

**BETH C. DRAIN, CA CSR NO. 7152**

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: VIA ZOOM

DATE: OCTOBER 26, 2023  
9 A.M.

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

FILE NO.: 2023-33

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**I N D E X**

<b>ITEM DESCRIPTION</b>	<b>PAGE NO.</b>
<b>OPEN SESSION</b>	
1. CALL TO ORDER	3
2. ROLL CALL	3
<b>ACTION ITEMS</b>	
3. CONSIDERATION OF APPLICATIONS SUBMITTED IN RESPONSE TO TRANSLATIONAL PROJECTS PROGRAM ANNOUNCEMENT (TRAN 1, 2, 3 OR 4)	4
<b>DISCUSSION ITEMS</b>	
4. GENERAL COMMENTS ON ARS PROCESS	NONE
5. PUBLIC COMMENT	NONE
6. ADJOURNMENT	77

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OCTOBER 26, 2023; 9 A.M.

MR. TOCHER: VITO, YOU ARE WELCOME TO OPEN THE MEETING.

CHAIRMAN IMBASCIANI: GOOD MORNING, EVERYONE. WE ARE READY TO START. YES.

MR. TOCHER: GREAT. OKAY. THEN WE'LL ARE TURN TO GIL TO DO THE PRESENTATION ON THESE -- ON THE GRANT APPLICATIONS BEFORE US TODAY.

VICE CHAIR BONNEVILLE: WE NEED A ROLL CALL VOTE, SCOTT?

MR. TOCHER: SORRY.

DAN BERNAL.

MR. BERNAL: PRESENT.

MR. TOCHER: MARIA BONNEVILLE.

VICE CHAIR BONNEVILLE: PRESENT.

MR. TOCHER: LEONDRA CLARK-HARVEY.

DR. CLARK-HARVEY: PRESENT.

MR. TOCHER: YSABEL DURON.

MS. DURON: HERE.

MR. TOCHER: MARK FISCHER-COLBRIE.

DR. FISCHER-COLBRIE: HERE.

MR. TOCHER: FRED FISHER.

DR. FISHER: PRESENT.

MR. TOCHER: ELENA FLOWERS.

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1 DR. FLOWERS: PRESENT.  
2 MR. TOCHER: DAVID HIGGINS.  
3 DR. HIGGINS: HERE.  
4 MR. TOCHER: VITO IMBASCIANI.  
5 CHAIRMAN IMBASCIANI: PRESENT.  
6 MR. TOCHER: STEVEN JUELSGAARD.  
7 MR. JUELSGAARD: PRESENT.  
8 MR. TOCHER: RICH LAJARA.  
9 MR. LAJARA: PRESENT.  
10 MR. TOCHER: CHRIS MIASKOWSKI. LAUREN  
11 MILLER-ROGEN.  
12 MS. MILLER-ROGEN: HERE.  
13 MR. TOCHER: ADRIANA PADILLA.  
14 DR. PADILLA: HERE.  
15 MR. TOCHER: JOE PANETTA.  
16 MR. PANETTA: HERE.  
17 MR. TOCHER: ANNE-MARIE DULIEGE. JUDY  
18 CHOU. MARV SOUTHARD. KAROL WATSON. KEVIN XU.  
19 OKAY. GREAT. WE HAVE A QUORUM. GIL.  
20 DR. MELMED: I WASN'T CALLED. I'M SORRY.  
21 MR. TOCHER: HI, SHLOMO. THANK YOU. YES.  
22 I WAS JUST TAKING THE POLL OF THE ARS MEMBERS, BUT  
23 THANK YOU FOR LETTING ME KNOW YOU'RE HERE.  
24 DR. SAMBRANO: OKAY. GOOD MORNING,  
25 EVERYONE. I'M GOING TO START THE PRESENTATION.

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1 SO TODAY I'M GOING TO PRESENT THE  
2 RECOMMENDATIONS FROM THE GRANTS WORKING GROUP  
3 RELATED TO THE LATEST CYCLE OF THE TRANSLATIONAL  
4 PROGRAM. AS ALWAYS, WE BEGIN WITH A STATEMENT OF  
5 OUR MISSION, ACCELERATE WORLD-CLASS SCIENCE TO  
6 DELIVER TRANSFORMATIVE REGENERATIVE MEDICINE  
7 TREATMENTS IN AN EQUITABLE MANNER TO A DIVERSE  
8 CALIFORNIA AND WORLD.

9 AS ALWAYS, THIS REPRESENTS WHAT OUR  
10 ULTIMATE GOAL IS. IT IS WHAT WE HELP ALIGN THE  
11 GRANTS WORKING GROUP IN THEIR ASSESSMENT OF  
12 APPLICATIONS FOR ANY OF OUR PROGRAMS. THE  
13 TRANSLATIONAL PROGRAM IN PARTICULAR IS PART OF OUR  
14 RECURRING SET OF FUNDING OPPORTUNITIES TO SUPPORT  
15 PROGRAMS THAT MIGHT BEGIN WITH A NEW IDEA AND TAKES  
16 THEM THROUGH TO THE CLINIC. IN PARTICULAR, THE  
17 TRANSLATION PROGRAM OFFERS SUPPORT FOR FOUR  
18 DIFFERENT PRODUCT TYPES. THE MAJORITY OF WHICH WE  
19 GET ARE THERAPEUTIC PRODUCTS, BUT WE ALSO SUPPORT  
20 DIAGNOSTIC, MEDICAL DEVICE, AND TOOLS. AND THE  
21 PROGRAM IS SET UP SO THAT IT OFFERS THE APPROPRIATE  
22 LENGTH OF TIME FROM 24 TO 30 MONTHS AND THE  
23 APPROPRIATE AMOUNT OF FUNDING FOR EACH PRODUCT TYPE  
24 TO TAKE THEM THROUGH TRANSLATIONAL ACTIVITIES THAT  
25 WILL ALLOW THEM TO GET TO A PRESUBMISSION MEETING OR

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1 TO TRANSFER A TOOL TO BROAD END USE.

2 AND SO THIS IS AN ILLUSTRATION OF WHAT  
3 REQUIREMENTS ARE TO COME IN TO THE TRANSLATION  
4 PROGRAM. SO FOR A THERAPEUTIC WE EXPECT APPLICANTS  
5 TO HAVE A CANDIDATE, THERAPEUTIC CANDIDATE, WHERE  
6 THEY'VE DEMONSTRATED DISEASE-MODIFYING ACTIVITY.  
7 AND SIMILARLY FOR THE DIAGNOSTIC, DEVICES, AND  
8 TOOLS, THAT THEY HAVE A PROTOTYPE AND A PROOF OF  
9 CONCEPT WITH THAT PROTOTYPE WHEN THEY COME IN.

10 AT THE END OF THE TRANSLATION AWARD, WE  
11 EXPECT THAT THE ACTIVITIES WILL ALLOW THEM TO EITHER  
12 COMPLETE A PRE-IND MEETING, IF IT'S A THERAPEUTIC,  
13 OR ANOTHER PRESUBMISSION MEETING WITH THE FDA FOR  
14 THOSE THAT FOLLOW A REGULATORY PATH. AND FOR A  
15 TOOL, FOR THEM TO BE AT A STAGE WHERE THEY CAN  
16 TRANSFER THE DESIGN TO MANUFACTURING FOR  
17 COMMERCIALIZATION OR FOR MAKING AVAILABLE BROADLY TO  
18 THE SCIENTIFIC COMMUNITY.

19 THE SCIENTIFIC REVIEW CRITERIA THAT ARE  
20 UTILIZED BY THE GRANTS WORKING GROUP TO ASSESS THESE  
21 APPLICATIONS ARE BASED ON FIVE QUESTIONS. DOES THE  
22 PROJECT HOLD THE NECESSARY SIGNIFICANCE AND  
23 POTENTIAL FOR IMPACT? MEANING WHAT VALUE DOES IT  
24 OFFER, AND IS IT SOMETHING THAT'S WORTH DOING? IS  
25 THE RATIONALE SOUND? IS IT WELL-PLANNED AND

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1 DESIGNED? IS IT FEASIBLE, INCLUDING HAVING THE  
2 APPROPRIATE MEMBERS ON THEIR TEAM AND ALL THE  
3 AVAILABLE RESOURCES TO CONDUCT THE PROJECT? AND  
4 DOES THE PROJECT UPHOLD THE PRINCIPLES OF DIVERSITY,  
5 EQUITY, AND INCLUSION?

6 THE SCORING SYSTEM THAT'S USED BY THE  
7 GRANTS WORKING GROUP IS A SCALE OF 1 TO 100. A  
8 SCORE OF 85 TO A 100 MEANS IT'S RECOMMENDED FOR  
9 FUNDING IF FUNDS ARE AVAILABLE. ANYTHING BELOW A  
10 SCORE OF 85 MEANS THAT IT'S NOT RECOMMENDED FOR  
11 FUNDING. AND ALL APPLICATIONS ARE SCORED BY THE  
12 SCIENTIFIC MEMBERS OF THE GRANTS WORKING GROUP  
13 WITHOUT A CONFLICT. AND WE USE THE MEDIAN OF ALL  
14 THE INDIVIDUAL GRANTS WORKING GROUP SCORES TO  
15 DETERMINE WHAT THE FINAL SCORE IS.

16 WE ALSO IN THE TRANSLATION PROGRAM,  
17 SIMILAR TO THE CLINICAL PROGRAM, HAVE BEEN UTILIZING  
18 ALSO A DEI SCORE. SO THE PATIENT ADVOCATE AND NURSE  
19 MEMBERS OF THE BOARD WHO ARE PART OF THE GRANTS  
20 WORKING GROUP PROVIDE A DEI SCORE FROM ZERO TO TEN  
21 WITH TEN BEING THE BEST OF POSSIBLE SCORE BASED ON  
22 THEIR OVERALL ASSESSMENT OF THE APPLICANT'S RESPONSE  
23 TO THE DEI QUESTIONS AND ELEMENTS THAT WE POSE. AND  
24 THEY USE A RUBRIC, WHICH IS ILLUSTRATED HERE, TO  
25 GUIDE THEIR SCORING.

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1 THE COMPOSITION OF THE GRANTS WORKING  
2 GROUP INCLUDES THE SCIENTIFIC MEMBERS THAT, AS I  
3 MENTIONED, HAVE THE DIVERSITY OF BACKGROUND TO  
4 PROVIDE A SCIENTIFIC SCORE AND MAKE THE SCIENTIFIC  
5 ASSESSMENT. OUR GRANTS WORKING GROUP BOARD MEMBERS,  
6 WHO ARE THE PATIENT ADVOCATE AND NURSE MEMBERS,  
7 PROVIDE THE PATIENT PERSPECTIVE ON THE SIGNIFICANCE  
8 AND POTENTIAL FOR IMPACT AS WELL AS OVERSIGHT ON THE  
9 PROCESS AND PROVIDE A DEI SCORE ON THE APPLICATION.  
10 WE ALSO HAVE AS PART OF THE PANEL SCIENTIFIC  
11 SPECIALISTS WHO ARE NONVOTING MEMBERS WHO  
12 PARTICIPATE ON AN AD HOC BASIS FOR SPECIFIC  
13 APPLICATIONS AS THEIR EXPERTISE IS NEEDED.

14 ALL RIGHT. SO WE GET TO THE  
15 RECOMMENDATIONS OF THE GRANTS WORKING GROUP FOR THIS  
16 PARTICULAR CYCLE. THERE WERE 30 APPLICATIONS THAT  
17 WERE REVIEWED AND CONSIDERED BY THE WORKING GROUP.  
18 TEN WERE RECOMMENDED FOR FUNDING, RECEIVING A SCORE  
19 OF 85 OR ABOVE. THE TOTAL REQUEST FOR THOSE TEN  
20 APPLICATIONS IS ABOUT 33.5 MILLION. THE FUNDS  
21 AVAILABLE ARE 84.6 MILLION. THE FUNDS AVAILABLE ARE  
22 INTENDED TO SUPPLY TWO ROUNDS OF TRAN. THIS IS THE  
23 FIRST CYCLE. SO WE WILL HAVE ANOTHER CYCLE OF TRAN  
24 THAT THAT 84 WILL ALSO HELP COVER.

25 SO LET ME SPEND A MINUTE ON MINORITY



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1       REPORTS. SO UNDER PROP 14 ANY APPLICATION THAT'S  
2       NOT RECOMMENDED FOR FUNDING BY THE GRANTS WORKING  
3       GROUP, BUT WHICH HAD 35 PERCENT OR MORE OF THE  
4       MEMBERS SCORE IT TO FUND THE APPLICATION MUST  
5       INCLUDE A MINORITY REPORT. THE MINORITY REPORT IS  
6       INCLUDED IN THE REVIEW SUMMARY. SO WE HAVE PROVIDED  
7       THOSE TO YOU, AND IT PROVIDES A BRIEF SYNOPSIS OF  
8       THE OPINION OF THE REVIEWERS THAT SCORED THE  
9       APPLICATION 85 OR ABOVE.

10               SO IN THIS PARTICULAR CYCLE, WE HAD ONE  
11       APPLICATION THAT QUALIFIED FOR A MINORITY REPORT.  
12       THAT WAS TRAN1-15209. THE TITLE IS "CLINICAL  
13       DEVELOPMENT OF EXTRACELLULAR VESICLE-BASED THERAPY  
14       FOR ALPORT SYNDROME." THE FUNDS REQUESTED IS 5.1  
15       MILLION. AND THE SCORE THAT IT RECEIVED WAS AN 80.

16               IN THIS PARTICULAR CASE, THE CIRM TEAM  
17       SPORTS THE MAJORITY POSITION, MEANING TO NOT FUND,  
18       THE APPLICATION FOR TRAN1-15209, AND WE RECOMMEND  
19       THAT THE APPLICANTS REVISE AND RESUBMIT FOR THE NEXT  
20       TRANSLATIONAL ROUND. AND THE DEADLINE FOR THAT IS  
21       UPCOMING DECEMBER 5. AND THE REASON FOR THIS IS  
22       THAT THERE WERE PRETTY CLEAR AND SPECIFIC ELEMENTS  
23       THAT CAN BE ADDRESSED BY THE APPLICANTS IN A  
24       RESUBMISSION. IN PARTICULAR, THE PROJECT WOULD  
25       BENEFIT FROM A REVISION THAT ADDRESSES PRELIMINARY

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1 DATA CONCERNS WHERE PARTICULAR DATA RELATED TO USE  
2 OF THE SPECIFIC EXTRACELLULAR VESICLES THAT ARE THE  
3 CANDIDATE IN A MODEL WOULD BE IMPORTANT TO HAVE AS  
4 WELL AS INCORPORATE FEEDBACK FROM REGULATORY AND CMC  
5 EXPERTS, WHICH THEY COULD DO AS PART OF A REVISION.

6 SO THAT'S THE RECOMMENDATION ON THE  
7 MINORITY REPORT. THIS IS JUST A REMINDER OF BOARD  
8 MEMBERS THAT HAVE A CONFLICT OF INTEREST WITH A TRAN  
9 APPLICATION. AND SO, AS MENTIONED EARLIER, PLEASE  
10 BE AWARE OF THOSE CONFLICTS AND LOOK TO SCOTT TOCHER  
11 FOR WHEN IT MAY BE OKAY TO MAKE A COMMENT IF YOU  
12 WANT TO DO THAT.

13 AND SO NOW LET ME STOP SHARING THIS AND  
14 SHARE WITH YOU THE SPREADSHEET THAT SHOWS THE  
15 APPLICATIONS IN RANK ORDER. GIVE ME ONE SECOND.  
16 OKAY. HERE IS THE APPLICATIONS IN RANK ORDER.  
17 THOSE IN GREEN ARE THOSE THAT ARE RECOMMENDED FOR  
18 FUNDING. THERE ARE TEN OF THOSE. THE ONE WITH THE  
19 MINORITY REPORT IS ACTUALLY A COUPLE OF SLOTS BELOW  
20 THAT FUND LINE, WHICH IS HERE. AND WE ARE NOT  
21 RECOMMENDING THAT FOR FUNDING. AND HERE ARE THE  
22 REMAINDER OF THE APPLICATIONS. SO I TURN IT BACK TO  
23 YOU, MR. CHAIR, FOR DISCUSSION.

24 CHAIRMAN IMBASCIANI: GREAT. SO WE START  
25 THIS DISCUSSION ON ALL THESE APPLICATIONS. YOU KNOW

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1 THIS IS THE ONE WHERE WE DO THE FUNNY DANCE. SO I  
2 WOULD LIKE TO LOOK AT THOSE THAT ARE RECOMMENDED NOT  
3 TO BE FUNDED, THOSE THAT ARE IN TIER II. GIL, COULD  
4 YOU TELL US HOW MANY THERE ARE? IT SEEMS TO SCROLL  
5 RIGHT OFF THE SCREEN.

6 DR. SAMBRANO: YEAH. SO THERE'S  
7 ABOUT -- THERE WERE 20 THAT WERE NOT RECOMMENDED.  
8 SOME WITHDREW, SO THERE MAY BE JUST SLIGHTLY LESS  
9 THAN 20 IN THIS FRAME.

10 CHAIRMAN IMBASCIANI: SO I'D LIKE TO START  
11 THE DISCUSSION BY ASKING FOR A MOTION, THAT WE LOOK  
12 AT TIER II. AND THE MOTION WOULD BE -- IS THERE ANY  
13 APPLICATION IN THIS GROUP THAT YOU WOULD LIKE TO  
14 EXCERPT, MEANING YOU WOULD LIKE TO DISCUSS  
15 CONSIDERATION OF FUNDING THIS IN SPITE OF THE CIRM  
16 TEAM'S RECOMMENDATION NOT TO FUND AND, THEREBY, MOVE  
17 IT FROM TIER II UP TO TIER I.

