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: OCTOBER 9, 2023
2 P.M.

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

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I N D E X

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OCTOBER 9, 20/23; 2 P.M.

CHAIRPERSON BONNEVILLE: WHY DON'T WE GET STARTED AND HOPEFULLY WE HAVE ONE MORE MEMBER JOIN. WE ARE JUST ONE SHORT OF QUORUM RIGHT NOW, BUT I THINK WE CAN GET STARTED AND GO FROM THERE. SO DO YOU WANT TO START THE RECORDING. GREAT. THANK YOU.

I'D LIKE TO CALL THIS MEETING TO ORDER. DOUG, CAN YOU PLEASE TAKE THE ROLL.

MR. GUILLEN: KIM BARRETT. DAN BERNAL.

MR. BERNAL: PRESENT.

MR. GUILLEN: MARIA BONNEVILLE.

CHAIRPERSON BONNEVILLE: PRESENT.

MR. GUILLEN: ANN BOYNTON.

MS. BOYNTON: PRESENT.

MR. GUILLEN: JAMES DEBENEDETTI.

MR. DEBENEDETTI: HERE.

MR. GUILLEN: DANA DORNSIFE. TED GOLDSTEIN.

DR. GOLDSTEIN: PRESENT.

MR. GUILLEN: DAVID HIGGINS.

DR. HIGGINS: PRESENT.

MR. GUILLEN: VITO IMBASCIANI.

CHAIRMAN IMBASCIANI: PRESENT.

MR. GUILLEN: DARIUS LAKDAWALLA. HARLAN

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LEVINE. HE WAS ON HERE JUST A MOMENT AGO.

DR. LEVINE: HERE.

MR. GUILLEN: PAT LEVITT.

DR. LEVITT: PRESENT.

MR. GUILLEN: ADRIANA PADILLA.

DR. PADILLA: HERE.

MR. GUILLEN: AMMAR QADAN. DAVID SERRANO-SEWELL. MAHESWARI SENTHIL. ADRIENNE SHAPIRO.

MS. SHAPIRO: HERE.

MR. GUILLEN: THANK YOU.

CHAIRPERSON BONNEVILLE: THANKS, DOUG.

BEFORE I TURN THIS OVER TO GEOFF, I WANTED TO FIRST BRING YOU UP TO SPEED ON THE PATIENT SUPPORT PROGRAM. SINCE OUR MEETING LAST IN JUNE, THE CIRM TEAM HAS POSTED THE CIRM PATIENT SUPPORT SERVICES RFA. IN AUGUST THE RFA WAS REVISED TO INCLUDE SOME CLARIFICATIONS FOR APPLICATIONS, AND THE APPLICATION WAS MADE AVAILABLE IN OUR GRANTS MANAGEMENT SYSTEM. CORRESPONDINGLY, THE APPLICATION DEADLINE WAS EXTENDED TO OCTOBER 31ST TO ALLOW APPLICANTS ADEQUATE TIME TO PREPARE AND SUBMIT RESPONSIVE APPLICATIONS TO THE RFA.

THE INTERNAL TEAM HAS ENGAGED 22 POTENTIAL APPLICANT ORGANIZATIONS TO DESCRIBE THE PROGRAM AND

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ADDRESS QUESTIONS. A FREQUENTLY ASKED QUESTIONS DOCUMENT IS POSTED ON THE CIRM WEBSITE. WE'VE IDENTIFIED EXPERT REVIEWERS TO SUPPORT THE APPLICATION EVALUATION PROCESS. AND THE INTERNAL TEAM HAS BEEN WORKING ON GETTING ALL OF YOU SCHEDULED FOR REVIEW TRAINING. SO HOW TO USE OUR GRANTS MANAGEMENT SYSTEMS, WHAT TO EXPECT FROM THE REVIEW, AND TO REVIEW THE APPLICATION ITSELF.

THE REVIEW IS ON FEBRUARY 8TH. YOU SHOULD HAVE RECEIVED A MEETING INVITE FOR THAT DATE FROM LANA. IF YOU DON'T HAVE IT ON YOUR CALENDAR, PLEASE LET ME KNOW AND WE'LL FORWARD YOU THE MEETING INVITE.

I WANT TO THANK THE MED AFFAIRS TEAM AND BUSINESS DEVELOPMENT TEAM FOR ALL OF YOUR HARD WORK ON THIS PROGRAM. AND I LOOK FORWARD TO GETTING THIS UNDER WAY. SO THANK YOU.

AND NOW I'M GOING TO TURN IT OVER TO GEOFF, WHO'S GOING TO WALK US THROUGH THE COMMUNITY CARE CENTERS OF EXCELLENCE CONCEPT PROPOSAL.

DR. LOMAX: THANK YOU VERY MUCH. I AM GOING TO BRING MY SCREEN UP. EVERYONE IS SEEING THAT, I HOPE. VERY GOOD. THANK YOU VERY MUCH.

SO I'M GEOFF LOMAX. I'M ASSOCIATE DIRECTOR FOR MEDICAL AFFAIRS AND POLICY AT CIRM AND

WORKING WITH THE TEAM TO DEVELOP THIS CONCEPT PLAN. AND VERY EXCITED TO BE ABLE TO PREVIEW IT TODAY AND FOR YOUR FEEDBACK.

SO AS A REMINDER, OUR MISSION IS ACCELERATING WORLD-CLASS SCIENCE TO DELIVER TRANSFORMATIVE REGENERATIVE MEDICINE TREATMENTS IN AN EQUITABLE MANNER TO A DIVERSE CALIFORNIA AND THE WORLD. THIS CONCEPT IS CERTAINLY IN SERVICE OF THAT MISSION IN A VERY SUBSTANTIAL WAY.

I WOULD LIKE TO RECAP THE HISTORY OF HOW WE GOT TO THIS PHASE AND WHERE WE'RE GOING MOVING FORWARD. SO IN OCTOBER THROUGH MARCH, STARTING OCTOBER 2022 AND THROUGH THE SPRING, WE CONDUCTED A SERIES OF LISTENING SESSIONS. AND WE'VE, IF YOU MAY RECALL, PROVIDED YOU UPDATES TO THOSE SESSIONS ALONG THE WAY. AND THAT WORK CULMINATED WITH A PUBLIC WORKSHOP IN SACRAMENTO. AND, AGAIN, A NUMBER OF YOU PARTICIPATED IN THE WORKSHOP. IT WAS BOTH VIRTUAL AND LIVE. AND IT REALLY HELPED SHAPED THE NEEDS, THE THINKING, AND THE OPPORTUNITIES TO DEVELOP THIS PROGRAM IN A WAY CONSISTENT WITH ITS INTENT.

SO WE'VE SINCE THAT SACRAMENTO MEETING, WE'VE PUT TOGETHER A DRAFT CONCEPT. AGAIN, THAT IS NOW POSTED AND AVAILABLE FOR YOUR REVIEW. WE ARE CONSULTING WITH THE VARIOUS WORKING GROUPS, ACCESS

AND AFFORDABILITY TODAY, AND WE'LL MEET WITH THE SCIENCE SUBCOMMITTEE IF YOU RECOMMEND WE DO THAT. AND THEN THEY WOULD RECOMMEND -- FORWARD THAT RECOMMENDATION TO THE BOARD SHOULD THEY MAKE THAT DETERMINATION. AND THAT WOULD MOVE US INTO A PHASE WHERE WE WOULD ANTICIPATE HAVING AN EARLY APPLICATION IN EARLY 2024. AND I THINK AT THAT POINT, HOPEFULLY, WE'D KNOW LATER IN THE YEAR WE'D HAVE THOSE AWARDS, BUT WE HAVEN'T PROJECTED ALL THOSE DATES OUT THAT FAR. BUT WE'RE LOOKING AT EARLY 2024 TO HAVE APPLICATIONS OPEN SHOULD THE PROCESS PROCEED AS I JUST DESCRIBED.

THERE WE GO. SO I WANT -- SORRY. I'M JUST MOVING MY VIEW AROUND HERE SO I CAN SEE THE SLIDE. VERY GOOD.

SO THE COMMUNITY CARE CENTERS OF EXCELLENCE, AS A REMINDER, THEY'RE AN INFRASTRUCTURE PROGRAM THAT ARE ACTUALLY CALLED OUT IN PROPOSITION 14. THEY ARE DESCRIBED AS GEOGRAPHICALLY DIVERSE CENTERS OF EXCELLENCE WITH THE INTENT OF EXPANDING ACCESS TO BOTH CIRM-FUNDED CLINICAL TRIALS AND APPROVED THERAPIES SUPPORTED BY CIRM IN THE FUTURE. AND A PRIMARY AIM IS TO ENHANCE ACCESS TO PATIENTS REGARDLESS OF ECONOMIC MEANS AND GEOGRAPHIC LOCATION.

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SO ONE OF THE THINGS THAT CAME UP IN INTERACTIONS WITH A LOT OF DIFFERENT FOLKS, INCLUDING MEMBERS OF THIS WORKING GROUP, WAS A LITTLE BIT OF WHAT DO THESE CENTERS LOOK LIKE. SO TYPICALLY, AND THIS IS THE ALPHA CLINICS, WHICH TO SOME DEGREE THEY'RE MODELED AFTER, THESE CENTERS ARE TEAMS. THEY'RE PERSONNEL. THEY ALSO INCLUDE EQUIPMENT. BUT IT'S THESE TEAMS THAT ARE ABLE TO REALLY ENGAGE IN A COLLECTIVE MISSION ACROSS THE ORGANIZATION TO SUPPORT DELIVERY OF CELL AND GENE THERAPY TREATMENTS AND TRANSLATE THEM INTO A WORLD-CLASS SYSTEM CAPABLE OF DELIVERING REAL-WORLD SOLUTIONS. SO IT'S THE PEOPLE THAT CAN MOVE THOSE PATIENTS INTO CLINICAL RESEARCH AND REALLY SERVE THE MISSION.

