

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: OCTOBER 9, 2023
2 P.M.

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

FILE NO.: 2023-31

**133 HENNA COURT, SANDPOINT, IDAHO 83864
208-920-3543 DRAIBE@HOTMAIL.COM**

BETH C. DRAIN, CA CSR NO. 7152

I N D E X

ITEM DESCRIPTION	PAGE NO.
OPEN SESSION	
1. CALL TO ORDER	3
2. ROLL CALL	3
3. CONSIDERATION OF COMMUNITY CARE CENTERS OF EXCELLENCE (CCCE) CONCEPT PLAN	5
4. PUBLIC COMMENT	NONE
5. ADJOURNMENT	44

BETH C. DRAIN, CA CSR NO. 7152

OCTOBER 9, 20/23; 2 P.M.

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25

CHAIRPERSON BONNEVILLE: WHY DON'T WE GET STARTED AND HOPEFULLY WE HAVE ONE MORE MEMBER JOIN. WE ARE JUST ONE SHORT OF QUORUM RIGHT NOW, BUT I THINK WE CAN GET STARTED AND GO FROM THERE. SO DO YOU WANT TO START THE RECORDING. GREAT. THANK YOU.

I'D LIKE TO CALL THIS MEETING TO ORDER. DOUG, CAN YOU PLEASE TAKE THE ROLL.

MR. GUILLEN: KIM BARRETT. DAN BERNAL.

MR. BERNAL: PRESENT.

MR. GUILLEN: MARIA BONNEVILLE.

CHAIRPERSON BONNEVILLE: PRESENT.

MR. GUILLEN: ANN BOYNTON.

MS. BOYNTON: PRESENT.

MR. GUILLEN: JAMES DEBENEDETTI.

MR. DEBENEDETTI: HERE.

MR. GUILLEN: DANA DORNSIFE. TED GOLDSTEIN.

DR. GOLDSTEIN: PRESENT.

MR. GUILLEN: DAVID HIGGINS.

DR. HIGGINS: PRESENT.

MR. GUILLEN: VITO IMBASCIANI.

CHAIRMAN IMBASCIANI: PRESENT.

MR. GUILLEN: DARIUS LAKDAWALLA. HARLAN

BETH C. DRAIN, CA CSR NO. 7152

1 LEVINE. HE WAS ON HERE JUST A MOMENT AGO.
2 DR. LEVINE: HERE.
3 MR. GUILLEN: PAT LEVITT.
4 DR. LEVITT: PRESENT.
5 MR. GUILLEN: ADRIANA PADILLA.
6 DR. PADILLA: HERE.
7 MR. GUILLEN: AMMAR QADAN. DAVID
8 SERRANO-SEWELL. MAHESWARI SENTHIL. ADRIENNE
9 SHAPIRO.
10 MS. SHAPIRO: HERE.
11 MR. GUILLEN: THANK YOU.
12 CHAIRPERSON BONNEVILLE: THANKS, DOUG.
13 BEFORE I TURN THIS OVER TO GEOFF, I WANTED
14 TO FIRST BRING YOU UP TO SPEED ON THE PATIENT
15 SUPPORT PROGRAM. SINCE OUR MEETING LAST IN JUNE,
16 THE CIRM TEAM HAS POSTED THE CIRM PATIENT SUPPORT
17 SERVICES RFA. IN AUGUST THE RFA WAS REVISED TO
18 INCLUDE SOME CLARIFICATIONS FOR APPLICATIONS, AND
19 THE APPLICATION WAS MADE AVAILABLE IN OUR GRANTS
20 MANAGEMENT SYSTEM. CORRESPONDINGLY, THE APPLICATION
21 DEADLINE WAS EXTENDED TO OCTOBER 31ST TO ALLOW
22 APPLICANTS ADEQUATE TIME TO PREPARE AND SUBMIT
23 RESPONSIVE APPLICATIONS TO THE RFA.
24 THE INTERNAL TEAM HAS ENGAGED 22 POTENTIAL
25 APPLICANT ORGANIZATIONS TO DESCRIBE THE PROGRAM AND

BETH C. DRAIN, CA CSR NO. 7152

1 ADDRESS QUESTIONS. A FREQUENTLY ASKED QUESTIONS
2 DOCUMENT IS POSTED ON THE CIRM WEBSITE. WE'VE
3 IDENTIFIED EXPERT REVIEWERS TO SUPPORT THE
4 APPLICATION EVALUATION PROCESS. AND THE INTERNAL
5 TEAM HAS BEEN WORKING ON GETTING ALL OF YOU
6 SCHEDULED FOR REVIEW TRAINING. SO HOW TO USE OUR
7 GRANTS MANAGEMENT SYSTEMS, WHAT TO EXPECT FROM THE
8 REVIEW, AND TO REVIEW THE APPLICATION ITSELF.

9 THE REVIEW IS ON FEBRUARY 8TH. YOU SHOULD
10 HAVE RECEIVED A MEETING INVITE FOR THAT DATE FROM
11 LANA. IF YOU DON'T HAVE IT ON YOUR CALENDAR, PLEASE
12 LET ME KNOW AND WE'LL FORWARD YOU THE MEETING
13 INVITE.

14 I WANT TO THANK THE MED AFFAIRS TEAM AND
15 BUSINESS DEVELOPMENT TEAM FOR ALL OF YOUR HARD WORK
16 ON THIS PROGRAM. AND I LOOK FORWARD TO GETTING THIS
17 UNDER WAY. SO THANK YOU.

18 AND NOW I'M GOING TO TURN IT OVER TO
19 GEOFF, WHO'S GOING TO WALK US THROUGH THE COMMUNITY
20 CARE CENTERS OF EXCELLENCE CONCEPT PROPOSAL.

21 DR. LOMAX: THANK YOU VERY MUCH. I AM
22 GOING TO BRING MY SCREEN UP. EVERYONE IS SEEING
23 THAT, I HOPE. VERY GOOD. THANK YOU VERY MUCH.

24 SO I'M GEOFF LOMAX. I'M ASSOCIATE
25 DIRECTOR FOR MEDICAL AFFAIRS AND POLICY AT CIRM AND

BETH C. DRAIN, CA CSR NO. 7152

1 WORKING WITH THE TEAM TO DEVELOP THIS CONCEPT PLAN.
2 AND VERY EXCITED TO BE ABLE TO PREVIEW IT TODAY AND
3 FOR YOUR FEEDBACK.

4 SO AS A REMINDER, OUR MISSION IS
5 ACCELERATING WORLD-CLASS SCIENCE TO DELIVER
6 TRANSFORMATIVE REGENERATIVE MEDICINE TREATMENTS IN
7 AN EQUITABLE MANNER TO A DIVERSE CALIFORNIA AND THE
8 WORLD. THIS CONCEPT IS CERTAINLY IN SERVICE OF THAT
9 MISSION IN A VERY SUBSTANTIAL WAY.

10 I WOULD LIKE TO RECAP THE HISTORY OF HOW
11 WE GOT TO THIS PHASE AND WHERE WE'RE GOING MOVING
12 FORWARD. SO IN OCTOBER THROUGH MARCH, STARTING
13 OCTOBER 2022 AND THROUGH THE SPRING, WE CONDUCTED A
14 SERIES OF LISTENING SESSIONS. AND WE'VE, IF YOU MAY
15 RECALL, PROVIDED YOU UPDATES TO THOSE SESSIONS ALONG
16 THE WAY. AND THAT WORK CULMINATED WITH A PUBLIC
17 WORKSHOP IN SACRAMENTO. AND, AGAIN, A NUMBER OF YOU
18 PARTICIPATED IN THE WORKSHOP. IT WAS BOTH VIRTUAL
19 AND LIVE. AND IT REALLY HELPED SHAPED THE NEEDS,
20 THE THINKING, AND THE OPPORTUNITIES TO DEVELOP THIS
21 PROGRAM IN A WAY CONSISTENT WITH ITS INTENT.

22 SO WE'VE SINCE THAT SACRAMENTO MEETING,
23 WE'VE PUT TOGETHER A DRAFT CONCEPT. AGAIN, THAT IS
24 NOW POSTED AND AVAILABLE FOR YOUR REVIEW. WE ARE
25 CONSULTING WITH THE VARIOUS WORKING GROUPS, ACCESS

BETH C. DRAIN, CA CSR NO. 7152

1 AND AFFORDABILITY TODAY, AND WE'LL MEET WITH THE
2 SCIENCE SUBCOMMITTEE IF YOU RECOMMEND WE DO THAT.
3 AND THEN THEY WOULD RECOMMEND -- FORWARD THAT
4 RECOMMENDATION TO THE BOARD SHOULD THEY MAKE THAT
5 DETERMINATION. AND THAT WOULD MOVE US INTO A PHASE
6 WHERE WE WOULD ANTICIPATE HAVING AN EARLY
7 APPLICATION IN EARLY 2024. AND I THINK AT THAT
8 POINT, HOPEFULLY, WE'D KNOW LATER IN THE YEAR WE'D
9 HAVE THOSE AWARDS, BUT WE HAVEN'T PROJECTED ALL
10 THOSE DATES OUT THAT FAR. BUT WE'RE LOOKING AT
11 EARLY 2024 TO HAVE APPLICATIONS OPEN SHOULD THE
12 PROCESS PROCEED AS I JUST DESCRIBED.

13 THERE WE GO. SO I WANT -- SORRY. I'M
14 JUST MOVING MY VIEW AROUND HERE SO I CAN SEE THE
15 SLIDE. VERY GOOD.

16 SO THE COMMUNITY CARE CENTERS OF
17 EXCELLENCE, AS A REMINDER, THEY'RE AN INFRASTRUCTURE
18 PROGRAM THAT ARE ACTUALLY CALLED OUT IN PROPOSITION
19 14. THEY ARE DESCRIBED AS GEOGRAPHICALLY DIVERSE
20 CENTERS OF EXCELLENCE WITH THE INTENT OF EXPANDING
21 ACCESS TO BOTH CIRM-FUNDED CLINICAL TRIALS AND
22 APPROVED THERAPIES SUPPORTED BY CIRM IN THE FUTURE.
23 AND A PRIMARY AIM IS TO ENHANCE ACCESS TO PATIENTS
24 REGARDLESS OF ECONOMIC MEANS AND GEOGRAPHIC
25 LOCATION.

BETH C. DRAIN, CA CSR NO. 7152

1 SO ONE OF THE THINGS THAT CAME UP IN
2 INTERACTIONS WITH A LOT OF DIFFERENT FOLKS,
3 INCLUDING MEMBERS OF THIS WORKING GROUP, WAS A
4 LITTLE BIT OF WHAT DO THESE CENTERS LOOK LIKE. SO
5 TYPICALLY, AND THIS IS THE ALPHA CLINICS, WHICH TO
6 SOME DEGREE THEY'RE MODELED AFTER, THESE CENTERS ARE
7 TEAMS. THEY'RE PERSONNEL. THEY ALSO INCLUDE
8 EQUIPMENT. BUT IT'S THESE TEAMS THAT ARE ABLE TO
9 REALLY ENGAGE IN A COLLECTIVE MISSION ACROSS THE
10 ORGANIZATION TO SUPPORT DELIVERY OF CELL AND GENE
11 THERAPY TREATMENTS AND TRANSLATE THEM INTO A
12 WORLD-CLASS SYSTEM CAPABLE OF DELIVERING REAL-WORLD
13 SOLUTIONS. SO IT'S THE PEOPLE THAT CAN MOVE THOSE
14 PATIENTS INTO CLINICAL RESEARCH AND REALLY SERVE THE
15 MISSION.

