

BETH C. DRAIN, CA CSR NO. 7152

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

LOCATION: VIA ZOOM

DATE: FEBRUARY 22, 2024
8 A.M.

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

FILE NO.: 2024-12

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CLOSED SESSION

NONE

11. DISCUSSION OF CONFIDENTIAL INTELLECTUAL PROPERTY OR WORK PRODUCT, PREPUBLICATION DATA, FINANCIAL INFORMATION, CONFIDENTIAL SCIENTIFIC RESEARCH OR DATA, AND OTHER PROPRIETARY INFORMATION RELATING TO APPLICATIONS SUBMITTED IN RESPONSE TO AGENDA ITEMS 8, 9, AND 10 ABOVE. (HEALTH & SAFETY CODE 125290.30(F) (3) (B) AND (C)).

OPEN SESSION

12. DISCUSSION OF MANAGEMENT'S RESPONSE TO THE PERFORMANCE AUDIT POSTPONED

13. GENERAL COMMENTS ON ARS PROCESS NONE

14. PUBLIC COMMENT NONE

15. ADJOURNMENT 157

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FEBRUARY 22, 2024; 8 A.M.

CHAIRMAN IMBASCIANI: GOOD MORNING,
EVERYONE. THIS IS VITO IMBASCIANI SPEAKING, THE
CHAIRMAN OF THE CIRM BOARD. I'D LIKE TO CALL THE
MEETING TO ORDER NOW THAT WE HAVE QUORUM. WE'RE
GOING TO START WITH A ROLL CALL CONDUCTED BY OUR
CHIEF LEGAL COUNSEL. RAFAEL.

MR. AGUIRRE-SACASA: THANK YOU, VITO.

MOHAMED ABOUSALEM.

DR. ABOUSALEM: PRESENT.

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MR. AGUIRRE-SACASA: KIM BARRETT.
DR. BARRETT: PRESENT.
MR. AGUIRRE-SACASA: DAN BERNAL. GEORGE
BLUMENTHAL.
DR. BLUMENTHAL: HERE.
MR. AGUIRRE-SACASA: MARIA BONNEVILLE.
VICE CHAIR BONNEVILLE: PRESENT.
MR. AGUIRRE-SACASA: LINDA BOXER. MONICA
CARSON.
DR. CARSON: PRESENT.
MR. AGUIRRE-SACASA: JUDY CHOU.
DR. CHOU: HERE.
MR. AGUIRRE-SACASA: CAROL CHRIST.
LEONDRA CLARK-HARVEY.
DR. CLARK-HARVEY: PRESENT.
MR. AGUIRRE-SACASA: ANNE-MARIE DULIEGE.
YSABEL DURON. LEON FINE.
DR. FINE: PRESENT.
MR. AGUIRRE-SACASA: MARK FISCHER-COLBRIE.
DR. FISCHER-COLBRIE: HERE.
MR. AGUIRRE-SACASA: FRED FISHER.
DR. FISHER: HERE.
MR. AGUIRRE-SACASA: ELENA FLOWERS. JUDY
GASSON.
DR. GASSON: HERE.

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1 MR. AGUIRRE-SACASA: LARRY GOLDSTEIN.
2 DR. GOLDSTEIN: HERE.
3 MR. AGUIRRE-SACASA: DAVID HIGGINS.
4 DR. HIGGINS: PRESENT.
5 MR. AGUIRRE-SACASA: VITO IMBASCIANI.
6 CHAIRMAN IMBASCIANI: HERE.
7 MR. AGUIRRE-SACASA: STEPHEN JUELSGAARD.
8 MS. MANDAC: GO BACK TO HIM BECAUSE HE GOT
9 OUT, AND HE'S COMING BACK IN.
10 RICH LAJARA.
11 MR. LAJARA: PRESENT.
12 MR. AGUIRRE-SACASA: PAT LEVITT.
13 DR. LEVITT: HERE.
14 MR. AGUIRRE-SACASA: LINDA MALKAS.
15 DR. MALKAS: HERE.
16 MR. AGUIRRE-SACASA: CHRISTINE MIASKOWSKI.
17 DR. MIASKOWSKI: HERE.
18 MR. AGUIRRE-SACASA: LAUREN MILLER-ROGEN.
19 MS. MILLER-ROGEN: HERE.
20 MR. AGUIRRE-SACASA: ADRIANA PADILLA.
21 DR. PADILLA: HERE.
22 MR. AGUIRRE-SACASA: JOE PANETTA.
23 MR. PANETTA: HERE.
24 MR. AGUIRRE-SACASA: MARVIN SOUTHARD.
25 DR. SOUTHARD: HERE.

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MR. AGUIRRE-SACASA: SUZANNE SANDMEYER.
DR. SANDMEYER: PRESENT.
MR. AGUIRRE-SACASA: KAROL WATSON.
DR. WATSON: HERE.
MR. AGUIRRE-SACASA: KEVIN XU.
MR. XU: HERE.
MR. AGUIRRE-SACASA: KEITH YAMAMOTO.
DR. YAMAMOTO: HERE.

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1 MR. AGUIRRE-SACASA: STEVE JUELSGAARD.

2 MR. JUELSGAARD: HERE.

3 MR. AGUIRRE-SACASA: THANK YOU. WE HAVE A
4 QUORUM.

5 CHAIRMAN IMBASCIANI: THANK YOU, CHIEF
6 LEGAL COUNSEL RAFAEL.

7 I'D LIKE TO DIRECT THE BOARD MEMBERS TO
8 THE CONSENT CALENDAR NEXT. IT CONSISTS OF AGENDA
9 NO. 3 AND 4. THREE IS THE CONSIDERATION OF MINUTES
10 FROM THE LAST MEETING, WHICH I HOPE YOU'VE TAKEN A
11 LOOK AT. AND ITEM NO. 4 ARE THE REQUESTS TO ATTEND
12 REMOTELY FROM THREE BOARD MEMBERS.

13 THE CHAIR WILL ENTERTAIN A MOTION TO
14 ACCEPT CORRECTIONS TO THE MINUTES OR ANYTHING ELSE
15 RELATED TO THE CONSENT CALENDAR.

16 DR. BLUMENTHAL: MOVE TO APPROVE THE
17 CONSENT CALENDAR.

18 CHAIRMAN IMBASCIANI: WE HAVE A MOTION
19 FROM BOARD MEMBER BLUMENTHAL. DO WE HAVE A SECOND?

20 VICE CHAIR BONNEVILLE: SECOND.

21 CHAIRMAN IMBASCIANI: THANK YOU. ANY
22 DISCUSSION? ANY COMMENT FROM THE PUBLIC ON THE
23 CONSENT CALENDAR?

24 MS. MANDAC: THERE ARE NO HANDS RAISED.

25 CHAIRMAN IMBASCIANI: NO HANDS ARE RAISED.

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1 WE CAN PROCEED TO A VOTE, RAFAEL.
2 MR. AGUIRRE-SACASA: MOHAMMED ABOUSALEM.
3 DR. ABOUSALEM: YES.
4 MR. AGUIRRE-SACASA: KIM BARRETT.
5 DR. BARRETT: YES.
6 MR. AGUIRRE-SACASA: GEORGE BLUMENTHAL.
7 DR. BLUMENTHAL: YES.
8 MR. AGUIRRE-SACASA: MARIA BONNEVILLE.
9 VICE CHAIR BONNEVILLE: YES.
10 MR. AGUIRRE-SACASA: MONICA CARSON.
11 DR. CARSON: YES.
12 MR. AGUIRRE-SACASA: JUDY CHOU.
13 DR. CHOU: YES.
14 MR. AGUIRRE-SACASA: CAROL CHRIST.
15 LEONDRA CLARK-HARVEY.
16 DR. CLARK-HARVEY: YES.
17 MR. AGUIRRE-SACASA: ANNE-MARIE DULIEGE.
18 YSABEL DURON. LEON FINE.
19 DR. FINE: YES.
20 MR. AGUIRRE-SACASA: MARK FISCHER-COLBRIE.
21 DR. FISCHER-COLBRIE: YES.
22 MR. AGUIRRE-SACASA: FRED FISHER.
23 DR. FISHER: YES.
24 MR. AGUIRRE-SACASA: ELENA FLOWERS. JUDY
25 GASSON.

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1 DR. GASSON: YES.
2 MR. AGUIRRE-SACASA: LARRY GOLDSTEIN.
3 DR. GOLDSTEIN: YES.
4 MR. AGUIRRE-SACASA: DAVID HIGGINS.
5 DR. HIGGINS: YES.
6 MR. AGUIRRE-SACASA: VITO IMBASCIANI.
7 CHAIRMAN IMBASCIANI: YES.
8 MR. AGUIRRE-SACASA: STEPHEN JUELSGAARD.
9 MR. JUELSGAARD: YES.
10 MR. AGUIRRE-SACASA: RICH LAJARA.
11 MR. LAJARA: YES.
12 MR. AGUIRRE-SACASA: PAT LEVITT.
13 DR. LEVITT: YES.
14 MR. AGUIRRE-SACASA: LINDA MALKAS.
15 DR. MALKAS: YES.
16 MR. AGUIRRE-SACASA: CHRISTINE MIASKOWSKI.
17 DR. MIASKOWSKI: YES.
18 MR. AGUIRRE-SACASA: LAUREN MILLER-ROGEN.
19 ADRIANA PADILLA.
20 DR. PADILLA: YES.
21 MR. AGUIRRE-SACASA: JOE PANETTA.
22 MR. PANETTA: YES.
23 MR. AGUIRRE-SACASA: MARVIN SOUTHARD.
24 DR. SOUTHARD: YES.
25 MR. AGUIRRE-SACASA: SUZANNE SANDMEYER.

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DR. SANDMEYER: YES.
MR. AGUIRRE-SACASA: KAROL WATSON.
DR. WATSON: YES.
MR. AGUIRRE-SACASA: KEVIN XU.
MR. XU: YES.
MR. AGUIRRE-SACASA: KEITH YAMAMOTO.
DR. YAMAMOTO: YES.

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1 MR. AGUIRRE-SACASA: THANK YOU. MOTION
2 PASSES.

3 CHAIRMAN IMBASCIANI: MOTION PASSES.
4 THANK YOU VERY MUCH.

5 IF I CAN ORIENT EVERYONE TO THE AGENDA.
6 THE NEXT FOUR ITEMS ON THE AGENDA IN ORDER WILL BE
7 AGENDA ITEMS NO. 7, 8, 9, AND 10. SO WE WILL
8 PROCEED NOW TO ITEM NO. 7. THIS IS THE SHARED LABS
9 CONCEPT AMENDMENT. AND OUR DISCUSSION PRESENTATION
10 WILL BE LED BY UTA GRIESHAMMER AND ROSA
11 CANET-AVILES. I THINK YOU'RE ON ALSO. WHO'S
12 PRESENTING? ROSA.

13 DR. CANET-AVILES: THANK YOU, MR.
14 CHAIRMAN. ON BEHALF OF DR. GRIESHAMMER AND THE
15 SCIENTIFIC PROGRAMS AND EDUCATION TEAM, I WILL BE
16 PRESENTING THIS AMENDMENT TODAY.

17 MR. CHAIRMAN, MADAM VICE CHAIR, MEMBERS OF
18 THE BOARD, AND THE PUBLIC, IN ADVANCE OF DR.
19 SAMBRANO'S PRESENTATION, WHICH IS ITEM NO. 8 FOR THE
20 APPLICATION REVIEW SUBCOMMITTEE CONSIDERATION OF THE
21 SHARED RESOURCE LABS AND GRANT WORKING GROUP
22 RECOMMENDATIONS, OUR TEAM IS PRESENTING AN AMENDMENT
23 FOR YOUR CONSIDERATION AND VOTE.

24 NEXT. FOR CONTEXT PURPOSES, THIS SLIDE
25 PROVIDES A TIMELINE REPRESENTATION OF THE KEY

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1 MILESTONES IN THE DEVELOPMENT AND IMPLEMENTATION OF
2 THE SHARED RESOURCE LABS PROGRAM. THE BOARD
3 APPROVED THIS CONCEPT BACK IN OCTOBER OF 2022 AND
4 SUBSEQUENTLY APPROVED AN AMENDMENT IN DECEMBER TO
5 CHANGE THE STRUCTURE OF THE LEADERSHIP TEAM
6 COMMITMENT. SINCE THEN, AS YOU CAN SEE IN THIS
7 SLIDE, WE HAD THE POSTING OF THE RFA, WE HAD THE
8 APPLICATIONS, AS WELL AS A WEBINAR FOR APPLICANTS TO
9 UNDERSTAND WHAT WE WERE LOOKING FOR. AND THEN WE
10 HAD THE GRANTS WORKING GROUP REVIEW AND THE
11 FACILITIES WORKING GROUP REVIEWS.

12 AND WE ARE COMING TO YOU TODAY BEFORE THE
13 ARS DECISION TO ASK YOU TO CONSIDER AN AMENDMENT
14 WITH REGARDS TO THE PROGRAM BUDGET DETAIL.
15 IMPORTANTLY, WE ARE NOT GOING TO BE ASKING FOR A
16 CHANGE IN TOTAL BUDGET, ONLY A DETAIL ON HOW IT WAS
17 APPROVED BACK IN 2022 WHICH COULD ALLOW TO INCREASE
18 THE TOTAL NUMBER OF AWARDS THAT CAN BE MADE WITH THE
19 SAME TOTAL BUDGET ALLOCATION.

20 NEXT SLIDE. THANK YOU, CLAUDETTE.

21 I'LL NOW DELVE INTO AN OVERVIEW OF THIS
22 PROGRAM AS DR. SAMBRANO WILL BE GOING OVER THIS
23 TODAY. HOWEVER, FOR THE PURPOSES OF THIS CONCEPT
24 AMENDMENT AND AS A QUICK REMINDER, IN ORDER TO
25 ENSURE BROAD ACCESS, WHICH WAS ONE OF THE GOALS OF

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1 THIS PROGRAM, ONE OF THE MAJOR GOALS, TO ENSURE
2 BROAD ACCESS TO STEM CELL-BASED MODELS ACROSS
3 CALIFORNIA, WE CREATED TWO TYPES OF AWARD
4 OPPORTUNITIES FOR THE SHARED RESOURCE LABS PROGRAM.

5 ONE WAS ESTABLISHING SRL'S. THESE WERE
6 INTENDED TO PROVIDE ACCESS TO STEM CELL-BASED
7 MODELING EXPERTISE IN GEOGRAPHIC AREAS WHERE ACCESS
8 TO MODELS IS LIMITED. AND THE OTHER PART WAS THE
9 ENHANCING AND EXPANSION SRL'S, WHICH HAVE BEEN
10 DESIGNED TO TARGET INSTITUTIONS THAT HAVE CUTTING
11 EDGE STEM CELL-BASED MODELING EXPERTISE.

12 THESE TWO TYPES OF SRL'S WOULD ULTIMATELY
13 LEAD TO FULFILLING THE OBJECTIVES OF THIS
14 OPPORTUNITY WHICH YOU CAN SEE ARE IN THESE FOUR
15 BULLET POINTS. THE MAIN GOALS WERE TO BROADEN
16 ACCESS TO STEM CELL-BASED MODELS ACROSS CALIFORNIA.
17 THE SECOND WAS TO ADVANCE STANDARDS AND
18 REPRODUCIBILITY OF STEM CELL-BASED MODELS. THE
19 THIRD WAS TO INCREASE THE ACCESS TO EDUCATIONAL
20 OPPORTUNITIES AND STEM CELL-BASED TECHNIQUES. AND
21 THIS IS OBVIOUSLY WITHIN THE NETWORK AS WELL OF OUR
22 EDUCATION PROGRAMS. AND THE FOURTH IS TO DEVELOP A
23 SUSTAINABLE STEM CELL CORE INFRASTRUCTURE. THAT'S
24 IMPORTANT BECAUSE IT'S THE FIRST PROGRAM THAT WE
25 IMPLEMENTED A SUSTAINABILITY PLAN. WE ARE PILOTING

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1 A NEW MODEL HERE. WE ENVISION THAT FUNDED SRL'S
2 WILL FUNCTION AS A NETWORK AS WELL.

3 NEXT SLIDE.

4 THIS IS JUST A REMINDER OF THE STRUCTURE
5 OF THE INDIVIDUAL AWARDS AND THE AMOUNT ALLOCATED TO
6 EACH TYPE OF AWARD. THE MAIN POINT THAT I WANT TO
7 MAKE HERE IS THAT THE TOTAL AMOUNT AWARDED WAS
8 DIFFERENT FROM THE TWO TYPES, REFLECTING THE FACT
9 THAT ESTABLISHING SRL'S HAVE A BUDGET FOR RENOVATING
10 CORE FACILITY SPACE WHILE THE OTHER ONES DO NOT, AND
11 BOTH HAVE A BUDGET FOR EQUIPPING AND OPERATIONS.

12 NOW, THE NEXT SLIDE IS WHAT -- NEXT SLIDE.
13 I HAVE THE ANIMATION SO I COULD GO POINT BY POINT.
14 BUT THAT'S ALL GOOD.

15 ON OUR INTRODUCTORY SLIDE WE MENTIONED
16 THAT THIS AMENDMENT IS NOT ASKING FOR A CHANGE IN
17 THE TOTAL BUDGET. WE'RE ASKING FOR A CHANGE ON HOW
18 THE LIMITS WERE APPROVED BACK IN 2022. ON THE LEFT
19 GRAPHIC, WE HAVE THE ORIGINAL BUDGET LIMIT BACK WHEN
20 THE CONCEPT WAS APPROVED. THE ORIGINAL BUDGET OF 50
21 MILLION LIMITED THE AMOUNT OF OPERATIONAL BUDGET TO
22 24 MILLION AND THE BUILD AND EQUIP TO 26 MILLION.

23 NOW, IF WE REMOVE THE LIMIT ON OPERATIONAL
24 FUNDS CURRENTLY AT 24 MILLION AND ALLOW ANY UNUSED
25 BUILD AND EQUIP FUNDS TO BE USED FOR OPERATION, THIS

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1 COULD ALLOW FOR TWO MORE FUNDED APPLICATIONS. SO
2 WHAT WE ARE PROPOSING IS TO REMOVE THE LIMITS OF THE
3 OPERATIONAL BUDGET TO BE ABLE TO USE SOME BUILD AND
4 EQUIP. THIS DOES NOT CHANGE THE OVERALL 50 MILLION
5 BUDGET ALLOCATION. IT DOES NOT EXCEED THE 26
6 MILLION SPENDING ON BUILD AND EQUIP THAT IS
7 ALLOCATED BY PROPOSITION 14.

8 AND IF APPROVED, THIS IS WHAT'S IMPORTANT
9 AND WHY WE ARE COMING BEFORE THE ARS AND
10 PRESENTATION BY DR. SAMBRANO, THIS AMENDMENT WILL
11 INCREASE THE TOTAL NUMBER OF AWARDS THAT CAN BE MADE
12 WITH THE SAME TOTAL BUDGET ALLOCATION.

13 NEXT SLIDE. SO WITH THAT, I WOULD LIKE TO
14 ASK THE BOARD TO CONSIDER THE APPROVAL TO REMOVE THE
15 LIMIT OF OPERATIONAL FUNDS INITIALLY SET AT \$24
16 MILLION. THANK YOU. ANY QUESTIONS?

17 CHAIRMAN IMBASCIANI: THANK YOU, ROSA, FOR
18 THAT PRESENTATION. BEFORE WE DISCUSS, WE SHOULD
19 PROBABLY HAVE A MOTION.

20 VICE CHAIR BONNEVILLE: SO MOVED.

21 DR. YAMAMOTO: SECOND.

22 CHAIRMAN IMBASCIANI: WE HAVE A MOTION AND
23 SECOND TO CONSIDER THE AMENDMENT. BOARD MEMBER
24 BLUMENTHAL.

25 DR. BLUMENTHAL: THANK YOU. YOU MENTIONED

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1 THE FACT THAT WE WOULD NOT BE USING THE FULL \$26
2 MILLION FOR CONSTRUCTION. COULD YOU GO INTO A
3 LITTLE BIT MORE DEPTH THERE ABOUT WHY THAT MONEY IS
4 NOT NEEDED?

5 DR. CANET-AVILES: YES. SO INITIALLY ON
6 SLIDE NO. 4, WE HAD THE BUDGET FOR THE ESTABLISHING
7 SRL'S AND THE ENHANCING AND EXPANSIONS. WHEN WE
8 FIRST SET UP THIS BUDGET, WE THOUGHT WE WERE GOING
9 TO GET MORE ESTABLISHING SRL'S WHICH REQUIRE MORE
10 BUILD TO RENOVATE BUDGET. AND THE APPLICATIONS THAT
11 WE HAD, WE ENDED UP WITH LESS OF THOSE. AND OF
12 THOSE, AS YOU WILL SEE BY DR. SAMBRANO, THERE IS
13 ONLY ONE RECOMMENDED FOR FUNDING. SO WE ARE LEFT
14 WITH A LOT MORE BUILDING BUDGET TO SPEND THAT COULD
15 BE USED FOR OPERATIONS; WHEREAS, THE OPERATIONS
16 BUDGET HAS BEEN USED BY ALL OF THEM. SO WE'VE
17 EXHAUSTED THE OPERATION BUDGET.

18 DR. BLUMENTHAL: THANK YOU.

19 CHAIRMAN IMBASCIANI: THANK YOU. ANY
20 QUESTIONS FOR DR. CANET-AVILES? I DON'T SEE ANY.
21 DOES ANY MEMBER OF THE PUBLIC WANT TO COMMENT ON THE
22 PROPOSED AMENDMENT?

23 MS. MANDAC: NO HANDS RAISED.

24 CHAIRMAN IMBASCIANI: THERE ARE NO HANDS
25 RAISED. I THINK WE'RE READY TO PROCEED TO A VOTE ON

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1 THE AMENDMENT. RAFAEL, IF YOU WOULD DO THE HONORS.
2 MR. AGUIRRE-SACASA: MOHAMED ABOUSALEM.
3 DR. ABOUSALEM: YES.
4 MR. AGUIRRE-SACASA: GEORGE BLUMENTHAL.
5 DR. BLUMENTHAL: YES.
6 MR. AGUIRRE-SACASA: MARIA BONNEVILLE.
7 VICE CHAIR BONNEVILLE: YES.
8 MR. AGUIRRE-SACASA: MONICA CARSON.
9 DR. CARSON: YES.
10 MR. AGUIRRE-SACASA: JUDY CHOU.
11 DR. CHOU: YES.
12 MR. AGUIRRE-SACASA: LEONDRA CLARK-HARVEY.
13 DR. CLARK-HARVEY: YES.
14 MR. AGUIRRE-SACASA: LEON FINE.
15 DR. FINE: YES.
16 MR. AGUIRRE-SACASA: MARK FISCHER-COLBRIE.
17 DR. FISCHER-COLBRIE: YES.
18 MR. AGUIRRE-SACASA: FRED FISHER.
19 DR. FISHER: YES.
20 MR. AGUIRRE-SACASA: JUDY GASSON.
21 DR. GASSON: YES.
22 MR. AGUIRRE-SACASA: LARRY GOLDSTEIN.
23 DR. GOLDSTEIN: YES.
24 MR. AGUIRRE-SACASA: DAVID HIGGINS.
25 DR. HIGGINS: YES.

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MR. AGUIRRE-SACASA: VITO IMBASCIANI.
CHAIRMAN IMBASCIANI: YES.
MR. AGUIRRE-SACASA: STEPHEN JUELSGAARD.
MR. JUELSGAARD: ABSTAIN. I'M NOT SURE I
CAN VOTE ON THIS.
VICE CHAIR BONNEVILLE: STEVE, YOU CAN
VOTE ON THIS ITEM.
MR. JUELSGAARD: ALL RIGHT. THEN YES.
MR. AGUIRRE-SACASA: RICH LAJARA.
MR. LAJARA: YES.
MR. AGUIRRE-SACASA: PAT LEVITT.
DR. LEVITT: YES.
MR. AGUIRRE-SACASA: LINDA MALKAS.
DR. MALKAS: YES.
MR. AGUIRRE-SACASA: CHRISTINE MIASKOWSKI.
DR. MIASKOWSKI: YES.
MR. AGUIRRE-SACASA: LAUREN MILLER-ROGEN.
ADRIANA PADILLA.
DR. PADILLA: YES.
MR. AGUIRRE-SACASA: JOE PANETTA.
MR. PANETTA: YES.
MR. AGUIRRE-SACASA: MARVIN SOUTHARD.
DR. SOUTHARD: YES.
MR. AGUIRRE-SACASA: SUZANNE SANDMEYER.
DR. SANDMEYER: YES.

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MR. AGUIRRE-SACASA: KAROL WATSON.

DR. WATSON: YES.

MR. AGUIRRE-SACASA: KEVIN XU.

MR. XU: YES.

MR. AGUIRRE-SACASA: KEITH YAMAMOTO.

DR. YAMAMOTO: YES.

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1 MR. AGUIRRE-SACASA: THANK YOU. MOTION
2 CARRIES.

3 CHAIRMAN IMBASCIANI: THANK YOU VERY MUCH.
4 NOW THAT WE HAVE PASSED THE AMENDMENT TO THE SHARED
5 RESOURCES LABORATORY CONCEPT, LET'S PROCEED TO THE
6 APPLICATIONS. THIS IS AGENDA ITEM NO. 8. THE
7 DISCUSSION WILL BE LED BY GIL SAMBRANO. THANK YOU.

8 DR. SAMBRANO: GOOD MORNING, EVERYONE. SO
9 I'M SHARING MY SCREEN HERE. LET ME SET UP THE
10 PRESENTATION.

11 SO I'M GOING TO PRESENT TO YOU THE
12 RECOMMENDATIONS BOTH FROM THE GRANTS WORKING GROUP
13 AND FACILITIES WORKING GROUP FOR THE SHARED RESOURCE
14 LABORATORIES. AND AS ALWAYS, WE START WITH OUR
15 MISSION TO ACCELERATE WORLD-CLASS SCIENCE TO DELIVER
16 TRANSFORMATIVE REGENERATIVE MEDICINE TREATMENTS IN
17 AN EQUITABLE MANNER TO A DIVERSE CALIFORNIA AND
18 WORLD.

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1 SO THE SHARED RESOURCE LABORATORIES IS AN
2 EXTENSION OF OUR FIVE-YEAR STRATEGIC PLAN TO DEVELOP
3 COMPETENCY HUBS, BUILD KNOWLEDGE NETWORKS, AND BUILD
4 A DIVERSE AND HIGHLY SKILLED WORKFORCE. SO ALL OF
5 THESE ELEMENTS THAT ARE PART OF OUR STRATEGIC THEMES
6 ARE A PART OF THE SHARED LABORATORIES PROGRAM. AND,
7 OF COURSE, THE SHARED LABORATORIES PROGRAM IS
8 SOMETHING THAT IS SPECIFICALLY CALLED OUT IN PROP 14
9 AS SOMETHING THAT THE INSTITUTE SHOULD CONTINUE TO
10 EMBARK ON.

11 AND SO THE PROGRAM ITSELF IS STRUCTURED IN
12 ORDER TO ACHIEVE SEVERAL THINGS. MAINLY TO PROVIDE
13 RESEARCHERS BOTH LOCALLY AND REGIONALLY ACCESS TO
14 CELL CULTURE FACILITIES WHERE THEY CAN CONDUCT STEM
15 CELL-BASED MODELING EXPERIMENTS AND OTHER HIGHLY
16 SPECIALIZED TECHNOLOGIES, ALSO ACCESS TO
17 WELL-CHARACTERIZED UNMODIFIED AND MODIFIED HUMAN
18 PLURIPOTENT STEM CELL COLLECTIONS, PARTIALLY OR
19 FULLY DIFFERENTIATED STEM CELL-BASED MODELS, AND
20 TRAINING OF INDIVIDUAL INVESTIGATORS. THAT MEANS
21 ANY RESEARCH INVESTIGATOR WHO IS INTERESTED IN
22 LEARNING ABOUT THESE STEM CELL MODELS OR HUMAN
23 PLURIPOTENT STEM CELL LINES CAN COME TO THESE SHARED
24 LABS TO LEARN HOW TO UTILIZE THEM, HOW TO CULTURE
25 THEM, AND SO ON.

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1 IN ADDITION, IT PROVIDES A FORMAL
2 TECHNIQUES COURSE FOR STUDENT EDUCATION AND OTHER
3 STUDENT EXPERIENCES. THE FORMAL TECHNIQUES COURSE
4 IS OPTIONAL, BUT I THINK MOST OF THE APPLICANTS
5 REQUESTED FUNDS TO CONDUCT A FORMAL TECHNIQUES
6 COURSE. AND THIS ALLOWS THESE INSTITUTIONS TO
7 PROVIDE SUCH COURSES TO, FOR EXAMPLE, THE BRIDGES
8 STUDENTS. SO OFTEN IT'S BEEN THE CASE THAT BRIDGES
9 STUDENTS TAKE THESE COURSES AS PART OF THEIR
10 EDUCATIONAL PROGRAM.

11 WE ALSO ASK THEM ALL TO IMPLEMENT A
12 SUSTAINABILITY PLAN TO DEVELOP A FEE FOR SERVICE OR
13 RECHARGE OR OTHER ALTERNATIVE FUNDING SOURCES WITH
14 WHICH THEY CAN CONTINUE TO MAINTAIN OPERATIONS EVEN
15 BEYOND CIRM SUPPORT.

16 SO, AGAIN, JUST TO REITERATE A LITTLE BIT
17 OF WHAT ALREADY HAS BEEN SAID, THERE ARE TWO
18 DIFFERENT TYPES OF PROGRAMS. YOU HAVE THE
19 ESTABLISHING SHARED RESOURCE LABORATORIES THAT ARE
20 INTENDED TO FUND THOSE PROGRAMS IN GEOGRAPHIC AREAS
21 WHERE ACCESS TO THESE MODELS IS LIMITED. AND AS
22 SUCH, THESE ARE NEW PROGRAMS THAT WOULD REQUIRE
23 RENOVATION OF MORE SPACE AND ACQUISITION OF MAJOR
24 EQUIPMENT.

25 THE OTHER TYPE IS THE ENHANCING/EXPANDING.

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1 HERE WE EXPECT THAT THESE PROGRAMS ALREADY HAVE
2 LABORATORY SPACE WHERE CUTTING-EDGE STEM CELL-BASED
3 MODELING IS OCCURRING, BUT THE GOAL HERE IS TO
4 EXPAND OR ENHANCE THOSE CAPABILITIES AND MAKE THEM
5 ACCESSIBLE TO OTHERS. BUT WE ARE PROVIDING FUNDS
6 FOR THEM TO ACQUIRE MAJOR EQUIPMENT THAT WOULD ALLOW
7 THEM TO MAKE THAT KIND OF ENHANCEMENT OR EXPANSION.

8 FOR ALL OF THEM, THE OPERATIONS ARE
9 FOCUSED ON PROVIDING ACCESS, AS MENTIONED IN THE
10 PREVIOUS SLIDES, TO SHARE THEIR MODELS DURING THE
11 RESEARCH AND PROVIDE AN ADDITIONAL RESOURCE.

12 ALSO AS MENTIONED, THE IDEA BEHIND THESE
13 PROGRAMS IS TO HAVE A NETWORK THAT IS BUILT FROM THE
14 ESTABLISHING AS WELL AS THE ENHANCING AND CIRM STAFF
15 AND CIRM ITSELF TO DEVELOP A SET OF BEST PRACTICES,
16 TO SHARE IN THE LEARNINGS OF EACH OF THE
17 INSTITUTIONS, AND CREATE A GREATER WHOLE THROUGH
18 THIS PROCESS. AND SO THIS MIMICS WHAT WE'VE DONE
19 WITH THE ALPHA CLINICS AND MANUFACTURING NETWORK IN
20 TRYING TO JOIN ALL OF THESE DIFFERENT PROGRAMS IN
21 ORDER TO SYNERGIZE THEIR EFFORTS.

22 NOW, WE ALREADY SHOWED THIS SLIDE THAT
23 SHOWS A LITTLE BIT MORE DETAIL ABOUT THE DIFFERENT
24 ELEMENTS BEHIND THE ESTABLISHING VERSUS
25 ENHANCING/EXPANSION SRL, INCLUDING THE AWARD

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1 AMOUNTS. THE ONLY OTHER THING I'LL ADD HERE IS THAT
2 THERE IS A CO-FUNDING REQUIREMENT FOR THE
3 ENHANCING/EXPANSION SRL'S OF 20 PERCENT OF THEIR
4 OPERATIONAL COSTS. THERE WAS NO CO-FUNDING REQUIRED
5 FOR THE ESTABLISHING.

6 ALSO IMPORTANT TO NOTE IS THAT THE
7 STRUCTURE OF THESE AWARDS IS SUCH THAT ALL OF THE
8 PROGRAMS WILL GO THROUGH DIFFERENT PHASES DURING THE
9 AWARD PERIOD. SO FOR THE ESTABLISHING SRL'S,
10 THERE'S A PHASE A, WHICH GOES TO 18 MONTHS, WHICH
11 ALLOWS THEM TO RENOVATE THEIR SPACE BEFORE THEY
12 ACTUALLY BEGIN OPERATIONS. PHASE B IS THE
13 OPERATIONS PHASE WHERE THEY LAUNCH THE PROGRAM AND
14 OPEN THEIR SERVICES. AND THEN A PHASE C, WHICH IS
15 THE LAST 18 MONTHS OF THE AWARD, WHERE THE
16 OPERATIONAL FUNDS PROVIDED BY CIRM IS 50 PERCENT AND
17 WHERE THEY BEGIN TO IMPLEMENT THEIR SUSTAINABILITY
18 PLAN AND CONTRIBUTE THE OTHER 50 PERCENT WITH A GOAL
19 OF EVENTUALLY BECOMING COMPLETELY SELF-SUSTAINED.

20 THE ENHANCING/EXPANSION SRL'S ALSO GO
21 THROUGH THIS THREE-PHASE STEP, BUT THE INITIAL PHASE
22 A IS ONLY SIX MONTHS. SINCE THERE IS NO RENOVATION
23 HAPPENING FOR THEM, THEY ARE FOCUSED ON REALLY
24 STAFFING AND EQUIPPING THEIR LAB, WHICH CAN HAPPEN
25 MUCH MORE QUICKLY.

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1 OTHER ELEMENTS THAT MUST BE INCLUDED IN
2 THESE PLANS IS THAT THEY MUST INCLUDE A PLAN TO
3 ADDRESS DEI, INCLUDING HOW SRL CORE USERS AND
4 RECIPIENTS OF THE MODELS REPRESENT DIVERSE GOALS,
5 APPROACHES, AND PERSPECTIVES AND BACKGROUNDS,
6 PARTICIPATION IN THE EDUCATIONAL COMPONENTS BY
7 UNDERSERVED POPULATIONS, THAT THE TEAM ITSELF
8 REPRESENTS AND IS AWARE OF DIVERSE AND INCLUSIVE
9 PERSPECTIVES AND EXPERIENCES, AND THE INCLUSION OF
10 ANCESTRAL AND SEX DIVERSITY WITHIN THE STEM CELL
11 LINES THAT ARE OFFERED IN THE CORE.

