

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 BLVD.
SACRAMENTO, CALIFORNIA

DATE: MARCH 26, 2026
8:30 A.M.

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

FILE NO.: 2026-10

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18.	DISCUSSION OF CONFIDENTIAL INTELLECTUAL PROPERTY OR WORK PRODUCT, PREPUBLICATION DATA, FINANCIAL INFORMATION, CONFIDENTIAL SCIENTIFIC RESEARCH OR DATA, AND OTHER PROPRIETARY INFORMATION RELATING TO AGENDA ITEM #11 ABOVE. (HEALTH & SAFETY CODE 125290.30(F) (3) (B) AND (C)).	
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MARCH 26, 2026; 8:30 A.M.

CHAIRMAN IMBASCIANI: ALL RIGHT. GOOD MORNING, EVERYONE. WELCOME TO THIS MEETING OF THE INDEPENDENT CITIZEN'S OVERSIGHT COMMITTEE, THE CIRM BOARD, AND THE APPLICATION REVIEW SUBCOMMITTEE. HERE WE ARE IN SACRAMENTO, CALIFORNIA. AND I'M GOING TO ASK THAT WE CALL THE MEETING TO ORDER, AND WE'LL START WITH THE PLEDGE OF ALLEGIANCE IF MR. SCOTT TOCHER WILL DO THE HONORS AND LEAD US. THANK YOU.

MR. TOCHER: SURE. THE FLAG IS BY THE PODIUM. PLEASE STAND IF YOU ARE ABLE.

(THE PLEDGE OF ALLEGIANCE.)

CHAIRMAN IMBASCIANI: THANK YOU, SCOTT. WILL YOU PLEASE CONTINUE AND CALL THE ROLL.

MR. TOCHER: SURE. AYAD ALMASRI.

DR. ALMASRI: PRESENT.

MR. TOCHER: KIM BARRETT.

DR. BARRETT: PRESENT.

MR. TOCHER: DAN BERNAL. GEORGE BLUMENTHAL. MARIA BONNEVILLE.

VICE CHAIR BONNEVILLE: PRESENT.

MR. TOCHER: JOHN CARETHERS.

DR. CARETHERS: PRESENT.

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1 MR. TOCHER: MONICA CARSON.
2 DR. CARSON: PRESENT.
3 MR. TOCHER: THANK YOU VERY MUCH.
4 MARGUERITE CASILLAS?
5 MS. CASILLAS: PRESENT.
6 MR. TOCHER: JUDY CHOU?
7 DR. CHOU: PRESENT.
8 MR. TOCHER: LEONDRA CLARK-HARVEY.
9 DR. CLARK-HARVEY: PRESENT.
10 MR. TOCHER: SHANNON DAHL.
11 DR. DAHL: PRESENT.
12 MR. TOCHER: ANNE-MARIE DULIEGE.
13 DR. DULIEGE: PRESENT.
14 MR. TOCHER: YSABEL DURON.
15 MS. DURON: HERE.
16 MR. TOCHER: MARK FISCHER-COLBRIE.
17 MR. FISCHER-COLBRIE: HERE.
18 MR. TOCHER: ELENA FLOWERS.
19 DR. FLOWERS: PRESENT.
20 MR. TOCHER: OH, SORRY. THAT WAS SO
21 QUIET.
22 JUDY GASSON.
23 DR. GASSON: HERE.
24 MR. TOCHER: JEFF GOLDEN.
25 DR. GOLDEN: PRESENT.

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1 MR. TOCHER: VITO IMBASCIANI.
2 CHAIRMAN IMBASCIANI: PRESENT.
3 MR. TOCHER: RICH LAJARA.
4 MR. LAJARA: PRESENT.
5 MR. TOCHER: PAT LEVITT.
6 DR. LEVITT: PRESENT.
7 MR. TOCHER: HALA MADANAT.
8 DR. MADANAT: PRESENT.
9 MR. TOCHER: LINDA MALKAS.
10 DR. MALKAS: HERE.
11 MR. TOCHER: CAROLYN MELTZER. CHRISTINE
12 MIASKOWSKI.
13 DR. MIASKOWSKI: PRESENT.
14 MR. TOCHER: ADRIANA PADILLA.
15 DR. PADILLA: HERE.
16 MR. TOCHER: JOE PANETTA. JOYCE SACKY.
17 DR. SACKY: HERE.
18 MR. TOCHER: MARV SOUTHARD.
19 DR. SOUTHARD: PRESENT.
20 MR. TOCHER: SHAUNA STARK.
21 MS. STARK: HERE.
22 MR. TOCHER: KAROL WATSON.
23 DR. WATSON: HERE.
24 MR. TOCHER: YAEL WHITE. KEVIN XU.
25 MR. XU: HERE.

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1 MR. TOCHER: KEITH YAMAMOTO.

2 DR. YAMAMOTO: HERE.

3 MR. TOCHER: GREAT. THANK YOU VERY MUCH.

4 MR. CHAIR, WE HAVE A QUORUM.

5 CHAIRMAN IMBASCIANI: WE HAVE A QUORUM.

6 THANK YOU, SCOTT.

7 THE FIRST ORDER OF BUSINESS IS TO CONSIDER
8 THE CONSENT AGENDA, WHICH IS A LITTLE LONGER THAN
9 USUAL TODAY. IT CONSISTS OF THE MINUTES FROM THE
10 DECEMBER 11TH AND THE JANUARY 29TH MEETING OF THE
11 ICOC, APPOINTMENTS AND REAPPOINTMENTS OF THE
12 SCIENTIFIC MEMBERS TO THE GRANTS WORKING GROUP. AND
13 FOR THOSE -- I PRESUME EVERYONE HAS LOOKED AT THIS.
14 THERE'S ONE NEW APPOINTMENT OF A DR. MARK
15 FITZGERALD, MD.PH.D., FROM THE PERELMAN SCHOOL OF
16 MEDICINE AT THE UNIVERSITY OF PENNSYLVANIA. THERE
17 ARE ONE, TWO, THREE, FOUR, FIVE, SIX REAPPOINTMENTS
18 OF SCIENTISTS.

19 AND THERE'S ALSO A VERY INTERESTING GRAPH
20 APPENDED TO THIS REPORT THAT QUANTIFIES THE
21 REPRESENTATION OF WOMEN SCIENTIFIC MEMBERS ON THE
22 GRANTS WORKING GROUP. AND YOU'LL SEE THAT THE
23 ATTENDANCE AND PARTICIPATION OF WOMEN SCIENTISTS ON
24 THE GWG HAS NEARLY DOUBLED OVER THE TIME SPAN OF
25 2020 TO 2025, REACHING A TOTAL OF 50 PERCENT.

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1 THERE ARE OTHER ITEMS ON THE CONSENT
2 AGENDA. ONE IS A RECOMMENDATION FROM THE GOVERNANCE
3 SUBCOMMITTEE REGARDING THE PROCESS OF EVALUATING THE
4 CHAIR, THE VICE CHAIR, AND THE PRESIDENT AND CEO FOR
5 THIS UPCOMING YEAR. AND, FINALLY, THERE ARE SOME
6 AMENDMENTS TO THE FUNDING MECHANISM FOR CIRM RELATED
7 TO THE EDUCATION¹ OR EDUC¹ PROGRAM.

8 SO THE WAY THE CONSENT AGENDA WORKS, IF
9 ANYONE WANTS TO DISCUSS ANYTHING THAT I JUST
10 MENTIONED, IT NEEDS TO BE ABSTRACTED BY YOU BY
11 VOICE. AND THEN WE CAN CLOSE OUT THE REST OF THE
12 AGENDA AND THEN PROCEED TO A DISCUSSION OF THE ITEM
13 THAT YOU WOULD LIKE.

14 DO I HEAR ANY ABSTRACTIONS TO THE CONSENT
15 AGENDA, ITEMS 3, 4, 5, AND 6? NOT IN THE ROOM. AND
16 PERHAPS ANYONE ONLINE? NO. OKAY.

17 CAN I HAVE A MOTION TO CLOSE THE CONSENT
18 AGENDA PLEASE?

19 DR. CLARK-HARVEY: SO MOVED.

20 CHAIRMAN IMBASCIANI: LEONDRA HAS MOVED.

21 VICE CHAIR BONNEVILLE: SECOND.

22 CHAIRMAN IMBASCIANI: MARIA SECONDED.

23 SCOTT --

24 MR. TOCHER: BOARD COMMENT? PUBLIC
25 COMMENT?

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1 ALL THOSE IN THE ROOM IN FAVOR SAY AYE.
2 OPPOSED? ABSTENTIONS? AND I'LL POLL THE MEMBERS ON
3 THE ZOOM.
4 MONICA CARSON.
5 DR. CARSON: AYE.
6 MR. TOCHER: JUDY CHOU.
7 DR. CHOU: AYE.
8 MR. TOCHER: YSABEL DURON.
9 MS. DURON: AYE.
10 MR. TOCHER: MARK FISCHER-COLBRIE.
11 MR. FISCHER-COLBRIE: AYE.
12 MR. TOCHER: JUDY GASSON.
13 DR. GASSON: YES.
14 MR. TOCHER: JEFF GOLDEN.
15 DR. GOLDEN: AYE.
16 MR. TOCHER: RICH LAJARA.
17 MR. LAJARA: AYE.
18 MR. TOCHER: PAT LEVITT.
19 DR. LEVITT: YES.
20 MR. TOCHER: HALA MADANAT.
21 DR. MADANAT: AYE.
22 MR. TOCHER: CHRIS MIASKOWSKI.
23 DR. MIASKOWSKI: YES.
24 MR. TOCHER: MARV SOUTHARD.
25 DR. SOUTHARD: YES.

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1 MR. TOCHER: KAROL WATSON.

2 DR. WATSON: YES.

3 MR. TOCHER: AND KEVIN XU.

4 MR. XU: AYE.

5 MR. TOCHER: OH, AND KEITH YAMAMOTO.

6 DR. YAMAMOTO: YES.

7 MR. TOCHER: GREAT. THANK YOU. THAT
8 MOTION CARRIES.

9 CHAIRMAN IMBASCIANI: THANK YOU, SCOTT.
10 BOARD MEMBER SHANNON DAHL HAS A COMMENT ON THE
11 CONSENT AGENDA.

12 DR. DAHL: YEAH. I HAD A COMMENT ABOUT
13 THE GRANT WORKING GROUP COMMITTEE. I THINK, JUST
14 LOOKING AT THE NEW APPOINTMENT AND THE
15 REAPPOINTMENTS, AND LOOKING BACK AT THE LIST, I'M
16 REALLY IMPRESSED BY THE GROUP THAT WE HAVE REVIEWING
17 OUR GRANTS. AND THEY'RE SUCH A CRITICAL PIECE OF
18 THE ORGANIZATION AND MOVING THE PROGRAMS FORWARD.
19 I'M EXCITED ABOUT THE NEW APPOINTMENTS AND THE
20 RENEWALS.

21 AS WE LOOK AT OUR PORTFOLIO AT LARGE AND
22 THE WAY IN WHICH WE'RE ADVANCING MORE PROGRAMS INTO
23 LATER STAGE, I THINK IT WOULD BE HELPFUL TO JUST
24 TAKE A STEP BACK AND SAY DO WE NEED TO ADD
25 ADDITIONAL LATER STAGE EXPERTISE TO THE GROUP TO

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1 ENSURE THAT EVERY TIME WE'RE GOING FROM PHASE 1 TO
2 BLA, THAT WE HAVE ENOUGH REVIEWERS IN THE ROOM WITH
3 THAT PERSPECTIVE. I SEE WE HAVE SOME ON OUR LIST,
4 WHICH IS GREAT, BUT THEY'RE SMALLER IN NUMBER. SO I
5 WOULD JUST ASK THAT THE TEAM TAKE THAT INTO
6 CONSIDERATION. THANK YOU.

7 CHAIRMAN IMBASCIANI: THANK YOU, SHANNON.

8 GOING TO MOVE NOW TO AGENDA ITEM NO. 7,
9 THE CONSIDERATION OF APPLICATIONS THAT HAVE BEEN
10 SUBMITTED TO CIRM IN RESPONSE TO OUR DISCOVERY
11 PROGRAM ANNOUNCEMENTS OR DISC4. AND THIS
12 PRESENTATION IS GOING TO BE LED BY OUR VICE
13 PRESIDENT FOR PORTFOLIO DEVELOPMENT AND REVIEW, DR.
14 GIL SAMBRANO. THANK YOU, GIL.

15 DR. SAMBRANO: GOOD MORNING, EVERYONE.
16 SO, YES, I'M GOING TO PRESENT TO YOU THE
17 RECOMMENDATIONS FROM THE GRANTS WORKING GROUP AS IT
18 RELATES TO THE DISC4 PROGRAM. SO LET'S GET STARTED
19 WITH THAT.

20 WE ALWAYS BEGIN WITH OUR MISSION, TO
21 ACCELERATE WORLD-CLASS SCIENCE TO DELIVER
22 TRANSFORMATIVE REGENERATIVE MEDICINE TREATMENTS IN
23 AN EQUITABLE MANNER TO A DIVERSE CALIFORNIA AND
24 WORLD. AND THIS IS IMPORTANT IN SETTING THE STAGE
25 FOR WHAT WE DO AND WHY WE DO IT. OF COURSE, TO HELP

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1 US ACHIEVE THAT MISSION, WE HAVE A STRATEGY WITH
2 VERY SPECIFIC GOALS THAT WE WANT TO ACHIEVE. AS IT
3 RELATES TO DISCOVERY PROGRAMS, THOSE DISCOVERY
4 PROGRAMS ARE SET UP TO SUPPORT COMPREHENSIVE
5 DISCOVERY RESEARCH, AND THEY ALSO ENCOURAGE
6 COLLABORATIVE, MULTIDISCIPLINARY APPROACHES WHERE
7 POSSIBLE.

8 AND IN PARTICULAR, THE DISC4 AWARDS THAT
9 ARE BASED ON THE ORIGINAL REMIND PROGRAM ARE VERY
10 MUCH INTENDED TO SUPPORT CROSS-DISCIPLINARY, VERY
11 COLLABORATIVE, AND INTEGRATED STUDIES ACROSS A RANGE
12 OF TECHNOLOGIES AND APPROACHES TO ADDRESS
13 BOTTLENECKS AND OTHER KNOWLEDGE GAPS IN HUMAN
14 DISEASE.

15 SO FOR THE DISC4 AWARDS, ANYBODY WHO
16 APPLIES, WE EXPECT THAT THEY'RE GOING TO ACHIEVE ONE
17 OR MORE OF THE THREE OUTCOMES LISTED, WHICH IS TO
18 DISCOVER NOVEL MECHANISTIC INSIGHTS OR ADVANCE
19 UNDERSTANDING OF HUMAN DISEASE PATHOBIOLOGY, EXTEND
20 UNDERSTANDING OF DISEASE MECHANISMS ACROSS AFFECTED
21 HUMAN POPULATIONS, AND/OR IDENTIFY AND VALIDATE
22 NOVEL THERAPEUTIC STRATEGIES, TARGETS, AND
23 BIOMARKERS.

24 THE WAY THE DISC4 PROGRAM WAS DESIGNED, IT
25 WAS DESIGNED USING PREFERENCE TOPICS FOR EACH CYCLE.

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1 AND SO THE BOARD APPROVED PREFERENCE TOPIC FOR THIS
2 PARTICULAR CYCLE WAS NEUROLOGICAL DISEASES. AND SO
3 THAT INCLUDES CONDITIONS AND DISORDERS OF THE BRAIN,
4 SPINAL CORD, AND PERIPHERAL NERVOUS SYSTEM.

5 ALL RIGHT. SO A LITTLE MORE ABOUT THE
6 PROGRAM STRUCTURE ITSELF. THE DURATION OF THE AWARD
7 IS FOUR YEARS. IT OFFERS 13 OR UP TO 13 MILLION AND
8 AN ADDITIONAL MILLION WITH MATCHING FUNDS FROM THE
9 APPLICANT. THE APPLICANT TEAM ITSELF INCLUDES THE
10 PRINCIPAL INVESTIGATOR ALONG WITH A MINIMUM OF FOUR
11 CO-INVESTIGATORS WHO WORK COLLABORATIVELY TO
12 ACHIEVE, HOPEFULLY, SOMETHING THAT SYNERGIZES AND
13 CAN ACHIEVE MORE THAN EITHER ONE ALONE.

14 SO THE ALLOCATION THAT WE HAVE FOR THIS
15 PARTICULAR CYCLE IS 84 MILLION TOTAL WHICH SUPPORTS
16 ROUGHLY UP TO SIX AWARDS. AND SO LET ME TELL YOU A
17 LITTLE BIT ABOUT, THEN, THE REVIEW PROCESS THAT'S
18 UTILIZED FOR THE DISC4 APPLICATIONS.

19 SO THIS UTILIZED A PRESUBMISSION PROCESS
20 AT THE BEGINNING, AT THE ONSET. SO THESE WERE
21 SHORT, THREE-PAGE PRESUBMISSIONS THAT WERE REVIEWED
22 BY THE CIRM STAFF. AND THE SET OF PREFERENCES THAT
23 YOU'VE SEEN BEFORE WERE APPLIED HERE. WE HAD 138
24 PRESUBMISSIONS, AND OF THOSE 24 WERE INVITED TO
25 COMPLETE A FULL APPLICATION.

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1 THOSE FULL APPLICATIONS WERE ASSESSED FOR
2 ELIGIBILITY. ALL WERE ELIGIBLE AND WENT ON TO THE
3 MERIT REVIEW STAGE. AND WE ARE GOING TO THEN SHARE
4 WITH YOU THE RECOMMENDATIONS FROM THE GRANTS WORKING
5 GROUP THAT EVALUATED THOSE.

6 SO THIS IS JUST A REMINDER OF THE
7 COMPOSITION OF THE GRANTS WORKING GROUP PANEL. IT
8 INCLUDES SCIENTIFIC MEMBERS WHO EVALUATE THE
9 APPLICATIONS BASED ON BROAD SUBJECT AREA OR METHODS
10 EXPERTISE, AND THEY ARE THE ONES WHO ENTER THE
11 SCIENTIFIC SCORE FOR EVERY APPLICATION. AND WE ALSO
12 HAVE WHAT WE CALL GRANTS WORKING GROUP BOARD
13 MEMBERS. SO THOSE ARE ICOC PATIENT ADVOCATE MEMBERS
14 WHO SIT ON THE GRANTS WORKING GROUP. THEY OFFER
15 THEIR PATIENT PERSPECTIVE ON THE SIGNIFICANCE AND
16 POTENTIAL IMPACT OF PROJECTS, AND THEY ALSO PROVIDE
17 OVERSIGHT ON THE PROCESS ITSELF. THEY DO NOT ENTER
18 SCORES.

19 WE ALSO HAVE VISITING SPECIALISTS. THOSE
20 ARE SCIENTIFIC MEMBERS THAT WE INVITE TO FILL
21 KNOWLEDGE GAPS WHEN NECESSARY FOR A PARTICULAR SET
22 OF APPLICATIONS OR EVEN MAYBE ONE APPLICATION AT A
23 TIME. AND THEY PROVIDE THEIR INSIGHT TO THE PANEL
24 ON APPLICATIONS.

25 THE SCORING SYSTEM THAT WE USE IS ON A

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1 SCALE OF 1 TO 100. A MEDIAN SCORE OF 85 TO 100
2 MEANS THAT IT HAS EXCEPTIONAL MERIT AND WARRANTS
3 FUNDING. A MEDIAN SCORE OF 1 TO 84 IS NOT
4 RECOMMENDED FOR FUNDING. THE SCORING THAT IS
5 UTILIZED IS HOLISTIC AND BASED UPON ALL FACETS OF
6 THE EXPERT REVIEWS, AND WE DO ENCOURAGE REVIEWERS TO
7 USE THE FULL RANGE.

8 ALL RIGHT. AND THE CRITERIA THAT ARE THE
9 BASIS FOR THE SCORE ARE HIGHLIGHTED HERE. THESE ARE
10 JUST THE HIGH-LEVEL ELEMENTS OF THE FIVE MAIN
11 CRITERIA, WHICH INCLUDE THE SIGNIFICANCE AND
12 POTENTIAL IMPACT OF THE PROJECT, INNOVATION RELATIVE
13 TO THE CURRENT STATE OF RESEARCH FOR THE PROJECT,
14 THE SCIENTIFIC RATIONALE, THE PROJECT PLAN AND
15 DESIGN, AND THE APPLICANT'S CONSIDERATION OF IMPACT
16 ACROSS AFFECTED POPULATIONS.

17 THIS TABLE SUMMARIZES THE RECOMMENDATIONS
18 FROM THE GRANTS WORKING GROUP AS IT RELATES TO THIS
19 SET OF APPLICATIONS. SO FOR THOSE 24 APPLICATIONS
20 THAT WERE EVALUATED, EIGHT OF THEM WERE RECOMMENDED
21 BY THE WORKING GROUP, 16 WERE NOT. THE TOTAL BUDGET
22 REQUEST FOR THE EIGHT APPLICATIONS TOTALS 108.5
23 MILLION. AND AS NOTED EARLIER, THE FUNDS AVAILABLE
24 FOR THE CYCLE IS 84 MILLION. SO THIS EXCEEDS THE
25 AMOUNT THAT WE HAVE AVAILABLE TO SUPPORT ALL THE

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1 PROJECTS.

2 SO THE SCORING IN THE REVIEW SOMETIMES
3 RESULTS IN A MINORITY REPORT. AND THAT HAPPENS WHEN
4 ANY APPLICATION THAT'S NOT RECOMMENDED FOR FUNDING
5 BY THE GRANTS WORKING GROUP, BUT HAD 35 PERCENT OR
6 MORE OF THE MEMBERS SCORE IN THE FUNDING RANGE,
7 THOSE INCLUDE A MINORITY REPORT WHICH IS BASICALLY A
8 PARAGRAPH THAT SUMMARIZES THE MINORITY POSITION.
9 AND WE USUALLY CHECK IN WITH THOSE REVIEWERS TO
10 ENSURE IT MIRRORS THEIR PERSPECTIVE. IN THIS
11 PARTICULAR CYCLE THERE WERE NO APPLICATIONS THAT
12 QUALIFIED FOR A MINORITY REPORT.

13 ALL RIGHT. THIS TABLE SUMMARIZES THE
14 EIGHT APPLICATIONS THAT WERE RECOMMENDED BY THE
15 GRANTS WORKING GROUP. IT SHOWS THEM IN RANK ORDER
16 IN TERMS OF THE MEDIAN SCORE, WHICH RANGES FROM 85
17 TO 90, ALONG WITH THE BUDGET REQUEST. THE OTHER
18 THING TO MAKE NOTE OF IS YOU SEE THE Y AND THE N IN
19 THE SECOND TO LAST AND THIRD TO LAST COLUMNS. SO
20 THE Y MEANS, YES, THOSE ARE THE NUMBER OF GRANTS
21 WORKING GROUP MEMBERS THAT SCORED 85 OR ABOVE FOR
22 THAT APPLICATION, AND THE N MEANS NO, WHICH THOSE
23 ARE THE ONES THAT SCORED BELOW 85 FOR THAT
24 PARTICULAR APPLICATION.

25 AND SO YOU WILL NOTICE THAT, IN PARTICULAR

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1 FOR THE LAST TWO WHICH THE CIRM TEAM IS RECOMMENDING
2 NOT TO FUND IN ORDER TO ACCOMMODATE THE BUDGET, HAD
3 A DIFFERENCE OF EIGHT TO SIX. SO EIGHT MEMBERS
4 SCORING 85 OR ABOVE WHILE SIX SCORED BELOW 85. SO
5 IT'S JUST SOMETHING TO TAKE NOTE AS I DESCRIBE
6 THESE.

7 SO THE CIRM TEAM RECOMMENDATION, JUST TO
8 GIVE YOU A LITTLE BIT MORE ABOUT THE RATIONALE, WE
9 LOOKED AT ALL THE TOP APPLICATIONS AND IN PARTICULAR
10 THOSE THAT HAD A SCORE OF 85. THERE WERE THREE
11 APPLICATIONS THAT I SHOWED YOU ON THAT LIST THAT HAD
12 A SCORE OF 85. AND LOOKING AT THOSE, THE CIRM TEAM
13 IS RECOMMENDING THAT TWO OF THOSE APPLICATIONS NOT
14 BE FUNDED, WHICH IS DISC4-19196 AND DISC4-19226.
15 AND THIS IS SOLELY DUE TO THE FACT THAT WE DON'T
16 HAVE ENOUGH BUDGET TO COVER. I WANT TO EMPHASIZE
17 THE FACT THAT ALL HAVE MERIT. SO WE'RE NOT
18 SUGGESTING THAT ANY OF THESE DO NOT HAVE SCIENTIFIC
19 MERIT AS INDICATED BY THE WORKING GROUP, BUT WE HAD
20 TO DEVELOP A RATIONALE FOR WHY WE WOULD RECOMMEND
21 THE GROUP WE DID.

22 SO THE DISC4-19391 DID HAVE A GREATER
23 CONSENSUS ON MERIT. SO THAT'S THE ELEVEN MEMBERS
24 SCORING 85 OR ABOVE VERSUS THREE THAT SCORED BELOW
25 WHILE THE OTHER TWO HAD EIGHT TO SIX SPLIT.

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1 SO A LITTLE BIT MORE ABOUT THE TWO
2 APPLICATIONS THAT ARE NOT RECOMMENDED. SO THIS IS
3 19196, OR NOT RECOMMENDED BY THE CIRM TEAM. THEY
4 ARE RECOMMENDED BY GRANTS WORKING GROUP JUST TO BE
5 CLEAR. WE'RE NOT RECOMMENDING THIS ONE LARGELY
6 BECAUSE OF THE SCORE. THE APPLICATION ITSELF IN
7 TERMS OF THE TOPIC IS FOCUSED ON NEURODEGENERATIVE
8 DISEASES, PARTICULARLY ALS AND FRONTAL TEMPORAL
9 DEMENTIA, TO UNDERSTAND HOW RNA LOCALIZATION RELATES
10 TO THE DISEASE STATE.

11 REVIEWERS NOTED AN EXCELLENT TEAM,
12 INNOVATIVE APPROACHES, IMPACT OF THE DATASET TO BE
13 PRODUCED. BUT THERE WAS A RISK THAT WAS NOTED, THAT
14 WHILE THE MISLOCALIZATION OF THE RNA IS A COMMON
15 OBSERVATION IN ALS, THE REVIEWERS DID NOTE THIS
16 SEVERAL TIMES, AND YOU CAN SEE IT IN THE SUMMARY,
17 ABOUT THE UNCERTAINTY OF WHETHER THIS ACTUALLY PLAYS
18 A CAUSAL ROLE IN ALS. AND SO THE RISK IS THAT THE
19 EFFORT EXPENDED HERE MAY BE LIMITED IF IT TURNS OUT
20 THAT THERE IS NO CAUSAL RELATIONSHIP. SO ALSO WE
21 ARE ALREADY MENTIONED THE SCORE OF THE GRANTS
22 WORKING GROUP CONSENSUS BEING EIGHT TO SIX.

23 SO THEN THE NEXT APPLICATION, 19226, IS
24 THE OTHER ONE THAT WE'RE NOT RECOMMENDING FOR
25 FUNDING. SO THIS APPLICATION IS FOCUSED ON

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1 UNDERSTANDING CYTOKINE RESPONSES IN THE BRAIN AND
2 MICROGLIAL MECHANISMS IN THE CONTEXT OF ALZHEIMER'S
3 DISEASE. AGAIN, REVIEWERS NOTED AN EXCELLENT TEAM,
4 INNOVATIVE APPROACHES, AND THE POTENTIAL CREATION OF
5 A HIGH-VALUE DATASET. FOR SOME REVIEWERS THE
6 ENTHUSIASM WAS OFFSET BY SOME CONCERNS RELATED TO
7 THE LACK OF POWER CALCULATIONS AND OTHER TECHNICAL
8 ELEMENTS. THERE WAS ALSO SOME CONCERN ABOUT THE
9 FACT THAT THE PROJECTS WERE A LITTLE DISJOINTED,
10 DIDN'T SEEM TO RELATE CLEARLY TO ONE ANOTHER AS TO
11 WHY THEY WERE PUT TOGETHER AS PROPOSED. AND, AGAIN,
12 THIS ALSO HAD A GWG GROUP VOTE THAT WAS EIGHT
13 MEMBERS VOTING 85 OR ABOVE AND SIX THAT DID NOT.

14 ALL RIGHT. SO WITH THIS, THEN WE CAN
15 TRANSITION TO THE EXCEL SPREADSHEET, THE TABLE THAT
16 SHOWS YOU ALL OF THE APPLICATIONS FOR DISCUSSION.
17 AND, CHAIRMAN IMBASCIANI, I'LL JUST TURN IT BACK TO
18 YOU FOR DISCUSSION.

19 CHAIRMAN IMBASCIANI: DR. SAMBRANO, THANK
20 YOU SO MUCH FOR THAT PRESENTATION AND THE
21 EXPLANATION OF THE DELIBERATIONS YOU WENT THROUGH.

22 IF I CAN HAVE THE TEMERITY TO SUMMARIZE
23 DR. SAMBRANO'S PRESENTATION, WE HAVE A LOT OF
24 APPLICATIONS, SOME OF WHICH WERE NOT RECOMMENDED FOR
25 FUNDING BY THE GWG. THE GRANTS WORKING GROUP DID

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1 RECOMMEND EIGHT FOR FUNDING, BUT THAT BUDGETARY
2 REQUEST WOULD HAVE EXCEEDED THE \$84 MILLION WE HAVE
3 AVAILABLE. IN FACT, IT TOTALED 108 MILLION. AND AS
4 IT HAPPENS, THERE IS A THREE-WAY TIE AT THE BOTTOM.
5 GIL VERY ELOQUENTLY DESCRIBED THE DIFFERENCES
6 BETWEEN THOSE THREE AND WHAT GUIDED THE TEAM TO
7 RECOMMEND ONE OVER THE OTHER. THEREFORE, THERE
8 ARE -- EVEN THOUGH THE GRANTS WORKING GROUP
9 RECOMMENDED EIGHT FOR FUNDING, WE CAN ONLY FUND SIX.
10 AND IT'S GOING TO BE INCUMBENT UPON THE BOARD TO
11 CHOOSE THAT.

12 SO TO SIMPLIFY THIS FROM A MOTION POINT OF
13 VIEW, I THINK IT WOULD BE EASIEST IF WE HAD A MOTION
14 NOT TO FUND THOSE FROM NO. 9 DOWN. THAT IS, NOT TO
15 FUND THE ONES THAT WERE NOT RECOMMENDED BY THE
16 GRANTS WORKING GROUP. HE'S SHOWING THAT NOW, ALL
17 THE ONES THAT FALL BELOW POSITION EIGHT.

18 DR. BARRETT: SO MOVED.

19 MR. TOCHER: FROM A PROCESS STANDPOINT,
20 BECAUSE THE PROGRAM IS WHAT WE CALL OVERSUBSCRIBED
21 AT THE MOMENT, FOR THOSE VOTING MEMBERS OF THE
22 APPLICATION REVIEW SUBCOMMITTEE WHO HAVE A CONFLICT
23 WITH ANY APPLICATION IS CONSIDERED TO HAVE A
24 CONFLICT WITH ALL OF THEM FOR THE PURPOSES OF MAKING
25 A MOTION AND SECONDING A MOTION AND FOR THE

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1 DISCUSSION. WHEN I CALL YOUR NAME DURING THE ROLL
2 CALL VOTE, YOUR ANSWER WILL BE AYE OR NAY WITH
3 RESPECT TO THE MOTION AND THEN ADD "EXCEPT FOR THOSE
4 APPLICATIONS WITH WHICH I AM IN CONFLICT," SOME
5 VERSION OF THAT.

6 SO AT THE MOMENT THE VOTING MEMBERS OF THE
7 ARS WITH A CONFLICT AND THUS SHOULD NOT PARTICIPATE
8 IN THE MAKING OF THE MOTION OR DISCUSSION ARE
9 MEMBERS DAHL, BONNEVILLE, DURON, DULIEGE, FLOWERS,
10 FISCHER-COLBRIE, MIASKOWSKI, AND WATSON. THAT MEANS
11 THERE IS A CONFLICT, SO PLEASE REFRAIN FROM --

12 DR. GOLDEN: THIS IS JEFF GOLDEN. I THINK
13 I HAVE A CONFLICT WITH ONE OF THEM AS WELL, 19444.

14 MR. TOCHER: YES, 19350 YOU HAVE A
15 CONFLICT.

16 CHAIRMAN IMBASCIANI: THANK YOU, SCOTT.
17 OKAY. SO THE CHAIR WOULD LIKE TO ENTERTAIN A MOTION
18 NOT TO FUND THOSE APPLICATIONS NOT RECOMMENDED FOR
19 FUNDING BY THE GRANTS WORKING GROUP.

20 DR. SOUTHARD: SO MOVED.

21 DR. CARETHERS: I WILL SECOND
22 DR. BARRETT'S MOTION.

23 MR. TOCHER: SORRY. YOU'RE NOT A VOTING
24 MEMBER OF THE --

25 CHAIRMAN IMBASCIANI: IT HAS TO BE COMING

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1 FROM A MEMBER OF THE APPLICATION REVIEW
2 SUBCOMMITTEE.

3 DR. CARETHERS: MY APOLOGIES.

4 CHAIRMAN IMBASCIANI: THAT'S QUITE ALL
5 RIGHT.

6 DR. SOUTHARD: SECOND.

7 MS. CASILLAS: I'LL MAKE THAT MOTION.

8 CHAIRMAN IMBASCIANI: OKAY. WE HAVE A
9 MOTION. IT CAN BE SECONDED BY?

10 DR. SOUTHARD: I WILL SECOND. MARV
11 SOUTHARD.

12 CHAIRMAN IMBASCIANI: MARV, THANK YOU.

13 OKAY. ANY DISCUSSION ON THIS EARLY MOTION
14 NOT TO FUND THOSE GRANTS NOT RECOMMENDED BY THE GWG
15 FROM BOARD MEMBERS? BOARD MEMBERS ONLINE? OR ANY
16 MEMBER OF THE PUBLIC LIKE TO SPEAK TO THIS? THERE'S
17 A GENTLEMAN IN THE AUDIENCE THAT MIGHT HAVE --

18 MS. MORALEZ: ALL RIGHT. SO WE'RE GOING
19 TO NOW OPEN THE FLOOR FOR PUBLIC COMMENT. IF YOU'RE
20 JOINING IN PERSON, PLEASE APPROACH THE PODIUM. IF
21 YOU LIKE, YOU MAY STATE YOUR NAME FOR THE RECORD,
22 AND PLEASE KEEP YOUR REMARKS WITHIN THREE MINUTES.

23 DR. QI: I'M ACTUALLY DISCUSSING ABOUT
24 PROPOSAL 19196. SHOULD I WAIT UNTIL LATER?

25 MR. TOCHER: CORRECT. IT'S NOT PART OF

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1 THIS MOTION.

2 CHAIRMAN IMBASCIANI: THAT'S OKAY. DON'T
3 GO AWAY.

4 MS. MORALEZ: ANY PARTICIPANTS ON THE
5 PHONE THAT WOULD LIKE TO TALK ABOUT THESE
6 APPLICATIONS, PLEASE PRESS STAR NINE TO RAISE YOUR
7 HAND. ALL RIGHT. WE HAVE ONE MEMBER OF THE PUBLIC
8 NUMBER ENDING IN 3564. IF YOU PRESS STAR SIX TO
9 UNMUTE YOURSELF, IF YOU'D STATE YOUR NAME FOR THE
10 RECORD, AND PLEASE KEEP YOUR COMMENTS WITHIN THREE
11 MINUTES.

12 MS. MILLER: MY NAME IS LAURA MILLER, AND
13 I AM COMMENTING ON 19391. I AM A PERSON LIVING WITH
14 ALS. ALS BEING A DISEASE THAT SLOWLY TAKES AWAY A
15 PERSON'S ABILITY TO LIVE (INAUDIBLE). FOR MOST OF
16 US ABOUT 90 PERCENT --

17 MS. MORALEZ: WE'RE NOT ON THAT
18 APPLICATION YET. WE'RE GOING TO SAVE YOUR COMMENTS
19 FOR WHEN WE GET TO THAT APPLICATION NUMBER.

20 CHAIRMAN IMBASCIANI: THANKS, LANA, FOR
21 THAT CLARIFICATION.

22 TO THE SPEAKER, WE HAVEN'T -- THE
23 APPLICATION YOU WOULD LIKE TO SPEAK TO HAS NOT BEEN
24 PUT THE TABLE FOR A MOTION, BUT DON'T GO AWAY.

25 OKAY. IF THERE'S NO OTHER COMMENT, JUST

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1 VERIFYING WITH BOARD SUPPORT, NO. NO OTHER
2 COMMENTS. WE CAN PROCEED TO A ROLL CALL VOTE ON
3 THIS MOTION.

4 MR. TOCHER: MARIA BONNEVILLE.

5 VICE CHAIR BONNEVILLE: YES, EXCEPT FOR
6 THOSE WITH WHICH I HAVE A CONFLICT.

7 MR. TOCHER: MARGUERITE CASILLAS.

8 MS. CASILLAS: YES.

9 MR. TOCHER: JUDY CHOU.

10 DR. CHOU: YES.

11 MR. TOCHER: LEONDRA CLARK-HARVEY.

12 DR. CLARK-HARVEY: YES.

13 MR. TOCHER: SHANNON DAHL.

14 DR. DAHL: YES, EXCEPT FOR THOSE WITH
15 WHICH I HAVE A CONFLICT.

16 MR. TOCHER: ANNE-MARIE DULIEGE.

17 DR. DULIEGE: YES, EXCEPT FOR THOSE WITH
18 WHICH I HAVE A CONFLICT.

19 MR. TOCHER: YSABEL DURON.

20 MS. DURON: YES, EXCEPT FOR THOSE WITH
21 WHICH I HAVE A CONFLICT.

22 MR. TOCHER: MARK FISCHER-COLBRIE.

23 MR. FISCHER-COLBRIE: YES, EXCEPT FOR
24 THOSE WITH WHICH I HAVE A CONFLICT.

25 MR. TOCHER: ELENA FLOWERS.

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1 DR. FLOWERS: YES, EXCEPT FOR THOSE WITH
2 WHICH I HAVE A CONFLICT.

3 MR. TOCHER: VITO IMBASCIANI.

4 CHAIRMAN IMBASCIANI: YES.

5 MR. TOCHER: RICH LAJARA.

6 MR. LAJARA: YES.

7 MR. TOCHER: CHRIS MIASKOWSKI.

8 DR. MIASKOWSKI: YES, EXCEPT FOR THOSE
9 WITH WHICH I HAVE A CONFLICT.

10 MR. TOCHER: ADRIANA PADILLA.

11 DR. PADILLA: YES.

12 MR. TOCHER: MARV SOUTHARD.

13 DR. SOUTHARD: YES.

14 MR. TOCHER: KAROL WATSON.

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

17 MR. TOCHER: KEVIN XU.

18 MR. XU: YES.

19 MR. TOCHER: THANK YOU. THE MOTION
20 CARRIES.

21 CHAIRMAN IMBASCIANI: THANK YOU, SCOTT.
22 OKAY.

23 NOW WE ARE LEFT WITH EIGHT APPLICATIONS
24 THAT HAVE BEEN RECOMMENDED FOR FUNDING BY THE GWG.
25 BUT AS DR. SAMBRANO HAS EXPLAINED, OUR BUDGET WILL

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1 ONLY SUPPORT SIX OF THOSE. WE ARE OVERSUBSCRIBED.
2 SO WE CAN DO THIS IN SEVERAL WAYS. THE SIMPLEST WAY
3 WOULD BE IF SOMEONE MOVED TO ACCEPT THE
4 RECOMMENDATION OF THE CIRM TEAM TO FUND THE SIX THAT
5 HAVE BEEN RECOMMENDED AND NOT TO FUND THE TWO
6 ALTHOUGH THEY TIED IN THAT LOW SCORE.

7 MS. CASILLAS: SO MOVED.

8 CHAIRMAN IMBASCIANI: MARGUERITE CASILLAS
9 HAS MOVED.

10 DR. CARETHERS: I'LL SECOND THE MOTION.

11 CHAIRMAN IMBASCIANI: THAT'S A SECOND
12 SECOND THERE.

13 MR. TOCHER: AGAIN, A VOTING MEMBER
14 WITHOUT A CONFLICT. SO THOSE WITH A CONFLICT AT THE
15 MOMENT ARE DAHL, DURON, FISCHER-COLBRIE, FLOWERS,
16 MIASKOWSKI, AND WATSON. SO THE REMAINING VOTING
17 MEMBERS ARE ELIGIBLE.

18 DR. DULIEGE: I SECOND.

19 CHAIRMAN IMBASCIANI: THANK YOU. SO ANY
20 DISCUSSION ON THE MOTION FROM BOARD MEMBERS?

21 ANNE-MARIE DULIEGE.

22 DR. DULIEGE: JUST, GIL, THANK YOU AGAIN
23 FOR THAT GREAT PRESENTATION. WE REALIZE THAT IT'S
24 REALLY A CHALLENGE WHEN WE COME TO AN OVERBUDGET
25 SORT OF SCORING. WE RECEIVED A NUMBER OF LETTERS

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1 ABOUT THESE APPLICATIONS IN GENERAL TO THESE TWO.
2 CAN YOU SUMMARIZE SOME OF THE CONCERN EXPRESSED IN
3 THE LETTERS AND HOW WE WOULD ADDRESS THEM? I KNOW
4 IT'S A GENERAL QUESTION, BUT MAYBE YOU READ THE
5 LETTERS, I ASSUME.

6 DR. SAMBRANO: YES. SO WE DID READ THE
7 LETTERS. SO I THINK THEY EACH ADVOCATE FOR THEIR
8 PROJECT HIGHLIGHTING ELEMENTS OF IN SOME CASES THE
9 SCIENTIFIC ELEMENTS THAT THE GRANTS WORKING GROUP
10 HIGHLIGHTED AND HOW THEY'VE ADDRESSED SOME OF THOSE
11 CONCERNS. OF COURSE, WE ALWAYS NOTE THE FACT THAT,
12 UNLESS THE GRANTS WORKING GROUP ACTUALLY SEES THEM,
13 IT'S DIFFICULT TO KNOW WHAT THEY WOULD THINK OF
14 THESE RESPONSES. SO WE DON'T EVALUATE THEM FROM A
15 SCIENTIFIC PERSPECTIVE TO CONFIRM THAT THEY WOULD
16 HAVE CHANGED THE OUTCOME. BUT THEY ARE NOTED THERE.

17 SOME OF THEM HIGHLIGHT ELEMENTS OF THE
18 FACT THAT THESE ARE AN IMPORTANT AREA. TWO OF THEM
19 IN PARTICULAR THAT ARE ON THE LINE RELATE TO ALS.
20 THEY BOTH HAPPEN TO COME FROM THE SAME INSTITUTION
21 ACTUALLY, BUT THEY ARE BOTH IMPORTANT PROJECTS, BOTH
22 HIGHLIGHTED AS MERITORIOUS BY THE GRANTS WORKING
23 GROUP.

24 SO I THINK THE DIFFICULTY IS ALSO THAT,
25 EVEN WITH THESE LETTERS, IT BECOMES DIFFICULT TO

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1 DETERMINE WHERE ONE DRAWS A LINE AND HOW ONE
2 RECOMMENDS THEM. SO THAT AT LEAST IS WHAT I CAN
3 OFFER AT THE MOMENT.

4 CHAIRMAN IMBASCIANI: THANKS, GIL. WE
5 HAVE COMMENT. BOARD MEMBER CASILLAS.

6 MS. CASILLAS: YEAH. IN ONE OF THE
7 LETTERS ABOUT THOSE TWO APPLICATIONS THAT CAME FROM
8 THE SAME INSTITUTION, THEY PROPOSE LIKE, WELL, TAKE
9 A LITTLE BIT OF MONEY OUT FROM THIS ONE AND PUT IT
10 TO THAT ONE. I MEAN IS THERE EVEN A MECHANISM FOR
11 THAT?

12 DR. SAMBRANO: IT'S SOMETHING THAT WE DO
13 NOT RECOMMEND. WE DO NOT WANT TO TAKE FUNDS FROM
14 OTHER PROJECTS IN ORDER TO ALLOW, OR EVEN IF THERE
15 ARE FUNDS REMAINING, SO YOU WOULD HAVE ABOUT THREE
16 AND A HALF MILLION REMAINING OUT OF THE 84 IF WE
17 FUND THE TOP SIX, IS NOT SUFFICIENT TO COVER THE
18 SCOPE AND INTENT OF THE PROJECT. THESE PROJECTS
19 WERE REVIEWED WITH THE EXPECTATION THAT, IF THEY
20 WERE TO BE FUNDED, THEY WOULD BE FUNDED IN FULL AND
21 WOULD BE ACCOMPLISHING THE GOALS THAT THEY SET OUT.
22 I THINK PROVIDING ANY LESS WOULD REALLY HAMPER
23 SIGNIFICANTLY THEIR ABILITY TO DO THAT.

24 MS. CASILLAS: AND THERE'S NO REASON THOSE
25 TWO APPLICATIONS THAT ARE NOT BEING RECOMMENDED

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1 COULDN'T REAPPLY?

2 DR. SAMBRANO: RIGHT. SO WE ARE GOING TO
3 HAVE ADDITIONAL CYCLES OF DISC4, NOTING, THOUGH,
4 THAT THEY'RE ARE PREFERENCE TOPICS FOR EACH. BUT WE
5 ARE NOT PREVENTING APPLICANTS FROM COMING INTO ANY
6 OF THESE CYCLES. SO THEY CAN REAPPLY.

7 WE HAVE ACTUALLY IN THE BATCH ONE
8 APPLICATION THAT IS IN THE TOP SIX THAT WAS AN
9 APPLICATION THAT FELL IN THE SAME SITUATION UNDER
10 THE REMIND4 PROGRAM THAT IS NOW BEING FUNDED,
11 ASSUMING THIS GOES FORWARD FOR THAT PROGRAM.

12 DR. DULIEGE: ONE QUESTION. I THINK I
13 KNOW THE ANSWER, BUT STILL I WILL ASK. THE ENVELOPE
14 FOR THIS CYCLE HAS BEEN FIXED. IS THERE SOME
15 FLEXIBILITY THERE? IS THAT THE BUDGET FOR THIS YEAR
16 WITH AN ADDITIONAL BUDGET FOR THE NEXT CYCLE REVIEW?
17 HOW DO YOU WE CONSIDER THAT?

18 DR. SAMBRANO: SO THE BUDGET FOR THE NEXT
19 CYCLE HAS NOT BEEN SET. SO THAT WILL COME IN JUNE.
20 SO THIS IS FOR ONE CYCLE PER YEAR. SO THE CYCLE
21 IS -- OR THE BUDGET FOR THIS IS FIXED.

22 CHAIRMAN IMBASCIANI: I DON'T SEE ANY
23 HANDS FROM BOARD MEMBERS ONLINE. WE CAN GO TO
24 PUBLIC COMMENT. I DO SEE A TELEPHONE CALL, AND WE
25 HAVE A GENTLEMAN IN THE ROOM. YES. SIR, IF YOU

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1 WOULD START AGAIN, TELL US YOUR NAME AGAIN.

2 DR. QI: NO. IT'S A TIE FOR THE TOP SIX.
3 WE ARE NO. 7.

4 MR. TOCHER: THE MOTION IS TO FUND THE TOP
5 SIX. SORRY. I ONLY HEARD TO FUND THE TOP SIX. SO
6 NOT FUND THE OTHER TWO.

7 CHAIRMAN IMBASCIANI: IT'S TO ACCEPT --
8 THE MOTION IS TO ACCEPT THE RECOMMENDATION OF THE
9 CIRM TEAM ON ALL EIGHT. SO HE IS IN ORDER TO SPEAK.

10 DR. QI: COULD I START? ALL RIGHT. GOOD
11 MORNING TO MEMBERS OF THE SUBCOMMITTEE. I'M STANLEY
12 QI FROM STANFORD REPRESENTING 19196.

13 SO ALS IS A DEVASTATING CRISIS FOR
14 CALIFORNIA. DESPITE DECADES OF EFFORTS, THE
15 SURVIVAL RATE REMAINS UNCHANGED. WE ARE HERE TODAY
16 BECAUSE OUR TEAM IS A FIRST-TIME PARTNERSHIP BETWEEN
17 STANFORD AND UCSD, AND WE ARE READY TO BRINGING A
18 NEW THERAPEUTIC SOLUTION TO YOUR PORTFOLIO NAMED
19 SPATIAL RNA MEDICINE.

20 THE GRANTS WORKING GROUP RAISED A CRITICAL
21 QUESTION. IS RNA LOCALIZATION A CAUSE OR A
22 CONSEQUENCE OF ALS? WE NOW HAVE THE ANSWER. IN
23 RECENT 2025 DATA, WE PROVED THAT RNA BEING IN THE
24 WRONG LOCATION KILL NEURONS. AND CRUCIALLY WE ALSO
25 SHOWN THAT USING OUR TECHNOLOGY TO MOVE ONE KEY RNA

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1 TO THE NEURONS, WE CAN TRIGGER X AMOUNT OF REGROWTH
2 BY 80 PERCENT. WE ARE NOW ABLE TO REWRITE THE RNA
3 GEOGRAPHY TO SAVE THE NEURON.

4 WE KNOW THE SUBCOMMITTEE IS FACING A
5 DIFFICULT TIE TODAY WITH THE REMAINING FUNDS IN THE
6 ALLOCATION. I WANT TO MENTION THAT OUR TEAM HAS
7 NEVER RECEIVED CIRM FUNDING. WHILE OUR PROPOSAL IS
8 COMPREHENSIVE, WE ARE STILL COMMITTED TO THE MISSION
9 THAT WE HAVE DEVELOPED IN NARROW SCOPE, FLEXIBLE
10 BUDGET MODEL. WE ARE PREPARED TO WORK IMMEDIATELY
11 WITH CIRM TO FIT OUR SCOPE INTO THE AVAILABLE FUNDS.
12 WE BELIEVE THAT IT'S IMPORTANT TO BRING THIS UNIQUE,
13 FIRST-CLASS PLATFORM INTO THE COMMUNITY NOW RATHER
14 THAN WAITING FOR ANOTHER YEAR OF WAITING BECAUSE FOR
15 PATIENTS, WAITING IS NOT AN OPTION.

16 IF YOU LOOK AT THE CURRENT CIRM PORTFOLIO,
17 YOU WILL FIND MANY WORK IN GENE EDITING AND CELL
18 THERAPY, BUT YOU WILL FIND ZERO PROJECTS ADDRESSING
19 SPATIAL RNA MEDICINE. BY FUNDING 19196, YOU ARE NOT
20 JUST FUNDING ANOTHER STUDY. YOU ARE FILLING A MAJOR
21 GAP IN CALIFORNIA'S PORTFOLIO WITH A TECHNOLOGY THAT
22 DOESN'T EXIST ELSEWHERE. IT'S NOT JUST A TOOL.
23 IT'S A MEDICINE TO STOP ALS.

24 FINALLY, I WANT TO SHARE WHY THIS PROJECT
25 IS SO URGENT. WE RECEIVED DIRECT AND A MOVING

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1 REQUEST FROM PATIENTS WHO ARE ASKING TO JOIN OUR
2 TEAM, NOT AS SUBJECTS, BUT AS RESEARCHERS TO FUND A
3 CURE FOR THEMSELVES. THEY AREN'T JUST LOOKING FOR A
4 TREATMENT. THEY ARE LOOKING FOR A WAY TO FIGHT
5 BACK. FOR THESE FAMILIES THE FUNDING IS NOT JUST A
6 BUDGET LINE, BUT IT'S THE LITERAL FUEL FOR THEIR
7 HOPE AND THEIR BELIEF THAT A BREAKTHROUGH IS FINALLY
8 WITHIN REACH.

9 LET'S NOT LEAVE THE HOPE TO CHANCE. SO I
10 HOPE THE COMMITTEE WILL CONSIDER LET'S BREAK THIS
11 TIE IN FAVOR OF INNOVATION AND HELP US MAKE THIS
12 SPATIAL RNA MEDICINE A REALITY FOR CALIFORNIA
13 FAMILIES. THANK YOU.

14 CHAIRMAN IMBASCIANI: THANK YOU FOR YOUR
15 REMARKS.

16 MS. MORALEZ: WE HAVE TWO PEOPLE ON THE
17 PHONE. LAURA MILLER ENDING IN 3564. LET'S TRY THIS
18 AGAIN. IF YOU PRESS STAR SIX, AND YOU CAN HAVE
19 THREE MINUTES FOR YOUR PUBLIC COMMENT.

20 MS. MILLER, ARE YOU AVAILABLE?

21 MS. MILLER: YES. THANK YOU. AGAIN, MY
22 NAME IS LAURA MILLER. I'M COMMENTING ON 19196. AND
23 I AM LIVING WITH ALS. ALS IS A DEVASTATING DISEASE;
24 AND DESPITE DECADES OF RESEARCH, WE STILL DON'T
25 UNDERSTAND ENOUGH ABOUT HOW THIS DISEASE WORKS.

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1 CONSEQUENTLY, THERE HAVE BEEN NO TREATMENTS
2 DEVELOPED TO STOP THIS PROGRESSING.

3 THIS PROJECT EXPLORES SOMETHING SCIENTISTS
4 ARE ONLY BEGINNING TO UNDERSTAND, THAT IN ALS
5 MOLECULES INSIDE NERVE CELLS MAY BE GOING TO THE
6 WRONG PLACES. IF WE CAN JUST LEARN HOW TO CORRECT
7 THAT PROCESS, IT CAN OPEN AN ENTIRELY NEW WAY TO
8 TREAT NEURODEGENERATIVE DISEASES.

9 BREAKTHROUGHS IN ALS RESEARCH DON'T JUST
10 HELP PEOPLE WITH ALS. THEY MAY UNLOCK THE BIOLOGY
11 OF MANY NEURODEGENERATIVE DISEASES.

12 SO AS SOMEONE LIVING WITH THIS DISEASE, I
13 STRONGLY SUPPORT FUNDING INNOVATIVE RESEARCH LIKE
14 THIS. THANK YOU.

15 MS. MORALEZ: THANK YOU VERY MUCH. WE
16 HAVE ONE MORE PUBLIC COMMENT -- TWO MORE. LAST FOUR
17 DIGITS IS 6378. IF YOU PRESS STAR SIX AND STATE
18 YOUR NAME, IF YOU WOULD LIKE, AND START YOUR THREE
19 MINUTES.

20 DR. SNYDER: THIS IS MICHAEL SNYDER. I'M
21 THE CONTACT PI OF 19391, THE ONE THAT WAS
22 RECOMMENDED FOR FUNDING. AND I'D JUST LIKE TO SAY,
23 FIRST OF ALL, THAT WE'RE OBVIOUSLY PLEASED THAT THE
24 REVIEWERS AND CIRM STAFF LIKED OUR APPLICATION AND
25 OVERWHELMINGLY SUPPORTED IT ELEVEN TO THREE IN

1 FAVOR.

2 WE DO BELIEVE THIS RESEARCH IS HIGHLY
3 IMPACTFUL, NOT JUST FOR THE SCIENCE, BUT FOR IT'S
4 TRANSLATION POTENTIAL. AND WE HAVE A VERY STRONG
5 AND EXPERIENCED TEAM THAT WE BELIEVE CAN PULL THIS
6 OFF.

7 THE GENETIC BASIS, AS YOU JUST HEARD, OF
8 SPORADIC ALS IS VERY POORLY UNDERSTOOD. AND WE HAVE
9 NEW, INNOVATIVE AI METHODS THAT PEOPLE REALLY
10 HAVEN'T DONE BEFORE. AND THEY DO FIND NEW GENES AND
11 POTENTIAL ALS TARGETS. AND WE'VE ALREADY FOUND MANY
12 GENES WITH THESE KINDS OF APPROACHES. AND SO WE
13 THINK THESE ARE GOING TO BE VERY, VERY POWERFUL. IN
14 FACT, WE'VE EVEN FOUND ONE POTENTIAL TARGET USING
15 THIS KIND OF APPROACH. SO WE ARE CONFIDENT THAT IT
16 CAN WORK AND BE VERY IMPACTFUL.

