BEFORE THE
ACCESSIBILITY AND AFFORDABILITY WORKING GROUP
TO 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: APRIL 30, 2025
2:30 P.M.

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

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I N D E X

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APRIL 30, 2025; 2:30 P.M.

VICE CHAIR BONNEVILLE: THANKS, EVERYONE. GOOD AFTERNOON, WORKING GROUP MEMBERS. THANKS FOR MAKING YOURSELVES AVAILABLE FOR TODAY'S MEETING.

GEOFF, CAN YOU PLEASE CALL THE ROLL.

DR. LOMAX: YES. KIM BARRETT.

DR. BARRETT: PRESENT.

DR. LOMAX: ELIZABETH BOILIEU.

DR. BOILIEU: PRESENT.

DR. LOMAX: MARIA BONNEVILLE.

VICE CHAIR BONNEVILLE: PRESENT.

DR. LOMAX: JAMES DEBENEDETTI.

MR. DEBENEDETTI: HERE.

DR. LOMAX: TED GOLDSTEIN.

DR. GOLDSTEIN: HERE.

DR. LOMAX: CHRISTINA HARTMAN. CHRISTINA IS NOT ON. DAVID HIGGINS.

DR. HIGGINS: HERE.

DR. LOMAX: VITO IMBASCIANI. DARIUS LAKDAWALLA.

DR. LAKADAWALLA: HERE.

DR. LOMAX: HARLAN LEVINE. PAT LEVITT.

DR. LEVITT: HERE.

DR. LOMAX: ADRIANA PADILLA.

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DR. PADILLA: HERE.

DR. LOMAX: AMMAR QADAN.

DR. QADAN: PRESENT.

DR. LOMAX: MAHESWARI SENTHIL. AND ADRIENNE SHAPIRO.

MS. SHAPIRO: HERE.

DR. LEVINE: I WAS OFF BY ONE PERSON, I THINK, IN ATTENDING THE ROLL CALL OR ADDRESSING THE ROLL CALL. HARLAN LEVINE IS HERE.

DR. LOMAX: OKAY.

VICE CHAIR BONNEVILLE: THANKS, HARLAN.

DR. LOMAX: THANK YOU, HARLAN.

VICE CHAIR BONNEVILLE: AND THANK YOU, GEOFF.

I'M GOING TO PUT LIZ ON THE SPOT. SHE'S OUR NEWEST MEMBER. SO, LIZ, I WAS HOPING YOU COULD INTRODUCE YOURSELF AND SHARE A BIT MORE ABOUT THE WORK YOU DO AT UC DAVIS.

DR. BOILIEU: SURE. GREAT. THANK YOU FOR THAT, MARIA. HI, EVERYONE. I'M LIZ BOILIEU. I AM THE VICE PRESIDENT AND CHIEF CONTRACTING OFFICER FOR MANAGED CARE AND PHARMACY CONTRACTING. SO WHAT THAT MEANS IS I GET TO BE RESPONSIBLE FOR ALL OF THOSE INSURANCE CONTRACTS THAT WE HAVE WITH PAYERS TO PAY FOR HEALTHCARE.

AND IN MY EXPERIENCES, AS I'VE BEEN DOWN HERE IN CALIFORNIA FOR ABOUT 18 MONTHS, I'M GETTING TO KNOW THE PAYERS A LITTLE BETTER EACH DAY. BUT I HAVE ABOUT 30 YEARS OF EXPERIENCE IN THIS FIELD, AND A NUMBER OF THOSE YEARS SPENT AT OHSU, THE ACADEMIC MEDICAL CENTER IN PORTLAND, OREGON, WHERE I HAD NUMEROUS OPPORTUNITIES TO ENGAGE WITH PAYERS AROUND THESE HIGH-END, HIGH-COST TREATMENTS RELATED TO CANCER CARE MOSTLY, BUT I KNOW THERE'S SO MANY OTHERS, AND BRING THAT EXPERIENCE DOWN HERE TO CALIFORNIA WHERE I'M RESIDING IN SACRAMENTO. AND LOOK FORWARD TO, HOPEFULLY, BEING A GOOD PARTICIPANT ON THE WORK GROUP HERE. SO HAPPY TO BE A PART OF THIS.

VICE CHAIR BONNEVILLE: THANK YOU, LIZ, SO MUCH. I'M SURE YOU WILL BE GETTING A LOT OF QUESTIONS FROM US OVER THE NEXT SEVERAL YEARS. SO APPRECIATE IT.

ROSA, I BELIEVE YOU WILL BE STARTING US OFF WITH A PRESENTATION.

DR. CANET-AVILES: THAT IS CORRECT, MADAM CHAIR. SO THANK YOU, MARIA, AND THANK YOU, MEMBERS OF THE ACCESSIBILITY AND AFFORDABILITY WORKING GROUP. I AM PRESENTING -- THIS PRESENTATION IS GOING TO BE DIVIDED BETWEEN ME AND THE LEADS FOR THE

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CLINICAL DEVELOPMENT TEAM, DR. JOE GOLD, AND THE LEAD FOR THE PRECLINICAL DEVELOPMENT TEAM, DR. SHYAM PATEL.

SO WITHOUT FURTHER ADO -- I ALSO WANT TO THANK GEOFF AND MARIA FOR ALL THE ADVICE AND FEEDBACK IN THE DEVELOPMENT OF THIS PRESENTATION AND MATERIALS AS WELL AS CARRIE WARREN AND THOMAS SHANE WHO HAVE HELPED PUTTING AND COORDINATING A LOT OF THIS WORK.

SO THIS PRESENTATION PROVIDES AN UPDATE ON OUR EFFORTS, CIRM'S EFFORTS, TO IMPLEMENT A STRUCTURED APPROACH TO ACCESS AND AFFORDABILITY ACROSS OUR FUNDING PROGRAMS, THE RELEVANT FUNDING PROGRAMS. AND IT'S GROUNDED IN THE INTENT OF PROPOSITION 14 AND GUIDED BY THE RECOMMENDATIONS OF THIS GROUP, THE ACCESSIBILITY AND AFFORDABILITY WORKING GROUP. AND OUR GOAL ULTIMATELY IS TO ENSURE THAT THE THERAPIES DEVELOPED WITH PUBLIC FUNDING ARE NOT ONLY SCIENTIFICALLY PROMISING, BUT THAT THEY WILL ALSO REALISTICALLY BE ACCESSIBLE AND AFFORDABLE TO ALL CALIFORNIANS, AND PARTICULARLY THOSE IN UNDERSERVED COMMUNITIES.

IMPORTANTLY, AFFORDABILITY IS NOT JUST ABOUT PRICE. IT'S ABOUT EVALUATING WHETHER THE THERAPIES CAN BE REIMBURSED, WHETHER THE NECESSARY

INFRASTRUCTURE EXISTS TO DELIVER THEM, AND WHETHER THE COST-RELATED BARRIERS LIKE TRAVEL, LODGING, AND OUT-OF-POCKET EXPENSES FOR PATIENTS ARE ADDRESSED THROUGH CIRM'S PROGRAMS, NOT ONLY WHAT WE WILL TALK ABOUT TODAY, BUT ALSO THE OTHER PROGRAMS THAT OUR COLLEAGUE DR. GEOFF LOMAX -- I DIDN'T THANK DR. GEOFF LOMAX, DID I?

DR. LOMAX: YOU DID.

DR. CANET-AVILES: OKAY. SORRY. -- HAVE BEEN ALSO PRESENTING TO US LIKE THE COMMUNITY CARE CENTERS OF EXCELLENCE AND THE PATIENT SUPPORT PROGRAM.

SO CIRM'S APPROACH TO AFFORDABILITY IS PRAGMATIC, AND WE RECOGNIZE THAT PRICING AND REIMBURSEMENT DECISIONS ARE COMPLEX AND COMPLEX SPECIFIC ESPECIALLY FOR NOVEL CELL AND GENE THERAPIES, WHICH IS OUR BUSINESS. AND THAT'S WHY THE FRAMEWORK THAT WE WILL BE PRESENTING TODAY EMPHASIZES EARLY PLANNING, STAKEHOLDER ENGAGEMENT, AND MILESTONE-BASED DEVELOPMENT TIED TO REAL-WORLD ACCESS POTENTIAL.

AND IN SUM FOR THIS INTRODUCTION, I JUST WANT TO SAY THAT WHEN WE TALK ABOUT AFFORDABILITY, WHAT WE MEAN IS ENSURING THAT THERAPIES ARE ACCESSIBLE TO CALIFORNIA PATIENTS REGARDLESS OF

THEIR INCOME, ZIP CODE, OR DISEASE TYPE. AND THE TOOLS AND POLICIES THAT WE WILL WORK THROUGH TODAY SUPPORT THAT VISION. AND THEY REPRESENT THAT THE MECHANISMS BY WHICH CIRM IS HOLDING ITSELF AND ITS AWARDEES ACCOUNTABLE TO THAT PROMISE. NEXT SLIDE PLEASE.

SO THIS IS AN OVERVIEW. AND PLEASE STOP ME AS WELL IF YOU NEED TO IN THE MIDDLE. BUT THIS IS THE OVERVIEW OF TODAY'S PRESENTATION. WE ARE GOING TO PROVIDE THE CONTEXT, THE CONTEXT WITHIN PROP 14, AND OUR NEW STRATEGY, THE STRATEGIC ALLOCATION FRAMEWORK GOAL 5, AS WELL AS THE FEEDBACK THAT WE RECEIVED FROM AUGUST 2024 ACTUALLY -- THERE'S A TYPO -- FROM THIS GROUP BACK LAST YEAR.

