

BETH C. DRAIN, CA CSR NO. 7152

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

LOCATION: VIA ZOOM

DATE: NOVEMBER 4, 2025
2 P.M.

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

FILE NO.: 2025-22

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2. ROLL CALL	3
3. UPDATE ON THE PATIENT SUPPORT PROGRAM	5
4. CONSIDERATION OF CIRM'S ACCESS & AFFORDABILITY STRATEGY	40
5. PUBLIC COMMENT	NONE
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VICE CHAIR BONNEVILLE: THANKS, EVERYONE.
I'D LIKE TO WELCOME YOU TODAY TO THE MEETING OF THE
ACCESS AND AFFORDABILITY WORKING GROUP. CAMERON, IF
YOU COULD PLEASE CALL THE ROLL.

MR. MALIK: ABSOLUTELY. MARIA BONNEVILLE.

VICE CHAIR BONNEVILLE: PRESENT.

MR. MALIK: VITO IMBASCIANI.

CHAIRMAN IMBASCIANI: PRESENT.

MR. MALIK: ADRIANA PADILLA.

DR. PADILLA: HERE.

MR. MALIK: TED GOLDSTEIN. NOT HERE.
AMMAR QADAN.

DR. QADAN: PRESENT.

MR. MALIK: JAMES DEBENEDETTI.

MR. DEBENEDETTI: HERE.

MR. MALIK: MAHESWARI SENTHIL. NOT HERE.
ADRIENNE SHAPIRO.

MS. SHAPIRO: HERE.

MR. MALIK: HARLAN LEVINE. NOT HERE. PAT
LEVITT. NOT HERE. DARIUS LAKDAWALLA.

DR. LAKDAWALLA: HERE.

MR. MALIK: CHRISTINA HARTMAN. NOT HERE.
KIM BARRETT.

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1 DR. BARRETT: PRESENT.

2 MR. MALIK: LIZ BOILEAU.

3 MS. BOILEAU: PRESENT.

4 MR. MALIK: AND YAEL WYTE.

5 MS. WYTE: HERE.

6 VICE CHAIR BONNEVILLE: THANK YOU.

7 THANKS, CAMERON.

8 FIRST ON OUR AGENDA IS THE ACCESS AND
9 AFFORDABILITY STRATEGY. THIS IS SOMETHING THAT THE
10 PATIENT ACCESS TEAM HAS BEEN WORKING ON FOR THE LAST
11 SEVERAL MONTHS. AND AS YOU ALL KNOW, THERE ARE
12 PROGRAMS IN CIRM THAT ALL WORK TOWARDS ACCESS AND
13 AFFORDABILITY AND BRINGING THESE THERAPIES TO PEOPLE
14 WHERE THEY ARE.

15 SO FAR IT HAS BEEN -- THERE HASN'T BEEN A
16 COHESIVE BRINGING TOGETHER OF ALL THESE PARTS. AND
17 SO OVER THE LAST SEVERAL MONTHS, THE TEAM HAS LOOKED
18 AT WHAT DO WE HAVE? WHAT DO WE NEED? AND HOW ARE
19 WE GOING TO GET THERE? AND SO THIS IS REALLY A
20 STRATEGY THAT HAS BEEN REVIEWED BY A LOT OF OUR
21 INTERNAL FOLKS. WE'VE HAD INPUT FROM MEMBERS OF
22 THIS COMMITTEE AND FROM OTHER EXTERNAL CONSULTANTS.
23 AND SO THANK YOU TO EVERYONE WHO'S CONTRIBUTED TO
24 THIS.

25 SO, ROSA, IF YOU COULD PLEASE START WITH

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1 THE PRESENTATION, THAT WOULD BE WONDERFUL.

2 DR. CANET-AVILES: THANK YOU, MARIA, FOR
3 THE GREAT INTRODUCTION. CAMERON, WHENEVER YOU ARE
4 READY.

5 SO AS MARIA WAS MENTIONING, THE TEAM, THE
6 PATIENT ACCESS, TOGETHER IN COLLABORATION WITH THE
7 PRECLINICAL DEVELOPMENT AND THE CLINICAL DEVELOPMENT
8 TEAMS HAVE BEEN WORKING ON THIS OVER THE LAST FEW
9 MONTHS IN COLLABORATION WITH OUR CHAIR OF THE
10 AAWG -- THANK YOU, MARIA, FOR YOUR LEADERSHIP AND
11 ADVICE -- AS WELL AS CONSULTANTS AND THE MEMBERS OF
12 THE AAWG.

13 NEXT SLIDE. SO THE AGENDA FOR TODAY IS
14 GOING TO BE WHAT'S THE MEETING GOAL? WHAT ARE WE
15 TRYING TO GET OUT OF THIS MEETING FIRST OF ALL?
16 THEN THE BACKGROUND AND OBJECTIVES THAT LED US TO
17 THIS STRATEGY. AND THEN WE WILL GO ONE BY ONE
18 THROUGH THE IMPLEMENTATION PLAN ON HOW DO WE INTEND
19 TO FULFILL THESE OBJECTIVES. AND THEN A SUMMARY OF
20 THE STRATEGY MILESTONES THAT ARE MAPPED THROUGH TO
21 THESE OBJECTIVES. AND FINALLY, THE RECOMMENDATION
22 THAT WE WOULD LIKE FOR THE ACCESS AND AFFORDABILITY
23 WORKING GROUP TO APPROVE TO GO TO THE BOARD.

24 AND PLEASE FEEL FREE TO STOP ME AT ANY
25 TIME IF YOU HAVE ANY QUESTIONS. NEXT SLIDE.

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1 SO THE PURPOSE OF TODAY'S MEETING IS TO
2 PRESENT THE STRATEGY TO THE ACCESSIBILITY AND
3 AFFORDABILITY WORKING GROUP FOR INPUT AND
4 RECOMMENDATION TO THE INDEPENDENT CITIZENS'
5 OVERSIGHT COMMITTEE. THAT WILL BE -- THE MEETING
6 WILL BE DECEMBER 11TH OF THIS YEAR.

7 NEXT SLIDE. SO NOW LET'S GO INTO
8 BACKGROUND AND OBJECTIVES. AS WE ALL KNOW,
9 PROPOSITION 14 GAVE US A CLEAR MANDATE TO ENHANCE
10 PATIENT ACCESS AND TO PROMOTE AFFORDABILITY. THIS
11 MANDATE IS NOT THEORETICAL. IT'S ACTIONABLE. AND
12 AS MARIA WAS VERY WELL SAYING, THERE HAS BEEN
13 SEVERAL COMPONENTS THAT NEEDED TO BE PUT TOGETHER IN
14 ORDER TO ACTION THIS MANDATE.

15 AND THE FIRST THING THAT THE TEAM DID WAS
16 TO ANALYZE WHERE THE BARRIERS OCCUR WITHIN THE
17 SYSTEM. AND WE DEVELOPED A STRATEGY THAT RESPONDS
18 DIRECTLY TO THOSE BARRIERS. AND WE'VE DIVIDED THEM
19 INTO THREE DIFFERENT AREAS.

20 THE STRATEGY LAYS OUT HOW WE MOVE FROM
21 INDIVIDUAL PROGRAM ELEMENTS TO A COORDINATED SYSTEM
22 THAT WILL ENSURE THAT CIRM-FUNDED THERAPIES ARE NOT
23 JUST DEVELOPED, BUT THAT THEY ALSO GET DELIVERED TO
24 THOSE CALIFORNIANS THAT NEED THEM.

25 NEXT SLIDE. THE STRATEGY IS BUILT ON

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1 THREE INTERCONNECTED OBJECTIVES. THE FIRST ONE IS
2 THE CLINICAL INFRASTRUCTURE INTEGRATION. OUR ALPHA
3 CLINICS, THE COMMUNITY CARE CENTERS OF EXCELLENCE
4 WERE JUST AWARDED, PART OF THEM, AND THE PATIENT
5 SUPPORT PROGRAM OPERATE AS -- NEED TO OPERATE AS A
6 UNIFIED STATEWIDE NETWORK. SO THE ACTIONS THAT WE
7 ARE GOING TO RECOMMEND FOR THIS OBJECTIVE HAVE TO DO
8 WITH THIS NETWORK UNIFICATION THAT NEEDS TO HAPPEN
9 FOR US TO MAXIMIZE, LEVERAGE THE VALUE OF THIS
10 INFRASTRUCTURE.

11 THE SECOND OBJECTIVE IS THE POLICY AND
12 PAYER ENGAGEMENT. THIS LEVERAGES CIRM'S PORTFOLIO
13 AND CONVENING POWER TO BUILD PAYER CONFIDENCE, SHAPE
14 REIMBURSEMENT MODELS, AND ADVANCE STATE-LED PILOTS
15 THAT ACCELERATE COVERAGE. AND WE WILL BE PROVIDING
16 SOME EXAMPLES OF HOW WE ARE THINKING ABOUT GOING
17 ABOUT THIS.

18 THIRD, THE AFFORDABILITY AND FINANCIAL
19 INNOVATION. AND THAT'S PLANNING EARLY TO REDUCE OR
20 ELIMINATE PATIENT OUT-OF-POCKET COST AND ENSURE
21 COVERAGE MODELS SO CURATIVE THERAPIES ARE TRULY
22 ACCESSIBLE TO ALL CALIFORNIANS.

23 WE ARE GOING TO GET STARTED WITH THE --
24 NEXT SLIDE. SO WHAT WE ARE GOING TO DO NOW IS WE'RE
25 GOING TO GO THROUGH THESE THREE OBJECTIVES. AND

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1 EACH ONE OF THE OBJECTIVES HAS A GOAL. IT HAS AN
2 ACTION PLAN. AND THEN IT HAS SOME MILESTONES.
3 THAT'S WHERE WE WILL GO ONE BY ONE.

4 NEXT SLIDE. OUR FIRST IMPLEMENTATION
5 OBJECTIVE IS ABOUT TRANSFORMING OUR EXISTING
6 CLINICAL PROGRAMS INTO A UNIFIED STATEWIDE ACCESS
7 NETWORK, AS I WAS SAYING EARLIER. THE GOAL IS VERY
8 CLEAR. IT'S TO BASICALLY CREATE A COHESIVE
9 PERFORMANCE DRIVEN NETWORK THAT DRIVES
10 GEOGRAPHICALLY DISTRIBUTED ACCESS OF CIRM-FUNDED
11 CLINICAL TRIALS AND ALSO THERAPIES ONCE WE GET THEM,
12 MAKING THE RESULTING TREATMENTS AND CURES BROADLY
13 ACCESSIBLE TO ALL CALIFORNIANS.

14 THIS REQUIRES ALIGNMENT AND INTEGRATION
15 ACROSS THE FOUR PILLARS OF OUR INFRASTRUCTURE, WHICH
16 ARE THE ALPHA CLINICS, THE COMMUNITY CARE CENTERS OF
17 EXCELLENCE, THE PATIENT SUPPORT PROGRAM, AND THE
18 COMMUNITY-BASED PARTNER ORGANIZATIONS TO ACCELERATE
19 TRIAL SETUP, TO ELIMINATE GEOGRAPHIC DISPARITIES,
20 AND ENSURE THAT CALIFORNIANS ALL ACROSS THE STATE
21 CAN RECEIVE THESE THERAPIES. AND THIS NETWORK IS
22 BUILT THROUGH FOUR INTEGRATED COMPONENTS THAT WE
23 WILL GO THROUGH. NEXT SLIDE.

24 THIS SLIDE SHOWS HOW EACH COMPONENT OF OUR
25 INFRASTRUCTURE CONTRIBUTES TO A UNIFIED SYSTEM

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1 THAT'S DESIGNED FOR EQUITABLE ACCESS AND ACCELERATED
2 DELIVERY AND THE ACTIONS THAT WE PROPOSE TO
3 IMPLEMENT THIS UNIFICATION AND INTEGRATION.

4 FIRST ONE IS THE ALPHA CLINICS. THE
5 ACTION COULD BE AND IS SOMETHING THAT WE ARE ALREADY
6 DOING, BUT IT COULD BE OPTIMIZED, TO ENHANCE
7 OPERATIONAL PERFORMANCE OF CIRM-FUNDED TRIALS,
8 PROMOTING COORDINATION BETWEEN THE CLIN2 AWARDEES
9 AND THE ALPHA CLINICS, TO REDUCE OPERATIONAL
10 BOTTLENECKS FOR RAPID ENROLLMENT OF CALIFORNIA
11 PATIENTS. AS I WAS SAYING, THIS IS ALREADY
12 UNDERGOING. IT'S JUST GOING TO BE OPTIMIZED.

13 THE SECOND IS TO DEPLOY STANDARDIZED
14 METRICS ACROSS ALPHA CLINICS, EXPANDING AND
15 IMPLEMENTING UNIFORM REPORTING FOR TRIAL VOLUME,
16 ENROLLMENT DIVERSITY, RETENTION, SOCIOECONOMIC
17 GEOGRAPHIC REACH TO EVALUATE THE IMPACT OF THE ALPHA
18 CLINICS AND ADAPT CIRM'S ACCESSIBILITY AND
19 AFFORDABILITY PROGRAMS TO BETTER SERVE CALIFORNIA
20 PATIENTS.

21 THIS IS SOMETHING THAT WE WILL ALSO BE
22 DOING FOR THE COMMUNITY CARE CENTERS OF EXCELLENCE.
23 SO THE ALPHA CLINICS HAVE BEEN UNDERGOING. WE ARE
24 REFINING A LITTLE BIT THOSE METRICS NOW. FOR THE
25 COMMUNITY CARE CENTERS, WE WILL HAVE LEARNED FROM

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1 THE ALPHA CLINICS. WE ARE IMPLEMENTING IT FROM THE
2 BEGINNING AS WE DEVELOP THE MILESTONES RIGHT NOW FOR
3 THE NEW AWARDEES.

4 SO FOR THE COMMUNITY CARE CENTERS OF
5 EXCELLENCE, THE ACTIONS THAT WE PROPOSE, THE FIRST
6 ONE IS PARTNERSHIP WITH THE ALPHA CLINICS.

