BEFORE THE

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

REGULAR MEETING

LOCATION: VIA ZOOM

DATE: MAY 31, 2023
9 A.M.

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

FILE NO.: 2023-19

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MAY 31, 2023; 9 A.M.

MR. TOCHER: ALL RIGHT. I'LL START WITH THE ROLL.

HAIFAA ABDULHAQ. MOHAMMED ABOUSALEM. JIM KOVACH.

DR. KOVACH: HERE.

MR. TOCHER: DAN BERNAL. GEORGE BLUMENTHAL.

DR. BLUMENTHAL: HERE.

MR. TOCHER: MARIA BONNEVILLE.

VICE CHAIR BONNEVILLE: PRESENT.

MR. TOCHER: MICHAEL BOTCHAN.

DR. BOTCHAN: HERE.

MR. TOCHER: LINDA BOXER.

DR. BOXER: PRESENT.

MR. TOCHER: JUDY CHOU. LEONDRA CLARK-HARVEY.

DR. CLARK-HARVEY: PRESENT.

MR. TOCHER: DEBORAH DEAS.

DR. DEAS: HERE.

MR. TOCHER: ANNE-MARIE DULIEGE. YSABEL DURAN.

MS. DURAN: HERE.

MR. TOCHER: MARK FISCHER-COLBRIE.

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DR. FISCHER-COLBRIE: HERE.
MR. TOCHER: FRED FISHER.
DR. FISHER: HERE.
MR. TOCHER: ELENA FLOWERS.
DR. FLOWERS: PRESENT.
MR. TOCHER: JUDY GASSON.
DR. GASSON: HERE.
MR. TOCHER: LARRY GOLDSTEIN.
MR. GOLDBERG: HERE.
MR. TOCHER: DAVID HIGGINS. VITO IMBASCIANI.
CHAIRMAN IMBASCIANI: HERE.
MR. TOCHER: STEVE JUELSGAARD.
DR. JUELSGAARD: PRESENT.
MR. TOCHER: RICH LAJARA.
MR. LAJARA: HERE.
MR. TOCHER: PAT LEVITT.
DR. LEVITT: HERE.
MR. TOCHER: LINDA MALKAS.
DR. MALKAS: HERE.
MR. TOCHER: SHLOMO MELMED. CHRISTINE MIASKOWSKI.
DR. MIASKOWSKI: PRESENT.
MR. TOCHER: LAUREN MILLER-ROGEN.
MS. MILLER-ROGEN: HERE.

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MR. TOCHER: ADRIANA PADILLA.
DR. PADILLA: HERE.
MR. TOCHER: JOE PANETTA.
MR. PANETTA: HERE.
MR. TOCHER: AL ROWLETT.
MR. ROWLETT: PRESENT.
MR. TOCHER: MARV SOUTHARD.
DR. SOUTHARD: HERE.
MR. TOCHER: MICHAEL STAMOS.
DR. STAMOS: HERE.
MR. TOCHER: KAROL WATSON.
DR. WATSON: HERE.
MR. TOCHER: AND KEITH YAMAMOTO.
DR. YAMAMOTO: HERE.
MR. TOCHER: EXCELLENT. THANK YOU VERY MUCH. VITO.
CHAIRMAN IMBASCIANI: THANK YOU, EVERYONE, FOR YOUR PARTICIPATION TODAY. MY REPORT WILL BE MORE FULL AT THE NEXT BOARD MEETING. I JUST WANT YOU TO KNOW THAT, IN ADDITION TO TODAY'S AND TOMORROW'S CONVOCATION UP HERE AT LAKE ARROWHEAD OF ALL THE SOUTHERN CALIFORNIA SCHOOLS AT WHICH REGENERATIVE MEDICINE IS STUDIED OR PERFORMED, THAT IN THE RECENT WEEKS, I HAVE BEEN TO THE LOS ANGELES CONVENTION CENTER, TO THE AMERICAN SOCIETY FOR THE

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ASGCT, FOLLOWED BY LAST WEEK'S CONVOCATION ON THE UCLA CAMPUS OF L.A. BEST.

AND I WANT TO THANK THE LEADERSHIP TEAM, ESPECIALLY MARIA, SITTING NEXT TO ME HERE, FOR VERY GRACIOUSLY INTRODUCING ME TO MANY OF THE PARTICIPANTS THERE. SO I'M GETTING A VERY EXPEDITED INTRODUCTION TO THE LANDSCAPE HERE THE BETTER TO SERVE THE BOARD.

SO WITH THAT -- AND I KNOW YOU'RE ALL IN RECEIPT OF A LETTER THAT I SENT OUT TO YOU THAT WILL MAKE MORE TAUT THE AGENDA FOR THE JUNE MEETING. SO I WOULD LIKE TO MOVE ON TO THE AGENDA. I WOULD LIKE TO NOW CONVENE AS THE APPLICATION REVIEW SUBCOMMITTEE TO CONSIDER APPLICATIONS THAT HAVE BEEN SUBMITTED IN RESPONSE TO THE CLINICAL TRIAL STAGE PROJECTS PROGRAM AND THE MANUFACTURING AWARDS PROGRAM. WE'RE GOING TO TAKE UP THE CLINICAL PROGRAM FIRST, AND I WOULD ASK DR. SAMBRANO TO MAKE HIS PRESENTATION.

DR. SAMBRANO: OKAY. THANK YOU VERY MUCH. GOOD MORNING, EVERYONE. I'M GOING TO SHARE MY SCREEN, SO GIVE ME ONE MOMENT. OKAY.

SO, FIRST, WE'RE GOING TO TALK ABOUT THE RECOMMENDATIONS OF THE GRANTS WORKING GROUP AS IT RELATES TO THE LATEST CYCLE OF OUR CLINICAL PROGRAM.

AND, AS ALWAYS, WE START WITH OUR MISSION STATEMENT. OUR MISSION AT CIRM IS TO ACCELERATE WORLD-CLASS SCIENCE TO DELIVER TRANSFORMATIVE REGENERATIVE MEDICINE TREATMENTS IN AN EQUITABLE MANNER TO A DIVERSE CALIFORNIA AND WORLD.

THIS IS A REMINDER OF WHERE WE ARE ON OUR BUDGET. THERE WAS 169 MILLION THAT WAS ALLOCATED TO CLINICAL STAGE PROGRAMS. CURRENTLY WE HAVE COMMITTED ABOUT 154 MILLION IN AWARDS. THE AMOUNT THAT'S REQUESTED TODAY FOR ONE APPLICATION IS 10.6 MILLION, WHICH WOULD LEAVE US A BALANCE OF 4.5 JUST AS WE ROUND UP THIS YEAR, THIS FISCAL YEAR, WHICH ENDS THIS COMING MONTH.

THE SCIENTIFIC SCORING SYSTEM THAT IS USED BY THE GRANTS WORKING GROUP FOR CLINICAL APPLICATIONS IS A SYSTEM OF 1, 2, OR 3. A SCORE OF 1 MEANS THAT AN APPLICATION HAS EXCEPTIONAL MERIT AND WARRANTS FUNDING. A SCORE OF 2 MEANS IT NEEDS IMPROVEMENT, DOESN'T WARRANT FUNDING, WHICH TYPICALLY GO BACK TO THE APPLICANT FOR THEM TO REVISE AND RESUBMIT FOR A FUTURE REVIEW. A SCORE OF 3 MEANS THAT IT'S SUFFICIENTLY FLAWED THAT WE BASICALLY HAVE THEM GO BACK TO THE DRAWING BOARD, AND WE DON'T ACCEPT THOSE APPLICATIONS BACK FOR AT LEAST SIX MONTHS.

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THE SCIENTIFIC REVIEW CRITERIA THAT THE GRANTS WORKING GROUP USES IN ORDER TO COME UP WITH THEIR SCORE ARE BASED ON THE FOLLOWING FIVE QUESTIONS. DOES THE PROJECT HOLD THE NECESSARY SIGNIFICANCE AND POTENTIAL FOR IMPACT? MEANING WHAT VALUE DOES IT OFFER AND IS IT SOMETHING THAT'S WORTH DOING? DOES IT HAVE A SOUND RATIONALE? IS IT WELL-PLANNED AND DESIGNED? AND, OF COURSE, IS IT FEASIBLE? IS IT SOMETHING THAT THEY CAN DO? DO THEY HAVE THE RIGHT TEAM AND THE RIGHT RESOURCES IN ORDER TO CARRY OUT WHAT IS PROPOSED? AND THEN, LASTLY, DOES THE PROJECT UPHOLD THE PRINCIPLES OF DIVERSITY, EQUITY, AND INCLUSION?

ALL RIGHT. ONE OF THE OTHER THINGS THAT THE GRANTS WORKING GROUP DOES, AND THIS IS PARTICULARLY THE PATIENT ADVOCATE AND NURSE MEMBERS THAT SERVE ON THE GRANTS WORKING GROUP, IS EVALUATE THE DEI IN ADDITION TO THE SCIENTIFIC MEMBERS, BUT THEN ALSO GIVE A SEPARATE SCORE. SO WE DEVELOPED BOTH A RUBRIC AND A SCORING SYSTEM. THE SCORING RANGES FROM ZERO TO TEN DEPENDING ON THE LEVEL OF RESPONSIVENESS BY THE APPLICANT AND BASED ON THE ASSESSMENT OF OUR BOARD MEMBERS. AND SO YOU WILL ALSO SEE A DEI SCORE BETWEEN ZERO AND TEN THAT'S GIVEN TO EACH APPLICATION.

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THE COMPOSITION OF THE GRANTS WORKING GROUP THAT ASSESSES THE CLINICAL APPLICATIONS INCLUDES 15 SCIENTIFIC MEMBERS THAT PROVIDE THE MAIN SCIENTIFIC EVALUATION. WE INCLUDE DISEASE AREA EXPERTS, REGULATORY EXPERTISE, CMC PRODUCT DEVELOPMENT, AND OTHER AREAS AS NEEDED. THE GRANTS WORKING GROUP BOARD MEMBERS PARTICIPATE NOT ONLY IN GIVING THE DEI EVALUATION, BUT ALSO PROVIDING THE PATIENT PERSPECTIVE ON THE SIGNIFICANCE AND POTENTIAL IMPACT OF THE PROPOSALS THAT COME TO US AND ALSO PROVIDE OVERSIGHT ON THE REVIEW PROCESS ITSELF.

WE HAVE, IN ADDITION, SCIENTIFIC SPECIALISTS THAT PARTICIPATE ON AN AD HOC BASIS DEPENDING ON WHETHER WE NEED TO FILL AREAS OF KNOWLEDGE OR HAVE KNOWLEDGE GAPS THAT WE NEED TO FILL.

SO WE HAVE ONE APPLICATION FOR CONSIDERATION TODAY. THESE ARE THE BOARD MEMBERS THAT HAVE DECLARED A CONFLICT OF INTEREST WITH THE APPLICATIONS. JUST PLEASE MAKE NOTE OF THAT. AND IT'S JUST A REMINDER AS WE GO INTO THE DETAILS OF THIS APPLICATION AND THE DISCUSSION OF IT.

SO THIS APPLICATION IS CLIN2-14338. IT IS ENTITLED "AUTOLOGOUS T-CELLS TO TREAT

REFRACTORY/RELAPSE PEDIATRIC LIVER CANCER." THE THERAPY IS AN AUTOLOGOUS THERAPY THAT INCLUDES T-CELLS THAT HAVE BEEN GENETICALLY MODIFIED TO TARGET AND KILL CANCER STEM CELLS. EXCUSE ME. NOT CANCER STEM CELLS. IT'S CANCER CELLS.

THE INDICATION IS FOR PEDIATRIC LIVER CANCERS OF DIFFERENT TYPES, AND THE GOAL IS TO COMPLETE A PHASE 1 CLINICAL TRIAL. THE FUNDS REQUESTED IS 10.6 MILLION. THE APPLICANT IS PROVIDING CO-FUNDING OF JUST OVER 7 MILLION, THE 40 PERCENT THAT'S REQUIRED FOR THIS STAGE.

SO A LITTLE BACKGROUND ON PEDIATRIC LIVER CANCERS. THESE INCLUDE DIFFERENT TYPES THAT THIS PARTICULAR THERAPY IS TARGETING. ALL OF THEM ARE RARE AND AFFECT YOUNG CHILDREN AS WELL AS ADOLESCENTS. THE CURRENT TREATMENT, OF COURSE, DEPENDS ON THE SEVERITY OF THE CANCER, BUT MAY INVOLVE SURGERY, CHEMOTHERAPY, LIVER TRANSPLANTATION. THE PROGNOSIS ALSO VARIES DEPENDING ON THE TYPE, BUT THERE ARE MANY HIGH RISK PATIENTS WHERE OVERALL SURVIVAL IS NOT MUCH BETTER THAN 60 PERCENT.

THE VALUE PROPOSITION OF THE PROPOSED THERAPY IS THAT IT OFFERS A POTENTIAL TREATMENT FOR RELAPSE/REFRACTORY PEDIATRIC LIVER CANCERS FOR WHICH

CURRENTLY THERE ARE NO APPROVED THERAPIES.

AND WHY IS THIS A STEM CELL OR GENE THERAPY PROJECT? WELL, THIS IS A CELL THERAPY THAT HAS BEEN GENETICALLY MODIFIED, SO IT QUALIFIES AS A GENE THERAPY APPROACH.

SO IF WE LOOK AT THE PORTFOLIO OF ACTIVE AWARDS AT CIRM, WE CURRENTLY DON'T HAVE ANY ACTIVE AWARDS THAT ARE ADDRESSING PEDIATRIC LIVER CANCERS. SO THIS WOULD REPRESENT A NOVEL AREA IN WHICH WE DON'T CURRENTLY HAVE PROJECTS, AT LEAST AT THE TRANSLATION AWARD CLINICAL STAGE. AND THEN THIS APPLICANT HAS NOT PREVIOUSLY RECEIVED A CIRM AWARD. SO THIS WOULD BE THEIR FIRST.

THE RECOMMENDATION FROM THE GRANTS WORKING GROUP, IN SUMMARY THEN, THIS IS AN APPLICATION THAT HAS EXCEPTIONAL MERIT AND WARRANTS FUNDING. THERE WERE 14 MEMBERS THAT GAVE THIS A SCORE OF 1, ONE MEMBER THAT GAVE IT A SCORE OF 2, AND NONE THAT GAVE IT A SCORE OF 3. THE DEI SCORE GIVEN BY OUR BOARD MEMBERS WAS AN 8 BASED ON THAT SCALE OF ONE TO TEN. AND THE CIRM TEAM RECOMMENDATION IS TO FUND FOR THE AMOUNT OF 10.6 MILLION.

AND SO BACK TO YOU, MR. CHAIRMAN.

CHAIRMAN IMBASCIANI: I'M SORRY FOR SOME TECHNICAL DIFFICULTIES, BUT I HEARD ALL OF THAT,

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GIL, THANK YOU.

ARE THERE ANY -- NO. I'M SORRY. DOES ANYONE HAVE A MOTION TO FUND THE RECOMMENDED APPLICATION?

DR. STAMOS: SO MOVED.

VICE CHAIR BONNEVILLE: SECOND.

CHAIRMAN IMBASCIANI: MOVEMENT FROM DR. STAMOS. WHO SECONDED?

VICE CHAIR BONNEVILLE: I DID.

MR. TOCHER: EXCUSE ME. MR. STAMOS CAN'T MAKE THE MOTION. WE NEED A MEMBER FROM THE APPLICATION REVIEW SUBCOMMITTEE.

DR. STAMOS: SORRY.

MR. ROWLETT: SO MOVED.

MR. TOCHER: THANK YOU, AL. AND WHO WAS THE SECOND?

VICE CHAIR BONNEVILLE: MARIA.

MR. TOCHER: THANK YOU, MARIA.

CHAIRMAN IMBASCIANI: ALL RIGHT. DISCUSSION FROM THE BOARD, PLEASE.

MS. DURAN: MR. CHAIR, I SEE SOMEONE ON THE PHONE WITH A HAND UP. I WOULD LIKE TO GO NEXT AFTER THE PHONE CALL.

CHAIRMAN IMBASCIANI: IF THE PHONE CALL IS A MEMBER OF THE PUBLIC, I'M GOING TO HOLD OFF UNTIL

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THE BOARD MEMBERS HAVE SPOKEN. MS. DURAN, PLEASE.

MS. DURAN: I'M JUST A LITTLE CURIOUS AND SO MAYBE GIL CAN ALSO ADD THIS NOTE OR SUBNOTE. I THINK AS WE, THE BOARD, TRY TO DISTINGUISH BETWEEN VERY RESPONSIVE AND RESPONSIVE ON THE DEI SCORES, I WOULD LOVE TO KNOW WHAT THOSE DISTINCTIONS ARE SO WE CAN ALL BEGIN TO SEE WHAT LOOKS VERY GOOD, WHAT IS VERY RESPONSIVE, AND WHY THEY'RE ONLY GETTING A RESPONSIVE OR LESS THAN RESPONSIVE.

I THINK THERE ARE FINE LINES THERE, BUT I THINK IT'S REALLY CRITICAL FOR US TO UNDERSTAND HOW THE PATIENT ADVOCATE OR THOSE WITH THE ABILITY TO GIVE THAT SCORE ARE VIEWING THIS. WHY ISN'T IT MEETING THE BEST? AND I WOULD LIKE TO KNOW WHAT THAT DISTINCTION IS.

SO MAYBE WHEN GIL REPORTS BACK, HE CAN INDICATE WHY IT DIDN'T GET THAT PERFECT SCORE. WHERE ARE OUR SCIENTIFIC APPLICANTS STILL NEEDING TO LEARN, OR WHAT ARE THEY NOT DOING AS WELL AS THEY COULD DO REACHING THAT PERFECT SCORE, IF YOU WILL. SO I HAVE THAT REQUEST IN, AND MAYBE GIL CAN EVEN ANSWER ON THIS ONE AT THIS STAGE.

DR. SAMBRANO: SURE. I THINK ACTUALLY SOME OF THE BOARD MEMBERS CAN PROBABLY SPEAK TO IT BETTER, BUT I CAN DEFINITELY TELL YOU THAT THIS HAS

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BEEN A WORK IN PROGRESS IN TERMS OF HAVING OUR BOARD MEMBERS USE THIS RUBRIC AND SORT OF GET COMFORTABLE WITH WHERE THEY WANT TO SCORE SOMETHING DEPENDING ON WHAT THEY SEE. SO I THINK IT HAS BEEN AN EDUCATIONAL PROCESS THAT WE'RE GOING TO CONTINUE TO TALK ABOUT SO THAT WE CAN COME UP WITH WHAT IS A PERFECT PROJECT AND WHAT DOES THAT LOOK LIKE VERSUS ONE THAT DOES NOT.

WE DO INCLUDE COMMENTS AND WE TRY TO ENCOURAGE ALL OF OUR BOARD MEMBERS TO INCLUDE COMMENTS THAT GO INTO THE SUMMARY FOR WHAT DROVE THEIR SCORE, WHAT MADE THIS AN 8 OR A 10 OR A 5, TO GIVE YOU A BETTER SENSE OF WHY THEY SCORED WHAT THEY DID. AND SO THAT'S ANOTHER ELEMENT THAT WE WILL CONTINUE TO WORK ON.

MS. DURAN: MAY I DO A FOLLOW-UP, MR. CHAIR?

CHAIRMAN IMBASCIANI: PLEASE.

MS. DURAN: SO, GIL, I'M THINKING -- AND THAT'S GOOD. THANK YOU FOR THAT EXPLANATION. BUT I'M ALSO THINKING THAT FOR THE APPLICANT, THEY NEED TO SEE WHAT LOOKS PERFECT IN OUR EYES OR UNDERSTAND THE THINKING PROCESS BECAUSE I'M HOPING THAT, AT SOME POINT IN TIME, WE CAN POST BEST PRACTICES. WHAT DO THOSE LOOK LIKE, REALLY, REALLY WONDERFUL

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DEI PLANS ASSOCIATED WITH THEIR APPLICATION. SO THAT'S KIND OF WHAT I'M THINKING, NOT JUST FOR US, THE BOARD, BUT ALSO FOR THOSE WHO WILL APPLY, WHAT WE ARE EXPECTING FROM THEM.

DR. SAMBRANO: YES. AND THAT MAKES A LOT OF SENSE. AND WE'VE TAKEN THE FIRST STEP TOWARDS THAT. WE'VE PLACED THE RUBRIC ON THE RESOURCE PAGE THAT WE POINT APPLICANTS TO SO THAT THEY SEE THE RUBRIC THAT'S USED TO SCORE; THAT IS, WHAT CRITERIA ARE USED SPECIFICALLY FOR SOMETHING THAT SCORES BETWEEN AN 8 AND A 10 VERSUS SOMETHING THAT DOES NOT SCORE WELL. SO HOPEFULLY THAT WILL HELP THE APPLICANTS ALSO GET A BETTER UNDERSTANDING.

MS. DURAN: THANK YOU, GIL.

CHAIRMAN IMBASCIANI: ALTHOUGH I SUSPECT THAT THERE IS A DIFFERENCE BETWEEN A RUBRIC AND AN ACTUAL BEST PRACTICE TO SUPPORT WHAT YSABEL WAS SAYING.

DR. SAMBRANO: YES, ABSOLUTELY.

MR. TOCHER: FRED FISHER HAS HIS HAND UP.

CHAIRMAN IMBASCIANI: OKAY. MR. FISHER.

DR. FISHER: THREE YEARS OF ZOOM AND I STILL HAVEN'T FIGURED OUT THE MUTE BUTTON. I DON'T KNOW IF BOARD MEMBERS HAVE SEEN THE RUBRIC, BUT HERE IT IS. AND SO IT MIGHT HELP JUST TO KNOW THAT. AND

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IF BOARD MEMBERS HAVEN'T SEEN THE RUBRIC, YOU SHOULD, BECAUSE THE RUBRIC MAKES IT REALLY EASY TO REVIEW A PROPOSAL AND DETERMINE THE EXTENT TO WHICH THE PROPOSAL IS RESPONSIVE TO THE ELEMENTS IN THE RUBRIC, WHICH IS DIVIDED INTO CATEGORIES. AND EACH OF US HAVE OUR OWN WAY OF IMPLEMENTING THE RUBRIC, BUT, INTERESTINGLY, WE TEND TO COME OUT IN THE SAME GENERAL AREA IN TERMS OF THE FINAL NUMERIC SCORE.

SO IT'S VERY CLEAR WHAT A PROPOSAL HAS TO CONTAIN ON I THINK IT'S -- WELL, THERE'S EIGHT CATEGORIES OR EIGHT RESPONSES ACROSS THREE DIFFERENT MAJOR CATEGORIES. AND DEPENDING ON YOUR RESPONSE DEPENDS ON YOUR SCORE. AND THE APPLICANTS HAVE THE RUBRIC, AND THEY GET SOME PRETTY GOOD INSTRUCTION AND I THINK SUPPORT FROM THE STAFF IN COMPLETING THAT. AND WE HAVE SEEN OVER THE LAST YEAR, I WOULD SAY, THE DEI SECTION HAS IMPROVED DRAMATICALLY FROM APPLICANTS.

I THINK WHERE IT TENDS TO FALL FLAT IS IN THE IMPLEMENTATION OF A PLAN. SO THEY CAN DO A GOOD JOB OF DESCRIBING THE TARGET POPULATION, THE ETHNIC DISTRIBUTION OF THAT POPULATION, ITS PREVALENCE IN CALIFORNIA. THEY DO ALL THAT PRETTY WELL IF THEY'VE DONE A LITTLE BIT OF HOMEWORK. WHERE THEY TEND TO FALL FLAT IS IN THE ACTUAL OUTREACH PLAN. AND OFTEN

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WHEN IT'S A COMPANY, THEY TEND TO PUNT THAT PLAN TO THE TRIAL SITES WHO HAVE GOOD REPUTATIONS, UC'S AND STANFORD AND ELSEWHERE. AND IT'S CLEAR THAT THIS PROCESS IS EDUCATING YOUNG COMPANIES ABOUT THE IMPORTANCE OF DEI, NOT JUST FOR THE APPLICATION, BUT FOR THE WAY THEY RUN THEIR COMPANY.

