

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: WESTIN SACRAMENTO, MONACO II
4800 RIVERSIDE BOULEVARD
SACRAMENTO, CALIFORNIA 95822

DATE: MARCH 27, 2025
9 A.M.

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

FILE NO.: 2025-9

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MARCH 27, 2025; 9 A.M.

CHAIRMAN IMBASCIANI: GOOD MORNING,
EVERYONE. HOW'S THE SOUND CHECK? GOOD? THANK YOU.
LIKE TO WELCOME EVERYONE, PUBLIC AND MEMBERS OF THE
BOARD OF THE INDEPENDENT CITIZENS OVERSIGHT
COMMITTEE FOR CIRM TO THIS MEETING HERE IN
SACRAMENTO, THE CAPITAL OF THE STATE. AND WE'RE
GOING TO START WITH THE PLEDGE OF ALLEGIANCE. I
WOULD ASK THOSE WHO ARE ABLE TO STAND AND PLACE
THEIR HAND OVER THEIR HEART FOR THE RECITATION.
SCOTT, WOULD YOU LEAD US PLEASE.

MR. TOCHER: PLEASE STAND IF YOU ARE ABLE.

(THE PLEDGE OF ALLEGIANCE.)

CHAIRMAN IMBASCIANI: THANK YOU, EVERYONE.
I'M GOING TO START WITH AN UPDATE --

MR. TOCHER: WE NEED TO TAKE ROLL.

CHAIRMAN IMBASCIANI: THE ROLL CALL.
THANK YOU.

MR. TOCHER: EYAD ALMASRI.

DR. ALMASRI: PRESENT.

MR. TOCHER: KIM BARRETT.

DR. BARRETT: PRESENT.

MR. TOCHER: DAN BERNAL. GEORGE
BLUMENTHAL.

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DR. BLUMENTHAL: HERE.
MR. TOCHER: MARIA BONNEVILLE.
VICE CHAIR BONNEVILLE: PRESENT.
MR. TOCHER: LINDA BOXER. JOHN CARETHERS.
DR. CARETHERS: PRESENT.
MR. TOCHER: MONICA CARSON. JUDY CHOU.
LEONDRA CLARK-HARVEY.
DR. CLARK-HARVEY: HERE.
MR. TOCHER: ANNE-MARIE DULIEGE.
DR. DULIEGE: PRESENT.
MR. TOCHER: YSABEL DURON.
MS. DURON: HERE.
MR. TOCHER: MARK FISCHER-COLBRIE.
MR. FISCHER-COLBRIE: HERE.
MR. TOCHER: ELENA FLOWERS.
DR. FLOWERS: PRESENT.
MR. TOCHER: JUDY GASSON.
DR. GASSON: HERE.
MR. TOCHER: DAVID HIGGINS.
DR. HIGGINS: HERE.
MR. TOCHER: VITO IMBASCIANI.
CHAIRMAN IMBASCIANI: HERE.
MR. TOCHER: RICH LAJARA.
MR. LAJARA: PRESENT.
MR. TOCHER: PAT LEVITT.

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1 DR. LEVITT: HERE.
2 MR. TOCHER: HALA MADANAT.
3 DR. MADANAT: HERE.
4 MR. TOCHER: LINDA MALKAS.
5 DR. MALKAS: HERE.
6 MR. TOCHER: SHLOMO MELMED.
7 DR. MELMED: HERE.
8 MR. TOCHER: CAROLYN MELTZER.
9 DR. MELTZER: PRESENT.
10 MR. TOCHER: CHRISTINE MIASKOWSKI.
11 DR. MIASKOWSKI: PRESENT.
12 MR. TOCHER: ADRIANA PADILLA.
13 DR. PADILLA: HERE.
14 MR. TOCHER: JOE PANETTA.
15 MR. PANETTA: HERE.
16 MR. TOCHER: MARVIN SOUTHARD.
17 DR. SOUTHARD: HERE.
18 MR. TOCHER: SUZANNE SANDMEYER.
19 DR. SANDMEYER: PRESENT.
20 MR. TOCHER: KAROL WATSON.
21 DR. WATSON: PRESENT.
22 MR. TOCHER: YAEL WYTE.
23 DR. WYTE: HERE.
24 MR. TOCHER: KEVIN XU.
25 MR. XU: HERE.

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1 MR. TOCHER: KEITH YAMAMOTO.

2 THANK YOU, MR. CHAIRMAN. WE HAVE A
3 QUORUM.

4 CHAIRMAN IMBASCIANI: THANK YOU, SCOTT. I
5 DIDN'T HEAR KEITH'S ANSWER.

6 MR. TOCHER: HE'S NOT PRESENT.

7 CHAIRMAN IMBASCIANI: I'D LIKE TO UPDATE
8 THE BOARD NEXT ON A SERIES OF DISCUSSIONS AND
9 MEETINGS I'VE HAD SINCE THE LAST MEETING ON THE
10 SUBJECT OF CIRM'S LONG-TERM, LONG-RANGE VIABILITY OR
11 SUSTAINABILITY PROJECT.

12 THE PURPOSE OF THESE MEETINGS I'VE HAD IS
13 TO ENRICH MY UNDERSTANDING OF THE ISSUES
14 UNDERPINNING EACH OF THE VARIOUS OPTIONS THAT
15 PRESENT THEMSELVES BY SPEAKING TO PEOPLE WITH
16 INTEREST IN AND IDEALLY EXPERIENCE IN THAT OPTION.
17 MY CANVASSING HAS LED ME TO DISCUSSIONS WITH PRESENT
18 AND FORMER ELECTED OFFICIALS IN BOTH THE LEGISLATIVE
19 AND EXECUTIVE BRANCHES OF STATE GOVERNMENT, MEDICAL
20 LEADERS IN THE STATE, PATIENT ADVOCATES, EXPERTS IN
21 BALLOT INITIATIVES AND CAMPAIGN LAW, LOBBYISTS WITH
22 EXPERIENCE IN REFERENDA AND INITIATIVES, PEOPLE
23 KNOWLEDGEABLE IN THE WORLD OF PHARMA. I HAVE NOT
24 YET MET WITH ANYONE WORKING IN THE AREA OF
25 CHARITABLE DEVELOPMENT OR PARTNERSHIPS WITH PHARMA

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1 OR INDUSTRY, ALTHOUGH FEELERS HAVE BEEN PUT OUT.

2 ALMOST EVERYONE I'VE SPOKEN WITH HAS
3 BROUGHT UP THE ROLE OF PHILANTHROPY IN CIRM'S FUTURE
4 AND OF FOUNDATIONS, BUT NONE OF THESE PEOPLE WERE
5 SANGUINE ABOUT THAT APPROACH. I'VE ALSO ASKED AND
6 FORMED A SMALL GROUP OF PRESENT AND FORMER BOARD
7 MEMBERS TO ADVISE ME AS A SORT OF KITCHEN CABINET ON
8 HOW THE CHAIR SHOULD BEST PROCEED IN THIS ENDEAVOR.

9 WE'VE HAD OUR FIRST OPENING MEETING TO
10 DISCUSS THE LANDSCAPE WHICH IS CHANGING EVERY DAY
11 AND TO BEGIN TO LOOK AT THESE OPTIONS AND WAYS THAT
12 WE MIGHT PROCEED. AND BECAUSE -- WELL, A FORMAL
13 PRESENTATION WILL BE PRESENTED TO THE BOARD AT THE
14 JUNE MEETING INSTEAD OF TODAY. AND THAT IS BECAUSE
15 THE AGENDA FOR TODAY'S MEETING IS LONG. IT INCLUDES
16 PHASE 1 RECOMMENDATIONS FOR THE STRATEGIC ALLOCATION
17 FRAMEWORK AND THE PRESENTATIONS AND DISCUSSIONS OF
18 FOUR NEW CONCEPT PLANS, AND REVISIONS TO EXISTING
19 PROGRAMS WILL LIKELY TAKE UP MUCH OF THE ALLOTTED
20 TIME, BUT THIS WILL ALSO AFFORD ME THE OPPORTUNITY
21 TO WORK FURTHER WITH THE GOVERNANCE SUBCOMMITTEE TO
22 REFINE THIS PRESENTATION BEFORE JUNE.

23 THAT IS THE CHAIR'S REPORT. I'M GOING TO
24 ASK NOW THE VICE CHAIR FOR HER REMARKS.

25 VICE CHAIR BONNEVILLE: I'M GOING TO

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1 WASHINGTON, D.C. NEXT WEEK TO MEET WITH THE SOME OF
2 THE CALIFORNIA CONGRESSIONAL DELEGATION AND THEIR
3 STAFF TO UPDATE THEM ON CIRM. THIS IS AN
4 EDUCATIONAL AND REALLY AROUND BASIC CIRM INFO, MONEY
5 SPENT IN CALIFORNIA, KEY INFRASTRUCTURE PROGRAMS
6 LIKE ALPHA CLINICS AND FUTURE COMMUNITY CARE CENTERS
7 OF EXCELLENCE, EDUCATION PROGRAMS, AND OUR RESEARCH
8 PILLARS.

9 IN ADDITION, I'LL BE SETTING UP SIMILAR
10 MEETINGS WITH CALIFORNIA STATE ASSEMBLY MEMBERS AND
11 SENATORS IN SACRAMENTO, MOSTLY THOSE WHO SIT ON THE
12 BUDGET, EDUCATION, AND HEALTH COMMITTEES. THESE
13 MEETINGS ARE FOCUSED ON REINFORCING CIRM'S CRITICAL
14 ROLE IN CONTINUING TO SUPPORT THE RESEARCH ECOSYSTEM
15 BY DEDICATED FUNDING FOR CELL AND GENE THERAPY
16 RESEARCH IN CALIFORNIA.

17 AND I'M ALSO IN CONTACT WITH THE
18 GOVERNOR'S OFFICE REGULARLY ABOUT THE EVERCHANGING
19 RESEARCH FUNDING LANDSCAPE.

20 THE AAWG MET THIS MONTH TO HEAR CHANGES TO
21 THE COMMUNITY CARE CENTER CONCEPT PLAN, AND NEXT
22 MONTH THEY WILL CONVENE TO GIVE GUIDANCE ON
23 STAGE-SPECIFIC ACCESS PLAN ACTIVITIES FOR OUR NEW
24 CONCEPT PLANS. THE TEAM WILL REPORT OUT TO THE
25 BOARD IN JUNE WITH THE RESULTS OF THAT MEETING.

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1 AND I'M HAPPY TO TAKE ANY QUESTIONS.

2 CHAIRMAN IMBASCIANI: OKAY. THANK YOU
3 VERY MUCH. THANK YOU, MARIA, FOR YOUR REPORT. I
4 DON'T SEE ANY HANDS RAISED, SO WE'RE GOING TO
5 PROCEED WITH THE REPORT FROM OUR PRESIDENT AND CEO,
6 JONATHAN THOMAS.

7 DR. THOMAS: MR. CHAIR, MADAM VICE CHAIR,
8 MEMBERS OF THE BOARD, CIRM TEAM, AND MEMBERS OF THE
9 PUBLIC, AS WE HAVE A PACKED AGENDA FOR TODAY'S
10 MEETING, I WANTED TO CONFINE MY PRESIDENT'S REPORT
11 TO THE FOLLOWING SET OF OPENING REMARKS.

12 THE SITUATION CONCERNING FUNDING FOR
13 SCIENTIFIC RESEARCH CONTINUES TO BE FLUID WITH
14 DEVELOPMENTS ON A VIRTUALLY DAILY BASIS. THROUGH
15 CONVERSATIONS WITH MANY OF OUR STAKEHOLDERS WE AT
16 CIRM UNDERSTAND HOW THIS UNCERTAINTY IMPACTS THE
17 SCIENTIFIC AND PATIENT COMMUNITIES AND CAN BE
18 CHALLENGING, ESPECIALLY FOR RESEARCHERS AND
19 INSTITUTIONS THAT RELY ON A STABLE FUNDING
20 ENVIRONMENT TO DRIVE SCIENTIFIC PROGRESS.

21 THROUGH MARIA'S EFFORTS AND WITH THE HELP
22 OF POLICY PARTNERS, WE ARE CLOSELY MONITORING THE
23 EVOLVING LANDSCAPE IN WASHINGTON, D.C. LIKewise,
24 WE'RE IN CLOSE COMMUNICATION WITH THE GOVERNOR'S
25 OFFICE AND INSTITUTIONS AROUND THE STATE TO TRACK

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1 ONGOING DEVELOPMENTS.

2 OUR MESSAGE TO ALL IS THAT CIRM REMAINS
3 RESOLUTE AND FULLY COMMITTED TO SUPPORTING
4 CALIFORNIA'S RESEARCH COMMUNITY AND TO ADVANCING
5 INNOVATIVE REGENERATIVE MEDICINE THERAPIES TO PEOPLE
6 ACROSS THE STATE.

7 LATER TODAY THE BOARD WILL BE CONSIDERING
8 FOUR CONCEPT PLANS APPROVED LAST FALL AS PART OF OUR
9 STRATEGIC ALLOCATION FRAMEWORK OR SAF. APPLICATIONS
10 FOR DISCOVERY, PRECLINICAL DEVELOPMENT, AND CLINICAL
11 PROGRAMS ARE EXPECTED TO OPEN IN THE SPRING WITH
12 DEADLINES THROUGHOUT THE SUMMER AND FALL. COMBINED
13 THIS FIRST ROUND OF FUNDING PROGRAMS WILL PROVIDE
14 MORE THAN \$425 MILLION TO SUPPORT DOZENS OF NEW CELL
15 AND GENE THERAPY RESEARCH PROJECTS.

16 ALSO LATER TODAY THE BOARD WILL BE
17 CONSIDERING PART 1 OF A REDEFINED CONCEPT PLAN FOR
18 THE DELIVERY FUNCTION OF THE COMMUNITY CARE CENTERS
19 OF EXCELLENCE, CCCE. PART 2 OF THAT PLAN FOCUSING
20 ON THE SUPPORT FUNCTION WILL BE COMING TO THE BOARD
21 LATER THIS YEAR.

22 IF THE BOARD APPROVES THESE CONCEPT PLANS
23 TODAY, THE NEXT STEP WILL BE TO IMPLEMENT ALL THE
24 PROGRAMS DEFINED IN THOSE PLANS. THAT PROCESS WILL
25 BEGIN IMMINENTLY AND EXTEND THROUGH THE SUMMER AND

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1 FALL.

2 THE NEXT ROUND OF SAF CONCEPT PLANS IS
3 SCHEDULED TO COME TO THE BOARD IN JANUARY, INCLUDING
4 THOSE FOR THE RARE DISEASE PILOT PLATFORM PROGRAM,
5 THE DATA COORDINATING AND MANAGEMENT CENTER, THE
6 PILOT TECHNOLOGY PLATFORM PROGRAM, AND THE CLIN-X
7 PROGRAM TO FUND PROJECTS THROUGH BLA.

8 IT IS IMPORTANT TO NOTE, PER THE MANDATE
9 OF PROPOSITION 14, THAT ALL SAF PROGRAMS ARE DRIVEN
10 BY CIRM'S CORE PRINCIPLES, WHICH ARE: NO. 1, THAT
11 PATIENTS ARE THE NORTH STAR OF EVERYTHING WE DO.
12 NO. 2, THAT OUR MISSION IS TO ENABLE WORLD-CLASS
13 SCIENCE TO HELP REDUCE HUMAN SUFFERING. AND NO. 3,
14 TO MAKE THERAPIES AND CURES THAT WE FUND AVAILABLE
15 TO ALL CALIFORNIANS IN NEED. THE COMMON THREAD TO
16 EACH OF THESE PRINCIPLES IS THAT ALL FUNDED PROJECTS
17 FROM DISCOVERY THROUGH CLINICAL TRIALS MUST BE
18 DESIGNED TO ULTIMATELY ADDRESS THE NEEDS OF ALL
19 COMMUNITIES AFFECTED BY THE DISEASES IN QUESTION.

20 OUR LAST ROUND OF CONCEPT PLANS DUE FOR
21 BOARD CONSIDERATION IN MID-2026 WILL DEAL WITH
22 EXTENSIONS AND IMPROVEMENTS TO OUR EDUCATION
23 PROGRAMS. THERE WE'RE LOOKING TO CONTINUE TO TRAIN
24 THE SCIENTISTS OF TOMORROW WHO WILL BOTH MATERIALLY
25 ADD TO THE REGENERATIVE MEDICINE WORKFORCE IN ALL

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1 CORNERS OF THE STATE AND THEMSELVES CONCEIVE AND
2 DEVELOP NEW TECHNOLOGIES IN CELL AND GENE THERAPIES
3 TO THE FURTHER BENEFIT OF ALL CALIFORNIANS WITH
4 UNMET MEDICAL NEEDS.

5 SINCE INCEPTION IN 2004, CIRM HAS BEEN
6 METICULOUSLY COMPLIANT WITH ALL FEDERAL AND STATE
7 LAWS, INCLUDING PROPOSITION 209. WE HAVE AND WILL
8 CONTINUE TO DEMONSTRATE THAT THE PURSUIT OF SCIENCE
9 IS NOT INCONSISTENT WITH THESE LEGAL PARAMETERS. AS
10 STAUNCH SUPPORTERS OF SCIENTIFIC INGENUITY AND
11 INNOVATION, WE ARE FORTUNATE THAT THE CITIZENS OF
12 CALIFORNIA HAVE GIVEN US THE OPPORTUNITY AND
13 PRIVILEGE TO CONTINUE TO LEAD THE WAY IN
14 ACCELERATING BEST-IN-CLASS SCIENCE.

15 AS WE EMBARK ON OUR THIRD DECADE, WE WILL
16 CONTINUE TO CHAMPION REGENERATIVE MEDICINE IN
17 CALIFORNIA AND CONTRIBUTE TO THE STATE'S LEADERSHIP
18 IN GLOBAL SCIENTIFIC BREAKTHROUGHS.

19 ONE ADMINISTRATIVE NOTE. AS WE CONTINUE
20 TO TRACK EVOLVING DEVELOPMENTS, WE MAY NEED BOARD
21 REVIEW AND APPROVAL OF REVISED CONCEPT PLANS OR
22 PROGRAMS. GIVEN THAT THE FULL BOARD GENERALLY MEETS
23 EVERY THREE MONTHS AND THAT WE MAY NEED REAL-TIME
24 DECISIONS IN SHORT ORDER, I WOULD REQUEST THAT THE
25 BOARD DELEGATE AUTHORITY TO ME IN CONSULTATION WITH

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1 THE HEADS OF THE GOVERNANCE, FINANCE, AND
2 COMMUNICATIONS SUBCOMMITTEES, AS WELL AS THE HEADS
3 OF THE JOINT SCIENCE SUBCOMMITTEE AND NEURO TASK
4 FORCE TO MAKE DECISIONS CONCERNING ANY SUCH
5 REVISIONS. THERE WILL BE A MOTION TO THIS EFFECT AT
6 THE TAIL END OF THE CONCEPT PLAN DISCUSSIONS LATER
7 TODAY.

8 I WOULD LIKE TO CLOSE WITH THE OBSERVATION
9 THAT, AS WAS THE CASE WITH THE SAF IN SEPTEMBER,
10 TODAY'S CONCEPT PLANS WERE THE RESULT OF A MONTHS'
11 LONG, VERY HEAVY LIFT BY THE ENTIRE CIRM TEAM IN
12 CONSULTATION WITH THE BOARD. WHILE THE PRESENTERS
13 OF EACH OF THE CONCEPT PLANS WILL THANK MEMBERS OF
14 THE RESPECTIVE TEAMS BY NAME, I WANTED TO MAKE SURE
15 TO PERSONALLY THANK ALL MY COLLEAGUES FOR THE A-PLUS
16 WORK PRODUCT WE'LL BE CONSIDERING LATER TODAY AND TO
17 CONGRATULATE ALL OF US, ONCE AGAIN, BOARD AND TEAM,
18 ON A JOB EXTRAORDINARILY WELL DONE.

19 MR. CHAIRMAN, THAT CONCLUDES MY REMARKS.

20 CHAIRMAN IMBASCIANI: THANK YOU, DR.
21 THOMAS. WE WILL NOT FORGET YOUR NEED FOR THAT
22 AMENDMENT.

23 THE NEXT ITEMS ON THE AGENDA ARE THE
24 CONSENT CALENDAR, ITEMS 6 AND 7. TODAY'S CONSENT
25 AGENDA INCLUDES THE MINUTES FROM THE JANUARY MEETING

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1 OF THE ICOC, WHICH I HAVE REVIEWED AND FIND NO ISSUE
2 WITH, BUT YOU SHOULD TAKE A LOOK AT THOSE. AND THE
3 ITEM 7 IS A REQUEST FOR THE BOARD OF DIRECTORS TO
4 APPOINT ELIZABETH BOILEAU TO THE ACCESS AND
5 AFFORDABILITY WORKING GROUP.

6 ARE THERE ANY ABSTRACTIONS TO BE
7 CONSIDERED OR DISCUSSED FROM THE CONSENT CALENDAR?
8 IF NOT, MAY I HAVE A MOTION TO ACCEPT SUCH?

9 DR. BLUMENTHAL: SO MOVED.

10 CHAIRMAN IMBASCIANI: WE HAVE GEORGE
11 BLUMENTHAL, MOTION.

12 DR. SOUTHARD: SECOND.

13 CHAIRMAN IMBASCIANI: AND A SECOND FROM
14 MARVIN. OKAY. ANY DISCUSSION? OR FROM THE PUBLIC?
15 NONE. THANK YOU, CLAUDETTE. SCOTT, WOULD YOU
16 PLEASE POLL THE MEMBERS.

17 MR. TOCHER: ALL THOSE IN THE ROOM IN
18 FAVOR SAY AYE. ANY OPPOSED? ABSTENTIONS? AND I'LL
19 POLL THE MEMBERS ON THE PHONE.

20 MONICA CARSON. YSABEL DURON.

21 MS. DURON: YES.

22 MR. TOCHER: RICH LAJARA.

23 MR. LAJARA: YES.

24 MR. TOCHER: SHLOMO MELMED.

25 DR. MELMED: YES.

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1 MR. TOCHER: CHRIS MIASKOWSKI.

2 DR. MIASKOWSKI: YES.

3 MR. TOCHER: JOE PANETTA.

4 MR. PANETTA: YES.

5 MR. TOCHER: SUZANNE SANDMEYER.

6 DR. SANDMEYER: YES.

7 MR. TOCHER: KAROL WATSON.

8 DR. WATSON: YES.

9 MR. TOCHER: AND KEVIN XU.

10 DR. XU: YES.

11 MR. TOCHER: THANK YOU. THE MOTION
12 CARRIES.

13 CHAIRMAN IMBASCIANI: THANK YOU, SCOTT.

14 WE'LL NOW CONVENE AS THE APPLICATION
15 REVIEW SUBCOMMITTEE TO CONSIDER THOSE APPLICATIONS
16 SUBMITTED IN RESPONSE TO CLINICAL TRIAL PROJECTS.
17 DR. HAYLEY LAM, THE DIRECTOR OF REVIEW, WILL MAKE
18 THE PRESENTATION. THANK YOU, HAYLEY.

19 DR. LAM: GOOD MORNING TO THE BOARD, MR.
20 CHAIR, MADAM VICE CHAIR, AND THE CIRM TEAM, AND THE
21 PUBLIC. IT IS MY PLEASURE TODAY TO PRESENT THE
22 GRANTS WORKING GROUP RECOMMENDATIONS FOR THE
23 CLINICAL PROGRAM.

24 AS ALWAYS, WE BEGIN WITH OUR MISSION,
25 ACCELERATING WORLD-CLASS SCIENCE TO DELIVER

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1 TRANSFORMATIVE REGENERATIVE MEDICINE TREATMENTS IN
2 AN EQUITABLE MANNER TO A DIVERSE CALIFORNIA AND
3 WORLD.

4 THE CURRENT CLINICAL BUDGET STATUS HAS AN
5 ALLOCATION OF 76.7 MILLION FOR THE SECOND HALF OF
6 THE FISCAL YEAR. THIS BOARD HAS APPROVED IN JANUARY
7 24 MILLION IN FUNDS THUS FAR, AND TODAY THERE'S A
8 TOTAL ASK OF 26.5 MILLION ACROSS THREE APPLICATIONS.

9 COUPLE THINGS ABOUT THE CLINICAL PROCESS.
10 THE CURRENT SCORING SYSTEM IS A 1, 2, AND 3. A 1 IS
11 A RECOMMENDATION FOR FUNDING, A 2 IS A DO NOT
12 RECOMMEND AT THIS TIME AND THE APPLICANT CAN
13 RESUBMIT WITH ADDRESSING CONCERNS FROM THE GRANTS
14 WORKING GROUP, AND A 3 IS DO NOT RECOMMEND AT THIS
15 TIME AND THE APPLICANT CANNOT RESUBMIT THE SAME
16 PROJECT FOR AT LEAST SIX MONTHS.

17 THE SCIENTIFIC EVALUATION IS A HOLISTIC
18 SCORE ACROSS THESE FIVE CRITERIA. THE FIRST IS DOES
19 THE PROJECT HOLD THE NECESSARY SIGNIFICANCE AND
20 POTENTIAL FOR IMPACT? IS THE RATIONALE SOUND? SO
21 DOES THE DATA SUPPORT MOVING THE PROJECT FORWARD?
22 IS THE PROJECT WELL PLANNED AND DESIGNED? SO ARE
23 THE ACTIVITIES THAT ARE PROPOSED FOR CIRM FUNDING
24 WELL DESIGNED? IS THE PROJECT FEASIBLE? SO DOES
25 THE TEAM HAVE THE RESOURCES IN PLACE TO EXECUTE THE

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1 PROJECT? AND THE DOES THE PROJECT UPHOLD PRINCIPLES
2 OF DIVERSITY, EQUITY, AND INCLUSION? SO DOES IT
3 CONSIDER PATIENT DIVERSITY?

4 THE CLINICAL PROGRAM IN ADDITION TO THE
5 SCIENTIFIC SCORE HAS DIVERSITY, EQUITY, AND
6 INCLUSION SCORE THAT IS SCORED BY THE GRANTS WORKING
7 GROUP BOARD MEMBERS. THE SCALE FOR THIS IS A ZERO
8 TO TEN, A TEN BEING AN OUTSTANDING RESPONSE. THE
9 CRITERIA USED FOR THIS ARE UNDER OVERARCHING
10 CATEGORIES RELATED TO THE APPLICANT'S COMMITMENT TO
11 DEI, THE PROJECT PLANS, AND TRAINING FOR CULTURAL
12 SENSITIVITY.

13 SO IN SUMMARY, THE REVIEW PANEL THAT
14 ASSESSES THESE APPLICATIONS ARE COMPOSED OF THREE
15 DIFFERENT TYPES: THE SCIENTIFIC GRANTS WORKING
16 GROUP MEMBERS WHO PROVIDE A SCIENTIFIC SCORE AND
17 EVALUATE ACROSS THE DISEASE AREAS, REGULATORY,
18 MANUFACTURING, AND PRODUCT DEVELOPMENT; THE GRANTS
19 WORKING GROUP BOARD MEMBERS WHO PROVIDE THE DEI
20 SCORE ON ALL APPLICATIONS AND SUGGESTED SCIENTIFIC
21 SCORES AS THEY SO DESIRE; AND OUR AD HOC SCIENTIFIC
22 SPECIALISTS. AND THESE FOLKS PROVIDE THE SCIENTIFIC
23 EVALUATION IN AREAS AND EXPERTISE NOT COVERED BY THE
24 GRANTS WORKING GROUP.

25 SO AS WE MOVE INTO THE INDIVIDUAL

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1 APPLICATIONS UNDER CONSIDERATION TODAY, WE HAVE
2 BOARD MEMBERS WITH CONFLICTS OF INTEREST HERE
3 DISPLAYED.

4 AND FOR YOUR CONSIDERATION, THE VERY FIRST
5 APPLICATION IS CLIN1-17103. THIS IS AN EXPRESSION
6 OF UBE3A BY THE HEMATOPOIETIC SYSTEM FOR THE
7 TREATMENT OF ANGELMAN SYNDROME. THIS IS AN
8 AUTOLOGOUS GENE-MODIFIED CELL THERAPY FOR ANGELMAN.
9 AND THE APPLICANT IS REQUESTING JUST UNDER FOUR AND
10 A HALF MILLION WITH NO REQUIRED CO-FUNDING FROM A
11 CALIFORNIA ORGANIZATION TO COMPLETE THE TASKS
12 NECESSARY TO FILE AN IND.

13 A LITTLE BIT OF BACKGROUND ON THE PROJECT.
14 SO ANGELMAN IS A RARE GENETIC NEURODEVELOPMENTAL
15 DISORDER. AND THE PEOPLE WITH ANGELMAN'S HAVE
16 SEIZURES, MOVEMENT, BALANCE, AND GAIT ISSUES, AND
17 OVERALL DEVELOPMENTAL DISABILITY, INCLUDING
18 INTELLECTUAL DISABILITIES AND IMPAIRED SPEECH. THIS
19 IS A PROGRESSIVE AND CHRONIC CONDITION AND REQUIRES
20 LIFELONG AID. AND THE CURRENT STANDARD OF CARE
21 TREATS SYMPTOMS ONLY; FOR EXAMPLE, MEDICATION FOR
22 ANTISEIZURES.

23 THE PROPOSED PRODUCT IS A ONE-TIME
24 TREATMENT THAT MODIFIES THE PATIENT'S OWN STEM CELLS
25 AND CORRECTS THE UBE3A GENE. TRANSPLANTED CELLS

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1 THEN DELIVER FUNCTIONAL PROTEIN AND HAVE THE
2 POTENTIAL TO PREVENT, HALT, OR REVERSE SYMPTOMS
3 ASSOCIATED WITH ANGELMAN'S.

4 CIRM CURRENTLY HAS ONE TRANSLATIONAL AWARD
5 THAT'S CURRENTLY UNDER CONTRACTING IN THIS
6 INDICATION. THIS WAS APPROVED WITH THE BATCH OF
7 TRANSLATIONAL APPLICATIONS IN JANUARY. THEY USE A
8 SIMILAR APPROACH OF CORRECTING THE UBE3A GENE.

9 THE APPLICANT TEAM HAS RECEIVED PRIOR
10 FUNDING FROM CIRM WITH TWO AWARDS IN TAY-SACHS
11 DISEASE, WHICH IS A DIFFERENT NEURODEVELOPMENTAL
12 DISORDER WITH A SIMILAR APPROACH TO THIS PROJECT.

13 SO THE RECOMMENDATION FROM THE GRANTS
14 WORKING GROUP WAS A UNANIMOUS RECOMMENDATION TO FUND
15 CLIN1-17103 WITH A DEI SCORE OF 8. AND THE CIRM
16 TEAM RECOMMENDATION CONCURS WITH THE GRANTS WORKING
17 GROUP FOR A RECOMMENDATION TO FUND THIS APPLICATION
18 FOR 4.48 MILLION. CHAIR IMBASCIANI.

19 CHAIRMAN IMBASCIANI: THANK YOU, HAYLEY,
20 FOR THE PRESENTATION. LIKE A MOTION TO ACCEPT THE
21 RECOMMENDATION PLEASE.

22 DR. CLARK-HARVEY: SO MOVED.

23 DR. SOUTHARD: SECOND.

24 CHAIRMAN IMBASCIANI: I HEARD THE SECOND.
25 THANK YOU. OPEN TO DISCUSSION ON THIS

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1 RECOMMENDATION BY BOARD MEMBERS. IF NO BOARD
2 COMMENT, ANYONE FROM THE PUBLIC LIKE TO COMMENT?
3 THANK YOU. SCOTT, YOU MAY PROCEED.

4 MR. TOCHER: MARIA BONNEVILLE.

5 VICE CHAIR BONNEVILLE: YES.

6 MR. TOCHER: LEONDRA CLARK-HARVEY.

7 DR. CLARK-HARVEY: YES.

8 MR. TOCHER: ANNE-MARIE DULIEGE.

9 DR. DULIEGE: YES.

10 MR. TOCHER: MARK FISCHER-COLBRIE.

11 MR. FISCHER-COLBRIE: YES.

12 MR. TOCHER: ELENA FLOWERS.

13 DR. FLOWERS: YES.

14 MR. TOCHER: DAVID HIGGINS.

15 DR. HIGGINS: YES.

16 MR. TOCHER: VITO IMBASCIANI.

17 CHAIRMAN IMBASCIANI: YES.

18 MR. TOCHER: RICH LAJARA.

19 MR. LAJARA: YES.

20 MR. TOCHER: CHRISTINE MIASKOWSKI.

21 DR. MIASKOWSKI: YES.

22 MR. TOCHER: ADRIANA PADILLA.

23 DR. PADILLA: YES.

24 MR. TOCHER: JOE PANETTA.

25 MR. PANETTA: YES.

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1 MR. TOCHER: MARVIN SOUTHARD.

2 DR. SOUTHARD: YES.

3 MR. TOCHER: KAROL WATSON.

4 DR. WATSON: YES.

5 MR. TOCHER: YAEL WYTE.

6 DR. WYTE: YES.

7 MR. TOCHER: KEVIN XU.

8 DR. XU: YES.

9 MR. TOCHER: THANK YOU. THE MOTION
10 CARRIES, MR. CHAIR.

11 CHAIRMAN IMBASCIANI: THANK YOU. HAYLEY,
12 YOU CAN PROCEED TO THE NEXT APPLICATION.

13 DR. LAM: THANK YOU. SO CONFLICTS OF
14 INTEREST NOTE HERE.

15 THE NEXT APPLICATION FOR YOUR
16 CONSIDERATION IS CLIN2-17080. THIS IS A PRODUCT FOR
17 THE PREVENTION OF GVHD IN PATIENTS RECEIVING HLA
18 MISMATCHED HSCT FOR THE TREATMENT OF HEMATOLOGIC
19 MALIGNANCIES. ESSENTIALLY THIS IS AN OFF-THE-SHELF
20 CELL THERAPY TO PREVENT GRAFT VERSUS HOST DISEASE.

21 THE APPLICANT IS REQUESTING 8 MILLION WITH
22 A 4.7 MILLION IN CO-FUNDING TO COMPLETE A PHASE 1
23 CLINICAL TRIAL.

24 LITTLE BIT OF BACKGROUND ON THIS PROJECT.
25 SO PEOPLE UNDERGOING MISMATCHED STEM CELL

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1 TRANSPLANTS FOR THE TREATMENT OF BLOOD CANCERS ARE
2 OFTEN AFFECTED BY WHAT'S CALLED GRAFT VERSUS HOST
3 DISEASE WHERE THE DONOR CELLS ATTACK THE RECIPIENT
4 TISSUE. THE STANDARD OF CARE TREATMENTS OFTEN DON'T
5 WORK AND ARE USUALLY STEROIDS THAT SUPPRESS THE
6 IMMUNE SYSTEM FURTHER AND INCREASE THE RISK OF
7 INFECTIONS AND CAN ALSO IMPACT THE EFFECTIVENESS OF
8 THE CANCER TREATMENT ITSELF. IN SOME PATIENTS GVHD
9 CAN BE POTENTIALLY LIFE-THREATENING AND CAUSE TISSUE
10 DAMAGE IN MULTIPLE ORGAN SYSTEMS.

11 THE PROPOSED ALLOGENEIC, OFF-THE-SHELF
12 ENGINEERED REGULATORY T-CELL PRODUCT COULD INCREASE
13 ACCESS TO THESE STEM CELL TRANSPLANTS FOR
14 INDIVIDUALS WHO ARE CANDIDATES FOR TRANSPLANTS, THE
15 LACK OF SUITABLE MATCH DONOR, AND ALSO REDUCE THE
16 BURDEN OF THE GVHD.

17 THE CIRM PORTFOLIO HAS TWO ACTIVE PROJECTS
18 TARGETING GVHD IN PEOPLE WITH BLOOD CANCER AT
19 DIFFERENT STAGES OF CLINICAL DEVELOPMENT. ONE IS A
20 PHASE 1 TRIAL THAT USES A SIMILAR REGULATORY T-CELL
21 PRODUCT. THE DIFFERENCE WITH THIS ONE IS THAT IT'S
22 AN AUTOLOGOUS DONOR TRANSPLANT AND IS NOT A
23 OFF-THE-SHELF PRODUCT.

24 THE OTHER IS AN IND-ENABLING STAGE
25 MESENCHYMAL STEM CELL PRODUCT THAT AIMS TO SUPPRESS

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1 THE DONOR RESPONSE.

2 THIS APPLICANT HAS RECEIVED PRIOR CIRM
3 FUNDING, AND THIS APPLICATION AND WOULD-BE AWARD
4 WOULD BE A PROGRESSION EVENT OFF OF THIS PRECLINICAL
5 STAGE PROJECT.

6 SO THE GRANTS WORKING GROUP RECOMMENDATION
7 FOR THIS APPLICATION WAS A UNANIMOUS VOTE TO
8 RECOMMEND FOR FUNDING WITH A DEI SCORE OF 8, AND THE
9 CIRM TEAM CONCURS WITH THAT RECOMMENDATION FOR THE
10 FUNDING OF 8 MILLION FOR THIS PROJECT. CHAIR
11 IMBASCIANI.

12 CHAIRMAN IMBASCIANI: THANK YOU, HAYLEY.
13 AND THE CHAIR WOULD LIKE TO RECEIVE A MOTION TO
14 ACCEPT THE RECOMMENDATION.

15 DR. CLARK-HARVEY: SO MOVED.

16 DR. SOUTHARD: SECOND.

17 CHAIRMAN IMBASCIANI: LEONDRA HAS MOVED
18 AND MARVIN HAS SECONDED. THANK YOU. DISCUSSION
19 FROM BOARD MEMBERS ON THIS APPLICATION FOR GRAFT
20 VERSUS HOST DISEASE.

21 DR. DULIEGE: JUST A BRIEF QUESTION. CAN
22 YOU TELL US THE SIZE OF THE TRIAL THAT IS --

23 DR. LAM: THE PROPOSED TRIAL?

24 DR. DULIEGE: HOW MANY PATIENTS?

25 DR. LAM: THEY'RE AIMING SOMEWHERE BETWEEN

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1 20 TO 39 SUBJECTS.

2 DR. DULIEGE: THANK YOU.

3 CHAIRMAN IMBASCIANI: OTHER COMMENT? OR
4 FROM THE PUBLIC? AND WE'RE SEEING NONE. THANK YOU.
5 SCOTT, YOU MAY PROCEED TO THE VOTE.

6 MR. TOCHER: THANK YOU. MARIA BONNEVILLE.

7 VICE CHAIR BONNEVILLE: YES.

8 MR. TOCHER: LEONDRA CLARK-HARVEY.

9 DR. CLARK-HARVEY: YES.

10 MR. TOCHER: ANNE-MARIE DULIEGE.

11 DR. DULIEGE: YES.

12 MR. TOCHER: YSABEL DURON.

13 MS. DURON: YES.

14 MR. TOCHER: MARK FISCHER-COLBRIE.

15 MR. FISCHER-COLBRIE: YES.

16 MR. TOCHER: ELENA FLOWERS.

17 DR. FLOWERS: YES.

18 MR. TOCHER: DAVID HIGGINS.

19 DR. HIGGINS: YES.

20 MR. TOCHER: VITO IMBASCIANI.

21 CHAIRMAN IMBASCIANI: YES.

22 MR. TOCHER: RICH LAJARA.

23 MR. LAJARA: YES.

24 MR. TOCHER: CHRISTINE MIASKOWSKI.

25 DR. MIASKOWSKI: YES.

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MR. TOCHER: ADRIANA PADILLA.

DR. PADILLA: YES.

MR. TOCHER: JOE PANETTA.

MR. PANETTA: YES.

MR. TOCHER: MARVIN SOUTHARD.

DR. SOUTHARD: YES.

MR. TOCHER: KAROL WATSON.

DR. WATSON: YES.

MR. TOCHER: YAEL WYTE.

DR. WYTE: YES.

MR. TOCHER: AND KEVIN XU.

DR. XU: YES.

MR. TOCHER: THANK YOU. MOTION CARRIES,
MR. CHAIR.

CHAIRMAN IMBASCIANI: THANK YOU, SCOTT.
HAYLEY, FOR THE THIRD APPLICATION.

DR. LAM: ALL RIGHT. THIRD AND FINAL
APPLICATION FOR YOUR CONSIDERATION. THE APPLICATION
IS CLIN2-17135, AN INHIBITORY INTERNEURON CELL
THERAPY FOR THE TREATMENT OF DRUG RESISTANT
BILATERAL TEMPORAL LOBE EPILEPSY. THIS IS AN
INTERNEURON CELL THERAPY, AND THE APPLICANT IS
REQUESTING JUST UNDER 14 MILLION WITH OVER 9 MILLION
IN CO-FUNDING FROM A CALIFORNIA ORGANIZATION TO
COMPLETE A PHASE 1-2 CLINICAL TRIAL.

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1 LITTLE BIT OF CLINICAL BACKGROUND ON THIS.
2 SO EPILEPSY IMPACTS ABOUT 1 PERCENT OF ADULTS IN THE
3 UNITED STATES AND IS A NEUROLOGICAL DISORDER THAT
4 CAUSES REOCCURRING SEIZURES. ANTISEIZURE
5 MEDICATIONS ARE THE MAIN STANDARD OF CARE; HOWEVER,
6 A THIRD OR MORE OF PEOPLE LIVING WITH EPILEPSY HAVE
7 DRUG-RESISTANT SEIZURES, MEANING TWO OR MORE
8 DIFFERENT TYPES OF MEDICATIONS DO NOT CONSISTENTLY
9 DECREASE THE SEIZURE IMPACT. AND THIS, OF COURSE,
10 IMPACTS QUALITY OF LIFE.

11 SO THE CURRENT TREATMENTS FOR THOSE WITH
12 DRUG-RESISTANT EPILEPSY INCLUDES SURGICAL METHODS
13 WHICH ESSENTIALLY DESTROY THE TISSUE, AND THIS CAN
14 CAUSE SERIOUS EFFECTS SUCH AS MEMORY LOSS AND SPEECH
15 AND OTHER COGNITIVE IMPAIRMENTS.

16 THE PROPOSED PRODUCT IS A TARGETED
17 NONTISSUE DESTRUCTIVE ONE-TIME DELIVERY OF CELLS
18 INTO THE IMPACTED BRAIN REGIONS. THE CELL
19 REPLACEMENT AIMS TO REBALANCE THE NEURAL ACTIVITY BY
20 SECRETING NEUROTRANSMITTERS IN THE LOCALIZED BRAIN
21 AREA AND HOPES TO PROVIDE A LONG-LASTING SEIZURE
22 REDUCTION.

23 CIRM HAS TWO ACTIVE LATER STAGE AWARDS IN
24 EPILEPSY. ONE FOR A CURRENT CLINICAL TRIAL IN A
25 SIMILAR INDICATION, BUT FOR A UNILATERAL MESIAL

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1 TEMPORAL LOBE EPILEPSY FOR THE SAME PRODUCT. CIRM
2 ALSO IS FUNDING A TRANSLATIONAL PRECLINICAL STAGE
3 PROJECT FOR THE SAME INDICATION, BUT A SIMILAR
4 CANDIDATE THAT WOULD BE A UNIVERSAL PRODUCT THAT
5 WOULD HOPEFULLY OBTAIN THE NEED FOR
6 IMMUNOSUPPRESSION.

7 THE APPLICANT TEAM HAS RECEIVED SEVERAL
8 PRIOR CIRM AWARDS THAT RESULT IN THE APPLICATION
9 BEFORE YOU TODAY. SO THERE'S BEEN ESSENTIALLY THREE
10 PROGRESSION AWARDS IN THE SORT OF HISTORY OF THIS
11 PROJECT ALL THE WAY BACK TO THE DISCOVERY STAGE AND
12 IN ADDITION TO THE CURRENT TRANSLATIONAL PROJECT
13 THAT I JUST MENTIONED PREVIOUSLY.

14 THEREFORE, THE GRANTS WORKING GROUP
15 RECOMMENDATION FOR THIS PROJECT WAS A UNANIMOUS
16 RECOMMENDATION FOR FUNDING WITH A DEI SCORE OF 8.
17 AND THE CIRM TEAM CONCURS WITH THAT RECOMMENDATION
18 FOR FUNDING THIS APPLICATION FOR JUST UNDER 14
19 MILLION. CHAIR IMBASCIANI.

20 CHAIRMAN IMBASCIANI: YES. THANK YOU
21 AGAIN, HAYLEY. I'D LIKE TO HAVE A MOTION TO ACCEPT
22 THE RECOMMENDATION.

23 DR. SOUTHARD: SO MOVED.

24 CHAIRMAN IMBASCIANI: MARVIN SOUTHARD HAS
25 MOVED.

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1 MR. FISCHER-COLBRIE: SECOND.

2 CHAIRMAN IMBASCIANI: THANK YOU, MARK,
3 SECOND. DISCUSSION FROM BOARD MEMBERS ON BILATERAL
4 TEMPORAL LOBE EPILEPSY. ANNE-MARIE.

5 DR. DULIEGE: HAYLEY, CAN YOU PLEASE HELP
6 US UNDERSTAND THE OTHER APPLICATION FROM THE SAME
7 TEAM THAT WE FUNDED, THE CLIN2, ON UNILATERAL
8 EPILEPSY AND HOW THEY COMPARE, HOW THEY DIFFER?
9 WILL ONE INDICATE SUCCESS FOR THE OTHER?

10 DR. LAM: SO THE UNILATERAL IS THE ONE
11 SIDE, AND THEN THIS ONE IS PROPOSING FOR BILATERAL,
12 SO BOTH SIDES OF THE BRAIN. THIS WAS ACTUALLY A
13 RESUBMISSION FROM THE APPLICANT BECAUSE THERE WAS
14 QUESTIONS FROM THE GRANTS WORKING GROUP REVIEWERS ON
15 HOW EXACTLY THAT THE CURRENT TRIAL FEEDS INTO THIS
16 ONE IN TERMS OF SAFETY ESPECIALLY FOR THE
17 PARTICIPANTS IN THE TRIAL. SO THEY WERE SATISFIED
18 WITH THE RESPONSE FROM THE APPLICANT. AND IT IS TWO
19 DIFFERENT PROTOCOLS.

20 CHAIRMAN IMBASCIANI: FOLLOW UP? THANK
21 YOU. ANY OTHER QUESTIONS OR COMMENTS FROM BOARD
22 MEMBERS? OR FROM MEMBERS OF THE PUBLIC? CLAUDETTE
23 IS SEEING NONE. OKAY. THANK YOU. SCOTT, WE MAY
24 PROCEED.

25 MR. TOCHER: MARIA BONNEVILLE.

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1 VICE CHAIR BONNEVILLE: YES.
2 MR. TOCHER: LEONDRA CLARK-HARVEY.
3 DR. CLARK-HARVEY: YES.
4 MR. TOCHER: ANNE-MARIE DULIEGE.
5 DR. DULIEGE: YES.
6 MR. TOCHER: MARK FISCHER-COLBRIE.
7 MR. FISCHER-COLBRIE: YES.
8 MR. TOCHER: DAVID HIGGINS.
9 DR. HIGGINS: YES.
10 MR. TOCHER: VITO IMBASCIANI.
11 CHAIRMAN IMBASCIANI: YES.
12 MR. TOCHER: RICH LAJARA.
13 MR. LAJARA: YES.
14 MR. TOCHER: ADRIANA PADILLA.
15 DR. PADILLA: YES.
16 MR. TOCHER: JOE PANETTA.
17 MR. PANETTA: YES.
18 MR. TOCHER: MARVIN SOUTHARD.
19 DR. SOUTHARD: YES.
20 MR. TOCHER: YAEL WYTE.
21 DR. WYTE: YES.
22 MR. TOCHER: KEVIN XU.
23 DR. XU: YES.
24 MR. TOCHER: THANK YOU VERY MUCH. MR.
25 CHAIR, THE MOTION CARRIES.

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1 CHAIRMAN IMBASCIANI: MOTION CARRIES.
2 THANK YOU. THANK YOU, DR. LAM, FOR THAT EXCELLENT
3 PRESENTATION.

4 OKAY. MOVING ON, THE BOARD ADOPTED THE
5 STRATEGIC ALLOCATION FRAMEWORK, THE SAF, IN
6 SEPTEMBER OF LAST YEAR. THE SAF CRYSTALLIZED INTO
7 SIX MAJOR RECOMMENDATIONS. AND THE CIRM TEAM HAS
8 BEEN WORKING ASSIDUOUSLY TO REALIZE THE PROMISE OF
9 THOSE RECOMMENDATIONS.

10 TODAY WE WILL HEAR NEW CONCEPT PLANS ON
11 THE FIRST FOUR PROGRAMS, DISC5, DISC4,
12 PREDEVELOPMENT OR PDEV, AND CLIN2 ALONG WITH AN
13 AMENDMENT TO THE REVIEW PROCESS AND THE GRANTS
14 WORKING GROUP BYLAWS. THE BOARD WILL BE ASKED TO
15 CONSIDER EACH PLAN SEPARATELY, BUT WE SHALL BEGIN BY
16 HAVING AN OVERLOOK OF THE ENTIRE PACKAGE BY DR. ROSA
17 CANET-AVILES, OUR CHIEF SCIENCE OFFICER. ROSA,
18 THANK YOU.

19 DR. CANET-AVILES: THANK YOU, MR.
20 CHAIRMAN, MADAM VICE CHAIR, DISTINGUISHED MEMBERS OF
21 THE BOARD, AND DISTINGUISHED PUBLIC AS WELL OF
22 CALIFORNIA, AND MY COLLEAGUES. I'M EXCITED TODAY
23 BECAUSE WE WERE -- WE HAD A THREE-HOUR PRESENTATION
24 BACK IN SEPTEMBER THAT WAS THE FRUIT OF LABOR OF
25 NEARLY A YEAR OF WORKING WITH DATA AND TRYING TO

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1 FIGURE OUT HOW TO BEST ALLOCATE OUR RESOURCES. AND
2 WE CAME UP WITH A PLAN TO YOU ALL. YOU PRESSURE
3 TESTED IT OVER THE MONTHS, AND WE ENDED UP WITH ALL
4 SIX RECOMMENDATIONS THAT OUR CHAIRMAN OF THE BOARD
5 WAS MENTIONING AND THAT OUR PRESIDENT, JONATHAN
6 THOMAS, PRESENTED EARLIER ON AS WELL.

7 SO TODAY WE HAVE, AS YOU'VE SEEN FROM ALL
8 THE MATERIALS THAT WE POSTED, ALL THOSE THOROUGH
9 MATERIALS, WHAT WE ARE GOING TO COME TO YOU TODAY IS
10 THE FIRST PHASE OF THAT IMPLEMENTATION. AND THIS IS
11 THESE FOUR CONCEPTS THAT MY COLLEAGUES ARE GOING TO
12 BE PRESENTING TODAY, AND DR. NOBLIN IS GOING TO GIVE
13 US AN OVERVIEW ABOUT.

14 SO AS WE'VE ALL BEEN LIVING THROUGH THE
15 PAST YEAR, THIS STRUCTURED PREFERENCE-SETTING
16 PROCESS IS A FRAMEWORK THAT WILL HELP KEEP FUNDING
17 PRIORITIES DYNAMIC, DATA DRIVEN, AND ALIGNED WITH
18 EMERGING OPPORTUNITIES AND PORTFOLIO NEEDS, WHICH,
19 AS YOU WILL SEE, WE ARE GOING TO BE HEARING IN A
20 RECURRENT MANNER EVERY JUNE OF EVERY YEAR A
21 PORTFOLIO ANALYSIS THAT WILL BE HELPING US KEEP UP
22 WITH THE EMERGING OPPORTUNITIES AND PRIORITIES.

23 SO WHAT WE ARE GOING TO PRESENT TODAY THIS
24 MORNING REFLECTS THE EFFORT OF MANY. AND I KNOW
25 THAT J.T. AND VITO MENTIONED IT, BUT WE'VE BEEN

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1 WORKING TOGETHER FOR MANY MONTHS. AND I WOULD LIKE
2 TO START BY ACKNOWLEDGING THE INCREDIBLE EFFORT THAT
3 HAS GONE GETTING US UP UNTIL THIS POINT. THIS HAS
4 BEEN A REAL TEAM EFFORT. I'M VERY PROUD OF ALL OF
5 YOU. AND I WANT TO RECOGNIZE NOT ONLY TODAY'S
6 PRESENTERS, WHICH ARE THE PEOPLE THAT HAVE BEEN
7 LEADING SOME OF THE EFFORTS, BUT ALSO THE TEAMS AND
8 LEADS FROM PROGRAMS, GRANTS MANAGEMENT, AT THE HELM
9 IS JENN LEWIS, BUT ALSO DOUG KEARNEY, REVIEW WITH
10 GIL SAMBRANO AND HAYLEY LAM, LEGAL WITH RAFAEL
11 AGUIRRE-SACASA, AND BOARD GOVERNANCE WITH OUR LOVELY
12 SCOTT TOCHER AND CLAUDETTE HELPING US WITH ALL OF
13 THIS. AND A SPECIAL THANKS TO OUR SCIENCE
14 SUBCOMMITTEE AND NEURO TASK FORCE CO-CHAIRS, DR. PAT
15 LEVITT, DR. CAROLYN MELTZER, DR. MARK
16 FISCHER-COLBRIE. I REALLY APPRECIATE YOUR HELP WITH
17 ALL THE MEETINGS AND ALL THE TIME IN YOUR BUSY
18 SCHEDULES TO GET US ALL TO THIS POINT. THANK YOU
19 VERY MUCH.

20 AND ALSO TO OUR BOARD CHAIR AND BOARD
21 GOVERNANCE. THANK YOU SO MUCH. THERE'S BEEN A LOT
22 OF MEETINGS, AND YOU GUYS HAVE BEEN VERY VALUABLE IN
23 GETTING US TO THIS. SO I HOPE THAT ALL THE FEEDBACK
24 WE'VE GATHERED FROM THEM WILL HELP US GET TO THE
25 FINISH LINE, WHICH IS NOT JUST THE CONCEPTS. IT'S

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1 ALL THE WORK THAT COMES AFTER THAT, RIGHT?

2 SO I THINK -- ONE LAST POINT I WANT TO
3 MAKE IS FOUR MONTHS OF HARD WORK, WHAT WE ARE
4 BRINGING TO YOU TODAY, WHAT WE'VE ACCOMPLISHED IN
5 THE LAST FOUR MONTHS IS PRETTY REMARKABLE. I THINK
6 THERE IS A LITTLE THING HERE THAT SHOWS MORE OR LESS
7 WHAT WE DID IN KIND OF TWO YEARS WITH THE REMIND AND
8 THE STRATEGIC ALLOCATION FRAMEWORK PROCESS, WHICH
9 UNFOLDED OVER ABOUT TWO YEARS. AND THE WORK THAT WE
10 HAVE DONE NOW HAS BEEN ONLY IN FOUR MONTHS, AND
11 WE'VE DONE IT EFFICIENTLY TO ALIGN THESE PROPOSALS
12 WITH THE SAF TO HAVE IT READY FOR CONSIDERATION.
13 AND THIS PACE WAS NECESSARY TO KEEP THE MOMENTUM AND
14 ENSURING CONTINUITY IN FUNDING, WHICH IS VERY
15 IMPORTANT IN THESE MOMENTS, RIGHT, AND SUPPORT OUR
16 RESEARCH AND CLINICAL COMMUNITIES.

17 DR. NOBLIN IS GOING TO COME IN A MINUTE.
18 SO GET READY, LIZ. SHE'S GOING TO SHOW TODAY'S
19 DISCUSSIONS ARE JUST A PART OF A LARGER TIMELINE AS
20 DR. JONATHAN THOMAS REFERENCED AND WITH PHASE 1
21 COMING NOW AND PHASE 2 TOWARDS THE END OF THE YEAR.
22 EARLY JANUARY WE HOPE TO BE ABLE TO PRESENT.

23 SO, LIZ, THE FLOOR IS YOURS. AND THANK
24 YOU ALL FOR EVERYTHING THAT YOU'VE DONE WITH US.

25 CHAIRMAN IMBASCIANI: THANK YOU, ROSA.

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1 DR. NOBLIN: THANKS VERY MUCH. GOOD
2 MORNING, EVERYONE. MY NAME IS LIZ NOBLIN, AND IT'S
3 MY PLEASURE TO PROVIDE AN INTRODUCTION AND SOME
4 BACKGROUND TO THE FOUR CONCEPTS THAT YOU WILL HEAR
5 ABOUT TODAY.

