

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: MAY 26, 2022
9 A.M.

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

FILE NO.: 2022-22

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

BETH C. DRAIN, CA CSR NO. 7152

I N D E X

ITEM DESCRIPTION	PAGE NO.
OPEN SESSION	
1. CALL TO ORDER	3
2. CALL TO ORDER	3
ACTION ITEMS	
3. CONSIDERATION OF APPLICATIONS SUBMITTED IN RESPONSE TO CLINICAL TRIAL STAGE PROJECTS PROGRAM ANNOUNCEMENT (CLIN 1 OR 2)	
DISCUSSION ITEMS	
4. PUBLIC COMMENT	NONE
5. ADJOURNMENT	18

BETH C. DRAIN, CA CSR NO. 7152

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25

MAY 26, 2022; 9 A.M.

CHAIRMAN THOMAS: OKAY. GOOD MORNING,
EVERYBODY. WELCOME TO THE MAY MEETING OF THE ICOC
AND THE APPLICATION REVIEW SUBCOMMITTEE. I'VE GOT
MYSELF ON BLOCKED VIDEO HERE BECAUSE IT'S A
POTENTIALLY UNSTABLE INTERNET. WANT TO MAKE SURE WE
DON'T LOSE THAT. SO THANK YOU ALL FOR ATTENDING.

MARIA, WILL YOU PLEASE CALL THE ROLL.

MS. BONNEVILLE: SURE. DAN BERNAL.
LEONDRA CLARK-HARVEY.

MS. CLARK-HARVEY: PRESENT.

MS. BONNEVILLE: ANNE-MARIE DULIEGE.

DR. DULIEGE: YES.

MS. BONNEVILLE: YSABEL DURON.

MS. DURON: YES.

MS. BONNEVILLE: ELENA FLOWERS.

DR. FLOWERS: PRESENT.

MS. BONNEVILLE: MARK FISCHER-COLBRIE.

DR. FISCHER-COLBRIE: HERE --

MS. BONNEVILLE: FRED FISHER.

DR. FISHER: HERE.

MS. BONNEVILLE: DAVID HIGGINS. STEVE
JUELSGAARD.

MR. JUELSGAARD: HERE.

BETH C. DRAIN, CA CSR NO. 7152

1 MS. BONNEVILLE: RICH LAJARA.
2 MR. LAHARA: HERE.
3 MS. BONNEVILLE: DAVE MARTIN.
4 DR. MARTIN: HERE.
5 MS. BONNEVILLE: CHRISTINE MIASKOWSKI.
6 DR. MIASKOWSKI: MORNING.
7 MS. BONNEVILLE: LAUREN MILLER-ROGEN.
8 MS. MILLER-ROGEN: HERE.
9 MS. BONNEVILLE: ADRIANA PADILLA.
10 DR. PADILLA: HERE.
11 MS. BONNEVILLE: JOE PANETTA.
12 MR. PANETTA: HERE.
13 MS. BONNEVILLE: AL ROWLETT.
14 MR. ROWLETT: HERE.
15 MS. BONNEVILLE: MARVIN SOUTHARD.
16 JONATHAN THOMAS.
17 CHAIRMAN THOMAS: HERE.
18 MS. BONNEVILLE: ART TORRES.
19 MR. TORRES: HERE.
20 MS. BONNEVILLE: KAROL WATSON. SO WE HAVE
21 QUORUM.
22 CHAIRMAN THOMAS: THANK YOU, MARIA.
23 WE WILL NOW GO STRAIGHT INTO THE
24 APPLICATION REVIEW SUBCOMMITTEE MEETING. WE HAVE
25 ONE ITEM FOR CONSIDERATION, WHICH IS CONSIDERATION

BETH C. DRAIN, CA CSR NO. 7152

1 OF APPLICATIONS SUBMITTED IN RESPONSE TO CLINICAL
2 TRIAL STAGE PROJECTS PROGRAM ANNOUNCEMENT, CLIN1, 2,
3 OR 3. WE'LL HAVE A PRESENTATION FROM DR. SAMBRANO.

4 DR. SAMBRANO: OKAY. THANK YOU, MR.
5 CHAIRMAN. GOOD MORNING, EVERYONE.

6 SO WE ARE STARTING THIS MEETING, AS WE DO
7 WITH ALL OTHERS, INCLUDING OUR GRANTS WORKING GROUP
8 MEETINGS. WHEN WE START THEM, WE ALSO MAKE SURE
9 THAT WE ARE ALL ON THE SAME PAGE IN TERMS OF WHAT
10 OUR MISSION IS AND WHAT OUR GOAL IS ULTIMATELY,
11 WHICH IS TO ACCELERATE WORLD-CLASS SCIENCE TO
12 DELIVER TRANSFORMATIVE REGENERATIVE MEDICINE
13 TREATMENTS IN AN EQUITABLE MANNER TO A DIVERSE
14 CALIFORNIA AND WORLD.

