BEFORE THE
ACCESSIBILITY AND AFFORDABILITY WORKING GROUP
OF THE
INDEPENDENT CITIZENS' OVERSIGHT COMMITTEE
TO THE
CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE
ORGANIZED PURSUANT TO THE
CALIFORNIA STEM CELL RESEARCH AND CURES ACT

REGULAR MEETING

LOCATION: VIA ZOOM

DATE: MARCH 10, 2025
3 P.M.

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

FILE NO.: 2025-6

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I N D E X

MARCH 10, 2025; 3 P.M.

VICE CHAIR BONNEVILLE: GOOD AFTERNOON, EVERYONE. THANK YOU FOR JOINING TODAY'S ACCESSIBILITY AND AFFORDABILITY WORKING GROUP MEETING. SCOTT, WILL YOU PLEASE TAKE THE ROLE.

MR. TOCHER: KIM BARRETT.

DR. BARRETT: PRESENT.

MR. TOCHER: BERNAL. MARIA BONNEVILLE.

VICE CHAIR BONNEVILLE: PRESENT.

MR. TOCHER: JAMES DEBENEDETTI.

MR. DEBENEDETTI: HERE.
MR. TOCHER: TED GOLDSTEIN.
DR. GOLDSTEIN: PRESENT.
MR. TOCHER: CHRISTINA HARTMAN. DAVID HIGGINS. VITO IMBASCIANI.
CHAIRMAN IMBASCIANI: PRESENT.
MR. TOCHER: DARIUS LAKDAWALLA. HARLAN LEVINE.
DR. LEVINE: PRESENT.
MR. TOCHER: PAT LEVITT. ADRIANA PADILLA.
DR. PADILLA: HERE.
MR. TOCHER: AMMAR QADAN.
MR. QADAN: PRESENT.
MR. TOCHER: MAHESWARI SENTHIL. ADRIENNE SHAPIRO.
WE'RE JUST TWO SHORT RIGHT NOW, MARIA, BUT WE'LL KEEP YOU POSTED.
MR. FISCHER-COLBRIE: MARK FISCHER-COLBRIE IS HERE JUST ON ADVISORY.
MR. TOCHER: THANK YOU, MARK.
VICE CHAIR BONNEVILLE: THANKS, MARK.
WE HAVE A GREAT AGENDA ITEM TODAY, SO I'M GOING TO HAVE GEOFF GET STARTED SO WE CAN GET THROUGH IT ALL. THANK YOU.
DR. LOMAX: OKAY. YOU CAN SEE THE SCREEN

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OKAY AND HEAR ME OKAY; IS THAT CORRECT? GREAT. THANKS VERY MUCH. THANK YOU, CO-CHAIR BONNEVILLE, FOR THE OPPORTUNITY TO PRESENT. I'M GOING TO PRESENT TODAY A REVISED CONCEPT PLAN FOR THE COMMUNITY CARE CENTERS OF EXCELLENCE PROGRAM.

I'D LIKE TO THANK THE EXECUTIVE TEAM AT CIRM FOR THE OPPORTUNITY TO SUPPORT THE DEVELOPMENT OF THIS PLAN AND REALLY ACKNOWLEDGE THAT THIS HAS BEEN A CIRM-WIDE EFFORT IN TERMS OF DEVELOPING THIS CONCEPT PLAN AND A HOST OF OTHER PLANS ACROSS THE ORGANIZATION. SO ALL THE INPUT AND SUPPORT FROM THE CIRM TEAM IS GREATLY APPRECIATED.

AS A REMINDER, THE CONCEPT PACKAGE IS AVAILABLE ON THE CIRM WEBSITE AS ARE A COPY OF THESE SLIDES AND THE LINK. THEY CAN ALL BE FOUND IN THE LINK TO TODAY'S MEETING.

I'M GOING TO NOTE THAT THERE ARE MEMBERS IN CONFLICT TODAY, AND SO THESE MEMBERS ARE IDENTIFIED HERE. AND IF YOU PLEASE REFRAIN FROM DISCUSSION OF ANY MOTIONS IN RELATION TO THIS CONCEPT PLAN. THANK YOU.

AND SO AS YOU ARE AWARE, THIS IS THE SECOND COMMUNITY CARE CENTERS OF EXCELLENCE CONCEPT PLAN WE ARE BRINGING FORWARD FOR YOUR CONSIDERATION. IN THE BACKGROUND SECTION, I WILL REVIEW THE OUTCOME

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FROM OUR INITIAL CYCLE AND PROVIDE A RATIONALE FOR OUR RECOMMENDATION THAT WE PUT FORWARD A REVISED PROGRAM.

AND IN THE SECOND PART OF THE PRESENTATION, I WILL SUMMARIZE THE KEY PROGRAMMATIC ELEMENTS OF THE REVISED PLAN, AND THEN WE WILL REQUEST A MOTION.

SO AS A REMINDER, PROPOSITION 14 MANDATES THE CREATION OF THE COMMUNITY CARE CENTERS OF EXCELLENCE. THE PROPOSITION SPECIFICALLY INDICATES THAT THESE CENTERS SHOULD EXPAND THE CAPACITY OF THE ALPHA CLINICS NETWORK, AND THEY'RE SPECIFICALLY CHARGED WITH CONDUCTING CLINICAL TRIALS AND MAKING TREATMENTS AVAILABLE TO CALIFORNIA PATIENTS. THE PROPOSITION ALSO CALLS OUT GEOGRAPHIC DIVERSITY AS A PROGRAM OBJECTIVE TO FACILITATE ACCESS TO POPULATIONS THAT ARE LESS LIKELY TO ENROLL IN AN ALPHA CLINIC TRIAL.

