR SOME OF THEM, IT MAY BE THEY WANT TO COME  
6 IN FOR THE INDUSTRY. THAT WILL BE THE NEXT CONCEPT  
7 THAT I'LL TALK TO YOU ABOUT. OR SOME OF THEM, MAYBE  
8 YOU'RE NOT READY NOW. MAYBE YOU'LL BE READY A YEAR  
9 FROM NOW. BECAUSE WE WANT TO POSITION THEM TO BE  
10 SUCCESSFUL. WE DON'T WANT THEM TO BE COMPETING IN A  
11 POOL OF PEOPLE WHERE THEY'RE NOT REALLY COMPETITIVE.

12 CHAIRMAN SHEEHY: OKAY. JOAN.

13 MS. SAMUELSON: YEAH. A COUPLE QUESTIONS.  
14 ONE IS DEFINITIONAL. WHAT DOES NARROWING OF  
15 INCLUSION CRITERIA MEAN?

16 CHAIRMAN SHEEHY: WELL, I THINK THAT IN  
17 ORDER TO NOT END UP TRYING TO REVIEW 40 GRANTS OR  
18 HAVING A PREAP PROCESS OR HAVING A DEVELOPMENT  
19 AWARD, APPLICATION DEVELOPMENT AWARD, THAT WE'RE  
20 LOOKING AT THE ENTIRE RANGE OF POTENTIAL WAYS TO  
21 NARROW THE NUMBER OF APPLICATIONS THAT MIGHT COME  
22 IN. THE DECISION WAS TO LOOK AT WHERE APPLICATIONS  
23 WOULD FALL ON THE DEVELOPMENT PIPELINE AND TO ONLY  
24 CHOOSE THOSE PROJECTS AT A MORE MATURE LEVEL KNOWING  
25 THAT THAT PROCESS WOULD GIVE US A SMALLER BASKET OF

**BARRISTERS' REPORTING SERVICE**

1 POTENTIAL APPLICATIONS.

2 MS. SAMUELSON: THIS DOESN'T MEAN  
3 NARROWING OF ELIGIBLE DISEASES?

4 CHAIRMAN SHEEHY: NO.

5 MS. SAMUELSON: OKAY. AND MY OTHER  
6 QUESTION, I GUESS IT'S A QUESTION FOR DUANE MAYBE AS  
7 MUCH AS ANYTHING. I APPRECIATE THE CONDITION YOU  
8 PUT IN YOUR MOTION. HOW WOULD THAT WORK? BECAUSE I  
9 REALLY AM CONCERNED WITH THE LIMITED AMOUNT OF  
10 INFORMATION I HAVE AS A BOARD MEMBER IN KNOWING WHAT  
11 THE STATE OF THE SCIENCE IS IN THE VARIOUS TARGET  
12 DISEASE AREAS THAT WE'RE RESPONSIBLE FOR MOVING  
13 AHEAD. AND I FEEL LIKE I NEED MORE.

14 MR. ROTH: SO I THINK WHAT I WAS TRYING TO  
15 COMMUNICATE IS BASED ON WHAT JEFF JUST OUTLINED,  
16 THAT IF YOU TELL PEOPLE YOU'RE LOOKING FOR PROJECTS  
17 THAT ARE WITHIN ONE YEAR OR 18 MONTHS OF BEGINNING A  
18 CLINICAL TRIAL, YOU'RE NOT GOING TO SEND SOMETHING  
19 IN THAT HASN'T EVEN GOT ROBUST PRECLINICAL DATA,  
20 BOTH SAFETY AND EFFICACY DATA, BECAUSE THEY'RE NOT  
21 GOING TO GET THROUGH THE SCREEN.

22 SO WHEN YOU'RE FOUR YEARS OUT, THAT'S  
23 PRETTY WIDE OPEN. WHEN YOU'RE ONE YEAR OUT, YOU  
24 REALLY HAVE TO HAVE YOUR PACKAGE TOGETHER OR IT'S  
25 NOT GOING TO GET THROUGH AND BE FUNDED BECAUSE WE'RE

**BARRISTERS' REPORTING SERVICE**

1 TELLING PEOPLE WE WANT VERY MATURE PROJECTS. SO I  
2 WAS HOPING BY THE MOTION THAT I SIMPLY SAID LET'S BE  
3 VERY CLEAR IN COMMUNICATING THAT TO THE APPLICANTS  
4 SO THEY DON'T DO THIS THING, THEY'RE CLEARLY THREE  
5 YEARS FROM AN IND OR THEY'VE NEVER EVEN TALKED TO  
6 THE FDA. THEY'RE GUESSING AT THINGS. THAT'S JUST  
7 NOT GOING TO GET THROUGH THIS SCREEN.

8 MS. SAMUELSON: AND THAT WILL SOLVE THOSE  
9 PROBLEMS. I'M NOT SURE HOW WE SOLVE THE ONE I'M  
10 FACING, WHICH IS I DON'T KNOW WHAT OUR MONEY -- HOW  
11 EFFECTIVE THE MONEY WE'VE SPENT AND HAVE DEDICATED  
12 IS AT THIS POINT TOWARDS ADVANCING THE MISSION.

13 MR. ROTH: I THINK ONE WAY --

14 MS. SAMUELSON: AND I NEED TO KNOW THAT.

15 MR. ROTH: ONE WAY WILL BE TO SEE HOW MANY  
16 OF THE PREVIOUS DISEASE TEAM I'S ACTUALLY APPLY FOR  
17 THIS ONE. THAT WILL TELL YOU THERE ARE SOME --

18 MS. SAMUELSON: IF YOU LOOK AT THE GRANTS  
19 WERE FUNDING RIGHT NOW AND KNOW WHAT'S GOING ON AND  
20 COMPARE THAT TO THE STATE OF THE SCIENCE FOR THE  
21 SAME DISEASES AROUND THE WORLD.

22 MR. ROTH: WE'LL HAVE THAT PRIOR TO US  
23 EVER VOTING OR EVER HAVING A REVIEW BEING DONE. SO  
24 I THINK THERE'S TIME TO DO THAT.

25 CHAIRMAN SHEEHY: JOAN, I THINK THAT THIS



## BARRISTERS' REPORTING SERVICE

1 WOULD BE A GREAT TOPIC FOR THE BOARD WORKSHOP THAT  
2 WE HAVE PLANNED FOR JANUARY. AND, OF COURSE, FOR  
3 DAVID JENSEN, I WANT TO MAKE CLEAR THAT THAT WILL BE  
4 OPEN TO THE PUBLIC. BUT THE BOARD WORKSHOP MIGHT BE  
5 A GOOD CHANCE FOR BOARD MEMBERS TO REALLY LOOK AT  
6 WHERE WE ARE IN TERMS OF THE SCIENCE. BUT I THINK  
7 DUANE'S METRIC ON SOME DEGREE OF WHAT SUCCESS WE ARE  
8 ACHIEVING WITH OUR PROGRAM WOULD BE ADVANCEMENT OF  
9 SOME OF OUR EARLIER STAGE PROJECTS INTO THIS ROUND.  
10 I THINK IT'S A PRETTY GOOD METRIC.

11 SO ARE THERE OTHER QUESTIONS, OR CAN  
12 I -- THIS IS OUR FIRST AGENDA ITEM. WE'RE HALFWAY  
13 THROUGH THE MEETING. SO IF NO ONE ELSE HAS ANY  
14 QUESTIONS, I THINK I'LL GO TO PUBLIC COMMENT.  
15 FIRST, I THINK DUANE ROTH HAS PUBLIC.

16 MR. ROTH: NO COMMENTS HERE.

17 CHAIRMAN SHEEHY: PUBLIC COMMENT IN SAN  
18 FRANCISCO? OKAY. I'LL CALL THE QUESTION. I JUST  
19 HAVE ONE MORE QUICK YES-OR-NO QUESTION. LOAN VERSUS  
20 GRANT, OPTIONAL?

21 DR. FEIGAL: WE USUALLY LET THEM DECIDE  
22 WHETHER IT'S A LOAN OR A GRANT.

23 CHAIRMAN SHEEHY: I WANT TO BE CLEAR. IT  
24 WAS MANDATORY. OKAY. SO, MARIA, COULD YOU CALL THE  
25 ROLL, PLEASE.

**BARRISTERS' REPORTING SERVICE**

1 MS. BONNEVILLE: SURE.

2 CHAIRMAN SHEEHY: AND, JAMES, COULD YOU  
3 RESTATE THE MOTION?

4 MR. HARRISON: YES. THE MOTION IS TO  
5 RECOMMEND APPROVAL OF THE DISEASE TEAM III CONCEPT  
6 PLAN WITH ENCOURAGEMENT OF INPUT PROVIDED BY BOARD  
7 MEMBERS.

