

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: JUNE 21, 2022
2 P.M.

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

FILE NO.: 2022-23

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I N D E X

ITEM DESCRIPTION	PAGE NO.
OPEN SESSION	
1. CALL TO ORDER	3
2. ROLL CALL	3
ACTION ITEMS	
3. CONSIDERATION OF PATIENT ASSISTANCE FUND MODEL (UPDATED 6/20/22)	6
DISCUSSION ITEMS	
4. NEXT STEPS	40
5. PUBLIC COMMENT	NONE
6. ADJOURNMENT	45

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TUESDAY, JUNE 21, 2022; 2 P.M.

CHAIRMAN TORRES: MARIA, PLEASE CALL THE
ROLL.

MS. BONNEVILLE: DOUG, WILL YOU START THE
RECORDING?

DAN BERNAL. ANN BOYNTON.

MS. BOYNTON: HERE.

MS. BONNEVILLE: JAMES BENEDETTI.

DANA DORNSIFE.

MS. DORNSIFE: HERE.

MS. BONNEVILLE: DAVID GOLDMAN. TED
GOLDSTEIN.

MR. GOLDSTEIN: HERE.

MS. BONNEVILLE: DAVID HIGGINS.

DR. HIGGINS: HERE.

MS. BONNEVILLE: HARLAN LEVINE.

DR. LEVINE: HERE.

MS. BONNEVILLE: PAT LEVITT.

DR. LEVITT: HERE.

MS. BONNEVILLE: AMMAR QADAN.

AL ROWLETT.

MR. ROWLETT: HERE.

MS. BONNEVILLE: MAHESWARI SENTHIL.

DR. SENTHIL: HERE.

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1 MS. BONNEVILLE: DAVID SERRANO-SEWELL.

2 MR. SERRANO-SEWELL: PRESENT.

3 MS. BONNEVILLE: ADRIENNE SHAPIRO.

4 MS. SHAPIRO: PRESENT.

5 MS. BONNEVILLE: JONATHAN THOMAS.

6 ART TORRES.

7 CHAIRMAN TORRES: HERE.

8 MS. BONNEVILLE: I THINK I GOT EVERYONE.

9 DID I MISS ANYONE?

10 DR. PADILLA: YOU MISSED ME.

11 MS. BONNEVILLE: YOU KNOW WHAT? I THOUGHT
12 SO. ADRIANA PADILLA.

13 DR. PADILLA: HERE.

14 MS. BONNEVILLE: GREAT. THANK YOU SO
15 MUCH.

16 CHAIRMAN TORRES: SO WE STILL DON'T HAVE A
17 QUORUM, CORRECT?

18 MS. BONNEVILLE: WE DO.

19 CHAIRMAN TORRES: OKAY. GREAT. CALL THE
20 MEETING TO ORDER OF OUR WORKING GROUP. AT CIRM'S
21 REQUEST, THE DEPARTMENT OF FINANCE HAS ESTABLISHED A
22 SEGREGATED ACCOUNT WITHIN THE GENERAL FUND, WHICH IS
23 THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE
24 LICENSING AND ROYALTIES REVENUES FUND, TO RECEIVE
25 ROYALTY REVENUES GENERATED FROM CIRM-FUNDED

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1 INITIATIVES -- RATHER INVENTIONS. UNDER PROP 14
2 THESE FUNDS ARE REQUIRED TO BE DEPOSITED INTO AN
3 INTEREST BEARING ACCOUNT IN THE GENERAL FUND AND, TO
4 THE EXTENT PERMITTED BY LAW, THE AMOUNT SO DEPOSITED
5 AND INTEREST THEREON SHALL BE APPROPRIATED FOR THE
6 PURPOSE OF OFFSETTING THE COST OF PROVIDING
7 TREATMENTS AND CURES ARISING FROM INSTITUTE-FUNDED
8 RESEARCH TO CALIFORNIA PATIENTS WHO HAVE
9 INSUFFICIENT MEANS TO PURCHASE SUCH TREATMENT OR
10 CURE, INCLUDING THE REIMBURSEMENT OF
11 PATIENT-QUALIFIED COSTS FOR RESEARCH PARTICIPATION.

12 BECAUSE CIRM IS IN THE PROCESS OF
13 DEVELOPING AN INPATIENT ASSISTANCE PROGRAM, CIRM HAS
14 WORKED WITH THE DEPARTMENT OF FINANCE AND A BUDGET
15 CHANGE PROPOSAL INCLUDED THIS YEAR IN THE GOVERNOR'S
16 BUDGET, ALREADY APPROVED, FOR AN INITIAL ALLOCATION
17 OF \$600,000 TO ASSIST CIRM IN ESTABLISHING THE CIRM
18 PATIENT ASSISTANCE PROGRAM WITH THE REMAINING FUNDS
19 TO BE APPROPRIATED TO CIRM OVER THE NEXT FIVE FISCAL
20 YEARS: TWO MILLION IN 2023/24, THREE MILLION IN
21 2024/25, AND FIVE MILLION IN 2025/26 AND 2026/27.

22 CIRM PLANS TO USE THESE FUNDS TO ASSIST
23 CALIFORNIA PATIENTS WITH INSUFFICIENT MEANS BY
24 OFFSETTING THE COST OF OBTAINING TREATMENTS AND
25 CURES ARISING FROM CIRM-FUNDED RESEARCH AND

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1 PARTICIPATING IN CIRM-FUNDED CLINICAL TRIALS. THESE
2 FUNDS WILL BE ADMINISTERED BY CIRM PURSUANT TO A
3 CONCEPT PLAN PRESENTED TO US, THE CIRM ACCESSIBILITY
4 AND AFFORDABILITY WORKING GROUP, FOR INPUT AND THEN
5 A RECOMMENDATION BY US TO THE ICOC BOARD OF
6 DIRECTORS FOR A FINAL VOTE.

7 SO, IN ESSENCE, NOTHING IS IN STONE AS WE
8 SPEAK TODAY. WE ARE IN THE PROCESS OF PREPARING THE
9 APPROACHES THAT WE MAY WANT TO TAKE AND, THEREFORE,
10 RECOMMENDING VERY SHORTLY A RECOMMENDATION TO OUR
11 OWN BOARD FOR THEIR APPROVAL. AND THEN WE CAN BEGIN
12 THE PROCESS TO ESTABLISH AN RFP AND AN
13 ADMINISTRATIVE PROCESS TO DETERMINE WHERE THESE
14 FUNDS WILL GO AND WHO WILL BE RECEIVING THESE FUNDS
15 BASED UPON A VERY COMPETITIVE AND IMPORTANT AND
16 SIGNIFICANT REVIEW.

17 SO I'D NOW LIKE TO CALL UPON OUR VICE
18 PRESIDENT FOR MEDICAL POLICY, SEAN TURBEVILLE.

19 DR. TURBEVILLE: THANK YOU, ART, FOR THAT
20 INTRODUCTION AND DEFINING HOW WE'RE GOING TO PROCEED
21 MOVING FORWARD.

22 SO LET ME START MY SLIDES AND WE'LL GO
23 FROM THERE. I DON'T THINK I'VE SEEN ANY NEW FACES.
24 AGAIN, AS ART MENTIONED, MY NAME IS SEAN TURBEVILLE.
25 AND THIS IS, WHAT, MY SECOND ACCESSIBILITY AND

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1 AFFORDABILITY WORKING GROUP. SO THIS IS A
2 CONTINUATION ACTUALLY OF THE PRESENTATION THAT I
3 GAVE ON MAY 17TH TO THE MEETING.

4 THE PURPOSE OF THIS PRESENTATION IS A
5 COUPLE OF THINGS. ONE, FOLLOW UP ON THE PATIENT
6 ASSISTANCE PROGRAM THAT WE PRESENTED DIFFERENT
7 CONCEPTS ON MAY 17TH. THE OTHER THING IS TO START
8 PRESENTING A LEAD OPTION BASED ON THE COMMENTS THAT
9 WE RECEIVED FROM THIS TEAM, WHICH I'LL ADDRESS IN A
10 FEW MINUTES, AND SPECIFICALLY ADDRESS THE LOGISTICAL
11 AND FINANCIAL BOTTLENECKS THAT WE ARE OBSERVING AND
12 OTHER ORGANIZATIONS ARE OBSERVING. THIS ISN'T
13 NECESSARILY JUST A CIRM NARRATIVE BY ANY MEANS, BUT
14 THEY'RE OBSERVING CELL AND GENE THERAPIES.

15 WE DO WANT TO PRESENT A FINAL CONCEPT
16 BASED AFTER THIS DISCUSSION TO THE AAWG ON AUGUST
17 2D, AND THEN WE'RE TEED UP FOR THE MOST PART
18 SEPTEMBER 29TH TO GO TO THE ICOC. AGAIN, THAT'S
19 BASED ON THE GUIDANCE THAT WE ARE GETTING FROM YOU
20 GUYS IN TERMS OF A FINAL CONCEPT PLAN THAT WE CAN
21 PRESENT WITH RESPECT TO AN RFP TO THE BOARD.
22 PERHAPS EVEN EARLIER. I KNOW THAT PUTS A LITTLE
23 PRESSURE ON EVERYBODY IN TERMS OF SCHEDULING. I'LL
24 LEAVE IT UP TO MARIA BONNEVILLE TO GIVE GUIDANCE IF
25 BY ANY CHANCE WE CAN GET ON PEOPLE'S RADAR A LITTLE

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1 BIT EARLIER THAN THE SEPTEMBER 29TH ICOC MEETING.
2 SO THERE'S BEEN SOME INTERESTING UPDATES
3 WITH RESPECT TO PATIENT SUPPORT SERVICES JUST WITHIN
4 THE LAST FOUR OR FIVE WEEKS. SO, ONE, CELL AND GENE
5 THERAPY TRIALS, AS I'M LEARNING AS WELL AS OTHER
6 FOLKS AS WELL, ARE UNIQUELY DEMANDING ON PATIENTS
7 AND REQUIRE ADDITIONAL SUPPORT BEYOND THE
8 TRADITIONAL CLINICAL TRIAL METHODOLOGY. AND TO
9 SUPPORT THAT STATEMENT, RECENTLY I WAS IN DC ABOUT
10 TWO WEEKS AGO FOR THE ALLIANCE FOR REGENERATIVE
11 MEDICINE MEETING. THIS WAS ON JUNE 14TH. AND THERE
12 WERE A NUMBER OF INITIATIVES THAT WE ARE DOING ON
13 THE LEGISLATIVE SIDE WITH RESPECT TO PDUFA, ETC.,
14 BUT IT DID GIVE ME AN OPPORTUNITY TO SPEAK WITH
15 ABOUT 40 OR 50 COMPANIES OUT THERE ABOUT SOME OF THE
16 THINGS THAT WE'RE THINKING ABOUT ON PATIENT SUPPORT
17 SERVICES AND WHAT THE BOTTLENECKS WERE FROM THEIR
18 PERSPECTIVE ON THE CLINICAL OPERATIONS SIDE. AND IT
19 WAS UNEQUIVOCALLY TRUE, AT LEAST IN MY EXPERIENCE
20 SPEAKING TO THESE FOLKS, THAT THIS IS A NUMBER ONE
21 PRIORITY, PARTICULARLY FOR SMALL COMPANIES, THAT
22 THEY'RE SEEING THESE BOTTLENECKS ALL THE WAY ACROSS
23 FROM ENROLLMENT TO POTENTIALLY COMMERCIALIZATION.
24 THE OTHER THING THAT WAS REALLY IMPRESSIVE
25 IS WE HAD AN OPPORTUNITY TO LISTEN TO A PATIENT.

