

BETH C. DRAIN, CA CSR NO. 7152

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

LOCATION: VIA ZOOM

DATE: NOVEMBER 30, 2023
10 A.M.

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

FILE NO.: 2023-37

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I N D E X

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| OPEN SESSION | |
| 1. CALL TO ORDER | 3 |
| 2. ROLL CALL | 3 |
| 3. CONSIDERATION OF AMENDMENTS TO DISC0, DISC2, TRAN, CLIN1 AND CLIN2 CONCEPT PLANS, AND NEW CLIN4 CONCEPT PLAN | 4 |
| 4. CONSIDERATION OF RECOMMENDATIONS FROM IP & INDUSTRY SUBCOMMITTEE REGARDING CHANGES TO THE CO-FUNDING REQUIREMENTS FOR TRANSLATIONAL AND CLINICAL PROGRAMS | 37 |
| 5. CONSIDERATION OF COMMUNITY CARE CENTERS OF EXCELLENCE (CCCE) CONCEPT PLAN | 70 |
| 6. PUBLIC COMMENT | NONE |
| 7. ADJOURNMENT | 91 |

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NOVEMBER 30, 2023; 10 A.M.

CHAIRMAN GOLDSTEIN: SO LET ME CALL US TO ORDER, AND THEN THE FIRST ORDER OF BUSINESS IS SCOTT CALLS THE ROLL.

MR. TOCHER: THANK YOU, LARRY. HAIFAA ABDULHAQ. MARIA BONNEVILLE.

VICE CHAIR BONNEVILLE: PRESENT.

MR. TOCHER: MONICA CARSON.

MEMBER SARKISIAN: PRESENT.

MR. TOCHER: HAL COLLARD. SHLOMO MELMED.

DR. MELMED: PRESENT.

MR. TOCHER: MARK FISCHER-COLBRIE.

DR. FISCHER-COLBRIE: HERE.

MR. TOCHER: ELENA FLOWERS.

DR. FLOWERS: PRESENT.

MR. TOCHER: JUDY GASSON.

DR. GASSON: HERE.

MR. TOCHER: LARRY GOLDSTEIN.

CHAIRMAN GOLDSTEIN: HERE.

MR. TOCHER: DAVID HIGGINS.

DR. HIGGINS: HERE.

MR. TOCHER: VITO IMBASCIANI.

DR. IMBASCIANI: HERE.

MR. TOCHER: PAT LEVITT. CHRISTINE

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1 MIASKOWSKI.

2 DR. MIASKOWSKI: HERE.

3 MR. TOCHER: AND KAROL WATSON.

4 WE HAVE TEN MEMBERS, WHICH IS A QUORUM.

5 CHAIRMAN GOLDSTEIN: OKAY. SO WE HAVE A
6 FAIRLY HEFTY LOAD OF BUSINESS TODAY, GUYS. SO HANG
7 IN THERE.

8 FIRST UP IS A DISCUSSION AND VOTE ON
9 AMENDMENTS TO DISC, TRAN, AND CLIN GRANTS. FIRST UP
10 IS DISC, AND I THINK THAT'S ROSA.

11 DR. CANET-AVILES: THAT IS CORRECT, YES.
12 SHOULD I JUST GET STARTED?

13 CHAIRMAN GOLDSTEIN: PLEASE.

14 DR. CANET-AVILES: CAN YOU SEE MY SCREEN?

15 UNIDENTIFIED SPEAKER: ROSA, WE CAN SEE
16 YOUR NOTES. YOU NEED TO SWAP IT.

17 DR. CANET-AVILES: THANK YOU. YOU SEE THE
18 SCREEN, NOT THE NOTES, CORRECT?

19 DR. IMBASCIANI: YES.

20 DR. CANET-AVILES: FANTASTIC. GOOD
21 MORNING, MR. CHAIRMAN AND MEMBERS OF THE SCIENCE
22 SUBCOMMITTEE. DR. CREASEY AND I ARE GOING TO BE
23 PRESENTING IN TANDEM THE PROPOSED AMENDMENTS FOR THE
24 DISCOVERY AND THE CLINICAL PROGRAM AWARDS.

25 SO THESE AMENDMENTS HAVE BEEN DEVELOPED BY

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1 OUR TEAMS TO ADAPT TO THE CURRENT NEEDS AND OPTIMIZE
2 THE DELIVERY OF OUR MISSION, WHICH IS ACCELERATE
3 WORLD-CLASS SCIENCE TO DELIVER TRANSFORMATIVE
4 REGENERATIVE MEDICINE TREATMENTS IN AN EQUITABLE
5 MANNER TO A DIVERSE CALIFORNIA AND THE WORLD.

6 THIS PRESENTATION IS STRUCTURED, AS I WAS
7 MENTIONING, INTO TWO MAIN PARTS. INITIALLY WE WILL
8 EXPLORE THE PROPOSED AMENDMENTS FOR THE DISC PILLAR.
9 AND FOLLOWING THAT, MY COLLEAGUE, DR. CREASEY, WILL
10 GUIDE US THROUGH THE DEVELOPMENTS IN THE CLINICAL
11 PILLAR.