12 WE ASK THAT ALL OF THEM INCLUDE A
13 KNOWLEDGE SHARING PLAN IN ORDER TO SHARE MODELS,
14 BEST PRACTICES, AND TO BETTER FUNCTION AS A NETWORK,
15 ALSO TO INCLUDE A DATA SHARING AND MANAGEMENT PLAN.
16 AND THEN ALSO TO HELP IN THE COORDINATION AND
17 NETWORKING ASPECT OF THE PROGRAM AS WHOLE, WE ARE
18 GOING TO COORDINATE A STEERING COMMITTEE THAT
19 INCLUDES ALL OF THE PROGRAM DIRECTORS FROM EACH OF
20 THE AWARDEES, AS WELL AS ANY EXTERNAL STAKEHOLDERS
21 THAT CAN HELP FACILITATE THE DEVELOPMENT OF
22 PROCESSES, STANDARDS, BEST PRACTICES, AND SO ON, AND
23 ALSO JUST DEVELOP COLLABORATIVE APPROACHES FROM
24 THEIR LEARNINGS THAT CAN HELP IMPROVE THE
25 REPRODUCIBILITY OF STEM CELL-BASED MODELS.

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1 OKAY. SO THAT'S A SUMMARY OF THE PROGRAM
2 ITSELF. SO I'M GOING TO GO OVER THE REVIEWS. AND
3 THIS IS A LITTLE BIT COMPLEX BECAUSE WE HAD TWO
4 WORKING GROUPS THAT WERE INVOLVED IN REVIEWING SOME
5 OF THESE, THE ONES THAT HAD RENOVATION.

6 SO WE HAVE FOR THE ESTABLISHING 6.1
7 PROGRAM, THERE WERE SIX APPLICATIONS THAT WERE
8 SUBMITTED AND REVIEWED. FOR THE 6.2 EXPANDING AND
9 ENHANCING, THERE WERE 14 APPLICATIONS THAT WERE
10 SUBMITTED AND REVIEWED. SO A TOTAL OF 20.

11 THE ESTABLISHING 6.1 REQUIRED BOTH REVIEW
12 BY THE GRANTS WORKING GROUP TO ASSESS THE SCIENTIFIC
13 PLAN AND MERIT OF DOING THE PROPOSED SCIENTIFIC
14 ACTIVITIES OF THE LAB AND ALSO A FACILITIES WORKING
15 GROUP REVIEW WHERE THEY ASSESSED THE DETAILS OF THE
16 RENOVATION PLANS THAT THEY HAD PROPOSED.

17 FOR THE EXPANDING/ENHANCING, BECAUSE THOSE
18 DID NOT HAVE A RENOVATION COMPONENT, THOSE ONLY
19 REQUIRED A GRANTS WORKING GROUP REVIEW AND NOT A
20 FACILITIES WORKING GROUP REVIEW.

21 SO I'M GOING TO GIVE YOU SORT OF THE
22 MANDATE BEHIND THE GRANTS WORKING GROUP, HOW THE
23 GROUP WAS COMPOSED, AND COMPARE THAT TO FACILITIES
24 WORKING GROUP. SO FOR THE GRANTS WORKING GROUP, THE
25 20 APPLICATIONS WERE REVIEWED BY THIS GROUP THAT HAD

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1 AND WAS COMPOSED OF 15 SCIENTIFIC GRANTS WORKING
2 GROUP MEMBERS WHO DID THE SCIENTIFIC EVALUATION AND
3 PROVIDED SCIENTIFIC SCORES ON ALL THE APPLICATIONS.
4 WE HAD OUR GRANTS WORKING GROUP BOARD MEMBERS WHO
5 PROVIDED THE PATIENT PERSPECTIVE ON DEI ELEMENTS,
6 SIGNIFICANCE AND POTENTIAL IMPACT, AND, OF COURSE,
7 PROVIDED OVERSIGHT ON THE PROCESS, AND THEY PROVIDED
8 A SUGGESTED SCIENTIFIC SCORE.

9 WE DID NOT MAKE USE OF SCIENTIFIC
10 SPECIALISTS SINCE THIS WAS A VERY FOCUSED REVIEW
11 WITHIN THE SHARED LABS PROGRAM.

12 THE SCORING SYSTEM THAT WAS USED BY THE
13 GRANTS WORKING GROUP WAS A SCORE OF 1, 2, OR 3 WITH
14 1 MEANING THAT THOSE APPLICATIONS HAVE EXCEPTIONAL
15 MERIT AND WARRANT FUNDING. A SCORE OF 2 MEANS IT
16 NEEDS IMPROVEMENT AND WOULDN'T WARRANT FUNDING AT
17 THIS TIME. AND SO THOSE MAY BE RESUBMITTED IF THE
18 APPLICATION REVIEW SUBCOMMITTEE FEELS THAT THERE IS
19 APPROPRIATE ROOM TO FUND ADDITIONAL APPLICATIONS
20 BEYOND WHAT HAS ALREADY BEEN FUNDED. THOSE THAT
21 RECEIVE A SCORE OF 3 ARE THOUGHT TO BE SUFFICIENTLY
22 FLAWED THAT THIS DOES NOT WARRANT ANY FUNDING.

23 SO THE BASIS FOR THE SCORE IS BASED ON
24 THESE FIVE KEY CRITERIA. DOES THE PROJECT OFFER A
25 SIGNIFICANT VALUE PROPOSITION IN TERMS OF WHAT THEY

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1 INTEND TO DO IN TERMS OF HOW THEY OFFER ACCESS TO
2 THE COMMUNITY AND THE TYPES OF MODELS THAT THEY
3 ULTIMATELY ARE GOING TO PROVIDE TO THE COMMUNITY.
4 DO THEY HAVE A WELL PLANNED AND DESIGNED APPROACH TO
5 MAKING THESE OFFERINGS AVAILABLE? IS IT FEASIBLE?
6 AND IF THEY PROPOSE A STEM CELL-TECHNIQUES COURSE,
7 IS THAT WELL DESIGNED? AND DOES THE PROJECT OVERALL
8 UPHOLD THE PRINCIPLES OF DIVERSITY, EQUITY, AND
9 INCLUSION?

10 ALL RIGHT. SO THAT IS THE GRANTS WORKING
11 GROUP. NOW, THE FACILITIES WORKING GROUP WHICH
12 LOOKED AT THE SIX ESTABLISHING APPLICATIONS AS WELL
13 IS COMPOSED OF FOUR REAL ESTATE EXPERTS. AND SO
14 THOSE REAL ESTATE EXPERTS EVALUATE ALL OF THE
15 FACILITIES COMPONENTS THAT ARE PART OF THIS
16 APPLICATION AND PROVIDE A SCORE ON ALL THE
17 APPLICATIONS, BUT WE ALSO HAVE BOARD MEMBERS FROM
18 THE ICOC WHO ARE PART OF THE FACILITIES WORKING
19 GROUP. SO THERE ARE, IF I REMEMBER CORRECTLY, NINE
20 BOARD MEMBERS WHO PROVIDE THE PATIENT PERSPECTIVE ON
21 THE SIGNIFICANCE AND POTENTIAL IMPACT, OVERSIGHT ON
22 THE PROCESS, AND THEY ALSO PROVIDE A SCORE ON THE
23 APPLICATIONS.

24 THE SCORING SCHEME IS THE SAME FOR THE
25 FACILITIES WORKING GROUP, 1, 2, OR 3, WITH THE SAME

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1 BASIC NARRATIVE FOR EACH OF THE SCORE TYPES. THE
2 CRITERIA, HOWEVER, THAT ARE USED TO COME UP WITH
3 THESE SCORES ARE DIFFERENT. THEY'RE FOCUSED ON THE
4 FACILITIES COMPONENTS. SO THE FIRST ONE IS DOES THE
5 PROPOSED RENOVATION AND FACILITIES IMPROVEMENT
6 PROJECT SUPPORT THE APPLICANT'S PROPOSED CORE
7 RESEARCH AND EDUCATIONAL ACTIVITIES? ARE THE
8 RENOVATIONS AND FACILITY IMPROVEMENTS FEASIBLE AS
9 PROPOSED? DOES THE PROPOSED SRL FACILITY INCLUDE
10 THE APPROPRIATE RESEARCH EQUIPMENT AND LABORATORY
11 CONFIGURATION IN SUPPORT OF THOSE ACTIVITIES? ARE
12 THE RENOVATION FACILITY IMPROVEMENT COSTS
13 APPROPRIATE? AND FINALLY, DOES THE APPLICANT ENSURE
14 DIVERSITY, EQUITY, AND INCLUSION GOALS FOR THE
15 DESIGN AND CONSTRUCTION ELEMENTS OF THE APPLICATION?
16 SO THOSE ARE THE CRITERIA TO THE FACILITIES WORKING
17 GROUP ASSESSMENT OF THOSE APPLICATIONS.

18 SO GIVEN THAT THERE IS A LITTLE BIT OF
19 COMPLEXITY WITH THESE, I'M GOING TO TRY TO CAREFULLY
20 GO OVER WHAT THE RECOMMENDATIONS OF THE WORKING
21 GROUPS ARE AS WELL AS WHAT CIRM'S RECOMMENDATIONS
22 ARE BASED ON THOSE OUTCOMES FROM THE WORKING GROUP.

23 SO WHAT I'M SHOWING YOU HERE IS A TABLE OF
24 THE SIX APPLICATIONS THAT CAME IN FOR THE
25 ESTABLISHING 6.1 PROGRAM. SO IN THE FIRST BLUE

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1 COLUMNS, YOU SEE THE GRANTS WORKING GROUP SCORE.
2 AND THEN NEXT TO IT THE 1-2-3; THAT IS, HOW MANY
3 MEMBERS OF THE WORKING GROUP GAVE A SCORE OF 1, 2,
4 OR 3. SO YOU SEE THAT THE GRANTS WORKING GROUP GAVE
5 THREE APPLICATIONS OUT OF THE SIX A SCORE OF 1, AND
6 THE OTHER THREE RECEIVED A SCORE OF 2.

7 NOW, IN ORANGE YOU SEE THE FACILITIES
8 WORKING GROUP SCORES. THERE WERE FOUR APPLICATIONS
9 THAT RECEIVED A SCORE OF 1 FROM THE FACILITIES
10 WORKING GROUP BECAUSE THEY FELT THE FACILITIES
11 COMPONENTS WERE ADEQUATE TO RECEIVE SUCH A SCORE.
12 AND THEN TWO APPLICATIONS THAT RECEIVED A SCORE OF 2
13 BECAUSE THEY FELT THERE WERE SOME ELEMENTS THAT
14 NEEDED ADDITIONAL WORK.

15 SO AS IT HAPPENS, YOU CAN SEE IN THE TOP
16 ROW, THERE'S ONLY ONE APPLICATION THAT GOT A 1 FROM
17 BOTH THE GRANTS WORKING GROUP AND THE FACILITIES
18 WORKING GROUP. BUT THAT IS A CLEAR RECOMMENDATION
19 ACROSS THE BOARD, AND SO THE CIRM RECOMMENDATION IS
20 TO FUND THAT APPLICATION.

21 FOR THE REMAINING APPLICATIONS, YOU HAVE
22 THESE NEXT TWO WHICH GOT A 1 FROM THE GRANTS WORKING
23 GROUP, BUT 2S FROM THE FACILITIES WORKING GROUP. SO
24 OUR RECOMMENDATION FOR THOSE IS TO HAVE THE
25 APPLICANTS REVISE THEIR FACILITY COMPONENT PROPOSAL

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1 AND HAVE THE FACILITIES WORKING GROUP LOOK AT THOSE
2 REVISIONS AND DETERMINE WHETHER THEY HAVE ADDRESSED
3 THE CONCERNS OF THE FACILITIES WORKING GROUP.

4 AND THEN FOR THE LAST THREE, WHICH DID
5 FINE IN THE FACILITIES WORKING GROUP, BUT GOT A 2
6 FROM THE GRANTS WORKING GROUP FOR THEIR SCIENTIFIC
7 PLAN, OUR RECOMMENDATION IS THAT THEY REVISE THE
8 SCIENTIFIC PROPOSAL AND THE GRANTS WORKING GROUP
9 REEXAMINE THOSE APPLICATIONS ONCE THEY RESUBMIT.

10 THOSE ARE THE RECOMMENDATIONS RELATED TO
11 THE 6.1 ESTABLISHING PROGRAM.

12 FOR THE 6.2 EXPANDING AND ENHANCING, AS
13 MENTIONED EARLIER, THERE WERE 14 APPLICATIONS. NOW,
14 THESE DID NOT HAVE ANY RENOVATION ELEMENTS TO THEM.
15 SO EVEN THOUGH I INCLUDED THESE COLUMNS HERE, THERE
16 WAS NO FACILITIES WORKING GROUP ASSESSMENT FOR THESE
17 APPLICATIONS. THAT WAS SOLELY A GRANTS WORKING
18 GROUP ASSESSMENT OF THE SCIENTIFIC VALUE OF THESE
19 PROGRAMS. AS YOU CAN SEE, THERE ARE SOME
20 APPLICATIONS THAT GOT A SCORE OF 1, SOME THAT GOT A
21 SCORE OF 2, AND SOME THAT GOT A SCORE OF 3.

22 SO BASED ON THIS, OUR RECOMMENDATION IS TO
23 FUND THE FOUR THAT GOT A SCORE OF 1 BY THE GRANTS
24 WORKING GROUP. FOR THOSE THAT GOT A SCORE OF 2, WE
25 RECOMMEND THAT THESE SIX APPLICATIONS REVISE AND

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1 RESUBMIT THEIR PROPOSAL TO THE GRANTS WORKING GROUP
2 FOR REVIEW IN ORDER TO ADDRESS CONCERNS. AND THEN
3 FOR THE FOUR THAT RECEIVED A SCORE OF 3, TO
4 RECOMMEND THAT THE APPLICATION REVIEW SUBCOMMITTEE
5 NOT FUND THOSE FOUR APPLICATIONS.

6 NOW, IN TERMS OF BUDGET, IF YOU WERE TO
7 FUND THE ONE ESTABLISHING SHARED RESOURCE LAB, WHICH
8 I SHOWED YOU IN THE FIRST TABLE THAT HAD BOTH A
9 RECOMMENDATION FROM FACILITIES WORKING GROUP AND
10 GRANTS WORKING GROUP, THE BUDGET REQUIRED FOR THAT
11 IS 5.4 MILLION. FOR THE FOUR APPLICATIONS IN THE
12 6.2 GROUP THAT HAD A RECOMMENDATION FROM THE GRANTS
13 WORKING GROUP, THOSE FOUR WOULD USE UP ABOUT 16
14 MILLION. SO THE TOTAL IS 21.3 MILLION TO FUND THOSE
15 THAT HAVE A CLEAR RECOMMENDATION FROM THE RESPECTIVE
16 WORKING GROUP.

17 THAT LEAVES A BALANCE OF ABOUT TO 28.6,
18 28.7 MILLION THAT IS ABLE TO SUPPORT UP TO SIX
19 ADDITIONAL AWARDS. SO THAT MEANS IF I GO BACK HERE,
20 YOU HAVE SIX THAT RECEIVED A SCORE OF 2 FROM THE
21 ENHANCING AS WELL AS THREE GOT A SCORE OF 2 FROM THE
22 GRANTS WORKING GROUP IN THE ESTABLISHING, AND THEN
23 THE TWO THAT GOT 2S FROM THE FACILITIES WORKING
24 GROUP. SO YOU HAVE A TOTAL OF ELEVEN THAT WILL BE
25 REVISING AND RESUBMITTING APPLICATIONS TO ONE OR THE

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1 OTHER WORKING GROUP, AND WE WOULD ULTIMATELY BE ABLE
2 TO FUND SIX OF THOSE JUST TO BE CLEAR ON ULTIMATELY
3 WHAT WE CAN FUND.

4 SO THOSE ARE THE RECOMMENDATIONS OF THE
5 WORKING GROUP. AND YOU HAVE THE TABLES AS PART OF
6 THE MATERIALS THAT WERE PROVIDED TO YOU ALONG WITH
7 THE SUMMARIES. SO I WILL STOP HERE AND TAKE ANY
8 QUESTIONS.

9 CHAIRMAN IMBASCIANI: THANK YOU, DR.
10 SAMBRANO. I WAS GOING TO COMPLIMENT YOU ON AN
11 EXTRAORDINARY PRESENTATION TO MAKING THIS VERY CLEAR
12 UNTIL I REALIZED THAT YOU ARE IN THE HABIT OF MAKING
13 EXTRAORDINARY PRESENTATIONS SEEM ORDINARY. THANK
14 YOU FOR THAT.

15 LET'S PROCEED NOW TO QUESTIONS DIRECTLY
16 ADDRESSED TO GIL. AND THEN I'M GOING TO TAKE A
17 PREROGATIVE TO EXPLAIN THE COMPLICATED VOTING SYSTEM
18 THAT IS GOING TO SUPPORT THE REALIZATION OF THIS
19 AGENDA ITEM AND THE CONFLICTS OF INTEREST. THIS MAY
20 BE THE MOST COMPLICATED BOARD VOTING EXERCISE
21 CERTAINLY THAT I'VE EVER SEEN. I'LL GIVE YOU A
22 ROADMAP TO IT WHEN WE'RE DONE WITH QUESTIONS TO DR.
23 SAMBRANO. THANK YOU. BOARD MEMBERS?

24 MS. MANDAC: JOE PANETTA HAS HIS HAND
25 RAISED.

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1 CHAIRMAN IMBASCIANI: JOE PANETTA.

2 MR. PANETTA: THANKS, VITO. AND I AGREE,
3 GIL, THAT WAS JUST A TERRIFIC PRESENTATION. YOU
4 EXPLAINED IT SO WELL. I DON'T HAVE A QUESTION ABOUT
5 THE CURRENT APPLICATIONS. MY CONCERN IS YOU SAID
6 THAT THERE ARE 11 APPLICATIONS THAT CAN COME BACK IN
7 WITH REVISIONS AND POTENTIALLY RECEIVE SCORES OF 1,
8 BUT YOU CAN ONLY FUND SIX. I CAN'T REMEMBER IF
9 WE'VE BEEN IN A POSITION LIKE THIS BEFORE. WHAT
10 HAPPENS JUST HYPOTHETICALLY IF MORE THAN SIX OF
11 THOSE, TEN OF THOSE COME IN AND THEY'RE ALL 1S?

12 DR. SAMBRANO: RIGHT. SO WE WOULD BRING
13 THOSE RECOMMENDATIONS TO THE APPLICATION REVIEW
14 SUBCOMMITTEE FOR CONSIDERATION. NOW, TYPICALLY
15 THEY'RE NOT ALL UNANIMOUS IN TERMS OF THE SCORING.
16 SO WE WILL HAVE SOME LEVEL OF GRANULARITY THAT WE
17 CAN SEE THAT WOULD ALLOW US TO DISTINGUISH AMONG
18 THOSE AS WELL AS RECOMMENDATIONS FROM CIRM STAFF
19 THAT CAN PROVIDE SOME GUIDANCE AS TO WHAT MIGHT MAKE
20 THE BEST DECISION FOR WHAT TO FUND.

21 SOME OF THE ELEMENTS THAT THE BOARD MAY
22 ALSO WANT TO CONSIDER ARE THE NUMBER OF ESTABLISHING
23 VERSUS ENHANCING/EXPANDING PROGRAMS THAT YOU WANT TO
24 FUND AS WELL AS THE GEOGRAPHIC DISTRIBUTION OF THESE
25 LABORATORIES THAT YOU MAY ALSO WANT TO TAKE INTO

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1 ACCOUNT IN TERMS OF ULTIMATELY WHAT TO FUND.

2 SO I THINK THOSE ELEMENTS ARE SOMETHING
3 THAT WE WOULD BRING TO YOU, AND WE WOULD TRY TO
4 SYNTHESIZE THOSE AS BEST WE COULD BASED ON WHATEVER
5 RECOMMENDATIONS COME FROM THE RESPECTIVE WORKING
6 GROUPS FOR THESE APPLICATIONS.

7 MR. PANETTA: THANK YOU.

8 CHAIRMAN IMBASCIANI: ARE THERE ANY OTHER
9 HANDS? IF THERE ARE NO OTHER COMMENTS FROM THE
10 BOARD MEMBERS OR QUESTIONS, DOES ANY MEMBER OF THE
11 GENERAL PUBLIC --

12 MS. MANDAC: WE DON'T HAVE A MOTION.

13 CHAIRMAN IMBASCIANI: WE DON'T HAVE A
14 MOTION. THANK YOU FOR THAT. THE CHAIR WILL
15 ENTERTAIN A MOTION TO PROCEED WITH VOTING ON THE
16 APPLICATIONS.

17 DR. SOUTHARD: SO MOVED.

18 DR. FISHER: SECOND.

19 CHAIRMAN IMBASCIANI: THANK YOU. WHO MADE
20 THE MOTION?

21 DR. FISHER: MARV AND FRED.

22 CHAIRMAN IMBASCIANI: FRED SECONDED.
23 THANK YOU.

24 MS. MANDAC: WHAT WAS THE MOTION? CAN WE
25 CLARIFY THE MOTION?

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1 CHAIRMAN IMBASCIANI: YES. I'M GOING TO
2 DO THAT NOW. SO WE HAVE A MOTION -- BEFORE WE
3 PROCEED, LET ME EXPLAIN. AS GIL SAMBRANO JUST
4 EXPLAINED, THIS IS COMPLICATED IN SEVERAL WAYS.
5 ONE, WE HAVE THREE TIERS, BUT WE HAVE TWO WORKING
6 GROUPS MAKING RECOMMENDATIONS. IN SOME CASES THEY
7 ALIGN AND SOME CASES THEY DON'T. SO HERE'S WHAT I
8 PROPOSE. AND BY THE WAY, I NEED TO MENTION THAT WE
9 ARE IN THE APPLICATION REVIEW SUBCOMMITTEE PHASE OF
10 THIS BOARD MEETING, WHICH MEANS THE VOTES WILL COME
11 FROM SOME BOARD MEMBERS AND NOT OTHERS.

12 AND I'M GOING TO PUT THE FOLLOWING EIGHT
13 POINTS ON THIS ROADMAP IN A PARTICULAR ORDER, EIGHT
14 STEPS, BECAUSE OF WHO IS CONFLICTED ON THE BOARD.
15 AND I'VE GROUPED THEM SO THAT THE CONFLICTS ALIGN IN
16 STEPS ONE THROUGH FOUR, AND THEN THE CONFLICTS
17 CHANGE FOR NOS. 5 THROUGH 8. AND THIS IS THE
18 FOLLOWING WHAT I'M GOING TO PROPOSE YOU SUPPORT
19 THROUGH YOUR MOTIONS.

20 NO. 1, I'M GOING TO ASK IF THERE ARE ANY
21 APPLICATIONS IN TIER III THAT YOU WANT TO FUND BY
22 MOVING TO TIER I. THEN I WILL ASK IF THERE ARE ANY
23 APPLICATIONS IN TIER III THAT YOU WANT TO MOVE UP TO
24 TIER II, WHICH MEANS TO BE FUNDED, BUT ONLY AFTER
25 RECONSIDERATION AND GOING BACK TO THE REVIEW

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1 COMMITTEE. NO. 3, THEN TO LOOK AT APPLICATIONS IN
2 TIER I OR TIER II YOU WANT TO NOT FUND THEM BY
3 MOVING THEM TO TIER III. AND THEN FINALLY, WE'LL
4 CLOSE THIS SECTION BY ASKING THAT WE CLOSE OUT ALL
5 APPLICATIONS IN TIER III, WHICH IS TO SAY DO NOT
6 FUND.

7 THIS MAY SOUND REDUNDANT, BUT FOR REASONS
8 I JUST EXPLAINED, IT'S IMPERATIVE. THEN I'LL MOVE
9 ON TO THE SECOND PART WITH DIFFERENT CONFLICTS OF
10 INTEREST AT FORCE HERE. I'LL ASK IF THERE ARE ANY
11 ITEMS IN TIER II THAT YOU WOULD LIKE TO MOVE UP
12 IMMEDIATELY TO BE FUNDED IN TIER I. THEN I'LL ASK
13 IF YOU WANT TO MOVE ANY ITEMS IN TIER I DOWN TO TIER
14 II. THEN WE WILL CLOSE OUT TIER II, WHICH IS DO NOT
15 FUND, BUT WILL GO BACK TO REVIEW. I THINK I MIGHT
16 HAVE MISSPOKEN A LITTLE WHILE AGO. TIER II MEANS DO
17 NOT FUND, BUT WILL BE RE-REVIEWED. AND FINALLY,
18 WE'LL CLOSE OUT THIS ENTIRE DISCUSSION BY FUNDING
19 ALL REMAINING APPLICATIONS IN TIER I.

20 THERE'S NO TEST ON THIS, BUT I WILL GO
21 OVER EACH POINT WHAT WE'RE ABOUT TODAY. OKAY?

22 MR. AGUIRRE-SACASA: IF I MAY, WE HAVE
23 SOME CONFLICTS HERE. SO THE FOLLOWING MEMBERS ARE
24 PRECLUDED FROM VOTING, SPEAKING, OR MAKING ANY
25 MOTIONS ON ANY OF THE APPLICATIONS HERE. MEMBERS

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1 BONNEVILLE, CLARK-HARVEY, JUELGAARD,
2 FISCHER-COLBRIE, WATSON, AND DURON, BUT SHE'S NOT
3 HERE. AND THE FOLLOWING MEMBERS CAN VOTE, SPEAK,
4 AND MAKE A MOTION AFTER THE TIER IIIS HAVE BEEN
5 CLEARED, SO THE FOURTH MOTION.

6 CHAIRMAN IMBASCIANI: YOU WANT TO HOLD OFF
7 ON THAT SECOND PART?

8 MR. AGUIRRE-SACASA: SURE.

9 CHAIRMAN IMBASCIANI: WE'LL COME TO THAT.
10 REMIND ME AT STEP FOUR. SO THE CHAIR -- MOVING --

11 MR. AGUIRRE-SACASA: THEY STILL CAN'T
12 SPEAK UNTIL THEY ARE CLEARED. SO IT'S MIASKOWSKI,
13 BERNAL, AND FLOWERS. THANK YOU.

14 CHAIRMAN IMBASCIANI: OKAY. SO THE CHAIR
15 WOULD LIKE TO START THIS PROCESS BY ENTERTAINING
16 MOTIONS TO MOVE ITEMS IN TIER III, DO NOT FUND, TO
17 TIER I TO BE FUNDED.

18 MR. AGUIRRE-SACASA: IS THERE A MOTION?

19 CHAIRMAN IMBASCIANI: OKAY. THANK YOU.
20 NOW, BOARD MEMBERS, ARE THERE ANY APPLICATIONS IN
21 TIER III YOU WOULD LIKE TO MOVE UP TO TIER II, WHICH
22 IS DO NOT FUND, BUT WILL BE RE-REVIEWED.

23 SEEING NO HANDS, MOVING ON TO NO. 3, IS
24 THERE ANY APPLICATION IN THE FUND TIER I CATEGORY
25 THAT YOU WANT TO MOVE DOWN TO TIER II OR TIER III?

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1 I DON'T SEE THE GALLERY, SO YOU'LL HAVE TO HELP ME.
2 ARE THERE ANY HANDS?

3 VICE CHAIR BONNEVILLE: THERE'S NO BOARD
4 MEMBERS THAT HAVE HANDS RAISED.

5 CHAIRMAN IMBASCIANI: NO BOARD MEMBERS.
6 OKAY. CHAIR WOULD LIKE TO ENTERTAIN A MOTION TO
7 CLOSE OUT TO SAY DO NOT FUND TIER III. I WILL NEED
8 A MOTION ON THIS.

9 DR. FISHER: CAN YOU RESTATE THE MOTION?

10 MR. AGUIRRE-SACASA: THE MOTION IS TO
11 CLOSE OUT TIER III APPLICATIONS; I.E., DO NOT FUND
12 THE TIER IIIS.

13 DR. FISHER: SO MOVED.

14 DR. LEVITT: SECOND.

15 MS. MANDAC: IT MUST BE A MEMBER OF THE
16 ARS.

17 DR. LEVITT: OKAY. FORGET IT.

18 DR. SOUTHARD: I'LL SECOND.

19 CHAIRMAN IMBASCIANI: THANK YOU, MARV.
20 OKAY. WE HAVE A MOTION TO CLOSE OUT TIER III, DO
21 NOT FUND THAT SET OF APPLICATIONS. DISCUSSION FROM
22 BOARD MEMBERS? ARE THERE ANY MEMBERS OF THE GENERAL
23 PUBLIC THAT WANT TO MAKE A COMMENT? WE HAVE TWO
24 HANDS RAISED?

25 MS. MANDAC: TWO HANDS RAISED.

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1 CHAIRMAN IMBASCIANI: REMIND THE MEMBERS
2 OF THE PUBLIC WHO WISH TO SPEAK, THEY HAVE THREE
3 MINUTES, BUT IT MUST BE ON THE MOTION.

4 MS. MANDAC: SO THIS IS RELATED TO THE
5 MOTION TO NOT FUND THE TIER III APPLICATIONS. SO IF
6 YOU'RE COMMENTING ON NOT FUNDING TIER III
7 APPLICATIONS, PLEASE RAISE YOUR HAND. WE HAVE FIRST
8 EVAN SNYDER. YOU HAVE THREE MINUTES. WE WILL KEEP
9 THE TIME.

10 MR. SNYDER: TELL ME WHEN TO BEGIN PLEASE.
11 CAN YOU HEAR ME? WHEN SHOULD I BEGIN?

12 I SPEAK ON BEHALF OF THE SANFORD BURNHAM
13 PREBYS APPLICATION WHICH WAS DEDICATED TO STEM CELL
14 HIGH THROUGHPUT BIOLOGY AND DRUG DISCOVERY. AND NOT
15 ONLY TRAINING IN THAT CUTTING-EDGE TECHNOLOGY, BUT
16 ALSO TEACHING BASIC STEM CELL SKILLS. I AM NOT
17 GOING TO REBUT OUR CRITIQUES, THOUGH SOME WERE
18 SCIENTIFICALLY OFF BASE, OR PLEA FOR IMMEDIATE
19 FUNDING. WE DID NOT SCORE WELL, WE BELIEVE, NOT
20 BECAUSE WE DID NOT HAVE DEPTH OF TALENT, PERSONNEL,
21 RESOURCES, EXPERIENCE, AND A 20-YEAR TRACK RECORD OF
22 PRODUCTIVITY AND IMPACT TO ACCOMPLISH THE
23 CUTTING-EDGE PROGRAM WE PROPOSED, RATHER, BECAUSE WE
24 DID A POOR JOB OF DEMONSTRATING THAT WE HAVE
25 ACCOMPLISHED AND CONTINUE TO ACCOMPLISH EVERYTHING

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1 WE PROPOSED.

2 WE RELIED TOO MUCH ON OUR REPUTATION IN
3 THE HIGH THROUGHPUT FIELD. WE PROPOSE TO BE THE
4 FIRST CIRM SRL DOING HIGH THROUGHPUT BIOLOGY AND
5 DRUG DISCOVERY AND BRINGING IT TO CALIFORNIA
6 INVESTIGATORS AND CLINICIANS THROUGH THE USE OF
7 PATIENT-DERIVED IPSC'S WHILE CONTINUING OUR
8 LONGSTANDING MISSION TO ENGAGE AND MENTOR LESS
9 EXPERIENCED STEM CELL INVESTIGATORS, HELPING THEM
10 ENTER THE DRUG DISCOVERY PIPELINE WHICH WILL LIKELY
11 DEFINE THE GOALS OF DISEASE MODELING FOR THE NEXT
12 GENERATION.

13 HOWEVER, ALTHOUGH WE WERE CRITICIZED FOR
14 BEING OVERLY AMBITIOUS, ONLY A CRO CAN DO WHAT WE'RE
15 DOING, THIS PROGRAM IS PRECISELY WHAT WE ARE ALREADY
16 DOING NOW. WE PLEASE SIMPLY REQUEST JUST THE
17 OPPORTUNITY TO RESUBMIT AND BE RE-JUDGED ON A
18 REVISED APPLICATION THAT CONSTRAINS THE SCOPE A BIT,
19 BUT, MOST IMPORTANTLY, HIGHLIGHTS WHAT WE ACTUALLY
20 ACCOMPLISH EVERY DAY, MUCH AS WE DID IN THE LETTER
21 TO YOU.

22 WE KNOW THAT CIRM TAKES DISEASE MODELING
23 SERIOUSLY. THEREFORE, IT MUST HAVE A DRUG DISCOVERY
24 CORE TO EXPLOIT THOSE DATA. HIGH THROUGHPUT
25 TECHNOLOGY IS THE FIRST STEP IN DEVELOPING A NEW

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1 DRUG. AND SBP, THROUGH ITS INFRASTRUCTURE OF ITS
2 WORLD RENOWN PREBYS CENTER, ARE THE ONES TO DO IT.
3 AND WE WERE THE ONLY ONES TO COME FORWARD TO CIRM TO
4 OFFER IT. WE SIMPLY PLEASE WANT YOUR PERMISSION TO
5 SUBMIT A REVISED APPLICATION SHOWING WE CAN BRING
6 THIS CUTTING-EDGE TECHNOLOGY TO THE CALIFORNIA STEM
7 CELL COMMUNITY. NOT ONLY THE EXPERTS, BUT ALSO
8 CLINICIANS WITH CLINICAL MATERIAL AND LESS
9 EXPERIENCED STEM CELL BIOLOGISTS.

10 SO OUR REQUEST PLEASE IS SIMPLY TO MOVE US
11 TO TIER II SO THAT WE CAN SUBMIT A REVISED
12 APPLICATION.

13 MS. MANDAC: THERE ARE NO OTHER HANDS
14 RAISED.

15 CHAIRMAN IMBASCIANI: NO OTHER COMMENTS
16 FROM BOARD MEMBERS OR FROM THE PUBLIC? THEREFORE,
17 WE'RE GOING TO PROCEED TO A VOTE.

18 MR. AGUIRRE-SACASA: THE MOTION IS TO NOT
19 FUND TIER IIIS.

20 JUDY CHOU.

21 DR. CHOU: YES.

22 MR. AGUIRRE-SACASA: FRED FISHER.

23 DR. FISHER: YES.

24 MR. AGUIRRE-SACASA: DAVID HIGGINS.

25 DR. HIGGINS: YES.

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1 MR. AGUIRRE-SACASA: VITO IMBASCIANI.

2 CHAIRMAN IMBASCIANI: YES.

3 MR. AGUIRRE-SACASA: RICH LAJARA.

4 MR. LAJARA: YES.

5 MR. AGUIRRE-SACASA: ADRIANA PADILLA.

6 DR. PADILLA: YES.

7 DR. FISHER: THERE'S A PROBLEM WITH THE
8 SOUND.

9 MR. AGUIRRE-SACASA: THANK YOU. ADRIANA
10 PADILLA, I GOT YOU AS A YES.

11 MARV SOUTHARD. COME BACK TO YOU. KEVIN
12 XU.

13 DR. XU: YES.

14 MR. AGUIRRE-SACASA: MARV. MOTION
15 CARRIES.

16 CHAIRMAN IMBASCIANI: THE MOTION CARRIES.
17 THANK YOU.

18 SO WE'RE NOW UP TO STEP FIVE. RAFAEL, DO
19 YOU WANT TO CLARIFY AGAIN AT THIS POINT?

20 MR. AGUIRRE-SACASA: AT THIS POINT, NOW
21 THAT THE TIER IIIS HAVE BEEN CLEARED OUT, THE
22 FOLLOWING BOARD MEMBERS CAN VOTE, SPEAK, AND MAKE
23 MOTIONS: MIASKOWSKI, BERNAL, AND FLOWERS. THANK
24 YOU.

