BEFORE THE
JOINT MEETING OF THE SCIENCE SUBCOMMITTEE AND THE
NEURO TASK FORCE 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: SEPTEMBER 13, 2024
8 A.M.

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

FILE NO.: 2024-36

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1. CALL TO ORDER	3
2. ROLL CALL	3
3. STRATEGIC ALLOCATION FRAMEWORK - PRESENTATION OF GOAL 5 (ACCESSIBILITY & AFFORDABILITY OF CIRM-FUNDED CELL & GENE THERAPIES) & GOAL 6 (DIVERSE WORKFORCE DEVELOPMENT); UPDATE ON GOALS 1, 2, 3, AND 4; AND CONSIDERATION OF THE OVERALL STRATEGIC ALLOCATION FRAMEWORK RECOMMENDATIONS	9
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SEPTEMBER 13, 2024; SEPTEMBER 13, 2024 A.M.

CHAIRMAN FISCHER-COLBRIE: CALL THE MEETING TO ORDER. AND WITH THAT, SCOTT, IF YOU CAN CALL THE ROLL.

MR. TOCHER: CERTAINLY. MARIA BONNEVILLE.

VICE CHAIR BONNEVILLE: PRESENT.

MR. TOCHER: LEONDRA CLARK-HARVEY. MONICA CARSON.

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DR. CARSON: HERE.
MR. TOCHER: MARK FISCHER-COLBRIE.
CHAIRMAN FISCHER-COLBRIE: HERE.
MR. TOCHER: ELENA FLOWERS. JUDY GASSON.
DR. GASSON: HERE.
MR. TOCHER: DAVID HIGGINS.
DR. HIGGINS: HERE.
MR. TOCHER: VITO IMBASCIANI.
CHAIRMAN IMBASCIANI: HERE.
MR. TOCHER: PAT LEVITT.
DR. LEVITT: HERE.
MR. TOCHER: SHLOMO MELMED.
DR. MELMED: HERE.
MR. TOCHER: CAROLYN MELTZER.
DR. MELTZER: PRESENT.
MR. TOCHER: LAUREN MILLER-ROGEN. CHRIS MIASKOWSKI.
DR. MIASKOWSKI: PRESENT.
MR. TOCHER: MARV SOUTHARD.
DR. SOUTHARD: HERE.
MR. TOCHER: KAROL WATSON. KEITH YAMAMOTO.
DR. YAMAMOTO: HERE.
MR. TOCHER: ALL RIGHT. THANK YOU VERY MUCH. AND, MARK, WE HAVE A QUORUM FOR BOTH

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COMMITTEES.

CHAIRMAN FISCHER-COLBRIE: THANK YOU VERY MUCH. BEFORE WE LAUNCH INTO THE FORMAL AGENDA, I WOULD LIKE TO ACKNOWLEDGE THE TREMENDOUS LOSS THAT WE COLLECTIVELY HAVE SHARED WITH THE PASSING OF FRED FISHER. THAT'S AN INDIVIDUAL, FROM MY PERSPECTIVE, SINCE I HAD A LOT OF CHANCE TO SPEND A LOT OF TIME WITH HIM FOR MANY HOURS ON A VARIETY OF SUBCOMMITTEES, AND DEFINITELY HAD HIT ME HARD. BUT WOULD LOVE TO HAVE VITO AND J.T. MAKE SOME COMMENTS AND THEN ACKNOWLEDGE FRED'S PASSING WITH A MOMENT OF SILENCE BEFORE WE GO TO THE FORMAL DISCUSSION. SO VITO, AND THEN J.T., IF YOU'D LIKE TO COMMENT ON FRED.

CHAIRMAN IMBASCIANI: THANK YOU, MARK. J.T. AND I HAD THE HONOR TO REPRESENT -- SORRY. IT WAS A VERY EMOTIONAL DAY YESTERDAY ACTUALLY. FRED'S LOSS TOUCHED SO MANY PEOPLE SO DEEPLY AND SO PERSONALLY. I HAVE BEEN TALKING TO MANY BOARD MEMBERS PRIOR TO THE UPCOMING BOARD MEETING. IT WAS ONLY A WEEK AGO I SPOKE TO FRED. I DIDN'T KNOW AT THE TIME THAT HE WAS GOING TO BE IN THE HOSPITAL THE FOLLOWING DAY. AND SO TYPICAL OF HIM, NEVER ONCE, AND THIS WAS TRUE ALSO WHEN WE MET FOR BREAKFAST MONTHS BEFORE, NEVER ONCE ALLUDING TO HIS -- HE TOLD

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ME HIS DIAGNOSIS, STAGE FOUR LUNG CANCER. HE TOLD ME, BUT THAT WAS IT. HE NEVER ONCE COMPLAINED ABOUT PAIN OR DISCOMFORT OR INABILITY TO BE WITH HIS FAMILY AND HOW IT CURTAILED HIS ACTIVITIES. NEVER ONCE ALLUDED TO THE FEAR THAT SOMEBODY MIGHT HAVE NATURALLY. HE WAS EXTRAORDINARY.

AND AS MUCH AS WE THINK AND KNOW HOW MUCH OF A PART OF OUR LIFE AT CIRM HE WAS, THE TESTIMONIALS THAT J.T. AND I HEARD YESTERDAY AT THE FUNERAL FROM FAMILY AND FRIENDS, FROM THE ALS COMMUNITY, HE WAS A HUGE PART OF SO MANY UNIVERSES. JUST EXTRAORDINARY THAT HE COULD DEDICATE -- I LEARNED THE HEBREW WORDS. I CAN'T REPEAT THEM TODAY -- TO DO GOOD IN THE WORLD. BOY, HE DID GOOD IN THE WORLD FOR SO MANY PEOPLE AND FOR SO LONG RIGHT UP TO THE VERY LAST DAY. GOD BLESS.

CHAIRMAN FISCHER-COLBRIE: J.T., IF YOU'D LIKE TO MAKE A COMMENT.

DR. THOMAS: YES, I WOULD. I CERTAINLY ECHO EVERYTHING VITO SAID ABOUT THE SERVICE YESTERDAY. BUT JUST FRED WAS A UNIQUE INDIVIDUAL. HE HAD A VERY DISTINCTIVE STYLE WHICH HE BROUGHT TO CIRM. HE WAS EXTREMELY ACTIVE AS A BOARD MEMBER AND PATIENT ADVOCATE, WHETHER IT WAS IN BOARD MEETINGS THEMSELVES OR THE VARIOUS SUBCOMMITTEES OF WHICH HE

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WAS A PART OR AS CO-CHAIR OF THE STANDARDS WORKING GROUP. AND HE WAS A VERY STRONG VOICE FOR PROCESS, WHICH IS SOMETHING THAT IS A VERY IMPORTANT PERSPECTIVE TO BRING TO THE TABLE WHEN WE'RE IN THE MIDDLE OF DISCUSSING THINGS THAT ARE VERY SERIOUS AND DISCONCERTING WITH RESPECT TO THE PROJECTS WE'RE EVALUATING, ET CETERA; BUT REGARDLESS OF WHERE A DISCUSSION MIGHT GO, HE ALWAYS GROUNDED US IN WE HAVE TO STICK TO OUR PROGRESS.

FOR THOSE OF YOU WHO REMEMBER OUR GREAT BOARD MEMBER WHO WENT OFF THE BOARD SEVERAL YEARS AGO, OS STEWARD, OS WAS VERY BIG ON PROCESS. AND FRED SORT OF INHERITED THAT MANTLE AND KEPT US ALL GROUNDED. BUT I THINK THE AMOUNT OF TIME AND ENERGY HE GAVE TO THE BOARD WAS SO IMPRESSIVE, SO APPRECIATED, AND, AS VITO SUGGESTED, HE BROUGHT THAT SAME LEVEL OF ENERGY AND ENTHUSIASM TO EVERYTHING THAT HE TOUCHED OUTSIDE OF CIRM, IN PARTICULAR HIS WORK WITH THE ALS COMMUNITY. AND THE TESTIMONIES FROM HIS FAMILY TAUGHT US A GREAT DEAL ABOUT HOW HE WAS AS AN ALL-IN FAMILY IN ALL RESPECTS, AND SOMEBODY THAT HIS FAMILY IS GOING TO MISS VERY MUCH AS WILL WE. SO THIS WAS VERY SAD, CRUSHING NEWS WHEN WE GOT IT A COUPLE DAYS AGO.

AND SO, MARK, I THANK YOU. I'LL TURN IT

BACK OVER TO YOU FOR THE MOMENT OF SILENCE.

DR. MELMED: BEFORE THE MOMENT OF SILENCE, VITO, CAN I JUST ADDRESS A DIFFERENT PERSPECTIVE, AND OBVIOUSLY I AGREE WITH EVERYTHING YOU SAID.

WE HAVE A VERY LARGE ALS POPULATION WHO WE SERVE, VERY LARGE. AND I MUST SAY OVER THE DECADES WE'VE WORKED WITH SEVERAL LEADERS OF THAT PATIENT ORGANIZATION AND PROFESSIONAL ORGANIZATION UNIFIED AND INTEGRATED AS ONE. HE HAS BEEN ABSOLUTELY REMARKABLE IN REPRESENTING PATIENT CARE, THEIR FAMILIES.

THE PROBLEM WITH A RARE DISEASE IS THAT ONCE THE PATIENT PASSES, THERE'S NO CONTINUITY OF FAMILY INVOLVEMENT IN A DISEASE FOR HEART OR CANCER. SO HE HAD A VERY, VERY CHALLENGING COMMUNITY ISSUE TO DEAL WITH. AND I REALLY WANT TO CONGRATULATE HIM ON HOW TO REPRESENT A RARE DISEASE BOTH AT CIRM AND FOR THE COMMUNITY -- RARE DISEASES ARE VERY, VERY DIFFICULT -- PATIENT CARE AND COMMUNITY REPRESENTATIONS TO MAKE TO THE GOVERNMENT, TO AUTHORITIES, TO US, EVEN TO INDIVIDUAL DOCTORS, AND HE DID IT REMARKABLY WELL AND BUILT A MODEL FOR ALL RARE DISEASES IN CALIFORNIA AND BEYOND. AND I WOULD URGE ALL OF OUR COLLEAGUES WHO REPRESENT PATIENTS WITH RARE DISEASES THAT THEY LOOK AT HIS MODEL AND

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LEARN FROM HIM AND HIS LEGACY. SO WE REALLY MISS HIM AND OUR PATIENTS REALLY MISS HIM.

CHAIRMAN IMBASCIANI: THANK YOU, SHLOMO.

CHAIRMAN FISCHER-COLBRIE: THANK YOU SO MUCH FOR THOSE GREAT COMMENTS. WITH THAT, I WOULD LIKE TO TAKE A MOMENT TO ACKNOWLEDGE FRED'S PASSING BEFORE WE START THE OFFICIAL JOINT NEURO TASK FORCE/SCIENCE SUBCOMMITTEE MEETING WITH INTRODUCTORY COMMENTS BY J.T. BUT IF WE COULD HAVE A MOMENT OF SILENCE, WE'LL START THAT NOW.

(MOMENT OF SILENCE.)

CHAIRMAN FISCHER-COLBRIE: WE'RE ALL GOING TO MISS FRED. AND WITH THAT, I KNOW HE WOULD LIKE US TO PROCEED WITH THIS INCREDIBLE WORK OF CIRM. SO, J.T., IF YOU COULD KICK US OFF WITH COMMENTS.

DR. THOMAS: SO AS WE KNOW, WE'RE COMING DOWN THE HOME STRETCH ON OUR MULTIMONTH EFFORT TO EVALUATE AND REPRIORITIZE HOW WE'RE GOING TO DEPLOY THE REMAINING $3.8 DOLLARS THAT WE HAVE GOING FORWARD. THIS HAS BEEN A VERY LENGTHY PROCESS TO THIS POINT, WHICH HAS LITERALLY INVOLVED ALL MEMBERS OF THE INTERNAL CIRM TEAM, ALL MEMBERS OF THESE TWO JOINT SUBCOMMITTEES, AND WE REACH TODAY AS THE LAST MEETING OF THIS JOINT GROUP BEFORE WE PROCEED TO THE BOARD ON THE 26TH TO DISCUSS THE ENTIRE SET OF

RECOMMENDATIONS IN A COMPREHENSIVE FASHION.

TODAY WE'RE GOING TO BE FOCUSING ON THE LAST TWO OF THE SIX ENUMERATED GOALS THAT WE HAVE DISCUSSED TO THIS POINT TO GET THE JOINT COMMITTEE HERE TO GET YOUR HOPEFUL BLESSING AND RECOMMENDATION FOR THE FULL BOARD WHEN IT MEETS ON THE 26TH. AND, AS ALWAYS ON THESE PRESENTATIONS, WE'RE GOING TO TURN THINGS OVER AT THIS POINT TO ROSA WHO WILL GIVE THE PRESENTATION ON GOALS 5 AND 6 AND IN ADDITION DO A BRIEF RECAP OF WHAT THE DISCUSSION YIELDED BY THE JOINT GROUP WITH RESPECT TO GOALS 3 AND 4 FROM THE LAST MEETING. SO WITHOUT FURTHER ADO, MARK, I'D LIKE TO TURN IT OVER TO ROSA.

CHAIRMAN FISCHER-COLBRIE: GREAT. THANK YOU. ROSA.

DR. CANET-AVILES: THANK YOU, MARK. THANK YOU ALSO J.T. AND ALSO THE CO-CHAIRS OF THE NEURO TASK FORCE, DRS. PAT LEVITT AND DR. CAROLYN MELTZER, AND ALL THE MEMBERS OF THE COMMITTEES.

SO ON BEHALF OF THE CIRM TEAM, I HAVE THE HONOR TO PRESENT THIS. AND, KELLY, JUST LET ME KNOW IF YOU ARE READY TO GO. THANK YOU FOR PRESENTING THE SLIDES, KELLY.

OKAY. SO NEXT SLIDE. SO THE MAIN ACTIONS FOR TODAY, AS J.T. SAID, REVIEW THE GOALS 5 AND 6

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WHICH ARE THE LAST TWO THAT WE WILL BE PRESENTING THROUGH THIS LONG PROCESS. AND WE WILL RECAP GOALS 1 TO 4 BEFORE WE ASK FOR AN ENDORSEMENT OF THE GOALS AND RECOMMENDATIONS TO THE BOARD. OBVIOUSLY THE DISCUSSION WILL BE AT THE LEVEL OF GOALS 5 AND 6, BUT THERE CAN BE OTHER DISCUSSION AND QUESTIONS.

ONE QUESTION THAT WE HAD WAS THE X WAS NOT POSTED. THE X MEANS THE IMPACT MEASURABLE -- THE MEASURE OF THE GOALS. IT IS GOING TO BE PRESENTED TODAY AS WELL AT THE END.