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1 AND THIS WAS ONE OF THE PATIENTS THAT WENT THROUGH
2 THE VERTEX TRIAL, CRISPR TRIAL AS WELL. I DON'T
3 KNOW THE EXACT PATIENT NUMBER, BUT MANY OF YOU HAVE
4 PROBABLY HEARD HIS PRESENTATION. IT WAS INCREDIBLY
5 ENLIGHTENING TO LEARN ABOUT THE PATIENT JOURNEY ALL
6 THE WAY FROM WHEN HE WAS A CHILD TO THE POINT WHERE
7 HE WAS INFUSED WITH THE GENE THERAPY.

8 SOME OF THE INTERESTING DYNAMICS THAT HE
9 BROUGHT UP, ONE, AND THIS WAS NOT A SOLICITED
10 REQUEST BY ANY MEANS, BUT HE DID MENTION THE FACT
11 THAT THE ANCILLARY COSTS ARE SIGNIFICANT FOR
12 PATIENTS TO PARTICIPATE IN THESE TRIALS. THAT HE
13 DID HAVE FINANCIAL RESOURCES, HE DID HAVE FAMILY
14 RESOURCES TO BE ABLE TO PARTICIPATE IN THESE TRIALS,
15 AND HE DID KNOW PATIENTS THAT WERE NOT ABLE TO
16 PARTICIPATE SIMPLY BECAUSE OF THOSE TWO RATE
17 LIMITING STEPS.

18 MANY OF YOU HAVE PROBABLY HEARD ABOUT THE
19 ASCO PRESS RELEASE. MAYBE SOME OF YOU DID ATTEND
20 ASCO. THE AMERICAN MEDICAL ASSOCIATION HOUSE OF
21 DELEGATES, HOD, DID APPROVE JUST RECENTLY, THERE IS
22 A PRESS RELEASE, ON THE ASCO-BACKED RESOLUTIONS ON
23 ANCILLARY CLINICAL TRIAL COSTS. SO, IN SUMMARY, AND
24 I CAN PROVIDE THIS FOR THE TEAM, WHAT THEY REQUIRED
25 THE AMA TO DO IS START LOOKING AT AND DEVELOPING

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1 STATE AS WELL AS FEDERAL LEGISLATION TO ALLOW
2 SPONSORS OF TRIALS, WHETHER THAT'S INDUSTRY OR
3 ACADEMIC, TO SUPPORT ALL ANCILLARY COSTS FOR THE
4 TRIAL. SO THERE'S A MOVEMENT HERE.

5 THE OTHER THING THAT I'VE NOTICED, AT
6 LEAST IN THE LAST FOUR WEEKS, AND I THINK GEOFF
7 COULD CONCUR, IS THAT WE RECEIVED A NUMBER OF UNIQUE
8 SLIDE DECKS FROM PATIENT ASSISTANCE PROGRAMS. SO IN
9 THE LAST FOUR WEEKS, THERE HAS BEEN A PUSH FOR
10 PROFIT AS WELL AS NONPROFIT ORGANIZATIONS. THEY ARE
11 STARTING TO ADD SOME UNIQUE PATIENT SUPPORT
12 MECHANISMS TO SUPPORT THE FINANCIAL BOTTLENECKS
13 ASSOCIATED WITH GENE, PARTICULARLY CELL AND GENE
14 THERAPY TRIALS. AND THIS ISN'T NECESSARILY JUST
15 SPECIFICALLY GENE. IT ALSO HAS TO DO WITH GOING
16 BACK TO THE ASCO PRESS RELEASE PARTICULARLY ON THE
17 ONCOLOGY SIDE AS WELL WHICH WE SUPPORT.

18 THE SERVICES HAVE RANGED ALL THE WAY FROM
19 OFFERING A NUMBER OF SUITE SERVICES, AGAIN I
20 MENTIONED, FROM EARLY STAGE CONSENT ALL THE WAY
21 THROUGH THE PROCESS AND EVEN TO THE POSTMARKETING
22 ASSESSMENTS AND REQUIREMENTS. AND THEN I HAVEN'T
23 EVEN LAYERED ON, TO BE HONEST WITH YOU, THE WHOLE
24 DIGITAL HEALTH MOVEMENT THAT'S TAKING PLACE WITH
25 RESPECT TO PATIENT SUPPORT SERVICES. JUST TO DROP A

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1 NAME, VERILY IS ENGAGED WITH THIS. THERE'S AN
2 OPPORTUNITY FOR US TO MEET WITH THEM AND START
3 EXCHANGING IDEAS WITH RESPECT TO NOT ONLY THIS
4 PROGRAM, BUT POTENTIALLY OTHER PROGRAMS THAT WILL
5 IMPACT ACCESS AND AFFORDABILITY.

6 THAT'S A QUICK LITTLE UPDATE. HERE IS
7 JUST BASICALLY A PLACEHOLDER, IF YOU WILL. IF YOU
8 REMEMBER, WE DID PRESENT A COUPLE OF DIFFERENT
9 BARRIERS WITH RESPECT TO ACCESS TO REGENERATIVE
10 MEDICINES. WE'RE NOT GOING TO FOCUS ON THOSE TODAY.
11 THE ONES THAT WE REALLY WANT TO FOCUS ON AND THAT
12 RESONATED WITHIN THE COMMENTS THAT I RECEIVED, WHICH
13 I'LL GET TO SHORTLY, ARE INFORMATIONAL, THE
14 LOGISTICAL COORDINATION FOR PATIENTS AROUND THOSE
15 TRIALS, AND MORE IMPORTANTLY THE FINANCIAL. AND WE
16 THINK ABOUT PATIENT SUPPORT SERVICES, AT LEAST FOR
17 THIS PROGRAM, WE REALLY ARE FOCUSING ON THE
18 FINANCIAL AND LOGISTICAL COORDINATION. I THINK THE
19 INFORMATIONAL IS A GIVEN. THOSE PATIENT NAVIGATORS
20 THAT I MENTIONED EARLIER CAN PROVIDE AN ENORMOUS
21 AMOUNT OF INFORMATION TO PATIENTS, NOT ONLY ON THE
22 CIRM-SUPPORTED TRIALS, BUT POTENTIALLY OTHER TRIALS
23 OUT THERE THAT ARE WITHIN OUR ALPHA CLINICS, ET
24 CETERA.

25 SO JUST ANOTHER PLACEHOLDER. WHAT WE WERE

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1 TALKING ABOUT EARLIER ARE TRADITIONAL ITEMS THAT ARE
2 SUPPORTED THROUGH OUR CLINICAL TRIALS: THE TRAVEL
3 EXPENSES, THE ACCOMMODATION, THE MEALS, THE
4 CHILDCARE, THE OUT-OF-POCKET HEALTHCARE EXPENSES,
5 THE ANCILLARY HEALTHCARE EXPENSES. THAT'S WHAT WE
6 ARE SEEING UNIVERSALLY. IT'S NOT JUST CIRM FOR THE
7 MOST PART. THERE ARE OTHER BENCHMARKS OUT THERE
8 THAT ARE DEMONSTRATING THAT THAT'S WHERE THE COSTS
9 ARE STARTING TO ACCUMULATE.

10 SO I DO WANT TO PROVIDE SOME DUE DILIGENCE
11 AND VISIBILITY FOR ALL OF THE UPDATES AND COMMENTS
12 THAT WE RECEIVED. I THOUGHT THEY WERE REALLY
13 IMPRESSIVE. THEY PROVIDED GOOD GUIDANCE. AND IF
14 YOU COULD BEAR WITH ME, I WOULD LIKE TO -- THIS
15 SLIDE FOR THE MOST PART PROVIDES A CROSS-SECTIONAL
16 SAMPLE OF ALL THE COMMENTS THAT WERE RECEIVED FROM
17 THE TEAM. IF YOU COULD BEAR WITH ME, I WOULD LIKE
18 TO READ THROUGH SOME OF THESE AND THEN MAYBE PAUSE
19 TO SEE IF THERE'S ANY COMMENTS OR UPDATES TO THE
20 SLIDE.

21 CHAIRMAN TORRES: SEAN, I THINK IT'S VERY
22 IMPORTANT THAT WE GO THROUGH THIS BECAUSE THOSE OF
23 US AT CIRM HAVE TAKEN VERY SERIOUSLY THE INPUT THAT
24 WE HAVE BEEN RECEIVING FROM OUTSIDE THE AGENCY
25 BECAUSE IT HELPS GUIDE US TO MORE FORMIDABLE

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1 SOLUTIONS. THANK YOU.

2 DR. TURBEVILLE: THANK YOU, ART.

3 SO ONE COMMENT, VITAL TO PROVIDE PATIENT
4 ASSISTANCE THAT COVERS RARE CONDITIONS, RECRUITS
5 OUTSIDE THE ACADEMIC MODEL AND MONITORS METRICS.
6 MANY OF YOU HAVE ALREADY BEEN EXPOSED TO THE PATIENT
7 SUPPORT SERVICES, THOSE FULL MODELS, SO I THINK THAT
8 IS REFLECTED IN SOME OF THESE COMMENTS.

9 A FULL SUPPORT SERVICE WITH
10 PATIENT-COORDINATED CARE WILL ADDRESS THE HEADWINDS
11 WITH RESPECT TO REGENERATIVE TRIALS.

12 THE COMMUNITY CARE CENTERS OF EXCELLENCE
13 COULD ADDRESS THE CULTURAL, SOCIAL, AND EDUCATIONAL
14 BARRIERS. PATIENT SUPPORT COULD ADDRESS THE
15 FINANCIAL AND LOGISTICAL BOTTLENECKS.