AND THE APPROACH HAS BEEN TO DEVELOP THIS TOOLKIT THAT WE WILL GO IN DETAIL AND TO INTEGRATE THAT INTO OUR PRECLINICAL AND CLINICAL PROGRAMS. AND A LOT OF THE DETAILS OF THESE ARE NOT IN THE PRESENTATION. THEY ARE IN THE BACKUP MATERIALS: THE MEMO, THE GUIDANCE DOCUMENT, THE RUBRIC, AND THE DETAILED CHECKLIST THAT WE HAVE PROVIDED. AND MY COLLEAGUES WILL GO THROUGH THIS AT A HIGH LEVEL, BUT THE QUESTIONS WILL PROBABLY REFER TO THE DETAIL DOCUMENTS. AND THEN WE ARE REQUESTING AND ASKING FOR INPUT AROUND THE STRUCTURE AND CATEGORIES OF THE

TOOLS, THE USEFULNESS, THE CLARITY, AND THE IMPLEMENTATION APPROACH. AND THAT'S DEFINED BY FIVE HIGH-LEVEL QUESTIONS THAT WE WILL BE PRESENTING AT THE BEGINNING AND AT THE END TO CONTEXTUALIZE THE PRESENTATION.

SO AS MENTIONED, NEXT SLIDE, THIS IS GROUNDED ON THE INTENT OF PROP 14 AND GUIDED BY THE RECOMMENDATIONS OF THIS GROUP. AND WE GATHERED FEEDBACK IN AUGUST OF 2024, AND THERE WAS A CONSENSUS TO OPERATIONALIZE ACCESSIBILITY AND AFFORDABILITY AT BOTH PROGRAMMATIC AND PROJECT LEVELS. AND THAT'S WHAT THE TOOLKIT WILL HELP US WITH. AND THERE WAS BROAD AGREEMENT THAT ACCESS STRATEGIES MUST ALIGN WITH THE STAGE OF DEVELOPMENT. AND WE ALSO NEEDED CONSISTENT EXPECTATIONS AND CLEARER GUIDELINES ACROSS CIRM FUNDING STAGES, WHICH IS WHAT WE WILL BE PRESENTING TODAY. NEXT SLIDE.

NOW, I RECOGNIZE THAT WE'VE BEEN ALL -- HERE AT CIRM WE LIVE THIS EVERY DAY, BUT I JUST WANTED TO, BEFORE DIVING INTO THE TOOLS AND UPDATES THAT WE ARE PRESENTING TODAY, I WANTED TO QUICKLY GROUND US IN OUR STRATEGIC ALLOCATION FRAMEWORK OR SAF.

THE SAF IS A DATA-DRIVEN APPROACH FOR PRIORITIZING WHEN AND HOW WE ALLOCATE CIRM'S

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RESOURCES. AND IT WAS DEVELOPED OVER THE PAST YEAR AND APPROVED BY OUR BOARD BACK IN SEPTEMBER OF 2024 TO ENSURE THAT CIRM IS NOT JUST FUNDING GREAT SCIENCE, BUT ALSO DELIVERING ON IMPACT. AND THIS SLIDE SUMMARIZES THE SIX IMPACT GOALS THAT DRIVE OUR WORK UNDER THE SAF, FROM ACCELERATING DISCOVERY, TO ADVANCING CLINICAL PROGRAMS, TO BUILDING A DIVERSE AND CAPABLE WORKFORCE. BUT IMPORTANTLY, GOAL 5, WHICH YOU SEE HIGHLIGHTED IN THE THIRD SECTION, IS THE CENTRAL FOCUS TODAY.

GOAL 5 COMMITS CIRM TO ENSURING THAT EVERY PROGRAM READY FOR A BLA, BIOLOGICS LICENSE APPLICATION, HAS A CLEAR STRATEGY FOR ACCESS AND AFFORDABILITY. AND THIS IS NOT A SITE CONSIDERATION. IT'S CORE TO HOW WE DEFINE SUCCESS BECAUSE SCIENTIFIC INNOVATION WITHOUT PATIENT ACCESS COULD BE BASICALLY A BROKEN PROMISE.

SO TODAY'S DISCUSSION IS ABOUT HOW WE PREVENT THIS AND MAKE A REAL COMMITMENT THROUGH STRUCTURED PLANNING, GUIDANCE, AND ACCOUNTABILITY INTO OUR PRECLINICAL AND CLINICAL PROGRAMS. NEXT SLIDE.

THESE ARE THE QUESTIONS THAT HAVE GUIDED THE DEVELOPMENT OF THE TOOLKIT. SO THE ACCESSIBILITY AND AFFORDABILITY WORKING GROUP BACK

IN AUGUST OF '24, THESE WERE THE MAIN QUESTIONS. WHAT STAGE-APPROPRIATE ACCESSIBILITY AND AFFORDABILITY ACTIVITIES SHOULD BE REQUIRED AND WHEN?

HOW CAN CIRM LEVERAGE ITS INFRASTRUCTURE TO INCENTIVIZE PLANNING EARLY WHILE ENSURING FEASIBILITY AND PROPORTIONALITY? WE MEAN BY INFRASTRUCTURE IT'S ALPHA CLINICS, THE COMMUNITY CARE CENTERS OF EXCELLENCE, BUT ALL OUR CLINICAL INFRASTRUCTURE AS WELL.

AND WHAT MECHANISMS AND METRICS ARE NEEDED TO TRACK AND SUPPORT EXECUTION OF ACCESSIBILITY AND AFFORDABILITY STRATEGIES? NEXT SLIDE.

THIS IS JUST TO CONTEXTUALIZE HOW WE SUPPORT FIVE PILLARS OF FUNDING. AND THIS IS FOCUSED MOSTLY IN THE R&D, DISCOVERY, PRECLINICAL, AND CLINICAL DEVELOPMENT -- NEXT SLIDE -- WHICH IS SHOWN HERE. TO FRAME HOW THE ACCESS AND AFFORDABILITY PLANNING TOOLS WILL BE USED, I THINK IT'S HELPFUL TO REVISIT CIRM'S CORE, CURRENT CORE FUNDING OPPORTUNITIES. I'M SAYING CURRENT BECAUSE WE JUST APPROVED THESE FOUR PROGRAM CONCEPTS BACK IN MARCH. THE BOARD APPROVED THE NEW CONCEPTS AND AMENDED FOR CLIN2 OF THESE FOUR PROGRAMS, BUT THERE ARE OTHER PROGRAMS THAT WILL BE COMPLEMENTING THIS

PIPELINE IN THE COMING YEAR.

AS SHOWN HERE, CIRM SUPPORTS PROJECTS ACROSS THE FULL PIPELINE FROM EARLY STAGE DISCOVERY RESEARCH TO PRECLINICAL DEVELOPMENT AND INTO CLINICAL DEVELOPMENT. AND EACH STAGE HAS DEDICATED FUNDING MECHANISMS. SO DISC4 AND 5 SUPPORT EXPLORATORY AND HYPOTHESIS DRIVEN RESEARCH. THE PRECLINICAL DEVELOPMENT FUNDS PROJECTS GOING FROM LEAD OPTIMIZATION UP TO PREPARATION OF AN IND TO ENTER THE CLINIC. CLIN2 SUPPORTS EARLY TO LATE STAGE CLINICAL TRIALS OFTEN WITH COMPLEX REGULATORY AND COMMERCIALIZATION NEEDS.

SO THE ACCESSIBILITY AND AFFORDABILITY TOOLKIT THAT WE WILL SPEAK ABOUT, THAT WE WILL BE DISCUSSING TODAY, IS BEING INTEGRATED SPECIFICALLY IN THE PDEV AND THE CLIN2 PROGRAMS. THESE ARE THE STAGES WHERE EARLY SIGNALS AROUND COST, FEASIBILITY, AND REAL-WORLD BARRIERS BECOME CRITICAL. AND OUR PLANNING FOR ACCESS MUST BEGIN IN EARNEST.

SO AS WE WALK THROUGH THE TOOLS TODAY, KEEP IN MIND THAT THEY ARE DESIGNED TO BE STAGE APPROPRIATE, FLEXIBLE, AND PROPORTIONAL AS SHYAM AND JOE WILL PROVIDE. AND THEY WILL BE GUIDING BOTH APPLICANTS AND REVIEWERS IN THINKING ABOUT HOW A PROMISING THERAPY CAN ULTIMATELY REACH THE PEOPLE

THAT IT'S MEANT TO HELP.

LASTLY, I HAVE THREE MORE SLIDES. I'LL GO QUICK BECAUSE I DON'T WANT TO TAKE SO MUCH TIME FROM MY COLLEAGUES. NEXT SLIDE.

TO BUILD ON WHAT WE'VE DISCUSSED, WE PROVIDED THESE IN THE MEMO. THIS IS WHAT HELPS CLARIFY HOW CIRM DEFINES THE INTERCONNECTED ELEMENTS THAT SHAPE WHETHER PATIENTS ACTUALLY BENEFIT FROM THE THERAPIES THAT WE SUPPORT. SO TO DEFINE ACCESSIBILITY IS ABOUT WHETHER INDIVIDUALS CAN PHYSICALLY AND LOGISTICALLY OBTAIN CARE, WHICH INCLUDES GEOGRAPHIC PROXIMITY, SYSTEM NAVIGATION, AND THE AVAILABILITY OF RESOURCES.

WHEREAS, AFFORDABILITY, ON THE OTHER HAND, SPEAKS ABOUT WHETHER THAT CARE IS FINANCIALLY REALISTIC FOR PATIENTS. IT'S NOT JUST ABOUT THE PRICE TAG OR THE THERAPY. IT'S ABOUT EVERYTHING FROM REIMBURSEMENT AND COVERAGE TO THE COST OF SUPPORTIVE SERVICES LIKE TRAVEL, LODGING, AND DIAGNOSTICS.

COMMERCIALIZATION AND MARKET ACCESS ARE THE ENGINES THAT DETERMINE WHETHER PRODUCT CAN EVEN REACH THE MARKET AND BE INTEGRATED INTO THE CARE DELIVERY. AND THEY'RE ABOUT ENSURING THERAPIES DON'T JUST EXIST IN THEORY, BUT THEY ARE

MANUFACTURABLE, APPROVED REIMBURSEMENT, AND ADOPTABLE IN REAL-WORLD SETTINGS.

SO TOGETHER, WITH THESE DEFINITIONS IN OUR HANDS, WE HOPE THAT WE CAN GET TO BREAKTHROUGH THERAPIES THAT HAVE PUBLIC VALUE SO PEOPLE CAN ACCESS THEM AND AFFORD THEM.

