

BETH C. DRAIN, CA CSR NO. 7152

BEFORE THE
ACCESS 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: DECEMBER 1, 2022
11 A.M.

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

FILE NO.: 2022-43

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

I N D E X

ITEM DESCRIPTION	PAGE NO.
OPEN SESSION	
1. CALL TO ORDER	3
2. ROLL CALL	3
DISCUSSION ITEMS	
3. UPDATE ON PATIENT SUPPORT PROGRAM REQUEST FOR PROPOSAL	4
4. UPDATE ON COMMUNITY CARE CENTERS OF EXCELLENCE FRESNO LISTENING SESSION	11
5. INTRODUCTION AND KICK-OFF OF ROADMAP FOR ACCESSIBILITY AND AFFORDABILITY	27
6. PUBLIC COMMENT	40
7. ADJOURNMENT	42

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

DECEMBER 1, 2022; 11 A.M.

(THE MEETING WAS DULY CALLED TO ORDER
BY CHAIRMAN TORRES, AND THE ROLL WAS BEGUN AND HEARD
AS FOLLOWS:)

MS. DEQUINA-VILLABLANCA: DAN BERNAL. ANN
BOYNTON.

MS. BOYNTON: HERE.

MS. DEQUINA-VILLABLANCA: JAMES BENEDETTI.

MR. BENEDETTI: HERE.

MS. DEQUINA-VILLABLANCA: DANA DORNSIFE.

MS. DORNSIFE: HERE.

MS. DEQUINA-VILLABLANCA: DANA GOLDMAN.
TED GOLDSTEIN.

DR. GOLDSTEIN: HERE.

MS. DEQUINA-VILLABLANCA: DAVID HIGGINS.

DR. HIGGINS: HERE.

MS. DEQUINA-VILLABLANCA: HARLAN LEVINE.

DR. LEVINE: HERE.

MS. DEQUINA-VILLABLANCA: PAT LEVITT.

DR. LEVITT: HERE.

MS. DEQUINA-VILLABLANCA: ADRIANA PADILLA.

DR. PADILLA: HERE.

MS. DEQUINA-VILLABLANCA: AMMAR QADAN. AL
ROWLETT.

BETH C. DRAIN, CA CSR NO. 7152

1 MR. ROWLETT: HERE.

2 MS. DEQUINA-VILLABLANCA: MAHESWARI

3 SENTHIL. DAVID SERRANO SEWELL. ADRIENNE SHAPIRO.

4 JONATHAN THOMAS.

5 CHAIRMAN THOMAS: HERE.

6 MS. DEQUINA-VILLABLANCA: ART TORRES.

7 MR. TORRES: HERE.

8 MS. DEQUINA-VILLABLANCA: OKAY.

9 CHAIRMAN THOMAS: HOW FAR SHORT ARE WE?

10 MS. DEQUINA-VILLABLANCA: WE ARE SHORT BY

11 ONE.

12 CHAIRMAN THOMAS: OKAY. THIS PROMISES TO

13 BE A VERY PRODUCTIVE MEETING, MEMBERS. AND IT'S

14 GOING TO BE BASICALLY AN OVERVIEW OF WHERE WE'VE

15 BEEN, WHERE WE ARE HEADED, AND ALSO A REVIEW OF OUR

16 FIRST AND LAST, NOT LAST, BUT OUR FIRST FIELD

17 MEETING WHICH TOOK PLACE IN THE CENTRAL VALLEY.

18 SO I'D LIKE TO ASK SEAN TO OPEN IT UP.

19 DR. TURBEVILLE: ALL RIGHT. THANK YOU,

20 SENATOR. LET ME START SHOWING MY SLIDES AND WE'LL

21 KICK THIS OFF. ALL RIGHT. ARE WE GOOD WITH SLIDES?

22 ANYBODY GIVE ME A THUMBS UP? THANK YOU. ALL RIGHT.

23 WELL, WELCOME, EVERYBODY, TO DECEMBER 1ST,

24 OUR AAWG MEETING. THIS IS THE LAST AAWG MEETING OF

25 THE YEAR. WE ARE NOW EXACTLY NINE MONTHS TO THIS

BETH C. DRAIN, CA CSR NO. 7152

1 DAY INTO THIS JOURNEY. WE'VE PRODUCED QUITE A BIT
2 OF SUCCESSES WITH RESPECT TO SOME OF THE WORK
3 STREAMS THAT WE PUT IN PLAY.

4 I DO WANT TO THANK A COUPLE PEOPLE RIGHT
5 OUT OF THE GATE. ONE IS MARIA MILLAN FOR HAVING THE
6 VISION OF MEDICAL AFFAIRS. I THINK TWO TO THREE
7 YEARS FROM NOW WE'RE GOING TO REALIZE THAT SHE IS A
8 VISIONARY WHEN IT COMES TO THE TYPE OF
9 INFRASTRUCTURE THAT'S GOING TO BE NEEDED TO SUPPORT
10 MANY OF THE CLINICAL TRIALS THAT ARE GOING TO SOON
11 HOPEFULLY READ OUT. AND THAT WILL ROLL INTO
12 COMMERCIAL APPROVAL, HOPEFULLY, FOR A COUPLE OF
13 THEM.

14 ALSO SENATOR TORRES, WHO HAS PROVIDED
15 SIGNIFICANT LEADERSHIP RIGHT OUT OF THE GATE ON DAY
16 ONE TO US. WITHOUT HIM, HE IS INTERACTIVE WITH A
17 NUMBER OF COLLEAGUES AT THE STATE LEVEL THAT HAVE
18 GOTTEN MEDICAL AFFAIRS EXPOSED TO ALL THE WAY TO THE
19 GOVERNOR'S OFFICE. AND I THINK SOME OF THOSE
20 COLLEAGUES WILL BE INSTRUMENTAL AS WE DEVELOP ACCESS
21 AND AFFORDABILITY MOVING FORWARD.

22 SO FOR TODAY WE HAVE FOUR ITEMS WE WANT TO
23 ADDRESS. ONE IS WE WANT TO PROVIDE AN UPDATE ON THE
24 PATIENT SUPPORT PROGRAM AND THE RFP. TWO, SCOTT
25 TOCHER FROM LEGAL, MANY OF YOU PROBABLY WORKED WITH

BETH C. DRAIN, CA CSR NO. 7152

1 HIM IN THE PAST, IS GOING TO PROVIDE A VERBAL UPDATE
2 ON OUR COI. NOW, THIS IS IMPORTANT BECAUSE, AS WE
3 START TO ROLL INTO 2023, WE HAVE A LOT OF
4 ACTIVITIES. IT'S GOING TO BE REALLY HEAVY. I'M
5 LOOKING FORWARD TO SOME OF THE ACTIVITIES WE GET TO
6 KICK OFF IN JANUARY. BUT IN ORDER TO DO THAT, WE DO
7 HAVE TO TAKE A LOOK AT CONFLICTS OF INTEREST. AND
8 SO SCOTT WILL PROVIDE AN UPDATE AND THE RATIONALE
9 WHY WE ARE KICKING THAT OFF.

10 THEN I'M GOING TO KICK IT OVER TO OUR
11 ESTEEMED COLLEAGUE GEOFF LOMAX AND MEDICAL AFFAIRS.
12 AS YOU KNOW, WE HAVE HAD OUR FIRST COMMUNITY CARE
13 CENTERS OF EXCELLENCE LISTENING SESSION. SO HE'S
14 GOING TO PROVIDE A ROBUST UPDATE FROM THE
15 UCSF/FRESNO MEETING.

16 AND THEN IT'S GOING TO PUNT BACK TO ME,
17 AND WE'LL FINISH UP WITH A QUICK INTRODUCTION WITH
18 THE KICKOFF OF OUR ROAD MAP FOR ACCESS AND
19 AFFORDABILITY.

20 SO FOR ME, GIVE YOU AN UPDATE ON THE
21 PATIENT SUPPORT PROGRAM. SO WE HAVE OUR FINAL RFP
22 THAT'S CIRCULATING RIGHT NOW FOR REVIEW. IT'S THE
23 FINAL REVIEW PROCESS. WE RECEIVED A LOT OF GREAT
24 INSIGHT AND COMMENTS FROM OUR CIRM COLLEAGUES. WE
25 HAVE ONE MORE PROCESS OF REVIEWS. OUR ANTICIPATION

BETH C. DRAIN, CA CSR NO. 7152

1 IS THAT WE'LL BE ABLE TO POST THIS BY THE END OF THE
2 YEAR, BEFORE THE END OF THE YEAR. AND IF ALL GOES
3 WELL, WE'LL BE ABLE TO AT LEAST FLIP THE SWITCH, IF
4 YOU WILL, ON Q2, Q3 AND START HELPING PATIENTS AS
5 QUICKLY AS POSSIBLE FOR THE CLINICAL TRIAL PROCESS.

6 SO WITH THAT, I WANT TO PUNT IT OVER TO
7 SCOTT TO GIVE US A QUICK UPDATE ON THE COI.

8 MR. TOCHER: THANK YOU, SEAN. AND GOOD
9 MORNING, EVERYONE. AS SEAN INDICATED, HE ASKED ME
10 TO BRIEF THE WORKING GROUP ON A COUPLE OF POLICIES
11 THAT WILL APPLY TO YOUR WORK AS IT MOVES FROM A
12 BROAD SORT OF GENERAL CONSIDERATION OF PROGRAMS AND
13 INTO CONSIDERATION OF RECOMMENDING SPECIFIC AWARDS
14 OR CONSIDERATION OF SPECIFIC CONTRACTS AND REVIEW OF
15 CONFIDENTIAL AND PROPRIETARY INFORMATION IN THE
16 COURSE OF THOSE REVIEWS OR RECEIVING CONFIDENTIAL
17 PORTFOLIO UPDATES OR OTHER TYPES OF NONPUBLIC
18 INFORMATION.

19 I KNOW THAT THIS IS NOT THE MOST EXCITING
20 TOPIC, SO I'LL TRY TO GET IT DONE QUICKLY. BUT IT
21 IS IMPORTANT BECAUSE, OF COURSE, EVERYTHING THAT
22 CIRM DOES IS SUBJECT TO GREAT SCRUTINY. AND
23 HISTORICALLY CONFLICTS OF INTEREST AND OUR APPROACH
24 TO MANAGING CONFLICTS HAVE DRAWN PARTICULAR
25 ATTENTION.

