

BETH C. DRAIN, CA CSR NO. 7152

BEFORE THE
TASK FORCE ON NEUROSCIENCE AND MEDICINE 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 25, 2023
2:30 P.M.

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

FILE NO.: 2023-26

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AUGUST 25, 2023; 2:30 P.M.

CHAIRMAN GOLDSTEIN: SO HERE WE GO. WE
HAVE TWO AGENDA ITEMS AS YOU WILL SEE LATER TODAY
AFTER SCOTT CALLS THE ROLL. SO, SCOTT, PLEASE CALL.

MR. TOCHER: GREAT. LEONDR A CLARK-HARVEY.

DR. CLARK-HARVEY: PRESENT.

MR. TOCHER: MARIA BONNEVILLE.

MS. BONNEVILLE: PRESENT.

MR. TOCHER: MASH FISCHER-COLBRIE.

DR. FISCHER-COLBRIE: HERE.

MR. TOCHER: FRED FISHER. JUDY GASSON.

DR. GASSON: HERE.

MR. TOCHER: LARRY GOLDSTEIN.

CHAIRMAN GOLDSTEIN: YEP. HERE.

MR. TOCHER: DAVID HIGGINS.

DR. HIGGINS: HERE.

MR. TOCHER: VITO IMBASCIANI.

CHAIRMAN IMBASCIANI: HERE.

MR. TOCHER: STEVE JUELSGAARD.

DR. JUELSGAARD: PRESENT.

MR. TOCHER: PAT LEVITT.

DR. LEVITT: PRESENT.

MR. TOCHER: LAUREN MILLER-ROGEN.

MS. MILLER-ROGEN: HERE.

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1 MR. TOCHER: MARVIN SOUTHARD.

2 DR. SOUTHARD: HERE.

3 MR. TOCHER: KEITH YAMAMOTO.

4 OKAY, LARRY. WE HAVE A QUORUM AND WE ARE
5 READY TO GO.

6 CHAIRMAN GOLDSTEIN: OKAY. SO LET'S TAKE
7 THE FIRST OF THE TWO AGENDA ITEMS, WHICH WILL BE THE
8 PRESENTATION AND DISCUSSION OF A REVISED
9 NEUROPSYCHIATRIC CONCEPT PLAN. ROSA, IF YOU WILL
10 TAKE THE SCREEN AND LET --

11 DR. CANET-AVILES: THANK YOU, DR.
12 GOLDSTEIN. CAN YOU ALL SEE THE MAIN SCREEN WITH THE
13 SLIDES OF THE CONCEPT?

14 MR. TOCHER: YES.

15 DR. CANET-AVILES: AND YOU CAN HEAR ME.
16 FANTASTIC.

17 CHAIRMAN GOLDSTEIN: YES.

18 DR. CANET-AVILES: SO THE NEURO TASK
19 FORCE, THIS IS ACTUALLY A COMPLEMENT. SO WE ARE
20 GOING TO PRESENT THE REVISED CONCEPT BASED ON THE
21 FEEDBACK THAT WE HAVE RECEIVED FROM THE LAST MEETING
22 OF THE NEURO TASK FORCE. AND THIS IS ACTUALLY A
23 COMPLEMENT TO THE CONCEPT DOCUMENT THAT WAS
24 DISTRIBUTED LAST FRIDAY AND THAT CONTAINS THE
25 BACKGROUND AND DETAILS COMPLEMENTARY TO THIS

1 PRESENTATION.

2 THROUGHOUT THE PRESENTATION TODAY, THE
3 INTENT IS REALLY TO ADDRESS THE ISSUES THAT WERE
4 RAISED IN THE PAST MEETING. AND WE WILL NOT BE
5 GOING OVER THE SAME GROUND THAT WE HAVE ALREADY
6 HEARD MULTIPLE TIMES. INSTEAD, THE FOCUS IS GOING
7 TO BE THE DIFFERENCES AND THE INFORMATION RESPONSIVE
8 TO THE CONCEPT THAT'S COMPLEMENTING THE
9 PRESENTATION. AND HERE IN THIS SLIDE YOU CAN SEE
10 WHAT THE PRIMARY AREAS WERE THAT WE IDENTIFIED THAT
11 NEEDED REVISION.

12 AS A REMINDER, THE REMIND INITIATIVE
13 CORRESPONDS TO THE DISCOVERY PHASE OF CIRM'S PILLAR
14 PROGRAMS, AND THE TRANSLATIONAL AND THE CLINICAL
15 WILL BE ADDRESSED SEPARATELY.

16 CIRM'S NEUROSCIENCE STRATEGY HAS BEEN
17 DEVELOPED, AS WE ALL KNOW, IN THE CONTEXT OF OUR
18 MISSION STATEMENT, AND IT MAPS OUT AND INTEGRATES
19 WITHIN OUR FIRST THEME OF ADVANCE WORLD-CLASS
20 SCIENCE. AND THE GOAL OF THE CONCEPT, REMIND
21 CONCEPT, IS ACTUALLY TO ACCELERATE THE DISCOVERY OF
22 MECHANISMS UNDERLYING NEUROPSYCHIATRIC DISORDERS
23 LEADING TO THE IDENTIFICATION AND VALIDATION OF
24 NOVEL TARGETS AND BIOMARKERS WITH A GOAL TO PROVIDE
25 NEW AVENUES AND RIGOROUS FOUNDATIONS FOR FUTURE

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1 TRANSLATIONAL AND CLINICAL INVESTIGATIONS.
2 OBVIOUSLY OUR GOAL IS TO LINK REALLY THE DISCOVERY
3 FOUNDATIONAL WORK WITH THE ADVANCEMENT OF THE
4 DEVELOPMENT OF THERAPIES, WHICH IS WHY THIS IS THE
5 GOAL.

6 IN ORDER TO DO THAT, THERE ARE THREE
7 OBJECTIVES. THE FIRST ONE IS ACCELERATE A
8 FOUNDATIONAL SCIENTIFIC UNDERSTANDING OF THE
9 NEUROPSYCHIATRIC DISEASE MECHANISMS AS WELL AS THE
10 DEVELOPMENT OR THE DEVELOPMENT OF MODELS, TOOLS, AND
11 TECHNOLOGIES WHICH WILL AT THE SAME TIME HELP
12 ACCELERATE OUR UNDERSTANDING OF THESE DEVASTATING
13 DISEASES.

14 THE SECOND OBJECTIVE IS TO CATALYZE
15 MULTIDISCIPLINARY INNOVATION, ATTRACTING TALENT AND
16 IDEAS INTO NEUROPSYCHIATRIC RESEARCH AND SEEDING NEW
17 PARTNERSHIPS.

18 AND THE THIRD OBJECTIVE IS TO DRIVE OPEN
19 AND COLLABORATIVE SCIENCE BY LEVERAGING CIRM-FUNDED
20 AND EXTERNALLY FUNDED INFRASTRUCTURE OR DATA
21 RESOURCES AND KNOWLEDGE SHARING.

22 SOME OF THE WORK OF THE NEURO TASK FORCE
23 OVER THE PAST FEW MONTHS HAS BEEN DISCUSSIONS AROUND
24 THE WAYS IN WHICH WE CAN ACHIEVE THIS GOAL AND
25 OBJECTIVES. AND ONE OF THE OUTCOMES FROM THE

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1 STAKEHOLDER DISCUSSIONS AND NEURO TASK FORCE
2 DISCUSSIONS WAS THAT THERE WAS A NEED TO DEVELOP A
3 PROGRAM WITH A STRUCTURE THAT COULD ALLOW FOR
4 MULTIDISCIPLINARY LARGE TEAMS TO WORK TOGETHER WITH
5 MORE TIME AND WITH LARGER AMOUNTS OF FUNDING. AND
6 THE STRUCTURE FOR THIS INITIATIVE PROGRAM RESPONDS
7 TO THOSE RECOMMENDATIONS AND PRIORITIZATION ELEMENTS
8 AND INCLUDES THESE TWO FUNDING OPPORTUNITIES THAT
9 I'M GOING TO GO OVER THAT HAVE DISTINCT AWARD
10 STRUCTURES AND THAT WILL BE OFFERED THROUGH TWO
11 INDEPENDENT REQUESTS FOR APPLICATIONS OR RFA'S.

12 THE FIRST ONE IS THE REMIND-L. THE L
13 STANDS FOR LARGE COLLABORATIVE PROJECTS. THE
14 REMIND-L RFA COULD SUPPORT EXPANSIVE
15 CROSS-DISCIPLINARY STUDIES LED BY LARGE
16 COLLABORATIVE TEAMS THAT COULD APPLY A RANGE OF
17 TECHNOLOGIES AND APPROACHES TO THEIR RESEARCH
18 PROPOSED. THESE COULD BE LEADING TO NOVEL
19 BIOLOGICAL INSIGHTS, FURTHER CURRENT UNDERSTANDING
20 OF DISEASE MECHANISMS, AND EXPANDING RESEARCH TO
21 INCLUDE THE STUDY OF DIVERSE HUMAN POPULATIONS AS
22 WELL AS IDENTIFYING AND VALIDATING NOVEL THERAPEUTIC
23 HYPOTHESES, TARGETS, AND/OR BIOMARKERS.

24 THE OTHER OPPORTUNITY IS REMIND-X. THE X
25 STANDS FOR EXPLORATORY. THE REMIND-X RFA COULD

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1 SUPPORT HIGH RISK EXPLORATORY STUDIES LED BY SMALL
2 MULTIDISCIPLINARY TEAMS. AND THE PROPOSED PROJECTS
3 WILL BE EXPECTED TO LEAD TO INITIAL VALIDATION OR
4 PROOF OF CONCEPT OF NOVEL MODELS, TOOLS,
5 TECHNOLOGIES, OR HYPOTHESES. MINIMAL PRELIMINARY
6 DATA IN THIS CASE WOULD BE REQUIRED.

7 NOW, IN TERMS OF FUNDING, THE REMIND-L
8 COULD BE FUNDING DIRECT PROJECT COSTS OF UP TO \$2
9 MILLION PER PROJECT PER YEAR AS A BASE COMPONENT AND
10 UP TO \$8 MILLION PER AWARD FOR UP TO FOUR YEARS IN
11 DURATION. AND WE WOULD EXPECT A MAXIMUM OF SIX
12 AWARDS OF THESE LARGE COLLABORATIVE PROJECTS.

13 THE REMIND-X COULD FUND DIRECT PROJECT
14 COSTS OF UP TO ONE MILLION PER AWARD FOR UP TO TWO
15 YEARS DURATION. AND TO BE SPECIFIC, HALF A MILLION
16 DOLLARS PER YEAR UP TO ONE MILLION IN TOTAL.

17 NOW, THERE IS AN OPTION FOR THE REMIND-L
18 PROGRAM WHICH COULD ALLOW FOR ADDITIONAL FUNDING OF
19 UP TO HALF A MILLION DOLLARS PER AWARD PER YEAR THAT
20 COULD BE REQUESTED IF AN EQUIVALENT OR LARGER AMOUNT
21 OF MATCHING FUNDS IS PROVIDED AND THE RESEARCH
22 ACTIVITIES SUPPORTED BY THIS SUPPLEMENTAL BUDGET ARE
23 DESCRIBED AND WELL JUSTIFIED. THE MATCHING FUNDS
24 MAY BE CONTRIBUTED BY EITHER CALIFORNIA OR
25 NON-CALIFORNIA ORGANIZATIONS AS A FOR-PROFIT OR

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1 NONPROFIT.

2 FOR THE REMIND-X, CIRM WILL FUND THE
3 DIRECT COST OF UP TO \$1 MILLION, AS I MENTIONED
4 EARLIER ON.

5 NOW, THE TOTAL AWARD BUDGET FOR REMIND-L
6 COMES UP TO \$88.2 MILLION, TAKING INTO ACCOUNT THE
7 INDIRECTS AND THE FACILITIES COSTS. AND THE
8 REMIND-X WOULD COME UP, ASSUMING 12 AWARDS, TO \$22.5
9 MILLION ALSO WITH THE INDIRECTS AND FACILITIES.

10 THIS SLIDE SHOWS A TIMELINE. IF YOU CAN
11 THINK ESSENTIALLY OF 2024 AS YEAR ONE FOR THIS
12 PROGRAM IN WHICH WE WOULD LAUNCH THE FIRST SET OF
13 REMIND-L AWARDS, AND THEN THE REMIND-X COULD LAUNCH
14 A YEAR LATER IN 2025.

15 NOW, IN TERMS OF ELIGIBILITY, THE CHANGES
16 FROM THE PRESENTATION LAST TIME INCLUDE THAT WE HAVE
17 LOWERED THE MINIMUM PERCENT EFFORT FOR THE
18 INVESTIGATORS. YOU CAN SEE FOR THE PI IN THE
19 REMIND-L, WE HAVE A 15-PERCENT MINIMUM EFFORT, AND
20 FOR CO-INVESTIGATORS THERE WILL BE FOUR OR MORE AT
21 10 PERCENT. IN THE REMIND-L, AGAIN, THESE ARE VERY
22 LARGE AWARDS. AND FOR THE REMIND-X, WE HAVE
23 PRINCIPAL INVESTIGATOR 5 PERCENT AND
24 CO-INVESTIGATORS ALSO A MINIMUM OF 5 PERCENT. AND
25 THERE WAS IN THE APPENDIX A COMPARATOR TABLE THAT

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1 SHOWS SIMILAR TYPE OF AWARDS FROM OTHER
2 ORGANIZATIONS AND WHAT ARE THE REQUIREMENTS SO YOU
3 CAN HAVE A REFERENCE THERE.

4 THE SECOND CHANGE THAT WE MADE TO THE
5 PRESENTATION HERE IS THAT WE CLARIFIED THE ROLES OF
6 THE INVESTIGATORS. SO THERE IS A PI IN BOTH OF THEM
7 AND THE REST ARE CO-INVESTIGATORS.

8 AND THEN THE THIRD ONE IS WE REMOVED
9 FAVORABLE CONSIDERATION FOR APPLICATIONS THAT
10 INCLUDE EARLY CAREER FACULTY AS PER YOUR FEEDBACK.

11 THIS IS THE PROJECT ELIGIBILITY. THE MAIN
12 CHANGE -- THERE ARE TWO CHANGES THAT WE MADE HERE.
13 THE FIRST POINT IS THAT WE ALIGNED -- WELL, WE
14 ALIGNED THE LANGUAGE WITH THE CONCEPT DOCUMENT, AND
15 WE CHANGED FROM INCLUDING STUDIES USING STEM CELLS/
16 GENETIC RESEARCH TO ACTUALLY EMPLOYING THE STEM
17 CELL/GENETIC AS PART OF THE CENTRAL APPROACH. WHAT
18 IT MEANS IS THAT IF YOU HAVE, SAY, FIVE DIFFERENT
19 PROJECTS MAKING THE LARGE COLLABORATIVE REMIND-L
20 PROJECT, THERE COULD BE A WAY THAT ONE OF THE
21 PROJECTS MIGHT NOT HAVE A STEM CELL/GENETIC RESEARCH
22 COMPONENT, BUT THAT IT WILL HELP VALIDATE THE REST
23 OF THE APPROACHES, THAT THEY WILL ALL HAVE A STEM
24 CELL AND GENETIC RESEARCH. THAT'S WHAT WE MEANT BY
25 THIS POINT. AND THEN -- AND THAT WERE ALL THE

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1 CHANGES THAT WE MADE IN TERMS OF PROJECT
2 ELIGIBILITY.

