

BETH C. DRAIN, CA CSR NO. 7152

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

LOCATION: VIA ZOOM

DATE: SEPTEMBER 20, 2022
9 A.M.

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

FILE NO.: 2022-34

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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 CLINICAL TRIAL STAGE PROJECTS PROGRAM ANNOUNCEMENT (CLIN 1 OR 2)	5
4. CONSIDERATION OF APPLICATIONS SUBMITTED IN RESPONSE TO DISCOVERY STAGE RESEARCH PROJECTS PROGRAM ANNOUNCEMENT (DISC0)	14
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 ITEM 3 AND 4 (HEALTH & SAFETY CODE 125290.30(F) (3) (B) AND (C))	
DISCUSSION ITEMS	
6. PUBLIC COMMENT	NONE
7. ADJOURNMENT	28

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SEPTEMBER 20, 2022; 9 A.M.

CHAIRMAN THOMAS: OKAY. GOOD MORNING,
EVERYBODY. WELCOME TO THE SEPTEMBER MEETING OF THE
ICOC AND APPLICATION REVIEW SUBCOMMITTEE. MARIA,
WILL YOU PLEASE CALL THE ROLL.

MS. BONNEVILLE: SURE. DAN BERNAL.

MR. BERNAL: PRESENT.

MS. BONNEVILLE: LEONDRA CLARK-HARVEY.
ANNE-MARIE DULIEGE.

DR. DULIEGE: PRESENT.

MS. BONNEVILLE: YSABEL DURON.

MS. DURON: PRESENT.

MS. BONNEVILLE: ELENA FLOWERS.

DR. FLOWERS: PRESENT.

MS. BONNEVILLE: MARK FISCHER-COLBRIE.

DR. FISCHER-COLBRIE: HERE.

MS. BONNEVILLE: FRED FISHER.

DR. FISHER: PRESENT.

MS. BONNEVILLE: DAVID HIGGINS.

DR. HIGGINS: HERE.

MS. BONNEVILLE: STEVE JUELGAARD.

MR. JUELGAARD: PRESENT.

MS. BONNEVILLE: RICH LAJARA.

MR. LAJARA: HERE.

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1 MS. BONNEVILLE: CHRISTINE MIASKOWSK.

2 DR. MIASKOWSKI: PRESENT.

3 MS. BONNEVILLE: LAUREN MILLER ROGEN.

4 ADRIANA PADILLA.

5 DR. PADILLA: HERE.

6 MS. BONNEVILLE: JOE PANETTA.

7 MR. PANETTA: HERE.

8 MS. BONNEVILLE: AL ROWLETT. MARVIN

9 SOUTHARD.

10 DR. SOUTHARD: HERE.

11 MS. BONNEVILLE: JONATHAN THOMAS.

12 CHAIRMAN THOMAS: HERE.

13 MS. BONNEVILLE: ART TORRES.

14 MR. TORRES: HERE.

15 MS. BONNEVILLE: KAROL WATSON.

16 DR. WATSON: HERE.

17 MS. BONNEVILLE: THANK YOU. WE HAVE A

18 QUORUM.

19 CHAIRMAN THOMAS: THANK YOU, MARIA.

20 OKAY. WE ARE GOING INTO THE APPLICATION

21 REVIEW SUBCOMMITTEE. AT THIS POINT WE HAVE TWO

22 ITEMS. THE FIRST ONE IS CONSIDERATION OF

23 APPLICATIONS SUBMITTED IN RESPONSE TO CLINICAL TRIAL

24 STAGE PROGRAM ANNOUNCEMENT CLINS 1, 2, AND 3. AS

25 ALWAYS, A PRESENTATION FROM DR. SAMBRANO. GIL.

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1 DR. SAMBRANO: THANK YOU. MR. CHAIRMAN.

2 LET ME PUT THIS IN PRESENTATION MODE, AND
3 WE WILL GET STARTED.

4 GOOD MORNING ALL. SO THIS INITIAL
5 PRESENTATION IS FOR THE CLINICAL PROGRAM AND LATEST
6 ROUND RECOMMENDATIONS FROM THE GRANTS WORKING GROUP.
7 AS ALWAYS, WE BEGIN OUR MEETINGS, INCLUDING OUR
8 REVIEW MEETINGS, WITH A DECLARATION OF OUR MISSION
9 SO WE KNOW WHY WE ARE ALL HERE. AND SO OUR MISSION,
10 OF COURSE, IS TO ACCELERATE WORLD-CLASS SCIENCE TO
11 DELIVER TRANSFORMATIVE REGENERATIVE MEDICINE
12 TREATMENTS IN AN EQUITABLE MANNER TO A DIVERSE
13 CALIFORNIA AND WORLD.

14 THIS IS AN UPDATE ON OUR CURRENT BUDGET
15 ALLOCATION FOR THE CLINICAL PROGRAM. WE JUST
16 STARTED THIS OUT IN JULY. SO WE ARE STILL EARLY ON
17 WITH THIS BUDGET. WE HAVE 7.8 MILLION THAT HAVE
18 BEEN APPROVED THUS FAR. TODAY THE ONE APPLICATION
19 BEING CONSIDERED WOULD ADD 6.9 MILLION, AND WE HAVE
20 REMAINING AFTER THAT 147.3 MILLION SHOULD THAT BE
21 APPROVED.

22 THIS IS A REMINDER OF THE SCIENTIFIC
23 SCORING SYSTEM THAT'S USED FOR CLINICAL APPLICATIONS
24 WHICH IS BASED ON A SCALE OF 1, 2, OR 3. A SCORE OF
25 1 MEANS THE APPLICATION HAS EXCEPTIONAL MERIT AND

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1 WARRANTS FUNDING. IT MIGHT HAVE SOME MINOR
2 RECOMMENDATIONS THAT ARE MADE BY THE GRANTS WORKING
3 GROUP, BUT IN GENERAL IT'S NOT SOMETHING THEY WOULD
4 WANT TO SEE AGAIN. A SCORE OF 2 IS ONE THAT NEEDS
5 IMPROVEMENT. THOSE APPLICATIONS NORMALLY GO BACK TO
6 THE APPLICANT FOR REVISIONS, AND THE GRANTS WORKING
7 GROUP GET'S ANOTHER OPPORTUNITY TO LOOK AT THOSE.
8 THOSE WITH A SCORE OF 3 ARE SUFFICIENTLY FLAWED THAT
9 WE DON'T ACCEPT THOSE BACK FOR AT LEAST SIX MONTHS.