SO NEXT SLIDE, KELLY. THANK YOU. SO TO ENSURE AMPLE TIME FOR DISCUSSION -- LET ME SEE. ARE YOU GETTING -- I THINK YOU ARE MISSING SOMETHING THERE, KELLY. CLICK AGAIN.

DR. TAYLOR: WE MIGHT HAVE TO GO INTO THE DESKTOP VERSION.

DR. CANET-AVILES: YOU NEED TO -- WE NEED TO GO INTO THE DESKTOP VERSION. IS THERE A CHANCE WE CAN DO THIS QUICKLY?

DR. TAYLOR: I CAN SHARE MY SCREEN.

DR. CANET-AVILES: OKAY. THANK YOU, SARA.

DR. SHEPARD: SORRY ABOUT THAT. I DO HAVE IT.

DR. CANET-AVILES: YOU HAVE IT. OKAY, KELLY. THEN GO AHEAD. GIVE IT A COUPLE MINUTES.

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SO WHILE KELLY IS DOING THIS, I'LL JUST GO OVER WHAT THIS SLIDE SAID BECAUSE IT'S JUST -- WE'VE HEARD IT MANY TIMES.

SO TO ENSURE AMPLE TIME FOR DISCUSSION, THE BACKGROUND OF THE SAF OVERVIEW IS NOT BEING PRESENTED. AND THERE IS A NOTE ON THE SLIDE THAT IT WAS GOING TO BE PRESENTED HERE THAT SAYS -- HAS LINKS THREE POINTS. ONE IS A YOUTUBE LINK TO THE BACKGROUND. THE OTHER ONE IS A YOUTUBE LINK TO THE JULY 11 JOINT SCIENCE SUBCOMMITTEE/NEURO TASK FORCE WHERE WE PRESENTED GOALS 1 AND 2. AND THEN THE LAST LINK IS DIRECTLY INTO THE YOUTUBE PRESENTATION FOR THE GOALS 3 AND 4. THANK YOU, KELLY. PERFECT.

SO DURING TODAY'S PRESENTATION, AS WE'VE SAID, WE WILL FOCUS ON GOALS 5. THAT'S THE ONE CORRESPONDING TO THE CATEGORY OF ACCESSIBILITY AND AFFORDABILITY OF CIRM-FUNDED CELL AND GENE THERAPIES. AND THE OTHER GOAL, 6, WHICH IS THE ONE THAT CORRESPONDS TO DIVERSE WORKFORCE DEVELOPMENT. AND THEN WE'LL FOLLOW WITH DISCUSSION. NEXT SLIDE.

VERY QUICKLY, FEEL FREE TO DO THE ANIMATION. THIS TIMELINE SHOWS THE ICOC SCIENCE SUBCOMMITTEE AND NEURO TASK FORCE MEETING THAT WE'VE HAD FROM WHEN WE STARTED -- I THINK YOU ARE PAST THE SLIDE, KELLY. YOU'VE GONE INTO -- LET'S STAY THERE.

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IT SHOWS ALL THE PROCESS SINCE FEBRUARY WHEN WE STARTED TALKING ABOUT THE PRIORITIZATION THAT HAD BEEN RECOMMENDED FROM THE, I THINK IT WAS, SEPTEMBER 2023 AND THEN IN MARCH WHEN WE STARTED THE DISCUSSIONS NEURO TASK FORCE, ET CETERA. SO THE ICOC IN JUNE WE PRESENTED, J.T. AND I PRESENTED THE PLAN. AND THEN WE'VE BEEN GOING BACK AND FORTH WITH THE BOARD GATHERING FEEDBACK OVER THE PAST MONTH LEADING TO TODAY'S MEETING, WHICH IS THE CULMINATION OF ALL THIS EFFORT THAT WILL LEAD TO THE 26TH. NEXT SLIDE.

NOW, IMPORTANTLY, THIS RECOMMENDATION, IF APPROVED OBVIOUSLY BY OUR BOARD, WE COULD END UP WITH ABOUT 13 CONCEPTS. SEVEN TO EIGHT WILL BE AMENDMENTS AND FIVE COULD BE FIVE NEW CONCEPTS. SO IN LINE WITH THIS STRATEGIC DIRECTION THAT WE ARE PROPOSING FOR ENDORSEMENT BY THE BOARD AND TO ENSURE EFFECTIVE AND TIMELY IMPLEMENTATION OF NEW INITIATIVES, WE WILL PROPOSE A STRATEGIC PAUSE IN THE REVIEW OF CURRENT PROGRAMS DURING THE UPCOMING BOARD MEETING. THE PAUSE IS CRITICAL AS IT WILL ALLOW US TO CONCENTRATE OUR EFFORTS ON THE DEVELOPMENT OF THESE 13 NEW AND AMENDED CONCEPTS WHILE SIMULTANEOUSLY AS WELL STREAMLINING OPERATIONS AND ENHANCING INTERNAL COLLABORATIONS IN ALIGNMENT

WITH THE REORGANIZATION THAT WILL BE PRESENTED BY J.T. ALSO AT THE BOARD MEETING. AND THAT HAS BEEN ENDORSED BY THE GOVERNANCE SUBCOMMITTEE AS OF YESTERDAY. SO THERE IS A REORGANIZATION THAT'S PARALLELING THIS STRATEGIC ALLOCATION FRAMEWORK, AS MANY OF YOU KNOW.

AS DEPICTED IN THIS TIMELINE, WE'LL PRESENT THE FINAL RECOMMENDATIONS AT THE SEPTEMBER 26TH MEETING. AND THE RESEARCH BUDGET COULD BE COMING IN DECEMBER, AND THE FIRST TRANCHE OF CONCEPTS COULD BE INTRODUCED IN THE JANUARY AND MARCH MEETINGS WHERE WE'LL HAVE A PRIORITIZATION OF WHICH CONCEPTS ARE COMING THERE. AND IT'S GOING TO BE ALIGNED WITH THE NEEDS OF CIRM AND THE GRANTEES AS WELL. WE WILL STRENGTHEN THE PIPELINE FIRST. R&D, DISCOVERY, TRANSLATIONAL, AND CLINICAL WOULD BE THE FIRST CONCEPTS COMING IN AND THEIR AMENDMENTS THERE.

THIS PHASED APPROACH WILL ENSURE THAT OUR R&D BUDGET IS DIRECTED TOWARDS THE MOST PROMISING AREAS OF RESEARCH AND THAT ALSO THE ADMINISTRATIVE PROCESSES AND OPERATIONAL PROCESSES ARE ALIGNED TO SUPPORT THE IMPLEMENTATION OF THESE NEW PROGRAMS. WE HOPE THAT BY DOING IT LIKE THIS, WE WILL OPTIMIZE OUR RESOURCES AND OPERATIONAL AGILITY, ENSURING THAT

WE REMAIN AT THE FOREFRONT OF REGENERATIVE MEDICINE AND INNOVATION. NEXT SLIDE, KELLY.

SO LET'S GO INTO THE MAIN POINT OF TODAY'S PRESENTATION. NEXT SLIDE. SO GOAL 5 UNDER THE CATEGORY OF ACCESSIBILITY AND AFFORDABILITY FOR CIRM-FUNDED CELL AND GENE THERAPY IS CENTERED ON ENSURING THAT EVERY BLA-READY PROGRAM AT CIRM HAS A ROBUST STRATEGY FOR ACCESSIBILITY AND AFFORDABILITY. AND THIS GOAL IS CRITICAL AS IT ALIGNS WITH OUR COMMITMENT TO MAKING ADVANCED THERAPIES ACCESSIBLE TO ALL WHO NEED THEM. NEXT SLIDE.

THIS SLIDE SHOWS WHAT ARE THE MAIN QUESTIONS, THE AREAS THAT WE ASKED OURSELVES IN ORDER TO MAKE THE RECOMMENDATIONS. WE EVALUATED THE LANDSCAPE, WHICH PROGRAMS, ENHANCEMENTS WE WOULD NEED TO TAKE INTO ACCOUNT TO ENSURE THIS GOAL EFFECTIVENESS, AND WHAT KIND OF EXTERNAL ENGAGEMENTS ARE MOST IMPORTANT FOR THIS TO HAPPEN. NEXT SLIDE.

THIS SLIDE, TO INFORM OUR STRATEGIES AND RECOMMENDATIONS, THE TEAM HAS RELIED ON A VARIETY OF ROBUST DATA SOURCES. FROM ONE SIDE WE'VE LOOKED AT OUR PORTFOLIO OF DATA. THE ACCESSIBILITY AND AFFORDABILITY WORKING GROUP CONSIDERATIONS CHAIRED BY CO-CHAIR BONNEVILLE. SO THE ACCESS AND AFFORDABILITY WORKING GROUP, AS YOU KNOW, HAS

PROVIDED KEY CONSIDERATIONS FOR THESE RECOMMENDATIONS DURING TWO MEETINGS IN THIS YEAR, IN MAY AND AUGUST. AND THESE CONSIDERATIONS HAVE GUIDED US IN THE UNDERSTANDING OF THE BARRIERS AS WELL AS THE OPPORTUNITIES IN IMPROVING ACCESS TO CELL AND GENE THERAPIES.

THIRDLY, WE'VE TAKEN INTO ACCOUNT GRANTS WORKING GROUP RECOMMENDATIONS FROM, ESPECIALLY, THE CLIN2 AWARDS. THESE RECOMMENDATIONS HAVE HELPED US IDENTIFY EFFECTIVE FUNDING STRATEGIES THAT DIRECTLY IMPACT THE ACCESSIBILITY OF OUR PROGRAMS AND THE PROJECTS.

CMS REGULATIONS, WE CONSIDERED THE LATEST RULINGS FROM THE CENTERS FOR MEDICARE AND MEDICAID SERVICES AND SPECIFICALLY THE HOSPITAL INPATIENT PPS FINAL ROLE FOR THE FISCAL YEAR 24 WHICH IMPACTS PRICING STRUCTURES THAT MIGHT AFFECT THE AFFORDABILITY OF THERAPIES UNDER OUR PROGRAMS.

AND THEN FINALLY, WE INCORPORATED FINDINGS FROM THE INSTITUTES FOR CLINICAL AND ECONOMIC REVIEW AND NEWDIGS WHICH OFFER WHITE PAPERS ON THE ACCESSIBILITY OF CELL AND GENE THERAPIES IN 2024. SO THIS SET OF DATA HELPED US ANSWER THE QUESTIONS THAT WE HAVE EXPOSED IN THE PREVIOUS SLIDE.

SO THE NEXT SLIDE PRESENTS A SUMMARY OF

HOW THE CIRM CLINICAL INFRASTRUCTURE PROGRAMS ARE DESIGNED TO REDUCE PATIENT BARRIERS TO CLINICAL TRIALS. BRIEFLY, THE BARRIERS IDENTIFIED, WHICH ARE THE FIVE COLUMNS TO THE RIGHT, ARE CLINICAL EXPERTISE TO DELIVER COMPLEX CELL AND GENE THERAPY TREATMENTS. THAT REQUIRES SPECIALIZED SKILLS, COORDINATION OF SPECIALIZED SKILLS INCLUDING MANUFACTURING, PROCESSING, PRODUCT PREPARATION, TREATMENT DELIVERY, PATIENT MONITORING AND FOLLOW-UP. SO THAT'S ONE OF THE BARRIERS THAT WE NEED TO TAKE INTO ACCOUNT.

THE SECOND ONE IS COHORT DEVELOPMENT. CLINICAL TRIALS HAVE A SPECIFIC ELIGIBILITY AND ENROLLMENT CRITERIA, AND THEY UTILIZE PATIENT REGISTRIES TO IDENTIFY PATIENTS AND NAVIGATORS TO ACHIEVE CLINICAL TRIAL AND RECRUITMENT OBJECTIVES. SO THAT'S ANOTHER IMPORTANT BARRIER TO ACCESS.

GEOGRAPHY IS ANOTHER ONE. TREATMENT PROTOCOLS ARE DEMANDING, REQUIRING FREQUENT VISITS TO TREATMENT CENTERS. AND THE TIME AND THE DISTANCE REQUIRED TO PARTICIPATE IS A BARRIER FOR MANY PATIENTS.

PATIENT KNOWLEDGE. PATIENTS MAY BE AWARE OF CLINICAL TRIAL OPPORTUNITIES -- SORRY -- THEY MIGHT BE UNAWARE OF CLINICAL TRIAL OPPORTUNITIES OR

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THEY DO NOT TRUST THE RESEARCH. SO THERE WE NEED TO EDUCATE AND PROVIDE INFORMATION SO THAT THE KNOWLEDGE AND EDUCATION TO COMMUNITIES -- THAT INVOLVES COMMUNITY-BASED ORGANIZATION AND HEALTH WORKERS AS WELL. THERE'S AN OUTREACH COMPONENT AS WELL THERE.

AND FINANCIAL. PATIENTS OFTEN INCUR COSTS TO PARTICIPATE IN CLINICAL TRIALS THAT MAY LEAD TO ATTRITION. AND WE NEED TO PROVIDE FINANCIAL SUPPORT AND LOGISTICAL COORDINATION TO REDUCE BURDENS TO PATIENTS TO INCREASE THE LIKELIHOOD OF COMPLETING CIRM-FUNDED TREATMENT PROTOCOLS.

SO WE CURRENTLY HAVE THREE PROGRAMS UNDER OUR CLINICAL INFRASTRUCTURE IN THESE AREAS. THE ALPHA CLINICS NETWORK THAT LAUNCHED IN 2015 IS ONE OF OUR LONGEST STANDING PROGRAMS. IT SUPPORTS CLINICAL TRIALS IN CELL AND GENE THERAPY AND HAS BEEN INSTRUMENTAL IN ADVANCING OVER 275 CLINICAL TRIALS, INCLUDING 71 FUNDED DIRECTLY BY CIRM. THESE CLINICS, THE ALPHA CLINICS, HELP IN OVERCOMING BARRIERS RELATED TO CLINICAL EXPERTISE AND COHORT DEVELOPMENT.

THE OTHER PROGRAM, WHICH IS A NEWER PROGRAM, THE COMMUNITY CARE CENTERS OF EXCELLENCE IS SET TO LAUNCH IN 2025, IN FACT, THE REVIEW IS COMING

UP SOON, AND WILL BUILD ON THE ALPHA CLINICS SUCCESS BY FURTHER ADDRESSING PATIENT ACCESS TO CLINICAL TRIALS, PARTICULARLY IN UNDERSERVED AREAS. THE GOAL HERE IS TO CENTRALIZE CLINICAL TRIAL ACCESS, MAKING IT EASIER FOR PATIENTS TO PARTICIPATE REGARDLESS OF THEIR LOCATION. AND WHILE THEY DON'T HAVE -- THE COMMUNITY CARE CENTERS OF EXCELLENCE WON'T HAVE AS MUCH FOCUS ON PROVIDING CLINICAL EXPERTISE AS THE ALPHA CLINICS, THEY WILL SIGNIFICANTLY IMPART COHORT DEVELOPMENT, GEOGRAPHIC ACCESS, AND PATIENT KNOWLEDGE.