12 FOR CONTEXT, THE DISCOVERY PILLAR IS
13 COMPOSED OF THREE TYPES OF AWARDS. WE WILL PRESENT
14 AMENDMENTS FOR THE FIRST TWO, WHICH CORRESPOND TO
15 THE DISC-0 OR THE FOUNDATION AWARDS THAT REPRESENT
16 THE BEDROCK FOR ALL THE DISCOVERY PILLARS AT CIRM,
17 EMPHASIZING THE GENERATION OF FOUNDATIONAL
18 KNOWLEDGE. AND THIS PROGRAM FOSTERS INITIAL
19 DISCOVERY RESEARCH AIMING TO EXPLORE NOVEL CONCEPTS
20 AND INNOVATIVE IDEAS THAT HAVE THE POTENTIAL TO
21 REVOLUTIONIZE OUR UNDERSTANDING AND TREATMENT OF
22 DISEASES.

23 THE DISC2, QUEST AWARDS, WHICH IS THE
24 OTHER PROGRAM THAT WE WILL PRESENT AMENDMENTS FOR,
25 SIGNIFY THE CRITICAL TRANSITION FROM FOUNDATIONAL

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1 KNOWLEDGE TO A TARGETED INQUIRY WHERE SPECIFIC
2 HYPOTHESES ARE TESTED. AND THESE AWARDS ARE
3 DESIGNED TO VALIDATE INITIAL FINDINGS AND ASSESS
4 THEIR POTENTIAL TO RESULT IN A SINGLE PRODUCT
5 CANDIDATE FOR THERAPEUTIC DEVELOPMENT.

6 SO FOR THE FIRST PROGRAM, WHICH IS THE
7 DISC2, OR THE QUEST AWARDS, WE ARE PROPOSING TWO
8 CHANGES. ONE IS TO THE AWARD TRACK AND THE OTHER IS
9 TO THE AWARD BUDGET, AND WE HAVE ONE SLIDE FOR EACH
10 WHICH DETAIL THE PROPOSED CHANGES.

11 FOR THE DISC2 AWARDS CHANGES IN TRACK,
12 CURRENTLY OUR PROGRAM IS STRUCTURED AROUND TWO
13 TRACKS. THE FIRST IS THE THERAPEUTIC CANDIDATE
14 TRACK, WHICH IS DEDICATED TO ADVANCING PROJECTS
15 TOWARDS THE DEVELOPMENT CANDIDATE READY FOR
16 PROGRESSION THROUGH VARIOUS STAGES OF THERAPEUTIC
17 DEVELOPMENT. AND THE SECOND IS TECHNOLOGY CANDIDATE
18 TRACK THAT HAS TRADITIONALLY BEEN ALIGNED WITH
19 DIAGNOSTICS, DEVICES, OR TOOLS. AND WHAT WE ARE
20 PROPOSING IS A SHIFT BY CONFORMING THIS TRACK INTO A
21 BIOMARKER CANDIDATE TRACK.

22 WHY ARE WE DOING THIS? WE ARE PROPOSING
23 THIS, THE RATIONALE IS BECAUSE THE TOOL/DEVICE
24 DEVELOPMENT SEGMENT OF THE CURRENT DISC2 IS ALREADY
25 SUPPORTED BY THE DISC-0 PROGRAM, BY THE FOUNDATIONAL

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1 AWARDS. THIS PROGRAM ACTUALLY DID NOT EXIST WHEN WE
2 FIRST DEVELOPED THESE TWO. SO POST PROPOSITION 14
3 WE INTRODUCED DISC-0, AND THIS PROGRAM ENCOMPASSED
4 TOOL AND DEVICE DEVELOPMENT, TACKLING BOTTLENECKS IN
5 CELL AND GENE THERAPY, AND ENHANCING RESEARCH TOOLS,
6 INCLUDING THOSE FOSTERING DIVERSITY, EQUITY, AND
7 INCLUSION IN SCIENCE. THEREFORE, WE PROPOSE THAT
8 THE ALLOCATION OF THE TOOL/DEVICE FOCUS EXCLUSIVELY
9 TO DISC-0, THEREBY ELIMINATING REDUNDANCY. AND
10 THESE TWO ARE MAKING A SPACE FOR THE CRITICAL
11 BIOMARKER TRACK.

12 THE INCLUSION OF A BIOMARKER TRACK IN
13 THESE TWO UNDERSCORES WIDESPREAD DEMAND FOR
14 BIOMARKERS -- THERE'S A BIG NEED -- AND IS CRUCIAL
15 FOR NOT ONLY GENERAL THERAPEUTIC DEVELOPMENT, BUT
16 PARTICULARLY VITAL IN THE REALM OF REGENERATIVE
17 MEDICINE AND CNS DISEASES.

18 BY PROPOSING THIS BIOMARKER TRACK, WE ARE
19 NOW EXPANDING TO SUPPORT NOT ONLY THE DIAGNOSTIC
20 BIOMARKERS, BUT TO INCLUDE OTHER BIOMARKERS LINKED
21 TO MEDICAL INTERVENTIONS FOR DISEASE CONDITIONS SUCH
22 AS PROGNOSTIC BIOMARKERS, RISK MONITORING
23 BIOMARKERS.

24 THE NEXT SLIDE HAS TO DO WITH THE CHANGE
25 IN BUDGET TO ADAPT TO WHAT WE ARE PROPOSING AS WELL.

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1 SO CURRENTLY THE THERAPEUTIC DEVELOPMENT CANDIDATE
2 HAS AN ALLOCATION OF \$1.5 MILLION FOR THREE YEARS.
3 THE \$1.5 MILLION IS FOR DIRECT PROJECT COSTS FOR THE
4 ENTIRE AWARD. WE ARE NOW PROPOSING AN INCREASE TO
5 \$1.75 MILLION. SO IT'S A \$250,000 INCREASE. THE
6 RATIONALE FOR THAT IS ALLOWANCE FOR HIGHER COST OF
7 TRAINEES AND RESEARCH.

