

BETH C. DRAIN, CA CSR NO. 7152

BEFORE 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 19, 2022
9 A.M.

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

FILE NO.: 2022-14

**133 HENNA COURT, SANDPOINT, IDAHO 83864
208-920-3543 DRAIBE@HOTMAIL.COM**

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).	5
4. CONSIDERATION OF APPLICATIONS SUBMITTED IN RESPONSE TO CLINICAL TRIAL STAGE PROJECTS PROGRAM ANNOUNCEMENT (CLIN 1, 2, 3, OR 4).	21
CLOSED SESSION	NONE
5. 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 ITEMS 3 AND 4 ABOVE. (HEALTH AND SAFETY CODE 125290.30(F)(3)(B) AND (C).	
DISCUSSION ITEMS	
6. PUBLIC COMMENT	NONE
7. ADJOURNMENT	53

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APRIL 19, 2022; 9 A.M.

CHAIRMAN THOMAS: OKAY. THANK YOU. BETH,
ARE WE LIVE HERE?

THE REPORTER: YES.

CHAIRMAN THOMAS: THANK YOU. AND GOOD
MORNING, EVERYBODY, AND WELCOME TO THE APRIL MEETING
OF THE APPLICATION REVIEW SUBCOMMITTEE AND THE ICOC.
MARIA B. HAS BEEN ON A TRIP WITH SON CHARLIE LOOKING
AT COLLEGES. SO MARIANNE IS GOING TO ABLY PINCH HIT
FOR US TODAY. SO, MARIANNE, COULD YOU PLEASE CALL
THE ROLL.

MS. DEQUINA-VILLABLANCA: SURE THING.

DAN BERNAL. LEONDRA CLARK-HARVEY.

DR. CLARK-HARVEY: PRESENT.

MS. DEQUINA-VILLABLANCA: ANNE-MARIE
DULIEGE. YSABEL DURON.

MS. DURON: HERE.

MS. DEQUINA-VILLABLANCA: ELENA FLOWERS.

DR. FLOWERS: PRESENT.

MS. DEQUINA-VILLABLANCA: MARK
FISCHER-COLBRIE.

DR. FISCHER-COLBRIE: HERE.

MS. DEQUINA-VILLABLANCA: FRED FISHER.

DR. FISHER: HERE.

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1 MS. DEQUINA-VILLABLANCA: DAVID HIGGINS.
2 DR. HIGGINS: HERE.
3 MS. DEQUINA-VILLABLANCA: STEVE
4 JUELSGAARD.
5 MR. JUELSGAARD: HERE.
6 MS. DEQUINA-VILLABLANCA: RICH LAJARA.
7 MR. LAJARA: HERE.
8 MS. DEQUINA-VILLABLANCA: DAVE MARTIN.
9 DR. MARTIN: HERE.
10 MS. DEQUINA-VILLABLANCA: CHRISTINE
11 MIASKOWSKI. LAUREN MILLER-ROGEN.
12 MS. MILLER-ROGEN: HERE.
13 MS. DEQUINA-VILLABLANCA: ADRIANA PADILLA.
14 DR. PADILLA: HERE.
15 MS. DEQUINA-VILLABLANCA: JOE PANETTA.
16 MR. PANETTA: HERE.
17 MS. DEQUINA-VILLABLANCA: AL ROWLETT.
18 MR. ROWLETT: HERE.
19 MS. DEQUINA-VILLABLANCA: MARVIN SOUTHARD.
20 DR. SOUTHARD: HERE.
21 MS. DEQUINA-VILLABLANCA: JONATHAN THOMAS.
22 CHAIRMAN THOMAS: HERE.
23 MS. DEQUINA-VILLABLANCA: ART TORRES.
24 MR. TORRES: HERE.
25 MS. DEQUINA-VILLABLANCA: KAROL WATSON.

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1 ALL RIGHT. WE'VE GOT A QUORUM.

2 CHAIRMAN THOMAS: OKAY. THANK YOU,
3 EVERYBODY. WE WILL GO IMMEDIATELY INTO THE
4 APPLICATION REVIEW SUBCOMMITTEE. THE FIRST ACTION
5 ITEM IS CONSIDERATION OF APPLICATIONS SUBMITTED IN
6 RESPONSE TO TRANSLATIONAL PROJECTS PROGRAM
7 ANNOUNCEMENT, WHICH WOULD BE TRANS1, 2, OR 3. WE
8 HAVE A PRESENTATION FROM DR. SAMBRANO.

9 DR. SAMBRANO: GOOD MORNING, EVERYONE.
10 LET ME JUST SHARE MY SCREEN, AND HOPEFULLY EVERYBODY
11 CAN SEE THIS.

12 SO WE ARE BRINGING TO YOU RECOMMENDATIONS
13 FROM THE GRANTS WORKING GROUP RELATED TO THE LAST
14 CYCLE FOR TRANSLATIONAL APPLICATIONS. AND WE'RE
15 GOING TO START, AS WE ALWAYS DO, WITH A REMINDER OF
16 OUR MISSION STATEMENT OF ACCELERATING WORLD CLASS
17 SCIENCE TO DELIVER TRANSFORMATIVE REGENERATIVE
18 MEDICINE TREATMENTS IN AN EQUITABLE MANNER TO A
19 DIVERSE CALIFORNIA AND WORLD.

20 AND JUST SO YOU KNOW, WE ARE MAKING SURE
21 THAT WHEN WE HOLD EVERY MEETING, INCLUDING OUR
22 GRANTS WORKING GROUP MEETINGS, THIS IS SOMETHING
23 THAT WE PRESENT BEFORE THE GROUP JUST TO MAKE SURE
24 THAT WE ARE ALL ON THE SAME PAGE AS TO WHAT WE ARE
25 TRYING TO ACHIEVE WITH EACH OF THESE REVIEW CYCLES

1 AND PROGRAMS.

2 AND SO SPEAKING OF OUR PROGRAMS AND
3 FUNDING OPPORTUNITIES, WE HAVE OUR RECURRING SET OF
4 FUNDING OPPORTUNITIES THAT SPAN FROM DISCOVERY TO
5 CLINICAL. SO THE TRANSLATION OPPORTUNITY SITS RIGHT
6 IN BETWEEN, TAKING A SINGLE PRODUCT CANDIDATE THAT
7 HAS SHOWN DISEASE MODIFYING ACTIVITY OR SOME KIND OF
8 PROOF OF CONCEPT AND TAKING THEM TO THE POINT OVER
9 THE COURSE OF TWO YEARS APPROXIMATELY TO PRE-IND OR
10 EQUIVALENT.

11 JUST TO GO INTO A LITTLE MORE DETAIL ON
12 THAT, THE TRANSLATIONAL PROGRAM SUPPORTS FOUR
13 DIFFERENT TYPES OF PRODUCTS. SO THE PRODUCT CAN BE
14 EITHER A THERAPEUTIC, A DIAGNOSTIC, A MEDICAL
15 DEVICE, OR A TOOL. AND DEPENDING ON THAT PRODUCT
16 TYPE, THE ALLOWANCE IN TERMS OF TIME TO CONDUCT
17 TRANSLATIONAL ACTIVITIES WILL VARY. IT WILL BE 30
18 MONTHS FOR THERAPEUTICS, 24 MONTHS FOR ALL THE
19 OTHERS, AND THE ALLOWABLE MAXIMUM COST FOR EACH ARE
20 ALSO TUNED IN TO THE TYPE OF PRODUCT AND THE RELATED
21 ACTIVITIES THAT WOULD BE CONDUCTED AT THIS STAGE.
22 SO THOSE MAXIMUM AMOUNTS VARY BY PRODUCT TYPE.

23 FOR ALL OF THESE, IN ONE WAY OR ANOTHER,
24 WHAT WE'RE LOOKING FOR IS A PRODUCT THAT HAS SHOWN
25 PROOF OF CONCEPT IN SOME WAY. SO FOR A THERAPEUTIC,

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1 IT MEANS THAT THEY'VE DEMONSTRATED DISEASE MODIFYING
2 ACTIVITY WITH THE CANDIDATE IN SOME KIND OF IN VIVO
3 OR IN VITRO MODEL AND JUST SHOWN THAT, AT A VERY
4 BASIC LEVEL, IT'S SOMETHING THAT CAN WORK.

5 FOR DIAGNOSTICS, DEVICES, AND TOOLS, WE
6 ARE LOOKING FOR A PROTOTYPE THAT HAS DEMONSTRATED
7 PROOF OF CONCEPT IN THAT IT ACHIEVES THE BASIC
8 PARAMETERS AND FUNCTIONS THAT THEY INTEND.

9 THE SUPPORT OF ACTIVITIES FOR TRAN1 SHOULD
10 LEAD THEM, OVER THE COURSE OF THIS TIME, TO A
11 PRE-IND MEETING WITH THE FDA OR ANOTHER
12 PRE-SUBMEETING, DEPENDING ON THE TYPE OF PRODUCT, OR
13 DESIGN TRANSFERRED TO MANUFACTURING, IF IT IS A
14 TOOL, WITH THE IDEA THAT THE TOOL IS INTENDED FOR
15 COMMERCIALIZATION.

16 MOST OF THE APPLICATIONS THAT WE GET, MORE
17 THAN 90 PERCENT OF THEM ARE GOING TO BE TRAN1,
18 MEANING THAT THEY'RE FOR A THERAPEUTIC AS OPPOSED TO
19 ANY OF THE OTHER PRODUCT TYPES. JUST TO DIAL IN A
20 LITTLE BIT MORE ON THE THERAPEUTIC TYPES AND HOW
21 THEY FIT IN AND WHAT THE TIMELINE LOOKS LIKE, YOU
22 MIGHT EXPECT THAT SOMEBODY WHO IS COMING IN AFTER
23 PERHAPS HAVING HAD A DISCOVERY AWARD WILL SPEND
24 ABOUT 30 MONTHS DOING TRANSLATIONAL ACTIVITIES THAT
25 WILL LEAD THEM INTO POTENTIALLY A CLIN1 OPPORTUNITY.

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1 SO THE CLIN1 AWARDS SUPPORT A FURTHER 18 TO 24
2 MONTHS BEFORE THEY EVEN GET TO THE ACTUAL CLINICAL
3 TRIAL .

4 SO THESE ARE CRITICAL ACTIVITIES IN WHAT
5 IS OFTEN REFERRED TO AS THE VALLEY OF DEATH, BUT
6 WILL ULTIMATELY, HOPEFULLY LEAD TO A CLINICAL TRIAL
7 AND MEETINGS WITH THE FDA TO GET ON THEIR WAY.

8 THE REVIEW CRITERIA THAT THE GRANTS
9 WORKING GROUP UTILIZES TO ASSESS THESE APPLICATIONS
10 IS BASED ON THESE FIVE QUESTIONS. DOES THE PROJECT
11 HOLD THE NECESSARY SIGNIFICANCE AND POTENTIAL FOR
12 IMPACT? MEANING WHAT IS THE VALUE THAT IT OFFERS
13 AND IS IT SOMETHING THAT'S WORTH DOING? DOES IT
14 HAVE A GOOD RATIONALE? IS THE PROJECT WELL PLANNED
15 AND DESIGNED? IS IT FEASIBLE, INCLUDING HAVING THE
16 APPROPRIATE TEAM AND RESOURCES AVAILABLE TO CONDUCT
17 THE PROPOSED STUDIES? AND, LASTLY, DOES THE PROJECT
18 ADDRESS THE NEEDS OF UNDERSERVED COMMUNITIES?

19 THE SCORING SYSTEM THAT IS USED FOR THE
20 TRANSLATION PROGRAM IS BASED ON A SCALE OF 1 TO 100.
21 A SCORE OF 85 TO 100 MEANS THAT IT'S RECOMMENDED FOR
22 FUNDING IF FUNDS ARE AVAILABLE. ANYTHING BELOW THAT
23 MEANS IT'S NOT RECOMMENDED FOR FUNDING. WE
24 ENCOURAGE THE GRANTS WORKING GROUP TO USE THE FULL
25 SCALE TO THE EXTENT POSSIBLE TO REFLECT HOW THEY

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1 FELT THE APPLICANTS DID AGAINST THIS SCALE. AND THE
2 FINAL SCORE IS REPRESENTED BY THE MEDIAN OF ALL THE
3 INDIVIDUAL GRANTS WORKING GROUP SCORES THAT WERE
4 GIVEN BY THE SCIENTIFIC MEMBERS.