15 THIS IS A REMINDER OF WHAT OUR 2021/22
16 BUDGET ALLOCATION IS FOR OUR CLINICAL PROGRAM. SO
17 FOR THE CLINICAL PROGRAM, THUS FAR THE BOARD, THE
18 APPLICATION REVIEW SUBCOMMITTEE, HAS APPROVED 70.1
19 MILLION IN AWARDS. TODAY WE HAVE PENDING 27 MILLION
20 SUCH THAT, IF ALL OF THOSE ARE APPROVED, YOU WOULD
21 HAVE AN UNUSED BALANCE OF ABOUT 65 MILLION REMAINING
22 FOR THE FISCAL YEAR WHICH ENDS AT THE END OF JUNE.

23 THIS IS A REMINDER OF HOW WE SCORE
24 CLINICAL APPLICATIONS. WE USE A SCALE OF 1, 2 OR 3.
25 SCORES OF 1 MEANS THAT THEY HAVE EXCEPTIONAL MERIT

BETH C. DRAIN, CA CSR NO. 7152

1 AND WARRANT FUNDING. THE SCORE OF 2 MEANS THAT THEY
2 NEED IMPROVEMENT AND DON'T WARRANT FUNDING. AND SO
3 THESE APPLICATIONS WILL TYPICALLY GO BACK TO THE
4 APPLICANT FOR CORRECTIONS, REVISIONS, PROVIDING SOME
5 ADDITIONAL DATA THAT CAN COME BACK TO WHATEVER THE
6 NEXT CYCLE IS FOR THE REVIEW. A SCORE OF 3 MEANS
7 THAT IT'S SUFFICIENTLY FLAWED, IT DOESN'T WARRANT
8 FUNDING, AND WE DON'T ACCEPT THOSE FOR AT LEAST SIX
9 MONTHS FROM THE TIME OF THE REVIEW.

10 THE REVIEW CRITERIA THAT ARE UTILIZED TO
11 GIVE THESE SCORES BY THE GRANTS WORKING GROUP ARE
12 BASED ON THE FOLLOWING QUESTIONS. DOES THE PROJECT
13 HOLD THE NECESSARY SIGNIFICANCE AND POTENTIAL FOR
14 IMPACT? MEANING WHAT VALUE DOES IT OFFER, AND IS IT
15 SOMETHING THAT'S WORTH DOING? DOES IT HAVE A GOOD
16 RATIONALE? IS IT WELL-PLANNED AND DESIGNED? IS THE
17 PROJECT FEASIBLE, MEANING THEY HAVE THE APPROPRIATE
18 TEAM AND THE RESOURCES AVAILABLE TO CARRY OUT THE
19 PROPOSED ACTIVITIES? AND THEN, LASTLY, DOES THE
20 PROJECT ADDRESS THE NEEDS OF UNDERSERVED
21 COMMUNITIES?

22 THIS IS A REMINDER OF WHAT THE COMPOSITION
23 OF THE GRANTS WORKING GROUP ITSELF IS. IT INCLUDES
24 SCIENTIFIC GRANTS WORKING GROUP MEMBERS WHO ARE
25 RESPONSIBLE FOR THE SCIENTIFIC EVALUATION OF IT.

BETH C. DRAIN, CA CSR NO. 7152

1 THEY ARE THE ONES THAT PROVIDE THE SCIENTIFIC SCORE
2 THAT YOU WILL SEE ON ALL APPLICATIONS. AND THERE'S
3 A VARIETY OF EXPERTS AND BACKGROUNDS THAT CONTRIBUTE
4 TO THESE REVIEWS. THERE ARE ALSO PATIENT ADVOCATE
5 AND NURSE MEMBERS WHO ARE ALSO MEMBERS OF THE BOARD
6 WHO ARE RESPONSIBLE FOR CONDUCTING THE DEI
7 EVALUATION OF THE APPLICATIONS, PROVIDING A PATIENT
8 PERSPECTIVE ON THE SIGNIFICANCE AND IMPACT OF THESE
9 PROPOSALS, AND ALSO PROVIDING OVERSIGHT ON THE
10 PROCESS.

11 SO YOU WILL SEE A DEI SCORE ON ALL
12 APPLICATIONS. THESE ARE FROM THE PATIENT ADVOCATE
13 AND NURSE MEMBERS. AND EACH APPLICATION GETS A VOTE
14 ON WHETHER THE PROCESS WAS CONDUCTED IN A FAIR
15 MANNER WHICH WAS CONDUCTED BY THOSE MEMBERS AS WELL.
16 IN ADDITION, WE WILL OFTEN HAVE SCIENTIFIC
17 SPECIALISTS WHO COME IN TO FILL IN THE GAPS THAT THE
18 PRIMARY 15 MEMBERS MAY NOT HAVE IN A GIVEN PANEL.
19 THEY WILL PROVIDE AN INITIAL, BUT NOT A FINAL,
20 SCIENTIFIC SCORE. SO BASICALLY THEY CONTRIBUTE
21 THEIR EXPERTISE THAT INFORMS THE REST OF THE GRANTS
22 WORKING GROUP.

