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: AUGUST 7, 2024
9 A.M.

REPORTER: BETH C. DRAIN, CA CSR
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I N D E X

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AUGUST 7, 2024; 9 A.M.

CHAIRWOMAN BONNEVILLE: GREAT. THANK YOU, EVERYONE FOR BEING HERE. I WANT TO WELCOME YOU ALL TO THIS MEETING OF THE ACCESS AND AFFORDABILITY WORKING GROUP. MY COLLEAGUES, GEOFF AND ROSA, WILL BE PRESENTING TODAY. AND I JUST WANTED TO REMIND EVERYONE THAT CIRM IS UNDERGOING A STRATEGIC ALLOCATION FRAMEWORK OR PRIORITIZATION OF HOW WE WILL BE ALLOCATING MONEY OVER THE COURSE OF THE NEXT SEVERAL YEARS AND WHAT WE'RE LOOKING FOR.

PART OF THIS GROUP'S TASK IS TO UNDERSTAND HOW WE CAN BE HELPFUL TO PROVIDE SUGGESTIONS ON HOW TO GET SOME OF THESE PRODUCTS THROUGH AND ALSO HOW TO PROVIDE A FRAMEWORK FOR ACCESS AND AFFORDABILITY AT THE SAME TIME.

SO, GEOFF, IF YOU WANT TO START, THANK YOU VERY MUCH.

DR. LOMAX: YES. LET ME START WITH THE ROLL.

MARIA BONNEVILLE.

CHAIRWOMAN BONNEVILLE: PRESENT.

DR. LOMAX: KIM BARRETT.

DR. BARRETT: PRESENT.

DR. LOMAX: DAN BERNAL. DAVID HIGGINS.

VITO IMBASCIANI.

CHAIRMAN IMBASCIANI: PRESENT.

DR. LOMAX: PAT LEVITT.

DR. LEVITT: PRESENT.

DR. LOMAX: ADRIANA PADILLA.

DR. PADILLA: HERE.

DR. LOMAX: ANN BOYNTON.

DR. BOYNTON: HERE.

DR. LOMAX: JAMES DEBENEDETTI.

MR. DEBENEDETTI: HERE.

DR. LOMAX: DANA DORNSIFE. TED GOLDSTEIN. DARIUS LAKDAWALLA. HARLAN LEVINE.

DR. LEVINE: PRESENT.

DR. LOMAX: AMMAR QADAN.

DR. QADAN: PRESENT.

DR. LOMAX: MAHESWARI SENTHIL. ADRIENNE SHAPIRO.

MS. SHAPIRO: PRESENT.

DR. LOMAX: CHRISTINA HARTMAN.

DR. HARTMAN: PRESENT.

CHAIRWOMAN BONNEVILLE: THANK YOU. GEOFF, IF YOU'D LIKE TO START WITH THE PRESENTATION, THAT WOULD BE WONDERFUL.

DR. LOMAX: IT'S NOT MOVING. CAN I GET THE NEXT SLIDE PLEASE. THANK YOU.

WE HAVE BROKEN THE AGENDA INTO TWO PARTS. FIRST WE'D LIKE TO PROVIDE SOME SHORT UPDATES ON PROGRAM ACTIVITIES FOLLOWED BY AN IN-DEPTH DISCUSSION OF OUR STRATEGIC ALLOCATION FRAMEWORK WHERE WE INTEND TO DEDICATE THE MAJORITY OF THE MEETING TIME. SO LET ME JUST BEGIN WITH SOME UPDATES. NEXT SLIDE, PLEASE.

FIRST OF ALL, ON THE PATIENT SUPPORT PROGRAM, WE'D LIKE TO ACKNOWLEDGE OUR NEWEST TEAM MEMBER, BLANCA BATLLE. BLANCA BRINGS OVER 20 YEARS OF EXPERIENCE IN THE BIOTECH INDUSTRY WITH EXPERTISE SPANNING PROGRAM MANAGEMENT, LAUNCH READINESS, TRAINING, AND ACCESS REIMBURSEMENT. HER AREAS OF FOCUS LIE IN THE ACCESS AND REIMBURSEMENT DOMAIN WHERE SHE HAS EXCELLED IN LEADING PATIENT ASSISTANCE PROGRAMS, FACILITATING PATIENT ONBOARDING, AND PROVIDING FIELD SUPPORT. BLANCA IS LEADING UP THE EFFORT TO DESIGN THE PATIENT SUPPORT PROGRAM AROUND THE NEEDS OF OUR CLINICAL PARTNERS. AND WE REALLY APPRECIATE HER EFFORT.

AS PART OF THAT PROCESS, WE HAD A KICKOFF MEETING. WE HAD THAT BEFORE THE MAY MEETING, BUT WE SKIPPED THIS UPDATE. SO WE WERE GOING TO UPDATE YOU IN MAY ON THE KICKOFF. AND THEN WE'VE BEEN MEETING WEEKLY WITH THE AWARDEE EVERSANA WITH THE AIM OF

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PILOTING THE SUPPORT PROGRAM IN THE FINAL QUARTER OF THIS YEAR AND THE FIRST QUARTER OF '25. NEXT SLIDE PLEASE.

THE COMMUNITY CARE CENTERS OF EXCELLENCE PROGRAM, I'D LIKE TO ACKNOWLEDGE EMILY CROTTI FOR HER EFFORTS. SHE'S REALLY LED THE ORGANIZING AND MANAGEMENT OF THE APPLICATION OF THE RFA AND APPLICATION PROCESS.

WE'VE SPONSORED TWO WEBINARS. THE FIRST WEBINAR PROVIDED AN OVERVIEW OF THE PROGRAM AIMS AND OBJECTIVES, AND THE SECOND FOCUSED ON THE MECHANICS OF THE APPLICATION AND BUDGETING PROCESS.

THE COMMUNITY CARE CENTERS OF EXCELLENCE PROGRAM IS ATTRACTING A NUMBER OF APPLICANTS THAT ARE NEW TO THE CIRM PROCESS. SO THESE WEBINARS PROVIDED AN OPPORTUNITY TO ADDRESS THEIR QUESTIONS.

AND WITH THAT, I'D LIKE TO ALSO ACKNOWLEDGE THE GRANTS MANAGEMENT REVIEW TEAMS AS THEIR EXPERTISE HAS BEEN ESSENTIAL FOR GUIDING APPLICANTS AND RECRUITING QUALIFIED REVIEWERS.

NEXT SLIDE PLEASE.

IN JUNE THE NIH ISSUED A REQUEST FOR INFORMATION ON A PROPOSED POLICY REQUIRING ACCESS PLANS FOR CLINICAL RESEARCH PROGRAMS WITHIN ITS INTRAMURAL RESEARCH PROGRAM, IT'S MAIN FUNDING

PORTFOLIO. THE DEADLINE TO COMMENT ON THIS REQUEST FOR INFORMATION WAS IN JULY, WHICH WAS BETWEEN AAWG MEETINGS. SO WE CONVENED A SMALL GROUP OF ADVISORS TO PROVIDE FEEDBACK AND COMMENTS ON THE POLICY. THIS FEEDBACK HAS BEEN POSTED ON THE WEBSITE AS PART OF THE MEETING NOTICE.

TO SUMMARIZE, I THINK THE SPIRIT OF OUR COMMENTS, WE SUGGESTED THE OVERALL APPROACH COULD BE MERITORIOUS, IN FACT IT'S CONSISTENT WITH SOME OF THE RECOMMENDATIONS WE'RE GOING TO CONSIDER TODAY, BUT NOTED THAT THE NIH EMPHASIZED MANY STRATEGIES THAT MAKE IT INCUMBENT ON THE INVESTIGATOR OR SPONSOR TO OFFER FLEXIBLE IP OR LICENSING AGREEMENT TERMS.

SO WE EMPHASIZED IN THE CONTEXT OF CELL AND GENE THERAPIES ONE MUST BE AWARE OF THE SUBSTANTIAL DEMAND SIDE OR MARKET BARRIERS THAT LIMIT AVAILABILITY AND SUSTAINABILITY OF CELL AND GENE THERAPY PRODUCTS. AND WE OFFERED SOME EXAMPLES OF ACTIONS NIH COULD TAKE TO ADDRESS THESE BARRIERS.

WE FELT IT WAS IMPORTANT TO COMMENT BECAUSE THE NIH EFFORT REPRESENTS A PROPOSAL FOR A FOUNDATIONAL NATIONAL POLICY FRAMEWORK TO PROMOTE ACCESS TO PRODUCTS STEMMING FROM CLINICAL RESEARCH. AND, AGAIN, THIS POLICY FRAMEWORK APPEARS CONSISTENT

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WITH OUR STRATEGIC ALLOCATION FRAMEWORK DISCUSSION.