5 SO JUST BY WAY OF A REMINDER OF THE GRANTS
6 WORKING GROUP COMPOSITION IN THOSE ROLES, SO THE
7 SCORES, AS MENTIONED, ARE GIVEN BY THE SCIENTIFIC
8 GWG MEMBERS WHO DO THE MAIN SCIENTIFIC EVALUATION OF
9 THESE APPLICATIONS. AND SO WE GET DIVERSE EXPERTISE
10 AS NEEDED TO COVER THE TYPES OF APPLICATIONS THAT WE
11 ARE LOOKING AT. OF COURSE, WE ALSO HAVE OUR PATIENT
12 ADVOCATE AND NURSE GWG MEMBERS WHO PARTICIPATE IN
13 THESE REVIEWS TO PROVIDE THE PATIENT PERSPECTIVE ON
14 SIGNIFICANCE AND POTENTIAL IMPACT AND PROVIDE
15 OVERSIGHT ON THE PROCESS. THEY ALSO ARE ASSIGNED TO
16 EACH APPLICATION AND PROVIDE A SUGGESTED SCIENTIFIC
17 SCORE.

18 UNDER THE TRAN PROGRAM WE ARE NOT YET
19 DOING SCORING OF DEI, WHICH WE WILL TRANSITION INTO,
20 BUT THE DEI ELEMENTS ARE EVALUATED BY THE FULL
21 PANEL.

22 WE ALSO HAVE SCIENTIFIC SPECIALISTS WHO
23 ARE NONVOTING MEMBERS WHO PROVIDE AD HOC EXPERT
24 ADVICE AS NEEDED.

25 HERE IS, THEN, THE SUMMARY OF THE

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1 APPLICATIONS THAT WERE REVIEWED AND WHAT THE GRANTS
2 WORKING GROUP THOUGHT ABOUT THEM. SO WE HAVE FOUR
3 APPLICATIONS THAT WERE SCORED IN THE RECOMMENDED FOR
4 FUNDING RANGE. THE TOTAL APPLICANT REQUESTS FROM
5 THOSE FOUR APPLICATIONS IS JUST OVER 18 MILLION.
6 THE FUNDS THAT ARE AVAILABLE IN OUR ALLOCATION IS
7 41, ALMOST 42 MILLION. SO THERE ARE SUFFICIENT
8 FUNDS TO COVER THAT. THERE WERE SEVEN THAT WERE NOT
9 RECOMMENDED FOR FUNDING. AND THERE WERE NO
10 APPLICATIONS, AT LEAST IN THIS CYCLE, THAT QUALIFIED
11 FOR A MINORITY REPORT.

12 AND SO THAT CONCLUDES THE SLIDES. LET ME
13 JUST QUICKLY ALSO SHOW YOU THE SPREADSHEET SO I CAN
14 SHOW YOU WHAT THE TOP APPLICATIONS LOOK LIKE.
15 HOPEFULLY YOU CAN SEE THIS. AND SO THE TOP FOUR
16 APPLICATIONS THAT WERE RECOMMENDED FOR FUNDING ARE
17 SHOWN HERE.

18 THE FIRST IS AN OPTIGENETIC THERAPY FOR
19 TREATING RETINITIS PIGMENTOSA. AND THE SECOND IS A
20 VASCULAR GRAFT THAT HAS A RENEWABLE ENDOTHELIUM FOR
21 HEMODIALYSIS FOR END-STAGE KIDNEY DISEASE. THERE IS
22 A CAR-T CELL THERAPY FOR PROSTATE CANCER. AND THEN
23 THE FOURTH ONE IS AN AUTOLOGOUS HEMATOPOIETIC STEM
24 CELL/PROGENITOR CELL GENE-MODIFIED THERAPY FOR
25 PULMONARY ARTERIAL HYPERTENSION. AND SO THOSE ARE

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1 THE FOUR.

2 AND I WILL TURN IT BACK TO YOU, MR.

3 CHAIRMAN.

4 CHAIRMAN THOMAS: THANK YOU VERY MUCH,

5 GIL.

6 FIRST, DO WE HAVE ANY OF THE GRANTS THAT
7 WERE IN THE NOT FOR RECOMMENDED RANGE THAT ANYBODY
8 WOULD LIKE TO MOVE UP TO THE APPROVED, RECOMMENDED
9 FOR FUNDING RANGE AT THIS TIME? HEARING NONE, DO WE
10 HAVE -- WE'RE GOING TO TAKE ALL THOSE RECOMMENDED
11 FOR FUNDING AS A BLOCK. SO DO WE HAVE A MOTION TO
12 APPROVE THE FOUR PROJECTS RECOMMENDED FOR FUNDING?

13 DR. MARTIN: SO MOVED.

14 DR. SOUTHARD: SECOND.

15 CHAIRMAN THOMAS: THANK YOU, GENTLEMEN.

16 DO WE HAVE QUESTIONS OR COMMENTS FROM
17 MEMBERS OF THE BOARD? GIL, YOU MUST HAVE GIVEN A
18 VERY PERSUASIVE PRESENTATION.

19 MS. DURON: ACTUALLY, MR. CHAIRMAN.
20 SORRY. I WAS MUTED. I DON'T KNOW HOW THAT
21 HAPPENED. BUT I DID WANT TO BRING SOMETHING UP
22 BECAUSE, QUITE FRANKLY, I AM UNSURE AND I'M SURE
23 MARIANNE WILL REMIND ME WHETHER OR NOT I CAN VOTE IN
24 THE NEXT BLOCK OF CLIN BECAUSE, IF NOT, I WANT TO
25 SAY THIS NOW.

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1 I WAS, IN LOOKING AT SOME OF THE COMMENTS
2 ON DEI, AND I REMEMBER WHAT GIL JUST SAID ABOUT DEI
3 NOT BEING ABSOLUTELY, TOTALLY ENGAGED FOR THIS
4 PARTICULAR PROCESS OR THIS GROUP OF PROPOSALS, BUT
5 WHAT I WANTED TO SAY WAS I NOTED WHERE REVIEWERS
6 SAID IT SEEMS LIKE THEY HAVE A PLAN OR IT SEEMS LIKE
7 THEY DON'T HAVE A PLAN. AND I'M CONCERNED ABOUT THE
8 SEEMS. I THINK THAT STAFF NEEDS TO CREATE A
9 TEMPLATE THAT LEAVES NO QUESTIONS ABOUT IT SEEMS.

10 SO THE TEMPLATE SHOULD SAY FOR DEI AND FOR
11 WHETHER OR NOT THIS MEETS, I THINK, A CERTAIN
12 BASELINE FOR DEI ENGAGEMENT OF RACIAL AND ETHNIC
13 MINORITIES AND OTHER UNDERSERVED, THAT THEY
14 SHOULD -- THE REVIEWERS SHOULD BE ABLE TO LOOK AT A
15 TEMPLATE THAT SHOWS THE STEPS AND THE AIMS OF THE
16 RESEARCHER, THE MILESTONES, THE ACTIVITIES, AND THE
17 PARTNERSHIPS THAT THEY HAVE TO ENGAGE IN DIVERSE
18 COMMUNITIES SO THAT THERE'S NO QUESTION ABOUT WHAT
19 THE PLAN IS, THERE'S NO QUESTION THAT THE SCIENTISTS
20 OR RESEARCHER WANTS TO SAY, WELL, WHAT DO THEY NEED
21 TO SEE FOR ME TO SHOW THAT THIS IS A DIVERSE AND
22 ENGAGED -- THAT I'M ENGAGING MULTIPLE AUDIENCES.

23 I DON'T THINK WE SHOULD LEAVE IT TO
24 GUESSING. I THINK WE SHOULD CREATE A TEMPLATE THAT
25 IS VERY SPECIFIC ABOUT WHAT WE NEED TO SEE IN ORDER

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1 TO KNOW THAT THEY KNOW HOW TO ENGAGE AND REACH OUT
2 AND BRING IN UNDERSERVED COMMUNITIES.

3 I DON'T KNOW. MAYBE GIL HAS AN ANSWER FOR
4 THAT. MAYBE THEY'RE WORKING ON THAT.

5 DR. SAMBRANO: I DO HAVE A PARTIAL ANSWER
6 AT LEAST. FOR OUR CLINICAL PROGRAM, WE CERTAINLY
7 ARE -- WE HAVE A PROPOSED NEW SET OF TEMPLATES THAT
8 FOLLOW ALONG EXACTLY WHAT YOU ARE SAYING. SO WE'RE
9 GOING TO BE ASKING APPLICANTS TO COMPLETE A COUPLE
10 OF TABLES OF, FOR EXAMPLE, DISEASE BURDEN, WHAT
11 THEIR ENROLLMENT LOOKS LIKE, THE ACTIVITIES THAT
12 THEY'RE GOING TO CONDUCT, AND HOW THEY MIGHT ALIGN
13 WITHIN THEIR MILESTONES FOR ACHIEVING PARTICULAR
14 GOALS IN THAT ENROLLMENT FOR, AGAIN, THE CLINICAL
15 STAGE PROPOSALS.

16 FOR THE TRANSLATIONAL AND DISCOVERY, IT'S
17 A LITTLE DIFFERENT. THERE AREN'T SPECIFIC
18 ENROLLMENT GOALS, BUT THERE IS A WAY OF PROVIDING A
19 TEMPLATE THAT ALLOWS THEM TO ANSWER SPECIFIC
20 QUESTIONS. SO WE ARE DEFINITELY TRYING TO PROVIDE
21 AS MUCH GUIDANCE AS WE CAN TO GIVE THEM A BETTER
22 OPPORTUNITY TO HAVE COMPLETE ANSWERS THAT THEN
23 REVIEWERS CAN MORE FULLY ASSESS.

24 SO WE ARE FOLLOWING ALONG WITH THAT GOAL.
25 AND SO THOSE, WE ANTICIPATE, WILL BE IMPLEMENTED AS

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1 WE ARE IMPLEMENTING THE CHANGES THAT WERE JUST
2 RECENTLY APPROVED FROM THE LAST BOARD MEETING WITH
3 THE CONCEPTS. WE ARE IN THE PROCESS RIGHT NOW OF
4 PUTTING ALL OF THAT INTO APPLICATIONS, BUT IT WILL
5 TAKE A COUPLE MONTHS BEFORE THE NEXT CYCLE OF EACH
6 OF THESE HAPPENS AND WE SEE THE OUTCOME OF THAT.
7 BUT ABSOLUTELY AGREE WITH YOU, AND WE ARE WORKING ON
8 CREATING THOSE TEMPLATES THAT WILL PROVIDE THAT KIND
9 OF GUIDANCE.

10 MS. DURON: I APPRECIATE THAT, GIL. MOST
11 SPECIFICALLY BECAUSE I THINK WE SHOULD HOLD ANY
12 APPLICANT ACCOUNTABLE. AND SO BY PROVIDING THE
13 TEMPLATES, IT'S NOT ANYBODY JUST KIND OF GUESSING.
14 IT IS WHAT IS BASICALLY REQUIRED FOR US TO SEE THAT
15 THEY ARE IN FACT HOLDING THEMSELVES ACCOUNTABLE.

16 DR. SAMBRANO: CORRECT.

17 MS. DURON: THANK YOU.

18 CHAIRMAN THOMAS: THANK YOU, YSABEL.
19 DAVE.

20 DR. MARTIN: I HAVE A QUESTION FOR GIL.
21 ON 370, I JUST WANT TO MAKE CERTAIN THAT THE TARGET
22 THAT HAS BEEN IDENTIFIED HERE, WHICH I PRESUME IS
23 CONFIDENTIAL, IS ONE THAT IS NOT A COMPETITOR INTO
24 THE CLINIC AGAINST THE SAME TARGET, THAT IT'S EITHER
25 A NOVEL TARGET OR IT HAS AN OPPORTUNITY TO BE A LEAD

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1 IN THAT DISEASE.