8 AND THE SECOND IS THAT CURRENTLY THE DISC2
9 AWARDS HAVE ALREADY A SUPPLEMENT. WE ALLOW A
10 \$200,000 SUPPLEMENT FOR SPECIFIC PROJECT TYPES. AND
11 WHAT WE ARE DOING NOW IS EXPANDING AND INCREASING TO
12 ALLOW FOR ALL AWARDEES. AND IN THIS PROPOSAL
13 SCENARIO, THE SUPPLEMENT OF 200,000 COULD BE
14 ELIMINATED AS IT'S ALREADY INCLUDED. AND OBVIOUSLY,
15 ANYBODY THAT ASKS FOR THE MAXIMUM, THE BUDGET NEEDS
16 TO BE JUSTIFIED ANYWAY. SO THIS IS GOING TO BE
17 ALWAYS REVIEWED BY OUR GRANTS WORKING GROUP MEMBERS.

18 FOR THE BIOMARKER TRACK, WE ARE PROPOSING
19 \$1.5 MILLION, WHICH IS JUSTIFIED IN TERMS OF
20 DURATION AND SIZE OF COMPARABLE AWARDS. AND WE HAVE
21 DONE AN ANALYSIS OF OTHER FUNDING AGENCIES THAT FUND
22 SPECIFIC BIOMARKERS EARLY IDENTIFICATION AND EARLY
23 VALIDATION OF BIOMARKER PROJECTS. AND IT COMES TO
24 ABOUT \$500,000 PER YEAR ON AVERAGE AND IS ABOUT
25 BETWEEN TWO AND THREE YEARS.

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1 I DON'T KNOW IF, DR. GOLDSTEIN, IF YOU
2 WOULD LIKE TO STOP AT DISC-0 FOR QUESTIONS OR IF YOU
3 WOULD LIKE ME TO PROCEED TO DISC2 -- SORRY -- TO
4 STOP NOW FOR QUESTIONS OR PROCEED.

5 CHAIRMAN GOLDSTEIN: I'D SAY DO THE FULL
6 DISC LOAD, AND THEN WE'LL PAUSE FOR QUESTIONS AND A
7 VOTE PRIOR TO ABLA PRESENTING THE CLIN PROPOSALS.

8 DR. CANET-AVILES: SOUNDS GREAT. THANK
9 YOU, DR. GOLDSTEIN.

10 SO FOR THE DISC-0 FOUNDATIONAL AWARDS
11 CONCEPT, WE ARE PROPOSING THREE CHANGES. ONE IS TO
12 AWARDS TRACKS. THE OTHER IS TO AWARD BUDGETS. AND
13 THE LAST ONE IS TO THE PI PERCENT EFFORT.

14 FOR THE AWARD TRACK, DISC-0 OR
15 FOUNDATIONAL AWARDS, CURRENTLY HAS ONE TRACK. IT'S
16 THE SINGLE PI TRACK. BUT BEYOND THE UNIQUE
17 CONTRIBUTIONS OF INDIVIDUAL INNOVATORS, CIRM
18 RECOGNIZES THE VALUE OF TEAM SCIENCE IN MAKING
19 SCIENTIFIC BREAKTHROUGHS THAT COULD NOT BE
20 ACHIEVABLE BY INDIVIDUAL INVESTIGATORS WITHIN AN
21 AWARD PERIOD. AND THE DISC-0 FOUNDATIONAL AWARDS
22 CAPITALIZE ON BOTH APPROACHES BY SUPPORTING TWO
23 TYPES OF PROGRAMS OR COULD CAPITALIZE IF APPROVED
24 THESE AMENDMENTS.

25 IF WE COULD SUPPORT TWO TYPES OF PROGRAMS,

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1 ONE COULD BE THE CURRENT SINGLE PI TRACK THAT COULD
2 SUPPORT PROJECTS WITH DISCRETE OBJECTIVES THAT ARE
3 ACHIEVABLE UNDER THE LEADERSHIP OF A SINGLE
4 INVESTIGATOR. AND THEN ANOTHER TRACK, THE TEAM
5 TRACK, THAT COULD SUPPORT MULTIDISCIPLINARY
6 COLLABORATIONS OF TWO TO THREE INVESTIGATORS THAT
7 BRING SPECIFIC KNOWLEDGE AND SKILLS TO A PROJECT TO
8 CREATE A UNIQUE ADVANTAGE OR SYNERGY WHERE THEIR
9 PERSPECTIVES COULD DRIVE INNOVATION AND CREATIVITY
10 IN REGENERATIVE MEDICINE.

11 THIS IS ALSO SOMETHING THAT WE HAVE
12 LEARNED FROM DEVELOPING THE RECENTLY APPROVED REMIND
13 PROGRAM. WE ARE TRYING TO STIMULATE TEAM SCIENCE
14 AND INNOVATION AND MULTIDISCIPLINARY COLLABORATION.
15 SO THAT IS WHY WE ARE ADDING THIS TRACK.

