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

REGULAR MEETING

LOCATION: VIA ZOOM

DATE: SEPTEMBER 5, 2025
10 A.M.

REPORTER: BETH C. DRAIN, CA CSR
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SEPTEMBER 5, 2025; 10 A.M.

VICE CHAIR BONNEVILLE: THANK YOU. I WANT TO CALL THIS MEETING OF THE ACCESS AND AFFORDABILITY WORKING GROUP TO ORDER. AND, GEOFF, WILL YOU PLEASE TAKE ROLL.

DR. LOMAX: YES. I'D BE HAPPY TO. GOOD MORNING. THERE'S A LITTLE BIT OF NOISE ON THE LINE. IS THERE SOMETHING THAT NEEDS TO BE ADDRESSED? OKAY. APPARENTLY NOT.

MARIA BONNEVILLE.

VICE CHAIR BONNEVILLE: PRESENT.

DR. LOMAX: KIM BARRETT.

DR. BARRETT: PRESENT.

DR. LOMAX: DAVID HIGGINS. VITO IMBASCIANI. PAT LEVITT. ADRIANA PADILLA. LIZ BOILEAU.

DR. BOILEAU: PRESENT.

DR. LOMAX: JAMES DEBENEDETTI. TED GOLDSTEIN.

DR. GOLDSTEIN: PRESENT.

DR. LOMAX: CHRISTINA HARTMAN. DARIUS LAKDAWALLA.

DR. LAKADAWALLA: PRESENT.

DR. LOMAX: HARLAN LEVINE.

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DR. LEVINE: HERE.

DR. LOMAX: MAHESWARI SENTHIL.

DR. SENTHIL: PRESENT.

DR. LOMAX: ADRIENNE SHAPIRO. AMMAR QADAN.

VICE CHAIR BONNEVILLE: ADRIENNE IS ON.

MS. SHAPIRO: YES. I'M PRESENT.

DR. LOMAX: IS THERE ANYONE WHO'S JOINED THAT I'VE NOT CALLED THEIR NAME IN THE ROLL?

MS. WYTE: MY NAME WASN'T CALLED. YAEL WYTE.

VICE CHAIR BONNEVILLE: YAEL, YOU'RE NOT PART OF THE COMMITTEE.

THANKS, GEOFF.

SO WE'RE GOING TO START OFF. RAFAEL WILL BE GIVING AN OVERVIEW OF ACCESS PLAN REQUIREMENTS THAT ARE SET FORTH IN OUR OWN REQUIREMENTS. WHEN A CIRM-FUNDED PROGRAM GETS THROUGH BLA, THERE'S A REQUIREMENT THAT AN ACCESS PLAN BE PRESENTED TO OUR INTERNAL TEAM. AND HE'S GOING TO GO OVER WORKING WITH SOME PARTNERS WHAT THAT MEANS AND WHAT WE'LL BE ASKING OF OUR PARTNERS MOVING FORWARD. SO GO AHEAD, RAFAEL. THANK YOU.

MR. AGUIRRE-SACASA: THANK YOU, MARIA.

GOOD MORNING, EVERYONE, MEMBERS OF THE

BOARD, MEMBERS OF THE AAWG, AND COLLEAGUES. AS MARIA SAID, MY NAME IS RAFAEL AGUIRRE-SACASA. I'M THE GENERAL COUNSEL FOR CIRM. IT'S MY PLEASURE TODAY TO WELCOME CIRM'S ACCESS PLAN REQUIREMENTS, AN IMPORTANT COMPONENT OF OUR BROADER MANDATE, WHICH ARE EQUITABLE AND AFFORDABLE ACCESS TO CURES AND THERAPIES FOR ALL OF CALIFORNIANS.

BEFORE I BEGIN, I WANT TO TAKE A QUICK PAUSE TO (INAUDIBLE) BETWEEN FOUR RELATED BUT SEPARATE EFFORTS. FIRST ARE THE STATUTORY ACCESS PLAN REQUIREMENTS WHICH WE'LL GO THROUGH MOMENTARILY. THESE STATUTORY REQUIREMENTS LEGALLY OBLIGATE COMMERCIALIZING ENTITIES. I'LL THEN EXPLAIN HOW THESE REQUIREMENTS DOVETAIL WITH THE ACCESSIBILITY AND AFFORDABILITY INITIATIVES DEVELOPED EARLIER THIS YEAR BY THE PROGRAMS TEAM. WE'LL ALSO REVIEW INSIGHTS FROM OUR CONSULTANTS AT BLUE RIDGE LIFE SCIENCES WHO BENCHMARKED PATIENT ASSISTANCE PROGRAMS NATIONWIDE AND PROVIDED US WITH A FRAMEWORK FOR EVALUATING ACCESS PLANS. FINALLY, WE'LL CLOSE WITH A DISCUSSION OF NEXT STEPS, AND I LOOK FORWARD TO QUESTIONS AND FEEDBACK. NEXT SLIDE.

THANK YOU. CIRM'S ACCESS PLAN REQUIREMENTS STEM DIRECTLY FROM OUR IP REGULATIONS. THESE REGULATIONS REQUIRE THAT ANY COMMERCIALIZING

ENTITIES SELLING A DRUG DEVELOPED WITH CIRM FUNDS SUBMIT AN ACCESS PLAN TO CIRM THAT AFFORDS ACCESS TO CALIFORNIANS WHO OTHERWISE HAVE NO MEANS TO PURCHASE THE THERAPY.

SPECIFICALLY, DRUGS DEVELOPED WITH CIRM FUNDING MUST BE MADE AVAILABLE IN CALIFORNIA AT THE BENCHMARK PRICE ESTABLISHED BY THE CALIFORNIA DISCOUNT PRESCRIPTION DRUG PROGRAM OR ANY SUCCESSOR PROGRAM. WHEN WE SAY NO OTHER MEANS, WE MEAN PATIENTS WITHOUT PRESCRIPTION DRUG BENEFITS AND WHOSE FAMILY INCOME FALLS BELOW 300 PERCENT OF THE FEDERAL POVERTY LEVEL.

TIMING IS ALSO CRITICAL. ACCESS PLANS MUST BE SUBMITTED TO CIRM WITHIN TEN BUSINESS DAYS OF FDA APPROVAL. EXTENSIONS ARE POSSIBLE, AND I'LL RETURN TO THOSE SHORTLY.

ADDITIONALLY, THERE'S A WAIVER OPTION. A COMMERCIALIZING ENTITY MAY PETITION THE ICOC FOR WAIVER OF THE ACCESS PLAN REQUIREMENT WHICH CAN ONLY BE GRANTED AFTER A PUBLIC HEARING. WE'LL TALK ABOUT THAT AS WELL. ONCE SUBMITTED, ACCESS PLANS ARE SUBJECT TO CIRM APPROVAL FOLLOWING A PUBLIC HEARING. NEXT SLIDE.