SO THAT'S ALL I HAVE IN THE WAY OF UPDATES. I'LL PAUSE FOR A MOMENT TO SEE IF THERE'S ANY QUESTIONS OR COMMENTS. IF NOT, I CAN TURN IT OVER TO ROSA WHO INITIATE THE SECOND PART OF THE MEETING AGENDA TODAY.

CHAIRWOMAN BONNEVILLE: ANYONE HAVE ANY COMMENTS?

DR. LEVITT: I WAS GOING TO ASK -- THIS IS PAT. I WAS GOING TO ASK. THE CTSI PROGRAM HAS A MAJOR FOCUS ON COMMUNITY ENGAGEMENT, INCLUDING THE COMPONENTS OF AAWG. I'M WONDERING WHETHER THOSE INDIVIDUALS, THOSE PROGRAM FOLKS WHO OVERSEE THAT, HAVE THERE BEEN ANY CONVERSATIONS WITH THEM ABOUT WHAT THEY'RE LOOKING FOR? THERE'S RENEWABLES GOING IN ALL THE TIME. I WAS JUST AT A MEETING YESTERDAY FOR THE ONE HERE. AND I THINK WE SPENT MORE THAN HALF THE TIME TALKING ABOUT COMMUNITY ENGAGEMENT AND ACCESS, ETC. SO JUST WONDERING IF THE NIH ENGAGEMENT INCLUDED THE CTSI PROGRAMS WHICH THERE ARE A NUMBER OF THEM IN CALIFORNIA.

DR. LOMAX: SO IN THE REQUEST FOR INFORMATION THEY CERTAINLY AS A CATEGORY OF -- AS A STRATEGY THEY CALLED OUT COMMUNITY ENGAGEMENT AS A MAJOR ACTIVITY. I DON'T RECALL IF THEY CALLED OUT

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THE CTSI PROGRAMS SPECIFICALLY. BUT OBVIOUSLY I THINK IN OUR CASE TYPICALLY, BECAUSE THE ALPHA CLINICS HAVE REALLY INTEGRATED WITH THEIR CTSI PROGRAMS, THAT WOULD BE A MAJOR -- THAT RELATIONSHIP WOULD BE IMPORTANT TOWARDS THIS EFFORT.

BUT CERTAINLY THE ACTIVITIES THEMSELVES WERE, I THINK, ONE AMONG FIVE MAJOR ACTIVITIES THAT NIH RECOMMENDED AS PART OF THE ACCESS PLANNING.

DR. LEVITT: YEAH. SO IT MAY BE -- I MENTIONED CIRM YESTERDAY WHEN I WAS AT THAT MEETING HERE THAT INCLUDED -- THAT WAS THE USC/CHLA CTSI. TOM BUCHANAN WAS QUITE ENTHUSIASTIC ABOUT THINKING ABOUT HOW TO ENGAGE WITH YOU ALL TO SEE HOW THINGS CAN BE ALIGNED, WHICH WOULD LEVERAGE -- HAVE RESOURCES -- YOU HAVE RESOURCES, LEVERAGING THOSE WITHOUT -- I'M NOT TALKING ABOUT EXCHANGING FINANCE OR ANYTHING, BUT PLANNING SO THAT THEY'RE ALIGNED, WHICH MEANS THAT THE MORE WE GET DONE IN TERMS OF COMMUNITY ENGAGEMENT, WOULD BE SOMETHING TO HAVE A CONVERSATION ABOUT. IF YOU WANT AN INTRO. I THINK SOME OF YOU ON THE ZOOM KNOW TOM. I THINK UCLA HAS ONE, UCSF.

CHAIRWOMAN BONNEVILLE: YES.

DR. LEVITT: I THINK IT'S WORTH INVESTIGATING.

CHAIRWOMAN BONNEVILLE: I THINK PART OF WHAT GEOFF WAS ALLUDING TO IS THAT THE ALPHA CLINICS HAVE USED THEM AND INTEGRATED THEM INTO THEIR COMMUNITY ENGAGEMENT PLANS. BUT IT'S ABSOLUTELY WORTH IT TO REACH OUT TO THEM INDIVIDUALLY AS WELL. SO, GEOFF, THAT'S JUST SOMETHING WE SHOULD ADD TO THE PLANNING CALENDAR WHICH IS PACKED. SO, YES, ABSOLUTELY.

DR. LOMAX: AGREED. AND THAT IS DEFINITELY -- I'D SAY THERE'S ALREADY MOMENTUM IN THAT DIRECTION; BUT TO THE EXTENT WE CAN DOUBLE-DOWN ON THAT EFFORT, WE CAN DO THAT.

CHAIRWOMAN BONNEVILLE: KIM.

DR. BARRETT: TO ADD TO PAT'S HELPFUL COMMENT, I THINK A SIMILAR COMMENT CAN BE MADE ABOUT THE COMPREHENSIVE CANCER CENTERS THAT EXIST ACROSS THE LANDSCAPE IN CALIFORNIA. THEY ALSO HAVE MAJOR EFFORTS. AND I KNOW OUR CANCER CENTER AND OUR CTSC COLLABORATE AS WELL ON COMMUNITY OUTREACH. SO THERE'S AN OPPORTUNITY THERE AS WELL.

DR. LEVITT: YEAH. I MENTION THIS BECAUSE I'M GETTING THE FEELING THAT PEOPLE ARE SORT OF IN -- AND THE EFFORTS ARE EARNEST AND REALLY HIGH QUALITY, BUT I THINK THEY TEND TO BE -- ALL THIS IS BEING DONE IN LIKE SEPARATE LANES.

CHAIRWOMAN BONNEVILLE: I AGREE.

DR. LEVITT: SHARING INFORMATION ABOUT WHAT'S WORKING AND WHAT'S NOT WILL SAVE A LOT OF TIME AND EFFORT. AND THEN INCORPORATING THINGS THAT PEOPLE HAVE FOUND WORK WELL, PARTICULARLY IN COMMUNITIES WHERE IT'S BEEN EXTREMELY CHALLENGING TO MAKE INROADS IN TERMS OF EVEN TALKING ABOUT CLINICAL TRIALS AND PARTICIPATION AND ACCESS, I THINK, WOULD BE WORTH IT. MAYBE THE LANES CAN CROSS AT SOME POINT.

CHAIRWOMAN BONNEVILLE: I AGREE. I THINK WE CAN SAY THAT ABOUT A LOT OF THE THINGS THAT WE'RE TRYING TO DO. THERE ARE SO MANY EFFORTS BEING DONE COLLECTIVELY IN THE FIELD, AT INSTITUTIONS WE FUND, AND CONSOLIDATING OUR EFFORTS WOULD REALLY GO A LONG WAY. THANK YOU, PAT AND KIM. APPRECIATE THAT.

DR. LOMAX: MAYBE JUST TO ADD ONE MORE COMMENT ON THAT AS IT RELATES TO THE COMMUNITY CARE CENTERS OF EXCELLENCE. SO, PAT, YOUR MESSAGE HAS BEEN RECEIVED IN TERMS OF WE NEED TO REALLY INCREASE REFERRAL RATES. AND SO AS WE'VE BEEN MEETING WITH APPLICANTS, WE'VE REALLY BEEN SOCIALIZING THIS IDEA THAT THE CANCER CENTERS WILL BE AN IMPORTANT ELEMENT TO THOSE PATIENT REFERRALS, ACHIEVING THAT GOAL OF IMPROVING REFERRAL RATES.

SO, AGAIN, WE'VE GOT THE MESSAGE. IT'S DEFINITELY PART OF THE MESSAGE IN TERMS -- WHEN WE STRATEGIZE WITH POTENTIAL APPLICANTS ABOUT WAYS IN WHICH THEY CAN BE RESPONSIVE TO THE RFA. AND I ALSO WANT TO ACKNOWLEDGE THE ALPHA CLINICS, THAT THEY'VE OVER TIME -- REALLY THOSE RELATIONSHIPS WITH THE CANCER CENTERS HAVE MATURED TO THE POINT WHERE I THINK THEY'RE FAR MORE COLLABORATIVE THAN THEY WERE WHEN THE PROGRAM FIRST STARTED. SO I THINK THAT THERE IS CROSSOVER OCCURRING. TO THE EXTENT WE'VE OPTIMIZED THAT CROSSOVER, I DON'T KNOW, BUT IT'S DEFINITELY PART OF THE OVERALL STRATEGY WE'VE BEEN TAKING IN TERMS OF TRYING TO BE RESPONSIVE TO THAT REFERRAL GAP YOU'VE ALLUDED TO.