16 SO THE NEXT CHANGE THAT WE ARE PROPOSING
17 IS CHANGES IN BUDGET. CURRENTLY THE SINGLE PI TRACK
18 HAS A BUDGET OF \$1 MILLION FOR THREE YEARS. THIS
19 CORRESPONDS TO ABOUT \$353,000 IN DIRECT PROJECT
20 COSTS PER YEAR. AND WE ARE PROPOSING AN INCREASE TO
21 HALF A MILLION DOLLARS PER YEAR FOR THREE YEARS. A
22 TOTAL ON THE SINGLE PI'S IS \$1.5 MILLION, ACCOUNTING
23 FOR HIGHER PROJECT TRAINEE COST AND RESEARCH. AND
24 FOR THE TEAM TRACK, WE ARE DOUBLING THIS, TAKING
25 INTO ACCOUNT THAT WE WILL HAVE AT LEAST TWICE THE

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1 AMOUNT OF PROGRESSION EVENTS, ONE MAIN PI AND ONE
2 CO-PI AT LEAST, HOPEFULLY THREE.

3 AND THEN IN TERMS OF PERCENT OF EFFORT,
4 THE CURRENT PERCENT EFFORT FOR A SINGLE TRACK PI IS
5 20 PERCENT MINIMUM EFFORT. AND WE ARE PROPOSING A
6 DECREASE OF 5 PERCENT FOR THE SINGLE PI OF 15
7 PERCENT, ONE FIVE; AND FOR THE TEAM TRACK, THE PI
8 COULD BE ALSO 15 PERCENT, ONE FIVE; AND FOR THE
9 CO-INVESTIGATORS, 10 PERCENT MINIMUM REQUIREMENT.
10 AND THIS IS FROM A CHANGE THAT WE ARE PROPOSING
11 GIVEN BOARD FEEDBACK AND ALIGNMENT WITH OTHER
12 FUNDING BODIES.

13 AND WITH THAT, I'M FINISHING MY
14 PRESENTATION. AND WE WOULD LIKE -- CIRM REQUESTS
15 THE COMMITTEE TO RECOMMEND TO THE ICOC APPROVAL OF
16 THESE AMENDMENTS. AND I WOULD BE HAPPY TO ANSWER
17 ANY QUESTIONS. THANK YOU SO MUCH FOR YOUR
18 ATTENTION.

19 CHAIRMAN GOLDSTEIN: GREAT PRESENTATION,
20 ROSA. OKAY. SHLOMO, YOU'RE UP FIRST.

21 DR. MELMED: THANK YOU, ROSA, THAT WAS
22 TERRIFIC. THANK YOU.

23 I HAVE TWO QUESTIONS. ONE IS THE TERM
24 "BIOMARKER" IS EXTREMELY BROAD. DO WE HAVE TO,
25 ESPECIALLY FOR THIS COMMITTEE, DO WE HAVE TO BE MORE

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1 GRANULAR IN OUR DEFINITION? BECAUSE I'M CONCERNED
2 WE'RE GOING TO GET SWAMPED WITH ALL SORTS OF STUFF
3 FROM IMAGING TO MOLECULAR TO CLINICAL. IT WILL BE A
4 VERY, VERY WIDE CATCHMENT. SO I'M WONDERING IF
5 THAT'S THE INTENT. THAT'S FINE. BUT IF THE INTENT
6 IS TO BE MORE FOCUSED ON STEM CELL-SPECIFIC
7 BIOMARKERS, I THINK WE SHOULD BE MORE GRANULAR.

8 AND MY SECOND COMMENT RELATED TO THE FIRST
9 IS THE EFFORT. 15 PERCENT EFFORT SEEMS A LITTLE BIT
10 HIGH IF YOU ARE GOING TO DO A SIMPLE BIOMARKER.
11 WELL, THOSE ARE MY TWO QUESTIONS.

12 DR. CANET-AVILES: SO FOR THE FIRST ONE,
13 IN TERMS OF THE BIOMARKER, OUR TEAM HAS ALREADY
14 DEVELOPED IN THE PROGRAM ANNOUNCEMENT, IN THE
15 CONCEPT, WE HAVE MADE SOME CHANGES. AND THE
16 BIOMARKERS COULD HAVE TO BE RELATED TO STEM CELLS.
17 SO YOU WOULD HAVE TO EITHER USE STEM CELLS TO
18 DISCOVER THE BIOMARKER. AND IT'S GOING TO BE THAT
19 COULD HELP THE ADVANCEMENT OF THERAPIES, CLINICAL
20 THERAPIES, WITH THE BIOMARKER DISCOVERED. DOES THAT
21 ANSWER YOUR QUESTION?

22 DR. MELMED: NO. THOSE ARE TWO DIFFERENT
23 THINGS. USING STEM CELLS TO DISCOVER BIOMARKERS OR
24 USING BIOMARKERS TO MEASURE THE EFFICACY OF STEM
25 CELL THERAPY, THOSE ARE TWO DIFFERENT SCIENTIFIC

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1 QUESTIONS. ARE WE DOING BOTH? ARE WE DOING ONE? I
2 THINK WE SHOULD BE MORE SPECIFIC. I DON'T KNOW WHAT
3 THE INTENT IS IF SOMEONE READS IT. THERE ARE TWO
4 DIFFERENT HYPOTHETICAL APPROACHES TO THIS RFA.

5 DR. CANET-AVILES: YES. SO THE TYPE OF
6 BIOMARKER THAT WE ARE TRYING TO COVER HERE COULD BE
7 THOSE THAT SUPPORT THE DEVELOPMENT OF THE CLINICAL
8 USE OR THERAPEUTICS OF THE MODALITIES THAT WE DEFINE
9 FOR THE DISCOVERY RESEARCH. SO, FOR EXAMPLE, IN THE
10 DISCOVERY RESEARCH, WE ARE ALLOWING FOR THERAPEUTICS
11 THAT IS A CELL THERAPY WHERE A HUMAN PROGENITOR CELL
12 EITHER COMPOSE THE THERAPY OR ARE USED TO
13 MANUFACTURE THE CELL THERAPY OR THE GENE THERAPY
14 APPROACH.