SORRY. THAT PROCESS INCLUDES A PUBLIC COMMENT PERIOD WHICH MAY INCLUDE WRITTEN OR ORAL

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TESTIMONY. HERE'S HOW THE TIMING WORKS. NONCONFIDENTIAL PORTIONS OF THE ACCESS PLAN ARE POSTED ONLINE. THERE'S A SEVEN BUSINESS DAY PUBLIC COMMENT PERIOD. CIRM MUST THEN RENDER A DECISION WITHIN FIVE BUSINESS DAYS AFTER THE PUBLIC COMMENT PERIOD CLOSES. IMPORTANTLY, CIRM'S APPROVAL CANNOT BE UNREASONABLY WITHHELD AND CANNOT REQUIRE THAT ACCESS PLANS EXCEED INDUSTRY STANDARDS AT THE TIME OF COMMERCIALIZATION. EXTENSIONS OF UP TO 30 BUSINESS DAYS ARE AVAILABLE IF THE ENTITY FOLLOWS THE PROCESS. NEXT SLIDE PLEASE.

TO SUMMARIZE, AN ACCESS PLAN MUST ALIGN WITH INDUSTRY STANDARDS AT THE TIME OF COMMERCIALIZATION. IT MUST REFLECT THE RESOURCES OF THE ENTITY. FOR EXAMPLE, LARGE OR WELL-CAPITALIZED COMPANIES WILL BE EXPECTED TO DO MORE THAN SMALLER BIOTECH FIRMS.

FINALLY, THE PLAN MUST BE APPROVED BY CIRM FOLLOWING A PUBLIC HEARING PROCESS.

AS I NOTED EARLIER, COMPANIES CAN PETITION THE ICOC FOR A WAIVER. SUCH PETITIONS MUST ALSO BE SUBMITTED WITHIN TEN BUSINESS DAYS OF FDA APPROVAL UNLESS AN EXTENSION IS GRANTED. THE ICOC MAY GRANT A WAIVER IF AFTER A PUBLIC HEARING IT DETERMINES THAT THE OBJECTS OF SUCH A WAIVER WOULD UNREASONABLY

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HINDER DRUG DEVELOPMENT AND DELIVERY OR IF THE WAIVER ITSELF WOULD PROVIDE EQUAL OR GREATER BENEFITS TO THE STATE. NEXT SLIDE PLEASE.

CONFIDENTIALITY IS ALSO A MAJOR CONSIDERATION. THOUGH PROPOSITION 71 AND 14 EXPRESSLY PROTECT FROM DISCLOSURE ANY DOCUMENTS CONTAINING CONFIDENTIAL INTELLECTUAL PROPERTY OR WORK PRODUCT, COMMERCIALIZING ENTITIES MAY DESIGNATE PORTIONS OF THEIR ACCESS PLAN AS CONFIDENTIAL AND MUST EXPLAIN WHY THE INFORMATION SHOULD BE PROTECTED UNDER APPLICABLE LAW. CIRM'S LEGAL TEAM WILL REVIEW THESE CONFIDENTIALITY REQUESTS TO ENSURE THEY FALL WITHIN STATUTORY PROTECTIONS, INCLUDING THE PUBLIC RECORDS ACT. REQUESTS THAT DON'T COMPLY MAY BE WITHDRAWN AND RESUBMITTED.

IN ADDITION, THE ICOC MAY REVIEW PROPRIETARY MATERIALS IN CLOSED SESSION. AND NOTHING HERE PREEMPTS STRICTER STATE OR FEDERAL CONFIDENTIALITY REQUIREMENTS FROM APPLYING. NEXT SLIDE PLEASE.

THE STATUTORY ACCESS PLAN OBLIGATIONS I JUST REVIEWED ARE DESIGNED TO COMPLEMENT THE PROGRAMMATIC EFFORTS OF ROSA'S TEAMS PRESENTED TO YOU IN APRIL. THE PROGRAM TEAM'S STRUCTURED REVIEW AND ENGAGEMENT PROCESS INTRODUCES ACCESS AND

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AFFORDABILITY CONSIDERATIONS AT THE EARLIEST STAGES OF CIRM FUNDING. BY REQUIRING APPLICANTS TO ADDRESS CHECKLIST ITEMS AT BOTH THE APPLICATION AND MILESTONE PHASES, THE PROGRAM TEAM ASSURES THAT AWARDEES ARE ACTIVELY INCORPORATING PATIENT ACCESS PRINCIPLES THROUGHOUT THE AWARD'S DEVELOPMENT LIFE CYCLE.

THIS STAGED APPROACH PROVIDES VISIBILITY INTO POTENTIAL BARRIERS AND ESTABLISHES MEASURABLE COMMITMENTS THAT CAN BE TRACKED AND REFINED OVER TIME. IN THIS WAY APPLICANTS ARE GUIDED TOWARD BUILDING A FEASIBLE EQUITY-FOCUSED ACCESS STRATEGY WELL BEFORE THEIR THERAPY REACHES COMMERCIALIZATION.

IN SUMMARY, CIRM'S INTEGRATED APPROACH FROM APPLICATION TO COMMERCIALIZATION CREATES ACCOUNTABILITY AND CONSISTENCY, ENSURING THAT ACCESS AND AFFORDABILITY ARE NOT AN AFTERTHOUGHT, BUT A CORE EXPECTATION OF EVERY AWARD. NEXT SLIDE PLEASE.

NOW I'D LIKE TO TURN TO THE BENCHMARK WORK CONDUCTED BY BLUE RIDGE LIFE SCIENCES. JOINING US VIA ZOOM TODAY IS IVAR JENSEN, VICE PRESIDENT AND PRINCIPAL AT BLUE RIDGE, WHO HELPED LEAD THE EFFORTS ON THE RESEARCH AND IS AVAILABLE TO ANSWER ANY QUESTIONS WE MIGHT HAVE.

BLUE RIDGE CONDUCTED BOTH PRIMARY AND

SECONDARY RESEARCH, REVIEWING PUBLIC DOCUMENTS, INTERVIEWING EXPERTS IN THE PATIENT ASSISTANCE FIELD. THEIR FINDINGS HELPED US TO DISTILL BEST PRACTICES FOR ACCESS PLANS IN THE CELL AND GENE THERAPY SPACE. WHAT I'LL SHARE TODAY IS A CONDENSED VERSION OF THEIR RESEARCH WHICH CAN BE FOUND AS AN APPENDIX TO THIS PRESENTATION. THE GOAL WAS TO HIGHLIGHT COMMON COMPONENTS AND BEST PRACTICES THAT CAN GUIDE CIRM'S REVIEW OF THE SUBMITTED ACCESS PLANS.

AS A THRESHOLD MATTER, ACROSS THE FIELD PATIENT ASSISTANCE PROGRAMS TEND TO SHARE SEVERAL BASIC ELIGIBILITY REQUIREMENTS: U.S. CITIZENSHIP OR SOME FORM OF LEGAL RESIDENCY, A VALID PRESCRIPTION OFTEN WITH PRIOR AUTHORIZATION AND CONFIRMED DIAGNOSIS, INCOME THRESHOLD TYPICALLY BETWEEN 200 AND 600 PERCENT OF THE FEDERAL POVERTY LEVEL. MANY PROGRAMS EXCLUDED MEDICARE, MEDICAID, VA, AND TRICARE PATIENTS SINCE THOSE INDIVIDUALS ALREADY HAVE COVERAGE. THESE PATIENT ASSISTANCE PROGRAMS ARE PRIMARILY DESIGNED FOR COMMERCIALLY INSURED OR UNDERINSURED. NEXT SLIDE PLEASE.