IN ADDITION, ONE POINT NOT REFLECTED IN THIS SLIDE IS ALSO THE TIMELINE FOR THE COMMUNITY CARE CENTERS OF EXCELLENCE. THE PROPOSITION SUGGESTS A LAUNCH WITHIN THE CALENDAR YEAR 2025, WHICH IS THIS YEAR.

I WILL NOW TURN TO THE CIRM STRATEGIC ALLOCATION FRAMEWORK RECOMMENDATIONS. THE STRATEGIC

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ALLOCATION FRAMEWORK WAS APPROVED BY THE ICOC IN SEPTEMBER AFTER IT RECEIVED THE FIRST ROUND OF CCC SO THAT THE FRAMEWORK WAS APPROVED IN THE MIDDLE OF THE ORIGINAL PROGRAM.

CIRM'S STRATEGIC ALLOCATION FRAMEWORK PROVIDES A ROADMAP FOR THE STRATEGIC IMPLEMENTATION OF PROPOSITION 14'S MANDATES. AND GOAL 5 SPECIFICALLY FOCUSED ON PATIENT ACCESS BROADLY AND INCLUDED A SPECIFIC CALL-OUT TO ENSURE REFERRAL, ENROLLMENT, AND RETENTION OF CALIFORNIA PATIENTS IN CLINICAL TRIALS. THIS PRIORITIZATION WITHIN THE STRATEGIC ALLOCATION FRAMEWORK CAUSED US TO REFLECT ON WHETHER THE COMMUNITY CARE CENTERS OF EXCELLENCE PROGRAM IN ITS ORIGINAL FORMULATION WAS OPTIMALLY ALIGNED WITH OUR NEW GOAL.

AND I WOULD NOTE WE ARE IN THE PROCESS OF AMENDING MANY OF OUR CONCEPTS PURSUANT TO SAF IMPLEMENTATION. SO I'LL COME BACK TO THIS POINT MOMENTARILY WHEN I SUMMARIZE KEY INSIGHTS FROM THE FIRST ROUND OF THE COMMUNITY CARE CENTERS PROGRAM.

IN TERMS OF OPERATIONS, THE COMMUNITY CARE CENTERS OF EXCELLENCE ARE ONE PROGRAM WITHIN CIRM'S BROADER CLINICAL INFRASTRUCTURE PROGRAMS. THE FUNDAMENTAL AIM OF THIS INFRASTRUCTURE IS TO INCREASE REFERRAL, ENROLLMENT, AND RETENTION OF

PATIENTS SO CLINICAL TRIALS ARE COMPLETED SUCCESSFULLY. OUR STRATEGY IS TO DRIVE INTERCONNECTIVITY BETWEEN THESE COMPLEMENTARY EFFORTS.

CURRENTLY THE ALPHA CLINICS NETWORK IS SUPPORTING A ROBUST PORTFOLIO OF CLINICAL TRIALS, AND OUR PATIENT SUPPORT PROGRAM HAS LAUNCHED TO PROVIDE ADDITIONAL LOGISTICAL AND FINANCIAL SUPPORT TO PATIENTS. OUR CURRENT GAP IS THE CAPACITY TO BETTER SERVE PATIENTS IN UNDERSERVED AREAS WHERE THEY DO NOT HAVE TIMELY ACCESS TO AN ALPHA CLINIC SITE. AND WE PERFORMED A STATEWIDE NEEDS ASSESSMENT IN THE RUN UP TO THE FIRST CYCLE OF THE CCCE PROGRAM. AND DISTANCE TO TREATMENT CENTER AND TRAVEL BURDEN WAS CITED AS A LEADING FACTOR IN THE DECISION TO ENROLL IN A CLINICAL TRIAL. SO THIS EMPHASIS ON GEOGRAPHIC DIVERSITY IS INTENDED TO REDUCE THIS BURDEN.

SO I WILL NOW UPDATE YOU ON OUR EXPERIENCE WITH THE INITIAL CYCLE OF THE COMMUNITY CARE CENTERS PROGRAM. IN THE INITIAL CYCLE WE HAD A BIFURCATED PROGRAM STRUCTURE THAT ALLOWED APPLICANTS TO COME IN AS A SUPPORT SITE OR A SUPPORT AND CLINICAL TRIAL DELIVERY SITE. SUPPORT SITES WERE DESIGNATED TO BE PATIENT REFERRAL AND NAVIGATION CENTERS, BUT WERE

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NOT EXPECTED TO CONDUCT CLINICAL TRIALS OVER THE AWARD PERIOD. DELIVERY SITES, ON THE OTHER HAND, WERE EXPECTED TO CONDUCT REGENERATIVE MEDICINE CLINICAL TRIALS OVER THE AWARD PERIOD AND BUILD THAT CAPACITY ON AN ONGOING BASIS.

WE RECEIVED NINE APPLICATIONS WITH FOUR FOR SUPPORT-ONLY SITES AND FIVE FOR DELIVERY SITES. ONLY ONE OF THE NINE APPLICATIONS RECEIVED A FUNDING RECOMMENDATION FROM THE GRANTS WORKING GROUP, AND THIS WAS A SUPPORT-ONLY SITE. THIS REMAINING EIGHT WERE NOT RECOMMENDED FOR FUNDING.

