

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: APRIL 27, 2023
9 A.M.

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

FILE NO.: 2023-15

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I N D E X

ITEM DESCRIPTION	PAGE NO.
OPEN SESSION	
1. CALL TO ORDER	3
2. ROLL CALL	3
ACTION ITEMS	
3. CONSIDERATION OF APPLICATIONS SUBMITTED IN RESPONSE TO TRANSLATIONAL PROJECTS PROGRAM ANNOUNCEMENT (TRAN 1,2,3 OR 4)	6
4. CONSIDERATION OF APPLICATIONS SUBMITTED IN RESPONSE TO CLINICAL TRIAL STAGE PROJECTS PROGRAM ANNOUNCEMENT (CLIN 1 OR 2)	40
5. CLOSED SESSION	NONE
DISCUSSION OF CONFIDENTIAL INTELLECTUAL PROPERTY OR WORK PRODUCT, PREPUBLICATION DATA, FINANCIAL INFORMATION, CONFIDENTIAL SCIENTIFIC RESEARCH OR DATA, AND OTHER PROPRIETARY INFORMATION RELATING TO APPLICATIONS SUBMITTED IN RESPONSE TO AGENDA ITEM 3 OR 4 ABOVE. (HEALTH & SAFETY CODE 125290.30(F) (3) (B) AND (C)).	
DISCUSSION ITEMS	
6. GENERAL COMMENTS ON ARS PROCESS	NONE
7. PUBLIC COMMENT	NONE
8. ADJOURNMENT	79

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APRIL 27, 2023; 9 A.M.

CHAIRMAN IMBASCIANI: SO I'M GOING TO CALL TO ORDER THIS 27TH OF APRIL 2023 MEETING OF THE APPLICATION REVIEW SUBCOMMITTEE OF THE BOARD. I WANT TO WELCOME OUR PRESIDENT, DR. MILLAN, AND MEMBERS OF THE BOARD, AND ANY OF THE CITIZENS OF CALIFORNIA THAT ARE DIALING INTO THIS. I HOPE YOU WILL CUT ME A LITTLE BIT OF ROBERTS RULES OF ORDER SLACK. THIS IS A MAIDEN VOYAGE FOR ME. MAIDEN VOYAGES USUALLY END WELL EXCEPT FOR THE USS TITANIC. THAT DIDN'T END SO WELL, BUT WE'LL TRY NOT TO MIMIC THAT HISTORY. I'LL HAVE LOTS OF HELP AS WE GO FORWARD. BUT GIVEN WE HAD TO WAIT A FEW EXTRA MINUTES FOR QUORUM, I THINK WE SHOULD GET STARTED WITH THE CALLING OF THE ROLL. THANK YOU.

MS. DEQUINA-VILLABLANCA: DAN BERNAL.

MR. BERNAL: PRESENT.

MS. DEQUINA-VILLABLANCA: MARIA BONNEVILLE.

VICE CHAIR BONNEVILLE: PRESENT.

MS. DEQUINA-VILLABLANCA: JUDY CHOU.
LEONDRA CLARK-HARVEY.

DR. CLARK-HARVEY: PRESENT.

MS. DEQUINA-VILLABLANCA: ANNE-MARIE

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1 DULIEGE.
2 DR. DULIEGE: PRESENT.
3 MS. DEQUINA-VILLABLANCA: YSABEL DURON.
4 MS. DURON: HERE.
5 MS. DEQUINA-VILLABLANCA: MARK
6 FISCHER-COLBRIE.
7 DR. FISCHER-COLBRIE: HERE.
8 MS. DEQUINA-VILLABLANCA: FRED FISHER.
9 DR. FISHER: HERE.
10 MS. DEQUINA-VILLABLANCA: ELENA FLOWERS.
11 DAVID HIGGINS. WE'LL COME BACK.
12 VITO IMBASCIANI.
13 CHAIRMAN IMBASCIANI: PRESENT.
14 MS. DEQUINA-VILLABLANCA: STEVE
15 JUELSGAARD.
16 MR. JUELSGAARD: PRESENT.
17 MS. DEQUINA-VILLABLANCA: RICH LAJARA.
18 MR. LAJARA: PRESENT.
19 MS. DEQUINA-VILLABLANCA: CHRISTINE
20 MIASKOWSKI. LAUREN MILLER-ROGEN.
21 MS. MILLER-ROGEN: HERE.
22 MS. DEQUINA-VILLABLANCA: ADRIANA PADILLA.
23 WE ARE EXPECTING HER. JOE PANETTA.
24 MR. PANETTA: HERE.
25 MS. DEQUINA-VILLABLANCA: AL ROWLETT.

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1 MARVIN SOUTHARD. MARVIN, ARE YOU ON MUTE? I SEE
2 YOU.

3 DR. SOUTHARD: PRESENT.

4 MS. DEQUINA-VILLABLANCA: KAROL WATSON.

5 MR. AGUIRRE-SACASA: YOU WANT TO CHECK
6 WITH DAVID?

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1 MS. DEQUINA-VILLABLANCA: DAVID HIGGINS.

2 OKAY. WE CAN PROCEED, VITO.

3 CHAIRMAN IMBASCIANI: THANK YOU VERY MUCH.

4 WE HAVE TWO SETS OF APPLICATIONS TO REVIEW
5 TODAY. AND UNLESS THERE'S A PROCEDURAL REASON WHY
6 NOT, I'M GOING TO HAND THIS OVER TO GIL FOR THE
7 PRESENTATION OF THE TRANSLATIONAL APPLICATIONS.

8 DR. SAMBRANO: THANK YOU, VITO. SO THE
9 PRESENTATION TODAY IS GOING TO BE LED BY DR. HAYLEY
10 LAM. SO SHE IS THE ASSOCIATE DIRECTOR FOUR THE
11 PORTFOLIO DEVELOPMENT AND REVIEW TEAM. SO, HAYLEY,
12 WHENEVER YOU'RE READY, PLEASE FEEL FREE TO BEGIN.

13 DR. LAM: GOOD MORNING TO THE BOARD. IT'S
14 A PLEASURE TO PRESENT FOR YOU TODAY, AND I WILL
15 SHARE MY SCREEN SHORTLY. CAN EVERYONE SEE THAT?

16 MS. DURON: YES.

17 DR. LAM: FANTASTIC. THANK YOU.

18 SO, AS ALWAYS, WE BEGIN WITH OUR MISSION
19 STATEMENT: ACCELERATING WORLD-CLASS SCIENCE TO
20 DELIVER TRANSFORMATIVE REGENERATIVE MEDICINE
21 TREATMENTS IN AN EQUITABLE MANNER TO A DIVERSE
22 CALIFORNIA AND WORLD.

23 AND TODAY I'M HERE TO TALK TO YOU ABOUT
24 THE TRANSLATIONAL PROGRAM, WHICH FALLS SQUARELY IN
25 THE MIDDLE OF OUR PIPELINE. SO WE HAVE OUR

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1 DISCOVERY, EARLY CANDIDATE DISCOVERY, AND THEN OUR
2 TRANSLATION PROGRAM, AND OUR CLINICAL. AND SO A
3 LITTLE BIT MORE ABOUT THE TRANSLATIONAL PROGRAM.

4 THIS ACTUALLY IS A COMBINATION OF FOUR
5 DIFFERENT TYPES OF PRODUCTS THAT CAN BE SUBMITTED.
6 SO WE HAVE THERAPEUTICS, DIAGNOSTICS, MEDICAL
7 DEVICES, AND TOOLS. AND EACH OF THESE HAS SLIGHTLY
8 DIFFERENT TIMELINES AND BUDGETS ACCORDING TO THE
9 PRODUCT TYPE. AND IN ADDITION TO THAT, THERE ARE
10 SLIGHT DIFFERENCES IN TERMS OF WHAT THE EXPECTATIONS
11 ARE COMING INTO AND COMING OUT OF A TRAN AWARD.

12 SO HERE WE HAVE JUST OUTLINED BRIEFLY ALL
13 OF THE PROJECTS THAT COME INTO THE TRANSLATIONAL
14 PROGRAM NEED TO HAVE SOME KIND OF PROOF OF CONCEPT
15 WITH EITHER THE CANDIDATE OR THE PROTOTYPE OF THE
16 DEVICE. AND ON COMPLETION, HOPEFULLY SUCCESSFUL
17 COMPLETION, OF A TRANSLATIONAL AWARD, THE PROJECTS
18 WILL HAVE COMPLETED A PRE-IND OR OTHER EQUIVALENT
19 MEETING WITH THE FDA, OR FOR A TOOL PROCEED TO
20 TRANSFER TO MANUFACTURING.

21 SO DESPITE THE DIFFERENCES IN SOME OF
22 THESE PROGRAMS, ALL OF THEM ARE EVALUATED IN A
23 SIMILAR WAY. SO ALL OF THE PROJECTS ARE EVALUATED
24 WITH THE SAME SCIENTIFIC REVIEW CRITERIA, WHICH
25 WE'VE OUTLINED HERE. BUT VERY BRIEFLY, DOES THE

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1 PROJECT HAVE THE NECESSARY SIGNIFICANCE AND
2 POTENTIAL FOR IMPACT? DOES IT HAVE A SOUND
3 RATIONALE? IS IT WELL PLANNED AND DESIGNED? IS IT
4 FEASIBLE? AND DOES IT UPHOLD PRINCIPLES OF
5 DIVERSITY, EQUITY, AND INCLUSION?

6 AND THE SCORING SYSTEM FOR THE SCIENTIFIC
7 SCORE IS A SCALE OF ONE TO A HUNDRED. EVERYTHING
8 THAT IS SCORED 85 OR ABOVE IS A RECOMMENDATION FOR
9 FUNDING IF FUNDS ARE AVAILABLE, AND ANYTHING 84 AND
10 BELOW IS NOT RECOMMENDED FOR FUNDING. AND ALL OF
11 THE APPLICATIONS ARE SCORED BY MEMBERS OF THE
12 SCIENTIFIC MEMBERS OF THE PANEL WITH NO CONFLICT.
13 AND THE FINAL SCORE IS DETERMINED BY THE MEDIAN OF
14 ALL THE INDIVIDUAL SCORES SUBMITTED BY THE
15 SCIENTIFIC PANEL MEMBERS.

16 THE TRANSLATION PROGRAM ALSO HAS A DEI
17 SCORING, AND THIS IS SCORED BY THE GWG BOARD
18 MEMBERS. IT HAS A DIFFERENT SCALE. THE SCALE FOR
19 THE DEI SCORING IS A SCALE OF 0 TO 10, AND WE'VE
20 OUTLINED HERE SORT OF THE BREAKDOWN. A 9 TO 10 IS
21 CONSIDERED AN OUTSTANDING RESPONSE, 6 TO 8 IS
22 RESPONSIVE, 3 TO 5, NOT FULLY RESPONSIVE, AND 0 TO 2
23 IS NOT RESPONSIVE. AND WE HAVE THE RUBRIC HERE ON
24 THE LEFT THAT IS USED FOR EVALUATION OF THIS.

25 I'LL ALSO ACTUALLY NOTE THAT WE JUST

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1 RECENTLY POSTED THIS RUBRIC ON OUR WEBSITE, THE CIRM
2 WEBSITE, IF YOU'RE INTERESTED IN SEEING IT MORE
3 CLOSELY AND NOT SQUINTING AT THE TINY FONT HERE.

4 MS. DURON: HAYLEY. MR. CHAIR, MAY I ASK
5 A QUESTION?

6 DR. LAM: YES.

7 MS. DURON: THANK YOU. SO WE'VE GOT A
8 FABULOUS RUBRIC. WHAT ARE THE CONSEQUENCES --

9 UNIDENTIFIED SPEAKER: SHE'S GOT A
10 CONFLICT.

11 MS. DURON: SORRY. I HAVE A CONFLICT.
12 I'M SORRY.

13 MS. BONNEVILLE: THANK YOU.

14 DR. LAM: WELL, I WILL NOTE ACTUALLY,
15 SINCE WE ARE HERE, THAT -- SO JUST TO OUTLINE THE
16 ROLES AND COMPOSITION OF THE PANEL THAT EVALUATES
17 THESE APPLICATIONS, SCIENTIFIC MEMBERS SCORE THE
18 SCIENTIFIC SCORE, WHICH I OUTLINED PREVIOUSLY, THE 1
19 TO 100. AND THEN THE GWG BOARD MEMBERS, WHICH ARE
20 OUR PATIENT ADVOCATE AND NURSE MEMBERS, SCORE THE
21 DEI FOR A SCALE OF 0 TO 10 ON ALL APPLICATIONS. AND
22 THEN WE ALSO HAVE AD HOC PANEL MEMBERS, SCIENTIFIC
23 SPECIALISTS, THAT COME IN AND PROVIDE EXPERTISE ON
24 APPLICATIONS IN SPECIFIC AREAS THAT MAY NOT BE
25 COVERED BY OUR PANEL MEMBERS. AND THEY PROVIDE

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1 INITIAL SCORING, BUT DO NOT VOTE FOR THE FINAL
2 SCORE.

3 IN TERMS OF WHAT IS PRESENTED IN FRONT OF
4 YOU TODAY, WE HAD 20 TOTAL APPLICATIONS THAT WENT TO
5 FULL REVIEW FOR THE PANEL. AND NINE OF THEM ARE
6 RECOMMENDED AND ELEVEN ARE NOT RECOMMENDED. I WILL
7 SAY HERE THAT WE'VE OUTLINED RECOMMENDED FOR FUNDING
8 HAS A SCORE OF 85 TO 100 ON THE SCIENTIFIC SIDE;
9 HOWEVER, THAT ALSO INCLUDES THE DEI SCORING, WHICH
10 REQUIRES A MINIMUM OF A DEI SCORE OF 6 TO 10 TO ALSO
11 COME TO YOU AS THE ARS.

12 SO THIS IS THE GWG RECOMMENDATIONS.
13 HOWEVER, I WANT TO POINT OUT WE ALSO HAVE WHAT IS
14 CALLED MINORITY REPORTS. SO UNDER THE PROPOSITION
15 14, ANY APPLICATION THAT'S NOT RECOMMENDED FOR
16 FUNDING, HOWEVER, HAD 35 PERCENT OR MORE OF THE
17 MEMBERS SCORE IN THE FUNDABLE RANGE HAS TO INCLUDE A
18 MINORITY REPORT. AND SO THESE MINORITY REPORTS WERE
19 INCLUDED IN THE SUMMARIES THAT WERE POSTED TO ALL OF
20 YOU AND PROVIDES A SYNOPSIS OF WHAT THE REVIEWERS
21 WHO SUPPORTED FUNDING OF APPLICATION THOUGHT ON THAT
22 PARTICULAR APPLICATION.

23 AND SO THESE TWO -- IN THIS PARTICULAR
24 ROUND, THERE WERE TWO APPLICATIONS THAT RECEIVED
25 MINORITY REPORTS, WHICH I'M GOING TO DISCUSS IN MORE

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1 DETAIL. AND I WOULD LIKE TO NOTE THAT OF THESE TWO,
2 THE FIRST ONE, TRAN1-14710, HAS A RECOMMENDATION
3 FROM THE CIRM TEAM TO SUPPORT THE MINORITY POSITION
4 FOR THIS APPLICATION AND RECOMMEND FUNDING.

5 SO TO GO THROUGH BOTH OF THESE
6 APPLICATIONS INDIVIDUALLY, THE FIRST ONE,
7 TRAN1-14710, THE TITLE IS "AAV GENE THERAPY FOR
8 TREATING CONGENITAL HEREDITARY ENDOTHELIAL DYSTROPHY
9 ASSOCIATED WITH BIALLELIC MUTATIONS." SO THIS IS A
10 PEDIATRIC HEREDITARY DISEASE THAT CAN CAUSE
11 BASICALLY CLOUDING OF THE CORNEA. THE CURRENT
12 STANDARD OF CARE IS CORNEAL TRANSPLANTATION. AND
13 THIS INVOLVES SURGERY AND IS A TECHNICALLY DIFFICULT
14 PROCEDURE WITH A SIGNIFICANT BURDEN AND OFTEN NEEDS
15 TO BE REPEATED. SO THE IMPACT OF THIS PARTICULAR
16 PROPOSAL IS THAT THIS GENE THERAPY COULD OFFER AN
17 ALTERNATIVE TREATMENT FOR THIS RARE DISEASE, AND IT
18 COULD POTENTIALLY PAVE THE WAY FOR SIMILAR
19 TREATMENTS IN OTHER INHERITED CORNEAL DISEASES.

20 AND I WILL TAKE THE TIME HERE TO JUST READ
21 THE MINORITY REPORT. SO THIS IS DIRECTLY FROM THE
22 SUMMARY ITSELF.

23 13 SCIENTIFIC GWG MEMBERS SCORED THIS
24 APPLICATION. EIGHT GWG MEMBERS SCORED FROM 70 TO 80
25 AND FIVE SCORED 85 TO 90. ALL SCORING PANELISTS

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1 AGREED THAT THE PROJECT HAD THE SIGNIFICANCE AND
2 POTENTIAL IMPACT REQUIRED FOR A CIRM PROJECT AND
3 UPHELD THE PRINCIPLES OF DEI. NEARLY ALL THOUGHT
4 THE PROJECT HAD A SOUND RATIONALE AND ACTIVITIES
5 WERE FEASIBLE. ALL COMMENTS ON THE PRELIMINARY DATA
6 WERE POSITIVE. ONE SUPPORTIVE REVIEWER DESCRIBED
7 THE PRELIMINARY DATA AS, QUOTE, EXTENSIVE AND NOTED
8 THE APPLICANTS COMPLETED STUDIES IN THE RELEVANT
9 PRECLINICAL MODEL AND CORNEAL TISSUES FROM MULTIPLE
10 HUMANS, DOGS, RABBITS, AND CATS.