BY LOOKING AT THE PATIENT ASSISTANCE PROGRAM WEBSITES OF 14-FDA APPROVED CELL AND GENE THERAPIES, BLUE RIDGE IDENTIFIED EIGHT CORE

ATTRIBUTES THAT APPEAR ACROSS SUCCESSFUL ACCESS PLANS: CASE MANAGER/NAVIGATOR OVERSIGHT. BENEFITS INVESTIGATION AND VERIFICATION FOR ELIGIBILITY. FINANCIAL ASSISTANCE. LOGISTICAL COORDINATION. ANCILLARY HEALTHCARE PROVIDER WRAPAROUND SERVICES. PROGRAM EFFICIENCY. ACCESSIBILITY FACTORS, SUCH AS MULTILANGUAGE SUPPORT. AND ONGOING COMPLIANCE AND POST-TREATMENT FOLLOW-UP.

THESE ATTRIBUTES PROVIDE A FRAMEWORK FOR WHAT PATIENTS NEED TO ACCESS AND BENEFIT FROM ADVANCED THERAPIES. NEXT SLIDE PLEASE.

ONE COMMON THEME IS DEDICATED SUPPORT BY A CASE MANAGER/NAVIGATOR. MANY OF THESE PROGRAMS PROVIDE WHAT WE MIGHT CALL WHITE GLOVE SUPPORT, ENSURING PATIENTS RECEIVE ASSISTANCE AT EVERY STAGE OF THE PROCESS. FOR EXAMPLE, SUCCESSFUL PROGRAMS WOULD PROVIDE PATIENTS WITH ACCESS TO PROFESSIONALS WHO CAN HELP WITH THE BENEFITS INVESTIGATION ACTIVITIES, SUCH AS VERIFYING INSURANCE COVERAGE, RESPONDING TO DENIALS, AND MANAGING APPEALS. ELIGIBILITY TOOLS HELP PROVIDERS QUICKLY ASSESS WHETHER PATIENTS QUALIFY FOR SUPPORT. AND SUPPORT DOES NOT END WITH THE TREATMENT ADMINISTRATION. IT OFTEN EXTENDS TO ADHERENCE MONITORING, MILESTONE TRACKING, AND POST-TREATMENT FOLLOW-UP. IN SHORT,

EFFECTIVE PROGRAMS ACT AS A ONE-STOP SHOP, HELPING PATIENTS AND CAREGIVERS NAVIGATE WHAT CAN OTHERWISE BE A HIGHLY COMPLEX PROCESS. NEXT SLIDE PLEASE.

FINANCIAL AND LOGISTICAL SUPPORT ARE EQUALLY CRITICAL, BUT IT'S IMPORTANT TO NOTE THAT NOT ALL PROGRAMS OFFER FINANCIAL ASSISTANCE. SOME PROGRAMS MAY ONLY OFFER NAVIGATIONAL SUPPORT ACTIVITIES.

DIRECT COSTS THAT ARE COVERED BY PATIENT ASSISTANCE PROGRAMS GENERALLY FOCUS ON DRUG COVERAGE, COPAY ASSISTANCE, AND ADMINISTRATIVE FEES. INDIRECT COSTS CAN INCLUDE TRAVEL, LODGING, MEALS, AND CHILDCARE. MANY PROGRAMS ALSO COVER CAREGIVER EXPENSES AND OFFER TAILORED LOGISTICAL SUPPORT, INCLUDING COLD CHAIN, SHIPMENT COORDINATION FOR PRODUCT DELIVERY, AND SPECIALIZED TREATMENT SITE ARRANGEMENTS. IN COMBINATION THESE SERVICES REDUCE THE PRACTICAL BARRIERS THAT OFTEN PREVENT PATIENTS FROM ACCESSING THERAPIES. NEXT SLIDE.

BLUE RIDGE FOUND THAT ROUGHLY 88 PERCENT OF MANUFACTURERS OUTSOURCE AT LEAST SOME PATIENT ASSISTANCE SERVICES. THE REASONS ARE STRAIGHTFORWARD. 24/7 END-TO-END SUPPORT REQUIRES INFRASTRUCTURE AND EXPERTISE THAT MANY COMPANIES LACK INTERNALLY. LARGE PHARMACEUTICAL FIRMS OFTEN

USE HYBRID MODELS, KEEPING QUALITY CONTROL FUNCTIONS IN-HOUSE WHILE OUTSOURCING CALL CENTERS OR COMPLIANCE SERVICES. SMALLER BIOTECH COMPANIES TEND TO OUTSOURCE MORE EXTENSIVELY, PARTICULARLY FOR REIMBURSEMENT, FINANCIAL ASSISTANCE, AND LOGISTICS ACTIVITIES. OFTENTIMES THEY ENGAGE THE SERVICES OF THIRD-PARTY SERVICE PROVIDERS OR HUB SERVICE PROVIDERS. WE'VE INCLUDED A LIST OF POTENTIAL HUB SERVICE PROVIDERS IN THE APPENDIX FOR AWARDEES TO CONSIDER. THIS RELIANCE ON OUTSOURCING UNDERSCORES WHY MANY COMPANIES LOOK TO HYBRID MODELS FOR SUSTAINABILITY. NEXT SLIDE.

DESPITE THESE BEST PRACTICES, GAPS REMAIN. FOR EXAMPLE, WHAT IS THE BEST ADMINISTRATIVE MODEL? IN-HOUSE? HYBRID? OR FULLY OUTSOURCED? HOW TRANSPARENT SHOULD ELIGIBILITY CRITERIA BE TO PATIENTS? HOW DO WE BALANCE COMPREHENSIVE SUPPORT WITH COST OF SCALABILITY?

PROVIDER AWARENESS IS ALSO A CHALLENGE. STUDIES DEMONSTRATED THAT NEARLY HALF OF PATIENTS ARE UNAWARE THAT THESE PATIENT ASSISTANCE PROGRAMS EVEN EXIST. WITH THESE GAPS IN MIND, I WANT TO TALK BRIEFLY ABOUT A TIMELINE COMPANIES SHOULD FOLLOW TO PREPARE THEIR ACCESS PLANS.

AS I'VE MENTIONED, TIMING IS CRITICAL.

IDEALLY COMPANIES SHOULD BEGIN DEVELOPING PATIENT ASSISTANCE AND ACCESS PROGRAMS 18 TO 24 MONTHS BEFORE LAUNCH. THIS INCLUDES BENCHMARKING, DESIGNING SERVICES, CONTRACTING WITH HUB PROVIDERS, BUILDING I.T. INFRASTRUCTURE, TRAINING STAFF, PILOTING WORKFLOWS, AND PREPARING FOR LAUNCH. BY THE TIME OF COMMERCIAL LAUNCH, PROGRAMS SHOULD BE FULLY OPERATIONAL AND READY TO ADJUST BASED ON REAL-WORLD FEEDBACK. NEXT SLIDE.