SO EARLY ON -- EARLIER I INDICATED THE STRATEGIC ALLOCATION FRAMEWORK CAUSED US TO REFLECT ON WHERE THE CCCE PROGRAM IN ITS ORIGINAL FORMULATION WAS OPTIMALLY ALIGNED WITH OUR STRATEGIC ALLOCATION FRAMEWORK GOAL 5.

IN TERMS OF BUDGET CONSIDERATIONS, WE'RE CONCERNED THAT THE ORIGINAL STRUCTURE OF HAVING TWO FUNDING TYPES WOULD COMPROMISE THE OVERALL PROGRAM SUSTAINABILITY. AND LET ME EXPLAIN. PROPOSITION 14 SETS A LIFETIME CAP OF 78 MILLION ON THE COMMUNITY CARE CENTERS OF EXCELLENCE PROGRAM. BY COMBINING SUPPORT AND SUPPORT AND DELIVERY SITES INTO A SINGLE RFA, WE WOULD POTENTIALLY DEPLOY 77 PERCENT OR 60.2 MILLION OF THIS TOTAL ALLOCATION. THUS, THE

REMAINING FUNDS WOULD BE INSUFFICIENT TO SUPPORT THE CLINICAL TRIAL DELIVERY SITES OR EXPAND THE PROGRAM TO ADDITIONAL DELIVERY SITES. AND THIS EXTENSION AND EXPANDING MODEL IS ACTUALLY WHAT WE DID WITH THE ALPHA CLINICS PROGRAM, WHICH HAS RESULTED IN THEIR ABILITY TO SUPPORT A ROBUST PORTFOLIO AT THIS TIME.

SO THIS SLIDE SUMMARIZES ADDITIONAL INSIGHTS FROM THE FIRST ROUND. IN TERMS OF PROGRAM SUSTAINABILITY, AS I JUST NOTED, WE WERE AT RISK OF EXHAUSTING THE BUDGET IN ONE CYCLE WHICH WOULD FOREGO THE ABILITY TO RENEW OR EXPAND THE PROGRAM.

IN ADDITION, WE WANTED TO FOCUS ON GEOGRAPHIC DIVERSITY. WE HAVE -- WE'VE LOOKED AT A SERIES OF ELIGIBILITY REQUIREMENTS THAT WE BELIEVE CAN SERVE TO ENHANCE THE GEOGRAPHIC DIVERSITY AND EXPAND CLINICAL TRIAL REFERRAL IN A POOL IN UNDERSERVED REGIONS. AND THIS IS, AGAIN, IMPORTANT IN TERMS OF BOTH PROPOSITION 14 AND THE STRATEGIC ALLOCATION FRAMEWORK.

IN ADDITION, WE ARE RECOMMENDING FOCUSING THE REVISED PROGRAM ON PROPOSITION 14'S OBJECTIVES OF CLINICAL TRIALS DELIVERY. AND, AGAIN, THIS REQUIREMENT IS REFLECTED IN THE REVISED PROGRAM OBJECTIVE WHICH I'LL COVER MOMENTARILY.

HOWEVER, THE FIRST ROUND DID UNDERSCORE

THE VALUE OF FUNDING SUPPORT ACTIVITIES ALONGSIDE THE DELIVERY OF CLINICAL TRIALS. SO IN ADDITION TO OUR REVISED CONCEPT PLAN, WE'D ALSO LIKE TO SUGGEST HOW THE AAWG RESOURCES MAY BE DEPLOYED TO DEVELOP A STRONGER, MORE SUSTAINABLE, AND MORE IMPACTFUL APPROACH TO OUR OVERALL GOAL OF THE STRATEGIC ALLOCATION FRAMEWORK IN AIM 5.

SO I'LL TRY TO SUMMARIZE THIS APPROACH HERE. WE ARE RECOMMENDING A TWO-PHASED APPROACH WHERE THE COMMUNITY CARE CENTERS OF EXCELLENCE ARE DEFINED BY THEIR CAPACITY TO DELIVER CLINICAL TRIALS AND THESE CENTERS BE FUNDED EXCLUSIVELY FROM THE 78 MILLION PROPOSITION 14 EARMARK FOR THIS PROGRAM.

AS A REMINDER, PROPOSITION 14 ALSO ALLOCATES 93 MILLION FOR PATIENT ACCESS ALLOCATIONS RECOMMENDED BY THIS WORKING GROUP. SO IN TERMS OF ORDER OF OPERATION, WE'RE RECOMMENDING APPROVAL OF THIS CONCEPT PLAN SO WE CAN RELEASE A COMMUNITY CARE CENTERS RFA THIS YEAR. AND UNDER THE RFA, THE FIVE PRIOR SUPPORT AND DELIVERY SITE APPLICATIONS WOULD BE ELIGIBLE TO SUBMIT, AND THEY WOULD ALSO HAVE THE BENEFIT OF FEEDBACK THEY RECEIVED FROM THE GRANTS WORKING GROUP AND BROADER AWARENESS OF CIRM'S STRATEGIC ALLOCATION FRAMEWORK GOALS.

A MORE DETAILED TIMELINE FOR THIS RFA WILL

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BE SHOWN MOMENTARILY.

WITH REGARD TO SUPPORT ACTIVITIES, WE WILL ENGAGE YOU ALL OVER THE COURSE OF 2025 TO CONSIDER PATIENT SUPPORT ACTIVITIES DRAWING ON THE AAWG SUPPORT BUDGET.