11 THE PANEL WAS DIVIDED ON WHETHER THE
12 PROPOSED PROJECT PLAN WAS SUFFICIENTLY SOUND. FOR
13 THE MOST PART, SUPPORTIVE PANELISTS AGREED WITH THE
14 MAJORITY, THAT THE REGULATORY STRATEGY NEEDED WORK
15 WHILE THE MAJORITY WANTED TO SEE THE PROJECT PLAN
16 REVISED WITH A FULLER CHARACTERIZATION OF THE
17 PRODUCT AND MORE INPUT FROM THE FDA OR A REGULATORY
18 CONSULTANT.

19 THE REVIEWERS WHO SCORED 85 OR HIGHER
20 FOUND THE PROJECT MERITORIOUS DESPITE WEAKNESSES IN
21 THE CURRENT PROJECT PLANS. THE SUPPORT APPEARED TO
22 BE DERIVED BY THE VALUE PROPOSITION. SUPPORTIVE
23 REVIEWERS NOTED THAT THE PROPOSED GENE THERAPY WOULD
24 BE AN ALTERNATIVE TO CORNEAL TRANSPLANTATION, WHICH
25 REQUIRES DONOR TISSUE AND TRAINED SURGEONS. THE

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1 DISEASE INDICATION HAS A HIGH PREVALENCE IN SOME
2 UNDERSERVED RACIAL/ETHNIC GROUPS. AND THE PROJECT
3 COULD VALIDATE THE POTENTIAL FOR A GENE THERAPY FOR
4 MORE PREVALENT INHERITED OCULAR DISORDERS. AND,
5 FINALLY, THE APPLICANT IS TESTING A NOVEL DELIVERY
6 METHOD FOR GENE THERAPIES.

7 SO THAT IS THE MINORITY REPORT FOR THIS
8 APPLICATION.

9 AND A BRIEF EXPLANATION ON THE CIRM TEAM
10 RECOMMENDATION FOR THIS. SO THE CIRM TEAMS BELIEVES
11 THAT THE CONCERNS ABOUT THE PROJECT PLANS THAT WERE
12 OUTLINED IN THE MINORITY REPORT COULD BE RESOLVED
13 WITH THE CIRM POSTAWARD SUPPORT AND THE
14 COLLABORATION WITH THE FOUNDATION FOR NIH BESPOKE
15 GENE THERAPY CONSORTIUM OF WHICH THIS PROJECT WOULD
16 BE A PART. JUST AS A NOTE, THIS BESPOKE GENE
17 THERAPY CONSORTIUM IS A PUBLIC/PRIVATE PARTNERSHIP
18 WHICH INVOLVES A LOT OF DIFFERENT MULTIPLE NIH
19 INSTITUTIONS, PHARMA, BIOTECH, AND ADVOCACY GROUPS,
20 AS WELL AS THE FDA. AND SO THE SUPPORT FROM CIRM
21 TEAM IS THAT THE CONCERNS FROM THE PANEL AROUND THE
22 REGULATORY AND THE PLANNING FOR THE PROJECT COULD BE
23 RESOLVED WITH SUPPORT FROM CIRM AND THIS CONSORTIUM
24 IN TANDEM. SO THAT IS APPLICATION 14710.

25 AND MINORITY REPORT FOR THE SECOND

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1 APPLICATION, TRAN4-14725. SO THIS APPLICATION TITLE
2 IS "THE DEVELOPMENT OF A LOW COST CLINICAL GRADE IPS
3 MAINTENANCE MEDIUM FOR ENABLING STEM CELL THERAPY
4 MANUFACTURING." SO THE IMPACT HERE WOULD BE THAT
5 THIS MEDIA FOR MANUFACTURING OF IPS CELL-BASED
6 THERAPIES COULD OFFER A LOWER COST AND LOWER RISK
7 ALTERNATIVE FOR DEVELOPERS.

8 AND I WILL ALSO READ THE MINORITY REPORT
9 FOR THIS APPLICATION. THIS APPLICATION WAS SCORED
10 BY 14 GWG PANELISTS. ONE PANELIST SCORED 55, EIGHT
11 PANELISTS SCORED 75 TO 80, AND FIVE SCORED 85 TO 90.
12 THE REVIEWERS WHO RECOMMENDED THE APPLICATION FOR
13 FUNDING THOUGHT THAT THE DEVELOPMENT OF A CLINICAL
14 GRADE MEDIUM WOULD HAVE SIGNIFICANT VALUE. SOME
15 REVIEWERS WHO RECOMMENDED THE APPLICATION
16 ACKNOWLEDGED THAT THE PRODUCT WOULD NOT ADDRESS
17 OTHER BOTTLENECKS IN IPSC DEVELOPMENT, BUT THOUGHT
18 THAT IT WAS UNREALISTIC TO ADDRESS ALL BOTTLENECKS
19 AND THAT THIS APPLICATION TACKLES ONE OF MANY, A
20 SERUM FREE, CHEMICALLY DEFINED MEDIUM AS A TOOL FOR
21 MANUFACTURING FOR IPS CELL-BASED THERAPIES.

22 IN ADDITION, A REVIEWER WHO RECOMMENDED
23 THE APPLICATION ALSO ACKNOWLEDGES EVERY DEVELOPER
24 MAY HAVE THEIR OWN CUSTOMIZED MEDIA, BUT THIS
25 APPLICATION IS ABOUT OFFERING A NOVEL "BASE CELL

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1 CULTURE MEDIUM" WITH ALL CUSTOMIZATIONS ACHIEVED BY
2 THE ADDITION OF DIFFERENT SUPPLEMENTS AS IS TRUE FOR
3 EVERY PRODUCT IN PROCESS IN THE CELL THERAPY FIELD.

4 REVIEWERS AGREED THAT THE PLAN IS LOGICAL,
5 THE TIMELINE IS REASONABLE, AND THE SCIENTIFIC PROOF
6 OF CONCEPT IS ESTABLISHED. THE REVIEWERS WHO
7 RECOMMENDED THE APPLICATION LARGELY AGREED THAT THE
8 PROJECT ACKNOWLEDGED LIMITATIONS OF ADDRESSING DEI
9 AT THIS STAGE AND FOR THIS TYPE OF PRODUCT, THOUGH
10 ONE REVIEWER THOUGHT THE APPLICANTS COULD HAVE
11 PROVIDED MORE INFORMATION SPECIFIC TO THEIR PRODUCT.
12 SO THAT IS THE MINORITY REPORT FOR THE SECOND
13 APPLICATION.

14 AND THAT CONCLUDES MY PRESENTATION, I
15 BELIEVE. SO I WILL GO TO THE LAST SLIDE WITH BOARD
16 MEMBERS WITH CONFLICTS. THANK YOU. I'LL HAND IT
17 BACK TO DR. IMBASCIANI.

18 CHAIRMAN IMBASCIANI: THANKS. GIL, ARE WE
19 GO TO HEAR ANYTHING MORE NEXT ABOUT ANY OF THE
20 APPLICATIONS?

21 DR. SAMBRANO: WE SHOULD SHOW THE
22 SPREADSHEET SO ALL OF YOU HAVE THE RANK ORDER OF
23 THESE APPLICATIONS, THE NINE RECOMMENDED IN GREEN
24 AND THE TOTAL AMOUNT THAT THAT WOULD BE, WHICH IS
25 ABOUT 45 AND A HALF MILLION. AND THEN BELOW THAT,

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1 THE ONE THAT'S RIGHT UNDER THE LAST GREEN ONE IS THE
2 APPLICATION THAT THE CIRM TEAM IS RECOMMENDING FOR
3 FUNDING THAT HAS A MINORITY REPORT AND THEN THOSE
4 THAT ARE BELOW THAT.

5 CHAIRMAN IMBASCIANI: OKAY.

6 DR. LAM: CAN PEOPLE SEE THE SPREADSHEET
7 BEING SHARED?

8 MS. DURON: YES.

9 DR. LAM: OKAY. THANK YOU.

10 CHAIRMAN IMBASCIANI: I CAN SEE ALL OF THE
11 GREEN AND ONLY ONE OF THE MINORITY REPORTS. CAN YOU
12 SCROLL DOWN PERHAPS? OKAY. THERE IT IS, TRAN4.

13 SO IF I CAN ASK FOR LEGAL ADVICE AT THIS
14 POINT. ARE WE READY TO ACCEPT THE FIRST OF THE FOUR
15 STANDARD MOTIONS RELATED TO ACCEPTING THESE?

16 MS. DEQUINA-VILLABLANCA: VITO, THERE ARE
17 SOME QUESTIONS. FRED FISHER.

18 DR. FISHER: THANKS. COUPLE OF QUESTIONS
19 CONNECTED TO HAYLEY'S PRESENTATION. HAYLEY, I
20 THOUGHT I UNDERSTOOD YOU TO SAY THAT ANY
21 APPLICATIONS THAT DON'T RECEIVE A SCORE OF 6 OR
22 HIGHER ON THE DEI, BUT DID RECEIVE A SCORE OF 85 OR
23 HIGHER WOULD NOT COME TO THIS GROUP FOR APPROVAL.
24 IS THAT RIGHT? MY RECOLLECTION IS THE ONE OR TWO
25 TIMES THIS HAS HAPPENED, THOSE PROPOSALS HAVE BEEN

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1 MOVED TO NOT FUNDED BECAUSE THEY DID NOT ACHIEVE A
2 MINIMUM DEI SCORE OF 6 IF THAT HAPPENED.

3 DR. LAM: YES, CORRECT. SO THE
4 APPLICATIONS THAT ARE RECOMMENDED HERE HAVE 85 OR
5 ABOVE AND A DEI SCORE OF 6 OR ABOVE, CORRECT, YES.

6 DR. FISHER: IN THE FUTURE IS IT POSSIBLE
7 TO CREATE ANOTHER COLUMN THAT SHOWS THE DEI SCORES?

8 DR. LAM: I WAS JUST THINKING THAT THIS
9 MORNING AS I WAS LOOKING AT THE SPREADSHEET.
10 ABSOLUTELY.

11 DR. FISHER: AND ON APPLICATION 14710, I
12 DIDN'T HEAR YOU MENTION THE DEI DISCUSSION. DO YOU
13 HAVE THE DEI SCORE?

14 DR. LAM: YEAH. SO THE DEI SCORE FOR
15 14710 WAS A SCORE OF 7.

16 DR. FISHER: OKAY. THANK YOU.

17 MS. DEQUINA-VILLABLANCA: ANNE-MARIE.

18 DR. DULIEGE: THANK YOU. IT WAS DIFFICULT
19 FOR ME BECAUSE I DON'T KNOW IF IT'S ON MY SIDE ONLY,
20 BUT PRESENTATIONS WERE OFTEN INTERRUPTED WITH POOR
21 QUALITY INTERNET. IN ANY CASE, MY QUESTIONS FOR
22 THESE TWO APPLICATIONS AND PARTICULARLY THE FIRST
23 ONE IS, GIVEN THE SCORES, WHAT IS THE JUSTIFICATION
24 FOR POTENTIALLY CHANGING THIS, OR COULD WE ASK THE
25 TWO APPLICANTS TO GO BACK, IMPROVE THEIR

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1 APPLICATIONS BASED ON FEEDBACK, AND COME BACK A
2 SECOND TIME WITH HOPEFULLY HIGHER SCORES?

3 DR. LAM: YES. SO ANY APPLICATION THAT IS
4 NOT FUNDED BY THE ARS COMMITTEE CAN RETURN AND
5 SUBMIT AGAIN TO THE NEXT ROUND OF TRANSLATIONAL
6 APPLICATIONS. AND TO THAT EFFECT, I BELIEVE THE
7 NEXT ROUND OF TRANSLATIONAL APPLICATIONS HASN'T BEEN
8 RELEASED YET. WE JUST POSTED THE PA. BUT THE NEXT
9 FEW DAYS SHOULD BE, I BELIEVE, THE DUE DATE WILL BE
10 IN MID-JUNE. I CAN'T REMEMBER THE EXACT DATE AT THE
11 MOMENT OFF THE TOP OF MY HEAD.

12 CHAIRMAN IMBASCIANI: IF I UNDERSTAND THAT
13 QUESTION CORRECTLY, IT'S WHY ARE WE NOT RELEGATING
14 THESE TWO REPORTS TO A CATEGORY TO BE CONSIDERED IN
15 THE FUTURE AND NOT NOW.

16 DR. LAM: WELL, THEY ARE IN THE NOT
17 RECOMMENDED. THEY ARE IN THE NOT RECOMMENDED. IF
18 YOU LOOK AT THE SPREADSHEET, IT'S THIS ONE AND THIS
19 ONE. WE JUST BRING TO YOUR SPECIAL ATTENTION THESE
20 TWO PARTICULAR APPLICATIONS BECAUSE THEY HAVE THE
21 MINORITY REPORT. AND, AGAIN, AS I SAID, THERE IS A
22 CIRM TEAM RECOMMENDATION TO FUND THIS FIRST ONE.

23 DR. DULIEGE: BUT NOT THE SECOND ONE?

24 DR. LAM: BUT NOT THE SECOND ONE, CORRECT.

25 DR. FISHER: JUST TO FINISH THAT POINT,

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1 THE REASON FOR THE CIRM STAFF RECOMMENDATION TO FUND
2 14710 IS THAT THE TEAM FEELS THEY CAN ADDRESS THE
3 DEFICIENCIES WITH THE APPLICANT AS PART OF MOVING
4 FORWARD AS OPPOSED TO REQUIRING MAJOR WORK THAT
5 WOULD BE PART OF A REAPPLICATION PROCESS. I THINK
6 THAT'S WHAT I UNDERSTOOD.

7 DR. LAM: CORRECT.

8 MR. JUELSGAARD: READY FOR ME NOW?

9 MS. DEQUINA-VILLABLANCA: WE ARE READY,
10 STEVE.

11 MR. JUELSGAARD: I HAVE A SERIES OF
12 QUESTIONS RELATED TO 14726. THIS IS THE I'LL CALL
13 IT THE PROCESS SCIENCE APPLICATION. SO LET ME START
14 BY NOTING THAT ALL OF THESE APPLICATIONS WITH FEW
15 EXCEPTIONS, THESE ARE ALL REALLY FOCUSED ON DISEASES
16 THAT WANT TO BE ADDRESSED. THIS PARTICULAR
17 APPLICATION IS FOCUSED ON SOMETHING ENTIRELY
18 DIFFERENT, WHICH FALLS INTO THE REALM OF WHAT I CALL
19 PROCESS SCIENCES LEADING UP TO MANUFACTURING. SO
20 IT'S A VERY DIFFERENT BIRD, IF YOU WILL.

21 SO MY FIRST QUESTION IS WITH THE
22 COMPOSITION OF THE GWG, WHAT PERCENTAGE OF THE GWG
23 REVIEWERS HAD ANY EXPERIENCE OF IMPORT WITH PROCESS
24 SCIENCE ISSUES?

25 DR. LAM: SO FOR THE TRANSLATIONAL PANEL,

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1 WE HAVE A MIX OF SCIENTIFIC DISEASE AREA EXPERTS
2 WITH MANUFACTURING AND CMC EXPERTS WHICH WOULD
3 APPLY, I THINK, IN THIS PARTICULAR CASE AND ALSO
4 REGULATORY EXPERTS. AND SO THE COMPOSITION OF THE
5 PANEL IS BROKEN DOWN I WOULDN'T SAY EVENLY ACROSS
6 THOSE; BUT ACROSS THE PANEL OF 15, I DON'T HAVE
7 EXACT NUMBERS IN FRONT OF ME FOR THIS PARTICULAR
8 PANEL, BUT THERE WAS AT LEAST THREE OR FOUR
9 MANUFACTURING FOLKS THAT COULD SPEAK TO THIS
10 PARTICULAR APPLICATION ON THE PANEL.

11 MR. JUELSGAARD: SO FOR THOSE THREE FOR
12 FOUR, WHAT DID THEY THINK OF THIS APPLICATION?
13 FORGET ABOUT WHAT THE OTHERS THOUGHT ABOUT IT. WERE
14 THEY SUPPORTIVE OF THIS APPLICATION OR NOT? HERE'S
15 WHAT I WORRY ABOUT IS THAT THIS IS ONE OF THOSE
16 NONSEXY AREAS ALTHOUGH IT'S A REALLY IMPORTANT AREA.
17 IT'S VERY MUCH OVERLOOKED TYPICALLY SPEAKING. SO
18 THE WHOLE AREA OF DEVELOPING A PROCESS, IN THIS CASE
19 FOR THE MANUFACTURE OF CELLS OR THE DEVELOPMENT OF
20 CELLS, IN THIS CASE FOR CLINICAL GRADE MATERIAL, IS
21 REALLY A VERY IMPORTANT ISSUE. AND I DON'T THINK
22 ENOUGH PEOPLE APPRECIATE THAT.

23 SO WHAT I WOULD NOT LIKE TO SEE IS
24 SOMETHING THAT MAKES LIFE EASIER FOR PEOPLE THAT ARE
25 DEVELOPING CELL LINES FOR CLINICAL WORK, MAKING

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1 THEIR LIFE EASIER BY HAVING A MEDIA THAT ESSENTIALLY
2 CAN BE USED ACROSS CELL LINES, THAT THAT SOMEHOW
3 GETS SWEEPED UNDER THE CARPET SIMPLY BECAUSE WE DON'T
4 HAVE THE RIGHT PEOPLE MAKING THE DECISION ABOUT
5 WHETHER THIS IS A WORTHWHILE PROJECT OR NOT. SO IF
6 YOU COULD SPEAK TO THAT CONCERN, I WOULD VERY MUCH
7 APPRECIATE IT BECAUSE, FROM MY POINT OF VIEW, WHEN I
8 LOOKED AT THE REVIEW, I THOUGHT THE COMMENTS THAT
9 PEOPLE MADE, FIRST OF ALL, THERE WERE A BUNCH OF
10 BOTTLENECKS THAT THEY DIDN'T ADDRESS AND WHAT THE
11 MINORITY REPORT SAID IS, YEAH, BUT THOSE BOTTLENECKS
12 ARE IRRELEVANT TO WHAT THEY'RE TRYING TO DO. YEAH,
13 THERE ARE BOTTLENECKS, BUT THIS PARTICULAR PROJECT
14 IS DESIGNED TO ONLY ADDRESS ONE BOTTLENECK, NOT FIVE
15 BOTTLENECKS. AND THEN I DIDN'T SEE MUCH ELSE AROUND
16 THIS THAT SAID SO THIS IS NOT A WORTHWHILE PROJECT.
17 SO WHEN I LOOKED AT THIS IN TOTAL, I HAD A HARD TIME
18 UNDERSTANDING THE SCORING SYSTEM.