NEXT SLIDE IS TO TRANSLATE OUR ACCESS AND AFFORDABILITY GOALS INTO ACTION. CIRM COLLABORATED WITH BLUE RIDGE LIFE SCIENCES WHO WAS OUR CONSULTANT TO DEVELOP A PRACTICAL, STRUCTURED SET OF TOOLS THAT CAN BE EMBEDDED DIRECTLY INTO OUR FUNDING PROGRAMS. AND THE FIRST ONE IS THE CHECKLIST, WHICH IS AN INTERACTIVE, PHASE-APPROPRIATE LIST OF COMMERCIALIZATION AND MARKET ACCESS ACTIVITIES THAT INFLUENCE AFFORDABILITY. AND IT WILL HELP APPLICANTS UNDERSTAND WHAT'S EXPECTED AT EACH STAGE AND GIVES STAFF AND REVIEWERS A FRAMEWORK FOR ASSESSING THOSE EFFORTS AT THE TIME OF AWARDING, BUT ALSO THROUGHOUT THE LIFETIME OF THE PROGRAM.

NEXT IS THE EVALUATION RUBRIC WHICH ASSIGNS A COMPOSITE SCORE BASED ON BOTH THE RELEVANCE AND THE EXECUTION OF THOSE ACTIVITIES. AND IT BRINGS CONSISTENCY, TRANSPARENCY, AND ACCOUNTABILITY TO HOW WE EVALUATE A AND A, ACCESSIBILITY AND AFFORDABILITY, PLANNING DURING

REVIEW ESPECIALLY FOR THE PDEV AND CLIN2 APPLICATIONS.

AND FINALLY, WE HAVE THE GUIDANCE DOCUMENTS THAT WILL SUPPORT APPLICANTS AND REVIEWERS. AND THEY CLARIFY EXPECTATIONS, PROVIDE EXAMPLES, AND HELP ALIGN ALL PARTIES FROM APPLICATION TO MILESTONE SETTING ON WHAT THE STRONG AND ACTIONABLE ACCESS PLANNING TOOLS SHOULD LOOK LIKE. SO TOGETHER THESE TOOLS ARE DESIGNED TO DRIVE EARLY, REALISTIC PLANNING AROUND PATIENT ACCESS.

LASTLY, BEFORE WE PRESENT THE TOOLKIT -- WE'RE GETTING READY, JOE -- WE WANTED TO SHARE THE QUESTIONS. I ALWAYS FEEL I'M TALKING TOO MUCH. WE WANTED TO SHARE THE QUESTIONS AHEAD OF THE DETAILS. AND WE WANT TO GATHER YOUR INPUT ON SEVERAL IMPORTANT ASPECTS OF THE ACCESSIBILITY AND AFFORDABILITY TOOLS. AND THESE QUESTIONS ARE DESIGNED TO ENSURE THAT THE FRAMEWORK IS BOTH RIGOROUS AND USABLE AND THAT IT REALLY GENUINELY ADVANCES OUR SHARED GOAL OF MAKING THESE THERAPIES, CIRM-FUNDED THERAPIES, AVAILABLE AND AFFORDABLE TO ALL CALIFORNIANS THAT NEED THEM.

SO WE WOULD LIKE YOUR THOUGHTS ON, FIRST, WHETHER THE CATEGORIES AND ACTIVITIES IN THE CHECKLIST REFLECT THE RIGHT PRIORITIES AND WHETHER

THEY ARE SPECIFIC ENOUGH TO DRIVE MEANINGFUL PLANNING, BUT FLEXIBLE ENOUGH TO FIT DIVERSE TYPES OF PROJECTS.

WE'RE ALSO ASKING WHETHER THE EVALUATION CRITERIA ARE PHASE APPROPRIATE? DO THEY ENCOURAGE THOUGHTFUL PLANNING WITHOUT OVERBURDENING APPLICANTS, ESPECIALLY AT THE EARLY STAGES?

AND FINALLY, ARE THERE ANY GAPS OR RISKS THAT WE MAY NOT HAVE ACCOUNTED FOR? ARE WE SETTING THE RIGHT BENCHMARKS? SHOULD WE ALIGN WITH INDUSTRY NORMS OR SET THE BAR HIGHER TO REFLECT CIRM'S PUBLIC MISSION?

SO YOUR FEEDBACK WILL BE CRITICAL IN DEFINING HOW WE PUT TOGETHER THESE TOOLS AVAILABLE FOR THE APPLICANTS AND REVIEWERS. AND WITHOUT FURTHER ADO, I WOULD LIKE TO NOW LEAD TO MY COLLEAGUE, DR. JOE GOLD AND MY COLLEAGUE SHYAM PATEL. GO AHEAD.

DR. GOLD: THANK YOU, ROSA. NEXT SLIDE PLEASE.

SO AS ROSA MENTIONED, WE APPROACHED BLUE RIDGE CONSULTANTS BECAUSE WE WANTED TO GET AN UNDERSTANDING OF ACTIVITIES WHICH ARE REQUIRED FOR COMMERCIALIZATION OF THESE THERAPIES. AND THEY RESPONDED WITH A LIST OF 30 ACTIVITIES THAT WERE

STAGED ACCORDING TO WHERE EXACTLY THEY WOULD FALL IN THE DEVELOPMENT CYCLE OF PROJECTS, SOME MORE POINT AT THE EARLY STAGES, SOME IN THE MIDDLE, SOME AT THE END. BUT WE ASKED THEM TO ZERO IN ON ACTIVITIES WHICH WERE REALLY GOING TO IMPACT ACCESS AND AFFORDABILITY.

AND AMONG THOSE 30 ACTIVITIES, THEY IDENTIFIED 12, SOMETHING LIKE 12, AND THEY FURTHER SUBDIVIDED THEM AS THOSE WHICH WOULD DEFINITELY HAVE AN IMPACT ON ACCESS AND AFFORDABILITY VERSUS THOSE THAT MIGHT HAVE AN IMPACT. AND THE ONES WHICH HAVE, ACCORDING TO THEM, A DEFINITE IMPACT IN THE DARKER SIDE OF RED AND THOSE WHICH MIGHT HAVE AN IMPACT IN A LIGHTER SHADE THERE.

SO IF WE GO TO THE NEXT SLIDE, WE'RE JUST GOING TO FOCUS ON THESE ACTIVITIES FOR TODAY. AND IN THE BACKGROUND ARE THE LARGER DISCUSSION OF COMMERCIALIZATION, BUT REALLY FOCUSED ON THE ACCESS AND AFFORDABILITY.

IF WE GO TO THE NEXT SLIDE, YOU CAN SEE THAT WE'VE DEVELOPED A CHECKLIST. AND WHAT IT'S DESIGNED TO DO IS TO DELINEATE WHAT ACCESS AND AFFORDABILITY IMPACTING ACTIVITIES ARE REALLY REQUIRED AT DIFFERENT STAGES. AND IN SOME CASES THESE ARE ACTIVITIES WHICH WE CAN ANTICIPATE THAT AN

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APPLICANT COMES IN WITH AT THE VERY BEGINNING OF THEIR PROCESS, THEIR APPLICATION. IN OTHER CASES THEY'RE ONES WHICH WE WOULD EXPECT THEM TO DEVELOP DURING THE COURSE OF THE APPLICATION.

SO IF YOU LOOK, YOU CAN SEE WE'VE GOT THE LIST ON THE LEFT-HAND COLUMN OF THE ACTIVITIES, AND THE ONES WHICH ARE IN BOLD ARE THE ONES WHICH WERE IDENTIFIED AS HAVING THE GREATEST IMPACT. AND WE'RE LOOKING AT SORT OF THE SPAN BETWEEN THE PRECLINICAL TO BLA STAGE REALLY. SO THERE'S THE PDEV ASPECTS OF IT WHERE WE EXPECT THEM TO HAVE REALLY VERY FEW ACTIVITIES ALREADY TACKLED IN THIS CASE, BUT WE'RE GOING TO HAVE THEM DEVELOP SOME DURING THE COURSE OF THE AWARD AS MILESTONES.

AND THEN WHEN YOU GET INTO THE CLINICAL PHASES, AGAIN, IT STARTS OUT WITH SIMPLER REQUIREMENTS AT THE BEGINNING. FOR EXAMPLE, IN THE PHASE 1 AWARDS, WE WOULD EXPECT TO ONLY HAVE ONE OF THESE ACTIVITIES DONE. BUT AS THE PROJECT MATURING ALONG, WE WOULD EXPECT THAT THEY WOULD HAVE MORE AND MORE OF THESE ACTIVITIES ACCOMPLISHED, AND WE'D BE HELPING THEM BASICALLY HIT SOME OF THESE MILESTONES IN THE COURSE OF THE AWARDS.

SHYAM.

DR. PATEL: THANK YOU, JOE. SO I'M GOING

TO FOLLOW UP ON THAT. I HOPE YOU CAN HEAR ME. I'M THE ONE IN THE BACK OVER HERE. SO ON THE NEXT THREE SLIDES, WE'RE GOING TO WALK THROUGH HOW WE ARE IMPLEMENTING THE CHECKLIST REQUIREMENTS AS WELL AS THE AWARD PROGRESS REQUIREMENTS THAT JOE MENTIONED. SO NEXT SLIDE PLEASE.

SO STARTING OFF WITH PRECLINICAL, SO AS A REMINDER, AS ROSA AND JOE INDICATED, THIS IS THE PROGRAM THAT FUNDS ALL THE PRECLINICAL DEVELOPMENT ACTIVITIES FOR THERAPEUTIC CANDIDATES UP TO AND INCLUDING IND CLEARANCE. AND SO AS JOE NOTED, THERE'S GOING TO BE A FEW THINGS THAT THEY MAY HAVE DONE OVER THE COURSE PRIOR TO SUBMITTING AN APPLICATION TO CIRM, AND THERE'S GOING TO BE A FEW CRITICAL ACTIVITIES THAT THEY HAVE TO ACHIEVE OVER THE COURSE OF THAT AWARD.

