

BETH C. DRAIN, CA CSR NO. 7152

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

LOCATION: VIA ZOOM

DATE: APRIL 25, 2024
9 A.M.

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

FILE NO.: 2024-20

**133 HENNA COURT, SANDPOINT, IDAHO 83864
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I N D E X

ITEM DESCRIPTION	PAGE NO.
OPEN SESSION	
1. CALL TO ORDER	3
2. ROLL CALL	3
3. CONSIDERATION OF APPLICATIONS SUBMITTED IN RESPONSE TO CLINICAL TRIAL STAGE PROJECTS PROGRAM ANNOUNCEMENTS (CLIN 1 OR 2)	5
4. CLOSED SESSION	NONE
DISCUSSION OF CONFIDENTIAL INTELLECTUAL PROPERTY OR WORK PRODUCT, PREPUBLICATION DATA, FINANCIAL INFORMATION, CONFIDENTIAL SCIENTIFIC RESEARCH OR DATA, AND OTHER PROPRIETARY INFORMATION RELATING TO APPLICATIONS SUBMITTED IN RESPONSE TO AGENDA ITEM 3 ABOVE. (HEALTH & SAFETY CODE 125290.30(F)(3)(B) AND (C)).	
OPEN SESSION	
5. GENERAL COMMENTS ON ARS PROCESS	NONE
6. PUBLIC COMMENT	NONE
7. ADJOURNMENT	35

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APRIL 25, 2024; 9 A.M.

BETH C. DRAIN, CA CSR NO. 7152

1 CHAIRMAN IMBASCIANI: GOOD MORNING,
2 EVERYONE. THIS IS DR. IMBASCIANI. I'M THE CHAIR OF
3 THE INDEPENDENT CITIZENS OVERSIGHT COMMITTEE, THE
4 BOARD FOR CIRM. I'D LIKE TO CALL THIS MEETING OF
5 THE APPLICATION REVIEW SUBCOMMITTEE TOGETHER. WE
6 HAVE A QUORUM, AND I'M GOING TO ASK OUR DEPUTY
7 GENERAL COUNSEL BEN HUANG TO CALL THE ROLL AND
8 DURING THE MEETING TO TAKE WHATEVER VOTES ARE
9 REQUIRED. THANK YOU.

10 MR. HUANG: DAN BERNAL.

11 MR. BERNAL: PRESENT.

12 MR. HUANG: MARIA BONNEVILLE.

13 VICE CHAIR BONNEVILLE: PRESENT.

14 MR. HUANG: LEONDRA CLARK-HARVEY.

15 ANNE-MARIE DULIEGE. MARK FISCHER-COLBRIE.

16 MR. FISCHER-COLBRIE: HERE.

17 MR. HUANG: YSABEL DURON. MARK

18 FISCHER-COLBRIE.

19 DR. FISCHER-COLBRIE: HERE.

20 MR. HUANG: FRED FISHER.

21 DR. FISHER: HERE.

22 MR. HUANG: ELENA FLOWERS.

23 DR. FLOWERS: PRESENT.

24 MR. HUANG: DAVID HIGGINS.

25 DR. HIGGINS: PRESENT.

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MR. HUANG: VITO IMBASCIANI.
CHAIRMAN IMBASCIANI: HERE.
MR. HUANG: STEPHEN JUELSGAARD.
MR. JUELSGAARD: PRESENT.
MR. HUANG: RICH LAJARA.
MR. LAJARA: PRESENT.
MR. HUANG: LAUREN MILLER-ROGEN.
MS. MILLER-ROGEN: HERE.
MR. HUANG: JOE PANETTA.
MR. PANETTA: HERE.
MR. HUANG: MARVIN SOUTHARD.
DR. SOUTHARD: HERE.
MR. HUANG: KAROL WATSON. KEVIN XU.
MR. XU: HERE.
MR. HUANG: THANK YOU. WE HAVE QUORUM.
CHAIRMAN IMBASCIANI: THANK YOU VERY MUCH,
BEN.
SO OUR FIRST ORDER OF BUSINESS IS THE
CONSIDERATION OF APPLICATIONS THAT HAVE BEEN
SUBMITTED IN RESPONSE TO CLINICAL TRIAL STAGE
PROJECTS IN THE ANNOUNCEMENTS FOR CLIN1 AND 2. I'M
GOING TO ASK HAYLEY LAM. I SEE YOU THERE. YOU CAN
MAKE THE PRESENTATIONS. THANK YOU.
DR. LAM: THANK YOU. GOOD MORNING TO THE
BOARD. I'M GOING TO SHARE MY SCREEN. HOPEFULLY YOU

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CAN ALL SEE THAT.
SO I'LL TAKE YOU THROUGH THE SLIDES. GOOD
MORNING, EVERYONE. AS ALWAYS, WE BEGIN WITH OUR
MISSION STATEMENT: ACCELERATING WORLD-CLASS SCIENCE
TO DELIVER TRANSFORMATIVE REGENERATIVE MEDICINE
TREATMENTS IN AN EQUITABLE MANNER TO A DIVERSE
CALIFORNIA AND WORLD.

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1 THE CURRENT CLINICAL BUDGET STATUS FOR THE
2 FISCAL YEAR HAS A TOTAL ALLOCATION OF 252 MILLION.
3 168 MILLION HAS ALREADY BEEN APPROVED BY THIS GROUP
4 HERE. AND TODAY'S TOTAL AMOUNT REQUESTED ACROSS THE
5 FOUR APPLICATIONS IS 35.2 MILLION.

6 AS A REMINDER OF SORT OF THE STRUCTURE OF
7 THE PROGRAM, THE SCIENTIFIC SCORING SYSTEM FOR THE
8 CLINICAL PROGRAM IS SCORES OF 1, 2, AND 3. A 1 IS A
9 RECOMMENDATION FOR FUNDING. A 2 APPLICATION IS NOT
10 RECOMMENDED AT THIS TIME, BUT THE APPLICANT CAN
11 RETURN WITH A RESUBMISSION AND SHOULD HAVE SORT OF A
12 RECOMMENDATION THAT CAN BE REVISED AND ADDRESSED IN
13 A RESUBMISSION. A SCORE OF 3 IS A DO NOT RECOMMEND
14 FOR FUNDING, AND THE PANEL BELIEVES THAT THE
15 APPLICATION IS SUFFICIENTLY FLAWED THAT IT DOESN'T
16 WARRANT FUNDING AND THE SAME PROJECT CANNOT BE
17 RESUBMITTED FOR AT LEAST SIX MONTHS.

18 THE CRITERIA THAT ARE USED TO SCORE THE 1,
19 2, AND 3 ARE AS FOLLOWS: NO. 1, SORT OF THE OVERALL
20 VALUE AND IMPACT OF THE PROJECT, DOES IT HAVE THAT?
21 NO. 2, IS THE RATIONALE SOUND? SO DOES IT HAVE THE
22 DATA TO SUPPORT MOVING FORWARD? THREE, IS THE
23 PROJECT WELL PLANNED AND DESIGNED? SO DOES THE
24 PROJECT THE APPLICANT IS SEEKING FUNDING FOR HAVE
25 THE RIGHT ACTIVITIES TO REACH THE GOAL FOR THAT

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1 PARTICULAR CALL AND PA? NO. 4, IS THE PROJECT
2 FEASIBLE, AND DO THEY HAVE THE PEOPLE AND ALL OF THE
3 PIECES IN PLACE TO EXECUTE? AND NO. 5, DOES THE
4 PROJECT UPHOLD PRINCIPLES OF DIVERSITY, EQUITY, AND
5 INCLUSION?

