BEFORE THE

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

REGULAR MEETING

LOCATION:	WESTIN SACRAMENTO, MONACO II 4800 RIVERSIDE BOULEVARD SACRAMENTO, CALIFORNIA 95822
DATE:	MARCH 27, 2025 9 A.M.
REPORTER:	BETH C. DRAIN, CA CSR CSR. NO. 7152
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I N D E X

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I N D E X (CONT'D.)

MARCH 27, 2025; 9 A.M.

CHAIRMAN IMBASCIANI: GOOD MORNING, EVERYONE. HOW'S THE SOUND CHECK? GOOD? THANK YOU. LIKE TO WELCOME EVERYONE, PUBLIC AND MEMBERS OF THE BOARD OF THE INDEPENDENT CITIZENS OVERSIGHT COMMITTEE FOR CIRM TO THIS MEETING HERE IN SACRAMENTO, THE CAPITAL OF THE STATE. AND WE'RE GOING TO START WITH THE PLEDGE OF ALLEGIANCE. I WOULD ASK THOSE WHO ARE ABLE TO STAND AND PLACE THEIR HAND OVER THEIR HEART FOR THE RECITATION. SCOTT, WOULD YOU LEAD US PLEASE.

MR. TOCHER: PLEASE STAND IF YOU ARE ABLE.

(THE PLEDGE OF ALLEGIANCE.)

CHAIRMAN IMBASCIANI: THANK YOU, EVERYONE. I'M GOING TO START WITH AN UPDATE --

MR. TOCHER: WE NEED TO TAKE ROLL.

CHAIRMAN IMBASCIANI: THE ROLL CALL. THANK YOU.

MR. TOCHER: EYAD ALMASRI.

DR. ALMASRI: PRESENT.

MR. TOCHER: KIM BARRETT.

DR. BARRETT: PRESENT.

MR. TOCHER: DAN BERNAL. GEORGE BLUMENTHAL.

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DR. BLUMENTHAL: HERE.
MR. TOCHER: MARIA BONNEVILLE.
VICE CHAIR BONNEVILLE: PRESENT.
MR. TOCHER: LINDA BOXER. JOHN CARETHERS.
DR. CARETHERS: PRESENT.
MR. TOCHER: MONICA CARSON. JUDY CHOU.
LEONDRA CLARK-HARVEY.
DR. CLARK-HARVEY: HERE.
MR. TOCHER: ANNE-MARIE DULIEGE.
DR. DULIEGE: PRESENT.
MR. TOCHER: YSABEL DURON.
MS. DURON: HERE.
MR. TOCHER: MARK FISCHER-COLBRIE.
MR. FISCHER-COLBRIE: HERE.
MR. TOCHER: ELENA FLOWERS.
DR. FLOWERS: PRESENT.
MR. TOCHER: JUDY GASSON.
DR. GASSON: HERE.
MR. TOCHER: DAVID HIGGINS.
DR. HIGGINS: HERE.
MR. TOCHER: VITO IMBASCIANI.
CHAIRMAN IMBASCIANI: HERE.
MR. TOCHER: RICH LAJARA.
MR. LAJARA: PRESENT.
MR. TOCHER: PAT LEVITT.

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DR. LEVITT: HERE.
MR. TOCHER: HALA MADANAT.
DR. MADANAT: HERE.
MR. TOCHER: LINDA MALKAS.
DR. MALKAS: HERE.
MR. TOCHER: SHLOMO MELMED.
DR. MELMED: HERE.
MR. TOCHER: CAROLYN MELTZER.
DR. MELTZER: PRESENT.
MR. TOCHER: CHRISTINE MIASKOWSKI.
DR. MIASKOWSKI: PRESENT.
MR. TOCHER: ADRIANA PADILLA.
DR. PADILLA: HERE.
MR. TOCHER: JOE PANETTA.
MR. PANETTA: HERE.
MR. TOCHER: MARVIN SOUTHARD.
DR. SOUTHARD: HERE.
MR. TOCHER: SUZANNE SANDMEYER.
DR. SANDMEYER: PRESENT.
MR. TOCHER: KAROL WATSON.
DR. WATSON: PRESENT.
MR. TOCHER: YAEL WYTE.
DR. WYTE: HERE.
MR. TOCHER: KEVIN XU.
MR. XU: HERE.

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MR. TOCHER: KEITH YAMAMOTO.

THANK YOU, MR. CHAIRMAN. WE HAVE A QUORUM.

CHAIRMAN IMBASCIANI: THANK YOU, SCOTT. I DIDN'T HEAR KEITH'S ANSWER.

MR. TOCHER: HE'S NOT PRESENT.

CHAIRMAN IMBASCIANI: I'D LIKE TO UPDATE THE BOARD NEXT ON A SERIES OF DISCUSSIONS AND MEETINGS I'VE HAD SINCE THE LAST MEETING ON THE SUBJECT OF CIRM'S LONG-TERM, LONG-RANGE VIABILITY OR SUSTAINABILITY PROJECT.

THE PURPOSE OF THESE MEETINGS I'VE HAD IS TO ENRICH MY UNDERSTANDING OF THE ISSUES UNDERPINNING EACH OF THE VARIOUS OPTIONS THAT PRESENT THEMSELVES BY SPEAKING TO PEOPLE WITH INTEREST IN AND IDEALLY EXPERIENCE IN THAT OPTION. MY CANVASSING HAS LED ME TO DISCUSSIONS WITH PRESENT AND FORMER ELECTED OFFICIALS IN BOTH THE LEGISLATIVE AND EXECUTIVE BRANCHES OF STATE GOVERNMENT, MEDICAL LEADERS IN THE STATE, PATIENT ADVOCATES, EXPERTS IN BALLOT INITIATIVES AND CAMPAIGN LAW, LOBBYISTS WITH EXPERIENCE IN REFERENDA AND INITIATIVES, PEOPLE KNOWLEDGEABLE IN THE WORLD OF PHARMA. I HAVE NOT YET MET WITH ANYONE WORKING IN THE AREA OF CHARITABLE DEVELOPMENT OR PARTNERSHIPS WITH PHARMA

OR INDUSTRY, ALTHOUGH FEELERS HAVE BEEN PUT OUT.

ALMOST EVERYONE I'VE SPOKEN WITH HAS BROUGHT UP THE ROLE OF PHILANTHROPY IN CIRM'S FUTURE AND OF FOUNDATIONS, BUT NONE OF THESE PEOPLE WERE SANGUINE ABOUT THAT APPROACH. I'VE ALSO ASKED AND FORMED A SMALL GROUP OF PRESENT AND FORMER BOARD MEMBERS TO ADVISE ME AS A SORT OF KITCHEN CABINET ON HOW THE CHAIR SHOULD BEST PROCEED IN THIS ENDEAVOR.

WE'VE HAD OUR FIRST OPENING MEETING TO DISCUSS THE LANDSCAPE WHICH IS CHANGING EVERY DAY AND TO BEGIN TO LOOK AT THESE OPTIONS AND WAYS THAT WE MIGHT PROCEED. AND BECAUSE -- WELL, A FORMAL PRESENTATION WILL BE PRESENTED TO THE BOARD AT THE JUNE MEETING INSTEAD OF TODAY. AND THAT IS BECAUSE THE AGENDA FOR TODAY'S MEETING IS LONG. IT INCLUDES PHASE 1 RECOMMENDATIONS FOR THE STRATEGIC ALLOCATION FRAMEWORK AND THE PRESENTATIONS AND DISCUSSIONS OF FOUR NEW CONCEPT PLANS, AND REVISIONS TO EXISTING PROGRAMS WILL LIKELY TAKE UP MUCH OF THE ALLOTTED TIME, BUT THIS WILL ALSO AFFORD ME THE OPPORTUNITY TO WORK FURTHER WITH THE GOVERNANCE SUBCOMMITTEE TO REFINE THIS PRESENTATION BEFORE JUNE.

THAT IS THE CHAIR'S REPORT. I'M GOING TO ASK NOW THE VICE CHAIR FOR HER REMARKS.

VICE CHAIR BONNEVILLE: I'M GOING TO

WASHINGTON, D.C. NEXT WEEK TO MEET WITH THE SOME OF THE CALIFORNIA CONGRESSIONAL DELEGATION AND THEIR STAFF TO UPDATE THEM ON CIRM. THIS IS AN EDUCATIONAL AND REALLY AROUND BASIC CIRM INFO, MONEY SPENT IN CALIFORNIA, KEY INFRASTRUCTURE PROGRAMS LIKE ALPHA CLINICS AND FUTURE COMMUNITY CARE CENTERS OF EXCELLENCE, EDUCATION PROGRAMS, AND OUR RESEARCH PILLARS.

IN ADDITION, I'LL BE SETTING UP SIMILAR MEETINGS WITH CALIFORNIA STATE ASSEMBLY MEMBERS AND SENATORS IN SACRAMENTO, MOSTLY THOSE WHO SIT ON THE BUDGET, EDUCATION, AND HEALTH COMMITTEES. THESE MEETINGS ARE FOCUSED ON REINFORCING CIRM'S CRITICAL ROLE IN CONTINUING TO SUPPORT THE RESEARCH ECOSYSTEM BY DEDICATED FUNDING FOR CELL AND GENE THERAPY RESEARCH IN CALIFORNIA.

AND I'M ALSO IN CONTACT WITH THE GOVERNOR'S OFFICE REGULARLY ABOUT THE EVERCHANGING RESEARCH FUNDING LANDSCAPE.

THE AAWG MET THIS MONTH TO HEAR CHANGES TO THE COMMUNITY CARE CENTER CONCEPT PLAN, AND NEXT MONTH THEY WILL CONVENE TO GIVE GUIDANCE ON STAGE-SPECIFIC ACCESS PLAN ACTIVITIES FOR OUR NEW CONCEPT PLANS. THE TEAM WILL REPORT OUT TO THE BOARD IN JUNE WITH THE RESULTS OF THAT MEETING.

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AND I'M HAPPY TO TAKE ANY QUESTIONS.

CHAIRMAN IMBASCIANI: OKAY. THANK YOU VERY MUCH. THANK YOU, MARIA, FOR YOUR REPORT. I DON'T SEE ANY HANDS RAISED, SO WE'RE GOING TO PROCEED WITH THE REPORT FROM OUR PRESIDENT AND CEO, JONATHAN THOMAS.

DR. THOMAS: MR. CHAIR, MADAM VICE CHAIR, MEMBERS OF THE BOARD, CIRM TEAM, AND MEMBERS OF THE PUBLIC, AS WE HAVE A PACKED AGENDA FOR TODAY'S MEETING, I WANTED TO CONFINE MY PRESIDENT'S REPORT TO THE FOLLOWING SET OF OPENING REMARKS.

THE SITUATION CONCERNING FUNDING FOR SCIENTIFIC RESEARCH CONTINUES TO BE FLUID WITH DEVELOPMENTS ON A VIRTUALLY DAILY BASIS. THROUGH CONVERSATIONS WITH MANY OF OUR STAKEHOLDERS WE AT CIRM UNDERSTAND HOW THIS UNCERTAINTY IMPACTS THE SCIENTIFIC AND PATIENT COMMUNITIES AND CAN BE CHALLENGING, ESPECIALLY FOR RESEARCHERS AND INSTITUTIONS THAT RELY ON A STABLE FUNDING ENVIRONMENT TO DRIVE SCIENTIFIC PROGRESS.

THROUGH MARIA'S EFFORTS AND WITH THE HELP OF POLICY PARTNERS, WE ARE CLOSELY MONITORING THE EVOLVING LANDSCAPE IN WASHINGTON, D.C. LIKEWISE, WE'RE IN CLOSE COMMUNICATION WITH THE GOVERNOR'S OFFICE AND INSTITUTIONS AROUND THE STATE TO TRACK

ONGOING DEVELOPMENTS.

OUR MESSAGE TO ALL IS THAT CIRM REMAINS RESOLUTE AND FULLY COMMITTED TO SUPPORTING CALIFORNIA'S RESEARCH COMMUNITY AND TO ADVANCING INNOVATIVE REGENERATIVE MEDICINE THERAPIES TO PEOPLE ACROSS THE STATE.

LATER TODAY THE BOARD WILL BE CONSIDERING FOUR CONCEPT PLANS APPROVED LAST FALL AS PART OF OUR STRATEGIC ALLOCATION FRAMEWORK OR SAF. APPLICATIONS FOR DISCOVERY, PRECLINICAL DEVELOPMENT, AND CLINICAL PROGRAMS ARE EXPECTED TO OPEN IN THE SPRING WITH DEADLINES THROUGHOUT THE SUMMER AND FALL. COMBINED THIS FIRST ROUND OF FUNDING PROGRAMS WILL PROVIDE MORE THAN $425 MILLION TO SUPPORT DOZENS OF NEW CELL AND GENE THERAPY RESEARCH PROJECTS.

ALSO LATER TODAY THE BOARD WILL BE CONSIDERING PART 1 OF A REDEFINED CONCEPT PLAN FOR THE DELIVERY FUNCTION OF THE COMMUNITY CARE CENTERS OF EXCELLENCE, CCCE. PART 2 OF THAT PLAN FOCUSING ON THE SUPPORT FUNCTION WILL BE COMING TO THE BOARD LATER THIS YEAR.

IF THE BOARD APPROVES THESE CONCEPT PLANS TODAY, THE NEXT STEP WILL BE TO IMPLEMENT ALL THE PROGRAMS DEFINED IN THOSE PLANS. THAT PROCESS WILL BEGIN IMMINENTLY AND EXTEND THROUGH THE SUMMER AND

FALL.

THE NEXT ROUND OF SAF CONCEPT PLANS IS SCHEDULED TO COME TO THE BOARD IN JANUARY, INCLUDING THOSE FOR THE RARE DISEASE PILOT PLATFORM PROGRAM, THE DATA COORDINATING AND MANAGEMENT CENTER, THE PILOT TECHNOLOGY PLATFORM PROGRAM, AND THE CLIN-X PROGRAM TO FUND PROJECTS THROUGH BLA.

IT IS IMPORTANT TO NOTE, PER THE MANDATE OF PROPOSITION 14, THAT ALL SAF PROGRAMS ARE DRIVEN BY CIRM'S CORE PRINCIPLES, WHICH ARE: NO. 1, THAT PATIENTS ARE THE NORTH STAR OF EVERYTHING WE DO. NO. 2, THAT OUR MISSION IS TO ENABLE WORLD-CLASS SCIENCE TO HELP REDUCE HUMAN SUFFERING. AND NO. 3, TO MAKE THERAPIES AND CURES THAT WE FUND AVAILABLE TO ALL CALIFORNIANS IN NEED. THE COMMON THREAD TO EACH OF THESE PRINCIPLES IS THAT ALL FUNDED PROJECTS FROM DISCOVERY THROUGH CLINICAL TRIALS MUST BE DESIGNED TO ULTIMATELY ADDRESS THE NEEDS OF ALL COMMUNITIES AFFECTED BY THE DISEASES IN QUESTION.

OUR LAST ROUND OF CONCEPT PLANS DUE FOR BOARD CONSIDERATION IN MID-2026 WILL DEAL WITH EXTENSIONS AND IMPROVEMENTS TO OUR EDUCATION PROGRAMS. THERE WE'RE LOOKING TO CONTINUE TO TRAIN THE SCIENTISTS OF TOMORROW WHO WILL BOTH MATERIALLY ADD TO THE REGENERATIVE MEDICINE WORKFORCE IN ALL

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CORNERS OF THE STATE AND THEMSELVES CONCEIVE AND DEVELOP NEW TECHNOLOGIES IN CELL AND GENE THERAPIES TO THE FURTHER BENEFIT OF ALL CALIFORNIANS WITH UNMET MEDICAL NEEDS.

SINCE INCEPTION IN 2004, CIRM HAS BEEN METICULOUSLY COMPLIANT WITH ALL FEDERAL AND STATE LAWS, INCLUDING PROPOSITION 209. WE HAVE AND WILL CONTINUE TO DEMONSTRATE THAT THE PURSUIT OF SCIENCE IS NOT INCONSISTENT WITH THESE LEGAL PARAMETERS. AS STAUNCH SUPPORTERS OF SCIENTIFIC INGENUITY AND INNOVATION, WE ARE FORTUNATE THAT THE CITIZENS OF CALIFORNIA HAVE GIVEN US THE OPPORTUNITY AND PRIVILEGE TO CONTINUE TO LEAD THE WAY IN ACCELERATING BEST-IN-CLASS SCIENCE.

AS WE EMBARK ON OUR THIRD DECADE, WE WILL CONTINUE TO CHAMPION REGENERATIVE MEDICINE IN CALIFORNIA AND CONTRIBUTE TO THE STATE'S LEADERSHIP IN GLOBAL SCIENTIFIC BREAKTHROUGHS.

ONE ADMINISTRATIVE NOTE. AS WE CONTINUE TO TRACK EVOLVING DEVELOPMENTS, WE MAY NEED BOARD REVIEW AND APPROVAL OF REVISED CONCEPT PLANS OR PROGRAMS. GIVEN THAT THE FULL BOARD GENERALLY MEETS EVERY THREE MONTHS AND THAT WE MAY NEED REAL-TIME DECISIONS IN SHORT ORDER, I WOULD REQUEST THAT THE BOARD DELEGATE AUTHORITY TO ME IN CONSULTATION WITH

THE HEADS OF THE GOVERNANCE, FINANCE, AND COMMUNICATIONS SUBCOMMITTEES, AS WELL AS THE HEADS OF THE JOINT SCIENCE SUBCOMMITTEE AND NEURO TASK FORCE TO MAKE DECISIONS CONCERNING ANY SUCH REVISIONS. THERE WILL BE A MOTION TO THIS EFFECT AT THE TAIL END OF THE CONCEPT PLAN DISCUSSIONS LATER TODAY.

I WOULD LIKE TO CLOSE WITH THE OBSERVATION THAT, AS WAS THE CASE WITH THE SAF IN SEPTEMBER, TODAY'S CONCEPT PLANS WERE THE RESULT OF A MONTHS' LONG, VERY HEAVY LIFT BY THE ENTIRE CIRM TEAM IN CONSULTATION WITH THE BOARD. WHILE THE PRESENTERS OF EACH OF THE CONCEPT PLANS WILL THANK MEMBERS OF THE RESPECTIVE TEAMS BY NAME, I WANTED TO MAKE SURE TO PERSONALLY THANK ALL MY COLLEAGUES FOR THE A-PLUS WORK PRODUCT WE'LL BE CONSIDERING LATER TODAY AND TO CONGRATULATE ALL OF US, ONCE AGAIN, BOARD AND TEAM, ON A JOB EXTRAORDINARILY WELL DONE.

MR. CHAIRMAN, THAT CONCLUDES MY REMARKS.

CHAIRMAN IMBASCIANI: THANK YOU, DR. THOMAS. WE WILL NOT FORGET YOUR NEED FOR THAT AMENDMENT.

THE NEXT ITEMS ON THE AGENDA ARE THE CONSENT CALENDAR, ITEMS 6 AND 7. TODAY'S CONSENT AGENDA INCLUDES THE MINUTES FROM THE JANUARY MEETING

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OF THE ICOC, WHICH I HAVE REVIEWED AND FIND NO ISSUE WITH, BUT YOU SHOULD TAKE A LOOK AT THOSE. AND THE ITEM 7 IS A REQUEST FOR THE BOARD OF DIRECTORS TO APPOINT ELIZABETH BOILEAU TO THE ACCESS AND AFFORDABILITY WORKING GROUP.

ARE THERE ANY ABSTRACTIONS TO BE CONSIDERED OR DISCUSSED FROM THE CONSENT CALENDAR? IF NOT, MAY I HAVE A MOTION TO ACCEPT SUCH?

DR. BLUMENTHAL: SO MOVED.

CHAIRMAN IMBASCIANI: WE HAVE GEORGE BLUMENTHAL, MOTION.

DR. SOUTHARD: SECOND.

CHAIRMAN IMBASCIANI: AND A SECOND FROM MARVIN. OKAY. ANY DISCUSSION? OR FROM THE PUBLIC? NONE. THANK YOU, CLAUDETTE. SCOTT, WOULD YOU PLEASE POLL THE MEMBERS.

MR. TOCHER: ALL THOSE IN THE ROOM IN FAVOR SAY AYE. ANY OPPOSED? ABSTENTIONS? AND I'LL POLL THE MEMBERS ON THE PHONE.

MONICA CARSON. YSABEL DURON.

MS. DURON: YES.

MR. TOCHER: RICH LAJARA.

MR. LAJARA: YES.

MR. TOCHER: SHLOMO MELMED.

DR. MELMED: YES.

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MR. TOCHER: CHRIS MIASKOWSKI.
DR. MIASKOWSKI: YES.
MR. TOCHER: JOE PANETTA.
MR. PANETTA: YES.
MR. TOCHER: SUZANNE SANDMEYER.
DR. SANDMEYER: YES.
MR. TOCHER: KAROL WATSON.
DR. WATSON: YES.
MR. TOCHER: AND KEVIN XU.
DR. XU: YES.
MR. TOCHER: THANK YOU. THE MOTION CARRIES.
CHAIRMAN IMBASCIANI: THANK YOU, SCOTT.
WE'LL NOW CONVENE AS THE APPLICATION REVIEW SUBCOMMITTEE TO CONSIDER THOSE APPLICATIONS SUBMITTED IN RESPONSE TO CLINICAL TRIAL PROJECTS. DR. HAYLEY LAM, THE DIRECTOR OF REVIEW, WILL MAKE THE PRESENTATION. THANK YOU, HAYLEY.
DR. LAM: GOOD MORNING TO THE BOARD, MR. CHAIR, MADAM VICE CHAIR, AND THE CIRM TEAM, AND THE PUBLIC. IT IS MY PLEASURE TODAY TO PRESENT THE GRANTS WORKING GROUP RECOMMENDATIONS FOR THE CLINICAL PROGRAM.
AS ALWAYS, WE BEGIN WITH OUR MISSION, ACCELERATING WORLD-CLASS SCIENCE TO DELIVER

TRANSFORMATIVE REGENERATIVE MEDICINE TREATMENTS IN AN EQUITABLE MANNER TO A DIVERSE CALIFORNIA AND WORLD.

THE CURRENT CLINICAL BUDGET STATUS HAS AN ALLOCATION OF 76.7 MILLION FOR THE SECOND HALF OF THE FISCAL YEAR. THIS BOARD HAS APPROVED IN JANUARY 24 MILLION IN FUNDS THUS FAR, AND TODAY THERE'S A TOTAL ASK OF 26.5 MILLION ACROSS THREE APPLICATIONS.

COUPLE THINGS ABOUT THE CLINICAL PROCESS. THE CURRENT SCORING SYSTEM IS A 1, 2, AND 3. A 1 IS A RECOMMENDATION FOR FUNDING, A 2 IS A DO NOT RECOMMEND AT THIS TIME AND THE APPLICANT CAN RESUBMIT WITH ADDRESSING CONCERNS FROM THE GRANTS WORKING GROUP, AND A 3 IS DO NOT RECOMMEND AT THIS TIME AND THE APPLICANT CANNOT RESUBMIT THE SAME PROJECT FOR AT LEAST SIX MONTHS.

THE SCIENTIFIC EVALUATION IS A HOLISTIC SCORE ACROSS THESE FIVE CRITERIA. THE FIRST IS DOES THE PROJECT HOLD THE NECESSARY SIGNIFICANCE AND POTENTIAL FOR IMPACT? IS THE RATIONALE SOUND? SO DOES THE DATA SUPPORT MOVING THE PROJECT FORWARD? IS THE PROJECT WELL PLANNED AND DESIGNED? SO ARE THE ACTIVITIES THAT ARE PROPOSED FOR CIRM FUNDING WELL DESIGNED? IS THE PROJECT FEASIBLE? SO DOES THE TEAM HAVE THE RESOURCES IN PLACE TO EXECUTE THE

PROJECT? AND THE DOES THE PROJECT UPHOLD PRINCIPLES OF DIVERSITY, EQUITY, AND INCLUSION? SO DOES IT CONSIDER PATIENT DIVERSITY?

THE CLINICAL PROGRAM IN ADDITION TO THE SCIENTIFIC SCORE HAS DIVERSITY, EQUITY, AND INCLUSION SCORE THAT IS SCORED BY THE GRANTS WORKING GROUP BOARD MEMBERS. THE SCALE FOR THIS IS A ZERO TO TEN, A TEN BEING AN OUTSTANDING RESPONSE. THE CRITERIA USED FOR THIS ARE UNDER OVERARCHING CATEGORIES RELATED TO THE APPLICANT'S COMMITMENT TO DEI, THE PROJECT PLANS, AND TRAINING FOR CULTURAL SENSITIVITY.

SO IN SUMMARY, THE REVIEW PANEL THAT ASSESSES THESE APPLICATIONS ARE COMPOSED OF THREE DIFFERENT TYPES: THE SCIENTIFIC GRANTS WORKING GROUP MEMBERS WHO PROVIDE A SCIENTIFIC SCORE AND EVALUATE ACROSS THE DISEASE AREAS, REGULATORY, MANUFACTURING, AND PRODUCT DEVELOPMENT; THE GRANTS WORKING GROUP BOARD MEMBERS WHO PROVIDE THE DEI SCORE ON ALL APPLICATIONS AND SUGGESTED SCIENTIFIC SCORES AS THEY SO DESIRE; AND OUR AD HOC SCIENTIFIC SPECIALISTS. AND THESE FOLKS PROVIDE THE SCIENTIFIC EVALUATION IN AREAS AND EXPERTISE NOT COVERED BY THE GRANTS WORKING GROUP.

SO AS WE MOVE INTO THE INDIVIDUAL

APPLICATIONS UNDER CONSIDERATION TODAY, WE HAVE BOARD MEMBERS WITH CONFLICTS OF INTEREST HERE DISPLAYED.

AND FOR YOUR CONSIDERATION, THE VERY FIRST APPLICATION IS CLIN1-17103. THIS IS AN EXPRESSION OF UBE3A BY THE HEMATOPOIETIC SYSTEM FOR THE TREATMENT OF ANGELMAN SYNDROME. THIS IS AN AUTOLOGOUS GENE-MODIFIED CELL THERAPY FOR ANGELMAN. AND THE APPLICANT IS REQUESTING JUST UNDER FOUR AND A HALF MILLION WITH NO REQUIRED CO-FUNDING FROM A CALIFORNIA ORGANIZATION TO COMPLETE THE TASKS NECESSARY TO FILE AN IND.

A LITTLE BIT OF BACKGROUND ON THE PROJECT. SO ANGELMAN IS A RARE GENETIC NEURODEVELOPMENTAL DISORDER. AND THE PEOPLE WITH ANGELMAN'S HAVE SEIZURES, MOVEMENT, BALANCE, AND GAIT ISSUES, AND OVERALL DEVELOPMENTAL DISABILITY, INCLUDING INTELLECTUAL DISABILITIES AND IMPAIRED SPEECH. THIS IS A PROGRESSIVE AND CHRONIC CONDITION AND REQUIRES LIFELONG AID. AND THE CURRENT STANDARD OF CARE TREATS SYMPTOMS ONLY; FOR EXAMPLE, MEDICATION FOR ANTISEIZURES.

THE PROPOSED PRODUCT IS A ONE-TIME TREATMENT THAT MODIFIES THE PATIENT'S OWN STEM CELLS AND CORRECTS THE UBE3A GENE. TRANSPLANTED CELLS

THEN DELIVER FUNCTIONAL PROTEIN AND HAVE THE POTENTIAL TO PREVENT, HALT, OR REVERSE SYMPTOMS ASSOCIATED WITH ANGELMAN'S.

CIRM CURRENTLY HAS ONE TRANSLATIONAL AWARD THAT'S CURRENTLY UNDER CONTRACTING IN THIS INDICATION. THIS WAS APPROVED WITH THE BATCH OF TRANSLATIONAL APPLICATIONS IN JANUARY. THEY USE A SIMILAR APPROACH OF CORRECTING THE UBE3A GENE.

THE APPLICANT TEAM HAS RECEIVED PRIOR FUNDING FROM CIRM WITH TWO AWARDS IN TAY-SACHS DISEASE, WHICH IS A DIFFERENT NEURODEVELOPMENTAL DISORDER WITH A SIMILAR APPROACH TO THIS PROJECT.

SO THE RECOMMENDATION FROM THE GRANTS WORKING GROUP WAS A UNANIMOUS RECOMMENDATION TO FUND CLIN1-17103 WITH A DEI SCORE OF 8. AND THE CIRM TEAM RECOMMENDATION CONCURS WITH THE GRANTS WORKING GROUP FOR A RECOMMENDATION TO FUND THIS APPLICATION FOR 4.48 MILLION. CHAIR IMBASCIANI.

CHAIRMAN IMBASCIANI: THANK YOU, HAYLEY, FOR THE PRESENTATION. LIKE A MOTION TO ACCEPT THE RECOMMENDATION PLEASE.

DR. CLARK-HARVEY: SO MOVED.

DR. SOUTHARD: SECOND.

CHAIRMAN IMBASCIANI: I HEARD THE SECOND. THANK YOU. OPEN TO DISCUSSION ON THIS

RECOMMENDATION BY BOARD MEMBERS. IF NO BOARD COMMENT, ANYONE FROM THE PUBLIC LIKE TO COMMENT? THANK YOU. SCOTT, YOU MAY PROCEED.

MR. TOCHER: MARIA BONNEVILLE.

VICE CHAIR BONNEVILLE: YES.

MR. TOCHER: LEONDRA CLARK-HARVEY.

DR. CLARK-HARVEY: YES.

MR. TOCHER: ANNE-MARIE DULIEGE.

DR. DULIEGE: YES.

MR. TOCHER: MARK FISCHER-COLBRIE.

MR. FISCHER-COLBRIE: YES.

MR. TOCHER: ELENA FLOWERS.

DR. FLOWERS: YES.

MR. TOCHER: DAVID HIGGINS.

DR. HIGGINS: YES.

MR. TOCHER: VITO IMBASCIANI.

CHAIRMAN IMBASCIANI: YES.

MR. TOCHER: RICH LAJARA.

MR. LAJARA: YES.

MR. TOCHER: CHRISTINE MIASKOWSKI.

DR. MIASKOWSKI: YES.

MR. TOCHER: ADRIANA PADILLA.

DR. PADILLA: YES.

MR. TOCHER: JOE PANETTA.

MR. PANETTA: YES.

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MR. TOCHER: MARVIN SOUTHARD.
DR. SOUTHARD: YES.
MR. TOCHER: KAROL WATSON.
DR. WATSON: YES.
MR. TOCHER: YAEL WYTE.
DR. WYTE: YES.
MR. TOCHER: KEVIN XU.
DR. XU: YES.
MR. TOCHER: THANK YOU. THE MOTION CARRIES, MR. CHAIR.
CHAIRMAN IMBASCIANI: THANK YOU. HAYLEY, YOU CAN PROCEED TO THE NEXT APPLICATION.
DR. LAM: THANK YOU. SO CONFLICTS OF INTEREST NOTE HERE.
THE NEXT APPLICATION FOR YOUR CONSIDERATION IS CLIN2-17080. THIS IS A PRODUCT FOR THE PREVENTION OF GVHD IN PATIENTS RECEIVING HLA MISMATCHED HSCT FOR THE TREATMENT OF HEMATOLOGIC MALIGNANCIES. ESSENTIALLY THIS IS AN OFF-THE-SHELF CELL THERAPY TO PREVENT GRAFT VERSUS HOST DISEASE.
THE APPLICANT IS REQUESTING 8 MILLION WITH A 4.7 MILLION IN CO-FUNDING TO COMPLETE A PHASE 1 CLINICAL TRIAL.
LITTLE BIT OF BACKGROUND ON THIS PROJECT. SO PEOPLE UNDERGOING MISMATCHED STEM CELL

TRANSPLANTS FOR THE TREATMENT OF BLOOD CANCERS ARE OFTEN AFFECTED BY WHAT'S CALLED GRAFT VERSUS HOST DISEASE WHERE THE DONOR CELLS ATTACK THE RECIPIENT TISSUE. THE STANDARD OF CARE TREATMENTS OFTEN DON'T WORK AND ARE USUALLY STEROIDS THAT SUPPRESS THE IMMUNE SYSTEM FURTHER AND INCREASE THE RISK OF INFECTIONS AND CAN ALSO IMPACT THE EFFECTIVENESS OF THE CANCER TREATMENT ITSELF. IN SOME PATIENTS GVHD CAN BE POTENTIALLY LIFE-THREATENING AND CAUSE TISSUE DAMAGE IN MULTIPLE ORGAN SYSTEMS.

THE PROPOSED ALLOGENEIC, OFF-THE-SHELF ENGINEERED REGULATORY T-CELL PRODUCT COULD INCREASE ACCESS TO THESE STEM CELL TRANSPLANTS FOR INDIVIDUALS WHO ARE CANDIDATES FOR TRANSPLANTS, THE LACK OF SUITABLE MATCH DONOR, AND ALSO REDUCE THE BURDEN OF THE GVHD.

THE CIRM PORTFOLIO HAS TWO ACTIVE PROJECTS TARGETING GVHD IN PEOPLE WITH BLOOD CANCER AT DIFFERENT STAGES OF CLINICAL DEVELOPMENT. ONE IS A PHASE 1 TRIAL THAT USES A SIMILAR REGULATORY T-CELL PRODUCT. THE DIFFERENCE WITH THIS ONE IS THAT IT'S AN AUTOLOGOUS DONOR TRANSPLANT AND IS NOT A OFF-THE-SHELF PRODUCT.

THE OTHER IS AN IND-ENABLING STAGE MESENCHYMAL STEM CELL PRODUCT THAT AIMS TO SUPPRESS

THE DONOR RESPONSE.

THIS APPLICANT HAS RECEIVED PRIOR CIRM FUNDING, AND THIS APPLICATION AND WOULD-BE AWARD WOULD BE A PROGRESSION EVENT OFF OF THIS PRECLINICAL STAGE PROJECT.

SO THE GRANTS WORKING GROUP RECOMMENDATION FOR THIS APPLICATION WAS A UNANIMOUS VOTE TO RECOMMEND FOR FUNDING WITH A DEI SCORE OF 8, AND THE CIRM TEAM CONCURS WITH THAT RECOMMENDATION FOR THE FUNDING OF 8 MILLION FOR THIS PROJECT. CHAIR IMBASCIANI.

CHAIRMAN IMBASCIANI: THANK YOU, HAYLEY. AND THE CHAIR WOULD LIKE TO RECEIVE A MOTION TO ACCEPT THE RECOMMENDATION.

DR. CLARK-HARVEY: SO MOVED.

DR. SOUTHARD: SECOND.

CHAIRMAN IMBASCIANI: LEONDRA HAS MOVED AND MARVIN HAS SECONDED. THANK YOU. DISCUSSION FROM BOARD MEMBERS ON THIS APPLICATION FOR GRAFT VERSUS HOST DISEASE.

DR. DULIEGE: JUST A BRIEF QUESTION. CAN YOU TELL US THE SIZE OF THE TRIAL THAT IS --

DR. LAM: THE PROPOSED TRIAL?

DR. DULIEGE: HOW MANY PATIENTS?

DR. LAM: THEY'RE AIMING SOMEWHERE BETWEEN

20 TO 39 SUBJECTS.

DR. DULIEGE: THANK YOU.

CHAIRMAN IMBASCIANI: OTHER COMMENT? OR FROM THE PUBLIC? AND WE'RE SEEING NONE. THANK YOU. SCOTT, YOU MAY PROCEED TO THE VOTE.

MR. TOCHER: THANK YOU. MARIA BONNEVILLE.

VICE CHAIR BONNEVILLE: YES.

MR. TOCHER: LEONDRA CLARK-HARVEY.

DR. CLARK-HARVEY: YES.

MR. TOCHER: ANNE-MARIE DULIEGE.

DR. DULIEGE: YES.

MR. TOCHER: YSABEL DURON.

MS. DURON: YES.

MR. TOCHER: MARK FISCHER-COLBRIE.

MR. FISCHER-COLBRIE: YES.

MR. TOCHER: ELENA FLOWERS.

DR. FLOWERS: YES.

MR. TOCHER: DAVID HIGGINS.

DR. HIGGINS: YES.

MR. TOCHER: VITO IMBASCIANI.

CHAIRMAN IMBASCIANI: YES.

MR. TOCHER: RICH LAJARA.

MR. LAJARA: YES.

MR. TOCHER: CHRISTINE MIASKOWSKI.

DR. MIASKOWSKI: YES.

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MR. TOCHER: ADRIANA PADILLA.
DR. PADILLA: YES.
MR. TOCHER: JOE PANETTA.
MR. PANETTA: YES.
MR. TOCHER: MARVIN SOUTHARD.
DR. SOUTHARD: YES.
MR. TOCHER: KAROL WATSON.
DR. WATSON: YES.
MR. TOCHER: YAEL WYTE.
DR. WYTE: YES.
MR. TOCHER: AND KEVIN XU.
DR. XU: YES.
MR. TOCHER: THANK YOU. MOTION CARRIES, MR. CHAIR.
CHAIRMAN IMBASCIANI: THANK YOU, SCOTT. HAYLEY, FOR THE THIRD APPLICATION.
DR. LAM: ALL RIGHT. THIRD AND FINAL APPLICATION FOR YOUR CONSIDERATION. THE APPLICATION IS CLIN2-17135, AN INHIBITORY INTERNEURON CELL THERAPY FOR THE TREATMENT OF DRUG RESISTANT BILATERAL TEMPORAL LOBE EPILEPSY. THIS IS AN INTERNEURON CELL THERAPY, AND THE APPLICANT IS REQUESTING JUST UNDER 14 MILLION WITH OVER 9 MILLION IN CO-FUNDING FROM A CALIFORNIA ORGANIZATION TO COMPLETE A PHASE 1-2 CLINICAL TRIAL.

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LITTLE BIT OF CLINICAL BACKGROUND ON THIS. SO EPILEPSY IMPACTS ABOUT 1 PERCENT OF ADULTS IN THE UNITED STATES AND IS A NEUROLOGICAL DISORDER THAT CAUSES REOCCURRING SEIZURES. ANTISEIZURE MEDICATIONS ARE THE MAIN STANDARD OF CARE; HOWEVER, A THIRD OR MORE OF PEOPLE LIVING WITH EPILEPSY HAVE DRUG-RESISTANT SEIZURES, MEANING TWO OR MORE DIFFERENT TYPES OF MEDICATIONS DO NOT CONSISTENTLY DECREASE THE SEIZURE IMPACT. AND THIS, OF COURSE, IMPACTS QUALITY OF LIFE.

SO THE CURRENT TREATMENTS FOR THOSE WITH DRUG-RESISTANT EPILEPSY INCLUDES SURGICAL METHODS WHICH ESSENTIALLY DESTROY THE TISSUE, AND THIS CAN CAUSE SERIOUS EFFECTS SUCH AS MEMORY LOSS AND SPEECH AND OTHER COGNITIVE IMPAIRMENTS.

THE PROPOSED PRODUCT IS A TARGETED NONTISSUE DESTRUCTIVE ONE-TIME DELIVERY OF CELLS INTO THE IMPACTED BRAIN REGIONS. THE CELL REPLACEMENT AIMS TO REBALANCE THE NEURAL ACTIVITY BY SECRETING NEUROTRANSMITTERS IN THE LOCALIZED BRAIN AREA AND HOPES TO PROVIDE A LONG-LASTING SEIZURE REDUCTION.

CIRM HAS TWO ACTIVE LATER STAGE AWARDS IN EPILEPSY. ONE FOR A CURRENT CLINICAL TRIAL IN A SIMILAR INDICATION, BUT FOR A UNILATERAL MESIAL

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TEMPORAL LOBE EPILEPSY FOR THE SAME PRODUCT. CIRM ALSO IS FUNDING A TRANSLATIONAL PRECLINICAL STAGE PROJECT FOR THE SAME INDICATION, BUT A SIMILAR CANDIDATE THAT WOULD BE A UNIVERSAL PRODUCT THAT WOULD HOPEFULLY OBVIATE THE NEED FOR IMMUNOSUPPRESSION.

THE APPLICANT TEAM HAS RECEIVED SEVERAL PRIOR CIRM AWARDS THAT RESULT IN THE APPLICATION BEFORE YOU TODAY. SO THERE'S BEEN ESSENTIALLY THREE PROGRESSION AWARDS IN THE SORT OF HISTORY OF THIS PROJECT ALL THE WAY BACK TO THE DISCOVERY STAGE AND IN ADDITION TO THE CURRENT TRANSLATIONAL PROJECT THAT I JUST MENTIONED PREVIOUSLY.

THEREFORE, THE GRANTS WORKING GROUP RECOMMENDATION FOR THIS PROJECT WAS A UNANIMOUS RECOMMENDATION FOR FUNDING WITH A DEI SCORE OF 8. AND THE CIRM TEAM CONCURS WITH THAT RECOMMENDATION FOR FUNDING THIS APPLICATION FOR JUST UNDER 14 MILLION. CHAIR IMBASCIANI.

CHAIRMAN IMBASCIANI: YES. THANK YOU AGAIN, HAYLEY. I'D LIKE TO HAVE A MOTION TO ACCEPT THE RECOMMENDATION.

DR. SOUTHARD: SO MOVED.

CHAIRMAN IMBASCIANI: MARVIN SOUTHARD HAS MOVED.

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MR. FISCHER-COLBRIE: SECOND.

CHAIRMAN IMBASCIANI: THANK YOU, MARK, SECOND. DISCUSSION FROM BOARD MEMBERS ON BILATERAL TEMPORAL LOBE EPILEPSY. ANNE-MARIE.

DR. DULIEGE: HAYLEY, CAN YOU PLEASE HELP US UNDERSTAND THE OTHER APPLICATION FROM THE SAME TEAM THAT WE FUNDED, THE CLIN2, ON UNILATERAL EPILEPSY AND HOW THEY COMPARE, HOW THEY DIFFER? WILL ONE INDICATE SUCCESS FOR THE OTHER?

DR. LAM: SO THE UNILATERAL IS THE ONE SIDE, AND THEN THIS ONE IS PROPOSING FOR BILATERAL, SO BOTH SIDES OF THE BRAIN. THIS WAS ACTUALLY A RESUBMISSION FROM THE APPLICANT BECAUSE THERE WAS QUESTIONS FROM THE GRANTS WORKING GROUP REVIEWERS ON HOW EXACTLY THAT THE CURRENT TRIAL FEEDS INTO THIS ONE IN TERMS OF SAFETY ESPECIALLY FOR THE PARTICIPANTS IN THE TRIAL. SO THEY WERE SATISFIED WITH THE RESPONSE FROM THE APPLICANT. AND IT IS TWO DIFFERENT PROTOCOLS.

CHAIRMAN IMBASCIANI: FOLLOW UP? THANK YOU. ANY OTHER QUESTIONS OR COMMENTS FROM BOARD MEMBERS? OR FROM MEMBERS OF THE PUBLIC? CLAUDETTE IS SEEING NONE. OKAY. THANK YOU. SCOTT, WE MAY PROCEED.

MR. TOCHER: MARIA BONNEVILLE.

VICE CHAIR BONNEVILLE: YES.
MR. TOCHER: LEONDRA CLARK-HARVEY.
DR. CLARK-HARVEY: YES.
MR. TOCHER: ANNE-MARIE DULIEGE.
DR. DULIEGE: YES.
MR. TOCHER: MARK FISCHER-COLBRIE.
MR. FISCHER-COLBRIE: YES.
MR. TOCHER: DAVID HIGGINS.
DR. HIGGINS: YES.
MR. TOCHER: VITO IMBASCIANI.
CHAIRMAN IMBASCIANI: YES.
MR. TOCHER: RICH LAJARA.
MR. LAJARA: YES.
MR. TOCHER: ADRIANA PADILLA.
DR. PADILLA: YES.
MR. TOCHER: JOE PANETTA.
MR. PANETTA: YES.
MR. TOCHER: MARVIN SOUTHARD.
DR. SOUTHARD: YES.
MR. TOCHER: YAEL WYTE.
DR. WYTE: YES.
MR. TOCHER: KEVIN XU.
DR. XU: YES.
MR. TOCHER: THANK YOU VERY MUCH. MR. CHAIR, THE MOTION CARRIES.

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CHAIRMAN IMBASCIANI: MOTION CARRIES. THANK YOU. THANK YOU, DR. LAM, FOR THAT EXCELLENT PRESENTATION.

OKAY. MOVING ON, THE BOARD ADOPTED THE STRATEGIC ALLOCATION FRAMEWORK, THE SAF, IN SEPTEMBER OF LAST YEAR. THE SAF CRYSTALLIZED INTO SIX MAJOR RECOMMENDATIONS. AND THE CIRM TEAM HAS BEEN WORKING ASSIDUOUSLY TO REALIZE THE PROMISE OF THOSE RECOMMENDATIONS.

TODAY WE WILL HEAR NEW CONCEPT PLANS ON THE FIRST FOUR PROGRAMS, DISC5, DISC4, PREDEVELOPMENT OR PDEV, AND CLIN2 ALONG WITH AN AMENDMENT TO THE REVIEW PROCESS AND THE GRANTS WORKING GROUP BYLAWS. THE BOARD WILL BE ASKED TO CONSIDER EACH PLAN SEPARATELY, BUT WE SHALL BEGIN BY HAVING AN OVERLOOK OF THE ENTIRE PACKAGE BY DR. ROSA CANET-AVILES, OUR CHIEF SCIENCE OFFICER. ROSA, THANK YOU.

DR. CANET-AVILES: THANK YOU, MR. CHAIRMAN, MADAM VICE CHAIR, DISTINGUISHED MEMBERS OF THE BOARD, AND DISTINGUISHED PUBLIC AS WELL OF CALIFORNIA, AND MY COLLEAGUES. I'M EXCITED TODAY BECAUSE WE WERE -- WE HAD A THREE-HOUR PRESENTATION BACK IN SEPTEMBER THAT WAS THE FRUIT OF LABOR OF NEARLY A YEAR OF WORKING WITH DATA AND TRYING TO

FIGURE OUT HOW TO BEST ALLOCATE OUR RESOURCES. AND WE CAME UP WITH A PLAN TO YOU ALL. YOU PRESSURE TESTED IT OVER THE MONTHS, AND WE ENDED UP WITH ALL SIX RECOMMENDATIONS THAT OUR CHAIRMAN OF THE BOARD WAS MENTIONING AND THAT OUR PRESIDENT, JONATHAN THOMAS, PRESENTED EARLIER ON AS WELL.

SO TODAY WE HAVE, AS YOU'VE SEEN FROM ALL THE MATERIALS THAT WE POSTED, ALL THOSE THOROUGH MATERIALS, WHAT WE ARE GOING TO COME TO YOU TODAY IS THE FIRST PHASE OF THAT IMPLEMENTATION. AND THIS IS THESE FOUR CONCEPTS THAT MY COLLEAGUES ARE GOING TO BE PRESENTING TODAY, AND DR. NOBLIN IS GOING TO GIVE US AN OVERVIEW ABOUT.

SO AS WE'VE ALL BEEN LIVING THROUGH THE PAST YEAR, THIS STRUCTURED PREFERENCE-SETTING PROCESS IS A FRAMEWORK THAT WILL HELP KEEP FUNDING PRIORITIES DYNAMIC, DATA DRIVEN, AND ALIGNED WITH EMERGING OPPORTUNITIES AND PORTFOLIO NEEDS, WHICH, AS YOU WILL SEE, WE ARE GOING TO BE HEARING IN A RECURRENT MANNER EVERY JUNE OF EVERY YEAR A PORTFOLIO ANALYSIS THAT WILL BE HELPING US KEEP UP WITH THE EMERGING OPPORTUNITIES AND PRIORITIES.

SO WHAT WE ARE GOING TO PRESENT TODAY THIS MORNING REFLECTS THE EFFORT OF MANY. AND I KNOW THAT J.T. AND VITO MENTIONED IT, BUT WE'VE BEEN

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WORKING TOGETHER FOR MANY MONTHS. AND I WOULD LIKE TO START BY ACKNOWLEDGING THE INCREDIBLE EFFORT THAT HAS GONE GETTING US UP UNTIL THIS POINT. THIS HAS BEEN A REAL TEAM EFFORT. I'M VERY PROUD OF ALL OF YOU. AND I WANT TO RECOGNIZE NOT ONLY TODAY'S PRESENTERS, WHICH ARE THE PEOPLE THAT HAVE BEEN LEADING SOME OF THE EFFORTS, BUT ALSO THE TEAMS AND LEADS FROM PROGRAMS, GRANTS MANAGEMENT, AT THE HELM IS JENN LEWIS, BUT ALSO DOUG KEARNEY, REVIEW WITH GIL SAMBRANO AND HAYLEY LAM, LEGAL WITH RAFAEL AGUIRRE-SACASA, AND BOARD GOVERNANCE WITH OUR LOVELY SCOTT TOCHER AND CLAUDETTE HELPING US WITH ALL OF THIS. AND A SPECIAL THANKS TO OUR SCIENCE SUBCOMMITTEE AND NEURO TASK FORCE CO-CHAIRS, DR. PAT LEVITT, DR. CAROLYN MELTZER, DR. MARK FISCHER-COLBRIE. I REALLY APPRECIATE YOUR HELP WITH ALL THE MEETINGS AND ALL THE TIME IN YOUR BUSY SCHEDULES TO GET US ALL TO THIS POINT. THANK YOU VERY MUCH.

AND ALSO TO OUR BOARD CHAIR AND BOARD GOVERNANCE. THANK YOU SO MUCH. THERE'S BEEN A LOT OF MEETINGS, AND YOU GUYS HAVE BEEN VERY VALUABLE IN GETTING US TO THIS. SO I HOPE THAT ALL THE FEEDBACK WE'VE GATHERED FROM THEM WILL HELP US GET TO THE FINISH LINE, WHICH IS NOT JUST THE CONCEPTS. IT'S

ALL THE WORK THAT COMES AFTER THAT, RIGHT?

SO I THINK -- ONE LAST POINT I WANT TO MAKE IS FOUR MONTHS OF HARD WORK, WHAT WE ARE BRINGING TO YOU TODAY, WHAT WE'VE ACCOMPLISHED IN THE LAST FOUR MONTHS IS PRETTY REMARKABLE. I THINK THERE IS A LITTLE THING HERE THAT SHOWS MORE OR LESS WHAT WE DID IN KIND OF TWO YEARS WITH THE REMIND AND THE STRATEGIC ALLOCATION FRAMEWORK PROCESS, WHICH UNFOLDED OVER ABOUT TWO YEARS. AND THE WORK THAT WE HAVE DONE NOW HAS BEEN ONLY IN FOUR MONTHS, AND WE'VE DONE IT EFFICIENTLY TO ALIGN THESE PROPOSALS WITH THE SAF TO HAVE IT READY FOR CONSIDERATION. AND THIS PACE WAS NECESSARY TO KEEP THE MOMENTUM AND ENSURING CONTINUITY IN FUNDING, WHICH IS VERY IMPORTANT IN THESE MOMENTS, RIGHT, AND SUPPORT OUR RESEARCH AND CLINICAL COMMUNITIES.

DR. NOBLIN IS GOING TO COME IN A MINUTE. SO GET READY, LIZ. SHE'S GOING TO SHOW TODAY'S DISCUSSIONS ARE JUST A PART OF A LARGER TIMELINE AS DR. JONATHAN THOMAS REFERENCED AND WITH PHASE 1 COMING NOW AND PHASE 2 TOWARDS THE END OF THE YEAR. EARLY JANUARY WE HOPE TO BE ABLE TO PRESENT.

SO, LIZ, THE FLOOR IS YOURS. AND THANK YOU ALL FOR EVERYTHING THAT YOU'VE DONE WITH US.

CHAIRMAN IMBASCIANI: THANK YOU, ROSA.