25 CHAIRMAN IMBASCIANI: OKAY. THANK YOU.

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1 SO WE'RE AT THE POINT NOW WHERE I'M GOING TO ASK IF
2 THERE'S ANY APPLICATION IN TIER II, WHICH IS DO NOT
3 FUND, BUT RESUBMIT TO ELEVATE THEM TO TIER I TO BE
4 FUNDED. WE SEE NO HANDS. OKAY.

5 NOW, IS THERE ANY APPLICATION IN TIER I
6 THAT YOU WOULD LIKE TO MOVE TO TIER II? GOOD.
7 OKAY. THEN I WILL ENTERTAIN A MOTION, WHICH WE
8 REQUIRE NOW, TO CLOSE OUT TIER II, ONCE AGAIN, TIER
9 II, DO NOT FUND, BUT GO BACK FOR RE-REVIEW.

10 MS. MIASKOWSKI: SO MOVED.

11 DR. FISHER: SECOND.

12 CHAIRMAN IMBASCIANI: SECOND BY FRED
13 FISHER. THANK YOU. DISCUSSION BY MEMBERS OF THE
14 COMMITTEE? OKAY. ARE THERE ANY MEMBERS OF THE
15 GENERAL PUBLIC WHO WISH TO COMMENT ON THE MOTION,
16 WHICH IS TO CLOSE OUT TIER II, DO NOT FUND
17 IMMEDIATELY. THEY WILL BE SENT BACK TO THE REVIEW
18 GROUP FOR RE-REVIEW. WE HAVE A HAND.

19 PLEASE INTRODUCE -- DO YOU HAVE A
20 MICROPHONE?

21 DR. SHARMA: I CAN COME UP THERE.

22 CHAIRMAN IMBASCIANI: COME SIT AT THE
23 TABLE.

24 MR. SHARMA: MY NAME IS ARUN SHARMA. AND
25 I'M THE PROGRAM DIRECTOR FOR APPLICATION

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1 INFRASTRUCTURE 6.2-15475, A SHARED RESOURCE
2 LABORATORY FOR ADVANCED STEM CELL-BASED MODELING.
3 I'M AN ASSISTANT PROFESSOR AT CEDARS-SINAI MEDICAL
4 CENTER, AND I ACTUALLY WAS A CIRM-FUNDED TRAINEE AT
5 STANFORD STEM CELL TEACHING PROGRAM. I'D FIRST LIKE
6 TO THANK CIRM FOR THEIR SUPPORT OF STEM CELL
7 TRAINING IN CALIFORNIA. I WOULD NOT BE A STEM CELL
8 BIOLOGIST WITHOUT CIRM.

9 OUR PROPOSAL FOR A SHARED RESOURCE CORE
10 FACILITY OR CS-SRL AIMS TO PROVIDE TRAINING IN HUMAN
11 ORGAN CHIP AND ORGANOID TECHNOLOGIES. OUR PROPOSAL
12 RECEIVED A TIER I RECOMMENDATION BY THE GRANTS
13 WORKING GROUP WITH ONE VOTE FOR TIER I AND 13 VOTES
14 FOR TIER II.

15 I REQUEST THE OPPORTUNITY TO ADDRESS THE
16 CONCERNS RAISED REGARDING OUR APPLICATION. ONE
17 CONCERN WAS THE AVAILABILITY OF TRAINING AND SYSTEMS
18 THAT ARE NOT WIDELY ACCESSIBLE; HOWEVER, OUR
19 TRAINING METHODS ARE APPLICABLE TO ANY ORGAN CHIP
20 AND ORGANOID CULTURE WITH OR WITHOUT USING SYSTEMS
21 FROM THE ORGAN CHIP COMPANY EMULATE, INC. WITH WHOM
22 WE COLLABORATE.

23 ANOTHER CONCERN WAS THE ADEQUACY OF OUR
24 ORGAN CHIP EQUIPMENT FOR THE PROPOSED TRAINING
25 VOLUME. WE PLAN TO HAVE MULTIPLE EMULATE AUTOMATED

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1 SYSTEMS AT OUR CS-SRL, EACH CAPABLE OF HOLDING 12
2 ADDITIONAL ORGAN CHIPS, ACCOMMODATING UP TO 48 LABS
3 PER YEAR.

4 WE ALSO HAVE CONTINGENCY PLANS WITH
5 ADDITIONAL EMULATE SYSTEMS ON THE CEDARS-SINAI
6 CAMPUS TO ENSURE SUPPORT.

7 REVIEWERS ALSO RAISED CONCERNS ABOUT
8 DAY-TO-DAY OPERATIONS. AT CEDARS-SINAI WE HAVE
9 SIGNIFICANT EXPERIENCE RUNNING CORE FACILITIES. WE
10 HAVE WELL-TRAINED STAFF AND AMPLE *** TO MEET USER
11 NEEDS. WE CAN UTILIZE THE RESOURCES OF OUR ADJACENT
12 BIOMANUFACTURING CENTER IF DEMAND EXCEEDS CAPACITY.

13 REVIEWERS ALSO REQUESTED A CLEAR
14 EXPLANATION OF OUR DIVERSITY, EQUITY, AND INCLUSION
15 OR DEI PLANS. OUR BIOMANUFACTURING CENTER HAS OVER
16 A THOUSAND DIVERSE IPS LINES AVAILABLE, AND WE ARE
17 COMMITTED TO PROMOTING DEI BY PROVIDING EDUCATIONAL
18 OPPORTUNITIES TO UNDERSERVED COMMUNITIES AS WE HAVE
19 SHOWN VIA OUR CURRENT CIRM-FUNDED PROGRAMS CIRM
20 SPARK AND CIRM BRIDGES.

21 FINALLY, CONCERNS WERE RAISED ABOUT MY
22 EXPERIENCE MANAGING LARGE PROJECTS. WHILE I AM A
23 YOUNG INVESTIGATOR, I HAVE EXPERIENCE IN STEM CELL
24 CULTURE, ORGAN-CHIP WORKFLOWS, AND MANAGING COMPLEX
25 PROJECTS SUCH AS A MULTIPLE MILLION DOLLAR NASA

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1 AWARD AND AN AWARD FROM AMERICAN HEART ASSOCIATION.

2 TO FURTHER STRENGTHEN OUR PROPOSAL, DR.
3 JOSH BREUNIG WHO RUNS OUR IMAGING CORE AND DR. CLIVE
4 SVENDSEN, OUR INSTITUTE DIRECTOR, WILL PROVIDE
5 ADVISORY SUPPORT FOR THE CS-SRL.

6 IN CONCLUSION, CEDARS-SINAI POSSESSES
7 EXPERTISE IN ORGAN-CHIP AND ORGANOID CULTURE AND
8 APPLICATIONS, EDUCATION OF DIVERSE AND UNDERSERVED
9 POPULATIONS, AS WELL AS DERIVATION OF DIVERSE HUMAN
10 IPS LINES. WE HAVE A PROVEN TRACK RECORD OF
11 SUCCESSFULLY EXECUTING CIRM EDUCATION AND
12 INFRASTRUCTURE PROJECTS. I STRONGLY URGE THE
13 APPLICATION REVIEW SUBCOMMITTEE TO CONSIDER
14 APPROVING OUR INFRASTRUCTURE 6.2-5475 PROPOSAL FOR
15 FUNDING. THANK YOU.

16 MS. MANDAC: WE DO HAVE HANDS RAISED. OUR
17 NEXT ONE, DR. WILLERT. YOU HAVE THREE MINUTES.

18 DR. WILLERT: GOOD MORNING. CAN EVERYONE
19 HEAR ME?

20 CHAIRMAN IMBASCIANI: YES.

21 DR. WILLERT: MY NAME IS KARL WILLERT,
22 PROFESSOR AT UC SAN DIEGO, AND I'M THE PI ON OUR
23 INFRASTRUCTURE 6.2 GRANT APPLICATION, WHICH WAS
24 SCORED IN TIER II AND IS CURRENTLY NOT RECOMMENDED
25 FOR FUNDING. I'M HERE TODAY TO VOICE SUPPORT FOR

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1 STAFF RECOMMENDATION THAT APPLICATIONS IN TIER II,
2 INCLUDING OURS, BE GIVEN THE OPPORTUNITY TO REVISE
3 AND RESUBMIT.

4 WE CAREFULLY REVIEWED THE VALUABLE
5 COMMENTS MADE BY THE GRANTS WORKING GROUP, AND WE
6 FEEL STRONGLY THAT WE CAN READILY ADDRESS ALL
7 CONCERNS RAISED IN REVIEW AND RESUBMIT AN
8 APPLICATION THAT WILL MERIT FUNDING.

9 SOME BRIEF BACKGROUND. OUR SHARED
10 RESEARCH LAB, THE HUMAN EMBRYONIC STEM CELL CORE
11 FACILITY AT UC SAN DIEGO, HAS BEEN CONTINUOUSLY
12 OPERATIONAL FOR OVER -- FOR NEARLY TWO DECADES. WE
13 STARTED THIS CORE IN 2005, FIRST WITH INSTITUTIONAL
14 SUPPORT AND SUBSEQUENTLY WE RECEIVED CRITICAL
15 FUNDING FROM CIRM FROM 2007 TO 2014. THROUGHOUT
16 THIS TIME, OUR CORE HAS BEEN FULLY OPERATIONAL,
17 PROVIDING STATE-OF-THE-ART TECHNOLOGIES AND
18 RESOURCES ESSENTIAL TO STEM CELL RESEARCHERS AT UC
19 SAN DIEGO AS WELL AS NEIGHBORING INSTITUTES AND
20 BIOTECH INDUSTRIES. IMPORTANTLY, WE'VE ACHIEVED
21 FINANCIAL SUSTAINABILITY THROUGH FEE-FOR-SERVICE AND
22 RECHARGE MECHANISMS AS WELL AS ALTERNATIVE FUNDING
23 SOURCES.

24 WITH THE SUPPORT FROM THIS INFRASTRUCTURE
25 GRANT, WE WILL PROVIDE ACCESS LOCALLY AND REGIONALLY

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1 TO CELL CULTURE FACILITIES AND HIGHLY SPECIALIZED
2 TECHNOLOGIES. WE WILL ALSO PROVIDE
3 WELL-CHARACTERIZED STEM CELL LINES, UNDIFFERENTIATED
4 AND DIFFERENTIATED, INTO SPECIFIC LINEAGES WITH A
5 FOCUS ON NEURONS AND CARDIOMYOCYTES AS WELL AS 3D
6 ORGANOID SYSTEMS. WE STAND READY TO TAILOR OUR AIMS
7 AND GOALS TO OFFER CUTTING EDGE STEM CELL-BASED
8 MODELING EXPERTISE FOR RESEARCHERS IN CALIFORNIA.

9 TO BE CLEAR, WE RESPECTFULLY ASK THAT YOU
10 ADOPT THE STAFF RECOMMENDATION. PLEASE GIVE US THE
11 OPPORTUNITY TO RESUBMIT. THANK YOU FOR YOUR TIME
12 AND VALUABLE SERVICE TO THE STEM CELL COMMUNITY.
13 THANK YOU.

14 MS. MANDAC: THANK YOU SO MUCH, DR.
15 WILLERT. NEXT UP DR. BOURNIAS-VARDIABASIS.
16 I'M SO SORRY, NICOLE, FOR BUTCHERING YOUR NAME.

17 DR. BOURNIAS-VARDIABASIS: WELL, YOU'RE
18 QUITE OKAY. YOU DID JUST FINE. HELLO, EVERYBODY.
19 MY NAME IS DR. BOURNIAS-VARDIABASIS, AND I AM A
20 PROFESSOR OF BIOLOGY AT CAL STATE UNIVERSITY SAN
21 BERNARDINO. I SERVE AS THE DIRECTOR OF THE CIRM
22 BRIDGES PROGRAM, AND I'M ALSO DIRECTOR OF THE CIRM
23 COMPASS PROGRAM.

24 I AM HERE TO GIVE MY ENTHUSIASTIC SUPPORT
25 ON BEHALF OF UCR'S APPLICATION. THE GRANT NUMBER IS

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1 6.1-15366 AND ASK THAT IT BE MOVED TO IMMEDIATE
2 FUNDING. CAL STATE SAN BERNARDINO AND UCR HAVE A
3 LONG-STANDING RELATIONSHIP OF MUTUAL SUPPORT AS A
4 RESULT OF OUR BRIDGES GRANT AND ALSO OUR CIRM
5 COMPASS GRANT. OUR STUDENTS HAVE BENEFITED GREATLY
6 BOTH BY THE TRAINING PROVIDED BY THE STEM CELL CORE
7 AT UCR WHICH HAS SERVED FOR A LONG TIME WITHOUT ANY
8 UPDATE, AND SO THIS GRANT OBVIOUSLY WOULD SERVE THAT
9 ROLE.

10 AND WE HAVE HAD MANY OF OUR STUDENTS
11 PLACED IN STEM CELL LABS AT UCR, AND ALL OF THOSE
12 STUDENTS HAVE BEEN TRAINED IN THE TECHNIQUES COURSE
13 PROVIDED BY UCR.

14 THIS INFRASTRUCTURE GRANT WOULD PROVIDE A
15 CRITICAL NEED IN THE UNDERSERVED AREA OF THE INLAND
16 EMPIRE. THE GWG SCORE IS OBVIOUSLY OUTSTANDING, THE
17 HIGHEST RATING. AND SO OBVIOUSLY THE FWG SCORE IS
18 IN CATEGORY TWO. OUR INSTITUTION AND OTHER SIMILAR
19 INSTITUTIONS WOULD BENEFIT SUBSTANTIALLY BY THE
20 FUNDING OF THE GRANT, WHICH HAS BEEN INTENDED TO
21 SERVE UNDERSERVED PATIENTS AND COMMUNITIES AND
22 DISADVANTAGED STUDENTS. WE KNOW WHAT SUBSTANTIAL
23 BENEFITS OUR GRANTS HAVE PROVIDED TO OUR STUDENTS,
24 AND FUNDING THIS INFRASTRUCTURE GRANT WILL ESTABLISH
25 THE ONLY STEM CELL CORE IN THE INLAND EMPIRE REGION,

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1 A REGION WHICH IS BIGGER THAN SOME OF THE STATES
2 GEOGRAPHICALLY. IT IS BOUND TO RESULT IN
3 SUBSTANTIAL BENEFIT TO OUR REGION'S RESEARCHERS, OUR
4 EDUCATORS, TRAINEES, AND STUDENTS, AND FURTHER
5 SUPPORTS TRAINING AND RETENTION OF OUR STEM CELL
6 COMMUNITY.

7 THANK YOU FOR YOUR TIME. WE WOULD VERY
8 MUCH BE ABLE TO USE THE FACILITIES OF UCR WHEN THAT
9 TAKES PLACE.

10 CHAIRMAN IMBASCIANI: THANK YOU, PROFESSOR
11 VARDIABASIS.

12 MS. MANDAC: NEXT WE HAVE DR. BAGDASARIAN.
13 YOU HAVE THREE MINUTES.

14 DR. BAGDASARIAN: THANK YOU. MY NAME IS
15 ISABELLA BAGDASARIAN. I'D LIKE TO THANK THE MEMBERS
16 OF THE COMMITTEE FOR ALLOWING ME TO SPEAK TODAY. I
17 AM HERE TO URGE YOU TO CONSIDER FUNDING THE
18 ESTABLISHMENT OF THE SHARED RESEARCH AND TRAINING
19 FACILITY AT UNIVERSITY OF CALIFORNIA RIVERSIDE.

20 I'M A BIOENGINEERING PH.D. CANDIDATE AT UC
21 RIVERSIDE, AND I'M FORTUNATE ENOUGH TO BE FUNDED
22 THROUGH THE CIRM SCHOLARS PROGRAM FOR GRADUATE
23 STUDENTS. WITH THIS FUNDING, I HAVE BEEN WORKING
24 TOWARDS ENGINEERING A THREE-DIMENSIONAL VASCULARIZED
25 SKELETAL MUSCLE MODEL FROM HUMAN PLURIPOTENT STEM

1 CELLS.

2 MY RESEARCH IN THE ORGANOID FIELD HAS
3 PROVIDED ME WITH AN APPRECIATION FOR HOW INVOLVED
4 DEVELOPING 3D STEM CELL-BASED MODELS CAN BE.
5 TECHNIQUES IN 2D CULTURE SUCH AS IMMUNOFLUORESCENCE
6 AND IMAGE ANALYSIS PRESENT NEW AND UNIQUE CHALLENGES
7 IN COMPLEX ENGINEERED TISSUES.

8 THE ESTABLISHMENT OF THE BIOFORM CORE AT
9 UC RIVERSIDE WILL HELP TO ALLEVIATE THESE CHALLENGES
10 WHILE TRAINING THE NEXT GENERATION OF SCIENTISTS AND
11 ENGINEERS. THE BIOFORM CORE WOULD BRING CRUCIAL
12 INSTRUMENTATION LIKE BIOPRINTING TO THE UC RIVERSIDE
13 CAMPUS AND INLAND EMPIRE AS A WHOLE. CURRENTLY THE
14 NEAREST BIOPRINTER IS 60 MILES AWAY THROUGH SOUTHERN
15 CALIFORNIA TRAFFIC. THIS IS A MAJOR BARRIER TO UC
16 RIVERSIDE AND THE FIVE OTHER INLAND EMPIRE
17 UNIVERSITIES WHO RELY ON THE STEM CELL CORE HERE.

18 THE INLAND EMPIRE IS GEOGRAPHICALLY
19 ISOLATED AND HISTORICALLY UNDERSERVED BOTH
20 ECONOMICALLY AND MEDICALLY. RAPID ESTABLISHMENT OF
21 THE BIOFORM CORE IS CRITICAL IF WE WISH TO EMPOWER
22 DISADVANTAGED STUDENTS AND RESEARCHERS IN THE INLAND
23 EMPIRE.

24 IN THE CONTEXT OF MY RESEARCH, GAINING
25 ACCESS TO A TOOL LIKE A BIOPRINTER WOULD GREATLY

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1 ACCELERATE THE COMPLETION OF MY DISSERTATION WORK.
2 AND IN TURN I WOULD BE ABLE TO FOCUS ON DEVELOPING
3 METHODS TO SCALE UP THE ENGINEERING OF THESE COMPLEX
4 MUSCLE TISSUES FOR FUTURE REGENERATIVE MEDICINE
5 THERAPIES.

6 AS A LIFELONG RESIDENT OF THE INLAND
7 EMPIRE, I HAVE WITNESSED THE UNIVERSITY HERE EXPAND
8 AND INNOVATE IN A NUMBER OF AREAS. MOST
9 IMPORTANTLY, THOUGH, THE STEM CELL CORE HAS REMAINED
10 AN ESSENTIAL RESOURCE IN RECRUITING AND TRAINING
11 SCIENTISTS FROM HISTORICALLY UNDERSERVED
12 COMMUNITIES. THE BIOFORM CORE WILL EXPAND ON THIS
13 PROGRESS BY PROVIDING A DIVERSE GROUP OF RESEARCHERS
14 FROM THE ECONOMICALLY DEPRESSED INLAND EMPIRE
15 REGION, THE PLATFORMS NECESSARY FOR ADVANCED 3D
16 ORGAN ENGINEERING.

17 I HAVE BEEN FORTUNATE ENOUGH TO WORK WITH
18 LOCAL STUDENTS FROM THE INLAND EMPIRE, RANGING FROM
19 THE CIRM SPARKS PROGRAM, THROUGH CIRM BRIDGES, AND
20 HAVE OBSERVED FIRSTHAND THAT THEY OFTEN DO NOT HAVE
21 ROBUST AND CONSISTENT ACCESS TO THE TRAINING OR
22 INSTRUMENTATION NEEDED FOR 3D CULTURE MODELS BACK AT
23 THEIR HOME CAMPUSES. EXPEDITING THE FORMATION OF
24 THE BIOFORM CORE IS VITAL TO EMPOWERING THIS DIVERSE
25 GROUP OF RESEARCHERS MOVING FORWARD.

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1 THE BIOFORM CORE TRAINING PROGRAM
2 ADDRESSES A CRITICALLY UNMET NEED FOR THE INLAND
3 EMPIRE, ULTIMATELY REDUCING BARRIERS TO ENTRY FOR
4 SCIENTISTS AT EVERY EDUCATION LEVEL WHO WISH TO
5 DEVELOP 3D MODELS OF ORGANOID TISSUES AND ORGANS.

6 I IMPLORER YOU TO CONSIDER FUNDING THE
7 BIOFORM CORE AND HELP TO ESTABLISH THE INLAND EMPIRE
8 AS ONE OF SCIENTIFIC AND MEDICAL INNOVATION. ONCE
9 AGAIN, THANK YOU FOR ALLOWING ME TO SPEAK.

10 MS. MANDAC: YOUR TIME IS UP. NEXT DR.
11 MANILAY.

12 DR. MANILAY: THANK YOU. CAN YOU HEAR ME?
13 OKAY. GOOD MORNING. I'M DR. JENNIFER MANILAY, AND
14 I'M A PROFESSOR AT THE UNIVERSITY OF CALIFORNIA
15 MERCED. TODAY I REPRESENT OUR PRINCIPAL
16 INVESTIGATOR DR. KARA MCCLOSKEY, CO-PI'S DR. LI, AND
17 TECHNICAL DIRECTOR DR. DAVID GRAVANO ON APPLICATION
18 6.1-15413.

19 WE WERE EXCITED TO RECEIVE UNANIMOUS
20 SCORES OF 1S AND A RECOMMENDATION FOR FUNDING BY THE
21 FACILITIES WORKING GROUP. WE APPRECIATE THE
22 OPPORTUNITY TO ADDRESS SOME OF THE GRANT WORKING
23 GROUP'S COMMENTS IN AN EFFORT TO SECURE THIS
24 FUNDING.

25 THE GRANTS WORKING GROUP FELT OUR

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1 PROPOSAL'S OVERALL VALUE PROPOSITION MAY NOT ADDRESS
2 CRITICAL NEEDS OF CALIFORNIA RESEARCHERS IN
3 GEOGRAPHIC AREAS WHERE ACCESS TO STEM CELL MODELS
4 ARE LIMITED. IN RESPONSE, WE RESPECTFULLY NOTE THAT
5 THE CENTRAL VALLEY OF CALIFORNIA WHERE UC MERCED IS
6 LOCATED IS INDEED A GEOGRAPHIC AREA WHERE STEM CELL
7 MODELS ARE LIMITED. A SHARED RESOURCE LABORATORY IN
8 MERCED WOULD BE HIGHLY IMPACTFUL IN THE REGION AND
9 SUPPORT CURRENT AND FUTURE STEM CELL RESEARCHERS FOR
10 YEARS TO COME.

11 AT UC MERCED WE HAVE BEEN COMMITTED TO
12 DEVELOPING EXPERIMENTAL MODELS AND SHARED RESOURCE
13 LABS TO SUPPORT STEM CELL RESEARCH AND TRAINING
14 PROGRAMS SINCE 2005. OUR PROPOSAL IS AN EXTENSION
15 OF THIS COMMITMENT. WE ENVISION THAT THIS FACILITY
16 WILL BE UTILIZED BY RESEARCHERS WITHIN THE CENTRAL
17 VALLEY RANGING FROM SACRAMENTO TO BAKERSFIELD AND
18 OTHER REGIONS WHERE LOCAL FACILITIES MAY BE
19 IMPACTED.

20 THE GRANTS WORKING GROUP ALSO NOTED THE
21 PROPOSAL COULD BE IMPROVED BY LIMITING CELL TYPES TO
22 THOSE WITH THE GREATEST BENEFIT TO LOCAL RESEARCHERS
23 WHO LACK ACCESS TO STEM CELL MODELS. OUR SCIENTIFIC
24 PROPOSAL FOCUSED ON HUMAN CARDIOVASCULAR MODELS AS
25 THAT IS OUR CAMPUS' AREA OF STRENGTH. HOWEVER, WE

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1 ALSO PROPOSE TO GENERATE NOVEL HUMAN IPS LINES FROM
2 A WIDE RANGE OF ANCESTRIES BY INVITING PEOPLE OF ALL
3 RACES, ETHNICITIES, AND GENDERS REPRESENTED IN THE
4 MERCED COMMUNITY.

5 THESE DIVERSE IPSC'S WILL FILL A SEVERE
6 GAP AND UNMET NEED IN STEM CELL RESEARCH MODELS THAT
7 ARE REFLECTIVE OF THE DEMOGRAPHICS OF THE CALIFORNIA
8 POPULATION. BUILDING FROM THIS, WE CAN IMPROVE OUR
9 PROPOSED COMPREHENSIVE STEM CELL COURSE TO INCLUDE
10 CHARACTERIZATION OF THE NOVEL, DIVERSE IPS LINES.
11 THIS WOULD BE A UNIQUE ASPECT OF OUR COURSE, SERVING
12 NOT ONLY TO EDUCATE, BUT ALSO TO ADD IMPORTANT
13 SCIENTIFIC DATA ON THESE CELL LINES TO THE PUBLIC.

14 WE ALREADY HAVE EXPERIENCE OFFERING STEM
15 CELL CULTURE COURSES TO UC MERCED RESEARCHERS AND
16 TRAINEES AND HAVE DESIGNED THEM TO NOT INTERFERE
17 WITH THE SHARED RESOURCE LAB SERVICES. RATHER, WE
18 HAVE FOUND THE TRAINING COURSES UTILIZING IS SRL'S
19 PROMOTE EFFECTIVE --

20 MS. MANDAC: WE ARE AT TIME. SO SORRY.

21 CHAIRMAN IMBASCIANI: THANK YOU, PROFESSOR
22 MANILAY.

23 MS. MANDAC: THANK YOU SO MUCH. NEXT WE
24 HAVE DR. AL ALAM.

25 DR. AL ALAM: YES. HELLO. GOOD MORNING.

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1 MR. CHAIR, MADAM VICE CHAIR, BOARD MEMBERS, CIRM
2 STAFF, COLLEAGUES, AND MEMBERS OF THE PUBLIC. MY
3 NAME IS DENISE AL ALAM, AND I'M AN INVESTIGATOR AT
4 THE LUNDQUIST INSTITUTE AT HARBOR UCLA MEDICAL
5 CENTER IN TORRANCE. AND I'M THE PI ON THE
6 INFRASTRUCTURE 6.1-15363, STEM CELL-BASED
7 PARTNERSHIP RESOURCE FOR INVESTIGATING HUMAN
8 DISEASES AND TRAINING.

9 I WOULD FIRST LIKE TO EXTEND OUR GRATITUDE
10 TO THE BOARD MEMBERS AND THE CIRM STAFF FOR ALL THE
11 WORK THEY DO FOR US, FOR THE PEOPLE OF CALIFORNIA,
12 AND FOR GIVING US THE OPPORTUNITY TODAY TO MAKE THIS
13 STATEMENT AND DEFEND OUR APPLICATION.

14 SO I WOULD LIKE TO EMPHASIZE OUR
15 ENTHUSIASM FOR THIS PROJECT, THAT IT'S TRULY A TRUE
16 PARTNERSHIP BETWEEN THE LUNDQUIST INSTITUTE AND
17 LOCAL COLLEGES AROUND US, INCLUDING CHARLES DREW
18 COLLEGE, CAL STATE DOMINGUEZ HILLS, AND CAL STATE
19 L.A. THIS PARTNERSHIP WILL PROVIDE ACCESS TO STEM
20 CELL MODELING AND TRAINING IN A GEOGRAPHIC AREA OF
21 SOUTH L.A. AND SOUTH BAY WHERE THIS WOULD TRULY BE
22 ONE OF A KIND. IT WOULD BE THE FIRST STEM CELL CORE
23 IN THIS AREA.

24 THIS AREA IS HISTORICALLY AN UNDERSERVED
25 AND ECONOMICALLY DISADVANTAGED AREA, GEOGRAPHIC

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1 AREA. SO, THEREFORE, WE FEEL THAT THIS PROJECT
2 FULFILLS THE GOAL OF THE INFRASTRUCTURE 6.1, WHICH
3 IS TO ENSURE BROAD ACCESS TO STEM CELL-BASED MODELS
4 IN A GEOGRAPHIC AREA WHERE ACCESS IS LIMITED.

5 THE GRANTS WORKING GROUP WAS VERY
6 ENTHUSIASTIC ABOUT OUR PROJECT AND GAVE IT A SCORE
7 OF 1; HOWEVER, THE FACILITIES WORKING GROUP GAVE OUR
8 PROPOSAL A SCORE OF 2 AND HAD SOME ISSUES THAT WE
9 FEEL ARE ADDRESSABLE AND WE CAN ADDRESS.

10 THE MAJOR ISSUES WERE SPACE ISSUES, COST
11 ASSOCIATED WITH THE REMODEL, AND THERE WAS A MENTION
12 OF DEI. JUST TO BRIEFLY ADDRESS THOSE THREE ISSUES,
13 WE HAVE IDENTIFIED ADDITIONAL SPACE THAT HAS BEEN
14 COMPLETELY REMODELED IN 2023 IN OCTOBER AND IS
15 COMPLYING WITH ALL CALIFORNIA LAWS THAT WILL ALLOW
16 US TO EXPAND OUR TRAINING COURSES, BUT ALSO TO PLACE
17 OUR EQUIPMENT PROPERLY AS REQUESTED BY THE
18 FACILITIES WORKING GROUP.

19 THE SECOND POINT RELATES TO COST. WE HAVE
20 BEEN WORKING WITH DGF ARCHITECTS AND ENGINEERS NOW,
21 INDUSTRY LEADERS IN BIOMEDICAL AND RESEARCH BUILDING
22 DESIGN, TO ADDRESS THE DESIGN AND COST ISSUE. I
23 WANTED TO NOTE THAT WE KEPT OUR COST VERY LOW ON
24 REMODELING BECAUSE THE LUNDQUIST INSTITUTE IS
25 COMMITTED TO THE SUCCESS OF THIS PROJECT AND,

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1 THEREFORE, ARE WILLING TO PUT IN THE SOFT MONEY TO
2 DO THE REMODEL AND TO COVER ANY EXPENSES THAT ARE
3 RELATED TO THE REMODEL.

4 THE LAST POINT IS DEI. WE ACTUALLY
5 EXTENSIVELY ADDRESSED DEI IN OUR SCIENTIFIC PROPOSAL
6 AS POINTED OUT BY THE GRANTS WORKING GROUP.

7 MS. MANDAC: I'M SO SORRY. WE ARE AT
8 TIME.

9 CHAIRMAN IMBASCIANI: DR. AL ALAM, THANK
10 YOU FOR YOUR COMMENTS.

11 MS. MANDAC: NEXT WE HAVE DR. HAUSSLER.

12 DR. HAUSSLER: HELLO. YES. I'M DAVID
13 HAUSSLER. I'M THE DIRECTOR OF THE UC SANTA CRUZ
14 GENOMICS INSTITUTE, HOME OF THE UCSC GENOME BROWSER
15 WHICH IS WIDELY USED. WE HAVE A LONG HISTORY OF
16 CREATING RESOURCES THAT ARE VERY VALUABLE TO THE
17 BIOMEDICAL COMMUNITY.

18 I'D LIKE TO POINT OUT THAT OUR APPLICATION
19 IS QUITE DIFFERENT. IT'S VERY COMPLEMENTARY TO ALL
20 OF THE OTHER PROPOSALS. WE ARE PROPOSING A SCHEME
21 IN WHICH WE COULD EDUCATE STUDENTS IN STEM CELL WORK
22 BY LETTING THEM ACTUALLY EXPERIENCE A SCIENTIFIC
23 EXPERIMENT WITH HUMAN EMBRYONIC STEM CELLS JUST
24 USING THEIR CELL PHONE. SO WHAT WE HAVE IS A
25 THEATER PROGRAM THAT EXCITES STUDENTS ABOUT SCIENCE,

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1 LET'S THEM ACTUALLY DO AN EXPERIMENT, AND THEN GETS
2 THEM PREPARED FOR A SUBSEQUENT EXPERIENCE WHERE THEY
3 ARE IN PERSON DOING A LAB.

4 NOW, YOU HAVE TO FACE IT. WE CANNOT HAVE
5 A BSL2 LAB AT EVERY COMMUNITY COLLEGE AND EVERY
6 STATE COLLEGE. THERE IS NOT BUDGET TO BUILD THAT.
7 SO IF A STUDENT WANTS HANDS-ON EXPERIENCE WITH HUMAN
8 EMBRYONIC STEM CELLS OR ANY OF THE IPS CELLS OR
9 DERIVATIVES, THEY WOULD NEED TO BE CHOSEN TO HAVE A
10 SPECIAL PRIVILEGE TO GO TO ONE OF A FEW FACILITIES
11 THAT WILL ACTUALLY BE BUILT WITH THAT. WE HAVE A
12 FACILITY HERE AT SANTA CRUZ, AND WE WILL AND WE HAVE
13 BEEN ASKED, WE HAVE BEEN ASKING FOR SUPPORT FOR
14 ENGAGING IN AN EXPANSION OF THAT TO OFFER THESE
15 THINGS.

16 THIS PLATFORM HAS BEEN DEVELOPED BY DR.
17 MOSTAJO-RADJI WHO HAS TEN YEARS OF EXPERIENCE NOW
18 USING IT IN EDUCATING STUDENTS NOT ONLY IN
19 CALIFORNIA, BUT ALL OVER THE WORLD. AND I'VE SEEN
20 THEIR FACE LIGHT UP WHEN THEY DO THEIR FIRST
21 EXPERIMENT ON THIS. IT IS A VIRTUAL REALITY
22 EXPERIENCE WHERE THE ACTUAL EXPERIMENT IS BEING
23 CONDUCTED IN OUR BSL2 LAB, BUT IT'S BEING DRIVEN BY
24 THE STUDENTS THEMSELVES. THE STUDENTS WORK HARD,
25 THEY DESIGN THE EXPERIMENT, THEY EXECUTE THE

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1 EXPERIMENT, THEY ANALYZE THE DATA, WHICH IS ANOTHER
2 VERY, VERY IMPORTANT EXPERIENCE FOR THEM, AND AFTER
3 THAT THEY EXPERIENCE FIRSTHAND THE EXCITEMENT OF
4 DOING A SCIENTIFIC EXPERIMENT WITH ACTUAL HUMAN STEM
5 CELLS.

6 I WOULD LIKE TO REQUEST CONSIDERATION OF
7 FUNDING FOR THIS.

8 MS. MANDAC: I'M SORRY, DR. HAUSSLER, WE
9 ARE AT TIME.

10 CHAIRMAN IMBASCIANI: PROFESSOR HAUSSLER,
11 THANK YOU. WE'VE GOT YOUR COMMENTS. THANK YOU.

12 MS. MANDAC: NEXT WE HAVE DR. LIU.

13 DR. LIU: GOOD MORNING, EVERYONE. THANK
14 YOU. I REALLY APPRECIATE THE OPPORTUNITY TO SPEAK
15 ON BEHALF UC RIVERSIDE. I AM A PROFESSOR OF
16 BIOENGINEERING AT THE STEM CENTER IN THE MATERIAL
17 SCIENCE ENGINEERING PROGRAM. I'M ALSO THE DIRECTOR
18 OF THE CIRM SPARK AND COMPASS TRAINING PROGRAM AT
19 UCR. I'M ALSO CO-DIRECTOR OF THE CIRM SCHOLARS
20 TRAINING PROGRAM AT UCR.

21 SO, FIRST, SINCERELY APPRECIATE CIRM BOARD
22 MEMBERS AND THIS OPPORTUNITY TO SPEAK TO THE PUBLIC
23 REGARDING INFRASTRUCTURE 6.1-15266 PROPOSAL SHARED
24 RESEARCH AND TRAINING FACILITY FOR BIOFABRICATION OF
25 ORGANS FOR REGENERATIVE MEDICINE IN THE UNDERSERVED

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1 AREAS. SO THE BIOFORM FACILITY IS ESSENTIAL FOR
2 EQUITY AND ACCESS TO STEM CELL RESOURCES IN THE
3 INLAND EMPIRE REGION OF THE SOUTH CALIFORNIA.