10 THE REVIEW CRITERIA THAT ARE UTILIZED TO
11 COME UP WITH A SCORE ARE BASED ON THESE FIVE
12 QUESTIONS: DOES THE PROJECT HAVE THE NECESSARY
13 SIGNIFICANCE AND POTENTIAL FOR IMPACT? DOES IT HAVE
14 A GOOD RATIONALE? IS IT WELL PLANNED AND DESIGNED?
15 IS IT FEASIBLE, INCLUDING HAVING THE APPROPRIATE
16 TEAM AND RESOURCES TO CARRY IT OUT. AND LASTLY,
17 DOES THE PROJECT UPHOLD THE PRINCIPLES OF DIVERSITY,
18 EQUITY, AND INCLUSION?

19 THE COMPOSITION OF THE GRANTS WORKING
20 GROUP INCLUDES SEVERAL MEMBERS: THE CORE SCIENTIFIC
21 WORKING MEMBERS THAT CONDUCT THE SCIENTIFIC
22 EVALUATION AND PROVIDE EXPERTISE FROM A VARIETY OF
23 BACKGROUNDS, INCLUDING DISEASE AREA, REGULATORY, AND
24 SO ON. SO THESE MEMBERS SCORE ALL THE APPLICATIONS
25 AND PROVIDE THE SCIENTIFIC SCORE.

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1 WE ALSO HAVE OUR PATIENT ADVOCATE AND
2 NURSE GRANTS WORKING GROUP MEMBERS WHO ARE ALSO
3 MEMBERS OF THIS BOARD. THEY CONDUCT THE DEI
4 EVALUATION. THEY PROVIDE A PATIENT PERSPECTIVE ON
5 THE SIGNIFICANCE AND POTENTIAL IMPACT OF THE PROJECT
6 AND OVERSIGHT ON THE PROJECT. SO THESE MEMBERS
7 PROVIDE A DEI SCORE ON ALL APPLICATIONS AS WELL AS A
8 SUGGESTED SCIENTIFIC SCORE.

9 WE OFTEN WILL ALSO HAVE SCIENTIFIC
10 SPECIALISTS WHO ARE NONVOTING MEMBERS WHO WE USE TO
11 FILL IN KNOWLEDGE GAPS AMONG THE PANEL. AND SO THEY
12 MAY PROVIDE SCIENTIFIC EVALUATION AND PROVIDE AN
13 INITIAL, BUT NOT A FINAL, SCIENTIFIC SCORE.

14 ALL RIGHT. BEFORE WE GO ON INTO THE
15 APPLICATION DETAILS, I'M JUST GOING TO HIGHLIGHT THE
16 POTENTIAL CONFLICTS THAT MAY EXIST WITH THE
17 APPLICATION OR IDENTIFY A CONFLICT. THOSE THAT HAVE
18 THE RED ASTERISK ARE MEMBERS OF THE APPLICATION
19 REVIEW SUBCOMMITTEE. SO JUST BE MINDFUL ABOUT NOT
20 SPEAKING DURING THE DISCUSSION FOR THIS PARTICULAR
21 APPLICATION.

22 THIS APPLICATIONS IS ENTITLED "PHASE 1
23 CLINICAL RESEARCH PROGRAM FOR A FUNCTIONAL CURE OF
24 HIV WITH AN IN-VIVO GENE THERAPY." THIS IS A GENE
25 THERAPY THAT TARGETS LATENT HIV INFECTED CELLS. AND

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1 THE GOAL OF THIS PROPOSAL IS TO COMPLETE A PHASE I
2 CLINICAL TRIAL TO ASSESS THE SAFETY OF THIS
3 THERAPEUTIC.

4 THE AMOUNT REQUESTED FROM CIRM IS 6.85
5 MILLION. THE APPLICANT IS PROVIDING 7.23 MILLION IN
6 COFUNDING.

7 SOME BACKGROUND ON HIV. THERE'S
8 APPROXIMATELY 38 MILLION PEOPLE WORLDWIDE INFECTED
9 AND LIVING WITH HIV. THERE'S AN ESTIMATED 1.5
10 MILLION NEW CASES OF HIV THAT WERE REPORTED IN 2020.
11 THE STANDARD OF CARE, AS MANY OF YOU MAY KNOW, IS
12 ANTI-RETROVIRAL THERAPY OR ART, WHICH, IF SUCCESSFUL
13 IN CONTROLLING THE INFECTION, BUT IT DOES REQUIRE
14 LIFELONG ADHERENCE, AND IS NOT A CURE. EVEN WITH
15 THE ART THERAPY, THE HIV WILL PERSIST IN THE BODY IN
16 THE FORM OF INTEGRATED PROVIRAL DNA IN LATENTLY
17 INFECTED CELLS. SO THIS PROPOSED THERAPY WOULD
18 OFFER THE POTENTIAL TO EFFECTIVELY CURE PATIENTS OF
19 HIV INFECTION BY TARGETING AND REMOVING THAT
20 INTEGRATED PROVIRAL DNA IN LATENTLY INFECTED CELLS.

21 WHY DOES THIS QUALIFY FOR CIRM? THIS IS A
22 THERAPEUTIC CANDIDATE THAT IS A GENE THERAPY
23 TARGETING THE HIV-INFECTED CELLS.

24 ALL RIGHT. SO PROGRAMS WITHIN OUR
25 EXISTING ACTIVE PORTFOLIO THAT MAYBE HAVE SOME

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1 SIMILARITY TO THIS PROJECT INCLUDE THESE THREE THAT
2 ARE LISTED. NONE ARE SIMILAR IN THE SENSE THAT NONE
3 OF THESE ARE GENE THERAPY AS THE CURRENT PROPOSAL
4 AND SOME ARE NOT NECESSARILY JUST ON HIV.