17 THE REVIEWERS DID RAISE SOME CONCERNS. IT
18 SEEMED LIKE THE BIGGEST ONE WAS WHETHER WE WOULD
19 HAVE ACCESS TO SAMPLES. AND WE OBVIOUSLY DO. WE
20 HAVE A MEMBER OF OUR TEAM, HE'S PART OF TARGET ALS,
21 AND EVEN IN HIS OWN BIOBANK, HE HAS MANY POTENTIAL
22 TISSUES THAT WE CAN USE. SO I THINK THEIR MAJOR
23 CONCERN ISN'T REALLY A CONCERN. IT'S TECHNICAL
24 ISSUES AND OTHER TECHNICAL ISSUES AND PRETTY EASILY
25 ADDRESSABLE.

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1 SO THE BOTTOM LINE IS WE DO THINK OUR
2 PROJECT IS HUGELY INNOVATIVE AND CAN EASILY
3 TRANSLATE INTO THINGS THAT WILL BE HIGHLY IMPACTFUL
4 FOR ALS PATIENTS. AND SO WE'RE, AGAIN, QUITE
5 CONFIDENT WE CAN PULL THIS OFF AND HAVE A GREAT
6 IMPACT ON THIS VERY DEVASTATING DISEASE.

7 CHAIRMAN IMBASCIANI: THANK YOU, DR.
8 SNYDER.

9 MS. MORALEZ: WE HAVE A PUBLIC COMMENT
10 ENDING IN 4883. PLEASE PRESS STAR SIX TO UNMUTE
11 YOURSELF AND STATE YOUR NAME FOR THE RECORD. YOU
12 HAVE THREE MINUTES.

13 DR. DOUGHERTY: HELLO, EVERYONE. MY NAME
14 IS SARA DOUGHERTY, AND I'M THE SENIOR DIRECTOR OF
15 RESEARCH WITH THE ALS NETWORK. I'M SPEAKING IN
16 SUPPORT OF TWO APPLICATIONS TODAY, WHICH I REALIZE
17 NOW MIGHT NOT HELP WITH YOUR TIEBREAKER, BUT IT'S
18 REALLY IMPORTANT INFORMATION.

19 SO REGARDING ITEM 19391, THIS PROPOSAL
20 ADDRESSES AN UNMET NEED AND ONE OF THE MOST CRITICAL
21 CHALLENGES IN ALS RESEARCH, UNDERSTANDING THE
22 GENETIC AND MOLECULAR DRIVERS OF SPORADIC ALS, WHICH
23 WE MENTIONED REPRESENTS THE VAST MAJORITY OF ALS
24 CASES.

25 BY INTEGRATING MACHINE LEARNING, LARGE

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1 SCALE GENETICS, NEUROPATHOLOGY, AND STEM CELL-BASED
2 FUNCTIONAL SCREENING, THIS PROJECT TAKES A HIGHLY
3 INNOVATIVE AND COMPREHENSIVE APPROACH TO IDENTIFYING
4 NEW THERAPEUTIC TARGETS. WHAT MAKES THIS APPROACH
5 ESPECIALLY POWERFUL IS THAT IT MOVES BEYOND
6 OBSERVATION TO TRUE FUNCTIONAL DISCOVERY, LINKING
7 GENETIC FINDINGS DIRECTLY TO DISEASE MECHANISMS.

8 THE ULTIMATE GOAL IS TO GENERATE NEW
9 GENETIC TARGETS FOR SPORADIC ALS, AN ESSENTIAL STEP
10 TOWARDS DEVELOPING THERAPIES THAT CAN BENEFIT THE
11 BROADER ALS POPULATION. THIS EXCEPTIONAL
12 MULTIDISCIPLINARY TEAM REPRESENTING LEADING
13 CALIFORNIA INSTITUTIONS HAS THE POTENTIAL TO BUILD A
14 STRONG PIPELINE OF TARGETS THAT COULD MEANINGFULLY
15 IMPACT PATIENTS. FOR THE ALS COMMUNITY, THIS KIND
16 OF DISCOVERY-DRIVEN RESEARCH IS ESSENTIAL TO
17 UNLOCKING NEW TREATMENTS AND ADVANCING THE FIELD
18 TOWARD REAL PROGRESS.

19 AND THEN PERHAPS UNCONVENTIONALLY IN
20 SUPPORT OF 19196, ALSO AN ALS PROJECT, THIS PROPOSAL
21 REPRESENTS A BOLD, INNOVATIVE APPROACH TO TACKLING
22 ALS. IN THIS INSTANCE, RATHER THAN FOCUSING ON
23 GENES OR PROTEINS, AS DR. QI MENTIONED, THIS WORK
24 EXPLORES HOW THE SPATIAL ORGANIZATION OF RNA WITHIN
25 CELLS CONTRIBUTES TO DISEASE AND SO CRITICALLY HOW

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1 TO CORRECT IT. THIS IS A FUNDAMENTALLY NEW WAY OF
2 THINKING ABOUT NEURODEGENERATION. THIS WORK OPENS
3 THE DOOR TO AN ENTIRELY NEW THERAPEUTIC STRATEGY
4 SPACE THAT GOES BEYOND CURRENT APPROACHES.
5 IMPORTANTLY, THESE MECHANISMS ARE SHARED ACROSS
6 MULTIPLE NEURODEGENERATIVE DISEASES, GIVING BROAD
7 IMPACT.

8 THIS EXCEPTIONAL TEAM IS GROUNDED IN A
9 HIGHLY COLLABORATIVE ENVIRONMENT. THE PROJECT HAS
10 BOTH SCIENTIFIC RIGOR AND INNOVATIVE EDGE THAT IS
11 NEEDED TO DRIVE MEANINGFUL PROGRESS. FROM A
12 FUNDER'S PERSPECTIVE, THIS KIND OF FORWARD THINKING
13 RESEARCH IS WHAT IS NEEDED TO MOVE FROM INCREMENTAL
14 ADVANCES TOWARD TRULY TRANSFORMATIVE THERAPIES. I
15 THANK YOU FOR YOUR TIME AND TRULY REQUEST THAT YOU
16 CONSIDER BOTH OF THESE PROPOSALS.

17 CHAIRMAN IMBASCIANI: THANK YOU TO THE
18 SPEAKER. I SEE ANOTHER CALL COMING IN, LANA.

19 MS. MORALEZ: WE DO. OKAY. THE PHONE
20 NUMBER ENDING IN 7366, IF YOU WOULD PRESS STAR SIX
21 TO UNMUTE YOURSELF AND, IF YOU'D LIKE, STATE YOUR
22 NAME FOR THE RECORD, AND YOU HAVE THREE MINUTES. I
23 SEE THAT YOU'RE UNMUTED. YOU CAN START SPEAKING.

24 DR. ICHIDA: OH, YES. THANK YOU. THIS IS
25 JUSTIN ICHIDA. I'M ONE OF THE CO-I'S FOR 19391.

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1 I'M FROM USC. I'VE BEEN WORKING IN THE ALS FIELD
2 FOR OVER A DECADE NOW. AND I THINK WHAT WE'RE
3 BEGINNING TO SEE IS THAT THIS DISEASE IS REVERSIBLE
4 IF YOU IDENTIFY THE RIGHT TARGET. FOR EXAMPLE, THE
5 ASO TARGETING SOD1, WE'VE BEEN SEEING THAT CAN HALT
6 THE DISEASE, IN SOME CASES IMPROVE THE MOTOR
7 FUNCTION OF PATIENTS WITH SOD1 ALS.

8 I THINK THE CHALLENGE IS THAT MOST OF THE
9 PATIENTS WITH ALS ARE SPORADIC, AND WE DON'T YET
10 KNOW WHAT THE RIGHT GENETIC TARGETS ARE FOR THEIR
11 DISEASE DUE TO THE COMPLEXITY.

12 AND SO WHAT WE'VE SEEN WITH SOME OF THE
13 NEW TECHNIQUES WITH AI AND MULTI-OM ANALYSIS IS THAT
14 WE CAN ACTUALLY NOW USE THOSE TO BETTER HARNESS THE
15 GENETIC INFORMATION AND SEQUENCING THAT WE HAVE TO
16 FIND THESE NEW GENETIC TARGETS FOR SPORADIC ALS.
17 WE'VE HAD SOME SUCCESS ALREADY WITH ONE OF THEM, AND
18 WE ARE NOW LOOKING TO DO MORE. AND I THINK THIS
19 GRANT WOULD BE PIVOTAL IN ENABLING US TO DO THAT AND
20 COME UP WITH A SERIES OF STRONG GENETIC TARGETS FOR
21 SPORADIC ALS WHERE THERE'S A HUGE UNMET NEED.

22 THANKS VERY MUCH FOR YOUR CONSIDERATION.

23 CHAIRMAN IMBASCIANI: THANK YOU. LANA, I
24 THINK I DO NOT SEE ANY MORE HANDS RAISED.

25 MS. MORALEZ: YOU ARE CORRECT.

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1 CHAIRMAN IMBASCIANI: OKAY. ANY BOARD
2 MEMBER WANT TO MAKE ANY FINAL COMMENTS BEFORE WE
3 PROCEED TO A VOTE?

4 DR. DULIEGE: GIL, I'M TRYING TO SEE HOW
5 WE CAN OFFER A CREATIVE SOLUTION FOR THE TWO THAT
6 ARE PROPOSED NOT TO BE FUNDED RIGHT NOW BECAUSE OF
7 THE TIE. IS THERE ONLY ONE CYCLE REVIEW FOR DISC4
8 EVERY FISCAL YEAR, OR ARE THERE MORE THAN THAT? AND
9 DOES IT MEAN THAT IF THESE APPLICANTS WANT TO
10 REAPPLY, THIS WILL BE IN ONE YEAR WITH AN UNKNOWN
11 BUDGET AND UNKNOWN SCOPE OF PROPOSALS? OR IS THERE
12 SOMETHING THAT CAN BE DONE ABOUT THAT?

13 DR. SAMBRANO: RIGHT. THERE IS ONE CYCLE
14 PER YEAR. AND SO THE SCOPE OF THE NEXT ONE, MAYBE
15 ROSA CAN SPEAK TO IT BECAUSE THAT'S PART OF THE
16 PROPOSAL FOR A LITTLE LATER.

17 DR. CANET-AVILES: THANK YOU, DR. DULIEGE.
18 CAN YOU HEAR ME.

19 SO THE NEXT APPLICATION WILL BE OPEN IN
20 APRIL FOR THE DISC4. AND AS WE WILL BE PROPOSING --
21 OF COURSE, IT'S TO THE PREROGATIVE OF THE BOARD.
22 BUT AS WE WILL BE PROPOSING TODAY, DR. SHEPARD WILL
23 BE PRESENTING THE FOCUS RECOMMENDATION. AND IT'S
24 ACTUALLY A MUCH LARGER SYSTEM SCOPE THAT WE DISCUSS
25 LATER. SO IT WOULD INCLUDE THESE THERAPEUTIC AREAS.

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1 MOST LIKELY THEY COULD BE ABLE TO REAPPLY. AND WE
2 HAVE ONE A YEAR THAT IS \$84 MILLION, BUT WE ALSO
3 HAVE DISC5, WHICH IS \$50 MILLION INVESTMENT. SO IN
4 TOTAL WE ARE INVESTING AROUND 135 MILLION IN
5 DISCOVERY EVERY YEAR THROUGH THOSE TWO. AND LIKE
6 SMALLER AWARDS CAN COME THROUGH THE DISC5 WHICH IS
7 ALSO OPEN.

8 DR. DULIEGE: I THINK WHAT WE'RE SAYING IS
9 THAT THESE TWO APPLICANTS COULD REAPPLY IN APRIL,
10 ALTHOUGH THE REVIEW PROCESS WILL TAKE A YEAR. IS
11 THAT RIGHT? AND IF THEY WERE GRANTED, IF THEY WERE
12 ACCEPTED, THEY WOULD RECEIVE THE MONEY IN?

13 DR. CANET-AVILES: WHEN IS THE ARS
14 SCHEDULED FOR DISC1?

15 DR. SAMBRANO: I THINK IT WOULD COME BACK
16 A YEAR FROM NOW. SO IT WOULD BE NEXT MARCH
17 ULTIMATELY TO THE BOARD.

18 DR. CANET-AVILES: IT'S A LONG PROCESS
19 BECAUSE THERE IS PRESUBMISSION AS WELL. SO WE HAVE
20 LIKE THE PRESUBMISSION, THEY ARE SELECTED, THAT THEY
21 ARE INVITED, THEN THE FULL TEAM PUTS TOGETHER THE
22 PROPOSAL, THEN THAT'S REVIEWED.

23 CHAIRMAN IMBASCIANI: OKAY. LET ME
24 CLARIFY THIS. A POSITIVE VOTE, A YES VOTE, ON THIS
25 MOTION WILL BE A VOTE TO FUND DISC4-19200, 19271,

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1 19334, 19371, 19291, AND 19391 AND TO NOT FUND --

2 DR. SAMBRANO: AND TO NOT FUND 19196 AND
3 19226.

4 CHAIRMAN IMBASCIANI: THAT'S CORRECT.

5 MR. TOCHER: SO FOR THE FOLLOWING MEMBERS,
6 PLEASE VOTE IN THE SAME MANNER THAT I DESCRIBED
7 EARLIER, YES OR NO, EXCEPT FOR THOSE APPLICATIONS
8 WITH WHICH YOU ARE IN CONFLICT. THOSE MEMBERS ARE
9 DAHL, DURON, FISCHER-COLBRIE, FLOWERS, MIASKOWSKI,
10 AND WATSON.

11 MARIA BONNEVILLE.

12 VICE CHAIR BONNEVILLE: YES.

13 MR. TOCHER: MARGUERITE CASILLAS.

14 MS. CASILLAS: YES.

15 MR. TOCHER: JUDY CHOU.

16 DR. CHOU: YES.

17 MR. TOCHER: LEONDRA CLARK-HARVEY.

18 DR. CLARK-HARVEY: YES.

19 MR. TOCHER: SHANNON DAHL.

20 DR. DAHL: YES, EXCEPT FOR THOSE WITH
21 WHICH I HAVE A CONFLICT.

22 MR. TOCHER: ANNE-MARIE DULIEGE.

23 DR. DULIEGE: YES.

24 MR. TOCHER: YSABEL DURON.

25 MS. DURON: YES, EXCEPT FOR THOSE WITH

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1 WHICH I HAVE A CONFLICT.

2 MR. TOCHER: MARK FISCHER-COLBRIE.

3 MR. FISCHER-COLBRIE: YES, EXCEPT FOR
4 THOSE WITH WHICH I HAVE A CONFLICT.

5 MR. TOCHER: ELENA FLOWERS.

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

8 MR. TOCHER: VITO IMBASCIANI.

9 CHAIRMAN IMBASCIANI: YES.

10 MR. TOCHER: RICH LAJARA.

11 MR. LAJARA: YES.

12 MR. TOCHER: CHRIS MIASKOWSKI.

13 DR. MIASKOWSKI: YES, EXCEPT FOR THOSE
14 WITH WHICH I HAVE A CONFLICT.

15 MR. TOCHER: ADRIANA PADILLA.

16 DR. PADILLA: YES.

17 MR. TOCHER: MARV SOUTHARD.

18 DR. SOUTHARD: YES.

19 MR. TOCHER: KAROL WATSON.

20 DR. WATSON: YES.

21 MR. TOCHER: EXCEPT FOR THOSE WITH WHICH
22 YOU ARE IN CONFLICT?

23 DR. WATSON: EXCEPT FOR THOSE WITH WHICH
24 I'M IN CONFLICT.

25 MR. TOCHER: THANK YOU VERY MUCH.

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1 KEVIN XU.

2 MR. XU: YES.

3 MR. TOCHER: GREAT. THANK YOU VERY MUCH.
4 THAT MOTION CARRIES.

5 CHAIRMAN IMBASCIANI: OKAY. ALL RIGHT.
6 THANK YOU, SCOTT. AND THANK YOU, EVERYONE, FOR THE
7 DISCUSSION, AND THANK YOU, GIL.

8 I'M GOING TO INVITE DR. HAYLEY LAM UP TO
9 THE PODIUM WHERE WE CONSIDER AGENDA ITEM NO. 8,
10 APPLICATIONS SUBMITTED IN RESPONSE TO OUR CLIN2
11 PROGRAM ANNOUNCEMENT.

12 DR. LAM: THANK YOU, DR. IMBASCIANI, AND
13 GOOD MORNING TO THE BOARD. GOOD MORNING. IT'S MY
14 PLEASURE TODAY TO PRESENT THE GRANTS WORKING GROUP
15 RECOMMENDATIONS FOR THE CLIN2 CLINICAL TRIAL AWARDS.

16 AS ALWAYS, WE BEGIN WITH OUR MISSION,
17 ACCELERATING WORLD-CLASS SCIENCE TO DELIVER
18 TRANSFORMATIVE REGENERATIVE MEDICINE TREATMENTS IN
19 AN EQUITABLE MANNER TO A DIVERSE CALIFORNIA AND
20 WORLD.

21 OUR STRATEGIC GOALS FOR THE CLIN2 PROGRAM
22 FOCUS AROUND GOAL 4, PROPELLING 15 TO 20 THERAPIES
23 TARGETING DISEASES AFFECTING CALIFORNIANS TO LATE
24 STAGE TRIALS. WE'VE BEEN FUNDING CLINICAL TRIAL
25 PROGRAMS FOR A WHILE NOW, AND THE RE-UPDATED CLIN2

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1 PROGRAM HAS A COUPLE OF CHANGES THAT ALLOWED US TO
2 SUPPORT EMERGING NOVEL CLINICAL TRIAL DESIGNS,
3 INCENTIVIZES MARKET ACCESS STRATEGY DEVELOPMENT AND
4 PRECOMMERCIALIZATION ACTIVITIES, AND PRIORITIZES
5 INNOVATIVE THERAPIES FOR DISEASES THAT AFFECT
6 CALIFORNIANS.

7 THE OVERALL PROGRAM OBJECTIVE IS TO
8 SUPPORT THE COMPLETION OF INTERVENTIONAL TRIALS FOR
9 INNOVATIVE STEM CELL-BASED OR GENETIC THERAPIES
10 ADDRESSING SERIOUS UNMET NEEDS AND WITH THE
11 POTENTIAL FOR TRANSFORMATIVE BENEFITS TO PATIENTS,
12 FAMILIES, AND THE HEALTHCARE SYSTEM.

13 A LITTLE BIT ABOUT THE PROGRAM STRUCTURE.
14 SO THIS PROGRAM IS OFFERED FOUR TIMES PER YEAR WITH
15 A MAX DURATION OF FOUR YEARS, AND THE FUNDING LIMITS
16 DEPEND ON THE AWARD STAGE AND WHETHER THE APPLICANT
17 IS A FOR-PROFIT OR NONPROFIT. THE PROGRAM EXPECTS
18 AWARDS OF SOMEWHERE RANGING BETWEEN NINE TO 16
19 AWARDS PER YEAR. AND THE BOARD HAS APPROVED FOR
20 THIS CURRENT FISCAL YEAR A TOTAL OF 135 MILLION.
21 FORTY-TWO OF THAT HAS BEEN EXPENDED THUS FAR.

22 A LITTLE BIT ABOUT THE REVIEW PROCESS. SO
23 THE CLIN2 PROGRAM ALLOWS APPLICANTS TO SUBMIT A FULL
24 APPLICATION, AND THOSE FULL APPLICATIONS FOR THIS
25 CURRENT ROUND HAD 18 APPLICATIONS GO THROUGH THE

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1 QUALIFICATION PROCESS. THIS ALLOWS THE CIRM TEAM TO
2 APPLY THE PROGRAM PREFERENCES AND FOR THE GRANTS
3 WORKING GROUP TO APPLY THE VALUE PROPOSITION
4 EVALUATION. FROM THIS PROCESS, THE TOP SEVEN
5 APPLICATIONS ADVANCE TO OUR TYPICAL INTERNAL CIRM
6 ELIGIBILITY REVIEW AND GO TO THE SCIENTIFIC MERIT
7 REVIEW BY THE GRANTS WORKING GROUP. FROM THERE THEY
8 GET RECOMMENDATIONS THAT COME TO HERE FOR FINAL
9 FUNDING DECISIONS.

10 A LITTLE BIT ON HOW THE GRANTS WORKING
11 GROUP EVALUATES THE APPLICATIONS. SO THE
12 COMPOSITION IS UP TO 15 SCIENTIFIC MEMBERS OF THE
13 GRANTS WORKING GROUP THAT PROVIDE EXPERTISE ON
14 DISEASE AREAS, REGULATORY, MANUFACTURING, AND
15 CLINICAL OPERATIONS. WE HAVE OUR ACCESS AND
16 AFFORDABILITY EXPERTS TO PROVIDE AN EVALUATION ALONG
17 THOSE AREAS. WE ALSO HAVE OUR BOARD MEMBERS THAT
18 PROVIDE A PATIENT PERSPECTIVE AND IMPACT AND PROVIDE
19 OVERSIGHT ONTO THE PROCESS. AND WE ALSO HAVE
20 SCIENTIFIC AD HOC SPECIALISTS THAT COME IN AND
21 PROVIDE EXPERTISE ON SPECIFIC AREAS OF THE
22 APPLICATIONS.

23 THE SCORING SYSTEM FOR THE CLINICAL
24 PROGRAM IS THE SAME AS OUR OTHER SCIENTIFIC PROGRAMS
25 USING A SCALE OF 1 TO 100. A MEDIAN SCORE OF 85 TO

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1 100 IS A RECOMMENDATION FROM THE GROUP TO FUND IF
2 THEY ARE AVAILABLE. AND A MEDIAN SCORE OF 1 TO 84
3 IS A DO NOT RECOMMEND FOR FUNDING. THE SCORING IS
4 MEANT TO BE HOLISTIC AND BASED ON ALL FACETS OF THE
5 EXPERT REVIEWERS. AND THE GRANTS WORKING GROUP IS
6 ENCOURAGED TO MAKE USE OF THE FULL RANGE OF THE
7 SCORING TO SIGNAL THEIR ENTHUSIASM FOR THE PROJECT
8 OVERALL.

9 THEY EVALUATE THESE PROJECTS BASED ON FIVE
10 REVIEW CRITERIA. THE FIRST BEING VALUE PROPOSITION;
11 SECOND, RATIONALE; THIRD, THE PROJECT PLAN AND
12 DESIGN; FOURTH, THE PROJECT TEAM AND RESOURCES; AND
13 FINALLY, THE POPULATION IMPACT.

14 A NOTE ON ACCESS AND AFFORDABILITY. SO
15 ALL APPLICATIONS IN THE CLIN2 PROGRAM ARE EVALUATED
16 BY SUBJECT MATTER EXPERTS IN THIS, AND THEIR REVIEWS
17 ARE PRESENTED AT THE GRANTS WORKING GROUP MEETINGS
18 ALONG WITH THE SCIENTIFIC EVALUATIONS AND THE BOARD
19 MEMBER REVIEWERS. THESE MAY INFORM THE SCORING OF
20 THE REVIEW CRITERIA, AND THERE IS RECOGNITION FOR
21 ESPECIALLY THE EARLY STAGE TRIALS, THAT ANY
22 DEFICIENCIES IN THESE PROGRAMS CAN BE ADDRESSED
23 DURING THE AWARD PERIOD.

24 SO TO SUMMARIZE, THE GRANTS WORKING GROUP
25 RECOMMENDATIONS FOR THIS RECENT ROUND OF CLINICAL

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1 APPLICATIONS, SEVEN APPLICATIONS WERE REVIEWED AND
2 THREE ARE RECOMMENDED FOR FUNDING, FOR A TOTAL
3 APPLICANT REQUEST OF 31 MILLION EVEN. AS I
4 MENTIONED BEFORE, SO THERE'S 135 MILLION APPLICATION
5 FOR THE FISCAL YEAR, AND WE CURRENTLY HAVE 92 OF
6 THAT AVAILABLE BASED ON THE PRIOR FIRST ROUND OF
7 CLIN2 APPROVED ABOUT 42 MILLION. SO WE'RE AT 92 FOR
8 THE CURRENT FISCAL YEAR AVAILABLE.

9 IN TERMS OF MINORITY REPORTS, AS GIL
10 DESCRIBED EARLIER FOR THE DISC4 PROGRAM, THE
11 REQUIREMENTS FOR MINORITY REPORTS IS THE SAME FOR
12 ALL OF OUR PROGRAMS. AND FOR THIS PARTICULAR ROUND
13 OF CLIN2, THERE ARE NO MINORITY REPORTS IN THIS
14 CYCLE.

15 AND TO PRESENT THE CIRM TEAM
16 RECOMMENDATIONS, THE CIRM TEAM CONCURS WITH THE
17 GRANTS WORKING GROUP RECOMMENDATIONS TO FUND THE
18 THREE APPLICATIONS LISTED HERE: CLIN2-19270,
19 CLIN2-19119, AND CLIN2-19416 FOR A TOTAL OF 31
20 MILLION.

21 AND I'LL PASS IT -- CAN WE SHOW THE EXCEL
22 SPREADSHEET? AND I'LL PASS IT TO CHAIR IMBASCIANI.
23 THANK YOU.

24 CHAIRMAN IMBASCIANI: THANK YOU, HAYLEY.
25 SO WHILE THERE MIGHT BE CHANGES IN THE FUTURE TO HOW

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1 WE CONSIDER CLINICAL APPLICATIONS AT THIS STAGE FOR
2 FUNDING, I'D LIKE TO MAINTAIN THE SYSTEM WE'VE
3 ALWAYS DONE, WHICH IS TO CONSIDER THE CLINICAL
4 APPLICATIONS FOR FUNDING ONE AT A TIME. SO THERE
5 ARE THREE RECOMMENDED BY THE TEAM, AND THE CHAIR
6 WOULD LIKE TO ENTERTAIN A MOTION TO ACCEPT ONE OF
7 THE ONES THAT HAVE BEEN RECOMMENDED FOR FUNDING.

8 DR. CLARK-HARVEY: SO MOVED.

9 CHAIRMAN IMBASCIANI: WOULD YOU SPECIFY
10 WHICH ONE, LEONDRA? YOU COULD DO THEM IN ORDER.

11 DR. CLARK-HARVEY: 19270.

12 CHAIRMAN IMBASCIANI: IT'S NOT AN EYE
13 TEST. IT'S CLIN2-19270 IS THE MOTION.

14 DR. CLARK-HARVEY: IT FELT LIKE AN EYE
15 TEST. THANK YOU.

16 CHAIRMAN IMBASCIANI: DO I HAVE A SECOND?

17 MS. CASILLAS: I CAN SECOND.

18 CHAIRMAN IMBASCIANI: THANK YOU. WE HAVE
19 A MOTION AND A SECOND. ANY DISCUSSION FROM BOARD
20 MEMBERS? HAYLEY, YOU MIGHT WANT TO MAYBE SAY
21 SOMETHING -- ANNE-MARIE.

22 DR. DULIEGE: IT'S SIMPLY A QUESTION. WE
23 HAVE HAD ALL THE DOCUMENTS, BUT FOR THESE THREE, CAN
24 YOU TELL US OR REMIND US WHICH STAGE THEY ARE? IS
25 THERE ENTRY INTO PHASE 1, PHASE 1 TO PHASE 2? WHERE

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1 ARE THEY ALONG THE LINE WHERE WE'D LIKE TO SEE THEM
2 PROGRESS TOWARDS CLOSE TO PHASE 3?

3 DR. LAM: THIS PARTICULAR APPLICATION
4 ACTUALLY HAS AN ACTIVE CLIN² CLINICAL TRIAL RIGHT
5 NOW. AND THIS PROJECT WOULD BE AN EXPANSION OF THAT
6 EXISTING TRIAL BASED ON FDA FEEDBACK.

7 DR. DULIEGE: OKAY. FOR EACH OF THE
8 THREE?

9 DR. LAM: I'M JUST SPEAKING OF 19270,
10 WHICH IS THE CURRENT APPLICATION UNDER DISCUSSION.

11 DR. DULIEGE: OKAY.

12 DR. LAM: I'M NOT SURE IF I CAN SPEAK TO
13 THE OTHER TWO. IS THAT OKAY?

14 CHAIRMAN IMBASCIANI: NO ACTUALLY. IT
15 WOULD BE MORE APPROPRIATE TO WAIT. ANY OTHER
16 DISCUSSION ON 19270? ANYONE IN THE AUDIENCE OR IN
17 THE PUBLIC WANT TO SPEAK TO THIS? IF NOT, SCOTT, I
18 THINK WE CAN PROCEED.

19 MR. TOCHER: JUST ONE MOMENT. ALL RIGHT.
20 I WON'T BE CALLING THE NAMES OF THOSE WHO HAVE A
21 CONFLICT WITH THIS APPLICATION.

22 MARIA BONNEVILLE.

23 VICE CHAIR BONNEVILLE: YES.

24 MR. TOCHER: MARGUERITE CASILLAS.

25 MS. CASILLAS: YES.

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1 MR. TOCHER: JUDY CHOU.
2 DR. CHOU: YES.
3 MR. TOCHER: LEONDRA CLARK-HARVEY.
4 DR. CLARK-HARVEY: YES.
5 MR. TOCHER: ANNE-MARIE DULIEGE.
6 DR. DULIEGE: YES.
7 MR. TOCHER: SHANNON DAHL.
8 DR. DAHL: YES.
9 MR. TOCHER: YSABEL DURON. WAIT. I'M
10 SORRY. I'M READING ACROSS. NO YSABEL. APOLOGIES.
11 MARK FISCHER-COLBRIE.
12 MR. FISCHER-COLBRIE: YES.
13 MR. TOCHER: VITO IMBASCIANI.
14 CHAIRMAN IMBASCIANI: YES.
15 MR. TOCHER: RICH LAJARA.
16 MR. LAJARA: YES.
17 MR. TOCHER: ADRIANA PADILLA.
18 DR. PADILLA: YES.
19 MR. TOCHER: MARV SOUTHARD.
20 DR. SOUTHARD: YES.
21 MR. TOCHER: KAROL WATSON.
22 DR. WATSON: YES.
23 MR. TOCHER: AND KEVIN XU.
24 MR. XU: YES.
25 MR. TOCHER: THANK YOU. THAT MOTION

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1 CARRIES.

2 CHAIRMAN IMBASCIANI: THANK YOU. WE CAN
3 NOW CONSIDER ONE OF THE OTHER TWO REMAINING
4 APPLICATIONS THAT HAVE BEEN RECOMMENDED BY THE CIRM
5 TEAM. HAYLEY IS IN PLACE IN CASE ANYONE HAS ANY
6 QUESTIONS. SO IF A BOARD MEMBER WOULD PICK ONE AND
7 NOMINATE IT FOR FUNDING.

8 MS. CASILLAS: I'LL NOMINATE 19119.

9 CHAIRMAN IMBASCIANI: YES. THANK YOU VERY
10 MUCH.

11 VICE CHAIR BONNEVILLE: SECOND.

12 CHAIRMAN IMBASCIANI: AND WE HAVE A SECOND
13 FROM VICE CHAIR BONNEVILLE. DISCUSSION FROM BOARD
14 MEMBERS? THIS IS THE APPLICATION ON PITT-HOPKINS
15 SYNDROME.

16 DR. LAM: TO ADDRESS THE QUESTION EARLIER
17 ABOUT THE STAGE OF THE PROGRAM, THIS ONE IS A PHASE
18 1 FIRST-IN-HUMAN TRIAL.

19 DR. DULIEGE: FIRST-IN-PATIENT TRIAL; IS
20 THAT RIGHT?

21 DR. LAM: YES.

22 CHAIRMAN IMBASCIANI: COMMENTS FROM BOARD
23 MEMBERS OR ONLINE? THANK YOU. IF NOT, ANYONE IN --
24 ANY MEMBER OF THE PUBLIC WANT TO SPEAK ON THIS?
25 OKAY. SCOTT.

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1 MR. TOCHER: MARIA BONNEVILLE.
2 VICE CHAIR BONNEVILLE: YES.
3 MR. TOCHER: MARGUERITE CASILLAS.
4 MS. CASILLAS: YES.
5 MR. TOCHER: JUDY CHOU.
6 DR. CHOU: YES.
7 MR. TOCHER: LEONDRA CLARK-HARVEY.
8 DR. CLARK-HARVEY: YES.
9 MR. TOCHER: SHANNON DAHL.
10 DR. DAHL: YES.
11 MR. TOCHER: ANNE-MARIE DULIEGE.
12 DR. DULIEGE: YES.
13 MR. TOCHER: MARK FISCHER-COLBRIE.
14 MR. FISCHER-COLBRIE: YES.
15 MR. TOCHER: VITO IMBASCIANI.
16 CHAIRMAN IMBASCIANI: YES.
17 MR. TOCHER: RICH LAJARA.
18 MR. LAJARA: YES.
19 MR. TOCHER: ADRIANA PADILLA.
20 DR. PADILLA: YES.
21 MR. TOCHER: MARV SOUTHARD.
22 DR. SOUTHARD: YES.
23 MR. TOCHER: KAROL WATSON.
24 DR. WATSON: YES.
25 MR. TOCHER: KEVIN XU.

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1 MR. XU: YES.

2 MR. TOCHER: THANK YOU. THE MOTION
3 CARRIES.

4 CHAIRMAN IMBASCIANI: THANK YOU. WE HAVE
5 ONE FINAL APPLICATION RECOMMENDED FOR FUNDING BY THE
6 CIRM TEAM, AND THAT WOULD BE 19416, BLINDING EYE
7 DISEASE.

8 VICE CHAIR BONNEVILLE: SO MOVED.

9 MS. CASILLAS: I'LL SECOND.

10 CHAIRMAN IMBASCIANI: WE HAVE A MOTION AND
11 SECOND. ANY DISCUSSION FROM BOARD MEMBERS?

12 DR. LAM: AGAIN, TO ADDRESS THE QUESTION
13 EARLIER, THIS IS ALSO A FIRST-IN-HUMAN TRIAL, FIRST
14 IN PATIENT.

15 CHAIRMAN IMBASCIANI: OKAY. ANY MEMBERS
16 OF THE PUBLIC WANT TO COMMENT? ARE YOU READY TO GO,
17 SCOTT, AGAIN?

18 MR. TOCHER: UH-HUH.

19 CHAIRMAN IMBASCIANI: THANKS.

20 MR. TOCHER: MARIA BONNEVILLE.

21 VICE CHAIR BONNEVILLE: YES.

22 MR. TOCHER: MARGUERITE CASILLAS.

23 MS. CASILLAS: YES.

24 MR. TOCHER: JUDY CHOU.

25 DR. CHOU: YES.

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1 MR. TOCHER: LEONDRA CLARK-HARVEY.
2 DR. CLARK-HARVEY: YES.
3 MR. TOCHER: SHANNON DAHL.
4 DR. DAHL: YES.
5 MR. TOCHER: ANNE-MARIE DULIEGE.
6 DR. DULIEGE: YES.
7 MR. TOCHER: YSABEL DURON.
8 MS. DURON: YES.
9 MR. TOCHER: MARK FISCHER-COLBRIE.
10 MR. FISCHER-COLBRIE: YES.
11 MR. TOCHER: ELENA FLOWERS.
12 DR. FLOWERS: YES.
13 MR. TOCHER: VITO IMBASCIANI.
14 CHAIRMAN IMBASCIANI: YES.
15 MR. TOCHER: RICH LAJARA.
16 MR. LAJARA: YES.
17 MR. TOCHER: CHRIS MIASKOWSKI.
18 DR. MIASKOWSKI: YES.
19 MR. TOCHER: ADRIANA PADILLA.
20 DR. PADILLA: YES.
21 MR. TOCHER: MARV SOUTHARD.
22 DR. SOUTHARD: YES.
23 MR. TOCHER: AND KEVIN XU.
24 MR. XU: YES.
25 MR. TOCHER: THANK YOU. AND THAT CARRIES

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1 AS WELL.

2 CHAIRMAN IMBASCIANI: THANKS, SCOTT.

3 SO THE FINAL PART OF THIS AGENDA ITEM
4 WOULD BE TO CLOSE OUT THE RECOMMENDATIONS. SO CHAIR
5 WOULD LIKE TO ENTERTAIN A MOTION NOT TO FUND THE
6 REMAINING APPLICATIONS.

7 MS. CASILLAS: I'LL MAKE THAT MOTION.

8 CHAIRMAN IMBASCIANI: THANK YOU. BOARD
9 MEMBER CASILLAS MOVED.

10 DR. CLARK-HARVEY: SECOND.

11 CHAIRMAN IMBASCIANI: LEONDRAS SECONDED.
12 THANK YOU.

13 DR. CARETHERS: MAY I ASK A QUESTION?

14 MR. TOCHER: LET ME CHECK. OKAY.

15 DR. CARETHERS: I JUST HAD A GENERAL
16 COMMENT. I NOTICED THAT WITH THESE APPLICATIONS AND
17 I NOTICED THE SCORE CUTOFF, BUT I ALSO NOTICED THE
18 AMOUNT. I WAS WONDERING IF SOMEONE CAN EXPLAIN.
19 WAS THIS THE AMOUNT FOR JUST THIS ROUND, OR IS IT
20 ALL THE CLINICAL APPLICATIONS? AND THEN DOES THAT
21 GO BACK IN THE GENERAL POOL, OR IS THERE GOING TO BE
22 ANOTHER CLINICAL ROUND?

23 DR. LAM: THERE WILL BE ONE MORE CLINICAL
24 ROUND FOR THIS FISCAL YEAR COMING.

25 DR. CARETHERS: AND IT'S THE REMINDING

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1 FUNDS THAT GO INTO THIS OR WAS IT --

2 DR. LAM: WHATEVER IS LEFT AFTER TODAY
3 WILL BE APPLIED TO THE THIRD ROUND FOR THIS FISCAL
4 YEAR.

5 DR. CARETHERS: OKAY. SO THERE WAS NO
6 LIMIT ON THE AMOUNT ON THIS ROUND. IT'S JUST THAT
7 THAT'S FOR ALL ROUNDS?

8 DR. LAM: THE 135 APPROVED BY THE BOARD IS
9 FOR THE ENTIRE FISCAL YEAR, WHICH FOR THIS
10 PARTICULAR FISCAL YEAR COVERS THREE CLIN2 ROUNDS. I
11 HOPE THAT MAKES SENSE. AND ONE ROUND HAS ALREADY
12 BEEN VOTED ON AND APPROVED LAST YEAR, AND THEN THIS
13 IS THE SECOND, AND THERE WILL BE ONE MORE COMING.

14 DR. CARETHERS: OKAY. THANK YOU.

15 CHAIRMAN IMBASCIANI: THAT WAS GOOD TO
16 CLARIFY. ANY OTHER QUESTIONS FROM BOARD MEMBERS?
17 THERE IS A HAND RAISED FROM THE PUBLIC. LANA, WE
18 COULD TAKE IT NOW.

19 MS. MORALEZ: ALL RIGHT. WE'RE NOW
20 OPENING THE FLOOR FOR PUBLIC COMMENT. IF YOU ARE
21 JOINING US IN PERSON, WHICH THERE'S QUITE A FEW OF
22 YOU GUYS, ONE AT A TIME, PLEASE APPROACH THE
23 MICROPHONE RIGHT HERE. IF YOU'D LIKE TO STATE YOUR
24 NAME FOR THE RECORD, AND WE WILL KEEP YOU TO THREE
25 MINUTES.

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1 DR. GAENSLER: GOOD MORNING. I'M KARIN
2 GAENSLER, PI FOR CLIN2 ENTITLED TRILEUKEVAX OR TLV,
3 A FIRST-IN-HUMAN ACUTE MYELOGENOUS LEUKEMIA VACCINE
4 FOR RELAPSE PREVENTION.

5 WE APPRECIATE THE GRANT REVIEW AND ALSO
6 THE OPPORTUNITY TO SPEAK IN FRONT OF THE ARS TODAY.
7 AML IS THE MOST COMMON LEUKEMIA AFFECTING ABOUT 1800
8 CALIFORNIANS PER YEAR WHOM I'VE BEEN TREATING FOR
9 THE LAST 35 YEARS. WHILE ABOUT HALF OF PATIENTS
10 ACHIEVE REMISSION, WITHOUT TRANSPLANT, MOST PATIENTS
11 RELAPSE AND DIE.

12 I WANT TO MAKE THREE POINTS VERY IMPORTANT
13 FOR THE ARS CLIN2 FUNDING THIS MORNING. POINT NO.
14 1, NEW STRATEGIES TO PREVENT RELAPSE ARE URGENTLY
15 NEEDED. WE DEVELOPED OUR NOVEL IMMUNOTHERAPY TLV --
16 THANK YOU -- TO ELIMINATE PERSISTING LEUKEMIA AND
17 ADDRESS THIS NEED. BY ENGINEERING PATIENT'S OWN
18 LEUKEMIA CELLS TO MAKE TLV, WE ARE CREATING A
19 PERSONALIZED THERAPY THAT COULD BE USED FOR ANY
20 PATIENT.

21 THIS STRATEGY IS BASED ON THE ESTABLISHED
22 BIOLOGY OF GRAFT VERSUS LEUKEMIA EFFECTS AFTER STEM
23 CELL TRANSPLANT WHERE DONOR IMMUNE CELLS CAN
24 ELIMINATE RESIDUAL LEUKEMIA. THE GOAL OF TLV
25 ADMINISTRATION IS TO STIMULATE THE PATIENT'S OWN

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1 IMMUNE SYSTEM TO RECOGNIZE AND KILL THE RESIDUAL
2 LEUKEMIA THAT CAUSES RELAPSE. OUR PEER-REVIEWED
3 PRECLINICAL DATA STRONGLY SUPPORTS THIS CONCEPT.

4 POINT NO. 2, THE PHASE 1 CLINICAL TRIAL IS
5 READY TO GO NOW. WITH SEVEN YEARS OF CIRM FUNDING,
6 WE HAVE BUILT THE INFRASTRUCTURE FOR THE
7 MANUFACTURING OF TLV, WHICH MY COLLEAGUE, DR. DONALD
8 KOHN, WILL DESCRIBE. WE'VE ALSO OBTAINED THE
9 NECESSARY REGULATORY APPROVALS AT OUR INSTITUTIONS
10 AND BY THE FDA.

11 THE IMPORTANCE OF OUR APPROACH IS
12 SUPPORTED BY THE FACT THAT THE FDA GRANTED TLV BOTH
13 ORPHAN DRUG AND FAST-TRACK DESIGNATIONS IN
14 RECOGNITION OF THE NOVELTY OF OUR IMMUNE THERAPY AND
15 THE CRITICAL NEED THAT IT ADDRESSES.

16 POINT NO. 3, OUR MAJOR GOAL IS TO MAKE TLV
17 BROADLY AVAILABLE TO ALL CALIFORNIANS. AGAIN, ANY
18 PATIENT CAN POTENTIALLY RECEIVE TLV. THIS IS IN
19 CONTRAST TO STEM CELL TRANSPLANTS WHERE ACCESS FOR
20 OLDER PATIENTS IS LIMITED BY THE NEED FOR MATCHED
21 DONOR, HIGH RISK, AND RIGOROUS HEALTH REQUIREMENTS.
22 ONCE MANUFACTURED, TLV CAN BE AVAILABLE AND SHIPPED
23 TO AN OUTPATIENT THERAPY IN VIRTUALLY ANY COMMUNITY.

24 THE NINE OPEN LETTERS SUBMITTED TO THE
25 BOARD LAST WEEK STRONGLY SUPPORT OUR SCIENTIFIC

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1 VALIDATION, REGULATORY AND MANUFACTURING READINESS,
2 AND A CLEAR PATH TO CLINICAL AND COMMERCIAL
3 DEVELOPMENT.

4 IN SUMMARY, OUR CLINICAL TRIAL IS URGENTLY
5 NEEDED AND CRITICAL TO ADDRESSING THE DEVASTATING
6 ILLNESS. IT IS READY FOR ENROLLMENT NOW AND WILL
7 MAXIMIZE ACCESS AND AVAILABILITY TO PATIENTS ALL
8 OVER CALIFORNIA. I THEREFORE RESPECTFULLY URGE YOU
9 TO PLEASE FUND TLV THIS MORNING. THANK YOU FOR YOUR
10 ATTENTION.

11 MS. MORALEZ: ALL RIGHT. NEXT PERSON UP,
12 YOU HAVE THREE MINUTES.

13 MR. HARRINGTON: GOOD MORNING. MY NAME IS
14 KEVIN HARRINGTON. I'M AN AML SURVIVOR. I'M HERE
15 TODAY TO STRONGLY URGE THE BOARD TO CONTINUE FUNDING
16 DR. GAENSLER'S TRILEUKEVAX PROGRAM.

17 THE TWO WORST DAYS IN AN AML PATIENT'S
18 JOURNEY ARE THE DAY OF DIAGNOSIS AND ALL TOO OFTEN
19 THE DAY THE DISEASE RETURNS OR RELAPSES. THE
20 JOURNEY BETWEEN THOSE TWO EVENTS IS DAUNTING, IN MY
21 CASE AN INTENSIVE CHEMOTHERAPY, INDUCTION
22 CONSOLIDATION, AND IF YOU REACH AND MAINTAIN
23 REMISSION, THE BONE MARROW TRANSPLANT. THAT IN
24 ITSELF CAN BE LETHAL.

25 AS A SURVIVOR, I KNOW THAT MY RECOVERY WAS

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1 A BRUTE FORCE MIRACLE OF MODERN MEDICINE. IT
2 DOESN'T END THERE, HOWEVER. POST BMT, MULTIPLE ICU
3 STAYS, INTUBATION, BLOOD CLOTS IN BOTH LEGS, ARMS,
4 LUNGS REQUIRING TWO OPERATIONS, MULTIPLE AMBULANCE
5 RIDES TO SUPPORT THE MOUNTING HOSPITAL STAYS, GI
6 BLEEDING, REPERCUSSIONS OF AN INFECTED BMT DONATION,
7 C DIFF, AND A SIGNIFICANT DECONDITIONING AFTER
8 STEROID TREATMENT FOR GBHD RESULTING IN TIME SPENT
9 IN A REHAB FACILITY TO LEARN HOW TO WALK AGAIN.

10 WHILE THIS MAY SEEM LIKE WORST CASE
11 SCENARIO AFTER SPENDING SIGNIFICANT OVER THE YEARS
12 IN AML AND BMT ONLINE FORUMS, IT'S NOT UNUSUAL, NOR
13 IS IT UNUSUAL FOR THE LARGE NUMBER OF PATIENTS WHO
14 HAVE SURVIVED BMT OR LESS FORTUNATE WHO WERE
15 TRANSPLANTED AND ELIGIBLE TO FALL INTO RELAPSE.
16 THEIR OPTION, TO GO THROUGH THAT AGAIN OR SIMPLY
17 WAIT.

18 REMISSION IS NOT THE END OF FEAR. IT'S
19 THE BEGINNING OF A DIFFERENT KIND OF WATCH. EVERY
20 BLOOD TEST, EVERY BRUISE, EVERY FATIGUE TRIGGERS THE
21 SAME RESPONSE: IS IT BACK? TO THIS DAY I STILL
22 POUR OVER AND TREND MY TEST RESULTS.

23 ALSO WANT TO MENTION THE HOSPITAL STAFF
24 WHO, DESPITE NEVER ENDING REVOLVING DOOR IN AND OUT
25 OF TREATMENT, CONTINUE AN AMAZING LEVEL OF CARE

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1 WHILE WEARING MULTIPLE HATS, LONG SHIFTS, ON CALL,
2 MAKING ROUNDS, AND IN MANY CASES DEVELOPING THE VERY
3 RESEARCH THAT SAVES OUR LIVES AND FOR THE FIRST TIME
4 DELIVERS REAL HOPE TO OUR COMMUNITY. THEIR
5 DEDICATION TO BOTH PATIENTS AND INNOVATIVE RESEARCH
6 LIKE TLV SHOWS HOW VITAL THE SUPPORT IS FOR PROGRAMS
7 THAT COMBINE COMPASSION AND SCIENTIFIC PROCESS --
8 PROGRESS.

9 BY FUNDING INITIATIVES LIKE THIS, WE HONOR
10 NOT JUST THE PATIENTS, BUT ALSO THE STAFF AND THE
11 COMMITMENT THAT DRIVES THESE BREAKTHROUGHS. I ASK
12 ON BEHALF OF ALL AML PATIENTS, PARTICULARLY THE 50
13 PERCENT THAT WILL RELAPSE, TO FUND THE TRILEUKEVAX
14 PROGRAM. THANK YOU FOR YOUR TIME.

15 MS. MORALEZ: THANK YOU VERY MUCH. ALL
16 RIGHT. NEXT PERSON UP, PLEASE STEP CLOSE TO THE
17 MICROPHONE AND STATE YOUR NAME, AND YOU HAVE THREE
18 MINUTES.

19 MR. BROWN: GOOD MORNING. I'M WILLIAM L.
20 BROWN, A RETIRED VENTURE CAPITALIST AND BIOTECH CEO.
21 I WANT TO TALK ABOUT TWO THINGS: TIME AND LEVERAGE.

22 I HAVE A RARE LEUKEMIA, ONE FOR WHICH
23 THERE'S NOT ENOUGH DATA TO SUGGEST A DEFINITIVE
24 TREATMENT. FOR ALL AML PATIENTS AND FOR ME, THERE'S
25 NO CERTAINTY OF A CURE. WE LIVE IN HOPE EACH DAY

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1 THAT ONE WILL BE ANNOUNCED.

2 ONE IN THREE LEUKEMIA PATIENTS HAVE AML.
3 OVER 130,000 AML PATIENTS WILL DIE THIS YEAR ALONE.
4 FOR EACH OF THEM, TIME WILL RUN OUT.

5 THE DEVELOPMENT OF NEW PHARMACEUTICALS
6 EVEN BY THE BEST SCIENTISTS TAKES TIME AND TIME
7 COSTS MONEY. I'VE LEARNED THAT YOU CAN'T HURRY
8 SCIENCE, BUT WE HAVE HERE A DRUG CANDIDATE WHERE THE
9 TIME HAS BEEN INVESTED AND HUMAN TRIALS CAN BEGIN
10 WITHIN THREE MONTHS OF FUNDING. NO OTHER DRUG OR
11 DRUG CANDIDATE REPRODUCES ALL OF THE FEATURES OF
12 TRILEUKEVAX. EXISTING THERAPIES ARE TOXIC,
13 UNPREDICTABLE, AND NOT A RELIABLE CURE.

14 TRILEUKEVAX IS A PERSONALIZED VACCINE THAT
15 CAN BE MADE FOR ANY AML PATIENT, SHIPPED ANYWHERE,
16 AND ADMINISTERED IN COMMUNITY HEMATOLOGY CLINICS.
17 IT'S TUMOR CELL APPROACH COULD BECOME A GENERALIZED
18 PLATFORM FOR VACCINE DELIVERY. RECOGNIZING THE
19 POTENTIAL FOR A CURE AND THE NEED TO MOVE QUICKLY,
20 THE FDA HAS FAST-TRACKED TRILEUKEVAX FOR PHASE 1
21 TRIALS.

22 EACH OF US HERE TODAY IS MOTIVATED TO
23 LEVERAGE THE CIRM'S FUNDS TO TREAT AS MANY PATIENTS
24 AS QUICKLY AS POSSIBLE. SO HOW CAN WE ACHIEVE THIS
25 LEVERAGE? TO DO SO WE NEED TO INVOLVE BIG PHARMA TO

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1 COMPLETE PHASES 2 AND 3 AND TO DO THE MARKETING AND
2 DISTRIBUTION. BIG PHARMA HAS BECOME VERY PARTICULAR
3 IN WHAT THEY WILL FUND. AND IF YOU DON'T HAVE PHASE
4 1 DATA, YOUR CANDIDATE WON'T BE CONSIDERED.

5 MY EXPERIENCE IN THE BIOTECH INDUSTRY
6 TELLS ME THAT POSITIVE PHASE 1 DATA WOULD GENERATE
7 SUFFICIENT BIG PHARMA INTEREST TO COMPLETE THE
8 DEVELOPMENT PROCESS. MAYBE MORE IMPORTANTLY, BIG
9 PHARMA WILL BE INTRIGUED BY THE POSSIBILITY OF A
10 GENERALIZED VACCINE DELIVERY PLATFORM AND THE
11 LEVERAGE IT WILL CREATE FOR NEW DEVELOPMENT. AND
12 THIS LEVERAGE WOULD EXTEND BEYOND TRILEUKEVAX BY
13 EARNING UCSF THE FUNDS TO CONTINUE THE DEVELOPMENT
14 OF NEW DISCOVERIES.

15 FOR THE OVER 200,000 WORLDWIDE AML
16 PATIENTS, MOST OF WHOM WILL OTHERWISE DIE --

17 MS. MORALEZ: THANK YOU VERY MUCH.
18 ANYBODY NEXT? ANYBODY ELSE IN PERSON FOR PUBLIC
19 COMMENT? PLEASE STEP UP AND CLOSE TO THE MIC SO WE
20 CAN HEAR YOU AND STATE YOUR NAME, AND WE'LL START
21 YOUR THREE MINUTES.

22 MR. AINSWORTH: THANK YOU VERY MUCH. I'M
23 SEAN AINSWORTH WITH IMMUSOFT. REALLY I JUST WANT TO
24 EXPRESS MY THANKS TO CIRM AND THE BOARD AND THE GWG
25 FOR THE SUPPORT THAT YOU'VE PROVIDED IMMUSOFT. IT'S

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1 BEEN TRANSFORMATIONAL FOR US. IT'S ALLOWED US TO
2 ACCELERATE OUR LEAD PROGRAM INTO THE CLINIC. WE'VE
3 SEEN SOME GREAT EXCITEMENT FROM THE COMMUNITY AS A
4 RESULT OF THAT. AND WE VERY MUCH APPRECIATE THE
5 CONTINUED SUPPORT.

6 AND I WOULD ADD THAT WE TAKE THE TRUST
7 THAT CIRM AND THE CALIFORNIA TAXPAYERS PLACED IN US
8 VERY SERIOUSLY. AND WE WILL BE GOOD, DISCIPLINED
9 SHEPHERDS OF THAT TRUST AND BE TRANSPARENT WITH OUR
10 PROGRESS. AND WE'RE VERY HONORED TO BE PART OF THE
11 CIRM PORTFOLIO. SO THANK YOU VERY MUCH.

12 MS. MORALEZ: ALL RIGHT. IF YOU ARE ON
13 THE PHONE FOR PUBLIC COMMENT, PLEASE PRESS STAR NINE
14 TO RAISE YOUR HAND. ANYBODY ELSE LEFT IN PERSON FOR
15 THESE TWO APPLICATIONS AT THE BOTTOM? ALL RIGHT. I
16 HAVE A PHONE NUMBER ENDING IN 7541. IF YOU WOULD
17 PRESS STAR SIX TO UNMUTE.

18 DR. MILLER: THANK YOU AND HELLO. MY NAME
19 IS WES MILLER. I'M A CHIEF MEDICAL OFFICER AT
20 EPICRISPR BIOTECHNOLOGY. THANK YOU FOR ALLOWING ME
21 TO PUBLICLY COMMENT ON THE REVIEWER RESPONSES TO OUR
22 APPLICATION 19378.

23 AS A CALIFORNIA-BASED START-UP, WE VIEW
24 OURSELVES AS A CRUCIAL PARTNER IN HELPING CIRM
25 REALIZE ITS MISSION TO DEVELOP NOT ONLY A DIVERSE

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1 PORTFOLIO OF EFFECTIVE AND TRANSFORMATIVE THERAPIES,
2 BUT ALSO TO MAKE SUCH MEDICINES ACCESSIBLE AND
3 AFFORDABLE TO PATIENTS.