6 WITHIN THIS BACKGROUND AND INTRODUCTION,
7 THIS WILL FOCUS ON RELATING THESE CONCEPTS TO THE
8 SAF AND CIRM'S IMPACT GOALS. I'LL ALSO TOUCH
9 BRIEFLY ON OUR DEVELOPMENT PROCESS, AND THEN
10 HIGHLIGHT THE LAUNCH TIMELINE ASSUMING APPROVAL TO
11 MOVE FORWARD TODAY.

12 SO THE SAF OR STRATEGIC ALLOCATION
13 FRAMEWORK WAS CIRM'S STRUCTURED APPROACH TO DIRECT
14 OUR EFFORTS AND OUR FUNDING TO MAXIMIZE IMPACT IN
15 THE FIELD OF REGENERATIVE MEDICINE. THE IMPACT
16 GOALS WERE FOCUSED INTO FOUR AREAS OF ACCELERATING
17 DISCOVERY AND TRANSLATION, CELL AND GENE THERAPY
18 APPROVALS, ACCESS AND AFFORDABILITY FOR CIRM-FUNDED
19 THERAPIES, AND DEVELOPING A DIVERSE WORKFORCE.

20 WITHIN THOSE FOUR CATEGORIES, THERE WERE
21 SPECIFIC MEASURABLE IMPACT GOALS THAT GUIDED THE
22 DEVELOPMENT OF OUR CONCEPTS TODAY. SO TODAY
23 SPECIFICALLY WE WILL HEAR ABOUT THE NEW CONCEPTS
24 THAT ARE ADDRESSING GOAL 1, WHICH WAS TO CATALYZE
25 THE IDENTIFICATION AND VALIDATION OF AT LEAST FOUR

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1 NOVEL TARGETS AND BIOMARKERS. GOAL NO. 4, WHICH IS
2 PROPELLING 15 TO 20 THERAPIES TO LATE STAGE TRIALS.
3 AND BY DESIGN, THESE CONCEPTS INCORPORATE THE
4 IMPORTANT ELEMENTS OF GOAL 5, WHICH IS ENSURING THAT
5 EVERY BLA-READY PROGRAM HAS A STRATEGY FOR ACCESS
6 AND AFFORDABILITY.

7 FOLLOWING THE APPROVAL OF THE SAF IN
8 SEPTEMBER, AS HAS BEEN MENTIONED, THIS KICKED OFF AN
9 INTENSIVE PROCESS TO THEN CONVERT THOSE IMPACT GOALS
10 INTO REAL FUNDING OPPORTUNITIES FOR OUR RESEARCH
11 INSTITUTIONS. SO PENDING THE BOARD'S DECISION
12 TODAY, WE HAVE BEEN COLLABORATING WITH ALL OF OUR
13 COLLEAGUES AT CIRM AND ARE READY TO LAUNCH THOSE
14 FUNDING OPPORTUNITIES THROUGHOUT THE REMAINDER OF
15 THE CALENDAR YEAR.

16 IN ADDITION TO THAT, WE WILL THEN BEGIN
17 THE DESIGN AND DEVELOPMENT OF THE NEXT PHASE OF
18 CONCEPTS FOR DISCUSSION WITH THE BOARD IN THE COMING
19 MONTHS. THIS IS ON TOP OF OUR ONGOING WORK TO
20 MANAGE OUR ACTIVE PORTFOLIO OF AWARDS AND CONTINUING
21 TO ASSESS OUR PROGRAMS.

22 SO TO TOUCH BRIEFLY ON OUR PROCESS FOR
23 DESIGNING THESE CONCEPTS, AGAIN, THIS ALL BEGAN WITH
24 THE APPROVAL OF THE SAF AND THE IMPACT GOALS THERE.
25 THERE WAS DATA ANALYSIS THAT WAS PART OF THE SAF.

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1 AND IN ADDITION, THERE'S BEEN CONTINUED ANALYSIS OF
2 CIRM'S PORTFOLIO, OF THE WORK THAT WAS DONE AS PART
3 OF THE NEURO TASK FORCE, LOOKING AT THE CURRENT
4 STATE OF THE CELL AND GENE THERAPY LANDSCAPE, AND
5 ALSO THE OUTCOMES OF CIRM'S HISTORICAL AWARDS. AND
6 SO ALL OF THOSE DATA HAVE BEEN INCORPORATED INTO THE
7 CONCEPTS THAT THE TEAM WILL PRESENT TODAY.

8 SO NOW JUST TO ORIENT US ALL TO WHAT'S
9 COMING AND GIVE A VERY BRIEF OVERVIEW, OUR CONCEPTS
10 SPAN MULTIPLE PHASES OF THE RESEARCH AND DEVELOPMENT
11 PIPELINE. STARTING WITHIN THE DISCOVERY PHASE, WE
12 HAVE THE DISC4 AND DISC5 CONCEPTS, WHICH BOTH FOCUS
13 ON TEAM-BASED SCIENCE AND HAVE EITHER A SMALLER TEAM
14 STRUCTURE IN DISC5 OR A LARGE TEAM STRUCTURE IN
15 DISC4 TO LEAD TO THOSE DISCOVERIES IN REGENERATIVE
16 MEDICINE.

17 WITHIN THE DISC4 CONCEPT, YOU WILL ALSO
18 HEAR ABOUT CYCLICAL FOCUS AREAS THAT WERE DRIVEN BY
19 NTF RECOMMENDATIONS AND OUR PORTFOLIO. PDEV IS
20 CIRM'S NEW PRECLINICAL DEVELOPMENT FUNDING
21 OPPORTUNITY, WHICH INTEGRATES OUR FORMER
22 TRANSLATIONAL FUNDING OPPORTUNITY AS WELL AS OUR
23 CLIN1 FUNDING OPPORTUNITY INTO A STREAMLINED PATH
24 SOLELY FOCUSED ON GETTING PROMISING CANDIDATES TO
25 IND.

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1 AND THEN FINALLY, WITHIN OUR CLINICAL
2 TRIAL STAGES, WE HAVE UPDATES TO THE CLIN2 PROGRAM
3 THAT HAVE BEEN MADE TO ALIGN WITH THE SAF IMPACT
4 GOALS AND RECOMMENDATIONS. AND IN PDEV AND CLIN2
5 WE'LL ALSO DISCUSS RECOMMENDATIONS FOR PREFERENCE
6 SETTING THAT, AGAIN, ARE ALIGNED WITH MANDATES FROM
7 PROP 14 AS WELL AS THE STRATEGIC ALLOCATION
8 FRAMEWORK.

9 AND THEN FINALLY, THIS VERY COLORFUL SLIDE
10 JUST GIVES YOU A SNAPSHOT OF THE WORK THAT'S AHEAD
11 FOR US PENDING BOARD DECISION TODAY. WE ARE POISED
12 WITH ALL OF THE BACKGROUND WORK ONGOING TO OPEN
13 THESE FUNDING OPPORTUNITIES THROUGHOUT THE SPRING
14 AND THEN BEGIN OUR FIRST ROUND OF GRANTS WORKING
15 GROUP REVIEWS IN THE FALL WITH THE FIRST SET OF
16 APPLICATIONS FOR ARS RECOMMENDATIONS SCHEDULED TO
17 COME IN EARLY 2026. THIS IS IN ADDITION TO
18 CONTINUING THE CURRENTLY OPEN DISC-0 FUNDING
19 OPPORTUNITY AND ALSO RELAUNCHING THE COMMUNITY CARE
20 CENTERS FUNDING OPPORTUNITY THAT WE WILL HEAR ABOUT
21 LATER TODAY.

22 SO WITH THAT, I'M SURE YOU'RE ALL EXCITED
23 TO GET INTO SOME OF THE SPECIFICS. SO I WOULD LOVE
24 TO HAND THINGS OVER TO DR. KELLY SHEPARD, DIRECTOR
25 OF DISCOVERY AND EDUCATION, TO PRESENT THE DISC5

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1 CONCEPT.

2 CHAIRMAN IMBASCIANI: THANK YOU, LIZ.

3 DR. SHEPARD: GOOD MORNING, DISTINGUISHED
4 BOARD MEMBERS, MR. CHAIRMAN, MADAM CHAIRWOMAN,
5 MEMBERS OF THE PUBLIC, AND THE CIRM TEAM. IT'S MY
6 PLEASURE TO COME HERE FOR YOU TODAY AND KICK OFF A
7 SERIES OF DISCUSSIONS ABOUT THESE NEW CONCEPTS THAT
8 WE ARE BRINGING FOR YOUR CONSIDERATION TODAY. WE'RE
9 GOING TO BEGIN WITH DISC5.

10 BEFORE WE DO THAT, I JUST WANT TO
11 INTRODUCE THE OVERALL FORMAT OF MY PRESENTATION
12 BECAUSE THIS IS GOING TO BE A FORMAT THAT WILL BE
13 REPEATED FOR EACH SERIES OF CONCEPTS THAT YOU WILL
14 BE HEARING ABOUT TODAY AND HOPEFULLY KEEP THINGS
15 ORGANIZED IN YOUR MINDS AS WELL AS IN OUR
16 PRESENTATIONS.

17 SO WE'LL BEGIN WITH A LITTLE BIT OF
18 BACKGROUND ABOUT THESE DISCOVERY PROGRAMS AND HOW
19 THEY'RE ALIGNED WITH THE SAF GOALS. WE'LL THEN
20 INTRODUCE THE OBJECTIVE OF DISC5 AS WELL AS THE
21 SCOPE AND THE STRUCTURE OF THESE AWARDS, AND THEN
22 WE'LL ONCE AGAIN GO OVER THE TIMELINE FOR WHEN WE
23 EXPECT TO BE ABLE TO BRING THESE NEW OPPORTUNITIES
24 TO OUR CONSTITUENTS. AND FINALLY, A REQUEST FOR
25 MOTION BEFORE WE MOVE ON TO THE NEXT SECTION WHICH

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1 MY COLLEAGUE DR. CHAN LEK TAN WILL INTRODUCE THE
2 DISC4 OPPORTUNITY.

3 SO LET'S JUST BEGIN BY BRIEFLY RESTATING
4 WHICH STRATEGIC ALLOCATION FRAMEWORK RECOMMENDATION
5 THAT THIS PROGRAM WAS DESIGNED TO SUPPORT, WHICH IS
6 THE FIRST GOAL: CATALYZING THE IDENTIFICATION AND
7 VALIDATION OF AT LEAST FOUR NOVEL TARGETS AND
8 BIOMARKERS, ENSURING INTEGRATION INTO PRECLINICAL OR
9 CLINICAL RESEARCH FOR DISEASES IN CALIFORNIA.

10 BECAUSE WE HAVE TWO DISCOVERY CONCEPTS
11 THAT WE'RE DISCUSSING TODAY, I JUST WANT TO GIVE YOU
12 THE OVERALL VISION FOR OUR DISCOVERY PROGRAMS AND
13 HOW THEY WORK TOGETHER TO IMPACT THIS GOAL. SO
14 DISC4 AND DISC5 HAVE A COMMON OBJECTIVE, WHICH IS,
15 AGAIN, REPHRASING STRATEGIC ALLOCATION FRAMEWORK
16 GOAL 1 ESSENTIALLY, IS TO SUPPORT COMPREHENSIVE
17 DISCOVERY RESEARCH ACROSS A DIVERSE RANGE OF
18 DISEASES AND BOTTLENECKS TO ACCELERATE THE
19 DEVELOPMENT OF POTENTIAL THERAPEUTICS AND BIOMARKERS
20 IN REGENERATIVE MEDICINE.

21 SO THIS WILL INCLUDE TWO COMPLEMENTARY
22 AWARD STRUCTURES THAT HAVE SOME DIFFERENCES AND SOME
23 SIMILARITIES. SOME OF THE MOST IMPORTANT
24 DIFFERENCES THAT WE'LL GO OVER ARE THE SCALE OF THE
25 RESEARCH THAT IS SUPPORTED AND THE LEVEL OF THE

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1 MATURITY OF THE RESEARCH THAT IS SUPPORTED. SO
2 DR. NOBLIN ALREADY INTRODUCED THAT DISC4 WOULD
3 INVOLVE LARGE MULTIDISCIPLINARY COLLABORATIONS;
4 WHEREAS, DISC5 WILL FOCUS ON SMALLER TEAM
5 COLLABORATIONS. AND WE'LL BEGIN TO GET INTO THE
6 DETAILS OF DISC5 SPECIFICALLY IN MY NEXT FEW SLIDES.

7 NOW, IN ADDITION TO THE FACT THAT DISC4
8 AND DISC5 ARE DESIGNED TO WORK IN A COMPLEMENTARY
9 FASHION, THEY ARE ALSO DESIGNED TO BE COMPLEMENTARY
10 TO ONGOING INFRASTRUCTURE PROGRAMS AND OTHER
11 INITIATIVES AT CIRM THAT ARE EITHER ALREADY
12 ESTABLISHED OR IN DEVELOPMENT. THESE INCLUDE THINGS
13 LIKE PROGRAM AND GRANTEE MEETINGS, SUCH AS AN
14 UPCOMING REMIND CONFERENCE THAT WE ARE PLANNING TO
15 BRING THE DIFFERENT TEAMS INVOLVED IN OUR REMIND
16 PROGRAM TOGETHER, SHARE KNOWLEDGE, DEVELOP
17 STANDARDS, DECIDE ON COLLABORATIVE CONSORTIUM TYPE
18 OF GOALS OR SUBGOALS.

19 WE HAVE ESTABLISHED SOME DATA SHARING
20 INFRASTRUCTURE AS WELL AS SOME THAT IS COMING THAT
21 THESE PROGRAM CAN TAP INTO. IT ALSO ALLOWS THEM TO
22 LEVERAGE INTERNAL AND EXTERNAL PARTNERSHIPS,
23 INCLUDING PARTNERSHIPS WITH SOME OF OUR OTHER
24 PROGRAMS SUCH AS OUR EDUCATION PROGRAMS, PROVIDE
25 TRAINEES WHO CAN WORK WITH THESE INVESTIGATORS, AND

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1 ALSO KNOWLEDGE AND KNOW-HOW FROM OUR SHARED RESOURCE
2 LABORATORIES AND MANUFACTURING CENTERS THAT CAN BE
3 SHARED AND LEVERAGED.

4 THAT SAID, LET'S NOW DIVE INTO DISC5. SO
5 AGAIN, THE OBJECTIVE IS TO SUPPORT COMPREHENSIVE
6 DISCOVERY RESEARCH ACROSS A DIVERSE RANGE OF
7 DISEASES AND BOTTLENECKS AND TO ACCELERATE THE
8 DEVELOPMENT OF POTENTIAL THERAPEUTICS AND BIOMARKERS
9 IN REGENERATIVE MEDICINE THROUGH THE KNOWLEDGE THAT
10 EMERGES FROM THIS PROGRAM.

11 THE APPROACH IS TO REALLY SUPPORT
12 EXPLORATORY AND INNOVATIVE FOUNDATIONAL RESEARCH
13 THAT WILL BE LED BY PAIRS OF INVESTIGATORS. THERE'S
14 A WIDE VARIETY OF ACTIVITIES THAT CAN FALL IN THIS
15 SCOPE, BUT THEY MUST BE DESIGNED TO ACHIEVE ONE OR
16 MORE OF THESE FOLLOWING OUTCOMES: ADVANCING OUR
17 UNDERSTANDING OF HUMAN STEM AND PROGENITOR CELLS AS
18 THEY PERTAIN TO HUMAN HEALTH AND/OR HUMAN DISEASE,
19 ADVANCING THE USE AND IMPACT OF STEM CELLS IN THE
20 EXPLORATION OF DISEASE MECHANISMS AND THERAPEUTIC
21 TARGET DISCOVERY. SO THAT'S USING STEM CELLS AS A
22 TOOL BASICALLY TO UNCOVER NEW DISEASE TARGETS AND
23 MECHANISMS. IDENTIFY BIOLOGICAL INSIGHTS TO ADDRESS
24 KEY BOTTLENECKS IN STEM CELL AND GENE THERAPY AND
25 OTHER REGENERATIVE MEDICINE APPROACHES. AND

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1 FINALLY, ADVANCING APPLICABILITY OF STEM CELLS AND
2 GENE THERAPY AND OTHER REGENERATIVE MEDICINE
3 APPROACHES TO DIVERSE HUMAN POPULATIONS.

4 SOME OF THESE GOALS SOUND FAMILIAR TO YOU
5 BECAUSE THEY ARE CORE TO OUR MISSION, AND THEY'VE
6 BEEN A PART OF OUR ONGOING DISC-0 PROGRAM THAT WE
7 HAVE BEEN SUPPORTING FOR THE PAST COUPLE OF YEARS.
8 HOWEVER, DISC5 IS A NEW CONCEPT THAT WE BUILT
9 STARTING WITH THAT SUCCESSFUL FRAMEWORK OF DISC0,
10 BUT THEN IMPROVING IT IN SEVERAL WAYS TO HELP IT
11 ALIGN MORE EFFECTIVELY WITH THE STRATEGIC ALLOCATION
12 FRAMEWORK GOAL NO. 1.

13 AND THE TWO MOST IMPORTANT CHANGES OR
14 IMPROVEMENTS THAT WE WILL BE DISCUSSING TODAY
15 INVOLVE SHIFTING FROM A SINGLE INVESTIGATOR-DRIVEN
16 APPROACH TO A COLLABORATION OR SMALL TEAM DRIVEN
17 APPROACH. SO RATHER THAN BEING LED BY A SINGLE PI,
18 THIS NEW PROGRAM WILL HAVE A DUAL HEAD PROGRAM
19 STRUCTURE WHERE A CO-I AND A CO-INVESTIGATOR
20 CONTRIBUTE EQUALLY, AND THEY ARE EXPECTED TO BRING
21 DIFFERING APPROACHES AND EXPERTISE TO CREATE A NEW
22 TYPE OF SYNERGY TO BEAR ON A PROBLEM.

23 THE SECOND IS AN INCREASED EMPHASIS ON
24 INNOVATION AND ENHANCING EXPLORATORY, HIGH RISK,
25 HIGH REWARD TYPE OF RESEARCH.

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1 THIS TABLE IS SHOWING THE GENERAL AWARD
2 STRUCTURE. WE'RE GOING TO GO INTO A LITTLE BIT MORE
3 DETAIL ABOUT A COUPLE OF THESE FEATURES. WHAT I
4 WANT TO HIGHLIGHT HERE IS THAT THIS IS AN
5 OPPORTUNITY THAT WE EXPECT TO RECUR ANNUALLY. IT
6 WILL BE A THREE-YEAR AWARD. SO IT'S FINANCIAL
7 SUPPORT FOR THREE YEARS OF RESEARCH OPEN TO
8 CALIFORNIA FOR-PROFIT, NON-PROFIT INSTITUTIONS LED
9 BY A TEAM OF TWO INVESTIGATORS. THE MAXIMUM AWARD
10 AMOUNT WILL BE \$2.5 MILLION. AND AT THIS LEVEL WE
11 EXPECT TO BE ABLE TO SUPPORT ABOUT 15 TO 20 NEW
12 AWARDS EVERY YEAR FOR AN ANNUAL BUDGET OF \$50
13 MILLION.

14 SO JUST A COUPLE OF WORDS ABOUT THE TOTAL
15 AWARD CAP, WHICH IS SOMETHING THAT IS DIFFERENT THAN
16 DISC-0. IN DISC0 WE HAVE AN AWARD CAP BASED ON
17 DIRECT PROJECTS COSTS, NOT OVERHEAD, WHICH WAS 1 TO
18 \$1.5 MILLION. IN THIS NEW AWARD STRUCTURE FOR
19 DISC5, WE'RE PROPOSING A TOTAL AWARD COST CAP OF
20 \$2.5 MILLION. WE DECIDED FOR THIS APPROACH BECAUSE
21 IT REMOVES A DISINCENTIVE FOR MULTI-INSTITUTIONAL
22 COLLABORATIONS SINCE INSTITUTIONS SEPARATE FROM THE
23 PRINCIPAL INVESTIGATOR RECEIVE THEIR FUNDS THROUGH A
24 SUBCONTRACT TO THE PRIMARY GRANTEE. AND SECONDLY,
25 THIS IS TO CREATE CONSISTENCY IN THE WAY WE'RE

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1 HANDLING AWARD AMOUNTS BETWEEN AND ACROSS ALL OF OUR
2 PROGRAMS, AND IT MAKES THINGS EASIER FOR APPLICANTS
3 WHO ARE LOOKING AT MULTIPLE PROGRAMS WHEN THERE'S
4 NOT A DIFFERENT RULE FOR EVERY PROGRAM.

5 SO IN ORDER TO BE ELIGIBLE TO SUBMIT A
6 DISC5 APPLICATION, PROJECTS MUST ADDRESS A KEY
7 KNOWLEDGE GAP OR A RESEARCH BOTTLENECK THAT COULD
8 LEAD TO ONE OR MORE OF THOSE EXPECTED OUTCOMES THAT
9 I INTRODUCED A COUPLE SLIDES AGO. THEY SHOULD FOCUS
10 ON AND CENTER ON STUDIES THAT EMPLOY HUMAN STEM
11 CELLS AND/OR GENETIC RESEARCH AS PART OF THE CENTRAL
12 APPROACH OR HYPOTHESIS. WE DO ALLOW USE OF NONHUMAN
13 CELLS OR MODELS IF THERE'S STRONG JUSTIFICATION AND
14 HOW THAT WOULD BE IN SUPPORT OF THE OVERALL GOAL
15 WHICH IS TO UNDERSTAND HUMAN BIOLOGY AND HUMAN
16 DISEASE BIOLOGY.

17 AGAIN, THE APPLICANTS MUST BE CALIFORNIA
18 NON-PROFIT OR FOR-PROFIT RESEARCH INSTITUTIONS. THE
19 CORE TEAM, AS I MENTIONED PREVIOUSLY, WILL BE LED
20 EQUALLY BY TWO INVESTIGATORS, A PRINCIPAL
21 INVESTIGATOR WHO IS DESIGNATED AS SUCH AS THEY ARE
22 THE MAIN POINT OF CONTACT WITH CIRM STAFF, AND THE
23 CO-INVESTIGATOR WHO MUST BE FROM A DIFFERENT LAB
24 FROM THE PRINCIPAL INVESTIGATOR.

25 THIS PROGRAM ALSO REQUIRES EXPERTISE OF A

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1 DATA PROJECT MANAGER WHERE DATA IS GENERATED AND IS
2 EXPECTED TO BE SHARED. AND THE MINIMUM EFFORT
3 REQUIREMENTS FOR THE CORE TEAM MEMBERS IS 5 PERCENT.

4 WE ANTICIPATE A VERY LARGE VOLUME OF THESE
5 APPLICATIONS BASED ON PRECEDENT FROM ALL OF OUR
6 EARLIER DISCOVERY STAGE PROGRAMS. WE PLAN TO USE
7 OUR ESTABLISHED TWO-STAGE REVIEW PROCESS IN ORDER TO
8 PROCESS AND REVIEW THESE APPLICATIONS. I'LL BRIEFLY
9 GO OVER THIS. THIS WAS A PROCESS THAT WAS
10 ESTABLISHED BACK IN 2015 WHEN WE FIRST INTRODUCED
11 DISCOVERY PROGRAMS. AND IT WAS SPECIFICALLY
12 DESIGNED TO HELP US HANDLE PROGRAMS WHERE WE RECEIVE
13 LARGE NUMBER OF APPLICATIONS.

14 SO APPLICANTS WILL SUBMIT A FULL
15 APPLICATION. AND THEN FROM THAT POOL, IT WILL BE
16 PRESENTED TO THE GRANTS WORKING GROUP MEMBERS WHO
17 WILL GO THROUGH AND REVIEW THEM, AND EACH WILL BE
18 ALLOWED TO SELECT A SPECIFIC NUMBER OF APPLICATIONS
19 THAT WILL MOVE FORWARD TO THE SECOND STAGE OF
20 REVIEW. WE CALL THAT PROCESS POSITIVE SELECTION.
21 THOSE THAT ARE SELECTED MOVE FORWARD TO FULL REVIEW,
22 WHICH IS THE CONVENTIONAL GRANTS WORKING GROUP
23 REVIEW THAT YOU ARE ALL FAMILIAR WITH, RESULTS IN
24 SCORING OF APPLICATIONS AND RECOMMENDATIONS FOR
25 FUNDING THAT THEN COME TO OUR APPLICATION REVIEW

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1 SUBCOMMITTEE FOR DECISIONS.

2 ONE OTHER ATTRIBUTE I WANT TO MENTION IS
3 THAT THIS PROGRAM WILL INCLUDE DATA SHARING AND
4 MANAGEMENT PLANS. THIS IS SOMETHING THAT WE
5 INTRODUCED IN DISC-0 AND HAVE BEEN REFINING AND
6 IMPROVING AND EXPANDING UPON. SO WE DO EXPECT THAT
7 THE DATA GENERATED FROM OUR FUNDING WILL BE SHARED
8 AND WILL ADHERE TO FAIR PRINCIPLES THAT MEANS THE
9 DATA WILL BE FINDABLE, ACCESSIBLE, INTEROPERABLE,
10 AND REUSABLE. IN ORDER FOR THAT TO HAPPEN, IT
11 REQUIRES CAREFUL MANAGEMENT AND CURATION DURING THE
12 COURSE OF THE AWARD.

13 SO WE ARE REQUIRING THAT OUR APPLICANTS
14 HAVE A PLAN ABOUT HOW THEY'RE GOING TO DO THIS, AND
15 WE MONITOR IT ONCE THE AWARDS ARE FUNDED. WE WILL
16 ALSO REQUIRE THAT DISC5 GRANTEES COORDINATE WITH OUR
17 ONGOING AND ANY FUTURE DATA INITIATIVES THAT WE
18 ANTICIPATE.

19 SO WHEN WILL THIS PROGRAM COME? WELL,
20 PENDING CONCEPT APPROVAL TODAY, WE WOULD ANTICIPATE
21 POSTING THE PROGRAM ANNOUNCEMENT THIS SUMMER AND
22 THEN HAVING APPLICATIONS OPEN IN THE FALL.

23 NOW, THAT MIGHT SEEM FAR OFF, BUT
24 ACTUALLY, AS DR. NOBLIN MENTIONED, WE DO HAVE AN
25 OPEN DISC0 OPPORTUNITY AT THIS TIME WITH

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1 APPLICATIONS DUE ON APRIL 10TH IN FACT. AND SO WE
2 WILL BE CONTINUING TO SUPPORT THIS VERY IMPORTANT
3 STAGE OF RESEARCH OVER THE NEXT FEW MONTHS WHILE
4 WE'RE WAITING FOR THIS NEW PROGRAM TO COME OUT AND
5 CREATE NEW OPPORTUNITIES FOR THESE INVESTIGATORS TO
6 SUPPORT THEIR IMPORTANT AND IMPACTFUL RESEARCH.

7 SO WE ARE GOING TO BE REQUESTING YOUR
8 APPROVAL FOR THE PROPOSED DISC5 CONCEPT PLAN. BUT
9 BEFORE WE GO INTO THAT, I WOULD BE HAPPY TO TAKE ANY
10 QUESTIONS OR LISTEN TO ANY OF YOUR FEEDBACK.

11 CHAIRMAN IMBASCIANI: THANK YOU, KELLY,
12 FOR THAT WONDERFUL PRESENTATION. I SEE WE HAVE
13 QUESTIONS. WE'LL START WITH KIM BARRETT.

14 DR. BARRETT: THANK YOU FOR A VERY CLEAR
15 PRESENTATION. I WASN'T ENTIRELY SURE HOW YOU
16 ARRIVED AT THE RECOMMENDATION FOR TWO
17 CO-INVESTIGATORS. AND WILL YOU ELABORATE THAT
18 FURTHER? WHY DID YOU DECIDE ON TWO? DO THEY HAVE
19 TO BE FROM DISTINCT DISCIPLINES? WHAT'S THE PLAN?

20 DR. SHEPARD: YES. SO WE HAVE CONSIDERED
21 DIFFERENT CONFIGURATIONS. WE NOW HAVE SOME
22 EXPERIENCE WITH FOUR OR FIVE CO-INVESTIGATORS FROM
23 THE PILOT DISC4 PROGRAM, WHICH IS KNOWN AS REMIND.
24 WE ALSO HAVE EXPERIENCE WITH OUR CURRENT DISC0
25 OPPORTUNITY WHERE WE OFFER TWO TRACKS, A SINGLE

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1 INVESTIGATOR TRACK AND A TEAM TRACK, WHICH SUPPORTED
2 UP TO TWO OR THREE. AND WE'VE COME TO REALIZE
3 THROUGH THESE DISCUSSIONS THAT WE THINK FOR THIS
4 SMALLER, FOR APPROXIMATELY THIS AMOUNT OF FUNDING
5 TWO IS REALLY IDEAL. IT DOESN'T MEAN THERE CAN'T BE
6 MORE INVESTIGATORS INVOLVED. IT JUST MEANS THAT
7 THERE ARE TWO THAT ARE LEADING. THEY CAN HAVE AS
8 MANY COLLABORATORS IN THE USUAL FASHION AS THEY
9 LIKE.

10 BUT WE THINK TWO IS A GOOD NUMBER, AND WE
11 ARE REQUIRING THAT THEY HAVE SOME DIFFERENCES THEY
12 BRING TOGETHER TO CREATE SOMETHING NEW. OTHERWISE,
13 IT WOULDN'T BE TERRIBLY DIFFERENT THAN A TRADITIONAL
14 AWARD WHICH ALSO ALLOW CO-INVESTIGATORS AND
15 COLLABORATORS. BUT IN THIS CASE WE'RE PUTTING THEM
16 ON EQUAL FOOTING, AND WE'RE ASKING THEM TO BRING
17 THEIR OWN INDIVIDUAL EXPERTISE AND APPROACHES TO THE
18 TABLE SO THAT THE COMBINATION CREATES A UNIQUE
19 COLLABORATIVE SYNERGY. AND WE ENVISION THAT THAT IS
20 SOMETHING THAT THE REVIEWERS WILL BE ABLE TO
21 CONTEMPLATE THE VALUE OF THROUGH THE REVIEW
22 CRITERIA, EMPHASIZING THE SYNERGY AND THE FACT THAT
23 THE COMPOSITION OF THE COLLABORATION CREATES A TOTAL
24 THAT IS GREATER THAN THE SUM OF THE PARTS.

25 DR. BARRETT: CAN YOU EDUCATE ME WHAT

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1 WOULD HAPPEN IF ONE OF THE TWO INVESTIGATORS WAS NO
2 LONGER ABLE TO CONTINUE THE PROJECT OR MOVED OUTSIDE
3 OF CALIFORNIA?

4 DR. SHEPARD: SO WE WOULD TREAT THAT
5 SITUATION THE SAME WAY AS WE TREAT A SITUATION WHEN
6 A PRINCIPAL INVESTIGATOR IS LEAVING THE STATE OR CAN
7 NO LONGER PARTICIPATE IN THE PROJECT. THEY WOULD
8 SUBMIT -- IF THEY WANTED TO CONTINUE THE AWARD, THEY
9 WOULD HAVE TO SUBMIT A PRIOR APPROVAL REQUEST TO
10 CIRM WITH THE NEW REPLACEMENT INVESTIGATOR, THEIR
11 CV, THEIR EXPERTISE, AND A STRONG JUSTIFICATION FOR
12 HOW REPLACING THAT INDIVIDUAL WOULD NOT NEGATIVELY
13 IMPACT THE PROJECT. AND THEN IT WOULD BE OUR
14 DECISION WHETHER OR NOT THAT WOULD BE ACCEPTABLE.

15 CHAIRMAN IMBASCIANI: THANK YOU. JUDY.

16 DR. GASSON: THANK YOU, KELLY, FOR THAT
17 PRESENTATION. I HAVE A QUESTION AND A COMMENT.

18 IN TERMS OF THE POSITIVE SELECTION, YOU'RE
19 ANTICIPATING YOU MIGHT GET AS MANY AS 150 TO 200
20 APPLICATIONS, AND THIS IS AN OPPORTUNITY THAT ARISES
21 ONCE A YEAR. SO HOW MANY APPLICATION OUT OF THAT
22 POOL DO YOU EXPECT WILL ACTUALLY GO TO A FULL
23 REVIEW?

24 DR. SHEPARD: BASED ON WHAT WE'VE BEEN
25 DOING TRADITIONALLY, WE TYPICALLY TAKE BETWEEN 40

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1 AND 50 TO REVIEW.

2 DR. GASSON: MY COMMENT ON THE DATA
3 SHARING IS WHAT KIND OF GUIDANCE IS GOING TO BE
4 GIVEN TO THE INVESTIGATORS IN TERMS OF WHAT TYPES OF
5 DATA AND HOW THEY'RE TO BE SHARED AND WHO'S DECIDING
6 ON THAT POLICY?

7 DR. SHEPARD: WE ACTUALLY HAVE SOME
8 GUIDANCE THAT'S POSTED ON OUR WEBSITE, AND WE HAVE A
9 NEW FUNCTION ON OUR TEAM, THE DATA INFRASTRUCTURE,
10 WHO HAS DEVELOPED -- WE ACTUALLY HAVE A PROCESS THAT
11 HAS BEEN ESTABLISHED AND WE'VE BEEN PILOTING AND
12 USING WITH DISCO WHERE WE INTAKE. WE BASICALLY HAVE
13 THEM CREATE A CATALOG OF THE DIFFERENT TYPES OF DATA
14 THAT THEY'RE PRODUCING IN THE AWARD, PROCESSED AND
15 UNPROCESSED, AND THE METADATA STANDARDS THAT WILL BE
16 ASSOCIATED WITH AND WHERE THEY'RE GOING TO DEPOSIT
17 IT.

18 DR. JANIE BYRAM IS LEADING THAT EFFORT,
19 AND SHE'S NOT HERE TO SPEAK ABOUT IT, BUT I WANT TO
20 HAND THE MICROPHONE TO ROSA IF YOU WANT TO SAY
21 ANYTHING FURTHER THAN THAT. SORRY. I THOUGHT YOU
22 WANTED TO SAY SOMETHING.

23 DR. CANET-AVILES: WHAT I WAS GOING TO SAY
24 IS THAT THERE IS -- AS KELLY WAS VERY WELL
25 MENTIONING, WE HAVE THIS DATA FUNCTION, DATA

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1 INFRASTRUCTURE FUNCTION LED BY JANIE BYRAM. AND ONE
2 OF THE THINGS THAT WE ARE GOING TO PRESENT TO THE
3 BOARD NEXT IS A DATA DASHBOARD AS WELL THAT WE HAVE
4 CREATED WHERE PEOPLE WILL BE ABLE TO GO INTO OUR
5 CIRM WEBSITE AND CLICK AND SEE WHERE THE DATA THAT
6 HAS BEEN GENERATED WITH CIRM FUNDING IS AND WHAT
7 KIND OF DATA.

8 BUT IN TERMS OF TELLING THEM THE
9 GUIDELINES, WE ACTUALLY STARTED THIS TWO AND A HALF
10 YEARS AGO, AND WE MODELED IT TO THE DATA MANAGEMENT
11 AND SHARING POLICIES OF THE NIH. SO WE DERIVE FROM
12 THAT SO THAT WE CAN ALIGN WITH THE NIH AND WORK WITH
13 THEM AND LEVERAGE THEIR DATA AS WELL AND
14 INFRASTRUCTURE. THANK YOU.

15 CHAIRMAN IMBASCIANI: PAT.

16 DR. LEVITT: SO THE CONCEPT PLAN IN TERMS
17 OF THE CONTENT AND THE FOCUS IS GREAT. I HAVE SOME
18 QUESTIONS ABOUT THE POSITIVE SELECTION PLAN.

19 IN ONE OF THE DOCUMENTS, THE FIRST
20 SELECTION STARTS AT 300 APPLICATIONS. HOW LONG IS
21 THE APPLICATION? HOW MANY PAGES IS A DISC5
22 APPLICATION? LIKE FOR AN R21 AT NIH, IT'S SIX PAGES
23 FOR THE RESEARCH PLAN AND A SPECIFIC AIMS PAGE. SO
24 IT'S A SEVEN-PAGE DOCUMENT OF CONTENT, AND THEN
25 YOU'VE GOT BUDGET AND ET CETERA. WHAT'S THE LENGTH

1 OF IT?

2 DR. SHEPARD: IT'S NOT TERRIBLY DIFFERENT
3 THAN THAT. THERE'S A SIGNIFICANCE AND IMPACT
4 SECTION, WHICH IS ONE TO TWO PAGES. THEN THERE'S
5 THE RESEARCH PLAN. ONE THING THAT MIGHT BE
6 DIFFERENT IS WE HAVE BEEN ASKING FOR THE SPECIFIC
7 AIMS SEPARATELY AND PRELIMINARY DATA SECTION
8 SEPARATELY FROM THE RESEARCH PLAN, BUT WE'RE TALKING
9 ABOUT MAKING EVERYTHING MORE EFFICIENT AND
10 STREAMLINED IN THE NEW VERSIONS OF OUR APPLICATION.
11 SO WE'RE THINKING ABOUT COMBINING THAT.

12 WE HAVE BEEN RESPONSIVE AND WE'VE HEARD
13 THE CONCERNS DISCUSSED AT THE BOARD AND AMONGST OUR
14 APPLICANTS ABOUT A LOT OF SECTIONS AND LENGTHY
15 THINGS. SO WE'RE DEFINITELY STREAMLINING THINGS AND
16 COMBINING SECTIONS WHERE NECESSARY. I DON'T THINK
17 IT'S SUBSTANTIALLY MORE THAN WHAT THEY'VE BEEN USED
18 TO OVER THE YEARS AND NOT TERRIBLY DIFFERENT FROM
19 WHAT THEY WOULD PUT INTO AN R21 APPLICATION.

20 DR. LEVITT: RIGHT. SO WITH THIS NUMBER
21 STARTING AT 300, MY GUESS IS THAT IN TERMS OF
22 ADMINISTRATIVE CRITERIA, JUST MEETING THE GOALS OF
23 CIRM, THERE'S GOING TO BE A SMALL NUMBER THAT ARE
24 NOT GOING TO QUALIFY. THEY'RE ALL GOING TO BE STEM
25 CELL, GENE THERAPY BASED, WHATEVER DISCOVERY AREAS,

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1 AND CERTAINLY THE DISEASE AREAS, WHICH IS VERY
2 BROADLY DEFINED BY CIRM, IS GOING TO BE MET.

3 SO ABOUT 50 PERCENT OF THOSE ARE GOING TO
4 GO AWAY THROUGH THE POSITIVE SELECTION PROCESS.
5 THOSE ARE FULL APPLICATIONS WHERE THEY WON'T GET A
6 FULL REVIEW, RIGHT?

7 DR. SHEPARD: YES. SO THE APPLICATIONS
8 THAT ARE SUBMITTED ARE FULL APPLICATIONS. SO THE
9 GRANTS WORKING GROUP LOOK AT THEM, AND THERE ARE
10 SECTIONS THAT ARE MORE KIND OF HIGH LEVEL OVERVIEWS
11 THAT THEY LOOK AT FIRST TO HELP THEM KIND OF PARSE
12 HOW THEY'RE GOING TO GO THROUGH THEM. THEY HAVE
13 ACCESS TO THE ENTIRE APPLICATION HOWEVER SO THEY CAN
14 LOOK AS DEEPLY AS THEY LIKE. BUT THEIR
15 RESPONSIBILITY IS TO GO THROUGH AND SELECT THE ONES
16 THAT THEY THINK ARE THE MOST INTERESTING OR MOST
17 IMPACTFUL BASED ON THE REVIEW CRITERIA. AND THEN
18 THOSE GET FORWARDED FOR THE SECOND STAGE OF REVIEW.

19 THE ONES THAT DO NOT PASS, THE ACTION IS
20 JUST ENDED ON THEM, AND THEY CAN REAPPLY IN THE
21 FUTURE TO THIS OPPORTUNITY.

22 DR. LEVITT: RIGHT. SO THEY HAVE TO WAIT
23 ANOTHER YEAR.

24 SO MY CONCERN IS HAVING -- GOING THROUGH A
25 FULL APPLICATION PROCESS AND ENDING UP WITH ABOUT 30

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1 TO 50 THAT ARE GOING TO BE FULLY REVIEWED, THERE'S
2 OTHER CONCEPT PLANS THAT ARE GOING TO BE DISCUSSED
3 IN WHICH THERE'S AN LOI, THERE'S LOTS OF
4 CONVERSATION WE'VE HAD ABOUT LOI'S. SO I'M NOT
5 UNDERSTANDING WHY THE LOI IS NOT BEING USED HERE
6 WHERE IT BASICALLY SAVES THE INVESTIGATOR TIME AND
7 TO SOME EXTENT, SPEAKING AS AN INVESTIGATOR WHO
8 WRITES GRANTS ALL THE TIME, AGONY OF WRITING A FULL
9 PROPOSAL AND THEN BASICALLY 80 PERCENT OR MORE ARE
10 GOING TO GO WITHOUT A FULL REVIEW.

11 THAT'S A REALLY DIFFICULT PILL TO SWALLOW
12 AS OPPOSED TO AN LOI WHERE THERE'S INFORMATION THAT
13 YOU'RE ASKING FOR -- I'M NOT GOING TO GO INTO IT
14 NOW -- BUT LOOKS QUITE APPROPRIATE AND SAVES BOTH
15 CIRM TIME AS WELL AS THE INVESTIGATOR'S TIME IN
16 TERMS OF WRITING A FULL PROPOSAL.

17 DR. SHEPARD: I WOULD SAY THAT THE REASON
18 THAT WE'RE PROPOSING THIS METHOD IS BECAUSE IT HAS
19 BEEN WORKING FOR US. AND I'VE BEEN AT CIRM FOR A
20 LONG TIME, AND I THINK DR. SAMBRANO WILL TALK ABOUT
21 THIS. WE'VE TRIED VARIOUS DIFFERENT TWO-STEP
22 APPLICATION PROCESSES IN THE PAST. WHILE WE'RE
23 GETTING AROUND 150 OR SO APPLICATIONS THROUGH THIS
24 METHOD, WHEN WE HAD A SHORT, NOT AN LOI, BUT A
25 PREAPPLICATION WHICH IS SIMILAR TO AN LOI, WE WERE

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1 GETTING 350, 400. AND I THINK IF WE DID THAT, WE
2 COULD EASILY SEE -- IN THIS CLIMATE WE COULD SEE
3 THOUSANDS. WE'RE LIMITED IN HOW MANY MEMBERS OF THE
4 GRANTS WORKING GROUP CAN PARTICIPATE IN REVIEW OF
5 APPLICATIONS.

6 SO AN LOI ISN'T AN APPLICATION, BUT AN
7 APPLICATION HAS TO BE REVIEWED BY THE GRANTS WORKING
8 GROUP. SO IT CREATES -- WE HAVE TO WORK WITHIN OUR
9 STATUTE. I'M HAPPY TO LET DR. SAMBRANO SPEAK ON
10 THIS MORE IF YOU HAVE FURTHER QUESTIONS BECAUSE THIS
11 IS REALLY HIS REALM AND HE'S BEEN INVOLVED IN ALL OF
12 THE DESIGN OF ALL OF THESE PROCESSES AND COULD
13 PROBABLY DO A BETTER JOB THAN ME.

14 DR. SAMBRANO: YOU DID GREAT. YES, I WILL
15 SPEAK MORE ABOUT THIS. WE TALKED AND I UNDERSTAND
16 THE CONCERN. I THINK THERE IS A BURDEN ON
17 APPLICANTS THAT WE ARE TRYING TO ALSO ACCOUNT FOR,
18 THAT THERE'S A CERTAIN THRESHOLD THEY HAVE TO MEET
19 IN ORDER TO APPLY.

20 WE HAVE BEEN COGNIZANT OF THAT WHILE AT
21 THE SAME TIME TRYING TO MANAGE THE NUMBERS OF
22 APPLICATIONS THAT WE CAN DEAL WITH. SO AS KELLY
23 MENTIONED, THERE IS AN EXPECTATION THAT IF THE
24 NUMBER IS SO HIGH, THAT IT WOULD BE BECOME VERY
25 DIFFICULT FOR US TO EVEN MANAGE WHAT'S AN LOI.

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1 ON THE OTHER HAND, I ALSO WANT TO SAY THAT
2 PART OF WHAT I WANTED TO EXPRESS IN MY PRESENTATION
3 A LITTLE LATER IS THAT THERE'S A LEVEL OF
4 FLEXIBILITY THAT WE WANT TO BE ABLE TO EXERCISE IN
5 PIVOTING FROM ONE METHOD TO ANOTHER IF THE NEED
6 ARISES, MEANING YOUR SUGGESTION IS WHY NOT USE THE
7 LOI OR PRESUBMISSION PROCESS IN THIS CASE. IF THE
8 NUMBERS ARE SUCH THAT WE CAN DO THAT AND THAT IT
9 MAKES SENSE FOR THE PROGRAM TO PLUG IT IN, IT'S
10 SOMETHING THAT WE COULD CONSIDER FOR FUTURE
11 ITERATIONS.

12 AT THIS TIME WE'RE WORKING ON WHAT WE KNOW
13 WITH THE POSITIVE SELECTION FOR THIS PROGRAM THAT
14 BASICALLY MIRRORS DISC0, AND WE ARE TRYING THE LOI
15 PRESUBMISSION PROCESS IN THE PDEV AND DISC4 WHICH
16 ARE NEW PROGRAMS. AND WE WANT TO SEE HOW THAT GOES.
17 THOSE PROGRAMS ALSO HAVE MUCH LARGER APPLICATIONS
18 THAT WOULD BE A MUCH GREATER BURDEN FOR THEM TO FILL
19 OUT IF THEY WERE OTHERWISE TO COME IN THROUGH A
20 PROCESS LIKE POSITIVE SELECTION.

21 DR. LEVITT: OKAY. PART OF THE CONCEPT
22 PLAN, I THINK IT WAS IN THE CONCEPT PLAN, I THINK
23 IT'S THE CONCEPT PLAN, IN TERMS OF FOCUS AREAS. CAN
24 YOU ELABORATE ON THAT?

25 DR. SHEPARD: FOR THIS PROGRAM, DISC5,

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1 THERE ARE NO FOCUS AREAS. IT'S OPEN AS LONG AS IT
2 ADDRESSES THOSE MISSION-SPECIFIC OUTCOMES THAT I
3 MENTIONED, SUCH AS USING STEM CELLS AND BASICALLY
4 THE PROPOSITION 14 REQUIREMENTS. THE FOCUS AREAS
5 THAT YOU'RE THINKING ABOUT ARE GOING TO BE DISCUSSED
6 WHEN MY COLLEAGUE, DR. CHAN LEK TAN, INTRODUCES THE
7 DISC4 PROGRAM. I'M VERY EXCITED TO HEAR YOUR ROBUST
8 DISCUSSION ABOUT THAT.

9 DR. LEVITT: SO FOR DISC5, NO
10 NEURO-SPECIFIC FOCUS AREAS?

11 DR. SHEPARD: NOT PRIORITIZED. BUT, OF
12 COURSE, JUST BASED ON HISTORICAL PRECEDENT, WE
13 EXPECT THAT PROBABLY A THIRD OF OUR APPLICATIONS
14 WILL BE IN NEURO.

15 DR. LEVITT: OKAY.

16 CHAIRMAN IMBASCIANI: THANK YOU, PAT. AND
17 NOW ANNE-MARIE DULIEGE.

18 DR. DULIEGE: A VERY QUICK SCIENTIFIC
19 QUESTION. YOU MENTIONED A FEW TIMES STEM CELL AND
20 GENE THERAPY AND OTHER REGENERATIVE MEDICINE
21 APPROACHES. VERY HIGH LEVEL, CAN YOU TELL US WHAT
22 YOU'RE REFERRING TO VERY BRIEFLY?

23 DR. SHEPARD: YES. SO THERE COULD BE
24 SITUATIONS WHERE YOU COULD TAP INTO A PATHWAY THAT
25 CREATES ENDOGENOUS REGENERATION. POTENTIALLY WITH A

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1 SMALL MOLECULE OR A BIOLOGIC, THIS MIGHT ACTUALLY
2 BE CATEGORIZED AS GENE THERAPY TOO UNDER A
3 REGULATORY REGIME. BUT BASICALLY WE'RE INTERESTED
4 IN APPROACHES THAT REGENERATE, REPLACE, OR RESTORE
5 LOST TISSUE. AND WHILE STEM CELLS ARE KIND OF THE
6 MAIN WAY WE THINK ABOUT THAT HAPPENING, WE NOW HAVE
7 GENETIC THERAPY IN OUR ARSENAL AND GENETIC
8 APPROACHES. AND IT MAY BE POSSIBLE. OFTEN GENE
9 THERAPY IS REPLACING A GENE THAT'S MISSING, RIGHT.
10 BUT IT COULD BE THAT THOSE TYPES OF APPROACHES COULD
11 BE USED, NOT NECESSARILY TO REPLACE A GENE, BUT TO
12 REGENERATE A TISSUE THAT'S ALREADY BEEN DAMAGED BY
13 SOME OTHER MECHANISM. AND SO WE JUST WANTED TO BE
14 OPEN TO THOSE KINDS OF APPROACHES BECAUSE WE'RE NOT
15 SMART ENOUGH TO IMAGINE EVERYTHING THAT MIGHT
16 POSSIBLY COME IN, AND WE WANT TO BE ABLE TO SUPPORT
17 SOMETHING SUPER EXCITING AND INTERESTING AND NOVEL.

18 DR. DULIEGE: THANK YOU. AND THANK YOU
19 FOR YOUR EXCELLENT PRESENTATION AND THE TEAMWORK
20 WITH YOUR COLLEAGUES.

21 DR. SHEPARD: THANK YOU.

22 CHAIRMAN IMBASCIANI: NOW THAT THE
23 QUESTIONS -- ONE MORE QUESTION.

24 DR. FLOWERS: THANKS. AND THANK YOU SO
25 MUCH FOR THE INFORMATION. I'M JUST WONDERING IF

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1 THERE'S A PLAN FOR DISC-0 APPLICANTS WHO RECEIVE A
2 TWO IN THE CURRENT CYCLE TO BE ABLE TO COME BACK AS
3 A RESUBMISSION TO DISC5.

4 DR. SHEPARD: SO THE DISC0 APPLICANTS WILL
5 ACTUALLY RECEIVE A SCORE OF ONE TO A HUNDRED UNDER
6 THAT REGIME. AND 85 -- BUT SIMILARLY TO WHAT -- I'M
7 GOING TO ADDRESS THE QUESTION WHICH IS WHAT YOU
8 REALLY WANT TO KNOW WHICH IS WHETHER THEY CAN
9 RESUBMIT. AND YES, THE PEOPLE WHO ARE APPLYING FOR
10 DISC0 ARE THE CLIENTS THAT WE WOULD ANTICIPATE WOULD
11 BE HIGHLY INTERESTED AND MOTIVATED TO APPLY FOR
12 DISC5. AND SO WE EXPECT THAT ANYBODY WHO IS NOT
13 SUCCESSFUL IN THIS UPCOMING DISC-0 ROUND WILL HAVE
14 OPPORTUNITIES TO APPLY THROUGH DISC5 IN THE FUTURE.

15 CHAIRMAN IMBASCIANI: ELENA, THANK YOU.
16 I'M GOING TO NOW ASK FOR A MOTION.

17 VICE CHAIR BONNEVILLE: SO THIS IS A LONG
18 MOTION, BUT I'D LIKE IT MAKE A MOTION TO APPROVE THE
19 DISC5 CONCEPT PLAN AND TO DELEGATE TO THE CEO THE
20 AUTHORITY TO MAKE AND IMPLEMENT CHANGES TO THIS
21 CONCEPT PLAN IN BETWEEN BOARD MEETINGS UPON
22 CONSULTATION OF THE CHAIRS AND CO-CHAIRS OF THE ICOC
23 SUBCOMMITTEES AND TO BRING THOSE CHANGES BEFORE THE
24 BOARD AT THE NEXT OPPORTUNITY FOR RATIFICATION.

25 CHAIRMAN IMBASCIANI: THANK YOU, MADAM

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1 VICE CHAIR. I NEED A SECOND.

2 DR. GASSON: SECOND.

3 DR. BARRETT: SECOND.

4 CHAIRMAN IMBASCIANI: AND A THIRD. YES.

5 VERY GOOD. NOW MEMBERS OF THE BOARD ARE FREE TO

6 DISCUSS THIS. DO WE HAVE ANY MEMBER OF THE PUBLIC?

7 NO. OKAY.

8 MR. TOCHER: DOESN'T APPEAR SO.

9 CHAIRMAN IMBASCIANI: IT DOESN'T APPEAR
10 SO. THANK YOU. LET'S PROCEED TO THE VOTE THEN.

11 MR. TOCHER: ALL RIGHT. ALL THOSE IN THE
12 ROOM IN FAVOR SAY AYE. THOSE OPPOSED SAY NAY. ANY
13 ABSTENTIONS? AND I'LL POLL THE MEMBERS ON THE
14 PHONE.

15 MONICA CARSON. YSABEL DURON.

16 MS. DURON: YES.

17 MR. TOCHER: RICH LAJARA.

18 MR. LAJARA: YES.

19 MR. TOCHER: SHLOMO MELMED.

20 DR. MELMED: YES.

21 MR. TOCHER: CHRIS MIASKOWSKI.

22 DR. MIASKOWSKI: YES.

23 MR. TOCHER: JOE PANETTA.

24 MR. PANETTA: YES.

25 MR. TOCHER: SUZANNE SANDMEYER.

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1 DR. SANDMEYER: YES.

2 MR. TOCHER: KAROL WATSON.

3 DR. WATSON: YES.

4 MR. TOCHER: AND KEVIN XU.

5 DR. XU: YES.

6 MR. TOCHER: THANK YOU VERY MUCH. THE
7 MOTION CARRIES, MR. CHAIR.

8 CHAIRMAN IMBASCIANI: KELLY, THAT WAS AN
9 EXCELLENT PRESENTATION. THANK YOU. I JUST WANT TO
10 MAKE SURE THAT WE'RE COGNIZANT OF PEOPLE'S TITLES.
11 KELLY SHEPARD IS THE DIRECTOR OF DISCOVERY AND
12 EDUCATION AT CIRM, AND SHE WAS PRECEDED BY DR. LIZ
13 NOBLIN WHO IS A CIRM FELLOW.

14 DR. SHEPARD: THANK YOU VERY MUCH. AND
15 NOW I AM EXCITED TO INTRODUCE YOU TO MY COLLEAGUE
16 FROM THE DISCOVERY AND EDUCATION TEAM SENIOR SCIENCE
17 OFFICER DR. CHAN LEK TAN TO TELL YOU ABOUT DISC4.

18 DR. TAN: THANK YOU, KELLY. THANK YOU TO
19 THE CHAIRMAN, VICE CHAIR, MEMBERS OF THE BOARD. MY
20 NAME IS CHAN LEK TAN. AND I'M PLEASED TO BE ABLE TO
21 PRESENT THE DISC4 AMENDMENTS ON BEHALF OF THE CIRM
22 TEAM.

23 SO IN THIS PRESENTATION I WILL QUICKLY
24 REMIND YOU OF THE BACKGROUND TO THIS CONCEPT
25 AMENDMENT, ITS BROAD OBJECTIVES, SCOPE, AND KEY

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1 ELEMENTS OF THE AWARD STRUCTURE BEFORE MOVING TO A
2 REQUEST FOR APPROVAL.

3 THE TWO DISCOVERY STAGE CONCEPTS THAT YOU
4 ARE HEARING TODAY IS GUIDED BY GOAL 1 AND THE
5 CORRESPONDING RECOMMENDATIONS TO SUPPORT
6 COMPREHENSIVE DISCOVERY RESEARCH THROUGH THESE TWO
7 FUNDING STRUCTURES. THE GOAL OF THESE ARE TO
8 PRODUCE SCIENTIFIC FINDINGS THAT WILL LAY THE
9 FOUNDATION FOR FUTURE THERAPEUTIC DEVELOPMENT,
10 INCLUDING THROUGH PROGRAMS AT CIRM.

11 AS KELLY HAS ALREADY DESCRIBED, WE
12 ARTICULATED A SIMPLE COMMON OBJECTIVE FOR BOTH DISC4
13 AND DISC5 BASED ON THE SAF RECOMMENDATION ITSELF.
14 THE APPROACH THAT DISC4 WILL TAKE SHORTLY IS ONE
15 THAT IS COMPLEMENTARY TO THE DISC5 CONCEPT. THE
16 DISC4 CONCEPT SUPPORTS LARGE COLLABORATIVE TEAMS
17 THAT PROPOSE EXPANSIVE STUDIES INTEGRATING MULTIPLE
18 DISCIPLINES AND APPROACHES WITH A PRIMARY FOCUS ON
19 DISEASE BIOLOGY.