OUR PATIENT SUPPORT PROGRAM WILL ALSO LAUNCH IN 2025, AND IT'S DESIGNED TO SUPPORT THE FINANCIAL AND LOGISTIC NEEDS OF PATIENTS PARTICIPATING IN CIRM-FUNDED TRIALS. THIS PROGRAM WILL TACKLE KEY BARRIERS, SUCH AS THE FINANCIAL BURDEN OF PATIENTS, WHICH IS A CRITICAL FACTOR THAT OFTEN LIMITS ACCESS TO GROUNDBREAKING THERAPIES.

SO JUST TO SAY THAT THE LEVEL OF THE WAY THAT WE ARE TALKING ABOUT THIS GOAL IS A LITTLE DIFFERENT THAN THE OTHERS BECAUSE THE PATIENT ACCESS PROGRAMS ARE NASCENT, BUT THEY AIM TO REDUCE PATIENT BARRIERS TO CLINICAL TRIALS. AND THIS IS A NEW MANDATE ON THE PROPOSITION 14 ACCESS AND AFFORDABILITY WHICH IS ESSENTIAL, AND THAT IS WHY

THE LEVEL OF DATA AS WELL FOR THIS ONE IS A LITTLE DIFFERENT.

NEXT SLIDE, KELLY. THANK YOU. THIS IS A TWO-PART SLIDE, THIS NEXT ONE. IT HIGHLIGHTS SOME OF THE KEY BARRIERS THAT WE MUST ADDRESS TO ENSURE THAT CELL AND GENE THERAPIES CAN REACH THE PATIENTS WHO NEED THEM MOST. THIS IS SO THAT WE CAN ADDRESS THESE CHALLENGES THROUGH DIFFERENT PROGRAMS AND RECOMMENDATIONS. THERE WILL BE ANOTHER SLIDE AT THE END OF THE RECOMMENDATIONS THAT WILL SUMMARIZE HOW THESE ACCESS CHALLENGES TO CELL AND GENE THERAPIES ARE BEING TACKLED BY THE DIFFERENT RECOMMENDATIONS THAT WE ARE MAKING TO THE BOARD. AND WE WILL MAP THE RECOMMENDATIONS AGAINST THESE CHALLENGES.

SO VERY QUICKLY, GOING AROUND THESE CHALLENGES, THE FIRST ONE IS LIMITED CLINICAL EVIDENCE GENERATED PRIOR TO APPROVAL, AND THIS CAN MAKE IT DIFFICULT TO FULLY UNDERSTAND THE LONG-TERM EFFICACY AND DURABILITY OF THESE THERAPIES COMPARED TO THE STANDARD OF CARE. AND THIS UNCERTAINTY AFFECTS BOTH CLINICIANS' AND PATIENTS' CONFIDENCE IN THE TREATMENT AMONGST OTHER THINGS.

SECOND CHALLENGE IS THE HIGH INITIAL COST OF TREATMENTS. IT PRESENTS A SUBSTANTIAL BARRIER. AS WE KNOW, CELL AND GENE THERAPIES OFTEN COME WITH

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A SIGNIFICANTLY HIGHER THAN TRADITIONAL PRICE TAG THAN TRADITIONAL SMALL MOLECULES AND BIOLOGICS. AND THIS CAN BE A DETERRENT FOR BOTH PAYERS AND PATIENTS.

THE THIRD CHALLENGE IS THE NECESSITY OF SPECIALIZED TREATMENT CENTERS. THE DELIVERY OF CELL AND GENE THERAPIES REQUIRES SPECIALIZED SKILLS AND INFRASTRUCTURE THAT ARE NOT WIDELY AVAILABLE, AND THIS LIMITS PATIENT ACCESS TO THESE TREATMENTS BASED ON GEOGRAPHIC LOCATION.

FOURTH CHALLENGE IDENTIFIED IS THE VARIABILITY IN COVERAGE AND REIMBURSEMENT RATES ACROSS MEDICARE, MEDICAID, AND PRIVATE INSURANCE, WHICH ADDS ANOTHER LAYER OF COMPLEXITY. AND WITHOUT CONSISTENT AND ROBUST REIMBURSEMENT POLICIES, PATIENTS MAY FIND IT DIFFICULT TO AFFORD THESE TREATMENTS, LEADING TO DISPARITIES IN ACCESS.

AND THE FIFTH CHALLENGE IS THE COMPLEX MANUFACTURING AND SUPPLY CHAINS, PARTICULARLY FOR AUTOLOGOUS GENE-MODIFIED CELL THERAPIES. THEY POSE CERTAIN CHALLENGES. THESE THERAPIES OFTEN REQUIRE PERSONALIZED APPROACH, AS WE KNOW, WHERE CELLS ARE TAKEN FROM THE PATIENTS, MODIFIED, AND THEN RETURNED FOR TREATMENT. AND THE INTRICACIES OF THIS PROCESS CAN RESULT IN DELAYS AND ADDITIONAL COST.

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SO IN SUMMARY, WHILE CELL AND GENE THERAPIES HOLD IMMENSE PROMISES, THESE CHALLENGES HIGHLIGHT THE NEED FOR COORDINATED EFFORTS TO IMPROVE THESE CHALLENGES. AND THIS IS WHAT THE RECOMMENDATIONS WILL BE TACKLING. NEXT SLIDE.

SO UNDER GOAL 5 OUR PRIORITY OBJECTIVE, AS WE'VE BEEN TALKING ABOUT, IS TO PROMOTE ACCESSIBILITY AND AFFORDABILITY OF CIRM-FUNDED THERAPEUTICS TO ALL CALIFORNIA PATIENTS DURING CLINICAL TRIALS AND BEYOND. SO THIS GOAL IS PIVOTAL, AS WE SAID, TO ENSURING THAT OUR BREAKTHROUGHS IN REGENERATIVE MEDICINE ARE TRANSLATING TO TANGIBLE BENEFITS FOR PATIENTS.

SO AS YOU WILL SEE IN THE NEXT SLIDES, OUR APPROACH INCLUDES TWO KEY STRATEGIES. THE FIRST ONE WILL BE FOCUSED ON LEVERAGING CIRM CLINICAL INFRASTRUCTURE, AND THE SECOND WILL BE FOCUSED ON INFLUENCING POLICY FOR BROADER IMPACT POLICY ALSO SLASH PARTNERSHIPS. NEXT SLIDE.

THIS SLIDE SHOWS THE RECOMMENDATIONS THAT ARE FOCUSED ON MAXIMIZING LEVERAGING CIRM CLINICAL INFRASTRUCTURE. FIRST, WE AIM TO STRENGTHEN CLINICAL INFRASTRUCTURE CONNECTIVITY BY BUILDING ROBUST INTERCONNECTIVITY AND PERFORMANCE METRICS ACROSS OUR CLINICAL INFRASTRUCTURE, WHICH, AS WE

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PRESENTED, INCLUDES THE ALPHA CLINICS, THE COMMUNITY CARE CENTERS OF EXCELLENCE, AND THE PATIENT SUPPORT PROGRAM. WE AIM TO ENHANCE OUR CAPABILITIES IN REFERRING, ENROLLING, AND RETAINING CALIFORNIA PATIENTS IN CLINICAL TRIALS. THIS IS CRUCIAL FOR ENSURING THAT OUR ADVANCEMENTS ARE NOT ONLY REACHED, BUT ALSO EFFECTIVELY ADMINISTERED AND BENEFICIAL TO PATIENTS ACROSS THE STATE.

SOME EXAMPLES OF THIS INTERCONNECTIVITY BUILDING ARE, FOR EXAMPLE, COORDINATE THE PATIENT NAVIGATION USING ELECTRONIC HEALTH RECORDS TO SUPPORT ENROLLMENT, UNDERSTANDING ELIGIBILITY AND INSURANCE CONSIDERATIONS, ADDRESSING LOGISTICAL BARRIERS, FINANCIAL BARRIERS. SO THESE ARE SOME OF THE EXAMPLES OF WHAT WE WOULD BE TACKLING IN THIS INTERCONNECTIVITY WITHIN THE INFRASTRUCTURE PROGRAMS.

OTHER TYPES OF INTERCONNECTIVITY HAVE TO DO BETWEEN INFRASTRUCTURE AND THE TRAINING. FOR EXAMPLE, WE ARE CONNECTING WITH OUR TRAINING PROGRAMS IN TERMS OF WORKFORCE DEVELOPMENT. THE ALPHA CLINIC SITES, FOR EXAMPLE, WILL COLLABORATE WITH THE COMMUNITY CARE CENTERS OF EXCELLENCE TO TRAIN FOR ACCREDITATION FOR DELIVERY OF CELL AND GENE THERAPIES AND IMMUNE SURVEILLANCE. THERE WILL

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BE COMMUNITY CARE CENTERS OF EXCELLENCE WILL ENROLL STUDENTS IN ALPHA CLINIC RESEARCH COORDINATION, TRAINING CERTIFICATE PROGRAMS, FOR EXAMPLE. SO THOSE ARE DIFFERENT TYPES OF CONNECTIVITY THAT WE ARE GOING TO MAKE.

JUST AS SOMETHING THAT WE WILL BE PRESENTING AT A LATER DATE, THERE'S A CIRM HUB. AND IT CONNECTS ALL OUR ON INFRASTRUCTURE PROGRAMS. WE'LL PRESENT THIS ANOTHER DAY. THAT'S A LOT OF INFORMATION.

THE SECOND RECOMMENDATION WITHIN THE CLINICAL INFRASTRUCTURE IS TO LOOK AT THE DEVELOPMENT OF MARKET ACCESS AND REIMBURSEMENT STRATEGIES. THIS INVOLVES RESOURCING OUR CLINICAL PROGRAMS TO SUPPORT STAGE-APPROPRIATE PLANNING AND EVIDENCE GENERATION, INFORMING ROBUST MARKET ACCESS AND REIMBURSEMENT STRATEGIES. IT'S ABOUT MAKING SURE THAT THE THERAPIES DEVELOPED ARE NOT ONLY EFFECTIVE, BUT ALSO ACCESSIBLE AND AFFORDABLE.

EXAMPLES OF EARLY STAGE ACTIVITIES HAVE TO DO WITH THE DISEASE BURDEN, THE NATURAL HISTORY, REIMBURSEMENT PATHWAYS, AND ECONOMIC MODELING, FOR EXAMPLE. AND LATER-STAGE ACTIVITIES IN THIS DEVELOPMENT OF MARKET ACCESS AND REIMBURSEMENT STRATEGIES COULD BE MARKET ANALYSIS, REIMBURSEMENT

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GAPS, COVERAGE LIMITATIONS, ET CETERA. SO THOSE ARE SOME OF THE REIMBURSEMENT STRATEGIES THAT WE WILL BE THINKING ABOUT.

THE NEXT SLIDE SHOWS -- CONTINUES WITH OUR COMMITMENT FOR GOAL 5. THE THIRD RECOMMENDATION AND FOURTH RECOMMENDATION HAVE TO DO WITH POLICY AND PARTNERSHIPS.

SO THE THIRD RECOMMENDATION IS TO FURTHER INFLUENCE POLICY THROUGH THE RESOURCES OF THE ACCESS AND AFFORDABILITY WORKING GROUP TO ADVOCATE FOR POLICIES THAT DIRECTLY INFLUENCE CLINICAL ACCESS AND A BROADER ADOPTION OF APPROVED THERAPIES. THIS HAS BEEN LED BY OUR CO-CHAIR OF THE BOARD AND CHAIR OF THE AAWG, MARIA BONNEVILLE, AND THIS HAS ALREADY BEEN UNDERGOING.

AND SOME OF THE EXAMPLES ARE EVOLVING STATE AND NATIONAL POLICIES THAT IMPACT ACCESS TO CLINICAL TRIALS AND APPROVED PRODUCTS, FACTORS SUCH AS ELIGIBLE POPULATIONS, DISEASE CONDITIONS COVERED, COST OF TREATMENTS, PAYMENT REIMBURSEMENT RATES, AND DURABILITY OF EFFECT MAY IMPACT ACCESS. AND THOSE ARE SOME OF THE THINGS UNDER DISCUSSION. AND MARIA CAN PROVIDE PROBABLY A LOT MORE DETAIL ON SOME OF THOSE DISCUSSIONS.

THE FOURTH RECOMMENDATION IS TO ENHANCE

PARTNERSHIPS. OUR WORK DOESN'T END WITH POLICY INFLUENCE. TO STRENGTHEN ACCESS TO CLINICAL TRIALS AND APPROVED THERAPIES, CIRM WILL INTENSIFY ITS COLLABORATIONS WITH INFLUENTIAL ORGANIZATIONS ACROSS THE SPECTRUM, INCLUDING THE CALIFORNIA MEDICAL CENTERS, ASCGT, ISSCR, THE FDA, AND MEDI-CAL. BY CONVENING WORKSHOPS AND BUILDING CONSENSUS AROUND SUPPORTIVE POLICIES, WE ARE NOT JUST PARTICIPATING IN THE CONVERSATION, BUT WE ARE A MAIN LEAD IN IT.

OUR AIM IS TO PRESENT SOLUTIONS IN FORMATS THAT POLICYMAKERS CAN ACT UPON. AND ENSURING ACCESS TO REGENERATIVE MEDICINES IS NOT JUST A POSSIBILITY, BUT IT WILL HOPEFULLY BECOME A REALITY.

SO THE LAST SLIDE ON GOAL 5 SHOWS THE SECOND PART OF THAT -- THERE YOU GO. THANK YOU, KELLY. THE SECOND PART OF THAT SLIDE THAT I HAD SHOWN EARLIER ON, AND IT FOCUSES ON THE CHALLENGES AND THE STRATEGIC RESPONSES THAT CIRM HAS DEVISED TO ADDRESS THESE CHALLENGES, MAPPING INTO THE RECOMMENDATIONS. AND THIS INCLUDES GOALS 2 AND 4 AS WELL. SOME OF THESE CHALLENGES ARE NOT ONLY ABOUT GOAL 5, BUT ALSO INCLUDES SOME OF THE RECOMMENDATIONS THAT WE'VE ALREADY PRESENTED.

SO IN TERMS OF THE LIMITED CLINICAL EVIDENCE ON THE LEFT. ON THE RIGHT WE HAVE THAT

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CIRM, THROUGH GOAL 4, WE WILL UPDATE THE CLINICAL 2 PROGRAMS TO INCENTIVIZE THE DEVELOPMENT OF ACCESS STRATEGIES AND TO PROVIDE ROBUST ACCESSIBILITY AND AFFORDABILITY WORKING GROUP SUPPORT.

THE SECOND CHALLENGE, WHICH HAD TO DO WITH THE HIGH INITIAL COST OF TREATMENTS, OUR PATIENT ASSISTANCE FUND INITIATIVE WILL ENSURE BROADER ACCESS TO CIRM-FUNDED TREATMENTS, HELPING PATIENTS OVERCOME FINANCIAL BARRIERS.