SO IN THIS PARTICULAR INSTANCE, GIVEN THAT THE SCALE AND SOPHISTICATION OF THESE ACTIVITIES IS NOT AS RIGOROUS OR AS DETAILED AS FOR THE CLINICAL PROGRAM, THE WAY THIS IS BEING IMPLEMENTED AS A PDEV PROGRAM IS THAT WE'RE INCORPORATING THOSE ACTIVITIES THAT THEY MAY HAVE DONE TO DATE INTO THE APPLICATION COMPONENTS.

SO THEY MIGHT DESCRIBE IT IN THE VALUE PROPOSITION SECTION OR THEY MAY DESCRIBE IT IN THE

PROJECT PLAN AND COMMERCIALIZATION PLAN SECTION. AND THEY WOULD ALSO INDICATE IN THAT APPLICATION PROPOSAL THE STAGE-APPROPRIATE ACTIVITIES THAT THEY PLAN TO DO OVER THE COURSE OF THE PDEV AWARD. AND THESE ARE LARGELY FOCUSED ON THINGS LIKE UNDERSTANDING THE MARKET LANDSCAPE AND THEN STARTING TO DEVELOP A REIMBURSEMENT STRATEGY BY UNDERSTANDING THE LANDSCAPE FOR THAT IN THAT PARTICULAR INDICATION FOR THAT PARTICULAR THERAPY.

SO IN TERMS OF THE REVIEW ITSELF, SO THE GRANTS WORKING GROUP CURRENTLY REVIEWS ALL PDEV APPLICATIONS. AND THEY WOULD BE REVIEWING THESE COMPONENTS AS PART OF THEIR OVERALL HOLISTIC SCORE OF WHETHER TO FUND -- WHETHER TO RECOMMEND THIS PARTICULAR PROJECT FOR FUNDING.

ULTIMATELY THAT REVIEW OUTCOME FROM THE GRANTS WORKING GROUP AND THEIR COMMENTS WILL INFORM THE CIRM TEAM RECOMMENDATION AS WELL AS THE APPROVAL BY THE ARS OF THE ICOC. THAT REVIEW FEEDBACK WE'LL ULTIMATELY PROVIDE IT TO THE APPLICANT. AND THEN THE CIRM TEAM WILL USE THAT INFORMATION TO MANAGE THE AWARDS.

IN THE NEXT SLIDE I'M GOING TO GO OVER THE CLINICAL SIDE. SO IN THE CLINICAL SIDE, AS JOE MENTIONED, DEPENDING ON WHAT PHASE OF TRIAL THEY'RE

COMING IN, THERE'S GOING TO BE A LARGER NUMBER OF ACTIVITIES THEY MUST HAVE COMPLETED PRIOR TO REQUESTING FUNDING FOR THE CURRENT CLINICAL TRIAL. AND THERE'S GOING TO BE A SIGNIFICANT NUMBER OF ACTIVITIES THAT THEY SHOULD BE CONDUCTING OVER THE COURSE OF THAT TRIAL. GIVEN THAT RISE IN SCALE AND SOPHISTICATION ACROSS DIFFERENT CLIN2 AWARDS, AS WELL AS THAT IT'S DIFFERENT FROM PDEV, WE TOOK A DIFFERENT APPROACH HERE.

SO HERE THEY WOULD BE PROVIDING THE ACTIVITIES THEY'VE COMPLETED TO DATE IN MORE OF A CHECKLIST SORT OF FORMAT SO THAT IT MAKES IT EASIER FOR EVALUATION. AND THEY'LL ALSO BE PROVIDING THEIR PLAN FOR ACHIEVEMENT OF THOSE ACTIVITIES SIMILAR TO THE PDEV PROGRAM.

THE INITIAL CIRM REVIEW, THE ELIGIBILITY REVIEW THAT WOULD BE DONE WOULD LOOK TO MAKE SURE THAT THEY'VE COMPLETED THOSE ITEMS, THAT THEY PROVIDED SOME INFORMATION THAT CAN BE REVIEWED. AND WHEN IT GOES TO THE GRANTS WORKING GROUP REVIEW, INSTEAD OF THE GRANTS WORKING GROUP REVIEWING THESE CHECKLIST ITEMS, THERE WILL BE A SPECIALIST CONSULTANT WHO HAS SPECIFIC EXPERTISE IN THESE AREAS WHO WILL BE REVIEWING THOSE APPLICATIONS FOR COMPLETENESS AND ADEQUACY OF WHAT THEY'VE ACHIEVED

TO DATE AS WELL AS WHAT THEY PLAN TO PROPOSE TO CONDUCT OVER THE COURSE OF THE CLINICAL TRIAL.

NOW, EACH OF THOSE ACTIVITIES WILL BE SCORED, AND I WILL SHOW YOU THAT RUBRIC IN THE NEXT SLIDE. AND THEN THEY'LL ALSO PROVIDE QUALITATIVE ASSESSMENTS OF THE ACTIVITIES IN THE OVERALL PLANNING THAT WOULD BE INFORMATIVE FOR THE APPLICANT, FOR CIRM, AS WELL AS FOR THE BOARD.

SO ULTIMATELY THE SPECIALIST ASSESSMENT OF COMPLETED ACTIVITIES AS WELL AS PLANNED ACTIVITIES IS GOING TO INFORM THE GRANTS WORKING GROUP RECOMMENDATION, IT'S GOING TO INFORM THE CIRM TEAM RECOMMENDATION, AS WELL AS THE ICOC/ARS APPROVAL.

THE CONSULTANT FEEDBACK, SIMILAR TO PDEV, WILL BE PROVIDED TO THE APPLICANT. SO THEY'LL HAVE ACTIONABLE FEEDBACK AS PART OF THIS PROCESS. AND FINALLY, ALL OF THIS INFORMATION WILL BE INFORMATIVE FOR CIRM AS IT MANAGES ANY APPROVED AWARDS THAT MIGHT COME OUT OF THIS.

SO NEXT SLIDE IS A QUICK WALK-THROUGH OF THE RUBRIC ITSELF. SO AS ROSA MENTIONED, THERE IS A CHECKLIST THAT IDENTIFIES ALL THE ACTIVITIES. IT IDENTIFIES THE IMPORTANCE OF THOSE ACTIVITIES, THEIR ACHIEVING THEM, AS WELL AS PRACTICAL WAYS TO ACHIEVE THOSE ACTIVITIES.

WHEN THE SPECIALIST CONSULTANT SCORES THESE, WHAT THEY'RE DOING IS THAT THEY'RE USING A FIVE-POINT SCALE TO SCORE WHAT THEY'VE DONE TO DATE. THIS COULD RANGE FROM NOT HAVING STARTED THE ACTIVITY AT ALL TO HAVING COMPLETED IT IN THE LAST 12 MONTHS. SO THERE'S BOTH A COMPLETENESS AS WELL AS AN ADEQUACY CHECK AS PART OF THAT INDIVIDUAL ACTIVITY RUBRIC.

NOW, ALL THE ACTIVITIES HAVE DIFFERENT PRIORITY SCORES BASED ON WHETHER THEY SHOULD HAVE BEEN DOING THEM AT THIS PARTICULAR STAGE OR A LATER STAGE. AND WHAT ENDS UP HAPPENING IS THAT THE INDIVIDUAL SCORE FOR EVERY ACTIVITY PLUS ITS PRIORITY SCORE IS AGGREGATED TO CREATE AN OVERALL AGGREGATE COMPOSITE SCORE THAT IS A QUICK CHECK TO DETERMINE HOW MUCH PROGRESS HAS THIS APPLICANT MADE TO DATE ON THESE ACTIVITIES AND TO WHAT LEVEL HAVE THEY DONE THAT. THAT SHOULD BE INFORMATIVE FOR THE GRANTS WORKING GROUP, FOR CIRM, AS WELL AS THE ARS.

ON TOP OF THAT, THE SPECIALIST CONSULTANT IS ALSO PROVIDING WRITTEN FEEDBACK ON AREAS THAT MAY BE GAPS OR AREAS OF IMPROVEMENT OR AREAS WHERE THEY'RE AHEAD OF THE GAME. ALL OF THAT WILL BE ALSO USEFUL AS WELL. NEXT SLIDE PLEASE.

SO AFTER THE AWARDS HAVE BEEN APPROVED,

DURING THE AWARD MANAGEMENT PHASE, WE ARE ALIGNING BETWEEN THE TWO PROGRAMS ON HOW THESE ACTIVITIES ARE GOING TO BE TRACKED AND SUPPORTED AND MANAGED. SO FOR BOTH PROGRAMS, WE WILL FUND THE STAGE-APPROPRIATE, ALLOWABLE ACCESS AND AFFORDABLE ACTIVITIES. THE APPLICANTS CAN REQUEST FUNDING FOR THOSE ACTIVITIES.

OVER THE COURSE OF THE AWARD, THE AWARDEE WILL BE PROVIDING A PROGRESS REPORT ON THOSE ACTIVITIES. THEY ALREADY PROVIDE PROGRESS REPORTS FOR SCIENTIFIC ACTIVITIES. THEY'LL BE INCORPORATING ACTIVITY PROGRESS ALONG THE WAY AS WELL.

THE SPECIFIC ACCESS AND AFFORDABILITY ACTIVITIES THAT JOE SHOWED IN HIS CHECKLIST EARLIER WILL ACTUALLY BE INCORPORATED INTO THE AWARD MILESTONES. SO THEY'LL BE PART OF WHAT THE SCIENCE OFFICERS REVIEW TO ALLOW THAT PROJECT TO MOVE ON TO THE NEXT MILESTONE TO GET THE NEXT DISBURSEMENT OF CIRM FUNDING.

AND FINALLY, AT THE END OF THE AWARD, THE AWARDEE WILL PROVIDE A FINAL OVERALL REPORT OF ALL THE ACTIVITIES THAT THEY HAVE CONDUCTED TO DATE, AND THAT SHOULD BE INFORMATIVE AND PREPARATORY FOR THEM TO APPLY FOR THE NEXT STAGE OF CIRM FUNDING BECAUSE IT HELPS THEM MEET ALL THE CHECKLIST REQUIREMENTS

FOR THE NEXT STAGE OF CIRM FUNDING.