5 SO THE FIRST ONE, THE CLIN2 AT THE VERY
6 TOP, IS FOR HIV-RELATED LYMPHOMA. IT IS AN
7 AUTOLOGOUS GENE-CORRECTED HEMATOPOIETIC STEM CELL
8 THERAPY THAT WOULD TREAT LYMPHOMA IN HIV INFECTED
9 PATIENTS. WE HAVE A COUPLE OF PROJECTS, A CLIN 1
10 AND A CLIN2, THAT ARE USING A CAR-T CELL APPROACH
11 WITH DIFFERENT TARGETS FOR HIV WITH THE GOAL TO RID
12 THE BODY OF HIV INFECTED CELLS. SO THOSE ARE THE
13 MOST CLOSELY RELATED PROJECTS TO THE CURRENT
14 PROPOSAL.

15 THE APPLICANT HAS NOT PREVIOUSLY RECEIVED
16 A CIRM AWARD. SO THIS WILL BE THE FIRST FOR THIS
17 PARTICULAR APPLICANT.

18 SO IN SUMMARY THE RECOMMENDATION FROM THE
19 GRANTS WORKING GROUP IS A SCORE OF 1 WITH TEN
20 MEMBERS GIVING IT A SCORE OF 13, THREE GIVING IT A
21 SCORE OF 2, AND TWO MEMBERS GIVING IT A SCORE OF 3.
22 THE DEI SCORE IS 8 ON A SCALE OF 1 TO 10 WITH 10
23 BEING THE BEST POSSIBLE SCORE. THE CIRM TEAM
24 RECOMMENDATION IS TO FUND THIS APPLICATION IN THE
25 AMOUNT OF 6.85 MILLION. AND I WILL TURN IT BACK TO

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1 YOU, MR. CHAIRMAN.

2 CHAIRMAN THOMAS: THANK YOU VERY MUCH, DR.
3 SAMBRANO.

4 DO WE HAVE A MOTION TO APPROVE?

5 DR. SOUTHARD: SO MOVED.

6 CHAIRMAN THOMAS: I'M NOT SURE WHO WAS
7 FIRST THERE. MARIA, DID YOU GET THAT SEQUENCE?

8 MS. BONNEVILLE: I THINK IT WAS MARVIN,
9 AND I DIDN'T KNOW WHO THE SECOND.

10 MR. BERNAL: DAN. I'LL SECOND.

11 MS. BONNEVILLE: THANK YOU, DAN.

12 CHAIRMAN THOMAS: IT'S BEEN MOVED AND
13 SECONDED. QUESTIONS OR COMMENTS FROM MEMBERS OF THE
14 BOARD? ANNE-MARIE.

15 DR. DULIEGE: AS ALWAYS, THANK YOU, GIL,
16 FOR THIS PRESENTATION. WE ARE PARTICULARLY
17 INTERESTED IN THE DEBATE THAT MAY HAVE HAPPENED.
18 CAN YOU TELL US MORE ABOUT THE PEOPLE WHO DIDN'T
19 VOTE IN FAVOR OR WERE BORDERLINE, THE NATURE OF THE
20 DEBATE?

21 DR. SAMBRANO: SURE. SO I THINK EVERYONE
22 AGREED THAT THE PROPOSAL ITSELF WAS VERY GOOD.
23 WHERE THE GRANTS WORKING GROUP HAD A LITTLE BIT OF A
24 STRUGGLE WAS IN THE OVERALL POTENTIAL BENEFIT AND
25 SAFETY TO PATIENTS, JUST GIVEN THAT THIS IS A GENE

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1 THERAPY THAT MAY REQUIRE HIGH TITERS AND THE
2 POTENTIAL FOR SERIOUS ADVERSE EVENTS. GIVEN THAT
3 THIS IS A NONFATAL CONDITION, WHERE THEY DRAW THE
4 LINE, I THINK, WAS PART OF THE DEBATE ON HOW MUCH
5 RISK IS WORTH TAKING FOR THIS THERAPY.

6 THE OTHER IS THAT BECAUSE IT'S AN
7 ADENOVIRUS THERAPY, SOME PATIENTS ALREADY MAY HAVE
8 ANTIBODIES AGAINST ADENOVIRUS WHICH WOULD MAKE IT
9 INEFFECTIVE AND WOULD ALSO, IF YOU HAVE ONE DOSE,
10 WILL LIKELY LEAD TO THE DEVELOPMENT OF ANTIBODIES
11 AND SO A SECOND DOSE WOULD PROBABLY BE UNLIKELY TO
12 BE EFFECTIVE. SO THOSE ARE THE CONCERNS THAT I
13 THINK THEY WERE STRUGGLING WITH.

14 THEY DID FEEL, HOWEVER, THAT THE
15 APPLICANTS HAVE DONE A PRETTY GOOD JOB OF DESIGNING
16 THE TRIAL AND SETTING UP THE COHORTS TO ACCOUNT FOR
17 THOSE SAFETY CONCERNS AND THINK CAREFULLY AND SPACE
18 APART EACH OF THE TREATMENTS SO THAT THERE IS ENOUGH
19 TIME TO UNDERSTAND THE POTENTIAL IMPLICATIONS OF
20 GIVING THIS TREATMENT TO THE PATIENT.