BETH C. DRAIN, CA CSR NO. 7152

1 SO BY WAY OF BACKGROUND, BECAUSE THIS
2 WORKING GROUP AND OTHER CIRM WORKING GROUPS ARE
3 PURELY ADVISORY BODIES, THE LAW THAT CREATED CIRM
4 AND THIS WORKING GROUP EXEMPTS THE MEMBERS OF THIS
5 WORKING GROUP, THE NON-ICOC MEMBERS, FROM THE
6 STATE'S CONFLICT OF INTEREST LAWS AMONG OTHER
7 THINGS. HOWEVER, THE LAW DOES REQUIRE THAT OUR
8 GOVERNING BOARD, THE ICOC, ADOPT POLICIES GOVERNING
9 CONFLICTS OF INTEREST TO APPLY TO MEMBERS OF THIS
10 WORKING GROUP.

11 SO TO THAT END, THE ICOC HAS ADOPTED COI
12 POLICIES BASED IN PART ON NIH GUIDELINES THAT GOVERN
13 A VARIETY OF POTENTIAL SOURCES OF CONFLICT OF
14 INTEREST TO ENSURE THAT ANY FUNDING RECOMMENDATIONS
15 ARE MADE IN A FAIR MANNER THAT IS FREE FROM
16 CONFLICTS.

17 SO PURSUANT TO THE BYLAWS THAT THIS
18 WORKING GROUP REVIEWED AND THAT WERE ADOPTED BY THE
19 ICOC THIS YEAR, THE ICOC WILL BE ADOPTING A COI
20 POLICY, HOPEFULLY THIS MONTH, TO FULFILL THAT
21 REQUIREMENT IN THE BYLAWS AND THE ACT THAT THIS BODY
22 OPERATE PURSUANT TO A COI POLICY. AND, AGAIN, THESE
23 RULES WILL BE MODELED VERY CLOSELY ON RULES THAT THE
24 ICOC HAS ALREADY ADOPTED TO APPLY TO ANOTHER OF ITS
25 AWARD RECOMMENDING BODIES, THE GRANTS WORKING GROUP.

BETH C. DRAIN, CA CSR NO. 7152

1 SO THE RULES WILL BE FAIRLY, I THINK,
2 INTUITIVE IN APPLICATION AND WILL IDENTIFY
3 CONFIDENTIALLY FINANCIAL INTERESTS THAT WOULD
4 DISQUALIFY MEMBERS FROM PARTICIPATING IN THE
5 CONSIDERATION OF A PARTICULAR APPLICATION OR
6 CONTRACT IN THE EVENT THAT A MEMBER HAS A CONFLICT.

7 THE ICOC GENERALLY DEFINES POTENTIAL
8 CONFLICTS ACCORDING TO THREE TYPES: FINANCIAL,
9 PERSONAL, AND PROFESSIONAL. SO, FOR INSTANCE, IF A
10 MEMBER OF THIS WORKING GROUP OR HIS OR HER IMMEDIATE
11 FAMILY MEMBER IS AN EMPLOYEE OF AN APPLICANT
12 INSTITUTION OR A KEY PERSON ON THE APPLICATION OR IS
13 PROMISED INCOME OF A CERTAIN THRESHOLD FROM THE
14 APPLICANT OR IF THE MEMBER IS UNDER CONSIDERATION
15 FOR EMPLOYMENT WITH THE APPLICANT INSTITUTION OR
16 OTHERWISE RECEIVE SOME FINANCIAL BENEFIT, THEN A
17 CONFLICT WILL EXIST AND WE WILL PRECLUDE THE MEMBER
18 FROM PARTICIPATING IN THE CONSIDERATION OF THAT
19 AWARD.

20 A PROFESSIONAL CONFLICT WOULD BE ONE WHERE
21 THE MEMBER AND AN INDIVIDUAL ON AN APPLICATION ARE
22 ENGAGED IN OR PLANNING TO ENGAGE IN A JOINT PROJECT
23 OF SOME SORT.

24 AND PERSONAL CONFLICT WOULD BE PRESENT
25 WHERE AN IMMEDIATE FAMILY MEMBER OR CLOSE PERSONAL

BETH C. DRAIN, CA CSR NO. 7152

1 FRIEND IS LISTED ON THE APPLICATION OR WHERE THE
2 MEMBER AND A PERSON ON THE APPLICATION HAVE BEEN ON
3 OPPOSING SIDES IN A LAWSUIT.

4 SO AS PART OF THE PROCESS, PRIOR TO THE
5 MEETING OF THIS WORKING GROUP TO CONSIDER AN
6 APPLICATION, A MODULE WILL BE SET UP WITH OUR GRANTS
7 WORKING GROUP PERSONNEL WHO WILL HELP SET THIS UP
8 FOR US. A MODULE WILL BE SET UP IN ADVANCE OF THE
9 MEETING THAT WILL IDENTIFY KEY INSTITUTIONS AND KEY
10 PERSONNEL AND INDIVIDUALS ON AN APPLICATION. AND
11 YOU HAVE WILL THE OPPORTUNITY TO REVIEW THAT LIST
12 AND IDENTIFY POTENTIAL CONFLICTS.

13 I ALSO WANTED TO ADDRESS A SEPARATE BUT
14 EQUALLY IMPORTANT POLICY THAT'S PERTINENT TO THE
15 WORKING GROUP WORK WHEN IT CONSIDERS SPECIFIC
16 APPLICATIONS OR REVIEWS NONPUBLIC CONFIDENTIAL
17 INFORMATION.

18 AS PART OF YOUR BYLAWS THAT YOU REVIEWED
19 AND WERE RECOMMENDED BY THIS WORKING GROUP AND
20 ADOPTED BY THE BOARD, MEMBERS OF THE WORKING GROUP
21 ARE GOVERNED BY A CONFIDENTIALITY POLICY TO ENSURE
22 THE PROTECTION OF CONFIDENTIAL AND PROPRIETARY
23 INFORMATION THAT YOU RECEIVE WHEN DOING THE WORK OF
24 THIS GROUP. WE MAINTAIN THE CONFIDENTIALITY DURING
25 THE REVIEW PROCESS OF A PARTICULAR APPLICATION TO

BETH C. DRAIN, CA CSR NO. 7152

1 PROTECT THE INTERESTS OF THE APPLICANTS AND TO
2 ENCOURAGE CANDOR AMONG YOURSELVES WHEN YOU ARE
3 REVIEWING THE VALUE OF AN APPLICATION OR CONTRACT.
4 AND, AGAIN, PRETTY STRAIGHTFORWARD. WHERE
5 CONFIDENTIAL INFORMATION IS PART OF AN APPLICATION,
6 IT'S OUR OBLIGATION AND THE MEMBERS TO SAFEGUARD IT.
7 THEREFORE, THE POLICY PROHIBITS DISCLOSURE OF ANY
8 REVIEW MATERIALS OR CONTENTS OF THE DISCUSSIONS
9 DURING THE REVIEW WITH ANY OUTSIDE PARTIES.
10 SIMILARLY ANY HARDCOPY MATERIALS, FOR INSTANCE, THAT
11 MIGHT BE GENERATED DURING THE REVIEW MUST NOT BE
12 SHARED AND MUST BE DESTROYED AFTER THE MEETING.

13 SO THOSE ARE JUST THE HIGHLIGHTS OF A
14 COUPLE OF KEY POLICIES THAT WILL GOVERN THE WORK
15 THAT SEAN DESCRIBED GOING INTO 2023. AND I JUST
16 APPRECIATE THE OPPORTUNITY TO BRING THEM TO YOUR
17 ATTENTION.

18 CHAIRMAN TORRES: THANK YOU VERY MUCH,
19 SCOTT. AND, OF COURSE, I KNOW THERE WILL BE
20 QUESTIONS DOWN THE ROAD. SO PLEASE FEEL FREE TO
21 COMMUNICATE WITH SCOTT ANY QUESTIONS YOU MIGHT HAVE,
22 WHAT ISSUES COME UP AS WE GO THROUGH THIS PROCESS.
23 THANK YOU AGAIN.

24 SO NOW WE'RE GOING TO HAVE AN UPDATE ON
25 OUR FIRST CCCE LISTENING SESSION. I THINK DR. LOMAX

BETH C. DRAIN, CA CSR NO. 7152

1 IS GOING TO PROVIDE US THE OVERVIEW.

2 DR. TURBEVILLE: CORRECT. GEOFF, IT'S ALL
3 YOURS.

4 DR. LOMAX: GREAT. CAN I HAVE THE NEXT
5 SLIDE. THANK YOU. AND THANK YOU, SENATOR TORRES.

6 BY WAY OF INTRODUCTION, AGAIN, I'M GEOFF
7 LOMAX. I'M A SENIOR SCIENCE OFFICER ON THE MEDICAL
8 AFFAIRS AND POLICY TEAM. AND I'VE HAD THE PLEASURE
9 OF BEING ABLE TO WORK WITH THE TEAM TO KICK OFF OUR
10 PROCESS FOR THE DEVELOPMENT OF THE COMMUNITY CARE
11 CENTERS OF EXCELLENCE PROGRAM.

12 SO TO GIVE YOU A SENSE OF THE PROCESS, AND
13 AGAIN, A REMINDER, THE END GAME HERE IS TO COME UP
14 WITH WHAT WE CALL A REQUEST FOR APPLICATIONS. SO
15 COMING UP WITH A DOCUMENT THAT WOULD ALLOW
16 ORGANIZATIONS TO COME IN AND APPLY FOR FUNDING TO
17 THIS PROGRAM. AND THIS IS A FAIRLY STANDARD
18 PROCEDURE AT CIRM, AND I'VE APPLIED IT TO THE
19 COMMUNITY CARE CENTERS OF EXCELLENCE PROGRAM.