18 SO I'D LIKE TO ENTERTAIN A MOTION. IN A  
19 SENSE THIS IS A CONSENT CALENDAR, AND I'M ASKING YOU  
20 TO EXCERPT ANYTHING FROM THE CONSENT CALENDAR FOR  
21 DISCUSSION. LET THAT PERCOLATE JUST FOR A LITTLE  
22 BIT.

23 MR. TOCHER: VITO, THIS IS SCOTT. CALL AN  
24 AUDIBLE HERE. IF I MAY MAKE A SUGGESTION TO THE  
25 SUBCOMMITTEE. AS I INDICATED JUST BEFORE WE JOINED,

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1 BECAUSE THE OVERALL ASK OF THE ENTIRE SLATE OF  
2 APPLICATIONS EXCEEDS THE BUDGET, OUR CONFLICT OF  
3 INTEREST RULES REQUIRE THAT WE -- THAT MEMBERS WITH  
4 A CONFLICT AS TO ANY APPLICATION, WHETHER IT'S IN  
5 THE TIER I OR TIER II CATEGORY, SUCH INDIVIDUALS ARE  
6 PRECLUDED FROM MAKING A MOTION OR PARTICIPATING IN  
7 THE DISCUSSION AS TO ANY APPLICATION UNLESS SUCH  
8 TIME AS THE OVERALL DEMAND IS BELOW THAT TOTAL  
9 BUDGET, WHICH IS 84 MILLION.

10 SO THAT WOULD MEAN THAT MEMBERS  
11 JUELSGAARD, BERNAL, FLOWERS, PANETTA, AND BONNEVILLE  
12 AT THIS MOMENT ARE PRECLUDED FROM MAKING A MOTION OR  
13 PARTICIPATING IN ANY DISCUSSION AS TO ANY  
14 APPLICATION REGARDLESS OF WHETHER IT IS THE ONE THAT  
15 THEY'RE IN CONFLICT WITH. ALL THIS IS A LONG WAY OF  
16 SAYING ALL WE NEED TO DO IS GET THE OVERALL BUDGET  
17 OF SITTING APPLICATIONS THAT HAVE NOT BEEN DISPENSED  
18 WITH, EITHER FUNDED OR UNFUNDED, IS TO GET THAT LINE  
19 FROM WHERE IT STANDS, WHICH IS 87.3 MILLION DOWN TO  
20 BELOW 84 MILLION.

21 SO AS I LOOK AT GIL'S LIST, APPLICATION  
22 15279, WHICH, I BELIEVE, IS AT THE BOTTOM OF YOUR  
23 SCREEN, HAS A BUDGET AMOUNT THAT, IF THERE WAS A  
24 MOTION NOT TO FUND THIS AND IT IS NOT RECOMMENDED  
25 FOR FUNDING, AND WE HANDLE THAT DISCRETELY, WE WOULD

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1 THEN BE ABLE TO OPEN UP THE WHOLE REST OF THE  
2 CONSIDERATION OF THE SLATE OF APPLICATIONS UNDER OUR  
3 NORMAL PROCESS. SO I APOLOGIZE FOR TAKING UP  
4 EVERYONE'S TIME WITH THIS PROCESS POINT, BUT IT  
5 WOULD ALLOW GREATER PARTICIPATION BY THE BOARD IF WE  
6 HAD A DISCRETE MOTION WITH RESPECT TO THIS  
7 APPLICATION.

8 CHAIRMAN IMBASCIANI: DISCRETE SPELLED  
9 C-R-E-T-E, YES?

10 MR. TOCHER: YES. IN OTHER WORDS, A  
11 MOTION NOT TO FUND THIS APPLICATION COULD NOT BE  
12 MADE OR SECONDED BY ANY OF THE MEMBERS THAT I JUST  
13 IDENTIFIED --

14 CHAIRMAN IMBASCIANI: RIGHT.

15 MR. TOCHER: -- FOR DISCUSSION, PUBLIC  
16 COMMENT, AND THEN A VOTE. AND IF THAT MOTION  
17 PASSED, THEN OUR OVERALL EXPOSURE WOULD BE LESS THAN  
18 THE BUDGET AMOUNT AND WE COULD PROCEED AS NORMAL.

19 CHAIRMAN THOMAS: I THINK THAT'S AN  
20 ELEGANT SOLUTION. I DON'T WANT A MOTION TO REMOVE  
21 ALL OF THESE, INCLUDING THE ONE WITH THE MINORITY  
22 REPORT.

23 SO THEN I GUESS I SHOULD AMEND MY OWN ASK  
24 OF THE BOARD AND ASK FOR A MOTION TO ABSTRACT -- NO,  
25 I'M SORRY -- TO SPECIFICALLY NOT FUND TRAN1-15279.

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1 DR. FISHER: SO MOVED.

2 MR. TOCHER: CAN YOU IDENTIFY YOURSELF  
3 PLEASE?

4 DR. FISHER: FRED FISHER.

5 MR. TOCHER: GREAT. THANKS, FRED.

6 DR. FISCHER-COLBRIE: SECOND.

7 MR. TOCHER: THANK YOU, MARK.

8 CHAIRMAN IMBASCIANI: WE HAVE A MOTION AND  
9 A SECOND. ANY DISCUSSION FROM THE BOARD MEMBERS  
10 FIRST?

11 MS. DURON: THIS IS YSABEL, VITO. I JUST  
12 NEED CLARIFICATION. SCOTT, I THOUGHT I HAD A  
13 CONFLICT.

14 MR. TOCHER: YES.

15 MS. DURON: AND I DIDN'T HEAR MY NAME, SO  
16 I JUST NEED TO CLARIFY THAT BEFORE I SAY ANYTHING.

17 MR. TOCHER: THAT'S CORRECT. IT'S YSABEL  
18 AND STEVE, DAN, ELENA, JOE.

19 MS. DURON: SORRY, VITO. I CAN'T SAY  
20 ANYTHING.

21 CHAIRMAN IMBASCIANI: NO. THAT'S A VERY  
22 WELL TIME COMMENT, YSABEL, CONSIDERING ALL THE  
23 PROBLEMS THAT CAN ENSUE IF YOU DIDN'T.

24 ALL RIGHT. I DON'T HEAR ANY CONVERSATION  
25 FROM THE BOARD. IS THERE ANY PUBLIC, ANY MEMBER OF

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1 THE PUBLIC THAT WOULD LIKE TO COMMENT ON THIS  
2 MOTION?

3 MR. TOCHER: IT DOESN'T APPEAR SO.

4 CHAIRMAN IMBASCIANI: OKAY. ALL RIGHT.  
5 THEN, SCOTT, WOULD YOU PLEASE -- DISCUSSION IS  
6 CLOSED -- WOULD YOU PLEASE CALL THE VOTE.

7 MR. TOCHER: YES. AND THIS IS WHERE --  
8 LEONDRA CLARK-HARVEY.

9 DR. CLARK-HARVEY: YES.

10 MR. TOCHER: THANK YOU. MARK  
11 FISCHER-COLBRIE.

12 DR. FISCHER-COLBRIE: AYE.

13 MR. TOCHER: FRED FISHER.

14 DR. FISHER: AYE.

15 MR. TOCHER: ELENA FLOWERS.

16 DR. FLOWERS: I --

17 MR. TOCHER: SORRY. DAVID HIGGINS.

18 DR. HIGGINS: YES.

19 MR. TOCHER: VITO IMBASCIANI.

20 CHAIRMAN IMBASCIANI: YES.

21 MR. TOCHER: RICH LAJARA.

22 MR. LAJARA: YES.

23 MR. TOCHER: LAUREN MILLER-ROGEN.

24 MS. MILLER-ROGEN: YES.

25 MR. TOCHER: ADRIANA PADILLA.

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1 DR. PADILLA: YES.

2 MR. TOCHER: AND I THINK THAT'S EVERYONE.

3 CHAIRMAN IMBASCIANI: OKAY.

4 MR. TOCHER: GREAT. THANK YOU.

5 SO WITH THAT NOW, THE NORMAL PROCESS WOULD  
6 APPLY. ANYONE CAN MAKE A MOTION AND PARTICIPATE IN  
7 THE DISCUSSION WITH RESPECT TO THE APPLICATION AS  
8 LONG AS THEY'RE NOT IN CONFLICT WITH IT. HOWEVER,  
9 IT'S AN OMNIBUS MOTION; IN OTHER WORDS, IT'S A  
10 MOTION THAT INVOLVES MULTIPLE APPLICATIONS. IT CAN  
11 ONLY COME FROM A MEMBER WHO IS NOT IN CONFLICT WITH  
12 ANY OF THE SUBJECT APPLICATIONS.

13 CHAIRMAN IMBASCIANI: SCOTT, THANK YOU FOR  
14 SOLVING OUR DILEMMA HERE. CAN I ASK, SCOTT, SHOULD  
15 WE FOCUS ON TRAN 15209 NEXT?

16 MR. TOCHER: IT UP TO THE PLEASURE OF THE  
17 COMMITTEE ON HOW IT WOULD LIKE TO PROCEED NEXT. BUT  
18 TYPICALLY, YES, WE WOULD DEAL WITH TIER II  
19 APPLICATIONS NEXT.

20 CHAIRMAN IMBASCIANI: WELL, SINCE THERE IS  
21 A MINORITY REPORT ON THIS, I THINK WE PROBABLY  
22 SHOULD HAVE A SHORT DISCUSSION ON IT. LET'S SEE.  
23 DO I HAVE TO ABSTRACT THIS AGAIN AS WE DID THE LAST  
24 ONE?

25 MR. TOCHER: YOU CAN JUST ASK FOR A MOTION



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1 REGARDING IT.

2 CHAIRMAN IMBASCIANI: OKAY. BOARD  
3 MEMBERS, HAVING HEARD OUR COUNSEL HERE --

4 DR. FISHER: SO MOVED. I MOVE THAT WE NOT  
5 FUND APPLICATION 15209.

6 CHAIRMAN IMBASCIANI: THANK YOU, FRED. A  
7 SECOND PLEASE.

8 DR. FISCHER-COLBRIE: SECOND. MARK  
9 FISCHER-COLBRIE.

10 CHAIRMAN IMBASCIANI: OKAY. I HEAR THE  
11 SECOND. SO THIS 15209 APPLICATION IS OPEN FOR  
12 DISCUSSION FOR NOT FUNDING. GIL HAS ALREADY GIVEN  
13 US THE CIRM STAFF'S OPINION. IS THERE ANYONE WOULD  
14 LIKE TO HAVE MORE INFORMATION ON THAT?

15 MS. MANDAC: ADRIANA HAS HER HAND RAISED.

16 CHAIRMAN IMBASCIANI: I CAN'T SEE THAT,  
17 BUT THANK YOU, CLAUDETTE. ADRIANA, PLEASE.

18 DR. PADILLA: YEAH. I JUST WANTED TO HEAR  
19 MORE FROM GIL AS TO WHY THE CIRM COMMITTEE AND  
20 ACTUALLY WHY IT WAS DEEMED TO NEED TO BE  
21 RESUBMITTED. CAN I JUST HEAR THE REASONS WHY?

22 CHAIRMAN IMBASCIANI: EXCELLENT. THANK  
23 YOU. GIL.

24 DR. SAMBRANO: SURE. ABSOLUTELY. SO  
25 GENERALLY I THINK OUR DEFAULT POSITION FOR

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1 APPLICATIONS THAT ARE NOT RECOMMENDED BY THE GRANTS  
2 WORKING GROUP IS THAT THEY HAVE THE OPPORTUNITY TO  
3 REVISE THEIR APPLICATION AND RESUBMIT IN THE NEXT  
4 CYCLE. SO WE OFFER THESE CYCLES WITH THE GOAL OF  
5 TRYING TO MAKE SURE THE APPLICATIONS IMPROVE AND  
6 UTILIZE THE CRITIQUES FROM THE GRANTS WORKING GROUP  
7 TO MAKE THOSE IMPROVEMENTS.

8 SO IN THIS PARTICULAR CASE, WE LOOKED AT  
9 APPLICATIONS TO SEE IF THERE WERE CONCERNS THAT  
10 COULD BE ADDRESSED THROUGH A RESUBMISSION. SO IN  
11 PARTICULAR, THE MAJOR CONCERNS THAT WERE RAISED WERE  
12 RELATED TO THE EFFICACY DATA. SO SPECIFICALLY, IN  
13 THIS PROPOSAL THEIR CANDIDATE IS HUMAN AMNIOTIC  
14 FLUID STEM CELL-DERIVED EXTRACELLULAR VESICLES.  
15 THEY PROVIDE DATA THAT USES A MOUSE VERSION OF THE  
16 CELLS AS WELL AS THE EV'S, BUT NOT WITH THE HUMAN  
17 VERSION OF EV'S. SO REVIEWERS THOUGHT IT WOULD BE  
18 IMPORTANT TO HAVE THAT PRELIMINARY DATA TO GIVE MORE  
19 CONFIDENCE THAT THIS IS LIKELY TO WORK.

20 AND THERE WERE SOME CONCERNS RAISED  
21 RELATED TO THE CMC, THE MANUFACTURING OF THESE EV'S  
22 AND THE REGULATORY PATH THAT COULD BE ADDRESSED BY  
23 GETTING SOME EXPERT ADVICE. SO WE THOUGHT THAT WAS  
24 PRETTY STRAIGHTFORWARD IN TERMS OF WHAT THEY COULD  
25 DO THAT COULD BE ADDRESSED THROUGH A REVISION.

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1                   SOMETIMES WHEN WE RECOMMEND, AND JUST FOR  
2                   CONTEXT, AN APPLICATION THAT RECEIVES A MINORITY  
3                   REPORT, WE LOOK TO SEE IF THE CONCERNS ARE  
4                   ADDRESSABLE EITHER THROUGH A MILESTONE OR THROUGH  
5                   SOMETHING THAT AT CIRM WE CAN DO IN TERMS OF  
6                   MONITORING THE PROJECT VERSUS HAVING THEM MAKE THE  
7                   REVISIONS. HERE WE FELT THAT MAKING THE REVISIONS  
8                   WAS THE APPROPRIATE COURSE, AND THAT'S WHY WE MADE  
9                   THAT RECOMMENDATION.

10                   CHAIRMAN IMBASCIANI: THANK YOU, GIL.  
11                   ADRIANA, YOU SATISFIED?

12                   DR. PADILLA: YES. I JUST FELT LIKE WE  
13                   NEEDED TO HEAR THAT.

14                   CHAIRMAN IMBASCIANI: THANK YOU. I AGREE.  
15                   ANY OTHER COMMENTS? ANY MEMBER OF THE  
16                   PUBLIC WHICH TO COMMENT ON FUNDING APPLICATION  
17                   15209? CLAUDETTE?

18                   MS. MANDAC: I DO NOT SEE ANY HANDS  
19                   RAISED.

20                   CHAIRMAN IMBASCIANI: NO HANDS. ALL  
21                   RIGHT. SCOTT, WE CAN PROCEED TO A VOTE ON THIS.  
22                   THANK YOU.

23                   MR. TOCHER: ALL RIGHT. THERE ARE NO  
24                   CONFLICTS, SO EVERYONE IS ELIGIBLE TO VOTE.

25                   DAN BERNAL.

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1 MR. BERNAL: AYE.  
2 MR. TOCHER: MARIA BONNEVILLE.  
3 VICE CHAIR BONNEVILLE: AYE.  
4 MR. TOCHER: LEONDRA CLARK-HARVEY.  
5 DR. CLARK-HARVEY: AYE.  
6 MR. TOCHER: YSABEL DURON.  
7 MS. DURON: YES.  
8 MR. TOCHER: MARK FISCHER-COLBRIE.  
9 MR. FISCHER-COLBRIE: AYE.  
10 MR. TOCHER: FRED FISHER.  
11 DR. FISHER: AYE.  
12 MR. TOCHER: ELENA FLOWERS.  
13 DR. FLOWERS: YES.  
14 MR. TOCHER: DAVID HIGGINS.  
15 DR. HIGGINS: YES.  
16 MR. TOCHER: VITO IMBASCIANI.  
17 CHAIRMAN IMBASCIANI: YES.  
18 MR. TOCHER: STEVE JUELSGAARD.  
19 MR. JUELSGAARD: YES.  
20 MR. TOCHER: RICH LAJARA.  
21 MR. LAJARA: YES.  
22 MR. TOCHER: LAUREN MILLER-ROGEN.  
23 MS. MILLER-ROGEN: YES.  
24 MR. TOCHER: ADRIANA PADILLA.  
25 DR. PADILLA: YES.

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1 MR. TOCHER: JOE PANETTA.

2 MR. PANETTA: YES.

3 MR. TOCHER: THANK YOU. AND THE MOTION  
4 CARRIES. SO THAT APPLICATION IS -- WILL NOT BE  
5 FUNDED.

6 CHAIRMAN IMBASCIANI: OKAY. GOOD. HAVING  
7 HEARD NO EARLIER MOTION TO ABSTRACT ANYTHING FROM  
8 THIS DO NOT FUND CONSENT CALENDAR, I'D LIKE TO HEAR  
9 A MOTION FROM THE BOARD NOT TO FUND THE REMAINDER OF  
10 TIER II.

11 DR. FISHER: SO MOVED.

12 CHAIRMAN IMBASCIANI: MOTION FROM  
13 MR. FISHER. THANK YOU. I NEED A SECOND ON THIS.

14 DR. FISCHER-COLBRIE: SECOND.

15 CHAIRMAN IMBASCIANI: MARK. THANK YOU,  
16 MARK.

17 ANY FURTHER DISCUSSION FROM THE MEMBERS OF  
18 THE BOARD?

19 MR. TOCHER: STEVE JUELSGAARD HAS HIS  
20 HAND.

21 CHAIRMAN IMBASCIANI: THANK YOU. STEVE.

22 MR. JUELSGAARD: THIS IS ACTUALLY JUST A  
23 QUESTION FOR GIL OF GENERAL INFORMATION. SO THE  
24 AMOUNT OF THESE AWARDS IS LIMITED TO \$4 MILLION; IS  
25 THAT RIGHT, GIL?