19 IN PARTICULAR, WHEN YOU HAVE A STANDARD
20 DEVIATION OF NINE, WHICH IS EXTREMELY HIGH, AND YOU
21 HAVE ONE PERSON WHO SCORES IT AT A 55, AND IF I WERE
22 A MANUFACTURING PROCESS SCIENCE PERSON, THAT WOULD
23 END THE DISCUSSION FOR ME. IF IT'S NOT, THEN I
24 WORRY ABOUT THEIR CAPABILITY OF REALLY SCORING
25 SOMETHING LIKE THIS. SO I'M LOOKING AT GWG PROCESS

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1 AND TRYING TO UNDERSTAND IF IT'S A FAIR PROCESS FOR
2 THIS APPLICATION IN THIS SETTING.

3 DR. LAM: SO I GUESS I CAN SPEAK A LITTLE
4 BIT TO SORT OF WHAT I TOOK AS THE KEY CONCERNS ON
5 THIS APPLICATION TO SPEAK MORE GENERALLY, I THINK.
6 AND THOSE SORT OF FELL INTO, I THINK, THREE
7 DIFFERENT AREAS. SO THE FIRST WAS JUST THE VALUE
8 PROPOSITION, WHICH, AS YOU POINTED OUT, THOSE
9 REVIEWERS THAT SCORED TO RECOMMEND THE APPLICATION
10 DID THINK THAT THIS PARTICULAR ONE DID ADDRESS ONE
11 BOTTLENECK OF MANY. I THINK THE PANELISTS WHO WERE
12 IN THE MAJORITY PERHAPS FELT THAT THE APPLICANT
13 DIDN'T -- THE APPLICANT PERHAPS DIDN'T DISCUSS THE
14 OTHER BOTTLENECKS THAT WERE POSSIBLE.

15 SO I THINK WHAT HAPPENS OFTEN WHEN
16 REVIEWERS COMMENT ON VALUE PROPOSITION IS NOT
17 NECESSARILY THAT THEY DON'T THINK THAT THE
18 PARTICULAR PROJECT HAS PROMISE OR HAS VALUE, BUT
19 THAT THEY DON'T DISCUSS IT IN CONTEXT WITH THE OTHER
20 POSSIBLE BOTTLENECKS WITHIN THE FIELD OF IPSC CELL
21 THERAPY.

22 THE OTHER THING, THE OTHER CONCERNS ON
23 THIS APPLICATION WERE SOME DETAILS IN THE QUALITY
24 SYSTEMS. THEY THOUGHT THAT THE APPLICANT COULD HAVE
25 PROVIDED A LITTLE BIT MORE DETAIL ON THOSE AREAS.

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1 AND THE FINAL THING WAS THAT THEY ALSO
2 THOUGHT THAT THERE COULD BE SOME IMPROVEMENT ON THE
3 DEI. THE DEI SCORE FOR THIS ONE WAS A SIX. SO THAT
4 WAS SORT OF THE THREE MAIN THINGS. I DON'T KNOW IF
5 GIL WANTS TO JUMP IN HERE AS WELL BECAUSE I SEE HIS
6 HAND.

7 MR. JUELSGAARD: GIL.

8 DR. SAMBRANO: I WAS NOT GOING TO DIRECTLY
9 COMMENT ON WHAT HAYLEY JUST SAID, WHICH IS ACCURATE.
10 I THINK THE ONLY THING I WOULD ADD IS THAT WHEN WE
11 DETERMINE WHO'S GOING TO REVIEW APPLICATIONS, WE
12 ASSIGN EACH OF THESE TO THREE SCIENTIFIC MEMBERS AND
13 ONE OF THE PATIENT ADVOCATE MEMBERS. SO OF THE
14 PANEL, WE SELECT THE ONES THAT ARE MOST APPROPRIATE
15 AND HAVE THE GREATEST LEVEL OF EXPERTISE TO DO THE
16 PRIMARY ASSESSMENT OF THESE APPLICATIONS.

17 THE SECOND THING I WANTED TO POINT OUT,
18 WHICH IS JUST MORE GENERAL, IS THE AMOUNT OF FUNDING
19 THAT WE HAVE AVAILABLE FOR THIS ROUND. SO IF YOU
20 LOOK AT THE AMOUNT THAT'S RECOMMENDED BY THE GRANTS
21 WORKING GROUP, AS MENTIONED EARLIER, IT'S 45 AND A
22 HALF MILLION. THE AMOUNT THAT WE HAVE IN OUR BUDGET
23 IS ABOUT 49, WHICH MEANS IF THE APPLICATION REVIEW
24 SUBCOMMITTEE WERE TO FUND THE NINE PLUS THE ONE
25 RECOMMENDED BY THE TEAM, THAT WOULD ESSENTIALLY EAT

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1 UP ALL OF THE BUDGET. SO WE WOULD NOT HAVE
2 ADDITIONAL FUNDS FOR ANY OTHER APPLICATIONS.

3 SO I JUST WANT TO POINT THAT OUT IN TERMS
4 OF THE CONSIDERATION OF THE APPLICATIONS, THAT THAT
5 NEEDS TO BE TAKEN INTO ACCOUNT IF YOU CHOOSE TO DO A
6 DIFFERENT ONE OR ADDITIONAL ONES.

7 MR. JUELSGAARD: THAT'S HELPFUL, GIL. SO
8 I UNDERSTAND THAT PART OF IT. I WANT TO GO BACK TO
9 THE COMMENTS THAT HAYLEY MADE. FIRST OF ALL,
10 HAYLEY, THOSE PEOPLE WHO COMMENTED ON ADDITIONAL
11 BOTTLENECKS NOT BEING ADDRESSED, I MEAN IN SOME
12 SENSE ONLY VALIDATES MY POINT, WHICH IS IT SEEMS TO
13 ME THAT THEY'RE MORE FOCUSED ON THINGS THAT THIS
14 PROJECT WASN'T DESIGNED TO DEAL WITH WHICH ARE
15 IRRELEVANT TO THIS PROJECT. SO I DON'T QUITE
16 UNDERSTAND THAT CRITICISM COMING IN FROM REVIEWERS.
17 IF IT WERE PROCESS SCIENCES PEOPLE MAKING THESE
18 COMMENTS, I WOULD FIND THAT SURPRISING.

19 AND AS FAR AS THE DEI GOES, WE ARE TALKING
20 ABOUT CULTURE MEDIA HERE. WE ARE TALKING ABOUT
21 SOMETHING THAT'S ABOUT AS NEUTRAL TO THE WORLD AS
22 YOU CAN IMAGINE. IT'S BASICALLY HOW CAN WE BEST
23 GROW CELLS CONSISTENTLY ACROSS A WHOLE VARIETY OF
24 CELL TYPES? SO I'M NOT QUITE SURE -- I THINK WE
25 HAVE TO BE CAREFUL WITH DEI BECAUSE THERE ARE SOME

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1 PLACES IN WHICH REALLY THE ROLE IT PLAYS IS REALLY
2 DIFFICULT TO SEE VIS-A-VIS THE PROJECT THAT'S IN
3 PLAY. AND I THINK THIS IS ONE OF THOSE BECAUSE, AS
4 I SAID, CELL TYPES ARE CELL TYPES. AND THIS IS
5 DESIGNED TO ADDRESS AS MANY AS IS POSSIBLE WHEREVER
6 THEY COME FROM, WHETHER THEY COME FROM A HOMOGENOUS
7 POPULATION OR A HETEROGENEOUS POPULATION.

8 ANYWAY, I'M DONE WITH MY COMMENTS. MY
9 CONCERN IS REALLY ABOUT THE PROCESS. I WANT TO MAKE
10 SURE, WHEN WE IN THE FUTURE ADDRESS THESE KIND OF
11 PROGRAMS THAT INVOLVE EITHER PROCESS SCIENCES OR
12 MANUFACTURING, THEY DON'T GET LOST IN THE SHUFFLE
13 SIMPLY BECAUSE WE DON'T HAVE THE RIGHT PEOPLE AT THE
14 TABLE.

15 DR. LAM: ABSOLUTELY. WE DEFINITELY
16 MAKE -- YOUR POINT IS WELL ACKNOWLEDGED. JUST FOR
17 REFERENCE, OUT OF THE 20 APPLICATIONS THAT WERE
18 REVIEWED, 16 OF THEM WERE THE TRAN1 THERAPEUTICS.
19 THERE WAS ONE DIAGNOSTIC, TWO DEVICES, AND ONE TOOL.
20 SO IT'S WELL ACKNOWLEDGED THAT DEFINITELY THERE IS A
21 GREATER EMPHASIS ON THOSE TRAN1 APPLICATIONS. SO
22 WE'LL DEFINITELY BE PAYING CLOSE -- WE HAVE BEEN
23 PAYING CLOSE ATTENTION TO THAT AND WILL DO SO IN THE
24 FUTURE AS WELL. THANK YOU.

25 MR. JUELSGAARD: THANK YOU.

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1 MS. DEQUINA-VILLABLANCA: NO MORE HANDS
2 RAISED, VITO.

3 CHAIRMAN IMBASCIANI: MARIANNE, I'M SORRY.
4 THAT WAS NO MORE HANDS RAISED?

5 MS. DEQUINA-VILLABLANCA: YEAH. THERE'S
6 NO MORE HANDS RAISED.

7 CHAIRMAN IMBASCIANI: ALL RIGHT. THEN I
8 WOULD LOVE TO HEAR A MOTION THAT WOULD, IN OUR TIME
9 HONORED TRADITION OF HOW TO HANDLE THE GROUPS OF
10 THESE APPLICATIONS, THE FIRST MOTION I WOULD LIKE TO
11 ENTERTAIN WOULD BE DOES ANY BOARD MEMBER WANT TO
12 ELEVATE ANY OF THE APPLICATIONS RESIDING IN THE NOT
13 RECOMMENDED RANGE MOVE IT UP TO THE RECOMMENDED
14 RANGE FOR FUNDING. AND THAT CAN INCLUDE MINORITY
15 REPORTS THAT CIRM RECOMMENDS WE MOVE UP.

16 DR. SOUTHARD: I MOVE THAT WE MOVE UP
17 14710.

18 DR. FISHER: SECOND.

19 CHAIRMAN IMBASCIANI: THANK YOU, MARVIN.
20 I WOULD LIKE A SECOND.

21 DR. FISHER: SECOND.

22 CHAIRMAN IMBASCIANI: WHO SAID THAT? I'M
23 SORRY.

24 VICE CHAIR BONNEVILLE: THAT WAS FRED
25 FISHER.

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1 CHAIRMAN IMBASCIANI: THANK YOU, FRED.

2 I GUESS THE FLOOR IS OPEN FOR DISCUSSION
3 ON THE MOTION.

4 VICE CHAIR BONNEVILLE: ANNE-MARIE HAS HER
5 HAND RAISED, VITO.

6 CHAIRMAN IMBASCIANI: ANNE-MARIE, THANK
7 YOU.

8 DR. DULIEGE: THANK YOU. I'M SORRY. I
9 DON'T KNOW IF IT'S ON MY SIDE THAT THE VOICE DOESN'T
10 WORK AND I HEAR ABOUT HALF OF THE DIALOGUE.
11 NONETHELESS, MY QUESTION IS STILL WHAT WOULD BE THE
12 JUSTIFICATION FOR US TO DO THAT VERSUS ASKING THE
13 APPLICANT TO REVISE THEIR APPLICATION AND SUBMIT IT
14 IN JUNE?

15 CHAIRMAN IMBASCIANI: I'M GOING TO PASS
16 THAT QUESTION TO THE TEAM.

17 DR. SAMBRANO: HAYLEY, IF YOU ADDRESS THAT
18 IN TERMS OF A RECOMMENDATION.

19 DR. LAM: YES. SO IN TERMS OF THE TEAM
20 RECOMMENDATION, WE BELIEVE THAT THE CONCERNS THAT
21 WERE OUTLINED BY THE GRANTS WORKING GROUP CAN BE
22 RESOLVED WITH CIRM SUPPORT AND WITH THE WORK THAT
23 THEY WILL BE DOING WITH THE BESPOKE GENE THERAPY
24 CONSORTIUM, WHICH THIS APPLICATION WOULD BE A PART
25 OF OR THIS PROJECT, RATHER, WOULD BE A PART OF,

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1 WHICH OFFERS NIH AND FDA AND AS WELL AS INDUSTRY
2 IN-KIND SUPPORT FOR THE PROJECTS THAT ARE WITHIN
3 THAT CONSORTIUM.

4 DR. DULIEGE: AM I THE ONLY ONE TO HEAR
5 ONLY SENTENCE OUT OF TEN? IS IT GOOD INTERNET
6 CONNECTION FOR ALL OF YOU AND IT'S MY PROBLEM, WHICH
7 IS POSSIBLY THE CASE?

8 DR. SOUTHARD: I CAN HEAR PERFECTLY.

9 DR. DULIEGE: THANK YOU. IT'S BECAUSE I'M
10 IN FRANCE. AND YOU KNOW IN FRANCE EVEN THE INTERNET
11 IS ON STRIKE.

12 MS. DEQUINA-VILLABLANCA: ANNE-MARIE, IT
13 MAYBE IT MIGHT HELP TO TURN YOUR VIDEO OFF AND YOU
14 MIGHT BE ABLE TO HEAR BETTER THAT WAY.

15 DR. DULIEGE: THAT COULD BE. WELL, THANK
16 YOU. I DIDN'T HEAR MOST OF YOUR EXPLANATION, BUT
17 THE FACT THAT TIER 1 IS ENOUGH FOR ME TO VOTE YES.

18 CHAIRMAN IMBASCIANI: ARE THERE ANY OTHER
19 HANDS RAISED? I WOULD HAVE TO SCROLL DOWN TO SEE
20 THAT.

21 MS. DEQUINA-VILLABLANCA: NO.

22 CHAIRMAN IMBASCIANI: NO OTHER HANDS
23 RAISED. SO WE HAVE A MOTION ON THE FLOOR TO ELEVATE
24 TRAN1-14710 -- THIS IS AN EYE TEST HERE -- FROM THE
25 NOT RECOMMENDED TO THE RECOMMENDED FOR FUNDING

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1 CATEGORY.

2 MR. AGUIRRE-SACASA: VITO, WE SHOULD ASK
3 FOR PUBLIC COMMENT PLEASE.

4 CHAIRMAN IMBASCIANI: OH, THANK YOU. DO
5 WE HAVE ANYONE ON THE LINE OR IN PERSON AT THE
6 HEADQUARTERS BUILDING WHO WOULD LIKE TO SPEAK TO
7 THIS MOTION?

8 MS. DEQUINA-VILLABLANCA: CURRENTLY, NO,
9 WE DON'T.

10 CHAIRMAN IMBASCIANI: OKAY. HEARING NO
11 ADDITIONAL COMMENT, I THINK WE ARE PREPARED TO CALL
12 THE ROLL. JUST TO BE CLEAR, A YES VOTE MEANS YOU
13 WILL MOVE UP TRAN1-14710 INTO THE RECOMMENDED FOR
14 FUNDING CATEGORY.

15 DR. FISHER: SINCE THIS MOTION WAS
16 SPECIFIC TO THIS PARTICULAR PROJECT, IS THERE GOING
17 TO BE THE OPPORTUNITY FOR MOTIONS TO MOVE ANY OTHER
18 PROPOSALS? OR IS THE ASSUMPTION THAT THERE ARE NO
19 OTHER PROPOSALS BECAUSE THIS MOTION WAS JUST ABOUT
20 THIS ONE.

21 VICE CHAIR BONNEVILLE: YES. FRED, MY
22 UNDERSTANDING IS THAT WE DO NOT HAVE THE FUNDS TO
23 MOVE ANOTHER APPLICATION UP. IS THAT CORRECT, GIL?

24 DR. LAM: THAT IS CORRECT.

25 DR. SAMBRANO: THAT'S CORRECT. I THINK

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1 THE MOTION RIGHT NOW IS JUST TO MOVE THE ONE
2 APPLICATION INTO THE FUNDING ZONE, BUT THAT DOESN'T
3 PREVENT THE COMMITTEE FROM MOVING DOWN SOME
4 APPLICATIONS, IF YOU WERE TO DO THAT, IN ORDER TO
5 ALLOW OTHERS TO COME UP. IN OTHER WORDS, IF YOU
6 MOVE THIS ONE UP AND ALL NINE PLUS THAT ONE ARE
7 FUNDED, IT WOULD TAKE UP THE FULL BUDGET.

8 CHAIRMAN IMBASCIANI: THAT PRESENTS THE
9 QUANDARY OF WE CANNOT ELEVATE ANOTHER ONE OF THE
10 NONRECOMMENDED UP UNTIL WE MOVE ONE OF THE OTHERS
11 DOWN. SO WE WILL HAVE TO COME BACK TO THIS THEN,
12 AND THAT'S FINE. WE CAN ENTERTAIN A MOTION FROM THE
13 FLOOR.