16 AND AS A REMINDER, THE BACKBONE OF THIS
17 SYSTEM AT THE MOMENT ARE OUR ALPHA CLINICS NETWORK.
18 AND WHAT YOU SEE IS -- THIS IS FROM OUR RECENT ALPHA
19 CLINICS SYMPOSIUM. THESE ARE SOME OF THE PEOPLE
20 THAT HELP MAKE THESE CENTERS POSSIBLE.

21 MORE SPECIFICALLY, AND THIS IS REALLY
22 MODELED AFTER WHAT A COMPLETE CENTER WOULD LOOK LIKE
23 THAT SPECIALIZES IN CELL AND GENE THERAPY RESEARCH,
24 IS THEY'RE TEAMS THAT OPERATE IN A NUMBER OF AREAS
25 AND THEY SUPPORT SPONSOR ENGAGEMENT, PATIENT

BETH C. DRAIN, CA CSR NO. 7152

1 EDUCATION. THERE'S A STRONG REGULATORY AND COVERAGE
2 ANALYSIS COMPONENT, REGULATORY IN PARTICULAR FOR
3 CELL AND GENE THERAPY PRODUCTS IS VERY DISTINCT FROM
4 TRADITIONAL MODES. PRODUCT MANAGEMENT, THAT WILL
5 INCLUDE EVERYTHING FROM MANUFACTURING TO HANDLING
6 PRODUCTS DEPENDING ON THE NEEDS. AND THERE'S A
7 CONSIDERABLE DATA MANAGEMENT COMPONENT OBVIOUSLY
8 BECAUSE WE ARE DEALING WITH CLINICAL RESEARCH.

9 SO I'M GOING TO TRANSITION NOW TO THE NEXT
10 COUPLE OF SLIDES THAT DESCRIBE SOME OF OUR
11 ACTIVITIES TO DATE. AGAIN, I MENTIONED THIS IN ONE
12 OF THE EARLIER SLIDES TO EMPHASIZE THESE ARE THE
13 LOCATIONS AND DATES OF OUR LISTENING SESSIONS. AND
14 I'D LIKE TO ACKNOWLEDGE EMILY REYES IN PARTICULAR ON
15 OUR TEAM WHO REALLY HELPED COORDINATE THE LOGISTICS
16 AND MAKE THESE EVENTS HAPPEN. AND, AGAIN, WE
17 PROVIDED A REPORT BACK IN YOUR DECEMBER, FEBRUARY,
18 AND MARCH MEETINGS FOR EACH OF THESE SESSIONS. SO
19 I'M NOT GOING TO GO INTO A LOT OF DETAIL THERE, BUT
20 WE DO HAVE MATERIALS FROM THOSE MEETINGS THAT
21 PROVIDE SOME OF THE SUBSTANCE THAT WE PULLED FROM
22 THESE MEETINGS. AND THEN, AGAIN, SACRAMENTO IN
23 JUNE.

24 THIS GIVES YOU A SENSE OF THE RANGE OF
25 ORGANIZATIONS THAT HAVE ENGAGED IN THE PROCESS.

BETH C. DRAIN, CA CSR NO. 7152

1 THEY INCLUDE ACADEMIC CENTERS, REGIONAL HOSPITALS,
2 MORE DISTRIBUTED REGIONAL CARE NETWORKS. AND SO ONE
3 OF THE THINGS WE REALLY TOOK AWAY IS THERE'S A LOT
4 OF EXCITEMENT AND INTEREST IN THIS PROGRAM AMONGST A
5 VERY DIVERSE GROUP OF STAKEHOLDERS IN THE CLINICAL
6 CARE COMMUNITY. SO WE'VE AIMED TO DRAFT A CONCEPT
7 PLAN IN A MANNER THAT IS RESPONSIVE TO THIS
8 DIVERSITY AND CAN ACCOMMODATE IT.

9 SO EARLIER I ALLUDED TO WORLD-CLASS
10 SYSTEMS CAPABLE OF DELIVERING REAL-WORLD SOLUTIONS.
11 SO I WANTED TO PUT THE COMMUNITY CARE CENTERS IN
12 THAT CONTEXT OF THE LARGER CIRM SYSTEM BECAUSE THEY
13 WOULD EXIST IN THAT. SO IT'S IMPORTANT THAT ALL
14 THESE PIECES INTERACT IN A WAY TO SERVE PATIENTS.

15 SO THIS IS THE ATTEMPT TO REALLY SHOW SOME
16 OF THESE RELATIONSHIPS. FOR EXAMPLE, WE HAVE THE
17 ALPHA CLINICS NETWORK WHICH ARE ALREADY ACTIVE.
18 THEY ARE CLINICAL CENTERS THAT ARE WHERE MOST OF
19 CIRM-FUNDED TRIALS ARE ACTIVE. AND OUR TRIALS OVER
20 HERE, WE HAVE ABOUT 55 ACTIVE TRIALS OCCURRING IN
21 THIS NETWORK. AND NOW WE ARE AT A PHASE WHERE WE
22 ARE TRYING TO SORT OF BUTTRESS THIS SYSTEM THAT'S
23 ALREADY IN PLACE WITH TWO IMPORTANT PROGRAMS THAT
24 DRIVE ACCESS, AFFORDABILITY, AND OPPORTUNITY FOR
25 PATIENTS. THE PATIENT SUPPORT PROGRAM, AS CHAIR

BETH C. DRAIN, CA CSR NO. 7152

1 BONNEVILLE POINTED OUT, WE ARE IN THE APPLICATION
2 PHASE THERE, AND THAT WILL BE COMING ONLINE, NOT
3 SIMULTANEOUSLY, BUT IN THE SIMILAR TIME FRAME AS THE
4 COMMUNITY CARE CENTERS OF EXCELLENCE, WHICH AT THE
5 MOMENT WE HAVE A DRAFT CONCEPT PLAN.

6 SO THERE'S SOME OTHER IMPORTANT
7 INFRASTRUCTURE PIECES SORT OF BEHIND HERE AS WELL,
8 INCLUDING A MANUFACTURING NETWORK AND OUR EDUCATION
9 NETWORK, WHICH WILL POTENTIALLY INTERACT WITH THOSE
10 PROGRAMS. THIS, I HOPE, GIVES YOU A SENSE OF HOW
11 COLLECTIVELY OUR SORT OF BOTH CLINICAL AND
12 INFRASTRUCTURE PROGRAMS ALONG WITH PATIENT SUPPORT
13 REALLY COME TOGETHER TO SERVE PATIENTS AND MEET
14 THEIR NEEDS IN THEIR COMMUNITIES.

15 ONE EXAMPLE OF HOW POTENTIALLY THE
16 COMMUNITY CARE CENTERS BECOME AN ACCESS FACILITATOR.
17 SOME OF THESE EXAMPLES WERE KIND OF WORKED THROUGH
18 DURING OUR ENGAGEMENT SESSIONS. THE COMMUNITY CARE
19 CENTER CAN REALLY SERVE AS THE TOUCHPOINT FOR THE
20 COMMUNITY AND NAVIGATE PATIENTS TOWARDS SOME OF THE
21 EXISTING CLINICAL TRIALS THAT ARE OPERATIONAL; FOR
22 EXAMPLE, IN THE ALPHA CLINICS. AND THAT THOSE
23 PATIENTS CAN BE TREATED, AND THEN SUBSEQUENT
24 FOLLOW-UP AND LONG-TERM SUPPORT COULD OCCUR IN THE
25 COMMUNITY SETTING. AND IN ADDITION, WE HAVE A

BETH C. DRAIN, CA CSR NO. 7152

1 PATIENT SUPPORT OVERLAY WHICH IS THE PROGRAM YOU ALL
2 RECOMMENDED, WHICH, IN ADDITION TO HAVING THE CARE
3 GEOGRAPHICALLY LOCATED CLOSER TO THE PATIENT OR
4 PROXIMATE TO THE PATIENT, THERE WOULD ALSO BE A
5 FINANCIAL SUPPORT COMPONENT SUPPORTING THOSE
6 PATIENTS WITH FINANCIAL NEEDS. THIS IS AN EXAMPLE.

7 I'M GOING TO NOW TRANSITION TO THE CONCEPT
8 PLAN ITSELF. AND I HAVE A COUPLE MORE SLIDES AND
9 THEN WE CAN OPEN IT UP.

10 SO THE CORE ELIGIBILITY AND ACTIVITIES
11 THAT WE'VE PROPOSED ARE, FIRST OF ALL, THE APPLICANT
12 MUST HAVE THE ABILITY TO SUPPORT CLINICAL
13 OPERATIONS. AND THE KEY TERM HERE IS TO SUPPORT
14 HUMAN SUBJECTS PROTOCOLS. I'M GOING IN THE NEXT
15 SLIDE KIND OF CONTRAST SORT OF THE DIFFERENCE --
16 SORT OF SUPPORTING VERSUS CONDUCTING CLINICAL
17 TRIALS. AND IN ADDITION, WE'VE ALSO STIPULATED THAT
18 THE APPLICANT CENTERS WOULD NOT BE ADMINISTERING
19 UNAUTHORIZED STEM CELL TREATMENTS. THESE WOULD BE
20 TREATMENTS THAT HAVE NOT RECEIVED AN IND FROM THE
21 FDA.

22 IN ADDITION, WE'VE INCLUDED A CAREER
23 DEVELOPMENT COMPONENT. AND THAT'S REALLY THE
24 APPLICANT OR THE APPLICANT -- IN MANY CASES WE
25 EXPECT THERE MAY BE APPLICANTS PROPOSING

BETH C. DRAIN, CA CSR NO. 7152

1 PARTNERSHIPS AMONG MULTIPLE INSTITUTIONS IF THEY
2 HAVE THE CAPACITY TO SUPPORT EDUCATION, TRAINING,
3 AND CAREER DEVELOPMENT OF REALLY, AGAIN, GOING BACK
4 TO THAT SLIDE WHERE IT SHOWED SORT OF ALL THE
5 DIFFERENT COMPONENTS OF WHAT IT TAKES TO DELIVER
6 THESE TREATMENTS. THESE ARE SOME OF THE ROLES THAT
7 SORT OF FILL THERE: PHYSICIANS, NURSES, RESEARCH
8 COORDINATORS, COMMUNITY HEALTH WORKERS, OR OTHER
9 MEDICAL PROFESSIONALS. AND REALLY EMPHASIZING THE
10 CAREER DEVELOPMENT ASPECT THERE.

