

BETH C. DRAIN, CA CSR NO. 7152

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

LOCATION: VIA ZOOM

DATE: AUGUST 29, 2024
9 A.M.

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

FILE NO.: 2024-34

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I N D E X

ITEM DESCRIPTION	PAGE NO.
OPEN SESSION	
1. CALL TO ORDER	3
2. ROLL CALL	3
3. CONSIDERATION OF APPLICATIONS SUBMITTED IN RESPONSE TO DISCOVERY PROGRAM ANNOUNCEMENTS (DISC4 REMIND)	5
CLOSED SESSION	NONE
4. DISCUSSION OF CONFIDENTIAL INTELLECTUAL PROPERTY OR WORK PRODUCT, PREPUBLICATION DATA, FINANCIAL INFORMATION, CONFIDENTIAL SCIENTIFIC RESEARCH OR DATA, AND OTHER PROPRIETARY INFORMATION RELATING TO APPLICATIONS SUBMITTED IN RESPONSE TO AGENDA ITEM 3 ABOVE. (HEALTH & SAFETY CODE 125290.30(F) (3) (B) AND (C)).	
OPEN SESSION	
5. GENERAL COMMENTS ON ARS PROCESS	NONE
6. PUBLIC COMMENT	NONE
7. ADJOURNMENT	60

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AUGUST 29, 2024; 9 A.M.

CHAIRMAN IMBASCIANI: GOOD MORNING
EVERYONE, SIGNING INTO THIS THE 58TH MEETING OF THE
APPLICATION REVIEW SUBCOMMITTEE OF THE INDEPENDENT
CITIZENS OVERSIGHT COMMITTEE, CIRM'S BOARD. SIGNING
IN FROM ALL OVER THE WORLD IT LOOKS LIKE. SO THANK
YOU ALL FOR -- THANK YOU, JUDY. THANK YOU ALL FOR
GIVING UP THE TIME THIS MORNING. WE HAVE AN
INTERESTING AGENDA, AND I'M GOING DO ASK SCOTT
TO KICK OFF THE MEETING BY CALLING OUR ROLL.

MR. TOCHER: DAN BERNAL. MARIA
BONNEVILLE.

VICE CHAIR BONNEVILLE: PRESENT.

MR. TOCHER: JUDY CHOU.

DR. CHOU: PRESENT.

MR. TOCHER: LEONDRA CLARK-HARVEY.
ANNE-MARIE DULIEGE. THUMBS UP. THAT WILL WORK.

YSABEL DURON.

MS. DURON: PRESENT.

MR. TOCHER: MARK FISCHER-COLBRIE.

DR. FISCHER-COLBRIE: HERE.

MR. TOCHER: FRED FISHER.

DR. FISHER: PRESENT.

MR. TOCHER: ELENA FLOWERS.

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1 DR. FLOWERS: PRESENT.
2 MR. TOCHER: DAVID HIGGINS.
3 DR. HIGGINS: HERE.
4 MR. TOCHER: VITO IMBASCIANI.
5 CHAIRMAN IMBASCIANI: HERE.
6 MR. TOCHER: RICH LAJARA.
7 MR. LAJARA: PRESENT.
8 MR. TOCHER: CHRISTINE MIASKOWSKI. LAUREN
9 MILLER-ROGEN.
10 MS. MILLER-ROGEN: HERE.
11 MR. TOCHER: ADRIANA PADILLA.
12 DR. PADILLA: HERE.
13 MR. TOCHER: JOE PANETTA.
14 MR. PANETTA: HERE.
15 MR. TOCHER: MARVIN SOUTHARD.
16 DR. SOUTHARD: HERE.
17 MR. TOCHER: KAROL WATSON. KEVIN XU.
18 DR. XU: HERE.
19 MR. TOCHER: THANK YOU. WE HAVE A QUORUM.
20 CHAIRMAN IMBASCIANI: THIS IS GOOD. THANK
21 YOU VERY MUCH.
22 THE MAIN ORDER OF BUSINESS TODAY IS ITEM
23 NO. 3 ON THE AGENDA, THE CONSIDERATION OF THE
24 APPLICATIONS THAT HAVE BEEN SUBMITTED IN RESPONSE TO
25 OUR NEW DISCOVERY PROGRAM, THE DISC4, OTHERWISE

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1 KNOWN AS THE REMIND PROGRAM. AND TO PRESENT THE
2 FORMAL PRESENTATION, I'M GOING TO HAND OVER TO DR.
3 GIL SAMBRANO.

4 DR. SAMBRANO: OKAY. THANK YOU VERY MUCH.
5 AND GOOD MORNING, EVERYONE. THANK YOU FOR JOINING
6 US. I'M GOING TO GIVE YOU AN OVERVIEW ON THE
7 REMIND-L PROGRAM AND THE RECOMMENDATIONS FROM THE
8 GRANTS WORKING GROUP RELATED TO APPLICATIONS
9 SUBMITTED TO THIS OPPORTUNITY.

10 SO WE ARE HERE AND CIRM EXISTS TO
11 ACCELERATE WORLD-CLASS SCIENCE TO DELIVER
12 TRANSFORMATIVE REGENERATIVE MEDICINE TREATMENTS IN
13 AN EQUITABLE MANNER TO A DIVERSE CALIFORNIA AND
14 WORLD.

15 THE REMIND PROGRAM OVERALL IS ONE
16 MECHANISM BY WHICH WE TRY TO ACHIEVE THIS MISSION.
17 I'LL TELL YOU A BIT ABOUT THE BROADER PROGRAM ITSELF
18 AND THEN GO INTO THE REMIND-L.

19 THE REMIND INITIATIVE IS A NEW MECHANISM
20 THAT WE BEGAN THAT STANDS FOR RESEARCH USING
21 MULTIDISCIPLINARY, INNOVATIVE APPROACHES IN NEURO
22 DISEASES. AND IT IS A MECHANISM THAT HAS A COUPLE
23 OF DIFFERENT FLAVORS THAT I'LL TAKE YOU THROUGH.
24 MORE SPECIFICALLY, WE'RE STARTING AND LAUNCHING THIS
25 REMIND INITIATIVE WITH ACCELERATING THE DISCOVERY OF

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1 MECHANISMS, IN PARTICULAR, FOR NEUROPSYCHIATRIC
2 DISORDERS WITH A GOAL OF IDENTIFYING, VALIDATING
3 POTENTIAL NOVEL TARGETS AND BIOMARKERS THAT COULD
4 LEAD TO TRANSLATIONAL STUDIES AND PERHAPS EVEN
5 CLINICAL STUDIES DOWN THE LINE.

6 SO THESE AWARDS GENERALLY ARE STRUCTURED
7 TO SUPPORT EARLY STAGE DISCOVERY WORK, TO ACCELERATE
8 FOUNDATIONAL SCIENTIFIC UNDERSTANDING OF DISEASE
9 MECHANISMS, AND POTENTIALLY DEVELOP TOOLS AND
10 TECHNOLOGIES THAT CAN AID US IN THAT, BUT ALSO TO
11 BRING TOGETHER MULTIDISCIPLINARY, INNOVATIVE
12 APPROACHES, MEANING MULTIPLE PLAYERS, MULTIPLE
13 LABORATORIES, AND PI'S TOGETHER IN THESE EFFORTS,
14 AND TO DRIVE OPEN AND COLLABORATIVE SCIENCE THROUGH
15 DATA, RESOURCE, AND KNOWLEDGE SHARING.

16 SO AS MENTIONED, THERE ARE TWO TYPES OF
17 PROGRAMS UNDER THE OVERALL REMIND MECHANISM.
18 THERE'S THE REMIND-L WHICH ARE THE LARGE
19 COLLABORATIVE PROJECTS WITH A DURATION OF ABOUT FOUR
20 YEARS. THEY ARE PROVIDED A BUDGET OF EIGHT TO TEN
21 MILLION. AND THE GOAL HERE IS TO BRING TOGETHER A
22 MINIMUM OF FIVE INVESTIGATORS TO DO COLLABORATIVE
23 WORK ON A GIVEN EFFORT. WE HAVE A TARGET NUMBER OF
24 SIX AWARDS THAT WE'D LIKE TO ISSUE UNDER THIS FIRST
25 REMIND-L PROGRAM.

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1 THE REMIND-X IS A DIFFERENT TYPE OF
2 OPPORTUNITY. THESE ARE EXPLORATORY, HIGH RISK
3 PROJECTS. THE DURATION IS TWO YEARS, AND THE
4 MAXIMUM BUDGET IS ONE MILLION. SO THESE ARE MORE
5 AKIN TO A SEED TYPE OF AWARD. BUT NEVERTHELESS, IT
6 STILL IS PROMOTING COLLABORATION BY REQUIRING A
7 MINIMUM OF TWO INVESTIGATORS. AND THERE WE WOULD
8 EXPECT TO HAVE MORE AWARDS, AND I THINK THE ORIGINAL
9 PROPOSAL WAS TO TARGET 12 ONCE WE GET THAT PROGRAM
10 GOING.

11 SO JUST COMING BACK, THEN, TO THE
12 REMIND-L, THAT'S THE APPLICATIONS WE ARE DEALING
13 WITH TODAY. REMIND-L AWARDS ARE GOING TO SUPPORT
14 EXPANSIVE CROSS-DISCIPLINARY AND INTEGRATED STUDIES
15 LED BY LARGE COLLABORATIVE TEAMS APPLYING A RANGE OF
16 TECHNOLOGIES AND APPROACHES. SO THERE ARE SEVERAL
17 OUTCOMES THAT MAY BE PROPOSED THROUGH THESE TYPES OF
18 APPLICATIONS. IT COULD BE DISCOVERY OF NOVEL
19 MECHANISTIC INSIGHTS OR FURTHERING OUR CURRENT
20 UNDERSTANDING OF NEUROPSYCHIATRIC MECHANISMS,
21 ADDRESSING MAJOR BOTTLENECKS IN THE STUDY OF
22 NEUROPSYCHIATRIC DISORDERS, EXPANDING UNDERSTANDING
23 OF DISEASE MECHANISMS TO DIVERSE HUMAN POPULATIONS,
24 AND IDENTIFYING AND VALIDATING NEW THERAPEUTIC
25 HYPOTHESES, TARGETS, AND/OR BIOMARKERS. SO THAT'S

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1 SORT OF THE GENERAL UNIVERSE OF WHAT MAY BE
2 PROPOSED.

3 BUT THERE ARE SOME REQUIREMENTS UNDER
4 REMIND-L. THEY MUST ALL ADDRESS A KEY KNOWLEDGE GAP
5 OR RESEARCH BOTTLENECK IN OUR UNDERSTANDING OF
6 NEUROPSYCHIATRIC DISEASES. THEY MUST INCLUDE
7 STUDIES THAT EMPLOY STEM CELLS OR GENETIC RESEARCH
8 AS PART OF THE CENTRAL APPROACH OR HYPOTHESIS, AND
9 THEY MUST JUSTIFY ANY PROPOSED USE OF NONHUMAN
10 MODELS AND VALIDATE THE FINDINGS USING HUMAN TISSUE
11 OR MODELS.

12 SOME ADDITIONAL FEATURES. SOME OF THESE
13 I'VE ALREADY MENTIONED, BUT I JUST WANT TO FOCUS IN
14 ON THE TEAM OF INVESTIGATORS. THERE'S A MINIMUM
15 EFFORT REQUIRED FOR THE PARTICIPATION OF THE FIVE
16 COLLABORATING INVESTIGATORS WITH 15 PERCENT FOR THE
17 PI AND 10 PERCENT EACH FOR THE OTHER
18 CO-INVESTIGATORS. THERE'S ALSO A REQUIREMENT TO
19 HAVE AT LEAST ONE OF THE MEMBERS OF THE TEAM HAVE
20 RELEVANT CLINICAL EXPERTISE TO BRING THAT
21 PERSPECTIVE INTO THE CONSIDERATION OF THE STUDIES
22 THAT THEY ARE CONDUCTING WITH THE HOPE THAT THESE
23 WILL EVENTUALLY BECOME WORK THAT CAN BE TRANSLATED
24 OR EVEN REACH CLINICAL STUDY.

25 ANOTHER MEMBER HAS TO HAVE RELEVANT

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1 COMPUTATIONAL BIOLOGY EXPERTISE AND ALSO HAVE A DATA
2 PROJECT MANAGER AS PART OF THE TEAM TO HELP
3 COORDINATE THE DATA MANAGEMENT AND COLLECTION AND
4 THE SHARING OF THAT DATA.

5 MATCHING FUNDS, JUST BRIEFLY, MATCHING
6 FUNDS ARE SOMETHING THAT ARE ALLOWED UNDER THIS
7 PROGRAM IN ORDER TO INCREASE THE AMOUNT OF FUNDING
8 THEY RECEIVE FROM CIRM. SO ADDITIONAL FUNDS OF UP
9 TO HALF A MILLION PER YEAR CAN BE REQUESTED IF THE
10 APPLICANT PROVIDES EQUAL OR LARGER AMOUNT OF
11 MATCHING FUNDS AS PART OF THEIR AWARD. SO THERE ARE
12 SOME THAT DID TAKE ADVANTAGE OF THIS TO INCREASE
13 THEIR OVERALL AWARD AMOUNT, KNOWING THAT THEY ARE
14 GOING TO CONTRIBUTE MATCHING FUNDS. AND THERE ARE
15 SPECIFIC REQUIREMENTS AND ELIGIBLE EXPENSES THAT ARE
16 RELATED TO THIS THAT I WON'T GO INTO AT THE MOMENT.

17 SO THAT'S THE PROGRAM ITSELF. THE GRANTS
18 WORKING GROUP WAS TASKED WITH REVIEWING THE
19 APPLICATIONS THAT CAME IN IN RESPONSE TO THIS
20 REMIND-L INITIATIVE. THE COMPOSITION OF THE WORKING
21 GROUP THAT WAS PUT TOGETHER FOR THIS INCLUDED OUR
22 SCIENTIFIC GRANTS WORKING GROUP MEMBERS THAT SERVE
23 ON THE PANEL TO PROVIDE THE SCIENTIFIC EVALUATION
24 AND PROVIDE SCIENTIFIC SCORES ON ALL APPLICATIONS.
25 THERE ARE OUR BOARD MEMBERS WHO ARE PATIENT ADVOCATE

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1 AND NURSE MEMBERS FROM THE ICOC WHO PROVIDE THE
2 PATIENT PERSPECTIVE ON DEI, SIGNIFICANCE AND
3 POTENTIAL IMPACT, AND ALSO OVERSIGHT ON THE REVIEW
4 PROCESS ITSELF, AND THEY OFTEN PROVIDE A SUGGESTED
5 SCIENTIFIC SCORE.