3 IN TERMS OF THE DATA SHARING AND DEI, DATA
4 SHARING AND KNOWLEDGE PRODUCED FROM CIRM-FUNDED
5 PROJECTS IS KEY, AS WE KNOW, TO ADVANCING THE FIELD
6 OF REGENERATIVE MEDICINE AND ACCELERATING TREATMENTS
7 FOR PATIENTS. AND SINCE THE PASSING OF OUR PROP 14,
8 CIRM HAS IMPLEMENTED A SET OF GUIDELINES TO SHARE
9 AND MANAGE DATA, ALL WITH A VISION TO ENABLE A
10 COLLABORATIVE ECOSYSTEM INFRASTRUCTURE THAT REMIND
11 WILL BE PART OF. AND AS SUCH, WE WILL BE REQUIRING
12 DATA SHARING AND MANAGEMENT PLANS BASED ON THE DATA
13 SHARING AND MANAGEMENT PLAN GUIDELINES AS WELL AS WE
14 WILL COORDINATE WITH OTHER CIRM DATA INITIATIVES
15 THAT MIGHT BE COMING UP IN THE FUTURE, ALWAYS
16 SUBJECT TO THE BOARD'S APPROVAL.

17 AND IN TERMS OF DIVERSITY, EQUITY, AND
18 INCLUSION, THE REMIND PROGRAM WILL ALSO UPHOLD THE
19 PRINCIPLES OF THE DEI, AND APPLICANTS WILL BE
20 REQUIRED TO INCLUDE PLANS TO ADDRESS CONSISTENT WITH
21 ALL THE PROGRAMS WITHIN CIRM'S OFFERINGS.

22 THIS IS THE OVERALL VISION OF HOW THIS
23 PROGRAM WILL LEAD TO ACCELERATE WORLD-CLASS SCIENCE,
24 TO FURTHER ACCELERATE THE DISCOVERY OF NOVEL
25 INSIGHTS INTO MECHANISMS OF NEUROPSYCHIATRIC

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1 DISEASES. THE REMIND PROGRAM WILL AIM TO ESTABLISH
2 A COLLABORATIVE NETWORK OF MULTIDISCIPLINARY
3 RESEARCH THROUGH NEW FUNDING STRUCTURES WHICH ARE
4 THE LARGE TEAMS THAT WE WERE TALKING ABOUT, THE
5 REMIND-L AND THE REMIND-X EARLIER PROJECTS, BUT ALSO
6 COMPLEMENTARY TO OUR CURRENT DISC-0 AND THESE TWO
7 CIRM DISC PILLAR PROJECTS. AND FURTHERMORE,
8 LEVERAGING WITH CIRM-FUNDED INFRASTRUCTURE ELEMENTS
9 LIKE THE SHARED RESOURCE LABS THAT WE ARE RIGHT NOW
10 HAVING APPLICATIONS FOR AND OTHERS AND EXTERNAL
11 CONSORTIA NETWORKS AND DATA PLATFORMS THAT WE ARE
12 CURRENTLY UNDER DISCUSSIONS WITH ALWAYS DEPENDENT ON
13 HOW THIS CONCEPT MOVES FORWARD.

14 THIS IS JUST TO SHOW THAT ECOSYSTEM TYPE
15 OF INFRASTRUCTURE WILL ULTIMATELY DRIVE THE
16 OBJECTIVES THAT WE MENTIONED EARLIER ON AND
17 CONNECTING OUR THREE PILLARS OF RESEARCH AND
18 DEVELOPMENT LEADING TO INCREASING THE EFFICIENCY AND
19 SUCCESS OF CLINICAL TRIALS IF WE ARE SUCCESSFUL.

20 AND THIS IS A SUMMARY OF THE UPDATED
21 PROGRAM BUDGET REFLECTING THE CHANGES THAT WERE MADE
22 BASED UPON YOUR FEEDBACK. AND AS A REMINDER, IN
23 JUNE THE AGENCY'S RESEARCH BUDGET HAD A PLACEHOLDER
24 OF \$62.2 MILLION FOR THE REMIND CONCEPT PLAN, THE
25 REMIND-L CONCEPT PLAN, A NUMBER THAT WAS UNDERSTOOD

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1 TO BE SUBJECT TO REVISION AS THE CONCEPT PLAN WAS
2 FURTHER REFINED. WITH THE BENEFIT OF THE WORK OF
3 THIS TASK FORCE, THE ACTUAL PROGRAM BUDGET IS NOW
4 CLEAR AND WILL REQUIRE 26 MILLION MORE FOR REMIND-L
5 FOR THE FISCAL YEAR 23/24 BUDGET. THIS ADDITIONAL
6 ALLOCATION WILL BE SOUGHT OF THE FULL BOARD AT THE
7 SEPTEMBER ICOC CONSIDERATION OF THIS CONCEPT PLAN,
8 ASSUMING, OF COURSE, THAT THE TASK FORCE RECOMMENDS
9 BRINGING THE CONCEPT PLAN TO THAT MEETING. AND THE
10 REMIND-X BUDGET COULD BE MADE THE YEAR AFTER AS PART
11 OF THE FISCAL YEAR 24/25 RESEARCH BUDGET.

12 IN TERMS OF THE FINAL SLIDE, THE ACTION
13 THAT WE REQUEST COULD BE TO HAVE THE BOARD APPROVE
14 THE PROPOSED REMIND PROGRAM CONCEPT. THANK YOU SO
15 MUCH FOR THE OPPORTUNITY TO PRESENT THIS CONCEPT AND
16 TO GATHER THE FEEDBACK AND IMPLEMENT IT INTO THIS.
17 THANK YOU.

18 CHAIRMAN GOLDSTEIN: THANK YOU, ROSA.
19 THAT WAS TERRIFIC. AND THOSE ARE EXCELLENT CHANGES
20 IN RESPONSE TO SUGGESTIONS FROM THE LAST MEETING.

21 SO QUESTIONS FOR ROSA. JUDY.

22 DR. GASSON: THANK YOU, LARRY. GREAT JOB,
23 ROSA.

24 SOME OF MY COLLEAGUES LOOKED AT THE
25 CONCEPT PLAN THAT YOU SENT OUT AND HAD A COUPLE

1 QUESTIONS. THERE'S A FOOTNOTE RIGHT IN THE
2 BEGINNING THAT DESCRIBES THE TOPIC OF NEUROSCIENCE.
3 AND IF YOU GO ALL THE WAY TO THE END OF THE
4 DOCUMENT, AND I APOLOGIZE I DON'T HAVE IT OPEN, IT'S
5 A VERY BROAD DEFINITION OF NEURO. IT'S NOT SPECIFIC
6 TO NEUROPSYCH. AND I JUST WONDERED WHAT THE PURPOSE
7 OF THAT FOOTNOTE WAS.

8 DR. CANET-AVILES: THANK YOU FOR THE
9 QUESTION, JUDY. THIS DEFINITION CAME FROM FEEDBACK
10 FROM ONE OF THE BOARD MEMBERS THAT REQUESTED TO
11 CLARIFY. IF WE THINK ABOUT PROPOSITION 14, THE WAY
12 THAT IT WAS DEFINED, DISEASES OF THE BRAIN AND THE
13 CNS, IN SOME WAYS IT'S NOT REALLY TELLING US WHICH
14 BRAIN DISEASES WE ARE TACKLING. AND THE FOOTNOTE, I
15 THINK, THE INTENTION WAS TO CLARIFY WHAT KIND OF
16 DISEASES THE OVERALL PROP 14 COULD BE TACKLING
17 EVENTUALLY. WHAT IS IT THAT WE ARE INTERESTED IN
18 WORKING OUR RESEARCH TOWARDS?

19 DR. GASSON: IT'S REALLY THE BROAD
20 DEFINITION.

21 DR. CANET-AVILES: YES. IT WAS A BROAD
22 DEFINITION OF WHAT NEURO IS. WE THINK ABOUT IT,
23 NEURO IS CNS AS WELL AS CNS AND PNS, THE PERIPHERAL
24 NERVOUS SYSTEM, AS WELL. SO IT'S NOT JUST THE CNS
25 THAT WE COULD BE TACKLING. AND THAT'S WHAT THIS HAD

1 THE INTENTION OF.

2 DR. GASSON: ANOTHER NOTE THAT YOU TALKED
3 ABOUT WAS BEHAVIORAL PHENOTYPING AS ONE OF THE AREAS
4 OF INTEREST. CAN YOU JUST SAY A WORD, ROSA, ABOUT
5 WHAT YOU'RE CATEGORIZING AS BEHAVIORAL PHENOTYPING?

6 DR. CANET-AVILES: WELL, THAT WAS
7 INITIALLY BEHAVIORAL PHENOTYPING IN TERMS OF
8 NEUROPSYCHIATRIC DISORDERS. WE KNOW THAT THERE ARE
9 STUDIES THAT WE HAVE CONSIDERED, MENTAL HEALTH
10 DISORDERS, IN THE CONTEXT OF THE CURRENT DIAGNOSTIC
11 CATEGORIES. BUT THERE ARE ALSO THE NEUROBEHAVIORAL
12 DOMAINS, THAT R-DOC, THAT IT'S SOMETHING THAT WE ARE
13 INTERESTED ALSO IN TAKING INTO ACCOUNT. SO THAT'S
14 WHAT WE WERE CONVEYING BY THIS.

15 DR. GASSON: GREAT. THANK YOU. AND THEN
16 JUST ONE FINAL POINT. ONE OF MY COLLEAGUES BROUGHT
17 UP WHAT WOULD HAPPEN AT THE END OF THE FOUR YEARS.
18 AND I KNOW WE'VE TALKED ABOUT POSSIBLY TRANSITIONING
19 TO THE EXISTING TRANSLATION OR CLINICAL PROGRAMS.
20 BUT THE COLLEAGUE ASKED IF WE COULD AT LEAST
21 CONSIDER THAT MORE FULLY, WHETHER THAT WOULD BE THE
22 RIGHT TRANSITION OR WHETHER THERE SHOULD BE SOME
23 SORT OF OTHER PROCESS AT THE END OF THIS JUST FOR
24 FUTURE CONSIDERATION.

25 SO THANK YOU AGAIN, ROSA. GREAT

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1 PRESENTATION AND GREAT CONCEPT DOCUMENT.

2 DR. CANET-AVILES: THANK YOU, JUDY.

3 CHAIRMAN GOLDSTEIN: THANK YOU. PAT.

4 DR. LEVITT: THANKS VERY MUCH, ROSA. IT
5 WAS GREAT. JUST A FEW QUESTIONS.

6 ONE IS THERE'S BEEN SOME MODEST LANGUAGE
7 CHANGES THAT, AS I READ IT, WOULD -- MIGHT ATTRACT
8 RESEARCH USING ANIMAL MODELS BECAUSE THERE'S
9 GENETIC -- THERE'S MANIPULATION OF DNA AND NUCLEIC
10 ACIDS. AND THERE'S SOMETHING IN WHAT YOU DESCRIBE
11 WHERE THEY WOULD HAVE TO JUSTIFY THAT. AND WHILE I
12 DO THAT KIND OF RESEARCH, I'M WORRIED THAT THERE
13 WOULD BE A LARGE CADRE OF APPLICATIONS COMING IN
14 FROM INDIVIDUALS LIKE MYSELF WHO ARE DOING ANIMAL
15 MODEL WORK, WHICH I THINK IS, FROM WHAT WE HEARD
16 FROM THE PRESENTATIONS, NOT NECESSARILY THE MOST
17 RAPID PATH FORWARD, PARTICULARLY THE WORK THAT CIRM
18 SUPPORTS.

19 CERTAINLY THE WORK WE HEARD FROM RUSTY
20 GAGE WHERE HE'S DOING XENOGRAPHS WHERE HE'S USING
21 HUMAN STEM CELLS INTO ANIMAL MODELS WOULD CERTAINLY
22 BE FULLY APPROPRIATE BECAUSE THERE'S THE USE OF
23 HUMAN STEM CELLS. BUT I JUST PUT THAT ON THE TABLE.
24 I AM A LITTLE WORRIED THAT WE'RE GOING TO GET LIKE A
25 BUNCH OF APPLICATIONS FOR MOUSE MODELS OR RODENT

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1 MODELS OF DISEASE WHICH THE NIH IS FULLY INUNDATED
2 WITH. I DON'T KNOW IF YOU WANT TO COMMENT ABOUT
3 THAT.

4 DR. CANET-AVILES: I THINK WHAT WE WOULD
5 HOPE TO DO IS HAVE -- I MEAN OBVIOUSLY THERE ARE
6 STUDIES ABOUT NEUROCIRCUITS AND CONNECTIVITY THAT WE
7 WILL NEED THOSE MODELS. BUT WHAT WE HOPE IS THAT
8 THERE WILL BE COMPLEMENTARY APPROACHES. AND BY THE
9 WAY THAT WE PROVIDE INSTRUCTIONS THROUGH OUR REVIEW
10 CRITERIA AND OUR RFA, IT WILL BE CLEAR THAT THE
11 APPROACHES NEED TO BE COMPLEMENTARY AND VALIDATE
12 EACH OTHER, AND THERE WILL HAVE TO BE A MINIMUM OF
13 HUMAN -- SORRY -- HAVE TO BE STEM CELL AND GENE AND
14 GENETIC RESEARCH APPROACHES THAT WILL BE SUBSTANTIAL
15 AND THAT WILL UTILIZE HUMAN MODELS.

16 BUT OBVIOUSLY WE MIGHT NEED ANIMAL MODELS
17 AS WELL, AND IT WILL ALL BE A QUESTION OF THE
18 BALANCE AND THE REVIEW CRITERIA WHEN WE DEVELOP THEM
19 FOR THE REVIEWERS.

20 DR. LEVITT: SO IN THE TEAM'S VISION OF
21 THIS IN TERMS OF THE RFA, BECAUSE THE RFA WILL
22 REALLY DEFINE THE KIND OF APPLICATIONS THAT ARE
23 GOING TO COME IN, THERE'S GOING TO BE A MINIMUM
24 REQUIREMENT FOR USE OF HUMAN STEM CELLS, IF I
25 UNDERSTAND IT, OR JUST STEM CELLS IN GENERAL

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1 BECAUSE, OF COURSE, ALL VERTEBRATE AND INVERTEBRATE
2 SPECIES HAVE STEM CELLS, RIGHT?