AND AS A REMINDER, THE BACKBONE OF THIS SYSTEM AT THE MOMENT ARE OUR ALPHA CLINICS NETWORK. AND WHAT YOU SEE IS -- THIS IS FROM OUR RECENT ALPHA CLINICS SYMPOSIUM. THESE ARE SOME OF THE PEOPLE THAT HELP MAKE THESE CENTERS POSSIBLE.

MORE SPECIFICALLY, AND THIS IS REALLY MODELED AFTER WHAT A COMPLETE CENTER WOULD LOOK LIKE THAT SPECIALIZES IN CELL AND GENE THERAPY RESEARCH, IS THEY'RE TEAMS THAT OPERATE IN A NUMBER OF AREAS AND THEY SUPPORT SPONSOR ENGAGEMENT, PATIENT

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EDUCATION. THERE'S A STRONG REGULATORY AND COVERAGE ANALYSIS COMPONENT, REGULATORY IN PARTICULAR FOR CELL AND GENE THERAPY PRODUCTS IS VERY DISTINCT FROM TRADITIONAL MODES. PRODUCT MANAGEMENT, THAT WILL INCLUDE EVERYTHING FROM MANUFACTURING TO HANDLING PRODUCTS DEPENDING ON THE NEEDS. AND THERE'S A CONSIDERABLE DATA MANAGEMENT COMPONENT OBVIOUSLY BECAUSE WE ARE DEALING WITH CLINICAL RESEARCH.

SO I'M GOING TO TRANSITION NOW TO THE NEXT COUPLE OF SLIDES THAT DESCRIBE SOME OF OUR ACTIVITIES TO DATE. AGAIN, I MENTIONED THIS IN ONE OF THE EARLIER SLIDES TO EMPHASIZE THESE ARE THE LOCATIONS AND DATES OF OUR LISTENING SESSIONS. AND I'D LIKE TO ACKNOWLEDGE EMILY REYES IN PARTICULAR ON OUR TEAM WHO REALLY HELPED COORDINATE THE LOGISTICS AND MAKE THESE EVENTS HAPPEN. AND, AGAIN, WE PROVIDED A REPORT BACK IN YOUR DECEMBER, FEBRUARY, AND MARCH MEETINGS FOR EACH OF THESE SESSIONS. SO I'M NOT GOING TO GO INTO A LOT OF DETAIL THERE, BUT WE DO HAVE MATERIALS FROM THOSE MEETINGS THAT PROVIDE SOME OF THE SUBSTANCE THAT WE PULLED FROM THESE MEETINGS. AND THEN, AGAIN, SACRAMENTO IN JUNE.

THIS GIVES YOU A SENSE OF THE RANGE OF ORGANIZATIONS THAT HAVE ENGAGED IN THE PROCESS.

THEY INCLUDE ACADEMIC CENTERS, REGIONAL HOSPITALS, MORE DISTRIBUTED REGIONAL CARE NETWORKS. AND SO ONE OF THE THINGS WE REALLY TOOK AWAY IS THERE'S A LOT OF EXCITEMENT AND INTEREST IN THIS PROGRAM AMONGST A VERY DIVERSE GROUP OF STAKEHOLDERS IN THE CLINICAL CARE COMMUNITY. SO WE'VE AIMED TO DRAFT A CONCEPT PLAN IN A MANNER THAT IS RESPONSIVE TO THIS DIVERSITY AND CAN ACCOMMODATE IT.

SO EARLIER I ALLUDED TO WORLD-CLASS SYSTEMS CAPABLE OF DELIVERING REAL-WORLD SOLUTIONS. SO I WANTED TO PUT THE COMMUNITY CARE CENTERS IN THAT CONTEXT OF THE LARGER CIRM SYSTEM BECAUSE THEY WOULD EXIST IN THAT. SO IT'S IMPORTANT THAT ALL THESE PIECES INTERACT IN A WAY TO SERVE PATIENTS.

SO THIS IS THE ATTEMPT TO REALLY SHOW SOME OF THESE RELATIONSHIPS. FOR EXAMPLE, WE HAVE THE ALPHA CLINICS NETWORK WHICH ARE ALREADY ACTIVE. THEY ARE CLINICAL CENTERS THAT ARE WHERE MOST OF CIRM-FUNDED TRIALS ARE ACTIVE. AND OUR TRIALS OVER HERE, WE HAVE ABOUT 55 ACTIVE TRIALS OCCURRING IN THIS NETWORK. AND NOW WE ARE AT A PHASE WHERE WE ARE TRYING TO SORT OF BUTTRESS THIS SYSTEM THAT'S ALREADY IN PLACE WITH TWO IMPORTANT PROGRAMS THAT DRIVE ACCESS, AFFORDABILITY, AND OPPORTUNITY FOR PATIENTS. THE PATIENT SUPPORT PROGRAM, AS CHAIR

BONNEVILLE POINTED OUT, WE ARE IN THE APPLICATION PHASE THERE, AND THAT WILL BE COMING ONLINE, NOT SIMULTANEOUSLY, BUT IN THE SIMILAR TIME FRAME AS THE COMMUNITY CARE CENTERS OF EXCELLENCE, WHICH AT THE MOMENT WE HAVE A DRAFT CONCEPT PLAN.

SO THERE'S SOME OTHER IMPORTANT INFRASTRUCTURE PIECES SORT OF BEHIND HERE AS WELL, INCLUDING A MANUFACTURING NETWORK AND OUR EDUCATION NETWORK, WHICH WILL POTENTIALLY INTERACT WITH THOSE PROGRAMS. THIS, I HOPE, GIVES YOU A SENSE OF HOW COLLECTIVELY OUR SORT OF BOTH CLINICAL AND INFRASTRUCTURE PROGRAMS ALONG WITH PATIENT SUPPORT REALLY COME TOGETHER TO SERVE PATIENTS AND MEET THEIR NEEDS IN THEIR COMMUNITIES.

ONE EXAMPLE OF HOW POTENTIALLY THE COMMUNITY CARE CENTERS BECOME AN ACCESS FACILITATOR. SOME OF THESE EXAMPLES WERE KIND OF WORKED THROUGH DURING OUR ENGAGEMENT SESSIONS. THE COMMUNITY CARE CENTER CAN REALLY SERVE AS THE TOUCHPOINT FOR THE COMMUNITY AND NAVIGATE PATIENTS TOWARDS SOME OF THE EXISTING CLINICAL TRIALS THAT ARE OPERATIONAL; FOR EXAMPLE, IN THE ALPHA CLINICS. AND THAT THOSE PATIENTS CAN BE TREATED, AND THEN SUBSEQUENT FOLLOW-UP AND LONG-TERM SUPPORT COULD OCCUR IN THE COMMUNITY SETTING. AND IN ADDITION, WE HAVE A

PATIENT SUPPORT OVERLAY WHICH IS THE PROGRAM YOU ALL RECOMMENDED, WHICH, IN ADDITION TO HAVING THE CARE GEOGRAPHICALLY LOCATED CLOSER TO THE PATIENT OR PROXIMATE TO THE PATIENT, THERE WOULD ALSO BE A FINANCIAL SUPPORT COMPONENT SUPPORTING THOSE PATIENTS WITH FINANCIAL NEEDS. THIS IS AN EXAMPLE.

I'M GOING TO NOW TRANSITION TO THE CONCEPT PLAN ITSELF. AND I HAVE A COUPLE MORE SLIDES AND THEN WE CAN OPEN IT UP.

SO THE CORE ELIGIBILITY AND ACTIVITIES THAT WE'VE PROPOSED ARE, FIRST OF ALL, THE APPLICANT MUST HAVE THE ABILITY TO SUPPORT CLINICAL OPERATIONS. AND THE KEY TERM HERE IS TO SUPPORT HUMAN SUBJECTS PROTOCOLS. I'M GOING IN THE NEXT SLIDE KIND OF CONTRAST SORT OF THE DIFFERENCE -- SORT OF SUPPORTING VERSUS CONDUCTING CLINICAL TRIALS. AND IN ADDITION, WE'VE ALSO STIPULATED THAT THE APPLICANT CENTERS WOULD NOT BE ADMINISTERING UNAUTHORIZED STEM CELL TREATMENTS. THESE WOULD BE TREATMENTS THAT HAVE NOT RECEIVED AN IND FROM THE FDA.

IN ADDITION, WE'VE INCLUDED A CAREER DEVELOPMENT COMPONENT. AND THAT'S REALLY THE APPLICANT OR THE APPLICANT -- IN MANY CASES WE EXPECT THERE MAY BE APPLICANTS PROPOSING

PARTNERSHIPS AMONG MULTIPLE INSTITUTIONS IF THEY HAVE THE CAPACITY TO SUPPORT EDUCATION, TRAINING, AND CAREER DEVELOPMENT OF REALLY, AGAIN, GOING BACK TO THAT SLIDE WHERE IT SHOWED SORT OF ALL THE DIFFERENT COMPONENTS OF WHAT IT TAKES TO DELIVER THESE TREATMENTS. THESE ARE SOME OF THE ROLES THAT SORT OF FILL THERE: PHYSICIANS, NURSES, RESEARCH COORDINATORS, COMMUNITY HEALTH WORKERS, OR OTHER MEDICAL PROFESSIONALS. AND REALLY EMPHASIZING THE CAREER DEVELOPMENT ASPECT THERE.