16 I'M GOING TO PAUSE THERE JUST FOR A SECOND
17 BECAUSE THE COMMENTS THAT WE DID RECEIVE WITH
18 RESPECT TO THE ALPHA CLINICS AND THE COMMUNITY CARE
19 CENTERS OF EXCELLENCE, THAT WAS FAIRLY NOVEL, TO BE
20 HONEST WITH YOU. I DID NOT THINK ABOUT
21 INCORPORATING THESE INTO THE PROGRAM. AND THAT'S
22 PROVIDED ANOTHER LAYER THAT WE CAN START THINKING
23 THROUGH OF HOW NOT ONLY CAN THIS PROGRAM SUPPORT THE
24 ALPHA CLINICS FROM THE TOP-DOWN APPROACH, BUT ALSO
25 THE COMMUNITY CARE CENTERS, WHICH IS ANOTHER

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1 INITIATIVE THAT WE HAVEN'T REALLY ADDRESSED THAT I
2 WILL BRING TO THE AAWG IN SUBSEQUENT MEETINGS.

3 CONSIDER ADDITIONAL FINANCIAL SUPPORT FOR
4 ALL GRANT AWARDEES THROUGH AFFORDABILITY AND
5 ACCESSIBILITY WORKING GROUP, THE AAWG. I DO WANT TO
6 COMMENT I THINK THAT WE WILL BE CONTINUING THAT
7 PROGRAM. THIS IS BY NO MEANS GOING TO BE
8 CANNIBALIZING THAT PROGRAM. THIS IS GOING TO BE
9 SUPPORTIVE ON TOP OF THAT. WE WILL MAKE SURE THAT
10 THERE'S NO DUPLICATIVE PROCESS OR PAYMENTS, IF YOU
11 WILL. AND THAT PROCESS IS UNDER WAY INTERNALLY WITH
12 RESPECT TO THE GAP ANALYSIS.

13 UPDATE MEDI-CAL PHYSICIAN REIMBURSEMENT TO
14 IMPROVE ACCESSIBILITY AND AFFORDABILITY. IF NOT, IT
15 WILL BE DIFFICULT TO ADOPT NEW REGENERATIVE MEDICINE
16 TREATMENTS FOR TEACHING HOSPITALS.

17 PROVIDE, 1, FINANCIAL SUPPORT; 2, CARE
18 COORDINATION TO ADDRESS PATIENT'S OVERALL HOLISTIC
19 NEEDS; 3, HEALTH BENEFITS COORDINATION TO ADDRESS
20 THE HEADWINDS FROM INSURANCE COVERAGE; FOR EXAMPLE,
21 PATIENT CARE OUTSIDE OF INSTITUTIONS; COVERAGE DELAY
22 IN OR LACK OF COVERAGE DISCOURAGES PEOPLE FROM
23 ENROLLING. SO CONSIDER ALL OF THESE WHEN YOU
24 PRESENT YOUR RFP.

25 WE'VE HEARD FROM NUMEROUS COLLEAGUES HERE

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1 ON THE FORUM TO FOCUS ON MEDICARE AND UNINSURED
2 PATIENTS.

3 AND THEN FINALLY, THIS IS SOMETHING I
4 WOULD LIKE THE OPPORTUNITY TO WRAP IN PROBABLY AT
5 ANOTHER TIME, BUT ADDRESS THE FINANCIAL
6 CONSTRAINTS/RESOURCES BY THE ALPHA CLINICS AND THEN
7 THE COMMUNITY CARE CENTERS OF EXCELLENCE.

8 SO, ART, IF YOU DON'T MIND, I'D LIKE TO
9 PAUSE THERE TO PERHAPS SEE IF THERE'S ANY HANDS UP
10 FOR COMMENTS WITH RESPECT TO THE COMMENTS WE
11 RECEIVED FROM THE TEAM.

12 CHAIRMAN TORRES: ANY QUESTIONS?

13 MS. BONNEVILLE: HARLAN HAS A QUESTION.

14 CHAIRMAN TORRES: YEAH. IF YOU COULD JUST
15 POINT IT OUT, MARIA, BECAUSE I CAN'T SEE THE FULL
16 SCREEN.

17 MS. BONNEVILLE: YES.

18 DR. LEVINE: SOME OF MY BEST INPUT IS
19 WHILE ON MUTE.

20 SEAN, THANK YOU FOR THIS. I THINK IT'S A
21 VERY THOROUGH UPDATE. TWO QUESTIONS.

22 IN TERMS OF HOW WE SUPPORT THIS AS A BODY,
23 WHERE DO YOU THINK YOU ARE ALONG THE LEARNING
24 CONTINUUM, MEANING CIRM'S NOT NEW, BUT I THINK THIS
25 IDEA OF THE SUPPORT IS NEW. AND THERE'S ALWAYS A

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1 PART OF ME THAT SAYS YOU GOT TO START SOMEWHERE, BUT
2 YOU'VE GOT TO HAVE FLEXIBILITY BUILT IN BECAUSE
3 WE'RE GOING TO FIND STUFF ALONG THE WAY WE HAVEN'T
4 JUST THOUGHT OF. SO HOW DO WE ACCOUNT FOR THAT?
5 LET ME JUST DO ONE AT A TIME. I ONLY HAVE TWO
6 QUESTIONS, BUT I'LL STOP THERE AND GET YOUR
7 THOUGHTS.

8 DR. TURBEVILLE: THANK YOU FOR THE
9 QUESTION. SO THIS IS A NEW CONCEPT. THIS IS MORE
10 OF AN ACTIONABLE CONCEPT THAT WE'RE GOING TO BE
11 PUTTING OUT THERE FOR PATIENTS. WELL, TO USE THE
12 PHRASE, THERE'S BABY STEPS TO BEGIN WITH. WHAT WE
13 ARE THINKING ABOUT RIGHT NOW IS REALLY THE
14 FINANCIAL, REALLY MAKING SURE WE UNDERSTAND THAT
15 SPACE AND WE CAN PROVIDE THE SERVICE, AND THEN
16 MOVING INTO THE COORDINATED CARE.

17 SO THERE IS GOING TO BE A LITTLE BIT OF
18 EDUCATION INTERNALLY AS WELL AS A LEARNING PROCESS.
19 WHAT'S UNIQUE ABOUT THE RFP IS A LOT OF THE INTEL
20 THAT WE'RE TRYING TO SEEK IS REALLY OUTSIDE OF CIRM,
21 TO BE HONEST WITH YOU. AND SO THERE'S AN
22 OPPORTUNITY FOR US, NOT ONLY TO INITIATE BASIC
23 SERVICES, BUT ALSO LEARN FROM THE GAP ANALYSIS WHILE
24 THE SERVICE IS RUNNING. SO JUST AS A BENCHMARK,
25 THERE ARE ORGANIZATIONS OUT THERE THAT RUN A HUNDRED

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1 PATIENT SUPPORT SERVICE PROGRAMS, ALL UNIQUELY
2 DIFFERENT, BUT THEY HAVE THE BENCHMARK OF ALL THE
3 INFORMATION THAT WE CAN USE FROM AN INTEL
4 STANDPOINT, AND WE WILL PUT THAT IN THE RFP THAT
5 WILL HELP GUIDE THIS MOVING FORWARD.

6 SO I THINK IT'S GOING TO BE BABY SCALE TO
7 BEGIN WITH, AND THEN WE'LL BE ABLE TO SCALE UP FROM
8 THERE TO ADDITIONAL SERVICES DEPENDING ON THE
9 GUIDANCE OF THE AAWG.

10 CHAIRMAN TORRES: ANYTHING ELSE TO ADD,
11 HARLAN?

12 DR. LEVINE: YEAH. JUST A QUICK COMMENT.
13 IN MY EXPERIENCE, MY CAREER HAS REALLY BEEN IN
14 POPULATION HEALTH AND CARE MANAGEMENT AND
15 NAVIGATION. THE POPULATIONS VARY DRAMATICALLY
16 BETWEEN WHAT MEDICARE NEEDS ARE VERSUS MEDICAID OR
17 MEDI-CAL. SO WE'RE GOING TO HAVE TO THINK ABOUT HOW
18 DO YOU REALLY TAILOR TO THE NEED OF THE TARGETED
19 SEGMENT.

20 AND THEN THE OTHER AREA THAT I THINK I
21 WOULD JUST HIGHLIGHT IS THESE PATIENTS ARE GETTING
22 TREATED BECAUSE THEY HAVE A CHRONIC ILLNESS OR SOME
23 CONDITION. THE BEHAVIORAL HEALTH ASPECTS OF THAT
24 HAVE REALLY BECOME CLEAR OVER TIME. I JUST THINK
25 WHOEVER IS FILLING OUT RFP'S, YOU'VE REALLY GOT TO

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1 BE DEALING WITH BEHAVIORAL HEALTH ISSUES IN ADDITION
2 TO THE FINANCIAL STRESSES THAT PEOPLE MAY BE FACING.
3 OTHERWISE YOU CAN GIVE THEM ALL THE MONEY AND
4 SUPPORT IN THE WORLD. IF THEY DON'T HAVE THE
5 STABILITY FROM A MENTAL HEALTH POINT OF VIEW, IT MAY
6 BE HARD TO TAKE FULL ADVANTAGE OF IT.

7 CHAIRMAN TORRES: EXCELLENT POINT. I JUST
8 WANT TO LET THE GROUP KNOW THAT I'VE BEEN IN
9 DISCUSSIONS WITH SECRETARY GHALY, AND I'M GOING TO
10 BE HAVING DISCUSSIONS WITH MICHELLE BASS, WHO HEADS
11 UP MEDI-CAL FOR THE STATE, TO MAKE SURE THAT WE
12 INTERFACE WITH THAT AGENCY BECAUSE IT'S, AS YOU
13 SAID, HARLAN, VERY WELL PUT, IT'S THAT POPULATION
14 THAT REALLY IS GOING TO BEG THE QUESTION OF WHETHER
15 WE ARE COMPLYING WITH DIVERSITY ESPECIALLY.

16 DANA.

17 DR. DORNSIFE: HI, THERE. JUST A COUPLE,
18 SEAN, COUPLE THINGS THAT YOU MIGHT WANT TO JUST TAKE
19 A PEEK AT. SO LAZEREX CANCER FOUNDATION HAS BEEN
20 CARRYING THIS EQUITABLE ACCESS TORCH FOR QUITE SOME
21 TIME, BUT SPECIFICALLY IN RELATION TO CANCER. AND
22 IN 2017 WE WERE ABLE TO PASS LEGISLATION IN HERE IN
23 THE STATE OF CALIFORNIA THAT DOES IDENTIFY OUT OF
24 POCKET EXPENSE AS A BARRIER. THAT BILL NUMBER IS
25 AB 1823. I'M HAPPY TO SHARE THAT WITH YOU IF YOU

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1 LIKE OR YOU CAN LOOK IT UP. JUST AS A FRAMEWORK OF
2 REFERENCE FOR YOU, IT MIGHT HELP BYPASS SOME THINGS
3 FOR YOU.