7 ESTABLISH STRUCTURED REFERRAL STANDARDS AND DATA
8 SHARING ACROSS COMMUNITY CARE CENTERS AND ALPHA
9 CLINICS TO CREATE COORDINATED PATIENT PIPELINES.

10 THE SECOND ONE IS GEOGRAPHIC EXPANSION.
11 SO THIS COULD COME LATER ON AS THIS FIRST SET OF
12 COMMUNITY CARE CENTERS OF EXCELLENCE WILL ALREADY BE
13 UNDERGOING, BUT IT COULD BE TO EXPAND GEOGRAPHIC
14 REACH OF PROGRAMS THROUGH FUTURE FUNDING. THERE'S
15 ALSO THE ASK THAT WE HAVE THAT WE ARE GOING TO COME
16 WITH A PLAN FOR THE FIRST ROUND OF THE CCC'S THAT
17 WERE \$10 MILLION LEFT ON THE TABLE, AND WE'VE BEEN
18 ASKED TO COME UP WITH PLAN TO FIGURE OUT HOW TO
19 COVER THE NORTH OF THE STATE. AND THAT'S SOMETHING
20 THAT COULD ALSO BE PART OF THIS.

21 EARLY PHASE READINESS. THIS IS ABOUT
22 BUILDING CAPACITY AT THE COMMUNITY CARE CENTERS TO
23 SUPPORT IND-ENABLING AND FIRST-IN-HUMAN STUDIES.
24 AND ENHANCEMENT, NAVIGATION, AND SOCIAL SUPPORT.
25 THIS IS ABOUT INTEGRATION OF NAVIGATION SERVICES

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1 THAT ADDRESS SOCIAL DETERMINANTS. FOR EXAMPLE,
2 TRANSPORTATION, HOUSING STABILITY, LANGUAGE, AND
3 OTHER BARRIERS THAT COULD REDUCE THE BARRIERS TO
4 PARTICIPATION AND IMPROVE REPRESENTATION OF
5 POPULATIONS THAT HAVE HISTORICALLY NOT BEEN ABLE TO
6 BE INCLUDED IN THE CLINICAL RESEARCH.

7 THE FINAL ACTION HERE FOR THE COMMUNITY
8 CARE CENTERS OF EXCELLENCE IS THE DEPLOYMENT OF
9 STANDARDIZE METRICS ACROSS THE COMMUNITY CARE
10 CENTERS IN THE SAME WAY THAT WE WERE PROPOSING FOR
11 THE ALPHA CLINICS.

12 FOR THE PATIENT SUPPORT PROGRAM, THE
13 ACTIONS THAT WE PROPOSE ARE TO INTEGRATE WITH THE
14 ALPHA CLINICS AND THE CLIN2S. THE ANCILLARY SUPPORT
15 IS SOMETHING THAT -- AND OUR COLLEAGUE NIMIT RUPAREL
16 WHO'S PRESENTING THE PSP UPDATE AFTER ME IS GOING TO
17 ACTUALLY GO DEEPER INTO ALL OF THIS. SO I'M JUST
18 GOING TO ENUNCIATE VERY HIGH LEVEL WHAT IS IT THAT
19 WE ARE PLANNING FOR THIS. BUT THE ANCILLARY SUPPORT
20 HAS TO DO WITH EXPANDING TO COVER ADDITIONAL
21 CLINICAL TRIAL COSTS, TO REDUCE BARRIERS FOR
22 UNDERSERVED PATIENTS. AND HE WILL GO INTO THIS.

23 THE OUTCOME AND EQUITY TRAINING WOULD BE
24 TO MEASURE AND TRACK PATIENT REFERRALS,
25 DEMOGRAPHICS, AND SERVICES USED TO EVALUATE THE

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1 IMPACT OF THE PATIENT SUPPORT PROGRAM AND ADAPT TO
2 HOW BEST PROVIDE PATIENT SUPPORT SERVICES TO
3 CALIFORNIA PATIENT POPULATIONS.

4 AND FINALLY, THE FOURTH COMPONENT OF THIS
5 OBJECTIVE OF INTEGRATING THE CLINICAL INFRASTRUCTURE
6 HAS TO DO WITH THE COMMUNITY-BASED ORGANIZATIONS.
7 WE ARE PROPOSING AN EXPANSION OF THE PROGRAM. AND
8 THE FIRST THING THAT WE ARE GOING TO HAVE TO DO IS A
9 GAP ANALYSIS AND MAPPING. WE NEED TO COMPARE SOME
10 TRIAL PARTICIPANTS WITH CALIFORNIA DEMOGRAPHIC
11 DISTRIBUTION TO BE ABLE TO IDENTIFY WHICH ARE THE
12 UNDERSERVED POPULATIONS AND GEOGRAPHIES THAT ARE NOT
13 YET COVERED BY THE COMMUNITY-BASED ORGANIZATIONS
14 THAT WE ARE ALREADY WORKING WITH THROUGH THE
15 COMMUNITY CARE CENTERS OF EXCELLENCE.

16 SO THIS WILL LEAD TO DEVELOPMENT OF A
17 PROGRAM THAT WILL BE A PILOT TO LAUNCH COMPETITIVE
18 AWARDS FOR COMMUNITY-BASED ORGANIZATIONS BEYOND THE
19 COMMUNITY CARE CENTERS OF EXCELLENCE, PRIORITIZING
20 HIGH NEED REGIONS IDENTIFIED IN THIS GAP ANALYSIS.

21 THE THIRD COMPONENT OF THE COMMUNITY-BASED
22 ORGANIZATION EXPANSION PROGRAM IS TO COLLECT DATA ON
23 OUTREACH, REFERRALS, AND TRIAL ENROLLMENT, AND
24 EQUITY IMPACTS, ALSO ALIGN WITH THE METRICS THAT WE
25 ARE IMPLEMENTING IN THE OTHER PROGRAMS.

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1 AND FINALLY IS THE COORDINATION OF THE
2 COMMUNITY-BASED ORGANIZATIONS TO ALIGN AND
3 COORDINATE THEM AND STANDARDIZING EDUCATIONAL AND
4 CULTURALLY RELEVANT OUTREACH MATERIALS.

5 THE GOAL ULTIMATELY IS THAT BY
6 IMPLEMENTING ALL THESE ACTIONS FROM INDIVIDUAL SITES
7 AND PROGRAMS TO A COORDINATED STATEWIDE
8 INFRASTRUCTURE BUILT FOR EQUITY AND SPEED, WE WILL
9 BE ABLE TO ACHIEVE THE DELIVERY OF THESE THERAPIES
10 ACROSS CALIFORNIA TO ALL, NOT ONLY THOSE THAT LIVE
11 IN CLOSE URBAN AREAS, BUT ALSO THOSE THAT ARE
12 GEOGRAPHICALLY DISTANT OR DON'T HAVE ECONOMIC --
13 THEY CANNOT AFFORD THOSE THERAPIES.

14 NEXT SLIDE. THESE ARE THE MEASURABLE
15 OUTCOMES THAT DEMONSTRATE IMPACT, NOT ACTIVITY. WE
16 EXPECT TO SEE YEAR OVER YEAR INCREASES IN
17 PARTICIPATION FROM UNDERSERVED POPULATIONS, SHOWING
18 THAT THIS INFRASTRUCTURE IS ACTIVELY CLOSING EQUITY
19 GAPS. BY 27, FISCAL YEAR 27/28, WE HOPE TO ACHIEVE
20 A HUNDRED PERCENT -- IT'S NO MORE OR EQUAL. IT HAS
21 TO BE -- I DON'T THINK WE CAN DO MORE. MAYBE WE
22 CAN -- A HUNDRED PERCENT OF THE ALPHA CLINICS AND
23 THE COMMUNITY CARE CENTERS OF EXCELLENCE REPORTING
24 STANDARDIZED METRICS ANNUALLY BY THIS TIME. IT'S
25 ACTUALLY JUST HUNDRED PERCENT. WE NEED TO MODIFY

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1 THAT FOR THE BOARD MEETING. AND THE GOOD THING IS
2 THAT WE WILL HAVE A STATEWIDE MAP IDENTIFYING
3 EXACTLY WHERE CALIFORNIANS CAN ACCESS TRIALS AND
4 THERAPIES. AND WE WILL EXPAND OUR GEOGRAPHIC
5 COVERAGE AND ALIGNMENT WITH THE POPULATION NEED, NOT
6 WITH HISTORICAL CONVENIENCE.

7 FINALLY, WE WILL ACHIEVE CONSISTENCY IN
8 OUTREACH AND ENGAGEMENT ACROSS THE NETWORK, ENSURING
9 THAT NO COMMUNITY IS LEFT BEHIND SIMPLY BECAUSE THEY
10 ARE NOT CONNECTED TO A MAJOR MEDICAL CENTER. SO
11 THIS IS THE FIRST OBJECTIVE. I'M HAPPY TO STOP
12 HERE, OR I CAN CONTINUE TILL THE END, AND THEN WE
13 CAN OPEN FOR QUESTIONS. HOW DO YOU PREFER TO DO
14 THAT, MARIA?

15 VICE CHAIR BONNEVILLE: WE CAN TAKE
16 QUESTIONS NOW IF ANYONE HAS ANY QUESTIONS CURRENTLY.
17 SO WHY DON'T YOU CONTINUE, AND THEN WE'LL GO TO THE
18 NEXT PART.

19 DR. CANET-AVILES: THERE CAN ALWAYS BE
20 QUESTIONS ABOUT THIS AT THE END.

21 NEXT SLIDE. OUR SECOND STRATEGIC
22 OBJECTIVE ADDRESSES ONE OF THE BIGGEST BARRIERS TO
23 PATIENT ACCESS TO DATE, WHICH IS NOT THE SCIENCE,
24 BUT THE REIMBURSEMENT. PAYERS ARE FACING REAL
25 UNCERTAINTY AROUND THE DURABILITY AND LONG-TERM

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1 VALUE OF THESE THERAPIES, WHICH LEADS TO
2 INCONSISTENT COVERAGE DECISIONS AND DELAYS IN
3 PATIENT ACCESS. WE BELIEVE THAT CIRM IS UNIQUELY
4 POSITIONED TO CHANGE THAT AS A STEWARD OF
5 CALIFORNIA'S INVESTMENT AND WITH VISIBILITY ACROSS
6 THE THERAPEUTIC DEVELOPMENT PIPELINE THROUGH OUR
7 PRECLINICAL DEVELOPMENT AND OUR CLINICAL
8 DEVELOPMENT. WE CAN USE OUR PORTFOLIO DATA AND THE
9 GRANTEES AND THE INFRASTRUCTURE TO BUILD PAYER
10 CONFIDENCE AND SHAPE REIMBURSEMENT MODELS AS WELL AS
11 HELP DRIVE POLICY SOLUTIONS, NOT AFTER THERAPIES ARE
12 APPROVED, BUT IN PARALLEL WITH THEIR DEVELOPMENT.

13 THIS PILLAR HAS THREE OPPONENTS. THE
14 FIRST ONE IS A STRUCTURED PAYER ENGAGEMENT FRAMEWORK
15 TO FACILITATE EARLY DATA DRIVEN DIALOGUE. AND THIS
16 COULD BE LEVERAGING OUR PORTFOLIO AND
17 INFRASTRUCTURE, AS I WAS MENTIONING.

18 THE SECOND ONE IS THE CALIFORNIA CELL AND
19 GENE THERAPY REIMBURSEMENT PILOT TO TEST NEW PAYMENT
20 MODELS IN PARTNERSHIP WITH PUBLIC AND COMMERCIAL
21 PAYERS.

22 AND THE THIRD ONE IS POLICY ADVOCACY TO
23 ENSURE EQUITY AND COVERAGE ARE BUILT INTO STATEWIDE
24 SYSTEMS. THIS IS HOW WE WILL ENSURE THAT CURATIVE
25 THERAPIES MOVE FROM SCIENTIFIC BREAKTHROUGH TO

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1 REAL-WORLD ACCESS FOR CALIFORNIANS. AND JUST TO SAY
2 THAT THESE COMPONENTS, WE STILL NEED TO -- THERE'S A
3 WHOLE FUNCTION FOR THE ACCESSIBILITY AND
4 AFFORDABILITY FUNCTION AT CIRM THAT NEEDS TO BE
5 DEVELOPED SO THAT WE CAN ACTUALLY -- WITH CERTAIN
6 EXPERTISE SO THAT WE CAN ACTUALLY ENGAGE IN ALL
7 THESE THREE ACTION COMPONENTS. NEXT SLIDE.

8 THIS IS SLIDE ALIGNS THE PROPOSED ACTIONS
9 ON HOW WE COULD OPERATIONALIZE OUR PAYER ENGAGEMENT
10 STRATEGY. A LOT OF THIS ACTUALLY HAS BEEN DRIVEN
11 ALL THIS TIME BY OUR CHAIR OF THE AAWG, BY MARIA.

12 WHAT WE ARE PROPOSING ON THIS OBJECTIVE IS
13 A PROACTIVE APPROACH TO BUILD PAYER READINESS IN
14 PARALLEL WITH THE DEVELOPMENT OF THE THERAPIES.
15 FIRST AND THROUGH THE STRUCTURED PAYER ENGAGEMENT
16 FRAMEWORK, WE COULD INITIATE TARGETED ENGAGEMENT
17 WITH PUBLIC AND PRIVATE PAYERS TO ADDRESS SHARED
18 CHALLENGES SUCH AS DURABILITY EVIDENCE, LONG-TERM
19 COST MODELING, AND BUDGET IMPACT. WE WOULD DO THAT
20 USING CIRM'S PORTFOLIO AS A FOUNDATION FOR DATA
21 DRIVEN DIALOGUE. AND WE PROPOSE THAT WE COULD
22 CONVENE TECHNICAL EVIDENCE EXCHANGE SESSIONS TO
23 REVIEW EMERGING OUTCOMES AND DURABILITY DATA AND TO
24 IDENTIFY EVIDENCE GAPS WITH THESE PUBLIC AND PRIVATE
25 PAYERS EARLY. AND THIS FRAMEWORK COULD LAY THE

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1 GROUNDWORK FOR FUTURE REIMBURSEMENT PILOT MODELS
2 TIED TO CIRM-FUNDED THERAPIES.