6 WE ALSO HAVE SCIENTIFIC SPECIALISTS.
7 THESE ARE NONVOTING, AD HOC MEMBERS WHO MAY
8 CONTRIBUTE TO ONE OR TWO OF THE APPLICATIONS WHEN
9 NEEDED TO BRING IN SPECIALIZED EXPERTISE.

10 THE SCORING OF THE REMIND APPLICATIONS
11 USED THE METHOD OF 1, 2, OR 3 WITH A SCORE OF 1
12 BEING EXCEPTIONAL MERIT AND WARRANTING FUNDING. A
13 SCORE OF 2 MEANS IT NEEDS IMPROVEMENT AND DOESN'T
14 WARRANT FUNDING, BUT COULD BE RESUBMITTED. AND I'LL
15 PROVIDE MORE DETAIL ON THAT IN JUST A SECOND. OR A
16 SCORE OF 3 IF IT'S SUFFICIENTLY FLAWED AND DOES NOT
17 WARRANT FUNDING.

18 THE SCORES ARE BASED ON THESE OVERALL
19 QUESTIONS OR CRITERIA. DOES THE PROJECT HOLD THE
20 NECESSARY SIGNIFICANCE AND POTENTIAL FOR IMPACT?
21 HERE WE ALSO WANT TO STRESS INNOVATION. SO IS THE
22 PROPOSAL INNOVATIVE? DOES IT HAVE A GOOD RATIONALE?
23 IS IT WELL PLANNED AND DESIGNED? IS IT FEASIBLE,
24 INCLUDING HAVING AN APPROPRIATE TEAM AND ALL THE
25 RESOURCES THAT ARE NEEDED TO ACCOMPLISH THE GOALS?

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1 AND DOES THE PROJECT UPHOLD THE PRINCIPLES OF
2 DIVERSITY, EQUITY, AND INCLUSION?

3 SO THIS TABLE SUMMARIZES THE OUTCOMES OF
4 THE GRANTS WORKING GROUP REVIEW AND THEIR
5 RECOMMENDATIONS. WE HAD 26 APPLICATIONS THAT WERE
6 REVIEWED. THAT WAS A PRETTY HIGH NUMBER, AND WE
7 DIDN'T EXPECT SUCH A LARGE NUMBER, BUT WE GOT IT.
8 SO IT PROVED TO BE A POPULAR OPPORTUNITY.

9 THERE WERE FIVE APPLICATIONS THAT EARNED A
10 SCORE OF 1. AND SO THOSE FIVE TOTAL TO 67.5 OR SO
11 MILLION. THE FUNDS THAT WE HAVE AVAILABLE IN ORDER
12 TO FUND APPLICATIONS IS 88.2. SO THOSE FIVE ARE
13 CERTAINLY WITHIN THE FUNDS AVAILABLE.

14 THERE ARE NINE APPLICATIONS THAT RECEIVED
15 A SCORE OF 2. THE TOTAL REQUEST OUT OF THOSE NINE
16 WOULD BE 112.2 MILLION, AND THEN THERE WERE 12 THAT
17 RECEIVED A SCORE OF 3.

18 WITH ALL OUR REVIEWS UNDER PROP 14, ANY
19 APPLICATION THAT IS NOT RECOMMENDED FOR FUNDING BY
20 THE GRANTS WORKING GROUP, BUT WHICH HAS 35 PERCENT
21 OR MORE OF THE MEMBERS SCORE TO FUND THE APPLICATION
22 NEEDS TO INCLUDE A MINORITY REPORT. AND THE
23 MINORITY REPORT REALLY IS A SUMMARY OF THE OPINION
24 OF THOSE THAT SCORED IN FAVOR OF FUNDING. THAT'S
25 INCLUDED WITHIN THE OVERALL REVIEW SUMMARY ITSELF.

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1 SO IT'S JUST MEANT TO HIGHLIGHT THE POINTS FROM THAT
2 GROUP TO THE EXTENT THAT WE ARE ABLE TO PUT THAT
3 TOGETHER. AND SO IN ORDER TO QUALIFY, THEN, YOU
4 HAVE TO HAVE 35 PERCENT OF THE MEMBERS SCORE A 1.

5 AND THERE WAS ONE APPLICATION THAT MET
6 THOSE CRITERIA AND QUALIFIED FOR A MINORITY REPORT,
7 WHICH WAS THE 16337. IT HAD OR RECEIVED A SCORE OF
8 1 FROM SEVEN MEMBERS AND A SCORE OF 2 FROM SEVEN
9 OTHER MEMBERS. BY DEFAULT, AND ABSENT OF A
10 MAJORITY, RESULTS IN A SCORE OF 2, AND SO THAT'S WHY
11 IT RECEIVED A SCORE OF 2.

12 THE TEAM IN TERMS OF ITS OWN
13 RECOMMENDATION REGARDING THIS APPLICATION SUPPORTS
14 THE SCORE OF 2, WHICH IS TO NOT FUND, BUT ALLOW THE
15 APPLICANTS TO REVISE AND RESUBMIT THIS APPLICATION.

16 AS MENTIONED BEFORE, THERE WERE ACTUALLY A
17 TOTAL OF NINE APPLICATIONS, INCLUDING THE ONE THAT
18 QUALIFIED FOR A MINORITY REPORT, THAT RECEIVED A
19 SCORE OF 2. AND SO THE SCORE OF 2 ALLOWS
20 RESUBMISSION IF TWO CONDITIONS ARE MET. ONE, THAT
21 THE TARGET NUMBER OF APPLICATIONS, IN THIS CASE SIX,
22 IS NOT REACHED. WE HAD FIVE. SO WE WERE ONE UNDER
23 THE GOAL. AND THE APPLICATION REVIEW SUBCOMMITTEE
24 AGREES TO CONSIDER ADDITIONAL APPLICATIONS FOR
25 FUNDING. SO THE APPLICATION REVIEW SUBCOMMITTEE CAN

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1 CHOOSE TO GO WITH JUST FIVE, OR YOU CAN CHOOSE TO
2 HAVE THOSE THAT ARE A 2 REVISE AND RESUBMIT TO GET
3 ADDITIONAL APPLICATIONS.

4 NOW, THE CAVEAT IS THAT THE REMAINING
5 BUDGET IS GOING TO ALLOW FOR ONE ADDITIONAL
6 APPLICATION, POSSIBLY TWO, ONLY IF THE APPLICANTS
7 REDUCE THEIR REQUESTED BUDGET WHEN THEY RESUBMIT.
8 SO DEPENDING ON THE EXTENT TO WHICH THAT HAPPENS, IF
9 IT HAPPENS, WE'RE LOOKING AT ONE, MAYBE TWO
10 APPLICATIONS AT BEST.

11 SO GIVEN ALL OF THAT, THE CIRM TEAM
12 RECOMMENDATION AS IT RELATES TO THESE APPLICATIONS
13 IS FOR THE APPLICATION REVIEW SUBCOMMITTEE TO
14 APPROVE FUNDING FOR THE FIVE APPLICATIONS THAT
15 RECEIVED A SCORE OF 1, TO NOT APPROVE FUNDING FOR
16 ALL THE APPLICATIONS THAT RECEIVED A SCORE OF 3, SO
17 THOSE ARE ALL THE ONES THAT DID NOT HAVE MERIT, AND
18 TO ALLOW FOR REVISION AND RESUBMISSION OF
19 APPLICATIONS THAT RECEIVED A SCORE OF 2. SO THAT
20 WOULD BE THE NINE APPLICATIONS.

21 THIS SLIDE IS JUST TO SHOW YOU THE BOARD
22 MEMBERS THAT HAVE INDICATED A CONFLICT OF INTEREST
23 WITH DISC4 APPLICATIONS. SO PLEASE BE MINDFUL OF
24 THAT IN TERMS OF DISCUSSION AND VOTING. I AM SURE
25 SCOTT AND CLAUDETTE WILL REMIND YOU IF THERE IS ANY

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1 INCURSION ON THAT.

2 LET ME SHARE SOMETHING ELSE. I WANT TO
3 SHARE WITH YOU THE SPREADSHEET THAT SHOWS THE RANK
4 ORDER BEFORE WE GO INTO DISCUSSION. SO GIVE ME ONE
5 SECOND. SO HERE YOU CAN SEE THE FIVE APPLICATIONS
6 THAT RECEIVED A SCORE OF 1 AND THE RELATIVE NUMBER
7 OF VOTES THAT IT RECEIVED FROM THE WORKING GROUP
8 MEMBERS. SO THOSE ARE THE RECOMMENDED ONES. BELOW
9 THAT ARE THE NINE APPLICATIONS THAT WE RECOMMEND
10 REVISE AND RESUBMIT. SO THOSE ARE THE NINE THAT
11 INCLUDE THE ONE WITH THE MINORITY REPORT AND BELOW
12 THAT ARE THOSE THAT SCORED A 3.

13 SO I WILL LEAVE THIS UP THERE. AND, MR.
14 CHAIRMAN, I'LL TURN IT BACK TO YOU.

15 CHAIRMAN IMBASCIANI: THANK YOU, GIL, FOR
16 YOUR PRESENTATION. I'M GOING TO ASK FOR A COMMENT
17 FIRST FROM SCOTT TOCHER IF YOU WOULD.

18 MR. TOCHER: THANK YOU, VITO. BECAUSE, AS
19 GIL ALLUDED, THE BUDGET OF ALL PENDING APPLICATIONS
20 EXCEEDS THE PROGRAM BUDGET AUTHORIZED FOR THIS RFA
21 BY THE ICOC. FOR NOW I WOULD ASK MEMBERS DURON AND
22 FLOWERS TO REFRAIN FROM MAKING OR SECONDING ANY
23 MOTIONS OR SPEAKING AT THIS TIME REGARDING
24 APPLICATIONS UNTIL SUCH TIME AS THEIR CONFLICTED
25 APPLICATIONS HAVE BEEN DISPENSED WITH. YOU'RE STILL

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1 A CRITICAL COMPONENT OF THE FINAL VOTES, AND I'LL
2 HAVE FURTHER INSTRUCTION ON HOW YOU CAN PHRASE THAT
3 AT THE APPROPRIATE TIME. THANK YOU, VITO.

4 CHAIRMAN IMBASCIANI: THANK YOU, SCOTT.

5 SO THE CHAIR WOULD LIKE TO ENTERTAIN A
6 MOTION TO ACCEPT THE RECOMMENDATIONS OF OUR GRANTS
7 REVIEW TEAM.

8 MR. FISCHER-COLBRIE: SO MOVED. MARK
9 FISCHER-COLBRIE.

10 CHAIRMAN IMBASCIANI: I HEAR SECONDS. I
11 DON'T HEAR THE MOTION.

12 MR. TOCHER: MARK MADE THE MOTION.
13 SECONDED BY DAVID.

14 CHAIRMAN IMBASCIANI: MARK MADE THE MOTION
15 AND SECONDED BY DAVID HIGGINS. THANK YOU.

16 SO WE CAN COMMENCE WITH DISCUSSION ON THE
17 MOTION TO ACCEPT THE RECOMMENDATIONS OF THE GRANTS
18 REVIEW TEAM WITH COMMENTS FROM BOARD MEMBERS FIRST.
19 I'M NOT SEEING THE GALLERY VIEW. I'M SORRY,
20 CLAUDETTE. IS THERE A WAY TO...

21 MS. MANDAC: THERE ARE CURRENTLY NO HANDS
22 RAISED.

23 CHAIRMAN IMBASCIANI: ASKING THE BOARD
24 MEMBERS ONCE AGAIN IF THERE'S ANY COMMENT ON THE
25 MOTION, WHICH WOULD BE TO FUND THE FIVE IN TIER I,

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1 NOT TO FUND THE SIX IN TIER III, AND TO ALLOW
2 RECONSIDERATION OF THE NINE IN TIER II.

3 DR. DULIEGE: SO THIS IS ANNE-MARIE.
4 ACTUALLY I DO HAVE A COMMENT; BUT BECAUSE I'M DOING
5 THIS VIA MY CELL PHONE, RIGHT NOW I DON'T SEE HOW TO
6 RAISE MY HANDS ON THE TRADITIONAL WAY. CAN I ASK A
7 QUESTION ABOUT THIS?

8 CHAIRMAN IMBASCIANI: ABSOLUTELY,
9 ANNE-MARIE. IT'S YOURS.

10 DR. DULIEGE: SO THIS QUESTION IS NOT
11 ABOUT THE FIRST FIVE APPLICATIONS. BUT RIGHT NOW
12 WHAT WE'RE SAYING WITH THIS MOTION IS THAT WE DO NOT
13 RECOMMEND TO FUND TIER II; IS THAT CORRECT?

14 CHAIRMAN IMBASCIANI: THAT'S CORRECT WITH
15 THE PROVISIO THAT THEY ARE ALLOWED TO BE
16 RECONSIDERED -- RESUBMITTED FOR RECONSIDERATION.

17 DR. DULIEGE: SO A QUESTION FOR ANYONE,
18 PARTICULARLY FOR GIL. THERE IS THE, I'LL CALL IT A
19 PROBLEMATIC APPLICATION, BUT MAYBE PROBLEMATIC IS
20 NOT THE RIGHT WORD, OF 337. AND I THINK WE HAVE THE
21 OPPORTUNITY TO REVIEW THE APPLICATION AS WELL AS THE
22 LETTERS SUBMITTED BY THE TEAM.

23 AS I LOOK AT THE SCORES, THIS ONE DIFFERS
24 FROM ANY OTHER APPLICATION IN THE SENSE THAT THE
25 SCORE OF SEVEN AND SEVEN IS NOT QUITE AS HIGH BY FAR

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1 AS THE FIRST FIVE. ON THE OTHER HAND, IT'S ALSO
2 BETTER THAN THE OTHER APPLICATIONS BELOW WHICH HAVE
3 A VAST MAJORITY OF SCORES OF 2. AND THE APPLICANTS
4 MADE THE COMMENT THAT NOT 15 MEMBERS COULD VOTE,
5 SEVEN/SEVEN, WHAT'S GOING ON? IT'S A BIT UNFAIR.