4 THE FACILITY HAS BEEN DESIGNED TO BALANCE
5 THE TRAINING IN STEM CELL BIOLOGY AND THE
6 BIOENGINEERING THAT IS AT THE FOREFRONT OF STEM CELL
7 RESEARCH. AS THE ONLY STEM CELL RESEARCH
8 INFRASTRUCTURE LOCATED IN THE SOCIOECONOMICALLY,
9 EDUCATIONALLY, AND MEDICALLY UNDERSERVED INLAND
10 EMPIRE REGION, BIOFORM IS A CRITICAL RESOURCE FOR
11 AREA -- FOR THE REGION WITH LIMITED ACCESS TO STEM
12 CELL-BASED MODELS, FACILITIES, AND THERAPIES AS
13 DEMONSTRATED WITH A WIDE RANGE OF STAKEHOLDERS
14 REPRESENTED IN OUR 63 SUPPORT LETTERS IN THE
15 ORIGINAL SUBMISSION.

16 BUILDING ON THE UC RIVERSIDE CURRENT STEM
17 CELL CORE, BIOFORM WILL BE THE FIRST STEM CELL
18 MODELING FACILITY FOR THE UNDERSERVED COMMUNITIES IN
19 THE INLAND EMPIRE REGION AND ALSO ADJACENT REGIONS.

20 SO THE GRANTS WORKING GROUP, WE SINCERELY
21 APPRECIATE THEY UNDERSTAND THE SCIENTIFIC VALUE OF
22 OUR PROPOSAL AND RANKED IT IN THE TIER I WITH THE
23 HIGHEST VOTING NUMBER FOR THE TIER I.

24 THE FACILITY GROUP RAISED SEVERAL CONCERNS
25 WITH THE FACILITY PORTION OF OUR PROPOSAL. AND WE

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1 UNDERSTAND THE ISSUES AND HAVE ADDRESSED THOSE
2 ISSUES CLEARLY IN OUR PUBLIC COMMENT LETTER IN
3 RESPONSE TO THE CONCERNS ABOUT SUSTAINABILITY AND
4 THE SPECIAL INTEGRATION, AS WELL AS THE PLANNING AND
5 TIMELINE AND THE CONSTRUCTION OF OUR BIOFORM
6 FACILITY.

7 SO ALL THE DETAILS OUTLINED IN OUR
8 LETTERS, SO CONSIDER TIME, I WILL ONLY BRIEFLY
9 EMPHASIZE FEW KEY POINTS. REGARDING THE
10 SUSTAINABILITY, BIOFORM WILL BE ESTABLISHED ON THE
11 SUCCESS OF UCR'S ORIGINAL STEM CELL CORE WHICH WE
12 HAVE MAINTAINED OPERATIONAL SINCE ITS COMPLETION IN
13 2009 AND EVEN AFTER END OF INITIAL CIRM FUNDING.
14 WITH UCR'S LEADERSHIP SUPPORT AND RESOURCES, WE
15 REMAINED OPERATIONAL --

16 MS. MANDAC: I'M SO SORRY, DR. LIU. WE
17 ARE AT TIME.

18 CHAIRMAN IMBASCIANI: DR. LIU, THANK YOU.
19 WE HAVE A FEW MORE MEMBERS OF THE PUBLIC STILL WITH
20 THEIR HANDS RAISED, JUST ONE OR TWO MORE. WHO'S
21 NEXT?

22 MS. MANDAC: DR. MOSTAJO-RADJI.

23 DR. MOSTAJO-RADJI: THANK YOU VERY MUCH.
24 MY NAME IS MOHAMMED MOSTAJO-RADJI AND TOGETHER WITH
25 DR. HAUSSLER I'M A CORE PROGRAM DIRECTOR FOR GRANT

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1 INFRASTRUCTURE 6.1-15478, THE LIFE CELL
2 BIOTECHNOLOGY DISCOVERY LAB WHICH WE REQUEST TO BE
3 MOVED TO TIER I.

4 I WANT TO START BY SAYING THAT BOTH THE
5 MANDATE OF PROPOSITION 14 AS WELL AS THIS RFA IS TO
6 BRING EQUITY FOR STEM CELL MODELING AND EDUCATION
7 THROUGHOUT THE STATE OF CALIFORNIA. NOW, LET'S FACE
8 IT. THE MAJORITY OF UNDERREPRESENTED STUDENTS ARE
9 IN SMALL UNIVERSITIES AND COMMUNITY COLLEGES. IT
10 IS, AS DR. HAUSSLER MENTIONED, ECONOMICALLY
11 UNFEASIBLE TO ESTABLISH SRL'S IN EVERY UNIVERSITY OR
12 COMMUNITY COLLEGE THROUGHOUT THE STATE.

13 CLOUD TECHNOLOGISTS CAN BRIDGE THIS GAP
14 AND, IN FACT, IN THE RFA CLOUD TECHNOLOGIES WERE
15 ENCOURAGED TO APPLY AND DEMONSTRATING THE INTEREST
16 FROM CIRM TO ACTUALLY DEPLOY SOME OF THIS TECHNOLOGY
17 IN THE LOCATION SETTING.

18 WHAT WE PROPOSED IN OUR SRL IS TO GENERATE
19 2-DIMENSIONAL AND 3-DIMENSIONAL STEM CELL-DERIVED
20 MODELS AND CONNECT THEM VIA THE CLOUD AND DIFFERENT
21 EQUIPMENT SUCH AS MICROSCOPY, ELECTROPHYSIOLOGY, AND
22 FLUIDICS CONTROL TO ENABLE STUDENTS FROM ALL AROUND
23 THE STATE TO CONTROL EXPERIMENTS REMOTELY.

24 FURTHERMORE, WE WILL LEVERAGE OUR STRONG BACKGROUND
25 AND EXPERTISE IN CREATING PROJECT-BASED EDUCATION, A

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1 FORM OF EDUCATION THAT HAS BEEN PROVEN TO WORK WITH
2 STUDENTS FROM UNDERREPRESENTED BACKGROUNDS.

3 FINALLY, WE HAVE PROPOSED TO CREATE A
4 REPOSITORY IN BOTH ENGLISH AND SPANISH TO ENABLE
5 OTHER SCHOOLS AS WELL AS MEMBERS OF THE GENERAL
6 PUBLIC TO REUSE THE MATERIAL.

7 I WANT TO MENTION THAT THE REVIEWERS
8 RANKED HIGHLY OUR VALUE PROPOSITION FOR THE STATE OF
9 CALIFORNIA. THEY SAID OUR PROGRAM WAS FEASIBLE AND
10 UPHOLDS THE PRINCIPLES OF DIVERSITY. HOWEVER, THERE
11 WERE CONCERNS IN TWO MAJOR POINTS. ONE, OUR REACH
12 TO OTHER COMMUNITY COLLEGES BEYOND THE ONES THAT WE
13 HAVE ALREADY PROPOSED IN THE ORIGINAL SUBMISSION. I
14 WANT TO MENTION WE HAVE OVER THREE DOZEN OF FACULTY
15 FROM COMMUNITY COLLEGES SUPPORTING OUR APPLICATION,
16 INCLUDING FACULTY AT BAKERSFIELD COLLEGE, ONE OF THE
17 LARGEST HISPANIC SERVING INSTITUTIONS IN THE REGION.

18 ADDITIONAL COMMITMENTS HAVE BEEN ENSURED
19 OVER THE PAST MONTH FROM SOME OF OUR ALREADY
20 PARTNERS BOTH HERE AS WELL AS SOMEWHERE ELSE -- AS
21 WELL AS OTHER UNIVERSITIES. SORRY.

22 I ALSO WANT TO SAY THAT THE CONCERN FOR
23 ADDITIONAL FUNDING BEYOND THE LENGTH OF THIS GRANT,
24 WE HAVE ALREADY ADDRESSED THIS IN TWO DIFFERENT
25 WAYS. ONE, BY ALREADY APPLYING WITH THE COMMUNITY

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1 COLLEGES AND LEVERAGING THE INFRASTRUCTURE AT UCSC
2 TO BRING IN ADDITIONAL GRANT THAT CAN PAY FOR THIS
3 SRL BEYOND THE FIVE YEARS, AS WELL AS GETTING
4 COMMITMENTS FROM RESEARCH FACULTY AT UCSC AND
5 BEYOND --

6 MS. MANDAC: I'M SORRY, DR. MOSTAJO-RADJI.
7 WE ARE AT TIME. THANK YOU SO MUCH FOR YOUR
8 COMMENTS.

9 CHAIRMAN IMBASCIANI: THANK YOU,
10 PROFESSOR. WE HAVE ONE MORE SPEAKER, I THINK
11 MS. LAUREN LINTON. WHAT'S YOUR TITLE, MA'AM?

12 MS. LINTON: THANK YOU. THANK YOU FOR
13 ALLOWING ME TO SPEAK TODAY. MY NAME IS LAUREN
14 LINTON. I'M THE EXECUTIVE DIRECTOR OF THE GENOMICS
15 INSTITUTE AT UNIVERSITY OF SANTA CRUZ, CALIFORNIA
16 SANTA CRUZ.

17 I'M HERE TODAY ON BEHALF OF THIS PROPOSAL
18 15478, BUT MAINLY TO GIVE YOU A SENSE OF THE
19 INSTITUTIONAL COMMITMENT. UC SANTA CRUZ IS ONE OF
20 THREE R1 HISPANIC, ASIAN, AMERICAN, AND NATIVE
21 AMERICAN, PACIFIC ISLANDER SERVING INSTITUTIONS IN
22 CALIFORNIA, AND ONE OF ONLY 20 NATIONWIDE. WE HAVE
23 A FIRM COMMITMENT, LONG TRADITION OF OFFERING RICH
24 CONTENT, ROBUST ONRAMPS TO MINORITIZED GROUPS AND
25 COMMUNITIES.

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1 TO THE GENOMICS INSTITUTE THE TERM
2 "UNDERSERVED COMMUNITY" IS CORE TO OUR RESEARCH
3 PURPOSE AND MISSION. WE ALSO HAVE A LONG TRADITION
4 AND RICH HISTORY OF WORKING WITH THESE COMMUNITIES,
5 SHAPING OUR WORK AROUND THEIR NEEDS. THIS INCLUSION
6 IN AND ACCESS TO GENOMIC DATA TO DEVELOPING SOCIALLY
7 JUST POLICIES AND FRAMEWORKS FOR THAT DATA, TO
8 DECADES OF COMMITMENT OF OPEN SHARE POLICIES. THE
9 GI HAS BEEN AT THE FOREFRONT OF DRIVING INCLUSION IN
10 EDUCATION AND IN RESEARCH.

11 WE CURRENTLY OFFER SEVERAL GRANT AND
12 FOUNDATION-FUNDED AND HIGHLY IMPACTFUL ONRAMP
13 PROGRAMS TO MINORITIZED STUDENTS AS THEY ENTER THE
14 GENOMICS AND BIOINFORMATICS FIELDS. WITHIN THE
15 GENOMICS INSTITUTE, THE LIVE CELL BIOTECHNOLOGY
16 DISCOVERY LAB BUILDS ON THIS GENOMIC INSTITUTE
17 HISTORY TO BRING ACCESS TO STEM CELL MODELS, STEM
18 CELL RESEARCH TO THESE STUDENT POPULATIONS.

19 UCSC HAS LONG BEEN DEEPLY COMMITTED TO
20 MAKING OUR WORK, THIS WORK, A SUCCESS. AND OVER THE
21 YEARS IT HAS PROVIDED RESEARCH INFRASTRUCTURE,
22 DEVELOPED LAB SPACE, SUPPLIED ADMINISTRATIVE AND
23 RESEARCH SUPPORT TO BOTH THE INSTITUTE AND THE LIVE
24 CELL BIOTECHNOLOGY DISCOVERY LAB. THIS CONTINUES
25 WITH THEIR MATCH OF COMMITMENT OF 10 TO \$14 MILLION

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1 INVESTMENT TO MATCH THE COMMITMENT OF CIRM IN
2 DEVELOPING THIS LABORATORY SPACE AND PROGRAM.

3 THIS IS AN EXCEPTIONAL, IF NOT
4 UNPARALLELED, LEVEL OF COMMITMENT AND DESIRE TO WORK
5 WITH CIRM TO MAKE STEM CELL MODELS ACCESSIBLE
6 THROUGHOUT THE STATE, ESPECIALLY UNDERSERVED
7 COMMUNITIES.

8 THIS DOLLAR AMOUNT IS HUGE FOR UC SANTA
9 CRUZ. AND FOR ME, IT'S HEARTENING TO SEE THE
10 UNIVERSITY PRIORITIZE PROGRAMS SUCH AS THESE AND
11 TRULY WALK THE TALK. WHEN IT COMES TO PROVIDING
12 PROJECT-BASED LEARNING, RESEARCH EXPERIENTIAL
13 TRAINING TO UNDERPROVEN STUDENTS OF LATINO
14 BACKGROUND, WE ARE PROUD TO TALK TO YOU TODAY, AND
15 THANK YOU FOR THE OPPORTUNITY.

16 MS. MANDAC: THANK YOU.

17 CHAIRMAN IMBASCIANI: THANK YOU, DIRECTOR
18 LINTON. I DON'T SEE ANY OTHER COMMENTS.

19 ALLOW THE CHAIR JUST TO MAKE A REMARK OR
20 TWO. FIRST OF ALL, I WANT TO THANK ALL THE SPEAKERS
21 FROM THE PUBLIC FOR THEIR ELOQUENCE AND THE CARE
22 WITH WHICH THEY PUT INTO THEIR REMARKS. ALL OF YOUR
23 REMARKS ARE RECORDED AND WILL, IN FACT, GO TO THE
24 GRANTS REVIEW GROUP BECAUSE ALL OF THE APPLICATIONS
25 WE'VE BEEN TALKING ABOUT NOW IN TIER II ARE GOING

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1 BACK FOR RE-REVIEW AND WILL, IN FACT, COME BACK TO
2 THE BOARD FOR RECONSIDERATION, IF YOU WILL. SO YOUR
3 COMMENTS ARE VERY, VERY MUCH APPRECIATED.

4 WITH RESPECT TO THE THREE-MINUTE LIMIT,
5 YOU SEE THE CARE WITH WHICH THE BOARD IS CONCERNED
6 WITH FAIRNESS EVEN WITHIN THE BOARD WITH OUR
7 CONFLICTS OF INTEREST. SO DO NOT MISINTERPRET THE
8 THREE-MINUTE LIMIT. WE IMPOSE IT ONLY FOR FAIRNESS
9 SAKE, NOT OUT OF ANY SIGN OF DISRESPECT FOR YOUR
10 REMARKS.

11 HAVING SAID THAT, WE HAVE A MOTION ON THE
12 TABLE TO CLOSE OUT TIER II, WHICH IS NOT TO FUND,
13 BUT TO GO BACK TO GRANTS REVIEW FOR RECONSIDERATION.

14 ARE THERE ANY FURTHER COMMENTS FROM THE
15 BOARD? CLAUDETTE, YOU SEE ANY HANDS? I DON'T SEE
16 ANY HANDS. I THINK THAT MEANS, RAFAEL --

17 MS. MANDAC: ADRIANA JUST RAISED HER HAND.

18 CHAIRMAN IMBASCIANI: ADRIANA, YOU RAISED
19 YOUR HAND. GO AHEAD.

20 DR. PADILLA: THANK YOU. WHAT IS THE TIME
21 FRAME FOR THE RE-REVIEW PROPOSALS?

22 CHAIRMAN IMBASCIANI: GIL, CAN YOU ANSWER
23 THAT?

24 DR. SAMBRANO: SO WE'RE PLANNING TO DO
25 THIS THREE TO FOUR MONTHS OUT FROM NOW. SO IN MOST

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1 CASES THERE'S ONLY JUST ONE OF THE WORKING GROUPS,
2 BUT WE STILL HAVE TO PUT BOTH WORKING GROUPS
3 TOGETHER. SO WE'RE LOOKING AT THREE TO FOUR MONTHS.

4 DR. PADILLA: THANK YOU.

5 CHAIRMAN IMBASCIANI: THANKS, GIL. ANY
6 OTHER BOARD MEMBERS HAVE ANY FINAL QUESTIONS OR
7 COMMENTS? I'M GOING TO ASK OUR LEGAL COUNSEL RAFAEL
8 AGUIRRE-SACASA TO CALL THE ROLL.

9 MR. AGUIRRE-SACASA: OKAY. VOTING TO
10 CLOSE OUT TIER IIS AND SEND TO RE-REVIEW.

11 JUDY CHOU.

12 DR. CHOU: YES.

13 MR. AGUIRRE-SACASA: FRED FISHER.

14 DR. FISHER: YES.

15 MR. AGUIRRE-SACASA: DAVID HIGGINS.

16 DR. HIGGINS: YES.

17 MR. AGUIRRE-SACASA: VITO IMBASCIANI.

18 CHAIRMAN IMBASCIANI: YES.

19 MR. AGUIRRE-SACASA: RICH LAJARA.

20 MR. LAJARA: YES.

21 MR. AGUIRRE-SACASA: CHRIS MIASKOWSKI.

22 DR. MIASKOWSKI: YES.

23 MR. AGUIRRE-SACASA: ADRIANA PADILLA.

24 DR. PADILLA: YES.

25 MR. AGUIRRE-SACASA: JOE PANETTA.

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1 MR. PANETTA: YES.

2 MR. AGUIRRE-SACASA: MARV SOUTHARD.

3 DR. SOUTHARD: YES.

4 MR. AGUIRRE-SACASA: AND KEVIN XU.

5 DR. XU: YES.

6 MR. AGUIRRE-SACASA: THANK YOU. MOTION
7 CARRIES.

8 CHAIRMAN IMBASCIANI: THANK YOU SO MUCH.
9 I WAS LOOKING AHEAD.

10 SO WE NOW COME TO THE FINAL SECTION OF
11 THIS. I WOULD ENTERTAIN A MOTION TO FUND ALL THE
12 APPLICATIONS IN TIER I.

13 DR. SOUTHARD: SOUTHARD MOVES.

14 CHAIRMAN IMBASCIANI: MARVIN SOUTHARD
15 MOVES. DO I HAVE A SECOND?

16 MR. PANETTA: SECOND.

17 CHAIRMAN IMBASCIANI: THANK YOU, JOE
18 PANETTA. OKAY. WE HAVE A MOTION AND A SECOND.
19 OPEN TO COMMENTS AND QUESTIONS FROM BOARD MEMBERS.
20 OKAY. ANY MEMBERS FROM THE GENERAL PUBLIC WANT TO
21 COMMENT ON THIS MOTION?

22 MS. MANDAC: THERE ARE NO HANDS RAISED.

23 CHAIRMAN IMBASCIANI: NO HANDS ARE RAISED.
24 RAFAEL, WE MAY PROCEED WITH THE FINAL VOTE ON THIS
25 SECTION.

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1 MR. AGUIRRE-SACASA: THANK YOU. THE
2 MOTION IS TO FUND TIER I APPLICATIONS.
3 JUDY CHOU.
4 DR. CHOU: YES, APPROVE.
5 MR. AGUIRRE-SACASA: FRED FISHER.
6 DR. FISHER: YES.
7 MR. AGUIRRE-SACASA: DAVID HIGGINS.
8 DR. HIGGINS: YES.
9 MR. AGUIRRE-SACASA: VITO IMBASCIANI.
10 CHAIRMAN IMBASCIANI: YES.
11 MR. AGUIRRE-SACASA: RICH LAJARA.
12 MR. LAJARA: YES.
13 MR. AGUIRRE-SACASA: CHRIS MIASKOWSKI.
14 DR. MIASKOWSKI: YES.
15 MR. AGUIRRE-SACASA: ADRIANA PADILLA.
16 DR. PADILLA: YES.
17 MR. AGUIRRE-SACASA: JOE PANETTA.
18 MR. PANETTA: YES.
19 MR. AGUIRRE-SACASA: MARVIN SOUTHARD.
20 DR. SOUTHARD: YES.
21 MR. AGUIRRE-SACASA: KEVIN XU.
22 DR. XU: YES.
23 MR. AGUIRRE-SACASA: THANK YOU ALL.
24 MOTION CARRIES.
25 CHAIRMAN IMBASCIANI: THANK YOU. THANK

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1 YOU, RAFAEL. WE'RE GOING TO MOVE ON NOW TO AGENDA
2 ITEM 9 WHICH WILL ALSO BE LED BY A MEMBER OF GRANTS
3 REVIEW. I THINK HAYLEY, DR. LAM, IS GOING TO TAKE
4 US THROUGH CONSIDERATION OF APPLICATIONS FOR THE
5 CLINICAL PROJECTS.

6 DR. LAM: THANK YOU. GIVE ME A MOMENT TO
7 SHARE MY SCREEN. IS THAT VISIBLE TO FOLKS? THANK
8 YOU.

9 SO I'M PRESENTING ON BEHALF OF GIL
10 SAMBRANO THE CLINICAL PROGRAM GRANTS WORKING GROUP
11 RECOMMENDATIONS. AS ALWAYS, WE BEGIN WITH OUR
12 MISSION STATEMENT, ACCELERATING WORLD-CLASS SCIENCE
13 TO DELIVER TRANSFORMATIVE REGENERATIVE MEDICINE
14 TREATMENTS IN AN EQUITABLE MANNER TO A DIVERSE
15 CALIFORNIA AND WORLD.

16
17
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25

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1 THE FISCAL YEAR CLINICAL BUDGET STATUS IS
2 AS FOLLOWS. THE ALLOCATION WAS 252 MILLION. THE
3 AMOUNT THAT HAS BEEN APPROVED UP TO TODAY, SO THUS
4 FAR, IS OVER 105 MILLION. AND ON THE TABLE FOR
5 DISCUSSION 56.5 MILLION. THAT WOULD LEAVE JUST
6 UNDER 90 MILLION REMAINING IF ALL AWARDS TODAY ARE
7 APPROVED.

8 THE SCIENTIFIC SCORING SYSTEM FOR THE
9 CLINICAL PROGRAM IS VERY SIMILAR TO THE SHARED LABS
10 PROGRAM THAT YOU JUST DISCUSSED, SCORES OF 1, 2, AND
11 3. A ONE IS A RECOMMENDATION FOR FUNDING BY THE
12 GRANTS WORKING GROUP. A 2 IS A DO NOT FUND AT THIS
13 TIME, BUT THE APPLICANT CAN RESUBMIT. A SCORE OF 3
14 IS A DO NOT RECOMMEND FOR FUNDING, AND THE APPLICANT
15 CANNOT RESUBMIT THE SAME PROJECT FOR AT LEAST SIX
16 MONTHS.

17 THE CRITERIA THAT LEADS INTO THAT SCORING
18 ARE THE FIVE KEY QUESTIONS. DOES THE PROJECT HOLD
19 THE NECESSARY SIGNIFICANCE AND POTENTIAL FOR IMPACT?
20 IS THE RATIONALE SOUND? IS THE PROJECT WELL-PLANNED
21 AND DESIGNED? IS THE PROJECT FEASIBLE? AND DOES
22 THE PROJECT UPHOLD PRINCIPLES OF DIVERSITY, EQUITY,
23 AND INCLUSION?

24 FOR THE CLINICAL PROGRAM, IN ADDITION TO
25 THE SCIENTIFIC SCORING, HAVE DEI SCORING THAT IS

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1 COMPLETED BY THE BOARD MEMBERS. AND THE SCORING
2 SYSTEM FOR THE DEI IS A SCALE OF 0 TO 10 WITH 10
3 BEING AN OUTSTANDING RESPONSE; 6 TO 8, RESPONSIVE; 3
4 TO 5, NOT FULLY RESPONSIVE; AND 0 TO 2, NOT
5 RESPONSIVE. WE'VE INCLUDED HERE SORT OF A VISUAL OF
6 THE RUBRIC THAT CAN BE FOUND ON OUR WEBSITE THAT IS
7 USED TO EVALUATE THE DEI SCORING.

8 THE PANEL THAT REVIEWS THESE APPLICATIONS
9 FOR THE CLINICAL PROGRAM IS COMPOSED OF THREE
10 DIFFERENT GROUPS OF FOLKS. THE FIRST AT THE TOP
11 HERE IS UP TO 15 MEMBERS OF THE SCIENTIFIC GRANTS
12 WORKING GROUP, AND THEY PROVIDE A SCIENTIFIC
13 EVALUATION IN THE AREAS OF DISEASE, REGULATORY,
14 MANUFACTURING, AND PRODUCT DEVELOPMENT, AND THEY
15 PROVIDE A SCIENTIFIC SCORE ON ALL APPLICATIONS.

16 WE ALSO HAVE OUR GRANTS WORKING GROUP
17 BOARD MEMBERS. SO THESE ARE THE PATIENT ADVOCATE
18 AND NURSE MEMBERS OF THE BOARD THAT SIT ON THE
19 GRANTS WORKING GROUP PANELS, AND THEY EVALUATE THE
20 DEI AND ALSO PROVIDE A DEI SCORE ON ALL APPLICATIONS
21 AS WELL AS A SUGGESTED SCIENTIFIC SCORE.

22 AND, FINALLY, WE HAVE NONVOTING SCIENTIFIC
23 SPECIALISTS THAT COME ON AS AD HOC REVIEWERS IN
24 AREAS OF EXPERTISE THAT ARE NOT COVERED BY THE ABOVE
25 FOLKS. AND THEY PROVIDE AN INITIAL SCORE, BUT DO

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1 NOT PROVIDE A FINAL SCIENTIFIC SCORE.

2 SO MOVING ON TO THE APPLICATIONS TODAY,
3 THE VERY FIRST APPLICATION IS CLIN2-14801. AND SO
4 HERE I SHOW THE BOARD MEMBERS WITH CONFLICTS OF
5 INTEREST: YSABEL DURON AND KAROL WATSON.

6 GOING INTO THE APPLICATIONS. SO THIS
7 IS -- THE TITLE IS "STEM CELL-DERIVED IL13RA2
8 CHIMERIC ANTIGEN RECEPTOR T CELLS FOR PATIENTS WITH
9 MELANOMA AND ADVANCED SOLID TUMORS." THE GOAL FOR
10 THIS PROJECT IS TO COMPLETE A FIRST-IN-HUMAN
11 CLINICAL TRIAL. AND THE APPLICANT IS ASKING FOR
12 JUST OVER 10 MILLION WITH NO CO-FUNDING REQUIRED FOR
13 THIS.

14 TO GO INTO A LITTLE BIT OF BACKGROUND,
15 THIS APPLICATION IS AIMING TO TARGET THE SOLID
16 TUMORS AND MELANOMA IN PARTICULAR, WHICH IS A FORM
17 OF SKIN CANCER. AND THE PROPOSED THERAPY WOULD
18 TARGET THESE SOLID TUMORS, AND THEY AIM TO TEST THE
19 SAFETY AND EFFICACY FIRST WITH THE SKIN CANCER
20 MELANOMA. AND THIS IS A STEM CELL PROJECT AS IT IS
21 COMPOSED OF T-MEMORY STEM CELLS AND INVOLVES GENE
22 MANIPULATION OF THOSE CELLS.

23 IN TERMS OF CIRM PORTFOLIO PROJECTS, THERE
24 ARE TWO OTHER TRANSLATIONAL AND CLINICAL STAGE
25 AWARDS THAT TARGET MELANOMA. BOTH OF THEM ARE

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1 EARLIER STAGE. ONE IS A TRAN1 AND ONE IS A CLIN1.
2 AND THE APPLICANT TEAM ALSO HAS PRIOR
3 FUNDING. THEY ARE MOSTLY IN BRAIN CANCERS, AND THE
4 TWO APPLICATIONS THAT ARE COMPLETE HAD ALL
5 MILESTONES COMPLETED AND WERE ACHIEVED. AND THERE
6 IS ONE AWARD THAT IS LAUNCHING.

7 SO FOR THE CONSIDERATION OF THE BOARD, THE
8 RECOMMENDATION FROM THE GRANTS WORKING GROUP IS TO
9 RECOMMEND FUNDING. THE DEI SCORE WAS A 7, AND THE
10 CIRM TEAM RECOMMENDATION CONCURS WITH THE GWG
11 RECOMMENDATION FOR THE AWARD AMOUNT OF 10.2 MILLION.

12 CHAIRMAN IMBASCIANI: OKAY. THANK YOU,
13 HAYLEY. I'M GOING TO ENTERTAIN A MOTION TO ACCEPT
14 AND MOVE THIS FORWARD.

15 VICE CHAIR BONNEVILLE: SO MOVED.

16 DR. SOUTHARD: SECOND.

17 MR. AGUIRRE-SACASA: THANK YOU, MARV.

18 CHAIRMAN IMBASCIANI: THANK YOU.

19 DISCUSSION ON THIS APPLICATION FROM BOARD MEMBERS?
20 IF NOT, WE WILL ASK MEMBERS OF THE PUBLIC IF THEY
21 HAVE ANY COMMENTS.

22 MS. MANDAC: NO HANDS RAISED.

23 CHAIRMAN IMBASCIANI: NO HANDS ARE RAISED.
24 RAFAEL.

25 MR. AGUIRRE-SACASA: THIS IS TO FUND

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APPLICATION 14801.
DAN BERNAL. MARIA BONNEVILLE.
VICE CHAIR BONNEVILLE: YES.
MR. AGUIRRE-SACASA: JUDY CHOU.
DR. CHOU: YES.
MR. AGUIRRE-SACASA: LEONDR A CLARK-HARVEY.
DR. CLARK-HARVEY: YES.
MR. AGUIRRE-SACASA: ANNE-MARIE DULIEGE.
MARK FISCHER-COLBRIE.
MR. FISCHER-COLBRIE: YES.
MR. AGUIRRE-SACASA: FRED FISHER.
DR. FISHER: YES.
MR. AGUIRRE-SACASA: DAVID HIGGINS.
DR. HIGGINS: YES.
MR. AGUIRRE-SACASA: VITO IMBASCIANI.
CHAIRMAN IMBASCIANI: YES.
MR. AGUIRRE-SACASA: STEVE JUELSGAARD.
MR. JUELSGAARD: YES.
MR. AGUIRRE-SACASA: RICH LAJARA.
MR. LAJARA: YES.
MR. AGUIRRE-SACASA: CHRIS MIASKOWSKI.
DR. MIASKOWSKI: YES.
MR. AGUIRRE-SACASA: LAUREN MILLER-ROGEN.
ADRIANA PADILLA.
DR. PADILLA: YES.

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1 MR. AGUIRRE-SACASA: JOE PANETTA.

2 ME. PANETTA: YES.

3 MR. AGUIRRE-SACASA: MARV SOUTHARD.

4 DR. SOUTHARD: YES.

5 MR. AGUIRRE-SACASA: KEVIN XU.

6 MOTION CARRIES.

7 CHAIRMAN IMBASCIANI: THANK YOU. HAYLEY,
8 YOU CAN CONTINUE WITH THE NEXT ITEM.

9 DR. LAM: THANK YOU. SO THE NEXT
10 APPLICATION UP FOR DISCUSSION IS CLIN1-14845. THIS
11 IS A "NEURAL STEM CELL-DERIVED ONCOLYTIC
12 VIRO-IMMUNOTHERAPY FOR OVARIAN CANCER." AND THIS IS
13 AN IND-ENABLING STAGE CLIN1 APPLICATION THAT IS
14 REQUESTING 5.3 MILLION WITH NO CO-FUNDING REQUIRED.

15 A LITTLE BIT OF BACKGROUND ON THIS
16 APPLICATION. SO THIS IS -- OVARIAN CANCER IMPACTS
17 OVER 20,000 WOMEN EACH YEAR, AND THE SURVIVAL RATE
18 IS ONLY ABOUT HALF. AND THE PROPOSED THERAPY, IF IT
19 IS SUCCESSFUL, HOPEFULLY WILL PROVIDE A SAFER AND
20 MORE EFFECTIVE OPTION FOR PATIENTS WITH THIS
21 PARTICULAR CANCER.

22 THE CURRENT STANDARD OF CARE IS AGGRESSIVE
23 CHEMOTHERAPY WHICH HAS TOXIC SIDE EFFECTS. AND THIS
24 IS A STEM CELL OR GENE THERAPY PROJECT BECAUSE THE
25 THERAPY ITSELF INVOLVES NEURAL STEM CELLS.

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1 SIMILAR CIRM PORTFOLIO PROJECTS INCLUDE
2 ONE CLIN2 THAT IMPACTS ALL SOLID TUMORS, INCLUDING
3 OVARIAN CANCER. PRIOR FUNDING FOR THE APPLICANT
4 TEAM INCLUDES PRIOR AWARDS FOR A TRAN1 AND DISEASE
5 TEAM. THE TRAN1 AWARD IS A DIRECT PROGRESSION EVENT
6 THAT HAS LED TO THIS APPLICATION UP FOR YOUR
7 CONSIDERATION TODAY. THAT PARTICULAR AWARD WAS
8 COMPLETED AND OBVIOUSLY SUCCESSFUL COMING HERE AS A
9 CLIN1.

10 FOR YOUR CONSIDERATION TODAY, THE GWG
11 RECOMMENDED THIS APPLICATION FOR FUNDING WITH
12 UNANIMOUS TIER I SCORES AND A DEI SCORE OF 8, AND
13 THE CIRM TEAM CONCURS WITH THE RECOMMENDATIONS FOR
14 THE AWARD AMOUNT OF 5.3 MILLION.

15 CHAIRMAN IMBASCIANI: THANK YOU, HAYLEY.
16 BOARD WILL ENTERTAIN A MOTION TO ACCEPT THE GWG
17 RECOMMENDATION.

18 VICE CHAIR BONNEVILLE: SO MOVED.

19 DR. SOUTHARD: MARV SOUTHARD SECONDS.

20 CHAIRMAN IMBASCIANI: WE HAVE A MOTION AND
21 SECOND. COMMENTS FROM THE BOARD ON THIS
22 APPLICATION? OKAY. ANY MEMBERS OF THE PUBLIC WANT
23 TO COMMENT ON THIS APPLICATION?

24 MS. MANDAC: THERE ARE NO HANDS RAISED.

25 CHAIRMAN IMBASCIANI: NO HANDS ARE RAISED.

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1 WE'RE GOING TO PROCEED TO A VOTE. THANK YOU.
2 MR. AGUIRRE-SACASA: THIS IS TO FUND
3 APPLICATION 14845.
4 MARIA BONNEVILLE.
5 VICE CHAIR BONNEVILLE: YES.
6 MR. AGUIRRE-SACASA: JUDY CHOU.
7 DR. CHOU: YES.
8 MR. AGUIRRE-SACASA: LEONDR A CLARK-HARVEY.
9 DR. CLARK-HARVEY: YES.
10 MR. AGUIRRE-SACASA: MARK FISCHER-COLBRIE.
11 MR. FISCHER-COLBRIE: YES.
12 MR. AGUIRRE-SACASA: FRED FISHER.
13 DR. FISHER: YES.
14 MR. AGUIRRE-SACASA: DAVID HIGGINS.
15 DR. HIGGINS: YES.
16 MR. AGUIRRE-SACASA: VITO IMBASCIANI.
17 CHAIRMAN IMBASCIANI: YES.
18 MR. AGUIRRE-SACASA: STEVE JUELSGAARD.
19 MR. JUELSGAARD: YES.
20 MR. AGUIRRE-SACASA: RICH LAJARA.
21 MR. LAJARA: YES.
22 MR. AGUIRRE-SACASA: CHRIS MIASKOWSKI.
23 DR. MIASKOWSKI: YES.
24 MR. AGUIRRE-SACASA: ADRIANA PADILLA.
25 DR. PADILLA: YES.