LOOKING AHEAD, OUR NEXT STEPS INCLUDE DEVELOPING TOOLS AND CHECKLISTS FOR SCORING ACCESS PLANS THAT WOULD TRACK THE INFORMATION DISCUSSED TODAY. IDENTIFYING AND ONBOARDING A CONSULTANT EXPERT TO SUPPORT THE REVIEW OF THESE ACCESS PLANS. DELINEATING ENGAGEMENT AND COMMUNICATIONS PLAN FOR AWARDEES APPROACHING BLA SUBMISSION. AND THESE WOULD ENSURE THAT AN AWARDEE HAS RECEIVED THE SUPPORT AND GUIDANCE NEEDED TO SUBMIT ROBUST AND COMPLETE ACCESS PLANS FOR CONSIDERATION.

THAT CONCLUDES MY PREPARED REMARKS. I'D NOW BE HAPPY TO TAKE ANY QUESTIONS OR COMMENTS THAT YOU MIGHT HAVE.

VICE CHAIR BONNEVILLE: THANK YOU SO MUCH. I'D LIKE TO OPEN THE FLOOR FOR ANY COMMENTS FROM THE WORKING GROUP MEMBERS. KIM, YOU HAVE YOUR HAND

RAISED.

DR. BARRETT: YEAH. I FEEL LIKE I'M CHANNELING YSABEL FROM A PREVIOUS MEETING. BUT I WAS STRUCK BY THE FINDING THAT MOST OF THESE PROGRAMS ARE ONLY AVAILABLE TO CITIZENS AND PERMANENT RESIDENTS. IS THAT WHAT WE PLAN TO DO FOR CIRM?

MR. AGUIRRE-SACASA: AGAIN, WE CAN'T MANDATE WHO IS SUBJECT TO THE ACCESS PLAN. BUT OBVIOUSLY WE ENCOURAGE AS MUCH OUTREACH TO UNDERSERVED AND UNDERREPRESENTED COMMUNITIES AS POSSIBLE, KIM. AND SO I THINK WORKING WITH THEM FROM THE APPLICATION STAGE, WE WILL TRY AND INFLUENCE THAT TO THE EXTENT WE CAN.

DR. LEVINE: THERE IS A PART AT THE VERY BEGINNING I DIDN'T UNDERSTAND. DID YOU MENTION SOMETHING ABOUT THE PRICING OF THE DRUGS AND CIRM'S RELATIONSHIP TO WHAT THE PHARMACEUTICAL COMPANIES DO, OR DID I MISUNDERSTAND THAT?

MR. AGUIRRE-SACASA: NO, I DIDN'T MENTION THE PRICING, BUT THE PRICING HAS TO BE SOLD AT THE BENCHMARK PRICE THAT IS SET FORTH IN THE CALIFORNIA DISCOUNT PRESCRIPTION DRUG PROGRAM. IS THAT WHAT YOU'RE REFERRING TO, HARLAN?

DR. LEVINE: CORRECT. YEAH.

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MR. AGUIRRE-SACASA: AND SO WHATEVER THE BENCHMARK PRICE IS SET FORTH THEREIN IS WHAT NEEDS TO BE FOLLOWED. I'M NOT SURE THAT THAT PRESCRIPTION DRUG PROGRAM ACTUALLY HAS SET FORTH ANYTHING RIGHT NOW. SO I THINK THAT'S SOMETHING THAT NEEDS TO BE WORKED THROUGH MOVING FORWARD.

DR. LEVINE: RIGHT. I WASN'T AWARE THAT WE HAD SET ANY OF THOSE BENCHMARKS YET. OKAY. THANK YOU.

MR. AGUIRRE-SACASA: IF THEY ARE EVER SET, THAT'S WHAT THE COMMERCIALIZING ENTITIES WOULD HAVE TO FOLLOW.

DR. LEVINE: THAT MAKES SENSE.

VICE CHAIR BONNEVILLE: SCOTT, YOU HAVE YOUR HAND RAISED. WOULD YOU LIKE TO COMMENT?

MR. TOCHER: SURE. JUST TO PROVIDE A LITTLE CONTEXT TO THE QUESTION HARLAN ASKED. THIS WAS DEVELOPED A NUMBER OF YEARS AGO WHEN THE STATE LEGISLATURE PASSED THE CDPDP; HOWEVER, IT WAS UNFUNDED IN THE SUBSEQUENT BUDGET YEARS. SO TECHNICALLY THIS PROGRAM IS ON THE BOOKS, BUT AWAITS FUNDING. SO WHAT WE WANTED TO DO WAS, JUST AS A SAFETY MEASURE, JUST STRAP THAT REQUIREMENT. IF IT EVER GETS FUNDED AND THE CDPDP MOVES FORWARD, THEN WE WILL WANT TO TAKE ADVANTAGE OF THAT PROGRAM ONCE

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IT'S UP AND RUNNING.

VICE CHAIR BONNEVILLE: THANK YOU, SCOTT.

DR. LEVINE: THANK YOU.

VICE CHAIR BONNEVILLE: I WANT TO GO TO GEOFF FOR A MOMENT BECAUSE HE WANTS TO ALSO ADDRESS SOMETHING FOR KIM'S QUESTION.

DR. LOMAX: JUST A REMINDER, DR. BARRETT. IN TERMS OF THIS ANALYSIS, A SUBSTANTIAL PORTION OF THE POPULATION THAT WOULD BE UNDERSERVED POTENTIALLY WOULD BE COVERED THROUGH A MEDI-CAL POLICY, WHICH IS ALL THE STATE HAS BEEN A BIT CHALLENGED THERE. BUT CERTAINLY THERE'S BEEN A MOVE TO MAKE MEDI-CAL AS INCLUSIVE AS POSSIBLE WHICH WOULD, AS BEEN NOTED IN THE EARLIER REMARKS, POTENTIALLY THAT POPULATION GENERALLY ISN'T COVERED THROUGH THESE MECHANISMS. SO I JUST WANTED TO POINT OUT THE MEDI-CAL MECHANISM IS ONE THAT FACILITATES ACCESS TO POPULATIONS IN CALIFORNIA THROUGH A VERY DELIBERATE POLICY EFFORT ON THE MEDI-CAL SIDE.

DR. BARRETT: MAYBE I'M MISSING SOMETHING, BUT SOME OF THE OTHER ASPECTS OF THIS PATIENT ASSISTANCE PROGRAM ISN'T NECESSARILY JUST PROVIDING WAYS FOR THEM TO ACCESS THE THERAPY, BUT IT'S SORT OF ANCILLARY SUPPORT. AND MAYBE I AM NOT FULLY INFORMED WHAT MEDI-CAL DOES. BUT I WASN'T AWARE

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THAT THEY PROVIDED CHILDCARE ASSISTANCE OR HOUSING ASSISTANCE OR ALL THESE OTHER THINGS THAT MIGHT BE NECESSARY FOR PATIENTS TO ACCESS THESE TYPES OF COMPLEX THERAPIES.