AND WE'VE SEEN COMMENTS THAT REFLECT SORT OF AN EYE-OPENING EXPERIENCE GOING THROUGH THE DEI AND SOME OF THE QUESTIONS, PARTICULARLY WHEN IT COMES TO HAVING A PLAN TO INCREASE CULTURAL SENSITIVITY ON THE TEAM OR AT PARTNER INSTITUTIONS AND THINGS LIKE THAT. I WON'T GO INTO THE DETAILS OF THE RUBRIC, BUT YOU GET THE IDEA. HOPEFULLY THAT'S HELPFUL.

CHAIRMAN IMBASCIANI: THANK YOU. VICE CHAIR BONNEVILLE HAS HER HAND UP.

VICE CHAIR BONNEVILLE: GOOD MORNING. I ALSO WANTED TO MENTION LAST YEAR AT ISSCR THERE WAS A DEI ROUNDTABLE CONVERSATION. AND THE FACILITATORS OF THAT WE APPROACHED AFTERWARDS. THEY REALLY WERE SO WONDERFUL AND UNDERSTOOD WORKING WITH SCIENCE ORGANIZATIONS TO IMPROVE DEI IN WHATEVER SORT OF MANNER THAT INSTITUTION OR THAT ORGANIZATION NEEDED. THEY WORK WITH NIH AND OTHERS. AND THEY ARE UNDER CONTRACT WITH US NOW. THEY'RE THE CONSULTANTS THAT

WE ARE USING, AND THEY'VE BEEN TALKING TO GIL, THE GWG, THEY'VE LISTENED IN TO UNDERSTAND WHERE THE CHALLENGES ARE. THEY'VE LOOKED AT THE RUBRIC, AND THEY ARE WORKING -- I THINK, YSABEL, YOU MIGHT HAVE SPOKEN TO THEM. AND THEY HAVE REACHED OUT TO SOME OTHER BOARD MEMBERS.

SO I THINK OVER TIME IT WILL ONLY GET BETTER. AND I KNOW THAT THEY HAVE BEEN IMPRESSED WITH A LOT OF WHAT WE'VE PUT IN PLACE. WE ALSO KNOW THAT WE HAVE A WAYS TO GO. SO I THINK THAT WE ARE ON THE RIGHT TRACK. BUT THANKS, YSABEL, FOR THOSE COMMENTS, AND MAYBE WE CAN DO SORT OF A PRESENTATION LATER ON IN THE YEAR ONCE THEY'VE HAD A CHANCE TO SYNTHESIZE EVERYTHING, AND WE CAN GO OVER EVERYTHING THAT WAY.

CHAIRMAN IMBASCIANI: GREAT. THANK YOU. I DON'T SEE ANY OTHER HANDS RAISED IN --

MR. TOCHER: AL ROWLETT HAS HIS HAND RAISED.

CHAIRMAN IMBASCIANI: YES. THERE YOU GO.

MR. ROWLETT: I'D ADD TO MEMBERS OF THE BOARD THAT I'VE SEEN A BETTER AND IMPROVED RESPONSE AND APPRECIATION FOR DEI FROM THE GRANT EVALUATORS. THAT MEMBERS OF -- THE SCIENTIFIC EVALUATORS THAT ARE MEMBERS OF THE GRANT EVALUATION TEAM HAVE ALSO

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BEGUN TO APPRECIATE THE OPERATIONAL COMPONENTS THAT ARE ABSENT IN A PLAN. AND THAT IF IT'S JUST PLATITUDES, A WORD THAT I OFTEN USE, THAT ARE RECITED FROM AN ACADEMIC INSTITUTION WITHOUT SPECIFIC DETAIL, ACTION COMPONENTS, THAT YOU ARE NOW HEARING THE OTHER SCIENTIFIC REVIEWERS TALK ABOUT DEI THAT WAY.

AND, YSABEL, I CAN TELL YOU THAT THAT'S ALMOST A SEISMIC SHIFT FOR ME TO HAVE REVIEWERS BEGIN TO APPRECIATE DEI FROM THAT PERSPECTIVE.

CHAIRMAN IMBASCIANI: THANK YOU, BOARD MEMBER ROWLETT.

SCOTT, DO YOU SEE ANY OTHER HANDS RAISED FROM THE BOARD MEMBERS?

MR. TOCHER: I DON'T SEE ANY OTHER HANDS RAISED FROM THE BOARD, JUST ONE POSSIBLE PUBLIC COMMENT.

CHAIRMAN IMBASCIANI: YES. RIGHT. SO HOW DO WE --

MR. TOCHER: MARIANNE.

MS. DEQUINA-VILLABLANCA: SO FOR THE PHONE NUMBER 1-588-822 1777, IF YOU CAN PRESS STAR 6 TO UNMUTE, AND YOU HAVE THREE MINUTES TO MAKE YOUR COMMENT.

DR. KAUFMAN: YES. MY APOLOGIES. I'M IN

LINE FOR THE MANUFACTURING NETWORK DISCUSSION. I CAN GO BACK ON MUTE AND KEEP IN THE QUEUE FOR THAT.

MR. TOCHER: YES. WE'LL TAKE THAT UP AT THE DISCUSSION OF THAT PROGRAM IN JUST A MOMENT. SO, VITO, THERE'S NO OTHER PUBLIC COMMENT, IT APPEARS.

CHAIRMAN IMBASCIANI: THERE BEING NO OTHER DISCUSSION OR COMMENTS, SCOTT, I COULD ASK YOU TO PLEASE TAKE THE ROLL CALL ON THE MOTION.

MR. TOCHER: SURE. AND JUST TO RESTATE IT, THE MOTION IS TO FUND CLIN2-14338.

MARIA BONNEVILLE.

VICE CHAIR BONNEVILLE: YES.

MR. TOCHER: JUDY CHOU. LEONDRA CLARK-HARVEY.

DR. CLARK-HARVEY: YES.

MR. TOCHER: ANNE-MARIE DULIEGE.

DR. DULIEGE: YES.

MR. TOCHER: YSABEL DURAN.

MS. DURAN: YES.

MR. TOCHER: MARK FISCHER-COLBRIE.

DR. FISCHER-COLBRIE: YES.

MR. TOCHER: FRED FISHER.

DR. FISHER: YES.

MR. TOCHER: VITO IMBASCIANI.

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CHAIRMAN IMBASCIANI: YES.
MR. TOCHER: STEVE JUELSGAARD.
DR. JUELSGAARD: YES.
MR. TOCHER: RICH LAJARA.
MR. LAJARA: YES.
MR. TOCHER: LAUREN MILLER-ROGEN.
MS. MILLER-ROGEN: YES.
MR. TOCHER: ADRIANA PADILLA.
DR. PADILLA: YES.
MR. TOCHER: JOE PANETTA.
MR. PANETTA: YES.
MR. TOCHER: AL ROWLETT.
MR. ROWLETT: YES.
MR. TOCHER: MARV SOUTHARD.
DR. SOUTHARD: YES.
MR. TOCHER: KAROL WATSON.
DR. WATSON: YES.
MR. TOCHER: SUPER. THANK YOU. THE MOTION CARRIES.
CHAIRMAN IMBASCIANI: THANK YOU, BOARD MEMBERS. WE'D LIKE TO NOW MOVE ON TO CONSIDERATION OF THE MANUFACTURING NETWORK PHASE 1 PROGRAM. GIL, WOULD YOU CONTINUE WITH YOUR PRESENTATION.
DR. SAMBRANO: YES. THANK YOU. AND LET ME SHARE MY SCREEN AGAIN.

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SO THESE ARE THE RECOMMENDATIONS FROM THE GRANTS WORKING GROUP RELATED TO THE MANUFACTURING PHASE 1 AWARDS. AND ONCE AGAIN, STARTING WITH OUR MISSION, I THINK IN THIS CASE ONE OF THE IMPORTANT ELEMENTS OF THIS MISSION IS THAT IT'S OUR GUIDING POST FOR THE STRATEGIC PLAN THAT WE HAVE DEVELOPED AND THAT YOU ARE AWARE OF. AND SO THAT COMES INTO PLAY HERE.

WE HAVE WITHIN THE STRATEGIC PLAN THREE MAJOR STRATEGIC THEMES TO ADVANCE WORLD-CLASS SCIENCE, DELIVER REAL-WORLD SOLUTIONS, AND PROVIDE OPPORTUNITY FOR ALL. AND WITHIN EACH OF THESE THEMES, WE HAVE SEVERAL INITIATIVES THAT ARE PROPOSED THAT WE ARE TAKING ACTION ON AND TRYING TO SEE THROUGH. AMONG THEM IS TO CREATE A MANUFACTURING PARTNERSHIP NETWORK AS PART OF DELIVERING REAL-WORLD SOLUTIONS, ALONG WITH OTHER PROGRAMS THAT YOU ARE PROBABLY FAMILIAR WITH, SUCH AS THE ALPHA CLINIC NETWORK AND ITS EXPANSION AND THE CREATION OF THE FUTURE COMMUNITY CARE CENTERS OF EXCELLENCE.

SO WE'RE GOING TO FOCUS HERE ON THE MANUFACTURING PARTNERSHIP NETWORK AND THE VISION OF WHAT THIS MAY LOOK LIKE IF IT'S SUCCESSFUL. WHAT WE HOPE TO BUILD IS A NETWORK OF ACADEMIC GMP

FACILITIES. SO THESE ARE EXISTING GMP FACILITIES THAT ARE AT VARIOUS STAGES OF OPERATION, MEANING SOME ARE BRAND-NEW THAT HAVE JUST OPENED THEIR DOORS WHILE OTHERS HAVE BEEN IN EXISTENCE FOR MANY YEARS. BUT THROUGH A NETWORKING APPROACH, WE WANT TO CREATE SYNERGY BETWEEN AND AMONG ALL OF THESE ACADEMIC CENTERS.

BUT WE ALSO SEE THEM PARTNERING WITH OTHER ELEMENTS THAT WE SUPPORT, SUCH AS THE ALPHA CLINIC NETWORK, FOR EXAMPLE, BY BEING ABLE TO PRODUCE THERAPEUTIC PRODUCTS THAT IS USED AT THOSE CLINICAL SITES, WITH OUR EDUCATION PROGRAM IN ORDER TO SUPPORT TRAINING IN MANUFACTURING AT DIFFERENT LEVELS. SO THAT IS AN IMPORTANT ELEMENT THAT WE ARE INTRODUCING. AND THEN OVER TIME TO DEVELOP PARTNERSHIPS WITH INDUSTRY AND NATIONAL ORGANIZATIONS THAT WILL STRENGTHEN THE NETWORK AND ALLOW THEM TO GAIN A BETTER UNDERSTANDING OF WHAT STANDARDS CAN BE DEVELOPED BOTH THAT COME OUT OF THE NETWORK OR THAT ARE ADOPTED BY THE NETWORK WITH THESE DIFFERENT ORGANIZATIONS AND INDUSTRY.

AND ULTIMATELY THE GOAL IS TO ACCOMPLISH THESE THREE THINGS, TO ACCELERATE AND DERISK THE PATH TO COMMERCIALIZATION FOR THERAPIES THAT INVOLVE CELL AND GENE THERAPY, TO ADVANCE STANDARDS AND

QUALITY BY DESIGN, AND TO BUILD MANUFACTURING LEADERSHIP AND A WORKFORCE THAT WILL SUPPORT THESE MANUFACTURING EFFORTS.

SO THAT'S THE VISION. AND THE WAY WE ARE IMPLEMENTING THIS AT THE MOMENT IS THROUGH TWO DIFFERENT RFA'S. THIS IS A CONCEPT THAT WAS APPROVED BY THE BOARD LAST YEAR. THERE'S TWO PHASES FOR THESE AWARDS. PHASE 1, WHICH IS WHAT WE'RE GOING TO BE TALKING ABOUT TODAY, IS A TWO-YEAR AWARD TO FUND ACADEMIC GMP FACILITIES TO MAKE INITIAL PROGRESS TOWARDS THOSE NETWORK GOALS AND OVERALL VISION. AND I WILL EXPLAIN WHAT SOME OF THOSE CORE ACTIVITIES ARE.

ONCE THIS TWO-YEAR PHASE 1 PROGRAM ENDS, THERE WILL BE A PHASE 2. SO THIS WOULD BE A FUTURE RFA THAT WOULD FUND COLLABORATIVE EFFORTS WITH THESE GMP FACILITIES AND PARTNERS IN INDUSTRY AND OTHERS TO ENHANCE AND SCALE UP THE ACTIVITIES THAT WERE SUPPORTED UNDER THE PHASE 1.

WE ALSO ENVISION THAT THROUGHOUT THIS WHOLE SEQUENCE OF EVENTS, BEGINNING WITH THE LAUNCHING OF THE PHASE 1, THAT WE WOULD SET UP A STEERING COMMITTEE THAT IS DRIVEN BY CIRM BUT ALSO COMPOSED OF AWARDEES, MEANING THE PROGRAM DIRECTORS AS WELL AS INDUSTRY PARTNERS AND OTHER EXTERNAL

REPRESENTATIVES THAT TOGETHER CAN HELP DRIVE COLLABORATION, KNOWLEDGE SHARING, AND STANDARD SETTING FOR THIS NETWORK.

THE CORE ACTIVITIES UNDER THE PHASE 1 AWARDS ARE THREE MAIN AREAS. WE HAVE ASKED ALL THE APPLICANTS TO ADDRESS THESE IN THEIR APPLICATION. THE FIRST IS IMPLEMENTATION OF QUALITY DRIVEN ENHANCEMENTS THAT WOULD BE DERISK AND ACCELERATE EARLY AND LATE STAGE PROCESS DEVELOPMENT AND GMP MANUFACTURING OF CELL AND GENE THERAPIES. THESE ARE ENHANCEMENTS THAT ARE IN ADDITION TO WHAT THEY MAY BE DOING ALREADY, ADOPTING QUALITY BY DESIGN APPROACHES, DEVELOPING ELECTRONIC SYSTEMS FOR BATCH RECORDS AND SO ON THAT MAY BE APPROPRIATE FOR THEIR GMP FACILITY GIVEN, AGAIN, THAT THEY ARE ALL AT PERHAPS DIFFERENT STAGES OF DEVELOPMENT.

WE ALSO ASK THAT THEY ALL IDENTIFY AN AREA OF SPECIALIZATION, THIS CAN BE ONE OR MORE AREAS, THAT OVERCOME A BOTTLENECK IN DEVELOPMENT AND DELIVERY OF CELL AND GENE THERAPIES. SO SOME OF THESE COULD BE, FOR EXAMPLE, A FOCUS ON RARE DISEASES. IT COULD BE A FOCUS ON DEVELOPING VECTOR MANUFACTURING OR CELL MANUFACTURING. SO THOSE ARE SOME EXAMPLES.

AND THEN ALL OF THEM ARE ASKED TO DEVELOP

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A WORKFORCE DEVELOPMENT PROGRAM FOR TECHNICAL AND LEADERSHIP POSITIONS, MEANING A TRAINING PROGRAM OF SOME SORT TO HELP UNDERSTAND AND ENHANCE THE WORKFORCE IN THE MANUFACTURING ARENA. AND IDEALLY THIS COULD BE DONE IN PARTNERSHIP WITH CIRM EDUCATION PROGRAMS SUCH AS BRIDGES OR COMPASS, OR EVEN SPARKS MAYBE. IT IS UP TO THE APPLICANT TO PROPOSE THIS, BUT THEY ALL HAVE TO INCLUDE EACH OF THESE THREE ELEMENTS.

IN ADDITION TO THAT, WE ALSO ASK THE APPLICANTS TO CONSIDER VERY CAREFULLY KNOWLEDGE SHARING. APPLICANTS NEED TO DEVELOP CLEAR PLANS THAT ARE INTENDED TO CAPTURE, DISSEMINATE WITHIN THE NETWORK THEIR OPERATIONAL DATA PROTOCOLS, THEIR PROCESS EXPERTISE, AND SO ON WITH THE EXPECTATION THAT IF THEY'RE GOING TO FUNCTION AS A NETWORK, THEY NEED TO HAVE A WELL-DEVELOPED APPROACH FOR SHARING THAT KNOWLEDGE WITH OTHERS. AND, OF COURSE, THIS MAY ULTIMATELY EXTEND BEYOND THE NETWORK TO OTHER PARTNERS OR PARTNERSHIPS THAT THEY DEVELOP.

WE ALSO ASK THEM TO PRESENT AN ORGANIZATIONAL BUSINESS PLAN. SO ALL APPLICANTS ARE REQUIRED TO DESCRIBE HOW THEY WILL MAINTAIN SUSTAINABILITY OF THEIR OPERATIONS, PARTICULARLY THE ENHANCEMENTS THAT ARE MADE THROUGH THIS AWARD,

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BEYOND THE IMMEDIATE PROJECT PERIOD AS THEY MOVE INTO PHASE 2 AND/OR POTENTIALLY BEYOND. YOU WANT A NETWORK THAT IS CREATED THROUGH THESE EFFORTS TO BE ONE THAT IS SUSTAINED AND CONTINUED BEYOND CIRM'S ABILITY TO SUPPORT IT.

AND THEN, LASTLY, WE ASK ALL APPLICANTS TO INCLUDE PLANS TO ADDRESS UNDERSERVED COMMUNITIES, HOW IT IS THAT THE PROPOSED PROJECT ACTIVITIES ARE GOING TO IMPROVE ACCESS TO CELL AND GENE THERAPIES BY UNDERSERVED AND DISPROPORTIONATELY AFFECTED POPULATIONS, HOW THE PROJECT TEAM WILL BRING DIVERSE AND INCLUSIVE PERSPECTIVES AND EXPERIENCE INTO IMPLEMENTING THOSE ACTIVITIES, HOW WELL THE PROJECT TEAM DEMONSTRATES A SUCCESSFUL TRACK RECORD FOR PROMOTING AND VALUING DEI AND HOW ANY PROPOSED WORKFORCE DEVELOPMENT PROGRAM WILL INCREASE WORKFORCE PARTICIPATION BY UNDERSERVED AND DISPROPORTIONATELY AFFECTED POPULATIONS IN CALIFORNIA.

ALL RIGHT. SO A SUMMARY OF THE AWARD FEATURES FOR THIS PROGRAM. AS MENTIONED, THE BOARD HAS ALREADY APPROVED THE CONCEPT THAT ALLOCATED 80 MILLION TO SUPPORT THE TWO AWARD PHASES. THE PHASE 1 AWARDS, WHICH WE ARE TALKING ABOUT TODAY, HAVE AN ALLOCATION OF 20 MILLION. AND EACH PHASE 1 AWARD

PROVIDES UP TO 2 MILLION FOR TWO YEARS. SO THAT ALLOWS FOR UP TO TEN APPLICATIONS TO BE SUPPORTED.

WE HAVE NINE APPLICATIONS THAT WERE SUBMITTED AND ACCEPTED FOR REVIEW. SO CLEARLY, THE BUDGET WOULD SUPPORT ALL OF THEM IF NEED BE. AND JUST TO NOTE, THREE IN PARTICULAR ARE RELATIVELY NEW MANUFACTURING FACILITIES WHILE OTHERS HAVE BEEN ESTABLISHED FOR A WHILE. OUR INSTRUCTIONS TO THE GRANTS WORKING GROUP WAS TO LOOK AT THESE APPLICANTS AT THE STAGE THEY ARE IN AND THEIR PROPOSAL TO CREATE THOSE ENHANCEMENTS WITHIN THE TWO-YEAR TIME PERIOD SUCH THAT THEY'RE NOT COMPETING WITH EACH OTHER NECESSARILY, BUT THAT THEY SHOULD BE LOOKED AT FROM THE STARTING POSITION TO WHERE THEY WANT TO BE IN TWO YEARS IS THE BASIS FOR ASSESSING MERIT.

THE GRANTS WORKING GROUP WAS ALSO INSTRUCTED TO RECOMMEND AS MANY OR AS FEW AS THEY FIND MERITORIOUS. THE SCORING SYSTEM THAT WAS USED IS SIMILAR TO CLIN IN THAT IT USES THE SYSTEM OF 1, 2, OR 3. HOWEVER, IN THIS CASE THE SCORE OF 2 IS NOT AUTOMATIC. AND THIS IS BECAUSE THIS IS NOT A RECURRING OPPORTUNITY. THIS IS A ONE-TIME OPPORTUNITY THAT WE ARE GIVING. AND SO DEPENDING ON THE CIRCUMSTANCES OF THE REVIEW, IT IS UP TO THE APPLICATION REVIEW SUBCOMMITTEE TO ALLOW THAT

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REVISION AND RESUBMISSION TO MOVE FORWARD IF WARRANTED. AND I'LL COME BACK TO THAT AGAIN A LITTLE LATER AS IT'S PERTINENT TO THE RECOMMENDATIONS THAT WE ARE MAKING ON THIS.

THE SCIENTIFIC REVIEW CRITERIA THAT IS THE BASIS FOR THE SCIENTIFIC SCORE IS BASED ON THESE FOUR QUESTIONS. DOES THE PROJECT OFFER A SIGNIFICANT VALUE PROPOSITION THAT WOULD CONTRIBUTE TO THE CREATION OF A CALIFORNIA CELL AND GENE THERAPY NETWORK CAPABLE OF ACCELERATING MANUFACTURING DEVELOPMENTS, ADVANCING INDUSTRY STANDARDS IN MANUFACTURING, AND BUILDING AN INCLUSIVE MANUFACTURING WORKFORCE. SO THAT'S BASICALLY IS THE OVERALL VALUE PROPOSITION.

BUT IN ADDITION, IS THE PROJECT WELL PLANNED AND DESIGNED? IS IT FEASIBLE? AND DOES IT SERVE THE NEEDS OF UNDERSERVED AND DISPROPORTIONATELY AFFECTED COMMUNITIES, MEANING DOES IT UPHOLD THE PRINCIPLES OF DEI?

I WANT TO POINT OUT JUST A UNIQUE FEATURE OF THE REVIEW THAT WE IMPLEMENTED FOR THE MANUFACTURING, WE ALSO DID THIS FOR ALPHA CLINICS, WHERE THE APPLICANT INTERACTS WITH THE GRANTS WORKING GROUP PANEL FOR PART OF THE REVIEW. THE REVIEW PANEL HAS AN INITIAL DISCUSSION ABOUT EACH

APPLICATION, BUT THEN WE INVITE THE APPLICANT TO GIVE A TEN-MINUTE PRESENTATION OR PITCH ABOUT THEIR APPLICATION TO THE GRANTS WORKING GROUP FOLLOWED BY A Q AND A PERIOD WHERE THE PANEL CAN GET CLARIFICATION OR ADDITIONAL INFORMATION ABOUT THE APPLICATION AND/OR PROPOSAL.

AND THEN THERE'S A WRAP-UP AFTER THAT, DISCUSSION ONCE THE APPLICANT LEAVES, BY THE GRANTS WORKING GROUP IN DOING THEIR ASSESSMENT. AND SO WE GO THROUGH AND WENT THROUGH THIS PROCESS EACH OF THE NINE APPLICATIONS THAT WERE SUBMITTED.

THE COMPOSITION FOR THE GRANTS WORKING GROUP WAS SLIGHTLY DIFFERENT IN THIS CASE. WE DID NOT HAVE THE NEED FOR SCIENTIFIC SPECIALISTS SINCE WE WERE ABLE TO ASSEMBLE A PANEL THAT WAS FOCUSED ON MANUFACTURING EXPERTISE AND EDUCATIONAL TRAINING IN MANUFACTURING AMONG THE 15 MEMBERS THAT WE HAD. SO THE COMPOSITION OF THE GRANTS WORKING GROUP IN THIS CASE WAS JUST THE SCIENTIFIC GWG MEMBERS AND THE GRANTS WORKING GROUP BOARD MEMBERS.