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DR. NOBLIN: THANKS VERY MUCH. GOOD MORNING, EVERYONE. MY NAME IS LIZ NOBLIN, AND IT'S MY PLEASURE TO PROVIDE AN INTRODUCTION AND SOME BACKGROUND TO THE FOUR CONCEPTS THAT YOU WILL HEAR ABOUT TODAY.

WITHIN THIS BACKGROUND AND INTRODUCTION, THIS WILL FOCUS ON RELATING THESE CONCEPTS TO THE SAF AND CIRM'S IMPACT GOALS. I'LL ALSO TOUCH BRIEFLY ON OUR DEVELOPMENT PROCESS, AND THEN HIGHLIGHT THE LAUNCH TIMELINE ASSUMING APPROVAL TO MOVE FORWARD TODAY.

SO THE SAF OR STRATEGIC ALLOCATION FRAMEWORK WAS CIRM'S STRUCTURED APPROACH TO DIRECT OUR EFFORTS AND OUR FUNDING TO MAXIMIZE IMPACT IN THE FIELD OF REGENERATIVE MEDICINE. THE IMPACT GOALS WERE FOCUSED INTO FOUR AREAS OF ACCELERATING DISCOVERY AND TRANSLATION, CELL AND GENE THERAPY APPROVALS, ACCESS AND AFFORDABILITY FOR CIRM-FUNDED THERAPIES, AND DEVELOPING A DIVERSE WORKFORCE.

WITHIN THOSE FOUR CATEGORIES, THERE WERE SPECIFIC MEASURABLE IMPACT GOALS THAT GUIDED THE DEVELOPMENT OF OUR CONCEPTS TODAY. SO TODAY SPECIFICALLY WE WILL HEAR ABOUT THE NEW CONCEPTS THAT ARE ADDRESSING GOAL 1, WHICH WAS TO CATALYZE THE IDENTIFICATION AND VALIDATION OF AT LEAST FOUR

NOVEL TARGETS AND BIOMARKERS. GOAL NO. 4, WHICH IS PROPELLING 15 TO 20 THERAPIES TO LATE STAGE TRIALS. AND BY DESIGN, THESE CONCEPTS INCORPORATE THE IMPORTANT ELEMENTS OF GOAL 5, WHICH IS ENSURING THAT EVERY BLA-READY PROGRAM HAS A STRATEGY FOR ACCESS AND AFFORDABILITY.

FOLLOWING THE APPROVAL OF THE SAF IN SEPTEMBER, AS HAS BEEN MENTIONED, THIS KICKED OFF AN INTENSIVE PROCESS TO THEN CONVERT THOSE IMPACT GOALS INTO REAL FUNDING OPPORTUNITIES FOR OUR RESEARCH INSTITUTIONS. SO PENDING THE BOARD'S DECISION TODAY, WE HAVE BEEN COLLABORATING WITH ALL OF OUR COLLEAGUES AT CIRM AND ARE READY TO LAUNCH THOSE FUNDING OPPORTUNITIES THROUGHOUT THE REMAINDER OF THE CALENDAR YEAR.

IN ADDITION TO THAT, WE WILL THEN BEGIN THE DESIGN AND DEVELOPMENT OF THE NEXT PHASE OF CONCEPTS FOR DISCUSSION WITH THE BOARD IN THE COMING MONTHS. THIS IS ON TOP OF OUR ONGOING WORK TO MANAGE OUR ACTIVE PORTFOLIO OF AWARDS AND CONTINUING TO ASSESS OUR PROGRAMS.

SO TO TOUCH BRIEFLY ON OUR PROCESS FOR DESIGNING THESE CONCEPTS, AGAIN, THIS ALL BEGAN WITH THE APPROVAL OF THE SAF AND THE IMPACT GOALS THERE. THERE WAS DATA ANALYSIS THAT WAS PART OF THE SAF.

AND IN ADDITION, THERE'S BEEN CONTINUED ANALYSIS OF CIRM'S PORTFOLIO, OF THE WORK THAT WAS DONE AS PART OF THE NEURO TASK FORCE, LOOKING AT THE CURRENT STATE OF THE CELL AND GENE THERAPY LANDSCAPE, AND ALSO THE OUTCOMES OF CIRM'S HISTORICAL AWARDS. AND SO ALL OF THOSE DATA HAVE BEEN INCORPORATED INTO THE CONCEPTS THAT THE TEAM WILL PRESENT TODAY.

SO NOW JUST TO ORIENT US ALL TO WHAT'S COMING AND GIVE A VERY BRIEF OVERVIEW, OUR CONCEPTS SPAN MULTIPLE PHASES OF THE RESEARCH AND DEVELOPMENT PIPELINE. STARTING WITHIN THE DISCOVERY PHASE, WE HAVE THE DISC4 AND DISC5 CONCEPTS, WHICH BOTH FOCUS ON TEAM-BASED SCIENCE AND HAVE EITHER A SMALLER TEAM STRUCTURE IN DISC5 OR A LARGE TEAM STRUCTURE IN DISC4 TO LEAD TO THOSE DISCOVERIES IN REGENERATIVE MEDICINE.

WITHIN THE DISC4 CONCEPT, YOU WILL ALSO HEAR ABOUT CYCLICAL FOCUS AREAS THAT WERE DRIVEN BY NTF RECOMMENDATIONS AND OUR PORTFOLIO. PDEV IS CIRM'S NEW PRECLINICAL DEVELOPMENT FUNDING OPPORTUNITY, WHICH INTEGRATES OUR FORMER TRANSLATIONAL FUNDING OPPORTUNITY AS WELL AS OUR CLIN1 FUNDING OPPORTUNITY INTO A STREAMLINED PATH SOLELY FOCUSED ON GETTING PROMISING CANDIDATES TO IND.

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AND THEN FINALLY, WITHIN OUR CLINICAL TRIAL STAGES, WE HAVE UPDATES TO THE CLIN2 PROGRAM THAT HAVE BEEN MADE TO ALIGN WITH THE SAF IMPACT GOALS AND RECOMMENDATIONS. AND IN PDEV AND CLIN2 WE'LL ALSO DISCUSS RECOMMENDATIONS FOR PREFERENCE SETTING THAT, AGAIN, ARE ALIGNED WITH MANDATES FROM PROP 14 AS WELL AS THE STRATEGIC ALLOCATION FRAMEWORK.

AND THEN FINALLY, THIS VERY COLORFUL SLIDE JUST GIVES YOU A SNAPSHOT OF THE WORK THAT'S AHEAD FOR US PENDING BOARD DECISION TODAY. WE ARE POISED WITH ALL OF THE BACKGROUND WORK ONGOING TO OPEN THESE FUNDING OPPORTUNITIES THROUGHOUT THE SPRING AND THEN BEGIN OUR FIRST ROUND OF GRANTS WORKING GROUP REVIEWS IN THE FALL WITH THE FIRST SET OF APPLICATIONS FOR ARS RECOMMENDATIONS SCHEDULED TO COME IN EARLY 2026. THIS IS IN ADDITION TO CONTINUING THE CURRENTLY OPEN DISC-0 FUNDING OPPORTUNITY AND ALSO RELAUNCHING THE COMMUNITY CARE CENTERS FUNDING OPPORTUNITY THAT WE WILL HEAR ABOUT LATER TODAY.

SO WITH THAT, I'M SURE YOU'RE ALL EXCITED TO GET INTO SOME OF THE SPECIFICS. SO I WOULD LOVE TO HAND THINGS OVER TO DR. KELLY SHEPARD, DIRECTOR OF DISCOVERY AND EDUCATION, TO PRESENT THE DISC5

CONCEPT.

CHAIRMAN IMBASCIANI: THANK YOU, LIZ.

DR. SHEPARD: GOOD MORNING, DISTINGUISHED BOARD MEMBERS, MR. CHAIRMAN, MADAM CHAIRWOMAN, MEMBERS OF THE PUBLIC, AND THE CIRM TEAM. IT'S MY PLEASURE TO COME HERE FOR YOU TODAY AND KICK OFF A SERIES OF DISCUSSIONS ABOUT THESE NEW CONCEPTS THAT WE ARE BRINGING FOR YOUR CONSIDERATION TODAY. WE'RE GOING TO BEGIN WITH DISC5.

BEFORE WE DO THAT, I JUST WANT TO INTRODUCE THE OVERALL FORMAT OF MY PRESENTATION BECAUSE THIS IS GOING TO BE A FORMAT THAT WILL BE REPEATED FOR EACH SERIES OF CONCEPTS THAT YOU WILL BE HEARING ABOUT TODAY AND HOPEFULLY KEEP THINGS ORGANIZED IN YOUR MINDS AS WELL AS IN OUR PRESENTATIONS.

SO WE'LL BEGIN WITH A LITTLE BIT OF BACKGROUND ABOUT THESE DISCOVERY PROGRAMS AND HOW THEY'RE ALIGNED WITH THE SAF GOALS. WE'LL THEN INTRODUCE THE OBJECTIVE OF DISC5 AS WELL AS THE SCOPE AND THE STRUCTURE OF THESE AWARDS, AND THEN WE'LL ONCE AGAIN GO OVER THE TIMELINE FOR WHEN WE EXPECT TO BE ABLE TO BRING THESE NEW OPPORTUNITIES TO OUR CONSTITUENTS. AND FINALLY, A REQUEST FOR MOTION BEFORE WE MOVE ON TO THE NEXT SECTION WHICH

MY COLLEAGUE DR. CHAN LEK TAN WILL INTRODUCE THE DISC4 OPPORTUNITY.

SO LET'S JUST BEGIN BY BRIEFLY RESTATING WHICH STRATEGIC ALLOCATION FRAMEWORK RECOMMENDATION THAT THIS PROGRAM WAS DESIGNED TO SUPPORT, WHICH IS THE FIRST GOAL: CATALYZING THE IDENTIFICATION AND VALIDATION OF AT LEAST FOUR NOVEL TARGETS AND BIOMARKERS, ENSURING INTEGRATION INTO PRECLINICAL OR CLINICAL RESEARCH FOR DISEASES IN CALIFORNIA.

BECAUSE WE HAVE TWO DISCOVERY CONCEPTS THAT WE'RE DISCUSSING TODAY, I JUST WANT TO GIVE YOU THE OVERALL VISION FOR OUR DISCOVERY PROGRAMS AND HOW THEY WORK TOGETHER TO IMPACT THIS GOAL. SO DISC4 AND DISC5 HAVE A COMMON OBJECTIVE, WHICH IS, AGAIN, REPHRASING STRATEGIC ALLOCATION FRAMEWORK GOAL 1 ESSENTIALLY, IS TO SUPPORT COMPREHENSIVE DISCOVERY RESEARCH ACROSS A DIVERSE RANGE OF DISEASES AND BOTTLENECKS TO ACCELERATE THE DEVELOPMENT OF POTENTIAL THERAPEUTICS AND BIOMARKERS IN REGENERATIVE MEDICINE.

SO THIS WILL INCLUDE TWO COMPLEMENTARY AWARD STRUCTURES THAT HAVE SOME DIFFERENCES AND SOME SIMILARITIES. SOME OF THE MOST IMPORTANT DIFFERENCES THAT WE'LL GO OVER ARE THE SCALE OF THE RESEARCH THAT IS SUPPORTED AND THE LEVEL OF THE

MATURITY OF THE RESEARCH THAT IS SUPPORTED. SO DR. NOBLIN ALREADY INTRODUCED THAT DISC4 WOULD INVOLVE LARGE MULTIDISCIPLINARY COLLABORATIONS; WHEREAS, DISC5 WILL FOCUS ON SMALLER TEAM COLLABORATIONS. AND WE'LL BEGIN TO GET INTO THE DETAILS OF DISC5 SPECIFICALLY IN MY NEXT FEW SLIDES.

NOW, IN ADDITION TO THE FACT THAT DISC4 AND DISC5 ARE DESIGNED TO WORK IN A COMPLEMENTARY FASHION, THEY ARE ALSO DESIGNED TO BE COMPLEMENTARY TO ONGOING INFRASTRUCTURE PROGRAMS AND OTHER INITIATIVES AT CIRM THAT ARE EITHER ALREADY ESTABLISHED OR IN DEVELOPMENT. THESE INCLUDE THINGS LIKE PROGRAM AND GRANTEE MEETINGS, SUCH AS AN UPCOMING REMIND CONFERENCE THAT WE ARE PLANNING TO BRING THE DIFFERENT TEAMS INVOLVED IN OUR REMIND PROGRAM TOGETHER, SHARE KNOWLEDGE, DEVELOP STANDARDS, DECIDE ON COLLABORATIVE CONSORTIUM TYPE OF GOALS OR SUBGOALS.

WE HAVE ESTABLISHED SOME DATA SHARING INFRASTRUCTURE AS WELL AS SOME THAT IS COMING THAT THESE PROGRAM CAN TAP INTO. IT ALSO ALLOWS THEM TO LEVERAGE INTERNAL AND EXTERNAL PARTNERSHIPS, INCLUDING PARTNERSHIPS WITH SOME OF OUR OTHER PROGRAMS SUCH AS OUR EDUCATION PROGRAMS, PROVIDE TRAINEES WHO CAN WORK WITH THESE INVESTIGATORS, AND

ALSO KNOWLEDGE AND KNOW-HOW FROM OUR SHARED RESOURCE LABORATORIES AND MANUFACTURING CENTERS THAT CAN BE SHARED AND LEVERAGED.

THAT SAID, LET'S NOW DIVE INTO DISC5. SO AGAIN, THE OBJECTIVE IS TO SUPPORT COMPREHENSIVE DISCOVERY RESEARCH ACROSS A DIVERSE RANGE OF DISEASES AND BOTTLENECKS AND TO ACCELERATE THE DEVELOPMENT OF POTENTIAL THERAPEUTICS AND BIOMARKERS IN REGENERATIVE MEDICINE THROUGH THE KNOWLEDGE THAT EMERGES FROM THIS PROGRAM.

THE APPROACH IS TO REALLY SUPPORT EXPLORATORY AND INNOVATIVE FOUNDATIONAL RESEARCH THAT WILL BE LED BY PAIRS OF INVESTIGATORS. THERE'S A WIDE VARIETY OF ACTIVITIES THAT CAN FALL IN THIS SCOPE, BUT THEY MUST BE DESIGNED TO ACHIEVE ONE OR MORE OF THESE FOLLOWING OUTCOMES: ADVANCING OUR UNDERSTANDING OF HUMAN STEM AND PROGENITOR CELLS AS THEY PERTAIN TO HUMAN HEALTH AND/OR HUMAN DISEASE, ADVANCING THE USE AND IMPACT OF STEM CELLS IN THE EXPLORATION OF DISEASE MECHANISMS AND THERAPEUTIC TARGET DISCOVERY. SO THAT'S USING STEM CELLS AS A TOOL BASICALLY TO UNCOVER NEW DISEASE TARGETS AND MECHANISMS. IDENTIFY BIOLOGICAL INSIGHTS TO ADDRESS KEY BOTTLENECKS IN STEM CELL AND GENE THERAPY AND OTHER REGENERATIVE MEDICINE APPROACHES. AND

FINALLY, ADVANCING APPLICABILITY OF STEM CELLS AND GENE THERAPY AND OTHER REGENERATIVE MEDICINE APPROACHES TO DIVERSE HUMAN POPULATIONS.

SOME OF THESE GOALS SOUND FAMILIAR TO YOU BECAUSE THEY ARE CORE TO OUR MISSION, AND THEY'VE BEEN A PART OF OUR ONGOING DISC-0 PROGRAM THAT WE HAVE BEEN SUPPORTING FOR THE PAST COUPLE OF YEARS. HOWEVER, DISC5 IS A NEW CONCEPT THAT WE BUILT STARTING WITH THAT SUCCESSFUL FRAMEWORK OF DISC0, BUT THEN IMPROVING IT IN SEVERAL WAYS TO HELP IT ALIGN MORE EFFECTIVELY WITH THE STRATEGIC ALLOCATION FRAMEWORK GOAL NO. 1.

AND THE TWO MOST IMPORTANT CHANGES OR IMPROVEMENTS THAT WE WILL BE DISCUSSING TODAY INVOLVE SHIFTING FROM A SINGLE INVESTIGATOR-DRIVEN APPROACH TO A COLLABORATION OR SMALL TEAM DRIVEN APPROACH. SO RATHER THAN BEING LED BY A SINGLE PI, THIS NEW PROGRAM WILL HAVE A DUAL HEAD PROGRAM STRUCTURE WHERE A CO-I AND A CO-INVESTIGATOR CONTRIBUTE EQUALLY, AND THEY ARE EXPECTED TO BRING DIFFERING APPROACHES AND EXPERTISE TO CREATE A NEW TYPE OF SYNERGY TO BEAR ON A PROBLEM.

THE SECOND IS AN INCREASED EMPHASIS ON INNOVATION AND ENHANCING EXPLORATORY, HIGH RISK, HIGH REWARD TYPE OF RESEARCH.

THIS TABLE IS SHOWING THE GENERAL AWARD STRUCTURE. WE'RE GOING TO GO INTO A LITTLE BIT MORE DETAIL ABOUT A COUPLE OF THESE FEATURES. WHAT I WANT TO HIGHLIGHT HERE IS THAT THIS IS AN OPPORTUNITY THAT WE EXPECT TO RECUR ANNUALLY. IT WILL BE A THREE-YEAR AWARD. SO IT'S FINANCIAL SUPPORT FOR THREE YEARS OF RESEARCH OPEN TO CALIFORNIA FOR-PROFIT, NON-PROFIT INSTITUTIONS LED BY A TEAM OF TWO INVESTIGATORS. THE MAXIMUM AWARD AMOUNT WILL BE $2.5 MILLION. AND AT THIS LEVEL WE EXPECT TO BE ABLE TO SUPPORT ABOUT 15 TO 20 NEW AWARDS EVERY YEAR FOR AN ANNUAL BUDGET OF $50 MILLION.

SO JUST A COUPLE OF WORDS ABOUT THE TOTAL AWARD CAP, WHICH IS SOMETHING THAT IS DIFFERENT THAN DISC-0. IN DISC0 WE HAVE AN AWARD CAP BASED ON DIRECT PROJECTS COSTS, NOT OVERHEAD, WHICH WAS 1 TO $1.5 MILLION. IN THIS NEW AWARD STRUCTURE FOR DISC5, WE'RE PROPOSING A TOTAL AWARD COST CAP OF $2.5 MILLION. WE DECIDED FOR THIS APPROACH BECAUSE IT REMOVES A DISINCENTIVE FOR MULTI-INSTITUTIONAL COLLABORATIONS SINCE INSTITUTIONS SEPARATE FROM THE PRINCIPAL INVESTIGATOR RECEIVE THEIR FUNDS THROUGH A SUBCONTRACT TO THE PRIMARY GRANTEE. AND SECONDLY, THIS IS TO CREATE CONSISTENCY IN THE WAY WE'RE

HANDLING AWARD AMOUNTS BETWEEN AND ACROSS ALL OF OUR PROGRAMS, AND IT MAKES THINGS EASIER FOR APPLICANTS WHO ARE LOOKING AT MULTIPLE PROGRAMS WHEN THERE'S NOT A DIFFERENT RULE FOR EVERY PROGRAM.

SO IN ORDER TO BE ELIGIBLE TO SUBMIT A DISC5 APPLICATION, PROJECTS MUST ADDRESS A KEY KNOWLEDGE GAP OR A RESEARCH BOTTLENECK THAT COULD LEAD TO ONE OR MORE OF THOSE EXPECTED OUTCOMES THAT I INTRODUCED A COUPLE SLIDES AGO. THEY SHOULD FOCUS ON AND CENTER ON STUDIES THAT EMPLOY HUMAN STEM CELLS AND/OR GENETIC RESEARCH AS PART OF THE CENTRAL APPROACH OR HYPOTHESIS. WE DO ALLOW USE OF NONHUMAN CELLS OR MODELS IF THERE'S STRONG JUSTIFICATION AND HOW THAT WOULD BE IN SUPPORT OF THE OVERALL GOAL WHICH IS TO UNDERSTAND HUMAN BIOLOGY AND HUMAN DISEASE BIOLOGY.

AGAIN, THE APPLICANTS MUST BE CALIFORNIA NON-PROFIT OR FOR-PROFIT RESEARCH INSTITUTIONS. THE CORE TEAM, AS I MENTIONED PREVIOUSLY, WILL BE LED EQUALLY BY TWO INVESTIGATORS, A PRINCIPAL INVESTIGATOR WHO IS DESIGNATED AS SUCH AS THEY ARE THE MAIN POINT OF CONTACT WITH CIRM STAFF, AND THE CO-INVESTIGATOR WHO MUST BE FROM A DIFFERENT LAB FROM THE PRINCIPAL INVESTIGATOR.

THIS PROGRAM ALSO REQUIRES EXPERTISE OF A

DATA PROJECT MANAGER WHERE DATA IS GENERATED AND IS EXPECTED TO BE SHARED. AND THE MINIMUM EFFORT REQUIREMENTS FOR THE CORE TEAM MEMBERS IS 5 PERCENT.

WE ANTICIPATE A VERY LARGE VOLUME OF THESE APPLICATIONS BASED ON PRECEDENT FROM ALL OF OUR EARLIER DISCOVERY STAGE PROGRAMS. WE PLAN TO USE OUR ESTABLISHED TWO-STAGE REVIEW PROCESS IN ORDER TO PROCESS AND REVIEW THESE APPLICATIONS. I'LL BRIEFLY GO OVER THIS. THIS WAS A PROCESS THAT WAS ESTABLISHED BACK IN 2015 WHEN WE FIRST INTRODUCED DISCOVERY PROGRAMS. AND IT WAS SPECIFICALLY DESIGNED TO HELP US HANDLE PROGRAMS WHERE WE RECEIVE LARGE NUMBER OF APPLICATIONS.

SO APPLICANTS WILL SUBMIT A FULL APPLICATION. AND THEN FROM THAT POOL, IT WILL BE PRESENTED TO THE GRANTS WORKING GROUP MEMBERS WHO WILL GO THROUGH AND REVIEW THEM, AND EACH WILL BE ALLOWED TO SELECT A SPECIFIC NUMBER OF APPLICATIONS THAT WILL MOVE FORWARD TO THE SECOND STAGE OF REVIEW. WE CALL THAT PROCESS POSITIVE SELECTION. THOSE THAT ARE SELECTED MOVE FORWARD TO FULL REVIEW, WHICH IS THE CONVENTIONAL GRANTS WORKING GROUP REVIEW THAT YOU ARE ALL FAMILIAR WITH, RESULTS IN SCORING OF APPLICATIONS AND RECOMMENDATIONS FOR FUNDING THAT THEN COME TO OUR APPLICATION REVIEW

SUBCOMMITTEE FOR DECISIONS.

ONE OTHER ATTRIBUTE I WANT TO MENTION IS THAT THIS PROGRAM WILL INCLUDE DATA SHARING AND MANAGEMENT PLANS. THIS IS SOMETHING THAT WE INTRODUCED IN DISC-0 AND HAVE BEEN REFINING AND IMPROVING AND EXPANDING UPON. SO WE DO EXPECT THAT THE DATA GENERATED FROM OUR FUNDING WILL BE SHARED AND WILL ADHERE TO FAIR PRINCIPLES THAT MEANS THE DATA WILL BE FINDABLE, ACCESSIBLE, INTEROPERABLE, AND REUSABLE. IN ORDER FOR THAT TO HAPPEN, IT REQUIRES CAREFUL MANAGEMENT AND CURATION DURING THE COURSE OF THE AWARD.

SO WE ARE REQUIRING THAT OUR APPLICANTS HAVE A PLAN ABOUT HOW THEY'RE GOING TO DO THIS, AND WE MONITOR IT ONCE THE AWARDS ARE FUNDED. WE WILL ALSO REQUIRE THAT DISC5 GRANTEES COORDINATE WITH OUR ONGOING AND ANY FUTURE DATA INITIATIVES THAT WE ANTICIPATE.

SO WHEN WILL THIS PROGRAM COME? WELL, PENDING CONCEPT APPROVAL TODAY, WE WOULD ANTICIPATE POSTING THE PROGRAM ANNOUNCEMENT THIS SUMMER AND THEN HAVING APPLICATIONS OPEN IN THE FALL.

NOW, THAT MIGHT SEEM FAR OFF, BUT ACTUALLY, AS DR. NOBLIN MENTIONED, WE DO HAVE AN OPEN DISC0 OPPORTUNITY AT THIS TIME WITH

APPLICATIONS DUE ON APRIL 10TH IN FACT. AND SO WE WILL BE CONTINUING TO SUPPORT THIS VERY IMPORTANT STAGE OF RESEARCH OVER THE NEXT FEW MONTHS WHILE WE'RE WAITING FOR THIS NEW PROGRAM TO COME OUT AND CREATE NEW OPPORTUNITIES FOR THESE INVESTIGATORS TO SUPPORT THEIR IMPORTANT AND IMPACTFUL RESEARCH.

SO WE ARE GOING TO BE REQUESTING YOUR APPROVAL FOR THE PROPOSED DISC5 CONCEPT PLAN. BUT BEFORE WE GO INTO THAT, I WOULD BE HAPPY TO TAKE ANY QUESTIONS OR LISTEN TO ANY OF YOUR FEEDBACK.

CHAIRMAN IMBASCIANI: THANK YOU, KELLY, FOR THAT WONDERFUL PRESENTATION. I SEE WE HAVE QUESTIONS. WE'LL START WITH KIM BARRETT.

DR. BARRETT: THANK YOU FOR A VERY CLEAR PRESENTATION. I WASN'T ENTIRELY SURE HOW YOU ARRIVED AT THE RECOMMENDATION FOR TWO CO-INVESTIGATORS. AND WILL YOU ELABORATE THAT FURTHER? WHY DID YOU DECIDE ON TWO? DO THEY HAVE TO BE FROM DISTINCT DISCIPLINES? WHAT'S THE PLAN?

DR. SHEPARD: YES. SO WE HAVE CONSIDERED DIFFERENT CONFIGURATIONS. WE NOW HAVE SOME EXPERIENCE WITH FOUR OR FIVE CO-INVESTIGATORS FROM THE PILOT DISC4 PROGRAM, WHICH IS KNOWN AS REMIND. WE ALSO HAVE EXPERIENCE WITH OUR CURRENT DISC0 OPPORTUNITY WHERE WE OFFER TWO TRACKS, A SINGLE

INVESTIGATOR TRACK AND A TEAM TRACK, WHICH SUPPORTED UP TO TWO OR THREE. AND WE'VE COME TO REALIZE THROUGH THESE DISCUSSIONS THAT WE THINK FOR THIS SMALLER, FOR APPROXIMATELY THIS AMOUNT OF FUNDING TWO IS REALLY IDEAL. IT DOESN'T MEAN THERE CAN'T BE MORE INVESTIGATORS INVOLVED. IT JUST MEANS THAT THERE ARE TWO THAT ARE LEADING. THEY CAN HAVE AS MANY COLLABORATORS IN THE USUAL FASHION AS THEY LIKE.

BUT WE THINK TWO IS A GOOD NUMBER, AND WE ARE REQUIRING THAT THEY HAVE SOME DIFFERENCES THEY BRING TOGETHER TO CREATE SOMETHING NEW. OTHERWISE, IT WOULDN'T BE TERRIBLY DIFFERENT THAN A TRADITIONAL AWARD WHICH ALSO ALLOW CO-INVESTIGATORS AND COLLABORATORS. BUT IN THIS CASE WE'RE PUTTING THEM ON EQUAL FOOTING, AND WE'RE ASKING THEM TO BRING THEIR OWN INDIVIDUAL EXPERTISE AND APPROACHES TO THE TABLE SO THAT THE COMBINATION CREATES A UNIQUE COLLABORATIVE SYNERGY. AND WE ENVISION THAT THAT IS SOMETHING THAT THE REVIEWERS WILL BE ABLE TO CONTEMPLATE THE VALUE OF THROUGH THE REVIEW CRITERIA, EMPHASIZING THE SYNERGY AND THE FACT THAT THE COMPOSITION OF THE COLLABORATION CREATES A TOTAL THAT IS GREATER THAN THE SUM OF THE PARTS.

DR. BARRETT: CAN YOU EDUCATE ME WHAT

WOULD HAPPEN IF ONE OF THE TWO INVESTIGATORS WAS NO LONGER ABLE TO CONTINUE THE PROJECT OR MOVED OUTSIDE OF CALIFORNIA?

DR. SHEPARD: SO WE WOULD TREAT THAT SITUATION THE SAME WAY AS WE TREAT A SITUATION WHEN A PRINCIPAL INVESTIGATOR IS LEAVING THE STATE OR CAN NO LONGER PARTICIPATE IN THE PROJECT. THEY WOULD SUBMIT -- IF THEY WANTED TO CONTINUE THE AWARD, THEY WOULD HAVE TO SUBMIT A PRIOR APPROVAL REQUEST TO CIRM WITH THE NEW REPLACEMENT INVESTIGATOR, THEIR CV, THEIR EXPERTISE, AND A STRONG JUSTIFICATION FOR HOW REPLACING THAT INDIVIDUAL WOULD NOT NEGATIVELY IMPACT THE PROJECT. AND THEN IT WOULD BE OUR DECISION WHETHER OR NOT THAT WOULD BE ACCEPTABLE.

CHAIRMAN IMBASCIANI: THANK YOU. JUDY.

DR. GASSON: THANK YOU, KELLY, FOR THAT PRESENTATION. I HAVE A QUESTION AND A COMMENT.

IN TERMS OF THE POSITIVE SELECTION, YOU'RE ANTICIPATING YOU MIGHT GET AS MANY AS 150 TO 200 APPLICATIONS, AND THIS IS AN OPPORTUNITY THAT ARISES ONCE A YEAR. SO HOW MANY APPLICATION OUT OF THAT POOL DO YOU EXPECT WILL ACTUALLY GO TO A FULL REVIEW?

DR. SHEPARD: BASED ON WHAT WE'VE BEEN DOING TRADITIONALLY, WE TYPICALLY TAKE BETWEEN 40

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AND 50 TO REVIEW.

DR. GASSON: MY COMMENT ON THE DATA SHARING IS WHAT KIND OF GUIDANCE IS GOING TO BE GIVEN TO THE INVESTIGATORS IN TERMS OF WHAT TYPES OF DATA AND HOW THEY'RE TO BE SHARED AND WHO'S DECIDING ON THAT POLICY?

DR. SHEPARD: WE ACTUALLY HAVE SOME GUIDANCE THAT'S POSTED ON OUR WEBSITE, AND WE HAVE A NEW FUNCTION ON OUR TEAM, THE DATA INFRASTRUCTURE, WHO HAS DEVELOPED -- WE ACTUALLY HAVE A PROCESS THAT HAS BEEN ESTABLISHED AND WE'VE BEEN PILOTING AND USING WITH DISC0 WHERE WE INTAKE. WE BASICALLY HAVE THEM CREATE A CATALOG OF THE DIFFERENT TYPES OF DATA THAT THEY'RE PRODUCING IN THE AWARD, PROCESSED AND UNPROCESSED, AND THE METADATA STANDARDS THAT WILL BE ASSOCIATED WITH AND WHERE THEY'RE GOING TO DEPOSIT IT.

DR. JANIE BYRAM IS LEADING THAT EFFORT, AND SHE'S NOT HERE TO SPEAK ABOUT IT, BUT I WANT TO HAND THE MICROPHONE TO ROSA IF YOU WANT TO SAY ANYTHING FURTHER THAN THAT. SORRY. I THOUGHT YOU WANTED TO SAY SOMETHING.

DR. CANET-AVILES: WHAT I WAS GOING TO SAY IS THAT THERE IS -- AS KELLY WAS VERY WELL MENTIONING, WE HAVE THIS DATA FUNCTION, DATA

INFRASTRUCTURE FUNCTION LED BY JANIE BYRAM. AND ONE OF THE THINGS THAT WE ARE GOING TO PRESENT TO THE BOARD NEXT IS A DATA DASHBOARD AS WELL THAT WE HAVE CREATED WHERE PEOPLE WILL BE ABLE TO GO INTO OUR CIRM WEBSITE AND CLICK AND SEE WHERE THE DATA THAT HAS BEEN GENERATED WITH CIRM FUNDING IS AND WHAT KIND OF DATA.

BUT IN TERMS OF TELLING THEM THE GUIDELINES, WE ACTUALLY STARTED THIS TWO AND A HALF YEARS AGO, AND WE MODELED IT TO THE DATA MANAGEMENT AND SHARING POLICIES OF THE NIH. SO WE DERIVE FROM THAT SO THAT WE CAN ALIGN WITH THE NIH AND WORK WITH THEM AND LEVERAGE THEIR DATA AS WELL AND INFRASTRUCTURE. THANK YOU.

CHAIRMAN IMBASCIANI: PAT.

DR. LEVITT: SO THE CONCEPT PLAN IN TERMS OF THE CONTENT AND THE FOCUS IS GREAT. I HAVE SOME QUESTIONS ABOUT THE POSITIVE SELECTION PLAN.

IN ONE OF THE DOCUMENTS, THE FIRST SELECTION STARTS AT 300 APPLICATIONS. HOW LONG IS THE APPLICATION? HOW MANY PAGES IS A DISC5 APPLICATION? LIKE FOR AN R21 AT NIH, IT'S SIX PAGES FOR THE RESEARCH PLAN AND A SPECIFIC AIMS PAGE. SO IT'S A SEVEN-PAGE DOCUMENT OF CONTENT, AND THEN YOU'VE GOT BUDGET AND ET CETERA. WHAT'S THE LENGTH

OF IT?

DR. SHEPARD: IT'S NOT TERRIBLY DIFFERENT THAN THAT. THERE'S A SIGNIFICANCE AND IMPACT SECTION, WHICH IS ONE TO TWO PAGES. THEN THERE'S THE RESEARCH PLAN. ONE THING THAT MIGHT BE DIFFERENT IS WE HAVE BEEN ASKING FOR THE SPECIFIC AIMS SEPARATELY AND PRELIMINARY DATA SECTION SEPARATELY FROM THE RESEARCH PLAN, BUT WE'RE TALKING ABOUT MAKING EVERYTHING MORE EFFICIENT AND STREAMLINED IN THE NEW VERSIONS OF OUR APPLICATION. SO WE'RE THINKING ABOUT COMBINING THAT.

WE HAVE BEEN RESPONSIVE AND WE'VE HEARD THE CONCERNS DISCUSSED AT THE BOARD AND AMONGST OUR APPLICANTS ABOUT A LOT OF SECTIONS AND LENGTHY THINGS. SO WE'RE DEFINITELY STREAMLINING THINGS AND COMBINING SECTIONS WHERE NECESSARY. I DON'T THINK IT'S SUBSTANTIALLY MORE THAN WHAT THEY'VE BEEN USED TO OVER THE YEARS AND NOT TERRIBLY DIFFERENT FROM WHAT THEY WOULD PUT INTO AN R21 APPLICATION.

DR. LEVITT: RIGHT. SO WITH THIS NUMBER STARTING AT 300, MY GUESS IS THAT IN TERMS OF ADMINISTRATIVE CRITERIA, JUST MEETING THE GOALS OF CIRM, THERE'S GOING TO BE A SMALL NUMBER THAT ARE NOT GOING TO QUALIFY. THEY'RE ALL GOING TO BE STEM CELL, GENE THERAPY BASED, WHATEVER DISCOVERY AREAS,

AND CERTAINLY THE DISEASE AREAS, WHICH IS VERY BROADLY DEFINED BY CIRM, IS GOING TO BE MET.

SO ABOUT 50 PERCENT OF THOSE ARE GOING TO GO AWAY THROUGH THE POSITIVE SELECTION PROCESS. THOSE ARE FULL APPLICATIONS WHERE THEY WON'T GET A FULL REVIEW, RIGHT?

DR. SHEPARD: YES. SO THE APPLICATIONS THAT ARE SUBMITTED ARE FULL APPLICATIONS. SO THE GRANTS WORKING GROUP LOOK AT THEM, AND THERE ARE SECTIONS THAT ARE MORE KIND OF HIGH LEVEL OVERVIEWS THAT THEY LOOK AT FIRST TO HELP THEM KIND OF PARSE HOW THEY'RE GOING TO GO THROUGH THEM. THEY HAVE ACCESS TO THE ENTIRE APPLICATION HOWEVER SO THEY CAN LOOK AS DEEPLY AS THEY LIKE. BUT THEIR RESPONSIBILITY IS TO GO THROUGH AND SELECT THE ONES THAT THEY THINK ARE THE MOST INTERESTING OR MOST IMPACTFUL BASED ON THE REVIEW CRITERIA. AND THEN THOSE GET FORWARDED FOR THE SECOND STAGE OF REVIEW.

THE ONES THAT DO NOT PASS, THE ACTION IS JUST ENDED ON THEM, AND THEY CAN REAPPLY IN THE FUTURE TO THIS OPPORTUNITY.

DR. LEVITT: RIGHT. SO THEY HAVE TO WAIT ANOTHER YEAR.

SO MY CONCERN IS HAVING -- GOING THROUGH A FULL APPLICATION PROCESS AND ENDING UP WITH ABOUT 30

TO 50 THAT ARE GOING TO BE FULLY REVIEWED, THERE'S OTHER CONCEPT PLANS THAT ARE GOING TO BE DISCUSSED IN WHICH THERE'S AN LOI, THERE'S LOTS OF CONVERSATION WE'VE HAD ABOUT LOI'S. SO I'M NOT UNDERSTANDING WHY THE LOI IS NOT BEING USED HERE WHERE IT BASICALLY SAVES THE INVESTIGATOR TIME AND TO SOME EXTENT, SPEAKING AS AN INVESTIGATOR WHO WRITES GRANTS ALL THE TIME, AGONY OF WRITING A FULL PROPOSAL AND THEN BASICALLY 80 PERCENT OR MORE ARE GOING TO GO WITHOUT A FULL REVIEW.

THAT'S A REALLY DIFFICULT PILL TO SWALLOW AS OPPOSED TO AN LOI WHERE THERE'S INFORMATION THAT YOU'RE ASKING FOR -- I'M NOT GOING TO GO INTO IT NOW -- BUT LOOKS QUITE APPROPRIATE AND SAVES BOTH CIRM TIME AS WELL AS THE INVESTIGATOR'S TIME IN TERMS OF WRITING A FULL PROPOSAL.

DR. SHEPARD: I WOULD SAY THAT THE REASON THAT WE'RE PROPOSING THIS METHOD IS BECAUSE IT HAS BEEN WORKING FOR US. AND I'VE BEEN AT CIRM FOR A LONG TIME, AND I THINK DR. SAMBRANO WILL TALK ABOUT THIS. WE'VE TRIED VARIOUS DIFFERENT TWO-STEP APPLICATION PROCESSES IN THE PAST. WHILE WE'RE GETTING AROUND 150 OR SO APPLICATIONS THROUGH THIS METHOD, WHEN WE HAD A SHORT, NOT AN LOI, BUT A PREAPPLICATION WHICH IS SIMILAR TO AN LOI, WE WERE

GETTING 350, 400. AND I THINK IF WE DID THAT, WE COULD EASILY SEE -- IN THIS CLIMATE WE COULD SEE THOUSANDS. WE'RE LIMITED IN HOW MANY MEMBERS OF THE GRANTS WORKING GROUP CAN PARTICIPATE IN REVIEW OF APPLICATIONS.

SO AN LOI ISN'T AN APPLICATION, BUT AN APPLICATION HAS TO BE REVIEWED BY THE GRANTS WORKING GROUP. SO IT CREATES -- WE HAVE TO WORK WITHIN OUR STATUTE. I'M HAPPY TO LET DR. SAMBRANO SPEAK ON THIS MORE IF YOU HAVE FURTHER QUESTIONS BECAUSE THIS IS REALLY HIS REALM AND HE'S BEEN INVOLVED IN ALL OF THE DESIGN OF ALL OF THESE PROCESSES AND COULD PROBABLY DO A BETTER JOB THAN ME.

DR. SAMBRANO: YOU DID GREAT. YES, I WILL SPEAK MORE ABOUT THIS. WE TALKED AND I UNDERSTAND THE CONCERN. I THINK THERE IS A BURDEN ON APPLICANTS THAT WE ARE TRYING TO ALSO ACCOUNT FOR, THAT THERE'S A CERTAIN THRESHOLD THEY HAVE TO MEET IN ORDER TO APPLY.

WE HAVE BEEN COGNIZANT OF THAT WHILE AT THE SAME TIME TRYING TO MANAGE THE NUMBERS OF APPLICATIONS THAT WE CAN DEAL WITH. SO AS KELLY MENTIONED, THERE IS AN EXPECTATION THAT IF THE NUMBER IS SO HIGH, THAT IT WOULD BE BECOME VERY DIFFICULT FOR US TO EVEN MANAGE WHAT'S AN LOI.

ON THE OTHER HAND, I ALSO WANT TO SAY THAT PART OF WHAT I WANTED TO EXPRESS IN MY PRESENTATION A LITTLE LATER IS THAT THERE'S A LEVEL OF FLEXIBILITY THAT WE WANT TO BE ABLE TO EXERCISE IN PIVOTING FROM ONE METHOD TO ANOTHER IF THE NEED ARISES, MEANING YOUR SUGGESTION IS WHY NOT USE THE LOI OR PRESUBMISSION PROCESS IN THIS CASE. IF THE NUMBERS ARE SUCH THAT WE CAN DO THAT AND THAT IT MAKES SENSE FOR THE PROGRAM TO PLUG IT IN, IT'S SOMETHING THAT WE COULD CONSIDER FOR FUTURE ITERATIONS.

AT THIS TIME WE'RE WORKING ON WHAT WE KNOW WITH THE POSITIVE SELECTION FOR THIS PROGRAM THAT BASICALLY MIRRORS DISC0, AND WE ARE TRYING THE LOI PRESUBMISSION PROCESS IN THE PDEV AND DISC4 WHICH ARE NEW PROGRAMS. AND WE WANT TO SEE HOW THAT GOES. THOSE PROGRAMS ALSO HAVE MUCH LARGER APPLICATIONS THAT WOULD BE A MUCH GREATER BURDEN FOR THEM TO FILL OUT IF THEY WERE OTHERWISE TO COME IN THROUGH A PROCESS LIKE POSITIVE SELECTION.

DR. LEVITT: OKAY. PART OF THE CONCEPT PLAN, I THINK IT WAS IN THE CONCEPT PLAN, I THINK IT'S THE CONCEPT PLAN, IN TERMS OF FOCUS AREAS. CAN YOU ELABORATE ON THAT?

DR. SHEPARD: FOR THIS PROGRAM, DISC5,

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THERE ARE NO FOCUS AREAS. IT'S OPEN AS LONG AS IT ADDRESSES THOSE MISSION-SPECIFIC OUTCOMES THAT I MENTIONED, SUCH AS USING STEM CELLS AND BASICALLY THE PROPOSITION 14 REQUIREMENTS. THE FOCUS AREAS THAT YOU'RE THINKING ABOUT ARE GOING TO BE DISCUSSED WHEN MY COLLEAGUE, DR. CHAN LEK TAN, INTRODUCES THE DISC4 PROGRAM. I'M VERY EXCITED TO HEAR YOUR ROBUST DISCUSSION ABOUT THAT.

DR. LEVITT: SO FOR DISC5, NO NEURO-SPECIFIC FOCUS AREAS?

DR. SHEPARD: NOT PRIORITIZED. BUT, OF COURSE, JUST BASED ON HISTORICAL PRECEDENT, WE EXPECT THAT PROBABLY A THIRD OF OUR APPLICATIONS WILL BE IN NEURO.

DR. LEVITT: OKAY.

CHAIRMAN IMBASCIANI: THANK YOU, PAT. AND NOW ANNE-MARIE DULIEGE.

DR. DULIEGE: A VERY QUICK SCIENTIFIC QUESTION. YOU MENTIONED A FEW TIMES STEM CELL AND GENE THERAPY AND OTHER REGENERATIVE MEDICINE APPROACHES. VERY HIGH LEVEL, CAN YOU TELL US WHAT YOU'RE REFERRING TO VERY BRIEFLY?

DR. SHEPARD: YES. SO THERE COULD BE SITUATIONS WHERE YOU COULD TAP INTO A PATHWAY THAT CREATES ENDOGENOUS REGENERATION. POTENTIALLY WITH A

SMALL MOLECULE OR A BIOLOGIC, THIS MIGHT ACTUALLY BE CATEGORIZED AS GENE THERAPY TOO UNDER A REGULATORY REGIME. BUT BASICALLY WE'RE INTERESTED IN APPROACHES THAT REGENERATE, REPLACE, OR RESTORE LOST TISSUE. AND WHILE STEM CELLS ARE KIND OF THE MAIN WAY WE THINK ABOUT THAT HAPPENING, WE NOW HAVE GENETIC THERAPY IN OUR ARSENAL AND GENETIC APPROACHES. AND IT MAY BE POSSIBLE. OFTEN GENE THERAPY IS REPLACING A GENE THAT'S MISSING, RIGHT. BUT IT COULD BE THAT THOSE TYPES OF APPROACHES COULD BE USED, NOT NECESSARILY TO REPLACE A GENE, BUT TO REGENERATE A TISSUE THAT'S ALREADY BEEN DAMAGED BY SOME OTHER MECHANISM. AND SO WE JUST WANTED TO BE OPEN TO THOSE KINDS OF APPROACHES BECAUSE WE'RE NOT SMART ENOUGH TO IMAGINE EVERYTHING THAT MIGHT POSSIBLY COME IN, AND WE WANT TO BE ABLE TO SUPPORT SOMETHING SUPER EXCITING AND INTERESTING AND NOVEL.

DR. DULIEGE: THANK YOU. AND THANK YOU FOR YOUR EXCELLENT PRESENTATION AND THE TEAMWORK WITH YOUR COLLEAGUES.

DR. SHEPARD: THANK YOU.

CHAIRMAN IMBASCIANI: NOW THAT THE QUESTIONS -- ONE MORE QUESTION.

DR. FLOWERS: THANKS. AND THANK YOU SO MUCH FOR THE INFORMATION. I'M JUST WONDERING IF

THERE'S A PLAN FOR DISC-0 APPLICANTS WHO RECEIVE A TWO IN THE CURRENT CYCLE TO BE ABLE TO COME BACK AS A RESUBMISSION TO DISC5.

DR. SHEPARD: SO THE DISC0 APPLICANTS WILL ACTUALLY RECEIVE A SCORE OF ONE TO A HUNDRED UNDER THAT REGIME. AND 85 -- BUT SIMILARLY TO WHAT -- I'M GOING TO ADDRESS THE QUESTION WHICH IS WHAT YOU REALLY WANT TO KNOW WHICH IS WHETHER THEY CAN RESUBMIT. AND YES, THE PEOPLE WHO ARE APPLYING FOR DISC0 ARE THE CLIENTS THAT WE WOULD ANTICIPATE WOULD BE HIGHLY INTERESTED AND MOTIVATED TO APPLY FOR DISC5. AND SO WE EXPECT THAT ANYBODY WHO IS NOT SUCCESSFUL IN THIS UPCOMING DISC-0 ROUND WILL HAVE OPPORTUNITIES TO APPLY THROUGH DISC5 IN THE FUTURE.

CHAIRMAN IMBASCIANI: ELENA, THANK YOU. I'M GOING TO NOW ASK FOR A MOTION.

VICE CHAIR BONNEVILLE: SO THIS IS A LONG MOTION, BUT I'D LIKE IT MAKE A MOTION TO APPROVE THE DISC5 CONCEPT PLAN AND TO DELEGATE TO THE CEO THE AUTHORITY TO MAKE AND IMPLEMENT CHANGES TO THIS CONCEPT PLAN IN BETWEEN BOARD MEETINGS UPON CONSULTATION OF THE CHAIRS AND CO-CHAIRS OF THE ICOC SUBCOMMITTEES AND TO BRING THOSE CHANGES BEFORE THE BOARD AT THE NEXT OPPORTUNITY FOR RATIFICATION.

CHAIRMAN IMBASCIANI: THANK YOU, MADAM

VICE CHAIR. I NEED A SECOND.

DR. GASSON: SECOND.

DR. BARRETT: SECOND.

CHAIRMAN IMBASCIANI: AND A THIRD. YES. VERY GOOD. NOW MEMBERS OF THE BOARD ARE FREE TO DISCUSS THIS. DO WE HAVE ANY MEMBER OF THE PUBLIC? NO. OKAY.

MR. TOCHER: DOESN'T APPEAR SO.

CHAIRMAN IMBASCIANI: IT DOESN'T APPEAR SO. THANK YOU. LET'S PROCEED TO THE VOTE THEN.

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

MONICA CARSON. YSABEL DURON.

MS. DURON: YES.

MR. TOCHER: RICH LAJARA.

MR. LAJARA: YES.

MR. TOCHER: SHLOMO MELMED.

DR. MELMED: YES.

MR. TOCHER: CHRIS MIASKOWSKI.

DR. MIASKOWSKI: YES.

MR. TOCHER: JOE PANETTA.

MR. PANETTA: YES.

MR. TOCHER: SUZANNE SANDMEYER.

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DR. SANDMEYER: YES.
MR. TOCHER: KAROL WATSON.
DR. WATSON: YES.
MR. TOCHER: AND KEVIN XU.
DR. XU: YES.
MR. TOCHER: THANK YOU VERY MUCH. THE MOTION CARRIES, MR. CHAIR.
CHAIRMAN IMBASCIANI: KELLY, THAT WAS AN EXCELLENT PRESENTATION. THANK YOU. I JUST WANT TO MAKE SURE THAT WE'RE COGNIZANT OF PEOPLE'S TITLES. KELLY SHEPARD IS THE DIRECTOR OF DISCOVERY AND EDUCATION AT CIRM, AND SHE WAS PRECEDED BY DR. LIZ NOBLIN WHO IS A CIRM FELLOW.
DR. SHEPARD: THANK YOU VERY MUCH. AND NOW I AM EXCITED TO INTRODUCE YOU TO MY COLLEAGUE FROM THE DISCOVERY AND EDUCATION TEAM SENIOR SCIENCE OFFICER DR. CHAN LEK TAN TO TELL YOU ABOUT DISC4.
DR. TAN: THANK YOU, KELLY. THANK YOU TO THE CHAIRMAN, VICE CHAIR, MEMBERS OF THE BOARD. MY NAME IS CHAN LEK TAN. AND I'M PLEASED TO BE ABLE TO PRESENT THE DISC4 AMENDMENTS ON BEHALF OF THE CIRM TEAM.
SO IN THIS PRESENTATION I WILL QUICKLY REMIND YOU OF THE BACKGROUND TO THIS CONCEPT AMENDMENT, ITS BROAD OBJECTIVES, SCOPE, AND KEY

ELEMENTS OF THE AWARD STRUCTURE BEFORE MOVING TO A REQUEST FOR APPROVAL.

THE TWO DISCOVERY STAGE CONCEPTS THAT YOU ARE HEARING TODAY IS GUIDED BY GOAL 1 AND THE CORRESPONDING RECOMMENDATIONS TO SUPPORT COMPREHENSIVE DISCOVERY RESEARCH THROUGH THESE TWO FUNDING STRUCTURES. THE GOAL OF THESE ARE TO PRODUCE SCIENTIFIC FINDINGS THAT WILL LAY THE FOUNDATION FOR FUTURE THERAPEUTIC DEVELOPMENT, INCLUDING THROUGH PROGRAMS AT CIRM.

AS KELLY HAS ALREADY DESCRIBED, WE ARTICULATED A SIMPLE COMMON OBJECTIVE FOR BOTH DISC4 AND DISC5 BASED ON THE SAF RECOMMENDATION ITSELF. THE APPROACH THAT DISC4 WILL TAKE SHORTLY IS ONE THAT IS COMPLEMENTARY TO THE DISC5 CONCEPT. THE DISC4 CONCEPT SUPPORTS LARGE COLLABORATIVE TEAMS THAT PROPOSE EXPANSIVE STUDIES INTEGRATING MULTIPLE DISCIPLINES AND APPROACHES WITH A PRIMARY FOCUS ON DISEASE BIOLOGY.