4 AND THEN, ALSO, WE WERE SUCCESSFUL IN
5 GETTING THE FDA TO PUBLISH GUIDANCE LANGUAGE AROUND
6 THE SAME THING, REGARDING REIMBURSEMENT OF OUT OF
7 POCKET EXPENSE AND REALLY LOOKING AT THAT AS A
8 PLATFORM OF PARITY. AND SO HAPPY TO SHARE THAT WITH
9 YOU AS WELL IF YOU WOULD LIKE AND THEN JUST AS A
10 GUIDELINE FOR YOU TO MOVE FORWARD.

11 AND THEN THE THIRD THING IS THAT IT'S BEEN
12 OUR EXPERIENCE, AND WE'VE REIMBURSED LITERALLY
13 THOUSANDS AND THOUSANDS OF PATIENTS IN CANCER
14 CLINICAL TRIALS, HAS THERE BEEN ANY DISCUSSION
15 AROUND REIMBURSEMENT OF TRAVEL EXPENSE FOR THE
16 CARETAKER OR THE TRAVEL COMPANION BECAUSE I WOULD
17 SAY HALF OF OUR PATIENTS, PROBABLY LIKE 47 PERCENT,
18 REALLY NEED A TRAVEL COMPANION. THEY CANNOT TRAVEL
19 BY THEMSELVES. THEY JUST CAN'T DO IT.

20 CHAIRMAN TORRES: I'M VERY MUCH IN SUPPORT
21 OF THAT. AS A MATTER OF FACT, BOB KLEIN AND I
22 TALKED ABOUT THAT AS WE WERE DRAFTING THE LANGUAGE
23 FOR PROP 14 BECAUSE IN MY EXPERIENCE WITH ONE
24 LEGACY, THE ORGAN TRANSPLANT FOUNDATION OUT OF LOS
25 ANGELES, I'VE BEEN ON THEIR BOARD FOR OVER 20 YEARS,

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1 ONE OF THE MOST IMPORTANT ELEMENTS IS TO MAKE SURE
2 THAT THE CAREGIVER ACCOMPANIES THE PATIENT AND STAYS
3 WITH THEM THROUGHOUT THE PROCESS. OTHERWISE IT CAN
4 BE A VERY LONELY AND SCARY SOLO JOURNEY IF THAT
5 DOESN'T HAPPEN.

6 SO FOR ME ANY RFP THAT WE PUT OUT IN THE
7 FUTURE HAS TO INCLUDE THE OPPORTUNITY FOR THAT
8 EXPENSE TO BE REIMBURSED.

9 MR. SERRANO-SEWELL: THANK YOU, SENATOR.

10 SO SOMETHING HARLAN MENTIONED WHICH GOT ME
11 THINKING, AND THAT IS, SEAN, AS YOU WERE PRESENTING
12 THIS TO THE FULL BOARD BASED ON OUR OBSERVATIONS,
13 IT'S GOING TO GO TO THE FULL GOVERNING BOARD,
14 THEY'LL MAKE THEIR DECISIONS AND SORT OF INFLUENCE
15 IT AND PUT THE TIMELINE ON IT AS WELL. TIME BEING
16 OF THE ESSENCE HERE, BECAUSE, AS THE SENATOR
17 MENTIONED, THIS WAS A KEY COMPONENT, I'D LIKE TO
18 THINK, IS A KEY COMPONENT TO THE INITIATIVE'S
19 PASSAGE. SO THE RFP HAS THE SPECIFICITY AND
20 FLEXIBILITY SO THAT WHEN YOU GET THOSE RESPONSES,
21 THEY DON'T CHECK ALL THE BOXES, THEY CHECK ENOUGH OF
22 THEM SUCH THAT YOU CAN CONTINUE WITH IT SO WE ARE
23 NOT BACK HERE WITH SOME UNRESPONSIVE OR LACKING THE
24 FULLNESS THAT THE GOVERNING BOARD MAY WANT, THAT
25 THERE IS THAT DELEGATION OF AUTHORITY TO WHOMEVER WE

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1 NEED TO BE DELEGATED TO, THAT THEY CAN HAVE THOSE
2 DISCUSSIONS WITH THE SUCCESSFUL PROPOSERS OR HOWEVER
3 YOU'RE GOING TO SHAPE IT.

4 CIRM HAS DONE A FANTASTIC JOB, AND THE
5 REASON WHY IT'S BEEN SO SUCCESSFUL IS BECAUSE IT HAS
6 BUILT IN SO MUCH FLEXIBILITY BECAUSE WHAT IT HAS
7 BEEN DOING IS SO UNIQUE. SO PLEASE CONTINUE WITH
8 THAT TRADITION WITH THIS IMPORTANT RFP AND
9 INITIATIVE.

10 MY FIRST COMMENT AT THE FIRST PRESENTATION
11 WAS MY COMFORT LEVEL, AND I DIDN'T SAY ANYTHING, BUT
12 MY COMFORT LEVEL WITH THE TIMELINE WAS I THOUGHT IT
13 WAS TAKING A LITTLE TOO LONG, BUT I UNDERSTAND THAT
14 THESE ARE ALL THE STEPS, THESE ARE ALL THE MEETINGS,
15 AND THESE ARE ALL THE DISCUSSIONS THAT WE HAVE TO
16 HAVE, BUT I WOULD HATE TO SEE ANOTHER DELAY.

17 CHAIRMAN TORRES: WELL, THERE HASN'T BEEN
18 ANY DELAYS.

19 MR. SERRANO-SEWELL: I KNOW. I KNOW, BUT
20 I'D HATE TO SEE --

21 CHAIRMAN TORRES: AND QUITE FRANKLY,
22 THAT'S WHAT PEOPLE SAID ABOUT YOUR COMMITTEE WHEN
23 YOU WERE HEADING UP THE FACILITIES COMMITTEE.
24 YOU'RE TAKING TOO LONG TO GET STEPS, YET YOU DID IT.
25 AND IT'S GOING TO TAKE TIME. THERE'S NO QUESTION

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1 ABOUT THAT. AND YOU RAISE SOME EXCELLENT POINTS
2 BECAUSE, AT THE END OF THE DAY, THIS IS A NEW
3 FRONTIER THAT WE ARE ADDRESSING AND CONFRONTING.
4 WE'VE JUST GOT TO MAKE SURE WE GET IT RIGHT. WE MAY
5 NOT GET IT RIGHT THE FIRST TIME, BUT I KNOW WE'RE
6 GOING TO CONTINUE TO GET IT RIGHT AS WE MOVE ALONG.
7 THANK YOU FOR YOUR WORK IN THAT AREA.

8 AL ROWLETT.

9 MR. ROWLETT: FROM MY EXPERIENCE IS THAT
10 THE SOCIAL DETERMINANTS OF HEALTH, AND I THINK THAT
11 THAT IS THE UMBRELLA THAT I TYPICALLY UTILIZE TO
12 BEST SPEAK TO WHAT HARLAN WAS REFERENCING. ARE
13 THERE PRIMARY IMPEDIMENTS TO PATIENT PARTICIPATION
14 FOR THE UNINSURED AND MEDI-CAL POPULATION? AND ANY
15 APPLICANT THAT RESPONDS TO THIS SHOULD BE ABLE TO
16 DEMONSTRATE AN ABILITY TO ENGAGE IN AN EFFECTIVE WAY
17 THAT GROUP OF CITIZENS OR INDIVIDUALS THAT
18 UNDERPARTICIPATE IN TRIALS LIKE THIS AND TYPICALLY,
19 AS WE HAVE DISCUSSED ON NUMEROUS OCCASIONS, ARE NOT
20 REPRESENTED IN TERMS OF DIVERSITY, EQUITY, AND
21 INCLUSION AS WELL. AND OFTENTIMES THOSE ARE
22 COMMUNITIES OF COLOR WHERE YOU SEE THE SOCIAL
23 DETERMINANTS OF HEALTH OR BEHAVIORAL HEALTH
24 IMPEDIMENTS GETTING IN THE WAY OF THEM BEING ABLE TO
25 PARTICIPATE.

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1 SO BEING ABLE TO STRUCTURE AN RFP THAT
2 SOLICITS AN APPLICANT'S ABILITY TO SUCCESSFULLY
3 ENGAGE OR OVERCOME THOSE IMPEDIMENTS IS VERY
4 IMPORTANT TO ME AND I THINK ADVANCES WHAT HAS
5 CLEARLY BEEN ONE OF THE MORE IMPORTANT ELEMENTS OF
6 OUR STRATEGIC PLAN: DIVERSITY, EQUITY, AND
7 INCLUSION.

8 CHAIRMAN TORRES: HARLAN, I SEE YOU HAD
9 SOMETHING ELSE TO ADD.

10 DR. LEVINE: YES, I DO. IT WAS BASED ON A
11 COMMENT THAT YOU MADE, SENATOR. I THINK WE SHOULD,
12 AS WE'RE GOING THROUGH THIS, WE SHOULD TRY TO
13 MEASURE THE IMPACT OF THE PROGRAM BECAUSE ONE OF MY
14 CONCERNS IS THAT CIRM WILL EITHER GO AWAY ONE DAY OR
15 THINGS WILL NO LONGER BE PART OF RESEARCH. THEY'LL
16 BE PART OF STANDARD OF CARE. AND THEN THERE'LL BE A
17 DROP-OFF IN THE SUPPORT FOR PATIENTS. SO WE'LL DO
18 ALL THE RIGHT THINGS DURING THE LEARNING PHASE; BUT
19 AS IT BECOMES PART OF MAINSTREAM MEDICINE, WE WON'T
20 HAVE SUPPORT, AND THEN WE'LL FIND WE HAVE THE SAME
21 DISPARITIES IN HEALTHCARE AND ACCESS AFTER THESE
22 THINGS HIT MAINSTREAM. SO I THINK WE'RE GOING TO
23 WANT TO PICK UP PROOF POINTS ALONG THE WAY OF THE
24 BENEFIT OF THE INTERVENTIONS AND WHY THEY RETURNED
25 VALUE.

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1 CHAIRMAN TORRES: EXCELLENT POINT. I
2 THINK, SEAN, YOU MENTIONED TO ME A FEW WEEKS AGO
3 THAT THERE WERE SOME COMPANIES THAT ARE ALREADY
4 STARTING TO PROVIDE THIS KIND OF PATIENT ASSISTANCE.
5 CAN YOU ENLIGHTEN US ON THAT?

6 DR. TURBEVILLE: CERTAINLY. I THINK WE'RE
7 TALKING ABOUT METRICS HERE, AND THAT'S THE REASON
8 WHY WE WANT TO GO TO A CENTRAL HUB, WHICH I'LL TALK
9 ABOUT IN A FEW MINUTES WHEN WE TALK ABOUT THE RFP.
10 WE NEED METRICS TO BE ABLE TO BENCHMARK AND LOOK AT
11 IMPROVEMENTS, ACTUALLY CRITICAL. EVERY CALL CENTER
12 THAT I'VE SET UP, THAT'S, I DON'T WANT TO USE THE
13 TERM "INDUSTRY STANDARD," BUT THAT IS STANDARD IN MY
14 EXPERIENCE.