4 OUR APPLICATION IS FOCUSED ON EPI-321, THE
5 FIRST AND ONLY EPIGENETIC EDITING THERAPY IN THE
6 U.S. BEING EVALUATED IN AN ONGOING FIRST-IN-HUMAN
7 AND FIRST-IN-PATIENT CLINICAL STUDY.

8 EPI-321 WAS DEVELOPED AS A POTENTIAL CURE
9 FOR FSHD, ONE OF THE MOST COMMON FORMS OF MUSCULAR
10 DYSTROPHY AFFECTING ABOUT ONE MILLION PEOPLE
11 GLOBALLY AND APPROXIMATELY 5,000 CALIFORNIANS ALONE.
12 CURRENTLY NO DISEASE MODIFYING OPTIONS ARE AVAILABLE
13 FOR PATIENTS, REPRESENTING A MAJOR UNMET MEDICAL
14 NEED. EPI-321 IS A POTENTIAL ONE-TIME TREATMENT FOR
15 PATIENTS WHO DESPERATELY NEED A TREATMENT FOR THIS
16 CHRONIC DISEASE AND HAS BEEN GRANTED ORPHAN DRUG
17 FAST-TRACK, AND RARE PEDIATRIC DESIGNATIONS BY THE
18 FDA.

19 SEVERAL REVIEWERS EXPRESSED CONCERNS THAT
20 PLANNED EPI-321 CLINICAL DOSES IN THE LOW 10 TO THE
21 13TH VECTOR GENOME PER KILOGRAM I.V. RANGE WOULD BE
22 INSUFFICIENT FOR BIOLOGICAL EFFECT AND CLINICAL
23 BENEFIT FOR FSHD. HOWEVER, THREE LINES OF EVIDENCE
24 SUPPORT THE CONTRARY AND MUST BE STRESSED. FIRST,
25 PEOPLE WITH FSHD EXHIBIT CLINICALLY ATTENUATED TO

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1 ABSENT DISEASE IN THE SETTING OF 30 TO 50 PERCENT
2 NORMAL NUCLEI. THIS SUGGESTS THAT DEFINITIVE AND
3 DURABLE SILENCING OF DUX4 IN ONLY THIS FRACTION OF
4 NUCLEI MAY BE SUFFICIENT TO ABROGATE CLINICAL FSH.

5 SECOND, IN ALIGNING WITH THESE NATURAL
6 HISTORY OBSERVATIONS, EPI-321 NONCLINICAL EFFICACY
7 DATA FROM VARIOUS UNIQUE FSHD PATIENT MUSCLE CELL
8 LINES SHOWED DEEP SUPPRESSION OF THE DUX4 PATHWAY,
9 REDUCED APOPTOSIS, AND RESCUED MUSCLE CONTRACTUAL
10 FUNCTION AT BIODISTRIBUTION LEVELS IN THIS RANGE
11 OF .3 TO .6 SECTOR GENOMES PER DIPLOID GENOME.

12 THIRD, PUBLISHED CLINICAL DATA FROM OVER
13 80 INDIVIDUALS ADMINISTERED VARIOUS I.V. DOSES OF
14 AVRH 74 PREDICT THAT THESE PLANNED EPI-321 CLINICAL
15 DOSES WILL EXCEED THIS MUSCLE BIODISTRIBUTION
16 THRESHOLD, AND PRELIMINARY DATA FROM THE ONGOING
17 FIRST-IN-HUMAN STUDY ARE BEGINNING TO CONFIRM THIS
18 PREDICTION.

19 FINALLY, THE COMPANY IS DEDICATED TO
20 DEVELOPING NOVEL THERAPIES THAT CAN BE ACCESSIBLE
21 AND AFFORDABLE TO PATIENTS WHO CURRENTLY HAVE NO
22 THERAPEUTIC OPTIONS. RECENT IMPROVEMENTS IN PROCESS
23 DEVELOPMENT HAVE BROUGHT DOWN THE COST OF
24 MANUFACTURING BY UPWARDS OF 60 PERCENT ALREADY.
25 HOWEVER, CONTINUED EFFORTS TO IMPROVE THE

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1 MANUFACTURING PROCESS ARE NEEDED TO BRING DOWN THE
2 COST IN LATE STAGE CLINICAL IN EVENTUAL COMMERCIAL
3 SETTINGS.

4 WE STRONGLY BELIEVE THIS SQUARELY ALIGNS
5 WITH CIRM'S MISSION. I HOPE THIS HELPS ADDRESS THE
6 REMAINING REVIEWER CONCERNS AND THAT CIRM WILL
7 STRONGLY CONSIDER OUR APPLICATION FOR FUNDING THIS
8 CYCLE AND HELP TO BRING EPI-321 TO PATIENTS WHO NEED
9 IT MOST. THANKS SO MUCH FOR YOUR TIME.

10 MS. MORALEZ: GREAT. THANK YOU SO VERY
11 MUCH. IS THERE ANY OTHER PUBLIC COMMENT? I THINK
12 WE'RE GOOD, CHAIR.

13 CHAIRMAN IMBASCIANI: OKAY. SO CLEARLY
14 THERE'S A LOT OF INTEREST IN THE TWO APPLICATIONS
15 THAT WERE NOT RECOMMENDED BY THE TEAM. IF THERE IS
16 INTEREST ON THE PART OF BOARD MEMBERS IN FUNDING ONE
17 OF THOSE, WE NEED TO DEFEAT THE MOTION ON THE TABLE.
18 AND PREPARATORY TO THAT AND WITH RESPECT TO THE
19 CLOSENESS OF THE SCORES AND OUR REMAINING BUDGET,
20 I'M GOING TO ASK DR. LAM IF YOU WOULD COMMENT A
21 LITTLE FURTHER ON YOUR DELIBERATIONS, ON YOUR
22 RECOMMENDATIONS.

23 DR. LAM: THANK YOU. SO THE CIRM TEAM DID
24 AN INTERNAL CHECK OF BOTH OF THESE APPLICATIONS. I
25 WILL NOTE FOR JUST ADDITIONAL INFORMATION FOR THE

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1 BOARD. LET'S SEE. SO ADDRESSING BOTH OF THEM
2 SEPARATELY, 19378, THE FSHD APPLICATION, THIS
3 APPLICATION DOES NOT HAVE -- OR THIS INDICATION, THE
4 CIRM PORTFOLIO DOES NOT HAVE ANY ACTIVE AWARDS IN
5 THE PDEV OR THE CLIN2 PORTFOLIO.

6 AND THEN REGARDING 19191, THIS IS THE AML
7 APPLICATION. THIS ONE, THE CIRM ACTIVE PORTFOLIO
8 HAS NO PDEV AWARDS, BUT THERE ARE TWO CLIN2 ACTIVE
9 AWARDS IN AML, BUT WITH A DIFFERENT MODALITY FROM
10 THE CURRENT APPLICATION. JUST FOR ADDITIONAL
11 INFORMATION FOR FOLKS IF THAT'S HELPFUL AT ALL.

12 CHAIRMAN IMBASCIANI: THANKS, HAYLEY.
13 BOARD MEMBERS PROBABLY HAVE SOME QUESTIONS FOR
14 HAYLEY.

15 DR. DULIEGE: YES. FIRST, IN GENERAL, I
16 WANTED TO THANK THE MEMBERS OF THE PUBLIC,
17 SCIENTISTS AND PATIENTS, WHO HAVE SINCE THIS
18 MORNING, INCLUDING FOR DISC4, HAVE THE COURAGE TO
19 COME TO THE MICROPHONE OR TO THE PHONE TO THE
20 EXPLAIN THE URGENCY AND THE IMPORTANCE OF THE
21 PROGRAM. AND I WANT TO ASSURE THAT THE BOARD AT
22 LARGE IS VERY SENSITIVE TO THAT. AND THANK YOU FOR
23 THIS.

24 SECOND, I WANTED TO KNOW IF YOU COULD TELL
25 US A LITTLE BIT ABOUT THE COMMENTS THAT WERE MADE BY

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1 THE GRANTS WORKING GROUP PARTICULARLY IN REGARD TO
2 APPLICATION 19191, THE AUTOLOGOUS AML VACCINE,
3 BECAUSE THIS ONE HAD RELATIVELY A LOW SCORE COMPARED
4 TO WHAT'S THE MINIMUM THRESHOLD TO BE CONSIDERED, 80
5 VERSUS 85? CAN YOU TELL US ABOUT WHAT JUSTIFY THIS
6 LOW SCORE WHEN WE HEAR OTHERWISE THAT THIS IS AN
7 INTERVENTION THAT IS READY, THAT HAS BEEN APPROVED
8 IN ESSENCE BY THE FDA TO START? THERE'S A LOT OF
9 POSITIVE THINGS ABOUT THAT.

10 DR. LAM: YES. I THINK THE REVIEWERS
11 AGREED ON THOSE POINTS. IT'S A NEEDED OPTION FOR
12 AML FOR THOSE THAT ARE INELIGIBLE FOR THE STANDARD
13 OF CARE OR TRANSPLANTS AND CANNOT UNDERGO THE HIGH
14 DOSE CHEMOS.

15 I THINK THE CONCERNS FROM THE GRANTS
16 WORKING GROUP MAINLY WERE AROUND THE DESIGN OF THE
17 CLINICAL TRIAL. SO THE CONCERNS -- I THINK THE
18 PRIMARY DRIVER OF THE SCORING, I GUESS, THERE WERE
19 SOME MINOR CONCERNS AROUND THE MANUFACTURING, JUST
20 IT BEING COMPLEX, AND POSSIBLE CONCERNS WITH THE
21 YIELD OF THE PRODUCT. BUT I THINK THE MAJOR CONCERN
22 GOING BACK FROM THE -- TO SPEAK TO THE TRIAL DESIGN
23 WAS THEY BELIEVE THAT THE DESIGN OF THE TRIAL WOULD
24 ULTIMATELY BE SAFE AS A PHASE 1 TRIAL, BUT IT WOULD
25 BE DIFFICULT TO INTERPRET THE DATA AND UNDERSTAND

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1 WHETHER IT WOULD GO FORWARD AS A GO/NO-GO DECISION.
2 THAT KIND OF SUMMARIZES THE GRANTS WORKING
3 GROUP SENTIMENT IN TERMS OF HOW THEY VOTED.
4 BASICALLY IT WOULD BE -- THEY WOULD BE ABLE TO
5 DETERMINE WHETHER THE PRODUCT WAS SAFE, BUT NOT
6 WHETHER -- THEY WOULDN'T BE ABLE TO UNDERSTAND
7 WHETHER IT WORKS AND WHETHER TO MOVE FORWARD TO THE
8 NEXT STAGE OF PHASE TRIALS.

9 DR. DULIEGE: ISN'T THAT THE MAIN GOAL FOR
10 PHASE 1 STUDY, TO DETERMINE SAFETY, BUT NOT
11 NECESSARILY TO HAVE A SIGNAL TO MOVE AHEAD? THE
12 SIGNAL IS GIVEN BY A PHASE 2 TRIAL WITH A MORE
13 COMPLEX DESIGN. SO IT'S HARD TO EXPECT SUBSTANTIAL
14 EFFICACY INFORMATION AT THE END OF A PHASE 1 IN
15 PATIENT STUDIES.

16 DR. LAM: YES.

17 DR. DAHL: COULD YOU PROVIDE THE SAME
18 PERSPECTIVE ON THE OTHER AWARD AS WELL, OTHER GRANT?

19 DR. LAM: JUST SO WE'RE CLEAR, 19378, FOR
20 THE FSHD. SO FOR THIS ONE ALSO HIGH UNMET NEED, AND
21 IT'S POTENTIALLY A ONE-TIME TREATMENT WITH A NOVEL
22 APPROACH ON THE EPIGENETIC SIDE.

23 THE CONCERN FROM THE GRANTS WORKING GROUP
24 HERE FOCUSED MAINLY ON THE TOXICITY OF THE --
25 POTENTIAL TOXICITY OF THE TREATMENT, WHICH WAS ALSO

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1 COMMENTED BY THE PUBLIC COMMENT AS WELL. AND,
2 AGAIN, THEY THOUGHT THAT THE PROPOSED DOSES FOR THE
3 TRIAL WERE, AGAIN, LIKELY TO BE SAFE, BUT NOT LIKELY
4 TO MAKE A DIFFERENCE IN TERMS OF DISEASE
5 MODIFICATION.

6 DR. DAHL: I GUESS IT'S THE SAME COMMENT
7 ANNE-MARIE MADE ABOUT THE OTHER ONE. SAFETY IS THE
8 GOAL OF PHASE 1.

9 CHAIRMAN IMBASCIANI: SCOTT, COULD I ASK
10 YOU TO REPEAT THE MOTION OR BETH?

11 MR. TOCHER: THE MOTION IS TO NOT FUND THE
12 REMAINING TWO CLIN'S. SO THOSE WOULD BE 19378 AND
13 19191.

14 DR. DULIEGE: VITO, ASKING FELLOW BOARD
15 MEMBERS OR MEMBERS OF THE CIRM TEAM TO HELP US, HOW
16 CAN WE ADDRESS THE ISSUE WHERE THE COMMENTS FROM THE
17 GRANTS WORKING GROUP WAS THAT THERE WOULD BE
18 INSUFFICIENT DATA AT THE END OF THIS TRIAL TO GIVE
19 AN INDICATION OF EFFICACY, NOT PROOF, BUT INDICATION
20 AND RECOGNIZE THAT THE DESIGN OF PHASE 1 TRIAL IS
21 NOT -- CANNOT GENERATE THAT?

22 DR. LAM: YES. I THINK THAT IS THE
23 UNDERSTANDING FROM THE GRANTS WORKING GROUP, THAT IT
24 IS A SAFETY TRIAL. I THINK THEIR HOPE IS THAT --
25 THE HOPE WOULD BE THAT THERE COULD BE SOME SIGNAL

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1 AND SOME DATA FROM SOME OF THESE TRIALS, ESPECIALLY
2 FOR THE MORE RARE CONDITIONS. BUT I THINK I WOULD
3 ALSO SAY THAT IT'S -- THE APPLICATIONS ARE SCORED IN
4 THESE CLINICAL REVIEWS ACROSS ALL SEVEN
5 APPLICATIONS. SO THERE IS SOME CONSIDERATION FOR
6 THE RELATIVE ENTHUSIASM THAT THEY MIGHT HAVE FOR
7 PROJECTS ACROSS THE COHORT.

8 DR. SAMBRANO.

9 DR. SAMBRANO: SO I THINK ONE OTHER THING
10 TO NOTE IS ONE OF THE THINGS THAT WE STRESS WITH THE
11 GRANTS WORKING GROUP IS THAT WE'RE LOOKING FOR
12 NOVEL, TRANSFORMATIVE THERAPIES. SO PART OF IT IS
13 THAT IT IS NOT NECESSARILY, AS WAS NOTED, THAT AN
14 INITIAL PHASE 1 TRIAL SHOW ANY EFFICACY OR
15 NECESSARILY ANY SIGNAL. THEY'RE OFTEN DESIGNED TO
16 ASSESS SAFETY. BUT I THINK THEY ARE ALSO LOOKING AT
17 IS THIS A THERAPY THAT'S LIKELY TO, EITHER WHEN IT
18 GOES BEYOND THE PHASE 1, TO BE EFFECTIVE AND TO HAVE
19 A MEANINGFUL IMPACT ON THE PATIENT POPULATION.

20 AND SO I THINK THAT IS PART OF THE
21 CALCULUS THAT IS IN THERE. AND SO THE REASON THEY
22 LOOK FOR AT LEAST A HOPE FOR SOME SIGNAL EFFICACY IS
23 THAT IT'S GOING TO ALSO SIGNAL THAT THIS IS REALLY,
24 TRULY A TRANSFORMATIVE THERAPY.

25 NOW, THAT DOESN'T MEAN THAT, OF COURSE,

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1 THAT WE CAN'T FUND A PROPOSAL THAT IS FOCUSED ON
2 SAFETY. I THINK THAT IS OKAY.

3 I THINK THE OTHER THING TO CONSIDER IN
4 TERMS OF JUST THE BUDGET, SO THAT YOU'RE AWARE, I
5 THINK HAYLEY NOTED, THE BUDGET IS AT 92 MILLION
6 CURRENTLY. THIS WOULD BRING US DOWN TO ABOUT 60
7 MILLION -- IS THAT CORRECT, HAYLEY? -- IF WE FUNDED
8 THE TOP THREE FOR ONE MORE CYCLE. SO I THINK IN
9 TERMS OF IS THERE FLEXIBILITY IN THE BUDGET TO
10 INCLUDE AN ADDITIONAL OR TWO ADDITIONAL, YOU COULD
11 KNOWING THAT THE NEXT CYCLE COULD BE IMPACTED, BUT
12 AT THE MOMENT EACH CYCLE IS USING UP ABOUT MAYBE 40
13 MILLION PER CYCLE. SO THE REMAINDER WOULD STILL
14 LIKELY BE ADEQUATE. SO I THINK THAT IS SOMETHING
15 THAT YOU CAN ALSO TAKE INTO ACCOUNT.

16 DR. LAM: JUST TO LOOK AT THE NUMBERS, IF
17 THESE TWO APPLICATIONS WERE FUNDED, THAT WOULD BE AN
18 ADDITIONAL 20 MILLION FOR THIS ROUND. AND THAT
19 WOULD BRING THE TOTAL AWARDED FOR THIS ROUND TO 51
20 MILLION OUT OF THE 92 REMAINING. SO THAT WOULD BE
21 41 REMAINING FOR THE LAST ROUND IF THESE TWO
22 APPLICATIONS WERE FUNDED.

23 CHAIRMAN IMBASCIANI: THANK YOU, HAYLEY.
24 IN ORDER TO, IN A SENSE, PROMPT OR FORCE FURTHER
25 DISCUSSION AMONG BOARD MEMBERS, I'D LIKE TO AMEND

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1 THE MOTION. I'D LIKE TO AMEND THE MOTION TO INCLUDE
2 FUNDING APPLICATION CLIN2-19191.

3 MR. TOCHER: ONLY THAT ONE?

4 CHAIRMAN IMBASCIANI: YEAH. WE CAN DO
5 THEM ONE AT A TIME. I THINK IT WOULD BE CLEANER TO
6 DO IT ONE AT A TIME.

7 MR. TOCHER: SO THE MOTION IS TO AMEND THE
8 MOTION ON THE TABLE TO FUND 19191. IS THERE A
9 SECOND?

10 DR. DULIEGE: I SECOND.

11 CHAIRMAN IMBASCIANI: MARK
12 FISCHER-COLBRIE. MARK, YOU NEED TO UNMUTE I THINK.

13 MR. FISCHER-COLBRIE: SORRY ABOUT THAT.
14 IS IT OKAY TO MAKE A COMMENT?

15 MR. TOCHER: IT IS.

16 CHAIRMAN IMBASCIANI: THE FLOOR IS YOURS.

17 MR. FISCHER-COLBRIE: I JUST WANTED TO
18 COMMENT THAT THE REVIEWERS ARE EXTREMELY FAMILIAR
19 WITH THE FACT THAT PHASE 1 IS INTENSELY FOCUSED ON
20 SAFETY, AND THERE'S ALMOST NEVER GOING TO BE A
21 DETERMINATION OR EVEN A NOD IN TERMS OF WHETHER OR
22 NOT THERE'S A SIGNAL BECAUSE OF THE HIGHLY LIMITED
23 NUMBER OF PATIENTS. SO THE REVIEWERS VERY MUCH
24 FACTOR THAT INTO THEIR CONSIDERATION. THAT'S PART
25 OF THE DNA OF THE REVIEW CYCLE.

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1 SO I DIDN'T WANT THERE TO BE AN INTIMATION
2 THAT THERE IS A CLEAR WAIT FOR A SIGNAL OUT OF A
3 PHASE 1 TRIAL BECAUSE EVERYONE KNOWS THAT'S HIGHLY
4 UNLIKELY. AND THIS IS IN A CIRCUMSTANCE, JUST TO
5 GIVE NUANCE TO THE PREVIOUS COMMENTS, IN THE CONTEXT
6 THAT PEOPLE ARE LOOKING AT WHAT'S NEXT AND WHAT IS
7 THE RISK PROFILE FOR ACHIEVING THE PHASE 2 TRIAL
8 WORK AND WHAT ARE THE CHARACTERISTICS IN THE PHASE 2
9 WHERE A SIGNAL MIGHT BE ABLE TO BE DETERMINED, COME
10 INTO PLAY. I JUST WANTED TO CLARIFY SOME OF THE
11 COMMENTS RELATED TO HOW PEOPLE MAKE THEIR
12 DETERMINATIONS ON THE SCORING. THANKS.

13 CHAIRMAN IMBASCIANI: THANK YOU, MARK.
14 JOHN CARETHERS.

15 DR. CARETHERS: YES. THANK YOU. I
16 THOUGHT YOU WERE GOING TO MAKE THE MOTION ON 19378
17 AS THE ONE BECAUSE THE SCORES WERE SO CLOSE. SO I
18 WAS WONDERING IF ROSA COULD ADD -- SOMEONE CAN ADD
19 COMMENTS. MY UNDERSTANDING THAT 191, THE SCORE WAS
20 LOWER FROM SOME OF THE PREVIOUS COMMENTS. I WAS
21 WONDERING IF THERE WAS SOME ADDITIONAL DETAIL. I
22 GOT CONFUSED.

23 CHAIRMAN IMBASCIANI: THE DOOR IS NOT
24 CLOSED, NOT AT ALL.

25 DR. CARETHERS: I DON'T THINK I CAN MAKE A

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1 MOTION, BUT IT COULD SEEM LIKE 19378 WOULD BE THE
2 ONE I WOULD INCLUDE, NOT 191.

3 DR. CANET-AVILES: THANK YOU, DR.
4 CARETHERS. SO FOR 19191, IN OUR VIEW THAT'S HOW WE
5 AGREED WITH THE GRANTS WORKING GROUP RECOMMENDATION
6 IS THAT IT'S HARD TO JUSTIFY FUNDING AS SUBMITTED.
7 THE APPLICATION AS IT WAS PROVIDED BY THE VERY GOOD
8 PUBLIC SPEAKERS, IT ADDRESSES A VERY REAL NEED. BUT
9 THE RECORD SUPPORTS THE GRANTS WORKING GROUP VIEW
10 THAT THE TRIAL IS NOT SUFFICIENTLY DIFFERENTIATING
11 ACTUALLY OR INTERPRETABLE FOR A 12 MILLION
12 FIRST-IN-HUMAN AWARD BECAUSE ISSUES ARE NOT THAT THE
13 BIOLOGY IS NOT PLAUSIBLE. THE REVIEWERS DID SAY
14 THAT THE RATIONALE IS SOUND AND THE PRECLINICAL DATA
15 ARE SUPPORTED.

16 THE PROBLEM IS THAT THE APPLICATION DIDN'T
17 CONVINCINGLY SHOW THAT THIS VACCINE IS MEANINGFULLY
18 BETTER THAN PRIOR AML VACCINE EFFORTS. AND THE
19 PROPOSED TRIAL MAY NOT GENERATE THE CLEAR GO/NO-GO
20 ANSWERS.

21 SO WITH THAT, OUR STRONG RECOMMENDATION IS
22 THEY CAN COME BACK AND ADDRESS THE REVIEWERS'
23 COMMENTS AND REAPPLY.

24 ONE OF THE THINGS THAT WE WILL HAVE TODAY
25 IN THE DISCUSSION THAT WE WILL BE PROVIDING WITH

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1 REGARDS TO THE PREFERENCES GOING INTO GUIDING
2 PRINCIPLES IS WHAT ARE OUR GUIDING PRINCIPLES. AND
3 WE'RE GOING TO REVIEW WHAT THE GUIDING PRINCIPLES
4 FOR CLIN2 ARE. WE WANT TRANSFORMATIVE THERAPIES
5 THAT DIFFERENTIATE FROM WHAT'S ALREADY OUT THERE.
6 RIGHT. AND WE HAVE A LIMITED AMOUNT OF FUNDING AND
7 TIME. RIGHT.

8 SO WITH THAT, OUR RECOMMENDATION COULD BE
9 WHAT THE GRANTS WORKING GROUP SAID, ADDRESS THOSE
10 ISSUES AND COME BACK. AND THERE ARE FOUR INSTANCES
11 OF CLINICAL APPLICATIONS A YEAR.

12 DR. CARETHERS: THANK YOU. VERY HELPFUL.

13 CHAIRMAN IMBASCIANI: ANY OTHER QUESTIONS
14 FROM BOARD MEMBERS? I PRESUME WE'RE GOING TO HEAD
15 TO A VOTE ON THE AMENDMENT FIRST BEFORE THE MAIN
16 MOTION. ANY MEMBER OF THE PUBLIC WANT TO COMMENT ON
17 THE AMENDMENT? PLEASE. IF I REMEMBER, DR.
18 GAENSLER, YES?

19 DR. GAENSLER: I'M PERMITTED?

20 CHAIRMAN IMBASCIANI: YES. FLOOR IS
21 YOURS.

22 DR. GAENSLER: THANK YOU VERY MUCH FOR ALL
23 THIS DISCUSSION. I THINK WHAT HAS GOTTEN BURIED IS
24 THE VERY PROMISING DATA THAT WE DO HAVE. IN OUR
25 PROOF OF CONCEPT DATA, WE LOOKED AT THE ABILITY OF

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1 THIS VACCINE TO ERADICATE ACTIVE, AGGRESSIVE
2 LEUKEMIA, WHICH IT DID IN 80 PERCENT OF MODELS OF
3 THE VERY AGGRESSIVE DISEASE. I KNOW THAT'S A MOUSE
4 MODEL. HOWEVER, IN OUR IN VIVO DATA, WE WERE ABLE
5 TO TAKE PATIENT IMMUNE CELLS AFTER REMISSION
6 INDUCTION AND CO-CULTURE THEM WITH THE VACCINE AND
7 SEE SPECIFIC LEUKEMIALYTIC EFFECTS THAT DID NOT
8 TARGET THE NORMAL BONE MARROW IN MOST PATIENTS. AND
9 WHILE THESE WERE VARIABLE, THEY WERE STRIKING
10 BECAUSE THE IMMUNE EFFECTS WERE SEEN IN REMISSION
11 PATIENT CELLS WHO HAD RECEIVED LYMPHODEPLETING
12 THERAPY.

13 SO I THINK THIS IS VERY STRONG EVIDENCE
14 THAT THIS COULD HAVE ACTIVITY. AND IT IS VERY
15 DIFFERENT, AND I'LL NOW BE A LITTLE BIT SCIENTIFIC,
16 FROM OTHER VACCINES BECAUSE WE HAVE PROVIDED THE
17 COAST IMMULATORY SIGNAL, CD 80, TO ACTUALLY TRIGGER
18 CYTOLYTIC T-CELL EFFECTS. AND FOR THAT REASON, IT
19 IS DIFFERENT FROM EVERY OTHER VACCINE ON THE MARKET
20 AND CAN BE MADE FOR ANY PATIENT EXCLUSIVE OF HLA
21 ETHNIC OR OTHER DESCRIPTORS OF PATIENTS.

22 SO THIS IS A UNIVERSALLY APPLICABLE
23 VACCINE THAT WE KNOW HOW TO MAKE. UNFORTUNATELY,
24 DON KOHN WAS NOT ABLE TO GET ON AND TELL YOU THAT
25 THE MANUFACTURING IS HIGHLY DEVELOPED AND EFFICIENT.

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1 AND SO IT IS VERY ATTRACTIVE TO HAVE A THERAPY THAT
2 REALLY ANY PATIENT COULD GET IN THEIR OWN COMMUNITY
3 WITHOUT TRAVELING TO A MAJOR MEDICAL CENTER WITH THE
4 FINANCIAL COST AND DIFFICULTIES ATTENDANT. THANK
5 YOU FOR LETTING ME SPEAK.

6 CHAIRMAN IMBASCIANI: THANK YOU. OUR
7 PRESIDENT AND CEO, J.T.

8 DR. THOMAS: YES. THANK YOU, MR.
9 CHAIRMAN. THANK YOU, EVERYBODY, FOR YOUR COMMENTARY
10 TODAY. I JUST WANT TO, AS A GENERIC MATTER, NOTE TO
11 THE BOARD THAT THE GRANTS WORKING GROUP IN ANY
12 APPLICATION SEES ALL OF THE DATA THAT IS SUBJECT
13 MATTER OF COMMENTARY ON PARTICULAR APPLICATIONS AND
14 THROUGH RIGOROUS PROCESS COMES TO CONCLUSION, WHICH
15 IS EITHER TO FUND OR NOT FUND. IT'S IMPOSSIBLE AS
16 THE BOARD SITS HERE TODAY TO HEAR COMMENTARY THAT
17 ADDRESSES THE SCIENCE THAT YOU CAN EVALUATE AS TO
18 WHETHER THAT IS PERSUASIVE OVER AND ABOVE WHAT THE
19 GRANTS WORKING GROUP IN RIGOROUS AND ROBUST DEBATE
20 HAS ALREADY CONTEMPLATED.

21 SO I JUST MAKE THAT POINT, NOT WITH
22 SPECIFICITY TO ANY PARTICULAR APPLICATION, BUT JUST
23 GENERICALLY AS YOU CONSIDER MOTIONS LIKE THIS.
24 THANK YOU, MR. CHAIRMAN.

25 CHAIRMAN IMBASCIANI: THANKS, JONATHAN.

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1 YES, ADRIANA.

2 DR. PADILLA: DURING THE GWG
3 DELIBERATIONS, DID THE QUESTIONS GO OUT TO THE
4 PROJECT COORDINATORS ABOUT THE CHALLENGES THAT WERE
5 BEING NOTED SO THAT THEY COULD RE-DELIBERATE?

6 DR. LAM: SO THE REVIEW PROCESS ALLOWS
7 REVIEWERS TO ASK QUESTIONS TO THE APPLICANT AND
8 RESPOND IF THERE ARE ANY. I AM NOT A HUNDRED
9 PERCENT SURE ON THIS PARTICULAR APPLICATION, BUT I
10 WOULD HAVE TO DOUBLE-CHECK.

11 DR. PADILLA: I ALSO FEEL THERE'S A LOT OF
12 SCIENCE HERE THAT I CAN'T ASSESS. I REALLY NEED THE
13 GWG TO ASSESS THAT.

14 DR. LAM: THE GRANTS WORKING GROUP ALSO
15 HAS THE OPTION, IF THERE ARE SORT OF SCORED DRIVING
16 QUESTIONS, ALLOWS US TO CALL OUT LIVE DURING THE
17 MEETINGS TO THE APPLICANT IF THERE'S AN OUTSTANDING
18 QUESTION THAT THE ANSWER TO WHICH WOULD INFLUENCE
19 HOW THEY RECOMMEND THE APPLICATION IN THE FINAL
20 SCORING AS WELL.

21 DR. DAHL: I HAVE A QUESTION. CAN YOU
22 ALSO CLARIFY IF THERE'S ANOTHER -- YOU MENTION THERE
23 IS ANOTHER ROUND OF REVIEWS FOR THIS CLIN2 PROGRAM
24 THIS YEAR WITH THE BUDGET. WHAT IS THE TIMELINE FOR
25 THAT? SO IF SOMEBODY WAS GOING TO RESUBMIT SO THAT

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1 THE GWG COULD REVIEW AGAIN WITH THESE RESPONSES,
2 WHEN WOULD THAT UNFOLD?

3 DR. LAM: RIGHT. SO FROM THIS COHORT, IF,
4 FOR EXAMPLE, THERE WERE APPLICATIONS THAT ARE NOT
5 RECOMMENDED, THEY COULD COME IN AT THE END OF APRIL.
6 THERE'S A DEADLINE AT THE END OF APRIL FOR NEW
7 APPLICATIONS FOR WHICH THESE WOULD BE ELIGIBLE OR
8 ANY PROJECTS THAT AREN'T FUNDED ARE ELIGIBLE TO
9 SUBMIT AT THE END OF APRIL. I THINK IT'S APRIL
10 28TH.

11 DR. DULIEGE: THE DURATION OF THE REVIEW
12 CYCLE BECAUSE WHAT MATTERS IS WHEN THEY COULD -- IF
13 A GROUP REAPPLIES, WHEN WOULD BE THE REVIEW AND THE
14 DURATION OF THE PROCESS AND WHEN THEY WOULD HEAR
15 ABOUT A POTENTIAL OUTCOME OF THE REAPPLICATION?

16 DR. LAM: RIGHT. SO FOR THE APRIL, I
17 BELIEVE IT WOULD BE COMING TO SEPTEMBER ARS. I MEAN
18 IT WOULD COME TO THE BOARD IN SEPTEMBER.

19 DR. DULIEGE: OKAY.

20 CHAIRMAN IMBASCIANI: MARGUERITE.

21 MS. CASILLAS: JUST TO ADRIANA'S QUESTION.
22 SO I'M A PATIENT REVIEWER. WE ARE NOTIFIED OF WHEN
23 QUESTIONS ARE DUE. I FEEL LIKE THE CIRM TEAM DOES A
24 GOOD JOB TO ENCOURAGE US TO ASK QUESTIONS. EVERY
25 TIME I HAVE, I HAVE GOTTEN GOOD RESPONSES FROM

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1 APPLICANTS. SO THAT PIECE IS WORKING, I THINK.

2 CHAIRMAN IMBASCIANI: I DON'T SEE ANY MORE
3 COMMENTS FROM BOARD MEMBERS INCLUDING THOSE OUTSIDE
4 THE ROOM. ANY MEMBER OF THE PUBLIC WANT TO COMMENT?
5 NO. WE CAN PROCEED TO A VOTE ON THE AMENDMENT,
6 SCOTT.

7 MR. TOCHER: SO TO BE CLEAR, THIS IS A
8 MOTION TO AMEND THAT WE'RE VOTING ON. SO THERE WILL
9 STILL BE ANOTHER STEP ULTIMATELY. YOU WILL STILL BE
10 TAKING A VOTE ON THE UNDERLYING MOTION ASSUMING
11 THERE ISN'T ANOTHER MOTION TO AMEND WITH REGARD TO
12 THE OTHER APPLICATION. SO THE RESULTS OF THIS VOTE,
13 I'M NOT GOING TO CALL ON THOSE MEMBERS WHO HAVE A
14 CONFLICT AS TO EITHER OF THE APPLICATIONS BECAUSE
15 THIS AFFECTS THAT PENDING MOTION.

16 SO, AGAIN, THIS WILL JUST BE A MOTION TO
17 WHETHER THE ORIGINAL WILL BE AMENDED. SO AN AYE
18 VOTE WILL ESSENTIALLY BE TO FUND APPLICATION 19191
19 AND THEN NOT FUND 19378. THAT WILL BE THE NEW SHAPE
20 OF THE UNDERLINING MOTION.

21 CHAIRMAN IMBASCIANI: I SEE KEITH'S HAND
22 UP.

23 DR. YAMAMOTO: YES. I DON'T KNOW IF I
24 CAN --

25 MR. TOCHER: WAIT. WAIT. KEITH HAS A

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1 CONFLICT.

2 CHAIRMAN IMBASCIANI: THANK YOU. KEITH,
3 I'M SORRY, BUT I THINK YOU'RE CONFLICTED ON THIS.
4 SORRY TO INTERRUPT.

5 MR. TOCHER: SO I'LL TAKE THE VOTE NOW.
6 MARGUERITE CASILLAS.

7 MS. CASILLAS: NO.

8 MR. TOCHER: JUDY CHOU.

9 DR. CHOU: YES.

10 MR. TOCHER: LEONDRA CLARK-HARVEY.

11 DR. CLARK-HARVEY: NO.

12 MR. TOCHER: SHANNON DAHL.

13 DR. DAHL: NO.

14 MR. TOCHER: ANNE-MARIE DULIEGE.

15 DR. DULIEGE: YES.

16 MR. TOCHER: MARK FISCHER-COLBRIE.

17 MR. FISCHER-COLBRIE: NO.

18 MR. TOCHER: VITO IMBASCIANI.

19 CHAIRMAN IMBASCIANI: YES.

20 MR. TOCHER: RICH LAJARA.

21 MR. LAJARA: NO.

22 MR. TOCHER: ADRIANA PADILLA.

23 DR. PADILLA: NO.

24 MR. TOCHER: MARV SOUTHARD.

25 DR. SOUTHARD: NO.

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1 MR. TOCHER: AND KEVIN XU.

2 MR. XU: NO.

3 MR. TOCHER: THE MOTION TO AMEND DOES NOT
4 PASS.

5 CHAIRMAN IMBASCIANI: OKAY. DISCUSSION
6 AGAIN ON THE ORIGINAL MOTION. ARE WE FINISHED WITH
7 THE DISCUSSION ON THAT? IF ANY BOARD MEMBER WANTS
8 TO MAKE A COMMENT OR A MEMBER OF THE PUBLIC. DO YOU
9 SEE ANY HANDS, CLAUDETTE? NO. OKAY. SCOTT, WE CAN
10 GO TO THE ORIGINAL MOTION UNLESS THERE'S ANOTHER.

11 DR. DULIEGE: CAN YOU REPEAT THE ORIGINAL
12 MOTION FOR CLARITY PLEASE?

13 MR. TOCHER: CERTAINLY. THE MOTION IS TO
14 NOT FUND APPLICATIONS 19378 AND 19191.

15 SO FOR THE FOLLOWING MEMBERS, BONNEVILLE,
16 DURON, FLOWERS, MIASKOWSKI, AND WATSON, YOU HAVE A
17 CONFLICT. SO PLEASE INDICATE YOUR VOTE, AGAIN, WITH
18 THE EXCEPTION OF THOSE WITH WHICH YOU HAVE A
19 CONFLICT.

20 MARIA BONNEVILLE.

21 VICE CHAIR BONNEVILLE: YES, EXCEPT FOR
22 THOSE WITH WHICH I HAVE A CONFLICT.

23 MR. TOCHER: MARGUERITE CASILLAS.

24 MS. CASILLAS: YES.

25 MR. TOCHER: JUDY CHOU.

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DR. CHOU: YES.

MR. TOCHER: LEONDRA CLARK-HARVEY.

DR. CLARK-HARVEY: YES.

MR. TOCHER: SHANNON DAHL.

DR. DAHL: YES.

MR. TOCHER: ANNE-MARIE DULIEGE.

DR. DULIEGE: NO.

MR. TOCHER: YSABEL DURON.

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

MR. TOCHER: MARK FISCHER-COLBRIE.

MR. FISCHER-COLBRIE: YES.

MR. TOCHER: ELENA FLOWERS.

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

MR. TOCHER: VITO IMBASCIANI.

CHAIRMAN IMBASCIANI: YES.

MR. TOCHER: RICH LAJARA.

MR. LAJARA: YES.

MR. TOCHER: CHRIS MIASKOWSKI.

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

MR. TOCHER: ADRIANA PADILLA.

DR. PADILLA: YES.

MR. TOCHER: MARV SOUTHARD.

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1 DR. SOUTHARD: YES.

2 MR. TOCHER: KAROL WATSON.

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

5 MR. TOCHER: KEVIN XU.

6 MR. XU: YES.

7 MR. TOCHER: THANK YOU. AND THAT MOTION
8 CARRIES.

9 CHAIRMAN IMBASCIANI: GREAT. THANK YOU
10 AND THANK YOU, HAYLEY. YOU WANT A BREAK?

11 MR. TOCHER: WE WOULD LOVE A TEN-MINUTE
12 BREAK.

13 CHAIRMAN IMBASCIANI: YES. YOU MAY HAVE.

14 MR. TOCHER: THANK YOU. SO WE'LL SEE YOU
15 AT 10:30.

16 (A RECESS WAS TAKEN.)

17 CHAIRMAN IMBASCIANI: I PRESUME WE CAN
18 CONVENE AGAIN. OKAY. WE'RE GOING TO START
19 IMMEDIATELY. OKAY. WE'RE GOING TO TAKE UP WHERE WE
20 LEFT OFF AND DIRECT EVERYONE'S ATTENTION TO AGENDA
21 ITEM NO. 9. THIS IS GOING TO BE A DISCUSSION OF
22 AMENDMENTS TO THE COMMUNITY CARE CENTER OF
23 EXCELLENCE CONCEPT PLAN OR INFRASTRUCTURE 8. AND
24 THE PRESENTATION WILL BE LED BY THE ASSISTANT
25 DIRECTOR OF PATIENT ACCESS, DR. GEOFF LOMAX.

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1 DR. LOMAX: THANK YOU, MR. CHAIRMAN.

2 BETH, ARE WE OKAY SOUNDWISE?

3 THE REPORTER: YES.

4 DR. LOMAX: THANK YOU. I'D LIKE TO THANK
5 THE CIRM LEADERSHIP FOR GIVING US THE OPPORTUNITY TO
6 PRESENT THIS ITEM AND ACKNOWLEDGE THE PATIENT ACCESS
7 TEAM FOR THEIR EFFORT IN PULLING THESE MATERIALS
8 TOGETHER AND ALL THE THOUGHT BEHIND IT.

9 SO, AGAIN, THIS IS FOR YOUR CONSIDERATION
10 THE REOPENING OF OUR INFR8 PROGRAM, WHICH IS MORE
11 COMMONLY KNOWN AS THE COMMUNITY CARE CENTERS OF
12 EXCELLENCE PROGRAM. JUST A BRIEF REMINDER OF THE
13 CONTOURS OF THIS PROGRAM. IT IS MANDATED BY
14 PROPOSITION 14 TO ESTABLISH THE COMMUNITY CARE
15 CENTERS OF EXCELLENCE.

16 THE AIM OF THE PROGRAM IS TO EXPAND THE
17 CAPACITY OF OUR EXISTING CLINICAL TRIAL NETWORK
18 WHICH IS EMBODIED IN THE ALPHA CLINICS NETWORK WITH
19 THE AIM OF PROMOTING ACCESS TO BOTH HUMAN CLINICAL
20 TRIALS AND TREATMENTS THAT ARISE FROM THOSE TRIALS,
21 PARTICULARLY INSTITUTE-FUNDED PROGRAMS.

22 AND A MAIN CRITERIA FOR PRIORITIZING FOR
23 THE PROGRAM ITSELF IS TO ENSURE THERE'S GEOGRAPHIC
24 DIVERSITY IN THOSE CENTERS. AND SO WE KNOW THAT
25 GEOGRAPHIC DIVERSITY IS CRITICAL TO MAKING

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1 TREATMENTS BROADLY AVAILABLE TO PATIENTS AS WE HEARD
2 FROM A NUMBER OF COMMENTS, THAT PROXIMITY AND ACCESS
3 GO HAND IN HAND. SO THIS PROGRAM IS INTENDED TO
4 ACHIEVE THAT OUTCOME.

5 I'M GOING TO UPDATE YOU ON THE STATUS OF
6 THE PROGRAM AS IT STANDS AT THE MOMENT. IN OCTOBER
7 OF 2025, YOU APPROVED THREE AWARDS PURSUANT TO THE
8 INFR8 PROGRAM. THOSE AWARDS TOTALED A \$27 MILLION
9 COMMITMENT. THE ORIGINAL BUDGET THAT YOU AUTHORIZED
10 IN THE CONCEPT PLAN WAS 36 MILLION. SO THERE WAS
11 REMAINING FUNDS AVAILABLE THROUGH YOUR INITIAL
12 AUTHORIZATION FOR THIS PROGRAM. THOSE FUNDS ARE
13 STILL REMAINING.

14 ALSO WANT TO GIVE YOU A PERSPECTIVE OF THE
15 CURRENT STATUS OF OUR CLINICAL INFRASTRUCTURE
16 PROGRAM AS IT STANDS RIGHT NOW. AND THAT'S
17 ILLUSTRATED BY THE MAP ON THE RIGHT SIDE OF THIS
18 SLIDE. WE'VE GOT THE ALPHA CLINICS IN RED AND THE
19 COMMUNITY CARE CENTERS IN BLUE. AND I THINK WHAT
20 WE'RE TRYING TO GET ACROSS AND THAT MAP ILLUSTRATES
21 QUITE NICELY IS OUR CURRENT FOOTPRINT IS WITHIN THE
22 STATE, BUT SOUTH OF SACRAMENTO. SO THERE'S ABOUT
23 ONE-THIRD OF THE AREA OF THE STATE THERE IS NO
24 CLINICAL FOOTPRINT TO SERVE PATIENTS.

25 AND DURING THE OCTOBER MEETING, THE ICOC

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1 EXPRESSED CONCERNS ABOUT THIS GEOGRAPHIC GAP. AND
2 POINTING OUT THAT THIS REGION IS NOT SERVED BY ANY
3 CURRENT CLINICAL INFRASTRUCTURE. THAT REPRESENTS A
4 POPULATION OF ABOUT 3 MILLION CALIFORNIANS. AND SO
5 THE BOARD DIRECTED THE TEAM TO IDENTIFY OPTIONS TO
6 EXPAND THE REACH OF OUR CLINICAL INFRASTRUCTURE INTO
7 NORTHERN CALIFORNIA. AND SO WE SET ABOUT DOING
8 THAT.

9 WE'VE ACTUALLY ENGAGED WITH CENTERS -- WE
10 KNOW THERE IS CAPACITY IN THAT REGION. AND BECAUSE
11 THERE IS SUCH CAPACITY, WHAT WE'RE RECOMMENDING IS
12 THAT WE REOPEN THE COMMUNITY CARE CENTER OF
13 EXCELLENCE REQUEST FOR APPLICATIONS. THAT WOULD
14 REQUIRE SOME VERY MINOR TECHNICAL AMENDMENTS. WE'RE
15 ASKING THE AUTHORIZATION OF \$9 MILLION WHICH WOULD
16 FUND ONE AWARD. AND THAT 9 MILLION REPRESENTS THE
17 UNCOMMITTED FUNDS FROM THE PREVIOUS CONCEPT PLAN YOU
18 APPROVED LAST YEAR. WE WOULD OBVIOUSLY HAVE TO
19 MODIFY OUR DEADLINES AS WE HAVE TO HAVE NEW DATES.
20 AND WE WOULD LIMIT ELIGIBILITY TO APPLICANT
21 ORGANIZATIONS WITH CLINICAL OPERATIONS IN THOSE
22 NORTHERN COUNTIES WHICH WERE ILLUSTRATED IN THE
23 PREVIOUS SLIDE IN THE BOX.

24 WE WOULD ALSO PROPOSE A SOMEWHAT EXPEDITED
25 TIMELINE. SO THE LAUNCH, IF THERE IS AN APPLICATION

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1 THAT'S RECOMMENDED FOR FUNDING AND APPROVED BY THIS
2 BOARD, THAT THE START-UP WOULD COINCIDE AS QUICKLY
3 AS POSSIBLE WITH THE EXISTING AWARDS WHICH WE'VE
4 ACTUALLY JUST FINALIZED THE CONTRACT OF TWO OF THE
5 PROGRAMS YOU APPROVED IN OCTOBER. AND JUST AS A
6 SIDEBAR NOTE, THE EXCITEMENT AND THE ENTHUSIASM IS
7 PALPABLE. THOSE PROGRAMS ARE JUST SO EXCITING, AND
8 IT'S JUST A PLEASURE TO BE A PART OF THAT.

9 SO WE'D LIKE ANY NEW AWARD TO BE AS CLOSE
10 AS POSSIBLE TO THAT PROGRAM. SO WE'RE RECOMMENDING
11 THE PROGRAM WOULD CLOSE AT THE END OF JUNE, AND IT
12 WOULD COME TO THE APPLICATION REVIEW SUBCOMMITTEE IN
13 SEPTEMBER.

14 I'M GOING TO HAVE TO TAKE A CLASS IN
15 CLICKER. THERE WE GO. SO THE REQUEST IS THAT THE
16 BOARD REOPEN THE COMMUNITY CARE CENTERS OF
17 EXCELLENCE PROGRAM, WHICH IS INFR8, AND THAT THE
18 APPROVED CONCEPT PLAN, WHICH IS PART OF THE
19 MATERIALS NOTICED FOR THIS MEETING, THAT IT INCLUDES
20 THOSE MINOR MODIFICATIONS WHICH I COVERED IN THE
21 PREVIOUS SLIDE. SO WITH THAT, I TURN IT BACK TO THE
22 CHAIR.

23 CHAIRMAN IMBASCIANI: VICE CHAIR
24 BONNEVILLE.

25 VICE CHAIR BONNEVILLE: I'D LIKE MAKE A

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1 MOTION TO REOPEN THE COMMUNITY CARE CENTERS OF
2 EXCELLENCE FUNDING OPPORTUNITY WITH THE MODIFIED
3 CONCEPT PLAN.

4 DR. BARRETT: SECOND.

5 CHAIRMAN IMBASCIANI: OKAY. MOTION IS ON
6 THE TABLE. WE HAVE THE OPPORTUNITY TO DISCUSS.
7 ANNE-MARIE.

8 DR. DULIEGE: JUST CAN YOU GIVE US A
9 LITTLE BIT OF HISTORY OR PERSPECTIVE? YOU MAKE TO
10 REOPEN THIS CCE. WHEN THEY OPENED BEFORE, DID THEY
11 CLOSE? WHAT'S THE REOPENING?

12 DR. LOMAX: JUST TO BE CLEAR, SO THIS IS A
13 NEW PROGRAM. WE'VE JUST GONE THROUGH THE FIRST
14 FUNDING CYCLE AND APPROVED THREE AWARDS. AND THE
15 REOPENING IS NOT -- IS TO ALLOW -- WHEN WE APPROVED
16 THOSE AWARDS, ONE OF THE ELEMENTS OF THE APPROVAL
17 WAS TO TAKE THE MONEY OFF THE TABLE, SO TO SPEAK,
18 THAT 8 MILLION. SO THE REOPENING, IF YOU WILL, IS A
19 CONFUSING WAY OF SAYING CAN WE RE-ACCESS THAT 8
20 MILLION SO WE CAN ALLOW THE RFA TO OPEN AND ACCESS
21 THOSE FUNDS IF THERE IS A SUCCESSFUL APPLICANT
22 PURSUANT TO THAT RFA.

23 DR. DULIEGE: GREAT. THANK YOU.

24 VICE CHAIR BONNEVILLE: I WANT TO THANK
25 THE PATIENT ACCESS TEAM AND ALSO THE BOARD FOR

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1 DIRECTING THAT WE EXPLORE MORE IN THIS PART OF THE
2 STATE BECAUSE IT WAS CLEAR THAT WE NEEDED TO GO BACK
3 OUT AND ASSESS WHETHER OR NOT THERE WERE COMMUNITY
4 CARE CENTERS IN THAT REGION THAT COULD APPLY TO
5 EXPAND OUR FOOTPRINT. SO I REALLY APPRECIATE IT.
6 AND THERE'S BEEN A LOT OF WORK THAT'S BEEN DONE WITH
7 OUTREACH AND VISITING DIFFERENT SITES. AND SO THANK
8 YOU. I APPRECIATE IT. AND THANKS TO THE BOARD FOR
9 UNDERSTANDING HOW IMPORTANT THIS IS.

10 DR. SACKY: SIMILARLY, I WANT TO THANK
11 YOU FOR THE WORK. THIS IS REALLY EXCITING AND IT IS
12 IMPORTANT. I ALSO WANT TO THANK THE BOARD FOR
13 MAKING THE CALL THAT THIS WAS NOT SERVING THE WHOLE
14 STATE.

15 SO I GUESS MY QUESTION IS GOING FORWARD --
16 AND I'M ENTIRELY SUPPORTIVE OF REALLY REOPENING IT
17 TO ENSURE THAT WE HAVE GEOGRAPHIC DIVERSITY HERE.
18 BUT I GUESS MY QUESTION IS GOING FORWARD, WHEN WE
19 HAVE NEW INITIATIVES, WHAT WILL BE THE PROCESS THAT
20 WE WILL TAKE SO THAT FROM THE GET-GO WE'RE LOOKING
21 AT THIS DATA AS A WHOLE? I MEAN I KNOW THAT THESE
22 THINGS ARE ITERATIVE, BUT IT JUST SEEMS TO ME THAT
23 NOW THAT YOU'RE SHOWING THE GRAPH, IT SEEMS QUITE
24 OBVIOUS THAT WE HAD A GAP. SO WHAT STEPS WOULD WE
25 TAKE IN THE FUTURE TO ENSURE THAT IT WOULDN'T TAKE

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1 THE BOARD REACTING TO HAVE SOMETHING THAT IS
2 COMPREHENSIVE AND INCLUSIVE?

3 DR. LOMAX: THANK YOU FOR THAT QUESTION.
4 SO WHILE THE GAP COULD BE INTERPRETED AS WE WERE
5 REMISS AND MISSED SOMETHING, WE HAVE IN THE PRIOR
6 ROUND, WE DID ENGAGE APPLICANTS. AND I WOULD
7 NOTE -- AND THERE WERE A NUMBER OF AWARDS THAT
8 WEREN'T RECOMMENDED FOR FUNDING. LET'S SAY HAD ALL
9 THE AWARDS IN THE ORIGINAL ROUND BEEN RECOMMENDED
10 FOR FUNDING, THAT MAP WOULD HAVE LOOKED A BIT
11 DIFFERENT.

12 SO AT THE END OF THE DAY, WE AIM TO
13 FULFILL THE OBJECTIVES OF THE PROGRAM. BUT, AGAIN,
14 WE'RE STILL DEPENDENT ON THE APPLICANT TO SUBMIT AN
15 APPLICATION THAT IS DEEMED MERITORIOUS. AND SO IT
16 WASN'T A QUESTION OF NOT RECOGNIZING THE NEED. IT
17 WAS A QUESTION OF APPLICATIONS THAT WERE ULTIMATELY
18 FUNDED WHEN AT THE END OF THE DAY WE WERE LEFT WITH
19 THAT GAP.

20 SO THE PROCESS WORKED. AND WE'RE JUST
21 TRYING TO RESTART IT AGAIN NOW WITH THAT MORE NARROW
22 SET OF CONDITIONS TO ENSURE WE ACHIEVE THAT OUTCOME
23 AS BEST WE CAN PROVIDED THERE'S A FUNDABLE
24 APPLICATION THAT COMES THROUGH THE PROCESS.

25 DR. SACKY: THANK YOU FOR THE

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1 CLARIFICATION. SO ESSENTIALLY WHAT YOU'RE SAYING IS
2 THAT IT WAS THE CALIBER OF THE APPLICATIONS YOU
3 RECEIVED THAT LED TO WHAT APPEARED TO BE A GAP IN
4 NORTHERN CALIFORNIA?

5 DR. LOMAX: THAT'S CORRECT.

6 DR. SACEY: AND SO WHAT STEPS ARE WE
7 TAKING THEN NOW THAT WE'RE GOING TO FOCUS ON THEM?
8 I WOULD IMAGINE WE STILL WANT TO HAVE HIGH CALIBER
9 APPLICATIONS. SO DOES CIRM HAVE AN OPPORTUNITY TO
10 MAYBE HELP BUILD THE CAPACITY SO THAT THE
11 APPLICATIONS THAT COME FORWARD ARE, IN FACT, STRONG
12 ENOUGH THAT WE WERE ABLE TO FUND THEM?

13 DR. LOMAX: SO WE ALWAYS ENCOURAGE
14 APPLICANTS TO CONTACT THE CIRM TEAM AND ASK
15 QUESTIONS TO STRENGTHEN THEIR APPLICATION. AND IN
16 ADDITION, THERE ARE -- WITHIN THE NETWORK ITSELF, WE
17 SAW THIS IN THE FIRST ROUND AND I HAVE EVERY
18 EXPECTATION THIS WOULD OCCUR IF YOU WERE TO REOPEN
19 THIS APPLICATION, THAT THE APPLICANT ORGANIZATIONS
20 THEMSELVES WILL REACH OUT TO THE EXISTING CIRM
21 NETWORK OF ALPHA CLINICS AND IN THIS CASE COMMUNITY
22 CARE CENTERS AND ENGAGE WITH THOSE CENTERS AND
23 DEVELOP THE APPLICATION IN SUCH A WAY WHERE IT WILL
24 BE AS COMPETITIVE AS POSSIBLE. AND WE VERY MUCH
25 ENCOURAGE AND WILL FACILITATE THOSE COLLABORATIONS

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1 OR COMMUNICATIONS DURING THE PROCESS.