AND AS YOU'VE ALSO HEARD, BOTH DISCOVERY PROGRAMS WILL MAKE USE OF PROGRAM INFRASTRUCTURE, SOME OF WHICH ARE BEING PILOTED IN THE REMIND PROGRAM, INCLUDING GRANTEE MEETINGS, DATA SHARING, INFRASTRUCTURE, AND THE ABILITY TO LEVERAGE INTERNAL AND EXTERNAL PARTNERSHIPS TO INCREASE SCIENTIFIC

IMPACT AND THE POTENTIAL FOR TRANSLATION.

WITH THAT INTRODUCTION OUT OF THE WAY, I'M GOING TO TURN BACK TO FOCUS SPECIFICALLY ON DISC4. JUST TO REITERATE THE KEY RATIONALE FOR THIS PROGRAM AND THE REMIND PROGRAM BEFORE IT, WHICH COMES FROM THE APPRECIATION THAT SOUND, ACTIONABLE TARGETS BASED ON STRONG BIOLOGICAL UNDERSTANDING REMAINS PERHAPS THE GREATEST BOTTLENECK FOR EFFECTIVE TREATMENTS. AND SOME OF THIS REFLECTS THE DEEP COMPLEXITIES OF BIOLOGY, OF DISEASE BIOLOGY.

SO THE TEAM SCIENCE APPROACH THAT WE ARE PROPOSING HERE WHICH INTEGRATES EVIDENCE FROM MULTIPLE DISCIPLINES AND MODALITIES IS LIKELY TO HAVE SUBSTANTIAL VALUE.

SO THE DISC4 PROGRAM WILL SUPPORT THIS MULTIDISCIPLINARY APPROACH TO DISCOVERY RESEARCH. PROPOSALS MUST AIM TO ACHIEVE ONE OR MORE OF THE FOLLOWING OUTCOMES: A BETTER UNDERSTANDING OF HUMAN DISEASE BIOLOGY THROUGH NOVEL MECHANISTIC INSIGHTS, EXTENDING HOW THESE INSIGHTS MAY APPLY TO DIVERSE POPULATIONS, AND IDENTIFYING NEW TARGETS, STRATEGIES, AND BIOMARKERS.

FOR A LITTLE BIT OF HISTORY, THE DISC4 PROGRAM WILL BE BUILT ON A FRAMEWORK PILOTED BY THE NEURO TASK FORCE WITH THE REMIND-L PROGRAM. IN THE

REMIND-L PROGRAM, TO EFFECTIVELY PRIORITIZE FUNDING, THE NEURO TASK FORCE CATEGORIZED NEUROLOGICAL DISEASES INTO CLUSTERS BASED ON SHARED MOLECULAR AND CELLULAR PATHWAYS TO PREVENT SILOED APPROACHES AND TO ENABLE DISCOVERIES TO BE ABLE TO TRANSLATE ACROSS MULTIPLE CONDITIONS.

THIS MODEL AS A FRAMEWORK WAS USED TO PRIORITIZE FUNDING FOR NEUROPSYCHIATRIC DISEASES IN THE PILOT CYCLE AND NEURODEGENERATIVE DISEASES AS YOU WILL SEE IN THE CURRENT CYCLE.

THE AMENDMENTS WE ARE PROPOSING TODAY INCLUDE TWO MAJOR CHANGES. THE FIRST IS THE EXPANSION TO SUPPORT A BROADER SET OF DISEASES WHILE CONTINUING THE FRAMEWORK THAT WAS PILOTED BY THE NEURO TASK FORCE WITH THE REMIND-L PROGRAM. THE SECOND SET OF CHANGES IS AIMED AT FACILITATING PROGRESSION TO NOVEL DISCOVERIES AND NEW PRECLINICAL EFFORTS. SO WE WANT TO POSITION THE TEAMS FOR READINESS FOR TARGET VALIDATION BY THE END OF THE AWARD WITHOUT DETRACTING FROM THE PRIMARY FOCUS ON DISEASE BIOLOGY INSIGHTS.

SO GOING TO THE AREAS OF FUNDING, IN EXPANDING FROM OUR INITIAL SPECIFIC FOCUS IN OUR PILOT CYCLE TO A BROADER OPPORTUNITY AVAILABLE ACROSS ALL DISEASE AREAS, THE CIRM TEAM WANTED TO

STRIKE A BALANCE ACROSS SEVERAL FACTORS INCLUDING THE POTENTIAL FOR EXTREMELY HIGH APPLICATION VOLUMES, ENSURING THAT WE HAVE A REVIEW PANEL WITH SUFFICIENTLY FOCUSED EXPERTISE, AND PRESERVING SOME OF THE OTHER ADVANTAGES THAT WE FOUND WITH THE MORE FOCUSED APPROACH.

IN LIGHT OF THESE CONSIDERATIONS AND WITH BOARD MEMBER FEEDBACK, WE HAVE COME TO THE FOLLOWING FORMULATION THAT IS SHOWN HERE. THE DISC4 AWARD WILL BE OPEN TO ALL ELIGIBLE PROPOSALS REGARDLESS OF DISEASE INDICATION OR RESEARCH TOPIC SO THAT PARTICULARLY IMPACTFUL AND EXCEPTIONAL PROPOSALS MAY GET A CHANCE FOR REVIEW IN ANY CYCLE.

IN PARALLEL, SELECT PREFERENCE TOPICS WILL BE PRIORITIZED FOR CONSIDERATION EACH YEAR. HAVING THESE PREFERENCE TOPICS HAS MANY ADVANTAGES AS LISTED HERE. FIRST, THEY ALLOW US TO ADDRESS THE AREAS OF OPPORTUNITIES THAT WERE IDENTIFIED BY THE NEUROSCIENCE TASK FORCE PREVIOUSLY. THEY ALLOW US TO MAXIMIZE THE POTENTIAL FOR SYNERGY AND THE POTENTIAL TO LEVERAGE COMMON EXTERNAL PARTNERSHIPS. THEY ALLOW US TO CAPITALIZE ON EMERGING OPPORTUNITIES IN THE RESEARCH LANDSCAPE AND ADDRESS ANY PORTFOLIO GAPS THAT MAY EMERGE.

FOR THE UPCOMING CYCLE, CORRESPONDING TO

FISCAL YEAR 25/26, PREFERENCES WILL BE GIVEN TO APPLICATIONS ADDRESSING NEURODEGENERATIVE DISEASES SHOWN IN THE CENTER SQUARE, AN AREA OF OPPORTUNITY THAT WAS PREVIOUSLY IDENTIFIED BY THE NEURO SCIENCE TASK FORCE. AND THIS FOLLOWS THE NEUROPSYCHIATRIC DISEASE FOCUS AREA SHOWN IN GRAY, WHICH WAS THE FOCUS FOR THE PILOT PHASE.

IN SUBSEQUENT CYCLES AND IN A STAGGERED FASHION, WE WILL CONTINUE TO PRIORITIZE NEUROSCIENCE AREAS IDENTIFIED BY THE NEUROSCIENCE TASK FORCE, INCLUDING NEURO-INJURY AS SHOWN IN THE DARK YELLOW. AND IN ALTERNATIVE CYCLES, WE WILL PRESENT TO THE BOARD RECOMMENDATIONS FOR FUNDING PREFERENCES AS PART OF THE ANNUAL PORTFOLIO REVIEW THAT TAKES PLACE AT THE END OF THE FISCAL YEAR.

IN EACH CASE THE PREFERENCES WILL BE APPROVED BY THE ICOC AND INCORPORATED INTO PROGRAM ANNOUNCEMENTS FOR THE SUBSEQUENT YEAR. THESE PREFERENCES FOR APPLICATIONS, SO ADDRESSING NEURODEGENERATIVE DISEASES FOR THE UPCOMING CYCLE, WILL BE IMPLEMENTED DURING THE PRESUBMISSION PHASE WHICH I WILL DESCRIBE IN THE LATER SLIDES.

SO THIS TABLE SUMMARIZES ALL THE MAJOR ELEMENTS OF THE AWARD CYCLE. IN BOLD ARE THE ELEMENTS WHERE CHANGES HAVE BEEN MADE COMPARED TO

THE REMIND PROGRAM. AND YOU'VE SEEN THAT WE ARE KEEPING MOST ELEMENTS OF WHAT WE BELIEVE TO BE A FAIRLY SUCCESSFUL DESIGN. THESE ARE FOUR-YEAR AWARDS FOR TEAMS OF AT LEAST FIVE CALIFORNIA-BASED INVESTIGATORS. THE AWARD IS CAPPED AT A BASE BUDGET OF $13 MILLION TOTAL COST, AND WE EXPECT TO FUND SIX TEAMS A YEAR FOR AN ANNUAL BUDGET OF $84 MILLION.

GOING INTO THE AWARD BUDGETS IN A LITTLE BIT MORE DETAIL, THE BUDGETS ARE CAPPED AT 13 MILLION IN TOTAL COST PER AWARD INCLUSIVE OF OVERHEADS. THIS IS MOVING FROM A DIRECT COST CAP THAT WE HAD IN REMIND TO BETTER ALIGN WITH PROGRAMS ACROSS CIRM AND WITH THE NEW DISC5 PROGRAM. AND IT ALSO HAS THE ADVANTAGE OF REMOVING A DISINCENTIVE FOR MULTI-INSTITUTIONAL TEAMS.

TO GET TO THIS NEW NUMBER, WE ARE APPLYING THE DIRECT COST CAP THAT WE HAD FOR REMIND AT $8 MILLION AND THE APPLYING THE HISTORICAL OVERHEAD RATE OF 60 PERCENT. AND SIMILAR TO THE PILOT PHASE, AN ADDITIONAL $1 MILLION CAN BE REQUESTED TO GET TO A MAXIMUM OF $14 MILLION WITH ELIGIBLE MATCHING FUND CONTRIBUTIONS OF EQUAL OR GREATER VALUE.

SO THIS SLIDE LISTS SOME OF THE PROJECT ELIGIBILITY REQUIREMENTS THAT MUST BE MET BY ALL PROPOSALS REGARDLESS OF TOPIC. ALL APPS FIRST MUST

ADDRESS KNOWLEDGE GAPS OR BOTTLENECKS IN THE UNDERSTANDING OF HUMAN DISEASES. NO. 2, TO ENSURE ALIGNMENT WITH CIRM'S MISSION, THE OVERALL PROJECT MUST INCLUDE STUDIES THAT EMPLOY HUMAN STEM CELLS AND/OR GENETIC RESEARCH AS PART OF THE CENTRAL APPROACH. OF COURSE, HAVING FULFILLED THESE REQUIREMENTS, TEAMS ARE ALSO ENCOURAGED TO INCORPORATE A VARIETY OF APPROACHES AND TECHNOLOGIES IN ORDER TO MAXIMIZE SCIENTIFIC IMPACT. AND FINALLY, PROPOSALS, SIMILAR TO DISC5, MUST BE CENTERED ON HUMAN BIOLOGY. AND APPLICANTS MAY INCLUDE NONHUMAN MODELS TO ACHIEVE SPECIFIC OBJECTIVES AND AIMS AS LONG AS THEY PROVIDE STRONG JUSTIFICATION FOR ANY PROPOSED USE OF NONHUMAN MODELS.

AGAIN, THIS AWARD IS OPEN TO CALIFORNIA-BASED NON-PROFIT OR FOR-PROFIT ORGANIZATIONS. EACH TEAM MUST HAVE A SCIENTIFIC LEADERSHIP, WHAT WE CALL A CORE TEAM, THAT HAS A MINIMUM OF FIVE CALIFORNIA-BASED INVESTIGATORS, A SINGLE CONTACT PI, OR FOUR OR MORE CO-INVESTIGATORS. THIS CORE TEAM MUST BE MULTI-INSTITUTIONAL, MEANING AT LEAST ONE OF THE MEMBERS OF THE CORE TEAM MUST BE BASED OUTSIDE OF THE PRINCIPAL INVESTIGATOR INSTITUTION. THIS IS NEW TO THIS AMENDMENT. JUST

AS A REFERENCE, SIX OF THE SEVEN FUNDED TEAMS WITH REMIND WERE MULTI-INSTITUTIONAL BASED ON THIS CRITERIA.

TO ENSURE THAT THE PROPOSAL REFLECTS PERSPECTIVES FROM DIFFERENT DISCIPLINES AND PERSPECTIVES, THE BROADER TEAM MUST ALSO INCLUDE KEY PERSONS THAT HAVE AT LEAST ONE MEMBER EACH WITH THE RELEVANT CLINICAL, COMPUTATIONAL, AND INDUSTRY OR TRANSLATIONAL EXPERTISE. IN ADDITION, ALL TEAMS MUST HAVE A DATA PROJECT MANAGER THAT WILL WORK WITH CIRM TO ENSURE DATA SHARING AND REPORTING REQUIREMENTS ARE FULFILLED.

SIMILARLY TO OTHER CIRM PROGRAMS YOU WILL HEAR ABOUT TODAY, THE DISC4 PROGRAM WILL IMPLEMENT A NEW PRESUBMISSION PROCESS SIMILAR TO THE LOI FORMATS THAT YOU MIGHT HAVE SEEN FROM OTHER FUNDING OPPORTUNITIES. WE ARE DOING THIS TO ENSURE THAT PROGRAMS ALIGN WITH THE SCOPE AND OBJECTIVES OF THIS AWARD AND TO HELP PRIORITIZE PROPOSALS THAT ARE IN THE CHOSEN PREFERENCE TOPIC AREA. THIS PROCESS WILL ALSO REDUCE TIME BURDEN FOR APPLICANTS, ESPECIALLY THOSE WITH A POOR FIT FOR THIS PROGRAM. IT EXTENDS THE TIMELINE TO ALLOW APPLICANTS TO FORM NEW COLLABORATIONS THAT WILL LEAD TO MORE IMPACTFUL PROPOSALS. AND IT WOULD ALSO GIVE US THE

FLEXIBILITY TO MANAGE HIGH APPLICATION VOLUMES AND PREPLAN FOR THE APPROPRIATE REVIEW PANELS.

SO HOW THIS WILL WORK IS IN THIS PROCESS THE PROSPECTIVE APPLICANTS WILL SUBMIT A SHORT PRESUBMISSION FORM ONLINE. AND WE HAVE SHARED AN ILLUSTRATIVE EXAMPLE WITH MEMBERS OF THE BOARD. THIS INCLUDES AN ONLINE INTAKE FORM AND A THREE-PAGE PROPOSAL OUTLINE AND A BRIEF QUESTIONNAIRE.

SUBSEQUENT TO THIS SUBMISSION, CIRM STAFF WILL EVALUATE AND RANK PRESUBMISSIONS BASED ON ALIGNMENT WITH PROGRAM OBJECTIVES AND SCOPE AS WELL AS THE FUNDING PREFERENCE TOPICS. PRESUBMISSIONS WILL NOT BE EVALUATED FOR SCIENTIFIC MERIT OR FEASIBILITY. AND BASED ON THIS EVALUATION AND RANKING, CIRM WILL INVITE APPROXIMATELY 30 TEAMS TO SUBMIT A FULL APPLICATION. AND THEY WILL HAVE ABOUT 90 DAYS TO COMPLETE THAT FULL APPLICATION.

AND THIS IS AN EXAMPLE OF THE RUBRIC AND KEY CONSIDERATIONS BY WHICH THESE PRESUBMISSIONS WILL BE EVALUATED, SO PLACED IN ORDER OF WEIGHT AND IMPORTANCE. FIRST, WE WILL SEE IF THEY ADDRESS THE PREFERENCE TOPIC WHICH IS NEURODEGENERATION FOR THE CURRENT CYCLE. WE WILL ALSO CONSIDER OBJECTIVE CRITERIA SHOWN HERE BASED ON CORE PROGRAM OBJECTIVES, INCLUDING RELEVANCE TO HUMAN DISEASE

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BIOLOGY, INCLUSION OF CROSS-DISCIPLINARY FRAMEWORKS, AND THE APPLICATION OF STEM CELL AND GENETIC RESEARCH INNOVATIONS.

AND WE HAVE ALSO DATA SHARING AND MANAGEMENT PLAN AND COORDINATION REQUIREMENTS WITH CIRM'S DATA INITIATIVES, WHICH ARE VERY SIMILAR TO WHAT KELLY HAS ALREADY TOLD YOU WITH THE DISC5 PROGRAM. AND I WON'T REPEAT ALL OF THAT HERE. AND ASSUMING BOARD APPROVAL, WE EXPECT THE PA TO BE POSTED BY EARLY APRIL WITH PRESUBMISSIONS OPEN SOON OF AFTER THAT AND DUE BY LATE JUNE.

SO WITH THAT, I'M HAPPY TO TAKE ANY QUESTIONS. AND WE REQUEST THE ICOC BOARD APPROVE THE PROPOSED DISC4 CONCEPT PLAN. THANK YOU.

CHAIRMAN IMBASCIANI: THANK YOU, DR. TAN. BOARD MEMBER HAVE ANY QUESTIONS FOR HIM? PAT AND THEN KIM. HALA.

DR. MADANAT: SORRY. I WAS JUST GOING TO ASK ABOUT THE LOI. IT SEEMS LONG, NOT REALLY A SHORT SUBMISSION. THE LOI SEEMS VERY LONG TO ME. CAN YOU REPEAT EXACTLY WHAT YOU WERE EXPECTING THEM TO MEET?

DR. TAN: THE LOI HAS THREE SECTIONS, ACTUALLY MAYBE TWO SECTIONS, I WOULD SAY, AN ONLINE SECTION WHICH IS JUST WHO YOUR TEAM MEMBERS ARE,

QUICK CHECKS ON WHETHER YOU'VE READ THE PA AND THE ELIGIBILITY REQUIREMENT, A SHORT QUESTIONNAIRE OF FOUR QUESTIONS, BASICALLY A THOUSAND WORDS TO KIND OF GET US TO FOCUS ON THE EVALUATION CRITERIA, SO THE FOUR CRITERIA THAT WE'VE LISTED THERE. SO FOUR SHORT QUESTIONS. AND THEN THERE'S AN UPLOAD FOR A PROPOSAL OUTLINE WHICH IS ABOUT THREE PAGES LONG WHICH THEY CAN INCLUDE THE RESEARCH PLAN, THE RESEARCH OUTLINES, A SIMPLE RATIONALE FOR THAT, AND MAJOR OBJECTIVES AND AIMS. THAT'S THE FRAMEWORK.

AND WE'VE COME TO THIS LOOKING AT A NUMBER OF DIFFERENT LOI-TYPE FORMATS THAT OTHER FUNDING AGENCIES HAVE APPLIED. ONE EXAMPLE THAT GOES QUITE CLOSELY TO THIS IS THE SIMONS COLLABORATION. THEY HAD A CALL FOR A VISION FOR PROGRESSION IN NEUROSCIENCE. AND THE STRUCTURE AND PAGE LENGTH ARE QUITE SIMILAR TO WHAT WE'RE PROPOSING HERE.

DR. LEVITT: IT WOULD BE HELPFUL, I THINK, FOR THE BOARD TO SEE EXACTLY WHAT YOU'RE ASKING FOR. THEY'RE NOT SHORT QUESTIONS, IN MY OPINION. WHEN YOU ADD UP THE NUMBER OF PAGES THAT INVESTIGATORS HAVE TO FILL OUT FOR THIS, IT'S ABOUT SIX OR SEVEN. SO --

DR. TAN: WE'LL DEFINITELY TAKE THAT FEEDBACK.

DR. LEVITT: SO MAYBE IT WOULD BE HELPFUL FOR US TO ACTUALLY SEE BOXES. THERE'S AN ONLINE COMPONENT WHICH IS ASKING OVERLAPPING, BUT NOT IDENTICAL QUESTIONS TO WHAT YOU'RE ASKING FOR IN TERMS OF REALLY THESE RATIONALE-SPECIFIC AIMS, SOME DETAIL. THAT'S THREE PAGES. THAT ALONE IS THREE PAGES, PLUS UP TO THREE PAGES OF PRELIMINARY DATA. SO I'M NOT EVEN COUNTING THAT, AND THEN YOU'VE GOT THE QUESTIONNAIRE ONLINE. SO THAT NEEDS TO BE MORE CLEARLY DEFINED BECAUSE IT'S PRETTY LONG.

DR. TAN: WE HAVE AN EXAMPLE WITH THE MATERIAL POSTED. WE ARE NOT ASKING SPECIFICALLY FOR THREE PAGES OF PRELIMINARY DATA. IT'S THREE PAGES OF AN OUTLINE --

DR. LEVITT: THREE PAGES OF OUTLINE AND THEN UP TO THREE PAGES FOR FIGURES OR PRELIMINARY DATA. THAT'S WHAT IT SAID IN THE INSTRUCTIONS.

DR. TAN: THAT'S NOT WHAT THE INTENT WAS.

CHAIRMAN IMBASCIANI: ROSA, DO YOU WANT TO ADD A CLARIFICATION?

DR. CANET-AVILES: DR. LEVITT, I APPRECIATE YOUR COMMENTS. ONE OF THE THINGS THAT WE COULD DO, AS THIS IS GOING TO BE PRESENTED BY DR. SAMBRANO LATER ON, AND WE COULD ACTUALLY SUGGESTING TO APPROVE THE CONCEPT AND THE PRESUBMISSION

CONDITION UNDER DISCUSSION THAT WILL HAPPEN LATER.

DR. LEVITT: I'M HAPPY TO DO THAT. THAT'S GREAT. SO REGARDING THE CONCEPT PLAN, THE RATIONALE FOR DISC4, AS YOU IDENTIFIED, AS THE BOARD HAS AGREED TO, IS THIS BOTTLENECK OF PARTICULARLY DISCOVERY OF TARGETS. AND SO I'D LIKE TO KNOW MORE ABOUT THE RATIONALE FOR STARTING WITH NEURODEGENERATION BECAUSE WHEN YOU LOOK AT THE CURRENT STATE OF MONEY THAT GOES INTO NEURODEGENERATION COMPARED TO NEUROPSYCHIATRY, THE REMIND PROGRAM HAS BEEN INSTRUMENTAL IN GOING FROM WHERE WE WERE BEFORE, WHICH IS ZERO FOR THE NEUROPSYCHIATRIC DISORDERS, TO NOW IS SOMETHING THAT'S REALLY EXCITING. I THINK THERE ARE WHAT, THERE ARE EIGHT, I THINK, OR SOMETHING LIKE THAT.

WHEN YOU LOOK AT THE DATA ON HISTORICAL NEURO INVESTMENT IN TRAN AND CLIN, MY CALCULATION, LOOKING AT GRANTS, WE HAVE GRANTS THAT HAVE STARTED AT A DISCOVERY PHASE AND NOW ARE AT CLIN IS LIKE FIVE TO SEVEN YEARS IT LOOKS LIKE TO ME. SOMETHING REALLY FAST WOULD BE FIVE.

SO IF WE'RE GOING SEPARATE OUT THE NEURO INTO THREE PHASES, WE'RE TALKING ABOUT NEUROPSYCHIATRY COMING AROUND IN FY '28 OR '29. AND THEN TO GET THEM TO -- SO RIGHT NOW

NEURODEGENERATION AWARDS SPENT 317 MILLION, NEURO-INJURY 311. THIS IS ON THE TRAN AND CLIN. THE NEUROPSYCHIATRY AND NEURODEVELOPMENTAL ARE 47 MILLION.

SO GIVEN THE RATIONALE FOR DISC4, WHICH I'M REALLY IN FAVOR OF AND I LOVE THE PROGRAM, WHY NOT JUST HAVE NEURO AS AN EMPHASIS AREA, LEAVING IT TO THE INVESTIGATORS TO SUBMIT? IF WE SINGLE OUT ONE, IT'S GOING TO LIMIT OR REDUCE OR ELIMINATE GRANTS THAT ARE GOING TO BE COMING IN IN THESE OTHER AREAS. AND I'M VERY CONCERNED ABOUT WHERE WE ARE IN TERMS OF TARGET DISCOVERY FOR NEUROPSYCHIATRY, WHICH IS REALLY LOW.

DR. CANET-AVILES: SO THAT'S REALLY THE PREMISE OF THE BOARD. THAT WAS A PROPOSAL OF HOW TO DO IT BASED ON THE CLUSTERS FROM THE NEURO TASK FORCE AS DR. GOLDSTEIN HAD PROPOSED AND WAS VOTED IN AUGUST OF 2023. SO WE STARTED LIKE THAT, BUT DEFINITELY THIS IS SOMETHING THAT, IF THE BOARD PREFERS THAT WE DO CYCLES OF NEURO AND THEN EVERYTHING BASED ON THE PRIORITIES OF THE YEAR AND THE ANALYSIS THAT WE WILL BE PROVIDING EVERY JUNE, WE COULD DO THAT. BECAUSE AT THE END OF THE DAY, IF YOU THINK ABOUT THE COMMONALITIES OF ALL THESE DISEASES, WE COULD JUST LEAVE IT UP TO THE

APPLICANTS TO COME WITH THE MOST RELEVANT AND IMPACTFUL APPLICATIONS. SO THAT COULD BE ANOTHER WAY THAT WE COULD TRANSFORM THIS.

AND WE JUST ADDED THIS BACKUP SLIDE THAT HAS THE HISTORICAL NEURO INVESTMENTS IN TRAN AND CLIN. WE ALSO HAVE DISCOVERY -- IT'S THE ONE EARLIER -- THAT WILL SHOW BY THE CLUSTERS AS WELL THIS IS HOW MUCH INCLUDING THE NEW REMIND-L.

AND I WANT TO THANK DR. SARA TAYLOR FOR A LOT OF WORK PUTTING THIS AND CODING ALL THE AWARDS ALSO. SHE'S THE MASTER BEHIND ALL THESE WONDERFUL SLIDES.

CHAIRMAN IMBASCIANI: THANK YOU, ROSA. WE'RE STILL IN THE QUESTION PHASE HERE. DR. BARRETT.

DR. BARRETT: THANK YOU VERY MUCH FOR THE PRESENTATION. I HAD A VERY PRACTICAL QUESTION. SO IN THE CONCEPT PLAN, YOU DEFINE TWO TYPES OF POTENTIAL MATCHING SUPPORT. ONE OF WHICH TO ME SOUNDS AS IF IT'S SORT OF IN KIND. IT COULD BE CELL LINES; IT COULD BE BIOREPOSITORIES. HOW WOULD THAT BE VALUED? I COULD SAY MY CELL LINE IS WORTH A MILLION DOLLARS. SO I'M MATCHING WITH MY MILLION DOLLAR CELL LINE.

DR. TAN: THAT'S GOING INTO THE

NITTY-GRITTY. WE HAVE HAD SOME EXPERIENCE WITH THE REMIND PROGRAM WITH IN-KIND CONTRIBUTIONS THAT THEY HAVE SUBMITTED. WE STARTED CONVERSATION WITH THE APPLICANTS HOW THEY TEND TO VALUE THE CELL LINES. AND WE USUALLY ASK FOR JUSTIFICATION, INDUSTRY STANDARDS, COMPARABLE EVALUATIONS OF RESOURCES. AND THAT'S SOMETHING THAT WE WILL DETERMINE WITH COLLABORATION WITH OUR GRANTS MANAGEMENT TEAM AND IN COLLABORATION WITH THE APPLICANT TEAM TO KIND OF GET TO A REASONABLE EVALUATION TO THOSE MATCHING FUND CONTRIBUTIONS.

CHAIRMAN IMBASCIANI: ARE THERE ANY OTHER QUESTIONS?

DR. LEVITT: IS THERE A COMPONENT OF THE APPLICATION THAT ASKS ABOUT CIRM-FUNDED CORES THAT ARE BEING USED FOR RESEARCH? I SHOULD HAVE ASKED IT BEFORE FOR THE OTHER. IS THERE A COMPONENT OF THAT WHERE YOU GET THAT INFORMATION? ONE IS KEEPING TRACK OF HOW THE INVESTIGATORS ARE CONNECTING WITH CIRM-FUNDED INFRASTRUCTURE AT VARIOUS INSTITUTIONS TO DETERMINE WHETHER WE'RE LEVERAGING THOSE WELL.

DR. LEK TAN: FOR THIS CYCLE THAT'S A WORK IN PROGRESS. DEFINITELY WE ENCOURAGE THEM, AND WE'VE PROVIDED RESOURCES IN THE PA AND ON OUR WEBSITE ABOUT OTHER RESOURCES THAT THEY CAN TAP

INTO. IT ISN'T FORMALLY A REQUIREMENT OR ANYTHING OF THAT NATURE WITHIN THE PROGRAM.

DR. CANET-AVILES: I THINK IT'S A VERY RELEVANT QUESTION TO LEVERAGE THE SHARED RESOURCE LABS FOR CELL MODELING, FOR EXAMPLE, AND THE IPS REPOSITORY. IN FACT, YOU'VE DONE THAT THROUGH THE REMIND-L WITH NEUROPSYCH. SO THAT'S A VERY GOOD POINT THAT WE COULD ADD --

DR. LEVITT: IT'S SHORT AND IT ALLOWS YOU ALL TO KEEP TRACK OF HOW THESE ARE BEING ACCESSED, WHICH IS ONE OF THE MAJOR GOALS OF THE INVESTMENT.

DR. TAN: WE WILL CHECK THOSE INTERACTIONS.

VICE CHAIR BONNEVILLE: I JUST HAVE A CLARIFYING QUESTION. PAT, WAS IT SETTLED THAT WE WOULD LEAVE IT SO THAT IT'S OPEN TO ALL NEURO PROGRAMS OR APPLICATIONS AND NOT A DIRECTED CATEGORY EACH TIME? I'M UNCLEAR. SO I WOULD ASSUME PERHAPS THE TEAM IS UNCLEAR. SO I JUST WANT TO GET --

DR. LEVITT: SO I HAVE MY OWN BIASES, WHICH YOU PROBABLY CAN FIGURE OUT.

DR. CANET-AVILES: VICE CHAIR, COULD YOU REPEAT THE QUESTION?

VICE CHAIR BONNEVILLE: IT'S A QUESTION FOR PAT. PAT HAD MENTIONED THAT HE WANTED THE NEURO

ROUNDS TO BE -- I THINK WHAT HE'S ASKING FOR IS JUST NEUROPSYCH. BUT I THINK IN THE ABSENCE OF JUST GOING STRAIGHT FOR NEUROPSYCH, HE'S ASKING THAT THE NEURO ROUND BE OPEN SO THAT IT'S NOT DIRECTED TO A SPECIFIC AREA. AND SO I JUST WANTED TO CLARIFY. I DON'T KNOW WHERE WE ENDED UP.

DR. LEVITT: SO ONE OF THE ADVANTAGES OF DOING THAT WAY IS THAT ONE OF THE CRITERIA THAT THE TEAM IS USING TO DETERMINE AN APPLICATION MOVING FORWARD IS WHETHER OR NOT IT'S MEETING A GAP, RIGHT? AND SO IF, FOR EXAMPLE, NEURODEGENERATION SWAMPS THE INITIAL APPLICATION PROCESS AND SOME OF THOSE ARE FUNDED, WHEN YOU COME IN THE NEXT YEAR, IT'S LIKELY THAT YOU'RE GOING TO LOOK IN THIS, WE'VE ALREADY FUNDED THAT. THERE'S NOT A GAP THERE. AND SO THOSE ARE COMING IN OTHER DOMAINS.

SO MY PREFERENCE IS AT LEAST TO LEAVE IT OPEN AND NOT HAVE A PARTICULAR AREA OF NEUROSCIENCE, CLINICAL NEUROSCIENCE, RELEGATED TO WAITING THREE PLUS YEARS BECAUSE YOU KNOW HOW INVESTIGATORS WORK. IF IT SAYS THE FOCUS IS GOING TO BE NEURODEGENERATION, THAT'S WHAT IT'S GOING TO GET IN ADDITION TO THESE OTHER AREAS. SO MY PREFERENCE IS LEAVE IT OPEN. THE TEAM IS GOING TO RECOGNIZE THOSE WHERE THERE'S A LOT OF FUNDING ALREADY AND MAKE

THOSE DECISIONS.

CHAIRMAN IMBASCIANI: CAROLYN.

DR. MELTZER: I VERY MUCH AGREE WITH KEEPING IT OPEN. I THINK THE SCIENCE NEEDS TO DRIVE IT.

DR. CANET-AVILES: AND YOU ARE THE NEURO TASK FORCE CO-CHAIR. SO WE APPRECIATE YOUR LEADERSHIP. IF THAT'S THE CALL, WE WILL DEFINITELY DO THAT. WE ARE HAPPY TO DO IT THIS WAY.

CHAIRMAN IMBASCIANI: TOUCHE. THANK YOU. I DON'T SEE ANY OTHER QUESTIONS. I'M GOING TO PROCEED TO A -- SINCE IT'S A COMPLICATED MOTION, MARIA IS GOING TO HANDLE THIS.

VICE CHAIR BONNEVILLE: IT'S LIKE THE OTHER ONE. SO I'D LIKE TO MAKE A MOTION TO APPROVE THE DISC4 CONCEPT PLAN AND TO DELEGATE TO THE CEO THE AUTHORITY TO MAKE AND IMPLEMENT CHANGES TO THE CONCEPT PLAN IN BETWEEN BOARD MEETINGS UPON CONSULTATION OF THE CHAIRS AND CO-CHAIRS OF THE ICOC SUBCOMMITTEES AND TO BRING THOSE CHANGES BEFORE THE BOARD AT THE NEXT OPPORTUNITY FOR RATIFICATION.

CHAIRMAN IMBASCIANI: THANK YOU. SO A SECOND IS REQUIRED.

DR. SOUTHARD: SECOND.

CHAIRMAN IMBASCIANI: MARV SECOND.

DISCUSSION AMONG BOARD MEMBERS? OR AMONG THE MEMBERS OF THE PUBLIC. DOESN'T APPEAR. THANK YOU SO MUCH. SCOTT, WILL YOU PROCEED TO A VOTE.

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

MONICA CARSON. YSABEL DURON.

MS. DURON: YES.

MR. TOCHER: RICH LAJARA.

MR. LAJARA: YES.

MR. TOCHER: SHLOMO MELMED.

DR. MELMED: YES.

MR. TOCHER: CHRIS MIASKOWSKI.

DR. MIASKOWSKI: YES.

MR. TOCHER: JOE PANETTA. SUZANNE SANDMEYER.

DR. SANDMEYER: YES.

MR. TOCHER: KAROL WATSON.

DR. WATSON: YES.

MR. TOCHER: KEVIN XU.

DR. XU: YES.

MR. TOCHER: THANKS. THE MOTION CARRIES, MR. CHAIR.

CHAIRMAN IMBASCIANI: MOTION CARRIES. THANK YOU SO MUCH, SCOTT. AND THANK YOU, DR. TAN.

GREAT PRESENTATION. APPRECIATE IT. WE'RE GOING TO MOVE TO --

MR. TOCHER: WE'RE GOING TO TAKE A TEN-MINUTE BREAK. WE WILL SEE YOU AT TEN MINUTES BEFORE THE HOUR.

(A RECESS WAS TAKEN.)

CHAIRMAN IMBASCIANI: THANK YOU, SCOTT. WE'RE COMING BACK OUT OF RECESS NOW, AND WE'RE GOING TO MOVE TO THE NEXT AGENDA ITEM, WHICH IS THE CONSIDERATION OF THE THIRD OF THE FOUR CONCEPT PLANS ON PRECLINICAL DEVELOPMENT. AND IT'S GOING TO BE PRESENTED BY OUR ASSOCIATE VICE PRESIDENT FOR PRECLINICAL DEVELOPMENT, SHYAM PATEL. SHYAM, THE FLOOR IS YOURS.

DR. PATEL: THANK YOU. GOOD MORNING AND WELCOME BACK FROM YOUR SEVENTH INNING STRETCH. MY NAME IS SHYAM PATEL, AND I'LL BE PRESENTING TODAY ON THE PDEV CONCEPT. SO, FIRST OF ALL, THANK YOU TO CHAIR IMBASCIANI, VICE CHAIR GONZALEZ-BONNEVILLE, AND TO ALL MEMBERS OF THE ICOC FOR THIS OPPORTUNITY TO PRESENT TO YOU THE PDEV CONCEPT PLAN FOR YOUR CONSIDERATION TODAY.

BEFORE I BEGIN, I WANT TO ACKNOWLEDGE THE CONTRIBUTION OF THE PDEV TEAM, WHICH WAS A TEAM EFFORT ON THIS PROJECT. THAT INCLUDES DR. ROSS

OKAMURA, DR. JIM CAMPENELLI, DR. LISA MCGINLEY, AND DR. DONG CHIN LEE, AS WELL AS TOM STRINGH. AND I'LL JUMP RIGHT INTO THE PRESENTATION NOW.

SO THE PDEV CONCEPT, THE PRESENTATION IS SIMILAR IN SCOPE TO THE OTHER ONES. I'LL SPEND A LITTLE BIT MORE TIME ON THE BACKGROUND AND THE SCOPE OF THIS PARTICULAR FUNDING MECHANISM AND THEN RUN THROUGH THE STRUCTURE OF THE PROGRAM.

SO JUST AS A REMINDER, THE PDEV PROGRAM IS IN SERVICE OF SAF GOAL 4. THIS IS TO PROPEL 15 TO 20 THERAPIES TARGETING DISEASES AFFECTING CALIFORNIANS TO LATE STAGE TRIALS. THERE WERE TWO SPECIFIC RECOMMENDATIONS THAT WE HAD TO ADDRESS AS PART OF THIS FUNDING MECHANISM. THE FIRST WAS TO CONSOLIDATE PRECLINICAL FUNDING MECHANISMS TO INCENTIVIZE MULTIDISCIPLINARY COLLABORATIONS AND RAPID PROGRESSION TO IND AND START FIRST-IN-HUMAN CLINICAL TRIALS. AND THE SECOND WAS TO INCORPORATE PRIORITIZATION OF INNOVATIVE THERAPIES FOR DISEASES THAT AFFECT CALIFORNIANS.

SO I'LL TALK ABOUT HOW WE HAVE DESIGNED THIS PROGRAM TO ADDRESS BOTH OF THOSE PRIORITIES THAT WERE DEFINED BY THE SAF. BEFORE I GET INTO THAT, I'M GOING TO PROVIDE A LITTLE BIT MORE BACKGROUND ON THE LANDSCAPE AS WELL AS OUR INTERNAL

LEARNINGS FROM YEARS OF MANAGING PRECLINICAL DEVELOPMENT PROGRAMS.

FIRST OF ALL, AS YOU ALL KNOW VERY WELL, OVER THE LAST DECADE THERE HAVE BEEN VARIOUS MILESTONES IN THE APPROVAL OF CELL AND GENE THERAPIES. AND THE NUMBER OF CELL AND GENE THERAPIES THAT ARE APPROVED EVERY YEAR IS INCREASING. SIMILARLY, ON THE DEVELOPMENT LANDSCAPE SIDE, WHICH IS WHAT THIS MASSIVE CHART PORTRAYS, IS THAT THERE IS AN INCREDIBLE NUMBER OF THERAPIES IN DEVELOPMENT BOTH AT THE PRECLINICAL STAGE AS WELL AS THE CLINICAL STAGE. AND THE ONE MAJOR THING TO NOTE HERE IS, DESPITE THE SIGNIFICANT INVESTMENT IN ONCOLOGY, THERE ARE CANDIDATES THAT ARE TARGETING ALL MAJOR THERAPEUTIC AREAS. IN PARTICULAR, THIS IS VERY TRUE FOR GENE THERAPY, WHICH IS THE RED BARS THAT YOU SEE ACROSS THE ENTIRE SPECTRUM.

AND SO ON THAT NOTE, THERE IS A LOT OF ACTIVITY IN DEVELOPING CELL AND GENE THERAPIES ACROSS MULTIPLE THERAPEUTIC AREAS. HOWEVER, AT THE SAME TIME, THE INVESTMENT IN CELL AND GENE THERAPIES HAS FLATLINED. SO THE BAR FOR INDUSTRY INVESTMENT IN CELL AND GENE THERAPY DEVELOPMENT HAS GOTTEN SIGNIFICANTLY HIGH IN THE LAST FEW YEARS.

SO ON THE LEFT, THERE IS A CHART THAT'S

SHOWING HOW VENTURE INVESTMENT, WHICH IS THE LIFEBLOOD FOR SMALL COMPANIES, HAS BASICALLY FLATLINED COMPARED TO SMALL MOLECULES AND BIOLOGICS OVER THE LAST FEW YEARS. AT THE SAME TIME, BOTH VENTURE CAPITAL FIRMS AS WELL AS BIOPHARMA PARTNERS ARE PRIORITIZING INVESTMENTS IN CLINICAL STAGE CELL AND GENE THERAPY COMPANIES.

IN FACT, THIS IS PLAYED OUT IN OUR OWN PORTFOLIO. LAST YEAR IN 2024 WE TRACKED OVER $2 BILLION IN INDUSTRY SUPPORT TO CIRM-FUNDED PROGRAMS, BUT ONLY A SMALL FRACTION OF THAT WAS ACTUALLY DEDICATED TO PRECLINICAL STAGE COMPANIES.

SO IN SUM, FROM ALL OF THIS EXTERNAL LANDSCAPE, THERE IS STILL A VERY IMPORTANT ROLE FOR CIRM TO PLAY IN DERISKING AND SUPPORTING THE DEVELOPMENT OF CELL AND GENE THERAPIES ACROSS THE TRANSLATIONAL VALLEY OF DEATH, BUT WE HAVE TO DO IT IN A STRUCTURED AND FOCUSED AND DELIBERATE WAY PER THE SAF.

I'M GOING TO SPEND A LITTLE BIT OF TIME TALKING ABOUT OUR EXPERIENCE OVER THE LAST TEN YEARS MANAGING PRECLINICAL DEVELOPMENT PROGRAMS. AS YOU KNOW, PRECLINICAL DEVELOPMENT IN CIRM'S CURRENT FUNDING MODEL IS SPREAD ACROSS THREE DISTINCT BUT PROGRESSIVE FUNDING OPPORTUNITIES STARTING WITH

DISC2, WHICH FOCUSES ON THE DEVELOPMENT AND DISCOVERY OF A THERAPEUTIC CANDIDATE. FROM THAT POINT ON, THE TRANSLATIONAL PROGRAM SUPPORTS EARLY TRANSLATIONAL ACTIVITIES RESULTING AND CULMINATING IN A PRE-IND MEETING. AND FINALLY, THE CLIN1 PROGRAM WHICH SUPPORTS ALL IND-ENABLING ACTIVITIES RESULTING IN THE SUBMISSION OF AN IND APPLICATION TO THE FDA.

OVER THE LAST TEN YEARS, WE'VE LEARNED A FEW THINGS ACROSS OUR PROGRAMS, AND I'M GOING TO HIGHLIGHT ON TWO AREAS. ONE OF THOSE IS AN ACCELERATION, WHICH IS A MAJOR FOCUS AREA FOR CIRM, AND, SECONDLY, IS SCOPE-BASED OBSERVATIONS. ALL OF THESE HAVE FED INTO THE DESIGN OF THE PDEV PROGRAM.

SO FIRST AND FOREMOST, ON THE TRANSLATIONAL SIDE, WE ARE WITNESSING MULTIPLE TRAN1 AWARDS THAT ARE PROGRESSING TO PRE-IND MEETINGS MUCH EARLIER THAN EXPECTED. NOW, IN OUR CURRENT MECHANISM, THIS REQUIRES AWARD AMENDMENTS TO USE THE REMAINING FUNDING TO CONDUCT STUDIES THAT WERE INFORMED BY THE FDA FEEDBACK. BECAUSE ALL OF OUR PROGRAMS HAVE DISTINCT ACTIVITIES THEY CAN DO, THERE'S ALSO SOME LIMITATION TO HOW MUCH ACTIVITIES THEY CAN ACTUALLY GET DONE IN A TRAN1 AWARD AFTER HAVING THAT PRE-IND MEETING.

SO BUILDING ON THAT, A TRAN1 AWARDEE THAT HAS A SUCCESSFUL PRE-IND MEETING, THE LAG TIME TO GO FROM THAT TO HAVING THE CLIN1 AWARD START IS ON THE MEDIAN OF 16 MONTHS. THIS IS BASED ON THE FACT THAT THEY HAVE TO APPLY AND THEN GO THROUGH THE MECHANISM OF REVIEW AND AWARD APPROVAL. SO THERE'S AN OPPORTUNITY THERE ON THE ACCELERATION SIDE.

ON THE SCOPE SIDE, BECAUSE ALL THREE PROGRAMS HAVE DISTINCT ACTIVITIES THAT THEY CAN SUPPORT, YOU HAVE INSTANCES WHERE A TRAN STAGE PROJECT MIGHT WANT TO CONDUCT SOME CANDIDATE OPTIMIZATION BEFORE IT EMBARKS ON ALL OF ITS DEVELOPMENT ACTIVITIES TO GET TO A PRE-IND MEETING. PARTICULARLY TRUE FOR GENE THERAPIES WHERE THEY MAY WANT TO OPTIMIZE SOME GENETIC SEQUENCE OR RNA OR CHANGE OUT THEIR PROMOTER. UNDER OUR CURRENT MECHANISM, THEY WOULD HAVE TO FIRST APPLY TO DISC2 BEFORE THEY CAN ACTUALLY COME BACK IN FOR TRAN1 FUNDING. SIMILARLY, IF YOU HAVE A PROJECT THAT IS SIX TO 12 MONTHS FROM ITS PRE-IND MEETING, IT DOESN'T REALLY FIT INTO THE TRAN1 OR CLIN1 FUNDING MECHANISM. THEY'RE KIND OF IN BETWEEN.

SO IN SUM, THIS PRESENTS CIRM AN OPPORTUNITY TO ENHANCE ITS FUNDING PROGRAMS TO SET A REALLY CLEAR GOAL ON GETTING TO THAT FIRST-IN-HUMAN

CLINICAL TRIAL AND TO HOLISTICALLY SUPPORT ALL ACTIVITIES TO GET THERE ALONG THE WAY. AND THAT'S THE PROGRAM THAT WE'RE PROPOSING TO YOU TODAY.

BEFORE WE GET TO THAT, I DO WANT TO NOTE THAT OTHER FUNDING AGENCIES HAVE ALSO MADE SIMILAR OBSERVATIONS. IN THE LAST FEW YEARS, THEY HAVE DEVELOPED SIMILAR PROGRAMS. NIH IN PARTICULAR HAS SEVERAL DIFFERENT MECHANISMS WHERE THEY HAVE SOME THINGS IN COMMON. THE FIRST IS THAT THEY ALLOW FOR MULTIPLE ENTRY POINTS. THE PROJECT COMES IN AT THE STAGE THAT IT'S READY, AND IT'S FUNDED ACROSS MULTIPLE CLASSICAL DEVELOPMENT STAGES. SO, FOR EXAMPLE, AN AWARD COULD SUPPORT EVERYTHING FROM LEAD OPTIMIZATION TO IND FILING. AND SOME OF THESE PROGRAMS EVEN SUPPORT A CLINICAL TRIAL AS PART OF THAT AWARD.

SO BUILDING ON ALL OF THAT BACKGROUND KNOWLEDGE AND OBSERVATIONS WITHIN OUR PORTFOLIO AND EXTERNAL LANDSCAPE, WE'RE PROPOSING TO YOU A PDEV PROGRAM WITH THE OBJECTIVE OF ACCELERATING COMPLETION PRECLINICAL DEVELOPMENT, FDA IND CLEARANCE, AND CLINICAL START-UP FOR STEM CELL-BASED AND GENETIC THERAPIES. WHAT THIS PROGRAM WILL DO IS SET A SHARED GOAL BETWEEN CIRM AND THE AWARDEE ON ACCELERATING PRECLINICAL DEVELOPMENT TO IND

CLEARANCE AND START OF THAT FIRST-IN-HUMAN CLINICAL TRIAL. THEN IT WILL HOLISTICALLY SUPPORT ALL THE ACTIVITIES NECESSARY TO GET THERE.

SO, IN EFFECT, WHAT WE'RE TALKING ABOUT IS COMBINING OUR TRAN1 AND CLIN1 PROGRAM. AND THE NEW PROGRAM, THE PDEV PROGRAM, NOW FITS INTO THE NEW STRUCTURE OF CIRM FUNDING PROGRAMS THAT DR. CANET-AVILES HAD LED THROUGH THE SAF IMPLEMENTATION. AND IT'S BRACKETED BY AN EARLY DEVELOPMENT PROGRAM. THIS IS THE REPLACEMENT TO DISC2 TO SUPPORT CANDIDATE DISCOVERY AS WELL AS THE ENHANCED CLIN2 PROGRAM WHICH WILL BE UP FOR YOUR CONSIDERATION AFTER MY PRESENTATION.

SO I'M GOING TO SPEND A FEW SLIDES NOW TALKING ABOUT THE STRUCTURE OF THAT CONSOLIDATION AFTER HAVING TALKED A LITTLE BIT ABOUT THE SCOPE.

SO THE PDEV PROGRAM, AS I MENTIONED, IS A COMBINATION OF ACTIVITIES THAT SPAN EVERYTHING FROM LEAD OPTIMIZATION TO IND SUBMISSION, BUT ALL AWARDS THAT COME IN FOR THE PDEV PROGRAM WILL HAVE THAT SINGULAR OUTCOME OF IND CLEARANCE. SO WE THINK OF THIS AS TWO DIFFERENT STAGES THAT ARE BEING EXPLAINED HERE ON THIS EARLY PDEV, WHICH IS THE PRE-IND STAGE, AND LATE PDEV, WHICH IS THE IND-ENABLING STAGE, BUT THESE TWO STAGES ARE

INTRICATELY LINKED.

ACTIVITIES THAT ARE CONDUCTED IN THIS ARE ACROSS FOUR MAJOR AREAS. FIRST, YOU HAVE MANUFACTURING, THEN YOU HAVE NONCLINICAL DEVELOPMENT, CLINICAL PLANNING, AS WELL AS REGULATORY PLANNING. SO ACROSS THESE FOUR AREAS IN THE EARLY PRE-IND STAGE INVOLVES PROCESS DEVELOPMENT, SOME PILOT NONCLINICAL STUDIES, INITIAL PLANNING FOR THE CLINICAL DEVELOPMENT, AS WELL AS PLANNING FOR THAT REGULATORY INTERACTION. ALL LEADING UP TO A WELL-DEFINED, WELL-CONSTRUCTED PRE-IND MEETING.

AND THEN THE FEEDBACK FROM THE FDA ALONG WITH ALL THE PILOT AND DEVELOPMENT WORK THAT HAD BEEN DONE PREVIOUSLY ALLOWS FOR A STREAMLINED AND DIRECTED EXECUTION OF MANUFACTURING FOR THE DRUG PRODUCT, COMPLETION OF ALL THE GLP STUDIES TO GET TO IND, AS WELL AS A FINAL CLINICAL PROTOCOL, AND THEN THE SUBMISSION OF THE IND PACKAGE.

SO ALL THIS IS INTRICATELY LINKED TOGETHER WHERE ONE STAGE IS INFORMING THE NEXT STAGE. AND BY ALLOWING FOR A HOLISTIC APPROACH, WE CAN ACTUALLY ALLOW THE AWARDEE TO STRUCTURE AND STAGE THOSE ACTIVITIES AS APPROPRIATE AND NECESSARY TO GET TO IND FOR THAT PARTICULAR THERAPEUTIC CANDIDATE.