11 AND, FINALLY, THE PIECE THAT'S REALLY
12 UNIQUE TO THIS PROGRAM IN A SUBSTANTIAL WAY IS THE
13 OUTREACH AND ENGAGEMENT WORK. THIS IS SOMETHING
14 THAT WE HEARD A LOT ABOUT DURING OUR NEEDS
15 ASSESSMENT. AND THAT PARTICULARLY THE ROLE OF
16 COMMUNITY-BASED ORGANIZATIONS IN FORMING THE TRUST
17 BUILDING AND THE WORK THAT OUR STAKEHOLDERS SAID
18 REALLY NEEDS TO HAPPEN TO ENGAGE THE COMMUNITY IN A
19 WAY THAT'S GOING TO BUILD TRUST AND CONFIDENCE IN
20 THIS CLINICAL RESEARCH. AND SO WE'VE INCLUDED A
21 PIECE THAT INVOLVES BOTH COMMUNITY ENGAGEMENT AND
22 PARTNERSHIPS WITH COMMUNITY-BASED ORGANIZATIONS TO
23 SUPPORT THE PROGRAM.

24 SO I'D LIKE TO JUST CONTRAST THAT A LITTLE
25 BIT WITH THE ALPHA CLINICS BECAUSE THAT'S A QUESTION

BETH C. DRAIN, CA CSR NO. 7152

1 THAT CAME UP VERY FREQUENTLY AMONGST A NUMBER OF
2 FOLKS. THE ALPHA CLINICS, IN TERMS OF THE CLINICAL
3 PIECE, THE REQUIREMENT WAS THAT THEY'RE ACTUALLY
4 DELIVERING CELL AND GENE THERAPY PRODUCTS. THAT WAS
5 A REQUIREMENT. SO THEY WOULD HAVE TO HAVE THE
6 CAPACITY TO SUPPORT A CIRM CLIN2 APPLICATION IN THE
7 CLINICAL SETTING.

8 WHEN WE SAY SUPPORTING, WHAT WE ARE
9 SUGGESTING THERE IS THAT THEY DON'T NECESSARILY HAVE
10 TO BE ABLE TO DELIVER AN INVESTIGATIONAL PRODUCT,
11 ALTHOUGH WE THINK THERE ARE CENTERS THAT ARE ABLE TO
12 DO THAT OR CERTAINLY INTERESTED IN DEVELOPING THAT
13 CAPACITY, BUT THEY COULD PROVIDE PATIENT NAVIGATION,
14 SUPPORT ENROLLMENT, DO COHORT DEVELOPMENT, DO
15 LONG-TERM FOLLOW-UP, THE WHOLE SET OF WRAPAROUND
16 SERVICES THAT A PATIENT MAY NEED AND MAINTAIN SORT
17 OF PROXIMITY TO THEIR COMMUNITY. TO THE EXTENT THEY
18 CAN SUPPORT THOSE ACTIVITIES, WE REALLY SEE VALUE
19 THERE.

20 IN THE CONTEXT OF TRAINING, THE ALPHA
21 CLINICS REALLY WERE CREATING PROGRAMS, DE NOVO
22 PROGRAMS. IN THE CASE OF THE COMMUNITY CARE
23 CENTERS, WHAT WE'D REALLY LIKE TO ENCOURAGE IS THAT
24 THOSE CENTERS BECOME A PLACE WHERE EXISTING TRAINING
25 PROGRAM, EITHER TRAINEES OR CURRICULA, CAN BE

BETH C. DRAIN, CA CSR NO. 7152

1 ADAPTED OR TRAINEES CAN GO TO REALLY DEVELOP A
2 COMMUNITY PERSPECTIVE, ADDITIONAL SITES WHERE OUR
3 STUDENTS FROM ALL OUR EDUCATION PROGRAMS CAN GAIN
4 THE EXPERIENCE AND ADDITIONAL TRAINING TO GROW INTO
5 THE FIELD OF REGENERATIVE MEDICINE.

6 AND THEN ON THE ENGAGEMENT SIDE, THE ALPHA
7 CLINICS DO HAVE SUBSTANTIAL ENGAGEMENT AND
8 NAVIGATION CAPACITY OFTEN THROUGH THE CLINICAL
9 TRANSLATIONAL SCIENCES UNITS BECAUSE MOST OF THOSE
10 SITES CAN DRAW ON THAT CAPACITY.

11 IN TERMS OF THE COMMUNITY CARE CENTERS,
12 WHAT WE ARE SUGGESTING IS THAT CERTAINLY THAT
13 ENGAGEMENT AND NAVIGATION COMPONENT IS THERE AND
14 SHOULD GROW AND DEVELOP, BUT ALSO COMMUNITY
15 ENGAGEMENT FOR BOTH CLIN PROGRAMS AND OTHER, THAT
16 THEY ACTUALLY GO OUT AND THIS COULD BE EDUCATING THE
17 COMMUNITY. IT COULD BE TALKING TO THE COMMUNITY
18 ABOUT, AGAIN, SOME OF THE TREATMENTS THAT ARE OUT
19 THERE THAT MAY POSE RISKS TO THEIR FINANCIAL OR
20 THEIR HEALTH BECAUSE THEY'RE NOT FDA AUTHORIZED.

21 AND, AGAIN, A BIG FOCUS ON COMMUNITY-BASED
22 PARTNERSHIPS BECAUSE, AGAIN, IT'S THAT COMMUNITY
23 REACH THAT WE THINK IS GOING TO BE VITAL TO THE
24 SUCCESS OF THIS PROGRAM. CERTAINLY THAT WAS A BIG
25 MESSAGE FROM THE STAKEHOLDERS.

BETH C. DRAIN, CA CSR NO. 7152

1 SO FINALLY, TO WALK THROUGH HOW WE ARE
2 REALLY PROPOSING THAT. WE'VE SUGGESTED UP TO SIX
3 AWARDS. AND THE FUNDING FOR THE COOPERATIONS
4 ANNUALLY IS JUST OVER A MILLION. AND TO GIVE YOU A
5 LITTLE BIT OF BACKGROUND ON THAT NUMBER, WE SORT OF
6 LOOKED THROUGH THE ALPHA CLINICS IN TERMS OF THE
7 TYPES OF PERSONNEL, THOSE PERSONNEL COSTS. THIS
8 WOULD BE FOR A CLINIC REALLY AIMING TO DEVELOP AND
9 DELIVER -- CERTAINLY IF THEY'RE DELIVERING
10 TREATMENTS, THIS IS SORT OF THE PERSONNEL LEVEL.
11 IT'S ROUGHLY TEN PEOPLE. WE DON'T KNOW IF EVERY
12 APPLICANT WOULD BE AT THAT LEVEL, BUT CERTAINLY WE'D
13 LIKE TO BE ABLE TO FUND UP TO THAT LEVEL IF THE
14 APPLICANT HAD THAT CAPACITY.

15 THE COMMUNITY-BASED PARTNERSHIPS, WE ARE
16 PROJECTING AT ABOUT 250,000 A YEAR. THAT'S FOR TWO
17 PARTNERSHIPS. AND THAT FIGURE WAS BASED LOOKING AT
18 THE ALL ABUZZ RESEARCH PROGRAM AND THE LINE ITEMS
19 THEY WERE PROPOSING FOR REGIONAL ENGAGEMENT
20 PROGRAMS. SO THAT WAS OUR BENCHMARK THERE.

21 THERE'S FACILITY FUNDS IN THIS AWARD. AND
22 THE REASON -- I WANT TO -- I THINK THE ORIGINAL
23 SLIDE DECK HAD A NUMBER HERE, BUT WE WANT TO BE
24 CAREFUL WITH FACILITY FUNDS. WE DON'T NECESSARILY
25 WANT TO APPLY THOSE ACROSS ALL THE AREAS. THOSE

BETH C. DRAIN, CA CSR NO. 7152

1 FUNDS MAY BE FRONT-LOADED, BUT THEY'RE UP TO 2.5
2 MILLION PER AWARD, NOT NECESSARILY ON AN ANNUALIZED
3 BASIS, BUT 2.5 MILLION UP TO. THE 2.5 MILLION
4 FIGURE WAS BASED ON ENGAGEMENT WITH LOOKING AT SOME
5 OF THE COSTS NOW. IF YOU'RE LOOKING AT CAR-T AND
6 MOBILE MANUFACTURING FACILITIES, THESE ARE SOME OF
7 THE COSTS IF YOU WERE LEASING UNITS THAT WOULD
8 ENABLE YOU TO DO CELL PROCESSING AND SOME OF THE
9 IMMUNOTHERAPY WORK. SO THAT WAS THE BASIS FOR THAT
10 ESTIMATE.

11 YOU'VE GOT YOUR INDIRECT COSTS. SO THAT
12 PUTS US AT JUST OVER TWO MILLION PER YEAR ON AN
13 ANNUAL BASIS. SO WITH THAT, I WILL STOP AND LOOK
14 FORWARD TO QUESTIONS, COMMENTS.

15 CHAIRPERSON BONNEVILLE: THANK YOU, GEOFF.
16 I'D LIKE TO OPEN THIS UP TO ANY MEMBERS WHO HAVE ANY
17 QUESTIONS OR COMMENTS. GO AHEAD, HARLAN.

18 DR. LEVINE: THIS IS HARLAN. I'M HAVING
19 CONNECTION TROUBLES. MY QUESTION IS I FEEL LIKE
20 THERE'S GOING TO BE A LOT OF SCRUTINY OVER
21 EVERYTHING WE DO. SO I GET THE ELEVATOR SPEECH WHY
22 WE'RE DOING IT AND I FULLY SUPPORT IT. HOW ARE WE
23 GOING TO MEASURE THE IMPACT OF THIS? WHAT ARE WE
24 LOOKING FOR OVER TIME?

25 DR. LOMAX: OUR BENCHMARKS HAVE REALLY

1 BEEN AROUND THE ENGAGEMENT OF PATIENTS AND THE
2 ABILITY TO SORT OF NAVIGATE PATIENTS TO CLINICAL
3 TRIALS. SO AT ONE LEVEL IT WOULD BE, IF YOU LOOKED,
4 FOR EXAMPLE, OUR CLINICAL TRIAL OBJECTIVES NOW, WE
5 NOW HAVE DEI OBJECTIVES WITHIN THOSE TRIALS. SO I
6 THINK CERTAINLY THE ABILITY TO MEASURE THE CAPACITY
7 OF THESE SITES TO SUPPORT ENROLLMENT CONSISTENT WITH
8 THE DEI OBJECTIVES OF THE TRIALS SORT OF AT AN
9 IMMEDIATE INITIAL LEVEL WOULD BE VERY IMPORTANT.
10 BUT I THINK OVER TIME MORE SUBSTANTIALLY, IT'S
11 REALLY THE ABILITY OF THESE SITES, I THINK, TO,
12 AGAIN, SUPPORT TRIALS IN A CLINICALLY MEANINGFUL
13 WAY.