8 MS. BONNEVILLE: SUE BRYANT.

9 DR. BRYANT: YES.

10 MS. BONNEVILLE: MARCY FEIT.

11 MS. FEIT: YES.

12 MS. BONNEVILLE: MICHAEL FRIEDMAN.

13 DR. FRIEDMAN: YES.

14 MS. BONNEVILLE: BERT LUBIN. SHLOMO  
15 MELMED. PHIL PIZZO.

16 DR. PIZZO: YES.

17 MS. BONNEVILLE: DUANE ROTH.

18 MR. ROTH: YES.

19 MS. BONNEVILLE: JOAN SAMUELSON.

20 MS. SAMUELSON: NO.

21 MS. BONNEVILLE: JEFF SHEEHY.

22 CHAIRMAN SHEEHY: YES.

23 MS. BONNEVILLE: JON SHESTACK.

24 MR. SHESTACK: YES.

25 MS. BONNEVILLE: OS STEWARD.

**BARRISTERS' REPORTING SERVICE**

1 DR. STEWARD: YES.

2 MS. BONNEVILLE: ART TORRES. JONATHAN  
3 THOMAS.

4 CHAIRMAN THOMAS: YES.

5 MS. BONNEVILLE: CHRISTINA VUORI.

6 DR. VUORI: YES.

7 CHAIRMAN SHEEHY: OKAY. SO FOR THE NEXT  
8 AGENDA ITEM, I THINK DR. FEIGAL WILL LEAD US INTO  
9 THAT, CONSIDERATION OF THE STRATEGIC PARTNERSHIP II  
10 CONCEPT PLAN.

11 DR. FEIGAL: YEAH. AND HERE WHAT IT IS IS  
12 A MODIFICATION OF THE STRATEGIC PARTNERSHIP II. AS  
13 YOU KNOW, WE WENT THROUGH THE REVIEW OR MAYBE YOU  
14 DON'T, BUT WE WENT THROUGH THE REVIEW OF THE FIRST  
15 ITERATION OF STRATEGIC PARTNERSHIPS JUST RECENTLY.  
16 WE'RE GOING TO BE COMING TO THE BOARD WITH THE  
17 RECOMMENDATIONS FROM THE GRANT REVIEW GROUP FOR THAT  
18 PARTICULAR AWARD.

19 WHAT WE'D LIKE TO DO IS ACTUALLY REISSUE  
20 THE -- IN KEEPING WITH WHAT YOU APPROVED BACK ON  
21 OCTOBER 25TH OF 2011, TO HAVE THE ITERATION OF THE  
22 STRATEGIC PARTNERSHIP COME OUT EVERY SIX MONTHS. SO  
23 THE NEXT ONE WILL BE COMING OUT EARLY NEXT YEAR WITH  
24 A SOLICITATION FOR NOVEMBER.

25 WHAT WE'D LIKE TO DO IS MAKE A SLIGHT

## BARRISTERS' REPORTING SERVICE

1 MODIFICATION, TO KEEP THE TOTAL AWARD AMOUNT PER  
2 PROJECT AT 10 MILLION, BUT TO ALLOW THE POSSIBILITY  
3 TO INCREASE THE AWARD TO 15 MILLION PER PROJECT  
4 SUBJECT TO ICOC APPROVAL AND ONLY UNDER EXCEPTIONAL  
5 CIRCUMSTANCES AND WOULD HAVE TO BE ACCOMPANIED BY A  
6 FULL, DETAILED BUDGET AND JUSTIFICATION.

7 TO REFRESH YOUR MEMORY ON THE STRATEGIC  
8 PARTNERSHIP PROGRAM, IT'S TO CREATE INCENTIVES AND  
9 PROCESSES THAT WILL ENHANCE THE LIKELIHOOD THAT  
10 CIRM-FUNDED PROJECTS WILL OBTAIN FUNDING FOR LATER  
11 STAGE PHASE III CLINICAL TRIALS, WHAT WE CALL  
12 FOLLOW-ON FINANCING. SECONDLY, THAT WILL PROVIDE A  
13 SOURCE OF CO-FUNDING IN THE EARLIER STAGES OF  
14 CLINICAL DEVELOPMENT; AND, THIRDLY, THAT WILL ENABLE  
15 CIRM-FUNDED PROJECTS TO ACCESS EXPERTISE WITHIN THE  
16 BIOTECH AND PHARMACEUTICAL PARTNERS IN THE AREAS OF  
17 DISCOVERY, PRECLINICAL, REGULATORY, CLINICAL TRIAL  
18 DESIGN, AND MANUFACTURING PROCESS DEVELOPMENT.

19 RIGHT NOW EACH RFA DEFINES THE SCOPE OF  
20 FUNDED RESEARCH WHICH MAY BE NARROWER THAN THE  
21 CURRENTLY APPROVED CONCEPT SCOPE WHICH ENCOMPASSED A  
22 REALLY BROAD RANGE ALL THE WAY FROM BASIC RESEARCH  
23 TO PHASE II CLINICAL TRIALS.

24 THE STRATEGIC PARTNERSHIP CONTAINS TWO  
25 UNIQUE FEATURES IN ADDITION TO THE TWICE YEARLY

## BARRISTERS' REPORTING SERVICE

1 SOLICITATION THAT DISTINGUISH IT FROM THE DISEASE  
2 TEAM CONCEPT. THE STRATEGIC PARTNERSHIP, ONE,  
3 REQUIRES APPLICANTS TO SHOW EVIDENCE OF EITHER  
4 HAVING THE FINANCIAL CAPACITY TO MOVE THE PROJECT  
5 THROUGH DEVELOPMENT AND HAVE FINANCIAL STRENGTH OR  
6 CAPITAL TO DO SO OR, TWO, IT REQUIRES CO-FUNDING  
7 FROM THE APPLICANT OR FROM THEIR STRATEGIC PARTNER  
8 REGARDLESS OF THE STAGE OF RESEARCH.

9 SO, AS YOU KNOW, THE FIRST RFA UNDER THE  
10 STRATEGIC PARTNERSHIP INITIATIVE IS ANTICIPATED FOR  
11 ICOC CONSIDERATION AT THE NEXT BOARD MEETING OCTOBER  
12 25TH. AND THE PLAN WAS TO HAVE ISSUED REPEAT CALLS  
13 APPROXIMATELY EVERY SIX TO NINE MONTHS IN FISCAL  
14 YEAR 2013. ONCE AGAIN, THESE PROJECTS WILL ALSO  
15 HAVE ACTIVE MANAGEMENT WITHIN CIRM'S EXTERNAL  
16 ADVISORY PANEL, A KEY DECISION POINT, SUCH AS THE  
17 TRANSITION FROM IND FILING TO THE INITIATION OF A  
18 CLINICAL TRIAL.

19 SO THE ONLY MODIFICATION WE'RE ASKING IS,  
20 IF THERE MAY BE EXCEPTIONAL CIRCUMSTANCES, TO  
21 CONSIDER THE POSSIBILITY TO INCREASE THE AWARD TO  
22 \$15 MILLION PER PROJECT SUBJECT TO ICOC APPROVAL AND  
23 WITH FULL, DETAILED BUDGET AND JUSTIFICATION.

24 CHAIRMAN SHEEHY: SO DO I HAVE A MOTION ON  
25 THIS?

**BARRISTERS' REPORTING SERVICE**

1 DR. FRIEDMAN: I SO MOVE.

2 MR. TORRES: SECOND.

3 CHAIRMAN SHEEHY: WHO WAS THE SECOND?

4 MR. TORRES: TORRES.

5 CHAIRMAN SHEEHY: ART. THANK YOU. OKAY.  
6 ANY DISCUSSION?

7 MR. ROTH: YEAH, JEFF. IT'S DUANE. I  
8 JUST HAVE A QUICK COMMENT AS FOLLOW-UP TO THE LAST  
9 REVIEW. AND ELLEN AND ALAN, YOU WERE THERE WHEN THE  
10 CHAIR OF THE REVIEW MADE THE COMMENT ABOUT THE  
11 POSSIBILITY OF A PHASE I/PHASE II IN THESE. AND I  
12 WONDER IF YOU REALLY DISCUSSED THAT, ELLEN, AND  
13 CONSIDERED ADDING THAT AS A FEATURE OF THIS TYPE OF  
14 A GRANT. PHASE I MEANING A CRITICAL PRECLINICAL  
15 STUDY WHERE THEY'VE GOT A PARTNER AND YOU COMPLETE  
16 THAT. AND IF IT IS COMPLETED, THEN YOU CAN  
17 AUTOMATICALLY MOVE TO THE PHASE II PART OF THAT.

18 DR. FEIGAL: WELL, WE ACTUALLY IN PRACTICE  
19 HAVE THE ABILITY TO DO THAT. WHAT WE'RE THINKING OF  
20 DOING, BUT WE DIDN'T THINK WE ACTUALLY NEEDED TO GO  
21 TO THE ICOC FOR THIS, IS EVEN THOUGH WE HAVE A TOTAL  
22 AWARD AMOUNT THAT'S AVAILABLE, THAT WE CAN PUT  
23 DIFFERENT CEILINGS ON PARTICULAR ASPECTS OF THE  
24 RESEARCH SUCH THAT WHAT WE WANT TO MAKE SURE OF IS  
25 THAT THEY DON'T BURN THROUGH THE ENTIRE AMOUNT

## BARRISTERS' REPORTING SERVICE

1 BEFORE THEY ACTUALLY GET TO A KEY PART OF THE  
2 RESEARCH THAT'S NEEDED AND IS PART OF THE PROJECT.

3 SO WE DEFINITELY ARE THINKING ABOUT HAVING  
4 DIFFERENT CEILINGS; FOR EXAMPLE, THE IND ENABLING  
5 STAGE AND THEN THE CLINICAL TRIAL STAGE. AND WE ARE  
6 PLANNING TO HAVE AN EXTERNAL ADVISORY PANEL LOOK AT  
7 THE DATA AND LOOK AT THEIR PROGRESS AT THOSE VERY  
8 KEY MILESTONES WHEN THEY'RE GOING FROM THE FILING OF  
9 THE IND BEFORE THEY START THEIR CLINICAL TRIAL.