3 THE SECOND THING THAT WE PROPOSE IS
4 SUPPORTING THE LAUNCH OF A CALIFORNIA-BASED CELL AND
5 GENE THERAPY REIMBURSEMENT PILOT IN PARTNERSHIP WITH
6 THE PUBLIC PAYER TO TEST SCALABLE PAYMENT APPROACHES
7 THAT LINK COST TO OUTCOMES AND DISTRIBUTE FINANCIAL
8 RISKS. AND WE WOULD DO THAT USING REAL-WORLD
9 EVIDENCE EMERGING FROM OUR CLINICAL PROGRAMS, AND
10 THE PILOT COULD BE IN A SPECIFIC DISEASE THERAPY.
11 RIGHT NOW MEDI-CAL HAS THE SICKLE CELL DISEASE
12 REIMBURSEMENT PILOT. WHAT WE PROPOSE HERE IS THAT
13 WE WOULD WORK TOWARDS GETTING ONE FOR A CIRM-FUNDED
14 THERAPY, AT LEAST ONE.

15 AND THIRD, THROUGH POLICY ADVOCACY, WE
16 COULD WORK WITH STATE AGENCIES TO ALIGN EARLY LIFE
17 SCREENING PATHWAYS WITH CLINICAL INFRASTRUCTURE,
18 ENSURE EQUITY REMAINS CENTRAL UNDER PROPOSITION 14,
19 AND HELP SHAPE POLICY OPTIONS THAT CAN ENABLE TIMELY
20 COVERAGE ONCE THESE THERAPIES ARE READY FOR PATIENT
21 DELIVERY.

22 NEXT SLIDE. IF THIS STRATEGY IS APPROVED,
23 THESE ARE THE OUTCOMES THAT WE AIM TO ACHIEVE TO
24 SHOW IMPACT OVER TIME. FIRST, WE WOULD ESTABLISH
25 FORMAL ENGAGEMENT CHANNELS WITH A PUBLIC PAYER AND

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1 AT LEAST TWO MAJOR COMMERCIAL PAYERS BY FISCAL YEAR
2 28/29. CREATING THESE PROACTIVE PATHWAYS THAT WE
3 ARE TALKING ABOUT FOR COVERAGE RATHER THAN WAITING
4 FOR REIMBURSEMENT DECISIONS AFTER APPROVAL.

5 THE SECOND THING THAT WE PROPOSE TO DO IS
6 TO SUPPORT THE LAUNCH OF A CALIFORNIA REIMBURSEMENT
7 PILOT FOR CELL OR GENE THERAPY BY FISCAL YEAR 34/35.
8 WE HOPE THAT WE WOULD HAVE THIS A LITTLE EARLIER;
9 BUT IF WE THINK ABOUT THE WAY THAT WE'VE PROJECTED
10 FUNDS AND HOW CIRM WILL BE SHOWING IMPACT, WE HAVE
11 ABOUT SIX YEARS OF FUNDING PLUS THE TAIL, WHICH IS
12 ABOUT FOUR MORE YEARS, RIGHT. SO FISCAL YEAR 31/32
13 IS WHEN THE FUNDING WOULD END, AND WE WOULD HOPE
14 THAT WE COULD START SEEING THERAPIES THAT HAVE
15 REACHED BLA AND THEY ARE COMMERCIALIZING AROUND LIKE
16 AFTER THAT. SO WE ARE ADDING THIS DATE AS THE
17 MAXIMUM TIME THAT WE COULD HAVE THIS CALIFORNIA
18 PILOT FOR ONE OF THESE THERAPIES.

19 ANOTHER EXPECTED OUTCOME IS THAT OUR
20 POLICY ADVOCACY WORK HELPS LEAD TOWARDS INTEGRATING
21 EARLY DIAGNOSIS AND GENETIC SCREENING PATHWAYS INTO
22 TRIAL ENROLLMENT TO ENSURE THAT ELIGIBLE PATIENTS,
23 NOT JUST DIAGNOSED PATIENTS, HAVE ACCESS AT THE
24 EARLIEST POSSIBLE POINT.

25 AND LASTLY, THE GOAL IS MEASURABLE

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1 REDUCTION IN ACCESS DISPARITIES TIED TO
2 SOCIOECONOMIC BARRIERS, DEMONSTRATING THAT THIS
3 STRATEGY IS NOT ONLY FEASIBLE, BUT IMPACTFUL TO
4 PATIENTS ACROSS CALIFORNIA.

5 THE THIRD OBJECTIVE RECOGNIZES -- AND THIS
6 IS THE LAST ONE, AND THEN WE WILL WRAP UP WITH HIGH
7 LEVEL MILESTONES FOR EACH ONE OF THEM. THE THIRD
8 OBJECTIVE RECOGNIZES THAT A THERAPY IS ONLY AS
9 IMPACTFUL AS IT IS ACCESSIBLE. EVEN WHEN A
10 TREATMENT IS CURATIVE, IF PATIENTS CANNOT AFFORD IT
11 OR PAYERS ARE NOT PREPARED TO COVER IT, THE PROMISE
12 OF THESE THERAPIES IS LOST.

13 THE PROPOSAL THAT WE ARE MAKING HERE IS TO
14 EMBED AFFORDABILITY PLANNING EARLY WITHIN THE
15 RESEARCH AND DEVELOPMENT PROCESS RATHER THAN WAITING
16 UNTIL COMMERCIALIZATION. AS YOU ALL KNOW BECAUSE
17 YOU APPROVED THESE, YOU REALIZED IT, GAVE US ADVICE,
18 AND APPROVED IT, WE HAVE AN ACCESSIBILITY AND
19 AFFORDABILITY TOOLKIT THAT OUR COLLEAGUES, THE LEADS
20 OF PRECLINICAL DEVELOPMENT, DR. SHYAM PATEL AND
21 DR. JOE GOLD IN CLINICAL DEVELOPMENT, THEY HAVE
22 IMPLEMENTED INTO THEIR PROGRAMS, AND THEY'VE BEEN
23 DEVELOPING THE RUBRICS, ET CETERA. SO THAT'S
24 SOMETHING THAT WE ALREADY HAVE ONGOING AND WE HAVE
25 PILOTED AND IT WILL BE REFINED AS WE MOVE FORWARD.

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1 ON THIS STRATEGY CIRM COULD USE ITS
2 FUNDING AND CONVENING POWER AS WELL TO REQUIRE
3 STRUCTURED AFFORDABILITY MILESTONES WITHIN AWARDS
4 AND TO TEST INNOVATIVE FINANCIAL MODELS THAT REDUCE
5 THE PATIENT COST AND THE RISK PAYER ADOPTION. THIS
6 INCLUDES ADDRESSING COST DRIVERS IN MANUFACTURING,
7 INTEGRATING REIMBURSEMENT EXPECTATIONS INTO
8 PORTFOLIO MANAGEMENT, AND DEVELOPING STATEWIDE
9 PILOTS FOR SUSTAINABLE ACCESS.

10 THE GOAL IS NOT JUST SCIENTIFIC SUCCESS,
11 BUT ENSURING THAT, AS I WAS SAYING EARLIER ON, EVERY
12 CIRM-FUNDED THERAPY IS DELIVERABLE IN A WAY THAT IS
13 ACCESSIBLE AND ALIGNED WITH CALIFORNIA'S COMMITMENT
14 TO PUBLIC BENEFIT.

15 NEXT SLIDE. THE OBJECTIVE OF
16 AFFORDABILITY AND FINANCIAL INNOVATION HAS FOUR
17 COMPONENTS. AND THE FIRST ONE IS THAT WE ARE
18 FORMALIZING ACCESS AND AFFORDABILITY PLANNING WITHIN
19 THE AWARDS. AS YOU KNOW, EVERY CLIN2 AND PDEV
20 PROJECT FOR CLINICAL DEVELOPMENT PROJECT NOW
21 INCLUDES EMBEDDED MILESTONES TO DEMONSTRATE EARLY
22 PAYER ENGAGEMENT AND COST PLANNING BASED ON THE
23 ACCESSIBILITY AND AFFORDABILITY TOOLKIT. AND WE
24 ALSO WORK WITH EXPERT CONSULTANTS TO HELP US ADVISE
25 ON HOW TO DEVELOP THOSE MILESTONES AND MAKE SURE

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1 THAT WE HELP THE AWARDEES.

2 SECOND, WE PROPOSE ADVANCING FINANCIAL
3 MODELING AND INNOVATION TO ENSURE LONG-TERM
4 SUSTAINABILITY. THIS COULD INCLUDE DEVELOPING NOVEL
5 FINANCIAL APPROACHES IN COLLABORATION WITH LEADING
6 EXPERTS. AND IMPORTANTLY, WE HAVE AN EXPERT
7 IN-HOUSE. OUR PRESIDENT BRINGS EXPERIENCE IN THE
8 DEVELOPMENT OF SUCH MODELS AND WILL PLAY A KEY ROLE
9 IN HELPING DRIVE AND SHAPE THESE PATHWAYS AS THEY
10 REFINED AND BROUGHT FORWARD FOR BOARD CONSIDERATION.

11 WE COULD ALSO HERE INTEGRATE THESE MODELS
12 INTO FUNDING DECISIONS AND LEVERAGE OUR PROGRAMS TO
13 REDUCE COST THROUGH MANUFACTURING INNOVATION.

14 AND THIRD AND LAST, WE ARE PROPOSING A
15 RARE DISEASE COMMERCIALIZATION AND FINANCIAL
16 INNOVATION PROGRAM TO ADDRESS THERAPIES WITH LIMITED
17 COMMERCIAL INCENTIVES. THIS WILL ALLOW US TO TEST
18 NEW MODELS FOR SUSTAINABLE DELIVERY WHERE
19 TRADITIONAL REIMBURSEMENT PATHWAYS FALL SHORT.
20 TOGETHER ALL THESE ACTIONS ENSURE THAT THERAPIES
21 EMERGING FROM CIRM'S PIPELINE ARE NOT JUST
22 SCIENTIFICALLY VIABLE, BUT ALSO AFFORDABLE,
23 SCALABLE, AND DELIVERABLE TO PATIENTS IN THE REAL
24 WORLD.

25 THE EXPECTED OUTCOMES, IF THIS STRATEGY IS

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1 APPROVED, ARE THAT WE COULD EXPECT HUNDRED PERCENT
2 OF CLIN2 AND PDEV, PRECLINICAL DEVELOPMENT, AWARDEES
3 TO INTEGRATE THE ACCESSIBILITY AND AFFORDABILITY
4 TOOLKIT-BASED REIMBURSEMENT AND AFFORDABILITY
5 MILESTONES BY FISCAL YEAR 26/27, AND WE ARE ALREADY
6 UNDER WAY WITH THAT.

7 THE SECOND ONE IS IMPLEMENTATION OF AT
8 LEAST ONE CALIFORNIA-BASED FINANCIAL PILOT BY FISCAL
9 YEAR 31/32. THIS COULD BE DESIGNED TO TEST NEW
10 AFFORDABILITY MODELS IN PARTNERSHIP WITH PAYERS AND
11 BUILD FOR BROADER ADOPTION.

12 AND LONG TERM THE GOAL IS TO SUSTAIN
13 ADOPTION OF AFFORDABILITY FRAMEWORKS BY MEDI-CAL AND
14 COMMERCIAL PAYERS FOR THERAPIES EMERGING FROM CIRM'S
15 PIPELINE.

16 IN THE NEXT SLIDE I'M JUST GOING TO
17 SUMMARIZE NOW THE STRATEGY MILESTONES. AND I KNOW
18 I'M A LITTLE OFF TODAY. I HAD A VERY EARLY FLIGHT,
19 AND YOU KNOW WHEN YOUR HEAD BUZZES, THAT'S HOW. SO
20 THE NEXT SLIDE, THESE ARE THE NEAR-TERM MILESTONES
21 THAT REPRESENT THE FOUNDATIONAL STEPS THAT WE COULD
22 TAKE UPON APPROVAL TO OPERATIONALIZE THIS STRATEGY
23 OVER THE NEXT TWO FISCAL YEARS. WE'VE DIVIDED THEM
24 IN THE OBJECTIVES, BUT THERE IS ALSO ONE THAT'S
25 OPERATIONAL. OPERATIONAL IS WHAT I WAS TALKING

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1 ABOUT AT THE VERY BEGINNING. OUR FIRST PRIORITY IS
2 TO FINALIZE THE INTERNAL -- COULD BE, IF APPROVED,
3 TO FINALIZE THE INTERNAL ACCESSIBILITY AND
4 AFFORDABILITY FUNCTION GOVERNANCE STRUCTURE TO
5 ENSURE ACCOUNTABILITY, CLARITY OF ROLES, AND
6 COORDINATION ACROSS PROGRAMS.

7 ACCESSIBILITY AND AFFORDABILITY FUNCTION
8 IS NOT ONLY PATIENT ACCESS. IT'S PRECLINICAL
9 DEVELOPMENT, IT'S CLINICAL DEVELOPMENT, IT'S LEGAL,
10 IT'S COMMUNICATIONS. IT'S A LOT OF PEOPLE
11 ULTIMATELY CORRESPONDING AND MAPPING TO THE
12 ACCESSIBILITY AND AFFORDABILITY WORKING GROUP THAT
13 ADVISES AND APPROVES.

14 FOR OBJECTIVE ONE, WE COULD IMPLEMENT
15 STANDARDIZED METRICS ACROSS ALPHA CLINICS AND
16 COMMUNITY CARE CENTERS OF EXCELLENCE AND EXPAND OUR
17 REACH TO UNDERREPRESENTED POPULATIONS BY ONBOARDING
18 ADDITIONAL COMMUNITY-BASED PARTNERS THAT SUPPORT
19 ENGAGEMENT, REFERRAL, AND ENROLLMENT.