2 DR. SAMBRANO: IT'S A TARGET THAT HAS BEEN
3 USED BEFORE, BUT IT IS A -- I THINK THE IDEA BEHIND
4 THIS IS THAT THEY HAVE DEVELOPED A VECTOR WITH THAT
5 TARGET THAT THEY ANTICIPATE WILL BEGIN IMPROVEMENT
6 IN TERMS OF ACHIEVING BETTER SUCCESS. SO IT IS ONE
7 THAT HAS BEEN USED IN THE PAST.

8 DR. MARTIN: AND THE REVIEWERS WERE WELL
9 AWARE OF WHAT WAS GOING ON IN THE FIELD, I PRESUME.

10 DR. SAMBRANO: YES. AND THERE WERE
11 COMMENTS RELATED TO THAT.

12 DR. MARTIN: OKAY. THANK YOU.

13 CHAIRMAN THOMAS: THANK YOU, DAVE. FRED,
14 DID WE SEE YOUR HAND UP?

15 DR. FISHER: YOU DID. YOU CAUGHT ME. I
16 WANTED TO RESPOND IN SUPPORT OF WHAT YSABEL WAS
17 SAYING AND MAYBE ADD A LITTLE MORE CONTEXT IN TERMS
18 OF THE WORK THAT WE HAVE TALKED ABOUT NEEDING TO BE
19 DONE IN THIS SPACE. AND, AGAIN, COMING FROM A
20 PATIENT ADVOCATE POINT OF VIEW, IT'S EASIER FOR ME
21 TO SEE THE DEI COMPONENT IN THE CONTEXT OF A CLIN
22 PROPOSAL.

23 WHEN WE ARE LOOKING AT EARLY BASIC SCIENCE
24 RESEARCH, I DON'T THINK WE'VE QUITE NAILED THE
25 RELEVANCE OF THE DEI OR WHAT IT OUGHT TO LOOK LIKE

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1 IN THE CONTEXT OF A TRANSLATIONAL EARLY STAGE
2 PROGRAM, ONE THAT MAY NOT EVEN INVOLVE PATIENTS AT
3 THAT POINT. THERE ARE, OF COURSE, WAYS TO DO IT,
4 BUT I DON'T THINK WE'VE REALLY HONED IN ON WHAT THAT
5 IS.

6 AND THE OTHER PIECE THAT IS RELEVANT TO
7 CLIN IS THAT WE HAVEN'T ANSWERED THE QUESTION "SO
8 WHAT" IF WE ARE LOOKING AT A PROPOSAL THAT IS RANKED
9 VERY HIGH FROM A SCIENTIFIC POINT OF VIEW, BUT
10 QUESTIONABLE FROM A DEI POINT OF VIEW, AND CAN THE
11 DEI SCORE ACTUALLY SYNC THE PROPOSAL IN TERMS OF
12 FUNDING. NOW, FORTUNATELY WE HAVE THE OPPORTUNITY
13 TO SEND THE STAFF BACK AND GET MORE COMMENT FROM THE
14 APPLICANTS, BUT I DON'T THINK WE ARE THERE YET ON
15 ANY OF THESE ISSUES. AND I KNOW WE ARE WORKING ON
16 IT; I KNOW WE ARE FOCUSED ON IT, BUT THERE ARE SOME
17 BIG QUESTIONS THAT REMAIN TO BE ANSWERED.

18 CHAIRMAN THOMAS: THANK YOU, FRED. ANY
19 OTHER QUESTIONS OR COMMENTS FROM MEMBERS OF THE
20 BOARD? AL.

21 MR. ROWLETT: I WANTED TO ADD TO ONE
22 COMMENT THAT FRED SAID REGARDING DEI AND ITS
23 INFLUENCE ON THE OUTCOME. AND MY EXPERIENCE IN AT
24 LEAST ONE APPLICATION THAT I WAS A PART OF IS THAT
25 THE DEI SCORE CAN INFLUENCE THE SCIENTIFIC REVIEWERS

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1 SIGNIFICANTLY. AND A DEI SECTION THAT WAS MORE OR
2 LESS COMPLETE RESULTED IN A CHANGE IN THE SCORE.

3 NOW, I SAID MORE OR LESS BECAUSE I DIDN'T
4 WANT TO TALK SPECIFICALLY ABOUT WHAT THE DEI
5 COMMENTS WERE. HOWEVER, MY EXPERIENCE WAS THAT,
6 YSABEL, IT HAD IMPACT ON THE OUTCOME IN THAT
7 PARTICULAR REVIEW. SO WE ARE MAKING, AS GIL
8 INDICATED, THOSE INCREMENTAL IMPROVEMENTS THAT
9 YOU'VE ALWAYS NOTED FOR US, AND I APPRECIATE IT.

10 CHAIRMAN THOMAS: THANK YOU, AL.

11 ANY OTHER QUESTIONS OR COMMENTS FROM
12 MEMBERS OF THE BOARD? ANY COMMENTS ON THIS MOTION
13 FROM MEMBERS OF THE PUBLIC?

14 MS. DEQUINA-VILLABLANCA: I DO NOT SEE
15 ANY, J.T.

16 CHAIRMAN THOMAS: THANK YOU. HEARING AND
17 SEEING NONE, MARIANNE, WILL YOU PLEASE CALL THE
18 ROLL.

19 MS. DEQUINA-VILLABLANCA: YES. LEONDR
20 CLARK-HARVEY.

21 DR. CLARK-HARVEY: PRESENT.

22 MS. DEQUINA-VILLABLANCA: I THINK WE NEED
23 A YES OR NO.

24 DR. CLARK-HARVEY: YES.

25 MS. DEQUINA-VILLABLANCA: YSABEL DURON.

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1 MS. DURON: YES.
2 MS. DEQUINA-VILLABLANCA: ELENA FLOWERS.
3 DR. FLOWERS: YES.
4 MS. DEQUINA-VILLABLANCA: MARK
5 FISCHER-COLBRIE.
6 DR. FISCHER-COLBRIE: YES.
7 MS. DEQUINA-VILLABLANCA: FRED FISHER.
8 DR. FISHER: YES.
9 MS. DEQUINA-VILLABLANCA: DAVID HIGGINS.
10 DR. HIGGINS: YES.
11 MS. DEQUINA-VILLABLANCA: STEVE
12 JUELSGAARD.
13 MR. JUELSGAARD: YES.
14 MS. DEQUINA-VILLABLANCA: RICH LAJARA.
15 MR. LAJARA: YES.
16 MS. DEQUINA-VILLABLANCA: DAVE MARTIN.
17 DR. MARTIN: YES.
18 MS. DEQUINA-VILLABLANCA: LAUREN
19 MILLER-ROGEN.
20 MS. MILLER-ROGEN: YES.
21 MS. DEQUINA-VILLABLANCA: ADRIANA PADILLA.
22 DR. PADILLA: YES.
23 MS. DEQUINA-VILLABLANCA: JOE PANETTA.
24 MR. PANETTA: YES.
25 MS. DEQUINA-VILLABLANCA: AL ROWLETT.

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1 MR. ROWLETT: YES.

2 MS. DEQUINA-VILLABLANCA: MARVIN SOUTHARD.

3 DR. SOUTHARD: YES.

4 MS. DEQUINA-VILLABLANCA: JONATHAN THOMAS.

5 CHAIRMAN THOMAS: YES.

6 MS. DEQUINA-VILLABLANCA: ART TORRES.

7 MR. TORRES: I THINK I'M IN CONFLICT.

8 MS. DEQUINA-VILLABLANCA: IT'S FOR THE
9 GROUP. WITH TWO OF THEM YOU ARE, SO IF YOU SAY
10 WITH --

11 MR. TORRES: AYE, WITHOUT APPROVAL OF
12 THOSE WITH WHICH I HAVE A CONFLICT.

13 MS. DEQUINA-VILLABLANCA: GOT IT. OKAY.
14 MOTION CARRIES.

15 CHAIRMAN THOMAS: THANK YOU. TO ROUND OUT
16 THIS TRAN VOTE, WE NOW NEED A MOTION THAT WE NOT
17 APPROVE THOSE GRANTS THAT ARE IN THE NOT RECOMMENDED
18 FOR FUNDING RANGE. DO I HEAR A MOTION TO THAT
19 EFFECT?

20 MR. ROWLETT: SO MOVED.

21 DR. SOUTHARD: SECOND.

22 CHAIRMAN THOMAS: MOVED BY AL, SECONDED BY
23 MARV. ANY DISCUSSIONS OR COMMENTS, QUESTIONS,
24 MEMBERS OF THE BOARD, ON THIS MOTION? ANY COMMENTS
25 FROM MEMBERS OF THE PUBLIC?

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1 MS. DEQUINA-VILLABLANCA: I SEE NONE.

2 CHAIRMAN THOMAS: HEARING NONE, MARIANNE,
3 WILL YOU PLEASE CALL THE ROLL.

4 MS. DEQUINA-VILLABLANCA: LEONDRA
5 CLARK-HARVEY.

6 DR. CLARK-HARVEY: YES.

7 MS. DEQUINA-VILLABLANCA: YSABEL DURON.

8 MS. DURON: YES.

9 MS. DEQUINA-VILLABLANCA: ELENA FLOWERS.

10 DR. FLOWERS: YES.

11 MS. DEQUINA-VILLABLANCA: MARK
12 FISCHER-COLBRIE.

13 DR. FISCHER-COLBRIE: YES.

14 MS. DEQUINA-VILLABLANCA: FRED FISHER.

15 DR. FISHER: YES.

16 MS. DEQUINA-VILLABLANCA: DAVID HIGGINS.

17 DR. HIGGINS: YES.

18 MS. DEQUINA-VILLABLANCA: STEVE
19 JUELSGAARD.

20 MR. JUELSGAARD: YES.

21 MS. DEQUINA-VILLABLANCA: RICH LAJARA.

22 MR. LAJARA: YES.

23 MS. DEQUINA-VILLABLANCA: DAVE MARTIN.

24 DR. MARTIN: YES.

25 MS. DEQUINA-VILLABLANCA: LAUREN

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1 MILLER-ROGEN.

2 MS. MILLER-ROGEN: YES.

3 MS. DEQUINA-VILLABLANCA: ADRIANA PADILLA.

4 DR. PADILLA: YES.

5 MS. DEQUINA-VILLABLANCA: JOE PANETTA.

6 MR. PANETTA: YES.

7 MS. DEQUINA-VILLABLANCA: AL ROWLETT.

8 MR. ROWLETT: YES.

9 MS. DEQUINA-VILLABLANCA: MARVIN SOUTHARD.

10 DR. SOUTHARD: YES.

11 MS. DEQUINA-VILLABLANCA: JONATHAN THOMAS.

12 CHAIRMAN THOMAS: YES.

13 MS. DEQUINA-VILLABLANCA: ART TORRES.

14 MR. TORRES: AYE.

15 MS. DEQUINA-VILLABLANCA: MOTION CARRIES.

16 CHAIRMAN THOMAS: THANK YOU, MARIANNE.

17 ON TO ACTION ITEM NO. 4, CONSIDERATION OF
18 APPLICATIONS SUBMITTED IN RESPONSE TO CLINICAL TRIAL
19 STAGE PROJECT PROGRAM ANNOUNCEMENT, CLIN1, 2, OR 3.
20 AGAIN, WE HAVE A PRESENTATION FROM DR. SAMBRANO.

21 GIL.

22 DR. SAMBRANO: THANK YOU, MR. CHAIRMAN.

23 SO THESE ARE THE RECOMMENDATIONS FROM THE GRANTS
24 WORKING GROUP RELATED TO THE LATEST ROUND OF CLIN.
25 AND JUST AS A REMINDER OF WHERE WE ARE IN TERMS OF

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1 BUDGET, WE HAVE AN ANNUAL ALLOCATION FOR THE FISCAL
2 YEAR OF 162 MILLION THAT ENDS IN JUNE, AND THUS FAR
3 THE BOARD HAS APPROVED JUST OVER 70 MILLION IN CLIN
4 AWARDS. THE TWO APPLICATIONS THAT WE HAVE PENDING
5 TODAY WOULD TOTAL AN ADDITIONAL 12 MILLION. AND SO
6 IF THOSE ARE APPROVED, THAT WOULD LEAVE US WITH JUST
7 ABOUT 80 MILLION REMAINING IN THAT ALLOCATION.