10 SO I THINK, IN ESSENCE, WE'LL BE ABLE TO  
11 ACCOMPLISH SOME OF THE THINGS THAT WERE BROUGHT UP.

12 MR. ROTH: SO I'M NOT GOING TO BELABOR IT,  
13 BUT I WOULD LIKE TO SEE US CLEARLY COMMUNICATE SO  
14 THAT BOTH THE REVIEWERS AND THE APPLICANTS  
15 UNDERSTAND THAT NUANCE, THAT THEY CAN COME IN WITH A  
16 PROGRAM THAT IS CLEARLY DEPENDENT ON THE RESULTS OF  
17 EARLY WORK TO BE DONE, LIKE PRECLINICAL, AND THAT  
18 THAT WILL NOT PENALIZE THEM FOR THE FULL PROGRAM,  
19 BUT IT WILL BE A HARD STOP IF THAT DATA DOES NOT  
20 COME TOGETHER IN A PARTICULAR PERIOD OF TIME.

21 DR. FEIGAL: I THINK ACTUALLY WE COULD  
22 ACCOMPLISH THAT WITH CLEAR MILESTONES, GO/NO-GO  
23 MILESTONES.

24 MR. ROTH: I AGREE, BUT LET'S CLEARLY  
25 COMMUNICATE THAT TO BOTH SIDES BECAUSE I FELT, FROM

## BARRISTERS' REPORTING SERVICE

1 LISTENING TO THAT REVIEW, THERE MAY HAVE BEEN  
2 ANOTHER THREE OR FOUR THAT WOULD HAVE BEEN, IF YOU  
3 JUST FOCUSED ON THE PRECLINICAL, AND I GOT TOO  
4 CARRIED AWAY WITH THE CLINICAL, MAYBE WOULD HAVE  
5 BEEN FUNDED. SO THAT'S WHY I JUST -- I DO THINK YOU  
6 HAVE THE TOOLS TO DO IT, BUT LET'S CLEARLY  
7 COMMUNICATE THAT TO THE REVIEWERS ESPECIALLY AND TO  
8 THE APPLICANTS, THAT IF YOU'RE SOFT ON YOUR  
9 PRECLINICAL, YOU MAY HAVE A GREAT CLINICAL PLAN, BUT  
10 IF THAT'S SOFT, WE'RE NOT GOING TO GO BEYOND THAT  
11 TILL YOU HAVE HARD DATA THERE.

12 CHAIRMAN SHEEHY: IS THIS SOMETHING YOU  
13 WANT TO AMEND THE MOTION?

14 MR. ROTH: NO. I DON'T THINK WE NEED TO  
15 AMEND IT. I THINK IT'S FINE. GO AHEAD AND HAVE A  
16 VOTE.

17 DR. FEIGAL: I THINK WHAT WE WILL BE CLEAR  
18 ABOUT IS ON -- PERHAPS IT WILL COME OUT IN THE  
19 OCTOBER SESSION, BUT AT ANY RATE WE WANT TO MAKE  
20 SURE THAT THEY KNOW THAT THE INITIAL PIECE HAS TO BE  
21 STRONG AND THE ABILITY TO DO THAT SECOND PART, THE  
22 ACTUAL CLINICAL TRIAL, WILL BE DEPENDENT OBVIOUSLY  
23 ON THEM BEING ABLE TO SUCCESSFULLY COMPLETE THE  
24 FIRST PART.

25 MR. ROTH: THAT'S RIGHT. AND REMEMBER



## BARRISTERS' REPORTING SERVICE

1 THEY HAVE A STRATEGIC PARTNER THAT'S FUNDING THAT  
2 EARLY STAGE TOO, I MEAN CO-FUNDING. IT SHOULD WORK.

3 CHAIRMAN SHEEHY: ARE THERE ADDITIONAL  
4 QUESTIONS, COMMENTS FROM BOARD MEMBERS?

5 MS. SAMUELSON: YEAH. THIS IS JOAN. I  
6 GUESS -- AND THIS FOLLOWS SOMEWHAT FROM DUANE'S  
7 COMMENTS. I'D LIKE TO KNOW WHAT IT IS ABOUT THE  
8 STATE OF FUNDING AND STEM CELL SCIENCE THAT TELLS  
9 THE STAFF THAT THIS IS THE BEST USE OF THOSE FUNDS  
10 AT THIS POINT. AND I WOULD SAY MORE, BUT I DON'T  
11 THINK I SHOULD BE TALKING ABOUT --

12 DR. TROUNSON: JOAN, ALAN HERE. LET ME  
13 JUST TRY AND ANSWER PART OF THAT.

14 MS. SAMUELSON: THANK YOU.

15 DR. TROUNSON: SO WITH THESE INDUSTRY  
16 AWARDS, WHAT WE'RE LOOKING FOR ARE PARTNERSHIPS WITH  
17 SUBSTANTIAL FUNDING THAT'S GOING TO COME TO THE  
18 PROJECT SO THAT WE'RE NOT ACTUALLY FUNDING THE WHOLE  
19 OF THE PROJECT. IT DOES TWO THINGS. IT OFTEN  
20 BRINGS, GENERALLY BRINGS A VERY FOCUSED PARTNER WHO  
21 IS USUALLY VERY EXPERIENCED IN THESE AREAS. ALSO  
22 BRINGS MONEY THAT OTHERWISE WE WOULD BE EXPENDING IN  
23 THESE PROJECTS. SO IT'S LEVERING OUR DOLLARS.

24 MS. SAMUELSON: I'M FAMILIAR WITH THE RFA  
25 SINCE WE RECENTLY WENT THROUGH IT.

**BARRISTERS' REPORTING SERVICE**

1 DR. TROUNSON: RIGHT. AND THEN THE REALLY  
2 CRITICAL PART AS WELL IS THAT IT WILL VERY LIKELY  
3 LEAVE THAT PROJECT WITH A FOLLOW-ON FUNDING PARTNER,  
4 PARTICULARLY IF THE PROJECT IS SUCCESSFUL. IF IT'S  
5 NOT SUCCESSFUL, IT WILL BE WOUND UP. BUT IN THE  
6 EVENT THAT IT'S SUCCESSFUL, IT'S VERY LIKELY TO HAVE  
7 A FOLLOW-ON FUNDING PARTNER, SOMETHING THAT WE WOULD  
8 PROBABLY NOT BE ABLE TO OURSELVES FUND IN PHASE III  
9 OR PHASE IV.

10 SO I THINK THESE KIND OF COMPONENTS ARE  
11 REALLY CRITICAL FOR ENABLING THESE STUDIES TO GET TO  
12 THE MARKETPLACE IN A VERY EFFICIENT AND EFFECTIVE  
13 WAY.

14 DR. FEIGAL: AND THEY STILL, JOAN, HAVE TO  
15 BE COMPELLING IN TERMS OF THEIR RATIONALE. SO IT'S  
16 NOT JUST THESE PROJECTS ARE FEASIBLE, BUT THEY HAVE  
17 TO HAVE A STRONG UNDERPINNING EITHER WITH THE  
18 SCIENTIFIC RATIONALE IN THE DATA THAT THEY PRESENT.  
19 SO THESE ARE ALL EVIDENCE-BASED PROJECTS THAT ARE  
20 COMING FORWARD.

21 MS. SAMUELSON: RIGHT. RIGHT. AND THAT'S  
22 WHERE MY CONCERN IS.

23 DR. FEIGAL: OKAY.

24 MR. ROTH: JEFF, CAN WE CALL THE QUESTION?

25 CHAIRMAN SHEEHY: OKAY. DO WE HAVE ANY

**BARRISTERS' REPORTING SERVICE**

1 PUBLIC COMMENT AT YOUR SITE, DUANE?

2 MR. ROTH: NO.

3 CHAIRMAN SHEEHY: ANY PUBLIC COMMENT IN  
4 SAN FRANCISCO? THEN I THINK WE'RE READY TO GO TO A  
5 ROLL CALL. AND COULD YOU RESTATE THE MOTION, JAMES?