20 FOR OBJECTIVE TWO, WE COULD INITIATE PAYER
21 ENGAGEMENT FRAMEWORK AND FIRST KNOWLEDGE EXCHANGE
22 SESSION. AND THIS IS ALL BY FISCAL YEAR 26/27.

23 AND FOR THE THIRD OBJECTIVE, IN TERMS OF
24 AFFORDABILITY AND FINANCIAL INNOVATION, WE EXPECT TO
25 BRING EXTERNAL FINANCIAL MODELING EXPERTS TO DELIVER

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1 RECOMMENDATIONS THAT WILL INFORM FUTURE PILOTS AND
2 ENSURE CIRM-FUNDED THERAPIES ARE POSITIONED FOR
3 SUSTAINABLE ACCESS.

4 AND THESE EARLY MILESTONES ARE DESIGNED TO
5 BUILT MOMENTUM QUICKLY AND ESTABLISH ALIGNMENT AND
6 BEGIN GENERATING THE DATA THAT WE NEED TO GUIDE THE
7 LONG-TERM DECISION-MAKING. THAT'S WHY THIS IS
8 NEAR-TERM FISCAL YEAR 26/27, WHICH IS NEXT YEAR.

9 THESE ARE THE LONG-TERM MILESTONES.
10 LOOKING AHEAD TO FISCAL YEAR 34/35, THESE ARE THE
11 LONG-TERM MILESTONES THAT THIS STRATEGY IS DESIGNED
12 TO DELIVER. IF APPROVED, UNDER OBJECTIVE ONE, WHICH
13 IS CLINICAL INFRASTRUCTURE INTEGRATION, WE AIM TO
14 DEMONSTRATE MEASURABLE INCREASES IN PARTICIPATION
15 FROM UNDERREPRESENTED POPULATIONS ACROSS ALL ALPHA
16 CLINICS AND THE COMMUNITY CARE CENTERS OF
17 EXCELLENCE, SHOWING THAT ACCESS IS NOT ONLY
18 AVAILABLE, BUT EQUITABLE IN PRACTICE.

19 FOR THE SECOND OBJECTIVE IN POLICY AND
20 PAYER ENGAGEMENT, WE COULD SUPPORT THE INITIATION OF
21 A CALIFORNIA REIMBURSEMENT PILOT IN PARTNERSHIP WITH
22 A PUBLIC PAYER AND AT LEAST TWO COMMERCIAL PAYERS,
23 CREATING A FUNCTIONING MODEL THAT CAN BE SCALED
24 STATEWIDE. BY THIS STAGE, OUR GOAL IS THAT A
25 HUNDRED PERCENT OF BLA-READY THERAPIES EMERGING FROM

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1 CIRM'S PORTFOLIO WILL HAVE CONCRETE ACCESS AND
2 REIMBURSEMENT PLANS WHICH WILL POSITION THEM FOR
3 REAL-WORLD DELIVERY.

4 AND FINALLY, UNDER OBJECTIVE THREE, WE AIM
5 TO OPERATIONALIZE A SUSTAINABLE COMMERCIALIZATION
6 MODEL FOR AT LEAST ONE RARE DISEASE THERAPY,
7 DEMONSTRATING THAT CIRM CAN ADDRESS DISEASES WITH
8 LIMITED COMMERCIAL PATHWAYS AND STILL DELIVER IMPACT
9 FOR CALIFORNIA PATIENTS.

10 THESE MILESTONES ALTOGETHER REPRESENT A
11 MAJOR SHIFT FROM PROGRAMS THAT GENERATE
12 GROUNDBREAKING SCIENCE TO A COORDINATED SYSTEM AT
13 CIRM THAT ENSURES CALIFORNIA PATIENTS WILL HAVE
14 ACCESS TO CURES THAT THEIR PUBLIC INVESTMENT HELPED
15 CREATE.

16 AND FINALLY, WE HAVE THE ASK FROM THE
17 ACCESS AND AFFORDABILITY WORKING GROUP. CIRM
18 REQUESTS THE RECOMMENDATION FROM THE ACCESS AND
19 AFFORDABILITY WORKING GROUP TO ADVANCE THE DRAFT
20 ACCESS AND AFFORDABILITY STRATEGY TO THE INDEPENDENT
21 CITIZENS OVERSIGHT COMMITTEE FOR APPROVAL ON
22 DECEMBER 11TH. AND WITH THAT, I'D LIKE TO THANK YOU
23 FOR YOUR ATTENTION AND YOUR TIME, AND WE ARE OPEN
24 FOR QUESTIONS. THANK YOU.

25 VICE CHAIR BONNEVILLE: THANK YOU, ROSA,

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1 SO MUCH FOR THAT PRESENTATION. SO I'D LIKE TO OPEN
2 THE FLOOR TO ANY MEMBERS THAT WOULD LIKE TO ASK
3 QUESTIONS ABOUT THE STRATEGY. ADRIANA.

4 DR. PADILLA: YES. THANK YOU. THAT WAS
5 GREAT. YOU MENTIONED THAT THE SICKLE CELL PROGRAM
6 HAS ALREADY IMPLEMENTED A LOT OF THESE OBJECTIVES.
7 CAN YOU -- I WAS TRYING TO KIND OF CORRELATE THE
8 PLAN WITH SOMETHING THAT'S TANGIBLE ALREADY. HAS
9 THE SICKLE CELL PROGRAM GONE THROUGH MOST OF THESE
10 OBJECTIVES AS WELL OR NOT, OR WHERE ARE THEY? OR
11 HOW CAN WE COMPARE AND CONTRAST SO THAT WE CAN KIND
12 OF LIKE SEE THE POSSIBILITIES FOR SOME OF THESE
13 PROGRAMS DOWN THE ROAD?

14 DR. CANET-AVILES: THANK YOU, ADRIANA.
15 ACTUALLY I THINK I MIGHT HAVE MADE IT MORE
16 CONVOLUTED BY MENTIONING THE SICKLE CELL DISEASE
17 REIMBURSEMENT PROGRAM. I WAS ONLY REFERRING TO THE
18 SICKLE CELL DISEASE REIMBURSEMENT PROGRAM IN THE
19 CONTEXT OF THE OBJECTIVES THAT WE HAVE IN TERMS OF
20 THE POLICY AND PAYER ENGAGEMENT.

21 WHAT I WAS TALKING ABOUT WAS THAT BY
22 PARTNERING WITH PAYERS AND LEVERAGING OUR PORTFOLIO
23 AND BY ENGAGING WITH THEM THAT WE WILL EVENTUALLY
24 COLLABORATE WITH THEM TO HELP INFORM THE DEVELOPMENT
25 OF A PILOT REIMBURSEMENT MODEL AND THEN MENTIONED

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1 THAT THERE IS A SICKLE CELL DISEASE. BUT I DON'T
2 KNOW IF, MARIA, YOU WANT TO TALK A BIT MORE ABOUT
3 THESE. IT IS A BIT CONFUSING, I THINK.

4 VICE CHAIR BONNEVILLE: ADRIANA, CMS AND
5 CMMI PILOT PROGRAM WAS DEVELOPED BECAUSE OF THE
6 SICKLE CELL CURES THAT CAME ON THE MARKET LAST YEAR.
7 AND SO -- OR TWO YEARS AGO NOW ALMOST. GOODNESS.
8 AND THAT PILOT PROGRAM IS SOMETHING THAT CALIFORNIA
9 HAS JOINED. AND SO AS PART OF THE LESSONS LEARNED
10 TO UNDERSTAND HOW THAT PILOT PROGRAM IS BEING
11 IMPLEMENTED AND WHAT THE SUCCESSES ARE AND LESSONS
12 LEARNED WILL BE REALLY VALUABLE FOR US MOVING
13 FORWARD TO BE ABLE TO COLLABORATE WITH BOTH PRIVATE
14 AND PUBLIC PAYERS TO DEVELOP SOME SORT OF PILOT
15 PROGRAM FOR CIRM-FUNDED THERAPIES.

16 DR. PADILLA: SO FOR THEM, ARE THEY
17 ALREADY -- HAVE THEY IMPLEMENTED --

18 VICE CHAIR BONNEVILLE: YES.

19 DR. PADILLA: -- THEIR ACCESSING POINTS
20 BASICALLY?

21 VICE CHAIR BONNEVILLE: THAT IS AROUND
22 HOW -- THAT'S AROUND REIMBURSEMENT. IT IS NOT
23 AROUND ACCESS IN THE WAY SOMETIMES WE REFER TO
24 ACCESS ALTHOUGH THERE WAS AN ANCILLARY PROGRAM THAT
25 ALSO ALLOCATED MONEY AROUND DIFFERENT PARTNERS THAT

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1 COULD HELP WITH PATIENT NAVIGATION. AND THAT WAS
2 MONEY THAT WAS ALLOCATED DIRECTLY AS WELL TO STATES
3 THAT APPLY FOR THAT. BUT I DON'T HAVE A WINDOW INTO
4 HOW THAT'S GOING IN CALIFORNIA YET, BUT THAT'S
5 SOMETHING DEFINITELY WE CAN GET BACK TO YOU WITH AND
6 ASK.

7 DR. PADILLA: I JUST TRYING TO PUT SOME
8 TANGIBLES ABOUT HOW THIS MIGHT WORK IN THE FUTURE.

9 VICE CHAIR BONNEVILLE: ABSOLUTELY. SO TO
10 THAT POINT, I THINK THAT THERE ARE A COUPLE, ROSA
11 AND TEAM, AND THIS IS SOMETHING I WAS THINKING ABOUT
12 AS YOU WERE GIVING THE PRESENTATION, THERE ARE SOME
13 AREAS WHERE, WHEN WE TALK ABOUT A GOAL WE MAY HAVE,
14 WE DON'T REALLY HAVE -- THERE'S ALREADY A BASELINE
15 PERHAPS IN THE FIELD OR IN CALIFORNIA OR WHATEVER IT
16 MIGHT BE FOR THAT SPECIFIC GOAL. SO UNDERSTANDING
17 WHAT THE BASELINE IS SO THEN, WHEN WE SAY, FOR
18 EXAMPLE, I THINK IT WAS THE DEMONSTRABLE REDUCTION
19 IN ACCESS TO DISPARITIES BASED ON SOCIOECONOMIC
20 FACTORS, WE DON'T KNOW WHAT A REDUCTION IS UNLESS WE
21 KNOW WHERE TO START. AND SO IT WOULD BE
22 INTERESTING -- I THINK THERE'S SOME WORK THAT NEEDS
23 TO BE DONE IN DIFFERENT GOALS WHERE THERE IS A
24 BASELINE THAT HAS ALREADY BEEN ESTABLISHED AND THEN
25 WHAT IT MEANS TO REDUCE OR INCREASE OR WHATEVER IT

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1 MIGHT BE.

2 DR. PADILLA: THANK YOU.

3 DR. CANET-AVILES: THANK YOU. THAT'S A
4 GREAT POINT, UNDERSTANDING THE BASELINE BENCHMARK.

5 VICE CHAIR BONNEVILLE: DOES ANYONE HAVE
6 ANY OTHER QUESTIONS? VITO.

7 CHAIRMAN IMBASCIANI: HI. THANKS, ROSA.
8 VERY COMPREHENSIVE. A QUESTION CAME TO ME. THIS IS
9 WITH RESPECT TO GOAL NO. 1, INTEGRATING ACCESS AND
10 AFFORDABILITY INTO THE CLINICAL INFRASTRUCTURE. AND
11 MY QUESTION WAS REFINED BY LAST WEEK'S APPLICATION
12 REVIEW SUBCOMMITTEE IN WHICH WE AWARDED THREE
13 ENTITIES AN INFRASTRUCTURE & GRANT TO EXPAND THE CCE
14 NETWORKS.

15 AND YOU WILL NOTICE, WHEN YOU LOOK AT THE
16 RESULTANT MAP, THAT THERE ARE MANY, MANY COUNTIES
17 THAT WILL NOT BE ANYWHERE NEAR A SERVICE AREA. EVEN
18 THOUGH WE ASKED THE TEAM TO THINK ABOUT EXPANDING
19 INTO THE NORTH COUNTRY, THERE ARE, EVEN IF J.T. AND
20 HIS TEAM ARE SUCCESSFUL IN BRINGING SOMETHING BACK
21 EXPANDING THE RAF TO CREATE A FOURTH CCCE UP IN THE
22 NORTHERN COUNTRY, THERE'S STILL GOING TO BE MANY
23 COUNTIES THAT WILL NOT HAVE AN ALPHA CLINIC OR A
24 CCCE.

25 AND I'M LOOKING AT THE LAST OF THE

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1 HIERARCHY THAT YOU DELINEATED. SORRY THIS QUESTION
2 IS CONVOLUTED, AND I HAVEN'T EVEN GOTTEN TO IT YET,
3 BUT IT'S A HIERARCHY OF ALPHA CLINICS AND THE
4 CENTERS OF EXCELLENCE AND THEN THE PATIENT SUPPORT
5 SYSTEM, AND THEN THE VERY NEBULOUS COMMUNITY-BASED
6 ORGANIZATIONS, SOMETHING THAT ANOTHER BOARD MEMBER
7 BROUGHT UP POINTEDLY AT THE APPLICATION REVIEW
8 SUBCOMMITTEE.

9 ROSA, I CAN TELL YOU ALPINE COUNTY HAS
10 1,000 CITIZENS UP THERE AND SIERRA COUNTY HAS GOT
11 3,000 CITIZENS. TRUST ME. THERE ARE NO
12 COMMUNITY-BASED ORGANIZATIONS OF ANY KIND. THEY
13 JUST DON'T HAVE THE DEPTH -- THEY DON'T HAVE THE
14 POPULATION. AND IT'S POSSIBLE THAT MAYBE AMONG THE
15 THREE MOST NORTHERN COUNTIES, SISKIYOU WITH A
16 POPULATION OF 42,000, MIGHT HAVE TO BE THE SOURCE OF
17 COMMUNITY-BASED ORGANIZATIONS FOR THE TWO COUNTIES
18 ON EITHER SIDE, WHICH HAVE FEWER THAN 8,000 PEOPLE
19 AND VERY, VERY FAR AWAY EVEN FROM SHASTA COUNTY AND
20 REDDING. AND ANYBODY FROM SACRAMENTO ON THE CALL
21 WILL KNOW EVEN REDDING IS NOT THAT CLOSE TO UC
22 DAVIS.