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IN THIS PRESENTATION AND THE NEXT FEW SLIDES, I TALK ABOUT EARLY PDEV AND LATE PDEV. FOR US THAT'S A WAY TO MORE EASILY MANAGE APPLICATION COMPONENTS, AWARD MANAGEMENT, AWARD BUDGETS, AND SO ON. SO RECOGNIZE THAT THAT'S THE REASON WHY YOU SEE THOSE DISTINCTIONS COMING UP IN THE REST OF THE PROPOSAL.

SO LET'S START WITH AWARD AMOUNT AND DURATION. WE ARE PROPOSING TO HAVE SEPARATE LIMITS FOR EACH OF THE TWO STAGES, EARLY PDEV AND LATE PDEV, TO HELP DEFINE THE ACTIVITIES AND TIMELINES FOR THE AWARDEES. SO FOR THE EARLY PDEV, THIS IS INFORMED BY OUR EXISTING TRAN1 MECHANISM, THE MAX AWARD AMOUNT WOULD BE $5.5 MILLION IN TOTAL COST AND THE MAX STAGE DURATION IS 30 MONTHS. FOR THE LATE PDEV STAGE, THE MAX AMOUNT THEY CAN REQUEST IN TOTAL COSTS FROM CIRM IS 7.5 MILLION, AND THE MAX STAGE DURATION IS 30 MONTHS.

NOW, YOU CAN HAVE APPLICANTS WHO ARE COMING IN REQUESTING FUNDING FOR BOTH THAT EARLY PDEV AND LATE PDEV STAGE OR JUST FOR THE LATE PDEV STAGE. SO ON THAT NOTE, THE MAXIMUM AWARD AMOUNT FOR A PDEV PROGRAM WOULD BE $13 MILLION IF THEY'RE REQUESTING FUNDING MAXING OUT FOR BOTH OF THOSE STAGES, AND THE MAX AWARD DURATION WOULD BE FIVE

YEARS.

SO TO WRAP UP ON THE SCOPE SIDE OF THIS PROGRAM, I'M GOING TO SPEND A COUPLE OF SLIDES TALKING ABOUT THE PRIORITIZATION ELEMENTS TO ADDRESS THE SECOND SAF RECOMMENDATION OF INNOVATIVE THERAPIES FOR DISEASES THAT AFFECT CALIFORNIANS.

WE ARE PROPOSING A PREFERENCE-BASED MECHANISM FOR THE PDEV PROGRAM. AND THIS IS TO HELP ACHIEVE THE SAF GOAL. AND THE WAY THIS IS GOING TO WORK IS THAT THERE ARE SEVERAL GUIDING PRINCIPLES THAT ARE GOING TO ALLOW US TO DEFINE PREFERENCES ON AN ANNUALIZED BASIS. SO THE GUIDING PRINCIPLES ARE TO FUND THERAPIES THAT OFFER POTENTIAL FOR TRANSFORMATIVE CLINICAL IMPACT, TO FUND THERAPIES THAT ADDRESS BOTTLENECKS TO ACCESS AND AFFORDABILITY CHALLENGES THAT ARE KNOWN IN THE FIELD, AND, LASTLY, TO FUND THERAPIES THAT ARE NOT ADEQUATELY SUPPORTED BY FEDERAL FUNDING OR PRIVATE INVESTMENT.

AND HOW WE DEFINE AND IMPLEMENT THESE PREFERENCES IS IN THE IMPLEMENTATION PLAN. SO THE GOAL IS TO EVOLVE THESE PREFERENCES OVER THE COURSE OF THE ENTIRE LIFETIME OF THIS PROGRAM AND TO DO SO BASED ON INFORMATION FROM INTERNAL PORTFOLIO AND EXTERNAL LANDSCAPE ANALYSES. SO THE IDEA HERE IS THAT BY DOING THIS WE CAN BUILD A DIVERSE PORTFOLIO

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OF THERAPEUTIC APPROACHES BY CONSTANTLY ADAPTING THOSE PREFERENCES BASED ON OUR INTERNAL PORTFOLIO AND THE EXTERNAL LANDSCAPE ANALYSES. AND THIS SET OF PREFERENCES WOULD BE APPROVED ON A FISCAL YEAR BASIS FOR THE ICOC BASED ON DATA AND ANALYSIS OF OUR INTERNAL PORTFOLIO AND THE EXTERNAL LANDSCAPE.

SO TO PUT THAT ABSTRACT INTO PRACTICE, FOR THE FIRST FISCAL YEAR, WE ARE PROPOSING A SET OF PREFERENCES THAT ARE FOCUSED ALONG TWO TRACKS. THE FIRST IS TO ADDRESS PROP 14 PRIORITIES, AND THE SECOND IS TO ACCELERATE PROGRAMS.

SO THE FIRST FOUR PREFERENCES THAT ARE LISTED HERE ARE DESIGNED TO ADDRESS PROP 14 PRIORITIES. THERE'S THREE MODALITY-BASED PREFERENCES, PLURIPOTENT STEM CELL-DERIVED THERAPIES, IN VIVO GENETIC THERAPIES, AND NONVIRAL NUCLEIC ACID DELIVERY. SO THESE ARE MEANT TO HAVE POTENTIAL TO ADDRESS PATIENT ACCESS AND AFFORDABILITY BARRIERS. AND THE LAST OF THE FOUR PROP 14 PREFERENCES, OF COURSE, IS TO PRIORITIZE FOR DISEASES OF THE BRAIN AND CNS.

THE LAST TWO PREFERENCES HERE ARE ACCELERATION FOCUSED. SO, FOR EXAMPLE, IF WE SUPPORTED A PROJECT THROUGH DISC2 OR TRAN1, THAT PROGRAM WOULD BE PREFERRED IN SOME WAY TO ADVANCE TO

THE PDEV PROGRAM TO SUPPORT ITS PROGRESSION TO IND CLEARANCE.

AND LASTLY, IF THE APPLICANT HAS CONDUCTED A PRE-IND OR INTERACT MEETING THAT HAS INFORMED THIS PATHWAY, THAT ALSO IS AN ACCELERATING MECHANISM TO IND CLEARANCE.

ALL THESE PREFERENCES WOULD BE IMPLEMENTED DURING THE PRESUBMISSION STAGE, WHICH I'LL DESCRIBE IN THE NEXT FEW SLIDES, AS WELL AS DURING THE ARS REVIEW BY MEMBERS OF THE BOARD.

SO I'M GOING TO SPEND A FEW SLIDES DESCRIBING THE PRESUBMISSION PROCESS AS IT'S TAILORED FOR THE PDEV PROGRAM. AND DR. GIL SAMBRANO WILL PROVIDE MORE DETAILS. THERE'S ALREADY BEEN A RICH DISCUSSION ON THIS, SO I'M NOT GOING TO SPEND TOO MUCH TIME ON THIS PARTICULAR SLIDE. BUT THE RATIONALE FOR THE PRESUBMISSION PROCESS IS SIMILAR TO WHAT YOU HEARD FOR DISC4, WHICH IS TO HELP MANAGE THE HIGH APPLICATION VOLUME, TO REDUCE THE OVERALL BURDEN ON THE APPLICATION BY FIRST HAVING THEM SUBMIT A PRESUBMISSION BEFORE THEY HAVE TO COMMIT TO A FULL APPLICATION SUBMISSION. IT ALSO ALLOWS US TO EFFICIENTLY AND EFFECTIVELY IMPLEMENT THE PROGRAM PREFERENCES THAT YOU SAW ON THE PREVIOUS SLIDE. AND LASTLY, IT ALLOWS THE CIRM TEAM TO PREPLAN FOR THE

GWG EXPERTISE AND COMPOSITION BY A COUPLE MONTHS TO HAVE A MORE INFORMED AND ROBUST SCIENTIFIC REVIEW.

SO THE WORKFLOW IS SIMILAR TO WHAT YOU HEARD FOR DISC4. AN APPLICANT WILL COMPLETE A SHORT PRESUBMISSION FORM IN THE GMS, AND THE CIRM TEAM WILL FILTER AND RANK ORDER THE PRESUBMISSIONS BASED ON PREFERENCES AS WELL AS RELATED OBJECTIVE CRITERIA, WHICH I'LL DESCRIBE IN THE NEXT SLIDE. AND THEN LASTLY, THOSE PRESUBMISSIONS THAT ARE SELECTED ARE INVITED TO APPLY FOR THE FULL APPLICATION.

SO FOR THE PDEV PROGRAM, THE RUBRIC FOR PRESUBMISSION RANK ORDERING IS BASED ON THE PREFERENCES THAT I JUST NOTED IN THE PREVIOUS SLIDE, THE PROP 14 AND OTHER PREFERENCES, AS WELL AS A COUPLE OF OTHER CRITERIA THAT ARE DESIGNED TO PREFER PROJECTS THAT ARE ADDRESSING THERAPEUTIC AREAS OR THERAPEUTIC APPROACHES THAT ARE UNDERREPRESENTED IN CIRM'S PORTFOLIO. FOR EXAMPLE, IF IT'S A PROJECT THAT'S TARGETING A DISEASE AREA THAT'S UNDERREPRESENTED IN CIRM'S PORTFOLIO, IT MAY GET SOME ADDITIONAL POINTS. OR IF IT'S A REALLY NOVEL APPROACH THAT IS NOT REPRESENTED IN CIRM'S PORTFOLIO, IT WOULD ALSO GET ADDITIONAL POINTS.

SO IN COMBINATION OF THE CONSOLIDATION OF

THE PROGRAMS AS WELL AS THE PREFERENCES, THAT'S SETS THE SCOPE FOR THE PROGRAM. IN THE NEXT FEW SLIDES, I'M GOING TO FOCUS ON THE STRUCTURE ELEMENTS OF THE PROGRAM. AND I'LL HIGHLIGHT AREAS WHERE THIS DIFFERS SIGNIFICANTLY FROM OUR EXISTING PROGRAMS IN THE INTEREST OF TIME.

SO FOR PROGRAM STRUCTURE, THE PDEV PROGRAM WILL BE AVAILABLE TWICE A YEAR, AND IT WILL BE OPEN ONLY TO CALIFORNIA ORGANIZATIONS. THESE ARE EITHER NON-PROFIT OR FOR-PROFIT ORGANIZATIONS. IT WILL RETAIN THE CO-FUNDING REQUIREMENT THAT OUR CURRENT PROGRAMS HAVE, WHICH IS 20 PERCENT FOR NON-PROFITS THAT HAVE A PARTNER OR FOR-PROFITS. AND BASED ON OUR INTERNAL PROJECTIONS FOR HOW MANY AWARDS WE WOULD NEED TO MEANINGFULLY CONTRIBUTE TO THE SAF GOAL, WE ARE REQUESTING AN ANNUAL BUDGET FOR THE FIRST YEAR OF $160 MILLION FOR THIS PROGRAM.

GIVEN WHAT I SAID PREVIOUSLY, BECAUSE IT DEPENDS ON THE SIZE OF THOSE AWARDS AND THE STAGE THAT THEY'RE REQUESTING FUNDING FOR, YOU CAN ANTICIPATE BETWEEN 12 TO 21 AWARDS BEING FUNDED WITH THAT $160 MILLION ALLOCATION IN THAT FIRST FISCAL YEAR.

HERE I'VE GIVEN YOU A PROJECTION THAT INDICATES SEVEN EARLY PDEV AWARDS AND NINE LATE PDEV

AWARDS WITH THAT ALLOCATION IN THE FIRST FISCAL YEAR. IF THIS WERE ACHIEVED, WE'D BE IN PRETTY GOOD SHAPE. YOU WOULD HAVE NINE AWARDS IN THE LATE STAGE THAT WOULD HAVE A GOOD CHANCE OF CONTRIBUTING FAIRLY RAPIDLY TO THE CLINICAL PIPELINE AND ALSO BEING ABLE TO SUPPORT SEVEN INNOVATIVE THERAPIES IN THIS ACCELERATION-BASED MODEL TO GET TO IND CLEARANCE.

SO AS YOU KNOW, ALL CIRM FUNDING PROGRAMS HAVE VARIOUS ELIGIBILITY REQUIREMENTS. THIS PROGRAM HAS SIMILAR ELIGIBILITY REQUIREMENTS TO THE EXISTING TRAN AND CLIN1. AND SO AS I MENTIONED, THE APPLICANT MUST BE A CALIFORNIA ORG. IN ADDITION TO THAT, IT HAS CANDIDATE READINESS REQUIREMENTS, PI AND PROJECT MANAGER EFFORT REQUIREMENTS, A REQUIREMENT TO START THE AWARD 90 DAYS AFTER APPROVAL, AND THEN TO DEMONSTRATE THAT IT CAN ACTUALLY CO-FUND THE AWARD AT THE TIME OF APPLICATION.

NOW I'M GOING TO HIGHLIGHT A FEW AREAS WHERE WE'RE IMPLEMENTING NEW OR MODIFIED REQUIREMENTS TO THIS PROGRAM AS COMPARED TO THE EXISTING TRAN AND CLIN1. ON THIS SLIDE YOU SEE THREE AREAS THAT ARE ALL BROADLY FOCUSED ON BEING ABLE TO ACCELERATE DEVELOPMENT AND COMMERCIALIZATION OF THERAPIES AND TO DO SO IN A MORE COLLABORATIVE

MANNER.

SO FIRST AND FOREMOST, AS MANY OF YOU KNOW, CELL AND GENE THERAPY DEVELOPMENT CAN PROGRESS VERY RAPIDLY. THE MOST FAMOUS EXAMPLE BEING CSH CHEVY WHICH HAS GONE FROM CRISPR BEING DISCOVERED IN A TEST TUBE TO AN APPROVED THERAPY IN TEN YEARS. GIVEN THAT, OUR AWARDEES SHOULD BE ACTIVELY PLANNING AND BE SUPPORTED FOR PLANNING FOR MARKET ACCESS STRATEGIES. AND WE WANT THOSE MARKET ACCESS STRATEGIES TO FOCUS AND HAVE A PARTICULAR CONSIDERATION FOR PATIENT ACCESS AND AFFORDABILITY PLANNING. AND SO THE AWARDEES WILL BE REQUIRED TO PROPOSE ACTIVITIES DURING THE PDEV STAGE THAT ARE PHASE APPROPRIATE FOR THAT STAGE AND TO DEMONSTRATE COMPLETION OF THOSE OVER THE COURSE OF THAT AWARD.

SIMILARLY TO THE OTHER PROGRAMS THAT HAVE BEEN HIGHLIGHTED TODAY, THERE WILL BE A DATA SHARING REQUIREMENT. SO THEY'LL HAVE TO PROPOSE A DATA SHARING AND MANAGEMENT PLAN, AND THIS WILL BE COORDINATED WITH CIRM'S OVERALL DATA SHARING INITIATIVES THAT KELLY, DR. SHEPARD, AND DR. TAN HAVE ALREADY HIGHLIGHTED.

LASTLY IS THE ONE THAT'S A PRIORITY FOR OUR TEAM, WHICH IS TO BE ABLE TO CREATE A KNOWLEDGE SHARING NETWORK WITHIN OUR AWARDEES. THE IDEA HERE

IS TO REQUIRE AND FACILITATE PRECOMPETITIVE SHARING BETWEEN THE PDEV AWARDEES ON BEST PRACTICES FOR REGULATORY INTERACTIONS OR ROBUST STUDY DESIGNS AND FOR COMMON ASSAY DEVELOPMENT, ALL OF WHICH CAN HELP RISE ALL BOATS.

SO THE INTENT HERE IS THAT BY SHARING BEST PRACTICES, THEY'RE HELPING EACH OTHER ADVANCE MUCH MORE RAPIDLY TO THE CLINIC.

AND ON THAT THEME OF HELPING ALL OF OUR PROGRAMS RAPIDLY ADVANCE, WE ARE ALSO COMMITTING TO MAKING A FEW CHANGES ON THE AWARD MANAGEMENT SIDE WITHIN OUR TEAM. FIRST AND FOREMOST IS THAT WE WANT TO INCREASE REAL-TIME INTERACTIONS BETWEEN CIRM AND THE AWARDEE PROJECT TEAMS. AND THIS WILL ALSO INCORPORATE DIRECT INTERACTION WITH THE MANUFACTURING LEADS ON THOSE PROGRAMS AS WELL AS CIRM BEING A PARTNER IN ANY FDA INTERACTIONS.

AND WE ALSO WILL IMPLEMENT AN EXTERNAL PRODUCT DEVELOPMENT EXPERT NETWORK. THIS IS A TEAM OF ADVISORS THAT CIRM CAN DRAW ON TO HELP WITH ISSUES SUCH AS MILESTONE ACHIEVEMENT, HELPING OVERCOME BOTTLENECKS, HELPING REVIEW AND STRATEGIZE ON PRE-IND MEETING SUBMISSIONS AND OTHER FDA INTERACTIONS.

AND THE WAY TO THINK ABOUT THIS NETWORK IS

THAT IT WILL BE A BRAIN TRUST FOR THE SO'S AND IT WILL COMPLEMENT THE CIRM SO'S INTERNAL EXPERTISE. SO WE ARE EXPECTING THESE EXPERTS TO SPAN AREAS SUCH AS NONCLINICAL TESTING, CLINICAL DEVELOPMENT, AND REGULATORY AND CMC.

AND WE CONTINUE -- WE WILL ADOPT THE CLIN1 OPERATIONAL MILESTONE-DRIVEN MANAGEMENT STRUCTURE. SO JUST AS A REMINDER, THE TRAN, CLIN1, AND CLIN2 PROGRAMS, THOSE AWARDS ARE MILESTONE-BASED DISBURSEMENTS. SO THEY ARE GIVEN AN INITIAL DISBURSEMENT TO ACHIEVE THE FIRST MILESTONE. UPON ACHIEVING THE FIRST MILESTONE, THEY GET THE DISBURSEMENT TO ACHIEVE THE NEXT MILESTONE. AND THAT'S HOW CIRM MANAGES ITS RISK IN THESE PROJECTS.

SO IN THIS INSTANCE A DELAY OF MORE THAN FOUR MONTHS ON AN OPERATIONAL MILESTONE WILL TRIGGER AN AWARD TERMINATION REVIEW. HOWEVER, BECAUSE OF THE PROACTIVE COMMUNICATION, WE'RE HOPING THAT THAT WILL ACTUALLY ALLOW US TO WORK REALLY COLLABORATIVELY WITH THE TEAM AND TO MITIGATE ANY PROJECT DELAYS GOING FORWARD.

SO WITH THAT, I'M GOING TO WRAP UP WITH THE TIMELINE. SO IF THE ICOC APPROVES THIS CONCEPT TODAY, WE WILL ROLL THIS PROGRAM OUT IN THE NEXT TWO MONTHS AND OPEN UP THE PRESUBMISSION PROCESS. THE

CYCLE GOING FROM PRESUBMISSION TO AWARD START FOR THIS PROGRAM IS ANTICIPATED TO LAST TEN MONTHS.

SO WITH THAT, THE CIRM TEAM REQUESTS THAT THE ICOC APPROVE THE PROPOSED PDEV CONCEPT PLAN.

CHAIRMAN IMBASCIANI: SHYAM, THANK YOU FOR THE PRESENTATION, EXCELLENT. QUESTIONS FIRST MAYBE? IF NOT, I'M GOING TO ASK MARIA TO OFFER THE MOTION.

VICE CHAIR BONNEVILLE: HERE WE GO. I'D LIKE TO MAKE A MOTION TO APPROVE THE PRECLINICAL DEVELOPMENT CONCEPT PLAN AND TO DELEGATE TO THE CEO THE AUTHORITY TO MAKE AND IMPLEMENT CHANGES TO THE CONCEPT PLAN IN BETWEEN BOARD MEETINGS UPON CONSULTATION OF THE CHAIRS, THE CO-CHAIRS FOR THE ICOC SUBCOMMITTEES AND TO BRING THOSE CHANGES BEFORE THE BOARD AT THE NEXT OPPORTUNITY FOR RATIFICATION.

DR. GASSON: SECOND.

CHAIRMAN IMBASCIANI: JUDY GASSON SECONDED. AND I WILL ENTERTAIN DISCUSSION AMONG THE BOARD MEMBERS. EVERYONE DID THEIR HOMEWORK. AND THERE'S NOTHING FROM THE PUBLIC; IS THAT CORRECT, SCOTT? NO ONE FROM THE PUBLIC. OKAY. WE CAN PROCEED TO A VOTE. THANK YOU.

DR. PATEL: THANK YOU.

MR. TOCHER: ARE YOU SURE? ALL THOSE IN THE ROOM IN FAVOR SAY AYE. THOSE OPPOSED SAY NAY.

ANY ABSTENTIONS? AND I'LL POLL THE MEMBERS ON THE PHONE.

MONICA CARSON. YSABEL DURON.

MS. DURON: YES.

MR. TOCHER: RICH LAJARA.

MR. LAJARA: YES.

MR. TOCHER: SHLOMO MELMED.

DR. MELMED: YES.

MR. TOCHER: CHRIS MIASKOWSKI.

DR. MIASKOWSKI: YES.

MR. TOCHER: JOE PANETTA. SUZANNE SANDMEYER.

DR. SANDMEYER: YES.

MR. TOCHER: KAROL WATSON.

DR. WATSON: YES.

MR. TOCHER: AND KEVIN XU.

DR. XU: YES.

MR. TOCHER: THANK YOU, MR. CHAIR. THE MOTION CARRIES.

AND WE HAVE A MODIFICATION TO THE SCHEDULE. IF IT PLEASES THE COURT, WE ARE RUNNING A LITTLE EARLY AND LUNCH IS UNAVAILABLE BEFORE NOON. SO WE WOULD SUGGEST MOVING TO THE NEXT CONCEPT PLAN ITEM WHICH IS CONSIDERATION OF AMENDMENTS TO THE CLIN2 CONCEPTS, WHICH IS YOUR ITEM NO. 12 ON THE

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AGENDA.

CHAIRMAN IMBASCIANI: SO THE NEXT TWO ITEMS WILL INVOLVE AMENDMENTS. ITEM 12, I'D LIKE TO DR. LISA KADYK, OUR CIRM FELLOW. LISA, WOULD YOU COME AND MAKE THE PRESENTATION.

DR. KADYK: GOOD MORNING, MR. CHAIR, MADAM VICE CHAIR, MEMBERS OF THE BOARD, MY COLLEAGUES, AND MEMBERS OF THE PUBLIC. I'M LISA KADYK. I'M HERE TO PRESENT TO YOU SOME UPDATES TO THE CLIN2 FUNDING OPPORTUNITY THAT FUNDS CLINICAL TRIAL AWARDS AT CIRM.

AND MY TALK WILL FOLLOW THE SAME STRUCTURE THAT WAS OUTLINED ORIGINALLY BY DR. SHEPARD, AND SO YOU SHOULD BE FAMILIAR WITH IT.

SO LIKE THE PRECLINICAL DEVELOPMENT PROGRAM THAT YOU JUST HEARD ABOUT, THE CLIN2 PROGRAM IS DESIGNED TO ADDRESS SAF GOAL 4, PROPELLING 15 TO 20 THERAPIES TO LATE STAGE CLINICAL TRIALS. AND THERE WERE THREE AREAS THAT WERE CALLED OUT FOR UPDATES FOR THE CLIN2 PROGRAM UNDER THIS SAF GOAL, INCLUDING NOW ALLOWING SUPPORT FOR EMERGING NOVEL CLINICAL TRIAL DESIGNS, INCENTIVIZING STAGE-APPROPRIATE MARKET ACCESS STRATEGY DEVELOPMENT, AND PRECOMMERCIALIZATION ACTIVITIES, AS WELL AS, LIKE THE PRECLINICAL PROGRAM,

PRIORITIZATION OF INNOVATIVE THERAPIES FOR DISEASES THAT AFFECT CALIFORNIANS.

SO TO BETTER UNDERSTAND THE CHALLENGES AND OPPORTUNITIES OF OUR EXISTING CLIN2 PROGRAM, OUR CLINICAL DEVELOPMENT TEAM DID AN ANALYSIS OF PREVIOUSLY FUNDED CLINICAL TRIAL AWARDS AT CIRM. AND OUT OF 110 AWARDS THAT HAVE BEEN PREVIOUSLY FUNDED, WE FOUND SOME COMMON CHALLENGES THAT ARE SOMETIMES ARISING FOR THOSE PROGRAMS. AND THESE INCLUDE DELAYS IN REACHING OPERATIONAL MILESTONES, LACK OF ADVANCEMENT TO THE NEXT PHASE TRIAL, LACK OF PARTNERSHIPS THAT CAN CARRY THE PROGRAMS TO BEYOND CIRM FUNDING, AS WELL AS LACK OF EMPHASIS ON COMMERCIALIZATION PLANNING.

SO IN PARALLEL TO THIS INTERNAL ANALYSIS THAT WE DID, WE ALSO STUDIED AN EXTERNAL LANDSCAPE ANALYSIS THAT WAS DONE ON THE CELL AND GENE THERAPY FIELD. AND ONE CONCLUSION FROM THAT ANALYSIS WAS THAT 50 PERCENT OF MARKETED CELL AND GENE THERAPIES THAT ORIGINATE IN ACADEMIA OR EMERGING BIOPHARMA ARE EVENTUALLY LAUNCHED BY A LARGER COMPANY. AND GIVEN THAT ACADEMIA AND EMERGING BIOPHARMA ARE THE CLIN2 CLIENTELE, WE CONCLUDE THAT OUR PROGRAMS OR AT LEAST HALF OF THEM WILL EVENTUALLY DEPEND ON PARTNERING TO GET TO BLA FILING AND COMMERCIALIZATION.

SO WE THINK THERE'S AN OPPORTUNITY TO BETTER POSITION THESE PROGRAMS TO BE ATTRACTIVE FOR PARTNERING DOWN THE ROAD SHOULD THE CLINICAL DATA BE SUPPORTIVE. AND SO TO THAT END, WE ARE PROPOSING SOME MODIFICATIONS TO THE EXISTING PROGRAM TO ENCOURAGE EARLIER DEVELOPMENT OF CLINICAL AND MANUFACTURING STRATEGIES, A MARKET ACCESS STRATEGY, AND STAGE-APPROPRIATE PRECOMMERCIALIZATION ACTIVITIES.

SO THE OBJECTIVE OF THE CLIN2 PROGRAM IS TO ACCELERATE CLINICAL DEVELOPMENT OF STEM CELL-BASED AND GENETIC THERAPIES TO LATE STAGE TRIALS BY ENCOURAGING INNOVATIVE TRIAL DESIGNS AND INCENTIVIZING STAGE-APPROPRIATE MARKET ACCESS STRATEGY, AND PRECOMMERCIALIZATION ACTIVITIES.

SO ON THIS SLIDE I'M GOING TO GO OVER THE SCOPE OF THE CLIN2 PROGRAM. IT, OF COURSE, FUNDS PHASE 1, 2, 3 CLINICAL TRIALS, INCLUDING REGISTRATIONAL TRIALS, USING A REGENERATIVE MEDICINE APPROACH. AND I'VE DIVIDED THESE ACTIVITIES INTO REQUIRED ACTIVITIES AND THOSE THAT ARE ALLOWED, BUT NOT NECESSARILY REQUIRED.

SO STARTING WITH THE REQUIRED ACTIVITIES, OF COURSE, WE WOULD EXPECT THE APPLICANTS TO PROPOSE COMPLETION OF A CLINICAL TRIAL. AND WE ARE

ENCOURAGING THOSE THAT HAVE ACCELERATING CLINICAL TRIAL DESIGNS. WE WOULD ALSO REQUIRE THAT APPLICANTS OR AWARDEES ESTABLISH A STRATEGIC PLANNING COMMITTEE. AND THIS WOULD BE A COMMITTEE OF ADVISORS THAT HAVE EXPERIENCE TAKING A CELL AND/OR GENE THERAPY ALL THE WAY TO BLA FILING. AND THE PURPOSE OF THIS COMMITTEE WOULD BE THEN TO BE VERY STRATEGIC AND FORWARD LOOKING PLANNING FOR THIS PROGRAM IN THE AREAS OF CLINICAL DEVELOPMENT, REGULATORY, MANUFACTURING, AND PRECOMMERCIALIZATION ACTIVITIES. AND MANY OF THESE PROGRAMS COULD REALLY BENEFIT FROM THAT KIND OF EXPERIENCE AND EXPERTISE TO ACCELERATE THEIR PROGRAMS.

WE WOULD ALSO, LIKE ALL THE OTHER CIRM PROGRAMS, HAVE A DATA SHARING REQUIREMENT SO THAT EVENTUALLY CLINICAL TRIAL DATA THAT COMES FROM CIRM FUNDING COULD BE FINDABLE AND ACCESSIBLE FOR THOSE WHO COULD BENEFIT FROM IT LATER.

WE WOULD ALSO CONTINUE TO REQUIRE OUTREACH ACTIVITIES SO THAT CLINICAL TRIALS WOULD ENROLL DEMOGRAPHICS OF THE -- PATIENT DEMOGRAPHICS THAT MATCH THE PATIENT DEMOGRAPHIC OF THE POPULATION AT LARGE.

AND FINALLY, WE WILL REQUIRE STAGE APPROPRIATE COMMERCIALIZATION, PRECOMMERCIALIZATION,

AND ACCESS AND AFFORDABILITY ACTIVITIES.

AND THEN WE ALSO HAVE SOME OTHER ACTIVITIES THAT ARE ALLOWABLE, INCLUDING FUNDING OF NATURAL HISTORY STUDIES IF THEY ARE FDA APPROVED AS THEY MIGHT BE NEEDED FOR BASELINE OR CONTROL DATA FOR AN INTERVENTIONAL TRIAL THAT WAS ALSO FUNDED UNDER THAT SAME AWARD.

AND WE WOULD ALSO ALLOW MANUFACTURING FOR THE NEXT PHASE TRIAL. AND THIS IS, OF COURSE, A VERY EXPENSIVE ACTIVITY. MANUFACTURING FOR THE NEXT PHASE TRIAL IS AN EXPENSIVE ACTIVITY. HOWEVER, DOING IT EARLY CAN POTENTIALLY REALLY ACCELERATE A PROGRAM. SO WE WOULD ALLOW APPLICANTS TO PROPOSE THAT ACTIVITY; HOWEVER, WE WOULD WANT THE ACTUAL INITIATION OF THAT ACTIVITY TO BE GATED ON EVALUATION OF THE CURRENT CLINICAL TRIAL DATA AND THE PROGRESS OF THAT PROGRAM BY BOTH CIRM AND SOME EXTERNAL EXPERTS AS WELL AS THE ABILITY OF THE AWARDEE OR THE PARTNER OF THE AWARDEE TO PROVIDE 50-PERCENT CO-FUNDING FOR THAT PARTICULAR ACTIVITY. AND THAT WOULD BE -- THE ASTERISK WOULD BE ONLY IF THAT AWARD HAS A CO-FUNDING REQUIREMENT ALREADY. AND I WILL IN A COUPLE SLIDES EXPLAIN TO YOU WHAT THE CO-FUNDING REQUIREMENTS ARE FOR THE CLIN2 PROGRAM.

BEFORE I GET THERE, I JUST WANT TO REMIND YOU THAT, LIKE THE PRECLINICAL DEVELOPMENT PROGRAM, WE ARE GOING TO INCORPORATE PRIORITIZATION OF INNOVATIVE THERAPIES FOR DISEASES THAT AFFECT CALIFORNIANS. SO HOW DO WE DO THAT PRIORITIZATION?

AND THIS IS A SLIDE THAT SHOULD LOOK FAMILIAR TO YOU. IT'S THE SAME SLIDE THAT DR. PATEL JUST PRESENTED ON HOW THE CLIN2 PROGRAM WOULD INCORPORATE PROGRAM PREFERENCES ON AN ANNUAL BASIS, AGAIN, WITH THE GUIDING PRINCIPLES OF FUNDING THERAPIES THAT WILL HAVE TRANSFORMATIVE IMPACT, ADDRESS BOTTLENECKS TO ACCESS AND AFFORDABILITY, AND ARE NOT ADEQUATELY SUPPORTED BY FEDERAL FUNDING OR PRIVATE INVESTMENT.

AND SO TO DO THAT, WE WOULD HAVE ON AN ANNUAL BASIS A REVIEW OF THE PORTFOLIO, BOTH INTERNAL AND ETERNAL, IN ORDER TO SET PREFERENCES, HAVE THE BOARD APPROVE PREFERENCES FOR THE PROGRAM.

OKAY. AND THIS IS THE PROPOSED PREFERENCES FOR THE FISCAL YEAR 25/26 FOR THE CLIN2 PROGRAM. THE FIRST FOUR ROWS MAY LOOK FAMILIAR TO YOU. THEY ARE THE SAME FOUR PREFERENCES THAT WERE DESCRIBED BY DR. PATEL. THE FIRST THREE ARE DIFFERENT THERAPEUTIC MODALITIES THAT HAVE THE POTENTIAL TO ADDRESS PATIENT ACCESS AND

AFFORDABILITY BARRIERS. AND THEN, OF COURSE, DISEASES OF THE BRAIN AND CNS IS A PROP 14 PRIORITY.

AND THEN THE BOTTOM FOUR ROWS ARE CLIN2-SPECIFIC PREFERENCES. ONE IS GIVE PREFERENCES TO APPLICANTS THAT ARE CALIFORNIA ORGANIZATIONS. SECOND IS TO FUND PIPELINE PROGRAMS THAT ARE MOVING FROM AN IND-ENABLING STAGE OR FROM AN EARLIER PHASE CLINICAL TRIAL TO A LATER PHASE TRIAL. WE WOULD ALSO GIVE PREFERENCES TO PROGRAMS THAT HAVE FDA DESIGNATIONS, SUCH AS FAST TRACK, RMAT, OR BREAKTHROUGH DESIGNATIONS THAT ARE ACCELERATING AND GIVE GREATER ACCESS TO FDA FOR DEVELOPING THE PROGRAM. AND FINALLY A PREFERENCE FOR PROGRAMS THAT ARE PROPOSING PIVOTAL OR REGISTRATIONAL TRIALS.

AND THESE PREFERENCES, AGAIN, WOULD BE FACTORED IN BOTH IN THE PREREVIEW PROCESS WHICH IN CLIN2 WE'RE CALLING QUALIFICATION. I'LL DESCRIBE THAT A LITTLE BIT MORE. AND THEN DR. SAMBRANO WILL DESCRIBE IT IN MUCH MORE DETAIL LATER TODAY. AND THEN IT COULD ALSO BE FACTORED IN DURING APPLICATION REVIEW SUBCOMMITTEE OF THE BOARD.

SO THE CLIN2 APPLICATION AND REVIEW PROCESS IS DIFFERENT FROM THE ONE THAT YOU JUST HEARD ABOUT FROM DR. PATEL. WE WOULD HAVE FULL APPLICATIONS BE SUBMITTED, AND THEN IT GOES TO THE

REVIEW TEAM TO EXCLUDE ANY INELIGIBLE OR INCOMPLETE APPLICATIONS. AND THEN IN CASES WHERE THERE ARE HIGH APPLICATION VOLUMES THAT PRECLUDE ALL APPLICATIONS GOING TO FULL REVIEW, THAT IS WHEN THIS QUALIFICATION PROCESS WOULD BE PUT INTO PLAY USING OBJECTIVE PROGRAM PREFERENCES SUCH AS THE ONES I JUST DESCRIBED TO YOU.

SO THIS IS JUST AN OUTLINE OF WHAT I JUST SAID HERE. SO THAT APPLICATIONS WOULD BE SUBMITTED IN FULL, ELIGIBILITY REVIEW WOULD BE DONE TO DETERMINE WHICH ONES ARE ELIGIBLE, AND THEN ONLY IN THE CASE WHERE THERE ARE TOO MANY APPLICATIONS TO GO TO FULL REVIEW WOULD THE REVIEW TEAM THEN APPLY OBJECTIVE PREFERENCES TO RANK IN ORDER APPLICATIONS THAT WOULD THEN EVENTUALLY BE SELECTED FOR FULL REVIEW.

AND SO THE NEXT SLIDE HERE JUST SHOWS THE RUBRIC THAT WE'RE PROPOSING FOR THIS FISCAL YEAR COMING UP. SO INCLUDING THE PROP 14 PREFERENCES OF PLURIPOTENT STEM CELL DERIVED-THERAPIES, IN VIVO GENE THERAPIES, AND DISEASES OF THE BRAIN OR CNS AS WELL AS SOME OF THE OTHER PREFERENCES THAT I OUTLINED ON THE PREVIOUS SLIDE. AND THEN WE WOULD ALSO, AS WAS THE CASE FOR THE PRECLINICAL PROGRAM, TAKE INTO ACCOUNT NOVELTY OF THE THERAPEUTIC

APPROACH RELATIVE TO THE CLIN2 EXISTING ACTIVE AWARDS AS WELL AS APPROACHES THAT ARE UNDERREPRESENTED IN TERMS OF DISEASE AREA IN OUR ACTIVE AWARDS.

YOU'LL HEAR MORE ABOUT THIS FROM DR. SAMBRANO THIS AFTERNOON.

SO THIS SLIDE IS JUST TO PRESENT THE STRUCTURE OF THE CLIN2 PROGRAM. THIS PROGRAM WILL BE OFFERED FOUR TIMES PER YEAR, AND THE AWARDS WOULD HAVE A MAXIMUM DURATION OF FOUR YEARS. THIS PROGRAM, UNLIKE THE OTHER CIRM PROGRAMS, WOULD BE OPEN TO BOTH CALIFORNIA AND NON-CALIFORNIA ORGANIZATIONS WHICH IT ALWAYS HAD BEEN. I JUST WANT TO NOTE THAT FOR NON-CALIFORNIA ORGANIZATIONS, THEY ARE REQUIRED TO SPEND ALL OF THEIR CIRM DOLLARS IN THE STATE OF CALIFORNIA. AND WE HAVE THIS ALLOWANCE BECAUSE IT IS POSSIBLE THEN TO ATTRACT INNOVATIVE THERAPIES THAT MIGHT HAVE BEEN ORIGINALLY DEVELOPED ELSEWHERE INTO THE STATE OF CALIFORNIA TO BENEFIT CALIFORNIA PATIENTS.

THE TOTAL AWARD AMOUNTS FOR THE CLIN2 PROGRAM VARIES DEPENDING ON THE PHASE OF A CLINICAL TRIAL THAT'S BEING PROPOSED. SO FIRST IN HUMAN, PHASE 2, OR SUBSEQUENT. SUBSEQUENT MEANS IT COULD BE A PHASE 1 THAT'S HAPPENING AFTER THE FIRST IN

HUMAN IS ALREADY DONE OR THEN PHASE 3. AND THE CO-FUNDING REQUIREMENTS ARE DIFFERENT DEPENDING ON WHETHER THE APPLICANT IS A FOR-PROFIT OR A NON-PROFIT ORGANIZATION.

SO FOR A FOR-PROFIT, AT FIRST IN HUMAN STAGE WE REQUIRE 30 PERCENT. AND THEN FOR ANY LATER STAGE TRIAL IT WOULD BE 50 PERCENT CO-FUNDING. IN CONTRAST FOR A NON-PROFIT ORGANIZATION, THERE WOULD BE NO CO-FUNDING REQUIREMENT UNTIL GETTING TO THE PHASE 3 OR PIVOTAL STAGE WHICH IS REALLY GETTING CLOSE TO COMMERCIALIZATION WHERE YOU REALLY NEED TO HAVE A PARTNER TO CO-INVEST.

WE WOULD PROPOSE A TOTAL BUDGET FOR THIS COMING YEAR OF 135 MILLION. THIS AMOUNT SHOULD COVER A VARIETY OF DIFFERENT SCENARIOS DEPENDING ON WHAT PHASE OF TRIAL AND WHETHER THE ORGANIZATION IS FOR-PROFIT OR NON-PROFIT. WE COULD FUND UP TO, FOR EXAMPLE, NINE LATER STAGE TRIALS, PHASE 2 OR BEYOND, AT $15 MILLION EACH. HOWEVER, THE TRUTH IS 80 PERCENT OF OUR TRIALS HISTORICALLY ARE AT THE FIRST-IN-HUMAN STAGE, WHICH HAVE A LOWER FUNDING CAP. SO WE THINK THAT WE COULD GET A NUMBER OF AWARDS APPROVED. THAT'S PROBABLY GOING TO BE AT LEAST THE AMOUNT THAT WE GET HISTORICALLY PER YEAR WHICH IS 13 PER YEAR THAT WERE FUNDED AND PERHAPS

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EVEN BEYOND.

AND THIS SLIDE JUST SHOWS THE ELIGIBILITY REQUIREMENTS. SEVERAL OF THE POINTS HERE I'VE COVERED ON PREVIOUS SLIDES. BUT I DO WANT TO POINT OUT ONE AREA THAT'S SLIGHTLY MODIFIED FROM WHAT WE'VE DONE HISTORICALLY WHICH IS IN THE CANDIDATE READINESS REQUIREMENT. HISTORICALLY WE'VE ALWAYS REQUIRED THAT TO SUBMIT AN APPLICATION FOR A CLIN2 AWARD, THE IND MUST HAVE ALREADY BEEN CLEARED BY THE FDA. AND WE WILL STILL MAINTAIN THAT REQUIREMENT FOR ANY PROGRAMS THAT ARE NOT IN THE CIRM PIPELINE, THEY'RE NEW TO CIRM. HOWEVER, WE WOULD LIKE TO GIVE A SLIGHT ADVANTAGE OR JUST ENABLE THE SMOOTH TRANSITION FOR PIPELINE PROGRAMS SUCH THAT WE WOULD NOT REQUIRE THE IND TO BE CLEARED, BUT IT WOULD HAVE TO BE SUBMITTED BEFORE THEY COULD SUBMIT AN APPLICATION. AND THERE'S A 30-DAY WINDOW THERE WHEN THEY WOULD HEAR BACK FROM THE FDA WHETHER IT'S BEEN CLEARED. THEY WOULD BE REQUIRED TO SUBMIT EVIDENCE THAT THE IND WAS CLEARED IN ORDER FOR THE APPLICATION TO GO TO FULL GRANTS WORKING GROUP REVIEW. AND THIS IS JUST TO HELP ALLOW SMOOTH TRANSITION OF OUR PIPELINE PROGRAMS.

THE OTHER CHANGE IS THE TIME TO LAUNCH BETWEEN ICOC APPROVAL AND OFFICIAL LAUNCH OF THE

AWARD WOULD NOW BE 60 DAYS INSTEAD OF 45 DAYS TO ALLOW FOR THE ADMINISTRATIVE WORK THAT NEEDS TO BE DONE DURING THAT STAGE. AND WE HAVE SIMILAR PI AND PROGRAM MANAGER REQUIREMENTS FOR FTE LEVELS THAT WE'VE ALWAYS HAD.

AND THIS SLIDE IS JUST TO REITERATE SOME OF THE THINGS I MENTIONED EARLIER, THE NEWER REQUIREMENTS FOR THIS PROGRAM WHICH ARE ALSO REQUIRED FOR OUR OTHER PROGRAMS. WE WOULD REQUIRE THAT APPLICANTS PROPOSE PATIENT ACCESS AND AFFORDABILITY PLANNING IN THEIR PROPOSALS. AND ALSO WE WOULD NOW REQUIRE A DATA SHARING AND MANAGEMENT PLAN BE PROPOSED SO THAT ULTIMATELY, AGAIN, THESE DATA WOULD BE FINDABLE AND ACCESSIBLE FOR THOSE WHO COULD BENEFIT FROM IT IN THE FUTURE.

THE CLIN2 PROGRAM HAS ALWAYS BEEN VERY PROACTIVE WITH AWARD MANAGEMENT. WE WOULD CONTINUE TO REQUIRE QUARTERLY SCIENTIFIC PROGRESS REPORTS WHICH ARE ENTERED INTO OUR GRANTS MANAGEMENT SYSTEM. THE SCIENTIFIC OFFICERS READ THOSE AND THEN SCHEDULE FOLLOW-UP CALLS WITH THE AWARDEE TO FOLLOW UP ON ANY QUESTIONS THAT ARISE AND GET MORE DETAIL IF NEEDED. CIRM HAS ALWAYS REQUIRED THAT WE BE INCLUDED IN ANY FDA MEETINGS OR OTHER FDA INTERACTIONS, AND WE WILL STILL REQUIRE THAT. AND WE WOULD ALSO ASK THAT CIRM

BE INCLUDED IN ANY OF THE STRATEGIC PLANNING COMMITTEE MEETINGS.

AS YOU KNOW, THESE ARE ALL OPERATIONAL MILESTONE-DRIVEN AWARDS. IN THE CASE THAT AN AWARDEE HAS EXHAUSTED THE FUNDING THAT WAS DISBURSED TO REACH A GIVEN OPERATIONAL MILESTONE, THEN WE REQUIRE THAT THEY HAVE CONTINGENCY FUNDING IN PLACE TO GET TO THAT MILESTONE AND TO GET TO THE NEXT CIRM DISBURSEMENT. AND AN OPERATION MILESTONE DELAY OF MORE THAN FOUR MONTHS WOULD TRIGGER AN EVALUATION JUST TO EVALUATE THE FEASIBILITY THAT THIS PROGRAM WOULD CONTINUE. AND IF IT SEEMS FUTILE, THEN THERE IS THE RIGHT TO TERMINATE THE AWARD IF NEED BE.

SO TO CONCLUDE, I JUST WANT TO SHOW YOU THE TIMELINE FOR POTENTIALLY LAUNCHING THE NEW CLIN2 PROGRAM. IF YOU SHOULD APPROVE THIS CONCEPT TODAY, WE WOULD OPEN THE APPLICATIONS IN MID-MAY WITH THE FIRST APPLICATION DEADLINES IN JULY, THE FIRST GRANTS WORKING GROUP IN SEPTEMBER, AND THE FIRST APPLICATION REVIEW SUBCOMMITTEE TO LOOK AT THOSE RECOMMENDED BY THE GRANTS WORKING GROUP IN NOVEMBER OF 2025. AND THEN A SECOND CYCLE WILL OPEN IN EARLY AUGUST.

SO WITH THAT, I'D LIKE TO CONCLUDE MY PRESENTATION, REQUEST THAT YOU APPROVE THE PROPOSED

CONCEPT PLAN, BUT ALSO ASK IF YOU HAVE ANY QUESTIONS IN ADVANCE.

CHAIRMAN IMBASCIANI: THANK YOU, LISA. ANNE-MARIE DULIEGE AND THEN CAROLYN.

DR. DULIEGE: JUST EXCELLENT PRESENTATION. A QUICK CLARIFICATION. YOU MENTIONED THAT THE PROGRAM COULD GO UP TO 135 MILLION PER YEAR; IS THAT RIGHT?

DR. KADYK: THAT WOULD BE THE ANNUAL BUDGET.

DR. DULIEGE: THAT'S AN ANNUAL BUDGET. BUT BECAUSE THIS IS UP TO A FOUR-YEAR PROGRAM POTENTIALLY BASED ON APPLICATIONS, THE TOTAL AMOUNT OF FUNDING THAT WE NEED TO THINK WE PUT ASIDE IS FOUR TIMES THAT MUCH; IS THAT RIGHT?

DR. KADYK: NO. NO. IT'S JUST DONE ON AN ANNUAL BASIS. SO FOR THE UPCOMING YEAR WE WOULD HAVE BUDGET OF 135 MILLION. THE NEXT YEAR IT COULD BE A DIFFERENT BUDGET.

DR. DULIEGE: I GET THAT. BUT WHEN WE THINK ABOUT THE TOTAL ENVELOPE WE HAVE YEAR AFTER YEAR, THAT COULD BE UP TO FOUR TIMES THAT MUCH.

DR. KADYK: YEAH. IF THE BOARD APPROVES SIMILAR BUDGET LEVELS, THAT'S RIGHT. YES.

DR. DULIEGE: YES.

DR. MELTZER: THANK YOU, LISA. THIS IS JUST A WONDERFULLY EXCITING PROPOSAL. I WAS JUST WONDERING HOW IT MIGHT INTERACT OR TAKE ADVANTAGE OF THE ALPHA CLINICS NETWORK.

DR. KADYK: VERY GOOD QUESTION. AND THAT ACTUALLY IS REALLY GOING TO BE INTEGRAL TO THE PROGRAM ANNOUNCEMENT. ACTUALLY MOST OF OUR CLINICAL TRIAL AWARDS DO HAVE CLINICAL SITES AT THE ALPHA CLINICS, BUT THAT IS GOING AN AREA THAT WE'RE GOING TO EMPHASIZE AND COLLECT EVEN AT THE TIME OF APPLICATION WHETHER THEY'RE WORKING WITH THE ALPHA CLINICS AND TRYING TO ENSURE THAT ANY TRIALS THAT ARE DONE AT AN ALPHA CLINIC SITE ARE WORKING WITH THE ALPHA CLINIC THERE.

DR. LEVITT: SO THE LAST SLIDE LOOKS LIKE THE TIMELINES ARE CHANGED, RIGHT, IN TERMS OF OPEN APPLICATION AND APPLICATION REVIEW FROM WHAT WAS. IT'S MY READING OF THAT SLIDE WHICH IS COMPLICATED.

DR. KADYK: SOMEHOW I'M HAVING TROUBLE BACKING IT UP.

DR. CANET-AVILES: I CAN PROVIDE THE CLARIFICATION.

DR. LEVITT: IT MAY BE A CONVERSATION I WANT TO HAVE WITH GIL, I GUESS. I DON'T KNOW.

DR. CANET-AVILES: NO. THAT'S A

CONVERSATION -- IT ACTUALLY HAS TO DO WITH THE PROGRAMS THE WAY THAT WE HAVE DEVELOPED THIS. SO THE PART OF THE ACCESS AND AFFORDABILITY PART OF THE APPLICATION IS BEING DEVELOPED, AND IT HAS TO BE APPROVED THROUGH THE ACCESS AND AFFORDABILITY WORKING GROUP. AND THAT MEETING IS APRIL 30TH. SO THAT IS DELAYING THE READINESS OF THE APPLICATION AND THE PROGRAM DETAILS WHICH WILL BE UNDER OUR CO-CHAIR OF THE BOARD AND ALSO CHAIR OF THE ACCESSIBILITY AND AFFORDABILITY WORKING GROUP. SO WE ARE WORKING ON THAT, AND THAT IS WHY THE TIMELINE IS A LITTLE BIT LATER. THANK YOU.

DR. LEVITT: SO IF YOU SUBMIT IN JUNE, YOU GET THE DECISION SOMETIME, WHEN, AS AN APPLICANT, YOU GET IT IN DECEMBER OR JANUARY THEN?

DR. KADYK: WELL, THE APPLICATION REVIEW SUBCOMMITTEE WOULD BE IN NOVEMBER, SO YOU WOULD HEAR IMMEDIATELY AFTER THAT.

DR. LEVITT: SO IMMEDIATELY AFTER THAT. SO YOU GET IT BY DECEMBER, WHICH MEANS THAT YOU THEN CAN REAPPLY -- THE NEXT TIME YOU COULD REAPPLY WOULD BE THE FOLLOWING JUNE?

DR. KADYK: YEAH. WELL, YOU WILL RECEIVE THE GRANTS WORKING GROUP SCORE IN SEPTEMBER. IF YOU ARE NOT GETTING A LIKELY RECOMMENDED SCORE, YOU

WOULD KNOW AT THAT STAGE.

DR. LEVITT: SO YOU HAVE ACCESS TO THE EARLY NOVEMBER IF YOU COULD MUSTER UP THE --

DR. KADYK: YES. OF COURSE, IT WON'T HAVE GONE TO THE APPLICATION REVIEW SUBCOMMITTEE UNTIL NOVEMBER. GO AHEAD.