ALL RIGHT. SO THE SUMMARY OF THE RECOMMENDATIONS FROM THE GRANTS WORKING GROUP PANEL ON THESE NINE APPLICATIONS IS AS FOLLOWS. THERE WERE FIVE RECEIVED A SCORE OF 1 TO FUND. THE TOTAL AMOUNT REQUESTED FOR THOSE FIVE APPLICATIONS IS JUST

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UNDER 10 MILLION. WE HAVE 20 MILLION AVAILABLE AS NOTED BEFORE. THERE WERE FOUR APPLICATIONS THAT RECEIVED A SCORE OF 2, AND THAT TOTALS ABOUT 7.5 MILLION. THERE WERE NO APPLICATIONS THAT RECEIVED A SCORE OF 3.

AND IN THE SCORING THERE'S ALSO THE OPPORTUNITY TO QUALIFY FOR A MINORITY REPORT. SO WHAT A MINORITY REPORT IS, JUST AS A REMINDER, IS ANY APPLICATION THAT'S NOT RECOMMENDED FOR FUNDING, MEANING IN THIS CASE THAT IT DID NOT RECEIVE A SCORE OF 1, BUT WHICH HAD 35 PERCENT OR MORE MEMBERS SCORE TO FUND THE APPLICATION MUST INCLUDE A MINORITY REPORT. AND SO THAT MINORITY REPORT IS BASICALLY A PARAGRAPH THAT WE INCLUDE WITH THE REVIEW SUMMARY THAT PROVIDES A SYNOPSIS OF THE OPINION OF REVIEWERS THAT SCORED THAT APPLICATION NOT 85 OR ABOVE, BUT A 1.

SO THERE WERE TWO APPLICATIONS THAT, BECAUSE THEY HAD ENOUGH MEMBERS GIVING IT A SCORE OF 1, THAT THEY QUALIFIED FOR A MINORITY REPORT. AND SO THOSE ARE THESE TWO APPLICATIONS DOWN HERE. THE MINORITY REPORT HAS TYPICALLY BEEN A TRIGGER FOR US TO LOOK MORE CAREFULLY AT THOSE APPLICATIONS TO SEE IF WE WANT TO PROVIDE A RECOMMENDATION ONE WAY THE OTHER ON THOSE. BUT GIVEN THE CIRCUMSTANCES OF THIS

REVIEW, WE ESSENTIALLY LOOKED AT ALL FOUR THAT RECEIVED A SCORE OF 2. AND IN LOOKING AT THESE APPLICATIONS, BECAUSE THEY RECEIVED A SCORE OF 2, THIS IS A NEEDS IMPROVEMENT. IT'S NOT A RECOMMENDATION TO NOT FUND, AND IT'S NOT A RECOMMENDATION TO FUND. IT REALLY IS SOMETHING THAT THE GRANTS WORKING GROUP SCORED WITH THE IDEA AND THE POSSIBILITY THAT THESE COULD COME BACK IN A REVISED FORM WITH ADDITIONAL INFORMATION FOR THEM TO LOOK AT. BUT, AGAIN, SINCE THIS IS NOT A RECURRING OPPORTUNITY, IT NEEDS THE ACTIVE AGREEMENT OF APPLICATION REVIEW SUBCOMMITTEE TO DO THAT.

SO WE LOOKED AT THESE APPLICATIONS. WE FEEL THAT ALL OF THESE APPLICATIONS HAVE CONCERNS FROM THE GRANTS WORKING GROUP THAT ARE ALL ADDRESSABLE, MEANING THEY ARE CLARIFICATIONS AND/OR ADDITIONAL INFORMATION THAT CAN BE PROVIDED BY THE APPLICANT TO ADDRESS THOSE CONCERNS. WE FEEL THAT A REVISION, AS USUALLY IS THE CASE WITH THE CLINICAL PROGRAM, ALLOWS AN OPPORTUNITY FOR A REAL IMPROVEMENT OF THESE PROPOSALS. AND WE HAVE A BUDGET THAT'S ALLOCATED THAT ALLOWS US TO FUND ALL THE PROGRAMS SHOULD THEY ALL MERIT IT.

WE ALSO FEEL THAT THE NETWORK AS A WHOLE AND THAT VISION THAT I SHOWED YOU AT THE BEGINNING

BENEFITS FROM HAVING AS MANY PROGRAMS WITHIN IT AS POSSIBLE.

SO GIVEN ALL OF THAT, OUR TEAM RECOMMENDATION IS THAT ALL OF THE APPLICATIONS THAT RECEIVED A SCORE OF 2, THESE FOUR, BE GIVEN THE OPPORTUNITY TO REVISE THOSE APPLICATIONS AND RESUBMIT IT SO THAT WE CAN THEN BRING IT BACK TO THE PANEL TO EVALUATE THOSE REVISIONS AND CONSIDER THEM AGAIN. THIS IS A PROCESS THAT WE CAN IMPLEMENT WITHIN A THREE-MONTH PERIOD. WE ENVISION THAT WE WOULD HAVE A REVIEW THAT WOULD OCCUR AT EITHER THE END OF JULY OR BEGINNING OF AUGUST AND WOULD COME BACK TO THE BOARD IN AUGUST OR SEPTEMBER, ASSUMING WE WOULD GO FORWARD WITH THAT.

SO THAT'S ON THOSE FOUR. WE ALSO WOULD AGREE WITH THE GRANTS WORKING GROUP RECOMMENDATIONS TO FUND THE APPLICATIONS THAT RECEIVED A SCORE OF 1. SO THOSE ARE THE RECOMMENDATIONS FROM US AND THE GRANTS WORKING GROUP.

AND BEFORE WE GET INTO DISCUSSION, ONCE AGAIN, A REMINDER OF THOSE THAT HAVE DECLARED A CONFLICT OF INTEREST WITH APPLICATIONS THAT ARE INVOLVED IN THE MANUFACTURING NETWORK OPPORTUNITY. SO IF YOUR NAME IS UP HERE, JUST BE MINDFUL OF THE FACT THAT YOU HAVE A CONFLICT.

I WILL ALSO SHOW THE TABLE THAT SHOWS ALL THE APPLICATIONS, AND I'LL PUT THAT UP IN JUST A SECOND. OTHERWISE, I'LL TURN IT BACK TO YOU.

CHAIRMAN IMBASCIANI: THANK YOU. I DON'T WANT TO PROCEED UNTIL I SEE THAT RANKING.

DR. SAMBRANO: THERE WE GO.

CHAIRMAN IMBASCIANI: GOOD. OKAY. FOR THE NEWER BOARD MEMBERS, NOW WE BEGIN THAT PART WHICH I LIKEN TO CAT'S CRADLE. IT MAY BE A LITTLE CONFUSING AT TIMES; BUT AT THE END, THE CIRCLE HAS BEEN SQUARED AND WE'VE COVERED ALL THE BASES. WHAT I MEAN BY THAT IS I'D LIKE TO ENTERTAIN A MOTION FROM ANYONE ON THE BOARD IF THEY LIKE TO MOVE ANY OF THE APPLICATIONS THAT ARE IN TIER II, THAT IS THE ONES WITH A SCORE 2 AT THE BOTTOM, IF THEY WOULD LIKE TO MOVE THEM FROM TIER II UP TO TIER I. I DO SEE THE ONE FROM THE PUBLIC. DO WE HAVE SOMEONE FROM THE BOARD YET?

DR. FISCHER-COLBRIE: YEAH. MARK FISCHER-COLBRIE FROM THE BOARD. I'D LIKE TO HAVE A DISCUSSION ABOUT THAT POSSIBILITY, IN PARTICULAR WITH 14562, AS I NOTE THAT THE VOTE WAS SEVEN TO SEVEN. BUT AS ONE LOOKS AT THE DETAILED CONSIDERATION FOR EACH OF THE BUCKETS, THE PRETTY OVERWHELMING MAJORITY FOR EACH OF THE INDIVIDUAL

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BUCKETS THAT REPRESENT THE DETAILED BUILDUP OF THAT SCORE. THERE WAS VERY FAVORABLE RESPONSE AND DISCUSSION. SO I'M TRYING TO RECONCILE THE INDIVIDUAL BUCKETS, IF YOU WILL, OF THE AGGREGATED TOTAL. AND FURTHER, CONFIRM THE STAFF'S VIEW ON, IN PARTICULAR, 14562.

DR. SOUTHARD: SO WITH REGARD TO THE MOTION, I WOULD A MAKE A MOTION TO MOVE ALL FOUR UP TO TIER I.

CHAIRMAN IMBASCIANI: ALL RIGHT. WE HAVE A MOTION. DO WE HAVE A SECOND TO MOVE ALL FOUR TO TIER I? I DON'T HEAR A SECOND YET. FAILING A SECOND, MARV, SORRY TO SAY THE MOTION DOESN'T STAND. LET'S GO BACK TO THE REQUEST. ARE THERE ANY APPLICATIONS THAT MEMBERS WOULD LIKE TO MOVE INDIVIDUALLY FROM TIER II UP TO TIER I?

DR. SOUTHARD: I WILL MAKE -- TRY AGAIN AND TRY TO MOVE 14562 AND 14667 UP.

CHAIRMAN IMBASCIANI: I'M WONDERING, AND I'M GOING TO ASK SCOTT OR OTHERS WITH MORE EXPERIENCE, WOULD IT BE BETTER FOR MARV TO SEPARATE THESE OUT INDIVIDUALLY AND MAKE -- TO REITERATE ONE AFTER THE OTHER RATHER THAN LUMP THEM TOGETHER?

MR. TOCHER: THANK YOU. THAT'S A GOOD QUESTION. SOMETIMES FOR CONFLICTS PURPOSES, WE LIKE

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TO SPLIT THEM OUT JUST TO ALLOW THE GREATEST PARTICIPATION POSSIBLE. IN THIS CASE THERE IS ONE MEMBER WITH A CONFLICT AS TO THOSE APPLICATIONS. SO IT'S REALLY THE PLEASURE OF THE MOVER.

CHAIRMAN IMBASCIANI: MARVIN, THAT WAS A FRIENDLY SUGGESTION, I THINK.

DR. SOUTHARD: SO I'LL ASK US TO CONSIDER JUST 14562 THEN.

CHAIRMAN IMBASCIANI: THANK YOU. THERE'S A MOTION. DO WE HAVE A SECOND?

DR. FISCHER-COLBRIE: SECOND.

MR. TOCHER: WHO IS THAT?

DR. FISCHER-COLBRIE: MARK FISCHER-COLBRIE.

CHAIRMAN IMBASCIANI: OKAY. WE CAN DISCUSS THIS. AND TO THE MEMBER OF THE PUBLIC WITH HIS HAND RAISED, I PRESUME IT'S RAISED FOR THIS PARTICULAR NUMBER, 14562.

DR. KAUFMAN: YES, THAT'S CORRECT.

CHAIRMAN IMBASCIANI: OKAY. HOLD YOUR THOUGHTS UNTIL WE HEAR FROM THE BOARD MEMBERS. THANK YOU SO MUCH. MEMBER DULIEGE.

DR. DULIEGE: YES. GOOD MORNING, EVERYBODY. VITO, NICE TO SEE YOU AT THE HELM NOW. I'M WONDERING WHY WE SHOULD DO THAT. I WANT TO

APPLAUD, AGAIN, ONCE MORE, MANY MORE TIMES BEFORE, THE VERY CAREFUL WAY THE CIRM IS HANDLING THIS SELECTION PROCESS OF GRANTS. AND THERE'S A REASON FOR THAT. AND WE SHOULD ONLY APPROVE GRANTS THAT HAVE THE VAST MAJORITY OF ONE. THAT'S THE QUALITY LEVEL WE WANT TO SUPPORT.

FOR THOSE THAT ARE ABOUT EVEN, AND I WOULD SAY THAT THE TWO THAT ARE IN QUESTION TODAY ARE JUST ABOUT EVEN, THERE IS AN OPPORTUNITY FOR THESE APPLICANTS TO IMPROVE THEIR APPLICATION, GO BACK, AND THEY WILL VERY LIKELY BE FUNDED. SO I WOULD NOT SUPPORT CHANGING A PROCESS THAT HAS BEEN VERY CAREFULLY EVALUATED, EXPERIENCE, VETTED BY THE CIRM AND BY THE BOARD OVER THE YEARS TO SPEED UP THINGS. IT IS NOT A SITUATION WHERE WE WANT TO SPEED UP CMC PROCESS THAT IS SO COMPLEX, SO INNOVATIVE IN THE CONTEXT OF STEM CELLS MANUFACTURING THAT WE REALLY WANT TO FUND ONLY THE VERY BEST APPLICANTS THAT CAN PROVE THAT THEY CAN BE THE BEST APPLICANTS.

CHAIRMAN IMBASCIANI: THANK YOU, ANNE-MARIE. I SEE DR. JUELSGAARD.

MR. JUELSGAARD: YES. THANK YOU, DR. IMBASCIANI. SO THIS IS REALLY -- THIS QUESTION IS AIMED AT GIL. IT'S ACTUALLY A REITERATION OF MARV'S QUESTION BECAUSE I DO FIND, AND IT'S A PROCESS

QUESTION, BECAUSE I FIND IT BOTH COUNTERINTUITIVE AND CONFUSING. IF YOU LOOK AT, AS MARV SUGGESTED, THAT THE INDIVIDUAL SCORING FOR EACH OF THE COMPONENT AREAS, YOU WILL NOTICE THAT THE BROAD MAJORITY OF PEOPLE VOTED FAVORABLY, VOTED YES IN EACH OF THOSE. AND YET WHEN IT CAME DOWN TO THE COMPOSITE SCORE, SOMEHOW THE SWITCH FLIPPED AND PEOPLE DECIDED, WELL, IT REALLY WASN'T THAT GOOD AFTER ALL.

SO, GIL, CAN YOU HELP -- YOU WERE INVOLVED IN ALL OF THIS -- HELP DESCRIBE HOW THIS HAPPENS, HOW IT IS THAT PEOPLE SEEM TO GO FROM THINKING THIS IS IN ITS INDIVIDUAL SEGMENTS QUITE ACCEPTABLE TO THINKING OVERALL IT'S NOT WORTHY OF APPROVAL?

DR. SAMBRANO: YEAH. THANK YOU FOR THE QUESTION. AND IT CAN BE CONFUSING. SO LET ME TRY TO TAKE YOU THROUGH THAT.

WHEN THE GRANTS WORKING GROUP IS MAKING AN ASSESSMENT OF AN APPLICATION, THEY ARE FOCUSED ON THE OVERALL SCORE THAT THEY WANT TO GIVE IT. SO WHEN THEY ENGAGE IN THE DISCUSSION AND SHARE WHAT SCORE THEY'RE GOING TO GIVE IT, THEY SAY IT'S EITHER A ONE, A TWO, OR A THREE. AND THE CONVERSATION ALL RELATES TO ULTIMATELY DO THEY WANT TO FUND IT OR NOT. SO WHEN THEY COME TO A SCORE OF 2, IT MEANS

THAT THEY REALLY THINK IT NEEDS HELP.

NOW, WHEN THEY GO TO WRITE THEIR CRITIQUE, WHICH IS WHAT YOU SEE IN THE SUMMARY, AND PUT IN THEIR FINAL COMMENTS, WHICH WE ASK THEM TELL US WHAT ULTIMATELY DROVE YOUR SCORE. AND IF THEY LOOK AT EACH OF THE REVIEW CRITERIA, LIKE THE SIGNIFICANCE AND IMPACT, THE QUESTION IS DID THEY MEET THIS CRITERION OR NOT. AND IN MOST CASES, IT MAY BE A YES DESPITE A SCORE OF 2 OR EVEN SOMETIMES DESPITE A SCORE OF 3. IN SOME CASES YOU WILL SEE THAT THEY WILL ONLY HAVE ONE AREA, MAYBE IT'S FEASIBILITY, WHERE MOST OF THE DIFFERENCE IN OPINION MIGHT EXIST AND THAT POINTS YOU TO WHERE THAT LOWER SCORE MAY HAVE MOSTLY HINGED UPON.

AND SO THE NUMBERS THAT YOU SEE RELATED TO EACH OF THE CRITERIA ARE NOT PART OF THE SCORE. THEY DON'T -- THEY'RE NOT A COMPOSITE OR THEY DON'T MAKE UP WHAT ULTIMATELY IS THE SCORE. IT ACTUALLY WORKS THE OTHER WAY AROUND. IT'S MORE OF AN EXPLANATION OF WHERE IT IS THAT THE SCORE DID WELL OR NOT SO WELL.

SO I KNOW IT'S CONFUSING, BUT HOPEFULLY THAT PROVIDES A LITTLE MORE LIGHT AS TO HOW THAT WORKS.

MR. JUELSGAARD: WELL, THANK YOU FOR THAT,

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GIL. FOR ME IT STILL SUGGESTS A DISCONNECT. I FAIL TO SEE HOW YOU CAN SAY, WELL, IT NEEDS HELP, BUT THEN IN THE INDIVIDUAL SCORING, NOBODY -- THE MAJORITY DON'T SEE A WAY THAT IT NEEDS HELP. SO I'M STILL A LITTLE, I GUESS, LESS THAN SANGUINE ABOUT HOW THIS APPROACH WORKS. BUT NONETHELESS, I ACCEPT WHAT YOU SAID.

CHAIRMAN IMBASCIANI: I SEE MARK FISCHER-COLBRIE PLEASE.

DR. FISCHER-COLBRIE: YEAH. JUST A COUPLE OF QUICK FOLLOW-UP QUESTIONS. IF YOU CAN REMIND ME, RELATED TO A 2 ON OTHER GRANTS, THERE'S A TIME CYCLE FOR RESUBMISSION AND REAPPLICATION. CAN YOU REMIND ME WHEN THIS GRANT WOULD COME UP AGAIN IS THE FIRST QUESTION.

AND THE SECOND QUESTION IS IS THERE A PARTICULAR POSITION BY THE STAFF ON THIS PARTICULAR APPLICATION AS TO FUND, NOT FUND, OR JUST AGNOSTIC ABOUT IT? SO THANKS FOR THE ANSWER FOR BOTH QUESTIONS.

DR. SAMBRANO: SURE. ABSOLUTELY. AS I MENTIONED BEFORE, THIS IS NOT A RECURRING OPPORTUNITY AS WE DO WITH CLIN WHERE YOU HAVE A DEADLINE AT THE END OF EVERY MONTH. AND SO THEN WE HAVE A REVISION SYSTEM THAT CAN EASILY BE

IMPLEMENTED. HERE IT REQUIRES AGREEMENT BY THE APPLICATION REVIEW SUBCOMMITTEE FOR US TO MOVE FORWARD WITH HAVING ANOTHER REVIEW. SO IF WE HAVE APPLICATIONS THAT HAVE A SCORE OF 2, THAT MEANS THAT THE GRANTS WORKING GROUP REALLY FELT THESE NEED IMPROVEMENT AND CAN IMPROVE AND THEY WOULD LIKE TO SEE THEM AGAIN. SO WE WOULD SCHEDULE ANOTHER REVIEW FOLLOWING A REVISION PERIOD. AND SO WE WOULD GIVE THE APPLICANTS ABOUT A MONTH TO REVISE, A FEW WEEKS FOR THE COMMITTEE, THE GRANTS WORKING GROUP, TO LOOK AT THESE. SO WE ARE LOOKING AT ABOUT THE END OF JULY, BEGINNING OF AUGUST WHEN THEY WOULD BE REVIEWED AGAIN. AND THEN EITHER END OF AUGUST OR SEPTEMBER WHEN IT WOULD COME BACK TO THE APPLICATION REVIEW SUBCOMMITTEE FOR A RECONSIDERATION OF THOSE APPLICATIONS.

DR. FISCHER-COLBRIE: OKAY. AND THEN STAFF'S PARTICULAR --

DR. SAMBRANO: WELL, NO, OUR POSITION OR RECOMMENDATION IS THAT ALL THAT RECEIVED A SCORE OF 2 BE ALLOWED TO REVISE AND RESUBMIT. WE THINK THAT ALL OF THEM HAVE AREAS THAT ARE QUITE ADDRESSABLE. EVEN THOUGH, AS WAS NOTED, YOU HAVE ONE APPLICATION THAT HAD A SPLIT VOTE OF SEVEN OF ONE AND TWO AND OTHERS AT THE OTHER EXTREME, THEY ALL HAVE THE

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OPPORTUNITY TO IMPROVE AND VERY LIKELY ARE GOING TO COME OUT OF THAT PROCESS WITH A BETTER APPLICATION OR A BETTER PROPOSAL TO THE BENEFIT EVERYONE.

SO OUR RECOMMENDATION IS TO HAVE THEM ALL GIVEN THE OPPORTUNITY TO REVISE THEIR APPLICATION AND RESUBMIT IT FOR ANOTHER LOOK BY THE GRANTS WORKING GROUP.

DR. FISCHER-COLBRIE: OKAY. GIVEN THAT THERE IS CLARITY AROUND THE PROCESS FOR A FOLLOW-UP FOR A CORRECTION, IF YOU WILL, THEN I'M IN FAVOR OF NOT MOVING THE APPLICATION FORWARD.

DR. SOUTHARD: I JUST WANTED TO CLARIFY THE PROCESS. SO IF WE -- ALL FOUR OF THEM WILL HAVE A CHANCE TO RESUBMIT IF WE SAY DON'T MOVE TO THE TIER I AT THIS POINT? OR DO WE NEED TO MOVE THEM TO TIER I IN ORDER TO HAVE THEM HAVE A CHANCE TO RESUBMIT?

DR. SAMBRANO: NO. YOU DON'T HAVE TO MOVE THEM UP TO TIER I FOR THEM TO RESUBMIT. YOU JUST HAVE TO AFFIRM THAT WITH A SCORE OF 2, YOU WANT THEM TO RESUBMIT AND REVISE THEIR APPLICATIONS.

DR. SOUTHARD: OKAY. THANK YOU. THAT HELPS.

MR. TOCHER: VITO, I BELIEVE YOU'RE MUTED IF YOU'RE TRYING TO SPEAK.

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CHAIRMAN IMBASCIANI: THANK YOU. MARIANNE, DO YOU SEE ANY OTHER HANDS PLEASE?

MR. TOCHER: FRED FISHER'S HAND IS UP.

CHAIRMAN IMBASCIANI: OKAY. BOARD MEMBER FISHER PLEASE.

DR. FISHER: I'M JUST WONDERING -- BY THE WAY, I SUPPORT THE IDEA OF NOT MOVING THOSE FOUR UP AND HAVING THEM RESUBMIT. I DON'T KNOW IF WE NEED A MOTION ABOUT THAT OR NOT. BUT IF THE FIVE THAT ARE IN GREEN ARE FUNDED, WHAT GAPS REMAIN IN THE STATE'S MANUFACTURING NETWORK INFRASTRUCTURE THAT SUGGESTS THAT WE NEED MORE -- WE NEED MORE PROPOSALS BECAUSE WE DON'T HAVE ENOUGH? DO WE LOOK AT IT THAT WAY?

DR. SAMBRANO: WOULD YOU LIKE ME TO RESPOND TO THAT?

CHAIRMAN IMBASCIANI: YES.

DR. SAMBRANO: SO, FRED, THAT'S A GREAT QUESTION. I THINK THE WAY WE'VE BEEN LOOKING AT IT, ALL OF THESE REPRESENT THE MANUFACTURING FACILITIES THAT ARE CURRENTLY IN OPERATION AND THAT IDEALLY WE WOULD LIKE ALL OF THEM TO BE PART OF THE SAME SET OF STANDARDS, THE SAME NETWORK THAT WOULD HELP SYNERGIZE AND CREATE THE VISION THAT I TALKED ABOUT IN THE INTRODUCTION. SO IN AN IDEAL WORLD, ALL OF THEM ARE MERITORIOUS AND ALL OF THEM PARTICIPATE IN

THIS NETWORK SO THAT THEY CAN TAKE ADVANTAGE OF THEIR AREAS OF SPECIALTY AND CONTRIBUTE TO IT, AND ALSO BECAUSE WE HAVE A BUDGET THAT ALLOWS FOR US TO SUPPORT THAT MANY.