15 SO I WOULD NEVER COME WITH QUALITATIVE
16 METRICS, FOR THE MOST PART, BACK TO THE COMMITTEE.
17 WE WANT TO LOOK AT QUANTITATIVE METRICS WHERE WE'RE
18 MAKING IMPROVEMENTS, WHERE THE PATIENTS ARE DOING
19 WELL, AND WHERE THERE'S AREAS THAT WE MIGHT BE ABLE
20 TO IMPROVE ON.

21 CHAIRMAN TORRES: ADRIANA, THANK YOU AGAIN
22 FOR YOUR COMMENTS. I READ YOUR E-MAILS WITH GREAT
23 INTEREST. AND THANK YOU FOR GIVING US THAT INPUT.
24 AND NOW IT'S YOUR CALL. GO AHEAD.

25 DR. PADILLA: THANK YOU. I'M LISTENING

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1 REALLY WELL ON THE COMMENTS FOR DEVELOPING THIS RFP.
2 MOST OF THE COMMENTS ARE FOCUSED ON THE
3 AFFORDABILITY FOR PATIENTS PARTICIPATING IN RESEARCH
4 TRIALS. I WANT TO FOCUS ON THE ACCESSIBILITY.

5 I'M FROM THE CENTRAL VALLEY, AND MOST OF
6 CALIFORNIA IS EITHER RURAL OR FRONTIER. SMALLER
7 AMOUNTS ARE IN THE LARGE URBAN CENTERS, BUT THAT'S
8 WHERE ALL THE RESEARCH IS AT AT THIS POINT IN TIME.
9 SO I AM REALLY WANTING TO MAKE SURE THAT WHATEVER
10 RFP COMES FROM THIS COMMITTEE IS REALLY FOCUSING ON
11 THE ACCESSIBILITY TO REALLY LOOK AT A DECENTRALIZED
12 MODEL. THAT'S WHERE I WAS REALLY INTERESTED IN THE
13 COMMUNITY CARE CENTERS OF EXCELLENCE AS A BASE HUB
14 STARTING FROM MANY DIFFERENT LOCATIONS IN CALIFORNIA
15 TO PROVIDE WHATEVER IT TAKES TO INFORM POTENTIAL
16 PARTICIPANTS IN THESE RESEARCH PROGRAMS THAT ARE
17 HAPPENING MORE IN LARGE TERTIARY CARE CENTERS, LARGE
18 URBAN CENTERS, ET CETERA. SO I JUST WANTED TO MAKE
19 THAT FOCUS A PART OF THIS RFP THAT'S COMING UP.

20 CHAIRMAN TORRES: THAT'S AN EXCELLENT
21 POINT. YOU WELL KNOW, HAVING GROWN UP IN THE UNITED
22 FARM WORKERS UNIONS, I'M REALLY SENSITIVE TO RURAL
23 COMMUNITIES AND THEIR ACCESSIBILITY TO HEALTHCARE
24 TODAY, WHICH IS STILL NOT ENOUGH AS FAR AS I'M
25 CONCERNED.

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1 SO I SEE DR. GOLDSTEIN. YOU HAD YOUR HAND
2 UP, TED. DID YOU WANT SOMETHING TO ADD?

3 DR. GOLDSTEIN: SO JUST VERY QUICKLY, I
4 THINK ONE OF THE THINGS HERE IS TO BE MINDFUL AND
5 REINFORCING WHAT HARLAN SAID ABOUT HAVING SOME
6 SUCCESS STORIES TO SHOW TO KEEP THE MOMENTUM GOING
7 FOR CIRM. AND I THINK IN THIS RFP WE NEED TO GIVE
8 THE ADVICE WE ALWAYS GIVE COLLEGE STUDENTS. YOU
9 WANT TO T-SHAPE EDUCATION, BROAD IN MANY AREAS, DEEP
10 IN AT LEAST ONE. AND SO IT SEEMS TO ME THAT CIRM
11 TOUCHES A GREAT MANY DISEASE AREAS. WE NEED TO PICK
12 PERHAPS A SMALL NUMBER TO GET STARTED WITH THAT WE
13 WILL BE VERY SUCCESSFUL WITH SO THAT WE CAN SHOW THE
14 WORLD WHAT WE'VE ACCOMPLISHED.

15 IT FEELS TO ME LIKE WE DO HAVE SOME
16 EXCELLENT CHOICES AMONG THE CLINICAL TRIALS THAT ARE
17 EMERGING, BUT I THINK WE MAY WANT TO REVIEW IN A
18 FUTURE MEETING AND DISCUSS WHAT IS GOING TO
19 ESSENTIALLY BE THE CLINICAL TRIALS THAT WE CAN
20 SUPPORT, THAT WE CAN BRING TOGETHER ACCESSIBLE TO
21 PEOPLE AND SUCCESS ON THE SCIENTIFIC FRONT.

22 CHAIRMAN TORRES: THANK YOU.

23 DAVID, I WANTED TO ASK YOU A FOLLOW-UP
24 QUESTION. ON THE STEM CELL LABS ONE, WHEN YOU AND
25 YOUR COMMITTEE, WHEN YOU WERE ON THE BOARD AT CIRM,

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1 WHAT SPECIFIC ROADBLOCKS DID YOU ENCOUNTER IN TERMS
2 OF OUTREACH?

3 MR. SERRANO-SEWELL: WE DIDN'T -- I
4 CAN'T -- SENATOR, I CAN'T RECALL OFF THE TOP OF MY
5 MIND AN OUTREACH CHALLENGE. THERE WAS A LOT OF
6 EXCITEMENT AND INTEREST FROM THE INSTITUTIONS AROUND
7 SEEKING THE FUNDS. BUT I CAN SHARE THAT THE
8 COMMUNICATION WAS SO IMPORTANT IN JUST LETTING
9 EVERYBODY KNOW THAT THEY WERE POTENTIAL APPLICANTS,
10 IF YOU WILL, THAT THEY COULD ACCESS THOSE FUNDS EVEN
11 IF ON THE FACE OF IT THEY MAY NOT BE AN INSTITUTION
12 OR THEY MAY NOT HAVE THOUGHT OF THEMSELVES AS
13 SOMEONE WHO COULD RECEIVE THE FUNDS. THEY WERE A
14 RESEARCH INSTITUTION, BUT THEY MAY NOT HAVE BEEN AT
15 THE SCALE OF A UC OR A STANFORD OR SOMEWHERE IN
16 TORREY PINES. THERE WERE OTHER INSTITUTIONS OF
17 SMALLER OR MEDIUM SIZE LEVEL THAT WE REACHED OUT TO,
18 AND WE WERE ABLE TO GET THEIR INTEREST IN THIS.

19 AND THEN THE OTHER THING, OTHER
20 OBSERVATION I WOULD LIKE TO SHARE IS ABOUT MIDCOURSE
21 IN THE PROCESS, TOWARDS THE END, I GUESS, WE WERE
22 SOME WAYS INTO IT, WE WERE ABLE TO DO, I WOULDN'T
23 CALL IT A COURSE CORRECTION, BUT WE WERE ABLE TO
24 MAKE SOME CHANGES IN THE RFP THAT ACTUALLY IN THE
25 AWARD PROCESS WE WERE ABLE TO MAKE CHANGES BECAUSE

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1 WE BUILT IN THAT FLEXIBILITY TO THE AWARD TO HAVE A
2 GREATER NUMBER OF GRANT RECIPIENTS. AND THAT WAS
3 SOMETHING THAT BOB AND I CAME UP WITH AND THE
4 COMMITTEE CAME UP WITH. WE WERE ABLE TO SAY, HEY,
5 LOOK. HOW CAN WE GET MORE PEOPLE INVOLVED IN THIS?

6 AND I COULD SHARE AT SOME OTHER TIME HOW
7 WE DID THAT, BUT THE POINT BEING COMMUNICATION, TO
8 YOUR POINT, IS KEY AND HAVING THAT FLEXIBILITY TO
9 SAY, HEY, LOOK, WE MIGHT BE ABLE TO EXPAND THIS, AND
10 HERE'S A WAY TO DO IT. LET'S HAVE A CONVERSATION
11 AND LET'S ACT ON IT.

12 CHAIRMAN TORRES: OKAY. I THINK THE
13 CHALLENGE ALSO WAS FOR THOSE SMALLER INSTITUTIONS
14 THAT, ALTHOUGH OUR GRANTS WERE ABOUT 75 MILLION
15 APIECE, GETTING THE EXTRA MONEY BEYOND THAT WAS THE
16 CHALLENGE.

17 MR. SERRANO-SEWELL: THAT WAS IT. THAT
18 WAS EXACTLY IT.

19 DR. MILLAN.

20 DR. MILLAN: THANK YOU SO MUCH. I DON'T
21 WANT TO TAKE UP TIME IF OTHER MEMBERS WANT TO FIRST
22 PIPE IN. BUT THERE WERE JUST THREE TOPICS THAT I
23 WANTED TO BRING UP ONLY BECAUSE I THINK THEY'LL BE
24 CRITICAL IN TERMS OF WHAT NEEDS TO BE DONE IN ORDER
25 FOR US TO BE ABLE TO BRING SOMETHING TO THE BOARD.

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1 SO IF I MAY.

2 CHAIRMAN TORRES: PLEASE.

3 DR. MILLAN: SEAN, WITH YOUR PERMISSION
4 TOO, I'M JUST GOING TO BRING THESE THREE THINGS UP.
5 OKAY?

6 DR. TURBEVILLE: CERTAINLY.

7 DR. MILLAN: MARIA BONNEVILLE IS THERE SO
8 SHE CAN ALSO ADVISE US ON PROCESS.

9 I'D LIKE TO START OFF WITH A PROCESS ISSUE
10 WHICH WAS BROUGHT UP. I THINK THE QUESTION WAS WHO
11 IS GOING TO MAKE THE DECISION. LET'S SAY THE BOARD
12 APPROVES THIS. IT SOUNDS LIKE A GREAT IDEA.
13 THERE'S AN RFP. THEN WE HAVE APPLICANTS FOR THIS
14 RFP AND THEN IT GETS ADJUDICATED. I WANTED TO JUST
15 MAKE SURE THAT -- THAT'S CRITICAL, RIGHT, SO WE CAN
16 BRING SOMETHING TO THE BOARD. BUT ONCE IT'S
17 APPROVED, WE'LL BE SOLICITING RFP'S, AND THEN IT HAS
18 TO GO THROUGH AN EVALUATION AND APPROVAL PROCESS.