23 ALL RIGHT. SO THE FIRST APPLICATION UNDER
24 CONSIDERATION IS CLIN2-12823, AND THIS IS ONE THAT I
25 PRESENTED THE GRANTS WORKING GROUP RECOMMENDATIONS

BETH C. DRAIN, CA CSR NO. 7152

1 OF LAST MONTH. AND THE APPLICATION REVIEW
2 SUBCOMMITTEE VOTED ON THIS UNANIMOUSLY TO APPROVE
3 IT. HOWEVER, WE HAVE AN ADMINISTRATIVE ERROR THAT
4 CHAIRMAN THOMAS WILL EXPAND ON AND EXPLAIN.
5 CHAIRMAN THOMAS.

6 CHAIRMAN THOMAS: SO THANK YOU, GIL. SO
7 AS GIL SAYS, YOU WILL RECALL THAT THIS WAS VOTED ON
8 PREVIOUSLY AT OUR LAST ARS MEETING AND WAS
9 UNANIMOUSLY PASSED. SUBSEQUENTLY WE DETERMINED
10 THERE WAS ADMINISTRATIVE ERROR WHEREBY ONE OF THE
11 MEMBERS OF THE ARS WHO WAS CONFLICTED ON THIS
12 PARTICULAR APPLICATION, WAS INADVERTENTLY CALLED
13 UPON AND INADVERTENTLY VOTED ON THIS PARTICULAR
14 GRANT, WHICH IS WHAT GIVES RISE TO THE CONFLICT HERE
15 AND THE NEED IMMEDIATELY TO RECTIFY AT THE FIRST
16 AVAILABLE MOMENT, WHICH IS THIS MEETING.

17 SO THAT MEMBER, BY THE WAY, HAS REPORTED,
18 SELF-REPORTED TO THE FPPC TO OUTLINE THIS
19 ADMINISTRATIVE ERROR AND ACTION IN THE INTEREST OF
20 IMMEDIATE AND FULL TRANSPARENCY AND IS WAITING TO
21 HEAR BACK FROM THE FPPC WITH RESPECT TO THAT REPORT.

22 BECAUSE THIS WAS A VOTE THAT DID HAVE THIS
23 CONFLICT, I'M RESCINDING THE RESULTS OF THAT VOTE.
24 AND AS A RESULT, WE NEED TO HAVE A REVOTE WITH THAT
25 MEMBER NOT VOTING ON THIS OCCASION. AND SO WOULD

BETH C. DRAIN, CA CSR NO. 7152

1 LIKE TO ASK AT THIS POINT FOR A MOTION TO APPROVE
2 THIS GRANT.

3 DR. FISHER: SO MOVED.

4 DR. DULIEGE: I SECOND.

5 CHAIRMAN THOMAS: ANY DISCUSSION BY
6 MEMBERS OF THE BOARD? ANY DISCUSSION BY MEMBERS OF
7 THE PUBLIC? OKAY.

8 GIL, I'M SORRY. I DIDN'T MEAN TO GET IN
9 THE MIDDLE OF YOUR PRESENTATION. YOU CAN JUST
10 COMPLETE THE SLIDE PRESENTATION PLEASE.

11 DR. SAMBRANO: OKAY. DO YOU WANT ME TO GO
12 OVER THIS PARTICULAR APPLICATION AGAIN?

13 CHAIRMAN THOMAS: I DON'T THINK THAT'S
14 NECESSARY. WE HAD A FULL VETTING OF IT THE LAST
15 TIME, BUT I THINK IT'S GOOD FOR THE BOARD TO SEE THE
16 STRONG SUPPORT THAT IT HAD BOTH FROM THE GWG AND
17 FROM A DEI PERSPECTIVE.

18 MR. TORRES: THERE'S NO ACTION REQUIRED ON
19 OUR PART?

20 CHAIRMAN THOMAS: WE NEED TO REVOTE. WE
21 HAVE THIS MOTION HERE THAT WAS JUST MOVED AND
22 SECONDED. SO ARE THERE ANY PUBLIC COMMENTS ON THIS
23 MOTION?

24 MS. BONNEVILLE: THERE ARE NO PUBLIC
25 COMMENTS.

BETH C. DRAIN, CA CSR NO. 7152

1 CHAIRMAN THOMAS: THANK YOU. MARIA, WILL
2 YOU PLEASE CALL THE ROLL.
3 MS. BONNEVILLE: LEONDRA CLARK-HARVEY.
4 MS. CLARK-HARVEY: YES.
5 MS. BONNEVILLE: ANNE-MARIE DULIEGE.
6 DR. DULIEGE: YES.
7 MS. BONNEVILLE: YSABEL DURON.
8 ELENA FLOWERS.
9 DR. FLOWERS: YES.
10 MS. BONNEVILLE: MARK FISCHER-COLBRIE.
11 DR. FISCHER-COLBRIE: AYE.
12 MS. BONNEVILLE: FRED FISHER.
13 DR. FISHER: AYE.
14 MS. BONNEVILLE: STEVE JUELSGAARD.
15 MR. JUELSGAARD: YES.
16 MS. BONNEVILLE: RICH LAJARA.
17 MR. LAHARA: YES.
18 MS. BONNEVILLE: DAVE MARTIN.
19 DR. MARTIN: YES.
20 MS. BONNEVILLE: CHRISTINE MIASKOWSKI.
21 DR. MIASKOWSKI: YES.
22 MS. BONNEVILLE: LAUREN MILLER-ROGEN.
23 MS. MILLER-ROGEN: YES.
24 MS. BONNEVILLE: ADRIANA PADILLA.
25 DR. PADILLA: YES.