14 MR. AGUIRRE-SACASA: SO, VITO, WE HAVE A
15 MOTION ON THE TABLE THAT WE NEED TO VOTE ON PLEASE.

16 CHAIRMAN IMBASCIANI: THAT'S RIGHT. SO
17 ONCE AGAIN, YOU ARE VOTING TO ELEVATE TRAN1-14710 TO
18 BE FUNDED.

19 MR. AGUIRRE-SACASA: READY?

20 DAN BERNAL.

21 MR. BERNAL: AYE.

22 MR. AGUIRRE-SACASA: MARIA BONNEVILLE.

23 VICE CHAIR BONNEVILLE: YES.

24 MR. AGUIRRE-SACASA: JUDY CHOU.

25 DR. CHOU: AYE.

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1 MR. AGUIRRE-SACASA: LEONDR A CLARK-HARVEY.

2 MS. CLARK-HARVEY: AYE.

3 MR. AGUIRRE-SACASA: ANNE-MARIE DULIEGE.

4 DR. DULIEGE: AYE.

5 MR. AGUIRRE-SACASA: YSABEL DURON.

6 MS. DURON: I WILL SAY YES EXCEPT FOR
7 THOSE WITH WHICH I'M IN CONFLICT IF THAT IS THE
8 CORRECT LANGUAGE TO USE.

9 MR. AGUIRRE-SACASA: YES IS GOOD ENOUGH
10 FOR THIS ONE. THANK YOU.

11 MARK FISCHER-COLBRIE.

12 DR. FISCHER-COLBRIE: YES.

13 MR. AGUIRRE-SACASA: FRED FISHER.

14 DR. FISHER: YES.

15 MR. AGUIRRE-SACASA: DAVID HIGGINS.

16 DR. HIGGINS: YES.

17 MR. AGUIRRE-SACASA: VITO IMBASCIANI.

18 CHAIRMAN IMBASCIANI: YES.

19 MR. AGUIRRE-SACASA: STEVE JUELSGAARD.

20 MR. JUELSGAARD: YES.

21 MR. AGUIRRE-SACASA: RICH LAJARA.

22 MR. LAJARA: YES.

23 MR. AGUIRRE-SACASA: LAUREN MILLER-ROGEN,
24 ARE YOU STILL ON? ADRIANA PADILLA.

25 DR. PADILLA: YES.

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1 MR. AGUIRRE-SACASA: JOE PANETTA.

2 MR. PANETTA: YES.

3 MR. AGUIRRE-SACASA: AND MARVIN SOUTHARD.

4 DR. SOUTHARD: YES.

5 MR. HUANG: RAFAEL, I THOUGHT, BECAUSE WE
6 HAVE NOT CLOSED OUT THE NOT RECOMMENDED RANGE, THAT
7 THIS MOTION WOULD ENTERTAIN ALL THE CONFLICTS FOR
8 ALL THE APPLICATIONS, ESPECIALLY THERE'S A LIMITED
9 FUND. SO I THINK WE SHOULD REDO THE VOTE AND NOT
10 CALL ON ALL THE CONFLICTED MEMBERS BECAUSE WE HAVE
11 NOT CLOSED OUT THE NOT RECOMMENDED RANGE.

12 MR. AGUIRRE-SACASA: WE'LL DO THAT AGAIN.
13 THANK YOU, BEN. PARDON ME. IF YOU'RE CONFLICTED,
14 AND WE HAVE THE LIST AT THE BEGINNING, WE CAN DO IT
15 AGAIN. THANK YOU.

16 DAN BERNAL.

17 MR. BERNAL: AYE.

18 MR. AGUIRRE-SACASA: JUDY CHOU.

19 DR. CHOU: YES.

20 MR. AGUIRRE-SACASA: ANNE-MARIE DULIEGE.
21 YOU ARE ON MUTE, ANNE-MARIE. OKAY. WE'LL COME
22 BACK.

23 FRED FISHER.

24 DR. FISHER: YES.

25 MR. AGUIRRE-SACASA: DAVID HIGGINS.

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1 DR. HIGGINS: YES.
2 MR. AGUIRRE-SACASA: VITO IMBASCIANI.
3 CHAIRMAN IMBASCIANI: YES.
4 MR. AGUIRRE-SACASA: STEVE JUELSGAARD.
5 MR. JUELSGAARD: YES.
6 MR. AGUIRRE-SACASA: RICH LAJARA.
7 MR. LAJARA: YES.
8 MR. AGUIRRE-SACASA: ADRIANA PADILLA.
9 DR. PADILLA: YES.
10 MR. AGUIRRE-SACASA: AND MARVIN SOUTHARD.
11 DR. SOUTHARD: YES.
12 MR. AGUIRRE-SACASA: ANNE-MARIE DULIEGE.
13 YOU WERE ON MUTE BEFORE.
14 MS. DEQUINA-VILLABLANCA: ANNE-MARIE, ARE
15 YOU THERE?
16 MR. AGUIRRE-SACASA: ALL RIGHT. MOTION
17 PASSES. MOTION PASSES. THANK YOU.
18 CHAIRMAN IMBASCIANI: MOTION PASSES.
19 THANK YOU, EVERYONE.
20 AND NOW WITH RESPECT TO OUR SECOND MOTION,
21 I WOULD LIKE TO HEAR ANY MOTIONS FOR CONSIDERATION
22 OF MOVING A RECOMMENDED APPLICATION DOWN INTO THE
23 NOT RECOMMENDED RANGE EITHER BY VIRTUE IPSO FACTO,
24 IF YOU WILL, OR BY VIRTUE OF BUDGET CONSIDERATIONS
25 AS WE TALKED ABOUT EARLIER.

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1 VICE CHAIR BONNEVILLE: HAYLEY HAS HER
2 HAND RAISED.

3 CHAIRMAN IMBASCIANI: I SEE. HAYLEY,
4 THANK YOU.

5 DR. LAM: I JUST HAVE A BRIEF UPDATE
6 BECAUSE I GOT A NOTIFICATION FROM THE TEAM THAT WAS
7 ABLE TO LOOK UP THE DETAILS ON THE VOTING FOR
8 APPLICATION TRAN4-14726, THE MEDIA APPLICATION, IN
9 REGARDS TO STEVEN JUELSGAARD'S QUESTION ABOUT THE
10 VOTING BREAKDOWN. SO TWO OF THE PANELISTS WHO WERE
11 MANUFACTURING EXPERTS SCORED IN THE NONFUNDABLE
12 RANGE. SO JUST A POINT OF INFORMATION THERE. THANK
13 YOU.

14 CHAIRMAN IMBASCIANI: THANK YOU FOR THAT.

15 MR. JUELSGAARD: THANKS, HAYLEY.

16 CHAIRMAN IMBASCIANI: THAT SPECIFICALLY
17 ADDRESSES ONE OF STEPHEN'S CONCERNS.

18 SO ONCE AGAIN, LOOKING FOR ANY MOTION --
19 I'M NOT COMPULSIVE -- FOR ANY OF THE ONES THAT ARE
20 COLORED GREEN. THESE ARE RECOMMENDED BY THE CIRM
21 TEAM FOR FUNDING. DO WE WANT TO REMOVE ANY OF THESE
22 RECOMMENDED APPLICATIONS FROM THE FUNDED GROUP?

23 HEARING NO MOTION FROM THE FLOOR, I WANT
24 TO MAKE SURE THAT WE ARE HEARING ANNE-MARIE.
25 ANNE-MARIE, CAN YOU GIVE US ACKNOWLEDGEMENT THAT YOU

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1 HEARD THAT?

2 DR. DULIEGE: YES, ABSOLUTELY. I
3 APOLOGIZE BECAUSE CLEARLY MY LACK OF QUALITY OF THE
4 INTERNET DOESN'T HELP THE FLOW OF THE MEETING. SO
5 APOLOGIES, BUT I DID HEAR THIS ONE. THANK YOU.

6 CHAIRMAN IMBASCIANI: ALL RIGHT. SO IT IS
7 MY IMPRESSION, CORRECT ME IF I'M WRONG, THAT THERE
8 ARE NO MOTIONS TO MOVE ANY OF THESE GREEN FUNDED
9 RECOMMENDATIONS DOWN. SO HEARING NO MOTION, WE CAN
10 NOW PROCEED.

11 CAN WE HAVE A MOTION FROM THE FLOOR TO NOT
12 FUND THOSE THAT ARE IN THE NOT RECOMMENDED RANGE?
13 SO THESE WOULD BE ALL THE ONES THAT ARE IN WHITE.
14 AND I SEE THAT YOU'VE NOW GREENED OUT THE 1-14710.
15 THANK YOU. SO THERE ARE EIGHT THAT I'M ASKING FOR A
16 MOTION NOT TO FUND THESE EIGHT.

17 DR. SOUTHARD: SO MOVED.

18 MR. BERNAL: SECOND.

19 CHAIRMAN IMBASCIANI: WE HAVE A MOTION AND
20 SECOND THAT I'M SURE WERE CAPTURED BY MARIANNE.

21 MS. DEQUINA-VILLABLANCA: YES.

22 CHAIRMAN IMBASCIANI: DISCUSSIONS FROM THE
23 BOARD? DISCUSSIONS FROM THE PUBLIC?

24 MS. DEQUINA-VILLABLANCA: THERE ARE NONE.

25 CHAIRMAN IMBASCIANI: THERE ARE NONE.

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1 OKAY. WE CAN PROCEED TO A VOTE, RAFAEL.

2 MR. AGUIRRE-SACASA: OKAY. YES. IF YOU
3 CAN VOTE YES OR NO EXCEPT FOR WHERE YOU ARE
4 CONFLICTED, THAT WOULD BE GREAT.

5 DAN BERNAL.

6 MR. BERNAL: AYE.

7 MR. AGUIRRE-SACASA: MARIA BONNEVILLE.

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

10 MR. AGUIRRE-SACASA: JUDY CHOU.

11 DR. CHOU: YES.

12 MR. AGUIRRE-SACASA: LEONDR A CLARK-HARVEY.

13 MS. CLARK-HARVEY: YES.

14 MR. AGUIRRE-SACASA: ANNE-MARIE DULIEGE.

15 DR. DULIEGE: YES.

16 MR. AGUIRRE-SACASA: YSABEL DURON.

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

19 MR. AGUIRRE-SACASA: MARK FISCHER-COLBRIE.

20 DR. FISCHER-COLBRIE: JUST A QUICK
21 QUESTION. I WOULD SUSPECT, BECAUSE WE'RE HITTING A
22 DOLLAR LIMIT, THAT I'M NOT ABLE TO VOTE ON THIS EVEN
23 THOUGH I CAN SAY YES EXCEPT FOR THOSE WHICH I HAVE A
24 CONFLICT, BUT JUST WANT TO CLARIFY WHETHER I'M
25 ELIGIBLE TO VOTE OR NOT.

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1 MR. AGUIRRE-SACASA: YES, WITH THAT CAVEAT
2 YOU ARE.

3 DR. FISCHER-COLBRIE: WELL, THEN YES WITH
4 THAT CAVEAT.

5 MR. AGUIRRE-SACASA: FRED FISHER.

6 DR. FISHER: YES.

7 MR. AGUIRRE-SACASA: DAVID HIGGINS.

8 DR. HIGGINS: YES.

9 MR. AGUIRRE-SACASA: VITO IMBASCIANI.

10 CHAIRMAN IMBASCIANI: YES.

11 MR. AGUIRRE-SACASA: STEVE JUELSGAARD.

12 MR. JUELSGAARD: YES.

13 MR. AGUIRRE-SACASA: RICH LAJARA.

14 MR. LAJARA: YES.

15 MR. AGUIRRE-SACASA: ADRIANA PADILLA.

16 DR. PADILLA: YES.

17 MR. AGUIRRE-SACASA: JOE PANETTA.

18 MR. PANETTA: YES, EXCEPT FOR THOSE WITH
19 WHICH I HAVE A CONFLICT.

20 MR. AGUIRRE-SACASA: MARVIN SOUTHARD.

21 DR. SOUTHARD: YES.

22 MR. AGUIRRE-SACASA: LEONDRA, COULD YOU
23 PLEASE VOTE AGAIN WITH CAVEAT IF NECESSARY BECAUSE
24 YOU'RE CONFLICTED ON A COUPLE?

25 DR. CLARK-HARVEY: I'M SORRY.

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1 MR. AGUIRRE-SACASA: YOU'RE CONFLICTED ON
2 AN APPLICATION OR TWO. SO IF YOU COULD VOTE YES OR
3 NO WITH THE CAVEAT OF EXCEPT FOR WHERE I'M
4 CONFLICTED.

5 MS. CLARK-HARVEY: OKAY. THANK YOU. YES,
6 EXCEPT WHERE I'M CONFLICTED.

7 MR. AGUIRRE-SACASA: THANK YOU VERY MUCH.
8 NO WORRIES. APPRECIATE IT. MOTION PASSES.

9 CHAIRMAN IMBASCIANI: THANK YOU, RAFAEL.
10 OKAY.

11 THEN WE ARE AT A POINT NOW WHERE WE NEED A
12 MOTION TO FUND THE APPLICATIONS OF ALL THE ONES IN
13 GREEN; THAT IS, THE ONES THAT ARE RECOMMENDED BY THE
14 TEAM FOR FUNDING. MAY I HAVE A MOTION AND A SECOND?

15 MR. BERNAL: SO MOVED.

16 CHAIRMAN IMBASCIANI: AND A SECOND?
17 SECOND FROM?

18 VICE CHAIR BONNEVILLE: FRED.

19 CHAIRMAN IMBASCIANI: FRED AND MARVIN.

20 DR. FISHER: NO. NO. IT'S NOT ME.

21 MS. DEQUINA-VILLABLANCA: MARVIN IS
22 SECOND.

23 CHAIRMAN IMBASCIANI: ALL RIGHT. WE HAVE
24 MOVEMENT AND A SECOND. I NEED DISCUSSION, FINAL
25 DISCUSSION, FROM MEMBERS OF THE BOARD. NO HANDS

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1 RAISED. ANY COMMENTS FROM THE GENERAL PUBLIC?

2 MS. DEQUINA-VILLABLANCA: THERE ARE NONE.

3 CHAIRMAN IMBASCIANI: THANK YOU, MARIANNE.

4 I THINK WE CAN PROCEED, RAFAEL, TO A VOTE.

5 MR. AGUIRRE-SACASA: OKAY. SAME PROCESS,
6 YES OR NO WITH THE CAVEAT OF WHERE YOU ARE
7 CONFLICTED.

8 DAN BERNAL. MARIA BONNEVILLE.

9 VICE CHAIR BONNEVILLE: YES.

10 MR. AGUIRRE-SACASA: JUDY CHOU.

11 DR. CHOU: YES.

12 MR. AGUIRRE-SACASA: LEONDRA CLARK-HARVEY.

13 MS. CLARK-HARVEY: YES, EXCEPT FOR THOSE
14 WITH WHICH I AM CONFLICTED.

15 MR. AGUIRRE-SACASA: ANNE-MARIE DULIEGE.
16 YSABEL DURON.

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

19 MR. AGUIRRE-SACASA: MARK FISCHER-COLBRIE.

20 DR. FISCHER-COLBRIE: YES, EXCEPT FOR
21 THOSE WITH WHICH I HAVE A CONFLICT.

22 MR. AGUIRRE-SACASA: FRED FISHER.

23 DR. FISHER: YES.

24 MR. AGUIRRE-SACASA: DAVID HIGGINS.

25 DR. HIGGINS: YES.

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1 MR. AGUIRRE-SACASA: VITO IMBASCIANI.

2 CHAIRMAN IMBASCIANI: YES.

3 MR. AGUIRRE-SACASA: STEVE JUELSGAARD.

4 MR. JUELSGAARD: YES.

5 MR. AGUIRRE-SACASA: RICH LAJARA.

6 MR. LAJARA: YES.

7 MR. AGUIRRE-SACASA: ADRIANA PADILLA.

8 DR. PADILLA: YES.

9 MR. AGUIRRE-SACASA: JOE PANETTA.

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

12 MR. AGUIRRE-SACASA: MARVIN SOUTHARD.

13 DR. SOUTHARD: YES.

14 MR. AGUIRRE-SACASA: MOTION PASSES.

15 THANK YOU.

16 CHAIRMAN IMBASCIANI: THANK YOU. GOOD.
17 THAT CLOSES OUT THE SECTION OF THE AGENDA DEALING
18 WITH THE TRANSLATIONAL APPLICATIONS. SO, GIL, MAY I
19 ASK YOU TO INTRODUCE THE NEXT ORDER OF BUSINESS,
20 WHICH ARE THE CLINICAL APPLICATIONS.

21 DR. SAMBRANO: YES. THANK YOU, MR.
22 CHAIRMAN. LET ME SHARE MY SCREEN SO I CAN GO
23 THROUGH THAT SLIDE DECK. I'M GOING TO PRESENT TO
24 YOU THE RECOMMENDATIONS FROM THE GRANTS WORKING
25 GROUP RELATED TO THE LATEST ROUND OF CLINICAL

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1 APPLICATIONS THAT WE RECEIVED.

2 AGAIN, POINTING OUT OUR MISSION AS WE DO
3 WITH THE GRANTS WORKING GROUP AND ALL OF THE
4 MEETINGS THAT WE HOLD.

5 THIS IS AN UPDATE ON THE CLINICAL BUDGET
6 STATUS FOR THE CLINICAL PROGRAM. WE ALLOCATED 169
7 MILLION, AND THIS IS WHERE WE ARE TODAY. SO FAR 115
8 MILLION HAVE BEEN APPROVED BY THIS COMMITTEE. THE
9 AMOUNT THAT'S REQUESTED TODAY IS 38.8 MILLION, WHICH
10 WOULD LEAVE AN UNUSED BALANCE OF 15.1 IF ALL ARE
11 APPROVED FOR FUNDING. AND THAT'S FOR THE FISCAL
12 YEAR WHICH ENDS IN JUNE.