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1 DR. SAMBRANO: YES, IN DIRECT PROJECT  
2 COSTS FOR THAT ARE THERAPEUTIC.

3 MR. JUELSGAARD: ON THE INDIRECT COST THE  
4 LIMIT IS 25 PERCENT OF THE AWARD AMOUNT; IS THAT  
5 RIGHT?

6 DR. SAMBRANO: WELL, THE INDIRECT COST IS  
7 20 PERCENT, BUT THEN THERE ARE DIRECT FACILITIES  
8 COSTS WHICH VARY BY THE INSTITUTION.

9 MR. JUELSGAARD: SO THERE ARE FACILITIES  
10 COSTS EMBEDDED IN SOME OF THESE?

11 DR. SAMBRANO: YES.

12 MR. JUELSGAARD: SO COULD YOU EXPLAIN TO  
13 ME, THEN, THE DIFFERENCE BETWEEN THOSE WITH  
14 FACILITIES COSTS THAT ARE EMBEDDED IN THESE AND  
15 THOSE WITHOUT? HOW DO FACILITIES COSTS BECOME  
16 EMBEDDED IN THESE AWARDS?

17 DR. SAMBRANO: SO FACILITIES COSTS ARE  
18 PART OF WHAT I THINK MOST OF US ARE USED TO HAVING  
19 AS AN INDIRECT COST. BUT UNDER PROP 71 AND UNDER  
20 PROP 14, THEY ARE DESIGNATED AS DIRECT FACILITIES  
21 COSTS. SO INDIRECT COSTS USUALLY HAVE AN  
22 ADMINISTRATIVE COMPONENT AND A FACILITIES COMPONENT.  
23 WE SEPARATE THEM OUT. SO THE ADMINISTRATIVE  
24 COMPONENT IS 20 PERCENT, AND THEN THE FACILITIES  
25 COMPONENT IS VARIABLE DEPENDING ON THE INSTITUTION.

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1 AND SO THOSE ARE COMBINED, IF YOU WILL, TO BE THE  
2 OVERHEAD THAT GOES INTO ALL OF THESE APPLICATIONS.  
3 SO ALL OF THEM HAVE THE 20 PERCENT AS WELL AS THE  
4 ALLOWABLE FACILITIES COSTS.

5 MR. JUELSGAARD: ALL RIGHT. SO MAYBE I'M  
6 MISREADING THE SECTION THAT DEALS WITH INDIRECT  
7 COSTS IN TERMS OF HOW IT WORKS. BECAUSE THE WAY I  
8 READ IT IS THAT THE AWARD OF ADDITIONAL FACILITIES  
9 COSTS ACTUALLY APPLY TO AWARDS FOR FACILITIES, NOT  
10 NECESSARILY FOR RESEARCH GRANTS.

11 DR. SAMBRANO: IT'S DIFFERENT. IT'S A  
12 DISTINCT COST CATEGORY. SO THIS IS NOT FOR  
13 RENOVATION, CONSTRUCTION, OR BUILDING. THIS IS  
14 FOR --

15 MR. JUELSGAARD: I'LL CONTINUE THIS  
16 OFFLINE WITH SCOTT. I JUST -- I'M HAVING A LITTLE  
17 BIT OF DIFFICULTY TRANSLATING THE LANGUAGE OF PROP  
18 71 INTO THE PRACTICE. I'LL TALK TO SCOTT.

19 DR. SAMBRANO: OKAY.

20 MR. JUELSGAARD: THANK YOU.

21 CHAIRMAN IMBASCIANI: ANY OTHER COMMENTS  
22 FROM BOARD MEMBERS? COMMENTS FROM THE PUBLIC?

23 MR. TOCHER: WE SHOULD HAVE SUBSTANTIAL  
24 PUBLIC COMMENT, I BELIEVE, VITO. SO JUST STAND BY  
25 WHILE WE --

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1 CHAIRMAN IMBASCIANI: THANK YOU, SCOTT.

2 MR. TOCHER: -- REACH OUT THE MEMBERS OF  
3 THE PUBLIC WHO HAVE REACHED OUT DURING THE WEEK AND  
4 POSTED LETTERS. I UNDERSTAND THAT THERE ARE FOLKS  
5 WHO ARE WAITING TO SPEAK.

6 CHAIRMAN IMBASCIANI: GOOD.

7 MR. TOCHER: SO JUST STAND BY. PAUL  
8 BRESGE.

9 DR. BRESGE: YES. CAN YOU HEAR ME?

10 MR. TOCHER: YES, WE CAN HEAR YOU.

11 DR. BRESGE: EXCELLENT. SO FIRST, THANK  
12 YOU VERY MUCH FOR THE OPPORTUNITY TO ADDRESS YOU  
13 TODAY. MY NAME IS PAUL BRESGE, AND I'M THE CEO OF  
14 RAY THERAPEUTICS.

15 I ALSO WANT TO THANK THE REVIEWERS FOR THE  
16 EXCELLENT FEEDBACK THAT THEY PROVIDED WITH RESPECT  
17 TO OUR TRAN1 GRANT APPLICATION FOR OPTOGENETIC  
18 THERAPY FOR THE TREATMENT OF GEOGRAPHIC ATROPHY.

19 I'M GOING TO ASK THE ICOC TO PLEASE  
20 CONSIDER APPROVING OUR APPLICATION GIVEN THE FACT  
21 THAT WE HAD SUCH A HIGH SCORE OF 84, ONE BELOW THE  
22 REQUIRED THRESHOLD OF 85 FOR FUNDING. WE WERE VERY  
23 GRATIFIED BY THE SUPPORT THAT WE RECEIVED FROM THE  
24 REVIEWERS FOR THE PROGRAM, AND OVERALL IT WAS VERY  
25 STRONG SUPPORT FOR ALL ASPECTS OF OUR APPLICATION.



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1 IT APPEARS THAT THE ISSUE THAT INFLUENCED  
2 OUR SCORE TO RESULT IN THE 84 INSTEAD OF THE 85 IS  
3 PRIMARILY GUIDED BY A SINGLE REQUEST THAT WE UTILIZE  
4 AN ADDITIONAL ANIMAL MODEL IN OUR PHARMACOLOGY  
5 STUDIES. WE AGREE WITH THE RATIONALE TO INCLUDE  
6 THIS ANIMAL IN OUR STUDIES, AND WE CAN READILY WORK  
7 WITH THE CIRM ADMINISTRATORS TO INCLUDE THIS MODEL  
8 IN OUR CIRM GRANT MILESTONES.

9 WE'VE ALREADY RESEARCHED THE AVAILABILITY  
10 OF THESE ANIMALS, AND WE CAN IMPLEMENT IT INTO THE  
11 PROGRAM IN PARALLEL WITH OUR OTHER ACTIVITIES,  
12 THEREFORE, AVOIDING A DELAY BY BRINGING THIS  
13 IMPORTANT THERAPY TO PATIENTS.

14 BUDGET IMPACT IS NOMINAL, AND WE CAN  
15 ACTUALLY FUND IT THROUGH THE COMPANY. SO WE ARE  
16 ASKING THIS DECISION TO BE MADE NOW INSTEAD OF  
17 HAVING TO RESUBMIT BECAUSE OF PATIENT NEED. THE  
18 GEOGRAPHIC ATROPHY FORM OF AGE-RELATED  
19 MULTIDISCIPLINARY IS AN ABSOLUTELY DEVASTATING  
20 DISEASE THAT CAUSES MAJOR VISION LOSS. THERE ARE  
21 MORE THAN A HUNDRED FIFTY ON THE PATIENTS IN  
22 CALIFORNIA ALONE THAT CURRENTLY SUFFER FROM  
23 BLINDNESS WITH THIS DISEASE, AND THOUSANDS DEVELOP  
24 THIS CONDITION EVERY YEAR.

25 THERE ARE CURRENTLY NO APPROVED THERAPIES

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1 THAT CAN IMPROVE THEIR VISION. TIME FOR THESE  
2 PATIENTS AND THEIR FAMILIES AND CAREGIVERS IS  
3 CRITICAL. YOU WILL HEAR MORE ABOUT THE PATIENT  
4 EXPERIENCE FROM MY COLLEAGUES, GARY ABRAMS AND PETER  
5 FRANCIS.

6 MY PERSONAL EXPERIENCE WITH CIRM OVER THE  
7 LAST 12 YEARS IS TO FOLLOW THE COLLECTIVE ADVICE OF  
8 CIRM STAFF, REVIEWERS, AND ADVISORS. AND I HOPE  
9 THAT WE CAN TAKE THE SAME COLLABORATIVE APPROACH  
10 WITH CIRM TO PROGRESS THIS GEOGRAPHIC ATROPHY  
11 PROGRAM AND BRING IT TO PATIENTS.

12 WE ARE VERY GRATEFUL TO CIRM FOR FUNDING  
13 OUR PREVIOUS TRAN1 GRANT APPLICATION FOR DEVELOPMENT  
14 OF A THERAPEUTIC FOR RETINITIS PIGMENTOSA, AND WE  
15 ARE VERY PLEASED TO ADVISE THAT WE COMPLETED ALL OF  
16 OUR ACTIVITIES SUCCESSFULLY AND AHEAD OF SCHEDULE.  
17 WE HOPE THAT WE WILL BE ABLE TO DO THE SAME THING  
18 WITH THIS APPLICATION. IF APPROVED, WE'LL PARTNER  
19 WITH CIRM TO CREATE A SUCCESSFUL AND ROBUST PROGRAM  
20 THAT WILL LEAD TO A SUCCESSFUL PRE-IND MEETING WITH  
21 FDA AND ULTIMATELY SUCCESSFUL THERAPEUTIC FOR  
22 PATIENTS.

23 I JUST WANT TO CLOSE BY SAYING THAT I HAVE  
24 SAID MANY TIMES IN PRIVATE, PUBLIC, AND THROUGH  
25 MULTIPLE PRESS RELEASES THAT I HAVE NOTHING BUT

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1 GRATITUDE FOR CIRM AND ALL THAT CIRM DOES FOR  
2 PATIENTS IN THE STATE OF CALIFORNIA AND WORLDWIDE.  
3 ONE OF THOSE PATIENTS HAPPENS TO BE MY OWN DAUGHTER,  
4 TAMAR, WHO LIVES IN CALIFORNIA AND STUDIES IN  
5 CALIFORNIA, AND SHE ALSO SUFFERS WITH A BLINDING  
6 DISEASE.

7 WITH THAT, I'LL HAND IT OVER TO GARY  
8 ABRAMS.

9 DR. ABRAMS: THANK YOU, PAUL.

10 CHAIRMAN IMBASCIANI: MR. ABRAMS.

11 DR. ABRAMS: YES.

12 CHAIRMAN IMBASCIANI: GO AHEAD. THE FLOOR  
13 IS YOURS. THANK YOU.

14 DR. ABRAMS: I'D LIKE TO THANK THE MEMBERS  
15 OF THE COMMITTEE FOR ALLOWING ME TO SPEAK. MY NAME  
16 IS GARY ABRAMS. I AM AN OPHTHALMOLOGIST, AND I'M A  
17 RETINA SPECIALIST.

18 I SEE MANY PATIENTS WITH GEOGRAPHIC  
19 ATROPHY ASSOCIATED WITH, MOST OF THEM, WITH  
20 AGE-RELATED MACULAR DEGENERATION. GEOGRAPHIC  
21 ATROPHY IS LOSS OF THE PHOTORECEPTORS. THESE ARE  
22 THE VISION CELLS OF THE RETINA THAT ARE IN THE BACK  
23 OF THE EYE IN THE CENTRAL SEEING AREA. IT'S MOST  
24 COMMON WITH AGE-RELATED MACULAR DEGENERATION, BUT  
25 YOU ALSO FIND IT PRESENT IN SOME INHERITED DISEASES,

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1 SUCH AS STARGARDT'S DISEASE AND CONE DYSTROPHY.

2 I WANT TO EMPHASIZE THAT PATIENTS WITH  
3 GEOGRAPHIC ATROPHY ARE TRULY DISABLED. IT'S A  
4 SERIOUS PROBLEM THAT CAUSES GREAT LOSS OF ABILITY TO  
5 PARTICIPATE IN DAILY LIFE. JUST TO GET AN IDEA OF  
6 WHAT THESE PEOPLE FACE, I'D LIKE FOR YOU TO ACTUALLY  
7 CLOSE ONE EYE AND PUT YOUR FIST IN FRONT OF YOUR  
8 OPEN EYE LIKE THIS (INDICATING), AND WHAT DO YOU  
9 SEE? WELL, YOU'VE GOT A HUGE CENTRAL BLIND SPOT,  
10 AND YOU CAN SEE AROUND THE EDGE OF IT, BUT YOU  
11 REALLY CAN'T SEE ANYTHING CENTRALLY.

12 SO WHAT HAPPENS? YOU CAN'T READ. YOU  
13 CAN'T DRIVE. YOU CAN'T SEE YOUR FOOD ON YOUR PLATE.  
14 YOU CAN'T COOK. BUT WHAT'S INTERESTING IS  
15 MOST -- THE THING THAT SEEMS TO BE MOST DISTURBING  
16 TO MANY OF THESE PEOPLE IS THEY CAN'T RECOGNIZE THE  
17 FACES OF FRIENDS AND LOVED ONES.

18 THERE'S NO TREATMENT FOR ESTABLISHED  
19 GEOGRAPHIC ATROPHY. WHILE NEW DRUGS MAY SLOW THE  
20 PROGRESSION OF GEOGRAPHIC ATROPHY, THERE'S NO  
21 CURRENT TREATMENT THAT CAN RESTORE VISION IN THESE  
22 FOLKS WHO HAVE LOST THEIR VISION.

23 RTX021 HAS THE POTENTIAL TO RESTORE VISUAL  
24 FUNCTION IN THESE PATIENTS WITH A SINGLE INJECTION  
25 INTO THE EYE THAT CAN BE DONE BY ANY TRAINED

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1 OPTHALMOLOGIST. AND IT'S LIKELY THIS WILL LAST A  
2 LIFETIME.

3 WITH CIRM'S HELP, WE THINK WE CAN IMPROVE  
4 THE LIVES OF THOUSANDS OF PATIENTS IN CALIFORNIA AND  
5 THE REST OF THE WORLD WHO SUFFER FROM THIS  
6 DEVASTATING DISEASE. ONCE AGAIN, THANK YOU FOR  
7 ALLOWING ME TO SPEAK.

8 CHAIRMAN IMBASCIANI: THANK YOU,  
9 MR. ABRAMS. THANK YOU FOR YOUR INPUT AND YOUR  
10 CLINICAL EXPERTISE.

11 DR. ABRAMS: I'M GOING TO TURN THIS OVER  
12 TO PETER FRANCIS FOR OUR CONCLUSION.

13 CHAIRMAN IMBASCIANI: MR. FRANCIS, THE  
14 FLOOR IS YOURS.

15 DR. FRANCIS: GOOD MORNING, EVERYBODY.  
16 I'M DR. PETER FRANCIS. I'M AN M.D./PH.D.  
17 OPTHALMOLOGIST. I'M CURRENTLY THE CSO AND CMO OF  
18 RAY THERAPEUTICS. AND LIKE DR. ABRAMS, I HAVE MORE  
19 THAN 30 YEARS EXPERIENCE AS AN OPTHALMOLOGIST AND  
20 RETINA SPECIALIST PARTICULARLY TREATING PATIENTS  
21 WITH AGE-RELATED MACULAR DEGENERATION.

22 AND I COMMEND PROFESSOR ABRAMS FOR HIS  
23 DESCRIPTION OF THE SUBSTANTIAL UNMET MEDICAL NEED IN  
24 GEOGRAPHIC ATROPHY. TO ADD TO THAT, ACCORDING TO  
25 SURVEYS, JUST TO GIVE YOU A FLAVOR, PATIENTS EQUATE

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1 HAVING GEOGRAPHIC ATROPHY AND THE RESULTING SENSORY  
2 LOSS AND PSYCHOLOGICAL IMPACT OF THE DISEASE WITH  
3 SEVERE AND ADVANCED SYSTEMIC DISEASES LIKE HEART  
4 DISEASE. AT RAY THERAPEUTICS WE HAVE A COMPANY AND  
5 MANAGEMENT TEAM WITH AN EXEMPLARY TRACK RECORD OF  
6 SUCCESSFUL CIRM GRANT EXECUTION, MEETING MILESTONES  
7 AHEAD OF SCHEDULE, ON BUDGET, AND WITH HIGH IMPACT  
8 FOR THE CITIZENS OF CALIFORNIA.

9 IN REGARDS TO THIS CURRENT TRAN1 GRANT, I  
10 CAN CONFIRM WE HAVE THE TEAM TO IMPLEMENT, THE  
11 FACILITIES TO CONDUCT, AND THE PROGRAM MANAGEMENT  
12 CAPABILITIES TO EFFICIENTLY IMPLEMENT THE MILESTONES  
13 AS OF NOW.

