

BETH C. DRAIN, CA CSR NO. 7152

BEFORE THE
APPLICATION REVIEW SUBCOMMITTEE OF THE
INDEPENDENT CITIZENS'S OVERSIGHT COMMITTEE
CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE
ORGANIZED PURSUANT TO THE
CALIFORNIA STEM CELL RESEARCH AND CURES ACT
REGULAR MEETING

LOCATION: VIA ZOOM

DATE: NOVEMBER 29, 2022
9 A.M.

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

FILE NO.: 2022-42

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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)	32
4. CONSIDERATION OF APPLICATIONS SUBMITTED IN RESPONSE TO CLINICAL TRIAL STAGE PROJECTS PROGRAM ANNOUNCEMENT (CLIN 1 OR 2)	4
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 & SAFETY CODE 125290.30(F) (3) (B) AND (C)).	
DISCUSSION ITEMS	
6. PUBLIC COMMENT	NONE
7. ADJOURNMENT	61

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NOVEMBER 29, 2022; 9 A.M.

CHAIRMAN THOMAS: OKAY. ARE WE ON
RECORDING YET? THANK YOU.

GOOD MORNING, EVERYBODY, AND WELCOME TO
THE NOVEMBER MEETING OF THE APPLICATION REVIEW
SUBCOMMITTEE OF THE ICOC. MARIA, WILL YOU PLEASE
CALL THE ROLL.

MS. BONNEVILLE: YES. DAN BERNAL.

MR. BERNAL: PRESENT.

MS. BONNEVILLE: JUDY CHOU.

DR. CHOU: PRESENT.

MS. BONNEVILLE: LEONDRAL CLARK-HARVEY.

MS. CLARK-HARVEY: PRESENT.

MS. BONNEVILLE: ANNE-MARIE DULIEGE.

DR. DULIEGE: YES.

MS. BONNEVILLE: YSABEL DURON. MARK
FISCHER-COLBRIE.

DR. FISCHER-COLBRIE: HERE.

MS. BONNEVILLE: FRED FISHER.

DR. FISHER: HERE.

MS. BONNEVILLE: ELENA FLOWERS.

DR. FLOWERS: HERE.

MS. BONNEVILLE: DAVID HIGGINS.

DR. HIGGINS: HERE.

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1 MS. BONNEVILLE: STEVE JUELSGAARD. RICH
2 LAJARA.
3 MR. LAJARA: HERE.
4 MS. BONNEVILLE: CHRISTINE MIASKOWSKI.
5 DR. MIASKOWSKI: HERE.
6 MS. BONNEVILLE: LAUREN MILLER-ROGEN.
7 MS. MILLER-ROGEN: HERE.
8 MS. BONNEVILLE: ADRIANA PADILLA.
9 DR. PADILLA: HERE.
10 MS. BONNEVILLE: JOE PANETTA.
11 MR. PANETTA: HERE.
12 MS. BONNEVILLE: AL ROWLETT. MARVIN
13 SOUTHARD.
14 DR. SOUTHARD: HERE.
15 MS. BONNEVILLE: JONATHAN THOMAS.
16 CHAIRMAN THOMAS: HERE.
17 MS. BONNEVILLE: ART TORRES.
18 MR. TORRES: PRESENT.
19 MS. BONNEVILLE: KAROL WATSON.
20 WE HAVE A QUORUM, J.T.
21 CHAIRMAN THOMAS: THANK YOU, MARIA.
22 OKAY. WE'RE GOING TO TAKE ITEM 4 IN
23 ADVANCE OF ITEM 3 TO KEEP EVERYBODY ON THEIR TOES
24 THIS MORNING. AND ITEM 4 IS CONSIDERATION OF
25 APPLICATIONS SUBMITTED IN RESPONSE TO CLINICAL TRIAL

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1 STAGE PROJECTS PROGRAM ANNOUNCEMENTS, CLIN1, 2, OR
2 3. WE HAVE A PRESENTATION BY DR. SAMBRANO.

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

4 ALL RIGHT. GOOD MORNING, EVERYONE. SO
5 TODAY WE HAVE THE RECOMMENDATION FROM THE GRANTS
6 WORKING GROUP FOR OUR LATEST ROUND OF CLINICAL
7 PROJECTS. AND AS ALWAYS, WE START WITH OUR MISSION
8 AS THE GROUNDING FOR US AS WE START THIS AND ALSO
9 WHEN WE START OUR REVIEWS. OUR MISSION IS TO
10 ACCELERATE WORLD-CLASS SCIENCE TO DELIVER
11 TRANSFORMATIVE REGENERATIVE MEDICINE TREATMENTS IN
12 AN EQUITABLE MANNER TO A DIVERSE CALIFORNIA AND
13 WORLD.

14 THIS IS A REMINDER OF THE STATUS OF OUR
15 CLINICAL BUDGET. WE HAVE AN ANNUAL ALLOCATION FOR
16 THIS FISCAL YEAR OF 169 MILLION. CURRENTLY WE HAVE
17 29.8 THAT HAVE BEEN APPROVED BY THE BOARD, AND WE
18 HAVE 25.1 THAT ARE PENDING TODAY. SHOULD ALL OF
19 THOSE BE APPROVED, WE WOULD HAVE A REMAINDER OF
20 ABOUT 114 MILLION IN OUR ANNUAL BUDGET.

21 THE SCIENTIFIC SCORING SYSTEM THAT IS USED
22 FOR CLINICAL PROGRAM APPLICATIONS IS A 1-2-3 SCALE
23 WITH A SCORE OF 1 MEANING IT HAS EXCEPTIONAL MERIT
24 AND WARRANTING FUNDING. A SCORE OF 2 MEANS THAT
25 THOSE APPLICATIONS TYPICALLY GO BACK TO THE

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1 APPLICANT FOR REVISION TO COME BACK AT THE NEXT
2 AVAILABLE CYCLE WITH ANY COMMENTS RELATED TO
3 CONCERNS FROM REVIEWERS. A SCORE OF 3 MEANS THAT
4 THE APPLICATION IS SUFFICIENTLY FLAWED THAT IT NEEDS
5 TO GO BACK AND CAN'T COME BACK TO CIRM FOR SIX
6 MONTHS.

7 THE REVIEW CRITERIA THAT THE GRANTS
8 WORKING GROUP USES TO SCORE THE APPLICATIONS ARE
9 BASED ON THE FOLLOWING FIVE QUESTIONS: DOES THE
10 PROJECT HOLD THE NECESSARY SIGNIFICANCE AND
11 POTENTIAL FOR IMPACT? MEANING WHAT VALUE DOES IT
12 OFFER AND IS IT SOMETHING THAT IS WORTH DOING? DOES
13 IT HAVE A GOOD RATIONALE? IS THE PROJECT WELL
14 PLANNED AND DESIGNED? AND IS IT FEASIBLE, INCLUDING
15 WHETHER THEY HAVE THE APPROPRIATE RESOURCES AND
16 PERSONNEL TO CARRY OUT THE PROJECT. AND LASTLY,
17 DOES THE PROJECT UPHOLD THE PRINCIPLES OF DIVERSITY,
18 EQUITY, AND INCLUSION?

19 THE GRANTS WORKING GROUP ITSELF IS
20 COMPOSED OF DIFFERENT MEMBER TYPES THAT HAVE
21 DIFFERENT ROLES. WE HAVE OUR SCIENTIFIC GRANTS
22 WORKING GROUP MEMBERS WHO ARE ALL FROM OUTSIDE OF
23 CALIFORNIA. THEY PROVIDE THE SCIENTIFIC EXPERTISE
24 IN EVALUATION, AND WE BRING TOGETHER A PANEL THAT
25 BRINGS DIFFERENT PERSPECTIVES SCIENTIFICALLY TO THE

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1 REVIEW TO MAKE SURE THAT WE COVER THE NEEDS OF EACH
2 APPLICATION. WE ALSO HAVE OUR PATIENT ADVOCATE AND
3 NURSE GRANTS WORKING GROUP MEMBERS WHO PERFORM THE
4 DEI EVALUATION, PROVIDE US WITH A PATIENT
5 PERSPECTIVE ON THE SIGNIFICANCE AND IMPACT OF THESE
6 PROJECTS, AND ALSO PROVIDE OVERSIGHT ON THE PROCESS.
7 AND OUR PATIENT ADVOCATE/NURSE MEMBERS PROVIDE A DEI
8 SCORE ON ALL APPLICATIONS AND PROVIDE A SUGGESTED
9 SCIENTIFIC SCORE.

10 WE ALSO HAVE, DEPENDING ON THE
11 APPLICATION, SCIENTIFIC SPECIALISTS WHO ARE
12 NONVOTING MEMBERS THAT WILL PARTICIPATE ON AN AD HOC
13 BASIS. THEY PROVIDE AN INITIAL, BUT NOT A FINAL
14 SCIENTIFIC SCORE AND CONTRIBUTE TO ANY KNOWLEDGE
15 GAPS WE MAY HAVE IN THE PANEL.

16 SO BEFORE I INTRODUCE EACH OF THE
17 APPLICATIONS, JUST A NOTE, AGAIN, ABOUT CONFLICTS OF
18 INTEREST. BOARD MEMBERS LISTED MAY HAVE A CONFLICT
19 OF INTEREST WITH ONE OR MORE OF THE APPLICATIONS
20 THAT WE WILL BE TALKING ABOUT. SO BEAR THAT IN
21 MIND.

22 ALL RIGHT. SO THEN THE FIRST APPLICATION
23 IS ENTITLED "GENOME EDITING OF AUTOLOGOUS
24 HEMATOPOIETIC STEM CELLS TO TREAT SEVERE
25 MUCOPOLYSACCHARIDOSIS TYPE 1 OR HURLER SYNDROME."

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1 THE THERAPY ITSELF IS AN AUTOLOGOUS BLOOD STEM CELL
2 THAT IS EDITED TO RESTORE THE IDURONIDASE ENZYME
3 EXPRESSION IN THOSE CELLS. SO THE INDICATION IS FOR
4 SEVERE MPS1. THE GOAL OF THIS PROJECT IS COMPLETE
5 PRE-IND ENABLING STUDIES AND THE FILING OF AN IND.
6 SO THIS IS A CLIN1 PROPOSAL. THE FUNDS REQUESTED IS
7 JUST UNDER 6 MILLION BY THE APPLICANT.

8 A LITTLE BACKGROUND ON MPS1. THIS IS A
9 LYSOSOMAL STORAGE DISEASE THAT AFFECTS CHILDREN AND
10 RESULTS IN NEUROLOGIC, MUSCULOSKELETAL, AND
11 CARDIORESPIRATORY DETERIORATION. AND IN A SEVERE
12 FORM, THE DISEASE IS DIAGNOSED AT INFANCY AND IS
13 FATAL WITHIN THE FIRST TEN YEARS OF LIFE.

14 THE CURRENT STANDARD OF CARE INVOLVES
15 ENZYME REPLACEMENT THERAPY AND AN ALLOGENEIC BLOOD
16 CELL TRANSPLANT, NEITHER OF WHICH IS ADEQUATELY
17 EFFECTIVE IN TREATING THESE PATIENTS.

18 THE PROPOSED AUTOLOGOUS THERAPY DOES HOLD
19 THE POTENTIAL FOR A SAFER AND HOPEFULLY A MORE
20 EFFECTIVE TREATMENT FOR PATIENTS WITH MPS1. AND
21 THIS THERAPEUTIC CANDIDATE IS COMPOSED OF BLOOD OR
22 HEMATOPOIETIC STEM CELLS AND IS WHY IT QUALIFIED FOR
23 CIRM FUNDING.

24 THERE ARE NOT OTHER SIMILAR CIRM PORTFOLIO
25 PROJECTS OR AT LEAST ANY THAT ARE FOCUSED ON THIS

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1 INDICATION. ALTHOUGH WE DO IN OUR PORTFOLIO HAVE
2 SEVERAL OTHERS THAT IN ONE WAY OR ANOTHER ADDRESS A
3 RARE DISEASE AND/OR A LYSOSOMAL STORAGE DISEASE OF
4 SOME TYPE. WE HAVE ONE THAT'S MUCH EARLIER STAGE, I
5 BELIEVE A TRAN, FOR MPS3, WHICH IS A DIFFERENT
6 LYSOSOMAL STORAGE DISORDER, BUT NOTHING THAT IS
7 FOCUSED ON MPS1. THE APPLICANTS HAVE ALSO NOT
8 PREVIOUSLY RECEIVED A CIRM AWARD.

9 THE GRANTS WORKING GROUP RECOMMENDATION
10 FOR THIS APPLICATION IS SHOWN HERE. WE HAD 13 VOTES
11 FOR A SCORE OF 1, NO VOTES FOR A SCORE OF 2 OR 3.
12 THE DEI SCORE, ON A SCALE OF 1 TO 10, IS AN 8 FROM
13 OUR PATIENT ADVOCATE AND NURSE MEMBERS. AND THE
14 CIRM TEAM RECOMMENDATION IS TO FUND THIS APPLICATION
15 FOR 5.999 MILLION.

16 AND, MR. CHAIRMAN, I'LL GIVE THIS BACK TO
17 YOU.

18 CHAIRMAN THOMAS: THANK YOU, GIL. DO WE
19 HAVE A MOTION TO APPROVE?

20 DR. DULIEGE: I MOVE.

21 CHAIRMAN THOMAS: MOVED BY ANNE-MARIE. IS
22 THERE A SECOND?

23 MR. BERNAL: SECOND.

24 CHAIRMAN THOMAS: WHO WAS THAT? SORRY.

25 MR. BERNAL: BERNAL.

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1 CHAIRMAN THOMAS: THANKS, DAN.