VICE CHAIR BONNEVILLE: THANK YOU, KIM. I THINK THAT'S SOMETHING, RAFAEL, IF YOU COULD PERHAPS DIG INTO THAT A LITTLE MORE AND COME BACK LATER WITH SOME FINE-TUNING. SO WITH THAT, THAT WOULD BE GREAT.

MR. AGUIRRE-SACASA: SURE. THANK YOU.

VICE CHAIR BONNEVILLE: TED.

DR. GOLDSTEIN: HI. SO VERY INTERESTING. AND I WAS INTRIGUED BY A SMALL COMMENT YOU MADE ABOUT A LOT OF THE WORK TENDS TO BE OUTSOURCED TO THIRD PARTIES. SO WHO ARE THE HEALTHCARE HUBS? ARE THESE COMPANIES LIKE MCKESSON AND EVERSANA? AND HAVE WE SPOKEN TO THEM AND DISCUSSED THE PLAN, AND DID THEY ADD ANYTHING, HAVE ANY REACTIONS? PERHAPS WE SHOULD THINK ABOUT THINGS LIKE; FOR EXAMPLE, HAVING A CERTIFICATION FOR VENDORS SO THAT WE CAN KEEP A CLOSE EYE ON WHAT THEY ARE DOING.

MR. AGUIRRE-SACASA: SO, AGAIN, JUST READING FROM THE SLIDE HERE, CARDINAL HEALTH, CENCORA OR CENCORA, EVERSANA, INSPIROGENE, ORSINI, AND PROPHARMA ARE SOME OF THE HUBS THAT WE CAME UP

WITH AS PART OF THE BLUE RIDGE RESEARCH.

WE DON'T ENGAGE WITH THESE ON BEHALF OF THE COMMERCIALIZING ENTITY. WE CAN CERTAINLY POINT THEM IN THESE DIRECTIONS, BUT IT'S UP TO THEM TO ENGAGE WITH THEM CONTRACTUALLY, TED. SO WE CAN'T INFLUENCE THEM ONE WAY OR THE OTHER. THEY MAY NOT WANT TO USE ANY OF THESE AND THEY WANT TO USE SOMEONE ELSE. OUR GOAL HERE IS TO AT LEAST ALERT THEM THAT THEY ARE HERE AND THAT THEY HAVE THESE AS RESOURCES AND THAT THEY'RE WELL-RESPECTED IN THE ENVIRONMENT FOR PROVIDING THESE HUB SERVICES.

DR. GOLDSTEIN: I'M JUST TRYING TO SEE IF WHAT WE ARE DISCUSSING FITS WITHIN THEIR MODEL OF BUSINESS BECAUSE IT'S QUITE POSSIBLE THAT WHAT WE WANT HERE IS SOMETHING VERY DIFFERENT.

MR. AGUIRRE-SACASA: IVAR, DO YOU WANT TO COMMENT ON THAT A LITTLE BIT?

MR. JENSEN: YEAH. SO THERE'S NOT REALLY A REQUIREMENT PER SE THAT A COMPANY PUTS TOGETHER A PATIENT ASSISTANCE PROGRAM. BUT WITH THESE KINDS OF THERAPIES, THEY'RE SO COMPLEX AND THEY REQUIRE AN ENORMOUS AMOUNT OF COORDINATION OF CARE, THAT WE HAVE IN -- THIS PRESENTATION IS WHAT DOES GOOD LOOK LIKE. RIGHT? AND THEN IT'S SORT OF A MATTER OF WHAT CAN THE COMPANY AFFORD TO DO, RIGHT, AND WHAT

ARE THEY WILLING TO INCLUDE INTO THEIR PLAN.

SO THAT'S -- I'M NOT SURE IF YOU CAN NECESSARILY DRIVE THAT CONTENT, IF YOU WILL. THERE ARE SORT OF BARE MINIMUMS; BUT THEN IN TERMS OF BEING ABLE TO DELIVER CARE AND AFFORD ACCESS TO PATIENTS THAT OTHERWISE DON'T HAVE THE MEANS, YOU WOULD HAVE TO KIND OF GO TO THAT FINANCIAL LEVEL OF SUPPORT. SOME OF THE BENEFITS INVESTIGATIONS IS ALWAYS HELPFUL TO HELP THOSE PATIENTS AND CAREGIVERS IN THAT PATHWAY AND SO ON.

SO I THINK IT'S A STRATEGIC DECISION INTERNALLY AT THE COMPANIES ABOUT HOW FAR AND WHAT DO THEY WANT TO INCLUDE IN THEIR PROGRAM.

DR. GOLDSTEIN: YEAH. I THINK I HAVE A DIFFERENT PERSPECTIVE ON THIS. TO ME THIS FALLS INTO A VERY GENERAL SPACE OF NEW PARADIGM PRODUCT SUPPORT. RIGHT? AT APPLE NO ONE HAD GENIUS BARS BEFORE APPLE HAD GENIUS BARS. NOW EVERYBODY HAS GENIUS BARS. AND THE NOTION OF WHAT DOES IT MEAN TO FILL IN THE GAPS AND MAKE UP FOR A TYPICAL TEAM'S PRODUCT HAS SOME COMPLEXITY TO IT. AND THERE'S BEST PRACTICES THAT YOU QUICKLY LEARN AND CAN CLONE. AND WHAT'S GOING ON WITH THE STEM CELL THERAPY IS GOING TO BE NO DIFFERENT SINCE THE IMPACT ON THE PATIENT IS REMARKABLY SIMILAR WITH HOSPITAL STAYS AND

ABLATION AND REPEATED FOLLOW-UPS AND COPING WITH INFECTIONS AND SO ON.

AND SO IT STRIKES ME THAT THIS IS A WONDERFUL TIME TO GET THESE GUYS TOGETHER. I DON'T BELIEVE WE ARE STEALING ANYTHING FROM THE COMPANIES, AND I DON'T -- OUR MISSION IS NOT NECESSARILY TO HELP -- TO GET IN THE WAY OR HELP COMPANIES SUCCEED OR FAIL. OUR MISSION IS TO MAKE THE WHOLE TECHNOLOGY WORK FOR CALIFORNIA. AND SO IF WE CAN COME UP WITH THE, HEY, HERE'S THE GUIDELINES AND GET THESE HUB FIRMS WHO ARE GOING TO BE INSTRUMENTAL IN ACTUALLY DOING THE WORK IN THE SAME ROOM LEARNING FROM EACH OTHER STRIKES ME.

SO THE MODIFICATION TO THE PLAN THAT I SEE HERE IS WE SHOULD HAVE AN INVITATION TO MEET TOGETHER, TO COME UP WITH PROVISIONAL PLANS, AND, JUST LIKE WE HAVE WITH THE ALPHA CLINICS, TO SHARE RESULTS. MAKE SENSE?

VICE CHAIR BONNEVILLE: RAFAEL.

MR. AGUIRRE-SACASA: THANK YOU, TED. AGAIN, IT SOUNDS LIKE YOU'RE SUGGESTING THAT WE SHOULD TRY AND SEE IF THERE ARE ANY EFFORTS THAT WE CAN DO TO GET SOME COLLABORATIVE EFFORTS FROM THESE HUB PROVIDERS -- SORRY. THERE'S A LOT OF BACKGROUND NOISE -- FOR A STANDARD APPROACH THAT THIS BE USED

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ACROSS THE CELL AND GENE THERAPIES. THAT CORRECT, TED?