20 AND AS YOU'VE ALSO HEARD, BOTH DISCOVERY
21 PROGRAMS WILL MAKE USE OF PROGRAM INFRASTRUCTURE,
22 SOME OF WHICH ARE BEING PILOTED IN THE REMIND
23 PROGRAM, INCLUDING GRANTEE MEETINGS, DATA SHARING,
24 INFRASTRUCTURE, AND THE ABILITY TO LEVERAGE INTERNAL
25 AND EXTERNAL PARTNERSHIPS TO INCREASE SCIENTIFIC

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1 IMPACT AND THE POTENTIAL FOR TRANSLATION.

2 WITH THAT INTRODUCTION OUT OF THE WAY, I'M
3 GOING TO TURN BACK TO FOCUS SPECIFICALLY ON DISC4.
4 JUST TO REITERATE THE KEY RATIONALE FOR THIS PROGRAM
5 AND THE REMIND PROGRAM BEFORE IT, WHICH COMES FROM
6 THE APPRECIATION THAT SOUND, ACTIONABLE TARGETS
7 BASED ON STRONG BIOLOGICAL UNDERSTANDING REMAINS
8 PERHAPS THE GREATEST BOTTLENECK FOR EFFECTIVE
9 TREATMENTS. AND SOME OF THIS REFLECTS THE DEEP
10 COMPLEXITIES OF BIOLOGY, OF DISEASE BIOLOGY.

11 SO THE TEAM SCIENCE APPROACH THAT WE ARE
12 PROPOSING HERE WHICH INTEGRATES EVIDENCE FROM
13 MULTIPLE DISCIPLINES AND MODALITIES IS LIKELY TO
14 HAVE SUBSTANTIAL VALUE.

15 SO THE DISC4 PROGRAM WILL SUPPORT THIS
16 MULTIDISCIPLINARY APPROACH TO DISCOVERY RESEARCH.
17 PROPOSALS MUST AIM TO ACHIEVE ONE OR MORE OF THE
18 FOLLOWING OUTCOMES: A BETTER UNDERSTANDING OF HUMAN
19 DISEASE BIOLOGY THROUGH NOVEL MECHANISTIC INSIGHTS,
20 EXTENDING HOW THESE INSIGHTS MAY APPLY TO DIVERSE
21 POPULATIONS, AND IDENTIFYING NEW TARGETS,
22 STRATEGIES, AND BIOMARKERS.

23 FOR A LITTLE BIT OF HISTORY, THE DISC4
24 PROGRAM WILL BE BUILT ON A FRAMEWORK PILOTED BY THE
25 NEURO TASK FORCE WITH THE REMIND-L PROGRAM. IN THE

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1 REMIND-L PROGRAM, TO EFFECTIVELY PRIORITIZE FUNDING,
2 THE NEURO TASK FORCE CATEGORIZED NEUROLOGICAL
3 DISEASES INTO CLUSTERS BASED ON SHARED MOLECULAR AND
4 CELLULAR PATHWAYS TO PREVENT SILOED APPROACHES AND
5 TO ENABLE DISCOVERIES TO BE ABLE TO TRANSLATE ACROSS
6 MULTIPLE CONDITIONS.

7 THIS MODEL AS A FRAMEWORK WAS USED TO
8 PRIORITIZE FUNDING FOR NEUROPSYCHIATRIC DISEASES IN
9 THE PILOT CYCLE AND NEURODEGENERATIVE DISEASES AS
10 YOU WILL SEE IN THE CURRENT CYCLE.

11 THE AMENDMENTS WE ARE PROPOSING TODAY
12 INCLUDE TWO MAJOR CHANGES. THE FIRST IS THE
13 EXPANSION TO SUPPORT A BROADER SET OF DISEASES WHILE
14 CONTINUING THE FRAMEWORK THAT WAS PILOTED BY THE
15 NEURO TASK FORCE WITH THE REMIND-L PROGRAM. THE
16 SECOND SET OF CHANGES IS AIMED AT FACILITATING
17 PROGRESSION TO NOVEL DISCOVERIES AND NEW PRECLINICAL
18 EFFORTS. SO WE WANT TO POSITION THE TEAMS FOR
19 READINESS FOR TARGET VALIDATION BY THE END OF THE
20 AWARD WITHOUT DETRACTING FROM THE PRIMARY FOCUS ON
21 DISEASE BIOLOGY INSIGHTS.

22 SO GOING TO THE AREAS OF FUNDING, IN
23 EXPANDING FROM OUR INITIAL SPECIFIC FOCUS IN OUR
24 PILOT CYCLE TO A BROADER OPPORTUNITY AVAILABLE
25 ACROSS ALL DISEASE AREAS, THE CIRM TEAM WANTED TO

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1 STRIKE A BALANCE ACROSS SEVERAL FACTORS INCLUDING
2 THE POTENTIAL FOR EXTREMELY HIGH APPLICATION
3 VOLUMES, ENSURING THAT WE HAVE A REVIEW PANEL WITH
4 SUFFICIENTLY FOCUSED EXPERTISE, AND PRESERVING SOME
5 OF THE OTHER ADVANTAGES THAT WE FOUND WITH THE MORE
6 FOCUSED APPROACH.

7 IN LIGHT OF THESE CONSIDERATIONS AND WITH
8 BOARD MEMBER FEEDBACK, WE HAVE COME TO THE FOLLOWING
9 FORMULATION THAT IS SHOWN HERE. THE DISC4 AWARD
10 WILL BE OPEN TO ALL ELIGIBLE PROPOSALS REGARDLESS OF
11 DISEASE INDICATION OR RESEARCH TOPIC SO THAT
12 PARTICULARLY IMPACTFUL AND EXCEPTIONAL PROPOSALS MAY
13 GET A CHANCE FOR REVIEW IN ANY CYCLE.

14 IN PARALLEL, SELECT PREFERENCE TOPICS WILL
15 BE PRIORITIZED FOR CONSIDERATION EACH YEAR. HAVING
16 THESE PREFERENCE TOPICS HAS MANY ADVANTAGES AS
17 LISTED HERE. FIRST, THEY ALLOW US TO ADDRESS THE
18 AREAS OF OPPORTUNITIES THAT WERE IDENTIFIED BY THE
19 NEUROSCIENCE TASK FORCE PREVIOUSLY. THEY ALLOW US
20 TO MAXIMIZE THE POTENTIAL FOR SYNERGY AND THE
21 POTENTIAL TO LEVERAGE COMMON EXTERNAL PARTNERSHIPS.
22 THEY ALLOW US TO CAPITALIZE ON EMERGING
23 OPPORTUNITIES IN THE RESEARCH LANDSCAPE AND ADDRESS
24 ANY PORTFOLIO GAPS THAT MAY EMERGE.

25 FOR THE UPCOMING CYCLE, CORRESPONDING TO

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1 FISCAL YEAR 25/26, PREFERENCES WILL BE GIVEN TO
2 APPLICATIONS ADDRESSING NEURODEGENERATIVE DISEASES
3 SHOWN IN THE CENTER SQUARE, AN AREA OF OPPORTUNITY
4 THAT WAS PREVIOUSLY IDENTIFIED BY THE NEURO SCIENCE
5 TASK FORCE. AND THIS FOLLOWS THE NEUROPSYCHIATRIC
6 DISEASE FOCUS AREA SHOWN IN GRAY, WHICH WAS THE
7 FOCUS FOR THE PILOT PHASE.

8 IN SUBSEQUENT CYCLES AND IN A STAGGERED
9 FASHION, WE WILL CONTINUE TO PRIORITIZE NEUROSCIENCE
10 AREAS IDENTIFIED BY THE NEUROSCIENCE TASK FORCE,
11 INCLUDING NEURO-INJURY AS SHOWN IN THE DARK YELLOW.
12 AND IN ALTERNATIVE CYCLES, WE WILL PRESENT TO THE
13 BOARD RECOMMENDATIONS FOR FUNDING PREFERENCES AS
14 PART OF THE ANNUAL PORTFOLIO REVIEW THAT TAKES PLACE
15 AT THE END OF THE FISCAL YEAR.

16 IN EACH CASE THE PREFERENCES WILL BE
17 APPROVED BY THE ICOC AND INCORPORATED INTO PROGRAM
18 ANNOUNCEMENTS FOR THE SUBSEQUENT YEAR. THESE
19 PREFERENCES FOR APPLICATIONS, SO ADDRESSING
20 NEURODEGENERATIVE DISEASES FOR THE UPCOMING CYCLE,
21 WILL BE IMPLEMENTED DURING THE PRESUBMISSION PHASE
22 WHICH I WILL DESCRIBE IN THE LATER SLIDES.

23 SO THIS TABLE SUMMARIZES ALL THE MAJOR
24 ELEMENTS OF THE AWARD CYCLE. IN BOLD ARE THE
25 ELEMENTS WHERE CHANGES HAVE BEEN MADE COMPARED TO

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1 THE REMIND PROGRAM. AND YOU'VE SEEN THAT WE ARE
2 KEEPING MOST ELEMENTS OF WHAT WE BELIEVE TO BE A
3 FAIRLY SUCCESSFUL DESIGN. THESE ARE FOUR-YEAR
4 AWARDS FOR TEAMS OF AT LEAST FIVE CALIFORNIA-BASED
5 INVESTIGATORS. THE AWARD IS CAPPED AT A BASE BUDGET
6 OF \$13 MILLION TOTAL COST, AND WE EXPECT TO FUND SIX
7 TEAMS A YEAR FOR AN ANNUAL BUDGET OF \$84 MILLION.

8 GOING INTO THE AWARD BUDGETS IN A LITTLE
9 BIT MORE DETAIL, THE BUDGETS ARE CAPPED AT 13
10 MILLION IN TOTAL COST PER AWARD INCLUSIVE OF
11 OVERHEADS. THIS IS MOVING FROM A DIRECT COST CAP
12 THAT WE HAD IN REMIND TO BETTER ALIGN WITH PROGRAMS
13 ACROSS CIRM AND WITH THE NEW DISC5 PROGRAM. AND IT
14 ALSO HAS THE ADVANTAGE OF REMOVING A DISINCENTIVE
15 FOR MULTI-INSTITUTIONAL TEAMS.

16 TO GET TO THIS NEW NUMBER, WE ARE APPLYING
17 THE DIRECT COST CAP THAT WE HAD FOR REMIND AT \$8
18 MILLION AND THE APPLYING THE HISTORICAL OVERHEAD
19 RATE OF 60 PERCENT. AND SIMILAR TO THE PILOT PHASE,
20 AN ADDITIONAL \$1 MILLION CAN BE REQUESTED TO GET TO
21 A MAXIMUM OF \$14 MILLION WITH ELIGIBLE MATCHING FUND
22 CONTRIBUTIONS OF EQUAL OR GREATER VALUE.

23 SO THIS SLIDE LISTS SOME OF THE PROJECT
24 ELIGIBILITY REQUIREMENTS THAT MUST BE MET BY ALL
25 PROPOSALS REGARDLESS OF TOPIC. ALL APPS FIRST MUST

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1 ADDRESS KNOWLEDGE GAPS OR BOTTLENECKS IN THE
2 UNDERSTANDING OF HUMAN DISEASES. NO. 2, TO ENSURE
3 ALIGNMENT WITH CIRM'S MISSION, THE OVERALL PROJECT
4 MUST INCLUDE STUDIES THAT EMPLOY HUMAN STEM CELLS
5 AND/OR GENETIC RESEARCH AS PART OF THE CENTRAL
6 APPROACH. OF COURSE, HAVING FULFILLED THESE
7 REQUIREMENTS, TEAMS ARE ALSO ENCOURAGED TO
8 INCORPORATE A VARIETY OF APPROACHES AND TECHNOLOGIES
9 IN ORDER TO MAXIMIZE SCIENTIFIC IMPACT. AND
10 FINALLY, PROPOSALS, SIMILAR TO DISC5, MUST BE
11 CENTERED ON HUMAN BIOLOGY. AND APPLICANTS MAY
12 INCLUDE NONHUMAN MODELS TO ACHIEVE SPECIFIC
13 OBJECTIVES AND AIMS AS LONG AS THEY PROVIDE STRONG
14 JUSTIFICATION FOR ANY PROPOSED USE OF NONHUMAN
15 MODELS.

16 AGAIN, THIS AWARD IS OPEN TO
17 CALIFORNIA-BASED NON-PROFIT OR FOR-PROFIT
18 ORGANIZATIONS. EACH TEAM MUST HAVE A SCIENTIFIC
19 LEADERSHIP, WHAT WE CALL A CORE TEAM, THAT HAS A
20 MINIMUM OF FIVE CALIFORNIA-BASED INVESTIGATORS, A
21 SINGLE CONTACT PI, OR FOUR OR MORE CO-INVESTIGATORS.
22 THIS CORE TEAM MUST BE MULTI-INSTITUTIONAL, MEANING
23 AT LEAST ONE OF THE MEMBERS OF THE CORE TEAM MUST BE
24 BASED OUTSIDE OF THE PRINCIPAL INVESTIGATOR
25 INSTITUTION. THIS IS NEW TO THIS AMENDMENT. JUST

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1 AS A REFERENCE, SIX OF THE SEVEN FUNDED TEAMS WITH
2 REMIND WERE MULTI-INSTITUTIONAL BASED ON THIS
3 CRITERIA.

4 TO ENSURE THAT THE PROPOSAL REFLECTS
5 PERSPECTIVES FROM DIFFERENT DISCIPLINES AND
6 PERSPECTIVES, THE BROADER TEAM MUST ALSO INCLUDE KEY
7 PERSONS THAT HAVE AT LEAST ONE MEMBER EACH WITH THE
8 RELEVANT CLINICAL, COMPUTATIONAL, AND INDUSTRY OR
9 TRANSLATIONAL EXPERTISE. IN ADDITION, ALL TEAMS
10 MUST HAVE A DATA PROJECT MANAGER THAT WILL WORK WITH
11 CIRM TO ENSURE DATA SHARING AND REPORTING
12 REQUIREMENTS ARE FULFILLED.

13 SIMILARLY TO OTHER CIRM PROGRAMS YOU WILL
14 HEAR ABOUT TODAY, THE DISC4 PROGRAM WILL IMPLEMENT A
15 NEW PRESUBMISSION PROCESS SIMILAR TO THE LOI FORMATS
16 THAT YOU MIGHT HAVE SEEN FROM OTHER FUNDING
17 OPPORTUNITIES. WE ARE DOING THIS TO ENSURE THAT
18 PROGRAMS ALIGN WITH THE SCOPE AND OBJECTIVES OF THIS
19 AWARD AND TO HELP PRIORITIZE PROPOSALS THAT ARE IN
20 THE CHOSEN PREFERENCE TOPIC AREA. THIS PROCESS WILL
21 ALSO REDUCE TIME BURDEN FOR APPLICANTS, ESPECIALLY
22 THOSE WITH A POOR FIT FOR THIS PROGRAM. IT EXTENDS
23 THE TIMELINE TO ALLOW APPLICANTS TO FORM NEW
24 COLLABORATIONS THAT WILL LEAD TO MORE IMPACTFUL
25 PROPOSALS. AND IT WOULD ALSO GIVE US THE

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1 FLEXIBILITY TO MANAGE HIGH APPLICATION VOLUMES AND
2 PREPLAN FOR THE APPROPRIATE REVIEW PANELS.

3 SO HOW THIS WILL WORK IS IN THIS PROCESS
4 THE PROSPECTIVE APPLICANTS WILL SUBMIT A SHORT
5 PRESUBMISSION FORM ONLINE. AND WE HAVE SHARED AN
6 ILLUSTRATIVE EXAMPLE WITH MEMBERS OF THE BOARD.
7 THIS INCLUDES AN ONLINE INTAKE FORM AND A THREE-PAGE
8 PROPOSAL OUTLINE AND A BRIEF QUESTIONNAIRE.

9 SUBSEQUENT TO THIS SUBMISSION, CIRM STAFF
10 WILL EVALUATE AND RANK PRESUBMISSIONS BASED ON
11 ALIGNMENT WITH PROGRAM OBJECTIVES AND SCOPE AS WELL
12 AS THE FUNDING PREFERENCE TOPICS. PRESUBMISSIONS
13 WILL NOT BE EVALUATED FOR SCIENTIFIC MERIT OR
14 FEASIBILITY. AND BASED ON THIS EVALUATION AND
15 RANKING, CIRM WILL INVITE APPROXIMATELY 30 TEAMS TO
16 SUBMIT A FULL APPLICATION. AND THEY WILL HAVE ABOUT
17 90 DAYS TO COMPLETE THAT FULL APPLICATION.

18 AND THIS IS AN EXAMPLE OF THE RUBRIC AND
19 KEY CONSIDERATIONS BY WHICH THESE PRESUBMISSIONS
20 WILL BE EVALUATED, SO PLACED IN ORDER OF WEIGHT AND
21 IMPORTANCE. FIRST, WE WILL SEE IF THEY ADDRESS THE
22 PREFERENCE TOPIC WHICH IS NEURODEGENERATION FOR THE
23 CURRENT CYCLE. WE WILL ALSO CONSIDER OBJECTIVE
24 CRITERIA SHOWN HERE BASED ON CORE PROGRAM
25 OBJECTIVES, INCLUDING RELEVANCE TO HUMAN DISEASE

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1 BIOLOGY, INCLUSION OF CROSS-DISCIPLINARY FRAMEWORKS,
2 AND THE APPLICATION OF STEM CELL AND GENETIC
3 RESEARCH INNOVATIONS.

4 AND WE HAVE ALSO DATA SHARING AND
5 MANAGEMENT PLAN AND COORDINATION REQUIREMENTS WITH
6 CIRM'S DATA INITIATIVES, WHICH ARE VERY SIMILAR TO
7 WHAT KELLY HAS ALREADY TOLD YOU WITH THE DISC5
8 PROGRAM. AND I WON'T REPEAT ALL OF THAT HERE. AND
9 ASSUMING BOARD APPROVAL, WE EXPECT THE PA TO BE
10 POSTED BY EARLY APRIL WITH PRESUBMISSIONS OPEN SOON
11 OF AFTER THAT AND DUE BY LATE JUNE.

12 SO WITH THAT, I'M HAPPY TO TAKE ANY
13 QUESTIONS. AND WE REQUEST THE ICOC BOARD APPROVE
14 THE PROPOSED DISC4 CONCEPT PLAN. THANK YOU.

15 CHAIRMAN IMBASCIANI: THANK YOU, DR. TAN.
16 BOARD MEMBER HAVE ANY QUESTIONS FOR HIM? PAT AND
17 THEN KIM. HALA.

18 DR. MADANAT: SORRY. I WAS JUST GOING TO
19 ASK ABOUT THE LOI. IT SEEMS LONG, NOT REALLY A
20 SHORT SUBMISSION. THE LOI SEEMS VERY LONG TO ME.
21 CAN YOU REPEAT EXACTLY WHAT YOU WERE EXPECTING THEM
22 TO MEET?

23 DR. TAN: THE LOI HAS THREE SECTIONS,
24 ACTUALLY MAYBE TWO SECTIONS, I WOULD SAY, AN ONLINE
25 SECTION WHICH IS JUST WHO YOUR TEAM MEMBERS ARE,

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1 QUICK CHECKS ON WHETHER YOU'VE READ THE PA AND THE
2 ELIGIBILITY REQUIREMENT, A SHORT QUESTIONNAIRE OF
3 FOUR QUESTIONS, BASICALLY A THOUSAND WORDS TO KIND
4 OF GET US TO FOCUS ON THE EVALUATION CRITERIA, SO
5 THE FOUR CRITERIA THAT WE'VE LISTED THERE. SO FOUR
6 SHORT QUESTIONS. AND THEN THERE'S AN UPLOAD FOR A
7 PROPOSAL OUTLINE WHICH IS ABOUT THREE PAGES LONG
8 WHICH THEY CAN INCLUDE THE RESEARCH PLAN, THE
9 RESEARCH OUTLINES, A SIMPLE RATIONALE FOR THAT, AND
10 MAJOR OBJECTIVES AND AIMS. THAT'S THE FRAMEWORK.

11 AND WE'VE COME TO THIS LOOKING AT A NUMBER
12 OF DIFFERENT LOI-TYPE FORMATS THAT OTHER FUNDING
13 AGENCIES HAVE APPLIED. ONE EXAMPLE THAT GOES QUITE
14 CLOSELY TO THIS IS THE SIMONS COLLABORATION. THEY
15 HAD A CALL FOR A VISION FOR PROGRESSION IN
16 NEUROSCIENCE. AND THE STRUCTURE AND PAGE LENGTH ARE
17 QUITE SIMILAR TO WHAT WE'RE PROPOSING HERE.

18 DR. LEVITT: IT WOULD BE HELPFUL, I THINK,
19 FOR THE BOARD TO SEE EXACTLY WHAT YOU'RE ASKING FOR.
20 THEY'RE NOT SHORT QUESTIONS, IN MY OPINION. WHEN
21 YOU ADD UP THE NUMBER OF PAGES THAT INVESTIGATORS
22 HAVE TO FILL OUT FOR THIS, IT'S ABOUT SIX OR SEVEN.
23 SO --

24 DR. TAN: WE'LL DEFINITELY TAKE THAT
25 FEEDBACK.

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1 DR. LEVITT: SO MAYBE IT WOULD BE HELPFUL
2 FOR US TO ACTUALLY SEE BOXES. THERE'S AN ONLINE
3 COMPONENT WHICH IS ASKING OVERLAPPING, BUT NOT
4 IDENTICAL QUESTIONS TO WHAT YOU'RE ASKING FOR IN
5 TERMS OF REALLY THESE RATIONALE-SPECIFIC AIMS, SOME
6 DETAIL. THAT'S THREE PAGES. THAT ALONE IS THREE
7 PAGES, PLUS UP TO THREE PAGES OF PRELIMINARY DATA.
8 SO I'M NOT EVEN COUNTING THAT, AND THEN YOU'VE GOT
9 THE QUESTIONNAIRE ONLINE. SO THAT NEEDS TO BE MORE
10 CLEARLY DEFINED BECAUSE IT'S PRETTY LONG.

11 DR. TAN: WE HAVE AN EXAMPLE WITH THE
12 MATERIAL POSTED. WE ARE NOT ASKING SPECIFICALLY FOR
13 THREE PAGES OF PRELIMINARY DATA. IT'S THREE PAGES
14 OF AN OUTLINE --

15 DR. LEVITT: THREE PAGES OF OUTLINE AND
16 THEN UP TO THREE PAGES FOR FIGURES OR PRELIMINARY
17 DATA. THAT'S WHAT IT SAID IN THE INSTRUCTIONS.

18 DR. TAN: THAT'S NOT WHAT THE INTENT WAS.

19 CHAIRMAN IMBASCIANI: ROSA, DO YOU WANT TO
20 ADD A CLARIFICATION?

21 DR. CANET-AVILES: DR. LEVITT, I
22 APPRECIATE YOUR COMMENTS. ONE OF THE THINGS THAT WE
23 COULD DO, AS THIS IS GOING TO BE PRESENTED BY DR.
24 SAMBRANO LATER ON, AND WE COULD ACTUALLY SUGGESTING
25 TO APPROVE THE CONCEPT AND THE PRESUBMISSION

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1 CONDITION UNDER DISCUSSION THAT WILL HAPPEN LATER.

2 DR. LEVITT: I'M HAPPY TO DO THAT. THAT'S
3 GREAT. SO REGARDING THE CONCEPT PLAN, THE RATIONALE
4 FOR DISC4, AS YOU IDENTIFIED, AS THE BOARD HAS
5 AGREED TO, IS THIS BOTTLENECK OF PARTICULARLY
6 DISCOVERY OF TARGETS. AND SO I'D LIKE TO KNOW MORE
7 ABOUT THE RATIONALE FOR STARTING WITH
8 NEURODEGENERATION BECAUSE WHEN YOU LOOK AT THE
9 CURRENT STATE OF MONEY THAT GOES INTO
10 NEURODEGENERATION COMPARED TO NEUROPSYCHIATRY, THE
11 REMIND PROGRAM HAS BEEN INSTRUMENTAL IN GOING FROM
12 WHERE WE WERE BEFORE, WHICH IS ZERO FOR THE
13 NEUROPSYCHIATRIC DISORDERS, TO NOW IS SOMETHING
14 THAT'S REALLY EXCITING. I THINK THERE ARE WHAT,
15 THERE ARE EIGHT, I THINK, OR SOMETHING LIKE THAT.

16 WHEN YOU LOOK AT THE DATA ON HISTORICAL
17 NEURO INVESTMENT IN TRAN AND CLIN, MY CALCULATION,
18 LOOKING AT GRANTS, WE HAVE GRANTS THAT HAVE STARTED
19 AT A DISCOVERY PHASE AND NOW ARE AT CLIN IS LIKE
20 FIVE TO SEVEN YEARS IT LOOKS LIKE TO ME. SOMETHING
21 REALLY FAST WOULD BE FIVE.

22 SO IF WE'RE GOING SEPARATE OUT THE NEURO
23 INTO THREE PHASES, WE'RE TALKING ABOUT
24 NEUROPSYCHIATRY COMING AROUND IN FY '28 OR '29. AND
25 THEN TO GET THEM TO -- SO RIGHT NOW

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1 NEURODEGENERATION AWARDS SPENT 317 MILLION,
2 NEURO-INJURY 311. THIS IS ON THE TRAN AND CLIN.
3 THE NEUROPSYCHIATRY AND NEURODEVELOPMENTAL ARE 47
4 MILLION.

5 SO GIVEN THE RATIONALE FOR DISC4, WHICH
6 I'M REALLY IN FAVOR OF AND I LOVE THE PROGRAM, WHY
7 NOT JUST HAVE NEURO AS AN EMPHASIS AREA, LEAVING IT
8 TO THE INVESTIGATORS TO SUBMIT? IF WE SINGLE OUT
9 ONE, IT'S GOING TO LIMIT OR REDUCE OR ELIMINATE
10 GRANTS THAT ARE GOING TO BE COMING IN IN THESE OTHER
11 AREAS. AND I'M VERY CONCERNED ABOUT WHERE WE ARE IN
12 TERMS OF TARGET DISCOVERY FOR NEUROPSYCHIATRY, WHICH
13 IS REALLY LOW.

14 DR. CANET-AVILES: SO THAT'S REALLY THE
15 PREMISE OF THE BOARD. THAT WAS A PROPOSAL OF HOW TO
16 DO IT BASED ON THE CLUSTERS FROM THE NEURO TASK
17 FORCE AS DR. GOLDSTEIN HAD PROPOSED AND WAS VOTED IN
18 AUGUST OF 2023. SO WE STARTED LIKE THAT, BUT
19 DEFINITELY THIS IS SOMETHING THAT, IF THE BOARD
20 PREFERS THAT WE DO CYCLES OF NEURO AND THEN
21 EVERYTHING BASED ON THE PRIORITIES OF THE YEAR AND
22 THE ANALYSIS THAT WE WILL BE PROVIDING EVERY JUNE,
23 WE COULD DO THAT. BECAUSE AT THE END OF THE DAY, IF
24 YOU THINK ABOUT THE COMMONALITIES OF ALL THESE
25 DISEASES, WE COULD JUST LEAVE IT UP TO THE

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1 APPLICANTS TO COME WITH THE MOST RELEVANT AND
2 IMPACTFUL APPLICATIONS. SO THAT COULD BE ANOTHER
3 WAY THAT WE COULD TRANSFORM THIS.

4 AND WE JUST ADDED THIS BACKUP SLIDE THAT
5 HAS THE HISTORICAL NEURO INVESTMENTS IN TRAN AND
6 CLIN. WE ALSO HAVE DISCOVERY -- IT'S THE ONE
7 EARLIER -- THAT WILL SHOW BY THE CLUSTERS AS WELL
8 THIS IS HOW MUCH INCLUDING THE NEW REMIND-L.

9 AND I WANT TO THANK DR. SARA TAYLOR FOR A
10 LOT OF WORK PUTTING THIS AND CODING ALL THE AWARDS
11 ALSO. SHE'S THE MASTER BEHIND ALL THESE WONDERFUL
12 SLIDES.

13 CHAIRMAN IMBASCIANI: THANK YOU, ROSA.
14 WE'RE STILL IN THE QUESTION PHASE HERE. DR.
15 BARRETT.

16 DR. BARRETT: THANK YOU VERY MUCH FOR THE
17 PRESENTATION. I HAD A VERY PRACTICAL QUESTION. SO
18 IN THE CONCEPT PLAN, YOU DEFINE TWO TYPES OF
19 POTENTIAL MATCHING SUPPORT. ONE OF WHICH TO ME
20 SOUNDS AS IF IT'S SORT OF IN KIND. IT COULD BE CELL
21 LINES; IT COULD BE BIOREPOSITORIES. HOW WOULD THAT
22 BE VALUED? I COULD SAY MY CELL LINE IS WORTH A
23 MILLION DOLLARS. SO I'M MATCHING WITH MY MILLION
24 DOLLAR CELL LINE.

25 DR. TAN: THAT'S GOING INTO THE

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1 NITTY-GRITTY. WE HAVE HAD SOME EXPERIENCE WITH THE
2 REMIND PROGRAM WITH IN-KIND CONTRIBUTIONS THAT THEY
3 HAVE SUBMITTED. WE STARTED CONVERSATION WITH THE
4 APPLICANTS HOW THEY TEND TO VALUE THE CELL LINES.
5 AND WE USUALLY ASK FOR JUSTIFICATION, INDUSTRY
6 STANDARDS, COMPARABLE EVALUATIONS OF RESOURCES. AND
7 THAT'S SOMETHING THAT WE WILL DETERMINE WITH
8 COLLABORATION WITH OUR GRANTS MANAGEMENT TEAM AND IN
9 COLLABORATION WITH THE APPLICANT TEAM TO KIND OF GET
10 TO A REASONABLE EVALUATION TO THOSE MATCHING FUND
11 CONTRIBUTIONS.

12 CHAIRMAN IMBASCIANI: ARE THERE ANY OTHER
13 QUESTIONS?

14 DR. LEVITT: IS THERE A COMPONENT OF THE
15 APPLICATION THAT ASKS ABOUT CIRM-FUNDED CORES THAT
16 ARE BEING USED FOR RESEARCH? I SHOULD HAVE ASKED IT
17 BEFORE FOR THE OTHER. IS THERE A COMPONENT OF THAT
18 WHERE YOU GET THAT INFORMATION? ONE IS KEEPING
19 TRACK OF HOW THE INVESTIGATORS ARE CONNECTING WITH
20 CIRM-FUNDED INFRASTRUCTURE AT VARIOUS INSTITUTIONS
21 TO DETERMINE WHETHER WE'RE LEVERAGING THOSE WELL.

22 DR. LEK TAN: FOR THIS CYCLE THAT'S A WORK
23 IN PROGRESS. DEFINITELY WE ENCOURAGE THEM, AND
24 WE'VE PROVIDED RESOURCES IN THE PA AND ON OUR
25 WEBSITE ABOUT OTHER RESOURCES THAT THEY CAN TAP

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1 INTO. IT ISN'T FORMALLY A REQUIREMENT OR ANYTHING
2 OF THAT NATURE WITHIN THE PROGRAM.

3 DR. CANET-AVILES: I THINK IT'S A VERY
4 RELEVANT QUESTION TO LEVERAGE THE SHARED RESOURCE
5 LABS FOR CELL MODELING, FOR EXAMPLE, AND THE IPS
6 REPOSITORY. IN FACT, YOU'VE DONE THAT THROUGH THE
7 REMIND-L WITH NEUROPSYCH. SO THAT'S A VERY GOOD
8 POINT THAT WE COULD ADD --

9 DR. LEVITT: IT'S SHORT AND IT ALLOWS YOU
10 ALL TO KEEP TRACK OF HOW THESE ARE BEING ACCESSED,
11 WHICH IS ONE OF THE MAJOR GOALS OF THE INVESTMENT.

12 DR. TAN: WE WILL CHECK THOSE
13 INTERACTIONS.

14 VICE CHAIR BONNEVILLE: I JUST HAVE A
15 CLARIFYING QUESTION. PAT, WAS IT SETTLED THAT WE
16 WOULD LEAVE IT SO THAT IT'S OPEN TO ALL NEURO
17 PROGRAMS OR APPLICATIONS AND NOT A DIRECTED CATEGORY
18 EACH TIME? I'M UNCLEAR. SO I WOULD ASSUME PERHAPS
19 THE TEAM IS UNCLEAR. SO I JUST WANT TO GET --

20 DR. LEVITT: SO I HAVE MY OWN BIASES,
21 WHICH YOU PROBABLY CAN FIGURE OUT.

22 DR. CANET-AVILES: VICE CHAIR, COULD YOU
23 REPEAT THE QUESTION?

24 VICE CHAIR BONNEVILLE: IT'S A QUESTION
25 FOR PAT. PAT HAD MENTIONED THAT HE WANTED THE NEURO

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1 ROUNDS TO BE -- I THINK WHAT HE'S ASKING FOR IS JUST
2 NEUROPSYCH. BUT I THINK IN THE ABSENCE OF JUST
3 GOING STRAIGHT FOR NEUROPSYCH, HE'S ASKING THAT THE
4 NEURO ROUND BE OPEN SO THAT IT'S NOT DIRECTED TO A
5 SPECIFIC AREA. AND SO I JUST WANTED TO CLARIFY. I
6 DON'T KNOW WHERE WE ENDED UP.

7 DR. LEVITT: SO ONE OF THE ADVANTAGES OF
8 DOING THAT WAY IS THAT ONE OF THE CRITERIA THAT THE
9 TEAM IS USING TO DETERMINE AN APPLICATION MOVING
10 FORWARD IS WHETHER OR NOT IT'S MEETING A GAP, RIGHT?
11 AND SO IF, FOR EXAMPLE, NEURODEGENERATION SWAMPS THE
12 INITIAL APPLICATION PROCESS AND SOME OF THOSE ARE
13 FUNDED, WHEN YOU COME IN THE NEXT YEAR, IT'S LIKELY
14 THAT YOU'RE GOING TO LOOK IN THIS, WE'VE ALREADY
15 FUNDED THAT. THERE'S NOT A GAP THERE. AND SO THOSE
16 ARE COMING IN OTHER DOMAINS.

17 SO MY PREFERENCE IS AT LEAST TO LEAVE IT
18 OPEN AND NOT HAVE A PARTICULAR AREA OF NEUROSCIENCE,
19 CLINICAL NEUROSCIENCE, RELEGATED TO WAITING THREE
20 PLUS YEARS BECAUSE YOU KNOW HOW INVESTIGATORS WORK.
21 IF IT SAYS THE FOCUS IS GOING TO BE
22 NEURODEGENERATION, THAT'S WHAT IT'S GOING TO GET IN
23 ADDITION TO THESE OTHER AREAS. SO MY PREFERENCE IS
24 LEAVE IT OPEN. THE TEAM IS GOING TO RECOGNIZE THOSE
25 WHERE THERE'S A LOT OF FUNDING ALREADY AND MAKE

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1 THOSE DECISIONS.

2 CHAIRMAN IMBASCIANI: CAROLYN.

3 DR. MELTZER: I VERY MUCH AGREE WITH
4 KEEPING IT OPEN. I THINK THE SCIENCE NEEDS TO DRIVE
5 IT.

6 DR. CANET-AVILES: AND YOU ARE THE NEURO
7 TASK FORCE CO-CHAIR. SO WE APPRECIATE YOUR
8 LEADERSHIP. IF THAT'S THE CALL, WE WILL DEFINITELY
9 DO THAT. WE ARE HAPPY TO DO IT THIS WAY.

10 CHAIRMAN IMBASCIANI: TOUCHE. THANK YOU.
11 I DON'T SEE ANY OTHER QUESTIONS. I'M GOING TO
12 PROCEED TO A -- SINCE IT'S A COMPLICATED MOTION,
13 MARIA IS GOING TO HANDLE THIS.

14 VICE CHAIR BONNEVILLE: IT'S LIKE THE
15 OTHER ONE. SO I'D LIKE TO MAKE A MOTION TO APPROVE
16 THE DISC4 CONCEPT PLAN AND TO DELEGATE TO THE CEO
17 THE AUTHORITY TO MAKE AND IMPLEMENT CHANGES TO THE
18 CONCEPT PLAN IN BETWEEN BOARD MEETINGS UPON
19 CONSULTATION OF THE CHAIRS AND CO-CHAIRS OF THE ICOC
20 SUBCOMMITTEES AND TO BRING THOSE CHANGES BEFORE THE
21 BOARD AT THE NEXT OPPORTUNITY FOR RATIFICATION.

22 CHAIRMAN IMBASCIANI: THANK YOU. SO A
23 SECOND IS REQUIRED.

24 DR. SOUTHARD: SECOND.

25 CHAIRMAN IMBASCIANI: MARV SECOND.

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1 DISCUSSION AMONG BOARD MEMBERS? OR AMONG THE
2 MEMBERS OF THE PUBLIC. DOESN'T APPEAR. THANK YOU
3 SO MUCH. SCOTT, WILL YOU PROCEED TO A VOTE.

4 MR. TOCHER: ALL THOSE IN THE ROOM IN
5 FAVOR SAY AYE. OPPOSED SAY NAY. ANY ABSTENTIONS?
6 I'LL POLL THE MEMBERS ON THE ZOOM.

7 MONICA CARSON. YSABEL DURON.

8 MS. DURON: YES.

9 MR. TOCHER: RICH LAJARA.

10 MR. LAJARA: YES.

11 MR. TOCHER: SHLOMO MELMED.

12 DR. MELMED: YES.

13 MR. TOCHER: CHRIS MIASKOWSKI.

14 DR. MIASKOWSKI: YES.

15 MR. TOCHER: JOE PANETTA. SUZANNE
16 SANDMEYER.

17 DR. SANDMEYER: YES.

18 MR. TOCHER: KAROL WATSON.

19 DR. WATSON: YES.

20 MR. TOCHER: KEVIN XU.

21 DR. XU: YES.

22 MR. TOCHER: THANKS. THE MOTION CARRIES,
23 MR. CHAIR.

24 CHAIRMAN IMBASCIANI: MOTION CARRIES.

25 THANK YOU SO MUCH, SCOTT. AND THANK YOU, DR. TAN.

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1 GREAT PRESENTATION. APPRECIATE IT. WE'RE GOING TO
2 MOVE TO --

3 MR. TOCHER: WE'RE GOING TO TAKE A
4 TEN-MINUTE BREAK. WE WILL SEE YOU AT TEN MINUTES
5 BEFORE THE HOUR.

6 (A RECESS WAS TAKEN.)

7 CHAIRMAN IMBASCIANI: THANK YOU, SCOTT.
8 WE'RE COMING BACK OUT OF RECESS NOW, AND WE'RE GOING
9 TO MOVE TO THE NEXT AGENDA ITEM, WHICH IS THE
10 CONSIDERATION OF THE THIRD OF THE FOUR CONCEPT PLANS
11 ON PRECLINICAL DEVELOPMENT. AND IT'S GOING TO BE
12 PRESENTED BY OUR ASSOCIATE VICE PRESIDENT FOR
13 PRECLINICAL DEVELOPMENT, SHYAM PATEL. SHYAM, THE
14 FLOOR IS YOURS.

15 DR. PATEL: THANK YOU. GOOD MORNING AND
16 WELCOME BACK FROM YOUR SEVENTH INNING STRETCH. MY
17 NAME IS SHYAM PATEL, AND I'LL BE PRESENTING TODAY ON
18 THE PDEV CONCEPT. SO, FIRST OF ALL, THANK YOU TO
19 CHAIR IMBASCIANI, VICE CHAIR GONZALEZ-BONNEVILLE,
20 AND TO ALL MEMBERS OF THE ICOC FOR THIS OPPORTUNITY
21 TO PRESENT TO YOU THE PDEV CONCEPT PLAN FOR YOUR
22 CONSIDERATION TODAY.

23 BEFORE I BEGIN, I WANT TO ACKNOWLEDGE THE
24 CONTRIBUTION OF THE PDEV TEAM, WHICH WAS A TEAM
25 EFFORT ON THIS PROJECT. THAT INCLUDES DR. ROSS

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1 OKAMURA, DR. JIM CAMPENELLI, DR. LISA MCGINLEY, AND
2 DR. DONG CHIN LEE, AS WELL AS TOM STRINGH. AND I'LL
3 JUMP RIGHT INTO THE PRESENTATION NOW.

4 SO THE PDEV CONCEPT, THE PRESENTATION IS
5 SIMILAR IN SCOPE TO THE OTHER ONES. I'LL SPEND A
6 LITTLE BIT MORE TIME ON THE BACKGROUND AND THE SCOPE
7 OF THIS PARTICULAR FUNDING MECHANISM AND THEN RUN
8 THROUGH THE STRUCTURE OF THE PROGRAM.

9 SO JUST AS A REMINDER, THE PDEV PROGRAM IS
10 IN SERVICE OF SAF GOAL 4. THIS IS TO PROPEL 15 TO
11 20 THERAPIES TARGETING DISEASES AFFECTING
12 CALIFORNIANS TO LATE STAGE TRIALS. THERE WERE TWO
13 SPECIFIC RECOMMENDATIONS THAT WE HAD TO ADDRESS AS
14 PART OF THIS FUNDING MECHANISM. THE FIRST WAS TO
15 CONSOLIDATE PRECLINICAL FUNDING MECHANISMS TO
16 INCENTIVIZE MULTIDISCIPLINARY COLLABORATIONS AND
17 RAPID PROGRESSION TO IND AND START FIRST-IN-HUMAN
18 CLINICAL TRIALS. AND THE SECOND WAS TO INCORPORATE
19 PRIORITIZATION OF INNOVATIVE THERAPIES FOR DISEASES
20 THAT AFFECT CALIFORNIANS.

21 SO I'LL TALK ABOUT HOW WE HAVE DESIGNED
22 THIS PROGRAM TO ADDRESS BOTH OF THOSE PRIORITIES
23 THAT WERE DEFINED BY THE SAF. BEFORE I GET INTO
24 THAT, I'M GOING TO PROVIDE A LITTLE BIT MORE
25 BACKGROUND ON THE LANDSCAPE AS WELL AS OUR INTERNAL

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1 LEARNINGS FROM YEARS OF MANAGING PRECLINICAL
2 DEVELOPMENT PROGRAMS.

3 FIRST OF ALL, AS YOU ALL KNOW VERY WELL,
4 OVER THE LAST DECADE THERE HAVE BEEN VARIOUS
5 MILESTONES IN THE APPROVAL OF CELL AND GENE
6 THERAPIES. AND THE NUMBER OF CELL AND GENE
7 THERAPIES THAT ARE APPROVED EVERY YEAR IS
8 INCREASING. SIMILARLY, ON THE DEVELOPMENT LANDSCAPE
9 SIDE, WHICH IS WHAT THIS MASSIVE CHART PORTRAYS, IS
10 THAT THERE IS AN INCREDIBLE NUMBER OF THERAPIES IN
11 DEVELOPMENT BOTH AT THE PRECLINICAL STAGE AS WELL AS
12 THE CLINICAL STAGE. AND THE ONE MAJOR THING TO NOTE
13 HERE IS, DESPITE THE SIGNIFICANT INVESTMENT IN
14 ONCOLOGY, THERE ARE CANDIDATES THAT ARE TARGETING
15 ALL MAJOR THERAPEUTIC AREAS. IN PARTICULAR, THIS IS
16 VERY TRUE FOR GENE THERAPY, WHICH IS THE RED BARS
17 THAT YOU SEE ACROSS THE ENTIRE SPECTRUM.

18 AND SO ON THAT NOTE, THERE IS A LOT OF
19 ACTIVITY IN DEVELOPING CELL AND GENE THERAPIES
20 ACROSS MULTIPLE THERAPEUTIC AREAS. HOWEVER, AT THE
21 SAME TIME, THE INVESTMENT IN CELL AND GENE THERAPIES
22 HAS FLATLINED. SO THE BAR FOR INDUSTRY INVESTMENT
23 IN CELL AND GENE THERAPY DEVELOPMENT HAS GOTTEN
24 SIGNIFICANTLY HIGH IN THE LAST FEW YEARS.

25 SO ON THE LEFT, THERE IS A CHART THAT'S

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1 SHOWING HOW VENTURE INVESTMENT, WHICH IS THE
2 LIFEBLOOD FOR SMALL COMPANIES, HAS BASICALLY
3 FLATLINED COMPARED TO SMALL MOLECULES AND BIOLOGICS
4 OVER THE LAST FEW YEARS. AT THE SAME TIME, BOTH
5 VENTURE CAPITAL FIRMS AS WELL AS BIOPHARMA PARTNERS
6 ARE PRIORITIZING INVESTMENTS IN CLINICAL STAGE CELL
7 AND GENE THERAPY COMPANIES.

8 IN FACT, THIS IS PLAYED OUT IN OUR OWN
9 PORTFOLIO. LAST YEAR IN 2024 WE TRACKED OVER \$2
10 BILLION IN INDUSTRY SUPPORT TO CIRM-FUNDED PROGRAMS,
11 BUT ONLY A SMALL FRACTION OF THAT WAS ACTUALLY
12 DEDICATED TO PRECLINICAL STAGE COMPANIES.

13 SO IN SUM, FROM ALL OF THIS EXTERNAL
14 LANDSCAPE, THERE IS STILL A VERY IMPORTANT ROLE FOR
15 CIRM TO PLAY IN DERISKING AND SUPPORTING THE
16 DEVELOPMENT OF CELL AND GENE THERAPIES ACROSS THE
17 TRANSLATIONAL VALLEY OF DEATH, BUT WE HAVE TO DO IT
18 IN A STRUCTURED AND FOCUSED AND DELIBERATE WAY PER
19 THE SAF.

20 I'M GOING TO SPEND A LITTLE BIT OF TIME
21 TALKING ABOUT OUR EXPERIENCE OVER THE LAST TEN YEARS
22 MANAGING PRECLINICAL DEVELOPMENT PROGRAMS. AS YOU
23 KNOW, PRECLINICAL DEVELOPMENT IN CIRM'S CURRENT
24 FUNDING MODEL IS SPREAD ACROSS THREE DISTINCT BUT
25 PROGRESSIVE FUNDING OPPORTUNITIES STARTING WITH

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1 DISC2, WHICH FOCUSES ON THE DEVELOPMENT AND
2 DISCOVERY OF A THERAPEUTIC CANDIDATE. FROM THAT
3 POINT ON, THE TRANSLATIONAL PROGRAM SUPPORTS EARLY
4 TRANSLATIONAL ACTIVITIES RESULTING AND CULMINATING
5 IN A PRE-IND MEETING. AND FINALLY, THE CLIN1
6 PROGRAM WHICH SUPPORTS ALL IND-ENABLING ACTIVITIES
7 RESULTING IN THE SUBMISSION OF AN IND APPLICATION TO
8 THE FDA.

9 OVER THE LAST TEN YEARS, WE'VE LEARNED A
10 FEW THINGS ACROSS OUR PROGRAMS, AND I'M GOING TO
11 HIGHLIGHT ON TWO AREAS. ONE OF THOSE IS AN
12 ACCELERATION, WHICH IS A MAJOR FOCUS AREA FOR CIRM,
13 AND, SECONDLY, IS SCOPE-BASED OBSERVATIONS. ALL OF
14 THESE HAVE FED INTO THE DESIGN OF THE PDEV PROGRAM.

15 SO FIRST AND FOREMOST, ON THE
16 TRANSLATIONAL SIDE, WE ARE WITNESSING MULTIPLE TRAN1
17 AWARDS THAT ARE PROGRESSING TO PRE-IND MEETINGS MUCH
18 EARLIER THAN EXPECTED. NOW, IN OUR CURRENT
19 MECHANISM, THIS REQUIRES AWARD AMENDMENTS TO USE THE
20 REMAINING FUNDING TO CONDUCT STUDIES THAT WERE
21 INFORMED BY THE FDA FEEDBACK. BECAUSE ALL OF OUR
22 PROGRAMS HAVE DISTINCT ACTIVITIES THEY CAN DO,
23 THERE'S ALSO SOME LIMITATION TO HOW MUCH ACTIVITIES
24 THEY CAN ACTUALLY GET DONE IN A TRAN1 AWARD AFTER
25 HAVING THAT PRE-IND MEETING.

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1 SO BUILDING ON THAT, A TRAN1 AWARDEE THAT
2 HAS A SUCCESSFUL PRE-IND MEETING, THE LAG TIME TO GO
3 FROM THAT TO HAVING THE CLIN1 AWARD START IS ON THE
4 MEDIAN OF 16 MONTHS. THIS IS BASED ON THE FACT THAT
5 THEY HAVE TO APPLY AND THEN GO THROUGH THE MECHANISM
6 OF REVIEW AND AWARD APPROVAL. SO THERE'S AN
7 OPPORTUNITY THERE ON THE ACCELERATION SIDE.

8 ON THE SCOPE SIDE, BECAUSE ALL THREE
9 PROGRAMS HAVE DISTINCT ACTIVITIES THAT THEY CAN
10 SUPPORT, YOU HAVE INSTANCES WHERE A TRAN STAGE
11 PROJECT MIGHT WANT TO CONDUCT SOME CANDIDATE
12 OPTIMIZATION BEFORE IT EMBARKS ON ALL OF ITS
13 DEVELOPMENT ACTIVITIES TO GET TO A PRE-IND MEETING.
14 PARTICULARLY TRUE FOR GENE THERAPIES WHERE THEY MAY
15 WANT TO OPTIMIZE SOME GENETIC SEQUENCE OR RNA OR
16 CHANGE OUT THEIR PROMOTER. UNDER OUR CURRENT
17 MECHANISM, THEY WOULD HAVE TO FIRST APPLY TO DISC2
18 BEFORE THEY CAN ACTUALLY COME BACK IN FOR TRAN1
19 FUNDING. SIMILARLY, IF YOU HAVE A PROJECT THAT IS
20 SIX TO 12 MONTHS FROM ITS PRE-IND MEETING, IT
21 DOESN'T REALLY FIT INTO THE TRAN1 OR CLIN1 FUNDING
22 MECHANISM. THEY'RE KIND OF IN BETWEEN.

23 SO IN SUM, THIS PRESENTS CIRM AN
24 OPPORTUNITY TO ENHANCE ITS FUNDING PROGRAMS TO SET A
25 REALLY CLEAR GOAL ON GETTING TO THAT FIRST-IN-HUMAN

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1 CLINICAL TRIAL AND TO HOLISTICALLY SUPPORT ALL
2 ACTIVITIES TO GET THERE ALONG THE WAY. AND THAT'S
3 THE PROGRAM THAT WE'RE PROPOSING TO YOU TODAY.

4 BEFORE WE GET TO THAT, I DO WANT TO NOTE
5 THAT OTHER FUNDING AGENCIES HAVE ALSO MADE SIMILAR
6 OBSERVATIONS. IN THE LAST FEW YEARS, THEY HAVE
7 DEVELOPED SIMILAR PROGRAMS. NIH IN PARTICULAR HAS
8 SEVERAL DIFFERENT MECHANISMS WHERE THEY HAVE SOME
9 THINGS IN COMMON. THE FIRST IS THAT THEY ALLOW FOR
10 MULTIPLE ENTRY POINTS. THE PROJECT COMES IN AT THE
11 STAGE THAT IT'S READY, AND IT'S FUNDED ACROSS
12 MULTIPLE CLASSICAL DEVELOPMENT STAGES. SO, FOR
13 EXAMPLE, AN AWARD COULD SUPPORT EVERYTHING FROM LEAD
14 OPTIMIZATION TO IND FILING. AND SOME OF THESE
15 PROGRAMS EVEN SUPPORT A CLINICAL TRIAL AS PART OF
16 THAT AWARD.

17 SO BUILDING ON ALL OF THAT BACKGROUND
18 KNOWLEDGE AND OBSERVATIONS WITHIN OUR PORTFOLIO AND
19 EXTERNAL LANDSCAPE, WE'RE PROPOSING TO YOU A PDEV
20 PROGRAM WITH THE OBJECTIVE OF ACCELERATING
21 COMPLETION PRECLINICAL DEVELOPMENT, FDA IND
22 CLEARANCE, AND CLINICAL START-UP FOR STEM CELL-BASED
23 AND GENETIC THERAPIES. WHAT THIS PROGRAM WILL DO IS
24 SET A SHARED GOAL BETWEEN CIRM AND THE AWARDEE ON
25 ACCELERATING PRECLINICAL DEVELOPMENT TO IND

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1 CLEARANCE AND START OF THAT FIRST-IN-HUMAN CLINICAL
2 TRIAL. THEN IT WILL HOLISTICALLY SUPPORT ALL THE
3 ACTIVITIES NECESSARY TO GET THERE.

4 SO, IN EFFECT, WHAT WE'RE TALKING ABOUT IS
5 COMBINING OUR TRAN1 AND CLIN1 PROGRAM. AND THE NEW
6 PROGRAM, THE PDEV PROGRAM, NOW FITS INTO THE NEW
7 STRUCTURE OF CIRM FUNDING PROGRAMS THAT DR.
8 CANET-AVILES HAD LED THROUGH THE SAF IMPLEMENTATION.
9 AND IT'S BRACKETED BY AN EARLY DEVELOPMENT PROGRAM.
10 THIS IS THE REPLACEMENT TO DISC2 TO SUPPORT
11 CANDIDATE DISCOVERY AS WELL AS THE ENHANCED CLIN2
12 PROGRAM WHICH WILL BE UP FOR YOUR CONSIDERATION
13 AFTER MY PRESENTATION.

14 SO I'M GOING TO SPEND A FEW SLIDES NOW
15 TALKING ABOUT THE STRUCTURE OF THAT CONSOLIDATION
16 AFTER HAVING TALKED A LITTLE BIT ABOUT THE SCOPE.

17 SO THE PDEV PROGRAM, AS I MENTIONED, IS A
18 COMBINATION OF ACTIVITIES THAT SPAN EVERYTHING FROM
19 LEAD OPTIMIZATION TO IND SUBMISSION, BUT ALL AWARDS
20 THAT COME IN FOR THE PDEV PROGRAM WILL HAVE THAT
21 SINGULAR OUTCOME OF IND CLEARANCE. SO WE THINK OF
22 THIS AS TWO DIFFERENT STAGES THAT ARE BEING
23 EXPLAINED HERE ON THIS EARLY PDEV, WHICH IS THE
24 PRE-IND STAGE, AND LATE PDEV, WHICH IS THE
25 IND-ENABLING STAGE, BUT THESE TWO STAGES ARE

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1 INTRICATELY LINKED.

2 ACTIVITIES THAT ARE CONDUCTED IN THIS ARE
3 ACROSS FOUR MAJOR AREAS. FIRST, YOU HAVE
4 MANUFACTURING, THEN YOU HAVE NONCLINICAL
5 DEVELOPMENT, CLINICAL PLANNING, AS WELL AS
6 REGULATORY PLANNING. SO ACROSS THESE FOUR AREAS IN
7 THE EARLY PRE-IND STAGE INVOLVES PROCESS
8 DEVELOPMENT, SOME PILOT NONCLINICAL STUDIES, INITIAL
9 PLANNING FOR THE CLINICAL DEVELOPMENT, AS WELL AS
10 PLANNING FOR THAT REGULATORY INTERACTION. ALL
11 LEADING UP TO A WELL-DEFINED, WELL-CONSTRUCTED
12 PRE-IND MEETING.

13 AND THEN THE FEEDBACK FROM THE FDA ALONG
14 WITH ALL THE PILOT AND DEVELOPMENT WORK THAT HAD
15 BEEN DONE PREVIOUSLY ALLOWS FOR A STREAMLINED AND
16 DIRECTED EXECUTION OF MANUFACTURING FOR THE DRUG
17 PRODUCT, COMPLETION OF ALL THE GLP STUDIES TO GET TO
18 IND, AS WELL AS A FINAL CLINICAL PROTOCOL, AND THEN
19 THE SUBMISSION OF THE IND PACKAGE.

20 SO ALL THIS IS INTRICATELY LINKED TOGETHER
21 WHERE ONE STAGE IS INFORMING THE NEXT STAGE. AND BY
22 ALLOWING FOR A HOLISTIC APPROACH, WE CAN ACTUALLY
23 ALLOW THE AWARDEE TO STRUCTURE AND STAGE THOSE
24 ACTIVITIES AS APPROPRIATE AND NECESSARY TO GET TO
25 IND FOR THAT PARTICULAR THERAPEUTIC CANDIDATE.