3 DR. CANET-AVILES: YES.

4 DR. LEVITT: SO YOU COULD IMAGINE
5 APPLICATIONS COMING IN -- I'M NOT TRYING TO BE
6 DIFFICULT. I'M JUST POINTING OUT WHAT THE
7 POSSIBILITIES ARE AND THAT WE ARE REALLY TRYING TO
8 ATTRACT -- THERE ARE MODELS, GREAT MODELS, GREAT
9 BIOLOGICAL AND NEUROSCIENCE MODELS IN DROSOPHILA AND
10 C. ELEGANS THAT DO STEM CELL WORK.

11 DR. CANET-AVILES: YEAH. SO WE WILL
12 ASK -- SORRY FOR INTERRUPTING, PAT. I WAS GOING TO
13 CLARIFY BECAUSE THIS IS IN THE CONCEPT. WE ARE
14 GOING TO ASK THAT ANY KNOWN USE OF KNOWN HUMAN
15 MODELS NEED TO BE JUSTIFIED AND NEED TO INCLUDE THE
16 RESEARCH TO VALIDATE ANY DISCOVERIES MADE IN THOSE
17 NONHUMAN MODEL SYSTEMS WITH COMPARABLE STUDIES USING
18 RELEVANT TISSUES AND MODELS BASED IN HUMANS. SO
19 THAT'S PART OF THE CONCEPT, AND IT'S GOING TO BE THE
20 SAME ELIGIBILITY OF THE PROJECT TRANSLATED INTO THE
21 RFA.

22 AND THEN IN TERMS OF THE STUDIES THAT
23 EMPLOY STEM CELLS AND GENETIC RESEARCH, WHAT WE ARE
24 ASKING IS THAT RESEARCHERS, AS PART OF THEIR OVERALL
25 APPROACH, INCLUDE THE STUDIES THAT EMPLOY STEM CELLS

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1 AND GENETIC RESEARCH AS PART OF THE STEM CELL
2 APPROACH OR HYPOTHESIS, THAT THEY WILL BE TESTED IN
3 THESE MULTIDISCIPLINARY AREAS. AND THEN WE ALLOW
4 THAT, BECAUSE THERE IS -- WE ARE ASKING FOR
5 MULTIDISCIPLINARY -- WE ARE ASKING FOR APPLICANTS TO
6 PROVIDE THE JUSTIFICATION IF THERE ARE STUDIES THAT
7 DO NOT DIRECTLY INVOLVE THESE STEM CELLS OR GENETIC
8 RESEARCH, BUT HOW THOSE GENETIC -- KNOWN GENETIC
9 RESEARCH AND STEM CELLS WILL BE ACTUALLY PROVIDING
10 UTILITY AND VALIDITY TO THE STEM CELL AND GENETIC
11 COMPONENT OF THE STUDY IN THE STUDY OF
12 NEUROPSYCHIATRIC DISEASES. DOES THAT ANSWER YOUR
13 QUESTION?

14 DR. LEVITT: YEAH. OKAY.

15 DR. CANET-AVILES: THANK YOU. THIS IS A
16 VERY IMPORTANT QUESTION. SO THANK YOU FOR ASKING.

17 DR. LEVITT: YEAH. I JUST WANT TO MAKE
18 SURE THAT THE RFA IS WRITTEN IN A WAY WHERE WE
19 REALLY PROMOTE THE -- GENERATE EXCITEMENT IN THE
20 FIELD ABOUT REALLY GETTING -- ROLLING OUR SLEEVES UP
21 AND GETTING TO THE DISEASE MODELS THAT ALL OUR
22 EXPERTS WHO CAME TO TALK TO US SAY ARE THE MOST
23 LIKELY APPROACHES THAT ARE GOING TO YIELD BENEFITS.

24 THE OTHER THING THAT I -- THIS IS BASED ON
25 ONE OF THE QUESTIONS THAT JUDY POSED OR ONE OF THE

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1 COMMENTS FROM SOMEONE WHO READ THE INITIAL ONE.
2 THAT INSTEAD OF SAYING BEHAVIORAL PHENOTYPING, WHICH
3 THEN -- I READ THAT AS WELL AND SAID, OH, SO WE'RE
4 GOING TO BE DOING THE BEHAVIORAL PHENOTYPING IN
5 MOUSE MODELS AGAIN, RIGHT. BUT YOU COULD CHANGE THE
6 WORD "BEHAVIORAL" TO "FUNCTIONAL PHENOTYPING," WHICH
7 MEANS THAT YOU COULD BE DOING ANYTHING FROM
8 BEAUTIFUL CELL BIOLOGY TO ELECTROPHYSIOLOGY ON
9 ORGANIDS AND OTHER THINGS. AND THAT'S FUNCTIONAL
10 PHENOTYPING AND WOULD AVOID SORT OF THIS CONSTRUCT
11 WHERE PEOPLE READ THAT AND SAY, OH, SO BEHAVIORAL
12 PHENOTYPING OF DISEASE MODELS IS SOMETHING THAT CIRM
13 WANTS TO SEE, WHICH I THINK IS PROBABLY NOT
14 NECESSARILY THE CASE. I DON'T KNOW IF OTHERS AGREE
15 WITH THAT, BUT I THINK CHANGING FROM BEHAVIORAL TO
16 FUNCTIONAL MIGHT BE HELPFUL.

17 DR. CANET-AVILES: THAT'S A VERY GOOD
18 POINT. THANK YOU, PAT. NOW, I SEE WHERE JUDY WAS
19 COMING FROM.

20 DR. LEVITT: THAT'S IT.

21 DR. CANET-AVILES: THANK YOU.

22 CHAIRMAN GOLDSTEIN: FRED.

23 DR. FISHER: THANK YOU. IF THERE ARE
24 OTHER HANDS UP PERTAINING TO THE CONCEPT PLAN, YOU
25 SHOULD TAKE THOSE QUESTIONS FIRST AND I'LL JUST WAIT

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1 TILL THE END WITH THIS. OTHERWISE, I WILL PLAY MY
2 BROKEN RECORD.

3 CHAIRMAN GOLDSTEIN: SO LET ME JUST ADD TO
4 PAT'S CONCERN. I WONDER IF WE COULD JUST TIGHTEN UP
5 THE LANGUAGE A LITTLE BIT TO PROMOTE A FOCUS ON
6 HUMANS PRIMARILY IN THE APPLICATIONS.

7 DR. CANET-AVILES: OKAY. SO DO YOU HAVE
8 ANY SUGGESTIONS BESIDES THE --

9 CHAIRMAN GOLDSTEIN: I WOULD HAVE TO GO
10 BACK THROUGH THE LANGUAGE OF THE CONCEPT PLAN, AND
11 I'LL DO THAT AND SEND THEM TO YOU.

12 DR. CANET-AVILES: OKAY. YES, WE CAN DO
13 THAT. WHAT WE SAY RIGHT NOW IS WE ASK THAT THE
14 APPLICANT MUST JUSTIFY ANY PROPOSED USE OF NONHUMAN
15 MODELS AND INCLUDE RESEARCH TO VALIDATE ANY
16 DISCOVERIES MADE IN NONHUMAN MODEL SYSTEMS WITH
17 COMPARABLE STUDIES USING RELEVANT TISSUES AND MODELS
18 BASED IN HUMAN CELLS. CIRM PERMITS VITAL STUDIES
19 THAT ARE ONLY FEASIBLE USING NONHUMAN MODELS;
20 HOWEVER, APPLICANTS MAY BE ASKED TO PROVIDE
21 ADDITIONAL SCIENTIFIC JUSTIFICATION IN SUCH CASES.
22 HAPPY TO REVISE OFFLINE.

23 CHAIRMAN GOLDSTEIN: GOOD. THANK YOU.
24 ANYBODY ELSE BEFORE WE GO TO FRED? FRED, YOU'RE ON.

25 DR. FISHER: SO I GUESS I'LL ASK THE STAFF

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1 THIS QUESTION. ROSA, YOU MAY BE THE BEST. OF THE
2 PROPOSALS THAT WE INTEND TO GET FROM THIS CONCEPT
3 PLAN, WHICH ARE CURRENTLY DISQUALIFIED FROM FUNDING
4 THROUGH ANY OF CIRM'S EXISTING FUNDING PATHWAYS?

5 DR. CANET-AVILES: BASICALLY WE ARE NOT
6 FUNDING THIS TYPE OF RESEARCH AT THE SCALE --

7 DR. FISHER: NO. THAT'S NOT WHAT I ASKED.
8 I ASKED -- WE ARE NOT TALKING ABOUT THE SCALE
9 BECAUSE FUNDING AT A DIFFERENT SCALE MEANS MARKETING
10 TO THE SCIENTIFIC COMMUNITY THE OPPORTUNITY TO
11 SUBMIT PROPOSALS FOCUSED ON ANY ONE OF A MILLION
12 SPECIFIC AREAS. AND GIVEN THAT WE HAVE BEEN
13 ENTIRELY PREOCCUPIED BY NEUROPSYCH FOR EVERY SINGLE
14 ONE OF OUR MEETINGS, I WANT TO KNOW WHICH OF THE
15 PROPOSALS THAT ARE BEING IMAGINED, BECAUSE NOW WE
16 FOUND OURSELF GOING DOWN A SCIENTIFIC RABBIT HOLE
17 ABOUT WHETHER WE'RE GOING TO FUND ANIMAL MODELS OR
18 NOT. AND I REALLY DON'T SEE ANY OF THAT AS THE
19 PURVIEW OF THIS COMMITTEE, BUT IT CERTAINLY INVITED,
20 BECAUSE OF THE NATURE OF WHAT THE DISCUSSION HAS
21 BEEN AND I KEEP COMING BACK TO, IT'S THE SAME
22 QUESTION I ASKED OF THE PERSON CONNECTED TO THE
23 LETTERS THAT WE WERE -- THE COMMENTS WE WERE
24 RECEIVING ABOUT THE WORK OF THIS WORK GROUP. AND I
25 ASKED ISN'T THAT SOMETHING THAT CAN BE CONSIDERED

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1 THROUGH ONE OF CIRM'S EXISTING FUNDING PATHWAYS.
2 AND THE ANSWER I GOT, I THINK, WAS A YES
3 OR A QUALIFIED YES. AND SO I WANT TO KEEP COMING
4 BACK TO UNDERSTANDING WHAT IS IT ABOUT NEUROPSYCH
5 THAT IS SO UNIQUE THAT IT CANNOT BE FUNDED THROUGH
6 ONE OF CIRM'S EXISTING FUNDING PATHWAYS? I'M NOT
7 TALKING ABOUT THE VOLUME OF PROPOSALS. WE'VE
8 ALREADY DETERMINED NEUROPSYCH IS UNDERREPRESENTED IN
9 THE THINGS CIRM FUNDS. THAT'S A DIFFERENT QUESTION
10 THAN COULD CIRM BE FUNDING THOSE THINGS IF PEOPLE
11 APPLIED. AND IS A CONCEPT PLAN THE WAY TO GET
12 PEOPLE TO APPLY WHO OTHERWISE WOULD NOT REGARDLESS
13 OF THE BUDGET BECAUSE GOING BACK TO WHAT I
14 UNDERSTAND OUR CHARGE TO BE IN THE LEGISLATION AND
15 FROM THE BOARD MAYBE IS WE ARE SUPPOSED TO EVALUATE
16 THE EXTENT TO WHICH WE'RE GOING TO MEET OR EXCEED
17 WHAT THE PROPOSITION MANDATES.

18 SO HERE WE ARE INVOLVED IN GRANULAR
19 CONSIDERATIONS ABOUT THE KIND OF SCIENCE THAT COULD
20 OR SHOULD BE FUNDED. IT JUST HAS ME WONDERING
21 COULDN'T OR SHOULDN'T ALL OF THIS SCIENCE BE FUNDED
22 THROUGH ONE OF CIRM'S EXISTING PATHWAYS OR TELL ME
23 THERE IS NO PATHWAY FOR NEUROPSYCH. I BELIEVE THAT
24 THERE IS. I BELIEVE THE PROBLEM WITH NEUROPSYCH IS
25 IT HAS NOT BEEN FUNDED FOR A NUMBER OF REASONS THAT

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1 HAVE NOTHING TO DO WITH HAVING A CONCEPT PLAN. TELL
2 ME I'M WRONG.

3 DR. LEVITT: SO, FRED, THIS IS PAT. SO
4 WHAT DO YOU SEE AS THE PATHS? GIVEN WHAT WE HEARD
5 FROM, I THINK WE WOULD ALL AGREE, ARE NATIONAL
6 EXPERTS IN THIS AREA USING A VARIETY OF DIFFERENT
7 APPROACHES, WHAT WOULD YOU SAY ARE THE PATHS THAT
8 CURRENTLY EXIST TO ADDRESS THE CHALLENGES THAT WERE
9 RAISED BY THE PRESENTERS, NOT BY THIS COMMITTEE, BUT
10 BY THE PRESENTERS, ABOUT WHY RESEARCH FOCUSED ON
11 NEUROPSYCHIATRIC DISORDERS HAS CHALLENGES, CURRENT
12 STATE CHALLENGES, THAT COULD BE RESOLVED BY THE
13 CURRENT FUNDING SCHEMES THAT CIRM HAS?

14 DR. FISHER: CLIN, DISCOVERY, I MEAN ALL
15 OF THOSE. AND IF THERE'S A --

16 DR. LEVITT: WE HEARD THAT --

17 DR. FISHER: -- A PROBLEM WITH THOSE, THEN
18 WE SHOULD FIX THAT PROBLEM. WE SHOULDN'T GO CREATE
19 A WHOLE NEW THING AND SPEND SO MUCH TIME IN THIS
20 COMMITTEE FOCUSED ON NEUROPSYCH WHEN WE CAN MAKE
21 SOME SMALL TWEAKS OR RECOMMEND SOME SMALL TWEAKS TO
22 OTHER EXISTING FUNDING PATHWAYS THAT SOLVE WHATEVER
23 THE PROBLEM IS.

24 DR. LEVITT: SO CLIN AND TRANSLATION, TWO
25 OF THOSE, FROM THE EXPERTS BASICALLY SAID THAT

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1 NEUROPSYCH IS NOT READY AND THAT THE FOCUS REALLY
2 NEEDS TO BE ON DISCOVERY OF MECHANISMS BECAUSE IT
3 LAGS FAR BEHIND OTHER BRAIN AND PERIPHERAL NERVOUS
4 SYSTEM DISORDERS.

5 DR. FISHER: OKAY.

6 DR. LEVITT: THAT WAS A PRETTY CONSISTENT
7 MESSAGE FROM EVERYONE WHO PRESENTED. SO IT'S ALMOST
8 ALL IN THE REALM OF DISCOVERY NOW, RIGHT.