WE CERTAINLY COULD SUPPORT FEWER AND STILL HAVE A MANUFACTURING NETWORK, BUT THEN THERE ARE GOING TO BE A FEW OUT THERE THAT ARE THEN NOT GOING TO BE A PART OF IT. SO WE KNOW THAT THESE HAVE THE POTENTIAL TO BE GOOD CONTRIBUTORS AND A GOOD MEMBER OF THAT NETWORK. AND SO WE FEEL THAT IT WOULD BE IMPORTANT TO GIVE THEM THE OPPORTUNITY TO AT LEAST DEMONSTRATE IT THROUGH A REVISION PROCESS IF WE CAN. AND IF IT TURNS OUT THAT, IF EVEN THROUGH THAT REVISION PROCESS, THEY'RE NOT, THAT THEY DON'T MEET THE STANDARD, THEN AT THAT POINT WE ARE COMFORTABLE GOING WITH THE RECOMMENDATION OF THE WORKING GROUP.

DR. FISHER: SO DO YOU WANT OR DO WE NEED A MOTION TO REQUEST THAT THOSE THAT SCORED 2 SUBMIT REVISED PROPOSALS, OR DOES THAT HAPPEN AUTOMATICALLY? I'M SEEING VITO SHAKING HIS HEAD NO AND YES.

DR. SAMBRANO: WE NEED A MOTION.

DR. FISHER: WE DO? WE DON'T. OKAY.

MR. TOCHER: IF I COULD JUST STEP IN FOR A MOMENT, VITO, TO ADDRESS FRED'S QUESTION. WE HAVE A

MOTION ON THE TABLE AT THE MOMENT, SO WE NEED TO CLOSE OUT THAT MOTION EITHER BY VOTING ON IT OR BY CONSENT TO WITHDRAWING IT.

AS TO THE QUESTION OF HOW TO HANDLE THOSE IN TIER II THAT FRED WAS DISCUSSING, WHAT WE HAD ANTICIPATED DOING WAS IDENTIFYING ANY APPLICATIONS IN TIER II TO MOVE UP, ANY IN TIER I TO MOVE DOWN, WHICH IS THE NORMAL PROCEDURE ON HOW WE HANDLE REVIEWS SUCH AS THIS. AND THEN HAVING A MOTION TO DO AS YOU ARE SUGGESTING, FRED, WHICH IS TO ALLOW RESUBMISSION BY ALL THOSE APPLICATIONS WHICH RECEIVED A 2. I KNOW THERE ARE SEVERAL STEPS TO THIS, BUT AT LEAST THAT WAS THE APPROACH WE WERE ANTICIPATING.

DR. SOUTHARD: SO I'LL BEGIN BY WITHDRAWING MY MOTION.

DR. FISCHER-COLBRIE: I'LL WITHDRAW MY SECOND.

CHAIRMAN IMBASCIANI: OKAY.

MR. TOCHER: I THINK WE STILL HAVE PUBLIC COMMENT.

CHAIRMAN IMBASCIANI: YES. SO, MARIANNE, CAN WE ALLOW THE GENTLEMAN FROM THE PUBLIC TO ADDRESS THE BOARD.

MS. DEQUINA-VILLABLANCA: YES.

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858-822-1777, STAR 6 TO UNMUTE AND YOU HAVE THREE MINUTES.

DR. KAUFMAN: OKAY, YES. I THINK I'M ON THE LINE NOW.

MS. DEQUINA-VILLABLANCA: YES. WE CAN HEAR YOU.

DR. KAUFMAN: OKAY. THANK YOU. GOOD MORNING. I'M DAN KAUFMAN. I'M A PROFESSOR AT UC SAN DIEGO AND THE PROGRAM DIRECTOR FOR THE APPLICATION 14562 THAT'S BEEN UNDER DISCUSSION HERE.

AS YOU'VE NOTED, WE RECEIVED A TIE VOTE OF SEVEN TIER I AND SEVEN TIER II, AND I UNDERSTAND THAT THIS DEFAULTS TO TIER II. HOWEVER, THIS WOULD ALSO MEAN WE'D BE SPENDING CONSIDERABLE TIME AND EFFORT TO RESUBMIT THIS PROPOSAL. AND WE'D, AS HAS BEEN DISCUSSED, LIKE TO ENCOURAGE THE ICOC TO VOTE FOR FUNDING THIS PROPOSAL NOW AS TIER I TO ENABLE US TO JOIN AND START WORK AS PART OF THIS NETWORK RIGHT AWAY.

AND ALSO AS HAS BEEN MENTIONED, I'D LIKE TO HIGHLIGHT THAT WHILE WE RECEIVED THIS SEVEN TO SEVEN TIE VOTE, EACH OF THE FOUR SCORED COMPONENTS WERE THE VAST MAJORITY OF YES VOTES. THEREFORE, THERE IS QUITE A DISCORDANCE BETWEEN THE FINAL SEVEN TO SEVEN VOTE. INDEED, THE SECTION RELATED TO

SERVING UNDERSERVED COMMUNITIES, AND DEI SUPPORT WAS FAVORABLY SCORED 14 TO ZERO WITH COMMENTS NOTING THAT THIS IS, QUOTE, A SOLID PLAN AND OUR GROUP HAS STRONG TIES TO EXISTING DEI-ORIENTED CIRM INITIATIVES.

I WOULD LIKE TO SPECIFICALLY ADDRESS TWO MAIN CONCERNS NOTED; THAT IS, ISSUES RELATED TO THE SIZE OF OUR FACILITY AND THE INITIATION OF A PROCESS DEVELOPMENT TEAM AS ONE OF OUR KEY PLANNED ENHANCEMENTS.

ON THE SUBJECT OF SPACE, SINCE THE SUBMISSION OF THIS PROPOSAL, WE'VE SOLIDIFIED AND SIGNED A CONTRACT FOR ADDITIONAL LAB SPACE THAT WILL SUPPORT THE ADDITION OF OUR DEDICATED PD GROUP. THIS IS 5,000 SQUARE FEET OF LAB SPACE COMMITMENT THAT IS NOTED, ALONG WITH FLOOR PLANS, IN THE NEW LETTER OF SUPPORT FROM DR. JAMIESON.

REGARDING OR PD GROUP AND ISSUES RELATED TO SUCCESS CRITERIA, THE CURRENT MANUFACTURING PERSONNEL ARE CROSS-TRAINED TO PERFORM BOTH PD AND GMP PROCESSES. HOWEVER, GMP ACTIVITIES ARE PRIORITIZED, AND THIS LEADS TO LONG WAIT TIMES FOR THE EXECUTION OF PD STUDIES. THEREFORE, THERE ARE INDEED CLEAR GOALS AND SUCCESS CRITERIA FOR THIS PD GROUP. THE SUCCESS WILL BE DEMONSTRATED AND

QUANTIFIED BY REDUCED TECH TRANSFER TIME FOR INCOMING PROJECTS, FASTER GMP IMPLEMENTATION, AND EFFECTIVE TECH TRANSFER EXECUTION TO EFFICIENTLY MOVE LATER STAGE PROJECTS FROM OUR ACTL TO COMMERCIAL CDMO'S.

I'D ALSO LIKE TO AGAIN EMPHASIZE OUR COMMITMENT TO BUILDING AN INCLUSIVE WORKFORCE. THIS INCLUDES A NEW INTERNSHIP PROGRAM AND IMPORTANT CAREER DEVELOPMENT OPPORTUNITIES FOR BOTH ENTRY LEVEL AND LEADERSHIP POSITIONS.

FINALLY, AS OUR FACILITY IS THE ONLY ACADEMIC GMP FACILITY IN OUR REGION AND WE FEEL WE'VE ALREADY ADDRESSED KEY CONCERNS NOTED BY THE GRANTS WORKING GROUP, I'D LIKE TO ENCOURAGE THE ICOC TO MOVE OUR SEVEN TO SEVEN TIE VOTE TO TIER I SUPPORT FOR FUNDING NOW AS THIS WILL AVOID DELAYS IN IMPLEMENTING WHAT WE FEEL WILL BE VERY VALUABLE CONTRIBUTIONS TO THIS NETWORK AND SAVE US THE TIME AND EFFORT OF REMISSION. THANK YOU FOR YOUR TIME AND HELP.

CHAIRMAN IMBASCIANI: THANK YOU, DR. KAUFMAN, FOR THOSE REMARKS.

I HAVE A QUESTION FOR GIL. IF THE BOARD WERE TO FOLLOW DR. KAUFMAN'S ADVICE, WOULD THE DEFICIENCIES THAT WERE REMARKED ON BY THE WORKING

GROUP STILL HAVE ANY FORCE? MEANING, WOULD WE WORK WITH UCSD AND DR. KAUFMAN TO ELEVATE THOSE WHAT WERE PERCEIVED BY US AS DEFICIENCIES?

DR. SAMBRANO: YES. I MEAN THAT'S ALWAYS THE CASE. ANYTHING THAT CIRM FUNDS WE'RE GOING TO SUPPORT AND PUT IN THE POSITION WHERE THEY'RE GOING TO BE LIKELY TO SUCCEED. SO WE WOULD ABSOLUTELY ADDRESS THE CONCERN.

I THINK SOME OF THE CONCERNS, THOUGH, THAT ARE PRESENT IN THIS APPLICATION AS WELL AS SOME OF THE OTHERS ARE A REQUEST FOR MORE INFORMATION OR GETTING ADDITIONAL CLARITY ON THE PROCESS THAT THEY'RE GOING TO USE TO DEVELOP SOME OF THE ENHANCEMENTS, SOME OF THE PROJECTS THAT THEY ARE PROPOSING TO DO WHICH THE WORKING GROUP FELT WAS NOT ADEQUATELY ADDRESSED IN THE APPLICATION OR ENOUGH DETAIL WAS BROUGHT TO BEAR IN ORDER TO FULLY UNDERSTAND IT.

SO EVEN THOUGH WE CAN HELP WITH SOME OF THE CONCERNS, THERE ARE SOME THINGS THAT THE DETAILS WOULD NOT BE KNOWN TO US UNTIL WE ACTUALLY START WORKING WITH AND GIVEN THE NATURE OF SOME OF THOSE COMMENTS.

MS. DEQUINA-VILLABLANCA: YOU'RE MUTED, VITO.

CHAIRMAN IMBASCIANI: I KNOW -- SCOTT, THIS IS FOR YOU. I KNOW THE MOTION HAS BEEN MADE AND SECONDED AND THEN THE MOTION AND SECOND WAS WITHDRAWN. I'M NOT SURE THAT THE MATTER IS STILL NOT FORMALLY IN FRONT OF US AND NEEDS A VOTE.

DR. SOUTHARD: I WITHDRAW MY WITHDRAWAL.

CHAIRMAN IMBASCIANI: THANK YOU, MARVIN. I THINK THAT'S THEY CLEANEST WAY TO PROCEED.

MR. TOCHER: YES. YOU'RE RIGHT, DR. IMBASCIANI, THAT THE MATTER BELONGS TO THE BODY AT THIS POINT. ONE CLEAN WAY OF HANDLING IT WOULD JUST BE TO ASK IF THERE IS NO OBJECTION, THE MATTER WOULD BE WITHDRAWN. THAT WAY A MEMBER WHO WISHES TO PROCEED WITH A VOTE COULD EXERCISE THAT RIGHT AND WE COULD PROCEED WITH A VOTE.

YOUR OPTION IS LEGITIMATE AS WELL AND APPROPRIATE UNDER ROBERTS RULES OF ORDER. SO HOWEVER YOU WOULD LIKE TO PROCEED.

CHAIRMAN IMBASCIANI: WELL, THANK YOU, MR. PARLIAMENTARIAN. I THINK WE SHOULD PROCEED TO A VOTE, BUT I THINK AFTER THIS DISCUSSION, YOU NEED TO RESTATE SO THAT EVERYONE UNDERSTANDS.

MR. TOCHER: OKAY. SO THE MOTION IS TO MOVE APPLICATION 14562 FROM TIER I UP TO -- CORRECTION -- FROM TIER II UP TO TIER I INTO THE

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FUNDABLE CATEGORY. WOULD YOU LIKE ME TO TAKE ROLL CALL AND VOTE?

CHAIRMAN IMBASCIANI: PLEASE START THE ROLL CALL. THANK YOU.

MR. TOCHER: LEONDRA CLARK-HARVEY.

MS. CLARK-HARVEY: YES.

MR. TOCHER: ANNE-MARIE DULIEGE.

DR. DULIEGE: I WANT TO BE CLEAR WHAT I'M VOTING FOR.

MR. TOCHER: SURE.

DR. DULIEGE: THE MOTION IS TO MOVE THIS FIRST APPLICATION 562 TO TIER I?

MR. TOCHER: THAT'S CORRECT. SO IT WOULD MOVE IT FROM TIER II UP TO TIER I, THE FUNDABLE CATEGORY.

DR. DULIEGE: NO.

MR. TOCHER: THANK YOU.

YSABEL DURAN.

MS. DURAN: SORRY. THOUGHT I HAD A CONFLICT ON THIS GROUP.

MR. TOCHER: NO. YOU'RE GOOD.

MS. DURAN: YES.

MR. TOCHER: MARK FISCHER-COLBRIE.

DR. FISCHER-COLBRIE: NO.

MR. TOCHER: FRED FISHER.

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DR. FISHER: NO.
MR. TOCHER: ELENA FLOWERS.
DR. FLOWERS: CONFIRMING THAT I DON'T HAVE A CONFLICT.
MR. TOCHER: YOU DO NOT.
DR. FLOWERS: OKAY. NO.
MR. TOCHER: VITO IMBASCIANI.
CHAIRMAN IMBASCIANI: NO.
MR. TOCHER: STEVE JUELSGAARD.
MR. JUELSGAARD: YES.
MR. TOCHER: RICH LAJARA.
MR. LAHARA: YES.
MR. TOCHER: CHRISTINE MIASKOWSKI.
DR. MIASKOWSKI: NO.
MR. TOCHER: LAUREN MILLER-ROGEN.
MS. MILLER-ROGEN: NO.
MR. TOCHER: ADRIANA PADILLA.
DR. PADILLA: YES.
MR. TOCHER: JOE PANETTA.
MR. PANETTA: YES.
MR. TOCHER: AL ROWLETT.
MR. ROWLETT: NO.
MR. TOCHER: MARV SOUTHARD.
DR. SOUTHARD: YES.
MR. TOCHER: KAROL WATSON.

DR. WATSON: NO.

MR. TOCHER: THE MOTION FAILS, SEVEN AYE VOTES TO NINE NO VOTES. SO THE APPLICATION WILL REMAIN IN TIER II.

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CHAIRMAN IMBASCIANI: THANK YOU, SCOTT.

NOW I'M GOING TO ASK IF THERE ARE ANY APPLICATION MEMBERS WHO WOULD LIKE TO MOVE AN APPLICATION OUT OF TIER I AND INTO TIER II. PARDON ME. THE REVERSE OF THE LAST SITUATION. ONCE AGAIN, WE ARE NOT HAVING A HEARING PROBLEM WITH ME, ARE WE, SCOTT?

MR. TOCHER: NO. WE CAN HEAR YOU JUST FINE.

CHAIRMAN IMBASCIANI: GREAT.

MR. TOCHER: I DON'T SEE ANY HANDS RAISED AT THE MOMENT.

CHAIRMAN IMBASCIANI: OKAY. ALL RIGHT. GOING ONCE. OKAY.

MR. TOCHER: I DO HAVE A SUGGESTION, DR. IMBASCIANI.

CHAIRMAN IMBASCIANI: PLEASE.

MR. TOCHER: GIVEN THAT THERE ARE NO MORE MOTIONS TO REALLOCATE THE RANKING OF THE APPLICATIONS, WE COULD SEEK A MOTION FROM ANYONE ON THE ARS WHO DOES NOT HAVE A CONFLICT AS TO ANY APPLICATION TO FUND THOSE APPLICATIONS IN TIER I AND ALLOW RESUBMISSION AND RE-REVIEW OF THOSE APPLICATIONS IN TIER II.

CHAIRMAN IMBASCIANI: I WAS GOING TO DO

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THAT AS TWO SEPARATE MOTIONS.

MR. TOCHER: I WAS JUST GOING TO -- FOR EFFICIENCY, WE COULD WRAP THAT ALL UP IN ONE.

CHAIRMAN IMBASCIANI: WE CAN DO IT. OKAY. FINE. SO STATE IT AGAIN AND WE'LL PROCEED TO A ROLL CALL.

MR. TOCHER: SO WE WOULD STILL NEED A MAKER AND A SECOND.

DR. FISHER: SO MOVED.

DR. CLARK-HARVEY: SO MOVED.

MR. TOCHER: I THINK I HEARD FRED FISHER FIRST. SO, LEONDRA, I'LL HAVE YOU AS THE SECOND.

DR. CLARK-HARVEY: SURE. THANK YOU.

MR. TOCHER: SO THE MOTION IS TO FUND ALL APPLICATIONS IN TIER I AND ALLOW FOR REVISION AND RESUBMISSION OF THOSE APPLICATIONS IN TIER II. AND THE FLOOR IS OPEN FOR BOARD DISCUSSION. I DON'T SEE ANY.

CHAIRMAN IMBASCIANI: NO ONE ON THE BOARD. MARIANNE, IS THERE ANYONE IN THE PUBLIC?

MS. DURAN: MR. CHAIR.

CHAIRMAN IMBASCIANI: YES, MEMBER DURAN.

MS. DURAN: SORRY BECAUSE I'M -- MY TONGUE IS HALF CONFLICTED HERE. I'M NEVER SURE WHEN I SHOULD SPEAK AND WHEN I SHOULDN'T. SO --

MR. TOCHER: YSABEL.

MS. DURAN: YES.

MR. TOCHER: SORRY. THIS IS SCOTT. YOU DO HAVE A CONFLICT AS TO AN APPLICATION THAT IS THE SUBJECT OF THIS MOTION. SO IF YOU HAVE A PROCESS QUESTION?

MS. DURAN: NO. I HAVE A COMMENT NOT SPECIFIC TO ANY ONE OF THESE BUT MORE GENERIC.

MR. TOCHER: THANK YOU. WE ACTUALLY DO HAVE AN ITEM ON THE AGENDA FOR ARS PROCESS THAT WE CAN ADDRESS AFTER THIS MOTION.

MS. DURAN: WHERE I CAN MAKE A GENERAL COMMENT?

MR. TOCHER: CORRECT.

MS. DURAN: VERY GOOD. THANK YOU.

MR. TOCHER: MARIANNE, SORRY. WAS THERE ANY PUBLIC COMMENT?

MS. DEQUINA-VILLABLANCA: NO.

CHAIRMAN IMBASCIANI: ALL RIGHT. OKAY. SCOTT, YOU CAN PROCEED TO A ROLL CALL VOTE.

MR. TOCHER: SURE. THANK YOU. AND FOR MEMBERS DURAN, MIASKOWSKI, FLOWERS, AND BONNEVILLE, WHEN I CALL YOUR NAME, YOU CAN STATE YOUR VOTE, BUT EXCEPT FOR THOSE APPLICATIONS WITH WHICH I HAVE A CONFLICT. ALL RIGHT.

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MARIA BONNEVILLE.

VICE CHAIR BONNEVILLE: YES EXCEPT FOR THOSE WITH WHICH I HAVE A CONFLICT.

MR. TOCHER: LEONDRA CLARK-HARVEY.

MS. CLARK-HARVEY: YES.

MR. TOCHER: ANNE-MARIE DULIEGE.

DR. DULIEGE: YES.

MR. TOCHER: YSABEL DURAN.

MS. DURAN: YES EXCEPT FOR THOSE WITH WHICH I HAVE A CONFLICT.

MR. TOCHER: MARK FISCHER-COLBRIE.

DR. FISCHER-COLBRIE: YES.

MR. TOCHER: FRED FISHER.

DR. FISHER: YES.

MR. TOCHER: ELENA FLOWERS.

DR. FLOWERS: YES EXCEPT THOSE WITH WHICH I HAVE A CONFLICT.

MR. TOCHER: VITO IMBASCIANI.

CHAIRMAN IMBASCIANI: YES.

MR. TOCHER: STEVE JUELSGAARD.

MR. JUELSGAARD: YES.

MR. TOCHER: RICH LAJARA.

MR. LAHARA: YES.

MR. TOCHER: CHRISTINE MIASKOWSKI.

DR. MIASKOWSKI: YES EXCEPT FOR THOSE WITH

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WHICH I HAVE A CONFLICT.

MR. TOCHER: LAUREN MILLER-ROGEN.

MS. MILLER-ROGEN: YES.

MR. TOCHER: ADRIANA PADILLA.

DR. PADILLA: YES.

MR. TOCHER: JOE PANETTA.

MR. PANETTA: YES.

MR. TOCHER: AL ROWLETT.

MR. ROWLETT: YES.

MR. TOCHER: MARV SOUTHARD.

DR. SOUTHARD: YES.

MR. TOCHER: KAROL WATSON.

KAROL, ARE YOU PERHAPS MUTED? JUST WANT TO MAKE SURE. I DON'T SEE KAROL. MAYBE SHE DROPPED OFF.

THE MOTION CARRIES UNANIMOUSLY.

CHAIRMAN IMBASCIANI: THANK YOU VERY MUCH, SCOTT. AND THANK YOU, BOARD MEMBERS, FOR THE AT TIMES CONFUSING PROCESS THAT WE ALL FOLLOWED VERY SUCCESSFULLY. THANK YOU.

I HAVE A PLACEHOLDER HERE FOR MARIA BONNEVILLE. IS THIS THE APPROPRIATE TIME FOR HER TO MAKE HER REMARKS?

VICE CHAIR BONNEVILLE: IT WAS YSABEL'S QUESTION.

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CHAIRMAN IMBASCIANI: MARIA, ARE YOU WANTING TO HOLD OFF OR --

MR. TOCHER: THAT WAS YSABEL DURAN, VITO, WHO HAD A COMMENT NOT LONG AGO. AND YES, WE CAN SKIP TO THAT ITEM FOR GENERAL COMMENTS ABOUT THE ARS PROCESS. WE CAN TAKE UP THAT IF YOU'D LIKE.

CHAIRMAN IMBASCIANI: YEAH. I WOULD LIKE TO DO THAT NOW.

MR. TOCHER: OKAY. YSABEL.

MS. DURAN: OKAY. THANK YOU. THANK YOU VERY MUCH, MR. CHAIR AND EVERYBODY.

I APPRECIATE THE PROCESS, APPRECIATE THAT DEI IS BEING CONSIDERED WITHIN THE CONCEPT OF THE MANUFACTURING GROUPS. AND I THINK THAT IS ALSO CRITICAL. I APPRECIATE THAT WE ARE THINKING ABOUT THE INCLUSION FACTOR FOR BRINGING IN DISPARATE GROUPS, GIVING PEOPLE OPPORTUNITIES TO LEARN THE TRADE, MOVE UP INTO THE SYSTEMS, ET CETERA.