DR. GOLDSTEIN: YES. IT REALLY IS GOING TO BE -- THE TECHNOLOGY CAN WORK GREAT, BUT THE FOLLOW-UP CARE AND CONTINUITY OF CARE IS GOING TO BE THE PLACE WHERE EVERYBODY IS LEARNING AND WHERE THE FAILURES ARE GOING TO HAPPEN. AND WE SEND THEM OUT OF THE HOSPITAL, OUT OF THE CLINIC HEALTHY AND THE LOCAL HOSPITALS MAY NOT KNOW WHAT TO DO. WE CAN OFFER THEM PERHAPS -- TURN SOMETHING THAT -- AN EMERGENT SET OF SYMPTOMS AND MANAGE IT VERSUS SENDING THEM TO THE ER WHERE THE PATIENT, THEY HAVE NO BACKGROUND KNOWLEDGE ON HOW TO COPE WITH THE PATIENT.

AND SO WE'RE REALLY IN AN IMPORTANT PHASE HERE TO DESIGN THE WHOLE PRODUCT OF GENE THERAPY. AND I THINK A LOT OF THAT IS GOING TO COME ON THE BACK END OF PRE- AND POST-THERAPY DELIVERY.

VICE CHAIR BONNEVILLE: THANK YOU, TED. THAT'S VERY IMPORTANT.

RAFAEL, LET'S TALK ABOUT THAT INTERNALLY AND SEE WHAT WE CAN DO.

DR. GOLDSTEIN: THANKS.

VICE CHAIR BONNEVILLE: THANK YOU.

MAHESWARI, YOU HAVE YOUR HAND RAISED.

DR. SENTHIL: YES. THANK YOU. MY QUESTION IS REGARDING THE ELIGIBILITY CRITERIA THAT WAS SHARED BASED OFF THE BLUE RIDGE RESEARCH. AND QUESTION IS WHAT PERCENTAGE OF CALIFORNIANS, BASED ON THE ELIGIBILITY CRITERIA THAT WAS PRESENTED, WOULD BE INELIGIBLE FOR THIS ACCESS PLAN? DO WE HAVE AN ASSESSMENT OF WHAT PERCENTAGE OF CALIFORNIANS WE'RE TALKING ABOUT FOR THIS?

MR. AGUIRRE-SACASA: NO. I DON'T THINK WE HAVE THAT INFORMATION. IVAR, I DON'T THINK THAT INFORMATION --

MR. JENSEN: YEAH, WE DON'T HAVE THAT LEVEL OF DETAIL.

DR. SENTHIL: THE REASON BEHIND MY QUESTION IS THAT IF YOU LOOK AT THE CRITERIA THAT WE ARE SUGGESTING, THIS PROBABLY PIGGYBACKS TO DR. BARRETT'S QUESTION AS WELL, U.S. CITIZENSHIP, 200 TO 600 PERCENT FEDERAL POVERTY LINE, AND MANY OTHER -- LIKE THERE ARE FIVE CRITERIA THAT WE ARE DEFINING. THAT MIGHT FILTER DOWN INTO A VERY SMALL GROUP OF PEOPLE FOR WHOM WE ARE CREATING THIS WONDERFUL ACCESS PLAN. AND, HENCE, IF WE KNOW THE PERCENTAGE OF CALIFORNIANS WE ARE TALKING ABOUT BASED ON THE ELIGIBILITY CRITERIA, MAYBE THAT WOULD GIVE US AN OPPORTUNITY TO RETHINK WHAT THE CRITERIA SHOULD BE.

MR. AGUIRRE-SACASA: SORRY. ARE YOU DONE? NO, I THINK YOU'RE RIGHT. THE POINTS YOU AND KIM RAISE ARE OBVIOUSLY CORE TO CIRM'S MISSION HERE, PROVIDING THERAPIES FOR ALL CALIFORNIANS. AT THE END OF THE DAY, THESE ARE BEST PRACTICES. THESE AREN'T NECESSARILY WHAT EVERY PATIENT ASSISTANCE PROGRAM WILL HAVE. EACH ONE WILL BE CUSTOMIZED TO THEIR OWN SPECIFIC USER GROUP, IF YOU WILL, PATIENT GROUP.

I THINK THAT THE RESEARCH PROVES THAT ABOUT 80 PERCENT OF THESE PLANS SHOULD HAVE SIMILAR COMPONENTS. THE OTHER 20 PERCENT WILL BE CUSTOMIZED TO THE PARTICULAR THERAPY. AND I THINK THAT'S WHERE MOST OF THESE OUTREACH EFFORTS WILL HAVE TO MANIFEST ITSELF DURING THE PROCESS. BUT THAT'S SOMETHING CERTAINLY THAT WE CAN TRY AND INFLUENCE TO THE EXTENT WE CAN. THAT'S OUR WHOLE MISSION. SO THAT'S WHAT WE TRY TO GO THROUGH. AND, AGAIN, THAT'S WHAT WE CAN CERTAINLY RELAY TO THESE COMMERCIALIZING ENTITIES, THAT THAT'S WHAT WE THINK ARE THE BEST PRACTICES FOR THESE ACCESS PLANS.

DR. SENTHIL: YEAH. AND THE REASON WHY, ONCE AGAIN, I'M EMPHASIZING THIS POINT IS THAT THE DEMOGRAPHICS OF CALIFORNIA MIGHT BE VERY DIFFERENT FROM THE GENERAL PLANS THAT WE HAVE ACROSS THE

COUNTRY. AND KEEPING THAT IN MIND WHILE WE ARE CREATING A PLAN THAT IS SPECIFICALLY FOCUSED TO CALIFORNIANS SHOULD DEPEND UPON THE PERCENTAGE OF CALIFORNIANS THAT WE ARE ACTUALLY TALKING ABOUT BASED ON THE ELIGIBILITY CRITERIA THAT WE ARE DEVELOPING. AND THIS MIGHT BE IN -- THESE EARLIER STAGES OF DEVELOPING THIS PLAN MIGHT BE THE BEST OPPORTUNITY FOR US TO DEFINE WHO ARE ELIGIBLE.

MR. AGUIRRE-SACASA: YEAH. GREAT POINT. ABSOLUTELY. HUNDRED PERCENT AGREE. THE SOONER THE BETTER.

VICE CHAIR BONNEVILLE: THANK YOU. HARLAN.

DR. LEVINE: YEAH. JUST TWO QUICK THINGS, AND THEY ACTUALLY SEEM PRETTY TRIVIAL COMPARED TO THE MEATY DISCUSSIONS WE JUST HAD. BUT I WAS ALSO ON A SLIDE, I'M CURIOUS, I SAW ABOUT IVF OR MAYBE IT WAS FERTILITY. I CAN'T REMEMBER IF IT WAS ONE OR THE OTHER. WHAT WAS THAT CONNOTING? ARE WE SUGGESTING THAT IVF AND FERTILITY TREATMENTS BE PART OF THE TREATMENT OR JUST THAT IT BE SPECIFIED WHETHER IT'S PART OF THE BENEFITS FOR SOME OF THESE TREATMENTS?