13 THE SCIENTIFIC SCORING SYSTEM THAT'S USED
14 FOR CLINICAL APPLICATIONS IS DIFFERENT THAN IT IS
15 FROM THE TRAN. HERE WE USE A SCORE OF 1, 2, OR 3
16 WHERE A SCORE OF 1 MEANS THAT THOSE APPLICATIONS
17 HAVE EXCEPTIONAL MERIT AND WARRANT FUNDING. A SCORE
18 OF 2 MEANS THEY NEED IMPROVEMENT AND DON'T WARRANT
19 FUNDING, BUT CAN BE REVISED TO ADDRESS AREAS OF
20 CONCERN. AND THOSE TYPICALLY GO BACK TO THE
21 APPLICANT FOR RESUBMISSION AND SUBSEQUENT REVIEW BY
22 THE GRANTS WORKING GROUP. A SCORE OF 3 MEANS THAT
23 THEY ARE SUFFICIENTLY FLAWED THAT IT DOESN'T WARRANT
24 FUNDING AT THIS TIME, AND THEY CAN'T BE SUBMITTED
25 FOR AT LEAST SIX MONTHS.

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1 THE REVIEW CRITERIA THAT ARE USED MIRROR
2 WHAT HAYLEY ALSO SHOWED FOR TRAN, WHICH ARE THE FIVE
3 UMBRELLA CRITERIA THAT ARE USED. DOES THE PROJECT
4 HOLD THE NECESSARY SIGNIFICANCE AND POTENTIAL FOR
5 IMPACT? DOES IT HAVE A GOOD RATIONALE? IS IT WELL
6 PLANNED AND DESIGNED? IS IT FEASIBLE, INCLUDING
7 HAVING ALL THE APPROPRIATE RESOURCES AND TEAM
8 MEMBERS? AND DOES THE PROJECT UPHOLD THE PRINCIPLES
9 OF DIVERSITY, EQUITY, AND INCLUSION?

10 COMPOSITION OF THE WORKING GROUP IS MUCH
11 THE SAME AS HAYLEY ALSO SHOWED FOR A CLINICAL
12 PROGRAM. WE HAVE OUR SCIENTIFIC GRANTS WORKING
13 GROUP MEMBERS CONDUCT THE SCIENTIFIC EVALUATION.
14 HERE TOO WE BRING IN A VARIETY OF DISEASE AREA
15 EXPERTISE, REGULATORY, CMC, AND OTHER EXPERTISE AS
16 DICTATED BY THE TYPES OF APPLICATIONS THAT ARE BEING
17 REVIEWED. OUR GRANTS WORKING GROUP BOARD MEMBERS
18 CONDUCT THE DEI EVALUATION, PROVIDE THE PATIENT
19 PERSPECTIVE ON SIGNIFICANCE AND IMPACT, AND THEN
20 PROVIDE OVERSIGHT ON THE PROCESS. WE ALSO BRING
21 SCIENTIFIC SPECIALISTS AS NEEDED TO PROVIDE AD HOC
22 ADVICE WHERE THERE ARE KNOWLEDGE GAPS IN THE MAIN
23 PANEL.

24 BEFORE I GET STARTED WITH EACH OF THESE
25 APPLICATIONS, IN THIS CASE WE'RE GOING TO TAKE EACH

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1 APPLICATION INDIVIDUALLY. THESE, HOWEVER, ARE
2 MEMBERS THAT HAVE A CONFLICT WITH ONE OR MORE OF
3 THESE APPLICATIONS.

4 THE FIRST APPLICATION THAT WE'RE GOING TO
5 DISCUSS IS CLIN2-14315. SO BEING A CLIN2, THIS IS
6 FOR A CLINICAL TRIAL. THE TITLE IS "REDUCED
7 INTENSITY CONDITIONING WITH THE CANDIDATE PRODUCT,
8 WHICH WE REDACTED, PRIOR TO TCR ALPHA BETA POSITIVE
9 T-CELL/CD19 POSITIVE B-CELL DEPLETED HEMATOPOIETIC
10 STEM CELL TRANSPLANT FOR FANCONI ANEMIA PATIENTS."

11 THIS THERAPY IS AN ANTIBODY THAT TARGETS
12 BLOOD STEM CELLS FOR A CONDITIONING REGIMEN THAT IS
13 THEN FOLLOWED BY THE ALPHA BETA DEPLETED BLOOD STEM
14 CELL TRANSPLANT. AND THE INDICATION IS FOR PATIENTS
15 WITH FANCONI ANEMIA. THE GOAL OF THE PROJECT IS TO
16 COMPLETE A PHASE 1 CLINICAL TRIAL THAT'S TESTING
17 THIS NEW REGIMEN IN COMBINATION WITH THE TRANSPLANT.
18 THE FUNDS REQUESTED ARE 11.8 MILLION FOR THIS
19 PARTICULAR APPLICATION.

20 SO A LITTLE BIT OF BACKGROUND ON FANCONI
21 ANEMIA AND THE CONDITION. SO CONDITIONING REGIMENS
22 IN GENERAL WHICH ARE USED FOR BLOOD STEM CELL
23 TRANSPLANTS ARE NEEDED IN ORDER TO REMOVE THE
24 EXISTING DISEASED BLOOD STEM CELLS BEFORE THE NEW
25 TRANSPLANT CAN TAKE PLACE. AND THAT OFTEN REQUIRES

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1 THE USE OF TOXIC AGENTS THAT ARE GENOTOXIC, MEANING
2 THAT THEY CAN CAUSE MUTATIONS IN CELLS AND AFFECT
3 THE DNA OF CELLS AND POTENTIALLY CAUSE CANCER OR
4 TUMORS.

5 FOR PATIENTS WITH FANCONI ANEMIA, THOSE
6 INDIVIDUALS HAVE A SIGNIFICANT PROPENSITY FOR
7 DEVELOPING LEUKEMIAS AND OTHER SOLID ORGAN CANCERS.
8 SO GOING THROUGH THIS PROCESS IS PARTICULARLY
9 DIFFICULT BECAUSE IT EXACERBATES THE POSSIBILITY OF
10 DEVELOPING TUMORS AND/OR CANCERS.

11 SO THE VALUE PROPOSITION OF THIS PROJECT
12 IS THAT THE PROPOSED THERAPY UTILIZES A NEW
13 CONDITIONING REGIMEN THAT MAKES USE OF THIS ANTIBODY
14 THAT IS NOT PHENOTOXIC AND HOLDS THE POTENTIAL FOR A
15 MUCH SAFER AND MORE EFFECTIVE BLOOD STEM CELL
16 TRANSPLANT IN PATIENTS WITH FANCONI ANEMIA.

17 WHY IS THIS A STEM CELL OR GENE THERAPY
18 PROJECT? THE CANDIDATE IS A BIOLOGIC THAT ACTS ON
19 BLOOD STEM CELLS AND IS ALSO USED IN CONJUNCTION
20 WITH A BLOOD STEM CELL TRANSPLANT.

21 IN TERMS OF OTHER PROJECTS IN OUR
22 PORTFOLIO THAT ARE SIMILAR, WE HAVE ONE OTHER
23 CLINICAL TRIAL THAT UTILIZES THE SAME CANDIDATE
24 ACTUALLY, THE MONOCLONAL ANTIBODY, TO DEplete BLOOD
25 STEM CELLS, BUT IN A DIFFERENT INDICATION AND LED BY

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1 A DIFFERENT TEAM. BUT IT IS ALSO TESTING THIS
2 CONDITIONING REGIMEN IN THAT INDICATION. AND THAT
3 IS ALSO A CLINICAL TRIAL PHASE 1 AWARD.

4 IN TERMS OF PREVIOUS FUNDING FOR THE
5 APPLICANT TEAM, SO THIS APPLICANT HAS RECEIVED CIRM
6 AWARDS IN THE PAST. THREE OF THOSE WHICH WERE
7 CLIN1, A DISC2, AND A TRAN, HAVE ALL NOW CLOSED OUT,
8 BUT CONTINUES TO BE -- THE PI IS THE PROGRAM
9 DIRECTOR FOR ONE OF OUR ALPHA CLINICS. SO THESE ARE
10 ALL DIFFERENT PROJECTS THAT THIS APPLICANT HAS HAD,
11 AND ALL IN GENERAL HAVE ACCOMPLISHED THEIR
12 MILESTONES ON TIME AND HAVE GENERALLY BEEN
13 SUCCESSFUL PROJECTS.

14 SO THIS IS THE GRANTS WORKING GROUP
15 RECOMMENDATION FOR THIS PROJECT. THIS RECEIVED A
16 SCORE OF 1 WITH TEN VOTES FOR A SCORE OF 1, THREE
17 VOTES FOR A SCORE OF 2, AND TWO VOTES FOR A SCORE OF
18 3 FROM THE PANEL. IT RECEIVED A DEI SCORE OF 9 ON
19 THE SCALE OF 1 TO 10. AND THE CIRM TEAM
20 RECOMMENDATION IS TO FUND THIS FOR THE AWARD AMOUNT
21 OF 11.8 MILLION.

22 MR. CHAIRMAN, I'LL TURN IT BACK TO YOU FOR
23 CONSIDERATION OF THIS APPLICATION.

24 CHAIRMAN IMBASCIANI: THANK YOU, GIL, FOR
25 THAT. SO I WOULD LIKE TO HEAR A MOTION TO FUND

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1 APPLICATION CLIN2-14315.

2 VICE CHAIR BONNEVILLE: ANNE-MARIE HAS A
3 QUESTION, VITO.

4 CHAIRMAN IMBASCIANI: BEFORE WE HAVE A
5 MOTION. OKAY. ANNE-MARIE.

6 DR. DULIEGE: WE CAN WAIT FOR A MOTION,
7 EITHER WAY. ANYWAY, HERE'S MY QUESTION. I DON'T
8 HAVE A QUESTION ON THE MERIT OF THE APPLICATION FOR
9 SURE. THE AMOUNT REQUESTED TO THE CIRM IS PRETTY
10 HIGH. I ASSUME IT'S AMONG THE HIGHEST GRANTS THAT
11 WE HAVE FUNDED EVER. YOU MAY HAVE SAID IT, BUT IS
12 THERE A MATCHING FUND? AND HOW DOES THE TEAM
13 JUSTIFY SUCH A HIGH FUNDING? IS IT A PHASE 2, A
14 PHASE 3?

15 DR. SAMBRANO: THIS IS A PHASE 1 TRIAL.
16 SO EACH -- THE AWARD AMOUNT IS NOT UNUSUAL. SO IT
17 IS NOT THE HIGHEST. THE HIGHEST THAT WE CAN FUND IS
18 15 MILLION. AND WE ACTUALLY HAVE ONE THAT IS
19 REQUESTING 15 MILLION IN THIS GROUP OF APPLICATIONS.
20 THE HIGHEST AWARD AMOUNT THAT CAN BE REQUESTED FOR
21 THIS TYPE OF PHASE 1 PROJECT WOULD BE 12 MILLION.
22 NO CO-FUNDING IS PROVIDED, AND IT'S NOT REQUIRED
23 BECAUSE THIS IS AN ACADEMIC INSTITUTION WHERE WE
24 DON'T IMPOSE A CO-FUNDING REQUIREMENT FOR A PHASE 1
25 PROJECT. BUT, IN GENERAL, THIS IS WITHIN THE RANGE

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1 OF PROJECTS AND BUDGETS THAT WE TYPICALLY FUND.

2 THAT SAID, AND I MENTIONED THIS BEFORE, WE
3 HAVE BEEN LOOKING AT SPECIFIC WAYS IN WHICH WE CAN
4 PROVIDE TO YOU MORE DATA AND INFORMATION ON THE
5 BENCHMARKING THAT IS CONDUCTED BY OUR GRANTS
6 MANAGEMENT TEAM. SO ALL OF THESE PROJECTS ARE
7 INDEED BENCHMARKED, AND WE ALSO GET ADVICE AND
8 RECOMMENDATIONS FROM THE GRANTS WORKING GROUP ITSELF
9 THAT OFTEN POINT OUT SPECIFIC AREAS WHERE THEY THINK
10 COSTS MAY BE HIGH FOR US TO TAKE A CLOSER LOOK.

11 SO FOLLOWING THE APPROVAL OF ANY AWARD,
12 THE GRANTS MANAGEMENT TEAM DOES TAKE A CLOSER LOOK
13 TO ANSWER THAT ALL COSTS ARE ALLOWABLE AND WITHIN
14 REASONABLE LIMITS. AND THE OTHER THING THAT WE DO
15 IS ASK FOR ADDITIONAL JUSTIFICATION FROM THE
16 APPLICANT WHERE IT MAY BE WARRANTED.

17 DR. DULIEGE: GIL, THANK YOU. YOU ALWAYS
18 RESPOND IN A VERY CONVINCING MANNER. FOR ONE THING,
19 \$12 MILLION IS NOT UNUSUAL FOR A PHASE 1. THAT'S
20 ROUGHLY THE COST OF A PHASE 1. IN THAT CASE IT'S
21 EXPLAINED BY THE FACT THAT THERE'S NO CO-MATCHING OR
22 MATCHING FUNDS. AND I KNOW THE CIRM TEAM IS VERY
23 DILIGENT IN MANAGING THAT PART OF THE PROJECT AS
24 WELL.

25 MAYBE MY SECOND PART OF THE QUESTION IS

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1 THE CIRM SO FAR HAS A PRETTY BROAD PIPELINE IN
2 SINGLE-CELL DISEASE, WHICH THIS ONE IS ABOUT; IS
3 THAT RIGHT?

4 DR. SAMBRANO: THIS ONE IS WITH A RARE
5 DISEASE, THE FANCONI ANEMIA.

6 DR. DULIEGE: SO EXHUME MY COMMENT. I GOT
7 CONFUSED. THANK YOU. NO MORE COMMENTS ON MY PART.

8 CHAIRMAN IMBASCIANI: OKAY. SO I'D LIKE
9 TO GO BACK TO REGULAR ORDER WHERE WE ASK -- JUST A
10 REMINDER TO BOARD MEMBERS. MAKING A MOTION IS NOT
11 AN INDICATION OF YOUR SUPPORT OR LACK OF SUPPORT
12 FOR. IT'S JUST A METHOD OF PUTTING AN ISSUE ON THE
13 TABLE FOR DISCUSSION. SO I'D LIKE TO START --

14 DR. SOUTHARD: MOTION. I MOVE THE MATTER.

15 CHAIRMAN IMBASCIANI: WE HAVE A MOVEMENT
16 FOR CONSIDERATION BY MARVIN. I NEED A SECOND.

17 DR. FISHER: SECOND.

18 CHAIRMAN IMBASCIANI: THE FLOOR IS NOW
19 OPEN FOR FURTHER DISCUSSION BY BOARD MEMBERS.

20 MS. DEQUINA-VILLABLANCA: FRED HAS HIS
21 HAND RAISED.

22 CHAIRMAN IMBASCIANI: THANK YOU, FRED.

23 DR. FISHER: SO GIVEN THAT A THIRD OF THE
24 GWG MEMBERS WANTED THIS PROPOSAL TO EITHER COME BACK
25 AFTER MORE WORK OR GO AWAY ALTOGETHER, CAN YOU GIVE

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1 US SOME INSIGHT INTO WHAT THOSE ISSUES WERE AND
2 WHETHER OR NOT THEY SHOULD GIVE US PAUSE?

3 DR. SAMBRANO: THAT'S A GOOD QUESTION,
4 FRED. THANK YOU FOR ASKING. SO THIS WAS AN
5 APPLICATION THAT WENT TO THE GRANTS WORKING GROUP A
6 COUPLE OF TIMES, MEANING IT HAD RECEIVED A TWO AND
7 CAME BACK, I BELIEVE. AND THERE WAS SIGNIFICANT
8 DISCUSSION ABOUT THE MERITS. THERE WAS NO CONCERN
9 ABOUT THE TEAM ITSELF, THE SIGNIFICANCE OF THE
10 PROPOSAL IN TERMS OF WHAT IT'S TRYING TO DO, NOR ITS
11 OVERALL RATIONALE FOR DOING THIS.

12 I BELIEVE WHERE REVIEWERS WERE DIVIDED WAS
13 ULTIMATELY ON WHETHER THIS WAS GOING TO HAVE AN
14 IMPACT GIVEN THE DESIGN OF THE PROJECT OR NOT. AND
15 SO THERE ARE SHORT-TERM BENEFITS THAT USING THIS
16 CONDITIONING REGIMEN WOULD BRING TO THE TABLE FOR
17 PATIENTS WITH FANCONI ANEMIA THAT WOULD MEAN LESS
18 LIKELIHOOD OF EXPERIENCING GRAFT VERSUS HOST DISEASE
19 AS WELL AS OTHER SIDE EFFECTS OF THE CONDITIONING.
20 SO THE CONDITIONING OVERALL WOULD BE AN IMPROVEMENT.

21 WHERE SOME OF THE REVIEWERS HAD CONCERN
22 WAS THAT IT MAY NOT ANSWER THE LONGER TERM QUESTION
23 OF WHETHER THIS CONDITIONING REGIMEN ACTUALLY
24 REDUCES THE INCIDENCE OF OTHER TUMORS OR CANCERS
25 THAT RESULT FROM HAVING THE CONVENTIONAL

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1 CONDITIONING REGIMEN BECAUSE IT MAY TAKE UP TO 15
2 YEARS, AND IT MAY NOT BE DESIGNED PROPERLY TO TEASE
3 THAT OUT. THAT WAS ONE OF THE MAIN POINTS OF
4 DISCUSSION AND CONCERNS.

5 THE PANEL OVERALL FELT THAT THERE WAS
6 SUFFICIENT SIGNIFICANCE, AND THE MAJORITY OF THE
7 PANEL MEMBERS THOUGHT THAT THE OPPORTUNITY TO
8 DECREASE THE MORBIDITY, THE MORTALITY ON THE SHORT
9 TERM WAS WELL WORTH THE INVESTMENT IN THIS
10 PARTICULAR PROJECT.