NEXT SLIDE PLEASE. SO WITH THAT, I'M GOING TO TURN IT BACK OVER TO DR. GOLD FOR THE DISCUSSION.

DR. GOLD: THANKS, SHYAM. SO WHAT WE'RE SEEKING IS SOME FEEDBACK HERE. AND I HOPE YOU'VE HAD A CHANCE TO LOOK AT THESE MATERIALS BECAUSE IT'S OBVIOUSLY VERY DIFFICULT TO READ THEM OFF THE SLIDES. WHAT WE'RE TRYING TO UNDERSTAND ARE THESE CATEGORIES COMPREHENSIVE? DO YOU THINK THESE ARE THE RIGHT ACTIVITIES WE SHOULD BE FOCUSING ON? AND DO WE HAVE THEM AT THE APPROPRIATE STAGES? ARE THERE GAPS IN HOW THESE TOOLS MIGHT BE APPLIED?

AND WE'RE REALLY ALSO VERY INTERESTED IN WHAT KIND OF BENCHMARKS COULD BE SET. WE'VE STRUGGLED WITH THIS ITEM BECAUSE, FOR EXAMPLE, DO WE WANT TO SAY THAT IT'S GOOD ENOUGH FOR A NEW THERAPY TO MEET THE INDUSTRY STANDARD FOR ACCESS AND AFFORDABILITY? WOULD THAT BE BETTER THAN THE CURRENT THERAPY? WHAT IF IT'S A NEW TRANSFORMATIVE THERAPY? WHAT IF IT'S SOMETHING CURATIVE WHERE THE PREVIOUS THERAPY WAS ONLY TREATING SYMPTOMS? IS IT OKAY THEN IF IT'S THE INDUSTRY STANDARD FOR ACCESS AND AFFORDABILITY?

THESE ARE THE KIND OF QUESTIONS WE'RE

ASKING FOR SOME FEEDBACK ON. WE'D APPRECIATE THAT.

VICE CHAIR BONNEVILLE: THANK YOU SO MUCH, JOE, ROSA, AND SHYAM.

SO I WANT TO OPEN THIS UP TO THE WORKING GROUP FOR ANY QUESTIONS OR THOUGHTS AROUND THE DISCUSSION ITEMS.

DR. LAKADAWALLA: I'LL JUMP IN. I THOUGHT THIS WAS WELL DONE. I THINK THESE ARE THE RIGHT CATEGORIES. THEY MAKE SENSE.

IN TERMS OF THE LAST QUESTION ABOUT INDUSTRY STANDARD VERSUS ABOVE AND BEYOND, I ACTUALLY THINK THAT IF CIRM GRANTEES, AWARDEES ARE FOLLOWING INDUSTRY STANDARDS, THEY ACTUALLY KIND OF ARE ABOVE AND BEYOND WHEN YOU ACCOUNT FOR THE FACT THAT THEY'RE TYPICALLY SMALL BIOTECHS WHO ARE OFTEN NOT DOING THE SAME KIND OF ROBUST ANALYSES THAT A LARGE PHARMA COMPANY IS DOING. AND INDUSTRY STANDARD REALLY IN MUCH OF WHAT YOU'VE LISTED IS KIND OF MORE TOWARDS WHAT YOU WOULD EXPECT FROM A FAIRLY SOPHISTICATED, LARGE PHARMA COMPANY.

SO I THINK YOU'RE ALREADY KIND OF SETTING, I DON'T THINK IT'S AN UNREASONABLY HIGH BAR, BUT I THINK IT IS A HIGH BAR, AND IT'S A USEFULLY HIGH BAR FOR THESE KINDS OF THERAPIES.

THE ONLY THING THAT I'VE ALWAYS EMPHASIZED

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IS IT'S REALLY USEFUL TO GET THESE COMPANIES THINKING ABOUT THE PROVIDER LANDSCAPE AS PART OF THEIR ACCESS STRATEGY. I THINK THAT'S JUST A DETAIL THAT WOULD NEED TO BE COMMUNICATED AS PEOPLE DEVELOP THEIR PLANS.

VICE CHAIR BONNEVILLE: THANK YOU, DARIUS. PAT.

DR. LEVITT: YEAH. SO THERE ARE A LOT OF ACTIVITIES LISTED. I'M JUST WONDERING WHAT THE EXPECTATIONS ARE OR AT LEAST IN TERMS OF INSTRUCTIONS GOING TO APPLICANTS ABOUT WHAT THE EXPECTATIONS ARE IN TERMS OF HOW MANY ACTIVITIES AND A CHECKLIST OF STARTING AND WHERE THEY ARE IN TERMS OF TIME OF ACCOMPLISHING ACTIVITY. I GUESS THEY'LL DESCRIBE THE ACTIVITY. IT SOUNDED LIKE THERE'S GOING TO BE A SINGLE CONSULTANT OR EXPERT THAT'S GOING TO EVALUATE THE QUALITY OF WHAT IS BEING PROPOSED IN EACH OF THE ACTIVITIES.

I MEAN I'M NOT -- I HAVE NO EXPERTISE IN THIS AREA, BUT I READ SOME OF THESE ACTIVITIES AND THEY'RE SO BROADLY DEFINED. LIKE A MARKET, YOU CAN DO MARKET ANALYSES THAT ARE REALLY DETAILED AND TAKE TIME AND ARE REALLY QUITE GOOD IN TERMS OF QUALITY OF THE ANALYSIS, AND THEN YOU CAN DO THINGS THAT ARE RELATIVELY SUPERFICIAL AND NOT VERY GOOD.

SO MAYBE A LITTLE BIT OF CLARITY AROUND THAT, LIKE HOW MANY OF THESE ACTIVITIES DO YOU WANT TO SEE AND IS THERE A PRIORITY AND HOW IS THE CONTENT AS OPPOSED TO STARTING AND MAKING PROGRESS GOING TO BE EVALUATED?

DR. GOLD: SURE. THOSE ARE VERY GOOD QUESTIONS. AND ONE THING WE DID NOT SHOW HERE WAS SORT OF THE GUIDANCE DOCUMENTS WE'RE BUILDING TO HELP THE APPLICANTS. SO IT WILL LIST THE ACTIVITIES, IT WILL LIST -- DEFINE THEM. IT WILL TELL THEM HOW THEY MIGHT ACCOMPLISH THEM. AND IT WILL TELL THEM IN WHAT STAGE WE EXPECT THEM TO HAVE THESE ACTIVITIES COMPLETED VERSUS WE'LL BE WORKING WITH THEM TO DEVELOP THEM.

AND WITH REGARD TO HOW IT WILL BE EVALUATED, WE'RE GOING TO HAVE MORE THAN ONE CONSULTANT FOR THIS. WE HAVE TO HAVE A POOL REALLY TO PULL UPON IN CASE THERE'S ANYBODY CONFLICTED FOR A PARTICULAR APPLICATION. BUT THEY WILL BE EVALUATING, AS SHYAM POINTED OUT, NOT JUST WHETHER OR NOT SOMEONE HAS DONE AN ACTIVITY OR THEY STARTED AN ACTIVITY, BUT HOW WELL THEY'VE DONE IT, HOW COMPLETE IT IS.

SO WHAT WE'RE REALLY LOOKING TO DO HERE IS NOT TO RULE PEOPLE OUT, BUT TO HELP EDUCATE THEM AND

BRING THEM ALONG BECAUSE I THINK WE WOULD ALL AGREE THAT IF WE HAVE SOMETHING THAT HAS GREAT SCIENCE AND GREAT MEDICINE BEHIND IT, IT JUST NEEDS TO BE TWEAKED TO MAKE IT MORE ACCESSIBLE AND AFFORDABLE TO PATIENTS. THERE'S WAYS OF DOING THAT. THERE'S CONSULTANTS WE CAN BRING IN. THERE'S ADVICE WE CAN GET FOR THEM. SO WE REALLY WANT TO GET THAT FEEDBACK TO THEM SO THEY CAN IMPROVE WHAT THEY'RE SUBMITTING TO US SO WE CAN FUND IT.

DR. LEVITT: YEAH. SO I WOULD IMAGINE, THEN, THAT THE PROGRESS REPORTS WHERE THEY'RE GOING TO REPORT BACK, INCLUDING THE SCIENCE THAT THEY'RE DOING, BUT ALSO THESE EFFORTS IN TERMS OF ACTIVITIES ARE GOING TO BE INCLUDED AT SOME LEVEL OF DETAIL THAT'S GOING TO BE ABLE TO BE EVALUATED IN TERMS OF PROGRESS, RIGHT?

DR. GOLD: ABSOLUTELY CORRECT. AND THE ACTIVITIES WHICH WE'RE NOT REQUIRING THEM TO COME IN WITH, DEPENDING ON WHAT STAGE THEY'RE AT, THEY WILL HAVE TO ACHIEVE THEM. THOSE WILL BE OBJECTIVE MILESTONES THEY'RE GOING TO HAVE TO HIT. SO IT WILL REALLY BE A FOCUS OF THEIR ACTIVITIES.

DR. LEVITT: OKAY. THANKS.

VICE CHAIR BONNEVILLE: HARLAN.

DR. LEVINE: YEAH. AND PAT MAY HAVE

ADDRESSED MY QUESTION. IS THIS ALL SELF-ASSESSMENT? AND IF IT IS SELF-ASSESSMENT, TO WHAT DEGREE WILL CIRM DO SOME AUDITING OR OTHERWISE REVIEW THE SELF-ASSESSMENT?

DR. GOLD: SELF-ASSESSMENT DURING THE PROGRESS REPORTS, DO YOU MEAN?

DR. LEVINE: YEAH. LIKE FILLING OUT THE CHECKLIST, IS IT -- ARE THE INVESTIGATORS OR THE APPLICANTS FILLING OUT THE CHECKLIST? OR IS IT A DIALOGUE WITH CIRM TO DECIDE WHAT THE RIGHT ANSWER SHOULD BE, WHAT THE CORRECT CHECKMARK SHOULD BE?