6 AT CIRM HERE WE SCORE A SEPARATE SCORE FOR
7 DIVERSITY, EQUITY, AND INCLUSION IN ADDITION TO THE
8 SCIENTIFIC SCORE. THE DEI SCORE IS A SCORE OF ZERO
9 TO 10, 10 BEING THE MOST OUTSTANDING RESPONSE AND
10 SORT OF A SCALE BETWEEN THAT. THE DEI SCORE IS
11 SCORED BY ALL GWG BOARD MEMBERS WITH NO CONFLICT.

12 THE COMPOSITION OF THE GROUP THAT SCORES
13 BOTH THE SCIENTIFIC AND THE DEI SCORES IS AS
14 FOLLOWS: WE HAVE UP TO 15 SCIENTIFIC GRANTS WORKING
15 GROUP MEMBERS THAT PROVIDE A SCIENTIFIC SCORE ON ALL
16 THE APPLICATIONS AND THEY EVALUATE ACCORDING TO
17 THEIR DISEASE AREA EXPERTISE, REGULATORY,
18 MANUFACTURING, AND PRODUCT DEVELOPMENT.

19 WE HAVE OUR GRANTS WORKING GROUP BOARD
20 MEMBERS WHO PROVIDE A DEI EVALUATION AND PROVIDE A
21 PATIENT INSIGHT ON TO THE APPLICATIONS, AND THEY
22 PROVIDE DEI SCORES ON ALL APPLICATIONS AS SUGGESTED
23 SCIENTIFIC SCORES.

24 AND FINALLY, WE ALSO HAVE SPECIALISTS,
25 NONVOTING SCIENTISTS, THAT WE CALL IN ON AN AD HOC

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1 BASIS FOR APPLICATIONS FOR WHICH WE DON'T HAVE
2 EXPERTISE COVERAGE WITHIN OUR GRANTS WORKING GROUP.

3 AND MOVING ON TO THE APPLICATIONS TODAY.

4 SO HOW COME MY SLIDES AREN'T ADVANCING?

5 SO THE FIRST APPLICATION UP FOR DISCUSSION
6 TODAY IS CLIN1-15343. THIS IS A PHASE 1 STUDY FOR
7 EVALUATING THE SAFETY AND EFFICACY OF AN ALLOGENEIC
8 CELL THERAPY IN SUBJECTS WITH CLEAR CELL RENAL CELL
9 CARCINOMA. AND THE THERAPY IS AN ALLOGENEIC
10 APPROACH OF CAR-T CELLS. THE INDICATION, AGAIN, AS
11 INDICATED IN THE TITLE, IS FOR ADVANCED OR
12 METASTATIC CLEAR CELL OR RENAL CELL CARCINOMA.

13 AND THE GOAL FOR THIS PROJECT IS TO
14 COMPLETE A PHASE 1B TRIAL. FUNDS REQUESTED FROM
15 CIRM IS AN EVEN 15 MILLION, AND THE APPLICANT IS
16 CO-FUNDING A LITTLE BIT OVER 42.6 MILLION.

17 A LITTLE BIT MORE ABOUT THIS APPLICATION.
18 SO A BACKGROUND ON THE RENAL CELL CARCINOMA. IT'S
19 ONE OF THE MOST COMMON TYPES OF KIDNEY CANCER IN
20 ADULTS. THE CURRENT STANDARD OF CARE INCLUDES
21 SURGERY AND IMMUNOTHERAPY, BUT THERE'S LIMITED
22 OPTIONS BEYOND THAT FOR PATIENTS WHEN OR IF THE
23 CANCER REOCCURS.

24 THE PROPOSED THERAPY, THERE'S A COUPLE
25 MODIFICATIONS IN THE THERAPY THAT AIM TO IMPROVE THE

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1 TUMOR KILLING BY THE PATIENT T-CELLS. AND IF
2 SUCCESSFUL, IT HOPEFULLY CAN BE APPLIED TO SIMILAR
3 APPROACHES IN OTHER CANCERS.

4 IN ADDITION, THIS IS AN OFF-THE-SHELF OR
5 THIS WOULD BE AN OFF-THE-SHELF THERAPY WHICH COULD
6 POTENTIALLY SHORTEN THE TIMELINE TO TREATMENT TO
7 IMPROVE THE PATIENT ACCESS AS COMPARED TO AUTOLOGOUS
8 TREATMENTS WHERE THE CELLS HAVE TO BE HARVESTED AND
9 THEN PREPARED FOR TREATMENT, WHICH TAKES A LONGER
10 TIMELINE.

11 AND THIS PROJECT IS A GENETIC MANIPULATION
12 OF T-CELLS, WHICH IS WHY IT FALLS UNDER CIRM'S
13 PURVIEW. THERE ARE CURRENTLY NO CURRENT PORTFOLIO
14 PROJECTS IN THE TRANSLATIONAL AND CLINICAL STAGE
15 THAT ADDRESS KIDNEY CANCER. AND THE APPLICANT TEAM
16 HAS NOT RECEIVED PRIOR CIRM FUNDING.

17 SO IN SUMMARY, THE RECOMMENDATION FROM THE
18 GRANTS WORKING GROUP WAS A UNANIMOUS VOTE OF A
19 RECOMMENDATION FOR FUNDING OF TIER I. THE DEI SCORE
20 ON THIS APPLICATION WAS A 7, AND THE CIRM TEAM
21 RECOMMENDATION CONCURS WITH THE GRANTS WORKING GROUP
22 FOR A TOTAL CIRM AWARD AMOUNT ASK OF 15 MILLION.

23 PASS IT BACK. OH, THERE'S A QUESTION? I
24 CAN'T HEAR YOU. YOU'RE MUTED AGAIN.

25 MR. JUELSGAARD: SORRY ABOUT THAT. NO,

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1 IT'S JUST A QUESTION THAT HAS TO DO WITH THE VERY
2 LAST PART OF THIS. THE CIRM AWARD AMOUNT IS 15
3 MILLION, BUT THERE'S AN ASTERISK TO SAY THAT THE
4 FINAL AWARD AMOUNT SHALL NOT EXCEED THIS AMOUNT AND
5 MAY BE REDUCED ON CIRM'S FINAL ASSESSMENT OF
6 ALLOWABLE COSTS AND ACTIVITIES.

7 SO THIS APPEARS TO BE AN OUT-OF-STATE
8 COMPANY BASED ON -- WITHOUT KNOWING ANYTHING MORE,
9 BUT MY ASSESSMENT OF WHAT'S BEING PRESENTED. AND
10 WHAT THEY HAVE IS THEY HAVE A MANUFACTURING FACILITY
11 AT LEAST FOR CLINICAL MATERIAL IN CALIFORNIA. AND
12 TWO OF THE 17 SITES ARE REPORTED TO BE CALIFORNIA
13 SITES FOR THE CLINICAL STUDIES. SO THAT'S THEIR
14 CONNECTION TO CALIFORNIA.