14 I SUPPOSE -- I GUESS THE QUESTION BECOMES
15 THEN HOW DO WE -- WHAT DO THOSE METRICS OR
16 BENCHMARKS LOOK LIKE AND HOW MIGHT WE INCORPORATE
17 THEM INTO THE APPLICATION. THAT'S ONE WHERE I THINK
18 IT WOULD BE INTERESTING TO SORT OF THINK ABOUT HOW
19 WE COULD DO THAT.

20 CHAIRPERSON BONNEVILLE: GEOFF, TO GO ON
21 TO WHAT HARLAN WAS SAYING, ALSO, I GUESS, THE
22 ABILITY TO BE ABLE -- SINCE THIS IS REALLY OUR FIRST
23 FORAY INTO THIS SORT OF PROGRAM OUT IN AREAS THAT
24 DON'T HAVE THIS CAPACITY, ANOTHER QUESTION WOULD BE
25 DO WE HAVE THE ABILITY TO COURSE CORRECT THROUGHOUT

BETH C. DRAIN, CA CSR NO. 7152

1 THE LIFE OF THE GRANT AND MAKE ADJUSTMENTS AS
2 NECESSARY. SO THAT'S SOMETHING THAT WE MAY WANT TO
3 CONSIDER INCORPORATING INTO THE RFA WHERE WE THINK
4 WE CAN AND WHERE IT MAKES THE MOST SENSE.

5 PAT HAS HIS HAND RAISED.

6 DR. LEVITT: THANKS VERY MUCH. I THOUGHT
7 THAT IT WAS GREAT.

8 TWO THINGS. ONE IS TWO OF THE THREE BOXES
9 ARE ABOUT WHEN YOU ARE COMPARING THE ALPHA CLINICS
10 AND THE CCC'S ABOUT TRAINING AND ENGAGEMENT. AND
11 THIS HAS, AT LEAST CONCEPTUALLY, A UNIQUE KIND OF
12 TRAINING BECAUSE OF THE FOCUS ON THE TOPIC AREA.
13 AND I'M WONDERING IF THERE WAS ANY DISCUSSION OR ANY
14 CONVERSATION AROUND THE FUNDED SITES SHARING COMMON
15 APPROACHES TO THIS IN TERMS OF EXPERIENCES, EVEN
16 CURRICULA THAT WOULD BE PART OF EACH OF THE SITES SO
17 THAT, ONE, THEY'RE NOT TRYING TO REINVENT THE WHEEL
18 AND, TWO, BECAUSE IT'S SO UNUSUAL IN TERMS OF THE
19 KIND OF TRAINING THAT LIKELY WOULD HAVE TO OCCUR TO
20 HAVE SORT OF A SHARED EFFORT.

21 I WOULD SAY THE SAME THING ABOUT EDUCATING
22 THE COMMUNITY. LIKE SOME OF US ON THIS CALL HAVE
23 TRIED TO DO A LOT OF IT, AND SOMETIMES IT GOES WELL
24 AND SOMETIMES IT GOES TERRIBLY FOR A WHOLE LOT OF
25 REASONS.

BETH C. DRAIN, CA CSR NO. 7152

1 I WOULD SAY THERE, AGAIN, BECAUSE IT HAS
2 TO BE ADAPTIVE FOR THE DIFFERENT COMMUNITIES, RIGHT,
3 FOR COMMUNITIES THAT MAY BE MORE RURAL OR MORE
4 URBAN, WHATEVER IT MIGHT BE. SO THERE HAS TO BE
5 SOME ADAPTATION. AGAIN, SHARED APPROACHES TO HOW TO
6 COMMUNICATE THIS FROM A THERAPEUTIC AND A SCIENTIFIC
7 PERSPECTIVE. IT'S HARD TO COMMUNICATE THIS WELL.
8 AND SCIENTISTS AND RESEARCHERS GENERALLY DO A BAD
9 JOB. I'M A RESEARCHER, SO I CAN SAY THAT ABOUT
10 MYSELF.

11 THOSE ARE TWO THINGS ABOUT FIGURING OUT
12 HOW THESE SITES CAN ACTUALLY GET TOGETHER AND WORK
13 TOGETHER TO COME UP WITH SOMETHING MORE ROBUST THAN
14 AN INDIVIDUAL SITE WOULD.

15 DR. LOMAX: THANK YOU FOR THAT. HONESTLY,
16 THAT'S ONE OF THOSE COMMENTS THAT KIND OF KEEPS US
17 AWAKE AT NIGHT. SO LET ME JUST POINT TO A COUPLE OF
18 DEVELOPMENTS WHERE I THINK WE CAN ADDRESS THAT
19 COMMENT AND THEN ENCOURAGE MY CIRM COLLEAGUES TO
20 COMMENT AS WELL.

21 FIRST OF ALL, SOME OF THE ALPHA CLINIC
22 SITES IN THE IMPLEMENTATION PHASE NOW DOING THIS DID
23 PROPOSE IN THEIR INITIAL APPLICATION THE DEVELOPMENT
24 OF CURRICULA AND PORTABLE TRAINING OPTIONS THAT THEY
25 INTEND TO DEPLOY OUT TO THIS NETWORK IN ADVANCE

BETH C. DRAIN, CA CSR NO. 7152

1 BECAUSE WE ASKED THEM TO CONSIDER THAT. SO ONE IN
2 PARTICULAR IS A RESEARCH COORDINATOR PROGRAM THAT'S
3 BEING LED BY UC IRVINE. SO THERE ARE A NUMBER OF
4 INITIATIVES LIKE THAT WHERE THE ALPHA CLINICS ARE,
5 AGAIN, TRYING TO PROVIDE THOSE CURRICULA AND THOSE
6 RESOURCES, MAKE THEM AVAILABLE. AND THEN WE'RE
7 GOING TO ALLOW THEM -- ENCOURAGE INTERACTION WITH
8 THE APPLICANT SITES TO REALLY ALLOW THOSE TO SORT OF
9 COME THROUGH THE APPLICATION.

10 THERE IS -- WE ALSO ARE DEVELOPING OUR
11 EDUCATION NETWORK WITHIN CIRM. THAT'S REALLY BEING
12 LED UP BY THE DISCOVERY TEAM THAT MANAGES THE BULK
13 OF OUR EDUCATION PROGRAMS. BUT THERE IS A MORE
14 FORMAL NETWORK STRUCTURE THAT WE'LL BE DEVELOPING IN
15 PART TO GET INTERNAL CONSISTENCY IN TERMS OF THE
16 CURRICULA, THE METHODS, THE MATERIALS. AND SO,
17 AGAIN, THAT'S, AGAIN, ANOTHER RESOURCE WE CAN TAP
18 INTO THIS PROGRAM.

19 ONE OF THE OTHER ONES I THINK IS VERY
20 EXCITING OR TWO OTHER ONES THAT ARE VERY EXCITING,
21 AGAIN, OPPORTUNITIES HERE THAT CAN REALLY LEVERAGE
22 OUT THROUGH THIS NETWORK IS THERE IS NOW
23 CERTIFICATION PROGRAMS FOR NAVIGATORS. WE'VE HAD
24 SOME INTERACTION, FOR EXAMPLE, WITH SOME OF THE
25 ORGANIZATIONS THAT ARE GOING TO BE LEADING UP THOSE

BETH C. DRAIN, CA CSR NO. 7152

1 CERTIFICATION EFFORTS. AND OUR READOUT IS THAT THEY
2 WOULD BE VERY INTERESTED IN COLLABORATING WITH US TO
3 REALLY BUILD THAT REGENERATIVE MEDICINE COMPONENT
4 INTO A CURRICULA WHICH WOULD SERVE AS THE BASIS FOR
5 THE CERTIFICATION OF NAVIGATORS.

6 WHY THAT'S IMPORTANT IS WITH THAT
7 CERTIFICATION, THAT THEN BECOMES REIMBURSABLE
8 THROUGH MEDI-CAL. SO IT'S TYING THE REIMBURSEMENT
9 OF THE PROGRAM AND THE TRAINING THROUGH THIS NETWORK
10 WITH A STRONG REGENERATIVE MEDICINE FOCUS.

11 AND THERE'S, I THINK, A SIMILAR MODEL
12 THAT'S AVAILABLE FOR COMMUNITY HEALTH WORKERS AS
13 WELL WHICH THEN WOULD TIE TO MEDI-CAL REIMBURSEMENT.
14 SO THESE ARE ALL, I THINK, OPPORTUNITIES THAT ALLOW
15 US TO AT LEAST DEPLOY SOME OF OUR MATERIALS AND
16 ASSETS IN TRAINING INTO A FAIRLY SUSTAINABLE SYSTEM
17 OF BOTH NAVIGATION AND ENGAGEMENT. SO WE'RE GOING
18 TO CONTINUE TO TRY TO DEVELOP THOSE. THESE ARE
19 DEVELOPING IN REAL TIME; BUT I THINK BY THE TIME WE
20 GET TO THE APPLICATION PHASE, I THINK WE CAN COME UP
21 WITH SOME WAYS OF REALLY TYING THAT IN.

22 AND THEN THE LAST THING IS I THINK CIRM'S
23 OWN ENGAGEMENT PROGRAM IS REALLY LOOKING TO -- THE
24 PROGRAM YOU ALL ARE DEVELOPING ON THE COMMUNICATION
25 SIDE IS REALLY LOOKING TO DEVELOP A SET OF

BETH C. DRAIN, CA CSR NO. 7152

1 RESOURCES, MATERIALS, AND INTERNAL CONSISTENCY IN
2 THAT PIECE. SO THE THINKING IS THAT ALL -- WE CAN
3 INCENTIVIZE A WAY FOR MANY OF THOSE PIECES TO COME
4 TOGETHER. HOPEFULLY WE ARRIVE AT A PLACE THAT I
5 THINK ADDRESSES YOUR COMMENT, BUT I'LL LEAVE THAT TO
6 YOU.

7 DR. LEVITT: IT DOES ADDRESS IT. AND THAT
8 WAS GREAT. THERE ARE A NUMBER OF DIFFERENT MOVING
9 PARTS --

10 DR. LOMAX: YEAH.

11 DR. LEVITT: -- AS CLEARLY YOU KNOW THIS.
12 SO IT'S GREAT TO HAVE EVERYBODY PLAYING ALL THESE
13 DIFFERENT INSTRUMENTS COME TOGETHER TO FORM THE
14 ORCHESTRA. SOMEBODY HAS GOT TO BE THE CONDUCTOR.
15 MAYBE THAT'S YOU. I DON'T KNOW. BUT I THINK THERE
16 ARE PIECES THERE THAT ADDRESS THIS. AND I THINK IT
17 WOULD REALLY CREATE SOMETHING VERY ROBUST AS HARLAN
18 SAID. THE EYES ARE GOING TO BE -- A LOT OF EYES ON
19 WHAT CIRM IS DOING. SO THAT'S GREAT. THANK YOU.