6 GIL OR ANYONE ELSE, COULD YOU PROVIDE A
7 PERSPECTIVE ON THIS PLEASE?

8 DR. SAMBRANO: SURE. I'M HAPPY TO IF
9 THAT'S ALL RIGHT. SO THANK YOU. THERE WERE A TOTAL
10 OF 14 MEMBERS THAT PROVIDED A SCORE. AND SO AS
11 EVERYONE RECOGNIZES, THERE ARE 15 MEMBERS ON THE
12 PANEL. THERE ARE CASES FOR SOME OF THE
13 APPLICATIONS, AND YOU MAY SEE IT FOR A COUPLE OF
14 OTHERS, WHERE YOU HAVE ONE OR TWO FEWER VOTES
15 BECAUSE OF A CONFLICT. SO THOSE THAT ARE CONFLICTED
16 CAN'T. OR IF THEY DID NOT FOR SOME REASON
17 PARTICIPATE IN THE REVIEW OF THAT APPLICATION.

18 A SCORE OF SEVEN VERSUS SEVEN, BASED ON
19 THE SCORING METHOD THAT WE HAVE, BY DEFAULT GOES TO
20 A SCORE OF 2 RATHER THAN UPGRADING IT TO A SCORE OF
21 1. AND THE REASON WE DO THAT IS BECAUSE, AT LEAST
22 FROM OUR PERSPECTIVE, IF THERE IS NO MAJORITY, THEN
23 IT IS BEST TO HAVE THE APPLICANTS ADDRESS CONCERNS
24 AND RESUBMIT. GIVEN THAT THERE IS ENOUGH CONCERN
25 OUT OF THOSE SEVEN THAT SCORED IT A 2, THAT IN OUR

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1 VIEW WOULD WARRANT AT LEAST ADDRESSING THOSE
2 COMMENTS IN SOME FORM.

3 JUST MORE BROADLY, IN TERMS OF HOW THAT
4 APPLICATION COMPARES TO THE OTHER EIGHT THAT
5 RECEIVED A SCORE OF 2, WE LOOKED AT ALL OF THOSE
6 CAREFULLY TO DETERMINE IS IT WORTH THAT THE CIRM
7 TEAM RECOMMEND THE APPLICATION WITH A MINORITY
8 REPORT OR PERHAPS ANY OF THE OTHERS. AND WE FELT
9 THAT IT WAS IMPORTANT TO GIVE ALL OF THEM AN
10 OPPORTUNITY TO REVISE BECAUSE THEY ALL HAVE FIXABLE
11 ELEMENTS THAT COULD BE ADDRESSED. AND MANY OF THESE
12 HAVE PROMISING APPROACHES AND INNOVATIVE METHODS
13 THAT THEY HAVE INCLUDED IN THE APPLICATION THAT MAY
14 BE WORTHWHILE.

15 SO FROM OUR PERSPECTIVE, WE THOUGHT IT
16 MIGHT BE MOST FAIR TO GIVE ALL OF THEM THE
17 OPPORTUNITY TO ADDRESS THE CONCERNS OF THE GRANTS
18 WORKING GROUP AND HAVE THEM LOOK AT IT AGAIN IN
19 ORDER TO DETERMINE WHAT THEN MOVES FORWARD.

20 CHAIRMAN IMBASCIANI: MARVIN SOUTHARD.
21 ANNE-MARIE, YOU WANT TO FOLLOW UP?

22 DR. DULIEGE: APPRECIATE THIS PERSPECTIVE,
23 GIL. IT ALL MAKES SENSE. AND, AGAIN, THESE ARE
24 SORT OF RULES THAT YOU HAVE APPLIED ACROSS THE BOARD
25 AND OVER TIME. IN SOME WAY, HOWEVER, I COULD SEE A

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1 PERSPECTIVE SAYING IT'S A BIT UNFAIR IN THE SENSE
2 THAT ONE REVIEWER WAS MISSING FOR GOOD REASON. HAD
3 THESE REVIEWERS SCORED 1, IT WOULD BE A SLIGHT
4 MAJORITY, BUT THIS WOULD HAVE MOVED THE APPLICATION
5 IN THE FIRST TIER. AND IN THAT CASE IT DIFFERS FROM
6 THE OTHERS; IS THAT RIGHT?

7 DR. SAMBRANO: YEAH. BUT SINCE WE REALLY
8 DON'T KNOW WHAT THAT FIFTEENTH REVIEWER WOULD HAVE
9 SCORED, IT COULD HAVE EASILY BEEN A 2 AS WELL.

10 DR. DULIEGE: THE CHALLENGE THAT I SEE
11 HERE, AND I WOULD WELCOME COMMENTS FROM MY
12 COLLEAGUES, IS THAT THERE'S ROOM FOR ONE MORE ONLY
13 OUT OF THE, I BELIEVE, NINE APPLICATIONS THAT ARE
14 INVITED TO REVISE AND RESUBMIT.

15 DR. SAMBRANO: CORRECT.

16 DR. DULIEGE: IS THIS GOING TO BE ON A
17 DEADLINE BASIS, OR THE FIRST ONE WAS THE TIME AND IS
18 PROMPT TO RESUBMIT AND IMPROVE THEIR SCORE WILL THEN
19 BE THE WINNER. HOW IS THE PROCESS GOING TO TAKE
20 PLACE?

21 DR. SAMBRANO: RIGHT. SO THE PROCESS IS
22 THE SAME AS WE'VE USED FOR OTHER OUR INFRASTRUCTURE
23 PROGRAMS WHERE WE WILL SCHEDULE AND HOLD ANOTHER
24 REVIEW. EVERY APPLICANT THAT RECEIVED A SCORE OF 2
25 IS GOING TO RECEIVE INSTRUCTIONS FOR HOW TO SUBMIT

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1 THEIR REVISION. SO THIS IS A REVISION. IT'S NOT
2 STARTING OVER. THEY WILL BE ASKED TO ADDRESS THE
3 CONCERNS. AND SO THESE WILL ALL GO TO BASICALLY THE
4 SAME PANEL OF REVIEWERS TO LOOK AT AGAIN AND
5 DETERMINE IF THE CONCERNS HAVE BEEN ADDRESSED. AND
6 THEN THEY WILL ISSUE ANOTHER SCORE BASED ON THAT AND
7 DISCUSSION THAT THEY HAVE AT A SCHEDULED MEETING.

8 DR. DULIEGE: OKAY. WHEN DO YOU
9 ANTICIPATE THAT THAT WILL HAPPEN? THREE MONTHS?

10 DR. SAMBRANO: YEAH. SO WE ANTICIPATE
11 PROVIDING A COUPLE OF MONTHS FOR APPLICANTS TO
12 REVISE THEIR APPLICATIONS AND SUBMIT THEM. AND THEN
13 TWO TO THREE MONTHS BEYOND THAT BEFORE IT COMES TO
14 THE BOARD AGAIN.

15 DR. DULIEGE: THANK YOU, GIL. YOUR
16 RESPONSES HAVE BEEN VERY HELPFUL TO ME. I CAN SAY
17 THAT THERE'S NOTHING UNFAIR IN WHAT YOU HAVE
18 EXPLAINED TO ME. I CAN UNDERSTAND CERTAINLY THE
19 FRUSTRATION OF THE APPLICANTS, BUT THERE'S NO FLAW
20 TO THE PROCESS THAT HAS BEEN APPLIED BY THE CIRM
21 TEAM. SO THANK YOU. I WELCOME ANY OTHER COMMENTS.

22 CHAIRMAN IMBASCIANI: THANK YOU,
23 ANNE-MARIE. I THINK MARVIN SOUTHARD IS NEXT.

24 DR. SOUTHARD: I WOULD SUPPORT FUNDING
25 THAT ADDITIONAL APPLICATION MOSTLY IN THE CAUSE OF

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1 EFFICIENCY. THERE WOULD BE A LOT OF PEOPLE DOING A
2 LOT OF WORK FOR CHASING THIS, AND IT'S LIKELY THAT
3 THAT ONE WOULD WIN. SO I WOULD SAY LET'S BE
4 EFFICIENT AND FUND IT NOW.

5 CHAIRMAN IMBASCIANI: ANYONE ELSE? THANK
6 YOU, MARVIN.

7 MR. TOCHER: ADRIANA PADILLA.

8 CHAIRMAN IMBASCIANI: ADRIANA PADILLA IS
9 NEXT.

10 DR. PADILLA: THANK YOU. IS THIS THE ONLY
11 OPPORTUNITY TO APPLY, OR IS THIS GOING TO BE AN
12 ONGOING APPLICATION PROCESS FOR THOSE IN THE SCORE 2
13 CATEGORY? SAY, FOR INSTANCE, THERE'S GOING TO BE
14 ANOTHER CALL FOR APPLICATIONS DOWN THE ROAD IN
15 ANOTHER YEAR.

16 DR. SAMBRANO: RIGHT. YES, THAT'S A GOOD
17 QUESTION. SO THERE WOULD BE THE REVISION IF YOU
18 VOTE IN FAVOR OF HAVING THEM REVISE; BUT IN TERMS OF
19 ADDITIONAL OPPORTUNITIES, THE REMIND PROGRAM WILL
20 COME BACK AGAIN; HOWEVER, IT MAY NOT BE FOCUSED ON
21 NEUROPSYCHIATRIC DISEASES. SO IT WILL LIKELY NOT
22 HAVE THE SAME EMPHASIS, MEANING THAT THE STRUCTURE
23 OF THE PROGRAM WITH THIS FOCUS MAY NOT COME BACK,
24 BUT IT WILL LIKELY BE INCLUSIVE. I THINK THE GOAL
25 IS TO MAKE IT BROADER, BUT IT'S NOT GOING TO BE

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1 QUITE EXACTLY THE SAME.

2 DR. PADILLA: THANK YOU.

3 CHAIRMAN IMBASCIANI: THANK YOU, GIL AND
4 ADRIANA. FRED FISHER.

5 DR. FISHER: SO FOR BOARD MEMBERS THAT
6 HAVE NOT BEEN PART OF A REVIEW PROCESS, THEY MAY NOT
7 HAVE AN APPRECIATION FOR HOW MUCH EFFORT ACTUALLY
8 GOES INTO THESE REVIEWS. I KNOW MARV UNDERSTANDS
9 THIS QUITE WELL. AND I THINK FOR US TO DISREGARD
10 THE CONCERNS OF HALF OF THE REVIEWERS WOULD BE NOT
11 ONLY A DEPARTURE FROM OUR REGULAR PRACTICE, BUT
12 REALLY AN INSULT TO THE TIME AND EFFORT THAT THOSE
13 REVIEWERS SPENT ACTUALLY OUTLINING THEIR CONCERNS
14 AND DOING SO IN A WAY THAT THE APPLICANT CAN EASILY
15 RESPOND TO.

16 IT'S NOT A NEW APPLICATION. IT'S SIMPLY
17 RESPONDING TO THE CONCERNS. WITH SO MANY OF THE
18 REVIEWERS AGREEING THAT THIS NEEDS TO COME BACK WITH
19 SOME ISSUES ADDRESSED, I DON'T THINK WE WANT TO BE
20 FUNDING PROPOSALS WHERE HALF THE REVIEW COMMITTEE
21 SAYS DON'T FUND IT NOW. LET THEM COME BACK AND
22 RESPOND TO THESE ISSUES.

23 SO I THINK WE OUGHT TO STICK TO OUR
24 PRACTICE. WE OUGHT TO STICK TO THE RECOMMENDATION
25 OF THE CIRM TEAM. AND WE OUGHT TO RESPECT THE

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1 EFFORTS OF THE REVIEWERS WHO ARE EXPERTS IN THE
2 FIELD WHO THOUGHT ENOUGH OF THIS PROPOSAL TO WARRANT
3 IT A 2 RATHER THAN A 3. BUT WE OUGHT TO NOT SIMPLY
4 IGNORE THEIR CONCERNS MOVING FORWARD WITH FUNDING
5 WITHOUT ADDRESSING THEIR CONCERNS.

6 CHAIRMAN IMBASCIANI: THANK YOU, FRED.

7 I'M GOING TO ASK JOE PANETTA, AND HE'LL BE
8 FOLLOWED BY DAVID HIGGINS. JOE.

9 MR. PANETTA: THANK YOU. I THINK MARV
10 JUST PRETTY MUCH SAID IT ALL FOR ME. THE ONLY OTHER
11 THING THAT I WOULD ADD IS THAT WE MIGHT POSSIBLY
12 SPLIT THE WAY THAT WE MAKE A MOTION ON THIS AND
13 MAYBE MOVE PAST THE FIRST GROUP AND THEN TAKE A
14 SEPARATE VOTE ON THE SECOND GROUP IF THAT MAKES
15 SENSE BECAUSE MAYBE THERE ARE VARYING OPINIONS ABOUT
16 THAT 50-50 SPLIT IN THE VOTE ON THAT APPLICATION.

17 IN ALL THE TIME THAT I'VE BEEN ON THIS
18 COMMITTEE I CAN'T REMEMBER -- MAYBE THERE'S SOME
19 EXAMPLES -- BUT I CAN'T REMEMBER WHEN WE'VE APPROVED
20 AN APPLICATION THAT'S HAD THAT KIND OF A SPLIT IN
21 THE VOTE. THANK YOU.

22 CHAIRMAN IMBASCIANI: THANKS, JOE. DAVID.

23 DR. HIGGINS: JUST A QUICK QUESTION
24 REALLY. WE'VE HAD THIS CONVERSATION HERE ABOUT THE
25 NUMBERS, THE 1-2-3 SCORING SYSTEM, FOR THESE VARIOUS

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1 GRANTS. HAS ANY CONSIDERATION BEEN GIVEN TO THE
2 CONTENT OF THE GRANTS, LIKE ONE IS PARTICULARLY
3 MORE -- WE BEING FOLKS AT CIRM UNDERSTAND WHAT'S
4 IMPORTANT IN THE FIELD AND, THEREFORE, WE MIGHT BIAS
5 OUR GRANT PROCESS TO THOSE THAT ARE DEVELOPING
6 CERTAIN TECHNOLOGIES OR SCIENTIFIC QUESTIONS? I
7 DON'T THINK WE DO. MAYBE THERE'S NO MECHANISM TO DO
8 THAT, BUT I JUST WANTED TO CLARIFY THAT.

9 CHAIRMAN IMBASCIANI: A QUESTION FOR GIL?

10 DR. HIGGINS: A QUESTION FOR GIL. THANK
11 YOU.

12 DR. SAMBRANO: WELL, IF I UNDERSTAND YOUR
13 QUESTION, WE DID LOOK AT ALL OF THESE APPLICATIONS
14 THAT SCORED A 2 WITH THE QUESTION OF DO THESE HAVE
15 VALUE? ARE THEY PROMISING? AND WE FELT THAT THERE
16 ARE MANY WITHIN THAT GROUP THAT HOLD PROMISE. AND,
17 AGAIN, MANY OF THEM HAVE CONCERNS FROM THE GRANTS
18 WORKING GROUP THAT ARE ADDRESSABLE. AND SO WE FELT,
19 RATHER THAN TRYING TO CHOOSE ONE, THAT IT WOULD BE
20 BETTER FOR THE APPLICANTS TO PRESENT THEIR CASE TO
21 THE GRANTS WORKING GROUP AND HAVE THEM DETERMINE
22 WHAT THEY FEEL IS MOST MERITORIOUS.