15 DR. LAM: I JUST -- I'M SORRY TO
16 INTERRUPT, BUT IT IS -- AS FAR AS I KNOW, IT IS A
17 CALIFORNIA ENTITY.

18 MR. JUELSGAARD: OKAY. WHAT WOULD BE
19 HELPFUL, I THINK, IN THESE PRESENTATIONS IS TO
20 DESIGNATE WHETHER THEY ARE CALIFORNIA BASED; THAT
21 IS, THEIR HEADQUARTERS ARE IN CALIFORNIA, OR WHETHER
22 THEY'RE NOT BECAUSE THE LITTLE BIT THAT I READ WAS
23 THEY WERE GOING TO MANUFACTURE HERE, AND THEY WERE
24 GOING TO DO TWO OF 17 CLINICAL TRIALS HERE. I JUST
25 WANTED TO BE SURE THAT, AS I UNDERSTAND IT, THAT

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1 WHATEVER WE PAY THEM IS FOR THEIR ACTIVITY IN
2 CALIFORNIA AND NOT FOR ACTIVITY OUTSIDE OF THE
3 STATE.

4 DR. LAM: ABSOLUTELY. WE CAN START ADDING
5 THAT TO THE SLIDES. I'LL HAVE TO THINK ABOUT THE
6 BEST SPOT MAYBE, BUT DEFINITELY CAN DO THAT.

7 MR. JUELSGAARD: I DON'T KNOW IF ANY OF
8 THE OTHERS THAT ARE COMING UP, THE NEXT ONE MAY BE A
9 NON-CALIFORNIA COMPANY. BUT AS WE BEGIN TO FOCUS ON
10 WHAT WE'RE GOING TO FUND IN THE FUTURE, ONCE WE GET
11 PAST THE END OF MAY OR WHATEVER, I THINK ONE OF THE
12 THINGS WE OUGHT TO TAKE A LOOK AT IS THE DEGREE OF
13 CALIFORNIA CONNECTION THAT THE APPLICANT HAS IN OUR
14 CONSIDERATION OF HOW TO FUND THEM BECAUSE IN SOME
15 CASES IT'S A LITTLE MORE TENUOUS THAN IN OTHERS.
16 THAT'S THE BASIS OF MY QUESTION IS I'M STARTING TO
17 THINK ABOUT WHERE WE MIGHT BE GOING HERE.

18 MR. AGUIRRE-SACASA: SORRY, STEVE. THIS
19 IS RAFAEL. IN THE PROGRAM ANNOUNCEMENT, THERE'S
20 CLEAR DELINEATION AS TO WHICH COSTS ARE ASSOCIATED
21 FOR, FOR EXAMPLE, IF IT'S A NON-CALIFORNIA
22 APPLICANT, BUT IT'S GENERALLY FOR ACTIVITIES
23 CONDUCTED IN CALIFORNIA OR FOR CALIFORNIA PATIENTS.
24 SO THERE IS SOME GUIDANCE ON THAT, AND I'M HAPPY TO
25 SEND THAT TO YOU.

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1 DR. JUELSGAARD: THAT'S THE MONEY THEY'RE
2 ASKING FOR IS THAT AMOUNT. THEN THEY SAY, OKAY.
3 WELL, WE'RE GOING TO SPEND \$15 MILLION IN
4 CALIFORNIA. THAT'S HOW THEY MAKE THE APPLICATION.

5 DR. LAM: JUST TO KIND OF GIVE A LITTLE
6 BIT MORE INSIGHT INTO THE OVERALL PROCESS FOR THESE
7 CLINICAL APPLICATIONS, RIGHT NOW THE CURRENT PROCESS
8 IS EVERY APPLICATION THAT COMES THROUGH AND GOES TO
9 THE GRANTS WORKING GROUP HAS A FIRST LOOK BY OUR
10 GRANTS MANAGEMENT TEAM. AND THEY DO AN INITIAL
11 BUDGET REVIEW OF ALL THE APPLICATIONS TO JUST TAKE A
12 LOOK THAT EVERYTHING LOOKS SORT OF SQUARED AWAY, I
13 GUESS, AND TO BE GENERAL ABOUT IT IN TERMS OF WHAT
14 THEY'RE ASKING FOR BEING OVERALL WITHIN THE
15 ALLOWABLE COSTS FOR WHAT'S IN OUR PA'S IN TERMS OF
16 CALIFORNIA ORGANIZATIONS AND WHAT THEY ARE ALLOWED
17 TO REQUEST FUNDING FOR AND NON-CALIFORNIA AND WHAT
18 THEY'RE ALLOWED, THAT SORT OF THING.

19 SO THERE ARE INITIAL CHECKS ON THAT, BUT
20 LIKE THE ASTERISK INDICATES, WHICH WE HAVE ON EVERY
21 APPLICATION, ALL OF THE FUNDING APPROVED HERE IN
22 THIS COMMITTEE IS SUBJECT TO THE FINAL CONTRACTING
23 WITH EACH OF THOSE APPLICANTS OR ACTUAL AWARDEES AT
24 THIS POINT WHERE THE GRANTS MANAGEMENT WILL CONTINUE
25 WORKING WITH THOSE APPLICANTS AND DETERMINING --

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1 MAKING FINAL DECISIONS ON WHETHER ALL OF THOSE
2 ACTIVITIES ARE ALLOWABLE AND FALL UNDER CIRM
3 FUNDING.

4 MR. JUELSGAARD: GREAT. THANK YOU.

5 DR. CLARK-HARVEY: THIS IS LEONDR A. I'M
6 ON MY CELL PHONE. CAN'T FIND THE RAISE MY HAND
7 FUNCTION. I APOLOGIZE. I'M IN TRANSIT.

8 REALLY APPRECIATE THE QUESTION AND COMMENT
9 BROUGHT UP BY STEVE. AND ON THAT, I APPRECIATE THE
10 ANSWERS AND I WONDER IF IT WOULD BE HELPFUL TO CIRM
11 REVIEWERS AND STAFF AS WELL AS THE COMMITTEE IF WE
12 ACTUALLY ASK THEM TO SHARE HOW -- OR SHARE THE
13 SPECIFIC CALIFORNIA IMPACT. IT'S ONE THING TO SAY
14 WE EXPECT TO USE IT, AND THEN CIRM STAFF HAVING TO
15 DO THE CHECKS AND BALANCES. WHAT IF WE ASK THEM UP
16 FRONT AS PART OF THE APPLICATION TO IDENTIFY, MAYBE
17 IT'S AN EXTRA QUESTION, CONSIDERING WE WANT
18 CALIFORNIA IMPACT. CAN YOU EXPLAIN HOW THESE FUNDS
19 WILL BE UTILIZED SPECIFICALLY IN THIS STATE? IF
20 THERE IS A QUESTION THAT DOES THIS ALREADY, THEN MY
21 COMMENT IS MOOT; BUT IF NOT, IT MIGHT JUST BE
22 SOMETHING TO CONSIDER.