23 SO MY QUESTION IS YOU SAY EXPAND THE CBO.
24 DO YOU REALLY KNOW WHAT YOU ARE ASKING? DO YOU
25 REALLY KNOW WHAT YOU'RE GETTING INTO? YOU MAY HAVE

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1 TO CREATE CBO'S OR ENCOURAGE OTHER PEOPLE TO DO SO.

2 VICE CHAIR BONNEVILLE: VITO, THANK YOU
3 FOR THAT. I THINK THAT THE SUPPORT RFA THAT IS
4 BEING ENVISIONED AROUND THE COMMUNITY CARE CENTERS
5 AS WELL AS JUST SUPPORT IN GENERAL TO REACH
6 POPULATIONS THAT DO NOT HAVE ACCESS TO THIS WILL
7 HAVE TO BE CREATED IN WHAT WE ASK FOR AND HOW WE
8 BRING SUPPORT TO THESE COMMUNITIES.

9 AND I THINK THAT THAT'S PART OF WHAT ROSA
10 WAS SAYING AND PART OF WHAT THE TEAM IS SUGGESTING
11 IS THAT THERE HAS TO BE A LANDSCAPE ANALYSIS THERE
12 OF WHAT IS IN EACH COUNTY. WHAT ARE WE MISSING?
13 WHERE DO WE HAVE INFRASTRUCTURE? CAN WE POTENTIALLY
14 BRING ACTUAL INFRASTRUCTURE TO A LOCATION? WHERE DO
15 WE KNOW THAT THAT'S POSSIBLE? SO WHAT CAN WE ELSE
16 BRING TO THAT?

17 AND I DO KNOW THAT -- AND I SEE ADRIENNE'S
18 HAND RAISED. SO DEFINITELY WHAT TO HEAR FROM
19 ADRIENNE. AND I KNOW THAT OTHER MEMBERS OF BOTH OUR
20 BOARD AND THIS WORKING GROUP ARE PARTS OF, NOT ONLY
21 COMMUNITY-BASED ORGANIZATIONS, BUT PATIENT SUPPORT
22 SERVICES THAT REALLY ALSO HAVE A WINDOW INTO HOW WE
23 CAN HELP IN THIS AREA. SO IT'S CERTAINLY NEVER
24 GOING TO BE PERFECT; BUT IF WE CAN MAKE SOME DENT IN
25 AND SOME EFFORTS TOWARDS BRINGING THESE SERVICES OR

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1 SERVICES THAT CAN HELP COMMUNITY MEMBERS ACCESS
2 THIS, I THINK WE'LL BE IN GREAT SHAPE.

3 SO I WANT TO DEFINITELY HEAR FROM
4 ADRIENNE. AND, MARGUERITE, IF YOU HAD ANYTHING YOU
5 WANTED TO ADD, WE'D LOVE TO HEAR FROM YOU AS WELL.
6 SO, ADRIENNE.

7 MS. SHAPIRO: HI. SO WE'VE BEEN REALLY
8 THINKING ABOUT THIS. AND WE'RE SORT OF SEEING WHERE
9 YOU SAID CREATE OUR OWN SORT OF COMMUNITY-BASED
10 ORGANIZATION. AND ONE OF THE THINGS THAT WE ARE
11 GOING TO PILOT HERE IS ARE SEVERAL SMALLER SICKLE
12 CELL ORGANIZATIONS, RIGHT, WHO COME TOGETHER AND
13 HAVE -- AS A BIG -- TO TALK ABOUT WHAT'S HAPPENING
14 IN TERMS OF GENE AND CELL THERAPY, HOW WE CAN
15 SUPPORT PEOPLE, AND HOW WE, I DON'T WANT TO SAY
16 TRICKLE DOWN THAT SUPPORT AND EDUCATION, BUT HOW WE
17 WORK TOGETHER.

18 THE OTHER THING WE'RE THINKING IS MAYBE
19 THE OPPORTUNITY HERE IS TO CREATE COMMUNITY-BASED
20 ORGANIZATIONS AROUND THE CONCEPT OF GENE THERAPY AND
21 REGENERATIVE MEDICINE CURES RATHER THAN US BEING
22 DIVIDED BY DISEASES, WHICH IS MOSTLY WHAT'S
23 HAPPENING NOW. WE'RE ALL DIVIDED BY WHATEVER RARE
24 DISEASE THAT WE ARE WORKING, BUT IT'S DEFINITELY ON
25 OUR MINDS. AND ALSO LOOKING AT, AGAIN, THE HUB AND

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1 SPOKE MODEL. AND I'LL BE REALLY INTERESTED IN
2 SEEING ONCE THEY GET THE LANDSCAPE DONE. RIGHT?

3 THE OTHER THING IS THAT WHAT WE'RE
4 LEARNING IS THERE'S -- ALTHOUGH WE'VE HAD TWO YEARS,
5 RIGHT, SINCE APPROVAL, THE UPDATE FOR THE ACTUAL
6 NUMBER OF PEOPLE ACTUALLY GOING THROUGH THE THERAPY
7 IS VERY LOW. AND PEOPLE IN THE BEGINNING WERE --
8 KIND OF THE MINDSET WAS THEY WERE ALL GOING TO BE
9 ALL 100,000 OF US IN THE COMMUNITY GOING FOR THIS.

10 SO I THINK WE NEED TO BE, I'M GOING TO
11 SAY, MINDFUL OF HOW LONG IT'S REALLY GOING TO TAKE
12 FOR US TO GET ENOUGH PEOPLE INTO IT IN ORDER TO BE
13 ABLE TO EVALUATE WHAT IT IS THAT WE'RE REALLY
14 PUTTING TOGETHER. I DON'T KNOW IF THAT MAKES SENSE.
15 BUT AT THIS POINT WE'VE GOT 12 PEOPLE IN ONE AREA,
16 ANOTHER WHERE WE HAVE CLOSE TO 30. SO THESE NUMBERS
17 ARE LOW.

18 VICE CHAIR BONNEVILLE: THANK YOU,
19 ADRIENNE. I THINK AS WE -- GEOFF LOMAX WILL BE
20 WORKING ON THIS RFA. AS HE STARTS TO DO THE
21 ANALYSIS AND WORKS WITH THE TEAM, THERE WILL
22 DEFINITELY BE OPPORTUNITIES TO WEIGH IN AND TO GIVE
23 US YOUR EXPERIENCE AND UNDERSTANDING OF HOW YOU ARE
24 DOING IT AND WHAT MAKES SENSE AND WHAT DOESN'T
25 BECAUSE WE DEFINITELY -- WE DON'T WANT TO REINVENT

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1 SOMETHING AND WE WANT TO WORK TOGETHER WITH OTHERS
2 SO THAT OUR EFFORTS GO FARTHER. I THINK THAT JUST
3 MAKES THE MOST SENSE. SO THANK YOU FOR THAT.

4 MS. SHAPIRO: AND THEN ONE OTHER THING IS
5 WE ALSO ARE REALLY NOT SURPRISED, BUT THE ACTUAL
6 LENGTH OF TIME BETWEEN ACTUALLY ENTERING THE PROCESS
7 AND THEN GOING THROUGH, WE'RE LOOKING AT 18 MONTHS.

8 VICE CHAIR BONNEVILLE: SURE.

9 MS. SHAPIRO: AGAIN, JUST TO BE AWARE AT
10 LEAST OF WHAT IS HAPPENING RIGHT NOW. WE HOPE THAT
11 CHANGES, BUT IT'S A LONG, VERY LONG PROCESS EVEN
12 WHERE YOU'RE GETTING IN TO GET THE THINGS THAT YOU
13 NEED.

14 VICE CHAIR BONNEVILLE: THANK YOU. I
15 APPRECIATE THAT. MARGUERITE.

16 MS. CASILLAS: HEY, MARIA. THANK YOU SO
17 MUCH FOR INVITING ME TO SPEAK. AND I WANT TO
18 ACKNOWLEDGE THAT I'M VERY NEW TO THE BOARD, AND THIS
19 IS THE FIRST MEETING I'M AT, AND I'M NOT A MEMBER OF
20 THE TEAM. IT'S A TOPIC THAT I'M VERY INTERESTED IN.
21 THIS KIND OF ALIGNS WITH MY ADVOCACY WORK.

22 AND SO I MORE HAD A QUESTION, AND IT MIGHT
23 BE KIND OF RELATED TO WHAT ADRIENNE WAS JUST TALKING
24 ABOUT. IS THERE CONSIDERATION OF WHAT WE MIGHT NEED
25 TO DO TO HELP PEOPLE UNDERSTAND THE VALUE OF

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1 PARTICIPATING IN CLINICAL TRIALS? THE EDUCATION
2 THAT THEY MIGHT NEED AND THE UNDERSTANDING OF WHAT
3 HARMS HAVE BEEN DONE IN THE PAST, FRANKLY, WITH SOME
4 MARGINALIZED COMMUNITIES. AND THAT JUST STILL SEEMS
5 TO ME TO BE WEIRD. WE'RE ALL HERE BECAUSE WE
6 BELIEVE IN THE SCIENCE AND WE'RE EXCITED ABOUT IT,
7 BUT I THINK SOME PEOPLE ARE STILL VERY WARY ABOUT
8 SCIENCE IN GENERAL AND CLINICAL TRIALS. SO THAT WAS
9 JUST A QUESTION I HAD.

10 VICE CHAIR BONNEVILLE: THAT DOES COME UP
11 IN CONVERSATION A LOT. AND I WAS GOING TO HAVE
12 GEOFF ANSWER THAT QUESTION.

13 DR. LOMAX: SO AS A LEAD-UP TO THE
14 COMMUNITY CARE CENTERS OF EXCELLENCE RFA, WE DID
15 SPEND QUITE A BIT OF TIME IN LISTENING SESSIONS.
16 THREE OF THEM THROUGHOUT REGIONS THAT WERE SORT OF
17 DESERT, CENTRAL VALLEY. THE TRUST THEME, WHICH YOU
18 RAISE, IS ONE THAT WAS PREDOMINANT IN EVERY SESSION.
19 SO IT WAS CONSISTENT THROUGHOUT THOSE SETS OF
20 CONVERSATIONS.

21 I THINK WHERE THE AUDIENCE, AND THE
22 AUDIENCE INCLUDED -- EACH OF THE SESSIONS HAD
23 COMMUNITY HEALTH WORKERS AND A NUMBER OF
24 PARTICIPANTS WHO HAD VERY INTIMATE TOUCHPOINTS WITH
25 THESE COMMUNITIES. SO THEY WERE REALLY VALUABLE, I

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1 WON'T QUITE SAY AMBASSADORS, BUT THEY WERE VALUABLE
2 IN THE CONTEXT OF A LISTENING SESSION.

3 I THINK THE POINT THAT IS PARTICULARLY
4 IMPORTANT TO EMPHASIZE IN TERMS OF CIRM'S PORTFOLIO
5 AND CIRM'S EFFORT IS THAT WE TEND TO BE SUPPORTING
6 TREATMENTS FOR WHICH THERE IS LITTLE OR NO
7 ALTERNATIVE AT THIS TIME. I THINK THAT POINT IS
8 PARTICULARLY IMPORTANT BECAUSE NOT ALL CLINICAL
9 TRIALS ARE CREATED EQUAL. AND THERE ARE STILL
10 CLINICAL TRIALS OUT THERE THAT ONE WOULD SAY ARE
11 MAYBE POTENTIALLY MARGINAL OR MAYBE YOU HAVE
12 QUESTIONS ABOUT. BUT WHEN WE GOT INTO THE
13 DISCUSSION ABOUT THE TYPES OF DISEASES WE TREAT, HOW
14 THEY CAN OFTEN BE CONDITIONS FOR WHICH THERE ARE
15 LITTLE OR NO OTHER OPTIONS, THAT SEEMED TO AT SOME
16 LEVEL BE PERSUASIVE OR COMFORTING IN THAT CONTEXT.
17 BUT AS YOU'VE INDICATED, THERE'S STILL AN
18 EDUCATIONAL PROCESS TO LEAD SOMEONE UP TO THAT POINT
19 TO BRING FORWARD THAT UNDERSTANDING.

20 SO I THINK WE'VE HEARD THAT. WE'VE SORT
21 OF THOUGHT ABOUT IT IN RELATION TO WHAT WE FUND.
22 AND I THINK THAT'S GOT TO BE SOMETHING THAT'S
23 INCORPORATED THROUGH THE COMMUNITY CARE PROGRAM. I
24 THINK IT'S THERE IN TERMS OF WHAT THE APPLICANTS
25 HAVE PROPOSED. SO WE'VE GOT A STARTING POINT AT

1 LEAST.

2 MS. SHAPIRO: I JUST WANT TO STEP IN AND
3 SAY THAT WE'VE REALLY BEEN LOOKING AT IT BECAUSE, OF
4 COURSE, THE SLOW UPTAKE FOR US WAS REALLY
5 SURPRISING. AND ONE OF THE KEY ISSUES ALSO COMES IN
6 IN PROVIDER TRAINING. SO AS A PATIENT, YOU CAN GO
7 OUT AND LOOK UP A TRIAL, RIGHT, BUT MANY, MANY
8 PATIENTS, THAT PERSON THAT THEY'RE REALLY DEPENDING
9 ON TO HELP THEM OR LET THEM KNOW ABOUT THINGS ARE
10 THEIR PROVIDERS.