21 DR. DULIEGE: THANK YOU, GIL. AND I AGREE
22 THAT THE DESIGN OF THE TRIAL SEEMS TO BE ADEQUATE
23 FROM WHAT I'VE SEEN. WERE THERE ANY DIALOGUE AROUND
24 THE POTENTIAL VALUE OF THE TREATMENT IN PUBLIC
25 HEALTH IN A FIELD THAT, ALTHOUGH ABSOLUTELY THERE IS

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1 NO CURE FOR HIV, WE'RE STILL WORKING ON A VACCINE AT
2 SOME POINT AT LEAST TO PREVENT, BUT THERE'S MULTIPLE
3 TREATMENTS THAT ARE AVAILABLE AND THAT MAKE HIV A
4 LONG-TERM DISEASE WHERE PEOPLE CAN LIVE ACTUALLY
5 WELL WITH THIS DISEASE. I'M NOT TRYING TO MINIMIZE
6 SOME ASPECTS OF IT. IT SHOULD BE MORE AVAILABLE IN
7 DEVELOPING COUNTRIES, BUT GENE THERAPY I'M NOT SURE
8 WILL BE MORE AVAILABLE TO PEOPLE COSTWISE BY THE
9 TIME IT'S AN ACCEPTED WAY OF TREATING HIV, EVEN
10 CURING HIV. IS THAT REALISTIC?

11 DR. SAMBRANO: WELL, THAT WAS NOT
12 PARTICULARLY PART OF THE DEBATE AT THE GRANTS
13 WORKING GROUP. THE GRANTS WORKING GROUP CERTAINLY
14 RECOGNIZED THAT, IF THIS WERE SUCCESSFUL, IT WOULD
15 BE HIGHLY IMPACTFUL. WHETHER IT WAS PRACTICE OR
16 REALISTICALLY IN THE NEAR TERM TO HAVE PATIENTS
17 GETTING A GENE THERAPY WAS NOT REALLY DISCUSSED. IT
18 IS CERTAINLY A GOOD QUESTION, BUT NOT SOMETHING THAT
19 WAS DISCUSSED AT LENGTH AT THE GRANTS WORKING GROUP.

20 DR. DULIEGE: THANK YOU.

21 CHAIRMAN THOMAS: THANK YOU, ANNE-MARIE.

22 OTHER QUESTIONS OR COMMENTS FROM MEMBERS
23 OF THE BOARD? SEEING NONE, DO WE HAVE ANY COMMENTS
24 FROM MEMBERS OF THE PUBLIC?

25 MS. BONNEVILLE: I DO NOT SEE ANY HANDS

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1 RAISED.
2 CHAIRMAN THOMAS: THANK YOU. IN THAT
3 CASE, MARIA, WILL YOU PLEASE CALL THE ROLL.
4 MS. BONNEVILLE: SURE. DAN BERNAL.
5 MR. BERNAL: AYE.
6 MS. BONNEVILLE: ANNE-MARIE DULIEGE.
7 DR. DULIEGE: NO.
8 MS. BONNEVILLE: MARK FISCHER-COLBRIE.
9 DR. FISCHER-COLBRIE: AYE.
10 MS. BONNEVILLE: FRED FISHER.
11 DR. FISHER: AYE.
12 MS. BONNEVILLE: DAVID HIGGINS.
13 DR. HIGGINS: YES.
14 MS. BONNEVILLE: STEVE JUELSGAARD.
15 MR. JUELSGAARD: YES.
16 MS. BONNEVILLE: RICH LAJARA.
17 MR. LAJARA: YES.
18 MS. BONNEVILLE: LAUREN MILLER ROGEN.
19 MS. MILLER-ROGEN: YES.
20 MS. BONNEVILLE: ADRIANA PADILLA.
21 DR. PADILLA: YES.
22 MS. BONNEVILLE: JOE PANETTA.
23 MR. PANETTA: YES.
24 MS. BONNEVILLE: MARVIN SOUTHARD.
25 DR. SOUTHARD: YES.

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1 MS. BONNEVILLE: JONATHAN THOMAS.

2 CHAIRMAN THOMAS: YES.

3 MS. BONNEVILLE: THE MOTION CARRIES.

4 CHAIRMAN THOMAS: OKAY. THANK YOU VERY
5 MUCH.

6 ON TO THE NEXT ITEM, WHICH IS
7 CONSIDERATION OF APPLICATIONS --

8 MR. HUANG: SORRY. CAN I INTERRUPT A
9 SECOND? I BELIEVE KAROL WATSON IS NOT CONFLICTED ON
10 THIS. SO I THINK YOU CAN CALL FOR HER VOTE.

11 MS. BONNEVILLE: THANK YOU. KAROL WATSON.
12 OKAY. SHE'S NOT RESPONDING. I THINK WE CAN MOVE
13 ON.

14 CHAIRMAN THOMAS: OKAY. THANK YOU.

15 SECOND AND LAST ITEM FOR TODAY'S
16 APPLICATION REVIEW SUBCOMMITTEE IS CONSIDERATION OF
17 APPLICATIONS SUBMITTED IN RESPONSE TO DISCOVERY
18 STAGE RESEARCH PROJECTS PROGRAM ANNOUNCEMENT
19 SO-CALLED DISC0. PRESENTATION FROM DR. SAMBRANO.
20 GIL.

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

22 ALL RIGHT. SO THESE ARE THE
23 RECOMMENDATIONS FROM THE GRANTS WORKING GROUP
24 RELATED TO THE DISC-0 PROGRAM. I'LL JUST GO OVER A
25 FEW BACKGROUND SLIDES RELATED TO THIS PROGRAM.

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1 SO THE DISC-0 IS BRAND-NEW. IT IS A
2 PROGRAM THAT FITS INTO OUR RECURRING SET OF
3 OPPORTUNITIES IN THE DISCOVERY AREA. IT'S NOT
4 SPECIFICALLY INTENDED TO FEED INTO A PRODUCT
5 DEVELOPMENT PIPELINE; BUT, RATHER, IT'S INTENDED TO
6 MORE BROADLY SUPPORT BASIC RESEARCH.

7 SO THE PURPOSE AND OBJECTIVE OF THE
8 PROGRAM IS THE REINITIATION OF FUNDING BASIC STEM
9 CELL/PROGENITOR CELL SCIENCE AND GENETIC RESEARCH.
10 IT IS TO SUPPORT RIGOROUS STUDIES ADDRESSING
11 CRITICAL BASIC KNOWLEDGE GAPS OR BOTTLENECKS IN THE
12 FIELD OF REGENERATIVE MEDICINE, AND, OF COURSE, TO
13 ADVANCE DEVELOPMENT OF STEM CELL-BASED TOOLS FOR
14 INNOVATION. SO THIS PROGRAM ALLOWS BOTH FOR TOOL
15 DEVELOPMENT AS WELL AS KNOWLEDGE GAP AND BOTTLENECK
16 RESEARCH.