DR. LEVITT: THAT'S GREAT. TO GIVE FULL CREDIT FOR CHRIS YOUNG, WHO WAS A COMPASS SCHOLAR, BY THE WAY. HE'S AN UNDERGRADUATE WHO WAS THE INITIATOR OF THE CONVERSATIONS THAT HE AND I HAD AND THEN BROUGHT IN GEOFF. HE DESERVES -- THE COMPASS SCHOLAR PROGRAM DESERVES A TON OF CREDIT FOR HAVING PEOPLE, STUDENTS AS TALENTED AS CHRIS TO EVEN THINK ABOUT THIS. SO HE DESERVES A TON OF CREDIT.

CHAIRWOMAN BONNEVILLE: THANK YOU, PAT. KIM.

DR. BARRETT: NOT TO ADD YET ANOTHER

POTENTIAL PARTNER INTO THE MIX, BUT WE'VE BEEN HAVING LOTS OF CONVERSATIONS WITH THE VA AROUND ACCESS FOR CLINICAL TRIALS. AND OBVIOUSLY THEY SERVE AN INCREDIBLY DIVERSE POPULATION ACROSS THE STATE AND REALLY IN ALL SORTS OF NOOKS AND CRANNIES, PARTICULARLY OUR NORTHERN CALIFORNIA VA, WHICH HAS AN INCREDIBLY LARGE CATCHMENT AREA, BUT THEY ARE VERY INTERESTED IN PARTNERING AT LEAST WITH US AND PROBABLY AS A PARTNER WITH THESE SORTS OF EFFORTS. MAYBE VITO WOULD WANT TO COMMENT ON THAT AS WELL.

CHAIRMAN IMBASCIANI: THANKS, KIM. I KNOW THE MEDICAL DIRECTOR AT THE SACRAMENTO-BASED CENTER AT MATHER. AND I KNOW THAT HE IS VERY, VERY EAGER TO EXPAND THE FOURTH MISSION. IT'S NOT JUST TRAINING AND TO BE AVAILABLE IN TIME OF NATIONAL CATASTROPHE, BUT TO TRAIN THE NEXT GENERATION OF HEALTHCARE WORKERS. AND THIS WOULD BE -- AND ACCESS WOULD BE PART OF HIS MISSION.

SO DAVID STOCKWELL, HE'S INCREDIBLY ENGAGED. I'M SURE YOU KNOW HIM PERSONALLY. IF I CAN PERSONALLY INTERVENE OR BE AN ADJUNCT TO YOUR EFFORTS, CONSIDER ME AVAILABLE TO YOU.

DR. BARRETT: THANK YOU.

CHAIRWOMAN BONNEVILLE: ANY OTHER COMMENTS BEFORE WE MOVE ON? OKAY. I THINK ROSA IS UP NEXT.

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THANK YOU, EVERYONE.

DR. CANET-AVILES: THANK YOU, MADAM CHAIR BONNEVILLE. LET ME JUST CHECK THAT THIS IS WORKING.

THE REPORTER: EXCUSE ME. THIS IS BETH. I'M HAVING A HARD TIME HEARING ROSA.

DR. CANET-AVILES: LET ME JUST MOVE THE COMPUTER. WE'RE ACHIEVING THE SITUATION HERE. JUST GIVE US A SECOND.

AS CHAIR BONNEVILLE WAS MENTIONING, WE HAVE BEEN UNDERGOING A STRATEGIC ALLOCATION FRAMEWORK. NEXT SLIDE. I'LL JUST KEEP TELLING YOU NEXT. AS WE ALREADY MENTIONED DURING OUR LAST ACCESS AND AFFORDABILITY WORKING GROUP MEETING BACK IN MAY, WE PRESENTED HOW WE ARE DEVELOPING THE GOALS AND THE RECOMMENDATIONS. AND JUST TO ENSURE AMPLE TIME FOR DISCUSSION, THE BACKGROUND THAT WE'VE PROVIDED SEVERAL TIMES TO THE BOARD AND ALSO TO THIS WORKING GROUP WILL NOT BE PRESENTED DURING TODAY'S MEETING. AND FOR THOSE INTERESTED, THESE SECTIONS WERE PREVIOUSLY PRESENTED AT LENGTH DURING THE JUNE 27TH ICOC MEETING. SO FEEL FREE TO REVIEW THOSE SLIDES ACCORDINGLY.

WE ARE GOING TO MOVE ON TO THE TIMELINE JUST AS A REFRESH. NEXT SLIDE. CAN YOU HEAR ME, BETH?

THE REPORTER: THAT'S BETTER.

DR. CANET-AVILES: SO AS WE SAW BACK IN -- AS WE PRESENTED BACK IN MAY, THE GOAL FOR DISCUSSIONS OF THIS GROUP IN THE CONTEXT OF THE ACCESS AND AFFORDABILITY GOAL WERE TO BRAINSTORM AROUND THE DIFFERENT TYPES OF QUESTIONS THAT COULD BE NECESSARY TO ANSWER THE MAIN QUESTION, WHICH IS TO ENSURE THAT EVERY CIRM-FUNDED PROJECT COMPLETING A LATE STAGE CLINICAL TRIAL HAS A STRATEGY THAT ENABLES ACCESS AND AFFORDABILITY BY ALL CALIFORNIA PATIENTS. AND THAT QUESTION WAS PRESENTED BACK IN MAY.

AND THE WORK THAT THIS WORKING GROUP, WITH GEOFF AND MARIA'S LEADERSHIP, HAS BEEN UNDERGOING IS TO EVALUATE THE TYPE OF QUESTIONS AND DATA THAT WE WOULD NEED TO MAKE RECOMMENDATIONS AT THE SEPTEMBER 13TH SCIENCE SUBCOMMITTEE AND NEURO TASK FORCE MEETING WHERE WE WILL BE PRESENTING ALL THE RECOMMENDATIONS FOR EACH ONE OF THE IMPACT GOALS.

SO TODAY WE ARE GOING TO GO OVER SOME OF THE CONSIDERATIONS THAT THIS GROUP HAS CONVENED. AND THESE CONSIDERATIONS WILL BE THE ONES THAT WILL HELP US DERIVE RECOMMENDATIONS AND PRESENT THEM AT THE SEPTEMBER MEETING. SO JUST TO -- NEXT SLIDE.

AS I WAS MENTIONING, WE HAVE FOUR

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CATEGORIES IN WHICH WE'VE BEEN DEVELOPING THIS STRATEGIC ALLOCATION FRAMEWORK. AND THERE'S A FULL CATEGORY FOR ACCESS AND AFFORDABILITY OF CIRM-FUNDED CELL AND GENE THERAPIES, WHICH IS OBVIOUSLY VERY RELEVANT BECAUSE THAT'S KIND OF WHERE WE ARE GOING, TO MAKE THERAPIES FOR PATIENTS AND THAT THEY ARE ACCESSIBLE AND AFFORDABLE AS PER PROPOSITION 14.

SO THIS GROUP DEVELOPED, WITH CIRM STAFF, DEVELOPED A GOAL, AN IMPACT GOAL, WHICH WAS TO ENSURE THAT EVERY CIRM-FUNDED PROJECT COMPLETING A LATE STAGE CLINICAL TRIAL HAS A STRATEGY THAT ENABLES ACCESS AND AFFORDABILITY BY ALL CALIFORNIA PATIENTS, PARTICULARLY UNDERSERVED POPULATIONS.

AND WHAT WE WERE TALKING ABOUT EARLIER IN TERMS OF INCREASING REFERRAL RATES AND ALIGNING WITH FEDERAL AND ALSO CALIFORNIA GOVERNMENT POLICY STRATEGIES, ALL THIS FITS WITHIN THE GRANULARITY OF WHAT WE NEED TO DO IN THIS EXERCISE, WHICH IS TO PROVIDE RECOMMENDATIONS AT A HIGH LEVEL, EITHER PROGRAMMATIC OR POLICY OR PROCESS RECOMMENDATIONS, THAT WILL THEN BE IMPLEMENTED. IN ORDER TO DO THAT, WE NEED TO GATHER DATA. AND THAT'S WHAT GEOFF HAS BEEN DOING WITH CHAIR BONNEVILLE'S LEADERSHIP.

SO THE NEXT SLIDE PROVIDES AN OVERVIEW OF THE HIGH LEVEL QUESTIONS. NEXT SLIDE. GO BACK. SO

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THE GOAL TODAY WILL BE TO GO OVER THE HIGH LEVEL QUESTIONS THAT WERE DEVELOPED, THE CONSIDERATIONS THAT GEOFF WILL BE RUNNING US THROUGH, AND THEN A DISCUSSION FRAMED WITHIN SOME HIGH LEVEL QUESTIONS THAT CHAIR BONNEVILLE HAS SHARED WITH THIS WORKING GROUP. NEXT SLIDE.