AND, FINALLY, THE PIECE THAT'S REALLY UNIQUE TO THIS PROGRAM IN A SUBSTANTIAL WAY IS THE OUTREACH AND ENGAGEMENT WORK. THIS IS SOMETHING THAT WE HEARD A LOT ABOUT DURING OUR NEEDS ASSESSMENT. AND THAT PARTICULARLY THE ROLE OF COMMUNITY-BASED ORGANIZATIONS IN FORMING THE TRUST BUILDING AND THE WORK THAT OUR STAKEHOLDERS SAID REALLY NEEDS TO HAPPEN TO ENGAGE THE COMMUNITY IN A WAY THAT'S GOING TO BUILD TRUST AND CONFIDENCE IN THIS CLINICAL RESEARCH. AND SO WE'VE INCLUDED A PIECE THAT INVOLVES BOTH COMMUNITY ENGAGEMENT AND PARTNERSHIPS WITH COMMUNITY-BASED ORGANIZATIONS TO SUPPORT THE PROGRAM.

SO I'D LIKE TO JUST CONTRAST THAT A LITTLE BIT WITH THE ALPHA CLINICS BECAUSE THAT'S A QUESTION

THAT CAME UP VERY FREQUENTLY AMONGST A NUMBER OF FOLKS. THE ALPHA CLINICS, IN TERMS OF THE CLINICAL PIECE, THE REQUIREMENT WAS THAT THEY'RE ACTUALLY DELIVERING CELL AND GENE THERAPY PRODUCTS. THAT WAS A REQUIREMENT. SO THEY WOULD HAVE TO HAVE THE CAPACITY TO SUPPORT A CIRM CLIN2 APPLICATION IN THE CLINICAL SETTING.

WHEN WE SAY SUPPORTING, WHAT WE ARE SUGGESTING THERE IS THAT THEY DON'T NECESSARILY HAVE TO BE ABLE TO DELIVER AN INVESTIGATIONAL PRODUCT, ALTHOUGH WE THINK THERE ARE CENTERS THAT ARE ABLE TO DO THAT OR CERTAINLY INTERESTED IN DEVELOPING THAT CAPACITY, BUT THEY COULD PROVIDE PATIENT NAVIGATION, SUPPORT ENROLLMENT, DO COHORT DEVELOPMENT, DO LONG-TERM FOLLOW-UP, THE WHOLE SET OF WRAPAROUND SERVICES THAT A PATIENT MAY NEED AND MAINTAIN SORT OF PROXIMITY TO THEIR COMMUNITY. TO THE EXTENT THEY CAN SUPPORT THOSE ACTIVITIES, WE REALLY SEE VALUE THERE.

IN THE CONTEXT OF TRAINING, THE ALPHA CLINICS REALLY WERE CREATING PROGRAMS, DE NOVO PROGRAMS. IN THE CASE OF THE COMMUNITY CARE CENTERS, WHAT WE'D REALLY LIKE TO ENCOURAGE IS THAT THOSE CENTERS BECOME A PLACE WHERE EXISTING TRAINING PROGRAM, EITHER TRAINEES OR CURRICULA, CAN BE

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ADAPTED OR TRAINEES CAN GO TO REALLY DEVELOP A COMMUNITY PERSPECTIVE, ADDITIONAL SITES WHERE OUR STUDENTS FROM ALL OUR EDUCATION PROGRAMS CAN GAIN THE EXPERIENCE AND ADDITIONAL TRAINING TO GROW INTO THE FIELD OF REGENERATIVE MEDICINE.

AND THEN ON THE ENGAGEMENT SIDE, THE ALPHA CLINICS DO HAVE SUBSTANTIAL ENGAGEMENT AND NAVIGATION CAPACITY OFTEN THROUGH THE CLINICAL TRANSLATIONAL SCIENCES UNITS BECAUSE MOST OF THOSE SITES CAN DRAW ON THAT CAPACITY.

IN TERMS OF THE COMMUNITY CARE CENTERS, WHAT WE ARE SUGGESTING IS THAT CERTAINLY THAT ENGAGEMENT AND NAVIGATION COMPONENT IS THERE AND SHOULD GROW AND DEVELOP, BUT ALSO COMMUNITY ENGAGEMENT FOR BOTH CLIN PROGRAMS AND OTHER, THAT THEY ACTUALLY GO OUT AND THIS COULD BE EDUCATING THE COMMUNITY. IT COULD BE TALKING TO THE COMMUNITY ABOUT, AGAIN, SOME OF THE TREATMENTS THAT ARE OUT THERE THAT MAY POSE RISKS TO THEIR FINANCIAL OR THEIR HEALTH BECAUSE THEY'RE NOT FDA AUTHORIZED.

AND, AGAIN, A BIG FOCUS ON COMMUNITY-BASED PARTNERSHIPS BECAUSE, AGAIN, IT'S THAT COMMUNITY REACH THAT WE THINK IS GOING TO BE VITAL TO THE SUCCESS OF THIS PROGRAM. CERTAINLY THAT WAS A BIG MESSAGE FROM THE STAKEHOLDERS.

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SO FINALLY, TO WALK THROUGH HOW WE ARE REALLY PROPOSING THAT. WE'VE SUGGESTED UP TO SIX AWARDS. AND THE FUNDING FOR THE COOPERATIONS ANNUALLY IS JUST OVER A MILLION. AND TO GIVE YOU A LITTLE BIT OF BACKGROUND ON THAT NUMBER, WE SORT OF LOOKED THROUGH THE ALPHA CLINICS IN TERMS OF THE TYPES OF PERSONNEL, THOSE PERSONNEL COSTS. THIS WOULD BE FOR A CLINIC REALLY AIMING TO DEVELOP AND DELIVER -- CERTAINLY IF THEY'RE DELIVERING TREATMENTS, THIS IS SORT OF THE PERSONNEL LEVEL. IT'S ROUGHLY TEN PEOPLE. WE DON'T KNOW IF EVERY APPLICANT WOULD BE AT THAT LEVEL, BUT CERTAINLY WE'D LIKE TO BE ABLE TO FUND UP TO THAT LEVEL IF THE APPLICANT HAD THAT CAPACITY.

THE COMMUNITY-BASED PARTNERSHIPS, WE ARE PROJECTING AT ABOUT 250,000 A YEAR. THAT'S FOR TWO PARTNERSHIPS. AND THAT FIGURE WAS BASED LOOKING AT THE ALL ABUZZ RESEARCH PROGRAM AND THE LINE ITEMS THEY WERE PROPOSING FOR REGIONAL ENGAGEMENT PROGRAMS. SO THAT WAS OUR BENCHMARK THERE.

THERE'S FACILITY FUNDS IN THIS AWARD. AND THE REASON -- I WANT TO -- I THINK THE ORIGINAL SLIDE DECK HAD A NUMBER HERE, BUT WE WANT TO BE CAREFUL WITH FACILITY FUNDS. WE DON'T NECESSARILY WANT TO APPLY THOSE ACROSS ALL THE AREAS. THOSE

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FUNDS MAY BE FRONT-LOADED, BUT THEY'RE UP TO 2.5 MILLION PER AWARD, NOT NECESSARILY ON AN ANNUALIZED BASIS, BUT 2.5 MILLION UP TO. THE 2.5 MILLION FIGURE WAS BASED ON ENGAGEMENT WITH LOOKING AT SOME OF THE COSTS NOW. IF YOU'RE LOOKING AT CAR-T AND MOBILE MANUFACTURING FACILITIES, THESE ARE SOME OF THE COSTS IF YOU WERE LEASING UNITS THAT WOULD ENABLE YOU TO DO CELL PROCESSING AND SOME OF THE IMMUNOTHERAPY WORK. SO THAT WAS THE BASIS FOR THAT ESTIMATE.

YOU'VE GOT YOUR INDIRECT COSTS. SO THAT PUTS US AT JUST OVER TWO MILLION PER YEAR ON AN ANNUAL BASIS. SO WITH THAT, I WILL STOP AND LOOK FORWARD TO QUESTIONS, COMMENTS.

CHAIRPERSON BONNEVILLE: THANK YOU, GEOFF. I'D LIKE TO OPEN THIS UP TO ANY MEMBERS WHO HAVE ANY QUESTIONS OR COMMENTS. GO AHEAD, HARLAN.

DR. LEVINE: THIS IS HARLAN. I'M HAVING CONNECTION TROUBLES. MY QUESTION IS I FEEL LIKE THERE'S GOING TO BE A LOT OF SCRUTINY OVER EVERYTHING WE DO. SO I GET THE ELEVATOR SPEECH WHY WE'RE DOING IT AND I FULLY SUPPORT IT. HOW ARE WE GOING TO MEASURE THE IMPACT OF THIS? WHAT ARE WE LOOKING FOR OVER TIME?

DR. LOMAX: OUR BENCHMARKS HAVE REALLY

BEEN AROUND THE ENGAGEMENT OF PATIENTS AND THE ABILITY TO SORT OF NAVIGATE PATIENTS TO CLINICAL TRIALS. SO AT ONE LEVEL IT WOULD BE, IF YOU LOOKED, FOR EXAMPLE, OUR CLINICAL TRIAL OBJECTIVES NOW, WE NOW HAVE DEI OBJECTIVES WITHIN THOSE TRIALS. SO I THINK CERTAINLY THE ABILITY TO MEASURE THE CAPACITY OF THESE SITES TO SUPPORT ENROLLMENT CONSISTENT WITH THE DEI OBJECTIVES OF THE TRIALS SORT OF AT AN IMMEDIATE INITIAL LEVEL WOULD BE VERY IMPORTANT. BUT I THINK OVER TIME MORE SUBSTANTIALLY, IT'S REALLY THE ABILITY OF THESE SITES, I THINK, TO, AGAIN, SUPPORT TRIALS IN A CLINICALLY MEANINGFUL WAY.

I SUPPOSE -- I GUESS THE QUESTION BECOMES THEN HOW DO WE -- WHAT DO THOSE METRICS OR BENCHMARKS LOOK LIKE AND HOW MIGHT WE INCORPORATE THEM INTO THE APPLICATION. THAT'S ONE WHERE I THINK IT WOULD BE INTERESTING TO SORT OF THINK ABOUT HOW WE COULD DO THAT.