19 SO I DO BELIEVE WE DRAFTED A PROCESS THAT
20 I'D LIKE MARIA TO JUST, IF IT'S OKAY, ART, FOR MARIA
21 TO REMIND THE TEAM WHAT THAT KIND OF LOOKS LIKE AS A
22 DRAFT AND MAKE SURE WE ARE ALL ON THE SAME PAGE ON
23 THAT. MARIA, DO YOU MIND?

24 MS. BONNEVILLE: NO, IF I CAN REMEMBER
25 CORRECTLY.

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1 DR. MILLAN: YOU HAD A REALLY NICE
2 FLOWSHEET.

3 MS. BONNEVILLE: THANKS FOR THE HEADS-UP.

4 CHAIRMAN TORRES: JUST TAKE SOME TIME, AND
5 WE'LL COME BACK TO YOU.

6 DR. MILLAN: I CAN ACTUALLY -- IF YOU
7 DON'T MIND, MARIA, THIS IS WHAT I REMEMBER, AND YOU
8 CAN CORRECT ME IF THAT'S OKAY BECAUSE I DON'T WANT
9 TO PUT YOU ON THE SPOT.

10 MS. BONNEVILLE: WHAT I RECALL IS THE RFP,
11 THE AAWG IS ACTUALLY THE BODY THAT REVIEWS THE
12 PROPOSALS THAT COME IN AND MAKES THE RECOMMENDATION
13 AS TO WHICH ONE TO GO FORWARD WITH. AND THEN IT
14 GOES TO THE BOARD FOR THE FINAL THUMBS UP. IS THAT
15 WHAT YOU REMEMBER?

16 DR. MILLAN: YES, IT IS, MARIA.

17 CHAIRMAN TORRES: AS A COMPARISON, WE'LL
18 BE OFF-ROADING LIKE A GRANTS REVIEW GROUP.

19 MS. BONNEVILLE: CORRECT.

20 CHAIRMAN TORRES: AND THEN REVIEW THOSE
21 PROPOSALS THAT COME IN WITH THE INPUT FROM ALL OUR
22 INCREDIBLE MEMBERS OF THIS GROUP AND THEN MAKE THAT
23 RECOMMENDATION OR RECOMMENDATIONS TO THE FULL BOARD
24 FOR THEIR APPROVAL.

25 DR. MILLAN: SO OUR TEAM WILL MAKE SURE,

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1 UNDER SEAN'S LEADERSHIP, THAT WE BRING MATERIALS TO
2 YOU SO YOU CAN EVALUATE TO THE BEST OF YOUR ABILITY,
3 BUT YOU WILL BE THE RECOMMENDING BODY TO THE BOARD.

4 SO IN TERMS OF THAT CONCERN THAT YOU
5 BROUGHT UP, DAVID, IN TERMS OF MAKING SURE THAT WE
6 ARE REASONABLE, WE MAY HAVE ALL THESE ASPIRATIONS,
7 BUT WHAT'S REALLY IMPORTANT, IT WILL BE UP TO THE
8 AAWG TO DETERMINE THAT AND MAKE THOSE DETERMINATIONS
9 AS THEY MAKE RECOMMENDATIONS.

10 THE SECOND THING IS DR. PADILLA'S COMMENT
11 ABOUT THE IMPORTANCE OF THE COMMUNITY AND NOT BEING
12 OVERLY CENTRALIZED TO THE -- THAT MAY DETER US FROM
13 BEING ABLE TO SERVE THE COMMUNITY, AND SHE BROUGHT
14 UP THE COMMUNITY. AND, DR. PADILLA, YOU BROUGHT UP
15 THE COMMUNITY CARE CENTERS OF EXCELLENCE. I JUST
16 WANT TO MAKE SURE THAT WE TRY TO TAKE THIS IN THE
17 CONTEXT IN TERMS OF SEQUENCING AND TIMELINEWISE.

18 SO THE COMMUNITY CARE CENTERS OF
19 EXCELLENCE CONCEPT PROPOSAL WILL NOT EVEN BE
20 SOMETHING THAT IS -- IT'S SOMETHING THAT'S GOING TO
21 BE DEVELOPED. AS SEAN HAD ALLUDED TO, HE'LL BE
22 BRINGING IT TO THIS BODY FOR INPUT. THERE MAY BE
23 WORKSHOPS OR ADDITIONAL INPUT IN TERMS OF WHAT THAT
24 REALLY LOOKS LIKE. HOWEVER, I DO BELIEVE SEAN AND I
25 AND THE TEAM HAVE BEEN TALKING ABOUT WE WANT TO

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1 ABSOLUTELY ENSURE THAT, AS WE ROLL OUT THIS PROGRAM,
2 THAT THIS WILL BE COMPATIBLE WITH SUPPORTING. SO IT
3 WILL BE DRIVEN FROM THE COMMUNITY CARE CENTERS SIDE
4 OF IT, IF YOU WILL, WHICH HAS A LOT MORE FUNDING
5 OBVIOUSLY THAT CAN BE ATTACHED TO THAT. SO I JUST
6 WANTED TO BRING THAT UP, DR. PADILLA.

7 DR. LEVINE: DR. MILLAN, ON THAT TOPIC,
8 NOT TO BE A CONTRARIAN, BUT REALLY JUST TO RAISE THE
9 QUESTION, SOME OF THESE THERAPIES REQUIRE A HUGE
10 AMOUNT OF INTENSITY AND ACCESS TO SPECIALIZED
11 INPATIENT CAPABILITIES. WE JUST NEED TO MAKE SURE
12 WE MATCH UP VERY CAREFULLY WHAT THE CLINICAL
13 COMMUNITY FEELS IS --

14 DR. MILLAN: ABSOLUTELY. PATIENTS FIRST.
15 SO QUALITY HEALTHCARE, QUALITY CLINICAL TRIALS,
16 QUALITY HEALTHCARE DELIVERY IS GOING TO BE PARAMOUNT
17 TO ANYTHING WE DO, BUT IT'S JUST A MATTER OF HOW IT
18 ALL GETS INTEGRATED AND THE FLOW OF ACCESS, AND THE
19 FLOW OF OPPORTUNITIES CAN FLOW FROM THE COMMUNITY
20 VIA THE BACK AND FORTH FROM THE ACADEMIC CENTERS.

21 I GUESS MY MAJOR REASON FOR BRINGING IT UP
22 IS THAT WE DON'T HAVE THAT ALL FIGURED OUT YET, AND
23 YOU WILL SEE ALL THAT, AND YOU WILL HAVE A CHANCE TO
24 COMMENT ON THAT, DR. LEVINE, IN TERMS OF -- AS WELL
25 AS OTHERS, OBVIOUSLY, ON THIS COMMITTEE AND EXTERNAL

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1 EXPERTS IN TERMS OF THE BEST STRUCTURE AND
2 FEASIBILITY OF WHATEVER GETS PROPOSED FOR STRUCTURE
3 FOR COMMUNITY CARE CENTERS OF EXCELLENCE.

4 IF I MAY, THE THIRD THING, IF IT'S OKAY,
5 AND I'M GOING TO LEAVE THE STAGE BECAUSE I THINK
6 THAT IT'S MORE IMPORTANT THAT EVERYBODY HAVE THIS
7 CONVERSATION, BUT I WANTED TO JUST BRING IT UP
8 BECAUSE I DO BELIEVE THESE ARE CRITICAL GATING
9 ITEMS. IF WE TAKE IT ON, IT COULD INHIBIT US FROM
10 BEING ABLE TO COME UP WITH SOMETHING FOR THE VARIOUS
11 REASONS THAT I BROUGHT UP.

12 THE THIRD THING, DR. GOLDSTEIN, IS
13 CRITICAL. AND THAT IS YOU'RE ABSOLUTELY RIGHT. WE
14 HAVE A DIVERSE PORTFOLIO OF 80 CLINICAL TRIALS, NOT
15 ALL OF THEM ARE ACTIVE, MAYBE THERE ARE 45, 50
16 RECRUITING. I'LL HAVE TO ASK DR. CREASEY FOR THE
17 EXACT NUMBERS. BUT WE HAVE A SIGNIFICANT NUMBER OF
18 TRIALS THAT PROCESS ACROSS INDICATIONS AND
19 TECHNOLOGY PLATFORMS. BUT I WANTED TO BRING UP THE
20 IDEA THAT WHAT IS BEING PROPOSED ON THE PATIENT
21 ASSISTANCE PROGRAM, IT PROPOSES -- IT'S NOT A
22 DISEASE-SPECIFIC NEEDS PER SE. THEY ARE
23 CROSSCUTTING NEEDS ACROSS TO ADDRESS ACCESS TO
24 COMMUNITIES. SO THEY'RE CROSSCUTTING SOCIAL
25 DETERMINANTS, THEY'RE CROSSCUTTING NEEDS OF

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1 UNDERSERVED POPULATIONS, OR JUST CROSSCUTTING NEEDS
2 OF THE POPULATION OR THE COMMUNITY AT LARGE FOR
3 BEING ABLE TO PARTICIPATE IN THESE TRIALS.

4 SO I HOPING THAT ONE OF THE THINGS THAT I
5 WANTED TO JUST SAY IS I DO BELIEVE THAT THE PROPOSED
6 STRUCTURE AND SOME OF THE SCOPE THAT'S BEING
7 DISCUSSED TODAY WOULD BE RELEVANT ACROSS DISEASE
8 INDICATIONS AND ACROSS TRIALS. SO THOSE ARE JUST MY
9 THREE STATEMENTS, SENATOR TORRES, AND I WILL JUST
10 MUTE MYSELF.

11 CHAIRMAN TORRES: THANK YOU, DR. MILLAN.
12 I SEE ADRIENNE SHAPIRO, YOU HAD YOUR HAND
13 UP.

14 MS. SHAPIRO: YES. I WANT TO THANK YOU
15 FOR THAT CLARIFICATION BECAUSE I SAW THE CENTERS,
16 AND I WAS LIKE, OH, MY GOD. WE HAVE TO DEFINE THEM.
17 WERE WE HAVING OVERSIGHT? ARE WE DOING SPOKEN WILL
18 MODELS? SO THAT'S SOMETHING THAT MADE MY STOMACH
19 TURN. I WAS LIKE HOW ARE YOU GOING TO DO ALL THAT
20 IN ENOUGH TIME.

21 I GUESS THE OTHER QUESTION I HAVE, AND
22 MAYBE THAT WILL COME LATER IN THE RFP, WILL WE BE
23 RESPONSIBLE OR WILL THERE BE SOME KIND OF GUIDELINES
24 FOR GEOGRAPHICAL LOCATIONS? AND IS THAT SOMETHING
25 THAT WE HAVE TO LOOK AT NOW?