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1 IN THIS PRESENTATION AND THE NEXT FEW
2 SLIDES, I TALK ABOUT EARLY PDEV AND LATE PDEV. FOR
3 US THAT'S A WAY TO MORE EASILY MANAGE APPLICATION
4 COMPONENTS, AWARD MANAGEMENT, AWARD BUDGETS, AND SO
5 ON. SO RECOGNIZE THAT THAT'S THE REASON WHY YOU SEE
6 THOSE DISTINCTIONS COMING UP IN THE REST OF THE
7 PROPOSAL.

8 SO LET'S START WITH AWARD AMOUNT AND
9 DURATION. WE ARE PROPOSING TO HAVE SEPARATE LIMITS
10 FOR EACH OF THE TWO STAGES, EARLY PDEV AND LATE
11 PDEV, TO HELP DEFINE THE ACTIVITIES AND TIMELINES
12 FOR THE AWARDEES. SO FOR THE EARLY PDEV, THIS IS
13 INFORMED BY OUR EXISTING TRAN1 MECHANISM, THE MAX
14 AWARD AMOUNT WOULD BE \$5.5 MILLION IN TOTAL COST AND
15 THE MAX STAGE DURATION IS 30 MONTHS. FOR THE LATE
16 PDEV STAGE, THE MAX AMOUNT THEY CAN REQUEST IN TOTAL
17 COSTS FROM CIRM IS 7.5 MILLION, AND THE MAX STAGE
18 DURATION IS 30 MONTHS.

19 NOW, YOU CAN HAVE APPLICANTS WHO ARE
20 COMING IN REQUESTING FUNDING FOR BOTH THAT EARLY
21 PDEV AND LATE PDEV STAGE OR JUST FOR THE LATE PDEV
22 STAGE. SO ON THAT NOTE, THE MAXIMUM AWARD AMOUNT
23 FOR A PDEV PROGRAM WOULD BE \$13 MILLION IF THEY'RE
24 REQUESTING FUNDING MAXING OUT FOR BOTH OF THOSE
25 STAGES, AND THE MAX AWARD DURATION WOULD BE FIVE

1 YEARS.

2 SO TO WRAP UP ON THE SCOPE SIDE OF THIS
3 PROGRAM, I'M GOING TO SPEND A COUPLE OF SLIDES
4 TALKING ABOUT THE PRIORITIZATION ELEMENTS TO ADDRESS
5 THE SECOND SAF RECOMMENDATION OF INNOVATIVE
6 THERAPIES FOR DISEASES THAT AFFECT CALIFORNIANS.

7 WE ARE PROPOSING A PREFERENCE-BASED
8 MECHANISM FOR THE PDEV PROGRAM. AND THIS IS TO HELP
9 ACHIEVE THE SAF GOAL. AND THE WAY THIS IS GOING TO
10 WORK IS THAT THERE ARE SEVERAL GUIDING PRINCIPLES
11 THAT ARE GOING TO ALLOW US TO DEFINE PREFERENCES ON
12 AN ANNUALIZED BASIS. SO THE GUIDING PRINCIPLES ARE
13 TO FUND THERAPIES THAT OFFER POTENTIAL FOR
14 TRANSFORMATIVE CLINICAL IMPACT, TO FUND THERAPIES
15 THAT ADDRESS BOTTLENECKS TO ACCESS AND AFFORDABILITY
16 CHALLENGES THAT ARE KNOWN IN THE FIELD, AND, LASTLY,
17 TO FUND THERAPIES THAT ARE NOT ADEQUATELY SUPPORTED
18 BY FEDERAL FUNDING OR PRIVATE INVESTMENT.

19 AND HOW WE DEFINE AND IMPLEMENT THESE
20 PREFERENCES IS IN THE IMPLEMENTATION PLAN. SO THE
21 GOAL IS TO EVOLVE THESE PREFERENCES OVER THE COURSE
22 OF THE ENTIRE LIFETIME OF THIS PROGRAM AND TO DO SO
23 BASED ON INFORMATION FROM INTERNAL PORTFOLIO AND
24 EXTERNAL LANDSCAPE ANALYSES. SO THE IDEA HERE IS
25 THAT BY DOING THIS WE CAN BUILD A DIVERSE PORTFOLIO

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1 OF THERAPEUTIC APPROACHES BY CONSTANTLY ADAPTING
2 THOSE PREFERENCES BASED ON OUR INTERNAL PORTFOLIO
3 AND THE EXTERNAL LANDSCAPE ANALYSES. AND THIS SET
4 OF PREFERENCES WOULD BE APPROVED ON A FISCAL YEAR
5 BASIS FOR THE ICOC BASED ON DATA AND ANALYSIS OF OUR
6 INTERNAL PORTFOLIO AND THE EXTERNAL LANDSCAPE.

7 SO TO PUT THAT ABSTRACT INTO PRACTICE, FOR
8 THE FIRST FISCAL YEAR, WE ARE PROPOSING A SET OF
9 PREFERENCES THAT ARE FOCUSED ALONG TWO TRACKS. THE
10 FIRST IS TO ADDRESS PROP 14 PRIORITIES, AND THE
11 SECOND IS TO ACCELERATE PROGRAMS.

12 SO THE FIRST FOUR PREFERENCES THAT ARE
13 LISTED HERE ARE DESIGNED TO ADDRESS PROP 14
14 PRIORITIES. THERE'S THREE MODALITY-BASED
15 PREFERENCES, PLURIPOTENT STEM CELL-DERIVED
16 THERAPIES, IN VIVO GENETIC THERAPIES, AND NONVIRAL
17 NUCLEIC ACID DELIVERY. SO THESE ARE MEANT TO HAVE
18 POTENTIAL TO ADDRESS PATIENT ACCESS AND
19 AFFORDABILITY BARRIERS. AND THE LAST OF THE FOUR
20 PROP 14 PREFERENCES, OF COURSE, IS TO PRIORITIZE FOR
21 DISEASES OF THE BRAIN AND CNS.

22 THE LAST TWO PREFERENCES HERE ARE
23 ACCELERATION FOCUSED. SO, FOR EXAMPLE, IF WE
24 SUPPORTED A PROJECT THROUGH DISC2 OR TRAN1, THAT
25 PROGRAM WOULD BE PREFERRED IN SOME WAY TO ADVANCE TO

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1 THE PDEV PROGRAM TO SUPPORT ITS PROGRESSION TO IND
2 CLEARANCE.

3 AND LASTLY, IF THE APPLICANT HAS CONDUCTED
4 A PRE-IND OR INTERACT MEETING THAT HAS INFORMED THIS
5 PATHWAY, THAT ALSO IS AN ACCELERATING MECHANISM TO
6 IND CLEARANCE.

7 ALL THESE PREFERENCES WOULD BE IMPLEMENTED
8 DURING THE PRESUBMISSION STAGE, WHICH I'LL DESCRIBE
9 IN THE NEXT FEW SLIDES, AS WELL AS DURING THE ARS
10 REVIEW BY MEMBERS OF THE BOARD.

11 SO I'M GOING TO SPEND A FEW SLIDES
12 DESCRIBING THE PRESUBMISSION PROCESS AS IT'S
13 TAILORED FOR THE PDEV PROGRAM. AND DR. GIL SAMBRANO
14 WILL PROVIDE MORE DETAILS. THERE'S ALREADY BEEN A
15 RICH DISCUSSION ON THIS, SO I'M NOT GOING TO SPEND
16 TOO MUCH TIME ON THIS PARTICULAR SLIDE. BUT THE
17 RATIONALE FOR THE PRESUBMISSION PROCESS IS SIMILAR
18 TO WHAT YOU HEARD FOR DISC4, WHICH IS TO HELP MANAGE
19 THE HIGH APPLICATION VOLUME, TO REDUCE THE OVERALL
20 BURDEN ON THE APPLICATION BY FIRST HAVING THEM
21 SUBMIT A PRESUBMISSION BEFORE THEY HAVE TO COMMIT TO
22 A FULL APPLICATION SUBMISSION. IT ALSO ALLOWS US TO
23 EFFICIENTLY AND EFFECTIVELY IMPLEMENT THE PROGRAM
24 PREFERENCES THAT YOU SAW ON THE PREVIOUS SLIDE. AND
25 LASTLY, IT ALLOWS THE CIRM TEAM TO PREPLAN FOR THE

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1 GWG EXPERTISE AND COMPOSITION BY A COUPLE MONTHS TO
2 HAVE A MORE INFORMED AND ROBUST SCIENTIFIC REVIEW.

3 SO THE WORKFLOW IS SIMILAR TO WHAT YOU
4 HEARD FOR DISC4. AN APPLICANT WILL COMPLETE A SHORT
5 PRESUBMISSION FORM IN THE GMS, AND THE CIRM TEAM
6 WILL FILTER AND RANK ORDER THE PRESUBMISSIONS BASED
7 ON PREFERENCES AS WELL AS RELATED OBJECTIVE
8 CRITERIA, WHICH I'LL DESCRIBE IN THE NEXT SLIDE.
9 AND THEN LASTLY, THOSE PRESUBMISSIONS THAT ARE
10 SELECTED ARE INVITED TO APPLY FOR THE FULL
11 APPLICATION.

12 SO FOR THE PDEV PROGRAM, THE RUBRIC FOR
13 PRESUBMISSION RANK ORDERING IS BASED ON THE
14 PREFERENCES THAT I JUST NOTED IN THE PREVIOUS SLIDE,
15 THE PROP 14 AND OTHER PREFERENCES, AS WELL AS A
16 COUPLE OF OTHER CRITERIA THAT ARE DESIGNED TO PREFER
17 PROJECTS THAT ARE ADDRESSING THERAPEUTIC AREAS OR
18 THERAPEUTIC APPROACHES THAT ARE UNDERREPRESENTED IN
19 CIRM'S PORTFOLIO. FOR EXAMPLE, IF IT'S A PROJECT
20 THAT'S TARGETING A DISEASE AREA THAT'S
21 UNDERREPRESENTED IN CIRM'S PORTFOLIO, IT MAY GET
22 SOME ADDITIONAL POINTS. OR IF IT'S A REALLY NOVEL
23 APPROACH THAT IS NOT REPRESENTED IN CIRM'S
24 PORTFOLIO, IT WOULD ALSO GET ADDITIONAL POINTS.

25 SO IN COMBINATION OF THE CONSOLIDATION OF

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1 THE PROGRAMS AS WELL AS THE PREFERENCES, THAT'S SETS
2 THE SCOPE FOR THE PROGRAM. IN THE NEXT FEW SLIDES,
3 I'M GOING TO FOCUS ON THE STRUCTURE ELEMENTS OF THE
4 PROGRAM. AND I'LL HIGHLIGHT AREAS WHERE THIS
5 DIFFERS SIGNIFICANTLY FROM OUR EXISTING PROGRAMS IN
6 THE INTEREST OF TIME.

7 SO FOR PROGRAM STRUCTURE, THE PDEV PROGRAM
8 WILL BE AVAILABLE TWICE A YEAR, AND IT WILL BE OPEN
9 ONLY TO CALIFORNIA ORGANIZATIONS. THESE ARE EITHER
10 NON-PROFIT OR FOR-PROFIT ORGANIZATIONS. IT WILL
11 RETAIN THE CO-FUNDING REQUIREMENT THAT OUR CURRENT
12 PROGRAMS HAVE, WHICH IS 20 PERCENT FOR NON-PROFITS
13 THAT HAVE A PARTNER OR FOR-PROFITS. AND BASED ON
14 OUR INTERNAL PROJECTIONS FOR HOW MANY AWARDS WE
15 WOULD NEED TO MEANINGFULLY CONTRIBUTE TO THE SAF
16 GOAL, WE ARE REQUESTING AN ANNUAL BUDGET FOR THE
17 FIRST YEAR OF \$160 MILLION FOR THIS PROGRAM.

18 GIVEN WHAT I SAID PREVIOUSLY, BECAUSE IT
19 DEPENDS ON THE SIZE OF THOSE AWARDS AND THE STAGE
20 THAT THEY'RE REQUESTING FUNDING FOR, YOU CAN
21 ANTICIPATE BETWEEN 12 TO 21 AWARDS BEING FUNDED WITH
22 THAT \$160 MILLION ALLOCATION IN THAT FIRST FISCAL
23 YEAR.

24 HERE I'VE GIVEN YOU A PROJECTION THAT
25 INDICATES SEVEN EARLY PDEV AWARDS AND NINE LATE PDEV

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1 AWARDS WITH THAT ALLOCATION IN THE FIRST FISCAL
2 YEAR. IF THIS WERE ACHIEVED, WE'D BE IN PRETTY GOOD
3 SHAPE. YOU WOULD HAVE NINE AWARDS IN THE LATE STAGE
4 THAT WOULD HAVE A GOOD CHANCE OF CONTRIBUTING FAIRLY
5 RAPIDLY TO THE CLINICAL PIPELINE AND ALSO BEING ABLE
6 TO SUPPORT SEVEN INNOVATIVE THERAPIES IN THIS
7 ACCELERATION-BASED MODEL TO GET TO IND CLEARANCE.

8 SO AS YOU KNOW, ALL CIRM FUNDING PROGRAMS
9 HAVE VARIOUS ELIGIBILITY REQUIREMENTS. THIS PROGRAM
10 HAS SIMILAR ELIGIBILITY REQUIREMENTS TO THE EXISTING
11 TRAN AND CLIN1. AND SO AS I MENTIONED, THE
12 APPLICANT MUST BE A CALIFORNIA ORG. IN ADDITION TO
13 THAT, IT HAS CANDIDATE READINESS REQUIREMENTS, PI
14 AND PROJECT MANAGER EFFORT REQUIREMENTS, A
15 REQUIREMENT TO START THE AWARD 90 DAYS AFTER
16 APPROVAL, AND THEN TO DEMONSTRATE THAT IT CAN
17 ACTUALLY CO-FUND THE AWARD AT THE TIME OF
18 APPLICATION.

19 NOW I'M GOING TO HIGHLIGHT A FEW AREAS
20 WHERE WE'RE IMPLEMENTING NEW OR MODIFIED
21 REQUIREMENTS TO THIS PROGRAM AS COMPARED TO THE
22 EXISTING TRAN AND CLIN1. ON THIS SLIDE YOU SEE
23 THREE AREAS THAT ARE ALL BROADLY FOCUSED ON BEING
24 ABLE TO ACCELERATE DEVELOPMENT AND COMMERCIALIZATION
25 OF THERAPIES AND TO DO SO IN A MORE COLLABORATIVE

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1 MANNER.

2 SO FIRST AND FOREMOST, AS MANY OF YOU
3 KNOW, CELL AND GENE THERAPY DEVELOPMENT CAN PROGRESS
4 VERY RAPIDLY. THE MOST FAMOUS EXAMPLE BEING CSH
5 CHEVY WHICH HAS GONE FROM CRISPR BEING DISCOVERED IN
6 A TEST TUBE TO AN APPROVED THERAPY IN TEN YEARS.
7 GIVEN THAT, OUR AWARDEES SHOULD BE ACTIVELY PLANNING
8 AND BE SUPPORTED FOR PLANNING FOR MARKET ACCESS
9 STRATEGIES. AND WE WANT THOSE MARKET ACCESS
10 STRATEGIES TO FOCUS AND HAVE A PARTICULAR
11 CONSIDERATION FOR PATIENT ACCESS AND AFFORDABILITY
12 PLANNING. AND SO THE AWARDEES WILL BE REQUIRED TO
13 PROPOSE ACTIVITIES DURING THE PDEV STAGE THAT ARE
14 PHASE APPROPRIATE FOR THAT STAGE AND TO DEMONSTRATE
15 COMPLETION OF THOSE OVER THE COURSE OF THAT AWARD.

16 SIMILARLY TO THE OTHER PROGRAMS THAT HAVE
17 BEEN HIGHLIGHTED TODAY, THERE WILL BE A DATA SHARING
18 REQUIREMENT. SO THEY'LL HAVE TO PROPOSE A DATA
19 SHARING AND MANAGEMENT PLAN, AND THIS WILL BE
20 COORDINATED WITH CIRM'S OVERALL DATA SHARING
21 INITIATIVES THAT KELLY, DR. SHEPARD, AND DR. TAN
22 HAVE ALREADY HIGHLIGHTED.

23 LASTLY IS THE ONE THAT'S A PRIORITY FOR
24 OUR TEAM, WHICH IS TO BE ABLE TO CREATE A KNOWLEDGE
25 SHARING NETWORK WITHIN OUR AWARDEES. THE IDEA HERE

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1 IS TO REQUIRE AND FACILITATE PRECOMPETITIVE SHARING
2 BETWEEN THE PDEV AWARDEES ON BEST PRACTICES FOR
3 REGULATORY INTERACTIONS OR ROBUST STUDY DESIGNS AND
4 FOR COMMON ASSAY DEVELOPMENT, ALL OF WHICH CAN HELP
5 RISE ALL BOATS.

6 SO THE INTENT HERE IS THAT BY SHARING BEST
7 PRACTICES, THEY'RE HELPING EACH OTHER ADVANCE MUCH
8 MORE RAPIDLY TO THE CLINIC.

9 AND ON THAT THEME OF HELPING ALL OF OUR
10 PROGRAMS RAPIDLY ADVANCE, WE ARE ALSO COMMITTING TO
11 MAKING A FEW CHANGES ON THE AWARD MANAGEMENT SIDE
12 WITHIN OUR TEAM. FIRST AND FOREMOST IS THAT WE WANT
13 TO INCREASE REAL-TIME INTERACTIONS BETWEEN CIRM AND
14 THE AWARDEE PROJECT TEAMS. AND THIS WILL ALSO
15 INCORPORATE DIRECT INTERACTION WITH THE
16 MANUFACTURING LEADS ON THOSE PROGRAMS AS WELL AS
17 CIRM BEING A PARTNER IN ANY FDA INTERACTIONS.

18 AND WE ALSO WILL IMPLEMENT AN EXTERNAL
19 PRODUCT DEVELOPMENT EXPERT NETWORK. THIS IS A TEAM
20 OF ADVISORS THAT CIRM CAN DRAW ON TO HELP WITH
21 ISSUES SUCH AS MILESTONE ACHIEVEMENT, HELPING
22 OVERCOME BOTTLENECKS, HELPING REVIEW AND STRATEGIZE
23 ON PRE-IND MEETING SUBMISSIONS AND OTHER FDA
24 INTERACTIONS.

25 AND THE WAY TO THINK ABOUT THIS NETWORK IS

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1 THAT IT WILL BE A BRAIN TRUST FOR THE SO'S AND IT
2 WILL COMPLEMENT THE CIRM SO'S INTERNAL EXPERTISE.
3 SO WE ARE EXPECTING THESE EXPERTS TO SPAN AREAS SUCH
4 AS NONCLINICAL TESTING, CLINICAL DEVELOPMENT, AND
5 REGULATORY AND CMC.

6 AND WE CONTINUE -- WE WILL ADOPT THE CLIN1
7 OPERATIONAL MILESTONE-DRIVEN MANAGEMENT STRUCTURE.
8 SO JUST AS A REMINDER, THE TRAN, CLIN1, AND CLIN2
9 PROGRAMS, THOSE AWARDS ARE MILESTONE-BASED
10 DISBURSEMENTS. SO THEY ARE GIVEN AN INITIAL
11 DISBURSEMENT TO ACHIEVE THE FIRST MILESTONE. UPON
12 ACHIEVING THE FIRST MILESTONE, THEY GET THE
13 DISBURSEMENT TO ACHIEVE THE NEXT MILESTONE. AND
14 THAT'S HOW CIRM MANAGES ITS RISK IN THESE PROJECTS.

15 SO IN THIS INSTANCE A DELAY OF MORE THAN
16 FOUR MONTHS ON AN OPERATIONAL MILESTONE WILL TRIGGER
17 AN AWARD TERMINATION REVIEW. HOWEVER, BECAUSE OF
18 THE PROACTIVE COMMUNICATION, WE'RE HOPING THAT THAT
19 WILL ACTUALLY ALLOW US TO WORK REALLY
20 COLLABORATIVELY WITH THE TEAM AND TO MITIGATE ANY
21 PROJECT DELAYS GOING FORWARD.

22 SO WITH THAT, I'M GOING TO WRAP UP WITH
23 THE TIMELINE. SO IF THE ICOC APPROVES THIS CONCEPT
24 TODAY, WE WILL ROLL THIS PROGRAM OUT IN THE NEXT TWO
25 MONTHS AND OPEN UP THE PRESUBMISSION PROCESS. THE

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1 CYCLE GOING FROM PRESUBMISSION TO AWARD START FOR
2 THIS PROGRAM IS ANTICIPATED TO LAST TEN MONTHS.

3 SO WITH THAT, THE CIRM TEAM REQUESTS THAT
4 THE ICOC APPROVE THE PROPOSED PDEV CONCEPT PLAN.

5 CHAIRMAN IMBASCIANI: SHYAM, THANK YOU FOR
6 THE PRESENTATION, EXCELLENT. QUESTIONS FIRST MAYBE?
7 IF NOT, I'M GOING TO ASK MARIA TO OFFER THE MOTION.

8 VICE CHAIR BONNEVILLE: HERE WE GO. I'D
9 LIKE TO MAKE A MOTION TO APPROVE THE PRECLINICAL
10 DEVELOPMENT CONCEPT PLAN AND TO DELEGATE TO THE CEO
11 THE AUTHORITY TO MAKE AND IMPLEMENT CHANGES TO THE
12 CONCEPT PLAN IN BETWEEN BOARD MEETINGS UPON
13 CONSULTATION OF THE CHAIRS, THE CO-CHAIRS FOR THE
14 ICOC SUBCOMMITTEES AND TO BRING THOSE CHANGES BEFORE
15 THE BOARD AT THE NEXT OPPORTUNITY FOR RATIFICATION.

16 DR. GASSON: SECOND.

17 CHAIRMAN IMBASCIANI: JUDY GASSON
18 SECONDED. AND I WILL ENTERTAIN DISCUSSION AMONG THE
19 BOARD MEMBERS. EVERYONE DID THEIR HOMEWORK. AND
20 THERE'S NOTHING FROM THE PUBLIC; IS THAT CORRECT,
21 SCOTT? NO ONE FROM THE PUBLIC. OKAY. WE CAN
22 PROCEED TO A VOTE. THANK YOU.

23 DR. PATEL: THANK YOU.

24 MR. TOCHER: ARE YOU SURE? ALL THOSE IN
25 THE ROOM IN FAVOR SAY AYE. THOSE OPPOSED SAY NAY.

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1 ANY ABSTENTIONS? AND I'LL POLL THE MEMBERS ON THE
2 PHONE.

3 MONICA CARSON. YSABEL DURON.

4 MS. DURON: YES.

5 MR. TOCHER: RICH LAJARA.

6 MR. LAJARA: YES.

7 MR. TOCHER: SHLOMO MELMED.

8 DR. MELMED: YES.

9 MR. TOCHER: CHRIS MIASKOWSKI.

10 DR. MIASKOWSKI: YES.

11 MR. TOCHER: JOE PANETTA. SUZANNE
12 SANDMEYER.

13 DR. SANDMEYER: YES.

14 MR. TOCHER: KAROL WATSON.

15 DR. WATSON: YES.

16 MR. TOCHER: AND KEVIN XU.

17 DR. XU: YES.

18 MR. TOCHER: THANK YOU, MR. CHAIR. THE
19 MOTION CARRIES.

20 AND WE HAVE A MODIFICATION TO THE
21 SCHEDULE. IF IT PLEASES THE COURT, WE ARE RUNNING A
22 LITTLE EARLY AND LUNCH IS UNAVAILABLE BEFORE NOON.
23 SO WE WOULD SUGGEST MOVING TO THE NEXT CONCEPT PLAN
24 ITEM WHICH IS CONSIDERATION OF AMENDMENTS TO THE
25 CLIN2 CONCEPTS, WHICH IS YOUR ITEM NO. 12 ON THE

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1 AGENDA.

2 CHAIRMAN IMBASCIANI: SO THE NEXT TWO
3 ITEMS WILL INVOLVE AMENDMENTS. ITEM 12, I'D LIKE TO
4 DR. LISA KADYK, OUR CIRM FELLOW. LISA, WOULD YOU
5 COME AND MAKE THE PRESENTATION.

6 DR. KADYK: GOOD MORNING, MR. CHAIR, MADAM
7 VICE CHAIR, MEMBERS OF THE BOARD, MY COLLEAGUES, AND
8 MEMBERS OF THE PUBLIC. I'M LISA KADYK. I'M HERE TO
9 PRESENT TO YOU SOME UPDATES TO THE CLIN2 FUNDING
10 OPPORTUNITY THAT FUNDS CLINICAL TRIAL AWARDS AT
11 CIRM.

12 AND MY TALK WILL FOLLOW THE SAME STRUCTURE
13 THAT WAS OUTLINED ORIGINALLY BY DR. SHEPARD, AND SO
14 YOU SHOULD BE FAMILIAR WITH IT.

15 SO LIKE THE PRECLINICAL DEVELOPMENT
16 PROGRAM THAT YOU JUST HEARD ABOUT, THE CLIN2 PROGRAM
17 IS DESIGNED TO ADDRESS SAF GOAL 4, PROPELLING 15 TO
18 20 THERAPIES TO LATE STAGE CLINICAL TRIALS. AND
19 THERE WERE THREE AREAS THAT WERE CALLED OUT FOR
20 UPDATES FOR THE CLIN2 PROGRAM UNDER THIS SAF GOAL,
21 INCLUDING NOW ALLOWING SUPPORT FOR EMERGING NOVEL
22 CLINICAL TRIAL DESIGNS, INCENTIVIZING
23 STAGE-APPROPRIATE MARKET ACCESS STRATEGY
24 DEVELOPMENT, AND PRECOMMERCIALIZATION ACTIVITIES, AS
25 WELL AS, LIKE THE PRECLINICAL PROGRAM,

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1 PRIORITIZATION OF INNOVATIVE THERAPIES FOR DISEASES
2 THAT AFFECT CALIFORNIANS.

3 SO TO BETTER UNDERSTAND THE CHALLENGES AND
4 OPPORTUNITIES OF OUR EXISTING CLIN2 PROGRAM, OUR
5 CLINICAL DEVELOPMENT TEAM DID AN ANALYSIS OF
6 PREVIOUSLY FUNDED CLINICAL TRIAL AWARDS AT CIRM.
7 AND OUT OF 110 AWARDS THAT HAVE BEEN PREVIOUSLY
8 FUNDED, WE FOUND SOME COMMON CHALLENGES THAT ARE
9 SOMETIMES ARISING FOR THOSE PROGRAMS. AND THESE
10 INCLUDE DELAYS IN REACHING OPERATIONAL MILESTONES,
11 LACK OF ADVANCEMENT TO THE NEXT PHASE TRIAL, LACK OF
12 PARTNERSHIPS THAT CAN CARRY THE PROGRAMS TO BEYOND
13 CIRM FUNDING, AS WELL AS LACK OF EMPHASIS ON
14 COMMERCIALIZATION PLANNING.

15 SO IN PARALLEL TO THIS INTERNAL ANALYSIS
16 THAT WE DID, WE ALSO STUDIED AN EXTERNAL LANDSCAPE
17 ANALYSIS THAT WAS DONE ON THE CELL AND GENE THERAPY
18 FIELD. AND ONE CONCLUSION FROM THAT ANALYSIS WAS
19 THAT 50 PERCENT OF MARKETED CELL AND GENE THERAPIES
20 THAT ORIGINATE IN ACADEMIA OR EMERGING BIOPHARMA ARE
21 EVENTUALLY LAUNCHED BY A LARGER COMPANY. AND GIVEN
22 THAT ACADEMIA AND EMERGING BIOPHARMA ARE THE CLIN2
23 CLIENTELE, WE CONCLUDE THAT OUR PROGRAMS OR AT LEAST
24 HALF OF THEM WILL EVENTUALLY DEPEND ON PARTNERING TO
25 GET TO BLA FILING AND COMMERCIALIZATION.

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1 SO WE THINK THERE'S AN OPPORTUNITY TO
2 BETTER POSITION THESE PROGRAMS TO BE ATTRACTIVE FOR
3 PARTNERING DOWN THE ROAD SHOULD THE CLINICAL DATA BE
4 SUPPORTIVE. AND SO TO THAT END, WE ARE PROPOSING
5 SOME MODIFICATIONS TO THE EXISTING PROGRAM TO
6 ENCOURAGE EARLIER DEVELOPMENT OF CLINICAL AND
7 MANUFACTURING STRATEGIES, A MARKET ACCESS STRATEGY,
8 AND STAGE-APPROPRIATE PRECOMMERCIALIZATION
9 ACTIVITIES.

10 SO THE OBJECTIVE OF THE CLIN2 PROGRAM IS
11 TO ACCELERATE CLINICAL DEVELOPMENT OF STEM
12 CELL-BASED AND GENETIC THERAPIES TO LATE STAGE
13 TRIALS BY ENCOURAGING INNOVATIVE TRIAL DESIGNS AND
14 INCENTIVIZING STAGE-APPROPRIATE MARKET ACCESS
15 STRATEGY, AND PRECOMMERCIALIZATION ACTIVITIES.

16 SO ON THIS SLIDE I'M GOING TO GO OVER THE
17 SCOPE OF THE CLIN2 PROGRAM. IT, OF COURSE, FUNDS
18 PHASE 1, 2, 3 CLINICAL TRIALS, INCLUDING
19 REGISTRATIONAL TRIALS, USING A REGENERATIVE MEDICINE
20 APPROACH. AND I'VE DIVIDED THESE ACTIVITIES INTO
21 REQUIRED ACTIVITIES AND THOSE THAT ARE ALLOWED, BUT
22 NOT NECESSARILY REQUIRED.

23 SO STARTING WITH THE REQUIRED ACTIVITIES,
24 OF COURSE, WE WOULD EXPECT THE APPLICANTS TO PROPOSE
25 COMPLETION OF A CLINICAL TRIAL. AND WE ARE

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1 ENCOURAGING THOSE THAT HAVE ACCELERATING CLINICAL
2 TRIAL DESIGNS. WE WOULD ALSO REQUIRE THAT
3 APPLICANTS OR AWARDEES ESTABLISH A STRATEGIC
4 PLANNING COMMITTEE. AND THIS WOULD BE A COMMITTEE
5 OF ADVISORS THAT HAVE EXPERIENCE TAKING A CELL
6 AND/OR GENE THERAPY ALL THE WAY TO BLA FILING. AND
7 THE PURPOSE OF THIS COMMITTEE WOULD BE THEN TO BE
8 VERY STRATEGIC AND FORWARD LOOKING PLANNING FOR THIS
9 PROGRAM IN THE AREAS OF CLINICAL DEVELOPMENT,
10 REGULATORY, MANUFACTURING, AND PRECOMMERCIALIZATION
11 ACTIVITIES. AND MANY OF THESE PROGRAMS COULD REALLY
12 BENEFIT FROM THAT KIND OF EXPERIENCE AND EXPERTISE
13 TO ACCELERATE THEIR PROGRAMS.

14 WE WOULD ALSO, LIKE ALL THE OTHER CIRM
15 PROGRAMS, HAVE A DATA SHARING REQUIREMENT SO THAT
16 EVENTUALLY CLINICAL TRIAL DATA THAT COMES FROM CIRM
17 FUNDING COULD BE FINDABLE AND ACCESSIBLE FOR THOSE
18 WHO COULD BENEFIT FROM IT LATER.

19 WE WOULD ALSO CONTINUE TO REQUIRE OUTREACH
20 ACTIVITIES SO THAT CLINICAL TRIALS WOULD ENROLL
21 DEMOGRAPHICS OF THE -- PATIENT DEMOGRAPHICS THAT
22 MATCH THE PATIENT DEMOGRAPHIC OF THE POPULATION AT
23 LARGE.

24 AND FINALLY, WE WILL REQUIRE STAGE
25 APPROPRIATE COMMERCIALIZATION, PRECOMMERCIALIZATION,

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1 AND ACCESS AND AFFORDABILITY ACTIVITIES.

2 AND THEN WE ALSO HAVE SOME OTHER
3 ACTIVITIES THAT ARE ALLOWABLE, INCLUDING FUNDING OF
4 NATURAL HISTORY STUDIES IF THEY ARE FDA APPROVED AS
5 THEY MIGHT BE NEEDED FOR BASELINE OR CONTROL DATA
6 FOR AN INTERVENTIONAL TRIAL THAT WAS ALSO FUNDED
7 UNDER THAT SAME AWARD.

8 AND WE WOULD ALSO ALLOW MANUFACTURING FOR
9 THE NEXT PHASE TRIAL. AND THIS IS, OF COURSE, A
10 VERY EXPENSIVE ACTIVITY. MANUFACTURING FOR THE NEXT
11 PHASE TRIAL IS AN EXPENSIVE ACTIVITY. HOWEVER,
12 DOING IT EARLY CAN POTENTIALLY REALLY ACCELERATE A
13 PROGRAM. SO WE WOULD ALLOW APPLICANTS TO PROPOSE
14 THAT ACTIVITY; HOWEVER, WE WOULD WANT THE ACTUAL
15 INITIATION OF THAT ACTIVITY TO BE GATED ON
16 EVALUATION OF THE CURRENT CLINICAL TRIAL DATA AND
17 THE PROGRESS OF THAT PROGRAM BY BOTH CIRM AND SOME
18 EXTERNAL EXPERTS AS WELL AS THE ABILITY OF THE
19 AWARDEE OR THE PARTNER OF THE AWARDEE TO PROVIDE
20 50-PERCENT CO-FUNDING FOR THAT PARTICULAR ACTIVITY.
21 AND THAT WOULD BE -- THE ASTERISK WOULD BE ONLY IF
22 THAT AWARD HAS A CO-FUNDING REQUIREMENT ALREADY.
23 AND I WILL IN A COUPLE SLIDES EXPLAIN TO YOU WHAT
24 THE CO-FUNDING REQUIREMENTS ARE FOR THE CLIN2
25 PROGRAM.

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1 BEFORE I GET THERE, I JUST WANT TO REMIND
2 YOU THAT, LIKE THE PRECLINICAL DEVELOPMENT PROGRAM,
3 WE ARE GOING TO INCORPORATE PRIORITIZATION OF
4 INNOVATIVE THERAPIES FOR DISEASES THAT AFFECT
5 CALIFORNIANS. SO HOW DO WE DO THAT PRIORITIZATION?

6 AND THIS IS A SLIDE THAT SHOULD LOOK
7 FAMILIAR TO YOU. IT'S THE SAME SLIDE THAT DR. PATEL
8 JUST PRESENTED ON HOW THE CLIN2 PROGRAM WOULD
9 INCORPORATE PROGRAM PREFERENCES ON AN ANNUAL BASIS,
10 AGAIN, WITH THE GUIDING PRINCIPLES OF FUNDING
11 THERAPIES THAT WILL HAVE TRANSFORMATIVE IMPACT,
12 ADDRESS BOTTLENECKS TO ACCESS AND AFFORDABILITY, AND
13 ARE NOT ADEQUATELY SUPPORTED BY FEDERAL FUNDING OR
14 PRIVATE INVESTMENT.

15 AND SO TO DO THAT, WE WOULD HAVE ON AN
16 ANNUAL BASIS A REVIEW OF THE PORTFOLIO, BOTH
17 INTERNAL AND EXTERNAL, IN ORDER TO SET PREFERENCES,
18 HAVE THE BOARD APPROVE PREFERENCES FOR THE PROGRAM.

19 OKAY. AND THIS IS THE PROPOSED
20 PREFERENCES FOR THE FISCAL YEAR 25/26 FOR THE CLIN2
21 PROGRAM. THE FIRST FOUR ROWS MAY LOOK FAMILIAR TO
22 YOU. THEY ARE THE SAME FOUR PREFERENCES THAT WERE
23 DESCRIBED BY DR. PATEL. THE FIRST THREE ARE
24 DIFFERENT THERAPEUTIC MODALITIES THAT HAVE THE
25 POTENTIAL TO ADDRESS PATIENT ACCESS AND

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1 AFFORDABILITY BARRIERS. AND THEN, OF COURSE,
2 DISEASES OF THE BRAIN AND CNS IS A PROP 14 PRIORITY.

3 AND THEN THE BOTTOM FOUR ROWS ARE
4 CLIN2-SPECIFIC PREFERENCES. ONE IS GIVE PREFERENCES
5 TO APPLICANTS THAT ARE CALIFORNIA ORGANIZATIONS.
6 SECOND IS TO FUND PIPELINE PROGRAMS THAT ARE MOVING
7 FROM AN IND-ENABLING STAGE OR FROM AN EARLIER PHASE
8 CLINICAL TRIAL TO A LATER PHASE TRIAL. WE WOULD
9 ALSO GIVE PREFERENCES TO PROGRAMS THAT HAVE FDA
10 DESIGNATIONS, SUCH AS FAST TRACK, RMAT, OR
11 BREAKTHROUGH DESIGNATIONS THAT ARE ACCELERATING AND
12 GIVE GREATER ACCESS TO FDA FOR DEVELOPING THE
13 PROGRAM. AND FINALLY A PREFERENCE FOR PROGRAMS THAT
14 ARE PROPOSING PIVOTAL OR REGISTRATIONAL TRIALS.

15 AND THESE PREFERENCES, AGAIN, WOULD BE
16 FACTORED IN BOTH IN THE PREREVIEW PROCESS WHICH IN
17 CLIN2 WE'RE CALLING QUALIFICATION. I'LL DESCRIBE
18 THAT A LITTLE BIT MORE. AND THEN DR. SAMBRANO WILL
19 DESCRIBE IT IN MUCH MORE DETAIL LATER TODAY. AND
20 THEN IT COULD ALSO BE FACTORED IN DURING APPLICATION
21 REVIEW SUBCOMMITTEE OF THE BOARD.

22 SO THE CLIN2 APPLICATION AND REVIEW
23 PROCESS IS DIFFERENT FROM THE ONE THAT YOU JUST
24 HEARD ABOUT FROM DR. PATEL. WE WOULD HAVE FULL
25 APPLICATIONS BE SUBMITTED, AND THEN IT GOES TO THE

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1 REVIEW TEAM TO EXCLUDE ANY INELIGIBLE OR INCOMPLETE
2 APPLICATIONS. AND THEN IN CASES WHERE THERE ARE
3 HIGH APPLICATION VOLUMES THAT PRECLUDE ALL
4 APPLICATIONS GOING TO FULL REVIEW, THAT IS WHEN THIS
5 QUALIFICATION PROCESS WOULD BE PUT INTO PLAY USING
6 OBJECTIVE PROGRAM PREFERENCES SUCH AS THE ONES I
7 JUST DESCRIBED TO YOU.

8 SO THIS IS JUST AN OUTLINE OF WHAT I JUST
9 SAID HERE. SO THAT APPLICATIONS WOULD BE SUBMITTED
10 IN FULL, ELIGIBILITY REVIEW WOULD BE DONE TO
11 DETERMINE WHICH ONES ARE ELIGIBLE, AND THEN ONLY IN
12 THE CASE WHERE THERE ARE TOO MANY APPLICATIONS TO GO
13 TO FULL REVIEW WOULD THE REVIEW TEAM THEN APPLY
14 OBJECTIVE PREFERENCES TO RANK IN ORDER APPLICATIONS
15 THAT WOULD THEN EVENTUALLY BE SELECTED FOR FULL
16 REVIEW.

17 AND SO THE NEXT SLIDE HERE JUST SHOWS THE
18 RUBRIC THAT WE'RE PROPOSING FOR THIS FISCAL YEAR
19 COMING UP. SO INCLUDING THE PROP 14 PREFERENCES OF
20 PLURIPOTENT STEM CELL DERIVED-THERAPIES, IN VIVO
21 GENE THERAPIES, AND DISEASES OF THE BRAIN OR CNS AS
22 WELL AS SOME OF THE OTHER PREFERENCES THAT I
23 OUTLINED ON THE PREVIOUS SLIDE. AND THEN WE WOULD
24 ALSO, AS WAS THE CASE FOR THE PRECLINICAL PROGRAM,
25 TAKE INTO ACCOUNT NOVELTY OF THE THERAPEUTIC

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1 APPROACH RELATIVE TO THE CLIN2 EXISTING ACTIVE
2 AWARDS AS WELL AS APPROACHES THAT ARE
3 UNDERREPRESENTED IN TERMS OF DISEASE AREA IN OUR
4 ACTIVE AWARDS.

5 YOU'LL HEAR MORE ABOUT THIS FROM DR.
6 SAMBRANO THIS AFTERNOON.

7 SO THIS SLIDE IS JUST TO PRESENT THE
8 STRUCTURE OF THE CLIN2 PROGRAM. THIS PROGRAM WILL
9 BE OFFERED FOUR TIMES PER YEAR, AND THE AWARDS WOULD
10 HAVE A MAXIMUM DURATION OF FOUR YEARS. THIS
11 PROGRAM, UNLIKE THE OTHER CIRM PROGRAMS, WOULD BE
12 OPEN TO BOTH CALIFORNIA AND NON-CALIFORNIA
13 ORGANIZATIONS WHICH IT ALWAYS HAD BEEN. I JUST WANT
14 TO NOTE THAT FOR NON-CALIFORNIA ORGANIZATIONS, THEY
15 ARE REQUIRED TO SPEND ALL OF THEIR CIRM DOLLARS IN
16 THE STATE OF CALIFORNIA. AND WE HAVE THIS ALLOWANCE
17 BECAUSE IT IS POSSIBLE THEN TO ATTRACT INNOVATIVE
18 THERAPIES THAT MIGHT HAVE BEEN ORIGINALLY DEVELOPED
19 ELSEWHERE INTO THE STATE OF CALIFORNIA TO BENEFIT
20 CALIFORNIA PATIENTS.

21 THE TOTAL AWARD AMOUNTS FOR THE CLIN2
22 PROGRAM VARIES DEPENDING ON THE PHASE OF A CLINICAL
23 TRIAL THAT'S BEING PROPOSED. SO FIRST IN HUMAN,
24 PHASE 2, OR SUBSEQUENT. SUBSEQUENT MEANS IT COULD
25 BE A PHASE 1 THAT'S HAPPENING AFTER THE FIRST IN

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1 HUMAN IS ALREADY DONE OR THEN PHASE 3. AND THE
2 CO-FUNDING REQUIREMENTS ARE DIFFERENT DEPENDING ON
3 WHETHER THE APPLICANT IS A FOR-PROFIT OR A
4 NON-PROFIT ORGANIZATION.

5 SO FOR A FOR-PROFIT, AT FIRST IN HUMAN
6 STAGE WE REQUIRE 30 PERCENT. AND THEN FOR ANY LATER
7 STAGE TRIAL IT WOULD BE 50 PERCENT CO-FUNDING. IN
8 CONTRAST FOR A NON-PROFIT ORGANIZATION, THERE WOULD
9 BE NO CO-FUNDING REQUIREMENT UNTIL GETTING TO THE
10 PHASE 3 OR PIVOTAL STAGE WHICH IS REALLY GETTING
11 CLOSE TO COMMERCIALIZATION WHERE YOU REALLY NEED TO
12 HAVE A PARTNER TO CO-INVEST.

13 WE WOULD PROPOSE A TOTAL BUDGET FOR THIS
14 COMING YEAR OF 135 MILLION. THIS AMOUNT SHOULD
15 COVER A VARIETY OF DIFFERENT SCENARIOS DEPENDING ON
16 WHAT PHASE OF TRIAL AND WHETHER THE ORGANIZATION IS
17 FOR-PROFIT OR NON-PROFIT. WE COULD FUND UP TO, FOR
18 EXAMPLE, NINE LATER STAGE TRIALS, PHASE 2 OR BEYOND,
19 AT \$15 MILLION EACH. HOWEVER, THE TRUTH IS 80
20 PERCENT OF OUR TRIALS HISTORICALLY ARE AT THE
21 FIRST-IN-HUMAN STAGE, WHICH HAVE A LOWER FUNDING
22 CAP. SO WE THINK THAT WE COULD GET A NUMBER OF
23 AWARDS APPROVED. THAT'S PROBABLY GOING TO BE AT
24 LEAST THE AMOUNT THAT WE GET HISTORICALLY PER YEAR
25 WHICH IS 13 PER YEAR THAT WERE FUNDED AND PERHAPS

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1 EVEN BEYOND.

2 AND THIS SLIDE JUST SHOWS THE ELIGIBILITY
3 REQUIREMENTS. SEVERAL OF THE POINTS HERE I'VE
4 COVERED ON PREVIOUS SLIDES. BUT I DO WANT TO POINT
5 OUT ONE AREA THAT'S SLIGHTLY MODIFIED FROM WHAT
6 WE'VE DONE HISTORICALLY WHICH IS IN THE CANDIDATE
7 READINESS REQUIREMENT. HISTORICALLY WE'VE ALWAYS
8 REQUIRED THAT TO SUBMIT AN APPLICATION FOR A CLIN2
9 AWARD, THE IND MUST HAVE ALREADY BEEN CLEARED BY THE
10 FDA. AND WE WILL STILL MAINTAIN THAT REQUIREMENT
11 FOR ANY PROGRAMS THAT ARE NOT IN THE CIRM PIPELINE,
12 THEY'RE NEW TO CIRM. HOWEVER, WE WOULD LIKE TO GIVE
13 A SLIGHT ADVANTAGE OR JUST ENABLE THE SMOOTH
14 TRANSITION FOR PIPELINE PROGRAMS SUCH THAT WE WOULD
15 NOT REQUIRE THE IND TO BE CLEARED, BUT IT WOULD HAVE
16 TO BE SUBMITTED BEFORE THEY COULD SUBMIT AN
17 APPLICATION. AND THERE'S A 30-DAY WINDOW THERE WHEN
18 THEY WOULD HEAR BACK FROM THE FDA WHETHER IT'S BEEN
19 CLEARED. THEY WOULD BE REQUIRED TO SUBMIT EVIDENCE
20 THAT THE IND WAS CLEARED IN ORDER FOR THE
21 APPLICATION TO GO TO FULL GRANTS WORKING GROUP
22 REVIEW. AND THIS IS JUST TO HELP ALLOW SMOOTH
23 TRANSITION OF OUR PIPELINE PROGRAMS.

24 THE OTHER CHANGE IS THE TIME TO LAUNCH
25 BETWEEN ICOC APPROVAL AND OFFICIAL LAUNCH OF THE

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1 AWARD WOULD NOW BE 60 DAYS INSTEAD OF 45 DAYS TO
2 ALLOW FOR THE ADMINISTRATIVE WORK THAT NEEDS TO BE
3 DONE DURING THAT STAGE. AND WE HAVE SIMILAR PI AND
4 PROGRAM MANAGER REQUIREMENTS FOR FTE LEVELS THAT
5 WE'VE ALWAYS HAD.

6 AND THIS SLIDE IS JUST TO REITERATE SOME
7 OF THE THINGS I MENTIONED EARLIER, THE NEWER
8 REQUIREMENTS FOR THIS PROGRAM WHICH ARE ALSO
9 REQUIRED FOR OUR OTHER PROGRAMS. WE WOULD REQUIRE
10 THAT APPLICANTS PROPOSE PATIENT ACCESS AND
11 AFFORDABILITY PLANNING IN THEIR PROPOSALS. AND ALSO
12 WE WOULD NOW REQUIRE A DATA SHARING AND MANAGEMENT
13 PLAN BE PROPOSED SO THAT ULTIMATELY, AGAIN, THESE
14 DATA WOULD BE FINDABLE AND ACCESSIBLE FOR THOSE WHO
15 COULD BENEFIT FROM IT IN THE FUTURE.

16 THE CLIN2 PROGRAM HAS ALWAYS BEEN VERY
17 PROACTIVE WITH AWARD MANAGEMENT. WE WOULD CONTINUE
18 TO REQUIRE QUARTERLY SCIENTIFIC PROGRESS REPORTS
19 WHICH ARE ENTERED INTO OUR GRANTS MANAGEMENT SYSTEM.
20 THE SCIENTIFIC OFFICERS READ THOSE AND THEN SCHEDULE
21 FOLLOW-UP CALLS WITH THE AWARDEE TO FOLLOW UP ON ANY
22 QUESTIONS THAT ARISE AND GET MORE DETAIL IF NEEDED.
23 CIRM HAS ALWAYS REQUIRED THAT WE BE INCLUDED IN ANY
24 FDA MEETINGS OR OTHER FDA INTERACTIONS, AND WE WILL
25 STILL REQUIRE THAT. AND WE WOULD ALSO ASK THAT CIRM

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1 BE INCLUDED IN ANY OF THE STRATEGIC PLANNING
2 COMMITTEE MEETINGS.

3 AS YOU KNOW, THESE ARE ALL OPERATIONAL
4 MILESTONE-DRIVEN AWARDS. IN THE CASE THAT AN
5 AWARDEE HAS EXHAUSTED THE FUNDING THAT WAS DISBURSED
6 TO REACH A GIVEN OPERATIONAL MILESTONE, THEN WE
7 REQUIRE THAT THEY HAVE CONTINGENCY FUNDING IN PLACE
8 TO GET TO THAT MILESTONE AND TO GET TO THE NEXT CIRM
9 DISBURSEMENT. AND AN OPERATION MILESTONE DELAY OF
10 MORE THAN FOUR MONTHS WOULD TRIGGER AN EVALUATION
11 JUST TO EVALUATE THE FEASIBILITY THAT THIS PROGRAM
12 WOULD CONTINUE. AND IF IT SEEMS FUTILE, THEN THERE
13 IS THE RIGHT TO TERMINATE THE AWARD IF NEED BE.

14 SO TO CONCLUDE, I JUST WANT TO SHOW YOU
15 THE TIMELINE FOR POTENTIALLY LAUNCHING THE NEW CLIN2
16 PROGRAM. IF YOU SHOULD APPROVE THIS CONCEPT TODAY,
17 WE WOULD OPEN THE APPLICATIONS IN MID-MAY WITH THE
18 FIRST APPLICATION DEADLINES IN JULY, THE FIRST
19 GRANTS WORKING GROUP IN SEPTEMBER, AND THE FIRST
20 APPLICATION REVIEW SUBCOMMITTEE TO LOOK AT THOSE
21 RECOMMENDED BY THE GRANTS WORKING GROUP IN NOVEMBER
22 OF 2025. AND THEN A SECOND CYCLE WILL OPEN IN EARLY
23 AUGUST.

24 SO WITH THAT, I'D LIKE TO CONCLUDE MY
25 PRESENTATION, REQUEST THAT YOU APPROVE THE PROPOSED

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1 CONCEPT PLAN, BUT ALSO ASK IF YOU HAVE ANY QUESTIONS
2 IN ADVANCE.

3 CHAIRMAN IMBASCIANI: THANK YOU, LISA.
4 ANNE-MARIE DULIEGE AND THEN CAROLYN.

5 DR. DULIEGE: JUST EXCELLENT PRESENTATION.
6 A QUICK CLARIFICATION. YOU MENTIONED THAT THE
7 PROGRAM COULD GO UP TO 135 MILLION PER YEAR; IS THAT
8 RIGHT?

9 DR. KADYK: THAT WOULD BE THE ANNUAL
10 BUDGET.

11 DR. DULIEGE: THAT'S AN ANNUAL BUDGET.
12 BUT BECAUSE THIS IS UP TO A FOUR-YEAR PROGRAM
13 POTENTIALLY BASED ON APPLICATIONS, THE TOTAL AMOUNT
14 OF FUNDING THAT WE NEED TO THINK WE PUT ASIDE IS
15 FOUR TIMES THAT MUCH; IS THAT RIGHT?

16 DR. KADYK: NO. NO. IT'S JUST DONE ON AN
17 ANNUAL BASIS. SO FOR THE UPCOMING YEAR WE WOULD
18 HAVE BUDGET OF 135 MILLION. THE NEXT YEAR IT COULD
19 BE A DIFFERENT BUDGET.

20 DR. DULIEGE: I GET THAT. BUT WHEN WE
21 THINK ABOUT THE TOTAL ENVELOPE WE HAVE YEAR AFTER
22 YEAR, THAT COULD BE UP TO FOUR TIMES THAT MUCH.

23 DR. KADYK: YEAH. IF THE BOARD APPROVES
24 SIMILAR BUDGET LEVELS, THAT'S RIGHT. YES.

25 DR. DULIEGE: YES.

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1 DR. MELTZER: THANK YOU, LISA. THIS IS
2 JUST A WONDERFULLY EXCITING PROPOSAL. I WAS JUST
3 WONDERING HOW IT MIGHT INTERACT OR TAKE ADVANTAGE OF
4 THE ALPHA CLINICS NETWORK.

5 DR. KADYK: VERY GOOD QUESTION. AND THAT
6 ACTUALLY IS REALLY GOING TO BE INTEGRAL TO THE
7 PROGRAM ANNOUNCEMENT. ACTUALLY MOST OF OUR CLINICAL
8 TRIAL AWARDS DO HAVE CLINICAL SITES AT THE ALPHA
9 CLINICS, BUT THAT IS GOING AN AREA THAT WE'RE GOING
10 TO EMPHASIZE AND COLLECT EVEN AT THE TIME OF
11 APPLICATION WHETHER THEY'RE WORKING WITH THE ALPHA
12 CLINICS AND TRYING TO ENSURE THAT ANY TRIALS THAT
13 ARE DONE AT AN ALPHA CLINIC SITE ARE WORKING WITH
14 THE ALPHA CLINIC THERE.

15 DR. LEVITT: SO THE LAST SLIDE LOOKS LIKE
16 THE TIMELINES ARE CHANGED, RIGHT, IN TERMS OF OPEN
17 APPLICATION AND APPLICATION REVIEW FROM WHAT WAS.
18 IT'S MY READING OF THAT SLIDE WHICH IS COMPLICATED.

19 DR. KADYK: SOMEHOW I'M HAVING TROUBLE
20 BACKING IT UP.

21 DR. CANET-AVILES: I CAN PROVIDE THE
22 CLARIFICATION.

23 DR. LEVITT: IT MAY BE A CONVERSATION I
24 WANT TO HAVE WITH GIL, I GUESS. I DON'T KNOW.

25 DR. CANET-AVILES: NO. THAT'S A

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1 CONVERSATION -- IT ACTUALLY HAS TO DO WITH THE
2 PROGRAMS THE WAY THAT WE HAVE DEVELOPED THIS. SO
3 THE PART OF THE ACCESS AND AFFORDABILITY PART OF THE
4 APPLICATION IS BEING DEVELOPED, AND IT HAS TO BE
5 APPROVED THROUGH THE ACCESS AND AFFORDABILITY
6 WORKING GROUP. AND THAT MEETING IS APRIL 30TH. SO
7 THAT IS DELAYING THE READINESS OF THE APPLICATION
8 AND THE PROGRAM DETAILS WHICH WILL BE UNDER OUR
9 CO-CHAIR OF THE BOARD AND ALSO CHAIR OF THE
10 ACCESSIBILITY AND AFFORDABILITY WORKING GROUP. SO
11 WE ARE WORKING ON THAT, AND THAT IS WHY THE TIMELINE
12 IS A LITTLE BIT LATER. THANK YOU.

13 DR. LEVITT: SO IF YOU SUBMIT IN JUNE, YOU
14 GET THE DECISION SOMETIME, WHEN, AS AN APPLICANT,
15 YOU GET IT IN DECEMBER OR JANUARY THEN?

16 DR. KADYK: WELL, THE APPLICATION REVIEW
17 SUBCOMMITTEE WOULD BE IN NOVEMBER, SO YOU WOULD HEAR
18 IMMEDIATELY AFTER THAT.

19 DR. LEVITT: SO IMMEDIATELY AFTER THAT.
20 SO YOU GET IT BY DECEMBER, WHICH MEANS THAT YOU THEN
21 CAN REAPPLY -- THE NEXT TIME YOU COULD REAPPLY WOULD
22 BE THE FOLLOWING JUNE?

23 DR. KADYK: YEAH. WELL, YOU WILL RECEIVE
24 THE GRANTS WORKING GROUP SCORE IN SEPTEMBER. IF YOU
25 ARE NOT GETTING A LIKELY RECOMMENDED SCORE, YOU

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1 WOULD KNOW AT THAT STAGE.