2 DR. PADILLA: THANK YOU. THAT WAS ONE OF
3 MY QUESTIONS. I WAS GOING TO ASK IS CIRM GOING TO
4 BE NURTURING SOME OF THE ORGANIZATIONS THAT APPLIED
5 DURING THE FIRST ROUND AND TO ASSIST THEM TO MOVE
6 INTO A MORE SUCCESSFUL SELECTION?

7 DR. LOMAX: AGAIN, WE OBVIOUSLY DO
8 EVERYTHING WE CAN TO MAKE THIS OPPORTUNITY VISIBLE
9 TO ORGANIZATIONS THAT APPEAR TO BE POSITIONED TO
10 APPLY. WE HELP FACILITATE THE NETWORKING
11 COMMUNICATIONS AS I HAD JUST INDICATED. AND AS
12 CO-CHAIR BONNEVILLE INDICATED AS WELL, WE'VE BEEN
13 OUT INTO THE REGION AND RECOGNIZE THERE ARE
14 ORGANIZATIONS THAT WOULD APPEAR TO BE ELIGIBLE FOR
15 THIS PROGRAM. AND SO, AGAIN, SHOWING THAT
16 VISIBILITY, GIVING THEM INFORMATION ABOUT THE
17 PROCESS. AND, AGAIN, I ANTICIPATE WE WILL HAVE
18 QUALITY APPLICANTS IN THIS ROUND.

19 I THINK WE HAVE TO BE VERY CAREFUL, I
20 THINK, ONCE WE OPEN AN APPLICATION, THAT WE'RE BEING
21 FAIR AND OBJECTIVE AND NOT GOING BEYOND OUR REMIT AS
22 WHAT WE CAN DO IN TERMS OF THE APPLICATIONS
23 THEMSELVES.

24 DR. PADILLA: ONLY BECAUSE THESE SITES
25 ALSO HAVE LIMITED RESOURCES TO PULL FROM, THEY MAY

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1 NOT HAVE THE EXPERTISE TO BUILD A ROBUST APPLICATION
2 PROCESS. AND IT WOULD BE INCUMBENT ON THE MAJOR
3 UNIVERSITY INSTITUTIONS IN NORTHERN CALIFORNIA TO
4 ALSO REALIZE THAT AND REACH OUT FROM THIS CALL OF
5 THIS NEW PROPOSAL.

6 DR. LOMAX: YEAH. AGAIN, I THINK THAT
7 INTEREST IS THERE WITH THE EXISTING CENTERS. AND
8 THERE'S CERTAINLY HEADROOM WITHIN OUR EXISTING
9 CLINICAL NETWORK FOR THOSE TEAMS TO SUPPORT SOME OF
10 THESE EFFORTS. SO I THINK IF THE INTEREST AND THE
11 TEAMS AND THE BRAIN POWER IS THERE, WE JUST NEED TO
12 GET -- PULL THOSE APPLICATIONS THROUGH.

13 CHAIRMAN IMBASCIANI: GOOD. BOARD MEMBER
14 ALMASRI.

15 DR. ALMASRI: SO I UNDERSTAND THAT WE
16 MISSED A BIG PART OF THE GEOGRAPHY, BUT DO WE HAVE
17 AT LEAST ROUGH ESTIMATE OF WHAT'S THE POPULATION OF
18 THIS AREA? IS IT 5 PERCENT OR 10 PERCENT OF THE
19 STATE? BECAUSE OBVIOUSLY WE ARE AFTER THE HUMAN SO
20 I TOTALLY UNDERSTAND BECAUSE ALSO LIMITING THE
21 REMAINING FUND TO ONLY SMALL GEOGRAPHIC AREA WHO MAY
22 NOT HAVE THE EXPERTISE AND RESOURCES TO CONDUCT WHAT
23 WE ARE TRYING TO DO CAN BE ALSO RESTRICTIVE.

24 DR. LOMAX: I'LL MAKE THIS COMMENT ON A
25 COUPLE OF REALITIES WE'VE SURFACED DURING OUR NEEDS

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1 ASSESSMENT AND LEAVE IT TO THE BOARD TO DETERMINE
2 HOW COMPELLING THEY ARE IN TERMS OF YOUR DECISION.
3 AGAIN, AS I INDICATED, WE'RE ROUGHLY ABOUT 3 MILLION
4 RESIDENTS. THAT AREA IS -- TWO OF THE EXISTING
5 MAJOR MEDICAL CENTERS IN THAT REGION ARE UNDER, AS
6 WE UNDERSTAND IT, TREMENDOUS STRAIN LARGELY BECAUSE
7 OF FEDERAL FUNDING CUTS. SO I WON'T CALL THEM OUT
8 BECAUSE I DON'T WANT TO SORT OF REPRESENT THEM, BUT
9 THAT AREA IS EXPERIENCING SUBSTANTIAL STRAIN IN
10 TERMS OF PATIENT ACCESS TO HEALTHCARE IN GENERAL.
11 THESE ARE MAJOR MEDICAL FACILITIES.

12 SO TO THE EXTENT THERE'S A NEED, IT'S
13 AMPLIFIED IN THAT REGION GIVEN CUTS TO FEDERAL
14 HEALTH FUNDING. THEY'RE ALSO, INTERESTINGLY ENOUGH,
15 LOOKING AT SORT OF THE EPIDEMIOLOGY OF THE REGION.
16 THERE ARE COMPARATIVELY HIGH INCIDENCE OF CANCERS
17 THROUGHOUT THE NORTHERN PART OF THE STATE. ACTUALLY
18 I HAD AN EARLIER MAP OF THAT. I'M SORRY I DON'T
19 HAVE IT IN THE APPENDIX OR I WOULD SHOW IT. THOSE
20 ARE CONDITIONS WHICH ARE SORT OF UNIQUELY ALIGNED
21 WITH REGENERATIVE MEDICINE TREATMENTS.

22 SO IN TERMS OF THE BURDEN OF DISEASE, THAT
23 REGION IS SOMEWHAT UNUSUAL IN TERMS OF WHAT WE'RE
24 SEEING IN THE CANCER REGISTRY IN PARTICULAR. SO
25 THERE'S PERHAPS A UNIQUE OPPORTUNITY TO REALLY HELP

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1 PATIENTS IN THAT REGION. SO WITHIN THOSE NUMBERS,
2 HAVING A LARGER PROPORTION OF PATIENTS THAT COULD
3 POTENTIALLY BENEFIT IS A REAL POTENTIAL VALUE
4 PROPOSITION FOR THIS PROGRAM.

5 AND I THINK, FINALLY, JUST OVERALL CIRM'S,
6 WITH THE EXCEPTION OF A COUPLE OF CENTERS, OUR
7 FOOTPRINT IS SOMEWHAT LIMITED IN THAT REGION. AND
8 IF WE GO BACK TO THE PROPOSITION AND THE MANDATE FOR
9 SORT OF GEOGRAPHIC DIVERSITY AND ACCESS, OUR
10 INTERPRETATION WAS THAT WHAT WE'RE BRINGING FORWARD
11 TODAY DOES ALIGN WITH WHAT THE PROPOSITION IS ASKING
12 FOR. SO I HOPE THAT'S HELPFUL IN TERMS OF HOW YOU
13 WEIGH THE BENEFITS OR THE VALUE PROPOSITION OF WHAT
14 WE'RE PROPOSING.

15 DR. SACKY: QUESTION.

16 CHAIRMAN IMBASCIANI: JOYCE.

17 DR. SACKY: A LOT OF WHAT YOU JUST SAID,
18 THAT THE MAJOR INSTITUTIONS IN THE REGION ARE UNDER
19 SUCH CONSTRAINTS, I WONDER, I WONDER WHETHER
20 LIMITING THIS EXTENDED DEADLINE TO ONLY THAT REGION
21 MIGHT, IN FACT, ACHIEVE WHAT WE'RE LOOKING FOR. IS
22 THERE A WAY IN WHICH WE MIGHT ENCOURAGE
23 COLLABORATION BETWEEN INSTITUTIONS IN THE CENTRAL
24 REGION, IN THE SOUTHERN SIDE OF CALIFORNIA WHO MIGHT
25 ACTUALLY HAVE THE CAPACITY AND ARE NOT AS DISTRACTED

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1 BY THE FUNDING CUTS TO SUPPORT THE APPLICANTS WHO
2 ARE GOING TO COME FROM THIS REGION?

3 DR. LOMAX: SO, AGAIN, JUST TO GIVE YOU A
4 LITTLE BIT OF A SENSE OF HOW WE TRY THROUGH A NEEDS
5 ASSESSMENT PROCESS LOOK AT ISSUES LIKE FEASIBILITY,
6 CAPACITY, AND IN TERMS OF THEN INFORMING THE
7 TIMELINES. SO IN DISCUSSIONS, AND I'LL ACKNOWLEDGE
8 BECAUSE THERE IS NO -- IN DISCUSSIONS, FOR EXAMPLE,
9 WITH FRESNO, WHO WE'VE JUST FUNDED IN THE FIRST
10 ROUND, THEY WERE EXTREMELY OPEN AND MOTIVATED TO
11 ENGAGE APPLICANTS AS A SORT OF PEER TO PEER BECAUSE
12 THEY'RE A CENTER THAT THEY HAVE A LOT OF
13 CHARACTERISTICS OF THE TYPE OF APPLICANT THAT WOULD
14 COME INTO THIS PROGRAM.

15 SO IN TERMS OF THE COLLABORATIONS YOU'RE
16 ALLUDING TO, I THINK THERE'S VERY MUCH A WILLINGNESS
17 AMONGST THE EXISTING CENTERS TO DRIVE THOSE
18 COLLABORATIONS, SUPPORT THOSE APPLICANTS. AND
19 THEY'RE FRESH OFF OF COMING THROUGH IN OCTOBER.

20 SO OUR SENSE IS THAT THAT SUPPORT WILL BE
21 THERE, BUT ACKNOWLEDGE THAT THESE CENTERS CAN HAVE
22 MORE LIMITED CAPACITY. I THINK IT GOES BACK TO THE
23 COMMENT PREVIOUSLY. BUT WE DO TRY TO MATCHMAKE AND
24 SORT OF PROVIDE THOSE SUPPORT STRUCTURES BECAUSE
25 OBVIOUSLY OUR MISSION IS TO GET -- OUR GOAL IS TO

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1 GET THE BEST APPLICATIONS POSSIBLE. SO IT'S
2 STRIKING THAT BALANCE.

3 CHAIRMAN IMBASCIANI: OKAY. BOARD MEMBER
4 PAT LEVITT IS NEXT. UNMUTE PLEASE.

5 DR. LEVITT: I AM UNMUTED. CAN YOU HEAR
6 ME?

7 DR. SOUTHARD: YES, WE CAN HEAR YOU.

8 DR. LEVITT: ALL RIGHT. THANK YOU. I
9 JUST WANTED TO SAY THAT THE COMMUNITY CARE CENTERS
10 OF EXCELLENCE ARE REALLY CRITICAL IN TERMS OF THEIR
11 OPERATIONS LOCALLY. AND THAT RIGHT NOW 3 MILLION
12 PEOPLE IN THAT PART OF THE STATE, IF THEY WANT TO
13 GET ACCESS TO THE PROGRAMS THAT WOULD FACILITATE AND
14 IMPROVE EVEN REFERRALS FOR WHAT WE'RE TRYING TO DO
15 FOR CLINICAL TRIALS AND FOR OTHER KINDS OF
16 TREATMENTS, WE NEED THEM LOCALLY IN THAT REGION.
17 IT'S 3 MILLION PEOPLE.

18 I'VE TALKED TO GEOFF ABOUT THIS. THERE IS
19 A LOT OF COLLABORATION ALREADY AMONGST THOSE THAT
20 HAVE BEEN FUNDED AND A WILLINGNESS TO SHARE THEIR
21 STRATEGIES FOR HOW THEY IMPROVE ACCESS AND ENGAGE
22 WITH THE COMMUNITIES. SO I THINK THIS IS A REALLY
23 POSITIVE MOVE. I THINK THE CIRM TEAM HAS DONE A LOT
24 OF DUE DILIGENCE IN TERMS OF UNDERSTANDING WHAT THE
25 OPPORTUNITIES ARE IN THAT REGION FOR FUNDING REALLY

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1 STRONG APPLICATIONS. THANKS.

2 CHAIRMAN IMBASCIANI: THANK YOU, PAT.

3 YES, KIM.

4 DR. BARRETT: YEAH. I JUST WANTED TO
5 COMMENT ON WHAT I SEE AS THE GREAT IMPORTANCE OF
6 THIS PROPOSAL. AS THE ACADEMIC MEDICAL CENTER THAT
7 IS THE FURTHEST NORTH IN CALIFORNIA, AT UC DAVIS WE
8 HAVE A LOT OF INTERACTIONS WITH MEDICAL FACILITIES
9 IN THIS PART OF THE STATE. THERE'S CERTAINLY A HUGE
10 AMOUNT OF NEED. BUT ALSO SOME VERY ENERGETIC AND
11 ENTHUSIASTIC PARTNERS THAT WE'VE HAD DISCUSSIONS
12 WITH ABOUT OTHER TYPES OF COLLABORATION. BUT THOSE
13 CONVERSATIONS LET US KNOW HOW MUCH THIS IS NEEDED.
14 AND WHEN WE'RE TALKING ABOUT ALL THE WAY UP TO THE
15 BORDER WITH OREGON, THOSE PEOPLE ARE WAY TOO FAR
16 FROM THE EXISTING CENTERS TO HAVE THE ABILITY TO
17 ACCESS.

18 CHAIRMAN IMBASCIANI: THANK YOU, KIM.
19 ANNE-MARIE.

20 DR. DULIEGE: JUST TO SAY THAT I'M ALSO
21 VERY MUCH IN FAVOR OF THIS PROPOSAL. BUT MAYBE A
22 MORE BASIC QUESTION FOR SOME OF US WHO MAY NOT HAVE
23 BEEN PART OF THE BOARD FOR A LONG TIME, CAN YOU
24 REMIND US THE MANDATE OF THE COMMUNITY CARE CENTERS
25 OF EXCELLENCE? WHAT DEFINES A GREAT CENTER? AND

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1 FOR THOSE CENTERS THAT HAVE BEEN OPEN FOR SOME TIME
2 NOW, HOW HAVE THEY HELPED THE MISSION OF THE CIRM?
3 WHAT DIFFERENCE THEY HAVE MADE. I'M SURE IT WOULD
4 BE GREAT TO HAVE THAT.

5 DR. LOMAX: THANK YOU FOR THAT. I JUST
6 WANT IT TO GO BACK AS A REMINDER. SO THIS PROGRAM
7 WE HAVE -- THIS PROGRAM IS THREE DAYS OLD. WE HAVE
8 JUST -- WE'VE JUST SIGNED OUR FIRST CONTRACT. SO
9 THIS IS A NEW PROGRAM. YOUR OCTOBER DECISION WAS
10 THE INITIAL ROUND OF FUNDING FOR THIS PROGRAM. AND
11 SO WE DON'T -- WE CAN'T GIVE YOU OUTCOMES AT THIS
12 TIME. SO THIS IS AN EXPERIMENT, BUT IT'S PROBABLY
13 ONE OF THE COOLEST EXPERIMENTS IN REGENERATIVE
14 MEDICINE RIGHT NOW. EVERYONE, AGAIN, I THINK TWO
15 YEARS OF NEEDS ASSESSMENTS, INTERACTING BOTH WITH
16 COMMERCIAL PROVIDERS WHO HAVE APPROVED THERAPIES AND
17 OUR CLINICAL TRIALISTS WHO ARE TRYING TO REACH
18 PATIENTS, EVERYONE COMES BACK TO THE VALUE AND THE
19 IMPORTANCE OF WORKING OUTSIDE OF THE ACADEMIC
20 CENTERS TO ENGAGE THESE PATIENTS.

21 AND SO WE THINK, BASED ON THAT SORT OF
22 COLLECTIVE WISDOM, WE'VE REALLY LINED UP A PROGRAM
23 THAT'S GOING TO BE FIT FOR PURPOSE, BUT WE JUST
24 CAN'T ANSWER AT THIS TIME.

25 I DO WANT TO COME BACK TO THE POINT THAT

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1 IF WE CAN GET THEM ALL WORKING AT THE SAME CADENCE,
2 WHICH IS WHAT WE'RE TRYING TO DO HERE, IS TO ALLOW
3 THIS FIRST COHORT TO MOVE AT ROUGHLY THE SAME
4 CADENCE, WE SEE A LOT OF VALUE IN THAT BECAUSE
5 THERE'S A LOT CO-LEARNING AND LEARNING IN THAT SORT
6 OF INITIAL UPTAKE PROCESS, ACCREDITATION, THE
7 CLINICAL RESEARCH ASPECTS OF IT. IF THEY CAN SORT
8 OF WORK WITH EACH OTHER IN A PARTNERED ENVIRONMENT,
9 WE THINK WE CAN GET THAT ONE PLUS ONE EQUALS THREE
10 IN THE VALUE OF THE NETWORK. BUT, LIKE I SAY, THIS
11 IS ONE OF THOSE GREAT CIRM EXPERIMENTS.

12 CHAIRMAN IMBASCIANI: I THINK PART OF THAT
13 QUESTION WAS THE MANDATE.

14 DR. LOMAX: I'VE JUST COME BACK TO THE
15 SLIDE TO KIND OF REMIND US OF HOW PROP 14 PUT
16 FORWARD THIS REQUEST OR PUT FORWARD THIS MANDATE IN
17 THE PROPOSITION.

18 CHAIRMAN IMBASCIANI: YES. GOOD. NO
19 OTHER COMMENTS FROM BOARD MEMBERS OR QUESTIONS FOR
20 GEOFF? WE'LL OPEN IT UP TO MEMBERS OF THE PUBLIC.
21 THERE ARE NONE. OKAY.

22 SO WE HAVE A REQUEST OF THE BOARD TO --
23 PUT THE REQUEST BACK UP AGAIN -- TO ALTER THE
24 INFRASTRUCTURE 8 PROGRAM WITH AMENDMENTS THAT GEOFF
25 HAS GONE THROUGH AND APPROVE THE MODIFIED CONCEPT

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1 PLAN. SO I THINK WE CAN GO TO A VOTE.
2 MR. TOCHER: OKAY. SO I'LL TAKE A VOICE
3 VOTE IN THE ROOM, AND THEN I MUST POLL MEMBERS
4 INDIVIDUALLY ON THE ZOOM. SO ALL THOSE IN THE ROOM
5 IN FAVOR SAY AYE. THOSE OPPOSED NAY. ANY
6 ABSTENTIONS? AND I'LL POLL THE MEMBERS ON THE ZOOM.
7 MONICA CARSON.
8 DR. CARSON: AYE.
9 MR. TOCHER: JUDY CHOU.
10 DR. CHOU: AYE.
11 MR. TOCHER: YSABEL DURON.
12 MS. DURON: AYE.
13 MR. TOCHER: MARK FISCHER-COLBRIE.
14 MR. FISCHER-COLBRIE: AYE.
15 MR. TOCHER: JUDY GASSON.
16 DR. GASSON: AYE.
17 MR. TOCHER: JEFF GOLDEN.
18 DR. GOLDEN: AYE.
19 MR. TOCHER: RICH LAJARA.
20 MR. LAJARA: AYE.
21 MR. TOCHER: PAT LEVITT.
22 DR. LEVITT: YES.
23 MR. TOCHER: HALA MADANAT. CHRIS
24 MIASKOWSKI.
25 DR. MIASKOWSKI: YES.

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1 MR. TOCHER: MARV SOUTHARD.

2 DR. SOUTHARD: YES.

3 MR. TOCHER: KAROL WATSON.

4 DR. WATSON: YES.

5 MR. TOCHER: KEVIN XU.

6 MR. XU: AYE.

7 MR. TOCHER: AND KEITH YAMAMOTO.

8 DR. YAMAMOTO: YES.

9 MR. TOCHER: GREAT. THANK YOU VERY MUCH.

10 THAT MOTION CARRIES.

11 CHAIRMAN IMBASCIANI: THAT CARRIES. THANK
12 YOU, SCOTT. SO GOOD. HAPPY TO MOVE ON TO AGENDA
13 ITEM NO. 10, WHICH WILL TAKE US UP TO OUR LUNCH
14 BREAK. THIS IS THE SECOND INSTALLMENT OF A NEW AND
15 REGULARLY OCCURRING AGENDA ITEM THAT FEATURES
16 RESEARCHERS AND PATIENTS WHO HAVE BENEFITED FROM
17 CIRM'S ACTIVITIES. AND TO LEAD THE DISCUSSION, OUR
18 DIRECTOR OF COMMUNICATIONS, AMY ADAMS.

19 MS. ADAMS: THANK YOU, EVERYONE. I'M
20 EXCITED TO ANNOUNCE TWO SPEAKERS TODAY. YOU'RE
21 FIRST GOING TO HEAR FROM DR. JAMES DEKLOE, WHO IS
22 DISTINGUISHED PROFESSOR OF BIOTECHNOLOGY AND
23 BIOMANUFACTURING AT SOLANO COLLEGE, WHICH IS IN
24 FAIRFIELD. HE RUNS OUR COMPASS PROGRAM IN
25 FAIRFIELD, AND THEY'VE DONE SOME INCREDIBLY

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1 INNOVATIVE STUFF THERE.

2 JIM WILL INTRODUCE SOME STUDENTS FROM THE
3 PROGRAM WHO WILL ALSO PRESENT. AND I JUST WANT TO
4 POINT OUT JIM IS SO DEDICATED TO THIS PROGRAM. AND
5 TALKING ABOUT IT WITH ALL OF YOU, HE TOOK A RED EYE.
6 IN THIS FLIGHT ENVIRONMENT, HE TOOK A RED EYE TO GET
7 HERE. SO I'M JUST INCREDIBLY GRATEFUL FOR THAT.

8 FOLLOWING THAT PRESENTATION, YOU'RE GOING
9 TO HEAR FROM DIANA FARMER. SHE IS SURGEON IN CHIEF
10 AT THE CHILDREN'S HOSPITAL OF THE UNIVERSITY OF
11 CALIFORNIA DAVIS AND CHIEF OF PEDIATRIC SURGERY AT
12 SHRINER'S CHILDREN'S NORTHERN CALIFORNIA.

13 SHE'S GOING TO PRESENT RESULTS FROM HER
14 WORK DEVELOPING A STEM CELL TREATMENT FOR SPINA
15 BIFIDA. CIRM HAS SUPPORTED SEVERAL STAGES OF HER
16 WORK AND IS CURRENTLY SUPPORTING A CLINICAL TRIAL.

17 SO, JIM, I'LL TURN IT OVER TO YOU.

18 (THE CLOSER TO CURES PRESENTATIONS
19 WERE THEN HEARD, NOT REPORTED NOR HEREIN
20 TRANSCRIBED.)

21 (A RECESS WAS TAKEN.)

22 CHAIRMAN IMBASCIANI: WE'RE COMING BACK
23 INTO LIVE SESSION HERE. THANK YOU, EVERYONE. I
24 HOPE YOU ENJOYED YOUR LUNCH.

25 WE ARE GOING TO JUST JUMP AHEAD

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1 TEMPORARILY TO AGENDA ITEM NO. 12. WE'LL COME BACK
2 TO 11 IN A MINUTE. THIS IS THE CONSIDERATION OF AN
3 AMENDMENT TO OUR WARRANT CO-FUNDING PROGRAM. THE
4 DISCUSSION WILL BE LED CHIEF COUNSEL RAFAEL
5 AGUIRRE-SACASA. RAFAEL.

6 MR. AGUIRRE-SACASA: THANK YOU, DR.
7 IMBASCIANI. GOOD AFTERNOON, EVERYONE. MY NAME IS
8 RAFAEL AGUIRRE-SACASA, AND I'M THE GENERAL COUNSEL.
9 AND I'M HERE TO UPDATE YOU ON THE WARRANT PROGRAM.
10 I'D ALSO LIKE TO THANK DR. SHYAM PATEL AND J.T.
11 WHO'VE ALSO BEEN HELPING ME WITH THE STRUCTURE AND
12 THE UPDATES HERE TO THIS PROGRAM.

13 WHAT WE'RE TALKING ABOUT TODAY IS A
14 TARGETED REFINEMENT TO THE CIRM WARRANT PROGRAM
15 WHICH WAS APPROVED BY THE ICOC IN DECEMBER OF 2023.
16 BEFORE WE GET TO THE SLIDES, I WANT TO GIVE YOU A
17 QUICK UPDATE ON THE STATUS OF THE PROGRAM.

18 AT A HIGH LEVEL, THE PROGRAM IS WORKING AS
19 IT'S INTENDED. IT PERMITS COMPANIES TO SATISFY
20 THEIR CO-FUNDING OBLIGATIONS THROUGH WARRANTS
21 INSTEAD OF CASH. AND THIS ALLOWS CIRM TO
22 PARTICIPATE IN THE UPSIDE OF ANY SUCCESSFUL
23 PROGRAMS.

24 WHERE WE'VE ENCOUNTERED CHALLENGES IS WITH
25 EARLY STAGE COMPANIES THAT HAVE NOT YET COMPLETED A

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1 PRICED EQUITY FINANCING. IN THOSE CASES THE CURRENT
2 STRUCTURE USES AN ASSIGNED PLACEHOLDER VALUATION OF
3 \$1 WHICH WE FOUND CAN CREATE DISTORTIONS AND MAKE
4 PARTICIPATION IN THE WARRANT PROGRAM MORE DIFFICULT.

5 SO WHAT WE'RE PROPOSING TODAY IS A NARROW,
6 PRACTICAL FIX BY INTRODUCING A SAFE WARRANT HYBRID.
7 WE'LL TALK ABOUT SAFE IN A MINUTE. AND THAT DEFERS
8 VALUATION UNTIL THERE'S A REAL MARKET FINANCING
9 WHICH PRESERVES THE SAME UPSIDE FOR CIRM IN THE
10 FUTURE. NOW TO THE SLIDES.

11 OUR ORIGINAL CO-FUNDING WARRANT STRUCTURE,
12 APPLICANTS COULD, AGAIN, SATISFY THE CO-FUNDING
13 REQUIREMENT BY ISSUING WARRANTS TO CIRM IN LIEU OF
14 CASH. AS A POINT OF REFERENCE, UNDER STATE LAW, WE,
15 CIRM, CANNOT HOLD EQUITY. AND THAT'S WHY WE
16 STRUCTURED THIS AS A WARRANT PROGRAM. THE CORE
17 STRUCTURE IS THAT CIRM RECEIVES A STOCK WARRANT
18 EQUAL TO THE WAIVED CO-FUNDING AMOUNT, AND THE
19 SHARES ARE DETERMINED BY DIVIDING THE CO-FUNDING
20 AMOUNT BY A REFERENCE PRICE.

21 FOR THE REFERENCE PRICE DETERMINATION, IT
22 DEPENDS ON THE CAPITALIZATION AND STRUCTURE OF THE
23 APPLICANT COMPANY. IF PREFERRED FINANCING EXISTS,
24 WE RECEIVE A PREFERRED WARRANT WITH A REFERENCE
25 PRICE EQUAL TO THE PRICE PER SHARES OF THE MOST

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1 RECENT PREFERRED STOCK FINANCING. FOR PUBLIC
2 COMPANIES, PRETTY STRAIGHTFORWARD. COMMON WARRANT,
3 REFERENCE PRICE IS THE AVERAGE OF THE CLOSING BID
4 ASK PRICES OR THE CLOSING PRICE FOR THE TEN-DAY
5 TRADING PERIOD ENDING FIVE TRADING DAYS BEFORE THE
6 ISSUE DATE. IN BOTH THOSE CASES, IT'S EASY TO
7 DETERMINE THE REFERENCE PRICE.

8 IN THE LAST SITUATION WHERE THERE IS NO
9 PREFERRED FINANCING, UNDER THE CURRENT STRUCTURE WE
10 RECEIVE A COMMON WARRANT, AND THE REFERENCE PRICE IS
11 THE DEFAULT \$1 PER SHARE SUBJECT TO ADJUSTMENT AND
12 NEGOTIATION. THE OTHER KEY WARRANT TERMS ARE AN
13 EXERCISED PRICE OF A PENNY PER SHARE, TEN-YEAR TERM
14 FOR THE WARRANT, ANTI-DILUTION PROTECTIONS THAT NOW
15 AUTOMATICALLY EXERCISES UPON IPO AND ACQUISITION,
16 WHICH ARE PRETTY STANDARD FOR WARRANT TERMS.

17 AS I MENTIONED, THE IMPLEMENTATION
18 CHALLENGE HAS ARISEN WHEN COMPANIES HAVE NOT YET
19 COMPLETED A PRICED EQUITY FINANCING, AND THAT MAKES
20 IT HARD TO DETERMINE THE RIGHT REFERENCE PRICE UNDER
21 THE ORIGINAL WARRANT STRUCTURE. WE INITIALLY USED A
22 \$1 REFERENCE PRICE, WHICH WE HAVE FOUND, AND WE'VE
23 HEARD FROM OUR APPLICANTS, SO THIS IS BASED ON
24 FEEDBACK THAT WE HAVE RECEIVED, THAT IT RAISES
25 ARBITRARY EVALUATION ASSUMPTIONS WHICH CAN CREATE

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1 POTENTIAL DISTORTIONS TO OWNERSHIP PERCENTAGES AND
2 OBVIOUSLY CAN CREATE UNCERTAINTY FOR FUTURE
3 INVESTORS.

4 TO ADDRESS THESE VALUATION CHALLENGES, WE
5 ARE PROPOSING A WARRANT PROGRAM THAT INTRODUCES THE
6 SAFE WARRANT HYBRID STRUCTURE, WHICH WE'LL TALK
7 ABOUT IN A MINUTE. AND, AGAIN, THIS WOULD ONLY
8 APPLY TO COMPANIES WHERE A PUBLIC MARKET DOES NOT
9 EXIST FOR ITS COMMON STOCK AND NO SHARES OF
10 PREFERRED STOCK HAVE BEEN ISSUED. ANY QUESTIONS SO
11 FAR? OKAY. WE'LL CONTINUE WITH THE SECURITIES LAW
12 UPDATE.

13 THE UPDATED STRUCTURE, TO ADDRESS THESE
14 VALUATION CHALLENGES, WE'RE PROPOSING THE WARRANT
15 PROGRAM INTRODUCE A SAFE WARRANT STRUCTURE. THE
16 SAFE STANDS FOR A SIMPLE AGREEMENT FOR FUTURE
17 EQUITY. HOW THIS WORKS IS THAT WE WOULD RECEIVE A
18 SAFE WARRANT -- WE WOULD ENTER INTO A SAFE AGREEMENT
19 WITH THE APPLICANT. THE SAFE WOULD BE CONVERTIBLE
20 INTO WARRANTS EQUAL TO THE WAIVED CO-FUNDING AMOUNT,
21 SO SIMILAR TO WHAT WE HAD BEFORE. THE SAFE WOULD
22 CONVERT INTO PREFERRED STOCK WARRANT.

23 NOW, THE DIFFERENCE HERE IS THAT THE
24 WARRANT SHARES WOULD BE DETERMINED ON THE PREFERRED
25 FINANCING ROUND, WHENEVER THAT HAPPENS AT A FUTURE

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1 DATE. PART OF THAT IS THAT WE, CIRM, WOULD GET AN
2 ECONOMIC EQUIVALENT OF A 20-PERCENT DISCOUNT TO NEW
3 INVESTORS ON THE SALES PRICE, GIVING US 20 PERCENT
4 MORE RETURN ON THE SHARES OBVIOUSLY.

5 THERE WOULD ALSO BE A SIDE LETTER
6 PROVIDING FOR INFORMATION RIGHTS TO MAKE SURE THAT
7 CIRM IS APPRISED OF ALL SITUATIONS AND INFORMATION
8 THAT APPLY TO THE APPLICANT. AND THERE'S ALSO A
9 MOST FAVORED NATION CLAUSE THAT MEANS THAT WE WOULD
10 GET THE SAME TERMS AS OTHER INVESTORS IF THEY ARE
11 BETTER TERMS THAN WHAT HAPPENED AT THE MOST RECENT
12 FINANCING. SO WE ARE PROTECTED MOVING FORWARD.

13 THE KEY ADVANTAGES IS IT ALLOWS START-UPS
14 WITHOUT A PRICED EQUITY ROUND TO PARTICIPATE IN THE
15 PROGRAM. WE'VE RECEIVED DIRECT FEEDBACK FROM SOME
16 APPLICANTS THAT THEY WOULD NOT BE ABLE TO
17 PARTICIPATE UNDER THE CURRENT STRUCTURE BECAUSE THEY
18 FEEL IT WOULD CAUSE THEM PROBLEMS IN THE INVESTOR
19 COMMUNITY.

20 USING THE SAFE PRICE MECHANICS, WHICH ARE
21 WIDELY USED IN THE VALLEY AND ACROSS THE COUNTRY,
22 THIS ALIGNS WITH VENTURE MARKET PRACTICES. OF
23 COURSE, IT STILL PRESERVES OUR UPSIDE PROTECTION AS
24 WE WOULD HAVE HAD WITH THE ORIGINAL WARRANT
25 STRUCTURE. AND MOST IMPORTANTLY, IT AVOIDS A LOT OF

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1 FRICITION IN THE WHOLE PROCESS BECAUSE IT AVOIDS THE
2 NEED TO ASSIGN AN ARBITRARY VALUATION TO EARLY STAGE
3 COMPANIES WHICH CAN CREATE THOSE DISTORTIONS I'VE
4 TALKED ABOUT.

5 SO TO SUMMARIZE, THE UPDATED STRUCTURE
6 MAINTAINS OUR ABILITY TO CAPTURE VALUE, IT PRESERVES
7 OUR WARRANT-BASED UPSIDE PARTICIPATION, SIMPLIFIES
8 THE PARTICIPATION FOR EARLY STAGE COMPANIES BY
9 DEFERRING VALUATION UNTIL REAL FINANCING OCCURS,
10 AND, FINALLY, IT ALIGNS THE PROGRAM WITH CURRENT
11 VENTURE FINANCING PRACTICES.

12 AND THEN THE REQUEST IS THAT THE ICOC
13 APPROVE THE PROPOSED SAFE WARRANT STRUCTURE FOR USE
14 IN APPLICABLE FUNDING PROGRAMS WHERE A COMPANY HAS
15 NOT YET COMPLETED A PRICED EQUITY FINANCING. I'M
16 HAPPY TO ANSWER ANY QUESTIONS AT THIS TIME.

17 CHAIRMAN IMBASCIANI: THANK YOU, RAFAEL.
18 I'M GOING TO MOVE THAT THE BOARD ACCEPT THE REQUEST,
19 THAT WE APPROVE THIS CHANGE TO THE SAFE WARRANT
20 STRUCTURE. I'M MAKING A MOTION, YES.

21 VICE CHAIR BONNEVILLE: SECOND.

22 CHAIRMAN IMBASCIANI: SO THAT WILL OPEN
23 THE FLOOR TO DISCUSSION. THANKS FOR THAT LUCID
24 PRESENTATION. I KNOW THIS IS DENSE MATERIAL.
25 ANYONE HAVE ANY QUESTIONS OF THE -- J.T.

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1 DR. THOMAS: I WANT TO THANK RAFAEL AND
2 SHYAM FOR PUTTING THIS TOGETHER AND FOR SORTING OUT
3 THAT THIS IS SOMETHING THAT WE SHOULD BE DOING.
4 THIS IS JUST FOR MEMBERS OF THE BOARD. THIS IS AN
5 EXTREMELY CONVENTIONAL INSTRUMENT IN THE FINANCING
6 SPACE FOR EARLY STAGE COMPANIES AND SOMETHING
7 THAT'S -- WE'RE NOT REINVENTING ANYTHING HERE.
8 WE'RE JUST SORT OF TAKING THINGS MORE INTO THE
9 MAINSTREAM. SO STRONGLY ENDORSE THIS.

10 CHAIRMAN IMBASCIANI: THANK YOU, J.T.
11 SCOTT.

12 MR. TOCHER: NOT SURE WHERE THE FEEDBACK
13 IS COMING FROM. THE TEAM HAD THE OPPORTUNITY TO
14 PRESENT THIS TO CO-CHAIRS, KIM BARRETT'S ALTERNATE,
15 DON TAYLOR, AND HALA MADANAT, AND WALKED THROUGH IT
16 AS WELL, AND THEY ENDORSED THE APPROACH THAT YOU SEE
17 HERE.

18 CHAIRMAN IMBASCIANI: OKAY. THAT'S
19 IMPORTANT NEWS. THANK YOU.

20 MS. MANDAC: HALA HAS HER HAND RAISED.

21 CHAIRMAN IMBASCIANI: HALA. YES, I SEE
22 IT. HI, HALA. THANK YOU. THE FLOOR IS YOURS.

23 DR. MADANAT: I HAD MY HAND RAISED. I WAS
24 GOING TO SAY EXACTLY THE SAME THING, THAT WE MET AND
25 BOTH DON AND I AGREED THAT THIS WAS REALLY A GOOD

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1 IDEA. SO THAT'S ALL I WAS GOING TO SAY. THAT'S WHY
2 I LOWERED MY HAND.

3 MR. AGUIRRE-SACASA: THANK YOU, HALA.

4 CHAIRMAN IMBASCIANI: ANYONE ELSE HAVE
5 ANY -- QUESTIONS OR COMMENTS FROM ANYONE ELSE?
6 OKAY. MOTION, COMMENT, ANYONE? ANY COMMENTS FROM
7 THE PUBLIC EITHER IN THE AUDIENCE OR REMOTE? YOU
8 DON'T SEE ANY. ALL RIGHT. SCOTT, WE CAN PROCEED TO
9 A VOTE.

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

13 MONICA CARSON.

14 DR. CARSON: AYE.

15 MR. TOCHER: JUDY CHOU.

16 DR. CHOU: AYE.

17 MR. TOCHER: YSABEL DURON.

18 MS. DURON: YES.

19 MR. TOCHER: MARK FISCHER-COLBRIE.

20 MR. FISCHER-COLBRIE: YES.

21 MR. TOCHER: JUDY GASSON.

22 DR. GASSON: YES.

23 MR. TOCHER: JEFF GOLDEN.

24 DR. GOLDEN: YES.

25 MR. TOCHER: RICH LAJARA.

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1 MR. LAJARA: YES.
2 MR. TOCHER: PAT LEVITT.
3 DR. LEVITT: YES.
4 MR. TOCHER: HALA MADANAT.
5 DR. MADANAT: YES.
6 MR. TOCHER: CHRIS MIASKOWSKI.
7 DR. MIASKOWSKI: YES.
8 MR. TOCHER: MARV SOUTHARD.
9 DR. SOUTHARD: YES.
10 MR. TOCHER: KAROL WATSON.
11 DR. WATSON: YES.
12 MR. TOCHER: KEVIN XU.
13 MR. XU: AYE.
14 MR. TOCHER: AND KEITH YAMAMOTO.
15 DR. YAMAMOTO: YES.
16 MR. TOCHER: GREAT. THANK YOU VERY MUCH.
17 THAT MOTION CARRIES.
18 MR. AGUIRRE-SACASA: THANK YOU, BOARD.
19 CHAIRMAN IMBASCIANI: THANK YOU, RAFAEL.
20 WE'RE GOING NOW BACK TO AGENDA ITEM NO.
21 11. WE'VE DEDICATED A SUBSTANTIAL AMOUNT OF TIME ON
22 THE AGENDA FOR THIS LENGTHY DISCUSSION HERE. THE
23 CONSIDERATION OF PROGRAM PREFERENCES AND GUIDING
24 PRINCIPLES. AND I WOULD LIKE TO INVITE J.T.
25 DR. THOMAS: I THINK WE'RE GOING TO MARK

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1 FIRST AND THEN TO ME. MARK WANTED TO GIVE SOME
2 OPENING COMMENTS.

3 CHAIRMAN IMBASCIANI: OKAY.

4 MR. FISCHER-COLBRIE: THANK YOU, J.T.
5 JUST AS A REMINDER TO SET THE STAGE A LITTLE BIT,
6 AND I'M SURE J.T. WILL AMPLIFY THIS AS WELL, WE'RE
7 IN AN ENVIRONMENT WHERE, DUE TO LACK OF FUNDING IN
8 BIOTECH AND WITH THE IMPACT OF WHAT'S GOING ON AT
9 NIH AND OTHER FUNDING SOURCES, THERE HAS CONTINUED
10 TO BE A MASSIVE INCREASE IN THE NUMBER OF
11 APPLICATIONS SUBMITTED TO CIRM ACROSS THE BOARD FOR
12 ADVANCING RESEARCH. THAT'S POINT NO. 1.

13 POINT NO. 2 IS THAT, AS CIRM HAS CONTINUED
14 ITS GOALS OF IMPROVEMENT AND ACCELERATION, THE
15 STRATEGIC ALLOCATION FRAMEWORK THAT'S BEEN
16 IMPLEMENTED THAT HAS BEEN SUCH AN INCREDIBLY STRONG
17 PROCESS BECAUSE OF THE FACT THAT IT IS DERIVED ON
18 DEEP DATA, DEEP THOUGHT, AND ELEMENTS THAT A LOT OF
19 PEOPLE HAVE NOT BEEN ABLE TO CONSIDER IN THE PAST,
20 IT'S ACTUALLY IN MY VIEW WORTHY OF PUBLICATION AS A
21 ROADMAP FOR OTHER ORGANIZATIONS FOR CONSIDERATION.

22 WITH THOSE TWO ACTIVITIES HAVING KICKED
23 OFF THE ALLOCATION OF FUNDING IN MIND, THAT'S A
24 CONDITION WHERE THE MECHANISMS FOR DETERMINING HOW
25 DO YOU MAKE THE PROPER DECISIONS RELATED TO BOTH THE

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1 STRATEGIC ALLOCATION FRAMEWORK AND THE VOLUME OF
2 APPLICATIONS COMING IN? AND OUR FIRST ATTEMPT AT
3 THAT WAS CLEARLY BASED ON DOING THE BEST JOB WE
4 COULD TO CREATE COMPLETELY OBJECTIVE CRITERIA THAT
5 WE CALL PREFERENCES THAT HAVE A NUMERICAL SCORE
6 ASSOCIATED WITH THAT; AND, WHEREAS, THAT HAD SOME
7 EFFECT IN TERMS OF ENSURING THAT IT WAS NOT SUBJECT
8 TO DEBATE ABOUT WHAT DO THOSE NUMBERS MEAN AND HOW
9 DOES THAT WORK IN TERMS OF THE CRITERIA THAT WENT
10 INTO THAT?

11 IT CAUSED A NUMBER OF ISSUES THAT A LOT OF
12 PEOPLE THEN RESPONDED TO AND SAID, HEY, WE NEED TO
13 MAKE CHANGES IN TERMS OF HOW WE MAKE THAT TRIAGE
14 DECISION. WITH THAT IN MIND THEN, YOU WILL SEE IN
15 THE PRESENTATION TWO PRIMARY TOPIC AREAS AROUND
16 THAT. THE FIRST HAS TO DO WITH WHAT WE CALL THE
17 VOLUME CONTROL, WHICH WILL GET COVERED IN DETAIL, AS
18 TO HOW TO MAKE THOSE DECISIONS WITH A FULL
19 SCIENTIFIC REVIEW. THAT IS A REVIEW CYCLE THAT IS A
20 MODIFICATION OF WHAT THE GWG DOES. AS AN INITIAL
21 STEP, IT IS LOOSELY CALLED POSITIVE SELECTION, BUT
22 FOR THE DEEP INSIDE BASEBALL PEOPLE, IT'S NOT THE
23 SAME AS THE POSITIVE SELECTION AS WHAT'S BEEN DONE
24 PREVIOUSLY IN OTHER AREAS IN THE PERSPECTIVE THAT
25 THERE ARE A DEDICATED NUMBER OF PEOPLE WITH

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1 SCIENTIFIC BACKGROUND WHO HAVE TO REVIEW ALL THE
2 APPLICATIONS. YOU WILL HEAR MORE ABOUT THAT IN THE
3 DECISION PROCESS.

4 THERE'S A MECHANISM, THEN, AROUND VOLUME
5 CONTROL. THE OTHER ONE IS THE REMOVAL OF THE
6 PREFERENCES, SCORING, AND CRITERIA, BUT RATHER A
7 SHIFT TO WHAT IS CALLED GUIDING PRINCIPLES. AND
8 THAT IS HELPING TO FRAME THE OBJECTIVES OF THE
9 STRATEGIC ALLOCATION FRAMEWORK WITH DIRECTIONS ABOUT
10 HOW TO LOOK AT THINGS. AND SO THE KEY ELEMENTS THAT
11 PEOPLE SHOULD BE TAKING INTO CONSIDERATION AS THE
12 TRIAGING IS BEING DONE ARE TRANSFORMATIONAL ELEMENTS
13 AND OTHER CHARACTERISTICS ALONG WITH A REFRAMING OF
14 THE COMMUNICATION OF THE WORD "AFFORDABILITY" IN THE
15 CONTEXT THAT THAT CAUSED A LOT OF PROBLEMS FOR
16 PEOPLE BECAUSE THE PRESUMPTION WAS AFFORDABILITY
17 JUST MEANT LOW COST.

18 AND THERE'S AN UPDATE ON THE FRAMING FOR
19 THAT DISCUSSION AROUND ACCESS AND AFFORDABILITY
20 WHERE THE FOCUS IS ON HOW CAN ACCESS BE ACHIEVED
21 WITH THE VIEW OF LOOKING AT ACCESS AS WHAT ARE THE
22 CHARACTERISTICS THAT ARE GOING TO BE HELPFUL FOR
23 SOMEBODY LOOKING AT A CLINICAL TRIAL DESIGN AND
24 OTHER ELEMENTS TO BE ABLE TO ACCELERATE AND ENABLE
25 COMMERCIALIZATION OF THE CLINICAL TRIAL WORK AS

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1 POSITIVE RESULTS COME IN.

2 SO WITH THAT IN MIND, YOU WILL HEAR THE
3 SPECIFICS AND THE DETAILS ABOUT HOW THE GUIDING
4 PRINCIPLES AND HOW THE VOLUME CONTROL IS BEING
5 MANAGED. WE'VE HAD FOUR TO FIVE HOURS OF DISCUSSION
6 ON THE SCIENTIFIC COMMITTEE MARCH 5TH AND MARCH 19TH
7 AROUND THIS. THERE'S A VERY STRONG CONSENSUS THAT
8 THERE'S A REAL NEED FOR CHANGING OUR VOLUME CONTROL
9 SYSTEM AND PROCESS, AND THERE'S A STRONG CONSENSUS
10 THAT THE NEW MECHANISMS THEY PROPOSED ARE FULLY
11 SUPPORTED BY THE SCIENCE SUBCOMMITTEE.

12 SO I WANT TO MAKE SURE TO GET THAT OUT
13 THERE FRONT AND CENTER, THAT WE'RE ALL BEHIND WHAT
14 THE PROPOSALS ARE RELATED TO THIS. THERE WERE A
15 COUPLE OF OPEN ISSUES THAT WE FELT WERE RELATIVELY
16 SMALL IN SCALE FOR FURTHER CONSIDERATION. FOR
17 EXAMPLE, ONE WOULD BE THERE'S A NUMERICAL ELEMENT TO
18 THE SCIENTIFIC REVIEW FOR THE FIRST PASS BEFORE
19 LEADING TO THE FULL GRANT WORKING GROUP REVIEW ON DO
20 YOU LOOK AT A TRUE SCORING SYSTEM, OR DO YOU LOOK AT
21 A RANKING OF THE PROPOSALS THAT THOSE SCIENTISTS ARE
22 REVIEWING? YOU WILL SEE SOME INFORMATION ABOUT THAT
23 AS WELL. SO WE DIDN'T COME TO A FINAL DETERMINATION
24 ON THAT, BUT WE FELT THAT WAS VERY MUCH ON THE
25 MARGIN RELATED TO WHAT THE UNDERLYING PROPOSALS ARE.

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1 SO BASICALLY THE SCIENCE COMMITTEE THEN IS
2 IN FAVOR OF THIS. THERE ARE OTHER NUANCES OF
3 CLARIFICATION OF THE PATIENT ADVOCATE ROLE IN THIS
4 ELEMENT AND OTHER THINGS THAT YOU WILL HEAR IN THE
5 PRESENTATION, BUT THE SCIENCE COMMITTEE IS IN
6 SUPPORT OF THE OVERALL PROPOSAL. AND WE JUST WANTED
7 TO GIVE SOME CHARACTERIZATION OF THAT SO THAT WE
8 DIDN'T NECESSARILY WANT TO GET INTO A LONG, EXTENDED
9 DEBATE ABOUT PARTICULAR WORDING OR OTHER THINGS.
10 BUT I WANT TO ENSURE THAT THERE'S ADEQUATE
11 DISCUSSION FOR THE BOARD TO MAKE SURE THAT THE BIG
12 MOVING PARTS IN HOW THIS IS GOING TO WORK IS
13 UNDERSTOOD. SO WITH THAT, I'LL TURN IT OVER TO J.T.
14 AND I KNOW THE TEAM WILL DO A GREAT JOB, MUCH BETTER
15 THAN I CAN, OF PRESENTING THE INFORMATION GOING
16 FORWARD HERE. SO J.T.

17 DR. THOMAS: THANKS VERY MUCH, MARK. THAT
18 WAS A VERY GOOD, CONCISE SUMMARY OF MANY THINGS THAT
19 YOU ALL ARE GOING TO HEAR ABOUT TODAY. AND I DON'T
20 HAVE ANY INTRODUCTORY REMARKS THAT COULD DO BETTER
21 THAN THAT OTHER THAN TO NOTE THAT THE RUN OF SHOW
22 THAT YOU ARE GOING TO HAVE, ROSA IS GOING TO START
23 WITH THE PRESENTATION ON THE SWITCH FROM PREFERENCES
24 TO GUIDING PRINCIPLES. GIL WILL FOLLOW THAT WITH A
25 NUMBER OF REMARKS ABOUT VOLUME CONTROL. DR. KELLY

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1 SHEPARD WILL -- ACTUALLY, SORRY, AFTER GIL, ROSA
2 WILL COME BACK AND TALK ABOUT HOW THIS SHIFT IN THE
3 GUIDING PRINCIPLES WILL INFORM PROGRAMMATIC
4 DISCUSSION AT THE ARS. THEN AFTER THAT WILL BE DR.
5 KELLY SHEPARD TALKING BRIEFLY ABOUT THE ISSUE OF THE
6 FOCUS OF THE NEXT DISC4. AND THEN, FINALLY, WE'LL
7 CLOSE WITH DR. SHYAM PATEL TALKING ABOUT THE
8 QUESTION OF GOING FROM TWO PDEV ROUNDS A YEAR TO
9 ONE.

10 SO THAT'S WHAT YOU ARE GOING TO HEAR. ALL
11 OF THIS, OF COURSE, KEEP IN MIND, IS IN OUR NEVER
12 ENDING QUEST TO PRODUCE THE BEST POSSIBLE PRODUCT TO
13 BENEFIT PATIENTS IN THE STATE OF CALIFORNIA. AND WE
14 THINK THAT ALL OF WHAT YOU ARE ABOUT TO HEAR IS A
15 MAJOR STEP FORWARD WITH RESPECT TO ALL OF THE TOPICS
16 TO BE DISCUSSED AS WE PROCEED. SO WITHOUT FURTHER
17 ADO, ROSA.

18 DR. CANET-AVILES: THANK YOU, J.T. AND
19 THANK YOU, MARK, FOR THE VERY GOOD SUMMARY OF -- AND
20 ONE POINT THAT YOU MADE, YOU'VE MADE IT SEVERAL
21 TIMES, I WANT TO ACKNOWLEDGE IT IS THAT WE SHOULD
22 PUBLISH THE STRATEGIC ALLOCATION FRAMEWORK, THE
23 PROCESS AND THE OUTCOMES AND THE LEARNINGS. THIS IS
24 PART OF THE LEARNINGS. AND I PROMISE YOU WE'LL DO
25 THIS.

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1 SO AS J.T. MENTIONED AND AS MARK
2 MENTIONED, THIS ITEM DEALS WITH THE RESPONSE THAT
3 THE CIRM TEAM HAS AROUND THE DISCUSSION THAT WE HAD
4 ABOUT THE PREFERENCES. THAT STARTED ALREADY IN
5 DECEMBER.

6 BEFORE I GO INTO THIS, I HAVE TO THANK A
7 LOT OF PEOPLE. SO I WOULD LIKE TO START WITH
8 THANKING THE FULL SCIENCE SUBCOMMITTEE FOR ALL THEIR
9 TIME, SUPPORT, THE DISCUSSIONS, THE EXTRA HOURS BACK
10 AND FORTH THAT HAS BEEN VERY IMPORTANT.

11 SECONDLY, I WANT TO THANK MY COLLEAGUES,
12 ESPECIALLY DR. SHYAM PATEL -- SHYAM, YOU CAN SAY
13 HI -- BUT SHYAM STEPPED UP TO PRESENT DURING BOTH
14 SCIENCE SUBCOMMITTEES WHEN I WAS NOT AVAILABLE. AND
15 HE'S BEEN A GREAT PARTNER IN CRIME IN DEVELOPING
16 THIS. I ALSO WANT TO THANK THE TWO OTHER LEADS OF
17 TEAMS, DR. KELLY SHEPARD, WHO LEADS DISCOVERY AND
18 EDUCATION, AND DR. JOE GOLD, WHO LEADS THE CLINICAL
19 DEVELOPMENT TEAM, FOR THEIR JOINED FORCES IN
20 DEVELOPING THESE ANSWERS AND GOING THROUGH GUIDING
21 PRINCIPLES, ETC. DR. SARA TAYLOR AND DR. LIZ
22 NOBLIN, AS YOU CAN SEE, THERE IS A 50-PAGE SUMMARY
23 AND MEMO THAT REQUIRES A LOT OF COORDINATION. AND I
24 WANT TO THANK THEM FOR WRANGLING EVERYBODY AS WELL.
25 MY PARTNER IN CRIME IS GIL, DR. GIL SAMBRANO, WHO WE

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1 ARE GOING TO TAG TEAM IN THIS PRESENTATION, BUT HIM
2 AND HIS TEAM ALSO I WANT TO THANK. MY COLLEAGUES AT
3 THE EXECUTIVE TEAM AND REALLY EVERYBODY ELSE AND
4 OBVIOUSLY J.T. FOR HIS LEADERSHIP.

5 AM I MISSING ANYBODY? HOPEFULLY NOT.

6 SO WITHOUT FURTHER ADO, I'M JUST GOING TO
7 GET STARTED. SO THE FIRST THING I WANT TO START
8 MENTIONING IS THAT WE ARE NOT STEPPING AWAY FROM, AS
9 MARK SAID, FROM THE STRATEGIC ALLOCATION FRAMEWORK.
10 WE ARE ACTUALLY PROVIDING A REFINEMENT OF HOW WE
11 IMPLEMENT THIS.

12 AS J.T. NOTED, IN THE LAST FEW MONTHS THE
13 BOARD HAS PROVIDED EXTENSIVE FEEDBACK AROUND THE
14 PREFERENCES AND THE PREFERENCES-BASED EVALUATION
15 PROCESS. SOME OF THE THINGS THAT WE'VE HEARD IS
16 THAT WE CANNOT FUND ALL PROJECTS AND THAT THE USER
17 PREFERENCES CAN FILTER AND EXCLUDE SOME MODALITIES,
18 CLASSES, OR INNOVATIVE PROJECTS, AND THAT
19 APPLICATIONS AS A CONSEQUENCE ARE BEING TRIAGED
20 WITHOUT ANY SCIENTIFIC EVALUATION. THESE ARE SOME
21 OF THE THINGS THAT WE'VE HEARD.