8 THE SCIENTIFIC SCORING SYSTEM FOR THE
9 CLINICAL APPLICATIONS, AS MANY OF YOU KNOW, IS
10 DIFFERENT FROM TRANSLATIONAL AND DISCOVERY. WE USE,
11 INSTEAD OF ONE TO A HUNDRED, WE USE A SYSTEM OF 1,
12 2, OR 3, WITH A SCORE OF 1 BEING EXCEPTIONAL MERIT,
13 A SCORE OF 2 MEANING IT NEEDS IMPROVEMENT. AND
14 OFTEN THESE GO BACK TO THE APPLICANT TO REVISE AND
15 PROVIDE CLARITY ON ANYTHING THAT REVIEWERS HAD
16 CONCERN ABOUT. THOSE USUALLY GO BACK TO THE NEXT
17 CYCLE FOR THE GRANTS WORKING GROUP TO REVIEW AGAIN.
18 THOSE THAT GET A SCORE OF 3 ARE THOSE THAT ARE
19 SUFFICIENTLY FLAWED THAT WOULDN'T WARRANT FUNDING AT
20 THIS TIME.

21 THE REVIEW CRITERIA ARE BASED ON THE SAME
22 FIVE ESSENTIAL QUESTIONS ON SIGNIFICANCE AND
23 POTENTIAL FOR IMPACT, RATIONALE, PLAN AND DESIGN,
24 FEASIBILITY, AND ADDRESSING NEEDS OF UNDERSERVED
25 COMMUNITIES. OF COURSE, GIVEN THAT THESE ARE NOW

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1 EITHER IND-ENABLING STAGE FOR CLIN1 OR CLINICAL
2 TRIAL FOR CLIN2, THE UNDERLYING QUESTIONS FOR EACH
3 OF THESE ARE GOING TO BE A LITTLE BIT DIFFERENT,
4 MORE ADVANCED THAN FOR THE TRAN PROGRAM.

5 WE WENT OVER THIS ALREADY, BUT I DO JUST
6 WANT TO POINT OUT THAT THE DIFFERENCE HERE FOR THE
7 ROLE OF THE PATIENT ADVOCATE AND NURSE MEMBERS IS
8 THAT THEY DO HAVE A MORE FORMAL DEI EVALUATION,
9 PROVIDE A DEI SCORE ON THESE APPLICATIONS AS OPPOSED
10 TO WHAT YOU SAW IN TRAN.

11 ALL RIGHT. SO THERE ARE TWO APPLICATIONS.
12 THE FIRST ONE IS A CLIN2, MEANING IT'S A CLINICAL
13 TRIAL. THE SECOND ONE IS GOING TO BE A CLIN1, WHICH
14 IS FOR IND-ENABLING ACTIVITIES. AND I'M GOING TO GO
15 OVER EACH ONE, AND THEN WE'LL DO A VOTE. SO WE WILL
16 TAKE THESE ONE AT A TIME.

17 SO THIS FIRST APPLICATION IS A PHASE 1
18 OPEN LABEL DOSE ESCALATION STUDY OF AN ONCOLYTIC
19 VIRUS-LOADED CYTOKINE INDUCED KILLER CELL IN
20 PATIENTS WITH ADVANCED SOLID TUMORS. THE THERAPY
21 ITSELF ARE WHAT THEY CALL CYTOKINE INFUSED KILLER
22 CELLS THAT HAVE THIS ONCOLYTIC VIRUS IN THEM THAT
23 THEN -- THE CELLS TARGET THE CANCER, RELEASE THE
24 VIRUS THAT THEN DESTROYS THE TUMORS.

25 THE INDICATION IS FOR A VARIETY OF

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1 ADVANCED REFRACTORY SOLID TUMORS SUCH AS BREAST,
2 COLON, OVARIAN, AND OTHER TYPES OF ADVANCED CANCERS.
3 THE GOAL IS TO COMPLETE A PHASE 1 CLINICAL TRIAL TO
4 ASSESS SAFETY AND TOLERANCE, AND THE FUNDS REQUESTED
5 ARE JUST UNDER EIGHT MILLION.

6 SO A LITTLE BACKGROUND ON THIS. SO
7 REFRACTORY SOLID TUMORS, AS MENTIONED, SUCH AS
8 COLORECTAL, OVARIAN, BREAST, AND OSTEOSARCOMA, THAT
9 FAIL TO RESPOND TO STANDARD TREATMENTS REPRESENT A
10 SIGNIFICANT UNMET NEED. THE STANDARD OF CARE IS
11 GOING TO VARY, OBVIOUSLY, FOR EACH TUMOR TYPE, BUT
12 OFTEN INVOLVES CHEMOTHERAPY, RADIATION, RESECTION,
13 OR WHATEVER AVAILABLE DRUGS AND THERAPIES MAY EXIST.
14 IF SUCCESSFUL, THE PROPOSED THERAPY WOULD PROVIDE
15 ANOTHER SAFE AND EFFECTIVE OPTION FOR PATIENTS WITH
16 THESE SOLID TUMORS, PARTICULARLY WHERE APPROACHES
17 SUCH AS CAR-T, WHICH HAS BEEN MORE SUCCESSFUL IN
18 BLOOD CANCERS AND MUCH LESS SUCCESSFUL IN SOLID
19 TUMORS, IT WOULD GIVE A NEW OPTION HERE.

20 SO WHY IS THIS A STEM CELL OR A GENE
21 THERAPY PROJECT? THIS USES HEMATOPOIETIC PROGENITOR
22 CELLS AS PART OF THE MANUFACTURING PROCESS FOR THE
23 THERAPY.

24 OTHER SIMILAR PORTFOLIO PROJECTS THAT WE
25 HAVE, WE HAVE ONE OTHER PROJECT THAT IS USING

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1 ONCOLYTIC VIRUS THAT IS IN NEURAL STEM CELLS
2 SPECIFICALLY. THIS IS A TRAN STAGE PROJECT THAT IS
3 LOOKING TO ACHIEVE A PRE-IND, AND THEY SHOULD BE
4 PRETTY CLOSE TO ACHIEVING THAT BY NOW. AND SO
5 THESE, AGAIN, ARE NEURAL STEM CELLS THAT HOME AND
6 TARGET TO SOLID TUMORS TO DELIVER ONCOLYTIC VIRUS.
7 AND SO THAT'S THE ONLY OTHER PROJECT THAT WE HAVE IN
8 OUR PORTFOLIO THAT WOULD BE SIMILAR.

9 THIS PARTICULAR APPLICANT HAS NOT
10 PREVIOUSLY RECEIVED A CIRM AWARD. SO THIS WOULD BE
11 A NEW AWARDEE IF THEY SUCCEED.

12 THIS IS A SUMMARY OF THE RECOMMENDATION
13 FROM THE GRANTS WORKING GROUP. THE APPLICANTS
14 RECEIVED A SCIENTIFIC SCORE OF 1 WITH 14 VOTES.
15 THERE WAS ONE MEMBER THAT GAVE IT A SCORE OF 2. THE
16 DEI SCORE FROM OUR PATIENT ADVOCATE NURSE MEMBERS IS
17 A SCORE OF 8. THE CIRM TEAM RECOMMENDATION IS TO
18 FUND IN CONCURRENCE WITH THE GRANTS WORKING GROUP
19 RECOMMENDATION FOR THE AMOUNT OF JUST UNDER 8
20 MILLION.

21 AND SO THAT CONCLUDES THE PRESENTATION FOR
22 THE FIRST APPLICATION. SO I'LL STOP SHARING
23 MOMENTARILY. MR. CHAIRMAN.

24 CHAIRMAN THOMAS: THANK YOU, GIL. DO WE
25 HEAR A MOTION TO APPROVE THIS GRANT?

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1 DR. FISHER: SO MOVED.

2 CHAIRMAN THOMAS: SECOND?

3 MR. ROWLETT: SECOND.

4 CHAIRMAN THOMAS: MOVED BY FRED, SECONDED
5 BY AL. QUESTIONS OR COMMENTS FROM MEMBERS OF THE
6 BOARD? DAVE.

7 DR. MARTIN: MY QUESTION IS JUST THE
8 GENERIC ONE IN THIS TYPE OF APPROACH. TARGETING
9 SPECIFICITY FOR AN AGENT LIKE THIS THAT'S LETHAL TO
10 CELL TYPES THAT IT BINDS AND ACTIVATES THE VIRUS, I
11 GATHER THAT THE WORKING GROUP MUST HAVE BEEN VERY
12 COMFORTABLE WITH THIS TO GIVE IT THOSE SCORES. GIL,
13 IS THAT TRUE? THEY WERE, I HOPE, SKEPTICAL, BUT
14 CONVINCED?

15 DR. SAMBRANO: YES. I THINK THE WORKING
16 GROUP FELT THAT THEY HAD GOOD PRELIMINARY DATA
17 SHOWING EVIDENCE THAT IT DOES INDEED TARGET THE
18 CELLS, THE TUMOR CELLS WELL. WHAT THEY CALL THESE
19 CIK CELLS ARE KIND OF AN EQUIVALENT TO A NATURAL
20 KILLER CELL, SO UTILIZING SIMILAR ANTIGEN TARGETS.
21 AND SO I THINK THEY WERE COMFORTABLE WITH THAT.

22 DR. MARTIN: THANK YOU.

23 CHAIRMAN THOMAS: OTHER QUESTIONS OR
24 COMMENTS?

25 MS. DURON: J.T., YSABEL HERE.

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1 CHAIRMAN THOMAS: YSABEL .

2 MS. DURON: I JUST WANTED TO SAY I THANK
3 DAVE FOR ASKING THE SCIENTIFIC HARD QUESTIONS THAT
4 ARE REALLY CRITICAL THAT I AS A NONSCIENTIST REALLY
5 APPRECIATE HEARING. I GUESS WHEN I LOOK AT
6 SOMETHING LIKE THIS, DAVID, I THINK ABOUT HOPE, AND
7 I THINK ABOUT THE PEOPLE WHO, PARTICULARLY IN
8 UNDERREPRESENTED COMMUNITIES, WHO SOMETIMES HAVE
9 VERY LITTLE AND VERY LITTLE OPTIONS FOR THESE REALLY
10 SCIENCE APPROACHES. SO PART OF ME, IF I WAS TO
11 REVIEW, I WOULD BE VOTING FOR HOPE. BUT THANK YOU
12 VERY MUCH FOR YOUR QUESTION. I REALLY APPRECIATE
13 THE SCIENTIFIC GUIDANCE.

14 DR. MARTIN: I VOTE FOR HOPE ALSO.

15 CHAIRMAN THOMAS: THANK YOU, YSABEL .
16 FRED.

17 DR. FISHER: JUST IN THE CONTEXT OF THE
18 LAST CONVERSATION ABOUT DEI, I THINK THESE TWO
19 PROPOSALS THAT WE'RE LOOKING AT PROVIDE SOME
20 INTERESTING INSIGHT INTO THE DYNAMICS OF HOW DEI IS
21 SCORED. AND THIS PROPOSAL, WHERE THERE WAS A VERY
22 STRONG, UNANIMOUS AGREEMENT, AND THE NEXT ONE WE'RE
23 GOING TO LOOK AT WHERE ACTUALLY IT'S A PRETTY WEAK
24 DEI SCORE, AND YOU CAN SEE THE THINGS THAT THE
25 REVIEWERS COMMENTED ON, AND IT REPRESENTS THE WORK

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1 IN PROGRESS THAT'S UNDER WAY AROUND THIS ISSUE.