ONE OF THE THINGS I HAVE A BIGGER CONCERN ABOUT, AND I HOPE I'M NOT MAKING THIS COMMENT OUT OF SCHOOL. I'M SURE I'LL BE CORRECTED. BUT WHEN WE TALK ABOUT ACCESS, WE ARE NOT JUST TALKING ABOUT MODERATE AND LOW INCOME COMMUNITIES HAVING ACCESS TO THIS WONDERFUL NEW WAY OF BEING TREATED, BUT WE ARE ALSO TALKING ABOUT COST CONTAINMENT. THAT FINANCIAL

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TOXICITY IN THE MEDICAL INDUSTRY FOR THESE GROUPS OF PEOPLE IS HUGE, AND I WOULD LIKE TO KNOW IF SOMEHOW WE BUILD INTO THOSE DEI FACTORS OR, GIL, SOME OF THOSE OTHER AREAS, EVEN AT THE MANUFACTURING LEVEL, THAT THEY START TO THINK ABOUT COST CONTAINMENT AND SAVINGS IN THE WAY THEY DO WORK THAT CAN GET PASSED ON ULTIMATELY TO THE PATIENT. BECAUSE THE COST OF THESE ARE SO HUGE FOR MANY PEOPLE; BUT EVEN IF THERE'S SUPPOSED ACCESS, THEY CAN'T AFFORD IT OVER A PERIOD OF TIME.

SO I WOULD LIKE FROM THE MANUFACTURING, THE BEGINNING OF MAKING THE WIDGET ALL THE WAY DOWN TO CLINICAL APPLICATION, THAT COSTS ARE ALWAYS CONSIDERED IN TERMS OF APPLYING TO THESE PATIENTS WHO ARE THE MOST VULNERABLE AND WHO HAVE THE MOST PROBLEM MEETING COSTS. SO I DON'T KNOW IF WE CAN BUILD THAT INTO THIS IN SOME WAY, WHICH MANUFACTURERS ALSO SEE THAT THIS IS PALATABLE, BUT I THINK THAT THE COST OF MANUFACTURING ALL THE WAY DOWN TO THE COST OF BUYING A DRUG IS ACTUALLY UNCONSCIONABLE AND OUT OF CONTROL.

I KNOW THIS IS PERHAPS A NEW MANUFACTURING AREA, BUT I DO THINK THAT WE HAVE TO SEND A MESSAGE THAT ULTIMATELY ALL OF THIS WONDERFUL RESEARCH AND WORK DOES NO GOOD IF HALF THE PATIENTS CAN'T HAVE

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ACCESS TO IT BECAUSE THEY CAN'T AFFORD IT. SO...

CHAIRMAN IMBASCIANI: THANK YOU, MEMBER DURAN, FOR THE COMMENT. APPRECIATE IT.

LET'S SEE. HAVE WE -- WE'VE CLOSED OUT THE APPLICATION REVIEW SUBCOMMITTEE. SO I'D LIKE TO NOW RECONVENE AS THE WHOLE BOARD AND MOVE ON TO OUR NEXT AGENDA ITEM AND INVITE SEAN TURBEVILLE TO DELIVER HIS PRESENTATION OR IS GEOFF GOING TO START? GEOFF, YOU'RE GOING TO FOLLOW, I THINK, RIGHT? SEAN, ARE YOU ON?

DR. TURBEVILLE: YES, SIR. I'M GOING TO BEGIN.

CHAIRMAN IMBASCIANI: GOOD MORNING.

DR. TURBEVILLE: GOOD MORNING. SO I'LL GO AHEAD AND SHARE MY SLIDES. I WANT TO MAKE SURE THUMBS UP EVERYBODY CAN SEE THESE.

SO GOOD MORNING, MR. CHAIRMAN, VICE CHAIR, MEMBERS OF THE BOARD, MEMBERS OF THE PUBLIC. TODAY I WILL BE PRESENTING ON TWO TOPICS. ONE IS GOING TO BE AN INTRODUCTION TO THE PROPOSED ROADMAP FOR ACCESS AND AFFORDABILITY. AND FOR BACKGROUND, WE STARTED THIS INITIATIVE WITH THE AAWG IN JANUARY OF 2023. AND THE ROADMAP IS PART OF OUR FIVE-YEAR STRATEGIC PLAN. AND ALL I'M DOING TODAY IS PROVIDING A BRIEF INTRODUCTION OF WHAT THE ROADMAP

IS AND MORE OF A HEADS UP THAT THE ROADMAP WILL LIKELY BE PRESENTED TO THE ICOC FOR FINAL CONSIDERATION ON JUNE 29TH. AFTER THIS MEETING, WE WILL PRESENT TO THE AAWG ON JUNE 6TH, AND THEN BASED ON THEIR RECOMMENDATIONS, PRESENT TO THE ICOC ON THE JUNE 29TH MEETING.

AND THE OTHER UPDATE I WANT TO PROVIDE IS TO THE COMMUNITY CARE CENTERS OF EXCELLENCE WHICH HAS SIGNIFICANT, WELL, I'D SAY A LOT OF INPUT AND CERTAINLY HAS MADE SIGNIFICANT PROGRESS IN TERMS OF THE FIVE-YEAR STRATEGIC PLAN.

WITH RESPECT TO THE PROPOSED ROADMAP, PROP 14 AND THE FIVE-YEAR STRATEGIC PLAN STATE THAT CIRM CREATE A ROADMAP FOR ACCESS AND AFFORDABILITY FOR CELL AND GENE THERAPIES. AND THIS ROADMAP WILL INCLUDE A STRATEGY NOT ONLY FOR GATHERING THE DATA TO SUPPORT REIMBURSEMENTS, BUT ALSO ENGAGING POLICYMAKERS, REGULATORS, AND DEVELOPING NOVEL HEALTHCARE DELIVERY MODELS.

I THINK IT'S SAFE TO SAY THAT THERE IS A PROBLEM STATEMENT. AND THAT IS THERE ARE SEVERAL LOGISTICAL AND FINANCIAL BARRIERS TO ACCESS AND AFFORDABILITY FOR CELL AND GENE THERAPIES. AND WE SEE THAT ON THE CLINICAL TRIAL SIDE, AND WE ARE NOW STARTING TO OBSERVE THAT IN THE COMMERCIAL

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LANDSCAPE.

THE OPPORTUNITY FOR US, PROP 14 PROVIDES DEDICATED FUNDING AND THE FORMATION OF THE ACCESSIBILITY AND AFFORDABILITY WORKING GROUP TO ADDRESS SOME OF THESE BARRIERS.

SO THE GOAL OF THE ROADMAP IS TO IDENTIFY NEAR-TERM AND LONG-TERM INITIATIVES TO HELP PATIENTS OVERCOME SOME OF THESE BARRIERS WITH RESPECT TO ACCESS AND AFFORDABILITY.

SO THIS SLIDE SUMMARIZES THE BARRIERS TO ACCESS AND AFFORDABILITY. AND BY NO MEANS IS IT ALL OF THEM. WE ARE TRYING TO FOCUS FOR THE MOST PART ON CLINICAL TRIAL BARRIERS, BUT WE ARE ALSO STARTING TO THINK, AND I WOULD SAY MAYBE ASPIRATIONAL, ON THE COVERAGE SIDE. SO LET ME WALK YOU THROUGH A COUPLE OF THESE. AND MANY OF YOU ARE SUBJECT MATTER EXPERTS, AND I PRESENTED THIS SLIDE TO THE AAWG AND TO THE ICOC SOME TIME AGO. BUT WE CERTAINLY KNOW THERE'S CULTURAL AND SOCIAL DETERMINANTS THAT IMPACT CARE DELIVERY. LOWER CLINICAL TRIAL ENROLLMENT FOR MINORITIES. THERE'S RECENTLY BEEN THREE OR FOUR PUBLICATIONS IN THE LAST THREE MONTHS THAT DEMONSTRATE THAT ETHNIC MINORITIES REMAIN LARGELY UNDERREPRESENTED IN TRIAL POPULATIONS. WE KNOW THAT SOCIOECONOMIC STATUS, UNEMPLOYMENT, EDUCATION, ALL

OF THESE ARE INDEPENDENTLY ASSOCIATED WITH REDUCED ACCRUAL RATE IN CLINICAL TRIAL PARTICIPATION. OTHER BARRIERS INCLUDE PATIENT POPULATIONS, THE SIZE, THE GEOGRAPHY OF THE PATIENT, AND ALSO THE STIGMA OF THE DISEASE.

WHEN WE THINK ABOUT INFORMATIONAL BARRIERS, WE KNOW THAT THERE'S LIMITED INFORMATION ABOUT DISEASE AND THE THERAPY. WE ALSO OBSERVE THAT MEDICAL MISTRUST AND MISINFORMATION STILL EXIST ABOUT REGENERATIVE MEDICINE AND RECENTLY A LACK OF FAMILIARITY WITH THE ADMINISTRATION AND SAFETY PROFILES OF CELL AND GENE THERAPIES; AS AN EXAMPLE, COMMUNITY ONCOLOGISTS. THERE'S A BIG PUSH TO GO OUT THERE AND START ADMINISTERING CAR-T THERAPIES. AND THOSE COMMUNITY DOCS WANT TO BE FAMILIAR WITH THE ADMINISTRATION AND THE SAFETY PROFILE.

WITH RESPECT TO LOGISTICAL BARRIERS, WE KNOW THEY'RE A SIGNIFICANT BURDEN FOR FAMILIES. WE'VE DONE OUR DUE DILIGENCE IN THE LITERATURE. WE'VE CERTAINLY INTERVIEWED QUITE A FEW ALPHA CLINICS, TALKED TO PATIENTS. MANY OF THOSE BARRIERS INCLUDE RELIABLE TRANSPORTATION, WORK OR CHILDCARE REQUIREMENTS. THERE ARE NOW GEOGRAPHICAL LIMITATIONS TO APPROVE CLINICAL SITES. AND JUST RECENTLY INCREASED OPERATIONAL CONSTRAINTS ON

HEALTHCARE PROVIDER STAFF. PARTICULARLY THE BURDEN ON TRIAL COORDINATORS MAY CAUSE DISPROPORTIONATE TIME FOCUSED ON THE CLINICAL TRIAL REIMBURSEMENT PHASE AND ALL THE PAPERWORK AND ADMINISTRATION AND LESS TIME FOCUSED ON PATIENTS AND THE ACTUAL TRIAL.

AND THEN IF WE THINK SORT OF ASPIRATIONALLY WHAT'S HAPPENING ON THE COVERAGE SIDE, SO WE DO KNOW THAT THE COST OF REGENERATIVE MEDICINES AND INSURANCE BENEFITS MAY INCLUDE HIGH COPAYS AND LIFETIME BENEFIT CAPS. JUST RECENTLY WE PRESENTED TO THE AAWG ON RESTRICTIVE COVERAGE POLICIES FOR CELL AND GENE THERAPY, AND THAT'S TRUE FOR THE CELLULAR, CAR-T'S OF THE WORLD, AS WELL AS THE GENE THERAPIES.

AND THEN MORE IMPORTANTLY, WHAT'S COMING UP IN THE LITERATURE, MANY OF THE MEETINGS, L.A. BEST IS A GOOD EXAMPLE, IS THE LACK OF UNDERSTANDING OF OUTCOMES-BASED PAYMENT MODELS. SO WHILE THESE ARE JUST SOME OF THE BARRIERS, AND CIRM CANNOT ADDRESS ALL OF THEM, WE DO HAVE A UNIQUE OPPORTUNITY WHERE WE CAN ATTEMPT TO ADDRESS SOME OF THESE THROUGH THE ROADMAP.

SO THESE ARE THE FOCUS AREAS THAT WE TEND TO IMPLEMENT OR CONTINUE RESEARCHING IN OUR ROADMAP. AND, AGAIN, WE ARE FOCUSING ON FOR THE MOST PART

CLINICAL TRIALS, BUT WE, AGAIN, ARE BEGINNING TO RESEARCH ON ACCESS TO APPROVED THERAPIES, PARTICULARLY FOR CIRM'S PORTFOLIO, IF ANY OF CIRM'S PORTFOLIO GOES TO MARKETING AUTHORIZATION.

SO IF WE THINK ABOUT INITIATIVES THAT WE HAVE HERE AT CIRM THAT COULD MITIGATE THE NEGATIVE SOCIAL AND CULTURAL DETERMINANTS OF HEALTH, FIRST, WE HAD THE EXPANSION OF THE ALPHA CLINICS. WE JUST EXPANDED FROM SIX TO NINE. THERE'S A NUMBER OF ACTIVITIES AND RESEARCH ACTIVITIES WITHIN THOSE AWARDS. IT WAS JUST RECENTLY MENTIONED ABOUT OUTREACH PROGRAMS. THERE'S A NUMBER OF OUTREACH PROGRAMS THAT ARE IN THESE AWARDS. THE OPPORTUNITY HERE WITH THE ALPHA CLINICS IS TO GATHER SOME ADDITIONAL INFORMATION AND DATA AS THIS DATA BECOMES AVAILABLE TO US AT CIRM THAT CAN GIVE US GUIDANCE ON WHERE WE CAN POTENTIALLY USE SOME ADDITIONAL INFORMATION WITH RESPECT TO THE ROADMAP.

ANOTHER AREA IS THE COMMUNITY OUTREACH AND EDUCATION. SO THE COMMUNICATIONS TEAM HERE AT CIRM IS BUILDING OUTREACH GUIDELINES, TOOL KITS TO SUPPORT OUR EDUCATIONAL PROGRAM WITH TRAINEES, WITH OUTREACH AND ENGAGEMENT. ANOTHER AREA IS THE FUTURE COMMUNITY CARE CENTERS OF EXCELLENCE. AND THIS IS A BIG INITIATIVE. THIS IS WHERE WE WILL HAVE THE

OPPORTUNITY TO FUND A NUMBER OF SITES OUT IN THE RURAL COMMUNITIES THAT WILL PROVIDE NOT ONLY RESEARCH CAPABILITY, BUT EDUCATIONAL CAPABILITIES AND ENGAGEMENT CAPABILITIES WITH PATIENTS AS WELL AS HEALTHCARE PROVIDERS.

AND THEN, FINALLY, WHAT WE LEARNED IS COMMUNITY PARTNERS. ENGAGING THE COMMUNITY PARTNERS AT THE GRASS ROOT LEVELS CERTAINLY CAN PROVIDE US WITH A COMPONENT OF THE ROADMAP THAT WOULD MITIGATE SOME OF THE NEGATIVE SOCIAL AND CULTURAL DETERMINANTS.

WHEN WE THINK ABOUT PROGRAMS AT CIRM TO ADDRESS INFORMATIONAL BARRIERS, THIS IS WHERE THE PATIENT SUPPORT PROGRAM SITS. SO THERE'S TWO MAIN COMPONENTS HERE. ONE IS EDUCATION, EDUCATING PATIENTS, FAMILY MEMBERS ABOUT CIRM-FUNDED TRIALS. AND THE OTHER IS NAVIGATING, NAVIGATING PATIENTS TO OUR CIRM-FUNDED TRIALS.

THERE'S A UNIQUE OPPORTUNITY HERE THAT WAS JUST BROUGHT TO OUR ATTENTION, AND THAT IS THE STEM CELL COUNSELORS. AND THIS IS INTERESTING IN THE SENSE THAT IT IS BASED OFF OF GENETIC COUNSELORS AND HOW IMPACTFUL GENETIC COUNSELORS HAVE BEEN, NOT ONLY AT THE ACADEMIC INSTITUTIONS, BUT IN INDUSTRY, BUT ALSO IN THE COMMUNITY. AND SO OUR VISION HERE WITH

RESPECT TO INFORMATIONAL BARRIERS IS THE INTEGRATION WITH THE ALPHA CLINICS, THE COMMUNITY CARE CENTERS OF EXCELLENCE, THE COMMUNITY PARTNERS, THE PATIENT SUPPORT PROGRAM, WOULD ALLOW US A MUCH MORE ROBUST RESEARCH HUB TO IMPACT EDUCATION, ACCESS AND AFFORDABILITY.

WITH RESPECT TO PROGRAMS TO HELP PATIENTS NAVIGATE LOGISTICAL BARRIERS, AGAIN, PATIENT SUPPORT PROGRAM. THE SECOND IS THE PATIENT ASSISTANCE FUND. AND THIS SITS WITHIN THE PATIENT SUPPORT PROGRAM, AND THERE'S LOTS OF OPPORTUNITIES HERE FOR US TO EXPAND AND SCALE THESE SERVICES. BUT THE PATIENT ASSISTANCE FUND WILL PROVIDE ADDITIONAL FUNDING FOR PATIENTS WHO DO QUALIFY TO PARTICIPATE IN CIRM-FUNDED TRIALS.

AND THEN THERE'S ANOTHER IDEA THAT WAS RECENTLY BROUGHT TO OUR ATTENTION AND THAT IS THE PATIENT NAVIGATORS AT THE COMMUNITY LEVEL AND WHAT IMPACT THEY COULD HAVE EITHER THROUGH THE COMMUNITY CARE CENTERS OF EXCELLENCE OR EVEN CURRENTLY RIGHT NOW THE EXPANSION OF THE ALPHA CLINICS.

NOW, WE THINK ABOUT A LITTLE BIT FURTHER DOWN THE ROAD. AND THE WAY WE APPROACH THE ROADMAP IS THINKING NOT ONLY THROUGH THE PATIENT JOURNEY, WHICH I'M TRYING TO ARTICULATE HERE, BUT ALSO SORT

OF THROUGH THAT CLINICAL DEVELOPMENT PROGRAM. AND SO WHEN WE THINK ABOUT SUPPORTING BROAD AND FAIR COVERAGE FOR CELL AND GENE THERAPIES, WE DO KNOW THAT WE WANT TO CONTINUE TO RESEARCH ON THE REAL-WORLD EVIDENCE AND HEALTH OUTCOMES OPPORTUNITIES.

SO JUST FOR DEFINITIONAL PURPOSES, REAL-WORLD EVIDENCE REFERS TO DATA AND INFORMATION COLLECTED FROM REAL-WORLD SOURCES, SUCH AS ELECTRONIC HEALTH RECORDS, INSURANCE CLAIMS DATABASES, PATIENT REGISTRIES, AND OTHER SOURCES OF HEALTHCARE INFORMATION. SO IT PROVIDES UNIQUE INSIGHTS INTO THE SAFETY AND EFFECTIVENESS OUT IN THE REAL WORLD; WHEREAS, CLINICAL TRIAL DATA, OF COURSE, IS CONDUCTED IN CONTROLLED SETTINGS.

AND THE REASON WHY THIS IS IMPORTANT IS BECAUSE, ONE, IT'S BECOMING MORE DISPROPORTIONATELY INFLUENCED WITH RESPECT TO NOT ONLY REGULATORY AUTHORITIES, BUT ALSO ON THE PAYER SIDE. WE JUST HEARD FROM PTC HAVE A POSITIVE OPINION, AND MUCH OF THAT WAS DUE WITH RESPECT TO REAL-WORLD EVIDENCE THAT THEY COLLECTED AND NATURAL HISTORIES WITH RESPECT TO THE PATIENTS.

THE OTHER THING THAT WE WOULD LIKE TO PUT IN PLAY THAT WE ARE CONSIDERING IS ENGAGEMENT WITH

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PAYERS TO INCENTIVIZE BROAD ACCESS AND TRANSPARENT COVERAGE POLICY. SO I MENTIONED EARLIER THAT WE ALREADY IDENTIFIED SOME RESTRICTIONS ON POLICIES. IT WOULD BE GOOD FOR US TO GET IN FRONT OF THE PAYERS. THERE'S AN OPPORTUNITY FOR US TO DO THAT, TO HAVE A CANDID CONVERSATION ABOUT WHAT THEIR CONCERNS ARE AND WHERE THERE'S GAPS POTENTIALLY FROM A DATA STANDPOINT WITH OUR AWARDEES THAT WE MIGHT BE ABLE TO MITIGATE WITH REAL-WORLD EVIDENCE, FOR EXAMPLE.

AND THIS LEADS INTO THE EVALUATING OF OUTCOMES-BASED PAYMENT MODELS. THIS IS A HOT TOPIC RIGHT NOW. MEDICARE, FOR EXAMPLE, JUST REACHED OUT TO STATES TO ASK FOR GUIDANCE ON WHAT THOSE OUTCOMES-BASED PAYMENT MODELS SHOULD LOOK LIKE. THEY ARE IMPORTANT WITH RESPECT TO, LET'S SAY, TO SICKLE CELL OR HEMOPHILIA. BUT OTHER THERAPEUTIC AREAS IT'S UNCLEAR, PARTICULARLY LIKE IN THE NEUROMUSCULAR SPACE.

SO THESE ARE OPPORTUNITIES THAT WE HAVE IN OUR WHEELHOUSE AND IN THE ROADMAP THAT WE INTEND TO IMPLEMENT THAT WOULD IMPACT PATIENTS' ACCESS AND AFFORDABILITY TO CELL AND GENE THERAPIES.

SO THIS SLIDE IS A HIGHLY LEVEL EXAMPLE OF SOME ELEMENTS IN THE ROADMAP WE ARE CONSIDERING.

AND THE WAY WE SET THIS UP IS BASICALLY STRATIFICATIONS. ONE IS WHAT ARE OUR NEAR-TERM OBJECTIVES AND NEAR-TERM OPPORTUNITIES? WHAT ARE ADDITIONAL INITIATIVES THAT WE WANT TO DO SOME RESEARCH ON THAT WOULD LEAD TO NEW CONCEPTS? I'D LIKE TO SAY THAT WE HAVE A FULL BAKED ROADMAP THAT HAS ALL THE ANSWERS FOR ACCESS AND AFFORDABILITY FOR CELL AND GENE THERAPIES, AND WE MAY GET THERE. BUT IN THE INTERIM, THIS IS A PROCESS. AND WE HAVE SOME LOW HANGING FRUIT THAT WE COULD CERTAINLY PUT IN PLAY, AND THERE'S OTHER INITIATIVES THAT WE NEED TO CONSIDER.

SO WITH RESPECT TO NEAR TERM, I MENTIONED THE EXPANSION OF THE ALPHA CLINICS. THAT ALREADY KICKED OFF IN JANUARY 2023. I MENTIONED THE PATIENT SUPPORT PROGRAM. I'M HAPPY TO REPORT WITH A COMBINED EFFORT CROSS-FUNCTIONALLY FROM GIL, FROM GEOFF, FROM JENNIFER, FROM ICOC MEMBERS, AAWG MEMBERS THAT THE RFA IS NOW POSTED. AND THEN THE COMMUNITY CARE CENTERS OF EXCELLENCE, AND I'LL ABOUT THIS IN A FEW MINUTES WHERE WE ARE AT AND WHERE WE'RE GOING, BUT THE ANTICIPATION IS THAT WE'D BE ABLE TO KICK THAT OFF IN MARCH OF 2024.

IN TERMS OF INTERNAL INITIATIVES, WE'D LIKE TO RECOMMEND ADDITIONAL RESEARCH ON REAL-WORLD

EVIDENCE AND HEOR OPPORTUNITIES. SO OUR RECOMMENDATION TO THE AAWG IS POTENTIALLY TO KICK THIS OFF IN SEPTEMBER OF THIS YEAR AND REPORT OUR FINDINGS TO THE AAWG AND HOPEFULLY TO THE ICOC AT A LATER TIME.

THIS ALSO LEADS INTO THE PAYER ADVISORY GROUP MEETING THAT I JUST MENTIONED. AND IMPORTANTLY, THE PERFORMANCE-BASED PAYMENT MODELS.

SO IN CONCLUSION, THIS IS A QUICK UPDATE OF WHERE WE ARE AT RIGHT NOW. WE ARE GETTING READY TO PRESENT THE ROADMAP TO THE AAWG ON JUNE 6TH AND THEN HOPEFULLY, BASED ON THEIR GUIDANCE AND INPUT, PRESENT TO THE ICOC ON JUNE 29TH.

SO NOW WHAT I'D LIKE TO DO IS PROVIDE, SHIFTING GEARS A LITTLE BIT, AN UPDATE TO THE COMMUNITY CARE CENTERS OF EXCELLENCE. SO THIS IS THE CCCE INITIATIVE. AND THE COMMUNITY CARE CENTERS OF EXCELLENCE IS AN EXAMPLE OF A PROGRAM THAT NOT ONLY IS INCLUDED IN OUR ROADMAP, BUT OBVIOUSLY WE WILL OPERATIONALIZE UNDER THE MEDICAL AFFAIRS DEPARTMENT.