DR. CANET-AVILES: IT'S NOT SELF-ASSESSMENT. THEY WILL BE FILLING UP AND WE WILL BE EVALUATING AND WE WILL HAVE CONSULTANTS TO HELP US ADVISE OR FIGURE OUT WHETHER CERTAIN ACTIVITIES WERE SUPPOSED TO BE DONE OR THOUGHT OF AT THAT STAGE OR NOT. RIGHT?

SO, NO, THERE'S NO SELF-ASSESSMENT. WE WILL BE SUPPORTING THEM. AS JOE REMARKED, THIS IS ALL ABOUT EDUCATING AND HELPING. IT'S NOT ABOUT TRYING TO CATCH THEM ON SOMETHING. RIGHT? IT'S ABOUT TRYING TO FIGURE OUT HOW ARE WE GOING TO EDUCATE OUR GRANTEES AND APPLICANTS INTO WHAT DO THEY NEED TO HAVE IN ORDER TO MAKE SURE THAT THIS WILL BE REACHING THE RIGHT PATIENTS OR THE PATIENTS

THAT NEED THE THERAPY ONCE DEVELOPED.

DID WE ANSWER YOUR QUESTION, HARLAN?

DR. LEVINE: YOU DID. I THINK I MISSED THE POINT THAT THIS IS OUR EVALUATION OF -- THIS IS OUR CHECKLIST. THIS IS NOT -- I ASSUME -- SELF-ASSESSMENT REALLY WASN'T WHAT I MEANT. I ASSUME THAT WE WERE DOING THE CHECKLIST OFF OF INFORMATION THEY SUBMITTED TO US. SO I WAS JUST TRYING TO FIGURE OUT ARE WE -- HOW ARE WE VALIDATING THE INFORMATION THAT'S SUBMITTED, BUT I THINK YOU'VE ANSWERED THE QUESTION THAT I WAS ASKING.

DR. LEVITT: CAN I JUST FOLLOW UP ON SOMETHING? WHEN YOU LOOK AT THE DIFFERENT ACTIVITIES, THEY HAVE, AT LEAST FROM MY PERSPECTIVE, OVERLAPPING, BUT NOT IDENTICAL EXPERTISE THAT'S NEEDED IN ORDER TO PULL THEM OFF. RIGHT? AND SO HOW IS THE -- I'M NOT FAMILIAR. HOW IS THE BUDGET ORGANIZED OR STRUCTURED IN A WAY WHERE THE TEAMS ARE GOING TO HAVE THE TALENT TO BE ABLE TO DO SOME OF THESE ACTIVITIES BECAUSE IT'S NOT GOING TO BE A SINGLE PERSON EMBEDDED WITHIN A FUNDED PROJECT THAT'S GOING TO BE ABLE TO HAVE EXPERTISE TO DO ALL OF THESE BECAUSE THERE ARE THINGS ABOUT MARKETING AND COMMERCIALIZATION THAT ARE NOT IDENTICAL IN TERMS OF UNDERSTANDING HOW TO DO THOSE EVALUATIONS

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WELL? SO HOW IS THE BUDGET STRUCTURED IN A WAY WHERE THEY'RE GOING TO HAVE THE TALENT TO BE ABLE TO PULL THIS OFF?

DR. PATEL: SO YOU'RE ASKING ABOUT THE AWARDEE AND HOW THEY MIGHT EXECUTE ON THE ACTIVITIES?

DR. LEVITT: YES. UH-HUH.

DR. PATEL: THAT'S A GOOD QUESTION. SO THEY WOULD HAVE TO -- IN SOME INSTANCES THEY MIGHT HAVE SOME IN-HOUSE MEMBERS WHO MAY BE ABLE TO DO SOME OF THAT, BUT YOU'RE RIGHT, THAT IT COVERS A BROAD RANGE. AS JOE POINTED OUT, YOU'VE GOT HOER, YOU HAVE MARKETING. YOU HAVE MARKET ACCESS ELEMENTS AND THEN COMMERCIALIZATION ELEMENTS AS WELL. SO IN THOSE PARTICULAR INSTANCES, THERE'S SOME OTHER OPTIONS THEY CAN LEVERAGE. THEY CAN LEVERAGE INSTITUTIONAL SUPPORT IF THERE IS A STAFF ON THE INSTITUTIONAL LEVEL. AND THERE ARE A RANGE OF CONSULTANTS THAT THEY CAN ALSO WORK WITH.

ON OUR SIDE ONE OF THE THINGS THAT WE ARE DOING IS THAT WE ARE ENGAGING WITH DIFFERENT CONSULTANTS IDENTIFYING WHAT THEIR STRENGTHS ARE AND THEN BEING ABLE TO PROVIDE SOME OF THESE RESOURCES THAT POTENTIAL APPLICANTS CAN USE IF THEY WANT TO. BUT AT THE END OF THE DAY, THEY'D HAVE TO BUDGET FOR

THOSE ACTIVITIES WITHIN THE AWARD WITH RESPECT TO ALL THE OTHER ACTIVITIES THAT THEY NEED TO DO IN ORDER TO GET TO THE OBJECTIVE OF THAT AWARD.

VICE CHAIR BONNEVILLE: THANK YOU, SHYAM. ADRIANA.

DR. PADILLA: YES. THANK YOU. I LIKE THE STRUCTURE. I THINK IT'S WELL STRUCTURED. I HAD A QUESTION ONLY BECAUSE I SIT ON THE GWG. THE MARKET ACCESS STRATEGY, WE'RE HAVING CHALLENGES ON THE ACCESS TO DIFFERENT PROJECTS IN THE CLINICAL LEVEL BECAUSE THAT'S WHERE I SIT ON THE GWG IS ON THE CLINICAL SIDE. AND SO WHO IS IN CHARGE OF MAKING SURE THAT ALL OF THE ACCESS TO THE APPROPRIATE POPULATION THAT THIS IS GOING TO AFFECT? IS IT THE REVIEW? IS IT THE RESEARCH PROJECT PERSON? IS IT CIRM OR WHO?

DR. CANET-AVILES: THIS IS GOING TO BE A MIX. I THINK THERE WILL BE A MIX BETWEEN THE PROGRAMS TEAM HOW WE ARE RIGHT NOW. AS YOU'VE VOTED, WE'VE AMENDED THE CONCEPT FOR CLIN2 AND WE ARE IMPLEMENTING ON OUR PROMISE. AND GIL SAMBRANO HAS BEEN LEADING, TOGETHER WITH OUR PRESIDENT, THE NEW PATIENT POPULATION IMPACT EFFORT, WHICH IS GOING TO BE INTEGRATED INTO THE NEW LIKE PROGRAMS, THE APPLICATIONS, THE REVIEW CRITERIA. RIGHT? SO

THAT'S GOING TO BE INTEGRAL TO THAT.

AND AT THE SAME TIME ACCESSIBILITY AND AFFORDABILITY WILL BE AS WE ARE PRESENTING TODAY AN INTEGRAL COMPONENT OF THE REVIEW OF THE APPLICATIONS FOR CLINICAL. RIGHT? AND PRECLINICAL IN AN EARLIER STAGE. RIGHT? SO THAT WILL ALL BE INTEGRATED BETWEEN PROGRAMS REVIEW AND THE NEW EFFORT WITH THE POPULATION IMPACT -- PATIENT POPULATION IMPACT THAT WE ARE DOING.

DOES THAT ANSWER YOUR QUESTION, ADRIANA?

DR. PADILLA: YEAH. SO I THINK WHAT I WAS GETTING AT IS THERE'S GOING TO BE A STRONG EMPHASIS ON POPULATION IMPACT; WHEREAS, US AS REVIEWERS, WE'RE MORE NEEDING TO LOOK AT IT FROM THE DEI, WHICH IS NOW OUT THE DOOR, BUT POPULATION IMPACT IS -- I JUST WANTED TO KNOW HOW WELL THAT'S GOING TO BE ASSESSED FOR THESE PROJECTS COMING THROUGH IN THE CLINICAL REALM.

DR. CANET-AVILES: MAY I REFER TO MY COLLEAGUE?

DR. GOLD: I DON'T KNOW HOW TO ANSWER.

DR. CANET-AVILES: I THINK WHAT WE CAN SAY IS THAT WE ARE DEVELOPING THE PROCESSES AND THAT IT'S GOING TO BE INTEGRAL TO OUR NEW WAY OF REVIEWING, THAT WE WILL NOT BE LOSING THE MEANING OF

THE GOAL. RIGHT? I DON'T KNOW IF ANYBODY WANTS TO ANSWER.

DR. THOMAS: YEAH. I'D JUST ADD TO THAT THAT WHILE WE'RE NOT USING PERHAPS THAT SPECIFIC TERMINOLOGY, THE CORE VALUE, WHICH IS THAT ANYTHING WE FUND NEEDS TO ULTIMATELY BE SOMETHING THAT WOULD BE ACCESSIBLE TO ALL AFFECTED COMMUNITIES OR THE PARTICULAR DISEASE IN QUESTION, IS GOING TO BE PART AND PARCEL OF WHAT ARE THE KEY THINGS TO EVALUATE ACROSS THE BOARD IN ANY REVIEW. AND SO WE'RE JUST IN THE PROCESS OF WORKING OUT SOME OF THE DETAILS OF THAT, BUT THIS IS NOT A DEVIATION FROM WHERE WE'VE BEEN IN THE PAST. IT'S HONING IN ON THE SPECIFIC CORE VALUE OF GREATEST IMPORTANCE.

DR. PADILLA: IT'S FROM THIS PART OF THE GOALS WE'LL BE REVIEWING THE -- WE'LL BE TAKING IT OVER AND REVIEWING THE APPLICATIONS FOR APPROPRIATENESS THEN? IT'S NOT GOING TO BE THE GWG REVIEWERS, BOARD MEMBERS?

DR. THOMAS: GIL, DO YOU WANT TO --

DR. SAMBRANO: I DON'T KNOW WHAT SHE'S ASKING.