11 CHAIRMAN IMBASCIANI: DO WE HAVE ANY
12 OTHER --

13 DR. FISHER: THANK YOU.

14 CHAIRMAN IMBASCIANI: ANY OTHER COMMENTS
15 FROM THE BOARD?

16 MS. DEQUINA-VILLABLANCA: NO MORE HANDS
17 RAISED, VITO.

18 CHAIRMAN IMBASCIANI: NO HANDS ARE RAISED.
19 THANK YOU. IS THERE ANYONE WANTING TO COMMENT FROM
20 THE PUBLIC?

21 MS. DEQUINA-VILLABLANCA: THERE ARE NONE.

22 CHAIRMAN IMBASCIANI: THANK YOU. RAFAEL,
23 I THINK WE CAN CLOSE THE MOTION AND TAKE A VOTE.

24 MR. AGUIRRE-SACASA: YSABEL DURON, JUST A
25 REMINDER. YOU'RE CONFLICTED ON THIS ONE.

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1 SO FROM THE TOP, DAN BERNAL.
2 MR. BERNAL: AYE.
3 MR. AGUIRRE-SACASA: MARIA BONNEVILLE.
4 VICE CHAIR BONNEVILLE: YES.
5 MR. AGUIRRE-SACASA: JUDY CHOU.
6 DR. CHOU: YES.
7 MR. AGUIRRE-SACASA: LEONDR A CLARK-HARVEY.
8 MS. CLARK-HARVEY: YES, EXCEPT FOR THOSE
9 WITH WHICH I HAVE A CONFLICT.
10 MR. AGUIRRE-SACASA: WE'RE DOING THEM ONE
11 BY ONE. YOU DON'T HAVE TO DO THE CAVEATS THIS TIME.
12 ANNE-MARIE DULIEGE.
13 DR. DULIEGE: YES.
14 MR. AGUIRRE-SACASA: MARK FISCHER-COLBRIE.
15 DR. FISCHER-COLBRIE: YES.
16 MR. AGUIRRE-SACASA: FRED FISHER.
17 DR. FISHER: YES.
18 MR. AGUIRRE-SACASA: DAVID HIGGINS.
19 VITO IMBASCIANI.
20 CHAIRMAN IMBASCIANI: YES.
21 MR. AGUIRRE-SACASA: STEVE JUELSGAARD.
22 MR. JUELSGAARD: YES.
23 MR. AGUIRRE-SACASA: RICH LAJARA.
24 MR. LAJARA: YES.
25 MR. AGUIRRE-SACASA: ADRIANA PADILLA.

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1 DR. PADILLA: YES.

2 MR. AGUIRRE-SACASA: JOE PANETTA.

3 MR. PANETTA: YES.

4 MR. AGUIRRE-SACASA: AND MARVIN SOUTHARD.

5 DR. SOUTHARD: YES.

6 MR. AGUIRRE-SACASA: MOTION PASSES. THANK
7 YOU.

8 CHAIRMAN IMBASCIANI: THANK YOU, RAFAEL.
9 GIL, THE SECOND APPLICATION.

10 DR. SAMBRANO: OKAY. SECOND APPLICATION
11 IS CLIN2-14516. SO THIS IS ALSO A CLINICAL TRIAL.
12 IT'S ENTITLED "PHASE 2B CLINICAL STUDY OF A TOPICAL
13 OPHTHALMIC HUMAN MESENCHYMAL STEM CELL SECRETOME FOR
14 THE TREATMENT OF PERSISTENT CORNEAL EPITHELIAL
15 DEFECT."

16 THIS IS BASICALLY EYEDROPS THAT ARE
17 PRODUCED FROM THE SECRETIONS OF MESENCHYMAL STEM
18 CELLS THAT CONTAIN FACTORS THAT ALLOW HEALING OF THE
19 CORNEA FOR PATIENTS THAT HAVE PERSISTENT CORNEAL
20 EPITHELIAL DEFECT. THE INDICATION OBVIOUSLY IS FOR
21 PATIENTS. THE GOAL IS TO COMPLETE A PHASE 2B
22 CLINICAL TRIAL. THE AMOUNT REQUESTED IS 15 MILLION.
23 THAT'S THE MAXIMUM AMOUNT. BUT THE APPLICANT IS
24 PROVIDING CO-FUNDING OF 14.3 MILLION. 40 PERCENT IS
25 REQUIRED FOR A TRIAL OF THIS TYPE.

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1 A LITTLE BACKGROUND ON THE PERSISTENT
2 CORNEAL EPITHELIAL DEFECT OR PCED WHICH RESULTS IN
3 DELAY OF CORNEAL HEALING. AND THAT CAN BE DUE TO
4 TRAUMA, DISEASE, OR A VARIETY OF OTHER FACTORS. AND
5 THIS DELAY INITIALLY MIGHT BE PAIN AND REDNESS, BUT
6 IT CAN PROGRESS TO INFECTION, CORNEAL ULCERS,
7 SCARRING, AND EVEN ULTIMATELY LEAD TO BLINDNESS.
8 PCED IS A SIGNIFICANT BURDEN ON PATIENTS AND
9 CAREGIVERS.

10 THE CURRENT STANDARD OF CARE INVOLVES
11 TREATMENT OF THE DAMAGED TISSUE AND PREVENTS FURTHER
12 DAMAGE WHERE POSSIBLE. THERE IS ONE APPROVED DRUG
13 THAT'S CALLED OXERVATE WHICH IS FOR TREATMENT OF
14 PCED IN ONLY A SUBSET OF PATIENTS, ABOUT A THIRD WHO
15 HAVE A PARTICULAR ETIOLOGY FOR THAT CONDITION. AND
16 THE PROPOSED THERAPY WOULD OFFER IN THIS CASE A
17 TREATMENT THAT'S AIMED AT REPAIRING AND HEALING
18 CORNEAL TISSUES REGARDLESS OF ANY ETIOLOGY ACROSS
19 ALL PATIENTS.

20 WHY IS THIS A STEM CELL OR GENE THERAPY
21 PROJECT? THE THERAPEUTIC CANDIDATE IS MANUFACTURED
22 FROM MESENCHYMAL STEM CELLS.

23 THE OTHER PROJECTS THAT ARE IN OUR CURRENT
24 ACTIVE PORTFOLIO THAT ARE SIMILAR, WELL, WE DON'T
25 HAVE ANYTHING THAT'S DIRECTLY ADDRESSING THIS

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1 CONDITION. THE CLOSEST THING IS FOR LIMBAL STEM
2 CELL DEFICIENCY. THIS IS A PHASE 1 CLINICAL TRIAL,
3 CLIN2. THE CANDIDATE IS AUTOLOGOUS LIMBAL STEM
4 CELLS. THAT WOULD BE THE ONLY PROJECT THAT IS
5 ANYWHERE NEAR THE CURRENT PROPOSAL.

6 THIS PARTICULAR APPLICANT HAS NOT
7 PREVIOUSLY RECEIVED A CIRM AWARD. SO THIS WILL BE A
8 FIRST FOR THIS TEAM.

9 THE RECOMMENDATION FROM THE GRANTS WORKING
10 GROUP IS AS FOLLOWS. WE HAD A SCORE OF 1 GIVEN BY
11 THE PANEL WITH TEN MEMBERS GIVING IT A SCORE OF 1,
12 FOUR A SCORE OF 2, AND NONE A SCORE OF 3. THE DEI
13 SCORE IS A 9, AND THE CIRM TEAM RECOMMENDATION IS TO
14 FUND THIS PROJECT FOR THE REQUESTED AMOUNT OF 15
15 MILLION.

16 MR. CHAIRMAN.

17 CHAIRMAN IMBASCIANI: THANK YOU VERY MUCH.

18 MAY I HAVE A MOTION TO DISCUSS CLIN2-14516
19 PLEASE.

20 MR. HUANG: IT'S ACTUALLY A MOTION TO
21 PASS, RIGHT?

22 CHAIRMAN IMBASCIANI: YES. SORRY.
23 THANKS, BEN.

24 MS. DURON: SO MOVED.

25 DR. SOUTHARD: I'LL SECOND.

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1 CHAIRMAN IMBASCIANI: WE HAVE A MOVEMENT
2 FROM YSABEL, I THINK, AND A SECOND FROM MARVIN.
3 APOLOGIES IF I GOT THAT WRONG. THE FLOOR IS OPEN TO
4 DISCUSSION.

5 MIGHT I START WITH A QUESTION, GIL? \$15
6 MILLION FOR A CLINICAL TRIAL THAT INVOLVES TOPICAL
7 EYEDROPS, IF YOU WILL, IS THERE A JUSTIFICATION FOR
8 THAT? IT MUST BE IN THE MANUFACTURING COMPONENT.

9 DR. SAMBRANO: YES. THESE ARE PRODUCED
10 FROM MESENCHYMAL STEM CELLS. SO IN ORDER TO
11 GENERATE THE PRODUCT, YOU STILL HAVE TO GROW THE
12 STEM CELLS AND COLLECT THE SECRETOME, AS IT'S
13 CALLED, THAT CONTAINS THE FACTORS THAT ARE THEN USED
14 TO PUT THESE TOGETHER.

15 MS. DEQUINA-VILLABLANCA: THERE ARE NO
16 HANDS RAISED, VITO.

17 CHAIRMAN IMBASCIANI: DO THEY -- IF I CAN
18 CONTINUE WITH THAT, DO THEY ESTIMATE HOW MANY
19 PATIENTS THEY'RE GOING TO RECRUIT AND WHERE THESE
20 PATIENTS WILL BE?

21 DR. SAMBRANO: YES. SO THEY ARE
22 RECRUITING A RELATIVELY LARGER NUMBER OF PATIENTS
23 FOR THIS. IT IS A PHASE 2B. SO THIS IS -- I
24 THOUGHT I HAD THAT WRITTEN DOWN. I THINK IT'S ON
25 THE ORDER OF 50 OR MORE. I CAN LOOK THAT UP JUST TO

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1 BE PRECISE, BUT THEY ALSO HAVE SEVERAL CLINICAL
2 SITES WHERE THEY'RE LOOKING AT THIS.

3 IF ABLA OR ANYONE ON THE CALL HAS THAT
4 DATA POINT, WE CAN PROVIDE THAT TO YOU.

5 CHAIRMAN IMBASCIANI: WELL, I KNOW IT GOT
6 A DEI SCORE OF 9, SO IT MUST HAVE CONSIDERED ALL OF
7 THOSE FACTORS. THERE'S NO -- WAIT. WE HAVE JENN
8 AND THEN YSABEL.

9 MS. LEWIS: I JUST WANTED TO JUMP IN FOR
10 GIL. IT'S 90 PATIENTS WILL BE TREATED, 270
11 ENROLLED, AND I THINK IT'S OVER 42 SITES OR SO
12 ESTIMATED CLINICAL SITES.

13 DR. SAMBRANO: THANK YOU, JEN.

14 CHAIRMAN IMBASCIANI: UH-HUH. TWO HUNDRED
15 FORTY ENROLLED. OKAY.

16 YSABEL, PLEASE.

17 MS. DURON: OKAY, MR. CHAIR. THANK YOU.
18 AND I'M SURE I WILL BE PUT IN MY PLACE IF THIS IS AN
19 EDITORIAL REMARK AND NOT ALLOWED, BUT --

20 VICE CHAIR BONNEVILLE: YOU'RE ALLOWED.

21 MS. DURON: PARDON ME?

22 VICE CHAIR BONNEVILLE: YOU'RE ALLOWED.

23 MS. DURON: THANK YOU. I THINK ALL OF
24 THESE, THE WORK OF MANY OF THESE IS FABULOUS, AND
25 I'D LOVE TO SEE ALL COME TO MARKET. MY CONCERN IS

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1 THAT IT COMES TO MARKET AND THE VERY PEOPLE THAT WE
2 TALK ABOUT IN TERMS OF INCLUSION AND DIVERSITY
3 CANNOT AFFORD THE PRODUCT. EVEN MIDDLE AMERICANS
4 CAN'T AFFORD THE PRODUCTS. AND I'M WONDERING IF --
5 SORRY, GUYS, IF THIS GOES TO POLITICS. YOU'LL TELL
6 ME -- WHETHER OR NOT WE CAN EVEN HAVE ANY SAY WITH
7 THE LEGISLATURE ABOUT ASSESSING, GIVEN OUR
8 INVESTMENT, WHETHER WHEN THEY GO TO MARKET THERE ARE
9 SOME KINDS OF REDUCED PRICING AVAILABLE GIVEN YOUR
10 SES. I JUST THINK THAT SOMEHOW WE CAN INVEST IN ALL
11 OF THESE GREAT FINDS; BUT IF PEOPLE CAN'T AFFORD
12 THEM, THEN WHAT IS WE, RESPONSIBLE CITIZENS AS WELL
13 AND AS OVERSIGHTERS ON THIS BOARD, ACTUALLY DOING TO
14 HELP AMELIORATE THAT INABILITY TO ENGAGE IN
15 SOMETHING THAT IS HEALTHY FOR EACH PATIENT?

16 MR. HUANG: CAN I ANSWER FOR CIRM?

17 MS. DURON: PLEASE.

18 MR. HUANG: IN OUR IP REGS THERE ARE
19 SECTIONS FOR ACCESS AND PRICING. SO ANY ENTITY THAT
20 IS COMMERCIALIZING A PRODUCT THAT ORIGINATES WITH
21 CIRM FUNDING WILL HAVE TO PROVIDE AN ACCESS PLAN
22 COMMENSURATE WITH THE SIZE OF THE COMPANY AND FOR
23 THE INDICATION. AND THAT ACCESS PLAN WILL BE
24 PRESENTED TO THE BOARD.

25 SO CIRM, THE CIRM BOARD, WILL BE ABLE TO

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1 SEE THE ACCESS PLAN AND -- WE DON'T GO INTO
2 SPECIFICS, BUT ACTUALLY APPROVE IT AS WELL. SO
3 THAT'S -- THAT WILL BE UP TO THE BOARD.

4 THERE'S ALSO A SECTION ON PRICING, AND
5 IT'S ACTUALLY LINKED TO STATE LAW. I THINK
6 INITIALLY BACK WHEN THE REGULATION, THE FIRST SET OF
7 REGS WAS PASSED IN 2009, THERE WAS A REFERENCE TO
8 THE CALIFORNIA DRUG PRICING PROGRAM WHICH WAS PASSED
9 BY THE LEGISLATURE, BUT NEVER FUNDED. BUT IF THERE
10 IS A SUCCESSOR PROGRAM, THEY WOULD ALSO BE BOUND TO
11 THAT SUCCESSOR PROGRAM FOR DRUG PRICING. BUT THEY
12 DO HAVE TO PROVIDE AN ACCESS PLAN TO THE BOARD. I
13 JUST WANTED TO PROVIDE THAT CONTEXT.

14 MS. DURON: THANK YOU. MAY I FOLLOW, MR.
15 CHAIR?

16 CHAIRMAN IMBASCIANI: PLEASE.

17 MS. DURON: BECAUSE ACTUALLY SHAME ON ME
18 FOR NOT BEING TOTALLY AWARE OF THAT.

19 SECOND OF ALL, HAVE WE EVER HAD SOMETHING
20 COME BEFORE US IN TERMS OF THIS KIND OF REVIEW?

21 AND THIRDLY, HAVE WE ACTUALLY HELD --
22 MAYBE WE HAVEN'T DONE ONE YET, BUT HAVE WE ACTUALLY
23 HELD ANYBODY'S FEET TO THE FIRE ON MAKING SURE THAT
24 THEY'RE FOLLOWING THE RULES AND REGS?

25 MR. HUANG: ACTUALLY NONE OF OUR PROGRAMS

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1 HAVE YET ACHIEVED THAT STAGE IN WHICH THEY HAVE TO
2 PROVIDE THAT ACCESS PLAN.

3 MS. DURON: OKAY.

4 VICE CHAIR BONNEVILLE: YSABEL, IF I MAY.
5 THESE ARE THE VERY ISSUES THAT COME BEFORE THE
6 ACCESS AND AFFORDABILITY WORKING GROUP. THAT'S
7 SOMETHING THAT THE INTERNAL TEAM WILL BE PROVIDING
8 DIFFERENT TACTICS TO GET US CLOSER TO BEING ABLE TO
9 ACHIEVE THAT MISSION.

10 AND I ALSO WANT TO POINT OUT THAT THE
11 PATIENT SUPPORT PROGRAM, ONCE IT COMES -- IT GETS
12 THROUGH AND WE GET SOMEBODY TO COME IN AND HANDLE
13 THAT FOR US, THOSE FUNDS CAN BE USED FOR THINGS LIKE
14 THIS, FOR ACCESS TO SOME OF THESE TRIALS AND
15 PRODUCTS. SO I JUST WANTED TO PUT THAT IN THERE.

16 MS. DURON: THANK YOU, MARIA.

17 CHAIRMAN IMBASCIANI: THANK YOU. AND
18 THANK YOU, BEN. AND, BEN, IF I COULD ASK YOU. I
19 DON'T KNOW IF I'M THE ONLY PERSON INTERESTED. IF
20 YOU COULD SEND ME A REFERENCE TO THE GOVERNMENT CODE
21 WHERE I CAN READ ON THE REGULATIONS ON DRUG PRICING
22 FROM 2009.

23 MR. HUANG: YES. I'LL GO FIND IT.

24 CHAIRMAN IMBASCIANI: THANKS.

25 MS. DURON: VITO, ONCE YOU FRESHEN UP ON

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1 THAT, YOU CAN COME AND GIVE US A LITTLE PRIMER.

2 CHAIRMAN IMBASCIANI: LET'S HOPE THAT THIS
3 WILL BECOME AN EVEN MORE PRESSING ISSUE AS MORE
4 THINGS COME THIS FAR ALONG. THANKS FOR THAT,
5 YSABEL.

6 RAFAEL, ARE WE TO THE POINT WITH NO OTHER
7 HANDS SO WE CAN CONDUCT --

8 MR. AGUIRRE-SACASA: NO PUBLIC COMMENTS.
9 YEAH. WE'RE READY TO VOTE. AND THERE ARE NO
10 CONFLICTS ON THIS MOTION TO FUND CLIN1-14516.