23 DR. HIGGINS: THANK YOU.

24 CHAIRMAN IMBASCIANI: THANK YOU, DAVID AND
25 GIL. ANY OTHER BOARD MEMBERS WANT TO COMMENT ON THE

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1 MOTION? IF NOT, AND I CAN COME BACK TO YOU IF YOU
2 HAVE A SUBSEQUENT THOUGHT, I'M GOING TO ASK IF
3 THERE'S ANY MEMBER OF THE PUBLIC THAT WOULD LIKE TO
4 COMMENT ON THE MOTION.

5 MS. MANDAC: THERE ARE FIVE HANDS RAISED.

6 CHAIRMAN IMBASCIANI: THERE ARE FIVE HANDS
7 RAISED. I'M GOING TO ASK CLAUDETTE TO MONITOR THIS.

8 MS. MANDAC: SO EVERYONE WITH THEIR HANDS
9 RAISED, YOU DO HAVE THREE MINUTES EACH. WE WILL
10 KEEP A TIMER. YOU WILL BE ABLE TO SEE THIS TIMER ON
11 THE TOP CORNER OF YOUR ZOOM MEETING ROOM. WHEN YOUR
12 TIME IS UP, WE WILL MUTE YOU. SO PLEASE MAKE SURE
13 TO PAY ATTENTION TO THE TIME.

14 WE'RE STARTING WITH DR. BHADURI AND WILL
15 BE FOLLOWED BY DR. KORNBLUM. SO, DR. BHADURI, YOU
16 HAVE THE FLOOR.

17 DR. BHADURI: THANK YOU VERY MUCH FOR THE
18 OPPORTUNITY. AND I REALLY APPRECIATE THE EMPHASIS
19 AND FOCUS FROM CIRM ON FUNDING GRANTS RELATED TO
20 NEUROPSYCHIATRIC DISEASES, WHICH ARE AN IMPORTANT
21 CHALLENGE IN OUR COMMUNITY AND IN CALIFORNIA.

22 I'M WRITING AS A CONTACT PI ON APPLICATION
23 16337. AND I BELIEVE THAT WE HAVE BEEN SUBJECTED TO
24 AN UNFAIR DECISION PROCESS. I THINK THAT THIS
25 TRACKS WITH A LOT OF THE COMMENTS THAT HAVE BEEN

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1 DISCUSSED IN THE MEETING AS WELL. SO I WILL TRY TO
2 KEEP THIS BRIEF.

3 BUT I THINK THE ARGUMENTS THAT SEVEN VOTES
4 ARE BEING IGNORED FOR TIER II ALSO IGNORES THE FACT
5 THAT SEVEN VOTES FOR TIER I ARE BEING IGNORED. IN
6 BASEBALL A TIE GOES TO THE RUNNER, AND IN FOOTBALL A
7 TIE GOES TO THE RECEIVER. AND SO WE FEEL THAT THE
8 AUTOMATIC CLASSIFICATION TO TIER II IS A BIT
9 ARBITRARY.

10 I WOULD LIKE TO SECOND SOME OF THE POINTS
11 MADE BY MARVIN SOUTHARD, THAT EFFICIENCY IN THIS
12 PROCESS IS REALLY IMPORTANT BOTH FOR THE URGENCY OF
13 THE PROBLEM AND FOR THE RESOURCES OF THE STATE OF
14 CALIFORNIA. ADDITIONALLY, THE COMMENTS THAT WERE
15 HIGHLIGHTED IN THE MINORITY REPORT AND IN OUR
16 APPLICATION SPECIFICALLY HIGHLIGHTED THE INNOVATIVE
17 HYPOTHESIS AND THE STRENGTH OF THE APPLICATION TEAM
18 THAT DROVE THE RECOMMENDATION, WHICH IS SOMETHING
19 THAT GIL REALLY NICELY OUTLINED AS A KEY FOCUS OF
20 THIS REMIND PROGRAM.

21 THEY ALSO HIGHLIGHTED THAT THEY WERE VERY
22 ENTHUSIASTIC ABOUT THE PROPOSAL AND THAT ALTERED
23 METABOLISM VIA DIETARY INTERVENTIONS CAN IMPACT
24 DEVELOPMENT IN NEUROPSYCHIATRIC DISEASES. AND MORE
25 ON THE SPECIFIC SCIENTIFIC CONTENT WILL BE

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1 HIGHLIGHTED BY MY OTHER TEAM MEMBERS. WE THINK THAT
2 THIS IS A REALLY EXCITING, POTENTIAL NONINVASIVE
3 TREATMENT.

4 HAVING LISTENED TO THE RECENT CIRM BOARD
5 DISCUSSIONS WITH GREAT THE ATTENTION, WE REALIZE
6 YOUR DESIRE TO RESPECT THE PROCESS AND THE
7 RECOMMENDATIONS OF THE CIRM STAFF. AND SO WE WOULD
8 LIKE TO PROPOSE AN ALTERNATIVE BECAUSE WE FEEL IT'S
9 UNFAIR, AS HAS BEEN HIGHLIGHTED BY OTHERS ON THIS
10 CALL, INCLUDING ANNE-MARIE, THAT THE CATEGORIZATION
11 OF OUR PROPOSAL IN THE SAME PRIORITY CLASSIFICATION
12 AS THE REMAINING TIER II APPLICATIONS IS UNFAIR
13 GIVEN THAT THE CLOSEST ONLY HAS TWO VOTES.

14 HOWEVER, THE CONSTRUCTIVE AND FULLY
15 ADDRESSABLE CRITICISMS OFFERED BY THE REVIEWERS WERE
16 HELPFUL. AND WE WOULD PROPOSE A LIMITED REVISION
17 WHERE ONLY A HANDFUL SPECIFICALLY OF OUR APPLICATION
18 WOULD BE OFFERED A REVISION OPPORTUNITY. AND WE
19 WOULD BE HAPPY TO WORK WITH THE PROGRAM OFFICERS TO
20 DISCUSS THESE CONCERNS, WHICH COULD ADDRESS BOTH THE
21 EFFICIENCY OF THE PROCESS, THE URGENCY OF THE
22 PROBLEM, AND THE CONCERNS OF THE WORKING GROUP
23 REGARDING THE COMMENTS FROM THE REVIEWERS THAT GAVE
24 IT A TIER II CLASSIFICATION. WE FEEL THAT THIS
25 WOULD BE THE MOST COMPREHENSIVE AND FAIR PROCESS

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1 THAT WOULD ALLOW US TO BALANCE THE CONCERNS OF THE
2 REVIEWERS, THE CONTENTS OF OUR SCIENTIFIC PROPOSAL
3 AND ITS INNOVATION, AS WELL AS THE EFFICIENCY AND
4 TAXPAYER MONEY THAT WOULD OTHERWISE BE SPENT ON THIS
5 PROCESS.

6 THANK YOU FOR THE TIME AND FOR THE
7 OPPORTUNITY, AND THANK YOU TO ALL OF THE REVIEWERS
8 WHO WERE ABLE TO GIVE US FEEDBACK ON OUR PROPOSAL.
9 WE'RE REALLY EXCITED ABOUT THE SCIENCE AND HOPE THAT
10 WE CAN TRANSLATE THIS TO THE CLINIC VERY SOON.

11 CHAIRMAN IMBASCIANI: THANK YOU, DR.
12 BHADURI.

13 MS. MANDAC: THANK YOU SO MUCH, DR.
14 BHADURI. NEXT WE HAVE DR. KORNBLUM TO BE FOLLOWED
15 BY DR. CROUCH. DR. KORNBLUM, YOU HAVE THE FLOOR.
16 THREE MINUTES.

17 DR. KORNBLUM: GOOD MORNING. I'LL READ MY
18 STATEMENT FOR EFFICIENCY SAKE. MY NAME IS HARLEY
19 KORNBLUM. I'M A BOARD CERTIFIED PEDIATRIC
20 NEUROLOGIST, THE DIRECTOR OF THE UCLA INTELLECTUAL
21 AND DEVELOPMENTAL DISABILITIES RESEARCH CENTER, AND
22 A COLLABORATOR ON THE BHADURI REMIND-L GRANT
23 APPLICATION. I'M SPEAKING ON BEHALF OF MY PATIENTS,
24 THEIR FAMILIES, AND MY OWN FAMILY.

25 IN MY CLINICAL PRACTICE, I FREQUENTLY SEE

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1 CHILDREN WITH NEURODEVELOPMENTAL AND
2 NEUROPSYCHIATRIC DISORDERS. MY FIRST RESEARCH
3 EFFORTS WERE IN THE FIELD OF BASIC DEVELOPMENTAL
4 NEUROSCIENCE. HOWEVER, A FEW EVENTS DIRECTED ME
5 TOWARDS TRANSLATIONAL STUDY OF AUTISTIC SPECTRUM
6 DISORDER. FIRST, MY LAB WAS INTIMATELY INVOLVED IN
7 THE DISCOVERY THAT A GENE CALLED PTEN PLAYS A
8 CRITICAL ROLE IN NEURODEVELOPMENT AND NEURO STEM
9 CELLS. MUTATIONS IN THIS GENE AND PATHWAY AND THE
10 PATHWAY THAT IT REGULATES WAS LATER SHOWN TO CAUSE
11 AUTISTIC SPECTRUM DISORDERS AND FOCAL EPILEPSIES,
12 BOTH DISORDERS THAT I TREAT AS A CLINICIAN.

13 SECOND, MY NEPHEW AVIE HAD A SEVERE
14 AUTISTIC REGRESSION AT THE AGE OF TWO, GOING FROM A
15 BRIGHT, TALKATIVE CHILD TO AN INDIVIDUAL THAT COULD
16 NOT COMMUNICATE WITH THE OUTER WORLD. THIS BROKE
17 OUR HEARTS AND STEELED MY RESOLVE TO CONTRIBUTE BY
18 WHATEVER MEANS TO IMPROVING THE LIVES OF AUTISTIC
19 CHILDREN.

20 A RECENT PART OF THIS EFFORT IS TO
21 INVESTIGATE HOW PTEN INFLUENCES NEURODEVELOPMENT
22 THROUGH ITS EFFECTS ON METABOLISM. WHY IS THIS TYPE
23 OF APPROACH IMPORTANT? IT'S BECAUSE METABOLISM IS
24 TARGETABLE NOT ONLY BY MEDICATION, BUT ALSO BY DIET.

25 IN OUR CLINICAL PRACTICE WE HAVE BEEN

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1 USING DIET AND NUTRIENT INTERVENTIONS FOR A NUMBER
2 OF DEVELOPMENTAL DISORDERS. SOME OF THESE DISORDERS
3 CALLED INBORN ERRORS OF METABOLISM REQUIRE DIETS
4 THAT LACK OR SUBSTITUTE CERTAIN NUTRIENTS, DIETS
5 THAT QUITE LITERALLY KEEP CHILDREN ALIVE AND
6 FUNCTIONING.

7 EPILEPSY, ONE OF THE MOST COMMON CHILDHOOD
8 NEUROLOGICAL DISORDERS, CAN ALSO BE TARGETED BY
9 DIET, INCLUDING THE KETOGENIC DIET WITH WHICH A
10 NUMBER OF MY PATIENTS HAVE BEEN TREATED. OUR REMIND
11 PROPOSAL EXAMINES THE ROLE OF METABOLISM IN THE
12 DEVELOPMENT AND POTENTIAL TREATMENT OF TWO
13 CATEGORIES OF DISORDERS THAT ARE FOUNDED IN
14 NEURODEVELOPMENT, AUTISTIC SPECTRUM DISORDER AND
15 SCHIZOPHRENIA.

16 DESPITE AMAZING ADVANCES IN UNDERSTANDING
17 THE GENETIC UNDERPINNING OF THESE DISORDERS,
18 TREATMENT OPTIONS ARE UNSATISFACTORY TO SAY THE
19 LEAST. THE CONCEPT THAT DIETARY INTERVENTIONS COULD
20 BE USED TO TREAT OR EVEN PREVENT THESE SYNDROMES IS
21 MORE THAN A LITTLE EXCITING TO ME. COULD DIETARY
22 THERAPIES BE USED TO ALLOW CHILDREN AND ADULTS WITH
23 AUTISM AND SCHIZOPHRENIA TO LEAD MORE FULFILLING AND
24 ENRICHED LIVES? OUR PROPOSAL IS A FIRST STEP
25 TOWARDS THESE GOALS. IT USES RIGOROUS SCIENCE AD

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1 STATE-OF-THE-ART MODELS TO ESTABLISH HOW METABOLISM
2 INFLUENCES BRAIN DEVELOPMENT, WHAT ROLES IT PLAYS IN
3 THE DEVELOPMENT OF THESE DISORDERS, AND WHETHER
4 DIETARY MODULATION CAN BE USED TO INFLUENCE THESE
5 PROCESSES.

6 NEW APPROACHES ARE URGENTLY NEEDED.
7 PLEASE ALLOW US THE OPPORTUNITY TO TAKE THESE FIRST
8 STEPS.

9 MS. MANDAC: THANK YOU VERY MUCH, DR.
10 KORNBLUM. NEXT UP WE HAVE DR. CROUCH TO BE FOLLOWED
11 BY DR. QUADRATO. DR. CROUCH, YOU HAVE THE FLOOR.

12 DR. CROUCH: THANK YOU. HI, EVERYONE. MY
13 NAME IS BETSY CROUCH, AND I'M A PI ALSO ON THE 337
14 APPLICATION. I'M A BOARD CERTIFIED PEDIATRICIAN AND
15 A NEONATOLOGIST. I AM ALSO A VASCULAR BIOLOGIST AND
16 A NEUROSCIENTIST AT THE UNIVERSITY OF CALIFORNIA SAN
17 FRANCISCO.

18 CLINICALLY I WORK PRIMARILY IN THE
19 NEONATAL INTENSIVE CARE UNIT TAKING CARE OF
20 PREMATURE BABIES AND OTHER BABIES WHO HAVE HEALTH
21 CHALLENGES. TO TAKE A HISTORICAL APPROACH, IN THE
22 1960S FIRST LADY JACKIE KENNEDY GAVE BIRTH TO
23 PATRICK KENNEDY, WHO DIED TWO DAYS LATER DUE TO
24 COMPLICATIONS OF PREMATUREITY. THIS TRAGEDY INSPIRED
25 MUCH RESEARCH AND INDEED WAS A MAJOR FACTOR IN THE

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1 CREATION OF NICHD.