2 ARE THERE QUESTIONS OR COMMENTS FROM
3 MEMBERS OF THE BOARD? ANY QUESTIONS OR COMMENTS
4 FROM THE PUBLIC?

5 DR. FISHER: I HAVE MY HAND UP.

6 CHAIRMAN THOMAS: I CAN'T SEE ON MY SCREEN
7 FOR SOME REASON. SORRY, FRED. GO AHEAD.

8 DR. FISHER: SO NO QUESTIONS ABOUT THE
9 PROPOSAL IN PARTICULAR EXCEPT TWO THINGS THAT MAYBE
10 GIL CAN CLARIFY. NO. 1, ARE WE INTENTIONALLY
11 BLINDED TO WHO THE APPLICANT IS ON THESE SUMMARIES?

12 DR. SAMBRANO: YES.

13 DR. FISHER: MY SECOND QUESTION IS WITH
14 WHAT FREQUENCY DO THESE AWARDS HAVE OR THESE
15 APPLICATIONS HAVE ZERO MATCHING FUNDS?

16 DR. SAMBRANO: THE MATCHING FUNDS USUALLY
17 INDICATE WHAT THE REQUIREMENT IS. SO FOR CLIN1 AND
18 PHASE 1, IT'S THEY'RE AN ACADEMIC INSTITUTION.
19 THERE IS NO CO-FUNDING REQUIRED AND TYPICALLY NO
20 CO-FUNDING PROVIDED. FOR COMPANY, THE CO-FUNDING
21 REQUIREMENT BEGINS AT CLIN1 AT USUALLY 30 PERCENT
22 AND THEN GOES UP TO 40 PERCENT DEPENDING ON THE
23 PHASE OF THE TRIAL. TYPICALLY THAT WILL INDICATE
24 WHETHER IT'S A LATE STAGE FILE IF IT'S ACADEMIC OR
25 IF IT'S A COMPANY THAT'S COMING IN.

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1 DR. FISHER: THANKS FOR THAT.

2 CHAIRMAN THOMAS: MARIA, ANY OTHER
3 COMMENTS OR QUESTIONS FROM THE BOARD?

4 MS. BONNEVILLE: THERE ARE NO OTHER HANDS
5 RAISED.

6 CHAIRMAN THOMAS: THANK YOU. COMMENTS
7 FROM MEMBERS OF THE PUBLIC?

8 MS. BONNEVILLE: I DO NOT SEE ANY HANDS
9 RAISED.

10 CHAIRMAN THOMAS: THANK YOU. WILL YOU
11 PLEASE CALL THE ROLL.

12 MS. BONNEVILLE: YES. DAN BERNAL.

13 MR. BERNAL: AYE.

14 MS. BONNEVILLE: JUDY CHOU.

15 DR. CHOU: AYE.

16 MS. BONNEVILLE: LEONDRA CLARK-HARVEY.

17 MS. CLARK-HARVEY: AYE.

18 MS. BONNEVILLE: ANNE-MARIE DULIEGE.

19 DR. DULIEGE: AYE.

20 MS. BONNEVILLE: MARK FISCHER-COLBRIE.

21 DR. FISCHER-COLBRIE: AYE.

22 MS. BONNEVILLE: FRED FISHER.

23 DR. FISHER: AYE.

24 MS. BONNEVILLE: ELENA FLOWERS.

25 DR. FLOWERS: YES.

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1 MS. BONNEVILLE: DAVID HIGGINS.
2 DR. HIGGINS: YES.
3 MS. BONNEVILLE: RICH LAJARA.
4 MR. LAJARA: YES.
5 MS. BONNEVILLE: CHRISTINE MIASKOWSKI.
6 DR. MIASKOWSKI: YES.
7 MS. BONNEVILLE: LAUREN MILLER-ROGEN.
8 MS. MILLER-ROGEN: YES.
9 MS. BONNEVILLE: ADRIANA PADILLA.
10 DR. PADILLA: YES.
11 MS. BONNEVILLE: JOE PANETTA.
12 MR. PANETTA: YES.
13 MS. BONNEVILLE: MARVIN SOUTHARD.
14 DR. SOUTHARD: YES.
15 MS. BONNEVILLE: JONATHAN THOMAS.
16 CHAIRMAN THOMAS: YES.
17 MS. BONNEVILLE: ART TORRES.
18 MR. TORRES: AYE.
19 MS. BONNEVILLE: KAROL WATSON.
20 MOTION CARRIES.
21 CHAIRMAN THOMAS: THANK YOU, MARIA.
22 GIL, NEXT APPLICATION PLEASE.
23 DR. SAMBRANO: OKAY. THANK YOU, MR.
24 CHAIRMAN.
25 THE NEXT APPLICATION IS CLIN2-14024. SO

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1 THIS IS A CLINICAL TRIAL APPLICATION. THE TITLE IS
2 "SEQUENTIAL SAME DONOR ALPHA BETA-DEPLETED HSCT FROM
3 AN HLA-PARTIALLY MATCHED DONOR ALLOWING
4 IMMUNOSUPPRESSION FREE KIDNEY TRANSPLANT."

5 THE THERAPY IS AN ALLOGENEIC BLOOD STEM
6 CELL PRODUCT DEPLETED OF T CELLS OF THE ALPHA BETA
7 TYPE ALONG WITH CD19+ B CELLS. THE INDICATION IS
8 FOR RENAL FAILURE DUE TO ONE OF FOUR GENETIC AND/OR
9 IMMUNOLOGICAL DISEASES. THE GOAL OF THIS STUDY IS
10 TO COMPLETE A PHASE 1 STUDY TO ASSESS FEASIBILITY
11 AND SAFETY, AND THE FUNDS REQUESTED FOR THIS ARE
12 11.9 MILLION.

13 BACKGROUND ON THESE INDICATIONS. SO THIS
14 STUDY IS FOCUSED ON PEDIATRIC AND YOUNG ADULT KIDNEY
15 TRANSPLANTATION AND IMPROVEMENT. AND LONG-TERM
16 OUTCOME FOR THESE PATIENTS REMAINS AN UNMET MEDICAL
17 NEED DUE TO IMMUNE-MEDIATED GRAFT REJECTION AND
18 INFECTION. AND MOST CHILDREN THAT REQUIRE A KIDNEY
19 TRANSPLANT ARE GOING TO NEED AN ADDITIONAL
20 TRANSPLANT AT SOME POINT AND DOES REQUIRE LIFELONG
21 IMMUNOSUPPRESSION.

22 SO THE PROPOSED THERAPY HAS THE POTENTIAL
23 TO REDUCE THE RISK OF CHRONIC TRANSPLANT REJECTION
24 AND THE NEED FOR REPEAT TRANSPLANT PATIENTS, AND THE
25 NEED FOR IMMUNOSUPPRESSION BY RETRAINING THE IMMUNE

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1 SYSTEM TO DEVELOP TOLERANCE TO THE DONOR KIDNEY.

2 THE PROJECT ITSELF IS A STEM CELL PROJECT
3 BECAUSE THE THERAPEUTIC CANDIDATE IS COMPOSED OF
4 BLOOD STEM CELLS.

5 WE HAVE SEVERAL PROJECTS IN OUR PORTFOLIO
6 THAT ADDRESS KIDNEY FAILURE, THREE OF THEM THAT HAVE
7 SOMEWHAT SIMILAR APPROACHES IN THAT THEY ARE TRYING
8 TO ACHIEVE TOLERANCE OF THE TRANSPLANT THROUGH
9 SLIGHTLY DIFFERENT, BUT ALSO SOMEWHAT SIMILAR
10 APPROACHES OF PROVIDING DONOR STEM CELLS THAT ARE
11 DEPLETED IN T CELLS IN A VARIETY OF WAYS.

12 WE ALSO HAVE ANOTHER PROJECT THAT'S
13 FOCUSED ON CYSTINOSIS. CYSTINOSIS IS ONE OF THE
14 TARGET INDICATIONS THAT ALSO HAS KIDNEY FAILURE AS A
15 PART OF IT. THIS PARTICULAR PROJECT IS FOCUSED ON
16 TREATING AND CURING CYSTINOSIS, NOT NECESSARILY JUST
17 THE KIDNEY FAILURE PART, BUT I INCLUDED THAT AS AN
18 FYI.

19 THIS PARTICULAR APPLICANT HAS NOT
20 PREVIOUSLY RECEIVED A CIRM AWARD. AND THE GRANTS
21 WORKING GROUP RECOMMENDATION IS AS FOLLOWS. THERE
22 WERE 15 MEMBERS THAT GAVE IT A SCORE OF 1 AND NO
23 MEMBERS GIVING IT A SCORE OF 2 OR 3. THE DEI SCORE
24 ON A SCALE OF 1 TO 10 WAS A 9 AS GIVEN BY OUR
25 PATIENT ADVOCATE AND NURSE MEMBERS, AND THE CIRM

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1 TEAM RECOMMENDATION IS TO FUND THIS APPLICATION FOR
2 THE AWARD AMOUNT SHOWN. MR. CHAIRMAN.

3 CHAIRMAN THOMAS: THANK YOU, GIL.

4 IS THERE A MOTION TO APPROVE?

5 MR. TORRES: MOVE TO APPROVE.

6 CHAIRMAN THOMAS: THANK YOU, SENATOR
7 TORRES.

8 IS THERE A SECOND?

9 DR. CLARK-HARVEY: SECOND.

10 CHAIRMAN THOMAS: THANK YOU, LEONDRAS.
11 QUESTIONS OR COMMENTS FROM MEMBERS OF THE BOARD?

12 MS. BONNEVILLE: GO AHEAD, ANNE-MARIE.

13 DR. DULIEGE: GIL, ACTUALLY THANK YOU
14 AGAIN FOR A VERY CLEAR PRESENTATION. DO YOU THINK
15 THERE IS A LOT OF REDUNDANCY BETWEEN THIS PROJECT
16 AND THE OTHER PROJECT THAT YOU MENTIONED OR ANY
17 FUNDED FOR SIMILAR INDICATIONS OF RENAL TRANSPLANT?
18 WHAT'S THE DEGREE OF REDUNDANCY?

19 DR. SAMBRANO: THERE IS SOME REDUNDANCY
20 SIMPLY IN THE OVERALL GENERAL APPROACH TO TRY TO
21 ACHIEVE TOLERANCE, BUT EACH OF THEM IS FOCUSED ON A
22 SLIGHTLY DIFFERENT WAY OF DOING IT. THIS ONE IS
23 PARTICULARLY DIFFERENT BECAUSE IT IS FOCUSED ON
24 CHILDREN AND YOUNG ADULTS AS OPPOSED TO THE OTHERS
25 THAT ARE MORE FOCUSED ON ADULT PATIENTS. SO IT DOES

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1 DISTINGUISH ITSELF A BIT FROM THOSE OTHERS.

2 DR. DULIEGE: IN ANY CASE SHOULD WE VIEW
3 OUR JUDGMENT BASED ON THE OVERALL MERIT OF THE
4 APPLICATION, OR SHOULD WE BE INFLUENCED BY THE FACT
5 THAT WE HAVE ALREADY INVESTED A LOT OF MONEY ON
6 RENAL TRANSPLANT? SHOULD THAT BE A CONSIDERATION?

7 DR. SAMBRANO: WELL, I THINK THAT'S A
8 CONSIDERATION OF THE BOARD ABSOLUTELY IN TERMS OF
9 LOOKING AT OUR OVERALL PORTFOLIO AND WHETHER THE
10 BOARD THINKS THAT THE INVESTMENT MADE HERE IS EITHER
11 TOO REDUNDANT, TO WHAT EXTENT WE WANT TO CONTINUE
12 FUNDING PROJECTS IN THIS AREA OR NOT. IN GENERAL,
13 AT CIRM WE'VE TAKEN THE APPROACH THAT SEVERAL SHOTS
14 ON GOAL IS GENERALLY A GOOD IDEA BECAUSE WE DON'T
15 EXPECT THAT EVERYTHING WILL WORK. BUT I THINK THE
16 PROGRAMMATIC CONSIDERATION AT THE BOARD IS
17 DEFINITELY SOMETHING TO TAKE INTO ACCOUNT.

18 DR. DULIEGE: THANK YOU.

19 CHAIRMAN THOMAS: ANNE-MARIE, IN RESPONSE
20 TO THAT QUESTION, I WILL TROT OUT MY OLD COMMENT
21 ABOUT THE CHILEAN MINERS WHO WERE, IF YOU RECALL,
22 STUCK IN THAT CAVE A NUMBER OF YEARS AGO. AND THEY
23 BORE THREE DIFFERENT TUNNELS IN THE HOPES THAT ONE
24 OF THEM AT LEAST WOULD REACH THE MINERS AND ALLOW
25 THEM TO BE FREED. SO THAT IS SORT OF WHAT I VIEW

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1 OUR TASK AS BEING.

2 I AGREE THAT MULTIPLE SHOTS ON GOAL FROM
3 SLIGHTLY DIFFERENT APPROACHES ARE SOMETHING THAT WE
4 DO STRONGLY CONSIDER IN THE HOPES THAT ONE OR MORE
5 OF THESE WILL ACTUALLY WORK IN THE END. SO I, WITH
6 RESPECT TO THIS APPLICATION, FOR EXAMPLE, WOULD
7 STRONGLY BE IN FAVOR THAT WE APPROVE IT.