SO THIS CONCLUDES THE BACKGROUND SECTION. I'D NOW LIKE TO TURN TO THE PHASE 1 CONCEPT PLAN AGAIN WHICH HAS BEEN INCLUDED IN THE MEETING MATERIALS, AND THERE'S A MORE -- A LONGER DESCRIPTION OF IT IN THE DOCUMENT ASSOCIATED WITH THIS ITEM.

SO IN TERMS OF PROGRAM OBJECTIVE, THE AIM IS TO EXPAND GEOGRAPHICALLY DIVERSE CENTERS OF EXCELLENCE ACROSS CALIFORNIA TO ENHANCE ACCESS TO REGENERATIVE MEDICINE TREATMENTS PRIMARILY BY EXPANDING THE REACH AND DELIVERY OF CLINICAL TRIALS AND APPROVED THERAPIES, BUT CONSISTENT WITH THE ORIGINAL RFA AND CIRM INFRASTRUCTURE PROGRAM ALSO INCLUDING PROVISIONS FOR DEVELOPING A SKILLED WORKFORCE TO SUPPORT THE DELIVERY OF REGENERATIVE MEDICINE TREATMENTS AND ENSURE BROAD ACCESSIBILITY PARTICULARLY IN UNDERSERVED COMMUNITIES.

THE STRUCTURE, AGAIN, REMAINS FAIRLY SIMILAR. IT WOULD BE A FIVE-YEAR AWARD. APPLICANTS WOULD BE -- IT WOULD BE OPEN TO NON-PROFIT OR

FOR-PROFIT RESEARCH INSTITUTIONS IN GOOD STANDING. THEY MUST HAVE A COMMITMENT TO CELL AND GENE THERAPY TREATMENTS FROM ANY SOURCE. SO ALLOWING ANY TREATMENT IN CIRM'S PORTFOLIO TO BE SUPPORTED OR DELIVERED AT THE SITE. THE ORGANIZATION MAY NOT HAVE AN ALPHA CLINICS AWARD ALREADY. THIS IS THE INFRA4 AWARD PROGRAM. AND, AGAIN, AS WE HAVE WITH THE ALPHA CLINICS AND PREVIOUS RFA, THE CENTER MAY ONLY PROVIDE FDA AUTHORIZED CELL AND GENE THERAPY TREATMENTS.

THE CORE REQUIREMENT IN TERMS OF THE TEAM IS A PROGRAM DIRECTOR AT 30 PERCENT TIME. THE MAXIMUM AWARD AMOUNT WOULD BE -- IS PROPOSED AT 9 MILLION WITH AN OVERALL PROGRAM BUDGET OF 36 MILLION, WHICH WOULD BE ABLE TO SUPPORT UP TO FOUR SITES.

DR. CANET-AVILES: ACTUALLY THE NUMBER IS 39 MILLION.

DR. LOMAX: 39?

DR. CANET-AVILES: YEAH.

DR. LOMAX: OKAY. SO 39 MILLION.

DR. LEVINE: GEOFF, IF MULTIPLE BIDDERS OR SUBMITTERS CAME IN UNDER 9 MILLION, WOULD WE SUPPORT MORE THAN FOUR SITES?

DR. LOMAX: AS LONG AS THE BUDGET COULD

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SUPPORT THE APPLICATION POOL, YES. WE ALWAYS TRY TO HEDGE ON IF EVERYTHING WAS APPLIED TO THE MAX, WHAT WOULD WE BE ABLE TO SUPPORT? THAT'S WHAT THAT STATEMENT REFLECTS.

DR. LEVINE: THANK YOU.

DR. LOMAX: AND THERE'S A LITTLE BIT OF REDUNDANCY HERE. THE ELIGIBILITY REQUIREMENTS, AGAIN, CALIFORNIA ORGANIZATION MUST NOT BE FUNDED UNDER THE ALPHA CLINICS PROGRAM. AND THE EXPECTED OUTCOMES, AGAIN, THIS IS WHERE THE REVISED RFA IS A LITTLE BIT DIFFERENT THAN THE ORIGINAL ROUND, THEY MUST HAVE A DEMONSTRATED ABILITY TO PERFORM HUMAN CLINICAL TRIALS AND DEVELOP THE CAPACITY OVER THE AWARD PERIOD TO DEVELOP REGENERATIVE MEDICINE CLINICAL TRIALS AND THE CAPACITY TO PROVIDE APPROVED PRODUCTS.

IN ADDITION, THIS IS CONSISTENT WITH, AGAIN, THE PRIOR ROUND. THEY MUST PROPOSE AT LEAST ONE PARTNERSHIP WITH A COMMUNITY-BASED ORGANIZATION TO SUPPORT CLINICAL RESEARCH, CAREER DEVELOPMENT, OR BROADER COMMUNITY ENGAGEMENT.

FAIRLY STANDARD, MUST BE READY TO INITIATE WORK ON THE FUNDED PROJECT WITHIN 120 DAYS OF THE AWARD PERIOD. AND, AGAIN, REITERATING THE PERCENT EFFORT OF THE PROGRAM DIRECTOR AT 30 PERCENT.