20 AND SO WE ARE AT THE BEGINNING OF THE
21 PROCESS WHICH I'VE DESCRIBED AS THE NEEDS ASSESSMENT
22 PHASE WHERE WE ARE PLANNING ON A SERIES OF REGIONAL
23 LISTENING SESSIONS THAT INCLUDES PROVIDERS,
24 INDIVIDUALS INVOLVED IN WORKFORCE DEVELOPMENT, AND
25 ALSO COMMUNITY MEMBERS WITH THE AIM OF REALLY

BETH C. DRAIN, CA CSR NO. 7152

1 UNDERSTANDING BOTH THE NEEDS AND CAPACITIES OF
2 PROVIDERS, THE WORKFORCE, AND THE COMMUNITY.

3 IN THE NEEDS ASSESSMENT PHASE, WE INCLUDE
4 MEMBERS OF THE ICOC, SPECIFICALLY THE PATIENT
5 ADVOCATES. WE HAVE A LIMITED NUMBER THAT CAN ATTEND
6 BECAUSE THESE ARE SMALL GROUP SESSIONS, AND WE ARE
7 BEING RESPECTFUL OF THE LIMITS ON THE NUMBER OF
8 MEMBERS THAT CAN BE INVOLVED IN A MEETING. AND WE
9 ARE AIMING TO HOLD A SERIES OF SESSIONS THROUGH THE
10 END OF JANUARY, PERHAPS EARLY FEBRUARY. I'M GOING
11 TO UPDATE YOU ON A MEETING THAT OCCURRED IN THE
12 FRESNO AREA. WE ARE ALSO LOOKING -- WE'VE JUST HAD
13 CONFIRMATION THAT WE'LL BE HAVING A SESSION IN
14 RIVERSIDE IN LATE JANUARY. AND WE ARE ALSO LOOKING
15 TOWARDS THE REDDING AREA TO COVER NORTHERN
16 CALIFORNIA. AND WE MAY INCLUDE ADDITIONAL SITES.

17 AFTER THE NEEDS ASSESSMENT PHASE, WE ARE
18 PLANNING ON A WORKSHOP WHERE WE TRY TO BRING
19 TOGETHER THE BROADER GROUP OF STAKEHOLDERS, AND
20 WE'LL BE ABLE TO HAVE A PUBLIC WORKSHOP WHERE WE CAN
21 HAVE PARTICIPATION WITH ICOC MEMBERS WITHOUT
22 LIMITATION ON THE NUMBERS.

23 FINALLY, FROM THIS WORKSHOP WE ARE AIMING
24 TO COME UP WITH A DRAFT CONCEPT PLAN WHICH WE WILL
25 BE WORKING WITH THIS WORKING GROUP AND THE SCIENCE

BETH C. DRAIN, CA CSR NO. 7152

1 SUBCOMMITTEE OF THE ICOC TO PRESENT A DRAFT WHICH
2 WILL THEN BE GOING TO THE ICOC FOR FINAL APPROVAL IN
3 JUNE. CAN I HAVE THE NEXT SLIDE PLEASE.

4 SO WHAT I'D LIKE TO DO NOW IS COVER AN
5 UPDATE ON THE LISTENING SESSIONS THEMSELVES, HOW WE
6 ORGANIZE THEM, AND GIVE YOU SOME HIGHLIGHTS FROM OUR
7 FIRST SESSION. BEFORE I DO THIS, I'D ALSO LIKE TO
8 RECOGNIZE THE CONTRIBUTIONS OF TWO CRITICAL TEAM
9 MEMBERS, EMILY REYES AND MARIVEL DE LA TORRE, WHO
10 ARE PROGRAM MANAGERS ON OUR TEAM, AND THEY'VE REALLY
11 DONE A TREMENDOUS LIFT HERE IN TERMS OF PULLING THE
12 MEETINGS TOGETHER AND MAKING SURE EVERYTHING RUNS
13 SMOOTHLY.

14 SO THE REGIONAL MEETINGS ARE INTENDED TO
15 DO THREE THINGS IN TERMS OF INFORMATION GATHERING.
16 ONE IS TO UNDERSTAND THE CAPACITIES OF REGIONAL
17 PROVIDERS TO SUPPORT CLINICAL RESEARCH. THE SECOND
18 IS TO IDENTIFY WORKFORCE TRAINING NEEDS TO SUPPORT
19 PATIENTS IN REGENERATIVE MEDICINE. AND THE THIRD IS
20 TO IDENTIFY OPPORTUNITIES TO PARTNER WITH
21 COMMUNITY-BASED ORGANIZATIONS TO BRING PATIENT
22 GROUPS INTO CLINICAL RESEARCH AND REALLY WORK AT THE
23 COMMUNITY LEVEL REALLY WITH THE AIM OF TRUST
24 BUILDING, WHICH IS A THEME THAT'S COME UP WITHIN
25 THESE SESSIONS.

BETH C. DRAIN, CA CSR NO. 7152

1 SO LET ME GO TO THE NEXT SLIDE WHICH
2 SUMMARIZES SOME OF WHAT WE ARE CALLING OUR
3 TAKEAWAYS. AND, AGAIN, I WANT TO BE A LITTLE BIT
4 CAREFUL HERE. WHAT I WANT TO PRESENT TO YOU IN THIS
5 SLIDE IS, A, HOW WE ARE SORT OF ORGANIZING OUR
6 THINKING AND GIVING YOU SOME PRELIMINARY THOUGHTS,
7 BUT I WANT TO SORT OF CONTEXT THAT WITH THE FACT
8 THAT THIS IS OUR FIRST MEETING. SO SOMETIMES SLIDES
9 CAN TAKE ON A LITTLE BIT OF A LARGER THAN LIFE SORT
10 OF PERSONA. AND SO THIS IS VERY PRELIMINARY, BUT
11 IT'S REALLY, AGAIN, HOW WE ARE TRYING TO ARRAY THE
12 INFORMATION AND GIVE YOU SOME THINKING AND GET
13 FEEDBACK FROM YOU ALL IN TERMS OF ARE WE ON THE
14 RIGHT TRACK IN TERMS OF BOTH HOW WE ARE ORGANIZING
15 OUR THINKING AND PRESENTING SOME OF THE RESULTS.

16 SO ONE THING WE LEARNED VERY MUCH FROM THE
17 FRESNO EXPERIENCE WAS THERE IS A VERY COMPREHENSIVE
18 INFRASTRUCTURE ALREADY TO SUPPORT CLINICAL RESEARCH
19 IN TERMS OF CLINICAL NETWORKS, THE TECHNOLOGY, THE
20 CLINICAL FOOTPRINT. IN ADDITION, THEY ARE EAGER TO
21 COLLABORATE WITH OUR ALPHA CLINICS NETWORK. AND
22 THERE'S A NUMBER OF POTENTIAL OPPORTUNITIES AND
23 COLLABORATIONS THAT WERE IDENTIFIED IN THAT
24 DISCUSSION. WE HAD ALPHA CLINIC TEAMS PARTICIPATE
25 IN THIS DISCUSSION WITH FOLKS FROM CLOVIS/FRESNO.

BETH C. DRAIN, CA CSR NO. 7152

1 AND I'M SHOWING YOU THIS ARROW HERE.

2 THE MAIN TAKEAWAY WAS NOT -- IT WAS
3 INTERESTING. IT WASN'T THAT THEY FELT THEY NEEDED
4 THE INFRASTRUCTURE. IT WAS REALLY THE KNOW-HOW AND
5 THE TRAINING AND THE ABILITY TO SORT OF NETWORK WITH
6 OUR EXISTING CLINICAL SITES TO DEVELOP THE ABILITY
7 TO SUPPORT CLINICAL TRIALS LOCALLY IN THE
8 FRESNO/CLOVIS AREA. SO, AGAIN, SORT OF MAKING THIS
9 CONNECTION, IF YOU SEE THAT ARROW, CONNECTING
10 CLINICAL READINESS TO TRAINING. THAT WAS WHAT WE
11 CALL A VERY STRONG THEME THAT EMERGED FROM THIS
12 DISCUSSION.

13 IN ADDITION, LOOKING AT THE -- IF YOU MOVE
14 OVER TO THE SIDE OF INCREASING PATIENT ACCESS, THERE
15 WAS A VERY ROBUST DISCUSSION THAT INVOLVED LOCAL
16 PHYSICIANS THAT BOTH WERE AFFILIATED WITH A MEDICAL
17 CENTER, BUT ALSO PRIMARY CARE PHYSICIANS FROM THE
18 COMMUNITY. AND THE THEME THAT EMERGED THERE WAS
19 THAT, AGAIN, SORT OF CONNECTING PHYSICIAN CAPACITY
20 AND KNOWLEDGE TO THIS SORT OF WHAT WE ARE CALLING
21 TRAINING AND EDUCATION AS THE PHYSICIANS LOCALLY
22 FELT THAT THERE WAS STILL VERY LIMITED KNOWLEDGE
23 ABOUT REGENERATIVE MEDICINE, CELL AND GENE THERAPY.
24 THE TYPES OF PROGRAMS WE ARE SUPPORTING REALLY ARE
25 NOT VISIBLE AND NOT PART OF THE CONVERSATION,

BETH C. DRAIN, CA CSR NO. 7152

1 PARTICULARLY WITH LOCAL DOCTORS OR PRIMARY CARE
2 PHYSICIANS.

3 AND THE SUGGESTION THERE WAS THERE REALLY
4 NEEDS TO BE ENGAGEMENT WITH GROUPS LIKE THE
5 CALIFORNIA MEDICAL ASSOCIATION, THE PRIMARY CARE
6 ASSOCIATION THAT BRINGS VISIBILITY TO THE TYPES OF
7 PROGRAMS WE ARE SUPPORTING AND WHAT THE
8 OPPORTUNITIES WOULD BE TO THEN HAVE LOCAL PHYSICIANS
9 REFER PATIENTS TO, HOPEFULLY, LOCAL SITES WHICH
10 WOULD THEN BE ABLE TO CONNECT THE PATIENTS WITH
11 EITHER THE CLINICAL TRIALS OR THE THERAPIES IN THE
12 FUTURE.

13 SO I WANT TO PAUSE THERE. I COULD TOUCH
14 ON A FEW OTHER OF THESE POINTS, BUT YOU HAVE THE
15 SLIDES. TO THE EXTENT ANY OF THESE POINTS PEAK YOUR
16 INTEREST, BE HAPPY TO ELABORATE ON THEM. AND ALSO
17 ASK SEAN IF HE HAD -- I KNOW, SEAN, YOU MIGHT HAVE
18 SOME COMMENTS IN TERMS OF HOW THE PATIENT ASSISTANCE
19 PROGRAM FITS IN HERE. SO IF YOU WANT TO CHIME IN,
20 PLEASE DO SO.