THE THIRD ONE THAT HAS TO DO WITH SPECIALIZED TREATMENT CENTERS, THE COMMUNITY CARE CENTERS OF EXCELLENCE AND THE ALPHA CLINICS PARTNERSHIP COORDINATION BY EXPANDING OUR NETWORK, WE CAN ADDRESS THE NECESSITY FOR SPECIALIZED TREATMENT CENTERS AND ENHANCE PATIENT ACCESS STATEWIDE.

THE VARIABLE COVERAGE AND REIMBURSEMENT CHALLENGE WILL BE TACKLED THROUGH POLICY ENGAGEMENT. WE ARE ACTIVELY, AS I MENTIONED, THROUGH MARIA'S LEADERSHIP ENGAGING WITH POLICY PARTNERS TO SHAPE FRAMEWORKS THAT FACILITATE ACCESS AND ARE DEPLOYING ACCESSIBILITY AND AFFORDABILITY WORKING GROUP RESOURCES TO BOLSTER AND FOCUS THE EFFORTS.

AND FINALLY, THE TECHNOLOGY -- SORRY. THE COMPLEXITY OF MANUFACTURING AND SUPPLY CHAINS WILL

BE TACKLED THROUGH OUR TECHNOLOGY AND MANUFACTURING NETWORKS, WHICH ARE RIGHT NOW UNDER PRECLINICAL DEVELOPMENT GROUP, TO ADDRESS THE BOTTLENECKS, LED BY DR. SHYAM PATEL. AND TO ADDRESS BOTTLENECKS IN MANUFACTURING AND SUPPLY, OUR ON TECHNOLOGY PLATFORM PROGRAM WILL OPTIMIZE PRODUCTION PROCESSES AND INFRASTRUCTURE.

SO THIS IS A SUMMARY OF HOW AT A HIGH LEVEL CIRM PLANS TO ADDRESS THE CHALLENGES THAT WE'VE IDENTIFIED IN A HOLISTIC AND COORDINATED MANNER THROUGH OUR PROGRAMS, DIFFERENT PROGRAMS, AND THE ACCESSIBILITY AND AFFORDABILITY WORKING GROUP EFFORTS.

I'M NOW GOING TO GO INTO GOAL 6 UNLESS, MARK, IF YOU DEEM IT -- IF YOU WANT TO STOP AND DISCUSS GOAL 5 FIRST. I'LL FOLLOW YOUR GUIDANCE.

CHAIRMAN FISCHER-COLBRIE: NO. LET'S PROCEED AND CONTINUE WITH THE DISCUSSION. SO THANK YOU.

DR. CANET-AVILES: OKAY. GOAL 6. THANK YOU, KELLY. AND ACTUALLY, AS YOU ALL KNOW, DIFFERENT LEADERS IN OUR GROUPS HAVE BEEN LEADING. SO THE LAST SLIDE WAS DR. GEOFF LOMAX. AND ACTUALLY KELLY SHEPARD WITH DAISY. CHIN AND SARA TAYLOR HAVE BEEN WORKING ON THIS GOAL. SO, KELLY, YOU ARE

PASSING THE SLIDES AND I'M GOING TO DO THE PRESENTATION, BUT THANK YOU FOR ALL THE WORK THAT YOU'VE DONE ON THIS.

SO UNDER GOAL 6, WE ARE FOCUSING ON BOLSTERING CIRM WORKFORCE DEVELOPMENT PROGRAMS TO EFFECTIVELY ADDRESS THE GAPS AND MEET THE EVOLVING DEMANDS IN REGENERATIVE MEDICINE. THIS GOAL IS CRUCIAL AS IT UNDERPINS OUR ABILITY TO SUSTAIN INNOVATION AND EXCELLENCE IN OUR FIELD.

SO THE NEXT SLIDE, WE ARE TACKLING THIS GOAL BY CONSIDERING THREE KEY AREAS. AND THIS IS WHERE WE'VE DEVELOPED THE MAIN QUESTIONS. THE FIRST ONE IS WE IDENTIFIED COMPETENCY GAPS. SECOND ONE WAS INCREASING DIVERSITY AND REPRESENTATION. AND THE THIRD ONE WAS THE QUESTIONS AROUND LEVERAGING COLLABORATIONS AND BEST PRACTICES. WHAT KIND OF QUESTIONS WE HAD TO ASK OURSELVES IN ORDER TO FIGURE OUT WHAT WOULD BE THE BEST RECOMMENDATIONS HERE.

THE NEXT SLIDE SHOWS THE SOURCES THAT HAVE INFORMED OUR UNDERSTANDING OF THE WORKFORCE GAPS AND THE EVOLVING DEMANDS IN REGENERATIVE MEDICINE. IN TERMS OF -- WE LOOKED AT THE BIOTECH INDUSTRY ANALYSIS AND DREW INSIGHTS FROM WORKFORCE GAP ANALYSES, FROM FORUMS AND DATA REPORTS FROM ENTITIES SUCH AS THE CALIFORNIA ECONOMIC IMPACT REPORT. AND

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THESE DOCUMENTS PROVIDED TO US A VERY THOROUGH ASSESSMENT OF SKILLS NEEDED WITHIN THE BIOTECHNOLOGY SECTOR, FOR EXAMPLE.

IN TERMS OF CELL AND GENE THERAPY WORKFORCE ANALYSIS, WE ALSO CONSIDERED REPORTS SPECIFICALLY TAILORED TO OUR FIELD. AND THESE REPORTS HAVE HELPED US UNDERSTAND SPECIFIC NEEDS WITHIN THE CELL AND GENE THERAPY WORKFORCE, NOT NOW, BUT ALSO WHAT IS COMING UP BECAUSE THE FIELD IS EVOLVING. AND SOME OF THESE NEEDS ARE GOING TO BE CHANGING IN THE NEXT FIVE TO TEN YEARS. SO WE'VE TAKEN THAT INTO ACCOUNT IN OUR ANALYSIS.

WE'VE ALSO DONE A CIRM INTERNAL ANALYSIS, OUR OWN PORTFOLIO AND TRAINEE ANALYSIS, WHICH SPANS FROM 2009 TO THE PRESENT. THIS OFFERS A LONGITUDINAL VIEW OF OUR INTERNAL DEVELOPMENT AND THE EFFECTIVENESS OF OUR TRAINING PROGRAMS. AND WE'VE LOOKED AT THIS VERY THOROUGHLY.

WE'VE LOOKED INTO THE RESEARCH ON HYBRID SKILL SET TRAINING NEEDS. THIS IS VERY IMPORTANT. TO ENSURE OUR WORKFORCE IS VERSATILE AND WELL PREPARED, WE REVIEWED A VARIETY OF RESEARCH ARTICLES AND PEER REVIEW PAPERS THAT DISCUSS THE INTEGRATION OF DIVERSE SKILL SETS IN THE BIOTECH INDUSTRY. AND THIS ALSO CAME FROM A NATIONAL ACADEMY OF SCIENCE

REPORT ABOUT THE NEED FOR HYBRID SKILL SETS.

WE LOOKED AT THE CALIFORNIA EDUCATIONAL LANDSCAPE AND EXAMINED THE DATA FROM THE CALIFORNIA DEPARTMENT OF EDUCATION AND THE U.S. CENSUS BUREAU, AND THE CALIFORNIA COMMISSION ON TEACHER CREDENTIALING. THESE RESOURCES HAVE GIVEN US INSIGHT INTO THE BROADER EDUCATIONAL TRENDS THAT IMPACT OUR WORKFORCE STRATEGY.

WE LOOKED AT DEMOGRAPHIC AND DIVERSITY REPORTS AS WELL TO UNDERSTAND THE DIVERSITY OF OUR WORKFORCE AND ANALYZED REPORTS FROM THE UC INFORMATION CENTER, THE CALIFORNIA STATE UNIVERSITY ENROLLMENT DATA, AND THE CALIFORNIA COMMUNITY COLLEGES RESEARCH AND DATA ANALYSIS.

AND FINALLY, WE LOOKED AT STAKEHOLDER ENGAGEMENT. OUR STRATEGY IS ALSO SHAPED BY DIRECT INTERACTIONS WITH EDUCATION STAKEHOLDERS. AND WE REACHED OUT. WE ACTUALLY WERE VERY FORTUNATE BECAUSE WE HAD THE PINE TRAINEE NETWORK CONFERENCE. AND MANY OF THESE VERY RELEVANT STAKEHOLDERS WERE THERE. SO WE SET MEETINGS DURING THE PINE CONFERENCE, BUT ALSO AFTERWARDS. AND THESE CONVERSATIONS HAVE HELPED US ENSURE THAT OUR INITIATIVES ARE WELL ALIGNED WITH BROADER EDUCATIONAL AND WORKFORCE DEVELOPMENT GOALS AND NOT

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JUST WHAT WE WERE SEEING. SO WE THINK THAT WE HAVE A PRETTY HOLISTIC VIEW ON THIS STRATEGY.

NEXT SLIDE, KELLY. THIS SLIDE HIGHLIGHTS THE ALIGNMENT OR LACK THEREOF BETWEEN CURRENT COMPETENCIES IN THE CELL AND GENE THERAPY SECTOR AND THE TRAINING OPPORTUNITIES AVAILABLE THROUGH BOTH ACADEMIC AS WELL AS CIRM-SPONSORED PROGRAMS AS WE STRIVE TO ADDRESS THE WORKFORCE NEEDS IN REGENERATIVE MEDICINE. UNDERSTANDING THIS ALIGNMENT, WE THINK, IS CRUCIAL.

SO ON THE LEFT SIDE THERE A COLUMN ABOUT THE COMPETENCIES. THE COMPETENCIES LISTED HERE ARE DERIVED FROM A COMPREHENSIVE ANALYSIS OF TECHNICAL NEEDS, HIGH DEMAND BIOTECH JOB LISTINGS RELEVANT TO CELL AND GENE THERAPIES, AND ALSO THE ANTICIPATED GROWTH THAT WILL BE HAPPENING, AND GAP ANALYSIS FROM KEY STAKEHOLDERS IN THE TYPES OF SKILLS AND POSITIONS THAT ARE MOST NEEDED AS THE NASCENT CELL AND GENE THERAPY FIELD PROGRESSES TOWARDS IND AND REGULATORY APPROVALS.

THE NEXT COLUMN IS THE ACADEMIC TRAINING IN CALIFORNIA. ACADEMIC TRAINING MEANS CERTIFICATE AND DEGREE PROGRAMS OFFERED TO INDIVIDUALS THROUGH POST HIGH SCHOOL EDUCATION. THIS MEANS PUBLIC UNIVERSITIES AND COLLEGES, THE UC'S, CSU'S, THE

COMMUNITY COLLEGES, AND ALSO SOME PRIVATE EDUCATIONAL INSTITUTIONS THAT HAVE ACCESS TO CELL AND GENE THERAPY FACULTY AND PROGRAMMING.

AND THEN LASTLY, WE HAVE THE CIRM EDUCATION AND INFRASTRUCTURE TRAINING BECAUSE WE DON'T PROVIDE TRAINING THROUGH EDUCATION PILLAR ONLY, BUT ALSO, AS YOU CAN SEE, THROUGH THE MANUFACTURING, ALPHA CLINICS, THE SHARED RESOURCES LAB, AND NOW THE CCCE WHICH IS NOT SHOWN HERE BECAUSE IT'S VERY NEW AND IT'S NOT LAUNCHED YET, BUT IT WILL BE COMING.

SO THROUGH THE CIRM EDUCATION INFRASTRUCTURE TRAINING OPPORTUNITIES, THE CHECKMARKS HERE INDICATE THE EXTENT TO WHICH TRAINEES IN CIRM'S VARIOUS EDUCATIONAL PROGRAMS, LIKE THE SPARK, THE COMPASS, THE BRIDGES, AND OTHERS, HAVE OPPORTUNITIES TO GAIN EXPERIENCE IN THESE AREAS.

A HOLLOW CIRCLE DENOTES THAT SOME TRAINEES GAIN THIS EXPERIENCE POSSIBLY THROUGH INTERNSHIPS WHILE A SOLID CIRCLE MEANS THAT MOST OF ALL DO. SO HOLLOW IS SOME AND SOLID MEANS ALL OF THEM, MOST OF THEM. SO, FOR EXAMPLE, ALL TRAINEES IN THE MANUFACTURING PROGRAM GAIN MANUFACTURING-RELATED SKILLS, BUT ONLY A SUBSET IN THE BRIDGES OR COMPASS

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PROGRAMS MIGHT GET THIS KIND OF TRAINING IN PROCESS DEVELOPMENT, MANUFACTURING, AND QA AND CONTROL.

ONE THING NOT REFLECTED HERE ON THIS SLIDE IS THE RECENT INCEPTION IS THE COMMUNITY CARE CENTERS OF EXCELLENCE APPLICATIONS THAT WILL HOLD A SUBSTANTIAL -- THEY HAVE A SUBSTANTIAL PART IN THEIR PROPOSAL IN WORKFORCE DEVELOPMENT, ESPECIALLY IN CLINICAL SETTING, BUT THIS IS NOT SOMETHING THAT WE HAVE YET. SO WE JUST WANTED TO SHOW IT.

SO I'M JUST GIVING A COUPLE SECONDS TO JUST DIGEST THIS SLIDE, BUT JUST TO MENTION THAT BY ADDING THESE GAPS AND LEVERAGING NEW AND EXISTING PROGRAMS, CIRM WILL AIM TO ENHANCE THE READINESS OF THE CALIFORNIA WORKFORCE TO MEET THE EVOLVING DEMANDS OF THE REGENERATIVE MEDICINE INDUSTRY EFFECTIVELY. AND ALSO TO SAY THAT PUTTING TOGETHER THIS SLIDE, IT WAS COMPLEX BECAUSE WE GATHERED A LOT OF INFORMATION AND JUST SUMMARIZED IT IN THIS WAY WHICH I THINK IS VERY TELLING.

NEXT SLIDE. THIS SLIDE EMPHASIZES THE VITAL ROLE THAT HYBRID SKILL SETS PLAY IN DRIVING INNOVATION WITHIN OUR FIELD OF REGENERATIVE MEDICINE. SO AS WE AIM TO BRIDGE THE GAP BETWEEN MULTIPLE DISCIPLINES, FOSTERING WORKFORCE THAT INVOLVES DIVERSE HYBRID SKILL SETS WILL BECOME

PARAMOUNT.

SO BEYOND A GROWING NEED FOR TRAINED PROFESSIONALS WITH THE COMPETENCIES NOTED, IT'S IMPORTANT TO MENTION THAT THE CELL AND GENE THERAPY FIELD IS PRETTY NASCENT AND MUCH INNOVATION IS NEEDED TO ADAPT TRADITIONAL DRUG DEVELOPMENT SKILL SETS TO THE PROCESS OF TRANSLATING COMPLEX PRODUCTS WITH UNCHARTERED REGULATORY PATHS TO SAFE AND AVAILABLE TREATMENTS WITH REGULATORY APPROVALS. AND THIS PATHWAY INCLUDES MANY UNKNOWNS.