11 STARTING FROM THE TOP, DAN BERNAL.

12 MR. BERNAL: AYE.

13 MR. AGUIRRE-SACASA: MARIA BONNEVILLE.

14 VICE CHAIR BONNEVILLE: YES.

15 MR. AGUIRRE-SACASA: JUDY CHOU. COME
16 BACK.

17 DR. CHOU: YES. SORRY. I FORGOT TO
18 UNMUTE.

19 MR. AGUIRRE-SACASA: LEONDRA CLARK-HARVEY.

20 MS. CLARK-HARVEY: YES.

21 MR. AGUIRRE-SACASA: ANNE-MARIE DULIEGE.

22 DR. DULIEGE: YES.

23 MR. AGUIRRE-SACASA: YSABEL DURON.

24 MS. DURON: YES.

25 MR. AGUIRRE-SACASA: MARK FISCHER-COLBRIE.

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1 DR. FISCHER-COLBRIE: YES.
2 MR. AGUIRRE-SACASA: FRED FISHER.
3 DR. FISHER: YES.
4 MR. AGUIRRE-SACASA: VITO IMBASCIANI.
5 CHAIRMAN IMBASCIANI: YES.
6 MR. AGUIRRE-SACASA: STEVE JUELSGAARD.
7 MR. JUELSGAARD: YES.
8 MR. AGUIRRE-SACASA: RICH LAJARA.
9 MR. LAJARA: YES.
10 MR. AGUIRRE-SACASA: ADRIANA PADILLA.
11 DR. PADILLA: YES.
12 MR. AGUIRRE-SACASA: JOE PANETTA.
13 MR. PANETTA: YES.
14 MR. AGUIRRE-SACASA: MARVIN SOUTHARD.
15 DR. SOUTHARD: YES.
16 MR. AGUIRRE-SACASA: MOTION CARRIES.
17 THANK YOU.
18 CHAIRMAN IMBASCIANI: GREAT. THANK YOU.
19 GIL, FOR NO. 3.
20 DR. SAMBRANO: THANK YOU, MR. CHAIRMAN.
21 THE NEXT APPLICATION IS CLIN1-14602. BEING A CLIN1,
22 THIS IS NOT YET A CLINICAL TRIAL, BUT A PRE-IND OR
23 IND-ENABLING ACTIVITIES THAT THE PROJECT WOULD
24 PROPOSE.
25 THE TITLE OF THIS APPLICATION IS "CLINICAL

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1 TRANSLATION OF AUTOLOGOUS REGENERATIVE PLURIPOTENT
2 STEM CELL THERAPY FOR BLINDNESS."

3 THERAPY IS AN AUTOLOGOUS INDUCED
4 PLURIPOTENT STEM CELL-DERIVED RETINAL PIGMENT
5 EPITHELIAL CELL PRODUCT. THE INDICATION IS FOR ANY
6 MACULOPATHY, AS THEY ARE TERMED, THAT WOULD BE
7 RELATED TO RETINAL PIGMENT EPITHELIAL ATROPHY. SO
8 THIS IS WHERE THE EPITHELIAL CELLS ATROPHY FOR SOME
9 REASON AND CAUSE A VARIETY OF DISEASES, SUCH AS
10 MACULAR DEGENERATION.

11 THE GOAL TO COMPLETE THE PRECLINICAL
12 STUDIES TO FILE AN IND. THE AMOUNT REQUESTED IS 6
13 MILLION. THE CO-FUNDING AMOUNT PROVIDED IS 1.7
14 MILLION ALTHOUGH NONE IS REQUIRED.

15 THE BACKGROUND ON THIS PROPOSAL.
16 MACULOPATHIES SUCH AS MACULAR DEGENERATION AND
17 STARGARDT DISEASE REPRESENT AN UNMET MEDICAL NEED AS
18 THERE ARE NO APPROVED TREATMENTS THAT DIRECTLY
19 ADDRESS THE PROBLEM OF RETINAL PIGMENT EPITHELIAL
20 ATROPHY THAT CAN LEAD TO THESE CONDITIONS.
21 COLLECTIVELY MACULOPATHIES ARE THE LEADING CAUSE OF
22 BLINDNESS IN THE DEVELOPED WORLD.

23 THE VALUE PROPOSITION FOR THE PROPOSED
24 THERAPY IS THAT IT OFFERS THE POTENTIAL FOR A SAFE
25 AND EFFECTIVE TREATMENT THAT MAY PRESERVE AND EVEN

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1 POSSIBLY RESTORE VISION FOR SOME MACULOPATHIES.

2 WHY IS THIS A STEM CELL OR GENE THERAPY
3 PROJECT? THE THERAPEUTIC CANDIDATE IS MANUFACTURED
4 FROM INDUCED PLURIPOTENT STEM CELLS.

5 IN TERMS OF SIMILAR PROJECTS IN OUR
6 PORTFOLIO, WE HAVE EARLIER STAGE, A TRAN1 PRE-IND
7 PROJECT THAT SPECIFICALLY ADDRESSES AGE-RELATED
8 MACULAR DEGENERATION AND USES ALLOGENEIC NEURAL STEM
9 CELLS AS THE POTENTIAL CANDIDATE PRODUCT, BUT WE
10 DON'T HAVE ANY OTHER PROJECTS IN OUR ACTIVE
11 PORTFOLIO THAT WOULD ADDRESS MORE BROADLY THE
12 MACULOPATHIES THAT ARE RELATED TO THE RETINAL
13 PIGMENT EPITHELIUM ATROPHY.

14 THE APPLICANT HAS RECEIVED A TRAN AWARD
15 THAT IS ACTUALLY THE DIRECT PREDECESSOR TO THIS ONE.
16 SO THIS WOULD REPRESENT A CONTINUATION OF THE
17 PROJECT THAT WAS INITIALLY FUNDED UNDER A TRAN AWARD
18 FOR MACULOPATHIES. THE PROJECT OUTCOME SOUGHT FOR
19 THE TRAN AWARD WAS A PRE-IND MEETING WHICH WAS
20 COMPLETED AND MILESTONES WERE ALL ACHIEVED ON THAT,
21 A COUPLE WITH SOME DELAYS DUE TO THE PANDEMIC, BUT
22 OTHERWISE PROGRESSED TOWARDS WHAT IS NOW THIS CLIN1
23 PROPOSAL.

24 SO THE RECOMMENDATION FROM THE GRANTS
25 WORKING GROUP IS OVERALL A SCORE OF 1 WITH 13

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1 MEMBERS GIVING IT A SCORE OF 1, TWO MEMBERS GIVING
2 IT A SCORE OF 2. IT RECEIVED A DEI SCORE OF 8, AND
3 THE CIRM TEAM RECOMMENDS FUNDING THIS AWARD FOR THE
4 AMOUNT OF 6 MILLION AS REQUESTED.

5 MR. CHAIRMAN.

6 CHAIRMAN IMBASCIANI: THANK YOU,
7 MR. SAMBRANO.

8 SO A MOTION PLEASE TO ACCEPT THIS
9 APPLICATION.

10 VICE CHAIR BONNEVILLE: SO MOVED.

11 DR. DULIEGE: I SECOND.

12 CHAIRMAN IMBASCIANI: THE FLOOR IS OPEN TO
13 DISCUSSION ON MACULOPATHY.

14 MS. DEQUINA-VILLABLANCA: THERE ARE NO
15 HANDS RAISED.

16 CHAIRMAN IMBASCIANI: GIL, I THINK THIS IS
17 TESTIMONY TO THE PROGRESS OF THE REVIEW. THERE ARE
18 NO QUESTIONS. DO I HEAR ANYTHING FROM THE PUBLIC?

19 MS. DEQUINA-VILLABLANCA: THERE ARE NONE.

20 CHAIRMAN IMBASCIANI: ALL RIGHT. MR.
21 CHIEF COUNSEL.

22 MR. AGUIRRE-SACASA: ALL RIGHT. WE'RE
23 GOING TO VOTE ON A MOTION TO FUND CLIN APP 14602.
24 MARK FISCHER-COLBRIE AND KAROL WATSON ARE CONFLICTED
25 OFF THIS ONE.

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1 SO TAKING IT FROM THE TOP, DAN BERNAL.
2 MR. BERNAL: AYE.
3 MR. AGUIRRE-SACASA: MARIA BONNEVILLE.
4 VICE CHAIR BONNEVILLE: YES.
5 MR. AGUIRRE-SACASA: JUDY CHOU.
6 DR. CHOU: AYE.
7 MR. AGUIRRE-SACASA: LEONDR A CLARK-HARVEY.
8 MS. CLARK-HARVEY: AYE.
9 MR. AGUIRRE-SACASA: ANNE-MARIE DULIEGE.
10 DR. DULIEGE: AYE.
11 MR. AGUIRRE-SACASA: YSABEL DURON.
12 MS. DURON: YES.
13 MR. AGUIRRE-SACASA: FRED FISHER.
14 DR. FISHER: YES.
15 MR. AGUIRRE-SACASA: VITO IMBASCIANI.
16 CHAIRMAN IMBASCIANI: YES.
17 MR. AGUIRRE-SACASA: STEVE JUELSGAARD.
18 MR. JUELSGAARD: YES.
19 MR. AGUIRRE-SACASA: RICH LAJARA.
20 MR. LAJARA: YES.
21 MR. AGUIRRE-SACASA: ADRIANA PADILLA.
22 DR. PADILLA: YES.
23 MR. AGUIRRE-SACASA: JOE PANETTA.
24 MR. PANETTA: YES.
25 MR. AGUIRRE-SACASA: AND MARVIN SOUTHARD.

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1 DR. SOUTHARD: YES.

2 MR. AGUIRRE-SACASA: THANK YOU. MOTION
3 PASSES.

4 CHAIRMAN IMBASCIANI: THANK YOU VERY MUCH,
5 MR. CHIEF COUNSEL.

6 GIL, I THINK YOU'RE UP TO NO. 4,
7 APPLICATION NO. 4 NOW.

8 DR. SAMBRANO: THANK YOU. SO THIS IS THE
9 LAST APPLICATION. THIS IS ALSO A CLIN1 IND-ENABLING
10 STUDY. SO THIS IS CLIN1-14764. THE TITLE IS
11 "TREATMENT OF TEMPORAL MANDIBULAR JOINT OR TMJ DISC
12 COMPLEX."

13 THE THERAPY IS A TISSUE-ENGINEERED IMPLANT
14 THAT USES EXPANDED ALLOGENEIC CHRONDROPROGENITOR
15 CELLS AS PART OF THE IMPLANT. THIS IS FOR DEFECTS
16 OF THE TEMPORAL MANDIBULAR JOINT DISC COMPLEX. AND
17 THE GOAL IS TO COMPLETE PRECLINICAL STUDIES TO FILE
18 AN IND. FUNDS REQUESTED ARE 6 MILLION. THERE IS NO
19 CO-FUNDING PROVIDED, BUT NONE IS REQUIRED FROM THIS
20 APPLICANT FOR THIS STAGE OF WORK.

21 THE CLINICAL BACKGROUND ON TMJ, THE JOINT
22 ITSELF, OF WHICH WE HAVE TWO, CONNECTS THE LOWER JAW
23 TO THE SKULL AND ALLOWS FOR BASIC ACTIONS SUCH AS
24 CHEWING, TALKING, YAWNING, SPEAKING. IT ALLOWS THE
25 JAW TO MOVE TO OPEN AND CLOSE AS WELL AS TO MOVE

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1 LATERALLY SIDWAYS. SO IT'S QUITE A COMPLEX JOINT
2 ACTUALLY. AND PATHOLOGY DUE TO TMJ OCCUR IN 5 TO 25
3 PERCENT OF THE GENERAL POPULATION AND CAN BE
4 OBVIOUSLY PRETTY DEBILITATING AS THEY BECOME MORE
5 SEVERE. ABOUT 70 PERCENT OF THE TMJ PATHOLOGIES
6 INVOLVE THE DISC ITSELF AND INVOLVE REPLACEMENT OF
7 OR REQUIRE REPLACEMENT OF THAT.

8 THE CURRENT STANDARD OF CARE INCLUDES
9 STEROID INJECTIONS AND REMOVAL OF THE TMJ DISC
10 COMPLEX WHICH CAN RESULT IN FURTHER JOINT
11 DEGENERATION. FOR END STAGE CASES, ONLY TOTAL JOINT
12 REPLACEMENTS ARE AVAILABLE. SO WHAT THE PROPOSED
13 THERAPY WOULD DO IS PROVIDE OR FULFILL AN UNMET NEED
14 BETWEEN THE EARLY STAGE AND THE VERY END STAGE CASES
15 AND THE POSSIBILITY OF TMJ DISC COMPLEX HEALING AND
16 RESTORATION WHERE POSSIBLE TO REGAIN SOME FUNCTION.

17 WHY IS THIS A STEM CELL OR GENE THERAPY
18 PROJECT? THE THERAPEUTIC CANDIDATE IS COMPOSED OF
19 CHRONDROPROGENITOR CELLS.

20 OUR PORTFOLIO, WE REALLY DON'T HAVE ANY
21 ACTIVE AWARDS ADDRESSING TMJ PATHOLOGIES OR ANYTHING
22 THAT I COULD FIND THAT WOULD BE SIMILAR. WE DO HAVE
23 AN APPLICATION THAT WAS PREVIOUSLY FUNDED FOR THIS
24 APPLICANT. THIS WAS ALSO A TRAN STAGE PROJECT FOR
25 CARTILAGE INJURY REPAIR. THEY WERE FUNDED TO

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1 CONDUCT PRECLINICAL STUDIES BETWEEN 2013 AND 2016.
2 THIS PROJECT IS UNRELATED TO THE CURRENT PROPOSAL,
3 BUT THEY ACHIEVED THEIR MILESTONES AND WERE
4 OTHERWISE SUCCESSFUL WITH THE PREVIOUS CIRM AWARD.

5 THE GRANTS WORKING GROUP RECOMMENDATION ON
6 THIS PROJECT IS TO FUND. THERE WERE 15 VOTES FOR A
7 SCORE OF 1. THERE WERE ZERO VOTES FOR A 2 OR A 3.
8 THE DEI SCORE IS AN 8. AND THE CIRM TEAM
9 RECOMMENDATION IS TO FUND THIS PROJECT FOR THE
10 REQUESTED AMOUNT OF 6 MILLION.

11 MR. CHAIRMAN.

12 CHAIRMAN IMBASCIANI: THANK YOU, MR.
13 SAMBRANO. THAT'S A NICE PRESENTATION.

14 MAY I HAVE A MOTION TO ACCEPT THE
15 APPLICATION?

16 VICE CHAIR BONNEVILLE: SO MOVED.

17 DR. FISHER: SECOND.

18 CHAIRMAN IMBASCIANI: WE HAVE A MOTION AND
19 A SECOND. MAY I START WITH A QUESTION, GIL?

20 ARE ALL OF THE PATIENTS THAT HAVE THIS
21 CONDITION AS AN ACQUIRED CONDITION, OR ARE THEY
22 LOOKING AT INFANTS OR OTHER YOUNG PEOPLE WITH
23 CONGENITAL PROBLEMS WITH THEIR CARTILAGE?

24 DR. SAMBRANO: THAT'S NOT SPECIFICALLY
25 SPECIFIED BECAUSE THEY'RE NOT YET AT THE CLINICAL

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1 TRIAL STAGE. THEIR FOCUS IS ON ACTIVITIES TO
2 DEVELOP THE MANUFACTURING FOR THE PRODUCT AND OTHER
3 PRECLINICAL STUDIES TO DETERMINE SAFETY IN ANIMAL
4 MODELS. SO I DON'T HAVE INFORMATION ON WHETHER THE
5 INTENDED PATIENT POPULATION WOULD BE BROAD ENOUGH TO
6 INCLUDE DIFFERENT CONDITIONS FOR THE TMJ
7 PATHOLOGIES.

8 CHAIRMAN IMBASCIANI: THANK YOU. OTHER
9 COMMENTS OR QUESTIONS?

10 MS. DEQUINA-VILLABLANCA: I SEE NONE.

11 CHAIRMAN IMBASCIANI: AND FROM THE PUBLIC?

12 MS. DEQUINA-VILLABLANCA: NO.

13 CHAIRMAN IMBASCIANI: OKAY. NO ONE WANTS
14 TO EXERCISE THEIR TMJ IN DISCUSSING THIS ANY
15 FURTHER. NO FURTHER COMMENTS. SO, MR. CHIEF
16 COUNSEL.

17 MR. AGUIRRE-SACASA: OKAY. WE'RE GOING TO
18 VOTE TO FUND CLIN APPLICATION 14764. NO CONFLICTS
19 ON THIS APPLICATION.

20 DAN BERNAL.

21 MR. BERNAL: AYE.

22 MR. AGUIRRE-SACASA: MARIA BONNEVILLE.

23 VICE CHAIR BONNEVILLE: YES.

24 MR. AGUIRRE-SACASA: JUDY CHOU.

25 DR. CHOU: AYE.

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1 MR. AGUIRRE-SACASA: LEONDR A CLARK-HARVEY.
2 MS. CLARK-HARVEY: AYE.
3 MR. AGUIRRE-SACASA: ANNE-MARIE DULIEGE.
4 DR. DULIEGE: AYE.
5 MR. AGUIRRE-SACASA: YSABEL DURON.
6 MS. DURON: AYE.
7 MR. AGUIRRE-SACASA: MARK FISCHER-COLBRIE.
8 DR. FISCHER-COLBRIE: YES.
9 MR. AGUIRRE-SACASA: FRED FISHER.
10 DR. FISHER: YES.
11 MR. AGUIRRE-SACASA: VITO IMBASCIANI.
12 CHAIRMAN IMBASCIANI: YES.
13 MR. AGUIRRE-SACASA: STEVE JUELSGAARD.
14 MR. JUELSGAARD: YES.
15 MR. AGUIRRE-SACASA: RICH LAJARA.
16 MR. LAJARA: YES.
17 MR. AGUIRRE-SACASA: ADRIANA PADILLA.
18 DR. PADILLA: YES.
19 MR. AGUIRRE-SACASA: JOE PANETTA.
20 MR. PANETTA: YES.
21 MR. AGUIRRE-SACASA: LAST BUT NOT LEAST,
22 MARVIN SOUTHARD.
23 DR. SOUTHARD: YES.
24 MR. AGUIRRE-SACASA: MOTION PASSES. I
25 THINK THAT'S IT.