MR. AGUIRRE-SACASA: I THINK IT'S THE LATTER. IT'S ONE OF THE BENEFITS FOR THESE

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TREATMENTS. IVAR, I DON'T KNOW IF YOU HAVE ANY ADDITIONAL --

MR. JENSEN: YEAH. THAT PARTICULAR CASE IS VERY SPECIFIC TO THE THERAPY, RIGHT, THAT WAS FOR SICKLE CELL DISEASE. THE TYPE OF TREATMENT, IF THE PATIENT HAS WISHED TO BECOME PREGNANT LATER ON, THEN THEY WOULD NEED TO GO THROUGH THAT PROCESS. RIGHT? SO IN OTHER TYPES OF THERAPIES, THAT MIGHT NOT BE A REQUIREMENT. RIGHT. SO IT'S VERY CONTEXTUAL TO THE TREATMENT THAT'S UNDER DEVELOPMENT.

DR. LEVINE: OFF THE TOP, I KNOW LIKE WITH VERTEX, BLUEBIRD, THE PAYERS DIFFER ON WHETHER OR NOT THEY'LL COVER IVF AND FERTILITY. SOME DO NEITHER, SOME DO BOTH, SOME DO ONE AND NOT THE OTHER. FERTILITY PRESERVATION JUST FOR EXACTNESS. SO I THINK WE PROBABLY NEED TO ALIGN WITH WHAT MEDI-CAL BENEFITS ARE OR AT LEAST UNDERSTAND WHAT MEDI-CAL BENEFITS ARE.

WHICH THEN GETS ME TO THE OTHER COMMENT, AND I DON'T THINK WE NEED SOLVE IT HERE. BUT IN TERMS OF ELIGIBILITY, I DON'T KNOW IF ANY OF THE CHANGES THAT ARE HAPPENING AT THE FEDERAL LEVEL OR WITH -- I THINK GOVERNOR NEWSOM HAS BEEN PRETTY RESOLUTE THAT WE WILL CONTINUE TO COVER PEOPLE, JUST AT DIFFERENT COPAYS AND RATES. BUT I JUST WANT TO

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MAKE SURE WE STAY IN ALIGNMENT WITH THE REALITY OF WHAT FEDERAL AND STATE GOVERNMENTS ARE DOING IN TERMS OF MEDI-CAL AND EXCHANGE EXPANSION ELIGIBILITY.

MR. AGUIRRE-SACASA: NO. ABSOLUTELY. WE OBVIOUSLY TRACK THAT; BUT, AGAIN, WE ARE CALIFORNIA AND WE ARE FOR CALIFORNIA PATIENTS. SO THAT IS OUR FOCUS, AND WE'VE GOT TO KEEP AN EYE ON THAT.

DR. LEVINE: WELL, I MEAN THE FEDERAL LAWS AS IT PERTAINS TO MEDI-CAL, A RESHUFFLING OF MEDI-CAL ONCE THERE'S SOME CLARITY AND NEGOTIATION WITH CHS -- CHA. SO WE JUST HAVE TO FIGURE OUT WHAT THIS IS GOING TO LOOK LIKE.

MR. AGUIRRE-SACASA: ABSOLUTELY. WE'RE CONSTANTLY MONITORING. AS YOU PROBABLY HAVE HEARD THROUGHOUT, IF YOU FOLLOW THE CIRM, OTHER CIRM WORKING GROUPS AND BOARD MEETINGS, WE'RE PAYING CLOSE ATTENTION TO WHAT'S HAPPENING IN WASHINGTON AS IT AFFECTS OUR AWARDEES AND COULD POTENTIALLY AFFECT OUR PATIENTS.

VICE CHAIR BONNEVILLE: ADRIENNE.

MS. SHAPIRO: YEAH. SO WE -- THE SICKLE CELL COMMUNITY HAS BEEN ON SUCH A ROLLER COASTER WITH THIS. SO TWO THINGS I'D LIKE FOR US, SINCE WE ARE AT THE BEGINNING OF THIS, TO THINK ABOUT. ONE

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IS WHAT HAPPENS WHEN A PATIENT GOES THROUGH, HAS GENE THERAPY AND WE'RE FINDING THERE'S A PERCENTAGE THAT THEN REMAIN SYMPTOMATIC AFTER BEING CURED. AND THEN THEY FALL OUT OF THIS RANGE OF YOU HAVE A GENETIC ILLNESS AND YOU HAVE ACCESS TO COVERAGE AND SUPPORT. AND SO THEN WE HAVE THESE PEOPLE WHO HAVE GONE THROUGH IT AND I'M GOING TO SAY NORMALLY CAN BE SYMPTOMATIC FOR MAYBE LIKE A YEAR IS OUR EXPERIENCE WITH PAIN AND THINGS LIKE THAT, BUT THEN YOU LOSE YOUR ACCESS TO INSURANCE BECAUSE YOU HAVE BEEN CURED. AND I THINK WE NEED TO LOOK AT THAT.

AND THE OTHER IS WHEN IT COMES TO THE MEDI-CAL REQUIREMENTS AND THINGS LIKE THAT, IS THERE ANY KIND OF OPPORTUNITY FOR US TO CARVE OUT, SINCE ALL OF THIS IS SO NEW, RIGHT, IS THERE ANY WAY THAT WE CAN CARVE OUT OR EXPLORE WAYS TO GIVE PEOPLE WHO HAVE THAT INSURANCE BECAUSE 70 PERCENT OF THE SICKLE COMMUNITY IN THE STATE OF CALIFORNIA HAVE MEDI-CAL. SO THEY HAVE MEDI-CAL AND GHPP, AND IF THEY'RE LUCKY THEY HAVE MEDICARE, MEDI-CAL. IS THERE AN OPPORTUNITY FOR US TO LOOK AT SOMEHOW WORKING SOMETHING OUT SO THAT THE PEOPLE THAT ARE THIS AND DO NOT HAVE ACCESS TO THE THINGS WHICH WE KNOW ARE IMPORTANT TO THEM, IMPORTANT TO THEIR RECOVERY, THEIR LAUNCH TO THEIR NEW LIFE DISEASE FREE, IS

THERE SOMETHING THAT WE CAN DO?

MR. AGUIRRE-SACASA: OKAY. WE'LL TAKE A LOOK AT THOSE.

VICE CHAIR BONNEVILLE: THANK YOU, ADRIENNE. LIZ.