DR. THOMAS: SHE'S ASKING IF IT'S GOING TO BE THE GWG MEMBERS, SAY THE 15, ARE THE ONES WHO WILL BE EVALUATING THE ACCESSIBILITY ASPECT OF THE

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APPLICATION.

DR. PADILLA: -- PART OF THIS DISCUSSION, AND I'M SORRY ABOUT THAT. SO MY APOLOGY IF IT'S NOT.

DR. SAMBRANO: ADRIANA, WE'RE STILL WORKING OUT THE PROCESS. SO THE ELEMENTS -- THERE ARE SOME ELEMENTS, PARTICULARLY IN PDEV, WHERE I THINK SHYAM POINTED OUT THAT THE GWG WOULD BE EVALUATING THE ACCESS AND AFFORDABILITY PART. IN CLIN WE ARE STILL WORKING THROUGH BECAUSE IT'S A BIT MORE COMPLEX AS TO WHERE THAT COMES IN.

THE POPULATION IMPACT IS IDENTIFIED AS A SEPARATE REVIEW CRITERION THAT THE GWG WOULD CONTINUE TO EVALUATE IN BOTH CASES.

DR. PADILLA: I JUST NEEDED SOME CLARIFICATION. SO I GOT CONFUSED ABOUT THAT PROCESS OF THIS PART OF THE GOAL.

VICE CHAIR BONNEVILLE: THANK YOU. AMMAR.

DR. QADAN: THANK YOU. I WOULD GO TO THE LIST OF QUESTIONS HERE AND ANSWER THEM QUICKLY. THE CATEGORIES ARE VERY COMPREHENSIVE. AS DARIUS PROBABLY MENTIONED, THAT THIS IS BECOMING STANDARD WITHIN THE INDUSTRY. AND SO IT IS VERY COMPREHENSIVE.

ARE THE ACTIVITIES IDENTIFIED AS IMPACTING

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ACCESS AND AFFORDABILITY APPROPRIATE? THEY'RE VERY APPROPRIATE.

AND THE EVALUATION CRITERIA IS MEANINGFUL AND APPROPRIATE BY PHASE.

TWO THINGS AROUND THE LAST TWO QUESTIONS. THE GAPS AND RISKS, I THINK THE MAIN RISK THAT COMES TO MIND IS THE DEPTH THAT YOU CAN GO IN THOSE CATEGORIES BECAUSE THAT NEEDS A LOT OF EXPERTISE, BUT AT LEAST THINKING ABOUT THEM TO START WITH IS CRITICAL. AND SO THERE WILL BE ALWAYS THAT RISK OF THE DEPTH ASSOCIATED WITH THE ANALYSIS AND THE ASSESSMENT THEY DO.

AND THE LAST QUESTION, THERE ARE ALSO MANY BENCHMARKS TODAY WHETHER IT IS PUBLISHED OR PRESENTED. MANY OF THOSE COMPANIES CAN REFER ALSO TO WHETHER IT IS THE HEALTH TECHNOLOGY ASSESSMENT OF SOME OF THOSE TECHNOLOGIES, WHETHER IN THE U.S. WITH ORGANIZATIONS LIKE ISSCR OR EVEN OUTSIDE THE U.S., JUST TO THINK ABOUT HOW HEALTHCARE SYSTEMS THINK ABOUT ACCESS AND AFFORDABILITY WHEN IT COMES TO THOSE INNOVATIONS. SO GREAT TOOL, DEFINITELY. THANK YOU.

VICE CHAIR BONNEVILLE: THANK YOU, AMMAR. LIZ.

DR. BOILIEU: JUST A QUICK SORT OF

FOLLOW-UP QUESTION TO ADRIANA'S QUESTIONS ABOUT HOW THE GWG MIGHT BE LOOKING AT THIS. AS I LISTEN TO THIS, AFTER READING THROUGH THE MATERIALS, QUESTION COMES TO MIND IS WHEN WE'RE TALKING ABOUT THE MARKETABILITY AND WE'RE REALLY TALKING ABOUT BRINGING THESE PRODUCTS TO MARKET, IN WHICH AREAS WE SCORE FOLKS WHEN WE'RE -- AND I'M THINKING MORE IN THE CLINICAL 2, 3, AND 4 PHASES WITH REGARDS TO REIMBURSEMENT AND PI'S BEGINNING TO ACTUALLY GENERATE REVENUE FOR THESE SERVICES. ARE WE ASKING THEM TO BE ABLE TO TELL US THAT WHILE IT'S STILL IN CLINICAL TRIAL OR THEIR ASSESSMENT OF WHAT WILL BE THE AFFORDABILITY OF THE PRODUCT IF IT WERE TO BE ABLE THEN TO GO TO MARKET IF THAT MAKES SENSE?

DR. GOLD: I'LL TAKE THE LATTER. REALLY THE ULTIMATE GOAL WOULD BE YOU HAVE TO PREDICT.

DR. BOILIEU: OKAY.

DR. GOLDSTEIN: SO IT'S GOING TO BE A PREDICTION. IT'S NOT GOING TO BE VERIFIABLE.

DR. BOILIEU: OKAY. THE ONLY REASON I BRING THE QUESTION UP IS THEN LISTENING TO IT AND THEN READING THE MATERIALS IS CERTAINLY WHAT WE HAVE GOING FOR US IS ANYTHING THAT THE FDA ULTIMATELY APPROVES, FROM WHAT I'VE SEEN IN OUR MARKETPLACE IN THE STATE OF CALIFORNIA IS THAT ALL PAYERS WOULD

JOIN IN AND COVER THAT SERVICE OR PRODUCT, WHICH IS GREAT.

IT'S IN THE CLINICAL DEVELOPMENT PHASE THAT WE RUN INTO TROUBLE WITH HOW DO THE RESEARCHERS FUND WHAT THEY'RE DOING BECAUSE THEY AREN'T INDUSTRY. THEY DON'T HAVE MILLIONS OF DOLLARS BEHIND THEM THAT ALLOWS THEM TO BUILD THROUGH THE PHASES. RIGHT? IF WE ALWAYS LISTEN TO THE NEWS AS TO HOW INDUSTRY ALWAYS HAS TO RECOUP THEIR RESEARCH AND DEVELOPMENT, OUR PROVIDERS THROUGH OUR SYSTEMS ARE DOING THAT ON A SHOESTRING BASICALLY COMPARED TO WHAT INDUSTRY COULD DO. SO TRYING TO THEN ASCERTAIN HOW MUCH SUPPORT WE CAN PROVIDE THEM THROUGH THAT CLINICAL DEVELOPMENT BECAUSE ONCE WE GET IT TO MARKET OR SOMEONE GETS SOMETHING TO MARKET, I THINK WE WILL BE ABLE TO MEET OUR GOAL OF THAT ACCESSIBILITY AND AFFORDABILITY ACROSS ALL MARKET SEGMENTS.

AND HOPEFULLY, AND I KNOW THE GOAL IS CAN WE THEN BE ABLE TO DO THAT AT A MUCH LOWER RATE THAN MAYBE WHAT'S HAPPENING NOW. I THINK OF THE CAR-T WORK THAT THE ALPHA CLINICS ARE WORKING ON NOW, RIGHT, AND CAN WE BRING THAT TO A LOWER PRICE POINT IN THE MARKET, WHICH ACTUALLY MAKES IT FAR MORE AFFORDABLE FOR ALL MARKET SEGMENTS.

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SO I JUST WANTED TO CLARIFY THAT POINT. THANKS FOR THAT BECAUSE I THINK I WANT TO MAKE SURE THAT WE DON'T PUT TOO MUCH OF AN ONUS ON THE PI'S TO TRY AND MAKE SURE THAT THEY'RE FULLY FUNDED AND HAVE ALL THAT THEY NEED THROUGH THEIR CLINICAL TRIAL JUST BECAUSE I THINK THAT'S A HUGE LIFT, AND I DON'T THINK WE HAVE THE RESOURCES TO DO THAT FOR THEM. AND I DON'T WANT THEM TO THINK THEY SHOULDN'T BE REACHING AFTER SOMETHING SIMPLY BECAUSE OF THAT.

VICE CHAIR BONNEVILLE: THANK YOU. I REALLY -- I ALSO WANT TO STOP FOR A MOMENT AND REFLECT ON THIS IS REALLY GOING TO BE A DIFFERENT WAY OF LOOKING AT WHAT WE FUND MOVING FORWARD FOR US AS AN ORGANIZATION AND FOR THE APPLICATION REVIEW SUBCOMMITTEE AND THE BOARD TO TAKE INTO ACCOUNT BECAUSE NOW WE'RE GOING BEYOND IS IT SCIENTIFICALLY MERITORIOUS, BUT ALSO DO WE SEE THIS MOVING FORWARD AND BEING COMMERCIALIZED AND GETTING TO PATIENTS. AND I THINK THAT THAT'S REALLY GOING TO TAKE AN EDUCATION FOR US AS A BOARD AND FOR THE APPLICATION REVIEW SUBCOMMITTEE TO UNDERSTAND WHAT THAT MEANS NOW AND HOW WE DETERMINE ALL OF THAT AND HOW WE EVALUATE IT.

SO THIS IS SOMETHING THAT WE REALLY WILL NEED TO SPEND SOME TIME ON. AND, AGAIN, WHAT THAT

REVIEW PROCESS LOOKS LIKE AND HOW IS IT DIFFERENT NOW? AND I THINK THAT THAT'S JUST IMPORTANT TO MESSAGE AND SO THAT EVERYONE IS UNDER THE SAME UNDERSTANDING OF WHAT THIS MEANS.

HARLAN.