SO BY WAY OF BACKGROUND, THE COMMUNITY CARE CENTERS OF EXCELLENCE PROGRAM IS DESCRIBED IN PROPOSITION 14 AND OUR FIVE-YEAR STRATEGIC PLAN. THE PROGRAM AIMS INCLUDE ESTABLISHING GEOGRAPHICALLY

DIVERSE CENTERS TO SUPPORT CLINICAL RESEARCH AND TREATMENTS ARISING FROM CIRM-FUNDED RESEARCH. PROPOSITION 14 ALSO INDICATES THAT BOTH THE ALPHA CLINICS NETWORK AND THE COMMUNITY CARE CENTERS OF EXCELLENCE SHALL INCLUDE PLANS FOR ENHANCING ACCESS TO PATIENTS. THUS, THIS INFRASTRUCTURE PROGRAMS COMBINED WITH RELATED ACCESS AND AFFORDABILITY EFFORTS PROVIDE THE FOUNDATION FOR FILLING CIRM'S STRATEGIC GOAL OF PROVIDING CLINICAL OPPORTUNITIES FOR ALL.

AND, FINALLY, THE ALPHA CLINICS NETWORKS WILL BE INSTRUMENTAL IN PROVIDING THREE THINGS WITH RESPECT TO THE COMMUNITY CARE CENTERS OF EXCELLENCE. ONE, THEY'LL PROVIDE THE CLINICAL EXPERTISE. TWO, PROVIDE THE EDUCATIONAL AND TRAINING CURRICULA. AND, THREE, DEVELOP CONSISTENT MEANS FOR PATIENT ENGAGEMENT.

SO THIS IS A SLIDE, GEOGRAPHICAL SLIDE. WE INITIATED SEVERAL LISTENING SESSIONS THROUGHOUT THE STATE, ONE IN CLOVIS ON OCTOBER 25TH, ONE AT UC RIVERSIDE/INLAND EMPIRE, AND THE OTHER JUST RECENTLY IN PALM DESERT. AND MANY OF THE ICOC AND AAWG MEMBERS HERE ON THIS CALL PARTICIPATED. THE TEAM ALSO ENGAGED KEY INFORMANTS FROM REDDING AND SHASTA AREA. AND REPRESENTATIVES FROM THAT AREA WILL

PARTICIPATE IN OUR STATEWIDE PUBLIC WORKSHOP THAT I'LL TALK ABOUT IN A FEW MINUTES. BUT THIS JUST GIVES YOU A GEOGRAPHICAL AREA OF WHERE THOSE LISTENING SESSIONS TOOK PLACE.

SO IN TERMS OF THE STAKEHOLDER INSIGHTS, THERE WERE THREE THEMES THAT EMERGED FROM THE LISTENING SESSIONS. ONE WAS CLINICAL READINESS OR CLINICAL CAPACITY. AND WE DID LEARN THAT SEVERAL REGIONAL MEDICAL CENTERS ARE DEVELOPING REGIONAL REGENERATIVE MEDICINE CAPACITY. AND COMMUNITY PROVIDERS HAVE SUPPORTED CLINICAL RESEARCH IN COLLABORATION WITH ACADEMIC MEDICAL CENTERS INCLUDING THE ALPHA CLINICS. SO THERE IS SOME EXPERIENCE WITH THE CLINICAL ACUMEN SUPPORTING CLINICAL TRIALS AND ENGAGING WITH THE ALPHA CLINICS.

THE OTHER THEME WAS THE EDUCATION AND TRAINING. SO WE HEARD FROM THE CLINICIANS WE WANT CONTINUING MEDICAL EDUCATION. THERE'S A LOT OF STUFF IN CELL AND GENE THERAPY, NOT ONLY JUST IN CLINICAL TRIALS, BUT WHAT'S ANTICIPATED OF THE TSUNAMI OF APPROVALS THAT ARE GOING TO TAKE PLACE IN THE NEXT TWO TO THREE YEARS. AND WE ALSO HEARD FROM THE PATIENTS WHO WANTED CONTINUING MEDICAL EDUCATION OR EDUCATION, IF YOU WILL, ABOUT REGENERATIVE MEDICINE. AND SO ORGANIZATIONS PROVIDE US LINKS

WITH EXISTING AND EMERGING TRAINING EDUCATIONAL PROGRAMS THAT WERE LOCAL, THAT WE CAN CERTAINLY UTILIZE FROM AN EDUCATIONAL TRAINING STANDPOINT.

AND THE OTHER IS THE ACCESS AND ENGAGEMENT. AND THIS REALLY DEALS WITH THE COMMUNITY-BASED ORGANIZATIONS. SO WHAT WE LEARNED IS THAT THE COMMUNITY-CENTERED PATIENT AND FAMILY ENGAGEMENT IS HIGHLY VALUED. AND THAT SUCH ENGAGEMENT IS CRITICAL TO ADDRESSING NOT ONLY THE SOCIAL DETERMINANTS, BUT ALSO IMPACTING PARTICIPATION IN RESEARCH.

WE ALSO HEARD A REPEATED REFERENCE TO FINANCIAL CHALLENGES TO PATIENTS AND FAMILY MEMBERS. AND WE HEARD EARLIER ABOUT FINANCIAL TOXICITY. AND THIS GAVE US SOME GUIDANCE IN TERMS OF NOT ONLY THE PATIENT SUPPORT, BUT ALSO SOME ADDITIONAL COMPONENTS THAT WE MIGHT BE ABLE TO PUT INTO THE ROADMAP THAT WOULD HELP FROM A FINANCIAL STANDPOINT.

SO THESE ARE SOME NOTEWORTHY COMMENTS FROM THE LISTENING SESSIONS. AND I'LL JUST READ THEM VERBATIM. ONE, THERE IS NO CENTER IN THE CENTRAL VALLEY RIGHT NOW THAT CAN OFFER THESE KINDS OF NOVEL THERAPIES. THERE IS A REAL NEED PARTICULARLY FOR POOR AND UNDERSERVED COMMUNITIES. ANOTHER IS ASK PHYSICIANS TO IDENTIFY TRUSTED COMMUNITY RESOURCES

TO DO EDUCATION AND ENGAGE PATIENTS. THAT IS, YOU CANNOT PROVIDE TALKING POINTS TO EDUCATE PATIENTS FROM CLINICIANS THAT DON'T HAVE THE TIME. AND ANOTHER IS THERE'S A DEMAND FOR ACCESS TO CLINICAL TRIALS IN HER COMMUNITY. THIS PARTICIPANT SEES MANY PATIENTS LEAVING THE COUNTRY TO ACCESS STEM CELL TREATMENTS AND THERAPIES.

SO THESE ARE SOME OF THE NOTEWORTHY COMMENTS FROM THE LISTENING SESSION, AND THERE ARE OTHERS.

SO WHERE ARE WE AT? SO RIGHT NOW WE ARE IN THE NEEDS -- FINALIZING THE NEEDS ASSESSMENT PHASE. WE JUST FINISHED THE THREE LISTENING SESSIONS. WE ARE NOW MOVING TO THE STATEWIDE PUBLIC WORKSHOP WHERE WE'LL GET ADDITIONAL INFORMATION FROM THE PUBLIC. THAT WILL TAKE PLACE IN SACRAMENTO. IT WILL ALSO BE LIVE AND VIRTUAL, AND THAT WILL TAKE PLACE ON JUNE 22D. AFTER WE COLLECT ALL THAT INFORMATION, THE TEAM WILL THEN GO TO THE BOARD REVIEW. WE WILL HAVE A DRAFT CONCEPT PLAN, AND THAT WILL GO TO THE AAWG FOR CONSIDERATION AND RECOMMENDATIONS, IT WILL GO TO THE SCIENCE SUBCOMMITTEE, AND THEN TO THE ICOC FOR FINAL CONSIDERATION.

THEN WE WILL MOVE TO THE APPLICATION PHASE

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WHERE WE'LL POST THE RFA. WE WILL CREATE A WEBINAR TO ADDRESS FREQUENTLY ASKED QUESTIONS ABOUT THE RFA AND THE PROCESS. AND AT THAT POINT WE'LL BASICALLY OPEN UP THE APPLICATION PROCESS. AND WE ARE ANTICIPATING THAT WILL TAKE PLACE IN EARLY 2024.

SO THIS IS AN EXCITING PROGRAM. I THINK THIS WILL PROVIDE A SIGNIFICANT FOUNDATION OUT IN THE RURAL COMMUNITIES TO ADDRESS MANY ACCESS AND AFFORDABILITY CHALLENGES, PARTICULARLY THE PARTICIPATION IN CLINICAL TRIALS, THE EDUCATIONAL, AND THE ENGAGEMENT. THERE'S GOING TO BE SIGNIFICANT INTERACTION WITH THE ALPHA CLINICS. AND THE PATIENT SUPPORT PROGRAM, OF COURSE, WILL PROVIDE ADDITIONAL SUPPORT TO BOTH ORGANIZATIONS.

SO WITH THAT, I WANT TO SAY THANK YOU AND HOPEFULLY THAT PROVIDES A SNAPSHOT OF WHERE WE ARE AT. THESE ARE BOTH BIG INITIATIVES. I DO WANT TO THANK THE TEAM INTERNALLY AND, OF COURSE, THE EXTERNAL TEAMS, THE CROSS-FUNCTIONAL TEAMS THAT HELPED US TAKE BOTH CONCEPTS TO THE STARTING LINE.

SO WITH THAT, VICE CHAIR, I'LL GO AHEAD AND HAND IT OVER TO YOU, OUR VICE CHAIRMAN, AND OPEN IT UP TO QUESTIONS OR COMMENTS.

CHAIRMAN IMBASCIANI: THANK YOU, SEAN, FOR YOUR PRESENTATION. SO, BOARD MEMBERS, DO YOU HAVE

ANY QUESTIONS FOR MR. TURBEVILLE?

MS. DEQUINA-VILLABLANCA: STEVE HAS HIS HAND RAISED.

CHAIRMAN IMBASCIANI: I SEE IT. MEMBER JUELSGAARD.

MR. JUELSGAARD: YES. SEAN, THANK YOU FOR THAT PRESENTATION. I WANT TO ASK YOU A QUESTION IN REGARDS PARTICULARLY SOMETHING THAT'S ON SLIDE 6 THAT'S CALLED THE PATIENT SUPPORT PROGRAM WITH AN RFA POSTING THIS COMING JULY. I TAKE IT YOU MEAN BY THAT CLINICAL TRIAL PATIENTS OR CLINICAL TRIAL SUBJECTS SUPPORT PROGRAM. IS THAT WHAT YOU'RE REFERRING TO?

DR. TURBEVILLE: SO, FIRST, LET ME CLARIFY. THE RFA IS POSTED NOW. SO THAT IS LIVE. SO WE ARE A LITTLE BIT AHEAD OF SCHEDULE. SO THAT'S A GREAT THING. BUT THIS REFERRED TO THE PATIENT SUPPORT PROGRAM, CORRECT, THAT NOT ONLY INCLUDES PATIENT NAVIGATION, PATIENT EDUCATION, BUT ALSO THAT'S WHERE THE PATIENT ACCESS FUND SITS WHERE THEY CAN PROVIDE ADDITIONAL SUPPORT, FINANCIAL SUPPORT, TO PATIENTS THAT PARTICIPATE IN CIRM-FUNDED TRIALS.

MR. JUELSGAARD: RIGHT. SO THE QUESTION ULTIMATELY, THEN, IS HOW DOES THIS INTERLOCK WITH THE ACTUAL CLINICAL TRIALS THAT AN INSTITUTION WOULD

COME FORWARD WITH FOR CLINICAL SUPPORT? SO ASSUME IT'S EITHER AN ACADEMIC OR A FOR-PROFIT INSTITUTION AND THEY'VE GOT A CLINICAL TRIAL THAT THEY WANT TO ENGAGE IN. HOW DOES THAT DESIRE ON THEIR PART LINK UP WITH THIS SUPPORT PROGRAM WHEN IT COMES TO SUPPORTING PATIENTS TO BE ABLE TO PARTICIPATE IN THE CLINICAL TRIAL PROGRAMS?

I KNOW WE SPENT A LOT OF TIME TALKING ABOUT DIVERSITY, EQUITY, AND INCLUSION, AND WE LOOK AT THE INSTITUTIONS THAT ARE INVOLVED AND THE LABORING OAR THAT THEY HAVE WITH THAT REGARD, BUT WE ALSO HAVE A LABORING OAR IN ALL OF THIS. AND MY QUESTION IS HOW ARE WE GOING TO INTERLOCK THAT LABORING OAR ON OUR PART WITH ONE OF THE ACADEMIC OR FOR-PROFIT INSTITUTIONS?

DR. TURBEVILLE: CERTAINLY. IF, IN FACT, IT IS A CIRM-FUNDED TRIAL AND THEY WANT TO GET ACCESS TO THE PATIENT SUPPORT PROGRAM, THOSE PATIENTS WOULD QUALIFY FOR THAT SERVICE. SO THAT SITE COULD UTILIZE THIS SERVICE FOR INFORMATION NOT ONLY ON THE TRIAL, BUT ALSO ACCESSING ADDITIONAL RESOURCES IF THE PATIENTS QUALIFY FROM A FINANCIAL STANDPOINT.

WITH RESPECT TO THE DEI, SO THE PATIENT SUPPORT PROGRAM DOES HAVE A ROBUST AND CONCURRENT

DEI WITH NOT ONLY THE ALPHA CLINICS, AND MANY OF THE ICOC MEMBERS AND AAWG MEMBERS PROVIDED GUIDANCE TO THAT. SO THAT IS LISTED IN THE RFA WITH RESPECT, AND IT'S A HEAVY DEI REQUEST OF SERVICE PROVIDERS. BUT WE DID DO QUITE A BIT OF DUE DILIGENCE TO MAKE SURE THAT THERE'S CONCORDANCE NOT ONLY ACROSS OTHER FUNDING MECHANISMS, BUT ALSO WHAT'S IMPORTANT FROM THE PATIENT SUPPORT PROGRAM.

I THINK, STEVE, YOU HAD ONE MORE QUESTION; IS THAT CORRECT?

MR. JUELSGAARD: NO. THAT WAS FUNDAMENTALLY THE QUESTION. I THINK THIS IS STILL A WORK IN PROGRESS AND FIGURING OUT HOW WE BRING TOGETHER ON THE ONE HAND THE DESIRE OF AN INSTITUTION, LET'S JUST LEAVE IT AT THAT, TO DO A CLINICAL TRIAL AND TO INCLUDE AS MANY PATIENTS AS THEY CAN WHO CAN'T NECESSARILY AFFORD FOR WHATEVER REASON TO PARTICIPATE IN A CLINICAL TRIAL, TIME INVOLVED, DISTANCE, ALL THOSE FACTORS, HOW WE INTERLOCK THAT WITH WHERE OUR SUPPORT PROGRAM IS GOING TO BE BROUGHT DOWN TO THE INDIVIDUAL CLINICAL TRIAL LEVEL. I THINK WE STILL -- WE NEED TO HAVE A PROCESS BY WHICH THAT HAPPENS. I'M NOT SURE QUITE I UNDERSTAND THE BROAD RFA OTHER THAN PUTTING TOGETHER SOME AMOUNT OF MONEY THAT WOULD GO TO THIS, BUT

BEYOND THAT HOW IT ACTUALLY WORKS IN PRACTICE AT THE CLINICAL TRIAL LEVEL, I THINK WE'LL WIND UP WAITING TO SEE HOW THAT WORKS OUT.

CHAIRMAN IMBASCIANI: THANK YOU. CONTINUING WITH BOARD COMMENTS, I HAVE MEMBER DULIEGE.

DR. DULIEGE: YES. MAYBE MY QUESTION IS AN EXTENSION OF STEVE'S QUESTION. SO, SEAN, THANK YOU SO MUCH. VERY CLEAR PRESENTATION. VERY GOOD SENSE OF DIRECTION. CAN YOU HELP US UNDERSTAND HOW THIS WOULD TRANSLATE FOR EXTREMELY RARE DISEASES? AND GENERALLY ALL THE GRANTS WE FUND ARE FOR FAIRLY RARE DISEASES, MOST OR SOME, MANY OTHERS. BUT AS AN EXAMPLE, THE ONE WE APPROVED TODAY IS PEDIATRIC LIVER CANCER, TALKING ABOUT AN EXTREMELY RARE INDICATION, THANK GOD. HOW WOULD YOUR PROGRAM HELP THE CENTER ENROLL PATIENTS FASTER IN AN EASIER FASHION? WHAT WILL YOUR PROGRAM, THIS PROGRAM THAT YOU SUGGEST, DO FOR PATIENTS OR TO PATIENTS?

DR. TURBEVILLE: YEAH. CERTAINLY. SO YOU CAN ENVISION A FAMILY MEMBER, A COMMUNITY PHYSICIAN WHO'S REPRESENTING THE PATIENT LOOKING FOR INFORMATION FOR CIRM-FUNDED TRIALS THAT WOULD MEET THIS PATIENT'S DIAGNOSIS. SO THAT WOULD BE THE FIRST THING. IT'S BASICALLY A HUB WHERE THEY CAN

GET INFORMATION QUICKLY TO SEE IF THEY POTENTIALLY QUALIFY AND THEN, MORE IMPORTANTLY, BEING ABLE TO TRIAGE THAT PATIENT TO THE SITE SO THAT THEY CAN ENGAGE WITH THE CLINICAL COORDINATOR. SO IT'S PATIENT EDUCATION. IT COULD BE HEALTHCARE EDUCATION ABOUT ALL OF OUR CIRM-FUNDED SITES AND WHAT THEY'RE ASKING AND, MORE IMPORTANTLY, THE NAVIGATION AND EVEN POTENTIALLY A WARM TRANSFER TO THE SITE ITSELF.

DR. DULIEGE: YEAH. THAT ABSOLUTELY MAKES A LOT OF SENSE, SEAN. AND WITHOUT GETTING INTO TOO MANY DETAILS AT THE BOARD LEVEL HERE, CLEARLY PHYSICIANS WHO KNOW ABOUT THESE PATIENTS ARE THOSE VERY RARE PHYSICIANS WHO ARE PEDIATRIC ONCOLOGISTS AND, IN FACT, MORE SPECIFICALLY, PEDIATRIC GI ONCOLOGISTS. IS THIS THE GROUP OF PHYSICIANS YOU WOULD BE TARGETING IN THIS CASE?

DR. TURBEVILLE: I DON'T KNOW IF WE'D BE TARGETING ANY PARTICULAR PHYSICIANS. I WOULDN'T SAY WE'D BE TARGETING ANY PARTICULAR THERAPEUTIC AREA. WE HAVE OBVIOUSLY 88 PLUS TRIALS GOING ON ACROSS A NUMBER OF DIFFERENT THERAPEUTIC AREAS. BUT CERTAINLY WE COULD PROVIDE INFORMATION TO THE CENTERS OF EXCELLENCE THAT BASICALLY HAS THAT LEVEL OF THERAPEUTIC EXPERTISE, IF YOU THINK ABOUT PEDS AND ONCOLOGY. AND IF THERE IS A PARTICULAR

CIRM-FUNDED TRIAL THAT WE ARE SUPPORTING, YEAH, I WOULD SAY THAT THIS WOULD BE A GOOD SYNERGY WITH RESPECT TO FACILITATING INFORMATION AND GETTING INFORMATION QUICKLY TO THE HEALTHCARE PROVIDER WHO THEN PERHAPS CAN MAKE A DECISION WITH THE PATIENT OF WHETHER OR NOT IT'S A GOOD TRIAL FOR THEM.

DR. DULIEGE: THANK YOU. VERY GOOD. THANK YOU VERY MUCH.

CHAIRMAN IMBASCIANI: GOOD ANSWER.

MS. DEQUINA-VILLABLANCA: LARRY HAS HIS HAND RAISED.

DR. GOLDSTEIN: MR. CHAIRMAN, MAY I SPEAK?

CHAIRMAN IMBASCIANI: YES. THE FLOOR IS YOURS.

DR. GOLDSTEIN: THANK YOU. SEAN, TERRIFIC PROGRESS, INTERESTING PRESENTATION. I DO WANT TO RETURN TO AN ISSUE THAT YSABEL RAISED ABOUT AN HOUR AGO, WHICH IS ONE OF THE MOST IMPORTANT BARRIERS TO ACCESS AND AFFORDABILITY AND THAT IS JUST THE SHEER DEVELOPMENT COSTS OF DEVELOPING THESE THERAPIES. I'VE TALKED TO A FEW OTHER BOARD MEMBERS ABOUT THIS ISSUE. AND I HAVE BEEN WONDERING MUST WE ALWAYS HAVE A COMMERCIAL PARTNER TO DEVELOP A THERAPY? BECAUSE SOMETIMES THE COMMERCIAL PARTNER DECIDES, WELL, THEY'RE NOT GOING TO BE ABLE TO CHARGE ENOUGH

TO MAKE IT WORTH THEIR WHILE OR THEY REORGANIZE. AND THEN WE HAVE THE SITUATION WE HAD WITH ORCHARD WHERE FUNDS AND INTELLECTUAL PROPERTY HAD TO BE CLAWED BACK.

IS THERE VALUE TO DEVELOPING A COMPLETELY NONPROFIT TRACK FOR THE DEVELOPMENT OF SOME OF THESE THERAPIES AND ADDRESSING ACCESS AND AFFORDABILITY IN THAT WAY AS PART OF THE PROBLEM?

DR. TURBEVILLE: YEAH. IT'S A GOOD QUESTION. THERE ARE CERTAINLY VEHICLES NOW THAT ARE BEING DISCUSSED WHERE A DIFFERENT MECHANISM COULD BE PROVIDED FROM A NOT-FOR-PROFIT ORGANIZATION TO SUPPORT THE CLINICAL TRIAL PROCESS FOR PATIENTS AND NOT ONLY THE MANUFACTURING AS WELL. BUT I'D HAVE TO DEFER PROBABLY TO OUR CEO, DR. MILLAN, IF SHE CAN PROVIDE ANY GUIDANCE ON THAT SPECIFIC QUESTION.

DR. MILLAN: THANK YOU SO MUCH. CAN YOU HEAR ME NOW?

MS. DEQUINA-VILLABLANCA: YES, WE CAN HEAR YOU.

DR. MILLAN: THANK YOU FOR THAT QUESTION, DR. GOLDSTEIN. IT'S A VERY IMPORTANT QUESTION. IT COMES UP AT ALL THE LARGE MEETINGS THAT WE RECENTLY ATTENDED AT THE ASGCT, AT THE VARIOUS CONGREGATION OF INDUSTRY, ACADEMIA, PATIENT ADVOCACY, AND THE

PUBLIC REGARDING THE QUESTION OF HOW WE BRING THESE INNOVATIONS ESPECIALLY TO THE SMALLER POPULATIONS OR THOSE THAT DON'T HAVE ACCESS IN AN EVOLVING WORLD FOR BOTH THE INDUSTRY, THE PAYER LANDSCAPE, AND ALL OF THE OTHER SUPPORTING INFRASTRUCTURE AND POLICY ARE STILL IN EVOLUTION.

TO BE MORE CONCRETE ABOUT IT, WE DO HAVE OUR INTERNAL TEAM, INCLUDING DR. ABLA CREASEY FROM OUR THERAPEUTICS DEVELOPMENT TEAM, THE MEDICAL AFFAIRS POLICY TEAM, OUR BOARD MEMBERS, BUSINESS DEVELOPMENT, AND OTHER MEMBERS ENGAGED IN A VARIETY OF CONVERSATIONS WITH STAKEHOLDERS WHO WANT TO LOOK AT, INCLUDING PATIENT FOUNDATIONS WHO ARE ACTUALLY GOING AT IT ALONE AND GOING ABOUT IT THE RIGHT WAY WORKING WITH REGULATORS AND SCIENTISTS AND PARTNERS TO ACHIEVE THAT VERY -- TO TRY TO OVERCOME THE VERY PROBLEM THAT YOU JUST STATED.