6 MR. HARRISON: YES. THAT MOTION IS TO  
7 RECOMMEND APPROVAL OF STRATEGIC PARTNERSHIP II  
8 CONCEPT PROPOSAL.

9 MS. BONNEVILLE: SUE BRYANT.

10 DR. BRYANT: YES.

11 MS. BONNEVILLE: MARCY FEIT.

12 MS. FEIT: YES.

13 MS. BONNEVILLE: MICHAEL FRIEDMAN.

14 DR. FRIEDMAN: YES.

15 MS. BONNEVILLE: SHLOMO MELMED. PHIL  
16 PIZZO.

17 DR. PIZZO: YES.

18 MS. BONNEVILLE: DUANE ROTH.

19 MR. ROTH: YES.

20 MS. BONNEVILLE: JOAN SAMUELSON.

21 MS. SAMUELSON: NO.

22 MS. BONNEVILLE: JEFF SHEEHY.

23 CHAIRMAN SHEEHY: YES.

24 MS. BONNEVILLE: JON SHESTACK.

25 MR. SHESTACK: YES.

**BARRISTERS' REPORTING SERVICE**

1 MS. BONNEVILLE: OS STEWARD.  
2 DR. STEWARD: ABSTAIN.  
3 MS. BONNEVILLE: ART TORRES.  
4 MR. TORRES: AYE.  
5 MS. BONNEVILLE: JONATHAN THOMAS.  
6 CHAIRMAN THOMAS: YES.  
7 MS. BONNEVILLE: CHRISTINA VUORI.  
8 DR. VUORI: YES.  
9 CHAIRMAN SHEEHY: OKAY. THAT MOTION  
10 CARRIES.

11 THE NEXT ITEM WE HAVE IS CONSIDERATION OF  
12 INCLUDING THE BUDGET AS A FORMAL CRITERION FOR  
13 APPLICATION REVIEWS. STAFF HAS A PROPOSAL. DR.  
14 FEIGAL, COULD YOU LEAD US THROUGH THAT?

15 DR. FEIGAL: YES. YOU ALL HAVE A PREREAD.  
16 SO LET ME TRY AND CAPTURE THE HIGHLIGHTS OF WHAT  
17 THIS IS ABOUT, THE MEMO FROM SEPTEMBER 28TH. SO THE  
18 TOPIC OF BUDGETARY REVIEW FOR CIRM RESEARCH AWARDS  
19 WAS CONCEPTUALLY DISCUSSED AT THE JULY 25TH SCIENCE  
20 SUBCOMMITTEE MEETING, AND THE RECOMMENDATION WAS TO  
21 RETURN TO THE SCIENCE SUBCOMMITTEE IN ADVANCE OF THE  
22 ICOC OCTOBER MEETING TO HAVE A MORE IN-DEPTH  
23 DISCUSSION OF THE ISSUES.

24 AT THE JULY DISCUSSION, THE SCIENCE  
25 SUBCOMMITTEE STRONGLY RECOMMENDED AGAINST

## BARRISTERS' REPORTING SERVICE

1 INCORPORATING BUDGETARY CONSIDERATIONS INTO THE  
2 SCORING FOR A PROJECT WHICH THEY FELT SHOULD REMAIN  
3 FOCUSED ON THE SCIENTIFIC MERITS UNLESS THE BUDGET  
4 DIRECTLY IMPACTED ON THE DESIGN AND FEASIBILITY OF  
5 THE PROJECT. OTHERWISE, IT SHOULD JUST BE COMMENTS  
6 THAT ARE CAPTURED AND COMMUNICATED TO THE ICOC.

7 THE SCIENCE SUBCOMMITTEE SUGGESTED THAT  
8 BUDGET CONSIDERATIONS BE A SEPARATE DISCUSSION ITEM  
9 FROM THE SCORING OF EACH APPLICATION WITH COMMENTS  
10 TO BE CAPTURED AS PART OF THE SUMMARY. THE SCIENCE  
11 SUBCOMMITTEE NOTED THAT ICOC SHOULD EXPLICITLY ALLOW  
12 CIRM OFFICERS TO HAVE THE FLEXIBILITY AND THE  
13 DISCRETION TO CONSIDER THESE COMMENTS AND OTHER  
14 APPROPRIATE CHANGES IN THEIR DISCUSSIONS WITH THE  
15 APPLICANTS AT THE TIME OF THE PREFUNDING  
16 ADMINISTRATIVE REVIEW.

17 CURRENTLY THE GRANTS WORKING GROUP  
18 SCIENTIFIC MEMBERS DISCUSSION AND SCORING ON  
19 SUBMITTED APPLICATIONS TO CIRM'S INITIATIVE HAVE  
20 PRIMARILY FOCUSED ON SCIENTIFIC MERITS OF EACH  
21 APPLICATION, AND THEY DO NOT REFLECT BUDGETARY OR  
22 OTHER FINANCIAL MATTERS.

23 THE BUDGET CONSIDERATIONS ARE INDIRECTLY  
24 BROUGHT INTO THE SCORING ON THE PRINCIPAL  
25 INVESTIGATOR COMPONENT FOR THE OVERALL SCORE OF A

## BARRISTERS' REPORTING SERVICE

1 PROPOSAL IF THE GRANT REVIEW GROUP THINKS THE BUDGET  
2 ADVERSELY IMPACTS ON THE DESIGN OR ON THE  
3 FEASIBILITY OF ACCOMPLISHING THE OBJECTIVES OF THE  
4 RESEARCH. OTHERWISE, THE BUDGET AND THE FINANCIAL  
5 CONSIDERATIONS ON GWG RECOMMENDED AND ICOC APPROVED  
6 AWARDS ARE SET BY THE CIRM SCIENCE OFFICERS AND THE  
7 CIRM GRANTS MANAGEMENT STAFF DURING THE PREFUNDING  
8 ADMINISTRATIVE REVIEW.

9 AT THIS STAGE, HOWEVER, IT'S OFTEN VERY  
10 CHALLENGING TO MAKE SUBSTANTIVE CHANGES TO THE  
11 BUDGET BASED ON THE APPROPRIATENESS OF STUDY  
12 ACTIVITIES AND COSTS GIVEN THE ICOC APPROVAL AT A  
13 GIVEN BUDGET AMOUNT.

14 IN RECOGNITION OF CIRM'S RESPONSIBILITY TO  
15 BE GOOD STEWARDS OF THE TAXPAYER DOLLARS, WE WOULD  
16 LIKE TO AUGMENT OUR CURRENT PROCEDURES TO INCREASE  
17 BUDGET SCRUTINY AS PART OF THE PRIMARY REVIEW  
18 PROCESS. WE THINK THAT ALL APPLICATIONS FOR CIRM  
19 AWARDS SHOULD BE CAREFULLY EXAMINED FOR BUDGETARY  
20 APPROPRIATENESS, BUT PARTICULARLY FOR THE  
21 TRANSLATIONAL INITIATIVES AND THE LARGE COMPLEX AND  
22 EXPENSIVE EARLY TRANSLATION AND DISEASE TEAM AWARDS.  
23 THEY ALL MERIT INCREASED AND FOCUSED ATTENTION ON  
24 THE BUDGET DURING THE GWG DISCUSSION BY THE  
25 APPROPRIATE EXPERTISE TO ENSURE THAT APPROPRIATE AND

## BARRISTERS' REPORTING SERVICE

1 REASONABLE ALIGNMENT WITH THE PROJECT OBJECTIVES AND  
2 ACTIVITIES ARE MAINTAINED.

3 THE PREREAD GIVES YOU SOME EXAMPLES OF  
4 SOME THINGS THAT WE'VE IDENTIFIED AS ISSUES DURING  
5 THE REVIEW OF SOME OF THESE PROPOSALS. PEOPLE MAY  
6 EITHER GROSSLY UNDERESTIMATE OR GROSSLY OVERESTIMATE  
7 THEIR BUDGET NEEDS. AND UNTIL BUDGET AND FINANCIAL  
8 ISSUES ALONG WITH THEIR POTENTIAL RESOLUTION ARE  
9 EXPLICITLY ADDRESSED, IT MAY BE VERY DIFFICULT FOR  
10 CIRM OFFICERS TO ADDRESS AND NEGOTIATE THESE ISSUES  
11 POST ICOC APPROVAL.

12 SO OUR RECOMMENDATION IS THE FOLLOWING:  
13 AS PART OF CIRM'S RESPONSIBILITY TO BE GOOD STEWARDS  
14 OF THESE DOLLARS, WE PROPOSE AUGMENTING THE CURRENT  
15 REVIEW PROCEDURES TO INCREASE THE BUDGET REVIEW AS  
16 PART OF THE PRIMARY REVIEW PROCESS. THIS POLICY  
17 WOULD APPLY TO ALL REVIEWS OF THE DISEASE TEAMS,  
18 THESE EARLY TRANSLATIONAL DEVELOPMENT CANDIDATES,  
19 AND THE STRATEGIC PARTNERSHIP RFA, AND IT COULD  
20 POTENTIALLY BE APPLIED TO OTHER NEW RFA'S AS DEEMED  
21 APPROPRIATE.