CHAIRPERSON BONNEVILLE: GEOFF, TO GO ON TO WHAT HARLAN WAS SAYING, ALSO, I GUESS, THE ABILITY TO BE ABLE -- SINCE THIS IS REALLY OUR FIRST FORAY INTO THIS SORT OF PROGRAM OUT IN AREAS THAT DON'T HAVE THIS CAPACITY, ANOTHER QUESTION WOULD BE DO WE HAVE THE ABILITY TO COURSE CORRECT THROUGHOUT

THE LIFE OF THE GRANT AND MAKE ADJUSTMENTS AS NECESSARY. SO THAT'S SOMETHING THAT WE MAY WANT TO CONSIDER INCORPORATING INTO THE RFA WHERE WE THINK WE CAN AND WHERE IT MAKES THE MOST SENSE.

PAT HAS HIS HAND RAISED.

DR. LEVITT: THANKS VERY MUCH. I THOUGHT THAT IT WAS GREAT.

TWO THINGS. ONE IS TWO OF THE THREE BOXES ARE ABOUT WHEN YOU ARE COMPARING THE ALPHA CLINICS AND THE CCC'S ABOUT TRAINING AND ENGAGEMENT. AND THIS HAS, AT LEAST CONCEPTUALLY, A UNIQUE KIND OF TRAINING BECAUSE OF THE FOCUS ON THE TOPIC AREA. AND I'M WONDERING IF THERE WAS ANY DISCUSSION OR ANY CONVERSATION AROUND THE FUNDED SITES SHARING COMMON APPROACHES TO THIS IN TERMS OF EXPERIENCES, EVEN CURRICULA THAT WOULD BE PART OF EACH OF THE SITES SO THAT, ONE, THEY'RE NOT TRYING TO REINVENT THE WHEEL AND, TWO, BECAUSE IT'S SO UNUSUAL IN TERMS OF THE KIND OF TRAINING THAT LIKELY WOULD HAVE TO OCCUR TO HAVE SORT OF A SHARED EFFORT.

I WOULD SAY THE SAME THING ABOUT EDUCATING THE COMMUNITY. LIKE SOME OF US ON THIS CALL HAVE TRIED TO DO A LOT OF IT, AND SOMETIMES IT GOES WELL AND SOMETIMES IT GOES TERRIBLY FOR A WHOLE LOT OF REASONS.

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I WOULD SAY THERE, AGAIN, BECAUSE IT HAS TO BE ADAPTIVE FOR THE DIFFERENT COMMUNITIES, RIGHT, FOR COMMUNITIES THAT MAY BE MORE RURAL OR MORE URBAN, WHATEVER IT MIGHT BE. SO THERE HAS TO BE SOME ADAPTATION. AGAIN, SHARED APPROACHES TO HOW TO COMMUNICATE THIS FROM A THERAPEUTIC AND A SCIENTIFIC PERSPECTIVE. IT'S HARD TO COMMUNICATE THIS WELL. AND SCIENTISTS AND RESEARCHERS GENERALLY DO A BAD JOB. I'M A RESEARCHER, SO I CAN SAY THAT ABOUT MYSELF.

THOSE ARE TWO THINGS ABOUT FIGURING OUT HOW THESE SITES CAN ACTUALLY GET TOGETHER AND WORK TOGETHER TO COME UP WITH SOMETHING MORE ROBUST THAN AN INDIVIDUAL SITE WOULD.

DR. LOMAX: THANK YOU FOR THAT. HONESTLY, THAT'S ONE OF THOSE COMMENTS THAT KIND OF KEEPS US AWAKE AT NIGHT. SO LET ME JUST POINT TO A COUPLE OF DEVELOPMENTS WHERE I THINK WE CAN ADDRESS THAT COMMENT AND THEN ENCOURAGE MY CIRM COLLEAGUES TO COMMENT AS WELL.

FIRST OF ALL, SOME OF THE ALPHA CLINIC SITES IN THE IMPLEMENTATION PHASE NOW DOING THIS DID PROPOSE IN THEIR INITIAL APPLICATION THE DEVELOPMENT OF CURRICULA AND PORTABLE TRAINING OPTIONS THAT THEY INTEND TO DEPLOY OUT TO THIS NETWORK IN ADVANCE

BECAUSE WE ASKED THEM TO CONSIDER THAT. SO ONE IN PARTICULAR IS A RESEARCH COORDINATOR PROGRAM THAT'S BEING LED BY UC IRVINE. SO THERE ARE A NUMBER OF INITIATIVES LIKE THAT WHERE THE ALPHA CLINICS ARE, AGAIN, TRYING TO PROVIDE THOSE CURRICULA AND THOSE RESOURCES, MAKE THEM AVAILABLE. AND THEN WE'RE GOING TO ALLOW THEM -- ENCOURAGE INTERACTION WITH THE APPLICANT SITES TO REALLY ALLOW THOSE TO SORT OF COME THROUGH THE APPLICATION.

THERE IS -- WE ALSO ARE DEVELOPING OUR EDUCATION NETWORK WITHIN CIRM. THAT'S REALLY BEING LED UP BY THE DISCOVERY TEAM THAT MANAGES THE BULK OF OUR EDUCATION PROGRAMS. BUT THERE IS A MORE FORMAL NETWORK STRUCTURE THAT WE'LL BE DEVELOPING IN PART TO GET INTERNAL CONSISTENCY IN TERMS OF THE CURRICULA, THE METHODS, THE MATERIALS. AND SO, AGAIN, THAT'S, AGAIN, ANOTHER RESOURCE WE CAN TAP INTO THIS PROGRAM.

ONE OF THE OTHER ONES I THINK IS VERY EXCITING OR TWO OTHER ONES THAT ARE VERY EXCITING, AGAIN, OPPORTUNITIES HERE THAT CAN REALLY LEVERAGE OUT THROUGH THIS NETWORK IS THERE IS NOW CERTIFICATION PROGRAMS FOR NAVIGATORS. WE'VE HAD SOME INTERACTION, FOR EXAMPLE, WITH SOME OF THE ORGANIZATIONS THAT ARE GOING TO BE LEADING UP THOSE

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CERTIFICATION EFFORTS. AND OUR READOUT IS THAT THEY WOULD BE VERY INTERESTED IN COLLABORATING WITH US TO REALLY BUILD THAT REGENERATIVE MEDICINE COMPONENT INTO A CURRICULA WHICH WOULD SERVE AS THE BASIS FOR THE CERTIFICATION OF NAVIGATORS.

WHY THAT'S IMPORTANT IS WITH THAT CERTIFICATION, THAT THEN BECOMES REIMBURSABLE THROUGH MEDI-CAL. SO IT'S TYING THE REIMBURSEMENT OF THE PROGRAM AND THE TRAINING THROUGH THIS NETWORK WITH A STRONG REGENERATIVE MEDICINE FOCUS.

AND THERE'S, I THINK, A SIMILAR MODEL THAT'S AVAILABLE FOR COMMUNITY HEALTH WORKERS AS WELL WHICH THEN WOULD TIE TO MEDI-CAL REIMBURSEMENT. SO THESE ARE ALL, I THINK, OPPORTUNITIES THAT ALLOW US TO AT LEAST DEPLOY SOME OF OUR MATERIALS AND ASSETS IN TRAINING INTO A FAIRLY SUSTAINABLE SYSTEM OF BOTH NAVIGATION AND ENGAGEMENT. SO WE'RE GOING TO CONTINUE TO TRY TO DEVELOP THOSE. THESE ARE DEVELOPING IN REAL TIME; BUT I THINK BY THE TIME WE GET TO THE APPLICATION PHASE, I THINK WE CAN COME UP WITH SOME WAYS OF REALLY TYING THAT IN.

AND THEN THE LAST THING IS I THINK CIRM'S OWN ENGAGEMENT PROGRAM IS REALLY LOOKING TO -- THE PROGRAM YOU ALL ARE DEVELOPING ON THE COMMUNICATION SIDE IS REALLY LOOKING TO DEVELOP A SET OF

RESOURCES, MATERIALS, AND INTERNAL CONSISTENCY IN THAT PIECE. SO THE THINKING IS THAT ALL -- WE CAN INCENTIVIZE A WAY FOR MANY OF THOSE PIECES TO COME TOGETHER. HOPEFULLY WE ARRIVE AT A PLACE THAT I THINK ADDRESSES YOUR COMMENT, BUT I'LL LEAVE THAT TO YOU.

DR. LEVITT: IT DOES ADDRESS IT. AND THAT WAS GREAT. THERE ARE A NUMBER OF DIFFERENT MOVING PARTS --

DR. LOMAX: YEAH.

DR. LEVITT: -- AS CLEARLY YOU KNOW THIS. SO IT'S GREAT TO HAVE EVERYBODY PLAYING ALL THESE DIFFERENT INSTRUMENTS COME TOGETHER TO FORM THE ORCHESTRA. SOMEBODY HAS GOT TO BE THE CONDUCTOR. MAYBE THAT'S YOU. I DON'T KNOW. BUT I THINK THERE ARE PIECES THERE THAT ADDRESS THIS. AND I THINK IT WOULD REALLY CREATE SOMETHING VERY ROBUST AS HARLAN SAID. THE EYES ARE GOING TO BE -- A LOT OF EYES ON WHAT CIRM IS DOING. SO THAT'S GREAT. THANK YOU.

DR. LOMAX: THANK YOU FOR THAT. HONESTLY THE OPPORTUNITY IS A REAL PLEASURE. SO THANK YOU FOR THE OPPORTUNITY.

CHAIRPERSON BONNEVILLE: THANKS, PAT. ANN. YOU'RE ON MUTE.

MS. BOYNTON: I'M ON MUTE. I'M TRYING TO

LOWER MY HAND. THERE'S TOO MANY THINGS GOING ON.