9 DR. FISHER: OKAY.

10 DR. LEVITT: AND SO WE HAVE A DISC
11 PROGRAM, AND WHILE I UNDERSTAND THE POINT THAT
12 YOU'RE TRYING TO MAKE, SCALE MATTERS A LOT DEPENDING
13 UPON THE KIND OF RESEARCH. IT CAN'T BE IGNORED.
14 SCALE MATTERS A LOT DEPENDING UPON THE LEVEL OF
15 COMPLEXITY OF THE RESEARCH THAT HAS TO BE DONE IN
16 ORDER TO MAKE THE BREAKTHROUGH DISCOVERIES. SO I
17 WOULD ARGUE THAT THE SCALE MATTERS. AND IF YOU'RE
18 SUGGESTING THAT WE JUST CHANGE THE SCALE OF THE
19 CURRENT DISC COMPONENTS, I'M NOT SAVVY ENOUGH TO
20 KNOW HOW THAT WOULD WORK IN TERMS OF WHAT CIRM
21 IS --

22 DR. FISHER: BY SCALE DO YOU MEAN THE
23 NUMBER OF PROPOSALS FUNDED, OR DO YOU MEAN THE
24 AMOUNT OF FUNDING? I DON'T KNOW -- MAYBE I DON'T
25 UNDERSTAND WHAT YOU MEAN BY SCALE.

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1 DR. LEVITT: SO THE REASON WHY, FOR
2 EXAMPLE, NIMH CAME UP WITH THE CONTE CENTERS
3 APPROACH IS THAT INDIVIDUAL RO1 GRANTS WERE
4 INSUFFICIENT TO ADDRESS MAJOR CHALLENGES OF
5 UNDERSTANDING MECHANISMS OF DISORDERS AND OTHER
6 GOALS THAT THEY HAD AT NIMH. SO THEY CAME UP
7 SOMETHING CALLED THE CONTE CENTERS, WHICH WAS AN
8 INTERDISCIPLINARY APPROACH, CAN'T BE DONE IN A
9 SINGLE GRANT, AND SCALED IT IN TERMS OF HOW MUCH
10 RESOURCES WERE AVAILABLE IN ORDER TO MAKE IT VIABLE
11 TO ACTUALLY DO THE STUDIES.

12 SO THEY CAME UP WITH A DIFFERENT APPROACH.
13 THEY ALREADY HAD RO1 MECHANISMS IN PLACE, AND THEY
14 CAME UP WITH A NEW APPROACH TO TRY TO ATTRACT AND TO
15 TRY TO BUILD A LARGER EFFORT IN WHAT THEY VIEWED AS
16 A MAJOR GAP IN KNOWLEDGE. THAT WAS THEIR APPROACH.
17 AND I THINK THIS IS A PRETTY SIMILAR, FROM MY
18 PERSPECTIVE, A PRETTY SIMILAR APPROACH BECAUSE I
19 PERSONALLY PARTICIPATED IN MULTIPLE CONTE CENTERS AS
20 WELL AS HAVING RO1S. AND THEY ARE DIFFERENT IN
21 TERMS OF WHAT THEY'RE TRYING TO ACCOMPLISH. I DON'T
22 KNOW IF OTHERS WANT TO COMMENT ON IT. BUT
23 THAT'S --

24 DR. FISHER: SO JUST SO IN MY LAY MIND,
25 BECAUSE I AM NOT A SCIENTIST, I'M NOT FAMILIAR WITH

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1 ANYTHING THAT YOU'RE TALKING ABOUT. SO MY SIMPLE
2 MIND IS WHAT HAS TO CHANGE ABOUT DISC IN ORDER TO
3 ACCOMMODATE NEUROPSYCH FUNDING APPLICATIONS?

4 DR. CANET-AVILES: A LOT. A LOT.

5 DR. FISHER: LIKE WHAT?

6 DR. CANET-AVILES: SO RIGHT NOW WE
7 HAVE -- MARV WANTS TO SAY SOMETHING. MARV.

8 DR. SOUTHARD: FRED, AS YOU SAID, THIS IS
9 A RERUN. WE HAVE HAD THIS DISCUSSION BEFORE. AND
10 THE ANSWER BEFORE WAS THE NEUROPSYCH -- MENTAL
11 HEALTH DISORDERS CURRENTLY HAS ZERO FUNDING. WE
12 WENT ON THIS PATH TO FIND OUT HOW WE FIX THE ZERO
13 FUNDING. AND THIS PLAN THAT WE'VE COME UP WITH WAS
14 THE PLAN THAT CAME TO BE DEVELOPED SO THAT WE CAN DO
15 FOR MENTAL HEALTH DISEASES WHAT IS DONE IN OTHERS.
16 THAT'S REALLY WHAT THIS IS ALL ABOUT. AND AS YOU
17 SAID, WE HAVE HAD THIS DISCUSSION BEFORE. AND
18 THAT'S WHY THE STAFF HAS DONE, TO MY MIND, THIS
19 WONDERFUL JOB OF PUTTING TOGETHER A PLAN THAT CAN
20 OPEN DOORS THAT HAVE BEEN PREVIOUSLY CLOSED.

21 DR. CANET-AVILES: AND IF YOU DON'T MIND
22 ME ADDING SOMETHING. THERE ARE TWO DISTINCT
23 QUESTIONS HERE. THE DISEASE AREA OF NEUROPSYCH CAN
24 BE SUPPORTED BY DISC, TRAN, OR CLIN AS YOU VERY WELL
25 SAID, FRED. HOWEVER, THE REMIND PROGRAM IS

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1 STRUCTURALLY VERY DIFFERENT FROM THIS, AND IT'S THE
2 ONLY MULTIPLE INVESTIGATOR OPPORTUNITY FOR RESEARCH
3 AT CIRM. AND WE ARE PROPOSING A NEW MECHANISM HERE
4 WITH NEUROPSYCH AS THE STARTING POINT, BUT WE COULD
5 EVENTUALLY EXPAND FROM THERE. AND THAT'S WHAT WE
6 STARTED IN JANUARY. IT WAS A NEW PROPOSAL FOR A NEW
7 WAY TO THINK ABOUT HOW TO FUND DISCOVERY RESEARCH IN
8 NEURO. AND WE STARTED WITH ADVANCING OUR DISEASE
9 MECHANISM RESEARCH, ACCELERATING DISEASE MECHANISM
10 RESEARCH, CATALYZING MULTIDISCIPLINARY,
11 MULTI-INVESTIGATOR, AND DRIVING COLLABORATION. AND
12 THOSE ARE VERY DISTINCT FROM WHAT WE HAVE RIGHT NOW.
13 LARRY.

14 DR. FISHER: DID THE NEUROPSYCH COMMUNITY
15 SAY THIS IS WHAT WE WANT? WE WANT MULTISITE
16 COLLABORATIVE PROJECTS. THAT WILL HELP US FIX OUR
17 PROBLEM, AND WE WANT SMALL INVESTIGATOR GRANTS AND
18 THAT WILL HELP FIX OUR PROBLEM. LIKE IS THIS
19 SOLUTION WHAT WE HAVE HEARD FROM THOSE WE ARE
20 EXPECTING TO GET PROPOSALS FROM BUT HAVE NOT?

21 DR. CANET-AVILES: YES. THE ANSWER TO
22 THAT IS YES.

23 DR. FISHER: GREAT. OKAY.

24 DR. CANET-AVILES: AND WE HAVE ALSO
25 CONSULTED WITH THE NATIONAL INSTITUTES OF MENTAL

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1 HEALTH PROGRAM DIRECTORS AND DIRECTORS OF DIVISION
2 ABOUT THE THINGS THAT WE COULD DO TO COMPLEMENT AND
3 WHAT THEY ARE BEING ASKED. AND THOSE ARE THE THEMES
4 THAT WE'VE BEEN HEARING.

5 DR. FISHER: GREAT. SO NOW I HAVE A
6 BIGGER PICTURE QUESTION.

7 CHAIRMAN GOLDSTEIN: HANG ON A SECOND,
8 FRED. I'D LIKE TO JUST ADD TO THIS PART OF THE
9 CONVERSATION.

10 DR. FISHER: OKAY. GO AHEAD.

11 CHAIRMAN GOLDSTEIN: AND I THINK THE OTHER
12 THING I'D LIKE TO ADD IS THAT PART OF THE POINT FOR
13 THAT SERIES OF SPEAKERS THAT WE HAD WAS TO ACTUALLY
14 TELL US THAT THE FIELD IS READY FOR THIS KIND OF
15 INTERDISCIPLINARY PROJECT TO MAKE SOME HEADWAY. BY
16 AND LARGE, IF YOU HAD ASKED, SAY, A YEAR OR TWO AGO,
17 IT'S NOT OBVIOUS TO ME THAT THE FIELD WOULD NOT HAVE
18 BEEN QUITE AS READY. BUT THERE HAVE BEEN
19 BREAKTHROUGHS IN TECHNOLOGY AND THERE HAVE BEEN
20 BREAKTHROUGHS IN INSIGHTS THAT MAKE AN APPROACH LIKE
21 THIS ACTUALLY FEASIBLE; WHEREAS, BEFORE I THINK IT
22 WOULD NOT HAVE BEEN.

23 DR. FISHER: GREAT. MY BIGGER PICTURE
24 QUESTION IS WONDERING WHAT HAPPENS WHEN WE, THIS
25 GROUP, STOP TALKING ABOUT NEUROPSYCH. WHAT IS OUR

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1 PROCESS GOING TO BE GOING FORWARD? ARE WE GOING
2 TO --

3 CHAIRMAN GOLDSTEIN: FRED, THAT'S THE REST
4 OF THE MEETING AFTER WE FINISH THIS PART.

5 DR. FISHER: OKAY. AND I GUESS I'LL BE
6 INTERESTED BECAUSE, IF THIS IS THE PATTERN, WE PICK
7 A DISEASE AREA OR WE PICK AN INDICATION, WE SPENT
8 WEEKS ON IT, AND THEN WE CREATE A CONCEPT PLAN FOR
9 THAT, AND THEN WE DO ANOTHER ONE AND WE CREATE A
10 CONCEPT PLAN FOR THAT. THIS WAS NOT AT ALL WHAT I
11 SIGNED UP FOR, WHICH IS WHY I KEEP HAVING SO MUCH
12 TROUBLE WITH IT. AND MAYBE I SHOULDN'T BE HERE.
13 I'VE GOT THINGS TO SAY ABOUT NEURO, BUT THIS PROCESS
14 IS NOT HELPING ANSWER THE QUESTION: ARE WE GOING TO
15 MEET THE REQUIREMENTS OF THE -- IN TERMS OF THE
16 SPENDING REQUIREMENTS OF THE PROPOSITION? THIS
17 PARTICULAR CONCEPT PLAN AND ALL THE TIME WE HAVE
18 SPENT IN ADVANCE OF IT HOPEFULLY WILL GENERATE
19 REQUESTS FOR FUNDING IN NEUROPSYCH. I JUST AM
20 CURIOUS TO KNOW IF THIS IS THE MODEL THAT THIS GROUP
21 IS GOING TO BE USING GOING FORWARD BECAUSE IT WILL
22 BE ARDUOUS AND TAKE A VERY LONG TIME. BUT I GUESS
23 I'LL WAIT TO SEE WHAT THAT LOOKS LIKE LATER IN THE
24 MEETING.

25 CHAIRMAN GOLDSTEIN: THANK YOU. LEONDRA.

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1 DR. CLARK-HARVEY: HEY, EVERYONE. JUST
2 WANT TO SHARE A FEW COMMENTS. FIRST OF ALL, THANK
3 YOU. THANK YOU TO THE STAFF. I REALLY APPRECIATE
4 AT THE LAST MEETING YOU SHARING WITH US THE
5 CONCEPTS. AND I REMAIN VERY EXCITED ABOUT ALL OF
6 IT.

7 I ALSO THINK THAT, TO KIND OF FRED'S
8 COMMENT AROUND WHAT HAPPENS WHEN WE STOP TALKING
9 ABOUT IT OR FOCUSING ON IT, MY PERSONAL OPINION IS
10 THAT RIGHT NOW THE PSYCH GUYS, THE POLITICAL CLIMATE
11 IS VERY MUCH FOCUSED ON KIND OF BEHAVIORAL HEALTH,
12 RIGHT. SO IT'S THE PERFECT OPPORTUNITY TO BE DOING
13 THIS. I THINK IT'S TIMELY AND WE NEED TO TAKE
14 ADVANTAGE OF EVERY KIND OF POLITICAL WIN THAT WE CAN
15 GET RIGHT NOW AND SUPPORT WHEN WE HAVE A GOVERNOR
16 THAT'S COMMITTED TO BEHAVIORAL HEALTH IN PLACE AND
17 SO MANY THINGS THAT ARE HAPPENING IN THIS REALM. SO
18 I THINK NOW IS THE RIGHT TIME. I'M EXCITED THAT WE
19 HAVE THIS GROUP, THAT IT WAS CARVED OUT. I'M
20 EXCITED THAT THERE'S WORK HAPPENING HERE AND TO BE A
21 PART OF THE GROUP.

22 AND I ALSO WANT TO THANK FRED FOR KEEPING
23 US HONEST AND REALLY CHECKING IN AROUND THE PROCESS
24 AND WHAT MAKES SENSE AS WE GO FORWARD. I THINK FOR
25 MY PERSONAL OPINION AND PROFESSIONAL OPINION IS THAT

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1 RIGHT NOW THIS IS A GREAT WAY TO ATTACK IT AND TO
2 STRATEGIZE AND TO WORK WITH LIKE MINDS, AND I ALSO
3 THINK FRED IS THINKING AHEAD. OKAY. SO WHAT
4 HAPPENS WHEN THE THING POPS UP AND HOW DO WE
5 ORGANIZE THIS AS A CIRM KIND OF FAMILY TO ADDRESS
6 ISSUES? AND I ENCOURAGE AND SUPPORT MORE THOUGHT
7 THERE, AND IS THERE A BETTER PROCESS TO BE DOING
8 THAT? IS THIS THE BEST WAY? NOT SAYING THAT THIS
9 ISN'T, BUT I THINK THAT WE HAVE TO KEEP CONSIDERING
10 THAT AS WELL.

11 SO REALLY GRATEFUL. I THINK THIS IS A
12 WONDERFUL PROCESS AND METHOD FOR DOING IT, AND I'M
13 OPEN TO ALSO WHAT MIGHT BE BETTER. SO ENCOURAGING
14 STAFF AND THE TEAM TO CONTINUE TO LOOK AT THAT AND
15 TO TAKE THAT IN.

16 CHAIRMAN GOLDSTEIN: THANK YOU, LEONDR.

17 BEFORE I CALL FOR A MOTION, I JUST WANT TO
18 ADD ONE BIT OF NUMEROLOGY THAT WE'VE DONE IN THE
19 PAST, WHICH IS WHEN WE'VE COMPUTED THE PERCENTAGE OF
20 AWARDED GRANTS HISTORICALLY, IN FACT, WE ARE IN
21 GENERAL ON PATH TO MEET THE 1.5 BILLION COMMITMENT.
22 SO IT'S NOT OBVIOUS TO ME THAT THERE'S A LIKELY
23 PROBLEM THERE, BUT WE WILL RETURN TO THIS TOPIC
24 SHORTLY.