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1 MR. AGUIRRE-SACASA: JOE PANETTA.

2 MR. PANETTA: YES.

3 MR. AGUIRRE-SACASA: MARV SOUTHARD.

4 DR. SOUTHARD: YES.

5 MR. AGUIRRE-SACASA: KAROL WATSON.

6 DR. WATSON: I THINK I'M IN CONFLICT.

7 MR. AGUIRRE-SACASA: NOT ON THIS ONE,

8 KAROL.

9 DR. WATSON: OKAY. YEAH.

10 MR. AGUIRRE-SACASA: THANK YOU. MOTION

11 CARRIES.

12 CHAIRMAN IMBASCIANI: THANK YOU, RAFAEL.

13 14845 HAS BEEN APPROVED. WE MOVE ON TO THE THIRD

14 ONE, HAYLEY.

15 DR. LAM: YES. THANK YOU. THE NEXT

16 APPLICATION UP FOR DISCUSSION IS CLIN1-15337,

17 "CHIMERIC TGFB SIGNALING RECEPTOR ENABLED ANTI-B7H3

18 CAR-T CELL THERAPY IN CHILDREN AND AYA WITH

19 RECURRENT SOLID TUMORS." AYA MEANING ADOLESCENTS

20 AND YOUNG ADULTS JUST TO BE CLEAR HERE.

21 THE GOAL OF THIS APPLICATION IS COMPLETE

22 IND-ENABLING ACTIVITIES AND FILE THAT IND BY THE END

23 OF THE AWARD. AND THE FUNDS REQUESTED ARE 6 MILLION

24 WITH NO CO-FUNDING REQUIRED.

25 A LITTLE BIT OF BACKGROUND ON THIS

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1 APPLICATION. SO THIS IS ALSO TARGETING SOLID
2 TUMORS, BUT FOR CHILDREN AND YOUNG ADULTS, AND
3 PARTICULARLY IS LOOKING AT METASTATIC SARCOMAS. AND
4 THE OVERALL SURVIVAL RATE FOR THIS PARTICULAR CANCER
5 IS VERY LOW. THERE'S MANY COMPLICATIONS FROM THE
6 STANDARD CHEMO AND RADIATION TREATMENTS.

7 SO THE IDEA HERE IS THAT THE CAR-T CELL
8 THERAPY COULD TARGET THESE SOLID TUMORS AND COULD
9 POTENTIALLY ADDRESS SOME OF THE LIMITATIONS THAT
10 IMPACT THE EFFECTIVENESS OF THE CURRENT STANDARD OF
11 CARE. THIS PARTICULAR PROJECT IS A GENE THERAPY.
12 THE APPLICANT -- THE CIRM PORTFOLIO DOES NOT HAVE
13 ANY AWARDS ADDRESSING METASTATIC SARCOMAS IN
14 CHILDREN AND YOUNG ADULTS. AND THE APPLICANT HAS
15 NOT PREVIOUSLY RECEIVED A CIRM AWARD.

16 SO FOR YOUR CONSIDERATION IS A
17 RECOMMENDATION FROM THE GRANTS WORKING GROUP OF A
18 SCIENTIFIC SCORE OF 1 FROM 11 VOTES AND A SCORE OF 2
19 FROM FOUR, WHICH IS A RECOMMENDATION FOR FUNDING, A
20 DEI SCORE OF 10, AND THE CIRM TEAM CONCURS WITH THE
21 SCIENTIFIC RECOMMENDATION FOR FUNDING FOR THE AWARD
22 AMOUNT OF 6 MILLION.

23 CHAIRMAN IMBASCIANI: THANK YOU AGAIN,
24 HAYLEY. A MOTION TO ACCEPT THE RECOMMENDATION TO
25 FUND.

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1 VICE CHAIR BONNEVILLE: SO MOVED.

2 DR. FISHER: SECOND.

3 CHAIRMAN IMBASCIANI: WE HAVE A SECOND
4 FROM FRED. DISCUSSION FROM BOARD MEMBERS. ANY
5 COMMENT FROM THE PUBLIC ON THIS CAR-T CELL
6 APPLICATION? DO WE SEE ANY, CLAUDETTE?

7 MS. MANDAC: NO HANDS RAISED.

8 CHAIRMAN IMBASCIANI: NO HANDS ARE RAISED.
9 LET'S PROCEED TO A VOTE.

10 MR. AGUIRRE-SACASA: VOTING TO FUND
11 APPLICATION 15337.

12 MARIA BONNEVILLE.

13 VICE CHAIR BONNEVILLE: YES.

14 MR. AGUIRRE-SACASA: JUDY CHOU.

15 DR. CHOU: YES.

16 MR. AGUIRRE-SACASA: LEONDRA CLARK-HARVEY.

17 DR. CLARK-HARVEY: YES.

18 MR. AGUIRRE-SACASA: MARK FISCHER-COLBRIE.

19 MR. FISCHER-COLBRIE: YES.

20 MR. AGUIRRE-SACASA: FRED FISHER.

21 DR. FISHER: YES.

22 MR. AGUIRRE-SACASA: DAVID HIGGINS.

23 DR. HIGGINS: YES.

24 MR. AGUIRRE-SACASA: VITO IMBASCIANI.

25 CHAIRMAN IMBASCIANI: YES.

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1 MR. AGUIRRE-SACASA: STEVE JUELSGAARD.
2 MR. JUELSGAARD: YES.
3 MR. AGUIRRE-SACASA: RICH LAJARA.
4 MR. LAJARA: YES.
5 MR. AGUIRRE-SACASA: CHRIS MIASKOWSKI.
6 DR. MIASKOWSKI: YES.
7 MR. AGUIRRE-SACASA: ADRIANA PADILLA.
8 DR. PADILLA: YES.
9 MR. AGUIRRE-SACASA: JOE PANETTA.
10 MR. PANETTA: YES.
11 MR. AGUIRRE-SACASA: MARV SOUTHARD.
12 DR. SOUTHARD: YES.
13 MR. AGUIRRE-SACASA: KAROL WATSON.
14 DR. WATSON: YES.
15 MR. AGUIRRE-SACASA: THANK YOU. MOTION
16 CARRIES.
17 CHAIRMAN IMBASCIANI: MOTION CARRIES.
18 THANK YOU VERY MUCH. HAYLEY, APPLICATION NO. 4.
19 DR. LAM: HI. SORRY. HAVING ISSUES WITH
20 MY CLICKING HERE.
21 NEXT APPLICATION HAS A BUNCH OF CONFLICTS.
22 SO IF YOU HEAR YOUR NAME, PLEASE DO NOT VOTE ON THE
23 FOLLOWING APPLICATIONS: DAN BERNAL, YSABEL DURON,
24 ELENA FLOWERS, CHRIS MIASKOWSKI, AND KAROL WATSON.
25 THE APPLICATION FOR DISCUSSION IS

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1 CLIN2-15547, "PHASE 1/2A DOSE ESCALATION STUDY OF
2 AUTOLOGOUS NEURON REPLACEMENT IN SPORADIC
3 PARKINSON'S DISEASE."

4 THE GOAL FOR THIS APPLICATION IS TO
5 COMPLETE A FIRST-IN-HUMAN CLINICAL TRIAL. AND THE
6 APPLICANT IS REQUESTING 8 MILLION AND HAS THE
7 REQUIRED 30-PERCENT CO-FUNDING OF OVER 3.6 MILLION.

8 A LITTLE BIT OF BACKGROUND ON THIS
9 APPLICATION. SO THIS IS FOCUSED ON PARKINSON'S
10 DISEASE, WHICH IS A PROGRESSIVE NEURODEGENERATIVE
11 DISEASE AFFECTING ALMOST A MILLION AMERICANS. AND
12 IT IS CAUSED BY DOPAMINE NEURAL CELL DEATH IN
13 CERTAIN REGIONS OF THE BRAIN. THERE'S CURRENTLY NO
14 CURE, AND THE CURRENT STANDARD OF CARE JUST CONTROLS
15 SYMPTOMS. AND THERE IS ALSO A DEEP BRAIN
16 STIMULATION SURGERY THAT CAN ALSO CONTROL SYMPTOMS.

17 THE PROPOSED THERAPY HAS THE POTENTIAL TO
18 REPLACE THOSE LOST DOPAMINERGIC NEURONS AND
19 HOPEFULLY INCREASE AND IMPROVE DISEASE OUTCOMES.
20 AND THE THERAPY IS DERIVED FROM INDUCED PLURIPOTENT
21 STEM CELLS.

22 THERE ARE SEVERAL CIRM PORTFOLIO PROJECTS
23 THAT ARE SIMILAR ADDRESSING PARKINSON'S DISEASE.
24 TWO OF THEM ARE EARLIER STAGE, TRAN1 AND CLIN1. AND
25 THERE IS ONE OTHER CLINICAL TRIAL THAT IS

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1 CIRM-FUNDED FOR PARKINSON'S, BUT THE APPROACH IS
2 VERY DIFFERENT. IT'S A GENE THERAPY.

3 THE APPLICANT TEAM HAS PRIOR CIRM FUNDING
4 FOR A DISC2 EARLY DISCOVERY STAGE PROJECT THAT WAS
5 ALSO RELATED TO PARKINSON'S DISEASE, AND IT WAS
6 COMPLETED SUCCESSFULLY.

7 SO FOR YOUR CONSIDERATION, THE GRANTS
8 WORKING GROUP HAS RECOMMENDED THIS APPLICATION FOR
9 FUNDING WITH A UNANIMOUS TIER I SCORE. THE DEI
10 SCORE WAS 8. AND THE CIRM TEAM CONCURS WITH THE
11 SCIENTIFIC RECOMMENDATION WITH THE AWARD AMOUNT
12 REQUESTED AT 8 MILLION.

13 CHAIRMAN IMBASCIANI: THANK YOU, HAYLEY.
14 THE BOARD WOULD LIKE TO ENTERTAIN A MOTION TO ACCEPT
15 THE RECOMMENDATION ON THIS PARKINSON'S-RELATED
16 APPLICATION.

17 DR. HIGGINS: SO MOVED.

18 DR. SOUTHARD: SECOND.

19 CHAIRMAN IMBASCIANI: WE HAVE A MOTION
20 FROM HIGGINS, AND MARV SECONDED. THANK YOU.

21 COMMENTS FROM THE BOARD? OKAY. COMMENTS
22 FROM THE PUBLIC? I THINK WE CAN PROCEED TO VOTE,
23 RAFAEL.

24 MR. AGUIRRE-SACASA: THANK YOU. AND THE
25 MOTION IS TO FUND APPLICATION 15547.

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1 MARIA BONNEVILLE.
2 VICE CHAIR BONNEVILLE: YES.
3 MR. AGUIRRE-SACASA: JUDY CHOU.
4 DR. CHOU: YES.
5 MR. AGUIRRE-SACASA: LEONDR A CLARK-HARVEY.
6 DR. CLARK-HARVEY: YES.
7 MR. AGUIRRE-SACASA: MARK FISCHER-COLBRIE.
8 MR. FISCHER-COLBRIE: YES.
9 MR. AGUIRRE-SACASA: FRED FISHER.
10 DR. FISHER: YES.
11 MR. AGUIRRE-SACASA: DAVID HIGGINS.
12 DR. HIGGINS: YES.
13 MR. AGUIRRE-SACASA: VITO IMBASCIANI.
14 CHAIRMAN IMBASCIANI: YES.
15 MR. AGUIRRE-SACASA: STEVE JUELSGAARD.
16 MR. JUELSGAARD: YES.
17 MR. AGUIRRE-SACASA: RICH LAJARA.
18 MR. LAJARA: YES.
19 MR. AGUIRRE-SACASA: ADRIANA PADILLA.
20 DR. PADILLA: YES.
21 MR. AGUIRRE-SACASA: JOE PANETTA.
22 MR. PANETTA: YES.
23 MR. AGUIRRE-SACASA: MARV SOUTHARD.
24 DR. SOUTHARD: YES.
25 MR. AGUIRRE-SACASA: THANK YOU. MOTION

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1 CARRIES.

2 CHAIRMAN IMBASCIANI: THANK YOU VERY MUCH.
3 WE'RE GOING TO PROCEED TO THE FIFTH OF SEVEN
4 APPLICATIONS. HAYLEY, THE FLOOR IS YOURS.

5 DR. LAM: THANK YOU. CAN I ASK ANYBODY
6 WHO'S NOT SPEAKING TO MUTE. I THINK THE LINE IS A
7 LITTLE BIT WONKY. THANK YOU.

8 SO THE NEXT APPLICATION, THERE'S A COUPLE
9 OF CONFLICTS. SO IF YOU HEAR YOUR NAME, DAN BERNAL,
10 YSABEL DURON, ELENA FLOWERS, CHRIS MIASKOWSKI,
11 PLEASE DO NOT VOTE ON THIS FOLLOWING APPLICATION.

12 THE NEXT APPLICATION IS CLIN2-15562,
13 "PHASE 1 STUDY OF AUTOLOGOUS E-SYNC T-CELLS IN ADULT
14 PARTICIPANTS WITH EGFRVIII GLIOBLASTOMA." THE GOAL
15 FOR THIS APPLICATION IS TO COMPLETE THE
16 FIRST-IN-HUMAN TRIAL, AND THE FUNDS REQUESTED ARE
17 JUST UNDER 11 MILLION WITH THE CO-FUNDING OF 300,000
18 WITH NONE REQUIRED.

19 A LITTLE BIT ABOUT THIS APPLICATION. SO
20 GLIOBLASTOMA IS A COMMON BRAIN TUMOR IN ADULTS AND
21 HAS A VERY POOR SURVIVAL RATE, AND THE CURRENT
22 STANDARD OF CARE INVOLVES A SURGERY TO REMOVE THE
23 TUMOR AND FOLLOWED BY RADIATION AND CHEMO. AND
24 SURVIVAL IS STILL POOR BASED ON THESE CURRENT
25 TREATMENTS. THE PROPOSED THERAPY AIMS TO IMPROVE

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1 THE SURVIVAL AND QUALITY OF LIFE FOR THE PATIENTS
2 WITH GLIOBLASTOMA VIA A CAR-T CELL APPROACH THAT
3 WOULD IDEALLY REQUIRE A ONE-TIME TREATMENT. AND THE
4 THERAPY IS RELEVANT TO CIRM AS GENE MANIPULATION OF
5 AUTOLOGOUS T-CELLS.

6 IN TERMS OF SIMILAR CIRM PORTFOLIO
7 PROJECTS, CIRM HAS FUNDED QUITE A FEW PHASE 1
8 CLINICAL TRIALS IN VARIOUS FORMS OF BRAIN CANCER.
9 AND ALL OF THESE APPROACHES ARE ALSO AUTOLOGOUS
10 CAR-T APPROACHES; HOWEVER, THEY ARE EACH OF THEM, AS
11 INDICATED HERE IN THE MECHANISM OF ACTION ON THE
12 RIGHT, TARGETING DIFFERENT -- THEY HAVE DIFFERENT
13 TARGETS FOR EACH OF THE CAR-T'S. SO THIS WOULD BE
14 AN ADDITIONAL CAR-T APPROACH THAT WOULD TARGET THE
15 EGFR INSTEAD OF THESE OTHER CIRM PORTFOLIO ONES THAT
16 HAVE THE DIFFERENT TARGETS INDICATED HERE.

17 IN TERMS OF PRIOR FUNDING FROM CIRM TO THE
18 APPLICANT TEAM, THEY'VE RECEIVED A TRANSLATIONAL
19 AWARD AND A DISCOVERY AWARD BOTH IN THE SAME DISEASE
20 AREA AND COMPLETED THEM.

21 AND FOR YOUR CONSIDERATION IS A
22 RECOMMENDATION FROM THE GRANTS WORKING GROUP WITH A
23 UNANIMOUS RECOMMENDATION FOR FUNDING AND A DEI SCORE
24 OF 8 WITH THE CIRM TEAM CONCURRING WITH THE
25 RECOMMENDATION FOR THE AWARD AMOUNT OF JUST UNDER 11

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1 MILLION, 10.9 MILLION. THANK YOU.

2 CHAIRMAN IMBASCIANI: THANK YOU, HAYLEY.

3 SO A MOTION FROM THE BOARD TO ACCEPT THE

4 RECOMMENDATION FROM THE GWG.

5 DR. FISHER: SO MOVED.

6 CHAIRMAN IMBASCIANI: DO I HAVE A SECOND?

7 VICE CHAIR BONNEVILLE: SECOND.

8 DR. SOUTHARD: SOUTHARD SECOND.

9 CHAIRMAN IMBASCIANI: THANK YOU. COMMENTS
10 FROM THE BOARD ON THIS APPLICATION? AND FROM THE
11 GENERAL PUBLIC?

12 MS. MANDAC: NO HANDS RAISED.

13 CHAIRMAN IMBASCIANI: NO HANDS RAISED. WE
14 MAY PROCEED TO A VOTE.

15 MR. AGUIRRE-SACASA: AND THIS IS TO FUND
16 APPLICATION 15562.

17 MARIA BONNEVILLE.

18 VICE CHAIR BONNEVILLE: YES.

19 MR. AGUIRRE-SACASA: JUDY CHOU.

20 DR. CHOU: YES.

21 MR. AGUIRRE-SACASA: LEONDRA CLARK-HARVEY.

22 DR. CLARK-HARVEY: YES.

23 MR. AGUIRRE-SACASA: MARK FISCHER-COLBRIE.

24 MR. FISCHER-COLBRIE: YES.

25 MR. AGUIRRE-SACASA: FRED FISHER.

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1 DR. FISHER: YES.
2 MR. AGUIRRE-SACASA: DAVID HIGGINS.
3 DR. HIGGINS: YES.
4 MR. AGUIRRE-SACASA: VITO IMBASCIANI.
5 CHAIRMAN IMBASCIANI: YES.
6 MR. AGUIRRE-SACASA: STEVE JUELSGAARD.
7 MR. JUELSGAARD: YES.
8 MR. AGUIRRE-SACASA: RICH LAJARA.
9 MR. LAJARA: YES.
10 MR. AGUIRRE-SACASA: ADRIANA PADILLA.
11 DR. PADILLA: YES.
12 MR. AGUIRRE-SACASA: JOE PANETTA.
13 MR. PANETTA: YES.
14 MR. AGUIRRE-SACASA: MARV SOUTHARD.
15 DR. SOUTHARD: YES.
16 MR. AGUIRRE-SACASA: KAROL WATSON.
17 DR. WATSON: YES.
18 MR. AGUIRRE-SACASA: THANK YOU. MOTION
19 CARRIES.
20 CHAIRMAN IMBASCIANI: THANK YOU VERY MUCH.
21 MOVING ON TO APPLICATION NO. 6, HAYLEY.
22 DR. LAM: THANK YOU. SO THE CONFLICTS OF
23 INTEREST FOR THIS FOLLOWING APPLICATION ARE DAN
24 BERNAL, YSABEL DURON, ELENA FLOWERS, CHRIS
25 MIASKOWSKI, AND KAROL WATSON.

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1 THE APPLICATION FOR YOUR CONSIDERATION IS
2 CLIN2-16063, "A PHASE 1/2 STUDY TO EVALUATE
3 BISPECIFIC CD19/CD20 DIRECTED CAR-T CELL IN
4 REFRACTORY LUPUS NEPHRITIS AND SYSTEMIC LUPUS
5 ERYTHEMATOSUS." AND THE GOAL FOR THIS APPLICATION
6 IS TO COMPLETE A FIRST-IN-HUMAN CLINICAL TRIAL. AND
7 THE FUNDS REQUESTED ARE EXACTLY 8 MILLION WITH
8 CO-FUNDING OF OVER 10 MILLION WITH 30 PERCENT
9 REQUIRED.

10 A LITTLE BIT OF BACKGROUND ON THIS
11 APPLICATION. SO LUPUS IS AN AUTOIMMUNE DISEASE THAT
12 AFFECTS MULTIPLE ORGANS AND CAUSES WIDESPREAD
13 INFLAMMATION THAT CAN LEAD TO ORGAN DAMAGE AND
14 EVENTUALLY DEATH. AND LUPUS PARTICULARLY IS
15 PREVALENT AMONG AFRICAN-AMERICAN AND HISPANIC WOMEN.
16 STANDARD OF CARE CURRENTLY IS LARGELY SYMPTOMATIC
17 AND INVOLVES IMMUNOSUPPRESSION, INCLUDING
18 CORTICOSTEROIDS.

19 SO THE PROPOSED THERAPY IS TO ESSENTIALLY
20 TRY TO DAMPEN DOWN THE AUTOIMMUNE RESPONSE, AND IT
21 USES CAR-T'S TO DO THAT. AND THE THERAPY ITSELF
22 INVOLVES GENETIC MANIPULATION OF THE CELLS TO CREATE
23 THE CAR-T'S, WHICH IS HOW IT'S RELEVANT TO CIRM.

24 THE CURRENT CIRM PORTFOLIO DOES NOT
25 INCLUDE ANY TRAN OR CLIN AWARDS ADDRESSING LUPUS.

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1 AND THE APPLICANT HAS ALSO NOT RECEIVED ANY PRIOR
2 CIRM FUNDING. SO THE GRANTS WORKING GROUP
3 RECOMMENDATION TO THE BOARD IS TO A RECOMMENDATION
4 FOR FUNDING WITH THE SCORES SPLIT AS FOLLOWS. THE
5 TIER I, THERE WERE NINE VOTES IN TIER I, TWO VOTES
6 IN TIER II, AND ONE VOTE IN TIER III WITH AN OVERALL
7 RECOMMENDATION FOR FUNDING. THE DEI SCORE WAS 9,
8 AND THE CIRM TEAM RECOMMENDATION CONCURS WITH THE
9 SCIENTIFIC RECOMMENDATION FOR THE REQUESTED AWARD
10 AMOUNT OF 8 MILLION. THANK YOU.

11 CHAIRMAN IMBASCIANI: THANK YOU, HAYLEY.
12 CHAIR WILL ENTERTAIN A MOTION TO ACCEPT THE
13 RECOMMENDATION.

14 VICE CHAIR BONNEVILLE: SO MOVED.

15 DR. SOUTHARD: SECOND.

16 CHAIRMAN IMBASCIANI: THANK YOU. COMMENTS
17 FROM THE BOARD ON THIS LUPUS-RELATED APPLICATION?
18 STEVE JUELSGAARD.

19 MR. JUELSGAARD: YES. I'D LIKE TO ADDRESS
20 THE APPLICATION WE'RE ABOUT TO REVIEW AFTER THIS
21 SINCE IT'S ALSO AIMED AT SYSTEMIC LUPUS
22 ERYTHEMATOSUS. IT'S ALSO ADDRESSING THE CD19
23 RECEPTOR ON B CELLS. CAN YOU HELP ME DISTINGUISH
24 BETWEEN THESE TWO APPLICATIONS PLEASE? ARE WE
25 BASICALLY ADDRESSING -- TRYING TO ADDRESS THE SAME

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1 PROBLEM IN THE SAME WAY BY FUNDING TWO VERY, VERY,
2 VERY SIMILAR APPLICATIONS?

3 DR. LAM: YES. SO THERE'S TWO ANSWERS TO
4 THAT. THE FIRST IS THAT THE CURRENT APPLICATION
5 UNDER DISCUSSION, 16063, IS AN AUTOLOGOUS APPROACH
6 THAT HAS TWO TARGETS. SO IT'S BISPECIFIC CD19/CD20.
7 AND THE OTHER APPLICATION FOR CONSIDERATION, I'M NOT
8 SURE IF I CAN ADDRESS THIS, BUT IT'S 16303. SO THAT
9 APPLICATION IS AN ALLOGENEIC APPROACH.

10 MR. JUELSGAARD: SO THE REASON I RAISE
11 THIS IS BECAUSE WE'RE GOING TO HAVE A DISCUSSION
12 SUBSEQUENTLY ABOUT REMAINING FUNDS AND OUR ABILITY
13 TO USE THOSE FUNDS TO FUND FUTURE APPLICATIONS. AND
14 THE MOMENT THAT SOMETHING LIKE THAT COMES UP, THEN,
15 FOR ME AT LEAST, I SORT OF LOOK AT WHAT WE'RE DOING
16 AND SAYING, WELL, ARE WE SPENDING OUR MONEY WISELY?
17 AND IN THE WORLD OF INDUSTRY, YOU PROBABLY WOULDN'T
18 HAVE, YOU WOULDN'T BE FUNDING TWO PROJECTS THAT
19 OVERLAP AS MUCH AS THESE TWO. I UNDERSTAND THERE
20 ARE TWO DIFFERENT CELL TYPES THAT ARE BEING USED,
21 BUT ULTIMATELY THE IDEA IS IF YOU DEplete THE CD19
22 RECEPTOR ON B-CELLS OR YOU ATTACK THE B-CELLS WITH
23 CD19 ON THEM, THAT YOU WILL HAVE AN EFFECT ON
24 SYSTEMIC LUPUS ERYTHEMATOSUS OR LUPUS NEPHRITIS.
25 AND I JUST REALLY WONDER ABOUT THE WISDOM OF

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1 SPENDING THIS AMOUNT OF MONEY ON TWO SEPARATE
2 PROJECTS THAT ARE DOING VERY, VERY SIMILAR THINGS.

3 DR. LAM: SO I GUESS I COULD JUST SAY THAT
4 PROGRAMMATIC DECISIONS ARE UP TO THE ARS. BUT IN
5 TERMS OF THE RECOMMENDATION FROM THE GRANTS WORKING
6 GROUP FROM SCIENTIFIC REVIEWERS, THEY WERE BOTH
7 RECOMMENDED. THERE WAS SOME DISCUSSION IN THE PANEL
8 ON THIS AS WELL. AND THEY AGREED THAT FOR THIS
9 PARTICULAR APPLICATION 16063 OVERALL THAT THIS
10 BISPECIFIC APPROACH HAS NOT BEEN TRIED YET IN HUMANS
11 AND WAS WORTH SEEING IF IT HAS A GREATER IMPACT.

12 DR. SAMBRANO: HAYLEY, I WOULD ALSO ADD
13 THAT THE TWO APPROACHES ARE A BIT DIFFERENT,
14 PARTICULARLY SINCE THE OTHER ONE, WHICH USES IPSC'S
15 AND IS INTENDED TO BE ALLOGENEIC, IS SORT OF AN
16 OFF-THE-SHELF APPROACH. AND THAT TYPICALLY HAS NOT
17 BEEN DONE WITH CAR-T'S. THAT IS A VERY DIFFERENT
18 WAY OF DOING IT. AND SO IT MEANS THAT THE TREATMENT
19 FOR THE PATIENTS WOULD ALSO BE SIGNIFICANTLY
20 DIFFERENT SINCE THEY WOULDN'T BE IN THAT SCENARIO
21 TAKING AUTOLOGOUS CELLS IN ORDER TO CREATE THE
22 PRODUCT.

23 SO THERE ARE SOME SIGNIFICANT DIFFERENCES
24 IN THE TWO EVEN THOUGH THEY ARE ADDRESSING LARGELY
25 THE SAME DISEASE. AND IN BOTH CASES THEY ARE BOTH

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1 ADDRESSING THE B-CELL COMPONENT AND TRYING TO DAMPEN
2 THE IMMUNE RESPONSE TO THE B-CELL.

3 (SHORT PAUSE IN PROCEEDING.)

4 MS. MANDAC: FRED.

5 DR. FISHER: GIL, COULD YOU JUST REMIND
6 US, SINCE WE DON'T OFTEN SEE SPREADS LIKE THIS,
7 WHERE 25 PERCENT OF THE REVIEWERS THOUGHT IT SHOULD
8 EITHER COME BACK OR GO AWAY FOR GOOD? CAN YOU GIVE
9 US SORT OF A HIGH LEVEL? WHAT WAS THE OBJECTION FOR
10 THE SCORE OF 3 AND THE SCORES OF 2?

11 DR. SAMBRANO: THE SCORE OF 3 IS FROM A
12 REVIEWER WHO FELT THAT THE APPLICANTS REALLY DIDN'T
13 DISTINGUISH ADEQUATELY BETWEEN THEIR APPROACH FOR
14 DEVELOPING THIS CAR-T THERAPY FOR AN AUTOIMMUNE
15 DISEASE VERSUS WHAT IS TYPICALLY USED FOR BLOOD
16 CANCERS. MEANING THEY WERE TAKING AN APPROACH THAT
17 WAS ALMOST EQUIVALENT TO BLOOD CANCERS AND NOT
18 SUFFICIENTLY TAKING INTO ACCOUNT THE FACT THAT THIS
19 IS A VERY DIFFERENT DISEASE AND THE SAME ELEMENTS
20 MAY NOT APPLY.

21 SO, FOR EXAMPLE, ONE OF THE CONCERNS WAS
22 WHY IS IT NECESSARY IN THIS CASE TO INCLUDE CD20 AS
23 WELL AS CD19 BECAUSE THAT IS AN ISSUE THAT IS
24 LARGELY IMPACTED IN BLOOD CANCERS, BUT MAY NOT BE
25 RELEVANT TO THE AUTOIMMUNE DISEASE. SO I THINK THAT

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1 WAS THE PERSPECTIVE FROM THIS ONE REVIEWER.

2 I THINK THE OTHER REVIEWERS FELT THAT THE
3 APPROACH IS NOVEL ENOUGH THAT IT IS WORTH TESTING.

4 I THINK, HAYLEY, YOU MAY WANT TO HELP ME WITH THE
5 ONES THAT SCORED A 2, BUT I THINK GENERALLY THOSE
6 THAT SCORE A 2 ARE LOOKING FOR ADDITIONAL
7 INFORMATION OR DATA OR CLARIFICATION, BUT YOU MAY
8 HAVE MORE ON THAT.

9 DR. LAM: I DON'T REALLY HAVE MUCH MORE TO
10 ADD.

11 DR. FISHER: THANK YOU. APPRECIATE IT.

12 CHAIRMAN IMBASCIANI: WE'RE STILL ON
13 COMMENTS FROM BOARD MEMBERS AT THIS POINT. ANY
14 OTHER BOARD MEMBER WANT TO RESPOND TO THE GENERAL
15 DISCUSSION OR TO MR. JUELSGAARD'S SPECIFIC COMMENT?
16 OKAY. IF NOT, I'M GOING TO OPEN IT UP TO COMMENT
17 FROM THE PUBLIC. BUT CAN I JUST REMIND YOU THAT THE
18 COMMENTS HAVE TO BE RESTRICTED TO CLIN2-16063 AT
19 THIS POINT. THANK YOU. WHO'S NEXT?

20 MS. MANDAC: LIZ MORASSO. YOU HAVE THREE
21 MINUTES.

22 MS. MORASSO: HI. MY NAME IS LIZ. IT'S
23 REALLY NICE TO MEET EVERYBODY. I AM ACTUALLY A
24 LICENSED CLINICAL SOCIAL WORKER THAT PRIMARILY WORKS
25 WITH THE ONCOLOGY AND RHEUMATOLOGY POPULATIONS. I'M

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1 VERY FAMILIAR WITH CAR-T IN THE ONCOLOGY COMMUNITY,
2 BUT I WAS ALSO DIAGNOSED WITH LUPUS AT AGE 16. AND
3 TALKING WITH THIS GROUP A LITTLE BIT ABOUT WHAT THIS
4 WOULD LOOK LIKE, ALSO GIVEN MY EXPERIENCE
5 SPECIFICALLY WITH LUPUS NEPHRITIS AND GENERAL SLE, I
6 GOT REALLY EXCITED. AS TO WHAT WAS INITIALLY
7 PRESENTED, IMMUNOSUPPRESSION REALLY HAS BEEN THE
8 ONLY THING THAT HAS KEPT MY DISEASE AT BAY.
9 HOWEVER, THE SIDE EFFECTS OF THAT ARE SO EXHAUSTING
10 AND OFTEN I'M TAKING MEDICATIONS TO HELP WITH THOSE
11 SIDE EFFECTS.

12 AND SO WHEN TALKING WITH THE IMPACT TEAM,
13 IT JUST SEEMED LIKE SUCH A RELIEF AND SUCH AN
14 INCREDIBLE CHANGE TO THE USUAL NARRATIVE THAT I HEAR
15 AROUND MY CARE AND ALSO WHEN THE POPULATIONS THAT I
16 WORK WITH PROFESSIONALLY IN MY CLINICAL PRACTICE AND
17 ALSO AT UCLA WHERE I WAS A PRACTITIONER IN CHLA,
18 ALSO WORKED WITH ONCOLOGY AND RHEUMATOLOGY PATIENTS.
19 SO I JUST WANTED TO OFFER THAT PATIENT-FOCUS VOICE,
20 BUT ALSO BE AN ADVOCATE FOR THE PATIENTS AND CLIENTS
21 AND FAMILY THAT I WORK WITH PROFESSIONALLY. SO
22 THANK YOU SO MUCH FOR ALLOWING ME TO OFFER THAT
23 PERSPECTIVE. I'M HAPPY TO SPEAK TO THE PATIENT SIDE
24 OF THIS AS WELL IF THAT WOULD BE HELPFUL.

25 CHAIRMAN IMBASCIANI: I APPRECIATE YOUR

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1 COMMENTS. WE HAVE ANOTHER MEMBER OF THE PUBLIC,
2 JONATHAN BENJAMIN. MR. BENJAMIN.

3 DR. BENJAMIN: YES. THANK YOU FOR
4 ALLOWING ME TO SPEAK AND TO ADDRESS SOME OF THE
5 COMMENTS. I REPRESENT IMPACT BIO, AND I'M A
6 PRINCIPAL INVESTIGATOR ON THIS GRANT.

7 I DID WANT TO SAY THAT IN TERMS OF THE
8 CD19 AND CD20 STORY, THERE IS, I THINK, A VERY
9 IMPORTANT ASPECT OF LUPUS IN PARTICULAR AS THE
10 HETEROGENEITY OF CD19 EXPRESSION, PARTICULARLY IN
11 PATIENTS WITH ANTI-DOUBLE STRANDED DNA ANTIBODIES,
12 SOMETHING THAT IS REPORTED IN THE LITERATURE AND
13 THAT WE HAVE ALSO OBSERVED. THAT'S, OF COURSE,
14 AMONG B-CELLS.

15 I ALSO WANT TO SAY THAT THERE'S GREAT
16 PROOF OF CONCEPT FOR THIS APPROACH AS WAS PUBLISHED
17 RECENTLY, IN FACT YESTERDAY, IN THE *NEW ENGLAND*
18 *JOURNAL OF MEDICINE* FOR USING SIMILAR
19 LYMPHODEPLETION AND APPROACHES. BUT WE BELIEVE
20 HAVING CD20 TARGETING WILL ADD TO THE EFFICACY.

21 ADDITIONALLY, THIS CAR-T CELL HAS BEEN
22 TESTED IN LYMPHOMA AT A UCLA STUDY WITH OUTSTANDING
23 SAFETY AS WELL AS DURABLE EFFICACY. SO I WOULD LIKE
24 FOR THE BOARD MEMBERS TO KEEP THAT IN CONSIDERATION
25 AS THEY EVALUATE THIS GRANT.

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1 CHAIRMAN IMBASCIANI: THANK YOU, DR.
2 BENJAMIN. I APPRECIATE IT.