SO IT'S ON OUR RADAR. WE HOPE TO BE BRINGING BACK TO THE BOARD OVER THE COURSE OF MONTHS AND YEARS SOME IDEAS ON HOW CIRM COULD PLAY A ROLE IN SOME OF THE POTENTIAL SOLUTIONS VIA PARTNERSHIPS AND MAYBE EVEN THROUGH HOW WE IMPLEMENT OUR FUNDING PROGRAMS. WE HAVE A LOT OF OPPORTUNITIES HERE AT CIRM.

SO WE DON'T HAVE ANYTHING CONCRETE TO

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SHARE. IT'S A VERY IMPORTANT QUESTION, BUT IT'S NOT SOMETHING THAT NECESSARILY WILL BE ADDRESSED BY THE PATIENT SUPPORT PROGRAM PER SE. I THINK THE PATIENT SUPPORT PROGRAM AND ANY OTHER INFRASTRUCTURE THAT CIRM INVESTS IN ARE ALL IN SERVICE OF THE BIG PICTURE OF THESE OPPORTUNITIES AS THEY GO FORWARD, BUT NOTHING SPECIFIC RELATED TO THIS PARTICULAR INITIATIVE.

I'M HAPPY TO TAKE OTHER QUESTIONS, BUT I HOPE THAT'S SUFFICIENT FOR NOW. BUT PLEASE KNOW THAT THIS IS DEFINITELY ON OUR RADAR, AND WE ARE VERY MUCH LOOKING FORWARD TO ENGAGING ACTIVELY WITH THE BOARD, THE SUBCOMMITTEES, THE WORKING GROUPS IN VARIOUS WORKSTREAMS THAT ALL CULMINATE TO ADDRESS THIS QUESTION AS WELL AS OTHER RELATED QUESTIONS TO BROADER DISEASE INDICATIONS AS WELL BECAUSE THE ENTIRE FIELD, EVEN CAR-T WHERE THERE ARE APPROVED THERAPIES, IT'S VERY WELL-KNOWN THE ACCESS IS VERY MUCH IMPERFECT. THERE'S A SIGNIFICANT PROPORTION OF PATIENTS WITH ADVANCED MALIGNANCIES WHO DON'T HAVE ACCESS TO CAR-T THERAPIES THAT HAVE ALREADY BEEN APPROVED. AND THAT IS SOMETHING THAT IS ALSO ON THE RADAR AND IS IN ACTIVE EVOLUTION RIGHT NOW. THANK YOU.

DR. GOLDSTEIN: THANK YOU, MARIA. I JUST

WANT TO MAKE ONE OTHER POINT ABOUT THAT, WHICH IS CERTAINLY IN THE HISTORY OF MEDICAL THERAPY DEVELOPMENT, NOT EVERYTHING GOES THROUGH THE EYE OF THE NEEDLE OF A PRIVATE COMPANY THAT NEEDS TO MAKE A PROFIT. YOU AS A TRANSPLANT SURGEON KNOW THAT BETTER THAN MOST, THAT TRANSPLANT MEDICINE WAS LARGELY DEVELOPED IN ACADEMIC HEALTH CENTERS AND PRIVATE HOSPITALS AND ARE DELIVERED WITHOUT NECESSARILY REQUIRING THAT THERE BE A PROFIT ON THE THERAPY WHEN IT'S DELIVERED. SO JUST A POINT. YOU DON'T NEED TO RESPOND.

DR. MILLAN: I DO WANT TO RESPOND BECAUSE I THINK THAT'S A REALLY IMPORTANT POINT. BUT THERE ARE -- WITH ORGAN TRANSPLANT, FOR INSTANCE, WE ENCOUNTERED HISTORICALLY THE SAME TYPES OF CHALLENGES THAT WE ARE DEALING WITH NOW WITH NEW INNOVATION, FOR INSTANCE, COVERAGE. SO THE HEALTHCARE ECONOMICS (UNINTELLIGIBLE) ARGUMENT NEEDED TO BE MADE TO DEMONSTRATE VALUE IN TERMS OF KIDNEY TRANSPLANT OVER DIALYSIS. SO THAT REQUIRED REALLY HARD DATA, IMPORTANT INFORMATION TO MAKE IT CLEAR THAT YOU MAKE A VALUE CALL THERE AND THAT CMS WOULD COVER IT. AND THEN SAME THING WITH IMMUNOSUPPRESSION, INITIAL INCENTIVES FOR IMMUNOSUPPRESSION MEDICATIONS AND EVERYTHING RELATED

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TO TRANSPLANT, ALL OF THE PICKS AND SHOVELS THAT ARE RELATED TO THE INDUSTRY, EVEN THOUGH IT REMAINS LARGELY ACADEMIC BASED IN PRACTICE.

SO I THINK THAT WAS A VERY -- IT'S A VERY GOOD ANALOGY. AND, IN FACT, IT'S AN ANALOGY IN MANY OF THESE BROAD CONVERSATIONS THAT DOES ARISE IN TERMS OF MODELS THAT ARE NOT (INAUDIBLE).

CHAIRMAN IMBASCIANI: THANK YOU, MARIA.

ANY OTHER QUESTIONS OR COMMENTS FOR SEAN?

MS. DEQUINA-VILLABLANCA: I DON'T SEE ANY OTHER HANDS RAISED, VITO.

CHAIRMAN IMBASCIANI: ARE THERE ANY MEMBERS OF THE PUBLIC WHO WOULD LIKE TO MAKE SOME COMMENTS ON THIS SUBJECT?

MS. DEQUINA-VILLABLANCA: THERE ARE NONE IN THE QUEUE.

CHAIRMAN IMBASCIANI: THANK YOU, MARIANNE.

ALL RIGHT. SO WE'RE GOING TO NOW PROCEED TO OUR LAST SUBSTANTIVE ITEM ON THE AGENDA, WHICH IS THE UPDATE TO OUR NEURO TASK FORCE. LARRY GOLDSTEIN, I SHOULD HAVE ASKED YOU TO STAY RIGHT WHERE ARE.

DR. GOLDSTEIN: I DIDN'T MOVE. DON'T WORRY. OKAY. I'LL BE RELATIVELY BRIEF BECAUSE I THINK PEOPLE ARE STARTING TO GET A LITTLE TIRED.

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YOU WILL RECALL AT AN ICOC MEETING BACK IN THE WINTER WE AGREED TO SET UP A SUBCOMMITTEE OF THE BOARD IN PARTNERSHIP WITH MEMBERS OF THE CIRM TEAM TO LOOK AT THE QUESTION OF THE ONE AND A HALF BILLION SET-ASIDE FOR GENERAL NEURO RELATED DISORDERS CALLED OUT IN THE TEXT OF PROPOSITION 14.

AND I THINK TO FRAME THE QUESTION OF WHAT SHOULD OR SHOULDN'T BE DONE IS JUST TO REMEMBER THAT, WHEN WE USE GRANT REVIEW TO DETERMINE WHAT WE FUND, WE ARE IN A SENSE, UNLESS WE PUT TIGHT DESCRIPTORS ON THE CALL FOR APPLICATIONS, THE GRANT REVIEW GROUP IS MAKING PRIORITY DECISIONS FOR US. AND SO IT MAKES SENSE THAT WE MAY WANT TO CALL OUT PARTICULAR AREAS THAT WE WOULD WANT TO FUND OR SUPPORT.

AND SO THE NEURO TASK FORCE MEMBERSHIP AS SHOWN HERE HAS BEEN WORKING WITH THAT QUESTION. AT OUR INITIAL MEETING, WE HAD EXCELLENT PRESENTATIONS FROM CIRM TEAM MEMBERS ABOUT THE PORTFOLIO OF CIRM-SUPPORTED PROJECTS IN THE NEURO SPACE AND ALSO SOME ANALYSIS OF WHAT WAS HAPPENING IN THE CALIFORNIA INDUSTRY SPACE. AND ONE OF THE EASIEST WAYS TO GET TRACTION ON AN ISSUE LIKE THIS, BECAUSE MAKING PRIORITY DECISIONS CAN BE A TRICKY BUSINESS IN MY EXPERIENCE, WAS TO SIMPLY ASK IS THERE

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ANYTHING MISSING FROM OUR PORTFOLIO. AND, IN FACT, WHAT WAS GLARINGLY OBVIOUS IS THAT WE REALLY HAD VERY LITTLE IN THE WAY OF FUNDING SUPPORT OF NEUROPSYCHIATRIC DISORDERS, DEPRESSION, ANOREXIA, BIPOLAR, A WHOLE COLLECTION OF REALLY TERRIBLE DISEASES, MANY OF WHICH AFFLICT UNDERSERVED POPULATIONS MORE SERIOUSLY THAN THE WEALTHY IN THE STATE. AND IT LOOKED LIKE AN AREA WHERE WE COULD MAKE A DIFFERENCE.

AND SO WE SCHEDULED OVER THE COURSE OF THE A FEW MONTHS EXPERTS IN THE NEUROPSYCHIATRIC AREA TO COME IN AND TELL US WHAT HAS BEEN LEARNED RECENTLY. AND SO AS SHOWN HERE, THE MARCH MEETING FOCUSED ON NEUROPSYCHIATRIC GENETICS WHERE WE ASKED AND GOT SOME ANSWERS TO THE QUESTION OF WHAT PROPORTION OF THE SUSCEPTIBILITY TO THESE DIFFERENT DISORDERS IS CAUSED BY GENETIC ELEMENTS. BECAUSE IF YOU ARE GOING TO USE STEM CELLS TO TRY TO DEVELOP MODELS OF A DISEASE, IT REALLY HELPS IF YOU HAVE GENETIC ELEMENTS IDENTIFIED THAT ARE KNOWN TO DRIVE THE DISEASE IN HUMAN PATIENTS AND, THEREFORE, THAT STEM CELL MODELS OF THAT DISEASE CAN BE MADE IN THE CULTURE DISH.

AND SO BEN NEAL AND JONATHAN SABAT GAVE US A VERY GOOD RENDITION OF WHAT'S GOING ON IN THE

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FIELD. AND TO MAKE A LONG STORY SHORT, THERE ARE SUBSTANTIAL GENETIC CONTRIBUTIONS TO MANY OF THESE NEUROPSYCHIATRIC DISORDERS. IN SOME CASES THEY ARE RARE STRONG VARIANTS. IN OTHER CASES THEY ARE COMBINATIONS OF COMMON SMALL EFFECT VARIANTS. BUT THE GENETIC UNDERPINNINGS OF THE DISORDERS ARE, IN GENERAL, STRONG ENOUGH THAT DEVELOPING STEM CELL MODELS FOR ANALYSIS OF MECHANISM AND THEN THE IDENTIFICATION OF POTENTIAL THERAPEUTIC INTERVENTIONS LOOKS TO BE, WELL, PERHAPS NOT STRAIGHTFORWARD, BUT ABSOLUTELY ACHIEVABLE.

AND SO THE SUBSEQUENT TWO MONTHS WERE SPENT ON DIFFERENT WAYS OF ANALYZING WHAT WOULD GO -- WHAT WAS GOING WRONG IN NEURONS IN OTHER PARTS OF THE BRAIN OR IN CELLS IN CULTURE MADE FROM STEM CELL MODELS. AND REALLY ONE OF THE BEST PRESENTATIONS ABOUT THIS CAME FROM TOM SUDHOF AT STANFORD. TOM WON THE NOBEL PRIZE A FEW YEARS AGO FOR HIS WORK ON THE BIOCHEMISTRY OF HOW SYNAPSES WORK; THAT IS, HOW NEURONS TALK TO EACH OTHER IN THE BRAIN. AND HE PRESENTED A LOVELY EXAMPLE WHERE THEY CHASED DOWN ONE PARTICULAR NEUROPSYCHIATRIC DISORDER TO DEFECTS IN A KEY SYNAPTIC PROTEIN THAT WAS INVOLVED IN THE ABILITY OF NEURONS TO CONVERSE WITH EACH OTHER.

AND SO WHILE THAT KNOWLEDGE BY ITSELF DOES NOT ESTABLISH A THERAPY, IT GIVES YOU THE TRACTION TO THINK ABOUT IDENTIFYING EITHER A DRUG THERAPY, A GENE THERAPY, A CELLULAR THERAPY, WHAT HAVE YOU, USING THE KINDS OF METHODOLOGIES THAT WE'VE BEEN TALKING ABOUT FOR THE PAST MANY YEARS IN CIRM-FUNDED PROGRAMS.

AND SO WHERE WE SIT AT THIS POINT IS THAT DR. CANET-AVILES WILL BE DEVELOPING A CONCEPT PLAN THAT THE BOARD WILL SEE IN THE FALL WITH THE IDEA OF BEGINNING TO PULL TOGETHER INTERDISCIPLINARY COLLABORATIVE GROUPS ACROSS THE STATE TO MAKE HEADWAY ON SOME OF THESE TERRIBLE PROBLEMS THAT ARE, IN MY VIEW, UNDERSTUDIED USING THE KIND OF METHODOLOGY WE HAVE BEEN SUPPORTING FOR MANY YEARS.

MEANWHILE, WE WILL GO BACK TO THE WELL AND SEE IF WE CAN DO A DEEPER DIVE ON WHAT'S IN OUR PORTFOLIO AND WHETHER THE DISTRIBUTION OF FUNDING REFLECTS OUR SENSE OF VALUES AND PRIORITIES THAT WILL BEGIN WITH THE JUNE MEETING AND CONTINUE ON THROUGH THE SUMMER. AND PERHAPS I CAN GIVE YOU AN UPDATE THEN IN THE FALL.

SO THAT'S ALL I WANT TO SAY, MR. CHAIRMAN. I'M HAPPY TO ENTERTAIN QUESTIONS FROM THE FLOOR OR FROM ANYBODY ELSE.

CHAIRMAN IMBASCIANI: THANK YOU, DR. GOLDSTEIN. I'M SURE THERE WILL BE SOME COMMENTS FROM THE BOARD. LET'S SEE HERE. I'M SCROLLING THROUGH. I DON'T SEE ANYTHING YET.

MS. DEQUINA-VILLABLANCA: LEONDRA HAS HER HAND RAISED.

CHAIRMAN IMBASCIANI: LEONDRA AND THEN I SEE FRED FISHER. OKAY. IN THAT ORDER.

DR. CLARK-HARVEY: THANK YOU SO MUCH. I JUST WANT TO SUPPORT THE GOOD REPORT OUT OF THE WORK OF THE GROUP AND REALLY APPRECIATE BEING PART OF THE CONVERSATION AND JUST WANTED TO ADD THOSE COMMENTS IN SUPPORT OF THE WORK THAT'S HAPPENING THERE.

CHAIRMAN IMBASCIANI: THANK YOU.

DR. GOLDSTEIN: THANK YOU, LEONDRA.

CHAIRMAN IMBASCIANI: SO WE HAVE BOARD MEMBER FISHER.

DR. FISHER: I'M ALSO ON THE GROUP AND PARTICIPATED IN ALL THE MEETINGS. I HOPE THAT WHATEVER CONCEPT PLAN IS BEING PUT TOGETHER WILL ADDRESS THE OBSTACLES THAT WE HEARD FROM THE NEUROPSYCH FOLKS AS TO WHY THEY'RE NOT APPLYING TO CIRM FOR FUNDING. IT'S NOT THAT WE ARE INVISIBLE TO THEM. IT'S NOT THAT THERE ISN'T RELEVANCE BETWEEN WHAT IT IS WE DO AND WHAT IT IS THEY DO. IT'S NOT

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BECAUSE WE ARE AN INAPPROPRIATE SOURCE OF FUNDING FOR THEIR WORK. IT'S BECAUSE OF OUR OWN PROCESS AND THEIR EXPERIENCE OF IT.

ON THE LAST CALL WE HEARD SOME ABOUT THAT. I REGRET NOT ASKING THE QUESTION IN THE PRIOR SESSIONS, BUT NO PROJECT PLAN WILL BE SUCCESSFUL WITHOUT ADDRESSING THE OBSTACLES THAT WE IMPOSE ON THOSE RESEARCHERS THAT ACTUALLY RESULT IN NEUROPSYCH BEING UNDERREPRESENTED IN THE PROJECTS WE FUND.

DR. GOLDSTEIN: YEAH. IF I MIGHT RESPOND, FRED, I THINK THAT'S ABSOLUTELY AN IMPORTANT POINT. BUT I THINK ONE OF THE POINTS OF HOPE IS THAT SOME OF THE FOLKS WHO WORK IN THAT FIELD HAVE CONTACTED ME INDEPENDENTLY OF FORMAL MEETINGS TO EXPRESS THEIR INTEREST IN TRYING TO WORK WITH CIRM IN A VARIETY OF WAYS. AND I THINK THAT DIALOGUE CONTINUING FORWARD WILL HELP US DEVELOP FUNDING PROGRAMS THAT THEY WILL FIND APPROPRIATE FOR THE KIND OF WORK THEY WANT TO DO.

DR. FISHER: I HOPE SO. I JUST THINK IT'S IMPORTANT FOR THE BOARD TO UNDERSTAND THAT IT IS NOT DUE TO NEGLECT OR INVISIBILITY OR LACK OF UNDERSTANDING. IT IS DUE TO THEIR EXPERIENCE OF CIRM AND OUR APPLICATION PROCESS. AND IF WE DON'T ADDRESS THAT, NEUROPSYCH WILL CONTINUE TO BE

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UNDERREPRESENTED. THAT WAS MY TAKEAWAY FROM THE COMMENTS I HEARD.

DR. GOLDSTEIN: FAIR POINTS. WE NEED TO WORK ON THAT.

CHAIRMAN IMBASCIANI: MEMBER -- MARVIN, I SEE YOUR HAND.

DR. SOUTHARD: YES. I JUST WANTED TO CONCUR WITH FRED'S COMMENTS ABOUT THE PROCESS. I THINK THAT IS REALLY A CRUCIAL POINT THAT WE NEED TO ADDRESS. BUT I ALSO WANT TO COMMEND LARRY FOR THE PRESENTATIONS. I LEARNED SO MUCH IN AREAS I WAS NOT FURTHER FAMILIAR. SO EXCELLENT SCHEDULING OF PRESENTATIONS, AND THEY WERE VERY, VERY USEFUL TO ME. THANK YOU.

DR. GOLDSTEIN: THANK YOU, MARV.

CHAIRMAN IMBASCIANI: MEMBER BONNEVILLE -- VICE CHAIR BONNEVILLE.

VICE CHAIR BONNEVILLE: I JUST WANTED TO SAY I THINK THAT THE TEAM WILL UNDERGO THAT SORT OF REVIEW TO ENSURE THAT WHATEVER FUNDING MECHANISM IS, THAT IT WORKS FOR THE NEUROPSYCH COMMUNITY IF THEY'VE EXPRESSED SOME CONCERN. WE'VE ONLY HEARD FROM ONE PERSON REALLY ABOUT THAT. SO I JUST WANT TO MAKE SURE THAT IT'S A REAL CONCERN VERSUS GOING DOWN A PATH THAT WE MAY NOT NEED TO. AND I'M SURE

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THAT THAT'S SOMETHING THAT THE TEAM WILL EVALUATE.

SO I JUST DIDN'T WANT THAT RHETORIC TO GET OUT, THAT SOMEHOW OUR FUNDING MECHANISMS DON'T WORK FOR PEOPLE. IT MAY NOT HAVE WORKED IN THAT ONE INSTANCE. WE DON'T KNOW. SO I JUST WANT TO MAKE SURE THAT -- OF COURSE, THE TEAM WILL LOOK AT IT AS PART OF THEIR REVIEW WHEN THEY BRING A CONCEPT PLAN TOGETHER, BUT I JUST WANTED TO MAKE SURE EVERYBODY KNOWS THAT WE'LL JUST -- THE TEAM WILL LOOK AT IT AND THEN WE'LL MOVE FORWARD FROM THERE.

DR. FISHER: I THINK WE HEARD FROM BOTH PRESENTERS THAT DAY, NOT JUST ONE. THERE WERE TWO PRESENTERS THAT DAY. IT OCCURRED TO ME TO ASK THE QUESTION, AND WE HEARD ANSWERS THAT REFLECTED THE PROBLEM. I DON'T KNOW HOW BIG THE PROBLEM IS.

VICE CHAIR BONNEVILLE: SURE. THAT'S EXACTLY RIGHT. THAT'S WHAT I WAS JUST GETTING AT IS THAT I DON'T KNOW. AND SO I DO WANT THE TEAM TO LOOK AT IT SO THAT WE UNDERSTAND IF THERE IS A PROBLEM OR IF IT WAS JUST SORT OF AN ISOLATED SITUATION.

CHAIRMAN IMBASCIANI: MEMBER JUELSGAARD. STEVE, THE FLOOR IS YOURS. WHILE HE'S --

MR. JUELSGAARD: SORRY ABOUT THAT. I HAVE TWO COMPUTERS GOING, AND ONE OVERRIDES THE OTHER.

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SO BACK TO THE DISCUSSION THAT WE JUST HAD A LITTLE BIT OF THAT FRED RAISED, BUT FROM A DIFFERENT POINT OF VIEW. SO PROPOSITION 14 SPECIFICALLY ALLOCATES, IT'S THE FIRST TIME THAT EITHER PROP 71 OR PROP 14 EVER DID THIS, WAS TO ALLOCATE A SPECIFIC AMOUNT OF MONEY THAT IS NO LESS THAN $1.5 BILLION IN THE AREA OF THE BRAIN AND THE CNS SYSTEM. ALL RIGHT. SO THAT MONEY CAN'T BE SPENT, IN MY VIEW ANYWAY, FOR OTHER THERAPEUTIC AREAS AND OTHER DISEASES.

NOW, THAT'S A TREMENDOUS AMOUNT OF MONEY ALTOGETHER. AND IT ALMOST SUGGESTS A SPECIAL TREATMENT FOR THIS AREA IN TERMS OF HOW WE THINK ABOUT IT. AND THAT INCLUDES THE COST, NOT ONLY OF DISCOVERY RESEARCH, WHICH CAN BE MORE EXPENSIVE IN THIS AREA THAN, SAY, IN OTHER WELL-TROD AREAS LIKE ONCOLOGY, FOR EXAMPLE, WHERE THERE'S A LOT OF EFFORT THAT'S BEEN GOING ON HISTORICALLY, AND CAN EXTEND INTO CLINICAL TRIALS, ET CETERA.

AND I THINK THAT ONE OF THE THINGS THAT ALONG THE WAY, AND I HAVE RAISED THIS KIND OF PERIPHERALLY AT THE NEURO TASK GROUP AREA, AND WILL MORE SPECIFICALLY AS WE GET INTO THIS, WHETHER OR NOT WE NEED, AT LEAST FOR THIS AREA, TO CHANGE HOW WE LOOK AT FUNDING OF THE EFFORTS THAT GO INTO THIS

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GIVEN THAT WE HAVE SUCH A SIGNIFICANT AMOUNT OF MONEY TO SPEND VERSUS ALL THE OTHER AREAS AND THE RATE AT WHICH WE ARE SPENDING IT IN THE NEURO AREA. WE ARE NOT NEARLY SPENDING IT AT THE RATE WE ARE, GENERALLY SPEAKING, TO ADD ONE AND A HALF MILLION BEFORE WE RUN OUT OF MONEY IN THE OTHER AREAS.