WHAT REALLY DRIVES TRANSFORMATIVE INNOVATION IS A COMBINATION OF SKILL SETS IN DIVERSE INDIVIDUALS. AND IN OUR VIEW A HOLISTIC UNDERSTANDING OF PROCESS TO BE DEVELOPED, INNOVATION EMERGES WHEN DIVERSITY OF THOUGHT IS MARRIED TO STRONG TECHNICAL COMPETENCIES PLUS CURIOSITY-DRIVEN APPROACHES TO PROBLEM SOLVING. AND THERE ARE FEW OPPORTUNITIES TO GAIN THIS HYBRID SKILL SET TYPE OF TRAINING WHILE PURSUING HIGHER EDUCATION.

AND WHAT WE FOUND IS THAT INDIVIDUALS WITH SUCH HYBRID SKILL SETS ARE IN HIGH DEMAND. AND WE ALSO NEED PEOPLE WITH NEW COMBINATIONS OF SKILLS TO HELP DEFINE AND OVERCOME THE KNOWN UNKNOWNS. AND THIS IS SOMETHING THAT WE'VE HEARD THROUGH DIFFERENT PLACES; BUT AS I MENTIONED, THE NATIONAL ACADEMY'S

REGENERATIVE MEDICINE FORUM WORKFORCE DISCUSSION THIS YEAR AND A COUPLE OTHER REFERENCES HAVE REALLY REINFORCED THIS CONCEPT. AND A LOT OF THE CONVERSATIONS WE HAD WITH THE EDUCATION STAKEHOLDERS ALSO REINFORCED THIS CONCEPT, THAT TO DRIVE INNOVATION, WE NEED HYBRID SKILL SETS.

AND THE THIRD DATA SLIDE AND THE LAST ONE, SO THERE ARE THREE DATA SLIDES, AND THEN THERE'S GOING TO BE A DATA ANALYSIS SUMMARY BEFORE THE RECOMMENDATION.

SO THE THIRD DATA SLIDE ILLUMINATES A CRITICAL ISSUE IN THE DEMOGRAPHIC TRENDS WITHIN OUR EDUCATION SYSTEM, PARTICULARLY HIGHLIGHTING THE ATTRITION OF UNDERREPRESENTED GROUPS THAT BEGINS EARLY AND PERSISTS THROUGH HIGHER EDUCATION. SO WHAT WE CAN SEE HERE IS THE OVERVIEW OF ACADEMIC DEMOGRAPHICS. THE BARS REPRESENT THE DEMOGRAPHIC COMPOSITIONS FROM K TO 12 THROUGH COMMUNITY COLLEGES, STATE UNIVERSITIES, AND UNIVERSITY CALIFORNIA SYSTEM.

AS WE SEE, THE DIVERSITY PRESENTING EARLY EDUCATION DIMINISHES AS STUDENTS PROGRESS TO HIGHER LEVELS OF ACADEMIA. THERE ARE ALSO CHALLENGES HIGHLIGHTED HERE. THE DATA REVEALS A SIGNIFICANT REDUCTION IN REPRESENTATION, PARTICULARLY OF

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HISPANIC/LATINO STUDENTS, AS THEY TRANSITION FROM K TO 12 TO HIGHER EDUCATION SECTORS. THIS DIMINISHING DIVERSITY IS NOT JUST A STATISTIC. IT REPRESENTS A LOSS OF POTENTIAL TALENT AND DURATION IN FIELDS THAT ARE CRITICAL TO OUR FUTURE.

AND THEN CIRM'S TRAINING PROGRAMS ON THE RIGHT, YOU CAN SEE HOW CIRM'S TRAINING PROGRAMS, SUCH AS SPARK, COMPASS, AND BRIDGES, AND SCHOLARS, ARE DESIGNED TO ENGAGE STUDENTS AT VARIOUS EDUCATION LEVELS. WHILE SPARK TARGETS YOUNGER STUDENTS IN GRADES 10 TO 12, COMPASS AND BRIDGES EXTEND INTO COLLEGE AND BEYOND, AIMING TO SUPPORT AND SUSTAIN INTEREST AND PARTICIPATION IN SCIENTIFIC RESEARCH ACROSS ALL DEMOGRAPHICS.

THE UNDERLYING MESSAGE HERE IS THAT TARGETED AND CONSISTENT OUTREACH STARTED FROM EARLY EDUCATION, K THROUGH 10TH GRADE, IS CRUCIAL. AND BY ENGAGING STUDENTS EARLY, WE CAN BETTER SUPPORT THEIR ACADEMIC JOURNEY AND HELP PREVENT THE ATTRITION OF UNDERREPRESENTED STUDENTS IN HIGHER EDUCATION AND SUBSEQUENTLY IN THE WORKFORCE. NEXT SLIDE.

SO THESE ARE THE TAKE-HOME MESSAGES FROM THE DATA COLLECTED AND ANALYZED TO INFORM RECOMMENDATIONS. SO WE'VE IDENTIFIED COMPETENCY GAPS. OUR FINDINGS INDICATE SIGNIFICANT GAPS IN

EXPOSURE AND TRAINING WITH CALIFORNIA'S ACADEMIC LANDSCAPE, PARTICULARLY IN MANUFACTURING AND CLINICAL CAREER PATH RELATED TO GENE THERAPIES. AND THERE ARE FEW OPPORTUNITIES FOR HANDS-ON TRAINING AND DEVELOPMENT, MANUFACTURING, AND TRANSLATIONAL CELL AND GENE THERAPIES, AS WELL AS THE DEVELOPMENT OF CROSS-DISCIPLINARY SKILL SETS.

THE SECOND IS THAT WE HAVE IDENTIFIED THE WORRYING TREND OF DEMOGRAPHIC ATTRITION THAT BEGINS PRIOR TO COLLEGE ENTRY, HIGHLIGHTING A LOSS OF DIVERSE PERSPECTIVES EARLY IN THE EDUCATION PIPELINE.

AND LASTLY, LEVERAGING COLLABORATIONS AND BEST PRACTICES. THERE'S A SUBSTANTIAL OPPORTUNITY TO INCREASE PROGRAM CONNECTIVITY AND COLLABORATION, PARTICULARLY BETWEEN EDUCATIONAL INSTITUTIONS AND INDUSTRY.

SO NEXT SLIDE. THE OBJECTIVES OF THE EDUCATION GOAL ARE TO INCREASE ACCESS TO IN-DEMAND CELL AND GENE THERAPIES WORKFORCE COMPETENCIES THAT ARE CURRENTLY LIMITED IN ACADEMIC TRAINING ENVIRONMENTS AND INCREASE THE DIVERSITY OF THE FUTURE CELL AND GENE THERAPY WORKFORCE. THOSE ARE THE OBJECTIVES DERIVED FROM ALL OF THE ANALYSIS.

AND THE TWO APPROACHES THAT WE ARE GOING

TO PRESENT THROUGH THE RECOMMENDATIONS ARE TO ENHANCE THE SCOPE OF OUR CIRM CORE EDUC PROGRAMS AND TO IMPLEMENT OUTREACH AND EDUCATION CAMPAIGNS TO INTRODUCE REGENERATIVE MEDICINE CONCEPTS AND CAREER POSSIBILITIES TO CALIFORNIA'S DIVERSE COMMUNITIES.

SO WITH THAT, THE THREE RECOMMENDATIONS ARE IN THIS SLIDE. THE FIRST RECOMMENDATION IS THAT WE WILL -- WHICH IS TO PROVIDE HIGH-DEMAND TECHNICAL TRAINING VIA BRIDGES AND COMPASS PROGRAMS UPDATES. THIS WILL INCREASE TRAINING OFFERINGS, DIVERSE INTERNSHIP TYPES, AND INCREASE INTEGRATION WITH CIRM R&D PROGRAMS.

AND THE SECOND RECOMMENDATION IS TO CREATE A NEW TRAINING PROGRAM THAT WILL SPECIFICALLY INSTILL INDIVIDUALS WITH HYBRID SKILL SETS OF VALUE THAT ARE NECESSARY TO MOVE THE NEEDLE IN THE TRANSLATION OF CELL AND GENE THERAPIES FROM BENCH TO BEDSIDE. AND THIS PROGRAM WILL TARGET INDIVIDUALS WITH EXPERTISE IN ONE KEY DISCIPLINE THAT WANT TO GAIN HANDS-ON EXPERIENCE IN A COMPLEMENTARY DISCIPLINE AS INFORMED BY THE RESEARCH THAT WE'VE DONE IN THIS STRATEGIC ALLOCATION FRAMEWORK EXERCISE.

SOME OF THE EXAMPLES OF THE MOST VALUABLE COMBINATIONS WILL BE INTERNSHIPS IN GMP PROCESSES,

QA/QC, REGULATORY AFFAIRS FOR THOSE WITH AN ACADEMIC RESEARCH BACKGROUND, FOR EXAMPLE.

AND THIRDLY, THE RECOMMENDATION TO LAUNCH OUTREACH CAMPAIGNS TO EDUCATE THE PUBLIC AND INCREASE DIVERSITY OF CALIFORNIA'S REGENERATIVE MEDICINE WORKFORCE. WORKING WITH INTERNAL AND EXTERNAL PARTNERS, WE WILL BOTH COLLATE AND CREATE RESOURCES AND PROGRAMMING TO RAISE AWARENESS AND BRING EDUCATIONAL OPPORTUNITIES IN REGENERATIVE MEDICINE-RELATED AREAS TO COMMUNITIES AND POPULATIONS THAT ARE UNDERRESOURCED OR UNDERREPRESENTED IN STEM. THIS WILL INCLUDE WORKSHOPS AND BOOT CAMPS FOR TEACHERS AND JOURNALISTS, EVENTS FOR FAMILIES, K TO 12 STUDENTS TO EDUCATE ON VARIOUS CAREER PATHS THAT ARE OPEN TO CURIOUS MINDS AND INTRODUCE THE PROMISE OF CELL AND GENE THERAPIES AND IS ALIGNED WITH CIRM'S STRATEGIC PRIORITIES TO BOTH DIVERSIFY AND BOLSTER THE CELL AND GENE THERAPY WORKFORCE.

AND SOMETHING I WANT TO SAY AS WELL IS THAT WE HAVE ALREADY STARTED THIS BECAUSE THIS HAS BECOME ORGANIC TO THE EVOLUTION OF OUR PROGRAMS. SO WE'VE IDENTIFIED SOME THINGS, AND SOME PARTNERS HAVE ALREADY BEEN REACHING OUT TO US, AND WE ARE UNDERGOING SOME OF THESE THINGS.

ALSO, IN TERMS OF THE AVAILABILITY OF THE RESOURCES THAT WE ARE PUTTING TOGETHER, ONE OF THE THINGS THAT WE CREATED OVER THE PAST YEAR THAT NEEDS TO BE PRESENTED TO THE BOARD IS THE CIRM HUB THAT PROVIDES RESOURCES AND INTERCONNECTS ALL THESE DIFFERENT COMMUNITIES AND PROGRAMS WITHIN CIRM.

SO LASTLY, THIS WAS THE FINAL PART OF GOAL 6 RECOMMENDATIONS, BUT WE HAVE TWO MORE ADDITIONAL RECOMMENDATIONS TO THE BOARD THAT DO NOT FIT IN ANY OF THE SIX GOALS. AND THOSE ARE -- ONE IS THAT WE WOULD LIKE TO -- IN ORDER TO SUPPORT ALL THE GOALS, WE WOULD LIKE TO RECOMMEND THE BOARD TO CONSIDER RESTARTING THE GRANTEE CONFERENCE TO REPORT ON SAF GOAL PROGRESS. SO BASICALLY WE HAVE HAD A GRANTEE CONFERENCE IN THE PAST AND THAT WAS YEARLY. AND THE WAY WE WOULD ORGANIZE THE GRANTEE CONFERENCE NOW WOULD BE ALIGNED WITH THE GOALS. SO WE WOULD HAVE PROBABLY ONE OR TWO DAYS IN WHICH WE COULD GROUP THE DIFFERENT PRESENTATIONS AND OUTCOMES AROUND EVALUATING THE PROGRESS AGAINST OUR IMPACT GOALS. SO THAT'S NO. 1.

AND THE SECOND RECOMMENDATION IS, AS WE ALL KNOW, WE HAVE THE EDUC1 MECHANISM AND 2 AT THE MOMENT PAUSED. AND WE WOULD LIKE TO RECOMMEND TO KEEP THE CONFERENCE GRANTS MECHANISM 2, WHICH IS THE

ONE THAT'S ALIGNED WITH CIRM NEEDS. SO IN THIS CASE THE GRANTEE RETAINS THE PRIMARY RESPONSIBILITY FOR PLANNING, DIRECTING, AND EXECUTING THE PROPOSED EVENT. AND THE CIRM TEAM WORKS CLOSELY WITH THE GRANTEE TO DESIGN AND IMPLEMENT AN EVENT RESPONSIVE TO CIRM'S SPECIFIC NEED.

SO AN EXAMPLE OF THIS HAS BEEN THIS YEAR'S TRAINEE PINE CONFERENCE, WHICH WAS VERY SUCCESSFUL. THE SPARK CONFERENCE IS ANOTHER ONE. BUT UPCOMING IT'S GOING TO CONSORTIUM LIKE THE REMIND WILL NEED ONE OF THOSE, MANUFACTURING WILL NEED ONE OF THOSE, DIFFERENT PROGRAMS WILL NEED ONE OF THOSE. SO THAT IS WHAT WE WOULD BE RECOMMENDING TO THE BOARD.

AND NOW I THINK LET'S GO TO THE NEXT SLIDE. WE COULD GO INTO DISCUSSION AND NEXT STEPS. AND I DON'T KNOW IF WE WANT TO GO INTO THIS NOW. WE HAVE A FEW MORE SLIDES, AS YOU'VE ALL SEEN IN THE MATERIALS, THAT SHOW WHAT'S COMING, THE TIMELINE AGAIN, AND THE STAFF RECOMMENDATIONS, ALL OF THEM, BEFORE THE ASK. BUT I THINK PERHAPS, MARK, WE SHOULD STOP NOW AND PAUSE FOR QUESTIONS FOR GOALS 5 AND 6.

CHAIRMAN FISCHER-COLBRIE: YOU BET. LET'S GO AHEAD AND DO THAT. AND I SEE LEONDRA WITH A QUESTION.

DR. CLARK-HARVEY: GOOD MORNING, EVERYONE. I JUST WANT TO JUST MAKE A FEW COMMENTS. FIRST, I THINK THAT THIS PRESENTATION WAS INCREDIBLY THOROUGH AND THOUGHTFUL AND REFLECTIVE OF THE TIME AND ENERGY THAT'S GONE INTO REALLY THINKING THIS THROUGH. SO I FEEL REALLY PROUD OF THIS, AND I JUST REALLY WANT TO COMPLIMENT THE STAFF ON THE WORK.