14 IN CONCLUSION, AS A TECHNOLOGY  
15 OPTOGENETICS IN THE VISION SPACE HAS BEEN SHOWN TO  
16 WORK IN RESTORING VISION TO BLIND PATIENTS. SO IT  
17 IS SIGNIFICANTLY DERISKED. WHILE THE FIELD HAS  
18 LACKED THE OPTOGENETICS METHODS THAT ARE ENGINEERED  
19 TO OPTIMIZE THE VISION OUTCOME, AND THAT'S WHAT WE  
20 ACTUALLY HAVE HERE AT RAY THERAPEUTICS WITH OUR  
21 RTX021 PROGRAM, THE REALISTIC POTENTIAL TO REALIZE  
22 THE FULL VISUAL IMPROVEMENT THAT CAN BE GAINED BY  
23 OPTOGENETICS IN GEOGRAPHIC ATROPHY.

24 AS YOU HEARD, THE PATIENTS ARE EAGERLY  
25 WAITING FOR OUR HIGHLY DIFFERENTIATED AND DERISKED

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1 TREATMENT. AND I THANK THE CIRM ICOC MEMBERS FOR  
2 THEIR ATTENTION AND KIND CONSIDERATION OF OUR  
3 REQUEST TO FUND OUR CURRENT TRAN1 APPLICATION.  
4 THANK YOU VERY MUCH.

5 CHAIRMAN IMBASCIANI: THANK YOU, MR.  
6 FRANCIS. AND I THANK ALL OF THE SPEAKERS FOR THE  
7 CARE WITH WHICH THEY CRAFTED THEIR REMARKS TO THE  
8 BOARD. THANK YOU.

9 MR. TOCHER: VITO, WE HAVE MORE PUBLIC  
10 COMMENT.

11 MS. MANDAC: NEXT ONE IS KAREN CHRISTMAN,  
12 IF YOU COULD UNMUTE AND INTRODUCE YOURSELF.

13 DR. CHRISTMAN: YEAH. HELLO. GOOD  
14 MORNING, EVERYONE. SO MY NAME IS KAREN CHRISTMAN.  
15 I'M A PROFESSOR OF BIOENGINEERING AT UC SAN DIEGO,  
16 AND I'M THE PI OF TRAN1-15291, WHICH IS ON A  
17 PRO-REGENERATIVE INFUSIBLE EXTRACELLULAR MATRIX  
18 BIOMATERIAL FOR TREATING ACUTE MYOCARDIAL  
19 INFARCTION. SO THIS IS A COST-EFFECTIVE  
20 REGENERATIVE MEDICINE SOLUTION WHERE YOU CAN  
21 ACTUALLY DELIVER AT THE TIME SOMEBODY COMES INTO THE  
22 HOSPITAL WITH A HEART ATTACK. IT'S GETTING AN STENT  
23 PLACED, AND YOU CAN USE BIOMATERIAL TO REPAIR THE  
24 HEART.

25 SO OUR SCORE WAS AN 83, SO VERY CLOSE.

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1 AND WHILE I KNOW YOU GET A LOT OF PEOPLE ARGUING WHY  
2 SCIENTIFICALLY THEY SHOULD BE UP JUST A COUPLE  
3 POINTS HIGHER, AND I CAN EASILY DO THAT. BUT WHAT I  
4 WANTED TO PROPOSE WHY WE SHOULD BE FUNDED NOW IS  
5 ACTUALLY A LITTLE BIT DIFFERENT IN THAT WE HAVE A  
6 VERY UNIQUE OPPORTUNITY IF THE CIRM TRAN GRANT IS  
7 FUNDED TODAY TO REALLY ACCELERATE THE WHOLE PROJECT  
8 TOWARDS AN IND AND INTO PATIENTS, WHICH I THINK  
9 EVERYBODY IS WELL AWARE HEART DISEASE IS THE LEADING  
10 KILLER IN THE U.S. AND CALIFORNIA.

11 SO THE UNIQUE OPPORTUNITY IS THAT THE  
12 COMPANY I CO-FOUNDED, VENTRIX BIO, JUST RECEIVED AN  
13 SBIR GRANT FROM THE NATIONAL INSTITUTE OF HEALTH  
14 FROM THE NATIONAL HEART LUNG BLOOD INSTITUTE. AND  
15 I'M CO-INVESTIGATOR ON THE GRANT, AND IT PROVIDES  
16 COMPLEMENTARY SUPPORT FOR PRECLINICAL DEVELOPMENT OF  
17 THE INFUSIBLE EXTRACELLULAR MATRIX PRODUCT.

18 SO WHAT'S UNIQUE IN THIS SITUATION IS  
19 THAT, UNLIKE THE SBIR, CIRM FUNDS MADE A KEY  
20 MANUFACTURING DEVELOPMENT IN MAKING INITIAL BATCHES  
21 OF MATERIAL. SO WHAT WILL ACCELERATE US IS THAT, IF  
22 THE CIRM PROJECT IS FUNDED NOW, WE'LL BE ABLE TO DO  
23 THE PRECLINICAL STUDIES UNDER THE SBIR IN ADDITION  
24 TO THE ONES WITH THE CIRM GRANT WITH THE  
25 MANUFACTURED MATERIAL THAT HAS BEEN SCALED UP AND IS



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1 AT THE SAME CLINICAL GRADE PROCESS THAT WILL BE USED  
2 IN PATIENTS.

3 AND SO WHAT THIS MEANS IS THAT WE'LL BE  
4 ABLE TO ACTUALLY REDUCE SOME COSTS ON THE CIRM GRANT  
5 ON THINGS THAT WE ARE NOT GOING TO HAVE TO REPEAT  
6 WITH THAT MANUFACTURE PROCESS, BUT ALSO OUR  
7 MANUFACTURED PRODUCT, BUT ALSO THAT WE CAN REALLY  
8 ACCELERATE THIS. SO BASICALLY WE THINK THIS WILL  
9 FUND WITH THE SBIR AND THE TRAN GRANT NOW, WE CAN DO  
10 IT ON MANUFACTURED MATERIAL AND DO THE MAJORITY OF  
11 STUDIES THAT WOULD LEAD TO SUBMISSION OF AN IND.  
12 AND WE THINK, BASED ON PREVIOUS EXPERIENCE WITH  
13 MYSELF AND VENTRIX, ANOTHER MATERIAL THAT WENT INTO  
14 PHASE 1 CLINICAL TRIAL IN HEART FAILURE PATIENTS,  
15 THIS WOULD REALLY ALLOW US ACCELERATE BY ABOUT A  
16 YEAR AS OPPOSED TO IF IT'S NOT FUNDED NOW AND WE  
17 HAVE TO DO A RESUBMISSION, WE ARE NOT GOING TO BE  
18 ABLE TO DO THE SBIR STUDIES WITH THE NEW INJECTION  
19 MATERIAL WHICH THEN WILL HAVE TO BE REPEATED AND SET  
20 US BACK.

21 SO THAT'S WHY I'D LIKE TO ADVOCATE FOR  
22 FUNDING NOW VERSUS IN SIX MONTHS AND REALLY  
23 ACCELERATE THIS TECHNOLOGY TO PATIENTS, AGAIN, FOR  
24 THE LEADING CAUSE OF DEATH IN CALIFORNIA. SO THANK  
25 YOU VERY MUCH.

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1 CHAIRMAN IMBASCIANI: THANK YOU FOR YOUR  
2 COMMENTS, PROFESSOR.

3 SCOTT, ARE THERE MORE COMMENTS FROM THE  
4 GENERAL PUBLIC?

5 MR. TOCHER: YES, THERE ARE. I BELIEVE  
6 DR. IRV WEISSMAN HAS INDIVIDUALS, INCLUDING HIMSELF.  
7 IRV, ARE YOU ON THE LINE?

8 MS. MANDAC: WE DID HAVE A CALLER THAT HAD  
9 TRIED TO RAISE A HAND AND THEN DISCONNECTED.

10 CHAIRMAN IMBASCIANI: IF THAT CALLER WOULD  
11 LIKE TO TRY DIALING BACK IN AGAIN.

12 DR. CHRISTMAN: THAT MIGHT HAVE BEEN ME.  
13 I WAS ON MY PHONE EARLIER WHEN I CLOSED IT AND  
14 REALIZED I COULD JUST DO IT ON ZOOM. SO THAT WAS  
15 PROBABLY ME IF IT WAS A 510 NUMBER.

16 MS. MANDAC: OKAY. YES, IT WAS.

17 CHAIRMAN IMBASCIANI: ALL RIGHT. GREAT.  
18 THANK YOU, DR. CHRISTMAN.

19 MR. TOCHER: IS THERE ANY OTHER PUBLIC  
20 COMMENT ON THE LINE?

21 MS. MANDAC: 650.

22 DR. WEISSMAN: HELLO. CAN YOU HEAR ME?

23 MR. TOCHER: YES.

24 DR. WEISSMAN: YES, YOU CAN HEAR ME?

25 CHAIRMAN IMBASCIANI: YES, WE CAN HEAR

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1 YOU. CAN YOU IDENTIFY YOURSELF, THEN START?

2 DR. WEISSMAN: YES. I'M IRV WEISSMAN,  
3 PROFESSOR AT STANFORD UNIVERSITY AND FOUNDER OF THE  
4 INSTITUTE FOR STEM CELL BIOLOGY AND REGENERATIVE  
5 MEDICINE AND CO-AUTHOR OF PROP 71 AND PROP 14.

6 I'M TALKING TO YOU TODAY ABOUT TRAN4-15225  
7 WE WISH TO BRING PURIFIED HUMAN BLOOD-FORMING STEM  
8 CELLS FOR TRANSPLANT TO PATIENTS WITH CANCER AND  
9 PATIENTS WITH GENETIC BLOOD DISEASES. WE DEVELOPED  
10 A METHOD IN 1992 TO PURIFY BLOOD-FORMING STEM CELLS,  
11 WHICH WE CALL CD34+, 90+ HSC. THESE STEM CELLS AS  
12 OBTAINED FROM THE PATIENTS OR THE DONORS ARE CANCER  
13 FREE AND T-CELL FREE. UNFORTUNATELY, THE GRANTS  
14 WORKING GROUP COUNTERED WITH CD34 ONLY SELECTED  
15 CELLS.

16 CD34 SELECTED CELL ISOLATIONS STILL HAVE  
17 CANCER CELLS AND T-CELLS IN THEM, AND WE SHOWED THAT  
18 DATA IN THE GRANT. WE NEVER PROPOSED CD34. CD34  
19 CELLS WILL NOT WORK IN THE SITUATION WE ARE DEALING  
20 WITH, AND THEY ARE NOT COMPARABLE. SO SOMEHOW THAT  
21 MISTAKE WAS MADE DURING THE GWG.

22 IN 1996 SYSTEMIX, A COMPANY I FOUNDED AND  
23 STARTED, A TRIAL WITH WOMEN WITH METASTATIC BREAST  
24 CANCER. AFTER HIGH DOSE COMBINATION CHEMOTHERAPY,  
25 WHICH ELIMINATES NOT ONLY MOST OF THEIR CANCER, BUT

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1 THEIR WHOLE BLOOD-FORMING SYSTEM, 15 PATIENTS WERE  
2 RESCUED WITH THEIR OWN HIGHLY PURIFIED STEM CELLS  
3 AND 74 WITH UNPURIFIED STARTING MATERIAL. THIS WAS  
4 THE FIRST AND ONLY TIME PURIFIED STEM CELLS WERE  
5 TRANSPLANTED TO PATIENTS, BLOOD-FORMING STEM CELLS.

6 NOW, YEARS LATER THE MEDIAN SURVIVAL OF  
7 PATIENTS RESCUED WITH THEIR OWN MOBILIZED BLOOD, THE  
8 STANDARD PRACTICE THEN, WAS TWO YEARS AND ALL WERE  
9 DEAD OR RELAPSED BY 12 YEARS. THE MEDIAN SURVIVAL,  
10 HOWEVER, OF PATIENTS RESCUED WITH THEIR OWN  
11 CANCER-FREE STEM CELLS MEDIAN WAS TEN YEARS AND  
12 ONE-THIRD OF THEM ARE ALIVE BOTH AT 12 YEARS AND NOW  
13 AT 24 YEARS.

14 THE LARGE PHARMA THAT BOUGHT SYSTEMIX SHUT  
15 IT DOWN IN EARLY 2000 WITHOUT SEEING THESE RESULTS.  
16 I'M GUESSING IT WAS A BUSINESS DECISION, BUT IT'S  
17 JUST A GUESS.

18 PATIENTS WITH GENETICALLY DEFECTIVE BLOOD  
19 AND IMMUNE SYSTEMS CAN BE RESCUED WITH HEALTHY  
20 BLOOD-FORMING SYSTEMS OR WITH GENE THERAPY. WE HAVE  
21 SHOWN THAT PURE BLOOD-FORMING STEM CELLS LACKING  
22 MATURE T-CELLS CAN BE TRANSPLANTED DONOR TO HOST  
23 WITHOUT GRAFT VERSUS HOST DISEASE, AND THEY REPLACE  
24 THE DISEASE BLOOD-FORMING SYSTEMS. CD34 SELECTED  
25 CELLS HAVE T-CELLS, AND WE AND OTHERS HAVE SHOWN

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1 CAUSE GRAFT VERSUS HOST DISEASE.

2 WE NEGOTIATED WITH THE LARGE PHARMA THAT  
3 BOUGHT US AND RETRIEVED THE RIGHTS TO ISOLATE PURE  
4 BLOOD-FORMING STEM CELLS AT STANFORD AT NO ADDED  
5 COST IN A NOT-FOR-PROFIT METHOD. WE PROPOSE A  
6 BREAST CANCER TRIAL EXTENSIONS FIRST AND HEALTHY  
7 DONOR BLOOD-FORMING STEM CELLS FOR SICKLE CELL  
8 DISEASE NEXT, HOPEFULLY THROUGH CIRM ALPHA CLINIC  
9 STEM CELL CLINICS.

10 PLEASE RESTORE TRUE STEM CELL  
11 TRANSPLANTATION, THE ONLY TRUE, PURE STEM CELL  
12 TRANSPLANTATION FOR AN ENORMOUS SET OF UNMET NEED  
13 FROM CANCER TO GENETIC BLOOD DISEASES AND FOR ORGAN  
14 AND OTHER TISSUE STEM CELL TRANSPLANTS. THANK YOU.

15 CHAIRMAN IMBASCIANI: THANK YOU, PROFESSOR  
16 WEISSMAN.

17 MR. TOCHER: IRV, THIS IS SCOTT. ARE  
18 THERE ANY OTHER MEMBERS OF THE PUBLIC THAT YOU  
19 BROUGHT TO THE MEETING? ARE THERE ANY OTHER MEMBERS  
20 OF THE PUBLIC?

21 DR. WEISSMAN: DID JOE GANTZ PROVIDE A  
22 DOCUMENT OR THE VIDEO OR AN AUDIO FOR THIS SESSION?

23 MR. TOCHER: HE PROVIDED THE VIDEO IN HE  
24 HAS A LETTER YESTERDAY WHICH WAS DISTRIBUTED TO THE  
25 BOARD YESTERDAY.

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1 DR. WEISSMAN: SO I WOULD URGE EITHER  
2 LICENSING TO THE AUDIO PORTION OR ON YOUR OWN PLEASE  
3 WATCH THE VIDEO.

4 CHAIRMAN IMBASCIANI: OKAY.

5 MR. JUELSGAARD: YES. CALL THE QUESTION.

6 CHAIRMAN IMBASCIANI: STEVEN, DID YOU SAY  
7 CALL THE QUESTION?

8 MR. JUELSGAARD: YES. PROCEED TO A VOTE.

9 CHAIRMAN IMBASCIANI: YES. WELL, IT'S A  
10 LITTLE COMPLICATED RIGHT NOW. SO WHAT I WOULD LIKE  
11 TO DO, IF THE BOARD WILL ALLOW ME, IS TO ABSTRACT  
12 THE THREE THAT WERE JUST COMMENTED ON FOR INDIVIDUAL  
13 CONVERSATION AND VOTE AND THEN PROCEED TO A MOTION  
14 TO CONSIDER ALL THE RESIDUAL APPLICATIONS IN TIER  
15 II. TO DO THAT, I NEED THE APPLICATION NUMBER FOR  
16 THE GEOGRAPHIC ATROPHY ONE AGAIN PLEASE.

17 DR. FISHER: WELL, CAN OUR PARLIAMENTARIAN  
18 CONFIRM THAT THE BOARD CHAIR CAN DETERMINE TO DO  
19 THIS WHEN THERE IS A MOTION AND A SECOND, THEN A  
20 CALL FOR THE QUESTION ON THE TABLE?

21 CHAIRMAN IMBASCIANI: THAT'S A GOOD  
22 QUESTION, FRED. I MEAN THE ALTERNATIVE IS TO ASK  
23 FOR AMENDMENTS TO THE MOTION.

24 DR. FISHER: I JUST DON'T WANT YOU TO BE  
25 OUT OF COMPLIANCE WITH PARLIAMENTARY PROCEDURE.

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1           CHAIRMAN IMBASCIANI:  THANK YOU.  WHO IS  
2   OUR PARLIAMENTARIAN?

3           DR. FISHER:  I'M GUESSING IT'S SCOTT.

4           MR. TOCHER:  YES.  FRED RAISES THE POINT,  
5   AND, VITO, YOU ARE CORRECT, THAT THE APPROPRIATE  
6   NEXT STEP WOULD BE A MOTION TO AMEND --

7           CHAIRMAN IMBASCIANI:  OKAY.

8           MR. TOCHER:  -- TO BE TAKEN UP BEFORE THE  
9   MOTION ON THE TABLE.

10          CHAIRMAN IMBASCIANI:  THAT'S FINE.  WE'LL  
11   DO IT BY ROBERTS RULES.

12          SO MAY I HEAR FROM THE BOARD ANY MOTION TO  
13   ABSTRACT ONE OR MORE OF THESE APPLICATIONS FROM THE  
14   VOTE?  THE VOTE THAT I'M REFERRING TO WILL BE NOT TO  
15   FUND ALL THE APPLICATIONS IN TIER II.  SO IF YOU  
16   WANT TO CONSIDER FUNDING ONE OF THESE IN TIER II,  
17   I'M ASKING FOR A MOTION TO ABSTRACT THAT NOW.