2 NOW, AS EVIDENCE OF OUR PROGRESS, PATRICK
3 KENNEDY HAD A 90-PERCENT CHANCE OF DYING AT HIS
4 BIRTH WEIGHT AND GESTATIONAL AGE IN 1963. TODAY HE
5 WOULD HAVE OVER A 95-PERCENT CHANCE OF SURVIVING.
6 OUR PREMATURE BABIES CAN NOW SURVIVE WHEN BORN
7 EXTREMELY EARLY, JUST OVER HALF WAY THROUGH THE
8 TYPICAL PREGNANCY, BUT WE KNOW THAT SURVIVAL IS NOT
9 THE WHOLE STORY. ALL PREMATURE BABIES AND
10 ESPECIALLY THE YOUNGEST ONE CARRY A HIGH RISK OF
11 NEUROLOGICAL AND MENTAL HEALTH PROBLEMS. ACCORDING
12 TO A 2023 PUBLICATION, PREMATURELY BORN CHILDREN
13 HAVE A 30-PERCENT HIGHER RISK OF AUTISM SPECTRUM
14 DISORDERS THAN THOSE WHO ARE BORN FULL TERM. AND,
15 OF COURSE, ASD IS ONE OF THE FOCUSES OF OUR
16 PROPOSAL.

17 IN ADDITION, BABIES WHO ARE BORN BEFORE 33
18 WEEKS OF GESTATION HAVE DOUBLE THE RISK OF
19 DEVELOPING SCHIZOPHRENIA, THE OTHER FOCUS OF OUR
20 PROPOSAL, AND PSYCHOSIS AS ADULTS, AND THAT RISK
21 INCREASES BY ALMOST SEVENFOLD IN OUR YOUNGEST
22 BABIES.

23 I WORKED IN THE NICU EARLIER THIS MONTH
24 AND TOOK CARE OF A FAMILY WITH TWINS WHO WERE BORN
25 AT OUR YOUNGEST GESTATIONAL AGE. ONE OF THEM

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1 ALREADY HAS EVIDENCE OF BRAIN INJURY, A SEVERE BRAIN
2 HEMORRHAGE THAT I ALSO STUDY IN MY LAB. THIS
3 HEMORRHAGE POINTS TO THE CENTRAL ROLE OF THE
4 VASCULATURE IN NEURAL DEVELOPMENT AS IT COORDINATES
5 THE METABOLISM BETWEEN THE BLOOD AND THE BRAIN
6 AMONGST ITS OTHER ROLES.

7 THIS NEW FIELD OF VASCULAR NEUROSCIENCE IS
8 TRULY THE FRONTIER BOTH SCIENTIFICALLY AND
9 THERAPEUTICALLY BECAUSE THE VASCULATURE, AS DR.
10 KORNBLUM MENTIONED, IS HIGHLY TARGETABLE.

11 NOW BACK TO MY PATIENT. HIS PARENTS ARE
12 MOTIVATED TO TRY EVERYTHING TO HELP THIS BABY. AND
13 I WAS TELLING THEM ABOUT OUR STUDY AND THE POTENTIAL
14 IMPACT OF DIETARY INTERVENTIONS ON AUTISM SPECTRUM
15 DISORDERS AND SCHIZOPHRENIA. THEY WERE ENTHUSIASTIC
16 AND ASKED ME WHEN THEIR SON COULD BE ENROLLED. I,
17 OF COURSE, ENCOURAGED CAUTION, BUT WAS INSPIRED TO
18 ADVOCATE EVEN MORE STRONGLY FOR FUNDING OUR PROPOSAL
19 NOW.

20 SO THIS PERSONAL STORY ABOUT ONE BABY IS
21 JUST THE TIP OF THE ICEBERG. IN 2022 THERE WERE
22 OVER 38,000 PRETERM BIRTHS IN CALIFORNIA. THAT'S
23 OVER 40,000 CALIFORNIA CHILDREN PER YEAR WHO
24 POTENTIALLY COULD BENEFIT FROM OUR DISCOVERIES AND
25 THE CAUSE IS URGENT. THANK YOU FOR THIS OPPORTUNITY

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1 TO ADVOCATE ON BEHALF MY PATIENTS WHO CANNOT SPEAK
2 FOR THEMSELVES.

3 MS. MANDAC: THANK YOU VERY MUCH, DR.
4 CROUCH. NEXT UP WE HAVE DR. QUADRATO TO BE FOLLOWED
5 BY MR. GRAGLIA. DR. QUADRATO, YOU HAVE THE FLOOR.

6 DR. QUADRATO: GOOD MORNING, BOARD
7 MEMBERS. I'M GIORGIA QUADRATO. I'M THE PI ON THE
8 PROPOSAL DISC4-16360. I'M AN ASSISTANT PROFESSOR OF
9 STEM CELL BIOLOGY AND REGENERATIVE MEDICINE AT THE
10 UNIVERSITY OF SOUTHERN CALIFORNIA. SO TODAY I'M
11 HERE REPRESENTING A TEAM OF INVESTIGATORS FROM USC,
12 CALTECH, UCLA, AND CHILDREN'S HOSPITAL LOS ANGELES.

13 THANK YOU SO MUCH FOR THE OPPORTUNITY TO
14 EXPLAIN WHY OUR PROPOSAL FOR USING PATIENT-DERIVED
15 BRAIN ORGANIDS FOR EARLY DIAGNOSIS AND PROGNOSIS OF
16 INTELLECTUAL DISABILITY SHOULD BE URGENTLY
17 PRIORITIZED FOR FUNDING. WE KNOW THAT INTELLECTUAL
18 DISABILITY AFFECTS BETWEEN 2 TO 3 PERCENT OF
19 CALIFORNIA'S CHILDREN WITH A DISPROPORTIONATE IMPACT
20 OF UNDERREPRESENTED MINORITIES.

21 CURRENTLY THERE ARE NO ACCURATE METHODS TO
22 DIAGNOSE AND MONITOR INTELLECTUAL DISABILITY. SO
23 IT'S HARD TO TRACK THE PROGRESS OF THIS DISEASE AND
24 PROVIDE PERSONALIZED CARE, ESPECIALLY FOR URM
25 CHILDREN WHO FACE BARRIERS TO GETTING HEALTHCARE.

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1 ONE OF THE MAIN GOAL OF OUR PROPOSAL IS TO
2 USE MACHINE LEARNING APPROACHES TO CORRELATE BRAIN
3 ORGANOID FINDINGS WITH CLINICAL EG DATA TO DISCOVER
4 BIOMARKERS FOR INTELLECTUAL DISABILITY. THESE
5 BIOMARKERS WILL CHANGE THE WAY WE DIAGNOSE AND
6 MANAGE ID WITHOUT NEEDING LENGTHY CLINICAL TRIALS.

7 IN ADDITION, WE ARE PROPOSING TO ESTABLISH
8 NEW PARADIGMS FOR NEUROMODULATION THAT WOULD
9 POTENTIALLY REVOLUTIONIZE THE TREATMENT OF
10 INTELLECTUAL DISABILITY.

11 WE ARE DELIGHTED THAT WE HAVE BROUGHT
12 TOGETHER A TEAM OF TOP EXPERTS FROM VARIOUS FIELDS
13 PROVIDING FRESH PERSPECTIVE ON NEUROPSYCHIATRIC
14 RESEARCH. IF THIS PROPOSAL ISN'T FUNDED, WE WILL
15 MISS THE OPPORTUNITY TO ATTRACT THESE TALENTS TO
16 THIS FIELD.

17 WE ARE HAPPY TO REPORT THAT THE GRANT
18 WORKING GROUP SHOWED GREAT ENTHUSIASM FOR OUR
19 PROPOSAL. IN FACT, IT RECEIVED UNANIMOUS SUPPORT
20 WITH 14 VOTES IN FAVOR AND ZERO AGAINST IN THREE KEY
21 CATEGORIES, WHICH ARE SIGNIFICANCE AND IMPACT,
22 INNOVATION, AND DIVERSITY, EQUITY, AND INCLUSION.
23 SOME REVIEWERS HAVE EXPRESSED CONCERN ABOUT USING
24 ORGANOIDS TO MODEL BRAIN NETWORK ACTIVITY; HOWEVER,
25 OPINIONS ON THIS MATTER VARIED AMONG REVIEWERS.

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1 NEVERTHELESS, ORGANOIDS HAVE CONSISTENTLY
2 PROVEN TO BE VALUABLE IN MODELING NEURAL NETWORK
3 ABNORMALITIES, OUTPERFORMING ANY OTHER HUMAN-BASED
4 CELLULAR MODELS. SO OVERALL, WE FEEL THIS PROJECT
5 IS A MUCH NEEDED INVESTMENT IN DEEPENING OUR
6 KNOWLEDGE AND EXPANDING OUR TOOLKIT FOR MODELING
7 BRAIN NETWORK ACTIVITY. IT WILL ALSO OPEN DOORS TO
8 TRANSLATIONAL OPPORTUNITIES FOR A RANGE OF OTHER
9 NEUROPSYCHIATRIC DISORDERS. THEREFORE, WE STRONGLY
10 BELIEVE THAT NOW IS REALLY THE TIME TO INVEST IN
11 THIS RESEARCH. AND BY FUNDING OUR PROJECT, YOU ARE
12 NOT JUST SUPPORTING A SINGLE STUDY. YOU ARE REALLY
13 PROPELLING THE ENTIRE FIELD FORWARD. THANK YOU SO
14 MUCH FOR YOUR CONSIDERATION.

15 MS. MANDAC: THANK YOU SO MUCH, DR.
16 QUADRATO. NEXT UP WE HAVE MR. GRAGLIA TO BE
17 FOLLOWED BY DR. SAMARASINGHE. MR. GRAGLIA, YOU HAVE
18 THE FLOOR.

19 MR. GRAGLIA: THANK YOU VERY MUCH FOR YOUR
20 TIME. THANK YOU FOR THE REVIEWERS AND THE BOARD FOR
21 HEARING US OUT. MY NAME IS MICHAEL GRAGLIA. I'M
22 THE FOUNDER AND MANAGING DIRECTOR OF THE SYNGAP
23 RESEARCH FUND OF THE NATIONAL AND PATIENT ADVOCACY
24 GROUP FOR SYNGAP¹. I'VE HAD THE GREAT PLEASURE OF
25 WORKING CLOSELY WITH DR. QUADRATO FOR A COUPLE OF

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1 YEARS, AND I CAN TESTIFY TO HER INCREDIBLE
2 COMMITMENT TO PATIENTS IN AN EXCEPTIONALLY
3 COLLABORATIVE NATURE.

4 AS YOU KNOW FROM REVIEWING HER PROPOSAL,
5 SYNGAP1 IS THE GENE THAT THEY WOULD START WITH AS
6 THEY TACKLE INTELLECTUAL DISABILITY. AND I WANT TO
7 EMPHASIZE FOR THE COMMITTEE WHAT A PERFECT CHOICE
8 THIS IS. AND I WANT TO EXPRESS MY CONFUSION BETWEEN
9 THE GREAT SCORES THAT ARE AVAILABLE IN THE PUBLIC
10 NOTES AND THIS SPLIT OF 2/13 ON A 1/2 BECAUSE, AS
11 DR. QUADRATO MENTIONED, THERE SEEMS TO BE STRONG
12 ENTHUSIASM, BUT LET ME FOCUS ON SYNGAP1.

13 PER CALIFORNIA'S OWN INFORMATION, THERE'S
14 OVER 600,000 KIDS WITH INTELLECTUAL DISABILITY --
15 PEOPLE WITH INTELLECTUAL DISABILITY IN CALIFORNIA.
16 WE DON'T KNOW HOW MANY THOUSANDS OF THOSE HAVE
17 SYNGAP1, BUT I ASSURE YOU THIS DISEASE IS RADICALLY
18 UNDERDIAGNOSED. AND I WANT TO EXPLAIN WHY.

19 I WANT TO ALSO NOTE, IF YOU LOOK AT
20 SATTERSTROM, ET. AL. OR FU, ET. AL., WHICH ARE TWO
21 OF THE BIGGEST STUDIES ON AUTISM GENES, SYNGAP IS
22 EITHER THE THIRD OR FOURTH MOST HIGHLY ASSOCIATED
23 GENE WITH AUTISM. SO WHEN WE'RE TALKING ABOUT
24 AUTISM, SYNGAP IS RIGHT THERE AT THE TABLE.

25 I WANT TO TELL YOU A LITTLE BIT ABOUT THE

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1 PATH OF DISEASE BECAUSE IT'S CRITICAL. OUR KIDS
2 START WITH INTELLECTUAL DELAY. THEY DO NOT BEGIN
3 SEIZING UNTIL -- WHOEVER IS ON MOM'S IPAD, PLEASE
4 MUTE -- THEY ARE TWO OR THREE. RIGHT? THEN AROUND
5 FIVE, SIX, SEVEN, EIGHT THEIR BEHAVIORS BECOME
6 EXCEPTIONAL. AND MANY OF OUR KIDS ARE CAUGHT ONLY
7 BECAUSE OF SEVERE PSYCHIATRIC AND BEHAVIORIAL
8 PRESENTATION. SYNGAP1 IS DOWN THE MIDDLE. INDEED
9 IT WAS FIRST DEFINED AS MRD5. RIGHT? THE PRIMARY
10 PHENOTYPE WAS INTELLECTUAL DISABILITY. BUT MY POINT
11 HERE IS THE BEHAVIORS OF SYNGAP, AND I CAN SHARE
12 STUDY AFTER STUDY THAT VALIDATE THIS, ARE
13 EXCEPTIONALLY CHALLENGING DEPENDING ON WHATEVER
14 DISEASE YOU'RE LOOKING AT. SO IT IS A PERFECT FIT
15 FOR THESE REMIND AWARDS.