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1 CHAIRMAN IMBASCIANI: THAT'S IT. AND I
2 WANT TO THANK OUR REVIEW TEAM AND GIL ESPECIALLY FOR
3 THE PRESENTATIONS. AND WE ARE AT THAT POINT WHERE
4 WE CAN GO INTO CLOSED SESSION. I'M SORRY, YSABEL.
5 I JUST SAW YOUR HAND GO UP.

6 MS. DURON: THAT'S OKAY. I JUST GOT IT
7 UP. THANK YOU, MR. CHAIR.

8 A POINT THAT I'D LIKE TO RAISE, AND I
9 WOULD -- I DON'T KNOW IF GIL HAS CARRIED IT THIS
10 FAR, BUT, FIRST OF ALL, I WANT TO THANK GIL AND THE
11 TEAM FOR A VERY ROBUST RUBRIC FOR THE DEI SCORING.
12 AND I'D LIKE ALSO TO COMMEND THE SCIENCE REVIEW FOLK
13 FOR STARTING TO REALLY UNDERSTAND THE NEED TO
14 EQUALIZE THE DEI SCORE ALONG WITH THE SCIENTIFIC
15 SCORE. I THINK THAT'S EQUALLY IMPORTANT.

16 FINALLY, I THINK SIX AS AN APPROVAL IS A
17 LITTLE LOW. I THINK IT NEEDS TO BE BETWEEN SEVEN
18 AND TEN IN TERMS OF A REALLY QUALITY PLAN.

19 AND FINALLY, WHAT I'D LIKE TO KNOW IS
20 WHETHER OR NOT WE ACTUALLY HAVE CREATED METRICS TO
21 MEASURE SUCCESS OF THIS PLAN AS THEY PROCEED THROUGH
22 THE RESEARCH STAGES. I MEAN IT'S ONE THING TO WRITE
23 UP A VERY GOOD PLAN, BUT ARE THEY FOLLOWING THROUGH?
24 AND ARE THEY BEING ABLE TO SHOW US THAT, IN FACT,
25 THEY HAVE CREATED THAT INCLUSION PATHWAY AND THAT

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1 THEY'VE BEEN SUCCESSFUL AT WHATEVER STEP THEY ARE IN
2 RECRUITING AND MAKING SURE THAT THE COMMUNITIES WE
3 ARE TALKING ABOUT WHEN WE TALK ABOUT DEI ARE, IN
4 FACT, SEEING OR SEEN AN INCREASE IN THEIR
5 PARTICIPATION AND THEIR ABILITY TO PARTICIPATE AT
6 THE RESEARCH STAGES AND THE IMPLEMENTATION STAGES?

7 CHAIRMAN IMBASCIANI: THANK YOU FOR THAT,
8 MS. DURON. I THINK THAT'S AN EXCELLENT QUESTION OF
9 NOT JUST SETTING UP HIGH STANDARDS AT THE BEGINNING,
10 BUT IN A SENSE YOU'RE ASKING FOR BENCHMARKS AS WE GO
11 ALONG, AND I LIKE THAT VERY MUCH.

12 MARIA BONNEVILLE AND I ARE GOING TO
13 PROMISE THE BOARD THAT ANY QUESTION RAISED AT THE
14 BOARD IS GOING TO GET ANSWERED. IF NOT AT THE
15 PRESENT MEETING, WE'RE GOING TO COME BACK TO YOU
16 WITH AN ANSWER.

17 I'M WONDERING IF ANYONE ON THE STAFF WANTS
18 TO TAKE A STAB AT THIS RIGHT NOW. OTHERWISE, WE MAY
19 ASK SOMEONE TO REPORT BACK AT THE NEXT MEETING.

20 DR. SAMBRANO: I CAN TAKE JUST AN INITIAL
21 STAB AND SAY THAT, YES, THIS IS SOMETHING THAT WE
22 ARE ACTIVELY WORKING ON AND THINKING ABOUT. SO
23 WE'VE ALREADY IMPLEMENTED A WAY IN WHICH THE
24 APPLICANTS PROVIDE IN THEIR PROGRESS REPORT DATA ON,
25 FOR EXAMPLE, THE ENROLLMENT AS IT PERTAINS TO ALL

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1 THE DEMOGRAPHICS THAT WE ASK FOR AT THE BEGINNING
2 AND ALSO IMPLEMENTING MILESTONES THAT ARE RELATED TO
3 SPECIFIC DEI ACTIVITIES THAT ARE SPECIFICALLY
4 OUTLINED IN THE PROPOSAL.

5 SO NOW, THE APPLICATION ITSELF ASKS FOR
6 NOT JUST THE SCIENTIFIC MILESTONES THAT THEY'LL
7 ACCOMPLISH, BUT ALSO THE MILESTONES AS IT RELATES TO
8 DEI SO THAT WE CAN BETTER TRACK THEIR PROGRESS
9 AGAINST THOSE MILESTONES.

10 BUT IN TERMS OF BRINGING BACK DATA TO YOU
11 ABOUT HOW THAT IS WORKING AND WAYS IN WHICH WE CAN
12 IMPROVE, I THINK THAT ABLA AND HER TEAM ARE WORKING
13 ON THAT. JENNIFER LEWIS AS WELL IS WORKING WITH
14 THEM TO DEVELOP AND AMPLIFY WHAT IT IS THAT WE CAN
15 DO AT THAT STAGE. SO WE ARE CERTAINLY ACTIVELY
16 THINKING ABOUT THAT. IT'S CLEARLY AN IMPORTANT
17 ELEMENT THAT WE HAVE TO FOLLOW THROUGH WITH TO
18 ENSURE THAT THE APPLICANTS ARE FOLLOWING THROUGH ON
19 ALL OF THIS.

20 MS. DURON: MAY I SAY, MR. CHAIR -- SORRY,
21 FRED -- JUST A FOLLOW-THROUGH. I THINK THAT IT
22 WOULD BE REALLY CRITICAL TO, IN FACT, WITH THOSE
23 MILESTONES SEE WHAT SUCCESSFUL DEI LOOKS LIKE AND
24 THEN ALSO PUT THAT OUT FOR THE PUBLIC AND FOR OTHER
25 INSTITUTIONS TO SEE BECAUSE I THINK WE ARE

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1 ESTABLISHING A VERY HIGH LEVEL, A PLATINUM PLAN, I'D
2 LIKE TO THINK, FOR WHAT DEI REALLY LOOKS LIKE IN
3 IMPLEMENTATION IN ACADEMIC INSTITUTIONS AND RESEARCH
4 AND OTHER ORGANIZATIONS THAT DO IT. AND I WOULD
5 LIKE US TO BE ABLE TO SHOW THEM, NOT JUST, HEY, WE
6 WROTE A GOOD PLAN, BUT THIS IS HOW WE WATCH AND
7 MEASURE AND DETERMINE WHAT IS SUCCESSFUL ALONG THAT
8 PATHWAY. THANKS, GIL. I REALLY APPRECIATE THAT.

9 CHAIRMAN IMBASCIANI: ANOTHER WAY TO LEAD
10 THE NATION IN SUCH QUALITY MEASURES.

11 GIL, THAT WAS AN EXCELLENT FIRST STAB.
12 SOME MIGHT ARGUE YOU DON'T NEED ANYTHING MORE THAN
13 THAT, BUT YOU'LL REPORT BACK.

14 FRED.

15 DR. FISHER: I'M NOT SURE IF THIS IS THE
16 PLACE TO DO IT. AND IF NOT, WE'LL FIND ANOTHER
17 PLACE. I WAS GOING TO RESPOND TO YSABEL'S
18 OBSERVATION OF A SCORE OF 6 AND WHAT THAT ACTUALLY
19 LOOKS LIKE AT THE GWG AND WHY 6 IS THE BOTTOM
20 THRESHOLD. I CAN DO THAT QUICKLY OR I CAN SAVE IT
21 FOR SOME OTHER TIME, WHATEVER YOU PREFER.

22 CHAIRMAN IMBASCIANI: FRED, WE'RE ACTUALLY
23 AT A POINT IN THE MEETING. WE HAVE NO OTHER -- WE
24 HAVE NO WORK OF THE BOARD THAT REQUIRES US TO GO
25 INTO CLOSED SESSION. SO I THINK YOU'RE PERFECTLY AT

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1 THE RIGHT PART OF THE MEETING TO MAKE THESE
2 COMMENTS.

3 DR. FISHER: GREAT. SO, YSABEL, I
4 APPRECIATE EVERYTHING YOU SAID AND AGREE WITH
5 EVERYTHING YOU SAID. SO THIS IS ONLY TO ADD COLOR
6 TO THE PROCESS. I DON'T KNOW THAT WE'VE EVER BEEN
7 ON A GWG WORK GROUP CONNECTED TO CLIN OR TRAN OR
8 ANYTHING ELSE. SO THE REASON 6 IS THE BOTTOM IS
9 THAT THAT'S JUST THE WAY THE RUBRIC IS STRUCTURED.
10 A SCORE OF 6 TO 8 IS RESPONSIVE. AND SO THAT'S WHY
11 6 IS THE BOTTOM, BECAUSE IT IS DEEMED THAT THE
12 APPLICANT HAS RESPONDED SUFFICIENTLY TO THE DEI
13 QUESTION.

14 WHERE 6 IS A SCORE IN MY EXPERIENCE, AND
15 OTHERS ON THIS CALL CAN ADD THEIR OWN PERSPECTIVE
16 AND CORRECT ME WHERE THEY THINK I'M WRONG.
17 APPLICANTS GET A 6 WHEN THEY ARE DEPENDING ON THE
18 SITES FOR DEI-RELATED OUTREACH AND INCLUSION. AND
19 WHAT WE'VE SEEN OVER THE LAST SEVERAL MONTHS AS THE
20 DEI IMPERATIVE HAS BEEN REINFORCED TO THE APPLICANTS
21 AND IS PART OF THE APPLICATION PROCESS, THAT WE ARE
22 EDUCATING THE APPLICANTS ABOUT THE IMPORTANCE OF
23 DEI. AND WE SEE THEM PRIORITIZING IT IN A WAY THAT
24 THEY HAVEN'T DONE BEFORE, AND THEY'RE ACKNOWLEDGING
25 THIS IN THEIR APPLICATIONS. THEY'RE SAYING JUST THE

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1 OTHER DAY, THEY SAY THINGS LIKE WE WILL START TO
2 TRAIN OUR STAFF ON DEI ISSUES AND CULTURAL
3 SENSITIVITY. WE WILL START TO ADD SECTIONS TO OUR
4 WEBSITE THAT DEFINE OUR DEI INITIATIVES.

5 AND SO OUR APPLICATION PROCESS IS REALLY
6 FORCING COMPANIES THAT HAVE BEEN MYOPICALLY FOCUSED
7 ON MOVING THEIR IDEA FORWARD AND NOT CONSIDERING DEI
8 AT ALL TO DO SO FOR WHAT OFTEN SOUNDS LIKE THE VERY
9 FIRST TIME. AND THEY'RE ACTUALLY RELYING ON THE
10 SITES WHICH ARE OFTEN OUR -- THE WORD IS ESCAPING
11 ME -- OUR SUPER NOVA CLINICS. THEY'RE ARE RELYING
12 ON THEM AND THEIR WELL ESTABLISHED DEI PLANS TO HELP
13 THEM ACHIEVE THE OUTREACH AND INCLUSION GOALS.

14 AND SO A 6 ENDS UP ACKNOWLEDGING THAT THEY
15 HAVE ADDRESSED IT AND THAT THEY WILL ADDRESS IT, AND
16 THAT'S WHY I AGREE WITH EVERYTHING YOU SAY IN TERMS
17 OF ACTUALLY MEASURING WHAT THEY ACTUALLY DO IS
18 REALLY IMPORTANT AROUND THAT. BUT A SIX REALLY
19 SAYS, OKAY, YOU GET IT. YOU RECOGNIZE IT. YOU HAVE
20 A PLAN TO GET THERE BOTH FOR THE SPECIFIC
21 APPLICATION, BUT ALSO FOR YOUR ORGANIZATION AS A
22 WHOLE.

23 AND SO UNLESS WE CHANGE THE STRUCTURE OF
24 THE RUBRIC, 6 BECOMES A WAY OF SIGNALING, YEAH,
25 YOU'VE SORT OF DONE THE MINIMUM SO THAT IF YOUR

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1 SCIENTIFIC SCORE IS STRONG ENOUGH, YOU'LL GET
2 FUNDED, BUT YOU'VE GOT WORK TO DO. AND THEY SEEM TO
3 ACKNOWLEDGE THAT IN THE APPLICATION. ANYWAY,
4 HOPEFULLY THAT HELPS UNDERSTAND WHY 6 IS THE BOTTOM
5 AND WHAT 6 LOOKS LIKE WHEN WE ARE REVIEWING THESE
6 APPLICATIONS, AT LEAST TO ME.

7 MS. DURON: YOU'RE SAYING, FRED, THAT
8 THAT'S THE DUH MOMENT. DUH.

9 DR. FISHER: WELL, IT'S THE AHA MOMENT IS
10 THE WAY I WOULD -- FOR THESE COMPANIES IT REALLY IS
11 AN AHA MOMENT WHEN YOU READ THESE APPLICATIONS. AND
12 THEY'RE QUITE TRANSPARENT ABOUT THE FACT THAT THEY
13 REALLY HAVEN'T CONSIDERED IT IN THE PAST, BUT IT IS
14 OUR REVIEW PROCESS THAT IS SORT OF FORCING THEM TO
15 DO IT. AND THEY DON'T SEEM RELUCTANT. WHAT THEY DO
16 AND HOW THEY DO IT, I LOOK FORWARD TO FIGURING OUT
17 HOW WE'RE GOING TO ASSESS THAT AND WHAT THAT'S GOING
18 TO LOOK LIKE.

19 MS. DURON: EXACTLY. THANK YOU.

20 CHAIRMAN IMBASCIANI: I'M SORRY. DAN AND
21 THEN MARVIN PLEASE.

22 MR. BERNAL: THANK YOU, YSABEL, FOR
23 RAISING THIS IMPORTANT ISSUE AND ALSO, FRED, FOR
24 YOUR FURTHER EXPLANATION. I THINK, YSABEL, I'D CALL
25 IT EITHER THE DUH MOMENT OR THE YEAH BUT MOMENT. SO

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1 IF YOU LOOK IN ACADEMIC SCALE FOR GRADING, A 6 OUT
2 OF 10 OR 60 PERCENT WOULD BE A D. AND THAT SEEMS TO
3 BE A PRETTY LOW THRESHOLD FOR UNDERSTANDING OF DEI
4 AND INCORPORATING IT INTO THEIR PROPOSALS.

5 SO I'M VERY INTERESTED, ALONG WITH YSABEL,
6 AND REALLY DIVING MORE DEEPLY INTO HOW WE MEASURE
7 THEIR DEI THROUGHOUT THE COURSE OF THE PROJECT. SO
8 I JUST WANTED TO ADD SUPPORT TO WHAT YSABEL SAID AND
9 THANK GIL FOR HIS EXPLANATION AND OFFER TO BE A PART
10 OF THAT PROCESS MOVING FORWARD.

11 CHAIRMAN IMBASCIANI: GREAT. THANK YOU.
12 MARVIN.

13 DR. SOUTHARD: I JUST WANTED TO SUPPORT
14 WHAT FRED SAID, BUT ALSO TO SAY THAT, AS I'VE
15 REVIEWED THE DEI IN MULTIPLE APPLICATIONS, SINCE THE
16 IMPLEMENTATION OF THE RUBRIC, THEY HAVE IMPROVED
17 VASTLY. SO ONE OF THE THINGS THAT'S ALSO EVOLVED IS
18 THE SIXES NOW ARE HIGHER THAN THE SIXES USED TO BE.
19 AND I THINK WE HAVE CHANGED THE GAME ALREADY.

20 CHAIRMAN IMBASCIANI: GREAT. THANK YOU
21 VERY MUCH FOR THE COMMENT. I DON'T SEE ANY OTHER
22 HANDS RAISED. UNLESS THERE'S ANY OTHER TOPIC, I'M
23 GOING TO ASK FOR COMMENTS ON ANY SUBJECT MATTER FROM
24 THE GENERAL PUBLIC.

25 MS. DEQUINA-VILLABLANCA: THERE ARE NONE.

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1 CHAIRMAN IMBASCIANI: THERE ARE NONE,
2 MARIANNE?

3 MS. DEQUINA-VILLABLANCA: NO.

4 CHAIRMAN IMBASCIANI: IN THAT CASE, UNLESS
5 THERE'S ANY NEW BUSINESS FROM MEMBERS OF THE BOARD,
6 CONGRATULATIONS. YOU'VE ACTUALLY ENDED A VERY, VERY
7 FULL AGENDA FIVE MINUTES EARLY CONSIDERING WE
8 STARTED TEN MINUTES LATE. SO I CONGRATULATE YOU
9 ALL. THANK YOU ALL. THIS WAS A REALLY GREAT
10 MEETING. YOU MADE IT VERY EASY FOR ME ON MY MAIDEN
11 VOYAGE, AND LOVE WORKING WITH YOU ALL.

12 AND ONE SIDE NOTE TO FRED, IF YOU'LL JUST
13 CHECK YOUR TEXTS. THANK YOU. SEE YOU NEXT TIME.

14 (THE MEETING WAS THEN CONCLUDED AT 10:53 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 APRIL 27, 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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