22 AND HERE'S THE PROCESS WE PROPOSE. TO  
23 ASSIST IN THE GRANT REVIEW GROUP REVIEW, WE WILL  
24 HAVE THE APPROPRIATE EXPERTISE ON BUDGET AND  
25 FINANCIAL MATTERS. THIS COULD BE A SPECIALIST

## BARRISTERS' REPORTING SERVICE

1 REVIEWER OR IT COULD BE ASSIGNED TO A GRANT REVIEW  
2 GROUP REVIEWER WHO HAS THE APPROPRIATE BACKGROUND  
3 AND EXPERTISE TO REVIEW BUDGET ISSUES TO REVIEW  
4 THESE APPLICATIONS FOR SOUND BUDGETING AND PROVIDE  
5 COMMENTS OR QUESTIONS TO THE GWG FOR CONSIDERATION  
6 BY THE REVIEWERS BEFORE THE REVIEWERS' FINAL SCORES  
7 ARE ENTERED.

8 IF ARE THE FINANCIAL OR THE BUDGETARY  
9 MATTERS POTENTIALLY DIRECTLY IMPACT ON THE DESIGN OR  
10 THE ABILITY TO ACTUALLY CONDUCT THE PROJECT, AND,  
11 FRANKLY, WE THINK THOSE WILL BE RARE, NOT COMMON  
12 INSTANCES, THEN THE GWG COULD CONSIDER THIS ISSUE IN  
13 THE SCORING. OTHERWISE, THE BUDGET AND THE  
14 FINANCIAL ISSUES IN QUESTION WILL NOT CONTRIBUTE TO  
15 THE SCIENTIFIC SCORE.

16 AS APPROPRIATE, THE REVIEW SUMMARIES THAT  
17 ARE SENT TO THE ICOC WILL IDENTIFY THE SCIENTIFIC AS  
18 WELL AS BUDGET OR OTHER ISSUES. AND TO THE EXTENT  
19 THAT IT'S ENDORSED BY THE GWG, THE REVIEW SUMMARIES  
20 WILL ALSO IDENTIFY POTENTIAL RESOLUTION SHOULD THE  
21 ICOC APPROVE A GIVEN AWARD WITH BUDGET ISSUES. AND  
22 THEN CIRM OFFICERS WOULD BE PROVIDED THE DISCRETION  
23 TO CONSIDER THE BUDGET COMMENTS AS WELL AS THE  
24 NONBUDGET RECOMMENDATIONS IN THEIR NEGOTIATION WITH  
25 THE APPLICANT.



## BARRISTERS' REPORTING SERVICE

1 WE THINK INCREASING THE IMPORTANCE OF THIS  
2 TYPE OF REVIEW AND ENCOURAGING APPLICANTS TO PROPOSE  
3 RIGOROUS, REALISTIC, AND VETTED BUDGETS WILL FURTHER  
4 OUR MISSION TO BE GOOD STEWARDS OF THESE TAXPAYER  
5 DOLLARS. AND THESE ADDITIONS WILL NOT SIGNIFICANTLY  
6 INCREASE THE WORKLOAD BURDEN AND WILL EXPLICITLY  
7 ACKNOWLEDGE THE PROGRAM GOALS, OUR SCIENTIFIC PLANS,  
8 OUR ACCURATE BUDGETING, AND OUR PROOF OF SPENDING  
9 ARE LINKED.

10 CHAIRMAN SHEEHY: DO WE HAVE QUESTIONS  
11 FROM THE BOARD MEMBERS?

12 MR. ROTH: MOTION TO APPROVE.

13 DR. PIZZO: SECOND.

14 CHAIRMAN SHEEHY: ANY DISCUSSION?

15 DR. VUORI: JEFF, THIS IS CHRISTINA. I  
16 WOULD LIKE TO MAKE ONE COMMENT OR MAYBE CLARIFYING  
17 QUESTION. I ACTUALLY THINK CONCEPTUALLY WOULD BE  
18 COMFORTABLE IN AN APPROACH WHERE THE SCIENTIFIC  
19 MERIT SCORE IS CLEARLY STATED BY THE GRANTS WORKING  
20 GROUP WITH NO INFLUENCE BY THE BUDGET CONSIDERATION  
21 OTHER THAN IF THE BUDGET DIRECTLY IMPACTS THE DESIGN  
22 AND FEASIBILITY OF THE PROJECT.

23 DR. FEIGAL: WE AGREE.

24 DR. VUORI: OKAY. ALL RIGHT. SO THAT'S  
25 TO CLARIFY THAT THAT'S STILL THE INTENT. IF THE

## BARRISTERS' REPORTING SERVICE

1 OTHER CONSIDERATIONS REGARDING THE BUDGET THAT MAY  
2 AFFECT THE RECOMMENDATION BY THE GRANTS WORKING  
3 GROUP, THEN STATE THAT SEPARATELY.

4 DR. FEIGAL: WE'RE IN AGREEMENT.

5 DR. VUORI: OKAY.

6 DR. FRIEDMAN: JEFF, THIS IS MIKE  
7 FRIEDMAN, ALTHOUGH I APPROVE OF THIS, I WASN'T THE  
8 ONE MAKING THE MOTION. I DON'T KNOW IF IT MATTERS.

9 CHAIRMAN SHEEHY: DR. PIZZO. OKAY. THANK  
10 YOU.

11 DR. BRYANT: IS THE LANGUAGE IN HERE CLEAR  
12 ENOUGH FOR THE GRANT WORKING GROUP TO KNOW THAT  
13 THEY'RE TO REVIEW THE SCIENCE FIRST AND THE FINANCES  
14 LATER? I WASN'T SURE ABOUT THAT THE WAY IT WAS  
15 WRITTEN.

16 DR. FEIGAL: THE WAY IT'S WRITTEN IS THAT  
17 ONLY IF -- THE BUDGET REMARKS WILL BE GIVEN, BUT  
18 THEY WILL BE VERY CLEARLY GUIDED THAT IT SHOULD ONLY  
19 IMPACT A SCIENTIFIC SCORE IF IT REALLY TRULY IMPACTS  
20 ON THE FEASIBILITY OR THE DESIGN OF THE PROJECT.  
21 THIS IS ACTUALLY THE LANGUAGE THAT THEY ALREADY HAVE  
22 IN THERE FOR THE PRINCIPAL INVESTIGATOR COMPONENT OF  
23 THEIR REVIEW. SO I'M NOT -- I HAVEN'T MADE UP NEW  
24 LANGUAGE. THIS IS ACTUALLY LANGUAGE THAT IS ALREADY  
25 PART OF THAT. WHAT WE'RE DOING IS JUST FORMALIZING

**BARRISTERS' REPORTING SERVICE**

1 IT.

2 MR. ROTH: SO, AGAIN, IN ADDITION TO MY  
3 MOTION, I WOULD SUGGEST THAT YOU TAKE THAT CLEARLY  
4 IN THAT KIND OF LANGUAGE.

5 DR. BRYANT: I AGREE. I THINK IT'S  
6 IMPORTANT FOR PEOPLE TO KNOW THAT IT'S THE  
7 FEASIBILITY OF THE SCIENCE THAT WE WANT TO ADDRESS  
8 FIRST, AND THEN WHAT IS IT GOING TO TAKE TO GET THAT  
9 DONE.

10 CHAIRMAN SHEEHY: CAN I ASK A QUESTION ON  
11 WHAT THE PROCESS, JUST TO BE VERY MECHANICAL ABOUT  
12 IT? HOW IS THIS GOING TO LOOK AT THE WORKING GROUP?  
13 MAYBE GIL CAN WALK US THROUGH WHAT THAT PROCESS  
14 WOULD LOOK LIKE. THAT WOULD HELP ME.

15 DR. SAMBRANO: I THINK IT WILL VARY FROM  
16 RFA TO RFA, BUT I THINK THE GENERAL IDEA IS ALL OF  
17 THIS WOULD BE CERTAINLY CLEARLY STATED IN THE RFA IN  
18 THE CRITERIA. AND THE PROCESS THAT WE NORMALLY TAKE  
19 WITH REVIEWERS IS WE PROVIDE A GUIDANCE DOCUMENT,  
20 AND WE USUALLY EXPLAIN TO THEM BOTH AT THE START OF  
21 THE REVIEW MEETING AND PRIOR TO THE REVIEW MEETING  
22 WHAT THOSE CRITERIA MEAN AND HOW THEY SHOULD BE  
23 INTERPRETED.

24 SO FOR SOMETHING LIKE THE BUDGET, WE WOULD  
25 HAVE A DISCUSSION ABOUT WHAT, FOR EXAMPLE, SHOULD BE

## BARRISTERS' REPORTING SERVICE

1 CONSIDERED AN ITEM THAT WOULD IMPACT ON THE SCORE OR  
2 SOMETHING THAT WOULD NOT. SO WE TAKE THIS THROUGH.

3 NOW, IN TERMS OF WHO WOULD BE THE  
4 QUALIFIED PERSON OR SPECIALIST REVIEWER WHO WOULD  
5 REVIEW THE BUDGET, I THINK IT ALSO DEPENDS. WE HAVE  
6 SOME RFA'S WHERE CERTAINLY KNOWLEDGE OF  
7 MANUFACTURING COSTS MIGHT REQUIRE A SPECIFIC  
8 INDIVIDUAL WITH THAT BACKGROUND TO BE ABLE TO  
9 COMMENT ON THAT. WHERE THERE ARE NOT MANUFACTURING  
10 COSTS OR OTHER COSTS, WE MAY HAVE TO HAVE ANOTHER  
11 EXPERT. SO THIS COULD ACTUALLY BE EITHER A GROUP OF  
12 EXPERTS THAT COULD COVER ALL THE TYPES OF COSTS THAT  
13 ARE REPRESENTED ACROSS THESE APPLICATIONS. IN MORE  
14 SIMPLE RFA'S OR COMPETITIONS, IT MIGHT BE  
15 INDIVIDUALS WHO CAN PROVIDE THAT COVERAGE.