FIRST IS AN EASY -- THEY'RE BOTH EASY QUESTIONS. BUT ARE THE FUNDS THAT IS THE AMOUNT OF MONEY THAT WE HAVE AVAILABLE? WE'RE ASSUMING SIX, WE'RE ASSUMING SORT OF FLAT DISTRIBUTION OF DOLLARS ACROSS ALL SIX, AND SIXTY -- IT LOOKED LIKE 60 MILLION FOR THE -- IS THAT SET OR IS THERE WIGGLE ROOM IN THAT?

DR. LOMAX: SO PROPOSITION 14 ALLOCATED APPROXIMATELY 78 MILLION TO THIS PROGRAM. IT'S -- AGAIN, THIS COMES OUT OF PROPOSITION 14. SO THAT'S THE LITERAL ALLOCATION. SO WE ARE AT AN AMOUNT THAT'S BELOW THAT AMOUNT. BUT, AGAIN, I THINK SORT OF LOOKING -- CERTAINLY I THINK SIX SITES IS AMBITIOUS, BUT IT'S EXCITING AS WELL. SO SORT OF THE -- THAT'S WHERE WE ARE.

MS. BOYNTON: COOL. THANK YOU.

THE SECOND IS JUST SOMETHING THAT -- AND I THINK ABOUT HOW DO WE IMPLEMENT THESE AND HOW DO WE GO THROUGH A PROCESS TO SELECT THEM. WE HAVE THIS INCREDIBLE TENSION IN CALIFORNIA BETWEEN WHERE THE BULK OF THE POPULATION LIVES AND 65,000 SQUARE MILES NORTH OF SACRAMENTO AND THE NEED TO -- SO THE PROPOSALS COULD BE WILDLY DIVERSE IN THE NUMBER OF COMMUNITY ORGANIZATIONS, THE COMPLEXITY OF THE

INTERACTIONS DEPENDING ON WHAT THE GEOGRAPHY IS THAT THEY ARE TRYING TO SERVE OR THE PATIENT TYPES.

AS WE ALL THINK ABOUT HOW TO FIND OUR WAY THROUGH THAT, AND YOU ARE WORKING ON THE EVALUATION CRITERIA, I THINK THAT'S AN AREA THAT I WOULD LOOK FOR SOME ADDITIONAL GUIDANCE ON HOW DO WE THINK ABOUT THESE TENSIONS.

DR. LOMAX: THANK YOU FOR THAT. AGAIN, I THINK THE CHALLENGE IS TO HONOR THAT DIVERSITY. AND MY SENSE IS THIS WILL BE -- THE ALPHA CLINICS PROGRAM WAS A VERY DEFINED SKILL SET. HERE I THINK BEING FLEXIBLE IN OUR THINKING AND ALLOWING THAT TO BE PART OF THE EVALUATION PROCESS VIS-A-VIS THE GRANTS WORKING GROUP WILL BE VITAL. THAT'S ABSOLUTELY WHAT WE LEARNED. IS IT A FEDERALLY QUALIFIED HEALTH CENTER? IS IT AN ACADEMIC CENTER? IS IT A COMMUNITY CLINIC THAT'S SUPPORTING CLINICAL TRIALS? IS IT A COMMUNITY HOSPITAL? IT'S ALL OF THOSE. SO THIS IS VERY DIFFERENT. AND I THINK WE CAN -- IT'S VERY EXCITING, BUT IT IS DIFFERENT, YES.

MS. BOYNTON: THANK YOU.

CHAIRPERSON BONNEVILLE: THANK YOU, ANN. ADRIANA.

DR. PADILLA: YES, IF I CAN GET MY MUTE DOWN.

SO I AGREE WITH PAT. THERE'S A LOT OF MOVING PARTS TO THIS AND A LOT OF INTERACTIONS THAT NEED TO BE WORKED OUT. SO I HAVE TWO QUESTIONS. WOULD AN APPLICANT HAVE TO -- IT SOUNDS LIKE THEY WOULD NEED TO COLLABORATE OR ASSOCIATE OR GO INTO THIS APPLICATION WITH ALL THE ALPHA CLINICS BECAUSE EACH ALPHA CLINICS DOES SOMETHING DIFFERENT. ALPHA CLINICS, I WOULD THINK, WANT TO ACCESS PATIENTS IN DIVERSE AREAS THROUGHOUT CALIFORNIA. SO IS THAT PART OF THE CRITERIA THAT WOULD BE LOOKED AT PER SE?

AND THEN NO. 2 IS ALPHA CLINICS HAVE FUNDING FOR OUTREACH AND DEVELOPMENT, AS I THINK PAT MENTIONED EARLIER, BUT SO DO THE AWARDEES FOR THE GRANTS FOR THE CLIN'S BASICALLY. THEY GET DOLLARS FOR OUTREACH DEVELOPMENT, CREATION OF RELATIONSHIPS WITH COMMUNITY-BASED ORGANIZATIONS. HOW DO YOU KIND OF MELD ALL THESE MOVING PARTS?

DR. LOMAX: SO I'M GOING TO START WITH THE SECOND ONE, I THINK. I THINK MOST IMPORTANT IS TO REALLY UNDERSTAND THE PARTS AND MAKE THEM VISIBLE TO THE APPLICANT AS A STARTING POINT. SO I THINK WE'RE ALREADY SEEING THAT HAPPEN TO SOME EXTENT, PARTICULARLY COMING OUT OF SACRAMENTO. IT WAS BOTH A PLANNING AND A LISTENING SESSION, BUT ALSO A NETWORKING SESSION WHERE SOME OF THOSE CONVERSATIONS

ARE OCCURRING.

AND SO PART OF IT IS SOCIALIZING WHAT WE ARE TRYING TO DO VIS-A-VIS THE CIRM MISSION WITH THE ALPHA CLINICS WHO, AS YOU SAY, ARE EAGER TO BUILD THESE RELATIONSHIPS AND THEN INTRODUCING THEM TO THE ORGANIZATIONS THAT I THINK SEEM LIKE THEY WOULD OR EXPRESSED INTEREST IN THIS PROGRAM. I THINK PART OF IT IS CREATING THAT VISIBILITY AND THOSE CONDITIONS WHERE THAT THINKING CAN REALLY DEVELOP. AND SO WE'VE DONE -- THAT'S WHAT'S NICE ABOUT THE CIRM PROCESS IS THE RUNWAY UP TO THAT, AT LEAST WE GET TO THAT POINT.

AND THEN I THINK THE EXTENT TO WHICH WE CAN USE THE APPLICATION PROCESS TO HIGHLIGHT SOME OF THESE SPECIFIC OUTCOMES THAT WE'RE INTERESTED IN, I THINK THAT'S WHERE WE'RE LOOKING FOR FEEDBACK FROM YOU ALL AS WELL IN TERMS OF ARE THERE VERY SPECIFIC THINGS WE ARE LOOKING FOR IN THE APPLICATION. SO HOPE THAT GETS SORT OF THE SECOND PART OF YOUR QUESTION.

AND THE FIRST PART, THE APPLICANTS, AGAIN, ABSOLUTELY ARE LOOKING TO THIS PROGRAM. I THINK THEY SEE OPPORTUNITIES IN A VARIETY OF AREAS. I'VE ALLUDED TO THE PIECE ABOUT TRAINING PROGRAMS. THERE'S A LOT OF ACTIVE WORK THERE.

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AND THEN A NUMBER OF THE ALPHA CLINICS, I THINK, ARE INTERESTED IN WORKING WITH SPECIFIC APPLICANTS, WHETHER IT'S ON THE CLINICAL, THE TRAINING, OR THE ENGAGEMENT PIECE. I THINK, AGAIN, THE KEY THERE IS WE CAN -- ARE THERE SPECIFIC THINGS YOU RECOMMEND THAT WE BE LOOKING FOR IN THOSE OPPORTUNITIES, AND CAN WE BRING THEM FORWARD IN THE APPLICATION ITSELF?

MAYBE I'LL PAUSE THERE. AND, AGAIN, IF ANY OF MY CIRM COLLEAGUES WOULD LIKE TO ADD TO THAT. WAS THAT HELPFUL? I JUST WANT TO MAKE SURE I ADDRESS THE QUESTION.

DR. PADILLA: I THINK THE FIRST QUESTION WAS ADDRESSED. THE SECOND ONE ABOUT THE FUNDING THAT ALPHAS HAVE FOR SOME OF THIS WORK THAT'S PROPOSED FOR THE CENTERS OF EXCELLENCE AND ALSO THE GRANT AWARDEES, I STILL DON'T KNOW HOW THAT'S GOING TO INTERACT WITH THE DOLLARS. IT SEEMS LIKE THE DOLLARS ARE ALL SEPARATE, BUT YET THEY SHOULD ALL BE TOGETHER. LOTS OF MOVING PARTS AND HOW DO YOU MELD ALL THAT. I DON'T HAVE A SENSE OF THAT YET.

DR. LOMAX: FROM MY PERSPECTIVE -- THANKS. I DID MISS THAT PIECE. FROM WHAT I'VE SEEN ON THE ALPHA CLINICS SIDE IS THE FUNDING THAT'S COME IN THROUGH THE AWARD HAS ENABLED THEM TO HAVE THE --

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RETAIN THE TIME OF SOME OF THE TEAMS THAT DO THE OUTREACH AND ENGAGEMENT AS A SPECIALTY AND REALLY OFFER THAT AS A SERVICE AND AN OPPORTUNITY.