20 DR. LOMAX: THANK YOU FOR THAT. HONESTLY
21 THE OPPORTUNITY IS A REAL PLEASURE. SO THANK YOU
22 FOR THE OPPORTUNITY.

23 CHAIRPERSON BONNEVILLE: THANKS, PAT.

24 ANN. YOU'RE ON MUTE.

25 MS. BOYNTON: I'M ON MUTE. I'M TRYING TO

BETH C. DRAIN, CA CSR NO. 7152

1 LOWER MY HAND. THERE'S TOO MANY THINGS GOING ON.

2 FIRST IS AN EASY -- THEY'RE BOTH EASY
3 QUESTIONS. BUT ARE THE FUNDS THAT IS THE AMOUNT OF
4 MONEY THAT WE HAVE AVAILABLE? WE'RE ASSUMING SIX,
5 WE'RE ASSUMING SORT OF FLAT DISTRIBUTION OF DOLLARS
6 ACROSS ALL SIX, AND SIXTY -- IT LOOKED LIKE 60
7 MILLION FOR THE -- IS THAT SET OR IS THERE WIGGLE
8 ROOM IN THAT?

9 DR. LOMAX: SO PROPOSITION 14 ALLOCATED
10 APPROXIMATELY 78 MILLION TO THIS PROGRAM. IT'S --
11 AGAIN, THIS COMES OUT OF PROPOSITION 14. SO THAT'S
12 THE LITERAL ALLOCATION. SO WE ARE AT AN AMOUNT
13 THAT'S BELOW THAT AMOUNT. BUT, AGAIN, I THINK SORT
14 OF LOOKING -- CERTAINLY I THINK SIX SITES IS
15 AMBITIOUS, BUT IT'S EXCITING AS WELL. SO SORT OF
16 THE -- THAT'S WHERE WE ARE.

17 MS. BOYNTON: COOL. THANK YOU.

18 THE SECOND IS JUST SOMETHING THAT -- AND I
19 THINK ABOUT HOW DO WE IMPLEMENT THESE AND HOW DO WE
20 GO THROUGH A PROCESS TO SELECT THEM. WE HAVE THIS
21 INCREDIBLE TENSION IN CALIFORNIA BETWEEN WHERE THE
22 BULK OF THE POPULATION LIVES AND 65,000 SQUARE MILES
23 NORTH OF SACRAMENTO AND THE NEED TO -- SO THE
24 PROPOSALS COULD BE WILDLY DIVERSE IN THE NUMBER OF
25 COMMUNITY ORGANIZATIONS, THE COMPLEXITY OF THE

BETH C. DRAIN, CA CSR NO. 7152

1 INTERACTIONS DEPENDING ON WHAT THE GEOGRAPHY IS THAT
2 THEY ARE TRYING TO SERVE OR THE PATIENT TYPES.

3 AS WE ALL THINK ABOUT HOW TO FIND OUR WAY
4 THROUGH THAT, AND YOU ARE WORKING ON THE EVALUATION
5 CRITERIA, I THINK THAT'S AN AREA THAT I WOULD LOOK
6 FOR SOME ADDITIONAL GUIDANCE ON HOW DO WE THINK
7 ABOUT THESE TENSIONS.

8 DR. LOMAX: THANK YOU FOR THAT. AGAIN, I
9 THINK THE CHALLENGE IS TO HONOR THAT DIVERSITY. AND
10 MY SENSE IS THIS WILL BE -- THE ALPHA CLINICS
11 PROGRAM WAS A VERY DEFINED SKILL SET. HERE I THINK
12 BEING FLEXIBLE IN OUR THINKING AND ALLOWING THAT TO
13 BE PART OF THE EVALUATION PROCESS VIS-A-VIS THE
14 GRANTS WORKING GROUP WILL BE VITAL. THAT'S
15 ABSOLUTELY WHAT WE LEARNED. IS IT A FEDERALLY
16 QUALIFIED HEALTH CENTER? IS IT AN ACADEMIC CENTER?
17 IS IT A COMMUNITY CLINIC THAT'S SUPPORTING CLINICAL
18 TRIALS? IS IT A COMMUNITY HOSPITAL? IT'S ALL OF
19 THOSE. SO THIS IS VERY DIFFERENT. AND I THINK WE
20 CAN -- IT'S VERY EXCITING, BUT IT IS DIFFERENT, YES.

21 MS. BOYNTON: THANK YOU.

22 CHAIRPERSON BONNEVILLE: THANK YOU, ANN.
23 ADRIANA.

24 DR. PADILLA: YES, IF I CAN GET MY MUTE
25 DOWN.

BETH C. DRAIN, CA CSR NO. 7152

1 SO I AGREE WITH PAT. THERE'S A LOT OF
2 MOVING PARTS TO THIS AND A LOT OF INTERACTIONS THAT
3 NEED TO BE WORKED OUT. SO I HAVE TWO QUESTIONS.
4 WOULD AN APPLICANT HAVE TO -- IT SOUNDS LIKE THEY
5 WOULD NEED TO COLLABORATE OR ASSOCIATE OR GO INTO
6 THIS APPLICATION WITH ALL THE ALPHA CLINICS BECAUSE
7 EACH ALPHA CLINICS DOES SOMETHING DIFFERENT. ALPHA
8 CLINICS, I WOULD THINK, WANT TO ACCESS PATIENTS IN
9 DIVERSE AREAS THROUGHOUT CALIFORNIA. SO IS THAT
10 PART OF THE CRITERIA THAT WOULD BE LOOKED AT PER SE?

11 AND THEN NO. 2 IS ALPHA CLINICS HAVE
12 FUNDING FOR OUTREACH AND DEVELOPMENT, AS I THINK PAT
13 MENTIONED EARLIER, BUT SO DO THE AWARDEES FOR THE
14 GRANTS FOR THE CLIN'S BASICALLY. THEY GET DOLLARS
15 FOR OUTREACH DEVELOPMENT, CREATION OF RELATIONSHIPS
16 WITH COMMUNITY-BASED ORGANIZATIONS. HOW DO YOU KIND
17 OF MELD ALL THESE MOVING PARTS?

18 DR. LOMAX: SO I'M GOING TO START WITH THE
19 SECOND ONE, I THINK. I THINK MOST IMPORTANT IS TO
20 REALLY UNDERSTAND THE PARTS AND MAKE THEM VISIBLE TO
21 THE APPLICANT AS A STARTING POINT. SO I THINK WE'RE
22 ALREADY SEEING THAT HAPPEN TO SOME EXTENT,
23 PARTICULARLY COMING OUT OF SACRAMENTO. IT WAS BOTH
24 A PLANNING AND A LISTENING SESSION, BUT ALSO A
25 NETWORKING SESSION WHERE SOME OF THOSE CONVERSATIONS

BETH C. DRAIN, CA CSR NO. 7152

1 ARE OCCURRING.

2 AND SO PART OF IT IS SOCIALIZING WHAT WE
3 ARE TRYING TO DO VIS-A-VIS THE CIRM MISSION WITH THE
4 ALPHA CLINICS WHO, AS YOU SAY, ARE EAGER TO BUILD
5 THESE RELATIONSHIPS AND THEN INTRODUCING THEM TO THE
6 ORGANIZATIONS THAT I THINK SEEM LIKE THEY WOULD OR
7 EXPRESSED INTEREST IN THIS PROGRAM. I THINK PART OF
8 IT IS CREATING THAT VISIBILITY AND THOSE CONDITIONS
9 WHERE THAT THINKING CAN REALLY DEVELOP. AND SO
10 WE'VE DONE -- THAT'S WHAT'S NICE ABOUT THE CIRM
11 PROCESS IS THE RUNWAY UP TO THAT, AT LEAST WE GET TO
12 THAT POINT.

13 AND THEN I THINK THE EXTENT TO WHICH WE
14 CAN USE THE APPLICATION PROCESS TO HIGHLIGHT SOME OF
15 THESE SPECIFIC OUTCOMES THAT WE'RE INTERESTED IN, I
16 THINK THAT'S WHERE WE'RE LOOKING FOR FEEDBACK FROM
17 YOU ALL AS WELL IN TERMS OF ARE THERE VERY SPECIFIC
18 THINGS WE ARE LOOKING FOR IN THE APPLICATION. SO
19 HOPE THAT GETS SORT OF THE SECOND PART OF YOUR
20 QUESTION.

21 AND THE FIRST PART, THE APPLICANTS, AGAIN,
22 ABSOLUTELY ARE LOOKING TO THIS PROGRAM. I THINK
23 THEY SEE OPPORTUNITIES IN A VARIETY OF AREAS. I'VE
24 ALLUDED TO THE PIECE ABOUT TRAINING PROGRAMS.
25 THERE'S A LOT OF ACTIVE WORK THERE.

BETH C. DRAIN, CA CSR NO. 7152

1 AND THEN A NUMBER OF THE ALPHA CLINICS, I
2 THINK, ARE INTERESTED IN WORKING WITH SPECIFIC
3 APPLICANTS, WHETHER IT'S ON THE CLINICAL, THE
4 TRAINING, OR THE ENGAGEMENT PIECE. I THINK, AGAIN,
5 THE KEY THERE IS WE CAN -- ARE THERE SPECIFIC THINGS
6 YOU RECOMMEND THAT WE BE LOOKING FOR IN THOSE
7 OPPORTUNITIES, AND CAN WE BRING THEM FORWARD IN THE
8 APPLICATION ITSELF?

9 MAYBE I'LL PAUSE THERE. AND, AGAIN, IF
10 ANY OF MY CIRM COLLEAGUES WOULD LIKE TO ADD TO THAT.
11 WAS THAT HELPFUL? I JUST WANT TO MAKE SURE I
12 ADDRESS THE QUESTION.

13 DR. PADILLA: I THINK THE FIRST QUESTION
14 WAS ADDRESSED. THE SECOND ONE ABOUT THE FUNDING
15 THAT ALPHAS HAVE FOR SOME OF THIS WORK THAT'S
16 PROPOSED FOR THE CENTERS OF EXCELLENCE AND ALSO THE
17 GRANT AWARDEES, I STILL DON'T KNOW HOW THAT'S GOING
18 TO INTERACT WITH THE DOLLARS. IT SEEMS LIKE THE
19 DOLLARS ARE ALL SEPARATE, BUT YET THEY SHOULD ALL BE
20 TOGETHER. LOTS OF MOVING PARTS AND HOW DO YOU MELD
21 ALL THAT. I DON'T HAVE A SENSE OF THAT YET.

22 DR. LOMAX: FROM MY PERSPECTIVE -- THANKS.
23 I DID MISS THAT PIECE. FROM WHAT I'VE SEEN ON THE
24 ALPHA CLINICS SIDE IS THE FUNDING THAT'S COME IN
25 THROUGH THE AWARD HAS ENABLED THEM TO HAVE THE --

BETH C. DRAIN, CA CSR NO. 7152

1 RETAIN THE TIME OF SOME OF THE TEAMS THAT DO THE
2 OUTREACH AND ENGAGEMENT AS A SPECIALTY AND REALLY
3 OFFER THAT AS A SERVICE AND AN OPPORTUNITY.