DR. SAMBRANO: JUST TO CLARIFY. SO THERE ARE FOUR CYCLES PER YEAR. GIVEN THE LENGTH OF THE REVIEW PROCESS, SOMEBODY WHO FAILS DURING THE INITIAL CYCLE WILL SKIP A CYCLE AND GO TO THE NEXT ONE. SO IT WILL BE EVERY SIX MONTHS BASICALLY THAT SOMEBODY WOULD BE ABLE TO COME IN.

DR. LEVITT: EVERY SIX MONTHS.

CHAIRMAN IMBASCIANI: YES, JOHN.

DR. CARETHERS: WHAT DO YOU ANTICIPATE IS THE MIX BETWEEN, LET'S SAY, ACADEMIA AND INDUSTRY APPLYING FOR THIS?

DR. KADYK: I CAN JUST TELL YOU THAT HISTORICALLY WE'VE FUNDED ABOUT EQUAL NUMBERS OF FOR-PROFIT AND NON-PROFIT ORGANIZATIONS.

DR. CARETHERS: AND HOW MANY -- I KNOW THE MONEY IS SUPPOSED TO BE EXPENDED IN CALIFORNIA, BUT HOW MANY OUTSIDE BECAUSE IT'S OPEN TO NON-CALIFORNIA?

DR. KADYK: YEAH. IT'S ACTUALLY

RELATIVELY LOW PERCENT THAT COME FROM OUTSIDE CALIFORNIA. I DON'T HAVE THE EXACT NUMBER, BUT I WOULD SAY MAYBE 10 PERCENT, SOMETHING LIKE THAT.

DR. CARETHERS: THANK YOU.

MR. FISCHER-COLBRIE: YOU JUST MIGHT WANT TO CLARIFY WHAT IT MEANS TO BE OUTSIDE OF CALIFORNIA BECAUSE THAT COMES WITH A SEVERE LIMITATION. AND I'M NOT SURE THAT PEOPLE ARE COGNIZANT AS TO WHAT THAT IS. SO IT'S NOT BROADLY OPEN TO OUTSIDE CALIFORNIA.

DR. KADYK: WELL, FIRST OF ALL, WE HAVE A DEFINITION FOR A CALIFORNIA ORGANIZATION, THAT THEY NEED TO SPEND -- THEY HAVE TO HAVE AT LEAST MORE THAN -- 50 PERCENT PLUS ONE OF THE EMPLOYEES, THE W2 EMPLOYEES, HAVE TO BE PAID IN CALIFORNIA. IS THAT THE MAIN THING THAT YOU'RE DRIVING AT THERE?

MR. FISCHER-COLBRIE: FOR ORGANIZATIONS OUTSIDE OF CALIFORNIA, SOMETIMES IF THERE'S A CLINICAL TRIAL BEING HELD IN CALIFORNIA, MY UNDERSTANDING IS THERE'S A POSSIBILITY OF FUNDING FOR THAT.

DR. KADYK: YEAH. AS I WAS SAYING, ANY APPLICATION -- AWARDEE THAT'S BASED OUTSIDE OF CALIFORNIA HAS TO SPEND ALL THE DOLLARS IN CALIFORNIA. SO IN THE CASE OF A CLINICAL TRIAL, IT

WOULD BE THAT THEY HAVE TO BE SPENDING MONEY ON PATIENTS THAT ARE TREATED AT CLINICAL TRIAL SITES IN CALIFORNIA.

MR. FISCHER-COLBRIE: THANK YOU. I JUST WANTED TO MAKE SURE EVERYONE WAS AWARE OF THE DIFFERENCE.

CHAIRMAN IMBASCIANI: ARE THERE ANY OTHER QUALIFYING QUESTIONS? IF NOT, SURPRISE, SURPRISE, WE HAVE A MOTION.

VICE CHAIR BONNEVILLE: I'D LIKE MAKE A MOTION TO APPROVE THE CLIN2 CONCEPT PLAN AND TO DELEGATE TO THE CEO THE AUTHORITY TO MAKE AND IMPLEMENT CHANGES TO THE CONCEPT PLAN IN BETWEEN BOARD MEETINGS UPON CONSULTATION OF THE CHAIRS AND CO-CHAIRS OF THE ICOC SUBCOMMITTEES AND TO BRING THOSE CHANGES BEFORE THE BOARD AT THE NEXT OPPORTUNITY FOR RATIFICATION.

DR. BARRETT: SECOND.

CHAIRMAN IMBASCIANI: THANK YOU, DR. BARRETT. WE HAVE A MOTION AND SECOND. IT'S OPEN FOR DISCUSSION AMONG BOARD MEMBERS ON CLIN2 CONCEPT PLAN. NOT SEEING ANY BOARD MEMBERS' HANDS, AND MEMBERS OF THE PUBLIC ARE INVITED. AND NO ONE IN THE ROOM. THANK YOU VERY MUCH. SCOTT, WE CAN PROCEED TO A VOTE. THANK YOU.

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MR. TOCHER: ALL THOSE IN THE ROOM IN FAVOR SAY AYE. OPPOSED SAY NAY. ANY ABSTENTIONS? I'LL POLL THE MEMBERS ON THE PHONE.

MONICA CARSON. YSABEL DURON.

MS. DURON: YES.

MR. TOCHER: RICH LAJARA.

MR. LAJARA: YES.

MR. TOCHER: SHLOMO MELMED.

DR. MELMED: YES.

MR. TOCHER: CHRIS MIASKOWSKI.

DR. MIASKOWSKI: YES.

MR. TOCHER: JOE PANETTA. SUZANNE SANDMEYER.

DR. SANDMEYER: YES.

MR. TOCHER: KAROL WATSON.

DR. WATSON: YES.

MR. TOCHER: AND KEVIN XU.

DR. XU: YES.

CHAIRMAN IMBASCIANI: LOOK NOW FOR GUIDANCE. IS THE VOTE COMPLETE?

MR. TOCHER: THE MOTION CARRIES. AND WE HAVE ONE VERY BRIEF ITEM THAT WE CAN GET TO BEFORE LUNCH WHICH WILL EXPEDITE YOUR JOURNEY HOME THIS AFTERNOON. SO IF YOU WOULD LIKE, WE COULD PROCEED THEN WITH ITEM, I BELIEVE IT IS, 15.

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CHAIRMAN IMBASCIANI: YES. OKAY. I WOULD LIKE TO INTRODUCE -- THIS IS RECOMMENDATIONS FROM THE GOVERNANCE SUBCOMMITTEE REGARDING CIRM'S LONG-STANDING PURCHASING POLICY. AND WE HAVE AT THE PODIUM CHIEF COUNSEL RAFAEL AGUIRRE-SACASA AND DIRECTOR OF FINANCE MICHELLE LEWIS -- WE HAVE TWO LEWISES ON OUR PAYROLL NOW -- JOINED US IN DECEMBER AND HAS ALREADY MADE A GREAT IMPACT IN OUR FINANCIAL POSITIONING. THANK YOU.

MR. AGUIRRE-SACASA: THANK YOU VERY MUCH, CHAIR IMBASCIANI, VICE CHAIR BONNEVILLE, ICOC MEMBERS, MEMBERS OF THE PUBLIC, AND COLLEAGUES. THANK YOU FOR HAVING US TODAY. WE'RE HERE TO TALK ABOUT THE PURCHASING POLICY WHICH IS INTENDED TO REPLACE THE OLD CONTRACTING POLICY WHICH WAS APPROVED LAST BY THIS BOARD IN 2016.

I'M GOING TO GIVE A QUICK OVERVIEW OF THE MEMO AND THEN TURN IT OVER TO MICHELLE SO SHE CAN GO INTO HER PRESENTATION.

THE NEW POLICY REMOVES EXTRANEOUS CONTENT AND OPERATIONAL PROCEDURES, AND IT FOCUSES ON PROCUREMENT GOVERNANCE AND COMPLIANCE, CLARITY, AND EFFICIENCY. WE'RE IN THE PROCESS OF DEVELOPING THE STANDARD OPERATING PROCEDURES THAT WILL FLOW FROM THE POLICY, BUT WE WANTED TO GET THE POLICY

APPROVED. ONCE THOSE PROCEDURES ARE FINALIZED, WE'LL BE PRESENTING THEM TO J.T. FOR FINAL APPROVAL.

WE THINK THAT THE NEW POLICY WILL BE EASIER TO TRAIN, ADMINISTER, AND MOST IMPORTANTLY COMPREHEND FOR OUR USERS. THAT LEADS TO BETTER COMPLIANCE, OF COURSE.

SOME OF THE BIG TOPICS THAT WE DID IS THAT WE CLARIFIED THE CONTRACT DURATION LIMITS BY ESTABLISHING A MAXIMUM OF TEN YEARS, AND THAT INCLUDES ANY EXTENSIONS THEREOF. WE STANDARDIZED THE APPROVAL AUTHORITY TO ALIGN WITH OUR FINANCIAL THRESHOLD. AND THE NEW POLICY ENHANCES REPORTING COMPLIANCE REQUIREMENTS THROUGH STRICTER MONITORING MEASURES TO ENSURE CONTRACT ADHERENCE AND POTENTIAL ELIMINATION OF CONFLICTS OF INTEREST.

MICHELLE, TURN IT OVER TO YOU. THANK YOU.

MS. LEWIS: THANK YOU, MEMBERS OF THE BOARD, CIRM STAFF, AND MEMBERS OF THE PUBLIC. IN PRESENTING OUR NEW POLICY, I'D LIKE TO DISCUSS SOME OF THE PROPOSED CHANGES TO THE CURRENT CONTRACTING POLICY. WE'VE REVISED AND STREAMLINED THE PREVIOUS POLICY. SO THE NEW POLICY WOULD BE TITLED "PURCHASING POLICY."

THIS REVISED POLICY INCLUDES ALL PURCHASE TYPES AND FOCUSES ON PROCUREMENT GOVERNMENT,

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TRANSPARENCY, AND EFFICIENCY. IT REMOVES THE OPERATING PROCEDURES TO FOCUS ON A STREAMLINED DOCUMENT WITH HIGH LEVEL POLICY. AS RAFAEL STATED, WE ARE WORKING WITH THE FINANCE AND LEGAL TEAMS ON THE OPERATING PROCEDURES, AND THEN WE WILL PRESENT THEM TO THE PRESIDENT FOR APPROVAL.

THE REVISED POLICY REINFORCES COMPETITIVE BIDDING AND SUPPLIER DIVERSITY WHILE ALSO EMPHASIZING COMPLIANCE AND AUDITING MEASURES.

A FEW OF THE HIGHLIGHTS OF THE CHANGES ARE THAT WE REMOVED THE LOW LEVEL SCOPE THAT SHOULD BE PLACED IN A STANDARD OPERATING PROCEDURE. EXAMPLES OF SOME OF THOSE ARE THE LOWER LEVEL DEFINITIONS SUCH AS EMPLOYER TO EMPLOYEE RELATIONSHIP AND A LOT OF THE PAYMENT REQUIREMENTS THAT WERE MUCH LOWER LEVEL. WE ALSO REMOVED APPENDICES 1 THROUGH 3 THAT WERE BASICALLY JUST TYPES OF ONE CONTRACT THAT SHOULD ALSO BE PLACED IN A STANDARD OPERATING PROCEDURE.

THIS POLICY HAS ALREADY BEEN PRESENTED TO THE GOVERNANCE SUBCOMMITTEE WHO HAVE RECOMMENDED APPROVAL. SO CIRM ASKS FOR APPROVAL OF THE PURCHASING POLICY. THANK YOU.

MR. AGUIRRE-SACASA: I KNOW THERE'S BEEN DISCUSSION ABOUT PAGE COUNT. SO THE PREVIOUS POLICY

WAS ABOUT 20 PAGES. NOW WE'RE DOWN TO FOUR. SO MOVING IN THE RIGHT DIRECTION, I THINK.

CHAIRMAN IMBASCIANI: THE 20-PAGE VERSION WAS VERY USER UNFRIENDLY, AND THE NEW VERSION IS SO USER FRIENDLY PEOPLE WILL ACTUALLY REFER TO IT.

MR. FISCHER-COLBRIE: SO MOVED.

CHAIRMAN IMBASCIANI: WE HAVE A MOVEMENT TO ACCEPT. DISCUSSION AMONG BOARD MEMBERS?

DR. MADANAT: SECOND.

CHAIRMAN IMBASCIANI: WE HAVE A MOVEMENT -- MOTION AND SECOND. ANY DISCUSSION AMONG BOARD MEMBERS? OKAY. ANYONE FROM THE PUBLIC WANT TO COMMENT ON OUR NEW PURCHASING POLICY? NOT SEEING ANY, SCOTT, WE MAY VOTE AND GO TO LUNCH.

MR. TOCHER: ALL THOSE IN THE ROOM IN FAVOR SAY AYE. OPPOSED SAY NAY. ANY ABSTENTIONS? AND FOR THE MEMBERS ON ZOOM.

MONICA CARSON. YSABEL DURON.

MS. DURON: YES.

MR. TOCHER: RICH LAJARA.

MR. LAJARA: YES.

MR. TOCHER: SHLOMO MELMED.

DR. MELMED: YES.

MR. TOCHER: CHRIS MIASKOWSKI.

DR. MIASKOWSKI: YES.

MR. TOCHER: JOE PANETTA. SUZANNE SANDMEYER.

DR. SANDMEYER: YES.

MR. TOCHER: KAROL WATSON.

DR. WATSON: YES.

MR. TOCHER: AND KEVIN XU.

DR. XU: YES.

MR. TOCHER: GREAT. THANKS VERY MUCH. THAT MOTION CARRIES.

WE WILL ADJOURN MOMENTARILY FOR LUNCH. AND WE WOULD SUGGEST MEETING BACK AT 12:45. WE WILL HAVE -- WE ARE ABOUT TO PASS OUT YOUR LUNCH TICKETS THAT HAVE YOUR PREFERENCE FOR YOU. SO DON'T WANDER FAR. CLAUDETTE IS GOING TO HAND THOSE OUT TO YOU AND LANA AS WELL. FOR THOSE ON THE ZOOM, WE'LL SEE YOU AT ABOUT QUARTER TO ONE.

(A RECESS WAS TAKEN.)

CHAIRMAN IMBASCIANI: LADIES AND GENTLEMEN, I THINK WE'RE READY TO RECONVENE AFTER A LUNCH BREAK. I DIRECT YOUR ATTENTION TO AGENDA ITEM 14. WE'RE GOING TO SEGUE AWAY FROM THE SAF AND TAKE UP THE COMMUNITY CARE CENTERS OF EXCELLENCE CONCEPT PLAN, WHICH WILL BE PRESENTED BY VICE CHAIR MARIA BONNEVILLE.

VICE CHAIR BONNEVILLE: THANK YOU, VITO.

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EARLIER THIS MONTH THE AAWG RECOMMENDED TO THE BOARD A NEW CONCEPT PLAN FOR THE COMMUNITY CARE CENTERS. THE FACT THAT THE CCCE'S SPECIFICALLY CALLED OUT IN OUR PROPOSITION IS VERY SIGNIFICANT AND UNIQUE, AND IT SHOWS HOW IMPORTANT IT IS TO OUR MISSION.

THE TEAM IN LOOKING VERY HARD AT THIS PROGRAM HAS FOUND THAT WE CAN IMPROVE IT AND REACH MORE PATIENTS FOR A LONGER PERIOD WITH A REVISED CONCEPT PLAN. SO I WANT TO CONGRATULATE THE TEAM FOR HAVING THE COURAGE TO COURSE CORRECT AND COME TO US WITH THIS DECISION.

THE STRATEGIC ALLOCATION FRAMEWORK AND PRIORITIZATION HIGHLIGHT THE KEY ROLE OF CIRM'S INFRASTRUCTURE PROGRAMS AND THE ROLE THAT THEY PLAY IN DELIVERING TRIALS AND THERAPIES TO MORE CALIFORNIANS. THE CHANGES PROPOSED WILL ALLOW FOR TWO ROUNDS OF FUNDING MOVING FORWARD, AND THIS IS CRITICAL BECAUSE WE KNOW THAT OUR INFRASTRUCTURE PROGRAMS GET BETTER WITH MORE TIME. OFFERING TWO ROUNDS OF FUNDING GIVES THEM A CHANCE TO FIRMLY ESTABLISH THEMSELVES IN THE COMMUNITIES THEY SERVE TO TREAT MORE PATIENTS, AND IT ALIGNS WITH THE MISSION OF PROP 14 TO BRING TRIALS AND TREATMENTS TO THE PEOPLE OF CALIFORNIA. GEOFF LOMAX WILL WALK US THROUGH THE CONCEPT PLAN.

DR. LOMAX: THANK YOU VERY MUCH FOR THAT INTRODUCTION. AND THANKS TO THE CIRM EXECUTIVE TEAM FOR THE OPPORTUNITY TO GUIDE THIS PROGRAM IN ITS DEVELOPMENT. AND THE CIRM TEAM IN GENERAL, AS YOU'VE SEEN FROM ALL THESE PRESENTATIONS, THERE'S JUST BEEN AN AMAZING SUPPORT IN TERMS OF BRINGING TOGETHER THE INFORMATION, THE PRESENTATION. AND THAT'S BEEN A HUGE SUPPORT FOR ME BECAUSE MY TEAM IS A LITTLE BIT THIN AT THE MOMENT, SO IT TAKES A VILLAGE. SO THANK YOU FOR THAT.

JUST AS A REMINDER, THIS CONCEPT PACKAGE AND THE SUPPORTING MATERIALS, THE PRESENTATIONS ARE AVAILABLE UNDER THIS AGENDA ITEM ONLINE FOR FOLKS WHO MAY BE LISTENING ONLINE OR THE PUBLIC.

AND, AGAIN, AS MARIA NOTED, WHAT I'M PRESENTING WAS RECOMMENDED -- BROUGHT TO YOU WITH A RECOMMENDATION FOR APPROVAL BY THE ACCESS AND AFFORDABILITY WORKING GROUP, AND THAT MEETING WAS MARCH 10TH.

THESE ARE MEMBERS WITH A CONFLICT OF INTEREST. IT'S A FAIRLY EXTENSIVE LIST. SO JUST AS A REMINDER, IF THERE'S DISCUSSION OF THIS ITEM, YOU SHOULD NOT ENGAGE IN THAT DISCUSSION. I GOT A NOD FROM SCOTT. SO THAT IS A TRUE STATEMENT.

THIS PRESENTATION WILL DEVIATE A LITTLE

BIT FROM THE FORMULA WE HAD WITH THE OTHER ONES IN PART BECAUSE, AGAIN, THIS IS A LITTLE BIT OF A DIFFERENT CONTEXT WHERE WE'VE REVISING AN EXISTING CONCEPT PLAN. AND I'M GOING TO PROVIDE BACKGROUND WHICH WILL PROVIDE THE RATIONALE FOR WHY THE RECOMMENDATION TO REVISE IS BEING BROUGHT FORWARD TO YOU. AND THEN IN THE SECOND PART DESCRIBE THE CORE ELEMENTS OF THE CONCEPT PLAN FOLLOWED BY A REQUEST FOR A MOTION.

AGAIN, AS CO-CHAIR BONNEVILLE ALLUDED TO, IN THE CONTEXT OF THE COMMUNITY CARE CENTERS OF EXCELLENCE, THEY ARE ALSO CALLED OUT IN PROPOSITION 14 WITH THE AIM OF EXPANDING THE CAPACITY OF THE ALPHA CLINICS. AND THAT CAPACITY SPECIFICALLY IS THE ABILITY TO PROVIDE ACCESS AND CONDUCT CLINICAL TRIALS AND PROVIDE APPROVED TREATMENTS THAT ARISE FROM INSTITUTE-FUNDED RESEARCH.

FURTHER, THE PROPOSITION EMPHASIZES GEOGRAPHICALLY DIVERSE CENTERS. AGAIN, KNOWING THAT OUR CURRENT CLINICAL NETWORK IS SOMEWHAT CONCENTRATED, THE IDEA IS TO EXPAND THE REACH GEOGRAPHICALLY. AND THEN ONE POINT THAT ISN'T REFLECTED IN THIS SLIDE IS THAT THE PROPOSITION ALSO DIRECTS THE INSTITUTE TO HAVE THIS PROGRAM IN PLACE BY 2025. SO THERE'S SOMEWHAT OF A TIME IMPERATIVE

TO MOVE FORWARD BASED ON THE LANGUAGE OF THE PROPOSITION.

IN TERMS OF THE STRATEGIC ALLOCATION FRAMEWORK THAT WAS APPROVED IN SEPTEMBER, THE FRAMEWORK PROVIDES A ROADMAP FOR ALL OUR PROGRAMS. AND GOAL 5 REALLY FOCUSES ON OUR CLINICAL INFRASTRUCTURE BROADLY, INCLUDING, BUT NOT LIMITED TO, THE COMMUNITY CARE CENTERS OF EXCELLENCE. AND IN THIS CASE ONE OF THE SUB-OBJECTIVES IS TO DEPLOY THIS INFRASTRUCTURE IN A VERY STRATEGIC MANNER TO ENHANCE THE REFERRAL, ENROLLMENT, AND RETENTION OF CALIFORNIA PATIENTS IN CLINICAL TRIALS. SO TO REALLY BRING THAT TRIAL VISIBILITY AND ACCESS FORWARD TO CALIFORNIA PATIENTS.

AND ONE OF THE UNDERLYING RATIONALES FOR BRINGING A REVISED PLAN FORWARD TO YOU IS THAT WE BELIEVE IN ITS REVISED FORMAT IT BEST SERVES BOTH THE PREVIOUS OBJECTIVES OUTLINED IN PROPOSITION 14 AND GOAL 5 IN THE STRATEGIC ALLOCATION FRAMEWORK. THUS, PROVIDING STRONG ALIGNMENT AND DIRECTION MOVING FORWARD.

SO THE OBJECTIVE OF CIRM'S CLINICAL INFRASTRUCTURE. IN TERMS OF OPERATIONS, CIRM'S COMMUNITY CARE CENTERS OF EXCELLENCE WOULD FIT INTO A BROADER SET OF INFRASTRUCTURE. AND THE AIM IS TO

ENSURE OPERATIONAL INTERCONNECTIVITY BETWEEN THESE ELEMENTS BECAUSE THEY COMPLEMENT EACH OTHER IN TERMS OF SERVING PATIENTS.

AS YOU MAY BE AWARE, THE ALPHA CLINIC NETWORK CURRENTLY HAS SUPPORTED ABOUT 337 TRIALS AS OF LAST AUGUST. THAT INCLUDES BOTH CIRM-FUNDED TRIALS AND TRIALS IN THE REGENERATIVE MEDICINE SPACE MORE BROADLY. WE'VE LAUNCHED A PATIENT SUPPORT PROGRAM WHICH PROVIDES LOGISTICAL AND FINANCIAL SUPPORT TO PATIENTS WHO ARE ENROLLED IN CLINICAL TRIALS. AND, AGAIN, THE COMMUNITY CARE CENTERS OF EXCELLENCE WOULD BROADEN THE REACH OF THIS DELIVERY SYSTEM TO INCLUDE AREAS OF THE STATE THAT CURRENTLY HAVE LESS ACCESS TO CLINICAL TRIALS. AND THEN, AGAIN, THE CONNECTION TO CIRM'S CLINICAL PROGRAMS THAT WE DISCUSSED, AND QUESTIONS CAME UP EARLIER ABOUT THE ALPHA CLINICS, FOR EXAMPLE. WE'VE HAD CONNECTIVITY BETWEEN THE CLINICAL PROGRAMS AND THIS INFRASTRUCTURE.

SO I'LL NOW UPDATE YOU ON OUR EXPERIENCE WITH THE INITIAL CYCLE OF THE COMMUNITY CARE CENTERS PROGRAM. THE INITIAL CYCLE, I THINK MANY OF YOU ARE AWARE, MAYBE THE NEWER MEMBERS, JUST FOR YOUR BENEFIT, THERE WERE ACTUALLY TWO OPTIONS IN THE ORIGINAL PROGRAM. THE APPLICANT COULD COME IN AS A

SUPPORT SITE OR WHAT WE CALL A SUPPORT AND DELIVERY SITE.

SO SUPPORT SITES WERE DESIGNED TO BE PATIENT REFERRAL AND NAVIGATION CENTERS TO SUPPORT PATIENTS IN THEIR CLINICAL TRIAL JOURNEY, BUT NOT DELIVER THE THERAPEUTIC PRODUCT OR AN APPROVED PRODUCT.

A SUPPORT AND DELIVERY SITE WOULD PERFORM THOSE FUNCTIONS AS WELL, BUT IT WOULD ALSO INCLUDE THE CONDUCT AND DELIVERY OF A CLINICAL TRIAL AND THE CAPACITY TO DELIVER APPROVED TREATMENTS.

WE RECEIVED NINE TOTAL APPLICATIONS. FOUR WERE FOR SUPPORT ONLY SITES AND FIVE WERE FOR SUPPORT AND DELIVERY SITES. THOSE APPLICATIONS UNDERWENT -- ALL THE APPLICATIONS UNDERWENT A REVIEW BY THE GRANTS WORKING GROUP, AND A PORTION OF THOSE APPLICATIONS WERE REVIEWED BY THE FACILITIES WORKING GROUP. AND THE RESULT OF THAT, ONLY ONE APPLICATION RECEIVED A FUNDING RECOMMENDATION AND EIGHT OTHER APPLICATIONS WERE NOT RECOMMENDED FOR FUNDING. THE ONE THAT DID RECEIVE A FUNDING RECOMMENDATION WAS A SUPPORT ONLY SITE.

SO AS I INDICATED EARLIER, THE STRATEGIC ALLOCATION FRAMEWORK CAUSED US TO REFLECT ON WHETHER THE COMMUNITY CARE CENTERS OF EXCELLENCE IN ITS

ORIGINAL FORMULATION ALIGNED WITH OUR GOAL 5. AND ONE OF THE CAUSES FOR CONCERN IN THIS CASE WERE BUDGET CONSIDERATIONS. AND SO PROPOSITION 14 ESTABLISHES A TOTAL LIFETIME CAP ON EXPENDITURES FOR THIS PROGRAM, AND THAT CAP IS SET AT 78 MILLION. HAD WE MOVED FORWARD WITH THE APPLICATIONS WHICH I DESCRIBED IN THE PREVIOUS SLIDE WHERE WE HAD ONE RECOMMENDED FOR FUNDING AND THEN THERE WAS A NUMBER OF ADDITIONAL PROGRAMS THAT WE COULD HAVE BROUGHT BACK AS REAPPLICATION, COLLECTIVELY THERE WAS A POTENTIAL TO DEPLETE 60.2 MILLION OF THAT 78 MILLION ALLOCATION FOR THIS PROGRAM, WHICH WOULD HAVE LEFT A REMAINDER OF 17.8 MILLION.

THE CONCERN WE HAD WITH THAT REMAINING AMOUNT OF FUNDING IS THAT IT WOULD BE INSUFFICIENT TO DEVELOP THE PROGRAM. FOR EXAMPLE, IF THE SITES NEEDED A SECOND ROUND OF FUNDING, THE FUNDS SIMPLY WOULD NOT BE AVAILABLE. AND THE REASON THAT CONCERN IS QUITE RELEVANT IS WE DID LEARN WITH THE ALPHA CLINICS PROGRAM, FOR EXAMPLE, IT TOOK A NUMBER OF YEARS TO REALLY MOVE THAT PROGRAM TO THE POINT WHERE -- IT TOOK TWO FUNDING CYCLES TO WHERE WE ARE TODAY WHERE THOSE 337 TRIALS I POINTED OUT, THE VAST MAJORITY OF THEM HAVE COME ON BOARD IN THE LAST FIVE YEARS OR SO OF THE PROGRAM. SO THERE'S KIND OF A

RUN WAVE THAT WE EXPERIENCED WITH THESE PROGRAMS.

SO BY REVISING THE CONCEPT, WE AIM TO PROVIDE A SUSTAINABLE FINANCIAL FRAMEWORK FOR BOTH COMMUNITY CARE CENTERS, WHICH WOULD BE SITES THAT WOULD BE DELIVERING TREATMENTS SIMILAR TO AN ALPHA CLINIC AND FUTURE SUPPORT ONLY SITES. AND I'LL DESCRIBE THAT MOVING FORWARD.

SO SOME ADDITIONAL INSIGHTS FROM THE FIRST ROUND. AGAIN, THE SUSTAINABILITY CONCERNS, I DISCUSSED THAT ON THE PREVIOUS SLIDE. GEOGRAPHIC DIVERSITY GAPS. WHILE APPLICATIONS CAME FROM VARIOUS AREAS, THEY DIDN'T NECESSARILY FULLY ALIGN WITH WHAT WE WERE TRYING TO ACCOMPLISH IN TERMS OF SERVING POPULATIONS THAT WOULD OTHERWISE NOT HAVE ACCESS TO CLINICAL TRIAL OPPORTUNITIES.

AS I INDICATED AT THE BEGINNING, THE ALIGNMENT WITH PROPOSITION 14 AND THE ABILITY TO PROVIDE CLINICAL TRIAL DELIVERY WAS PARTIALLY THERE, BUT AGAIN WE HAD SOME CONCERNS WITH THE SUPPORT ONLY SITES. AND, AGAIN, WE FELT WE REALLY NEEDED THIS COMPREHENSIVE APPROACH TO FUND BOTH DELIVERY AND SUPPORT. AND I'LL TOUCH ON THAT IN A MOMENT.

AGAIN, WE'VE BROUGHT FORWARD A REVISED PLAN. WHAT I WANT TO DESCRIBE HERE IS SORT OF BOTH THE IDEA OF HOW WE WILL ADDRESS THE COMMUNITY CARE

CENTERS OF EXCELLENCE MOVING FORWARD AND OUR THINKING IN TERMS OF HOW SUPPORT SITES COULD BE INCLUDED IN SUBSEQUENT FUNDING PROGRAMS.

SO WE'RE SUGGESTING A TWO-PHASE APPROACH. FIRST OF ALL, THE REVISED RFA, WHICH YOU HAVE A REVISED CONCEPT PLAN WHICH YOU HAVE BEFORE YOU WOULD ALLOW FOR SITES THAT WERE PROPOSING THE DELIVERY OF CLINICAL TRIALS TO COME BACK IN THIS YEAR AND REAPPLY AS SUPPORT AND DELIVERY SITES UNDER THE COMMUNITY CARE CENTERS OF EXCELLENCE PROGRAM.

AND IN ADDITION DURING -- AND THIS PROGRAM WOULD BE FOCUSED ON DEPLOYING THE 78 MILLION WITH THE OPTION OF HAVING TWO FUNDING CYCLES. AGAIN, A CYCLE THIS YEAR AND A FUTURE FUNDING CYCLE IF THAT WAS WHAT THE BOARD CHOSE TO DO.

IN ADDITION, WE HAVE A SET OF FUNDS THAT THE ACCESS AND AFFORDABILITY WORKING GROUP CAN DEPLOY. THOSE FUNDS ARE ON THE ORDER OF 93 MILLION. AND THAT THOSE FUNDS BE DEDICATED TOWARDS THE PATIENT SUPPORT ACTIVITIES THAT WERE INCLUDED IN THE ORIGINAL CONCEPT PLAN.

SORRY. I JUST WANT TO GO BACK TO THAT SLIDE. I JUST HAD A COUPLE OF OTHER COMMENTS THERE.

ONE OF THE THINGS I WANTED TO SORT OF HIGHLIGHT WITH THIS APPROACH, BECAUSE I KNOW YOU'VE

SEEN A NUMBER OF -- THERE'S BEEN COMMENTS AND LETTERS SUBMITTED PURSUANT TO THIS ITEM -- IS THAT THIS APPROACH ACTUALLY PROVIDES A MUCH MORE ROBUST AND LONGER TERM FUNDING FOR BOTH PROGRAMS. IT ENABLES UP TO TWO CYCLES OF FUNDING FOR THE COMMUNITY CARE CENTERS, AND WITH AAWG SUPPORT IT DEDICATES ADDITIONAL RESOURCES THAT COULD SUPPORT THE PATIENT ACCESS ACTIVITIES. SOME OF THOSE CONCERNS HAVE COME UP IN COMMENTS AND LETTERS FROM APPLICANTS. AND, AGAIN, REALLY EMPHASIZING THAT THIS APPROACH DEDICATES -- ALLOWS US TO DEDICATE FAR GREATER RESOURCES TOWARDS THE COMBINED PROGRAMS.

SO WITH THAT, I'D LIKE TO SWITCH GEARS AND DESCRIBE THE CONCEPT PLAN YOU HAVE BEFORE YOU. JUST GOING TO TAKE ONE BREAK FOR A MOMENT.

SO THE OBJECTIVE OF THE REVISED CONCEPT PLAN IS TO EXPAND GEOGRAPHICALLY DIVERSE CENTERS OF EXCELLENCE ACROSS CALIFORNIA, AGAIN, TO ENHANCE PATIENT ACCESS TO REGENERATIVE MEDICINE TREATMENTS WITH EXPANDING THE REACH AND DELIVERY OF CLINICAL TRIALS AND APPROVED THERAPIES. IN ADDITION, CONSISTENT WITH THE ORIGINAL CONCEPT PLAN, THE AIM WOULD ALSO BE TO DEVELOP A SKILLED WORKFORCE AND SUPPORT THE DELIVERY OF REGENERATIVE MEDICINE TREATMENTS BROADLY, PARTICULARLY IN COMMUNITIES THAT

MAY, AGAIN, NOT HAVE ACCESS TO THOSE TREATMENTS. AGAIN, THE WORKFORCE COMPONENT IS SOMETHING THAT'S CONSISTENT ACROSS ALL OF OUR INFRASTRUCTURE PROGRAMS. SO THIS IS WHERE WE -- THIS IS OUR OPPORTUNITY TO DEVELOP THE CLINICAL WORKFORCE IN THE STATE.

THE MAXIMUM DURATION OF THE AWARD WILL BE FIVE YEARS. AGAIN, THIS IS ALL HIGHLY CONSISTENT WITH THE ORIGINAL CONCEPT PLAN. MUST BE A NON-PROFIT ORGANIZATION LOCATED IN CALIFORNIA. I WANT TO JUST HIGHLIGHT THAT POINT. I BELIEVE IN ONE OF THE PUBLISHED MATERIALS THE NON-PROFIT ORGANIZATION ASPECT MANY NOT HAVE BEEN CLEARLY STATED.

SO FOR THE RECORD, I'D LIKE TO STATE IT CLEARLY HERE. AGAIN, A COMMITMENT TO CELL AND GENE THERAPIES FROM ANY SOURCE. SO IF YOU'RE APPLYING FOR THIS PROGRAM, THE POINT THERE IS THAT, FOR EXAMPLE, IF THERE WAS A TREATMENT UTILIZING HUMAN EMBRYONIC STEM CELLS, THAT THAT TREATMENT WOULD HAVE TO BE MADE AVAILABLE IF YOU HAVE THE CAPACITY. WE WOULDN'T BE ABLE TO SORT OF DISCRIMINATE AGAINST ANY OF THE PRODUCTS IN OUR PIPELINE.

THE ORGANIZATION CANNOT HAVE AN EXISTING ALPHA CLINIC AWARD. INFR4 IS CODE FOR ALPHA CLINICS

PROGRAM. AND IN ADDITION, THIS GOES BACK TO THE ORIGINAL CONCEPT PLAN, THE APPLICANT ORGANIZATION CAN ONLY PROVIDE FDA-AUTHORIZED TREATMENTS. SO IF THE CENTER WAS PROVIDING TREATMENTS THAT WERE NOT AUTHORIZED FOR WHATEVER REASON, DIDN'T HAVE FDA APPROVAL, WE DO NOT WANT TO BE FUNDING INTO OPERATIONS THAT ARE DOING THAT TYPE OF ACTIVITY. SO ONLY FDA-AUTHORIZED TREATMENTS ARE ALLOWED FROM THE CENTER.

CORE TEAM, THE REQUIREMENT HERE IS A PROGRAM DIRECTOR AT 30-PERCENT TIME. THE MAXIMUM AWARD IN THIS CYCLE, THE BUDGET IS AT 9 MILLION. THAT'S ABOUT A 10-PERCENT REDUCTION FROM THE PREVIOUS BUDGET, JUST TO CALL THAT OUT. AND, AGAIN, IT'S A SLIGHT REDUCTION IN THIS ROUND, BUT IT AFFORDS THE OPPORTUNITY FOR A SECOND ROUND. SO, AGAIN, FROM A SUSTAINABILITY STANDPOINT, WE ARRIVED AT RECOMMENDING THE 9 MILLION MARK. THAT WOULD BRING THE TOTAL PROGRAM BUDGET, IF WE WERE TO FUND UP TO FOUR PROGRAMS, AT 36 MILLION.

AGAIN, I DON'T NEED TO READ THROUGH ALL THESE. THEY WERE TOUCHED ON IN THE PREVIOUS SLIDE. NOT-FOR-PROFIT ORGANIZATION, NOT AN ALPHA CLINIC. ONE OF THE POINTS THAT, AGAIN, IS DIFFERENT FROM THE ORIGINAL CONCEPT PLAN IS IT MUST HAVE A DEMONSTRATED

ABILITY TO PERFORM HUMAN CLINICAL TRIALS, THE DELIVERY. SO WE'VE MOVED THE BAR A LITTLE BIT, THAT ORGANIZATIONS COMING IN MUST HAVE THE CAPACITY TO PERFORM CLINICAL TRIALS AT THE TIME OF APPLICATION. THE AIM THERE TO ACCELERATE, AGAIN, THE INFRASTRUCTURE GOALS WHICH I DESCRIBED PREVIOUSLY. AND THE OVERALL AIM OF THE APPLICATION, IF THE APPLICANT ISN'T DOING SO ALREADY, IS TO HAVE THE CAPACITY TO DELIVER REGENERATIVE MEDICINE CLINICAL TRIALS OVER THE COURSE OF THE AWARD.

ONE OTHER PIECE, AND I KNOW A NUMBER OF MEMBERS WHO WERE VERY INSTRUMENTAL IN THIS RECOMMENDATION MAY BE CONFLICTED, BUT JUST TO EMPHASIZE AGAIN THAT WE'VE MAINTAINED THE REQUIREMENTS -- WE RECOMMEND RETAINING THE REQUIREMENTS FOR COMMUNITY-BASED PARTNERSHIPS. AGAIN, THIS GOES BACK TO ONE OF THE MAJOR RECOMMENDATIONS FROM THIS BOARD IS THAT IF WE ARE GOING TO TRULY ADVANCE THE REFERRAL, ENROLLMENT, AND RETENTION OF PATIENTS IN CLINICAL TRIALS, WE NEED DEEPER SUPPORT AT THE COMMUNITY LEVEL. THIS CONCEPT PLAN CONTINUES IN THAT SPIRIT AND THAT REQUIREMENT REMAINS. AND MUST BE READY TO WORK WITHIN 120 DAYS. AND, AGAIN, I'VE TOUCHED ON THE PROGRAM DIRECTOR.

THIS IS THE TIMELINE. AND, AGAIN, WE'RE

BRINGING THE RFA -- CONCEPT PLAN TO YOU TODAY SO WE CAN GET THE RFA POSTED AS EARLY AS POSSIBLE LOOKING AT DATES IN APRIL AT THE MOMENT. AND THAT'S THE GOAL. OPENING THE APPLICATION ONLINE IN THE SUMMER AND BRINGING IT TO THE GRANTS WORKING GROUP AND FACILITIES WORKING GROUP -- GRANTS WORKING GROUP IN SEPTEMBER. IF THERE NEEDS TO BE A FACILITIES REVIEW, THAT WOULD BE FOLLOWING THE GRANTS WORKING GROUP LATER IN SEPTEMBER WITH THE CONTRACTING PERIOD -- BRINGING IT TO THE BOARD FOR THE OCTOBER MEETING AND THEN CONTRACTING TOWARDS THE END OF THE YEAR. GETTING THAT AWARD LAUNCH A LITTLE BIT AFTER THE 2025 GOAL OF THE PROPOSITION, BUT FOR REASONS WE THINK ARE REASONABLE AND BASED ON THE RATIONALE I PROVIDED FOR YOU.

DURING THIS TIME, AGAIN, ACCESSIBILITY AND AFFORDABILITY WORKING GROUP WILL ALSO BE CONSIDERING OPPORTUNITIES FOR THE SUPPORT ONLY ACTIVITIES, AND THAT'S LOOKING AT THE SECOND HALF OF THE YEAR.

SO IN SUMMARY, WE ARE REQUESTING THAT THE ICOC WITHDRAW THE CURRENT INFR8 COMMUNITY CARE CENTERS OF EXCELLENCE CONCEPT AND ADOPT THE PROPOSED PLAN YOU HAVE BEFORE YOU, THE PROPOSED COMMUNITY CARE CENTERS INFR8 FUNDING OPPORTUNITY. AND WITH THAT, I WILL HAND IT BACK TO THE CHAIR.

CHAIRMAN IMBASCIANI: GEOFF, THAT'S BEAUTIFUL. SO WE WOULD LIKE A MOTION TO ACCEPT THE RECOMMENDATION TO REPLACE THE OLD INFRASTRUCTURE 8 WITH THE NEW FUNDING OPPORTUNITY.

DR. GASSON: SO MOVED.

DR. MALKAS: SECOND.

CHAIRMAN IMBASCIANI: WE HAVE A SECOND FROM LINDA MALKAS. THANK YOU.

MS. DURON: I SAW QUESTIONS. I SEE HANDS UP ON THE PHONE.

CHAIRMAN IMBASCIANI: YSABEL, I'M SORRY. GO AHEAD PLEASE.

MS. DURON: NOT ME, BUT I SAW TWO OTHER HANDS UP. THEY'RE ON THE PHONE.

MR. TOCHER: WE'RE TAKING THE BOARD DISCUSSION.

CHAIRMAN IMBASCIANI: I NEED TO ASK THE BOARD MEMBERS TO OPEN THE DISCUSSION BEFORE THE PUBLIC.

MS. DURON: IS THAT THE PUBLIC? OKAY.

CHAIRMAN IMBASCIANI: IT IS. THANK YOU. ANNE-MARIE, YES, DISCUSSION.

DR. DULIEGE: YSABEL, DID YOU HAVE A QUESTION?

MS. DURON: NO. I DON'T THINK I CAN EVEN

VOTE.

DR. DULIEGE: OKAY. GREAT. COUPLE OF QUESTIONS OR MAYBE JUST CLARIFICATIONS. BUT I WOULD SAY OVERALL THANK YOU TO YOU AND THE TEAM AGAIN FOR WHAT WE HAVE SEEN TODAY, MORE SO THAN EVER BEFORE, IS THE INTENT, THE WILLINGNESS TO EVALUATE WHAT DID NOT WORK BEFORE, WHY, AND MAKE AN ALTERNATIVE PROPOSAL. THAT JUST IS GREAT.

SO ONE IS WHAT'S THE DIFFERENCE FINANCIALLY BETWEEN THE PREVIOUS PROPOSAL AND THE CURRENT ONE?

SECOND IS I UNDERSTAND THAT THESE PROPOSALS ON ONE HAND ARE TO ACCELERATE CLINICAL TRIALS AND ON THE OTHER HAND TO ALSO INCREASE THE ACCESSIBILITY AND AFFORDABILITY OF FDA-APPROVED TREATMENT. CAN YOU TELL US WHICH OF THESE TWO IS MORE PROMINENT? HOW DO THEY SEPARATE IN TERMS OF NUMBER OF PROPOSALS AND FINANCIAL COMMITMENTS?

AND WHAT DID NOT WORK? CAN YOU TELL US MORE PRECISELY, WITHOUT TOO MANY DETAILS, WHAT DID NOT WORK REALLY WELL IN A MORE PRACTICAL MANNER FOR US TO UNDERSTAND? AND A LITTLE -- I'VE ALWAYS BEEN A LITTLE BIT CAUTIOUS ABOUT THIS BECAUSE MOST OF THE APPLICATIONS WE SEE ARE ON ORPHAN DRUG, RARE DISEASES. AND SO HOW CAN WE ACCELERATE ENROLLMENT

OF SOMETHING THAT IS -- DISEASE THAT IS EXTREMELY RARE, INCLUDING GEOGRAPHICALLY? SO THESE THREE CLARIFICATION POINTS.

DR. LOMAX: IF I MAY, I'LL START WITH THE WHAT DIDN'T WORK QUESTION. SO I THINK WHAT WE REALLY UNDERSTOOD WHEN WE LOOKED BACK AT THE ORIGINAL PROGRAM AS DESIGNED AND WHERE WE WOULD END UP IS THAT WE WOULD NOT HAVE THE FUNDING TO ALLOW THE SITES THAT WERE DOING THE CLINICAL TRIALS TO HAVE A LONG ENOUGH RUNWAY TO SUCCEED. WE THOUGHT THE FIVE-YEAR TIME WINDOW WOULD BE INSUFFICIENT. THAT'S BEEN BASED ON OUR EXPERIENCE WITH OTHER CLINICAL INFRASTRUCTURE. IT WAS, AGAIN, THE LIMITATION.

SO IT WAS THAT UNDERSTANDING THAT PROPOSITION 14 PUT A HARD CAP ON THIS PROGRAM AT 78 MILLION, AND WE WERE ESSENTIALLY GOING TO USE 80 TO 90 PERCENT OF THAT BUDGET.

SO THAT WAS A PROBLEM THAT WE -- AND WE HAD A SOLUTION WHICH, AGAIN, WAS TO GO TO A TWO BUDGETING -- ESSENTIALLY A TWO BUDGET APPROACH WHICH IS REFLECTED HERE. IN TERMS OF WHAT -- I THINK YOUR FIRST QUESTION IS THEN WHAT DOES THAT TRANSLATE TO IN TERMS FINANCIALLY. IT IS A 10-PERCENT REDUCTION. SO IN THE ORIGINAL PROPOSAL, TO REITERATE, YOU COULD

COME IN AS A CLINICAL TRIAL TREATMENT AND DELIVERY SITE OR A SUPPORT SITE. THE SUPPORT SITES WERE ABLE TO APPLY AT ROUGHLY ABOUT A $7 MILLION LEVEL. THE TREATMENT AND SUPPORT SITES WERE ABLE TO APPLY AT ABOUT JUST OVER 10 MILLION. THAT WAS BASED ON THE BUDGETING THAT WE SEE IN THE ALPHA CLINICS.

SO IN THIS NEW PROPOSAL, THEY'RE ABLE TO COME IN IT'S NOW AT 9 MILLION. NOT BECAUSE WE FELT THAT THAT WAS THE PERFECT NUMBER, BUT IN TERMS OF DISTRIBUTION OF THE FUNDS WE HAVE, THE 78 MILLION, THAT 9-MILLION FIGURE ALLOWS US AGAIN TO PROVIDE SUBSTANTIAL SUPPORT TO THOSE SITES AND PROVIDE IT IN TWO CYCLES IF WE CHOOSE TO DO SO.

SO IT'S A MINOR REDUCTION IN WHAT -- IT'S ROUGHLY A 10-PERCENT REDUCTION OF WHAT THE SITES HAD PREVIOUSLY BUDGETED FOR. SO THEY'RE GOING TO HAVE -- IF THE SITES THAT CAME IN ORIGINALLY CHOOSE TO COME BACK IN, THEY'RE GOING TO HAVE TO FIND SOME SAVINGS THERE.

AND THEN THERE WAS AN ACCESS AND AFFORDABILITY QUESTION IN THERE, I BELIEVE. I THINK WHAT WE'VE REALLY BEEN FOCUSING ON IN TERMS OF WHAT WE'VE BEEN ASKING FOR IN THE APPLICATION ARE QUESTIONS AROUND HOW WILL THEY PROVIDE THE VISIBILITY TO THE CLINICAL TRIALS. HOW CAN THEY

SUPPORT THE PATIENTS WHO ARE THEN INTERESTED IN THOSE CLINICAL TRIALS? SO I THINK IT'S A VERY ACCESS-FOCUSED PROGRAM. TO THE EXTENT IT'S GOING TO DRIVE AFFORDABILITY, I DON'T THINK IT WOULD BE FAIR TO SAY THIS IS AN AFFORDABILITY INITIATIVE PER SE. I THINK THE AFFORDABILITY ELEMENTS ARE WHAT WERE DESCRIBED IN THE CLINICAL TRIAL PROGRAMS THAT WERE REALLY TRYING TO ADDRESS THOSE QUESTIONS IN TERMS OF THE ACCESS STRATEGIES THAT THOSE PROGRAMS NEED TO DEVELOP. I DON'T THINK THAT WILL BE DRIVEN FROM THE CLINICAL INFRASTRUCTURE ALONE.

DID THAT COVER THE LIST?

DR. DULIEGE: FOR ONE THING, IT'S ACTUALLY VERY PLEASANT TO BE ASKED TO APPROVE A REDUCTION IN BUDGET. THAT DOESN'T HAPPEN VERY OFTEN. THIS IS THE FIRST TIME, I THINK.

EVEN WITH WHAT HAS BEEN SPENT SO FAR IN A PROGRAM THAT I THINK HAS BEEN, WHAT, ABOUT ONE YEAR IN EFFECT, THIS PROGRAM?

DR. LOMAX: IT HASN'T.

DR. DULIEGE: YOU CANNOT TELL US WHAT HAS BEEN ACHIEVED BECAUSE IT HASN'T STARTED.

DR. LOMAX: WE NEVER MOVED FORWARD WITH THE APPROVAL OF APPLICATIONS PURSUANT TO THE INITIAL PROGRAM.

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DR. DULIEGE: THANK YOU.

DR. MADANAT: IT'S A COMMENT, NOT A QUESTION. BUT I WANT TO SAY THANK YOU FROM MY PERSPECTIVE LOOKING AT IT FROM THE BEGINNING OF THE PROCESS TO NOW, WHAT'S BEING PROPOSED HERE IS MUCH MORE ALIGNED WITH PROPOSITION 14. I THINK IT'S GOING TO MAKE A HUGE DIFFERENCE IN THE WAY WE ARE FUNDING THESE PROJECTS ON A LONG-TERM PERSPECTIVE. SO I ECHO ANNE-MARIE. IT'S GREAT TO SEE US PAUSE AND DO WHAT WE THINK IS THE RIGHT OUTCOME.

DR. LOMAX: THANK YOU.

CHAIRMAN IMBASCIANI: THANK YOU, HALA. ANY OTHER BOARD MEMBERS HAVE A COMMENT OR QUESTION? IF NOT, CLAUDETTE, CAN YOU DIRECT US TO THE MEMBERS OF THE PUBLIC PLEASE.

MS. MANDAC: WE HAVE TWO HANDS RAISED. SO FOR MEMBERS OF THE PUBLIC, YOU WILL HAVE THREE MINUTES EACH TO SPEAK. THERE IS A TIMER. WE WILL MUTE YOU IF YOU EXCEED YOUR THREE MINUTES. AND THE CLOCK WILL SHOW UP ON THE TOP RIGHT-HAND CORNER OF YOUR SCREEN.

SO THE FIRST PERSON TO SPEAK WILL BE PHONE NUMBER (312) 485-6714. YOU HAVE THE FLOOR.

DR. JACOBS: HI, EVERYONE. MY NAME IS DR. DR. ELIZABETH JACOBS. I'M PROFESSOR AND CHAIR OF

MEDICINE AT UCR SCHOOL OF MEDICINE. I'M THE PRINCIPAL INVESTIGATOR ON THE TIER I RECOMMENDED FOR FUNDING APPLICATION FOR THIS RFA. AND I'M HERE TO TALK ABOUT WHY FUNDING THIS PROGRAM AND OUR PROGRAM IS VERY IMPORTANT AND WHY I DISAGREE THAT WITHDRAWING THE FUNDING AND STARTING ANEW WOULD MEET THE GOALS OF PROPOSITION 14.