11 AND SO WE'RE FINDING THE LACK OF, LET'S
12 SEE, NOT PROMOTION, BUT I'M GOING TO SAY EVEN
13 EDUCATION IN THE PROVIDER SPACE ABOUT WHAT THE
14 TRIALS ARE. THE POTENTIAL FOR THE TRIALS AND THE
15 SAFETY AND ALL OF THOSE THINGS, I THINK WE REALLY
16 NEED TO DO A BETTER JOB OF THAT. IT'S ONE THING FOR
17 ME AS A PARENT OR A PERSON LIVING WITH THE DISEASE
18 OF SAYING, OH, I'M GOING TO GO FIND OUT. I'M
19 DESPERATE. IT'S ANOTHER THING OF HAVING MY DOCTORS
20 OR PROVIDERS SAY TO ME, OH, BE A PROPONENT OF
21 CLINICAL TRIALS.

22 SO I WOULD LIKE TO SEE US -- MAYBE WE CAN
23 TALK ABOUT IT LATER OR AT SOME OTHER POINT, BUT WE
24 REALLY NEED TO DO, I THINK, MORE IN TERMS OF
25 PROVIDER EDUCATION.

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1 VICE CHAIR BONNEVILLE: THANK YOU,
2 ADRIENNE. DEFINITELY I THINK THAT'S SOMETHING GEOFF
3 IS LOOKING AT AND WOULD DEFINITELY BENEFIT FROM
4 HEARING MORE FROM YOU. SO THANK YOU.

5 AMMAR.

6 DR. QADAN: THANK YOU. IT'S NOT A
7 QUESTION, BUT A QUICK COMMENT TO THANK THE TEAM ON
8 THIS VERY COMPREHENSIVE STRATEGY. I COULD NOT THINK
9 OF A BETTER USE OF THE TAXPAYER MONEY IN THE STATE
10 OF CALIFORNIA. IT'S VERY ROBUST. AND AS I SAID
11 BEFORE, I'LL BE MORE THAN HAPPY TO HELP IN ANY WAY
12 OR SHAPE BEYOND JUST THIS MEETING. BUT IT'S REALLY
13 AMAZING TO SEE THE FOCUS ON CLINICAL ASPECTS, ON
14 POLICY ASPECTS, AND THEN ON FINANCIAL ASPECTS. SO
15 THANKS A LOT AND KUDOS TO THE TEAM FOR THIS WORK.
16 THANK YOU.

17 VICE CHAIR BONNEVILLE: THANK YOU VERY
18 MUCH. I AGREE COMPLETELY. I THINK THE TEAM PUT A
19 LOT OF HARD WORK INTO THIS AND REALLY TOOK THE TIME
20 TO JUST EVALUATE OUR OWN EXISTING PROGRAMS AND WHAT
21 NEEDED TO CHANGE, WHAT NEEDED TO BE INCLUDED, AND
22 HOW WE WERE GOING TO BRING ALL OF IT TOGETHER. SO
23 THANK YOU TO THE TEAM.

24 AND THIS IS ALSO JUST A REMINDER. THIS IS
25 A LIVING DOCUMENT. THERE ARE THINGS IN THE -- THERE

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1 ARE ASPECTS OF THE STRATEGY THAT MAY OR MAY NOT
2 WORK. WE MAY NEED TO COURSE CORRECT. AND I THINK
3 IT'S IMPORTANT THAT WE ALL KNOW THAT THIS IS SORT OF
4 UNCHARTERED TERRITORY INSOFAR AS BRINGING ALL THESE
5 THINGS TOGETHER, ESPECIALLY FOR CIRM. SO I
6 APPRECIATE THE EFFORT THAT EVERYONE HAS MADE.

7 ARE THERE ANY OTHER COMMENTS OR QUESTIONS
8 FROM THE BOARD OR THE WORKING GROUP? ARE THERE ANY
9 PUBLIC COMMENTS?

10 MR. MALIK: I DON'T BELIEVE SO.

11 VICE CHAIR BONNEVILLE: SO WHAT I WOULD
12 LIKE TO DO IS ASK FOR A MOTION THAT THE AAWG
13 RECOMMEND THE DRAFT ACCESS AND AFFORDABILITY
14 STRATEGY FOR CONSIDERATION TO THE ICOC.

15 DR. BARRETT: SO MOVED.

16 DR. PADILLA: SECOND.

17 VICE CHAIR BONNEVILLE: THANK YOU, KIM.
18 THANK YOU, ADRIANA. I'LL ASK FOR ANY OTHER PUBLIC
19 COMMENT? THEN, CAMERON, CAN YOU CALL THE ROLL FOR
20 THE VOTE.

21 MR. MALIK: ABSOLUTELY.

22 MARIA BONNEVILLE.

23 VICE CHAIR BONNEVILLE: YES.

24 MR. MALIK: VITO IMBASCIANI.

25 CHAIRMAN IMBASCIANI: YES.

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1 MR. MALIK: ADRIANA PADILLA.
2 DR. PADILLA: YES.
3 MR. MALIK: TED GOLDSTEIN. NOT HERE.
4 AMMAR QADAN.
5 DR. QADAN: YES.
6 MR. MALIK: THANK YOU. JAMES DEBENEDETTI.
7 MR. DEBENEDETTI: YES.
8 MR. MALIK: MAHESWARI. NOT HERE.
9 ADRIENNE SHAPIRO.
10 MS. SHAPIRO: YES.
11 MR. MALIK: HARLAN LEVINE. NOT HERE. PAT
12 LEVITT. NOT HERE. DARIUS LAKDAWALLA.
13 DR. LAKDAWALLA: YES.
14 MR. MALIK: THANK YOU. CHRISTINA HARTMAN.
15 NOT HERE. KIM BARRETT.
16 DR. BARRETT: AYE.
17 MR. MALIK: THANK YOU. LIZ BOILEAU.
18 MS. BOILEAU: YES.
19 MR. MALIK: THANK YOU. AND YAEL WYTE.
20 MS. WYTE: YES.
21 MR. MALIK: THANK YOU VERY MUCH.
22 VICE CHAIR BONNEVILLE: THANK YOU SO MUCH.
23 SO THE NEXT ITEM ON OUR AGENDA IS AN
24 UPDATE ON OUR PATIENT SUPPORT PROGRAM. NIMIT, WHEN
25 YOU ARE READY TO START, PLEASE FEEL FREE.

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1 MR. RUPAREL: GOOD AFTERNOON. AND THANK
2 YOU, MADAM CHAIR AND ACCESS AND AFFORDABILITY
3 WORKING GROUP MEMBERS, FOR THE OPPORTUNITY TO SHARE
4 THIS UPDATE ON THE PROGRESS OF THE PATIENT SUPPORT
5 PROGRAM.

6 MY NAME IS NIMIT RUPAREL. I AM THE
7 PROGRAM MANAGER FOR THE PSP. WE LAST PROVIDED AN
8 UPDATE DO THIS GROUP ABOUT THIS INITIATIVE BACK IN
9 FEBRUARY OF LAST YEAR. SO I'M EXCITED TO SHARE
10 THESE UPDATES ON THE PROGRESS WE'VE MADE WITH THE
11 PROGRAM.

12 BEFORE I BEGIN, I ALSO WANT TO THANK MY
13 CIRM COLLEAGUES AND PATIENT ACCESS, GRANTS
14 MANAGEMENT, FINANCE, AND LEGAL WHO HAVE BEEN KEY
15 PARTNERS IN INFORMING PROGRAM MANAGEMENT AND
16 IMPLEMENTATION OVER MY FIRST FIVE MONTHS HERE AT
17 CIRM.

18 SO THE GOALS OF MY PRESENTATION TODAY ARE
19 TO PROVIDE AN UPDATE ON THE STATUS OF THE PSP AND
20 WHAT WE'VE LEARNED FROM THE PROGRAM TO DATE AS WELL
21 AS ANSWER ANY QUESTIONS ABOUT THE PROGRAM.

22 I'M ALSO HOPING TO GATHER AAWG FEEDBACK IN
23 PREPARATION FOR A SIMILAR PRESENTATION TO THE CIRM
24 BOARD IN DECEMBER.

25 SO TODAY WE'RE GOING TO COVER A LITTLE BIT

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1 OF BACKGROUND AROUND THE PSP AND THEN DIVE INTO
2 PROGRAM IMPLEMENTATION TIMELINE, REVIEW OUR CURRENT
3 STATUS AND LEARNINGS FROM OUR PILOTS, AND THEN TALK
4 ABOUT WHERE WE'RE GOING NEXT WITH THE PROGRAM.

5 SO AS A QUICK REMINDER, THE PSP WAS
6 DEVELOPED AS A WAY TO EFFICIENTLY DISTRIBUTE FUNDS
7 FROM THE PATIENT ASSISTANCE FUND PER PROPOSITION 14,
8 WHICH STATES THAT ROYALTIES THAT ACCRUE TO CIRM FROM
9 FUNDED RESEARCH SHOULD BE DEPOSITED INTO A PATIENT
10 ASSISTANCE FUND THAT SHOULD BE USED TO REIMBURSE
11 RESEARCH PARTICIPANTS FOR QUALIFIED COSTS. AND IN
12 PROPOSITION 14 THIS WAS FURTHER DEFINED TO INCLUDE
13 THINGS LIKE TRAVEL, ASSOCIATED LODGING, CHILDCARE,
14 MEALS, AND OTHER EXPENSES THAT ARE INCURRED BY
15 PATIENTS AS A RESULT OF PARTICIPATING IN FUNDED
16 TRIALS.

17 THE PSP IS ALSO TIED INTO CIRM'S STRATEGIC
18 ALLOCATION FRAMEWORK, SAF, GOAL NO. 5, WHICH RELATES
19 TO STRENGTHENING OUR CLINICAL INFRASTRUCTURE
20 CONNECTIVITY TO ENSURE ENHANCED REFERRALS,
21 ENROLLMENT, AND RETENTION OF CALIFORNIA PATIENTS IN
22 CLINICAL TRIALS.

23 SO AS A QUICK REMINDER ON THE FUNDING
24 SOURCES FOR THIS PROGRAM, AS I MENTIONED EARLIER,
25 THE PATIENT ASSISTANCE FUND CREATED BY PROP 14 IS A

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1 DEDICATED FUND SET ASIDE FOR USE BY ELIGIBLE
2 CALIFORNIA RESIDENTS ENROLLED IN CIRM-FUNDED TRIALS.
3 AND IT CURRENTLY HAS ABOUT \$15.6 MILLION IN IT.

4 THE PSP ITSELF IS FUNDED BY A SEPARATE
5 \$2.5 MILLION WHICH WAS ISSUED AS AN INFRASTRUCTURE
6 AWARD FOR PROGRAM DESIGN, PLANNING, AND OPERATIONAL
7 EXPENSES SUPPORTED BY CIRM'S ACCESS AND
8 AFFORDABILITY BUDGET. AND THIS GRANT WAS ISSUED TO
9 ENSURE THAT A MECHANISM WAS CREATED TO DISTRIBUTE
10 FUNDS FROM THE PAF TO DIRECTLY ADDRESS PATIENT
11 FINANCIAL AND LOGISTICAL BARRIERS TO BEING ABLE TO
12 STAY ON AND COMPLETE CLINICAL TRIALS.

13 AND SO THE KEY POINT HERE IS THAT THERE
14 ARE TWO SEPARATE FUNDING SOURCES THAT ARE RELATED TO
15 THE PSP, AND WE ARE MONITORING UTILIZATION OF BOTH
16 IN ADMINISTERING THE PROGRAM.

17 SO THE PSP AWARDEES ARE THE RECIPIENTS OF
18 THE \$2.5 MILLION GRANT THAT I MENTIONED ON THE
19 PREVIOUS SLIDE. IT WAS REQUIRED TO PERFORM FOUR
20 OPERATIONAL ACTIVITIES, PRIMARY OPERATIONAL
21 ACTIVITIES. THE FIRST IS PATIENT INTAKE AND
22 NAVIGATION THROUGH DEVELOPING A CALL CENTER. THE
23 SECOND IS ASSESSING ELIGIBILITY FOR ACCESS TO PSP
24 SUPPORT. THE THIRD IS DISTRIBUTING PAYMENTS FOR
25 ELIGIBLE EXPENSES. AND THE FOURTH IS COORDINATING

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1 WITH CIRM AND TRIAL SITES TO MAINTAIN ACCOUNTING AND
2 ASSURANCE OF NONDUPLICATION OF PERMITTED COSTS.

3 AND SO THIS SLIDE PROVIDES AN OVERVIEW OF
4 THE TYPES OF SUPPORT THAT THE PSP OFFERS AS WELL AS
5 THE LIMITS WE APPLIED IN OUR BUSINESS RULES AROUND
6 HOW MUCH WE ALLOW FOR EACH OF THESE DIFFERENT
7 SUPPORT SERVICE TYPES.

8 AS ROSA MENTIONED EARLIER AND IN THE RFA,
9 OTHER SERVICE TYPES SUCH AS CHILDCARE WERE ALSO
10 DISCUSSED AS SUPPORT SERVICES THAT CAN BE PROVIDED
11 IN THIS PROGRAM. THAT'S SOMETHING THAT WE ARE
12 WORKING WITH OUR VENDORS TO ASSESS FEASIBILITY FOR
13 IN THE FUTURE. BUT FOR THE PILOT AND FOR THIS
14 UPDATE, THESE ARE THE FOUR SERVICE TYPES THAT WE'RE
15 ASSESSING.

16 ALSO I WANT TO ACKNOWLEDGE THAT WE'VE
17 IMPLEMENTED A PROCESS TO REVIEW EXCEPTIONS WHERE A
18 PATIENT MAY REQUEST ADDITIONAL FUNDS BEYOND WHAT'S
19 LISTED HERE ON A CASE-BY-CASE BASIS. AND THAT'S TO
20 MAKE SURE THAT THE PROGRAM IS REMAINING FLEXIBLE TO
21 PATIENTS.