25 ANY FURTHER QUESTIONS FOR ROSA? THEN CAN

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1 I CALL FOR A MOTION TO RECOMMEND SENDING THIS
2 CONCEPT PLAN ON TO THE SCIENCE SUBCOMMITTEE WHICH
3 WILL BE THE NEXT STEP?

4 DR. CLARK-HARVEY: SO MOVED.

5 DR. GASSON: SECOND.

6 CHAIRMAN GOLDSTEIN: OKAY. ANY FURTHER
7 DISCUSSION FROM THIS GROUP? SCOTT, DO WE HAVE
8 PUBLIC COMMENT?

9 MR. TOCHER: I WILL CHECK AND I'LL ASK IF
10 DOUG AND LANA CAN CHECK. IN THE MEANTIME, JUST FOR
11 CLARITY, LARRY, PERHAPS WE COULD HAVE THE MOTION AND
12 SECOND RESTATED TO RECOMMEND THAT THE SCIENCE
13 SUBCOMMITTEE CONSIDER THE CONCEPT PLAN AND THAT THE
14 BUDGET BE AUGMENTED IN THE AMOUNT THAT WAS DESCRIBED
15 BY ROSA, I BELIEVE, 26 MILLION. SO JUST THOSE TWO
16 RECOMMENDATIONS.

17 CHAIRMAN GOLDSTEIN: THANK YOU FOR THE
18 REVISION. DO THE MOTION OR THE SECOND HAVE ANY
19 OBJECTION TO THAT?

20 DR. GASSON: NO.

21 CHAIRMAN GOLDSTEIN: FRED, YOU HAVE A
22 QUESTION?

23 DR. FISHER: IF WE ARE IN THE DISCUSSION
24 PHASE ALONG THE FIRST AND THE SECOND, THEN I GUESS I
25 WOULD ASK WHY WE NEED A BUDGET AUGMENTATION AT ALL

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1 GIVEN THAT WE ARE SO EARLY IN THE FISCAL YEAR? IS
2 IT BECAUSE THIS WILL PRESUMABLY DRAIN RESOURCES
3 ALREADY ACCOUNTED FOR THROUGH OTHER CIRM PROGRAMS?

4 DR. CANET-AVILES: I'M HAPPY TO PROVIDE
5 THE ANSWER. THANK YOU, FRED. SO AS I WAS
6 MENTIONING IN THE PROGRAM BUDGET SUMMARY SLIDE, WHEN
7 WE PROPOSED THE JUNE RESEARCH BUDGET, THE \$62.2
8 MILLION THAT WE HAD ALLOCATED FOR THE REMIND-L,
9 WHICH IS WHAT WE WOULD DO THIS YEAR, WERE ACTUALLY A
10 PLACEHOLDER. AND IT WAS UNDERSTOOD AT THAT TIME
11 THAT IT WOULD BE SUBJECT TO REVISION AS THE CONCEPT
12 PLAN WAS FURTHER REFINED. GIVEN ALL THE INPUT AND
13 VARIATIONS THAT WE'VE RECEIVED, NOW THE BUDGET IS
14 CLEAR AND THE PROGRAM STRUCTURE IS CLEAR AND IT WILL
15 REQUIRE 26 MILLION MORE FOR THE REMIND-L. SO WE ARE
16 GOING FROM AN INITIAL ALLOCATION OF \$62.2 MILLION
17 FOR REMIND-L TO AN 88.2 MILLION NOW THAT WE HAVE IT
18 ALL SQUARED DOWN.

19 CHAIRMAN GOLDSTEIN: THANK YOU, ROSA.
20 SCOTT, NO PUBLIC COMMENT?

21 MR. TOCHER: IF THERE'S ANYONE ON THE
22 TELEPHONE WITH PUBLIC COMMENT, I BELIEVE YOU'RE
23 SUPPOSED TO PRESS THE NINE NUMBER NOW.

24 MS. MORALES: STAR NINE. NO PUBLIC
25 COMMENT.

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1 MR. TOCHER: NOT SEEING ANY, LARRY. I
2 THINK WE CAN PROCEED TO THE VOTE.

3 CHAIRMAN GOLDSTEIN: YES, PLEASE. CALL
4 THE ROLL. WHOOPS. THERE'S A HAND. SORRY. 3536,
5 PLEASE GO AHEAD AND SPEAK UP.

6 MR. TOCHER: AND YOU HAVE THREE MINUTES.

7 CHAIRMAN GOLDSTEIN: YOU ARE EITHER MUTED
8 OR WE CANNOT HEAR YOU. (714) 651-3536, WITH YOUR
9 HAND UP, DO YOU HAVE SOMETHING TO ADD PLEASE?

10 MR. REDAELLI: YES. YOU MUST FORGIVE ME.
11 CAN YOU HEAR ME?

12 CHAIRMAN GOLDSTEIN: YES, WE CAN HEAR YOU
13 NOW.

14 MR. REDAELLI: YEAH. MY NAME IS JOHN
15 REDAELLI. I MIGHT BE A LITTLE TOO EARLY. I
16 PROBABLY NEED TO WAIT TILL LATER ON IN THE PROGRAM.
17 I WAS GOING TO SPEAK TO THE NEURO TASK FORCE ON
18 BEHALF OF ATHERSYS. SHOULD I WAIT A LITTLE LATER?

19 CHAIRMAN GOLDSTEIN: ON BEHALF OF
20 ATHERSYS? IS THAT A COMPANY?

21 MR. REDAELLI: YES. ATHERSYS, THEY'RE
22 WORKING ON -- THEY'RE IN A PHASE 3 PIVOTAL TRIAL FOR
23 ISCHEMIC STROKE. I GUESS THE QUESTION IS WILL YOU
24 BE ASKING FOR COMMENTS AFTER YOU FINISH THE NEXT
25 SEGMENT OF YOUR MEETING?

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1 MR. TOCHER: YES, WE WILL BE.

2 MR. REDAELLI: THEN MAYBE I SHOULD WAIT
3 BECAUSE I'M A LITTLE PREMATURE.

4 CHAIRMAN GOLDSTEIN: OKAY. THANK YOU VERY
5 MUCH FOR YOUR CONSIDERATION.

6 ANY OTHER PUBLIC COMMENT? HEARING NONE,
7 CAN WE MOVE ON TO A ROLL CALL VOTE PLEASE.

8 MR. TOCHER: YES. LEONDR A CLARK-HARVEY.

9 DR. CLARK-HARVEY: YES.

10 MR. TOCHER: MARIA BONNEVILLE.

11 VICE CHAIR BONNEVILLE: YES.

12 MR. TOCHER: MARK FISCHER-COLBRIE.

13 DR. FISCHER-COLBRIE: AYE.

14 MR. TOCHER: THANK YOU. FRED FISHER.

15 DR. FISHER: YES.

16 MR. TOCHER: JUDY GASSON.

17 DR. GASSON: YES.

18 MR. TOCHER: LARRY GOLDSTEIN.

19 CHAIRMAN GOLDSTEIN: YES.

20 MR. TOCHER: DAVID HIGGINS.

21 DR. HIGGINS: YES.

22 MR. TOCHER: VITO IMBASCIANI.

23 CHAIRMAN IMBASCIANI: YES.

24 MR. TOCHER: STEVE JUELSGAARD.

25 MR. JUELSGAARD: YES.

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1 MR. TOCHER: PAT LEVITT.

2 DR. LEVITT: YES.

3 MR. TOCHER: LAUREN MILLER-ROGEN.

4 MS. MILLER-ROGEN: YES.

5 MR. TOCHER: AND MARVIN SOUTHARD.

6 DR. SOUTHARD: YES.

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

8 AND THE MOTION CARRIES.

9 CHAIRMAN GOLDSTEIN: GOOD. THANK YOU VERY
10 MUCH, MEMBERS OF THE TASK FORCE.

11 SO LET'S MOVE ON TO THE SECOND PART OF
12 THIS MEETING, WHICH IS TO TALK A LITTLE BIT ABOUT
13 WHAT THE ROADMAP SHOULD LOOK LIKE MOVING FORWARD. I
14 SENT QUESTIONS AROUND AS PART OF THE AGENDA. YOU'VE
15 ALL HAD A CHANCE TO LOOK AT THEM.

16 ONE THING I WANT TO DO BEFORE WE GET INTO
17 ANY MORE OF THE WEEDS, SO TO SPEAK, ABOUT WHAT SORTS
18 OF QUESTIONS WE WANT TO ASK MOVING FORWARD, PAT
19 LEVITT MADE A VERY GOOD, SIMPLIFYING SUGGESTION.
20 AND IF I COULD HAVE THE LAST SLIDE UP PLEASE, SCOTT,
21 OR WHOEVER IS CONTROLLING THE SCREEN.

22 SCOTT, IS THAT NOT YOU?

23 MR. TOCHER: LET ME SEE. GIVE ME TWO
24 SECONDS AND I WILL SHARE MY SCREEN, BUT I WILL PULL
25 IT UP.

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1 CHAIRMAN GOLDSTEIN: THANK YOU. IN BRIEF,
2 WHAT PAT POINTED OUT IN AN EMAIL HE SENT ME PRIOR TO
3 THIS MEETING IS THAT WE DEALT WITH NEUROPSYCHIATRIC
4 AS A WHOLE IN THINKING ABOUT IT. SO DEPRESSION,
5 MANIA, BIPOLAR, A VARIETY OF DIFFERENT -- SUBSTANCE
6 ABUSE, A VARIETY OF DIFFERENT DISORDERS WERE CLUMPED
7 TOGETHER AS WHOLE IN NEUROPSYCHIATRIC AS A CATEGORY
8 OF DISEASE. PAT SUGGESTED THAT IN MOVING FORWARD
9 AND THINKING ABOUT WHAT DO OUR CURRENT -- HERE WE
10 GO. DOWN TO THE LAST ONE WHERE IT SAYS POSSIBLE
11 CLUSTERING OF DISEASES. THANK YOU.

12 PAT SUGGESTED THAT IF WE TRIED TO MOVE
13 FORWARD AND REVIEW OUR COMMITMENTS AND THE QUALITY
14 OF OUR COMMITMENTS OR DISCOVERY OF UNFUNDED AREAS,
15 IF WE DID SO DISEASE BY DISEASE, IT WOULD, FIRST OF
16 ALL, BE COMPLETELY DISSIMILAR TO THE WAY WE'VE DEALT
17 WITH NEUROPSYCHIATRIC AS SHOWN HERE. AND SECOND OF
18 ALL, THERE ARE, IN A SENSE, SO MANY DIFFERENT
19 DISEASES, WE WOULD GET BOGGED DOWN PRETTY QUICKLY
20 TRYING TO MAKE IT THROUGH DISEASE BY DISEASE.

21 AND SO PAT SUGGESTED, AND I THINK THIS IS
22 A GOOD IDEA, WE'LL SEE WHAT THE REST OF THE TASK
23 FORCE THINKS, THAT WE DEAL WITH NEURODEGENERATIVE,
24 FOR EXAMPLE, AS A CLASS OF DISEASE THAT INCLUDES
25 SOME OF THE DISORDERS SHOWN HERE, ALZHEIMER'S, ALS,

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1 PARKINSON'S, ET CETERA, AND THAT WE HAVE AN
2 ADDITIONAL CLASS WHICH IS NEURO-INJURY, WHICH WOULD
3 INCLUDE STROKE, TRAUMATIC BRAIN INJURY, SPINAL CORD
4 INJURY, ET CETERA. YOU ALL CAN READ.

5 I THINK THAT'S JUST A GENERALLY VERY GOOD
6 SUGGESTION FOR ORGANIZING HOW WE PROCEED. WE CAN
7 ALWAYS LOOK AT THE INDIVIDUAL DISEASE LEVEL IF THAT
8 TURNS OUT TO BE IMPORTANT FOR SOME REASON, BUT THIS
9 IS SOMETHING THAT THE TASK FORCE NEEDS TO DISCUSS
10 AND EITHER ACCEPT OR NOT.

11 SO COMMENTS AND QUESTIONS ABOUT THIS MODE
12 OF PROCEEDING. LEONDRA.

13 DR. CLARK-HARVEY: ALL RIGHT. I HIT ALL
14 THE EMOJIS AT ONCE. THEY'RE FLYING ALL OVER. I'M
15 NOT WAVING. THAT WAS MY HAND UP.

16 FORGIVE ME IF I MISSED THAT. CAN YOU TALK
17 A LITTLE BIT MORE AROUND THE RATIONALE FOR DOING
18 THIS JUST A LITTLE BIT DEEPER ABOUT THAT? I THINK
19 FOR ME I'M ALWAYS THINKING ABOUT UNINTENDED
20 CONSEQUENCES. AND SO WHILE SOMETHING MAY SEEM
21 PRACTICAL, I THINK CONSIDERING A LOT OF THE STIGMA
22 AND KIND OF LACK OF FOCUS TRADITIONALLY IN THESE
23 AREAS, WHAT I DON'T WANT TO DO IS END UP WITH
24 NEUROPSYCHIATRIC, FOR EXAMPLE, GETTING LESS
25 ATTENTION OR THERE NOT BEING PARITY ACROSS THESE

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1 SUBCATEGORIES.

2 SO THERE MIGHT BE A REALLY GOOD REASON TO
3 DO THIS. I'M JUST TRYING TO UNDERSTAND IT A BIT
4 BETTER. SO THANK YOU FOR YOUR PATIENCE WITH ME, BUT
5 CAN YOU EXPLAIN JUST A LITTLE BIT MORE AROUND WHY WE
6 NEED TO DO THIS AND HOW IT WOULD REALLY BENEFIT THE
7 PROCESS HERE?

8 CHAIRMAN GOLDSTEIN: SURE. SO I'LL GIVE
9 YOU MY TAKE ON IT. YOU WANT TO COMMENT, STEVE, OR
10 IS THAT A DIFFERENT TOPIC?

11 MR. JUELSGAARD: I WANT TO COMMENT ON THIS
12 TOPIC WHEN YOU'RE DONE, LARRY.

13 CHAIRMAN GOLDSTEIN: ON THIS ONE; IS THAT
14 RIGHT?

15 MR. JUELSGAARD: YES, EXACTLY. ON YOUR
16 PROPOSAL. I HAVE A COMMENT, A DIFFERENT ONE.

17 CHAIRMAN GOLDSTEIN: A DIFFERENT. SO LET
18 ME ADDRESS AT LEAST MY VIEW OF AN ANSWER TO LEONDRA,
19 WHICH IS TO, FIRST, NEUROPSYCHIATRIC IN A SENSE SET
20 A MODEL FOR HOW WE CAN PERHAPS EFFICIENTLY THINK
21 ABOUT DIFFERENT AREAS OF NEURODISEASE RESEARCH.
22 NEUROPSYCHIATRIC IS A CATEGORY, NEURODEGENERATIVE IS
23 A CATEGORY, NEURO-INJURY IS A CATEGORY.