21 MS. DEQUINA-VILLABLANCA: J.T. HAS HIS
22 HAND RAISED.

23 CHAIRMAN THOMAS: SO THANK YOU, GEOFF.
24 AND I WANT TO ALSO CONGRATULATE GEOFF FOR RUNNING A
25 GREAT MEETING AT THE FRESNO/CLOVIS SITE. DR.

BETH C. DRAIN, CA CSR NO. 7152

1 PADILLA AND I REPRESENTED THE BOARD AT THAT MEETING.
2 MARIA BONNEVILLE WAS THERE AS WELL AS SEAN AND THE
3 MEDICAL AFFAIRS TEAM. IT WAS A HIGHLY ENTHUSIASTIC
4 MEETING. WHAT, GEOFF, WE HAD 20 TO 25 PEOPLE THERE,
5 SOMETHING LIKE THAT?

6 DR. LOMAX: I THINK, IF YOU INCLUDE THE
7 ONLINE PARTICIPATION, IT WAS ALMOST 30 FOLKS IN
8 TOTAL.

9 CHAIRMAN TORRES: YES. AND WHAT WAS VERY
10 EVIDENT IS HERETOFORE ANYBODY IN THE CENTRAL VALLEY
11 HOPING TO PARTICIPATE IN A CLINICAL TRIAL HAD FEW
12 OPTIONS. AND FREQUENTLY, IF THEY COULD AFFORD OR
13 MEANS WERE PROVIDED, THEY WOULD GET SENT TO UCSF OR
14 UC DAVIS OR WHATEVER. AND OBVIOUSLY THERE ARE A
15 NUMBER OF PEOPLE THAT COULDN'T DO THAT THAT WOULD
16 WISH TO BE INVOLVED. AND SO THERE WAS A TREMENDOUS
17 NEED ARTICULATED FOR THE COMMUNITY CARE CENTERS OF
18 EXCELLENCE IN THAT AREA. AND I THINK THAT THE FOLKS
19 IN ATTENDANCE WERE UNIFORMLY HIGHLY SUPPORTIVE OF
20 THIS. AND THE DISCUSSION WENT ON FOR QUITE SOME
21 TIME WITH GEOFF AS MODERATOR.

22 AND SO I THINK THAT IF THIS WAS ANY
23 INDICATION DOWN THE ROAD WHEN IT COMES TIME TO
24 ACTUALLY GO OUT WITH THE RFP FOR THIS, WE'RE GOING
25 TO SEE EXTREMELY ENTHUSIASTIC RESPONSE AND A TRUE

BETH C. DRAIN, CA CSR NO. 7152

1 EMPHASIS ON NEED FOR EXACTLY THIS SORT OF FACILITY,
2 AND TO BE ABLE TO CONNECT THIS TO THE ALPHA CLINIC
3 NETWORK WILL GREATLY ENHANCE THE NETWORK AND WILL
4 REALLY MATERIALLY ADVANCE THE AAWG'S GOAL OF
5 ACCESSIBILITY TO ALL THROUGHOUT THE STATE. SO I
6 THINK YOU'RE GOING TO FIND THAT THIS IS GOING TO BE
7 A VERY, VERY SUCCESSFUL PROGRAM.

8 CHAIRMAN TORRES: MR. LEVINE.

9 DR. LEVINE: SIR, THANK YOU. I HAD MAYBE
10 JUST A FEW FOUNDATIONAL QUESTIONS. MAYBE I MISSED
11 IT. SO COULD YOU COMMENT ON THE TYPE OF PHYSICIANS
12 OR PRACTICES THAT ARE REPRESENTED THAT SHOWED UP TO
13 THE MEETING, NO. 1? NO. 2, -- ACTUALLY LET ME STEP
14 BACK, GEOFF, AND SAY THANK YOU FOR THE SUMMARY. IT
15 WAS REALLY HELPFUL TO HEAR THE DISCUSSION. BUT JUST
16 WHO WERE THE DOCTORS WHO SHOWED UP, NO. 1?

17 NO. 2, WAS THIS REALLY ABOUT REFERRING
18 PATIENTS, OR WAS THERE ALSO INTEREST IN ACTIVELY
19 PARTICIPATING IN SOME OF THE TRIALS IN THEIR
20 OFFICES?

21 AND THEN, NO. 3, DID ANY OF THOSE KIND OF
22 OLD SCHOOL ISSUES OF LOSING PATIENTS COME UP OR ANY
23 HINT TO THAT COME UP IN ANY PART OF THE DISCUSSION?

24 DR. LOMAX: THANK YOU FOR THOSE QUESTIONS,
25 AND THEY'RE ALL GREAT QUESTIONS. SO FIRST OF ALL,

BETH C. DRAIN, CA CSR NO. 7152

1 THE TYPES OF PRACTICES. IT WAS PRIMARILY, I
2 BELIEVE, THREE DOCS WHO WERE AFFILIATED WITH THE
3 MEDICAL CENTER WERE PRESENT. AND THEY WERE
4 DESCRIBING ACTIVITIES -- THE ABILITY TO INTERACT
5 WITH EXISTING PATIENT POPULATIONS IN THE REGION.
6 THE PRIMARY AREAS THAT THEY WERE ENGAGED WITH
7 PATIENTS OR TREATING PATIENTS, THERE IS A SICKLE
8 CELL PROGRAM, THERE'S A SICKLE CELL CENTER
9 AFFILIATED IN THE MIX THERE. AND WE HAD ONE OF THE
10 DOCS ASSOCIATED WITH THAT CENTER. THERE'S ONCOLOGY
11 WHICH WAS REPRESENTED. AND THE THIRD -- I'M JUST
12 BLANKING ON THE THIRD. BUT THEY DID HAVE AN
13 AFFILIATION WITH THE CLOVIS/FRESNO CENTER. AND THEN
14 WE HAD AN OUTSIDE PHYSICIAN WHO WAS A PRIMARY CARE
15 PHYSICIAN IN THE COMMUNITY.

16 SO IN TERMS OF DOCTORS, I THINK THAT
17 ROUNDS OUT THE GROUP IN TERMS OF PARTICIPATION. I
18 MAY BE MISSING SOMEONE, BUT IT WAS PRIMARILY FOLKS
19 WHO WERE AFFILIATED -- WOULD BE WORKING WITH
20 PATIENTS. AND I THINK THIS WOULD JUMP TO YOUR THIRD
21 QUESTION AROUND THEIR POINT. THEY SPENT A LOT OF
22 TIME DISCUSSING THIS ISSUE OF LOSING PATIENTS. THE
23 TAKEAWAY THAT THEY PROVIDED US WAS THEY THOUGHT THE
24 VALUE OF HAVING THE CAPACITY, EVEN IF THE PATIENTS
25 NEEDED TO BE TREATED, SAY, AT A SPECIALTY SITE, SAY,

BETH C. DRAIN, CA CSR NO. 7152

1 WITHIN THE GENE THERAPY, THE ABILITY TO DO THE EVEN
2 PRETREATMENT. SO THE ELIGIBILITY SCREENING, TO DO
3 ALL THAT WORK IN THE COMMUNITY, TREAT, SAY, AT A
4 REMOTE SITE, AND THEN COME BACK AND DO THE FOLLOW-UP
5 IN THE COMMUNITY AND KEEPING THAT PATIENT IN THE
6 COMMUNITY WAS AMONG THE MOST IMPORTANT THINGS WE
7 COULD DO TO AVOID PATIENT LOSS. THAT WAS, I THINK,
8 A STRONG MESSAGE.

9 AND CAN YOU REMIND ME OF THE SECOND
10 QUESTION?

11 DR. LEVINE: YOU ANSWERED IT ACTUALLY,
12 WHICH IS THAT THEY WANT TO PARTICIPATE, BUT REALLY
13 THEY UNDERSTAND IT WOULD BE A BIT PRETREATMENT OR
14 THE ASSESSMENT AND THEN THE FOLLOW-UP. PROBABLY THE
15 MOST IMPORTANT TAKEAWAY IS THAT WE HAVE TO REALLY
16 STRUCTURE THIS IN A WAY THAT THE REFERRING
17 PHYSICIANS FEEL LIKE THEY'RE PART OF THE PROCESS AND
18 THAT THE PATIENTS REMAIN WITH THEM EVEN THOUGH WE
19 RECOGNIZE THE INTRICACIES OR THE SPECIFICS OF THE
20 TRIAL WILL NEED TO GET DONE AT AN ALPHA SITE.

21 DR. LOMAX: THAT'S CORRECT POTENTIALLY.
22 AND I'D LIKE -- LOOKING AT THE HANDS THAT ARE
23 RAISED, I THINK WE HAVE ADDITIONAL COMMENTS TO SORT
24 OF ADD TO MY RESPONSE. SO I'D ASK MY COLLEAGUES TO
25 PLEASE --

BETH C. DRAIN, CA CSR NO. 7152

1 CHAIRMAN TORRES: LET'S GO TO ADRIANA.

2 DR. PADILLA: I JUST WANTED TO REITERATE
3 WHAT GEOFF SAID. THERE WAS A VARIETY OF
4 PARTICIPANTS. IT WAS -- THERE WAS A LOT MORE FROM
5 THE CANCER CENTER THERE IN CLOVIS. AND THE ISSUE
6 ABOUT PATIENTS LEAVING THE AREA, THE WHOLE POINT OF
7 THE DISCUSSION WAS THEY WANT TO HAVE MORE
8 COLLABORATION WITH LARGE CENTERS, ALPHA CENTERS, THE
9 TERTIARY CARE INSTITUTIONS TO REALLY BRING THAT BACK
10 TO THE VALLEY. AND SO THAT CLOSE CONNECTION, THE
11 ABILITY TO DO A LOT OF PREWORK IN THE VALLEY, TO
12 HAVE ESSENTIAL SITE WHERE THERE'S EXPERTISE AND
13 COORDINATING ALL OF THESE EVENTS WITH PATIENTS WAS
14 HIGHLIGHTED.

15 SO IT'S NOT ABOUT LOSING PATIENTS. IT'S
16 ABOUT MORE OF DEVELOPING RELATIONSHIPS AND THE
17 ABILITY TO WORK ON INFRASTRUCTURE IN THE VALLEY IN
18 ORDER TO KEEP THE PATIENTS LOCALLY, WHICH PATIENTS
19 STRUGGLE WITH. NOBODY REALLY WANTS TO LEAVE IF YOU
20 CAN HAVE SERVICES AND THE EXPERTISE COMING IN AND
21 WORKING ALL AROUND YOU. THAT'S THE WIN-WIN FOR
22 EVERYBODY.