2 CHAIRMAN THOMAS: THANK YOU, FRED.

3 ANY OTHER QUESTIONS OR COMMENTS FROM
4 MEMBERS OF THE BOARD? SEEING NONE, ANY PUBLIC
5 COMMENTS ON THIS APPLICATION?

6 MS. DEQUINA-VILLABLANCA: I SEE NONE, J.T.

7 CHAIRMAN THOMAS: THANK YOU, MARIANNE.

8 WILL YOU PLEASE CALL THE ROLL.

9 MS. DEQUINA-VILLABLANCA: LEONDR
10 CLARK-HARVEY.

11 DR. CLARK-HARVEY: YES.

12 MS. DEQUINA-VILLABLANCA: YSABEL DURON.

13 MS. DURON: YES.

14 MS. DEQUINA-VILLABLANCA: ELENA FLOWERS.

15 DR. FLOWERS: YES.

16 MS. DEQUINA-VILLABLANCA: MARK
17 FISCHER-COLBRIE.

18 DR. FISCHER-COLBRIE: YES.

19 MS. DEQUINA-VILLABLANCA: FRED FISHER.

20 DR. FISHER: YES.

21 MS. DEQUINA-VILLABLANCA: DAVID HIGGINS.

22 DR. HIGGINS: YES.

23 MS. DEQUINA-VILLABLANCA: STEVE
24 JUELSGAARD.

25 MR. JUELSGAARD: YES.

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1 MS. DEQUINA-VILLABLANCA: RICH LAJARA.
2 MR. LAJARA: YES.
3 MS. DEQUINA-VILLABLANCA: DAVE MARTIN.
4 DR. MARTIN: YES.
5 MS. DEQUINA-VILLABLANCA: LAUREN
6 MILLER-ROGEN.
7 MS. MILLER-ROGEN: YES.
8 MS. DEQUINA-VILLABLANCA: ADRIANA PADILLA.
9 DR. PADILLA: YES.
10 MS. DEQUINA-VILLABLANCA: JOE PANETTA.
11 MR. PANETTA: YES.
12 MS. DEQUINA-VILLABLANCA: AL ROWLETT.
13 MR. ROWLETT: YES.
14 MS. DEQUINA-VILLABLANCA: MARVIN SOUTHARD.
15 DR. SOUTHARD: YES.
16 MS. DEQUINA-VILLABLANCA: JONATHAN THOMAS.
17 CHAIRMAN THOMAS: YES.
18 MS. DEQUINA-VILLABLANCA: ART TORRES.
19 MR. TORRES: DO I HAVE A CONFLICT HERE?
20 MS. DEQUINA-VILLABLANCA: CONFLICT, YES.
21 ALL RIGHT. MOTION CARRIES.
22 CHAIRMAN THOMAS: THANK YOU. GIL, SECOND
23 GRANT PLEASE.
24 DR. SAMBRANO: LET ME GO BACK TO SHARING
25 THE SCREEN. THE NEXT APPLICATION IS CLIN1-13315.

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1 AND SO THIS IS A HEMATOPOIETIC STEM CELL GENE
2 THERAPY FOR X-LINKED CHRONIC GRANULOMATOUS DISEASE
3 OR X-CGD. THIS IS AN AUTOLOGOUS GENE CORRECTED
4 HEMATOPOIETIC STEM CELL THERAPY, MEANING THESE ARE
5 BLOOD STEM CELLS THAT HAVE A GENE CORRECTION WITHIN
6 THEM FOR THIS RARE DISEASE INDICATION.

7 I'LL GIVE YOU A LITTLE BACKGROUND IN JUST
8 A SECOND. THEIR GOAL HERE IS TO COMPLETE
9 IND-ENABLING STUDIES AND SUBMIT THEIR IND. THE
10 FUNDS REQUESTED IS JUST UNDER 4 MILLION FOR THIS
11 PROPOSAL.

12 SO X-CGD IS A RARE IMMUNE DISORDER THAT
13 PREVENTS WHITE BLOOD CELLS FROM KILLING FOREIGN
14 INVADERS BASICALLY. AND SO THIS RESULTS IN SEVERE
15 RECURRENT INFECTIONS THAT IMPACTS QUALITY OF LIFE
16 AND THE LONGEVITY OF A PATIENT'S LIFE. SO THIS IS
17 OFTEN DIAGNOSED BEFORE AGE FIVE, AND CHILDREN CAN
18 DIE BEFORE THE AGE OF TEN ALTHOUGH THERE ARE ADULTS
19 THAT LIVE INTO THEIR 30S AND 40S WITH THIS DISEASE.

20 AND THE PROPOSED THERAPY IN TERMS OF ITS
21 VALUE PROPOSITION, GIVEN THAT THE CURRENT STANDARD
22 OF CARE REALLY MOSTLY INVOLVES ANTIBACTERIAL,
23 ANTIFUNGAL TREATMENT FOR INFECTIONS AND/OR
24 PREVENTION OF INFECTION, WOULD OFFER THE POTENTIAL
25 FOR RESTORING THE IMMUNE SYSTEM OF THESE PATIENTS

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1 AND POSSIBLY A CURE. AND SO THIS IS A STEM CELL OR
2 GENE THERAPY PROJECT. THIS IS A GENE MODIFIED
3 HEMATOPOIETIC STEM CELL, AND THAT'S HOW IT QUALIFIES
4 FOR CIRM FUNDING.

5 OTHER PROJECTS IN OUR PORTFOLIO THAT ARE
6 SIMILAR, WE HAVE SUPPORTED ANOTHER CLINICAL TRIAL
7 THAT WAS A PHASE 1-2 FOR THE SAME DISEASE
8 INDICATION, THE X-CGD. THE CANDIDATE IN THIS CASE
9 WAS AN AUTOLOGOUS GENE-CORRECTED CD34 POSITIVE CELLS
10 THAT USE A DIFFERENT LENTIVIRAL VECTOR CONSTRUCT TO
11 CORRECT THE GENE DEFECT. SO THE CURRENT PROPOSAL IS
12 SORT OF A SECOND GENERATION OF THIS.

13 THE CURRENT -- SO THE APPLICANT
14 ORGANIZATION HAS NOT PREVIOUSLY RECEIVED A CIRM
15 AWARD, BUT TEAM MEMBERS WHO HELPED DEVELOP AND THAT
16 WE SUPPORTED UNDER THE OTHER AWARD THAT WE HAVE ARE
17 MEMBERS OF THIS TEAM AS WELL. SO I JUST WANT TO
18 MAKE CLEAR THAT THERE IS A LITTLE BIT OF OVERLAP
19 ALTHOUGH THE APPLICANT ORGANIZATION HAS NOT ITSELF
20 PREVIOUSLY GOTTEN CIRM FUNDS.

21 SO THE RECOMMENDATIONS FROM THE GRANTS
22 WORKING GROUP ARE AS FOLLOWS. THIS RECEIVED A SCORE
23 OF 1 WITH EIGHT VOTES FROM THE SCIENTIFIC MEMBERS
24 GIVING IT A 1 AND SEVEN MEMBERS GIVING IT A SCORE OF
25 2, NOBODY GIVING IT A SCORE OF 3. THE DEI SCORE IS

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1 5.5 ON A SCALE OF 1 TO 10 AS GIVEN BY OUR PATIENT
2 ADVOCATE AND NURSE MEMBERS. AND THE CIRM TEAM
3 RECOMMENDATION IS TO FUND THIS PROJECT FOR THE AWARD
4 AMOUNT OF JUST UNDER 4 MILLION.

5 SO THAT CONCLUDES MY PRESENTATION, MR.
6 CHAIRMAN.

7 CHAIRMAN THOMAS: THANK YOU, GIL. DO WE
8 HEAR A MOTION TO APPROVE?

9 DR. FISCHER-COLBRIE: SO MOVED.

10 CHAIRMAN THOMAS: IS THERE A SECOND?

11 DR. SOUTHARD: SECOND.

12 CHAIRMAN THOMAS: THANK YOU, GENTLEMEN.
13 COMMENTS OR QUESTIONS FROM MEMBERS OF THE BOARD?
14 DAVE.

15 DR. MARTIN: GIL, I'M A LITTLE CONFUSED.
16 WHAT IS THE TARGET OF THIS ONE? IS THIS THE
17 MITOPEROXIDASE TARGET?

18 DR. SAMBRANO: NO. SO THIS IS A RARE
19 GENETIC DISEASE WHERE THEY ARE CORRECTING THE GENE
20 IN PATIENTS IN THEIR HEMATOPOETIC STEM CELLS. SO
21 BASICALLY IT'S A TRANSPLANT OF THE CELL THAT THEN
22 REPOPULATES THE CELLS AND ALLOWS RESTORATION OF
23 THEIR IMMUNE SYSTEM.

24 DR. MARTIN: THANKS. I WAS CONFUSED, I
25 THINK, WITH ANOTHER APP.

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1 MS. DURON: MR. CHAIR.

2 CHAIRMAN THOMAS: YES.

3 MS. DURON: I GUESS I'M ON THE FENCE ABOUT
4 PEOPLE ON THE FENCE, THE SEVEN PEOPLE AT A 2. AND
5 THERE WAS, AS FRED POINTED OUT AND WHAT GOT ME ON
6 THE DEI CANTALETA, THE SONG, ABOUT SEEMS LIKE
7 THEY'RE GETTING DEI. AND SO BETWEEN THOSE TWO
8 THINGS, I HAVE THIS KIND OF A RELUCTANCE. I LOVE
9 THE IDEA OF WHAT THEY WANT TO DO, BUT PART OF ME, IS
10 THIS THE ONE WHERE WE'RE GOING, DAVID, FOR A LOT OF
11 HOPE AND THE SCIENCE IS THEY'RE ON THE FENCE? I
12 NEED A LITTLE GUIDANCE HERE BEFORE I WANT TO SAY YEA
13 OR NAY. CAN SOMEONE HELP ME WITH THAT?

14 CHAIRMAN THOMAS: GIL, COULD YOU JUST
15 SPEAK TO THE SEVEN NO VOTES? WHAT WERE THE
16 PRINCIPAL CONCERNS FROM THE GWG?

17 DR. SAMBRANO: I'LL JUST REMIND EVERYONE
18 THAT A SCORE OF 2 MEANS THAT THEY WANT EITHER MORE
19 INFORMATION OR THERE ARE CONCERNS WHERE THEY WOULD
20 LIKE TO SEE THE APPLICATION AGAIN. SO IT DOESN'T
21 NECESSARILY MEAN THAT THEY FEEL THEY SHOULDN'T BE
22 FUNDED.

23 I THINK WHERE THOSE SEVEN WERE LOOKING FOR
24 MORE IS IN THE MANUFACTURING PLAN. SO THAT WAS ONE
25 EXAMPLE WHERE THEY FELT THERE WAS NOT ENOUGH DETAIL

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1 AND INFORMATION PROVIDED.

2 THERE WERE SOME COMMENTS RELATED TO SOME
3 OF THE EFFICACY STUDIES WHERE THEY WOULD HAVE LOVED
4 TO HAVE SEEN LARGER SAMPLE SIZES IN SOME OF THE
5 MOUSE STUDIES THAT THEY HAD. BUT I THINK FROM A BIG
6 PICTURE THEY THOUGHT THEY HAD GOOD SUPPORTING DATA,
7 THAT THIS IS SOMETHING THAT CAN GO FORWARD. AND, AS
8 MENTIONED, THERE IS ANOTHER CLINICAL TRIAL THAT HAS
9 A SIMILAR BASIS THAT SORT OF LENDS SUPPORT TO
10 FOLLOWING IN THIS PATH.

11 I THINK, AND IT'S HARD FOR ME TO SAY
12 BECAUSE ULTIMATELY I DON'T KNOW WHY THE SEVEN VOTED
13 THE WAY THEY DID, BUT IT MAY BE, AND SOME OF OUR
14 PATIENT ADVOCATE, NURSE MEMBERS CAN SPEAK TO THIS,
15 THAT THE DEI DISCUSSION MAY HAVE ALSO INFLUENCED
16 THAT SCORE, THE SCIENTIFIC SCORE, AS WELL AS THE DEI
17 SCORE. SO IF ANY OF OUR BOARD MEMBERS WOULD LIKE TO
18 SPEAK TO THAT, THAT MAY ALSO BE HELPFUL.