23 DR. LAM: THANK YOU.

24 MR. JUELSGAARD: I'M SORRY. JUST ONE
25 FOLLOW-UP. MY QUESTION IS PROBABLY MORE FUTURE

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1 RELATED THAN ANYTHING. AND I THINK ONE OF THE
2 THINGS WE GET, JUST A SUGGESTION ON MY PART, THAT WE
3 THINK ABOUT GOING FORWARD IS WHETHER WE WANT TO
4 CONSIDER HAVING A STRONGER FILTER FOR THESE
5 APPLICATIONS RELATED TO THEIR ASSOCIATION WITH
6 CALIFORNIA SO THAT WE HAVE CERTAIN EXPECTATIONS THAT
7 HAVE TO BE MET IN ORDER FOR IT TO BE FUNDED AS A
8 CALIFORNIA PROJECT. AND I'M NOT SUGGESTING THAT WE
9 DO ANYTHING ABOUT THESE, BUT IT'S MORE FUTURE
10 LOOKING BECAUSE I KNOW WE HAVE FUNDED THINGS IN THE
11 PAST WHERE ONLY PART OF THE WORK -- THE COMPANIES
12 ARE NOT CALIFORNIA COMPANIES, AND ONLY PART OF THE
13 WORK IS BEING DONE IN CALIFORNIA. AND I WONDER IF
14 WE WANT TO CONTINUE THAT OR NOT.

15 BUT ANYWAY, I DON'T WANT TO HAVE A MAJOR
16 DISCUSSION. IT'S JUST THESE BEGIN TO ASK -- BEG THE
17 QUESTIONS FROM MY POINT OF VIEW.

18 DR. THOMAS: STEVE, JUST TWO SECONDS VERY
19 QUICKLY. THAT SORT OF THING IS ONE OF VERY MANY
20 CONSIDERATIONS THAT ARE LOOKED AT IN THE WHOLE
21 REPRIORITIZATION PROCESS. SO THANK YOU FOR THAT
22 INPUT.

23 MR. JUELSGAARD: SURE.

24 CHAIRMAN IMBASCIANI: ANY OTHER QUESTIONS?
25 THE CHAIR WILL ENTERTAIN A MOTION.

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1 MR. HUANG: HAYLEY, WAS THERE A CONFLICT
2 SLIDE?

3 DR. LAM: YES.

4 MR. JUELGAARD: MARIA BONNEVILLE.

5 CO-CHAIR BONNEVILLE: NO. NOT THIS ONE.

6 MR. JUELGAARD: I'LL MOVE APPROVAL.

7 DR. SOUTHARD: SECOND.

8 CHAIRMAN IMBASCIANI: MARV SOUTHARD

9 SECONDED IT. OKAY. DEPUTY COUNSEL HUANG CAN CALL
10 THE ROLL.

11 MR. HUANG: DAN BERNAL.

12 MR. BERNAL: AYE.

13 MR. HUANG: LEONDRA CLARK-HARVEY.

14 DR. CLARK-HARVEY: AYE.

15 MR. HUANG: MARK FISCHER-COLBRIE.

16 MR. FISCHER-COLBRIE: YES.

17 MR. HUANG: YSABEL DURON. FRED FISHER.

18 DR. FISHER: AYE.

19 MS. DURON: I'M SORRY. I WAS ON MUTE.
20 YES.

21 MR. HUANG: I GOT FRED'S VOTE. ELENA
22 FLOWERS.

23 DR. FLOWERS: YES.

24 MR. HUANG: DAVID HIGGINS.

25 DR. HIGGINS: YES.

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MR. HUANG: VITO IMBASCIANI.
CHAIRMAN IMBASCIANI: YES.
MR. HUANG: STEPHEN JUELSGAARD.
MR. JUELSGAARD: YES.
MR. HUANG: RICH LAJARA.
MR. LAJARA: YES.
MR. HUANG: LAUREN MILLER-ROGEN. JOE
PANETTA.
MR. PANETTA: YES.
MR. HUANG: MARVIN SOUTHARD.
DR. SOUTHARD: YES.
MR. HUANG: KAROL WATSON. KEVIN XU.
MR. XU: YES.
MR. HUANG: THE MOTION PASSES.
DR. DULIEGE: DR. DULIEGE VOTED YES.
CHAIRMAN IMBASCIANI: IS THERE ANYONE ELSE
ON THE LINE THAT DID NOT HAVE THEIR VOTE RECORDED?
LAUREN DID. I THINK IT WAS --
MS. MANDAC: LAUREN, ONE LAST CALL. IT'S
OKAY. THE MOTION CARRIES.
CHAIRMAN IMBASCIANI: OKAY. GREAT. IS
THERE ANY MEMBER OF THE PUBLIC THAT WOULD LIKE TO
ADDRESS CLIN2-15343?
MS. MANDAC: THERE ARE NO HANDS RAISED.
CHAIRMAN IMBASCIANI: OKAY. HAYLEY, CAN

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1 YOU TAKE US TO THE NEXT APPLICATION.

2 DR. LAM: YES. THANK YOU. FOR THE NEXT
3 APPLICATION, WE HAVE ONE CONFLICT WITH A BOARD
4 MEMBER. AND THE APPLICATION IS CLIN2-15282. LET'S
5 SEE IF I CAN GET THROUGH THIS ALPHABET HERE.
6 RPESC-RPE THERAPY FOR DRY AGE-RELATED MACULAR
7 DEGENERATION. AND THE THERAPY IS RETINAL PIGMENT
8 EPITHELIAL STEM CELL-DERIVED RPE CELLS. THE
9 INDICATION IS FOR DRY AGE-RELATED MACULAR
10 DEGENERATION. AND THE GOAL FOR THIS PROJECT IS TO
11 COMPLETE A PHASE 1/2A TRIAL. THE FUNDS REQUESTED
12 FOR THIS APPLICATION IS JUST OVER 4 MILLION WITH THE
13 CO-FUNDING OF 3.3 MILLION.

14 A LITTLE BIT MORE ABOUT THIS APPLICATION.
15 SO DRY AGE-RELATED MACULAR DEGENERATION IS
16 ESSENTIALLY A BLINDING DISEASE OVER THE LONG TERM
17 AND IS DUE TO THE LOSS OF THE RETINAL PIGMENT
18 EPITHELIAL CELLS. THERE ARE FEW STANDARD OF CARE
19 TREATMENTS AVAILABLE, BUT ALL OF THEM AT THIS POINT
20 SLOW PROGRESSION, BUT DO NOT IMPROVE AND/OR RESTORE
21 VISION.

22 THE VALUE OF THE PROPOSED THERAPY IS TO
23 REPLACE THE CELLS, RPE CELLS, THAT HAVE BEEN LOST
24 DUE TO DISEASE. AND THERE IS SOME EARLY EVIDENCE
25 THAT THIS THERAPY HAS THE POTENTIAL TO IMPROVE

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1 VISION IN PATIENTS WITH DRY AMD. AND IN TERMS OF
2 THE RELEVANCE TO CIRM, THIS PROJECT, THE THERAPY, IS
3 COMPOSED OF CELLS DERIVED FROM RETINAL PIGMENT
4 EPITHELIAL STEM CELLS.

5 SIMILAR CIRM PORTFOLIO PROJECTS. SO THERE
6 ARE SEVERAL PROJECTS THAT ARE ALSO RELATED TO
7 AGE-RELATED MACULAR DEGENERATION AT SORT OF
8 DIFFERENT STAGES. AND IN TERMS OF INDICATION, AS
9 WELL AS THE AWARD, WE HAVE A COUPLE OF TRAN1 AWARDS
10 AND ONE CLIN1 AND ONE CLIN2.