8 MS. BONNEVILLE: THERE ARE TWO OTHER HANDS
9 RAISED.

10 CHAIRMAN THOMAS: COULD YOU NAME THEM
11 PLEASE, MARIA.

12 MS. BONNEVILLE: MARK FISCHER-COLBRIE IF
13 YOU'D LIKE TO GO NEXT.

14 CHAIRMAN THOMAS: MARK.

15 DR. COLBRIE-FISCHER: FIRST OF ALL,
16 ANNE-MARIE'S QUESTION IS AN OUTSTANDING ONE, AND I
17 THINK IT'S ONE WE SHOULD ALL BE ASKING. THAT'S A
18 TERRIFIC QUESTION.

19 AND WANTED TO ECHO J.T.'S COMMENTS IN THE
20 CONTEXT THAT I THINK, GIVEN THE HYPER CRITICALITY
21 AND POTENTIAL IMPACT OF WHAT COULD ARISE FROM THESE
22 OPPORTUNITIES, IT WOULD BE FANTASTIC FOR THE
23 CONTINUATION OF THIS PARTICULAR GRANT AWARD. SO
24 JUST A GENERAL COMMENT, BUT OUTSTANDING QUESTION
25 FROM ANNE-MARIE.

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1 MS. BONNEVILLE: DOUG.

2 CHAIRMAN THOMAS: THANKS, MARK. MARIA,
3 WHO ELSE IS --

4 MS. BONNEVILLE: IT'S JOE NEXT.

5 CHAIRMAN THOMAS: JOE. THANK YOU.

6 MR. PANETTA: THANKS, MARIA. THANKS, J.T.
7 I AGREE WITH EVERYTHING THAT'S BEEN SAID,
8 BUT I WAS JUST THINKING WE HAVE A REAL EXPERT IN
9 THIS ARENA ON THE TEAM IN OUR PRESENT CEO. AND I
10 WONDER IF THERE'S ANY MORE CLARIFICATION AS TO THE
11 REDUNDANCY THAT MARIA MIGHT BE ABLE TO PROVIDE TO
12 US.

13 DR. MILLAN: CHAIRMAN THOMAS, SHOULD I
14 RESPOND?

15 CHAIRMAN THOMAS: PLEASE.

16 DR. MILLAN: THANK YOU SO MUCH FOR THAT
17 QUESTION. AS YOU SAID, THIS IS AN AREA OF RESEARCH
18 THAT I WAS INVOLVED IN IN MY FORMER LIFE.

19 THE IDEA OF THIS PARTICULAR PROJECT, AS
20 DR. SAMBRANO HAD STATED, IS THAT THERE IS A
21 DIFFERENT TYPE OF BLOOD STEM CELL PREPARATION THAT'S
22 BEING GIVEN IN COMBINATION WITH A KIDNEY TRANSPLANT
23 TO INDUCE TOLERANCE FROM OUR PRIOR PROJECTS IN TERMS
24 OF HOW CERTAIN SUBPOPULATIONS ARE DEPLETED. AND SO
25 THE DATA, AS STATED IN THE SUMMARY, SUGGESTS THAT

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1 THIS INCREASES THE PROBABILITY OF SUCCESS OF THE
2 TRANSPLANTED DONOR STEM CELLS TO ESTABLISH ITSELF
3 AND CREATE THE IMMUNE SYSTEM THAT ALLOWS TOLERANCE
4 AND THE ACCEPTANCE OF THE TRANSPLANTED KIDNEY ITSELF
5 VERSUS NONSELF, WHICH ARE TYPICALLY REJECTED.
6 THAT'S ONE POINT OF THE APPROACH ITSELF.

7 THE SECOND POINT IS THE FACT THAT THIS IS
8 IN PEDIATRIC PATIENTS AND OUR OTHER PROGRAMS ARE NOT
9 IN PEDIATRIC PATIENTS AND THERE ARE DEFINITELY
10 DIFFERENCES. AS YOU KNOW, WITH ANY APPROACH,
11 TESTING PEDIATRICS VERSUS ADULTS IN TERMS OF IMPACT,
12 LONG-TERM IMMUNOSUPPRESSION, JUST BY SHEER RULES OF
13 PHYSICS, LONG-TERM IMMUNOSUPPRESSION IN CHILDREN,
14 THE RISK OF THAT IS GOING TO BE HIGHER BECAUSE OF
15 THE CUMULATIVE EFFECTS OF IMMUNOSUPPRESSION. ALSO,
16 CHILDREN ARE VERY, VERY HIGHLY SUSCEPTIBLE TO VIRAL
17 INFECTIONS AND CONSEQUENCES, SUCH AS EPSTEIN BAR
18 VIRUS, EBV, WHICH CAN ACTUALLY CAUSE LYMPHOMAS AND
19 THINGS LIKE THAT. SO THE CONSEQUENCE OF INFECTION
20 IN CHILDREN WHO ARE NAIVE ARE EVEN GREATER.

21 IN TERMS OF LONG-TERM IMMUNOSUPPRESSION,
22 THE RISK/BENEFIT FOR NOT HAVING IMMUNOSUPPRESSION
23 ALSO HEAVILY WEIGHTS FOR THE PEDIATRIC PATIENTS.

24 CHAIRMAN THOMAS: THANK YOU, MARIA.

25 MARIA B, ANY OTHER --

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1 MS. BONNEVILLE: YES. WE'VE GOT FRED AND
2 LARRY.

3 CHAIRMAN THOMAS: THANK YOU. FRED.

4 DR. FISHER: JUST FOR CLARIFICATION, ARE
5 THESE BLOOD STEM CELLS FROM EACH INDIVIDUAL PATIENT,
6 OR ARE THEY STEM CELLS THAT THE APPLICANT GETS FROM
7 SOMEWHERE AND USES? SO DOES THIS FALL WITHIN MORE
8 OF A PERSONALIZED MEDICINE APPROACH OR MORE GENERIC
9 STEM CELL APPROACH?

10 DR. SAMBRANO: THESE ARE FROM A MATCHED
11 DONOR OR A HAPLOIDENTICAL DONOR.

12 DR. FISHER: BUT NOT FROM THE PATIENTS
13 THEMSELVES?

14 DR. SAMBRANO: NOT FROM THE PATIENTS
15 THEMSELVES, BUT SOMEBODY THAT IS PARTIALLY MATCHED
16 TO THE PATIENT.

17 CHAIRMAN THOMAS: THANK YOU.

18 MS. BONNEVILLE: WE HAVE --

19 CHAIRMAN THOMAS: THAT ANSWER YOUR
20 QUESTION OKAY?

21 DR. FISHER: YEAH. IT LEADS TO MORE
22 QUESTIONS, BUT THIS IS PROBABLY NOT THE TIME OR
23 PLACE FOR THOSE.

24 CHAIRMAN THOMAS: THANK YOU.

25 MS. BONNEVILLE: LARRY IS NEXT.

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1 DR. GOLDSTEIN: I'LL MAKE TWO POINTS. ONE
2 IS THAT A CERTAIN DEGREE OF REDUNDANCY ENSURES
3 SUCCESS MOVING FORWARD.

4 AND SECOND, THIS GENERAL APPROACH FOR
5 TOLERIZING FOR ORGAN TRANSPLANT MAY NOT JUST BE FOR
6 KIDNEY, ULTIMATELY HEARTS, LIVER, LUNG, ALL THE REST
7 WHERE YOU HAVE ALLOGENEIC TRANSPLANTS. AND THE
8 NOTION OF USING TRANSPLANTATION OF A BLOOD-FORMING
9 SYSTEM FROM THE DONOR OF THE ORGAN TO TOLERIZE THE
10 RECIPIENT HAS BEEN ON BLACKBOARDS FOR YEARS. AND I
11 THINK, IF WE INVEST IN VERY CONCENTRATED AND EVEN
12 SOMEWHAT OVERLAPPING APPROACHES, IS ABSOLUTELY GOING
13 TO LEAD TO, WELL, I DON'T KNOW, SUCCESS, OF COURSE,
14 BUT IT IS THE RIGHT THING TO DO BECAUSE IT RAISES
15 OUR PROBABILITY OF SUCCESS, AND IT'S AN INCREDIBLY
16 IMPORTANT APPROACH GENERALLY.

17 CHAIRMAN THOMAS: THANK YOU, LARRY.

18 MARIA, ANY OTHER HANDS?

19 MS. BONNEVILLE: NO OTHER BOARD MEMBERS
20 HAVE THEIR HANDS RAISED.

21 CHAIRMAN THOMAS: THANK YOU, ALL BOARD
22 MEMBERS. THOSE ARE ALL EXCELLENT COMMENTS AS
23 ALWAYS.

24 ANY COMMENTS FROM MEMBERS OF THE PUBLIC?

25 MS. BONNEVILLE: I HAD NOTICED A HAND

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1 RAISED PREVIOUSLY. I'M NOT SURE THAT THAT IS STILL
2 THE CASE. I DO NOT SEE A HAND ANYMORE. OKAY.
3 NOPE. NO PUBLIC COMMENT.

4 CHAIRMAN THOMAS: THANK YOU. PLEASE CALL
5 THE ROLL.

6 MS. BONNEVILLE: YES. DAN BERNAL.

7 MR. BERNAL: AYE.

8 MS. BONNEVILLE: JUDY CHOU.

9 DR. CHOU: AYE.

10 MS. BONNEVILLE: LEONDRA CLARK-HARVEY.

11 MS. CLARK-HARVEY: AYE.

12 MS. BONNEVILLE: ANNE-MARIE DULIEGE.

13 DR. DULIEGE: AYE.

14 MS. BONNEVILLE: MARK FISCHER-COLBRIE.

15 DR. FISCHER-COLBRIE: AYE.

16 MS. BONNEVILLE: FRED FISHER.

17 DR. FISHER: AYE.

18 MS. BONNEVILLE: ELENA FLOWERS.

19 DR. FLOWERS: YES.

20 MS. BONNEVILLE: DAVID HIGGINS.

21 DR. HIGGINS: YES.

22 MS. BONNEVILLE: RICH LAJARA.

23 MR. LAJARA: YES.

24 MS. BONNEVILLE: CHRISTINE MIASKOWSKI.

25 DR. MIASKOWSKI: YES.

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1 MS. BONNEVILLE: LAUREN MILLER-ROGEN.

2 MS. MILLER-ROGEN: YES.

3 MS. BONNEVILLE: ADRIANA PADILLA.

4 DR. PADILLA: YES.

5 MS. BONNEVILLE: JOE PANETTA.

6 MR. PANETTA: YES.

7 MS. BONNEVILLE: MARVIN SOUTHARD.

8 DR. SOUTHARD: YES.

9 MS. BONNEVILLE: JONATHAN THOMAS.

10 CHAIRMAN THOMAS: YES.

11 MS. BONNEVILLE: ART TORRES.

12 MR. TORRES: AYE.

13 MS. BONNEVILLE: KAROL WATSON.

14 DR. WATSON: YES.

15 MS. BONNEVILLE: THANK YOU. THE MOTION
16 CARRIES.

17 CHAIRMAN THOMAS: THANK YOU. I WANT TO
18 AMEND MY COMMENT A SECOND AGO. EXCELLENT COMMENTS
19 FROM MEMBERS OF THE BOARD AS WELL AS DR. MILLAN.
20 VERY IMPORTANT PERSPECTIVE THAT YOU PROVIDED ON THAT
21 ANSWER AS WELL. THANK YOU.

22 ON TO THE THIRD APPLICATION, GIL.

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

24 THE LAST APPLICATION IS ALSO A CLINICAL
25 TRIAL APPLICATION, CLIN2-14232. THE TITLE IS "A

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1 POTENT, FIRST-IN-CLASS KDM4 INHIBITOR FOR ADVANCED
2 CANCERS."

3 THIS IS A SMALL MOLECULE INHIBITOR OF KDM4
4 HISTONE DEMETHYLASE. THE INDICATION IS FOR
5 COLORECTAL CANCER. THE GOAL IS COMPLETION OF A
6 PHASE 1 TRIAL TO ASSESS SAFETY AND INITIAL EFFICACY
7 OF THIS SMALL MOLECULE. AND FUNDS REQUESTED IS 4.1
8 MILLION, AND THE CO-FUNDING AMOUNT IS ABOUT 3
9 MILLION.

10 BACKGROUND ON THE --

11 DR. FISHER: IT SAYS 7.1 ON THE SLIDE. I
12 THINK I HEARD YOU SAY 4.1, BUT IT SAYS 7.1.

13 DR. SAMBRANO: I'M SORRY. 7.1 MILLION.

14 THE CLINICAL BACKGROUND ON THIS COLORECTAL
15 CANCER REMAINS AN UNMET MEDICAL NEED AND WAS THE
16 SECOND LEADING CAUSE OF CANCER DEATH IN THE U.S. IN
17 2020. ABOUT 15 PERCENT OF COLORECTAL CANCER
18 PATIENTS ARE NOT RESPONSIVE TO CHEMOTHERAPY DUE TO A
19 DEFICIENCY IN THE DNA REPAIR MECHANISMS. AND THAT
20 IS WHAT THIS THERAPEUTIC IS TARGETING.

21 THE STANDARD OF CARE FOR THIS ADVANCED
22 COLORECTAL CANCER IS UNRESPONSIVE TO FIRST-LINE
23 THERAPY, INCLUDING IMMUNO CHECKPOINT INHIBITORS
24 AND/OR OTHER AGENTS THAT TARGET ANGIOGENESIS OR
25 VASCULARIZATION. SO THOSE THAT ARE REFRACTORY TO

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1 THOSE NEED ADDITIONAL APPROACHES. SO IF THIS
2 THERAPY IS SUCCESSFUL, IT WOULD OFFER AN EFFECTIVE
3 THERAPY OPTION FOR PATIENTS.