22 WE'VE ALSO GOTTEN FEEDBACK THAT WE SHOULD
23 TAILOR THE GUIDING PRINCIPLES FOR EACH PROGRAM. AND
24 ONE OF THE THINGS THAT WE HEARD WAS THE BEGINNING IN
25 JANUARY WE PRESENTED THE START OF THE GUIDING

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1 PRINCIPLES. AND IN THE WORK THAT WE'VE DONE IN
2 PARTNERSHIP WITH THE SCIENCE SUBCOMMITTEE, WHAT
3 WE'VE DONE IS WE'VE BEEN REFINING THEM TO ADAPT TO
4 EACH ONE OF THE PROGRAMS.

5 AND SPECIFICALLY, WHAT MARK WAS MENTIONING
6 ABOUT ACCESS AND AFFORDABILITY, ONE OF THE ITEMS
7 THAT CAME OUT OF THE DISCUSSION ON MARCH 5TH THAT
8 WENT INTO MARCH 19 WAS THE FOCUS ON PDEV AND CLIN2,
9 THAT THEY SHOULD -- THAT THERE WAS A TERMINOLOGY
10 ISSUE, THAT WE SHOULD FOCUS ON ACCESS RATHER THAN
11 AFFORDABILITY WITH CLEAR EXPECTATIONS FOR
12 APPLICANTS, STAGE-APPROPRIATE EXPECTATIONS. RIGHT.

13 AND THEN THERE WERE CONCERNS AROUND THE
14 GUIDING PRINCIPLES AND PREFERENCES FOR DISCOVERY
15 PROGRAMS. THE MESSAGE WAS THAT WE NEED TO BE
16 SPECIFIC TO THE DISCOVERY. AND, AS YOU WILL SEE,
17 WE'VE BEEN SPECIFIC. AND THEN, AS YOU CAN SEE, MORE
18 TRANSPARENCY AND STRONGER COMMUNICATION OF
19 PREFERENCES NEEDED. MY COLLEAGUE AMY ADAMS HAS BEEN
20 AT THE HELM NOW FOR THE PAST -- IS IT SIX MONTHS,
21 AMY? -- AND SHE'S LIKE BREAKING GROUND. AS YOU CAN
22 SEE WITH THE MEMO AND ALL THE LETTERS AND
23 EVERYTHING, THERE IS ACTUALLY A COMMUNICATIONS PLAN
24 AS WELL. AND WE WILL BE -- DEPENDING ON WHAT COMES
25 OUT OF TODAY, THERE WILL BE COMMUNICATION TO THE

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1 APPLICANTS AND POTENTIAL APPLICANTS IN THE UPCOMING
2 CHANGES.

3 AND THEN THE REQUEST FOR DATA TO INFORM
4 THE DISCUSSION. THE MEMO HAS APPENDICES THAT
5 CONTAIN THE DATA OF HOW THE PREFERENCES APPLY TO THE
6 PROGRAMS FOR WHAT WERE THE OUTCOMES OF APPLYING THE
7 PREFERENCES. AND THERE'S ALSO PORTFOLIO ANALYSIS IN
8 THAT MEMO.

9 SO AS A RECAP OF THE PREFERENCES, THE
10 PREFERENCES FLOAT FROM THE GUIDING PRINCIPLES. AND
11 THE GUIDING PRINCIPLES ARE BASICALLY HOW -- THEY
12 DELINEATE HOW WE WILL FUND -- WHAT OUR PROGRAMS WILL
13 FUND. BASICALLY A GUIDING PRINCIPLE WILL TELL US
14 WHETHER HOW ARE WE GOING TO GET TO ACCELERATE LATER
15 STAGE CLINICAL TRIALS IN OUR PORTFOLIO OR TO
16 DISCOVER NOVEL MECHANISMS. THE WAY THAT WE DO THAT
17 IS THROUGH SHAPING OUR PROGRAMS THROUGH THESE
18 GUIDING PRINCIPLES. RIGHT.

19 SO WHEN WE PRESENTED THE PREFERENCES, THEY
20 HAD TWO GOALS. THERE WERE TWO SEPARATE OBJECTIVES.
21 THE FIRST ONE IS THAT THEY WERE GOING TO HELP US TO
22 PRIORITIZE WHAT WE FUND. AND THE SECOND WAS THAT
23 THEY WERE GOING HELP US CONTROL VOLUME AS WELL.
24 HOWEVER, IT KIND OF BACKFIRED BECAUSE THE VOLUME
25 CONTROL LED TO SOME LIMITATIONS, AS WE PRESENTED AND

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1 WHAT WE HEARD, BY APPLYING PRIOR TO SCIENTIFIC
2 REVIEW, THERE WAS SOME UNWANTED FILTERING THAT
3 HAPPENED, AND IT'S REFLECTED IN THE ANALYSIS OF THE
4 DATA THAT WE GOT THROUGH APPLYING THE PREFERENCES.

5 AND THEN BY HAVING PREFERENCES, WE WERE
6 ALSO GOING TO REQUIRE ITERATIVE CYCLE, TWO-CYCLE
7 CHANGES WHICH WAS NOT GOING TO BE FEASIBLE IN THE
8 LONG TERM.

9 SO WHAT WE PROPOSE IS TO REMOVE THE
10 PREFERENCES THEMSELVES AND ALSO AS THEY APPLY TO
11 VOLUME CONTROL MEASURE. INSTEAD, THE INTENT IS TO
12 GO BACK TO THE GUIDING PRINCIPLES, WHICH WE HAVE
13 ALWAYS BEEN IN THE BACKGROUND SHAPING OUR STRATEGY.
14 WE JUST NEVER LIKE SPECIFICALLY SPOKE ABOUT THEM IN
15 THE WAY THAT WE ARE TALKING ABOUT TODAY.

16 SO THE GOAL TODAY IS TO ENSURE THAT THE
17 BOARD HAS AGREEMENT ON HOW THESE PRINCIPLES SHAPE
18 WHAT WE FUND FOR EACH OF THE PROGRAMS AND HOW DO
19 THEY APPLY AT EACH STEP OF THE APPLICATION LIFE
20 CYCLE. THROUGHOUT THE PRESENTATION TODAY WITH GIL
21 AND I, WE ARE GOING TO REFERENCE TO THE STEPS IN
22 THIS SLIDE, THE VOLUME CONTROL, THE MERIT REVIEW,
23 AND THE FUNDING DECISIONS. THE GUIDING PRINCIPLES
24 ARE EMBEDDED IN EACH ONE OF THE STEPS, AND THE
25 PRESENTATION IS REALLY ABOUT HOW ARE WE APPLYING

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1 THESE GUIDING PRINCIPLES IN EACH STEP.

2 SO JUST FOR A REFERENCE IN TERMS OF THE
3 TERMINOLOGY, I WANT TO GO THROUGH EACH ONE OF THE
4 STEPS. THE VOLUME CONTROL STEP FOCUSES AS WELL AS
5 REDUCES THE NUMBER OF APPLICATIONS TO ALLOW
6 MEANINGFUL SCIENTIFIC REVIEW FOR EACH ONE OF THESE
7 PROGRAMS, THE DISC4, THE PDEV, AND THE CLIN2.

8 THE SECOND STEP, THE MERIT REVIEW, IS THAT
9 ONCE THOSE APPLICATIONS HAVE BEEN FORWARDED TO
10 SCIENTIFIC REVIEW, THE GRANTS WORKING GROUP WILL
11 REVIEW THOSE APPLICATIONS AND WILL PROVIDE
12 RECOMMENDATIONS TO THE BOARD.

13 AND THE THIRD STEP IS HOW THE BOARD MAKES
14 THOSE FUNDING DECISIONS BASED ON THE RECOMMENDATIONS
15 FROM THE GRANTS WORKING GROUP, BUT ALSO FROM
16 PROGRAMMATIC FACTORS THAT WILL BE PROVIDED TO THE
17 BOARD. AND OTHER INFORMATION LIKE BUDGET AVAILABLE,
18 ETC., AS YOU'VE SEEN TODAY IN THE DISC4, WE HAD TO
19 MAKE SOME TOUGH DECISIONS. RIGHT.

20 SO TODAY WE ARE GOING TO GO THROUGH EACH
21 ONE OF THE STEPS AND DISCUSS HOW THE GUIDING
22 PRINCIPLES HELP US SHAPE WHAT WE FUND.

23 SO WE ARE SEEKING TODAY FROM THE BOARD TWO
24 THINGS. THE FIRST ONE IS FEEDBACK AS WELL AS
25 AGREEMENT ON WHAT WE SHOULD FUND FOR EACH ONE OF

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1 THESE THREE PROGRAMS, THE DISC4, THE PDEV, AND THE
2 CLIN2. EFFECTIVELY WHAT ARE THE GUIDING PRINCIPLES
3 UNDERLYING THESE PROGRAMS? AND WE ARE GOING TO
4 PRESENT THEM FOR EACH ONE OF THE PROGRAMS.

5 SECONDLY, WE ARE SEEKING BOARD FEEDBACK ON
6 ENSURING THAT THE GUIDING PRINCIPLES ARE APPLIED BY
7 THE RIGHT PARTY WITH THE RIGHT INFORMATION AND AT
8 THE RIGHT TIME. AND THEN AS J.T. MENTIONED, WE ARE
9 GOING TO HAVE SOME UPDATES THAT ARE SEPARATE FROM
10 THESE GUIDING PRINCIPLES DISCUSSION WITH REGARDS TO
11 THE DISC4 AND THE PDEV PROGRAM THAT WILL BE
12 PRESENTED BY OUR COLLEAGUES.

13 SO I'M GOING STOP IN THE MIDDLE AS WE ARE
14 PRESENTING. AND IF THERE ARE QUESTIONS, PLEASE FEEL
15 FREE TO INTERRUPT ME AS I'M PRESENTING. BEFORE WE
16 GO AND JUMP RIGHT INTO THE GUIDING PRINCIPLES FOR
17 PDEV AND CLIN2, WHICH IS THE NEXT SLIDE, WE ARE
18 GOING TO JUST GOING JUMP RIGHT IT, THOSE PROGRAMS
19 ARE THE ONES THAT MOVE THERAPIES FROM PRECLINICAL UP
20 TO CLINICAL DEVELOPMENT AND HOPEFULLY
21 COMMERCIALIZATION EVENTUALLY.

22 BUT BEFORE WALKING THROUGH THEM, JUST A
23 LITTLE BIT OF FRAMING. THE CELL AND GENE THERAPY
24 FIELD HAS MADE REAL PROGRESS WITH THE FIRST
25 GENERATION OF CELL AND GENE THERAPIES OUT IN THE

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1 MARKET. WE HAVE CAR-T THERAPIES, WE HAVE AV
2 THERAPIES LIKE ZOLGENSMA AND LUXTURNA, AND WE ALSO
3 HAVE GENE-MODIFIED CELL THERAPIES FOR SICKLE CELL
4 DISEASE. RIGHT.

5 ONE OF THE THINGS THAT WE'VE LEARNED, AND
6 DR. FARMER WAS ALSO TALKING ABOUT THAT, IS THAT
7 THESE THERAPIES, WE ARE LEARNING NOW THERE ARE
8 ISSUES WITH ACCESS IN TERMS OF MANUFACTURABILITY AND
9 OTHER ISSUES THAT ARE PRECLUDING SOMETIMES FROM
10 MAXIMIZING THE ACCESS TO THESE THERAPIES FROM
11 PATIENTS. SO WE DO NEED TO TAKE THIS INTO ACCOUNT,
12 AND THAT WILL BE REFLECTED IN THE GUIDING
13 PRINCIPLES. AND THIS COMMENT CAME FROM THE MARCH
14 19TH DISCUSSION IN TERMS OF MAKING SURE WE DON'T
15 CONFLATE ACCESS AND AFFORDABILITY, THAT ACCESS IS
16 VERY NECESSARY AND WE HAVE TO TAKE IT INTO ACCOUNT.

17 SO GIVEN WHAT I JUST MENTIONED ABOUT THE
18 OVERALL LANDSCAPE OF THE CELL AND GENE THERAPIES,
19 THE GUIDING PRINCIPLES FOR THE PDEV PORTFOLIO AND
20 THE CLIN2 PORTFOLIO ARE VERY SIMILAR IN SCOPE AS YOU
21 CAN SEE. WE BELIEVE THAT OVERALL, AND THAT'S WHAT I
22 WAS MENTIONING THIS MORNING, FOR THE PDEV PORTFOLIO
23 AND THE CLIN2, THE THERAPIES THAT WE FUND SHOULD
24 OFFER THE POTENTIAL FOR TRANSFORMATIVE PATIENT
25 OUTCOMES. AND SPECIFICALLY, ON THE PDEV SIDE, THEY

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1 SHOULD BE LEVERAGING CUTTING EDGE THERAPEUTIC
2 TECHNOLOGIES TO SERVE THAT PURPOSE OF TRANSFORMING
3 THESE PATIENT OUTCOMES.

4 ACROSS THE PORTFOLIO WE EXPECT ALSO THAT
5 PROJECTS TO ALSO LEARN FROM THIS FIRST GENERATION OF
6 CGT BY TAKING PRACTICAL, STAGE-APPROPRIATE STEPS TO
7 ADDRESS PATIENT ACCESS BARRIERS. THAT'S THE SECOND
8 GUIDING PRINCIPLE. AND THAT MEANS THAT THEY NEED TO
9 TAKE DELIBERATE STAGE-APPROPRIATE STEPS TO ADDRESS
10 THOSE BARRIERS RATHER THAN TREATING THEM AS AN
11 AFTERTHOUGHT.

12 CONSISTENT WITH OUR PATIENT ACCESS
13 FRAMEWORK AND REVIEW PROCESSES, THIS ALSO INCLUDES
14 CHOICES FOR THERAPEUTIC DESIGN, DEVELOPMENT
15 STRATEGY, AND CLINICAL PLANNING THAT MAY AFFECT THE
16 ABILITY OF PATIENTS TO ULTIMATELY RECEIVE THESE
17 THERAPIES.

18 AND LASTLY, THE THERAPIES, AS THE MANDATE
19 OF OUR PROPOSITION MANDATE MAKES IT, THEY NEED TO
20 BROADLY ADDRESS BOTH PREVALENT AND RARE DISEASES
21 AFFECTING CALIFORNIANS.

22 I'M GOING TO STOP HERE FOR A SECOND IN
23 CASE THAT THERE ARE ANY COMMENTS OR QUESTIONS WITH
24 REGARDS TO PDEV, CLIN2. AND I DON'T KNOW IF, MARK,
25 IF YOU WANT TO MAKE ANY COMMENTS.

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1 MR. FISCHER-COLBRIE: PLEASE CONTINUE.

2 THAT'S EXCELLENT.

3 MR. TOCHER: KEITH YAMAMOTO HAS A
4 QUESTION.

5 DR. CANET-AVILES: KEITH. DR. YAMAMOTO.

6 DR. YAMAMOTO: SORRY. ON THE THIRD ONE, I
7 WONDER IF YOU WANT TO SAY BROADLY ADDRESS PREVALENT
8 OR RARE DISEASES AFFECTING CALIFORNIANS. I DON'T
9 KNOW IF YOU WANT TO ASK THE APPLICANTS TO COME
10 FORWARD WITH IDEAS THAT WOULD ADDRESS BOTH PREVALENT
11 AND RARE.

12 DR. CANET-AVILES: THANK YOU, DR.
13 YAMAMOTO. ACTUALLY, THE GUIDING PRINCIPLE REFERS TO
14 THE PORTFOLIO. IT'S NOT SO MUCH AN INDIVIDUAL
15 APPLICATION. SO WHAT THE GUIDING PRINCIPLE IS
16 REFERRING TO IS THAT CIRM, WHAT WE WANT TO FUND, WE
17 DO NOT REMOVE EITHER/OR. WE WILL FUND BOTH TYPES OF
18 DISEASES BECAUSE BOTH TYPES, RARE AND PREVALENT, DO
19 AFFECT CALIFORNIA POPULATION. MAYBE I WASN'T
20 EXPLICIT. SORRY ABOUT THAT.

21 DR. YAMAMOTO: THAT'S GOOD. THANKS.

22 DR. CANET-AVILES: DR. DULIEGE.

23 DR. DULIEGE: FIRST OF ALL, THANK YOU.
24 IT'S ACTUALLY VERY INTERESTING TO HAVE THIS
25 DIALOGUE. AND THANK YOU FOR ALL THE WORK THAT WENT

1 TO THAT.

2 CAN YOU OUTLINE WHAT'S DIFFERENT IN WHAT
3 YOU'RE PROPOSING VERSUS THE UNDERLYING PHILOSOPHY
4 THAT THE CIRM ALWAYS HAS HAD TO FUND CUTTING-EDGE
5 SCIENCE TO IMPROVE ACCESS TO PATIENTS? WHAT'S
6 SPECIFICALLY NEW IN THESE PRINCIPLES?

7 DR. CANET-AVILES: I THINK IT'S THE WAY
8 THAT WE ARE APPLYING AND IMPLEMENTING THIS. THE
9 PHILOSOPHY WAS THERE. BUT I BELIEVE THAT WHEN THE
10 RUBBER HITS THE ROAD, IT'S IN THE WAY THAT WE
11 IMPLEMENT IT THROUGH OUR PROGRAMS. SO WHAT'S
12 SPECIFIC NOW IS THAT, FOR EXAMPLE, AT THE VOLUME
13 CONTROL, AS DR. SAMBRANO WILL EXPLAIN, WE HAVE
14 DEVELOPED A SELECTION CRITERIA THAT DERIVE DIRECTLY
15 FROM THESE GUIDING PRINCIPLES. AND THEY HELP THE
16 GRANTS WORKING GROUP REVIEW DELINEATE WHAT WILL
17 MAKE -- GET THROUGH TO REVIEW, RIGHT, OF ALL THE
18 AWARDS.

19 FOR THE REVIEW CRITERIA, WE'VE ALWAYS HAD
20 THE REVIEW CRITERIA BASED ON THOSE GUIDING
21 PRINCIPLES AND THEY HAVEN'T CHANGED. WE'VE REFINED
22 A LITTLE BIT BECAUSE WE ARE NOT ADDING -- THERE WAS
23 A WHOLE NOMENCLATURE TERMINOLOGY BETWEEN CONFLATING
24 ACCESS AND AFFORDABILITY AND NOW IT'S BEEN REFINED.

25 AND THEN AT THE ARS, YOU JUST ASKED THE

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1 KEY QUESTION, ANNE-MARIE, BECAUSE IT'S WHAT WE ARE
2 GOING TO GO THROUGH, BUT AT THE ARS WE ARE GOING TO
3 BE MORE EXPLICIT AND TRANSPARENT IN THE WAY THAT WE
4 PROVIDE THE RECOMMENDATIONS TO THE ARS THAT HIT
5 THOSE GUIDING PRINCIPLES.

6 DOES THAT ANSWER YOUR QUESTION?

7 DR. DULIEGE: YEAH.

8 DR. CANET-AVILES: SO I WILL GO NOW TO THE
9 DISC4. SO DISC4 OPERATES UNDER DIFFERENT STRUCTURAL
10 LOGIC. IT IS PART OF OUR DISCOVERY ENGINE WHICH
11 LEADS TO ELUCIDATING DISEASE MECHANISMS AND SEEDING
12 THE FIELD WITH NEW PATHWAYS, DISCOVERING NEW TARGETS
13 AND BIOMARKERS. SO THE GUIDING PRINCIPLES REFLECT
14 THAT DESIGN. THE DISC4 PORTFOLIO IS INTENDED TO
15 CREATE MULTIDISCIPLINARY RESEARCH APPROACHES THAT
16 INTEGRATE DIVERSE SOURCES OF EVIDENCE, DIFFERENT
17 COMPUTATIONAL BIOLOGY, CLINICAL DATA, ANIMAL MODEL
18 DATA. THAT'S WHAT WE MEAN BY THAT. THAT THEY
19 INNOVATE THROUGH COLLABORATION NETWORK SYNERGY AND
20 DATA LEVERAGE. AND ULTIMATELY, THE GUIDING
21 PRINCIPLE ALSO REFLECTS THE MANDATE OF OUR
22 PROPOSITION THAT HAS BEEN MATERIALIZED THROUGH THE
23 NEURO TASK FORCE AS WELL AS OTHER ORGANIZATIONAL
24 PRIORITIES THAT WE MIGHT FIND AND WE LEFT IT AS A
25 MORE OPEN THING THERE.

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1 SO DISC4 PRINCIPLES ARE MORE ABOUT
2 CATALYZING THE ECOSYSTEM LEVEL IMPACT WHICH IS A
3 DIFFERENT TYPE OF APPROACH.

4 I WILL STOP HERE BECAUSE WE ARE GOING TO
5 BE SWITCHING GEARS A LITTLE BIT TO FOCUS ON ENSURING
6 THAT THE GUIDING PRINCIPLES ARE APPLIED TO THE RIGHT
7 PARTY WITH THE RIGHT INFORMATION AND AT THE RIGHT
8 TIME. SO BEFORE I GET THERE, ANY OTHER QUESTIONS?
9 AM I GOING TOO SLOW? FEEL FREE TO TELL ME. IT'S
10 THE POSTPRANDIAL TIME. I JUST WANT TO MAKE SURE WE
11 ALL KEEP THE CONVERSATION.

12 DR. DULIEGE: ONE THING ABOUT THAT. WILL
13 YOU SOME POINT OR GIL TALK ABOUT REMOVING THE
14 POINT-BASED PREFERENCES?

15 DR. CANET-AVILES: YES. SLIDE NO. --
16 WE'VE REMOVED THEM. THEY ARE REMOVED. YES. SLIDE
17 NO. 3, I BELIEVE IT WAS, CAN WE GO BACK? LET ME
18 SEE. HERE. SO THE SLIDE SAYS WE PROPOSE REMOVING
19 POINT-BASED PREFERENCES. SO WHAT ALL THIS IS ABOUT
20 IS, INSTEAD OF THE PREFERENCES, WE ARE GOING TO
21 UTILIZE THE GUIDING PRINCIPLES. AND I THINK I
22 PROBABLY WENT DOWN TOO MUCH INTO DETAIL OF WHAT
23 THESE GUIDING PRINCIPLES ARE. BUT NOW WE ARE GOING
24 TO TALK ABOUT HOW ARE THOSE GUIDING PRINCIPLES
25 APPLIED AT THOSE THREE DIFFERENT STEPS.

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1 FOR THE MERIT REVIEW AND THE FUNDING
2 DECISIONS, THEY'VE ALWAYS BEEN APPLIED. AND WE WILL
3 REVISIT THAT, AND GIL WILL GO INTO DETAIL OF HOW WE
4 DO THIS. FOR THE VOLUME CONTROL, I'M GOING TO SHOW
5 IT IN A MINUTE HOW IT CHANGES. BUT THANK YOU.
6 YOU'RE ON TOP OF IT, WHICH IS HELPFUL, BECAUSE IT
7 MAKES ME THEN HAVE THE DISCUSSION.

8 DR. DAHL: ONE QUESTION ABOUT YOU
9 MENTIONED THE PORTFOLIO REVIEW. IT MIGHT BE HELPFUL
10 FOR US AS A BOARD OVER TIME TO SEE WHAT THAT LOOKS
11 LIKE IN FIVE YEARS. JUST SOMETHING TO THINK ABOUT.

12 DR. CANET-AVILES: EXCELLENT. THAT'S AN
13 EXCELLENT QUESTION. AND WE ARE COMING -- THANK YOU
14 FOR ASKING THAT. I THINK IT COULD BE VERY GOOD FOR
15 US TO COME IN JUNE AS WE WERE PLANNING AND TO FRAME
16 IT IN THE CONTEXT OF, IF OTHER MEMBERS AGREE, TO
17 FRAME IT IN THE CONTEXT OF THIS IS WHAT WE HAVE NOW,
18 THIS IS HOW WE SEE IT EVOLVING IN FIVE YEARS, AND
19 THEN THE BOARD CAN ENTERTAIN LIKE, WELL, MAYBE THIS
20 MEANS THAT WE NEED TO PUSH SOMETHING ELSE OR WE
21 SHOULD STOP. IT WILL HELP WITH FRAMING THINGS. SO
22 THANK YOU FOR THE QUESTION.

23 SO TO FRAME THE PROPOSAL, WE'VE CLARIFIED
24 ROLES ACROSS THREE STAGES, AS I WAS SAYING: VOLUME
25 CONTROL, MERIT REVIEW, AND FUNDING DECISIONS, WHICH

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1 WE ARE GOING TO BE SHOWING ONE BY ONE. ON THIS LEFT
2 COLUMN, WE HAVE WHO IS GOING TO APPLY THE GUIDING
3 PRINCIPLES. AND HOPEFULLY THIS WILL ANSWER DR.
4 DULIEGE'S QUESTION. HOW THESE GUIDING PRINCIPLES
5 ARE APPLIED THROUGH SELECTION CRITERIA, THROUGH
6 MERIT REVIEW, OR THROUGH RECOMMENDATIONS, AND WHAT
7 HAPPENS WHEN WE DO THAT. SO I'M GOING TO GO STEP BY
8 STEP.

9 FOR THE FIRST ONE, THE VOLUME CONTROL, WE
10 ARE PROPOSING A CHANGE FROM THE PREFERENCE-BASED
11 APPROACH THAT'S CURRENTLY DRIVEN BY CIRM STAFF TO
12 ONE THAT'S GOING TO BE LED BY THE GRANTS WORKING
13 GROUP WHO COULD SELECT APPLICATIONS, NOT BASED ON
14 PREFERENCES, BUT BASED ON THE SELECTION CRITERIA
15 THAT ARE DEFINED AND ACTUALLY THEY ARE IN THE MEMO.
16 SOMETHING VERY IMPORTANT THAT'S REFLECTED IN THE
17 MEMO IS HOW THESE SCIENTIFIC CRITERIA ARE BEING
18 DEVELOPED, AND THEY ARE DERIVED FROM THE GUIDING
19 PRINCIPLES. WE CAN GO IN-DEPTH AND WE COULD PULL
20 THE MEMO IF YOU WANT.

21 AT THE NEXT STEP, WE HAVE THE MERIT REVIEW
22 WHICH IS THE RESPONSIBILITY OF THE GRANTS WORKING
23 GROUP AND HAS ALWAYS BEEN GROUNDED IN ESTABLISHED
24 REVIEW CRITERIA ALIGNED WITH THE GUIDING PRINCIPLES.

25 AND FINALLY, AS I WAS MENTIONING, THE

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1 FUNDING DECISIONS CONTINUE TO REST, AS ALWAYS, IN
2 THE APPLICATION REVIEW SUBCOMMITTEE OF THE ICOC. AS
3 YOU CAN SEE, THE GUIDING PRINCIPLES ARE APPLIED
4 DIRECTLY INTO THE CRITERIA USED AT EACH ONE OF THE
5 STEPS, SELECTION CRITERIA, REVIEW CRITERIA THAT HAS
6 ALWAYS BEEN THERE, AND THE PROGRAMMATIC FACTORS,
7 WHICH HAS BEEN THERE, BUT IT HASN'T BEEN STREAMLINED
8 AND IT HAD NOT BEEN AS TRANSPARENT AS WE ARE GOING
9 TO MAKE IT HAPPEN MOVING FORWARD.

10 UNDER ALL OF THIS IS THE ROLE OF THE CIRM
11 TEAM, WHICH OUR ROLE IS TO DESIGN AND SUPPORT THE
12 PROCESS, DEFINING THE CRITERIA, ASSEMBLING THE RIGHT
13 EXPERTISE, AND MAKING SURE THAT EACH GROUP HAS THE
14 INFORMATION NEEDED TO MAKE SOUND DECISIONS. AND
15 THIS INCLUDES PROVIDING MORE TRANSPARENT AND
16 STRUCTURED INFORMATION PACKAGE TO THE BOARD,
17 INCLUDING HOW EACH APPLICATION ALIGNS WITH THE
18 GUIDING PRINCIPLES ALONGSIDE WITH THE GRANTS WORKING
19 GROUP RECOMMENDATION.

20 AND WITH THAT OVERVIEW, I WILL TURN IT
21 OVER TO MY COLLEAGUE, DR. SAMBRANO, TO WALK THROUGH
22 THE DETAILS, PARTICULARLY OF THE VOLUME CONTROL.

23 DR. SAMBRANO: THANK YOU VERY MUCH. AND I
24 ALSO WANT TO EXTEND MY THANKS TO THE SCIENCE
25 SUBCOMMITTEE AND BOARD MEMBERS THAT WE HAVE HAD

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1 CONVERSATIONS ABOUT THIS PROCESS. I THINK IT HAS
2 BEEN VERY HELPFUL IN OUR THINKING AND IN WHAT WE ARE
3 PROPOSING. THANK YOU. ESSENTIAL PIECE OF EQUIPMENT
4 HERE.

5 SO WHAT I WANT TO SPEAK ABOUT TODAY IS THE
6 PROCESS THAT WE WOULD LIKE TO UTILIZE FOR THE VOLUME
7 CONTROL STEP. AND AS ROSA MENTIONED, THE VOLUME
8 CONTROL STEP COMES IN IMMEDIATELY AFTER APPLICATION
9 SUBMISSION BUT BEFORE THE FULL GRANTS WORKING GROUP
10 REVIEW. AND NOW THIS HAPPENS AND THE REASON WE NEED
11 TO HAVE IT HAS ALSO ALREADY BEEN MENTIONED. WE DO
12 GET A LARGE FLOOD OF APPLICATIONS ACROSS THE MANY
13 PROGRAMS, AND THAT HAS CONTINUED TO INCREASE OVER
14 TIME. AND OVER THE YEARS WE HAVE UTILIZED DIFFERENT
15 MECHANISMS. SO THIS IS NOT THE FIRST TIME THAT WE
16 ARE DEALING WITH THIS ISSUE. WE HAVE DEALT WITH IT
17 FOR MANY YEARS. WE'VE USED PREAPPLICATIONS, WE HAVE
18 EVEN LIMITED THE NUMBER OF APPLICATIONS THAT COULD
19 BE SUBMITTED BY AN INSTITUTION, WHICH, OF COURSE,
20 DID NOT WORK WELL. I THINK THERE ARE MANY REASONS
21 WHY THAT DOESN'T WORK. NEVERTHELESS, WE'VE TRIED
22 DIFFERENT THINGS. THE LATEST WAS THE USE OF THE
23 PREFERENCES AS A METHOD BY WHICH WE COULD DO THE
24 VOLUME CONTROL.

25 AND SO, AS WAS ALSO MENTIONED, WE WANT TO

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1 STEP AWAY FROM THOSE PREFERENCES AND PROPOSE
2 SOMETHING DIFFERENT. IN THE END THE PURPOSE OF
3 VOLUME CONTROL IDEALLY IS TO REMOVE OUT OF A POOL OF
4 APPLICATIONS THOSE THAT CLEARLY ARE NOT GOING TO BE
5 COMPETITIVE TO ENRICH THE POOL FOR THOSE THAT BEST
6 ALIGN WITH OUR GOALS AND TO ALLOW A MORE RIGOROUS
7 REVIEW OF THAT GROUP THAT IS MOST COMPETITIVE.

8 ALL RIGHT. SO IN GOING INTO WHAT THE
9 PROPOSED PROCESS LOOKS LIKE AND THE GOALS THAT WE
10 SET OUT TO ACHIEVE, THE VERY FIRST ONE IS TO REFOCUS
11 THE SELECTION OF APPLICATIONS ON THE SCIENCE RATHER
12 THAN ON STRICT PREFERENCES. WE LEARNED THAT THE
13 STRICT PREFERENCES DID NOT ALLOW FOR A NUANCED
14 ASSESSMENT OF THE SCIENTIFIC VALUE OF APPLICATIONS.
15 AND SO WE REALLY WANT TO MOVE AWAY FROM THOSE AND
16 BACK TO A MORE SCIENTIFIC-BASED REVIEW.

17 WE WANT TO ALIGN THE PROGRAMS ACROSS THE
18 BOARD SO THAT THEY ARE MORE CONSISTENT IN TERMS OF
19 HOW THE VOLUME CONTROL PROCESS IS IMPLEMENTED. THIS
20 ALLOWS A BETTER AND EASIER WAY OF COMMUNICATING IT
21 AND UNDERSTANDING IT FROM THE PERSPECTIVE OF
22 APPLICANTS. AND THEN WE ALSO WANT TO LEVERAGE, AND
23 AS YOU WILL SEE, LONG-STANDING LEARNINGS FROM OUR
24 POSITIVE SELECTION PROCESS THAT WAS IMPLEMENTED IN
25 2015, AGAIN, FOR THE SAME PURPOSE OF VOLUME CONTROL.

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1 AND SO WHAT WE PROPOSE IS A MODIFICATION OF THIS.

2 ONE OF THE THINGS THAT WE HAVE DONE WITH
3 POSITIVE SELECTION IS THAT THE PROCESS HAS EVOLVED.
4 WE HAVE A CONTINUED COLLECTION OF DATA AND ANALYSIS
5 TO ENSURE THAT THE PROCESS IS WORKING AS WE THINK IT
6 SHOULD. AND WHERE IT'S NOT, WE TRY TO MAKE TWEAKS
7 AND IMPROVEMENTS ALONG THE WAY. AND AS A RESULT, I
8 THINK HAVING A UNIFIED PROCESS ALLOWS INCREASED
9 EFFICIENCY IN THAT OPPORTUNITY TO LEARN AND
10 IMPLEMENT THOSE IMPROVEMENTS.

11 ALL RIGHT. SO THIS TABLE IS JUST A
12 DEPICTION OF WHAT FOR THE FOUR PROGRAMS SHOWN IN
13 THIS TABLE, DISC5, DISC4, PDEV, AND CLIN2, WHAT THE
14 CURRENT PROCESS IS. AND AS YOU SEE, IT VARIES.
15 IT'S POSITIVE SELECTION IN ONE CASE, PRESUBMISSION
16 IN A COUPLE, AND WHAT WE CALL QUALIFICATION IN
17 CLIN2. AND THEN ALSO IMPORTANTLY WHO MAKES THE
18 SELECTION IS ALSO VARIABLE. SO IN SOME CASES, IT'S
19 THE GRANTS WORKING GROUP, IN SOME CASES IT'S CIRM OR
20 A COMBINATION OF. AND THEN, LASTLY, THE BASIS FOR
21 THAT SELECTION HAS BEEN IN MANY CASES THE OBJECTIVE
22 PREFERENCES, BUT IN OTHER CASES IT HAS BEEN MORE THE
23 WHAT WE CALL SCIENTIFIC VALUE OR VALUE PROPOSITION.

24 NOW, THE VARIABILITY MAKES IT, AS
25 MENTIONED, HARD TO TRACK AND UNDERSTAND BY

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1 APPLICANTS AND ALSO VERY INEFFICIENT.

2 MR. TOCHER: I'M SORRY. YSABEL DURON HAS
3 HER HAND RAISED.

4 DR. SAMBRANO: SORRY. YSABEL.

5 MS. DURON: LET ME MAKE SURE. THANKS,
6 GIL. AND I MAY HAVE SHOULD HAVE PERHAPS ASKED ROSA
7 EARLIER BECAUSE WHAT I AM NOT SEEING IN ANY WAY,
8 SHAPE, OR FORM IS ANY -- WHEN YOU TALK ABOUT
9 SCIENTIFIC VALUE VERSUS STRICT PREFERENCES, I AM
10 VERY CONCERNED ABOUT WHERE WE HAVE BURIED DEI. I
11 KNOW HOW HARD YOU WORKED ON THAT. I KNOW HOW MUCH
12 WE WORKED AROUND THIS WHOLE ISSUE. AND I'M VERY
13 FEARFUL THAT IF WE PLAY LANGUAGE GAMES HERE, THAT
14 WE'RE GOING TO MISS THE TOTAL INTENT OF MAKING SURE
15 THAT THERE IS REPRESENTATION FROM ACROSS THIS STATE
16 WITHIN THE SCIENCE AND WITHIN THE CLINICAL TRIALS,
17 ET CETERA, ET CETERA.

18 I KNOW WE TALK, BUT PART OF ME NEEDS TO
19 SEE IT ON PAPER EXPRESSED SOMEWHERE SOMEHOW SO THAT
20 THE SCIENTIFIC APPLICANTS THEMSELVES ALSO KNOW WE
21 ARE STILL VERY COMMITTED TO THAT PRINCIPLE. AND I'M
22 NOT HEARING IT OR SEEING IT. AND I THINK, AS PEOPLE
23 KEEP PRAISING CIRM FOR BEING THE ONE GOOD GO-TO
24 PLACE, I'M HOPING WE'RE NOT LOSING ONE OF THE MOST
25 IMPORTANT CRITERIA, AND THAT WAS THE TURN TOWARDS

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1 DEI.

2 SO CAN YOU TELL ME WHERE WITHIN ALL OF
3 THIS WE ARE KEEPING OUR EYE ON THE PRIZE OF DEI WHEN
4 POINTS HAVE BEEN TAKEN AWAY, NOT BEING CONSIDERED,
5 ET CETERA, ET CETERA.

6 DR. SAMBRANO: RIGHT. SO THANK YOU,
7 YSABEL, FOR YOUR QUESTION. SO THE ELEMENTS OF DEI
8 CONTINUE TO EXIST IN WHAT WE CALL POPULATION IMPACT.
9 AND SO THAT IS STILL A CORE CRITERION THAT EXISTS
10 THROUGHOUT OUR DIFFERENT PROGRAMS AND SOMETHING THAT
11 IS EVALUATED BY THE GRANTS WORKING GROUP AS PART OF
12 THE SCORE THAT THEY DERIVE FOR THE APPLICATIONS
13 BEFORE IT COMES TO THE BOARD. SO THOSE KEY ELEMENTS
14 ARE THERE. THEY WILL CONTINUE TO BE THERE. AND SO
15 THAT, AT LEAST IN THIS WHOLE PROCESS, IS WHERE WE
16 CURRENTLY HAVE THEM.

17 MS. DURON: I'LL JUST SAY, GIL, I
18 APPRECIATE EVERYBODY'S BEST INTENTIONS. I DON'T
19 KNOW THAT I FEEL BETTER ABOUT IT RIGHT NOW. THANK
20 YOU.

21 DR. SAMBRANO: OKAY. UNDERSTOOD. THANK
22 YOU.

23 SO LET ME TRANSITION FROM THIS TABLE THAT
24 DESCRIBES OUR CURRENT PROCESS TO WHAT WE INTEND TO
25 DO FOR THE VOLUME CONTROL STEP. SO WE PROPOSE WHAT

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1 WE CALL GWG SELECTION JUST TO DISTINGUISH IT FROM
2 THE PREVIOUSLY KNOWN POSITIVE SELECTION BECAUSE IT
3 DOES DEVIATE IN TERMS OF THE METHODOLOGY A LITTLE
4 BIT AND UNIFYING THAT AROUND WHO IS MAKING THESE
5 SELECTIONS. SO IT'S THE GRANTS WORKING GROUP
6 MEMBERS THAT DO THE SELECTION. IN ALL CASES IT'S
7 BASED ON WHAT WE'RE CALLING THE SCIENTIFIC VALUE.
8 SO THAT SCIENTIFIC VALUE OR THE SELECTION CRITERIA,
9 AS ROSA MENTIONED, ARE DEFINED IN MORE DETAIL IN THE
10 MEMO BECAUSE THEY DIFFER FROM PROGRAM TO PROGRAM.
11 BUT THEY ARE ALIGNED WITH THE GUIDING PRINCIPLES,
12 PARTICULARLY THE FIRST OFTEN BULLET OF THE GUIDING
13 PRINCIPLES THAT IS LOOKING FOR THE MOST IMPACTFUL,
14 TRANSFORMATIVE PROJECTS, PARTICULARLY FOR PDEV AND
15 CLIN2, AND THOSE THAT OFFER A MEANINGFUL ADVANCE
16 COLLABORATION AND INNOVATION FOR PROJECTS LIKE DISC5
17 AND DISC4.

18 AND SO WITH THAT, I'M GOING TO GO OVER THE
19 PROCESS SO THAT YOU GET A SENSE OF WHAT THIS WOULD
20 LOOK LIKE. AND SO THIS IS A PROCESS THAT WE WOULD
21 APPLY TO ALL PROGRAMS THAT REQUIRE VOLUME CONTROL.
22 AND IT ALL BEGINS WITH ESTABLISHING A TARGET NUMBER.
23 SO FOR EACH OF THE DIFFERENT PROGRAMS, WE TARGET A
24 NUMBER OF APPLICATIONS THAT ALLOWS US TO HAVE A
25 FULL, ROBUST DISCUSSION WITH THE GRANTS WORKING

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1 GROUP PANEL AND ENSURE THAT EACH APPLICATION IS VERY
2 WELL CONSIDERED AND WE CAN BRING, THEREFORE,
3 APPROPRIATE RECOMMENDATIONS TO THE BOARD.

4 SO THE TARGET NUMBER -- AND THEN, OF
5 COURSE, THE NUMBER OF SUBMISSIONS WE GET WILL
6 DETERMINE THE NECESSARY PARAMETERS THAT WE HAVE TO
7 SET UP FOR HOW THAT SELECTION OCCURS. NOW, OF
8 COURSE, IF THE TARGET NUMBER IS THE SAME AS THE
9 NUMBER OF SUBMISSIONS WE GET, THEN THERE'S NO NEED
10 FOR VOLUME CONTROL. BUT, OF COURSE, THAT IS RARELY
11 THE CASE THESE DAYS.

12 SO IN THAT PROCESS, WHICH I WILL DESCRIBE,
13 SCIENTIFIC REVIEWERS ARE GOING DO TWO THINGS.
14 THEY'RE GOING TO SELECT AND RANK APPLICATIONS BASED
15 ON THE ASSESSMENT OF THE SCIENTIFIC VALUE THAT IS
16 APPROPRIATE FOR THAT SPECIFIC PROGRAM.

17 AND THIS IS JUST A TABLE THAT GIVES YOU A
18 SENSE ACROSS THESE FOUR DIFFERENT PROGRAMS WHAT THE
19 RELATIVE APPLICATION POOL MIGHT LOOK LIKE. SO
20 SOMETHING LIKE DISC5 WILL OFTEN GET IN THE ORDER OF
21 ABOUT 200, SOMETIMES MORE APPLICATIONS. WE DID HAVE
22 A RECENT DISC-0, I BELIEVE, THAT HAD 350
23 SUBMISSIONS. SO IT IS VARIABLE, BUT IN THE RANGE OF
24 THE COUPLE HUNDREDS. AND PDEV MAY BE AROUND 75. WE
25 USED ONLY PRESUBMISSIONS. SO THIS IS STILL A LITTLE

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1 BIT OF A GUESS. WE HAD, IN TERMS OF, PRESUBMISSIONS
2 ABOUT 130 OR SO THAT WE GOT. SO FOR APPLICATIONS IT
3 MIGHT BE A LITTLE LESS.

4 SO WHEN YOU LOOK AT THE POOLS AND THE
5 TARGET THAT WE WOULD TAKE TO A FULL PANEL REVIEW,
6 THAT HELPS US SET UP, THEN, THE NUMBER OF REVIEWERS
7 THAT WE MAY NEED, THE NUMBER OF APPLICATIONS EACH
8 REVIEWER NEEDS TO SEE IN THIS SELECTION PROCESS TO
9 ENSURE THAT EACH GETS ENOUGH VIEWS AND THE NUMBER OF
10 REVIEWS THAT EACH APPLICATION IS GOING TO RECEIVE.

11 AND SO WE'RE GOING TO FOLLOW ONE OF THESE.
12 SO WE'RE GOING TO TAKE THE PDEV AS AN EXAMPLE TO
13 FOLLOW THIS THROUGH. SO LET'S IMAGINE AN
14 APPLICATION POOL OF ABOUT 75 APPLICATIONS WHERE
15 WE'RE GOING TO USE 20 REVIEWERS AND WE'RE TARGETING
16 30 TO ADVANCE.

17 AND SO IN THAT SCENARIO, WE START WITH OUR
18 POOL OF 75 APPLICATIONS. AND SO THE FIRST THING WE
19 DO IS WE TAKE THE POOL AND SPLIT IT INTO 20
20 OVERLAPPING BATCHES OF 15 EACH. AND SO WITH THOSE
21 20 REVIEWERS, EACH REVIEWER GETS A BATCH OF 15. AND
22 WE'RE GOING TO FOLLOW WHAT HAPPENS TO ONE
23 APPLICATION. SO THAT APPLICATION THAT'S IN RED IS
24 GOING TO APPEAR IN FOUR DIFFERENT BATCHES THAT FOUR
25 DIFFERENT REVIEWERS WILL LOOK AT. AND SO EACH OF

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1 THOSE REVIEWERS WILL LOOK THROUGH THEIR BATCH OF 15,
2 AND THEY WILL SELECT WHAT THEY BELIEVE ARE THEIR
3 BEST FIVE APPLICATIONS AND THEN RANK THEM.

4 AND SO IN THIS EXAMPLE, REVIEWER NO. 1
5 SELECTED THE APPLICATION AND RANKED IT NO. 1. THE
6 SECOND REVIEWER ALSO SELECTED IT AND RANKED IT NO.
7 2. REVIEWER 3 DID NOT SELECT IT. SO THAT ONE IS
8 STILL SITTING IN THEIR PILE BETWEEN 6 AND 15. AND
9 THEN REVIEWER 4 ALSO PICKED IT AND RANKED IT NO. 1.
10 ALL RIGHT.

11 AND SO IF WE MOVE FORWARD WITH THAT, WE
12 TAKE THE VALUES OF SELECTION AND RANK IN ORDER TO
13 CREATE A COMPOSITE SCORE FOR THAT SPECIFIC
14 APPLICATION. AND SO WHAT THE COMPOSITE SCORE DOES
15 IS THAT EACH APPLICATION COMBINES TWO MEASUREMENTS,
16 THE SELECTION AND THE RANK FOR THAT APPLICATION.
17 AND WE WEIGHT THEM A LITTLE DIFFERENTLY. SO LET ME
18 FIRST TELL YOU WHAT THE SELECTION AND RANK IS
19 MEASURING.

20 SO THE SELECTION RANKS WHAT FRACTION OF
21 THE ASSIGNED REVIEWERS PICKED THE APPLICATIONS, AND
22 MEANING IS IT THAT MULTIPLE INDEPENDENT REVIEWERS
23 AGREE THIS APPLICATION SHOULD BE ADVANCED? THE RANK
24 MEASURES THE INTENSITY. HOW MUCH AMONG THE
25 APPLICATIONS THAT THEY SAW, DID THEY LIKE THIS

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1 APPLICATION COMPARED TO THEIR OTHER SELECTIONS? AND
2 SO WE WEIGHT THEM 60/40 PERCENT. WE WANT TO
3 PRIORITIZE SELECTION OVER RANK BECAUSE SELECTION IS
4 MORE PREDICTIVE OF APPLICATIONS THAT DO WELL IN
5 REVIEW OVER RANK. AND SO WE CREATE AN EQUATION FROM
6 THAT.

7 AND THEN ON THE NEXT SLIDE, I WILL SHOW
8 YOU HOW THAT CALCULATION HAPPENS. SO FOR OUR
9 EXAMPLE APPLICATION THAT I SHOWED YOU THAT HAD THOSE
10 FOUR REVIEWERS, BASED ON THEIR SELECTION AND RANK,
11 REVIEWER 1 SELECTED IT. AND SO THE APPLICATION GETS
12 A POINT FOR THAT SELECTION. IF IT'S NOT SELECTED,
13 LIKE REVIEWER 3, THEN THERE IS NO POINT. SO THIS IS
14 A BINARY CALCULATION. THEY EITHER GET ONE POINT OR
15 NO POINTS FOR FOUR REVIEWERS.

16 AND THEN BASED ON THE RANK, SO THE NO. 1
17 RANK GETS CONVERTED TO POINTS. NO. 1 RANK GETS FIVE
18 POINTS, NO. 2 GETS FOUR, NO. 3 GETS THREE AND SO ON.
19 SO WE PLUG THOSE INTO THE EQUATION SO THAT WE CAN
20 GET A COMPOSITE SCORE THAT'S BALANCED 60/40 PERCENT.
21 IF YOU DO THE CALCULATION, THAT GIVES YOU A
22 COMPOSITE NUMBER OF .73. AND SO WHAT DOES THAT
23 MEAN?

24 FOR A COMPOSITE SCORE, THE BEST POSSIBLE
25 COMPOSITE SCORE, MEANING EVERY REVIEWER SELECTED IT

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1 AND EVERY REVIEWER RANKED IT NO. 1, THE BEST
2 POSSIBLE SCORE IS A 1. THE WORST POSSIBLE SCORE
3 NOBODY SELECTED, THEREFORE, IT DIDN'T GET RANKED IS
4 A ZERO. SO THE COMPOSITE SCORE WILL ALWAYS BE
5 SOMEWHERE BETWEEN 0 AND 1. AND SO EACH APPLICATION
6 THEN GETS ITS COMPOSITE SCORE. AND IF YOU LOOK AT
7 THE DISTRIBUTION OF THE COMPOSITE SCORES FROM 0 TO 1
8 ACROSS THE EXAMPLE, 75 APPLICATIONS, THIS IS WHAT IT
9 WOULD LOOK LIKE.

10 AND SO THE DISTRIBUTION HERE AND THE
11 EXAMPLES THAT I'M SHOWING YOU, WE RAN THESE THROUGH
12 MONTE CARLO SIMULATIONS THAT ALLOWED US TO DO MANY
13 ITERATIONS OF THIS. SO ABOUT A HUNDRED RUNS FOR
14 EACH OF THE DIFFERENT PROGRAMS THAT WE HAVE IN ORDER
15 TO GET THE AVERAGES OF WHERE THE CUTOFF WOULD
16 GENERALLY FALL AND WHICH FRACTION WOULD ADVANCE AND
17 WHICH ONES ARE FILTERED OUT.

18 AND AS YOU SEE THE DISTRIBUTION, BECAUSE
19 THE REVIEWERS ARE DOING FIRST AS THEIR STEP IS A
20 SELECTION. THEY'RE FIRST DETERMINING, OUT OF THE
21 THESE 15 I HAVE, WHAT ARE MY TOP FIVE? SO THEY'RE
22 FIRST PICKING THEIR TOP THIRD. AND IN DOING SO, THE
23 LARGE FRACTION, THE LOWER TWO-THIRDS, IS FILTERED
24 OUT. AND THEN THEY ARE RANKING THEIR THEN TOP
25 SELECTIONS IN ORDER TO GET A SPREAD AND ESTABLISH A

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1 CUTOFF. AND SO THAT'S WHY YOU SEE THE DISTRIBUTION
2 AS IT SHOWS HERE.

3 DR. CARETHERS: BEFORE YOU GO ON, CAN I
4 JUST ASK A QUESTION? I JUST WONDER THOUGH WHY WAS
5 IT 60/40 THE WEIGHT PICKED VERSUS LIKE 50-50? I'M
6 JUST CURIOUS.

7 DR. SAMBRANO: YEAH. IT IS SIMPLY BECAUSE
8 WE WANT TO PRIORITIZE SELECTION OVER THE RANK.
9 BECAUSE THE SELECTION IS ACROSS DIFFERENT REVIEWERS.
10 SO THE MORE AN APPLICATION IS SELECTED, THE MORE
11 PREDICTIVE IT IS OF ITS SUCCESS. THE RANK IS REALLY
12 NOW LIMITED ONLY TO THAT TOP FRACTION, AND IT'S
13 GIVING YOU MORE LIMITED INFORMATION. IT'S TELLING
14 YOU ONLY WITHIN THE ONES THAT THEY LIKE, DID IT
15 HAPPEN TO BE THEIR NO. 1, THEIR NO. 2, AND NO. 3.
16 SO IT'S REALLY PRIORITIZING THE SELECTION OVER THE
17 VERY SPECIFIC RANK.

18 DR. CARETHERS: SO WHY NOT 75/25? I'M
19 JUST --

20 DR. SAMBRANO: IT COULD BE.

21 DR. CARETHERS: SO IT'S JUST WHERE TO
22 START.

23 DR. SAMBRANO: SO IT'S WHERE WE STARTED,
24 BUT IT'S ALSO WHAT THE MODEL SUGGESTED MIGHT BE THE
25 BEST, BUT THAT CAN BE TWEAKED. SO WE COULD DO A

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1 75/25 AND TRY THAT OUT.

2 DR. BARRETT: STOP TO TAKE QUESTIONS
3 BRIEFLY. I ALSO WONDERED HOW YOU SELECTED THE
4 NUMBER OF REVIEWERS FOR THE DIFFERENT PROGRAMS. WAS
5 THAT ALSO ARBITRARY?

6 DR. SAMBRANO: SO THE NUMBER OF REVIEWERS
7 THAT WE SELECT FOR THE OVERALL POOL IS NOT
8 NECESSARILY ARBITRARY. YOU CAN WORK WITHIN THE
9 RANGE. YOU HAVE TO HAVE ENOUGH REVIEWERS WHERE YOU
10 GET COVERAGE OF THE ENTIRE POOL AND THAT EVERY
11 APPLICATION GETS AT LEAST A THREE, FOUR, OR FIVE
12 VIEWS FROM THOSE REVIEWERS.

13 WHAT STARTS TO HAPPEN IF YOU HAVE TOO MANY
14 REVIEWERS IS THAT THEY DON'T GET ENOUGH
15 REPRESENTATION OF THE POOL. SO YOU WANT TO BALANCE
16 IT SO THAT EACH REVIEWER HAS ENOUGH POOL
17 REPRESENTATION WITHIN THEIR BATCHES, BUT AT THE SAME
18 TIME YOU HAVE ENOUGH REVIEWERS THAT YOU HAVE GOOD
19 OVERLAP AND ARE ABLE TO GET SUFFICIENT NUMBER OF
20 REVIEWS FOR EACH APPLICATION.

21 DR. BARRETT: BUT TO GET FIVE PEOPLE TO
22 LOOK AT EACH, I CAN'T REMEMBER WHICH PROGRAM, A CLIN
23 PROGRAM, RIGHT, YOU'RE TALKING ABOUT A LOT OF EXTRA
24 WORKLOAD. IS THAT FEASIBLE?

25 DR. SAMBRANO: YES. BECAUSE FOR THAT ONE,

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1 THE POOL NUMBER IS NOT AS BIG. AND SO THE NUMBER --
2 I MEAN WE WANT TO START WITH A MINIMUM OF 15
3 REVIEWERS. AND SO WITH THAT, THAT'S EASILY
4 ACHIEVABLE FOR CLIN.

5 DR. BARRETT: BUT THIS IS ADDING
6 ADDITIONAL WORKLOAD TO THE REVIEWERS TO DO THIS
7 UP-FRONT SELECTION, RIGHT?

8 DR. SAMBRANO: YES. IN SOME OF THE
9 PROGRAMS. BUT THIS IS SOMETHING THAT THEY'VE BEEN
10 DOING FOR OVER TEN YEARS IN SOME OF OUR OTHER
11 PROGRAMS THAT HAVE USED POSITIVE SELECTION.

12 DR. BARRETT: OKAY. THANKS.

13 DR. SACKY: THANK YOU FOR THIS OVERVIEW,
14 AND I LIKE THE EXERCISE YOU JUST WALKED US THROUGH
15 PICKING ONE APPLICATION AND WALKING IT THROUGH. I
16 GUESS MY QUESTION HAS TO DO WITH WHAT HAPPENS
17 UPSTREAM TO THIS STAGE. IT STRIKES ME THAT WE ARE
18 ASSUMING THAT -- I LIKE THE FACT WE'RE BEING
19 PRINCIPLED, BUT WE'RE ASSUMING THAT THE FOUR
20 REVIEWERS OR FIVE REVIEWERS ARE INTERPRETING THE
21 GUIDING PRINCIPLES THE SAME WAY IN TERMS OF HOW THEY
22 ARE ASCRIBING SCIENTIFIC VALUE. AND IT BRINGS TO ME
23 THE QUESTION THAT YSABEL HAD BEFORE BECAUSE WHEN YOU
24 DESCRIBED WHERE DEI HAS LANDED, YOU ACTUALLY USED
25 LANGUAGE THAT I THINK THERE MAY BE REVIEWERS WHO MAY

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1 NOT NECESSARILY INTERPRET SCIENTIFIC VALUE AS
2 INCLUDING POPULATION IMPACT.