BETH C. DRAIN, CA CSR NO. 7152

1 MS. BONNEVILLE: JOE PANETTA.

2 MR. PANETTA: YES.

3 MS. BONNEVILLE: AL ROWLETT.

4 MR. ROWLETT: YES.

5 MS. BONNEVILLE: MARVIN SOUTHARD.

6 JONATHAN THOMAS.

7 CHAIRMAN THOMAS: YES.

8 MS. BONNEVILLE: THE MOTION CARRIES.

9 CHAIRMAN THOMAS: THANK YOU. GIL, ON TO
10 THE NEXT PLEASE.

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

12 SO THE NEXT TWO APPLICATIONS WERE REVIEWED
13 DURING THE APRIL CYCLE OF THE GRANTS WORKING GROUP
14 CLINICAL REVIEW. AND SO WE'LL START WITH
15 CLIN2-13017.

16 AND SO THE TITLE OF THIS ONE IS A DOUBLE
17 BLIND RANDOMIZED PLACEBO CONTROLLED INVESTIGATION OF
18 AUTOLOGOUS MUSCLE-DERIVED PROGENITOR CELLS FOR THE
19 TREATMENT OF DYSPHASIA. AND SO THIS IS A PROGENITOR
20 CELL THERAPY. DYSPHASIA IS A SWALLOWING DISORDER
21 THAT OCCURS FOLLOWING CHEMOTHERAPY TREATMENT FOR
22 HEAD AND NECK CANCER. AND THE GOAL OF THIS PROPOSAL
23 IS TO COMPLETE A PHASE 1/2 CLINICAL TRIAL TO ASSESS
24 SAFETY AND PRELIMINARY EFFICACY. THE FUNDS
25 REQUESTED ARE JUST OVER 11 MILLION AND ARE PROVIDING

BETH C. DRAIN, CA CSR NO. 7152

1 CO-FUNDING OF ABOUT TWO MILLION.

2 A LITTLE BACKGROUND ON THIS DISEASE
3 INDICATION. TREATMENT FOR HEAD AND NECK CANCER WILL
4 OFTEN RESULT IN MUSCLE DAMAGE WHICH THEN AFFECTS THE
5 ABILITY OF MANY PATIENTS TO SWALLOW. AND SO THAT
6 DISORDER MAY CAUSE PATIENTS TO EXPERIENCE
7 MALNUTRITION, DEHYDRATION, AMONG OTHER THINGS, AND
8 EVEN POSSIBLY DEATH. AND SO THE VALUE OF THIS
9 PROPOSED THERAPY IS THAT THE CURRENT STANDARD OF
10 CARE TYPICALLY WILL INCLUDE REHABILITATION EXERCISES
11 OR SURGERY WHERE THEY REMOVE THE LARYNX. AND
12 THERE'S NO OTHER TREATMENTS REALLY THAT EXIST TO
13 EFFECTIVELY RESTORE FUNCTION. SO IF THIS IS
14 SUCCESSFUL, THE PROPOSED THERAPY WOULD OFFER
15 PATIENTS THE POTENTIAL FOR AN IMPROVEMENT OR ABILITY
16 TO RESTORE THEIR ABILITY TO SWALLOW.

17 AND THIS IS A STEM CELL PROJECT BECAUSE
18 THE THERAPEUTIC CANDIDATE ITSELF OF COMPOSED
19 MUSCLE-DERIVED PROGENITOR CELLS.

20 IN OUR PORTFOLIO WE DON'T HAVE ANY OTHER
21 CLINICAL STAGE AWARDS THAT ARE ACTIVE THAT ARE
22 ADDRESSING THIS INDICATION OR THAT WOULD OTHERWISE
23 BE SIMILAR TO THIS PROPOSAL. THE APPLICANT HAS
24 RECEIVED CIRM FUNDING IN THE PAST. THEY RECEIVED AN
25 IND-ENABLING AWARD FOR A DIFFERENT INDICATION WHICH

BETH C. DRAIN, CA CSR NO. 7152

1 WAS FOR AIRWAY STENOSIS AND DID DEVELOP A BIT OF A
2 COMPLEX PRODUCT THAT THEIR HOPE WAS TO FILE AN IND
3 AND BEGIN A CLINICAL TRIAL WITH. BUT UNFORTUNATELY
4 THE DEVELOPMENT OF THAT DID NOT WORK OUT DUE TO
5 TECHNICAL REASONS, NOT DUE TO PERFORMANCE. AND SO
6 THAT WAS ONE AWARD THEY RECEIVED IN THE PAST.