4 THIS THERAPEUTIC CANDIDATE TARGETS CANCER
5 STEM CELLS AND IS WHY IT QUALIFIES FOR CIRM FUNDING.

6 IN TERMS OF OTHER SIMILAR PROJECTS, WE
7 HAVE SEVERAL THAT ARE ADDRESSING DIFFERENT TUMOR
8 TYPES, SOME MORE GENERICALLY SOLID TUMORS. WE DON'T
9 HAVE ANYTHING THAT'S SPECIFICALLY FOCUSED SOLELY ON
10 COLORECTAL CANCER, BUT SOME LIKE THIS ONE THAT
11 INCLUDE COLORECTAL CANCER AS ONE OF THE TARGETED
12 CANCERS.

13 THIS ONE HAS A VERY DIFFERENT APPROACH.
14 THIS PROJECT USES CYTOKINE INDUCED KILLER CELLS THAT
15 CONTAIN AN ONCOLYTIC VIRUS. SO VERY DIFFERENT FROM
16 THE SMALL MOLECULE, BUT THE CLOSEST THING THAT WE
17 HAVE IN OUR PORTFOLIO CURRENTLY.

18 THIS PARTICULAR APPLICANT HAS NOT
19 PREVIOUSLY RECEIVED A CIRM AWARD.

20 AND THIS IS A SUMMARY OF THE
21 RECOMMENDATIONS FROM THE GRANTS WORKING GROUP. WE
22 HAD SEVEN MEMBERS GIVING IT A SCORE OF 1. WE HAD
23 SIX MEMBERS GIVING IT A SCORE OF 2. AND NO ONE
24 GIVING IT A SCORE OF 3. THE DEI SCORE BY PATIENT
25 ADVOCATE AND NURSE MEMBERS IS A SCORE OF 9 ON THE 1

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1 TO 10 SCALE. AND THE CIRM TEAM RECOMMENDATION IS TO
2 FUND THIS APPLICATION FOR THE AMOUNT OF 7.1 MILLION.

3 MR. CHAIRMAN.

4 CHAIRMAN THOMAS: THANK YOU, GIL. IS
5 THERE A MOTION TO APPROVE?

6 DR. CLARK-HARVEY: SO MOVED.

7 CHAIRMAN THOMAS: MOVED BY LEONDRA.
8 SECOND?

9 DR. SOUTHARD: SECOND.

10 CHAIRMAN THOMAS: DID YOU GET THAT, MARIA?

11 MS. BONNEVILLE: I THINK IT WAS MARVIN
12 THAT GOT IN FIRST.

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

15 MS. BONNEVILLE: FRED HAS HIS HAND RAISED.

16 CHAIRMAN THOMAS: MARIA, WHO DID YOU SAY?
17 SORRY.

18 MS. BONNEVILLE: FRED AND ANNE-MARIE.

19 CHAIRMAN THOMAS: LET'S GO WITH FRED FIRST
20 SINCE I THINK YOU MENTIONED HIM FIRST. FRED.

21 DR. FISHER: YOU KNOW, IN READING THE
22 COMMENTS, I HAD A HARD TIME FINDING THE REASONS WHY
23 NEARLY HALF OF THE GRANT WORKING GROUP WANTED TO
24 SEND THIS BACK TO THE APPLICANT FOR REVISIONS. AND
25 I COULDN'T REALLY TEASE OUT THE RATIONALE FOR THEIR

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1 SCORES OF 2. SO I'M WONDERING IF GIL CAN PROVIDE
2 SOME GREATER CONTEXT AROUND NEARLY HALF THE GROUP
3 WANTING TO SEND IT BACK AND THE STAFF'S
4 RECOMMENDATION TO MOVE IT FORWARD. I CAN'T SEE IT
5 FROM THE -- AT LEAST IT'S NOT JUMPING OUT AT ME FROM
6 THE SUMMARY ON THIS QUESTION.

7 CHAIRMAN THOMAS: THANK YOU, FRED. GIL.

8 DR. SAMBRANO: THAT'S A VERY GOOD
9 QUESTION. I THINK, IN LOOKING AT THE COMMENTS,
10 THERE ARE VERY FEW COMMENTS PROVIDED BY THOSE THAT
11 GAVE IT A SCORE OF 2 NECESSARILY. I THINK MANY OF
12 THEM HAD POSITIVE COMMENTS AS WELL. AND SOMETIMES
13 IT'S ALSO DIFFICULT TO DISCERN WHY THEY KIND OF FALL
14 ON THE BALANCE ON A 2 VERSUS A 1 DESPITE THEIR
15 COMMENTS.

16 SO THE THINGS THAT SEEM TO LEAD ME TO GO
17 HAS TO DO WITH THE DOSING. SO THE PROPOSAL IS
18 STUDYING OR IS INTENDING, AT LEAST IT SEEMS, IS
19 PREPARING A COHORT TO TRY TO UNDERSTAND WHAT THE
20 MAXIMUM TOLERATED DOSE FOR A PHASE 2 WOULD BE.

21 THERE WERE RECOMMENDATIONS FROM THE FDA
22 THAT, AS THEY PROCEED THROUGH THEIR CLINICAL TRIAL,
23 THAT THEY ASSESS SEVERAL DOSES. SO NOT JUST
24 NECESSARILY THE MAXIMUM TOLERATED DOSE, BUT
25 ADDITIONAL DOSES. AND IT WAS UNCLEAR WHETHER THEY

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1 WERE FOLLOWING FDA ADVICE ON THIS OR NOT. SO I
2 THINK THERE WAS CLARITY THAT WAS DESIRED ON THE PART
3 OF SOME OF THE REVIEWERS ON THAT.

4 THERE WERE SOME MINOR COMMENTS RELATED,
5 FOR EXAMPLE, TO THE DATA MONITORING COMMITTEE TO
6 MAKE SURE THAT IT IS INDEPENDENT AND IT'S NOT
7 INCLUSIVE OF THE PI OR OTHER PERSONNEL. THERE WAS A
8 QUESTION OF WHETHER ULTIMATELY THE TRIAL WAS GOING
9 TO HAVE AN APPROPRIATE POOL OF PATIENTS AND PATIENT
10 IDENTIFICATION AND WANTED MORE DETAIL ON THAT PART.
11 SO THOSE ARE THE THINGS, BASED ON THE COMMENTS, THAT
12 WE RECEIVED FROM THE REVIEWERS THAT WOULD SUGGEST
13 THAT'S WHAT LED THOSE SIX TO SCORE IT A 2 RATHER
14 THAN A 1.

15 DR. FISHER: JUST TO QUICKLY FOLLOW UP.
16 SO WAS THE APPLICANT SUGGESTING A SPECIFIC DOSE FOR
17 THE SAFETY AND TOLERABILITY, WHICH IS TYPICALLY THE
18 FOCUS OF A PHASE 1 TRIAL? AND THE GROUP OR SOME IN
19 THE GROUP OR THE FDA THOUGHT THEY SHOULD BROADEN
20 THEIR DOSING REGIME?

21 DR. SAMBRANO: YES. AND SO THERE'S A
22 SUGGESTION, BASED ON WHAT WAS PROPOSED FOR THE
23 TRIAL, THAT THEY WOULD DO A DOSE ESCALATION TO
24 RECEIVE A MAXIMUM TOLERATED DOSE; WHEREAS, THE FDA
25 SUGGESTION WAS TO INCLUDE MULTIPLE DOSES AS THEY

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1 MOVE FORWARD EVEN BEYOND THE PHASE 1, BUT IT WAS
2 UNCLEAR WHETHER THAT WAS THEIR INTENT IN DOING THE
3 MAXIMUM TOLERATED DOSE. THERE'S NOTHING WRONG
4 INHERENTLY WITH SETTING UP THE TRIAL TO DO THIS. IT
5 WAS JUST UNCLEAR HOW THEY WERE GOING TO MOVE FORWARD
6 WITH MULTIPLE DOSES AS RECOMMENDED BY THE FDA.

7 DR. FISHER: HAS THE APPLICANT RESPONDED
8 TO THOSE QUESTIONS OR CONCERNS?

9 DR. SAMBRANO: NO. WHICH I THINK WAS THE
10 REASON FOR GIVING A 2 IN TERMS OF WANTING TO SEE A
11 RESPONSE TO THAT.

12 DR. FISHER: THANK YOU.

13 CHAIRMAN THOMAS: ANNE-MARIE.

14 DR. DULIEGE: WELL, MY QUESTION WAS THE
15 SAME. BUT WHAT DOES IT MEAN IF A POTENTIAL
16 APPLICANT DOES NOT RESPOND TO COMMENTS? WERE THEY
17 GIVEN THE TIME TO DO IT? SHOULD WE BE CONCERNED
18 ABOUT THAT OR NOT?

19 DR. SAMBRANO: NO. SINCE IT GOT A SCORE
20 OF 1, WE DON'T SEEK A RESPONSE FROM THE APPLICANT.
21 WE BRING THOSE APPLICATIONS STRAIGHT TO THE BOARD.
22 ONLY IF IT GETS A 2 DO WE THEN REQUEST THOSE
23 COMMENTS.

24 DR. DULIEGE: THANK YOU.

25 CHAIRMAN THOMAS: MARIA, ARE THERE OTHER

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1 HANDS RAISED BY BOARD MEMBERS?

2 MS. BONNEVILLE: THERE ARE NO OTHER HANDS
3 RAISED.

4 CHAIRMAN THOMAS: OKAY. THANK YOU.
5 ANY COMMENTS FROM MEMBERS OF THE PUBLIC?

6 MS. BONNEVILLE: I ALSO DO NOT SEE A HAND
7 RAISED.

8 CHAIRMAN THOMAS: THANK YOU. WILL YOU
9 PLEASE CALL THE ROLL.

10 MS. BONNEVILLE: YES. DAN BERNAL.

11 MR. BERNAL: AYE.

12 MS. BONNEVILLE: JUDY CHOU.

13 DR. CHOU: AYE.

14 MS. BONNEVILLE: LEONDRAL CLARK-HARVEY.

15 MS. CLARK-HARVEY: AYE.

16 MS. BONNEVILLE: ANNE-MARIE DULIEGE.

17 DR. DULIEGE: AYE.

18 MS. BONNEVILLE: MARK FISCHER-COLBRIE.

19 DR. FISCHER-COLBRIE: AYE.

20 MS. BONNEVILLE: ELENA FLOWERS.

21 DR. FLOWERS: YES.

22 MS. BONNEVILLE: DAVID HIGGINS.

23 DR. HIGGINS: YES.

24 MS. BONNEVILLE: RICH LAJARA.

25 MR. LAJARA: YES.

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1 MS. BONNEVILLE: CHRISTINE MIASKOWSKI.
2 DR. MIASKOWSKI: YES.
3 MS. BONNEVILLE: LAUREN MILLER-ROGEN.
4 MS. MILLER-ROGEN: YES.
5 MS. BONNEVILLE: ADRIANA PADILLA.
6 DR. PADILLA: YES.
7 MS. BONNEVILLE: JOE PANETTA.
8 MR. PANETTA: YES.
9 MS. BONNEVILLE: MARVIN SOUTHARD.
10 DR. SOUTHARD: YES.
11 MS. BONNEVILLE: JONATHAN THOMAS.
12 CHAIRMAN THOMAS: YES.
13 MS. BONNEVILLE: ART TORRES.
14 MR. TORRES: AYE.
15 MS. BONNEVILLE: KAROL WATSON.
16 DR. WATSON: YES.
17 MS. BONNEVILLE: MOTION CARRIES.
18 CHAIRMAN THOMAS: THANK YOU, MARIA.
19 I'D JUST LIKE TO COMMENT EDITORIALY. I
20 WAS PERSONALLY VERY PLEASED TO SEE THE VERY HIGH
21 LEVEL OF DEI SCORES ON ALL THREE OF THOSE
22 APPLICATIONS AS SOMETHING THAT WE REALLY APPRECIATE
23 AND HOPE THAT ALL APPLICANTS ASPIRE TO. ALL
24 APPLICANTS HERE GAVE A GREAT DEAL OF ATTENTION TO
25 THAT, AND THAT IS REFLECTED IN THE 8, 9, 9 SCORES

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1 THAT WE HAD. LET'S KEEP THAT COMING. IT'S A VERY,
2 VERY APPRECIATED DEVELOPMENT.

3 OKAY. ON TO ITEM NO. 3, WHICH IS
4 CONSIDERATION OF APPLICATIONS SUBMITTED IN RESPONSE
5 TO TRANSLATIONAL PROJECT PROGRAM ANNOUNCEMENT TRAN1,
6 2, 3, OR 4. PRESENTATION FROM DR. SAMBRANO.

7 DR. SAMBRANO: THANK YOU, MR. CHAIRMAN.
8 OKAY.

9 SO THESE ARE THE RECOMMENDATIONS FROM THE
10 GRANTS WORKING GROUP FOR OUR LATEST ROUND OF TRAN
11 APPLICATIONS. ONCE AGAIN, WE ALWAYS START WITH OUR
12 MISSION STATEMENT.

13 LET ME GIVE A LITTLE BACKGROUND ON THE
14 TRANSLATION PROGRAM. THIS SITS SQUARELY BETWEEN OUR
15 DISCOVERY AND CLINICAL PROGRAMS IN ADVANCING
16 PRODUCTS THAT ARE THERAPEUTIC OR OTHERWISE TOWARD
17 CLINICAL TRIALS OR END USE. SO THIS IS AN
18 OPPORTUNITY THAT WE OFFER TWICE PER YEAR.