15 AND IN TERMS OF BIOMARKERS, WHAT WE ARE
16 ASKING IS THE SUPPORT OF DEVELOPMENT OR THE CLINICAL
17 USE OF THOSE THERAPEUTICS. AND THE SECOND IS FOR
18 WHICH HUMAN OR STEM CELL PROGENITOR CELLS ARE
19 UNIQUELY ENABLING FOR THE IDENTIFICATION, TESTING,
20 AND VALIDATION OF ASSESSMENT OF THE THERAPY. SO WE
21 ARE ACTUALLY INCLUDING THOSE TWO TYPES.

22 AND WHAT I'M HEARING FROM YOU IS THAT YOU
23 WOULD LIKE FOR US TO BE MORE SPECIFIC RESTRICTED TO
24 EITHER --

25 DR. MELMED: NO. BOTH ARE FINE AS LONG AS

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1 WE ARE -- WE ARE DETAILED BECAUSE THE MORE DETAIL
2 THE BETTER. I WANT TO PREVENT A SLAB OF IRRELEVANT
3 APPLICATIONS.

4 DR. CANET-AVILES: YES. NO --

5 DR. MELMED: NOT IRRELEVANT, BUT NOT
6 RELEVANT TO OUR MISSION.

7 DR. CANET-AVILES: NO. IT'S GOING TO BE
8 RELEVANT TO THE MISSION. AND IN THE CONCEPT, IT'S
9 VERY CONCRETE THE WAY THAT WE HAVE EXPLAINED THIS.
10 BUT WE WILL PROVIDE MORE SPECIFICS AND EXAMPLES WHEN
11 WE DEVELOP THE PROGRAM ANNOUNCEMENT.

12 DR. MELMED: OKAY. THANK YOU.

13 DR. CANET-AVILES: AND THEN THE SECOND
14 QUESTION WAS WITH REGARDS TO THE PERCENT EFFORT?

15 DR. MELMED: YEAH.

16 DR. CANET-AVILES: AND WHAT WAS THE
17 QUESTION? COULD YOU REPEAT IT?

18 DR. MELMED: 15 PERCENT MAY BE HIGH FOR A
19 SIMPLE IN VITRO BIOMARKER STUDY.

20 DR. CANET-AVILES: WELL, IT'S NOT A SIMPLE
21 IN VITRO BIOMARKER STUDY. THIS IS THE DEVELOPMENT
22 OF A BIOMARKER THAT SUPPORTS THE DEVELOPMENT OR THE
23 CLINICAL USE OF THE THERAPEUTICS. AND MY EXPERIENCE
24 HAS BEEN THIS REQUIRES QUITE A BIT OF EFFORT FROM
25 THE PI. I SEE THE SAME AS THE LEVEL OF A

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1 DEVELOPMENT CANDIDATE, BUT JUST IN THE BIOMARKER
2 MODALITY. SO I THINK THAT WE SHOULD REQUIRE 15
3 PERCENT, ESPECIALLY WITH THE BUDGET THAT WE ARE
4 ALLOCATING.

5 DR. MELMED: THANK YOU.

6 CHAIRMAN GOLDSTEIN: I THINK THAT'S GREAT.
7 AN INSIDE BASEBALL QUESTION, ROSA. AS WE INCREASE
8 THE NUMBER AND DIFFERENT OPTIONS FOR THESE VARIOUS
9 GRANTS, WHAT ARE THE IMPLICATIONS FOR INTERNAL
10 TRACKING OF THESE AWARDS? IS THIS GOING TO RAISE
11 THE OVERHEAD SUBSTANTIALLY?

12 DR. CANET-AVILES: NO, WE DON'T THINK THAT
13 BECAUSE I THINK IT'S GOING TO ACTUALLY BE AN
14 ADVANTAGE BECAUSE RIGHT NOW THE TOOLS/TECHNOLOGY
15 TYPE OF AWARDS, WHICH ARE CURRENTLY IN THE BUDGET
16 ALLOCATION AS WELL, THEY TEND TO NOT BE, I THINK,
17 REVIEWED AT THE SAME LEVEL AS THE OTHERS. SO THEY
18 DON'T DO SO WELL. AND RIGHT NOW WHAT I THINK WE ARE
19 GOING TO GET IS TWO TYPES OF AWARDS THAT WILL BE
20 AROUND THE SAME, AND WE WILL JUST GET ABOUT THE SAME
21 AMOUNT OF AWARDS AT THE END. THE BUDGET IS GOING TO
22 BE ESTABLISHED. FOR THIS ONE, THE BUDGET IS ALREADY
23 ESTABLISHED BECAUSE THE NEXT CALL WOULD BE IN MAY.
24 BUT I DON'T THINK IT COULD BE INCREASING THE AMOUNT
25 OF AWARDS. WE JUST COULD HAVE PROBABLY, OUR WISH

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1 COULD BE THAT IT'S HALF AND HALF ALLOCATION, BUT
2 IT'S NOT GOING TO BE MORE AWARDS. IT'S JUST GOING
3 TO BE DIFFERENT TYPES OF AWARDS.

4 CHAIRMAN GOLDSTEIN: GREAT. OTHER
5 QUESTIONS OR COMMENTS FROM THE SUBCOMMITTEE? SCOTT,
6 WE HAVE ANY PUBLIC COMMENT ON THE LINE?