3 I SEE ANOTHER HAND FROM THE PUBLIC, MS.
4 KATHLEEN ARNTSEN.

5 MS. ARNTSEN: YES. VERY GOOD ON THE NAME.
6 GOOD AFTERNOON. I SUBMIT THE FOLLOWING COMMENTS AS
7 THE PRESIDENT AND CEO OF LUPUS AND ALLIED DISEASES
8 ASSOCIATION, A NATIONAL PATIENT ADVOCATE
9 ORGANIZATION.

10 AS AN INDIVIDUAL WHO HAS LIVED WITH THE
11 DEBILITATING EFFECTS OF LUPUS SINCE CHILDHOOD, I
12 URGE YOU TO SUPPORT IMPACT BIO'S APPLICATION. AS A
13 LONGSTANDING PATIENT ADVOCATE, I UNDERSTAND THE
14 CRITICAL NEED FOR PIONEERING TREATMENTS FOR ALLIED
15 AND SLE. LUPUS IS HIGHLY INDIVIDUALIZED, EXTREMELY
16 VOLATILE, DIFFICULT TO DIAGNOSE, FATAL, PRESENTLY
17 INCURABLE, TOTALLY CAPRICIOUS, PAINFULLY LIMITING,
18 LIFE ALTERING, DREAMS STEALING, REAR-ENDING, AND
19 FINANCIALLY, EMOTIONALLY, AND PHYSICALLY
20 DEVASTATING. LUPUS IS A DISEASE WITH LIMITED
21 TREATMENT OPTIONS, A PROFOUND UNMET MEDICAL NEED.

22 I STRUGGLE WITH EIGHT DIFFERENT AUTOIMMUNE
23 DISORDERS AND COMORBID CONDITIONS AND TAKE 48
24 MEDICATIONS A DAY. I HAVE A PARALYZED GI TRACT,
25 KIDNEY DISEASE, AND AM BLIND IN MY RIGHT EYE. THERE

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1 ARE NO ONE-SIZE-FITS ALL PRODUCTS FOR PEOPLE LIKE
2 ME. I HAVE ENDURED DECADES OF DESTRUCTION AND
3 DISFIGUREMENTS FROM HARMFUL TREATMENTS. LUPUS CUT
4 ME DOWN IN THE PRIME OF MY LIFE AND HAS STOLEN
5 PRECIOUS TIME FROM ME AS WELL AS THE ABILITY TO HAVE
6 A CAREER, FINANCIAL SECURITY, OR TO BE A MOTHER.
7 DUE TO THE HETEROGENEITY OF LUPUS, NO TWO PATIENTS
8 ARE ALIKE. A DRUG THAT WORKS IN ONE PERSON MAY NOT
9 WORK IN ANOTHER. PHYSICIANS NEED AN ARMAMENTARIUM
10 OF THERAPIES TO TREAT US.

11 WE HAVE BEEN WAITING FOR MORE EFFECTIVE
12 AND SAFER GROUNDBREAKING TREATMENTS. AND IN A
13 PERFECT WORLD PEOPLE LIKE ME WITHOUT ONE TREATMENT
14 INSTEAD OF 48, WE DESPERATELY NEED SAFER, MORE
15 INNOVATIVE TREATMENTS THAT REDUCE SYMPTOMS AND
16 IMPROVE DAILY FUNCTIONING AND QUALITY OF LIFE.

17 IN CLOSING, I PASSIONATELY URGE YOU TO
18 SUPPORT IMPACT BIO'S APPLICATION AND STAND WITH
19 PEOPLE WITH LUPUS BY HELPING TO ADVANCE CAR-T
20 THERAPY. YOUR SUPPORT CAN BE A CATALYST IN
21 ADVANCING INNOVATIVE LUPUS TREATMENTS AND THE
22 PROSPECT THIS HOLDS FOR DISEASES OF UNMET NEED. YOU
23 WOULD PUT US ONE STEP CLOSER TO ENSURING THAT THE
24 NEXT GENERATION OF PEOPLE WITH LUPUS IS GIVEN THE
25 CHANCE AT A BETTER QUALITY OF LIFE AND BE ABLE TO

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1 PURSUE THEIR GOALS AND ACHIEVE THEIR DREAMS. THANK
2 YOU FOR THE OPPORTUNITY TO PROVIDE OUR PATIENT
3 VIEWPOINTS AND FOR RECOGNIZING THE VALUE OF LIVING
4 WITH A DISEASE IN THE PROCESS. I ALSO SUBMITTED
5 WRITTEN COMMENTS.

6 CHAIRMAN IMBASCIANI: MS. ARNTSEN, THANK
7 YOU VERY MUCH FOR YOUR STATEMENT. I APPRECIATE IT.
8 NO MORE PUBLIC COMMENT. THANK YOU.

9 WE'VE HAD BOARD COMMENT. ANY OTHER
10 MEMBERS OF THE BOARD WANT TO RESPOND TO ANYTHING OR
11 HAVE ANY ADDITIONAL QUESTIONS? IF NOT, WE'RE GOING
12 TO PROCEED TO A VOTE.

13 MR. AGUIRRE-SACASA: THE MOTION IS TO FUND
14 APPLICATION 16063.

15 MARIA BONNEVILLE.

16 VICE CHAIR BONNEVILLE: YES.

17 MR. AGUIRRE-SACASA: JUDY CHOU.

18 DR. CHOU: YES.

19 MR. AGUIRRE-SACASA: LEONDRA CLARK-HARVEY.

20 DR. CLARK-HARVEY: YES.

21 MR. AGUIRRE-SACASA: MARK FISCHER-COLBRIE.

22 MR. FISCHER-COLBRIE: YES.

23 MR. AGUIRRE-SACASA: FRED FISHER.

24 DR. FISHER: YES.

25 MR. AGUIRRE-SACASA: DAVID HIGGINS.

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1 DR. HIGGINS: YES.
2 MR. AGUIRRE-SACASA: VITO IMBASCIANI.
3 CHAIRMAN IMBASCIANI: YES.
4 MR. AGUIRRE-SACASA: STEVE JUELSGAARD.
5 MR. JUELSGAARD: YES.
6 MR. AGUIRRE-SACASA: RICH LAJARA.
7 MR. LAJARA: YES.
8 MR. AGUIRRE-SACASA: ADRIANA PADILLA.
9 DR. PADILLA: YES.
10 MR. AGUIRRE-SACASA: JOE PANETTA.
11 MR. PANETTA: YES.
12 MR. AGUIRRE-SACASA: MARV SOUTHARD.
13 DR. SOUTHARD: YES.
14 MR. AGUIRRE-SACASA: MOTION CARRIES.
15 CHAIRMAN IMBASCIANI: THANK YOU VERY MUCH,
16 RAFAEL. AND FINALLY, HAYLEY, OUR LAST
17 RECOMMENDATION FROM THE GWG.
18 DR. LAM: THANK YOU. FIRST A NOTE ON THE
19 CONFLICTS FOR THIS PARTICULAR APPLICATION: DAN
20 BERNAL, YSABEL DURON, ELENA FLOWERS, AND CHRIS
21 MIASKOWSKI.
22 SO THE APPLICATION FOR CONSIDERATION, AND
23 WE'VE MADE IT TO THE LAST ONE, FOLKS, IS
24 CLIN2-16303, "PHASE 1 STUDY OF CAR-T CELLS IN
25 PARTICIPANTS WITH MODERATE TO SEVERE ACTIVE SYSTEMIC

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1 LUPUS ERYTHEMATOSUS." SO THE GOAL HERE IS ALSO FOR
2 A FIRST-IN-HUMAN CLINICAL TRIAL. AND THE FUNDS
3 REQUESTED ARE JUST UNDER 8 MILLION WITH CO-FUNDING
4 OF OVER 3.4 MILLION WITH 30 PERCENT REQUIRED.

5 I WON'T BELABOR THE POINTS IN THE
6 BACKGROUND AS WE JUST DISCUSSED THEM THROUGH A PRIOR
7 APPLICATION ON THE CLINICAL BACKGROUND. THE VALUE
8 PROPOSITION FOR THIS PARTICULAR APPLICATION, AS GIL
9 ALREADY MENTIONED, IS THAT IT'S A SIMILAR APPROACH,
10 BUT FOR AN ALLOGENEIC, OFF-THE-SHELF THERAPY USING
11 IPS CELLS. AGAIN, THE CIRM PORTFOLIO DOES NOT
12 CURRENTLY HAVE ANY TRANSLATIONAL OR CLINICAL AWARDS
13 FOR LUPUS. AND THE APPLICANT TEAM HAS RECEIVED
14 PRIOR CIRM FUNDING FOR A CANCER INDICATION WITH FOUR
15 MILESTONES PROPOSED AND COMPLETED ON TIME.

16 SO THE APPLICATION BEFORE YOU HAS BEEN
17 RECOMMENDED UNANIMOUSLY BY THE GRANTS WORKING GROUP.
18 AND THE DEI SCORE FOR THIS APPLICATION WAS 8, AND
19 CIRM TEAM RECOMMENDATION CONCURS WITH THE ABOVE FOR
20 THE REQUESTED AWARD AMOUNT OF 7.9 MILLION. THANK
21 YOU.

22 CHAIRMAN IMBASCIANI: THANK YOU. CHAIR
23 WILL ENTERTAIN A MOTION TO ACCEPT THE
24 RECOMMENDATION.

25 VICE CHAIR BONNEVILLE: SO MOVED.

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1 CHAIRMAN IMBASCIANI: BONNEVILLE MOVES.

2 DR. SOUTHARD: SECOND.

3 CHAIRMAN IMBASCIANI: MARVIN, THANK YOU
4 FOR YOUR SECOND. COMMENTS FROM BOARD MEMBERS?
5 SEEING NONE, I'LL ASK THE PUBLIC IF THEY HAVE ANY
6 COMMENTS ON THIS FINAL APPLICATION?

7 MS. MANDAC: THERE ARE NO HANDS RAISED.

8 CHAIRMAN IMBASCIANI: THERE ARE NO HANDS
9 RAISED. RAFAEL.

10 MR. AGUIRRE-SACASA: THANK YOU. THE
11 MOTION IS TO APPROVE THE FUNDING OF APPLICATION
12 16303.

13 MARIA BONNEVILLE.

14 VICE CHAIR BONNEVILLE: YES.

15 MR. AGUIRRE-SACASA: JUDY CHOU.

16 DR. CHOU: YES.

17 MR. AGUIRRE-SACASA: LEONDRA CLARK-HARVEY.

18 DR. CLARK-HARVEY: YES.

19 MR. AGUIRRE-SACASA: MARK FISCHER-COLBRIE.

20 MR. FISCHER-COLBRIE: YES.

21 MR. AGUIRRE-SACASA: FRED FISHER.

22 DR. FISHER: YES.

23 MR. AGUIRRE-SACASA: DAVID HIGGINS.

24 DR. HIGGINS: YES.

25 MR. AGUIRRE-SACASA: VITO IMBASCIANI.

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CHAIRMAN IMBASCIANI: YES.

MR. AGUIRRE-SACASA: STEVE JUELSGAARD.

MR. JUELSGAARD: YES.

MR. AGUIRRE-SACASA: RICH LAJARA.

MR. LAJARA: YES.

MR. AGUIRRE-SACASA: ADRIANA PADILLA.

DR. PADILLA: YES.

MR. AGUIRRE-SACASA: JOE PANETTA.

MR. PANETTA: YES.

MR. AGUIRRE-SACASA: MARV SOUTHARD.

DR. SOUTHARD: YES.

MR. AGUIRRE-SACASA: KAROL WATSON.

DR. WATSON: YES.

MR. AGUIRRE-SACASA: THANK YOU. MOTION CARRIES.

CHAIRMAN IMBASCIANI: MOTION CARRIES. THANK YOU VERY MUCH. AND THANK YOU, HAYLEY, FOR STEERING US THROUGH THESE PRESENTATIONS. APPRECIATE IT.

WE NOW MOVE ON TO AGENDA NO. 10, WHICH IS GOING TO BE A DISCUSSION OF CLINICAL PROGRAM APPLICATION PROCESSES. THE DISCUSSION, WE'RE FORTUNATE TO HAVE NOT ONLY OUR INTERIM PRESIDENT AND CEO JONATHAN THOMAS, BUT FORMER BOARD CHAIR.

MR. THOMAS: THANK YOU, MR. CHAIRMAN,

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1 MADAM VICE CHAIR, MEMBERS OF THE BOARD. WITH NO
2 LACK OF RESPECT TO CHAIR AND VICE CHAIR AND BOARD
3 MEMBER BLUMENTHAL, I WILL LOOK TOWARDS THE SCREEN
4 HERE SO THAT I CAN BE SEEN BY MEMBERS OF THE BOARD
5 ON THE CALL HERE.

6 SO I'M SPEAKING TO YOU TODAY ABOUT AN
7 EXTRAORDINARY CIRCUMSTANCE THAT CONFRONTS CIRM
8 REALLY FOR THE FIRST TIME IN ITS HISTORY HAVING TO
9 DO WITH AN INORDINATELY HIGH NUMBER OF APPLICATIONS
10 IN CLIN, TRAN, AND DISC THAT HAVE COME INTO THE
11 AGENCY OVER THE PAST SEVERAL MONTHS AND THE ISSUES
12 CREATED BY THAT INCREASE.

13 A BIT OF HISTORICAL CONTEXT VERY QUICKLY.
14 AS YOU RECALL, EVER SINCE THE ADVENT OF CIRM 2.0, WE
15 HAVE IN THE CLINICAL SIDE, WHICH IS WHERE I
16 PRIMARILY FOCUS HERE, HAD MONTHLY MEETINGS OF THE
17 GWG TO CONSIDER APPLICATIONS SUBMITTED FOR ITS
18 CONSIDERATION. HISTORICALLY THAT BODY HAS REVIEWED
19 THREE TO FIVE GRANTS PER GWG MEETING. AND THAT
20 ENTITY, AS YOU KNOW, CONSISTS OF A SET NUMBER OF
21 OUTSIDE OF CALIFORNIA STEM CELL AND GENE THERAPY
22 EXPERTS WHO EVALUATE THE SCIENCE AS WELL AS MEMBERS
23 OF THE BOARD, SPECIFICALLY PATIENT ADVOCATES, WHO
24 OPINE ON THE DEI ELEMENTS OF EACH APPLICATION.

25 WITH THE NORMAL THREE TO FIVE NUMBER THAT

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1 WE USUALLY HAVE, MEETING MONTHLY IS STILL A MAJOR
2 CONSIDERATION FOR ALL MEMBERS OF THE GWG AND PATIENT
3 ADVOCATES. IT CAME TO OUR ATTENTION STARTING IN
4 NOVEMBER THAT WE WERE GETTING A DRAMATIC INFLUX OF
5 APPLICATIONS. THE PROCESS IS TYPICALLY APPLICATIONS
6 COME IN AT THE END OF THE MONTH. TWO MONTHS LATER
7 THEY GO TO GWG. WHATEVER IS RECOMMENDED FOR FUNDING
8 IS THEN CONSIDERED BY THE BOARD IN THE SUBSEQUENT
9 MONTH.

10 AT THE END OF NOVEMBER, UNLIKE THE NORMAL
11 THREE TO FIVE APPLICATIONS, WE RECEIVED 20 CLINICAL
12 APPLICATIONS. THOSE WENT TO THE JANUARY GWG. AT
13 THE END OF DECEMBER, WE RECEIVED EIGHT MORE. THESE
14 ARE NEW APPLICATIONS. AND THEN THE END OF JANUARY
15 ANOTHER EIGHT, AND THESE DON'T COUNT THE TIER II
16 RESUBMISSIONS THAT COME IN EACH MONTH AS WELL. SO
17 INSTEAD OF THE THREE TO FIVE PER MONTH, OVER THOSE
18 THREE MONTHS, WE HAD A TOTAL OF 36 NEW APPLICATIONS
19 THAT CAME IN.

20 THIS HAS PLACED A VERY MAJOR BURDEN ON OUR
21 REVIEW TEAM TO HANDLE THIS HIGH VOLUME. I SHOULD
22 SAY PARENTHETICALLY, SIMILARLY, THE HIGH VOLUME OF
23 TRAN AND DISC HAS ITS OWN ISSUES, BUT THOSE WOULD BE
24 DISCUSSED ANOTHER DAY.

25 THE PROBLEM IS PARTICULARLY ACUTE, NOT

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1 JUST FOR THE SCIENTIFIC MEMBERS, BUT FOR OUR PATIENT
2 ADVOCATE MEMBERS OF THE GWG WHO HAVE FULL-TIME JOBS.
3 AND WHEN CONFRONTED WITH THIS EXTREMELY HIGH VOLUME
4 OF APPLICATIONS TO REVIEW IS A REAL PROBLEM.

5 SO THE TEAM HERE HAS DISCUSSED THIS IN
6 GREAT DETAIL AND HAS PROPOSED, GIVEN THAT BURDEN,
7 AND, BY THE WAY, PARENTHETICALLY GIVEN THAT THERE
8 ARE SIGNIFICANT BUDGETARY REPERCUSSIONS OF THESE
9 VERY LARGE VOLUMES OF GRANTS THAT PERTAIN TO WHAT WE
10 HAVE LEFT IN OUR CLINICAL RESEARCH BUDGET IN THE
11 REMAINING FEW MONTHS OF THE FISCAL YEAR AND, OH, BY
12 THE WAY, IF WHAT WE'RE SEEING NOW HAPPENS TO BE A
13 NEW NORMAL GOING FORWARD, WE'LL HAVE SIGNIFICANT
14 REPERCUSSIONS FOR BUDGETARY CONSIDERATION IN FUTURE
15 YEARS AS WELL.

16 THE TEAM ON REFLECTION HAS RECOMMENDED
17 THROUGH THE MEMO THAT WAS POSTED ON THE AGENDA THAT
18 WE NOT ENTERTAIN GRANT APPLICATIONS FOR THE NEXT
19 SEVERAL MONTHS AND RECONSIDER WHERE WE ARE AS OF THE
20 JUNE ICOC MEETING TO GIVE THE TEAM TIME TO CATCH UP
21 ON WHERE WE ARE WITH ALL THESE LARGE NUMBERS OF
22 APPLICATIONS. AND, IN ADDITION, YOU MAY RECALL WE
23 SPOKE TO THE SCIENCE SUBCOMMITTEE ABOUT THE FACT
24 THAT THESE LARGE NUMBERS OF APPLICATIONS AND THE
25 BUDGETARY REPERCUSSIONS REQUIRE THAT WE TAKE A REAL

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1 LOOK AT WHERE WE WANT TO SPEND OUR REMAINING FUNDS
2 GOING FORWARD.

3 AND SO WE ARE IN THE PROCESS OF
4 PRESENTING -- PUTTING TOGETHER A PROPOSAL THAT WILL
5 BE TAKEN TO THE SCIENCE SUBCOMMITTEE AND THE BOARD
6 ON THE AREAS OF FOCUS THAT WE BELIEVE MOST WARRANT
7 CIRM'S ATTENTION GOING FORWARD. AND AS OF THE JUNE
8 ICOC MEETING, THAT PROCESS WILL BE WELL ALONG AND
9 WILL BE ABLE TO HELP INFORM THE DISCUSSION OF WHAT
10 WE PROPOSE AT THAT TIME.

11 SO THE PLAN IS TO NOT ENTERTAIN NEW CLIN1S
12 OR 2S THROUGH JUNE. WE WILL ENTERTAIN GRANTS THAT
13 ARE CURRENTLY IN THE PIPELINE AND ANY TIER II
14 RESUBMISSIONS ON GRANTS THAT RECEIVED THAT SCORE
15 THAT HAVE BEEN IN THE PIPELINE BEFORE AS WELL.

16 IN ADDITION, THE ONE PROGRAM WE ARE
17 PROPOSING TO KEEP ON TRACK, YOU WILL RECALL YOU
18 VOTED FOR THE CLIN4 CONCEPT PLAN. WE HAVE PROPOSALS
19 DUE ON THE CLIN4, AS YOU RECALL, THAT ARE DESIGNED
20 TO PROVIDE FUNDING FOR PROJECTS THAT ARE APPROACHING
21 BLA SUBMISSION. AND WE INSTITUTED THAT PROGRAM IN
22 THE EFFORT TO HELP THEM GET ACROSS THE FINISH LINE.
23 THOSE APPLICATIONS WILL BE RECEIVED ON SCHEDULE IN
24 APRIL, WILL GO TO THE GWG IN JUNE, AND TO THE ICOC
25 IN JULY, WHICH, OF COURSE, IS THE BEGINNING OF THE

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1 NEXT FISCAL YEAR.

2 SO ALL OF THOSE ELEMENTS I JUST DESCRIBED
3 OR RECOUNTED IN THE MEMO, THIS DOES REQUIRE BOARD
4 APPROVAL. THIS IS A RECOMMENDATION OF THE TEAM.
5 AND AS YOU'RE CONSIDERING THIS, I WOULD STRONGLY
6 URGE, ON BEHALF OF THE TEAM, THAT WE STICK TO OUR
7 BUDGETS THAT WE'VE SET FORTH, INCLUDING THIS YEAR.
8 AND WHILE I UNDERSTAND THIS CREATES DIFFICULTIES FOR
9 CERTAIN LABS TO HAVE A SEVERAL-MONTH GAP IN THE
10 PROCESS, I NONETHELESS URGE THAT WE NOT ENTERTAIN
11 ANY EXCEPTIONS TO THIS BECAUSE IF WE DO, THAT WILL
12 SET THE TABLE FOR MANY OTHER REQUESTS TO DO THE SAME
13 AND WILL REALLY CONTRAVENE THE EFFORTS THAT WE ARE
14 PROPOSING HERE. SO WITH THAT, I TURN IT BACK OVER
15 TO YOU, MR. CHAIRMAN, FOR DISCUSSION.

16 CHAIRMAN IMBASCIANI: THANK YOU FOR YOUR
17 PRESENTATION, PRESIDENT THOMAS.

18 VICE CHAIR BONNEVILLE: I JUST WANT TO
19 CLARIFY TWO THINGS. ONE, THIS IS A CHANGE TO THE
20 CONCEPT PLAN, CORRECT?

21 DR. THOMAS: YES, THAT'S THE MOTION THAT
22 WE NEED IS TO CHANGE THE CONCEPT PLAN.

23 VICE CHAIR BONNEVILLE: SECOND, THE
24 EFFECTIVE DATE WOULD BE BACKDATED TO FEBRUARY 1ST.
25 I'M NOT SURE THAT WAS CLEAR, AND I JUST WANT TO MAKE

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1 SURE THAT EVERYBODY IS AWARE THAT THE REQUEST IS
2 THAT IT IS BACKDATED TO FEBRUARY 1ST.

3 DR. THOMAS: IT'S ACTUALLY BACKDATED TO
4 JANUARY 31ST. SO, YES, THAT'S CORRECT. THANK YOU,
5 MADAM VICE CHAIR.

6 CHAIRMAN IMBASCIANI: OKAY. YOU'RE
7 COMFORTABLE WITH THAT CLARIFICATION?

8 DR. THOMAS: YES.

9 CHAIRMAN IMBASCIANI: GREAT. OKAY. SO I
10 THINK THEN WE SHOULD START WITH ENTERTAINING A
11 MOTION ON THE FLOOR.

12 DR. FISHER: SO MOVED.

13 CHAIRMAN IMBASCIANI: THANK YOU, FRED.
14 SECOND?

15 VICE CHAIR BONNEVILLE: SECOND.

16 CHAIRMAN IMBASCIANI: IF YOU CAN STATE
17 THAT MOTION.

18 MR. AGUIRRE-SACASA: YES. THIS IS TO
19 AMEND THE CLIN1 AND CLIN2 CONCEPT PLANS TO HALT THE
20 MONTHLY APPLICATION -- MONTHLY ACCEPTANCE OF
21 APPLICATIONS UNTIL FURTHER NOTICE AS DESCRIBED BY
22 J.T.

23 CHAIRMAN IMBASCIANI: THANK YOU FOR THE
24 STATEMENT. SO THE FLOOR IS OPEN FIRST TO MEMBERS OF
25 THE BOARD TO COMMENT ON THE AMENDMENT.

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1 MS. MANDAC: PAT LEVITT.

2 CHAIRMAN IMBASCIANI: THANK YOU. DR.
3 LEVITT.

4 DR. LEVITT: JUST ONE OR TWO
5 CLARIFICATIONS. THE RETROACTIVE COMPONENT OF THIS,
6 JANUARY 31ST, DOES THAT MEAN THAT THERE ARE NO
7 APPLICATIONS THAT HAVE BEEN RECEIVED DURING THE
8 MONTH OF FEBRUARY? THAT'S A QUESTION. HAVE
9 APPLICATIONS BEEN RECEIVED IN THE MONTH OF FEBRUARY?
10 CAN'T HEAR YOU.

11 DR. CLARK-HARVEY: WE CANNOT HEAR SOUND IN
12 THE ROOM. CAN YOU HEAR US?

13 VICE CHAIR BONNEVILLE: YES.

14 DR. CLARK-HARVEY: NOW WE CAN HEAR YOU.

15 DR. LEVITT: NOW WE CAN HEAR YOU. I CAN'T
16 HEAR J.T.

17 DR. FISHER: WE DIDN'T HEAR THE ANSWER TO
18 THE QUESTION.

19 VICE CHAIR BONNEVILLE: APPLICATIONS THAT
20 HAVE BEEN SUBMITTED IN FEBRUARY. DID YOU HEAR ME?

21 DR. LEVITT: WHAT DID YOU SAY? SAY THAT
22 AGAIN.

23 VICE CHAIR BONNEVILLE: YES, THERE ARE
24 APPLICATIONS THAT HAVE BEEN SUBMITTED IN FEBRUARY.

25 DR. LEVITT: SO THE REQUEST IS NOT TO

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1 PROCESS THOSE APPLICATIONS THAT HAVE ALREADY BEEN
2 RECEIVED IN FEBRUARY; IS THAT CORRECT?

3 DR. FISHER: THAT'S A PORTION OF THE
4 REQUEST.

5 DR. LEVITT: THAT'S A PORTION OF THE
6 REQUEST. OKAY. THAT'S ONE CLARIFICATION.

7 I GUESS THE OTHER CLARIFICATION IS -- I'LL
8 MAKE A COMMENT FIRST. I SEE THREE COMPONENTS TO
9 THIS. ONE IS LOGISTICS THAT WAS DESCRIBED; THAT IS,
10 THE SHEER NUMBER AND HOW THOSE ARE GOING TO BE
11 PROCESSED IN CURRENT STATE.

12 SECOND IS PRIORITIES. THAT IS LIKELY TO
13 BE A FUTURE CONVERSATION.

14 THIRD IS BUDGETS. I JUST WANT TO TRY TO
15 UNDERSTAND THAT. I KNOW THAT WE'VE HAD A HISTORIC
16 RATE OF SUCCESS. AND IS THE IMPLICATION THAT THAT'S
17 PART OF THE RATIONALE TO MAINTAIN THAT HISTORIC
18 LEVEL OF SUCCESS OF APPLICATIONS IN THE 40- TO
19 50-PERCENT RANGE? OR ARE WE IN THE SITUATION, AND
20 MAYBE THAT'S FOR MORE DISCUSSION, WHERE YOU MAKE A
21 WISH GROWING THIS AREA, AND THAT MEANS THERE ARE
22 MORE INVESTIGATORS. THAT MEANS THERE ARE GOING TO
23 BE MORE APPLICATIONS, BUT THERE'S A SET AMOUNT OF
24 MONEY. SO THE ONLY WAY THAT'S GOING TO BE DEALT
25 WITH, JUST LIKE AT NIH OR OTHER EXTRAMURAL FUNDING

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1 AGENCIES, IS THAT THE SUCCESS RATE GOES DOWN. IT'S
2 NOT NECESSARILY A GOAL TO MAINTAIN SUCCESS RATES FOR
3 APPLICATIONS AT STEADY STATE, PARTICULARLY WHEN THE
4 BUDGETS ARE SET. SO TO ME THAT'S A DIFFERENT ISSUE.

5 I'LL JUST SAY I'LL STOP AFTER THIS. I'M
6 CONCERNED ABOUT APPLICATIONS THAT HAVE BEEN
7 SUBMITTED IN GOOD FAITH FOR FEBRUARY AND ARE NOT
8 GOING TO BE PROCESSED AS THIS IS BEING PROPOSED.
9 I'LL STOP THERE.

10 DR. CLARK-HARVEY: THE SOUND IS DISTORTED.
11 YOU'RE GOOD. WE CAN HEAR YOU.

12 DR. FISHER: SOMEBODY'S CELL PHONE IN THE
13 ROOM IS NOT MUTED.

14 VICE CHAIR BONNEVILLE: HOW ABOUT NOW?
15 OKAY?

16 DR. CLARK-HARVEY: YES, THANK YOU.

17 VICE CHAIR BONNEVILLE: I JUST WANTED TO
18 MAKE A COMMENT ABOUT THE PROPOSAL ON THE TABLE.
19 ENTERTAIN INDIVIDUAL EXCEPTIONS AND PUBLIC COMMENT
20 ABOUT INDIVIDUAL APPLICATIONS. IF THE DESIRE IS BY
21 THE BOARD TO HALT ACCEPTANCE OF APPLICATIONS
22 STARTING FEBRUARY 29TH BECAUSE THERE IS A
23 SENSITIVITY TO THOSE WHO HAVE ALREADY PUT AN
24 APPLICATION IN, TO DEAL WITH THAT, IT'S BETTER TO
25 DEAL WITH AS AN AMENDMENT TO THE CONCEPT PLAN. WE

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1 CANNOT ENTERTAIN COMMENTS AND TALK ABOUT INDIVIDUAL
2 EXCEPTIONS BECAUSE THERE HAVE NOT BEEN CONFLICTS
3 THAT HAVE BEEN SCREENED FOR OUR BOARD MEMBERS IN
4 TRYING TO DECIDE IF ONE APPLICATION SHOULD MOVE
5 FORWARD VERSUS ANOTHER.

6 SO I JUST WANTED TO MAKE THAT CLEAR
7 BECAUSE THEY ARE STILL IN THE SYSTEM. WE HAVE NOT
8 SCREENED FOR CONFLICTS FOR THAT. SO WE CANNOT
9 ADDRESS INDIVIDUAL APPLICATIONS AT THIS MOMENT.

10 IF THAT IS THE DESIRE, WE CAN MOVE FORWARD
11 WITH THE POLICY, AND THOSE THINGS CAN BE TALKED
12 ABOUT IN MARCH. SO WE COULD EITHER DECIDE THAT
13 JANUARY 31ST IS THE DATE OR FEBRUARY 29TH IS THE
14 DATE, BUT NOT ON SPECIFIC INDIVIDUAL APPLICATIONS.

15 CHAIRMAN IMBASCIANI: FURTHER COMMENTS
16 FROM BOARD MEMBERS?

17 MR. JUELSGAARD: I HAVE A COMMENT.

18 DR. BARRETT: I HAVE A COMMENT ALSO, VITO.

19 DR. FISHER: AS DO I. AND, VITO, WE CAN'T
20 HEAR YOU.

21 CHAIRMAN IMBASCIANI: SO RIGHT NOW
22 PRESIDENT THOMAS HAS THE FLOOR, AND I SEE ALL OF
23 YOUR HANDS. BOARD MEMBERS WILL BE RECOGNIZED
24 SHORTLY.

25 DR. THOMAS: PAT, CAN YOU HEAR ME?

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1 DR. FISHER: BARELY.

2 DR. THOMAS: HOW IS THAT? IS THAT ANY
3 BETTER?

4 DR. FISHER: YES.

5 DR. THOMAS: OKAY. SO A COUPLE OF
6 COMMENTS. ONE OF THE THINGS WHEN YOU'RE TALKING
7 ABOUT QUALITY OF APPLICATIONS, ONE OF THE THINGS
8 WE'RE VERY CONCERNED ABOUT IS THE QUALITY OF THE
9 REVIEWS AND THAT THE INCREASED BURDEN THAT THIS IS
10 PLACING ON ALL THE REVIEWERS AND PATIENT ADVOCATES
11 WHO ARE PART OF REVIEW RESULTING IN BURNOUT AMONGST
12 REVIEWERS AND COULD AFFECT THE QUALITY OF THE
13 REVIEWS OF EACH OF THE APPLICATIONS. SO THAT'S SORT
14 OF PART AND PARCEL ONE OF THE ISSUES HERE.

15 THE SECOND, JUST SO EVERYBODY KNOWS, BASED
16 ON WHAT WE JUST APPROVED IN THE LAST AGENDA ITEM, WE
17 HAVE 90 MILLION LEFT IN OUR CLIN BUDGET FOR THIS
18 FISCAL YEAR. AND THE APPLICATIONS THAT ARE
19 CURRENTLY UP FOR REVIEW THAT REMAIN TOTAL 105
20 MILLION. OF COURSE, WE DON'T KNOW WHAT'S GOING TO
21 HAPPEN WITH RESPECT TO THOSE IN THE GWG, BUT WE'RE
22 ALREADY IN A PRECARIOUS POSITION WITH RESPECT TO
23 RUNNING THROUGH THE REMAINING CLIN BUDGET THAT WE
24 HAVE FOR THIS FISCAL YEAR, POTENTIALLY WELL BEFORE
25 THE END OF THE FISCAL YEAR ITSELF.

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1 CHAIRMAN IMBASCIANI: STEVE JUELSGAARD.

2 MR. JUELSGAARD: SO THIS IS BASIC. I'M
3 JUST GOING TO ECHO WHAT MR. THOMAS JUST SAID. I
4 THINK THE BIGGEST ISSUE WE'VE GOT IS BUDGET. AND
5 THERE IS A SIGNIFICANT LIKELIHOOD -- WHEN I DO THE
6 TOTAL OF THE NUMBERS, AT LEAST THAT I SAW YESTERDAY
7 IN THE ANSWERS TO QUESTIONS POSED BY DAVID JENSEN,
8 WE HAD A TOTAL OF SUBMISSIONS, THIS IS BOTH NEW
9 APPLICATIONS AND RESUBMISSIONS, OF 166 MILLION OR
10 CLOSE TO 167 MILLION WITH AN APPROVED BUDGET OF 90
11 MILLION.

12 SO ASSUMING THAT WE HAVE A 60-PERCENT
13 APPROVAL RATE OUT OF THAT, WE'RE ALREADY AT 99.6
14 MILLION VERSUS THE 90 MILLION IN THE BUDGET. SO IT
15 DOESN'T FOR ME MAKE A LOT OF SENSE TO SPEND A LOT OF
16 TIME WORKING ON FEBRUARY APPLICATIONS IF WE JUST
17 DON'T HAVE THE BUDGET MONEY. THAT'S NOT A GOOD USE
18 OF ANYBODY'S TIME. SO IF WE'RE GOING TO CONSIDER
19 FEBRUARY APPLICATIONS, LET'S DO IT IF AND WHEN WE
20 KNOW WE HAVE ANY MONEY TO BE ABLE TO SPEND ON THEM.
21 THAT'S MY THOUGHT. THANK YOU.

22 CHAIRMAN IMBASCIANI: THANK YOU, STEVE.
23 KIM BARRETT.

24 DR. BARRETT: YES. I ACTUALLY WANT TO
25 ECHO PAT'S COMMENTS. I'M VERY TROUBLED THAT

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1 INVESTIGATORS WHO IN GOOD FAITH HAVE PUT THEIR
2 BLOOD, SWEAT, AND TEARS INTO WRITING PROPOSALS, TO
3 SUBMITTING THEM, TO JUMPING THROUGH ALL THE HOOPS
4 THAT THEY NEED TO DO TO GET THEIR PROPOSALS OUT THE
5 DOOR, THAT THEN TURN AROUND AND SAY WE'RE NOT EVEN
6 GOING TO LOOK AT YOUR PROPOSALS. I THINK THAT RISKS
7 THE CREDIBILITY OF THE AGENCY, AND I CANNOT SUPPORT
8 ANY PROPOSAL THAT WOULD BE BACKDATED TO THE END OF
9 JANUARY.