THE CLINICAL -- I THINK YOU COULD HAVE SOMETHING -- THE MODEL FOR THE COMMUNITY CARE CENTERS COULD BE SIMILAR WHERE YOU'VE GOT THE PLATFORM, YOU'VE GOT THE OPPORTUNITY, YOU'VE GOT THE INFRASTRUCTURE. WHAT THE GRANT AWARD THEN PROVIDES IS THE ADDITIONAL FUNDS COMING IN TO REALLY HELP FOR THAT PARTICULAR PROGRAM THEN TO TAKE ON SOME OF THOSE COSTS. SO IT BECOMES A BIT MORE OF A FEE-FOR-SERVICE MODEL. IN ORDER TO OFFER THAT SERVICE, YOU NEED THAT INFRASTRUCTURE, YOU NEED THOSE TEAMS, YOU NEED TO DEVELOP THOSE MATERIALS, ALL THOSE PIECES. THE AWARD GIVES YOU, THEN, THE OPPORTUNITY TO DEPLOY THAT IN A SPECIFIC USE CASE. SO I THINK, AGAIN, THERE'S AN OPPORTUNITY THERE, AND THAT'S WHAT'S HAPPENING.

I THINK WE TEND -- TO THE EXTENT WE'RE SEEING THAT THAT'S WORKING IS, AGAIN, IN SOME OF THE DEI SCORES AND SOME OF THE SCORES WE ARE SEEING ON THE CLINICAL GRANTS. THEY'RE REVIEWING THOSE PROGRAMS AS BEING AT THE APPLICATION STAGE VERY EFFECTIVE. I THINK THAT'S, AGAIN, THE MODEL THAT WE ARE SORT OF LOOKING AT TO SORT OF EXPAND OUT FURTHER

133 HENNA COURT, SANDPOINT, IDAHO 83864
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THROUGH THIS PROGRAM.

DR. PADILLA: I WOULD SUGGEST THAT THE APPLICANTS FOR THE CENTERS OF EXCELLENCE NEED TO HAVE ACCESS TO WHAT IS -- WHAT PROGRAMS HAS ALPHAS CREATED, WHAT PROGRAMS HAVE THE ACTUAL GRANT AWARDEES CREATED, AND TRYING TO MELD AND MOVE INTO HOW TO AUGMENT THAT, HOW TO ENHANCE THAT, HOW TO IMPROVE THAT SO THAT THE FUNDS ARE BEING USED ALL AROUND FOR GOOD PURPOSE BASICALLY. JUST A SUGGESTION.

CHAIRPERSON BONNEVILLE: THAT'S GREAT, ADRIANA.

GEOFF, JUST FOR OUR OWN EXERCISE INTERNALLY, I THINK IT'S IMPORTANT TO BE ABLE TO SHOW THE DIFFERENT OUTREACH EFFORTS, WHO'S RESPONSIBLE FOR THEM, AND WHAT THEY ENTAIL JUST SO THAT WE HAVE OUR OWN MATRIX SO THAT THERE AREN'T DUPLICATIVE EFFORTS AND THAT THEY'RE ALL WORKING IN CONCERT TOGETHER IN THE AREAS WHERE THEY CAN AND SHOULD. THANK YOU, ADRIANA, FOR THAT.

HARLAN.

DR. LEVINE: THANK YOU. AND I WANT TO ACKNOWLEDGE THAT I'M BRINGING UP THIS POINT PROBABLY LATE IN THE GAME, BUT IT WAS THE CONVERSATION THAT JUST TOOK PLACE ABOUT THINGS WORKING IN CONCERT AND

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UNDERSTANDING THE ECONOMICS. A LOT OF TIMES THE TESTS THAT ARE DONE TO IDENTIFY PEOPLE WHO WOULD BE GOOD CANDIDATES ARE GENOMIC TESTING. AND IN A LOT OF THESE MANAGED CARE SETTINGS THERE'S A LOT OF PRESSURE ON CLINICS, MEDICAL GROUPS, NETWORKS NOT TO BE PERFORMING THESE TESTS.

SO I THINK IT'S IMPORTANT AS WE ARE SELECTING FINALISTS OR THINKING ABOUT CRITERIA, WE REALLY WANT TO UNDERSTAND THE COMMITMENT TO DO THE PREWORK, TO IDENTIFY THESE HIGH RISK PATIENTS, TO MAKE SURE THAT THEY'RE ACTING AS AN INTEGRATED BODY. MEANING THERE'S NOT A SUBSET THAT'S REALLY EXCITED ABOUT THIS AND THEN THERE'S GOING TO BE ANOTHER PART OF THE CLINIC THAT'S LIKE, WHOA, THAT'S NOT HOW WE PRACTICE MEDICINE.

SO I JUST FEEL LIKE WE NEED TO TAKE THAT INTO ACCOUNT BECAUSE I'M HERE AT A HEALTH CONFERENCE IN LAS VEGAS. AND I'M INTERVIEWING -- DOING A PANEL WITH TWO PEOPLE TALKING ABOUT DISPARITIES IN HEALTHCARE AND BARRIERS TO HEALTHCARE. A LOT OF IT IS EXACTLY THE ISSUE THAT I'M RAISING, WHICH IS THERE'S SORT OF THESE INHERENT PRESSURES NOT TO DO SOME OF THE LATEST AND GREATEST.

ANYWAY, I WON'T SAY IT A THIRD TIME. I KNOW I WAS A LITTLE REPETITIVE, BUT I WANT TO MAKE

SURE THAT I'M NOT GENERALIZING TO EVERY GROUP, BUT I THINK IT'S IMPORTANT THAT WE PICK OUT AND IDENTIFY THIS ISSUE.

DR. LOMAX: DO YOU HAVE A SUGGESTION IN TERMS -- THERE ARE THINGS WE COULD LOOK FOR IN TERMS OF COMMITMENT LETTERS OR -- IT SOUNDS LIKE IT'S SOME SORT OF INSTITUTIONAL BUY-IN THAT WE MIGHT WANT TO INCLUDE AS PART OF AN APPLICATION. IS THERE THINGS LIKE THAT YOU'D RECOMMEND?

DR. LEVINE: WELL, I THINK WE COULD ASK FOR WHAT GUIDELINES DO THEY FOLLOW? DO THEY HAVE UTILIZATION MANAGEMENT PROCESS? WHO MAKES THOSE DECISIONS? WHAT'S THEIR TRACK RECORD IN ORDERING? THERE'S SOME SPECIFIC CANCERS LIKE NON-SMALL CELL LUNG CANCER WHERE THE EVIDENCE HAS BEEN CRYSTAL CLEAR FOR YEARS THAT GENOMICS STUDIES SHOULD BE DONE. WE COULD ASK THEM TO PRESENT DATA ON WHAT THEIR PERFORMANCE IS IN THOSE AREAS.

I DON'T REALLY HAVE AN ANSWER TO YOUR QUESTION. BUT JUST OFF THE TOP OF MY HEAD, THOSE ARE SOME THINGS. WHAT I WOULD SUGGEST IS TO TALK TO SOME LEADING CLINICIANS WHO ARE ALREADY IN THE ALPHA CLINICS OR INTERESTED IN THIS. I CAN IDENTIFY PEOPLE AT CITY OF HOPE WHO ARE THOUGHTFUL ABOUT THIS AND ASK THEM WHAT WOULD THEY LOOK FOR IN A GROUP TO

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MAKE SURE THAT THE GROUP WAS DEMONSTRATING A CAPABILITY TO IDENTIFY THESE PATIENTS FOR THE CLINICAL TRIALS THAT WE ARE TALKING ABOUT.

DR. GOLDSTEIN: I'M SORRY. HARLAN, CAN YOU ELABORATE A LITTLE BIT ON WHAT YOU SEE AS THE GENOMIC PROCESS THAT WOULD GO INTO THIS PORTION OF THE COMMUNITY CARE EXCELLENCE?

DR. LEVINE: I'M NOT SURE I UNDERSTOOD YOUR QUESTION. LET ME TAKE A SHOT AT IT AND YOU TELL ME --

DR. GOLDSTEIN: YOU MENTIONED THAT GENOMICS WAS ONE POSSIBLE SEGMENT, FOR EXAMPLE, FOR SCREENING AND IDENTIFYING PATIENTS. COULD YOU GO JUST INTO A LITTLE BIT MORE DETAIL ABOUT HOW THAT WOULD PLAY A ROLE IN PATIENT IDENTIFICATION? WOULD IT GO TOWARDS SORTING PATIENTS TO POSSIBLE DIFFERENT THERAPIES OR WHAT --

DR. LEVINE: YEAH. IF YOU HAVE -- AGAIN, PLEASE REMEMBER I'M NOT AN ONCOLOGIST. BUT IF YOU HAVE LYMPHOMA, IF YOU DON'T DO CERTAIN GENETIC TESTING, YOU'RE GOING TO USE TRADITIONAL CHEMOTHERAPY AS OPPOSED TO SOME OF THE CELL-BASED THERAPIES OR THE MORE ADVANCED TREATMENTS. SO YOU HAVE TO IDENTIFY THE SUBTYPES OF SOME OF THESE CONDITIONS TO MAKE SURE THAT THEY QUALIFY.

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I WOULD IMAGINE AS WE MOVE INTO THESE NEW THERAPIES FOR SOLID TUMORS, THE PROBLEM IS GOING TO BE MAGNIFIED BECAUSE SOME OF THE LIQUID TUMORS THAT WE ADVANCED THE FIELD ON ARE ALREADY AT ACADEMIC CENTERS. BUT IN SOLID TUMOR, THE VAST MAJORITY OF THEM, SIGNIFICANT MAJORITY OF THEM ARE IN THE COMMUNITY. WE JUST WANT TO MAKE SURE THAT WE'RE IDENTIFYING THE SUBTYPES THAT WOULD BE GOOD CANDIDATES FOR ADVANCED RESEARCH TRIALS AS OPPOSED TO MAYBE BEING BETTER CANDIDATES FOR STANDARD OF CARE.

DR. GOLDSTEIN: I SEE. IT SOUNDS LIKE -- I'M GOING TO PUT WORDS IN YOUR MOUTH, BUT PLEASE REJECT IT IF IT'S WRONG. YOU COULD IMAGINE, FOR EXAMPLE, SORT OF A PAN CANCER APPROACH IN IDENTIFYING AND SORTING PATIENTS BASED ON THAT.