ALSO, I APPRECIATE THE ACKNOWLEDGEMENT OF PAYMENT AND SOME OF THE PAYMENT DIFFICULTIES. YOU CALLED OUT MEDI-CAL AND REALLY HOW THAT IMPACTS ACCESS TO TREATMENT. SO IT'S GOOD TO KNOW THAT YOU ALL ARE REALLY THINKING THROUGH THAT.

AND THEN THE FOCUS ON WORKFORCE, BUILDING THE PIPELINE, THE BARRIERS, THE ATTRITION, AND THE OPPORTUNITIES. IT WAS REALLY GOOD TO HEAR THAT. SO I'M VERY EXCITED ABOUT THE PROPOSALS AND SUPPORTING THOSE. THANK YOU.

DR. CANET-AVILES: THANK YOU, LEONDRA.

CHAIRMAN FISCHER-COLBRIE: ROSA, I'LL HAVE YOU, IF YOU CAN SEE THE QUESTIONS RAISED, I'LL HAVE YOU CALL THEM OUT IN SEQUENCE. YEAH, NEXT.

DR. CANET-AVILES: DR. MELMED.

CHAIRMAN FISCHER-COLBRIE: SHLOMO.

DR. MELMED: I ECHO THE CONGRATULATIONS. THIS IS A REALLY WELL-THOUGHT THROUGH AND

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COMPREHENSIVE DOCUMENT AND SET OF IDEAS AND PROPOSALS. THANK YOU VERY MUCH. CALIFORNIA WILL REALLY BENEFIT FROM THIS.

I WANT TO JUST BRIEFLY ASK, MAYBE ASK MARIA TO SHARE WITH US SOMETHING YOU ALLUDED TO IN THE EARLIER SLIDES WHICH IS GOING TO IMPACT ALL OF CALIFORNIA. THAT IS THE CAP ON HEALTHCARE SPENDING OF 3.5 PERCENT WHICH THE STATE HAS INSTITUTED. AND I'M VERY CONCERNED THAT WITH THAT CAP IN PLACE, INSTITUTIONS WILL BE RELUCTANT TO ADOPT EXPENSIVE NEW THERAPIES BECAUSE THIS WILL VIOLATE THEIR CAP IMPOSED BY THE STATE.

AND I'M WONDERING, MARIA, IF IN THE OTHER COMMITTEES WHICH DEAL WITH REGULATION, IF WE COULD APPROACH THE STATE FOR A CARVE-OUT TO EXEMPT STEM CELL THERAPIES FROM THE CAP OF INCREASED SPENDING. I KNOW THAT WILL REQUIRE A TREMENDOUS AMOUNT OF LOBBYING IN SACRAMENTO, BUT MAYBE YOU CAN SHARE WITH US, MARIA, YOUR COMMITTEE IF THEY'VE ACTUALLY CONSIDERED THAT BECAUSE MANY, MANY ORGANIZATIONS AND AMERICAN HOSPITAL ASSOCIATION ARE RIGHT NOW LOBBYING TO TRY TO OBTAIN THESE CARVE-OUTS FOR UNIQUE SITUATIONS. AND I THINK ACCESS TO STEM CELL THERAPY AND EXEMPTING NEW STEM CELL THERAPIES FROM THE FISCAL CAP WOULD HELP ADOPTION AND CERTAINLY HELP

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ACCESS.

VICE CHAIR BONNEVILLE: THANK YOU, DR. MELMED. THIS IS SOMETHING DEFINITELY THAT THE ACCESS AND AFFORDABILITY WORKING GROUP CAN TAKE UP. IT'S NOT ON OUR AGENDA QUITE YET, BUT THAT'S SOMETHING I CAN WORK WITH GEOFF LOMAX TO TAKE UP AND BRING TO THE COMMITTEE.

THE COMMITTEE HAS BEEN MOSTLY FOCUSED ON THINGS THAT WE CAN DO INTERNALLY IMMEDIATELY TO SET UP OUR GRANTEES IN A WAY THAT THEY WILL BE MORE SUCCESSFUL MOVING FORWARD POST BLA IN HAVING APPROPRIATE DATA. AND IN THE CONVERSATIONS WE'VE HAD WITH OTHER PARTNERS, WHAT THEY NEED TO SET THEMSELVES UP FOR REIMBURSEMENT AND POTENTIAL REIMBURSEMENT.

MOSTLY WE'VE BEEN TALKING AROUND THE PILOT PROGRAM THAT CAME OUT FOR SICKLE CELL FOR REIMBURSEMENT. AND SORT OF WILL THAT BE A MODEL MOVING FEDERALLY AND THEN AGAIN IN CALIFORNIA AS THEY APPLY TO BE PART OF THAT PILOT PROGRAM. SO WE HAVE BEEN TALKING TO MEDI-CAL ABOUT THAT THEIR THOUGHTS AROUND THIS AND WHAT THEY'RE LOOKING FOR AND WHAT THE CONFUSION IS PERHAPS IN THE INDUSTRY AROUND DATA COLLECTION AND OTHER SUCH COMPONENTS THAT ARE PART OF THAT PILOT PROGRAM.

BUT WE WILL DEFINITELY BRING THIS UP IN COMMITTEE. SO THANK YOU.

I DO THINK, ALSO TO ADD, I DO THINK THE VALUE THAT CIRM WILL BRING MOVING FORWARD IS IN POLICY. AS YOU KNOW, WE CAN'T AFFECT REALLY AT THE END OF THE DAY WHAT SOMEBODY CHARGES FOR THEIR THERAPY. BUT POLICY AROUND REIMBURSEMENT IS REALLY WHERE WE'RE GOING TO HAVE THE BIGGEST EFFECT. SO WE DID ENGAGE LOBBYISTS IN DC THIS YEAR TO HELP US THROUGH SOME OF THE POLICY THAT'S MOVING THERE. AND WE ALSO HAVE WONDERFUL LOBBYISTS IN SACRAMENTO WHO KEEP US APPRISED OF THE DIRECTION THAT SOME OF THIS IS GOING.

DR. MELMED: I WANT TO EMPHASIZE THIS IS NOT A FEDERAL ISSUE. IT'S A STATE ISSUE.

VICE CHAIR BONNEVILLE: I UNDERSTAND. SO I WAS JUST SORT OF GIVING CONTEXT TO WE'RE NOT JUST LOOKING AT IT, WE'RE NOT JUST LOOKING AT THIS FROM A STATE LEVEL. WE'RE LOOKING AT ALL POLICIES ACROSS THE BOARD.

CHAIRMAN FISCHER-COLBRIE: OTHER QUESTIONS?

DR. CANET-AVILES: SORRY, PAT.

DR. LEVITT: ROSA, THAT WAS GREAT. YOU'VE HEARD ME TALK ABOUT THIS BEFORE. ONE OF THE THINGS

THAT I WANTED TO MENTION, PARTICULARLY RELATED TO THE LAST GOALS AND WORKFORCE -- ENHANCING WORKFORCE SKILLS AND DIVERSITY. MANY OF OUR ACADEMIC INSTITUTIONS IN CALIFORNIA HAVE PROGRAMS THAT EVEN BEGIN IN GRADE SCHOOL IN TERMS OF OUTREACH, HIGH SCHOOL PROGRAMS, ET CETERA, ET CETERA.

SO I'M WONDERING IF PART OF THE STRATEGY MIGHT BE TO HAVE CIRM PREPARE MATERIALS THAT WOULD HELP THEM PROMOTE AS THEY DO THEIR PROGRAMS TO PROMOTE REGENERATIVE MEDICINE AND THERAPIES THAT WOULD PLANT THE SEEDS AS EARLY AS POSSIBLE ABOUT THE IMPORTANCE OF THIS AREA OF BIOMEDICINE.

RIGHT NOW A LOT OF THOSE PROGRAMS CREATE THEIR OWN MATERIALS TO SHARE. MANY OF THEM DON'T HAVE DEEP UNDERSTANDING OF CIRM AND ALL OF ITS AMAZING PROGRAMS. SO I'M THINKING THAT THAT MIGHT BE A WAY IN ADDITION TO OUR OWN PROGRAMS THAT WE HAVE, OUR OWN TRAINING PROGRAMS WE HAVE, TO ENGAGE WITH THE MANY PROGRAMS THROUGHOUT THE STATE IN ACADEMIC INSTITUTIONS THAT ARE DOING THIS. SO THEY WOULD BASICALLY BE THE FEET ON THE GROUND WITH THE ADDITIONAL HELP THAT WE CAN GIVE THEM FOR MATERIALS THAT WOULD HIGHLIGHT WHAT CIRM IS DOING.

DR. CANET-AVILES: ABSOLUTELY, PAT. THAT'S GREAT THINKING, AND THAT ACTUALLY ALIGNS WITH

OUR CURRENT PLANS. AND I WOULD LIKE TO INVITE DR. KELLY SHEPARD IF SHE WANTS TO ADD SOMETHING TO THIS BECAUSE THAT'S A VERY PERTINENT. AND GREAT MINDS THINK ALIKE. KELLY, DO YOU WANT TO THIS?

DR. SHEPARD: IF I CAN NAVIGATE SCREEN SHARING BECAUSE I SEEM TO BE HAVING SO MANY DIFFICULTIES. CAN EVERYBODY HEAR ME?

DR. CANET-AVILES: YES.

DR. SHEPARD: THAT'S ABSOLUTELY AGREED. IT'S A FANTASTIC IDEA, AND IT WAS ONE OF THE THINGS THAT WE HAD IN MIND. WE ACTUALLY -- AS YOU MAY KNOW, OUR CURRENT EDUCATION PROGRAMS, BRIDGES, COMPASS, CIRM SCHOLARS, ET CETERA, PART OF THEIR PROGRAMMING IN THEIR GRANT IS A REQUIREMENT TO DO COMMUNITY OUTREACH AND PATIENT ENGAGEMENT. AND IN FACT SOME OF THE BRIDGES PROGRAMS HAVE ALREADY PILOTED SOME VERY INTERESTING PARTNERSHIPS, FOR EXAMPLE, WITH BABEC IN THE BAY AREA. THEY ACTUALLY PARTNER -- BABEC DEVELOPS LAB KITS, PORTABLE LAB KITS, AND MATERIALS THAT HIGH SCHOOL TEACHERS CAN OBTAIN FOR LITTLE TO NOTHING AND TAKE IT TO THEIR CLASS. AND THERE'S LIKE A SELF-CONTAINED MODULE OF LESSONS. AND IT'S REALLY HELPFUL FOR TEACHERS WHO MAY NOT HAVE EXPOSURE OR KNOW MUCH ABOUT CERTAIN BIOTECH FIELDS, BUT TO HAVE ALL THOSE MATERIALS MADE

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DIRECTLY AVAILABLE TO THEM THAT THEY CAN THEN TAKE TO THEIR CLASS AND SHARE.

AND THE BRIDGES STUDENTS ACCOMPANY THIS, AND THEY INCLUDE A LECTURE AND A PRESENTATION ABOUT THEIR EXPERIENCES AS PART OF THAT. AND WE THINK THAT'S A REALLY GREAT MODEL. SO WE'RE LOOKING INTO WORKING WITH BABEC AND OTHER ORGANIZATIONS LIKE THIS TO DEVELOP REGENERATIVE MEDICINE-FOCUSED MODULES THAT CAN GO INTO THESE MATERIALS THAT ALREADY EXIST AND TO LEVERAGE THESE PARTNERSHIPS THAT ALREADY EXIST. AND THEY HAVE A NETWORK OF TEACHERS THROUGHOUT THE STATE THAT THEY WORK WITH.

SO I THINK WE CAN GET A LOT OF BANG FOR OUR BUCK BY TARGETING TEACHERS. WE CAN REACH A LOT MORE STUDENTS THAT WAY BY GETTING THROUGH THE TEACHERS. AND AS YOU JUST MENTIONED, THESE RESOURCES THAT THE UNIVERSITIES AND OTHERS THAT ALSO HAVE EDUCATION OUTREACH SYSTEMS, THAT'S ANOTHER VERY CLEAR AND IMPORTANT PLACE WHERE WE CAN LOOK TO ENGAGE AND ALSO SHARE THESE RESOURCES AND MATERIALS AND MAYBE EVEN TUNE SOME TO THEIR NEEDS SO THAT THEY CAN TAKE ADVANTAGE AND LEVERAGE THESE RESOURCES AS WELL.

DR. LEVITT: THAT'S GREAT. THANK YOU.

DR. CANET-AVILES: GREAT. KELLY, WE ARE

NOT THERE YET. KELLY.

DR. SHEPARD: YES.

DR. CANET-AVILES: GO BACK. THIS IS NOT READY YET.

DR. SHEPARD: OH, SORRY.

DR. CANET-AVILES: YOU'RE JUMPING THE GUN.

DR. SHEPARD: I DIDN'T REALIZE. I WAS LOOKING FOR MY UNMUTE. SORRY ABOUT THAT, EVERYBODY.

DR. CANET-AVILES: NOT A PROBLEM.

ANY OTHER QUESTIONS? OTHERWISE, WE CAN MOVE ON TO THE NEXT STEPS. BUT THIS IS A VERY INFORMATIVE SET OF QUESTIONS FOR US. AND THANK YOU. REALLY APPRECIATE. AND ALSO THE ENCOURAGEMENT.

NOW IT'S A QUESTION OF SEEING HOW ARE WE GOING TO FIT ALL OF THESE GOALS IN THE PRESENTATION AT THE BOARD MEETING. BUT WE HAVE SARA AND THOMAS THINKING ABOUT THAT.

OKAY. NO MORE QUESTIONS. MARK, SHALL WE MOVE ON?

CHAIRMAN FISCHER-COLBRIE: YES, LET'S MOVE ON.

DR. CANET-AVILES: QUESTIONS AND QUESTIONS AROUND THE NEXT. OKAY. SO, KELLY, IF YOU WANT TO JUST GO ONTO THE NEXT SLIDE.

JUST THE TIMELINE AND NEXT STEPS TO

POSITION EVERYBODY WHERE TODAY WE ARE DISCUSSING THE OVERALL RECOMMENDATIONS IN PREPARATION FOR THE SEPTEMBER ICOC. AND THEN WE HAVE THE SEPTEMBER ICOC IN A COUPLE OF WEEKS. NEXT SLIDE.

YOU CAN JUST PASS THIS ONE BECAUSE WE JUST DID THIS. AND THEN THIS ONE JUST AS A REMINDER THAT WE WOULD BE PAUSING CURRENT PROGRAMS. DURING THE UPCOMING BOARD MEETING, WE WILL BE PROPOSING THAT SO THAT WE CAN ALIGN WITH -- THAT WE CAN DEVELOP THESE CONCEPTS AS WELL AS ENSURING THAT OUR R&D BUDGET IS DIRECTED TOWARDS THE MOST PROMISING AREAS OF RESEARCH AND THAT OUR OPERATIONAL AND ADMINISTRATIVE PROCESSES ARE ALIGNED TO SUPPORT THE IMPLEMENTATION OF ALL THESE NEW PROGRAMS. JUST WANT TO MAKE SURE. OKAY.