16 AND I ALSO WANT TO EMPHASIZE THERE WAS ONE
17 LINE IN THE COMMENTS THAT STRUCK ME. IN ADDITION TO
18 A LARGE FRACTION OF PATIENTS, BLAH, BLAH, BLAH, IT
19 WILL BE DIFFICULT TO ESTABLISH DISTINCT
20 ELECTROPHYSIOLOGICAL MARKERS VERSUS ID FOR
21 EPILEPSY BECAUSE THESE KIDS HAVE SEIZURES. THAT'S
22 WRONG. WITH RESPECT, WHOEVER WROTE THAT DOESN'T
23 UNDERSTAND SYNGAP1. I CAN TELL YOU RIGHT NOW I HAVE
24 HUNDREDS OF PATIENTS WHO COME TO ME HAVING HAD AN
25 EEG AND THEY ARE TOLD BY NEUROLOGIST AFTER

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1 NEUROLOGIST YOU DON'T HAVE SEIZURES, BUT YOU'VE GOT
2 SOME VERY STRANGE EEG ACTIVITY. SO CONSISTENTLY OUR
3 PATIENTS PRESENT ABNORMAL EEG'S WHILE THEY ARE
4 EXPERIENCING ID BEFORE THEY HAVE EPILEPSY.

5 DR. QUADRATO IS A TESTAMENT TO HER
6 INCREDIBLE WORK, HAS FOUND A REALLY STRONG MODEL
7 HERE, AND I HOPE THAT UPON HER REVISION HER
8 APPLICATION IS GIVEN SERIOUS CONSIDERATION BECAUSE
9 THIS WORK IS HHMI INVESTIGATORS...

10 MS. MANDAC: THANK YOU SO MUCH, MR.
11 GRAGLIA. NEXT WE HAVE DR. SAMARASINGHE TO BE
12 FOLLOWED BY ZOE. DR. SAMARASINGHE, YOU HAVE THREE
13 MINUTES.

14 DR. SAMARASINGHE: THANK YOU. THANK YOU
15 TO THE BOARD FOR THIS OPPORTUNITY TO DISCUSS OUR
16 GRANT. MY NAME IS DR. RANMAL SAMARASINGHE. I'M A
17 CLINICAL EPILEPTOLOGIST AND A STEM CELL RESEARCHER
18 AT THE DAVID GEFFEN SCHOOL OF MEDICINE. AND I'M A
19 CO-INVESTIGATOR ON THE GRANT THAT WAS JUST
20 DISCUSSED, 16360. AND I WANT TO ADDRESS IN MY BRIEF
21 TIME A VERY SPECIFIC POINT WHICH WAS JUST BROUGHT UP
22 ABOUT THIS GRANT WHICH I THINK MAKES IT CHALLENGING
23 TO JUDGE, BUT ALSO INNOVATIVE AND VERY IMPORTANT.

24 AND THAT IS THE FACT THAT THIS GRANT,
25 COMPARED TO MANY OTHERS, NOT JUST IN THIS PARTICULAR

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1 FUNDING MECHANISM, BUT OUTSIDE OF THIS, IS FOCUSED
2 ON ELECTROPHYSIOLOGY. AND MOST FOLKS WHO ARE
3 WRITING GRANTS THAT INVOLVE STEM CELLS AND ORGANOIDS
4 OR EVEN EVALUATING THEM ARE EXPERTS IN STEM CELL
5 BIOLOGY, IN NEURODEVELOPMENTAL DISEASE, AND CELL
6 DEVELOPMENT, BUT NOT IN ELECTROPHYSIOLOGY. AND I
7 THINK THAT MAKES IT HARD TO JUDGE THIS GRANT, AND IT
8 HAS RESULTED IN SOME CONTRADICTORY REVIEWER
9 COMMENTS, WHICH I'LL HIGHLIGHT AND I'LL EXPLAIN
10 THIS.

11 SO, FOR EXAMPLE, ONE REVIEWER, AND THIS
12 GOES TO THE HEART OF THIS GRANT, SAID A REVIEWER HAS
13 HIGH ENTHUSIASM FOR ATTEMPTING TO DEMONSTRATE AN
14 ORGANOID ACTIVITY HUMAN EEG LINK, AND I'M
15 PARAPHRASING. IN GENERAL, THE OVERALL PROJECTS ARE
16 BASED UPON SOUND SCIENTIFIC RATIONALE, AND THE
17 APPROACHES WERE BASED ON ROBUST PRELIMINARY DATA.
18 AND THIS IS ABOUT THE ELECTROPHYSIOLOGY.

19 ALMOST IN THE SAME BREATH ANOTHER REVIEWER
20 WRITES, BASED ON PUBLISHED LITERATURE, ONLY 25
21 PERCENT OF ID PATIENTS SHOW EEG ABNORMALITIES.
22 INCORRECT. AND HENCE, IT WILL BE VERY DIFFICULT TO
23 ESTABLISH DIRECT ELECTROPHYSIOLOGICAL MARKERS FOR ID
24 VERSUS EPILEPSY.

25 AS A CLINICAL EPILEPTOLOGIST WHO SEES

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1 PATIENTS AND READS EEG'S, AND AS WAS STATED IN THE
2 PREVIOUS COMMENTS, THIS IS NOT CORRECT. THE FACT IS
3 THAT EEG ABNORMALITIES CAN BE SEEN IN
4 NEURODEVELOPMENTAL DISEASE IN PATIENTS WHO DON'T
5 HAVE ANY HISTORY OF EPILEPSY, WILL NOT GET EPILEPSY,
6 AND CERTAINLY PATIENTS WHO DON'T HAVE ACTIVE
7 SEIZURES.

8 AND THIS IS AT THE HEART OF THIS PROPOSAL.
9 I THINK IT'S HARD FOR SOME REVIEWERS TO UNDERSTAND
10 THIS, AND IT'S RESULTED IN THIS KIND OF
11 CONTRADICTORY REVIEW AND THE ONES THAT I THINK
12 PUSHED US TO A TWO IN STEADY OF A ONE. BUT WE CAN
13 CERTAINLY ADDRESS THIS.

14 AND IN THIS GRANT, BY THE WAY, AS A HUMAN
15 OBSERVER OR AN EEG READER, WE CAN CERTAINLY TELL THE
16 DIFFERENCE BETWEEN EEG FROM SOMEONE WHO'S SEIZING
17 WHO HAS EPILEPTIC DEFORMED DISCHARGES VERSUS AN EEG
18 OF A PATIENT WHO HAS INTELLECTUAL DISABILITY BASED
19 ON OTHER CHANGES LIKE SLOWING. BUT HERE WE'RE
20 PROPOSING TO USE COMPUTATIONAL APPROACHES LIKE
21 MACHINE LEARNING, LIKE DEEP LEARNING TO TEASE APART
22 THESE DIFFERENCES, WHICH IS GOING TO BE MUCH MORE
23 SOPHISTICATED THAN WHAT EVEN A HUMAN OBSERVER CAN
24 DO.

25 SO THIS IS JUST AN OPPORTUNITY TO SAY THAT

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1 THERE'S CONFLICT IN THESE REVIEWS. WE CAN ADDRESS
2 THIS. IT'S AT THE HEART OF THE RESISTANCE OF THIS
3 PROPOSAL, BUT I THINK THIS IS AN INCREDIBLE
4 OPPORTUNITY TO DO SOMETHING THAT'S PARTICULARLY
5 UNIQUE. AND I HOPE WE HAVE AT LEAST A CHANCE TO
6 ADDRESS THESE REVIEWS MOVING FORWARD. THANK YOU.

7 MS. MANDAC: THANK YOU VERY MUCH, DR.
8 SAMARASINGHE. NEXT UP WE HAVE ZOE TO BE FOLLOWED BY
9 DR. MOSTAJO-RADJI. ZOE, YOU HAVE THE FLOOR.

10 MS. BAILEY: HI. THANK YOU ALL FOR THE
11 OPPORTUNITY TO SPEAK HERE. I'M HERE IN SUPPORT FOR
12 GRANT 360. MY NAME IS ZOE BAILEY, AND MY FIRSTBORN,
13 BEAUTIFUL AND ADVENTUROUS, FUNNY, BROWN-SKINNED
14 FOUR-YEAR-OLD DAUGHTER KAIA WAS DIAGNOSED WITH
15 SYNGAP1-RELATED DISORDER ABOUT A YEAR AND A HALF AGO
16 ON MARCH 23, 2023, A DAY WE'LL NEVER FORGET.

17 OUR LIFE BEFORE THAT DAY IS ALMOST
18 UNRECOGNIZABLE TODAY, A DAY THAT INTRODUCED US TO
19 THE UNDERFUNDED AND UNDERREPRESENTED WORLD OF
20 DISABILITIES, ESPECIALLY FOR FAMILIES OF COLOR LIKE
21 OURS. AS A MOTHER TO MY BEAUTIFUL BLACK DAUGHTER, I
22 KNEW THE WORLD WOULD BE DIFFERENT FOR HER THAN HER
23 WHITE PEERS. I WAS PREPARED AS MUCH AS I COULD BE
24 FOR THAT. HOWEVER, ADDING THE REALITY THAT NOT ONLY
25 WOULD OUR UNEQUITABLE SYSTEM NOT AFFORD HER

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1 OPPORTUNITIES DUE TO HER RACE, BUT NOW ALSO BASED ON
2 HER BRAIN'S ABILITY TO FUNCTION.

3 OUR JOURNEY ADVOCATING FOR KAIA HAS BEEN
4 NOTHING SHORT OF HEARTBREAKING. KAIA'S INTELLECTUAL
5 DISABILITY AND SYNGAP1-RELATED DISORDER HAS ALTERED
6 THE TRAJECTORY OF OUR LIVES. AS OF NOW, SINCE THERE
7 IS NO TREATMENT, SHE WILL NEED FULL-TIME CARE FOR
8 HER ENTIRE LIFE. SHE IS CURRENTLY NONVERBAL, HAS
9 EXTREME ANGER OUTBURSTS TOWARDS THOSE CLOSEST TO
10 HER, ENGAGES IN SELF-INJURIOUS BEHAVIORS, AND DOES
11 NOT UNDERSTAND DANGER. KAIA'S DIAGNOSIS WAS ONE
12 THAT I NOW REALIZE WE WERE LUCKY TO GET SO EARLY ON
13 IN HER LIFE.

14 AS MIKE HAS MENTIONED BEFORE, SHE STILL
15 HAS CONCERNING EEG'S, BUT SHE'S NOT OFFICIALLY
16 DIAGNOSED WITH EPILEPSY, ALTHOUGH IT IS CLEAR
17 THERE'S INTELLECTUAL DISABILITY. THE DIAGNOSIS THAT
18 WE RECEIVED WAS DUE TO ACCESS TO TOP MEDICAL CARE,
19 TWO HIGHLY AVAILABLE, ENGAGED, WELL-EDUCATED
20 PARENTS, AND THE ACCESS TO TIME AND RESOURCES WHICH
21 WE KNOW CAN ALL BE COMPROMISED FOR OUR COMMUNITIES
22 OF COLOR.

23 AS A LICENSED CLINICAL SOCIAL WORKER WITH
24 YEARS OF EXPERIENCE WORKING IN THE CHILD WELFARE
25 SYSTEM AND SUPPORTING SEVERELY MENTALLY ILL TO

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1 SECURE HOUSING, I AM CLEAR THAT FAMILIES LIKE MINE,
2 FAMILIES OF COLOR, ARE DISPROPORTIONATELY DENIED
3 ACCESS AND SUPPORT NEEDED TO CARE FOR THEIR
4 CHILDREN. AND EVEN MORE SO WHOSE CHILDREN ARE
5 IMPAIRED AND IMPACTED BY THE CRUEL WORLD OF
6 INTELLECTUAL DISABILITY.

7 SINCE WE WERE AFFORDED THE GIFT OF A
8 DIAGNOSIS, I HAVE BECOME AN ACTIVE VOLUNTEER WITH
9 SYNGAP RESEARCH FUND, THE NATIONAL PATIENT ADVOCACY
10 GROUP FOR SYNGAP1-RELATED DISORDERS BASED HERE IN
11 CALIFORNIA. IT IS WITHOUT QUESTION THERE ARE
12 COUNTLESS PATIENTS OF COLOR AND OF ALL POPULATIONS
13 THAT ARE UNDIAGNOSED WITH SYNGAP1 AND OTHER CAUSES
14 OF INTELLECTUAL DISABILITY. INCREASING THE NUMBER
15 OF THOSE DIAGNOSED WITH INTELLECTUAL DISABILITY AND
16 FUNDING RESEARCH TOWARD TREATMENTS WOULD BE AN
17 INCREDIBLE STEP IN THE RIGHT DIRECTION. DR.
18 QUADRATO'S GRANT PROMISES TO BETTER UNDERSTAND
19 PATIENTS LIKE KAIA WHO ARE IN DESPERATE NEED OF
20 BETTER MEDICINES AND THERAPIES. THANK YOU ALL FOR
21 YOUR TIME.

22 AND I WANT TO SHOW YOU A PICTURE OF MY
23 DAUGHTER. I DON'T EVEN KNOW IF YOU CAN SEE IT.
24 THERE SHE IS. AND HERE SHE IS AGAIN. OKAY. THANK
25 YOU ALL AGAIN FOR YOUR TIME AND YOUR CONSIDERATION.

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1 CHAIRMAN IMBASCIANI: THANK YOU.

2 MS. MANDAC: THANK YOU SO MUCH, ZOE. NEXT
3 UP WE HAVE DR. MOSTAJO-RADJI TO BE FOLLOWED BY DR.
4 KRIEGSTEIN. DR. MOSTAJO-RADJI, YOU HAVE THAT FLOOR.

5 DR. MOSTAJO-RADJI: THANK YOU SO MUCH.
6 AND I WILL BE BRIEF. MY NAME IS MOHAMMED
7 MOSTAJO-RADJI. I'M A RESEARCH SCIENTIST AT THE UC
8 SANTA CRUZ GENOMICS INSTITUTE. I'M ALSO A
9 CO-INVESTIGATOR IN GRANT 17337, WHICH IS ONE OF THE
10 TIED VOTES.

11 I DO WANT TO MENTION A LITTLE BIT ABOUT
12 OUR PROPOSAL, WHICH I THINK IT'S VERY RELEVANT TO
13 THE REMIND CALL BECAUSE IT'S, I WOULD PROBABLY SAY,
14 ONE OF THE ONLY, IF NOT THE ONLY, APPLICATION THAT
15 IS GOING TO PROPOSE AN ACTUAL TREATMENT THAT CAN BE
16 GIVEN TO PATIENTS IN THE FOUR YEARS OF THE GRANT
17 DURATION. SO THAT TO ME IT'S A VERY, VERY IMPORTANT
18 FACT TO DISCUSS.

19 THE OTHER THING I WANT TO MENTION IS THAT
20 WE NEED TO BE EFFICIENT. WE NEED TO ACTUALLY GET
21 THESE TREATMENTS TO THE PATIENTS AS SOON AS
22 POSSIBLE. I BELIEVE THAT HAVING A THREE- TO
23 FIVE-MONTH REVIEW PROCESS WHEN THIS COULD BE SORTED
24 AT THE PREFUNDING APPLICATION REVIEW STAGE COULD
25 ACTUALLY BE MORE EFFICIENT INVESTMENT OF MONEY AND

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1 PUBLIC FUNDING AS WELL AS TAXPAYER MONEY
2 SPECIFICALLY HERE.