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1 CHAIRMAN TORRES: I THINK IN RESPONSE TO
2 THAT QUESTION, ADRIENNE, WE AS A WORKING GROUP, WHEN
3 WE'RE REVIEWING THE GRANTS, WE ESPECIALLY
4 CONCENTRATE ARE THESE GRANTS COMING FORWARD WITH
5 ENOUGH DIVERSITY IN THE PEOPLE THAT THEY'RE GOING TO
6 CALL ON FOR CLINICAL TRIALS. SO THAT WORKING GROUP
7 REALLY ADDRESSES THE GRANTS ON A CASE-BY-CASE BASIS.
8 I THINK THAT'S GOING TO BE THE CASE HERE. WE ARE
9 NOT GOING TO BE SUPPORTIVE OF PROPOSALS THAT DON'T
10 TAKE INTO ACCOUNT THE GEOGRAPHIC AND ETHNIC AND
11 RACIAL DIVERSITY OF THE STATE AND HAVING THOSE
12 PEOPLE HAVE ACCESS TO THOSE TRIALS.

13 I THINK THAT SPEAKS TO -- I KNOW YOU'RE
14 FAMILIAR WITH IT AND I KNOW ANN IS FAMILIAR WITH
15 SENATOR PORTANTINO'S BILL, I THINK IT'S SB 97, WHICH
16 TALKS ABOUT THAT VERY ISSUE. SO, YES, WE ARE GOING
17 TO BE SENSITIVE TO THAT.

18 MS. SHAPIRO: OKAY. AND THE OTHER THING
19 THAT KEEPS COMING IN MY MIND IS I HEAR US TALKING
20 ABOUT REIMBURSEMENT; BUT WHEN WE TALK ABOUT
21 REIMBURSEMENT FOR THINGS LIKE TRAVEL, IS THAT IN THE
22 SENSE IT'S REIMBURSEMENT, JUST COVERAGE OF COSTS, OR
23 IS IT REALLY ACTUALLY REIMBURSEMENT FOR, I'LL SAY,
24 THE PATIENT OR THE PARTICIPANT BECAUSE THAT'S REALLY
25 AN ISSUE TOO WITH A LOT OF THE PEOPLE?

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1 CHAIRMAN TORRES: WE ARE NOT ALLOWED UNDER
2 THE CONSTITUTIONAL INITIATIVE TO PROVIDE FOR
3 REIMBURSEMENT FOR SALARIES. WE ARE ONLY ALLOWED TO
4 REIMBURSE THOSE ISSUES THAT YOU SEE ON THE SLIDE
5 THAT SEAN PUT UP. AND I THINK THE PROCESS FOR DOING
6 THAT WILL BE HOW THE PROPOSERS TO ANY RFP SET OUT
7 HOW TO DO IT AND WE EVALUATE IT.

8 MS. SHAPIRO: THANK YOU.

9 CHAIRMAN TORRES: THANK YOU.

10 ANYONE ELSE HAVE THEIR HAND UP? SEAN, YOU
11 WANT TO CONTINUE.

12 DR. TURBEVILLE: CERTAINLY. SO JUST TO
13 SUMMARIZE REAL QUICKLY. I DID HEAR A COUPLE OF
14 THINGS.

15 CHAIRMAN TORRES: HOLD ON. PAT LEVITT HAD
16 HIS HAND UP, AND I FORGOT TO CALL HIM.

17 DR. LEVITT: I'M NOT CLEAR ABOUT THE
18 GEOGRAPHIC COMPONENTS. SO PATIENT FIRST. SO IT'S
19 GOING TO BE DEPENDENT IN LARGE PART ON WHERE THE
20 CLINICAL TRIALS ARE BEING DONE AND WHERE THE HIGHLY
21 COMPLEX PROTOCOLS ARE BEING ADMINISTERED. AND SO
22 THE QUESTION IS WHETHER THAT REQUIREMENT -- IS THERE
23 A REQUIREMENT OF WHERE IT'S DONE? IS THERE A
24 REQUIREMENT OF ACCEPTING --

25 CHAIRMAN TORRES: THERE ARE NO

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1 REQUIREMENTS, PERIOD, YET BECAUSE WE DON'T HAVE ANY
2 PROPOSALS BEFORE US TO EVALUATE.

3 DR. LEVITT: I UNDERSTAND THAT.

4 CHAIRMAN TORRES: I THINK THAT WHAT NEEDS
5 TO HAPPEN IS THAT ONCE WE PUT OUT THE RFP'S, KEEP IN
6 MIND, AND I WANT TO REMIND THE MEMBERS OF THIS
7 WORKING GROUP, WE ARE THE ONES THAT ARE GOING TO
8 EVALUATE THOSE PROPOSALS. AND THAT'S WHERE YOUR
9 QUESTIONS ARE GOING TO BE SO RELEVANT, PAT.

10 DR. LEVITT: OKAY.

11 CHAIRMAN TORRES: SEAN.

12 DR. TURBEVILLE: THANK YOU. I JUST WANT
13 TO RECAP REAL QUICKLY WHAT I HEARD FROM ALL THESE
14 COMMENTS BECAUSE OBVIOUSLY THIS IS RECORDED AND I'LL
15 GO BACK AND LISTEN TO IT.

16 ONE, REALLY SETTING UP A PROGRAM THAT HAS
17 FLEXIBILITY, NOT ONLY COVERS THE THERAPEUTIC AREAS
18 THAT MARIA JUST MENTIONED IN OUR CLINICAL TRIALS,
19 BUT HAVING THE ABILITY WITH THE METRICS TO BE ABLE
20 TO PIVOT, IF WE NEED TO, TO ADD IN ADDITIONAL LAYERS
21 OF SERVICES IF WE NEED TO. HARLAN MENTIONED
22 BEHAVIORAL. I DID NOT THINK ABOUT THAT. THERE ARE
23 PROGRAMS OUT THERE THAT DO PROVIDE THOSE SERVICES.
24 WE TALKED ABOUT ACCESSIBILITY AS WELL MORE AT THE
25 COMMUNITY CLINIC SIDE. FURTHERMORE, WE TALKED ABOUT

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1 GUIDELINES THAT I'VE HEARD ABOUT. CERTAINLY
2 FAMILIAR WITH THOSE AND WITH THE FDA IN TERMS OF
3 BEST PRACTICES.

4 SO CERTAINLY TAKING NOTES HERE.

5 MOVING ON TO THE NEXT SLIDE, WE DID TAKE A
6 STAB, I'D SAY WE DID ABOUT 80 PERCENT OF THE THINGS
7 THAT WE DISCUSSED TODAY. IN ADDITION TO THE NOTES,
8 WE WILL UPDATE THIS, BUT THIS SLIDE ADDRESSES THE
9 RFP CONCEPT THAT WE'RE GOING TO START DEVELOPING. I
10 DON'T KNOW IF YOU WANT ME TO GO THROUGH EACH ONE OF
11 THESE, BUT I THINK FOR THE MOST PART -- ACTUALLY LET
12 ME DO THAT BECAUSE I THINK IT WILL RESONATE WITH
13 MANY OF THE COMMENTS WE HAD TODAY.

14 CHAIRMAN TORRES: YES.

15 DR. TURBEVILLE: THANK YOU. ONE, OPEN THE
16 RFP TO PROFIT AS WELL AS NONPROFIT AND PATIENT
17 ADVOCACY ORGANIZATIONS. AS I MENTIONED EARLIER, IN
18 THE LAST FOUR WEEKS, I WAS REALLY IMPRESSED WITH
19 SOME OF THE PATIENT ADVOCACY ORGANIZATIONS THAT HAVE
20 SOME REALLY ROBUST PROGRAMS. SO WE DEFINITELY WANT
21 TO OPEN THE RFP FOR THEIR OPPORTUNITY.

22 WE DO WANT TO EMPHASIZE A HIGH-TOUCH,
23 SINGLE POINT OF CONTACT. THIS GOES TO THE METRICS
24 AND TO THE HUBS AND MAKING SURE THAT WE GET ALL THE
25 INFORMATION TO MAKE DECISIONS AS WE'RE MOVING

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1 THROUGH THIS FIVE-YEAR PROCESS. AND ALSO TO HAVE
2 THE CONTENT CENTRALLY MANAGED.

3 WE WILL FOCUS ON FINANCIAL SERVICES THAT
4 DIRECTLY SUPPORT PATIENT PARTICIPANTS IN CIRM
5 TRIALS.

6 WE WILL SEEK ADDITIONAL RECOMMENDATIONS ON
7 FINANCIAL CATEGORIES AND LIMITS. THAT IS A TOPIC
8 FOR DISCUSSION. THAT'S OUTSIDE OF CIRM, TO BE
9 HONEST WITH YOU. THERE'S A LOT OF MOVEMENT RIGHT
10 NOW ABOUT WHAT THAT BENCHMARK IS. WE'RE DOING THAT
11 GAP ANALYSIS, AND WE'LL PROVIDE SOME ADDITIONAL
12 INTEL IN FUTURE AAW MEETINGS.

13 OBVIOUSLY WE WILL AVOID AT ALL COST THE
14 DUPLICATE COSTS WITHIN OUR PROGRAMS.

15 EXPERIENCED PATIENT NAVIGATORS TO CONSIDER
16 PATIENT AS WELL AS CAREGIVER NEEDS. I THINK THAT
17 WAS MENTIONED EARLIER.

18 FINANCIAL SUPPORT FOR ALL INSURANCE TYPES.
19 WE WILL FOCUS SPECIFICALLY ON MEDICARE, UNINSURED,
20 AS WELL AS THE UNDERINSURED. AND AGAIN, AS HARLAN
21 MENTIONED, THOSE NEEDS ARE A LITTLE BIT DIFFERENT
22 DEPENDING ON THE TYPE OF INSURANCE AND PATIENT
23 POPULATION.

24 WE'VE HEARD OVER AND OVER AGAIN ABOUT THE
25 EXPERTISE IN RARE DISEASES.

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1 TECHNOLOGY ENABLED FOR DATA AS WELL AS THE
2 ANALYTICS.

3 CULTURAL ADAPTATIONS AND TRANSLATION.
4 EVERY SINGE CALL CENTER THAT I'VE SET UP, THAT IS
5 ACTUALLY A TRAINING REQUIREMENT, NOT ONLY ON
6 LANGUAGE CAPABILITIES, MULTIPLE LANGUAGE
7 CAPABILITIES, BUT ALSO UNDERSTANDING THE CULTURAL
8 DIFFERENCES WITH RESPECT TO PATIENTS AND THEIR
9 FAMILY MEMBERS THAT WILL BE CALLING IN.

10 FINALLY, AND THIS IS WHAT MARIA DISCUSSED,
11 THE OPPORTUNITY FOR THE SITE OF CARE COORDINATION
12 AND ABILITY TO COMPLEMENT THE ALPHA CLINICS AND
13 COMMUNITY CARE CENTERS OF EXCELLENCE.