18          DR. HIGGINS:  SO MOVED.  DAVID IN SAN  
19   DIEGO.

20          MR. JUELGAARD:  WAIT A MINUTE.  WHICH  
21   ONE, ONE OR ONES?  AND BY THE WAY, IT'S NOT REALLY  
22   ABSTRACTING THEM.  IT'S MOVING THEM FROM TIER II TO  
23   TIER I.  THAT'S THE MOTION THAT HAS TO BE MADE.

24          CHAIRMAN IMBASCIANI:  THANK YOU.

25          DR. FISHER:  I THINK THE MOTION IS -- I

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1 THINK YOU HAVE TO BASICALLY ASK THE PEOPLE WHO MADE  
2 THE ORIGINAL MOTION IF THEY'RE OPEN TO AMENDMENTS TO  
3 THEIR MOTION.

4 CHAIRMAN IMBASCIANI: I DON'T THINK WE  
5 NEED TO DO THAT.

6 MR. TOCHER: SORRY. FRED, ONCE THE MOTION  
7 IS MADE AND SECONDED, IT'S -- IT BELONGS TO THE  
8 WHOLE FLOOR, TO THE WHOLE COMMITTEE. SO, THEREFORE,  
9 PROCEDURALLY THE WAY TO HANDLE THIS IS A MOTION TO  
10 AMEND THIS MOTION, WHICH IS THEN PRIVILEGED AND IS  
11 VOTED UPON BEFORE THE UNDERLYING MOTION IS TAKEN UP.

12 SO -- BUT THE POINT IS WELL TAKEN AS TO  
13 DAVID'S ATTEMPT TO MAKE A MOTION. IF YOU CAN  
14 IDENTIFY, DAVID, TO WHICH APPLICATION YOU'RE SEEKING  
15 TO FUND.

16 DR. HIGGINS: SO WE HAVE TO PICK ONE AS  
17 OPPOSED TO --

18 CHAIRMAN IMBASCIANI: OR SEVERAL.

19 VICE CHAIR BONNEVILLE: CAN I ASK A  
20 QUESTION? I DON'T WANT TO HANDLE ALL THESE THE SAME  
21 WAY BECAUSE THEY'RE WILDLY DIFFERENT IN SCORE AND  
22 COMMENTS THAT HAVE BEEN MADE BY THE GWG. AND I  
23 DON'T THINK THAT THAT'S APPROPRIATE. THAT'S MY  
24 PERSONAL OPINION. SO IF WE NEED TO DO IT ON AN  
25 INDIVIDUAL BASIS, I WOULD PREFER THAT WE HANDLE IT



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1 THAT WAY. I MAY BE ALONE IN THINKING THAT, BUT I  
2 JUST WANTED TO CALL THAT OUT.

3 CHAIRMAN IMBASCIANI: MARIA, I THINK  
4 ULTIMATELY EACH OF THE ONES THAT WE WILL MOVE TO  
5 TIER I THROUGH THIS PROCESS WOULD GET THEIR OWN  
6 INDIVIDUAL VOTE.

7 VICE CHAIR BONNEVILLE: NOT IF WE EXTRACT  
8 ALL OF THEM AT ONCE.

9 MR. TOCHER: THE POINT IS TO HANDLE THESE  
10 ON A SINGLE BASIS --

11 CHAIRMAN IMBASCIANI: OKAY.

12 MR. TOCHER: -- BY MOTION. SO AGAIN,  
13 DAVID, CAN YOU IDENTIFY THE APPLICATION THAT YOU  
14 WOULD LIKE TO --

15 DR. HIGGINS: MOST CERTAINLY I CAN. I'M  
16 ENTHUSIASTIC ABOUT THIS. FOR 15291, I JUST DON'T  
17 FEEL -- WAIT A MINUTE. SORRY. NEXT ONE UP.  
18 GEOGRAPHIC ATROPHY, THAT'S 15341. SO THIS COMMENT  
19 IS GOING TO BE RELATIVE TO THAT.

20 I DON'T BELIEVE THAT THERE'S A DIFFERENCE  
21 BETWEEN 84 AND 85, NO. 1. AND NO. 2, I THINK THIS  
22 IS WORK THAT DESERVES TO BE FUNDED. SO MY MOTION  
23 WOULD APPLY TO THAT ONE.

24 MR. TOCHER: OKAY. SO THE MOTION IS TO  
25 MOVE APPLICATION 15341 UP TO TIER I AND TO FUND IT.

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1 DR. HIGGINS: THAT'S MY MOTION, YES.

2 THANK YOU.

3 MR. TOCHER: OKAY.

4 MS. DURON: MR. CHAIR, I SEE THAT ADRIANA  
5 PADILLA HAS HAD HER HAND UP FOR SOME TIME.

6 CHAIRMAN IMBASCIANI: I DO TOO. I'M JUST  
7 WONDERING, SCOTT, AS TO A MATTER OF PROCESS HERE.  
8 WE'VE GOT A MOTION FOR ONE APPLICATION TO BE REMOVED  
9 TO TIER I. SHOULD WE HANDLE THIS ONE DEFINITELY  
10 NOW AND THEN MOVE ON TO SUBSEQUENT MOTIONS? WE  
11 SHOULD. OKAY. WHY DON'T WE DO THAT. ADRIANA, CAN  
12 YOU --

13 MR. TOCHER: CAN I BE HEARD. OKAY.  
14 GREAT. WE JUST NEED A SECOND TO DAVID'S MOTION.

15 VICE CHAIR BONNEVILLE: I SECOND.

16 MR. TOCHER: THANK YOU.

17 CHAIRMAN IMBASCIANI: ADRIANA.

18 DR. PADILLA: YES. I WAS AGREEING WITH  
19 THE MOTION ON THE FLOOR. I ALSO WANTED TO CONSIDER  
20 MOVING THE TRAN 15291 ALSO FOR CONSIDERATION FOR  
21 FUNDING.

22 THEIR SCORE, IF YOU LOOK AT THE NUMBER OF  
23 GWG VOTES, IT WAS JUST RIGHT UP THERE. AND ACTUALLY  
24 THEY HAD FIVE PEOPLE WHO ULTIMATELY WERE WILLING TO  
25 FUND IT VERSUS TEN NOT. AND THAT'S PRETTY

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1 SIGNIFICANT NUMBERS THAT I SEE.

2 MR. JUELSGAARD: I THINK WE NEED TO DEAL  
3 WITH THIS ONE FIRST. WE HAVE A MOTION AND THEN WE  
4 CAN MOVE TO WHATEVER ELSE WE MIGHT BE INTERESTED IN  
5 MOVING FORWARD. LET'S JUST DO THIS SO WE DON'T ALL  
6 GET CONFUSED.

7 CHAIRMAN IMBASCIANI: I AGREE. SO,  
8 ADRIANA, WOULD YOU HOLD THAT IN RESERVE?

9 DR. PADILLA: SURE.

10 CHAIRMAN IMBASCIANI: JOE PANETTA. HELLO.

11 MR. PANETTA: HELLO, MR. CHAIRMAN. I  
12 HEARD SOME PRETTY COMPELLING TESTIMONY ABOUT 15341  
13 FROM THE THREE PRESENTERS, BUT I SEE THAT IT HAS A  
14 SCORE OF ONE YES AND 13 NOS. AND SO MAY I ASK A  
15 QUESTION OF GIL?

16 CHAIRMAN IMBASCIANI: I THINK, YES. GO  
17 AHEAD, GIL.

18 MR. PANETTA: SO, GIL, I THINK THE FIRST  
19 PRESENTER COMMENTED THAT THERE WAS A SINGLE  
20 DEFICIENCY THAT THEY CORRECTED IN THE PROPOSAL AND  
21 THAT THAT SHOULD THEN MAKE IT APPROPRIATE FOR  
22 APPROVAL. BUT WHAT I'M CURIOUS ABOUT IS WERE THOSE  
23 13 NO VOTES RELATIVE TO THAT DEFICIENCY?

24 DR. SAMBRANO: YEAH. NO, THAT'S A GREAT  
25 QUESTION. IT'S HARD TO KNOW EXACTLY IF THAT IS WHY.

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1 I THINK WE CAN SURMISE THAT THAT IS PROBABLY THE  
2 CASE BECAUSE THAT WAS THE MOST OUTSTANDING ISSUE  
3 THAT WAS RAISED RELATED TO THIS APPLICATION.  
4 MEANING THAT THERE WAS A MODEL THAT REVIEWERS WOULD  
5 LIKE TO HAVE SEEN DONE IN THE PRELIMINARY DATA THAT  
6 WAS NOT USED.

7 I THINK THE QUESTION HERE IS IS THIS  
8 SOMETHING THAT WE WOULD WANT NOT JUST SIMPLY FOR THE  
9 APPLICANTS TO DO, BUT ALSO WHETHER THE GRANTS  
10 WORKING GROUP COULD SEE THE OUTCOME OF THAT BEFORE  
11 MOVING FORWARD OR WHETHER THERE IS A MILESTONE THAT  
12 WE COULD PUT IN PLACE, IF WE DECIDE TO FUND IT, THAT  
13 WOULD HAVE THEM DO THAT STUDY BEFORE MOVING FORWARD.

14 MR. PANETTA: OKAY. THANKS. BECAUSE I  
15 JUST WANT TO BE SURE THAT IF IT WERE THAT SINGLE  
16 DEFICIENCY AND THAT WERE THE DECISION TO BE MADE,  
17 THAT THERE WERE NOT OTHER DEFICIENCIES THAT WE  
18 SHOULD CONSIDER IN THIS BECAUSE ONE YES AND 13 NOS  
19 IS PRETTY LOPSIDED.

20 DR. SAMBRANO: YEAH. I AGREE. I THINK  
21 THAT THE MAJOR CONCERN WAS THE USE OF THAT MODEL.

22 CHAIRMAN IMBASCIANI: LET ME REMIND THE  
23 BOARD MEMBERS. WE ARE NOW WORKING ON THE MOTION TO  
24 MOVE APPLICATION 15341, THE ONE DEALING WITH  
25 GEOGRAPHIC ATROPHY, FROM TIER II TO TIER I. SO

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1 LET'S CONTINUE THAT DISCUSSION.

2 MR. FISHER.

3 DR. FISHER: I HAD A SIMILAR QUESTION.

4 I'LL ASK IT IN A DIFFERENT WAY. I'M WONDERING IF  
5 GIL AGREES WITH THE APPLICANT'S CHARACTERIZATION OF  
6 THE DEFICIENCIES AND THEIR CONCLUSION THAT IT WAS  
7 THAT SOLE DEFICIENCY THAT WAS THE RESULT OF THEIR  
8 SCORE OR THEIR VOTES. AND DO THE STAFF AGREE THAT,  
9 WITH THAT DEFICIENCY CORRECTED, THIS BECOMES A  
10 FUNDABLE PROPOSAL?

11 DR. SAMBRANO: SO, FRED, I DO AGREE THAT  
12 THE MAJOR CONCERN WAS CONDUCTING THE PRECLINICAL  
13 EXPERIMENTS USING A MODEL THAT WAS NOT USED AND THAT  
14 REVIEWERS WOULD LIKE TO HAVE SEEN IT. I DO THINK  
15 THAT WAS THE MAJOR CONCERN.

16 I THINK ADDRESSING THAT WOULD IMPROVE THE  
17 APPLICATION OR WOULD HAVE IMPROVED THE APPLICATION,  
18 BUT I WOULD HESITATE TO SPEAK FOR THE GRANTS WORKING  
19 GROUP IN TERMS OF ULTIMATELY WHAT DROVE THEIR SCORE  
20 AND WHETHER THERE WERE ADDITIONAL CONCERNS THAT WERE  
21 NOT VOICED OR NOT REPRESENTED IN THE SUMMARY. BUT  
22 BASED ON THE SUMMARY THAT WE HAVE AND WHAT WE HEARD  
23 FROM THE GRANTS WORKING GROUP, I THINK THAT WAS THE  
24 MAJOR CONCERN.

25 DR. FISHER: GIVEN MY EXPERIENCE ON THE

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1 GRANTS WORKING GROUP, I AM TYPICALLY RELUCTANT TO  
2 OVERTURN THEIR DECISIONS GIVEN MY EXPERIENCE OF THE  
3 THOROUGHNESS AND THE SERIOUSNESS WITH WHICH THEY  
4 TAKE THEIR REVIEWS. SO IF, IN FACT, THIS IS THE  
5 SOLE DEFICIENCY, THEN I WOULD HOPE THAT IF WE  
6 ULTIMATELY RECOMMEND FUNDING THIS PROPOSAL, THAT  
7 THAT FUNDING WOULD BE CONDITIONAL UPON A RESULT OF  
8 THIS ADDITIONAL REQUIRED EXPERIMENT.

9 CHAIRMAN IMBASCIANI: OKAY. ANY FURTHER  
10 DISCUSSION FROM BOARD MEMBERS?

11 VICE CHAIR BONNEVILLE: STEVE HAS HIS HAND  
12 RAISED.

13 MR. TOCHER: STEVE, YOU'RE IN CONFLICT  
14 WITH THIS APPLICATION UNLESS IT'S A PROCESS  
15 QUESTION.

16 MR. JUELSGAARD: NO. I WAS -- I'M TRYING  
17 TO THINK WHETHER IT'S A PROCESS POINT OR NOT. NO,  
18 IT WASN'T. OKAY. SO I'M IN CONFLICT. ALL RIGHT.

19 CHAIRMAN IMBASCIANI: THANK YOU. THANKS,  
20 SCOTT. ANY OTHER MEMBERS OF THE BOARD WANT TO  
21 COMMENT ON THIS 15341? ANY MEMBERS OF THE PUBLIC WE  
22 HAVEN'T HEARD FROM YET? AFTER YOUR CHECK, SCOTT, I  
23 THINK YOU CAN PROCEED TO A VOTE. AN AYE VOTE, MAYBE  
24 YOU CAN CLARIFY WHAT THE AYE VOTE MEANS.

25 MR. TOCHER: YES. AN AYE VOTE WOULD BE TO

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1       FUND APPLICATION 15341.

2                   CHAIRMAN IMBASCIANI:   EXCUSE ME.   I THINK  
3       YOU MEAN TO PUT INTO TIER I, YES?

4                   MR. TOCHER:   THE MOTION WAS TO FUND.

5                   CHAIRMAN IMBASCIANI:   OKAY.   ALL RIGHT.

6                   MR. TOCHER:   DAN BERNAL.

7                   MR. BERNAL:   AYE.

8                   MR. TOCHER:   MARIA BONNEVILLE.

9                   VICE CHAIR BONNEVILLE:   YES.

10                  MR. TOCHER:   LEONDRA CLARK-HARVEY.

11                  DR. CLARK-HARVEY:   AYE.

12                  MR. TOCHER:   YSABEL DURON.

13                  MS. DURON:    YES.

14                  MR. TOCHER:   MARK FISCHER-COLBRIE.

15                  MR. FISCHER-COLBRIE:   AYE.

16                  MR. TOCHER:   FRED FISHER.

17                  DR. FISHER:    AYE.

18                  MR. TOCHER:   ELENA FLOWERS.

19                  DR. FLOWERS:   YES.

20                  MR. TOCHER:   DAVID HIGGINS.

21                  DR. HIGGINS:   YES.

22                  MR. TOCHER:   VITO IMBASCIANI.

23                  CHAIRMAN IMBASCIANI:   YES.

24                  MR. TOCHER:   RICH LAJARA.

25                  MR. LAJARA:    YES.

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1 MR. TOCHER: LAUREN MILLER-ROGEN.

2 MS. MILLER-ROGEN: YES.

3 MR. TOCHER: ADRIANA PADILLA.

4 DR. PADILLA: YES.

5 MR. TOCHER: AND JOE PANETTA.

6 MR. PANETTA: YES.

7 MR. TOCHER: ALL RIGHT. THAT MOTION  
8 CARRIES. THAT APPLICATION IS FUNDED AND IS NOT PART  
9 OF TIER II.

10 CHAIRMAN IMBASCIANI: ALL RIGHT. NOW I  
11 WOULD LIKE TO OPEN THE FLOOR TO MOTIONS TO MOVE TO  
12 TIER I OR TO FUND ANY OF THE OTHER TWO APPLICATIONS  
13 THAT WE TALKED ABOUT.

14 MR. TOCHER: I BELIEVE ADRIANA HAS HER  
15 HAND UP.

16 CHAIRMAN IMBASCIANI: YES, ADRIANA.

17 DR. PADILLA: I WANTED TO RETURN BACK TO  
18 MY MOTION PREVIOUSLY TO MOVE UP THE TRAN 15291 AGAIN  
19 FOR THE REASON THAT THE SCORING WAS FAVORABLE WITH  
20 THE FINAL VOTES FOR THE GWG GROUP FIVE FOR FUNDING  
21 AND TEN FOR NOT AND A DEI SCORE THAT WAS VERY  
22 REASONABLE AND FOR THE HEALTH PROBLEM THAT IS VERY  
23 SIGNIFICANT TO MAJOR POPULATIONS HERE IN CALIFORNIA.

24 CHAIRMAN IMBASCIANI: THANK YOU. WE NEED  
25 A SECOND FOR THIS MOTION OR DO WE ALREADY HAVE ONE?



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1 MR. TOCHER: WE DON'T HAVE ONE YET.