17 PROJECTS THAT COME INTO THE DISC-0
18 OPPORTUNITY SHOULD AS AN OUTCOME CULMINATE IN THE
19 DISCOVERY OR TECHNOLOGY THAT WOULD ADVANCE ONE OR
20 MORE OF THE FOLLOWING: UNDERSTANDING THE BIOLOGY OF
21 STEM CELLS THAT IS RELEVANT TO HUMAN BIOLOGY AND
22 DISEASE; GENETIC RESEARCH THAT'S RELEVANT TO HUMAN
23 BIOLOGY OR DISEASE THAT PERTAINS TO STEM CELLS OR
24 REGENERATIVE MEDICINE. SO THERE HAS TO BE A
25 REGENERATIVE MEDICINE CONNECTION TO THE GENETIC

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1 RESEARCH. THE DEVELOPMENT OF HUMAN STEM CELLS AS A
2 TOOL FOR BIOMEDICAL INNOVATION, AND/OR GREATER
3 APPLICABILITY OF REGENERATIVE MEDICINE DISCOVERIES
4 TO COMMUNITIES REPRESENTING THE FULL SPECTRUM OF
5 DIVERSITY.

6 SOME EXAMPLE ACTIVITIES OF WHAT WE CAN
7 SUPPORT UNDER THIS PROGRAM WOULD BE BASIC RESEARCH
8 INTO STEM CELL OR GENETIC RESEARCH MECHANISMS AS
9 THEY RELATE TO HUMAN BIOLOGY, BOTTLENECKS SUCH AS
10 TISSUE TARGETING, IMMUNOGENICITY OR TOXICITY IN THE
11 DEVELOPMENT OF A STEM CELL-BASED THERAPY,
12 UNDERSTANDING HEALTHY AND/OR DISEASED HUMAN CELLS,
13 OMICS PROFILING, OR THE DEVELOPMENT OF HUMAN CELL
14 TISSUE ATLASES, MECHANISTIC STUDIES FOR RATIONAL
15 DESIGN OF STEM CELL-BASED TREATMENTS, INVESTIGATION
16 OF STEM CELLS OR THEIR DERIVATIVES AS TOOLS FOR A
17 THERAPY OR FOR INNOVATION IN SOME WAY DEVELOPING A
18 MODEL OF DISEASE OR DISEASE IN A DISH AS IT'S OFTEN
19 CALLED, GENERATION OF OMICS DATA THAT COULD EXTEND
20 OR VALIDATE THE APPLICABILITY OF THE REGENERATIVE
21 MEDICINE TO UNDERSERVED RACIAL OR ETHNIC GROUPS. SO
22 THOSE ARE JUST EXAMPLE ACTIVITIES.

23 ALL APPLICATIONS COMING IN HAVE TO ADDRESS
24 ONE OF THESE ELEMENTS AT A HIGH LEVEL KNOWLEDGE GAP
25 OR BOTTLENECK OR DEVELOPMENT OF A TOOL THAT

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1 ADDRESSES THE KNOWLEDGE GAP OR BOTTLENECK. THE
2 AWARDS ARE FOR THREE YEARS AND UP TO ONE MILLION IN
3 DIRECT PROJECT COST. AND WE ANTICIPATE THAT THIS
4 DISC-0 OPPORTUNITY WILL OCCUR EVERY SIX MONTHS.

5 SO THE PROCESS FOR TAKING IN THESE
6 APPLICATIONS AND REVIEWING THEM INCLUDED GOING
7 THROUGH A POSITIVE SELECTION PROCESS. THIS IS
8 SOMETHING THAT WE PERFORM WHEN WE GET A TOTAL NUMBER
9 OF APPLICATIONS THAT WOULD EXCEED THE CAPACITY OF
10 THE GRANTS WORKING GROUP TO REVIEW IN THE SAME
11 SESSION. WE DO THIS, FOR EXAMPLE, WITH THE DISC2
12 AND OTHER DISCOVERY PROGRAMS.

13 SO WHAT HAPPENS IN THE FIRST STAGE, GRANTS
14 WORKING GROUP MEMBERS, SO THE PANEL, INCLUDING OUR
15 PATIENT ADVOCATE AND NURSE BOARD MEMBERS, CONDUCT A
16 PREREVIEW OF THE APPLICATIONS AND SELECT WHICH ONES
17 TO ADVANCE TO THE FULL REVIEW. ONCE THAT IS DONE,
18 THE CIRM PRESIDENT AND CIRM STAFF EXAMINE
19 NONSELECTED APPLICATIONS TO DETERMINE IF ANY OF
20 THOSE MERIT A FULL REVIEW. AND THOSE THAT REMAIN
21 ARE NOT CONSIDERED ANY FURTHER.

22 WE RECEIVED A TOTAL OF 75 ELIGIBLE
23 APPLICATIONS FOR THIS FIRST CYCLE, AND A TOTAL OF 45
24 ADVANCED TO THE FULL DISCUSSION STAGE BY THE GRANTS
25 WORKING GROUP.

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1 THE MEMBERS OF THE PANEL, AS I INDICATED
2 IN MY PREVIOUS PRESENTATION, INCLUDE THE SCIENTIFIC
3 GRANTS WORKING GROUP MEMBERS WHO PARTICIPATE IN THE
4 POSITIVE SELECTION AS WELL AS SCIENTIFIC EVALUATION
5 AND THEY SCORE ALL APPLICATIONS AND GIVE IT A
6 SCIENTIFIC SCORE. OUR BOARD MEMBERS ALSO
7 PARTICIPATE IN THE POSITIVE SELECTION. THEY PROVIDE
8 A PATIENT PERSPECTIVE ON SIGNIFICANCE AND POTENTIAL
9 IMPACT AND OVERSIGHT ON THE PROCESS. THEY DO NOT
10 PARTICIPATE IN ANY SCORING AT THIS LEVEL. AND THEN
11 OUR VISITING SPECIALISTS, WHO, AGAIN, FILL IN SOME
12 OF THE KNOWLEDGE GAP THAT WE MAY NEED ON THE PANEL
13 DURING THE COURSE OF THE REVIEW.