11 THE PRIOR FUNDING TO THE CIRM APPLICANT
12 TEAM, THEY'VE NOT RECEIVED A PRIOR CIRM AWARD.

13 AND THE RECOMMENDATION OF THE GRANTS
14 WORKING GROUP WAS A UNANIMOUS RECOMMENDATION TO FUND
15 OF A TIER I WITH 15 VOTES. AND THE OVERALL
16 DIVERSITY, EQUITY, INCLUSION SCORE WAS AN 8 FROM THE
17 BOARD MEMBERS, AND THE CIRM TEAM RECOMMENDATION
18 CONCURS WITH THE GRANTS WORKING GROUP FOR A TOTAL
19 AMOUNT REQUESTED TODAY OF JUST OVER 4 MILLION.
20 THANK YOU. PASS IT BACK, DR. IMBASCIANI.

21 CHAIRMAN IMBASCIANI: WHAT WAS THE
22 CONFLICT ON THIS ONE?

23 MS. MANDAC: YSABEL DURON.

24 MS. DURON: THANK YOU.

25 CHAIRMAN IMBASCIANI: THANK YOU. OKAY.

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1 QUESTIONS -- WE TECHNICALLY SHOULD START WITH A
2 MOTION TO CONSIDER. AND THEN ANY QUESTIONS OR
3 POINTS OF INFORMATION CAN BE DIRECTED TOWARD THE
4 TEAM.

5 DR. SOUTHARD: MOVED.

6 CHAIRMAN IMBASCIANI: MARV, YOU'RE MAKING
7 A MOTION TO WHAT?

8 DR. SOUTHARD: AS YOU SUGGESTED.

9 DR. CLARK-HARVEY: SECOND.

10 CHAIRMAN IMBASCIANI: THANK YOU, LEONDRA.
11 FLOOR IS OPEN TO DISCUSSION FROM MEMBERS OF THE
12 BOARD. IS THERE ANY MEMBER OF THE GENERAL PUBLIC
13 THAT WOULD LIKE TO COMMENT ON THIS?

14 MS. MANDAC: THERE ARE NO HANDS RAISED.

15 CHAIRMAN IMBASCIANI: THERE ARE NO HANDS
16 RAISED. BEN, I THINK IT'S UP TO YOU TO TAKE THE
17 ROLL.

18 MR. HUANG: DAN BERNAL.

19 MR. BERNAL: AYE.

20 MR. HUANG: MARIA BONNEVILLE.

21 CO-CHAIR BONNEVILLE: YES.

22 MR. HUANG: LEONDRA CLARK-HARVEY.

23 DR. CLARK-HARVEY: AYE.

24 MR. HUANG: ANNE-MARIE DULIEGE.

25 DR. DULIEGE: AYE.

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1 MR. HUANG: MARK FISCHER-COLBRIE.
2 MR. FISCHER-COLBRIE: YES.
3 MR. HUANG: FRED FISHER.
4 DR. FISHER: YES.
5 MR. HUANG: ELENA FLOWERS.
6 DR. FLOWERS: YES.
7 MR. HUANG: DAVID HIGGINS.
8 DR. HIGGINS: YES.
9 MR. HUANG: VITO IMBASCIANI.
10 CHAIRMAN IMBASCIANI: YES.
11 MR. HUANG: STEPHEN JUELSGAARD.
12 MR. JUELSGAARD: YES.
13 MR. HUANG: RICH LAJARA.
14 MR. LAJARA: YES.
15 MR. HUANG: LAUREN MILLER-ROGEN.
16 MS. MILLER-ROGEN: YES.
17 MR. HUANG: JOE PANETTA.
18 MR. PANETTA: YES.
19 MR. HUANG: MARVIN SOUTHARD.
20 DR. SOUTHARD: YES.
21 MR. HUANG: KEVIN XU.
22 MR. XU: YES.
23 MR. HUANG: THE MOTION PASSES.
24 CHAIRMAN IMBASCIANI: GOOD. THANK YOU.
25 HAYLEY, THE NEXT APPLICATION, 15311.

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1 DR. LAM: 15311, WE'VE GOT A COUPLE OF
2 FOLKS THAT ARE CONFLICTED ON THIS ONE. JUST FOR THE
3 SAKE OF NO CONFUSION HERE, DAN, YSABEL, ELENA, AND
4 CHRIS.

5 SO THE APPLICATION IS CLIN2-15311, A PHASE
6 1/2A STUDY TO EVALUATE THE EFFICACY OF A GENE
7 THERAPY WITH STANDARD OF CARE THERAPY IN NEWLY
8 DIAGNOSED HIGH-GRADE GLIOMA.

9 THE THERAPY IS A RETROVIRAL VECTOR WHICH
10 CONVERTS A PRODRUG TO AN ANTICANCER DRUG. AND THE
11 INDICATION IS, AGAIN, NEWLY DIAGNOSED HIGH-GRADE
12 GLIOMA.

13 AND THE GOAL OF THIS PROJECT IS TO
14 COMPLETE A PHASE 1/2A TRIAL. FUNDS REQUESTED FROM
15 CIRM ARE 11.8 MILLION, JUST OVER THAT, AND THERE IS
16 NO CO-FUNDING FROM THIS APPLICANT.

17 LITTLE BIT MORE ABOUT THE PROJECT. SO
18 HIGH-GRADE GLIOMAS ARE THE MOST COMMON PRIMARY BRAIN
19 TUMOR IN ADULTS, AND THEY HAVE OVERALL POOR
20 PROGNOSIS. THE CURRENT STANDARD OF CARE IS SURGERY
21 TO REMOVE THE TUMOR FOLLOWED BY RADIATION AND
22 CHEMOTHERAPY. AND THE MEDIAN OVERALL SURVIVAL WITH
23 THE STANDARD OF CARE TREATMENT IS LESS THAN 15
24 MONTHS.

25 THE PROPOSED THERAPY AIMS TO SORT OF

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1 ACTIVATE AN ANTICANCER DRUG ONLY IN CANCER CELLS AND
2 WORK IN COMBINATION WITH STANDARD OF CARE
3 TREATMENTS. SO THE AIM HERE IS TO PROVIDE LOCALIZED
4 KILLING OF THE CANCER CELLS AND ULTIMATELY COULD
5 INCREASE THE SURVIVAL FOR PATIENTS. AND THE
6 RELEVANCE TO CIRM HERE IS THAT THE THERAPY IS A GENE
7 THERAPY APPROACH.

8 SIMILAR CIRM PORTFOLIO PROJECTS. SO WE
9 HAVE QUITE A BIT OF FUNDING IN THE CLIN2 CLINICAL
10 TRIAL FOR SIMILAR BRAIN CANCERS. THEY'RE ALL PHASE
11 1S, AND THEY ARE ACTUALLY ALL AUTOLOGOUS CAR-T
12 APPROACHES.

13 THE APPLICANT TEAM HAS RECEIVED PRIOR CIRM
14 FUNDING, AND BOTH OF THOSE WERE MUCH EARLIER STAGE
15 RESEARCH. AND ONE OF THEM WAS RELATED TO THE
16 CURRENT AWARD IN THAT IT INVOLVES THE SAME VIRUS.

17 THE GRANTS WORKING GROUP RECOMMENDED THIS
18 APPLICATION FOR FUNDING WITH A UNANIMOUS VOTE OF 15
19 VOTES FOR TIER I. THE BOARD MEMBERS SCORED THIS
20 APPLICATION ON DEI AT AN 8, AND THE CIRM TEAM
21 CONCURS WITH THE RECOMMENDATION TO FUND FOR THE
22 TOTAL AWARD AMOUNT OF 11.8 MILLION.