SO IN TERMS OF THE DELIVERY SITES, AGAIN, THIS IS THE TIMELINE. WE ARE CURRENTLY MEETING IN MARCH. THE AIM IS TO HAVE AN RFA POSTED IN EARLY SPRING. APPLICATIONS, THE RFA WOULD ALLOW THE APPLICANTS TO BEGIN TO DEVELOP AND PUT TOGETHER THEIR APPLICATION WITH THE APPLICATION PERIOD OPENING IN EARLY JUNE, A DUE DATE IN JULY WITH THE GRANTS WORKING GROUP REVIEW IN SEPTEMBER, AND FACILITIES WORKING GROUP FOLLOWS THE GRANTS WORKING GROUP IF THERE ARE APPLICATIONS THAT REQUIRE FACILITIES WORKING GROUP EVALUATION. GOING TO THE APPLICATION REVIEW SUBCOMMITTEE IN OCTOBER AND HAVING THE AWARDS THAT ARE RECOMMENDED FOR FUNDING CONTRACTED AT THE END OF -- THE LAST QUARTER OF THIS YEAR AND LAUNCHING IN EARLY NEXT YEAR, 2026.

SIMULTANEOUSLY, WE PROPOSE TO ENGAGE THE ACCESSIBILITY AND AFFORDABILITY WORKING GROUP TO CONSIDER ADDITIONAL FUNDING OPPORTUNITIES FOR SUPPORT-ONLY ACTIVITIES DRAWING ON, AGAIN, THE SEPARATE BUDGET ALLOCATED FOR THAT PURPOSE.

SO AT THIS TIME THE REQUEST FOR THE MOTION IS WE REQUEST A MOTION THAT THE ACCESS AND AFFORDABILITY WORKING GROUP WOULD RECOMMEND APPROVAL OF THE REVISED CONCEPT PLAN FOR THE COMMUNITY CARE CENTERS OF EXCELLENCE PROGRAM AND THAT TO BE

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FORWARDED TO THE FULL BOARD, THE ICOC.

CHAIRMAN IMBASCIANI: MADAM CHAIR, THIS IS VITO. I'D LIKE TO MOVE THAT WE ACCEPT THE APPROVAL OF THE REVISED CCE CONCEPT PLAN.

CHAIRPERSON BONNEVILLE: THANK YOU. IS THERE A SECOND?

DR. QADAN: I SECOND THAT.

CHAIRPERSON BONNEVILLE: GREAT. THANK YOU SO MUCH. IT WAS VITO AND AMMAR. APPRECIATE THAT.

I WANT CLARIFICATION, HOWEVER. IS THE BUDGET 36 MILLION OR 39? MY UNDERSTANDING IS IT'S 36. BUT IF IT 39, WE CAN AMEND IT.

DR. CANET-AVILES: YOU ARE CORRECT, MARIA. YOU ARE CORRECT BECAUSE FOUR APPLICATIONS AT 9 MILLION MAKES IT 36.

CHAIRPERSON BONNEVILLE: OKAY. THANK YOU. ARE THERE QUESTIONS FROM MEMBERS OF THE COMMITTEE OR THE WORKING GROUP?

DR. GOLDSTEIN: I HAVE A QUESTION.

CHAIRPERSON BONNEVILLE: SCOTT.

MR. TOCHER: I'M SORRY, DR. GOLDSTEIN. YOU HAVE A CONFLICT WITH ONE OF THE APPLICATIONS THAT'S PENDING UNDER THIS ITEM. AND SO, THEREFORE, MEMBERS WITH SUCH CONFLICTS ARE UNABLE TO PARTICIPATE IN THE DISCUSSION OF THIS ITEM.

DR. GOLDSTEIN: OKAY. THANK YOU.

MR. TOCHER: THANK YOU.

CHAIRPERSON BONNEVILLE: SCOTT, ARE THERE ANY MEMBERS OF THE PUBLIC THAT HAVE COMMENTS?

MR. TOCHER: THERE ARE NONE HERE, BUT THERE'S ONE ON THE PHONE, THE 312 NUMBER. I'LL WAIT A MOMENT FOR CLAUDETTE TO BRING --

DR. JACOBS: CAN YOU HEAR ME?

MS. MANDAC: YES. LET ME START A TIMER. YOU HAVE THREE MINUTES FOR COMMENT. WE WILL MUTE YOU AS SOON AS THE THREE MINUTES ARE OVER.

DR. JACOBS: OKAY. GOOD AFTERNOON, EVERYONE. MY NAME IS DR. ELIZABETH JACOBS, AND I'M CHAIR AND PROFESSOR OF MEDICINE AT UCR SCHOOL OF MEDICINE. I'M THE PI ON THE ONE VERY HIGHLY RATED GRANT THAT WAS AN INFRASTRUCTURE GRANT.

WE RECEIVED 14 OF 15 VOTES FOR FUNDING. AND I AND WE AND OUR COMMUNITY MEMBERS WHO ARE VERY EXCITED ABOUT THIS AND COMMUNITIES WITHIN THE INLAND EMPIRE WERE VERY DISMAYED TO HEAR THAT OUR APPLICATION, THOUGH RESPONSIVE AND HIGHLY REVIEWED, WOULD NOT BE CONSIDERED FOR FUNDING.

IT'S VERY CONFUSING TO ME, PARTICULARLY AFTER THIS PRESENTATION, BECAUSE OUR APPLICATION IS 7 MILLION DOLLARS OVER FIVE YEARS. SO IT WOULDN'T

LEAVE $17.8 MILLION LEFT AS PORTRAYED IN THIS PRESENTATION. SO I FIND THAT VERY CONFUSING.

THE OTHER THING THAT'S VERY DISMAYING IS I DO BELIEVE THAT THE WAY THIS HAS BEEN PRESENTED AS MEETING PROPOSITION 14 IS MISLEADING. THE REASON WHY I SAY THAT IS MY ENTIRE CAREER HAS BEEN DEDICATED TO ADVANCING HEALTH EQUITY. AND WHAT HAPPENS IS WHEN YOU FUND CENTERS THAT CAN PROVIDE THESE CLINICAL TRIALS, FIRST OF ALL, THERE REALLY AREN'T CENTERS IN THE INLAND EMPIRE, WHICH IS A HEALTH PROFESSIONAL SHORTAGE AREA WITH HIGH HEALTH DISPARITIES, TO PROVIDE THESE SERVICES.