16 I THINK, IN GENERAL, WE DON'T ANTICIPATE  
17 THAT A GRANTS WORKING GROUP MEMBER NORMALLY HAS THE  
18 ABILITY TO COVER BUDGET. SO I THINK THE IDEA BEHIND  
19 THIS IS TO PROVIDE SPECIAL EXPERTISE THAT CAN ADD TO  
20 THE GRANTS WORKING GROUP IN ORDER TO PROVIDE THIS  
21 KIND OF ELEMENT. AND THEN TO PRESENT WHAT IS THEIR  
22 FINDING OR OPINION TO THE GRANTS WORKING GROUP. AND  
23 WHERE THEY FEEL IT MAY HAVE AN IMPACT ON DESIGN OR  
24 FEASIBILITY, TO APPROPRIATELY INCLUDE IT IN THE  
25 SCORE. WHERE IT WOULDN'T, IT WOULD BE SOMETHING

## BARRISTERS' REPORTING SERVICE

1 THAT WE WOULD ALSO JUST WANT TO FLAG SO THAT WHEN WE  
2 NEGOTIATE MILESTONES OR THE BUDGET WITH THEM, THAT  
3 IS IN HAND.

4 ALSO FOR THE BOARD TO UNDERSTAND WHEN  
5 THEY'RE APPROVING SUCH AWARDS WHAT THE RAMIFICATIONS  
6 IN THE BUDGET COULD BE.

7 CHAIRMAN SHEEHY: JUST HOW WOULD WE  
8 CAPTURE? TO DO AN ANALOGY, SO WE HAVE A DISCUSSION  
9 AT THE SCIENTIFIC MERITS OF AN APPLICATION. THEN  
10 REVIEWERS ENTER THEIR SCORES AND THEN THAT SCORE  
11 BECOMES THE SENSE OF THE PEER REVIEW COMMITTEE. SO  
12 MY QUESTION IS HOW DO WE CAPTURE THE CONSISTENT VIEW  
13 OF THE PEER REVIEW GROUP ON BUDGET ITEMS? ARE WE  
14 GOING TO HAVE THEM ASSIGN A SCORE? ARE WE GOING TO  
15 HAVE THEM VOTE THAT WE THINK THAT THIS IS  
16 PROBLEMATIC? OR IS IT JUST GOING TO BE A CALL OUT  
17 AND STAFF WILL PICK THE ONE THAT SEEMED LIKE THE  
18 GROUP IS MOST INTERESTED IN AND THEN STAFF WILL KIND  
19 OF ENFORCE IT?

20 I JUST FEEL LIKE WE'RE MOVING AWAY FROM A  
21 CONSENSUS PEER REVIEW VIEW UNLESS WE HAVE SOME  
22 MECHANISM OR SOME ACTIVITY THAT KIND OF GIVES PEOPLE  
23 A CHANCE TO COLLECTIVELY -- AT LEAST TO ME TO KEEP  
24 THE SAME SORT SENSE OF PEER REVIEW, SOME WAY THAT  
25 THE GROUP CAN COLLECTIVELY EXERCISE THEIR VOICE AND

## BARRISTERS' REPORTING SERVICE

1 HAVE A CONSENSUS VIEW.

2 MS. SAMUELSON: THAT WAS MY CONCERN TOO,  
3 BUT I COULDN'T PUT MY FINGER ON IT. THANK YOU.

4 DR. FEIGAL: RIGHT NOW, AS YOU KNOW,  
5 BUDGET AND FINANCIAL IS NOT A SUBSTANTIVE PART OF  
6 THE DISCUSSION RIGHT NOW AT THE GRANT REVIEW GROUP,  
7 AS I THINK MOST OF US KNOW WHAT WE'RE TRYING TO DO  
8 IS TO IMPLEMENT THAT WITH THIS SPECIALIST OR THE  
9 EXPERTISE. WHAT WE'RE SUGGESTING IS THAT THE  
10 SPECIALISTS OR EXPERTISE PROVIDE THEIR COMMENTS.  
11 THEY WILL GET A CHANCE TO REVIEW EVERYTHING IN  
12 ADVANCE OF THE REVIEW SESSION AND PROVIDE WRITTEN  
13 COMMENTS THAT PEOPLE WILL HAVE THE OPPORTUNITY TO  
14 SEE.

15 SO IF THERE IS A REALLY SIGNIFICANT ISSUE  
16 THAT THEY THINK REALLY IMPACTS ON THE ABILITY TO  
17 ACTUALLY DO THE PROJECT, THEN THE -- AND WE'LL GIVE  
18 THEM EXAMPLES, HYPOTHETICAL EXAMPLES, THEN THEY  
19 WOULD USE THEIR JUDGMENT TO INCORPORATE THAT INTO  
20 THEIR SCORE. OTHERWISE, THESE WILL BE CAPTURED AS  
21 COMMENTS THAT WERE BROUGHT UP DURING THE GRANT  
22 REVIEW GROUP.

23 I'M NOT SURE THAT THERE ACTUALLY HAS TO BE  
24 A CONSENSUS, BUT THESE ARE COMMENTS THAT ARE BROUGHT  
25 UP ABOUT, FOR EXAMPLE, SOMEBODY MAKES A MEDICARE

## BARRISTERS' REPORTING SERVICE

1 COVERAGE FOR X PROCEDURE. I KNOW IT'S 20,000 AND  
2 SOMEBODY IS ASKING FOR 200,000. I DON'T KNOW THAT  
3 THERE NEEDS TO BE CONSENSUS ON THAT. WE WILL  
4 ACTUALLY HAVE TO CHECK AND MAKE SURE THAT IS INDEED  
5 TRUE, BUT WHAT WE'RE TRYING TO DO IS CAPTURE  
6 ACTUALLY BIG-PICTURE BUDGET ITEMS, NOT IN THE WEEDS  
7 DURING THE GRANT REVIEW GROUP SESSION.

8 CHAIRMAN SHEEHY: WHERE DOES THE PEER  
9 REVIEW PART OF THIS COME IN? BECAUSE IT SEEMS LIKE  
10 YOU'RE BRINGING IN AN EXTERNAL REVIEWER TO OFFER  
11 COMMENTS ON THE BUDGET; AND THEN UNLESS THERE'S  
12 SOMETHING THAT'S DIRECTLY RELATED TO THE FEASIBILITY  
13 OF THE SCIENCE, IT'S NOT GOING TO BE INCLUDED IN THE  
14 SCORE. AND SO YOU'RE -- IN OTHER WORDS, THIS SHOULD  
15 EITHER BE SEPARATE FROM THE PEER REVIEW GROUP, IN MY  
16 MIND, OR IT SHOULD INCLUDE SOME PEER REVIEW PROCESS  
17 TO INCORPORATE PEOPLE'S EVALUATION OF THE EVIDENCE  
18 THAT'S BEEN PRESENTED THE SAME WAY AS THEY EVALUATE  
19 SPECIALIST INPUT ON THE SCIENTIFIC MERIT. BUT  
20 UNLESS THERE'S SOME WAY -- MAYBE THEY GET A BUDGET  
21 SCORE, BUT SOME WAY TO HAVE PEOPLE COLLECTIVELY  
22 ASSIGN A VALUE TO THE INFORMATION THAT THEY'VE HEARD  
23 AS OPPOSED TO, WELL, THESE ARE THESE COMMENTS.  
24 WE'VE HEARD THEM. THAT'S GREAT.

25 I MEAN HOW IS THAT DIFFERENT THAN WHAT WE

## BARRISTERS' REPORTING SERVICE

1 DO NOW WHERE INDIVIDUAL MEMBERS, WHICH IS REALLY THE  
2 MOTIVATION FOR THIS BUDGET ITEM, INDIVIDUAL MEMBERS  
3 CALL OUT ITEMS THAT THEY THINK ARE EXCESSIVE,  
4 THEY'RE CAPTURED BY STAFF, STAFF PICKS THOSE UP IN  
5 POSTAWARD NEGOTIATION. NOW WE'RE KIND OF APPLYING  
6 THE IMPRIMATUR OF THE PEER REVIEW GROUP ON THIS  
7 WITHOUT GIVING A PEER REVIEW PROCESS TO KIND OF  
8 FOLLOW THAT IMPRIMATUR.