7 MR. TOCHER: LOOKING NOW. I DON'T SEE
8 ANY. CLAUDETTE?

9 MS. MANDAC: NO. THERE ARE NO HANDS
10 RAISED.

11 CHAIRMAN GOLDSTEIN: OKAY. SO CAN
12 SOMEBODY MOVE FOR US TO MOVE FORWARD?

13 VICE CHAIR BONNEVILLE: SO MOVED.

14 DR. LEVITT: I SECOND.

15 CHAIRMAN GOLDSTEIN: OKAY. MOVED AND
16 SECONDED. SCOTT, WILL YOU PLEASE CALL THE ROLL.

17 MR. TOCHER: HAIFAA ABDULHAQ.

18 DR. ABDULHAQ: YES.

19 MR. TOCHER: MARIA BONNEVILLE.

20 VICE CHAIR BONNEVILLE: YES.

21 MR. TOCHER: MONICA CARSON.

22 DR. CARSON: YES.

23 MR. TOCHER: HAL COLLARD. SHLOMO MELMED.

24 DR. MELMED: YES.

25 MR. TOCHER: MARK FISCHER-COLBRIE.

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1 DR. FISCHER-COLBRIE: YES.
2 MR. TOCHER: ELENA FLOWERS.
3 DR. FLOWERS: YES.
4 MR. TOCHER: JUDY GASSON.
5 DR. GASSON: YES.
6 MR. TOCHER: LARRY GOLDSTEIN.
7 CHAIRMAN GOLDSTEIN: YES.
8 MR. TOCHER: DAVID HIGGINS.
9 DR. HIGGINS: YES.
10 MR. TOCHER: VITO IMBASCIANI.
11 DR. IMBASCIANI: YES.
12 MR. TOCHER: PAT LEVITT.
13 DR. LEVITT: YES.
14 MR. TOCHER: AND CHRISTINE MIASKOWSKI.
15 DR. MIASKOWSKI: YES.
16 MR. TOCHER: GREAT. THANKS VERY MUCH.

17 THAT MOTION CARRIES.

18 THE REPORTER: SCOTT, THIS IS BETH. I
19 DIDN'T HEAR THE SECOND. WHO WAS THAT PLEASE?

20 MR. TOCHER: SECOND WAS PAT LEVITT.

21 THE REPORTER: THANK YOU VERY MUCH.

22 CHAIRMAN GOLDSTEIN: OKAY. SO THAT
23 RECOMMENDATION WILL GO ON TO THE FULL ICOC.

24 NEXT UP IS ABLA CREASEY, WHO WILL TELL US
25 ABOUT PROPOSED AMENDMENTS AND CHANGES TO THE CLIN

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1 AWARD SERIES. ABLA, WHEREVER YOU ARE.

2 DR. CREASEY: THANK YOU. CAN YOU SEE MY
3 SCREEN?

4 CHAIRMAN GOLDSTEIN: YEP.

5 DR. CREASEY: GREAT. THANK YOU, DR.
6 GOLDSTEIN, MEMBERS OF THE SCIENCE SUBCOMMITTEE, CIRM
7 COLLEAGUES, AND THE PUBLIC.

8 SO I'M GOING TO COVER TODAY THE PROPOSED
9 CLIN CONCEPT AMENDMENTS AND SHARE WITH YOU A NEW
10 CONCEPT THAT WE ARE PROPOSING FOR CLIN, CLIN4.

11 SO WHAT ARE SOME OF THE THINGS WE'RE GOING
12 TO DISCUSS TODAY? WE ARE RECOMMENDING THE FOLLOWING
13 FOUR THINGS. ONE IS TO REMOVE THE CLINICAL TRACK
14 FOR MEDICAL DEVICES FROM THE CLIN PILLAR. SECOND,
15 INCREASE MAXIMUM AWARD AMOUNTS FOR CLIN1. AND I'LL
16 GO INTO MORE DETAILS ABOUT EACH. THIRD, UPDATE
17 CLIN2 PROGRAM ANNOUNCEMENT TO HIGHLIGHT SPECIFIC
18 ALLOWABLE ACTIVITIES FOR PRODUCT DEVELOPMENT. AND
19 THEN LAST WOULD BE TO INTRODUCE THIS NEW CLIN4
20 PROGRAM ANNOUNCEMENT TO FUND LATE-STAGE DEVELOPMENT
21 ACTIVITIES THAT ARE NECESSARY TO FILE A BIOLOGICS
22 LICENSE APPLICATION AND READINESS FOR PRODUCT
23 LAUNCH.

24 I JUST WOULD LIKE TO, BEFORE I PROCEED, TO
25 MENTION A COUPLE OF THINGS. ONE IS WE ARE MOVING

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1 OTHER DEVELOPMENT PROGRAMS TOWARDS POTENTIAL
2 ADVANCEMENT FOR APPROVAL AS WELL AS HARMONIZING WITH
3 WHAT YOU HEARD THROUGH THE AAWG ROADMAP SO THAT
4 THERE IS CONSISTENCY BETWEEN WHAT WE DELIVER FOR
5 ACCESS AND AFFORDABILITY. SO WHAT CLINICAL RESEARCH
6 IS DOING. SO THE MOST IMPORTANT THING HERE IS MAKE
7 SURE THAT OUR PORTFOLIO IS MOVING TOWARDS GETTING TO
8 THE PATIENTS.