NEXT SLIDE IS NOW, I KNOW SOME PEOPLE HAVE BEEN LOOKING FORWARD TO THIS. SO WE HAVE ADDED WHAT WE HAVE DONE, AND THIS IS OBVIOUSLY FOOD FOR THOUGHT. BUT WE HAVE VERY CAREFULLY DIVIDED IN TEAMS TO DEVELOP A RANGE OF IMPACT GOALS, THE RANGE, THE NUMERIC RANGE, AND WE HAVE JUSTIFIED IT IN DIFFERENT WAYS. SO I'M JUST GOING TO GO OVER READING THE GOALS AND THE RECOMMENDATIONS TO FRESHEN UP OUR MINDS, AND THEN WE CAN GO INTO QUESTIONS.

AND THE FINAL SLIDES -- THERE ARE FOUR

SLIDES. THESE THREE, BASICALLY THE OVERVIEW OF ALL THE GOALS NOW WITH THE X'S NOMINATED AND THE RECOMMENDATIONS, AND THEN THE FINAL ONE IS THE ENDORSEMENT ASK FROM THE SCIENCE SUBCOMMITTEE/NEURO TASK FORCE JOINT SUBCOMMITTEES TO GO TO THE BOARD.

SO WITH THAT, THE FIRST GOAL, AS WE ALL REMEMBER, IS TO CATALYZE THE IDENTIFICATION AND VALIDATION OF FIVE TO EIGHT NOVEL TARGETS AND BIOMARKERS, ENSURING THE INTEGRATION INTO PRECLINICAL OR CLINICAL RESEARCH FOR DISEASES IN CALIFORNIA. AND THIS IS ALIGNED WITH THE FACT THAT WE MIGHT HAVE AN INFLUENCE FOR PREVALENT DISEASES THAT MIGHT NOT COME STRAIGHT FROM THE CELL OR THE GENE THERAPY. IT MIGHT COME FROM THE FACT THAT WE WILL HAVE DISCOVERED A NEW TARGET OR PROVIDED A NEW BIOMARKER THAT WILL HELP US STRATIFY OR PROVIDE CLINICAL EFFICACY FOR THERAPIES AND DISEASES THAT RIGHT NOW HAVE THESE BOTTLENECKS AND CANNOT ADVANCE THE FIELD.

SO THAT IS WHERE THIS GOAL IS COMING FROM. AND FOR THAT, WE FOCUSED ON TWO RECOMMENDATIONS. THE FIRST ONE WAS TO SUPPORT COMPREHENSIVE DISCOVERY RESEARCH THROUGH DISC4 AND DISC5 FUNDING STRUCTURES. AS YOU RECALL, WE HAVE PILOTED THIS WITH THE NEUROPSYCHIATRIC REMIND PROGRAM, BUT THIS COULD THEN

EXPAND TO ALL DISEASES. AND WE COULD PROBABLY TAKE A SYSTEMS APPROACH, NOT FOCUSED IN ONE DISEASE IN PARTICULAR, BUT TO FOCUS ON A SPECIFIC SYSTEM TO GATHER DATA SO WE CAN ADVANCE THE FIELD. AND THIS WOULD ENCOURAGE COLLABORATIVE MULTIDISCIPLINARY INNOVATION IN STEM CELL AND GENETIC RESEARCH ACROSS DIVERSE DISCIPLINES AND DISEASE INDICATIONS WITH EARLY ENGAGEMENT OF INDUSTRY TO ADDRESS REPRODUCIBILITY AND SCALABILITY ISSUES. AND AS YOU RECALL, THE LAST PART OF THIS SENTENCE WAS WHAT WE ADDED AFTER VERY IMPORTANT FEEDBACK FROM YOUR INPUT.

THE SECOND ONE WILL BE TO ESTABLISH A DATA COORDINATING AND MANAGEMENT CENTER TO STREAMLINE DATA MANAGEMENT AND ENHANCE THE UTILITY OF CROSS-DISEASE DATA. THIS HAS TO DO WITH OUR DATA INFRASTRUCTURE. THE SHAPE OF THIS WE ARE STILL FIGURING IT OUT, BUT WE WOULD FUND AND DEVELOP A CENTRAL HUB FOR DATA COORDINATION, FACILITATING BETTER INTEGRATION WITH CONSORTIA AND OTHER RESEARCH INITIATIVES THAT HELP US LEVERAGE EACH OTHER'S DATA AND ENABLE -- WE WOULD ALSO ENABLE DATA SCIENCE COLLABORATIVE EFFORTS VIA DEDICATED GRANTS, WHICH WAS ALSO FEEDBACK THAT WE GATHERED FROM THE SCIENCE SUBCOMMITTEE AND NEURO TASK FORCE MEMBERS.

SECOND GOAL IS TO ACCELERATE THE

DEVELOPMENT AND UTILIZATION OF FIVE TO EIGHT TECHNOLOGIES THAT DEMONSTRATE IMPROVEMENT IN SAFETY, EFFICACY, OR QUALITY OF CELL AND GENE THERAPIES. FOR THAT WE WOULD BE PILOTING AN INFRASTRUCTURE TECHNOLOGY PLATFORM PROGRAM UNDER OUR PRECLINICAL DEVELOPMENT PROGRAMS TEAM TO BRIDGE THE GAP BETWEEN RESEARCH AND COMMERCIALIZATION. AND ONE OF THE THINGS THAT WE COULD DO IS TO FORCE PARTNERSHIPS BETWEEN ACADEMIC RESEARCHERS AND INDUSTRY PROFESSIONALS TO SUPPORT MULTISTAKEHOLDER TECHNOLOGY INCUBATION PROGRAMS THAT ACHIEVE DEFINED TECHNOLOGY READINESS LEVELS, FACILITATING RAPID APPLICATION IN CELL AND GENE THERAPY DEVELOPMENT.

JUST AS SOMETHING THAT I FORGOT TO SAY IN EACH ONE OF THESE RECOMMENDATIONS, THE FIRST RECOMMENDATION AND FIRST GOAL IS ACTUALLY AN AMENDMENT.

THE SECOND ONE WOULD BE A NEW CONCEPT, ALTHOUGH IT WOULD NOT BE AN URGENT CONCEPT. THE THIRD ONE COULD BE A NEW CONCEPT. IT'S ONE I JUST SPOKE ABOUT. AND THIS ONE COULD BE KIND OF LIKE A PRIORITY ONE, NOT KIND OF, IS A PRIORITY.

THE THIRD RECOMMENDATION, THE THIRD GOAL, SORRY, IS TO ADVANCE SIX TO TEN RARE DISEASE PROJECTS TO BLA. THIS HAD TWO RECOMMENDATIONS. ONE

WAS TO ACCELERATE THE CURRENT RARE DISEASE THERAPY PIPELINE. AND ONE OF THE THINGS WE HAVE -- AND DR. CREASEY CAN SPEAK TO THAT -- WE HAVE EVALUATED THROUGH OUR CLIN2 APPLICANTS IS TO INCREASE AND SCALE CLIN4 FUNDING TO COMPREHENSIVELY ADDRESS BLA-READINESS GAPS IN MANUFACTURING, CLINICAL, AND NONCLINICAL RESEARCH, AND PRECOMMERCIALIZATION.

AND THE SECOND ONE, AND THIS COULD BE AN AMENDMENT, AND THE SECOND RECOMMENDATION IS A NEW CONCEPT THAT DR. CREASEY IS DEVELOPING THAT IS TO DEVELOP THE PILOT PLATFORM-BASED THERAPY DEVELOPMENT, TO IMPLEMENT A PILOT PLATFORM-BASED APPROACH FOR GENE THERAPY DEVELOPMENT USING LIFE-THREATENING MONOGENIC NEUROLOGICAL DISORDERS AS A TEST CASE.

THE NEXT SLIDE HAS GOALS 4 AND 5. SO THE FIRST ONE IS TO PROPEL 15 TO 20 THERAPIES TARGETING DISEASES AFFECTING CALIFORNIANS TO LATE-STAGE TRIALS. FOR THIS WE HAVE TWO RECOMMENDATIONS.

THE FIRST ONE IS A NEW PROGRAM, A NEW CONCEPT WHICH COULD CORRESPOND TO A STREAMLINING PRECLINICAL DEVELOPMENT PROGRAMS, CONSOLIDATING DISC2, TRAN1, 2, 3, 4, AND CLIN1, TO ACCELERATE THE PRECLINICAL DEVELOPMENT, INCENTIVIZING MULTIDISCIPLINARY COLLABORATIONS AND RAPID

PROGRESSION TO IND, INCORPORATING PRIORITIZATION OF INNOVATIVE THERAPIES FOR DISEASES THAT AFFECT CALIFORNIANS. AND THIS ONE, WE DON'T KNOW IF IT WILL BE ONE PROGRAM IN TWO PARTS OR HOW IT WILL BE. THESE DETAILS WILL BE COMING AT THE FIRST -- THIS WOULD BE A PRIORITY CONCEPT AS WELL THAT WE HOPE WE WOULD BE ABLE TO PRESENT IN JANUARY ONLY IF WE CAN PAUSE REVIEWS FOR THE TIME BEING SO WE CAN REORGANIZE OURSELVES AND PRIORITIZE THESE VERY IMPORTANT PROGRAMS.

THE SECOND IS THE CLIN2 UPDATE. THIS COULD BE AN AMENDMENT, NOT A NEW CONCEPT, WHICH COULD ALSO COME AT THE JANUARY MEETING HOPEFULLY. AND THIS COULD ALLOW FOR SUPPORT OF EMERGING NOVEL CLINICAL TRIAL DESIGNS IN CLIN2 PROGRAM, INCENTIVIZING STAGE-APPROPRIATE MARKET ACCESS STRATEGY DEVELOPMENT AND PRECOMMERCIALIZATION ACTIVITIES IN CLIN2 PROGRAM AND INCORPORATE THE PRIORITIZATION OF INNOVATIVE THERAPIES FOR DISEASES THAT AFFECT CALIFORNIANS. THIS ONE IS ALSO ALIGNED WITH GOAL 5, THE CHALLENGES THAT WE SAW. THAT'S WHERE THE LINK COMES FROM.

FIFTH GOAL IS TO ENSURE THAT EVERY BLA-READY PROGRAM HAS A STRATEGY FOR ACCESS AND AFFORDABILITY. AND WE HAVE THE PROGRAM SITE AND THE

POLICY AND PARTNERSHIPS. AND I WON'T GO THROUGH IT BECAUSE WE'VE ALREADY GONE THROUGH IT TODAY. I WANT TO MAKE SURE WE HAVE TIME FOR QUESTIONS.

THE SIXTH GOAL, NEXT SLIDE. THANK YOU, KELLY. WE JUST WENT THROUGH IT. IT'S BOLSTERING THE CIRM WORKFORCE DEVELOPMENT PROGRAMS TO ADDRESS THE DEMANDS OF OUR EVOLVING FIELD. AND WE COULD GO THROUGH THE RECOMMENDATION OF AMENDING THE BRIDGES AND COMPASS PROGRAMS, UPDATING THEM, TO INCREASE THE TRAINING OFFERINGS, DIVERSIFYING INTERNSHIP TYPES, AND INCREASING INTEGRATION WITH THE R&D GRANTS.

THE SECOND WOULD BE THE NEW PROGRAM TO DEVELOP HYBRID SKILL SETS. AND THE LAST ONE IS THE OUTREACH CAMPAIGNS THAT PAT LEVITT PROVIDED SUCH RELEVANT FEEDBACK TODAY ALIGNED WITH SOME OF THE THOUGHTS THAT WE HAVE. AND THANK YOU.

AND THEN THE ADDITIONAL RECOMMENDATIONS TO START -- TO RESTART THE GRANTEE CONFERENCE AND TO KEEP CONFERENCE GRANTS JUST FOR THE MECHANISM TWO.

AND BEFORE WE GO, DO I GO NOW INTO THE ASK OF THE REQUESTED ACTION, OR SHOULD I STOP HERE, MARK?

CHAIRMAN FISCHER-COLBRIE: I THINK WE SHOULD GO FOR THE ASK BECAUSE THEY'RE BOTH ACTIONS.

DR. CANET-AVILES: OKAY. I'LL GO TO THE

REQUESTED ACTION. WITH THIS, OUR ESTEEMED BOARD MEMBERS, WE REQUEST A MOTION THAT THE SCIENCE SUBCOMMITTEE AND NEURO TASK FORCE MEMBERS RECOMMEND APPROVAL OF THIS TO THE FULL BOARD OF THESE GOALS AND RECOMMENDATIONS.

AND I WOULD LIKE TO THANK YOU ALL FOR LISTENING TO US AND FOR PROVIDING FEEDBACK THROUGHOUT ALL THIS PROCESS, WHICH HAS TAKEN A LOT OF YOUR TIME AS WELL, AND ESPECIALLY THE CO-CHAIRS. THANK YOU.

CHAIRPERSON FISCHER-COLBRIE: YEAH. AND I'D LIKE TO ACKNOWLEDGE CAROLYN. YEAH. GO AHEAD, CAROLYN.

DR. MELTZER: ROSA, THANK YOU FOR ALL OF YOUR AND YOUR TEAM'S WORK ON THIS IN-DEPTH -- IN THESE IN-DEPTH RECOMMENDATIONS. I'D LIKE TO GO AHEAD AND MAKE A MOTION TO APPROVE FOR THE FULL BOARD THE RECOMMENDATIONS AS DISCUSSED.

DR. LEVITT: THIS IS PAT.

CHAIRMAN FISCHER-COLBRIE: THANKS, CAROLYN. THANK YOU.

DR. LEVITT: I'D LIKE TO SECOND THAT MOTION.

CHAIRMAN FISCHER-COLBRIE: EXCELLENT. THANK YOU. SO THAT'S ON THE TABLE. OPEN FOR

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DISCUSSION FROM MEMBERS ON THE CALL HERE.

DR. LEVITT: I JUST WANTED TO ASK. ROSA, WE HAD A SESSION WITH EXPERTS IN GENE THERAPY, INCLUDING REPRESENTATIVES FROM THE FDA, TALKING ABOUT THERE'S A LOT OF DISCUSSION, AND THIS IS OUT OF MY AREA OF EXPERTISE, IT WAS A TON OF DISCUSSION. IN FACT, I THINK IT DOMINATED DISCUSSION ABOUT THE CHALLENGES TARGETING SPECIFIC DISEASES. THE MANUFACTURING COMPONENT SEEMS TO BE ON EVERYBODY'S HIGH ALERT IN TERMS OF THE CHALLENGES THERE.