3 SO I'M WONDERING IF MAYBE THERE NEEDS TO
4 BE SOMETHING MORE EXPLICIT TO ENSURE THAT WE KNOW
5 THAT THOSE REVIEWERS ARE IN FACT APPLYING THE
6 PRINCIPLES SIMILARLY. DO YOU SEE WHAT I'M TRYING TO
7 SAY?

8 DR. SAMBRANO: YES. AND THOSE ARE THINGS
9 WE WORRY ABOUT TOO. AND SO PART OF ADDRESSING THAT
10 AND MITIGATING THAT IS THAT WE HAVE A LOT OF
11 MEETINGS WITH REVIEWERS WHERE WE DO WHAT IS
12 ESSENTIALLY TRAINING. WE GO OVER THE REVIEW
13 CRITERIA, ADDRESS QUESTIONS TO ENSURE THAT THEY
14 UNDERSTAND THEM IN SIMILAR WAYS AND KNOW THAT THERE
15 ARE TWO DIFFERENT TASKS. SO THEY'RE GOING TO HAVE
16 THE TASK OF DOING THE SELECTION AND WHAT THE
17 SELECTION CRITERIA ARE, HOW THEY DIFFER FROM THE
18 REVIEW CRITERIA THAT THEY WOULD UTILIZE IN A FULL
19 DISCUSSION AND IN THE PANEL, AND HOW TO APPLY THEM.

20 SO THAT IS AN IMPORTANT ELEMENT BECAUSE
21 YOU WANT TO MAKE SURE, TO THE EXTENT POSSIBLE, THAT
22 ALL REVIEWERS ARE LOOKING AT THE APPLICATIONS IN THE
23 SAME WAY IN ORDER TO ENSURE THAT WE'RE ON THE SAME
24 PAGE OF WHY THEY'RE SELECTING THEM. BECAUSE
25 ESPECIALLY WHEN YOU HAVE SO MANY APPLICATIONS THAT

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1 IN GENERAL DO HAVE MERIT, FROM A SCIENTIFIC
2 PERSPECTIVE THEY MAY BE INTERESTING, THEY ARE GOOD
3 IDEAS, BUT NOT ALL GOOD IDEAS ARE THE ONES THAT WE
4 WANT TO HAVE WITHIN OUR PROGRAM. SO IT'S HOW WE
5 DEFINE THAT VERY SPECIFIC VALUE TO CIRM THAT WE WANT
6 TO MAKE SURE THEY UNDERSTAND. SO I THINK YOU'RE
7 VERY RIGHT, THAT THAT IS A KEY ELEMENT.

8 CHAIRMAN IMBASCIANI: GIL, WE HAVE BOARD
9 MEMBER YAMAMOTO FOLLOWED BY DR. LEVITT AND THEN
10 ANNE-MARIE.

11 DR. YAMAMOTO: GIL, THANK YOU FOR THIS.
12 CAN I ASK YOU TO GO BACK TO THE TABLE WHERE YOU
13 TALKED ABOUT THE DIFFERENT MECHANISMS AND THE NUMBER
14 OF APPLICATIONS THAT COME IN AND THE GOAL TO GET
15 DOWN TO A CERTAIN NUMBER. I'M SORRY. THIS ONE.

16 SO FIRST OF ALL, YOU SAID THAT -- I'M
17 SORRY. TWO QUESTIONS ABOUT THIS. THE FIRST IS THAT
18 YOU TOLD US THAT YOU WOULD APPLY THE VOLUME CONTROL
19 TO THE MECHANISMS THAT REQUIRE IT; THAT IS, WHERE
20 THE NUMBER OF -- THE APPLICANT POOL IS SO LARGE THAT
21 YOU REALLY NEED TO CUT DOWN TO SOME TARGET NUMBER,
22 WHICH YOU HAVE HERE. BUT NOW YOU'VE SHOWN US FOUR
23 MECHANISMS IN WHICH THE APPLICATION POOL RANGES OVER
24 AN ORDER OF MAGNITUDE. BUT FOR EACH OF THEM, IT
25 LOOKS LIKE YOU'RE STILL APPLYING THIS VOLUME CONTROL

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1 MECHANISM, IF I'M UNDERSTANDING THE SECOND LINE, THE
2 TARGET FOR ADVANCEMENT. IS THAT TRUE? SO IS THE
3 GOAL TO ACTUALLY APPLY THE VOLUME CONTROL MECHANISMS
4 TO EVERY MECHANISM NO MATTER WHAT THE NUMBER OF
5 APPLICATIONS THAT COMES IN? YOU GET 20 APPLICATIONS
6 COMING IN, WHY NOT JUST REVIEW THEM?

7 DR. SAMBRANO: RIGHT. FOR EXAMPLE, IF WE
8 CONTINUE TO FOLLOW THE PDEV, IF THE TARGET IS 30 AND
9 THE APPLICATION POOL THAT COMES IN IS 30, THEN THERE
10 IS NO VOLUME CONTROL. THERE'S NO NEED TO GO THROUGH
11 THIS STEP. BUT IF IT EXCEEDS THAT --

12 DR. YAMAMOTO: RIGHT. RIGHT.

13 DR. SAMBRANO: SO LIKE IN THIS EXAMPLE 75,
14 THEN YES. THEN WE WOULD IMPLEMENT IT.

15 DR. YAMAMOTO: WHAT DETERMINES THE TARGET
16 FOR ADVANCEMENT? I THOUGHT IT WAS THE CAPACITY OF
17 REVIEWERS THAT YOU HAVE.

18 DR. SAMBRANO: IT IS. IT IS HOW WE
19 CONDUCT THE REVIEW. AND SO WHY IS IT SO DIFFERENT,
20 SAY, BETWEEN CLIN2 AND DISC5? WELL, IT'S BECAUSE
21 THE NATURE OF THE REVIEW AND THE NUMBER OF REVIEWERS
22 THAT WE ASSIGN TO APPLICATIONS IN THE FULL REVIEW IS
23 VERY DIFFERENT. THE CONTENT OF THE APPLICATIONS
24 DIFFERS GREATLY. AND, FOR EXAMPLE, WITH CLIN2, WE
25 BRING DISEASE AREA EXPERTS, REGULATORY EXPERTS, CMC,

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1 WE HAVE THE ACCESS AND AFFORDABILITY REVIEW. SO THE
2 REVIEWS ARE MUCH MORE INVOLVED AND TAKE MORE TIME.

3 AND SO IN ORDER TO ALLOW FOR A FULL,
4 RIGOROUS DISCUSSION, THE TARGET NUMBER OF ABOUT TEN
5 IS WHAT WE THINK ALLOWS FOR A ROBUST DISCUSSION.
6 WHEREAS, I THINK FOR A DISC5, WE CAN DO AS MANY AS
7 50 WITH THAT TYPE OF APPLICATION.

8 DR. YAMAMOTO: OKAY. GOT IT. GOOD.
9 THANK YOU.

10 SO MY SECOND QUESTION. SO THANKS FOR
11 THAT. MY SECOND QUESTION IS HOW IS THE COMPOSITE
12 NUMBER USED TO ARRIVE AT THE TARGET TO REACH THE
13 TARGET FOR ADVANCEMENT?

14 DR. SAMBRANO: YEAH. OKAY. SO I WILL --
15 I HAVE MORE SLIDES IN WHICH I CAN SHOW YOU SOME OF
16 THAT. BUT I MEAN IN BRIEF, SO THE WAY WE DID THESE
17 SIMULATIONS, THEY INCLUDE THAT TARGET NUMBER IN
18 TERMS OF WHAT WE WOULD WANT, WHERE WE WOULD WANT TO
19 DO THE CUTOFF. SO IN MOST CASES THE COMPOSITE
20 NUMBER ENDS UP BEING SOMEWHERE BETWEEN .3 AND .4
21 WHERE THIS DISTRIBUTION LANDS WHERE THE 30TH
22 APPLICATION FALLS IN THAT GRAY ZONE AREA. AND SO I
23 WILL SHOW YOU A TABLE THAT SHOWS YOU THE RANK ORDER
24 OF HOW THEN WE WOULD DETERMINE THAT CUTOFF.

25 DR. YAMAMOTO: OKAY. SO THE GOAL OF

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1 THE -- WHEN WE TALK ABOUT VOLUME CONTROL, WHAT
2 YOU'RE TALKING ABOUT IS ARRIVING AT A REASONABLE
3 NUMBER OF APPLICATIONS THAT WILL BE DISCUSSED, NOT
4 ARRIVING AT A REASONABLE NUMBER OF APPLICATIONS THAT
5 WILL BE REVIEWED. SO ALL OF THE 200 APPLICATIONS
6 GET A FULL REVIEW?

7 DR. SAMBRANO: NO.

8 DR. YAMAMOTO: BUT ONLY A CERTAIN NUMBER
9 OF THEM WILL BE DISCUSSED; IS THAT CORRECT?

10 DR. SAMBRANO: NO. NO. SO THE SELECTION
11 PROCESS IS NOT THE SAME AS A FULL GRANTS WORKING
12 GROUP REVIEW. IT IS A TRIAGE STEP BASICALLY THAT
13 WHERE YOU LOOK AT THE APPLICATIONS ONLY AT A VERY
14 HIGH LEVEL. YOU'RE LOOKING AT THEM FROM WHAT ARE
15 THE SELECTION CRITERIA, NOT THE REVIEW CRITERIA. SO
16 THE SELECTION CRITERIA IN THESE TYPES OF PROGRAMS
17 ARE GOING TO BE IS THIS A TRANSFORMATIVE PROJECT
18 THAT IS GOING TO HAVE A MEANINGFUL IMPACT TO
19 PATIENTS? AND SO LOOKING AT THAT, NOT LOOKING AT
20 WHAT IS THEIR PLAN AND DESIGN, NOT LOOKING AT DO
21 THEY HAVE THE PRELIMINARY DATA AND APPROPRIATE
22 RATIONALE, NOT LOOKING AT THOSE DETAILS. IT IS
23 LOOKING AT WHAT WE FEEL IS THE MOST IMPORTANT AND
24 ALIGNED WITH THE GUIDING PRINCIPLES. IS THIS
25 SOMETHING THAT'S WORTH FUNDING TO START OFF WITH

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1 BEFORE YOU DIVE INTO THE DETAIL. AND IF IT IS, THEN
2 WE CAN DIVE IN DEEPER AND DISCUSS DOES THE PLAN AND
3 DESIGN, DOES THE TEAM AND ALL THAT SUPPORT THIS IDEA
4 THAT WE DETERMINED WAS A VALUABLE ONE?

5 DR. YAMAMOTO: SO ARE THE APPLICATIONS SET
6 UP IN SUCH A WAY THAT THE REVIEWERS CAN DO A SCAN OF
7 SOME SUMMARY LEVEL THING THAT FOCUSES ON THE GUIDING
8 PRINCIPLES AND MAKE SOME ASSESSMENT? IF I WAS A
9 REVIEWER, I WOULD FEEL I HAVE A RESPONSIBILITY TO
10 LOOK AT THESE THINGS PRETTY CAREFULLY KNOWING WHAT
11 THE CONSEQUENCES OF MY DECISION IS. AND SO I'M JUST
12 WONDERING, IT JUST SEEMS LIKE YOU MAY BE ASKING THE
13 REVIEWERS, UNLESS YOU PROVIDE THEM WITH SOME PAGE
14 THAT FOCUSES ON GUIDING PRINCIPLES THAT THE REVIEWER
15 CAN LOOK AT WITHOUT PLOWING THROUGH THE WHOLE
16 APPLICATION, THEN I WOULD THINK MANY REVIEWERS WOULD
17 FEEL IT'S THEIR RESPONSIBILITY IN FAIRNESS TO THE
18 APPLICANT TO LOOK AT THE APPLICATION VERY CAREFULLY.
19 THEN YOU'D BE IN A SITUATION WHERE EVERY APPLICATION
20 IS BEING REVIEWED WHERE THAT DOESN'T REALLY FIT WITH
21 THE VOLUME CONTROL PRINCIPLE.

22 DR. SAMBRANO: RIGHT. SO THE
23 APPLICATIONS, AS MENTIONED, ARE EACH KIND OF
24 TAILORED TO THE DIFFERENT TYPE OF PROGRAM. FOR THE
25 DISC5, BECAUSE WE HAVE HAD A LONG-STANDING USE OF

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1 THE POSITIVE SELECTION PROCESS, INCLUDE A PREVIEW
2 PAGE, WHICH IS A SUMMARY OF THEIR OVERALL AIMS, WHAT
3 THE GOALS ARE, AND WHAT THE ULTIMATE IMPACT OF THEIR
4 PROJECT, IF SUCCESSFUL, WOULD ACHIEVE. AND SO THERE
5 IS SORT OF THAT KIND OF FRONT-PAGE PREVIEW THAT
6 REVIEWERS CAN FOCUS ON, BUT HAVE THE FULL
7 APPLICATION AVAILABLE, AND WHICH THEY OFTEN UTILIZE,
8 IN ORDER TO CONFIRM OR TO REFERENCE ANY OF THE
9 ELEMENTS THAT THEY FEEL ARE IMPORTANT TO ASSESSING
10 WHETHER THIS PRESENTS A GOOD SCIENTIFIC VALUE.

11 FOR THE OTHER APPLICATIONS, LIKE THE
12 CLINICAL, THERE ARE CLEAR SECTIONS THAT ARE FOCUSED
13 SPECIFICALLY ON THE VALUE PROPOSITION OF THE
14 PROPOSAL THAT SUMMARIZES THE KEY ELEMENTS OF WHAT
15 THIS PROPOSED THERAPY INTENDS TO DO, WHAT THE
16 COMPLETION OF THE TRIAL WOULD ACHIEVE, AND, OF
17 COURSE, THE LONG-TERM IMPACT OF THE PROPOSED THERAPY
18 SHOULD IT BE SUCCESSFUL.

19 SO THOSE ELEMENTS ARE EASILY POINTED TO IN
20 THE APPLICATION. AND WE DO THAT AS PART OF OUR
21 TRAINING WITH REVIEWERS IN TERMS OF ADVISING OF
22 WHERE TO FIND THE INFORMATION AND HOW TO BEST ACCESS
23 IT. BUT WE ALSO DON'T WANT TO NECESSARILY LIMIT
24 WHERE THEY LOOK BECAUSE SOME OF THAT INFORMATION CAN
25 BE FOUND IN DIFFERENT PARTS OR ELEMENTS OF THE

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1 APPLICATION AS SOME REVIEWERS HAVE POINTED OUT TO
2 US.

3 SO IT IS SOMETHING WHERE PROVIDING THE
4 APPLICATION AS A WHOLE GIVES THEM THE OPPORTUNITY TO
5 LOOK WHERE NECESSARY TO FEEL COMFORTABLE THAT THEY
6 ARE MAKING AN APPROPRIATE SELECTION.

7 DR. YAMAMOTO: OKAY. WE CAN TALK ABOUT
8 THIS MORE AS YOU GO THROUGH THIS, BUT I HAVE
9 CONCERNS. AND WE'LL GET BACK TO THAT, THE CAPACITY
10 TO CUT DOWN 200 APPLICATIONS TO 50 BASED ON A
11 RELATIVELY CURSORY ASSESSMENT WHERE YOU'RE MAKING A
12 CLAIM THAT YOU ARE MAKING JUDGMENTS BASED ON
13 SCIENTIFIC MERIT. BUT WHY DON'T YOU GO AHEAD AND
14 WE'LL GET BACK TO IT.

15 CHAIRMAN IMBASCIANI: THANKS, KEITH.
16 PAT'S NEXT FOLLOWED BY ANNE-MARIE AND THEN
17 CHRISTINE.

18 DR. LEVITT: SO WE HAD LOTS OF DISCUSSIONS
19 ABOUT THIS, HOURS. FIRST, I WOULD SAY HAVING A
20 SINGLE PAGE SUMMARY ADDRESSING THE GUIDING
21 PRINCIPLES IS NOT GOING TO BE ANY BETTER THAN A
22 SPECIFIC AIMS PAGE THAT ALWAYS HAS TO HAVE A
23 RATIONALE SECTION FOR THE SPECIFIC AIMS THAT ARE
24 BEING PROPOSED.

25 SECOND IS THAT THE GUIDING PRINCIPLES

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1 DON'T GO AWAY WITH THE REVIEW. THEY'RE STILL PART
2 OF THE REVIEW, WHICH INCLUDES ACCESS AND
3 ACCESSIBILITY, WHICH IS REALLY NOW EMPHASIZED. WHEN
4 IT WAS COMBINED WITH AFFORDABILITY, AT LEAST FROM MY
5 PERSPECTIVE, IT GOT DILUTED. ACCESS IS REALLY
6 SOMETHING THAT THE INVESTIGATORS CAN ADDRESS IN
7 RELEVANT WAYS THAT INCLUDE DIVERSITY AND
8 EQUITABILITY OF ACCESS.

9 WE HAD DISCUSSIONS ABOUT HOW IT WAS SO
10 DIFFICULT FOR A STEM CELL BIOLOGIST DOING
11 TRANSPLANTS INTO A SPINA BIFIDA, PHYSICIAN, WOULD BE
12 ABLE TO ADDRESS AFFORDABILITY WHEN POLICYMAKERS AND
13 HEALTH ECONOMISTS CAN'T DO IT WELL. SO ACCESS IS A
14 KEY TO THE PRINCIPLE. AND IF I UNDERSTAND WHAT'S
15 BEEN DISCUSSED, THESE ARE GOING TO BE COMMUNICATED
16 VERY CLEARLY TO APPLICANTS. AND IF THEY UNDERSTAND
17 THAT THE GUIDING PRINCIPLES ARE BEING USED TO MAKE
18 SELECTIONS ABOUT FINALISTS AND IT'S STILL GOING TO
19 BE PART OF THE APPLICATION REVIEW PROCESS, IF THEY
20 DON'T ADDRESS THE GUIDING PRINCIPLES WITHIN A FULL
21 APPLICATION ITSELF, IT'S NOT GOING TO DO WELL. SO I
22 DON'T SEE IT GOING AWAY AND VANISHING.

23 THE OTHER IS THAT IT'S NOT A TERRIBLE
24 BURDEN TO READ A SPECIFIC AIMS PAGE AND ABSTRACT,
25 WHICH ARE ALL INCLUDED IN A FULL APPLICATION, AS

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1 WELL AS A SIGNIFICANT SECTION WHICH REALLY GIVES THE
2 REVIEWER A COMPLETE PICTURE OF WHY THIS IS SO
3 IMPORTANT FOR CIRM TO CONSIDER INDEPENDENT OF THE
4 DETAILS AND THE METHODS SECTION AND THE STATISTICS
5 AND OTHER THINGS THAT ARE GOING TO BE EVALUATED IN
6 THE FULL APPLICATION.

7 SO I WOULD ARGUE THAT A SINGLE PAGE IN
8 ADDITION TO WHAT THEY'RE ALREADY DOING OR JUST
9 HAVING A SINGLE PAGE IS NOT GOING TO SATISFY THOSE
10 WHO COMPLAIN THAT THERE WASN'T SCIENTIFIC MERIT FOR
11 THE INITIAL PROCESS THAT WAS USED FOR MAKING
12 SELECTION.

13 FINALLY, SOMETHING I LEARNED ALONG THE
14 WAY, I DIDN'T KNOW THIS WHEN I JOINED THE BOARD,
15 THERE'S A LIMITED NUMBER OF REVIEWERS ON THE GWG.
16 ONE SOLUTION WOULD BE JUST TO ADD MORE REVIEWERS,
17 BUT WE CAN'T. I GUESS THAT WAS THE SECOND TO FINAL
18 THING.

19 THE FINAL THING I WOULD SAY, IF YOU SHIFT
20 FROM 60/40 TO 75 TO 25, BASED ON GIL'S GRAY AREA,
21 THAT'S WHERE THE SHIFTS WOULD OCCUR. IT'S UNLIKELY,
22 IF YOU RUN MONTE CARLO, TO SEE SHIFTS GOING INTO
23 EITHER THE LOW RED AREA OR THE HIGHER AREA. IT'S
24 GOING TO BE WITHIN THAT RANGE, AND IT'S NOT GOING TO
25 MAKE REALLY A WHOLE LOT OF DIFFERENCE. SO WE COULD

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1 QUIBBLE ABOUT 75/25, 80/20, 60/40, BUT I DO DEGREE
2 WITH GIL THAT THE SELECTION ITSELF SHOULD BE THE
3 MOST IMPORTANT THING BECAUSE ONCE YOU START RANKING,
4 YOU'RE RANKING AGAINST FIVE. WHEN YOU'RE SELECTING,
5 YOU'RE SELECTING AGAINST THE WHOLE BATCH THAT YOU'VE
6 BEEN ASSIGNED. THANKS.

7 CHAIRMAN IMBASCIANI: THANKS, PAT.

8 DR. YAMAMOTO: CAN I INTERRUPT YOU? I
9 WANT TO SAY ONE THING ABOUT WHAT PAT TALKED ABOUT
10 AND -- BECAUSE IT'S WHAT'S WORRYING ME. YOU ARE
11 REALLY CONSTRAINED, GIL, YOU'RE TRYING TO WORK
12 WITHIN A VERY DIFFICULT CONSTRAINT, AND THAT IS THE
13 LIMITED NUMBER OF PEOPLE ON GWG. SO I'LL JUST
14 REMIND PEOPLE THAT WHEN THE NIH STARTED ITS PEER
15 REVIEW SYSTEM IN 1946, IT STARTED WITH TEN STUDY
16 SECTIONS. AND THE WAY THEY DEALT WITH VOLUME
17 CONTROL WAS TO ADD MORE STUDY SECTIONS. NOW THERE'S
18 240. STARTED WITH TEN, AND NOW THERE'S 240 IN ORDER
19 TO MANAGE THE VOLUME OF APPLICATIONS THAT COMES IN.
20 SO THAT WAS THEIR PRIMARY VOLUME CONTROL SYSTEM.

21 AND NOW THEY DO A TRIAGE IN WHICH THE GOAL
22 OF THE TRIAGE IS NOT TO LIMIT THE NUMBER OF
23 APPLICATIONS THAT HAVE TO BE READ BY A GIVEN
24 REVIEWER, BUT TO LIMIT THE NUMBER OF APPLICATIONS
25 THAT WILL BE REVIEWED IN THE STUDY SECTION MEETING.

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1 AND THAT CUTOFF, THAT TRIAGE LINE IS SET AT ROUGHLY
2 50 PERCENT, NOT EXACTLY, BUT ROUGHLY 50 PERCENT OF
3 THE APPLICATIONS THAT ARE ACTUALLY REVIEWED --
4 ACTUALLY DISCUSSED. AND THAT GIVES THE STUDY
5 SECTION THE TIME TO BE ABLE TO PUT THE KIND OF FOCUS
6 THAT'S DESERVED INTO THE APPLICATIONS THAT ARE
7 JUDGED AS BEING IN THE UPPER HALF. BUT THAT KIND OF
8 TRIAGE LINE DRAWING, IN MY VIEW, I'VE SAID THIS
9 BEFORE, IT'S VERY HARD TO DRAW A TRIAGE LINE THAT IS
10 MORE THAN A THUMBS UP AND THUMBS DOWN, MORE THAN A
11 50-PERCENT LINE THAT SAYS, NO, THIS ISN'T REALLY,
12 THIS DOESN'T REALLY DO IT. THAT'S NOT -- 50 PERCENT
13 IS NOT SO HARD, BUT THE 75 PERCENT, 80 PERCENT
14 YOU'RE TRYING TO DO WITH SOME OF THESE MECHANISMS, I
15 THINK IT'S VERY HARD.

16 SO JUST ACKNOWLEDGING, GIL, YOU'RE STUCK
17 WITH THIS CONSTRAINT WHERE YOU DON'T GET TO DEAL
18 WITH VOLUME CONTROL SIMPLY BY ADDING MORE REVIEWERS.
19 AND SO NOW WE'RE STRUGGLING ALL OF US TOGETHER TO
20 TRY TO COME UP WITH A SYSTEM THAT IS SCIENCE BASED,
21 AS YOU SAID, BUT STILL ALLOWS THE REVIEWERS TO BE
22 ABLE TO MOVE THROUGH THIS LARGE NUMBER OF
23 APPLICATIONS EFFICIENTLY. AND THE CRITERIA BY WHICH
24 IT'S DONE, THE STRUCTURE OF THE APPLICATION THAT
25 ALLOWS THEM TO DO THAT EFFICIENTLY IN WAYS THAT

1 IDEALLY ALL THE REVIEWERS WILL BE LOOKING AT THE
2 SAME STUFF, NOT SOME REVIEWERS FEELING LIKE THEY
3 HAVE TO READ THE WHOLE APPLICATION, OTHERS THAT KIND
4 OF PICK AND CHOOSE WHICH PARTS THEY'RE GOING TO
5 FOCUS ON, AND OTHERS THAT ARE JUST READING
6 ABSTRACTS. YOU DON'T REALLY WANT THAT, AND I THINK
7 THAT'S THE PROBLEM WE'RE STUCK WITH.

8 DR. LEVITT: I'LL JUST ADD, KEITH, THAT
9 THE NIH HAS NOW GONE TO TRIAGING 67 PERCENT, THE TOP
10 THIRD. THE TOP THIRD ONLY GET DISCUSSED AT STUDY
11 SECTION, TOP THIRD.

12 DR. YAMAMOTO: THAT'S NOT -- I'M NOT A FAN
13 OF THAT.

14 DR. LEVITT: I'M NOT JUSTIFYING IT, BUT
15 THAT'S THE NAME OF THE GAME.

16 AND THE OTHER THING IS THAT, FOR THOSE WHO
17 HAVE DONE REVIEWS ON STUDY SECTIONS, YOU KNOW THAT
18 EACH STUDY SECTION MEMBER HAS A DIFFERENT VIEW ON
19 WHAT INNOVATION IS AND HOW THEY DEFINE IT.

20 DR. YAMAMOTO: OF COURSE. OF COURSE.

21 DR. LEVITT: WHAT RIGOR IS, ET CETERA, ET
22 CETERA. SO THERE'S NO WAY OF GETTING AROUND ALL
23 THIS. I AGREE WITH YOU, THAT THE CIRM TEAM HAS A
24 REALLY CHALLENGING PROBLEM THAT IS TOUGH TO GET OUT
25 OF.

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1 CHAIRMAN IMBASCIANI: THANK YOU,
2 GENTLEMEN. ANNE-MARIE.

3 DR. DULIEGE: SO TWO QUESTIONS, GIL. ONE
4 IS ABOUT THE TOTAL NUMBER OF APPLICATION THAT WILL
5 GO TO THE REVIEW, THE GRANTS WORKING GROUP. SO MY
6 UNDERSTANDING OF THE CURRENT SYSTEM, THAT THE CIRM
7 TEAM WAS LOOKING AT THE APPLICATION WHEN THEY'RE
8 REVIEWED AND LOOKING AT BASIC COMPLETENESS AND
9 OVERALL COMPLETENESS BEFORE THEY WOULD SEND IT TO
10 THE GRANT WORKING GROUP. WILL THAT STILL APPLY?

11 DR. SAMBRANO: YES. WE WILL STILL LOOK --
12 ESSENTIALLY THAT'S THE ELIGIBILITY STAGE AS WE CALL
13 IT, ENSURE THAT THE APPLICATIONS ARE COMPLETE,
14 ELIGIBLE, AND SO ON. SO THAT'S A PROCESS THAT WE DO
15 IN PARALLEL AND CERTAINLY BEFORE THEY GO TO THE
16 PANEL.

17 DR. DULIEGE: GREAT. THANK YOU. THAT'S
18 REASSURING.

19 SECOND, ARE THERE A LIST OF GUIDING
20 PRINCIPLES? AND ARE THEY THE SAME? I ASSUME THEY
21 WILL BE DIFFERENT BETWEEN A DISC APPLICATION 4, 5
22 VERSUS, LET'S SAY, A CLINICAL APPLICATION?

23 DR. SAMBRANO: YES. THEY'RE EACH DESIGNED
24 AROUND THE DIFFERENT PROGRAMS. AND, AGAIN, I KNOW
25 WE KEEP USING THE GUIDING PRINCIPLES. THE GUIDING

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1 PRINCIPLES IS THE UMBRELLA TERM THAT WE USE FOR WHAT
2 WE WANT THE PORTFOLIO TO LOOK LIKE. AND SO IF YOU
3 LOOK AT THE FIRST BULLET, IN A LOT OF THESE IS WE
4 WANT SOMETHING THAT'S IMPACTFUL, SIGNIFICANT,
5 TRANSFORMATIVE. AND SO THAT'S GOING TO ALIGN WITH
6 ALSO, THEN, THE SELECTION CRITERIA THAT WE WOULD USE
7 AT THIS STEP AS WELL AS THE REVIEW CRITERIA.

8 ONE OF THE OTHER GUIDING PRINCIPLES IS
9 HAVING A BALANCE BETWEEN THE RARE AND PREVALENT
10 DISEASES. THAT'S NOT ONE THAT YOU WOULD APPLY
11 NECESSARILY AS A SELECTION CRITERIA OR AS A REVIEW
12 CRITERIA. THAT'S FOR US, CIRM, TO HAVE A PORTFOLIO
13 THAT INCLUDES ALL OF THOSE ELEMENTS.

14 SO I JUST WANT TO MAKE SURE WE'RE CAREFUL
15 IN TERMS OF LIKE HOW WE TRANSITION THE GUIDING
16 PRINCIPLES TO EACH OF THE SELECTION CRITERIA AND
17 REVIEW CRITERIA. THE SELECTION CRITERIA ARE GOING
18 TO BE REALLY FOCUSED ON IS THIS PROJECT FOR THOSE
19 FIRST BULLETS THE TRANSFORMATIVE, SIGNIFICANT TYPE
20 OF PROJECT THAT'S GOING TO MAKE A DIFFERENCE AND
21 THAT'S ALIGNED WITH OUR GOALS?

22 CHAIRMAN IMBASCIANI: FINALLY, CHRISTINA.

23 DR. MIASKOWSKI: I'D LIKE TO SPEAK IN
24 SUPPORT OF THIS PROCESS IN ITS TOTALITY. SELECTION
25 IS HARD. AND WE'RE FACED, AS I THINK KEITH SAID,

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1 WITH DIFFICULT DECISIONS. I'M INVOLVED IN A NUMBER
2 OF ORGANIZATIONS THAT ARE DOING THIS PROCESS, AND I
3 CAN ATTEST TO THE FACT THAT WHAT CIRM IS PROPOSING
4 AND THE LEADERSHIP IS PROPOSING IS RIGOROUS.

5 THE OTHER THING, HAVING SERVED ON THE GWG,
6 I DON'T KNOW NOW, FIVE YEARS, I WANT TO ACKNOWLEDGE
7 THAT THE STAFF, GIL'S GROUP, DOES VERY RIGOROUS
8 TRAINING OF THE REVIEWERS. SO IT IS TOP OF MIND
9 WHAT OUR PRIORITIES ARE. AND FROM MY PERSPECTIVE,
10 IN TERMS OF THE WAY THE APPLICATIONS ARE CONSTRUCTED
11 ACROSS OUR DIFFERENT MECHANISMS, IT'S VERY EASY TO
12 FIGURE OUT IF THE APPLICANT WHO'S PUTTING THE
13 APPLICATION UNDERSTANDS WHAT WE'RE TRYING TO
14 ACHIEVE. AND I'M SURE ALL OF US THAT HAVE READ
15 GRANTS KNOW THAT THERE ARE PEOPLE THAT DO THAT
16 REALLY, REALLY WELL AND FOLLOW THE DIRECTIONS AND
17 HIT ALL THE BULLET POINTS, AND THEN THERE ARE OTHER
18 PEOPLE THAT ARE COMPLETELY OFF THE PAGE.

19 I WANT TO REASSURE YSABEL AND OTHERS THAT
20 THE DEI ELEMENTS ARE STILL VIEWED AS VERY, VERY
21 IMPORTANT IN CIRM'S MISSION. AND THEY'RE NOT CALLED
22 OUT DEI FOR ALL THE REASONS WE KNOW ABOUT IN
23 RELATIONSHIP TO THE FEDERAL LANDSCAPE, BUT THE
24 APPLICANTS ARE ASKED TO PROVIDE US WITH CLEAR
25 INFORMATION ABOUT HOW THEY'RE VIEWING, IN TERMS OF

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1 MOVING A PRODUCT OR A THERAPY INTO THE CLINICAL
2 AREA, HOW THEY'RE VIEWING THE UNMET NEEDS, THE
3 DIVERSITY OF THE POPULATION THAT HAS THE PROBLEM
4 THAT'S UNDER CONSIDERATION, THE ECONOMIC VALUE
5 PROPOSITION IN TERMS OF WHAT THEY'RE DOING TO
6 SUPPORT INDIVIDUALS TO COME AND RECEIVE THIS
7 THERAPY.

8 I JUST WANT TO SPEAK OF HOW RIGOROUS THIS
9 PROCESS IS AND HOW, AS SOMEONE WHO'S A NURSE, HAS A
10 BACKGROUND IN CLINICAL TRIALS, BUT IS THERE AS AN
11 ADVOCATE FOR PATIENTS, EVERY COMMENT THE PATIENT
12 ADVOCATES MAKE ABOUT DEI ARE VALUED AND WE'RE PART
13 OF THE DISCUSSION.

14 AND THE LAST REVIEW THAT WE DID WITH PDEV,
15 EVERY APPLICATION GOT A FAIR REVIEW IN TERMS OF THE
16 SCIENCE, IN TERMS OF ITS POTENTIAL TO MOVE INTO THE
17 CLINIC, WAS IT A VALUE PROPOSITION, WAS IT SOMETHING
18 THAT SOCIETY NEEDED. AND WE HAD SOME APPLICATIONS
19 THAT WERE FOR RARE DISEASES. WE HAD APPLICATIONS
20 THAT WERE MORE FOR COMMON CONDITIONS. EACH ONE OF
21 THEM WAS VALUED AND DISCUSSED.

22 SO I JUST WANT TO SPEAK HIGHLY IN FAVOR OF
23 THIS EVEN THOUGH IT'S A VERY, VERY HARD THING THAT
24 WE HAVE TO DO. IT'S THE BEST WE HAVE AT THE TIME
25 WITH THE RESOURCES THAT WE HAVE, AND I JUST WANT TO

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1 APPLAUD THE STAFF FOR PUTTING IT TOGETHER. I THINK
2 YOU HAVE TO TRUST THAT THE GWG IS WELL EDUCATED,
3 WELL INFORMED TO MAKE INFORMATIVE DECISIONS. AND
4 VIRTUALLY EVERY MEETING GOES OVER BECAUSE WE SPEND
5 TIME -- THE AMOUNT OF TIME THAT APPLICATIONS NEED TO
6 GIVE THEM A FAIR REVIEW. AND I'LL STOP THERE.

7 CHAIRMAN IMBASCIANI: THANK YOU,
8 CHRISTINE. MARVIN, YOU'RE NEXT AND THEN LEONDR
9 WILL FOLLOW.

10 DR. SOUTHARD: I JUST WANTED TO SUPPORT
11 EVERYTHING THAT CHRISTINE JUST SAID, SUPPORTING THIS
12 CHANGE. AS SOMEONE WHO HAS SPENT HOURS AND HOURS
13 REVIEWING, I HAVE TO SAY THAT THE CHANGE ON DEI TO
14 ACCESS AND AFFORDABILITY, IF THE APPLICANT GETS IT,
15 THEY GET IT REALLY WELL. AND IF THEY MISS IT, WE
16 KNOW THAT THEY MISSED IT. SO I THINK THE PROCESS IS
17 FULLY SUPPORTED. THANK YOU.

18 DR. CLARK-HARVEY: WHEW. I DID THAT FOR
19 EVERYONE. THAT'S AN IMPORTANT BREATH BECAUSE I FEEL
20 VERY PRIVILEGED HERE AS A PATIENT ADVOCATE TO BE
21 SURROUNDED WITH COLLEAGUES THAT HAVE SUCH DEEP AND
22 INTENSE SUBJECT MATTER EXPERTISE. THAT'S WHY WE ARE
23 HERE. AND WITH THAT SAID, I THINK WE ALL BRING OUR
24 VARIOUS PERSPECTIVES ON THE SUBJECT MATTER AT HAND.
25 WE ALSO HAVE PERSPECTIVES ON THE PROCESS. BUT WE

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1 ARE A BOARD, AND WE HAVE A VERY CAPABLE STAFF. AND
2 I DO THINK THAT SOMETIMES WE CAN TEND TO DANCE ON
3 THE LINE BETWEEN EXPERTISE AND PROCESS. PROCESS
4 FALLS WITHIN THE HANDS AND THE PURVIEW OF THE STAFF.
5 OF COURSE, WE AS A BOARD CAN COMMENT ON THAT IF
6 THERE ARE CONCERNS, BUT I THINK WE HAVE REACHED A
7 POINT WHERE WE HAVE TO MOVE FORWARD. AND I AM VERY
8 COMFORTABLE WITH THE PROCESS THAT HAS BEEN PUT
9 FORTH. I APPRECIATE. I FEEL LIKE WE'VE HAD
10 RIGOROUS DEBATE. AND I ALSO TRUST AND WANT TO HONOR
11 MY COLLEAGUES THAT SPENT HOURS AND HOURS AND HOURS
12 POURING OVER THESE APPLICATIONS AND TRYING TO DO
13 WHAT'S RIGHT. SO THOSE ARE MY COMMENTS BASED ON
14 WHAT I'VE OBSERVED AND HOW I'D LIKE TO MOVE FORWARD.

15 CHAIRMAN IMBASCIANI: THANK YOU. GIL, I
16 DON'T SEE ANY OTHER HANDS RAISED.

17 DR. SAMBRANO: ALL RIGHT. THANK YOU VERY
18 MUCH FOR THE COMMENTS AND QUESTIONS.

19 SO LET ME JUST GO OVER THE NEXT FEW SLIDES
20 WHICH ADDRESS A PARTICULAR ELEMENT THAT CAME UP AT
21 THE LAST SCIENCE SUBCOMMITTEE OF OUR USE OF
22 SELECTION WITH RANKING VERSUS USING SELECTION WITH
23 SCORING AND WHETHER THAT MAY MAKE A DIFFERENCE IN
24 THE OUTCOMES. AND SO WE LOOKED AT THIS AND RAN SOME
25 MONTE CARLO SIMULATIONS UTILIZING BOTH RANK AND

1 SCORE.

2 AND SO JUST TO SHOW YOU WHAT THE POTENTIAL
3 DIFFERENCES ARE, I'M GOING TO WALK YOU THROUGH SOME
4 OF THESE SLIDES. SO THIS IS AN EXPANSION OF THE
5 SLIDE I PREVIOUSLY SHOWED YOU WHERE SELECTION MEANS
6 A BINARY DECISION YES OR NO AND, THEREFORE, A POINT
7 OR NO POINT. THAT WOULD REMAIN. AND THEN THE RANK,
8 AS I ALSO SHOWED YOU, GETS CONVERTED TO POINTS.
9 WELL, IF YOU LOOK AT A SCORE INSTEAD OF A RANK, AND
10 IF YOU HAVE A SCALE OF 1 TO 5, THAT CAN MIRROR
11 ALMOST EXACTLY A RANK BECAUSE YOU ARE CONVERTING
12 THINGS TO POINTS OR A SCORE.

13 IN THIS TABLE I'M JUST SHOWING YOU THE
14 ASSUMPTION THAT THE SCORE IS GOING TO BE EQUIVALENT
15 TO THE RANK. IT DOESN'T HAVE TO BE. AND ONE OF THE
16 THINGS WITH A SCORE IS THAT IT ALLOWS YOU TO SCORE
17 MANY APPLICATIONS THE SAME OR A RANK FORCES YOU TO
18 SEPARATE THEM. WE LOOKED AT A DIFFERENT SCALE. SO
19 LIKE 1 TO 10 GIVES YOU MORE GRANULARITY IN TERMS OF
20 WHAT THE OUTCOME MAY BE IN TERMS OF ASSIGNING AN
21 APPLICATION SOME DIFFERENCES. SO IN THIS EXAMPLE,
22 THE TOP AND THE BOTTOM ROW WHERE REVIEWER 1 AND
23 REVIEWER 4 GAVE THAT APPLICATION EITHER A SCORE OF 5
24 OR IT GOT 5 POINTS BECAUSE IT WAS RANKED NO. 1 IN
25 THEIR PILE. THERE MAY BE DIFFERENCES THAT A GREATER

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1 SCALE COULD OFFER OF DISTINGUISHING IT AS A 10
2 VERSUS A 9 IN THAT PARTICULAR CASE. OF COURSE,
3 THERE CAN BE MORE THAN THAT.

4 DIDN'T FINISH MAKING MY POINT. SORRY.
5 AND THEN AT THE BOTTOM YOU SEE WHAT THE COMPOSITE
6 SCORE WOULD LOOK LIKE FOR ALL OF THESE, AND THEY'RE
7 PRETTY MUCH IN THE SAME BALLPARK.

8 IF YOU LOOK AT AN EXAMPLE HERE OF FIVE
9 APPLICATIONS THAT ARE RANKED OR SCORED BY A GIVEN
10 REVIEWER, YOU SEE APPLICATIONS A, B, C, D, E. AND
11 SO IN THE RANKING, THEY ARE RANKED AND THEY ARE
12 FORCED TO BE RANKED AND GIVEN A UNIQUE VALUE. SO 1,
13 2, 3, 4, 5. BUT IF YOU SCORE, YOU CAN GET A MORE
14 VARIABLE OUTCOME IN TERMS OF WHAT A REVIEWER MAY
15 DECIDE TO SCORE THESE APPLICATIONS. BECAUSE
16 REMEMBER THESE TEND TO BE, IN THE EXAMPLE OF 5 OUT
17 OF 15, THESE ARE GOING TO BE LIMITED TO THE TOP
18 THIRD OF APPLICATIONS THAT THEY'RE LOOKING AT.

19 SO BY VIRTUE OF THAT, THE RANGE OF SCORES
20 THAT THEY'RE GOING TO UTILIZE ARE GOING TO TEND
21 TOWARDS THE TOP BECAUSE IT'S GOING TO COMPRESS THE
22 SCALE. AND SO IT IS LIKELY THAT YOU ARE GOING GET
23 MORE ASSIGNMENTS OF THE SAME SCORE TO MULTIPLE
24 APPLICATIONS. AND SO I IDENTIFIED AND KIND OF JUST
25 READ THE POSSIBILITY THAT YOU COULD GET MULTIPLE

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1 SCORES OF 5 OR 4 IN A SCALE OF 1 TO 5 OR MULTIPLE 8S
2 AND 10S AND SO ON IN A SCALE OF 1 TO 10.

3 SO WHAT DOES ALL THAT MEAN? WELL, IT
4 MEANS THAT YOU HAVE THE POTENTIAL FOR HAVING MORE
5 TIES. THE POSSIBILITY IS THAT YOU MAY END UP
6 GETTING MORE CLUMPING OF SCORES.

7 BUT WHEN WE RAN THE DISTRIBUTIONS ACROSS
8 THIS, THEY STILL LOOK LARGELY THE SAME. AND
9 ALTHOUGH THERE IS THE POSSIBILITY OF HAVING SOME
10 CLUMPING HERE OR THERE, IT DIDN'T NECESSARILY PAN
11 OUT IN ALL OF THE ITERATIONS THAT WE DID. BUT, OF
12 COURSE, THESE ARE JUST SIMULATIONS. THEY'RE NOT
13 ACTUAL VALIDATED, IN-PRACTICE SESSIONS. SO WE DON'T
14 KNOW EXACTLY WHAT WE WILL FIND IN TERMS OF IN REAL
15 PRACTICE WHETHER RANK AND SCORE ULTIMATELY MAKE A
16 SIGNIFICANT DIFFERENCE. BUT AT LEAST IN THE
17 SIMULATIONS, THEY SEEM TO BEHAVE VERY MUCH THE SAME.

18 AND SO THE SUMMARY OF THE ANALYSIS LOOKING
19 AT RANKING VERSUS SCORING SUGGESTS THAT WE END UP
20 WITH SIMILAR COMPOSITE SCORES, SIMILAR
21 DISTRIBUTIONS, AND GRAY ZONES OR CUTOFF. AND, OF
22 COURSE, KEY DIFFERENCES ARE THAT RANKING FORCES
23 SEPARATION OF APPLICATIONS WHILE SCORING CAN RESULT
24 IN SCORE COMPRESSION, WHICH COULD CREATE MORE TIES.
25 SCORING, HOWEVER, DOES PROVIDE COMPARABILITY ACROSS

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1 BATCHES, AND THAT MAY BE IMPORTANT, BUT IT IS
2 DIFFICULT TO KNOW IF, WHEN YOU SEE ANY DIFFERENCE,
3 IT'S DUE TO BATCHES ACTUALLY BEING DIFFERENT FROM
4 ONE ANOTHER IN TERMS OF QUALITY OR IF IT'S
5 DIFFERENCES IN THE REVIEWER THEMSELVES IN THAT ONE
6 REVIEWER WAS MORE LENIENT, ANOTHER ONE WAS MORE
7 STRICT. AND SO THAT'S NOT SOMETHING THAT YOU CAN
8 ASSESS.

9 SO WHEN COMPARING THESE, I THINK THE CIRM
10 TEAM, IN GENERAL, PREFERS THE USE OF RANKING BECAUSE
11 WE FEEL, AT LEAST AT THE ONSET TO TEST THIS OUT, WE
12 THINK IT WILL PROVIDE CONSISTENT SEPARATION OF
13 SCORES, PARTICULARLY AT THE CUTOFF. BUT LIKE
14 ANYTHING ELSE, THIS IS SOMETHING THAT WE WANT TO
15 CONTINUE TO COLLECT DATA ON AND MAKE SURE THAT WHAT
16 WE'RE EXPECTING IN PRACTICE IS WORKING AS WE THINK.

17 ALL RIGHT. SO HOW DO YOU ESTABLISH THE
18 CUTOFF? SO THIS IS THE TABLE I HAD MENTIONED
19 EARLIER. SO THE WAY WE WOULD ESTABLISH THE SPECIFIC
20 CUTOFF IS WE WOULD SET IT AT THE CLOSEST NUMERICAL
21 BREAK WHERE THERE ARE NO TIES TO THE TARGET NUMBER
22 OF APPLICATIONS THAT WOULD NOT EXCEED 10 PERCENT
23 MORE OR FEWER THAN THE TARGET NUMBER.

24 AND SO IN THIS EXAMPLE, YOU HAVE THE
25 APPLICATIONS THAT RANKED FROM 28 TO 32, AND YOU SEE

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1 THAT APPLICATIONS 29, 30, AND 31 HAVE THE EXACT SAME
2 COMPOSITE SCORES. THOSE ARE TIED. AND SO WE WOULD
3 LOOK FOR IS WHERE IS THE CLOSEST NUMERICAL BREAK
4 WITH NO TIES THAT OCCURS BETWEEN 31 AND 32. SO
5 THAT'S WHERE THE CUTOFF WOULD BE ESTABLISHED. AND
6 SO ANYTHING THAT IS .32 OR GREATER ADVANCES, AND
7 EVERYTHING ELSE BELOW THAT DOES NOT.

8 NOW, IF FOR SOME REASON AND, AGAIN, THE
9 MODELING SUGGESTS THAT IT WOULD BE A RARE OCCURRENCE
10 IF YOU CAN'T ESTABLISH THIS KIND OF CUTOFF, BUT IF
11 FOR SOME REASON WE CANNOT, THEN WE WILL TAKE THE
12 ENTIRE RANGE THAT OCCURS, WHICH IS LIKELY TO BE,
13 SAY, FIVE, SIX APPLICATIONS IN AN EXAMPLE LIKE THIS,
14 AND RANDOMIZE THEM IN ORDER TO SELECT THE TARGET
15 NUMBER IN ORDER TO AVOID ANY SPECIFIC SELECTION BIAS
16 IN DETERMINING WHAT ADVANCES.

17 ALL RIGHT. SO THEN THE LAST STEP IN THE
18 PROCESS IS THAT ONCE A CUTOFF IS ESTABLISHED, THEN
19 THE CIRM PRESIDENT, WITH RECOMMENDATION FROM THE
20 CIRM STAFF, WILL EXAMINE THE APPLICATIONS THAT FALL
21 BELOW THE CUTOFF AND MAY ADVANCE A LIMITED NUMBER OF
22 THOSE APPLICATIONS THAT COULD REPRESENT A UNIQUE
23 OPPORTUNITY ALIGNED WITH THE GOALS OF THE PARTICULAR
24 CYCLE. AND SO THIS IS, IF YOU WILL, SORT OF A
25 RESCUE PROCESS THAT'S BUILT INTO THIS.

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1 NOW, THE OTHER QUESTION THAT WE ADDRESSED
2 DURING THE SCIENCE SUBCOMMITTEE, WHICH IS A VERY
3 IMPORTANT ONE, IS THE ROLE OF PATIENT ADVOCATES IN
4 TERMS OF THIS PROCESS. SO ALTHOUGH NOT INVOLVED
5 DIRECTLY IN THE VOLUME CONTROL SELECTION, WHAT WE
6 WANT TO DO IS HAVE THE ROLE OF THE PATIENT ADVOCATE
7 STRENGTHENED AT THE GWG PANEL DISCUSSION. SO FOR
8 THOSE APPLICATIONS THAT ADVANCE, ONE OF THE IDEAS
9 THAT CAME THROUGH OUR ONGOING DISCUSSIONS WAS TO
10 DEFINE AND INCLUDE A PATIENT PERSPECTIVE SCORE. AND
11 SO THIS SCORE WOULD ALLOW US TO DEFINE SOME SPECIFIC
12 CRITERIA THAT COME FROM THE PATIENT PERSPECTIVE AND
13 UTILIZE A SCORE THAT THEN REPRESENTS THAT, THAT WE
14 WOULD BRING TO THE BOARD AS PART OF THE APPLICATION.
15 THIS IS AN ELEMENT THAT WE ARE STILL DISCUSSING WITH
16 THE PATIENT ADVOCATE MEMBERS THAT SERVE ON THE
17 GRANTS WORKING GROUP TO BETTER DEFINE IT BECAUSE IT
18 CERTAINLY NEEDS MORE DEFINITION AND SOMETHING THAT
19 WE WANT TO BRING BACK IDEALLY IN JUNE TO PRESENT TO
20 YOU AS PART OF THIS PACKAGE.

21 AND ONE OF THE OTHER ELEMENTS THAT WE
22 THOUGHT WOULD BE IMPORTANT WAS TO HAVE A
23 PREDISCUSSION ORIENTATION THAT INCLUDES THE PATIENT
24 ADVOCATES ALONG WITH THE GRANTS WORKING GROUP CHAIR
25 TO TALK ABOUT HOW TO LEVERAGE THE RESPECTIVE

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1 EXPERTISE GOING INTO THESE REVIEWS AND MAKING SURE
2 THAT THE PATIENT PERSPECTIVE IS SOMETHING THAT IS
3 INCLUDED IN THE DISCUSSION WHEN THESE APPLICATIONS
4 ARE BROUGHT TO THE TABLE.

5 SO THAT'S MY SLIDE, AND I THINK, ROSA, IT
6 COMES BACK TO YOU.

7 DR. YAMAMOTO: CAN WE DISCUSS?

8 CHAIRMAN IMBASCIANI: WHO'S SPEAKING?

9 VICE CHAIR BONNEVILLE: KEITH IS.

10 CHAIRMAN IMBASCIANI: KEITH, THERE YOU
11 ARE. YES.

12 DR. YAMAMOTO: SO I APOLOGIZE, GIL. I'M
13 STILL NOT CLEAR WHAT THE -- WHAT IS THE CUTOFF --
14 WHAT HAPPENS TO THE THINGS THAT ARE ABOVE AND BELOW
15 THE CUTOFF? THIS IS FOR FURTHER DISCUSSION TO THEN
16 DECIDE ON WHAT GETS FUNDED, WHAT WE RECOMMEND FOR
17 FUNDING?

18 DR. SAMBRANO: RIGHT. SO THE ONES THAT
19 ARE ABOVE THE CUTOFF ADVANCE TO, THEN, THE FULL
20 GRANTS WORKING GROUP REVIEW. AND SO THEY ARE
21 ASSIGNED A FULL SET OF REVIEWERS. SO IF IT'S
22 CLINICAL, FOR EXAMPLE, THE FULL SET OF DISEASE AREA
23 EXPERTS, CMC, AND SO ON, TO HAVE THAT FULL REVIEW
24 AND DISCUSSION. THE ONES THAT FALL BELOW THE CUTOFF
25 DO NOT ADVANCE, AND THAT'S SORT OF THE END FOR THOSE

1 APPLICATIONS.

2 DR. YAMAMOTO: RIGHT. RIGHT. RIGHT. SO
3 BEING ABOVE OR BELOW THE CUTOFF IS VERY CRITICAL OR
4 GETTING THE ATTENTION OF THE PRESIDENT IF YOU'RE
5 BELOW THE CUTOFF IS REALLY CRITICAL. IT'S REALLY
6 THE BALLGAME OF WHETHER YOU'RE GOING TO BE IN THE
7 RUNNING FOR GETTING FUNDED OR NOT. AND SO THAT'S
8 WHY I THINK IT'S PARTICULARLY IMPORTANT TO SORT OF
9 TRY TO GET THIS RIGHT. AND SO WHEN YOU SAY THAT THE
10 NICE THING ABOUT RANKING, AND YOU'RE CERTAINLY
11 CORRECT, THE NICE THING ABOUT RANKING IS THAT YOU
12 GET GOOD SEPARATION OF THE APPLICATIONS.

13 THE PROBLEM IS THAT THAT SEPARATION IS A
14 FALSE ONE. WHEN YOU'RE RANKING FIVE APPLICATIONS
15 THAT YOU'VE SELECTED, THE RANKINGS BY DEFINITION SAY
16 THAT YOU BELIEVE THAT THE QUALITY OF THEM, THE
17 SCIENTIFIC VALUE OF THEM DIFFERS BY 20 PERCENT AS
18 YOU GO FROM 1 TO 2 TO 3 TO 4 TO 5. THAT THE NO. 1
19 ONE IS 20 PERCENT BETTER THAN THE NO. 2 ONE.

20 IF YOU'RE SCORING, THAT ARTIFICIALNESS,
21 YOU'RE LIBERATED FROM THAT ARTIFICIALNESS. SO A
22 STRONG POOL COULD HAVE FIVE SELECTED APPLICATIONS IN
23 WHICH THREE OF THEM GET A 1 AND TWO OF THEM GET A 2.
24 IN A WEAK POOL, YOU COULD HAVE THE TOP RANKING ONE
25 COULD GET A 6. AND SO YOU'RE ABLE TO REALLY INSERT

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1 AN ASSESSMENT OF THE QUALITY -- THE SCIENTIFIC VALUE
2 IS WHAT WE'RE CLAIMING THAT WE'RE DOING IN THIS
3 PROCESS. AND I JUST THINK THAT -- AND SO WHEN YOU
4 RAN THE SIMULATIONS AND CAME UP WITH THE TWO
5 PROCESSES, RANKING AND SCORING, THEY WERE RELATIVELY
6 SIMILAR IS BECAUSE YOU ESSENTIALLY ASSIGNED THE
7 SCORES TO REFLECT THE RANKS. BUT WHAT I'M SAYING IS
8 THAT HOPEFULLY THAT WOULDN'T BE TRUE. THERE'S NO
9 REVIEWER THAT WOULD ACTUALLY BELIEVE THAT THE FIVE
10 THAT THEY'VE SELECTED DIFFER EACH FROM THE OTHER BY
11 20 PERCENT. THAT'S NOT TRUE. NOBODY WOULD BELIEVE
12 THAT.