9 SO FOR MOVING THE CLINICAL TRIAL TRACK FOR
10 MEDICAL DEVICES, THE RATIONALE FOR DOING THAT IS WE
11 HAVE NOT HAD ANY APPLICATIONS THAT ARE REQUIRING
12 MEDICAL DEVICE SANCTIONING BY THE FDA. AND FOR THAT
13 REASON, WE SUPPORT THE COMBINATION OF DEVICE
14 DEVELOPMENT WITH A CLINICAL TRIAL WITH A THERAPEUTIC
15 AGENT, BUT NOT NECESSARILY A MEDICAL DEVICE ALONE
16 BECAUSE WE HAVE NOT HAD THOSE TYPES OF APPLICATIONS.

17 SO AS A REMINDER, THE CLINICAL PROGRAMS
18 AWARDS OVERVIEW IS ON THIS SLIDE. YOU ARE ALL
19 FAMILIAR WITH CLIN1 AND CLIN2. THE CLIN1 IS FOR
20 IND-ENABLING. THIS IS MEANING INVESTIGATIONAL NEW
21 DRUG. AND THE CLIN1 REQUIRES THE TEAMS TO HAVE
22 CONDUCTED A PRE-IND MEETING, AND THE DURATION FOR
23 THAT GRANT IS 24 MONTHS.

24 FOR THE CLIN2, THIS IS FOR EMBARKING ON
25 CONDUCTING A CLINICAL TRIAL. AND THE APPLICANTS

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1 HAVE TO HAVE AN ACTIVE IND, AND THE LENGTH OF THE
2 GRANT IS 48 MONTHS. THOSE GRANTS HAVE TO START
3 WITHIN 45 DAYS AFTER ICOC APPROVAL.

4 THE NEW CONCEPT PLAN FOR CLIN4 IS REALLY
5 MEANINGFUL BECAUSE IT'S BIOLOGICS LICENSE
6 APPLICATION ENABLING. WE HAVE A NUMBER OF GRANTS
7 THAT ARE ON TRACK TOWARDS THAT STAGE. THE
8 REQUIREMENT FOR A CLIN4 CONCEPT IS AN ACTIVE CLIN2
9 AND/OR PHASE 2 MEETING WITH FDA. AND THE LENGTH FOR
10 THIS GRANT WOULD BE 48 MONTHS AND WILL LEAD TO A
11 CLIN2 APPLICATION.

12 SO FOR CLIN1 AWARDS, WHY ARE WE MAKING
13 THOSE CHANGES? SO FOR THE LENGTH OF TIME I'VE BEEN
14 AT CIRM, 2016, ALMOST SEVEN TO EIGHT YEARS, THE
15 CLIN1 AWARD HAS NOT BEEN GIVEN AN INCREASE IN
16 BUDGET. SO THE CURRENT BUDGET IS 6 MILLION FOR
17 NON-PROFITS WHILE FOR-PROFITS HAS BEEN 4 MILLION.
18 WE EVALUATED WHAT PERCENTAGE SHOULD BE AWARDED TO
19 THESE INCREASES SO THAT FOLKS HAVE NO TROUBLE
20 CONDUCTING THE NECESSARY ACTIVITIES. WE CAME UP
21 WITH ABOUT A 20-PERCENT INCREASE. SO THE NON-PROFIT
22 GOES FROM 6 MILLION TO ABOUT \$7 MILLION, AND
23 FOR-PROFITS GOES FROM 4 MILLION TO ABOUT 5 MILLION,
24 UP TO THOSE NUMBERS.

25 AGAIN, THE RATIONALE IS THAT WE HAVE HEARD

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1 FROM OUR GRANTEES, CURRENT AND FUTURE, IS THAT THE
2 TOXICOLOGY STUDIES HAVE COST A LOT MORE, ESPECIALLY
3 IF THEY'RE GOING TO HAVE TO USE NONHUMAN PRIMATES.
4 MANUFACTURING COST HAS INCREASED AND, EQUALLY
5 IMPORTANT, HIGHER WORKERS WAGES COSTS HAVE ALSO
6 INCREASED.

7 SO WITH THOSE REQUESTED OR PROPOSED BUDGET
8 INCREASES, THESE ARE AMOUNTS OF DOLLARS THAT ARE
9 WITHIN OUR BUDGET AND WILL NEED ONLY FOR US TO
10 MODIFY THE BUDGET FOR 23/24. THE DURATION OF THE
11 CLIN1 WILL REMAIN AT 24 MONTHS LIKE I DESCRIBED IN
12 THE PREVIOUS SLIDE.

13 SO CHANGES REGARDING THE CLIN2 CONCEPT
14 CHANGES THAT WE ARE PROPOSING. WE'D LIKE TO EXPLAIN
15 THE RATIONALE FOR THAT FIRST. CHANGES ARE NEEDED
16 BECAUSE MOST CIRM-FUNDED TRIALS THUS FAR OR IN THE
17 PAST HAVE BEEN IN EARLY-STAGE CLINICAL DEVELOPMENT,
18 EITHER PHASE 1 OR PHASE 2. THIS IS WHETHER IT'S A
19 CELL THERAPY OR A GENE THERAPY.

20 AS THE FIELD HAS MATURED, MORE PROGRAMS
21 ARE ENTERING LATE-STAGE DEVELOPMENT. AND I
22 MENTIONED EARLIER WE HAVE A NUMBER OF THEM THAT ARE
23 EMBARKING ON THE LATE STAGE, WHETHER IT'S A PHASE 3
24 OR, AS DISCUSSED WITH THE REGULATORS, TO BE A
25 PIVOTAL OR REGISTRATION TRIAL MOVING DIRECTLY

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1 INTO -- DEPENDENT, AGAIN, ON THE DISEASE INDICATION,
2 TOWARDS GETTING THAT REGISTRATION TO EMBARK ON
3 GETTING THE PRODUCT OUT TO THE PATIENTS AND THE
4 PRODUCT TO BE ON THE MARKET.

