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. LEONDRA 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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MR. TOCHER: MARVIN SOUTHARD.

DR. SOUTHARD: HERE.

MR. TOCHER: KEITH YAMAMOTO.

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

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

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

MR. TOCHER: YES.

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

CHAIRMAN GOLDSTEIN: YES.

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

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PRESENTATION.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

NONPROFIT.

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

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

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

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

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

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

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

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

CHANGES THAT WE MADE IN TERMS OF PROJECT ELIGIBILITY.

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

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

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

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

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

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

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

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

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

SO QUESTIONS FOR ROSA. JUDY.

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

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

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

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

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

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

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THE INTENTION OF.

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

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

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

SO THANK YOU AGAIN, ROSA. GREAT

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PRESENTATION AND GREAT CONCEPT DOCUMENT.

DR. CANET-AVILES: THANK YOU, JUDY.

CHAIRMAN GOLDSTEIN: THANK YOU. PAT.

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

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

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

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

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

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

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

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

DR. CANET-AVILES: YES.

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

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

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

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

DR. LEVITT: YEAH. OKAY.

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

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

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

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

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

DR. LEVITT: THAT'S IT.

DR. CANET-AVILES: THANK YOU.

CHAIRMAN GOLDSTEIN: FRED.

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

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

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

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

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

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

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

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

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

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

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

THROUGH ONE OF CIRM'S EXISTING FUNDING PATHWAYS.

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

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

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

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

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

DR. LEVITT: WE HEARD THAT --

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

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

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

DR. FISHER: OKAY.

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

DR. FISHER: OKAY.

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

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

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

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

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

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

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

DR. FISHER: LIKE WHAT?

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

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

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

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

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

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

DR. FISHER: GREAT. OKAY.

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

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

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

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

DR. FISHER: OKAY. GO AHEAD.

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

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

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

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

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

CHAIRMAN GOLDSTEIN: THANK YOU. LEONDRA.

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

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

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

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

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

CHAIRMAN GOLDSTEIN: THANK YOU, LEONDRA.

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

ANY FURTHER QUESTIONS FOR ROSA? THEN CAN

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

DR. CLARK-HARVEY: SO MOVED.

DR. GASSON: SECOND.

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

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

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

DR. GASSON: NO.

CHAIRMAN GOLDSTEIN: FRED, YOU HAVE A QUESTION?

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

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

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

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

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

MS. MORALEZ: STAR NINE. NO PUBLIC COMMENT.

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

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

MR. TOCHER: AND YOU HAVE THREE MINUTES.

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

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

CHAIRMAN GOLDSTEIN: YES, WE CAN HEAR YOU NOW.

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

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

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

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MR. TOCHER: YES, WE WILL BE.

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

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

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

MR. TOCHER: YES. LEONDRA CLARK-HARVEY.

DR. CLARK-HARVEY: YES.

MR. TOCHER: MARIA BONNEVILLE.

VICE CHAIR BONNEVILLE: YES.

MR. TOCHER: MARK FISCHER-COLBRIE.

DR. FISCHER-COLBRIE: AYE.

MR. TOCHER: THANK YOU. FRED FISHER.

DR. FISHER: YES.

MR. TOCHER: JUDY GASSON.

DR. GASSON: YES.

MR. TOCHER: LARRY GOLDSTEIN.

CHAIRMAN GOLDSTEIN: YES.

MR. TOCHER: DAVID HIGGINS.

DR. HIGGINS: YES.

MR. TOCHER: VITO IMBASCIANI.

CHAIRMAN IMBASCIANI: YES.

MR. TOCHER: STEVE JUELSGAARD.

MR. JUELSGAARD: YES.

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MR. TOCHER: PAT LEVITT.

DR. LEVITT: YES.

MR. TOCHER: LAUREN MILLER-ROGEN.

MS. MILLER-ROGEN: YES.

MR. TOCHER: AND MARVIN SOUTHARD.

DR. SOUTHARD: YES.

MR. TOCHER: GREAT. THANK YOU VERY MUCH. AND THE MOTION CARRIES.

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

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

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

SCOTT, IS THAT NOT YOU?

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

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

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

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

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

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

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

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

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

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SUBCATEGORIES.

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

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

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

CHAIRMAN GOLDSTEIN: ON THIS ONE; IS THAT RIGHT?

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

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

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

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

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

STEVE.

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

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

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

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

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OVER AND OVER AGAIN.

CHAIRMAN GOLDSTEIN: THANK YOU, PAT. STEVE.

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

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

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

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

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

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

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

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

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

MR. JUELSGAARD: SURE.

CHAIRMAN GOLDSTEIN: MARIA B.

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

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

CHAIRMAN GOLDSTEIN: ALL RIGHT. FRED.

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

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

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

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

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

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

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

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

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

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

IT.

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

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

CHAIRMAN GOLDSTEIN: THANK YOU, FRED.

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

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

CHAIRMAN GOLDSTEIN: IT HAS SEEMED TO ME

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

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

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

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

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

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

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

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

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

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

STEVE, YOU'RE ON.

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

CHAIRMAN GOLDSTEIN: THAT'S FINE.

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

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

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

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

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

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

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

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

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

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

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

CHAIRMAN GOLDSTEIN: WHAT THE PLANNING

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

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

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

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MR. JUELSGAARD: THANK YOU.

CHAIRMAN GOLDSTEIN: OTHER THOUGHTS?

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

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

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

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

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

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

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

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

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

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

MR. REDAELLI: CAN YOU HEAR ME?

CHAIRMAN GOLDSTEIN: YES. THANK YOU.

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

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

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

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

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

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

AS YOU WELL KNOW, STROKE IS A -- 17

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

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

SO LISTENING TO THIS --

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

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

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

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

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

VICE CHAIR BONNEVILLE: THANK YOU, EVERYONE.

(THE MEETING WAS THEN CONCLUDED.)

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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 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.

BETH C. DRAIN, CA CSR 7152
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