THE QUESTIONS AT A HIGH LEVEL IS HOW WILL CIRM ALIGN WITH THE CMS CELL AND GENE THERAPY ACCESS MODEL? WHAT ARE THE MOST IMPACTFUL FACTORS FOR ACHIEVING ACCESS AND AFFORDABILITY? WHAT IS THE RESEARCH THAT WE NEED TO UNDERSTAND THE LANDSCAPE FOR ACCESS AND AFFORDABILITY? AND HOW ARE WE GOING TO GATHER ALL THAT LANDSCAPE AND SUCCINCTLY PUT IT IN A WAY THAT WE CAN EVALUATE WHAT FITS BEST OUR NEEDS? AND ALL THIS OF NEEDS TO BE IN THE CONTEXT OF WHAT WE ARE TALKING ABOUT IN TERMS OF THE CELL AND GENE THERAPIES THAT WE ARE MOVING TO THE CLINIC AS WELL. SO THOSE ARE QUESTIONS THAT THIS GROUP NEEDS TO EVALUATE.

WHAT GENERAL POLICIES WITHIN CIRM COULD BE DEVELOPED TO FACILITATE ACCESS AND AFFORDABILITY? THIS LINKS TO NO. 3. WHAT ARE THE BARRIERS TO ACCESS AND AFFORDABILITY FOR CELL AND GENE THERAPIES? AT WHAT STAGE SHOULD THE APPLICANTS PROVIDE AN ACCESS AND AFFORDABILITY STRATEGY, FOR

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EXAMPLE? SO THIS COULD BE IN TERMS OF WHAT WOULD DERIVE FROM HERE WOULD BE PROGRAMMATIC, THE PROGRAM. THE AMENDMENTS TO PROGRAMS OR CHANGES TO ALREADY FUNDED PROGRAMS, THAT WE NEED TO TELL THEM NOW YOU NEED TO PROVIDE THIS AS WELL. SO THOSE ARE THE RECOMMENDATIONS THAT THIS GROUP CAN PROVIDE TO THE ICOC.

HOW CAN STRATEGIES BE SCALED IF THE THERAPY IS SUCCESSFUL? AND WHAT ARE ADDITIONAL OPPORTUNITIES FOR ACCESS AND AFFORDABILITY?

SO TAKING THESE VERY HIGH LEVEL QUESTIONS, WE WENT INTO SOME CONSIDERATIONS. NEXT SLIDE. AND WE WILL NOT GO THROUGH THESE CONSIDERATIONS BECAUSE THESE ARE PART OF THE GOAL 5 DOCUMENT THAT THE TEAM POSTED IN PREPARATION FOR THIS MEETING. AND I'M SURE THAT EVERYBODY HAS HAD A CHANCE TO GO OVER THEM.

AND WITH THAT PREAMBLE, I WILL JUST PASS THE BATON TO MY COLLEAGUE GEOFF LOMAX, WHO'S GOING TO RUN IS THROUGH THE NEXT SLIDES THAT PRESENT THE HIGH LEVEL FACTORS AND THE QUESTIONS.

DR. LOMAX: THANK YOU, ROSA. THANKS FOR THAT INTRODUCTION.

SO BEFORE JUMPING INTO WHAT WOULD OTHERWISE JUST BE A LIST OF POLICY OPTIONS, I WANTED

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TO PROVIDE A LITTLE BIT OF CONTEXT FOR HOW THESE OPTIONS RELATE TO THE DECISION-MAKING THAT IMPACTS ACCESS, AT LEAST AS I'VE COME TO UNDERSTAND THE SPACE.

THERE ARE THREE DRIVING FACTORS THAT IMPACT ACCESS. SO FIRST, PRICE BEING THE MOST OBVIOUS. IF WE'RE NOT DEALING WITH MULTI-MILLION DOLLAR TREATMENTS, WE'D PROBABLY NOT NEED THIS WORKING GROUP. AND IT'S WORTH NOTING THAT THERE ARE A NUMBER OF CELL AND GENE THERAPY PROGRAMS IN THE CIRM PORTFOLIO THAT ARE REALLY AIMING TO FORCE SUBSTANTIAL COST REDUCTIONS. SO PRICE AS A KIND OF OVERALL STRATEGY IS SOMETHING THAT HAS A STRONG POTENTIAL WITHIN OUR PORTFOLIO.

THE SECOND FACTOR, AGAIN, WHEN WE'RE LOOKING AT ACCESS AND REIMBURSEMENT POLICY IS HEALTH GAIN. HOW MUCH HEALTH DO WE GET FOR THAT PRICE? AND HOW DOES THAT COMPARE TO THE STANDARD OF CARE? AGAIN, AS NOTED IN THE BACKGROUND MATERIALS, ONE RATIONALE FOR CMS' SELECTION OF SICKLE CELL DISEASE IN THEIR GENE THERAPY PILOT WAS THAT THE CURRENT COST OF THE HEALTHCARE SYSTEM FOR MANAGING THIS DISEASE IS ESTIMATED AT AROUND $3 BILLION PER YEAR WITH ABOUT 50 TO 60 PERCENT OF THAT COST FALLING ON PUBLIC PAYERS.

SO THE POTENTIAL FOR AVOIDED COSTS ASSOCIATED WITH TREATMENTS CAN BE COMPELLING. AND THEN THE LINE BELOW, SORT OF THE INTERACTION BETWEEN PRICE AND HEALTH GAIN IS FUNDAMENTAL IN THE CONTEXT OF DISCUSSIONS OVER VALUE-BASED PRICING. AGAIN, AS NOTED IN THE BACKGROUND MATERIALS, THERE ARE A NUMBER OF CONSIDERATIONS THAT GO INTO THESE VALUE ASSESSMENTS, INCLUDING FACTORS LIKE MAGNITUDE OF EFFECT OR ABILITY OF THE TREATMENT AND DELIVERY FACTORS SUCH AS IN-AND-OUT PATIENT TREATMENT. AGAIN, THESE ARE OPTIONS SORT OF LAID OUT IN THE BACKGROUND DOCUMENT.

I'D ALSO BE REMISS IF I DIDN'T NOTE SOME WRITTEN COMMENTS PROVIDED BY DR. LEVINE NOTING THAT VALUE ASSESSMENT SHOULD NOT BE THE SOLE DETERMINANT OF WHETHER A THERAPY IS ACCESSIBLE TO PATIENTS. SO I WANTED TO NOTE THAT AS WELL.

IN THE CONTEXT OF GOAL 5, A FUNDAMENTAL QUESTION YOU MAY WANT TO CONSIDER IS TO WHAT EXTENT WE WOULD LIKE TO SEE OR RECOMMEND VALUE ASSESSMENTS BE INCORPORATED INTO ACCESS STRATEGIES OR PLANS.

AND THEN JUST RETURNING FOR A MOMENT TO OUR COMMENTS ON THE PROPOSED NIH POLICY, OUR COMMENTS SUGGESTED THAT NIH MAY BE OVEREMPHASIZING FACTORS RELATED TO PRICE, PUTTING THE ONUS ON

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DEVELOPERS TO CUT COSTS. BUT WHEN IT COMES TO CELL AND GENE THERAPIES, THEY MAY WANT TO CONSIDER VALUE IN THE BROADER CONTEXT OF MARKET BARRIERS AND HEALTH GAINS.

AND FINALLY, EVEN IF ONE CAN DEMONSTRATE VALUE, THERE'S NO ACCESS GUARANTEE. PAYERS REMAIN CONCERNED ABOUT ACTUARIAL UNCERTAINTY OR THE OVERALL DEMAND FOR THESE PRODUCTS. AND TO EMPHASIZE THIS, CMS JUST PUBLISHED THIS WEEK ITS REIMBURSEMENT RULES FOR THE 2025 FISCAL YEAR. AND DESPITE THE EVIDENCE OF LONG-TERM VALUE IN SICKLE CELL TREATMENTS, THEY DECIDED AGAINST INCREASING THE REIMBURSEMENT RATE FOR APPROVED SICKLE CELL TREATMENTS. SO THEY'VE REFUSED TO INCREASE RATES SO THEY'RE MORE IN LINE WITH PROVIDERS' COST.

AND CMS SPECIFICALLY STATED, "WE RECOGNIZE THE PAYMENTS WOULD NOT FULLY COVER A HOSPITAL'S COST. WE REMAIN CONCERNED ABOUT THE EXTREMELY HIGH COST OF THESE PRODUCTS AND WANT TO ENSURE WE DO NOT CREATE INCENTIVES TO INCREASE PRICES.

"SO CMS POLICY IS INDICATIVE OF A HEALTHCARE FINANCING SYSTEM THAT IS SENSITIVE TO THE FINANCIAL IMPACT OF THESE TREATMENTS, PARTICULARLY IF THERE'S A SURGE IN DEMAND. IN SHORT, THESE TREATMENTS ARE NOT WELL ALIGNED FOR A FINANCING

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SYSTEM THAT OPERATES ON ANNUAL APPROPRIATIONS AND OPEN ENROLLMENT PERIODS."