SO WE SERVE A VERY UNDERSERVED POPULATION IN CALIFORNIA, THE INLAND EMPIRE. AND OUR WHOLE GOAL WAS ACTUALLY TO INCREASE REFERRAL, RETENTION, AND ENROLLMENT IN OUR REGENERATIVE CLINICAL TRIALS BY PARTNERING WITH EXISTING ALPHA CENTERS. AND ONE OF THE REASONS WHY THIS AREA IS UNDERSERVED IN MEETING THE NEEDS AND MEETING WHAT PROPOSITION 14 INTENDED IS BECAUSE THESE INDIVIDUALS NEED HELP UNDERSTANDING TRIALS WITHIN THEIR LANGUAGE, WITHIN THEIR CULTURES, AND THEY NEED PEOPLE TO BE IN THEIR COMMUNITIES HELPING THEM AND ALSO COLLECTING DATA FROM THEM THAT MAYBE THEY COULD DO FOLLOW-UPS WITHIN THEIR COMMUNITY. THAT WAS PART OF WHAT WE HAD PLANNED.

AND I THINK IT'S QUITE UNFAIR THAT WE ARE HIGHLY REVIEWED, WE'RE MEETING THE NEEDS; AND BECAUSE YOU DIDN'T RECEIVE OTHER GOOD APPLICATIONS, WE'RE BEING PENALIZED FOR OTHER PEOPLE'S POOR

APPLICATIONS.

THE OTHER THING THAT I THINK IS VERY IMPORTANT FOR YOU TO UNDERSTAND IS THAT WE HAVE COLLABORATED WITH MULTIPLE COMMUNITY MEMBERS -- I THINK ONE IS HERE TODAY -- TO IMPLEMENT THIS GRANT AND TO APPLY FOR THIS GRANT. AND NOW WE HAVE TO GO BACK AND TELL THEM THAT CIRM DOES NOT WANT TO ENGAGE WITH THEM IN WAYS THAT WE TOLD THEM THAT CIRM DID INTEND TO AND IS WRITTEN INTO THE LAW.

SO I'M HERE TO ADVOCATE THAT YOU CONTINUE TO FUND -- I WOULD HOPE THAT YOU WOULD FUND OUR APPLICATION. IT WAS VERY FAVORABLY REVIEWED. IT ABSOLUTELY MEETS THE GOALS OF SB 14.

THE OTHER THING IS THAT IT IS GOING TO HELP YOU ADVANCE GETTING CLINICAL TRIALS OUT INTO THE COMMUNITY MUCH FASTER AND TO COMMUNITIES THAT EXPERIENCE DISPARITIES FASTER THAN IF YOU WAIT A WHOLE NOTHER YEAR TO ACTUALLY LOOK INTO FUNDING OUR TYPE OF SUPPORT MECHANISMS.

I WAS VERY HEARTENED TO SEE, THIS IS NOT SOMETHING I'VE SEEN BEFORE IN MY CONVERSATIONS WITH CIRM FOLKS, THAT YOU ARE THINKING ABOUT FUNDING THE SUPPORT CENTERS THROUGH ANOTHER MECHANISM, BUT I AM VERY CONCERNED THAT IF YOU PROCEED WITH THE CURRENT PLAN, YOU WILL BE EXACERBATING DISPARITIES AND

CREATING DISTRUST IN COMMUNITIES IN NEED RATHER THAN MEETING YOUR GOALS.

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

THE NEXT CALLER IS (503) 330-2407. THE FLOOR IS YOURS. (503) 330-2407, IF YOU COULD PLEASE UNMUTE.

DR. LECOMTE-HINELY: HI. MY NAME IS DR. JENNA LECOMTE-HINELY. I AM THE CEO OF HARC, WHICH IS A NON-PROFIT DEDICATED TO IMPROVING COMMUNITY-WIDE THROUGH DATA. WE ARE A PARTNER WITH UCR SCHOOL OF MEDICINE ON THE APPLICATION THAT WAS RECOMMENDED FOR FUNDING. AND I JUST ECHO DR. JACOBS IN BEING JUST SO DISAPPOINTED THAT, DESPITE PUTTING TOGETHER A GREAT PROPOSAL THAT WAS FIRMLY ROOTED IN THE COMMUNITY AND IN OUR COMMUNITY'S NEEDS BECAUSE WE ARE VERY UNDERSERVED COMMUNITY, THAT WE WILL NOT BE FUNDED FOR THESE ACTIVITIES.

AS DR. JACOBS MENTIONED, WE HAVE A COMMUNITY THAT IS GREATLY UNDERSERVED. HERE IN THE COACHELLA VALLEY WHERE I LIVE, IF SOMEONE IS DIAGNOSED AND WANTS TO PARTICIPATE IN A CLINICAL TRIAL, EVEN IF THEY KNOW WHAT IT IS, THEY HAVE TO LEAVE THE REGION. THEY CANNOT GET CARE HERE. AND PART OF THAT IS THAT WE HAVE A HUGE PROVIDER

SHORTAGE. IT IS THE -- WE HAVE THE FEWEST PROVIDERS PER POPULATION OF ANYWHERE IN CALIFORNIA. WE HAVE A HUGE POPULATION OF HISPANIC-LATINO PEOPLE WHO, AGAIN, AS DR. JACOBS MENTIONED, REALLY NEED A TRUSTED MESSENGER TO GET THIS MESSAGE OUT ABOUT CLINICAL TRIALS AND ABOUT THE OPPORTUNITY AND ABOUT THE IMPORTANCE.

AND BY NOT DOING THIS -- I'M VERY PASSIONATE ABOUT EQUITY FOR OUR UNDERSERVED INLAND EMPIRE. AND PUTTING MORE FUNDS TOWARDS SITES THAT ALREADY HAVE INFRASTRUCTURE ALONG THE COAST IN L.A. AND SAN DIEGO IS JUST PERPETUATING THE INEQUITIES THAT WE ALREADY EXPERIENCE.

OUR COMMUNITY HAS AN INHERENT DISTRUST OF AGENCIES WHO SAY THAT THEY'RE GOING TO MAKE GREAT CHANGE AND COME IN AND THEN DISAPPEAR. SO THIS IS VERY HARMFUL TO THE COMMUNITIES WHO HAVE BOUGHT IN, WHO HAVE BECOME EXCITED ABOUT THE OPPORTUNITY TO MAKE CLINICAL TRIALS ACCESSIBLE HERE IN OUR COMMUNITY. AND SO I JUST URGE YOU TO RECONSIDER OUR VERY STRONG, VERY COMPETITIVE APPLICATION FROM BOTH A RESIDENT OF THE INLAND EMPIRE, A LONG-TERM COMMUNITY-BASED RESEARCHER, PLEASE, I ENCOURAGE YOU TO PLEASE RECONSIDER FUNDING THE ONE APPLICATION THAT WAS LISTED AS FUNDABLE.

IF WE DON'T RECEIVE THAT, WE WILL, OF COURSE, TRY AGAIN BECAUSE WE ARE PASSIONATE AND WE ARE DEDICATED TO OUR COMMUNITY, BUT THIS IS A NEED NOW. THIS WAS A NEED YESTERDAY. SO IF IT'S AT ALL POSSIBLE TO MOVE THIS FORWARD FOR OUR POPULATION, WE WOULD GREATLY APPRECIATE THAT. THANK YOU.

MS. MANDAC: THANK YOU SO MUCH, DR. LECOMTE-HINELY. VITO, NO OTHER HANDS RAISED.

CHAIRMAN IMBASCIANI: NO OTHER COMMENTS FROM THE PUBLIC. FINAL COMMENTS FROM BOARD MEMBERS BEFORE WE PROCEED TO A VOTE? ANNE-MARIE.

DR. DULIEGE: CAN YOU, BECAUSE YOU ARE A MEMBER OF THE TEAM, PUT THE TWO COMMENTS FROM THE PUBLIC INTO CONTEXT? WHAT SHOULD WE DERIVE FROM THAT? WHAT IS YOUR RECOMMENDATION AFTER THESE TWO COMMENTS? THANK YOU.

DR. LOMAX: SO I THINK -- WE SPENT -- THE DEVELOPMENT OF THIS PROGRAM, WE WENT INTO THOSE COMMUNITIES. WE MET WITH THOSE STAKEHOLDERS. AND SO THE -- IT IS HARD TO SORT HAVE TO RECOMMEND A MODIFICATION TO THAT PROGRAM. WE WORKED DIRECTLY WITH THE APPLICANTS TO CRAFT WHAT ARE VERY COMPELLING APPLICATIONS.

I THINK WHAT WE'VE TRIED TO DO IN TERMS OF BOTH THE BUDGET AND THE TIMELINE AND THE PROCESS IS,

AGAIN, PUT TOGETHER A BUDGET FRAMEWORK THAT WILL ALLOW MORE TO BE DONE OVER TIME RATHER THAN LESS. SO IT WILL ACTUALLY CREATE A MORE SUSTAINABLE FOOTPRINT.

I THINK FROM THE PROCESS STANDPOINT, A LOT OF THAT HARD WORK WILL BE ABLE TO COME BACK IN. WE'RE NOT PROPOSING A WHOLESALE CHANGE OF THE APPLICATION. RATHER, WE'RE FINE-TUNING IT TO MEET OUR SAF OBJECTIVES TO BETTER ALIGN WITH PROPOSITION 14.

SO AT THE END OF THE DAY, I UNDERSTAND AND APPRECIATE THE FRUSTRATION, BUT THE ULTIMATE RESULT IS A SHIFT IN TIME. AND LATER IS NEVER WHAT ANYONE HOPES FOR, AND WE UNDERSTAND THAT. AGAIN, IN TERMS OF THE TIMELINE, THE BUDGET, AND WHAT WE ENVISION THE APPLICATION TO LOOK LIKE, WE'RE REALLY TRYING TO STAY TRUE TO THE STAKEHOLDERS, THEIR EFFORT WITH AN UNDERSTANDING THAT EVERYTHING -- IT IS IMPORTANT WORK, IT'S GREAT WORK, AND WE REALLY WANT TO HONOR THAT WORK AS BEST WE CAN WITHIN THE LIMITS THAT WE HAVE AS AN AGENCY.

DR. DULIEGE: A FINAL BRIEF COMMENT ON MY PART, AND I DON'T NEED AN ANSWER RIGHT NOW, BUT BACK TO THE TEAM. THERE WAS ONE SITE THAT WAS RECOMMENDED FOR FUNDING IN THE PREVIOUS SYSTEM AND

EIGHT THAT WERE NOT. SHOULD THERE BE A DIFFERENT CONSIDERATION AT THIS POINT FOR THE ONE SIDE VERSUS THE EIGHT? AGAIN, YOU CAN TAKE THIS UP LATER ON.

VICE CHAIR BONNEVILLE: SO THOSE APPLICATIONS WILL NO LONGER -- EVERYONE WILL REAPPLY UNDER THE NEW MECHANISM. SO THERE WILL BE TWO NEW CONCEPT PLANS. I THINK WHAT'S BEING MISSED IS THIS ALLOWS FOR MORE FUNDING FOR BOTH. YOU'RE APPLYING FOR DELIVERY. THERE WILL BE ACCESS TO TWO ROUNDS OF FUNDING IF YOU MEET THE OBJECTIVES. IF YOU APPLY FOR SUPPORT, THERE WILL BE MORE ROUNDS OF FUNDING THAN WOULD BE OTHERWISE AVAILABLE.

SO IT IS -- WHILE I UNDERSTAND IT IS DIFFICULT TO HAVE TO WAIT FOR THIS PROGRAM BECAUSE THE SUPPORT PROGRAM COMES LATER IN THE FALL, I JUST WANT TO MAKE SURE THAT EVERYONE UNDERSTANDS THAT WHAT WE'RE DOING IS ACTUALLY CREATING A LONGER RUNWAY FOR EVERYONE AND FOR PEOPLE IN CALIFORNIA TO BE ABLE TO HAVE ACCESS TO THIS FOR LONGER PERIODS OF TIME. WE'RE PLAYING THE LONG GAME, AND I UNDERSTAND IT'S HARD TO ACCEPT IF YOU'VE APPLIED, AND I UNDERSTAND COMPLETELY. I JUST THINK WE NEED TO LOOK AT IT IN THAT FRAME OF MIND.

CHAIRMAN IMBASCIANI: THANK YOU, ANNE-MARIE. AND THANK YOU, MARIA, FOR THAT

WONDERFUL EXPLICATION. NO OTHER COMMENT BEING HEARD, SCOTT, I THINK WE CAN PROCEED.

MR. TOCHER: GEORGE BLUMENTHAL.

DR. BLUMENTHAL: YES.

MR. TOCHER: MARIA BONNEVILLE.

VICE CHAIR BONNEVILLE: YES.

MR. TOCHER: LEONDRA CLARK-HARVEY.

DR. CLARK-HARVEY: YES.

MR. TOCHER: ANNE-MARIE DULIEGE.

DR. DULIEGE: YES.

MR. TOCHER: MARK FISCHER-COLBRIE.

MR. FISCHER-COLBRIE: YES.

MR. TOCHER: DAVID HIGGINS.

DR. HIGGINS: YES.

MR. TOCHER: VITO IMBASCIANI.

CHAIRMAN IMBASCIANI: YES.

MR. TOCHER: RICH LAJARA. HALA MADANAT.

DR. MADANAT: YES.

MR. TOCHER: LINDA MALKAS.

DR. MALKAS: YES.

MR. TOCHER: CAROLYN MELTZER.

DR. MELTZER: YES.

MR. TOCHER: JOE PANETTA. MARV SOUTHARD.

DR. SOUTHARD: YES.

MR. TOCHER: KEVIN XU.

DR. XU: YES.

MR. TOCHER: THANK YOU VERY MUCH. THE MOTION CARRIES, MR. CHAIR.

CHAIRMAN IMBASCIANI: THANK YOU. I THINK I'M GOING TO GO BACK NOW TO NO. 13, WHICH WOULD BE CONSIDERATION OF THE REVIEW PROCESS AND THE GRANTS WORKING GROUP BYLAWS. THE INTRODUCTION WILL BE DR. SAMBRANO -- I'M SORRY. BECAUSE OF TIME CONSTRAINTS, WE'RE GOING MOVE THIS AROUND. SO TAKE BACK WHAT I JUST SAID. THANK YOU SO MUCH.

THIS IS ABSOLUTELY A PLEASURE OF MINE, THE HIGHLIGHT OF MY SPEAKING DAY. YOU'VE ALREADY HEARD DR. LARRY GOLDSTEIN'S NAME MENTIONED HERE, AND WE'VE TALKED A LOT ABOUT THE CONSEQUENCES OF HIS ACTIONS ON THE BOARD. SO I'M GOING TO INTRODUCE YOU NOW TO RESOLUTION 2025-03.1 IN HONOR OF LAWRENCE GOLDSTEIN, PH.D., FOR HIS SERVICE TO THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE, TO STEM CELL RESEARCH, AND TO CALIFORNIA PATIENTS.

DR. GOLDSTEIN STARTED ON HIS ROAD TO SCHOLARSHIP AS AN UNDERGRADUATE STUDENT IN BIOLOGY AT UCSD. AND SAN DIEGO MUST HAVE SUNK ITS CLAWS IN PRETTY DEEPLY BECAUSE, AFTER MANY PEREGRINATIONS, A DOCTORATE IN GENETICS AT THE UNIVERSITY OF WASHINGTON IN SEATTLE, POSTDOCTORAL WORK AT THE

UNIVERSITY OF COLORADO AND MIT, AND RISING TO THE RANK OF FULL PROFESSOR AT HARVARD IN SIX YEARS, HE SETTLED BACK DOWN AT UCSD IN 1963.

AND THERE AS PROFESSOR OF CELLULAR AND MOLECULAR MEDICINE, HE FOUNDED THE STEM CELL PROGRAM AND THE SANFORD STEM CELL CLINICAL CENTER, OTHERWISE KNOWN AS OUR ALPHA CLINIC, AND HOLDS NOW MANY EMERITUS TITLES IN THE DEPARTMENTS OF NEUROSCIENCES AND THE SANFORD CONSORTIUM FOR REGENERATIVE MEDICINE, TO NAME ONLY A FEW.

LARRY IS A MEMBER OF THE AMERICAN ACADEMY OF ARTS AND SCIENCES AND THE NATIONAL ACADEMY OF SCIENCE. HE BROKE GROUND IN HIS RESEARCH ON THE MOLECULAR MECHANISMS OF INTRACELLULAR MOVEMENT IN NEURONS AND TRANSPORT DYSFUNCTION IN NEURODEGENERATIVE DISEASES.

DR. GOLDSTEIN JOINED THE CIRM BOARD IN JANUARY OF 2021, AND HE HAS MADE AN OUTSIZED IMPACT ON CIRM IN HIS FOUR YEARS OF BOARD SERVICE. HE HAD PREVIOUSLY SERVED ON SEVERAL PUBLIC SCIENCE ADVISORY COMMITTEES, INCLUDING THE ADVISORY BOARD FOR PROPOSITION 71 THAT CREATED CIRM. LARRY SERVED AS CHAIR OF THE SCIENCE SUBCOMMITTEE DURING MOST OF HIS BOARD TENURE DURING WHICH TIME CIRM DEVELOPED PROGRAMS FOR UNDERGRADUATE STUDENTS, EXPANDED THE

ALPHA CLINIC NETWORK, CREATED A NEW DISCOVERY PROGRAM, DEVELOPED THE CELL AND GENE THERAPY MANUFACTURING NETWORK, RELAUNCHED THE SHARED LABS PROGRAM, STARTED THE PROGRAM TO PROMOTE MULTIDISCIPLINARY RESEARCH IN NEUROPSYCHIATRIC DISEASES, AND OVERSAW THE ESTABLISHMENT OF A PROGRAM TO SUPPORT LATE STAGE CLINICAL DEVELOPMENT, AMONG OTHER ENDEAVORS.

HE SERVED AS THE FOUNDING CHAIR OF CIRM'S TASK FORCE ON NEUROSCIENCE AND MEDICINE WHICH TASKED ITSELF WITH GENERATING A PLAN TO ALLOCATE $1.5 BILLION SET ASIDE IN PROPOSITION 14 FOR TREATMENT OF DISEASES OF THE BRAIN AND CENTRAL NERVOUS SYSTEM. THE COMMUNICATIONS AND INTELLECTUAL PROPERTY AND INDUSTRY SUBCOMMITTEES ALSO COUNTED HIM AS A THOUGHTFUL AND CONTRIBUTING MEMBER. AND HE WAS A DELIGHT TO WORK WITH AT EVERY TURN.

AND TO UNDERSCORE THE ADAGE THAT WE CAN NEVER PREDICT HOW BIG THE TREE WILL GROW WHEN YOU PLANT THE SEED, I'LL EVEN -- I WAGER THAT EVEN LARRY -- I'M SORRY I LOST MY PLACE. EVEN LARRY WILL BE PLEASANTLY SURPRISED HOW THE REMIND PROGRAM WITH ITS DATA-DRIVEN AND PORTFOLIO-FOCUSED EMPHASIS ON NEUROPSYCHIATRIC DISEASES HAS ITSELF BECOME A MODEL FOR MUCH OF THE STRATEGIC ALLOCATION FRAMEWORK THAT

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HAS DRIVEN MUCH OF CIRM'S WORK IN THE LAST YEAR.

WE THANK YOU, LARRY, FOR YOUR INTELLIGENCE, YOUR DEDICATION, INSIGHT, AND LOYALTY TO THE MISSION AND THE IDEALS OF CIRM, AND WE ARE ONLY JUST BEGINNING TO SEE WHERE YOUR IMAGINATION WILL TAKE US.

I'M GOING TO ASK OTHER MEMBERS OF THE BOARD WHO MIGHT LIKE TO MAKE COMMENTS AT THIS TIME TO DO SO. DR. BARRETT.

DR. BARRETT: SO I'M ABSOLUTELY THRILLED TO HAVE THE OPPORTUNITY TO THANK LARRY FOR HIS CONTRIBUTIONS. HE JOINED THE FACULTY AT UC SAN DIEGO A FEW YEARS AFTER I DID, AND I WORKED CLOSELY WITH HIM, NOT NECESSARILY IN STEM CELL-RELATED AREAS, BUT IN GRADUATE EDUCATION AND VARIOUS SCIENTIFIC AREAS. HE WAS ALWAYS SUCH A PLEASURE TO WITH WORK WITH, AND WAS A GREAT JOY TO ME WHEN I WAS APPOINTED TO THE BOARD TO BE ABLE TO RENEW OUR ACQUAINTANCE.

YOU ARE GREATLY MISSED, LARRY. BUT AS VITO HAS INDICATED, YOUR INFLUENCE ON THE FIELD HAS BEEN IMMENSE, AND THE SEEDS THAT YOU HAVE SOWN WILL JUST AMPLIFY YOUR CONTRIBUTIONS FOR MANY, MANY DECADES TO COME. SO THANK YOU FOR EVERYTHING THAT YOU'VE DONE.

DR. GASSON: HI, LARRY. I WANT TO ACKNOWLEDGE THE ENORMOUS CONTRIBUTIONS THAT YOU'VE MADE BOTH IN YOUR OWN RESEARCH AT UCSD, BUT ALSO ON WORK THAT YOU'VE DONE AT THE NIH AND AT CIRM, WHICH HAS BEEN INCREDIBLY IMPACTFUL.

I HAD THE PLEASURE OF SERVING ON THE NEURO TASK FORCE WHILE YOU CHAIRED IT. AND IT WAS A CHALLENGING OPPORTUNITY TO TRY TO UNDERSTAND WHERE THE FIELD STOOD WITH THE GROUP OF PEOPLE, MANY OF WHOM ACTUALLY WERE NOT SCIENTISTS. I THINK YOU DID A MASTERFUL JOB OF ORGANIZING THOSE INFORMATION SEMINARS AND MOVING THE PROCESS FORWARD.

IN ADDITION, I CAN ALSO SAY THAT YOU EXHIBITED ENORMOUS GRACE IN THE WAY THAT YOU HANDLED THE MEMBERS OF THE COMMITTEE, THE OUTSIDE PEOPLE THAT WERE INVOLVED IN EVERY PROCESS TO BRING US TO A CONSENSUS THAT HAS RESULTED IN THE VERY SUCCESSFUL REMIND-L PROGRAM. SO THANK YOU FOR ALL OF THAT.

VICE CHAIR BONNEVILLE: I WANT TO THANK LARRY GOLDSTEIN FOR ALL HE'S DONE FOR CIRM, AND NOT JUST AS CHAIR OF THE SCIENCE SUBCOMMITTEE. LARRY IS OUR ULTIMATE CHEERLEADING. HE STARTED ADVOCATING FOR CIRM PRE-PROPOSITION 71, HELPING WITH THE CAMPAIGN AND AS A TRUSTED ADVISOR TO BOB KLEIN. HE HAS MENTORED SEVERAL OF THE SCIENTISTS OF CIRM

GRANTS, AND HE CONTINUES TO PROVIDE VALUABLE COUNSEL TO MANY OF US.

LARRY, YOU ARE MISSED HERE ON THE BOARD, AND THANK YOU FOR NOT LEAVING US COMPLETELY AND CONTINUING TO PROVIDE ADVICE AND ENTHUSIASM FOR CIRM.

DR. GOLDSTEIN: THANK YOU.

CHAIRMAN IMBASCIANI: JOHN CARETHERS.

DR. CARETHERS: LARRY, AS YOUR REPLACEMENT ON THE COMMITTEE, IT'S BIG SHOES TO FILL. I WANT TO RECOGNIZE YOU IN MY TWO TOURS AT UC SAN DIEGO AND KNOWING YOUR IMPORTANCE, DEDICATION, AND CONSISTENT PUSH FOR HELPING TO DEVELOP, ALONG WITH BOB KLEIN, CIRM. YOU ARE A CALIFORNIA MAN, AND YOU ARE A UNIVERSITY OF CALIFORNIA MAN. AND I PERSONALLY WANT TO ALSO THANK YOU FOR THE CONTRIBUTIONS YOU HAVE DONE FOR THE STATE AND OUR UNIVERSITY AND THIS BODY.

UNFORTUNATELY, I'M NOT GOING TO BEING ABLE TO PROJECT IT, BUT I WANTED TO SHARE A PICTURE OF YOUR EVENT BACK IN DECEMBER AT THE SANFORD STEM CELL BUILDING IN SAN DIEGO IN WHICH THE PAST THREE VICE CHANCELLORS, MYSELF, DAVID BRENNER, AND ED HOLMES, ALONG WITH LARRY. AND A WONDERFUL PAINTING OF LARRY IS NOW HANGING IN THAT BUILDING. SO MY THANKS TO YOU AND CONGRATULATIONS, LARRY.

DR. GOLDSTEIN: THANK OU, JOHN.

DR. LEVITT: HI, LARRY. SO THIS IS JUST MY OWN VIEW, THAT MOST NEUROSCIENTISTS WHO ARE SUCCESSFUL LIKE YOURSELF ARE OBSESSIVE COMPULSIVE. AND YOU DO EPITOMIZE OBSESSIVE COMPULSIVENESS BECAUSE OUT OF ALL THE COMMITTEES THAT I'VE BEEN TALKED INTO TO JOINING OR WORKING GROUPS, NEUROSCIENCE SUBCOMMITTEE HAS BEEN BY FAR THE MOST ENJOYABLE BECAUSE OF YOU, BECAUSE OF YOUR PREMEETING PLANNING AND STRUCTURE AND ORGANIZATION AND ALSO JUST A GREAT TALENT SCOUT. YOU HAD THE VERY BEST PEOPLE OUTSIDE OF CALIFORNIA JOIN US IN ALL THOSE MEETINGS.

IT WAS A GREAT NEW EDUCATION FOR A LOT OF US, AND IT'S ALL DUE TO YOUR PLANNING, YOUR SUCCESS. AND YOU CAN SEE CIRM IS REAPING THE BENEFITS OF ALL THE WORK THAT YOU PUT INTO IT. SO THANK YOU. I'M PROUD TO SAY I GOT MY NEUROSCIENCE PH.D. AT UCSD, AND IT WAS BECAUSE OF FACULTY LIKE YOURSELF FOR WHATEVER SUCCESS I'VE BEEN ABLE TO ACHIEVE. SO THANKS.

CHAIRMAN IMBASCIANI: MARK FISCHER-COLBRIE.

MR. FISCHER-COLBRIE: LARRY, YOUR CONTRIBUTIONS HAVE BEEN JUST PHENOMENAL, BUT I

WANTED TO THANK YOU ON A DIRECT PERSONAL LEVEL BECAUSE YOU'VE BEEN A TERRIFIC MENTOR, A GUIDE, SOMEONE TO EMULATE. AND I DEEPLY APPRECIATE WHAT YOU'VE DONE, NOT JUST FOR CIRM, BUT FOR MYSELF AS WELL. SO THANK YOU, LARRY.

CHAIRMAN IMBASCIANI: JONATHAN.

DR. THOMAS: HELLO, LARRY. SO I WANTED TO AMPLIFY A COUPLE POINTS THAT WERE MADE ALREADY. FIRST OF ALL, THE IMPORTANCE OF HAVING YOU ON THE BOARD AS SOMEBODY WHO HAD PERSPECTIVE ON LITERALLY THE ENTIRE LIFE OF CIRM. AND HAVING BEEN A PERSON WHO WAS INSTRUMENTAL IN GETTING IT INTO EXISTENCE IN THE FIRST PLACE, BUT BEING ABLE TO APPLY THAT PERSPECTIVE AS YOU WOULD LEAD US THROUGH THE VARIOUS DIFFERENT THINGS THAT WERE OF GREAT CONCERN TO YOU HAS BEEN SO IMPORTANT.

LIKEWISE, YOUR RESPECT NATIONALLY AND INTERNATIONALLY FOR YOUR WORK AND THE RESULTING NETWORK THAT AROSE FROM THAT FOR WHICH WE HAVE GREATLY BENEFITED IS SOMETHING THAT IS UNIQUE. NOT EVERYBODY CAN BRING THAT TO THE TABLE. AND WHEN YOU ADD THAT TO THE INSTITUTIONAL MEMORY AND THE FUNDAMENTAL UNDERSTANDING OF WHAT WE'RE ALL ABOUT, IT WAS MOST BENEFICIAL.

IN ADDITION TO THE NEURO TASK FORCE, AS I

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RECALL GETTING A CALL FROM YOU ONE DAY TALKING ABOUT A NEW PROGRAM THAT YOU THOUGHT WOULD BE GOOD FOR OUR EDUCATION PROGRAMS, AND FROM THAT AROSE COMPASS, WHICH IS NOW A BIG SUCCESS ACROSS THE STATE. SO THANK YOU FOR THAT.

AND JUST FOR YOUR SHEER LEVEL OF DEDICATION, ENTHUSIASM, AND AVAILABILITY AT ALL TIMES TO DISCUSS WHATEVER WAS OF IMPORTANCE TO YOU, TO THE ORGANIZATION, TO THE FIELD. SO YOU ARE A HUGE CONTRIBUTOR. JOHN DOES HAVE VERY BIG SHOES TO FILL. HE'S DOING A GOOD JOB, BY THE WAY, JUST SO YOU KNOW. AND WE SO APPRECIATED HAVING THE CHANCE TO WORK WITH YOU.

AND I PERSONALLY WOULD LIKE TO NOTE THAT HAVING THE OPPORTUNITY COINCIDENTALLY TO HAVE DINNER WITH YOU AT THE EVENT CELEBRATING DENNY'S TEN-YEAR ANNIVERSARY SINCE HIS GIFT DOWN IN SAN DIEGO WAS A HUGE PLUS, AND I REALLY GREATLY ENJOYED OUR DISCUSSION THERE AS ALWAYS. SO THANKS SO MUCH FOR ALL YOU'VE MEANT TO CIRM AND THE FIELD.

CHAIRMAN IMBASCIANI: GREAT. I WOULD LIKE TO HAVE A MOTION TO ADOPT THE RESOLUTION TO HONOR DR. LAWRENCE GOLDSTEIN. DR. BARRETT.

DR. BARRETT: I MOVE THAT WE ADOPT THE RESOLUTION IN HONOR OF PROFESSOR LARRY GOLDSTEIN.

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DR. SOUTHARD: SECOND.

CHAIRMAN IMBASCIANI: WE HAVE A SECOND. YES, GEOFF LOMAX.

DR. LOMAX: I GUESS I'M QUASI-PUBLIC, BUT DR. GOLDSTEIN, OVER MY EXPERIENCE HERE, THERE'S BEEN NUMEROUS, NUMEROUS THREATS TO SCIENCE AND SCIENTIFIC FREEDOM. AND EVERY TIME ONE OF THOSE THREATS EMERGED, IT WAS DR. LARRY GOLDSTEIN WHO WAS THE HEADLINE CHAMPION TO TRY TO CHANGE THAT. AND THAT ADVOCACY PROBABLY MADE YOU A VILLAIN AMONGST THOSE WHO WOULD CHOOSE TO LIMIT SCIENCE. AND SO FROM THAT STANDPOINT -- AND THAT'S NOT EASY. AND A LOT OF YOUR COLLEAGUES WEREN'T THERE. THEY WEREN'T QUOTED IN THAT ARTICLE. THEY WERE THE ANONYMOUS SOURCES.

SO THANK YOU FOR BEING A CHAMPION OF SCIENCE, AND THANK YOU FOR DEFENSE OF SCIENTIFIC FREEDOM.

CHAIRMAN IMBASCIANI: THAT WAS BEAUTIFUL, GEOFF. THANK YOU. SCOTT, I THINK WE'RE READY TO CALL THE ROLL.

MR. TOCHER: ALL THOSE IN THE ROOM IN FAVOR SAY AYE. OPPOSED? ABSTENTIONS? POLLING THE MEMBERS ON THE PHONE.

YSABEL DURON.

MS. DURON: YES.

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MR. TOCHER: RICH LAJARA. SHLOMO MELMED.
DR. MELMED: YES.
MR. TOCHER: CHRIS MIASKOWSKI.
DR. MIASKOWSKI: YES.
MR. TOCHER: JOE PANETTA. SUZANNE SANDMEYER. KAROL WATSON.
DR. WATSON: YES.
MR. TOCHER: KEVIN XU.
DR. XU: YES.
MR. TOCHER: THANK YOU. CARRIES UNANIMOUSLY, MR. CHAIR.
CHAIRMAN IMBASCIANI: THANK YOU, SCOTT, FOR DOING THAT. SO CAN I INVITE DR. SAMBRANO BACK TO THE PODIUM. I'M SORRY. OF COURSE, LARRY.
DR. GOLDSTEIN: SO I GET A REBUTTAL, VITO? I DO WANT TO THANK ALL THE BOARD MEMBERS FOR THEIR FRIENDSHIP AND SUPPORT AT A CHALLENGING TIME, BUT REALLY ENABLED THINGS I CARED ABOUT TO BE SUCCESSFUL. THE WORK YOU DO AND WILL CONTINUE TO DO MATTERS A GREAT DEAL TO ME. AND ALTHOUGH I'M NOT AN MD, THE IDEA OF HEALING THE SICK WITH STEM CELL AND RELATED APPROACHES IS SOMETHING THAT CONTINUES TO DRIVE MY THINKING ABOUT WHERE CERTAIN AVENUES I'M INVOLVED IN SHOULD GO.
SO A BIG THANK YOU TO THE BOARD, A SPECIAL

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CALL-OUT TO THE STAFF PEOPLE. YOU GUYS WERE KIND TO ME, YOU WERE SUPPORTIVE, YOU MADE SURE THAT SOME OF MY CRAZIER IDEAS COULD BE TRANSLATED INTO REALISTIC PROGRESS. AND THAT ALSO HAS MEANT A GREAT DEAL. SO I'LL WATCH WITH INTEREST IN THE COMING YEARS. I AM ALWAYS AVAILABLE FOR CONSULTATION AS VITO AND MARIA KNOW. AND I WILL CONTINUE TO CHEER FOR YOUR SUCCESS. SO KEEP UP THE GOOD WORK, GUYS.

CHAIRMAN IMBASCIANI: THANK YOU, LARRY. AND I WANT TO TELL YOU THAT THIS RESOLUTION WHICH THE BOARD JUST VOTED IN YOUR HONOR, WHILE NOT AS PRETTY AS THE PORTRAIT WE WERE JUST LOOKING AT, WILL BE SENT TO YOU IN SAN DIEGO IN GOOD CONDITION.

DR. GOLDSTEIN: THANK YOU. YES, WONDERFUL.

(APPLAUSE.)

CHAIRMAN IMBASCIANI: NOW WE'LL RETURN TO THE CONSIDERATION OF AGENDA ITEM NO. 13, THE REVIEW PROCESS AND THE GRANTS WORKING GROUP BYLAWS. DR. SAMBRANO, THE FLOOR IS YOURS.

DR. SAMBRANO: THANK YOU VERY MUCH, CHAIRMAN IMBASCIANI, MEMBERS OF THE BOARD, MEMBERS OF THE PUBLIC. GOOD AFTERNOON. THIS HAS BEEN SEEMINGLY HIGHLY ANTICIPATED BASED ON THE EARLIER DISCUSSION, SO I HOPE I DON'T DISAPPOINT. I DO WANT

TO WARN YOU THAT IT IS A LENGTHY PRESENTATION. AND SO THE INTENT IS TO DESCRIBE TO YOU THE REVIEW PROCESS THAT'S TO BE USED FOR THE FOUR NEW CONCEPTS THAT HAVE BEEN APPROVED, AND TO GIVE YOU A DEEPER UNDERSTANDING OF THE REVIEW PROCESS ITSELF, HOW IT IS THAT IT WORKS AT CIRM.

MOST OF WHAT I'M GOING TO DESCRIBE TO YOU IS SOMETHING THAT WE'VE DONE BEFORE, BUT IT'S IMPORTANT TO EXPLAIN HOW IT WORKS TO GIVE YOU A DEEPER UNDERSTANDING OF WHAT HAPPENS. AND, OF COURSE, SOME OF IT IS NEW, AND IT WAS DEVELOPED AROUND A COUPLE OF THE PROGRAMS THAT WERE ALREADY DESCRIBED TO YOU. THERE WILL BE A LITTLE BIT OF REPETITION, BUT I HOPE TO GET THROUGH THOSE MAYBE QUICKLY. I ALSO WANT TO INVITE YOU TO ASK QUESTIONS AS WE GO ALONG BECAUSE IT IS A LENGTHY PRESENTATION. I MAY NOT BE LOOKING UP. SO IF I'M NOT AND I DON'T SEE YOU ASKING, MAYBE CLAUDETTE OR SCOTT, IF YOU COULD ALERT ME, AND I'M HAPPY TO ADDRESS ANY QUESTIONS.

SO HERE WE GO. THIS IS THE PROPOSED AGENDA OR OUTLINE FOR THE DISCUSSION. I WANT TO START WITH AN INTRODUCTION TO THE GRANTS WORKING GROUP ITSELF AND HOW APPLICATION REVIEW WORKS UNDER THE CONTEXT OF THE GRANTS WORKING GROUP. INTRODUCE

YOU TO WHAT WE CALL TWO-STAGE REVIEW WHICH HAS SEVERAL FLAVORS OF APPROACHES THAT WE HAVE TRIED. I WANT TO GO THROUGH THE METHODS THAT ARE PROPOSED FOR EACH OF THE CONCEPTS THAT WERE DISCUSSED EARLIER: THE DISC5, CLIN2, PDEV, AND DISC4. I WANT TO SPEND A LITTLE BIT OF TIME ON THE SCORING METHODOLOGY THAT CIRM USES AND THE REASON FOR WHY WE WISH TO SCORE THIS WAY. AND THEN SPEND SOME TIME ON PROGRAMMATIC REVIEW AND TEAM RECOMMENDATIONS THAT COME TO THE BOARD, THE APPLICATION REVIEW SUBCOMMITTEE, FOR FINAL DECISIONS AND HOW WE INTEND TO PROVIDE YOU ENOUGH INFORMATION TO MAKE INFORMED DECISIONS.

SO LET'S START WITH THE GRANTS WORKING GROUP. THE GRANTS WORKING GROUP ITSELF IS THE BODY THAT'S RESPONSIBLE FOR EVALUATING SCIENTIFIC MERIT OF ALL APPLICATIONS UNDER PROPOSITION 71 AND PROP 14. AND THE OUTCOME OF THE GRANTS WORKING GROUP MEETING IS TO PROVIDE FUNDING RECOMMENDATIONS TO THE ICOC.

THE PANEL ITSELF IS COMPOSED OF UP TO 15 SCIENTIFIC MEMBERS THAT ARE FROM OUTSIDE OF CALIFORNIA. SO WE RECRUIT ALL OF THE MEMBERS FROM OUTSIDE OF CALIFORNIA MOSTLY FOR CONFLICT OF INTEREST ISSUES OR AT LEAST TO MINIMIZE IT, AND TO MAKE SURE THAT WE BRING IN THE APPROPRIATE

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EXPERTISE. IT ALSO INCLUDES SEVEN PATIENT ADVOCATE OR NURSE MEMBERS OF THE BOARD. SO SEVERAL OF YOU ARE APPOINTED TO THE GRANTS WORKING GROUP AS PATIENT ADVOCATE OR NURSE MEMBERS. AND THE CHAIR OF THE ICOC IS AN EX OFFICIO MEMBER OF THE PANEL.

ALL MEMBERS MUST BE APPOINTED BY THE ICOC. SO THAT'S BOTH THE SCIENTIFIC MEMBERS AND THE PATIENT ADVOCATE NURSE MEMBERS AND WILL SERVE FOR VARIABLE TERMS. THE GROUP ITSELF FUNCTIONS AS A SINGULAR BODY, BUT WITH ROTATING SCIENTIFIC MEMBERS. SO WE BRING THE APPROPRIATE SCIENTIFIC MEMBERS FOR THE NEEDS OF A PARTICULAR REVIEW; HOWEVER, OUR PATIENT ADVOCATE AND NURSE MEMBERS WE HAVE A FEWER NUMBER TO DRAW FROM. SO BASICALLY THAT IS YOU WHO SERVE THE BOARD THAT WE DRAW ON FOR THESE MEETINGS.

CIRM DOESN'T HAVE STANDING STUDY SECTIONS FOR REVIEW WHERE WE CAN HAVE PANELS THAT ARE DEDICATED TO ANY PARTICULAR FIELD OR AREA OF STUDY. SO INSTEAD, WE HAVE TO ASSEMBLE OUR PANELS AROUND A SPECIFIC SET OF APPLICATIONS AS WE GO THROUGH EACH OF THE CYCLES.

SO HOW DO WE THEN ASSEMBLE THE PANELS IN ORDER TO GATHER THE RIGHT EXPERTISE? SO WHAT WE DO IS, AS YOU HAVE SEEN OVER THE COURSE OF SEVERAL OF THESE BOARD MEETINGS, WE APPOINT AND BRING TO YOU

BIOS AND INFORMATION ABOUT DIFFERENT EXPERTS THAT WE WOULD LIKE TO NOMINATE TO THE GRANTS WORKING GROUP. AND THROUGH THAT PROCESS, WE MAINTAIN A POOL OF ABOUT 250 TO 300 APPOINTED MEMBERS THAT HAVE VARIABLE AREAS OF EXPERTISE, CLINICIANS, BASIC BIOLOGISTS, FOLKS WHO UNDERSTAND PRODUCT DEVELOPMENT OR REGULATORY AFFAIRS. AND WE UTILIZE THIS POOL IN ORDER TO CONSTRUCT A PANEL THAT'S APPROPRIATE FOR THE TYPE OF REVIEW THAT WE INTEND TO HAVE.

SO YOU CAN IMAGINE THAT A PANEL FOR A DISCOVERY SET OF APPLICATIONS IS GOING TO BE COMPOSED AND BE DIFFERENT FROM A CLINICAL PANEL, FOR EXAMPLE. WE NEED TO HAVE ENOUGH INDIVIDUALS WITHIN THAT POOL TO ENSURE THAT WE COVER ALL THE DIFFERENT AREAS THAT CAN COME TO US IN TERMS OF TOPICS AND APPLICATIONS, BUT STILL MAINTAIN THE UP TO 15 SCIENTIFIC MEMBERS FOR A GIVEN PANEL.

DR. LEVITT: IT'S A BORING QUESTION. GIVEN WHAT WE HEARD THIS MORNING ABOUT THE EXPECTATION OF THE TIDAL WAVE OF APPLICATIONS, IS THE 15-MEMBER COMPONENT, IS THAT IN THE PROPOSITION OR THAT'S INTERNAL?

DR. SAMBRANO: YES. IT'S IN THE PROPOSITION UP TO 15.

DR LEVITT: SO THAT'S CAPPED?

DR. SAMBRANO: YES.

DR. LEVITT: MAYBE IT VARIES. YOU HAVE THREE PANELS, DISC, TRAN, AND CLIN. WHAT'S THE AVERAGE NUMBER OF APPLICATIONS ASSIGNED TO A MEMBER?

DR. SAMBRANO: I WAS GOING TO GO OVER THAT. SO WHAT ARE THE NUMBERS? SO THE BEST COMPARATOR TO NIH, FOR EXAMPLE, LIKE A R01, FOR NIH IS TYPICALLY SIX TO EIGHT. SO WE AVERAGE ANYWHERE FROM SIX TO TEN, AND WE TEND TO PUSH IT A LOT OF TIMES TOWARDS THE LARGER NUMBER, PARTICULARLY FOR DISCOVERY PROPOSALS JUST BECAUSE THAT'S WHERE WE GET THE HIGHEST NUMBER OF APPLICATIONS.

ON THE FLIP SIDE, FOR CLINICAL, IT'S MUCH FEWER. SO WE CAN ACTUALLY CONCENTRATE THE EFFORTS IF A 15-MEMBER PANEL MUCH MORE EFFECTIVELY BECAUSE THE NUMBER OF APPLICATIONS IS SMALLER.

DR. LEVITT: OKAY. THANKS.

DR. SAMBRANO: OKAY. SO THE COMPOSITION, AGAIN, I MENTIONED THE SCIENTIFIC MEMBERS WHO ARE RESPONSIBLE FOR THE SCIENTIFIC EVALUATION, BUT THOSE ARE THE ONLY ONES THAT ACTUALLY DO THE SCIENTIFIC SCORING. SO WHENEVER YOU SEE THE SCIENTIFIC SCORING, IT COMES FROM THE 15 SCIENTISTS. OUR PATIENT ADVOCATE MEMBERS PARTICIPATE BY PROVIDING PERSPECTIVE ON THE SIGNIFICANCE AND POTENTIAL FOR

IMPACT. THEY MAY PROVIDE A DEI SCORE ON CLINICAL APPLICATIONS AND MAY ALSO PROVIDE SUGGESTED SCIENTIFIC SCORE, BUT THOSE ARE NOT RECORDED AS PART OF THE SCORE THAT WE ULTIMATELY SEE.

WE BRING IN TO ADD EXPERTISE WHERE POSSIBLE SCIENTIFIC SPECIALISTS. SO THESE ARE NONVOTING PARTICIPANTS WHO MAY COVER ONE OR TWO APPLICATIONS AS NEEDED TO BRING THAT ADDED EXPERTISE TO THE PANEL. AND SO ALTHOUGH THEY PROVIDE COMMENTARY AND PARTICIPATE IN THE DISCUSSION, THEY DO NOT PROVIDE A FINAL SCORE.

SO I WANT TO JUST UTILIZE THIS SLIDE TO SET THE STAGE FOR WHAT I'M GOING TO DISCUSS GOING FORWARD. THIS IS WHAT A TYPICAL GRANTS WORKING GROUP-BASED REVIEW TIMELINE WOULD LOOK LIKE OR AT LEAST PROCESS LINE WOULD LOOK LIKE. IT HAS THREE BASIC STEPS. ELIGIBILITY THAT'S ASSESSED BY CIRM STAFF WHEN APPLICATIONS COME IN. THOSE THAT ARE ACCEPTED GO TO THE GRANTS WORKING GROUP FOR THE MERIT REVIEW. THE RECOMMENDATION COMES FROM THE GRANTS WORKING GROUP THAT COMES TO THEN THE ICOC FOR A FINAL FUNDING DECISION.

SO ASSUMING THERE IS NO NEED FOR A TWO-STAGE PROCESS, THIS IS GENERALLY WHAT IT LOOKS LIKE.

NOW, THERE ARE SEVERAL CONSIDERATIONS THAT WE TAKE INTO ACCOUNT WHEN THINKING ABOUT WHAT IS THAT NUMBER WHERE WE FEEL WE'RE NOT GOING TO HAVE A QUALITY OR EFFECTIVE REVIEW? AND THERE ARE SEVERAL FACTORS. PAT, YOU BROUGHT ONE OF THE THEM UP WHICH IS RELATED TO HAVING ADEQUATE TIME FOR REVIEWERS TO DISCUSS APPLICATIONS. SO, OF COURSE, THE MORE APPLICATIONS THAT ARE IN A REVIEW CYCLE, THE LESS TIME IS AVAILABLE FOR EACH ONE. MINIMIZING THE APPLICATION ASSIGNMENT BURDEN PER REVIEWER. AS MENTIONED, THE MORE APPLICATIONS EACH REVIEWER IS ASSIGNED TO, THE LESS EFFORTS THAT IS THEN EXPENDED ON EACH ONE.

WE ALSO TO MAXIMIZE AS BEST WE CAN THE EXPERTISE THAT WE HAVE AVAILABLE FROM THE GWG TO THE SET OF APPLICATIONS THAT WE ARE REVIEWING. AND THE GREATER LEVEL OF EXPERTISE IS AVAILABLE WHEN YOU HAVE A MORE FOCUSED SET OF APPLICATIONS, AS YOU MIGHT IMAGINE, AND THE BROADER THE SCOPE, THE MORE DIFFICULT IT IS TO MAKE SURE THAT YOU HAVE EXPERTS AVAILABLE TO COVER EVERYTHING THAT NEEDS IT.

WE ALSO WANT TO MAKE SURE THAT WE ALIGN THE REVIEW WITH THE TARGETED NUMBER OF AWARDS WE SEEK. SO IN A LOT OF THE CONCEPT PRESENTATIONS, WE PRESENT THE TARGET NUMBER THAT WE HAVE EITHER ON AN

ANNUAL BASIS OR ON A PER CYCLE BASIS. AND SO WE WANT TO MAKE SURE THAT THE REVIEWS ARE CAPABLE OF GIVING US THE TARGETED NUMBER OF AWARDS AND THAT WE ARE ALIGNED WITH THAT.

SO GIVEN ALL OF THIS AND GIVEN THESE FACTORS, THE NUMBER THAT ULTIMATELY ALLOWS TO BALANCE THESE CONSIDERATIONS AND ACHIEVE QUALITY REVIEWS IS WHAT DETERMINES, THEN, THE CAPACITY. AND SO WHAT HAPPENS WHEN WE EXCEED THAT CAPACITY? AND THAT'S WHEN WE COME INTO THE IDEA OF SETTING UP A TWO-STAGE REVIEW PROCESS. AND SO, THEREFORE, THE PURPOSE OF IT IS THAT WHEN THE NUMBERS OF APPLICATIONS RECEIVED FOR FUNDING OPPORTUNITIES EXCEED THE CAPACITY OF THE GRANTS WORKING GROUP TO REVIEW IN A SINGLE CYCLE, WE IMPLEMENT IT.

AND TYPICALLY THIS HAS HAPPENED FOR OUR EARLY STAGE DISCOVERY TYPE OF OPPORTUNITIES, AND THAT HAS BEEN HAPPENING FOR MANY YEARS. SO ALMOST SINCE THE VERY BEGINNING THOSE WERE THE MOST POPULAR OF OUR OPPORTUNITIES. AND WE STARTED DEVELOPING DIFFERENT MECHANISMS FOR HOW WE WOULD SET UP A TWO-STAGE REVIEW PROCESS, DOING PREAPPLICATIONS OR LIMITING, FOR EXAMPLE, THE TOTAL NUMBER OF APPLICATIONS THAT COULD BE SUBMITTED BY AN INSTITUTION, WHICH THERE ARE A LOT OF REASONS NOT TO

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DO THAT, BUT IT WAS SOMETHING THAT WE ACTUALLY TRIED.

SO TODAY I WANT TO DISCUSS WHAT IT IS THAT WE'RE PROPOSING TO DO AS A TWO-STAGE REVIEW PROCESS FOR EACH OF THE CONCEPTS THAT WERE DISCUSSED EARLIER.

ALL RIGHT. SO HOW DID WE GO ABOUT, THEN, CHOOSING THE PROCESS FOR EACH OF THESE PROGRAMS? WE SET UP A SORT OF DECISION TREE. WE WORKED WITH THE REVIEW TEAM ALONG WITH EACH OF THE CONCEPT TEAMS TO UNDERSTAND THE NEEDS FOR EACH OF THE CONCEPTS THAT WERE BEING DEVELOPED, AND TO TRY TO ARRIVE AT A PROCESS THAT WAS AMENABLE AND WOULD WORK BEST FOR THAT GROUP. OF COURSE, THE GOALS WERE TO MANAGE LARGE NUMBERS OF APPLICATIONS, MAKE SURE WE COULD IMPLEMENT STRATEGIC PRIORITIES, AND WHERE POSSIBLE LIMIT THE BURDEN ON APPLICANTS.

AND SO QUESTIONS THAT WE ASKED OURSELVES IN DEVELOPING THIS PROCESS WERE CAN THE GRANTS WORKING GROUP APPROPRIATELY AND EFFECTIVELY REVIEW ALL ELIGIBLE APPLICATIONS? IF SO, THERE WOULD BE OBVIOUSLY NO NEED TO MAKE MUCH EFFORT IN A TWO-STAGE REVIEW PROCESS. WE HAVE LEARNED, HOWEVER, THAT WE HAVE BECOME MORE POPULAR IN TERMS OF APPLICATIONS COMING IN. I THINK WE HAVE ALL SEEN THAT IT HAS NOT

JUST EXISTED IN THE EARLY DISCOVERY STAGE, BUT IT HAS GONE INTO NOW TRANSLATIONAL STAGE PROJECTS AS WELL AS THE CLINICAL. SO FINDING EFFECTIVE WAYS TO DO THIS IS IMPORTANT.