2 DR. LEVITT: SO YOU HAVE ACCESS TO THE
3 EARLY NOVEMBER IF YOU COULD MUSTER UP THE --

4 DR. KADYK: YES. OF COURSE, IT WON'T HAVE
5 GONE TO THE APPLICATION REVIEW SUBCOMMITTEE UNTIL
6 NOVEMBER. GO AHEAD.

7 DR. SAMBRANO: JUST TO CLARIFY. SO THERE
8 ARE FOUR CYCLES PER YEAR. GIVEN THE LENGTH OF THE
9 REVIEW PROCESS, SOMEBODY WHO FAILS DURING THE
10 INITIAL CYCLE WILL SKIP A CYCLE AND GO TO THE NEXT
11 ONE. SO IT WILL BE EVERY SIX MONTHS BASICALLY THAT
12 SOMEBODY WOULD BE ABLE TO COME IN.

13 DR. LEVITT: EVERY SIX MONTHS.

14 CHAIRMAN IMBASCIANI: YES, JOHN.

15 DR. CARETHERS: WHAT DO YOU ANTICIPATE IS
16 THE MIX BETWEEN, LET'S SAY, ACADEMIA AND INDUSTRY
17 APPLYING FOR THIS?

18 DR. KADYK: I CAN JUST TELL YOU THAT
19 HISTORICALLY WE'VE FUNDED ABOUT EQUAL NUMBERS OF
20 FOR-PROFIT AND NON-PROFIT ORGANIZATIONS.

21 DR. CARETHERS: AND HOW MANY -- I KNOW THE
22 MONEY IS SUPPOSED TO BE EXPENDED IN CALIFORNIA, BUT
23 HOW MANY OUTSIDE BECAUSE IT'S OPEN TO
24 NON-CALIFORNIA?

25 DR. KADYK: YEAH. IT'S ACTUALLY

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1 RELATIVELY LOW PERCENT THAT COME FROM OUTSIDE
2 CALIFORNIA. I DON'T HAVE THE EXACT NUMBER, BUT I
3 WOULD SAY MAYBE 10 PERCENT, SOMETHING LIKE THAT.

4 DR. CARETHERS: THANK YOU.

5 MR. FISCHER-COLBRIE: YOU JUST MIGHT WANT
6 TO CLARIFY WHAT IT MEANS TO BE OUTSIDE OF CALIFORNIA
7 BECAUSE THAT COMES WITH A SEVERE LIMITATION. AND
8 I'M NOT SURE THAT PEOPLE ARE COGNIZANT AS TO WHAT
9 THAT IS. SO IT'S NOT BROADLY OPEN TO OUTSIDE
10 CALIFORNIA.

11 DR. KADYK: WELL, FIRST OF ALL, WE HAVE A
12 DEFINITION FOR A CALIFORNIA ORGANIZATION, THAT THEY
13 NEED TO SPEND -- THEY HAVE TO HAVE AT LEAST MORE
14 THAN -- 50 PERCENT PLUS ONE OF THE EMPLOYEES, THE W2
15 EMPLOYEES, HAVE TO BE PAID IN CALIFORNIA. IS THAT
16 THE MAIN THING THAT YOU'RE DRIVING AT THERE?

17 MR. FISCHER-COLBRIE: FOR ORGANIZATIONS
18 OUTSIDE OF CALIFORNIA, SOMETIMES IF THERE'S A
19 CLINICAL TRIAL BEING HELD IN CALIFORNIA, MY
20 UNDERSTANDING IS THERE'S A POSSIBILITY OF FUNDING
21 FOR THAT.

22 DR. KADYK: YEAH. AS I WAS SAYING, ANY
23 APPLICATION -- AWARDEE THAT'S BASED OUTSIDE OF
24 CALIFORNIA HAS TO SPEND ALL THE DOLLARS IN
25 CALIFORNIA. SO IN THE CASE OF A CLINICAL TRIAL, IT

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1 WOULD BE THAT THEY HAVE TO BE SPENDING MONEY ON
2 PATIENTS THAT ARE TREATED AT CLINICAL TRIAL SITES IN
3 CALIFORNIA.

4 MR. FISCHER-COLBRIE: THANK YOU. I JUST
5 WANTED TO MAKE SURE EVERYONE WAS AWARE OF THE
6 DIFFERENCE.

7 CHAIRMAN IMBASCIANI: ARE THERE ANY OTHER
8 QUALIFYING QUESTIONS? IF NOT, SURPRISE, SURPRISE,
9 WE HAVE A MOTION.

10 VICE CHAIR BONNEVILLE: I'D LIKE MAKE A
11 MOTION TO APPROVE THE CLIN2 CONCEPT PLAN AND TO
12 DELEGATE TO THE CEO THE AUTHORITY TO MAKE AND
13 IMPLEMENT CHANGES TO THE CONCEPT PLAN IN BETWEEN
14 BOARD MEETINGS UPON CONSULTATION OF THE CHAIRS AND
15 CO-CHAIRS OF THE ICOC SUBCOMMITTEES AND TO BRING
16 THOSE CHANGES BEFORE THE BOARD AT THE NEXT
17 OPPORTUNITY FOR RATIFICATION.

18 DR. BARRETT: SECOND.

19 CHAIRMAN IMBASCIANI: THANK YOU, DR.
20 BARRETT. WE HAVE A MOTION AND SECOND. IT'S OPEN
21 FOR DISCUSSION AMONG BOARD MEMBERS ON CLIN2 CONCEPT
22 PLAN. NOT SEEING ANY BOARD MEMBERS' HANDS, AND
23 MEMBERS OF THE PUBLIC ARE INVITED. AND NO ONE IN
24 THE ROOM. THANK YOU VERY MUCH. SCOTT, WE CAN
25 PROCEED TO A VOTE. THANK YOU.

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1 MR. TOCHER: ALL THOSE IN THE ROOM IN
2 FAVOR SAY AYE. OPPOSED SAY NAY. ANY ABSTENTIONS?
3 I'LL POLL THE MEMBERS ON THE PHONE.

4 MONICA CARSON. YSABEL DURON.

5 MS. DURON: YES.

6 MR. TOCHER: RICH LAJARA.

7 MR. LAJARA: YES.

8 MR. TOCHER: SHLOMO MELMED.

9 DR. MELMED: YES.

10 MR. TOCHER: CHRIS MIASKOWSKI.

11 DR. MIASKOWSKI: YES.

12 MR. TOCHER: JOE PANETTA. SUZANNE
13 SANDMEYER.

14 DR. SANDMEYER: YES.

15 MR. TOCHER: KAROL WATSON.

16 DR. WATSON: YES.

17 MR. TOCHER: AND KEVIN XU.

18 DR. XU: YES.

19 CHAIRMAN IMBASCIANI: LOOK NOW FOR
20 GUIDANCE. IS THE VOTE COMPLETE?

21 MR. TOCHER: THE MOTION CARRIES. AND WE
22 HAVE ONE VERY BRIEF ITEM THAT WE CAN GET TO BEFORE
23 LUNCH WHICH WILL EXPEDITE YOUR JOURNEY HOME THIS
24 AFTERNOON. SO IF YOU WOULD LIKE, WE COULD PROCEED
25 THEN WITH ITEM, I BELIEVE IT IS, 15.

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1 CHAIRMAN IMBASCIANI: YES. OKAY. I WOULD
2 LIKE TO INTRODUCE -- THIS IS RECOMMENDATIONS FROM
3 THE GOVERNANCE SUBCOMMITTEE REGARDING CIRM'S
4 LONG-STANDING PURCHASING POLICY. AND WE HAVE AT THE
5 PODIUM CHIEF COUNSEL RAFAEL AGUIRRE-SACASA AND
6 DIRECTOR OF FINANCE MICHELLE LEWIS -- WE HAVE TWO
7 LEWISES ON OUR PAYROLL NOW -- JOINED US IN DECEMBER
8 AND HAS ALREADY MADE A GREAT IMPACT IN OUR FINANCIAL
9 POSITIONING. THANK YOU.

10 MR. AGUIRRE-SACASA: THANK YOU VERY MUCH,
11 CHAIR IMBASCIANI, VICE CHAIR BONNEVILLE, ICOC
12 MEMBERS, MEMBERS OF THE PUBLIC, AND COLLEAGUES.
13 THANK YOU FOR HAVING US TODAY. WE'RE HERE TO TALK
14 ABOUT THE PURCHASING POLICY WHICH IS INTENDED TO
15 REPLACE THE OLD CONTRACTING POLICY WHICH WAS
16 APPROVED LAST BY THIS BOARD IN 2016.

17 I'M GOING TO GIVE A QUICK OVERVIEW OF THE
18 MEMO AND THEN TURN IT OVER TO MICHELLE SO SHE CAN GO
19 INTO HER PRESENTATION.

20 THE NEW POLICY REMOVES EXTRANEIOUS CONTENT
21 AND OPERATIONAL PROCEDURES, AND IT FOCUSES ON
22 PROCUREMENT GOVERNANCE AND COMPLIANCE, CLARITY, AND
23 EFFICIENCY. WE'RE IN THE PROCESS OF DEVELOPING THE
24 STANDARD OPERATING PROCEDURES THAT WILL FLOW FROM
25 THE POLICY, BUT WE WANTED TO GET THE POLICY

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1 APPROVED. ONCE THOSE PROCEDURES ARE FINALIZED,
2 WE'LL BE PRESENTING THEM TO J.T. FOR FINAL APPROVAL.

3 WE THINK THAT THE NEW POLICY WILL BE
4 EASIER TO TRAIN, ADMINISTER, AND MOST IMPORTANTLY
5 COMPREHEND FOR OUR USERS. THAT LEADS TO BETTER
6 COMPLIANCE, OF COURSE.

7 SOME OF THE BIG TOPICS THAT WE DID IS THAT
8 WE CLARIFIED THE CONTRACT DURATION LIMITS BY
9 ESTABLISHING A MAXIMUM OF TEN YEARS, AND THAT
10 INCLUDES ANY EXTENSIONS THEREOF. WE STANDARDIZED
11 THE APPROVAL AUTHORITY TO ALIGN WITH OUR FINANCIAL
12 THRESHOLD. AND THE NEW POLICY ENHANCES REPORTING
13 COMPLIANCE REQUIREMENTS THROUGH STRICTER MONITORING
14 MEASURES TO ENSURE CONTRACT ADHERENCE AND POTENTIAL
15 ELIMINATION OF CONFLICTS OF INTEREST.

16 MICHELLE, TURN IT OVER TO YOU. THANK YOU.

17 MS. LEWIS: THANK YOU, MEMBERS OF THE
18 BOARD, CIRM STAFF, AND MEMBERS OF THE PUBLIC. IN
19 PRESENTING OUR NEW POLICY, I'D LIKE TO DISCUSS SOME
20 OF THE PROPOSED CHANGES TO THE CURRENT CONTRACTING
21 POLICY. WE'VE REVISED AND STREAMLINED THE PREVIOUS
22 POLICY. SO THE NEW POLICY WOULD BE TITLED
23 "PURCHASING POLICY."

24 THIS REVISED POLICY INCLUDES ALL PURCHASE
25 TYPES AND FOCUSES ON PROCUREMENT GOVERNMENT,

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1 TRANSPARENCY, AND EFFICIENCY. IT REMOVES THE
2 OPERATING PROCEDURES TO FOCUS ON A STREAMLINED
3 DOCUMENT WITH HIGH LEVEL POLICY. AS RAFAEL STATED,
4 WE ARE WORKING WITH THE FINANCE AND LEGAL TEAMS ON
5 THE OPERATING PROCEDURES, AND THEN WE WILL PRESENT
6 THEM TO THE PRESIDENT FOR APPROVAL.

7 THE REVISED POLICY REINFORCES COMPETITIVE
8 BIDDING AND SUPPLIER DIVERSITY WHILE ALSO
9 EMPHASIZING COMPLIANCE AND AUDITING MEASURES.

10 A FEW OF THE HIGHLIGHTS OF THE CHANGES ARE
11 THAT WE REMOVED THE LOW LEVEL SCOPE THAT SHOULD BE
12 PLACED IN A STANDARD OPERATING PROCEDURE. EXAMPLES
13 OF SOME OF THOSE ARE THE LOWER LEVEL DEFINITIONS
14 SUCH AS EMPLOYER TO EMPLOYEE RELATIONSHIP AND A LOT
15 OF THE PAYMENT REQUIREMENTS THAT WERE MUCH LOWER
16 LEVEL. WE ALSO REMOVED APPENDICES 1 THROUGH 3 THAT
17 WERE BASICALLY JUST TYPES OF ONE CONTRACT THAT
18 SHOULD ALSO BE PLACED IN A STANDARD OPERATING
19 PROCEDURE.

20 THIS POLICY HAS ALREADY BEEN PRESENTED TO
21 THE GOVERNANCE SUBCOMMITTEE WHO HAVE RECOMMENDED
22 APPROVAL. SO CIRM ASKS FOR APPROVAL OF THE
23 PURCHASING POLICY. THANK YOU.

24 MR. AGUIRRE-SACASA: I KNOW THERE'S BEEN
25 DISCUSSION ABOUT PAGE COUNT. SO THE PREVIOUS POLICY

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1 WAS ABOUT 20 PAGES. NOW WE'RE DOWN TO FOUR. SO
2 MOVING IN THE RIGHT DIRECTION, I THINK.

3 CHAIRMAN IMBASCIANI: THE 20-PAGE VERSION
4 WAS VERY USER UNFRIENDLY, AND THE NEW VERSION IS SO
5 USER FRIENDLY PEOPLE WILL ACTUALLY REFER TO IT.

6 MR. FISCHER-COLBRIE: SO MOVED.

7 CHAIRMAN IMBASCIANI: WE HAVE A MOVEMENT
8 TO ACCEPT. DISCUSSION AMONG BOARD MEMBERS?

9 DR. MADANAT: SECOND.

10 CHAIRMAN IMBASCIANI: WE HAVE A
11 MOVEMENT -- MOTION AND SECOND. ANY DISCUSSION AMONG
12 BOARD MEMBERS? OKAY. ANYONE FROM THE PUBLIC WANT
13 TO COMMENT ON OUR NEW PURCHASING POLICY? NOT SEEING
14 ANY, SCOTT, WE MAY VOTE AND GO TO LUNCH.

15 MR. TOCHER: ALL THOSE IN THE ROOM IN
16 FAVOR SAY AYE. OPPOSED SAY NAY. ANY ABSTENTIONS?
17 AND FOR THE MEMBERS ON ZOOM.

18 MONICA CARSON. YSABEL DURON.

19 MS. DURON: YES.

20 MR. TOCHER: RICH LAJARA.

21 MR. LAJARA: YES.

22 MR. TOCHER: SHLOMO MELMED.

23 DR. MELMED: YES.

24 MR. TOCHER: CHRIS MIASKOWSKI.

25 DR. MIASKOWSKI: YES.

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1 MR. TOCHER: JOE PANETTA. SUZANNE
2 SANDMEYER.

3 DR. SANDMEYER: YES.

4 MR. TOCHER: KAROL WATSON.

5 DR. WATSON: YES.

6 MR. TOCHER: AND KEVIN XU.

7 DR. XU: YES.

8 MR. TOCHER: GREAT. THANKS VERY MUCH.
9 THAT MOTION CARRIES.

10 WE WILL ADJOURN MOMENTARILY FOR LUNCH.
11 AND WE WOULD SUGGEST MEETING BACK AT 12:45. WE WILL
12 HAVE -- WE ARE ABOUT TO PASS OUT YOUR LUNCH TICKETS
13 THAT HAVE YOUR PREFERENCE FOR YOU. SO DON'T WANDER
14 FAR. CLAUDETTE IS GOING TO HAND THOSE OUT TO YOU
15 AND LANA AS WELL. FOR THOSE ON THE ZOOM, WE'LL SEE
16 YOU AT ABOUT QUARTER TO ONE.

17 (A RECESS WAS TAKEN.)

18 CHAIRMAN IMBASCIANI: LADIES AND
19 GENTLEMEN, I THINK WE'RE READY TO RECONVENE AFTER A
20 LUNCH BREAK. I DIRECT YOUR ATTENTION TO AGENDA ITEM
21 14. WE'RE GOING TO SEGUE AWAY FROM THE SAF AND TAKE
22 UP THE COMMUNITY CARE CENTERS OF EXCELLENCE CONCEPT
23 PLAN, WHICH WILL BE PRESENTED BY VICE CHAIR MARIA
24 BONNEVILLE.

25 VICE CHAIR BONNEVILLE: THANK YOU, VITO.

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1 EARLIER THIS MONTH THE AAWG RECOMMENDED TO THE BOARD
2 A NEW CONCEPT PLAN FOR THE COMMUNITY CARE CENTERS.
3 THE FACT THAT THE CCCE'S SPECIFICALLY CALLED OUT IN
4 OUR PROPOSITION IS VERY SIGNIFICANT AND UNIQUE, AND
5 IT SHOWS HOW IMPORTANT IT IS TO OUR MISSION.

6 THE TEAM IN LOOKING VERY HARD AT THIS
7 PROGRAM HAS FOUND THAT WE CAN IMPROVE IT AND REACH
8 MORE PATIENTS FOR A LONGER PERIOD WITH A REVISED
9 CONCEPT PLAN. SO I WANT TO CONGRATULATE THE TEAM
10 FOR HAVING THE COURAGE TO COURSE CORRECT AND COME TO
11 US WITH THIS DECISION.

12 THE STRATEGIC ALLOCATION FRAMEWORK AND
13 PRIORITIZATION HIGHLIGHT THE KEY ROLE OF CIRM'S
14 INFRASTRUCTURE PROGRAMS AND THE ROLE THAT THEY PLAY
15 IN DELIVERING TRIALS AND THERAPIES TO MORE
16 CALIFORNIANS. THE CHANGES PROPOSED WILL ALLOW FOR
17 TWO ROUNDS OF FUNDING MOVING FORWARD, AND THIS IS
18 CRITICAL BECAUSE WE KNOW THAT OUR INFRASTRUCTURE
19 PROGRAMS GET BETTER WITH MORE TIME. OFFERING TWO
20 ROUNDS OF FUNDING GIVES THEM A CHANCE TO FIRMLY
21 ESTABLISH THEMSELVES IN THE COMMUNITIES THEY SERVE
22 TO TREAT MORE PATIENTS, AND IT ALIGNS WITH THE
23 MISSION OF PROP 14 TO BRING TRIALS AND TREATMENTS TO
24 THE PEOPLE OF CALIFORNIA. GEOFF LOMAX WILL WALK US
25 THROUGH THE CONCEPT PLAN.

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1 DR. LOMAX: THANK YOU VERY MUCH FOR THAT
2 INTRODUCTION. AND THANKS TO THE CIRM EXECUTIVE TEAM
3 FOR THE OPPORTUNITY TO GUIDE THIS PROGRAM IN ITS
4 DEVELOPMENT. AND THE CIRM TEAM IN GENERAL, AS
5 YOU'VE SEEN FROM ALL THESE PRESENTATIONS, THERE'S
6 JUST BEEN AN AMAZING SUPPORT IN TERMS OF BRINGING
7 TOGETHER THE INFORMATION, THE PRESENTATION. AND
8 THAT'S BEEN A HUGE SUPPORT FOR ME BECAUSE MY TEAM IS
9 A LITTLE BIT THIN AT THE MOMENT, SO IT TAKES A
10 VILLAGE. SO THANK YOU FOR THAT.

11 JUST AS A REMINDER, THIS CONCEPT PACKAGE
12 AND THE SUPPORTING MATERIALS, THE PRESENTATIONS ARE
13 AVAILABLE UNDER THIS AGENDA ITEM ONLINE FOR FOLKS
14 WHO MAY BE LISTENING ONLINE OR THE PUBLIC.

15 AND, AGAIN, AS MARIA NOTED, WHAT I'M
16 PRESENTING WAS RECOMMENDED -- BROUGHT TO YOU WITH A
17 RECOMMENDATION FOR APPROVAL BY THE ACCESS AND
18 AFFORDABILITY WORKING GROUP, AND THAT MEETING WAS
19 MARCH 10TH.

20 THESE ARE MEMBERS WITH A CONFLICT OF
21 INTEREST. IT'S A FAIRLY EXTENSIVE LIST. SO JUST AS
22 A REMINDER, IF THERE'S DISCUSSION OF THIS ITEM, YOU
23 SHOULD NOT ENGAGE IN THAT DISCUSSION. I GOT A NOD
24 FROM SCOTT. SO THAT IS A TRUE STATEMENT.

25 THIS PRESENTATION WILL DEVIATE A LITTLE

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1 BIT FROM THE FORMULA WE HAD WITH THE OTHER ONES IN
2 PART BECAUSE, AGAIN, THIS IS A LITTLE BIT OF A
3 DIFFERENT CONTEXT WHERE WE'VE REVISING AN EXISTING
4 CONCEPT PLAN. AND I'M GOING TO PROVIDE BACKGROUND
5 WHICH WILL PROVIDE THE RATIONALE FOR WHY THE
6 RECOMMENDATION TO REVISE IS BEING BROUGHT FORWARD TO
7 YOU. AND THEN IN THE SECOND PART DESCRIBE THE CORE
8 ELEMENTS OF THE CONCEPT PLAN FOLLOWED BY A REQUEST
9 FOR A MOTION.

10 AGAIN, AS CO-CHAIR BONNEVILLE ALLUDED TO,
11 IN THE CONTEXT OF THE COMMUNITY CARE CENTERS OF
12 EXCELLENCE, THEY ARE ALSO CALLED OUT IN PROPOSITION
13 14 WITH THE AIM OF EXPANDING THE CAPACITY OF THE
14 ALPHA CLINICS. AND THAT CAPACITY SPECIFICALLY IS
15 THE ABILITY TO PROVIDE ACCESS AND CONDUCT CLINICAL
16 TRIALS AND PROVIDE APPROVED TREATMENTS THAT ARISE
17 FROM INSTITUTE-FUNDED RESEARCH.

18 FURTHER, THE PROPOSITION EMPHASIZES
19 GEOGRAPHICALLY DIVERSE CENTERS. AGAIN, KNOWING THAT
20 OUR CURRENT CLINICAL NETWORK IS SOMEWHAT
21 CONCENTRATED, THE IDEA IS TO EXPAND THE REACH
22 GEOGRAPHICALLY. AND THEN ONE POINT THAT ISN'T
23 REFLECTED IN THIS SLIDE IS THAT THE PROPOSITION ALSO
24 DIRECTS THE INSTITUTE TO HAVE THIS PROGRAM IN PLACE
25 BY 2025. SO THERE'S SOMEWHAT OF A TIME IMPERATIVE

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1 TO MOVE FORWARD BASED ON THE LANGUAGE OF THE
2 PROPOSITION.

3 IN TERMS OF THE STRATEGIC ALLOCATION
4 FRAMEWORK THAT WAS APPROVED IN SEPTEMBER, THE
5 FRAMEWORK PROVIDES A ROADMAP FOR ALL OUR PROGRAMS.
6 AND GOAL 5 REALLY FOCUSES ON OUR CLINICAL
7 INFRASTRUCTURE BROADLY, INCLUDING, BUT NOT LIMITED
8 TO, THE COMMUNITY CARE CENTERS OF EXCELLENCE. AND
9 IN THIS CASE ONE OF THE SUB-OBJECTIVES IS TO DEPLOY
10 THIS INFRASTRUCTURE IN A VERY STRATEGIC MANNER TO
11 ENHANCE THE REFERRAL, ENROLLMENT, AND RETENTION OF
12 CALIFORNIA PATIENTS IN CLINICAL TRIALS. SO TO
13 REALLY BRING THAT TRIAL VISIBILITY AND ACCESS
14 FORWARD TO CALIFORNIA PATIENTS.

15 AND ONE OF THE UNDERLYING RATIONALES FOR
16 BRINGING A REVISED PLAN FORWARD TO YOU IS THAT WE
17 BELIEVE IN ITS REVISED FORMAT IT BEST SERVES BOTH
18 THE PREVIOUS OBJECTIVES OUTLINED IN PROPOSITION 14
19 AND GOAL 5 IN THE STRATEGIC ALLOCATION FRAMEWORK.
20 THUS, PROVIDING STRONG ALIGNMENT AND DIRECTION
21 MOVING FORWARD.

22 SO THE OBJECTIVE OF CIRM'S CLINICAL
23 INFRASTRUCTURE. IN TERMS OF OPERATIONS, CIRM'S
24 COMMUNITY CARE CENTERS OF EXCELLENCE WOULD FIT INTO
25 A BROADER SET OF INFRASTRUCTURE. AND THE AIM IS TO

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1 ENSURE OPERATIONAL INTERCONNECTIVITY BETWEEN THESE
2 ELEMENTS BECAUSE THEY COMPLEMENT EACH OTHER IN TERMS
3 OF SERVING PATIENTS.

4 AS YOU MAY BE AWARE, THE ALPHA CLINIC
5 NETWORK CURRENTLY HAS SUPPORTED ABOUT 337 TRIALS AS
6 OF LAST AUGUST. THAT INCLUDES BOTH CIRM-FUNDED
7 TRIALS AND TRIALS IN THE REGENERATIVE MEDICINE SPACE
8 MORE BROADLY. WE'VE LAUNCHED A PATIENT SUPPORT
9 PROGRAM WHICH PROVIDES LOGISTICAL AND FINANCIAL
10 SUPPORT TO PATIENTS WHO ARE ENROLLED IN CLINICAL
11 TRIALS. AND, AGAIN, THE COMMUNITY CARE CENTERS OF
12 EXCELLENCE WOULD BROADEN THE REACH OF THIS DELIVERY
13 SYSTEM TO INCLUDE AREAS OF THE STATE THAT CURRENTLY
14 HAVE LESS ACCESS TO CLINICAL TRIALS. AND THEN,
15 AGAIN, THE CONNECTION TO CIRM'S CLINICAL PROGRAMS
16 THAT WE DISCUSSED, AND QUESTIONS CAME UP EARLIER
17 ABOUT THE ALPHA CLINICS, FOR EXAMPLE. WE'VE HAD
18 CONNECTIVITY BETWEEN THE CLINICAL PROGRAMS AND THIS
19 INFRASTRUCTURE.

20 SO I'LL NOW UPDATE YOU ON OUR EXPERIENCE
21 WITH THE INITIAL CYCLE OF THE COMMUNITY CARE CENTERS
22 PROGRAM. THE INITIAL CYCLE, I THINK MANY OF YOU ARE
23 AWARE, MAYBE THE NEWER MEMBERS, JUST FOR YOUR
24 BENEFIT, THERE WERE ACTUALLY TWO OPTIONS IN THE
25 ORIGINAL PROGRAM. THE APPLICANT COULD COME IN AS A

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1 SUPPORT SITE OR WHAT WE CALL A SUPPORT AND DELIVERY
2 SITE.

3 SO SUPPORT SITES WERE DESIGNED TO BE
4 PATIENT REFERRAL AND NAVIGATION CENTERS TO SUPPORT
5 PATIENTS IN THEIR CLINICAL TRIAL JOURNEY, BUT NOT
6 DELIVER THE THERAPEUTIC PRODUCT OR AN APPROVED
7 PRODUCT.

8 A SUPPORT AND DELIVERY SITE WOULD PERFORM
9 THOSE FUNCTIONS AS WELL, BUT IT WOULD ALSO INCLUDE
10 THE CONDUCT AND DELIVERY OF A CLINICAL TRIAL AND THE
11 CAPACITY TO DELIVER APPROVED TREATMENTS.

12 WE RECEIVED NINE TOTAL APPLICATIONS. FOUR
13 WERE FOR SUPPORT ONLY SITES AND FIVE WERE FOR
14 SUPPORT AND DELIVERY SITES. THOSE APPLICATIONS
15 UNDERWENT -- ALL THE APPLICATIONS UNDERWENT A REVIEW
16 BY THE GRANTS WORKING GROUP, AND A PORTION OF THOSE
17 APPLICATIONS WERE REVIEWED BY THE FACILITIES WORKING
18 GROUP. AND THE RESULT OF THAT, ONLY ONE APPLICATION
19 RECEIVED A FUNDING RECOMMENDATION AND EIGHT OTHER
20 APPLICATIONS WERE NOT RECOMMENDED FOR FUNDING. THE
21 ONE THAT DID RECEIVE A FUNDING RECOMMENDATION WAS A
22 SUPPORT ONLY SITE.

23 SO AS I INDICATED EARLIER, THE STRATEGIC
24 ALLOCATION FRAMEWORK CAUSED US TO REFLECT ON WHETHER
25 THE COMMUNITY CARE CENTERS OF EXCELLENCE IN ITS

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1 ORIGINAL FORMULATION ALIGNED WITH OUR GOAL 5. AND
2 ONE OF THE CAUSES FOR CONCERN IN THIS CASE WERE
3 BUDGET CONSIDERATIONS. AND SO PROPOSITION 14
4 ESTABLISHES A TOTAL LIFETIME CAP ON EXPENDITURES FOR
5 THIS PROGRAM, AND THAT CAP IS SET AT 78 MILLION.
6 HAD WE MOVED FORWARD WITH THE APPLICATIONS WHICH I
7 DESCRIBED IN THE PREVIOUS SLIDE WHERE WE HAD ONE
8 RECOMMENDED FOR FUNDING AND THEN THERE WAS A NUMBER
9 OF ADDITIONAL PROGRAMS THAT WE COULD HAVE BROUGHT
10 BACK AS REAPPLICATION, COLLECTIVELY THERE WAS A
11 POTENTIAL TO DEplete 60.2 MILLION OF THAT 78 MILLION
12 ALLOCATION FOR THIS PROGRAM, WHICH WOULD HAVE LEFT A
13 REMAINDER OF 17.8 MILLION.

14 THE CONCERN WE HAD WITH THAT REMAINING
15 AMOUNT OF FUNDING IS THAT IT WOULD BE INSUFFICIENT
16 TO DEVELOP THE PROGRAM. FOR EXAMPLE, IF THE SITES
17 NEEDED A SECOND ROUND OF FUNDING, THE FUNDS SIMPLY
18 WOULD NOT BE AVAILABLE. AND THE REASON THAT CONCERN
19 IS QUITE RELEVANT IS WE DID LEARN WITH THE ALPHA
20 CLINICS PROGRAM, FOR EXAMPLE, IT TOOK A NUMBER OF
21 YEARS TO REALLY MOVE THAT PROGRAM TO THE POINT
22 WHERE -- IT TOOK TWO FUNDING CYCLES TO WHERE WE ARE
23 TODAY WHERE THOSE 337 TRIALS I POINTED OUT, THE VAST
24 MAJORITY OF THEM HAVE COME ON BOARD IN THE LAST FIVE
25 YEARS OR SO OF THE PROGRAM. SO THERE'S KIND OF A

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1 RUN WAVE THAT WE EXPERIENCED WITH THESE PROGRAMS.

2 SO BY REVISING THE CONCEPT, WE AIM TO
3 PROVIDE A SUSTAINABLE FINANCIAL FRAMEWORK FOR BOTH
4 COMMUNITY CARE CENTERS, WHICH WOULD BE SITES THAT
5 WOULD BE DELIVERING TREATMENTS SIMILAR TO AN ALPHA
6 CLINIC AND FUTURE SUPPORT ONLY SITES. AND I'LL
7 DESCRIBE THAT MOVING FORWARD.

8 SO SOME ADDITIONAL INSIGHTS FROM THE FIRST
9 ROUND. AGAIN, THE SUSTAINABILITY CONCERNS, I
10 DISCUSSED THAT ON THE PREVIOUS SLIDE. GEOGRAPHIC
11 DIVERSITY GAPS. WHILE APPLICATIONS CAME FROM
12 VARIOUS AREAS, THEY DIDN'T NECESSARILY FULLY ALIGN
13 WITH WHAT WE WERE TRYING TO ACCOMPLISH IN TERMS OF
14 SERVING POPULATIONS THAT WOULD OTHERWISE NOT HAVE
15 ACCESS TO CLINICAL TRIAL OPPORTUNITIES.

16 AS I INDICATED AT THE BEGINNING, THE
17 ALIGNMENT WITH PROPOSITION 14 AND THE ABILITY TO
18 PROVIDE CLINICAL TRIAL DELIVERY WAS PARTIALLY THERE,
19 BUT AGAIN WE HAD SOME CONCERNS WITH THE SUPPORT ONLY
20 SITES. AND, AGAIN, WE FELT WE REALLY NEEDED THIS
21 COMPREHENSIVE APPROACH TO FUND BOTH DELIVERY AND
22 SUPPORT. AND I'LL TOUCH ON THAT IN A MOMENT.

23 AGAIN, WE'VE BROUGHT FORWARD A REVISED
24 PLAN. WHAT I WANT TO DESCRIBE HERE IS SORT OF BOTH
25 THE IDEA OF HOW WE WILL ADDRESS THE COMMUNITY CARE

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1 CENTERS OF EXCELLENCE MOVING FORWARD AND OUR
2 THINKING IN TERMS OF HOW SUPPORT SITES COULD BE
3 INCLUDED IN SUBSEQUENT FUNDING PROGRAMS.

4 SO WE'RE SUGGESTING A TWO-PHASE APPROACH.
5 FIRST OF ALL, THE REVISED RFA, WHICH YOU HAVE A
6 REVISED CONCEPT PLAN WHICH YOU HAVE BEFORE YOU WOULD
7 ALLOW FOR SITES THAT WERE PROPOSING THE DELIVERY OF
8 CLINICAL TRIALS TO COME BACK IN THIS YEAR AND
9 REAPPLY AS SUPPORT AND DELIVERY SITES UNDER THE
10 COMMUNITY CARE CENTERS OF EXCELLENCE PROGRAM.

11 AND IN ADDITION DURING -- AND THIS PROGRAM
12 WOULD BE FOCUSED ON DEPLOYING THE 78 MILLION WITH
13 THE OPTION OF HAVING TWO FUNDING CYCLES. AGAIN, A
14 CYCLE THIS YEAR AND A FUTURE FUNDING CYCLE IF THAT
15 WAS WHAT THE BOARD CHOSE TO DO.

16 IN ADDITION, WE HAVE A SET OF FUNDS THAT
17 THE ACCESS AND AFFORDABILITY WORKING GROUP CAN
18 DEPLOY. THOSE FUNDS ARE ON THE ORDER OF 93 MILLION.
19 AND THAT THOSE FUNDS BE DEDICATED TOWARDS THE
20 PATIENT SUPPORT ACTIVITIES THAT WERE INCLUDED IN THE
21 ORIGINAL CONCEPT PLAN.

22 SORRY. I JUST WANT TO GO BACK TO THAT
23 SLIDE. I JUST HAD A COUPLE OF OTHER COMMENTS THERE.

24 ONE OF THE THINGS I WANTED TO SORT OF
25 HIGHLIGHT WITH THIS APPROACH, BECAUSE I KNOW YOU'VE

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1 SEEN A NUMBER OF -- THERE'S BEEN COMMENTS AND
2 LETTERS SUBMITTED PURSUANT TO THIS ITEM -- IS THAT
3 THIS APPROACH ACTUALLY PROVIDES A MUCH MORE ROBUST
4 AND LONGER TERM FUNDING FOR BOTH PROGRAMS. IT
5 ENABLES UP TO TWO CYCLES OF FUNDING FOR THE
6 COMMUNITY CARE CENTERS, AND WITH AAWG SUPPORT IT
7 DEDICATES ADDITIONAL RESOURCES THAT COULD SUPPORT
8 THE PATIENT ACCESS ACTIVITIES. SOME OF THOSE
9 CONCERNS HAVE COME UP IN COMMENTS AND LETTERS FROM
10 APPLICANTS. AND, AGAIN, REALLY EMPHASIZING THAT
11 THIS APPROACH DEDICATES -- ALLOWS US TO DEDICATE FAR
12 GREATER RESOURCES TOWARDS THE COMBINED PROGRAMS.

13 SO WITH THAT, I'D LIKE TO SWITCH GEARS AND
14 DESCRIBE THE CONCEPT PLAN YOU HAVE BEFORE YOU. JUST
15 GOING TO TAKE ONE BREAK FOR A MOMENT.

16 SO THE OBJECTIVE OF THE REVISED CONCEPT
17 PLAN IS TO EXPAND GEOGRAPHICALLY DIVERSE CENTERS OF
18 EXCELLENCE ACROSS CALIFORNIA, AGAIN, TO ENHANCE
19 PATIENT ACCESS TO REGENERATIVE MEDICINE TREATMENTS
20 WITH EXPANDING THE REACH AND DELIVERY OF CLINICAL
21 TRIALS AND APPROVED THERAPIES. IN ADDITION,
22 CONSISTENT WITH THE ORIGINAL CONCEPT PLAN, THE AIM
23 WOULD ALSO BE TO DEVELOP A SKILLED WORKFORCE AND
24 SUPPORT THE DELIVERY OF REGENERATIVE MEDICINE
25 TREATMENTS BROADLY, PARTICULARLY IN COMMUNITIES THAT

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1 MAY, AGAIN, NOT HAVE ACCESS TO THOSE TREATMENTS.
2 AGAIN, THE WORKFORCE COMPONENT IS SOMETHING THAT'S
3 CONSISTENT ACROSS ALL OF OUR INFRASTRUCTURE
4 PROGRAMS. SO THIS IS WHERE WE -- THIS IS OUR
5 OPPORTUNITY TO DEVELOP THE CLINICAL WORKFORCE IN THE
6 STATE.

7 THE MAXIMUM DURATION OF THE AWARD WILL BE
8 FIVE YEARS. AGAIN, THIS IS ALL HIGHLY CONSISTENT
9 WITH THE ORIGINAL CONCEPT PLAN. MUST BE A
10 NON-PROFIT ORGANIZATION LOCATED IN CALIFORNIA. I
11 WANT TO JUST HIGHLIGHT THAT POINT. I BELIEVE IN ONE
12 OF THE PUBLISHED MATERIALS THE NON-PROFIT
13 ORGANIZATION ASPECT MANY NOT HAVE BEEN CLEARLY
14 STATED.

15 SO FOR THE RECORD, I'D LIKE TO STATE IT
16 CLEARLY HERE. AGAIN, A COMMITMENT TO CELL AND GENE
17 THERAPIES FROM ANY SOURCE. SO IF YOU'RE APPLYING
18 FOR THIS PROGRAM, THE POINT THERE IS THAT, FOR
19 EXAMPLE, IF THERE WAS A TREATMENT UTILIZING HUMAN
20 EMBRYONIC STEM CELLS, THAT THAT TREATMENT WOULD HAVE
21 TO BE MADE AVAILABLE IF YOU HAVE THE CAPACITY. WE
22 WOULDN'T BE ABLE TO SORT OF DISCRIMINATE AGAINST ANY
23 OF THE PRODUCTS IN OUR PIPELINE.

24 THE ORGANIZATION CANNOT HAVE AN EXISTING
25 ALPHA CLINIC AWARD. INFR4 IS CODE FOR ALPHA CLINICS

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1 PROGRAM. AND IN ADDITION, THIS GOES BACK TO THE
2 ORIGINAL CONCEPT PLAN, THE APPLICANT ORGANIZATION
3 CAN ONLY PROVIDE FDA-AUTHORIZED TREATMENTS. SO IF
4 THE CENTER WAS PROVIDING TREATMENTS THAT WERE NOT
5 AUTHORIZED FOR WHATEVER REASON, DIDN'T HAVE FDA
6 APPROVAL, WE DO NOT WANT TO BE FUNDING INTO
7 OPERATIONS THAT ARE DOING THAT TYPE OF ACTIVITY. SO
8 ONLY FDA-AUTHORIZED TREATMENTS ARE ALLOWED FROM THE
9 CENTER.

10 CORE TEAM, THE REQUIREMENT HERE IS A
11 PROGRAM DIRECTOR AT 30-PERCENT TIME. THE MAXIMUM
12 AWARD IN THIS CYCLE, THE BUDGET IS AT 9 MILLION.
13 THAT'S ABOUT A 10-PERCENT REDUCTION FROM THE
14 PREVIOUS BUDGET, JUST TO CALL THAT OUT. AND, AGAIN,
15 IT'S A SLIGHT REDUCTION IN THIS ROUND, BUT IT
16 AFFORDS THE OPPORTUNITY FOR A SECOND ROUND. SO,
17 AGAIN, FROM A SUSTAINABILITY STANDPOINT, WE ARRIVED
18 AT RECOMMENDING THE 9 MILLION MARK. THAT WOULD
19 BRING THE TOTAL PROGRAM BUDGET, IF WE WERE TO FUND
20 UP TO FOUR PROGRAMS, AT 36 MILLION.

21 AGAIN, I DON'T NEED TO READ THROUGH ALL
22 THESE. THEY WERE TOUCHED ON IN THE PREVIOUS SLIDE.
23 NOT-FOR-PROFIT ORGANIZATION, NOT AN ALPHA CLINIC.
24 ONE OF THE POINTS THAT, AGAIN, IS DIFFERENT FROM THE
25 ORIGINAL CONCEPT PLAN IS IT MUST HAVE A DEMONSTRATED

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1 ABILITY TO PERFORM HUMAN CLINICAL TRIALS, THE
2 DELIVERY. SO WE'VE MOVED THE BAR A LITTLE BIT, THAT
3 ORGANIZATIONS COMING IN MUST HAVE THE CAPACITY TO
4 PERFORM CLINICAL TRIALS AT THE TIME OF APPLICATION.
5 THE AIM THERE TO ACCELERATE, AGAIN, THE
6 INFRASTRUCTURE GOALS WHICH I DESCRIBED PREVIOUSLY.
7 AND THE OVERALL AIM OF THE APPLICATION, IF THE
8 APPLICANT ISN'T DOING SO ALREADY, IS TO HAVE THE
9 CAPACITY TO DELIVER REGENERATIVE MEDICINE CLINICAL
10 TRIALS OVER THE COURSE OF THE AWARD.

11 ONE OTHER PIECE, AND I KNOW A NUMBER OF
12 MEMBERS WHO WERE VERY INSTRUMENTAL IN THIS
13 RECOMMENDATION MAY BE CONFLICTED, BUT JUST TO
14 EMPHASIZE AGAIN THAT WE'VE MAINTAINED THE
15 REQUIREMENTS -- WE RECOMMEND RETAINING THE
16 REQUIREMENTS FOR COMMUNITY-BASED PARTNERSHIPS.
17 AGAIN, THIS GOES BACK TO ONE OF THE MAJOR
18 RECOMMENDATIONS FROM THIS BOARD IS THAT IF WE ARE
19 GOING TO TRULY ADVANCE THE REFERRAL, ENROLLMENT, AND
20 RETENTION OF PATIENTS IN CLINICAL TRIALS, WE NEED
21 DEEPER SUPPORT AT THE COMMUNITY LEVEL. THIS CONCEPT
22 PLAN CONTINUES IN THAT SPIRIT AND THAT REQUIREMENT
23 REMAINS. AND MUST BE READY TO WORK WITHIN 120 DAYS.
24 AND, AGAIN, I'VE TOUCHED ON THE PROGRAM DIRECTOR.

25 THIS IS THE TIMELINE. AND, AGAIN, WE'RE

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1 BRINGING THE RFA -- CONCEPT PLAN TO YOU TODAY SO WE
2 CAN GET THE RFA POSTED AS EARLY AS POSSIBLE LOOKING
3 AT DATES IN APRIL AT THE MOMENT. AND THAT'S THE
4 GOAL. OPENING THE APPLICATION ONLINE IN THE SUMMER
5 AND BRINGING IT TO THE GRANTS WORKING GROUP AND
6 FACILITIES WORKING GROUP -- GRANTS WORKING GROUP IN
7 SEPTEMBER. IF THERE NEEDS TO BE A FACILITIES
8 REVIEW, THAT WOULD BE FOLLOWING THE GRANTS WORKING
9 GROUP LATER IN SEPTEMBER WITH THE CONTRACTING
10 PERIOD -- BRINGING IT TO THE BOARD FOR THE OCTOBER
11 MEETING AND THEN CONTRACTING TOWARDS THE END OF THE
12 YEAR. GETTING THAT AWARD LAUNCH A LITTLE BIT AFTER
13 THE 2025 GOAL OF THE PROPOSITION, BUT FOR REASONS WE
14 THINK ARE REASONABLE AND BASED ON THE RATIONALE I
15 PROVIDED FOR YOU.

16 DURING THIS TIME, AGAIN, ACCESSIBILITY AND
17 AFFORDABILITY WORKING GROUP WILL ALSO BE CONSIDERING
18 OPPORTUNITIES FOR THE SUPPORT ONLY ACTIVITIES, AND
19 THAT'S LOOKING AT THE SECOND HALF OF THE YEAR.

20 SO IN SUMMARY, WE ARE REQUESTING THAT THE
21 ICOC WITHDRAW THE CURRENT INFR8 COMMUNITY CARE
22 CENTERS OF EXCELLENCE CONCEPT AND ADOPT THE PROPOSED
23 PLAN YOU HAVE BEFORE YOU, THE PROPOSED COMMUNITY
24 CARE CENTERS INFR8 FUNDING OPPORTUNITY. AND WITH
25 THAT, I WILL HAND IT BACK TO THE CHAIR.

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1 CHAIRMAN IMBASCIANI: GEOFF, THAT'S
2 BEAUTIFUL. SO WE WOULD LIKE A MOTION TO ACCEPT THE
3 RECOMMENDATION TO REPLACE THE OLD INFRASTRUCTURE &
4 WITH THE NEW FUNDING OPPORTUNITY.

5 DR. GASSON: SO MOVED.

6 DR. MALKAS: SECOND.

7 CHAIRMAN IMBASCIANI: WE HAVE A SECOND
8 FROM LINDA MALKAS. THANK YOU.

9 MS. DURON: I SAW QUESTIONS. I SEE HANDS
10 UP ON THE PHONE.

11 CHAIRMAN IMBASCIANI: YSABEL, I'M SORRY.
12 GO AHEAD PLEASE.

13 MS. DURON: NOT ME, BUT I SAW TWO OTHER
14 HANDS UP. THEY'RE ON THE PHONE.

15 MR. TOCHER: WE'RE TAKING THE BOARD
16 DISCUSSION.

17 CHAIRMAN IMBASCIANI: I NEED TO ASK THE
18 BOARD MEMBERS TO OPEN THE DISCUSSION BEFORE THE
19 PUBLIC.

20 MS. DURON: IS THAT THE PUBLIC? OKAY.

21 CHAIRMAN IMBASCIANI: IT IS. THANK YOU.
22 ANNE-MARIE, YES, DISCUSSION.

23 DR. DULIEGE: YSABEL, DID YOU HAVE A
24 QUESTION?

25 MS. DURON: NO. I DON'T THINK I CAN EVEN

1 VOTE.

2 DR. DULIEGE: OKAY. GREAT. COUPLE OF
3 QUESTIONS OR MAYBE JUST CLARIFICATIONS. BUT I WOULD
4 SAY OVERALL THANK YOU TO YOU AND THE TEAM AGAIN FOR
5 WHAT WE HAVE SEEN TODAY, MORE SO THAN EVER BEFORE,
6 IS THE INTENT, THE WILLINGNESS TO EVALUATE WHAT DID
7 NOT WORK BEFORE, WHY, AND MAKE AN ALTERNATIVE
8 PROPOSAL. THAT JUST IS GREAT.

9 SO ONE IS WHAT'S THE DIFFERENCE
10 FINANCIALLY BETWEEN THE PREVIOUS PROPOSAL AND THE
11 CURRENT ONE?

12 SECOND IS I UNDERSTAND THAT THESE
13 PROPOSALS ON ONE HAND ARE TO ACCELERATE CLINICAL
14 TRIALS AND ON THE OTHER HAND TO ALSO INCREASE THE
15 ACCESSIBILITY AND AFFORDABILITY OF FDA-APPROVED
16 TREATMENT. CAN YOU TELL US WHICH OF THESE TWO IS
17 MORE PROMINENT? HOW DO THEY SEPARATE IN TERMS OF
18 NUMBER OF PROPOSALS AND FINANCIAL COMMITMENTS?

19 AND WHAT DID NOT WORK? CAN YOU TELL US
20 MORE PRECISELY, WITHOUT TOO MANY DETAILS, WHAT DID
21 NOT WORK REALLY WELL IN A MORE PRACTICAL MANNER FOR
22 US TO UNDERSTAND? AND A LITTLE -- I'VE ALWAYS BEEN
23 A LITTLE BIT CAUTIOUS ABOUT THIS BECAUSE MOST OF THE
24 APPLICATIONS WE SEE ARE ON ORPHAN DRUG, RARE
25 DISEASES. AND SO HOW CAN WE ACCELERATE ENROLLMENT

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1 OF SOMETHING THAT IS -- DISEASE THAT IS EXTREMELY
2 RARE, INCLUDING GEOGRAPHICALLY? SO THESE THREE
3 CLARIFICATION POINTS.

4 DR. LOMAX: IF I MAY, I'LL START WITH THE
5 WHAT DIDN'T WORK QUESTION. SO I THINK WHAT WE
6 REALLY UNDERSTOOD WHEN WE LOOKED BACK AT THE
7 ORIGINAL PROGRAM AS DESIGNED AND WHERE WE WOULD END
8 UP IS THAT WE WOULD NOT HAVE THE FUNDING TO ALLOW
9 THE SITES THAT WERE DOING THE CLINICAL TRIALS TO
10 HAVE A LONG ENOUGH RUNWAY TO SUCCEED. WE THOUGHT
11 THE FIVE-YEAR TIME WINDOW WOULD BE INSUFFICIENT.
12 THAT'S BEEN BASED ON OUR EXPERIENCE WITH OTHER
13 CLINICAL INFRASTRUCTURE. IT WAS, AGAIN, THE
14 LIMITATION.

15 SO IT WAS THAT UNDERSTANDING THAT
16 PROPOSITION 14 PUT A HARD CAP ON THIS PROGRAM AT 78
17 MILLION, AND WE WERE ESSENTIALLY GOING TO USE 80 TO
18 90 PERCENT OF THAT BUDGET.

19 SO THAT WAS A PROBLEM THAT WE -- AND WE
20 HAD A SOLUTION WHICH, AGAIN, WAS TO GO TO A TWO
21 BUDGETING -- ESSENTIALLY A TWO BUDGET APPROACH WHICH
22 IS REFLECTED HERE. IN TERMS OF WHAT -- I THINK YOUR
23 FIRST QUESTION IS THEN WHAT DOES THAT TRANSLATE TO
24 IN TERMS FINANCIALLY. IT IS A 10-PERCENT REDUCTION.
25 SO IN THE ORIGINAL PROPOSAL, TO REITERATE, YOU COULD

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1 COME IN AS A CLINICAL TRIAL TREATMENT AND DELIVERY
2 SITE OR A SUPPORT SITE. THE SUPPORT SITES WERE ABLE
3 TO APPLY AT ROUGHLY ABOUT A \$7 MILLION LEVEL. THE
4 TREATMENT AND SUPPORT SITES WERE ABLE TO APPLY AT
5 ABOUT JUST OVER 10 MILLION. THAT WAS BASED ON THE
6 BUDGETING THAT WE SEE IN THE ALPHA CLINICS.

7 SO IN THIS NEW PROPOSAL, THEY'RE ABLE TO
8 COME IN IT'S NOW AT 9 MILLION. NOT BECAUSE WE FELT
9 THAT THAT WAS THE PERFECT NUMBER, BUT IN TERMS OF
10 DISTRIBUTION OF THE FUNDS WE HAVE, THE 78 MILLION,
11 THAT 9-MILLION FIGURE ALLOWS US AGAIN TO PROVIDE
12 SUBSTANTIAL SUPPORT TO THOSE SITES AND PROVIDE IT IN
13 TWO CYCLES IF WE CHOOSE TO DO SO.

14 SO IT'S A MINOR REDUCTION IN WHAT -- IT'S
15 ROUGHLY A 10-PERCENT REDUCTION OF WHAT THE SITES HAD
16 PREVIOUSLY BUDGETED FOR. SO THEY'RE GOING TO
17 HAVE -- IF THE SITES THAT CAME IN ORIGINALLY CHOOSE
18 TO COME BACK IN, THEY'RE GOING TO HAVE TO FIND SOME
19 SAVINGS THERE.

20 AND THEN THERE WAS AN ACCESS AND
21 AFFORDABILITY QUESTION IN THERE, I BELIEVE. I THINK
22 WHAT WE'VE REALLY BEEN FOCUSING ON IN TERMS OF WHAT
23 WE'VE BEEN ASKING FOR IN THE APPLICATION ARE
24 QUESTIONS AROUND HOW WILL THEY PROVIDE THE
25 VISIBILITY TO THE CLINICAL TRIALS. HOW CAN THEY

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1 SUPPORT THE PATIENTS WHO ARE THEN INTERESTED IN
2 THOSE CLINICAL TRIALS? SO I THINK IT'S A VERY
3 ACCESS-FOCUSED PROGRAM. TO THE EXTENT IT'S GOING TO
4 DRIVE AFFORDABILITY, I DON'T THINK IT WOULD BE FAIR
5 TO SAY THIS IS AN AFFORDABILITY INITIATIVE PER SE.
6 I THINK THE AFFORDABILITY ELEMENTS ARE WHAT WERE
7 DESCRIBED IN THE CLINICAL TRIAL PROGRAMS THAT WERE
8 REALLY TRYING TO ADDRESS THOSE QUESTIONS IN TERMS OF
9 THE ACCESS STRATEGIES THAT THOSE PROGRAMS NEED TO
10 DEVELOP. I DON'T THINK THAT WILL BE DRIVEN FROM THE
11 CLINICAL INFRASTRUCTURE ALONE.

12 DID THAT COVER THE LIST?

13 DR. DULIEGE: FOR ONE THING, IT'S ACTUALLY
14 VERY PLEASANT TO BE ASKED TO APPROVE A REDUCTION IN
15 BUDGET. THAT DOESN'T HAPPEN VERY OFTEN. THIS IS
16 THE FIRST TIME, I THINK.

17 EVEN WITH WHAT HAS BEEN SPENT SO FAR IN A
18 PROGRAM THAT I THINK HAS BEEN, WHAT, ABOUT ONE YEAR
19 IN EFFECT, THIS PROGRAM?

20 DR. LOMAX: IT HASN'T.

21 DR. DULIEGE: YOU CANNOT TELL US WHAT HAS
22 BEEN ACHIEVED BECAUSE IT HASN'T STARTED.

23 DR. LOMAX: WE NEVER MOVED FORWARD WITH
24 THE APPROVAL OF APPLICATIONS PURSUANT TO THE INITIAL
25 PROGRAM.

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1 DR. DULIEGE: THANK YOU.

2 DR. MADANAT: IT'S A COMMENT, NOT A
3 QUESTION. BUT I WANT TO SAY THANK YOU FROM MY
4 PERSPECTIVE LOOKING AT IT FROM THE BEGINNING OF THE
5 PROCESS TO NOW, WHAT'S BEING PROPOSED HERE IS MUCH
6 MORE ALIGNED WITH PROPOSITION 14. I THINK IT'S
7 GOING TO MAKE A HUGE DIFFERENCE IN THE WAY WE ARE
8 FUNDING THESE PROJECTS ON A LONG-TERM PERSPECTIVE.
9 SO I ECHO ANNE-MARIE. IT'S GREAT TO SEE US PAUSE
10 AND DO WHAT WE THINK IS THE RIGHT OUTCOME.

11 DR. LOMAX: THANK YOU.

12 CHAIRMAN IMBASCIANI: THANK YOU, HALA.
13 ANY OTHER BOARD MEMBERS HAVE A COMMENT OR QUESTION?
14 IF NOT, CLAUDETTE, CAN YOU DIRECT US TO THE MEMBERS
15 OF THE PUBLIC PLEASE.

16 MS. MANDAC: WE HAVE TWO HANDS RAISED. SO
17 FOR MEMBERS OF THE PUBLIC, YOU WILL HAVE THREE
18 MINUTES EACH TO SPEAK. THERE IS A TIMER. WE WILL
19 MUTE YOU IF YOU EXCEED YOUR THREE MINUTES. AND THE
20 CLOCK WILL SHOW UP ON THE TOP RIGHT-HAND CORNER OF
21 YOUR SCREEN.

22 SO THE FIRST PERSON TO SPEAK WILL BE PHONE
23 NUMBER (312) 485-6714. YOU HAVE THE FLOOR.

24 DR. JACOBS: HI, EVERYONE. MY NAME IS DR.
25 DR. ELIZABETH JACOBS. I'M PROFESSOR AND CHAIR OF

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1 MEDICINE AT UCR SCHOOL OF MEDICINE. I'M THE
2 PRINCIPAL INVESTIGATOR ON THE TIER I RECOMMENDED FOR
3 FUNDING APPLICATION FOR THIS RFA. AND I'M HERE TO
4 TALK ABOUT WHY FUNDING THIS PROGRAM AND OUR PROGRAM
5 IS VERY IMPORTANT AND WHY I DISAGREE THAT
6 WITHDRAWING THE FUNDING AND STARTING ANEW WOULD MEET
7 THE GOALS OF PROPOSITION 14.