SO WITH THAT, NEXT SLIDE PLEASE.

SO WITH THAT BACKGROUND IN MIND, WE ASKED YOU TO CONSIDER TWO QUESTIONS. ARE THERE SPECIFIC OPTIONS CIRM SHOULD PRIORITIZE OR TRIAGE? AGAIN, THAT'S AMONG THE LIST OF OPTIONS THAT WE'VE DEVELOPED. AND IN ADDITION, ARE THERE OPPORTUNITIES THAT ARE REALLY MISSING FROM THE TABLE THAT SHOULD BE CONSIDERED IN THE CONTEXT OF THE STRATEGIC ALLOCATION FRAMEWORK?

AND WITH THAT, I'D LIKE TO TURN IT BACK TO CHAIR BONNEVILLE AND SEE IF YOU HAVE ANY ADDITIONAL COMMENTS.

CHAIRWOMAN BONNEVILLE: THANK YOU SO MUCH, GEOFF. THAT'S REALLY WELL LAID OUT. SO I APPRECIATE THAT.

AMMAR.

DR. QADAN: THANK YOU. THIS IS GREAT. THIS IS WHAT I LIVE DAY AND NIGHT BASICALLY AROUND DEMONSTRATING VALUE. I KNOW WE DISCUSSED THIS BEFORE. WHO'S RESPONSIBLE FOR THAT WITHIN THE CURRENT CLINICAL PRIOR PROGRAM? BECAUSE IN INDUSTRY, FOR EXAMPLE, WE HAVE A TEAM OF HEALTH ECONOMISTS WHO WOULD BE WORKING ON DEFINING THOSE

KINDS OF ENDPOINTS AND MAKING SURE THAT THOSE STUDIES ARE ALIGNED WITH THOSE ENDPOINTS SO THAT WE HAVE A GOOD READ ABOUT THAT VALUE ONCE THE STUDY IS DONE. WHO'S RESPONSIBLE HERE? THAT'S MY QUESTION.

AND THE SECOND, I SUGGESTED BEFORE THAT PROBABLY WE NEED A HEALTH ECONOMIST ON A FULL-TIME, MAYBE, BASIS. I KNOW SOME OF THE EXPERTS IN THIS GROUP ARE HEALTH ECONOMISTS AS WELL BY TRAINING. SOME OF THEM ARE ATTENDING ON REGULAR BASIS, SOME ARE NOT. SO THERE NEEDS TO BE MORE ACCOUNTABILITY ON HOW WE TRY THIS. THANK YOU.

CHAIRWOMAN BONNEVILLE: THANK YOU. GEOFF.

DR. LOMAX: SO I THINK IN TERMS OF WHO'S RESPONSIBLE, I THINK THE PROVERBIAL IT DEPENDS. IT DEPENDS ON THE SPONSOR. WE HAVE A VERY DIVERSE SET OF SPONSORS IN OUR PORTFOLIO. I THINK SOME DO APPLY THE APPROACH THAT WAS ALLUDED TO. OTHERS, THEY MAY NOT -- SORT OF THAT LEVEL OF PLANNING MAY NOT BE BAKED IN. I THINK THAT'S WHY THE OVERARCHING RECOMMENDATION IS THAT EVERY LATE STAGE PROGRAM SHOULD HAVE SOME KIND OF A STRATEGY. IT'S REALLY SPOKEN TO THE UNDERPINNINGS OF THIS RECOMMENDATION IS THAT AT SOME LEVEL THERE'S GOING TO BE SOME BASELINE LEVEL OF EXPECTATION THAT THIS ANALYSIS IS OCCURRING. CURRENTLY THAT IS NOT REQUIRED.

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CHAIRWOMAN BONNEVILLE: THANK YOU, GEOFF. HARLAN.

DR. LEVINE: THANK YOU. VERY GOOD REPORT. I HAVE A FEW COMMENTS. ONE IS I JUST WANT TO CLARIFY MY COMMENTS TO GEOFF, AND I THINK THE SICKLE CELL IS AN EXAMPLE. I AM A SUPPORTER THAT VALUE SHOULD TRUMP MANY DECISIONS, BUT I THINK MY POINT WAS THERE ARE SOME TREATMENTS THAT WILL HAVE SUCH SIGNIFICANT CLINICAL BENEFIT, THAT YOU CAN'T REALLY BALANCE PRICE AND BENEFIT, THAT WE AS A SOCIETY HAVEN'T DECIDED WE'RE GOING TO WITHHOLD TREATMENTS. IT'S THE HEALTH PLANS THAT ARE MAKING THESE DECISIONS. I THINK WE NEED TO PULL IT BACK TO MORE OF A SOCIETAL COMMENT.

ANYWAY, PUTTING THAT ASIDE, YOU TALKED ABOUT ON SLIDE 23, THE OTHER FEATURE I WOULD ADD IS CAPABILITY. SO THERE'S PRICE, THERE'S GAIN, THERE'S DEMAND, BUT THERE'S ALSO CAPABILITY TO DELIVER THESE PROGRAMS.

THE DECISION ON SICKLE CELL, I THINK, IS INDICATIVE OF TWO THINGS. ONE IS THE WILLINGNESS TO PUT THE BURDEN ON THE HOSPITAL SYSTEM INSTEAD OF PHARMA AND ALSO TO LEAVE THAT TENSION THERE AS A WAY TO REALLY LIMIT ACCESS. AND I THINK WE NEED TO BRING SYSTEM TRANSPARENCY AND SHINE SOME LIGHT ON

THAT. IT'S REALLY NO WAY TO ADDRESS THIS ISSUE BECAUSE WHAT IT DOES IS PERPETUATES INEQUALITY AS PEOPLE WITH BETTER HEALTH PLANS WILL HAVE BETTER .ACCESS TO THESE THINGS THAN PEOPLE WITHOUT.

THE MAIN LAST POINT AND MAIN POINT I WANT TO MAKE ON WHAT WAS MISSING ON THE LIST OF QUESTIONS, I THINK WE ASK OURSELVES WHAT PARTNERSHIPS ARE NEEDED TO DRIVE THE RESULTS THAT WE WANT? AND SO, FOR EXAMPLE, IF YOU WANT ACCESS TO UNDERREPRESENTED COMMUNITIES, HOW DO YOU TAP INTO THE MEDICAID HMO'S? LEFT TO THEIR OWN DEVICES, THEY WILL NEVER GET AT THIS; BUT IF YOU PARTNER WITH THEM WITH A CANCER CENTER OR SOME OTHER MULTI-HOSPITAL SYSTEM THAT DELIVER ON LATE PHASE TRIALS AND DELIVER EARLY RELEASE TO MEDICATIONS, YOU CAN BEGIN TO BAKE IT INTO -- FORCE BAKING IT INTO THEIR SYSTEM. THE PROBLEM TODAY IS A LOT OF THE DOCTORS IN THOSE NETWORKS WILL NEVER REFER PATIENTS BECAUSE IT'S NOT PART OF THEIR DAY-TO-DAY OPERATION. SO WE HAVE TO FIGURE OUT HOW TO TAKE THAT IN.

PROVIDENCE MAY NOT DO PHASE 1 TRIALS, BUT THEY HAVE A LARGE NETWORK. SO LET'S PARTNER THEM WITH SOMEONE WHO IS ABLE TO DO PHASE 1 TRIALS. I THINK PARTNERSHIPS ARE GOING TO BE KEY TO GET AT SOME OF THOSE MARKETS. UCLA AND CITY OF HOPE ARE

ALREADY IN UNDERREPRESENTED MARKETS. I DON'T KNOW ABOUT SOME OF THE OTHER MULTI-HOSPITAL ACADEMIC CENTERS, BUT I'M SURE THAT THEY ARE. WE SHOULD TAKE ADVANTAGE OF THEIR NETWORKS TO LEVERAGE THEIR CAPABILITY AND DRIVE IT INTO UNDERREPRESENTED COMMUNITIES.

DR. LOMAX: CAN I JUST ASK A QUICK FOLLOW-UP? IF YOU GO TO OUR SORT OF LIST OF OPTIONS, WE'VE CALLED OUT THE CALIFORNIA CANCER CARE ACT AS A POTENTIAL STARTING POINT FOR DRIVING SOME OF THOSE. SO THAT'S ONE OPPORTUNITY. I KNOW IT'S NOT QUITE IN LINE WITH THE ACCESS PLANNING, BUT WE THOUGHT IT WAS IMPORTANT TO INCLUDE AS PART OF THE BROADER STRATEGY AND POLICY INITIATIVES.

DO YOU SEE THAT PIECE OF LEGISLATION AS SORT OF A PRIMARY OPPORTUNITY WE CAN -- WE SHOULD BE DEVELOPING TO SORT OF ACHIEVE THE OUTCOME YOU JUST DESCRIBED?