2 DR. HIGGINS: I'LL SECOND.

3 CHAIRMAN IMBASCIANI: THAT WAS DAVID  
4 HIGGINS. THANK YOU. FURTHER DISCUSSION?

5 MS. MANDAC: FRED HAS HIS HAND RAISED.

6 CHAIRMAN IMBASCIANI: FRED. YES, I SEE IT  
7 NOW.

8 DR. FISHER: I THINK IT WOULD BE HELPFUL  
9 TO HEAR FROM GIL ABOUT THIS PROPOSAL AND THE STAFF'S  
10 THOUGHTS ABOUT APPROVING IT IN ITS CURRENT STATE.

11 DR. SAMBRANO: SO THIS APPLICATION IS  
12 PRO-REGENERATIVE INFUSIBLE ECM BIOMATERIAL FOR  
13 TREATING ACUTE MYOCARDIAL INFARCTION. SO THE  
14 CANDIDATE IS AN INJECTABLE BIOMATERIAL THAT'S  
15 DERIVED FROM SCAFFOLDING OF PIG HEART THAT'S USED TO  
16 FOLLOW TREATMENT OF MYOCARDIAL INFARCTION.

17 SO THE APPLICATION RECEIVED A SCORE OF 83.  
18 AND AS MENTIONED, THERE WERE FIVE MEMBERS WHO SCORED  
19 85 OR ABOVE AND TEN THAT SCORED BELOW.

20 THE MAJOR CONCERN THAT WAS HIGHLIGHTED BY  
21 REVIEWERS WAS THE NEED FOR THE APPLICANT TEAM TO  
22 SEEK ADVICE FROM THE FDA. THEY WERE CONCERNED THAT  
23 THE STUDIES THAT ARE PROPOSED, WHICH IN GENERAL  
24 PRESENT A GOOD RATIONALE, ARE WELL-PLANNED AND  
25 DESIGNED MAY NOT BE THE CORRECT STUDIES TO DO. AND

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1 THAT DEPENDING ON THE SPECIFIC REGULATORY ROUTE THAT  
2 THIS GOES THROUGH, WHETHER IT'S THROUGH CBIR OR  
3 WHETHER IT IS CONSIDERED A DEVICE MAY IMPACT ON WHAT  
4 THOSE STUDIES SHOULD BE AND HOW THEY'RE DONE.

5 THE APPLICANTS HAVE PUT THROUGH A VERY  
6 SIMILAR OR SAME PRODUCT THROUGH THE REGULATORY  
7 PROCESS IN THE PAST, BUT THERE WERE SOME KEY  
8 DIFFERENCES NOTED BY REVIEWERS RELATED TO THE TIMING  
9 AND THE SPECIFIC APPLICABILITY OF THIS PARTICULAR  
10 CASE USE THAT MAY MAKE IT DIFFERENT. AND SO I THINK  
11 THAT WAS THE PRIMARY CONCERN FROM REVIEWERS TO  
12 ENSURE THAT THE STUDIES THAT ARE BEING PROPOSED HERE  
13 HAVE HAD A LOOK BY THE FDA TO MAKE SURE THAT THEY  
14 ARE ON THE RIGHT PATH TO AVOID HAVING TO EITHER DO  
15 THEM AGAIN OR DO THEM DIFFERENTLY.

16 SO I THINK THAT WAS THE OVERLYING CONCERN.

17 DR. FISHER: AND DID THE APPLICANT,  
18 HEARING THAT FEEDBACK, HAVE A RESPONSE? I DIDN'T  
19 HEAR THEM ADDRESS THAT IN THE COMMENTS.

20 DR. SAMBRANO: CORRECT. I DID NOT SEE  
21 THAT EITHER.

22 DR. FISHER: I THINK IT SOUNDS TO ME LIKE  
23 IF WE ARE NOT SURE THAT THIS IS ON THE RIGHT PATH,  
24 THEN WE COULD BE SPENDING THIS MONEY ONLY TO FIND  
25 THAT IT WAS WASTED BECAUSE IT WAS ON THE WRONG PATH

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1 TOWARD FDA APPROVAL, WHICH IS WHAT WE ALL ULTIMATELY  
2 SEEK, INCLUDING THE APPLICANT. IT SEEMS LIKE THEY  
3 WOULD WANT THAT FEEDBACK BEFORE MOVING FORWARD ALSO.

4 AGAIN, IF PEOPLE ARE MOTIVATED TO FUND  
5 THIS PROPOSAL, THEN IS IT POSSIBLE FOR US TO MAKE  
6 FUNDING CONDITIONAL ON THE FDA AGREEING THAT THIS  
7 APPLICATION IS ACTUALLY ON THE RIGHT TRACK TOWARD  
8 APPROVAL?

9 DR. SAMBRANO: WE COULD DO THAT. I THINK  
10 THE QUESTION IS TO WHAT EXTENT DOES THE PROPOSAL  
11 POTENTIALLY CHANGE IN TERMS OF WHAT STUDIES HAVE TO  
12 BE CONDUCTED WITH THE BUDGET AS THEY LAID OUT. IF  
13 IT'S SIGNIFICANTLY DIFFERENT, THAT COULD POSE A  
14 PROBLEM MOVING FORWARD. IF IT SOLIDIFIES AND  
15 VALIDATES WHAT THEY HAVE ALREADY PROPOSED, THEN IT  
16 WOULD NOT BE AN ISSUE.

17 DR. FISHER: YEAH. I WOULD SUGGEST THAT  
18 IF THE FDA DOES NOT AGREE THAT THIS IS ON THE RIGHT  
19 PATH, THEN THE APPLICANT WOULD HAVE TO COME BACK  
20 WITH A NEW APPLICATION BECAUSE THE -- THEY WOULDN'T  
21 BE ELIGIBLE FOR THE FUNDING BASED ON THAT CONCLUSION  
22 BY THE FDA.

23 CHAIRMAN IMBASCIANI: THANK YOU, FRED. I  
24 HAVE NEXT STEPHEN JUELGAARD WHO'S GOING TO BE  
25 FOLLOWED BE DAN BERNAL AND THEN MARIA BONNEVILLE.

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1       STEPHEN.

2                   MR. TOCHER:   STEVE, YOU'RE MUTED.

3                   MR. JUELSGAARD:  SORRY.  MUTED AND OFF  
4       SCREEN.  THERE WE GO.

5                   A QUESTION, THEN A POINT.  SO THE QUESTION  
6       IS REALLY OF GIL.  SO FRED ASKED YOU THE QUESTION  
7       ABOUT THE STAFF'S VIEW OF THIS AND THE IMPORTANCE OF  
8       HAVING A MEETING WITH THE FDA AHEAD OF TIME TO MAKE  
9       SURE THAT YOU'RE ON THE RIGHT TRACK WITH RESPECT TO  
10      THE EXPECTED CLINICAL -- PRECLINICAL ENDPOINTS THAT  
11      YOU'RE LOOKING AT.  SO I TAKE IT BECAUSE YOU HAVEN'T  
12      APPROVED -- YOU'RE NOT RECOMMENDING THIS FOR  
13      APPROVAL, THAT YOU AGREE WITH ESSENTIALLY THE POINT  
14      OF VIEW THAT IT WOULD BE BEST FOR THIS PARTICULAR  
15      APPLICANT TO HAVE A MEETING WITH THE IND, A PRE,  
16      PRE-IND MEETING IS ESSENTIALLY WHAT IT RELATES TO,  
17      BUT AN EARLY MEETING TO MAKE SURE THAT THEY'RE ON  
18      THE RIGHT PATH.  SO THAT'S A QUESTION.  I'M GOING TO  
19      LET YOU ANSWER THAT IN JUST A SECOND.  SO LET ME  
20      JUST MAKE THE POINT.

21                  THE POINT IS IN THE LETTER THAT WAS  
22      SUBMITTED THAT WE HAD A CHANCE TO READ, I DIDN'T SEE  
23      ANYTHING REALLY ADDRESSING THAT POINT THAT WAS  
24      PICKED UP ON BY THE REVIEWERS.  THE LETTER, INSTEAD,  
25      FOCUSED ON THE FACT THAT WE HAVE APPROVED

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1 APPLICATIONS IN THE PAST THAT HAD LOWER THAN 85  
2 SCORES, WHICH I DON'T FIND PARTICULARLY HELPFUL.  
3 IT'S TRUE, BUT I'M NOT SURE WHY THAT SHOULD MATTER  
4 HERE. THEY DIDN'T REALLY ADDRESS THE ISSUE OF WHY  
5 IT'S NOT IMPORTANT TO HAVE A MEETING WITH THE -- AN  
6 EARLY MEETING WITH THE FDA.

7 SO ANYWAY, BACK TO YOU, GIL. WHAT'S YOUR  
8 VIEW OR THE STAFF'S VIEW OF THIS WHAT I'LL CALL A  
9 PRE, PRE-IND FDA MEETING?

10 DR. SAMBRANO: YEAH. THANK YOU. SO OUR  
11 RECOMMENDATION FOR ALL OF THESE APPLICATIONS THAT  
12 WERE IN HERE DO WAS TO ALIGN WITH THE GRANTS WORKING  
13 GROUP RECOMMENDATION. AGAIN, WE BELIEVE THAT THE  
14 PROCESS THAT WE HAVE IN PLACE THAT ALLOWS A  
15 RESUBMISSION AND A REVISION TO ADDRESS THE CONCERNS  
16 IS SOMETHING THAT LEADS TO IMPROVED AND BETTER  
17 APPLICATIONS. SO WE ARE GENERALLY COMFORTABLE WITH  
18 THAT RECOMMENDATION, AND WE DIDN'T SEE ANYTHING  
19 SPECIFIC ABOUT THIS ONE THAT WOULD PROMPT US TO  
20 SPECIFICALLY FUND IT NOW.

21 MR. JUELSGAARD: THANK YOU.

22 CHAIRMAN IMBASCIANI: THANK YOU, STEPHEN.  
23 THAT MEANS DAN IS NEXT.

24 MR. BERNAL: THANK YOU, MR. CHAIR.  
25 QUESTION FOR GIL. AND, GIL, FIRST OF ALL, THANK YOU

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1 SO MUCH FOR ALWAYS BEING SO WELL PREPARED AND ABLE  
2 TO ANSWER ALL OF OUR QUESTIONS DURING THESE  
3 MEETINGS.

4 IT SEEMS THAT THIS APPLICATION WAS SCORED  
5 JUST BELOW THE THRESHOLD FOR A MINORITY REPORT.  
6 THAT BEING SAID, IS THERE ANYTHING THAT STANDS OUT  
7 FROM ANY OF THE COMMENTS FROM THE REVIEWERS THAT  
8 MIGHT HAVE BEEN RELEVANT OR PARTICULARLY COMPELLING  
9 FROM WITHIN THOSE COMMENTS THAT MIGHT HAVE LED TO A  
10 MINORITY REPORT THAT WOULD SWAY THIS VOTE?

11 DR. SAMBRANO: YEAH. I THINK IN GENERAL  
12 THIS IS A VERY GOOD APPLICATION. AND I THINK  
13 REVIEWERS THINK THIS IS SOMETHING THAT ULTIMATELY  
14 CAN GO FORWARD. AND I THINK THERE'S ENTHUSIASM  
15 BEHIND TAKING THIS APPROACH AND HAVING THE APPLICANT  
16 MOVE FORWARD WITH THIS PATH.

17 I THINK THE CONCERN WAS, AGAIN, THAT  
18 WITHOUT HAVING DIRECTION FROM THE FDA, THEY MAY BE  
19 EMBARKING ON STUDIES THAT ARE EITHER INAPPROPRIATE  
20 OR MAY BE JUST A WASTE OF TIME. AND THAT THEY MAY  
21 ACTUALLY BE ABLE TO DO THIS FOR LESS, PARTICULARLY  
22 IF THIS IS CONSIDERED A DEVICE, AND MAY NOT HAVE TO  
23 GO THROUGH THE ROUTE AS PROPOSED.

24 SO I THINK FOR A MINORITY REPORT, IF THIS  
25 HAD QUALIFIED, I THINK THE SAME POINTS STAND. AND I

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1 DON'T SEE ANYTHING IN PARTICULAR BEYOND THAT THAT I  
2 THINK WOULD BE HIGHLIGHTED IN THE MINORITY REPORT.

3 MR. BERNAL: THANKS, GIL.

4 CHAIRMAN IMBASCIANI: MARIA, YOU HAD YOUR  
5 HAND UP. WHERE DID YOU GO?

6 VICE CHAIR BONNEVILLE: I LOWERED IT. MY  
7 QUESTION WAS ANSWERED. THANK YOU.

8 CHAIRMAN IMBASCIANI: OKAY. ADRIANA.

9 DR. PADILLA: JUST CLARIFICATION FROM GIL.  
10 THE POINT THAT WAS IN THE LETTER AS FAR AS A  
11 PREVIOUS AWARDED GRANT, WAS THAT PART OF THE  
12 APPLICATION OR WAS THAT AN AFTER FACT ISSUE THAT  
13 WASN'T TAKEN INTO CONSIDERATION?

14 DR. SAMBRANO: I'M SORRY. I DIDN'T  
15 UNDERSTAND THE QUESTION.

16 DR. PADILLA: THERE WAS A POINT IN THE  
17 LETTER ON THE REBUTTAL FROM THE GRANT PERSON THAT  
18 THEY HAD RECEIVED AN AWARD THAT WAS ON A TIME FRAME  
19 IMPORTANCE ISSUE. WAS THAT PART OF THE APPLICATION?  
20 WAS THAT A KNOWN ISSUE AT THE TIME OF THE REVIEW?

21 DR. SAMBRANO: I DON'T BELIEVE IT WAS.

22 DR. PADILLA: WOULD THAT HAVE MADE A  
23 DIFFERENCE?

24 DR. SAMBRANO: YOU KNOW, GENERALLY THE WAY  
25 WE ADVISE THE GRANTS WORKING GROUP IS TO FOCUS ON

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1 THE MERIT OF THE APPLICATION BEFORE THEM. THE  
2 TIMING OF OTHER FUNDING AND OTHER OPPORTUNITIES THAT  
3 MAY CONTRIBUTE TO THAT EASILY ISN'T A PART OF THE  
4 REVIEW. SO I THINK GENERALLY WE WOULD HAVE ADVISED  
5 THEM TO FOCUS ON THE MERIT OF THE APPLICATION ON ITS  
6 OWN.

7 DR. PADILLA: THANK YOU.

8 CHAIRMAN IMBASCIANI: SHLOMO MELMED.

9 DR. MELMED: THANKS. I'M NOT ADDRESSING  
10 THE MERITS OR NOT FOR THIS APPLICATION. JUST A  
11 GENERAL COMMENT. WE HAVE AN OUTSTANDING GRANTS  
12 REVIEW GROUP. WE HAVE A VERY PROFESSIONAL AND  
13 WELL-OILED STAFF SUPPORT OF THE PROCESS. AND I GET  
14 VERY NERVOUS WHEN WE START TRYING TO DO OUR OWN PEER  
15 REVIEW ON LIMITED INFORMATION. AND I THINK THAT AS  
16 A COMMITTEE, OUR ROLE IS NOT TO DO PEER REVIEW, AND  
17 SOMETIMES WE CROSS THAT BORDER. AND I WOULD CAUTION  
18 ALL OF US, THAT ABSENT A FULL PEER REVIEW PROCESS,  
19 IT'S VERY DIFFICULT FOR US TO SECOND-GUESS THE  
20 VOTING. AND I PERSONALLY TRUST OUR GRANTS WORKING  
21 GROUP AND I TRUST OUR STAFF. AND, AGAIN, I'M NOT  
22 EXPRESSING AN OPINION EITHER WAY FOR THIS MOTION.  
23 THANK YOU.

24 CHAIRMAN IMBASCIANI: THANK YOU, SHLOMO.  
25 WELL SAID.



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1                   HELP ME WITH THIS SCREEN HERE. I DON'T  
2                   SEE ANY OTHER HANDS FROM BOARD MEMBERS. ALL RIGHT.  
3                   THE FLOOR IS OPEN FOR ANY MEMBER OF THE PUBLIC TO  
4                   COMMENT.

5                   MS. MANDAC: DR. CHRISTMAN HAS HER HAND  
6                   RAISED.

7                   CHAIRMAN IMBASCIANI: YES. DR. CHRISTMAN.

8                   DR. CHRISTMAN: YES. THANK YOU VERY MUCH  
9                   FOR THE DISCUSSION. JUST WANT TO MAKE TWO QUICK  
10                  COMMENTS. PER THE LAST REVIEWER'S COMMENT, I WAS  
11                  KIND OF GIVEN ADVICE BY CIRM STAFF THAT THE BOARD  
12                  DOES NOT DEAL WITH KIND OF THE SCIENTIFIC REVIEW, TO  
13                  ACTUALLY NOT MAKE THOSE COMMENTS IN MY LETTER. SO  
14                  THAT'S WHY THEY WERE ABSENT.

15                 AND I WILL -- AND MY SECOND POINT IS THAT  
16                 WE KNOW FOR CERTAIN THAT THIS IS A BIOLOGIC. I  
17                 THINK THERE WERE SOME MEMBERS OF THE REVIEW  
18                 COMMITTEE THAT THOUGHT IT WAS A DEVICE, AND THAT LED  
19                 TO MANY OF THOSE COMMENTS ABOUT WHETHER WE ARE ON  
20                 THE WRONG PATHWAY AND WRONG STUDIES. BUT IF YOU  
21                 LOOK AT OUR DESIGNATION LETTER FOR OUR PREVIOUS  
22                 PROJECT, BASICALLY ANY DECELLULARIZED BIOMATERIAL  
23                 THAT CANNOT GO 5, 10K, THE FDA IS REGULATING ALL AS  
24                 BIOLOGICS. IF YOU LOOK AT HUMACYTE'S TUBE OF A  
25                 DECELLULARIZED SCAFFOLD, WHICH IS A PHYSICAL TUBE,

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1 YOU SEE THAT IT'S ALSO REGULATED AS A DEVICE.