3 ONE MORE THING -- ONE MORE POINT I WANTED
4 TO BRING UP IS I ALSO HAPPEN TO BE A CO-INVESTIGATOR
5 IN THE DATA COORDINATION CENTER OF THE
6 (UNINTELLIGIBLE) CONSORTIUM, WHICH IS THE LARGEST
7 CURRENT NIH INITIATIVE FOR NEUROPSYCHIATRIC
8 DISORDERS USING STEM CELL MODELS. AND I KNOW THE
9 IMPORTANCE, BUT THERE IS IN HAVING THE GROUPS SHARE
10 COMMON INTERESTS AND SHARE A LOT OF COMPLEMENTARY
11 COLLABORATIONS.

12 BRINGING INTO THIS EXPERIENCE, I WANT TO
13 HIGHLIGHT THE FACT THAT DR. APARNA BHADURI NOT ONLY
14 IS A YOUNG INVESTIGATOR WHO HAS STARTED HER LAB LESS
15 THAN THREE YEARS AGO, BUT ALSO HAPPENED TO HAVE
16 COLLABORATED WITH MOST OF THE GRANTS THAT ARE
17 CURRENTLY ON TIER I. SO THE EFFICIENCY OF GETTING
18 THIS COLLABORATION STARTED WILL BE IMMEDIATE. NOT
19 ONLY THAT, SHE ALSO HAPPENS TO BE A CO-INVESTIGATOR
20 IN ONE OF THE DATA GENERATION CENTERS OF THE
21 (UNINTELLIGIBLE) CONSORTIUM, WHICH MEANS THAT WE
22 WILL ALSO TAP INTO THE COLLABORATIONS THAT HAPPEN
23 OUTSIDE THE STATE OF CALIFORNIA AND COUNTRYWIDE.
24 THANK YOU SO MUCH.

25 MS. MANDAC: THANK YOU SO MUCH, DR.

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1 MOSTAJO-RADJI. NEXT UP WE HAVE DR. KRIEGSTEIN TO BE
2 FOLLOWED BY DR. CHRISTOFK. DR. KRIEGSTEIN, YOU HAVE
3 THE FLOOR.

4 DR. KRIEGSTEIN: YES. HI. I WANT TO
5 THANK YOU FOR THE OPPORTUNITY TO SPEAK. I SHOULD
6 INTRODUCE MYSELF AS A NEUROLOGIST AND DEVELOPMENTAL
7 NEUROBIOLOGIST AND A PI ON THE APPLICATION NO.
8 16283.

9 NOW, OURS IS A QUITE DIFFERENT APPLICATION
10 FROM THE OTHERS THAT HAVE BEEN DISCUSSED SO FAR. AS
11 YOU ALL KNOW, CALIFORNIA IS EXPERIENCING AN EPIDEMIC
12 OF DRUG USE RIGHT NOW WITH RELAXATION OF OUR PUBLIC
13 HEALTH POLICY ON CANNABIS CONSUMPTION, WHICH HAS
14 EXPOSED ACTUALLY MORE UNBORN BABIES TO CANNABIS THAN
15 EVER BEFORE. THERE ARE OVER 19 PERCENT OF WOMEN IN
16 CALIFORNIA WHO ACTIVELY USE MARIJUANA DURING
17 PREGNANCY. THAT'S EVEN THOUGH POPULATION STUDIES
18 HAVE REPEATEDLY SHOWN THAT MARIJUANA USE DURING
19 PREGNANCY IS ASSOCIATED WITH NEUROPSYCHIATRIC
20 OUTCOMES IN LATER LIFE.

21 HOWEVER, THE PUBLIC PERCEPTION IS THAT
22 MARIJUANA USE DURING PREGNANCY IS SAFE. AND THE
23 EXISTING POPULATION-ASSOCIATED DATA ARE CONSIDERED
24 WEAK, ANECDOTAL, NONCAUSAL, AND HAVEN'T BEEN
25 TRUSTED. SO CURRENT EVIDENCE -- THE CURRENT

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1 EVIDENCE THAT WE HAVE IS NOT STRONG ENOUGH TO MOVE
2 THAT NEEDLE, AND IT HASN'T CHANGED PUBLIC OPINION OR
3 BEHAVIOR.

4 WE FEEL THAT IT'S EXTREMELY IMPORTANT TO
5 PROVIDE MOLECULAR AND CELLULAR EVIDENCE OF THE
6 CAUSAL EFFECTS OF MARIJUANA USE ON FETAL BRAIN
7 DEVELOPMENT. OUR PRELIMINARY SINGLE CELL GENE
8 EXPRESSION DATA SUGGESTS THAT IN UTERO EXPOSURE TO
9 MARIJUANA STRONGLY AFFECTS NEURON PROLIFERATION,
10 AXON GROWTH, AND A PARTICULAR SUBSET OF INTERNEURONS
11 THAT EXPRESS CANNABINOID RECEPTORS. AND THE
12 AFFECTED GENES ARE STRONGLY RELATED TO AUTISM,
13 SCHIZOPHRENIA, AND ATTENTION DEFICIT HYPERACTIVITY
14 DISORDER.

15 SO WE FEEL THAT FINDING AND DEFINING THE
16 CELLULAR AND MOLECULAR CONSEQUENCES OF CANNABIS
17 EXPOSURE TO THE DEVELOPING HUMAN BRAIN CAN LEAD TO
18 ACTIONABLE INTERVENTIONAL SOLUTIONS THAT WILL HAVE A
19 DIRECT IMPACT ON PUBLIC HEALTH POLICIES.

20 WE'RE DEEPLY COMMITTED IN OUR PROPOSAL TO
21 COMMUNITY OUTREACH INITIATIVES, AND WE'RE ACTIVELY
22 COLLABORATING WITH SEVERAL COMMUNITY ORGANIZATIONS,
23 INCLUDING THE CALIFORNIA PRETERM BIRTH INITIATIVE,
24 SAN FRANCISCO DEPARTMENT OF PUBLIC HEALTH, AND THE
25 LOCAL AMERICAN INDIAN COMMUNITY, WHICH IS THE LAKOTA

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1 TRIBE, WERE ALL PART OF THE COMMUNITY ENGAGEMENT
2 PROGRAM THAT'S ASSEMBLED IN OUR PROJECT.

3 THE MAJOR CRITIQUE OF OUR PROPOSAL
4 CONCERNED A LACK OF INNOVATION IN OUR APPROACH
5 DESPITE THE FACT THAT OUR TECHNOLOGIES IN THE
6 PROPOSAL INCLUDE SINGLE CELL TRANSPORTOMICS AND
7 PROTEOMICS, SPATIAL TRANSPORTOMICS AND METABOLOMICS,
8 AND THEY'RE ALL CUTTING-EDGE TECHNIQUES THAT REALLY
9 HAVE NOT BEEN APPLIED TO THIS PROBLEM BEFORE.

10 WE FEEL IN THE END THAT THERE'S URGENCY IN
11 DETERMINING THE EFFECTS OF MARIJUANA USE ON THE
12 FETAL BRAIN. MOREOVER, WE FEEL THIS IS AN
13 APPLICATION WHERE STEM CELL TECHNOLOGY CAN HAVE AN
14 IMMEDIATE HEALTHCARE BENEFIT. WE'RE HAPPY TO
15 DISCUSS THE REVIEWER'S CONCERNS, AND WE HOPE THAT
16 THE BOARD WILL RECONSIDER OUR PROJECT.

17 AND THE FINAL COMMENT I WANT TO MAKE IS,
18 AS WAS MENTIONED EARLIER IN TODAY'S DISCUSSION,
19 THERE COULD BE FUNDING FOR TWO OF THE TIER II
20 PROJECTS WITH SOME SLIGHT RE-BUDGETING SOME OF THOSE
21 GRANTS. AND I WOULD URGE THE BOARD TO CONSIDER
22 FUNDING TWO OF THOSE. THANK YOU SO MUCH FOR YOUR
23 ATTENTION.

24 MS. MANDAC: THANK YOU SO MUCH, DR.
25 KRIEGSTEIN. NEXT WE HAVE DR. CHRISTOFK. DR.

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1 CHRISTOFK, YOU HAVE THE FLOOR.

2 DR. CHRISTOFK: THANK YOU. THANK YOU FOR
3 THIS OPPORTUNITY TO SPEAK. MY NAME IS HEATHER
4 CHRISTOFK, AND I'M A BIOCHEMIST AND A TEAM MEMBER OF
5 THE 16337 APPLICATION WITH MINORITY REPORT THAT WAS
6 DISCUSSED EARLIER BY SOME BOARD MEMBERS AND SOME OF
7 MY TEAM MEMBERS, DRS. BHADURI, KORNBLUM, CROUCH, AND
8 MOSTAJO-RADJI.

9 I'VE SPENT THE LAST 20 YEARS STUDYING HOW
10 METABOLISM IMPACTS HEALTH AND DISEASE AT A
11 MECHANISTIC LEVEL. METABOLISM IS THE PROCESS BY
12 WHICH WE DIGEST NUTRIENTS FROM OUR DIET TO DERIVE
13 THE ENERGY MACROMOLECULES WE NEED TO LIVE. DIETARY
14 APPROACHES TO DISEASE TREATMENT HAVE ACTUALLY BEEN
15 USED EFFECTIVELY IN MANY AREAS OF MEDICINE, NOT ONLY
16 AS A LIFESAVING APPROACH TO TREAT PATIENTS WITH
17 INBORN ERRORS OF METABOLISM AND TO TREAT CHILDHOOD
18 EPILEPSY, AS DR. KORNBLUM EARLIER MENTIONED, BUT
19 ALSO TO TREAT PATIENTS WITH AUTOIMMUNE CONDITIONS
20 SUCH AS CROHN'S DISEASE AND GOUT.

21 WE NOW KNOW THAT DIETS CAN INFLUENCE THE
22 LEVELS OF NEUROTRANSMITTERS IN THE BRAIN. SO IT
23 MAKES GOOD SENSE TO EXAMINE WHETHER AND HOW DIETS
24 MIGHT MODIFY CENTRAL NERVOUS SYSTEM DISORDERS SUCH
25 AS AUTISM AND SCHIZOPHRENIA. THIS IS AN EXCITING,

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1 NEW AREA OF RESEARCH THAT CAN LAY THE GROUNDWORK FOR
2 A NEW WAY TO TREAT NEURODEVELOPMENTAL AND
3 NEUROPSYCHIATRIC DISORDERS THROUGH DIETARY
4 INTERVENTIONS.

5 ALTHOUGH SOME OF OUR REVIEWERS RECOGNIZED
6 IT'S A GREAT INNOVATION AND POTENTIAL SIGNIFICANCE
7 OF OUR STUDY TO BENEFIT PATIENTS AND FAMILIES
8 DEALING WITH AUTISM OR SCHIZOPHRENIA, OTHER
9 REVIEWERS WERE CONCERNED ABOUT THE CORRELATIVE
10 NATURE OF SOME OF OUR PROPOSED EXPERIMENTS. AND WE
11 AGREE THAT THE NEUROMETABOLISM FIELD IS STILL IN ITS
12 INFANCY WHICH IS BOTH A CHALLENGE AND AN
13 OPPORTUNITY. STUDIES SUCH AS OURS WILL EXAMINE
14 WHETHER SOLID CONNECTIONS DO EXIST BETWEEN SPECIFIC
15 DIETS AND AUTISM AND SCHIZOPHRENIA PHENOTYPES BEFORE
16 THEN DELVING DEEPER INTO MECHANISM.

17 OUR PROPOSED MULTIDISCIPLINARY STUDY WILL
18 LAY THE GROUNDWORK TO EXAMINE MECHANISTIC
19 CONNECTIONS BETWEEN SPECIFIC DIETS, NEUROVASCULAR
20 METABOLISM, AND AUTISM OR SCHIZOPHRENIA. IF
21 ANYTHING PROMISING COMES OUT OF OUR STUDY, WE ARE
22 WELL EQUIPPED TO RAPIDLY TRANSLATE OUR FINDINGS TO
23 PATIENTS BY CONDUCTING DIET-BASED TRIALS AT UCLA.
24 WE HOPE THAT YOU RECONSIDER THE DECISION TO ONLY
25 FUND THE TOP FIVE AND CONSIDER DR. BHADURI'S

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1 PROPOSAL FOR A LIMITED REVISION OF OUR STUDY. THANK
2 YOU.

3 MS. MANDAC: THANK YOU SO MUCH, DR.
4 CHRISTOFK. THAT IS IT OF HANDS RAISED.

5 CHAIRMAN IMBASCIANI: THANK YOU. THANK
6 YOU FOR THE MEMBERS OF THE PUBLIC WHO TOOK THE TIME
7 TO COMMENT AND PUT THEIR THOUGHTS INTO SUCH A
8 LOGICAL AND COMPELLING FORMAT. I APPRECIATE THAT.

9 BEFORE WE PROCEED TO A VOTE ON THE MOTION,
10 ARE THERE ANY FINAL COMMENTS FROM BOARD MEMBERS?
11 HEARING NONE -- ANNE-MARIE, YOU HAVE YOUR HAND
12 RAISED, I'M TOLD.

13 DR. DULIEGE: I FINALLY FIND A WAY TO DO
14 IT. A COMMENT AND A QUESTION. SO THE COMMENT GOES
15 TO ALL THE SCIENTISTS, PARENTS, CLINICIANS WHO HAD
16 THE COURAGE AND TOOK THE TIME TO COMMENT, SORT OF
17 DEFEND THEIR PROJECT. HOW MUCH WE APPRECIATE ALL OF
18 THAT, THE TIME, THE COURAGE, THE WAY OF THINKING
19 ABOUT IT, AND I WANT TO ASSURE ON BEHALF OF MYSELF,
20 AND I'M PRETTY SURE I'M VERY SPEAKING ON BEHALF OF
21 OTHER BOARD MEMBERS, THAT WE ARE PAYING A LOT OF
22 ATTENTION TO THE QUALITY OF THE PROCESS WHEN IT
23 COMES TO CHALLENGING PROPOSALS SUCH AS THE ONE THAT
24 YOU HAVE PUT IN FRONT OF US. IT'S NOT EASY FOR YOU
25 TO HEAR THAT. IT'S NOT EASY FOR US TO JUDGE THAT,

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1 BUT THAT'S WHY WE HAVE BEEN APPOINTED TO THIS. AND
2 I WANT TO APPLAUD PARTICULARLY THE COURAGE OF
3 PARENTS TO COME IN FRONT OF US AND EXPLAIN TO US
4 THEIR SITUATION.