4 THE CLINICAL -- I THINK YOU COULD HAVE
5 SOMETHING -- THE MODEL FOR THE COMMUNITY CARE
6 CENTERS COULD BE SIMILAR WHERE YOU'VE GOT THE
7 PLATFORM, YOU'VE GOT THE OPPORTUNITY, YOU'VE GOT THE
8 INFRASTRUCTURE. WHAT THE GRANT AWARD THEN PROVIDES
9 IS THE ADDITIONAL FUNDS COMING IN TO REALLY HELP FOR
10 THAT PARTICULAR PROGRAM THEN TO TAKE ON SOME OF
11 THOSE COSTS. SO IT BECOMES A BIT MORE OF A
12 FEE-FOR-SERVICE MODEL. IN ORDER TO OFFER THAT
13 SERVICE, YOU NEED THAT INFRASTRUCTURE, YOU NEED
14 THOSE TEAMS, YOU NEED TO DEVELOP THOSE MATERIALS,
15 ALL THOSE PIECES. THE AWARD GIVES YOU, THEN, THE
16 OPPORTUNITY TO DEPLOY THAT IN A SPECIFIC USE CASE.
17 SO I THINK, AGAIN, THERE'S AN OPPORTUNITY THERE, AND
18 THAT'S WHAT'S HAPPENING.

19 I THINK WE TEND -- TO THE EXTENT WE'RE
20 SEEING THAT THAT'S WORKING IS, AGAIN, IN SOME OF THE
21 DEI SCORES AND SOME OF THE SCORES WE ARE SEEING ON
22 THE CLINICAL GRANTS. THEY'RE REVIEWING THOSE
23 PROGRAMS AS BEING AT THE APPLICATION STAGE VERY
24 EFFECTIVE. I THINK THAT'S, AGAIN, THE MODEL THAT WE
25 ARE SORT OF LOOKING AT TO SORT OF EXPAND OUT FURTHER

BETH C. DRAIN, CA CSR NO. 7152

1 THROUGH THIS PROGRAM.

2 DR. PADILLA: I WOULD SUGGEST THAT THE
3 APPLICANTS FOR THE CENTERS OF EXCELLENCE NEED TO
4 HAVE ACCESS TO WHAT IS -- WHAT PROGRAMS HAS ALPHAS
5 CREATED, WHAT PROGRAMS HAVE THE ACTUAL GRANT
6 AWARDEES CREATED, AND TRYING TO MELD AND MOVE INTO
7 HOW TO AUGMENT THAT, HOW TO ENHANCE THAT, HOW TO
8 IMPROVE THAT SO THAT THE FUNDS ARE BEING USED ALL
9 AROUND FOR GOOD PURPOSE BASICALLY. JUST A
10 SUGGESTION.

11 CHAIRPERSON BONNEVILLE: THAT'S GREAT,
12 ADRIANA.

13 GEOFF, JUST FOR OUR OWN EXERCISE
14 INTERNALLY, I THINK IT'S IMPORTANT TO BE ABLE TO
15 SHOW THE DIFFERENT OUTREACH EFFORTS, WHO'S
16 RESPONSIBLE FOR THEM, AND WHAT THEY ENTAIL JUST SO
17 THAT WE HAVE OUR OWN MATRIX SO THAT THERE AREN'T
18 DUPLICATIVE EFFORTS AND THAT THEY'RE ALL WORKING IN
19 CONCERT TOGETHER IN THE AREAS WHERE THEY CAN AND
20 SHOULD. THANK YOU, ADRIANA, FOR THAT.

21 HARLAN.

22 DR. LEVINE: THANK YOU. AND I WANT TO
23 ACKNOWLEDGE THAT I'M BRINGING UP THIS POINT PROBABLY
24 LATE IN THE GAME, BUT IT WAS THE CONVERSATION THAT
25 JUST TOOK PLACE ABOUT THINGS WORKING IN CONCERT AND

BETH C. DRAIN, CA CSR NO. 7152

1 UNDERSTANDING THE ECONOMICS. A LOT OF TIMES THE
2 TESTS THAT ARE DONE TO IDENTIFY PEOPLE WHO WOULD BE
3 GOOD CANDIDATES ARE GENOMIC TESTING. AND IN A LOT
4 OF THESE MANAGED CARE SETTINGS THERE'S A LOT OF
5 PRESSURE ON CLINICS, MEDICAL GROUPS, NETWORKS NOT TO
6 BE PERFORMING THESE TESTS.

7 SO I THINK IT'S IMPORTANT AS WE ARE
8 SELECTING FINALISTS OR THINKING ABOUT CRITERIA, WE
9 REALLY WANT TO UNDERSTAND THE COMMITMENT TO DO THE
10 PREWORK, TO IDENTIFY THESE HIGH RISK PATIENTS, TO
11 MAKE SURE THAT THEY'RE ACTING AS AN INTEGRATED BODY.
12 MEANING THERE'S NOT A SUBSET THAT'S REALLY EXCITED
13 ABOUT THIS AND THEN THERE'S GOING TO BE ANOTHER PART
14 OF THE CLINIC THAT'S LIKE, WHOA, THAT'S NOT HOW WE
15 PRACTICE MEDICINE.

16 SO I JUST FEEL LIKE WE NEED TO TAKE THAT
17 INTO ACCOUNT BECAUSE I'M HERE AT A HEALTH CONFERENCE
18 IN LAS VEGAS. AND I'M INTERVIEWING -- DOING A PANEL
19 WITH TWO PEOPLE TALKING ABOUT DISPARITIES IN
20 HEALTHCARE AND BARRIERS TO HEALTHCARE. A LOT OF IT
21 IS EXACTLY THE ISSUE THAT I'M RAISING, WHICH IS
22 THERE'S SORT OF THESE INHERENT PRESSURES NOT TO DO
23 SOME OF THE LATEST AND GREATEST.

24 ANYWAY, I WON'T SAY IT A THIRD TIME. I
25 KNOW I WAS A LITTLE REPETITIVE, BUT I WANT TO MAKE

BETH C. DRAIN, CA CSR NO. 7152

1 SURE THAT I'M NOT GENERALIZING TO EVERY GROUP, BUT I
2 THINK IT'S IMPORTANT THAT WE PICK OUT AND IDENTIFY
3 THIS ISSUE.

4 DR. LOMAX: DO YOU HAVE A SUGGESTION IN
5 TERMS -- THERE ARE THINGS WE COULD LOOK FOR IN TERMS
6 OF COMMITMENT LETTERS OR -- IT SOUNDS LIKE IT'S SOME
7 SORT OF INSTITUTIONAL BUY-IN THAT WE MIGHT WANT TO
8 INCLUDE AS PART OF AN APPLICATION. IS THERE THINGS
9 LIKE THAT YOU'D RECOMMEND?

10 DR. LEVINE: WELL, I THINK WE COULD ASK
11 FOR WHAT GUIDELINES DO THEY FOLLOW? DO THEY HAVE
12 UTILIZATION MANAGEMENT PROCESS? WHO MAKES THOSE
13 DECISIONS? WHAT'S THEIR TRACK RECORD IN ORDERING?
14 THERE'S SOME SPECIFIC CANCERS LIKE NON-SMALL CELL
15 LUNG CANCER WHERE THE EVIDENCE HAS BEEN CRYSTAL
16 CLEAR FOR YEARS THAT GENOMICS STUDIES SHOULD BE
17 DONE. WE COULD ASK THEM TO PRESENT DATA ON WHAT
18 THEIR PERFORMANCE IS IN THOSE AREAS.

19 I DON'T REALLY HAVE AN ANSWER TO YOUR
20 QUESTION. BUT JUST OFF THE TOP OF MY HEAD, THOSE
21 ARE SOME THINGS. WHAT I WOULD SUGGEST IS TO TALK TO
22 SOME LEADING CLINICIANS WHO ARE ALREADY IN THE ALPHA
23 CLINICS OR INTERESTED IN THIS. I CAN IDENTIFY
24 PEOPLE AT CITY OF HOPE WHO ARE THOUGHTFUL ABOUT THIS
25 AND ASK THEM WHAT WOULD THEY LOOK FOR IN A GROUP TO

BETH C. DRAIN, CA CSR NO. 7152

1 MAKE SURE THAT THE GROUP WAS DEMONSTRATING A
2 CAPABILITY TO IDENTIFY THESE PATIENTS FOR THE
3 CLINICAL TRIALS THAT WE ARE TALKING ABOUT.

4 DR. GOLDSTEIN: I'M SORRY. HARLAN, CAN
5 YOU ELABORATE A LITTLE BIT ON WHAT YOU SEE AS THE
6 GENOMIC PROCESS THAT WOULD GO INTO THIS PORTION OF
7 THE COMMUNITY CARE EXCELLENCE?

8 DR. LEVINE: I'M NOT SURE I UNDERSTOOD
9 YOUR QUESTION. LET ME TAKE A SHOT AT IT AND YOU
10 TELL ME --

11 DR. GOLDSTEIN: YOU MENTIONED THAT
12 GENOMICS WAS ONE POSSIBLE SEGMENT, FOR EXAMPLE, FOR
13 SCREENING AND IDENTIFYING PATIENTS. COULD YOU GO
14 JUST INTO A LITTLE BIT MORE DETAIL ABOUT HOW THAT
15 WOULD PLAY A ROLE IN PATIENT IDENTIFICATION? WOULD
16 IT GO TOWARDS SORTING PATIENTS TO POSSIBLE DIFFERENT
17 THERAPIES OR WHAT --

18 DR. LEVINE: YEAH. IF YOU HAVE -- AGAIN,
19 PLEASE REMEMBER I'M NOT AN ONCOLOGIST. BUT IF YOU
20 HAVE LYMPHOMA, IF YOU DON'T DO CERTAIN GENETIC
21 TESTING, YOU'RE GOING TO USE TRADITIONAL
22 CHEMOTHERAPY AS OPPOSED TO SOME OF THE CELL-BASED
23 THERAPIES OR THE MORE ADVANCED TREATMENTS. SO YOU
24 HAVE TO IDENTIFY THE SUBTYPES OF SOME OF THESE
25 CONDITIONS TO MAKE SURE THAT THEY QUALIFY.

BETH C. DRAIN, CA CSR NO. 7152

1 I WOULD IMAGINE AS WE MOVE INTO THESE NEW
2 THERAPIES FOR SOLID TUMORS, THE PROBLEM IS GOING TO
3 BE MAGNIFIED BECAUSE SOME OF THE LIQUID TUMORS THAT
4 WE ADVANCED THE FIELD ON ARE ALREADY AT ACADEMIC
5 CENTERS. BUT IN SOLID TUMOR, THE VAST MAJORITY OF
6 THEM, SIGNIFICANT MAJORITY OF THEM ARE IN THE
7 COMMUNITY. WE JUST WANT TO MAKE SURE THAT WE'RE
8 IDENTIFYING THE SUBTYPES THAT WOULD BE GOOD
9 CANDIDATES FOR ADVANCED RESEARCH TRIALS AS OPPOSED
10 TO MAYBE BEING BETTER CANDIDATES FOR STANDARD OF
11 CARE.