23 CHAIRMAN TORRES: RIGHT. RIGHT. THANK
24 YOU, ADRIANA. MARIA MILLAN.

25 DR. MILLAN: THANK YOU SO MUCH. I FOUND

BETH C. DRAIN, CA CSR NO. 7152

1 J.T.'S COMMENTS EXTREMELY PRODUCTIVE SESSION.

2 JUST TO YOUR QUESTION, HARLAN, SOME KIND
3 OF TANGIBLE EXAMPLES OF WHAT DR. PADILLA HAD POINTED
4 OUT IS THIS RELATIONSHIP WITH ACADEMIC MEDICAL
5 CENTERS AND BEING ABLE TO PROVIDE ACCESS TO ORGAN
6 TRANSPLANT, WHICH IS KIND OF A DEMONSTRATION CASE OF
7 THE TYPES OF REGENERATIVE MEDICINE TREATMENTS IN
8 TERMS OF THE LOCAL REFERRING PHYSICIANS AS WELL AS
9 THE TREATING PHYSICIANS AND THE LOCAL COMMUNITY
10 BEING BOTH TRAINED, AWARE, AND CONNECTED WITH THE
11 MEDICAL CENTER SO THAT THAT CAN HAPPEN MORE READILY
12 AND PROVIDE ACCESS.

13 AND ALSO AS ANOTHER EXAMPLE OF AS THE CAR
14 T FIELD STARTS TO MATURE, AND THERE ARE SOME CASES
15 AND SOME APPLICATIONS WHERE IT WILL BE FEASIBLE TO
16 BE ABLE TO THEN POTENTIALLY GENERALIZE THIS TO MORE
17 CENTERS THAT WOULD PROVIDE ACCESS TO OTHERS WHO
18 OTHERWISE MAY NOT BE ABLE TO ACCESS THE TRIALS AND
19 THE TREATMENTS FOR CANCER INDICATIONS. THANK YOU.

20 CHAIRMAN TORRES: THANK YOU, DR. MILLAN.
21 PAT LEVITT.

22 DR. LEVITT: THANK, ART. I THINK IT WAS
23 GEOFF WHO MENTIONED SORT OF A LACK OF UNDERSTANDING
24 OF CIRM AND STEM CELL INITIATIVES AND OTHER THINGS
25 THAT PERHAPS WE THOUGHT WERE MORE WIDELY KNOWN. AND

BETH C. DRAIN, CA CSR NO. 7152

1 SO I THINK, GEOFF, IT WAS YOU WHO, AS YOU WERE
2 REPORTING, NOTED THAT. I THINK THERE'S A
3 COMMUNICATIONS COMMITTEE, AND I SIT ON THAT
4 SUBCOMMITTEE. AND I THINK THEY NEED TO HEAR THIS
5 BECAUSE I THINK THAT WE HAVE MORE -- WE HAVE BROADER
6 TARGETS FOR COMMUNICATING WHAT WE DO AND WHAT THE
7 OPPORTUNITIES ARE THAN THE GENERAL PUBLIC WHICH IS
8 IMPORTANT AND POLICYMAKERS WHICH IS IMPORTANT.

9 BUT WHEN YOU MENTIONED THAT THERE ARE
10 PHYSICIANS AND OTHERS THERE WHO DIDN'T KNOW MUCH
11 ABOUT WHAT WE ARE ABOUT, I THINK THAT'S A CONCERN,
12 BUT ALSO MAYBE AN OPPORTUNITY FOR SOME
13 CROSS-COMMUNICATION BETWEEN SUBCOMMITTEES TO FIGURE
14 OUT HOW TO DEAL WITH THAT.

15 CHAIRMAN TORRES: THAT IS AN EXCELLENT
16 POINT, PAT, AND SOMETHING THAT I STRUGGLED WITH FOR
17 THE LAST 13 YEARS AT CIRM. HOW DO WE GET OUR
18 MESSAGE OUT THERE BECAUSE PEOPLE ARE JUST NOT
19 UNDERSTANDING WHO WE ARE YET FOR THE MOST PART. SO
20 MARIA GONZALEZ.

21 MS. BONNEVILLE: I WAS JUST GOING TO ECHO
22 THAT. WE DID HEAR THAT AT THE MEETING, AND I HEARD
23 SUBSEQUENTLY. WE HAD A CALL WITH SOME FOLKS FROM UC
24 MERCED ABOUT PERHAPS APPLYING TO DIFFERENT PROGRAMS
25 THAT WE OFFER THAT HAVE NOTHING TO DO WITH THE

BETH C. DRAIN, CA CSR NO. 7152

1 COMMUNITY CARE CENTERS OF EXCELLENCE BUT JUST IN
2 GENERAL. I DO THINK THERE'S SOME WORK WE NEED TO DO
3 IN THE VALLEY AND IN OTHER HARDER TO REACH AREAS
4 ABOUT WHO WE ARE AND WHAT SERVICES AND WHAT WE
5 PROVIDE. SO THAT'S NOTED.

6 AND, PAT, I THINK IT'S A GREAT IDEA TO
7 BRING THIS UP AT THE COMMUNICATIONS SUBCOMMITTEE. I
8 THINK WE'RE GOING TO SCHEDULE ONE FOR FEBRUARY. SO
9 I THINK THAT'S GREAT.

10 CHAIRMAN TORRES: GOOD. AND WE SHOULD
11 CONTINUE TO MOVE TO WORK MORE COLLABORATIVELY WITH
12 THE CHANCELLOR AT UC MERCED WHO I KNOW IS VERY
13 INTERESTED IN OUR WORK AND IS MOVING FORWARD TO
14 CREATE A MEDICAL CENTER, TEACHING SCHOOL THERE IN
15 THE VERY NEAR FUTURE WHICH THE GOVERNOR SUPPORTS.

16 ANYBODY ELSE ON THIS MATTER BEFORE WE MOVE
17 ON TO OUR FINAL SUBJECT, THE ROAD MAP FOR
18 ACCESSIBILITY AND AFFORDABILITY. SEAN, I WANT TO
19 THANK YOU AND MARIA MILLAN AND MARIVEL DE LA TORRE
20 FOR ALL OF YOUR EFFORTS AND WORK. MARIVEL FOR ALL
21 YOUR WORK AND EFFORTS.

22 I'VE BEEN IN CONTACT WITH THE GOVERNOR'S
23 OFFICE, AND THE POINT PERSON IN THE GOVERNOR'S
24 OFFICE IS RICHARD FIGUEROA. HE WAS MY FORMER STAFF
25 CONSULTANT WHEN I WAS A MEMBER OF THE SENATE HEALTH

BETH C. DRAIN, CA CSR NO. 7152

1 COMMITTEE. AND ALSO THEY HAVE JUST APPOINTED THE
2 EXECUTIVE DIRECTOR FOR THE OFFICE OF AFFORDABILITY,
3 VISHAAL, V-I-S-H-A-A-L, PEGANY, P-E-G-A-N-Y, AND
4 HE'S TAKEN OVER ALREADY TO BEGIN THE FIRST STEPS IN
5 SETTING UP THE OFFICE. SO THAT'S THE UPDATE FROM MY
6 END. AND, SEAN, YOU HAVE ANOTHER UPDATE.

7 DR. TURBEVILLE: YEAH. THAT WAS IT. AND
8 AGAIN, THANK YOU, SENATOR. SO WE ARE ALREADY
9 ENGAGED WITH QUITE A FEW INDIVIDUALS AT THE STATE
10 LEVEL, AS I MENTIONED EARLIER. AND I DON'T THINK WE
11 WOULD HAVE THOSE CONTACTS WITHOUT YOU. SO THANK YOU
12 VERY MUCH FOR TAKING THE INITIATIVE. I EXPECT WE'LL
13 HAVE PRETTY GOOD SYNERGIES WITH THE GOVERNOR'S
14 OFFICE. SO IT WOULD BE GOOD TO GET IN FRONT OF THEM
15 AS SOON AS POSSIBLE.

16 CHAIRMAN TORRES: AS WE CALL HIM, WE CALL
17 HIM FIG, RICHARD FIGUEROA. HE'S VERY COMPETENT,
18 VERY ASTUTE POLITICALLY. AND SO HE REALLY GETS IT.
19 AND WE HAVE HAD A COUPLE OF CONVERSATIONS ABOUT THE
20 OFFICE. AND HE WAS PART OF THE HISTORY WHEN WE WERE
21 DRAFTING PROP 14 AS WELL BECAUSE I INCLUDED HIM IN
22 SOME OF OUR DISCUSSIONS.

23 ANY OTHER MATTERS TO BE BROUGHT BEFORE
24 THIS GROUP? IF NOT, I WANT TO THANK ALL OF YOU FOR
25 PARTICIPATING. I KNOW IT TAKES TIME OUT OF YOUR

BETH C. DRAIN, CA CSR NO. 7152

1 VERY BUSY SCHEDULES. AND I HOPE THAT THE CONFLICT
2 OF INTEREST OVERVIEW BY SCOTT TOCHER WAS HELPFUL.
3 AND THANK YOU AGAIN, DR. LOMAX, MARIA, AND J.T., AND
4 MARIA MILLAN AND MARIA BONNEVILLE FOR YOUR
5 PARTICIPATION IN FRESNO AND ALSO, OF COURSE, TO DR.
6 LOMAX. SO THANK YOU SO MUCH. AND HAVE A WONDERFUL
7 HOLIDAY SEASON.

8 DR. TURBEVILLE: SENATOR, WE STILL HAVE
9 ONE LAST SLIDE.

10 CHAIRMAN TORRES: OH, SORRY.

11 DR. TURBEVILLE: THAT'S OKAY. ALL RIGHT.
12 WELL, THANK YOU, GEOFF. AND THANK YOU, SCOTT. SO
13 THAT WAS HELPFUL, AND WE'LL CONTINUE TO TALK ABOUT
14 COI AND THE COMMUNITY CARE CENTERS OF EXCELLENCE.
15 WE ARE TRACKING, BY THE WAY, ACCORDING TO PLAN WITH
16 THE CCCE. WE ANTICIPATE TWO OR THREE MORE MEETINGS,
17 AS GEOFF MENTIONED, AND THEN WE WILL LIKELY HAVE A
18 CONCEPT PLAN BY SUMMER OF NEXT YEAR.