DR. LEVINE: SO I'M HAPPY TO HAVE WORDS IN MY MOUTH BECAUSE I'M NOT AN EXPERT IN THIS AT ALL. WHAT I WOULD SUGGEST IS THAT WE DO HAVE AN EXPERT IDENTIFY THE UPSTREAM FUNNEL AND WHAT WOULD HAVE TO BE IN PLACE TO MAKE SURE THAT THESE PATIENTS ARE ACTUALLY GETTING IDENTIFIED. I DON'T THINK THEY JUST MAGICALLY POP OUT AND SELF-IDENTIFY AS BEING APPROPRIATE FOR A CIRM-RELATED STUDY.

I'M NOT ENCYCLOPEDIC IN KNOWLEDGE, BUT I

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WAS JUST TRYING TO PREPARE FOR THIS PANEL. I HAVE A THOUSAND PATIENTS WITH NON-SMALL CELL LUNG CANCER. FOUR HUNDRED SEVENTY-SEVEN TODAY DO NOT GET GENOMIC TESTING THAT THEY SHOULD GET, AND ANOTHER 147 GET THE GENOMIC TESTING, BUT THEY DON'T GET THE RIGHT THERAPY. SO THAT'S LIKE MORE THAN HALF THE PEOPLE.

SO THE QUESTION IS THINGS ARE MOVING SO FAST, THESE TRIALS ARE GOING TO BE REALLY SMALL TRIALS. HOW DO YOU FIND THAT NEEDLE IN A HAYSTACK? I THINK YOU HAVE TO MAKE SURE YOU'RE CASTING A WIDE ENOUGH NET.

DR. GOLDSTEIN: THANK YOU.

DR. LEVITT: LET JUST ME JUST SAY, HARLAN AND TED, THAT AT ACADEMIC MEDICAL CENTERS, THEY EAT THE LOSS FOR NONAPPROVED GENETIC TESTING, GENETIC TESTING THAT'S DONE LIKE IN PEDIATRICS FOR EVERY CANCER, BUT SOME OF THEM ARE NOT REIMBURSABLE. SO THE HOSPITAL EATS THE LOSS. AND THAT'S TRUE ACROSS MANY DIFFERENT DISEASES THAT IS GOING TO BE POTENTIAL TARGETS FOR THERAPIES IN THE ALPHA CLINICS. SO THE NUMBERS YOU QUOTED ARE EXACTLY RIGHT. AND IF THIS IS -- IF THIS EFFORT IS REALLY FOCUSED ON ACCESSIBILITY, IT'S GOING TO INVOLVE DIAGNOSES THAT ARE NOT OCCURRING AT ACADEMIC MEDICAL CENTERS THAT HAVE SOME LEVEL OF FLEXIBILITY IN TERMS

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OF DOING THIS.

DR. GOLDSTEIN: WE ARE TRYING TO FIND THE MISSING -- THE PATIENTS THAT WE MISS.

DR. LEVITT: YES. AND A LOT OF THEM ARE GONE TO BE IN COMMUNITY CLINICS AND OTHER HEALTHCARE SETTINGS THAT ARE GOING TO BE MISSED OR THEY'LL GET -- THEY WON'T HAVE ACCESS TO THIS KIND OF TREATMENT, TO THESE KINDS OF TREATMENTS. I'M NO EXPERT EITHER, BUT I CAN JUST TELL YOU THAT THERE'S A LOT OF DEFICIT BEING EATEN BECAUSE OF LACK OF -- FOR REASONS THAT STILL ESCAPE ME. I'M NOT A PHYSICIAN. I DON'T QUITE UNDERSTAND THE STANCE THAT YOU'VE GOT SOMETHING ABSOLUTELY IS CRITICALLY IMPORTANT FOR TREATMENT DESIGN AND SAVES A LOT OF MONEY, AND ECONOMISTS WILL SAY LIFE EXPECTANCY CHANGES DRAMATICALLY. SO THAT'S A REAL POSITIVE, RIGHT, IN TERMS OF ECONOMICS, BUT THEY'RE NOT APPROVED FOR REIMBURSEMENT. THAT'S ANOTHER CONVERSATION.

DR. LEVINE: YEAH. I WAS GOING TO SAY I CAN ANSWER THAT, BUT IT'S ANOTHER CONVERSATION. IT MIGHT BE INTERESTING TO HEAR MARIA'S THOUGHTS ON THIS, DR. MILLAN, BECAUSE SHE'S A PHYSICIAN CLOSER TO IT THAN I AM. SO SHE MIGHT HAVE A DIFFERENT POINT OF VIEW ON THIS OR BE ABLE TO VALIDATE IT.

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DR. MILLAN: THANK YOU SO MUCH. I THINK THIS IS A GREAT CONVERSATION. AND I THINK IT'S THE VERY BASIS FOR REALLY THE HUGE OPPORTUNITY FOR THE COMMUNITY CARE CENTERS OF EXCELLENCE BECAUSE ALL THIS CAN'T HAPPEN UNLESS THERE'S A SYSTEM IN KIND OF A COORDINATED WAY THAT THIS IS LINKED BETWEEN THE CANCER CENTERS AND THE ACADEMIC SETTING TO THE COMMUNITIES WHERE, AS YOU SAY, NOT ONLY IS THE DIAGNOSIS, THERE IS AN OPPORTUNITY FOR THE DIAGNOSTIC COMPONENT OF THIS, BUT ALSO IN THE REFERRAL WHERE THERE'S A HUGE FALL-OFF OF POTENTIAL PATIENTS WHO COULD MAKE IT INTO THESE TREATMENTS AND TRIALS.

SO I THINK WHAT GEOFF PRESENTED TODAY CREATES THE FORMAT FOR THIS TO HAPPEN. THESE CENTERS ARE NOT -- THERE MAY BE SOME CENTERS THAT ARE MORE ADVANCED THAN OTHERS IN THEIR COLLABORATION WITH SOME OF THE ACADEMIC CENTERS AND EVEN THE ALPHA CLINICS, BUT SOME OF THEM MAY NOT -- MAY BE COMING IN AT A LESS DEVELOPED POINT. AND THOSE ARE THE VERY ONES THAT WE ALSO WANT TO GET TO THE POINT THAT THEY ARE ABLE TO ACCEPT THAT PARTNERSHIP AND BE ABLE TO TAKE ON THE INTAKE KIND OF -- I DON'T WANT TO REDUCE THE IMPORTANCE OF THAT -- BUT KIND OF THE OUTREACH AND THE INTAKE AND THE REFERRAL ASPECTS OF

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WHAT'S NEEDED FOR THIS MACHINERY TO REALLY WORK AS WELL AS ALSO BE INVOLVED IN THE CARE, EITHER THE SCREENING, THE FOLLOW-UP, OR OTHER PARTS AND REALLY BE PART OF THE WHOLE CARE TEAM.

SO I DO BELIEVE THAT WHAT ALL OF THE MEMBERS HAVE SPOKEN OF TODAY WE WOULD BE LOOKING FOR IN THE APPLICANTS TO SEE DO THEY HAVE THE WILL, DO THEY HAVE THE STARTING POINT TO BE ABLE TO DO THIS. AND TO THE QUESTION OF HOW DOES THIS ALL COME TOGETHER, AS WITH OUR OTHER PROGRAMS, INCLUDING THE ALPHA CLINICS AND THE MANUFACTURING NETWORK AND THE SHARED LABS, THERE WILL BE A STEERING COMMITTEE WHERE THERE'S CIRM REPRESENTATION. THERE'S INTERACTIONS WITH EXTERNAL KEY OPINION LEADERS, BUT ALSO CIRM LEADERSHIP AND CIRM BOARD MEMBERS IN VARIOUS WAYS, AND THOSE ARE THE HUBS. THE STEERING COMMITTEES ARE KIND OF THE HUBS OF THIS KNOWLEDGE EXCHANGE SO THAT SOME OF THESE VERY CONVERSATIONS CAN BE BROUGHT TO A MORE MATURE STAGE IN IMPLEMENTATION.

SO I GUESS -- SO TO ANSWER THE FIRST QUESTION, I DO BELIEVE THAT WHAT EVERYBODY IS BRINGING UP IS VERY MUCH AN IMPORTANT CONSIDERATION. AND, IN FACT, I THINK THAT SOME OF HOW THIS HAS BEEN DESIGNED IS TO ADDRESS THAT. CIRM HAS IDENTIFIED

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THAT PERHAPS EARLY SCREENING AND DIAGNOSIS IS GOING TO BE CRITICAL, BUT HOW DO YOU DO THAT IN A FEASIBLE WAY THAT PARTNERS WITH KIND OF THE THERAPEUTICS DEVELOPMENT WHERE YOU NEED TO HAVE THE INFRASTRUCTURE AND THE TEAMS, AS GEOFF HAD PRESENTED, TO DO THAT.

SO THOSE ARE -- THROUGH THE COMMUNITY CARE CENTERS OF EXCELLENCE LISTENING SESSION, WE ACTUALLY DID GET TANGIBLE EXAMPLES OF HOW THESE KIND OF DEMONSTRATION CASES OF HOW THIS COULD WORK, IN FACT, FOR CAR-T THERAPIES FOR TRANSPLANTS. AND SO I THINK WHERE IT HAS WORKED IN SMALL SCALE, THE IDEA OF THIS CONCEPT IS TO HAVE AN OPPORTUNITY TO SCALE UP AND TO BRING SOME OF THE LESS DEVELOPED CENTERS OUT IN THE COMMUNITY TO A LEVEL THEY CAN PARTICIPATE.

CHAIRPERSON BONNEVILLE: THANK YOU. ADRIENNE.