22 SO JUST A REMINDER ABOUT THE PSP TIMELINE,
23 THIS PROGRAM HAS BEEN DISCUSSED FOR SEVERAL YEARS.
24 AND SO THE AAWG WAS CONVENED BACK IN 2022 TO
25 DETERMINE THE PROGRAM MECHANISM AND SCOPE. THE CIRM

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1 BOARD APPROVED THE CONCEPT PLAN INCLUDING THE \$2.5
2 MILLION ALLOCATION IN MARCH OF 2023. IN JUNE OF
3 2023, WE RELEASED THE RFA FOR THE PROGRAM. AND THEN
4 IN MARCH OF 2024, EVERSANA WAS SELECTED AS THE
5 VENDOR TO ADMINISTER THE PSP.

6 LATE LAST YEAR WE LAUNCHED A PILOT FOR THE
7 PROGRAM AT THREE OF OUR ALPHA CLINIC SITES WITH A
8 GOAL OF COMPLETING A FIVE-PATIENT ENROLLMENT PILOT
9 PHASE. AND THEN IN THE SUMMER OF THIS YEAR, WE DID
10 ENROLL OUR FIFTH PATIENT, AND I WAS HIRED AS PROGRAM
11 MANAGER TO MANAGE THE DAY-TO-DAY OPERATIONS OF THE
12 PROGRAM.

13 SO I MENTIONED THAT WE LAUNCHED AN INITIAL
14 PILOT. AND I'D LIKE TO REVIEW SOME OF WHAT WE HAVE
15 ACHIEVED SO FAR FROM THE PILOT HERE. SO BEAR IN
16 MIND THAT THIS PILOT WAS OVER A LIMITED SAMPLE SIZE.
17 IT WAS ONLY THREE CLINICAL TRIAL SITES AND INCLUDED
18 A SMALL PATIENT POPULATION OF FIVE.

19 BUT THE FIRST FINDING WAS THAT THE PROGRAM
20 WAS WELL RECEIVED BY PARTICIPATING ALPHA CLINICS AND
21 PATIENTS, IN PARTICULAR BECAUSE OF THE SMOOTH
22 ENROLLMENT PROCESS THROUGH TEXT AND EMAIL, WHICH
23 ALLOWS FOR EFFICIENT COMMUNICATION WITH PATIENTS.
24 OUR AGENTS ALSO MAINTAIN COMMUNICATION WITH THE
25 PATIENT TO CONFIRM THEIR UPCOMING STUDY VISITS,

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1 CHECK IN WITH THEM AFTER THEIR VISIT TO MAKE SURE
2 EVERYTHING WORKED SMOOTHLY FOR THEM IN ACCESSING
3 SUPPORT.

4 PATIENTS IN TRIAL SITES HAVE ALSO NOTED
5 THAT THEY APPRECIATE THE USE OF PREPAID DEBIT CARDS
6 IN OUR PROGRAM WHICH INCREASES ACCESSIBILITY. IT
7 ALSO REDUCES ADMINISTRATIVE BURDEN ON THE PATIENTS.
8 SO, FOR EXAMPLE, THERE HAVE BEEN CASES WHERE A
9 PATIENT HAS APPEARED ON-SITE. THEY WERE ENROLLED IN
10 THE TRIAL, BUT MAYBE WEREN'T GETTING ENROLLED IN THE
11 PSP, AND THEY WERE ABLE TO BE ENROLLED IN THE PSP,
12 ACCESS TO THEIR CARD ONE SITE, AND THEY WERE ABLE TO
13 BEGIN ACCESSING SUPPORT IMMEDIATELY, WHICH IS
14 SOMETHING THAT WOULDN'T HAVE BEEN POSSIBLE IN THE
15 REIMBURSEMENT SYSTEM.

16 AND THEN FINALLY THE PLATFORM HAS BEEN
17 SHOWN TO BE ADAPTABLE TO EMERGING NEEDS. SO, FOR
18 EXAMPLE, WHEN WE FIRST LAUNCHED, THE PROGRAM DIDN'T
19 HAVE THE ABILITY TO PROVIDE SUPPORT FOR GROUND
20 TRANSPORTATION, THINGS LIKE UBERS, THINGS LIKE CAR
21 SERVICE. AND THIS WAS IDENTIFIED AS A NEED BY OUR
22 CLINICAL TRIAL SITE PARTNERS, AND WE WERE ABLE TO
23 ADD IT ON THE FLY.

24 AND SO ALL OF THESE ARE NOTABLE SUCCESSES
25 THROUGH THE PILOT. WE ALSO IDENTIFIED SOME

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1 CHALLENGES WITH THE PROGRAM, WHICH I WANT TO COVER
2 ON THE NEXT SLIDE.

3 SO THE PILOT SURFACED A FEW KEY AREAS THAT
4 WE'VE BEEN FOCUSED ON IMPROVING WITH THE PROGRAM.
5 THE FIRST IS THE REPORTING. SO WE'VE IDENTIFIED
6 WAYS TO MAKE OUR REPORTING MORE COMPREHENSIVE AND
7 CLEAR IN TERMS OF TRACKING THE CATEGORIES OF
8 SPENDING THAT PATIENTS HAVE UTILIZED. AND THIS HAS
9 LED TO CHANGES THAT EVERSANA HAS ALREADY
10 IMPLEMENTED. AND I THINK THIS IS REALLY IMPORTANT
11 BECAUSE, AS I MENTIONED EARLIER, WE'RE TRACKING THE
12 TWO DIFFERENT FUNDING SOURCES IN IMPLEMENTING THE
13 PROGRAM. AND SO THIS ENHANCED REPORTING IS ALLOWING
14 US TO ENSURE COMPLIANT USAGE OF THE PATIENT
15 ASSISTANCE FUND.

16 SECOND, ALSO, ALTHOUGH USING DEBIT CARDS
17 DOES LEAD TO PROGRAM FLEXIBILITY, IT REQUIRES THAT
18 WE HAVE A VERY STRONG, ALLOWABLE MERCHANT CODE
19 SYSTEM IN PLACE TO ENSURE COMPLIANT USE OF FUNDS.
20 SO WE WORKED REALLY HARD DURING THE PILOT ON
21 REFINING THE ALLOWABLE MERCHANT CODES IN THE SYSTEM
22 TO REVIEW ALL OF THE CATEGORIES OFFERED BY OUR DEBIT
23 CARD VENDOR AND ALIGNING OUR SYSTEM WITH CATEGORIES
24 AS TYPICALLY SEEN CLINICAL TRIALS. AND THEN WE'VE
25 ALSO IMPLEMENTED SOME PROCESSES WHERE BOTH EVERSANA

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1 AND MYSELF WILL REGULARLY REVIEW TRANSACTIONS TO
2 ENSURE COMPLIANT USE OF THE PROGRAM.

3 THE THIRD KIND OF IMPROVEMENT AREA IS THAT
4 WE'VE IDENTIFIED THAT INCREASING KNOWLEDGE ABOUT THE
5 PROGRAM AMONG CLIN2 AWARDEES WILL HELP WITH
6 EXPANDING ENROLLMENT. SO I HAVE SPENT TIME DOING
7 ONBOARDING CALLS WITH OUR ALPHA CLINIC PARTNERS SO
8 THEY CAN MARKET PSP TO STUDY TEAMS AT THEIR SITE.
9 I'VE ALSO BEEN MEETING WITH THE STUDY COORDINATORS
10 FOR EACH OF THE TRIALS THAT ARE PARTICIPATING IN THE
11 PSP SO I CAN BUILD RELATIONSHIPS WITH THE STUDY
12 TEAMS, IDENTIFY AREAS FOR PROGRAM IMPROVEMENT, AND
13 EVALUATE THE INTERACTION BETWEEN THE STUDY TEAM AND
14 OUR VENDOR EVERSANA TO MAKE SURE THAT IF THERE'S
15 ANYTHING THAT WE CAN IMPROVE IN COMMUNICATION, WE'RE
16 ABLE TO DO THAT USING THAT.

17 FOURTH, THE PROGRAM AND ITS ENROLLMENT AND
18 USAGE HAS TRIGGERED ADDITIONAL ELIGIBILITY AND
19 COMPLIANCE QUESTIONS THAT REQUIRE -- THAT'S IN OUR
20 BUSINESS RULES. SO THESE ARE QUESTIONS LIKE WHEN
21 CAN A PATIENT BE CONSIDERED A CALIFORNIA RESIDENT
22 FOR PURPOSES OF PSP ELIGIBILITY? OR WOULD WE
23 SUPPORT A PATIENT WHO INITIALLY RESIDED IN
24 CALIFORNIA BUT MOVED OUTSIDE OF CALIFORNIA? AND SO
25 TO ANSWER THOSE QUESTIONS, WE'VE ENGAGED CIRM'S

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1 LEGAL AND FINANCE TEAMS ON AN ONGOING BASIS. AND
2 THEN WE REVISE OUR BUSINESS RULES BASED ON THOSE
3 DECISIONS.

4 FINALLY, THERE IS AN OPPORTUNITY, I THINK,
5 TO PROVIDE -- TO HAVE PSP DO ENHANCED CLINICAL TRIAL
6 REFERRALS. SO CURRENTLY EVERSANA IS CAPABLE OF
7 TAKING IN REFERRAL CALLS, AND THEY DO HANDLE BETWEEN
8 25 TO 30 OF THESE CALLS PER MONTH. THEIR ABILITY TO
9 DIRECT PATIENTS TO POTENTIAL TRIALS UP TO THIS POINT
10 HAS BEEN SOMEWHAT LIMITED. SO THIS MONTH CIRM STAFF
11 IS WORKING ON ROLLING OUT A NEW CLINICAL TRIAL
12 DASHBOARD WHICH WE WILL HOPEFULLY -- WHICH WE HOPE
13 TO INTEGRATE INTO EVERSANA'S CALL CENTER AND ENHANCE
14 THIS NAVIGATION FUNCTION. STAFF SUPPORT WILL BE
15 AVAILABLE ON THE CIRM PUBLIC WEBSITE AS WELL.

16 SO OUR INITIAL PILOT PHASE FOR THE PSP WAS
17 LAUNCHED IN NOVEMBER OF 2024 AND RAN THROUGH JUNE OF
18 THIS YEAR. AND AS PART OF THAT PILOT, WE DEVELOPED
19 AN OPERATING MODEL FOR THE PROGRAM, PUT IN CALL
20 CENTER SCRIPTING, AND BUSINESS RULES. WE CONTRACTED
21 WITH OUR VENDORS FOR TRAVEL AND FOR DEBIT CARD
22 IMPLEMENTATION, SIGNED OUR FISCAL AGREEMENT. WE
23 LAUNCHED INITIALLY AT A SELECT SET OF ALPHA CLINIC
24 SITES AND THEN WE EXPANDED THE PROGRAM TO PROVIDE
25 SUPPORT FOR SCREENING. THAT'S SOMETHING THAT WE

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1 HEARD FROM TALKING TO CLIN2 AWARDEES AND TO ALPHA
2 CLINIC PARTNERS. AND THEN WE -- BY AT THE END OF
3 THE INITIAL PILOT, WE EXPANDED THE PROGRAM TO ALL
4 EIGHT ALPHA CLINICS AND ALL CLIN2 AWARD SITES AND WE
5 ENROLLED OUR FIFTH PATIENT.

6 AND IN COMPLETING THIS INITIAL PILOT
7 PHASE, WE WERE ONLY ABLE TO ENROLL AN OVERALL
8 PATIENT VOLUME OF FIVE PATIENTS, WHICH WE FELT WOULD
9 GIVE US SOME ANSWERS ON HOW TO SHAPE THE PROGRAM
10 MOVING FORWARD. EVEN WITH THE SMALL NUMBER OF
11 PATIENTS WE ENROLLED, WE IDENTIFIED A BUNCH OF
12 ISSUES AND OPEN QUESTIONS THAT NEEDED TO BE
13 ADDRESSED TO STRENGTHEN OUR PROGRAM RULES AND GIVE
14 US A BETTER SENSE OF COST AND UTILIZATION. AND SO
15 THIS LED US TO THE CONCLUSION THAT WE NEEDED TO
16 EXTEND THE PILOT, GATHER MORE DATA, AND USE THESE
17 CASES TO DEVELOP STRONGER BUSINESS RULES.

18 SO IN JULY WE DECIDED TO RUN THE PILOT FOR
19 AN ADDITIONAL SIX MONTHS TO GIVE US SOME TIME TO DO
20 SOME OF THAT TARGETED MARKETING TO THE ALPHA
21 CLINICS, TO THE CLIN2S TO INCREASE ENROLLMENT,
22 ACCRUE MORE USAGE OF THE PROGRAM, STRENGTHEN OUR
23 PROGRAM REPORTING AND CLINICAL TRIAL NAVIGATION
24 CAPABILITIES, AND HAVE EVERSANA IMPLEMENT THE
25 REQUESTED REPORTING CHANGES AND ALSO SOME PROCESS

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1 IMPROVEMENTS. SO, FOR EXAMPLE, THEY HAVE LAUNCHED
2 AN EMAIL INBOX SO THAT THEY CAN MORE EFFICIENTLY
3 COMMUNICATE WITH TRIAL SITES AND WITH THE PATIENTS,
4 WHICH I THINK HAS BEEN REALLY WELL RECEIVED BY OUR
5 TRIAL SITE PARTNERS.

6 SO THE GOAL OF THIS EXPANDED PILOT WAS TO
7 INCREASE OVERALL ENROLLMENT, GATHER MORE DATA ON
8 COST AND UTILIZATION, AND STRENGTHEN OVERALL PROGRAM
9 INTEGRITY, AND ENHANCE OUR BUSINESS RULES AND
10 REPORTING. AND SO FAR WE HAVE ACCRUED MORE
11 ENROLLMENT. SO THIS EXTENSION APPEARS TO BE
12 WORKING. WE NOW HAVE ABOUT 15 PATIENTS AND
13 COUNTING, AND THIS INCREASED UTILIZATION OF THE
14 PROGRAM HAS ALLOWED US TO STRENGTHEN OUR BUSINESS
15 RULES IN A WAY THAT ENSURES THAT THE PROGRAM IS
16 OPERATING IN AN EFFICIENT AND COMPLIANT WAY MOVING
17 INTO THE FUTURE.