19 SO NOW WE'RE GOING TO MOVE ON TO THE ROAD
20 MAP TO ACCESS AND AFFORDABILITY. AS YOU RECALL, ONE
21 OF CIRM'S FIVE-YEAR STRATEGIC PLANS IS TO COORDINATE
22 WITH THE AAWG IN DEVELOPING A ROAD MAP FOR ACCESS
23 AND AFFORDABILITY FOR REGENERATIVE MEDICINES FOR ALL
24 CALIFORNIA PATIENTS. THIS ROAD MAP WILL INCLUDE A
25 STRATEGY FOR GATHERING THE NECESSARY INFORMATION, TO

BETH C. DRAIN, CA CSR NO. 7152

1 SUPPORT REIMBURSEMENT, TO ENGAGE WITH POLICYMAKERS
2 AND REGULATORS, AND DEVELOP HEALTHCARE DELIVERY
3 MODELS THAT COULD BE IMPLEMENTED WITH AND REFINED
4 WITH THE ALPHA CLINICS AND THE FUTURE COMMUNITY CARE
5 CENTERS OF EXCELLENCE.

6 SO IN JANUARY OF NEXT YEAR, WE WILL
7 OFFICIALLY KICK OFF THE DEVELOPMENT OF A ROAD MAP
8 FOR ACCESS AND AFFORDABILITY. WE'LL BE FOCUSING
9 PRIMARILY ON OUR CIRM-SUPPORTED TRIALS. ABOUT 60
10 PERCENT OF OUR EFFORTS WILL BE FOCUSING ON ACCESS
11 AND AFFORDABILITY WITHIN THOSE TRIALS, BUT WE ALSO
12 HAVE TO THINK ABOUT THE 40 PERCENT AS WE START TO
13 ROLL POTENTIALLY INTO COMMERCIALIZATION FROM SOME OF
14 OUR TRIALS. AND IT'S IMPORTANT, THIS GOES BACK TO
15 THE COI, IN ORDER FOR CLINICAL TO PRESENT IN JANUARY
16 THE STATUS OF OUR PORTFOLIO, WE DO NEED TO GET THOSE
17 COI'S IN PLAY. AND THIS IS CRITICAL BECAUSE HOW
18 THOSE TRIALS READ OUT WILL IMPACT THE TYPE OF ROAD
19 MAP THAT WE WANT TO PUT IN PLAY.

20 SO, FOR EXAMPLE IF, IN FACT, ONCOLOGY
21 ASSETS READ OUT FIRST, WELL, THEN, THAT'S SOMEWHAT
22 OF A DIFFERENT PLAYBOOK THAN, LET'S SAY, THE ORPHAN
23 DISEASES OF THE WORLD, RIGHT? SO THIS GOES BACK TO
24 WHY THE COI IS CRITICALLY IMPORTANT.

25 NOW, THIS SLIDE IS JUST AN EXAMPLE OF A

BETH C. DRAIN, CA CSR NO. 7152

1 NUMBER OF STRATEGIES THAT'S ALIGNED WITH THE
2 LANGUAGE IN PROPOSITION 14. THIS IS JUST A SNAPSHOT
3 TO GIVE THE AAWG AN IDEA OF SOME OF THE CONCEPTS
4 WE'D LIKE TO BRING TO THE TABLE FOR CONSIDERATION.
5 SO LET ME WALK THROUGH A COUPLE OF THESE, AND THEN
6 WE CAN TALK ABOUT OUR PLAN, OUR NEXT SIX-MONTH PLAN
7 FOR NEXT YEAR.

8 SO ONE OF OUR STRATEGIES THAT WE'D LIKE TO
9 PRESENT IS, OF COURSE, FACILITATING REIMBURSEMENT
10 AND LIMIT PATIENT EXPENSES, RIGHT. AND THIS CAN
11 INCLUDE, OF COURSE, OUT-OF-POCKET EXPENSES FOR
12 PATIENTS IN THE CLINICAL TRIAL SETTING. HENCE, THIS
13 IS WHERE THE PATIENT SUPPORT SERVICES SITS. AND
14 WHEN, IN FACT, WE GET THIS LAUNCHED, WE'LL BE ABLE
15 TO TAKE SOME OF THE DATA THAT WE ARE GETTING FROM
16 OUR SERVICE PROVIDER, BRING THAT BACK TO THE AAWG,
17 AND SHOW THE IMPACT THAT WE ARE HAVING FOR PATIENTS
18 ON THE FINANCIAL SIDE.

19 THERE ARE A NUMBER OF ADDITIONAL TACTICS
20 AND STRATEGIES WE'D LIKE TO PRESENT UNDER THIS
21 CATEGORY. WE CAN INCLUDE PATIENT NAVIGATORS, OF
22 COURSE, AT THE COMMUNITY CARE CENTERS OF EXCELLENCE.
23 I WON'T GO OVER ALL OF THESE, BUT YOU CAN SEE WE'VE
24 ALREADY STARTED THINKING ABOUT THIS ROAD MAP FOR
25 ACCESS AND AFFORDABILITY.

BETH C. DRAIN, CA CSR NO. 7152

1 ANOTHER AREA WE'VE ALREADY HEARD FROM IN
2 THE COMMUNITY, OF COURSE, IS THE COVERAGE ANALYSIS,
3 INSURANCE SUPPORT, COPAY ASSISTANCE, AND ACCESS AND
4 APPEALS, WHICH MANY OF YOU ARE FAMILIAR WITH. THAT
5 IS ONE TACTIC THAT WE CAN PUT IN PLAY, AGAIN, TO
6 HELP FACILITATE REIMBURSEMENT AND LIMIT PATIENT
7 EXPENSES.

8 ANOTHER STRATEGY IS TO SUPPORT NEW PAYER
9 MODELS. AND THERE ARE A NUMBER OF INTERESTING -- WE
10 ARE ON THE CUSP, QUITE FRANKLY, OF THIS
11 FASCINATING -- THE BEST WAY TO ARTICULATE THIS IS
12 SORT OF A MOVEMENT, IF YOU WILL, WITH THE CELL AND
13 GENE THERAPIES. YOU'VE SEEN QUITE A FEW CELL
14 THERAPIES THAT HAVE JUST BEEN APPROVED. PAYERS ARE
15 JUST GETTING FAMILIAR WITH SOME OF THOSE VALUE-BASED
16 CONTRACTS. THAT'S TRUE ON THE PUBLIC SIDE AS WELL
17 AS THE PRIVATE PAYERS. THERE'S AN OPPORTUNITY FOR
18 US AND THE AAWG TO THINK ABOUT HOW WE MIGHT BE ABLE
19 TO SUPPORT THOSE MODELS. BUT EVEN MORE CHALLENGING,
20 PERHAPS WE MIGHT BE ABLE TO COME UP WITH A MODEL
21 OURSELVES THAT WE CAN PRESENT TO THE AAWG AND MORE
22 IMPORTANTLY TO THE ICOC.

23 SO THERE'S A NUMBER OF STRATEGIES THAT
24 WE'LL PRESENT TO THE AAWG MOVING FORWARD. ANOTHER
25 ONE IS TO ADDRESS STATE POLICY ISSUES. THIS IS

BETH C. DRAIN, CA CSR NO. 7152

1 SOMETHING WE NEED TO THINK ABOUT. ARE WE ONLY GOING
2 TO ADDRESS STATE, CALIFORNIA, POLICY ISSUES? ARE WE
3 GOING TO PERHAPS RECOMMEND NEW POLICY ISSUES? OR DO
4 WE GO EVEN FURTHER AND THINK ABOUT THE FEDERAL
5 POLICIES. THERE ARE A NUMBER OF THINGS FROM A
6 TACTICS STANDPOINT WE CAN CONSIDER FROM TREATMENT
7 ACROSS STATE LINES WITH MANY OF THE CLINICIANS HERE
8 ON THE PANEL WHO UNDERSTAND THAT CLEARLY. INPATIENT
9 VERSUS OUTPATIENT REIMBURSEMENT IS ANOTHER TACTIC.
10 AND THEN, AS SENATOR TORRES MENTIONED, WE ARE
11 ALREADY ENGAGING WITH THE GOVERNOR'S PLAN ON THE
12 OFFICE OF HEALTH AND AFFORDABILITY. SO THERE CAN BE
13 SOME GREAT SYNERGIES FOR CIRM AND THE GOVERNOR'S
14 COLLEAGUES.

15 AND THEN FINALLY, TO EXPAND ON THE
16 CLINICAL INFRASTRUCTURE. NOW, THIS IS REALLY JUST
17 PIGGYBACKING ON WHAT CIRM HAS ALREADY PUT IN PLAY
18 WITH THE ROBUST ALPHA CLINICS. THERE'S A GREAT
19 OPPORTUNITY, OF COURSE, TO EXPAND AND ENHANCE
20 ACCESS, OF COURSE, TO PATIENTS OUT IN THE REAL
21 COMMUNITY WITH THE COMMUNITY CARE CENTERS OF
22 EXCELLENCE. SO THAT WORKSTREAM HAS ALREADY KICKED
23 OFF. BUT HERE IS WHERE WE CAN START KICKING IN SOME
24 OF THE RESEARCH.

25 SO IF YOU THINK ABOUT THE PATIENT AND

BETH C. DRAIN, CA CSR NO. 7152

1 POSTMARKETING REGISTRIES, WHICH ARE ABSOLUTELY
2 CRITICAL FOR CELL AND GENE THERAPIES, PARTICULARLY
3 WHEN YOU TIE IT BACK TO THE PAYERS, THAT'S SOMETHING
4 THAT PERHAPS WE MIGHT BE ABLE TO GET ENGAGED WITH.
5 THE OTHER IS THE REAL-WORLD EVIDENCE AND HOER. SO
6 WE HAVE AN ENORMOUS THINK TANK, IF YOU WILL, ACROSS
7 THE ALPHA CLINICS WHO CAN PROVIDE GUIDANCE, AND
8 THERE'S A LARGE REPOSITORY OF DATA THAT HOPEFULLY WE
9 CAN GET ACCESS TO TO START ADDRESSING SOME OF THE
10 STRATEGIES AND TACTICS.