2 SO WE KNOW FOR CERTAIN, ALTHOUGH I WOULD  
3 LOVE IT TO BE A DEVICE, THAT SHIP SAILED ABOUT A  
4 DECADE AGO. SO WE KNOW FOR CERTAIN IT IS A  
5 BIOLOGIC, AND I THINK THERE WAS SOME CONFUSION ON  
6 THE WORKING GROUP, THAT THEY THOUGHT IT WAS A DEVICE  
7 AND, THEREFORE, THOUGHT WE WERE NOT GOING ON THE  
8 RIGHT PATH. BUT WE ARE CERTAIN THAT IT IS A  
9 BIOLOGIC. AND OF COURSE (UNINTELLIGIBLE). THANK  
10 YOU.

11 CHAIRMAN IMBASCIANI: OKAY. I  
12 THINK -- ARE WE AT THE POINT, SCOTT, WHERE WE CAN  
13 TAKE A VOTE ON THIS? I THINK WE ARE.

14 MR. TOCHER: YEAH. JUST CHECKING TO SEE  
15 IF THERE'S ANY OTHER PUBLIC COMMENT.

16 CHAIRMAN IMBASCIANI: THANK YOU.

17 MR. TOCHER: IT DOESN'T APPEAR SO. IS  
18 THAT CORRECT?

19 MS. MANDAC: YES. THERE'S NO ADDITIONAL  
20 HANDS RAISED.

21 CHAIRMAN IMBASCIANI: SO IT MIGHT BE  
22 HELPFUL IF YOU JUST CLARIFIED AGAIN WHAT A YES OR A  
23 NO VOTE MEANS HERE.

24 MR. TOCHER: YES. THE MOTION IS TO MOVE  
25 APPLICATION 15291 UP TIER I. SO A YES VOTE WOULD

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1 MOVE THIS UP TO TIER I AND THEN PRESUMABLY BE  
2 FINALLY DISPENSED WITH WHEN ALL THE MOTIONS TO FUND  
3 TIER I IS MADE.

4 DAN BERNAL .

5 MR. BERNAL: AYE .

6 MR. TOCHER: MARIA BONNEVILLE .

7 VICE CHAIR BONNEVILLE: YES .

8 MR. TOCHER: LEONDRA CLARK-HARVEY .

9 DR. CLARK-HARVEY: NO .

10 MR. TOCHER: WAS THAT A NO?

11 DR. CLARK-HARVEY: THAT WAS A NO .

12 MR. TOCHER: YSABEL DURON .

13 MS. DURON: YES .

14 MR. TOCHER: MARK FISCHER-COLBRIE .

15 MR. FISCHER-COLBRIE: YES .

16 MR. TOCHER: FRED FISHER .

17 DR. FISHER: NO .

18 MR. TOCHER: ELENA FLOWERS .

19 DR. FLOWERS: NO .

20 MR. TOCHER: DAVID HIGGINS .

21 DR. HIGGINS: YES .

22 MR. TOCHER: VITO IMBASCIANI .

23 CHAIRMAN IMBASCIANI: NO .

24 MR. TOCHER: STEVE JUELSGAARD .

25 MR. JUELSGAARD: NO .

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1 MR. TOCHER: RICH LAJARA.

2 MR. LAJARA: YES.

3 MR. TOCHER: LAUREN MILLER-ROGEN.

4 MS. MILLER-ROGEN: YES.

5 MR. TOCHER: ADRIANA PADILLA.

6 DR. PADILLA: YES.

7 MR. TOCHER: JOE PANETTA.

8 MR. PANETTA: YES.

9 MR. TOCHER: THE MOTION CARRIES NINE AYE  
10 VOTES TO FIVE NO VOTES. SO THAT APPLICATION IS NOW  
11 IN TIER I.

12 CHAIRMAN IMBASCIANI: OH, GREAT. THANK  
13 YOU VERY MUCH, MEMBERS OF THE BOARD. I THINK WE ARE  
14 NOW READY TO HEAR A MOTION ON 15225, IF I HAVE THAT  
15 ONE RIGHT, PURIFICATION OF HUMAN HEMATOPOIETIC STEM  
16 CELLS. THE MOTION WOULD BE TO EXTRACT THIS FROM  
17 TIER II AND MOVE IT TO TIER I. OKAY. I DO NOT HEAR  
18 A MOTION. AM I MISSING ANYTHING? THE SCREEN GOES  
19 ON FOR MANY --

20 MR. TOCHER: I DON'T SEE ANY HANDS RAISED.

21 CHAIRMAN IMBASCIANI: OKAY.

22 DR. FISCHER-COLBRIE: SORRY. I WAS HAVING  
23 TROUBLE RAISING MY HAND. JUST A QUICK QUESTION FOR  
24 GIL WITH RESPECT TO THE COMMENT THAT WAS MADE  
25 EARLIER BY DR. WEISSMAN.

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1 CHAIRMAN IMBASCIANI: I CAN'T SEE WHO'S  
2 SPEAKING. I'M SORRY.

3 DR. FISCHER-COLBRIE: MARK  
4 FISCHER-COLBRIE.

5 CHAIRMAN THOMAS: THANK YOU.

6 DR. SAMBRANO: YES, MARK. WHAT IS YOUR  
7 QUESTION?

8 DR. FISCHER-COLBRIE: I THINK HIS COMMENT  
9 WAS, IF I'M NOT MISTAKEN, THAT THERE WAS A  
10 FUNDAMENTAL MISCONCEPTION WITH RESPECT TO THE  
11 MODELING SELECTION AND WAS THE PRIMARY BASIS FOR THE  
12 OBJECTION. AND JUST WANTED TO FOLLOW UP ON THAT  
13 COMMENT.

14 DR. SAMBRANO: SURE. SO BASED ON WHAT WE  
15 HEARD FROM REVIEWERS AND ON THE REVIEWER COMMENTS, I  
16 CERTAINLY UNDERSTAND THAT INTERPRETATION, BUT I  
17 DON'T AGREE THAT THE REVIEWERS VIEWED THIS AS A CD34  
18 ONLY FOCUS OR THAT CD34 SHOULD BE THE ONLY OR  
19 APPROPRIATE WAY OF PURIFYING OR SELECTING  
20 HEMATOPOIETIC STEM CELLS; BUT, RATHER, THAT THERE  
21 ARE NOW MANY DIFFERENT APPROACHES FOR ISOLATING  
22 HEMATOPOIETIC STEM CELLS AND HEMATOPOIETIC STEM CELL  
23 CD34 POSITIVE CELL POPULATIONS, MANY THAT REMOVE  
24 T-CELLS, SOME THAT ADD BACK REGULATORY T-CELLS, AND  
25 THERE ARE OTHER ANTIBODIES THAT ALSO CAN BE UTILIZED

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1 FOR THE SAME PURPOSE.

2 SO I DO THINK THAT THE REVIEWERS  
3 UNDERSTOOD WHAT THE DIFFERENCE BETWEEN THE CD34  
4 POSITIVE CELLS AND THEN THE SPECIFIC CD34 POSITIVE  
5 90 -- CD90 POSITIVE CELLS ARE. I THINK THEY WERE  
6 LOOKING FOR MORE EXPLANATION FROM THE APPLICANT ON  
7 WHY SPECIFICALLY REDEVELOPING THESE ANTIBODIES AND  
8 HOW THEY IN THE CURRENT SETTING OF WHAT EXISTS TODAY  
9 WOULD BE A BENEFIT AND ADDRESS AN UNMET MEDICAL  
10 NEED. SO I THINK THAT'S WHERE REVIEWERS WERE COMING  
11 FROM ON THAT POINT.

12 DR. FISCHER-COLBRIE: TERRIFIC. THANK YOU  
13 FOR THE CLARIFICATION. THANK YOU.

14 CHAIRMAN IMBASCIANI: HEARING NO MOTION  
15 FROM THE FLOOR, I THINK WE ARE NOW TO THE POINT  
16 WHERE WE ARE GOING TO ENTERTAIN A MOTION TO NOT  
17 FUND --

18 DR. FISHER: I MADE THE MOTION.

19 MR. TOCHER: THERE'S ALREADY A MOTION ON  
20 THE TABLE THAT'S BEEN MADE AND SECONDED.

21 CHAIRMAN IMBASCIANI: THANK YOU, SCOTT.  
22 YES. THANK YOU. SO WE CAN PROCEED, IF THERE'S NO  
23 FURTHER DISCUSSION ON TIER II, WE ARE ABOUT TO VOTE  
24 ON NOT VOTING AT THIS PRESENT TIME ALL THE  
25 APPLICATIONS REMAINING IN TIER II.

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1 MR. TOCHER: THAT'S RIGHT. AND FOR  
2 MEMBERS BONNEVILLE, BURRON, AND JUELSGAARD, IF YOU  
3 WOULD GIVE YOUR VOTE AND THEN STATE EXCEPT WITH  
4 REGARD TO THOSE APPLICATIONS WITH WHICH YOU HAVE  
5 CONFLICT.

6 CHAIRMAN IMBASCIANI: THAT'S GREAT. GO  
7 AHEAD, SCOTT. YOU CAN PROCEED TO THE VOTE.

8 DAN BERNAL.

9 MR. BERNAL: AYE.

10 MR. TOCHER: MARIA BONNEVILLE.

11 VICE CHAIR BONNEVILLE: YES, EXCEPT FOR  
12 THOSE WITH WHICH I HAVE A CONFLICT.

13 MR. TOCHER: LEONDRA CLARK-HARVEY.

14 DR. CLARK-HARVEY: AYE.

15 MR. TOCHER: YSABEL DURON.

16 MS. DURON: YES, EXCEPT FOR THOSE WITH  
17 WHICH I HAVE A CONFLICT.

18 MR. TOCHER: MARK FISCHER-COLBRIE.

19 MR. FISCHER-COLBRIE: AYE.

20 MR. TOCHER: FRED FISHER.

21 DR. FISHER: AYE.

22 MR. TOCHER: ELENA FLOWERS.

23 DR. FLOWERS: YES.

24 MR. TOCHER: DAVID HIGGINS.

25 DR. HIGGINS: YES.

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1 MR. TOCHER: VITO IMBASCIANI.

2 CHAIRMAN IMBASCIANI: YES.

3 MR. TOCHER: STEVE JUELSGAARD.

4 MR. JUELSGAARD: YES.

5 MR. TOCHER: EXCEPT FOR THOSE WITH WHICH  
6 YOU HAVE A CONFLICT?

7 MR. JUELSGAARD: EXCEPT FOR THOSE WITH  
8 WHICH I HAVE A CONFLICT.

9 MR. TOCHER: THANK YOU. RICH LAJARA.

10 MR. LAJARA: YES.

11 MR. TOCHER: LAUREN MILLER-ROGEN.

12 MS. MILLER-ROGEN: YES.

13 MR. TOCHER: ADRIANA PADILLA.

14 DR. PADILLA: YES.

15 MR. TOCHER: JOE PANETTA.

16 MR. PANETTA: YES.

17 MR. TOCHER: THANK YOU VERY MUCH. AND  
18 THAT MOTION CARRIES.

19 CHAIRMAN IMBASCIANI: GREAT. THANK YOU.  
20 NOW WE CAN DIRECT OUR ATTENTION AS A BOARD TO TIER  
21 I. BUT, OF COURSE, IT'S NEVER THAT EASY. SO WE'RE  
22 GOING TO START WITH IS THERE ANY APPLICATION IN ALL  
23 OF TIER I, INCLUDING -- THAT BOARD MEMBERS WOULD  
24 LIKE TO REMOVE, AND THAT WOULD MEAN NOT TO FUND? SO  
25 THERE ARE TEN, NOW PLUS TWO, 12, ENTRANTS INTO TIER



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1 I. ANY MOTIONS ON ABSTRACTING ANY OF THESE TO  
2 REMOVE THEM FROM FUNDING?

3 NOT HEARING ANY MOTION, WE CAN PROCEED TO  
4 ENTERTAIN A MOTION TO ACCEPT FOR FUNDING ALL  
5 APPLICATIONS IN TIER I.

6 MR. BERNAL: SO MOVED.

7 CHAIRMAN IMBASCIANI: DAN BERNAL MOVED. I  
8 NEED A SECOND.

9 MR. TOCHER: JUST A SECOND. FOR  
10 THOSE -- UNFORTUNATELY, DAN, --

11 MR. BERNAL: OH, THAT'S RIGHT. THANK YOU.

12 DR. CLARK-HARVEY: SO MOVED. SO MOVED.

13 DR. FISHER: SECOND.

14 CHAIRMAN IMBASCIANI: WE HAVE A MOVEMENT  
15 AND A SECOND. SO THE FLOOR IS NOW OPEN TO  
16 DISCUSSION ON THESE APPLICATIONS.

17 MS. DURON: YSABEL HERE. COULD I GET AN  
18 EXPLANATION ON 15298 WHY THE DEI SCORE IS SO LOW?

19 CHAIRMAN IMBASCIANI: THANK YOU, YSABEL.  
20 ONE FIVE -- SAY THE NUMBER AGAIN. 298.

21 MS. DURON: I BELIEVE THERE ARE TWO THAT  
22 ARE ACTUALLY SIXES THAT I SEE ON THIS. SO 15253 AND  
23 15298.

24 CHAIRMAN IMBASCIANI: SO I'M GOING TO  
25 DIRECT THIS QUESTION TO GIL, MAYBE STARTING WITH

1 298.

2 DR. SAMBRANO: YEAH, THANK YOU. SO I  
3 THINK BOTH OF THEM, IT'S A VERY GOOD OBSERVATION,  
4 YSABEL. THEY BOTH HAPPEN TO ALSO BE TOOL  
5 APPLICATIONS. THEY'RE THE TRAN4.

6 SO THE FIRST ONE, THE ONE THAT YOU ASKED  
7 ABOUT, IS TO DEVELOP AND IPSC MEDIUM. SO THIS IS A  
8 CULTURE MEDIUM THAT IS USED FOR IPSC STEM CELLS AND  
9 TO MAINTAIN THEM AND TO DEVELOP THIS FOR GMP  
10 MANUFACTURING.

11 SO I THINK PART OF THE CHALLENGE THAT BOTH  
12 APPLICATIONS HAVE IS IN MAKING A CLEAR CASE OF HOW  
13 THIS MEDIUM IS GOING TO INCORPORATE PRINCIPLES OF  
14 DIVERSITY, EQUITY, AND INCLUSION. AND I THINK FOR  
15 SOME OF THESE IT'S DIFFICULT BECAUSE THEY DON'T HAVE  
16 1, SAY, SPECIFIC DISEASE WHERE THEY CAN SPEAK TO THE  
17 DISEASE BURDEN OR THE SPECIFIC POPULATION OF  
18 INDIVIDUALS THAT WOULD BENEFIT FROM, SAY, A THERAPY  
19 GIVEN THAT THIS IS A TOOL. I THINK, IN GENERAL,  
20 REVIEWERS THOUGHT THAT THIS WAS SOMETHING THAT WAS  
21 BROADLY APPLICABLE AND THAT THERE WAS NO SPECIFIC  
22 CONCERN ABOUT A MEDIUM NOT BEING APPLICABLE TO  
23 CERTAIN OR SPECIFIC POPULATIONS.

24 I THINK IN BOTH CASES THIS OTHER SECOND  
25 ONE IS ABOUT IPSC CELLS THEMSELVES AND CREATING A

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1 UNIVERSAL DONOR CELL LINE. I THINK THERE MORE SO A  
2 DISCUSSION ABOUT HOW EITHER THE MEDIUM OR IN THIS  
3 CASE THE UNIVERSALITY OF THE IPSC CELLS THAT ARE  
4 GENERATED WOULD IMPACT ON DIFFERENT PATIENT  
5 POPULATIONS WOULD HAVE BEEN APPRECIATED. I THINK  
6 THERE WAS A LACK OF DISCUSSION, BUT I DON'T THINK  
7 THERE WAS ANY CONCERN FROM THE WORKING GROUP RELATED  
8 TO THIS.

9 GENERALLY A SCORE OF SIX, OUR PATIENT  
10 ADVOCATE AND NURSE MEMBERS HERE ON THE BOARD CAN  
11 SPEAK TO THIS, IS A PASSING GRADE, IF YOU WILL. THE  
12 SIX IS SORT OF LOW ON THE SCORES THAT THEY STILL  
13 BELIEVE IS ADEQUATE TO MOVE FORWARD; BUT IF THERE  
14 ARE MAYBE SPECIFIC COMMENTS OR OTHER CONCERNS THAT  
15 THE PATIENT ADVOCATE MEMBERS WHO GAVE THESE SCORES  
16 WOULD LIKE TO SPEAK TO, CERTAINLY WOULD INVITE THEIR  
17 VIEWS.

18 CHAIRMAN IMBASCIANI: THANK YOU, GIL.  
19 FRED FISHER.

20 DR. FISHER: I NEVER CEASE TO BE AMAZED BY  
21 GIL'S ABILITY TO RECOUNT THE DETAILS OF ALL OF THESE  
22 GRANTS AND HAVE IT AT YOUR FINGERTIPS AND ARTICULATE  
23 IT SO WELL. SO THANK YOU FOR THAT, GIL.

24 AND I HAD RAISED MY HAND TO BASICALLY  
25 STATE WHAT YOU STATED. A SIX IS ESSENTIALLY THE

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1 EQUIVALENT OF AN 85, THE BOTTOM SCORE THAT THE GRANT  
2 WORKING GROUP WOULD CONSIDER IN TERMS OF A FUNDABLE  
3 APPLICATION. SO I JUST WANTED TO CLARIFY THAT FOR  
4 BOARD MEMBERS WHO DON'T PARTICIPATE ON THE GWG.