12 DR. GOLDSTEIN: I SEE. IT SOUNDS LIKE --
13 I'M GOING TO PUT WORDS IN YOUR MOUTH, BUT PLEASE
14 REJECT IT IF IT'S WRONG. YOU COULD IMAGINE, FOR
15 EXAMPLE, SORT OF A PAN CANCER APPROACH IN
16 IDENTIFYING AND SORTING PATIENTS BASED ON THAT.

17 DR. LEVINE: SO I'M HAPPY TO HAVE WORDS IN
18 MY MOUTH BECAUSE I'M NOT AN EXPERT IN THIS AT ALL.
19 WHAT I WOULD SUGGEST IS THAT WE DO HAVE AN EXPERT
20 IDENTIFY THE UPSTREAM FUNNEL AND WHAT WOULD HAVE TO
21 BE IN PLACE TO MAKE SURE THAT THESE PATIENTS ARE
22 ACTUALLY GETTING IDENTIFIED. I DON'T THINK THEY
23 JUST MAGICALLY POP OUT AND SELF-IDENTIFY AS BEING
24 APPROPRIATE FOR A CIRM-RELATED STUDY.

25 I'M NOT ENCYCLOPEDIA IN KNOWLEDGE, BUT I

BETH C. DRAIN, CA CSR NO. 7152

1 WAS JUST TRYING TO PREPARE FOR THIS PANEL. I HAVE A
2 THOUSAND PATIENTS WITH NON-SMALL CELL LUNG CANCER.
3 FOUR HUNDRED SEVENTY-SEVEN TODAY DO NOT GET GENOMIC
4 TESTING THAT THEY SHOULD GET, AND ANOTHER 147 GET
5 THE GENOMIC TESTING, BUT THEY DON'T GET THE RIGHT
6 THERAPY. SO THAT'S LIKE MORE THAN HALF THE PEOPLE.

7 SO THE QUESTION IS THINGS ARE MOVING SO
8 FAST, THESE TRIALS ARE GOING TO BE REALLY SMALL
9 TRIALS. HOW DO YOU FIND THAT NEEDLE IN A HAYSTACK?
10 I THINK YOU HAVE TO MAKE SURE YOU'RE CASTING A WIDE
11 ENOUGH NET.

12 DR. GOLDSTEIN: THANK YOU.

13 DR. LEVITT: LET JUST ME JUST SAY, HARLAN
14 AND TED, THAT AT ACADEMIC MEDICAL CENTERS, THEY EAT
15 THE LOSS FOR NONAPPROVED GENETIC TESTING, GENETIC
16 TESTING THAT'S DONE LIKE IN PEDIATRICS FOR EVERY
17 CANCER, BUT SOME OF THEM ARE NOT REIMBURSABLE. SO
18 THE HOSPITAL EATS THE LOSS. AND THAT'S TRUE ACROSS
19 MANY DIFFERENT DISEASES THAT IS GOING TO BE
20 POTENTIAL TARGETS FOR THERAPIES IN THE ALPHA
21 CLINICS. SO THE NUMBERS YOU QUOTED ARE EXACTLY
22 RIGHT. AND IF THIS IS -- IF THIS EFFORT IS REALLY
23 FOCUSED ON ACCESSIBILITY, IT'S GOING TO INVOLVE
24 DIAGNOSES THAT ARE NOT OCCURRING AT ACADEMIC MEDICAL
25 CENTERS THAT HAVE SOME LEVEL OF FLEXIBILITY IN TERMS

1 OF DOING THIS.

2 DR. GOLDSTEIN: WE ARE TRYING TO FIND
3 THE MISSING -- THE PATIENTS THAT WE MISS.

4 DR. LEVITT: YES. AND A LOT OF THEM ARE
5 GONE TO BE IN COMMUNITY CLINICS AND OTHER HEALTHCARE
6 SETTINGS THAT ARE GOING TO BE MISSED OR THEY'LL
7 GET -- THEY WON'T HAVE ACCESS TO THIS KIND OF
8 TREATMENT, TO THESE KINDS OF TREATMENTS. I'M NO
9 EXPERT EITHER, BUT I CAN JUST TELL YOU THAT THERE'S
10 A LOT OF DEFICIT BEING EATEN BECAUSE OF LACK OF --
11 FOR REASONS THAT STILL ESCAPE ME. I'M NOT A
12 PHYSICIAN. I DON'T QUITE UNDERSTAND THE STANCE THAT
13 YOU'VE GOT SOMETHING ABSOLUTELY IS CRITICALLY
14 IMPORTANT FOR TREATMENT DESIGN AND SAVES A LOT OF
15 MONEY, AND ECONOMISTS WILL SAY LIFE EXPECTANCY
16 CHANGES DRAMATICALLY. SO THAT'S A REAL POSITIVE,
17 RIGHT, IN TERMS OF ECONOMICS, BUT THEY'RE NOT
18 APPROVED FOR REIMBURSEMENT. THAT'S ANOTHER
19 CONVERSATION.

20 DR. LEVINE: YEAH. I WAS GOING TO SAY I
21 CAN ANSWER THAT, BUT IT'S ANOTHER CONVERSATION. IT
22 MIGHT BE INTERESTING TO HEAR MARIA'S THOUGHTS ON
23 THIS, DR. MILLAN, BECAUSE SHE'S A PHYSICIAN CLOSER
24 TO IT THAN I AM. SO SHE MIGHT HAVE A DIFFERENT
25 POINT OF VIEW ON THIS OR BE ABLE TO VALIDATE IT.

BETH C. DRAIN, CA CSR NO. 7152

1 DR. MILLAN: THANK YOU SO MUCH. I THINK
2 THIS IS A GREAT CONVERSATION. AND I THINK IT'S THE
3 VERY BASIS FOR REALLY THE HUGE OPPORTUNITY FOR THE
4 COMMUNITY CARE CENTERS OF EXCELLENCE BECAUSE ALL
5 THIS CAN'T HAPPEN UNLESS THERE'S A SYSTEM IN KIND OF
6 A COORDINATED WAY THAT THIS IS LINKED BETWEEN THE
7 CANCER CENTERS AND THE ACADEMIC SETTING TO THE
8 COMMUNITIES WHERE, AS YOU SAY, NOT ONLY IS THE
9 DIAGNOSIS, THERE IS AN OPPORTUNITY FOR THE
10 DIAGNOSTIC COMPONENT OF THIS, BUT ALSO IN THE
11 REFERRAL WHERE THERE'S A HUGE FALL-OFF OF POTENTIAL
12 PATIENTS WHO COULD MAKE IT INTO THESE TREATMENTS AND
13 TRIALS.

14 SO I THINK WHAT GEOFF PRESENTED TODAY
15 CREATES THE FORMAT FOR THIS TO HAPPEN. THESE
16 CENTERS ARE NOT -- THERE MAY BE SOME CENTERS THAT
17 ARE MORE ADVANCED THAN OTHERS IN THEIR COLLABORATION
18 WITH SOME OF THE ACADEMIC CENTERS AND EVEN THE ALPHA
19 CLINICS, BUT SOME OF THEM MAY NOT -- MAY BE COMING
20 IN AT A LESS DEVELOPED POINT. AND THOSE ARE THE
21 VERY ONES THAT WE ALSO WANT TO GET TO THE POINT THAT
22 THEY ARE ABLE TO ACCEPT THAT PARTNERSHIP AND BE ABLE
23 TO TAKE ON THE INTAKE KIND OF -- I DON'T WANT TO
24 REDUCE THE IMPORTANCE OF THAT -- BUT KIND OF THE
25 OUTREACH AND THE INTAKE AND THE REFERRAL ASPECTS OF

BETH C. DRAIN, CA CSR NO. 7152

1 WHAT'S NEEDED FOR THIS MACHINERY TO REALLY WORK AS
2 WELL AS ALSO BE INVOLVED IN THE CARE, EITHER THE
3 SCREENING, THE FOLLOW-UP, OR OTHER PARTS AND REALLY
4 BE PART OF THE WHOLE CARE TEAM.

5 SO I DO BELIEVE THAT WHAT ALL OF THE
6 MEMBERS HAVE SPOKEN OF TODAY WE WOULD BE LOOKING FOR
7 IN THE APPLICANTS TO SEE DO THEY HAVE THE WILL, DO
8 THEY HAVE THE STARTING POINT TO BE ABLE TO DO THIS.
9 AND TO THE QUESTION OF HOW DOES THIS ALL COME
10 TOGETHER, AS WITH OUR OTHER PROGRAMS, INCLUDING THE
11 ALPHA CLINICS AND THE MANUFACTURING NETWORK AND THE
12 SHARED LABS, THERE WILL BE A STEERING COMMITTEE
13 WHERE THERE'S CIRM REPRESENTATION. THERE'S
14 INTERACTIONS WITH EXTERNAL KEY OPINION LEADERS, BUT
15 ALSO CIRM LEADERSHIP AND CIRM BOARD MEMBERS IN
16 VARIOUS WAYS, AND THOSE ARE THE HUBS. THE STEERING
17 COMMITTEES ARE KIND OF THE HUBS OF THIS KNOWLEDGE
18 EXCHANGE SO THAT SOME OF THESE VERY CONVERSATIONS
19 CAN BE BROUGHT TO A MORE MATURE STAGE IN
20 IMPLEMENTATION.

21 SO I GUESS -- SO TO ANSWER THE FIRST
22 QUESTION, I DO BELIEVE THAT WHAT EVERYBODY IS
23 BRINGING UP IS VERY MUCH AN IMPORTANT CONSIDERATION.
24 AND, IN FACT, I THINK THAT SOME OF HOW THIS HAS BEEN
25 DESIGNED IS TO ADDRESS THAT. CIRM HAS IDENTIFIED

BETH C. DRAIN, CA CSR NO. 7152

1 THAT PERHAPS EARLY SCREENING AND DIAGNOSIS IS GOING
2 TO BE CRITICAL, BUT HOW DO YOU DO THAT IN A FEASIBLE
3 WAY THAT PARTNERS WITH KIND OF THE THERAPEUTICS
4 DEVELOPMENT WHERE YOU NEED TO HAVE THE
5 INFRASTRUCTURE AND THE TEAMS, AS GEOFF HAD
6 PRESENTED, TO DO THAT.

7 SO THOSE ARE -- THROUGH THE COMMUNITY CARE
8 CENTERS OF EXCELLENCE LISTENING SESSION, WE ACTUALLY
9 DID GET TANGIBLE EXAMPLES OF HOW THESE KIND OF
10 DEMONSTRATION CASES OF HOW THIS COULD WORK, IN FACT,
11 FOR CAR-T THERAPIES FOR TRANSPLANTS. AND SO I THINK
12 WHERE IT HAS WORKED IN SMALL SCALE, THE IDEA OF THIS
13 CONCEPT IS TO HAVE AN OPPORTUNITY TO SCALE UP AND TO
14 BRING SOME OF THE LESS DEVELOPED CENTERS OUT IN THE
15 COMMUNITY TO A LEVEL THEY CAN PARTICIPATE.