11 SO THESE ARE JUST FOUR STRATEGIES THAT WE
12 WANTED TO PRESENT TODAY. WE WILL START KICKING THIS
13 OFF IN JANUARY. WHAT WE'D LIKE TO DO, AND, OF
14 COURSE, THE AAWG WILL GIVE US GUIDANCE ON OTHER
15 TACTICS, OTHER STRATEGIES, PROJECTS THAT WE HAVEN'T
16 THOUGHT ABOUT. AGAIN, THIS IS ALIGNED WITH THE
17 LANGUAGE IN PROPOSITION 14. WHAT WE'D LIKE TO DO
18 MOVING FORWARD STARTING JANUARY IS SORT OF PIECEMEAL
19 THIS. SO EVERY STRATEGY, WE WILL DO THE RESEARCH
20 INTERNALLY. THAT'S OUR JOB WITH RESPECT TO MEDICAL
21 AFFAIRS. THERE'S A LOT THAT WE NEED TO LEARN.
22 WE'LL BRING IN THE SUBJECT MATTER EXPERTS TO GIVE US
23 GUIDANCE. AND OUR THINKING IS THAT WE WOULD BRING
24 THIS INFORMATION TO THE AAWG ONCE A MONTH, EACH
25 STRATEGY AND TALK REALLY ABOUT A SWAT, IF YOU WILL.

BETH C. DRAIN, CA CSR NO. 7152

1 WHAT ARE THE STRENGTHS, OPPORTUNITIES? WHAT ARE THE
2 CHALLENGES? WHERE IS THERE OPPORTUNITY FOR US TO
3 ENGAGE? AND CAN WE INCLUDE THAT IN THE ROAD MAP AS
4 WE GO -- MOVE THROUGH THIS WHOLE PROCESS?

5 AND SO IF YOU THINK ABOUT IT, WE'RE GOING
6 TO BE DOING A LOT OF HEAVY LIFTING FOR THE NEXT SIX
7 MONTHS. EVERY MONTH WE WILL BE PRESENTING TO AAWG
8 ONE OF THESE CONCEPTS. AND THEN HOPEFULLY AT THE
9 END, WE WILL HAVE AN AAWG-APPROVED ROAD MAP THAT WE
10 CAN PRESENT TO THE ICOC.

11 AND FINALLY, THIS IS A PHENOMENALLY
12 CHALLENGING OPPORTUNITY FOR CIRM. THERE ARE GROUPS
13 THAT ARE DOING THIS OBVIOUSLY IN INDUSTRY AND THE
14 PRIVATE SECTOR, BUT THEY ARE NOT DISCLOSING IT IN
15 THE PUBLIC DOMAIN. SO THIS IS A GREAT OPPORTUNITY
16 FOR US, CIRM, TO TAKE LEADERSHIP, RIGHT, AND PERHAPS
17 PUT A MODEL OUT THERE THAT TRULY WOULD IMPACT
18 PATIENTS ALL THE WAY FROM THE CLINICAL SETTING TO
19 THE COMMERCIAL SETTING IF, IN FACT, SOME OF OUR
20 ASSETS GO TO COMMERCIALIZATION.

21 SO I LOOK FORWARD TO NEXT YEAR. I WANT TO
22 SAY THANK YOU. I THINK I'LL STOP HERE AND JUST OPEN
23 IT UP TO QUESTIONS, SENATOR.

24 CHAIRMAN TORRES: WE HAVE MAHESWARI.

25 DR. SENTHIL: YES. THANK YOU, SENATOR

1 TORRES.

2 GREAT PRESENTATION, AND I THINK MY
3 QUESTION ACTUALLY LINKS TO BOTH THE WORK THAT HAS
4 BEEN DONE BOTH WITH THE FRESNO OUTREACH THAT WE HAD
5 DISCUSSED AS WELL AS THIS WONDERFUL ROAD MAP THAT IS
6 BEING PRESENTED. AND WE ALL COMPLETELY AGREE THAT
7 COORDINATION AT THE COMMUNITY SITES IS
8 EXTRAORDINARILY IMPORTANT, AND THAT IS HOW WE'RE
9 GOING TO MAKE IT ACCESSIBLE TO OUR PATIENTS.

10 IN THIS PROCESS, THIS IS NOT JUST UNIQUE
11 JUST FOR ALPHA STEM CELL, YOU KNOW, THE CELL AND
12 GENE THERAPY. IT'S TRUE FOR ANY CLINICAL TRIALS
13 THAT WE ENCOUNTER. SOME OF THE ISSUES HAVE REVOLVED
14 AROUND REGULATORY ISSUES IN TERMS OF SPECIFIC SITES
15 BEING ELIGIBLE TO PARTICIPATE, THE NEEDED SERVICES
16 THAT NEED TO BE PRESENT, PI'S EXPERTISE. PRINCIPAL
17 INVESTIGATOR ESPECIALLY IN THIS LOCAL SITE AND THE
18 NEED FOR A VALIDATION WITH CENTERED REVIEWS AND SO
19 ON.

20 HAVE WE IDENTIFIED IN THIS PARTNERSHIP
21 UNDER THIS ROAD MAP THAT WE HAVE CREATED WHAT KIND
22 OF REGULATORY BARRIERS THAT WE NEED TO OVERCOME TO
23 MAKE SURE THAT THIS WILL BE ACCESSIBLE TO OUR
24 PATIENTS AT A BROAD RANGE OF COMMUNITY SITES?

25 DR. TURBEVILLE: WELL, LET ME RESPOND. I

BETH C. DRAIN, CA CSR NO. 7152

1 THINK THAT'S SIGNIFICANT INSIGHT. THAT IS SOMETHING
2 THAT WE CONSIDERED EARLY ON. I THINK WE DO NEED TO
3 DO IT, AND THIS IS A GREAT EXAMPLE. THAT'S ANOTHER
4 POTENTIAL STRATEGY THERE. SO I THINK WE DO NEED TO
5 DO SOME DUE DILIGENCE WITH THE ALPHA SITES AND FIND
6 THE TRUE NEED AND ASK FROM THE REGULATORY STANDPOINT
7 EVEN PRE-IND, NIH, IND, TO BLA. SO, YEAH, LET US
8 TAKE THAT ON. I THINK THAT'S GOOD INTEL.

9 CHAIRMAN TORRES: THAT'S QUITE A LABYRINTH
10 AS WELL. DR. LEVITT.

11 DR. LEVITT: SO THAT WAS A GREAT
12 PRESENTATION, AND THE ROAD MAP IS EXCITING. I DON'T
13 KNOW HOW HIGH THE BARRIERS ARE OR HOW MANY NAILS
14 THAT WILL BE IN THE ROAD TO CREATE FLAT TIRES.

15 I JUST WANT TO MAKE SURE THAT FOR THE
16 FIRST TWO IN TERMS OF FACILITATE REIMBURSEMENT,
17 LIMIT PATIENT EXPENSES, SUPPORT NEW PAYER MODELS,
18 AND I HAVE TO SPEAK UP BECAUSE I AM AT A CHILDREN'S
19 HOSPITAL, THAT PEDIATRICS IS NOT FORGOTTEN. AS YOU
20 WELL KNOW, CHILDREN MAKE UP 50 PERCENT OF MEDICAID
21 PATIENTS NATIONALLY, AS HIGH IN CALIFORNIA, AND
22 CALIFORNIA IS ONE OF THE WORST IN REIMBURSEMENT FOR
23 MEDI-CAL FOR PEDIATRIC PATIENTS. AND SO IF WE'RE
24 GOING TO PROVIDE ACCESS AND AFFORDABILITY FOR
25 FAMILIES WHO HAVE CHILDREN WHO ARE GOING TO BE

BETH C. DRAIN, CA CSR NO. 7152

1 UNDERGOING CARE AT THESE CLINICS, THERE HAS TO BE A
2 RECOGNITION THAT WHATEVER THE CHANGES ARE, WHATEVER
3 THE NEW MODELS ARE, THEY JUST CANNOT INCLUDE -- THEY
4 CANNOT ONLY INCLUDE ADULTS. PEDIATRIC POPULATIONS
5 HAVE TO BE RECOGNIZED BECAUSE THERE ARE TWO POCKETS.
6 ONE IS THE PATIENT POCKETS, THE OTHER IS THE
7 HOSPITAL POCKETS THAT WILL BE IN A VERY DIFFICULT
8 POSITION TO ACTUALLY PARTICIPATE IN THESE IF THE
9 PAYER MIX IS NOT GOING TO COVER EXPENSES.

10 SO NOW I'M OFF MY SOAPBOX.

11 CHAIRMAN TORRES: WELL, IT'S A GREAT
12 SOAPBOX. AND I REMEMBER YOU AND I HAVING THIS
13 CONVERSATION. I DON'T WANT TO FORGET THAT I STILL
14 HAVE BEEN WORKING ON IT. THIS IS NOT AN EASY
15 CHALLENGE TO UNDERTAKE. WHEN I WAS CHAIRMAN OF THE
16 ASSEMBLY HEALTH COMMITTEE BACK IN THE '70S, WE WERE
17 TALKING ABOUT THESE ISSUES. IT'S ALWAYS A MEDI-CAL
18 REIMBURSEMENT RATE.

19 DR. LEVITT: YEAH. I JUST WANT TO MENTION
20 MAYBE SOME FOLKS SAW THREE WEEKS AGO THERE WAS AN
21 ARTICLE IN THE *NEW YORK TIMES* ABOUT CHILDREN'S
22 HOSPITALS IN THE MIDWEST AND EAST CLOSING AND THEN
23 CHILDREN'S PROGRAMS WITHIN ADULT HOSPITALS CLOSING.
24 NOT LIKE ONE OR TWO, BUT LIKE IT'S --

25 CHAIRMAN TORRES: RIGHT.

BETH C. DRAIN, CA CSR NO. 7152

1 DR. LEVITT: IT'S QUITE SERIOUS BECAUSE
2 THE REIMBURSEMENT RATES IN GENERAL ARE NOT KEEPING
3 UP WITH WHAT THE COSTS ARE. AND IN CALIFORNIA IT'S
4 REALLY A SEVERE PROBLEM. AND WE ARE FUNDING
5 INITIATIVES AND CLINICAL TRIALS THAT INVOLVE
6 CHILDREN.