HOWEVER, WE HAVE PARTNERSHIPS WITH AN ALPHA CENTER AS WELL AS CITY OF HOPE WHERE WE CAN ACTUALLY HELP DELIVER THESE CLINICAL TRIALS EVEN THOUGH WE CAN'T INITIALLY DO THEM BECAUSE OF WHO WE ARE, AND OUR COMMUNITY MEMBERS ARE HIGHLY MOTIVATED TO HELP MAKE THAT HAPPEN.

AND SO I DON'T THINK THAT THIS CONCEPT PLAN IS ACTUALLY GOING TO MEET THE GOALS OF PROPOSITION 14. AND IT'S EXTREMELY DISAPPOINTING BECAUSE WHEN I SPOKE TO GIL SAMBRANO, HE LET ME KNOW THAT IT WASN'T AT ALL CLEAR WHEN WE WERE GOING TO BE ABLE TO APPLY AGAIN. AND NOW TO SEE THAT IT'S A YEAR LATER, IT'S JUST GOING TO PERPETUATE

DISPARITIES OF ACCESS TO REGENERATIVE MEDICINE AND CLINICAL TRIALS IN OUR COMMUNITY WITH THIS CURRENT PLAN ANOTHER YEAR AND A HALF OR TWO YEARS.

WHEREAS, IF WE WERE FUNDED NOW, WE COULD START RIGHT AWAY BY DISSEMINATING WHAT'S ALREADY OUT THERE AS CLINICAL TRIALS IN PARTNERSHIP WITH OUR -- WITH OUR COMMUNITY MEMBERS. SO IT'S REALLY DISMAYING TO BE ABLE TO APPLY, BE RESPONSIVE, TOLD WE'RE GOING TO GET FUNDING, AND THEN ALL OF A SUDDEN HAVE THE FUNDING PULLED. AND IT APPEARS FROM THIS PRESENTATION IT WOULDN'T IMPACT WHAT WAS BEING SHARED HERE TODAY.

CHAIRPERSON BONNEVILLE: THANK YOU. GEOFF, DID YOU WANT TO RESPOND TO THAT?

DR. LOMAX: IN TERMS OF THE BUDGET, JUST TO CLARIFY ON THE BUDGET POINT, SO IF YOU TAKE THE CUMULATIVE APPLICATIONS THAT WERE RECEIVED, THE NINE APPLICATIONS, WE COULDN'T HAVE FUNDED NINE BASED ON THE PROPOSED BUDGET. BUT BASED ON EVEN THE ONES THAT COULD RESUBMIT, WE WOULD STILL END UP, IF WE JUST ALLOWED EVERYONE TO COME BACK IN AND RESUBMIT AND FUNDED ONCE THEY WERE APPROVED, WE WOULD RUN IN -- THE OVERALL BUDGET WOULD HAVE BEEN ON THE ORDER OF 60 MILLION. SO FOR THAT PARTICULAR POINT, WE WERE CONSTRAINED IN TERMS OF THE BUDGET

ALLOCATION.

AND AS I EXPLAINED, THAT WAS THE RATIONALE FOR DRAWING ON SEPARATE BUDGETS IN ORDER TO FUND BOTH THE DELIVERY SITES AND SUPPORT AND DELIVERY SITES. IT'S SUPPORT SITES AND SUPPORT AND DELIVERY SITES.

SO I JUST WANT TO POINT OUT THAT THOSE NUMBERS REFLECTED THE ACTUALS IN THE FIRST ROUND.

DR. JACOBS: BUT YOU WOULDN'T FUND ALL OF THEM BECAUSE YOU'D FUND THE ONES THAT WERE FUNDABLE.

CHAIRPERSON BONNEVILLE: SO, HARLAN, I WANT TO GET BACK TO YOUR POINT ABOUT THERE WILL BE AN OPPORTUNITY TO APPLY FOR THE ACTIVITIES THAT YOU HAVE PROPOSED. WE'RE NOT SUGGESTING THAT THAT WILL NOT COME BACK IN A DIFFERENT FORMAT LATER THIS YEAR. SO IN ORDER TO BE ABLE TO SUSTAIN AND MAKE THESE COMMUNITY CARE CENTERS AS WELL AS THE SUPPORT SITES AS ROBUST AND BE ABLE TO LAST AS LONG AS THEY CAN, WE FELT THAT TWO ROUNDS OF FUNDING FOR EACH OF THE DIFFERENT ACTIVITIES WAS REALLY IMPORTANT. AND IN ORDER TO DO THAT, WHAT WE HAVE LAID OUT IS FUNDING FROM DIFFERENT PARTS OF OUR RESEARCH FUNDS.

SO FOR THIS ROUND, WE'RE FOCUSING ON CENTERS THAT CAN DELIVER THERAPIES, THE COMMUNITY CARE CENTERS THAT CAN DELIVER THERAPIES. THE SECOND

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ROUND OF FUNDING WILL COME LATER THIS YEAR, AND THAT WILL BE FOR SUPPORT SERVICES SPECIFICALLY. AND THAT IS WHERE THE -- THAT'S WHERE THE APPLICATIONS THAT CAME IN FOR SUPPORT WOULD THEN BE REDIRECTED FROM A DIFFERENT SET OF MONEY THAT COULD ALSO SUPPORT MORE THAN ONE ROUND OF FUNDING FOR THESE CENTERS AND ACTIVITIES.