10 CHAIRMAN IMBASCIANI: JUDY CHOU. THANK
11 YOU.

12 DR. CHOU: THANK YOU. I ACTUALLY SUPPORT
13 THE PROPOSAL, BUT I JUST WANT TO BRING UP A TOPIC
14 ABOUT, GIVEN OUR BUDGET WORK BE ALWAYS SOMEWHAT
15 LIMITED, AND WE SHOULD ANTICIPATE THE NUMBER OF
16 APPLICANTS OR PARTICULARLY GETTING TO THE CLINICAL
17 PHASE SHOULD BE INCREASED. AND I WOULD SUGGEST WE
18 START LOOKING AT MAYBE IMPLEMENTING SOME SCREENING
19 MECHANISMS. SO KIND OF LIKE INCREASE OUR EFFICIENCY
20 IN REVIEW AND TAKING THIS OPPORTUNITY TO COME TO
21 SOME METHOD THAT WILL BE MUCH MORE SUSTAINABLE DOWN
22 THE LINE.

23 CHAIRMAN IMBASCIANI: THANK YOU, JUDY. I
24 THINK MARVIN SOUTHARD IS NEXT FOLLOWED BY FRED
25 FISHER.

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1 DR. SOUTHARD: I WAS WONDERING HOW MANY
2 APPLICATIONS HAVE BEEN RECEIVED FROM FEBRUARY SO
3 FAR.

4 DR. SAMBRANO: SO WE HAVE TWO THAT WERE
5 SUBMITTED BEFORE THE DEADLINE. IT IS UNUSUAL FOR US
6 TO RECEIVE SUBMISSIONS THIS EARLY. THEY TYPICALLY
7 COME AT THE END OF THE MONTH, BUT WE HAVE RECEIVED
8 TWO AT THIS POINT.

9 CHAIRMAN IMBASCIANI: THANK YOU, GIL.
10 MARVIN, DOES THAT ANSWER YOUR QUESTION?

11 DR. SOUTHARD: IT DOES. IT SEEMS TO ME
12 THAT AT LEAST THOSE TWO OUGHT TO BE CONSIDERED.

13 CHAIRMAN IMBASCIANI: AS MARIA BONNEVILLE
14 MENTIONED, THOUGH, IT'S GOING TO BE DIFFICULT, IF
15 NOT ILLEGAL, FOR US TO CONSIDER THEM BECAUSE WE
16 HAVEN'T DONE THE CONFLICT OF INTEREST CHECK ON BOARD
17 MEMBERS.

18 FRED.

19 DR. FISHER: YEAH. I JUST WANT TO
20 REITERATE SUPPORT FOR THE ORIGINAL PROPOSAL. IT'S
21 NOT COMING TO US LIGHTLY. WE UNDERSTAND THE
22 IMPLICATIONS. OUR SYMPATHIES CAN GO OUT TO THOSE
23 WHO ARE VERY PROACTIVE IN GETTING THEIR APPLICATIONS
24 IN. BUT SUBMITTING AN APPLICATION IS NO GUARANTEE
25 THAT IT WILL BE REVIEWED AND CERTAINLY NO GUARANTEE

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1 IT WILL BE FUNDED. AND IT'S NOT AS IF, CORRECT ME
2 IF I'M WRONG, IT'S NOT AS IF THOSE APPLICATIONS WILL
3 GO INTO THE TRASH CAN. AT THE POINT AT WHICH WE ARE
4 READY TO RESTART THE CONSIDERATION OF APPLICATIONS,
5 THOSE APPLICATIONS CAN BE CONSIDERED IN DUE COURSE
6 WITH ANY OTHERS THAT ARE THERE.

7 SO I DON'T HAVE ANY CONCERNS WHATSOEVER
8 ABOUT US AS A MATURE FUNDING ORGANIZATION SAYING
9 HOLD ON. WE'RE AT A NEW PLACE, AND WE NEED TO MAKE
10 NEW CONSIDERATIONS. AND THOSE CONSIDERATIONS MIGHT
11 PROVIDE SOME INCONVENIENCE TO SOME, BUT IN THE
12 INTEREST OF A MATURE ORGANIZATION RUNNING THE WAY IT
13 NEEDS TO, WE NEED TO SUPPORT THIS PROPOSAL. AND
14 SOMEBODY TELL ME IF I'M WRONG, THAT THOSE
15 APPLICATIONS CAN BE HELD AND THOSE APPLICANTS CAN BE
16 QUERIED. SHOULD THE OPPORTUNITY TO REQUEST FOR
17 FUNDING REOPEN, THEY CAN BE ASKED IF THEIR
18 APPLICATIONS WANT TO BE CONSIDERED, OR THEY CAN
19 SIMPLY RESUBMIT THEM AT THAT TIME.

20 A SIMPLE MESSAGE THAT WE ARE NOT ACCEPTING
21 APPLICATIONS AS OF THIS DATE. THEREFORE, YOUR
22 APPLICATION WILL BE HELD UNTIL SUCH TIME AS WE
23 RESUME OUR PROCESS. THAT SEEMS COMPLETELY
24 REASONABLE GIVEN THE NATURE OF THIS ORGANIZATION AND
25 THE WORK THAT NEEDS TO BE DONE.

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1 CHAIRMAN IMBASCIANI: THANK YOU, FRED.
2 WE'RE GOING TO HEAR NEXT FROM SUZANNE SANDMEYER
3 FOLLOWED BY JOE PANETTA.

4 DR. SANDMEYER: THANK YOU. SO I'D LIKE TO
5 ECHO SOME OF THE COMMENTS MADE BY OTHER MEMBERS,
6 STARTING WITH PAT LEVITT. I FEEL THAT IT'S A RATHER
7 UNUSUAL MOVE FOR A FUNDING AGENCY SUCH AS OURS TO
8 JUST SUSPEND FUNDING. AND SO I'M WONDERING IF WE
9 HAVE CONSIDERED MECHANISMS SUCH AS ARE USED AT NIH
10 FOR TRIAGING GRANTS, RECOGNIZING THE INCREDIBLE
11 STRESS THAT THIS INCREASE IN APPLICATIONS HAS PUT ON
12 STAFF AND LAY MEMBERS OF THE REVIEW GROUPS.

13 SO THERE COULD BE TWO LEVELS OF REVIEW
14 THAT WOULD REDUCE THE EFFORT THAT HAS TO BE PUT IN
15 PER GRANT BASICALLY.

16 SECONDLY, I THINK WE HAVE TO CONSIDER
17 CHANGING THE PERCENT, THE SO-CALLED SUCCESS RATE,
18 MEANING THE FUNDING RATE HERE, AND THAT MIGHT
19 IMPROVE ACTUALLY THE QUALITY OF WHAT WE FUND. SO
20 I'M NOT COMPLETELY CLEAR ON WHY THAT CAN'T BE
21 IMPLEMENTED IMMEDIATELY TO ALLOW GRANTS IN THE
22 PIPELINE TO CONTINUE TO COMPETE, BUT BE UNDER A MORE
23 COMPETITIVE CONDITION. I'M A LITTLE CONCERNED ABOUT
24 WHAT HAPPENS IN JUNE IF WE OPEN FUNDING AGAIN. I
25 THINK THOSE GRANTS AND THE PROGRAMS THAT ARE IN THE

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1 PIPELINE, PARTICULARLY FOR CLINICAL OPERATIONS, WILL
2 CONTINUE TO BE THERE AND WE COULD BE FACING A REAL
3 TSUNAMI OF APPLICATIONS AT THAT POINT.

4 I JUST WANT TO CONCLUDE WITH A QUESTION
5 FOR CLARIFICATION. IF WE VOTE IN FAVOR OF THE
6 JANUARY DEADLINE, DOES THAT MEAN THAT WE WOULD HAVE
7 ANOTHER VOTE IN FAVOR OF ACCEPTING ONES THAT ARE
8 ALREADY IN THE PIPELINE FOR FEBRUARY? THANK YOU.

9 CHAIRMAN IMBASCIANI: YES. THANK YOU, DR.
10 SANDMEYER.

11 I THINK TO PARTIALLY ANSWER YOUR QUESTION
12 AT THE END THERE, WE'RE NOT ABLE TO FOR THE SAME
13 REASON THAT WE SPOKE TO BEFORE BECAUSE OF CONFLICTS.
14 BUT IT PROBABLY WILL COME ABOUT TO THAT AT SOME
15 POINT.

16 JOE PANETTA, FOLLOWED BY --

17 DR. THOMAS: CAN I JUST ADD ONE THING?

18 CHAIRMAN IMBASCIANI: YES.

19 DR. THOMAS: HOLD ON ONE SECOND. SUZANNE,
20 THANK YOU FOR YOUR COMMENTS.

21 I JUST WANTED TO ASSURE YOU THAT THE TEAM
22 IS IN THE PROCESS OF EVALUATING THE PROCESS ITSELF
23 ON MATTERS SUCH AS THOSE THAT YOU RAISE, AND WE WILL
24 BE GETTING BACK TO THE BOARD WITH SUGGESTIONS ON HOW
25 THAT PROCESS CAN BE IMPROVED. AGAIN, THIS IS ALL

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1 ASSUMING THIS IS SORT OF A NEW NORMAL, WHICH THREE
2 MONTHS OF DATA SEEMS TO INDICATE. SO WE'LL BE
3 GETTING BACK TO YOU ON THAT. THANK YOU VERY MUCH
4 FOR THOSE SUGGESTIONS.

5 CHAIRMAN IMBASCIANI: THANK YOU, DR.
6 THOMAS. JOE PANETTA PLEASE.

7 MR. PANETTA: THANK YOU, VITO. I FIND
8 MYSELF IN AN INTERESTING POSITION BECAUSE RUNNING
9 THE LIFE SCIENCE ASSOCIATION HERE IN CALIFORNIA WITH
10 SO MANY MEMBERS AT RESEARCH INSTITUTIONS AND
11 UNIVERSITIES, I'VE HEARD FROM THEM ALREADY,
12 ENCOURAGING US NOT TO STOP THIS PROCESS. BUT I
13 DON'T SERVE ON THIS BOARD AS THE CEO OF BIOCOM
14 CALIFORNIA, AND I'VE SERVED ON THE BOARD FOR A LONG
15 TIME AS A MEMBER OF THE GRANTS REVIEW COMMITTEE AS
16 WELL.

17 I THINK SOMETHING THAT J.T. SAID IS REALLY
18 OF PRIMARY IMPORTANCE. THE ONE THING THAT I'VE SEEN
19 OVER THE YEARS THAT WE'VE BEEN ENGAGED IN REVIEWING
20 AND APPROVING APPLICATIONS IS THAT WE HAVE A HIGH
21 DEGREE OF CONFIDENCE IN THE LEVEL OF RIGOR AND
22 DETAIL AND SCIENCE THAT'S GONE INTO THOSE REVIEWS BY
23 THE STAFF AND BY THE OUTSIDE REVIEWERS AS WELL. I'M
24 ALL FOR CREATING A COMPETITIVE PROCESS AND AN EVEN
25 MORE COMPETITIVE PROCESS. I AGREE WITH SOME OF WHAT

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1 SUZANNE SAID. BUT IT'S SENSELESS, I THINK, TO
2 CONTINUE TO ACCEPT APPLICATIONS AND TO CRAM THEM
3 INTO THE PIPELINE AND TO TRY TO IN SOME WAY CREATE
4 MORE EFFICIENCY TO GET THAT PROCESS. TO ME THAT
5 JUST ISN'T A WORKABLE SOLUTION. SO I SUPPORT THE
6 PROPOSAL THAT J.T. MADE. THANKS.

7 CHAIRMAN IMBASCIANI: THANK YOU, JOE.
8 BEFORE WE GO ON TO MONICA, WE HAVE BREAKING NEWS. I
9 THINK, GIL, YOU WANT TO CHANGE SOMETHING.

10 DR. SAMBRANO: SO WE WERE JUST LOOKING AT
11 WHAT WE HAVE AS OF TODAY IN TERMS OF SUBMITTED
12 APPLICATIONS FOR FEBRUARY. AND IT'S ACTUALLY FIVE.

13 CHAIRMAN IMBASCIANI: THANK YOU, GIL. WE
14 HAVE FIVE APPLICATIONS. MONICA FOLLOWED BY KIM
15 BARRETT AND THEN MARK FISCHER-COLBRIE.

16 DR. CARSON: I REALLY ENJOYED THE
17 DISCUSSION. I CAN HEAR ALL THE POINTS. I SERVE AS
18 SOMEBODY IN MY ROLE WHO IS VERY BUDGET CONSCIOUS,
19 AND I DO THINK THESE ARE APPROPRIATE TO CONSIDER
20 MEASURES. HOWEVER, I AM QUITE DISTURBED THAT WE ARE
21 BACKDATING THIS WITHOUT FORENOTICE. I THINK THAT IS
22 TROUBLESOME.

23 I DO AGREE WITH ALL THE THINGS, ESPECIALLY
24 MOSTLY RECENTLY, SAID BY DR. SANDMEYER ABOUT
25 INCREASED VARIOUS TRIAGE, ALL THE THINGS. I THINK

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1 THERE ARE LOTS OF MECHANISMS WE COULD GO TO THAT ALL
2 OF US WHO HAVE BEEN ON STUDY SECTIONS AND VARIOUS
3 FUNDING BOARDS COULD BE APPLIED HERE. HOWEVER, IT
4 IS TROUBLESOME, I FEEL, ABOUT BACKDATING THIS. IF
5 THIS PROPOSAL IS VOTED ON, IT FEELS MUCH MORE
6 COMFORTABLE TO SAY AS OF TODAY OR FORWARD PROGRESS
7 THAT THIS BECOMES INTO EFFECT.

8 I WON'T REITERATE EVERYBODY ELSE'S POINTS,
9 BUT I HEAR ALL THOSE POINTS AND WHY WE NEED TO BE
10 MAKING SOME CHANGES. THANK YOU.

11 CHAIRMAN IMBASCIANI: MONICA, THANK YOU.
12 IT'S KIM. YES, KIM BARRETT.

13 DR. BARRETT: I'D JUST LIKE TO POINT OUT I
14 THINK -- I CAN'T REMEMBER NOW WHO SAID THIS, MAYBE
15 IT WAS FRED, THAT THIS WAS AN INCONVENIENCE. BUT
16 IT'S MUCH MORE THAN INCONVENIENCE. AND WE HAVE BEEN
17 FOCUSING EXPLICITLY ON TRANSLATING DISCOVERIES INTO
18 THE CLINICAL REALM. SO I CAN ABSOLUTELY UNDERSTAND
19 THE BURDEN OF REVIEW, AND I AM VERY MUCH OF THE
20 OPINION THAT WE NEED TO EXPLORE MECHANISMS IN TERMS
21 OF THE COMPETITIVENESS OF THE PROCESS, THE LACK OF
22 GRANULARITY IN THE SCORING SYSTEM, ET CETERA, ET
23 CETERA, AND USING OTHER MECHANISMS TO REDUCE THE
24 LOAD ON THE REVIEWERS.

25 AS MONICA JUST SAID, BACKDATING THIS

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1 PROPOSAL IS REALLY A LOSS OF TRUST AND A LOSS OF
2 FAITH. AND I'M HEARING EVERYTHING THAT EVERYBODY IS
3 SAYING, BUT I WOULD RATHER SEE THE PROPOSALS THAT
4 HAVE BEEN SUBMITTED REVIEWED, EVEN IF THEY HAVE TO
5 BE HELD OVER FOR FUNDING TO THE NEXT FISCAL YEAR,
6 THAN NOT REVIEWING THEM AT ALL BECAUSE WHEN THEY
7 COME BACK, IF THEY WERE ASKED TO COME BACK OR THEY
8 WERE HELD FOR REVIEW AT SOME LATER DATE, THERE WILL
9 BE A PENT-UP DEMAND OF ALL THE PROPOSALS THAT
10 HAVEN'T SUBMITTED. AND SO WE'LL BE A DIFFERENT
11 COMPETITION, ESPECIALLY IF WE CHANGE THE HISTORICAL
12 SUCCESS RATE THAN THE ONE THAT THEY THOUGHT THEY
13 WERE SUBMITTING TO.

14 CHAIRMAN IMBASCIANI: THANK YOU, DR.
15 BARRETT. MARK FISCHER-COLBRIE.

16 MR. FISCHER-COLBRIE: JUST A COUPLE
17 COMMENTS. FIRST OF ALL, A GOOD CHUNK OF THIS IS IN
18 RESPONSE TO THE FACT THAT THIS IS CLEARLY A TSUNAMI.
19 THIS ISN'T JUST A CONDITION OF 2X INCREASE IN THE
20 NUMBER OF APPLICATIONS. IN SOME AREAS WE'RE LOOKING
21 CLOSER TO 10X IF I'M NOT MISTAKEN.

22 SO THAT IS CLEARLY A SITUATION THAT WILL
23 HAVE A DRAMATIC IMPACT ON THE ABILITY TO CAREFULLY
24 EVALUATE THESE PROPOSALS. SO THAT CAUSES A LOT OF
25 RISK.

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1 THE SECOND ELEMENT HERE IS THERE IS NO
2 TARGETED SUCCESS RATE. THAT'S A HISTORICAL NUMBER.
3 I JUST WANTED TO BRING THAT OUT BECAUSE I DON'T WANT
4 EVERYBODY TO HAVE A MISAPPREHENSION ABOUT THAT.
5 THAT'S JUST A TRACKING MECHANISM THAT WAS USED TO
6 FACILITATE A POTENTIAL FUTURE-FORWARD BUDGET
7 ANALYSIS ABOUT, YES, WITH THE TSUNAMI OF
8 APPLICATIONS, THAT HISTORICAL RATE IS APPLIED THAN
9 HERE ARE THE DOLLARS. SO JUST A CLARIFICATION
10 BECAUSE I'VE HEARD A COUPLE TIMES THAT THERE SEEMS
11 TO BE AN IMPRESSION THAT WE MIGHT BE TRYING TO
12 TARGET A CERTAIN SUCCESS NUMBER. AND TO MY
13 KNOWLEDGE, THAT'S NOT AT ALL WHAT IS INVOLVED IN THE
14 PROCESS AND JUST WANTED TO MAKE SURE THAT THAT WAS
15 UNDERSTOOD. SO THANKS.

16 CHAIRMAN IMBASCIANI: THANK YOU, MARK.
17 FRED FISHER IS NEXT.

18 DR. FISHER: SO I THINK IT'S COMPLETELY
19 UNWORKABLE TO REVIEW APPLICATIONS THAT MIGHT, IN
20 FACT, CONSUME EVERYTHING WE HAVE LEFT FOR THE FISCAL
21 YEAR. I THINK IT'S ALSO UNWORKABLE TO REVIEW
22 APPLICATIONS, HAVE THEM SCORED UNDER ONE PARADIGM
23 AND HOLD ON TO THEM, AND THEN HAVE A DIFFERENT
24 PARADIGM FOR APPLICATIONS THAT CAME IN AND TOO BAD
25 FOR THOSE OF YOU THAT WEREN'T PROACTIVE IN GETTING

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1 YOURS IN, AND NOW WE'VE GOT SETS OF APPLICATIONS
2 THAT FALL UNDER TWO DIFFERENT POTENTIAL SCORING AND
3 REVIEW RUBRICS.

4 SO WE HAVE A LIMITED BUDGET. WE HAVE
5 TREMENDOUS AWARENESS THAT IS GENERATING AN HISTORIC
6 NUMBER OF PROPOSALS, AND WE NEED TO CHANGE OUR
7 PROCESS. AND CHANGING THE PROCESS MIDSTREAM IS
8 RESPONSIBLE. IT'S NOT OFFENSIVE. IT MIGHT BE
9 UNPLEASANT. AND CERTAINLY I'VE RECEIVED PLENTY OF
10 LETTERS FROM FUNDING ORGANIZATIONS THAT SAY, THANKS
11 FOR YOUR GREAT PROPOSAL. UNFORTUNATELY WE DON'T
12 HAVE THE MONEY TO FUND ALL THE GREAT APPLICATIONS
13 THAT CAME IN. SO THIS IS NOTHING NEW IN THE WORLD
14 OF GRANTING.

15 AND I WOULD JUST REITERATE THAT WE NEED TO
16 BE -- AS A BOARD, WE'RE HERE TO BE RESPONSIBLE
17 STEWARDS FOR THE ORGANIZATION. WE'RE NOT HERE TO
18 CATER TO THE PEOPLE WHO MAKE APPLICATIONS. WE'RE
19 HERE TO HAVE A CLEAR PROCESS THAT IS ONE THAT IS IN
20 ALIGNMENT WITH THE NEEDS OF THE ORGANIZATION. AND
21 APPLICANTS WILL HAVE TO ADAPT TO THAT. THAT'S JUST
22 THE REAL WORLD. THANK YOU.

23 CHAIRMAN IMBASCIANI: THANKS, FRED.
24 FOLLOWED BY DR. LEVITT.

25 DR. LEVITT: SO THE CONVERSATIONS HAVE

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1 BEEN MOSTLY IN PRESENT TENSE AND FUTURE TENSE. AND
2 SO THE ISSUE I RAISED IS ABOUT PAST TENSE. PAST
3 TENSE IS WHEN THINGS ARE APPLIED RETROACTIVELY. SO,
4 FRED, WHAT YOU JUST SAID IS WHAT WE ALL LIVE WITH,
5 THOSE OF US WHO SUBMIT GRANT APPLICATIONS, THAT
6 THERE'S JUST NOT ENOUGH MONEY TO FUND THINGS THAT
7 MIGHT BE CONSIDERED TO BE FUNDABLE. SO THAT'S NOT
8 THE ISSUE AT ALL.

9 I UNDERSTAND THE LOGISTICS. I'M JUST
10 DISTURBED ABOUT THE CONVERSATIONS BEING PRESENT AND
11 FUTURE, AND THE PROPOSAL IS TO GO BACK IN TIME.
12 THAT'S THE ONLY ISSUE THAT I HAVE.

13 BUT IN TERMS OF DEALING WITH THE
14 LOGISTICS, I UNDERSTAND THAT AND A TEMPORARY
15 SOLUTION TO DEAL WITH WHAT'S IN THE PIPELINE NOW. I
16 CONSIDER A GRANT THAT'S BEEN SUBMITTED IN THE
17 PIPELINE, WHAT'S IN THE PIPELINE NOW. SO I'M OKAY
18 WITH A DECLARATIVE THAT THIS STARTS AT NOON,
19 FEBRUARY 22D. BUT I DON'T LIKE TO PERSONALIZE
20 THINGS, BUT I'VE BEEN SUBMITTING GRANTS FOR 40
21 SOMETHING YEARS, AND I OFTEN RECEIVE, FRED, AS YOU
22 SAID, DISAPPOINTING LETTERS SAYING THAT IT WAS A
23 GREAT PROPOSAL, BUT WE JUST DON'T HAVE ENOUGH FUNDS.
24 THAT'S EXPECTED. WHAT'S NOT EXPECTED AND WHICH HAS
25 NEVER HAPPENED, AT LEAST ANYBODY THAT I KNOW OR

1 MYSELF, IS TO HAVE A GRANT SUBMITTED AND NOT
2 PROCESSED.

3 I DON'T THINK THERE'S ANYTHING -- I DON'T
4 KNOW WHAT THE GUIDELINES ARE OF WHETHER THE
5 PROPOSITIONS DEFINE THAT GRANTS HAVE TO BE REVIEWED
6 WITHIN A CERTAIN PERIOD OF TIME, BUT THERE ARE
7 MECHANISMS TO BE ABLE TO DEAL WITH PRESENT AND
8 FUTURE AND NOT GO BACK TO PAST. THAT'S THE ONE
9 ISSUE THAT I HAVE PROBLEMS WITH.

10 DR. FISHER: IF I COULD JUST RESPOND
11 QUICKLY TO PAT. I THINK WE ARE DEALING WITH A
12 BUDGET ISSUE BECAUSE THE REALITY IS THOSE FIVE
13 PROPOSALS COULD CONSUME THE ENTIRE BUDGET FOR THE
14 REMAINDER OF THE FISCAL YEAR. SO ONE WAY OR ANOTHER
15 WE'RE GOING TO BE CHANGING OUR PROCESS. THE
16 QUESTION IS DO WE WANT TO BE OUT OF MONEY FOR THE
17 REMAINDER OF THE FISCAL YEAR, OR DO WE WANT TO
18 CHANGE THE WAY WE CONSIDER HOW WE SPEND THE MONEY
19 BECAUSE ONE WAY OR ANOTHER WE ARE RUNNING OUT OF
20 MONEY.

21 DR. LEVITT: FRED, I THINK THE GRANTS ARE
22 REVIEWED. I DON'T HAVE INSIGHT INTO FUTURE STATE
23 ABOUT HOW ANY GRANT WILL DO. THE GRANTS TEAM MAKES
24 RECOMMENDATIONS TO THE BOARD, AND THEY PRIORITIZE
25 GRANTS. AND SO THAT'S GOING TO HAPPEN. NO MATTER

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1 HOW MANY THERE ARE, THERE'RE GOING TO BE PRIORITIES
2 THAT ARE GOING TO BE SET BY THE GRANTS TEAM THAT IS
3 GOING TO COME TO THE BOARD AND THE BOARD WILL LOOK
4 AT THOSE GRANTS AND SAY WE AGREE OR WE DISAGREE.
5 THAT'S THE PROCESS THAT WE WORK UNDER. I DON'T KNOW
6 WHAT'S GOING TO HAPPEN. ALL THE GRANTS MAY BE
7 TERRIBLE OR ALL THE GRANTS MAY BE GREAT, AND THEN
8 THERE ARE HARDER DECISIONS TO MAKE.

9 BUT THE PROCESS IS THE PROCESS OF
10 RECOMMENDATIONS SET BY THE GRANTS TEAM, PRIORITIES
11 THAT THE ORGANIZATION HAS, AND THEN PRESENTATIONS TO
12 THE BOARD, AND THEN THE BOARD HAS TO MAKE SOMETIMES
13 VERY DIFFICULT DECISIONS ABOUT WHAT CAN BE AFFORDED
14 WITHIN A FISCAL YEAR. BUT IT'S A DECISION THAT I
15 THINK WE ALL AGREE WE CAN DO, AND THERE WILL BE
16 DISAPPOINTED PEOPLE WHO WON'T -- SCIENTISTS WHO
17 WON'T GET FUNDED, BUT THAT HAPPENS THROUGHOUT OUR
18 LIVES AS SCIENTISTS, TO BE HONEST. BUT NOT
19 PROCESSING SOMETHING THAT ALREADY EXISTS TO ME IS A
20 REAL CHALLENGE FOR ME TO SWALLOW.

21 CHAIRMAN IMBASCIANI: THANK YOU. WE HAVE
22 A FEW MORE BOARD MEMBERS TO SPEAK. JUDY FOLLOWED BY
23 LEONDRA. THANK YOU.

24 DR. GASSON: THANK YOU. I WON'T REPEAT
25 WHAT PAT SAID, BUT I AGREE WITH THE RATIONALE THAT

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1 THOSE THAT HAVE BEEN SUBMITTED SHOULD BE PROCESSED
2 BY THE ORGANIZATION. AND I'M ALSO TROUBLED BY
3 RETROACTIVELY STOPPING PROCESSING OF APPLICATIONS
4 WHEN WE DO HAVE SOME THAT ARE ALREADY IN THE
5 PIPELINE.

6 HAVING SAID THAT, I JUST WANT TO
7 COMPLIMENT J.T. AND THE STAFF AND THE LEADERSHIP
8 TEAM FOR RECOGNIZING THIS ISSUE AND TAKING THE BOLD
9 STEP TO SAY WE HAVE TO STOP AND ASK OURSELVES SOME
10 VERY HARD QUESTIONS BEFORE WE CAN GO FORWARD IN
11 TERMS OF PROCESS, PRIORITIES, AND THOSE TYPES OF
12 THINGS. SO THANK YOU FOR AGGRESSIVELY MANAGING THIS
13 PROCESS RIGHT NOW.

14 IN SOME WAYS I SUPPOSE WE SHOULD HAVE SEEN
15 THIS COMING BECAUSE FOR ALL OF THOSE 20 YEARS WHEN
16 WE WERE FUNDING THE BASIC RESEARCH, THE
17 TRANSLATIONAL RESEARCH, OF COURSE, OUR HOPE WAS THAT
18 IT WOULD LEAD TO CLINICAL TRIALS. AND SO NOW WE
19 WILL FIND A WAY TO DEAL WITH THAT. THANK YOU.

20 CHAIRMAN IMBASCIANI: THANK YOU, JUDY.

21 I'M GOING TO -- WE HAVE TWO BOARD MEMBERS
22 YET TO SPEAK. LEONDRA IS GOING TO BE FOLLOWED BY
23 KEITH. I DO WANT TO EXERCISE A SORT OF PREROGATIVE
24 OF THE CHAIR TO ASK THAT WE TAILOR THIS BY THE
25 CLOCK. WE CAN'T DEVOTE TOO MANY MORE MINUTES TO

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1 THIS. WE DON'T EVEN HAVE A MOTION YET ON THE TABLE.

2 LEONDRA.

3 DR. CLARK-HARVEY: THANK YOU SO MUCH.

4 I'LL BE QUICK.

5 DR. FISHER: WE DO HAVE A MOTION ON THE

6 TABLE. I MADE IT.

7 CHAIRMAN IMBASCIANI: THAT'S RIGHT, FRED.

8 WE HAVE THE PRELIMINARY MOTION. WE DON'T HAVE ANY

9 AMENDMENTS YET. THANK YOU. LEONDRA, WHERE ARE YOU?

10 DR. CLARK-HARVEY: SURE. I'M RIGHT HERE.

11 CAN YOU HEAR ME?

12 CHAIRMAN IMBASCIANI: YES, WE CAN. GO

13 AHEAD.

14 DR. CLARK-HARVEY: OKAY. GREAT. SO THANK

15 YOU. I'LL BE BRIEF. SO INTERESTINGLY ENOUGH,

16 DURING THIS MEETING I RECEIVED AN EMAIL ON A COUPLE

17 OF GRANTS THAT I HAVE APPLIED FOR AND WAITING TO

18 HEAR BACK ABOUT. AND I GOT THE NOTE THAT SAID, WE

19 NEED SOME EXTRA TIME. WE'RE SORRY. WE KNOW WE'RE

20 PAST A DEADLINE, AND WE'LL GET BACK TO YOU. AND I

21 WOULD SAY THAT THAT IS ACTUALLY A PRETTY ROUTINE

22 THING THAT HAPPENS UNFORTUNATELY WHEN EITHER AN

23 ORGANIZATION DOESN'T HAVE THE RESOURCES OR THE TIME

24 RESOURCES OR THE PERSON POWER. AND SO IN THIS

25 INSTANCE, I WOULD RATHER, AS UNFORTUNATE AS IT IS,

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1 WAIT TO DO A THOROUGH REVIEW WHEN WE HAVE ENOUGH
2 TIME AND MAYBE EXTRA FUNDS.

3 I'M NOT HEARING, AND MAYBE I HAVE THIS
4 INCORRECT, BUT I'M NOT HEARING, OH, THEY'RE IN THE
5 PIPELINE AND NOW WE'RE NOT GOING TO FUND THEM, OR
6 THEY'RE GOING TO HAVE TO RE-APPLY. WHAT I'M HEARING
7 IS IT'S A DELAY IN REVIEW OF THOSE APPLICATIONS.
8 AND WHILE DELAYS ARE UNFORTUNATE, THEY ARE NOT
9 UNPRECEDENTED. AND IF IT'S IN THE BEST INTEREST OF
10 THE STAFF AND THE BOARD MEMBERS AND WHATNOT IN TERMS
11 OF RESOURCES AND TIME, WHY WOULD WE NOT MAKE SURE
12 THAT WE CAN DO A THOROUGH REVIEW AT A LATER TIME
13 PERIOD VERSUS RUSH THROUGH?

14 AS AN APPLICANT, PUTTING MYSELF IN THE
15 SHOES OF FOLKS THAT APPLY, AND AGAIN I JUST GOT A
16 MESSAGE OR TWO, I GET IT. IT'S DISAPPOINTING.
17 YOU'RE WAITING ON PINS AND NEEDLES. AND IF RUSHING
18 IT MEANS THAT MY APPLICATION MAY HAVE LESS OF A
19 CHANCE BECAUSE OF LESS FUNDING OR TIMING OR
20 WHATEVER, THEN I'LL WAIT.

21 SO I'M JUST SHARING THAT PERSPECTIVE. I
22 HAVE BEEN ONE OF THE INDIVIDUALS THAT HAVE HAD TO
23 REVIEW A LOT OF APPLICATIONS THIS YEAR JUST BECAUSE
24 OF WHERE WE'RE AT. AND SO I DO THINK THAT IT'S
25 RESPONSIBLE TO WAIT AND TO DELAY THIS UNTIL WE'RE AT

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1 AN POSITION WHERE WE CAN DO THIS FULLY. THANK YOU.

2 CHAIRMAN IMBASCIANI: THANK YOU, LEONDRA.
3 BOARD MEMBER YAMAMOTO.

4 DR. YAMAMOTO: FIRST LET ME APOLOGIZE. I
5 HAD TO JUMP OFF OF THIS MEETING FOR A LITTLE WHILE
6 TO TAKE ANOTHER CALL. SO I MAY HAVE MISSED THE
7 CRITICAL PARTS OF THE DISCUSSION. BUT I'LL TRY TO
8 BE QUICK AS WELL TO SAY THAT I REALLY CONCUR WITH
9 WHAT PAT AND OTHERS HAVE SAID ABOUT TRYING TO
10 GENERATE THIS RETROACTIVE ACTION.

11 I THINK THAT THINGS THAT ARE IN THE
12 PIPELINE REALLY HAVE TO BE PROCESSED. AND J.T. MAY
13 HAVE MENTIONED THIS WHILE I WAS OUT, BUT HE AND I,
14 AND I'VE ALSO TALKED WITH LARRY GOLDSTEIN ABOUT
15 THIS, HAVE TALKED ABOUT CHANGES IN OUR PROCEDURES
16 THAT COULD INCREASE THE EFFICIENCY WITH WHICH THE
17 GRANT REVIEWS ARE DONE. THERE'S SEVERAL WAYS,
18 SUZANNE MENTIONED A FEW OF THEM, SEVERAL APPROACHES
19 THAT CAN BE TAKEN. SO FOR FUTURE ACTION, I THINK WE
20 CAN INCREASE THE EFFICIENCY, BUT DOING THIS
21 RETROACTIVE DECISION NOT TO REVIEW APPLICATIONS, I
22 THINK, IS UNFAIR AND WOULD BE SOMETHING THAT I, AT
23 LEAST, HAVE NOT EXPERIENCED BEFORE. I HEAR,
24 LEONDRA, WHAT YOU'RE SAYING, BUT IT'S SOMETHING THAT
25 I AND PAT AND OTHERS HAVE NOT EXPERIENCED BEFORE. I

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1 THINK IT WOULD BE REALLY VIEWED AS REALLY PATENTLY
2 UNFAIR FOR THE INVESTMENT OF TIME AND WORK THAT HAS
3 GONE INTO PREPARATION OF THE APPLICATIONS.