14 SO THAT WAS OUR FIRST STAB IN ADDITION TO
15 THE COMMENTS THAT WE RECEIVE TODAY. WE WILL UPDATE
16 THIS.

17 I THINK THE NEXT STEP IS THAT WE ARE STILL
18 FOCUSED ON THIS FIVE-YEAR TRAJECTORY. THERE'S
19 NOTHING THAT'S SYSTEMATICALLY CHANGED ON THIS
20 PROJECTION.

21 CHAIRMAN TORRES: RIGHT. WE ALSO NEED TO
22 MAKE SURE THAT ONCE WE HAVE SOME PROPOSALS THAT WE
23 WOULD, RATHER DRAFTS OF RFP'S, I WOULD REALLY
24 APPRECIATE THAT THE WORKING GROUP BE GIVEN ACCESS TO
25 THAT FOR THEIR INPUT IN CASE WE'VE LEFT ANYTHING

1 OUT.

2 DR. TURBEVILLE: THANK YOU.

3 I WANT STRESS TEST TO SEE IF THIS
4 RESONATES WITH EVERYBODY. ONE, WE'D LIKE TO PRESENT
5 A FINAL CONCEPT PLAN BASED ON THESE COMMENTS, DIGEST
6 ALL THIS INFORMATION, COME BACK TO YOU, I THINK, ON
7 AUGUST 2D WITH A MUCH MORE POLISHED RFP PROPOSAL AND
8 GET YOUR INPUT. UPON YOUR RECOMMENDATION, IF WE
9 HAVE TO TWEAK ANYTHING AT THAT POINT, GET THE GREEN
10 LIGHT TO PRESENT TO THE ICOC ON SEPTEMBER 29TH OR
11 POSSIBLY EARLIER, I'LL THROW THAT OUT THERE, BUT I
12 THINK THAT'S PUSHING THINGS ON THE SPEED FRONT.
13 WITH THAT, LET ME PAUSE HERE TO SEE IF THERE'S ANY
14 OTHER ADDITIONAL COMMENTS OR RECOMMENDATIONS.

15 CHAIRMAN TORRES: OF COURSE I HAVE SOME
16 ADDITIONAL COMMENTS. PEOPLE SAY HURRY UP, WHY IS
17 THIS BEING DELAYED, ETC., ETC. THOSE ARE LEGITIMATE
18 CONCERNS, AND I'M VERY SENSITIVE TO THAT. BUT LET'S
19 ALSO KEEP IN MIND, AND NOT EVERYBODY IN THE WORKING
20 GROUP WILL KNOW THE BACKGROUND STORY HERE, IF I HAD
21 NOT INTERVENED AND IF WE HAD NOT INTERVENED WITH THE
22 DEPARTMENT OF FINANCE TO PUT THIS LANGUAGE TO
23 APPROVE AT LEAST THE FIRST 600,000 OF THIS MONEY
24 INTO THE BUDGET, WE WOULD HAVE TO HAVE WAITED TILL
25 JANUARY 1 OF 2023 TO EVEN BEGIN THE DISCUSSIONS OF

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1 HOW TO CREATE A PROGRAM ON HOW TO SPEND THIS MONEY.

2 SO I THINK THAT WE'RE ACCELERATING THIS
3 PROGRAM AS QUICKLY AS WE CAN, BUT KEEP IN MIND, IF
4 WE HAD NOT INTERVENED EARLY ON IN THIS CURRENT
5 BUDGET, WHICH WAS APPROVED ON JUNE 15TH, WE WOULD
6 HAVE HAD TO HAVE WAITED FOR THE OTHER BILLS TO TAKE
7 EFFECT, WHICH WOULDN'T HAVE BEEN UNTIL JANUARY 1 OF
8 2023. I KNOW WE'RE GOING TO MOVE AT ALL DELIBERATE
9 SPEED, AND I JUST WANT TO ASK FOR THE PUBLIC'S
10 PATIENCE AND ADVOCATES' PATIENCE ON THIS. THIS IS
11 OUR FIRST TIME IN TRYING TO CONFRONT THIS, AND THERE
12 ARE MANY CHALLENGES, AND WE'LL GET THROUGH IT. BUT
13 I JUST WANT TO MAKE SURE THAT, AS WE DO THAT, WE
14 KEEP THE PROCESS TRANSPARENT, NO. 1; AND, NO. 2,
15 THAT WE RECEIVE AS MUCH INPUT AS POSSIBLE IN RESPECT
16 TO THE NATURE AND THE SCOPE OF ANY RFP'S. AND,
17 THEREFORE, THAT WILL HAVE A LOT TO DO WITH THE
18 EVALUATION PROCESS THAT WE AS A GROUP WILL DO WHEN
19 WE FINALLY MAKE OUR FINAL RECOMMENDATIONS TO THE
20 FULL BOARD. THANK YOU. GO AHEAD.

21 DR. TURBEVILLE: I THINK WE HAVE SOME MORE
22 QUESTIONS. I THINK HARLAN HAS HIS HAND UP.

23 CHAIRMAN TORRES: HARLAN, I SEE YOUR HAND
24 UP.

25 DR. LEVINE: SEAN, THANK YOU AND, SENATOR,

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1 THANK YOU. THREE QUICK COMMENTS.

2 ON THE SLIDE THAT MENTIONED PAYER GROUPS,
3 I DID NOT SEE MEDI-CAL. I KNOW WE TALKED ABOUT IT.
4 SO IF THAT'S MISSING, WE WOULD REINSERT. I'M NOT
5 EVELYN WOOD, SO I MIGHT HAVE JUST NOT READ IT IN
6 TIME. NO. 1.

7 NO. 2, I REALLY LIKE THE COMMENT ABOUT NOT
8 DUPLICATING COSTS. IT'S GOING TO GET TRICKY BECAUSE
9 WE HAVE A GROWING -- WELL, EVERYONE IN MEDI-CAL IS
10 PART OF A MANAGED CARE PROGRAM WHERE SOME OF THESE
11 SERVICES SHOULD BE COVERED. AND THEN AS PEOPLE MOVE
12 TO MEDICARE ADVANTAGE, SOME SHOULD BE COVERED AS
13 WELL. YOU DON'T NEED TO GET AS FORMAL AS
14 DELINEATION OF FINANCIAL RESPONSIBILITY, BUT I THINK
15 WE OUGHT TO FIGURE OUT LET'S NOT DOUBLE INVEST IN
16 SOMETHING IF WE'RE ALREADY PAYING FOR THOSE
17 SERVICES.

18 AND THE THIRD ONE IS --

19 CHAIRMAN TORRES: ON THAT POINT, HARLAN,
20 IF YOU LOOK AT BULLET NO. 5 ON PAGE 6 OF SEAN'S
21 PRESENTATION, IT SAYS TO UPDATE MEDI-CAL PHYSICIAN
22 REIMBURSEMENT TO IMPROVE ACCESSIBILITY.

23 DR. LEVINE: RIGHT. RIGHT. AGREE. THAT
24 MAY BE HARD TO DO, BUT I THOUGHT IT WAS A WORTHY
25 ASPIRATION TO DO THAT.

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1 CHAIRMAN TORRES: RIGHT. RIGHT.

2 DR. LEVINE: AND THEN THE LAST COMMENT I
3 WOULD MAKE IS WE SHOULD BE PRESCRIPTIVE WHEN -- WE
4 CAN TALK ABOUT THIS ON THE FINAL -- NEXT MEETING,
5 BUT, AS I SAID, I THINK THE POPULATION OF THE
6 SEGMENTS ARE SO DIFFERENT, WE SHOULD BE VERY, VERY
7 PRESCRIPTIVE OR SPECIFIC WITH RFP APPLICANTS. DO
8 THEY HAVE TO APPLY ACROSS THE ENTIRE POPULATION OR
9 CERTAIN SUBSEGMENTS BECAUSE THERE MAY BE VENDORS
10 THAT ARE VERY GOOD AT SOME AND NOT IN OTHERS, AND WE
11 JUST NEED TO TAKE THAT ALL INTO CONSIDERATION.

12 CHAIRMAN TORRES: EXCELLENT POINT. AGAIN,
13 I JUST WANT TO REITERATE THAT AS THIS PROCESS
14 EVOLVES, AND I KNOW MANY OF YOU MAY NOT HAVE BEEN
15 SIGNING UP FOR SUCH A LOT OF HARD WORK, BUT I JUST
16 VALUE YOUR INPUT. AND SO YOU WILL BE PART OF THIS
17 PROCESS, AND IT'S GOING TO TAKE SOME TIME. SO,
18 AGAIN, I WANT TO THANK YOU ALL FOR VOLUNTEERING YOUR
19 TIME TO DO THIS. AND I KNOW YOU'RE ALL DOING IT
20 BECAUSE OF YOUR PASSION AND COMMITMENT TO PATIENTS.

21 SEAN, ANYTHING ELSE YOU WANT TO ADD BEFORE
22 WE SIGN OFF?

23 DR. TURBEVILLE: NO, SIR. THAT'S IT.
24 THANK YOU.

25 CHAIRMAN TORRES: DR. MILLAN, ANYTHING?

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1 DR. MILLAN: IT WAS AN EXCELLENT MEETING.
2 THANK YOU FOR THE INPUT. I THINK THAT WHEN WE BRING
3 SOMETHING BACK, AGAIN, WE'RE GOING DO OUR VERY BEST.
4 SEAN IS REALLY WORKING HARD ON THIS, BUT WE'RE GOING
5 TO MAKE SURE THAT THE STRUCTURE IS RIGHT, THAT IT'S
6 THE CORRECT THING TO BRING TO THE BOARD FOR APPROVAL
7 IN SEPTEMBER.

8 CHAIRMAN TORRES: J.T., DID YOU HAVE
9 ANYTHING TO ADD?

10 CHAIRMAN THOMAS: NO. I THINK IT'S BEEN A
11 VERY ROBUST DISCUSSION, WELL LED BY YOU AS ALWAYS,
12 AND I THINK WITH THE INPUT OF THE GROUP, WE ARE
13 HOMING IN ON A GREAT GAME PLAN TO IMPLEMENT FOR THIS
14 FIRST TRANCHE OF MONEY. THANK YOU TO EVERYBODY.

15 CHAIRMAN TORRES: THANK YOU, J.T. THANK
16 YOU ALL. AS PROMISED, I'M TRYING TO KEEP THESE
17 MEETINGS TO AN HOUR BECAUSE I KNOW HOW VALUABLE THE
18 TIMES ARE OF ALL OUR PARTICIPANTS. SO, AGAIN, THANK
19 YOU FOR BEING WITH US, AND WE'LL GET BACK TO YOU.

20 (THE MEETING WAS THEN CONCLUDED AT 2:58
21 P.M.)

22
23
24
25

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 JUNE 21, 2022, 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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