SO I WANTED TO MAKE THAT DISTINCTION, THAT THIS IS NOT CLOSING OFF ANY MONEY THAT POTENTIALLY OTHER APPLICANTS WOULD HAVE ACCESS TO THAT WERE SUPPORT ONLY.

ARE THERE ANY OTHER PUBLIC COMMENTS, SCOTT?

MR. TOCHER: I DON'T SEE ANY OTHER HANDS RAISED. OH, WAIT. I'M SORRY. WHICH ONE? OH, OKAY. SORRY. I THOUGHT THAT WAS THE SAME ONE. GO AHEAD.

MS. MANDAC: ALL RIGHT. 312 NUMBER, YOUR TIME CAN START NOW. THE 31 --

MR. TOCHER: STAND BY, MARIA.

CHAIRPERSON BONNEVILLE: SURE.

DR. JACOBS: OKAY. I THINK I UNMUTED MYSELF. THANK YOU.

SO I JUST -- IT DOESN'T MAKE ANY SENSE THAT YOU WOULD DELAY FUNDING OF A VERY SUCCESSFUL

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AND HIGHLY REVIEWED APPLICATION BECAUSE WHAT WE WERE DOING WAS INCREASING GEOGRAPHIC ACCESS TO CLINICAL TRIALS AS WELL AS REGENERATIVE MEDICINE THERAPY. AND YOU DON'T HAVE TO FUND EVERYONE. I MEAN I WOULDN'T FUND A GRANT, NOR WOULD I RECOMMEND FOR FUNDING A GRANT THAT DIDN'T GET WELL REVIEWED.

SO IT DOESN'T MAKE ANY SENSE THAT YOU WOULD DELAY THE DELIVERY OF EFFLUENT INFRASTRUCTURE WHICH WE'VE DEVELOPED TO A VERY, VERY HIGH NEED COMMUNITY IN A PHASE 1 AND A PHASE 2 BECAUSE JUST DELAYING OUR ABILITY TO WHAT PROPOSITION 14 ASKS YOU TO DO.

CHAIRPERSON BONNEVILLE: THANK YOU FOR YOUR COMMENTS. SCOTT, ARE THERE OTHER PUBLIC COMMENTS?

MR. TOCHER: SORRY. THERE IS NONE.

CHAIRPERSON BONNEVILLE: THANK YOU. WE CAN PROCEED TO A ROLL CALL VOTE.

MR. TOCHER: MARIA BONNEVILLE.

CHAIRPERSON BONNEVILLE: YES.

MR. TOCHER: JAMES DEBENEDETTI.

MR. DEBENEDETTI: YES.

MR. TOCHER: DAVID HIGGINS. DAVID? DAVID, I'LL COME BACK TO YOU. VITO IMBASCIANI.

CHAIRMAN IMBASCIANI: YEAH. I'M YES.

MR. TOCHER: DARIUS LAKDAWALLA.

DR. LAKDAWALLA: YES.

MR. TOCHER: HARLAN LEVINE.

DR. LEVINE: YES FOR THE CURRENT PLANS. AND WE SHOULD HAVE A DISCUSSION ABOUT THE COMMENTS THAT WERE MADE, BUT IT DOESN'T CHANGE MY VOTE NOW TO VOTE YES.

MR. TOCHER: AMMAR QADAN.

DR. QADAN: YES.

MR. TOCHER: COME BACK TO DAVID HIGGINS. DAVID, WE'RE HAVING TROUBLE HEARING YOU.

AS IT STANDS, THE VOTE IS SIX TO ZERO, WHICH IS SUFFICIENT FOR QUORUM. AND IN THAT EVENT, THE MOTION CARRIES. MARIA.

CHAIRPERSON BONNEVILLE: THANK YOU SO MUCH. DO MEMBERS OF THE COMMITTEE HAVE ANY OTHER QUESTIONS THAT THEY'D LIKE TO ASK OR THINGS THEY WOULD LIKE ADDRESSED? HARLAN.

DR. LEVINE: WELL, I DON'T HAVE ENOUGH INFORMATION, I THINK, TO HAVE A FULL DISCUSSION. BUT I DO THINK THAT THERE SHOULD BE CLARIFICATION OF JUST UNDERSTANDING WHY THE THINGS WEREN'T FUNDED BEFORE. I THINK THERE'S A MISCOMMUNICATION.

CHAIRPERSON BONNEVILLE: I AGREE. MY UNDERSTANDING WAS THAT OUR INTERNAL TEAM HAD REACHED

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OUT TO UC RIVERSIDE TO EXPLAIN THE SITUATION AND THAT THIS HAD BEEN CLARIFIED. SO I APOLOGIZE IF THAT'S NOT WHAT OCCURRED.

GEOFF, DO YOU WANT TO WALK THROUGH THE DIFFERENCE OR THE -- THERE IS A MISCOMMUNICATION, I THINK, IN UNDERSTANDING WHERE WE ARE AND HOW THIS IS GOING TO MOVE FORWARD. SO DO YOU WANT TO JUST ADDRESS SOME OF THE COMMENTS THAT WERE MADE BY UC RIVERSIDE?