7 CHAIRMAN TORRES: RIGHT.

8 DR. LEVITT: SO WE WANT TO MAKE SURE
9 FAMILIES HAVE THAT ACCESS.

10 CHAIRMAN TORRES: MY SON'S LIFE WAS SAVED
11 AT CHILDREN'S HOSPITAL IN LOS ANGELES. I TOLD YOU
12 BEFORE. SO IT IS A PRIORITY FOR ME AS WELL.

13 DR. LOMAX.

14 DR. LOMAX: YEAH. JUST TO ADD TO THAT,
15 THE PREVIOUS QUESTION ABOUT THE REGULATORY SUPPORT,
16 WE'LL CALL IT, IS THAT A NUMBER OF THE ALPHA CLINIC
17 PROPOSALS IN THEIR ORIGINAL APPLICATIONS ACTUALLY
18 FLAGGED THESE AS INITIATIVES WHICH THEY HAVE ALREADY
19 BEGUN ACTUALLY. SO SOME OF THESE LINKAGES HAVE
20 ALREADY BEGUN BETWEEN SOME OF THE AWARDED SITES AND
21 SITES THAT ARE DEVELOPING A REGENERATIVE MEDICINE
22 PLATFORM. AND IN ADDITION, OUT OF THE FRESNO
23 MEETING THERE'S BEEN A NUMBER OF CONVERSATIONS
24 BETWEEN THE FRESNO SITE AND UC DAVIS ALREADY. AND
25 THIS RANGES FROM EVERYTHING FROM METHODS FOR DOING

BETH C. DRAIN, CA CSR NO. 7152

1 COVERAGE ANALYSIS OUT TO MATERIALS HANDLING,
2 COMPLIANCE, THE WHOLE SPECTRUM. SO THE GOOD THING
3 TO REPORT BACK AT THE MOMENT IS IT'S ABSOLUTELY A
4 CRITICAL ISSUE. AND FORTUNATELY IN THESE ORIGINAL
5 APPLICATIONS ON THE ALPHA SIDE, THE TEAMS HAVE
6 ALREADY STARTED SOME OF THOSE DISCUSSIONS AT SITES
7 THAT ARE LOOKING TO DEVELOP FURTHER.

8 SO I THINK WE'RE GOING TO SEE A TRUE
9 NETWORK, A KNOWLEDGE NETWORK, AROUND THESE ISSUES
10 AND THE ABILITY TO BOTH DISSEMINATE AND SUPPORT
11 SITES AS THEY GROW INTO THE FIELD.

12 CHAIRMAN TORRES: MAHESWARI, DO YOU HAVE
13 ANOTHER COMMENT?

14 DR. SENTHIL: YES. I JUST WANT -- DR.
15 LOMAX, THANK YOU SO MUCH FOR THAT. I SPEAK FROM A
16 VERY PERSONAL KIND OF EXPERIENCE ON THIS TOPIC
17 BECAUSE I'M THE DIRECTOR OF SENTHIL CLINICAL
18 RESEARCH AT UCI, AND I CLOSELY WORK WITH OUR ALPHA
19 STEM CELL CLINIC, DR. DANIELA BOTA, WHO IS THE
20 DIRECTOR OF THE ALPHA STEM CELL CLINIC. ONE OF THE
21 KEY TOP PRIORITIES FOR UCI IS ESTABLISHING COMMUNITY
22 ACCESS AND ESTABLISHING COMMUNITY SITES. AND THIS
23 IS ALSO PART OF THE ADVANCING CLINICAL TRIALS AT
24 POINT OF CARE INITIATED THAT IS NATIONALLY GOING ON.
25 THEY'RE ALSO PART OF IT. THE MAIN BARRIERS THAT, AS

BETH C. DRAIN, CA CSR NO. 7152

1 WE GO THROUGH THIS PROCESS AND AS WE ARE TO GO THIS
2 AT UCI BECAUSE WE ARE ONE OF THE ALPHA STEM CELL
3 CLINIC HAS BEEN FIGURING OUT THESE REGULATORY
4 BARRIERS AND AS TO HOW WE CAN MAKE THIS AN EASIER
5 PROCESS BECAUSE IT SEEMS LIKE PROTOCOL WE ARE TRYING
6 TO OVERCOME SOME OF THESE REGULATORY ISSUES. I
7 THINK AS WE ARE MOVING THROUGH THIS REALLY WONDERFUL
8 ROAD MAP, I THINK MORE GLOBAL SOLUTIONS TO THE
9 REGULATORY BARRIERS THAT LIMIT ACCESS TO THESE
10 CLINICAL STUDIES, NOT JUST ALPHA STEM CELL CLINIC.
11 I THINK IF YOU FIX IT FOR ALPHA STEM CELL, I THINK
12 IT WILL APPLY FOR OTHER CLINICAL TRIALS WOULD BE
13 NECESSARY TO ACHIEVE THE OUTCOME THAT WE ARE HOPING
14 TO ACHIEVE.

15 AND MY PROPOSAL WOULD BE HOPEFULLY HAVE
16 THESE ALPHA STEM CELL CLINICS THAT HAVE BEEN FUNDED
17 THROUGH CIRM TO REPORT BACK TO US IN SIX MONTHS OR
18 WHATEVER TIME WE CHOOSE TO TALK TO US ABOUT AS TO
19 HOW THEY HAVE BEEN ABLE TO ACCOMPLISH THIS OR WHAT
20 ARE THE KEY BARRIERS THAT ARE STILL LIMITING US TO
21 PROVIDE THESE ACCESS TO PATIENTS IN THE COMMUNITY
22 SITES SO THAT WE CAN PROBABLY HAVE A BRAINSTORMING
23 SESSION, FIGURE OUT AS TO HOW WE CAN SOLVE IT.

24 CHAIRMAN TORRES: GOOD IDEA. GOOD IDEA.
25 NO FURTHER COMMENTS FROM OUR WORKING GROUP. WE HAVE

BETH C. DRAIN, CA CSR NO. 7152

1 PUBLIC COMMENTS? I BELIEVE KEVIN MCCORMACK HAS A
2 STATEMENT TO READ.

3 MR. MC CORMACK: YES, I AM. CAN YOU HEAR
4 ME, SENATOR?

5 CHAIRMAN TORRES: YES.

6 MR. MC CORMACK: OKAY. GREAT. THIS IS
7 FROM DON REED. HE'S BEEN A LONGTIME CHAMPION OF
8 STEM CELL RESEARCH AND A GREAT FRIEND TO CIRM. HE'S
9 WRITTEN A NUMBER OF BOOKS ABOUT US, AND HE HAS ALSO
10 BEEN REALLY INSTRUMENTAL IN GETTING BOTH PROPOSITION
11 71 AND 14 PASSED. SO DON WRITES:

12 "AS A LONGTIME FAN OF THE CALIFORNIA
13 INSTITUTE FOR REGENERATIVE MEDICINE, I AM, OF
14 COURSE, DELIGHTED WITH THE FORWARD STEPS CIRM IS
15 TAKING, ESPECIALLY THIS COMMITTEE. LONG AGO AT THE
16 SEATTLE WORLDS FAIR, I SAW A GIGANTIC COMPUTER,
17 SEEMING, IN MY CHILD'S EYES, AS BIG AS A CITY BLOCK
18 AND ALSO BEING IMPRESSED THAT IT COULD BOTH ADD AND
19 SUBTRACT EIGHT NUMBERS. IT COST MILLIONS OF DOLLARS
20 AND WAS HAILED AT THE TIME AS A TREMENDOUS
21 ACCOMPLISHMENT. TODAY COMPUTERS THAT CAN DO FAR
22 MORE ARE AVAILABLE AS CHILDREN'S TOYS.

23 "SIMILARLY, I BELIEVE THERE WILL SOON BE
24 COST REDUCTIONS IN REGENERATIVE MEDICINE, WAYS TO
25 LOWER THE EXPENSES OF STEM CELL THERAPIES AND TO

BETH C. DRAIN, CA CSR NO. 7152

1 SAVE LIVES AND EASE SUFFERING. YOU ARE THE LEADING
2 EDGE OF THAT GREAT STRUGGLE. WE, THE PUBLIC, WILL
3 WATCH WHAT YOU DO WITH GREAT INTEREST AND FIND WAYS
4 TO LOWER COST AND INCREASE ACCESSIBILITY EITHER TO
5 CLINICAL TRIALS OR THE THERAPIES THEMSELVES. YOU
6 ARE DOING THE WORLD AN ENORMOUS FAVOR. YOU'RE
7 HELPING TO BRING CURES WITHIN THE REACH OF EVERYONE.
8 WE WISH YOU HEALTH AND STRENGTH AND JOY. THANK YOU
9 VERY MUCH. DON C. REED."

10 CHAIRMAN TORRES: THANK YOU, KEVIN. ANY
11 OTHER FURTHER PUBLIC COMMENT? ALL RIGHT. THERE
12 BEING NONE, AGAIN, I WANT TO THANK EMILY AND
13 MARIANNE AND MARIVEL AND GEOFF AND SEAN AND DR.
14 MILLAN FOR ALL OF YOUR HELP IN THIS EFFORT. AND
15 ADRIANA AND TO J.T. OBVIOUSLY AND MARIA GONZALEZ
16 BONNEVILLE FOR BEING PART OF THAT FRESNO MEETING.
17 IT WAS VERY IMPORTANT.

18 WHAT WAS EXCITING FOR ME IS THAT WHENEVER
19 I WOULD WRITE LEGISLATION, THE MOST IMPORTANT PART
20 WAS NOT GETTING IT PASSED OR SIGNED BY THE GOVERNOR.
21 IT'S TO SEE HOW IT BEGAN TO BE IMPLEMENTED. AND I
22 THINK NOW WITH BOB KLEIN AND MYSELF WRITING THE
23 LANGUAGE FOR ACCESS AND AFFORDABILITY IN PROPOSITION
24 14, WE ARE NOW SEEING THE POTENTIAL AND PIVOTAL
25 IMPLEMENTATION OF THAT LANGUAGE. AND I AM VERY

BETH C. DRAIN, CA CSR NO. 7152

1 EXCITED FOR PATIENTS ACROSS THE STATE. SO THANK YOU
2 AGAIN FOR ALL YOUR WORK. AND HAVE A WONDERFUL
3 HOLIDAY SEASON.

4 DR. TURBEVILLE: THANK YOU, SENATOR.

5 (THE MEETING WAS THEN CONCLUDED AT 11:53
6 A.M.)

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 ACCESS 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 DECEMBER 1, 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.

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