DR. LEVINE: YEAH. SO I THINK THAT'S A GREAT POINT THAT YOU MADE. I CAN TELL YOU FROM OUR EXPERIENCE WHERE WE WERE -- SHIFTED THE PENDULUM BETWEEN OUR EMPHASIS. SO THIS ISN'T ACROSS ALL OF CITY OF HOPE, BUT A SPECIFIC AREA WHERE WE FUNDED SPECIAL PROJECTS THAT WE THOUGHT HAD COMMERCIAL VALUE, WE WENT THROUGH A SHIFT FROM FOCUS ON, YEAH, GOOD SCIENCE AND COMMERCIAL VALUE TO MORE TOWARDS COMMERCIAL VALUE. WE FOUND OUT THAT OUR EXTERNAL ADVISORY TEAM NEEDED TO HAVE SOME MODIFICATIONS AND BRING IN THAT EXPERTISE. AND PLUS THE OPPORTUNITIES ARE SO VARIED, YOU REALLY CAN'T HAVE A TEAM THAT HAS NECESSARY EXPERTISE IN ALL THESE AREAS. SO WE HAD TO HAVE LIKE A PANEL OF CONSULTANTS ON THE OUTSIDE TO CHECK WITH. IT FELT UNCOMFORTABLE BECAUSE IT WAS ONE PERSON SOMETIMES THAT WAS THE EXPERT; WHEREAS, BEFORE, WHEN IT WAS ALL SMALL MOLECULES, IT WAS A TEAM OF EXPERTS. AND THEN WE WENT TO THE COMMERCIAL FOCUS. IT WAS LIKE, WELL, HALF OF THEM HAD COMMERCIAL EXPERIENCE.

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SO I'M GLAD YOU POINTED IT OUT. I APPRECIATE THE MESSAGING WILL BE IMPORTANT. AND I THINK IT'S GOING TO BE HARD WORK FOR CIRM TO MAKE THE SHIFT. SO THAT WAS ONE COMMENT.

AND THE LONGER OF MY TWO COMMENTS, THE SECOND ONE IS SOMEONE DID MENTION DEI. AS YOU MAY KNOW, THAT PI'S ARE BEING ASKED TO CERTIFY OR INSTITUTIONS ARE BEING ASKED TO CERTIFY THAT THEY DON'T PARTICIPATE IN ANY PROGRAMS THAT ARE NOW SUPPORTING ILLEGAL ACTIVITY. SO JUST FROM OUR PI APPLICANT POINT OF VIEW, WE JUST NEED TO BE REALLY CAREFUL THAT WE'RE NOT CREATING CONFLICTS FOR THEM IN SOME OF OUR CIRM PROJECTS, THAT WE'RE VERY ADHERENT TO FEDERAL LAW AND MAKE THAT REALLY CLEAR TO APPLICANTS, THAT THERE IS AN EXPECTATION THAT WE ADHERE TO FEDERAL LAW.

VICE CHAIR BONNEVILLE: YES, THANK YOU, HARLAN, FOR THAT.

DR. GOLDSTEIN: NEVERTHELESS, ONE OF THE GOALS OF OUR COMMITTEE IS TO DEAL WITH --

DR. LEVINE: ACCESS?

DR. GOLDSTEIN: -- ACCESS. THERE WE GO. THERE'S THE WORD. AND COMMUNITIES THAT HAVE NOT HAD AS MUCH ATTENTION. AND SO I THINK UNDERSTANDING WHAT IS THE BURDEN OF DISEASE, THE LIFE EXPECTANCY

IN POPULATIONS IS PART OF THIS. RIGHT? WHETHER THAT'S COUCHED IN LANGUAGE OF MARKETING OR THE ACCESS OF DEI, I THINK THE GOAL IS THE SAME. WE ARE BRINGING THERAPIES TO ALL CALIFORNIANS. AND THAT DOESN'T MEAN EACH AND EVERY CALIFORNIAN. IT MEANS THAT THERE ARE COMMUNITIES WITHIN CALIFORNIA THAT ARE UNDERSERVED.

SO THE LANGUAGE OF THIS REALLY GRATES ON ME A LITTLE BIT BECAUSE IT IS THE LANGUAGE OF MARKETING AND NOT THE LANGUAGE OF PUBLIC HEALTH. I THINK THAT MAY BE NECESSARY NOW TO DO THAT, BUT I THINK WE NEED TO MAKE SURE THAT WE STRIVE -- THAT PARTLY WHAT WE'RE ADDRESSING HERE ARE THE ECONOMIC IMPACTS THAT GO BEYOND PRODUCTS. RIGHT? IT'S THE ECONOMIC IMPACTS TO THE STATE AND EVERY COMMUNITY IN IT. AND I'M NOT SURE WHERE THAT IS, RIGHT, IN THIS. WHERE DOES THE IMPACT ON FAMILIES GET ASSESSED IN THE RUBRIC, IN THE CHECKLIST?

VICE CHAIR BONNEVILLE: I THINK THOSE ARE QUESTIONS WE ARE STILL -- THAT WE'RE TALKING ABOUT INTERNALLY. AND SO THAT'S DEFINITELY SOMETHING THAT WE CAN REPORT BACK OUT ON, BUT THESE ARE ISSUES THAT HAVE DEFINITELY COME UP RECENTLY. SO THEY'RE NOT BEING IGNORED, I PROMISE.

DR. GOLDSTEIN: I LOOK FORWARD TO THE NEXT

VERSION. THESE ARE DIFFICULT TOPICS. THERE'S NO MAGIC WAND HERE. RIGHT? BUT I THINK THE LANGUAGE OF MARKETING IS USEFUL AND MARKET ASSESSMENT AND CHANNELS AND SO ON. NOTHING WRONG WITH THAT. THE MEDICAL WORLD HAS ADOPTED THAT, AND THAT'S NOT GOING AWAY. BUT I BELIEVE THAT WE STILL NEED TO MAKE SURE THAT WE UNDERSTAND THE IMPACT ASSESSMENT FOR THERAPY GOES BEYOND MONEY.

VICE CHAIR BONNEVILLE: ABSOLUTELY. THANK YOU, TED.

AND, HARLAN, I THINK MAYBE I'LL ASK GIL AND ROSA TO FOLLOW UP WITH YOU AROUND YOUR EXPERIENCES THAT YOU REFERENCED EARLIER ABOUT BRINGING REVIEWERS ALONG AND TEAMS ALONG TO UNDERSTAND A SHIFT IN FOCUS AND HOW TO EVALUATE BECAUSE I THINK THAT WOULD BE HELPFUL FOR THE TEAM AS THEY LOOK TO ASSEMBLE A NEW TYPE OF REVIEW. SO THANK YOU.

DR. LEVINE: AWESOME.

VICE CHAIR BONNEVILLE: SO I'M GOING TO -- I'M GOING TO ASK FOR A MOTION NOW. AND THE MOTION IS TO APPROVE THE PROPOSED TOOLKIT AND GUIDANCE DOCUMENTS PERTAINING TO THE IMPLEMENTATION OF ACCESS AND AFFORDABILITY PLANNING IN CIRM PROGRAMS.

DR. BARRETT: SO MOVED.

VICE CHAIR BONNEVILLE: IS THERE A SECOND?

DR. BOILIEU: I'LL SECOND IT, MARIA.

VICE CHAIR BONNEVILLE: THANK YOU. IS THERE ANY OTHER BOARD COMMENT OR WORKING GROUP COMMENT I SHOULD SAY? SCOTT, IS THERE ANY PUBLIC COMMENT?

MR. TOCHER: I SEE NO HANDS RAISED.

VICE CHAIR BONNEVILLE: THANK YOU. THEN CAN YOU PLEASE CALL THE ROLL.

MR. TOCHER: ABSOLUTELY. KIM BARRETT.

DR. BARRETT: AYE.

MR. TOCHER: LIZ BOILIEU.

DR. BOILIEU: AYE.

MR. TOCHER: MARIA BONNEVILLE.

VICE CHAIR BONNEVILLE: YES.

MR. TOCHER: JAMES DEBENEDETTI.

MR. DEBENEDETTI: AYE.

MR. TOCHER: TED GOLDSTEIN.

DR. GOLDSTEIN: AYE.

MR. TOCHER: CHRISTINA HARTMAN.

DR. HARTMAN: AYE.

MR. TOCHER: DAVID HIGGINS. SORRY, DAVID, YOU ON MUTE?

DR. HIGGINS: I AM TRYING TO GET BACK ON.

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MR. TOCHER: OKAY. DARIUS LAKDAWALLA.
DR. LAKADAWALLA: AYE.
MR. TOCHER: HARLAN LEVINE.
DR. LEVINE: AYE.
MR. TOCHER: PAT LEVITT.
DR. LEVITT: YES.
MR. TOCHER: ADRIANA PADILLA.
DR. PADILLA: YES.
MR. TOCHER: AMMAR QADAN.
DR. QADAN: AYE.
MR. TOCHER: ADRIENNE SHAPIRO.
MS. SHAPIRO: AYE.
MR. TOCHER: THANK YOU VERY MUCH. MARIA, BACK TO YOU.
VICE CHAIR BONNEVILLE: THANK YOU. I REALLY WANT TO THANK THE TEAM. THIS IS GREAT WORK. AND IT'S A MANDATE WE HAVE, AND I THINK WE'RE GETTING THERE. SO THANK YOU SO MUCH FOR PUTTING ALL THAT WORK AND TIME INTO PUTTING THIS ALL TOGETHER. I THINK IT JUST MAKES OUR PROGRAMS STRONGER. SO I APPRECIATE ALL YOUR HARD WORK.
AND THANKS TO THE WORKING GROUP. I KNOW SEVERAL OF YOU GOT TO WEIGH IN. SO I APPRECIATE IT. AND WE WILL SEE YOU SOON. SO WITH THAT, WE ARE ADJOURNED.

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(THE MEETING WAS THEN CONCLUDED AT 3:28 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 APRIL 30, 2025, WAS HELD AS HEREIN APPEARS AND THAT THIS IS THE ORIGINAL TRANSCRIPT THEREOF AND THAT THE STATEMENTS THAT APPEAR IN THIS TRANSCRIPT WERE REPORTED STENOGRAPHICALLY BY ME AND TRANSCRIBED BY ME. I ALSO CERTIFY THAT THIS TRANSCRIPT IS A TRUE AND ACCURATE RECORD OF THE PROCEEDING.

BETH C. DRAIN, CA CSR 7152
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