AND SO I THINK WHEN YOU GO THROUGH THESE GOALS, I THINK, FOR THE FULL BOARD, HIGHLIGHTING THE ROLE THAT CIRM IS TRYING TO PLAY IN THAT AREA, I THINK, IS REALLY IMPORTANT BECAUSE I THINK THAT WE'RE NOT GOING TO BE ABLE TO SOLVE ALL THE PROBLEMS, BUT IT'S A HUGE DEAL. AND I THINK BOARD MEMBERS SHOULD UNDERSTAND HOW CHALLENGING THAT IS GOING TO BE UNTIL NEW TECHNOLOGIES COME FORWARD THAT MAKE IT A WHOLE LOT EASIER TO GENERATE THE MATERIALS FOR CLINICAL USE.

DR. CANET-AVILES: THANK YOU, PAT. THAT'S VERY PERTINENT. AND ACTUALLY I WOULD LIKE TO INVITE DR. SHYAM PATEL TO MAKE A COMMENT. AS PART OF THE RESTRUCTURE THAT OUR PRESIDENT J.T. PROVIDED YESTERDAY TO THE GOVERNANCE SUBCOMMITTEE THAT WILL

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BE COMING UNDER HIS PRESIDENTIAL REPORT AT THE ICOC, ONE OF THE THINGS WE ARE DOING IS WE'VE CREATED A PRECLINICAL DEVELOPMENT TEAM LED BY DR. SHYAM PATEL, WHO IS GOING TO BE OUR ASSOCIATE VICE PRESIDENT FOR CLINICAL DEVELOPMENT. AND UNDER HIS LEADERSHIP WE ARE GOING TO HAVE PRECLINICAL DEVELOPMENT THAT WILL CONTAIN THE INFRASTRUCTURE TECHNOLOGY PLATFORM PROGRAMS, THE PRECLINICAL DEVELOPMENT PROGRAMS, AND THE MANUFACTURING.

SO, SHYAM, I DON'T KNOW IF YOU WANT TO ADD ANYTHING HERE, BUT I JUST WANTED TO SAY WE'VE IDENTIFIED THAT AND THERE IS A VERY SPECIFIC GOAL AT CIRM THAT WE'LL BE TACKLING THIS WITH HIS EXPERTISE.

DR. PATEL: THANK YOU. I HOPE YOU CAN HEAR ME OKAY AND MAKE SURE MY SETTINGS ARE FINE.

DR. LEVITT: YEAH. IT'S GOOD.

DR. PATEL: THANKS, PAT, FOR RAISING THAT ISSUE. YOU'RE ABSOLUTELY RIGHT. AS THE BOARD KNOWS, THERE'S BEEN A SIGNIFICANT NUMBER OF CELL AND GENE THERAPIES THAT HAVE REACHED THE BLA STAGE, HAVE FILED THEIR BLA'S, AND THEN HAVE RUN INTO CMC ISSUES THAT HAVE EITHER STALLED THE BLA APPROVAL OR COMPLETELY -- OR DELAYED IT SIGNIFICANTLY.

SO WE HAVE BEEN TAKING A COMPREHENSIVE APPROACH ON THE MANUFACTURING SIDE ACROSS DIFFERENT

LEVELS. FIRST AND FOREMOST, AS YOU REMEMBER, A COUPLE YEARS AGO WE HAD ASKED YOU TO APPROVE A FUNDING OPPORTUNITY FOR A MANUFACTURING NETWORK. AND WHAT THAT WAS DESIGNED TO DO IN THE FIRST STAGE OF THAT IS TO ADDRESS THE FACT THAT MANY OF THESE THERAPIES ARE GOING THROUGH ACADEMIC GMP MANUFACTURING FACILITIES THAT HAVE THE EXPERTISE TO MANUFACTURE THOSE TYPES OF PRODUCTS. AND TO IMPLEMENT THEIR SPECIFIC SET OF IMPROVEMENTS AND COMPETENCIES THAT COULD HELP THESE PROJECTS MOVE MORE SMOOTHLY TO LATER-STAGE CLINICAL DEVELOPMENT.

AND SO THAT'S ONE OF THE THINGS THAT'S IN PLACE RIGHT NOW. AND THE SECOND PHASE OF THAT IS GOING TO BUILD ON THAT TO CREATE MORE INTERCONNECTIVITY BETWEEN THE ACADEMIC CENTERS AND THE INDUSTRY TO ALLOW FOR SMOOTHER PROGRESSION ON THESE PROJECTS BECAUSE ONE OF THE ISSUES THAT HAPPENS THAT LEADS TO THESE BLA DELAYS IS THAT MANUFACTURING IS PLAYING CATCH-UP WITH CLINICAL DEVELOPMENT FOR A LOT OF THESE CELL AND GENE THERAPIES. AND YOU HAVE ISSUES WITH COMPARABILITY OF A COMMERCIAL PROCESS OR DEVELOPMENT OF VARIOUS ASSAYS. AND SO THOSE ARE THE TYPES OF THINGS WE WANT TO ADDRESS BY CREATING A LOT MORE COLLABORATION AND COORDINATION BETWEEN THE ACADEMIC GMP FACILITIES

AND INDUSTRY FACILITIES THROUGH OUR FUNDING OPPORTUNITIES.

THE OTHER PART OF THIS IS TECHNOLOGY DEVELOPMENT THAT ROSA HAD MENTIONED, AND THAT'S WHERE WE CAN PROVIDE AN INVESTMENT TO ADDRESS SOME OF THESE CONCERNS AROUND AUTOMATION, CLOSING MANUFACTURING PROCESSES, OR DEVELOPMENT OF ASSAYS, PARTICULARLY POTENCY ASSAYS, THAT COULD ALLOW FOR BETTER PROGRESSION OF THE THERAPIES, A BETTER QUALIFICATION OF THOSE ASSAYS DOWN THE ROAD, AND BETTER VALIDATION AS WELL.

SO THOSE ARE THE TYPES OF THINGS THAT WE'RE TRYING TO PUT INTO PLACE. AND THE OTHER PART OF THAT IS THE CLIN4 MECHANISM THAT ROSA MENTIONED WOULD NEED TO BE OPTIMIZED BECAUSE IF THERE IS GOING TO BE SIGNIFICANT MANUFACTURING ISSUES AT THE END STAGE THERE, WE WANT TO MAKE SURE THAT WE ALLOW FOR APPROPRIATE RESOURCES AND FUNDING TO ADDRESS THOSE CHALLENGES AND ALSO BE ABLE TO ADDRESS THE COMMERCIALIZATION PLANNING THAT NEEDS TO BE DONE THERE.

SO IT'S A COMPREHENSIVE APPROACH STARTING WITH THEY EARLY STAGE AND MAKING SURE THAT WE CAN PROVIDE SUPPORT AND ADDRESS THESE CHALLENGES TO LATE STAGE.

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DR. LEVITT: THAT'S GREAT. AND THANKS VERY MUCH. AND IT'S A WAY FOR US -- FOR CIRM TO COMMUNICATE THE BREADTH OF WHAT WE'RE DOING TO RECOGNIZE THAT WE'RE NOT JUST MAKING IMPORTANT DISCOVERIES, IT'S NOT JUST, SO WE'RE MAKING IMPORTANT DISCOVERIES, TRANSLATING THOSE, BUT WE ALSO RECOGNIZE THAT GETTING IT OUT -- FACILITATING THE MARKET WHERE CALIFORNIA CITIZENS ARE REALLY GOING TO CARE IN TERMS OF ACCESS TO THE THERAPIES, I THINK, IS REALLY IMPORTANT FOR US TO COMMUNICATE, THAT WE'RE TAKING A MULTIPRONGED APPROACH. IT'S GREAT. THANKS.

DR. CANET-AVILES: THANK YOU, SHYAM.

CHAIRMAN FISCHER-COLBRIE: GREAT COMMENT.

DR. CANET-AVILES: KELLY WAS REMINDING ME THAT WE WILL ALSO COMPLEMENT THIS WITH OUR -- ENHANCE IT WITH OUR TRAINING REQUIREMENTS AS WELL AND OPPORTUNITIES. SO THANK YOU, KELLY.

CHAIRMAN FISCHER-COLBRIE: OTHER DISCUSSION, QUESTIONS? I'M NOT SEEING ANYTHING, BUT I JUST WANT TO MAKE SURE PEOPLE HAVE THE OPPORTUNITY BEFORE WE GO INTO PUBLIC COMMENT. SCOTT, I THINK THAT'S OUR NEXT STEP; IS THAT CORRECT?

MR. TOCHER: THAT'S CORRECT. WE'LL CHECK HERE. IT LOOKS LIKE -- IS THERE ANY PUBLIC COMMENT

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IN THE ROOM?

MS. MANDAC: NO, BUT THERE IS A MEMBER OF THE PUBLIC DIALING IN RIGHT NOW.

MR. TOCHER: STAND BY, MARK.

CHAIRMAN FISCHER-COLBRIE: WE'LL WAIT.

(PAUSE IN PROCEEDINGS.)

MS. MANDAC: NO HANDS RAISED FOR PUBLIC COMMENT.

CHAIRMAN FISCHER-COLBRIE: OKAY. WITH THAT, LET'S PROCEED TO THE VOTE.

MR. TOCHER: ALL RIGHT. MARIA BONNEVILLE.

VICE CHAIR BONNEVILLE: YES.

MR. TOCHER: MONICA CARSON.

DR. CARSON: YES.

MR. TOCHER: LEONDRA CLARK-HARVEY.

DR. CLARK-HARVEY: YES.

MR. TOCHER: MARK FISCHER-COLBRIE.

CHAIRMAN FISCHER-COLBRIE: YES.

MR. TOCHER: ELENA FLOWERS.

DR. FLOWERS: YES.

MR. TOCHER: JUDY GASSON.

DR. GASSON: YES.

MR. TOCHER: DAVID HIGGINS.

DR. HIGGINS: YES.

MR. TOCHER: VITO IMBASCIANI.

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CHAIRMAN IMBASCIANI: YES.
MR. TOCHER: PAT LEVITT.
DR. LEVITT: YES.
MR. TOCHER: SHLOMO MELMED.
DR. MELMED: YES.
MR. TOCHER: CAROLYN MELTZER.
DR. MELTZER: YES.
MR. TOCHER: CHRIS MIASKOWSKI.
DR. MIASKOWSKI: YES.
MR. TOCHER: MARV SOUTHARD.
DR. SOUTHARD: YES.
MR. TOCHER: AND KEITH YAMAMOTO.
DR. YAMAMOTO: YES.
MR. TOCHER: THANK YOU VERY MUCH. THE MOTION CARRIES, MARK.
CHAIRMAN FISCHER-COLBRIE: GREAT. WELL, QUICKLY BEFORE WE ADJOURN THE MEETING FOR TODAY, I JUST WANT TO CONTINUE TO ACKNOWLEDGE THE UNBELIEVABLE, TREMENDOUS, ENCOMPASSING WORK THAT THE CIRM TEAM COLLECTIVELY WITH MANY, MANY CONTRIBUTORS FROM CIRM TO MOVE THIS PROJECT FORWARD, THIS IS JUST PATHBREAKING WORK. AND THEIR DEDICATION AND HOURS TO SUPPORT THIS HAS BEEN UNBELIEVABLE. SO THANK YOU VERY MUCH.
DR. CANET-AVILES: THANK YOU.

CHAIRMAN FISCHER-COLBRIE: WITH THAT, I THINK WE CAN -- OH, I'M SORRY. VITO, YOU HAVE YOUR HAND RAISED.

CHAIRMAN IMBASCIANI: THANKS, MARK. I JUST WANTED TO PUNCTUATE YOURS AND OTHERS REMARKS. IT WAS ONLY WHAT, MARK, LAST OCTOBER THAT I ASKED YOU AND THE SCIENCE SUBCOMMITTEE TO TACKLE THE CONCEPT OF PRIORITIZATION AND HOW TO BEST MANAGE OUR REMAINING DOLLARS. I HAD NO IDEA IT WOULD GROW INTO THIS ABSOLUTELY WONDERFUL, COMPREHENSIVE, IN-DEPTH, DATA-SUPPORTED, DATA-DRIVEN, IMAGINATIVE PRODUCT. SO WHAT WAS THAT, ELEVEN MONTHS, JUST EXTRAORDINARY. SO THANK YOU ALL.

CHAIRMAN FISCHER-COLBRIE: WITH THAT, J.T., UNLESS THERE'S ANY COMMENTS YOU'D LIKE TO THROW IN THERE.

DR. THOMAS: NO. I JUST WANT TO THANK MEMBERS OF THE SCIENCE SUBCOMMITTEE AND NEURO TASK FORCE AND ALL OTHER BOARD MEMBERS WHO PARTICIPATED IN THE DEVELOPMENT OF THIS COMPREHENSIVE STRATEGY AND APPROACH FOR THE MANY, MANY MEETINGS AND CALLS THAT YOU'VE BEEN INVOLVED IN THAT HAVE DIRECTLY INFORMED EVERYTHING THAT HAS BEEN PRESENTED TODAY. SO I THINK IT'S BEEN A WONDERFUL EXAMPLE OF THE COLLABORATION AMONGST THE CIRM FAMILY WRIT LARGE IN

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PUTTING THIS ALTOGETHER. AND I DO WANT TO HAVE A SPECIAL SHOUT OUT TO ROSA FOR GUIDING US THROUGH ALL THIS AND HER PRESENTATIONS THESE MANY MONTHS, AND ALL MEMBERS OF OUR TEAM BECAUSE, AS NOTED, IT HAS INVOLVED LITERALLY EVERYBODY IN ONE STEP OR ANOTHER. AND WE SHOULD ALL BE VERY PROUD OF THE CUMULATIVE RESULT THAT WE'VE GOTTEN AS A TEAM. SO THANK YOU VERY MUCH TO EVERYBODY.

CHAIRMAN FISCHER-COLBRIE: GREAT. THANKS, J.T. AND I THINK WITH THAT, ROSA, DID YOU HAVE A COMMENT? IF NOT, WE CAN JUST ADJOURN.

DR. CANET-AVILES: NO. THANK YOU. I'LL SEE --

CHAIRMAN FISCHER-COLBRIE: THANKS, EVERYBODY. THIS IS GOING TO HAVE A BIG IMPACT. SO THANK YOU.

DR. CANET-AVILES: THANK YOU.

(THE MEETING WAS THEN CONCLUDED.)

REPORTER'S CERTIFICATE

I, BETH C. DRAIN, A CERTIFIED SHORTHAND REPORTER IN AND FOR THE STATE OF CALIFORNIA, HEREBY CERTIFY THAT THE FOREGOING TRANSCRIPT OF THE VIRTUAL PROCEEDINGS BEFORE THE JOINT MEETING OF THE SCIENCE SUBCOMMITTEE AND THE NEURO TASK FORCE OF THE INDEPENDENT CITIZEN'S OVERSIGHT COMMITTEE OF THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE IN THE MATTER OF ITS REGULAR MEETING HELD ON SEPTEMBER 13, 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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