14 UNLIKE CLINICAL, THE DISCOVERY PROGRAMS
15 ARE SCORED ON A SCALE OF 1 TO 100. AND SO A SCORE
16 OF 85 TO A HUNDRED MEANS IT'S RECOMMENDED FOR
17 FUNDING IF FUNDS ARE AVAILABLE. THOSE THAT SCORE
18 BETWEEN 80 AND 84 ARE NOT RECOMMENDED, BUT THOSE
19 APPLICATIONS HAVE BEEN DEEMED TO HAVE SUFFICIENT
20 MERIT BY THE GRANTS WORKING GROUP TO BYPASS THE
21 POSITIVE SELECTION PROCESS IN THE NEXT CYCLE IF THEY
22 REVISE AND RESUBMIT THEIR APPLICATION. SO THESE ARE
23 APPLICATIONS THAT ARE SORT OF BORDERLINE THAT THEY
24 WOULD LIKE TO SEE AGAIN, BUT THAT THEY REALLY FEEL
25 NEED SOME WORK BEFORE THEY ARE COMFORTABLE

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1 RECOMMENDING THEM. AND THOSE THAT RECEIVE A SCORE
2 BETWEEN 1 AND 75 ARE NOT RECOMMENDED FOR FUNDING.
3 AND THE SCORE IS BASED ON THE MEDIAN FROM ALL THE
4 INDIVIDUAL SCORES GIVEN BY THE SCIENTIFIC MEMBERS.

5 THE REVIEW CRITERIA ARE LARGELY THE SAME
6 QUESTIONS THAT WE ASK FOR CLINICAL PROGRAMS. AND
7 THE SUB-BULLETS, IF YOU WILL, AND HOW THEY'RE
8 APPLIED FOR OUR DISCOVERY PROGRAM ARE A LITTLE
9 DIFFICULT, HOWEVER; NEVERTHELESS, IT IS FOCUSED ON
10 OVERALL SIGNIFICANCE AND POTENTIAL FOR IMPACT,
11 RATIONALE, PLAN DESIGN, FEASIBILITY, AND UPHOLDING
12 THE PRINCIPLES OF DEI.

13 SO THIS IS A SUMMARY TABLE OF THE
14 RECOMMENDATIONS FROM THE GRANTS WORKING GROUP. AS
15 MENTIONED, THERE WERE 45 APPLICATIONS THAT WERE
16 REVIEWED IN THE LAST SESSION, AND THERE WERE 11 THAT
17 RECEIVED A SCORE OF 85 OR ABOVE THAT DEEMED THEM
18 RECOMMENDED FOR FUNDING.

19 THE TOTAL APPLICANT REQUEST FROM THESE 11
20 APPLICATIONS IS ABOUT 15.6 MILLION. THE FUNDS
21 AVAILABLE ARE CLOSE TO 34 MILLION TO SUPPORT THIS
22 PROGRAM. AND I WILL NOTE THAT THE BUDGET IS COMING
23 FROM THE 21/22 FISCAL YEAR. SO THIS IS FROM THE
24 LAST YEAR BUDGET THAT WE ARE CATCHING UP WITH WITH
25 THIS CYCLE OF DISC-0.

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1 ALL RIGHT. MINORITY REPORTS, SO YOU MAY
2 KNOW THAT UNDER PROP 14 ANY APPLICATION THAT IS NOT
3 RECOMMENDED FOR FUNDING BY THE GRANTS WORKING GROUP,
4 BUT WHICH HAS 35 PERCENT OR MORE OF THE MEMBERS
5 SCORING TO FUND THE APPLICATION MUST INCLUDE A
6 MINORITY REPORT. THE WAY WE DO THAT IS THAT WE
7 INCLUDE IT IN THE REVIEW SUMMARY AND PROVIDE A
8 SYNOPSIS OF THE OPINION OF THE MINORITY GROUP FOR
9 THOSE APPLICATIONS.

10 SO IN THIS PARTICULAR CYCLE, THERE WERE NO
11 APPLICATIONS THAT QUALIFIED FOR A MINORITY REPORT.
12 IT SEEMS THAT THE GRANTS WORKING GROUP, IN TERMS OF
13 THEIR SCORING, REACHED A PRETTY GENERAL CONSENSUS OF
14 THOSE THAT WERE RECOMMENDED VERSUS THOSE THAT WERE
15 NOT. SO, THEREFORE, NO MINORITY REPORTS.

16 THIS SLIDE IS JUST TO REMIND ALL OF YOU ON
17 THE APPLICATION REVIEW SUBCOMMITTEE WHO HAVE AN
18 ASTERISK OF CONFLICTS THAT YOU MAY HAVE WITH ANY ONE
19 OF THE APPLICATIONS AS WELL AS OTHER MEMBERS OF THE
20 BOARD IN GENERAL WHO MAY BE ON THE CALL TODAY JUST
21 SO YOU ARE AWARE THAT YOU MAY HAVE A CONFLICT WITH
22 THE APPLICATION. SO JUST BE MINDFUL OF THAT.

23 LET ME THEN STOP THE SHARE REAL QUICK, AND
24 I WILL SHOW YOU THE SPREADSHEET THAT HAS ALL OF THE
25 APPLICATIONS LISTED IN RANK ORDER. GIVE ME ONE

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1 SECOND TO PUT THAT UP. HOPEFULLY YOU CAN SEE THIS.