19 CHAIRMAN THOMAS: MARK.

20 DR. FISCHER-COLBRIE: I DON'T RECALL
21 ANYBODY NECESSARILY WITHHOLDING THEIR VOTE RELATED
22 TO THE DEI SCORE. A DEI SCORE OF 5.5 IS CONSIDERED
23 TO BE PASSING IN THAT RESPECT. AND A LOT OF TIMES
24 THAT HAS TO DO WITH THE NATURE OF THE ORGANIZATION
25 THAT'S PROVIDING THE MATERIALS. IT IS A MUCH MORE

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1 DIFFICULT HURDLE IN TERMS OF BEING ABLE TO HIT THE
2 REALLY HIGH DEI SCORES COMPARED TO IF THE
3 INSTITUTION IS, FOR EXAMPLE, A UC ENTITY.

4 SO THE 5.5 IS PASSING. AND I THINK, AS
5 GIL OUTLINED, A NUMBER OF THE 2 RATINGS, AGAIN, IS
6 NOT A CONDITION OF THEY WERE PER SE AGAINST THE
7 PROPOSAL TO BE A NO VOTE, BUT 2 REPRESENTS REQUESTS
8 FOR ADDITIONAL INFORMATION. SO THE FACT THAT THERE
9 ARE EIGHT WHO ARE SAYING, HEY, WE'VE GOT ENOUGH HERE
10 TO BE ABLE TO MOVE FORWARD, GAVE IT A POSITIVE
11 MOMENTUM TO MOVE FORWARD TO A FURTHER APPROVAL.

12 CHAIRMAN THOMAS: THANK YOU. ADRIANA.

13 DR. PADILLA: I WAS JUST LOOKING AT THE
14 LETTER OF SUPPORT FROM THE ORGANIZATION. I WAS
15 WONDERING IF GIL CAN ADD TO THAT FROM THE LETTER.
16 THEY SEEM TO TRY TO ADDRESS SOME OF THE ISSUES, AND
17 I'M TRYING TO UNDERSTAND THAT.

18 DR. SAMBRANO: YEAH. SO I THINK IN THEIR
19 LETTER THEY PROVIDED ADDITIONAL INFORMATION ON THE
20 ACTIVITIES THAT THEY ARE TAKING ON IN TRYING TO
21 ENSURE THAT THEY HAVE DIVERSITY WITHIN THEIR
22 ENROLLMENT OUTREACH TO PATIENT GROUPS AND
23 ORGANIZATIONS. SOME OF THIS WAS ALREADY IN THE
24 APPLICATION. I THINK PART OF THE CONCERN, PERHAPS,
25 AND I THINK OUR PATIENT ADVOCATE MEMBERS CAN SPEAK

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1 TO THIS BETTER THAN I COULD IN TERMS OF HOW THEY
2 SCORED, I THINK PART OF IT WAS MAKING SURE THAT THE
3 APPLICANTS HAVE A CONCRETE PLAN OF WHAT -- HOW TO
4 ADDRESS THE PROBLEM.

5 THEY DID A PRETTY GOOD JOB ON PRESENTING
6 THE FACTS ABOUT THERE BEING AN ISSUE WITH DIVERSITY
7 WITH THERE NEEDING, FOR EXAMPLE, TO BE A BROAD
8 WORLDWIDE GENETIC TESTING TO DETECT THIS RARE
9 DISEASE IN HELPING DIVERSIFY, BUT HOW SPECIFICALLY
10 THIS TEAM IS GOING TO ACT AND WHAT THEY'RE GOING TO
11 DO AND HOW THEY'RE GOING TO INCORPORATE THAT INTO
12 MILESTONES, FOR EXAMPLE, WITHIN THEIR CLINICAL TRIAL
13 WAS NOT AS CLEAR.

14 SO I THINK THAT MAY BE WHERE A LOT OF THE
15 CONCERN CAME FROM. THIS LETTER EXPANDS ON WHAT THEY
16 HAD IN THE APPLICATION TO SOME EXTENT AND DOES SPEAK
17 TO WHAT THEY'RE ATTEMPTING TO DO. I THINK IT'S UP
18 TO ALL OF YOU TO, I THINK, DETERMINE WHETHER THAT IS
19 SUFFICIENT OR NOT.

20 DR. PADILLA: THANK YOU.

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

23 MS. DURON: MR. CHAIR, YSABEL HERE AGAIN.
24 GIL, THIS IS WHY I'M WONDERING IF THEY HAD ACCESS TO
25 A TEMPLATE SO THAT THEY CAN ANSWER THESE QUESTIONS.

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1 AND THEN THERE'S NO GUESSING. A LETTER OF SUPPORT
2 IS ALSO GOOD, BUT SOMETIMES THERE IS A BIG GAP
3 BETWEEN INTENTION AND ACTION. AND SO IF THEY PUT IT
4 ON PAPER THAT THIS IS WHAT WE EXPECT THEM TO DO
5 BECAUSE THAT'S HOW THEIR PROPOSAL IS, THEN WE CAN
6 HOLD THEIR FEET TO THE FIRE ON NOT DELIVERING OR
7 DELIVERING, AND THEN THEY GET A BIG THUMBS UP FROM
8 ME.

9 THIS IS WHERE THIS GAP IS WHERE I'M GOING
10 DO I -- WHAT DO I DO? BUT IF I CAN SEE A PLAN, SEE
11 THAT THERE'S OBVIOUS MOVEMENT ON THEIR PART TO
12 ATTEMPT OR TO DO SOMETHING, THEN THEY'RE HOLDING
13 THEMSELVES ACCOUNTABLE, AND WE CAN HOLD THEM
14 ACCOUNTABLE AS WELL. WE HAVEN'T PROVIDED THEM WITH
15 THESE TEMPLATES YET, ANY OF THE APPLICANTS?

16 DR. SAMBRANO: SO WE HAVE NOT PROVIDED
17 THOSE TEMPLATES YET BECAUSE THOSE HAVE NOT ROLLED
18 OUT INTO THE APPLICATION. SO THAT'S WHAT WE HOPE TO
19 DO ACTUALLY BY THE END OF THE MONTH.

20 BUT THE QUESTIONS THAT ARE BEING ASKED ARE
21 RELATED TO WHAT THEIR ENROLLMENT PLAN IS. SO THERE
22 ARE QUESTIONS. THEY JUST ARE NOT IN THE TEMPLATE
23 FORMAT THAT WOULD KIND OF FORCE THEM DOWN THAT PATH
24 OF EXACTLY HOW TO ANSWER.

25 MS. DURON: GREAT. THANK YOU. I

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1 APPRECIATE THAT THOUGH. THANK YOU.

2 CHAIRMAN THOMAS: OTHER QUESTIONS OR
3 COMMENTS FROM MEMBERS OF THE BOARD?

4 SO I'LL JUST GIVE A COMMENT HERE. GIVEN
5 THAT THIS IS A VERY SPLIT VOTE THAT, HAD IT GONE ONE
6 MORE VOTE TO TIER II, WOULD HAVE BEEN NOT
7 RECOMMENDED FOR FUNDING AND SENT BACK FOR
8 REAPPLICATION AT THE CONVENIENCE OF THE APPLICANT.
9 AND GIVEN THAT WE HAVE WHAT, YES, IS A PASSING
10 NUMBER ON THE DEI, BUT JUST BARELY, AND THAT, GIL,
11 BASED ON YOUR COMMENTS THAT THEY'VE IDENTIFIED THE
12 ISSUES BUT HAVE NOT EXACTLY SPELLED OUT HOW THEY
13 PLAN TO AUGMENT THEIR WORK TO FACTOR IN INCREASED
14 DEI ACTION INTO THAT, I PERSONALLY WOULD BE IN FAVOR
15 OF THIS GOING BACK TO THE APPLICANT FOR
16 REAPPLICATION TO ADDRESS BOTH THE COMMENTS THAT LED
17 TO THE SEVEN VOTES IN TIER II AS WELL AS TO IMPROVE
18 UPON WHAT THEY ARE PROPOSING FOR DEALING WITH THE
19 DEI COMPONENT. JUST ONE REPORTER'S OPINION.

20 FRED.

21 DR. FISHER: THANK YOU FOR THAT. AND I
22 DON'T KNOW WHETHER WHOEVER IS MAKING THE MOTION
23 WOULD ACCEPT THAT AS A FRIENDLY AMENDMENT, BUT I'D
24 CERTAINLY BE PREPARED TO PROPOSE THAT.

25 ON THIS IDEA THAT THE DEI SCORE IS BARELY

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1 PASSING, IT MIGHT BE WORTH NOTING THAT ON THE
2 CURRENT SCALE, THE SCORE OF 3 TO 5 IS NOT FULLY
3 RESPONSIVE IS THE CATEGORY THAT THAT FALLS INTO.
4 AND THERE IS NOTHING BETWEEN A 5 AND A 6. THE NEXT
5 SECTION IS 6 TO 8 AND IT'S RESPONSIVE. AND SO I
6 GUESS IT DEPENDS IF YOU'RE ROUNDING UP OR ROUNDING
7 DOWN WHETHER THIS IS A BARELY PASSING SCORE.

8 AND GIVEN THE CONCERNS ABOUT THE PROPOSAL,
9 I'D BE INCLINED TO ROUND DOWN, WHICH I DON'T THINK
10 WE WANT TO BE SUPPORTING, PARTICULARLY CLIN
11 PROPOSALS, THAT ARE NOT FULLY RESPONSIVE,
12 UNDERSTANDING THE CHALLENGES OF RECRUITING A DIVERSE
13 POPULATION FOR A RARE DISEASE NOTWITHSTANDING. SO I
14 THINK IT'S WORTH GIVING THE APPLICANT AN OPPORTUNITY
15 TO ADDRESS SOME OF THE SCIENTIFIC CONCERNS THAT WERE
16 CLEARLY THERE AND ARE PROBABLY WELL DOCUMENTED IN
17 THE REVIEWERS' COMMENTS AS WELL AS DOING A LITTLE
18 MORE WORK ON THE DEI SIDE.

19 CHAIRMAN THOMAS: OTHER COMMENTS WITH
20 RESPECT TO MY AND FRED'S COMMENTS? OKAY. SEEING
21 NONE, I GUESS THE QUESTION WOULD BE FOR MARK. WOULD
22 YOU CONSIDER A FRIENDLY AMENDMENT TO THE --

23 DR. FISCHER-COLBRIE: SURE. YES. HAPPY
24 TO CONSIDER THAT AMENDMENT AND SUPPORT FOR THAT.

25 DR. MARKS: I'M SORRY. CAN YOU HOLD ON

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1 ONE SECOND PLEASE?

2 MR. HUANG: SORRY, J.T. I DON'T THINK THE
3 MOTION NEEDS TO BE AMENDED. IT'S WHETHER TO FUND OR
4 NOT FUND. AND IF IT DOESN'T GET FUNDED, IT WOULD
5 PRESUME TO BE IN TIER II AND BE SENT BACK TO THE
6 APPLICANT FOR THEM COME IN AGAIN. SO IT WOULDN'T BE
7 TREATED AS A TIER III OBVIOUSLY. SO I DON'T BELIEVE
8 AMENDING THE MOTION WOULD HELP.

9 CHAIRMAN THOMAS: OKAY. I JUST WANTED TO
10 MAKE IT CLEAR TO THE APPLICANT THAT THERE'S A REASON
11 WHY THE VOTE, IF THE VOTE WERE TO BE A NO VOTE FROM
12 THE APPLICATION REVIEW SUBCOMMITTEE, THAT THAT IS
13 THE REASON AND THE RECOMMENDATION IS THAT, IF THEY
14 SO CHOOSE, REAPPLY TO ADDRESS THOSE ISSUES
15 IDENTIFIED ON THIS MEETING HERE. OKAY. IF WE DON'T
16 NEED THAT THEN, ARE THERE ANY OTHER QUESTIONS? GIL.