9 DR. SAMBRANO: SO I DO UNDERSTAND WHERE  
10 YOU'RE COMING FROM BECAUSE THIS IS SOMETHING THAT I  
11 WAS CONSIDERING AS WELL IN TERMS OF HOW DO YOU  
12 DISCUSS A BUDGET AND THEN INCORPORATE IT INTO A WAY  
13 THAT THE GROUP ITSELF IS SAYING THIS IS OUR  
14 RECOMMENDATION OR PROPOSAL. BUT I THINK WE NEED TO  
15 CONSIDER THIS LIKE WE DO WITH ANY OTHER SPECIALIST.  
16 SO WHENEVER WE HAVE A SPECIALIST THAT COMES INTO THE  
17 GROUP, THEY ARE PROVIDING A UNIQUE PERSPECTIVE THAT  
18 IS NOT OTHERWISE PRESENT AMONG THE MEMBERS. SO THEY  
19 ARE CONTRIBUTING IT FOR THEIR CONSIDERATION, AND  
20 THEN THE GRANTS WORKING GROUP USES IT TO WHATEVER  
21 DEGREE OR EXTENT THEY FEEL IS APPROPRIATE.

22 IN THIS CASE WHAT THEY'RE GOING TO  
23 CONSIDER IS A VARIETY OF BUDGETARY ITEMS OF WHICH  
24 THEY'RE GOING TO HAVE TO CONSIDER DO THESE AFFECT  
25 FEASIBILITY AND DESIGN TO ANY EXTENT THAT I COULD



## BARRISTERS' REPORTING SERVICE

1 INCORPORATE THEM IN MY SCORE. THOSE THAT DO WILL GO  
2 INTO THE SCORE. THOSE THAT DO NOT WON'T. BUT IN  
3 ORDER TO MAKE THAT EVALUATION AND JUDGMENT, THEY  
4 REALLY NEED TO HEAR EVERYTHING.

5 AND SO WE WILL END UP WITH THINGS THAT MAY  
6 AFFECT SCORE, WHICH IS FINE. THOSE THAT DON'T, I  
7 THINK WE WOULD RECORD AND KEEP AS THIS WAS THE  
8 OPINION OF THE EXPERT THAT WAS CONTRIBUTING TO THIS  
9 REVIEW. I DON'T THINK WE CAN GET A CONSENSUS FROM  
10 THE WORKING GROUP GIVEN THAT NOT EVERYBODY THERE  
11 WOULD HAVE THAT EXPERTISE TO BE ABLE TO SAY I AGREE  
12 WITH IT.

13 CHAIRMAN SHEEHY: IN TERMS OF CONSENSUS, I  
14 JUST -- I'M USING THE WRONG WORD. CONSENSUS IS THE  
15 WRONG WORD, BUT SOME SORT OF COLLECTIVE VOTE OR SOME  
16 COLLECTIVE POSITION. THE EXTERNAL SPECIALIST AND  
17 THE SCIENTIFIC, THEIR VIEWS ARE DIRECTLY  
18 INCORPORATED IN SOME FASHION INTO THE SCIENTIFIC  
19 SCORE. THERE IS NO SCORE HERE. SO WE RELY ON THE  
20 REVIEWERS NOT NECESSARILY TO BE EXPERTS IN  
21 EVERYTHING THAT THEY HEAR, BUT TO BE GOOD JUDGES OF  
22 WHAT THEY HEAR AND PROVIDE AS A GROUP A SENSE OF THE  
23 VALUE OF WHAT THEY'VE HEARD AS EXPRESSED BY A  
24 NUMERICAL SCORE.

25 SO IN THIS INSTANCE WE DON'T HAVE ANY SORT

## BARRISTERS' REPORTING SERVICE

1 OF FORMAL WAY OF CAPTURING THAT INPUT.

2 DR. VUORI: WHY WOULDN'T THIS EXPERT WRITE  
3 A REVIEW AS ANY OTHER REVIEWER WOULD WRITE FOR A  
4 GRANT?

5 DR. FEIGAL: THEY WOULD.

6 DR. TROUNSON: SO ONE WAY OF DOING THIS,  
7 JUST LISTENING TO THE CONVERSATION, IS THAT WE COULD  
8 ASK THE REVIEWERS IF THEY FELT COMPLETELY  
9 COMFORTABLE WITH THE BUDGET. AND SO THAT MIGHT --  
10 50 PERCENT, NO CHANGE BECAUSE THERE'S NO ISSUE TO BE  
11 REALLY ADDRESSED. AND THEN THERE MAY BE 30 PERCENT  
12 WHERE THEY ALL FEEL THAT A VERY MUCH STRICTER VIEW  
13 OF PART OF THE BUDGET OR SOME OF THE BUDGET NEEDS TO  
14 BE UNDERTAKEN. AND THERE MAY BE IN A FEW PROJECTS  
15 WHERE IT'S COMPLETELY OUTRAGEOUS. AND THAT NEEDS TO  
16 BE BROUGHT TO THE ATTENTION OF THE APPLICANT AND  
17 SOME CORRECTIVE MEASURE DONE.

18 SO I THINK IF YOU ASKED THEM IN A  
19 SEMIQUALITATIVE WAY, YOU COULD GET, I THINK, THE  
20 KIND OF OUTCOME YOU'RE LOOKING FOR BECAUSE THEY  
21 WOULD HAVE HEARD THE COMMENTS FROM OTHER PEOPLE.

22 CHAIRMAN SHEEHY: MAYBE THAT'S THE OPTION  
23 IS JUST ADDING A WINDOW IN THEIR SCOREBOOKS WHERE  
24 THEY COULD -- MAYBE A TRIPARTITE, PROBLEMATIC,  
25 SEVERELY PROBLEMATIC, OR GREEN, YELLOW OR RED, BUT

## BARRISTERS' REPORTING SERVICE

1 SOMETHING THAT GIVES THEM THE OPPORTUNITY SO THAT WE  
2 CAN SAY THIS IS WHAT THE PEER REVIEWERS THOUGHT AS  
3 OPPOSED TO WE HEARD A REVIEW, PEOPLE KIND OF LIKE,  
4 SOME PEOPLE SAID SOMETHING, MOST PEOPLE DIDN'T, AND  
5 WE NEVER GOT THEM TO SAY, I LISTENED TO THAT AND I  
6 ACTUALLY THOUGHT THAT WAS A VERY SERIOUS CONCERN,  
7 AND YOU CAN'T GO FORWARD WITH THIS PROJECT UNTIL  
8 AFTER CIRM STAFF HAS HAD A CHANCE TO REALLY  
9 SERIOUSLY ADDRESS IT.

10 DR. FEIGAL: YEAH. AND, JEFF, I THINK  
11 THAT'S WHAT WE DO EVEN WITH CAPTURING SUMMARIES IS  
12 THAT -- YOU KNOW, AS YOU KNOW, THE STAFF ARE THERE  
13 TO CAPTURE THE DISCUSSION. AND THEY PUT DOWN THE  
14 KEY SCIENTIFIC REMARKS. THEY'RE THERE TO PUT  
15 DOWN -- I THINK THEY COULD CAPTURE THE KEY BUDGET  
16 REMARKS THAT WERE DISCUSSED OR NOT DISCUSSED OR NOT  
17 FELT TO BE CRITICAL OR IMPORTANT. SO I THINK WHAT  
18 IT IS IS ACTUALLY IT'S ADDING ANOTHER SPECIALIST AND  
19 IT'S CHANGING, I THINK, A LITTLE BIT OF THE TENOR OF  
20 THE DISCUSSION ABOUT BUDGET BECAUSE, FRANKLY, I  
21 THINK MOST OF US THINK THAT THERE NEEDS TO BE A  
22 LITTLE BIT MORE ATTENTION PAID FOR THESE VERY  
23 EXPENSIVE GRANTS ON SOME OF THE FINANCIAL ISSUES.  
24 AND UNLESS WE CAPTURE IT BEFORE IT GOES TO ICOC,  
25 IT'S VERY CHALLENGING TO ADDRESS IT OTHERWISE.

## BARRISTERS' REPORTING SERVICE

1           CHAIRMAN THOMAS:  MAYBE A WAY TO APPROACH  
2   THIS WOULD BE TO HAVE, SINCE I KNOW THE SCIENTISTS  
3   ON THE GRANTS WORKING GROUP REALLY WANT TO FOCUS ON  
4   THE SCIENCE AS THE BASIS FOR THEIR SCORE AND NOT  
5   NECESSARILY THE BUDGET, THEY COULD HAVE A SCIENTIFIC  
6   SCORE; BUT IF THERE ARE ISSUES THAT ARE SUFFICIENTLY  
7   LARGE IN THE BUDGETARY FRONT, MAKE IT CONDITIONAL TO  
8   STAFF WORKING OUT THOSE ISSUES WITH THE APPLICANTS  
9   BEFORE ANYTHING CAN GO FORWARD.  AND THEN THE REST  
10  OF THE SMALLER SCALE STUFF COULD BE ADDRESSED IN A  
11  NORMAL P FAR COURSE.