16 CHAIRPERSON BONNEVILLE: THANK YOU.
17 ADRIENNE.

18 MS. SHAPIRO: THIS IS SOMETHING THAT WE
19 REALLY HAVE BEEN DISCUSSING IN OUR COMMUNITY AND IN
20 OUR TALKS, THAT WE HAVE THE LACK OF OPPORTUNITY BY
21 OUR CARE PROVIDERS TO EVEN SUGGEST THAT WE HAVE
22 TESTING. AND THEN THE OTHER IS THE COST OF TESTING.
23 SO I THINK OUR COMMUNITY CARE CENTERS CAN HELP WITH
24 THAT AS WELL AS PART OF OUR EDUCATION WHICH WE CAN
25 DO THE PATIENTS TO REQUEST IT.

BETH C. DRAIN, CA CSR NO. 7152

1 BUT I ALSO WOULD LIKE TO KNOW IF THERE ARE
2 PEOPLE WORKING ON OR HOW DOES IT WORK TO REDUCE THE
3 COST OF THAT TESTING. ARE THERE ADVANCES? ARE
4 THERE GROUPS THAT ARE WORKING ON HOW TO MAKE IT, OR
5 IS THE TESTING JUST SPECIFIC SO THAT -- ARE WE
6 REALLY LOOKING AT THAT? BECAUSE IDEALLY IT WOULD BE
7 JUST SOMETHING THAT'S PART OF HEALTHCARE. YOU WOULD
8 BE ABLE TO BE TESTED LIKE YOU DO WERE YOU VACCINATED
9 OR WERE YOU THIS, THAT, OR THE OTHER, WHAT DO YOU
10 HAVE GOING ON TO HAVE THIS GENETIC TESTING DONE.

11 SO I GUESS THAT'S A QUESTION. IT MAY NOT
12 BE FOR HERE, BUT IF WE'RE REALLY TALKING ABOUT
13 ACCESS AND EVERYTHING AND EQUALITY, HAVING THAT BE
14 PART OF IT. SO I DON'T KNOW IF ANYBODY IS WORKING
15 ON IT OR THERE ARE THOUGHTS ABOUT IT OR WHAT, BUT
16 ULTIMATELY THAT WOULD BE PART OF THE GREAT
17 EQUALIZER, RIGHT, HAVING EVERYBODY AVAILABLE WITHOUT
18 MAYBE HAVING A PROVIDER THAT INSISTS THAT YOU'RE
19 BEING TESTED FOR A CERTAIN REASON.

20 CHAIRPERSON BONNEVILLE: HARLAN, WERE YOU
21 GOING --

22 DR. LEVINE: I JUST HAD A COMMENT.
23 THERE'S A BIOMARKER BILL OUT THERE. THERE'S A
24 BIOMARKER BILL OUT THERE GOING THROUGH THE SYSTEM
25 RIGHT NOW WHICH WILL MAKE IT EASIER TO GET, BUT

BETH C. DRAIN, CA CSR NO. 7152

1 THAT'S JUST A FIRST STEP. I THINK IT'S A WHOLE
2 EDUCATIONAL PROCESS, CULTURAL PROCESS TO GET THE
3 WORD OUT TO THE VARIOUS GROUPS. I THINK THE PRICE
4 OF THE TEST IS GOING DOWN ALSO. AND THEN THE NUMBER
5 OF CASES THAT ARE GETTING DENIED ARE LESS WITH WHAT
6 WE KNOW TODAY. BUT I THINK THE ISSUE HERE IS AS WE
7 WANT TO DO MORE -- THERE WILL BE NEWER TESTS.
8 THERE'S ALWAYS GOING TO BE THIS RESISTANCE NOT TO
9 APPROVE THINGS UNTIL THERE'S ABSOLUTE, OVERWHELMING
10 EVIDENCE, WHICH TAKES YEARS, AND WE DON'T LIVE IN AN
11 ENVIRONMENT OF YEARS ANYMORE. THINGS MOVE MORE
12 RAPIDLY. SO THAT GETS TO THE POINT JIM WAS MAKING
13 EARLIER. BUT IT'S GOING TO GET A LITTLE BETTER, BUT
14 IT'S ALWAYS GOING TO BE BARRIERS THAT WILL
15 DISPROPORTIONATELY AFFECT UNDERREPRESENTED
16 COMMUNITIES. I THINK YOU'RE RIGHT. WE NEED TO PUT
17 MORE EFFORT INTO THAT.

18 CHAIRPERSON BONNEVILLE: THANK YOU. SO
19 I'M GOING TO ASK THAT WE HAVE A MOTION TO RECOMMEND
20 THIS TO THE SCIENCE SUBCOMMITTEE FOR CONSIDERATION
21 AND RECOMMENDATION TO THE FULL BOARD.

22 DR. LEVITT: SO MOVED.

23 CHAIRPERSON BONNEVILLE: THANKS, PAT. DAN
24 DO YOU WANT TO BE SECOND?

25 MR. BERNAL: OH, YES. SORRY. I WAS

BETH C. DRAIN, CA CSR NO. 7152

1 MUTED.

2 CHAIRPERSON BONNEVILLE: IS THERE ANY
3 OTHER CONVERSATION THAT THE GROUP WANTS TO HAVE?

4 DR. GOLDSTEIN: I JUST WANT TO MAKE ONE
5 COMMENT, THAT IN REFINEMENT OF THE ACTUAL CONTRACT,
6 ANY TIME YOU HAVE DIRECT RESPONSIBILITY, YOU CAN --
7 OPTIMISTICALLY YOU HAVE OVERLAP. PESSIMISTICALLY
8 WHAT YOU HAVE IS FINGER POINTING. IT'S YOUR
9 RESPONSIBILITY. NO, IT'S YOUR RESPONSIBILITY TO GET
10 IT DONE. AND I JUST KNOW THAT THE DEVILS IN THE
11 DETAILS ON ANY ACTUAL CONTRACTING, ESPECIALLY IF IT
12 IS IN SUPPORT OF EXISTING PROGRAMS, EVERYBODY CAN
13 ALWAYS FIND A WAY TO TAKE MONEY IN A BUDGET THAT'S
14 ALREADY ALLOCATED FOR COMMUNITY OUTREACH AND FIND
15 OTHER USES FOR IT. SO JUST SPECIFICS THAT WILL NEED
16 TO BE GARNERED WHEN YOU ACTUALLY HAVE THE SIX OR SO
17 INDIVIDUAL DETAILED RELATIONSHIPS.

18 DR. LOMAX: YEAH. JUST A BRIEF COMMENT
19 THERE. THAT'S WHY WE ACTUALLY PULLED, FOR EXAMPLE,
20 THAT COMMUNITY ENGAGEMENT PIECE. THERE WAS A VERY
21 STRONG RECOMMENDATION THAT THERE'S A SUBSTANTIAL
22 COMMUNITY ENGAGEMENT PIECE. SO BY PULLING THAT OUT
23 AS A SEPARATE LINE ITEM, WE FELT THAT WAS AN
24 ADMINISTRATIVE MECHANISM TO ENSURE THAT THOSE FUNDS
25 FLOWED TO WHERE THEIR COMMITMENT LIES.

BETH C. DRAIN, CA CSR NO. 7152

1 DR. GOLDSTEIN: GREAT. THANK YOU.

2 CHAIRPERSON BONNEVILLE: DO WE HAVE ANY
3 PUBLIC COMMENT? I DON'T THINK WE HAVE ANY. THANK
4 YOU. SO I'M NOT SURE WHO'S CALLING FOR THE VOTE.
5 IS IT SCOTT, DOUG, OR -- I THINK MAYBE DOUG. SCOTT.

6 MR. TOCHER: SORRY. ONE OF THOSE DAYS.
7 THIS WILL BE A ROLL CALL ON THE MOTION TO RECOMMEND
8 APPROVAL TO THE SCIENCE SUBCOMMITTEE WITH FURTHER
9 RECOMMENDATION TO THE FULL BOARD.

10 KIM BARRETT. DAN BERNAL.

11 MR. BERNAL: AYE.

12 MR. TOCHER: MARIA BONNEVILLE.

13 CHAIRPERSON BONNEVILLE: YES.

14 MR. TOCHER: ANN BOYNTON.

15 MS. BOYNTON: AYE.

16 MR. TOCHER: JAMES DEBENEDETTI.

17 MR. DEBENEDETTI: AYE.

18 MR. TOCHER: DANA DORNSIFE. TED
19 GOLDSTEIN.

20 DR. GOLDSTEIN: AYE.

21 MR. TOCHER: DAVID HIGGINS.

22 DR. HIGGINS: YES.

23 MR. TOCHER: VITO IMBASCIANI. VITO.
24 HARLAN LEVINE.

25 DR. LEVINE: AYE.

BETH C. DRAIN, CA CSR NO. 7152

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25

MR. TOCHER: PAT LEVITT.

DR. LEVITT: AYE.

MR. TOCHER: ADRIANA PADILLA.

DR. PADILLA: YES.

MR. TOCHER: DAVID SERRANO-SEWELL.

MR. SERRANO-SEWELL: AYE.

MR. TOCHER: MAHESWARI SENTHIL.

DR. SENTHIL: YES.

MR. TOCHER: ADRIENNE SHAPIRO.

MS. SHAPIRO: AYE.

MR. TOCHER: AND, VITO, ONE LAST TRY. I
THINK YOU MAY HAVE BEEN ON MUTE. ALL RIGHT.

IN ANY EVENT, MARIA, THE MOTION CARRIES.

CHAIRPERSON BONNEVILLE: THANK YOU SO
MUCH, SCOTT. I WANT TO THANK EVERYONE FOR
PARTICIPATING. SO YOUR COMMENTS WERE INCREDIBLY
HELPFUL TO THE TEAM AND TO ME, AND YOUR WORK ON THE
COMMITTEE IS REALLY VALUABLE. SO THANK YOU.

AND ANOTHER SHOUT-OUT TO GEOFF AND EMILY
FOR ALL YOUR HARD WORK ON THIS. AND ALL THE OTHER
CIRM TEAM MEMBERS THAT HAVE REALLY BROUGHT THIS TO
FRUITION. THANK YOU AGAIN. BYE-BYE.

(THE MEETING WAS THEN CONCLUDED AT 3:07 P.M.)

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
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 OCTOBER 9, 2023, WAS HELD AS HEREIN APPEARS AND THAT THIS IS THE ORIGINAL TRANSCRIPT THEREOF AND THAT THE STATEMENTS THAT APPEAR IN THIS TRANSCRIPT WERE REPORTED STENOGRAPHICALLY BY ME AND TRANSCRIBED BY ME. I ALSO CERTIFY THAT THIS TRANSCRIPT IS A TRUE AND ACCURATE RECORD OF THE PROCEEDING.

BETH C. DRAIN, CA CSR 7152
133 HENNA COURT
SANDPOINT, IDAHO
(208) 920-3543