8 SO WE SERVE A VERY UNDERSERVED POPULATION
9 IN CALIFORNIA, THE INLAND EMPIRE. AND OUR WHOLE
10 GOAL WAS ACTUALLY TO INCREASE REFERRAL, RETENTION,
11 AND ENROLLMENT IN OUR REGENERATIVE CLINICAL TRIALS
12 BY PARTNERING WITH EXISTING ALPHA CENTERS. AND ONE
13 OF THE REASONS WHY THIS AREA IS UNDERSERVED IN
14 MEETING THE NEEDS AND MEETING WHAT PROPOSITION 14
15 INTENDED IS BECAUSE THESE INDIVIDUALS NEED HELP
16 UNDERSTANDING TRIALS WITHIN THEIR LANGUAGE, WITHIN
17 THEIR CULTURES, AND THEY NEED PEOPLE TO BE IN THEIR
18 COMMUNITIES HELPING THEM AND ALSO COLLECTING DATA
19 FROM THEM THAT MAYBE THEY COULD DO FOLLOW-UPS WITHIN
20 THEIR COMMUNITY. THAT WAS PART OF WHAT WE HAD
21 PLANNED.

22 AND I THINK IT'S QUITE UNFAIR THAT WE ARE
23 HIGHLY REVIEWED, WE'RE MEETING THE NEEDS; AND
24 BECAUSE YOU DIDN'T RECEIVE OTHER GOOD APPLICATIONS,
25 WE'RE BEING PENALIZED FOR OTHER PEOPLE'S POOR

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1 APPLICATIONS.

2 THE OTHER THING THAT I THINK IS VERY
3 IMPORTANT FOR YOU TO UNDERSTAND IS THAT WE HAVE
4 COLLABORATED WITH MULTIPLE COMMUNITY MEMBERS -- I
5 THINK ONE IS HERE TODAY -- TO IMPLEMENT THIS GRANT
6 AND TO APPLY FOR THIS GRANT. AND NOW WE HAVE TO GO
7 BACK AND TELL THEM THAT CIRM DOES NOT WANT TO ENGAGE
8 WITH THEM IN WAYS THAT WE TOLD THEM THAT CIRM DID
9 INTEND TO AND IS WRITTEN INTO THE LAW.

10 SO I'M HERE TO ADVOCATE THAT YOU CONTINUE
11 TO FUND -- I WOULD HOPE THAT YOU WOULD FUND OUR
12 APPLICATION. IT WAS VERY FAVORABLY REVIEWED. IT
13 ABSOLUTELY MEETS THE GOALS OF SB 14.

14 THE OTHER THING IS THAT IT IS GOING TO
15 HELP YOU ADVANCE GETTING CLINICAL TRIALS OUT INTO
16 THE COMMUNITY MUCH FASTER AND TO COMMUNITIES THAT
17 EXPERIENCE DISPARITIES FASTER THAN IF YOU WAIT A
18 WHOLE NOTHER YEAR TO ACTUALLY LOOK INTO FUNDING OUR
19 TYPE OF SUPPORT MECHANISMS.

20 I WAS VERY HEARTENED TO SEE, THIS IS NOT
21 SOMETHING I'VE SEEN BEFORE IN MY CONVERSATIONS WITH
22 CIRM FOLKS, THAT YOU ARE THINKING ABOUT FUNDING THE
23 SUPPORT CENTERS THROUGH ANOTHER MECHANISM, BUT I AM
24 VERY CONCERNED THAT IF YOU PROCEED WITH THE CURRENT
25 PLAN, YOU WILL BE EXACERBATING DISPARITIES AND

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1 CREATING DISTRUST IN COMMUNITIES IN NEED RATHER THAN
2 MEETING YOUR GOALS.

3 MS. MANDAC: THANK YOU SO MUCH, DR.
4 JACOBS.

5 THE NEXT CALLER IS (503) 330-2407. THE
6 FLOOR IS YOURS. (503) 330-2407, IF YOU COULD PLEASE
7 UNMUTE.

8 DR. LECOMTE-HINELY: HI. MY NAME IS DR.
9 JENNA LECOMTE-HINELY. I AM THE CEO OF HARC, WHICH
10 IS A NON-PROFIT DEDICATED TO IMPROVING
11 COMMUNITY-WIDE THROUGH DATA. WE ARE A PARTNER WITH
12 UCR SCHOOL OF MEDICINE ON THE APPLICATION THAT WAS
13 RECOMMENDED FOR FUNDING. AND I JUST ECHO DR. JACOBS
14 IN BEING JUST SO DISAPPOINTED THAT, DESPITE PUTTING
15 TOGETHER A GREAT PROPOSAL THAT WAS FIRMLY ROOTED IN
16 THE COMMUNITY AND IN OUR COMMUNITY'S NEEDS BECAUSE
17 WE ARE VERY UNDERSERVED COMMUNITY, THAT WE WILL NOT
18 BE FUNDED FOR THESE ACTIVITIES.

19 AS DR. JACOBS MENTIONED, WE HAVE A
20 COMMUNITY THAT IS GREATLY UNDERSERVED. HERE IN THE
21 COACHELLA VALLEY WHERE I LIVE, IF SOMEONE IS
22 DIAGNOSED AND WANTS TO PARTICIPATE IN A CLINICAL
23 TRIAL, EVEN IF THEY KNOW WHAT IT IS, THEY HAVE TO
24 LEAVE THE REGION. THEY CANNOT GET CARE HERE. AND
25 PART OF THAT IS THAT WE HAVE A HUGE PROVIDER

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1 SHORTAGE. IT IS THE -- WE HAVE THE FEWEST PROVIDERS
2 PER POPULATION OF ANYWHERE IN CALIFORNIA. WE HAVE A
3 HUGE POPULATION OF HISPANIC-LATINO PEOPLE WHO,
4 AGAIN, AS DR. JACOBS MENTIONED, REALLY NEED A
5 TRUSTED MESSENGER TO GET THIS MESSAGE OUT ABOUT
6 CLINICAL TRIALS AND ABOUT THE OPPORTUNITY AND ABOUT
7 THE IMPORTANCE.

8 AND BY NOT DOING THIS -- I'M VERY
9 PASSIONATE ABOUT EQUITY FOR OUR UNDERSERVED INLAND
10 EMPIRE. AND PUTTING MORE FUNDS TOWARDS SITES THAT
11 ALREADY HAVE INFRASTRUCTURE ALONG THE COAST IN L.A.
12 AND SAN DIEGO IS JUST PERPETUATING THE INEQUITIES
13 THAT WE ALREADY EXPERIENCE.

14 OUR COMMUNITY HAS AN INHERENT DISTRUST OF
15 AGENCIES WHO SAY THAT THEY'RE GOING TO MAKE GREAT
16 CHANGE AND COME IN AND THEN DISAPPEAR. SO THIS IS
17 VERY HARMFUL TO THE COMMUNITIES WHO HAVE BOUGHT IN,
18 WHO HAVE BECOME EXCITED ABOUT THE OPPORTUNITY TO
19 MAKE CLINICAL TRIALS ACCESSIBLE HERE IN OUR
20 COMMUNITY. AND SO I JUST URGE YOU TO RECONSIDER OUR
21 VERY STRONG, VERY COMPETITIVE APPLICATION FROM BOTH
22 A RESIDENT OF THE INLAND EMPIRE, A LONG-TERM
23 COMMUNITY-BASED RESEARCHER, PLEASE, I ENCOURAGE YOU
24 TO PLEASE RECONSIDER FUNDING THE ONE APPLICATION
25 THAT WAS LISTED AS FUNDABLE.

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1 IF WE DON'T RECEIVE THAT, WE WILL, OF
2 COURSE, TRY AGAIN BECAUSE WE ARE PASSIONATE AND WE
3 ARE DEDICATED TO OUR COMMUNITY, BUT THIS IS A NEED
4 NOW. THIS WAS A NEED YESTERDAY. SO IF IT'S AT ALL
5 POSSIBLE TO MOVE THIS FORWARD FOR OUR POPULATION, WE
6 WOULD GREATLY APPRECIATE THAT. THANK YOU.

7 MS. MANDAC: THANK YOU SO MUCH, DR.
8 LECOMTE-HINELY. VITO, NO OTHER HANDS RAISED.

9 CHAIRMAN IMBASCIANI: NO OTHER COMMENTS
10 FROM THE PUBLIC. FINAL COMMENTS FROM BOARD MEMBERS
11 BEFORE WE PROCEED TO A VOTE? ANNE-MARIE.

12 DR. DULIEGE: CAN YOU, BECAUSE YOU ARE A
13 MEMBER OF THE TEAM, PUT THE TWO COMMENTS FROM THE
14 PUBLIC INTO CONTEXT? WHAT SHOULD WE DERIVE FROM
15 THAT? WHAT IS YOUR RECOMMENDATION AFTER THESE TWO
16 COMMENTS? THANK YOU.

17 DR. LOMAX: SO I THINK -- WE SPENT -- THE
18 DEVELOPMENT OF THIS PROGRAM, WE WENT INTO THOSE
19 COMMUNITIES. WE MET WITH THOSE STAKEHOLDERS. AND
20 SO THE -- IT IS HARD TO SORT HAVE TO RECOMMEND A
21 MODIFICATION TO THAT PROGRAM. WE WORKED DIRECTLY
22 WITH THE APPLICANTS TO CRAFT WHAT ARE VERY
23 COMPELLING APPLICATIONS.

24 I THINK WHAT WE'VE TRIED TO DO IN TERMS OF
25 BOTH THE BUDGET AND THE TIMELINE AND THE PROCESS IS,

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1 AGAIN, PUT TOGETHER A BUDGET FRAMEWORK THAT WILL
2 ALLOW MORE TO BE DONE OVER TIME RATHER THAN LESS.
3 SO IT WILL ACTUALLY CREATE A MORE SUSTAINABLE
4 FOOTPRINT.

5 I THINK FROM THE PROCESS STANDPOINT, A LOT
6 OF THAT HARD WORK WILL BE ABLE TO COME BACK IN.
7 WE'RE NOT PROPOSING A WHOLESAL CHANGE OF THE
8 APPLICATION. RATHER, WE'RE FINE-TUNING IT TO MEET
9 OUR SAF OBJECTIVES TO BETTER ALIGN WITH PROPOSITION
10 14.

11 SO AT THE END OF THE DAY, I UNDERSTAND AND
12 APPRECIATE THE FRUSTRATION, BUT THE ULTIMATE RESULT
13 IS A SHIFT IN TIME. AND LATER IS NEVER WHAT ANYONE
14 HOPES FOR, AND WE UNDERSTAND THAT. AGAIN, IN TERMS
15 OF THE TIMELINE, THE BUDGET, AND WHAT WE ENVISION
16 THE APPLICATION TO LOOK LIKE, WE'RE REALLY TRYING TO
17 STAY TRUE TO THE STAKEHOLDERS, THEIR EFFORT WITH AN
18 UNDERSTANDING THAT EVERYTHING -- IT IS IMPORTANT
19 WORK, IT'S GREAT WORK, AND WE REALLY WANT TO HONOR
20 THAT WORK AS BEST WE CAN WITHIN THE LIMITS THAT WE
21 HAVE AS AN AGENCY.

22 DR. DULIEGE: A FINAL BRIEF COMMENT ON MY
23 PART, AND I DON'T NEED AN ANSWER RIGHT NOW, BUT BACK
24 TO THE TEAM. THERE WAS ONE SITE THAT WAS
25 RECOMMENDED FOR FUNDING IN THE PREVIOUS SYSTEM AND

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1 EIGHT THAT WERE NOT. SHOULD THERE BE A DIFFERENT
2 CONSIDERATION AT THIS POINT FOR THE ONE SIDE VERSUS
3 THE EIGHT? AGAIN, YOU CAN TAKE THIS UP LATER ON.

4 VICE CHAIR BONNEVILLE: SO THOSE
5 APPLICATIONS WILL NO LONGER -- EVERYONE WILL REAPPLY
6 UNDER THE NEW MECHANISM. SO THERE WILL BE TWO NEW
7 CONCEPT PLANS. I THINK WHAT'S BEING MISSED IS THIS
8 ALLOWS FOR MORE FUNDING FOR BOTH. YOU'RE APPLYING
9 FOR DELIVERY. THERE WILL BE ACCESS TO TWO ROUNDS OF
10 FUNDING IF YOU MEET THE OBJECTIVES. IF YOU APPLY
11 FOR SUPPORT, THERE WILL BE MORE ROUNDS OF FUNDING
12 THAN WOULD BE OTHERWISE AVAILABLE.

13 SO IT IS -- WHILE I UNDERSTAND IT IS
14 DIFFICULT TO HAVE TO WAIT FOR THIS PROGRAM BECAUSE
15 THE SUPPORT PROGRAM COMES LATER IN THE FALL, I JUST
16 WANT TO MAKE SURE THAT EVERYONE UNDERSTANDS THAT
17 WHAT WE'RE DOING IS ACTUALLY CREATING A LONGER
18 RUNWAY FOR EVERYONE AND FOR PEOPLE IN CALIFORNIA TO
19 BE ABLE TO HAVE ACCESS TO THIS FOR LONGER PERIODS OF
20 TIME. WE'RE PLAYING THE LONG GAME, AND I UNDERSTAND
21 IT'S HARD TO ACCEPT IF YOU'VE APPLIED, AND I
22 UNDERSTAND COMPLETELY. I JUST THINK WE NEED TO LOOK
23 AT IT IN THAT FRAME OF MIND.

24 CHAIRMAN IMBASCIANI: THANK YOU,
25 ANNE-MARIE. AND THANK YOU, MARIA, FOR THAT

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1 WONDERFUL EXPLICATION. NO OTHER COMMENT BEING
2 HEARD, SCOTT, I THINK WE CAN PROCEED.
3 MR. TOCHER: GEORGE BLUMENTHAL.
4 DR. BLUMENTHAL: YES.
5 MR. TOCHER: MARIA BONNEVILLE.
6 VICE CHAIR BONNEVILLE: YES.
7 MR. TOCHER: LEONDRA CLARK-HARVEY.
8 DR. CLARK-HARVEY: YES.
9 MR. TOCHER: ANNE-MARIE DULIEGE.
10 DR. DULIEGE: YES.
11 MR. TOCHER: MARK FISCHER-COLBRIE.
12 MR. FISCHER-COLBRIE: YES.
13 MR. TOCHER: DAVID HIGGINS.
14 DR. HIGGINS: YES.
15 MR. TOCHER: VITO IMBASCIANI.
16 CHAIRMAN IMBASCIANI: YES.
17 MR. TOCHER: RICH LAJARA. HALA MADANAT.
18 DR. MADANAT: YES.
19 MR. TOCHER: LINDA MALKAS.
20 DR. MALKAS: YES.
21 MR. TOCHER: CAROLYN MELTZER.
22 DR. MELTZER: YES.
23 MR. TOCHER: JOE PANETTA. MARV SOUTHARD.
24 DR. SOUTHARD: YES.
25 MR. TOCHER: KEVIN XU.

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1 DR. XU: YES.

2 MR. TOCHER: THANK YOU VERY MUCH. THE
3 MOTION CARRIES, MR. CHAIR.

4 CHAIRMAN IMBASCIANI: THANK YOU. I THINK
5 I'M GOING TO GO BACK NOW TO NO. 13, WHICH WOULD BE
6 CONSIDERATION OF THE REVIEW PROCESS AND THE GRANTS
7 WORKING GROUP BYLAWS. THE INTRODUCTION WILL BE DR.
8 SAMBRANO -- I'M SORRY. BECAUSE OF TIME CONSTRAINTS,
9 WE'RE GOING MOVE THIS AROUND. SO TAKE BACK WHAT I
10 JUST SAID. THANK YOU SO MUCH.

11 THIS IS ABSOLUTELY A PLEASURE OF MINE, THE
12 HIGHLIGHT OF MY SPEAKING DAY. YOU'VE ALREADY HEARD
13 DR. LARRY GOLDSTEIN'S NAME MENTIONED HERE, AND WE'VE
14 TALKED A LOT ABOUT THE CONSEQUENCES OF HIS ACTIONS
15 ON THE BOARD. SO I'M GOING TO INTRODUCE YOU NOW TO
16 RESOLUTION 2025-03.1 IN HONOR OF LAWRENCE GOLDSTEIN,
17 PH.D., FOR HIS SERVICE TO THE CALIFORNIA INSTITUTE
18 FOR REGENERATIVE MEDICINE, TO STEM CELL RESEARCH,
19 AND TO CALIFORNIA PATIENTS.

20 DR. GOLDSTEIN STARTED ON HIS ROAD TO
21 SCHOLARSHIP AS AN UNDERGRADUATE STUDENT IN BIOLOGY
22 AT UCSD. AND SAN DIEGO MUST HAVE SUNK ITS CLAWS IN
23 PRETTY DEEPLY BECAUSE, AFTER MANY PEREGRINATIONS, A
24 DOCTORATE IN GENETICS AT THE UNIVERSITY OF
25 WASHINGTON IN SEATTLE, POSTDOCTORAL WORK AT THE

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1 UNIVERSITY OF COLORADO AND MIT, AND RISING TO THE
2 RANK OF FULL PROFESSOR AT HARVARD IN SIX YEARS, HE
3 SETTLED BACK DOWN AT UCSD IN 1963.

4 AND THERE AS PROFESSOR OF CELLULAR AND
5 MOLECULAR MEDICINE, HE FOUNDED THE STEM CELL PROGRAM
6 AND THE SANFORD STEM CELL CLINICAL CENTER, OTHERWISE
7 KNOWN AS OUR ALPHA CLINIC, AND HOLDS NOW MANY
8 EMERITUS TITLES IN THE DEPARTMENTS OF NEUROSCIENCES
9 AND THE SANFORD CONSORTIUM FOR REGENERATIVE
10 MEDICINE, TO NAME ONLY A FEW.

11 LARRY IS A MEMBER OF THE AMERICAN ACADEMY
12 OF ARTS AND SCIENCES AND THE NATIONAL ACADEMY OF
13 SCIENCE. HE BROKE GROUND IN HIS RESEARCH ON THE
14 MOLECULAR MECHANISMS OF INTRACELLULAR MOVEMENT IN
15 NEURONS AND TRANSPORT DYSFUNCTION IN
16 NEURODEGENERATIVE DISEASES.

17 DR. GOLDSTEIN JOINED THE CIRM BOARD IN
18 JANUARY OF 2021, AND HE HAS MADE AN OUTSIZED IMPACT
19 ON CIRM IN HIS FOUR YEARS OF BOARD SERVICE. HE HAD
20 PREVIOUSLY SERVED ON SEVERAL PUBLIC SCIENCE ADVISORY
21 COMMITTEES, INCLUDING THE ADVISORY BOARD FOR
22 PROPOSITION 71 THAT CREATED CIRM. LARRY SERVED AS
23 CHAIR OF THE SCIENCE SUBCOMMITTEE DURING MOST OF HIS
24 BOARD TENURE DURING WHICH TIME CIRM DEVELOPED
25 PROGRAMS FOR UNDERGRADUATE STUDENTS, EXPANDED THE

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1 ALPHA CLINIC NETWORK, CREATED A NEW DISCOVERY
2 PROGRAM, DEVELOPED THE CELL AND GENE THERAPY
3 MANUFACTURING NETWORK, RELAUNCHED THE SHARED LABS
4 PROGRAM, STARTED THE PROGRAM TO PROMOTE
5 MULTIDISCIPLINARY RESEARCH IN NEUROPSYCHIATRIC
6 DISEASES, AND OVERSAW THE ESTABLISHMENT OF A PROGRAM
7 TO SUPPORT LATE STAGE CLINICAL DEVELOPMENT, AMONG
8 OTHER ENDEAVORS.

9 HE SERVED AS THE FOUNDING CHAIR OF CIRM'S
10 TASK FORCE ON NEUROSCIENCE AND MEDICINE WHICH TASKED
11 ITSELF WITH GENERATING A PLAN TO ALLOCATE \$1.5
12 BILLION SET ASIDE IN PROPOSITION 14 FOR TREATMENT OF
13 DISEASES OF THE BRAIN AND CENTRAL NERVOUS SYSTEM.
14 THE COMMUNICATIONS AND INTELLECTUAL PROPERTY AND
15 INDUSTRY SUBCOMMITTEES ALSO COUNTED HIM AS A
16 THOUGHTFUL AND CONTRIBUTING MEMBER. AND HE WAS A
17 DELIGHT TO WORK WITH AT EVERY TURN.

18 AND TO UNDERSCORE THE ADAGE THAT WE CAN
19 NEVER PREDICT HOW BIG THE TREE WILL GROW WHEN YOU
20 PLANT THE SEED, I'LL EVEN -- I WAGER THAT EVEN
21 LARRY -- I'M SORRY I LOST MY PLACE. EVEN LARRY WILL
22 BE PLEASANTLY SURPRISED HOW THE REMIND PROGRAM WITH
23 ITS DATA-DRIVEN AND PORTFOLIO-FOCUSED EMPHASIS ON
24 NEUROPSYCHIATRIC DISEASES HAS ITSELF BECOME A MODEL
25 FOR MUCH OF THE STRATEGIC ALLOCATION FRAMEWORK THAT

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1 HAS DRIVEN MUCH OF CIRM'S WORK IN THE LAST YEAR.

2 WE THANK YOU, LARRY, FOR YOUR
3 INTELLIGENCE, YOUR DEDICATION, INSIGHT, AND LOYALTY
4 TO THE MISSION AND THE IDEALS OF CIRM, AND WE ARE
5 ONLY JUST BEGINNING TO SEE WHERE YOUR IMAGINATION
6 WILL TAKE US.

7 I'M GOING TO ASK OTHER MEMBERS OF THE
8 BOARD WHO MIGHT LIKE TO MAKE COMMENTS AT THIS TIME
9 TO DO SO. DR. BARRETT.

10 DR. BARRETT: SO I'M ABSOLUTELY THRILLED
11 TO HAVE THE OPPORTUNITY TO THANK LARRY FOR HIS
12 CONTRIBUTIONS. HE JOINED THE FACULTY AT UC SAN
13 DIEGO A FEW YEARS AFTER I DID, AND I WORKED CLOSELY
14 WITH HIM, NOT NECESSARILY IN STEM CELL-RELATED
15 AREAS, BUT IN GRADUATE EDUCATION AND VARIOUS
16 SCIENTIFIC AREAS. HE WAS ALWAYS SUCH A PLEASURE TO
17 WITH WORK WITH, AND WAS A GREAT JOY TO ME WHEN I WAS
18 APPOINTED TO THE BOARD TO BE ABLE TO RENEW OUR
19 ACQUAINTANCE.

20 YOU ARE GREATLY MISSED, LARRY. BUT AS
21 VITO HAS INDICATED, YOUR INFLUENCE ON THE FIELD HAS
22 BEEN IMMENSE, AND THE SEEDS THAT YOU HAVE SOWN WILL
23 JUST AMPLIFY YOUR CONTRIBUTIONS FOR MANY, MANY
24 DECADES TO COME. SO THANK YOU FOR EVERYTHING THAT
25 YOU'VE DONE.

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1 DR. GASSON: HI, LARRY. I WANT TO
2 ACKNOWLEDGE THE ENORMOUS CONTRIBUTIONS THAT YOU'VE
3 MADE BOTH IN YOUR OWN RESEARCH AT UCSD, BUT ALSO ON
4 WORK THAT YOU'VE DONE AT THE NIH AND AT CIRM, WHICH
5 HAS BEEN INCREDIBLY IMPACTFUL.

6 I HAD THE PLEASURE OF SERVING ON THE NEURO
7 TASK FORCE WHILE YOU CHAIRED IT. AND IT WAS A
8 CHALLENGING OPPORTUNITY TO TRY TO UNDERSTAND WHERE
9 THE FIELD STOOD WITH THE GROUP OF PEOPLE, MANY OF
10 WHOM ACTUALLY WERE NOT SCIENTISTS. I THINK YOU DID
11 A MASTERFUL JOB OF ORGANIZING THOSE INFORMATION
12 SEMINARS AND MOVING THE PROCESS FORWARD.

13 IN ADDITION, I CAN ALSO SAY THAT YOU
14 EXHIBITED ENORMOUS GRACE IN THE WAY THAT YOU HANDLED
15 THE MEMBERS OF THE COMMITTEE, THE OUTSIDE PEOPLE
16 THAT WERE INVOLVED IN EVERY PROCESS TO BRING US TO A
17 CONSENSUS THAT HAS RESULTED IN THE VERY SUCCESSFUL
18 REMIND-L PROGRAM. SO THANK YOU FOR ALL OF THAT.

19 VICE CHAIR BONNEVILLE: I WANT TO THANK
20 LARRY GOLDSTEIN FOR ALL HE'S DONE FOR CIRM, AND NOT
21 JUST AS CHAIR OF THE SCIENCE SUBCOMMITTEE. LARRY IS
22 OUR ULTIMATE CHEERLEADING. HE STARTED ADVOCATING
23 FOR CIRM PRE-PROPOSITION 71, HELPING WITH THE
24 CAMPAIGN AND AS A TRUSTED ADVISOR TO BOB KLEIN. HE
25 HAS MENTORED SEVERAL OF THE SCIENTISTS OF CIRM

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1 GRANTS, AND HE CONTINUES TO PROVIDE VALUABLE COUNSEL
2 TO MANY OF US.

3 LARRY, YOU ARE MISSED HERE ON THE BOARD,
4 AND THANK YOU FOR NOT LEAVING US COMPLETELY AND
5 CONTINUING TO PROVIDE ADVICE AND ENTHUSIASM FOR
6 CIRM.

7 DR. GOLDSTEIN: THANK YOU.

8 CHAIRMAN IMBASCIANI: JOHN CARETHERS.

9 DR. CARETHERS: LARRY, AS YOUR REPLACEMENT
10 ON THE COMMITTEE, IT'S BIG SHOES TO FILL. I WANT TO
11 RECOGNIZE YOU IN MY TWO TOURS AT UC SAN DIEGO AND
12 KNOWING YOUR IMPORTANCE, DEDICATION, AND CONSISTENT
13 PUSH FOR HELPING TO DEVELOP, ALONG WITH BOB KLEIN,
14 CIRM. YOU ARE A CALIFORNIA MAN, AND YOU ARE A
15 UNIVERSITY OF CALIFORNIA MAN. AND I PERSONALLY WANT
16 TO ALSO THANK YOU FOR THE CONTRIBUTIONS YOU HAVE
17 DONE FOR THE STATE AND OUR UNIVERSITY AND THIS BODY.

18 UNFORTUNATELY, I'M NOT GOING TO BEING ABLE
19 TO PROJECT IT, BUT I WANTED TO SHARE A PICTURE OF
20 YOUR EVENT BACK IN DECEMBER AT THE SANFORD STEM CELL
21 BUILDING IN SAN DIEGO IN WHICH THE PAST THREE VICE
22 CHANCELLORS, MYSELF, DAVID BRENNER, AND ED HOLMES,
23 ALONG WITH LARRY. AND A WONDERFUL PAINTING OF LARRY
24 IS NOW HANGING IN THAT BUILDING. SO MY THANKS TO
25 YOU AND CONGRATULATIONS, LARRY.

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1 DR. GOLDSTEIN: THANK OU, JOHN.

2 DR. LEVITT: HI, LARRY. SO THIS IS JUST
3 MY OWN VIEW, THAT MOST NEUROSCIENTISTS WHO ARE
4 SUCCESSFUL LIKE YOURSELF ARE OBSESSIVE COMPULSIVE.
5 AND YOU DO EPITOMIZE OBSESSIVE COMPULSIVENESS
6 BECAUSE OUT OF ALL THE COMMITTEES THAT I'VE BEEN
7 TALKED INTO TO JOINING OR WORKING GROUPS,
8 NEUROSCIENCE SUBCOMMITTEE HAS BEEN BY FAR THE MOST
9 ENJOYABLE BECAUSE OF YOU, BECAUSE OF YOUR PREMEETING
10 PLANNING AND STRUCTURE AND ORGANIZATION AND ALSO
11 JUST A GREAT TALENT SCOUT. YOU HAD THE VERY BEST
12 PEOPLE OUTSIDE OF CALIFORNIA JOIN US IN ALL THOSE
13 MEETINGS.

14 IT WAS A GREAT NEW EDUCATION FOR A LOT OF
15 US, AND IT'S ALL DUE TO YOUR PLANNING, YOUR SUCCESS.
16 AND YOU CAN SEE CIRM IS REAPING THE BENEFITS OF ALL
17 THE WORK THAT YOU PUT INTO IT. SO THANK YOU. I'M
18 PROUD TO SAY I GOT MY NEUROSCIENCE PH.D. AT UCSD,
19 AND IT WAS BECAUSE OF FACULTY LIKE YOURSELF FOR
20 WHATEVER SUCCESS I'VE BEEN ABLE TO ACHIEVE. SO
21 THANKS.

22 CHAIRMAN IMBASCIANI: MARK
23 FISCHER-COLBRIE.

24 MR. FISCHER-COLBRIE: LARRY, YOUR
25 CONTRIBUTIONS HAVE BEEN JUST PHENOMENAL, BUT I

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1 WANTED TO THANK YOU ON A DIRECT PERSONAL LEVEL
2 BECAUSE YOU'VE BEEN A TERRIFIC MENTOR, A GUIDE,
3 SOMEONE TO EMULATE. AND I DEEPLY APPRECIATE WHAT
4 YOU'VE DONE, NOT JUST FOR CIRM, BUT FOR MYSELF AS
5 WELL. SO THANK YOU, LARRY.

6 CHAIRMAN IMBASCIANI: JONATHAN.

7 DR. THOMAS: HELLO, LARRY. SO I WANTED TO
8 AMPLIFY A COUPLE POINTS THAT WERE MADE ALREADY.
9 FIRST OF ALL, THE IMPORTANCE OF HAVING YOU ON THE
10 BOARD AS SOMEBODY WHO HAD PERSPECTIVE ON LITERALLY
11 THE ENTIRE LIFE OF CIRM. AND HAVING BEEN A PERSON
12 WHO WAS INSTRUMENTAL IN GETTING IT INTO EXISTENCE IN
13 THE FIRST PLACE, BUT BEING ABLE TO APPLY THAT
14 PERSPECTIVE AS YOU WOULD LEAD US THROUGH THE VARIOUS
15 DIFFERENT THINGS THAT WERE OF GREAT CONCERN TO YOU
16 HAS BEEN SO IMPORTANT.

17 LIKewise, YOUR RESPECT NATIONALLY AND
18 INTERNATIONALLY FOR YOUR WORK AND THE RESULTING
19 NETWORK THAT AROSE FROM THAT FOR WHICH WE HAVE
20 GREATLY BENEFITED IS SOMETHING THAT IS UNIQUE. NOT
21 EVERYBODY CAN BRING THAT TO THE TABLE. AND WHEN YOU
22 ADD THAT TO THE INSTITUTIONAL MEMORY AND THE
23 FUNDAMENTAL UNDERSTANDING OF WHAT WE'RE ALL ABOUT,
24 IT WAS MOST BENEFICIAL.

25 IN ADDITION TO THE NEURO TASK FORCE, AS I

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1 RECALL GETTING A CALL FROM YOU ONE DAY TALKING ABOUT
2 A NEW PROGRAM THAT YOU THOUGHT WOULD BE GOOD FOR OUR
3 EDUCATION PROGRAMS, AND FROM THAT AROSE COMPASS,
4 WHICH IS NOW A BIG SUCCESS ACROSS THE STATE. SO
5 THANK YOU FOR THAT.

6 AND JUST FOR YOUR SHEER LEVEL OF
7 DEDICATION, ENTHUSIASM, AND AVAILABILITY AT ALL
8 TIMES TO DISCUSS WHATEVER WAS OF IMPORTANCE TO YOU,
9 TO THE ORGANIZATION, TO THE FIELD. SO YOU ARE A
10 HUGE CONTRIBUTOR. JOHN DOES HAVE VERY BIG SHOES TO
11 FILL. HE'S DOING A GOOD JOB, BY THE WAY, JUST SO
12 YOU KNOW. AND WE SO APPRECIATED HAVING THE CHANCE
13 TO WORK WITH YOU.

14 AND I PERSONALLY WOULD LIKE TO NOTE THAT
15 HAVING THE OPPORTUNITY COINCIDENTALLY TO HAVE DINNER
16 WITH YOU AT THE EVENT CELEBRATING DENNY'S TEN-YEAR
17 ANNIVERSARY SINCE HIS GIFT DOWN IN SAN DIEGO WAS A
18 HUGE PLUS, AND I REALLY GREATLY ENJOYED OUR
19 DISCUSSION THERE AS ALWAYS. SO THANKS SO MUCH FOR
20 ALL YOU'VE MEANT TO CIRM AND THE FIELD.

21 CHAIRMAN IMBASCIANI: GREAT. I WOULD LIKE
22 TO HAVE A MOTION TO ADOPT THE RESOLUTION TO HONOR
23 DR. LAWRENCE GOLDSTEIN. DR. BARRETT.

24 DR. BARRETT: I MOVE THAT WE ADOPT THE
25 RESOLUTION IN HONOR OF PROFESSOR LARRY GOLDSTEIN.

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1 DR. SOUTHARD: SECOND.

2 CHAIRMAN IMBASCIANI: WE HAVE A SECOND.

3 YES, GEOFF LOMAX.

4 DR. LOMAX: I GUESS I'M QUASI-PUBLIC, BUT
5 DR. GOLDSTEIN, OVER MY EXPERIENCE HERE, THERE'S BEEN
6 NUMEROUS, NUMEROUS THREATS TO SCIENCE AND SCIENTIFIC
7 FREEDOM. AND EVERY TIME ONE OF THOSE THREATS
8 EMERGED, IT WAS DR. LARRY GOLDSTEIN WHO WAS THE
9 HEADLINE CHAMPION TO TRY TO CHANGE THAT. AND THAT
10 ADVOCACY PROBABLY MADE YOU A VILLAIN AMONGST THOSE
11 WHO WOULD CHOOSE TO LIMIT SCIENCE. AND SO FROM THAT
12 STANDPOINT -- AND THAT'S NOT EASY. AND A LOT OF
13 YOUR COLLEAGUES WEREN'T THERE. THEY WEREN'T QUOTED
14 IN THAT ARTICLE. THEY WERE THE ANONYMOUS SOURCES.

15 SO THANK YOU FOR BEING A CHAMPION OF
16 SCIENCE, AND THANK YOU FOR DEFENSE OF SCIENTIFIC
17 FREEDOM.

18 CHAIRMAN IMBASCIANI: THAT WAS BEAUTIFUL,
19 GEOFF. THANK YOU. SCOTT, I THINK WE'RE READY TO
20 CALL THE ROLL.

21 MR. TOCHER: ALL THOSE IN THE ROOM IN
22 FAVOR SAY AYE. OPPOSED? ABSTENTIONS? POLLING THE
23 MEMBERS ON THE PHONE.

24 YSABEL DURON.

25 MS. DURON: YES.

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1 MR. TOCHER: RICH LAJARA. SHLOMO MELMED.

2 DR. MELMED: YES.

3 MR. TOCHER: CHRIS MIASKOWSKI.

4 DR. MIASKOWSKI: YES.

5 MR. TOCHER: JOE PANETTA. SUZANNE

6 SANDMEYER. KAROL WATSON.

7 DR. WATSON: YES.

8 MR. TOCHER: KEVIN XU.

9 DR. XU: YES.

10 MR. TOCHER: THANK YOU. CARRIES

11 UNANIMOUSLY, MR. CHAIR.

12 CHAIRMAN IMBASCIANI: THANK YOU, SCOTT,

13 FOR DOING THAT. SO CAN I INVITE DR. SAMBRANO BACK

14 TO THE PODIUM. I'M SORRY. OF COURSE, LARRY.

15 DR. GOLDSTEIN: SO I GET A REBUTTAL, VITO?

16 I DO WANT TO THANK ALL THE BOARD MEMBERS FOR THEIR

17 FRIENDSHIP AND SUPPORT AT A CHALLENGING TIME, BUT

18 REALLY ENABLED THINGS I CARED ABOUT TO BE

19 SUCCESSFUL. THE WORK YOU DO AND WILL CONTINUE TO DO

20 MATTERS A GREAT DEAL TO ME. AND ALTHOUGH I'M NOT AN

21 MD, THE IDEA OF HEALING THE SICK WITH STEM CELL AND

22 RELATED APPROACHES IS SOMETHING THAT CONTINUES TO

23 DRIVE MY THINKING ABOUT WHERE CERTAIN AVENUES I'M

24 INVOLVED IN SHOULD GO.

25 SO A BIG THANK YOU TO THE BOARD, A SPECIAL

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1 CALL-OUT TO THE STAFF PEOPLE. YOU GUYS WERE KIND TO
2 ME, YOU WERE SUPPORTIVE, YOU MADE SURE THAT SOME OF
3 MY CRAZIER IDEAS COULD BE TRANSLATED INTO REALISTIC
4 PROGRESS. AND THAT ALSO HAS MEANT A GREAT DEAL. SO
5 I'LL WATCH WITH INTEREST IN THE COMING YEARS. I AM
6 ALWAYS AVAILABLE FOR CONSULTATION AS VITO AND MARIA
7 KNOW. AND I WILL CONTINUE TO CHEER FOR YOUR
8 SUCCESS. SO KEEP UP THE GOOD WORK, GUYS.

9 CHAIRMAN IMBASCIANI: THANK YOU, LARRY.
10 AND I WANT TO TELL YOU THAT THIS RESOLUTION WHICH
11 THE BOARD JUST VOTED IN YOUR HONOR, WHILE NOT AS
12 PRETTY AS THE PORTRAIT WE WERE JUST LOOKING AT, WILL
13 BE SENT TO YOU IN SAN DIEGO IN GOOD CONDITION.

14 DR. GOLDSTEIN: THANK YOU. YES,
15 WONDERFUL.

16 (APPLAUSE.)

17 CHAIRMAN IMBASCIANI: NOW WE'LL RETURN TO
18 THE CONSIDERATION OF AGENDA ITEM NO. 13, THE REVIEW
19 PROCESS AND THE GRANTS WORKING GROUP BYLAWS. DR.
20 SAMBRANO, THE FLOOR IS YOURS.

21 DR. SAMBRANO: THANK YOU VERY MUCH,
22 CHAIRMAN IMBASCIANI, MEMBERS OF THE BOARD, MEMBERS
23 OF THE PUBLIC. GOOD AFTERNOON. THIS HAS BEEN
24 SEEMINGLY HIGHLY ANTICIPATED BASED ON THE EARLIER
25 DISCUSSION, SO I HOPE I DON'T DISAPPOINT. I DO WANT

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1 TO WARN YOU THAT IT IS A LENGTHY PRESENTATION. AND
2 SO THE INTENT IS TO DESCRIBE TO YOU THE REVIEW
3 PROCESS THAT'S TO BE USED FOR THE FOUR NEW CONCEPTS
4 THAT HAVE BEEN APPROVED, AND TO GIVE YOU A DEEPER
5 UNDERSTANDING OF THE REVIEW PROCESS ITSELF, HOW IT
6 IS THAT IT WORKS AT CIRM.

7 MOST OF WHAT I'M GOING TO DESCRIBE TO YOU
8 IS SOMETHING THAT WE'VE DONE BEFORE, BUT IT'S
9 IMPORTANT TO EXPLAIN HOW IT WORKS TO GIVE YOU A
10 DEEPER UNDERSTANDING OF WHAT HAPPENS. AND, OF
11 COURSE, SOME OF IT IS NEW, AND IT WAS DEVELOPED
12 AROUND A COUPLE OF THE PROGRAMS THAT WERE ALREADY
13 DESCRIBED TO YOU. THERE WILL BE A LITTLE BIT OF
14 REPETITION, BUT I HOPE TO GET THROUGH THOSE MAYBE
15 QUICKLY. I ALSO WANT TO INVITE YOU TO ASK QUESTIONS
16 AS WE GO ALONG BECAUSE IT IS A LENGTHY PRESENTATION.
17 I MAY NOT BE LOOKING UP. SO IF I'M NOT AND I DON'T
18 SEE YOU ASKING, MAYBE CLAUDETTE OR SCOTT, IF YOU
19 COULD ALERT ME, AND I'M HAPPY TO ADDRESS ANY
20 QUESTIONS.

21 SO HERE WE GO. THIS IS THE PROPOSED
22 AGENDA OR OUTLINE FOR THE DISCUSSION. I WANT TO
23 START WITH AN INTRODUCTION TO THE GRANTS WORKING
24 GROUP ITSELF AND HOW APPLICATION REVIEW WORKS UNDER
25 THE CONTEXT OF THE GRANTS WORKING GROUP. INTRODUCE

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1 YOU TO WHAT WE CALL TWO-STAGE REVIEW WHICH HAS
2 SEVERAL FLAVORS OF APPROACHES THAT WE HAVE TRIED. I
3 WANT TO GO THROUGH THE METHODS THAT ARE PROPOSED FOR
4 EACH OF THE CONCEPTS THAT WERE DISCUSSED EARLIER:
5 THE DISC5, CLIN2, PDEV, AND DISC4. I WANT TO SPEND
6 A LITTLE BIT OF TIME ON THE SCORING METHODOLOGY THAT
7 CIRM USES AND THE REASON FOR WHY WE WISH TO SCORE
8 THIS WAY. AND THEN SPEND SOME TIME ON PROGRAMMATIC
9 REVIEW AND TEAM RECOMMENDATIONS THAT COME TO THE
10 BOARD, THE APPLICATION REVIEW SUBCOMMITTEE, FOR
11 FINAL DECISIONS AND HOW WE INTEND TO PROVIDE YOU
12 ENOUGH INFORMATION TO MAKE INFORMED DECISIONS.

13 SO LET'S START WITH THE GRANTS WORKING
14 GROUP. THE GRANTS WORKING GROUP ITSELF IS THE BODY
15 THAT'S RESPONSIBLE FOR EVALUATING SCIENTIFIC MERIT
16 OF ALL APPLICATIONS UNDER PROPOSITION 71 AND PROP
17 14. AND THE OUTCOME OF THE GRANTS WORKING GROUP
18 MEETING IS TO PROVIDE FUNDING RECOMMENDATIONS TO THE
19 ICOC.

20 THE PANEL ITSELF IS COMPOSED OF UP TO 15
21 SCIENTIFIC MEMBERS THAT ARE FROM OUTSIDE OF
22 CALIFORNIA. SO WE RECRUIT ALL OF THE MEMBERS FROM
23 OUTSIDE OF CALIFORNIA MOSTLY FOR CONFLICT OF
24 INTEREST ISSUES OR AT LEAST TO MINIMIZE IT, AND TO
25 MAKE SURE THAT WE BRING IN THE APPROPRIATE

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1 EXPERTISE. IT ALSO INCLUDES SEVEN PATIENT ADVOCATE
2 OR NURSE MEMBERS OF THE BOARD. SO SEVERAL OF YOU
3 ARE APPOINTED TO THE GRANTS WORKING GROUP AS PATIENT
4 ADVOCATE OR NURSE MEMBERS. AND THE CHAIR OF THE
5 ICOC IS AN EX OFFICIO MEMBER OF THE PANEL.

6 ALL MEMBERS MUST BE APPOINTED BY THE ICOC.
7 SO THAT'S BOTH THE SCIENTIFIC MEMBERS AND THE
8 PATIENT ADVOCATE NURSE MEMBERS AND WILL SERVE FOR
9 VARIABLE TERMS. THE GROUP ITSELF FUNCTIONS AS A
10 SINGULAR BODY, BUT WITH ROTATING SCIENTIFIC MEMBERS.
11 SO WE BRING THE APPROPRIATE SCIENTIFIC MEMBERS FOR
12 THE NEEDS OF A PARTICULAR REVIEW; HOWEVER, OUR
13 PATIENT ADVOCATE AND NURSE MEMBERS WE HAVE A FEWER
14 NUMBER TO DRAW FROM. SO BASICALLY THAT IS YOU WHO
15 SERVE THE BOARD THAT WE DRAW ON FOR THESE MEETINGS.

16 CIRM DOESN'T HAVE STANDING STUDY SECTIONS
17 FOR REVIEW WHERE WE CAN HAVE PANELS THAT ARE
18 DEDICATED TO ANY PARTICULAR FIELD OR AREA OF STUDY.
19 SO INSTEAD, WE HAVE TO ASSEMBLE OUR PANELS AROUND A
20 SPECIFIC SET OF APPLICATIONS AS WE GO THROUGH EACH
21 OF THE CYCLES.

22 SO HOW DO WE THEN ASSEMBLE THE PANELS IN
23 ORDER TO GATHER THE RIGHT EXPERTISE? SO WHAT WE DO
24 IS, AS YOU HAVE SEEN OVER THE COURSE OF SEVERAL OF
25 THESE BOARD MEETINGS, WE APPOINT AND BRING TO YOU

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1 BIOS AND INFORMATION ABOUT DIFFERENT EXPERTS THAT WE
2 WOULD LIKE TO NOMINATE TO THE GRANTS WORKING GROUP.
3 AND THROUGH THAT PROCESS, WE MAINTAIN A POOL OF
4 ABOUT 250 TO 300 APPOINTED MEMBERS THAT HAVE
5 VARIABLE AREAS OF EXPERTISE, CLINICIANS, BASIC
6 BIOLOGISTS, FOLKS WHO UNDERSTAND PRODUCT DEVELOPMENT
7 OR REGULATORY AFFAIRS. AND WE UTILIZE THIS POOL IN
8 ORDER TO CONSTRUCT A PANEL THAT'S APPROPRIATE FOR
9 THE TYPE OF REVIEW THAT WE INTEND TO HAVE.

10 SO YOU CAN IMAGINE THAT A PANEL FOR A
11 DISCOVERY SET OF APPLICATIONS IS GOING TO BE
12 COMPOSED AND BE DIFFERENT FROM A CLINICAL PANEL, FOR
13 EXAMPLE. WE NEED TO HAVE ENOUGH INDIVIDUALS WITHIN
14 THAT POOL TO ENSURE THAT WE COVER ALL THE DIFFERENT
15 AREAS THAT CAN COME TO US IN TERMS OF TOPICS AND
16 APPLICATIONS, BUT STILL MAINTAIN THE UP TO 15
17 SCIENTIFIC MEMBERS FOR A GIVEN PANEL.

18 DR. LEVITT: IT'S A BORING QUESTION.
19 GIVEN WHAT WE HEARD THIS MORNING ABOUT THE
20 EXPECTATION OF THE TIDAL WAVE OF APPLICATIONS, IS
21 THE 15-MEMBER COMPONENT, IS THAT IN THE PROPOSITION
22 OR THAT'S INTERNAL?

23 DR. SAMBRANO: YES. IT'S IN THE
24 PROPOSITION UP TO 15.

25 DR LEVITT: SO THAT'S CAPPED?

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1 DR. SAMBRANO: YES.

2 DR. LEVITT: MAYBE IT VARIES. YOU HAVE
3 THREE PANELS, DISC, TRAN, AND CLIN. WHAT'S THE
4 AVERAGE NUMBER OF APPLICATIONS ASSIGNED TO A MEMBER?

5 DR. SAMBRANO: I WAS GOING TO GO OVER
6 THAT. SO WHAT ARE THE NUMBERS? SO THE BEST
7 COMPARATOR TO NIH, FOR EXAMPLE, LIKE A R01, FOR NIH
8 IS TYPICALLY SIX TO EIGHT. SO WE AVERAGE ANYWHERE
9 FROM SIX TO TEN, AND WE TEND TO PUSH IT A LOT OF
10 TIMES TOWARDS THE LARGER NUMBER, PARTICULARLY FOR
11 DISCOVERY PROPOSALS JUST BECAUSE THAT'S WHERE WE GET
12 THE HIGHEST NUMBER OF APPLICATIONS.

13 ON THE FLIP SIDE, FOR CLINICAL, IT'S MUCH
14 FEWER. SO WE CAN ACTUALLY CONCENTRATE THE EFFORTS
15 IF A 15-MEMBER PANEL MUCH MORE EFFECTIVELY BECAUSE
16 THE NUMBER OF APPLICATIONS IS SMALLER.

17 DR. LEVITT: OKAY. THANKS.

18 DR. SAMBRANO: OKAY. SO THE COMPOSITION,
19 AGAIN, I MENTIONED THE SCIENTIFIC MEMBERS WHO ARE
20 RESPONSIBLE FOR THE SCIENTIFIC EVALUATION, BUT THOSE
21 ARE THE ONLY ONES THAT ACTUALLY DO THE SCIENTIFIC
22 SCORING. SO WHENEVER YOU SEE THE SCIENTIFIC
23 SCORING, IT COMES FROM THE 15 SCIENTISTS. OUR
24 PATIENT ADVOCATE MEMBERS PARTICIPATE BY PROVIDING
25 PERSPECTIVE ON THE SIGNIFICANCE AND POTENTIAL FOR

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1 IMPACT. THEY MAY PROVIDE A DEI SCORE ON CLINICAL
2 APPLICATIONS AND MAY ALSO PROVIDE SUGGESTED
3 SCIENTIFIC SCORE, BUT THOSE ARE NOT RECORDED AS PART
4 OF THE SCORE THAT WE ULTIMATELY SEE.

5 WE BRING IN TO ADD EXPERTISE WHERE
6 POSSIBLE SCIENTIFIC SPECIALISTS. SO THESE ARE
7 NONVOTING PARTICIPANTS WHO MAY COVER ONE OR TWO
8 APPLICATIONS AS NEEDED TO BRING THAT ADDED EXPERTISE
9 TO THE PANEL. AND SO ALTHOUGH THEY PROVIDE
10 COMMENTARY AND PARTICIPATE IN THE DISCUSSION, THEY
11 DO NOT PROVIDE A FINAL SCORE.

12 SO I WANT TO JUST UTILIZE THIS SLIDE TO
13 SET THE STAGE FOR WHAT I'M GOING TO DISCUSS GOING
14 FORWARD. THIS IS WHAT A TYPICAL GRANTS WORKING
15 GROUP-BASED REVIEW TIMELINE WOULD LOOK LIKE OR AT
16 LEAST PROCESS LINE WOULD LOOK LIKE. IT HAS THREE
17 BASIC STEPS. ELIGIBILITY THAT'S ASSESSED BY CIRM
18 STAFF WHEN APPLICATIONS COME IN. THOSE THAT ARE
19 ACCEPTED GO TO THE GRANTS WORKING GROUP FOR THE
20 MERIT REVIEW. THE RECOMMENDATION COMES FROM THE
21 GRANTS WORKING GROUP THAT COMES TO THEN THE ICOC FOR
22 A FINAL FUNDING DECISION.

23 SO ASSUMING THERE IS NO NEED FOR A
24 TWO-STAGE PROCESS, THIS IS GENERALLY WHAT IT LOOKS
25 LIKE.

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1 NOW, THERE ARE SEVERAL CONSIDERATIONS THAT
2 WE TAKE INTO ACCOUNT WHEN THINKING ABOUT WHAT IS
3 THAT NUMBER WHERE WE FEEL WE'RE NOT GOING TO HAVE A
4 QUALITY OR EFFECTIVE REVIEW? AND THERE ARE SEVERAL
5 FACTORS. PAT, YOU BROUGHT ONE OF THE THEM UP WHICH
6 IS RELATED TO HAVING ADEQUATE TIME FOR REVIEWERS TO
7 DISCUSS APPLICATIONS. SO, OF COURSE, THE MORE
8 APPLICATIONS THAT ARE IN A REVIEW CYCLE, THE LESS
9 TIME IS AVAILABLE FOR EACH ONE. MINIMIZING THE
10 APPLICATION ASSIGNMENT BURDEN PER REVIEWER. AS
11 MENTIONED, THE MORE APPLICATIONS EACH REVIEWER IS
12 ASSIGNED TO, THE LESS EFFORTS THAT IS THEN EXPENDED
13 ON EACH ONE.

14 WE ALSO TO MAXIMIZE AS BEST WE CAN THE
15 EXPERTISE THAT WE HAVE AVAILABLE FROM THE GWG TO THE
16 SET OF APPLICATIONS THAT WE ARE REVIEWING. AND THE
17 GREATER LEVEL OF EXPERTISE IS AVAILABLE WHEN YOU
18 HAVE A MORE FOCUSED SET OF APPLICATIONS, AS YOU
19 MIGHT IMAGINE, AND THE BROADER THE SCOPE, THE MORE
20 DIFFICULT IT IS TO MAKE SURE THAT YOU HAVE EXPERTS
21 AVAILABLE TO COVER EVERYTHING THAT NEEDS IT.

22 WE ALSO WANT TO MAKE SURE THAT WE ALIGN
23 THE REVIEW WITH THE TARGETED NUMBER OF AWARDS WE
24 SEEK. SO IN A LOT OF THE CONCEPT PRESENTATIONS, WE
25 PRESENT THE TARGET NUMBER THAT WE HAVE EITHER ON AN

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1 ANNUAL BASIS OR ON A PER CYCLE BASIS. AND SO WE
2 WANT TO MAKE SURE THAT THE REVIEWS ARE CAPABLE OF
3 GIVING US THE TARGETED NUMBER OF AWARDS AND THAT WE
4 ARE ALIGNED WITH THAT.

5 SO GIVEN ALL OF THIS AND GIVEN THESE
6 FACTORS, THE NUMBER THAT ULTIMATELY ALLOWS TO
7 BALANCE THESE CONSIDERATIONS AND ACHIEVE QUALITY
8 REVIEWS IS WHAT DETERMINES, THEN, THE CAPACITY. AND
9 SO WHAT HAPPENS WHEN WE EXCEED THAT CAPACITY? AND
10 THAT'S WHEN WE COME INTO THE IDEA OF SETTING UP A
11 TWO-STAGE REVIEW PROCESS. AND SO, THEREFORE, THE
12 PURPOSE OF IT IS THAT WHEN THE NUMBERS OF
13 APPLICATIONS RECEIVED FOR FUNDING OPPORTUNITIES
14 EXCEED THE CAPACITY OF THE GRANTS WORKING GROUP TO
15 REVIEW IN A SINGLE CYCLE, WE IMPLEMENT IT.

16 AND TYPICALLY THIS HAS HAPPENED FOR OUR
17 EARLY STAGE DISCOVERY TYPE OF OPPORTUNITIES, AND
18 THAT HAS BEEN HAPPENING FOR MANY YEARS. SO ALMOST
19 SINCE THE VERY BEGINNING THOSE WERE THE MOST POPULAR
20 OF OUR OPPORTUNITIES. AND WE STARTED DEVELOPING
21 DIFFERENT MECHANISMS FOR HOW WE WOULD SET UP A
22 TWO-STAGE REVIEW PROCESS, DOING PREAPPLICATIONS OR
23 LIMITING, FOR EXAMPLE, THE TOTAL NUMBER OF
24 APPLICATIONS THAT COULD BE SUBMITTED BY AN
25 INSTITUTION, WHICH THERE ARE A LOT OF REASONS NOT TO

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1 DO THAT, BUT IT WAS SOMETHING THAT WE ACTUALLY
2 TRIED.

3 SO TODAY I WANT TO DISCUSS WHAT IT IS THAT
4 WE'RE PROPOSING TO DO AS A TWO-STAGE REVIEW PROCESS
5 FOR EACH OF THE CONCEPTS THAT WERE DISCUSSED
6 EARLIER.

7 ALL RIGHT. SO HOW DID WE GO ABOUT, THEN,
8 CHOOSING THE PROCESS FOR EACH OF THESE PROGRAMS? WE
9 SET UP A SORT OF DECISION TREE. WE WORKED WITH THE
10 REVIEW TEAM ALONG WITH EACH OF THE CONCEPT TEAMS TO
11 UNDERSTAND THE NEEDS FOR EACH OF THE CONCEPTS THAT
12 WERE BEING DEVELOPED, AND TO TRY TO ARRIVE AT A
13 PROCESS THAT WAS AMENABLE AND WOULD WORK BEST FOR
14 THAT GROUP. OF COURSE, THE GOALS WERE TO MANAGE
15 LARGE NUMBERS OF APPLICATIONS, MAKE SURE WE COULD
16 IMPLEMENT STRATEGIC PRIORITIES, AND WHERE POSSIBLE
17 LIMIT THE BURDEN ON APPLICANTS.