24 I THINK SECOND, PAT'S POINT, AND I AGREE
25 WITH THIS, IS THAT IF IN THE REVIEW PROCESS WE TRY

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1 TO GO COMPLETELY DISEASE BY DISEASE RATHER THAN
2 CATEGORY, WE'LL BOG DOWN BECAUSE THERE ARE SO MANY
3 INDIVIDUAL DISORDERS. AND SOME OF THEM VERY RARE,
4 BUT THAT NONETHELESS WOULD DEMAND ATTENTION.

5 IT'S NOT AN IRREVERSIBLE COMMITMENT TO DO
6 IT THIS WAY WOULD BE MY FINAL POINT ABOUT THIS.
7 THAT IF, AS WE START TO ANALYZE OUR COMMITMENTS AND
8 EXPECTED FUTURE COMMITMENTS ABOUT NEURODEGENERATIVE
9 DISORDERS OR NEURO-INJURY DISORDERS, FOR EXAMPLE, WE
10 MIGHT FIND THAT IN SOME SET OF CASES WE DO NEED TO
11 DELVE MORE DEEPLY INTO AN INDIVIDUAL DISEASE. AND,
12 IN FACT, OUR SPEAKERS IN NEUROPSYCHIATRIC DID, FOR
13 THE MOST PART, TALK ABOUT INDIVIDUAL DISEASES THEY
14 WERE WORKING ON, WHICH ILLUSTRATED WHAT WAS POSSIBLE
15 IN THE NEUROPSYCHIATRIC AREA IN GENERAL. AND I'D
16 ARGUE THAT SOMETHING SIMILAR IS LIKELY TO PERTAIN AS
17 WE ANALYZE AND REVIEW OUR COMMITMENTS IN
18 NEURODEGENERATIVE AND NEURO-INJURY. SO THAT'S MY
19 TAKE.

20 STEVE.

21 DR. CLARK-HARVEY: THANKS. BEFORE YOU
22 MOVE ON, FIRST OF ALL, THANK YOU FOR THE
23 EXPLANATION. AND IF THIS IS JUST FOR TRACKING
24 PURPOSES AND DATA AND OUTCOMES, THEN I THINK THAT
25 MAKES SENSE. THANKS.

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1 DR. LEVITT: I WOULD ADD, SINCE I SENT THE
2 EMAIL, IT'S REALLY A STRUCTURAL, ORGANIZATIONAL WAY
3 OF THINKING ABOUT IT BECAUSE I THINK IT'S VERY
4 DIFFICULT, OR AT LEAST I FIND IT VERY DIFFICULT TO
5 WHAT WOULD AMOUNT TO HAVING A TASK SWITCH. LIKE IF
6 WE STARTED WITH SCHIZOPHRENIA AND THEN WE WENT TO
7 EPILEPSY AND THEN WE WENT TO HUNTINGTON'S, THE
8 COMMUNITIES THAT ARE DOING IMPORTANT RESEARCH IN
9 THESE AREAS ARE DIFFERENT. THEY SHARE A LOT OF
10 OVERLAP IN APPROACHES.

11 SO IT'S AN ORGANIZATIONAL WAY OF THINKING
12 SO THAT -- AND IT ALSO PROVIDES, I THINK, MEMBERS OF
13 THE NEURO TASK FORCE TO THEN MAKE RECOMMENDATIONS
14 ABOUT AREAS IN WHICH THEY FEEL THERE ARE OR THEY
15 KNOW EXPERTS WHO WOULD BENEFIT -- WHERE WE WOULD
16 BENEFIT FROM THEM PRESENTING. AND IF YOU GROUP IN
17 THIS WAY, YOU CAN HAVE SEVERAL IN A ROW THAT ARE
18 GOING TO TOUCH UPON SORT OF FUNDAMENTAL MECHANISMS
19 OF DEGENERATIVE PROCESSES OR INJURY-INDUCED
20 PROCESSES.

21 SO THAT WAS THE RATIONALE BEHIND IT. I
22 WASN'T THINKING ANYTHING ABOUT HOW TO ORGANIZE OR
23 EVEN THINK ABOUT HOW TO ORGANIZE FUNDING. THAT'S A
24 DIFFERENT CONVERSATION. SO IT'S REALLY VERY
25 ORGANIZATIONAL AND RESTRICTS HAVING TO TASK SWITCH

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1 OVER AND OVER AGAIN.

2 CHAIRMAN GOLDSTEIN: THANK YOU, PAT.
3 STEVE.

4 MR. JUELSGAARD: SO I HAVE TWO
5 OBSERVATIONS. THE FIRST IS THE REASON THAT WE
6 AGREED TO AN AREA LIKE NEUROPSYCHIATRY IS THAT, AS
7 WAS DEMONSTRATED IN ALL THE PRESENTATIONS THAT WERE
8 MADE LEADING UP TO TODAY'S DECISION, WE HAD
9 ABSOLUTELY NO FUNDING WITH REGARD TO THIS AREA IN
10 GENERAL, PUTTING ASIDE ANY OF THE INDIVIDUAL
11 CONDITIONS. WE TRIED TO UNDERSTAND WHY THAT WAS
12 TRUE, AND THEN WE TRIED TO COME UP WITH A SOLUTION
13 TO ALLEVIATE THAT ISSUE OF FAILURE TO BE ABLE TO
14 FUND THINGS. AND SO HOPEFULLY WE FOUND THAT.

15 SO I THINK THAT'S FINE. I THINK WE DID
16 WHAT WE OUGHT TO HAVE DONE TO GET THIS AREA UP AND
17 STARTED. WE'LL SEE HOW WELL IT WORKS OUT.

18 THE OTHER TWO AREAS NOW ARE LISTS OF
19 SPECIFIC DISEASES, MANY OF WHICH WE ALREADY HAVE
20 FUNDING AVAILABLE FOR. WE HAVE PROVIDED FUNDING FOR
21 INDIVIDUAL CONDITIONS. SO THEY'RE QUANTUM DIFFERENT
22 THAN THE NEUROPSYCHIATRIC AREA IN THE SENSE THAT
23 THEY'RE IDENTIFIED AREAS FOR FUNDING. BUT I THINK
24 ALL OF THIS BEGS A PREDICATE QUESTION. AND THAT
25 IS -- AND THIS IS WHAT I THINK THE PREDICATE

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1 QUESTION IS. WE HAVE TWO DIRECTIONS WE CAN GO. ONE
2 IS THE ONE YOU REFERRED TO OBLIQUELY, LARRY, EARLIER
3 ON, WHICH IS THAT WE ALREADY HAVE A FAIR AMOUNT OF
4 FUNDING IN THE NEURO AREA AND WE ARE ON A PATH OR A
5 PACE TO POTENTIALLY USE THE ONE AND A HALF BILLION
6 OUT OF THE TOTAL FIVE, EITHER FIVE OR 5.5 BILLION
7 TOTAL FUNDING. SO THAT PATH BASICALLY SAYS WE ARE
8 DONE PICKING A PARTICULAR AREA OR A PARTICULAR NEURO
9 DISEASE OR CONDITION. WE'RE GOING TO JUST -- WE'RE
10 GOING TO ACCEPT ALL APPLICATIONS AS WE ALWAYS HAVE
11 THAT HAVE TO DO WITH NEUROLOGICAL ISSUES, AND WE ARE
12 GOING TO LET THE BEST ONES THAT MEET SCIENTIFIC
13 MUSTER, WE'RE GOING TO LET THOSE PROCEED AND NOT
14 OTHERS THAT DON'T MEET THE REQUISITE SCIENTIFIC
15 APPROACH OR SCIENTIFIC MERIT. THAT'S WHAT I'M
16 LOOKING FOR. THAT'S ONE APPROACH. THAT'S ONE WE
17 HAVE BEEN USING HISTORICALLY. AND IN THEORY WE WILL
18 USE UP THE REST OF THE 1.4 BILLION OR SO OF OUR
19 FUNDS DOING THAT.

20 THE OTHER IS THE ONE THAT WE ARE KIND OF
21 EMBARKED ON RIGHT NOW WHICH IS DO WE ACTUALLY WANT
22 TO PICK AND CHOOSE. DO WE WANT TO PICK AND CHOOSE
23 DISEASE CONDITIONS BASED ON HOW THEY OCCURRED,
24 NEURODEGENERATION VERSUS INJURY, FOR EXAMPLE? AND
25 EVEN WITHIN ONE OF THOSE, DO WE WANT TO PICK AND

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1 CHOOSE? FOR EXAMPLE, DO WE WANT TO PICK AND CHOOSE
2 STROKE NEXT BECAUSE IT'S A MAJOR ISSUE FOR AN AGING
3 POPULATION IF YOU USE THE DALY, WHICH, OF COURSE, IS
4 IN AND OF ITSELF CONTROVERSIAL?

5 SO I THINK WE OUGHT TO HAVE A DISCUSSION
6 ABOUT WHETHER WE WANT TO GO ONE WAY OR THE OTHER
7 BEFORE WE GET INTO IF WE'RE GOING TO GO THE WAY OF
8 REALLY PICKING AND CHOOSING ONE, NEURODEGENERATION
9 VERSUS NEURO-INJURY OR SOME OTHER DIVISION OR EVEN
10 INTO INDIVIDUAL DISEASES.

11 LET'S DECIDE THAT'S WHAT WE WANT TO DO AS
12 OPPOSED TO LET'S JUST DO IT THE WAY WE'VE ALWAYS
13 DONE IT AND LET THE BEST APPLICATIONS PREVAIL,
14 WHATEVER NEUROLOGICAL AREA THEY'RE IN. END OF --
15 THAT'S IT.

16 CHAIRMAN GOLDSTEIN: GOOD. THANK YOU.
17 GOOD THOUGHTS. I THINK WE'LL COME BACK TO THIS WHEN
18 WE GO TO THE NEXT PART THAT I WAS HOPING WE WOULD
19 TAKE ON, STEVE. SO STAY TUNED.

20 MR. JUELSGAARD: SURE.

21 CHAIRMAN GOLDSTEIN: MARIA B.

22 VICE CHAIR BONNEVILLE: I ALSO WONDER WHAT
23 THE -- WHAT OUTCOME WE WANT. SO IT'S DIFFICULT
24 ENOUGH TO SORT OF NARROW DOWN HOW WE ARE -- HOW
25 WE'RE GOING TO APPROACH IT AND ALSO WHAT OUTCOME WE

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1 WANT FROM THIS. AND I THINK FRED ACTUALLY MENTIONED
2 THIS AT ONE OF THE FIRST MEETINGS. 1.5 BILLION
3 SOUNDS LIKE A TON OF MONEY. BUT IF WHAT YOU'RE
4 TRYING TO DO IS CURE OR FIND A CURE FOR A DISEASE,
5 THAT'S NOT A LOT OF MONEY. SO I GUESS I WOULD LOVE
6 TO ESTABLISH WHAT OUR OUTCOMES, WHAT WE HOPE TO GET
7 OUT OF THE FOCUSED AREAS.

8 CHAIRMAN GOLDSTEIN: ALL RIGHT. FRED.

9 DR. FISHER: IT TAKES ME LONGER THAN I'D
10 LIKE TO DRIVE THIS IPAD. WOULD IT BE TOO MUCH TO
11 REFRESH OUR RECOLLECTION ABOUT THE CHARGE OF THIS
12 COMMITTEE? BECAUSE WHAT I HEARD TODAY IS ONE OF OUR
13 CHARGES, I THINK, IS WE WILL MEET OR EXCEED THE
14 FUNDING REQUIREMENT IN NEURO. IT'S HELPFUL TO LOOK
15 AT WHAT THE OTHER CHARGE OF THIS COMMITTEE IS SO
16 THAT WE CAN COMPARE WHAT IT IS WE ARE TRYING TO DO
17 WITH WHAT WE'VE ACTUALLY BEEN CHARGED TO DO.
18 SOMEBODY IS BRINGING IT UP SOMEWHERE. THAT'S
19 AWESOME. THANK YOU. SOMEONE ELSE WILL HAVE TO READ
20 IT BECAUSE IT'S WAY TOO SMALL FOR ME.

21 CHAIRMAN GOLDSTEIN: OKAY. SO WHY DON'T I
22 GO AHEAD AND TRY TO READ THIS. IT'S ALSO A LITTLE
23 SMALL FOR ME. THE GOAL OF THE CIRM TASK FORCE ON
24 NEUROSCIENCE AND MEDICINE IS TO GENERATE A GENERAL
25 PLAN FOR THE 1.5 BILLION SET-ASIDE FOR NEUROSCIENCE

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1 AND RELATED MEDICINE AS SPECIFIED IN PROPOSITION 14
2 IN ADDITION TO GENERATING A GENERAL PLAN FOR
3 NEUROSCIENCE AND RELATED MEDICINE.

4 THE TASK FORCE AIMS TO IDENTIFY UNUSUAL
5 OPPORTUNITIES FOR HIGH IMPACT IN THESE AREAS FOR
6 ENHANCED INVESTMENT. THE TASK FORCE WILL WORK WITH
7 THE COMMUNITY IN CALIFORNIA AND BEYOND TO IDENTIFY
8 POTENTIALLY HIGH IMPACT OPPORTUNITIES IN BASIC
9 NEUROSCIENCE, NEURODEGENERATIVE DISEASE,
10 NEUROPSYCHIATRIC DISEASE, NEURAL DEVELOPMENT, AND
11 NORMAL BRAIN AGING.

12 THE GOAL OF THE TASK FORCE IS TO PROVIDE
13 FINAL RECOMMENDATIONS TO CIRM AND THE ICOC WITHIN
14 SIX MONTHS OF INCEPTION. I THINK WE'VE MISSED THAT
15 GOAL, BUT WE ARE MOVING ALONG.

16 SO THAT'S THE ORIGINAL CHARGE. I'LL POINT
17 OUT THAT IT COVERS WHAT WE'VE DONE WITH
18 NEUROPSYCHIATRIC AS IT WAS AN UNUSUAL OPPORTUNITY
19 THAT WAS IDENTIFIED THAT WE SHOULD PUT SOME
20 ADDITIONAL INVESTMENT INTO BECAUSE WE FELT WE WERE
21 UNDERINVESTED.

22 MOVING FORWARD, WE CAN HAVE A LOOK AT THE
23 DIFFERENT GENERAL AREAS, IT SEEMS TO ME, AND ASK ARE
24 THERE UNUSUAL HIGH IMPACT APPROACHES OR AREAS WITHIN
25 NEURODEGENERATIVE OR NEURO-INJURY OR WHAT HAVE YOU

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1 TO SEE IF THERE ARE POTENTIALLY HIGH IMPACT
2 OPPORTUNITIES THAT WE'VE BEEN MISSING THAT MIGHT
3 PROFIT FROM A DIFFERENT MECHANISM OF FUNDING THE WAY
4 ROSA AND HER TEAM HAVE DEVELOPED, REMIND-L AND X, OR
5 WHETHER SOMETHING ELSE MIGHT BE APPROPRIATE.