WE ALSO ASK WHETHER THE PREFERENCES OR PRIORITIES THAT WE SET ARE THINGS THAT CAN BE DETERMINED DISCRETELY OR COMPARATIVELY. DISCRETELY MEANING THAT AN APPLICATION ON ITS OWN CAN TELL YOU WHETHER THIS IS TRUE OR NOT OR WHETHER THE CRITERION IS MET. FOR EXAMPLE, ARE THEY A CALIFORNIA ORGANIZATION OR NOT? COMPARATIVELY FOR SOMETHING THAT A GIVEN APPLICATION IS MORE OR LESS OF THAN ANOTHER IN ORDER TO DETERMINE WHETHER A CRITERION IS MET.

IS A COMPLETE APPLICATION NECESSARY IN ORDER TO ASSESS THESE PRIORITIES? IN SOME CASES WE FELT IT WAS IMPORTANT TO HAVE A FULL APPLICATION.

SO THIS TABLE IS JUST A SUMMARY --

DR. LEVITT: CAN I ASK A QUESTION? YOU MENTIONED BEFORE -- I'M OBSESSING ABOUT THIS BECAUSE THIS PROCESS IS GOING TO DEFINE OUR FUNDED PROGRAMS. AND SO THE PROCESS IS REALLY IMPORTANT, TO ME AT LEAST. I THINK IT'S IMPORTANT TO EVERYBODY. SO YOU MENTIONED THAT ALL APPLICATIONS UNDER A SPECIFIC RUBRIC COMING IN AT A CERTAIN TIME GO TO ONE STUDY

SECTION.

DR. SAMBRANO: TO ONE GROUP.

DR. LEVITT: IS THAT A REQUIREMENT AS WELL? IS THAT A PROPOSITION REQUIREMENT?

DR. SAMBRANO: ALL APPLICATIONS ULTIMATELY HAVE TO GO THROUGH THE GRANTS WORKING GROUP.

DR. LEVITT: BUT I'M SAYING YOU HAVE ONE 15-MEMBER PLUS SEVEN PLUS WHATEVER YOU HAVE. YOU HAVE ONE WORKING GROUP FOR A PARTICULAR GRANT SUBMISSION, AND ALL THE GRANTS IN THAT SUBMISSION GO TO THAT ONE GROUP FOR A PARTICULAR PROJECT, OR A PARTICULAR RUBRIC.

DR. SAMBRANO: YES IN THE SENSE THAT IT'S THE GRANTS WORKING GROUP. SO AS I MENTIONED EARLIER, WE CAN ROTATE SCIENTIFIC MEMBERS IN AND OUT, AND TO SOME EXTENT WE CAN ROTATE --

DR. LEVITT: SURE. I GUESS WHAT I'M ASKING IS DO YOU EVER HAVE A SITUATION WHERE YOU HAVE TWO GWG'S?

DR. SAMBRANO: NO.

DR. LEVITT: UNDER THE SAME CONCEPT PLAN REVIEWING GRANTS AT THE SAME TIME?

DR. SAMBRANO: NO.

DR. LEVITT: IT'S ONLY ONE?

DR. SAMBRANO: IT'S ONLY ONE.

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DR. LEVITT: ALL RIGHT. SO IS NOT HAVING TWO, HAS THAT BEEN DISCUSSED, HAVING MORE THAN ONE?

DR. SAMBRANO: IT'S A FEASIBILITY ISSUE IN THE SENSE THAT WE DON'T HAVE ENOUGH MEMBERS, PATIENT ADVOCATE NURSE MEMBERS THAT WOULD SIMULTANEOUSLY BE ABLE TO DO THAT WORK. SO WE BASICALLY CAN ONLY HANDLE THEM ONE AT A TIME.

ALL RIGHT. SO THIS IS JUST A TABLE THAT SUMMARIZES WHAT I'M GOING TO TALK TO YOU ABOUT IN MORE DETAIL: THE TWO-STAGE METHOD THAT WAS SELECTED FOR EACH OF THE PROGRAMS, THE SUBMISSION CONTENT THAT WE EXPECT. SO FOR DISC5 AND CLIN2, FOR EXAMPLE, WE REQUIRE A FULL APPLICATION. BOTH OF THESE PROCESSES WERE ESTABLISHED AND WE HAVE SOME EXPERIENCE WITH THEM. THE CLIN2 QUALIFICATION PROCESS BEING THE NEWEST, WE TOOK THAT THROUGH TWO CYCLES LAST YEAR. AND SO THAT HAS BEEN OUR EXPERIENCE, LIMITED BUT INFORMATIVE AS WELL.

AND THEN FOR PDEV AND DISC4, WE HAVE A PRESUBMISSION OR LOI PROCESS THAT WE ARE PROPOSING WHICH IS NEW.

SO FOR DISC5, I'M GOING TO SHOW THE PROCESS AND TRY TO BREAK IT DOWN UTILIZING THE GRAPHIC OF THE STEPS ALONG THE REVIEW PROCESS THAT I SHOWED YOU EARLIER. AND SO COMPARED TO THE BASIC

PROCESS THAT I SHOWED YOU HERE, WE'RE INSERTING A STEP, POSITIVE SELECTION, FOR DISC5 WHICH COMES AFTER BEGINNING ELIGIBILITY AND BEFORE THE FINAL MERIT REVIEW BY THE GRANTS WORKING GROUP.

SO FOR THIS PROCESS, APPLICATIONS ARE SUBMITTED, AND THIS IS A FULL APPLICATION FOR DISC5. AND THERE'S AN INITIAL ELIGIBILITY REVIEW THAT'S MADE BY THE CIRM TEAM. THERE WE WANT TO MAKE SURE THAT WHAT COMES IN HAS AT LEAST SOME POSSIBILITY OF ADVANCING, THAT IT'S GENERALLY A COMPLETE APPLICATION, HAS ALL THE ELEMENTS, IF WE REQUIRE IT TO BE A CALIFORNIA ORGANIZATION, FOR EXAMPLE, THAT IT IS. AND THEN WE PUT THEM THROUGH THE NEXT STEP WHICH IS THE POSITIVE SELECTION. SO THOSE THAT ARE ACCEPTED FOR REVIEW AT THAT STAGE GO TO POSITIVE SELECTION.

AND HERE WE SELECT THE PANEL THAT IS ULTIMATELY GOING TO BE THE PANEL THAT DOES THE FINAL MERIT REVIEW TO ALSO BE THE MEMBERS THAT MAKE THE SELECTIONS. SO GRANTS WORKING GROUP MEMBERS GO THROUGH THE SET OF APPLICATIONS. LET'S SAY, FOR EXAMPLE, THERE'S A HUNDRED APPLICATIONS THAT THEY LOOK THROUGH, AND THEY CONDUCT A PREREVIEW TO ASSESS WHICH ONES THEY BELIEVE HAVE THE MOST POTENTIAL FOR IMPACT AND SELECT WHICH ONES TO ADVANCE.

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SOUNDS LIKE YOU HAVE A QUESTION.

DR. LEVITT: SO THOSE GRANTS THAT ARE -- ALL THE GRANTS ARE PREREVIEWED. THESE ARE FULL GRANTS. DO THE INVESTIGATORS RECEIVE FEEDBACK OF SOME SORT? THIS IS -- I'M TRYING TO FIGURE OUT IF THIS IS SIMILAR TO WHAT OTHER AGENCIES USE AS A TRIAGE PROCESS WHERE THERE'S A FULL GRANT, IT'S READ AND REVIEWED, AND THERE'S SOME RETURN OF INFORMATION BACK TO THE INVESTIGATOR ABOUT WHY IT WAS NOT EVEN DISCUSSED AT THE GRANT REVIEW.

DR. SAMBRANO: RIGHT. SO THIS IS NOT A FULL REVIEW IN THAT WAY. SO THE FEEDBACK THAT APPLICANTS RECEIVED IS MINIMAL. MEANING THEY DON'T -- THEY KNOW THAT THEY JUST DID NOT ADVANCE. WE CAN'T TELL THEM WHY BECAUSE THE POINT OF THE POSITIVE SELECTION IN THE INSTRUCTIONS TO REVIEWERS IS PLEASE TELL US WHICH ONES YOU THINK ARE THE BEST ONES, NOT TO CRITIQUE EACH ONE, BUT TO SELECT AMONG THESE APPLICATIONS AND TELL US WHICH YOU LIKE BEST. SO WE DON'T NECESSARILY KNOW WHY SOMETHING WASN'T PICKED, BUT WE CAN HAVE MUCH MORE INFORMATION ABOUT THE ONES THAT ARE.

DR. LEVITT: AND JUST REMIND ME, DISC-0, I GUESS YOU HAVE APPLICATIONS WHICH IS NOW BECOMING DISC5.

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DR. SAMBRANO: CORRECT, YES.

DR. LEVITT: SO HOW MANY APPLICATIONS DO YOU HAVE NOW FOR DISC0 IN THE HOPPER APPROXIMATELY?

DR. SAMBRANO: SO THE APPLICATION DEADLINE IS IN A FEW DAYS. SO IT'S APRIL 10TH. SO IN THE SYSTEM WE HAVE OVER 200 APPLICATIONS THAT ARE --

DR. LEVITT: ALREADY THERE.

DR. SAMBRANO: -- THAT ARE BEING WORKED ON, NOT YET SUBMITTED.

DR. LEVITT: ABOUT 200. OKAY. THANKS.

DR. SAMBRANO: SO THE GRANTS WORKING GROUP DOES THE FIRST STEP. SO THIS IS JUST A VIEW OF OUR GRANTS MANAGEMENT SYSTEM. AND THE WAYS IN WHICH THE REVIEWERS CAN SORT OR FILTER THE LIST OF APPLICATIONS TO IDENTIFY ONES THAT ARE WITHIN A SPECIFIC DISEASE AREA OR ONES THAT HAVE NOT BEEN SELECTED IN ORDER TO BRING THOSE TO THE TOP OR EVEN A RANDOM FILTER THAT ALLOWS THE APPLICATIONS TO BE RANDOMIZED SO THEY CAN SELECT THEM AND IT DOESN'T BIAS AN APPLICATION BASED ON WHERE IT EXISTS ALONG THE LIST.

AND REVIEWERS CAN VIEW ALL THE APPLICATIONS IN A TABLE FORMAT, EXAMINE EACH VIA A SUMMARY PAGE, OR DIG DEEP INTO EACH APPLICATION AND SEE THE FULL APPLICATION COMPONENTS.

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THE PROCESS ITSELF, AND THESE NUMBERS ARE INTENDED TO BE EXAMPLES, IS SOMETHING THAT CAN BE DONE IN AN ITERATIVE WAY. MEANING THAT YOU CAN SCALE TO A LARGE NUMBER OF APPLICATIONS AND JUST REPEAT THE SELECTION PROCESS SUCH THAT YOU CAN HAVE AN INITIAL SELECTION. IF WE WERE TO RECEIVE APPLICATIONS IN THE 300 PLUS RANGE, WE COULD DO AN INITIAL SELECTION AND THEN DO A SECOND ROUND OF SELECTION THAT NARROWS IT TO, SAY, A HUNDRED TO 150, AND THEN TO THE TARGETED NUMBER THAT MAY BE IN THE RANGE OF 30 TO 50. PAT.

DR. LEVITT: I BROUGHT THIS UP THIS MORNING. SO FULL APPLICATIONS ARE GOING TO BE USED TO BASICALLY ELIMINATE 50 TO 70 PERCENT OF THE -- 50 TO -- ONE-HALF TO TWO-THIRDS OF THE ULTIMATE APPLICATIONS. SO FOR THE GWG MEMBERS, THEY'RE LOOKING AT A FULL APPLICATION WHICH TAKES MORE TIME THAN AN LOI, AND FOR THE INVESTIGATORS THAT ARE WRITING A FULL APPLICATION, WHICH TAKES MORE TIME THAN AN LOI, I'M TRYING TO UNDERSTAND WHY DON'T USE AN LOI APPROACH HERE WHICH IS LIKELY THE GROUP THAT'S GOING TO GET THE LARGEST NUMBER OF APPLICATIONS IN THE FIRST PLACE. RIGHT. THIS IS THE ONSLAUGHT. ANYBODY CAN TAKE IT.

DR. CANET-AVILES: SO ONE CLARIFICATION.

SO GIL WAS BEING CONSERVATIVE BECAUSE WHAT HE'S PROBABLY REFERRING TO 200 APPLICATIONS IS THE ONES THAT MIGHT HAVE TITLE. AS OF NOW THE GRANTS MANAGEMENT SYSTEM, THERE ARE 681 OPEN APPLICATIONS.

DR. LEVITT: HOW MANY?

DR. CANET-AVILES: 681. WHAT THIS COULD TRANSLATE TO IS WE DO NOT ASK THEM FOR MORE THAN ONE-PAGE LOI. THIS COULD TRANSLATE IN HAVING SEVERAL HUNDRED OF THEM COMING TO THESE 15 GRANTS WORKING GROUP MEMBERS FOR POSITIVE SELECTION, WHICH IS A PROBLEM OF VOLUME FOR US TO MANAGE WITH THE PROP 14 RESTRICTIONS. I JUST WANTED TO MAKE THAT COMMENT.

DR. SAMBRANO: THANK YOU, ROSA, FOR THE CLARIFICATION. YES. THE 200 THAT I WAS SPEAKING TO, ONE OF THE THINGS WE DO ON ORDER TO ASSESS HOW MANY ARE GOING TO COME IN, BECAUSE A LOT OF PEOPLE WILL OPEN UP AN APPLICATION IN ORDER TO SEE WHAT IT LOOKS LIKE, IS TO DETERMINE IF THERE'S ANY ACTIVITY WITHIN LIKE THE LAST MONTH OR THAT THEY'VE SUBMITTED OR PUT A TITLE OR OTHER THINGS. SO I BELIEVE THAT'S IN THE RANGE OF 200. IF IT'S NOT, PLEASE CORRECT ME.

BUT I THINK THE POINT HERE FOR THIS SLIDE SIMPLY IS THAT SHOULD IT BE, LET'S SAY IT WERE 600

BECAUSE IT'S ALWAYS A POSSIBILITY, THAT THIS PROCESS DOES ALLOW US TO GO THROUGH ITERATIONS THAT WOULD ALLOW US TO GET DOWN TO WHAT WE NEED IN TERMS OF WHAT GOES TO FULL REVIEW.

DR. MADANAT: CAN YOU GIVE US MORE INSIGHT INTO THE SELECTION CRITERIA OR THE SELECTION PRIORITIES THAT ARE GIVEN TO THE COMMITTEE IN THE POSITIVE SELECTION STAGE? WHAT ARE THEY LOOKING FOR?

DR. SAMBRANO: YES. SO WHAT WE FOCUS THEM ON IS IMPACT. SO THE REVIEW CRITERIA THAT THEY UTILIZE IS DESCRIBED IN THE PROGRAM ANNOUNCEMENT OR RFA. AND SO THEY CAN UTILIZE ALL OF THOSE CRITERIA, BUT WE FOCUS THEM ON THE FIRST ONE, WHICH IS USUALLY VALUE PROPOSITION OR SIGNIFICANCE OR IMPACT FOR MAKING THESE SELECTIONS.

DR. LEVITT: SO, GIL, ONE WAY OF -- SO I UNDERSTAND, IN SOME WAYS THIS IS ACTING -- LIKE OF YOU HAVE TO SUBMIT A FULL APPLICATION. IT'S LIKELY YOU'RE NOT GOING TO GET THE ONE PAGE. YOU'RE GOING TO REDUCE THE NUMBER OF INDIVIDUALS WHO ARE GOING TO SUBMIT LIKE A ONE PAGER. IT'S NOT LIKE YOU CAN SNAP OFF A ONE-PAGER LIKE THAT, BUT IT'S GOING TO CREATE MORE WORK ON THE OTHER END FOR THE GWG AND FOR THE STAFF.

SO ONE POSSIBILITY IS TO HAVE A FULL APPLICATION, BUT THEN YOU ALSO HAVE A QUESTIONNAIRE HERE. MAYBE TO KEEP THINGS BALANCED IN TERMS OF MAKING THE FIRST DECISION SO THAT THOSE WHO ARE CHARGED WITH MAKING THOSE DECISIONS USE THE SAME INFORMATION IS TO HAVE THE QUESTIONNAIRE INCLUDED OR THEY HAVE TO ANSWER THAT BECAUSE WHAT YOU JUST ANSWERED IN TERMS OF CRITERIA IS EXACTLY WHAT YOU HAVE WRITTEN HERE IN TERMS OF THE QUESTIONNAIRE. THEY FILL THAT OUT AS PART OF THE APPLICATION PROCESS. AND THE GWG AND THE TEAM USES THAT TO MAKE THEIR DECISIONS, WHICH IS BASED EXACTLY ON WHAT YOU JUST SAID.

DR. SAMBRANO: SO THE CRITERIA THAT YOU'RE LOOKING AT, I BELIEVE, IS THE DISC4, THE PRESUBMISSION.

DR. LEVITT: YES.

DR. SAMBRANO: SO THAT'S FOR THE PRESUBMISSION FORM. AND SO, YES, WE COULD SIMILARLY ASK QUESTIONS OF THE APPLICANT FOR DISC5, AND YOU COULD HAVE A PRESUBMISSION PROCESS. THE REASON THAT WE'RE NOT --

DR. LEVITT: YOU COULD INCLUDE IT IN THE APPLICATION.

DR. SAMBRANO: I SEE WHAT YOU'RE SAYING.

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WELL, THERE IS. SO THERE'S A SUMMARY.

DR. LEVITT: IT'S THE SAME FOUR CRITERIA AND THEY SAY THUMBS UP OR THUMBS DOWN. IT SAVES THEM FROM HAVING TO GO THROUGH THE FULL APPLICATION.

DR. SAMBRANO: THEY DON'T HAVE TO. THERE'S A PREVIEW, WHAT WE CALL A PREVIEW PAGE WITHIN THE APPLICATION THAT SUMMARIZES THE KEY INFORMATION FOR REVIEWERS. SO THEY CAN SIMPLY LOOK AT THAT, BUT WE ALLOW THEM TO LOOK AT THE FULL APPLICATION IF THEY NEED TO BECAUSE IN MANY CASES IT'S A GOOD REFERENCE. SOME FIND THEMSELVES LOOKING AT THE FULL APPLICATION TO CONFIRM INFORMATION THAT THEY MAY SEE IN THE PREVIEW PAGE. JUDY.

DR. GASSON: SO I HAVE A SLIGHTLY DIFFERENT QUESTION ABOUT THE POSITIVE SELECTION. SO IF, IN FACT, YOU HAVE 300 APPLICATIONS COME IN AND YOU HAVE 15 PEOPLE ON THIS REVIEW PANEL, MY CONCERN IS THAT WE WORK IN SUCH BROAD AREAS, STEM CELL AND GENE THERAPY, MY CONCERN IS THAT YOU WOULDN'T HAVE ALL OF THE TYPES OF EXPERTISE IN THOSE 15 INDIVIDUALS TO POSITIVELY SELECT THOSE APPLICATIONS THAT COULD POTENTIALLY HAVE THE HIGHEST IMPACT.

DR. SAMBRANO: I AGREE WITH YOU. AND THAT IS ONE OF THE CHALLENGES THAT WE HAVE.

DR. GASSON: PAT GOES TWO STUDY SECTIONS,

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AND YOU SAID, NO, BECAUSE WE DON'T HAVE ENOUGH PEOPLE ON THE BOARD. MAYBE WE NEED TO THINK ABOUT -- I DON'T HAVE THE ANSWER.

VICE CHAIR BONNEVILLE: I THINK IT COMES DOWN TO THE PATIENT ADVOCATE MEMBERS OF THE BOARD. BUT WE DO HAVE THE ABILITY TO HAVE ALTERNATES TO THOSE PATIENT ADVOCATES. I DON'T KNOW IF THERE'S SOMETHING THAT WE CAN DO TO THEN CREATE MORE SPACE IN THAT WAY.

DR. SAMBRANO: WE CAN HAVE ALTERNATES WITHIN THE BOARD, BUT NOT OUTSIDE THE BOARD.

VICE CHAIR BONNEVILLE: I UNDERSTAND. I THINK WHAT THEY'RE ASKING IS CAN YOU DO ONE PANEL HERE, LIKE THEY'RE RUNNING SIMULTANEOUSLY, BUT YOU'RE RUNNING ONE AND HAYLEY IS RUNNING THE OTHER, FOR EXAMPLE, AND THEY'RE BOTH BEING RUN, THEY'RE BOTH FULLY STAFFED, AND THERE ARE BOARD MEMBERS THAT SIT ON BOTH. AND PERHAPS THERE'S NOT ENOUGH BOARD MEMBERS THAT YOU HAVE FULLY SEVEN PEOPLE AT EACH. MAYBE YOU HAVE FOUR AT ONE AND THREE AT THE OTHER, AND THAT'S A WAY OF MITIGATING. I HAVE NO IDEA IF THAT'S EVEN POSSIBLE. I KNOW RIGHT NOW YOU'RE LIKE WHY IS MARIA SAYING THIS OUT LOUD. SO I APOLOGIZE.

DR. SAMBRANO: I MEAN IT'S A GOOD POINT. IT'S NOT SOMETHING THAT WE HAVE CONSIDERED BECAUSE

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WE HAVE THOUGHT IT TO BE UNFEASIBLE.

VICE CHAIR BONNEVILLE: OKAY.

DR. SAMBRANO: BUT IT DOESN'T MEAN WE SHOULDN'T OR THAT WE CAN'T. WE'RE HAPPY TO THINK ABOUT THIS AND SEE IS THERE A WAY OF DOING THIS. BUT FOR EVERY REVIEW, AND EVEN WHEN WE'VE HAD TO DOUBLE UP REVIEWS COMING CLOSE TOGETHER, YOU ESSENTIALLY HAVE DIFFERENT PANELS WHO ARE RECEIVING DIFFERENT APPLICATIONS. THERE ARE CONSEQUENCES TO HAVING TWO DIFFERENT GROUPS AND HOW YOU SPLIT UP THE APPLICATIONS AND THEN HOW YOU PUT IT BACK TOGETHER SO THAT YOU KNOW THAT THE SCORING THEN IS COMPARABLE TO EACH. YOU KIND OF HAVE TO LOOK AT THEM INDEPENDENTLY AND THEN DECIDE MAYBE FROM THIS GROUP YOU PICK THE TOP TEN FROM THIS GROUP AND THEN THE TOP TEN FROM THIS OTHER GROUP. BUT IT'S SOMETHING THAT WE WOULD TO THINK THROUGH TO SEE HOW THAT WOULD WORK OUT.

DR. LEVITT: THERE ARE WAYS OF NORMALIZING. THAT'S WHAT OTHER AGENCIES DO. THEY HAVE MORE THAN ONE STUDY SECTION AND THEY NORMALIZE. IT IS THE CASE THAT SOME STUDY SECTIONS MAY SKEW WHERE THEIR SCORE IS A LITTLE BETTER OR MORE HARSH. THEY'RE PRETTY CLOSE TO EACH OTHER. THESE ARE ALL COMING UP BECAUSE WE'RE TRYING TO HELP WHAT SEEMS

LIKE A DAUNTING SITUATION AND WANTING TO DO DUE DILIGENCE BOTH IN TERMS OF THE INFRASTRUCTURE YOU ALL HAVE TO WORK WITH AND MAKING SURE THAT THE VERY BEST RESEARCH -- VERY BEST SCIENCE IS BEING FUNDED FOR THE TAXPAYERS OF CALIFORNIA.

DR. SAMBRANO: APPRECIATE IT.

DR. LEVITT: THIS IS A REAL CONUNDRUM.

DR. SAMBRANO: YEAH.

DR. PADILLA: DOES THE POSITIVE SELECTION PROCESS HAVE ANY PERSPECTIVE ON OR DOES IT INCLUDE ANY PERSPECTIVE ON THE CURRENT PORTFOLIO OF THE CIRM-APPROVED PROJECTS?

DR. SAMBRANO: IT DOES NOT BECAUSE THE GRANTS WORKING GROUP MEMBERS ARE REALLY JUST TASKED WITH THE CRITERIA WE GIVE THEM. THEY DON'T RECEIVE ANY PORTFOLIO INFORMATION THAT WOULD ALLOW THEM TO EXERCISE PREFERENCES, FOR EXAMPLE. BUT THAT'S AN IDEA.

DR. PADILLA: I FIND THAT A LITTLE BIT CHALLENGING. IF THERE'S A SIMILAR PROCESS, IS THERE SOMETHING THAT CAN BE NUANCED A LITTLE BIT IN THE APPROVAL PROCESS? WHAT BENEFIT IF THERE'S SOMETHING TWEAKED A LITTLE BIT TO THE OVERALL BENEFIT OF THE PORTFOLIO?

DR. CANET-AVILES: ONE ASPECT IS WE ARE

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TALKING ABOUT THE SLIDES; BUT AS DR. TAN AND DR. PATEL DISCUSSED EARLIER ON AND DR. KADYK FOR THE OTHERS, THE PREFERENCE SETTING IS GOING TO BE BASED ON PORTFOLIO ANALYSIS, RIGHT. AND THAT WILL BE AT THE PRESELECTION OR THE QUALIFICATION PROCESS OBJECTIVE CRITERIA. AND THE PREFERENCE SETTING IS BASED ON THE PORTFOLIO THAT WE WILL HAVE THAT WILL HAVE A PRESENTATION EVERY JUNE TO THE BOARD TO SET THOSE PREFERENCES. SO THAT IS BEING TAKEN INTO ACCOUNT IN THE OTHER THREE.

THIS ONE IS DIFFERENT BECAUSE OF THE VOLUME THAT WE HAVE. IT COULD BE VERY DIFFICULT FOR THEM TO HAVE AN OBJECTIVE CRITERIA THERE.

MR. TOCHER: CHRIS MIASKOWSKI HAS HER HAND RAISED.

DR. MIASKOWSKI: I'D LIKE TO MAKE MY COMMENTS IN THE CONTEXT OF THE FACT THAT I'VE SERVED ON MULTIPLE NIH STUDY SECTIONS AND CHAIRED THEM. AND I CAN HEAR THE CONCERNS, BUT I WANT TO SPEAK IN SUPPORT OF GIL. HAVING -- I DON'T KNOW HOW MANY YEARS I'VE BEEN DOING THIS NOW. AND I WAS A LITTLE SKEPTICAL ABOUT THE POSITIVE SELECTION PROCESS, BUT I CAN COMMENT THAT IT IS RIGOROUS. AND THE DISTRIBUTION OF GRANTS SEEMED REASONABLE TO ME.

THE OTHER PIECE I WOULD LIKE TO EMPHASIZE

IS THE COMPETENCY OF THE CIRM STAFF IN CREATING A STUDY SECTION THAT HAS THE REQUISITE EXPERTISE FOR THE VOLUME OF GRANTS WE'RE GOING TO DO. I MARVEL AT THE FACT THAT THE MIX IS APPROPRIATE, THAT THE PEOPLE WHO ARE SITTING AT THE TABLE ARE KNOWLEDGEABLE TO BE ABLE TO PROVIDE A SUBSTANTIVE SCIENTIFIC CRITIQUE AS WELL AS THE MANUFACTURING CRITIQUE, THE CONSIDERATIONS MOVING FORWARD TO THE FDA.

SO I CAN UNDERSTAND A SCIENTIST SITTING THERE WHO HAVEN'T PARTICIPATED IN THE PROCESS, THAT IT COULD BE QUESTIONED. BUT OVERALL I THINK THIS PROCESS THAT GIL IS OUTLINING WORKS REALLY, REALLY WELL. AND I REALLY DO NOT HAVE ANY CONCERNS ABOUT THE SCIENTIFIC EXPERTISE OF THE REVIEW. SO I WANTED TO PUT THAT FORWARD GIVEN HOW MANY OF THESE I'VE DONE NOW.

DR. SAMBRANO: THANK YOU, CHRIS. OTHER QUESTIONS OR I'LL GO ON.

I THINK I SKIPPED A SLIDE HERE. SO ONCE THE GRANTS WORKING GROUP MEMBERS GO THROUGH THE POSITIVE SELECTION PROCESS AND SELECT APPLICATIONS, AND AT THIS STEP THE PATIENT ADVOCATE MEMBERS CAN ALSO PARTICIPATE IN THE SELECTION OF THESE APPLICATIONS. ONCE THAT IS DONE, THEN THE CIRM

PROGRAM TEAM AND PRESIDENT EXAMINE ALL THE NON-SELECTED APPLICATIONS AND DETERMINE IF THERE'S ANY ADDITIONAL THAT SHOULD BE ADDED TO THE GROUP THAT WILL ADVANCE TO THE FULL GRANTS WORKING GROUP, AND THE REMAINDER ARE THEN NOT CONSIDERED FURTHER.

SO THEN THE GRANTS WORKING GROUP MEETS, ASSESSES THE APPLICATIONS. WE MAKE ASSIGNMENTS, TYPICALLY THREE SCIENTIFIC REVIEWERS PER APPLICATION. IN THE CASES WHERE THERE'S CLINICAL OR TRANSLATIONAL, WE ALSO ASSIGN A PATIENT ADVOCATE MEMBER TO EACH OF THOSE APPLICATIONS WHEN THE NUMBERS ARE SMALL ENOUGH.

THE RECOMMENDATION, THEN, AS ALWAYS, GOES TO THE BOARD FOR A DETERMINATION TO FUND OR NOT. AND SO THIS IS WHERE IT ALL FOLLOWS THE SAME PROTOCOL.

ALL RIGHT. SO FOR CLIN2, CLIN2 IS UTILIZING WHAT WE REFER TO AS QUALIFICATION. THIS PROCESS WAS INTRODUCED LAST YEAR IN JUNE IN ORDER TO DEAL WITH WHAT BEGAN TO BE A LARGE NUMBER OF CLINICAL APPLICATIONS COMING IN. BEFORE WE DIDN'T REALLY HAVE TO HAVE A TWO-STAGE PROCESS. AND THE WAY WE DESIGNED THIS WAS TO PUT AN INITIAL STEP, AND HERE I'M SHOWING IT AS SORT OF SIMILAR TO POSITIVE SELECTION IN THAT WE'RE SPLITTING THE REVIEW PROCESS

INTO THESE TWO STEPS. WE GET A FULL APPLICATION WHERE WE DO AN INITIAL ELIGIBILITY ASSESSMENT. AND SO IF AN APPLICATION IS ACCEPTED, IT MOVES ON TO THE QUALIFICATION PROCESS WHERE WE EXAMINE KEY INFORMATION IN THE APPLICATIONS TO SCORE THEM AGAINST VERY SPECIFIC OBJECTIVE CRITERIA THAT ARE DEFINED IN THE PROGRAM ANNOUNCEMENT OR IN THE RFA. AND SO THAT'S A SIMPLE POINT SYSTEM.

SO BASED ON SPECIFIC CRITERIA, FOR EXAMPLE, THIS IS A PLURIPOTENT STEM CELL APPROACH, A CALIFORNIA ORGANIZATION, THEY ARE A PIPELINE PROJECT, THEY WILL GET A POINT FOR EACH. THE ONES WITH THE MOST POINTS ADVANCE.

AND FOR A PROGRAM LIKE CLIN2 WHERE WE ANTICIPATE HAVING FOUR CYCLES WITH SEVEN APPLICATIONS PER CYCLE, WE WANT TO ADVANCE, THEN, WHAT WOULD BE THE SEVEN TOP APPLICATIONS.

THE CRITERIA -- LET ME MAKE A POINT ABOUT THE OVERALL PROCESS HERE. THE LENGTH OF TIME THAT EACH CYCLE TAKES WILL ALLOW APPLICANTS WHO SUBMIT BUT FAIL TO GARNER A FUNDING RECOMMENDATION OR APPROVAL BY THE BOARD EVERY SIX MONTHS. SO THE PROCESS IS ABOUT FIVE MONTHS TO GET TO THE ICOC DECISION. SO THEY'LL KNOW WELL BEFORE THAT WHAT THE OUTCOME IS OR LIKELY OUTCOME IS AND CAN APPLY TO

WHAT WOULD BE THE NEXT ONE.

SO JUST I KNOW THAT THE CALENDAR THAT YOU MAY HAVE SEEN OR THAT WAS SHOWN IN THE SLIDE MAY HAVE SUGGESTED OTHERWISE. BUT GIVEN THAT WE'RE OFFERING IT EVERY THREE MONTHS, THEY'LL BE ABLE TO SKIP ONE CYCLE AND GO TO THE NEXT.

SO THE PREFERENCES THAT WILL BE FACTORED INTO THAT QUALIFICATION PROCESS AND THAT WILL UTILIZE THE POINT SYSTEM HAVE BEEN SHARED PREVIOUSLY UNDER THE CONCEPT PRESENTATION, THINGS LIKE PLURIPOTENT STEM CELL-DERIVED THERAPIES AND THEN SOME OF THE NEW ELEMENTS, SUCH AS HAVING AN RMAT DESIGNATION OR PIVOTAL TRIAL, THOSE WOULD GARNER POINTS. THIS IS INTENDED TO BE HIGH LEVEL, KIND OF THE SAME INFORMATION IN TERMS OF THE PREFERENCES THAT WOULD BE SET FOR CLIN2.

NOW, IF EVEN WHEN WE GO THROUGH THIS PROCESS AND STILL END UP WITH TIES, WE STILL HAVE, SAY, MORE THAN SEVEN APPLICATIONS THAT CAN ADVANCE IN THAT CYCLE, THEN WE RESORT TO HAVING MEMBERS OF THE GRANTS WORKING GROUP WHO ARE ASKED TO SCORE A SUBSET OF THOSE TIED APPLICATIONS AGAINST MORE SUBJECTIVE CRITERIA. AND THOSE CRITERIA ARE ESSENTIALLY THE BULLETED POINTS THAT COME FROM THE OVERALL VALUE PROPOSITION OF THE PROGRAM. SO HOW

SIGNIFICANT IS THE UNMET NEED? HOW IMPACTFUL THE TREATMENT WOULD BE FOR PATIENTS IF SUCCESSFULLY DEVELOPED? AND SO ON. ALSO, THEIR RESPONSIVENESS TO DEI AND WHETHER THE APPLICATION INCLUDES ALL THE NECESSARY COMPONENTS FOR PROPER EVALUATION.

AND SO THROUGH THE HELP OF A SUBSET OF THE GRANTS WORKING GROUP MEMBERS, THEN WE CAN BREAK TIES AND DETERMINE WHAT ADVANCES.

AND THEN, AGAIN, THIS IS WHERE IT GOES BACK TO THE SAME PROCESS. IT GOES TO THE GRANTS WORKING. IN THIS CASE FOR CLINICAL APPLICATIONS, THE PANEL THAT WE ASSEMBLE AROUND, SAY, SEVEN APPLICATIONS, IS MUCH MORE ROBUST. AND SO WE TRY TO BRING IN INDIVIDUALS WHO HAVE DISEASE AREA EXPERTISE, MANUFACTURING EXPERTISE, PRODUCT DEVELOPMENT, REGULATORY EXPERTISE TO ALL OPINE AND PROVIDE INPUT ON THESE APPLICATIONS.

AND ONE OF THE OTHER BENEFITS IS THAT WITH THE NUMBER OF APPLICATIONS BEING THAT SMALL, MOST OF THE GRANTS WORKING GROUP MEMBERS CAN ACTUALLY EXAMINE AND LOOK AT ALL THE APPLICATIONS EVEN THOUGH THEY'RE NOT ASSIGNED TO GIVE A CRITIQUE. SO IT DOES ALLOW FOR A MORE ROBUST DISCUSSION AT THIS STAGE.

THE RECOMMENDATIONS FROM THE GRANTS WORKING GROUP THEN GO TO THE FUNDING DECISION BY THE

ICOC. NOW, THERE'S AN IMPORTANT DIFFERENCE HERE IN WHAT IS BEING PROPOSED FOR NOW WHAT WILL BECOME FOUR CYCLES PER YEAR FROM WHAT WE'VE DONE IN THE PAST. IT HAS TO DO BOTH WITH THE FACT THAT THE SCORING WILL BE DIFFERENT, AND I'LL SPEAK TO THAT A LITTLE LATER. YOU'VE BEEN USED TO HAVING A CLINICAL PROGRAM WHERE IT'S A 1, 2, OR 3. AND TYPICALLY WHAT YOU SEE COMING TO THE BOARD ARE THOSE THAT GET A SCORE OF 1 BECAUSE THOSE ARE THE SUCCESSFUL ONES.

THOSE THAT GOT A 2 HAVE AN OPPORTUNITY TO MAKE FIXES ON THAT APPLICATION AND COME BACK TO THE NEXT CYCLE. BUT THAT'S WHEN WE WERE HAVING ELEVEN CYCLES PER YEAR WHERE IT WAS EASY FOR THEM TO COME BACK. NOW WITH THE IDEA THAT WE HAVE MORE APPLICATIONS, THE ONE TO A HUNDRED SCORING IS GOING TO BRING ALL THE APPLICATIONS TO THE BOARD FOR REVIEW. MEANING WHETHER THEY GET A HIGH SCORE OR A LOW SCORE, YOU WILL SEE THEM ALL. YOU WILL SEE THAT ENTIRE COHORT OF APPLICATIONS COMING. AND I'LL SPEAK TO SOME OF THE APPROACHES AND METHODS THAT WE WILL USE TO PROVIDE TEAM RECOMMENDATIONS AS IT RELATES TO THESE AND OTHER APPLICATIONS. BUT JUST AN IMPORTANT DIFFERENCE TO NOTE.

SO FOR PDEV AND DISC4, THIS IS WHERE WE THEN DEVIATE A LITTLE BIT IN TERMS OF THE PROCESS.

AS WE'VE BEEN TALKING ABOUT, THIS IS THE PRESUBMISSION PROCESS OR LOI PROCESS. I'M GOING TO DESCRIBE IT AS A SINGULAR PROCESS BECAUSE IT APPLIES TO BOTH ALTHOUGH EACH WILL HAVE A DIFFERENT SET OF CRITERIA THAT WILL BE USED TO DETERMINE WHAT IS ULTIMATELY INVITED TO APPLY.

SO THE WAY THIS WORKS IS YOU HAVE A PRESUBMISSION STAGE, AND THEN THERE IS THE NEED TO HAVE A TIME PERIOD FOR APPLICANTS WHO ARE INVITED TO COMPLETE THEIR APPLICATION BEFORE THEY ENTER THE REGULAR APPLICATION REVIEW PROCESS.

SO AN APPLICANT SUBMITS AN ONLINE FORM. AND SO THAT FORM OR EXAMPLES OF IT HAVE BEEN PROVIDED TO YOU. AND WHAT YOU SEE IS NOT A VERY CLEAN, EASY TO SEE FORM BECAUSE IT'S A SET OF REQUIREMENTS THAT WE PROVIDE TO OUR GRANTS MANAGEMENT I.T. DEVELOPMENT TEAM IN ORDER TO CREATE THE ONLINE APPLICATION. THE APPLICATION ITSELF WILL BE MORE STREAMLINED, BUT IT DOES GIVE YOU THE FULL VIEW OF INSTRUCTIONS, THE FIELDS THAT WE INTEND TO CAPTURE, WHAT WE MAY ASK FOR IN TERMS OF AN UPLOAD AS WAS DISCUSSED FOR, I THINK, DISC4 THAT HAS A PROPOSAL UPLOAD, AND IT GIVES YOU THAT FULL VIEW ON WHAT WE'RE ASKING FOR.

SO FOR THE PRESUBMISSION PROCESS, WE ARE

ASKING FOR THINGS LIKE ELIGIBILITY. SO ONE OF THE THINGS WE WANT TO MAKE SURE THAT WE UNDERSTAND TO THE EXTENT THAT WE CAN IS A POTENTIAL APPLICATION THAT WE INVITE ULTIMATELY GOING TO BE ELIGIBLE OR NOT. IF THERE IS SOME CLARITY ON THAT, IT WOULD BE GOOD TO KNOW AT THAT STAGE SO THAT WE KNOW THAT WE'RE NOT ULTIMATELY INVITING AN APPLICANT THAT WILL NOT BE ELIGIBLE.

WE ASK ABOUT TEAM PERSONNEL, THE PROJECT TITLE AND KEYWORDS THAT ALLOW US TO FILTER AND SORT THE PROPOSALS, AND OTHER PROJECT INFORMATION THAT ALLOW US TO MAKE THESE ASSESSMENTS AND DECISIONS, INCLUDING PROPOSED ACTIVITIES.

OKAY. SO THE CIRM PROGRAM TEAM THEN EXAMINES THE PRESUBMISSIONS ONCE THEY COME IN. THERE IS A SET DEADLINE. THEY SCORE AND RANK THEM BASED ON THOSE DEFINED STRATEGIC PRIORITIES AND CRITERIA. AND THEN BASED ON THOSE, AND I WILL SHOW YOU WHAT THOSE ARE ALTHOUGH I THINK THEY WERE ALSO PRESENTED AS PART OF THE CONCEPT PRESENTATIONS --

DR. LEVITT: THAT SAID, ELIGIBILITY IS DETERMINED IN THE PRESUBMISSION PROCESS. THAT'S WHAT YOU JUST SAID, BUT THE ELIGIBILITY BLOCK THERE IS COMING AFTER THE COMPLETE APPLICATION?

DR. SAMBRANO: YEAH. I'LL SHOW YOU THAT.

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SO WHAT HAPPENS IS THE APPLICANTS ARE INVITED TO APPLY, BUT ALL WE HAVE IS THE PRESUBMISSION FORM AT THAT STAGE. SO WE DO NEED TO CONDUCT AN ELIGIBILITY STEP OF THE FULL APPLICATION TO ENSURE THAT IT IS. WE WANT TO MAKE IT A RARE INSTANCE WHERE SOMETHING THAT COMES IN AT THIS STAGE IS THEN NOT ELIGIBLE. WE CANNOT FULLY KNOW UNTIL WE SEE THE FULL APPLICATION WHETHER IT'S GOING TO BE ELIGIBLE.

AND SOMETHING, JUST AS A FOR EXAMPLE, ONE OF THE THINGS THAT CAN HAPPEN BETWEEN THE LOI AND THE APPLICATION IS THE STATUS OF THE PI, FOR EXAMPLE, THEY CAN BE ELIGIBLE AND THEN EXIT ELIGIBILITY OR THE COMPLETENESS OF THE APPLICATION ITSELF. THEY MAY HAVE A GREAT PROPOSAL, BUT ULTIMATELY WHEN THEY SUBMIT THE APPLICATION, IT IS INCOMPLETE AND DOESN'T HAVE ALL THE RELEVANT ELEMENTS. SO WE DO NEED TO HAVE THAT STEP.

THAT'S WHAT I JUST MENTIONED. SO WE GO THROUGH ELIGIBILITY. THOSE THAT ARE ACCEPTED GO THEN TO THE FULL GRANTS WORKING GROUP REVIEW PANEL DISCUSSION. AND THEN, OF COURSE, RECOMMENDATIONS TO THE BOARD, AND THE BOARD MAKES FINAL FUNDING DECISIONS ON THOSE.

SO THAT'S THE PROCESS. AS WAS NOTED EARLIER HERE, SOME OF THE CRITERIA FOR THE

PRESUBMISSION PROCESS FOR DISC4 SPECIFICALLY UTILIZING PREFERENCE TOPICS, RELEVANCE TO HUMAN DISEASE BIOLOGY, ACROSS DISCIPLINARY AND SYSTEMS BIOLOGY, AND STEM CELL OR GENETIC RESEARCH INNOVATIONS AS BROAD CATEGORIES OF WHAT WE'RE LOOKING FOR. AND ALSO CONCEPT PREFERENCES FOR PLURIPOTENT STEM CELL-DERIVED THERAPIES AND SO ON FOR PDEV. THESE ALSO WERE SHOWN AS PART OF THE CONCEPT WHICH WOULD BE USED TO ASSIGN POINTS TO THE PRESUBMISSIONS AND DETERMINE WHICH ONES ARE MOST CLOSELY ALIGNED WITH OUR GOALS. PAT.

DR. LEVITT: SO FOR CLIN2 AND THESE TWO, THERE'S IN THE INITIAL NOW PRESUBMISSION COMPONENTS, THERE'S INFORMATION THAT THE GWG MEMBERS ARE GETTING ABOUT PRIORITIES, CIRM PRIORITIES. LIKE FOR THESE TWO, FOR DISC4 AND PDEV'S, IF YOU LOOK --

DR. SAMBRANO: YOU MEAN THE CRITERIA WE'RE TALKING ABOUT HERE, ARE THOSE PROVIDED TO THEM?

DR. LEVITT: YES, PROVIDED TO THEM BECAUSE THE PRESUBMISSION FORM ASKS ABOUT THIS.

DR. SAMBRANO: THE PRESUBMISSION FORM GOES TO THE CIRM PROGRAM TEAM. SO THE CIRM STAFF -- THE GWG IS NOT PARTICIPATING IN THIS STEP.

DR. LEVITT: THEY'RE GETTING IT FOR CLIN2. THEY'RE GETTING THAT INFORMATION IN TERMS OF -- I'M

TRYING TO UNDERSTAND WHICH OF THE GRANT --

DR. SAMBRANO: FOR CLIN2, SO THE QUALIFICATION STEP, THERE'S TWO PARTS. SO THERE'S THE STAFF PART THAT THE REVIEW TEAM DOES. SO THOSE PREFERENCES ARE ASSIGNED POINTS BY CIRM STAFF. SO THE GWG DOESN'T PARTICIPATE IN THAT PART. IF THERE IS A NEED TO BREAK TIES IN THE QUALIFICATION, THEN THE GWG COMES IN. AND WHAT THEY ARE INSTRUCTED TO DO IS TO BASE THEIR DECISION ON SPECIFIC QUESTIONS THAT ARE ALIGNED WITH THE VALUE PROPOSITION, AND THAT'S WHAT THEY BASE THEIR ASSESSMENT ON.

DR. LEVITT: OKAY.

DR. SAMBRANO: FOR PDEV AND DISC5, THIS IS DONE BY THE CIRM STAFF IN TERMS OF DOING THE ASSESSMENTS AND THE ALIGNMENT WITH THESE PRIORITIES.

DR. LEVITT: OKAY. GWG IS NOT GETTING THE INFORMATION ABOUT PRIORITIES?

DR. SAMBRANO: CORRECT.

DR. LEVITT: ONE OTHER QUESTION. IN OUR PACKET THERE WERE EXAMPLES OF AN ONLINE QUESTIONNAIRE FOR FOUR DOMAINS, EACH ONE WITH 1500 CHARACTERS, ABOUT A PAGE. SO THERE'S FOUR PAGES THERE THAT THEY'RE GOING TO FILL OUT. AND THEN THERE'S AN ADDITIONAL REQUIREMENT OF UP TO THREE PAGES WHERE THEY'RE GOING TO DESCRIBE MORE. SO IT'S

ABOUT A SEVEN-PAGE PROCESS, PLUS I THINK THEY GET UP TO TWO OR THREE FIGURES OR SOMETHING LIKE THAT FOR PRELIMINARY DATA. SO THAT'S THEIR PACKAGE THAT THEY'RE GOING TO SUBMIT BEFORE THEY SUBMIT THEIR FINAL GRANT.

DR. SAMBRANO: YES.

DR. LEVITT: SO THAT'S SEVEN PAGES.

DR. SAMBRANO: YES.

DR. LEVITT: SO THAT SEEMS LIKE A LOT TO ME. I DON'T KNOW HOW OTHERS FEEL ABOUT IT.

DR. SAMBRANO: I THINK PART OF OUR CONSIDERATION WAS WHETHER THAT WAS --

DR. LEVITT: I KNOW IT SAYS UP TO.

DR. SAMBRANO: I THINK PART OF IT, AND THIS IS IMPORTANT BECAUSE, AS YOU SAID, THERE IS A BURDEN OF APPLICATION. AND WE WANT TO SIMPLIFY IT. ON THE OTHER HAND, WE ALSO WANT TO MAKE SURE WE GET THE INFORMATION THAT'S NECESSARY IN ORDER TO EVALUATE AND ASSIGN THE PREFERENCES. IN ORDER TO STRIKE THAT BALANCE, I THINK THIS IS WHERE THE TEAM ARRIVED AT WHAT WE NEEDED.

BUT TAKING YOUR FEEDBACK TO HEART, WE DO WANT TO MAKE SURE THAT THAT'S NOT EXCESSIVE. THAT IF WE CAN CUT IT DOWN AND IT MAKES SENSE, THAT WE WOULD.

DR. LEVITT: I'M WONDERING IF THE GWG MEMBERS, HAVE ANY OF THEM BEEN POLLED OR ASKED ABOUT WHAT THEY FEEL THE MOST PERTINENT INFORMATION TO BE ABLE DO THOSE EARLY DECISIONS.

DR. SAMBRANO: WE HAVE, BUT THESE EARLY DECISIONS, AT LEAST IN THIS INSTANCE, AND IN THE FORMS YOU SAW ARE FOR THE CIRM STAFF.

DR. TAN: HI. LET ME CLARIFY SOMETHING ABOUT THE PRESUBMISSION FORMS, AT LEAST FOR WHERE DISC4 IS RELEVANT. SO THE WAY -- WHAT WE SHARED IN THERE WAS TO SAY THAT THE PRESUBMISSION PROPOSAL UPLOAD IS THREE PAGES MAX. YOU COULD INCLUDE FIGURES IN THERE, BUT IT'S CAPPED OUT AT THREE PAGES. THAT THREE PAGES WOULD INCLUDE OUTLINE OF YOUR PROPOSAL, YOUR RATIONALE OR ANYTHING YOU WANT TO INCLUDE TO THAT. AND THEN IN ADDITION, THERE IS A SHORT QUESTIONNAIRE OF FOUR QUESTIONS. EACH OF THE QUESTION ANSWERS HAVE A TEXT LIMIT TO 1500 CHARACTERS, ABOUT TWO-PARAGRAPH RESPONSE TO EACH OF THE FOUR QUESTIONS.

DR. SAMBRANO: THANKS, CHAN.

SO I'M GOING TO LEAVE THE TWO-STAGE PROCESS, GO TO SCORING METHODOLOGY FOR A COUPLE OF SLIDES. SO AS I HAD MENTIONED EARLIER, FOR CLINICAL APPLICATIONS, WE USED THE 1-2-3 SYSTEM. AND I WANT

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TO DISTINGUISH THAT FROM OUR ONE TO A HUNDRED SCORING SYSTEM IN THAT THE 1-2-3 IS NONGRADED, MEANING IT'S SORT OF A THUMBS UP, THUMBS DOWN DECISION AND THAT'S IT. THERE'S NOT A LOT OF GRANULARITY IN THAT. VERSUS A GRADED APPROACH WHICH HAS A SCALE ONE TO A HUNDRED THAT ALLOWS MORE GRANULARITY AND THE ABILITY TO RANK APPLICATIONS AGAINST ONE ANOTHER.

WE CHOSE THE NONGRADED 1-2-3 APPROACH FOR CLINICAL BECAUSE, WHEN WE STARTED WITH THAT CLINICAL PROGRAM, WE WERE EXPECTING IN SOME CASES NOT MORE THAN ONE APPLICATION IN A GIVEN CYCLE. SO THERE'S NOTHING TO RANK OR SCORE AGAINST OR COMPARE IT TO, AND IT WAS BASICALLY HAVING IT STAND ON ITS OWN MERIT. OBVIOUSLY THINGS HAVE CHANGED SINCE THEN. AND SO IN TRYING TO RESPOND TO WHAT ARE NOW A GREATER NUMBER OF APPLICATIONS AND THE NEED TO ACTUALLY EXERCISE SOME DISCERNMENT BETWEEN APPLICATIONS, HAVING A MORE GRADED APPROACH IS SOMETHING WE THOUGHT WAS APPROPRIATE. AND IT IS SOMETHING THAT WE WOULD USE ACROSS ALL OF THE CONCEPTS THAT WERE CONSIDERED TODAY.