5 HAVING SAID THAT, I WOULD, IN GENERAL,
6 THINK MORE IN TERMS OF THE IMPORTANCE OF FAIRNESS
7 MORE SO THAN EFFICIENCY. EFFICIENCY IS IMPORTANT,
8 AND I KNOW THE CIRM TEAM IS EFFICIENT, BUT MAKING
9 THE BEST JUDGMENT AND THE FAIREST ONE IN MY MIND THE
10 MOST IMPORTANT ONE. SO THAT WAS FOR MY COMMENT.

11 AND MY QUESTION GOES TO EVERYONE, BUT
12 GENERALLY, GIL, YOU ARE THE RECIPIENT OF ALL OUR
13 QUESTIONS. COULD YOU TELL US YOUR THOUGHTS ABOUT
14 THE PROPOSAL THAT WAS MADE, I THINK, BY DR. BHADURI,
15 IF I'M CORRECT, ABOUT AN ANCILLARY REVIEW PROCESS.
16 I HAVE A SENSE THAT YOU WILL FIND IT NOT APPLICABLE
17 TO THE MISSION OF THE CIRM, BUT I THINK IT'S JUST
18 WORTH TWO MINUTES OF DISCUSSION AND YOUR FEEDBACK ON
19 THIS ONE. THANK YOU.

20 DR. SAMBRANO: I'M HAPPY TO RESPOND. I
21 JUST WANT TO MAKE SURE I'M RESPONDING TO THE RIGHT
22 THING. THIS WAS TO THE PROPOSAL OF HAVING THE
23 GRANTS WORKING GROUP REVIEW ONLY APPLICATION 16337
24 BUT NOT THE OTHERS?

25 DR. DULIEGE: DR. BHADURI WOULD BE THE

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1 BEST ONE TO EXPRESS THAT. WE'RE NOT GOING TO REOPEN
2 THE FLOOR, BUT THERE WAS A NOTION OF LIMITED
3 ANCILLARY REVIEW, WHICH IF THIS HAD MERIT, AND I'M
4 PUTTING THE IF IN CAPITAL LETTERS HERE, WE COULD
5 DECIDE NOT ONLY TO ONE, BUT TWO OF THESE. I'LL STOP
6 HERE.

7 DR. SAMBRANO: SO THAT IS SOMETHING THAT
8 THE APPLICATION REVIEW SUBCOMMITTEE COULD DO. BUT,
9 AGAIN, OUR RECOMMENDATION, IN THE INTEREST OF BEING
10 FAIR TO ALL OF THE APPLICATIONS THAT WE THINK HAVE
11 PROMISE, THAT WE WOULD ADVISE THAT ALL OF THE NINE
12 APPLICATIONS THAT RECEIVED A SCORE OF 2 GET THE
13 OPPORTUNITY TO ADDRESS THE CONCERNS OF THE PANEL AND
14 EXPLAIN HOW THEY WOULD IMPROVE THEIR APPLICATIONS
15 AND HAVE THE GRANTS WORKING GROUP LET US KNOW
16 WHETHER THEY FEEL THEY'VE BEEN ADEQUATELY ADDRESSED
17 OR NOT.

18 DR. DULIEGE: I UNDERSTAND. I AGREE.
19 THANK YOU.

20 CHAIRMAN IMBASCIANI: THANK YOU,
21 ANNE-MARIE. TO BE FOLLOWED BY FRED FISHER.

22 DR. FISHER: YEAH. WHILE I APPRECIATE ALL
23 OF THE ENTHUSIASM FOR THIS PARTICULAR PROPOSAL, WE
24 SHOULD NOT BE CREATING NEW POLICY WITH CHANGING
25 POLICY ON THE FLY AS A REACTIVE RESPONSE TO OUR

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1 INTEREST IN THE WORK THAT'S BEING PROPOSED. WE HAVE
2 A METHODOLOGY FOR DEALING WITH DEFICIENCIES IN
3 PROPOSALS THAT CAN BE ADDRESSED WITHIN OUR CURRENT
4 PROCESS RELATIVELY QUICKLY.

5 SO I THINK WE OUGHT TO MOVE FORWARD WITH
6 THE CIRM TEAM'S RECOMMENDATIONS AS WELL AS THE GRANT
7 REVIEWERS THAT THIS PROPOSAL HAVE THE DEFICIENCIES
8 ADDRESSED AND COME BACK WITH THE OPPORTUNITY TO BE
9 FULLY FUNDED. OTHERWISE WE WILL FIND OURSELVES TIME
10 AFTER TIME RENEGOTIATING OUR OWN POLICIES WHEN WE
11 THINK IT SUITS US, WHICH I DON'T THINK IS AN
12 APPROPRIATE WAY TO PROCEED GIVEN OUR ACCOUNTABILITY
13 TO CALIFORNIA TAXPAYERS OR A PROCESS THAT HAS
14 INTEGRITY AND CONSISTENCY. THAT DOESN'T MEAN THAT
15 THE BOARD CANNOT CONVENE A SEPARATE GROUP TO ADDRESS
16 SITUATIONS LIKE THIS AND PROPOSE AN ALTERNATIVE
17 METHODOLOGY, BUT IT SHOULD NOT HAPPEN WITHIN THE
18 CONTEXT OF DISCUSSING A SINGLE PROPOSAL DURING AN
19 APPLICATION REVIEW SUBCOMMITTEE MEETING. THIS IS
20 NOT THE PLACE FOR THAT. THANK YOU.

21 CHAIRMAN IMBASCIANI: THANK YOU, FRED. I
22 VERY MUCH APPRECIATE YOUR COMMENTS. SO SEEING NO
23 OTHER HANDS, I'M GOING TO ASK SCOTT TO CALL THE
24 ROLL, THE VOTE ON THE MOTION. MAYBE HE'D LIKE TO
25 RESTATE IT.

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1 MR. TOCHER: THE MOTION IS TO ACCEPT THE
2 RECOMMENDATIONS OF THE CIRM TEAM TO FUND THOSE
3 APPLICATIONS IN TIER I, TO NOT FUND THOSE IN TIER
4 III, AND TO ALLOW RESUBMISSION OF THOSE IN TIER II.

5 A PROCESS POINT FOR MEMBERS DURON AND
6 FLOWERS. WHEN YOU INDICATE YOUR VOTE ON THE MOTION,
7 IF YOU WOULD ALSO ADD WITH THE EXCEPTION AS TO THOSE
8 APPLICATIONS WITH WHICH YOU ARE IN CONFLICT, WE'LL
9 BE GOOD TO GO.

10 MARIA BONNEVILLE.

11 VICE CHAIR BONNEVILLE: YES.

12 MR. TOCHER: JUDY CHOU.

13 DR. CHOU: YES.

14 MR. TOCHER: ANNE-MARIE DULIEGE.

15 DR. DULIEGE: YES.

16 MR. TOCHER: YSABEL DURON.

17 MS. DURON: YES WITH THE EXCEPTION OF
18 THOSE FOR WHICH I'M IN CONFLICT.

19 MR. TOCHER: THANK YOU. MARK
20 FISCHER-COLBRIE.

21 MR. FISCHER-COLBRIE: YES.

22 MR. TOCHER: FRED FISHER.

23 DR. FISHER: YES.

24 MR. TOCHER: ELENA FLOWERS.

25 DR. FLOWERS: YES, EXCEPT FOR THOSE WITH

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1 WHICH I HAVE A CONFLICT.

2 MR. TOCHER: THANK YOU. DAVID HIGGINS.

3 DR. HIGGINS: YES.

4 MR. TOCHER: VITO IMBASCIANI.

5 CHAIRMAN IMBASCIANI: YES.

6 MR. TOCHER: RICH LAJARA.

7 MR. LAJARA: YES.

8 MR. TOCHER: LAUREN MILLER-ROGEN.

9 MS. MILLER-ROGEN: YES.

10 MR. TOCHER: ADRIANA PADILLA.

11 DR. PADILLA: YES.

12 MR. TOCHER: JOE PANETTA.

13 MR. PANETTA: YES.

14 MR. TOCHER: MARVIN SOUTHARD.

15 DR. SOUTHARD: YES.

16 MR. TOCHER: AND KEVIN XU.

17 DR. XU: YES.

18 MR. TOCHER: THANK YOU VERY MUCH. THE
19 MOTION CARRIES.

20 CHAIRMAN IMBASCIANI: THANK YOU VERY MUCH.

21 BEFORE WE MOVE ON TO SOME GENERAL COMMENTS, I'M
22 GOING TO GIVE THE FLOOR TO OUR VICE PRESIDENT FOR
23 SCIENTIFIC PROGRAMS AND EDUCATION. ROSA, ARE YOU ON
24 THE LINE? THERE YOU ARE. ROSA CANET-AVILES.

25 DR. CANET-AVILES: THANK YOU, DR.

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1 IMBASCIANI. THANK YOU, EVERYBODY, AND ESPECIALLY
2 THE PATIENT ADVOCATES THAT REMIND US OF HOW
3 IMPORTANT IT IS THE WORK THAT WE DO.

4 BUT I WANTED TO GIVE THANKS TO A FEW
5 SPECIAL PEOPLE BECAUSE THIS HAS BEEN THREE YEARS IN
6 THE MAKING, LEADING TO TODAY'S VOTES AND THEN THE
7 RE-REVIEW. AND I WANTED TO THANK DR. CHAN LEK TAN
8 WHO HAS BEEN THE SENIOR SCIENCE OFFICER IN OUR TEAM
9 AND HAS BEEN ACTUALLY INSTRUMENTAL IN THE
10 DEVELOPMENT OF THIS PROGRAM AND LOTS OF
11 CONSULTATIONS WITH A LOT OF THE APPLICANTS.

12 I ALSO WANT TO THANK DR. JAMIE BYRON WHO
13 HAS BEEN SUPPORTING DR. CHAN LEK TAN AND ALSO DR.
14 LINDA NEVIN WHO HAS BEEN THE REVIEW LEAD IN THE
15 OFFICE OF DR. GIL SAMBRANO, THE REVIEW OFFICE, AND
16 WHO HAS BEEN COLLABORATING AS WELL. AND THE GRANTS
17 MANAGEMENT TEAM, I WANT TO THANK THEM AS WELL
18 BECAUSE THEY HAVE BEEN WORKING VERY HARD IN
19 DEVELOPING THE APPLICATIONS, THE I.T. TEAM AS WELL.
20 SO THERE'S A LOT OF PEOPLE THAT WE WANT TO THANK.
21 AND ALSO THE GRANTS MANAGEMENT TEAM TOGETHER WITH
22 THE SCIENCE TEAM IS GOING TO BE VERY BUSY IN
23 DEVELOPING AND GOING THROUGH THE PREFUNDING
24 ADMINISTRATIVE REVIEW NOW. SO JUST GIVING THANKS TO
25 EVERYONE THAT MAKES THIS POSSIBLE. AND THAT'S IT.

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1 THANK YOU.

2 CHAIRMAN IMBASCIANI: THANK YOU, ROSA. I
3 APPRECIATE THAT.

4 MR. TOCHER: MARK FISCHER-COLBRIE HAS HIS
5 HAND RAISED.

6 CHAIRMAN IMBASCIANI: MARK, I SEE YOUR
7 HAND. HI.

8 MR. FISCHER-COLBRIE: THANK YOU SO MUCH.
9 AND I WANT TO AMPLIFY THE TREMENDOUS WORK THAT THE
10 CIRM TEAM HAS DONE TO ASSEMBLE THIS NOVEL PROGRAM
11 WITH REMIND-L AND REMIND-X. A HUGE AMOUNT OF EFFORT
12 HAS GONE IN BEHIND THIS, AND I THINK, EVEN FROM WHAT
13 YOU'RE HEARING FROM THE RESEARCHERS WHO PRESENTED
14 TODAY, THERE'S A CRITICAL NEED AND A HIGH DEGREE OF
15 URGENCY AROUND THIS TYPE OF ACTIVITY. AND THIS TYPE
16 OF PROGRAM IS EXEMPLIFYING THE KINDS OF IMPROVEMENTS
17 THAT HAVE BEEN ENABLED WITH A HUGE AMOUNT OF WORK BY
18 THE CIRM TEAM TO BE ABLE ACCELERATE THE PATHBREAKING
19 KINDS OF RESEARCH THAT CAN BE ACCOMPLISHED.

20 SO WE VERY MUCH LOOK FORWARD FOR A
21 CONTINUATION OF THIS KIND OF EFFORT, BUT I WANTED TO
22 ACKNOWLEDGE THE STAFF IN THEIR ROLE IN COMING UP
23 WITH THESE NOVEL PROGRAMS. SO THANK YOU.

24 CHAIRMAN IMBASCIANI: WELL, THANKS SO
25 MUCH. I DON'T THINK THERE'S ANYONE LEFT TO THANK.

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1 BUT I DO WANT TO COMMEND HERE IN THE ROOM SCOTT AND
2 CLAUDETTE HERE MAKE THESE -- THEY'RE OUR UNSUNG
3 HEROES IN WORKING OUT THE BACKGROUND MECHANICS OF
4 THIS. I APPRECIATE EVERYTHING THERE.

5 BEFORE WE END THE MEETING, THIS IS THE
6 TIME FOR MEMBERS OF THE PUBLIC TO COMMENT ON THINGS
7 THAT ARE NOT ON THE AGENDA OR GENERAL COMMENTS ON
8 THE PROCESS THAT WE USE FOR THE APPLICATION REVIEW
9 SUBCOMMITTEE.

10 MR. TOCHER: I DON'T SEE ANY.

11 CHAIRMAN IMBASCIANI: YOU DON'T SEE
12 ANYTHING. OKAY. THEN I'M GOING TO THANK YOU AGAIN,
13 BOARD MEMBERS, FROM WHEREVER YOU ARE IN THE WORLD,
14 FOR JOINING THIS VERY IMPORTANT MEETING TODAY. AND
15 CONGRATULATIONS TO LAUNCHING THE REMIND PROGRAM.
16 THANK YOU. MEETING IS ADJOURNED.

17 (THE MEETING WAS THEN CONCLUDED AT 10:16 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 APPLICATION REVIEW SUBCOMMITTEE OF THE INDEPENDENT CITIZEN'S OVERSIGHT COMMITTEE OF THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE IN THE MATTER OF ITS REGULAR MEETING HELD ON AUGUST 29, 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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