18 AND SO QUESTIONS THAT WE ASKED OURSELVES
19 IN DEVELOPING THIS PROCESS WERE CAN THE GRANTS
20 WORKING GROUP APPROPRIATELY AND EFFECTIVELY REVIEW
21 ALL ELIGIBLE APPLICATIONS? IF SO, THERE WOULD BE
22 OBVIOUSLY NO NEED TO MAKE MUCH EFFORT IN A TWO-STAGE
23 REVIEW PROCESS. WE HAVE LEARNED, HOWEVER, THAT WE
24 HAVE BECOME MORE POPULAR IN TERMS OF APPLICATIONS
25 COMING IN. I THINK WE HAVE ALL SEEN THAT IT HAS NOT

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1 JUST EXISTED IN THE EARLY DISCOVERY STAGE, BUT IT
2 HAS GONE INTO NOW TRANSLATIONAL STAGE PROJECTS AS
3 WELL AS THE CLINICAL. SO FINDING EFFECTIVE WAYS TO
4 DO THIS IS IMPORTANT.

5 WE ALSO ASK WHETHER THE PREFERENCES OR
6 PRIORITIES THAT WE SET ARE THINGS THAT CAN BE
7 DETERMINED DISCRETELY OR COMPARATIVELY. DISCRETELY
8 MEANING THAT AN APPLICATION ON ITS OWN CAN TELL YOU
9 WHETHER THIS IS TRUE OR NOT OR WHETHER THE CRITERION
10 IS MET. FOR EXAMPLE, ARE THEY A CALIFORNIA
11 ORGANIZATION OR NOT? COMPARATIVELY FOR SOMETHING
12 THAT A GIVEN APPLICATION IS MORE OR LESS OF THAN
13 ANOTHER IN ORDER TO DETERMINE WHETHER A CRITERION IS
14 MET.

15 IS A COMPLETE APPLICATION NECESSARY IN
16 ORDER TO ASSESS THESE PRIORITIES? IN SOME CASES WE
17 FELT IT WAS IMPORTANT TO HAVE A FULL APPLICATION.

18 SO THIS TABLE IS JUST A SUMMARY --

19 DR. LEVITT: CAN I ASK A QUESTION? YOU
20 MENTIONED BEFORE -- I'M OBSESSING ABOUT THIS BECAUSE
21 THIS PROCESS IS GOING TO DEFINE OUR FUNDED PROGRAMS.
22 AND SO THE PROCESS IS REALLY IMPORTANT, TO ME AT
23 LEAST. I THINK IT'S IMPORTANT TO EVERYBODY. SO YOU
24 MENTIONED THAT ALL APPLICATIONS UNDER A SPECIFIC
25 RUBRIC COMING IN AT A CERTAIN TIME GO TO ONE STUDY

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1 SECTION.

2 DR. SAMBRANO: TO ONE GROUP.

3 DR. LEVITT: IS THAT A REQUIREMENT AS
4 WELL? IS THAT A PROPOSITION REQUIREMENT?

5 DR. SAMBRANO: ALL APPLICATIONS ULTIMATELY
6 HAVE TO GO THROUGH THE GRANTS WORKING GROUP.

7 DR. LEVITT: BUT I'M SAYING YOU HAVE ONE
8 15-MEMBER PLUS SEVEN PLUS WHATEVER YOU HAVE. YOU
9 HAVE ONE WORKING GROUP FOR A PARTICULAR GRANT
10 SUBMISSION, AND ALL THE GRANTS IN THAT SUBMISSION GO
11 TO THAT ONE GROUP FOR A PARTICULAR PROJECT, OR A
12 PARTICULAR RUBRIC.

13 DR. SAMBRANO: YES IN THE SENSE THAT IT'S
14 THE GRANTS WORKING GROUP. SO AS I MENTIONED
15 EARLIER, WE CAN ROTATE SCIENTIFIC MEMBERS IN AND
16 OUT, AND TO SOME EXTENT WE CAN ROTATE --

17 DR. LEVITT: SURE. I GUESS WHAT I'M
18 ASKING IS DO YOU EVER HAVE A SITUATION WHERE YOU
19 HAVE TWO GWG'S?

20 DR. SAMBRANO: NO.

21 DR. LEVITT: UNDER THE SAME CONCEPT PLAN
22 REVIEWING GRANTS AT THE SAME TIME?

23 DR. SAMBRANO: NO.

24 DR. LEVITT: IT'S ONLY ONE?

25 DR. SAMBRANO: IT'S ONLY ONE.

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1 DR. LEVITT: ALL RIGHT. SO IS NOT HAVING
2 TWO, HAS THAT BEEN DISCUSSED, HAVING MORE THAN ONE?

3 DR. SAMBRANO: IT'S A FEASIBILITY ISSUE IN
4 THE SENSE THAT WE DON'T HAVE ENOUGH MEMBERS, PATIENT
5 ADVOCATE NURSE MEMBERS THAT WOULD SIMULTANEOUSLY BE
6 ABLE TO DO THAT WORK. SO WE BASICALLY CAN ONLY
7 HANDLE THEM ONE AT A TIME.

8 ALL RIGHT. SO THIS IS JUST A TABLE THAT
9 SUMMARIZES WHAT I'M GOING TO TALK TO YOU ABOUT IN
10 MORE DETAIL: THE TWO-STAGE METHOD THAT WAS SELECTED
11 FOR EACH OF THE PROGRAMS, THE SUBMISSION CONTENT
12 THAT WE EXPECT. SO FOR DISC5 AND CLIN2, FOR
13 EXAMPLE, WE REQUIRE A FULL APPLICATION. BOTH OF
14 THESE PROCESSES WERE ESTABLISHED AND WE HAVE SOME
15 EXPERIENCE WITH THEM. THE CLIN2 QUALIFICATION
16 PROCESS BEING THE NEWEST, WE TOOK THAT THROUGH TWO
17 CYCLES LAST YEAR. AND SO THAT HAS BEEN OUR
18 EXPERIENCE, LIMITED BUT INFORMATIVE AS WELL.

19 AND THEN FOR PDEV AND DISC4, WE HAVE A
20 PRESUBMISSION OR LOI PROCESS THAT WE ARE PROPOSING
21 WHICH IS NEW.

22 SO FOR DISC5, I'M GOING TO SHOW THE
23 PROCESS AND TRY TO BREAK IT DOWN UTILIZING THE
24 GRAPHIC OF THE STEPS ALONG THE REVIEW PROCESS THAT I
25 SHOWED YOU EARLIER. AND SO COMPARED TO THE BASIC

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1 PROCESS THAT I SHOWED YOU HERE, WE'RE INSERTING A
2 STEP, POSITIVE SELECTION, FOR DISC5 WHICH COMES
3 AFTER BEGINNING ELIGIBILITY AND BEFORE THE FINAL
4 MERIT REVIEW BY THE GRANTS WORKING GROUP.

5 SO FOR THIS PROCESS, APPLICATIONS ARE
6 SUBMITTED, AND THIS IS A FULL APPLICATION FOR DISC5.
7 AND THERE'S AN INITIAL ELIGIBILITY REVIEW THAT'S
8 MADE BY THE CIRM TEAM. THERE WE WANT TO MAKE SURE
9 THAT WHAT COMES IN HAS AT LEAST SOME POSSIBILITY OF
10 ADVANCING, THAT IT'S GENERALLY A COMPLETE
11 APPLICATION, HAS ALL THE ELEMENTS, IF WE REQUIRE IT
12 TO BE A CALIFORNIA ORGANIZATION, FOR EXAMPLE, THAT
13 IT IS. AND THEN WE PUT THEM THROUGH THE NEXT STEP
14 WHICH IS THE POSITIVE SELECTION. SO THOSE THAT ARE
15 ACCEPTED FOR REVIEW AT THAT STAGE GO TO POSITIVE
16 SELECTION.

17 AND HERE WE SELECT THE PANEL THAT IS
18 ULTIMATELY GOING TO BE THE PANEL THAT DOES THE FINAL
19 MERIT REVIEW TO ALSO BE THE MEMBERS THAT MAKE THE
20 SELECTIONS. SO GRANTS WORKING GROUP MEMBERS GO
21 THROUGH THE SET OF APPLICATIONS. LET'S SAY, FOR
22 EXAMPLE, THERE'S A HUNDRED APPLICATIONS THAT THEY
23 LOOK THROUGH, AND THEY CONDUCT A PREREVIEW TO ASSESS
24 WHICH ONES THEY BELIEVE HAVE THE MOST POTENTIAL FOR
25 IMPACT AND SELECT WHICH ONES TO ADVANCE.

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1 SOUNDS LIKE YOU HAVE A QUESTION.

2 DR. LEVITT: SO THOSE GRANTS THAT ARE --
3 ALL THE GRANTS ARE PREREVIEWED. THESE ARE FULL
4 GRANTS. DO THE INVESTIGATORS RECEIVE FEEDBACK OF
5 SOME SORT? THIS IS -- I'M TRYING TO FIGURE OUT IF
6 THIS IS SIMILAR TO WHAT OTHER AGENCIES USE AS A
7 TRIAGE PROCESS WHERE THERE'S A FULL GRANT, IT'S READ
8 AND REVIEWED, AND THERE'S SOME RETURN OF INFORMATION
9 BACK TO THE INVESTIGATOR ABOUT WHY IT WAS NOT EVEN
10 DISCUSSED AT THE GRANT REVIEW.

11 DR. SAMBRANO: RIGHT. SO THIS IS NOT A
12 FULL REVIEW IN THAT WAY. SO THE FEEDBACK THAT
13 APPLICANTS RECEIVED IS MINIMAL. MEANING THEY
14 DON'T -- THEY KNOW THAT THEY JUST DID NOT ADVANCE.
15 WE CAN'T TELL THEM WHY BECAUSE THE POINT OF THE
16 POSITIVE SELECTION IN THE INSTRUCTIONS TO REVIEWERS
17 IS PLEASE TELL US WHICH ONES YOU THINK ARE THE BEST
18 ONES, NOT TO CRITIQUE EACH ONE, BUT TO SELECT AMONG
19 THESE APPLICATIONS AND TELL US WHICH YOU LIKE BEST.
20 SO WE DON'T NECESSARILY KNOW WHY SOMETHING WASN'T
21 PICKED, BUT WE CAN HAVE MUCH MORE INFORMATION ABOUT
22 THE ONES THAT ARE.

23 DR. LEVITT: AND JUST REMIND ME, DISC-0, I
24 GUESS YOU HAVE APPLICATIONS WHICH IS NOW BECOMING
25 DISC5.

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1 DR. SAMBRANO: CORRECT, YES.

2 DR. LEVITT: SO HOW MANY APPLICATIONS DO
3 YOU HAVE NOW FOR DISCO IN THE HOPPER APPROXIMATELY?

4 DR. SAMBRANO: SO THE APPLICATION DEADLINE
5 IS IN A FEW DAYS. SO IT'S APRIL 10TH. SO IN THE
6 SYSTEM WE HAVE OVER 200 APPLICATIONS THAT ARE --

7 DR. LEVITT: ALREADY THERE.

8 DR. SAMBRANO: -- THAT ARE BEING WORKED
9 ON, NOT YET SUBMITTED.

10 DR. LEVITT: ABOUT 200. OKAY. THANKS.

11 DR. SAMBRANO: SO THE GRANTS WORKING GROUP
12 DOES THE FIRST STEP. SO THIS IS JUST A VIEW OF OUR
13 GRANTS MANAGEMENT SYSTEM. AND THE WAYS IN WHICH THE
14 REVIEWERS CAN SORT OR FILTER THE LIST OF
15 APPLICATIONS TO IDENTIFY ONES THAT ARE WITHIN A
16 SPECIFIC DISEASE AREA OR ONES THAT HAVE NOT BEEN
17 SELECTED IN ORDER TO BRING THOSE TO THE TOP OR EVEN
18 A RANDOM FILTER THAT ALLOWS THE APPLICATIONS TO BE
19 RANDOMIZED SO THEY CAN SELECT THEM AND IT DOESN'T
20 BIAS AN APPLICATION BASED ON WHERE IT EXISTS ALONG
21 THE LIST.

22 AND REVIEWERS CAN VIEW ALL THE
23 APPLICATIONS IN A TABLE FORMAT, EXAMINE EACH VIA A
24 SUMMARY PAGE, OR DIG DEEP INTO EACH APPLICATION AND
25 SEE THE FULL APPLICATION COMPONENTS.

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1 THE PROCESS ITSELF, AND THESE NUMBERS ARE
2 INTENDED TO BE EXAMPLES, IS SOMETHING THAT CAN BE
3 DONE IN AN ITERATIVE WAY. MEANING THAT YOU CAN
4 SCALE TO A LARGE NUMBER OF APPLICATIONS AND JUST
5 REPEAT THE SELECTION PROCESS SUCH THAT YOU CAN HAVE
6 AN INITIAL SELECTION. IF WE WERE TO RECEIVE
7 APPLICATIONS IN THE 300 PLUS RANGE, WE COULD DO AN
8 INITIAL SELECTION AND THEN DO A SECOND ROUND OF
9 SELECTION THAT NARROWS IT TO, SAY, A HUNDRED TO 150,
10 AND THEN TO THE TARGETED NUMBER THAT MAY BE IN THE
11 RANGE OF 30 TO 50. PAT.

12 DR. LEVITT: I BROUGHT THIS UP THIS
13 MORNING. SO FULL APPLICATIONS ARE GOING TO BE USED
14 TO BASICALLY ELIMINATE 50 TO 70 PERCENT OF THE -- 50
15 TO -- ONE-HALF TO TWO-THIRDS OF THE ULTIMATE
16 APPLICATIONS. SO FOR THE GWG MEMBERS, THEY'RE
17 LOOKING AT A FULL APPLICATION WHICH TAKES MORE TIME
18 THAN AN LOI, AND FOR THE INVESTIGATORS THAT ARE
19 WRITING A FULL APPLICATION, WHICH TAKES MORE TIME
20 THAN AN LOI, I'M TRYING TO UNDERSTAND WHY DON'T USE
21 AN LOI APPROACH HERE WHICH IS LIKELY THE GROUP
22 THAT'S GOING TO GET THE LARGEST NUMBER OF
23 APPLICATIONS IN THE FIRST PLACE. RIGHT. THIS IS
24 THE ONSLAUGHT. ANYBODY CAN TAKE IT.

25 DR. CANET-AVILES: SO ONE CLARIFICATION.

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1 SO GIL WAS BEING CONSERVATIVE BECAUSE WHAT HE'S
2 PROBABLY REFERRING TO 200 APPLICATIONS IS THE ONES
3 THAT MIGHT HAVE TITLE. AS OF NOW THE GRANTS
4 MANAGEMENT SYSTEM, THERE ARE 681 OPEN APPLICATIONS.

5 DR. LEVITT: HOW MANY?

6 DR. CANET-AVILES: 681. WHAT THIS COULD
7 TRANSLATE TO IS WE DO NOT ASK THEM FOR MORE THAN
8 ONE-PAGE LOI. THIS COULD TRANSLATE IN HAVING
9 SEVERAL HUNDRED OF THEM COMING TO THESE 15 GRANTS
10 WORKING GROUP MEMBERS FOR POSITIVE SELECTION, WHICH
11 IS A PROBLEM OF VOLUME FOR US TO MANAGE WITH THE
12 PROP 14 RESTRICTIONS. I JUST WANTED TO MAKE THAT
13 COMMENT.

14 DR. SAMBRANO: THANK YOU, ROSA, FOR THE
15 CLARIFICATION. YES. THE 200 THAT I WAS SPEAKING
16 TO, ONE OF THE THINGS WE DO ON ORDER TO ASSESS HOW
17 MANY ARE GOING TO COME IN, BECAUSE A LOT OF PEOPLE
18 WILL OPEN UP AN APPLICATION IN ORDER TO SEE WHAT IT
19 LOOKS LIKE, IS TO DETERMINE IF THERE'S ANY ACTIVITY
20 WITHIN LIKE THE LAST MONTH OR THAT THEY'VE SUBMITTED
21 OR PUT A TITLE OR OTHER THINGS. SO I BELIEVE THAT'S
22 IN THE RANGE OF 200. IF IT'S NOT, PLEASE CORRECT
23 ME.

24 BUT I THINK THE POINT HERE FOR THIS SLIDE
25 SIMPLY IS THAT SHOULD IT BE, LET'S SAY IT WERE 600

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1 BECAUSE IT'S ALWAYS A POSSIBILITY, THAT THIS PROCESS
2 DOES ALLOW US TO GO THROUGH ITERATIONS THAT WOULD
3 ALLOW US TO GET DOWN TO WHAT WE NEED IN TERMS OF
4 WHAT GOES TO FULL REVIEW.

5 DR. MADANAT: CAN YOU GIVE US MORE INSIGHT
6 INTO THE SELECTION CRITERIA OR THE SELECTION
7 PRIORITIES THAT ARE GIVEN TO THE COMMITTEE IN THE
8 POSITIVE SELECTION STAGE? WHAT ARE THEY LOOKING
9 FOR?

10 DR. SAMBRANO: YES. SO WHAT WE FOCUS THEM
11 ON IS IMPACT. SO THE REVIEW CRITERIA THAT THEY
12 UTILIZE IS DESCRIBED IN THE PROGRAM ANNOUNCEMENT OR
13 RFA. AND SO THEY CAN UTILIZE ALL OF THOSE CRITERIA,
14 BUT WE FOCUS THEM ON THE FIRST ONE, WHICH IS USUALLY
15 VALUE PROPOSITION OR SIGNIFICANCE OR IMPACT FOR
16 MAKING THESE SELECTIONS.

17 DR. LEVITT: SO, GIL, ONE WAY OF -- SO I
18 UNDERSTAND, IN SOME WAYS THIS IS ACTING -- LIKE OF
19 YOU HAVE TO SUBMIT A FULL APPLICATION. IT'S LIKELY
20 YOU'RE NOT GOING TO GET THE ONE PAGE. YOU'RE GOING
21 TO REDUCE THE NUMBER OF INDIVIDUALS WHO ARE GOING TO
22 SUBMIT LIKE A ONE PAGER. IT'S NOT LIKE YOU CAN SNAP
23 OFF A ONE-PAGER LIKE THAT, BUT IT'S GOING TO CREATE
24 MORE WORK ON THE OTHER END FOR THE GWG AND FOR THE
25 STAFF.

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1 SO ONE POSSIBILITY IS TO HAVE A FULL
2 APPLICATION, BUT THEN YOU ALSO HAVE A QUESTIONNAIRE
3 HERE. MAYBE TO KEEP THINGS BALANCED IN TERMS OF
4 MAKING THE FIRST DECISION SO THAT THOSE WHO ARE
5 CHARGED WITH MAKING THOSE DECISIONS USE THE SAME
6 INFORMATION IS TO HAVE THE QUESTIONNAIRE INCLUDED OR
7 THEY HAVE TO ANSWER THAT BECAUSE WHAT YOU JUST
8 ANSWERED IN TERMS OF CRITERIA IS EXACTLY WHAT YOU
9 HAVE WRITTEN HERE IN TERMS OF THE QUESTIONNAIRE.
10 THEY FILL THAT OUT AS PART OF THE APPLICATION
11 PROCESS. AND THE GWG AND THE TEAM USES THAT TO MAKE
12 THEIR DECISIONS, WHICH IS BASED EXACTLY ON WHAT YOU
13 JUST SAID.

14 DR. SAMBRANO: SO THE CRITERIA THAT YOU'RE
15 LOOKING AT, I BELIEVE, IS THE DISC4, THE
16 PRESUBMISSION.

17 DR. LEVITT: YES.

18 DR. SAMBRANO: SO THAT'S FOR THE
19 PRESUBMISSION FORM. AND SO, YES, WE COULD SIMILARLY
20 ASK QUESTIONS OF THE APPLICANT FOR DISC5, AND YOU
21 COULD HAVE A PRESUBMISSION PROCESS. THE REASON THAT
22 WE'RE NOT --

23 DR. LEVITT: YOU COULD INCLUDE IT IN THE
24 APPLICATION.

25 DR. SAMBRANO: I SEE WHAT YOU'RE SAYING.

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1 WELL, THERE IS. SO THERE'S A SUMMARY.

2 DR. LEVITT: IT'S THE SAME FOUR CRITERIA
3 AND THEY SAY THUMBS UP OR THUMBS DOWN. IT SAVES
4 THEM FROM HAVING TO GO THROUGH THE FULL APPLICATION.

5 DR. SAMBRANO: THEY DON'T HAVE TO.
6 THERE'S A PREVIEW, WHAT WE CALL A PREVIEW PAGE
7 WITHIN THE APPLICATION THAT SUMMARIZES THE KEY
8 INFORMATION FOR REVIEWERS. SO THEY CAN SIMPLY LOOK
9 AT THAT, BUT WE ALLOW THEM TO LOOK AT THE FULL
10 APPLICATION IF THEY NEED TO BECAUSE IN MANY CASES
11 IT'S A GOOD REFERENCE. SOME FIND THEMSELVES LOOKING
12 AT THE FULL APPLICATION TO CONFIRM INFORMATION THAT
13 THEY MAY SEE IN THE PREVIEW PAGE. JUDY.

14 DR. GASSON: SO I HAVE A SLIGHTLY
15 DIFFERENT QUESTION ABOUT THE POSITIVE SELECTION. SO
16 IF, IN FACT, YOU HAVE 300 APPLICATIONS COME IN AND
17 YOU HAVE 15 PEOPLE ON THIS REVIEW PANEL, MY CONCERN
18 IS THAT WE WORK IN SUCH BROAD AREAS, STEM CELL AND
19 GENE THERAPY, MY CONCERN IS THAT YOU WOULDN'T HAVE
20 ALL OF THE TYPES OF EXPERTISE IN THOSE 15
21 INDIVIDUALS TO POSITIVELY SELECT THOSE APPLICATIONS
22 THAT COULD POTENTIALLY HAVE THE HIGHEST IMPACT.

23 DR. SAMBRANO: I AGREE WITH YOU. AND THAT
24 IS ONE OF THE CHALLENGES THAT WE HAVE.

25 DR. GASSON: PAT GOES TWO STUDY SECTIONS,

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1 AND YOU SAID, NO, BECAUSE WE DON'T HAVE ENOUGH
2 PEOPLE ON THE BOARD. MAYBE WE NEED TO THINK
3 ABOUT -- I DON'T HAVE THE ANSWER.

4 VICE CHAIR BONNEVILLE: I THINK IT COMES
5 DOWN TO THE PATIENT ADVOCATE MEMBERS OF THE BOARD.
6 BUT WE DO HAVE THE ABILITY TO HAVE ALTERNATES TO
7 THOSE PATIENT ADVOCATES. I DON'T KNOW IF THERE'S
8 SOMETHING THAT WE CAN DO TO THEN CREATE MORE SPACE
9 IN THAT WAY.

10 DR. SAMBRANO: WE CAN HAVE ALTERNATES
11 WITHIN THE BOARD, BUT NOT OUTSIDE THE BOARD.

12 VICE CHAIR BONNEVILLE: I UNDERSTAND. I
13 THINK WHAT THEY'RE ASKING IS CAN YOU DO ONE PANEL
14 HERE, LIKE THEY'RE RUNNING SIMULTANEOUSLY, BUT
15 YOU'RE RUNNING ONE AND HAYLEY IS RUNNING THE OTHER,
16 FOR EXAMPLE, AND THEY'RE BOTH BEING RUN, THEY'RE
17 BOTH FULLY STAFFED, AND THERE ARE BOARD MEMBERS THAT
18 SIT ON BOTH. AND PERHAPS THERE'S NOT ENOUGH BOARD
19 MEMBERS THAT YOU HAVE FULLY SEVEN PEOPLE AT EACH.
20 MAYBE YOU HAVE FOUR AT ONE AND THREE AT THE OTHER,
21 AND THAT'S A WAY OF MITIGATING. I HAVE NO IDEA IF
22 THAT'S EVEN POSSIBLE. I KNOW RIGHT NOW YOU'RE LIKE
23 WHY IS MARIA SAYING THIS OUT LOUD. SO I APOLOGIZE.

24 DR. SAMBRANO: I MEAN IT'S A GOOD POINT.
25 IT'S NOT SOMETHING THAT WE HAVE CONSIDERED BECAUSE

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1 WE HAVE THOUGHT IT TO BE UNFEASIBLE.

2 VICE CHAIR BONNEVILLE: OKAY.

3 DR. SAMBRANO: BUT IT DOESN'T MEAN WE
4 SHOULDN'T OR THAT WE CAN'T. WE'RE HAPPY TO THINK
5 ABOUT THIS AND SEE IS THERE A WAY OF DOING THIS.
6 BUT FOR EVERY REVIEW, AND EVEN WHEN WE'VE HAD TO
7 DOUBLE UP REVIEWS COMING CLOSE TOGETHER, YOU
8 ESSENTIALLY HAVE DIFFERENT PANELS WHO ARE RECEIVING
9 DIFFERENT APPLICATIONS. THERE ARE CONSEQUENCES TO
10 HAVING TWO DIFFERENT GROUPS AND HOW YOU SPLIT UP THE
11 APPLICATIONS AND THEN HOW YOU PUT IT BACK TOGETHER
12 SO THAT YOU KNOW THAT THE SCORING THEN IS COMPARABLE
13 TO EACH. YOU KIND OF HAVE TO LOOK AT THEM
14 INDEPENDENTLY AND THEN DECIDE MAYBE FROM THIS GROUP
15 YOU PICK THE TOP TEN FROM THIS GROUP AND THEN THE
16 TOP TEN FROM THIS OTHER GROUP. BUT IT'S SOMETHING
17 THAT WE WOULD TO THINK THROUGH TO SEE HOW THAT WOULD
18 WORK OUT.

19 DR. LEVITT: THERE ARE WAYS OF
20 NORMALIZING. THAT'S WHAT OTHER AGENCIES DO. THEY
21 HAVE MORE THAN ONE STUDY SECTION AND THEY NORMALIZE.
22 IT IS THE CASE THAT SOME STUDY SECTIONS MAY SKEW
23 WHERE THEIR SCORE IS A LITTLE BETTER OR MORE HARSH.
24 THEY'RE PRETTY CLOSE TO EACH OTHER. THESE ARE ALL
25 COMING UP BECAUSE WE'RE TRYING TO HELP WHAT SEEMS

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1 LIKE A DAUNTING SITUATION AND WANTING TO DO DUE
2 DILIGENCE BOTH IN TERMS OF THE INFRASTRUCTURE YOU
3 ALL HAVE TO WORK WITH AND MAKING SURE THAT THE VERY
4 BEST RESEARCH -- VERY BEST SCIENCE IS BEING FUNDED
5 FOR THE TAXPAYERS OF CALIFORNIA.

6 DR. SAMBRANO: APPRECIATE IT.

7 DR. LEVITT: THIS IS A REAL CONUNDRUM.

8 DR. SAMBRANO: YEAH.

9 DR. PADILLA: DOES THE POSITIVE SELECTION
10 PROCESS HAVE ANY PERSPECTIVE ON OR DOES IT INCLUDE
11 ANY PERSPECTIVE ON THE CURRENT PORTFOLIO OF THE
12 CIRM-APPROVED PROJECTS?

13 DR. SAMBRANO: IT DOES NOT BECAUSE THE
14 GRANTS WORKING GROUP MEMBERS ARE REALLY JUST TASKED
15 WITH THE CRITERIA WE GIVE THEM. THEY DON'T RECEIVE
16 ANY PORTFOLIO INFORMATION THAT WOULD ALLOW THEM TO
17 EXERCISE PREFERENCES, FOR EXAMPLE. BUT THAT'S AN
18 IDEA.

19 DR. PADILLA: I FIND THAT A LITTLE BIT
20 CHALLENGING. IF THERE'S A SIMILAR PROCESS, IS THERE
21 SOMETHING THAT CAN BE NUANCED A LITTLE BIT IN THE
22 APPROVAL PROCESS? WHAT BENEFIT IF THERE'S SOMETHING
23 TWEAKED A LITTLE BIT TO THE OVERALL BENEFIT OF THE
24 PORTFOLIO?

25 DR. CANET-AVILES: ONE ASPECT IS WE ARE

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1 TALKING ABOUT THE SLIDES; BUT AS DR. TAN AND DR.
2 PATEL DISCUSSED EARLIER ON AND DR. KADYK FOR THE
3 OTHERS, THE PREFERENCE SETTING IS GOING TO BE BASED
4 ON PORTFOLIO ANALYSIS, RIGHT. AND THAT WILL BE AT
5 THE PRESELECTION OR THE QUALIFICATION PROCESS
6 OBJECTIVE CRITERIA. AND THE PREFERENCE SETTING IS
7 BASED ON THE PORTFOLIO THAT WE WILL HAVE THAT WILL
8 HAVE A PRESENTATION EVERY JUNE TO THE BOARD TO SET
9 THOSE PREFERENCES. SO THAT IS BEING TAKEN INTO
10 ACCOUNT IN THE OTHER THREE.

11 THIS ONE IS DIFFERENT BECAUSE OF THE
12 VOLUME THAT WE HAVE. IT COULD BE VERY DIFFICULT FOR
13 THEM TO HAVE AN OBJECTIVE CRITERIA THERE.

14 MR. TOCHER: CHRIS MIASKOWSKI HAS HER HAND
15 RAISED.

16 DR. MIASKOWSKI: I'D LIKE TO MAKE MY
17 COMMENTS IN THE CONTEXT OF THE FACT THAT I'VE SERVED
18 ON MULTIPLE NIH STUDY SECTIONS AND CHAIRED THEM.
19 AND I CAN HEAR THE CONCERNS, BUT I WANT TO SPEAK IN
20 SUPPORT OF GIL. HAVING -- I DON'T KNOW HOW MANY
21 YEARS I'VE BEEN DOING THIS NOW. AND I WAS A LITTLE
22 SKEPTICAL ABOUT THE POSITIVE SELECTION PROCESS, BUT
23 I CAN COMMENT THAT IT IS RIGOROUS. AND THE
24 DISTRIBUTION OF GRANTS SEEMED REASONABLE TO ME.

25 THE OTHER PIECE I WOULD LIKE TO EMPHASIZE

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1 IS THE COMPETENCY OF THE CIRM STAFF IN CREATING A
2 STUDY SECTION THAT HAS THE REQUISITE EXPERTISE FOR
3 THE VOLUME OF GRANTS WE'RE GOING TO DO. I MARVEL AT
4 THE FACT THAT THE MIX IS APPROPRIATE, THAT THE
5 PEOPLE WHO ARE SITTING AT THE TABLE ARE
6 KNOWLEDGEABLE TO BE ABLE TO PROVIDE A SUBSTANTIVE
7 SCIENTIFIC CRITIQUE AS WELL AS THE MANUFACTURING
8 CRITIQUE, THE CONSIDERATIONS MOVING FORWARD TO THE
9 FDA.

10 SO I CAN UNDERSTAND A SCIENTIST SITTING
11 THERE WHO HAVEN'T PARTICIPATED IN THE PROCESS, THAT
12 IT COULD BE QUESTIONED. BUT OVERALL I THINK THIS
13 PROCESS THAT GIL IS OUTLINING WORKS REALLY, REALLY
14 WELL. AND I REALLY DO NOT HAVE ANY CONCERNS ABOUT
15 THE SCIENTIFIC EXPERTISE OF THE REVIEW. SO I WANTED
16 TO PUT THAT FORWARD GIVEN HOW MANY OF THESE I'VE
17 DONE NOW.

18 DR. SAMBRANO: THANK YOU, CHRIS. OTHER
19 QUESTIONS OR I'LL GO ON.

20 I THINK I SKIPPED A SLIDE HERE. SO ONCE
21 THE GRANTS WORKING GROUP MEMBERS GO THROUGH THE
22 POSITIVE SELECTION PROCESS AND SELECT APPLICATIONS,
23 AND AT THIS STEP THE PATIENT ADVOCATE MEMBERS CAN
24 ALSO PARTICIPATE IN THE SELECTION OF THESE
25 APPLICATIONS. ONCE THAT IS DONE, THEN THE CIRM

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1 PROGRAM TEAM AND PRESIDENT EXAMINE ALL THE
2 NON-SELECTED APPLICATIONS AND DETERMINE IF THERE'S
3 ANY ADDITIONAL THAT SHOULD BE ADDED TO THE GROUP
4 THAT WILL ADVANCE TO THE FULL GRANTS WORKING GROUP,
5 AND THE REMAINDER ARE THEN NOT CONSIDERED FURTHER.

6 SO THEN THE GRANTS WORKING GROUP MEETS,
7 ASSESSES THE APPLICATIONS. WE MAKE ASSIGNMENTS,
8 TYPICALLY THREE SCIENTIFIC REVIEWERS PER
9 APPLICATION. IN THE CASES WHERE THERE'S CLINICAL OR
10 TRANSLATIONAL, WE ALSO ASSIGN A PATIENT ADVOCATE
11 MEMBER TO EACH OF THOSE APPLICATIONS WHEN THE
12 NUMBERS ARE SMALL ENOUGH.

13 THE RECOMMENDATION, THEN, AS ALWAYS, GOES
14 TO THE BOARD FOR A DETERMINATION TO FUND OR NOT.
15 AND SO THIS IS WHERE IT ALL FOLLOWS THE SAME
16 PROTOCOL.

17 ALL RIGHT. SO FOR CLIN2, CLIN2 IS
18 UTILIZING WHAT WE REFER TO AS QUALIFICATION. THIS
19 PROCESS WAS INTRODUCED LAST YEAR IN JUNE IN ORDER TO
20 DEAL WITH WHAT BEGAN TO BE A LARGE NUMBER OF
21 CLINICAL APPLICATIONS COMING IN. BEFORE WE DIDN'T
22 REALLY HAVE TO HAVE A TWO-STAGE PROCESS. AND THE
23 WAY WE DESIGNED THIS WAS TO PUT AN INITIAL STEP, AND
24 HERE I'M SHOWING IT AS SORT OF SIMILAR TO POSITIVE
25 SELECTION IN THAT WE'RE SPLITTING THE REVIEW PROCESS

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1 INTO THESE TWO STEPS. WE GET A FULL APPLICATION
2 WHERE WE DO AN INITIAL ELIGIBILITY ASSESSMENT. AND
3 SO IF AN APPLICATION IS ACCEPTED, IT MOVES ON TO THE
4 QUALIFICATION PROCESS WHERE WE EXAMINE KEY
5 INFORMATION IN THE APPLICATIONS TO SCORE THEM
6 AGAINST VERY SPECIFIC OBJECTIVE CRITERIA THAT ARE
7 DEFINED IN THE PROGRAM ANNOUNCEMENT OR IN THE RFA.
8 AND SO THAT'S A SIMPLE POINT SYSTEM.

9 SO BASED ON SPECIFIC CRITERIA, FOR
10 EXAMPLE, THIS IS A PLURIPOTENT STEM CELL APPROACH, A
11 CALIFORNIA ORGANIZATION, THEY ARE A PIPELINE
12 PROJECT, THEY WILL GET A POINT FOR EACH. THE ONES
13 WITH THE MOST POINTS ADVANCE.

14 AND FOR A PROGRAM LIKE CLIN2 WHERE WE
15 ANTICIPATE HAVING FOUR CYCLES WITH SEVEN
16 APPLICATIONS PER CYCLE, WE WANT TO ADVANCE, THEN,
17 WHAT WOULD BE THE SEVEN TOP APPLICATIONS.

18 THE CRITERIA -- LET ME MAKE A POINT ABOUT
19 THE OVERALL PROCESS HERE. THE LENGTH OF TIME THAT
20 EACH CYCLE TAKES WILL ALLOW APPLICANTS WHO SUBMIT
21 BUT FAIL TO GARNER A FUNDING RECOMMENDATION OR
22 APPROVAL BY THE BOARD EVERY SIX MONTHS. SO THE
23 PROCESS IS ABOUT FIVE MONTHS TO GET TO THE ICOC
24 DECISION. SO THEY'LL KNOW WELL BEFORE THAT WHAT THE
25 OUTCOME IS OR LIKELY OUTCOME IS AND CAN APPLY TO

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1 WHAT WOULD BE THE NEXT ONE.

2 SO JUST I KNOW THAT THE CALENDAR THAT YOU
3 MAY HAVE SEEN OR THAT WAS SHOWN IN THE SLIDE MAY
4 HAVE SUGGESTED OTHERWISE. BUT GIVEN THAT WE'RE
5 OFFERING IT EVERY THREE MONTHS, THEY'LL BE ABLE TO
6 SKIP ONE CYCLE AND GO TO THE NEXT.

7 SO THE PREFERENCES THAT WILL BE FACTORED
8 INTO THAT QUALIFICATION PROCESS AND THAT WILL
9 UTILIZE THE POINT SYSTEM HAVE BEEN SHARED PREVIOUSLY
10 UNDER THE CONCEPT PRESENTATION, THINGS LIKE
11 PLURIPOTENT STEM CELL-DERIVED THERAPIES AND THEN
12 SOME OF THE NEW ELEMENTS, SUCH AS HAVING AN RMAT
13 DESIGNATION OR PIVOTAL TRIAL, THOSE WOULD GARNER
14 POINTS. THIS IS INTENDED TO BE HIGH LEVEL, KIND OF
15 THE SAME INFORMATION IN TERMS OF THE PREFERENCES
16 THAT WOULD BE SET FOR CLIN2.

17 NOW, IF EVEN WHEN WE GO THROUGH THIS
18 PROCESS AND STILL END UP WITH TIES, WE STILL HAVE,
19 SAY, MORE THAN SEVEN APPLICATIONS THAT CAN ADVANCE
20 IN THAT CYCLE, THEN WE RESORT TO HAVING MEMBERS OF
21 THE GRANTS WORKING GROUP WHO ARE ASKED TO SCORE A
22 SUBSET OF THOSE TIED APPLICATIONS AGAINST MORE
23 SUBJECTIVE CRITERIA. AND THOSE CRITERIA ARE
24 ESSENTIALLY THE BULLETED POINTS THAT COME FROM THE
25 OVERALL VALUE PROPOSITION OF THE PROGRAM. SO HOW

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1 SIGNIFICANT IS THE UNMET NEED? HOW IMPACTFUL THE
2 TREATMENT WOULD BE FOR PATIENTS IF SUCCESSFULLY
3 DEVELOPED? AND SO ON. ALSO, THEIR RESPONSIVENESS
4 TO DEI AND WHETHER THE APPLICATION INCLUDES ALL THE
5 NECESSARY COMPONENTS FOR PROPER EVALUATION.

6 AND SO THROUGH THE HELP OF A SUBSET OF THE
7 GRANTS WORKING GROUP MEMBERS, THEN WE CAN BREAK TIES
8 AND DETERMINE WHAT ADVANCES.

9 AND THEN, AGAIN, THIS IS WHERE IT GOES
10 BACK TO THE SAME PROCESS. IT GOES TO THE GRANTS
11 WORKING. IN THIS CASE FOR CLINICAL APPLICATIONS,
12 THE PANEL THAT WE ASSEMBLE AROUND, SAY, SEVEN
13 APPLICATIONS, IS MUCH MORE ROBUST. AND SO WE TRY TO
14 BRING IN INDIVIDUALS WHO HAVE DISEASE AREA
15 EXPERTISE, MANUFACTURING EXPERTISE, PRODUCT
16 DEVELOPMENT, REGULATORY EXPERTISE TO ALL OPINE AND
17 PROVIDE INPUT ON THESE APPLICATIONS.

18 AND ONE OF THE OTHER BENEFITS IS THAT WITH
19 THE NUMBER OF APPLICATIONS BEING THAT SMALL, MOST OF
20 THE GRANTS WORKING GROUP MEMBERS CAN ACTUALLY
21 EXAMINE AND LOOK AT ALL THE APPLICATIONS EVEN THOUGH
22 THEY'RE NOT ASSIGNED TO GIVE A CRITIQUE. SO IT DOES
23 ALLOW FOR A MORE ROBUST DISCUSSION AT THIS STAGE.

24 THE RECOMMENDATIONS FROM THE GRANTS
25 WORKING GROUP THEN GO TO THE FUNDING DECISION BY THE

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1 ICOC. NOW, THERE'S AN IMPORTANT DIFFERENCE HERE IN
2 WHAT IS BEING PROPOSED FOR NOW WHAT WILL BECOME FOUR
3 CYCLES PER YEAR FROM WHAT WE'VE DONE IN THE PAST.
4 IT HAS TO DO BOTH WITH THE FACT THAT THE SCORING
5 WILL BE DIFFERENT, AND I'LL SPEAK TO THAT A LITTLE
6 LATER. YOU'VE BEEN USED TO HAVING A CLINICAL
7 PROGRAM WHERE IT'S A 1, 2, OR 3. AND TYPICALLY WHAT
8 YOU SEE COMING TO THE BOARD ARE THOSE THAT GET A
9 SCORE OF 1 BECAUSE THOSE ARE THE SUCCESSFUL ONES.

10 THOSE THAT GOT A 2 HAVE AN OPPORTUNITY TO
11 MAKE FIXES ON THAT APPLICATION AND COME BACK TO THE
12 NEXT CYCLE. BUT THAT'S WHEN WE WERE HAVING ELEVEN
13 CYCLES PER YEAR WHERE IT WAS EASY FOR THEM TO COME
14 BACK. NOW WITH THE IDEA THAT WE HAVE MORE
15 APPLICATIONS, THE ONE TO A HUNDRED SCORING IS GOING
16 TO BRING ALL THE APPLICATIONS TO THE BOARD FOR
17 REVIEW. MEANING WHETHER THEY GET A HIGH SCORE OR A
18 LOW SCORE, YOU WILL SEE THEM ALL. YOU WILL SEE THAT
19 ENTIRE COHORT OF APPLICATIONS COMING. AND I'LL
20 SPEAK TO SOME OF THE APPROACHES AND METHODS THAT WE
21 WILL USE TO PROVIDE TEAM RECOMMENDATIONS AS IT
22 RELATES TO THESE AND OTHER APPLICATIONS. BUT JUST
23 AN IMPORTANT DIFFERENCE TO NOTE.

24 SO FOR PDEV AND DISC4, THIS IS WHERE WE
25 THEN DEVIATE A LITTLE BIT IN TERMS OF THE PROCESS.

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1 AS WE'VE BEEN TALKING ABOUT, THIS IS THE
2 PRESUBMISSION PROCESS OR LOI PROCESS. I'M GOING TO
3 DESCRIBE IT AS A SINGULAR PROCESS BECAUSE IT APPLIES
4 TO BOTH ALTHOUGH EACH WILL HAVE A DIFFERENT SET OF
5 CRITERIA THAT WILL BE USED TO DETERMINE WHAT IS
6 ULTIMATELY INVITED TO APPLY.

7 SO THE WAY THIS WORKS IS YOU HAVE A
8 PRESUBMISSION STAGE, AND THEN THERE IS THE NEED TO
9 HAVE A TIME PERIOD FOR APPLICANTS WHO ARE INVITED TO
10 COMPLETE THEIR APPLICATION BEFORE THEY ENTER THE
11 REGULAR APPLICATION REVIEW PROCESS.

12 SO AN APPLICANT SUBMITS AN ONLINE FORM.
13 AND SO THAT FORM OR EXAMPLES OF IT HAVE BEEN
14 PROVIDED TO YOU. AND WHAT YOU SEE IS NOT A VERY
15 CLEAN, EASY TO SEE FORM BECAUSE IT'S A SET OF
16 REQUIREMENTS THAT WE PROVIDE TO OUR GRANTS
17 MANAGEMENT I.T. DEVELOPMENT TEAM IN ORDER TO CREATE
18 THE ONLINE APPLICATION. THE APPLICATION ITSELF WILL
19 BE MORE STREAMLINED, BUT IT DOES GIVE YOU THE FULL
20 VIEW OF INSTRUCTIONS, THE FIELDS THAT WE INTEND TO
21 CAPTURE, WHAT WE MAY ASK FOR IN TERMS OF AN UPLOAD
22 AS WAS DISCUSSED FOR, I THINK, DISC4 THAT HAS A
23 PROPOSAL UPLOAD, AND IT GIVES YOU THAT FULL VIEW ON
24 WHAT WE'RE ASKING FOR.

25 SO FOR THE PRESUBMISSION PROCESS, WE ARE

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1 ASKING FOR THINGS LIKE ELIGIBILITY. SO ONE OF THE
2 THINGS WE WANT TO MAKE SURE THAT WE UNDERSTAND TO
3 THE EXTENT THAT WE CAN IS A POTENTIAL APPLICATION
4 THAT WE INVITE ULTIMATELY GOING TO BE ELIGIBLE OR
5 NOT. IF THERE IS SOME CLARITY ON THAT, IT WOULD BE
6 GOOD TO KNOW AT THAT STAGE SO THAT WE KNOW THAT
7 WE'RE NOT ULTIMATELY INVITING AN APPLICANT THAT WILL
8 NOT BE ELIGIBLE.

9 WE ASK ABOUT TEAM PERSONNEL, THE PROJECT
10 TITLE AND KEYWORDS THAT ALLOW US TO FILTER AND SORT
11 THE PROPOSALS, AND OTHER PROJECT INFORMATION THAT
12 ALLOW US TO MAKE THESE ASSESSMENTS AND DECISIONS,
13 INCLUDING PROPOSED ACTIVITIES.

14 OKAY. SO THE CIRM PROGRAM TEAM THEN
15 EXAMINES THE PRESUBMISSIONS ONCE THEY COME IN.
16 THERE IS A SET DEADLINE. THEY SCORE AND RANK THEM
17 BASED ON THOSE DEFINED STRATEGIC PRIORITIES AND
18 CRITERIA. AND THEN BASED ON THOSE, AND I WILL SHOW
19 YOU WHAT THOSE ARE ALTHOUGH I THINK THEY WERE ALSO
20 PRESENTED AS PART OF THE CONCEPT PRESENTATIONS --

21 DR. LEVITT: THAT SAID, ELIGIBILITY IS
22 DETERMINED IN THE PRESUBMISSION PROCESS. THAT'S
23 WHAT YOU JUST SAID, BUT THE ELIGIBILITY BLOCK THERE
24 IS COMING AFTER THE COMPLETE APPLICATION?

25 DR. SAMBRANO: YEAH. I'LL SHOW YOU THAT.

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1 SO WHAT HAPPENS IS THE APPLICANTS ARE INVITED TO
2 APPLY, BUT ALL WE HAVE IS THE PRESUBMISSION FORM AT
3 THAT STAGE. SO WE DO NEED TO CONDUCT AN ELIGIBILITY
4 STEP OF THE FULL APPLICATION TO ENSURE THAT IT IS.
5 WE WANT TO MAKE IT A RARE INSTANCE WHERE SOMETHING
6 THAT COMES IN AT THIS STAGE IS THEN NOT ELIGIBLE.
7 WE CANNOT FULLY KNOW UNTIL WE SEE THE FULL
8 APPLICATION WHETHER IT'S GOING TO BE ELIGIBLE.

9 AND SOMETHING, JUST AS A FOR EXAMPLE, ONE
10 OF THE THINGS THAT CAN HAPPEN BETWEEN THE LOI AND
11 THE APPLICATION IS THE STATUS OF THE PI, FOR
12 EXAMPLE, THEY CAN BE ELIGIBLE AND THEN EXIT
13 ELIGIBILITY OR THE COMPLETENESS OF THE APPLICATION
14 ITSELF. THEY MAY HAVE A GREAT PROPOSAL, BUT
15 ULTIMATELY WHEN THEY SUBMIT THE APPLICATION, IT IS
16 INCOMPLETE AND DOESN'T HAVE ALL THE RELEVANT
17 ELEMENTS. SO WE DO NEED TO HAVE THAT STEP.

18 THAT'S WHAT I JUST MENTIONED. SO WE GO
19 THROUGH ELIGIBILITY. THOSE THAT ARE ACCEPTED GO
20 THEN TO THE FULL GRANTS WORKING GROUP REVIEW PANEL
21 DISCUSSION. AND THEN, OF COURSE, RECOMMENDATIONS TO
22 THE BOARD, AND THE BOARD MAKES FINAL FUNDING
23 DECISIONS ON THOSE.

24 SO THAT'S THE PROCESS. AS WAS NOTED
25 EARLIER HERE, SOME OF THE CRITERIA FOR THE

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1 PRESUBMISSION PROCESS FOR DISC4 SPECIFICALLY
2 UTILIZING PREFERENCE TOPICS, RELEVANCE TO HUMAN
3 DISEASE BIOLOGY, ACROSS DISCIPLINARY AND SYSTEMS
4 BIOLOGY, AND STEM CELL OR GENETIC RESEARCH
5 INNOVATIONS AS BROAD CATEGORIES OF WHAT WE'RE
6 LOOKING FOR. AND ALSO CONCEPT PREFERENCES FOR
7 PLURIPOTENT STEM CELL-DERIVED THERAPIES AND SO ON
8 FOR PDEV. THESE ALSO WERE SHOWN AS PART OF THE
9 CONCEPT WHICH WOULD BE USED TO ASSIGN POINTS TO THE
10 PRESUBMISSIONS AND DETERMINE WHICH ONES ARE MOST
11 CLOSELY ALIGNED WITH OUR GOALS. PAT.

12 DR. LEVITT: SO FOR CLIN2 AND THESE TWO,
13 THERE'S IN THE INITIAL NOW PRESUBMISSION COMPONENTS,
14 THERE'S INFORMATION THAT THE GWG MEMBERS ARE GETTING
15 ABOUT PRIORITIES, CIRM PRIORITIES. LIKE FOR THESE
16 TWO, FOR DISC4 AND PDEV'S, IF YOU LOOK --

17 DR. SAMBRANO: YOU MEAN THE CRITERIA WE'RE
18 TALKING ABOUT HERE, ARE THOSE PROVIDED TO THEM?

19 DR. LEVITT: YES, PROVIDED TO THEM BECAUSE
20 THE PRESUBMISSION FORM ASKS ABOUT THIS.

21 DR. SAMBRANO: THE PRESUBMISSION FORM GOES
22 TO THE CIRM PROGRAM TEAM. SO THE CIRM STAFF -- THE
23 GWG IS NOT PARTICIPATING IN THIS STEP.

24 DR. LEVITT: THEY'RE GETTING IT FOR CLIN2.
25 THEY'RE GETTING THAT INFORMATION IN TERMS OF -- I'M

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1 TRYING TO UNDERSTAND WHICH OF THE GRANT --

2 DR. SAMBRANO: FOR CLIN2, SO THE
3 QUALIFICATION STEP, THERE'S TWO PARTS. SO THERE'S
4 THE STAFF PART THAT THE REVIEW TEAM DOES. SO THOSE
5 PREFERENCES ARE ASSIGNED POINTS BY CIRM STAFF. SO
6 THE GWG DOESN'T PARTICIPATE IN THAT PART. IF THERE
7 IS A NEED TO BREAK TIES IN THE QUALIFICATION, THEN
8 THE GWG COMES IN. AND WHAT THEY ARE INSTRUCTED TO
9 DO IS TO BASE THEIR DECISION ON SPECIFIC QUESTIONS
10 THAT ARE ALIGNED WITH THE VALUE PROPOSITION, AND
11 THAT'S WHAT THEY BASE THEIR ASSESSMENT ON.

12 DR. LEVITT: OKAY.

13 DR. SAMBRANO: FOR PDEV AND DISC5, THIS IS
14 DONE BY THE CIRM STAFF IN TERMS OF DOING THE
15 ASSESSMENTS AND THE ALIGNMENT WITH THESE PRIORITIES.

16 DR. LEVITT: OKAY. GWG IS NOT GETTING THE
17 INFORMATION ABOUT PRIORITIES?

18 DR. SAMBRANO: CORRECT.

19 DR. LEVITT: ONE OTHER QUESTION. IN OUR
20 PACKET THERE WERE EXAMPLES OF AN ONLINE
21 QUESTIONNAIRE FOR FOUR DOMAINS, EACH ONE WITH 1500
22 CHARACTERS, ABOUT A PAGE. SO THERE'S FOUR PAGES
23 THERE THAT THEY'RE GOING TO FILL OUT. AND THEN
24 THERE'S AN ADDITIONAL REQUIREMENT OF UP TO THREE
25 PAGES WHERE THEY'RE GOING TO DESCRIBE MORE. SO IT'S

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1 ABOUT A SEVEN-PAGE PROCESS, PLUS I THINK THEY GET UP
2 TO TWO OR THREE FIGURES OR SOMETHING LIKE THAT FOR
3 PRELIMINARY DATA. SO THAT'S THEIR PACKAGE THAT
4 THEY'RE GOING TO SUBMIT BEFORE THEY SUBMIT THEIR
5 FINAL GRANT.

6 DR. SAMBRANO: YES.

7 DR. LEVITT: SO THAT'S SEVEN PAGES.

8 DR. SAMBRANO: YES.

9 DR. LEVITT: SO THAT SEEMS LIKE A LOT TO
10 ME. I DON'T KNOW HOW OTHERS FEEL ABOUT IT.

11 DR. SAMBRANO: I THINK PART OF OUR
12 CONSIDERATION WAS WHETHER THAT WAS --

13 DR. LEVITT: I KNOW IT SAYS UP TO.

14 DR. SAMBRANO: I THINK PART OF IT, AND
15 THIS IS IMPORTANT BECAUSE, AS YOU SAID, THERE IS A
16 BURDEN OF APPLICATION. AND WE WANT TO SIMPLIFY IT.
17 ON THE OTHER HAND, WE ALSO WANT TO MAKE SURE WE GET
18 THE INFORMATION THAT'S NECESSARY IN ORDER TO
19 EVALUATE AND ASSIGN THE PREFERENCES. IN ORDER TO
20 STRIKE THAT BALANCE, I THINK THIS IS WHERE THE TEAM
21 ARRIVED AT WHAT WE NEEDED.

22 BUT TAKING YOUR FEEDBACK TO HEART, WE DO
23 WANT TO MAKE SURE THAT THAT'S NOT EXCESSIVE. THAT
24 IF WE CAN CUT IT DOWN AND IT MAKES SENSE, THAT WE
25 WOULD.

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1 DR. LEVITT: I'M WONDERING IF THE GWG
2 MEMBERS, HAVE ANY OF THEM BEEN POLLED OR ASKED ABOUT
3 WHAT THEY FEEL THE MOST PERTINENT INFORMATION TO BE
4 ABLE DO THOSE EARLY DECISIONS.

5 DR. SAMBRANO: WE HAVE, BUT THESE EARLY
6 DECISIONS, AT LEAST IN THIS INSTANCE, AND IN THE
7 FORMS YOU SAW ARE FOR THE CIRM STAFF.

8 DR. TAN: HI. LET ME CLARIFY SOMETHING
9 ABOUT THE PRESUBMISSION FORMS, AT LEAST FOR WHERE
10 DISC4 IS RELEVANT. SO THE WAY -- WHAT WE SHARED IN
11 THERE WAS TO SAY THAT THE PRESUBMISSION PROPOSAL
12 UPLOAD IS THREE PAGES MAX. YOU COULD INCLUDE
13 FIGURES IN THERE, BUT IT'S CAPPED OUT AT THREE
14 PAGES. THAT THREE PAGES WOULD INCLUDE OUTLINE OF
15 YOUR PROPOSAL, YOUR RATIONALE OR ANYTHING YOU WANT
16 TO INCLUDE TO THAT. AND THEN IN ADDITION, THERE IS
17 A SHORT QUESTIONNAIRE OF FOUR QUESTIONS. EACH OF
18 THE QUESTION ANSWERS HAVE A TEXT LIMIT TO 1500
19 CHARACTERS, ABOUT TWO-PARAGRAPH RESPONSE TO EACH OF
20 THE FOUR QUESTIONS.

21 DR. SAMBRANO: THANKS, CHAN.

22 SO I'M GOING TO LEAVE THE TWO-STAGE
23 PROCESS, GO TO SCORING METHODOLOGY FOR A COUPLE OF
24 SLIDES. SO AS I HAD MENTIONED EARLIER, FOR CLINICAL
25 APPLICATIONS, WE USED THE 1-2-3 SYSTEM. AND I WANT

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1 TO DISTINGUISH THAT FROM OUR ONE TO A HUNDRED
2 SCORING SYSTEM IN THAT THE 1-2-3 IS NONGRADED,
3 MEANING IT'S SORT OF A THUMBS UP, THUMBS DOWN
4 DECISION AND THAT'S IT. THERE'S NOT A LOT OF
5 GRANULARITY IN THAT. VERSUS A GRADED APPROACH WHICH
6 HAS A SCALE ONE TO A HUNDRED THAT ALLOWS MORE
7 GRANULARITY AND THE ABILITY TO RANK APPLICATIONS
8 AGAINST ONE ANOTHER.