19 THE TRANSLATION PROGRAM SUPPORTS DIFFERENT
20 TYPES OF THERAPEUTIC OR DIFFERENT TYPES OF PRODUCT,
21 INCLUDING THERAPEUTICS, DIAGNOSTICS, MEDICAL DEVICES
22 OR TOOLS; AND IT'S TAILORED, DEPENDING ON THE
23 PRODUCT TYPE, WITH DIFFERENT AWARD AMOUNTS AND
24 DIFFERENT TIMING THAT IS BEST SUITED TO DEVELOP AND
25 TAKE EACH OF THESE PRODUCTS TO THE END GOAL THAT IS

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1 DESCRIBED HERE.

2 SO FOR THE TRANSLATION PROGRAM, WE EXPECT
3 ALL APPLICANTS TO COME IN WITH SOME TYPE OF PROOF OF
4 CONCEPT. IF IT'S A THERAPEUTIC, WE ASK THAT THEY
5 DEMONSTRATE DISEASE MODIFYING ACTIVITY WITH THAT
6 CANDIDATE BEFORE COMING IN IN, FOR EXAMPLE, IN VIVO
7 AND IN VITRO STUDIES SHOWING THAT THIS GENERALLY
8 WORKS IN SOME SETTING. IT'S ONE OF THE OTHER
9 PRODUCT TYPES, THAT THEY HAVE DEVELOPED A PROTOTYPE
10 OF SOME SORT THAT SHOWS A PROOF OF CONCEPT. AT THE
11 END OF THE AWARD PERIOD, WE EXPECT THE GRANTEES TO
12 HAVE COMPLETED PRE-IND OR OTHER PRESUBMISSION
13 MEETING WITH THE FDA IF IT'S PART OF THEIR
14 REGULATORY PROCESS; OR, IF IT'S A TOOL, FOR THEM TO
15 TRANSFER THEIR DESIGN IT A MANUFACTURER TO MAKE IT
16 AVAILABLE TO OTHERS AS A TOOL.

17 THIS SLIDE IS JUST TO SHOW THE SEQUENCE OF
18 EVENTS IN TERMS OF DEVELOPING A PRODUCT AND WHERE
19 TRANSLATION FITS IN. IF SOMEBODY IS FOLLOWING OUR
20 FUNDING OPPORTUNITIES AND RECEIVING AWARDS, IT WOULD
21 FOLLOW THEIR DISCOVERY AWARD WITH A TRAN AWARD FROM
22 A 24- TO 30-MONTH PERIOD BEFORE GOING INTO PERHAPS A
23 CLIN1 TO DO THEIR IND-ENABLING STUDIES AND MAYBE
24 SUBSEQUENTLY A CLINICAL TRIAL. SO THERE ARE AT
25 LEAST A COUPLE OF STEPS BEFORE GETTING TO PATIENTS

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1 IF THEY SUCCEED.

2 THE REVIEW CRITERIA THAT ARE USED BY THE
3 GRANTS WORKING GROUP TO ASSESS THESE PROJECTS ARE
4 SIMILAR TO THE CLINICAL PROGRAM FOCUSED ON
5 SIGNIFICANCE AND IMPACT, RATIONALE, PLAN AND DESIGN,
6 AND THE FEASIBILITY, AS WELL AS ADDRESSING NEEDS OF
7 UNDERSERVED COMMUNITIES. HOWEVER, THE SCORING FOR
8 THESE APPLICATIONS IS A LITTLE DIFFERENT. IT IS
9 BASED ON A SCALE OF 1 TO 100 WITH A SCORE OF 85 TO
10 100 MEANING THAT IT'S RECOMMENDED FOR FUNDING IF
11 FUNDS ARE AVAILABLE. AND ANYTHING THAT SCORES
12 BETWEEN 1 AND 84 IS NOT RECOMMENDED FOR FUNDING.
13 AND ALL THE APPLICATIONS ARE SCORED BY SCIENTIFIC
14 MEMBERS OF THE WORKING GROUP WITH NO CONFLICT, AND
15 WE TAKE THE MEDIAN OF ALL OF THE INDIVIDUAL SCORES
16 TO DETERMINE WHAT THE FINAL SCORE IS FOR THESE
17 APPLICATIONS.

18 AS WITH THE CLINICAL PROGRAM, WE HAVE THE
19 COMPOSITION OF THE GRANTS WORKING GROUP THAT INCLUDE
20 THE SCIENTIFIC MEMBERS WHO DO THE SCIENTIFIC
21 EVALUATION AND PROVIDE THE SCIENTIFIC SCORE. OUR
22 PATIENT ADVOCATE AND NURSE MEMBERS PROVIDE THE
23 PERSPECTIVE ON SIGNIFICANCE AND POTENTIAL IMPACT AND
24 OVERSIGHT ON PROCESS. AND THIS IS THE FIRST ROUND
25 WHERE THEY ARE ALSO NOW PROVIDING A DEI SCORE. SO

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1 WE'VE JUST INTRODUCED THE DEI SCORING ELEMENT INTO
2 THE TRANS PROGRAM AND THIS IS THE FIRST CYCLE.

3 ONCE AGAIN, WE BRING IN SCIENTIFIC
4 SPECIALISTS AS NEEDED TO HELP US ASSESS APPLICATIONS
5 WHEN NEEDED.

6 THIS IS A REMINDER OF THE CONFLICTS OF
7 INTEREST THAT MAY EXIST FOR THE TRAN APPLICATIONS.
8 SO THE MEMBERS HAVE A CONFLICT WITH ONE OR MORE OF
9 THE APPLICATIONS THAT WE WILL BE DISCUSSING.

10 THIS IS A SUMMARY TABLE OF THE GRANTS
11 WORKING GROUP RECOMMENDATIONS FOR THOSE TRAN
12 APPLICATIONS. THERE ARE FOUR APPLICATIONS THAT
13 RECEIVED A SCORE OF 85 OR ABOVE THAT ARE RECOMMENDED
14 FOR FUNDING. THOSE FOUR APPLICATIONS TOTAL TO 16.2
15 MILLION. THE FUNDS AVAILABLE TO FUND CURRENTLY ARE
16 70.4 THAT WERE ALLOCATED AT THE BEGINNING OF THE
17 YEAR FOR TWO CYCLES. THIS IS THE FIRST OF TWO
18 CYCLES. AND FOR EACH AWARD, THE FINAL AWARD AMOUNT,
19 AS NOTED BELOW, DOES NOT EXCEED THE AMOUNT APPROVED
20 BY THE BOARD AND COULD BE REDUCED CONTINGENT ON
21 CIRM'S ASSESSMENT OF ALLOWABLE COSTS AND ACTIVITIES.

22 I WANT TO REMIND EVERYONE ABOUT MINORITY
23 REPORTS. UNDER PROP 14 ANY APPLICATION THAT IS NOT
24 RECOMMENDED FOR FUNDING BY THE GRANTS WORKING GROUP,
25 MEANING THAT IT GOT A SCORE BELOW 85, BUT WHICH HAD

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1 35 PERCENT OR MORE OF THE MEMBERS SCORING TO FUND
2 THE APPLICATION, THAT THAT APPLICATION MUST INCLUDE
3 A MINORITY REPORT. AND THE MINORITY REPORT IS
4 INCLUDED AS PART OF THE REVIEW SUMMARY THAT WE
5 PREPARED FOR YOU AND PROVIDES A BRIEF SYNOPSIS OF
6 THE OPINION OF REVIEWERS THAT SCORED THE APPLICATION
7 85 OR ABOVE.

8 SO WE DID HAVE ONE APPLICATION THAT
9 QUALIFIED FOR A MINORITY REPORT, WHICH WAS
10 TRAN1-13996. AND SO, IN GENERAL, THE CIRM TEAM
11 CONCURS WITH THE GRANTS WORKING GROUP RECOMMENDATION
12 FOR FUNDING THE FOUR APPLICATIONS THAT WERE
13 MENTIONED THAT RECEIVED A SCORE OF 85 OR ABOVE, BUT
14 IN ADDITION THE CIRM TEAM SUPPORTS THE MINORITY
15 POSITION FOR THIS PARTICULAR APPLICATION,
16 TRAN1-13996, AND RECOMMENDS FUNDING OF THAT
17 APPLICATION.

18 NOW, THE RATIONALE FOR THAT IS IN PART
19 SUMMARIZED IN THE MINORITY REPORT ITSELF, BUT THE
20 REASON FOR CIRM'S RECOMMENDATION CENTERS ON TWO
21 ELEMENTS THAT WE THINK WERE THE KEY CONCERNS FOR THE
22 APPLICATION.

23 THE FIRST IS THAT IN THE APPLICATION THE
24 APPLICANTS DID MAKE A CLAIM OF SUPERIORITY OF THEIR
25 PRODUCT FOR WHICH ADEQUATE EVIDENCE WAS NOT

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1 PROVIDED, BUT IT IS SOMETHING THAT IS PLANNED AS
2 PART OF THEIR PROPOSAL. SO SOME OF THE REVIEWERS
3 WERE OKAY WITH THAT AND DIDN'T FEEL THAT ADDITIONAL
4 STUDIES AT THIS TIME WERE NECESSARY GIVEN THAT THEY
5 WERE PLANNED, BUT OTHERS DID PREFER TO SEE IT BEFORE
6 MOVING FORWARD AND, THEREFORE, THERE WAS THAT
7 DIVIDE.

8 CIRM IS COMFORTABLE FUNDING THIS AWARD AND
9 HAVING THE APPLICANTS CONDUCT THESE STUDIES DURING
10 THEIR INITIAL FUNDING PHASE, AND IT WOULD MAKE FOR A
11 LOGICAL MILESTONE.

12 THE SECOND ELEMENT THAT WE FELT WAS KEY
13 WAS THAT REVIEWERS WERE UNCLEAR ABOUT THE NEED TO
14 REPEAT SOME OF THE STUDIES THAT WERE PROPOSED WITH A
15 GMP VECTOR AND PLASMID. THE APPLICANTS DID, IN
16 THEIR LETTER, THEY PROVIDED A LETTER THAT'S
17 ADDRESSED TO THE BOARD WHERE THEY LAY OUT A KEY
18 REASON FOR NEEDING TO REDO MUCH OF THE WORK WHICH
19 WAS DONE INITIALLY BY A COMPANY. AND SO THEY NO
20 LONGER HAVE ACCESS TO THAT DATA IN ORDER TO SUBMIT
21 TO THE FDA AND MEET FDA REQUIREMENTS, NEEDING TO
22 REPEAT, UNFORTUNATELY, SOME OF THAT WORK. AND SO
23 CIRM ITSELF ALSO FEELS THAT IT IS IMPORTANT TO
24 CONDUCT THESE STUDIES AND WOULD BENEFIT THE PROJECT
25 TO DO SO; AND, THEREFORE, THE PROJECT AS PLANNED, WE

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1 BELIEVE, IS APPROPRIATE AND WHY WE ARE RECOMMENDING
2 IT FOR FUNDING.

3 IT IS IMPORTANT TO NOTE THAT THIS
4 APPLICANT HAS COME IN ALREADY. THIS IS A REVISED
5 APPLICATION THAT THEY CAME IN WITH IN THIS CYCLE AND
6 SO DID ALSO PROVIDE SOME IMPROVEMENTS TO THE
7 APPLICATION FROM THE PREVIOUS VERSION.

8 LET ME STOP THE SHARE ON THIS PARTICULAR
9 PRESENTATION AND THEN SHOW YOU THE LIST OF
10 APPLICATIONS. GIVE ME A SECOND. SO HOPEFULLY YOU
11 CAN SEE THE EXCEL FILE THAT SHOWS THE FOUR
12 RECOMMENDED APPLICATIONS HERE THAT TOTAL THE 15.2.
13 THE APPLICATION THAT RECEIVED A MINORITY REPORT OR
14 QUALIFIED FOR A MINORITY REPORT THAT THE CIRM STAFF
15 IS RECOMMENDING IS SHOWN HERE. SO WITH THAT, I'LL
16 TURN IT BACK TO YOU, MR. CHAIRMAN.

17 CHAIRMAN THOMAS: OKAY. THANK YOU VERY
18 MUCH, GIL.

19 SO OUR VOTING ON THESE AWARDS IS A LITTLE
20 MORE COMPLICATED THAN ON THE CLIN AWARDS. SO IT'S A
21 FOUR-STEP PROCESS. FIRST, I'M GOING TO ASK IF THERE
22 ARE ANY MOTIONS TO MOVE ANY OF THE PROJECTS
23 CURRENTLY NOT RECOMMENDED FOR FUNDING UP TO THE
24 FUNDING RANGE. SECONDLY, I WILL ASK FOR ANY MOTIONS
25 TO MOVE ANY THAT ARE RECOMMENDED FOR FUNDING DOWN TO

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1 THE NOT RECOMMENDED FOR FUNDING RANGE. THIRDLY, WE
2 WILL THEN CLOSE OUT THE PROJECTS IN THE NOT
3 RECOMMENDED FOR FUNDING RANGE. AND FINALLY, WE WILL
4 VOTE ON APPROVING THOSE PROJECTS IN THE RECOMMENDED
5 FOR FUNDING RANGE.

6 SO WITH THAT, I ASK ARE THERE ANY MOTIONS
7 TO MOVE ANY OF THE PROJECTS CURRENTLY NOT
8 RECOMMENDED FOR FUNDING UP TO THE FUNDED RANGE?