7 THE RECOMMENDATION FROM THE GRANTS WORKING
8 GROUP AS IT RELATES TO THIS CURRENT APPLICATION IS
9 FOLLOWS. THERE WAS A UNANIMOUS SCORING OF 1 FOR THE
10 APPLICATION. THERE WERE NO MEMBERS THAT SCORED IT A
11 2 OR A 3. THE DEI SCORE, GIVEN BY THE PATIENT
12 ADVOCATE AND NURSE MEMBERS, WAS A SCORE OF 9.
13 THAT'S THE MEDIAN FROM THE MEMBERS WHO SCORED. AND
14 THE CIRM TEAM RECOMMENDATION IS TO FUND THIS
15 APPLICATION FOR THE AMOUNT SHOWN OF JUST OVER \$11
16 MILLION. MR. CHAIRMAN.

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

19 MR. TORRES: SO APPROVED.

20 CHAIRMAN THOMAS: SECOND?

21 MS. BONNEVILLE: ART, YOU CANNOT MAKE THE
22 MOTION ON THIS PLEASE. THANK YOU.

23 MR. TORRES: SO I CAN'T EVEN SPEAK ON IT,
24 RIGHT?

25 MS. BONNEVILLE: NO.

BETH C. DRAIN, CA CSR NO. 7152

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25

DR. FISHER: I'LL MOVE.

MS. BONNEVILLE: FRED, WAS THAT YOU?

DR. FISHER: YES.

MS. BONNEVILLE: THANK YOU. AND DID WE
HAVE A SECOND? I'M SORRY I MISSED THAT.

DR. FLOWERS: SECOND.

CHAIRMAN THOMAS: THANK YOU. DO WE HAVE
DISCUSSION --

MS. BONNEVILLE: ELENA, YOU CANNOT BE THE
SECOND. I'M SORRY.

DR. CLARK-HARVEY: SECOND.

MS. BONNEVILLE: THANK YOU.

CHAIRMAN THOMAS: THANK YOU, MARIA.

MS. BONNEVILLE: YOU'RE WELCOME.

CHAIRMAN THOMAS: DO WE HAVE DISCUSSION BY
MEMBERS OF THE BOARD? ANY COMMENTS FROM MEMBERS OF
THE PUBLIC? HEARING NONE, MARIA, WILL YOU PLEASE
CALL THE ROLL.

MS. BONNEVILLE: YES.

LEONDRA CLARK-HARVEY.

MS. CLARK-HARVEY: YES.

MS. BONNEVILLE: ANNE-MARIE DULIEGE.

DR. DULIEGE: YES.

MS. BONNEVILLE: YSABEL DURON.

MS. DURON: YES.

BETH C. DRAIN, CA CSR NO. 7152

1 MS. BONNEVILLE: MARK FISCHER-COLBRIE.
2 DR. FISCHER-COLBRIE: YES.
3 MS. BONNEVILLE: FRED FISHER.
4 DR. FISHER: YES.
5 MS. BONNEVILLE: DAVID HIGGINS. STEVE
6 JUELSGAARD.
7 MR. JUELSGAARD: YES.
8 MS. BONNEVILLE: RICH LAJARA.
9 MR. LAHARA: YES.
10 MS. BONNEVILLE: DAVE MARTIN.
11 DR. MARTIN: YES.
12 MS. BONNEVILLE: LAUREN MILLER-ROGEN.
13 ADRIANA PADILLA.
14 DR. PADILLA: YES.
15 MS. BONNEVILLE: JOE PANETTA.
16 MR. PANETTA: YES.
17 MS. BONNEVILLE: AL ROWLETT.
18 MR. ROWLETT: YES.
19 MS. BONNEVILLE: JONATHAN THOMAS.
20 CHAIRMAN THOMAS: YES.
21 MS. BONNEVILLE: MOTION CARRIES.
22 CHAIRMAN THOMAS: THANK YOU. GIL, PLEASE
23 PROCEED TO THE THIRD AND FINAL GRANT FOR TODAY'S
24 MEETING.
25 DR. SAMBRANO: THANK YOU, MR. CHAIRMAN.

BETH C. DRAIN, CA CSR NO. 7152

1 SO THE NEXT APPLICATION IS CLIN2-13355. SO THE
2 TITLE OF THIS ONE IS "PHASE 1-2 STUDY OF A NEURAL
3 CELL THERAPY IN SUBJECTS WITH DRUG RESISTANT
4 UNILATERAL MESIAL TEMPORAL LOBE EPILEPSY."

5 AND SO THIS IS A CELL THERAPY DERIVED FROM
6 HUMAN EMBRYONIC STEM CELLS TO CREATE AN ALLOGENEIC
7 NEURAL CELL THERAPY. THE INDICATION IS FOR DRUG
8 RESISTANT UNILATERAL MESIAL TEMPORAL LOBE EPILEPSY.
9 THEIR GOAL IS TO COMPLETE A PHASE 1-2 CLINICAL TRIAL
10 TO ASSESS SAFETY AND PRELIMINARY EFFICACY. THE
11 FUNDS REQUESTED ARE JUST UNDER EIGHT MILLION, AND
12 THE CO-FUNDING PROVIDED IS ABOUT THREE AND A HALF
13 MILLION.