6 SIMILARLY, AS WE'LL SEE IN A COUPLE SLIDES
7 MOVING FORWARD, SOME OF THE QUESTIONS I THINK WE DO
8 NEED TO THINK ABOUT IS WHAT FRACTION OF THE 1.5
9 BILLION DO WE WANT TO SPECIFICALLY PROGRAM AS
10 OPPOSED TO WHAT COMES IN OVER THE TRANSOM FOR THE
11 GRANTS WORKING GROUP TO EVALUATE FOR MERIT AND
12 TECHNICAL SOPHISTICATION AND FEASIBILITY.

13 DR. FISHER: SO THE WAY MY TIRED BRAIN
14 WORKS, AND I APOLOGIZE TO ALL OF YOU FOR HAVING TO
15 SUFFER THROUGH IT, I'M TRYING TO -- AND IT'S REALLY
16 BACK TO MARIA'S QUESTION. I'M TRYING TO TEASE OUT
17 OF THAT CHARGE WHAT THE ACTUAL DELIVERABLES ARE
18 BECAUSE I HEARD GENERAL PLAN CONNECTED TO TWO
19 DIFFERENT SORTS OF THINGS. ONE, A GENERAL PLAN FOR
20 NEURO INVESTMENT, WHICH IS LIKE THE BIG PICTURE,
21 MACRO HOW CIRM IS INVESTING IN NEURO. AND WE HAVE
22 TO COME UP WITH A GENERAL PLAN FOR CIRM'S NEURO
23 INVESTMENT. AND THEN THERE WAS ANOTHER GENERAL PLAN
24 THAT WASN'T THAT. I CAN'T REMEMBER WHAT IT IS AND
25 WE'VE MOVED OFF OF IT, BUT SOMEONE HERE MUST KNOW

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1 IT.

2 SO IT WOULD BE HELPFUL TO REALLY BREAK
3 DOWN THESE DELIVERABLES, TEASE THEM OUT OF A LOT OF
4 WORDS THAT ARE THERE TO UNDERSTAND EXACTLY WHAT THE
5 DELIVERABLE IS, HOW MANY DELIVERABLES WE ACTUALLY
6 HAVE BECAUSE PART OF WHAT THAT CHARGE SAYS TO ME IS
7 OUR RESPONSIBILITY IS NOT JUST THE 1.5 BILLION, THAT
8 WE HAVE A RESPONSIBILITY FOR A GENERAL PLAN FOR
9 CIRM'S INVESTMENT IN NEURO, WHICH COULD GO WELL
10 BEYOND THAT.

11 SO I THINK -- I DON'T KNOW WHAT'S ON YOUR
12 NEXT SLIDE, BUT I THINK AT SOME POINT -- AND IF
13 SOMEONE COULD SEND ME THE LINK TO THAT PAGE OR JUST
14 SEND ME THE PAGE, I WOULD TEASE OUT THOSE WORDS INTO
15 SPECIFIC DELIVERABLES SO THAT WHAT WE CAN DO AS WE
16 CONTEMPLATE GOING FORWARD IS WE CAN EVALUATE WHAT WE
17 ARE DOING AND WHICH OF THE DELIVERABLES IT WILL HELP
18 US MEET. THANK YOU.

19 CHAIRMAN GOLDSTEIN: THANK YOU, FRED.

20 SCOTT, CAN YOU GO TO THE PREVIOUS SLIDE?
21 I'M HOPING THAT THIS IS GOING TO HELP THE
22 CONVERSATION.

23 MR. TOCHER: DOES THAT HELP? CAN YOU SEE
24 THAT?

25 CHAIRMAN GOLDSTEIN: IT HAS SEEMED TO ME

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1 IN THINKING ABOUT THIS -- THANK YOU FOR ENLARGING
2 THAT -- THAT THE SORTS OF QUESTIONS WE'RE GOING TO
3 NEED TO DEAL WITH ARE HERE. THIS IS NOT ALL OF THE
4 QUESTIONS WE MIGHT WANT TO ADDRESS, BUT IT STRIKES
5 ME THESE ARE SOME OF THE IMPORTANT ONES.

6 SO, FOR EXAMPLE, WHAT PERCENTAGE OF THE
7 ONE AND A HALF BILLION THAT'S SET ASIDE DOES THIS
8 TASK FORCE THINK WE SHOULD BE MAKING RECOMMENDATIONS
9 FOR? AND A COROLLARY OF THAT IS QUESTION TWO. WHAT
10 PERCENTAGE OF ONE AND A HALF BILLION PLUS SHOULD BE
11 ALLOCATED BASED ON QUALITY AND NOVELTY OF IDEAS AND
12 APPROACH ASSESSED BY THE GRANTS WORKING GROUP,
13 TAKING WHAT COMES IN OVER THE TRANSOM AS OPPOSED TO
14 CENTRALIZED PLANNING? AND I'LL POINT OUT THAT WHAT
15 WE HAVE DONE THUS FAR WAS TO IDENTIFY
16 NEUROPSYCHIATRIC AS AN AREA THAT WAS BEING MISSED
17 FOR ANY OF A VARIETY OF REASONS. WE PROBABLY SHOULD
18 NOT CONTINUE THAT PARTICULAR DISCUSSION AT THE
19 MOMENT. BUT WE NEED TO THINK ABOUT WHAT FRACTION DO
20 WE TACKLE AS AN UNUSUAL OPPORTUNITY OR A MISSED
21 AREA.

22 AND THAT'S WHAT'S THERE IN QUESTION FOUR.
23 ARE THERE ANY IMPORTANT AREAS THAT WE ARE MISSING IN
24 NEURODEGENERATIVE, IN NEURO-INJURY, OR PERHAPS
25 THERE'S ANOTHER CATEGORY THAT JUST DIDN'T OCCUR TO

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1 ME THAT WE NEED TO THINK ABOUT AND ASK WHETHER WE'VE
2 GOT AN APPROPRIATE INVESTMENT.

3 AND I'LL JUST ADD A POINT 3 HERE BECAUSE
4 FRED POINTED OUT A FEW MEETINGS AGO THAT DALY
5 ESTIMATES IMPACT IN A PARTICULAR WAY. SOME PEOPLE
6 FAVOR IT, SOME DON'T. THERE ARE OTHER POTENTIAL
7 MEASURES OF IMPACT THAT COULD BE USED THAT MIGHT
8 INFORM OUR THINKING.

9 PAT AND I HAVE BEEN TALKING ABOUT WHO WE
10 MIGHT IDENTIFY THAT'S A HEALTHCARE ECONOMIST WHO
11 COULD TELL US A LITTLE MORE IN A PRESENTATION TO US.
12 WHAT OTHER MEASURES OF DISEASE IMPACT MIGHT INFORM
13 OUR THINKING IN IDENTIFYING EITHER TARGETS OF
14 OPPORTUNITY OR UNDERFUNDED AREAS THAT WE ARE JUST
15 NOT MEETING THE BILL ON?

16 SO MY HOPE IS THESE QUESTIONS HELP US IN
17 THINKING ABOUT WHERE WE NEED TO GO MOVING FORWARD.

18 DR. FISHER: JUST FROM A LINGUISTIC POINT
19 OF VIEW, BECAUSE WORDS MATTER, IS THE 1.5 BILLION
20 TRULY A SET-ASIDE OR IS IT A BENCHMARK THAT WE ARE
21 EXPECTED TO MEET OR EXCEED IN TERMS OF CIRM'S TOTAL
22 FUNDING STRATEGY? I THINK HOW WE REFER TO IT, HOW
23 WE SORT OF THINK ABOUT IT, OBVIOUSLY A LOT OF WHAT
24 CIRM DOES FALLS IN THE NEURO SPACE. AND I'D
25 UNDERSTAND IF IT'S REALLY A SET-ASIDE OR WE HAVE

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1 DELIVERABLES IN TERMS OF PLANS FOR HOW CIRM INVESTS
2 IN WAYS THAT MEET OR EXCEED THE 1.5 BILLION WHICH WE
3 ALREADY SAID WE WILL.

4 CHAIRMAN GOLDSTEIN: STEVE, DO YOU HAVE AN
5 ANSWER TO THAT QUESTION FOR US? STEVE? WHILE STEVE
6 FINDS HIS UNMUTE BUTTON, I THINK IT'S THE LATTER,
7 FRED, WAS MY READING OF THE PROP. IT WASN'T SO MUCH
8 AN EXACT SET-ASIDE, A TRANCHE OF MONEY THAT WOULDN'T
9 BE TOUCHED TEMPORARILY OR JUST HAD TO BE SPENT ON
10 ITS OWN. IT REALLY IS A GOAL -- A STATUTORY GOAL.
11 WE HAVE TO DO IT, BUT IT'S NOT NECESSARILY HANDLED
12 AS A SECOND BANK ACCOUNT.

13 STEVE, YOU'RE ON.

14 MR. JUELSGAARD: I'LL BEG TO DIFFER JUST A
15 BIT ON THAT, LARRY.

16 CHAIRMAN GOLDSTEIN: THAT'S FINE.

17 MR. JUELSGAARD: FROM THE LANGUAGE OF PROP
18 14, THE INSTITUTE SHALL ALLOCATE AT LEAST \$1.5
19 BILLION, THE KEY WORD "ALLOCATE," AT LEAST \$1.5
20 BILLION OF THE PROCEEDS OF THE BONDS TO MAKE GRANTS
21 FOR RESEARCH THERAPY DEVELOPMENT AND THERAPY
22 DELIVERY INVOLVING DISEASES OF THE BRAIN AND CENTRAL
23 NERVOUS SYSTEM. AND THEN IT GOES ON TO LIST A
24 NUMBER OF CONDITIONS. SO THE WORD IS ALLOCATE. IT
25 HAD ALLOCATE AT LEAST 1 BILLION 500 MILLION.

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1 SO THAT TELLS ME THAT IT'S SET ASIDE FOR
2 THAT PARTICULAR USE. THEN THAT \$1.5 BILLION IS NOT
3 TO BE USED FOR ANYTHING ELSE OTHER THAN -- AND I'LL
4 ASK SCOTT, SINCE HE'S ADMINISTRATIVE OFFICER HERE,
5 WHAT HIS VIEWS ARE, BUT THAT'S MY READING OF THE
6 LANGUAGE.

7 MR. TOCHER: YEAH. I AGREE, STEVE. IT
8 TAKES ME A FEW MINUTES TO FIND IT IN THE NEW
9 PROPOSITION, BUT I THINK THAT'S RIGHT.

10 MR. JUELSGAARD: YEAH. IT'S ON PAGE -- I
11 DON'T KNOW. IT'S ON PAGE 103.

12 MR. TOCHER: HEALTH AND SAFETY CODE
13 125290.70.5(C) IT LOOKS LIKE.

14 CHAIRMAN GOLDSTEIN: SO, STEVE, DO YOU
15 THINK THAT THE WAY I LOOK AT IT AND THE WAY YOU LOOK
16 AT IT NECESSARILY TELLS US TO PROCEED IN A DIFFERENT
17 MANNER?

18 MR. JUELSGAARD: NO, I DON'T. I'M JUST
19 SAYING THIS WAS THE ISSUE THAT I RAISED SOME TIME
20 AGO. SO IF WE ARE ON A COURSE THAT WE SPEND \$1.5
21 BILLION ON DISEASES OF THE CENTRAL NERVOUS SYSTEM
22 AND BRAIN OR CONDITIONS AT THE SAME PACE THE REST OF
23 THE ORGANIZATION IS USING MONEY FOR OTHER AREAS
24 BESIDES THE NERVOUS SYSTEM, THEN WE ARE ALL FINE.
25 BUT IF -- LET'S IMAGINE THAT WE ARE SPENDING MONEY

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1 AT A FASTER RATE FOR EVERYTHING ELSE BUT THE NERVOUS
2 SYSTEM AND AT THE END OF THE DAY WE'VE SPENT THE \$4
3 BILLION OF OTHER MONEY FOR ALL THE OTHER THINGS THAT
4 ARE GOING ON, GENE THERAPY ISSUES, ET CETERA, ET
5 CETERA, AND WE STILL HAVE \$500 MILLION THAT HASN'T
6 BEEN SPENT ON CNS DISEASES. THEN WE'RE GOING TO
7 HAVE, ABSENT A REUPPING OF FUNDING, WHICH I ALWAYS
8 ASSUME IT ISN'T GOING TO HAPPEN AND THEN BE
9 PLEASANTLY SURPRISED WHEN IT DOES, WE'RE GOING TO
10 WIND UP HAVING A CIRM THAT'S DEDICATED TO THE CNS
11 AREA AS FAR AS FINDING ADDITIONAL FUNDING GOES.

12 SO THAT'S KIND OF HOW I'VE LOOKED AT IT.
13 BUT IF WE ARE ON A PACE TO SPEND AS MUCH MONEY ON
14 THE CNS AS WE ARE ON EVERYTHING ELSE, THEN THAT
15 SHOULDN'T BE AN ISSUE. IT'S WE'RE GOING TO HAVE TO
16 SEE AS TIME GOES ON HOW THAT WORKS.

17 CHAIRMAN GOLDSTEIN: MY RECOLLECTION IS
18 THAT WE ARE SPOT ON, STEVE, BUT I DID NOT BRING THE
19 NUMBERS TODAY OR I DON'T HAVE THEM PREPARED. I
20 PROMISE TO DO THAT AT THE NEXT TASK FORCE MEETING.

21 MR. JUELGAARD: NO. I THINK WE
22 PRETTY -- WE ARE PRETTY CLOSE AS OF TODAY. IT'S THE
23 QUESTION OF WHAT WILL HAPPEN DOWN THE ROAD.
24 ANYWAY...

25 CHAIRMAN GOLDSTEIN: WHAT THE PLANNING

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1 DISCUSSION MAY NEED TO REVOLVE AROUND IN PART IS
2 WHAT GUIDEPOSTS DO WE NEED TO BE SURE TO INSTALL FOR
3 THE NEXT SEVERAL YEARS TO MAKE SURE WE STAY ON TRACK
4 AND TO WHAT EXTENT DO WE WANT TO DO THAT VIA THE
5 CENTRALIZED PLANNING METHOD VERSUS TAKING WHAT COMES
6 IN OVER THE TRANSOM AS OPPOSED TO -- OR SOME
7 COMBINATION OF THE TWO. THESE ARE QUESTIONS ALL
8 FUNDING ORGANIZATIONS FACE IN MY EXPERIENCE. HOW
9 MUCH CENTRALIZED PLANNING DO YOU DO, SUCH AS WHAT WE
10 DID IN NEUROPSYCHIATRIC WHERE WE ARE HOPING TO GET A
11 LITTLE KICK-START OF THAT FIELD VERSUS WHAT WE HAVE
12 BEEN DOING, WHICH IS MORE OR LESS KEEPING US ON
13 TRACK IN A RELATIVELY PASSIVE WAY. TAKING THE BEST
14 THAT COMES IN FOR THE DIFFERENT SORTS OF RFA'S WE
15 HAVE IN PLACE AND TRUSTING THAT WE WILL CONTINUE AT
16 THE SAME RATE, BUT WE NEED TO KEEP AN EYE ON IT.