9 I'M GOING TO MOVE THAT WE MOVE NO. 13996
10 UP TO THE FUNDED RANGE, WHICH IS THE PROJECT GIL
11 JUST DESCRIBED. IS THERE A SECOND TO THAT MOTION?

12 DR. HIGGINS: I'LL SECOND THAT.

13 CHAIRMAN THOMAS: THANK YOU, DAVID IN SAN
14 DIEGO.

15 QUESTIONS OR COMMENTS FROM MEMBERS OF THE
16 BOARD? I WILL JUST START OFF BY NOTING THAT I AGREE
17 WITH THE TEAM'S ANALYSIS OF WHY THIS SHOULD BE MOVED
18 UP. I WILL SIMPLY ADD TO THAT THAT THIS WAS
19 SOMETHING THAT HAD SIX IN FAVOR OF FUNDING AND SEVEN
20 HAD IT BELOW THE FUNDING LINE. SO THIS IS NOT
21 SOMETHING THAT IS WAY BELOW IN TERMS OF THE OVERALL
22 VOTE. SO THIS IS A MINORITY REPORT WITH A MINORITY
23 THAT'S JUST BELOW THE MAJORITY. SO THIS RECOMMENDS
24 A MATERIAL NUMBER OF THE GRANTS WORKING GROUP
25 MEMBERS WHO WERE IN FAVOR OF THIS GETTING FUNDED.

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1 OTHER COMMENTS OR QUESTIONS FROM MEMBERS
2 OF THE BOARD?

3 MS. BONNEVILLE: JOE HAS HIS HAND RAISED.

4 MR. PANETTA: THANK YOU. MY QUESTION IS
5 ON 13996, J.T. I THINK THIS IS A VERY IMPORTANT
6 APPLICATION TO BE PURSUED. I'M JUST CURIOUS ABOUT
7 THIS BEING A RESUBMISSION. AND, GIL, IF YOU CAN
8 TELL US WHAT WAS THE PREVIOUS SCORE AND HOW DID THEY
9 IMPROVE ON THAT PLEASE?

10 DR. SAMBRANO: SURE. ABSOLUTELY. I DON'T
11 RECALL THE PREVIOUS SCORE. I THINK IT WAS ALSO
12 BETWEEN 80 AND 84.

13 CHAIRMAN THOMAS: I THINK IT HAD AN 83,
14 GIL, IF I'M NOT MISTAKEN.

15 DR. SAMBRANO: SO IT MAY HAVE HAD AN 83 AS
16 WELL BEFORE, BUT IT IS DIFFICULT TO COMPARE A SCORE
17 FROM THE PREVIOUS. IF IT FALLS WITHIN THE SAME
18 RANGE, IT MEANS THAT THE OVERALL IMPROVEMENT MAY
19 HAVE BEEN MADE ON THE CONCERNS THAT WERE HIGHLIGHTED
20 BY THE PREVIOUS PANEL; BUT THE NEW PANEL, EVEN
21 THOUGH WE TRY TO ASSIGN THE SAME REVIEWERS, MAY HAVE
22 VIEWED IT AS EITHER NOT ENOUGH TO ADDRESS THEIR
23 CONCERNS OR MAY HAVE FOUND ADDITIONAL CONCERNS. SO
24 IT IS -- SOMETIMES WHAT HAPPENS IS APPLICANTS WILL
25 MAKE IMPROVEMENTS ON THE THINGS THEY CAN, AND

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1 SOMETIMES THERE ARE THINGS THAT THEY CANNOT. I
2 THINK IN THIS PARTICULAR CASE THERE WAS THE QUESTION
3 OF BOTH THE SUPERIORITY AND THE DATA TO SHOW THAT,
4 WHICH IS INCLUDED IN THE PROPOSAL. THE APPLICANT --
5 THIS IS NOT NECESSARILY HIGHLIGHTED AS A PREVIOUS
6 CONCERN.

7 THE REPEAT OF SOME OF THE STUDIES WAS ALSO
8 NOT NECESSARILY PREVIOUSLY HIGHLIGHTED AS A MAJOR
9 CONCERN. AND SO THESE IN SOME WAYS ARE NEW, BUT WE
10 ALSO FEEL THAT THESE ARE THINGS THAT CAN EASILY BE
11 ADDRESSED AND/OR ARE BEING ADDRESSED RELATIVE TO THE
12 INITIAL APPLICATION THAT WAS SUBMITTED.

13 CHAIRMAN THOMAS: I'D LIKE TO SAY THAT
14 THOSE CONCERNS RAISED ARE ADDRESSED IN THE LETTER
15 THAT WAS SENT TO THE BOARD THAT'S INCLUDED IN YOUR
16 MATERIALS AND ONLINE.

17 OTHER QUESTIONS OR COMMENTS FROM MEMBERS
18 OF THE BOARD?

19 MS. BONNEVILLE: LARRY HAS HIS HAND RAISED
20 AND THEN FRED.

21 CHAIRMAN THOMAS: THANK YOU. LARRY.

22 DR. GOLDSTEIN: I WANT TO JUST SUPPORT
23 GIL'S ANALYSIS OF WHY THIS SHOULD BE MOVED UP FOR
24 FUNDING. AND, IN PARTICULAR, I'LL POINT OUT THAT
25 ULTIMATELY, FOR FDA APPROVAL, THE MANUFACTURING

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1 PROCESS IS GOING TO HAVE TO BE REPRODUCIBLE. AND SO
2 IT'S REALLY IMPORTANT FOR THIS GROUP TO DEMONSTRATE
3 THAT THEY CAN REPRODUCE WHAT WAS ORIGINALLY DONE IN
4 A COMPANY WITH PRODUCTION OF THE VECTOR. AND SO I
5 THINK THAT'S QUITE A SALIENT REMARK AND REALLY OUGHT
6 TO BE CONSIDERED.

7 CHAIRMAN THOMAS: THANK YOU, LARRY. I'M
8 SORRY, MARIA, WHO WS NEXT? WAS IT FRED?

9 DR. FISHER: I THINK IT WAS ME. SO FROM A
10 PROCESS POINT OF VIEW, WE DON'T HAVE THE BENEFIT OF
11 FEEDBACK FROM THE GROUP THAT REVIEWED THIS PROPOSAL
12 RELATED TO THE APPLICANT'S RESPONSE TO HEAR FROM
13 THEM WHETHER OR NOT THE APPLICANT'S RESPONSE IS
14 SUFFICIENT TO INCREASE THEIR SCORES OR RESOLVED
15 THEIR CONCERNS. I'M ASSUMING THAT'S THE CASE. BUT
16 JUST WONDERING BECAUSE IT WOULD BE NICE TO BE ABLE
17 TO BENEFIT FROM THE GROUP THAT HAD THE CONCERNS TO
18 ADDRESS ANY CHANGE OF HEART THEY'VE HAD AS A RESULT
19 OF READING THE RESPONSE.

20 DR. SAMBRANO: RIGHT. WELL, RIGHT. WE
21 DON'T HAVE THE BENEFIT OF THE REVIEWERS READING THE
22 LETTER TO THE BOARD IF THAT'S WHAT YOU MEAN.

23 DR. FISHER: YEAH.

24 DR. SAMBRANO: WE DO HOWEVER -- OKAY. BUT
25 I WAS JUST POINTING OUT THAT WE DO HAVE THE BENEFIT

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1 OF HAVING LARGELY THE SAME REVIEWERS LOOK AT THE
2 SECOND REVISED APPLICATION AS THOSE THAT SAW THE
3 INITIAL ONE.

4 CHAIRMAN THOMAS: AND I WOULD ADD, FRED,
5 THAT OUR TEAM, THEY KNOW WHAT THE CONCERNS WERE OF
6 THE GWG, AND THEY HAVE THE LETTER RESPONDING IN
7 FRONT OF THEM. AND THEY ACT AS A BIT OF A SURROGATE
8 OF SORTS TO RESPONDING TO THE RESPONSE AND, BASED ON
9 THAT, HAVE MADE A RECOMMENDATION THAT WE MOVE THIS
10 UP. SO IT'S NOT QUITE THE SAME, BUT WE HAVE A VERY
11 INFORMED ANALYSIS OF THAT LETTER BY GIL AND MEMBERS
12 OF THE TEAM TO GO BY HERE.

13 DR. FISHER: I APPRECIATE THAT AND HAVE
14 GREAT RESPECT FOR THE TEAM, AND CERTAINLY THAT
15 WEIGHS HEAVILY IN MY THINKING ABOUT MOVING THIS UP.
16 THANK YOU.

17 CHAIRMAN THOMAS: THANK YOU. MARIA,
18 QUESTIONS OR COMMENTS FROM MEMBERS OF THE BOARD?

19 MS. BONNEVILLE: THERE ARE NO OTHER HANDS
20 RAISED.

21 CHAIRMAN THOMAS: OKAY. DO WE HAVE
22 COMMENTS FROM MEMBERS OF THE PUBLIC?

23 MS. BONNEVILLE: I BELIEVE WE DO, BUT I DO
24 NOT SEE HANDS RAISED. PERHAPS NOT AFTER ALL.

25 DR. FISHER: LOOKS LIKE MARTIN HAS HIS

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1 HAND UP.

2 MS. BONNEVILLE: MARTIN, GO AHEAD. IS
3 THIS REGARDING THIS APPLICATION? YOU'RE ON MUTE.
4 I'M SORRY. MARTIN, IS IT IN REFERENCE TO THIS
5 APPLICATION?

6 DR. MARSALA: YES. IT'S 14001, AND I
7 SUBMITTED LETTER TO THE BOARD.

8 MS. BONNEVILLE: OH, NO. THIS IS A
9 DIFFERENT -- I'M SORRY. THIS IS A DIFFERENT
10 APPLICATION THAT WE ARE TALKING ABOUT RIGHT NOW.
11 THERE'S PUBLIC COMMENT FOR THIS APPLICATION.

12 DR. MARSALA: OKAY.

13 DR. TOSCANO: I DON'T KNOW IF YOU CAN HEAR
14 ME. THIS IS JOE TOSCANO, UC DAVIS. I THINK THERE
15 ARE SOME PUBLIC COMMENTS.

16 MS. BONNEVILLE: YES, I CAN HEAR YOU.

17 DR. TOSCANO: DR. WILLIAM MURPHY, I THINK,
18 IS GOING TO COMMENT AND THEN MYSELF AS WELL AND
19 MAYBE A PATIENT ADVOCATE.

20 MS. BONNEVILLE: GREAT. I JUST DON'T SEE
21 ANY HANDS RAISED AND NO ONE HAS UNMUTED THEMSELVES.
22 SO I CAN'T DISTINGUISH BETWEEN. SO IF YOU WANT TO
23 START --

24 DR. MURPHY: THIS IS BILL MURPHY. CAN YOU
25 HEAR ME NOW?

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1 MS. BONNEVILLE: YES, WE CAN. THANK YOU
2 SO MUCH. AND YOU'LL HAVE THREE MINUTES FOR PUBLIC
3 COMMENT.

4 DR. MURPHY: THANK YOU. I'LL BE BRIEF.
5 I'M SORRY. I WAS TRYING TO HIT 9 AND IT WOULDN'T
6 WORK.

7 FIRST, I WANT TO THANK THE COMMITTEE. I
8 FOUND THE COMMENTS WERE EXTREMELY HELPFUL. I HOPE
9 THAT THE LETTER THAT WE WROTE IN RESPONSE CLEARED UP
10 SOME OF THE ISSUES BECAUSE IT REALLY WASN'T CLEAR ON
11 WHY WE NEEDED TO GENERATE PRIMARY DATA BASED ON THE
12 EFFICACY THAT WAS SHOWN BY OUR COLLABORATORS IN THE
13 PAPER THAT WAS PUBLISHED IN *SCIENCE TRANSLATIONAL*
14 *MEDICINE*. I THINK THAT SORT OF CLARIFIES ON, AND
15 THAT WAS WHAT WAS KIND OF A CONFUSING PART AS FAR
16 WHY DID WE NEED TO REDO THINGS BASED ON THE VECTOR,
17 BUT THEN ALSO THE FACT THAT WE WERE ALREADY CLEARLY
18 SEEING TREMENDOUS SYNERGY AND ANTITUMOR EFFECTS.

19 SO I GUESS THE BOTTOM LINE IS I THINK
20 THAT, BASED ON WHAT WE WROTE IN THE LETTER,
21 HOPEFULLY IT CLARIFIES AS FAR AS HOW WE IMPROVED.
22 ALSO, OUR DEI RECEIVED EXCELLENT SCORES. SO WE
23 THINK THAT REALLY OVERALL WE'RE READY TO GO TO THE
24 NEXT STAGE. I JUST CAN'T SAY -- I'VE BEEN DOING
25 CANCER IMMUNOLOGY FOR 35 YEARS. AND CAR T CELLS ARE

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1 GOING TO BE, IN MY OPINION, THE NEXT WAVE. AND THIS
2 REQUIRES A DANCE BETWEEN MOLECULAR THERAPY, GENE
3 THERAPY, CELL ENGINEERING, IMMUNOLOGY, AND
4 PRECLINICAL MODELING. AND THE TEAM THAT I THINK IS
5 ASSEMBLED THAT IS GOING TO MAKE THIS NOW ACCESSIBLE
6 WITHIN OUR CATCHMENT AREA IS TREMENDOUS.