14 SO BACKGROUND ON THIS INDICATION, EPILEPSY
15 AFFECTS MORE THAN THREE MILLION PEOPLE IN THE U.S.,
16 AND APPROXIMATELY 143 TO ABOUT 191,000 CASES ARE OF
17 DRUG RESISTANT MESIAL TEMPORAL LOBE EPILEPSY.

18 SO PATIENTS THAT EXPERIENCE EPILEPTIC
19 SEIZURES ARE TREATED WITH ANTI-SEIZURE MEDICATIONS
20 OF WHICH THERE A VARIETY, BUT ONLY ABOUT 44 PERCENT
21 BECOME SEIZURE FREE. AND ABOUT A THIRD OF
22 INDIVIDUALS WITH EPILEPSY HAVE THE DRUG RESISTANT
23 SEIZURES.

24 THE STANDARD OF CARE MAY INVOLVE SURGICAL
25 RESECTION OF THE TEMPORAL LOBE AS ONE OPTION, BUT

BETH C. DRAIN, CA CSR NO. 7152

1 MANY PATIENTS EITHER AREN'T ELIGIBLE OR INTERESTED
2 IN SUCH AN INVASIVE PROCEDURE. SO IF THIS IS
3 SUCCESSFUL, THE PROPOSED THERAPY DOES OFFER PATIENTS
4 A POTENTIAL FOR A MUCH SAFER, LESS INVASIVE, AND
5 MORE EFFECTIVE OPTION TO TREAT THOSE SEIZURES.

6 AND SO WHY IS THIS A STEM CELL OR GENE
7 THERAPY PROJECT? THIS THERAPEUTIC CANDIDATE IS
8 MANUFACTURED FROM HUMAN EMBRYONIC STEM CELLS.

9 THERE ARE NO OTHER ACTIVE CLINICAL STAGE
10 AWARDS THAT ARE TARGETING THIS DISEASE INDICATION
11 CURRENTLY IN OUR PORTFOLIO. AND THE APPLICANT HAS
12 RECEIVED CIRM FUNDING IN THE PAST. ACTUALLY TWO
13 DIFFERENT AWARDS AT THE DISCOVERY STAGE AS WELL AS
14 THE TRANSLATIONAL STAGE THAT HAVE LED ULTIMATELY TO
15 THE CURRENT PROPOSAL THAT THEY HAVE BEFORE US IN
16 DEVELOPING THIS PROPOSED THERAPY FOR MESIAL TEMPORAL
17 LOBE EPILEPSY.

18 SO THE RECOMMENDATIONS FROM THE GRANTS
19 WORKING GROUP ARE SHOWN HERE. WE HAD A UNANIMOUS
20 VOTE OF A SCORE OF 1 BY THE SCIENTIFIC MEMBERS OF
21 THE WORKING GROUP. THE DEI SCORE WAS A NINE. THE
22 MEDIAN WAS SCORED BY THE PATIENT ADVOCATE AND NURSE
23 MEMBERS. THE CIRM TEAM RECOMMENDATION IS TO FUND
24 THIS APPLICATION FOR THE AWARD AMOUNT OF 7.99
25 MILLION. MR. CHAIRMAN.

BETH C. DRAIN, CA CSR NO. 7152

1 CHAIRMAN THOMAS: THANK YOU VERY MUCH,
2 GIL. DO WE HAVE A MOTION TO APPROVE?

3 DR. DULIEGE: I MOVE.

4 CHAIRMAN THOMAS: MOVED BY ANNE-MARIE. DO
5 WE HAVE A SECOND?

6 DR. CLARK-HARVEY: SECOND.

7 CHAIRMAN THOMAS: THANK YOU, BOTH OF YOU.
8 ARE THERE QUESTIONS OR COMMENTS FROM MEMBERS OF THE
9 BOARD?

10 DR. DULIEGE: YES. J.T., A QUESTION IF
11 POSSIBLE.

12 CHAIRMAN THOMAS: YES.

13 DR. DULIEGE: IT'S ACTUALLY NOT SO MUCH A
14 COMMENT. GIL, CAN YOU PLEASE EDUCATE ME ON WHETHER
15 THIS REPRESENTS A RATHER SMALL PORTION OF ALL THE
16 EPILEPSIES POSSIBLE? IS IT A VERY NARROW PATIENT
17 POPULATION, OR IS IT A BROADER POPULATION? AND WILL
18 THERE BEN AN POPULATION OF THIS TO A BROADER PATIENT
19 POPULATION PATIENTS WITH EPILEPSY?

20 DR. SAMBRANO: THAT'S A VERY GOOD
21 QUESTION. I THINK THE ESTIMATE, BASED ON BOTH THE
22 APPLICANTS AND SOME OF THE REVIEWERS, THAT YOU'RE
23 LOOKING AT ABOUT 12 PERCENT OF PEOPLE WITH TEMPORAL
24 LOBE EPILEPSY. AN TEMPORAL LOBE EPILEPSY IS THE
25 MOST COMMON TYPE THAT AFFECTS INDIVIDUALS.