DR. LEVINE: I DO. I THINK IT'S A TEMPLATE FOR TWO REASONS. FOR THOSE THAT DON'T KNOW, IT'S THE CALIFORNIA CANCER CARE EQUITY ACT. IT BASICALLY SAYS TWO THINGS. ONE IS THE PATIENTS HAVE A RIGHT TO GET TO THE LEVEL OF CARE THAT'S NEEDED FOR THEIR COMPLEX CANCER. BUT THE SECOND PIECE IS THERE'S AN AFFIRMATIVE OBLIGATION TO

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ACTUALLY INFORM THE PATIENT. WHETHER THAT'S HAPPENING OR NOT, I DON'T KNOW, BUT WE'RE HAVING DISCUSSIONS WITH THE STATE RIGHT NOW. IN FACT, THEY'RE HAVING DISCUSSIONS WITH US THAT ARE VERY POSITIVE ABOUT HAVING PEOPLE HIRED TO HELP WITH THE IMPLEMENTATION AND THE OVERSIGHT OF THE PROGRAM.

AND THE OTHER PIECE OF THE LEGISLATION THAT IS APPLICABLE HERE IS THERE'S GOING TO BE AN EVALUATION PROCESS EVERY YEAR TO SEE WHAT CONSTITUTES A NEW, COMPLEX NEED AS BEING UNMET. I THINK THAT'S EXACTLY THE TEMPLATE WE CAN USE HERE TO SAY THAT WE THINK THAT IT'S A RIGHT OF PATIENTS TO HAVE ACCESS TO THESE DRUGS. WE DON'T KNOW WHAT THEY ARE TODAY, BUT WE'LL SIT AND EVALUATE EVERY SIX MONTHS, EVERY 12 MONTHS, AND THEN MAKE SURE THAT THE HMO'S HAVE AN AFFIRMATIVE OBLIGATION TO MAKE PATIENTS AWARE, MAKE THE DOCTORS AWARE OF THESE OPPORTUNITIES.

AND THEN WE HAVE TO MEASURE IT. THAT'S THE PIECE THAT'S MISSING SO FAR. I THINK THE STATE HAS REALLY SHOWED GOOD INTENT TO TRY TO SOLVE THE PROBLEM OF IMPLEMENTATION AND OVERSIGHT.

CHAIRWOMAN BONNEVILLE: ABSOLUTELY, HARLAN. JUST SO YOU KNOW, OUR TEAM SAT WITH SOME OF THE FOLKS RESPONSIBLE FOR IMPLEMENTATION. I'M SURE

133 HENNA COURT, SANDPOINT, IDAHO 83864
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IT GOT BACK TO YOU BECAUSE CITY OF HOPE REPRESENTATIVES WERE THERE AS WELL. IT WAS INCREDIBLY HELPFUL AND PROVIDED AN OPPORTUNITY. SO MUCH OF WHAT PAT TALKS ABOUT IS THERE'S A LOT OF PEOPLE DOING THINGS THAT HELP MOVE THIS FORWARD. AND THE MORE WE CAN ALL BE ALIGNED AND THE MORE WE CAN ALL COME TOGETHER, IT REALLY HELPS. SO THANK YOU ALSO FOR YOUR HELP WITH THAT, HARLAN. APPRECIATE IT.

ADRIENNE, YOU HAD YOUR HAND RAISED, BUT IT'S NOT RAISED ANYMORE. SO I WANTED TO ASK IF YOU WANTED --

MS. SHAPIRO: I DID. ...WHAT HARLAN WAS SAYING. IT'S REALLY, REALLY IMPORTANT THAT, WHEN WE'RE LOOKING AT THIS AND WE ARE TALKING ABOUT CARE, WE HAVE TO LOOK BEYOND THE CARE THAT WE OFFER WITH THESE NEW TREATMENTS, BUT WHAT'S THE BASELINE CARE THAT PEOPLE WITH A GIVEN DISEASE ARE FACING ON A DAILY BASIS. AND SO I JUST WANTED TO SAY THANK YOU TO HIM. I KNOW I'M PREACHING TO THE CHOIR, BUT THE MORE OF OUR VOICES THAT SPEAK TO THAT THE BETTER. I WON'T GO OVER WHAT HE SAID AGAIN. I WON'T BE REDUNDANT, BUT THANK YOU.

CHAIRWOMAN BONNEVILLE: THANK YOU, ADRIENNE. I APPRECIATE THAT.

DOES ANYONE ELSE HAVE ANY QUESTIONS? I HAVE A QUESTION FOR THE GROUP IF NOBODY ELSE HAS A QUESTION.

IN PUTTING TOGETHER SORT OF OUR FUTURE RFA'S, PROGRAM ANNOUNCEMENTS, THINGS LIKE THAT, HOW MUCH WEIGHT DO YOU THINK SHOULD BE GIVEN TO ACCESS STRATEGIES AS PART OF THE OVERALL APPLICATION? AND HOW REASONABLE DO WE THINK IT IS THAT THEY WOULD BE IN A POSITION WHERE THEY COULD PUT SOMETHING LIKE THIS TOGETHER TO PROVIDE AS PART OF AN APPLICATION FOR FUNDING? AMMAR.

DR. QADAN: THANK YOU. I THINK THE SAME QUESTION AS BEING ASKED TODAY BY MANY START-UP COMPANIES WHEN THEY APPROACH VC'S AROUND FUNDING. THE TRADITIONAL APPROACH HAS BEEN FOCUSED JUST ON REGULATORY APPROVAL, GET THE PRODUCT TO MARKET, AND THAT'S IT. AND NOW THERE ARE MANY OF THEM WHO REALIZE THAT THEY NEED TO THINK ABOUT THOSE THINGS IN ADVANCE AS PROBABLY HARLAN MENTIONED.

SO THERE NEEDS TO BE AT LEAST A, I WOULD SAY, A VERY LEAN -- AND I'LL GO BACK AND BE MORE DIRECT. I THINK WE NEED TO HAVE AT LEAST ONE PERSON IN OUR ORGANIZATION WHO'S ABLE TO OVERSEE THOSE. SOMETIMES WE NEED TO DO IT OURSELVES IN THE MAJORITY OF THE CASES THROUGH PARTNERS.

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CHAIRWOMAN BONNEVILLE: SURE.

DR. QADAN: SO THE ANSWER, THE SHORT ANSWER IS WE NEED TO HAVE THAT AS PART OF ANY FUNDING IN THE FUTURE. THANK YOU.

CHAIRWOMAN BONNEVILLE: THANK YOU. DO YOU THINK IT SHOULD START EARLIER IN THE DEVELOPMENT CYCLE, OR IS IT APPROPRIATE AS THEY'RE PREPARING THE CRITICAL STAGE? IS IT SOMETHING THAT CAN BE DONE SOONER IN THE DEVELOPMENT PROCESS?

DR. QADAN: I THINK EARLIER IS BETTER. NOW, WE CAN DECIDE ON HOW MUCH EARLIER. DEFINITELY EARLIER IS BETTER. AS PRODUCTS MOVE FROM PHASE 1 TO PHASE 2, YOU NEED TO HAVE A STRATEGY PROBABLY.

CHAIRWOMAN BONNEVILLE: OKAY. THANK YOU. APPRECIATE THAT.

DR. LEVINE: I THINK MY THOUGHTS MIRROR AMMAR'S. I WOULD JUST SAY I LIKE THE WAY IT WAS WORDED AS LATE STAGE FOR NOW. I INTERVIEWED A LOT OF OUR SCIENTISTS HERE, AND I CAN'T SAY I AGREED WITH THEM, BUT THEY MADE A COMPELLING ARGUMENT, THAT IT'S VERY DIFFICULT IN EARLY STAGES WHEN YOU DON'T KNOW WHAT DIRECTION THINGS ARE GOING TO GO TO ALSO BE THINKING ABOUT COST. AND WHAT WE DECIDED WAS WE NEED TO LEVERAGE AI, NOT SO MUCH GAI, AI AND THE NEW TECHNIQUES TO LOWER THE COST. AND MAYBE THINK ABOUT

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REDUCING THE COST OF MANUFACTURING WHEN WE'RE CHOOSING PATH A VERSUS PATH B. BEYOND THAT, IT'S REALLY PUTTING A HEAVY BURDEN ON BASIC SCIENTISTS WHO DON'T EVEN --

CHAIRWOMAN BONNEVILLE: SURE.