17 MR. JUELSGAARD: JUST AS AN ASIDE, SCOTT,
18 HAVE YOU HAD A CHANCE TO FIND THAT PROVISION AND
19 LOOK AT IT, AND WHAT'S YOUR ASSESSMENT OF THE
20 LANGUAGE?

21 MR. TOCHER: YES, I HAVE. AND I AGREE
22 WITH YOU. IT'S A STRICT ALLOCATION. SO WHETHER YOU
23 CALL IT A SET-ASIDE OR BY ANOTHER NAME, IT'S SORT OF
24 WALLED OFF FROM ANY PURPOSE OTHER THAN THE PURPOSES
25 THAT ARE DELINEATED IN THE STATUTE.

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1 MR. JUELSGAARD: THANK YOU.

2 CHAIRMAN GOLDSTEIN: OTHER THOUGHTS?

3 DR. FISHER: I GUESS WHAT DOES IT MEAN FOR
4 US IF WE THINK WE ARE ON PACE TO DO 1.5 BILLION IN
5 NEURO, WHAT DOES IT MEAN FOR THE PURPOSE OF THIS?
6 HOW DOES THAT INFORM WHAT THIS GROUP DOES NEXT
7 BECAUSE WE'VE ALREADY ACCOMPLISHED OR BELIEVE WE
8 HAVE ACCOMPLISHED THAT GOAL, AND WE COULD PROBABLY,
9 IN TERMS OF A GENERAL PLAN, MAP OUT SOME ESTIMATES
10 ABOUT WHAT WE THINK WE'RE GOING TO SPEND IN THE
11 NEURO AREA AND EITHER TRY TO DO THAT AS A WHOLE OR
12 MORE GRANULARLY IN WAYS THAT INCLUDE CALLING OUT
13 NEUROPSYCH.

14 BUT IF WE THINK WE'LL MEET THE SPENDING
15 OBJECTIVES OF THE PROPOSITION, THERE ARE SOME OTHER
16 DELIVERABLES, IT SEEMS TO ME, THAT WE OUGHT TO BE
17 FOCUSED ON. AND THAT IN THE PASSIVE WAY YOU
18 DESCRIBED, I THINK, WE'LL END UP MEETING THE
19 FINANCIAL GOALS, BUT SORT OF THE OTHER GOALS IN OUR
20 CHARGE THAT WE HAVE TO BE FOCUSED ON. IS THAT AN
21 UNFAIR INTERPRETATION?

22 CHAIRMAN GOLDSTEIN: I THINK THAT'S
23 ENTIRELY REASONABLE, FRED. IT SEEMS LIKE WHAT WE
24 MIGHT DO, AS OPPOSED TO WORRYING ABOUT THE RATE OF
25 SPENDING, IS THINK ABOUT DO WE HAVE THE BALANCE

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1 RIGHT AMONG SOME OF THESE BROAD AREAS. AND AS IN
2 THE CASE OF NEUROPSYCHIATRIC, IS THERE SOMEPLACE
3 THAT WE ARE MISSING THE BOAT WHERE THERE'S BEEN A
4 TECHNICAL BREAKTHROUGH, TECHNOLOGICAL BREAKTHROUGH,
5 A BETTER UNDERSTANDING OF THE GENETICS OF SOME OF
6 THE DISORDERS, WHICH IS WHAT'S HAPPENED IN
7 NEUROPSYCHIATRIC, OR OTHER THINGS HAPPENING IN THE
8 FIELDS THAT LEAD US TO EITHER TRY TO IDENTIFY A
9 SPECIFIC NEED THAT WE FIND OR THAT WE THINK THE
10 BALANCE INTERNALLY IN NEURO IS NOT QUITE WHERE WE
11 WANT IT TO BE AND THAT WE WANT TO ADJUST IT.

12 SIMILARLY, I KNOW I KEEP HARPING ON THIS,
13 BUT WE DO NEED TO THINK ABOUT HOW MUCH OF THAT ONE
14 AND A HALF BILLION PLUS DO WE WANT TO PROGRAM. AND
15 I'LL JUST GIVE YOU MY BIAS. I THINK THAT THE
16 TRADITIONAL METHOD OF AWARDING GRANTS IS DOING A
17 PRETTY GOOD JOB AND THAT WHAT WE OUGHT TO BE DOING
18 IS TRYING TO IDENTIFY AREAS THAT ARE
19 UNDERREPRESENTED OR WHERE WE THINK THERE'S A TARGET
20 OF OPPORTUNITY THAT IS NEW OR THAT FOR SOME REASON
21 IS GETTING MISSED IN THE TRADITIONAL GRANTMAKING
22 OPERATION. BUT THAT'S MY OWN IDIOSYNCRATIC VIEW OF
23 WHAT WE SHOULD BE DOING.

24 OTHER THOUGHTS ON THIS? OKAY. WE HAVE
25 FIVE MINUTES LEFT, AND I'M GOING TO SUGGEST THAT WE

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1 PROCEED AS FOLLOWS, WHICH IS, FIRST, IF WE'RE GOING
2 TO TRY TO EVALUATE WHETHER THE BALANCE OF OUR
3 FUNDING IS REASONABLE AND THAT WE ARE ADDRESSING
4 NEEDS IN DIFFERENT PARTS OF THESE SUBAREAS
5 APPROPRIATELY, THAT WE'RE GOING TO HAVE TO LEARN AND
6 THINK A LITTLE BIT ABOUT WHAT ARE DIFFERENT WAYS OF
7 LOOKING AT THE IMPACT OF DISEASE AND THE TECHNICAL
8 METHODOLOGY THAT'S AVAILABLE TO TRY TO MEET THEM.
9 AND SO SHOULD WE BE DOING SOME ADJUSTING RELATIVE TO
10 WHERE OUR CURRENT ALLOCATIONS ARE COMMITTED? AND I
11 THINK THAT WILL HELP US DEAL WITH WHAT I THINK WAS
12 AN IMPORTANT QUESTION THAT FRED IDENTIFIED, WHICH IS
13 THAT WHEN YOU LOOK AT THE IMPACT OF ALS, DALY
14 DOESN'T REALLY CAPTURE ITS GENERAL IMPACT. AND THAT
15 NEEDS TO BE PART OF HOW WE THINK ABOUT ALLOCATING IN
16 SOME OF THESE AREAS.

17 SO TO ME WE NEED TO LEARN A LITTLE BIT
18 MORE TO BE ABLE TO REALLY TACKLE THESE QUESTIONS
19 SUBSTANTIVELY AND TO MAKE SOME DECISIONS AS TO WHAT
20 WE RECOMMEND TO THE ICOC FOR ALLOCATION METHODS,
21 PREPROGRAMMING VERSUS IDENTIFICATION OF UNUSUAL
22 OPPORTUNITIES, AS TWO OF THE MAJOR APPROACHES.

23 THOUGHTS ABOUT THIS? QUESTIONS? SEEING
24 NOTHING FROM THE GROUP, THIS MIGHT BE A GOOD TIME TO
25 GO TO THE PHONE LINES. SCOTT.

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1 MR. TOCHER: SURE. IF THERE'S NO FURTHER
2 DISCUSSION, THEN I WILL ASK FOR PUBLIC COMMENT. AND
3 SO FOR THE INDIVIDUAL WHO SPOKE EARLIER, IF YOU
4 PRESS STAR NINE AGAIN, I BELIEVE.

5 MR. REDAELLI: CAN YOU HEAR ME?

6 CHAIRMAN GOLDSTEIN: YES. THANK YOU.

7 MR. REDAELLI: IS IT APPROPRIATE FOR ME TO
8 TALK ABOUT A COMPANY THAT IS WORKING IN A PHASE 3
9 PIVOTAL TRIAL FOR ISCHEMIC STROKE, A COMPANY CALLED
10 ATHERSYS? THE COMPANY THAT I SENT TWO COMMENTS TO
11 LANA MORALEZ SHE WAS GOING TO FORWARD TO YOUR GROUP.
12 I'D BE INTERESTED TO KNOW IF YOU'VE RECEIVED IT AND
13 IF YOU'VE HAD A CHANCE TO READ IT. BUT, AGAIN, I GO
14 BACK TO MY FIRST QUESTION. IS IT APPROPRIATE AT
15 THIS TIME TO TALK ABOUT THIS? I WOULD LIKE TO TALK
16 ABOUT IT, BUT I DON'T WANT TO STEP ON ANYBODY'S
17 TOES. SHALL I CONTINUE ON?

18 CHAIRMAN GOLDSTEIN: SIR, YOU WOULD BE
19 WELCOME TO USE THREE MINUTES TO ADDRESS AN AREA
20 OF --

21 MR. REDAELLI: YES. I'M READING FROM THE
22 FIRST COMMENT THAT HOPEFULLY YOU'VE ALL RECEIVED.
23 YESTERDAY I SENT A SECOND COMMENT. IT'S A PDF FILE,
24 AN OVERVIEW OF A PRESENTATION FROM ATHERSYS. IT
25 GOES INTO DETAIL WITH SOME OF THE NEURO DISEASES

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1 YOU'RE WORKING ON, TRAUMA, BUT I'M PRIMARILY
2 INTERESTED IN ISCHEMIC STROKE.

3 AGAIN, MY NAME IS JOHN REDAELLI. I LIVE
4 IN HUNTINGTON BEACH. I'M A SHAREHOLDER IN ATHERSYS.
5 I'M WRITING TO YOU OR SPEAKING TO YOU NOW IN SUPPORT
6 OF CONSIDERATION BY CIRM OR HELP IN FUNDING OF
7 ATHERSYS MASTERS-2 PIVOTAL PHASE 3 CLINICAL TRIAL
8 FOR ACUTE ISCHEMIC STROKE PATIENTS. FOR YOUR
9 INFORMATION, MASTERS-2 IS A RANDOMIZED,
10 DOUBLE-BLIND, PLACEBO-CONTROLLED CLINICAL TRIAL
11 DESIGNED TO ENROLL 300 PATIENTS IN THE UNITED
12 STATES, INCLUDING PALO ALTO AND SACRAMENTO,
13 CALIFORNIA. THE STUDY IS EVALUATING THE EFFICIENCY,
14 THE EFFICACY, EXCUSE ME, AND SAFETY OF MULTISTEM
15 ALLOGENEIC CELL THERAPY VIA I.V. INFUSION IN
16 PATIENTS WHO HAVE SUFFERED MODERATE, TO
17 MODERATE-SEVERE ISCHEMIC STROKE.

18 THE MASTERS-2 STUDY HAS RECEIVED SEVERAL
19 REGULATORY DESIGNATIONS AND REGULATORY AGREEMENTS
20 INCLUDING SPECIAL PROTOCOL ASSESSMENT OR SPA, FAST
21 TRACK DESIGNATION, REGENERATIVE MEDICINE ADVANCED
22 THERAPY OR RMAT. I THEN INVESTED IN ATHERSYS. ONE
23 GREAT THING ABOUT ATHERSYS, THEY HAVE A GREAT
24 RELATIONSHIP WITH THE FDA.

25 AS YOU WELL KNOW, STROKE IS A -- 17

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1 MILLION PEOPLE SUFFER A STROKE EVERY YEAR, AND IT'S
2 THE LEADING CAUSE OF LONG-TERM DISABILITY. ATHERSYS
3 IS DEVELOPING MULTISTEM CELL THERAPY FOR THE
4 TREATMENT OF STROKE, WHICH MAY BE DELIVERED UP TO 36
5 HOURS AFTER THE STROKE. THIS DRAMATICALLY OPENS UP
6 THE TIME WINDOW FOR ALLOWING 90 TO 95 PERCENT OF
7 STROKE PATIENTS TO BE ELIGIBLE TO RECEIVE THE
8 THERAPY.

9 I'M READING FROM DR. ROBERT MAYS,
10 EXECUTIVE VICE PRESIDENT OF ATHERSYS. MEANINGFUL,
11 LONG-TERM IMPROVEMENTS IN PATIENTS' RECOVERY ARE THE
12 CORNERSTONE OF OUR HYPOTHESIS ABOUT HOW MULTISTEM
13 CELLS MAY PROVIDE BENEFIT. IT IS WHAT WE HAVE
14 OBSERVED IN MULTIPLE PRECLINICAL ANIMAL MODELS OF
15 NEUROLOGICAL INJURY. AND IT IS WHY WE HAVE BUILT A
16 365-DAY ENDPOINTS INTO THE MASTERS-2. HOWEVER, WHEN
17 LIMITED TO A 90-DAY EVALUATION WINDOW, THE FULL
18 POTENTIAL OF MULTISTEM CELL THERAPY IS NOT LIKELY
19 REALIZED.

20 SO LISTENING TO THIS --

21 MR. TOCHER: EXCUSE ME. I'M SORRY. I
22 JUST WANT TO LET YOU KNOW YOUR TIME IS UP. IF YOU
23 COULD WRAP UP YOUR COMMENT.

24 MR. REDAELLI: ANYWAY, I HOPE YOU HAVE THE
25 TIME. WHAT GOOD IS SENDING COMMENTS IF THEY'RE NOT

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1 READ. AND I KNOW HOW BUSY WE ALL ARE. I JUST HOPE
2 THAT YOU HAVE A CHANCE TO REVIEW THE PUBLIC COMMENTS
3 THAT I SENT. AND THAT'S ALL I CAN ASK, AND I
4 APPRECIATE THIS OPPORTUNITY TO SPEAK WITH YOU.

5 CHAIRMAN GOLDSTEIN: THANK YOU, SIR. I'LL
6 JUST RESPOND BRIEFLY BY SAYING THAT WE HAVE CLINICAL
7 TRIAL GRANT OPPORTUNITIES AT CIRM. ATHERSYS SHOULD
8 APPLY FOR ONE OF THOSE GRANTS, AND IT WILL BE JUDGED
9 ON A COMPETITIVE BASIS WITH OTHER CLINICAL TRIAL
10 GRANTS, BUT IT MAY WELL BE SUCCESSFUL. SO THEY
11 SHOULD APPLY FOR A GRANT.

12 WITH THAT, WE ARE TWO MINUTES OVER TIME.
13 SO LET ME THANK YOU ALL FOR LIVELY AND INTERESTING
14 DISCUSSION. AND I WILL SEE YOU AT THE NEXT MEETING.

15 VICE CHAIR BONNEVILLE: THANK YOU,
16 EVERYONE.

17 (THE MEETING WAS THEN CONCLUDED.)
18
19
20
21
22
23
24
25

REPORTER'S CERTIFICATE

I, BETH C. DRAIN, A CERTIFIED SHORTHAND REPORTER IN AND FOR THE STATE OF CALIFORNIA, HEREBY CERTIFY THAT THE FOREGOING TRANSCRIPT OF THE VIRTUAL PROCEEDINGS BEFORE THE NEURO TASK FORCE ON NEUROSCIENCE AND MEDICINE OF THE INDEPENDENT CITIZEN'S OVERSIGHT COMMITTEE OF THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE IN THE MATTER OF ITS REGULAR MEETING HELD ON AUGUST 25, 2023, 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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