2 SO WE HAVE THE 11 APPLICATIONS SHOWN HERE
3 THAT ARE RECOMMENDED FOR FUNDING THAT RANGE IN SCORE
4 FROM 85 HAVE TO 91, AND THEN THE REMAINING
5 APPLICATIONS THAT ARE NOT RECOMMENDED, ALTHOUGH WE
6 DO HAVE MANY THAT ARE IN THE 80 TO 84 THAT, SHOULD
7 THEY REVISE AND RESUBMIT, WILL BYPASS POSITIVE
8 SELECTION AT THE NEXT ROUND. MR. CHAIRMAN, I PASS
9 IT BACK TO YOU.

10 CHAIRMAN THOMAS: THANK YOU VERY MUCH,
11 GIL. OKAY. THIS IS ONE OF THESE SEQUENCES WHERE
12 WE'RE GOING TO HAVE MULTIPLE STEPS. FIRST, I'M
13 GOING TO ASK IF ANYBODY WANTS TO ELEVATE ANY
14 PROJECTS CURRENTLY NOT RECOMMENDED FOR FUNDING TO
15 THE FUNDING RANGE. SECONDLY, IF ANYBODY WANTS TO
16 TAKE ANY IN THE FUNDING RANGE AND MOVE IT DOWN TO
17 THE NOT RECOMMENDED RANGE. THIRDLY, WE'RE GOING TO
18 HAVE A VOTE ON WHETHER OR NOT TO NOT FUND THOSE IN
19 THE NOT RECOMMENDED RANGE. AND, FINALLY, A VOTE ON
20 THE TOP PROJECTS TO RECOMMEND FOR FUNDING, DO WE
21 WANT TO FUND THEM OR NOT. SO THAT'S THE SEQUENCE.

22 SO, FIRST, ARE THERE ANY PROJECTS IN THE
23 NOT RECOMMENDED FOR FUNDING RANGE THAT ANY MEMBERS
24 OF THE BOARD WISH TO ELEVATE TO THE RECOMMENDED
25 RANGE? HEARING NONE, GIL, IF YOU COULD GO BACK AND

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1 SHOW. THANK YOU. DO WE HAVE ANY PROJECTS IN THE
2 RECOMMENDED RANGE THAT ANY MEMBERS OF THE BOARD WISH
3 TO MOVE DOWN TO THE NOT RECOMMENDED RANGE? HEARING
4 NONE ON THAT, THE THIRD STEP IS --

5 MS. BONNEVILLE: J.T., ACTUALLY WHAT YOU
6 WILL WANT TO DO IS YOU'LL WANT TO TAKE A VOTE NOW TO
7 CLOSE OUT THAT CATEGORY.

8 CHAIRMAN THOMAS: CLOSE OUT THE
9 RECOMMENDED RANGE.

10 MS. BONNEVILLE: NO. NO. THE NOT
11 RECOMMENDED RANGE.

12 CHAIRMAN THOMAS: THAT WAS MY NEXT STEP.
13 SO THE NEXT STEP IS WE NEED TO VOTE ON -- DO WE HAVE
14 A MOTION TO NOT FUND THOSE PROJECTS IN THE NOT
15 RECOMMENDED RANGE? NEED A MOTION HERE.

16 MS. BONNEVILLE: I'M SORRY. WHO WAS THAT,
17 AND I HOPE IT'S NOT A MEMBER WHO HAS A CONFLICT.

18 DR. FISHER: I THINK IT WAS ME AND MARV.

19 MS. BONNEVILLE: GREAT.

20 DR. FISHER: AND MR. FISCHER-COLBRIE A
21 DISTANT THIRD.

22 MS. BONNEVILLE: THANK YOU ALL.

23 CHAIRMAN THOMAS: THANK YOU. QUESTIONS OR
24 COMMENTS FROM MEMBERS OF THE BOARD ON THIS MOTION?

25 MR. PANETTA: I HAVE A QUESTION, J.T.

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1 CHAIRMAN THOMAS: YES. JOE.

2 MR. PANETTA: THANK YOU. I SHOULD KNOW
3 THIS, BUT GIL SAID THAT THE APPLICATIONS THAT SCORE
4 FROM 80 TO 84 WILL HAVE THE OPPORTUNITY TO BE
5 UPGRADED AND THEN WILL BYPASS THE POSITIVE SELECTION
6 PROCESS. I DON'T REMEMBER WHAT THAT MEANS, IF YOU
7 JUST REFRESH MY MEMORY.

8 CHAIRMAN THOMAS: SURE. THAT MEANS THAT
9 IT GOES STRAIGHT INTO THE POOL OF GRANTS THAT WILL
10 BE FULLY REVIEWED ON THE NEXT CYCLE.

11 MR. PANETTA: THANK YOU.

12 CHAIRMAN THOMAS: ANY OTHER QUESTIONS OR
13 COMMENTS ON THIS MOTION FROM MEMBERS OF THE BOARD?
14 HEARING NONE, DO WE HAVE ANY PUBLIC COMMENT ON THIS
15 MOTION?

16 MS. BONNEVILLE: I DO NOT SEE ANY HANDS
17 RAISED, BUT I'LL GIVE IT A SECOND. I DO SEE A
18 COUPLE OF GUESTS ON. THERE ARE NO HANDS RAISED,
19 J.T.