7 SO I CAN'T SPEAK ENOUGH. AND ON ANOTHER
8 NOTE, WE'VE ALREADY BEEN SUCCESSFULLY ESTABLISHING
9 MODELS, AND WE HAVE -- THE DATA THAT WE'RE GETTING
10 NOW IS JUST INCREDIBLE. THIS TRI-SPECIFIC, THE DUAL
11 CAR CONSTRUCT IS, I THINK, IN CANCER BECAUSE ANTIGEN
12 LOSS IS ALWAYS THE ISSUE, MAJOR ISSUE. I THINK THIS
13 IS REALLY GOING TO BE A GAME CHANGER. AND THIS
14 COULD INCREASE APPLICABILITY FOR A VARIETY OF
15 PATIENT POPULATIONS.

16 SO, ANYWAY, THAT'S REALLY WHAT I WANTED TO
17 SAY, AND I APPRECIATE THE COMMITTEE'S ENTHUSIASM AND
18 REPORTS THAT WE'VE SEEN. HOPEFULLY THESE ISSUES
19 WERE CLEARED UP. I'VE BEEN DOING THESE PRECLINICAL
20 MODELS FOR 35 YEARS, AND I CAN TELL YOU WE'LL BE
21 LOOKING AT IT VERY CAREFULLY AS FAR AS ALL THE
22 CAVEATS POSED, EFFICACY AS WELL AS ON THE TUMOR, SO
23 NOTHING WILL BE UNTURNED. THAT'S IT FOR ME.

24 CHAIRMAN THOMAS: THANK YOU, DR. MURPHY.

25 DR. TOSCANO: THIS IS JOE TOSCANO, UC

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1 DAVIS. JUST A COUPLE OF QUICK COMMENTS. I'VE BEEN
2 AT UC DAVIS WORKING IN TRANSLATIONAL RESEARCH FOR
3 IMMUNOTHERAPEUTICS FOR 30 YEARS BOTH HERE AND NIH
4 AND ALSO HAVE A LARGE PORTFOLIO OF CLINICAL TRIALS,
5 TAKE CARE OF A LOT OF PATIENTS, DIRECTOR OF THE
6 TRANSPLANT PROGRAM HERE. SO I HAVE A BROAD
7 PERSPECTIVE AND HAVE WATCHED, HAD A GOOD PERSPECTIVE
8 ON TRANSLATING THINGS FROM BENCH TO BEDSIDE.

9 I THINK WE ARE ALL AWARE OF THE POTENTIAL
10 OF CAR T PRODUCTS. THE CURRENT FDA APPROVED
11 PRODUCTS, AGAIN, WORK VERY WELL, MOST RESPOND, BUT
12 THE VAST MAJORITY RELAPSE. THOSE PATIENTS THAT
13 RELAPSE HAVE A DISMAL PROGNOSIS. REALLY FEW
14 THERAPEUTIC OPTIONS THAT PRODUCE DURABLE REMISSIONS
15 WITH THE EXCEPTION OF ALLOGENEIC TRANSPLANT, WHICH
16 IS VERY TOXIC, AND MANY DON'T HAVE SUITABLE DONORS.
17 SO THAT'S NOT REALLY AN OPTION FOR THE MAJORITY OF
18 PATIENTS.

19 SO THIS PRODUCT REALLY WILL ADDRESS A
20 SIGNIFICANT UNMET CLINICAL NEED, HAS THE POTENTIAL
21 TO SIGNIFICANTLY REDUCE THE RELAPSE RATE, AND/OR BE
22 AN OPTION, A SALVAGE OPTION, FOR THESE PATIENTS THAT
23 FAIL FDA-APPROVED STANDARD OF CARE CAR T PRODUCTS.

24 I THINK THAT BILL MENTIONED THE TEAM. HE
25 DIDN'T DO IT JUSTICE. THE TEAM HERE IS IMPECCABLE.

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1 IT'S AMAZING. BILL MURPHY IS A WORLD RENOWN T CELL,
2 NTA CELL BIOLOGIST. JAN NOLTA, OH, MY GOSH, JUST A
3 WORLD RENOWNED STEM CELL BIOLOGIST. GERHARDT BAUER,
4 HE'S BEEN MAKING CAR T'S FOR OTHER UNIVERSITIES, OUR
5 UNIVERSITY, OTHER INDUSTRIES, UNIQUELY POISED TO
6 BRING THIS TO PATIENTS. MEHRDAD ABEDI AND THEN
7 CARING CROSS. CARING CROSS IS AN AMAZING
8 COLLABORATOR THAT REALLY FOCUSES ON BRINGING THINGS
9 TO PATIENTS, NOT NECESSARILY PROFIT. SO IT'S VERY
10 REFRESHING, AND I'LL STOP THERE.

11 CHAIRMAN THOMAS: THANK YOU VERY MUCH.
12 MARIA, ARE THERE OTHER HANDS RAISED FOR PUBLIC
13 COMMENT?

14 MS. BONNEVILLE: I BELIEVE HE MENTIONED
15 ONE OTHER PERSON WHO MIGHT BE GIVING PUBLIC COMMENT.
16 IF SO, YOU CAN UNMUTE YOURSELF. OTHERWISE, I THINK
17 WE'LL BE DONE. I THINK THAT'S IT.

18 DR. TOSCANO: NATHAN MCNEAL.

19 MS. BONNEVILLE: GO AHEAD. THANK YOU.

20 DR. TOSCANO: MR. MCNEAL?

21 MS. BONNEVILLE: YES.

22 DR. TOSCANO: HE WAS A PATIENT ADVOCATE,
23 BUT I GUESS HE COULDN'T STAY ON.

24 MS. BONNEVILLE: THANK YOU. J.T., THAT'S
25 IT.

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1 CHAIRMAN THOMAS: THANK YOU, MARIA. COULD
2 YOU PLEASE CALL THE ROLL ON THIS MOTION.

3 MS. BONNEVILLE: YES. DAN BERNAL.

4 MR. BERNAL: AYE.

5 MS. BONNEVILLE: JUDY CHOU.

6 DR. CHOU: AYE.

7 MS. BONNEVILLE: LEONDRAL CLARK-HARVEY.

8 MS. CLARK-HARVEY: AYE.

9 MS. BONNEVILLE: ANNE-MARIE DULIEGE.

10 DR. DULIEGE: AYE.

11 MS. BONNEVILLE: YSABEL DURON.

12 MS. DURON: AYE, EXCEPT IF I HAVE ANY
13 CONFLICTS.

14 MS. BONNEVILLE: YOU DON'T HAVE A CONFLICT
15 WITH THIS ONE.

16 MS. DURON: THANK YOU VERY MUCH. AYE.

17 MS. BONNEVILLE: YOU'RE WELCOME.

18 MARK FISCHER-COLBRIE. FRED FISHER.

19 DR. FISHER: AYE.

20 MS. BONNEVILLE: ELENA FLOWERS.

21 DR. FLOWERS: JUST CLARIFYING. THE
22 CURRENT MOTION IS JUST TO MOVE 13996 INTO THE
23 CONSIDERATION FOR FUNDING. YES.

24 MS. BONNEVILLE: DAVID HIGGINS.

25 DR. HIGGINS: YES.

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1 MS. BONNEVILLE: RICH LAJARA.
2 MR. LAJARA: YES.
3 MS. BONNEVILLE: CHRISTINE MIASKOWSKI.
4 DR. MIASKOWSKI: YES.
5 MS. BONNEVILLE: LAUREN MILLER-ROGEN.
6 MS. MILLER-ROGEN: YES.
7 MS. BONNEVILLE: ADRIANA PADILLA.
8 DR. PADILLA: YES.
9 MS. BONNEVILLE: JOE PANETTA.
10 MR. PANETTA: YES.
11 MS. BONNEVILLE: MARVIN SOUTHARD.
12 DR. SOUTHARD: YES.
13 MS. BONNEVILLE: JONATHAN THOMAS.
14 CHAIRMAN THOMAS: YES.
15 MS. BONNEVILLE: ART TORRES.
16 MR. TORRES: YES.
17 MS. BONNEVILLE: KAROL WATSON.
18 DR. WATSON: YES.
19 MS. BONNEVILLE: THE MOTION -- LET ME JUST
20 GO BACK TO IS MARK FISCHER-COLBRIE IN THE ROOM, IN
21 THE ZOOM ROOM? I DO NOT SEE HIM. OKAY. THE MOTION
22 CARRIES.
23 CHAIRMAN THOMAS: THANK YOU, MARIA.
24 OKAY. SO WE NOW GO ON TO STEP TWO. ARE
25 THERE ANY MOTIONS TO PULL ANY OF THE PROJECTS

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1 RECOMMENDED FOR FUNDING DOWN TO THE NOT RECOMMENDED
2 RANGE? OKAY. HEARING NONE --

3 MS. BONNEVILLE: J.T., WE MIGHT ASK IF
4 THERE ARE ANY OTHER APPLICATIONS THAT BOARD MEMBERS
5 WANTED TO MOVE UP.

6 CHAIRMAN THOMAS: I ASSUME SINCE NOBODY
7 HAD SAID ANYTHING. YES. WE'LL DO THAT. ARE THERE
8 ANY OTHER APPLICATIONS ANY BOARD MEMBERS WISH TO
9 MOVE UP TO THE RECOMMENDED FOR FUNDING RANGE?

10 OKAY. HEARING NONE, ARE THERE ANY
11 PROJECTS THAT BOARD MEMBERS WANT TO MOVE DOWN FROM
12 THE RECOMMENDED FOR FUNDING TO THE NOT RECOMMENDED
13 FOR FUNDING RANGE?

14 MS. BONNEVILLE: FRED HAS HAND RAISED.

15 DR. FISHER: SHOULD WE BE TALKING ABOUT
16 13997 GIVEN THAT IT WAS A SPLIT DECISION, WHICH I
17 ASSUME MEANS NO MINORITY REPORT SINCE THERE WASN'T A
18 MINORITY. SO I'M NOT EXACTLY MAKING A MOTION TO
19 MOVE IT DOWN, BUT I'M JUST WONDERING IF WE SHOULD BE
20 OR AT WHAT POINT WE SHOULD BE DISCUSSING WHAT WE
21 SHOULD TAKE AWAY FROM THAT SPLIT AND A BORDERLINE
22 SCORE.

23 CHAIRMAN THOMAS: SO IT IS IN THE
24 RECOMMENDED FOR FUNDING RANGE. IF THERE IS NO
25 MOTION TO MOVE IT DOWN, WE WILL NOT BE GENERATING

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1 ANY DISCUSSION ON THAT TOPIC. SO UNLESS YOU WOULD
2 LIKE TO RECOMMEND THAT IT BE MOVED DOWN FOR PURPOSES
3 OF DISCUSSION OR OTHERWISE, I THINK WE ARE TAKING IT
4 AS IS.

5 DR. FISHER: WELL, I'LL THEN MAKE THE
6 MOTION TO MOVE IT DOWN. AND IF THERE'S NO SECOND, I
7 WON'T BE INSULTED.

8 CHAIRMAN THOMAS: IT'S BEEN MOVED TO MOVE
9 PROJECT 13997 DOWN FROM THE FUNDED TO THE NOT
10 RECOMMENDED RANGE. IS THERE A SECOND? NOT HEARING
11 ONE, FRED. GOING TO GO AS IS. THANK YOU FOR
12 RAISING THAT QUESTION.

13 ARE THERE -- NOW WE'RE GOING TO GO DOWN TO
14 ARE THERE -- IS THERE A MOTION THAT WE NOT APPROVE,
15 IT'S A NEGATIVE, NOT APPROVE THOSE PROJECTS IN THE
16 NOT RECOMMENDED FOR FUNDING RANGE AS A GROUP? IS
17 THERE A MOTION TO THAT EFFECT?

18 DR. FISHER: SO MOVED.

19 CHAIRMAN THOMAS: MOVED BY FRED. IS THERE
20 A SECOND?

21 DR. SOUTHARD: SECOND.

22 CHAIRMAN THOMAS: SECONDED BY MARV.

23 ANY QUESTIONS OR COMMENTS FROM MEMBERS OF
24 THE BOARD ON THIS MOTION? MARIA, NONE, I'M
25 GUESSING?

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1 MS. BONNEVILLE: NO.

2 CHAIRMAN THOMAS: IS THERE ANY PUBLIC
3 COMMENT ON THIS MOTION?

4 MS. BONNEVILLE: I SEE A HAND RAISED. IF
5 YOU WOULD LIKE TO UNMUTE YOURSELF. THE NUMBER IS
6 646 -- GO AHEAD.

7 CHAIRMAN THOMAS: PLEASE IDENTIFY
8 YOURSELF.

9 MS. BERENT: HELLO. MY NAME IS ALLISON
10 BRENT. SO I WOULD LIKE TO TAKE THE OPPORTUNITY TO
11 JUST THANK THE CALIFORNIA INSTITUTE OF REGENERATIVE
12 MEDICINE, THE INDEPENDENT CITIZENS OVERSIGHT
13 COMMITTEE, AND THE APPLICATION REVIEW COMMITTEE ON
14 BEHALF OF THIS APPLICATION FOR THE TRAN1-13997, THE
15 DEVELOPMENT OF A GENE THERAPY FOR THE TREATMENT OF
16 PITT-HOPKINS SYNDROME.

17 MY NAME IS ALLYSON BERENT, AND I AM THE
18 CHIEF DEVELOPMENT OFFICER FOR MAHZI AND THE PI ON
19 THIS GRANT APPLICATION.