BETH C. DRAIN, CA CSR NO. 7152

1 SO IT IS A SUBPORTION, BUT THE APPLICANTS
2 DO INTEND BEYOND THIS INITIAL CLINICAL TRIAL TO
3 POTENTIALLY EXPAND IT TO OTHER EPILEPSY TYPES AND
4 MAYBE OTHER SEIZURE INDUCING CONDITIONS BEYOND
5 EPILEPSY IF IT'S SUCCESSFUL.

6 DR. DULIEGE: THANK YOU.

7 CHAIRMAN THOMAS: ANY OTHER COMMENTS OR
8 QUESTIONS FROM THE BOARD?

9 DR. MARTIN: JUST A QUICK QUESTION. IS
10 THIS THE STUDY -- I DIDN'T GO BACK AND LOOK IT UP --
11 THERE WERE 31 EXPERIMENTAL AND 31 CONTROLS IN THIS
12 STUDY?

13 DR. SAMBRANO: NO, THAT WAS THE PREVIOUS
14 APPLICATION. THIS ONE IS DONE IN TWO STAGES. SO
15 WE'RE STARTING WITH UP TO ABOUT TEN PATIENTS FIRST
16 TO ASSESS SAFETY AND THEN ABOUT 30 TO ASSESS THE
17 EFFICACY.

18 DR. MARTIN: THANK YOU.

19 MS. DURON: GIL, YSABEL HERE.

20 MS. BONNEVILLE: YSABEL, YOU CAN'T
21 COMMENT.

22 CHAIRMAN THOMAS: THANK YOU, MARIA. ANY
23 OTHER COMMENTS FROM MEMBERS OF THE BOARD? ANY
24 COMMENTS FROM THE PUBLIC? HEARING NONE, MARIA, WILL
25 YOU PLEASE CALL THE ROLL.

BETH C. DRAIN, CA CSR NO. 7152

1 MS. BONNEVILLE: YES.
2 LEONDRA CLARK-HARVEY.
3 MS. CLARK-HARVEY: YES.
4 MS. BONNEVILLE: ANNE-MARIE DULIEGE.
5 DR. DULIEGE: YES.
6 MS. BONNEVILLE: ELENA FLOWERS.
7 DR. FLOWERS: YES.
8 MS. BONNEVILLE: MARK FISCHER-COLBRIE.
9 DR. FISCHER-COLBRIE: AYE.
10 MS. BONNEVILLE: FRED FISHER.
11 DR. FISHER: YES.
12 MS. BONNEVILLE: STEVE JUELSGAARD.
13 MR. JUELSGAARD: YES.
14 MS. BONNEVILLE: RICH LAJARA.
15 MR. LAHARA: YES.
16 MS. BONNEVILLE: DAVE MARTIN.
17 DR. MARTIN: YES.
18 MS. BONNEVILLE: CHRISTINE MIASKOWSKI.
19 DR. MIASKOWSKI: MARIA, CAN I COMMENT ON
20 THIS ONE?
21 MS. BONNEVILLE: YES, YOU CAN.
22 DR. MIASKOWSKI: THEN YES.
23 MS. BONNEVILLE: LAUREN MILLER-ROGEN.
24 MS. MILLER-ROGEN: I'M SO SORRY. I WAS
25 RESTARTING AND MISSED THE ENTIRE PRESENTATION. SO

BETH C. DRAIN, CA CSR NO. 7152

1 I'M NOT SURE I SHOULD VOTE.

2 MS. BONNEVILLE: OKAY. THANK YOU.

3 ADRIANA PADILLA.

4 DR. PADILLA: YES.

5 MS. BONNEVILLE: JOE PANETTA.

6 MR. PANETTA: YES.

7 MS. BONNEVILLE: AL ROWLETT.

8 MR. ROWLETT: YES.

9 MS. BONNEVILLE: JONATHAN THOMAS.

10 CHAIRMAN THOMAS: YES.

11 MS. BONNEVILLE: ART TORRES.

12 MR. TORRES: AYE.

13 MS. BONNEVILLE: THANK YOU. THE MOTION

14 CARRIES.

15 CHAIRMAN THOMAS: THANK YOU, MARIA.

16 GIL, I BELIEVE THAT CONCLUDES YOUR

17 PRESENTATION?

18 DR. SAMBRANO: IT DOES.

19 CHAIRMAN THOMAS: OKAY. THANK YOU TO YOU

20 AND MEMBERS OF YOUR TEAM FOR YOUR USUAL OUTSTANDING

21 WORK.

22 WE ARE NOW OUT OF THE APPLICATION REVIEW

23 SUBCOMMITTEE AND INTO GENERAL PUBLIC COMMENT. DO WE

24 HAVE ANY PUBLIC COMMENT ON ANY MATTERS?

25 MS. BONNEVILLE: WE DON'T.

BETH C. DRAIN, CA CSR NO. 7152

1 CHAIRMAN THOMAS: OKAY. SO WE ARE
2 CONCLUDING THIS, BUT BEFORE WE DO, ITS A BITTERSWEET
3 NOTE THAT THIS IS THE LAST MEETING FOR DAVE MARTIN
4 AS A MEMBER OF THE ICOC AND THE APPLICATION REVIEW
5 SUBCOMMITTEE. DAVE IS PICKING UP SHOP AND MOVING
6 WITH FAMILY TO NORTH CAROLINA. AND, DAVE, WE WILL
7 GIVE YOU A PROPER RECOGNITION WITH THE FULL BOARD IN
8 JUNE. BUT IF YOU'D LIKE TO SAY A COUPLE COMMENTS AT
9 THIS POINT, TOTALLY WELCOME.