20 CHAIRMAN THOMAS: THANK YOU. MARIA, WILL
21 YOU PLEASE CALL THE ROLL.

22 MS. BONNEVILLE: SURE. DAN BERNAL.

23 MR. BERNAL: AYE.

24 MS. BONNEVILLE: ANNE-MARIE DULIEGE.

25 DR. DULIEGE: AYE.

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1 MS. BONNEVILLE: MARK FISCHER-COLBRIE.
2 DR. FISCHER-COLBRIE: AYE.
3 MS. BONNEVILLE: FRED FISHER.
4 DR. FISHER: AYE.
5 MS. BONNEVILLE: DAVID HIGGINS.
6 DR. HIGGINS: YES.
7 MS. BONNEVILLE: STEVE JUELSGAARD.
8 MR. JUELSGAARD: YES.
9 MS. BONNEVILLE: RICH LAJARA.
10 MR. LAJARA: YES.
11 MS. BONNEVILLE: LAUREN MILLER-ROGEN.
12 MS. MILLER-ROGEN: YES.
13 MS. BONNEVILLE: ADRIANA PADILLA.
14 DR. PADILLA: YES.
15 MS. BONNEVILLE: JOE PANETTA.
16 MR. PANETTA: YES.
17 MS. BONNEVILLE: MARVIN SOUTHARD.
18 DR. SOUTHARD: YES.
19 MS. BONNEVILLE: JONATHAN THOMAS.
20 CHAIRMAN THOMAS: YES.
21 MS. BONNEVILLE: MOTION CARRIES.
22
23
24
25

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1 CHAIRMAN THOMAS: THANK YOU. THE LAST,
2 THEN, CONSIDERATION FOR THIS ITEM IS DO WE HAVE A
3 MOTION TO APPROVE THOSE PROJECTS IN THE RECOMMENDED
4 RANGE?

5 DR. FISHER: SO MOVED.

6 CHAIRMAN THOMAS: MOVED BY FRED. IS THERE
7 A SECOND?

8 DR. SOUTHARD: MARV WILL SECOND.

9 CHAIRMAN THOMAS: MARV IS SECOND AND MARK,
10 AGAIN, A DISTANT THIRD.

11 DR. FISCHER-COLBRIE: GOT TO BE FASTER.

12 CHAIRMAN THOMAS: THANK YOU. QUESTIONS OR
13 COMMENTS FROM MEMBERS OF THE BOARD ON THIS MOTION?
14 ANY QUESTIONS OR COMMENTS OR, RATHER, COMMENTS FROM
15 MEMBERS OF THE PUBLIC?

16 MS. BONNEVILLE: THERE ARE NO HANDS
17 RAISED.

18 CHAIRMAN THOMAS: THANK YOU. IN THAT
19 CASE, MARIA, WILL YOU PLEASE CALL THE ROLL.

20 MS. BONNEVILLE: SURE. AND REMEMBER TO
21 RESPOND YES OR NO EXCEPT FOR THOSE WITH WHICH I HAVE
22 A CONFLICT.

23 DAN BERNAL.

24 MR. BERNAL: AYE.

25 MS. BONNEVILLE: ANNE-MARIE DULIEGE.

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1 DR. DULIEGE: AYE.

2 MS. BONNEVILLE: YSABEL DURON.

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

5 MS. BONNEVILLE: ELENA FLOWERS.

6 DR. FLOWERS: YES, EXCEPT FOR THOSE WITH
7 WHICH I HAVE A CONFLICT.

8 MS. BONNEVILLE: MARK FISCHER-COLBRIE.

9 DR. FISCHER-COLBRIE: AYE.

10 MS. BONNEVILLE: DAVID HIGGINS.

11 DR. HIGGINS: YES.

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. LAJARA: YES.

18 MS. BONNEVILLE: CHRISTINE MIASKOWSKI.

19 DR. MIASKOWSKI: YES, EXCEPT FOR THOSE
20 WITH WHICH I HAVE A CONFLICT.

21 MS. BONNEVILLE: LAUREN MILLER-ROGEN.

22 MS. MILLER-ROGEN: YES.

23 MS. BONNEVILLE: ADRIANA PADILLA.

24 DR. PADILLA: YES.

25 MS. BONNEVILLE: JOE PANETTA.

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1 MR. PANETTA: YES.

2 MS. BONNEVILLE: MARVIN SOUTHARD.

3 DR. SOUTHARD: YES.

4 MS. BONNEVILLE: JONATHAN THOMAS.

5 CHAIRMAN THOMAS: YES.

6 MS. BONNEVILLE: ART TORRES.

7 MR. TORRES: YES, EXCEPT FOR THOSE WITH
8 WHICH I HAVE A CONFLICT.

9 MS. BONNEVILLE: KAROL WATSON.

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

12 MS. BONNEVILLE: THANK YOU. THE MOTION
13 CARRIES.

14 CHAIRMAN THOMAS: THANK YOU, MARIA. AND,
15 GIL, THANK YOU TO YOU AND YOUR TEAM FOR THE USUAL
16 EXPERT REVIEW ON THIS BRAND NEW PROGRAM WHICH ADDS A
17 SIGNIFICANT NEW ELEMENT TO OUR PORTFOLIO. SO PLEASE
18 TO ALL OF THOSE MEMBERS OF THE REVIEW TEAM, THIS IS
19 GREAT TO HAVE AND DEFINITELY AUGMENTS THE PRODUCT
20 LINE HERE. SO THANK YOU VERY MUCH.

21 THAT CONCLUDES THE MEETING OF THE
22 APPLICATION REVIEW SUBCOMMITTEE. WE ARE NOW ON TO
23 PUBLIC COMMENT ON ANY ITEMS IN GENERAL. DO WE HAVE
24 ANY PUBLIC COMMENT? OKAY. HEARING NONE, I THINK
25 THAT PRETTY MUCH WRAPS IT UP. OUR NEXT --

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1 MS. BONNEVILLE: I WAS JUST GOING TO SAY
2 WHAT YOU'RE GOING TO SAY, BUT I'LL LET YOU SAY IT.

3 CHAIRMAN THOMAS: OUR NEXT BOARD MEETING,
4 WHICH IS A FULL BOARD MEETING, IS ON SEPTEMBER 29TH.

5 MS. BONNEVILLE: SO WE'LL SEE YOU ALL
6 AGAIN NEXT WEEK. IT'S ACTION PACKED.

7 CHAIRMAN THOMAS: YES. SO THANK YOU ALL
8 FOR --

9 MR. TORRES: EXCITING.

10 CHAIRMAN THOMAS: THANK YOU ALL FOR YOUR
11 ATTENDANCE AND PARTICIPATION, AND WE LOOK FORWARD TO
12 RECONVENING NEXT WEEK.

13 (THE MEETING WAS THEN CONCLUDED AT 9:36 A.M.)
14
15
16
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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 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 SEPTEMBER 20, 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.

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