13 AND SO IF YOU LIBERATE THE REVIEWERS TO
14 ACTUALLY ASCRIBE WHAT THEY THINK THE RELATIVE
15 SCIENTIFIC VALUE OF THE APPLICATIONS IS, THEN YOU
16 GET MUCH MORE INFORMATION. AND AS YOU SAID, YOU
17 ALSO GAIN INTERPOOL INFORMATION. SO I THINK THE TWO
18 ARE REALLY NOT AT ALL EQUIVALENT AND THAT THE
19 SCORING IS SUBSTANTIALLY SUPERIOR. AND THIS MAY
20 SOUND A LOT LIKE I'M QUIBBLING OVER DETAILS, AND I
21 APOLOGIZE TO THE GROUP FOR THAT, BUT BECAUSE
22 ESTABLISHING PRIORITY ABOVE AND BELOW THE CUTOFF IS
23 SO CRITICAL AND IT'S REALLY THE BALLGAME, I THINK WE
24 REALLY WANT TO TRY TO GET THIS RIGHT. AND WE OWE IT
25 TO THE APPLICANTS WHO HAVE DONE SO MUCH WORK

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1 PREPARING THEIR APPLICATIONS TO BE ABLE TO DO THAT.

2 DR. CARETHERS: THIS IS JOHN CARETHERS. I
3 JUST WANT TO SAY I SUPPORT THIS PROCESS. IN
4 ESSENCE, YOU'RE TAKING A PROCESS THAT APPLY TO THE
5 DIFFERENT PROGRAMS AND MORE STANDARDIZING ACROSS THE
6 PROGRAMS, AND YOU'RE JUST USING A DIFFERENT,
7 SLIGHTLY DIFFERENT WAY TO GET THE CUTOFF FOR THE
8 FINAL REVIEW. SO YOU'RE TAKING A HUNDRED
9 APPLICATIONS. YOU SHOWED THE DISTRIBUTION BETWEEN
10 THE TWO. THEY DON'T LOOK HORRIBLY DIFFERENT. I
11 KNOW THESE WERE MODELS. BUT I THINK THE PROCESS
12 WILL BE THE PROCESS.

13 I AM LESS WORRIED ABOUT ORDINAL RANKING
14 BECAUSE I THINK IT HELPS DIFFERENTIATE EVENTUALLY
15 WHICH ONES GET FUNDED BECAUSE WE DO HAVE LIMITED
16 FUNDING. IT'S ALWAYS HARD WHEN YOU SEE SCORES THAT
17 ARE ALL VERY TIGHTLY, EVEN THOUGH THAT REFLECTS THE
18 SCIENTIFIC RIGOR, AND MAYBE THERE COULD BE AN OPTION
19 FOR TWO SCORES, BUT THE ORDINAL RANKING PUTS THEM IN
20 ORDER BASED ON THE RIGOROUS REVIEW ON HOW SOMEONE IS
21 GOING TO MOVE FORWARD BASED ON THE LIMITATIONS OF
22 THE RESOURCES THAT ARE HAD FOR THAT ROUND. AND SO
23 YOU HAVE TO DIFFERENTIATE SOMEHOW.

24 I GUESS THE ONLY THING THAT I WOULD
25 POSSIBLY AGREE WITH KEITH ON THE ORDINAL VERSUS A

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1 SCORE RANKING IS HOW DO YOU COMPARE SOMEONE FROM
2 ROUND 1 TO SAY ROUND 5 IN THE CLINICAL ROUND WHEN
3 THE RULES HAVE CHANGED SLIGHTLY. I'M LESS WORRIED
4 ABOUT THE INDIVIDUAL ROUNDS, BUT THAT WOULD BE THE
5 ONLY THING I WOULD ASK.

6 DR. BARRETT: YEAH. THIS HAS BEEN A
7 REALLY USEFUL DISCUSSION, AND I DO APPLAUD THE TEAM
8 FOR WORKING VERY HARD ON THIS. AT THE RISK OF SORT
9 OF TRYING TO REINVENT THE WHEEL, DID YOU CONSIDER A
10 MODEL JUST BASED ON THE YES OR NO, IS IT IN THE TOP
11 THIRD? BECAUSE WHEN I WAS AT THE NSF, WE HAD A
12 SIMILAR PROBLEM WITH A VERY LARGE APPLICATION
13 PRESSURE AND A NEED TO VOLUME CONTROL ON THE FRONT
14 END. AND BEFORE I GOT THERE, THEY HAD A VERY
15 SIMILAR PROCESS WHERE PEOPLE WOULD PICK THEIR TOP, I
16 THINK IN THIS CASE IT WAS SEVEN, AND THEN THEY HAD
17 TO RANK THEM.

18 AND WE WERE ADVISED BY THE THEN DIRECTOR
19 OF THE SOCIAL AND BEHAVIORAL SCIENCES DIRECTORATE
20 THAT IT IS ACTUALLY VERY DIFFICULT FROM A SOCIAL
21 SCIENCE PERSPECTIVE FOR PEOPLE TO PUT THINGS IN
22 ORDER. IN THAT CASE IT WAS FOR SEVEN. BUT IT FELT
23 NOT TO REALLY ADD MEANINGFULLY TO THE PROCESS.

24 AND PERHAPS IF YOU ARE ONLY ASKING PEOPLE
25 TO PUT THEM IN THE TOP THIRD, YOU COULD ACTUALLY

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1 HAVE MORE REVIEWERS DO THAT AND MAKE THAT A SORT OF
2 MORE ROBUST NUMBER AND PRESUMABLY STILL HAVE A
3 SPREAD ACROSS A LARGE NUMBER OF REVIEWERS.

4 DR. SAMBRANO: SO WE DID THE MODELING. SO
5 THAT'S WHAT WE CALL SORT OF JUST A BINARY SELECTION,
6 WHICH IS SIMILAR TO WHAT WE HAVE DONE WITH POSITIVE
7 SELECTION. AND SO WE'VE ESSENTIALLY DONE THAT KIND
8 OF BINARY MODEL. BUT WHAT HAPPENS IS THAT YOU END
9 UP WITH A VERY LARGE GRAY AREA BECAUSE THE SELECTION
10 IS LIMITED IN TERMS OF ITS LEVEL OF GRANULARITY.
11 ADDING RANK OR SCORING, EITHER ONE, GIVES YOU
12 ANOTHER LEVEL OF GRANULARITY BECAUSE YOU HAVE
13 ANOTHER MEASURE THAT YOU CAN USE IN ORDER TO
14 DISTINGUISH APPLICATIONS, AND IT ALLOWS THAT GRAY
15 ZONE, THAT CUTOFF, TO NARROW SIGNIFICANTLY. AND SO
16 IT ALLOWS A BETTER CUTOFF.

17 BUT WE DID LOOK AT DIFFERENT APPROACHES IN
18 TERMS OF THE MODELING. AGAIN, A LOT OF THIS IS IN
19 PRACTICE WHAT'S GOING TO HAPPEN. I THINK KEITH MAY
20 BE ABSOLUTELY RIGHT, THAT SCORING WORKS BETTER.
21 FROM OUR PERSPECTIVE, WE THINK THAT RANKING MAY WORK
22 BETTER; BUT UNTIL WE DO IT, WE'RE NOT REALLY GOING
23 TO KNOW. SO WE WANT TO COLLECT THAT DATA, MAKE SURE
24 THAT IT'S WORKING AS WE EXPECT.

25 I ALSO JUST WANT TO CLARIFY IN TERMS OF A

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1 COUPLE OF THE POINTS MADE, WHEN WE DID THE MODELING,
2 WE DID NOT ASSUME THAT THEY WOULD HAVE UNIQUE
3 SCORES. THE SCORES WERE ALLOWED TO BE THE SAME.
4 AND THAT'S WHY YOU END UP GETTING THE ISSUE OF SCORE
5 COMPRESSION. AND SO IT MAKES THE USE OF THE SCALE,
6 IT JUST REALLY TIGHTENS IT. SO, FOR ME, THAT IS
7 SOMETHING THAT WE WANT TO BE CAREFUL ABOUT. BUT,
8 AGAIN, IT IS LOOKING AT A NUANCED ELEMENT. IT'S A
9 SECOND MEASURE. WHETHER SCORE OR RANK, I THINK THEY
10 WOULD BOTH ULTIMATELY WORK. BUT I CAN GET THIS
11 POINT, RANKING FOR US IS WHAT WE PREFER.

12 DR. BARRETT: I MEAN I'M WILLING TO
13 SUPPORT THE PROPOSAL NO MATTER WHAT, BUT YOU MIGHT
14 WANT TO CONSULT WITH A SOCIAL SCIENTIST WHO WORKS ON
15 VOTING PREFERENCES OR SOMETHING LIKE THAT JUST TO
16 MAKE SURE THAT YOU'RE NOT INTRODUCING AN ELEMENT
17 THAT'S NOT DEFENSIBLE FROM A HUMAN PSYCHOLOGY
18 STANDPOINT.

19 DR. SAMBRANO: SURE. THANK YOU.

20 CHAIRMAN IMBASCIANI: PAT LEVITT IS ON THE
21 LINE.

22 DR. LEVITT: YEAH. I WAS GOING TO SAY
23 WHEN YOU -- BECAUSE I'VE BEEN ON NSF PANELS AS WELL,
24 AND THE GRAY AREA IS VERY LARGE. IT'S ACTUALLY OUT
25 OF FOUR BINS, IT OCCUPIES TWO BINS WHEN THEY DEFINE

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1 THE BINS AS MUST FUND, AND THEN YOU HAVE TWO BINS
2 WHERE YOU'RE NOT SURE WHICH BIN IT SHOULD GO IN, TWO
3 OR THREE, AND THEN YOU HAVE FOUR YOU'RE NOT GOING TO
4 FUND AT ALL. SO YOU HAVE A VERY LARGE NUMBER OF
5 APPLICATIONS THAT ARE SITTING IN THE MIDDLE. SO
6 THAT TO ME IS A PROBLEM, BUT THAT'S HOW IT'S RUN A
7 AT THE NATIONAL SCIENCE FOUNDATION.

8 THE OTHER THING I WOULD SAY IS I AGREE TO
9 KEITH'S POINT, THAT IT WILL -- SCORING WILL DEAL
10 WITH INTERGROUP BATCH ISSUES. BUT THE PROBLEM WITH
11 SCORING HAS ALWAYS BEEN, AND THIS IS TRUE AT NIH AND
12 EVERY OTHER ORGANIZATION THAT USES SCORING, IS THAT
13 THERE'S SCORING COMPRESSION. THAT IS A SOCIAL
14 SCIENCE FACT. AND YOU NEED A THIN GRAY AREA HERE
15 AND YOU NEED SOME WAY OF DIFFERENTIATING WHICH THE
16 RANK DOES. SO I WOULD REALLY SUPPORT TRYING TO RANK
17 FIRST AND SEEING WHAT HAPPENS. AS YOUR GRAY ZONE,
18 AS YOU PREDICTED BASED ON YOUR MONTE CARLO, IS THERE
19 A CLEAR BREAK? AND THEN IF THERE'S SOME ISSUES,
20 GOING TO SCORING IS CERTAINLY WORTH A TRY, BUT I DO
21 THINK THAT REVIEWERS TEND TO COMPRESS. AND NIH HAS
22 GONE TO EXTREMES TO TRY TO GET REVIEWERS TO USE THE
23 WHOLE RANGE AND THEY NEVER DO. SO CONGRATULATIONS,
24 AND MAYBE WE'RE DONE WITH THIS.

25 CHAIRMAN IMBASCIANI: OKAY. SCOTT, WE'RE

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1 TAKING A BREAK.

2 MR. TOCHER: IF WE ARE FINISHED WITH THIS
3 PORTION.

4 CHAIRMAN IMBASCIANI: DO YOU WANT TO GO TO
5 A POINT WHERE YOU CAN PAUSE?

6 DR. SAMBRANO: THIS IS A POINT WHERE WE
7 CAN PAUSE.

8 MR. TOCHER: WE WILL TAKE A QUICK FIVE,
9 AND I KNOW THAT MEANS TEN, BIOBREAK. AND SO PLEASE
10 HURRY BACK AS SOON AS YOU CAN.

11 (A RECESS WAS TAKEN.)

12 DR. CANET-AVILES: SO, LET'S ROCK AND
13 ROLL. SO I'M NOW GOING TO FOCUS ON HOW THE GUIDING
14 PRINCIPLES ARE APPLIED IN THE LAST STEP IN THE
15 APPLICATION LIFE CYCLES, WHICH IS THE FUNDING
16 DECISIONS WHICH THE APPLICATION REVIEW SUBCOMMITTEE
17 OF THE BOARD MAKES.

18 AND SO, AGAIN, JUST TO ITERATE, WE ARE ON
19 THAT TARGET, THE GREEN PART RIGHT THERE. THAT'S THE
20 FUNDING DECISION. AND HISTORICALLY, JUST FOR
21 CONTEXT, THE CIRM TEAM HAS PROVIDED RECOMMENDATIONS
22 TO THE ARS BY PROVIDING AN ANALYSIS, A PROGRAMMATIC
23 ANALYSIS, TOGETHER WITH THE GRANTS WORKING GROUP
24 SUMMARIES AND THE PUBLIC COMMENT. BUT ULTIMATELY
25 THE ARS CONSIDERS MANY DIFFERENT THINGS IN HOW IT

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1 CHOOSES TO FUND WHICH APPLICATION.

2 SO WHAT WE ARE GOING TO DO NOW IS PROPOSE
3 A REFINEMENT. IT'S NOT A HUGE CHANGE. IT'S JUST A
4 REFINEMENT ON HOW THE CIRM TEAM RECOMMENDATIONS
5 ASSIST THE ARS IN MAKING THESE DECISIONS, WHICH IS
6 BASICALLY A MORE TRANSPARENT WAY TO PROVIDE
7 PROGRAMMATIC RECOMMENDATIONS BASED ON THE GUIDING
8 PRINCIPLES. SO THIS IS THE LAST STAGE, HOW TO APPLY
9 GUIDING PRINCIPLES TO THE RECOMMENDATIONS.

10 SO WHAT DOES THE CIRM TEAM RECOMMENDATIONS
11 INCLUDE? THE FIRST THING THAT THEY INCLUDE ARE --
12 SO WE'RE GOING FOCUS, JUST TO FOCUS THE ATTENTION,
13 THE PROGRAMMATIC FACTORS IS WHERE THE GUIDING
14 PRINCIPLES WILL GO. BUT WHEN WE PROVIDE
15 RECOMMENDATIONS TO THE ARS OF THE BOARD, WE PROVIDE
16 THE AVAILABLE PROGRAM BUDGETS OR SOMETIMES, LIKE
17 TODAY, WE DIDN'T HAVE ENOUGH MONEY TO FUND THE EIGHT
18 DISC4. SO WE HAD TO PROVIDE THE BUDGET AVAILABLE,
19 THE BUDGET ASK, AND THEN THE BOARD COULD MAKE THEIR
20 DECISIONS.

21 WE ALSO PROVIDE THE GRANTS WORKING GROUP A
22 SCORE AND THE COMMENTS, THE SUMMARY OF THE COMMENTS
23 FROM THE GRANTS WORKING GROUP, THE PROGRAMMATIC
24 FACTORS, WHICH IS WHERE THE GUIDING PRINCIPLES WILL
25 COME INTO PLAY AT THAT PORTFOLIO LEVEL. AND I'LL GO

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1 INTO SPECIFICS IN THE NEXT SLIDES. AND THEN PRIOR
2 AWARDEE PERFORMANCE LIKE IF THEY HAVE STRONG
3 EXECUTION, THAT BUILDS CONFIDENCE. RIGHT? BUT IF
4 THERE ARE PERSISTENT DELAYS, WE MIGHT BRING THIS UP
5 SO THAT THE BOARD IS AWARE THAT THOSE THINGS HAPPEN.
6 AND THEN ANY NEW INFORMATION, SCIENTIFIC OR
7 ADMINISTRATIVE INFORMATION, THAT COMES TO THE
8 ATTENTION OF CIRM STAFF THROUGH DIRECT COMMUNICATION
9 WITH APPLICANTS OR INSTITUTIONS OR PUBLICATIONS OR
10 OTHER.

11 SO IN THE NEXT SLIDES, WHAT I'M GOING TO
12 DESCRIBE IS HOW THESE GUIDING PRINCIPLES APPLY AND
13 ARE ASSESSED AND LEVERAGED IN THE CIRM TEAM
14 RECOMMENDATIONS AT THE PROGRAMMATIC LEVEL. SO
15 PROGRAMMATIC FACTORS FOR PDEV AND CLIN2, THERE ARE
16 THE THREE GUIDING PRINCIPLES THAT APPLY ON HOW THEY
17 ARE ASSESSED. THE FIRST ONE IS TRANSFORMATIVE
18 CLINICAL IMPACT. THE KIND OF INFORMATION THAT WE
19 LOOK AT ONCE THERE IS A GRANTS WORKING GROUP
20 RECOMMENDATION FOR US TO PROVIDE TO THE BOARD IS
21 THAT WE COMPARE THAT AWARD TO ACTIVE AWARDS AND
22 EXTERNAL LANDSCAPE WITHIN THE SAME INDICATION.

23 THE SECOND ASPECT IS PATIENT ACCESS, AND
24 THERE IS A DIFFERENCE HERE BETWEEN CLIN2 AND PDEV.
25 SO FOR CLIN2, BEYOND PROVIDING ANY KNOWLEDGE OF THE

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1 MODALITY AND ROUTE OF ADMINISTRATION WHICH DOES HAVE
2 AN EFFECT ON THE PATIENT OR HOW THE PATIENTS WILL BE
3 ABLE TO ACCESS THIS, WE ALSO PROVIDE A SUMMARY OF
4 THE ACCESS SPECIALIST REVIEWER COMMENTS. THERE WILL
5 BE ACCESS SPECIALISTS REVIEWERS IN THE GRANTS
6 WORKING GROUP OF CLIN2. AND THEN THE DISEASE
7 REPRESENTATION. WE COMPARE TO OUR ACTIVE AWARD
8 PORTFOLIO BY DISEASE AREA.

9 SO THE NEXT ONE IS THE DISC4. SO FOR
10 DISC4, THE THREE PRINCIPLES. THE FIRST ONE, THE
11 MULTIDISCIPLINARY RESEARCH APPROACH, DOES NOT APPLY.
12 WE DO NOT PROVIDE ANYTHING EXTRA. THERE IS AN
13 ASSESSMENT THAT'S ALREADY PROVIDED BY THE GRANTS
14 WORKING GROUP REVIEW SUMMARY, AND THAT'S WHAT THE
15 ARS WILL RECEIVE IN TERMS OF THAT PRINCIPLE.

16 BUT THEN FOR THE COLLABORATION NETWORK
17 SYNERGY AND DATA LEVERAGE, WE ARE GOING TO EVALUATE
18 HOW THE RESEARCH APPROACHES AND THE TOPIC AREA
19 COMPARE TO ACTIVE DISC4 PORTFOLIO AND PENDING AWARDS
20 TO FIGURE OUT IF THERE ARE WAYS THAT BY FUNDING THAT
21 AWARD WE COULD BE ABLE TO INCREASE THE NETWORK
22 SYNERGY, FOR EXAMPLE. SO THOSE KIND OF ELEMENTS
23 WILL BE IN CONSIDERATION IN THAT PROGRAMMATIC
24 RECOMMENDATION.

25 AND THEN THE NEURO TASK FORCE AND OTHER

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1 ORGANIZATIONAL PRIORITIES, BECAUSE, AS KELLY WILL
2 DESCRIBE, THE DISC4 IS OPEN TO ALL COMERS. WE JUST
3 HAVE A FOCUS AREA THAT WILL BE IN PLAY AT THE
4 SELECTION CRITERIA. SO IF THERE IS ONE THAT'S NOT
5 WITHIN THE ANNUAL FOCUS AREA, BUT IT MAKES IT TO
6 REVIEW, AND THEN WE CAN ONLY FUND, AGAIN, SIX OF
7 EIGHT, THOSE THAT ARE NOT WITHIN THE ANNUAL FOCUS
8 AREA, THAT WOULD BE A CONSIDERATION AND THEN ANY
9 ADDITIONAL CONSIDERATIONS CONCERNING EVOLVING
10 RESEARCH LANDSCAPE AND FUNDING NEEDS.

11 SO FINALLY, THE CIRM TEAM RECOMMENDATION
12 MEMO, THIS IS WHAT WE WILL PROVIDE TO THE ARS FOR
13 THE MEETING FOR CONSIDERATION. AND, AGAIN, THEY
14 CAN -- IT'S UP TO THE PREROGATIVE OF THE APPLICATION
15 REVIEW SUBCOMMITTEE TO CONSIDER THIS. SO WE WILL
16 INCLUDE, AND THERE IS AN EXAMPLE IN THE MEMO, A
17 SUMMARY TABLE AND RATIONALE FOR ALL THE
18 APPLICATIONS. ACTUALLY WE PUT RECOMMENDATIONS
19 THERE, BUT IT'S CONFUSING. SO ALL THE APPLICATIONS
20 THAT CAME IN, WE WILL HAVE A SUMMARY TABLE AND THE
21 RATIONALE. AND WE WILL HAVE GRANTS WORKING GROUP
22 WHETHER THEY RECOMMENDED FOR FUNDING AND THEN WHAT
23 THE TEAM, LIKE IF WE DISAGREE WITH THAT OR NOT.
24 RIGHT?

25 AND THEN BASED ON ALL THAT, THE ANALYSIS

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1 OF PROGRAMMATIC FACTORS FOR THE MINORITY REPORTS,
2 APPLICATIONS WHERE THE CIRM RECOMMENDATION DIFFERS
3 FROM GRANTS WORKING GROUP, ALL OF THOSE WILL HAVE AN
4 ANALYSIS OF THE FACTORS THAT WE JUST SAW. AND THEN
5 ANY APPLICATION, AND THIS IS A HANDFUL OF AN
6 EXPRESSION, BUT IF WE THINK ABOUT IT, ANY
7 APPLICATION WITH A GRANTS WORKING GROUP SCORE HIGHER
8 THAN OR TIED WITH THE LOWEST SCORING CIRM
9 RECOMMENDED APPLICATIONS.

10 SO LET'S IMAGINE THAT WE HAD AN 80 AND
11 THERE IS AN 83 THAT'S NOT RECOMMENDED, BUT WE
12 RECOMMEND FOR FUNDING THE 80 BECAUSE MAYBE IT HAS AN
13 ACCESS PATH THAT'S AMAZING AND WE THINK THAT IT WILL
14 MAKE IT, AND IT WILL BE A LOT OF VALUE FOR PATIENTS.
15 SO WE COULD ACTUALLY BE MAKING -- ANYTHING THAT'S
16 OVER THAT 80 COULD BE COMING WITH A PROGRAMMATIC AS
17 WELL BECAUSE WE NEED TO EXPLAIN TO THE BOARD HOW
18 THEY DIFFER. YOU NEED TO HAVE THOSE DETAILS. SO
19 THAT'S IT.

20 AND NOW OTHER UPDATES TO FUNDING PROGRAMS.
21 AND I WANT TO SAY SOMETHING ABOUT KELLY.
22 DR. SHEPARD -- SORRY.

23 VICE CHAIR BONNEVILLE: IT'S OKAY. I
24 WANTED TO MAKE A COMMENT ABOUT THE ARS AND THE
25 RECOMMENDATIONS THAT ARE GOING TO BE COMING AND HOW

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1 THOSE ARE COMING BECAUSE I THINK THAT'S WONDERFUL.
2 I THINK IT IS REALLY IMPORTANT TO HAVE ALL OF THAT
3 INFORMATION AS OUR FUNDING DOLLARS GET FEWER AND THE
4 DEMAND STAYS THE SAME AND MORE THINGS ARE
5 RECOMMENDED THAN WE CAN FUND. I THINK IT'S -- I
6 THINK HOW WE APPROACH THE ARS IS GOING TO HAVE TO
7 CHANGE A BIT OR AT LEAST BE CONSIDERED DIFFERENTLY
8 AND HOW THE PRESENTATIONS ARE DONE AND WHAT
9 INFORMATION IS GIVEN DURING THE PRESENTATION VERSUS
10 WHAT IS IN OUR BOARDABLE OR BOARD PACKETS IS ALSO
11 REALLY IMPORTANT. AND SO I THINK IT'S SOMETHING
12 THAT VITO HAS TO FIGURE OUT AS CHAIR OF THE ARS IS
13 HOW WE ARE GOING TO GO TO APPROACH THE APPLICATION
14 REVIEW SUBCOMMITTEE.

15 CHAIRMAN IMBASCIANI: YOU'RE ABSOLUTELY
16 RIGHT, MARIA. WE'VE JUST BEGUN TO HAVE
17 CONVERSATIONS ON THIS. IT IS GOING TO PUT A
18 SLIGHTLY, I EXPECT, LARGER ONUS, BURDEN, ON MEMBERS
19 OF THE ARS TO BE -- YOU'VE ALWAYS BEEN DILIGENT, OF
20 COURSE, IN COMING TO THESE MEETINGS, BUT AN EXTRA
21 DEGREE OF DILIGENCE IS GOING TO BE REQUIRED BECAUSE
22 YOU ARE GOING TO HAVE A MORE POWERFUL ROLE IN
23 SELECTING APPLICATIONS FOR FUNDING BASED ON THE
24 INFORMATION, THE REPORT CARDS, THE REVIEW CARDS THAT
25 ARE GOING TO BE COMING FROM THE TEAM. SO MORE

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1 HOMEWORK WILL HAVE TO BE DONE.

2 VICE CHAIR BONNEVILLE: IS THAT SOMETHING
3 THAT WE CAN START TO DISCUSS IN JUNE, WHAT THAT
4 PROCESS WILL BE? I KNOW THIS WON'T TAKE EFFECT --
5 WILL IT START FOR THE JUNE MEETING? NO. IT WILL
6 PROBABLY BE SEPTEMBER IS WHEN THE FIRST BUNCH OF
7 APPLICATIONS.

8 DR. CANET-AVILES: THE FIRST CLIN2 WILL BE
9 IN SEPTEMBER BECAUSE IT'S THE APRIL CLIN2.

10 VICE CHAIR BONNEVILLE: GREAT. SO WE
11 SHOULD START TALKING ABOUT THIS IN JUNE SO THAT BY
12 SEPTEMBER WE UNDERSTAND WHAT THE ASK IS.

13 CHAIRMAN IMBASCIANI: I'LL START TALKING
14 TODAY IF YOU WANT.

15 DR. CANET-AVILES: THANK YOU. I JUST
16 WANTED TO MENTION WE HEARD JIM DEKLOE TODAY. THE
17 EDUCATION AND THE WORKFORCE DEVELOPMENT HAS BEEN A
18 SET OF STAR PROGRAMS AT CIRM. AND I FEEL IT'D BE
19 REMISS TO NOT MENTION THE ROLE THAT DR. SHEPARD HAS
20 HAD IN THE DEVELOPMENT OF OUR WORKFORCE EDUCATION
21 PROGRAMS. SHE'S ALSO THE LEAD FOR THE DISCOVERY
22 PROGRAM. SO I JUST WANT TO THANK KELLY FOR ALL THE
23 WORK BECAUSE FOR THE LONGEST TIME SHE WAS HOLDING
24 THEM ON HER OWN. NOW SHE HAS A TEAM DOING THAT WITH
25 HER. AND THEY ARE POSSIBLE BECAUSE OF HER EFFORTS

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1 AND HER MENTORSHIP AS WELL OF THOSE DIRECTORS. SO
2 THANK YOU, KELLY.

3 AND NOW COME ON OVER. YOU HAVE THE DISC4
4 FOCUS.

5 DR. SHEPARD: GOOD AFTERNOON, MEMBERS OF
6 THE BOARD, MEMBERS OF THE PUBLIC. GOOD AFTERNOON,
7 EVERYONE, MEMBERS OF OUR BOARD, MEMBERS OF THE
8 PUBLIC, CIRM TEAM. IT'S MY PLEASURE TO COME HERE
9 BEFORE YOU TODAY TO PROPOSE TO YOU THE ANNUAL FOCUS
10 AREA FOR OUR NEXT DISC4 FUNDING OPPORTUNITY.

11 SO THIS IS JUST A QUICK REMINDER THAT WHEN
12 YOU APPROVED THE DISC4 CONCEPT LAST MARCH, IT
13 INCLUDED A ROTATING AREA FOCUS. THE FIRST OR PILOT
14 VERSION OF THIS PROGRAM WAS OUR REMIND PROGRAM, AND
15 IT HAD A FOCUS ON NEUROPSYCHIATRIC AND
16 NEURODEVELOPMENT PROGRAMS.

17 THE SECOND ITERATION WAS ALSO NEURO TASK
18 FORCE RECOMMENDED AREA FOCUS, WHICH WAS NEUROLOGICAL
19 DISORDERS. AND THE CULMINATION OF THAT ROUND OF
20 FUNDING IS THE SLATE OF OUTSTANDING DISC4
21 APPLICATIONS THAT YOU APPROVED THIS MORNING. AND WE
22 ARE REALLY THRILLED TO SEE THE INNOVATIVE SCIENCE
23 THAT CAME OUT OF THIS INITIATIVE.

24 SO TODAY WE'RE HERE TO TALK ABOUT WHAT THE
25 AREA FOCUS WILL BE FOR OUR NEXT CYCLE THAT WE WOULD

1 BRINGING TO YOU NEXT MARCH.

2 SO WE'VE CONSIDERED A LOT OF DIFFERENT
3 POSSIBILITIES ON OUR TEAM, CONSULTING LITERATURE AND
4 LOOKING AT THE TRENDS THAT WE'VE BEEN SEEING IN OUR
5 DISCOVERY PROGRAMS AND KIND OF SOME OF THE
6 OPPORTUNITIES THAT ARE OUT THERE. AND WHAT WE HAVE
7 DECIDED TO PROPOSE AS OUR FIRST SUGGESTION FOR THE
8 NEXT AREA OF FOCUS CAN BE DESCRIBED AS IMMUNE TISSUE
9 INTERACTIONS OR INTERPLAY IN THE CONTEXT OF DISEASE
10 AND REPAIR.

11 SO THIS IS SORT OF A SYSTEMS FOCUS RATHER
12 THAN A DISEASE OR TISSUE-SPECIFIC FOCUS BECAUSE, AS
13 YOU ALL KNOW, THE IMMUNE SYSTEM PLAYS A ROLE IN A
14 LOT OF OUR TISSUES AND PROCESSES IN OUR BODY. IT'S
15 NOT JUST ABOUT FIGHTING INFECTION. IT MAKES
16 CONTRIBUTIONS AT ALL LEVELS AND STAGES OF OUR HEALTH
17 AND OUR LIFETIME.

18 AND SO THIS FOCUS AREA IS APPLICABLE TO A
19 BROAD SPECTRUM OF DISEASES THAT AFFECT CALIFORNIANS.
20 SO THAT'S WHAT IS MEANT TO BE DEPICTED IN THAT
21 LITTLE FIGURE WE PUT TOGETHER. IT'S SHOWING THAT
22 ALL THESE DIFFERENT ORGAN SYSTEMS, THERE ARE
23 DISEASES THAT AFFECT THOSE ORGANS THAT SUFFER WHEN
24 THERE ARE DYSREGULATION OF IMMUNE FUNCTION. SO IT'S
25 APPLICABLE TO A BROAD SPECTRUM OF DISEASES. IT'S A

1 PROBLEM THAT IS WELL-SUITED FOR THE DISC4
2 INITIATIVE.

3 THE DISC4, AS YOU RECALL, IS THE LARGE,
4 MULTIDISCIPLINARY TEAM-BASED APPROACH, TAKING
5 ADVANTAGE OF CUTTING-EDGE NEW TOOLS AND OMICS-DRIVEN
6 APPROACHES. AND SO THIS IS THE PERFECT TYPE OF
7 APPLICATION OF AN INVESTMENT TO BEGIN TO UNRAVEL THE
8 COMPLEXITY OF HOW IMMUNE-TISSUE INTERACTIONS AFFECT
9 OUR DEVELOPMENT AND HOW THEY GO AWRY IN SITUATIONS
10 OF DISEASE AND HOW THEY CONTRIBUTE TO OUR BODY'S
11 ABILITY TO REPAIR ITSELF AFTER SICKNESS OR DISEASE.

12 THIS APPROACH, BECAUSE IT IS COMPLEX AND
13 INTERDISCIPLINARY AND INTERSYSTEMS APPROACH, IT WILL
14 ENABLE IDENTIFICATION OF NOVEL TARGETS AND
15 BIOMARKERS; FOR EXAMPLE, SUCH AS THOSE THAT
16 DISTINGUISH BETWEEN MALADAPTIVE VERSUS PRODUCTIVE
17 REPAIR. THIS IS PARTICULARLY USEFUL FOR IDENTIFYING
18 NOVEL TARGETS BECAUSE YOU NEED TO DO YOUR STUDIES IN
19 A SYSTEM WHERE THERE ARE MULTIPLE DIFFERENT TYPES OF
20 CELL TYPES WORKING TOGETHER TO IDENTIFY A POTENTIAL
21 PATHWAY TO TARGET, WHICH IS SOMETHING THAT WOULD BE
22 MISSED IN A SYSTEM WHERE YOU'RE ONLY LOOKING AT ONE
23 CELL TYPE FOR ONLY CELL AUTONOMOUS DEFECTS.

24 SO THERE'S POSSIBILITIES TO TAKE ADVANTAGE
25 OF THESE REALLY NEW TECHNOLOGIES TO UNDERSTAND

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1 SPATIAL OMICS IN CELLS, CELL/CELL INTERACTIONS, CELL
2 STATES, DIFFERENCES IN CELL STATES. THOSE ARE ALL
3 OPEN FIELDS OF INVESTIGATION THAT MIGHT LEAD TO NEW
4 AND INTERESTING TARGETS AND BIOMARKERS THAT COULD BE
5 OF BENEFIT AND PERHAPS RELEVANT IN MORE THAN ONE
6 DISEASE CONTEXT.

7 THIS IS ALSO AN AREA THAT REALLY SUPPORTS
8 AND TAKES ADVANTAGE OF THE IMPROVED HUMAN STEM CELL
9 AND ORGANOID MODELS THAT A LOT OF OUR GRANTEES ARE
10 WORKING ON, BUILDING THE NEXT GENERATION OF
11 ASSEMBLOIDS THAT INCLUDE IMMUNE CELLS IN ADDITION TO
12 THE TISSUE CELLS OF A PARTICULAR ORGANOID AND OTHER
13 SUPPORT CELLS.

14 AND, FINALLY, WE THINK THAT FOCUSING
15 AROUND SYSTEMS LIKE THIS WILL CREATE STRONG
16 OPPORTUNITIES FOR NETWORK SYNERGY ACROSS FUNDED
17 PROGRAMS. AND, INDEED, SOME OF THE TYPES OF
18 PROPOSALS WE SAW IN THE CYCLE THAT YOU DISCUSSED
19 THIS MORNING, WE WERE SEEING QUITE A FEW PROJECTS
20 THAT WERE ADDRESSING NEURAL IMMUNE INTERACTIONS.
21 AND SO THOSE TYPES OF PROGRAMS WILL FIND A HOME IN
22 THIS AREA FOCUS AS WELL.

23 SO THIS IS OUR RECOMMENDATION. AND I'D BE
24 HAPPY TO TAKE ANY QUESTIONS IF YOU ANY OF YOU HAVE
25 QUESTIONS BEFORE WE ASK FOR YOUR VOTE ON THIS.

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1 CHAIRMAN IMBASCIANI: I DON'T SEE ANY.

2 DR. DULIEGE: IS THAT STILL IN CYCLE OF
3 ONE PER YEAR, OR WILL THERE BE -- ARE THERE ANY
4 OPTION? I KNOW IT'S A LOT OF WORK AND DEPENDS OF
5 THE MONEY WE HAVE TO HAVE TWO CYCLES PER YEAR. I'M
6 SAYING THAT BECAUSE IF PEOPLE WANT TO BE GIVEN A
7 CHANCE TO REAPPLY, BASED ON SOME COMMENTS, ONE CYCLE
8 PER YEAR REALLY IS NOT PRACTICAL. SO I'M JUST
9 CURIOUS.

10 DR. SHEPARD: WELL, CURRENTLY THE WAY OUR
11 BUDGET REQUEST HAS BEEN IS IT HAS BEEN SET FOR ONE
12 CYCLE PER YEAR. AND I KNOW THAT WE COME AND DISCUSS
13 BUDGET WITH YOU EVERY YEAR. BUT THIS PARTICULAR
14 CYCLE IS READY. ASSUMING WE GET AN APPROVAL TODAY,
15 WE'LL BE READY TO POST THE PA IN APRIL AND BEGIN TO
16 START ACCEPTING THE PRESUBMISSIONS THAT WOULD BE DUE
17 LATER THIS SUMMER.

18 SO WE WOULD HAVE THAT GOING BEFORE ANY
19 DISCUSSIONS ABOUT THIS NEXT CYCLE AFTER THAT. BUT
20 AS DR. CANET-AVILES POINTED OUT THIS MORNING, WE
21 ALSO HAVE ANOTHER DISCOVERY OPPORTUNITY CALLED DISC5
22 WHICH SUPPORTS SIMILAR TYPES OF METHODOLOGICAL
23 STUDIES JUST WITH SMALLER TEAMS. AND WE'RE REALLY
24 HOPING THAT SOME OF THE PROJECTS THAT MIGHT BE
25 SUITABLE FOR THESE LARGE MULTIDISCIPLINARY

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1 APPROACHES COULD INDEED ALSO CHOOSE TO PARTICIPATE
2 FOR A SUBSET OF THOSE ACTIVITIES UNDER A FUTURE
3 DISC5. AND THEY WOULD STILL HAVE THE BENEFIT, IF
4 RECEIVING A DISC5 GRANT, OF INTERACTING WITH AND
5 JOINING PART OF THE NETWORK THAT WE'RE BUILDING FOR
6 OUR DISCOVERY PROGRAMS SO THAT THEY CAN LEVERAGE
7 DATA AND BUILD ON EACH OTHER'S FINDINGS TO THE
8 EXTENT THAT WE CAN LEVERAGE THAT.

9 VICE CHAIR BONNEVILLE: ALSO THIS DID COME
10 THROUGH THE SCIENCE SUBCOMMITTEE, AND EVERYONE --
11 AND THIS ISN'T ABOUT ONE OR TWO CYCLES, BUT
12 PRIMARILY THE FOCUS RECOMMENDATION WAS SOMETHING
13 THAT THE SCIENCE SUBCOMMITTEE READILY ENDORSED AND
14 THOUGHT WAS A GREAT IDEA. SO THANKS, KELLY.

15 THE QUESTION ABOUT TWO CYCLES VERSUS ONE
16 WOULD BE SOMETHING ROSA CAN ADDRESS IN FURTHER
17 DETAIL, ANNE-MARIE.

18 DR. CANET-AVILES: THANK YOU, DR. DULIEGE.

19 SO ONE OF THE -- THIS PROGRAM, THE DISC4,
20 WAS MODELED AFTER PUBLIC/PRIVATE PARTNERSHIPS LIKE
21 THE ACCELERATED MEDICINES PARTNERSHIPS. THOSE
22 PROGRAMS ARE ACTUALLY MULTIDISCIPLINARY
23 COLLABORATIONS. IT TAKES A LONG TIME TO PUT
24 TOGETHER, REVIEW. AS YOU SAW, WE GET LIKE A HUNDRED
25 PREAPPLICATIONS, PRESUBMISSIONS. RIGHT? SO THE

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1 PROCESS IS LONG. WE CAN ONLY DO ONE A YEAR.

2 BUT ALSO, IT WAS MODELED THROUGH -- THE
3 NIH FUNDING FOR THIS KIND OF PROGRAMS IS 80 MILLION
4 EVERY FIVE YEARS. SO WE ARE ACTUALLY HAVING 84
5 EVERY YEAR WHICH IS -- AND THAT'S WHY WE COMPLEMENT
6 WITH THE DISC5. RIGHT? SO THERE'S A DIFFERENT
7 NATURE TO THESE KIND OF PROGRAMS, AND HOPEFULLY THAT
8 HELPS ALSO WITH THE CONTEXT. THANK YOU.

9 DR. DULIEGE: THANK YOU.

10 CHAIRMAN IMBASCIANI: KELLY, MARK
11 FISCHER-COLBRIE IS ON THE LINE.

12 DR. SHEPARD: YES. THANK YOU, MARK.

13 MR. FISCHER-COLBRIE: THANK YOU, KELLY.
14 I'M VERY EXCITED ABOUT THIS OPPORTUNITY HERE BECAUSE
15 THIS FURTHER EXPANDS UPON OUR STRATEGIC DIRECTION
16 WITH RESPECT TO LOOKING AT THINGS AS SYSTEMS. AND
17 HAVING THAT KIND OF BROAD PERSPECTIVE HAS THE
18 OPPORTUNITY TO MAKE DRAMATIC IMPROVEMENTS ABOUT
19 KNOWLEDGE AND ABOUT HOW THINGS WORK. AND SO WITH
20 THIS KIND OF APPROACH AND WITH THIS PARTICULAR TOPIC
21 AREA, I THINK THERE IS INCREDIBLE OPPORTUNITIES FOR
22 ACCELERATION OF DISCOVERY. SO THANK YOU.

23 DR. SHEPARD: THANK YOU, MARK.

24 WELL, IF THERE ARE NO FURTHER QUESTIONS,
25 THANK YOU FOR YOUR ATTENTION. AND I THINK WE'LL

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1 HAVE DR. SHYAM PATEL PRESENT THE FINAL SLIDE HERE.

2 DR. PATEL: GOOD AFTERNOON. I HOPE THIS
3 IS WORKING. ALL RIGHT. GREAT. GOOD AFTERNOON.
4 I'M SHYAM PATEL, ASSOCIATE VICE PRESIDENT OF
5 PRECLINICAL DEVELOPMENT AT CIRM. I'M GETTING THE
6 EAR SIGNAL FROM MY COLLEAGUES. SO I'M GOING TO TRY
7 A LITTLE HARDER HERE.

8 SO BEFORE I BEGIN, I DO ALSO WANT TO
9 SECOND ROSA'S COMMENT ABOUT DR. KELLY SHEPARD AND
10 THE TEAM'S DEDICATION TO EDUC PROGRAMS. I CAN SEE
11 ON A DAILY BASIS HOW MUCH HEART THEY POUR INTO THAT.
12 AND I'VE SAID IT BEFORE AND I'LL SAY IT AGAIN. ON A
13 WEEKLY BASIS, WE COME ACROSS PEOPLE WHO ARE ALUMNI
14 OF THOSE PROGRAMS. TO GIVE YOU A EXAMPLE, DR. DIANA
15 FARMER EARLIER TODAY SPOKE ABOUT HER PROGRAM. SHE
16 MENTIONED DR. AIJUN WANG AS HER COLLABORATOR. HE
17 WAS A CIRM SCHOLAR.

18 SHE ALSO MENTIONED THAT THE ONE BIG
19 ADVANTAGE THAT THEY HAVE IS THE GMP MANUFACTURING
20 FACILITY AT UC DAVIS. THE DIRECTOR OF THAT
21 FACILITY, BRIAN FURY, WAS ONE OF THE FIRST BRIDGES
22 SCHOLARS. AND SO NOT ONLY ARE THEY BEING TRAINED
23 THROUGH THESE DIFFERENT INSTITUTIONS, THEY'RE GOING
24 ON TO HAVE CAREERS THAT DIRECTLY IMPACT CIRM
25 PROJECTS.

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1 OKAY. SO WITH THAT OUT OF THE WAY, I'M
2 GOING TO TALK ABOUT THE PDEV CYCLE RECURRENCE. SO
3 JUST A REMINDER, THE PDEV PROGRAM IS A PRECLINICAL
4 DEVELOPMENT PROGRAM. IT'S DESIGNED TO TAKE EVERY
5 SINGLE PROJECT THAT IT FUNDS TO IND CLEARANCE. SO
6 REGARDLESS OF WHAT STAGE IT'S AT, THEY GET FUNDING
7 TO GET ALL THE WAY TO IND CLEARANCE. THEY CAN COME
8 IN HAVING JUST DECLARED A CANDIDATE, OR THEY COULD
9 COME IN MIDSTREAM WITH THE PRE-IND MEETING OR AFTER
10 THEIR PRE-IND MEETING. SO AT ANY POINT ALONG THAT
11 SPECTRUM, THE TRANSLATIONAL VALLEY OF DEATH, THEY
12 CAN SUBMIT AN APPLICATION TO CIRM, GET FUNDED, AND
13 GET THE FUNDING THEY NEED TO GET ALL THE WAY TO IND
14 CLEARANCE.

15 SO WHEN WE FIRST DESIGNED THIS PROGRAM AND
16 WE BROUGHT IT TO THE BOARD FOR APPROVAL LAST YEAR,
17 WE HAD INCORPORATED TWO APPLICATION CYCLES PER
18 FISCAL YEAR FOR THAT PROGRAM. HOWEVER, HAVING GONE
19 THROUGH THE EXERCISE OF DOING THOSE TWO CYCLES,
20 WE'RE REALIZING THAT THE KEY BENEFITS OF HAVING TWO
21 CYCLES IS ACTUALLY NOT BEING REALIZED FOR THIS
22 PARTICULAR PROGRAM. AND WE ARE RECOMMENDING THAT
23 THE BOARD APPROVE MOVING TO ONE CYCLE. I'LL EXPLAIN
24 THAT IN A LOT OF EXCRUCIATING DETAIL BECAUSE IT'S
25 IMPORTANT.

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1 BUT I'LL START OFF FIRST BY SAYING THAT
2 OUR REASON TO HAVE MULTIPLE CYCLES IS THAT, IF YOU
3 HAVE SOME SORT OF KEY READINESS REQUIREMENT, THAT
4 THE PROJECTS HAVE THE ABILITY TO APPLY WHEN THEY ARE
5 READY. IN THIS PARTICULAR INSTANCE, WE DELIBERATELY
6 DESIGNED THIS PROGRAM TO ALLOW FOR ENTRY AT ANY
7 STAGE ACROSS THAT PRECLINICAL SPECTRUM. SO WE HAVE
8 PROJECTS WHO ARE APPLYING MIDSTREAM OF A PRE-IND
9 MEETING, OR THEY'RE APPLYING RIGHT WHEN THEY HAVE
10 DECLARED A CANDIDATE.

11 SO IN THAT SENSE, WHEN AN APPLICATION DUE
12 DATE IS AVAILABLE, IF A PROGRAM IS WITHIN THAT
13 SPECTRUM OF PRECLINICAL DEVELOPMENT, IT SHOULD BE
14 ABLE TO SUBMIT AN APPLICATION. SO THAT WAS ONE
15 ASPECT OF WHAT WE CONSIDERED HERE.

16 ANOTHER ASPECT WAS IF YOU HAVE MULTIPLE
17 CYCLES, WHAT THAT USUALLY DOES IT ADVANTAGES
18 RESUBMISSION SO THAT YOU CAN GET A CLOSE TO FUNDABLE
19 SCORE OR MAYBE YOU GOT A FUNDABLE SCORE AND YOU WERE
20 NOT FUNDED, YOU CAN COME BACK IN FOR A CYCLE THAT
21 MAY BE A COUPLE MONTHS DOWN THE ROAD. HOWEVER,
22 BECAUSE OF THE WAY WE HAVE TO LINE UP THESE TWO
23 CYCLES TO FIT WITHIN ONE FISCAL YEAR, THE CYCLES
24 HAVE OVERLAP. SO SOMEBODY WHO SUBMITS IN THAT FIRST
25 PDEV CYCLE ACTUALLY CAN'T APPLY IN THE SECOND ONE.

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1 THEY WOULD HAVE TO WAIT FOR THE THIRD CYCLE. SO IN
2 THAT SENSE, THAT RESUBMISSION BENEFIT WITH MULTIPLE
3 CYCLES IS NOT FULLY REALIZED WITH THESE TWO CYCLES.

4 LASTLY, THE ALLOWANCE OF HAVING TWO CYCLES
5 ALLOWS FROM AN ADMINISTRATIVE PERSPECTIVE TO BE ABLE
6 TO BATCH APPLICATIONS. YOU PRESUMABLY CAN GET HALF
7 THE APPLICATIONS GOING THROUGH REVIEW AND FUNDING IN
8 THAT FIRST CYCLE AND THE OTHER HALF IN THE SECOND
9 CYCLE. HOWEVER, WHAT WE'RE SEEING RIGHT NOW IS
10 THAT, BECAUSE OF THE REALLY HIGH VOLUME AND THE HIGH
11 SCIENTIFIC MERIT ACROSS THE BOARD, THAT WE'RE
12 EXHAUSTING A SIGNIFICANT AMOUNT OF THE PROGRAM
13 BUDGET IN THE FIRST CYCLE. AND THAT HAPPENED IN THE
14 FIRST CYCLE OF PDEV WHERE WE SPENT ABOUT 120
15 MILLION, LEAVING ABOUT 40 MILLION FOR THE SECOND
16 CYCLE.

17 AND SO IN THAT SENSE, IT'S JUST GOING TO
18 INCENTIVIZE APPLICANTS TO WANT TO SUBMIT THAT FIRST
19 CYCLE ANYWAY BECAUSE THEY GET A HIGHER SHOT AT A
20 BIGGER BUDGET THAT THEY CAN FUND.

21 SO WITH ALL THAT IN MIND, PLUS CONSIDERING
22 A LOT OF OTHER FACTORS, WE ARE RECOMMENDING MOVING
23 TO ONE CYCLE PER YEAR. SO WHAT THIS DOES IS THAT --
24 NOW, JUST TO BE CLEAR, ONE CYCLE PER YEAR DOES NOT
25 MEAN THAT THE PROGRAM BUDGET IS HALVED. THE PROGRAM

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1 BUDGET STAYS THE SAME. SO ONE CYCLE. EVERYBODY
2 APPLIES. THEY ALL HAVE ACCESS TO THE FULL PROGRAM
3 BUDGET. EVERYBODY COMPETES AT THE SAME TIME FOR THE
4 FULL PROGRAM BUDGET.

5 TO DO THIS, WE HAVE TO HAVE A HIGHER
6 VOLUME OF APPLICATIONS TO BE REVIEWED FOR THAT FULL
7 PROGRAM BUDGET. SO NUMBER OF APPLICATIONS ACTUALLY
8 REVIEWED WILL GO UP BECAUSE WE HAVE TO MAKE SURE
9 THAT WE CAN EXHAUST THE ENTIRE BUDGET. ANY UNFUNDED
10 APPLICATIONS WOULD HAVE TO RESUBMIT IN THE NEXT
11 FISCAL YEAR APPLICATION CYCLE. I KNOW ON PAPER IT
12 SOUNDS REALLY BAD; BUT ACTUALLY, IF YOU GO THROUGH
13 THE WHOLE CYCLE, THE NEXT APPLICATION CYCLE IS
14 PROBABLY ABOUT FOUR TO SIX MONTHS AWAY.

15 AND THEN LASTLY, THIS ALLOWS US TO
16 OPTIMIZE THE TIMELINES FOR ALL THE PROGRAM UPDATES
17 IN THE APPLICATION LIFE CYCLES AS WELL. RIGHT NOW
18 ONE OF THE THINGS THAT WE WERE STRUGGLING WITH WITH
19 HAVING TWO CYCLES WAS HOW DO WE LINE UP THE
20 APPLICATION LEAD-TIME, THE REVIEW LEAD-TIME, AND THE
21 ARS DATES. AS YOU ALL KNOW, WE HAVE AN ADDITIONAL
22 FACTOR WE HAVE TO WORRY ABOUT, WHICH THAT THE ARS
23 DATES NOW HAVE TO LINE UP WITH THE IN-PERSON ICOCS
24 PUTTING FOR ADDITIONAL CONSTRAINT. AND TO PUT TWO
25 CYCLES IN THERE, WE ACTUALLY HAD THE ISSUE WHERE ONE

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1 APPLICATION CYCLE OVERLAPPED ACROSS THE ENTIRE
2 HOLIDAY PERIOD. AND SO WE HAD TO MAKE IT MUCH
3 LONGER BECAUSE WE HAD TO GIVE APPLICANTS ENOUGH TIME
4 TO BE ABLE TO SUBMIT AN APPLICATION AND NOT WORRY
5 ABOUT STAFF BEING ON VACATION OR THE UNIVERSITIES
6 CLOSING DOWN DURING THE HOLIDAY PERIOD.

7 AT THE SAME TIME, ON THE FLIP SIDE, WE HAD
8 AN ISSUE WHERE THE APPLICATIONS WERE AWARDED BY THE
9 ARS, AND THE CONTRACTING PERIOD OVERLAPPED WITH THE
10 HOLIDAY PERIOD. SO WE HAD TO EXTEND THE TIMELINE
11 FOR CONTRACTING THOSE AWARDS. SO THOSE TYPES OF
12 THINGS IN TRYING TO MAKE TWO APPLICATION CYCLES FIT
13 INTO ONE FISCAL YEAR, WE CAN AVOID THAT BY
14 OPTIMIZING THAT ONE CYCLE. SO ULTIMATELY WITH THIS
15 ONE CYCLE, WHAT WE HOPE WE CAN DO IS LINE IT ALL UP
16 SO THE APPLICANTS HAVE ADEQUATE TIME TO MAKE THEIR
17 APPLICATION, THE GWG HAS ENOUGH TIME TO DO THE
18 SELECTION AND THE REVIEW, AND WE HAVE THE ADEQUATE
19 URGENCY AND APPROPRIATENESS TO MAKE IT -- TO GET IT
20 CONTRACTED. ULTIMATELY, IT HELPS US FUND AND LAUNCH
21 THE AWARDS THAT THE GWG RECOMMENDS AND THE ARS
22 APPROVES IN AN OPTIMAL MANNER WITH A SINGLE CYCLE.

23 HAPPY TO TAKE ANY QUESTIONS ON THAT IF
24 THERE ARE ANY.

25 CHAIRMAN IMBASCIANI: ANY QUESTIONS FROM

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1 IN THE ROOM? I DON'T SEE ANYONE. MARGUERITE.

2 MS. CASILLAS: HI. THANK YOU SO MUCH FOR
3 ADDRESSING THIS ISSUE. AS HAVING JUST GONE THROUGH
4 THE SECOND PDEV SESSION, IT WAS REALLY TOUGH TO SEE
5 ALL THOSE GREAT APPLICATIONS AND NOT VERY MUCH MONEY
6 LEFT. SO I AGREE SOMETHING REALLY NEEDS TO BE DONE.

7 THERE WAS A LETTER THAT WAS SUBMITTED. I
8 DIDN'T QUITE UNDERSTAND HOW THE CONCERNS THAT WERE
9 RAISED THERE WOULD REALLY -- WELL, HOW THIS CHANGE
10 WOULD RESULT IN THOSE CONCERNS THAT THAT WRITER
11 MENTIONED. DOES THE CIRM TEAM FEEL THAT THERE'S ANY
12 VALIDITY THERE IN TERMS OF THE ISSUES THAT WERE
13 RAISED?

14 DR. PATEL: SO IT'S A GOOD POINT. THERE
15 ARE A COUPLE OF QUESTIONS THAT WERE RAISED BY
16 APPLICANTS AND AWARDEES IN THE SENSE THAT IF THERE
17 ARE MULTIPLE APPLICATION DEADLINES, THEY WOULDN'T BE
18 ABLE TO HAVE AS MUCH LAG WITH A CIRM AWARD ENDING
19 AND THE NEXT ONE STARTING. AND IN THAT SENSE WE
20 CAN'T FULLY ACCOUNT FOR THE FINANCIAL SITUATION OR
21 THE AWARD LIFE CYCLES OF EVERY SINGLE AWARDEE. BUT
22 AT THE SAME TIME, BECAUSE WE DESIGNED THIS PROGRAM
23 TO ALLOW APPLICANTS TO SUBMIT AT ANY POINT IN THEIR
24 CYCLE, AS YOU'VE NOTICED, WE'VE HAD SEVERAL ACTIVE
25 TRAN AWARDEES ACTUALLY SUBMIT FOR A PDEV

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1 APPLICATION. AND SO IN THAT SENSE, THERE IS A WAY
2 TO OVERCOME SOME OF THAT, BUT THOSE ARE CONCERNS
3 THAT ARE VALID FROM THE APPLICANTS, THAT I'M GOING
4 TO HAVE A CIRM AWARD END. AND IF I HAVE MULTIPLE
5 DEADLINES, THEN I CAN REDUCE THE LAG TIME TO GET
6 FUNDED. WE RECOGNIZE THAT, BUT WE CAN'T FULLY
7 ACCOUNT FOR THAT IN ALL CIRCUMSTANCES.