SO I ONLY RAISE THIS BECAUSE I THINK THIS IS A VERY SPECIAL CASE THAT WE NEED TO TREAT AS A SPECIAL CASE. I SUGGEST WHAT -- I AGREE WITH FRED. THERE ARE ISSUES THAT WE'VE ALREADY HEARD ABOUT IN THIS THAT WE NEED TO TAKE SERIOUSLY. FOR ME THIS COMES -- THE ONE MAJOR ISSUE THAT HE IDENTIFIED, PERHAPS NOT AS SPECIFICALLY, IS THE COST OF DOING RESEARCH AND WHAT WE NEED TO THINK ABOUT IN TERMS OF FUNDING IT. AND I'M NOT SUGGESTING WE NECESSARILY NEED TO CHANGE OUR FUNDING FOR OTHER THERAPEUTIC AREAS, BUT WE VERY WELL MAY NEED TO CHANGE IT HERE JUST BECAUSE OF THE DIFFICULTY OF THE SLOPE THAT'S GOT TO BE GONE UP TO DEAL WITH THIS.

CHAIRMAN IMBASCIANI: THANK YOU, STEPHEN. PAT LEVITT, YOU WERE GOING TO FOLLOW.

DR. LEVITT: WELL, I DON'T HAVE TO ADD ANYTHING. STEPHEN JUST BASICALLY SAID EVERYTHING I WANTED TO SAY. THIS IS -- FROM MY PERSPECTIVE IN MY THINKING ABOUT THIS, AND I WAS ON THE TASK FORCE AS

WELL, I WASN'T ABOUT WE'RE WORRIED ABOUT WE'RE GOING TO SPEND THIS DOLLAR AMOUNT. IT IS THE CASE THAT THIS RESEARCH IS VERY PERSONNEL HEAVY AND VERY EXPENSIVE BOTH IN TERMS OF THE IPS CELL GENERATION THAT'S REQUIRED TO DO THIS KIND OF RESEARCH. AND THERE WAS A HUGE EMPHASIS BY ALL OF THE PRESENTERS ABOUT HUMAN SOURCES FOR THE STUDIES. AND ORGANOIDS ARE EVEN MORE DEMANDING IN TERMS OF WHAT'S REQUIRED.

SO THEY'RE VERY PERSONNEL HEAVY, AND I'M JUST AFRAID THAT WHATEVER THE CURRENT -- I'VE NEVER APPLIED FOR A CIRM GRANT, FOR A DISCOVERY GRANT OR ANYTHING, SO I DON'T KNOW EXACTLY WHAT THE FRAMEWORK IS. BUT I THINK IT NEEDS TO BE LOOKED AT BECAUSE IT'S CLEAR THAT THOSE METHODS ARE GOING TO BE THE LARGEST AREA OF EMPHASIS FOR BOTH NEURODEGENERATIVE AND NEUROPSYCHIATRIC DISORDERS, AND WE HAVE TO TAKE THAT INTO ACCOUNT GIVEN THE EXPENSE.

DR. GOLDSTEIN: LET ME JUST ADD SOMETHING THERE, PAT. BECAUSE I THINK I AGREE WITH A LOT OF POINTS THAT HAVE BEEN MADE, AND I THINK THIS IS A CASE WHERE THOUGHTFUL CONSTRUCTION OF INTERDISCIPLINARY TEAMS TO WORK ON THESE PROBLEMS MAY BE AN IMPORTANT PART OF THE ANSWER.

DR. LEVITT: YES.

DR. GOLDSTEIN: THAT THE NIH HAS BEEN

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EXPERIMENTING WITH THESE SORTS OF TEAMS. AND WHAT I'VE SEEN IS THAT IN MANY CASES IT'S WORKED OUT QUITE WELL FOR NEURODEVELOPMENTAL DISORDERS WHERE I WAS INVOLVED IN ONE SUCH TEAM. AND I THINK IT MAY BE A GOOD MODEL FOR US TO LOOK AT. AND THE GREAT THING ABOUT CALIFORNIA AS A NATION STATE IS WE HAVE THE INTELLECTUAL RESOURCES TO BE ABLE TO DEVELOP EXACTLY THOSE SORTS OF TEAMS. SO SORRY TO BUTT IN THERE, LEONDRA.

DR. LEVITT: I COMPLETELY AGREE. YOU MADE VERY IMPORTANT POINTS, THAT THIS DOES REQUIRE OR THIS WOULD BENEFIT FROM GREATER TEAM SCIENCE EFFORTS BECAUSE OF THE INTERDISCIPLINARY NATURE. TOM SUDHOF BASICALLY IS A POSTER CHILD FOR THAT. HE IS EXPERT IN BIOCHEMISTRY AND PHYSIOLOGY, AND HE'S HAD TO COLLABORATE WITH OTHERS IN ORDER TO DO WHAT HE DESCRIBED. SO I THINK THAT'S A GOOD MODEL TO CERTAINLY INVESTIGATE.

AND IT IS THE CASE THAT CALIFORNIA IS LOADED WITH INVESTIGATORS THAT ARE THE HIGHEST QUALITY IN THIS AREA. SO WE SHOULD LEVERAGE THAT.

CHAIRMAN IMBASCIANI: LEONDRA, YOU'RE NEXT.

DR. CLARK-HARVEY: THANK YOU. I AGREE. THERE ARE A LOT OF GREAT MINDS IN CALIFORNIA.

THERE'S A LOT OF GREAT MINDS ON THE NEURO TASK FORCE NO PUN INTENDED. FOLKS BROUGHT UP COST, AND THAT'S IMPORTANT. BUT ALSO THE THING THAT I REALLY WANTED TO HIGHLIGHT HERE IS THAT THEY ALSO TALKED ABOUT THE DIFFICULTY OF THE WAY THAT THE APPLICATION WAS CONSTRUCTED. AND THAT THEY ALMOST LOOKED AT IT AS IS IT WORTH THE MONEY TO GO THROUGH THIS PROCESS. SOMEONE SAID THAT IT WAS MORE DIFFICULT AND HAD MORE KIND OF REQUIRED COMPONENTS THAN THE NIH APPLICATIONS THEY DID. THAT REALLY STUCK OUT TO ME. AND I THINK THAT WE HAVE TO TAKE THAT SERIOUSLY.

AND I HEAR YOU, MARIA, ON MAKING SURE THAT THIS ISN'T AN ISOLATED INCIDENT. I TEND TO BELIEVE THAT THIS IS REFLECTIVE OF PROBABLY WHAT MULTIPLE PEOPLE ARE FEELING, BUT LET'S SAY IT IS AN ISOLATED INCIDENT OR INCIDENTS. I THINK THEN WE HAVE TO STRATEGIZE AND DO MORE RESEARCH AND BE INTENTIONAL AROUND IDENTIFYING THE TRUE IMPEDIMENTS IF IT'S NOT THE APPLICATION CONSTRUCTION, WHICH I DO SENSE THERE'S A PIECE OF THAT THERE, AND THE COST I THINK WORKS TOGETHER WITH THAT. SO I JUST WANTED TO SHARE THAT BECAUSE I KNOW THAT STRUCK ME LIKE, REALLY, IT'S MORE DIFFICULT THAN THE NIH APPLICATION. IT SHOULDN'T BE.

CHAIRMAN IMBASCIANI: OKAY. THANK YOU

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VERY MUCH. I SEE NOW BOARD MEMBER FISHER AGAIN.

DR. FISHER: SO JUST TO ADD SOME CONTEXT TO THIS CONVERSATION, THE LAST ROUND OF FUNDING, MY UNDERSTANDING IS CIRM SPENT ABOUT 1.5 BILLION ON NEURO. AND SO THE MAIN CHARGE OF CIRM IS THAT WE NOT SPEND LESS THAN 1.5 BILLION ON NEURO. SO THIS GROUP COULD BE TRACKING THE PACING OF NEURO FUNDING AND DETERMINING WHETHER IT IS AHEAD OF PACE OR BEHIND PACE OR ON PACE FOR, AGAIN, SPENDING A MINIMUM OF 1.5 BILLION. THAT'S NOT WHAT THIS WORK GROUP HAS DECIDED TO DO, WHICH IS FINE. BUT THEN WHAT'S NECESSARY, AND I THINK LARRY HAS STARTED US DOWN THIS PATH, IS TO UNDERSTAND THE GAP ANALYSIS OF WHAT'S BEEN FUNDED, WHAT KINDS OF PROJECTS HAVE BEEN FUNDED, WHAT KIND OF PROJECTS IN WHAT KIND OF AREAS HAVE NOT BEEN FUNDED AND WHETHER OR NOT SOME KIND OF PRIORITY, AND IN THE INSTANCE OF THE NEUROPSYCH WHERE THERE WILL BE A PROGRAM PLAN DEVELOPED TO ADDRESS THAT GAP, WHAT OTHER GAPS ARE THERE, AND HOW MIGHT THOSE BE FUNDED.

THIS IS WHAT I SEE AS THE TASK OF THIS GROUP, TO REALLY UNDERSTAND, NOTWITHSTANDING THE PRESENTATIONS STAFF DID THE VERY FIRST MEETING, I DON'T THINK THE GROUP HAS A FULL UNDERSTANDING OF WHAT CIRM HAS FUNDED IN THE NEURO SPACE, WHAT IT

HASN'T FUNDED IN THE NEURO SPACE, AND THEN DECIDE WHAT SHOULD BE FUNDED THAT HASN'T BEEN FUNDED IN THE NEURO SPACE BECAUSE CHANCES ARE WHAT HAS BEEN FUNDED IS GOING TO CONTINUE TO GET FUNDED, AND WE ARE GOING TO SPEND 1.5 BILLION.

SO THE QUESTION IS NOT ARE WE GOING TO SPEND 1.5 BILLION. IT'S GOING TO BE ARE WE GOING TO SPEND MORE THAN 1.5 BILLION AND ON WHAT, OR ARE WE GOING TO SPEND ABOUT 1.5 BILLION, BUT SPEND IT DIFFERENTLY, AND HOW ARE WE GOING TO GO AT THAT. THAT'S THE CONVERSATION WE'VE YET TO HAVE, AND I HOPE WE GET THERE SOONER RATHER THAN LATER.

DR. GOLDSTEIN: I COMPLETELY AGREE WITH YOUR THOUGHTS ON THIS, FRED. YOU LEAD A GRANTMAKING ORGANIZATION IN YOUR DAY JOB, AND YOU KNOW HOW TRICKY IT IS SOMETIMES TO BALANCE SPECIFIC PRIORITIES VERSUS LETTING THE CREATIVITY OF THE COMMUNITY BUBBLE UP THEIR IDEAS. AND SO IT IS SOMETHING WE'LL HAVE TO FIGURE OUT HOW TO BALANCE OUT, BUT WE ARE, I THINK, WELL POSITIONED TO DO THAT.

CHAIRMAN IMBASCIANI: FRED, CAN I ASK, FOR THOSE OF US WHO ARE TAKING NOTES, I WANT TO MAKE SURE THAT WE MEMORIALIZE. YOUR INITIAL COMMENT IN WHAT YOU JUST SAID, I THINK I'M QUOTING YOU, YOU

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STARTED BY SAYING THE LAST ROUND OF CIRM FUNDING AND YOU USED THE NUMBER 1.5 BILLION. DID I HEAR THAT CORRECTLY?

DR. FISHER: THAT'S MY UNDERSTANDING, THAT THE 1.5 BILLION THAT WAS PUT IN PROP 14, THAT NUMBER WAS DERIVED BECAUSE THAT'S ABOUT THE NUMBER THAT WAS SPENT DURING THE PROP 71 FUNDING.

CHAIRMAN IMBASCIANI: SO WE HAVE SOME HEADS SHAKING HERE THAT MIGHT WANT TO, NOT CORRECT --

DR. FISHER: CORRECT AWAY. I'M HAPPY TO BE CORRECTED.

CHAIRMAN IMBASCIANI: WHO WANTS TO SPEAK TO THIS?

VICE CHAIR BONNEVILLE: IT WAS BASED ON THE FACT THAT ABOUT 30 PERCENT OF THE CIRM FUNDING IN PROP 71 WAS SPENT ON NEURO. AND I BELIEVE THAT THAT'S HOW THE 1.5 BILLION WAS DERIVED FOR THIS ROUND. MARIA IS SHAKING HER HEAD YES. SO IT WAS THE 1.5 BILLION LAST TIME, FRED, BUT IT WAS 30 PERCENT OF THE 3 BILLION. AND SO THEY SORT OF -- THAT'S HOW THEY CAME TO THE 1.5 IS THAT IT'S 30 PERCENT OF THE 5.5. THAT'S MY UNDERSTANDING. I COULD BE WRONG. SO MARIA MILLAN.

DR. FISHER: WELL, IS 30 PERCENT 1.5?

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CHAIRMAN IMBASCIANI: I HAVE A NUMBER IN FRONT OF ME THAT THE AMOUNT OF DOLLARS SPENT ON NEURO AS A RESULT OF PROP 71 WAS 780 MILLION. AND EVERYONE IS SHAKING THEIR HEADS YES AROUND THE TABLE HERE.

DR. FISHER: WELL, I'LL LEAVE IT TO YOU ALL TO FIGURE OUT THE DISCONNECT BETWEEN 30 PERCENT WAS SPENT ON NEURO AND 780,000 WAS SPENT ON NEURO.

CHAIRMAN IMBASCIANI: OKAY. I'M GOING TO TAKE THE CHAIR'S PREROGATIVE. AS MARIA AND I PROMISED, EVERY TIME THERE'S A QUESTION LIKE THIS, WE'LL BRING IT BACK TO THE NEXT BOARD MEETING WITH EITHER AN EXPLANATION OR A SOLUTION. BUT THANKS FOR THAT.

OKAY. ARE THERE -- I NEED TO SCROLL THROUGH TO SEE IF THERE'S ANYONE ELSE THAT WANTS TO SPEAK OR ASK LARRY A QUESTION. I DON'T SEE ANY. SCOTT, DOES THAT MEAN WE ARE FREE TO MOVE TO THE NEXT.

MR. TOCHER: YES. IF THE ITEM IS CONCLUDED, THEN WE CAN -- THE LAST REMAINING ITEM IS JUST TO SEEK ANY PUBLIC COMMENT FOR ANYTHING THAT HAS NOT ALREADY BEEN AGENDIZED AND DISCUSSED.

CHAIRMAN IMBASCIANI: MEMBERS OF THE PUBLIC LISTENING TO THIS MEETING, YOU'RE WELCOME TO

ADDRESS THE BOARD.

UNIDENTIFIED SPEAKER: CAN I ASK A QUESTION?

MS. DEQUINA-VILLABLANCA: (626) 282-4227, YOU HAVE -- YES, YOU CAN SPEAK AND YOU HAVE THREE MINUTES.

UNIDENTIFIED SPEAKER: THANK YOU. I SALUTE THE VENERABLE KNOWLEDGE THAT I'M CONNECTED TO AT THIS MOMENT. I'M A BLUE SHIELD ADVANTAGE MEDICARE PATIENT WHO'S BEEN DIAGNOSED WITH PERIPHERAL NERVE DISORDER AND OSTEOPENIA. SO MY QUESTION IS I'M ALSO O NEGATIVE. I'M WONDERING IF HEMATOPOIETICALLY DERIVED STEM CELLS CAN BE BANKED MUCH AS BLOOD IS, AND UNIVERSAL DONORS CAN COME UP WITH A PLAN TO GIVE, DONATE THEIR STEM CELL LINES TO RESEARCH IN EXCHANGE FOR SOME KIND OF EXPERIMENTAL PARTICIPATION IN STEM CELL RESEARCH THERAPIES. YOU BANK O NEGATIVE STEM CELLS, AND CAN AN O NEG PATIENT QUALIFY IN A RESEARCH PROJECT?

DR. GOLDSTEIN: IF I MAY PROVIDE A PARTIAL ANSWER, MR. CHAIRMAN. THERE IS A NATIONAL PROGRAM CALLED BE THE MATCH WHICH SPECIALIZES IN TRYING TO FIND DONORS FOR RECIPIENTS WHO HAVE DISEASES THAT CAN BE TREATED BY STEM CELL TRANSPLANT.

THE TECHNICAL PROBLEMS ARE STILL

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SIGNIFICANT REGARDLESS OF BLOOD TYPE, BUT THAT'S THE MOST ORGANIZED EFFORT THAT I KNOW OF IN THE UNITED STATES.

UNIDENTIFIED SPEAKER: OKAY. KEEP MY NUMBER, IF ANYBODY WANTS IT, TO RESEARCH ME. I THINK I'D BE A GOOD SPECIMEN. THANK YOU.

CHAIRMAN IMBASCIANI: THANK YOU FOR YOUR GENEROSITY, MA'AM. AND THANK YOU, LARRY, FOR TAKING THAT QUESTION.

CHAIR'S PREROGATIVE, FRED'S QUESTION OF A LITTLE WHILE AGO PROMPTED A LOT OF ACTIVITY HERE. AND I'M GOING TO ASK OUR CEO/PRESIDENT MARIA MILLAN TO GIVE ANOTHER ANSWER TO THAT QUESTION.

DR. MILLAN: THANK YOU SO MUCH.

CHAIRMAN IMBASCIANI: WE ARE NOT AN ECHO CHAMBER HERE.

DR. MILLAN: HERE I AM. I JUST WANTED TO SUPPORT MARIA BONNEVILLE'S STATEMENT OF HOW THE ESTIMATE THAT MAY HAVE INFORMED THE PROPOSITION 14 STIPULATION FOR 1.5 OUT OF THE 5.5. THE 30-PERCENT FIGURE THAT SHE REFERENCED MAY HAVE COME FROM THE FACT THAT OF THE AVAILABLE FUNDS THAT WERE AVAILABLE UNDER PROPOSITION 14, BECAUSE NOT ALL OF THE 3 BILLION IS AVAILABLE FOR RESEARCH. OF THE AVAILABLE RESEARCH FUNDS, A THIRD OF THAT WOULD HAVE BEEN

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APPROXIMATELY 800 MILLION AND THE EXPENDITURE WAS 780 MILLION. SO IT DOES KIND OF -- IT'S COMPATIBLE WITH THAT NOTION.

AND IN ADDITION, JUST TO LET YOU KNOW, WE DO TRACK THIS. AND ALONG THE WAY, EVEN WITH THE PROPOSITION 14 EXPENDITURES, IT'S STILL TRACKING AROUND THAT PERCENTAGE. IT VARIES BY A COUPLE PERCENTAGE POINTS UP AND DOWN; BUT SURPRISINGLY, EVEN WITH THE ORGANIC METHODOLOGY THAT UTILIZES OUR STANDARD FUNDING MECHANISMS, IT'S COMING OUT THERE. THAT DOESN'T -- THAT'S NOT TO SAY THAT THERE ISN'T VALUE IN MAKING SURE THAT ALL THE CONVERSATIONS AND ALL THE EFFORTS TO DETERMINE THE BEST STRATEGY FOR NEURO ISN'T IMPORTANT.

BUT I ALSO WANTED TO SAY THAT THOSE ARE VERY IMPORTANT COMMENTS AND INPUT THAT WE RECEIVE FROM GRANTEES AND SPEAKERS THAT WERE DISCUSSED, THAT FRED FISHER AND LEONDRA CLARK-HARVEY HIGHLIGHTED. AND THE TEAM HAS BEEN TAKING VERY DETAILED NOTES ON THIS, AND WE'LL BE WORKING WITH THE REVIEW TEAM IN TRYING TO GET INPUT IN TERMS OF WHAT THESE IMPEDIMENTS MAY BE.

JUST RECENTLY THE DISCOVERY 0 PROGRAM ANNOUNCEMENT WAS JUST ROLLED OUT, AND THAT IS BASIC BIOLOGY RESEARCH, WHICH IS A SUBJECT OF MUCH OF THIS

DISCUSSION. AND CERTAINLY THE REVIEW TEAM IS ALWAYS WORKING TO REFINE AND IMPROVE ASPECTS OF THE APPLICATION PROCESS AND CRITERIA AND, WHERE NECESSARY, IT COMES BACK TO THE BOARD FOR CONCEPT AMENDMENTS. AND SO STAY TUNED FOR THAT BECAUSE THAT WAS VERY IMPORTANT INPUT THAT WILL BE INCORPORATED, NOT ONLY INTO FUTURE CONCEPTS, SUCH AS WHAT DR. VILLUS IS RIGHT NOW LEADING, BUT ALSO IN STANDING PROGRAM ANNOUNCEMENTS. THANK YOU.

DR. FISHER: COULD I RESPOND TO THAT, MR. CHAIR?

CHAIRMAN IMBASCIANI: PLEASE. PLEASE GO AHEAD.

DR. FISHER: WELL, THANKS FOR THE CLARIFICATION. THAT MEANS THAT WE HAVE ALMOST TWICE AS MUCH TO SPEND ON NEURO THAN WE SPENT LAST TIME, WHICH IS GREAT NEWS. AND IT REINFORCES IN MY MIND THE NEED FOR A VERY THOUGHTFUL PROCESS THAT INCLUDES A GAP ANALYSIS AND A PRIORITIZATION AROUND HOW WE OUGHT TO SPEND THE ADDITIONAL 700 MILLION OR SO. AND THAT I'D LIKE US NOT TO GO FORWARD DISCUSSING AN INDICATION AND CREATING A PROGRAM PLAN FOR IT AND DISCUSSING ANOTHER INDICATION AND CREATING A PROGRAM PLAN FOR THAT. I'D RATHER US TAKE A MORE 30,000 FOOT LEVEL AND HAVE AN UNDERSTANDING OF THE ENTIRE

ECOSYSTEM AND DETERMINE PRIORITIES WITHIN THAT ECOSYSTEM AND DEVELOP PROGRAM PLANS BASED ON THOSE PRIORITIES.

AND I HOPE THAT THE CHAIR OF THE TASK FORCE AND OTHERS WILL CONSIDER THAT APPROACH GOING FORWARD.

CHAIRMAN IMBASCIANI: SO, FRED, I DON'T WANT TO -- CAN YOU HEAR ME? I DON'T WANT TO SPEAK FOR THE LEADERSHIP TEAM, BUT I'M BEING GIVEN ASSURANCES THAT THE BOARD WILL BE GIVEN A LOT OF WHAT YOU'RE ASKING FOR, IF NOT ALL OF IT, AT UPCOMING MEETINGS. OKAY. SO THANK YOU FOR EXPRESSING THE NEED SO STRONGLY.

I THINK, SINCE THERE'S NO FURTHER PUBLIC COMMENT, WE'VE COME TO THE END OF OUR WORK AND I'M GOING TO GIVE YOU ALMOST A HALF-HOUR OF YOUR DAY BACK. I WANT TO THANK ALL THE BOARD MEMBERS WHO TOOK THE OPPORTUNITY TO JOIN US TODAY AND FOR YOUR WISDOM AND INSIGHT AND ACTIVE PARTICIPATION.

HEARING NO OBJECTION -- WE DON'T NEED A MOTION TO ADJOURN. I THINK WE ARE DONE. THANK YOU VERY MUCH. WE ARE ADJOURNED.

(THE MEETING WAS THEN CONCLUDED.)

REPORTER'S CERTIFICATE

I, BETH C. DRAIN, A CERTIFIED SHORTHAND REPORTER IN AND FOR THE STATE OF CALIFORNIA, HEREBY CERTIFY THAT THE FOREGOING TRANSCRIPT OF THE VIRTUAL PROCEEDINGS BEFORE THE INDEPENDENT CITIZEN'S OVERSIGHT COMMITTEE AND THE APPLICATION REVIEW SUBCOMMITTEE OF THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE IN THE MATTER OF ITS REGULAR MEETING HELD ON MAY 31, 2023, WAS HELD AS HEREIN APPEARS AND THAT THIS IS THE ORIGINAL TRANSCRIPT THEREOF AND THAT THE STATEMENTS THAT APPEAR IN THIS TRANSCRIPT WERE REPORTED STENOGRAPHICALLY BY ME AND TRANSCRIBED BY ME. I ALSO CERTIFY THAT THIS TRANSCRIPT IS A TRUE AND ACCURATE RECORD OF THE PROCEEDING.

BETH C. DRAIN, CA CSR 7152
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