4 AND REALLY IN REALITY, DEFERRING IN THIS
5 WAY WOULD SIMPLY BE PUTTING OFF A WORSE TSUNAMI WHEN
6 THE WELL IS OPENED BACK UP AGAIN. SO I WOULD SAY
7 THAT I CONCUR WITH THE POINTS THAT PAT AND OTHERS
8 HAVE RAISED AND JUST SAY THAT THERE ARE WAYS TO
9 INCREASE THE EFFICIENCY AND MAYBE EVEN THE FAIRNESS
10 OF THE REVIEW PROCESS GOING FORWARD.

11 FINALLY, THERE'S NOTHING GUARANTEED BY ANY
12 AGENCY, INCLUDING CIRM, ABOUT A PAYLINE. THESE
13 THINGS CHANGE. THE AGENCY HAS NO CONTROL OVER HOW
14 MANY APPLICATIONS COME IN. AND AT THE END OF THE
15 DAY, IT'S A FUNCTION OF THE MONEY THAT IS AVAILABLE
16 IS WHAT DETERMINES THE PAYLINE. AND NO APPLICANT IS
17 EVER GUARANTEED A PAYLINE OR SAID THAT THIS IS THE
18 WAY THAT WE -- THIS IS THE FRACTION OF APPLICATIONS
19 THAT WE'LL PAY. SO I DON'T THINK THAT'S A PROBLEM
20 COMING IN.

21 I THINK WHAT WE NEED TO DO IS INCREASE THE
22 EFFICIENCY WITH WHICH WE PROCESS APPLICATIONS. THAT
23 CAN BE EASILY DONE, BUT IT HAS TO BE DONE IN THE
24 FUTURE, NOT IN THE PAST.

25 CHAIRMAN IMBASCIANI: THANK YOU, KEITH.

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1 LISTEN, I'M LOOKING AT THE CLOCK, AND I
2 SEE THAT THIS SCHEDULED MEETING HAS ONLY TWO MINUTES
3 LEFT. THIS IS AN ITEM WE ABSOLUTELY MUST VOTE ON.
4 I'M GOING ASK THOSE BOARD MEMBERS TO PLEASE STAY ON
5 A LITTLE WHILE LONGER.

6 SO I DON'T KNOW HOW TO -- I GUESS WE'RE
7 GOING TO OPEN IT UP NOW TO PUBLIC COMMENT. AND I
8 SEE THERE'S AN ORDER ON MY SCREEN. IT LOOKS LIKE --

9 MR. AGUIRRE-SACASA: JUST TO REMIND THEM
10 THAT THEY CAN ONLY TALK ABOUT THE AMENDMENT TO THE
11 CONCEPT PLAN. WE'RE NOT TALKING ABOUT SPECIFIC
12 APPLICATIONS.

13 CHAIRMAN IMBASCIANI: DID EVERYONE HEAR
14 THAT POINT MADE BY OUR LEGAL COUNSEL?

15 DR. FISHER: NO.

16 CHAIRMAN IMBASCIANI: I'M GOING TO OPEN UP
17 NOW TO PUBLIC COMMENT, BUT THE COMMENTS HAVE TO BE
18 RESTRICTED NOT TO INDIVIDUAL APPLICATIONS, BUT TO
19 THE AMENDMENT ON THE TABLE TO THE CONCEPT PLAN,
20 WHICH IS THIS FLOW CONTROL AMENDMENT.

21 DR. JENNIFER PUCK.

22 DR. PUCK: YES. THANK YOU FOR LETTING ME
23 SHARE MY THOUGHTS. AND IN PARTICULAR I WANTED TO
24 DRAW THE ATTENTION OF THE BOARD TO THE CIRCUMSTANCES
25 OF APPLICANTS FOR SECOND CLIN2 AWARDS. AS YOU KNOW,

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1 THESE ARE THE ONES THAT ARE REALLY POISED TO GET A
2 BLA SOON. AND SO IT SEEMS TO ME THAT PROTECTING THE
3 PROGRESS OF THESE LATER STAGE PROJECTS MIGHT TAKE
4 PRIORITY OVER ONES THAT HAVE NOT YET BEGUN SO THAT
5 THEY DON'T FACE INTERRUPTION.

6 AND, FURTHERMORE, I WOULD ASK THE BOARD TO
7 LOOK AT THE APPROVAL THAT WAS GIVEN LAST DECEMBER TO
8 NON-PROFIT SETTINGS WHERE THE SECOND CLIN2 WOULD NOT
9 HAVE CORPORATE CO-FUNDING. AND IN THESE CASES, AN
10 ACADEMIC PARTNER WOULD PERHAPS BE THE SETTING FOR
11 FUTURE BLA MANAGEMENT. AND THIS IS A NEW AVENUE
12 THAT TURNS OUT TO BE NECESSARY FOR RARE DISEASES AND
13 FOR DISEASES THAT AFFECT UNDERREPRESENTED MINORITY
14 POPULATIONS.

15 SO I WOULD ASK THAT MAYBE A BLANKET HOLD
16 ON ALL APPLICATIONS MIGHT NOT BE THE RIGHT APPROACH
17 AND CONSIDERING THE LATE STAGE ONES, THE SECOND
18 CLIN2S, AND PARTICULARLY THE ONES FROM NON-PROFIT
19 APPLICANTS BE CONSIDERED. THANK YOU.

20 CHAIRMAN IMBASCIANI: THANKS, DR. PUCK,
21 VERY MUCH. NEXT SPEAKER IS BRIAN CULLEY.

22 MR. CULLEY: GOOD MORNING, EVERYONE. MY
23 NAME IS BRIAN CULLEY. I'M THE CEO AT LINEAGE CELL
24 THERAPEUTICS. I FEEL VERY COMFORTABLE SPEAKING ON
25 BEHALF OF MANY CORPORATE ENTITIES WHEN I SAY WE

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1 DEEPLY APPRECIATE THE HARD WORK AND THE COMMITMENT
2 OF THE CIRM REVIEW TEAM AND THE EXTENSIVE ASSOCIATED
3 RESOURCES WHICH GO INTO THE CONSIDERATION OF FUNDING
4 OF VARIOUS APPLICATIONS.

5 I BELIEVE WE SHOULD ALL SUPPORT A RIGOROUS
6 REVIEW PROCESS. AND IF THE PROCESS CHANGES OR LOWER
7 APPROVAL RATES REDUCES THE REVIEW BURDEN, I BELIEVE
8 THAT'S A BENEFIT FOR THE INDIVIDUALS AS WELL AS FOR
9 THE FIELD WITH IMPROVED QUALITY.

10 I ALSO WISH TO NOTE THAT THE PUBLIC
11 PROPOSAL TO DEAL WITH THE UNPRECEDENTED INFLUX OF
12 CLINICAL GRANT APPLICATIONS EXPLICITLY STATED THAT
13 IT'S IMPORTANT TO NOTE THAT THE ACTION WILL NOT
14 INTERFERE WITH CURRENT SUBMISSIONS MOVING FORWARD OR
15 ANY TIER II RESUBMISSIONS. I DID NOT SEE A
16 REFERENCE IN THAT NOTICE TO BACKDATING TO JANUARY
17 31ST OR THE ADDITIONAL POINTS REGARDING CONFLICT
18 CHECKS.

19 WE LEARNED TODAY THAT FIVE APPLICANTS
20 WORKED HARD TO SUBMIT THEIR APPLICATIONS IN GOOD
21 FAITH THIS MONTH, POSSIBLY IN SOME CASES BEFORE THIS
22 AGENDA ITEM WAS MADE PUBLIC OR IN ALL CASES
23 CERTAINLY BEFORE IT WAS TAKEN UP BY THE BOARD TODAY.
24 FOR THIS REASON, WE RESPECTFULLY ASK THE BOARD TO
25 CONSIDER THE EXTENSIVE WORK PUT INTO ALL SUCH RECENT

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1 APPLICATIONS AND TO GRANDFATHER THE CONTINUED REVIEW
2 OF ALL CURRENT SUBMISSIONS MADE BEFORE THIS MEETING,
3 WHICH WE BELIEVE WILL BE CONSISTENT WITH OUR
4 EXPECTATIONS IN THE PUBLIC NOTICE.

5 AND THE MAIN DIFFERENCE I WISH TO
6 HIGHLIGHT BETWEEN THE EXISTING AND PENDING
7 APPLICATIONS AT THIS TIME IS THAT THE FEBRUARY
8 APPLICATIONS HAVE REPRESENTED THROUGH THEIR
9 SUBMISSIONS THAT THEY'RE READY FOR REVIEW AND
10 PREPARED TO BEGIN WORK IMMEDIATELY. AND SO IF THEY
11 ARE FUNDED, A DELAY TO THESE ALREADY SUBMITTED
12 APPLICATIONS IS NOT JUST AN INCONVENIENCE, BUT A
13 MEASURABLE DELAY PLACED DIRECTLY ON PATIENTS AND
14 PROGRESS COMPARED TO THE DELAY OF FUTURE EXPECTED
15 SUBMISSIONS WHICH HAVE NOT INDICATED THEY'RE
16 PREPARED TO BEGIN WORK AT THIS TIME. BECAUSE IF
17 THEY WERE, PRESUMABLY THEY WOULD ALREADY HAVE
18 APPLIED.

19 SO I RESPECTFULLY SUBMIT, IN AGREEMENT
20 WITH DR. LEVITT AND OTHERS, THAT RATHER THAN
21 BACKDATING AND RATHER THAN SELECTING FEBRUARY 29TH,
22 WHICH MIGHT VALIDLY INVITE DOOR CRASHING OF
23 POTENTIALLY LOWER QUALITY OR RUSHED APPLICATIONS,
24 THAT IF TODAY, FEBRUARY 22D, IS THE DATE MORE
25 SUITABLE FOR THIS DIFFICULT SITUATION AND MAY HELP

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1 AVOID THE POTENTIAL FOR DECELERATING THE DEVELOPMENT
2 OF TRANSFORMATIVE REGENERATIVE MEDICINE, WHICH ARE
3 OTHERWISE READY TO ADVANCE AS DEMONSTRATED BY THEIR
4 SUBMISSION INTO THE CIRM PIPELINE. THANKS SO MUCH
5 FOR YOUR ATTENTION AND CONSIDERATION OF THIS INPUT
6 TODAY.

7 CHAIRMAN IMBASCIANI: MR. CULLEY, THANK
8 YOU VERY MUCH FOR YOUR COMMENTS. FOLLOWED BY MR.
9 TERRY PIROVOLAKIS.

10 MR. PIROVOLAKIS: HI, BOARD MEMBERS.
11 THANK YOU VERY MUCH FOR YOUR TIME. AS YOU HEARD
12 LAST MONTH WHEN I APPEALED OUR GRANT, WE WERE RATED
13 A TIER III AND SUGGESTED TO RE-APPLY. IN THAT
14 MODEL, WE'RE REALLY HOPING THAT, INSTEAD OF
15 DISALLOWING TWO APPLICATIONS DURING THE PAUSE
16 PERIOD, THAT YOU ALSO ALLOW TIER III APPLICATIONS
17 DURING THAT PAUSE PERIOD SO THAT WE ARE ABLE TO COME
18 BACK WITH OUR PIVOTAL STUDY APPLICATION THAT PERTAIN
19 TO THOSE PATIENTS IN AUGUST TO RE-APPLY.

20 I ALSO WANT TO MAKE A COMMENT THAT I'M
21 VERY IN TUNE WITH THE RARE DISEASE COMMUNITY, AND I
22 CAN TELL YOU THAT THE TSUNAMI THAT YOU'RE FEELING
23 RIGHT NOW IS JUST AN INKLING OF THE BEGINNING OF THE
24 TSUNAMI. THE TSUNAMI IS GOING TO BE SIGNIFICANTLY
25 BIGGER COMING EVERY MONTH GOING FORWARD BECAUSE

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1 THERE IS NO FUNDING MODELS OUT THERE. THIS IS THE
2 ONLY FUNDING MODEL FOR PEDIATRIC RARE DISEASES.

3 SO I JUST WANT TO LEAVE IT AT THAT. VERY
4 BRIEFLY, PLEASE CONSIDER TIER III APPLICATIONS AS
5 WELL. THANK YOU FOR WHAT YOU DO EVERY DAY AND FOR
6 SUPPORTING INDIVIDUALS, ACADEMICS, AND COMPANIES
7 LIKE OURS. WE DO NOT HAVE ANY OTHER METHOD AND WE
8 TRULY APPRECIATE IT. THANK YOU.

9 CHAIRMAN IMBASCIANI: DR. CHRISTMAN.

10 DR. CHRISTMAN: YES. HI, EVERYONE. THANK
11 YOU. SO I APPRECIATE THE BOARD DISCUSSION. I THINK
12 EVERYONE GETS THE KEY POINT. I THINK THE ONE THING
13 I JUST WANTED TO ADD ABOUT THE POINT ABOUT
14 BACKDATING NOT BEING JUST TO, SAY, DELAY AN
15 APPLICATION FOR FIVE MONTHS. SO I WON'T TALK ABOUT
16 THE DETAILS OF MY OWN APPLICATION, BUT WILL SAY
17 TIMING FOR APPLICATIONS IS OFTEN SUBMIT FOR SPECIFIC
18 REASONS. SO, FOR EXAMPLE, WE WANTED TO TIME OUR
19 RESUBMISSION WITH MANUFACTURING CAPABILITIES. SO
20 COULD HAVE RESUBMITTED IN NOVEMBER, LET CIRM KNOW
21 BOTH IN NOVEMBER AND IN JANUARY THAT WE INTEND TO
22 SUBMIT IN FEBRUARY. SO THIS DELAY OF FIVE MONTHS IS
23 NOT COMPLETELY TRIVIAL, AND I THINK, AS OTHERS HAVE
24 SAID, WE'RE USED TO NOT GETTING GRANTS FUNDED, BUT
25 HAVING SOMETHING THAT'S ALREADY SUBMITTED, NOT

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1 REVIEWED, I THINK, IS UNPRECEDENTED. IT MAKES IT
2 EXTRA DIFFICULT TO SWALLOW THE FACT THAT UPDATED IN
3 JANUARY, CONTINUE TO WORK ON THAT, PUSHING
4 EVERYTHING ASIDE FOR A MONTH OF INTENSE GRANT
5 ACTIVITY, THEN TO SAY NEVER MIND TO NOT HAVE IT
6 REVIEWED, IT'S DIFFICULT, SLOWING DOWN PROGRESSION,
7 AND TIMING THOSE RESUBMISSIONS IS SOMETHING THAT'S
8 REALLY IMPORTANT. DELAY OF FIVE MONTHS ISN'T
9 TRIVIAL. THANK YOU VERY MUCH.

10 CHAIRMAN IMBASCIANI: THANK YOU, DR.
11 CHRISTMAN. I APPRECIATE THAT. OUR LAST COMMENT IS
12 COMING FROM EVAN SNYDER.

13 DR. SNYDER: HI, CAN YOU HEAR ME? OKAY.
14 GREAT.

15 THANKS FOR LISTENING TO ME YET AGAIN. WE
16 UNDERSTAND THE BURDEN THAT THE TERRIFIC CLINICAL
17 PROGRAMS HAVE PUT ON THE OVERWORK AND EXCELLENT CLINICAL
18 STAFF, BUT, PLEASE, TO ABRUPTLY PUT A HIATUS ON A
19 PROGRAM THAT SO MANY SCIENTISTS AND PATIENTS HAVE
20 COME TO BUILD PROGRAMS AROUND WITHOUT A WIND-DOWN
21 PERIOD OF AT LEAST FOUR TO SIX MONTHS OR AT LEAST AN
22 INTERMEDIATE SOLUTION, FOR EXAMPLE, EVERY OTHER
23 MONTH DEADLINES, HAS THE VERY REAL POTENTIAL TO
24 CAUSE IRREPARABLE HARM.

25 NOW, MY COMMENTS ARE PERSONAL, BUT THEY'RE

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1 REPRESENTATIVE FOR ACADEMICS. WE ARE ACADEMICS, NOT
2 A COMPANY, IN THE LAST STAGES OF A VERY SUCCESSFUL
3 AND PROMISING CIRM TRANSLATIONAL PROGRAM, DEALING
4 WITH BRAIN INJURY IN BABIES, THE RUNWAY TO A CLIN1.
5 OUR PROGRAM HAS SUCCEEDED FAMOUSLY DESPITE THE
6 HEADWINDS OF THE PANDEMIC, HITTING ALL OUR
7 MILESTONES, SOME OF WHICH HAVE RESULTED IN HIGH-TIER
8 PUBLICATIONS, A COMPLETED PRE-IND MEETING WITH THE
9 FDA. THIS PROGRAM IS SUPPORTED ENTIRELY ON A TRAN
10 GRANT, WHICH IN CONJUNCTION --

11 VICE CHAIR BONNEVILLE: THIS IS ABOUT AN
12 INDIVIDUAL APPLICATION.

13 DR. SNYDER: I'M NOT TALKING ABOUT OUR
14 PARTICULAR APPLICATION. I'M USING THIS GENERICALLY
15 TO SAY THAT WE -- AND I PROMISE I WON'T DO THAT, BUT
16 JUST AS AN EXAMPLE, THAT IN CONJUNCTION WITH OUR
17 CIRM PROGRAM DIRECTOR, HAVE A PLAN TO TRANSITION TO
18 CLIN1 FUNDING MECHANISMS WITH A FEBRUARY AND LIKELY
19 MARCH SUBMISSION WITH A PLAN THAT'S BEEN IN PLACE
20 FOR ABOUT A YEAR. FUNDING IS LIKELY BECAUSE OF THE
21 SPECTACULAR --

22 MR. AGUIRRE-SACASA: WE HAVE TO KEEP IT AT
23 THE LEVEL OF THE CONCEPT PLAN AMENDMENT.

24 DR. SNYDER: I WILL NOT TALK ABOUT IT IN
25 PARTICULAR EXCEPT TO SAY THAT GIVEN THAT ACADEMICS

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1 ARE ENTIRELY BEING FUNDED ON A TRAN MECHANISM WITH
2 THE RUNWAY GOING TO CLIN, LAYOFFS WILL HAPPEN
3 BECAUSE WE ANTICIPATED A SMOOTH RUNWAY INTO CLIN.
4 THE TEAM THAT BROUGHT THIS WITHIN STRIKING DISTANCE
5 OF A CLINICAL TRIAL WILL BE DECIMATED AND MAYBE NOT
6 ABLE TO BE --

7 MR. AGUIRRE-SACASA: WE UNDERSTAND.
8 UNFORTUNATELY, IT'S JUST A LITTLE BIT TOO CLOSE TO
9 YOUR APPLICATION. THANK YOU.

10 CHAIRMAN IMBASCIANI: WE'LL FINISH THIS UP
11 WITH A FINAL COMMENT FROM JONATHAN THOMAS.

12 DR. THOMAS: SO I HOPE EVERYBODY CAN HEAR
13 ME. I, FIRST OF ALL, APPRECIATE ALL THE COMMENTS
14 ABOUT THE BACKDATING. AND I UNDERSTAND THAT THAT
15 SOUNDS UNUSUALLY DRACONIAN; BUT, AGAIN, THE REASON
16 FOR THAT IS TWOFOLD. ONE IS THE STRAIN ISSUE,
17 STRAIN AND BANDWIDTH ISSUES. I WANT TO GO BACK TO
18 WHAT STEVE SAID A NUMBER OF MINUTES AGO, WHICH IS
19 IT'S ENTIRELY POSSIBLE, WHEN YOU FACTOR IN THE 105
20 MILLION IN NEW APPLICATIONS IN CLIN1 AND CLIN2, PLUS
21 THE TIER II RESUBMISSIONS THAT ARE ALMOST CERTAINLY
22 LIKELY TO COME IN, IT'S ENTIRELY POSSIBLE THAT WE
23 WOULD HAVE NO MONEY AVAILABLE FOR ANY SUBMISSIONS IN
24 FEBRUARY. SO PLEASE KEEP THAT IN MIND. THOSE TWO
25 ISSUES ARE THE UNDERPINNINGS OF WHY I PROPOSED ON

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1 BEHALF OF THE TEAM TO BACKDATE.

2 CHAIRMAN IMBASCIANI: THANK YOU. OKAY.
3 SO THERE'S BEEN A VERY, VERY ROBUST POINT AND
4 COUNTERPOINT. SO THE FLOOR IS NOW OPEN FOR -- WELL,
5 I'M GOING TO ASK OUR LEGAL COUNSEL TO RESTATE THE
6 MOTION THAT WE'RE GOING TO CONSIDER WITH A VOTE FOR
7 AMENDMENTS.

8 MR. AGUIRRE-SACASA: THE MOTION IS TO
9 AMEND THE CLIN1 AND CLIN2 CONCEPT PLANS TO HALT
10 MONTHLY ACCEPTANCE OF PATIENTS UNTIL FURTHER REVIEW
11 WITH A SUBMISSION DATE OF JANUARY 31ST, TO BE CLEAR.
12 THAT'S THE MOTION.

13 CHAIRMAN IMBASCIANI: THAT IS THE MOTION
14 AND SECONDED.

15 MR. AGUIRRE-SACASA: THAT'S CORRECT. SO
16 WE ARE MOVING TO VOTE HERE.

17 CHAIRMAN IMBASCIANI: OKAY. ARE WE READY
18 TO VOTE?

19 MR. AGUIRRE-SACASA: MOHAMED ABOUSALEM.
20 KIM BARRETT.

21 DR. BARRETT: NO.

22 MR. AGUIRRE-SACASA: GEORGE BLUMENTHAL.

23 DR. BLUMENTHAL: YES.

24 MR. AGUIRRE-SACASA: MARIA BONNEVILLE.

25 VICE CHAIR BONNEVILLE: YES.

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1 MR. AGUIRRE-SACASA: MONICA CARSON.

2 DR. CARSON: I MISSED A POINT OF
3 CLARIFICATION. DOES THE -- IF WE HAVE SAID NO -- IF
4 THIS HAD -- DOESN'T THIS BOARD HAVE THE ABILITY TO,
5 EVEN AFTER REVIEW, SAY NO TO GRANTS TO PROTECT THE
6 FUNDING? I JUST WANT THAT CLARIFICATION JUST BEFORE
7 I VOTE. I TRIED TO GET THAT ANSWER, AND I JUST
8 HEARD TWO DIFFERENT THINGS IN THE DISCUSSION.

9 MR. AGUIRRE-SACASA: CAN YOU REPHRASE YOUR
10 QUESTION PLEASE?

11 DR. CARSON: I'M SORRY. SO THE POINT THAT
12 WAS JUST MADE IN THE SUMMARY WAS THAT IF WE DON'T DO
13 THIS, THESE GRANTS GET REVIEWED, AND THEN THE MONEY
14 IS ALL GONE, WORST-CASE SCENARIO, LIKE THERE WERE
15 FIVE REALLY GREAT ONES. BUT DOESN'T -- SO I'M JUST
16 ASKING FOR A POINT OF CLARIFICATION CONTROL.

17 IF THESE WERE ALL GIVEN ONES, THEY STILL
18 HAD TO COME HERE FOR A VOTE. AND SO THEY CAN
19 STILL -- THE BOARD STILL HAS THE ABILITY TO CONTROL
20 FUNDING BY NOT ACCEPTING THE SCIENTIFIC REVIEW. THE
21 ANSWER TO THAT AFFECTS MY VOTE.

22 VICE CHAIR BONNEVILLE: THE BOARD DOES
23 HAVE THE BOARD ABILITY TO SAY NO TO GRANTS THAT HAVE
24 BEEN RECOMMENDED BY THE GWG. YES, THAT IS CORRECT.

25 DR. CARSON: WELL, GIVEN THAT ANSWER, THEN

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1 I SAY NO.
2 MR. AGUIRRE-SACASA: JUDY CHOU.
3 DR. CHOU: YES, APPROVE.
4 MR. AGUIRRE-SACASA: LEONDR CLARK-HARVEY.
5 DR. CLARK-HARVEY: YES.
6 MR. AGUIRRE-SACASA: LEON FINE. MARK
7 FISCHER-COLBRIE.
8 MR. FISCHER-COLBRIE: YES.
9 MR. AGUIRRE-SACASA: FRED FISHER.
10 DR. FISHER: YES.
11 MR. AGUIRRE-SACASA: JUDY GASSON.
12 DR. GASSON: NO.
13 MR. AGUIRRE-SACASA: LARRY GOLDSTEIN.
14 DR. GOLDSTEIN: YES.
15 MR. AGUIRRE-SACASA: DAVID HIGGINS.
16 DR. HIGGINS: YES.
17 MR. AGUIRRE-SACASA: VITO IMBASCIANI.
18 CHAIRMAN IMBASCIANI: YES.
19 MR. AGUIRRE-SACASA: STEVE JUELSGAARD.
20 MR. JUELSGAARD: YES.
21 MR. AGUIRRE-SACASA: RICH LAJARA.
22 MR. LAJARA: YES.
23 MR. AGUIRRE-SACASA: PAT LEVITT.
24 DR. LEVITT: NO.
25 MR. AGUIRRE-SACASA: LINDA MALKAS.

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DR. MALKAS: NO.

MR. AGUIRRE-SACASA: CHRIS MIASKOWSKI.
ADRIANA PADILLA.

DR. PADILLA: YES.

MR. AGUIRRE-SACASA: JOE PANETTA.

MR. PANETTA: YES.

MR. AGUIRRE-SACASA: MARV SOUTHARD.

DR. SOUTHARD: NO.

MR. AGUIRRE-SACASA: SUZANNE SANDMEYER.

DR. SANDMEYER: NO.

MR. AGUIRRE-SACASA: KAROL WATSON.

DR. WATSON: YES.

MR. AGUIRRE-SACASA: KEITH YAMAMOTO.

DR. YAMAMOTO: NO.

MR. AGUIRRE-SACASA: MOTION CARRIES.

CHAIRMAN IMBASCIANI: THANK YOU. THANK
YOU TO THE BOARD AND TO THE PUBLIC FOR THEIR
COMMENTS ON THIS DIFFICULT ISSUE. THANK YOU,
RAFAEL, FOR LEADING US THROUGH IT.

I'M GOING TO CEDE THE FLOOR TO THE VICE
CHAIR OF THE PRESIDENTIAL SEARCH COMMITTEE. BOARD
MEMBER BLUMENTHAL, GEORGE.

DR. BLUMENTHAL: THANK YOU.

MR. AGUIRRE-SACASA: HOLD ON. WE'RE
TRYING TO SEE IF WE CAN FIX THE ROOM. SORRY,

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1 GEORGE .

2 MS. MANDAC: CAN YOU HEAR US OKAY IN THE
3 ROOM?

4 DR. FISHER: I'M HEARING YOU.

5 DR. YAMAMOTO: YES.

6 DR. BLUMENTHAL: THANK YOU. I KNOW WE'RE
7 ALREADY OVER TIME. I WANT TO GIVE A VERY BRIEF
8 UPDATE ON THE PRESIDENTIAL SEARCH. WE HAVE BEEN
9 HARD AT WORK, AND THE SEARCH COMMITTEE HAS MET.
10 PRIOR TO A MEETING, OUR PARTNERS WITH THE SEARCH
11 FIRM HAVE CONDUCTED A NUMBER OF INTERVIEWS WITH
12 STAKEHOLDERS, ON THE ORDER OF 25 TO 30 STAKEHOLDERS.
13 AND KIM BARRETT, MY CO-CHAIR AND I, HAVE ALSO DONE
14 INTERVIEWS AS WELL.

15 THE REPORTER: I'M SORRY, MR. CHAIRMAN.
16 THIS IS THE REPORTER. I STILL CANNOT HEAR DR.
17 BLUMENTHAL.

18 DR. BLUMENTHAL: CAN YOU HEAR ME NOW?

19 THE REPORTER: YES, I CAN.

20 DR. BLUMENTHAL: OKAY. GREAT. WE'LL
21 START AGAIN. VERY QUICKLY, I JUST WANT TO GIVE A
22 VERY BRIEF UPDATE ON THE PRESIDENTIAL SEARCH
23 PROCESS. WE HAVE BEEN BUSY. OUR SEARCH FIRM
24 PARTNERS HAVE CONDUCTED A NUMBER OF INTERVIEWS, ON
25 THE ORDER OF 25 TO 30, WITH VARIOUS STAKEHOLDERS OF

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1 CIRM TO TRY TO GET A BETTER UNDERSTANDING OF WHAT
2 SOME OF THE INTERESTS ARE. AND MY CO-CHAIR AND I,
3 KIM BARRETT AND I, HAVE ALSO DONE SOME INTERVIEWS AS
4 WELL.

5 WHAT IS BEFORE YOU TODAY ON THE AGENDA,
6 YOU WILL SEE REFERENCES TO THREE DOCUMENTS I WANT TO
7 CALL YOUR ATTENTION TO. THE FIRST OF THESE IS
8 CALLED THE EXECUTIVE BRIEF. AND THEN BASICALLY THE
9 JOB ANNOUNCEMENT THAT WILL BE GOING OUT TO ALL
10 POTENTIAL CANDIDATES AND PROSPECTS, THERE IS A
11 DOCUMENT THAT WAS PREPARED BY THE SEARCH FIRM. IT
12 WAS REVIEWED BY SCOTT, KIM, AND ME, AND THEN FURTHER
13 REVIEWED BY THE SEARCH COMMITTEE WHICH APPROVED IT.

14 SO IF YOU HAVE ANY COMMENTS ON THAT
15 DOCUMENT, PLEASE GET IT TO US, I GUESS, TO SCOTT
16 WITHIN THE NEXT COUPLE OF DAYS. BUT THAT IS
17 AVAILABLE AND WILL BE GOING OUT VERY SOON.

18 THE SECOND DOCUMENT THAT'S IN THE AGENDA
19 IS A CANDIDATE COMPETENCY PROFILE. THAT DOCUMENT IS
20 SOMETHING THAT WILL BE SENT TO CANDIDATES FOR THE
21 POSITION AND WILL BE A WAY OF THEM PUTTING INTO A
22 DOCUMENT THEIR QUALIFICATIONS IN A FORM THAT WILL BE
23 SIMILAR FOR ALL CANDIDATES. AND SO, AGAIN, IF THERE
24 ARE SUGGESTIONS THAT YOU HAVE FOR HOW THAT DOCUMENT
25 MIGHT BE CHANGED, FEEL FREE, AGAIN, TO GET IT TO US

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1 WITHIN THE NEXT COUPLE OF DAYS. IN PARTICULAR, SEND
2 IT TO SCOTT.

3 AND THEN THE THIRD DOCUMENT IS A TIMELINE.
4 WE WILL BE PRESENTING TIMELINES EVERY TIME WE MEET
5 TO MAKE SURE THAT WE ARE ADHERING TO THE CURRENT
6 TIMELINE AND IDENTIFYING ANY POSSIBLE SLIPPAGES THAT
7 MAY OCCUR. BUT THE TIMELINE IN THE IMMEDIATE FUTURE
8 IS THAT WE IMAGINE THAT THE EXECUTIVE BRIEF WILL BE
9 GOING OUT BY THE END OF THIS MONTH, SO IT WILL BE
10 OUT BY MARCH 1ST, WITH THE IDEA THAT WE WILL BE
11 PUTTING TOGETHER OR WE WILL BE SEEKING APPLICATIONS
12 OVER THE TIME PERIOD OF A MONTH WITH THE IDEA THAT
13 STARTING ON APRIL 1ST, THE SEARCH FIRM WILL BEGIN TO
14 PROCESS THOSE APPLICATIONS AND PUT TOGETHER FILES
15 THAT WILL ALLOW THE SEARCH COMMITTEE TO BEGIN WORK
16 IN MID-APRIL TO GENERATE A LONG LIST FOR BASICALLY
17 INITIAL INTERVIEWS.

18 SO THE TIME SCALE IS BASICALLY NOW THAT
19 WE'RE GOING OUT FOR APPLICATIONS. SO WHAT I'M
20 SUGGESTING TO YOU IS THAT IF YOU HAVE COMMENTS ON
21 THOSE FIRST TWO DOCUMENTS, THE BRIEF OR THE
22 CANDIDATE COMPETENCY PROFILE, PLEASE GET THEM TO US
23 AS SOON AS POSSIBLE. IN THE MEANTIME, SINCE WE ARE
24 GOING OUT FOR APPLICATIONS, IF THERE ARE POTENTIAL
25 CANDIDATES THAT YOU KNOW THAT YOU THINK WOULD BE A

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1 GOOD CANDIDATE FOR THE PRESIDENCY OF CIRM, I WANT TO
2 ENCOURAGE YOU TO ENCOURAGE THEM TO APPLY OR AT LEAST
3 TO GET IN TOUCH WITH SRI, THE SEARCH FIRM.

4 I THINK THOSE ARE THE HIGH POINTS OF WHAT
5 I WANTED TO BRING FORWARD. LET ME INVITE KIM. IS
6 THERE ANYTHING ELSE, KIM, THAT YOU THINK WE SHOULD
7 BRING FORTH AT THIS TIME?

8 DR. BARRETT: NO. IN THE INTEREST OF
9 TIME, I WILL NOT SAY VERY MUCH OTHER THAN TO SAY
10 THAT WE HAD A VERY ROBUST DISCUSSION WITH THE SEARCH
11 COMMITTEE, AND PEOPLE SEEM HAPPY WITH THE DOCUMENTS.

12 DR. BLUMENTHAL: AND I WOULD ENTERTAIN ANY
13 QUESTIONS NOW KNOWING THAT WE ARE SHORT ON TIME.
14 ANY QUESTIONS OR COMMENTS?

15 CHAIRMAN IMBASCIANI: THANK YOU, CO-CHAIRS
16 BARRETT AND BLUMENTHAL, FOR YOUR REPORT.

17 I NEED TO OPEN UP FOR FINAL PUBLIC COMMENT
18 ON THE AGENDA SO FAR, BUT OUT OF TIME. WE'RE NOT
19 GOING TO CONSIDER AGENDA ITEMS 5 OR 12 AT THIS
20 MEETING. WE'LL POSTPONE THEM TO THE NEXT.

21 (INTERNAL DISCUSSION.)

22 CHAIRMAN IMBASCIANI: IS THERE ANYONE FROM
23 THE PUBLIC THAT'S WANTING TO SPEAK? NO, THERE IS
24 NOT. SO I THINK WE ARE DONE FOR TODAY THEN, RIGHT?
25 NO OBJECTIONS TO ADJOURNING.

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1 THANK YOU, EVERYONE. THIS WAS A
2 DIFFICULT, INVOLVED, AND COMPLICATED MEETING. AND I
3 APPRECIATE ALL THE HELP OF THE STAFF IN GETTING US
4 TO THIS POINT. THANK YOU, EVERYONE.

5 (THE MEETING WAS THEN CONCLUDED AT 11:22 A.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 VIRTUAL PROCEEDINGS BEFORE THE INDEPENDENT CITIZEN'S OVERSIGHT COMMITTEE AND THE APPLICATION REVIEW SUBCOMMITTEE OF THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE IN THE MATTER OF ITS REGULAR MEETING HELD ON FEBRUARY 22, 2024, WAS HELD AS HEREIN APPEARS AND THAT THIS IS THE ORIGINAL TRANSCRIPT THEREOF AND THAT THE STATEMENTS THAT APPEAR IN THIS TRANSCRIPT WERE REPORTED STENOGRAPHICALLY BY ME AND TRANSCRIBED BY ME. I ALSO CERTIFY THAT THIS TRANSCRIPT IS A TRUE AND ACCURATE RECORD OF THE PROCEEDING.

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