8 CHAIRMAN IMBASCIANI: JOYCE.

9 DR. SACKY: THANK YOU FOR THE
10 PRESENTATION. I'M ALSO INFERRING, AND CORRECT ME IF
11 I'M WRONG, THAT AS WE ARE GETTING HIGHER AND HIGHER
12 VOLUME OF APPLICATIONS AND WE ARE TRYING TO,
13 THEREFORE, NOT BURN OUT OUR REVIEWERS, THAT THIS
14 MIGHT ALSO BE GOOD FOR WELL-BEING. IT WASN'T ONE OF
15 THE BULLET POINTS, BUT I WOULD IMAGINE EVERYBODY'S
16 TALKED ABOUT INCREASED NUMBER OF APPLICATIONS MAKES
17 SENSE. FEDERAL FUNDS ARE GETTING TRICKIER AND
18 TRICKIER. AND WE HAVE HUMAN BEINGS THAT WE'RE
19 RELYING ON TO REVIEW THESE APPLICATIONS. AND SO I
20 THINK IT'S A VALID THING IF THAT IS ACTUALLY -- THAT
21 INFERENCE IS CORRECT.

22 DR. PATEL: YES. TO DO IT AT A SINGLE
23 CYCLE, WE COULD ENSURE THAT THE FULL PROGRAM BUDGET
24 IS BEING REVIEWED ALL AT ONCE AND THAT WE'RE
25 DEPLOYING IT. AND SO THE GWG HAS ALL THE

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1 INFORMATION TO DEPLOY THAT FULL BUDGET AND SO DOES
2 THE ARS.

3 DR. SACKY: AND WELLNESS.

4 DR. PATEL: YES. WELLNESS IS IMPORTANT,
5 YES, ESPECIALLY FOR THE PATIENT ADVOCATE REVIEWERS
6 WHO HAVE TO REVIEW ACROSS MULTIPLE PROGRAMS.

7 DR. SACKY: HUNDRED PERCENT SUPPORTIVE OF
8 THIS PROPOSAL.

9 CHAIRMAN IMBASCIANI: THANK YOU, JOYCE.
10 ANYONE ELSE IN THE ROOM WANT TO ASK SHYAM QUESTIONS?
11 ANYONE ONLINE? OR ANYONE IN THE PUBLIC? OKAY.

12 MS. MORALEZ: WE DO HAVE ONE PUBLIC
13 COMMENT ON THE PHONE.

14 CHAIRMAN IMBASCIANI: THERE IS ONE. I'M
15 SORRY. I DIDN'T SEE IT. NOW I SEE IT.

16 DR. PATEL: WOULD YOU LIKE TO WAIT FOR THE
17 PUBLIC COMMENT UNTIL THE MOTION IS MADE?

18 CHAIRMAN IMBASCIANI: THERE'S NO MOTION
19 YET. SO, ROSA, DO YOU WANT TO COME UP AND LAY THIS
20 OUT AS A MOTION TO THE BOARD? AND I PRESUME IT'S
21 GOING TO BE AN OMNIBUS MOTION.

22 DR. CANET-AVILES: THANK YOU. THANK YOU,
23 SHYAM.

24 SO TO FINALIZE, WE HAVE KIND OF AN OVERALL
25 MOTION FOR ALL WHAT WE PRESENTED TODAY. THE CIRM

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1 STAFF REQUESTS, WITH THE RECOMMENDATION OF THE
2 SCIENCE SUBCOMMITTEE, FOR THE BOARD TO APPROVE THE
3 FOLLOWING: FIRST, AMENDMENTS TO THE DISC4, PDEV,
4 AND CLIN2 CONCEPT PLANS THAT ARE ALSO IN THE
5 DOCUMENTS THAT WE APPENDED WITH THIS ITEM. THERE
6 ARE TRACK CHANGES ON HOW THE GUIDING PRINCIPLES
7 APPLY TO THE OBJECTIVES OF THE PROGRAMS.
8 IMPLEMENTATION OF THE PROPOSED GRANTS WORKING GROUP
9 SELECTION PROCESS IN ALL PROGRAMS REQUIRING VOLUME
10 CONTROL. AND THEN, FINALLY, THE LAST TWO ITEMS THAT
11 WERE JUST PRESENTED BY KELLY AND SHYAM, THE DISC4
12 PROGRAM FOCUS AREA FOR THE FISCAL YEAR 26/27 FUNDING
13 CYCLE AND ONCE PER YEAR PDEV FUNDING CYCLE.

14 CHAIRMAN IMBASCIANI: OKAY. BOARD WOULD
15 ENTERTAIN A MOTION TO APPROVE THE FOLLOWING.

16 VICE CHAIR BONNEVILLE: SO MOVED.

17 DR. MALKAS: SECOND.

18 CHAIRMAN IMBASCIANI: WE HAVE A MOTION AND
19 LEONDRA SECONDED. SHE DID NOT. OH, SORRY, LINDA.

20 DR. MALKAS: I'M LIKE INVISIBLE.

21 CHAIRMAN IMBASCIANI: ACOUSTICALLY IT CAME
22 FROM THE LEFT. SO DISCUSSION?

23 PUBLIC SPEAKER: ARE YOU READY FOR MY
24 PUBLIC COMMENT?

25 VICE CHAIR BONNEVILLE: IT'S NOT TIME FOR

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1 PUBLIC COMMENT.

2 CHAIRMAN IMBASCIANI: WE'RE GOING TO HAVE
3 COMMENT FROM BOARD MEMBERS FIRST, AND THEN WE'LL
4 INVITE THE PUBLIC TO COMMENT. WE'LL START WITH
5 MONICA CARSON.

6 (INTERRUPTION IN PROCEEDINGS DUE TO
7 AUDIO ISSUES.)

8 CHAIRMAN IMBASCIANI: MONICA IS GOING TO
9 BE FOLLOWED BY A NUMBER OF PEOPLE, AND I'LL READ THE
10 LIST OFF SHORTLY. MONICA, THE FLOOR IS YOURS.

11 (CONTINUED INTERRUPTION IN PROCEEDINGS.)

12 MR. TOCHER: OKAY. MONICA CARSON, LONG
13 AWAITED. YOU ARE FIRST UP FOR COMMENT.

14 DR. CARSON: I WAS JUST TRYING TO GET
15 ORIGINAL ATTENTION ABOUT THE LACK OF SOUND.

16 VICE CHAIR BONNEVILLE: IS THERE ANY OTHER
17 BOARD COMMENT? IS THERE ANY PUBLIC COMMENT?

18 MS. MORALEZ: I DO SEE A HAND RAISED THAT
19 NOW WENT AWAY. NOW IT'S RAISED AGAIN. OKAY. SO
20 THE NUMBER ENDING IN 3158, IF YOU CAN UNMUTE
21 YOURSELF BY PRESSING STAR SIX, YOU'LL HAVE THREE
22 MINUTES.

23 MR. SYNDER: HI. THIS IS EVAN SNYDER FROM
24 SBP. THANKS FOR LETTING ME VOICE MY CONCERN ABOUT
25 THE PROPOSED REDUCTION IN FREQUENCY OF PDEV GRANT

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1 CYCLES, WHICH I FEAR WILL HAVE UNINTENDED AND
2 UNDESIRE CONSEQUENCES FOR CIRM'S MISSION AND
3 BREADTH OF CALIFORNIA SCIENTISTS, CLINICIANS,
4 BUSINESSES, AND PATIENTS WHO BENEFIT FROM CIRM.

5 I'VE UPLOADED A LETTER TO ICOC, SO I'LL
6 NOT READ THAT. I UNDERSTAND THE WORK AND FINANCIAL
7 BURDEN THE OLD FUNDING MODEL PRESENTED. I'LL USE MY
8 TIME SIMPLY TO SUGGEST WE FIGURE OUT OTHER CREATIVE
9 SOLUTIONS. CIRM WAS INITIALLY CONCEIVED TO IMMUNIZE
10 CALIFORNIANS FROM THE POLITICALLY DRIVEN VAGARIES OF
11 WASHINGTON, D.C. THAT THREAT IS NO LESS NOW THAN IT
12 WAS THEN, PROBABLY WORSE.

13 THE PRINCIPLES AND APPROACHES, TOPICS AND
14 PATIENT POPULATIONS WE HOLD DEAR ARE UNDER ATTACK.
15 THE SURGE IN APPLICATIONS TO CIRM IS A SYMPTOM OF
16 THAT. I FEAR THAT REDUCING THE NUMBER OF CYCLES
17 WILL SOFTEN OUR CORE MISSION. ROBUST PRECLINICAL
18 DEVELOPMENT HAS DEFINED CIRM. WHILE I APPRECIATE
19 THE IMMENSE BURDEN THIS EMPHASIS PLACES ON CIRM, ITS
20 MENU AND TIMELINE OF FUNDING OPPORTUNITIES HAS SO
21 ACCURATELY BEEN IN TUNE WITH THE TEMPO AND DYNAMICS
22 OF CUTTING-EDGE PRECLINICAL DEVELOPMENT. SUCH
23 PRECLINICAL AND CLINIC RESEARCH, PARTICULARLY IN
24 ACADEMIA AND SMALL COMPANIES, CANNOT LANGUISH
25 UNFUNDED AND UNACTUALIZED FOR AN ENTIRE YEAR.

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1 I KNOW WE CANNOT GO BACK TO THE OLD MODEL .
2 I WOULD SIMPLY SUGGEST, BEFORE WE MAKE SUCH A
3 CHANGE, THAT CIRM, IN CONJUNCTION WITH OTHER
4 CALIFORNIA SCIENTISTS, CLINICIANS, BUSINESSES,
5 PATIENTS, RETHINK CREATIVE WAYS NOT TO LEAD TO SOME
6 OF THE UNINTENDED CONSEQUENCES I FEAR.

7 SOME SUGGESTIONS MIGHT BE GIVING SMALLER
8 DOLLAR AMOUNTS PER GRANT WHILE MAINTAINING
9 FREQUENCY. MANY PDEV PROJECTS ARE NOT READY TO GO
10 THE FULL 13 MILLION. EARLY PDEV ONLY IS AN OPTION.
11 LATE PDEV ONLY IS AN OPTION, PARTICULARLY IF YOU'VE
12 BEEN IN THE CIRM PIPELINE. COMBINED EARLY AND LATE
13 PDEV WOULD BE A MINORITY OF PROJECTS MOSTLY FROM
14 PHARMA AND HOSPITAL-BASED ENTITIES. A SHORTER
15 MERIT-BASED LOI PRESELECTION PROCESS WOULD HELP
16 STREAMLINE THINGS. SHORTENING APPLICATIONS FOR
17 REVIEWERS TO READ TO ELIMINATE REDUNDANT SECTIONS OR
18 DETAILED APPROPRIATE ONLY AFTER A MERIT-BASED
19 FUNDABLE SCORE.

20 THANKS FOR CONSIDERING SOLUTIONS OTHER
21 THAN REDUCING PDEV GRANTING FREQUENCY.

22 CHAIRMAN IMBASCIANI: GREAT. THANK YOU
23 VERY MUCH. THE CHAIR RECOGNIZES HIMSELF FOR A
24 COMMENT WHICH I HAVEN'T HAD A CHANCE TO DO.

25 I SPEAK IN SUPPORT OF ALL FOUR COMPONENTS

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1 OF THIS MOTION. AND I'M GOING TO JUST FOCUS IN ON
2 ONE TO MAKE A COMMENT ON VOLUME CONTROL. I AM, I
3 THINK, THE ONLY EX OFFICIO MEMBER OF THE GRANTS
4 WORKING GROUP ALONG WITH ALL OUR PATIENT ADVOCATES
5 AND OUR NURSE REPRESENTATIVES. SO I HAVE EXPERIENCE
6 OF THE PROCESS. EVERY ONE OF THOSE MEETINGS I
7 ATTEND. SO I AGREE THAT WE HAVE TO IMPOSE A PROCESS
8 THAT WILL ALLOW OUR REVIEWERS TO ASSESS SCIENTIFIC
9 MERIT, BUT TO DO SO IN A REASONABLE FORMAT GIVEN
10 THAT THE NUMBER OF REVIEWERS WE HAVE ACCESS TO IS BY
11 LAW LIMITED.

12 THE PROPOSED SYSTEM IN THIS MOTION GIVES
13 THE LARGEST POSSIBLE EXPOSURE TO EACH APPLICATION --
14 GIVES THE LARGEST POSSIBLE EXPOSURE OF EACH
15 APPLICATION TO THE GREATEST NUMBER OF REVIEWERS
16 WITHOUT PHYSICALLY EXHAUSTING THEM OR DILUTING THEIR
17 CRITICAL APPARATUS. I TRUST THE GRANTS WORKING
18 GROUP TO GIVE GREAT EFFORT IN REVIEWING ALL
19 COMPONENTS OF AN APPLICATION, AND I TRUST THEIR
20 RECOMMENDATIONS. THANK YOU.

21 SCOTT, IF THERE'S NO MORE COMMENT EITHER
22 PUBLIC OR BOARD MEMBER, WE CAN PROCEED.

23 MR. TOCHER: ALL RIGHT. FOR THE RECORD,
24 DON TAYLOR, ALTERNATE FOR KIM BARRETT, HAS JOINED
25 THE MEETING.

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1 SO ALL THOSE IN THE ROOM IN FAVOR SAY AYE.
2 THOSE OPPOSED SAY NAY. ANY ABSTENTIONS? AND I'LL
3 POLL THE MEMBERS ON THE ZOOM.

4 MONICA CARSON.

5 DR. CARSON: AYE.

6 MR. TOCHER: JUDY CHOU.

7 DR. CHOU: AYE.

8 MR. TOCHER: YSABEL DURON.

9 MS. DURON: YES.

10 MR. TOCHER: MARK FISCHER-COLBRIE.

11 MR. FISCHER-COLBRIE: YES.

12 MR. TOCHER: JUDY GASSON.

13 DR. GASSON: YES.

14 MR. TOCHER: JEFF GOLDEN.

15 DR. GOLDEN: YES.

16 MR. TOCHER: RICH LAJARA.

17 MR. LAJARA: YES.

18 MR. TOCHER: PAT LEVITT.

19 DR. LEVITT: YES.

20 MR. TOCHER: HALA MADANAT.

21 DR. MADANAT: YES.

22 MR. TOCHER: CHRIS MIASKOWSKI.

23 DR. MIASKOWSKI: YES.

24 MR. TOCHER: MARV SOUTHARD.

25 DR. SOUTHARD: YES.

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1 MR. TOCHER: KEVIN XU.

2 MR. XU: AYE.

3 MR. TOCHER: AND KEITH YAMAMOTO.

4 DR. YAMAMOTO: NO.

5 MR. TOCHER: THANK YOU. THE MOTION
6 CARRIES.

7 CHAIRMAN IMBASCIANI: OKAY. THANK YOU
8 VERY MUCH. AND THANK YOU, ROSA, NOT JUST FOR
9 TODAY'S PRESENTATION.

10 WE NOW HAVE AN UPDATE, AGENDA ITEM NO. 13,
11 FROM THE COMMUNICATIONS TEAM LED BY DIRECTOR OF
12 COMMUNICATIONS, AMY ADAMS.

13 MS. ADAMS: OKAY. SO I WANT TO START BY
14 SAYING YOU DON'T HAVE TO VOTE ON ANYTHING IN WHAT
15 I'M ABOUT TO SAY. SO YOU CAN ALL SIT BACK. THERE'S
16 SOME POPCORN IN BACK OF THE ROOM. I'M GOING TO TRY
17 TO KEEP THIS EASY AND HOPEFULLY SHORT BECAUSE I
18 THINK I'M ALL THAT STANDS BETWEEN YOU AND THE
19 TRAFFIC.

20 SO LET'S START. FIRST OF ALL, THANK YOU,
21 BOARD MEMBERS, MEMBERS OF THE CIRM TEAM, AND
22 IMPORTANTLY ANY MEMBERS OF THE PUBLIC WHO ARE ON THE
23 CALL.

24 OKAY. I ALWAYS LIKE TO START MY
25 PRESENTATION WITH A REMINDER OF OUR MISSION.

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1 OBVIOUSLY WE ALL KNOW WHAT OUR MISSION IS, BUT IT IS
2 FRONT AND CENTER IN EVERYTHING WE DO IN
3 COMMUNICATIONS. AND THE WAY THAT THE COMMUNICATIONS
4 AND OUTREACH TEAM HELPS MOVE THAT MISSION FORWARD IS
5 BY DRIVING AWARENESS OF AND SUPPORT FOR CIRM'S
6 PROGRESS AND ACCOMPLISHMENTS.

7 A REMINDER. SO MY COMMUNICATION AND
8 OUTREACH STRATEGY HAS FOUR PILLARS. AND AS WITH
9 MOST OF MY PRESENTATIONS, WE ARE GOING TO GO THROUGH
10 THESE FOUR PILLARS AND TALK ABOUT WHAT WE'RE DOING
11 WITHIN EACH.

12 SO WE'RE GOING TO START WITH CREATING THE
13 STORY. AND THIS IS A REMINDER. I'M TAKING THIS ALL
14 THE WAY BACK, WAY, WAY BACK TO DECEMBER WHEN I
15 PRESENTED ALL OF YOU MY STRATEGY. SO WHAT I'M GOING
16 TO GO THROUGH TODAY IS FOR EACH OF THE PILLARS WHAT
17 I SAID I WAS GOING TO DO WITHIN THAT PILLAR IN THE
18 STRATEGY, AND THEN WE'RE GOING TO TALK ABOUT WHAT
19 WE'VE STARTED TO DO. OBVIOUSLY THAT WAS DECEMBER.
20 IT IS NOW MARCH. WE HAVE NOT DONE A LOT ON THE
21 STRATEGY, BUT WE ARE MAKING PROGRESS IN SEVERAL
22 PLACES.

23 SO YOU'LL SEE FOR EVERY -- THIS IS THE
24 ACTUAL SLIDE YOU SAW IN DECEMBER. UNDER WHAT WE'LL
25 DO, THERE'S A HANDFUL OF TACTICS. THE GREEN

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1 CHECKMARK, I THINK WE ALL KNOW WHAT THAT MEANS. THE
2 LITTLE PURPLE THING, THAT MEANS WE'RE WORKING ON IT.
3 AND THE RED X, THAT WILL BE THE NEXT BOARD MEETING.
4 SO THIS WILL BE THE FORMAT FOR EVERY PILLAR.

5 SO FIRST OF ALL, WITHIN CREATING THE
6 STORY, THIS IS THE ONE PLACE WHERE I THINK WE'VE
7 REALLY STARTED TO MAKE PROGRESS ALREADY. YOU'VE
8 ALREADY SEEN A VERSION OF THE CIRM STORY PRESENTED
9 BY J.T. AND WE'RE STARTING TO DEVELOP MANY VERSIONS
10 OF THAT. OBVIOUSLY ONE STORY DOESN'T WORK FOR ALL
11 AUDIENCES. THE ONE YOU SAW I THINK WAS REALLY
12 COMPELLING AND EMOTIONAL, BUT IT'S NOT RIGHT FOR
13 EVERYONE. SO WE'RE STARTING TO BUILD OUT DIFFERENT
14 VERSIONS OF THAT STORY AND MAKE IT EASY FOR EVERYONE
15 TO HAVE RESOURCES THEY NEED TO TELL CIRM'S STORY.

16 AND I'M GOING TO SHOW A COUPLE OF
17 EXAMPLES. WE'RE CREATING A NEW DECK, SOME NEW DECK
18 MATERIALS. AND WE'RE TRYING TO MAKE IT EASIER FOR
19 PEOPLE WITHIN CIRM TO HAVE ACCESS TO REALLY VISUAL
20 AND EMOTIONAL SLIDES EVEN FOR WHEN THEY'RE TALKING
21 ABOUT THE SCIENCE. AND I'M JUST GOING TO KIND GO
22 THROUGH A FEW JUST NICE EXAMPLES OF WAYS THAT I
23 THINK WE CAN BE LOOKING AT OUR STORY. OBVIOUSLY WE
24 DO SCIENCE AS WELL AS PATIENTS. SO WE'VE GOT SOME
25 GREAT SCIENCE IMAGES AS WELL.

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1 AND I'M JUST GOING TO LEAVE CREATE THE
2 STORY THERE AND MOVE ON TO SOME OF THE OTHER STUFF
3 WE'RE DOING.

4 SO TELL THE STORY. WHAT I TOLD YOU WE
5 WOULD DO IS A WHOLE BUNCH OF THINGS. ONE OF THEM
6 I'M GOING TO TALK ABOUT IS MAKE THE WEBSITE FULLY
7 ACCESSIBLE. SO WE HAVE AN ACCESSIBLE WEBSITE. WE
8 DID THAT. ACTUALLY THE PREVIOUS COMMUNICATIONS TEAM
9 DID THAT, AND I THINK THEY SHOULD BE REALLY PROUD OF
10 IT. THERE ARE SOME DOCUMENTS ON THE WEBSITE THAT
11 WERE NOT YET ACCESSIBLE, AND WE MADE THEM
12 ACCESSIBLE. SO THIS IS THE KIND OF THING THAT'S
13 HAPPENING BEHIND THE SCENES THAT I THINK IS
14 INCREDIBLY IMPORTANT AS A PUBLIC-FACING
15 ORGANIZATION, THAT WE BE ACCESSIBLE TO ALL PEOPLE
16 WHO MIGHT WANT TO ACCESS INFORMATION.

17 THE TWO THINGS I'M REALLY GOING TO TALK
18 ABOUT TODAY IS SOME OF OUR EXPANDED WRITTEN AND
19 VIDEO STORYTELLING. I'M NOT GOING TO TALK ABOUT
20 VIDEO. A STORYTELLING TOOLKIT THAT WE'RE TO BUILD
21 OUT TO HELP PEOPLE TALK ABOUT THE ORGANIZATION. SO
22 HERE'S SOME OF THE STORYTELLING THAT WE'RE DOING.

23 THE TWO CLOSER TO CURES IMAGES THERE, THAT
24 SHOULD LOOK FAMILIAR. THOSE ARE THE CLOSER TO CURES
25 THAT YOU HEARD AT THE LAST BOARD MEETING. SO AS WE

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1 ALL SEE, THIS IS REALLY FANTASTIC CONTENT AND WE'RE
2 TAKING ADVANTAGE OF IT. SO WE'VE WRITTEN STORIES
3 ABOUT EACH OF THE CLOSER TO CURES. WE'VE GOT THE
4 VIDEOS FROM THOSE EMBEDDED IN THE STORY. WE'RE
5 ROLLING THEM OUT OVER SOCIAL MEDIA. AND I WILL SAY
6 THEY ARE DOING EXTRAORDINARILY WELL ACROSS
7 PLATFORMS. I DON'T THINK IT HURTS THAT THESE
8 SCIENTISTS ARE WELL-KNOWN AND LIKED AND ARE
9 PROMOTING IT AND THEIR ORGANIZATIONS ARE DOING THE
10 SAME. SO I THINK IT REALLY HELPS GET OUR WORD OUT
11 WHEN WE'RE ALSO ABLE TO TAKE ADVANTAGE OF OTHER
12 ORGANIZATIONS THAT HAVE A GREAT PRESENCE. WE'RE
13 KIND OF PIGGYBACKING ON SOME GIANTS HERE.

14 AND THEN THE BEAUTIFUL PICTURE -- I VOID
15 RIGHT LEFT. THE BEAUTIFUL PICTURE ON THE RIGHT. SO
16 THIS IS A FAMILY THAT PARTICIPATED IN ONE OF THE
17 CIRM-FUNDED TRIALS. IT'S JUST AN INCREDIBLE STORY.
18 THE OLDER GIRLS WERE BOTH BORN WITH A DISEASE CALLED
19 LAD-1. IT'S AN IMMUNE DISORDER. PARENTS DIDN'T
20 KNOW THAT. THEY WERE JUST GETTING SICK A LOT. AND
21 THE PARENTS FINALLY GOT THESE GIRLS DIAGNOSED WITH
22 THIS INCREDIBLY RARE DISEASE THAT HAS NO CURE ASIDE
23 FROM A BONE MARROW TRANSPLANT, WHICH IS NOT AN EASY
24 ROAD. THE MOTHER WAS PREGNANT WITH THAT LITTLE BOY
25 THERE WHEN THEY FOUND THAT OUT.

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1 SO THE PARENTS -- THIS FAMILY CAME TO THE
2 ATTENTION OF OUR GRANTEE DOWN AT UCLA THAT WAS
3 RUNNING THIS TRIAL, DON KOHN. HE REACHED OUT TO
4 THEM AND INVITED THEM TO SEE IF THEY WERE ELIGIBLE,
5 BUT THEN THIS FAMILY WENT TO L.A., PARTICIPATED IN
6 THAT TRIAL, AND HERE THEY ARE AT DISNEYLAND, LIKE
7 THE WORLD'S GERMIEST PLACE. AND THESE LITTLE KIDS
8 BORN WITH AN IMMUNE DISORDER ARE SMILING WITH THEIR
9 LITTLE MOUSE EARS ON. SO THIS STORY ALSO DID VERY
10 WELL ACROSS CHANNELS BECAUSE IT'S SUCH A GREAT
11 STORY.

12 I WANT TO MOVE ON TO DELIVER THE STORY.
13 THE THING IS TELLING THE STORY IS ONE THING. IT'S
14 GREAT. SO WE WROTE A GREAT STORY. YAY. REALLY
15 CUTE KIDS AND IT'S A GREAT STORY. IT DOESN'T DO YOU
16 ANY GOOD UNLESS YOU GET THAT STORY TO THE PEOPLE WHO
17 NEED TO SEE THAT STORY. THAT'S A WHOLE SEPARATE
18 PART OF A STRATEGY. AND THAT REALLY IS EMAIL LISTS
19 AND SOCIAL MEDIA AND LEVERAGING OUR GRANTEES AND ALL
20 OF THAT WORK. SO I SEPARATE THOSE TWO OUT BECAUSE I
21 THINK THEY ARE TWO DIFFERENT ACTIVITIES.

22 WITHIN DELIVERING THE STORY, A HANDFUL OF
23 THINGS THAT WE'RE DOING. ONE I'VE MENTIONED
24 PREVIOUSLY. WE'VE HIRED A PR FIRM, AND I'M GOING TO
25 TALK A LITTLE BIT ABOUT SOME OF THE WORK THEY'RE

1 DOING.

2 WE HAVE STARTED TRAINING, I SAY,
3 ADVOCATES. IN THIS CASE THE ADVOCATES ARE OUR
4 INTERNAL CIRM TEAM. SO WE'RE STARTING TO TRAIN THE
5 CIRM TEAM ON HOW TO USE OUR MESSAGING AND OTHER
6 MATERIALS TO BE ABLE TO TALK ABOUT CIRM.

7 ONE OF THE ITEMS ON HERE IS CREATE A
8 STRATEGY FOR COMMUNICATING ABOUT CIRM, WHICH WE DID.

9 SO LET'S TALK ABOUT THE MESSAGING TRAINING
10 BECAUSE THIS WAS A LOT OF FUN, I THOUGHT. SO WE
11 INVITED EVERYONE IN CIRM TO THIS TRAINING. AND THIS
12 IS A SCREENSHOT FROM ONE OF THE TRAININGS. THERE
13 WERE ABOUT 60 ATTENDEES FROM WITHIN CIRM, WHICH IS A
14 GOOD PORTION OF THE ORGANIZATION. WE BROKE PEOPLE
15 INTO TEAMS, AND THEY WERE GIVEN SCENARIOS AND TOLD
16 HERE'S YOUR SCENARIO, AND WHAT WOULD YOU TELL THIS
17 PERSON ABOUT CIRM. SO THERE WERE ELEVEN SCENARIOS,
18 AND EACH TEAM CAME UP WITH MULTIPLE CHOICE, MANY
19 OPTIONS OF HOW THEY WOULD TALK TO THAT PERSON
20 BECAUSE THERE WERE A LOT OF THE IDEAS ABOUT HOW WE
21 SHOULD BE TELLING STORIES.

22 THIS IS STEP 1. I THINK THERE'S A LOT OF
23 MORE STEPS TO BE DONE TO HELP PEOPLE TALK ABOUT THE
24 ORGANIZATION, BUT IT'S ONE OF THE THINGS WE'VE BEEN
25 DOING.

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1 AND THEN I WANT TO TALK A BIT ABOUT THE PR
2 TEAM IS JUST DOING A FANTASTIC JOB. SO THE AT LAST
3 BOARD MEETING, YOU ALL APPROVED THE CONCEPT PLAN FOR
4 RAPID. THE PR TEAM PITCHED THAT PRETTY EXTENSIVELY.
5 AND I WILL SAY THAT DR. SHYAM PATEL DID HARD LABOR.
6 HE DID A LOT OF INTERVIEWS IN BETWEEN EVERYTHING
7 ELSE HE IS ALSO DOING. SO THAT WAS GREAT. AND THEN
8 BOTH J.T. AND ROSA HAVE DONE QUITE A FEW INTERVIEWS
9 ON RAPID. I HAVE A COUPLE OF EXAMPLES HERE.

10 GENETIC ENGINEERING AND BIOTECHNOLOGY
11 NEWS, WHICH IS AN OUTLET THAT REACHES A LOT OF THE
12 PEOPLE WHO WE REALLY WANT TO REACH, DID A NICE
13 STORY. STAT DID A STORY, AND I'VE GOT A QUOTE HERE
14 FROM J.T. THAT'S A RIGHT-ON MESSAGE ABOUT WHO CIRM
15 IS AND WHAT WE'RE TRYING TO DO. ALSO, CNBC CURES,
16 WHICH IS FOCUSED ON TELLING RARE DISEASE STORIES.
17 CNBC CURES, THEIR MAIN VEHICLE IS THEY PUT OUT A
18 NEWSLETTER. AND THAT'S WHERE MOST OF THEIR
19 STORYTELLING HAPPENS. AND THE TOP OF THE NEWSLETTER
20 WAS A LONG STORY ALL ABOUT RAPID WITH SOME REALLY
21 NICE QUOTES FROM DR. PATEL. I THINK J.T. IS GOING
22 TO TALK ABOUT AN INTERVIEW HE DID THAT HASN'T
23 PUBLISHED YET.

24 OKAY. THEN I WANT TO TALK ABOUT OUTREACH.
25 I'VE GOT A COUPLE -- I WANT TO LOOK AT MY NOTES

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1 BECAUSE I'VE GOT SOME NUMBERS HERE. SO SINCE THE
2 LAST BOARD MEETING, THE OUTREACH TEAM, THEY DID TEN
3 OUTREACH EVENTS REACHING ABOUT 250 PEOPLE. AND AT
4 THOSE OUTREACH EVENTS, EIGHT DIFFERENT STUDENTS FROM
5 OUR EDUCATION PROGRAMS PARTICIPATED IN THOSE EVENTS.
6 AND IN ADDITION, TWO PEOPLE FROM MY TEAM RECENTLY
7 MET WITH STUDENTS AT SAN JOSE STATE UNIVERSITY TO
8 TRAIN THEM IN HOW TO DO OUTREACH. SO THAT REACHED
9 AN ADDITIONAL SET OF STUDENTS.

10 THE IMAGES HERE, JUST TO GO THROUGH THEM,
11 SO YOU'VE GOT DR. JOE GOLD AND YSABEL DURON DOING
12 TWO DIFFERENT PRESENTATIONS AT ROTARY CLUBS. AND
13 THEN WE HAVE ADITI, VICE CHAIR BONNEVILLE, AND THEN
14 GEOFF LOMAX HERE. THAT WAS AT THE -- WHAT WAS THAT,
15 MARIA? -- THE ALAMEDA --

16 VICE CHAIR BONNEVILLE: COUNTY PUBLIC
17 HEALTH COMMISSION.

18 MS. ADAMS: EXACTLY. SO THESE ARE JUST
19 SOME EXAMPLES OF THE KINDS OF OUTREACH THAT ARE
20 GOING ON.

21 AND THEN I'M GOING TO ONLY BRIEFLY TOUCH
22 ON MEASURE THE IMPACT. SO WE MEASURE THINGS ALL THE
23 TIME. HERE'S THE THING. WE JUST STARTED REALLY --
24 WE JUST ROLLED OUT A NEW STRATEGY. SO ALL OF OUR
25 MEASUREMENTS ARE BASELINE. SO I CAN STAND HERE AND

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1 GIVE YOU BASELINE NUMBERS, BUT THEY'RE NOT GOING TO
2 MEAN A LOT. SOME NUMBER OF THOUSANDS OF PEOPLE SAW
3 A POST ON FACEBOOK. SO WHAT I PLAN TO DO IS START
4 REPORTING OUT ON MEASUREMENTS ONCE WE'VE GOT THE
5 BASELINE, AND THEN WE CAN REPORT OUT INCREASES OVER
6 TIME.

7 AND WITH THAT, I THANK YOU ALL. I'LL TAKE
8 QUESTIONS, OR I'LL LET YOU ALL JUMP IN YOUR CARS AND
9 GET IN TRAFFIC. ALL RIGHT. PAT. HI, PAT.

10 DR. LEVITT: HOW ARE YOU?

11 MS. ADAMS: I'M GOOD. THANK YOU.

12 DR. LEVITT: GOOD.

13 MS. ADAMS: YOU'RE COMING FROM THE SKY.

14 DR. LEVITT: YEAH. WELL, I'M GETTING OVER
15 MY COLD, AND THIS MEETING IS NOT HELPING. THAT WAS
16 JUST A JOKE. I LOVE THIS MEETING.

17 GETTING OUT THE STORY IS LIKE REALLY
18 IMPORTANT. AND I THINK I'D BE INTERESTED AT ANOTHER
19 TIME TO HEAR ABOUT HOW TO DO THIS IN A BROADER WAY.
20 BECAUSE PRESENTATIONS TO SMALL GROUPS ARE IMPORTANT,
21 PARTICULARLY KEY GROUPS; BUT FOR IT TO BECOME VIRAL,
22 AS YOU KNOW, NEEDS A DIFFERENT KIND OF STRATEGY.
23 AND IT'S NOT EASY, BUT I THINK THERE ARE MECHANISMS
24 THROUGH THAT. SO I JUST WANT TO MAKE THE COMMENT
25 THAT THING YOU EMPHASIZED, HAVING A GREAT STORY IS

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1 WONDERFUL EXCEPT THAT IT'S A SECRET UNTIL IT GETS
2 OUT THERE.

3 AND SO GREAT PROGRESS REALLY. AND THIS
4 NEXT STEP, I THINK, WILL BE REALLY CRITICAL. I'M
5 HAPPY TO TALK ABOUT IT WITH YOU BETWEEN MEETINGS.

6 MS. ADAMS: THANK YOU, PAT. I AGREE
7 COMPLETELY.

8 DR. TAYLOR: THANK YOU. PHENOMENAL WORK
9 IN PROGRESS. WHAT'S THE BIGGEST OBSTACLE THAT YOU
10 LOOK FORWARD TO OVERCOMING IF YOU COULD JUST PICK
11 ONE?

12 MS. ADAMS: OH, MY GOSH. THAT'S A REALLY
13 HARD QUESTION FOR LATE IN THE DAY. IT'S THE SIZE
14 AND DIVERSITY OF THE STATE. ACTUALLY I'M GOING TO
15 TAKE IT BACK. AND I'M SAYING THE SAME THING WHEN
16 I'M COMING IN FROM A DIFFERENT ANGLE. THE
17 FRAGMENTATION OF THE COMMUNICATIONS INFRASTRUCTURE
18 RIGHT NOW.

19 THERE WAS A PERIOD OF TIME EARLIER IN MY
20 CAREER WHERE YOU COULD LIKE PUT SOMETHING ON
21 FACEBOOK AND PEOPLE WOULD SEE IT. AND NOW IT TAKES
22 A LOT OF WORK. YOU HAVE TO REWRITE THINGS EACH
23 TIME. YOU HAVE TO PUT IT ON THE WEBSITE AND ON THE
24 BLOG AND IN AN EMAIL AND ON INSTAGRAM AND ON
25 FACEBOOK AND ON WHATEVER WE'RE CALLING THOSE OTHER

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1 THINGS NOW. AND GO TO CLUBS AND THINK ABOUT --
2 PAT'S EXACTLY RIGHT. IT'S GREAT TO REACH THESE HIGH
3 IMPACT PLACES, BUT HOW DO YOU SPEAK TO LARGER
4 AUDIENCES?

5 IT'S REALLY FRAGMENTED, AND EACH ONE OF
6 THOSE AUDIENCES REQUIRES SOMEONE TO TAKE THE TIME TO
7 DO THAT. SO I THINK IT'S EASY TO SAY TIME, MONEY,
8 PEOPLE, BUT I THINK IT'S REALLY THE FRAGMENTATION
9 THAT MAKES IT HARD FOR A REASONABLE -- WE HAVE A
10 REASONABLE STAFF, BUT IT JUST MAKES IT HARD RIGHT
11 NOW. I THINK THAT'S HARD NOT JUST FOR ME. THAT IS
12 WHERE WE ARE RIGHT NOW IN THE COMMUNICATIONS
13 LANDSCAPE.

14 CHAIRMAN IMBASCIANI: OTHER COMMENTS OR
15 QUESTIONS? I'M GOING TO THANK YOU AGAIN, AMY. ONE
16 OF THE HIGHLIGHTS OF OUR MEETING.

17 LISTEN, I OWE THE BOARD A VERY, VERY SHORT
18 CHAIR'S REPORT, WHICH I'M GOING TO DO, REALIZING
19 THAT I'M THE ONLY THING SEPARATING THE BOARD FROM
20 HEARING FROM OUR PRESIDENT WHO HAS SOME LATE
21 BREAKING NEWS. SO LET ME DO THIS VERY QUICKLY.
22 THIS WILL TAKE TWO MINUTES, J.T.

23 IT'S VERY APPROPRIATE, BOARD MEMBERS, THAT
24 I FOLLOW AMY'S TALK ON HOW TO TELL CIRM'S STORY. I
25 WOULD LIKE TO REPORT TO YOU OF A NEW INITIATIVE I'VE

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1 UNDERTAKEN WITH THE AIM OF BRINGING KNOWLEDGE OF
2 CIRM'S WORK AND ACCOMPLISHMENTS TO A WIDER
3 CALIFORNIA AUDIENCE. AND BY THAT I MEAN AUDIENCES
4 OUTSIDE THE TYPICAL SCIENTIFIC AND BIOTECHNOLOGY
5 WORLDS.

6 CAPITALIZING ON SOME LONGSTANDING
7 RELATIONSHIPS THAT I'VE DEVELOPED OVER THE YEARS,
8 I'VE BEGUN REACHING OUT TO SOME OF THE LARGEST
9 VETERAN ORGANIZATIONS IN THE STATE. MANY OF THESE
10 ASSOCIATIONS HAVE LARGE CONVENTIONS EACH YEAR THAT
11 ATTRACT MEMBERS FROM EVERY CORNER OF THE STATE. AS
12 A MATTER OF BACKGROUND, THERE ARE NOW PRESENTLY
13 ABOUT 1.6 MILLION VETERANS IN CALIFORNIA, MORE THAN
14 ANY OTHER STATE.

15 TO ADVOCATE FOR THEM, CONGRESS HAS
16 CHARTERED OVER 50 VETERAN SERVICE ORGANIZATIONS, THE
17 MOST FAMILIAR BEING THE VFW, VETERANS OF FOREIGN
18 WARS, AND THE AMERICAN LEGION. WHAT MEMBERS OF ALL
19 THESE ORGANIZATIONS HAVE IN COMMON VARIES. SOME
20 ATTRACT MEMBERS WHO SERVED IN A SPECIFIC WAR, LIKE
21 KOREA, VIETNAM, OR IN MY CASE THE TWO GULF WARS.
22 OTHERS ATTRACT MEMBERS OF SPECIFIC ETHNIC GROUPS.
23 SOME REQUIRE A DISTINGUISHING CHARACTERISTIC
24 RESULTING FROM THEIR COMBAT EXPERIENCE, SUCH AS THE
25 SOCIETY FOR THE PURPLE HEART, THE DISABLED VETERANS

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1 OF AMERICA. PARALYZED VETERANS HAVE THEIR OWN
2 ORGANIZATION AS DO THOSE EXPOSED TO IONIZING
3 RADIATION FROM HIROSHIMA, BIKINI ATOLL, OR THE
4 NEVADA TEST SITES. THE NAVY, THE MARINES, THE
5 COASTGUARD, THE OTHER SERVICE BRANCHES HAVE THEIR
6 OWN ORGANIZATIONS, AND SO ON.

7 THE TWO LARGEST AND OLDEST ORGANIZATIONS,
8 THE AMERICAN LEGION AND THE VFW, HAVE INVITED ME TO
9 ADDRESS THEIR ANNUAL CONVENTIONS THIS SUMMER. GIVEN
10 THAT ALL VETERANS GROUPS ARE CHARTERED TO FOSTER
11 THEIR MEMBERS' WELL-BEING, AND THAT ONE OF THEIR
12 LEADING CONCERNS IS HEALTH, MY OFFER TO ACQUAINT
13 THEM WITH CIRM'S WORK WAS SEEN AS CONSONANT WITH
14 THEIR NATIONAL MISSION.

15 ONE OF THE REASONS I THINK THAT THIS IS AN
16 IDEAL AUDIENCE TO EDUCATE IS THAT, AS A GROUP, THEY
17 ARE INVOLVED ACTIVELY IN THE AFFAIRS OF THEIR
18 COMMUNITIES. THEY ARE ALSO AMONG THE MOST
19 INTERESTED CITIZEN GROUPS IN LEARNING ABOUT ADVANCES
20 IN MEDICINE AND BIOLOGICAL SCIENCE PRECISELY
21 BECAUSE, AS A GROUP, THEY HAVE BEEN SO
22 DISPROPORTIONATELY AFFECTED BY WAR, WHETHER BY
23 EXPOSURE TO TOXIC ENVIRONMENTS, THINK AGENT ORANGE,
24 DEPLETED URANIUM, AND OTHER CARCINOGENS, OR TO BLAST
25 INJURIES THAT CAUSE CHRONIC AND TRAUMATIC

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1 ENCEPHALOPATHIES.

2 I'M EXPECTING SEVERAL HUNDRED VETERANS AND
3 THEIR AUXILIARIES TO BE IN EACH OF THESE AUDIENCES.
4 AND WHEN IT'S DONE, THEY WILL RETURN TO THE CITIES,
5 TOWNS, AND HAMLETS IN EVERY COUNTY IN THE STATE.
6 TAKE ALPINE COUNTY, IF YOU RECALL THE MAP THAT GEOFF
7 LOMAX SHOWED EARLIER. POPULATION OF ALPINE COUNTY
8 IS 1200 PEOPLE, BUT THEY TOO HAVE AN AMERICAN LEGION
9 AND A VFW POST. SO IT'S MY HOPE THAT ALL OF THESE
10 VETERANS WILL CARRY SOME KNOWLEDGE OF CIRM AND OUR
11 MISSION AND OUR SUCCESSES TO DATE BACK HOME WITH
12 THEM.

13 THANK YOU. NO QUESTIONS OR COMMENTS. I
14 AM EAGERLY AWAITING THE PRESIDENT'S REPORT. J.T.,
15 YOU WANT TO COME UP OR YOU'RE GOING TO STAY THERE?

16 PUBLIC SPEAKER: I'M ONE OF THE PUBLIC
17 MEMBERS. BEFORE WE --

18 MS. MORALEZ: NO, WE'RE NOT TAKING PUBLIC
19 COMMENT RIGHT NOW. THANK YOU.

20 DR. THOMAS: MR. CHAIR, MADAM VICE CHAIR,
21 MEMBERS OF THE BOARD, MEMBERS OF THE PUBLIC, AND
22 MEMBERS OF OUR ESTEEMED TEAM, WE HAVE A VERY
23 SIGNIFICANT, HOT-OFF-THE PRESS ANNOUNCEMENT TO MAKE,
24 WHICH IS THAT ROCKET PHARMACEUTICALS, WHICH IS A
25 CIRM AWARDEE, JUST HAD THEIR PRODUCT FOR ADDRESSING

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1 SEVERE LEUKOCYTE ADHESION DEFICIENCY TYPE 1, OR
2 LAD-1 OR LAD-1 FOR SHORT, APPROVED BY THE FDA, JUST
3 RECEIVED CLEARANCE ON THEIR BLA. SO THIS MARKS THE
4 FIRST PRODUCT THAT CIRM HAS HELPED FUND THAT IS NOW
5 PROCEEDING INTO COMMERCIALIZATION.

6 THIS IS A VERY LARGE EVENT FOR ROCKET AND
7 A VERY LARGE EVENT FOR CIRM. AND I WOULD LIKE JUST
8 TO READ TO YOU BRIEFLY FROM THE FDA WEBSITE ON WHICH
9 THIS NEWS IS POSTED. THE OFFICIAL WORD FROM THE
10 FDA: U.S. FOOD AND DRUG ADMINISTRATION TODAY
11 APPROVED KRESLADI, THE FIRST GENE THERAPY FOR THE
12 TREATMENT OF LAD-1. KRESLADI IS INDICATED FOR THE
13 TREATMENT OF PEDIATRIC PATIENTS WITH SEVERE
14 LEUKOCYTE ADHESION DEFICIENCY DUE TO A VARIETY OF
15 THINGS THAT AREN'T WORTH GETTING INTO EXTREME DETAIL
16 HERE, BUT JUST TO NOTE THAT THIS IS A VERY SERIOUS
17 CONDITION. THE FAMILY THAT AMY WAS REFERRING TO,
18 WHOSE EXTREMELY CUTE PICTURE WAS AT DISNEYLAND
19 WEARING ALL THE MOUSE EARS, WAS THE FAMILY THAT SHE
20 WROTE ABOUT THAT HAD THIS CONDITION. AND SO THIS IS
21 FOR THAT FAMILY AND FOR OTHERS WITH THIS CONDITION A
22 VERY MAJOR DEVELOPMENT.

23 SO I THOUGHT EVERYBODY WOULD BE MOST
24 INTERESTED TO HEAR THAT BECAUSE WE'VE BEEN WAITING
25 FOR OUR FIRST EVER BLA APPROVED PRODUCT TO COME OUT

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1 OF CIRM. DAVID, YOU HEAR THAT?

2 MR. LARSEN: YES, I DID. THANK YOU VERY
3 MUCH. HOW MUCH DID CIRM INVEST IN THIS ENTERPRISE?

4 DR. THOMAS: JOE, DO YOU KNOW THE ANSWER
5 TO THAT QUESTION?

6 MS. ADAMS: I HAVE THE ANSWER RIGHT HERE.
7 5,867,085.

8 MR. LARSEN: THANK YOU. AFTER ALL, MONEY
9 IS THE MOTHER'S MILK OF SCIENCE.

10 DR. THOMAS: THAT'S RIGHT. SO THAT IS THE
11 BIG NEWS.

12 WE HAVE OTHER PIECES OF NEWS THAT, BECAUSE
13 THIS SORT OF DWARFS EVERYTHING ELSE, I THINK WE'RE
14 GOING TO KEEP, IN THE INTEREST OF TIME, FOR THE NEXT
15 PRESIDENT'S REPORT OTHER THAN TO MENTION TWO QUICK
16 THINGS. ONE IS ANOTHER PATIENT STORY, WHICH I THINK
17 IS VERY IMPORTANT FOR YOU ALL TO HEAR, WAS
18 INTERVIEWED BY *U.S.A. TODAY* A NUMBER OF WEEKS AGO.
19 AND ON THAT CALL WAS A FAMILY WITH TWO CHILDREN THAT
20 HAD SCID, ONE OF WHICH WAS TEN YEARS BEFORE THE
21 OTHER. THAT ONE AT THAT POINT THE ONLY TREATMENT
22 AVAILABLE WAS A BONE MARROW TRANSPLANT, AND THAT
23 CHILD WHO HAD THAT TREATMENT HAS HAD NUMEROUS
24 ISSUES, WAS IN THE HOSPITAL FOR, I BELIEVE, A YEAR.
25 THE FAMILY WENT BANKRUPT AS A RESULT OF DEALING WITH

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1 THE HEALTHCARE ISSUES. IT WAS A VERY, VERY
2 DIFFICULT STORY TO HEAR IN THE COURSE OF THIS
3 INTERVIEW. AND YOUR HEART WENT OUT TO THE FAMILY.

4 THE SECOND CHILD, BY THE TIME THAT CHILD
5 WAS SIMILARLY DIAGNOSED, WHICH IS TERRIBLE IN AND OF
6 ITSELF, IF YOU CAN IMAGINE HAVING TWO CHILDREN WITH
7 THE SAME CONDITION. AND, OH, BY THE WAY, THE
8 HUSBAND'S UNCLE, I BELIEVE, HAD TWO OTHER CHILDREN
9 THAT HAD SCID AS WELL. BY THE TIME THE YOUNGEST OF
10 THE TWO IN THIS FAMILY THAT WAS BEING INTERVIEWED
11 DEVELOPED THE CONDITION, THEY WERE ABLE TO USE DON
12 KOHN'S APPROACH TO SCID TO GET TREATMENT AT UCLA.
13 AND THAT CHILD IS NOW THRIVING AND HAS NONE OF THE
14 LINGERING SIDE EFFECTS THAT THEIR OLDER CHILD HAD.

15 AND IT SHOWS -- FIRST OF ALL, IT WAS GREAT
16 NEWS TO HEAR, BUT MORE THAN ANYTHING, THAT'S THE
17 PRIMARY POINT, BUT CERTAINLY OF GREAT SIGNIFICANCE
18 IS THE DEMONSTRATION OF THIS AS THE HOPE THAT CELL
19 AND GENE THERAPY PRESENTS TO PATIENTS OF ALL SORTS
20 OF CURRENTLY INCURABLE DISEASE. SO THAT *U.S.A.*
21 *TODAY* ARTICLE IS GOING TO BE COMING OUT SHORTLY. WE
22 WILL DISTRIBUTE WHEN THE TIME COMES.

23 THE LAST THING I WANT TO MENTION IS, JUST
24 TO CLOSE ON A VERY POSITIVE NOTE, THAT I'D LIKE TO
25 HAVE EVERYBODY WISH JENN LEWIS OF THE OAKLAND

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1 LEWISES AND DR. LIZ NOBLIN A VERY HAPPY BIRTHDAY
2 TODAY. MR. CHAIR, I'M GOING TO CLOSE ON THAT. AND
3 THANK YOU, EVERYBODY.

4 CHAIRMAN IMBASCIANI: THANK YOU, J.T.
5 WHERE ARE YOU, JENN? HAPPY BIRTHDAY AND LIZ. OKAY.
6 THANK YOU. AND, J.T., WE'LL LOOK FORWARD TO THE
7 ADDENDUM TO THE REPORT AT A FUTURE DATE.

8 WE'RE AT THE POINT OF THE MEETING WHERE
9 WE ASK --

10 MR. TOCHER: WE HAVE A COMMENT BY MARK
11 FISCHER-COLBRIE.

12 CHAIRMAN IMBASCIANI: OH, THANK YOU.

13 MR. FISCHER-COLBRIE: THIS IS INCREDIBLY
14 EXCITING NEWS ABOUT ROCKET. AND PARALLELING THE
15 CONVERSATION AROUND SCID IS THE FACT THAT THERE ARE
16 A WHOLE SLEW OF VERY SUCCESSFUL PATIENT SOLUTIONS
17 AND TREATMENTS THAT HAVE BEEN ACHIEVED THROUGH
18 CIRM-SUPPORTED FUNDING. AND JUST WANTED TO EXPAND
19 UPON THAT CONCEPT WITH THE PERSPECTIVE OF WE'VE HAD
20 A LOT OF SUCCESSES, BUT WE DO WANT TO BALLYHOO AND
21 SUPPORT A BROADER COMMUNICATION AROUND ROCKET AND
22 WHAT'S HAPPENING SPECIFICALLY AROUND THE BLA
23 PROCESS. SO THANKS.

24 CHAIRMAN IMBASCIANI: THANK YOU, MARK.
25 BEFORE WE GO THE PUBLIC, ARE THERE ANY MEMBERS OF

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1 THE BOARD WHO WANT TO MAKE ANY COMMENT ON OUR ARS
2 PROCESS OR ON ANY ITEM THAT WASN'T ON THE AGENDA?
3 IF NOT, I KNOW WE HAVE A MEMBER OF THE PUBLIC THAT'S
4 ON THE PHONE. SO WE CAN LET THEM SPEAK.

5 MS. MORALEZ: ALL RIGHT. THE NUMBER
6 ENDING IN 3427, IF YOU WOULD UNMUTE YOURSELF, AND
7 YOU HAVE THREE MINUTES.

8 MR. BHATNAGER: MY NAME IS PARIJAT
9 BHATNAGER. I WOULD LIKE TO MAKE -- I WOULD LIKE TO
10 BRING SOMETHING IMPORTANT TO THE NOTICE OF THE
11 BOARD. I BROUGHT THIS TO YOUR NOTICE TWICE IN THE
12 PAST, BUT I HAVE BEEN WAITING FOR SOME ACTION ON
13 YOUR BEHALF. BASICALLY THE ISSUE IS THAT I HAVE
14 STARTED A NEW NONPROFIT. IT HAS BEEN ABOUT SIX
15 MONTHS OR ABOUT A YEAR. AND SOME OF THE -- ONE OF
16 THE REQUIREMENTS, ELIGIBILITY CONDITIONS, FOR
17 APPLYING FOR CIRM GRANT HAVE MADE US INELIGIBLE.
18 AND I'M SURE THAT IT WAS NOT INTENDED TO BE LIKE
19 THIS, BUT I WAS TOLD THAT SOMEBODY WOULD GET BACK TO
20 ME. I HAVE NOT BEEN CONTACTED ABOUT THIS SO FAR.

21 AND BASICALLY THERE IS A REQUIREMENT THAT
22 THE INSTITUTE NEEDS TO HAVE AT LEAST ONE W-2
23 EMPLOYEE. I HAVE PUT A LETTER TO THE BOARD ON THE
24 WEBSITE, AND I WAS HOPING YOU COULD HAVE A
25 DISCUSSION ON HOW THIS COULD BE ADDRESSED. WE HAVE

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1 ALL HEARD TODAY THAT HOW IMPORTANT THE FUNDING FROM
2 CIRM IS IN BRINGING GROUNDBREAKING TREATMENTS TO THE
3 PUBLIC, TO THE BENEFIT OF THE PUBLIC. AND I BELIEVE
4 THAT WE SHOULD ALSO GET A CHANCE TO HELP CALIFORNIA
5 WITH GROUNDBREAKING TREATMENT, AS WELL AS INCREASING
6 EMPLOYMENT OPPORTUNITIES FOR THOSE WHO WOULD BE
7 HELPING US ACCOMPLISH THIS GOAL. THANK YOU. I'M
8 LOOKING FORWARD TO A RESPONSE.

9 CHAIRMAN IMBASCIANI: OKAY. WE KNOW WHO
10 THIS IS THAT'S SPEAKING AND CONTACT INFORMATION? WE
11 DO. OKAY. THANK YOU, SPEAKER. WE'VE GOT YOUR
12 CONTACT INFORMATION, AND WE'LL LOOK INTO IT. I
13 APPRECIATE YOUR REMARKS.

14 I JUST WANT TO LET EVERYONE KNOW THAT THE
15 NEXT MEETING OF THE ICOC WILL BE ON THURSDAY 25 JUNE
16 2026 AT THE HYATT HOTEL IN BURLINGAME, CALIFORNIA.
17 IT WILL START AT NINE IN THE MORNING, NOT AT 8:30.
18 AND THIS MEETING IS NOW ADJOURNED.

19 (THE MEETING WAS THEN ADJOURNED AT 4:32 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 26, 2026, 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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