9 WE CHOSE THE NONGRADED 1-2-3 APPROACH FOR
10 CLINICAL BECAUSE, WHEN WE STARTED WITH THAT CLINICAL
11 PROGRAM, WE WERE EXPECTING IN SOME CASES NOT MORE
12 THAN ONE APPLICATION IN A GIVEN CYCLE. SO THERE'S
13 NOTHING TO RANK OR SCORE AGAINST OR COMPARE IT TO,
14 AND IT WAS BASICALLY HAVING IT STAND ON ITS OWN
15 MERIT. OBVIOUSLY THINGS HAVE CHANGED SINCE THEN.
16 AND SO IN TRYING TO RESPOND TO WHAT ARE NOW A
17 GREATER NUMBER OF APPLICATIONS AND THE NEED TO
18 ACTUALLY EXERCISE SOME DISCERNMENT BETWEEN
19 APPLICATIONS, HAVING A MORE GRADED APPROACH IS
20 SOMETHING WE THOUGHT WAS APPROPRIATE. AND IT IS
21 SOMETHING THAT WE WOULD USE ACROSS ALL OF THE
22 CONCEPTS THAT WERE CONSIDERED TODAY.

23 AND SO JUST A NOTE ABOUT THIS. I
24 MENTIONED ALREADY A COUPLE OF THESE BULLET POINTS.
25 WE HAVE OR I HAVE BEEN TRYING TO SPEND SOME TIME

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1 LOOKING AT PEER REVIEW LITERATURE. AND THERE'S NOT
2 A LOT OF IT OUT THERE, BUT THERE IS SOME THAT LOOKS
3 AT WHAT ARE THE BEST PRACTICES OR BEST APPROACHES
4 FOR SCORING FOR A REVIEW THAT GIVES YOU THE BETTER
5 GRADES OR ESTIMATES OF A PANEL'S CHOICES.

6 AND SO THERE IS CERTAINLY THE SUGGESTION
7 THAT USING LARGER NUMBER OF GRADES IS GENERALLY
8 BETTER AND THAT IT INCREASES WHAT IT ASSIGNS AS THE
9 CORRECTNESS OF THE PANEL'S CHOICES ALTHOUGH IT DOES
10 HAVE DIMINISHING RETURNS. AFTER YOU GET TO A
11 CERTAIN POINT, SO BEYOND TEN GRADES, YOU ARE NOT
12 GETTING MUCH MORE BENEFIT, BUT IT ALSO DOESN'T HURT
13 THE PROCESS.

14 I THINK ANOTHER IMPORTANT THING TO POINT
15 OUT ABOUT OUR ONE TO A HUNDRED SCORING METHOD IS
16 THAT IT IS DIFFERENT FROM OTHERS BECAUSE IT
17 ACCOMPLISHES TWO THINGS AT ONCE. IT IS BOTH BINARY,
18 MEANING IT'S A FUND OR DON'T FIND, THUMBS UP, THUMBS
19 DOWN BECAUSE THERE IS A SPECIFIC FUNDING LINE. IT
20 IS KNOWN TO REVIEWERS THAT IF YOU ARE SCORING AN
21 APPLICATION AN 85 OR ABOVE, YOU ARE SCORING IT TO
22 FUND IT. IF YOU SCORE BELOW, THEN YOU ARE SCORING
23 IT TO NOT FUND.

24 SO THEIR FIRST ASSESSMENT OF THE
25 APPLICATION IS TO DETERMINE WHETHER IT'S BELOW 85 OR

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1 85 OR ABOVE. AFTER THAT, IT'S DETERMINING HOW
2 ENTHUSIASTIC THEY ARE ABOUT WHETHER THIS IS ONE THEY
3 WANT TO FUND. IT'S AMONG THE BETTER ONES SO YOU
4 WANT TO SCORE IT CLOSER TO A HUNDRED OR CLOSER TO
5 85. SIMILAR WITH THOSE THAT LACK ENTHUSIASM, HOW
6 FAR AWAY FROM THE LINE WERE THEY IN TERMS OF MERIT?
7 SO IT DOES HAVE THAT BENEFIT.

8 NOW, NOTING THAT THERE MAY BE MORE
9 BENEFITS WITH A GRADED SYSTEM LIKE THIS, THE SCORES
10 BY THEMSELVES DON'T TELL US EVERYTHING AND THEY
11 DON'T GIVE THE FULL PICTURE THAT WOULD ALLOW US TO
12 DISTINGUISH APPLICATIONS. YOU CAN HAVE AN
13 APPLICATION OR TWO APPLICATIONS THAT SCORE 85 THAT
14 ARE COMPLETELY DIFFERENT. ONE THAT IS AN 85 BECAUSE
15 THERE WAS A UNANIMOUS SET OF REVIEWERS THAT ALL
16 SCORED 85, AND YOU MAY HAVE A DIFFERENT APPLICATION
17 THAT HAD A SPLIT SET OF SCORES. SO SOME SCORED 85
18 TO 90 AND SEVERAL SCORED BELOW THAT. AND WE HAVE
19 SOMETIMES SEEN A SPLIT WHERE IT'S EIGHT VERSUS
20 SEVEN. SO THAT INFORMATION IS USEFUL IN
21 ASCERTAINING SOME OF THE DIFFERENCES THAT MAY EXIST
22 BETWEEN WHAT ARE TWO SEEMINGLY SAME SCORING
23 APPLICATIONS.

24 AND WE PROVIDE THIS INFORMATION AS PART OF
25 THE PACKAGE THAT WE GIVE TO YOU. SO WE SHOW YOU THE

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1 MEAN, THE RANGE, AS WELL AS ALSO THE NUMBER OF
2 REVIEWERS THAT SCORED 85 OR ABOVE OR BELOW TO GIVE
3 YOU A BIT MORE NUANCE AS TO THOSE DIFFERENCES. ALSO
4 IMPORTANTLY, THE COMMENTS THAT THE REVIEWERS PROVIDE
5 IN THE SUMMARIES ARE IMPORTANT TO UNDERSTAND WHERE
6 THE APPLICANTS DID WELL, WHERE THEY DID NOT DO WELL
7 IN ORDER TO, AGAIN, TRY TO DISCERN DIFFERENCES. AND
8 SO DIGGING BEYOND THE SCORE IS GOING TO BE NECESSARY
9 IF WE HAVE A LOT OF APPLICATIONS THAT ARE AT A
10 SIMILAR PLACE SUCH AS 85.

11 I WANT TO TALK JUST BRIEFLY ABOUT
12 PROGRAMMATIC REVIEW AND TEAM RECOMMENDATIONS. AS
13 YOU KNOW, THE APPLICATION REVIEW SUBCOMMITTEE OF THE
14 ICOC MAKES ALL THE FINAL FUNDING DECISIONS ON
15 APPLICATIONS. THE DECISION-MAKING IS INFORMED BY
16 THE GRANTS WORKING GROUP RECOMMENDATIONS, CIRM TEAM
17 RECOMMENDATIONS, AS WELL AS PUBLIC COMMENTS.

18 AND SO THERE ARE DIFFERENT THINGS THAT THE
19 APPLICATION REVIEW SUBCOMMITTEE MAY CONSIDER. THE
20 FATE OR ALIGNMENT OF THE APPLICATION WITH CIRM
21 MISSION, STRATEGIC PLAN, POTENTIAL IMPACT ON
22 PATIENTS, THE PORTFOLIO, DEI ELEMENTS, AVAILABILITY
23 OF FUNDS, AND SO ON. THIS IS NOT A LIMITED LIST,
24 BUT JUST EXAMPLES OF DIFFERENT THINGS THE
25 APPLICATION REVIEW SUBCOMMITTEE CAN CONSIDER WHEN

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1 LOOKING AT AN APPLICATION AND DETERMINING ITS
2 FUNDING.

3 IN TERMS OF THEN AUGMENTING AND PROVIDING
4 MORE INFORMATION FOR YOU AND FOR THE APPLICATION
5 REVIEW SUBCOMMITTEE TO MAKE MORE INFORMED DECISIONS,
6 WE WANT TO LET YOU KNOW THAT WE WANT TO STRIVE TO
7 GIVE YOU MORE INFORMATION ALTHOUGH OUR PHILOSOPHY
8 HAS BEEN THAT GENERALLY THE CIRM TEAM WILL DEFAULT
9 TO THE GRANTS WORKING GROUP RECOMMENDATION IN THE
10 ABSENCE OF A GOOD REASON TO DO OTHERWISE. BUT WE
11 HAVE SEEN SEVERAL REASONS TO DO OTHERWISE IN THE
12 CONTEXT OF IN MANY CASES HAVING MORE APPLICATIONS
13 RECOMMENDED THAN THE BUDGET WOULD SUPPORT.

14 SO IN THAT CASE WE'RE FACED WITH MAKING
15 DECISIONS ABOUT A GROUP OF ALL SEEMINGLY MERITORIOUS
16 APPLICATIONS AND DECIDING AMONG THOSE WHICH ARE BEST
17 ONES. AND SO WE WANT TO OFFER ADDITIONAL
18 INFORMATION, SUCH AS RECOMMENDATIONS FROM THE CIRM
19 TEAM, THAT MIGHT IDENTIFY EITHER A UNIQUE
20 OPPORTUNITY TO ADVANCE AN URGENT GOAL OR NEED OR
21 PRIORITY ALIGNED WITH SAF, OFFER SOME PERSPECTIVE OF
22 AN APPLICATION THAT QUALIFIES FOR A MINORITY REPORT,
23 FOR EXAMPLE, OR ALLOWS US TO BETTER BALANCE OUR CIRM
24 PORTFOLIO OR OPTIMIZING THE USE OF AVAILABLE FUNDS
25 DEPENDING ON THE FUNDS REQUESTED AND SO ON. MAYBE

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1 INFORMATION THAT WOULD GIVE US A CLUE ABOUT THE
2 LIKELIHOOD OF SUCCESS BASED ON OUR OWN EXPERIENCE
3 MANAGING SIMILAR CIRM PROJECTS OR INFORMATION THAT
4 COMES TO CIRM'S ATTENTION THAT COULD IMPACT THE
5 POTENTIAL SUCCESS OF THE PROJECT.

6 OKAY. SO THAT IS THE AGENDA. BUT,
7 HOWEVER, THERE IS ANOTHER AGENDA ITEM, NOT ANOTHER
8 AGENDA ITEM, ANOTHER ELEMENT THAT'S RELATED TO THIS
9 THAT IS ATTACHED WHICH HAS TO DO WITH THE GRANTS
10 WORKING GROUP BYLAWS. SO THERE IS A MEMO THAT WAS
11 PROVIDED TO YOU ALONG WITH SOME EDITS FOR THE GRANTS
12 WORKING GROUP BYLAWS THAT RELATE TO THE SCORING.

13 AND THIS IS SOMETHING THAT NEEDS BOARD
14 APPROVAL TO ALLOW US TO USE THE PROPOSED SCORING
15 METHODS, MEANING THAT, AT LEAST FOR THESE FOUR
16 CONCEPTS, WE WANT TO MOVE TO THE ONE TO A HUNDRED
17 APPROACH. THE CURRENT BYLAWS WHICH SET THE VERY
18 SPECIFIC AND DEFINED SCORING METHODOLOGY THAT WAS
19 USED WAS BASED ON OUR OLD PROGRAMS THAT ARE CLOSING
20 OR NOW CLOSED. AND SO WE WANT TO ADD SOME
21 FLEXIBILITY BY AMENDING THE BYLAWS AND DESCRIBING
22 THE METHODOLOGY DIFFERENTLY.

23 SO WE PROPOSE ADDING A NEW SECTION, WHICH
24 IS COMPARABLE TO THAT THAT EXISTS IN THE AAWG
25 BYLAWS, WHICH STATES THAT THE SCORING METHODOLOGY

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1 USED BY THE GRANTS WORKING GROUP WILL BE THAT
2 DETERMINED BY CIRM TO BE THE MOST APPROPRIATE FOR
3 THE SPECIFIC FUNDING OPPORTUNITY AND THAT THE METHOD
4 WILL BE DESCRIBED IN THE RELEVANT RFA OR PROGRAM
5 ANNOUNCEMENT SO THAT IT'S CLEAR TO APPLICANTS. AND,
6 OF COURSE, WE WOULD BRING THAT TO YOU AS WELL SO
7 THAT YOU ARE AWARE OF THE METHODOLOGY THAT IS BEING
8 USED.

9 SO I THINK WE HAVE A SLIDE FOR REQUESTING
10 APPROVAL FOR THE AMENDMENTS TO THE GRANTS WORKING
11 GROUP BYLAWS.

12 CHAIRMAN IMBASCIANI: THANK YOU, GIL, FOR
13 THE PRESENTATION. AND CHAIR WOULD LIKE TO ENTERTAIN
14 A MOTION TO APPROVE THE AMENDMENTS TO SECTION 3, 4,
15 AND 5 AS GIL HAS ELUCIDATED TO THE BYLAWS OF THE
16 GWG.

17 DR. SOUTHARD: SO MOVED.

18 DR. BLUMENTHAL: SECOND.

19 CHAIRMAN IMBASCIANI: WE HAVE A MOVE.
20 MARV, I SAW YOU FIRST. AND MAYBE A SECOND FROM DR.
21 BLUMENTHAL. GEORGE SECONDED. THANK YOU. ANY
22 DISCUSSION ON THE AMENDMENTS TO THE BYLAWS FIRST
23 FROM BOARD MEMBERS? NOT SEEING ANY. I'M GOING TO
24 ASK CLAUDETTE IS THERE ANYONE IN THE PUBLIC THAT
25 WOULD LIKE TO COMMENT OR IN THE ROOM? NO. OKAY.

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1 SCOTT, I THINK WE CAN PROCEED.

2 MR. TOCHER: ALL THOSE IN THE ROOM IN
3 FAVOR SAY AYE. THOSE OPPOSED SAY NAY. ANY
4 ABSTENTIONS? I'LL POLL MEMBERS ON THE PHONE.

5 MONICA CARSON. YSABEL DURON.

6 MS. DURON: YES.

7 MR. TOCHER: RICH LAJARA. SHLOMO MELMED.
8 CHRIS MIASKOWSKI.

9 DR. MIASKOWSKI: YES.

10 MR. TOCHER: JOE PANETTA. SUZANNE
11 SANDMEYER. KAROL WATSON.

12 DR. WATSON: YES.

13 MR. TOCHER: KEVIN XU.

14 DR. XU: YES.

15 MR. TOCHER: THANK YOU VERY MUCH. THE
16 MOTION CARRIES, MR. CHAIR.

17 CHAIRMAN IMBASCIANI: THANK YOU AGAIN,
18 SCOTT.

19 MR. TOCHER: POINT OF ORDER. WE NEED TO
20 TAKE ABOUT A TEN-MINUTE BREAK. YOU WILL SEE
21 REFRESHMENTS BEHIND US. THOSE ON THE PHONE, WE'LL
22 COME BACK WITH THE NEXT ITEM OF BUSINESS FOR THE
23 UPDATE FROM COMMUNICATIONS. SO WE'LL MEET BACK UP
24 AT 3:15 SHARP.

25 (A RECESS WAS TAKEN.)

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1 CHAIRMAN IMBASCIANI: LADIES AND
2 GENTLEMEN, PLEASE TAKE YOUR SEATS. WE ARE READY TO
3 RESUME AFTER OUR RECESS. I'M GOING TO INVITE OUR
4 PRESIDENT AND CEO JONATHAN THOMAS TO TAKE US THROUGH
5 THE NEXT ITEM, OUR UPDATE ON COMMUNICATIONS. THANK
6 YOU, J.T.

7 DR. THOMAS: THANK YOU, MR. CHAIR. BEFORE
8 I INTRODUCE ESTEBAN TO GIVE THE BOARD A PRESENTATION
9 ON COMMUNICATION STRATEGIES RECENTLY OUTLINED TO THE
10 COMMUNICATIONS SUBCOMMITTEE IN LIGHT OF THE FLUID
11 FEDERAL LANDSCAPE, I WANTED TO LET THE BOARD KNOW
12 THAT WE HAVE POSTED THE JOB DESCRIPTION FOR THE
13 SENIOR DIRECTOR OF COMMUNICATIONS, WHOSE PRINCIPAL
14 RESPONSIBILITY WILL BE TO DEVELOP AND IMPLEMENT A
15 COMPREHENSIVE STRATEGIC COMMUNICATION PLAN TO REACH
16 AND INFORM CIRM'S MANY AND VARIED STAKEHOLDER
17 GROUPS.

18 WE HAVE IN A SHORT TIME ALREADY RECEIVED
19 57 APPLICATIONS AND EXPECT MORE IN THE DAYS AHEAD.
20 WE'LL KEEP YOU POSTED AS THE PROCESS PROCEEDS.

21 AS REGARDS COMMUNICATIONS ON DEVELOPMENTS
22 IN WASHINGTON, IT IS CRITICAL THAT OUR STAKEHOLDERS
23 KNOW THAT WE REMAIN COMMITTED TO THE CORE
24 PRINCIPLES, PROGRAMS, AND INITIATIVES DISCUSSED OVER
25 THE PAST SEVERAL HOURS. THAT'S WHY I AND CIRM

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1 LEADERSHIP WILL WORK CLOSELY WITH COMMUNICATIONS AND
2 THE BOARD TO ENSURE THAT WE ARE ALIGNED IN OUR
3 STANCE AND HOW WE COMMUNICATE THESE IMPORTANT
4 UPDATES.

5 ESTEBAN AND HIS TEAM HAVE DEVELOPED A
6 STRATEGY THAT WILL EMPHASIZE SOME OF THESE MESSAGES.
7 WE LOOK FORWARD TO HEARING YOUR FEEDBACK AND
8 SUGGESTIONS.

9 LAST, BUT NOT LEAST, I WANTED TO
10 COMMUNICATE THAT IN LESS THAN AN HOUR OPENING DAY AT
11 DODGER STADIUM WILL START. GO BLUE. ESTEBAN.

12 MR. CORTEZ: GOOD AFTERNOON, MEMBERS OF
13 THE BOARD, CHAIR IMBASCIANI, VICE CHAIR
14 GONZALEZ-BONNEVILLE, CIRM TEAM, AND MEMBERS OF THE
15 PUBLIC. I'M ESTEBAN CORTEZ. I'M THE DIRECTOR OF
16 MARKETING COMMUNICATIONS HERE AT CIRM. AND I KNOW
17 THAT I AM ONE OF THE LAST PRESENTERS, IF NOT THE
18 LAST, STANDING BETWEEN YOUR JOURNEY HOME. SO I
19 APPRECIATE YOUR TIME TODAY TO HEAR ABOUT SOME OF THE
20 RECENT WORK THAT WE'VE BEEN DOING.

21 OF COURSE, BEFORE WE AGAIN, HERE'S
22 REMINDER OF OUR MISSION, WHICH IS TO ACCELERATING
23 WORLD-CLASS SCIENCE TO DELIVER TRANSFORMATIVE
24 REGENERATIVE MEDICINE TREATMENTS IN AN EQUITABLE
25 MANNER TO A DIVERSE CALIFORNIA AND WORLD.

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1 I'M PART OF A SMALL BUT MIGHTY TEAM THAT
2 LEADS AND SUPPORTS THE ENTIRE AGENCY WITH VARIOUS
3 MARKETING, COMMUNICATIONS, INITIATIVES, AND CHANNEL
4 MANAGEMENT. THIS INCLUDES EXTERNAL AND INTERNAL
5 COMMUNICATIONS, SOCIAL MEDIA, EMAIL MARKETING, PRINT
6 PUBLICATIONS LIKE OUR ANNUAL REPORT, MANAGING OUR
7 WEBSITE AND BLOG, MEDIA, AND PRESS, AS WELL AS
8 SUPPORTING WITH COMMUNITY OUTREACH EFFORTS.

9 I'D LIKE TO RECOGNIZE MY TEAM. KATIE
10 SHARIFY, OUR COMMUNICATIONS TEAM COORDINATOR, AND
11 CHRISTINA SMITH WHO AREN'T HERE TODAY. CHRISTINA IS
12 OUR SOCIAL MEDIA AND CONTENT SPECIALIST. AND I'D
13 REALLY LIKE RECOGNIZE THEM FOR THEIR EFFORTS IN
14 DRIVING OUR MISSION FORWARD THROUGH OUR
15 COMMUNICATIONS EFFORTS.

16 SO TODAY I'D LIKE TO TALK ABOUT OUR
17 APPROACH IN KEEPING OUR AUDIENCES INFORMED ABOUT
18 CIRM'S ROLE IN LIGHT OF THESE RECENT FEDERAL
19 DEVELOPMENTS THAT WE'RE ALL AWARE OF. THERE HAS
20 BEEN A RECENT FLURRY OF EXECUTIVE ORDERS AND FEDERAL
21 DEVELOPMENTS THAT HAVE ALREADY HAD DRASTIC EFFECT ON
22 THE SCIENTIFIC COMMUNITY, INCLUDING MANY CIRM-FUNDED
23 RESEARCHERS AND INSTITUTIONS. WE RECOGNIZE THAT
24 THESE NEW DEVELOPMENTS ARE COMING AT US AT A RAPID
25 PACE AND THINGS CHANGE WEEK BY WEEK AND DAY BY DAY.

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1 THE COMMUNICATIONS TEAM, AS J.T.
2 MENTIONED, WILL BE HERE TO SUPPORT THE CIRM
3 PRESIDENT, THE EXECUTIVE TEAM, AND THE PROGRAM TEAMS
4 IN DELIVERING THESE IMPORTANT MESSAGES AND UPDATES
5 TO OUR AUDIENCES. THIS INCLUDES LAUNCHING EMAILS,
6 POSTING SOCIAL MEDIA UPDATES, RELEASING STATEMENTS
7 AND RESPONSES WHEN NEEDED TO SUPPORT LEADERSHIP'S
8 VISION.

9 I'LL BE PRESENTING A COMPREHENSIVE
10 COMMUNICATIONS STRATEGY WHICH YOU ALL HAVE ACCESS TO
11 IN RESPONSE TO RECENT FEDERAL DEVELOPMENTS AND
12 OUTLINE HOW CIRM WILL THROUGH ITS COMMUNICATION
13 EFFORTS CONTINUE TO ENGAGE WITH STAKEHOLDERS AND
14 REINFORCE OUR MISSION IN LIGHT OF THESE CHANGES.

15 AMIDST THIS UNCERTAINTY, CIRM HAS A UNIQUE
16 OPPORTUNITY TO POSITION ITSELF AS A LEADER, AS A
17 PROACTIVE LEADER, OUR ROLE AS A KEY RESEARCH FUNDER,
18 OUR ADVOCACY FOR SCIENTIFIC INNOVATION, AND OUR
19 SUPPORT OF INCLUSIVITY IN SCIENCE PUTS US IN A
20 STRONG POSITION TO NAVIGATE THESE CHALLENGES.

21 AT CIRM OUR MISSION TO ACCELERATE
22 WORLD-CLASS SCIENCE REMAINS UNSHAKEN, AND THAT'S WHY
23 OUR COMMUNICATION EFFORTS MUST REFLECT THIS
24 COMMITMENT.

25 IN THE COMMUNICATION STRATEGY, WHICH AGAIN

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1 WAS PROVIDED TO YOU IN THE AGENDA, IS DESIGNED TO
2 ENSURE THAT WE MEET SEVERAL KEY OBJECTIVES. FIRST,
3 WE WANT TO EMPHASIZE CIRM'S LEADERSHIP ROLE IN
4 REGENERATIVE MEDICINE AND UNDERScore CALIFORNIA'S
5 CRITICAL POSITION IN ADVANCING SCIENTIFIC RESEARCH.
6 WE WILL REASSURE STAKEHOLDERS THAT CIRM'S STRATEGIC
7 IMPACT GOALS THROUGH THE SAF AND MISSION REMAIN
8 UNCHANGED DESPITE FEDERAL POLICY SHIFTS. WE WILL
9 EMPHASIZE THE VALUE OF SCIENCE AND THE ONGOING NEED
10 FOR INVESTMENT IN RESEARCH. WE'LL REAFFIRM CIRM'S
11 COMMITMENT TO INCLUSIVITY THROUGH OUR STORIES AND
12 CONTENT, EMPHASIZING THE IMPORTANCE OF REPRESENTING
13 COMMUNITIES IN DRIVING SCIENTIFIC EXCELLENCE AND
14 EQUITABLE ACCESS TO THERAPIES. AND WE WILL CONTINUE
15 TO MAINTAIN AND DEEPEN OUR RELATIONSHIP WITH KEY
16 STAKEHOLDERS, INCLUDING RESEARCHERS, PATIENT
17 ADVOCACY GROUPS, ELECTED OFFICIALS, THE BROADER
18 SCIENTIFIC COMMUNITY, AND, OF COURSE, THE GENERAL
19 PUBLIC.

20 THESE OBJECTIVES WILL GUIDE OUR STRATEGY
21 AND ENSURE THAT WE COMMUNICATE CLEARLY AND
22 EFFECTIVELY DURING THIS TIME AND MOVING FORWARD.

23 THROUGH OUR COMMUNICATIONS EFFORTS, WE
24 WILL REACH A WIDE RANGE OF AUDIENCES, INCLUDING CIRM
25 STAFF AND BOARD, OUR AWARDEES AND APPLICANTS, THE

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1 REGENERATIVE MEDICINE SCIENTIFIC COMMUNITY, PATIENT
2 ADVOCACY GROUPS, KEY GOVERNMENT OFFICIALS AND
3 AGENCIES, AND THE GENERAL PUBLIC. BY ALIGNING OUR
4 MESSAGES WITH THESE AUDIENCES, WE CAN BUILD SUPPORT,
5 FOSTER COLLABORATION, AND ENSURE THAT CIRM'S MISSION
6 REMAINS STRONG AND VISIBLE.

7 SO TO ENSURE ALIGNMENT AND CONSISTENCY IN
8 OUR COMMUNICATIONS EFFORTS, WE HAVE DEVELOPED CORE
9 MESSAGING THAT REINFORCES OUR OBJECTIVES IN THE
10 PLAN. IN THE INTEREST OF TIME, I'M NOT GOING TO
11 COVER EACH MESSAGE IN DETAIL. SO I INVITE YOU TO
12 REVIEW FURTHER MESSAGING IN THE PROVIDED PLANNING
13 DOCUMENT. I'D ALSO LIKE TO MAKE IT CLEAR THAT WE
14 WILL BE STRATEGIC, INTENTIONAL, AND CAREFUL IN HOW
15 WE COMMUNICATE OUR MESSAGE TO ENSURE IT ALIGNS WITH
16 THE ORGANIZATION'S GOALS.

17 A KEY TAKEAWAY FROM RECENT CONVERSATIONS
18 AT THE BOARD MEETING IS THAT WE NEED TO REAFFIRM THE
19 STRENGTH AND COMMITMENT TO OUR MISSION. AND WE CAN
20 DO THIS BY CONTINUING TO HIGHLIGHT OUR IMPACT IN
21 CALIFORNIA, HIGHLIGHTING THE RESEARCH WE FUND, AND
22 PROMOTING OUR FUNDING OPPORTUNITIES TO SCIENTIFIC
23 COMMUNITIES.

24 A KEY MESSAGE THAT WE WANT TO EMPHASIZE,
25 FOR EXAMPLE, IS THAT CIRM'S MISSION IS STEADFAST AND

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1 GROUNDING IN SCIENTIFIC INTEGRITY AND PATIENT ACCESS.
2 WE WILL CONTINUE TO LEAD THE WAY IN REGENERATIVE
3 MEDICINE AND REMAIN A RELIABLE PARTNER TO OUR
4 STAKEHOLDERS, ENSURING THAT OUR FUNDING DRIVES
5 GROUNDBREAKING THERAPIES TO REACH PATIENTS WHO NEED
6 THEM MOST.

7 SO THIS MEANS THAT OUR CONTENT, USING THAT
8 MESSAGE AS AN EXAMPLE, OUR CONTENT AND OUR STORIES
9 ACROSS OUR CHANNELS SHOULD REFLECT THIS MESSAGING
10 AND OTHERS IDENTIFIED IN THIS PLAN WHEREVER
11 POSSIBLE. THAT'S THE INTENTION OF DEVELOPING THESE
12 CORE MESSAGES.

13 WE ALSO WANT TO HIGHLIGHT THAT CIRM
14 REMAINS COMMITTED TO CREATING AN INCLUSIVE RESEARCH
15 ENVIRONMENT IN REGENERATIVE MEDICINE, SUPPORTING
16 RESEARCH THAT BENEFITS COMMUNITIES AND DIVERSITY IN
17 SCIENTIFIC RESEARCH OUTCOMES. WHILE WE RECOGNIZE
18 THAT THERE HAVE BEEN MANY EFFORTS TO ELIMINATE MANY
19 OF THESE INITIATIVES AT THE FEDERAL LEVEL, CIRM HAS
20 AN OPPORTUNITY TO CONTINUE HIGHLIGHTING STORIES FROM
21 CIRM-FUNDED RESEARCH, CLINICAL TRIALS, AND OUR
22 EDUCATION PROGRAMS.

23 WE HAD A LIVELY DISCUSSION AT OUR RECENT
24 COMMUNICATIONS SUBCOMMITTEE MEETING. MEMBERS AGREED
25 THAT IT'S IMPORTANT TO CONTINUE TO SHARE THOSE

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1 STORIES THAT REALLY DRIVE ACROSS OUR VALLEYS AND
2 INSPIRE PEOPLE. THAT INCLUDES SHARING PATIENT
3 STORIES, HIGHLIGHTING PEOPLE WHO ARE RECEIVING
4 SERVICES SUPPORTED BY CIRM, AND HIGHLIGHTING THE HOW
5 THEY, THEIR FAMILIES, AND COMMUNITIES ARE POSITIVELY
6 IMPACTED BY THE SCIENCE CIRM SUPPORTS.

7 SO WE'LL CONTINUE TO STRATEGIZE AND WORK
8 WITH THE WIDER CIRM TEAM TO IDENTIFY THESE STORIES
9 AND ENSURE THAT THEY REFLECT OUR VALUES WHILE BEING
10 MINDFUL OF FURTHER DEVELOPMENTS.

11 AND FINALLY, WE WANT TO ENSURE THAT WE'RE
12 EMPHASIZING THE VALUE OF SCIENCE AND CONTINUED
13 INVESTMENTS IN RESEARCH. WE WILL DO THIS BY
14 PROMOTING OUR FUNDING OPPORTUNITIES AND AWARDS,
15 WORKING CLOSELY WITH THE TEAMS WHO ARE MANAGING
16 THOSE, COMMUNICATING WHY THIS RESEARCH POSITIVELY
17 IMPACTS CALIFORNIA COMMUNITIES.

18 OUR MESSAGING WILL ALSO HIGHLIGHT THE WORK
19 WE'RE DOING TO IMPROVE PATIENT OUTCOMES. AND THIS
20 PRESENTS US WITH OPPORTUNITIES TO FEATURE RECENT
21 INITIATIVES LIKE OUR PATIENT SUPPORT PROGRAM AND
22 CASE STUDIES THAT EMPHASIZE THE IMPORTANCE OF ACCESS
23 AND AFFORDABILITY.

24 WE'LL EXECUTE THE STRATEGY THROUGH A
25 VARIETY OF TACTICS. ON THE PR SIDE, FOR EXAMPLE, IN

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1 ADDITION TO LAUNCHING STATEMENTS AND DEVELOPING
2 TALKING POINTS AS NEEDED, WE'LL ENGAGE WITH CIRM
3 BOARD MEMBERS AND MEDIA TO AMPLIFY OUR MESSAGES.
4 WE'RE ALREADY SEEING AN INCREASE IN MEDIA COVERAGE
5 OVER THE PAST FEW WEEKS SINCE MANY OF THESE FEDERAL
6 CHANGES HAVE TAKEN EFFECT. SO WE'LL CONTINUE TO
7 TAKE THIS OPPORTUNITY TO REFINE OUR MEDIA STRATEGY
8 WITH LEADERSHIP.

9 WE WILL ALSO BE REACHING OUT TO OUR BOARD
10 MEMBERS ABOUT WAYS THAT YOU CAN LEND YOUR VOICE TO
11 THESE EFFORTS BY PROMOTING TESTIMONIALS, QUOTES, AND
12 STATEMENTS. AND WE'RE ALSO SEEING MORE ENGAGEMENT
13 ON SOCIAL MEDIA, ESPECIALLY AS IT RELATES TO CIRM
14 FUNDING ANNOUNCEMENTS. OUR AUDIENCES TRULY
15 RECOGNIZE THE IMPORTANCE OF CONTINUED FUNDING
16 ESPECIALLY DURING THIS TIME. SO WE'LL SHARE THESE
17 RECURRING UPDATES ON OUR SOCIAL CHANNELS THAT
18 HIGHLIGHT OUR CONTINUED FUNDING COMMITMENTS.

19 AND WE'LL ALSO CONTINUE TO FIND
20 OPPORTUNITIES TO MEET COMMUNITIES WHERE THEY ARE AND
21 IDENTIFY ONLINE PLATFORMS, COMMUNITY GROUPS, AND
22 FORUMS TO SHARE RELEVANT UPDATES AND JOIN
23 CONVERSATION ON IMPORTANT TOPICS.

24 BUILDING ON THE MOMENTUM OF OUR NEW
25 WEBSITE, WHICH I INVITE YOU ALL TO CHECK OUT IF YOU

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1 HAVEN'T ALREADY, AN INCREASED ENGAGEMENT ON SOCIAL
2 MEDIA PLATFORMS LIKE LINKED-IN WILL, OF COURSE,
3 UTILIZE OUR DIGITAL AND PRINT CHANNELS TO CONTINUE
4 SHARING RELEVANT UPDATES TO OUR AUDIENCES. THIS
5 INCLUDES BUILDING DEDICATED LANDING PAGES FOR
6 IMPORTANT ANNOUNCEMENTS, UPDATING OUR BLOG, THE
7 "STEM CELLAR," REGULARLY, AND DEVELOPING COLLATERAL
8 WHICH REINFORCES OUR KEY MESSAGES TO OUR OUTREACH
9 EVENTS.

10 WE RECOGNIZE THAT THIS IS A LOT OF WORK
11 FOR A SMALL TEAM. SO TO ENSURE THAT WE CAN BE
12 RESPONSIVE, WE'VE ONBOARDED ADDITIONAL WRITING
13 SUPPORT FROM A FORMER CIRM STAFFER, TURNED
14 CONSULTANT NAMED AMY ADAMS IN AN EFFORT TO DRIVE
15 SOME OF THIS CONTENT. WE LOOK FORWARD TO WORKING
16 WITH HER, CIRM STAFF, OUR COMMUNITY PARTNERS, AND
17 MANY OF YOU TO HELP DRIVE THIS STRATEGY.

18 SO WHILE I DIDN'T COVER EACH OF THESE KEY
19 MESSAGES AND TACTICS IN DETAIL FOR THE SAKE OF TIME,
20 THE COMMUNICATIONS TEAM APPRECIATES HEARING YOUR
21 FEEDBACK ON THIS APPROACH. THIS IS A VERY IMPORTANT
22 TOPIC FOR US AND WILL DRIVE OUR EFFORTS MOVING
23 FORWARD. SPECIFICALLY WE'D LIKE TO HEAR WHETHER YOU
24 FEEL THERE ARE OTHER KEY MESSAGES THAT WE SHOULD
25 EMPHASIZE OR IF THERE ARE ANY OTHER KEY

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1 COMMUNICATION STRATEGIES THAT WE MIGHT HAVE LEFT
2 OUT, THINGS FOR US TO CONSIDER. SO WE VALUE YOUR
3 FEEDBACK. SO I'D LIKE TO OPEN UP FOR DISCUSSION.

4 CHAIRMAN IMBASCIANI: THANKS, ESTEBAN. I
5 HEARD A LOT OF WONDERFUL ADJECTIVES, STEADFAST
6 COMMITMENT TO OUR IDEALS, COLLABORATIVE WORKING WITH
7 THE GOVERNMENT. ANYONE? WE'LL START WITH MARK
8 FISCHER-COLBRIE.

9 MR. FISCHER-COLBRIE: YEAH. FIRST OF ALL,
10 KUDOS FOR GETTING THE NEWS OUT ALREADY ON ACTIVITIES
11 FOR THE MEETING. SO WELL DONE.

12 AND SECOND, JUST IN GENERAL CURIOUS ABOUT
13 THOUGHTS AROUND INSTAGRAM AND TIKTOK AND FINDING
14 CHANNELS TO PREPACKAGE MATERIALS OR ALLOW PEOPLE WHO
15 HAVE A BROADER VOICE, I.E., INFLUENCERS, TO THE
16 RIGHT TYPE, PACKAGE STUFF UP FOR THEM TO PROPAGATE.
17 SO JUST GENERAL THOUGHTS ON THAT.

18 MR. CORTEZ: ABSOLUTELY. IN TERMS OF
19 SOCIAL MEDIA PLATFORMS LIKE INSTAGRAM, WE DO HAVE A
20 PRESENCE THERE. ACTUALLY HAVE BEEN SEEING MORE
21 ENGAGEMENT RECENTLY AND REALLY ARE CHANGING AROUND
22 HOW WE DELIVER SOME OF THOSE MESSAGES. I THINK IF
23 YOU EVEN GO VISIT THAT NOW, YOU WILL SEE THAT
24 THERE'S BEEN A CHANGE, AND WE'RE REALLY TRYING TO
25 JUST ALIGN MORE WITH HOW PEOPLE RECEIVE AND READ

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1 THEIR NEWS. SO I INVITE YOU TO GO CHECK THAT OUT.

2 WE DO NOT HAVE A TIKTOK ACCOUNT AT THE
3 MOMENT. ONE OF THE THINGS THAT WE ARE LOOKING TO
4 DO, IN ADDITION TO IDENTIFYING ANY INFLUENCERS,
5 PEOPLE IN THE SCIENTIFIC SPACE, IS REALLY LEVERAGING
6 OUR EXISTING AUDIENCES. AND ONE OF THE THINGS THAT
7 OFTEN COMES UP IS REALLY WORKING WITH OUR TRAINEES
8 IN OUR EDUCATION PROGRAMS WHO IN THEIR OWN RIGHT
9 HAVE SOME INFLUENCE AS WELL. SO REALLY WORKING ON
10 WAYS TO ENGAGE THEM, ENCOURAGE THEM TO DEVELOP SOME
11 OF THAT USER-GENERATED CONTENT.

12 SO THOSE ARE THINGS THAT WE'RE REALLY
13 LOOKING FORWARD TO DOING. AND WE'RE ALREADY TALKING
14 ABOUT DOING THAT FOR THE UPCOMING TRAINEE CONFERENCE
15 THAT'S COMING UP AND REALLY ARE LOOKING TO BOOST OUR
16 EFFORTS THERE.

17 CHAIRMAN IMBASCIANI: YES, ANNE-MARIE.

18 DR. DULIEGE: THANK YOU FOR WHAT YOU'VE
19 BEEN DOING IN PRESENTING. I WOULD SAY
20 CONGRATULATIONS, KUDOS TO THE TEAM FOR STANDING VERY
21 CLEARLY IN FAVOR OF THE DEI POLICY.

22 THANK YOU ALSO FOR THOSE OF YOU WHO
23 CONTRIBUTE TO THE MONTHLY NEWSLETTER. I THINK MOST
24 RECENTLY WAS SENT TO THE BOARD. AT LEAST I RECEIVED
25 ONE OR TWO EXAMPLES OF THIS MONTHLY NEWSLETTER, AN

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1 INITIATIVE THAT BRINGS US CONSTANTLY IN THE LOOP OF
2 WHAT'S HAPPENING, NOT ONLY AT THE MEETINGS, BUT
3 OUTSIDE THE MEETINGS WHERE AT TIMES WE COULD EVEN
4 PARTICIPATE IN. SO MUCH APPRECIATED. THANK YOU FOR
5 DOING THAT.

6 AND I RECALL ONE THING THAT I REGRET NOT
7 HAVING SEEN AT LEAST RECENTLY, IT'S PROBABLY ON THE
8 WEBSITE, THAT AT TIMES WE PARTICIPANTS DURING THESE
9 MEETINGS WHO HAVE BEEN IN CLINICAL TRIALS WHO HAVE
10 BENEFITED OR MAYBE KNOW EVEN BENEFITED. THEY WOULD
11 COME ON ZOOM, THEY WOULD COME IN PERSON AT TIMES, OR
12 AN INTERVENTION. AND IF WE COULD RESUME THAT AT
13 SOME POINT, THIS WOULD BE VERY BENEFICIAL.

14 MR. CORTEZ: THANK YOU. I DO WANT TO
15 RECOGNIZE THE BOARD GOVERNANCE TEAM IN LAUNCHING
16 THAT NEWSLETTER YOU MENTIONED BECAUSE THEY ARE
17 DRIVING THOSE EFFORTS. BUT WE DEFINITELY SEE THAT
18 AS AN OPPORTUNITY TO COLLABORATE WITH THEM. SO I DO
19 WANT TO RECOGNIZE CLAUDETTE, LANA, AND THE BOARD
20 TEAM FOR THAT.

21 I THINK IN RESPONSE TO INVITING PATIENTS
22 AND PATIENT ADVOCATES TO THE BOARD MEETING, WE DID
23 SEE THAT AT LAST MONTH'S MEETING WHERE WE DID WORK
24 WITH ANDREA, I FORGET HER FULL NAME, BUT THIS WAS A
25 PATIENT. SHE'S THE MOTHER OF A PATIENT WHO

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1 PARTICIPATED IN A CLINICAL TRIAL AT UCLA FOR A RARE
2 DISEASE. AND THAT WAS AN EFFORT THAT WE DROVE IN
3 WORKING WITH THEM, FEATURING THEIR STORY ON THE
4 BLOG. SO THAT IS A REALLY GREAT SUGGESTION. THAT'S
5 SOMETHING THAT WE THINK WILL HAVE GREAT IMPACT. SO
6 I APPRECIATE THAT.

7 CHAIRMAN IMBASCIANI: ESTEBAN, THANK YOU
8 FOR YOUR LEADING ROLE ON THIS. MARVIN.

9 DR. SOUTHARD: SO I JUST WONDERED HOW
10 ACTIVE A ROLE THAT YOU PLAN TO UNDERTAKE IN RESPONSE
11 TO THE FUNDING CHAOS THAT'S GOING TO BE INVOLVING
12 ALL OF OUR FIELDS RIGHT NOW.

13 MR. CORTEZ: WELL, WHAT WE WOULD DO IS WE
14 COULD, OF COURSE, MAKE SURE THAT WE'RE ALIGNING WITH
15 LEADERSHIP IN RELAYING SOME OF THOSE MESSAGES. SO I
16 DON'T HAVE A DIRECT ANSWER FOR YOU RIGHT NOW, BUT WE
17 WOULD ACTIVELY SUPPORT WITH GETTING THOSE MESSAGES
18 OUT. AND I THINK TO SOME EXTENT WE'VE ALREADY BEEN
19 PUTTING SOME OF THOSE THINGS OUT THERE IN SUPPORTING
20 LEADERSHIP. J.T., FOR EXAMPLE, AS HE GOES OUT TO
21 GIVE PRESENTATIONS. I'LL GIVE A VERY SPECIFIC
22 EXAMPLE.

23 WE WERE INVITED TO A COMMUNITY LECTURE AT
24 UC IRVINE. THAT WAS A COMMUNITY PUBLIC EVENT.
25 SUPPORTED HIM WITH DEVELOPING SOME OF THE SLIDE

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1 DECKS, THE MESSAGING, THE TALKING POINTS, AND REALLY
2 INCORPORATED SOME OF THOSE MESSAGES THAT YOU ALREADY
3 SEE HERE.

4 SO THE ANSWER IS WE'LL PLAY AN ACTIVE
5 ROLE, BUT WE'RE ALWAYS GOING TO MAKE SURE THAT WE'RE
6 BEING CAREFUL AND INTENTIONAL IN HOW WE DRIVE THOSE
7 MESSAGES OUT THERE.

8 DR. SOUTHARD: THANK YOU.

9 CHAIRMAN IMBASCIANI: ANYONE ELSE WHO'S
10 CONNECTED BY ZOOM? NO. OKAY. J.T., YOU HAVE ANY
11 FINAL COMMENTS? YSABEL.

12 MS. DURON: VITO, I'M VERY SORRY. I CAN'T
13 SEE MY HAND. ACTUALLY IN RESPONSE TO THE LAST
14 QUESTION, I THINK ON THE SUBCOMMITTEE -- WE HAVE A
15 COMMUNICATIONS SUBCOMMITTEE. WE HAVE DISCUSSED WHAT
16 CIRM'S RESPONSE NEEDS TO BE OR SHOULD BE IN TERMS OF
17 WHAT IS HAPPENING TO RESEARCH AND RESEARCHERS ACROSS
18 THE COUNTRY BASED ON HOW THE FEDERAL GOVERNMENT AND
19 ADMINISTRATION ARE RESPONDING AND ESPECIALLY
20 ATTACKING DEI.

21 AND SO I DO THINK WE NEED TO BE VERY
22 REACTIVE AND PROACTIVE, ALWAYS DEFENDING BOTH OUR
23 RESEARCHERS, RESEARCH, AND, I BELIEVE, DEI. I THINK
24 WE HAVE TO DO THAT IN A MEASURED WAY BECAUSE I DON'T
25 THINK EVERYBODY HERE IN THE ROOM IS GOING TO AGREE

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1 THAT WE NEED TO GO FULL ON EXCEPT ME. I EXPECT
2 EVERYBODY ELSE WANTS TO BE MEASURED. I'M SORRY I'M
3 NOT FEELING THAT WAY, BUT I'VE OFTEN SAID IN THESE
4 RECENT MONTHS TO J.T. AND DURING THE COMMUNICATIONS
5 SUBCOMMITTEE AS WELL AS TO ESTEBAN THAT WE DON'T
6 NEED TO SIT AROUND AND WAIT FOR STUFF TO HAPPEN,
7 THAT WE NEED TO TAKE THE REINS AND PARTICULARLY,
8 EVEN IF IT'S JUST CALIFORNIA, THAT WE'RE BEHIND
9 RESEARCH AND WE'RE BEHIND RESEARCHERS AS WELL AS THE
10 DIVERSITY OF OUR COMMUNITIES THAT WE'RE INCLUDING IN
11 THIS WORK.

12 I WOULD LIKE US TO SEEM TO BE ABLE TO --
13 SEEM TO BE STANDING FOR RESEARCH AND FOR DIVERSITY
14 AS A LEADER ACROSS THE COUNTRY. I DON'T KNOW THAT
15 THAT'S EVERYBODY'S PARTICULAR WAY OF WANTING OR
16 STRATEGY TO DO THIS, BUT I THOUGHT THAT, IN RESPONSE
17 TO THE QUESTION THAT WAS JUST ASKED, I FELT I NEED
18 TO PUT THAT OPINION OUT THERE. THERE MIGHT BE SOME
19 OTHERS WHO AGREE DESPITE WHAT'S HAPPENING AT THE
20 VARIOUS ACADEMIC INSTITUTIONS.

21 SO I DID RECOMMEND THAT WE SHOULD BE
22 FOLLOWING CLOSELY THE STORIES OF THE DAY IN WHICH WE
23 CAN RESPOND, FOR INSTANCE, IN THE CUTTING OUT OF ALL
24 DIABETES FUNDING FOR A LONG-TERM, 30-YEAR PROJECT.
25 AND SINCE WE'VE SUPPORTED DIABETES, WE COULD DO A

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1 RESPONSE. THAT'S SAD TO HEAR, TERRIBLE TO HEAR, THE
2 WRONG THING TO DO IN DISCOVERY, ET CETERA, ET
3 CETERA. THERE ARE WAYS TO KEEP OUR NAME AND OUR
4 WORK AND OUR CONCERNS IN THE NEWS ON AN ALMOST DAILY
5 BASIS UTILIZING THE WORK THAT WE HAVE BEEN DOING AND
6 BEING ABLE TO SUPPORT THE ADVANCE OF SCIENCE AND NOT
7 THE OPPRESSION OF SCIENCE IS THE WAY I SEE IT THESE
8 DAYS.

9 SO THAT'S JUST MY OPINION. I DON'T KNOW
10 HOW ANYBODY ELSE ON THE BOARD FEELS. BUT I DO THINK
11 WE SHOULD TAKE A MUCH MORE OVERT STAND THAN JUST
12 WAITING FOR THINGS TO HAPPEN.

13 CHAIRMAN IMBASCIANI: YSABEL, WE HAVE AT
14 LEAST ONE PERSON RESPONDING. JONATHAN.

15 DR. THOMAS: I WAS JUST GOING TO SAY THAT
16 WE ARE UNABASHEDLY ADVOCATES FOR SCIENCE, WHICH
17 WE'VE MADE VERY CLEAR IN EVERY PRONOUNCEMENT THAT
18 WE'VE HAD. AND SO I THINK THAT I'VE NOW GIVEN TWO
19 OR THREE INTERVIEWS WHERE THIS SORT OF THING IS
20 ASKED. I AM UNEQUIVOCAL THAT, NOTWITHSTANDING
21 DEVELOPMENTS ELSEWHERE, WE MAINTAIN OUR FULL
22 COMMITMENT TO SCIENCE IN GENERAL AND TO THE FIELD OF
23 REGENERATIVE MEDICINE SPECIFICALLY. SO LET NOBODY
24 THINK OTHERWISE ON THAT.

25 MS. DURON: I DIDN'T HEAR YOU SAY DEI,

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1 J.T. I PULL YOUR CHAIN ON THAT. YES, WE'RE ALL
2 COMMITTED TO SCIENCE, BUT ARE WE SAYING OUT LOUD
3 WE'RE STILL COMMITTED TO DEI?

4 DR. THOMAS: AS I SAID IN MY OPENING
5 COMMENTS TODAY, THE CORE VALUE THAT WE HAVE WITH
6 REGARD TO THAT HAS TO DO WITH ENSURING THAT ALL
7 PROGRAMS THAT WE FUND HAVE PLANS FOR HOW, WHATEVER
8 THE PARTICULAR PROJECT IS THAT THEY HAVE IN MIND,
9 WILL APPLY TO ALL AFFECTED COMMUNITIES WHO ARE
10 SUBJECT TO THE DISEASES IN QUESTION. SO YES. SHORT
11 ANSWER IS YES.

12 CHAIRMAN IMBASCIANI: DR. BARRETT.

13 DR. BARRETT: I WANTED TO ENDORSE WHAT
14 YSABEL SAID AND TO THANK CIRM BECAUSE, WHILE IT'S
15 REALLY IMPORTANT THAT CIRM IS ON A GOOD FOOTING WITH
16 THE FEDERAL GOVERNMENT AND COLLABORATIVE WITH THE
17 FEDERAL GOVERNMENT AND NEEDS THE FEDERAL GOVERNMENT
18 IN TERMS OF MAKING SURE THAT THESE THERAPIES MOVE
19 FORWARD, YOU ARE NOT AS FINANCIALLY DEPENDENT ON THE
20 FEDERAL GOVERNMENT AS THE INSTITUTIONS THAT MANY OF
21 US REPRESENT. AND SO YOU ACTUALLY HAVE A UNIQUE
22 ABILITY TO SPEAK UP, AND I APPRECIATE THAT YOU ARE
23 DOING SO.

24 MR. CORTEZ: THANK YOU. I VALUE THAT
25 FEEDBACK AND APPRECIATE YOUR SUGGESTION, YSABEL.

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1 THAT'S SOMETHING WE CAN DEFINITELY WORK TO IMPLEMENT
2 INTO TO OUR MESSAGING AND RESPONSES. THANK YOU.

3 CHAIRMAN IMBASCIANI: DR. CARETHERS.

4 DR. CARETHERS: I WAS JUST GOING TO ADD
5 I'M MAYBE THE NEWEST MEMBER ON THIS BOARD. AND I
6 LOOK AROUND THIS ROOM AND SEE THE DIVERSITY OF
7 BACKGROUNDS, BIRTHPLACES, INPUT FROM THE COMMUNITY,
8 ACADEMIA, INDUSTRY, ET CETERA. AND I'M PROUD TO BE
9 ON THIS BOARD. AND I WANT TO REMIND EVERYONE, FROM
10 MY OWN KNOWLEDGE, THAT THIS BOARD CAME INTO
11 EXISTENCE -- WE JUST HONORED LARRY GOLDSTEIN EARLIER
12 AS ONE OF THE EXAMPLES -- BECAUSE OF THE INACTION
13 AND BLOCKAGE OF ISSUES AT THE FEDERAL GOVERNMENT.

14 THAT WAS THE WORK ON STEM CELLS DURING
15 SEVERAL ADMINISTRATIONS AGO. AND I BELIEVE THAT
16 THIS IS THE SEVENTH -- CALIFORNIA IS 40 MILLION
17 PEOPLE, SEVENTH LARGEST ECONOMY IN THE WORLD. WE
18 CAN DO THINGS HERE. AND I'M SO PROUD THAT OUR
19 PUBLIC HAS APPROVED THE EXISTENCE OF THIS BOARD AND
20 THE THINGS THAT IT CAN DO. AND I THINK WE REALLY
21 NEED TO SERVE THE CONSTITUENCY OF CALIFORNIA, WHICH
22 IS A VERY DIVERSE POPULATION. AND SO I THINK WE
23 HAVE TO KEEP THAT IN MIND IRRESPECTIVE WHAT THE
24 FEDERAL SAID. I KNOW WE HAVE TO PLAY NICE. I GOT
25 IT. BUT WE SHOULDN'T STEER AWAY FROM OUR MISSION.

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1 MR. CORTEZ: THANK YOU.

2 CHAIRMAN IMBASCIANI: CAROLYN.

3 DR. MELTZER: I'D LIKE TO ECHO A NUMBER OF
4 THE COMMENTS THAT HAVE BEEN SAID AND ADD THAT I
5 DO -- I HAVE SERVED -- I SERVE ON A NUMBER OF
6 PROFESSIONAL SOCIETIES, BOARDS. AND IF THEY'RE NOT
7 DEPENDENT ON FEDERAL FUNDING, IT IS AN OPPORTUNITY
8 TO SPEAK OUT IN WAYS THAT MAYBE UNIVERSITIES ARE A
9 LITTLE BIT COWED RIGHT NOW. BUT WE ALSO NEED TO
10 THINK AS THE CIRM BOARD HOW TO BE REACTIVE IF THERE
11 ARE AREAS OF FUNDING THAT ARE CUT AT OUR
12 INSTITUTIONS THAT PROVIDE A FRAMEWORK FOR THE WORK
13 THAT CIRM SUPPORTS.

14 SO JUST THAT'S A LITTLE OUTSIDE OF
15 COMMUNICATIONS, BUT MORE A STRATEGY BECAUSE WE DON'T
16 KNOW WHERE THIS IS GOING EVERY DAY. AND THERE'S
17 THESE FRIDAY DUMPS OF THE GRANTS THAT ARE
18 DISCONTINUED.

19 MR. CORTEZ: THANK YOU.

20 CHAIRMAN IMBASCIANI: THANK YOU. ANYONE
21 ELSE? I DON'T WANT TO OVERLOOK ANYONE. OKAY.
22 THANK YOU, ESTEBAN.

23 MR. CORTEZ: THANK YOU SO MUCH, EVERYONE.

24 CHAIRMAN IMBASCIANI: THANK YOU, J.T.

25 OKAY. I'D LIKE -- THIS IS THE PART OF THE

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1 MEETING WHERE IF THERE'S ANY MEMBER OF THE BOARD WHO
2 WOULD LIKE TO MAKE ANY GENERAL COMMENTS ON OUR
3 APPLICATION REVIEW PROCESS. AND IF NOT, IS THERE
4 ANY MEMBER OF THE PUBLIC WHO WOULD LIKE TO MAKE ANY
5 COMMENT ON ANY ITEM ON THE AGENDA OR THAT WAS NOT ON
6 THE AGENDA? I'M TOLD THAT THERE IS NOT.

7 OKAY. AND IN THAT CASE WE HAVE COME TO
8 THE END OF THE MEETING. I WOULD LIKE TO INFORM ALL
9 BOARD MEMBERS THAT WE ARE GOING TO RECONVENE ON THE
10 26TH OF JUNE AT THE AIRPORT MARRIOTT HOTEL IN
11 BURLINGAME, CALIFORNIA, WHICH IS VERY CLOSE TO THE
12 AIRPORT IN SAN FRANCISCO, SFO. OKAY. THIS MEETING
13 IS ADJOURNED. THANK YOU VERY MUCH.

14 (THE MEETING WAS THEN CONCLUDED AT 3:41 P.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 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 MARCH 27, 2025, 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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