23 THANK YOU.

24 CHAIRMAN IMBASCIANI: THANK YOU, HAYLEY,
25 FOR THE PRESENTATION.

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1 THE CHAIR WILL ENTERTAIN FROM ANY MEMBER
2 OF THE APPLICATION REVIEW SUBCOMMITTEE THAT IS NOT
3 IN CONFLICT A MOTION TO FUND.

4 DR. SOUTHARD: MARV SOUTHARD MAKES THE
5 MOTION TO FUND.

6 CHAIRMAN IMBASCIANI: THANK YOU, MARVIN.

7 DR. CLARK-HARVEY: SECOND.

8 CHAIRMAN IMBASCIANI: THANK YOU, LEONDRA.
9 FLOOR IS OPEN TO DISCUSSION OR QUESTIONS FROM BOARD
10 MEMBERS.

11 AND SO I'D LIKE TO INVITE ANY MEMBER OF
12 THE PUBLIC WITH OPINIONS ON THIS APPLICATION TO COME
13 FORWARD.

14 MS. MANDAC: THERE ARE NO HANDS RAISED.

15 CHAIRMAN IMBASCIANI: OKAY. THEN, BEN, WE
16 CAN PROCEED TO THE FORMAL VOTE.

17 MR. HUANG: MARIA BONNEVILLE.

18 VICE CHAIR BONNEVILLE: YES.

19 MR. HUANG: LEONDRA CLARK-HARVEY.

20 DR. CLARK-HARVEY: YES.

21 MR. HUANG: ANNE-MARIE DULIEGE.

22 DR. DULIEGE: YES.

23 MR. HUANG: MARK FISCHER-COLBRIE.

24 MR. FISCHER-COLBRIE: YES.

25 MR. HUANG: FRED FISHER.

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1 DR. FISHER: YES.
2 MR. HUANG: DAVID HIGGINS.
3 DR. HIGGINS: YES.
4 MR. HUANG: VITO IMBASCIANI.
5 CHAIRMAN IMBASCIANI: YES.
6 MR. HUANG: STEPHEN JUELSGAARD.
7 MR. JUELSGAARD: YES.
8 MR. HUANG: RICH LAJARA.
9 MR. LAJARA: YES.
10 MR. HUANG: LAUREN MILLER-ROGEN.
11 MS. MILLER-ROGEN: YES.
12 MR. HUANG: JOE PANETTA.
13 MR. PANETTA: YES.
14 MR. HUANG: MARVIN SOUTHARD.
15 DR. SOUTHARD: YES.
16 MR. HUANG: KEVIN XU.
17 MR. XU: YES.
18 MR. HUANG: THE MOTION PASSES.
19 CHAIRMAN IMBASCIANI: GREAT. THANK YOU,
20 BEN.
21 AND, HAYLEY, WE CAN MOVE ON TO
22 CLIN1-14852. THANK YOU.
23 DR. LAM: ALL RIGHT. THANK YOU. WE HAVE
24 ONE CONFLICT HERE WITH YSABEL.
25 CLIN1-14852, SO THIS ONE IS IND-ENABLING

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1 STUDIES FOR A SECOND GENERATION VACCINE TARGETING
2 GLIOBLASTOMA. AND THIS THERAPY IS A VACCINE
3 DESIGNED TO ENHANCE IMMUNE RESPONSE AGAINST TUMORS
4 EXPRESSING EGFRVIII. THE INDICATION HERE IS
5 GLIOBLASTOMA, AND THE GOAL OF THIS PROJECT IS TO
6 HAVE AN APPROVED IND FROM THE FDA TO INITIATE A
7 PHASE 1 TRIAL.

8 THE FUNDS REQUESTED ON THIS APPLICATION IS
9 4.367 MILLION, AND NO CO-FUNDING IS PROVIDED FROM
10 THE APPLICANT FOR THIS PARTICULAR APPLICATION.

11 A LITTLE BIT MORE BACKGROUND ON THIS ONE.
12 SO SIMILAR TO THE PRIOR APPLICATION ACTUALLY, SO
13 IT'S ALSO A BRAIN CANCER APPLICATION AND IT'S A
14 CRITICAL UNMET NEED. IT'S A COMMON BRAIN TUMOR, AND
15 THE SURVIVAL RATE IS VERY LOW.

16 THE CURRENT STANDARD OF CARE, AS I JUST
17 MENTIONED AS WELL, IS SIMILAR HERE. SO SURGERY TO
18 REMOVE THE TUMOR FOLLOWED BY RADIATION AND
19 CHEMOTHERAPY. AND DESPITE THIS, THE SURVIVAL IS
20 STILL LOW. THE PROPOSED THERAPY MAY IMPROVE THE
21 SURVIVAL OF PATIENTS WITH GLIOBLASTOMA THAT EXPRESS
22 THIS MARKER.

23 AND IN TERMS OF THE RELEVANCE TO CIRM
24 HERE, IT'S A VACCINE THAT TARGETS CANCER STEM CELLS.
25 AGAIN, THIS SLIDE MIGHT LOOK FAMILIAR TO YOU. IT'S

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1 THE SAME ONE THAT WE PRESENTED A FEW MINUTES AGO FOR
2 THE OTHER APPLICATION. THE CIRM PORTFOLIO PROJECTS
3 ARE THE SAME. THESE ARE THE FIVE PHASE 1 TRIALS
4 THAT CIRM IS CURRENTLY FUNDING FOR GLIOBLASTOMA.

5 THE APPLICANT HAS RECEIVED PRIOR CIRM
6 FUNDING FOR THE DISC2 AND TRANSLATIONAL. AND THE
7 TRANSLATIONAL AWARD WOULD BE A DIRECT PROGRESSION
8 EVENT IF THIS AWARD WAS FUNDED.

9 THE GRANTS WORKING GROUP DID NOT RECOMMEND
10 THIS APPLICATION FOR FUNDING AND HAD A UNANIMOUS
11 VOTE TO SCORE IT TIER III, WARRANTING NO FUNDING AT
12 THIS TIME AND THE RECOMMENDATION TO RESUBMIT IN --
13 CANNOT RESUBMIT FOR AT LEAST SIX MONTHS.

14 THE DEI SCORE FROM THE BOARD MEMBERS WAS
15 AN 8, AND THE CIRM TEAM RECOMMENDATION CONCURS WITH
16 THE GRANTS WORKING GROUP TO NOT FUND THIS
17 APPLICATION FOR THE AWARD AMOUNT OF 4.367 MILLION.
18 THANK YOU.

19 CHAIRMAN IMBASCIANI: THANK YOU, HAYLEY.

20 SO, BOARD, AS IS CUSTOMARY, WE'LL
21 ENTERTAIN A MOTION FROM BOARD MEMBERS WHO WILL BE
22 FOLLOWED BY COMMENTS FROM MEMBERS AND FOLLOWED BY
23 COMMENTS FROM THE GENERAL PUBLIC. THE CHAIR WOULD
24 LIKE TO HEAR A MOTION FROM THE BOARD MEMBERS.

25 DR. FISHER: FRED FISHER MOVES NOT TO FUND

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1 CLIN1-14852.

2 CHAIRMAN IMBASCIANI: THANK YOU, FRED
3 FISHER.

4 DR. SOUTHARD: MARV SOUTHARD SECONDS.

5 CHAIRMAN IMBASCIANI: WE HAVE A SECOND
6 WHICH OPENS THE FLOOR TO CONVERSATION FROM THE
7 BOARD. DISCUSSION AND QUESTIONS?