20 ON BEHALF OF THE ENTIRE TEAM AT MAHZI,
21 WE'RE GRATEFUL FOR THE OPPORTUNITY TO ADVANCE OUR
22 PROGRAM FOR THIS ULTRA RARE DISEASE. IT'S CALLED
23 PITT-HOPKINS SYNDROME. THERE ARE ABSOLUTELY NO
24 APPROVED THERAPIES FOR THIS DISEASE THAT HAS A HUGE
25 CLINICAL UNMET NEED. WITH SUCH INCREDIBLY PROMISING

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1 PROOF OF CONCEPT DATA, WE ARE VERY GRATEFUL IF WE
2 ARE ABLE TO RECEIVE THE SUPPORT TO ADVANCE THIS
3 PROGRAM FOR CHILDREN LIVING WITH THIS DEVASTATING
4 DISORDER.

5 IN ADDITION, I'M THE MOTHER TO A BEAUTIFUL
6 LITTLE GIRL THAT LIVES WITH ANOTHER RARE, YET HIGHLY
7 DEVASTATING NEURODEVELOPMENTAL DISORDER CALLED
8 ANGELMAN SYNDROME, WHICH MANY OF YOU MAY KNOW. I
9 CAN ASSURE YOU THAT THE IMPACT THAT CIRM IS MAKING
10 ON SO MANY SCIENTIFIC AND PATIENT COMMUNITIES IS
11 ACTUALLY QUITE PROFOUND. THERE'S PROMISING CLINICAL
12 DATA IN HUMANS TO SUPPORT POSTNATAL DELIVERY OF
13 DISEASE MODIFYING THERAPIES, LIKE GENE THERAPIES, IN
14 NEURODEVELOPMENTAL DISORDERS, WHICH HAVE A LARGE
15 CLINICAL IMPACT ON THOSE LIVING WITH THESE
16 MONOGENETIC NONDEGENERATIVE DISEASES.

17 THIS IS A NEW ERA TO POTENTIALLY
18 PROFOUNDLY IMPROVE THE LIVES OF THESE CHILDREN AND
19 THEIR FAMILIES, AND WE'RE VERY HOPEFUL TO BE ABLE TO
20 REACH THIS GOAL FOR MANY OTHER MONOGENETIC
21 NEURODEVELOPMENTAL DISORDERS AND FUNDING AS WELL.

22 MAHZI THERAPEUTICS WAS STARTED TO ADVANCE
23 VERY PROMISING PROOF OF CONCEPT WORK IN
24 COLLABORATION WITH THE RESEARCH FOUNDATIONS MADE UP
25 OF FAMILIES OF THOSE IMPACTED TO ENSURE THAT PROPER

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1 DILIGENCE IS DONE, THAT THE PROGRAMS ARE ADVANCED,
2 AND THAT THESE THERAPIES HAVE EVERY CHANCE TO MAKE
3 IT TO HUMANS AS QUICKLY AND AS SAFELY AS POSSIBLE.
4 WE WORK CLOSELY WITH THE PITT-HOPKINS RESEARCH
5 FOUNDATION, A CALIFORNIA BASED NOT-FOR-PROFIT
6 ORGANIZATION. AND THEY TOO ARE INCREDIBLY GRATEFUL
7 AND OPTIMISTIC FOR YOUR SUPPORT OF THIS AWARD. THE
8 IMPACT YOU WILL BE MAKING ON SO MANY RARE DISEASES
9 AND LIVES OF THESE INDIVIDUALS NEEDS TO BE
10 RECOGNIZED. AND WE WANT TO THANK YOU FOR ALL OF
11 YOUR SUPPORT FOR THIS PROGRAM AND HOPEFULLY MANY
12 MORE IN THE FUTURE. THANK YOU.

13 CHAIRMAN THOMAS: THANK YOU VERY MUCH. WE
14 WILL FILE THAT COMMENT UNDER THE NEXT MOTION THAT
15 WILL BE RAISED AFTER WE VOTE ON THIS. BUT WE VERY
16 MUCH APPRECIATE THOSE COMMENTS AS VERY WELL
17 ARTICULATED. SO THANK YOU VERY MUCH.

18 SO, MARIA, ARE THERE ANY PUBLIC COMMENTS
19 ON THIS MOTION TO NOT APPROVE THOSE PROJECTS IN THE
20 NOT FOR RECOMMENDED FUNDING RANGE?

21 MS. BONNEVILLE: I DO NOT SEE ANY OTHER
22 HANDS RAISED.

23 CHAIRMAN THOMAS: WILL YOU PLEASE CALL
24 ROLL.

25 MS. BONNEVILLE: I'LL REMIND EVERYONE OF

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1 THE MOTION, AND THAT'S TO NOT FUND THOSE IN THE
2 UNFUNDABLE CATEGORY. AND IF YOU COULD PLEASE SAY
3 YES OR NO EXCEPT FOR THOSE WITH WHICH YOU HAVE A
4 CONFLICT IF YOU HAVE A CONFLICT. THANK YOU.

5 DAN BERNAL.

6 MR. BERNAL: AYE.

7 MS. BONNEVILLE: JUDY CHOU.

8 DR. CHOU: YES.

9 MS. BONNEVILLE: LEONDRAL CLARK-HARVEY.

10 MS. CLARK-HARVEY: YES.

11 MS. BONNEVILLE: ANNE-MARIE DULIEGE.

12 DR. DULIEGE: YES.

13 MS. BONNEVILLE: YSABEL DURON.

14 MS. DURON: YES, EXCEPT FOR THOSE WITH
15 WHICH I HAVE A CONFLICT.

16 MS. BONNEVILLE: MARK FISCHER-COLBRIE.

17 FRED FISHER.

18 DR. FISHER: AYE.

19 MS. BONNEVILLE: ELENA FLOWERS.

20 DR. FLOWERS: YES.

21 MS. BONNEVILLE: DAVID HIGGINS.

22 DR. HIGGINS: YES.

23 MS. BONNEVILLE: RICH LAJARA.

24 MR. LAJARA: YES.

25 MS. BONNEVILLE: CHRISTINE MIASKOWSKI.

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DR. MIASKOWSKI: YES.

MS. BONNEVILLE: LAUREN MILLER-ROGEN.

MS. MILLER-ROGEN: YES.

MS. BONNEVILLE: ADRIANA PADILLA.

DR. PADILLA: YES.

MS. BONNEVILLE: JOE PANETTA.

MR. PANETTA: YES.

MS. BONNEVILLE: MARVIN SOUTHARD.

DR. SOUTHARD: YES.

MS. BONNEVILLE: JONATHAN THOMAS.

CHAIRMAN THOMAS: YES.

MS. BONNEVILLE: ART TORRES.

MR. TORRES: AYE, EXCEPT FOR THOSE WITH WHICH I HAVE A CONFLICT.

MS. BONNEVILLE: KAROL WATSON.

DR. WATSON: YES, EXCEPT FOR THOSE WITH WHICH I HAVE A CONFLICT.

MS. BONNEVILLE: THANK YOU SO MUCH.

MOTION CARRIES.

CHAIRMAN THOMAS: THANK YOU, MARIA.

WE ARE ON TO PART FOUR OF THIS VOTING PROCESS, WHICH IS DO WE HAVE A MOTION TO APPROVE ALL THOSE PROJECTS LISTED IN THE RECOMMENDED FOR FUNDING RANGE?

DR. FISHER: SO MOVED.

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1 CHAIRMAN THOMAS: MOVED BY FRED.

2 DR. SOUTHARD: SECOND BY MARVIN.

3 CHAIRMAN THOMAS: SECONDED BY MARVIN. ANY
4 QUESTIONS OR COMMENTS, MEMBERS OF THE BOARD?

5 MS. BONNEVILLE: I SEE NO HANDS RAISED.

6 CHAIRMAN THOMAS: THANK YOU. ANY
7 QUESTIONS OR COMMENTS BY MEMBERS OF THE PUBLIC. AND
8 AS NOTED A COUPLE OF MINUTES AGO, WE INCORPORATED
9 THOSE IMPORTANT COMMENTS FROM THE LAST COMMENTER IN
10 THIS MOTION. ANY OTHER PUBLIC COMMENT ON THIS
11 MOTION?

12 MS. BONNEVILLE: THERE ARE NO MORE.

13 CHAIRMAN THOMAS: HEARING NONE, MARIA,
14 WILL YOU PLEASE CALL THE ROLL.

15 MS. BONNEVILLE: I'D LIKE TO REMIND
16 EVERYONE AGAIN, YES OR NO EXCEPT FOR THOSE WITH
17 WHICH YOU HAVE A CONFLICT IF YOU HAVE A CONFLICT.

18 DAN BERNAL.

19 MR. BERNAL: AYE.

20 MS. BONNEVILLE: JUDY CHOU.

21 DR. CHOU: YES.

22 MS. BONNEVILLE: LEONDRA CLARK-HARVEY.

23 MS. CLARK-HARVEY: YES.

24 MS. BONNEVILLE: ANNE-MARIE DULIEGE.

25 DR. DULIEGE: YES.

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1 MS. BONNEVILLE: YSABEL DURON.

2 MS. DURON: YES, EXCEPT FOR THOSE WITH
3 WHICH I HAVE A CONFLICT.

4 MS. BONNEVILLE: MARK FISCHER-COLBRIE.
5 FRED FISHER.

6 DR. FISHER: YES.

7 MS. BONNEVILLE: ELENA FLOWERS.

8 DR. FLOWERS: YES.

9 MS. BONNEVILLE: DAVID HIGGINS.

10 DR. HIGGINS: YES.

11 MS. BONNEVILLE: RICH LAJARA.

12 MR. LAJARA: YES.

13 MS. BONNEVILLE: CHRISTINE MIASKOWSKI.

14 DR. MIASKOWSKI: YES.

15 MS. BONNEVILLE: LAUREN MILLER-ROGEN.

16 MS. MILLER-ROGEN: YES.

17 MS. BONNEVILLE: ADRIANA PADILLA.

18 DR. PADILLA: YES.

19 MS. BONNEVILLE: JOE PANETTA.

20 MR. PANETTA: YES.

21 MS. BONNEVILLE: MARVIN SOUTHARD.

22 DR. SOUTHARD: YES.

23 MS. BONNEVILLE: JONATHAN THOMAS.

24 CHAIRMAN THOMAS: YES.

25 MS. BONNEVILLE: ART TORRES.

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1 MR. TORRES: AYE, EXCEPT FOR THOSE WITH
2 WHICH I HAVE A CONFLICT.

3 MS. BONNEVILLE: KAROL WATSON.

4 DR. WATSON: YES, EXCEPT FOR THOSE WITH
5 WHICH I HAVE A CONFLICT.

6 MS. BONNEVILLE: THANK YOU. THE MOTION
7 CARRIES.

8 CHAIRMAN THOMAS: THANK YOU, MARIA. THANK
9 YOU, GIL AND YOUR TEAM, FOR YOUR USUAL EXCELLENT
10 JOB. THAT CONCLUDES THE ACTION ITEMS ON TODAY'S
11 AGENDA.

12 WE ARE NOW DOWN TO PUBLIC COMMENT ON ANY
13 TOPICS OF ANY INTEREST. DO WE HAVE ANY SUCH PUBLIC
14 COMMENT? HEARING NONE, THAT THEN CONCLUDES THIS
15 AGENDA.

16 I WANT TO REMIND EVERYBODY OUR NEXT BOARD
17 MEETING IS DECEMBER 15TH. IT WILL BE A FULL BOARD
18 MEETING AND THAT IS A BIG ONE. WE ARE SCHEDULED TO
19 VOTE ON THE NEW CHAIR AT THAT MEETING. SO I WANT TO
20 MAKE SURE TO ENCOURAGE EVERYBODY TO HAVE THAT ON
21 YOUR CALENDAR AND PLEASE PLAN ON ATTENDING. AND
22 ALSO TO REMIND EVERYONE THAT THE JANUARY BOARD
23 MEETING, WHICH IS JANUARY 26TH, IS GOING TO BE IN
24 PERSON. AND AT THAT MEETING WE WILL OFFICIALLY
25 SWEAR IN OUR NEW CHAIR AND VICE CHAIR BONNEVILLE AS

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1 WELL AS SEND THE CURRENT CHAIR AND VICE CHAIR OFF
2 RIDING INTO THE SUNSET. SO PLEASE ASK EVERYBODY TO
3 MAKE SURE YOU ATTEND THAT MEETING IF AT ALL
4 POSSIBLE.

5 MR. TORRES: GO U.S.A. TODAY AT 11 O'CLOCK
6 AGAINST THOSE IRANIANS.

7 CHAIRMAN THOMAS: YES. BIG GAME. FOX TV.
8 SO --

9 MS. DURON: CAN I ADD IT'S NOT THE TEAM WE
10 SHOULD BE AGAINST. IT'S THE LEADERSHIP OF IRAN.

11 CHAIRMAN THOMAS: THANK YOU FOR MAKING
12 THAT POINT, YSABEL.

13 ANY OTHER SPORTS COMMENTS? YOU KNOW HOW
14 MUCH I WELCOME THAT SORT OF THING. NO. OKAY.
15 WELL, WITH THAT, EVERYBODY HAVE A NICE REST OF
16 NOVEMBER AND WE WILL SEE YOU NEXT MONTH. THANK YOU
17 VERY MUCH TO MARIA AND DOUG AND MARIANNE AND
18 EVERYBODY ELSE WHO MADE THIS MEETING RUN SO
19 SEAMLESSLY. SO THANKS VERY MUCH.

20 (THE MEETING WAS THEN CONCLUDED AT 10:19
21 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 APPLICATION REVIEW SUBCOMMITTEE OF THE INDEPENDENT CITIZEN'S OVERSIGHT COMMITTEE OF THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE IN THE MATTER OF ITS REGULAR MEETING HELD ON NOVEMBER 29, 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
133 HENNA COURT
SANDPOINT, IDAHO
(208) 920-3543