DR. LEVINE: THEY DON'T EVEN CARE ABOUT THE PROFITABILITY. THEY'RE IN IT FOR THE SCIENCE, AND IT WOULD BE A SEA CHANGE FOR THEM TO WORRY ABOUT IT. SO I THINK FOCUSING IN LATER STAGE, AND LETTING IT PERMEATE EARLIER OVER TIME IS THE RIGHT APPROACH. AND I DON'T WANT TO PUT WORDS IN AMMAR'S MOUTH. BUT THAT'S KIND OF WHAT I HEARD, AND I THINK THE RIGHT -- HE SAID IT MORE ELOQUENTLY, BUT I WANTED TO REINFORCE IT. WE SHOULD START WITH WHAT WE KNOW WE CAN DO, WHICH IS THE LATER STAGES, AND THEN NOT PUT AN UNREASONABLE EXPECTATION ON THE ACADEMIC CENTERS UNTIL WE'RE READY.

CHAIRPERSON BONNEVILLE: THANK YOU FOR THAT FEEDBACK. AND THANKS FOR CHECKING IN WITH SCIENTISTS AND GETTING AN OPINION. I APPRECIATE THAT.

ANN.

MS. BOYNTON: SORT OF ON HARLAN'S POINT, IS THERE A WAY THAT WE CAN -- I AGREE WITH FOCUSING ON LATER STAGE, BUT THEY COULD GET A VERY LONG WAYS

133 HENNA COURT, SANDPOINT, IDAHO 83864
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DOWN AND NOT HAVE THOUGHT ABOUT IT AT ALL. SO IS THERE A WAY EARLY ON TO BEGIN THE PROCESS OF MAKING SURE FOLKS ARE THINKING THAT WAY AS THEY MOVE THROUGH DEVELOPMENT?

DR. LOMAX: SO I THINK THE SENSE IS YES. THERE WOULD BE CERTAIN -- EARLY ON I THINK GOING BACK TO THAT THREE-POINT CHART, YOU'D CERTAINLY WANT TO BE ABLE TO -- I THINK THERE'S ISSUES BOTH OF COST. YOU COULD ASK A -- THERE COULD BE A SERIES OF PROBES, FOR EXAMPLE. LIKE WHAT HAVE YOU -- HAVE YOU CONSIDERED OPPORTUNITIES FOR COST REDUCTION? WE HAVE A MANUFACTURING NETWORK. WE HAVE A INFRASTRUCTURE IN THE CIRM ECOSYSTEM. AND PROBES AROUND TO WHAT EXTENT THOSE RESOURCES CAN BE BROUGHT TO BEAR EARLY ON. AT LEAST ASKING THOSE QUESTIONS IS USEFUL. OFTEN APPLICANTS MAY NOT EVEN HAVE VISIBILITY TO THOSE RESOURCES. AND HAVING PROCESSES WHERE WE CAN HAVE THE APPLICANTS INTERACT IS VALUABLE.

AS I INDICATED, WE ARE STARTING TO SEE APPLICATIONS COME IN THAT ARE REALLY LOOKING AT WAYS OF REDUCING COST, AND THAT'S IMPORTANT.

I THINK THE OTHER PIECE -- I THINK THE PART THAT'S A LITTLE BIT HARDER IS WHEN YOU START GETTING INTO THE QUESTIONS AROUND KIND OF

REIMBURSEMENT AND INSURANCE. BUT, AGAIN, THOSE MIGHT BECOME LATER STAGE BECAUSE YOU'RE NOT GOING TO KNOW AT THAT POINT. UNTIL YOU GO THROUGH THAT, IT COULD BE YEARS OFF. AND THEN YOU'VE GOT WHAT DOES THE REST OF THE MARKET LOOK LIKE? WHAT'S THE PRICE OF THE STANDARD OF CARE?

I THINK IT'S SORT OF LOOKING AT IT IN A STAGED WAY. AND I THINK IF YOU LOOK AT WHAT WAS IN THE NIH RFI, THEY ALLUDED TO A SIMILAR APPROACH, A KIND OF STAGED APPROACH WHERE THERE ARE THINGS YOU -- SMART QUESTIONS YOU CAN ASK EARLY, BUT RECOGNIZING SOME OF THE OTHER QUESTIONS YOU WON'T KNOW UNTIL YOU GET INTO THAT LATER STAGE OF DEVELOPMENT.

CHAIRWOMAN BONNEVILLE: THANK YOU, GEOFF.

DR. LOMAX: I THINK WHAT WE NEED TO DISENTANGLE MAYBE FOR ANOTHER MEETING IS WHAT ARE THE QUESTIONS AND WHERE TO START.

CHAIRWOMAN BONNEVILLE: DOES ANYONE ELSE HAVE ANY COMMENTS OR QUESTIONS OF THE GROUP?

GEOFF, DO YOU FEEL LIKE YOU'VE GOTTEN A GOOD START OR IDEA OF HOW THE GROUP FEELS ABOUT THE QUESTIONS MOVING FORWARD AND WHAT TO INCLUDE IN THE STRATEGIC ALLOCATION FRAMEWORK FOR CONSIDERATION?

DR. LOMAX: I GUESS YES AND NO. I THINK

WHAT WE'VE HEARD, IF I'M HEARING THE SENSE OF THE WORKING GROUP, IS THAT THE OVERALL IDEA OF ACCESS STRATEGY IS THAT THAT NEEDS TO HAPPEN. THAT NEEDS TO HAPPEN. AND IT NEEDS TO BE SORT OF APPROPRIATE FOR THE STAGE OF DEVELOPMENT.

WE HAVE MADE SOME SUGGESTIONS IN TERMS OF SORT OF SPECIFICS. MAYBE THEY'RE TOO GRANULAR. IT WOULD, AGAIN, BE HELPFUL, AND IT DOESN'T NECESSARILY HAVE TO HAPPEN AT THIS MEETING, BUT THROUGH FOLLOW-UP CORRESPONDENCE, IF YOU COULD SORT OF LOOK AT SOME OF THE SPECIFIC RECOMMENDATIONS -- I WOULDN'T SAY RECOMMENDATIONS, SPECIFIC OPTIONS AND GIVE US SOME SENSE IF THERE ARE THINGS YOU THINK THAT ARE MORE OR LESS IMPORTANT AT THIS TIME BECAUSE IT'S A LONG LIST. AS WE'VE ALLUDED TO HERE, SOME OF THEM REQUIRE SUBSTANTIAL ENGAGEMENT WITHIN THE STATE OF CALIFORNIA; FOR EXAMPLE, MEDI-CAL. OTHERS WOULD REQUIRE ENGAGEMENT WITH PERHAPS NIH. AND THAT DOES BRING UP SORT OF BANDWIDTH ISSUES AND PRIORITIZATION. WHERE SHOULD WE START? I KNOW THAT COULD CHANGE OVERNIGHT DEPENDING ON A NEW PIECE OF LEGISLATION. BUT TO THE EXTENT THERE'S FEEDBACK ON ANY OF THE SPECIFICS, THAT'S HELPFUL FOR GUIDING OUR SORT OF DAY-TO-DAY OPERATIONS.

CHAIRWOMAN BONNEVILLE: THANK YOU. AND

133 HENNA COURT, SANDPOINT, IDAHO 83864
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JUST AS AN UPDATE FOR THE GROUP, WE HAVE STARTED CONVERSATIONS WITH VARIOUS GROUPS WITHIN STATE GOVERNMENT, INCLUDING MEDI-CAL, ABOUT HOW TO PARTNER WITH THEM, HOW TO PARTNER AND BRING INFORMATION IN. THERE ARE NO SOLUTIONS TO THIS YET. THAT'S AN ONGOING PROCESS. BUT WE DO HAVE TOUCHPOINTS IN. THAT'S REALLY VALUABLE FOR EVERYONE AND I THINK WILL GO A LONG WAY.

WE ARE ALSO SPONSORING A COUPLE OF DIFFERENT CONFERENCES IN THE UPCOMING MONTHS WHERE SOME OF THESE QUESTIONS WILL BE ASKED. AND WE PLAN ON BRINGING ALL OF THAT FEEDBACK TO THIS GROUP TO GET THEIR INPUT AS WELL.

I JUST GOT A NOTE THAT SAID TED GOLDSTEIN HAS A COMMENT. SO I'M GOING TO SAY, TED, PLEASE UNMUTE YOURSELF AND ASK AWAY.

DR. GOLDSTEIN: THANKS SO MUCH. SO JUST ONE QUICK POINT THAT WE MAY WANT TO MAKE AS PART OF THE PUBLIC STRATEGY, THAT ANY OF THE -- THAT INCREASES THEIR POINTS AND LIKELIHOOD FOR FUNDING, IF THE CLINICAL TRIALS COME TO US WITH A STRATEGY FOR MASS PRODUCTION. AND THAT -- SO THAT WE TURN IT AROUND. WE KNOW THAT THIS SORT OF BESPOKE CREATION OF STEM CELLS IS NOT SCALABLE, BUT THERE IS CREATIVITY GOING ON IN THE COMMUNITY TO MAKE MORE OF

133 HENNA COURT, SANDPOINT, IDAHO 83864
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A COMMON MANUFACTURING TECHNOLOGY. AND IT WOULD BE VERY GOOD IF WE JUST SAID, HEY. COME TO US WITH YOUR IDEAS AND SOLUTIONS THAT WOULD INCREASE THE LIKELIHOOD OF FUNDING.