MS. SHAPIRO: THIS IS SOMETHING THAT WE REALLY HAVE BEEN DISCUSSING IN OUR COMMUNITY AND IN OUR TALKS, THAT WE HAVE THE LACK OF OPPORTUNITY BY OUR CARE PROVIDERS TO EVEN SUGGEST THAT WE HAVE TESTING. AND THEN THE OTHER IS THE COST OF TESTING. SO I THINK OUR COMMUNITY CARE CENTERS CAN HELP WITH THAT AS WELL AS PART OF OUR EDUCATION WHICH WE CAN DO THE PATIENTS TO REQUEST IT.

BUT I ALSO WOULD LIKE TO KNOW IF THERE ARE PEOPLE WORKING ON OR HOW DOES IT WORK TO REDUCE THE COST OF THAT TESTING. ARE THERE ADVANCES? ARE THERE GROUPS THAT ARE WORKING ON HOW TO MAKE IT, OR IS THE TESTING JUST SPECIFIC SO THAT -- ARE WE REALLY LOOKING AT THAT? BECAUSE IDEALLY IT WOULD BE JUST SOMETHING THAT'S PART OF HEALTHCARE. YOU WOULD BE ABLE TO BE TESTED LIKE YOU DO WERE YOU VACCINATED OR WERE YOU THIS, THAT, OR THE OTHER, WHAT DO YOU HAVE GOING ON TO HAVE THIS GENETIC TESTING DONE.

SO I GUESS THAT'S A QUESTION. IT MAY NOT BE FOR HERE, BUT IF WE'RE REALLY TALKING ABOUT ACCESS AND EVERYTHING AND EQUALITY, HAVING THAT BE PART OF IT. SO I DON'T KNOW IF ANYBODY IS WORKING ON IT OR THERE ARE THOUGHTS ABOUT IT OR WHAT, BUT ULTIMATELY THAT WOULD BE PART OF THE GREAT EQUALIZER, RIGHT, HAVING EVERYBODY AVAILABLE WITHOUT MAYBE HAVING A PROVIDER THAT INSISTS THAT YOU'RE BEING TESTED FOR A CERTAIN REASON.

CHAIRPERSON BONNEVILLE: HARLAN, WERE YOU GOING --

DR. LEVINE: I JUST HAD A COMMENT. THERE'S A BIOMARKER BILL OUT THERE. THERE'S A BIOMARKER BILL OUT THERE GOING THROUGH THE SYSTEM RIGHT NOW WHICH WILL MAKE IT EASIER TO GET, BUT

THAT'S JUST A FIRST STEP. I THINK IT'S A WHOLE EDUCATIONAL PROCESS, CULTURAL PROCESS TO GET THE WORD OUT TO THE VARIOUS GROUPS. I THINK THE PRICE OF THE TEST IS GOING DOWN ALSO. AND THEN THE NUMBER OF CASES THAT ARE GETTING DENIED ARE LESS WITH WHAT WE KNOW TODAY. BUT I THINK THE ISSUE HERE IS AS WE WANT TO DO MORE -- THERE WILL BE NEWER TESTS. THERE'S ALWAYS GOING TO BE THIS RESISTANCE NOT TO APPROVE THINGS UNTIL THERE'S ABSOLUTE, OVERWHELMING EVIDENCE, WHICH TAKES YEARS, AND WE DON'T LIVE IN AN ENVIRONMENT OF YEARS ANYMORE. THINGS MOVE MORE RAPIDLY. SO THAT GETS TO THE POINT JIM WAS MAKING EARLIER. BUT IT'S GOING TO GET A LITTLE BETTER, BUT IT'S ALWAYS GOING TO BE BARRIERS THAT WILL DISPROPORTIONATELY AFFECT UNDERREPRESENTED COMMUNITIES. I THINK YOU'RE RIGHT. WE NEED TO PUT MORE EFFORT INTO THAT.

CHAIRPERSON BONNEVILLE: THANK YOU. SO I'M GOING TO ASK THAT WE HAVE A MOTION TO RECOMMEND THIS TO THE SCIENCE SUBCOMMITTEE FOR CONSIDERATION AND RECOMMENDATION TO THE FULL BOARD.

DR. LEVITT: SO MOVED.

CHAIRPERSON BONNEVILLE: THANKS, PAT. DAN DO YOU WANT TO BE SECOND?

MR. BERNAL: OH, YES. SORRY. I WAS

MUTED.

CHAIRPERSON BONNEVILLE: IS THERE ANY OTHER CONVERSATION THAT THE GROUP WANTS TO HAVE?

DR. GOLDSTEIN: I JUST WANT TO MAKE ONE COMMENT, THAT IN REFINEMENT OF THE ACTUAL CONTRACT, ANY TIME YOU HAVE DIRECT RESPONSIBILITY, YOU CAN -- OPTIMISTICALLY YOU HAVE OVERLAP. PESSIMISTICALLY WHAT YOU HAVE IS FINGER POINTING. IT'S YOUR RESPONSIBILITY. NO, IT'S YOUR RESPONSIBILITY TO GET IT DONE. AND I JUST KNOW THAT THE DEVILS IN THE DETAILS ON ANY ACTUAL CONTRACTING, ESPECIALLY IF IT IS IN SUPPORT OF EXISTING PROGRAMS, EVERYBODY CAN ALWAYS FIND A WAY TO TAKE MONEY IN A BUDGET THAT'S ALREADY ALLOCATED FOR COMMUNITY OUTREACH AND FIND OTHER USES FOR IT. SO JUST SPECIFICS THAT WILL NEED TO BE GARNERED WHEN YOU ACTUALLY HAVE THE SIX OR SO INDIVIDUAL DETAILED RELATIONSHIPS.

DR. LOMAX: YEAH. JUST A BRIEF COMMENT THERE. THAT'S WHY WE ACTUALLY PULLED, FOR EXAMPLE, THAT COMMUNITY ENGAGEMENT PIECE. THERE WAS A VERY STRONG RECOMMENDATION THAT THERE'S A SUBSTANTIAL COMMUNITY ENGAGEMENT PIECE. SO BY PULLING THAT OUT AS A SEPARATE LINE ITEM, WE FELT THAT WAS AN ADMINISTRATIVE MECHANISM TO ENSURE THAT THOSE FUNDS FLOWED TO WHERE THEIR COMMITMENT LIES.

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DR. GOLDSTEIN: GREAT. THANK YOU.

CHAIRPERSON BONNEVILLE: DO WE HAVE ANY PUBLIC COMMENT? I DON'T THINK WE HAVE ANY. THANK YOU. SO I'M NOT SURE WHO'S CALLING FOR THE VOTE. IS IT SCOTT, DOUG, OR -- I THINK MAYBE DOUG. SCOTT.

MR. TOCHER: SORRY. ONE OF THOSE DAYS. THIS WILL BE A ROLL CALL ON THE MOTION TO RECOMMEND APPROVAL TO THE SCIENCE SUBCOMMITTEE WITH FURTHER RECOMMENDATION TO THE FULL BOARD.

KIM BARRETT. DAN BERNAL.

MR. BERNAL: AYE.

MR. TOCHER: MARIA BONNEVILLE.

CHAIRPERSON BONNEVILLE: YES.

MR. TOCHER: ANN BOYNTON.

MS. BOYNTON: AYE.

MR. TOCHER: JAMES DEBENEDETTI.

MR. DEBENEDETTI: AYE.

MR. TOCHER: DANA DORNSIFE. TED GOLDSTEIN.

DR. GOLDSTEIN: AYE.

MR. TOCHER: DAVID HIGGINS.

DR. HIGGINS: YES.

MR. TOCHER: VITO IMBASCIANI. VITO. HARLAN LEVINE.

DR. LEVINE: AYE.

MR. TOCHER: PAT LEVITT.

DR. LEVITT: AYE.

MR. TOCHER: ADRIANA PADILLA.

DR. PADILLA: YES.

MR. TOCHER: DAVID SERRANO-SEWELL.

MR. SERRANO-SEWELL: AYE.

MR. TOCHER: MAHESWARI SENTHIL.

DR. SENTHIL: YES.

MR. TOCHER: ADRIENNE SHAPIRO.

MS. SHAPIRO: AYE.

MR. TOCHER: AND, VITO, ONE LAST TRY. I THINK YOU MAY HAVE BEEN ON MUTE. ALL RIGHT.

IN ANY EVENT, MARIA, THE MOTION CARRIES.

CHAIRPERSON BONNEVILLE: THANK YOU SO MUCH, SCOTT. I WANT TO THANK EVERYONE FOR PARTICIPATING. SO YOUR COMMENTS WERE INCREDIBLY HELPFUL TO THE TEAM AND TO ME, AND YOUR WORK ON THE COMMITTEE IS REALLY VALUABLE. SO THANK YOU.

AND ANOTHER SHOUT-OUT TO GEOFF AND EMILY FOR ALL YOUR HARD WORK ON THIS. AND ALL THE OTHER CIRM TEAM MEMBERS THAT HAVE REALLY BROUGHT THIS TO FRUITION. THANK YOU AGAIN. BYE-BYE.

(THE MEETING WAS THEN CONCLUDED AT 3:07 P.M.)

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REPORTER'S CERTIFICATE

I, BETH C. DRAIN, A CERTIFIED SHORTHAND REPORTER IN AND FOR THE STATE OF CALIFORNIA, HEREBY CERTIFY THAT THE FOREGOING TRANSCRIPT OF THE VIRTUAL PROCEEDINGS BEFORE THE ACCESSIBILITY AND AFFORDABILITY WORKING GROUP OF THE INDEPENDENT CITIZEN'S OVERSIGHT COMMITTEE OF THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE IN THE MATTER OF ITS REGULAR MEETING HELD ON OCTOBER 9, 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
133 HENNA COURT
SANDPOINT, IDAHO
(208) 920-3543