DR. BOILEAU: YEAH. JUST ON THE CONVERSATION AROUND THE POPULATION OF WHAT COULD BECOME POTENTIALLY UNINSURED POPULATION, IT OBVIOUSLY WON'T. BECAUSE THEY BECOME UNINSURED DOESN'T EQUATE WITH THEM POTENTIALLY NOT HAVING A DISEASE THAT FALLS INTO CELL AND GENE THERAPY REQUIRED COVERAGE. AND SO I DON'T KNOW IF THERE'S OPPORTUNITY TO ADDRESS ANYTHING AT THE STATE LEVEL THAT MIGHT -- WE DID NOT REALLY CONTEMPLATE THE POTENTIAL OF GOING BACK INTO THIS UNINSURED POPULATION SCENARIO, WHICH WE HAD A NUMBER OF YEARS AGO BEFORE MANAGED MEDICAID CAME ACROSS THE UNITED STATES. AND WE'VE OBVIOUSLY LIMITED THE UNINSURED POPULATION, BUT THEY WILL COME BACK TO US.

AND CALIFORNIA OBVIOUSLY HAS A SIGNIFICANT AMOUNT OF PEOPLE THAT, IF THEY WERE REMOVED FROM THE MEDI-CAL ROLLS, LIKELY WILL STAY HERE, BUT WILL BECOME THAT UNINSURED POPULATION. UNFORTUNATELY WHAT THEY WILL DO IS THEY'LL COME TO US WITH THESE CONDITIONS THAT REQUIRE THESE SERVICES IN AN

UNINSURED MANNER GENERALLY RIGHT THROUGH THE EMERGENCY DEPARTMENT.

AND SO IT MIGHT BE INTERESTING TO SEE IF THERE'S A WAY -- IF WE THINK THAT POPULATION FALLS OUTSIDE OF THIS, IS THERE A WAY THAT WE CAN WORK WITH THE STATE TO POTENTIALLY ADDRESS THAT POPULATION AS ELIGIBLE FOR THESE SERVICES AS WELL IF FOR SOME REASON WE FIND THAT THEY FALL OUT BECAUSE THEY WILL STILL COME TO THE PROVIDERS WHO ARE OFFERING THESE SERVICES? AND WE WOULD NEED TO TAKE CARE OF THEM. THAT'S OUR MISSION. THOSE ARE OUR MISSIONS. AND SO MAYBE THERE'S ROOM IN THE WAY IN WHICH THE GOVERNOR'S OFFICE IS MANAGING THAT THOSE POPULATIONS WOULD REMAIN ELIGIBLE FOR THESE SERVICES BECAUSE THEY'RE PROBABLY MOST LIKELY GOING TO REMAIN IN THE STATE. AND THEY WILL COST THE SYSTEM -- IT'S EITHER THE COST AT THE PROVIDER LEVEL OR THE COST AT THE STATE LEVEL FOR THE MEDI-CAL COVERAGE. AND SO IT MIGHT BE INTERESTING TO BE ABLE TO EXPLORE CONTINUING TO COVER THOSE PEOPLE FOR THIS TYPE OF SERVICE.

VICE CHAIR BONNEVILLE: THANK YOU, LIZ.

MR. AGUIRRE-SACASA: JUST IT MAKES SENSE TO REMIND EVERYBODY THE STANDARD FROM THE REGULATION IS THAT THE STANDARDS THAT APPLY ARE FOR THE

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INDUSTRY -- SORRY. LET ME TAKE A STEP BACK. THE THINGS THAT THE REGULATIONS WOULD APPLY REQUIRE THAT THE ACCESS PLAN MEET INDUSTRY STANDARDS AT THE TIME OF COMMERCIALIZATION FOR THE SIZE AND EXPERTISE OF THE COMPANY. SO SOME OF THESE MAY BE ABLE TO BE ADDRESSED BY BIGGER PHARMAS AND MORE WELL-RESOURCED CORPORATIONS. SMALLER BIOTECHS AND LESS WELL-CAPITALIZED ENTITIES WILL PROBABLY HAVE A HARDER TIME REACHING THESE.

SO I JUST WANT TO PUT THAT IN CONTEXT, THAT, AGAIN, THERE'S ONLY SO MUCH WE CAN REQUIRE OF THESE ACCESS PLAN. AGAIN, WE THINK THAT THESE ARE BEST PRACTICES FOR COMPONENTS AND THAT, IF AN ENTITY WANTS TO HAVE A SUCCESSFUL PATIENT ASSISTANCE PROGRAM, THAT THEY SHOULD CONSIDER ALL OF THESE THINGS. AND WE CAN CERTAINLY TRY AND RAISE THESE ISSUES SO THAT THEY CAN BEST ADDRESS THEM. BUT I JUST WANTED TO MAKE SURE THAT WE LEVEL SET ON WHAT THE ACTUAL REGULATIONS REQUIRE FROM AN ACCESS PLAN THAT IS SUBMITTED FOR REVIEW.

VICE CHAIR BONNEVILLE: THAT SAID, I DO WANT TO REMIND EVERYONE WE DO HAVE OTHER AVENUES WITHIN CIRM. SO WE HAVE OUR OWN PATIENT ASSISTANCE FUND THAT CAN BE ACCESSED FOR THESE THERAPIES. AND OUR RESEARCH PROGRAMS ALSO HAVE BUDGETS AROUND

ACCESS AND AFFORDABILITY. SO THERE ARE OTHER MECHANISMS THAT WE CAN TURN TO IF NEEDED AND NECESSARY. AND THEN OBVIOUSLY WE'LL EXPLORE ALL THE OTHER OPTIONS THAT THE GROUP HAS LAID OUT. SO THANK YOU.

ARE THERE ANY OTHER COMMENTS? I WANT TO THANK EVERYONE FOR BEING HERE THIS MORNING. I WANT TO THANK RAFAEL AND THE TEAM FOR PUTTING THIS TOGETHER. AND BLUE RIDGE'S HELP HAS BEEN WONDERFUL. THANK YOU.

RAFAEL, I THINK WE HAVE SOME ITEMS TO TALK ABOUT INTERNALLY AND THEN COME BACK TO THIS GROUP, CIRCLE BACK WITH SOME OTHER INFORMATION.

AND IS THERE ANY PUBLIC COMMENT?

UNIDENTIFIED SPEAKER: I DON'T THINK SO, NO.

VICE CHAIR BONNEVILLE: OKAY. THANK YOU SO MUCH, EVERYONE. APPRECIATE ALL OF YOUR TIME AND YOUR COMMENTS THIS MORNING. AND I HOPE YOU HAVE A GREAT WEEKEND. THANK YOU.

(THE MEETING WAS THEN CONCLUDED AT 10:48 A.M.)

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REPORTER'S CERTIFICATE

I, BETH C. DRAIN, A CERTIFIED SHORTHAND REPORTER IN AND FOR THE STATE OF CALIFORNIA, HEREBY CERTIFY THAT THE FOREGOING TRANSCRIPT OF THE VIRTUAL PROCEEDINGS BEFORE THE TREATMENT AND CURES 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 SEPTEMBER 5, 2025, WAS HELD AS HEREIN APPEARS AND THAT THIS IS THE ORIGINAL TRANSCRIPT THEREOF AND THAT THE STATEMENTS THAT APPEAR IN THIS TRANSCRIPT WERE REPORTED STENOGRAPHICALLY BY ME AND TRANSCRIBED BY ME. I ALSO CERTIFY THAT THIS TRANSCRIPT IS A TRUE AND ACCURATE RECORD OF THE PROCEEDING.

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