CHAIRWOMAN BONNEVILLE: THANK YOU. GEOFF.

DR. LOMAX: AGREED. I THINK THAT RELATES -- AGAIN, BACK TO ANN'S COMMENT, SORT OF WHAT ARE -- I THINK ON THE MANUFACTURING SIDE, THAT'S PROBABLY SOMETHING THAT CAN BE LOOKED AT EARLIER IN TERMS OF STRATEGY. JUST TO ACKNOWLEDGE TOO, THAT'S A VERY DYNAMIC SPACE AT THE MOMENT. WE'RE SEEING THE EMERGENCE OF A LOT OF AUTOMATED SYSTEMS. THERE'S, AGAIN, A LOT OF INTEREST WITHIN OUR OWN INFRASTRUCTURE NETWORK TO DEPLOY SOME OF THESE NOVEL SYSTEMS THAT COULD REALLY IMPACT COST. THAT'S THE PLAN. THOSE ARE THINGS, I THINK, THAT AGAIN CAN COME UP EARLIER ON. AND A REMINDER, THAT ANY CLINICAL STAGE PROGRAM, IF THEY DON'T HAVE A COMPELLING AND FEASIBLE MANUFACTURING STRATEGY, THEY'RE NOT GOING TO GET FUNDED. SO WE ALREADY HAVE THE SORT OF FRAMEWORK WHERE THOSE SORTS OF ISSUES COME UP. AND TO THE EXTENT, AGAIN, THERE MIGHT BE ADDITIONAL QUESTIONS WE SHOULD BE ASKING AT CERTAIN STAGES, WE'D BRING THOSE QUESTIONS FORWARD.

CHAIRWOMAN BONNEVILLE: THANK YOU. TED,

DO YOU WANT TO --

DR. GOLDSTEIN: JUST IT STRIKES ME WHAT WE'RE LOOKING AT, OF COURSE, IS FUNDAMENTAL CHANGES TO THE IMMUNE ARCHITECTURE OF STEM CELLS. AND THAT ITSELF, OF COURSE, IS PROBABLY ITS OWN CIRM PROGRAM, BUT IF WE COULD POINT AND SHOW THE WAY TO IT. AND THERE ARE SOME PROPOSALS THAT I'VE SEEN THAT LOOK MORE OPTIMISTIC ABOUT TEACHING HOW TO COPE WITH THE COMPATIBILITY ISSUES AND OTHER SPECIFIC THINGS THAT ARE NOT NECESSARILY IMPORTANT TO THE SPECIFIC FIRST PRODUCT, BUT CLEARLY WOULD SHOW HOW TO CREATE FOLLOW-ON PRODUCTS.

SO, ANYWAY, OPTIMISTIC. AND I THINK IT'S PART OF AS WELL WHAT WE'RE GOING TO LEARN FROM -- WE NEED AT LEAST ONE LARGE-SCALE PROGRAM THAT DOESN'T BREAK THE BANK. SO...

CHAIRWOMAN BONNEVILLE: AGREE. THANK YOU.

DR. GOLDSTEIN: WE'RE ON THE RIGHT TRACK. THANK YOU.

CHAIRWOMAN BONNEVILLE: THANK YOU. DOES ANYONE ON THE WORKING GROUP HAVE ANY OTHER COMMENTS? ARE THERE ANY PUBLIC COMMENTS? CLAUDETTE OR EMILY, DO YOU SEE ANYTHING?

MS. MANDAC: THERE ARE NO HANDS RAISED.

CHAIRWOMAN BONNEVILLE: SUZANNE, I SEE YOU

JUST JOINED. THANK YOU. SUZANNE.

DR. SANDMEYER: ENOUGH PROMPTING. I AM AN ALTERNATE ON THE BOARD, BUT THIS IS THE FIRST TIME I'VE VISITED ONE OF THE SUBCOMMITTEES, I HAVE TO CONFESS.

SO MY QUESTION IS I APPRECIATED THE COMMENTS ABOUT COMBINING DIFFERENT APPROACHES TO TRY TO GET SOME BENEFIT OF COLLECTIVE PROBLEMS THAT ARE IN COMMON AND SOLVING THEM COLLECTIVELY. AND SO TO THAT POINT, I'M WONDERING WHAT KIND OF PRESSURE CAN BE BROUGHT TO BEAR ON THE NEW CGMP FACILITIES? AND ARE THERE SUPPLEMENTS AVAILABLE FOR THEM IDENTIFYING PROBLEMS THAT ARE IN MANUFACTURING, BUT MIGHT BE IN COMMON AMONG DIFFERENT DISEASES OR TRIALS OR PROGRAMS THAT THEY'RE EXECUTING ON? THAT WAS A QUESTION, BY THE WAY.

CHAIRWOMAN BONNEVILLE: THANK YOU. THANKS, SUZANNE, FOR JOINING. GEOFF.

DR. LOMAX: I DON'T WANT TO SPEAK FOR THE MANUFACTURING NETWORK, BUT WORKING IN CLOSE COLLABORATION BETWEEN THE ALPHA CLINICS AND THE MANUFACTURING NETWORKS, MY UNDERSTANDING IS THAT'S CERTAINLY THE INTENT. IT IS TO IDENTIFY THOSE OPPORTUNITIES. AND THEN I THINK WHAT'S HAPPENED AT THIS PHASE, AS I UNDERSTAND IT, IS THE FOUNDATION

HAS BEEN SET FOR THOSE SORT OF COLLABORATIVE APPROACHES. VERY PRACTICAL THINGS LIKE LANDING ON COMMON INFORMATION SYSTEMS AND ABILITY TO DO QC ACROSS THE MULTIPLE SITES, THE VERY FUNDAMENTAL MECHANICS NECESSARY TO ACHIEVE THAT OUTCOME.

I THINK THEN WITHIN THE CLINICAL PROGRAMS, TO THE EXTENT YOU SORT OF SAY IS THERE LEVERAGE, I THINK, AGAIN, THE CLINICAL PROGRAMS ARE SORT OF TO SOME EXTENT THE LEVERAGE OR THE RESOURCE THAT CAN THEN DRIVE THAT MACHINERY FORWARD IN THE CONTEXT OF VERY SPECIFIC CLINICAL PROGRAMS. SO, AGAIN, I THINK THAT'S ALL IN PLACE. I THINK TO THE EXTENT -- I THINK WHAT WILL BE INTERESTING IS TO WHAT EXTENT THIS WHOLE PROCESS, THIS FRAMEWORK, FROM SORT OF CLINICAL THROUGH TO INFRASTRUCTURE, THEN POINTS US TO WHAT OPPORTUNITIES SHOULD WE BE PURSUING. BUT I THINK THE FOUNDATION IS SET FOR THAT OUTCOME. AND I THINK IT'S CERTAINLY PART OF THE INTENT. IT WAS CERTAINLY PART OF THE INTENT OF THE MANUFACTURING NETWORK AND OUR VARIOUS INFRASTRUCTURE PROGRAMS TO POSITION US IN A WAY WHERE WE CAN TAKE THIS MORE COORDINATED APPROACH.

DR. SANDMEYER: SO PRESSURE ON THAT ARM OF THE PROGRAM SEEMS TO ME TO BE MORE APPROPRIATE THAN EARLY STAGE INVESTIGATION. I AGREE WITH THE

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COMMENTS ABOUT EARLY STAGE INVESTIGATION. SPEAKING AS A BASIC SCIENTIST, I THINK THAT TOO MUCH EMPHASIS ON COMMERCIAL VALUE, IF YOU WILL, AT EARLY STAGES MIGHT ACTUALLY LIMIT THE DIFFERENT APPROACHES THAT ARE DISCOVERED IN EARLY STAGES AND THEREBY LEAD YOU TO MISS SOME APPROACHES THAT MIGHT BE MORE EFFICIENT IN THE LONG RUN. JUST A COMMENT THERE.

CHAIRWOMAN BONNEVILLE: THANK YOU. IF THERE ARE NO OTHER COMMENTS, I BELIEVE THIS SHOULD BE THE END OF THE MEETING. THANK YOU ALL FOR JOINING THIS MORNING AND FOR YOUR FEEDBACK. APPRECIATE IT SO MUCH. AND GEOFF AND I WILL BE REACHING OUT TO SOME OF YOU TO GET SOME CLARIFICATION ON A FEW QUESTIONS. AND WE APPRECIATE EVERYTHING. SO THANK YOU SO MUCH.

(THE MEETING WS THEN CONCLUDED AT 9:56 A.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 ACCESSIBILTY 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 AUGUST 7, 2024, 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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