10 DR. MARTIN: ACTUALLY I SUBMITTED MY
11 RESIGNATION LETTER TO TREASURER MA AND I JUST VERY
12 SIMPLY STATED THAT IT'S BEEN A VERY INTERESTING
13 EXPERIENCE FOR ME BOTH EMOTIONALLY AND
14 INTELLECTUALLY. I'VE LEARNED A LOT, AND I VERY MUCH
15 APPRECIATE WHAT CIRM IS DOING. AND I'M ENTHUSIASTIC
16 ABOUT THE FUTURE OF CIRM AND THE PATIENTS, BOTH
17 CALIFORNIA CITIZENS AS WELL AS GLOBAL IMPACT OF
18 CIRM. AND IT'S QUITE STARTLING WHAT HAS BEEN
19 ACCOMPLISHED AND WHAT IS CLEARLY ON THE DRAWING
20 BOARD HERE.

21 AND AS I'VE SAID BEFORE, I THINK THAT
22 PROBABLY THE GREATEST LEGACY OF CIRM IS GOING TO BE
23 ITS EDUCATIONAL PROGRESS. IT'S BEEN QUITE AN
24 EXPERIENCE FOR ME. AND PART OF IT ALSO IS MEETING
25 PEOPLE, MANY OF YOU ON THIS ICOC BOARD, AND HAVING

BETH C. DRAIN, CA CSR NO. 7152

1 SOME INTERACTIONS WITH ALL OF YOU. AND PARTICULARLY
2 MEETING IN SITU AT THE HEADQUARTERS IN OAKLAND TO
3 ACTUALLY SEE AND BE ABLE TO INTERACT WITH ALL OF
4 YOU. SO I THANK YOU ALL, AND I THANK THE TREASURER
5 FOR ALLOWING ME TO PARTICIPATE IN CALIFORNIA
6 ACTIVITIES. THANK YOU VERY MUCH.

7 CHAIRMAN THOMAS: AND THANK YOU, DAVE.
8 AND AS I SAY, WE WILL GIVE YOU YOUR FULL AND PROPER
9 DUE WITH THE FULL COMPLEMENT OF YOUR BOARD
10 COLLEAGUES AT OUR MEETING IN JUNE WHICH WILL BE A
11 FULL BOARD MEETING. YOU MAY NEED TO REAPPRISE A
12 COUPLE OF THOSE STATEMENTS, BUT I THINK IT'S BEEN
13 TERRIFIC HAVING YOU ON THE BOARD. BUT I'M GOING TO
14 SAVE MY MAIN COMMENTS FOR JUNE. I DON'T WANT TO SAY
15 GOODBYE QUITE YET.

16 MARIA, WHAT IS THE JUNE DATE AGAIN FOR
17 MEMBERS OF THE ARS?

18 MS. BONNEVILLE: JUNE 27TH. YES, JUNE
19 27TH. AND IT REALLY IS A FULL BOARD MEETING. WE'VE
20 GOT A LOT ON THE AGENDA. WE ARE ALSO HAVING AN ARS
21 MEETING THE WEEK PRIOR. THERE'S SO MUCH ON THE
22 AGENDA THAT WE WANTED TO TAKE UP THE APPLICATIONS
23 SEPARATELY FROM THE FULL BOARD MEETING. SO YOU GUYS
24 GET TO COME TO TWO MEETINGS IN LIKE FIVE DAYS. I
25 KNOW YOU'RE REALLY EXCITED ABOUT THAT.

BETH C. DRAIN, CA CSR NO. 7152

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25

CHAIRMAN THOMAS: EXCELLENT. ALL RIGHT.
THANK YOU. ON THAT NOTE, THANK YOU ALL VERY MUCH
FOR ATTENDING AND HAVE A WONDERFUL REST OF YOUR DAY,
AND WE STAND ADJOURNED.

(THE MEETING WAS THEN CONCLUDED AT
9:30 A.M.)

REPORTER'S CERTIFICATE

I, BETH C. DRAIN, A CERTIFIED SHORTHAND REPORTER IN AND FOR THE STATE OF CALIFORNIA, HEREBY CERTIFY THAT THE FOREGOING TRANSCRIPT OF THE VIRTUAL PROCEEDINGS BEFORE THE 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 MAY 26, 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, CSR 7152
133 HENNA COURT
SANDPOINT, IDAHO
(208) 920-3543