AND SO JUST A NOTE ABOUT THIS. I MENTIONED ALREADY A COUPLE OF THESE BULLET POINTS. WE HAVE OR I HAVE BEEN TRYING TO SPEND SOME TIME

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LOOKING AT PEER REVIEW LITERATURE. AND THERE'S NOT A LOT OF IT OUT THERE, BUT THERE IS SOME THAT LOOKS AT WHAT ARE THE BEST PRACTICES OR BEST APPROACHES FOR SCORING FOR A REVIEW THAT GIVES YOU THE BETTER GRADES OR ESTIMATES OF A PANEL'S CHOICES.

AND SO THERE IS CERTAINLY THE SUGGESTION THAT USING LARGER NUMBER OF GRADES IS GENERALLY BETTER AND THAT IT INCREASES WHAT IT ASSIGNS AS THE CORRECTNESS OF THE PANEL'S CHOICES ALTHOUGH IT DOES HAVE DIMINISHING RETURNS. AFTER YOU GET TO A CERTAIN POINT, SO BEYOND TEN GRADES, YOU ARE NOT GETTING MUCH MORE BENEFIT, BUT IT ALSO DOESN'T HURT THE PROCESS.

I THINK ANOTHER IMPORTANT THING TO POINT OUT ABOUT OUR ONE TO A HUNDRED SCORING METHOD IS THAT IT IS DIFFERENT FROM OTHERS BECAUSE IT ACCOMPLISHES TWO THINGS AT ONCE. IT IS BOTH BINARY, MEANING IT'S A FUND OR DON'T FIND, THUMBS UP, THUMBS DOWN BECAUSE THERE IS A SPECIFIC FUNDING LINE. IT IS KNOWN TO REVIEWERS THAT IF YOU ARE SCORING AN APPLICATION AN 85 OR ABOVE, YOU ARE SCORING IT TO FUND IT. IF YOU SCORE BELOW, THEN YOU ARE SCORING IT TO NOT FUND.

SO THEIR FIRST ASSESSMENT OF THE APPLICATION IS TO DETERMINE WHETHER IT'S BELOW 85 OR

85 OR ABOVE. AFTER THAT, IT'S DETERMINING HOW ENTHUSIASTIC THEY ARE ABOUT WHETHER THIS IS ONE THEY WANT TO FUND. IT'S AMONG THE BETTER ONES SO YOU WANT TO SCORE IT CLOSER TO A HUNDRED OR CLOSER TO 85. SIMILAR WITH THOSE THAT LACK ENTHUSIASM, HOW FAR AWAY FROM THE LINE WERE THEY IN TERMS OF MERIT? SO IT DOES HAVE THAT BENEFIT.

NOW, NOTING THAT THERE MAY BE MORE BENEFITS WITH A GRADED SYSTEM LIKE THIS, THE SCORES BY THEMSELVES DON'T TELL US EVERYTHING AND THEY DON'T GIVE THE FULL PICTURE THAT WOULD ALLOW US TO DISTINGUISH APPLICATIONS. YOU CAN HAVE AN APPLICATION OR TWO APPLICATIONS THAT SCORE 85 THAT ARE COMPLETELY DIFFERENT. ONE THAT IS AN 85 BECAUSE THERE WAS A UNANIMOUS SET OF REVIEWERS THAT ALL SCORED 85, AND YOU MAY HAVE A DIFFERENT APPLICATION THAT HAD A SPLIT SET OF SCORES. SO SOME SCORED 85 TO 90 AND SEVERAL SCORED BELOW THAT. AND WE HAVE SOMETIMES SEEN A SPLIT WHERE IT'S EIGHT VERSUS SEVEN. SO THAT INFORMATION IS USEFUL IN ASCERTAINING SOME OF THE DIFFERENCES THAT MAY EXIST BETWEEN WHAT ARE TWO SEEMINGLY SAME SCORING APPLICATIONS.

AND WE PROVIDE THIS INFORMATION AS PART OF THE PACKAGE THAT WE GIVE TO YOU. SO WE SHOW YOU THE

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MEAN, THE RANGE, AS WELL AS ALSO THE NUMBER OF REVIEWERS THAT SCORED 85 OR ABOVE OR BELOW TO GIVE YOU A BIT MORE NUANCE AS TO THOSE DIFFERENCES. ALSO IMPORTANTLY, THE COMMENTS THAT THE REVIEWERS PROVIDE IN THE SUMMARIES ARE IMPORTANT TO UNDERSTAND WHERE THE APPLICANTS DID WELL, WHERE THEY DID NOT DO WELL IN ORDER TO, AGAIN, TRY TO DISCERN DIFFERENCES. AND SO DIGGING BEYOND THE SCORE IS GOING TO BE NECESSARY IF WE HAVE A LOT OF APPLICATIONS THAT ARE AT A SIMILAR PLACE SUCH AS 85.

I WANT TO TALK JUST BRIEFLY ABOUT PROGRAMMATIC REVIEW AND TEAM RECOMMENDATIONS. AS YOU KNOW, THE APPLICATION REVIEW SUBCOMMITTEE OF THE ICOC MAKES ALL THE FINAL FUNDING DECISIONS ON APPLICATIONS. THE DECISION-MAKING IS INFORMED BY THE GRANTS WORKING GROUP RECOMMENDATIONS, CIRM TEAM RECOMMENDATIONS, AS WELL AS PUBLIC COMMENTS.

AND SO THERE ARE DIFFERENT THINGS THAT THE APPLICATION REVIEW SUBCOMMITTEE MAY CONSIDER. THE FATE OR ALIGNMENT OF THE APPLICATION WITH CIRM MISSION, STRATEGIC PLAN, POTENTIAL IMPACT ON PATIENTS, THE PORTFOLIO, DEI ELEMENTS, AVAILABILITY OF FUNDS, AND SO ON. THIS IS NOT A LIMITED LIST, BUT JUST EXAMPLES OF DIFFERENT THINGS THE APPLICATION REVIEW SUBCOMMITTEE CAN CONSIDER WHEN

LOOKING AT AN APPLICATION AND DETERMINING ITS FUNDING.

IN TERMS OF THEN AUGMENTING AND PROVIDING MORE INFORMATION FOR YOU AND FOR THE APPLICATION REVIEW SUBCOMMITTEE TO MAKE MORE INFORMED DECISIONS, WE WANT TO LET YOU KNOW THAT WE WANT TO STRIVE TO GIVE YOU MORE INFORMATION ALTHOUGH OUR PHILOSOPHY HAS BEEN THAT GENERALLY THE CIRM TEAM WILL DEFAULT TO THE GRANTS WORKING GROUP RECOMMENDATION IN THE ABSENCE OF A GOOD REASON TO DO OTHERWISE. BUT WE HAVE SEEN SEVERAL REASONS TO DO OTHERWISE IN THE CONTEXT OF IN MANY CASES HAVING MORE APPLICATIONS RECOMMENDED THAN THE BUDGET WOULD SUPPORT.

SO IN THAT CASE WE'RE FACED WITH MAKING DECISIONS ABOUT A GROUP OF ALL SEEMINGLY MERITORIOUS APPLICATIONS AND DECIDING AMONG THOSE WHICH ARE BEST ONES. AND SO WE WANT TO OFFER ADDITIONAL INFORMATION, SUCH AS RECOMMENDATIONS FROM THE CIRM TEAM, THAT MIGHT IDENTIFY EITHER A UNIQUE OPPORTUNITY TO ADVANCE AN URGENT GOAL OR NEED OR PRIORITY ALIGNED WITH SAF, OFFER SOME PERSPECTIVE OF AN APPLICATION THAT QUALIFIES FOR A MINORITY REPORT, FOR EXAMPLE, OR ALLOWS US TO BETTER BALANCE OUR CIRM PORTFOLIO OR OPTIMIZING THE USE OF AVAILABLE FUNDS DEPENDING ON THE FUNDS REQUESTED AND SO ON. MAYBE

INFORMATION THAT WOULD GIVE US A CLUE ABOUT THE LIKELIHOOD OF SUCCESS BASED ON OUR OWN EXPERIENCE MANAGING SIMILAR CIRM PROJECTS OR INFORMATION THAT COMES TO CIRM'S ATTENTION THAT COULD IMPACT THE POTENTIAL SUCCESS OF THE PROJECT.

OKAY. SO THAT IS THE AGENDA. BUT, HOWEVER, THERE IS ANOTHER AGENDA ITEM, NOT ANOTHER AGENDA ITEM, ANOTHER ELEMENT THAT'S RELATED TO THIS THAT IS ATTACHED WHICH HAS TO DO WITH THE GRANTS WORKING GROUP BYLAWS. SO THERE IS A MEMO THAT WAS PROVIDED TO YOU ALONG WITH SOME EDITS FOR THE GRANTS WORKING GROUP BYLAWS THAT RELATE TO THE SCORING.

AND THIS IS SOMETHING THAT NEEDS BOARD APPROVAL TO ALLOW US TO USE THE PROPOSED SCORING METHODS, MEANING THAT, AT LEAST FOR THESE FOUR CONCEPTS, WE WANT TO MOVE TO THE ONE TO A HUNDRED APPROACH. THE CURRENT BYLAWS WHICH SET THE VERY SPECIFIC AND DEFINED SCORING METHODOLOGY THAT WAS USED WAS BASED ON OUR OLD PROGRAMS THAT ARE CLOSING OR NOW CLOSED. AND SO WE WANT TO ADD SOME FLEXIBILITY BY AMENDING THE BYLAWS AND DESCRIBING THE METHODOLOGY DIFFERENTLY.

SO WE PROPOSE ADDING A NEW SECTION, WHICH IS COMPARABLE TO THAT THAT EXISTS IN THE AAWG BYLAWS, WHICH STATES THAT THE SCORING METHODOLOGY

USED BY THE GRANTS WORKING GROUP WILL BE THAT DETERMINED BY CIRM TO BE THE MOST APPROPRIATE FOR THE SPECIFIC FUNDING OPPORTUNITY AND THAT THE METHOD WILL BE DESCRIBED IN THE RELEVANT RFA OR PROGRAM ANNOUNCEMENT SO THAT IT'S CLEAR TO APPLICANTS. AND, OF COURSE, WE WOULD BRING THAT TO YOU AS WELL SO THAT YOU ARE AWARE OF THE METHODOLOGY THAT IS BEING USED.

SO I THINK WE HAVE A SLIDE FOR REQUESTING APPROVAL FOR THE AMENDMENTS TO THE GRANTS WORKING GROUP BYLAWS.

CHAIRMAN IMBASCIANI: THANK YOU, GIL, FOR THE PRESENTATION. AND CHAIR WOULD LIKE TO ENTERTAIN A MOTION TO APPROVE THE AMENDMENTS TO SECTION 3, 4, AND 5 AS GIL HAS ELUCIDATED TO THE BYLAWS OF THE GWG.

DR. SOUTHARD: SO MOVED.

DR. BLUMENTHAL: SECOND.

CHAIRMAN IMBASCIANI: WE HAVE A MOVE. MARV, I SAW YOU FIRST. AND MAYBE A SECOND FROM DR. BLUMENTHAL. GEORGE SECONDED. THANK YOU. ANY DISCUSSION ON THE AMENDMENTS TO THE BYLAWS FIRST FROM BOARD MEMBERS? NOT SEEING ANY. I'M GOING TO ASK CLAUDETTE IS THERE ANYONE IN THE PUBLIC THAT WOULD LIKE TO COMMENT OR IN THE ROOM? NO. OKAY.

SCOTT, I THINK WE CAN PROCEED.

MR. TOCHER: ALL THOSE IN THE ROOM IN FAVOR SAY AYE. THOSE OPPOSED SAY NAY. ANY ABSTENTIONS? I'LL POLL MEMBERS ON THE PHONE.

MONICA CARSON. YSABEL DURON.

MS. DURON: YES.

MR. TOCHER: RICH LAJARA. SHLOMO MELMED. CHRIS MIASKOWSKI.

DR. MIASKOWSKI: YES.

MR. TOCHER: JOE PANETTA. SUZANNE SANDMEYER. KAROL WATSON.

DR. WATSON: YES.

MR. TOCHER: KEVIN XU.

DR. XU: YES.

MR. TOCHER: THANK YOU VERY MUCH. THE MOTION CARRIES, MR. CHAIR.

CHAIRMAN IMBASCIANI: THANK YOU AGAIN, SCOTT.

MR. TOCHER: POINT OF ORDER. WE NEED TO TAKE ABOUT A TEN-MINUTE BREAK. YOU WILL SEE REFRESHMENTS BEHIND US. THOSE ON THE PHONE, WE'LL COME BACK WITH THE NEXT ITEM OF BUSINESS FOR THE UPDATE FROM COMMUNICATIONS. SO WE'LL MEET BACK UP AT 3:15 SHARP.

(A RECESS WAS TAKEN.)

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CHAIRMAN IMBASCIANI: LADIES AND GENTLEMEN, PLEASE TAKE YOUR SEATS. WE ARE READY TO RESUME AFTER OUR RECESS. I'M GOING TO INVITE OUR PRESIDENT AND CEO JONATHAN THOMAS TO TAKE US THROUGH THE NEXT ITEM, OUR UPDATE ON COMMUNICATIONS. THANK YOU, J.T.

DR. THOMAS: THANK YOU, MR. CHAIR. BEFORE I INTRODUCE ESTEBAN TO GIVE THE BOARD A PRESENTATION ON COMMUNICATION STRATEGIES RECENTLY OUTLINED TO THE COMMUNICATIONS SUBCOMMITTEE IN LIGHT OF THE FLUID FEDERAL LANDSCAPE, I WANTED TO LET THE BOARD KNOW THAT WE HAVE POSTED THE JOB DESCRIPTION FOR THE SENIOR DIRECTOR OF COMMUNICATIONS, WHOSE PRINCIPAL RESPONSIBILITY WILL BE TO DEVELOP AND IMPLEMENT A COMPREHENSIVE STRATEGIC COMMUNICATION PLAN TO REACH AND INFORM CIRM'S MANY AND VARIED STAKEHOLDER GROUPS.

WE HAVE IN A SHORT TIME ALREADY RECEIVED 57 APPLICATIONS AND EXPECT MORE IN THE DAYS AHEAD. WE'LL KEEP YOU POSTED AS THE PROCESS PROCEEDS.

AS REGARDS COMMUNICATIONS ON DEVELOPMENTS IN WASHINGTON, IT IS CRITICAL THAT OUR STAKEHOLDERS KNOW THAT WE REMAIN COMMITTED TO THE CORE PRINCIPLES, PROGRAMS, AND INITIATIVES DISCUSSED OVER THE PAST SEVERAL HOURS. THAT'S WHY I AND CIRM

LEADERSHIP WILL WORK CLOSELY WITH COMMUNICATIONS AND THE BOARD TO ENSURE THAT WE ARE ALIGNED IN OUR STANCE AND HOW WE COMMUNICATE THESE IMPORTANT UPDATES.

ESTEBAN AND HIS TEAM HAVE DEVELOPED A STRATEGY THAT WILL EMPHASIZE SOME OF THESE MESSAGES. WE LOOK FORWARD TO HEARING YOUR FEEDBACK AND SUGGESTIONS.

LAST, BUT NOT LEAST, I WANTED TO COMMUNICATE THAT IN LESS THAN AN HOUR OPENING DAY AT DODGER STADIUM WILL START. GO BLUE. ESTEBAN.

MR. CORTEZ: GOOD AFTERNOON, MEMBERS OF THE BOARD, CHAIR IMBASCIANI, VICE CHAIR GONZALEZ-BONNEVILLE, CIRM TEAM, AND MEMBERS OF THE PUBLIC. I'M ESTEBAN CORTEZ. I'M THE DIRECTOR OF MARKETING COMMUNICATIONS HERE AT CIRM. AND I KNOW THAT I AM ONE OF THE LAST PRESENTERS, IF NOT THE LAST, STANDING BETWEEN YOUR JOURNEY HOME. SO I APPRECIATE YOUR TIME TODAY TO HEAR ABOUT SOME OF THE RECENT WORK THAT WE'VE BEEN DOING.

OF COURSE, BEFORE WE AGAIN, HERE'S REMINDER OF OUR MISSION, WHICH IS TO ACCELERATING WORLD-CLASS SCIENCE TO DELIVER TRANSFORMATIVE REGENERATIVE MEDICINE TREATMENTS IN AN EQUITABLE MANNER TO A DIVERSE CALIFORNIA AND WORLD.

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I'M PART OF A SMALL BUT MIGHTY TEAM THAT LEADS AND SUPPORTS THE ENTIRE AGENCY WITH VARIOUS MARKETING, COMMUNICATIONS, INITIATIVES, AND CHANNEL MANAGEMENT. THIS INCLUDES EXTERNAL AND INTERNAL COMMUNICATIONS, SOCIAL MEDIA, EMAIL MARKETING, PRINT PUBLICATIONS LIKE OUR ANNUAL REPORT, MANAGING OUR WEBSITE AND BLOG, MEDIA, AND PRESS, AS WELL AS SUPPORTING WITH COMMUNITY OUTREACH EFFORTS.

I'D LIKE TO RECOGNIZE MY TEAM. KATIE SHARIFY, OUR COMMUNICATIONS TEAM COORDINATOR, AND CHRISTINA SMITH WHO AREN'T HERE TODAY. CHRISTINA IS OUR SOCIAL MEDIA AND CONTENT SPECIALIST. AND I'D REALLY LIKE RECOGNIZE THEM FOR THEIR EFFORTS IN DRIVING OUR MISSION FORWARD THROUGH OUR COMMUNICATIONS EFFORTS.

SO TODAY I'D LIKE TO TALK ABOUT OUR APPROACH IN KEEPING OUR AUDIENCES INFORMED ABOUT CIRM'S ROLE IN LIGHT OF THESE RECENT FEDERAL DEVELOPMENTS THAT WE'RE ALL AWARE OF. THERE HAS BEEN A RECENT FLURRY OF EXECUTIVE ORDERS AND FEDERAL DEVELOPMENTS THAT HAVE ALREADY HAD DRASTIC EFFECT ON THE SCIENTIFIC COMMUNITY, INCLUDING MANY CIRM-FUNDED RESEARCHERS AND INSTITUTIONS. WE RECOGNIZE THAT THESE NEW DEVELOPMENTS ARE COMING AT US AT A RAPID PACE AND THINGS CHANGE WEEK BY WEEK AND DAY BY DAY.

THE COMMUNICATIONS TEAM, AS J.T. MENTIONED, WILL BE HERE TO SUPPORT THE CIRM PRESIDENT, THE EXECUTIVE TEAM, AND THE PROGRAM TEAMS IN DELIVERING THESE IMPORTANT MESSAGES AND UPDATES TO OUR AUDIENCES. THIS INCLUDES LAUNCHING EMAILS, POSTING SOCIAL MEDIA UPDATES, RELEASING STATEMENTS AND RESPONSES WHEN NEEDED TO SUPPORT LEADERSHIP'S VISION.

I'LL BE PRESENTING A COMPREHENSIVE COMMUNICATIONS STRATEGY WHICH YOU ALL HAVE ACCESS TO IN RESPONSE TO RECENT FEDERAL DEVELOPMENTS AND OUTLINE HOW CIRM WILL THROUGH ITS COMMUNICATION EFFORTS CONTINUE TO ENGAGE WITH STAKEHOLDERS AND REINFORCE OUR MISSION IN LIGHT OF THESE CHANGES.

AMIDST THIS UNCERTAINTY, CIRM HAS A UNIQUE OPPORTUNITY TO POSITION ITSELF AS A LEADER, AS A PROACTIVE LEADER, OUR ROLE AS A KEY RESEARCH FUNDER, OUR ADVOCACY FOR SCIENTIFIC INNOVATION, AND OUR SUPPORT OF INCLUSIVITY IN SCIENCE PUTS US IN A STRONG POSITION TO NAVIGATE THESE CHALLENGES.

AT CIRM OUR MISSION TO ACCELERATE WORLD-CLASS SCIENCE REMAINS UNSHAKEN, AND THAT'S WHY OUR COMMUNICATION EFFORTS MUST REFLECT THIS COMMITMENT.

IN THE COMMUNICATION STRATEGY, WHICH AGAIN

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WAS PROVIDED TO YOU IN THE AGENDA, IS DESIGNED TO ENSURE THAT WE MEET SEVERAL KEY OBJECTIVES. FIRST, WE WANT TO EMPHASIZE CIRM'S LEADERSHIP ROLE IN REGENERATIVE MEDICINE AND UNDERSCORE CALIFORNIA'S CRITICAL POSITION IN ADVANCING SCIENTIFIC RESEARCH. WE WILL REASSURE STAKEHOLDERS THAT CIRM'S STRATEGIC IMPACT GOALS THROUGH THE SAF AND MISSION REMAIN UNCHANGED DESPITE FEDERAL POLICY SHIFTS. WE WILL EMPHASIZE THE VALUE OF SCIENCE AND THE ONGOING NEED FOR INVESTMENT IN RESEARCH. WE'LL REAFFIRM CIRM'S COMMITMENT TO INCLUSIVITY THROUGH OUR STORIES AND CONTENT, EMPHASIZING THE IMPORTANCE OF REPRESENTING COMMUNITIES IN DRIVING SCIENTIFIC EXCELLENCE AND EQUITABLE ACCESS TO THERAPIES. AND WE WILL CONTINUE TO MAINTAIN AND DEEPEN OUR RELATIONSHIP WITH KEY STAKEHOLDERS, INCLUDING RESEARCHERS, PATIENT ADVOCACY GROUPS, ELECTED OFFICIALS, THE BROADER SCIENTIFIC COMMUNITY, AND, OF COURSE, THE GENERAL PUBLIC.

THESE OBJECTIVES WILL GUIDE OUR STRATEGY AND ENSURE THAT WE COMMUNICATE CLEARLY AND EFFECTIVELY DURING THIS TIME AND MOVING FORWARD.

THROUGH OUR COMMUNICATIONS EFFORTS, WE WILL REACH A WIDE RANGE OF AUDIENCES, INCLUDING CIRM STAFF AND BOARD, OUR AWARDEES AND APPLICANTS, THE

REGENERATIVE MEDICINE SCIENTIFIC COMMUNITY, PATIENT ADVOCACY GROUPS, KEY GOVERNMENT OFFICIALS AND AGENCIES, AND THE GENERAL PUBLIC. BY ALIGNING OUR MESSAGES WITH THESE AUDIENCES, WE CAN BUILD SUPPORT, FOSTER COLLABORATION, AND ENSURE THAT CIRM'S MISSION REMAINS STRONG AND VISIBLE.

SO TO ENSURE ALIGNMENT AND CONSISTENCY IN OUR COMMUNICATIONS EFFORTS, WE HAVE DEVELOPED CORE MESSAGING THAT REINFORCES OUR OBJECTIVES IN THE PLAN. IN THE INTEREST OF TIME, I'M NOT GOING TO COVER EACH MESSAGE IN DETAIL. SO I INVITE YOU TO REVIEW FURTHER MESSAGING IN THE PROVIDED PLANNING DOCUMENT. I'D ALSO LIKE TO MAKE IT CLEAR THAT WE WILL BE STRATEGIC, INTENTIONAL, AND CAREFUL IN HOW WE COMMUNICATE OUR MESSAGE TO ENSURE IT ALIGNS WITH THE ORGANIZATION'S GOALS.

A KEY TAKEAWAY FROM RECENT CONVERSATIONS AT THE BOARD MEETING IS THAT WE NEED TO REAFFIRM THE STRENGTH AND COMMITMENT TO OUR MISSION. AND WE CAN DO THIS BY CONTINUING TO HIGHLIGHT OUR IMPACT IN CALIFORNIA, HIGHLIGHTING THE RESEARCH WE FUND, AND PROMOTING OUR FUNDING OPPORTUNITIES TO SCIENTIFIC COMMUNITIES.

A KEY MESSAGE THAT WE WANT TO EMPHASIZE, FOR EXAMPLE, IS THAT CIRM'S MISSION IS STEADFAST AND

GROUNDED IN SCIENTIFIC INTEGRITY AND PATIENT ACCESS. WE WILL CONTINUE TO LEAD THE WAY IN REGENERATIVE MEDICINE AND REMAIN A RELIABLE PARTNER TO OUR STAKEHOLDERS, ENSURING THAT OUR FUNDING DRIVES GROUNDBREAKING THERAPIES TO REACH PATIENTS WHO NEED THEM MOST.

SO THIS MEANS THAT OUR CONTENT, USING THAT MESSAGE AS AN EXAMPLE, OUR CONTENT AND OUR STORIES ACROSS OUR CHANNELS SHOULD REFLECT THIS MESSAGING AND OTHERS IDENTIFIED IN THIS PLAN WHEREVER POSSIBLE. THAT'S THE INTENTION OF DEVELOPING THESE CORE MESSAGES.

WE ALSO WANT TO HIGHLIGHT THAT CIRM REMAINS COMMITTED TO CREATING AN INCLUSIVE RESEARCH ENVIRONMENT IN REGENERATIVE MEDICINE, SUPPORTING RESEARCH THAT BENEFITS COMMUNITIES AND DIVERSITY IN SCIENTIFIC RESEARCH OUTCOMES. WHILE WE RECOGNIZE THAT THERE HAVE BEEN MANY EFFORTS TO ELIMINATE MANY OF THESE INITIATIVES AT THE FEDERAL LEVEL, CIRM HAS AN OPPORTUNITY TO CONTINUE HIGHLIGHTING STORIES FROM CIRM-FUNDED RESEARCH, CLINICAL TRIALS, AND OUR EDUCATION PROGRAMS.

WE HAD A LIVELY DISCUSSION AT OUR RECENT COMMUNICATIONS SUBCOMMITTEE MEETING. MEMBERS AGREED THAT IT'S IMPORTANT TO CONTINUE TO SHARE THOSE

STORIES THAT REALLY DRIVE ACROSS OUR VALLEYS AND INSPIRE PEOPLE. THAT INCLUDES SHARING PATIENT STORIES, HIGHLIGHTING PEOPLE WHO ARE RECEIVING SERVICES SUPPORTED BY CIRM, AND HIGHLIGHTING THE HOW THEY, THEIR FAMILIES, AND COMMUNITIES ARE POSITIVELY IMPACTED BY THE SCIENCE CIRM SUPPORTS.

SO WE'LL CONTINUE TO STRATEGIZE AND WORK WITH THE WIDER CIRM TEAM TO IDENTIFY THESE STORIES AND ENSURE THAT THEY REFLECT OUR VALUES WHILE BEING MINDFUL OF FURTHER DEVELOPMENTS.

AND FINALLY, WE WANT TO ENSURE THAT WE'RE EMPHASIZING THE VALUE OF SCIENCE AND CONTINUED INVESTMENTS IN RESEARCH. WE WILL DO THIS BY PROMOTING OUR FUNDING OPPORTUNITIES AND AWARDS, WORKING CLOSELY WITH THE TEAMS WHO ARE MANAGING THOSE, COMMUNICATING WHY THIS RESEARCH POSITIVELY IMPACTS CALIFORNIA COMMUNITIES.

OUR MESSAGING WILL ALSO HIGHLIGHT THE WORK WE'RE DOING TO IMPROVE PATIENT OUTCOMES. AND THIS PRESENTS US WITH OPPORTUNITIES TO FEATURE RECENT INITIATIVES LIKE OUR PATIENT SUPPORT PROGRAM AND CASE STUDIES THAT EMPHASIZE THE IMPORTANCE OF ACCESS AND AFFORDABILITY.

WE'LL EXECUTE THE STRATEGY THROUGH A VARIETY OF TACTICS. ON THE PR SIDE, FOR EXAMPLE, IN

ADDITION TO LAUNCHING STATEMENTS AND DEVELOPING TALKING POINTS AS NEEDED, WE'LL ENGAGE WITH CIRM BOARD MEMBERS AND MEDIA TO AMPLIFY OUR MESSAGES. WE'RE ALREADY SEEING AN INCREASE IN MEDIA COVERAGE OVER THE PAST FEW WEEKS SINCE MANY OF THESE FEDERAL CHANGES HAVE TAKEN EFFECT. SO WE'LL CONTINUE TO TAKE THIS OPPORTUNITY TO REFINE OUR MEDIA STRATEGY WITH LEADERSHIP.

WE WILL ALSO BE REACHING OUT TO OUR BOARD MEMBERS ABOUT WAYS THAT YOU CAN LEND YOUR VOICE TO THESE EFFORTS BY PROMOTING TESTIMONIALS, QUOTES, AND STATEMENTS. AND WE'RE ALSO SEEING MORE ENGAGEMENT ON SOCIAL MEDIA, ESPECIALLY AS IT RELATES TO CIRM FUNDING ANNOUNCEMENTS. OUR AUDIENCES TRULY RECOGNIZE THE IMPORTANCE OF CONTINUED FUNDING ESPECIALLY DURING THIS TIME. SO WE'LL SHARE THESE RECURRING UPDATES ON OUR SOCIAL CHANNELS THAT HIGHLIGHT OUR CONTINUED FUNDING COMMITMENTS.

AND WE'LL ALSO CONTINUE TO FIND OPPORTUNITIES TO MEET COMMUNITIES WHERE THEY ARE AND IDENTIFY ONLINE PLATFORMS, COMMUNITY GROUPS, AND FORUMS TO SHARE RELEVANT UPDATES AND JOIN CONVERSATION ON IMPORTANT TOPICS.

BUILDING ON THE MOMENTUM OF OUR NEW WEBSITE, WHICH I INVITE YOU ALL TO CHECK OUT IF YOU

HAVEN'T ALREADY, AN INCREASED ENGAGEMENT ON SOCIAL MEDIA PLATFORMS LIKE LINKED-IN WILL, OF COURSE, UTILIZE OUR DIGITAL AND PRINT CHANNELS TO CONTINUE SHARING RELEVANT UPDATES TO OUR AUDIENCES. THIS INCLUDES BUILDING DEDICATED LANDING PAGES FOR IMPORTANT ANNOUNCEMENTS, UPDATING OUR BLOG, THE "STEM CELLAR," REGULARLY, AND DEVELOPING COLLATERAL WHICH REINFORCES OUR KEY MESSAGES TO OUR OUTREACH EVENTS.

WE RECOGNIZE THAT THIS IS A LOT OF WORK FOR A SMALL TEAM. SO TO ENSURE THAT WE CAN BE RESPONSIVE, WE'VE ONBOARDED ADDITIONAL WRITING SUPPORT FROM A FORMER CIRM STAFFER, TURNED CONSULTANT NAMED AMY ADAMS IN AN EFFORT TO DRIVE SOME OF THIS CONTENT. WE LOOK FORWARD TO WORKING WITH HER, CIRM STAFF, OUR COMMUNITY PARTNERS, AND MANY OF YOU TO HELP DRIVE THIS STRATEGY.

SO WHILE I DIDN'T COVER EACH OF THESE KEY MESSAGES AND TACTICS IN DETAIL FOR THE SAKE OF TIME, THE COMMUNICATIONS TEAM APPRECIATES HEARING YOUR FEEDBACK ON THIS APPROACH. THIS IS A VERY IMPORTANT TOPIC FOR US AND WILL DRIVE OUR EFFORTS MOVING FORWARD. SPECIFICALLY WE'D LIKE TO HEAR WHETHER YOU FEEL THERE ARE OTHER KEY MESSAGES THAT WE SHOULD EMPHASIZE OR IF THERE ARE ANY OTHER KEY

COMMUNICATION STRATEGIES THAT WE MIGHT HAVE LEFT OUT, THINGS FOR US TO CONSIDER. SO WE VALUE YOUR FEEDBACK. SO I'D LIKE TO OPEN UP FOR DISCUSSION.

CHAIRMAN IMBASCIANI: THANKS, ESTEBAN. I HEARD A LOT OF WONDERFUL ADJECTIVES, STEADFAST COMMITMENT TO OUR IDEALS, COLLABORATIVE WORKING WITH THE GOVERNMENT. ANYONE? WE'LL START WITH MARK FISCHER-COLBRIE.

MR. FISCHER-COLBRIE: YEAH. FIRST OF ALL, KUDOS FOR GETTING THE NEWS OUT ALREADY ON ACTIVITIES FOR THE MEETING. SO WELL DONE.

AND SECOND, JUST IN GENERAL CURIOUS ABOUT THOUGHTS AROUND INSTAGRAM AND TIKTOK AND FINDING CHANNELS TO PREPACKAGE MATERIALS OR ALLOW PEOPLE WHO HAVE A BROADER VOICE, I.E., INFLUENCERS, TO THE RIGHT TYPE, PACKAGE STUFF UP FOR THEM TO PROPAGATE. SO JUST GENERAL THOUGHTS ON THAT.

MR. CORTEZ: ABSOLUTELY. IN TERMS OF SOCIAL MEDIA PLATFORMS LIKE INSTAGRAM, WE DO HAVE A PRESENCE THERE. ACTUALLY HAVE BEEN SEEING MORE ENGAGEMENT RECENTLY AND REALLY ARE CHANGING AROUND HOW WE DELIVER SOME OF THOSE MESSAGES. I THINK IF YOU EVEN GO VISIT THAT NOW, YOU WILL SEE THAT THERE'S BEEN A CHANGE, AND WE'RE REALLY TRYING TO JUST ALIGN MORE WITH HOW PEOPLE RECEIVE AND READ

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THEIR NEWS. SO I INVITE YOU TO GO CHECK THAT OUT.

WE DO NOT HAVE A TIKTOK ACCOUNT AT THE MOMENT. ONE OF THE THINGS THAT WE ARE LOOKING TO DO, IN ADDITION TO IDENTIFYING ANY INFLUENCERS, PEOPLE IN THE SCIENTIFIC SPACE, IS REALLY LEVERAGING OUR EXISTING AUDIENCES. AND ONE OF THE THINGS THAT OFTEN COMES UP IS REALLY WORKING WITH OUR TRAINEES IN OUR EDUCATION PROGRAMS WHO IN THEIR OWN RIGHT HAVE SOME INFLUENCE AS WELL. SO REALLY WORKING ON WAYS TO ENGAGE THEM, ENCOURAGE THEM TO DEVELOP SOME OF THAT USER-GENERATED CONTENT.

SO THOSE ARE THINGS THAT WE'RE REALLY LOOKING FORWARD TO DOING. AND WE'RE ALREADY TALKING ABOUT DOING THAT FOR THE UPCOMING TRAINEE CONFERENCE THAT'S COMING UP AND REALLY ARE LOOKING TO BOOST OUR EFFORTS THERE.

CHAIRMAN IMBASCIANI: YES, ANNE-MARIE.

DR. DULIEGE: THANK YOU FOR WHAT YOU'VE BEEN DOING IN PRESENTING. I WOULD SAY CONGRATULATIONS, KUDOS TO THE TEAM FOR STANDING VERY CLEARLY IN FAVOR OF THE DEI POLICY.

THANK YOU ALSO FOR THOSE OF YOU WHO CONTRIBUTE TO THE MONTHLY NEWSLETTER. I THINK MOST RECENTLY WAS SENT TO THE BOARD. AT LEAST I RECEIVED ONE OR TWO EXAMPLES OF THIS MONTHLY NEWSLETTER, AN

INITIATIVE THAT BRINGS US CONSTANTLY IN THE LOOP OF WHAT'S HAPPENING, NOT ONLY AT THE MEETINGS, BUT OUTSIDE THE MEETINGS WHERE AT TIMES WE COULD EVEN PARTICIPATE IN. SO MUCH APPRECIATED. THANK YOU FOR DOING THAT.

AND I RECALL ONE THING THAT I REGRET NOT HAVING SEEN AT LEAST RECENTLY, IT'S PROBABLY ON THE WEBSITE, THAT AT TIMES WE PARTICIPANTS DURING THESE MEETINGS WHO HAVE BEEN IN CLINICAL TRIALS WHO HAVE BENEFITED OR MAYBE KNOW EVEN BENEFITED. THEY WOULD COME ON ZOOM, THEY WOULD COME IN PERSON AT TIMES, OR AN INTERVENTION. AND IF WE COULD RESUME THAT AT SOME POINT, THIS WOULD BE VERY BENEFICIAL.

MR. CORTEZ: THANK YOU. I DO WANT TO RECOGNIZE THE BOARD GOVERNANCE TEAM IN LAUNCHING THAT NEWSLETTER YOU MENTIONED BECAUSE THEY ARE DRIVING THOSE EFFORTS. BUT WE DEFINITELY SEE THAT AS AN OPPORTUNITY TO COLLABORATE WITH THEM. SO I DO WANT TO RECOGNIZE CLAUDETTE, LANA, AND THE BOARD TEAM FOR THAT.

I THINK IN RESPONSE TO INVITING PATIENTS AND PATIENT ADVOCATES TO THE BOARD MEETING, WE DID SEE THAT AT LAST MONTH'S MEETING WHERE WE DID WORK WITH ANDREA, I FORGET HER FULL NAME, BUT THIS WAS A PATIENT. SHE'S THE MOTHER OF A PATIENT WHO

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PARTICIPATED IN A CLINICAL TRIAL AT UCLA FOR A RARE DISEASE. AND THAT WAS AN EFFORT THAT WE DROVE IN WORKING WITH THEM, FEATURING THEIR STORY ON THE BLOG. SO THAT IS A REALLY GREAT SUGGESTION. THAT'S SOMETHING THAT WE THINK WILL HAVE GREAT IMPACT. SO I APPRECIATE THAT.

CHAIRMAN IMBASCIANI: ESTEBAN, THANK YOU FOR YOUR LEADING ROLE ON THIS. MARVIN.

DR. SOUTHARD: SO I JUST WONDERED HOW ACTIVE A ROLE THAT YOU PLAN TO UNDERTAKE IN RESPONSE TO THE FUNDING CHAOS THAT'S GOING TO BE INVOLVING ALL OF OUR FIELDS RIGHT NOW.

MR. CORTEZ: WELL, WHAT WE WOULD DO IS WE COULD, OF COURSE, MAKE SURE THAT WE'RE ALIGNING WITH LEADERSHIP IN RELAYING SOME OF THOSE MESSAGES. SO I DON'T HAVE A DIRECT ANSWER FOR YOU RIGHT NOW, BUT WE WOULD ACTIVELY SUPPORT WITH GETTING THOSE MESSAGES OUT. AND I THINK TO SOME EXTENT WE'VE ALREADY BEEN PUTTING SOME OF THOSE THINGS OUT THERE IN SUPPORTING LEADERSHIP. J.T., FOR EXAMPLE, AS HE GOES OUT TO GIVE PRESENTATIONS. I'LL GIVE A VERY SPECIFIC EXAMPLE.

WE WERE INVITED TO A COMMUNITY LECTURE AT UC IRVINE. THAT WAS A COMMUNITY PUBLIC EVENT. SUPPORTED HIM WITH DEVELOPING SOME OF THE SLIDE

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DECKS, THE MESSAGING, THE TALKING POINTS, AND REALLY INCORPORATED SOME OF THOSE MESSAGES THAT YOU ALREADY SEE HERE.

SO THE ANSWER IS WE'LL PLAY AN ACTIVE ROLE, BUT WE'RE ALWAYS GOING TO MAKE SURE THAT WE'RE BEING CAREFUL AND INTENTIONAL IN HOW WE DRIVE THOSE MESSAGES OUT THERE.

DR. SOUTHARD: THANK YOU.

CHAIRMAN IMBASCIANI: ANYONE ELSE WHO'S CONNECTED BY ZOOM? NO. OKAY. J.T., YOU HAVE ANY FINAL COMMENTS? YSABEL.

MS. DURON: VITO, I'M VERY SORRY. I CAN'T SEE MY HAND. ACTUALLY IN RESPONSE TO THE LAST QUESTION, I THINK ON THE SUBCOMMITTEE -- WE HAVE A COMMUNICATIONS SUBCOMMITTEE. WE HAVE DISCUSSED WHAT CIRM'S RESPONSE NEEDS TO BE OR SHOULD BE IN TERMS OF WHAT IS HAPPENING TO RESEARCH AND RESEARCHERS ACROSS THE COUNTRY BASED ON HOW THE FEDERAL GOVERNMENT AND ADMINISTRATION ARE RESPONDING AND ESPECIALLY ATTACKING DEI.

AND SO I DO THINK WE NEED TO BE VERY REACTIVE AND PROACTIVE, ALWAYS DEFENDING BOTH OUR RESEARCHERS, RESEARCH, AND, I BELIEVE, DEI. I THINK WE HAVE TO DO THAT IN A MEASURED WAY BECAUSE I DON'T THINK EVERYBODY HERE IN THE ROOM IS GOING TO AGREE

THAT WE NEED TO GO FULL ON EXCEPT ME. I EXPECT EVERYBODY ELSE WANTS TO BE MEASURED. I'M SORRY I'M NOT FEELING THAT WAY, BUT I'VE OFTEN SAID IN THESE RECENT MONTHS TO J.T. AND DURING THE COMMUNICATIONS SUBCOMMITTEE AS WELL AS TO ESTEBAN THAT WE DON'T NEED TO SIT AROUND AND WAIT FOR STUFF TO HAPPEN, THAT WE NEED TO TAKE THE REINS AND PARTICULARLY, EVEN IF IT'S JUST CALIFORNIA, THAT WE'RE BEHIND RESEARCH AND WE'RE BEHIND RESEARCHERS AS WELL AS THE DIVERSITY OF OUR COMMUNITIES THAT WE'RE INCLUDING IN THIS WORK.

I WOULD LIKE US TO SEEM TO BE ABLE TO -- SEEM TO BE STANDING FOR RESEARCH AND FOR DIVERSITY AS A LEADER ACROSS THE COUNTRY. I DON'T KNOW THAT THAT'S EVERYBODY'S PARTICULAR WAY OF WANTING OR STRATEGY TO DO THIS, BUT I THOUGHT THAT, IN RESPONSE TO THE QUESTION THAT WAS JUST ASKED, I FELT I NEED TO PUT THAT OPINION OUT THERE. THERE MIGHT BE SOME OTHERS WHO AGREE DESPITE WHAT'S HAPPENING AT THE VARIOUS ACADEMIC INSTITUTIONS.

SO I DID RECOMMEND THAT WE SHOULD BE FOLLOWING CLOSELY THE STORIES OF THE DAY IN WHICH WE CAN RESPOND, FOR INSTANCE, IN THE CUTTING OUT OF ALL DIABETES FUNDING FOR A LONG-TERM, 30-YEAR PROJECT. AND SINCE WE'VE SUPPORTED DIABETES, WE COULD DO A

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RESPONSE. THAT'S SAD TO HEAR, TERRIBLE TO HEAR, THE WRONG THING TO DO IN DISCOVERY, ET CETERA, ET CETERA. THERE ARE WAYS TO KEEP OUR NAME AND OUR WORK AND OUR CONCERNS IN THE NEWS ON AN ALMOST DAILY BASIS UTILIZING THE WORK THAT WE HAVE BEEN DOING AND BEING ABLE TO SUPPORT THE ADVANCE OF SCIENCE AND NOT THE OPPRESSION OF SCIENCE IS THE WAY I SEE IT THESE DAYS.

SO THAT'S JUST MY OPINION. I DON'T KNOW HOW ANYBODY ELSE ON THE BOARD FEELS. BUT I DO THINK WE SHOULD TAKE A MUCH MORE OVERT STAND THAN JUST WAITING FOR THINGS TO HAPPEN.

CHAIRMAN IMBASCIANI: YSABEL, WE HAVE AT LEAST ONE PERSON RESPONDING. JONATHAN.

DR. THOMAS: I WAS JUST GOING TO SAY THAT WE ARE UNABASHEDLY ADVOCATES FOR SCIENCE, WHICH WE'VE MADE VERY CLEAR IN EVERY PRONOUNCEMENT THAT WE'VE HAD. AND SO I THINK THAT I'VE NOW GIVEN TWO OR THREE INTERVIEWS WHERE THIS SORT OF THING IS ASKED. I AM UNEQUIVOCAL THAT, NOTWITHSTANDING DEVELOPMENTS ELSEWHERE, WE MAINTAIN OUR FULL COMMITMENT TO SCIENCE IN GENERAL AND TO THE FIELD OF REGENERATIVE MEDICINE SPECIFICALLY. SO LET NOBODY THINK OTHERWISE ON THAT.

MS. DURON: I DIDN'T HEAR YOU SAY DEI,

J.T. I PULL YOUR CHAIN ON THAT. YES, WE'RE ALL COMMITTED TO SCIENCE, BUT ARE WE SAYING OUT LOUD WE'RE STILL COMMITTED TO DEI?

DR. THOMAS: AS I SAID IN MY OPENING COMMENTS TODAY, THE CORE VALUE THAT WE HAVE WITH REGARD TO THAT HAS TO DO WITH ENSURING THAT ALL PROGRAMS THAT WE FUND HAVE PLANS FOR HOW, WHATEVER THE PARTICULAR PROJECT IS THAT THEY HAVE IN MIND, WILL APPLY TO ALL AFFECTED COMMUNITIES WHO ARE SUBJECT TO THE DISEASES IN QUESTION. SO YES. SHORT ANSWER IS YES.

CHAIRMAN IMBASCIANI: DR. BARRETT.

DR. BARRETT: I WANTED TO ENDORSE WHAT YSABEL SAID AND TO THANK CIRM BECAUSE, WHILE IT'S REALLY IMPORTANT THAT CIRM IS ON A GOOD FOOTING WITH THE FEDERAL GOVERNMENT AND COLLABORATIVE WITH THE FEDERAL GOVERNMENT AND NEEDS THE FEDERAL GOVERNMENT IN TERMS OF MAKING SURE THAT THESE THERAPIES MOVE FORWARD, YOU ARE NOT AS FINANCIALLY DEPENDENT ON THE FEDERAL GOVERNMENT AS THE INSTITUTIONS THAT MANY OF US REPRESENT. AND SO YOU ACTUALLY HAVE A UNIQUE ABILITY TO SPEAK UP, AND I APPRECIATE THAT YOU ARE DOING SO.

MR. CORTEZ: THANK YOU. I VALUE THAT FEEDBACK AND APPRECIATE YOUR SUGGESTION, YSABEL.

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THAT'S SOMETHING WE CAN DEFINITELY WORK TO IMPLEMENT INTO TO OUR MESSAGING AND RESPONSES. THANK YOU.

CHAIRMAN IMBASCIANI: DR. CARETHERS.

DR. CARETHERS: I WAS JUST GOING TO ADD I'M MAYBE THE NEWEST MEMBER ON THIS BOARD. AND I LOOK AROUND THIS ROOM AND SEE THE DIVERSITY OF BACKGROUNDS, BIRTHPLACES, INPUT FROM THE COMMUNITY, ACADEMIA, INDUSTRY, ET CETERA. AND I'M PROUD TO BE ON THIS BOARD. AND I WANT TO REMIND EVERYONE, FROM MY OWN KNOWLEDGE, THAT THIS BOARD CAME INTO EXISTENCE -- WE JUST HONORED LARRY GOLDSTEIN EARLIER AS ONE OF THE EXAMPLES -- BECAUSE OF THE INACTION AND BLOCKAGE OF ISSUES AT THE FEDERAL GOVERNMENT.

THAT WAS THE WORK ON STEM CELLS DURING SEVERAL ADMINISTRATIONS AGO. AND I BELIEVE THAT THIS IS THE SEVENTH -- CALIFORNIA IS 40 MILLION PEOPLE, SEVENTH LARGEST ECONOMY IN THE WORLD. WE CAN DO THINGS HERE. AND I'M SO PROUD THAT OUR PUBLIC HAS APPROVED THE EXISTENCE OF THIS BOARD AND THE THINGS THAT IT CAN DO. AND I THINK WE REALLY NEED TO SERVE THE CONSTITUENCY OF CALIFORNIA, WHICH IS A VERY DIVERSE POPULATION. AND SO I THINK WE HAVE TO KEEP THAT IN MIND IRRESPECTIVE WHAT THE FEDERAL SAID. I KNOW WE HAVE TO PLAY NICE. I GOT IT. BUT WE SHOULDN'T STEER AWAY FROM OUR MISSION.

MR. CORTEZ: THANK YOU.

CHAIRMAN IMBASCIANI: CAROLYN.

DR. MELTZER: I'D LIKE TO ECHO A NUMBER OF THE COMMENTS THAT HAVE BEEN SAID AND ADD THAT I DO -- I HAVE SERVED -- I SERVE ON A NUMBER OF PROFESSIONAL SOCIETIES, BOARDS. AND IF THEY'RE NOT DEPENDENT ON FEDERAL FUNDING, IT IS AN OPPORTUNITY TO SPEAK OUT IN WAYS THAT MAYBE UNIVERSITIES ARE A LITTLE BIT COWED RIGHT NOW. BUT WE ALSO NEED TO THINK AS THE CIRM BOARD HOW TO BE REACTIVE IF THERE ARE AREAS OF FUNDING THAT ARE CUT AT OUR INSTITUTIONS THAT PROVIDE A FRAMEWORK FOR THE WORK THAT CIRM SUPPORTS.

SO JUST THAT'S A LITTLE OUTSIDE OF COMMUNICATIONS, BUT MORE A STRATEGY BECAUSE WE DON'T KNOW WHERE THIS IS GOING EVERY DAY. AND THERE'S THESE FRIDAY DUMPS OF THE GRANTS THAT ARE DISCONTINUED.

MR. CORTEZ: THANK YOU.

CHAIRMAN IMBASCIANI: THANK YOU. ANYONE ELSE? I DON'T WANT TO OVERLOOK ANYONE. OKAY. THANK YOU, ESTEBAN.

MR. CORTEZ: THANK YOU SO MUCH, EVERYONE.

CHAIRMAN IMBASCIANI: THANK YOU, J.T.

OKAY. I'D LIKE -- THIS IS THE PART OF THE

MEETING WHERE IF THERE'S ANY MEMBER OF THE BOARD WHO WOULD LIKE TO MAKE ANY GENERAL COMMENTS ON OUR APPLICATION REVIEW PROCESS. AND IF NOT, IS THERE ANY MEMBER OF THE PUBLIC WHO WOULD LIKE TO MAKE ANY COMMENT ON ANY ITEM ON THE AGENDA OR THAT WAS NOT ON THE AGENDA? I'M TOLD THAT THERE IS NOT.

OKAY. AND IN THAT CASE WE HAVE COME TO THE END OF THE MEETING. I WOULD LIKE TO INFORM ALL BOARD MEMBERS THAT WE ARE GOING TO RECONVENE ON THE 26TH OF JUNE AT THE AIRPORT MARRIOTT HOTEL IN BURLINGAME, CALIFORNIA, WHICH IS VERY CLOSE TO THE AIRPORT IN SAN FRANCISCO, SFO. OKAY. THIS MEETING IS ADJOURNED. THANK YOU VERY MUCH.

(THE MEETING WAS THEN CONCLUDED AT 3:41 P.M.)

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REPORTER'S CERTIFICATE

I, BETH C. DRAIN, A CERTIFIED SHORTHAND REPORTER IN AND FOR THE STATE OF CALIFORNIA, HEREBY CERTIFY THAT THE FOREGOING TRANSCRIPT OF THE PROCEEDINGS BEFORE THE INDEPENDENT CITIZEN'S OVERSIGHT COMMITTEE AND THE APPLICATION REVIEW SUBCOMMITTEE OF THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE IN THE MATTER OF ITS REGULAR MEETING HELD ON MARCH 27, 2025, 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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