12           CHAIRMAN SHEEHY:  AGAIN, I'M NOT  
13  UNDERSTANDING AT WHAT POINT THE PEER REVIEW GROUP AS  
14  A GROUP WEIGHS IN ON THE BUDGET.  IF IT'S NOT  
15  SOMETHING THAT RAISES TO A SUFFICIENT LEVEL THAT  
16  THEY INCLUDE IT IN THEIR SCORE, WHAT WE HAVE IS A  
17  REVIEW THAT SUDDENLY THE GRANTS WORKING GROUP IS  
18  MAKING DETERMINATIVE, AND WE DON'T DO THAT WITH THE  
19  SPECIALIST REVIEWS WHEN WE DO THIS ON THE SCIENCE,  
20  BUT WE'RE GOING TO MAKE THE BUDGET REVIEW  
21  DETERMINATIVE WITHOUT GETTING A FULL PEER REVIEW  
22  GROUP EVALUATION OF THAT INFORMATION IN SOME SORT OF  
23  OBJECTIVE WAY THAT WE -- WHEN IT COMES TO THE BOARD,  
24  I CAN LOOK AND I CAN SAY THESE ISSUES ARE ONES THAT  
25  WERE VALIDATED BY THE PEER REVIEW GROUP.

**BARRISTERS' REPORTING SERVICE**

1 DR. FEIGAL: I MEAN JUST TO BE CLEAR, WE  
2 DON'T GET CONSENSUS ON EVERY REMARK THAT'S MADE BY  
3 THE SPECIALISTS, NOR DO WE ASK THE GRANT REVIEW  
4 GROUP IS IT RED, YELLOW, OR GREEN. DO YOU AGREE  
5 WITH THE SPECIALIST? BUT WE STILL CAPTURE WHAT THE  
6 SPECIALIST'S REMARKS MIGHT HAVE BEEN.

7 CHAIRMAN SHEEHY: WE GET A NUMBER. SO  
8 THEY LISTED THAT INFORMATION AND THEY GIVE THAT  
9 GRANT A 20, THEY GIVE IT A 50, THEY GIVE IT A 90.  
10 SO THEY HEARD THAT INFORMATION, THEY DIGESTED IT,  
11 AND THEN IT GETS TRANSLATED OUT, THEY HEAR SEVERAL  
12 REVIEWS, AND THAT TRANSLATES INTO A SCORE. WHAT'S  
13 HAPPENING HERE IS WE HAVE THE INPUT, BUT NO  
14 MEASURABLE, DEFINABLE -- AND I THINK JAMES HARRISON.

15 MR. HARRISON: I WAS JUST WONDERING IF FOR  
16 THOSE INSTANCES WHERE THE BUDGETARY INFORMATION DOES  
17 NOT DIRECTLY IMPACT ON THE DESIGN OR FEASIBILITY, SO  
18 THE BUDGET IS NOT REFLECTED IN THE SCORE, BUT THERE  
19 ARE CONCERNS ABOUT ITEMS IN THE BUDGET, IF THAT  
20 COULD BE PART OF PROGRAMMATIC DISCUSSION AND MOTIONS  
21 THAT ARE MADE RECOMMENDING APPROVAL IF THERE ARE  
22 CONDITIONS, FOR EXAMPLE, THAT MEMBERS OF THE WORKING  
23 GROUP THINK SHOULD BE IMPOSED AS A RESULT OF THE  
24 CONCERNS AND THAT COULD BE REFLECTED IN A MOTION.

25 MR. ROTH: JEFF, MAYBE I CAN, BECAUSE

## BARRISTERS' REPORTING SERVICE

1 WE'RE OUT OF TIME, BUT I THINK CONCEPTUALLY THE  
2 BUDGET SHOULD BE PART OF THE CONSIDERATION. AND I  
3 DON'T KNOW THAT ANYBODY WOULD ARGUE WITH THAT, THAT  
4 WE SHOULD BE VERY, VERY CLEAR THAT IF THERE'S NOT  
5 ENOUGH MONEY TO DO THIS PROJECT, THAT SHOULD BE  
6 FLAGGED. IF THERE'S TOO MUCH MONEY IN, THAT SHOULD  
7 BE FLAGGED AND LOOKED AT. HOW THAT GETS DONE  
8 OBVIOUSLY NEEDS SOME MORE DISCUSSION.

9 SO WHY DON'T WE JUST GO AHEAD AND APPROVE  
10 WHAT'S ON THE TABLE, WHICH IS THAT THE BUDGETARY  
11 PIECE OF THIS WILL IN ONE WAY OR ANOTHER GET INTO  
12 THE CONSIDERATION, WHICH IT SHOULD.

13 MS. SAMUELSON: PERHAPS AT THE ICOC  
14 MEETING WE COULD HAVE A DRAFT.

15 MR. ROTH: LET STAFF COME BACK WITH ALL  
16 THIS GREAT INPUT AND SAY HERE'S HOW WE RECOMMEND IT  
17 BE INCORPORATED.

18 DR. FEIGAL: DO YOU WANT IT TO COME TO --  
19 WELL, WE'VE ALREADY COME TO YOU IN JULY AND WE CAME  
20 BACK NOW IN OCTOBER. SO TELL US THE PROCESS FOR  
21 ACTUALLY HOW YOU'D LIKE TO GO TO THE NEXT LEVEL.

22 MS. SAMUELSON: MAYBE JAMES COULD  
23 INCORPORATE WHAT HE JUST SAID.

24 CHAIRMAN SHEEHY: I GUESS THE ORIGINAL  
25 THOUGHT ON THIS IS THAT THIS WOULD ACTUALLY HAVE A

## BARRISTERS' REPORTING SERVICE

1 ROLE IN THE SCORE. SO THE ORIGINAL PROPOSAL WAS  
2 THAT THIS WOULD HAVE A ROLE IN THE SCORE, AND THEN  
3 WE DECIDED THAT IT WOULD NOT NECESSARILY BE FEATURED  
4 IN THE SCORE. SO THAT'S WHAT WE SORT OF HEARD AT  
5 THE LAST MEETING.

6 I MEAN I THINK THIS IS AN IMPORTANT ISSUE,  
7 AND I THINK PERSONALLY, SINCE THIS INVOLVES MONEY  
8 GOING OUT TO GRANTEES, THAT WE SHOULD TRY TO GET IT  
9 RIGHT. I JUST -- I AM NOT COMFORTABLE. I WOULD NOT  
10 VOTE YES ON THIS AS CURRENTLY PROPOSED MYSELF, BUT  
11 I'M HAPPY TO CALL THE QUESTION AND LET BOARD MEMBERS  
12 VOTE ON WHETHER OR NOT TO PROCEED FORWARD WITH THIS.  
13 IF YOU WANT TO COMPROMISE AND ASK THAT WE TABLE THIS  
14 AND LET STAFF PERHAPS BRING SOMETHING TO THE FULL  
15 BOARD. IF THERE'S SOMETHING POTENTIALLY EMERGENT  
16 THERE, THEN WE CAN --

17 MR. ROTH: I'M FINE WITH THAT.

18 DR. BRYANT: COULD I MAKE A COMMENT,  
19 PLEASE? SO WHAT ABOUT HAVING TWO SCORES? YOU COULD  
20 HAVE A SCORE FOR EXCELLENCE IN SCIENCE, SCIENTIFIC  
21 MERIT AND FEASIBILITY OF THE PROJECT, AND THEN YOU  
22 COME HAVE THE APPROPRIATENESS OF THE BUDGET SCORE.

23 DR. STEWARD: COULD I JUST MAKE A  
24 SUGGESTION? I THINK THAT'S ACTUALLY A GREAT IDEA,  
25 BUT I REALLY WONDER IF WE OUGHT TO ENGAGE THE GRANTS

**BARRISTERS' REPORTING SERVICE**

1 WORKING GROUP IN THIS. AND BASICALLY WHAT I'M  
2 SAYING IS TO TABLE IT FOR NOW AND STUDY THIS MATTER  
3 A LITTLE BIT MORE AND A REALLY TRY TO ASK THE GRANTS  
4 WORKING GROUP WHAT THEY THINK WOULD BE THE MOST  
5 VALUABLE WAY TO IMPLEMENT THIS.

6 DR. FRIEDMAN: JEFF, I'M SORRY. THIS IS  
7 MIKE FRIEDMAN AND I APOLOGIZE, BUT I REALLY HAVE TO  
8 GET TO ANOTHER MEETING. AND I HAVE TO SIGN OFF NOW,  
9 AND I APOLOGIZE TO YOU AND TO EVERYONE THERE.

10 CHAIRMAN SHEEHY: THANK YOU, DR. FRIEDMAN.

11 MR. ROTH: I HAVE TO GO AS WELL, JEFF.

12 DR. STEWARD: IT SOUNDS LIKE WE'RE LACKING  
13 A QUORUM AND EFFECTIVELY TABLING IT ANYWAY.

14 CHAIRMAN SHEEHY: I PERSONALLY LIKE THE  
15 IDEA OF GIVING US A WAY TO ASSIGN A SCORE. I GUESS  
16 WE'RE DONE. I THINK WE'RE ADJOURNED. THANK YOU.  
17 EVERYBODY IS DISAPPEARING.

18 (LACKING A QUORUM, THE MEETING WAS  
19 THEN ADJOURNED AT 2:12 P.M.)

20  
21  
22  
23  
24  
25



**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 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 8, 2012, 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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