8 MS. MANDAC: FRED HAS HIS HAND RAISED.

9 CHAIRMAN IMBASCIANI: THANK YOU. FRED,
10 FLOOR IS YOURS.

11 DR. FISHER: NOT SPECIFIC TO THIS
12 PROPOSAL, BUT WHEN I SEE A LONG LIST OF OTHER CIRM
13 ACTIVITIES, IT RAISES THE QUESTION IN MY MIND, WHICH
14 I'M GATHERING WILL BE ADDRESSED BY THE GROUP LOOKING
15 AT PRIORITIZATION, WHETHER OR NOT WE WILL ENTERTAIN
16 CAPPING PROPOSALS BASED ON THE NUMBER OF CIRM-FUNDED
17 PROJECTS FOR THE SAME INDICATION. SO JUST PUTTING
18 THAT OUT THERE FOR THAT GROUP TO MULL ON. I'M NOT
19 SUGGESTING ONE WAY OR ANOTHER, BUT I THINK IT'S
20 PROBABLY WORTHY OF A CONVERSATION.

21 CHAIRMAN IMBASCIANI: THANK YOU, FRED. I
22 THINK THE MULLERS ARE IN THE ROOM AND SHALL TAKE
23 NOTE OF THAT.

24 VICE CHAIR BONNEVILLE: I THINK IT'S ALSO
25 IMPORTANT TO UNDERSTAND A LIST OF PROJECTS DOESN'T

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1 REALLY TELL US HOW THOSE PROJECTS ARE DOING. SO
2 HAVING A LIST THAT ALLOCATES MONEY TOWARDS A
3 SPECIFIC DISEASE INDICATIONS DOES NOT NECESSARILY
4 GIVE US AN IDEA ON HOW THOSE PROGRAMS ARE
5 PROGRESSING AND WHETHER OR NOT WE'RE MAKING HEADWAY
6 IN THOSE PROGRAMS.

7 SO I THINK MOVING FORWARD, AFTER WE'VE
8 DETERMINED PRIORITIZATION OR CHANGING THE FUNDING
9 MODELS OR WHATEVER MIGHT COME OF IT, I THINK THAT
10 LIST MIGHT BE EXPANDED OR WE MIGHT TAKE A DIFFERENT
11 APPROACH TO IT IN ORDER TO GIVE THE BOARD A BIGGER
12 PICTURE AS TO WHAT'S GOING ON SPECIFICALLY.

13 CHAIRMAN IMBASCIANI: THANK YOU. DO YOU
14 SEE ANY OTHER HANDS FROM BOARD MEMBERS?

15 MS. MANDAC: NO.

16 CHAIRMAN IMBASCIANI: OKAY. THEN I CAN
17 OPEN THE FLOOR TO ANY MEMBER OF THE GENERAL PUBLIC
18 THAT WOULD LIKE TO ADDRESS THE BOARD. IT'S OUR
19 TRADITION. GO AHEAD.

20 MS. MANDAC: DR. WONG, YOU'LL HAVE THREE
21 MINUTES. I WILL KEEP TIME. SO AS SOON AS THE CLOCK
22 ENDS, I WILL ASK YOU TO STOP.

23 DR. WONG: CAN I MAKE ANOTHER COMMENT THAT
24 WOULD (UNINTELLIGIBLE) TO THAT. WE DO HAVE PROGRESS
25 ON A TRANSLATION ONE THAT'S NOT REFLECTED. WE HAVE

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1 A PUBLICATION AS WELL AS TWO PATENTS. AND AS
2 DR. LAM MENTIONED, FOR OTHER CIRM-FUNDED AWARDS,
3 THEIR PROGRESS. SO I FEEL THAT'S VERY IMPORTANT
4 THAT WE DID ACCOMPLISH SOMETHING WITH THAT MONEY.

5 SO NOW I'D LIKE TO START MY PUBLIC
6 COMMENTS. SO THANKS FOR THE OPPORTUNITY TO ADDRESS
7 THE BOARD TODAY. I'VE SENT IN A VERY LENGTHY
8 REBUTTAL TO THE PREVIOUS REVIEW. AND THE REASON IS
9 THAT WE FELT EXTREMELY COMPELLED BASED ON THOSE
10 REVIEWS TO RESPOND BECAUSE WE FEEL THAT THERE'S MANY
11 IMPORTANT ASPECTS OVERLOOKED. IN FACT, ACTUALLY WE
12 CAN PRETTY MUCH NEGATE ANY CRITICISM THAT WAS
13 OFFERED. I REALLY HOPE THAT YOU CAN TAKE A LOOK AT
14 IT BECAUSE IT'S VERY COMPREHENSIVE.

15 BUT TODAY I ONLY HAVE THREE MINUTES OR
16 EVEN LESS NOW. AND I'M JUST GOING TO HIGHLIGHT
17 PARTICULAR ASPECTS THAT ILLUSTRATE WHY WE DON'T FEEL
18 THIS IS AN ACCURATE REVIEW.

19 FIRST OF ALL, WITH REGARDS TO RATIONALE,
20 THERE'S A QUESTION REGARDING THE PRESENCE AND
21 USEFULNESS OF EGFRVIII IN GLIOBLASTOMA. FIRST OF
22 ALL, WE WERE FUNDED THE TRANSLATIONAL AWARD A FEW
23 YEARS AGO. AND THEN VERY INTERESTINGLY JUST THREE
24 MONTHS AGO THE GWG REVIEWED AN APPLICATION ON
25 TARGETING EGFRVIII IN GLIOBLASTOMA STEM CELLS.

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1 THERE WAS NO PROBLEMS WITH REVIEWING THAT AT THAT
2 TIME. YET IN OUR APPLICATION THERE'S A QUESTION
3 NOW. SO THAT IS UNCLEAR WHY THAT HAPPENED.

4 THERE IS ANOTHER QUESTION OF RATIONALE,
5 THAT THE VACCINE EFFECT ON CANCER STEM CELLS. THAT
6 IS PRESENTED IN FIGURE 6 IN THE APPLICATION. WE
7 ALSO CITE FIVE OTHER STUDIES, THREE OF WHICH ARE
8 CLINICAL TRIALS WHICH SHOW EFFECT OF THE VACCINE ON
9 CANCER STEM CELLS. SO, AGAIN, THAT INFORMATION IS
10 OVERLOOKED.

11 WITH REGARDS TO PLAN DESIGN AND ALSO
12 RATIONALE, THERE'S AN ENORMOUS QUESTION ABOUT OUR
13 TOXICOLOGY PLAN. I WANT TO POINT OUT THAT I AM THE
14 FIRST HOLDER OF THE IND ON THE ORIGINAL VACCINE. SO
15 I HAVE EXTENSIVE EXPERIENCE ON THAT. AS POINTED
16 OUT, WE COLLABORATED WITH CELLDIX, WHICH IS THE
17 COMPANY SPONSOR THAT NOW HOLDS THE IND. WE HAVE
18 THEIR PROTOCOL. WE ARE USING THE SAME CRO'S. THAT
19 PLAN MADE TOTAL SENSE. IN FACT, WHEN THE FDA
20 REVIEWED OUR PRE-IND REQUEST, THEY FELT THAT OUR
21 PRODUCT WAS SUFFICIENT AND OUR PLAN WAS GOOD. SO
22 THEY DIDN'T HAVE ANY PROBLEMS WITH THAT. SO I'M NOT
23 SURE WHERE THESE COMMENTS FROM THE REVIEWERS COME
24 OUT REGARDING OUR TOXICOLOGY.