17 DR. SAMBRANO: SORRY. I JUST WANT TO SAY
18 THAT, TO BE CLEAR, IT WOULD HELP BECAUSE TYPICALLY
19 ANYTHING THAT'S NOT APPROVED BY THE BOARD, WE PRETTY
20 MUCH DISPENSE WITH. SO IT WOULD BE IMPORTANT TO
21 KNOW THAT THE DESIRE OF THE BOARD IS FOR THIS TO GO
22 TO THE APPLICANT FOR REVISIONS LIKE A TIER II AS
23 OPPOSED TO LIKE A TIER III WHERE WE WOULD JUST HAVE
24 THEM FULLY REAPPLY. SO AT LEAST FROM MY PERSPECTIVE
25 I THINK IT WOULD BE HELPFUL TO KNOW THAT.

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1 CHAIRMAN THOMAS: SO, GIL, DOES THAT MEAN
2 YOU WOULD RECOMMEND A MOTION TO THAT EFFECT OR NOT?

3 DR. SAMBRANO: WELL, JUST CLEAR GUIDANCE
4 ON WHAT THE INTENT OF THE MOTION IS.

5 CHAIRMAN THOMAS: OKAY. SO, BEN, IS THE
6 APPROPRIATE MOVE HERE JUST TO VOTE ON THE MOTION AS
7 IS WITH APPROPRIATE GUIDANCE AS GIL SUGGESTS?

8 MR. HUANG: I BELIEVE SO. BUT IF MARK CAN
9 TAILOR LANGUAGE, BECAUSE HE HAS HIS HAND UP, WE
10 SHOULD ENTERTAIN HOW HE WANTS TO AMEND THE MOTION.

11 CHAIRMAN THOMAS: OKAY. MARK.

12 DR. FISCHER-COLBRIE: I THINK IT WOULD BE
13 HELPFUL TO SAY THAT WE HIGHLY ENCOURAGE THE TEAM TO
14 RESUBMIT THEIR PROPOSAL TO INCLUDE THAT LANGUAGE IN
15 THE MOTION. SO IT WOULD BE A NO, BUT WE STRONGLY
16 ENCOURAGE A RESUBMISSION AND TAKE IT FROM THAT
17 PERSPECTIVE.

18 CHAIRMAN THOMAS: OKAY. THAT SOUNDS LIKE
19 WE DON'T NEED ANOTHER MOTION. WE JUST NEED GUIDANCE
20 POST VOTE HERE. FRED.

21 DR. FISHER: AS A NEWBIE HERE, I WAS UNDER
22 THE ASSUMPTION OF WHAT I THOUGHT I HEARD FROM GIL.
23 WHEN A PROPOSAL GETS A SCORE OF 2, THEY WORK WITH
24 THE STAFF TO MODIFY THEIR EXISTING PROPOSAL, AND WE
25 ACTUALLY SEE A RED-LINE VERSION OF THAT PROPOSAL,

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1 WHICH MAKES IT EASY FOR US TO TRACK THE CHANGES.

2 A SCORE OF 3, AS GIL SAID, REAPPLY, START
3 FROM SCRATCH BASICALLY, WITHOUT NECESSARILY THE
4 BENEFIT OF THE GUIDANCE THAT THE REVIEWERS PROVIDE.
5 PARTICULARLY IN A TIER II PROPOSAL, THE REVIEWERS
6 ARE ASKED TO DETAIL THEIR CONCERNS IN A WAY THAT
7 WILL INFORM THE SUBMISSION NOT OF A TECHNICALLY NEW
8 APPLICATION, BUT OF A MODIFIED APPLICATION IS MORE
9 MY UNDERSTANDING OF IT.

10 SO IT WAS CURIOUS TO ME THAT A NO VOTE
11 WOULD NECESSARILY DEFAULT TO THIS BECOMES A TIER II
12 PROPOSAL. IT MAY BE THAT THE MOTION IS THAT, AND I
13 DON'T KNOW THAT WE CAN DO THIS, BUT MAYBE THE MOTION
14 IS TO KNOCK THE SCORE DOWN TO A TIER II SCORE AND
15 PROVIDE THE APPLICANT WITH DETAILS ABOUT THE
16 CONCERNS SO THAT THEY CAN MODIFY THEIR APPLICATION
17 BECAUSE THAT'S MY UNDERSTANDING OF THE PROCESS.
18 HAPPY TO BE WRONG ABOUT THAT, BUT WE SHOULD ALL BE
19 CLEAR.

20 CHAIRMAN THOMAS: BEN, DO YOU WANT TO
21 RESPOND TO THAT?

22 MR. HUANG: I THINK FRED AND I ARE ON THE
23 SAME PAGE BECAUSE THERE WERE 8 TIER I'S AND SEVEN
24 TIER II'S THAT INITIALLY, IF THERE WAS A NO VOTE --
25 I APOLOGIZE. I PRESUMED IT WOULD BE A TIER I. I

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1 THINK GIL IS INDICATING THAT THE PROCESS IS
2 DIFFERENT. SO IF WE -- IF THE MOTION IS AMENDED TO
3 MAKE THIS -- SO WE AMEND THE MOTION TO SAY THAT THIS
4 IS NOT FUNDABLE, IT WOULD BE PUT IN THE TIER II
5 CATEGORY WITH COMMENTS FOR THE APPLICANT TO RESPOND
6 TO. I WOULD NOTE THAT WE ALSO NEED WHOEVER SECONDED
7 THE MOTION TO ALSO AGREE, BUT I THINK THAT COULD BE
8 DONE.

9 I THINK DR. MARTIN HAS A QUESTION OR
10 COMMENT.

11 CHAIRMAN THOMAS: BEFORE WE GET TO DAVE.
12 SO YOU'RE SAYING, THEN, THAT WE SHOULD MOVE THAT
13 THIS BE DEEMED A TIER II AND WITH THE CAVEAT OR
14 PROVISO THAT WE STRONGLY ENCOURAGE THE APPLICANT TO
15 REAPPLY. IS THAT WHAT YOU JUST SAID, BEN?

16 MR. HUANG: WELL, A TIER II, THEY CAN COME
17 BACK IN A COUPLE OF MONTHS. IF WE TREAT IT AS TIER
18 III, THEY HAVE TO COME BACK AFTER SIX MONTHS.

19 CHAIRMAN THOMAS: NOBODY IS CONTEMPLATING
20 THAT.

21 MR. HUANG: SO I THINK WE SHOULD BE VERY
22 SPECIFIC IN THE MOTION TO MAKE IT A TIER II THEN.

23 CHAIRMAN THOMAS: OKAY. COULD YOU JUST
24 STATE, IF MARK WOULD ENTERTAIN, EXACTLY WHAT THE
25 MOTION SHOULD SAY SO WE HAVE THAT VERY SPECIFICALLY?

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1 MR. HUANG: I THINK THE MOTION, AS WE HAVE
2 DISCUSSED, WOULD BE TO NOT FUND THE APPLICATION AT
3 THIS TIME AND MAKE THE -- TREAT THE APPLICATION AS A
4 TIER II, AS HAVING BEEN SCORED AS A TIER II
5 APPLICATION, WITH THE APPROPRIATE RESPONSE OF
6 COMMENTS BEING RETURNED BACK TO THE APPLICANT.

7 CHAIRMAN THOMAS: OKAY. DAVE, BEFORE WE
8 GET TO YOU, MARK, IS THAT LANGUAGE SUFFICIENT? ARE
9 YOU HAPPY MAKING THAT AS A REVISED MOTION?

10 DR. FISCHER-COLBRIE: YEAH. AS A TOP
11 LEVEL I DO WITH THE ADDED CONCEPT THAT WE ENCOURAGE
12 THE PROVISION OF ADDITIONAL INFORMATION JUST TO GIVE
13 A NOD TO OUR INTEREST.

14 CHAIRMAN THOMAS: MARV, I BELIEVE YOU WERE
15 THE SECOND ON THIS.

16 DR. SOUTHARD: THAT'S SATISFACTORY WITH
17 ME.

18 CHAIRMAN THOMAS: OKAY. THANK YOU. DAVE.

19 DR. MARTIN: I JUST WANTED TO CLARIFY, I
20 THINK THIS IS CORRECT, THAT THE RED LINE GOES BACK
21 TO THE GRANTS WORKING GROUP --

22 CHAIRMAN THOMAS: YES.

23 DR. MARTIN: -- TO REVIEW, NOT TO US. AND
24 THEN GET THAT BACK AS SOON AS THEY SUBMIT IT,
25 RESUBMIT A REVISION OR ANSWER THE QUESTIONS.

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1 CHAIRMAN THOMAS: THAT'S CORRECT. MARK,
2 YOU STILL HAVE YOUR HAND UP OR IS THAT RESIDUAL?

3 DR. FISCHER-COLBRIE: SORRY. RESIDUAL.
4 MY APOLOGIES.

5 CHAIRMAN THOMAS: OKAY. ARE THERE ANY
6 OTHER QUESTIONS OR COMMENTS? DAVE? OKAY.

7 DR. MARKS: J.T., IF I MAY. IN HEARING
8 ALL THE BACK AND FORTH, I JUST WANT TO PROPOSE
9 SOMETHING THAT I BELIEVE SIMPLIFIES THE PROCESS. WE
10 HAVE A CURRENT MOTION ON THE FLOOR TO APPROVE THIS,
11 IT SOUNDS LIKE. AND I'M NOT GOING TO BE PRESUMPTIVE
12 OF THE VOTE THAT THAT MAY NOT PASS. WHAT I SUGGEST
13 IS THAT WE LET THAT MOTION BE VOTED UPON AND THEN WE
14 PROPOSE A SECOND MOTION, IF THERE IS A PROPOSAL ON
15 THE FLOOR AT THAT STAGE, TO CLASSIFY THIS
16 APPLICATION AS A TIER II WITH INSTRUCTIONS TO GO
17 BACK TO THE APPLICANT.

18 CHAIRMAN THOMAS: OKAY. THAT WOULD WORK
19 AS WELL.

20 DR. MARKS: MY FEAR IS WE ARE TRYING TO
21 MANUFACTURE AN AMENDMENT. AND HONESTLY I'M NOT
22 CLEAR AS TO HOW WE WOULD EVEN PHRASE THIS. SO
23 PRESENTLY, AGAIN, WE HAVE A MOTION ON THE FLOOR TO
24 APPROVE. I WOULD SUGGEST WE ALLOW THAT MOTION TO GO
25 FORWARD FOR A VOTE.

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1 MR. TORRES: WE CAN PROVIDE FOR A
2 SUBSTITUTE MOTION WITHOUT HAVING TO GO THROUGH THAT
3 VOTE. A SUBSTITUTE MOTION IS ALWAYS IN ORDER
4 WITHOUT GOING TO A VOTE ON THE ORIGINAL MOTION.

5 CHAIRMAN THOMAS: YOU CAN ALWAYS HAVE A
6 FRIENDLY AMENDMENT BEFORE THE ORIGINAL MOTION IS
7 VOTED UPON.

8 DR. MARKS: THE CHALLENGE IS THE FRIENDLY
9 AMENDMENT NEEDS TO PLAY OFF OF THE ORIGINAL. SO
10 THIS DOESN'T SOUND TO ME AS A FRIENDLY AMENDMENT.
11 IT SOUNDS LIKE A COMPLETELY NEW MOTION. SO I'M FINE
12 IF YOU WANT TO ENTERTAIN A WITHDRAWAL OF THE MOTION
13 AND THEN A SUBSTITUTION MOTION AS WELL.

14 MARK HAS HIS HAND UP.

15 CHAIRMAN THOMAS: I'D LIKE TO HEAR ART
16 FINISH FIRST THOUGH. ART.

17 MR. TORRES: I JUST WANTED TO SAY THAT WE
18 CAN MOVE MORE SPEEDILY BY JUST PROVIDING FOR A
19 SUBSTITUTE MOTION.

20 MR. JUELSGAARD: WOULDN'T WE HAVE TO HAVE
21 THE ORIGINAL MOTION WITHDRAWN?

22 DR. MARKS: CORRECT.

23 MR. TORRES: NO. THE MOTION IS ALWAYS --

24 MR. JUELSGAARD: I DON'T UNDERSTAND THAT.
25 THAT DOESN'T SEEM RIGHT.

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1 MR. TORRES: A SUBSTITUTE MOTION CAN BE
2 MOVED AND VOTED UPON AND WILL TAKE CARE OF THE
3 ISSUE. I HAVE MY *ROBERT'S RULES FOR DUMMIES* BY MY
4 SIDE HERE.