18 MR. MALIK: ADRIENNE HAS HER --

19 MS. SHAPIRO: SO I JUST WANT TO -- LOOKING
20 AT COMPLIANCE AND THINGS. SO ARE THE ENROLLEES
21 RESPONSIBLE FOR PAYING TAXES AND REPORTING THE FUNDS
22 THAT THEY ARE ALLOCATED THROUGH THE PROGRAM?

23 MR. RUPAREL: NO. THE WAY THAT THE SYSTEM
24 IS SET UP, BECAUSE IT'S A DEBIT CARD SYSTEM AND WE
25 HAVE -- WE HAVE ACCESS TO ALL THE TRANSACTIONS. SO

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1 THE PATIENT DOESN'T ACTUALLY NEED TO REPORT IT TO
2 US. WE'RE COLLECTING IT BECAUSE WHEN THEY USE THEIR
3 VIRTUAL DEBIT CARD, THOSE TRANSACTIONS ARE ALL
4 REPORTED TO US. SO WE CAN TRACK WHAT'S BEING SPENT
5 AND WHAT CATEGORIES.

6 MS. SHAPIRO: THAT WASN'T THE QUESTION.
7 I'M SORRY. ARE THE ENROLLEES TAXED ON THE BENEFITS
8 THAT THEY RECEIVE? AND DOES IT GO INTO THEIR -- IS
9 IT CONSIDERED PART OF THEIR INCOME STREAM? AND IF
10 SO, DO WE HAVE ANY RESPONSIBILITY IN HANDLING THAT?

11 DR. LOMAX: ADRIENNE, WHEN THE ENROLLEE
12 RECEIVES AN AMOUNT FROM THE PROGRAM BEYOND A
13 THRESHOLD -- I DON'T KNOW OFF THE TOP OF MY HEAD
14 WHAT THAT THRESHOLD IS -- SOMEWHERE ON THE ORDER OF
15 \$700 IS COMING TO MIND. AND ALEX IS SHAKING HER
16 HEAD. SHE TENDS TO KNOW THESE THINGS FAR BETTER
17 THAN I DO. SO IN THAT RANGE. THEY WILL RECEIVE A
18 W-2 FROM THE PROGRAM. AND THEN IT IS THEN INCUMBENT
19 ON THE RECIPIENT OF THOSE SERVICES TO FILE IN
20 ACCORDANCE WITH THE IRS RULES.

21 MS. SHAPIRO: OKAY.

22 MR. RUPAREL: SORRY. I MISINTERPRETED.
23 THE 1099 FORM DOES GET ISSUED BY OUR VENDOR.

24 MS. SHAPIRO: OKAY.

25 MR. RUPAREL: SORRY ABOUT THAT. GO AHEAD.

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1 KIM, I THINK, HAS A QUESTION.

2 DR. BARRETT: JUST TO FOLLOW UP ON
3 ADRIENNE'S VERY IMPORTANT QUESTION. SO GIVEN THE
4 PATIENT POPULATION AND PERHAPS THESE PEOPLE WILL NOT
5 BE FILING A DETAILED TAX RETURN, WOULD THEY HAVE THE
6 OPPORTUNITY TO OFFSET THAT TAXABLE INCOME WITH THE
7 ACTUAL EXPENSES? AND HOW MUCH EDUCATION ARE YOU
8 GOING TO BE ABLE TO PROVIDE TO PEOPLE AS TO HOW TO
9 LIMIT THAT LIABILITY BECAUSE IT'S NOT MUCH OF A
10 BENEFIT IF THEY SUDDENLY GET A HUGE TAX BILL
11 ASSOCIATED WITH IT.

12 MS. SHAPIRO: OR IT PUTS THEM OVER A
13 CERTAIN AMOUNT OF LIMITS AND PUTS THEIR MONTHLY
14 SUPPORT SYSTEM IN JEOPARDY. SO I ACTUALLY THINK
15 \$700 ISN'T A LOT, BUT TO THE GOVERNMENT IT COULD
16 MEAN QUITE A BIT.

17 DR. LOMAX: YEAH. SO THE SHORT ANSWER IS
18 WE DO NOT HAVE A REMUNERATION POLICY FOR THE
19 PATIENT. NOW, KEEP IN MIND, THOUGH, ONLY A LIMITED
20 PORTION OF THE SERVICES PROVIDED UNDER THIS PROGRAM
21 ARE PROVIDED THROUGH THE DEBIT CARD. A NUMBER OF
22 THE SERVICES ARE PREPAID SERVICES SUCH AS LODGING
23 AND TRANSPORTATION. AND I AM -- I'M ACTUALLY
24 BLANKING ON -- I'M NOT SURE IF THOSE SERVICES COUNT
25 AS INCOME BECAUSE THEY'RE NOT COMING IN AS INCOME.

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1 THEIR SUPPORT IS PROVIDED AS PART OF BEING IN THE
2 TRIAL. I'LL STOP THERE BECAUSE I MAY NOT BE GETTING
3 THIS EXACTLY RIGHT, BUT MY UNDERSTANDING WAS THAT
4 THE TAX STATEMENT IS IN RELATION TO DEBIT CARD
5 FUNDING THAT THEY'VE BEEN PROVIDED, NOT THE ENTIRE
6 PACKAGE OF SERVICES. THAT'S THE POINT I'M TRYING TO
7 MAKE, BUT WE HAVE TO CLARIFY THAT.

8 VICE CHAIR BONNEVILLE: I THINK THAT'S
9 SOMETHING THAT WE CAN DEFINITELY LOOK INTO SO THAT
10 WE CAN HAVE THOSE ANSWERS TO THIS GROUP AS WELL AS
11 TO THE BOARD.

12 BUT TO SOMETHING THAT I THINK WAS BROUGHT
13 UP, I BELIEVE THAT THIS IS SOMETHING THAT WE NEED TO
14 ADDRESS. EVERSANA, AS AN EXPERT IN THESE SORTS OF
15 PROGRAMS, WOULD BE THE ONES TO SET ASIDE OR SET UP A
16 PROGRAM, WHETHER IT'S AN EDUCATION PROGRAM OR
17 OTHERWISE, SO THAT EVERYBODY UNDERSTANDS COMPLETELY
18 WHAT IT MEANS IF THEY ARE RECEIVING -- WHEN THEY
19 RECEIVE THE DEBIT CARDS OR WHEN THEY'RE RECEIVING
20 SERVICES AND WHAT THAT MEANS FOR THEIR FILINGS.

21 DR. BARRETT: I RATHER SUSPECT THAT,
22 UNLESS THIS IS RECONCILED WITH APPROPRIATE RECEIPTS,
23 EVEN IF IT'S A PREPAID SERVICE, IT WOULD STILL COUNT
24 AS TAXABLE INCOME. IF MY UNIVERSITY BOOKS A FLIGHT
25 FOR ME, I STILL HAVE TO COME BACK AND SHOW THAT I

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1 ACTUALLY TOOK THE FLIGHT. OTHERWISE IT GOES IN MY
2 TAXABLE INCOME.

3 VICE CHAIR BONNEVILLE: THANK YOU.
4 MARGUERITE.

5 MS. CASILLAS: I REALLY APPRECIATE THOSE
6 POINTS AND ESPECIALLY ABOUT THE POSSIBILITY OF
7 MAXIMIZING PEOPLE'S INCOME. THERE ARE SUCH LOW
8 LIMITS FOR SOME PEOPLE RECEIVING THOSE GOVERNMENT
9 SERVICES.

10 I'M ALSO JUST THINKING ABOUT THE OTHER
11 SIDE. JUST CURIOUS, AGAIN BECAUSE I'M NEW TO THIS.
12 APPRECIATE THE OPPORTUNITY TO LEARN ALL ABOUT THIS.
13 IS THERE ANYTHING GIVEN FOR PEOPLE'S, LIKE,
14 COMPENSATING FOR THEIR TIME, OR IS JUST STRICTLY
15 EXPENSES AT THIS POINT?

16 MR. RUPAREL: AT THIS POINT WE HAVE HEARD
17 FROM OUR TRIAL SITE PARTNERS ABOUT THINGS LIKE LOST
18 WAGES. AT THIS TIME WE'RE JUST PROVIDING SUPPORT
19 FOR THE FOUR CATEGORIES OF SERVICES THAT I COVERED
20 EARLIER.

21 THANK YOU FOR THIS FEEDBACK.

22 MS. SHAPIRO: JUST REAL QUICK. AND THIS
23 FUNDING IS FOR THE PATIENT ONLY, NOT THEIR CARE
24 PROVIDERS, THEIR PERSON, THEIR SUPPORT PERSON; IS
25 THAT CORRECT?

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1 MR. RUPAREL: NO. FOR LODGING AND FOR
2 NUTRITION, WE ALSO HAVE FUNDS FOR THE CAREGIVER AS
3 WELL.

4 MS. SHAPIRO: OKAY. THANK YOU.

5 MR. RUPAREL: BEFORE I FINISH, I WANT TO
6 PROVIDE A HIGH LEVEL OVERVIEW OF THE PSP
7 IMPLEMENTATION SCHEDULE FOR THE REMAINDER OF THE
8 AWARD. AND TODAY I COVERED WHAT WE WILL BE SEEING
9 BETWEEN NOW AND JUNE OF 2026 IN WHICH WE WILL
10 CONTINUE TO FOCUS ON INTEGRATING PSP INTO OUR
11 CLINICAL INFRASTRUCTURE, INCLUDING COORDINATING
12 REFERRALS TO THE PSP FROM ALPHA CLINICS, AND
13 DEVELOPING A REFERRAL INTAKE PROCESS WITH THE CCCE'S
14 WHICH WE WILL BE LAUNCHING HERE.

15 WE EXPECT A STEADY STATE FOR THE PROGRAM
16 WILL BE REACHED BY THE END OF NEXT YEAR, FOR YEARS
17 THREE AND FOUR OF OUR PSP AWARD, AND THEN BY YEAR
18 FIVE WE'LL BE ENGAGING IN A WIND-DOWN OR APPLICABLE
19 RAMPING UP OR EXTENDING FOR A NEW PHASE OF THE
20 PROGRAM.

21 AND THEN LASTLY, I WANT TO ACKNOWLEDGE THE
22 IMPORTANCE OF THE PATIENT JOURNEY AND HOW THIS
23 PROGRAM IS CENTRAL TO MAKING THAT JOURNEY AS SMOOTH
24 AS POSSIBLE. AND SO TO THAT END, OUR TEAM HAS BEEN
25 COLLABORATING WITH OUR COLLEAGUES IN COMMUNICATIONS

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1 TO COLLECT A CAREGIVER TESTIMONIAL REGARDING A
2 PARTICULAR PATIENT'S POSITIVE EXPERIENCE WITH THE
3 PSP. WE WERE UNABLE TO INTERVIEW THE CAREGIVER IN
4 ADVANCE OF THIS MEETING, BUT I'M HOPING THAT I'LL BE
5 ABLE TO HAVE THAT TESTIMONIAL COMPLETED IN TIME FOR
6 THE DECEMBER BOARD MEETING SO WE CAN SHARE THIS
7 FEEDBACK WITH THE FULL BOARD, ADD A LITTLE BIT MORE
8 ABOUT THE PATIENT EXPERIENCE TO THIS UPDATE. SO
9 STAY TUNED FOR THAT.

10 SO THANK YOU SO MUCH FOR THE OPPORTUNITY
11 TO SHARE THIS UPDATE. I'M HAPPY TO TAKE ANY
12 QUESTIONS FROM THE GROUP.

13 VICE CHAIR BONNEVILLE: DOES ANYONE HAVE
14 ANY QUESTIONS? I THINK AS A FOLLOW-UP, WE WILL
15 BRING BACK MORE INFORMATION AROUND THE POTENTIAL IRS
16 IMPLICATIONS AND THEN ANY SORT OF EDUCATION THAT WE
17 CAN ASK EVERSANA TO DO IN THIS REGARD TO MAKE SURE
18 THAT EVERYONE WHO RECEIVES THE SUPPORT IS AWARE OF
19 WHAT THAT MIGHT MEAN FOR THEM LATER ON.

20 THANK YOU SO MUCH. THANK YOU, NIMIT.
21 THAT WAS WONDERFUL. I'M REALLY EXCITED. IT WAS A
22 LONG ROAD TO GET TO THIS PATIENT SUPPORT PROGRAM.
23 AND I WANT TO THANK THE TEAM. THEY'VE DONE A GREAT
24 JOB. AND, NIMIT, YOU'VE JUST MADE SUCH AN IMPACT SO
25 QUICKLY. SO I REALLY WANT TO THANK YOU FOR THAT.

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1 AND THIS IS A REALLY IMPORTANT PROGRAM FOR US AND
2 FOR THE STATE OF CALIFORNIA. SO I'M REALLY PROUD OF
3 ALL OF YOU FOR YOUR HARD WORK. SO THANK YOU VERY
4 MUCH.

5 IF THERE ARE NO FURTHER QUESTIONS, ARE
6 THERE PUBLIC COMMENTS OR QUESTIONS?

7 MR. MALIK: NO PUBLIC COMMENTS.

8 VICE CHAIR BONNEVILLE: GREAT. THEN WITH
9 THAT, WE ARE ADJOURNED. THANK YOU SO MUCH FOR ALL
10 OF YOUR INPUT AND YOUR PARTICIPATION. WE APPRECIATE
11 IT VERY MUCH.

12 (THE MEETING WAS THEN CONCLUDED AT 3:18 P.M.)

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REPORTER'S CERTIFICATE

I, BETH C. DRAIN, A CERTIFIED SHORTHAND REPORTER IN AND FOR THE STATE OF CALIFORNIA, HEREBY CERTIFY THAT THE FOREGOING TRANSCRIPT OF THE VIRTUAL PROCEEDINGS BEFORE THE ACCESSIBILITY AND AFFORDABILITY WORKING GROUP OF THE INDEPENDENT CITIZEN'S OVERSIGHT COMMITTEE OF THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE IN THE MATTER OF ITS REGULAR MEETING HELD ON NOVEMBER 4, 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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