25 AND THEN THERE IS A QUESTION OF BUYING THE

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1 MASS SPECTROMETER. THAT IS REALLY MORE TO
2 FACILITATE OUR WORK. WE COULD EASILY DELETE THAT
3 REQUEST AT NO IMPACT TO OUR WORK. THAT WILL BRING
4 OUR TOTAL PROJECT COST DOWN TO 3.4 MILLION,
5 INCLUSIVE OF IDC'S, PROBABLY THE MOST ECONOMIC
6 PROJECT THE OC PRESENTED.

7 AND FINALLY, WITH REGARDS TO IMPACT,
8 THERE'S A QUESTION ABOUT WHETHER OR NOT THIS VACCINE
9 IS GOING TO WORK. AND I WANT TO ILLUSTRATE THAT WE
10 REALLY ARE ON THE CUSP OF SUCCESS WITH THIS VACCINE.
11 SO, FIRST OF ALL, IT IS A SECOND GENERATION VACCINE.
12 IT ENHANCES PROTEOSOMAL PROCESSING. WE MADE A MAJOR
13 DISCOVERY THAT WAS PUBLISHED IN *SCIENCE*
14 *TRANSLATIONAL MEDICINE* TO FIGURE OUT HOW TO DO THAT.
15 I DO WANT TO BRING UP IF PEOPLE COULD LOOK AT FIGURE
16 4 IN MY REBUTTAL, THOSE TWO FIGURES SHOW CLINICAL
17 SUCCESS FOR THE PRIOR VERSION OF THE VACCINE. WE
18 CAN --

19 MS. MANDAC: I'M SORRY, DR. WONG, TIME IS
20 UP.

21 DR. WONG: OKAY. SO I SHOULD --

22 CHAIRMAN IMBASCIANI: FINISH THAT SENTENCE
23 PLEASE.

24 DR. WONG: SO THOSE ARE SUCCESSFUL
25 CLINICAL TRIALS THAT WE CAN REPLICATE WITH OUR

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1 SECOND GENERATION VACCINE. BECAUSE IT'S A MORE
2 ROBUST VERSION, WE REALLY FEEL THAT WE'RE GOING TO
3 HAVE SUCCESS ON IT. SO, AGAIN, WE'RE NEGATING WHAT
4 THE REVIEWERS SAID. THANK YOU.

5 CHAIRMAN IMBASCIANI: IS THERE ANY OTHER
6 MEMBER OF THE PUBLIC THAT I CAN'T SEE?

7 MS. MANDAC: NO. THERE ARE NO OTHER HANDS
8 RAISED.

9 CHAIRMAN IMBASCIANI: OKAY.

10 MR. HUANG: SO THIS IS A MOTION FOR
11 CLIN1-14852 TO NOT FUND.

12 CHAIRMAN IMBASCIANI: SO I GUESS YOU
13 SHOULD EXPLAIN WHAT A YES VOTE MEANS.

14 MR. HUANG: SO A YES VOTE WOULD BE NOT TO
15 FUND THIS PROJECT. A NO VOTE WOULD PUT US IN A
16 SITUATION WHERE WE WOULD PROBABLY NEED ANOTHER
17 MOTION.

18 CHAIRMAN IMBASCIANI: THANK YOU.

19 MR. HUANG: DAN BERNAL.

20 MR. BERNAL: (UNINTELLIGIBLE.)

21 CHAIRMAN IMBASCIANI: DAN, WE'RE HAVING
22 TROUBLE WITH YOUR RECEPTION. I'M HEARING A VOICE
23 THAT'S NOT YOURS.

24 MR. BERNAL: YES. THAT IS NOT COMING FROM
25 ME. MY VOTE IS AYE.

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1 MR. HUANG: MARIA BONNEVILLE.
2 VICE CHAIR BONNEVILLE: YES.
3 MR. HUANG: LEONDRA CLARK-HARVEY.
4 DR. CLARK-HARVEY: AYE.
5 MR. HUANG: ANNE-MARIE DULIEGE.
6 DR. DULIEGE: AYE.
7 MR. HUANG: MARK FISCHER-COLBRIE.
8 MR. FISCHER-COLBRIE: YES.
9 MR. HUANG: FRED FISHER.
10 DR. FISHER: YES.
11 MR. HUANG: ELENA FLOWERS.
12 DR. FLOWERS: YES.
13 MR. HUANG: DAVID HIGGINS.
14 DR. HIGGINS: YES.
15 MR. HUANG: VITO IMBASCIANI.
16 CHAIRMAN IMBASCIANI: YES.
17 MR. HUANG: STEPHEN JUELSGAARD.
18 MR. JUELSGAARD: YES.
19 MR. HUANG: RICH LAJARA.
20 MR. LAJARA: YES.
21 MR. HUANG: LAUREN MILLER-ROGEN.
22 MS. MILLER-ROGEN: YES.
23 MR. HUANG: JOE PANETTA.
24 MR. PANETTA: YES.
25 MR. HUANG: MARVIN SOUTHARD.

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1 DR. SOUTHARD: YES.

2 MR. HUANG: KEVIN XU.

3 MR. XU: AYE.

4 MR. HUANG: THE MOTION PASSES.

5 CHAIRMAN IMBASCIANI: OKAY. THANK HAYLEY
6 AND THE ENTIRE GRANTS REVIEW TEAM FOR ALL OF THE
7 WORK THAT WENT INTO EVALUATING THESE APPLICATIONS
8 AND FOR YOUR PRESENTATION, HAYLEY. THANK YOU.

9 AND THANKS, BEN, FOR DOING THE ASPECTS OF
10 THIS. AND THANK THE MEMBERS OF THE PUBLIC FOR THEIR
11 PARTICIPATION.

12 WE HAVE ANOTHER ITEM. ARE THERE ANY
13 GENERAL COMMENTS THAT THE BOARD MEMBERS WANT TO MAKE
14 ON THE APPLICATION REVIEW PROCESS? NOTHING.

15 IS THERE ANY MEMBER OF THE PUBLIC WHO
16 WOULD LIKE TO MAKE ANY COMMENTS -- AND MEMBER OF THE
17 GENERAL PUBIC WOULD LIKE TO MAKE A COMMENT ABOUT
18 TODAY'S MEETING OR ABOUT ANY ITEM THAT WAS NOT ON
19 TODAY'S AGENDA? HEARING NONE, I THANK YOU ALL FOR
20 YOUR PARTICIPATION. THE MEETING IS ADJOURNED.

21 (THE MEETING WAS THEN CONCLUDED AT 9:41 A.M.)

22
23
24
25

REPORTER'S CERTIFICATE

I, BETH C. DRAIN, A CERTIFIED SHORTHAND REPORTER IN AND FOR THE STATE OF CALIFORNIA, HEREBY CERTIFY THAT THE FOREGOING TRANSCRIPT OF THE VIRTUAL PROCEEDINGS BEFORE THE INDEPENDENT CITIZEN'S OVERSIGHT COMMITTEE AND THE APPLICATION REVIEW SUBCOMMITTEE OF THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE IN THE MATTER OF ITS REGULAR MEETING HELD ON APRIL 25, 2024, 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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