5 MS. DURON: SO A SUBSTITUTE MOTION WILL
6 CANCEL OUT THE NEED TO VOTE ON THE OTHER?

7 MR. TORRES: YES.

8 CHAIRMAN THOMAS: I JUST WANT TO MAKE
9 SURE. THANK YOU, ART.

10 MR. TORRES: YES. OR YOU CAN PROCEED ON
11 THE ORIGINAL STRATEGY AND MAKE IT LESS CONFUSING FOR
12 EVERYONE.

13 CHAIRMAN THOMAS: KEVIN --

14 DR. MARKS: CAN I AGAIN SUGGEST --

15 CHAIRMAN THOMAS: -- MOTION MOST
16 COMFORTABLE WITH.

17 MR. MARKS: I'M MOST COMFORTABLE WITH
18 VOTING ON THE ORIGINAL MOTION CONSISTENT WITH
19 STEVE'S COMMENT AND THEN COMING UP WITH A SECONDARY
20 MOTION. I THINK IT'S CLEANER AND HAS MORE STRICT
21 ADHERENCE TO ROBERT RULES OF ORDER.

22 MR. TORRES: IT'S VERY CLEAR THAT THE
23 ORIGINAL MAKER OF THE MOTION CAN WITHDRAW THE
24 MOTION, AND THEN WE MOVE INTO THE SECOND MOTION AT
25 THE SAME TIME.

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1 CHAIRMAN THOMAS: THAT I BELIEVE IS
2 CERTAINLY TRUE. KEVIN, YOU COMFORTABLE WITH THAT?

3 DR. MARKS: THAT WOULD BE FINE. THANK
4 YOU.

5 CHAIRMAN THOMAS: OKAY. MARK, AS THE
6 ORIGINAL MAKER OF THE MOTION, WOULD YOU LIKE TO
7 WITHDRAW YOUR ORIGINAL MOTION? AND, MARV,
8 WOULD YOU --

9 DR. FISCHER-COLBRIE: YES.

10 CHAIRMAN THOMAS: OKAY. THANK YOU.

11 DR. FISCHER-COLBRIE: THAT WAS GOING TO BE
12 MY RECOMMENDATION, THAT I WITHDRAW MY ORIGINAL
13 MOTION.

14 CHAIRMAN THOMAS: OKAY. AND SO THE --
15 KEVIN --

16 MR. TORRES: (INAUDIBLE) AS WELL.

17 CHAIRMAN THOMAS: SORRY, ART. WE MISSED
18 THE FIRST PART OF THAT.

19 MR. TORRES: YOU NEED TO ASK THE PERSON
20 WHO MADE THE SECOND TO THAT MOTION TO WITHDRAW AS
21 WELL.

22 DR. FISHER: SO DONE.

23 CHAIRMAN THOMAS: OKAY. SO HAVING HEARD
24 THIS, KEVIN, CAN YOU PLEASE STATE WHAT, YOU'VE HEARD
25 THE DISCUSSION, WHAT THE MOTION SHOULD BE HERE AT

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1 THIS POINT?

2 DR. MARKS: SO I BELIEVE, BASED ON THE
3 CONVERSATION, THE MOTION IS TO MOVE THIS
4 APPLICATION -- I'M SORRY. THE MOTION SHOULD BE TO
5 DENY THIS APPLICATION, CONSIDER THE APPLICATION A
6 TIER II WITH INSTRUCTIONS TO GO BACK TO THE
7 APPLICANT WITH -- I'M SORRY. I DIDN'T GET THE
8 ADVICE THAT WAS GOING THAT YOU AND FRED WERE
9 DISCUSSING AS TO THE EXACT RECOMMENDATION. BUT FOR
10 THE FIRST PART, IT WOULD BE TO DECLINE THE FUNDING
11 FOR THIS APPLICATION AND CONSIDER IT A TIER II
12 APPLICATION.

13 CHAIRMAN THOMAS: RIGHT. AND THEN THE
14 APPLICANT WOULD BE ENCOURAGED, IF THEY SO CHOOSE, TO
15 REAPPLY AND TO ADDRESS THE COMMENTS GIVEN TO THEM BY
16 THE GWG BOTH SCIENTIFICALLY AND WITH RESPECT TO DEI.
17 SO THAT'S A BIT OF A WORDY MOTION. MARK, I BELIEVE,
18 DOES THAT CAPTURE THE ESSENCE OF WHAT YOU'D LIKE TO
19 PROPOSE HERE?

20 DR. FISCHER-COLBRIE: THAT'S CORRECT WITH,
21 AGAIN, WITH SOME KIND OF ENCOURAGEMENT LANGUAGE.

22 CHAIRMAN THOMAS: OKAY. MARV, YOU GOOD
23 WITH THAT?

24 DR. SOUTHARD: YES.

25 CHAIRMAN THOMAS: OKAY.

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1 DR. MARKS: SO WE OFFICIALLY HAVE A MOTION
2 PROPOSED BY MARK AND SECONDED BY MARV; IS THAT
3 CORRECT?

4 CHAIRMAN THOMAS: YES. ANY QUESTIONS OR
5 COMMENTS ON THIS NEW MOTION? ANY COMMENTS FROM
6 MEMBERS OF THE PUBLIC?

7 MS. DEQUINA-VILLABLANCA: I DON'T SEE ANY,
8 J.T.

9 CHAIRMAN THOMAS: MARIANNE, PLEASE CALL
10 THE ROLL.

11 MR. MARKS: SORRY, J.T. WE DO HAVE A HAND
12 UP.

13 CHAIRMAN THOMAS: SORRY.

14 MS. DEQUINA-VILLABLANCA: THERE WE GO.

15 CHAIRMAN THOMAS: ROGER.

16 DR. HOLLIS: YES. AS A MEMBER OF THE
17 PUBLIC, I'M ACTUALLY THE APPLICANT FOR THIS GRANT.
18 I JUST WANTED TO SAY THAT I REALLY WOULD LIKE TO
19 ECHO WHAT BOARD MEMBERS SAID EARLIER ABOUT PROVIDING
20 TEMPLATES WITH MORE INFORMATION. IT WOULD BE
21 MASSIVELY BENEFICIAL TO US TO GET MORE GUIDANCE ON
22 IT BECAUSE WE WORKED WITH MANY GROUPS TO TRY AND
23 INCLUDE WHAT WE COULD TO PUT INTO THIS GRANT THE
24 DIVERSITY AND INCLUSION. AND CLEARLY WE STILL WERE
25 BELOW THE BAR THAT WAS REQUIRED. SO IT REALLY,

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1 REALLY WOULD HELP US TO HAVE MORE GUIDANCE.

2 CHAIRMAN THOMAS: THANK YOU. AND DULY
3 NOTED. COULD YOU, JUST FOR THE RECORD, STATE YOUR
4 FULL NAME?

5 DR. HOLLIS: MY NAME IS ROGER HOLLIS.

6 CHAIRMAN THOMAS: AND YOUR AFFILIATION?

7 DR. HOLLIS: I'M THE CHIEF OPERATION
8 OFFICER AT IMMUNOVAC.

9 CHAIRMAN THOMAS: THANK YOU. ANY OTHER
10 COMMENTS FROM MEMBERS OF THE PUBLIC?

11 MS. DEQUINA-VILLABLANCA: I SEE NONE.

12 CHAIRMAN THOMAS: OKAY. MARIANNE, WILL
13 YOU PLEASE CALL THE ROLL.

14 MS. DEQUINA-VILLABLANCA: LEONDR
15 CLARK-HARVEY.

16 DR. CLARK-HARVEY: YES.

17 MS. DEQUINA-VILLABLANCA: YSABEL DURON.

18 MS. DURON: YES.

19 MS. DEQUINA-VILLABLANCA: ELENA FLOWERS.

20 DR. FLOWERS: SO I WANT TO MAKE SURE I'M
21 RESPONDING CORRECTLY. IS THE YES VOTE TO MAKE IT
22 TIER II?

23 CHAIRMAN THOMAS: YES.

24 MS. DEQUINA-VILLABLANCA: YES. THAT'S
25 CORRECT.

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1 DR. FLOWERS: YES.
2 MS. DEQUINA-VILLABLANCA: MARK
3 FISCHER-COLBRIE.
4 DR. FISCHER-COLBRIE: YES.
5 MS. DEQUINA-VILLABLANCA: FRED FISHER.
6 DR. FISHER: YES.
7 MS. DEQUINA-VILLABLANCA: DAVID HIGGINS.
8 DR. HIGGINS: YES.
9 MS. DEQUINA-VILLABLANCA: STEVE
10 JUELSGAARD.
11 MR. JUELSGAARD: YES.
12 MS. DEQUINA-VILLABLANCA: RICH LAJARA.
13 MR. LAJARA: YES.
14 MS. DEQUINA-VILLABLANCA: DAVE MARTIN.
15 DR. MARTIN: YES.
16 MS. DEQUINA-VILLABLANCA: LAUREN
17 MILLER-ROGEN.
18 MS. MILLER-ROGEN: YES.
19 MS. DEQUINA-VILLABLANCA: ADRIANA PADILLA.
20 DR. PADILLA: YES.
21 MS. DEQUINA-VILLABLANCA: JOE PANETTA.
22 MR. PANETTA: YES.
23 MS. DEQUINA-VILLABLANCA: AL ROWLETT.
24 MR. ROWLETT: YES.
25 MS. DEQUINA-VILLABLANCA: MARVIN SOUTHARD.

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DR. SOUTHARD: YES.

MS. DEQUINA-VILLABLANCA: JONATHAN THOMAS.

CHAIRMAN THOMAS: YES.

MS. DEQUINA-VILLABLANCA: MOTION CARRIES.

CHAIRMAN THOMAS: THANK YOU. THAT CONCLUDES THE ACTION ITEMS FOR TODAY'S APPLICATION REVIEW SUBCOMMITTEE. WE'VE NOW COME TO PUBLIC COMMENT. ARE THERE ANY QUESTIONS -- ANY COMMENTS FROM MEMBERS OF THE PUBLIC, QUESTIONS, DISCUSSION ITEMS ON ANY TOPIC OF ANY NOTE? THANK YOU.

MS. DEQUINA-VILLABLANCA: I SEE NONE.

CHAIRMAN THOMAS: OKAY. VERY GOOD. WELL, THAT CONCLUDES TODAY'S MEETING. THANK YOU VERY MUCH, EVERYBODY, FOR YOUR PARTICIPATION AS ALWAYS.

MARIANNE, THE DATE OF THE NEXT BOARD MEETING?

MS. DEQUINA-VILLABLANCA: IS MAY -- THE NEXT FULL BOARD MEETING IS MAY 26TH.

CHAIRMAN THOMAS: OKAY. GREAT. WITH THAT, EVERYBODY HAVE A WONDERFUL REST OF YOUR DAY, AND WE WILL SEE YOU ALL IN MAY. THANKS VERY MUCH.

(THE MEETING WAS THEN CONCLUDED AT 10:11 A.M.)

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 APPLICATION REVIEW SUBCOMMITTEE OF THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE IN THE MATTER OF ITS REGULAR MEETING HELD ON APRIL 19, 2022, WAS HELD AS HEREIN APPEARS AND THAT THIS IS THE ORIGINAL TRANSCRIPT THEREOF AND THAT THE STATEMENTS THAT APPEAR IN THIS TRANSCRIPT WERE REPORTED STENOGRAPHICALLY BY ME AND TRANSCRIBED BY ME. I ALSO CERTIFY THAT THIS TRANSCRIPT IS A TRUE AND ACCURATE RECORD OF THE PROCEEDING.

BETH C. DRAIN, CA CSR 7152
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