DR. LOMAX: WELL, AGAIN, WE'VE -- SO WE HAVE COMMUNICATED WITH MOST OF THE APPLICANTS. I'D HAVE TO JUST GO BACK AND CHECK IN TERMS OF THE -- BUT I BELIEVE THERE HAVE BEEN BOTH WRITTEN AND WE'VE INVITED COMMUNICATIONS OVER THE PHONE WITH DIFFERENT APPLICANTS.

DR. SAMBRANO: WE SPOKE WITH UC RIVERSIDE. THEY WERE THE FIRST TEAM THAT WE SPOKE WITH.

DR. LOMAX: THANK YOU, GIL.

AND AIM WAS IN THOSE COMMUNICATIONS BECAUSE WE DO ABSOLUTELY APPRECIATE THE WORK, THE EFFORT, EVERYTHING THAT GOES IN TO DEVELOPING A CIRM APPLICATION. AND THE SPIRIT OF THOSE DISCUSSIONS WERE ALONG THE LINE OF THE PRESENTATION TODAY WHERE WE WERE OUTLINING OUR AIM AND EFFORT TO DEVELOP A SET OF PROGRAMS THAT WOULD ALLOW THOSE ACTIVITIES TO

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PROCEED. NOW, ADMITTEDLY AND UNDERSTANDABLY, THE DELAY IS A CONCERN. I THINK MORE THAN ONE SITE EXPRESSED THAT THE DELAY IN FUNDING IS ALWAYS A CONSIDERATION. AND WE, AGAIN, OFFERED TO EXPLAIN BOTH OUR SENSE OF HOW THE PROCESS WOULD MOVE FORWARD AND THE TIMING AND THE FACT THAT, WE THINK, AS YOU HAD INDICATED PREVIOUSLY, THAT IN THE LONGER RUN FROM A STANDPOINT OF SUSTAINABILITY, BEING ABLE TO SERVE PATIENTS AND REALLY SUPPORT THE CLINICAL INFRASTRUCTURE BROADLY, THAT HAVING A MORE DURABLE AND SUSTAINABLE FUNDING PLATFORM WAS IN THE LONGER TERM INTERESTS OF WHAT WE'RE TRYING TO ACCOMPLISH BOTH WITHIN PROPOSITION 14 AND THE STRATEGIC ALLOCATION FRAMEWORK.

CHAIRPERSON BONNEVILLE: SO I JUST WANT TO FOLLOW UP. THIS MEETS OUR STRATEGIC GOALS AND ALLOWS FOR EVERYTHING THAT GEOFF DESCRIBED. I THINK THE DISAGREEMENT IS IN THE TIMING, AND WE ACKNOWLEDGE THE TIME HAS SHIFTED. THE APPLICATION -- THE RFA WILL COME LATER THIS YEAR. WE'RE NOT GETTING RID OF THIS PROGRAM. IT WILL CONTINUE TO SERVE THE LARGER GOALS OF THE ALPHA CLINICS AND OTHER COMMUNITY CARE CENTERS. SO I JUST WANT TO REASSURE EVERYONE THAT. IT'S JUST RIGHT NOW WE ARE FOCUSED ON MOVING FORWARD WITH THE DELIVERY

RFA AND THEN LATER HAVING THE SUPPORT PORTION OF THIS PROGRAM COME TO THE BOARD.

DR. LEVINE: THANK YOU, CHAIR BONNEVILLE. THAT SATISFIES MY REQUEST. I THINK ANY FURTHER DETAILS SHOULD JUST BE DONE ONE ON ONE WITH THE APPLICANTS, BUT I JUST FELT LIKE THE BROADER GROUP NEEDED TO HEAR THAT -- IT FELT LIKE WE WERE MAYBE TALKING PAST EACH OTHER AND NOT THE SAME TIMELINE. AND I THINK IT WAS IMPORTANT TO CLARIFY THAT. AND THERE WAS A SHIFT. I UNDERSTAND WHY THERE IS AN OPENING FOR MISUNDERSTANDING, BUT I THINK WE JUST SHIFTED STRATEGY, AND WE ACCEPT THAT, AND NOW WE'RE GOING TO MOVE FORWARD.

CHAIRPERSON BONNEVILLE: THANK YOU. IF THERE ARE NO FURTHER QUESTIONS, I THINK WE CAN ADJOURN THE MEETING. THANK YOU, EVERYONE, FOR YOUR TIME TODAY AND WE REALLY APPRECIATE YOUR FEEDBACK.

DR. QADAN: THANK YOU.

DR. LEVINE: THANK YOU, MARIA.

(THE MEETING WAS THEN CONCLUDED.)

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REPORTER'S CERTIFICATE

I, BETH C. DRAIN, A CERTIFIED SHORTHAND REPORTER IN AND FOR THE STATE OF CALIFORNIA, HEREBY CERTIFY THAT THE FOREGOING TRANSCRIPT OF THE VIRTUAL PROCEEDINGS BEFORE THE ACCESSIBILITY AND AFFORDABILITY WORKING GROUP OF INDEPENDENT CITIZEN'S OVERSIGHT COMMITTEE OF THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE IN THE MATTER OF ITS REGULAR MEETING HELD ON MARCH 10, 2025, WAS HELD AS HEREIN APPEARS AND THAT THIS IS THE ORIGINAL TRANSCRIPT THEREOF AND THAT THE STATEMENTS THAT APPEAR IN THIS TRANSCRIPT WERE REPORTED STENOGRAPHICALLY BY ME AND TRANSCRIBED BY ME. I ALSO CERTIFY THAT THIS TRANSCRIPT IS A TRUE AND ACCURATE RECORD OF THE PROCEEDING.

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