5 CHAIRMAN IMBASCIANI: THANK YOU, FRED.  
6 THANKS FOR YOUR COMMENT. I THINK THE ONLY THING  
7 THESE GRAPHS LACK IS A COLUMN THAT SCORES GIL'S  
8 ABILITY TO RECALL.

9 MS. DURON: VITO, CAN I SAY, FIRST OF ALL,  
10 THANK YOU, GIL. I APPRECIATE THAT. SECOND OF ALL,  
11 I OBVIOUSLY HAVE TO GO BACK TO SCHOOL FOR A VERY  
12 LONG TIME TO REALLY UNDERSTAND THIS STUFF. BUT I'M  
13 ALWAYS CONCERNED BECAUSE MAYBE SIX LOOKS GOOD ON AN  
14 AVERAGE, BUT I ALWAYS WORRY THAT, UNLESS THERE'S  
15 REAL INTENTION AT WHATEVER STAGE WE ARE AT TO  
16 MEASURE ITS IMPACT OR LACK OF IMPACT OR ACCESS, THAT  
17 WE LET IT GO. EVEN THE QUESTION ABOUT WHETHER OR  
18 NOT, BECAUSE A VERY SMART GROUP OF SCIENTISTS SAY  
19 IT'S A GOOD THING OR A BAD THING NOT TO HAVE, THAT  
20 PEOPLE IN GENERAL, PATIENT ADVOCATES, CONSUMERS ON  
21 THE STREET ALSO HAVE A VERY GOOD OPINION. AND  
22 SOMETIMES IT MIGHT COUNTER WHAT THE SCIENTISTS THINK  
23 OR SAY.

24 AND BECAUSE WE HAVE SEEN DISPARITIES FOR  
25 SO LONG OVER A LONG PERIOD OF TIME AND WE ARE STILL

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1 VERY FAR FROM REACHING SOME KIND OF EQUITY AND WE  
2 HAVE TO KEEP BRINGING THIS UP OVER AND OVER AND OVER  
3 AGAIN, I JUST DARE TO QUESTION SOMETHING AT A SIX  
4 BECAUSE I SAY, YOU KNOW, DO YOU HAVE A LATINO MOUSE?  
5 OR DO YOU HAVE A LATINO SPIT? OR IS THAT CELL LINE  
6 REALLY REPRESENTATIVE OF ALL OF US? AND SO I JUST  
7 WANT TO QUESTION IT, AND I WANT THE BOARD MEMBERS  
8 ALWAYS TO CONSIDER THAT WE HAVE YET TO REALLY,  
9 REALLY, REALLY, REALLY ADDRESS DISPARITIES WHEN IT  
10 COMES TO UNDERRESEARCHED, UNDERREPRESENTED GROUPS,  
11 RACIAL, ETHNIC, AND VULNERABLE POPULATIONS. SO WE  
12 SHOULD NEVER TAKE FOR GRANTED AVERAGE. AVERAGE IS  
13 NOT GOOD ENOUGH AS FAR AS I'M CONCERNED WHEN IT  
14 COMES TO ADDRESSING DISPARITIES. SO WE NEED TO BE  
15 VERY CLUED IN AND VERY ON TOP OF THIS ISSUE. THANK  
16 YOU, VITO.

17 CHAIRMAN IMBASCIANI: THANK YOU, YSABEL,  
18 VERY MUCH FOR THOSE COMMENTS.

19 FRED, BACK TO YOU AND THEN MR. STEVE REES.

20 DR. FISHER: FIRST, I'D LIKE TO ASK THE  
21 STAFF TO FORWARD TO YSABEL THE DEI RUBRIC SO SHE CAN  
22 SEE THE DIFFERENCE BETWEEN A SCORE OF SIX -- I THINK  
23 IT'S SIX, SEVEN, AND EIGHT VERSUS EIGHT, NINE, AND  
24 TEN, HOWEVER IT'S LAID OUT. AND, YSABEL, ANY  
25 INSIGHTS OR FEEDBACK THAT YOU HAVE, THE RUBRICS ARE

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1 A WORK IN PROGRESS. SO IF YOU THINK THAT THERE'S  
2 SOMETHING MISSING OR THERE'S SOMETHING YOU'D LIKE TO  
3 SHARE, WE ARE OPEN TO HEARING IT.

4 THE SECOND POINT IS THAT THE APPLICATION  
5 PROCESS IS TRAINING APPLICANTS TO BE MORE SENSITIVE  
6 TO THE ISSUES THAT YOU'RE DISCUSSING. IF I LOOK AT  
7 THE APPLICATIONS I LOOKED AT A YEAR AGO AND THEIR  
8 RESPONSES TO THE DEI SECTIONS VERSUS THE RESPONSES  
9 NOW, THEY ARE MARKEDLY IMPROVED.

10 AND THE FINAL POINT IS THAT WHILE YOUR  
11 COMMENTS ARE ALWAYS IMPORTANT, HAVE CONFIDENCE IN  
12 THOSE OF US THAT ARE ON THE GWG TO BE TAKING  
13 SERIOUSLY THE DEI COMPONENT. AND WHAT WE ARE  
14 ACTUALLY STARTING TO HEAR MORE OF NOW, USED TO BE  
15 JUST THE BOARD MEMBERS, GWG WOULD COMMENT ON DEI,  
16 AND NOW WE ARE HAVING THE SCIENTISTS ACTUALLY  
17 COMMENTING THOROUGHLY ON THE DEI SECTIONS. SO THIS  
18 IS AN ACCULTURATION PROCESS, IF THAT'S THE  
19 RIGHT WORD -- NO PUN INTENDED -- ON THE PART OF THE  
20 SCIENTIFIC COMMUNITY AND CERTAINLY A WORK IN  
21 PROGRESS ON THE GWG IN TERMS OF GETTING RIGHT HOW WE  
22 SCORE THESE PROPOSALS.

23 MS. DURON: MAY I RESPOND?

24 CHAIRMAN IMBASCIANI: PLEASE, YSABEL.

25 MS. DURON: THANK YOU VERY MUCH FOR THAT,

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1 FRED. I REALLY DO APPRECIATE IT. YOU SHOULD KNOW  
2 THAT I HAVE BEEN TOUTING THAT RUBRIC ALL OVER TOWN,  
3 IF YOU WILL, INCLUDING SHARING IT WITH THE NATIONAL  
4 ADVISORY -- THE CANCER ADVISORY BOARD AND THE NCI AS  
5 A MODEL FOR MEASURING AND ACCOUNTABILITY FOR THE  
6 RESEARCH GRANTS THAT THEY'RE GIVING OUT, WHICH  
7 NUMBER IN THE BILLIONS. SO, YES, I REALLY  
8 APPRECIATE THE RUBRIC AND GLAD THAT WE ARE STILL  
9 WORKING ON IT, DEVELOPING IT, AND, AS YOU SAID, WE  
10 ARE ALL BECOMING VERY SENSITIZED TO IT. I JUST  
11 REALLY APPRECIATE WHAT CIRM HAS DONE AND THANK YOU  
12 EVERY DAY FOR SUPPORTING THE WHOLE IDEA OF DEI.  
13 THAT'S WHERE IT STARTED. SO THANK YOU.

14 CHAIRMAN IMBASCIANI: THANK YOU. I WANT  
15 TO SAY TO MR. REES. I'M SORRY I CALLED ON YOU NEXT,  
16 BUT YOU HAVE TO WAIT. BY OUR RULES I NEED TO CALL  
17 ON BOARD MEMBERS FIRST. SO HOLD ON. DON'T GO AWAY.  
18 MARIA BONNEVILLE.

19 VICE CHAIR BONNEVILLE: I WAS JUST GOING  
20 TO MENTION TO YSABEL AND TO THE REST OF THE BOARD  
21 MEMBERS. WE HAD ASKED A DEI CONSULTANT TO COME ON  
22 BOARD AND TAKE A LOOK AT THE RUBRIC, THE GWG  
23 PROCESS, THINGS LIKE THAT. THEY'VE ISSUED -- THEY  
24 WILL BE PRESENTING TO THE BOARD IN DECEMBER SORT OF  
25 THEIR FEEDBACK ON THE PROCESS AND THE USE OF THE

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1 RUBRIC AND ANY RECOMMENDATIONS THAT THEY MIGHT HAVE.  
2 SO JUST AS A HEADS UP, THAT'S COMING TO THE BOARD IN  
3 DECEMBER. SO YOU WILL HEAR MORE ABOUT IT THERE,  
4 YSABEL, AND THEN THE BOARD MEMBERS ON SORT OF HOW WE  
5 ARE DOING AND ANY RECOMMENDATIONS THEY MAY HAVE.

6 CHAIRMAN IMBASCIANI: THANK YOU, MARIA.  
7 ANY OTHER BOARD MEMBERS HAVE THEIR HANDS RAISED? I  
8 DON'T SEE ANY. NOW WE ARE GOING TO TURN TO MEMBERS  
9 OF THE PUBLIC. I'M SORRY IF IT'S MR. OR PROFESSOR  
10 REES. I DON'T HAVE YOUR TITLE HERE. THE FLOOR IS  
11 YOURS.

12 DR. REES: SURE. THANK YOU. SO THIS IS  
13 STEVE REES. I'M THE CEO OF DEFINED BIOSCIENCE, AND  
14 WE'RE THE ONES THAT ASSEMBLED APPLICATION 15298 THAT  
15 WE ARE DISCUSSING NOW.

16 I SHOULD TELL YOU DURING OUR REVIEW  
17 PROCESS AND IN REWRITING THIS APPLICATION, DEI WAS  
18 AT THE FOREFRONT OF OUR MINDS WHEN IT CAME TO  
19 FIGURING OUT HOW DO WE BEST ADDRESS THIS FOR A  
20 TECHNOLOGY THAT SHOULD BE BROADLY APPLICABLE ACROSS  
21 DISEASE STATES AND NEEDS FOR STEM CELL CULTURE. AND  
22 THE POINTS THAT THE BOARD HAS ALREADY RAISED IN  
23 REGARDS TO CELL LINE AVAILABILITY AND HOW  
24 REPRESENTATIVE, GIVEN THE FEW NUMBER OF CELL LINES  
25 THAT WE HAVE FOR THESE UNDERREPRESENTED GROUPS, IT'S



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1 VERY HARD TO KNOW BECAUSE THERE'S VERY FEW CELL  
2 LINES AVAILABLE.

3 SO IN OUR RESEARCH WE FOUND THAT EVEN AS  
4 OF JUST A FEW YEARS AGO, IT WAS ABOUT A THIRD AS  
5 LIKELY TO FIND A CELL LINE OF AFRICAN DESCENT OR  
6 HALF AS LIKELY FOR ASIAN OR PACIFIC ISLANDER  
7 DESCENT, AND EVEN ONLY 5 PERCENT OF HUMANS STEM CELL  
8 LINES AVAILABLE FOR PRECLINICAL WORK WAS OF AFRICAN  
9 DESCENT AS WELL. AND WE KEPT SEEING THESE NUMBERS  
10 AND LOOKING FOR CELL LINES AND REALIZED THAT THERE'S  
11 JUST A VERY FEW NUMBER AVAILABLE FOR US TO EVEN KNOW  
12 IF WHAT WE HAVE IS REPRESENTATIVE.

13 SO FOR US IT WAS A BALANCE BETWEEN -- WITH  
14 A STUDY LIKE THIS, HAVING A LIMITED NUMBER OF CELL  
15 LINES WE CAN CONCEIVABLY TEST GIVEN THAT THIS STUDY  
16 FOCUSES ON IN-DEPTH STUDIES OF A MEDIA, YOU CAN ONLY  
17 COVER SO MANY LINES. AND WE WANTED TO BE CAREFUL TO  
18 CHOOSE LINES THAT WERE AS REPRESENTATIVE OF A LARGER  
19 COMMUNITY AS WE COULD MAKE THEM WHILE NOT  
20 SACRIFICING WHAT WE COULD LEARN FROM THE RESULTS OF  
21 THOSE STUDIES.

22 SO TO US WE KEPT THINKING THIS NEEDS TO BE  
23 ANOTHER PROPOSAL AND EFFORT FROM CIRM TO EXPAND THE  
24 NUMBER OF THESE CELL LINES THAT ARE AVAILABLE. IT'S  
25 CERTAINLY SOMETHING THE TEAM IS INTERESTED IN, AND

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1 WE JUST TRIED TO BALANCE THAT. AND THAT SEEMED TO  
2 BE RECEIVED WELL BY THE REVIEWERS, THAT THERE WAS  
3 JUST REALITIES OF LIMITATION THAT WE COULD FOCUS ON  
4 HERE. BUT IT'S AT THE FOREFRONT OF OUR MINDS, AND  
5 I'M SURE MANY RESEARCHERS. THANKS FOR THE CHANCE TO  
6 SPEAK HERE.

7 CHAIRMAN IMBASCIANI: THANK YOU, MR. REES,  
8 FOR YOUR COMMENTS AND YOUR SUGGESTION. SCOTT.

9 MR. TOCHER: JUST CHECKING TO SEE IF  
10 THERE'S ANY MORE.

11 CHAIRMAN IMBASCIANI: THANK YOU.

12 MR. TOCHER: THERE DOESN'T APPEAR TO BE.

13 CHAIRMAN IMBASCIANI: ALL RIGHT. THEN I  
14 CAN WE CAN PROCEED TO A VOTE ON ACCEPTING FOR  
15 FUNDING ALL THE APPLICATIONS IN TIER I.

16 MR. TOCHER: AND MEMBERS BERNAL,  
17 BONNEVILLE, FLOWERS, JUELGAARD, AND PANETTA, THE  
18 SAME ADMONITION WHEN YOU GIVE YOUR VOTE.

19 DAN BERNAL.

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

22 MR. TOCHER: MARIA BONNEVILLE.

23 VICE CHAIR BONNEVILLE: YES, EXCEPT FOR  
24 THOSE WITH WHICH I HAVE A CONFLICT.

25 MR. TOCHER: LEONDRA CLARK-HARVEY.

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1 DR. CLARK-HARVEY: YES.  
2 MR. TOCHER: YSABEL DURON.  
3 MS. DURON: YES, EXCEPT. YOU DIDN'T  
4 MENTION MY NAME AGAIN. EXCEPT FOR THOSE WITH WHICH  
5 I HAVE A CONFLICT.  
6 MR. TOCHER: THAT'S ALWAYS SAFE.  
7 MARK FISCHER-COLBRIE.  
8 MR. FISCHER-COLBRIE: YES.  
9 MR. TOCHER: FRED FISHER.  
10 DR. FISHER: YES.  
11 MR. TOCHER: ELENA FLOWERS.  
12 DR. FLOWERS: YES, EXCEPT FOR THOSE WITH  
13 WHICH I HAVE A CONFLICT.  
14 MR. TOCHER: DAVID HIGGINS.  
15 DR. HIGGINS: YES.  
16 MR. TOCHER: VITO IMBASCIANI.  
17 CHAIRMAN IMBASCIANI: YES.  
18 MR. TOCHER: STEVE JUELSGAARD.  
19 MR. JUELSGAARD: YES, EXCEPT FOR THOSE  
20 WITH WHICH I HAVE A CONFLICT.  
21 MR. TOCHER: RICH LAJARA.  
22 MR. LAJARA: YES.  
23 MR. TOCHER: LAUREN MILLER-ROGEN.  
24 MS. MILLER-ROGEN: YES.  
25 MR. TOCHER: ADRIANA PADILLA.

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1 DR. PADILLA: YES.

2 MR. TOCHER: JOE PANETTA.

3 MR. PANETTA: YES, EXCEPT FOR THOSE WITH  
4 WHICH I HAVE A CONFLICT.

5 MR. TOCHER: THANK YOU, JOE. AND THAT  
6 DOES IT. THE MOTION CARRIES.

7 CHAIRMAN IMBASCIANI: OKAY. THANK YOU,  
8 SCOTT. I DON'T HAVE THE AGENDA IN FRONT OF ME.  
9 IT'S ON A DIFFERENT SCREEN. WHAT IS NEXT?

10 MR. TOCHER: IF THERE ARE ANY PUBLIC  
11 COMMENT ABOUT ANY MATTERS NOT AGENDIZED.

12 CHAIRMAN IMBASCIANI: OKAY. WE ARE AT  
13 THAT FINAL POINT OF THE MEETING. IS THERE ANY  
14 MEMBER OF THE PUBLIC OUT THERE THAT WOULD LIKE TO  
15 MAKE SOME COMMENT ON A SUBJECT THAT WE HAVE NOT  
16 BROUGHT UP YET THIS MORNING?

17 MR. TOCHER: NOT SEEING ANY HANDS.

18 CHAIRMAN IMBASCIANI: IF NOT, ALL GOOD  
19 THINGS COME TO AN END. I THINK ANY FINAL COMMENTS  
20 FROM BOARD MEMBERS? IF NOT, I DON'T THINK WE NEED  
21 MOTIONS TO ADJOURN, CORRECT?

22 MR. TOCHER: THAT'S CORRECT.

23 CHAIRMAN IMBASCIANI: OKAY. BOARD  
24 MEMBERS, THANK YOU SO MUCH FOR YOUR PARTICIPATION  
25 THIS MORNING. I REALLY APPRECIATE IT. WE DID GOOD

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1 WORK. THANK YOU VERY MUCH.

2 VICE CHAIR BONNEVILLE: THANK YOU,  
3 EVERYONE.

4 (THE MEETING WAS THEN CONCLUDED AT 10:43 A.M.)  
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**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 VIRTUAL 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 OCTOBER 26, 2023, 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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