5 SO THE CURRENT CLIN2 PROGRAM ANNOUNCEMENT
6 IS NOT REALLY THAT CLEAR OR EXPLICIT ABOUT THE
7 SUPPORT OF SPECIFIC LATE-STAGE DEVELOPMENT
8 ACTIVITIES. WE, OUR TEAM AND THE THERAPEUTICS
9 DEVELOPMENT TEAM, DISCUSSED SOME OF THOSE. AND WE
10 ARE RECOGNIZING THAT WE NEED TO JUST MAKE WHAT WE
11 CAN FUND MORE CLEAR TO THE POTENTIAL APPLICANTS.
12 AND THAT WILL ENSURE BEST PRACTICES ALIGNMENT WITH
13 THE FDA. AND AS I SAID EARLIER, IT HARMONIZES AND
14 IS CONSISTENT WITH WHAT YOU HEARD IN THE DISCUSSION
15 AT AAWG, THE ROADMAP THAT WAS PRESENTED, AND THAT
16 WILL ALLOW US TO BE CLOSER TOWARDS WORKING TOWARDS
17 ACCESS AND AFFORDABILITY.

18 SO WHAT ARE THOSE ACTIVITIES? YOU'VE
19 HEARD IN THE PAST THAT THE FDA ALWAYS LIKES TO HAVE
20 PLACEBO CONTROLLED TRIALS. SOME OF THE GRANTS THAT
21 WE ARE GETTING IS WHERE PLACEBO CONTROLLED TRIALS IS
22 NOT POSSIBLE, SUCH AS IN RARE DISEASES. THERE'S A
23 NEED FOR ALTERNATIVE COMPARATOR DATA THAT IS
24 ACCEPTABLE TO THE FDA FOR A MARKETING APPROVAL
25 DECISION. AND THAT WAS INTENDED TO SUPPORT THE

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1 PROPOSED INTERVENTIONAL CLINICAL TRIAL IN, AS I
2 MENTIONED, WHERE PLACEBO OR SHAM CONTROLS ARE NOT
3 POSSIBLE.

4 SO THERE ARE OPTIONS, AND WE ARE ONLY
5 GIVING YOU EXAMPLES HERE. NATURAL HISTORY STUDIES.
6 OTHERS WOULD BE TO PURCHASE DATA REPOSITORIES FROM
7 VARIOUS U.S. REPOSITORIES THAT ACTUALLY COLLECT SUCH
8 DATA. AND THEY MUST HAVE DOCUMENTED THAT THE FDA
9 AGREEMENT ACCEPTS THOSE COMPARATORS WHILE IN
10 DISCUSSIONS WITH THE REGULATORS SO THERE ARE NO
11 SURPRISES. AND SO WE WILL MAKE SURE THAT THAT'S
12 WELL EXPLAINED TO THE APPLICANTS.

13 AND THEN COMPILATION OF PATIENT-REPORTED
14 OUTCOMES. THIS IS, AS I SAID, REALLY IMPORTANT
15 ESPECIALLY WHEN IT COMES TO THE FOLKS WHO MANAGE THE
16 CARE LIKE CMS, MEDICAID AND MEDICARE. AND SO WE
17 WOULD LIKE TO MAKE SURE THAT OUR GRANTEES UNDERSTAND
18 THAT THEY INCLUDE THAT AS WELL. AND THAT'S RELATED
19 TO THE CONDUCT OF THE PROPOSED TRIAL.

20 AND THEN COMPILATION OF REAL-WORLD DATA
21 AND REAL-WORLD EVIDENCE RELATED TO THE CONDUCT OF
22 THE PROPOSED TRIAL. THE FDA HAS PUT OUT MULTIPLE,
23 NOW, GUIDANCE DOCUMENTS THAT SAYS THEY WILL ACCEPT
24 SUCH DATA INSTEAD OF PLACEBO OR SHAM CONTROLLED.
25 AND SO WE WANT TO MAKE SURE WE ARE MAINSTREAM IN

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1 COLLABORATING CLOSELY WITH THE FDA TO ALLOW THE
2 STUDIES TO SUCCEED.

3 IN ADDITION, WE ALWAYS WANT TO MAKE SURE
4 THAT WE SUPPORT THE DEI GOALS BY ANY FUNDS THAT ARE
5 NEEDED. AND WE HAVE HEARD THAT SOMETIMES THEY NEED
6 MORE FUNDS FOR THAT ACTIVITY. AND SO WE WOULD JUST
7 LIKE TO MAKE SURE THAT, WHEN THEY BUDGET, THEY
8 BUDGET ACCORDINGLY.

9 SO NOW WE MOVE TO THE NEW CLIN4 CONCEPT
10 PLAN. SO WHAT DOES CLIN4 MEAN AND WHAT IS IT FOR?
11 SO THERE ARE CERTAIN KEY ACTIVITIES REQUIRED BY THE
12 FDA TO GET A BIOLOGICS LICENSE APPLICATION. WE
13 ALREADY HAVE ONE GRANTEE THAT HAS ARRIVED AT THAT
14 STAGE, AND FDA HAVE ACCEPTED THE BIOLOGICS LICENSE
15 APPLICATION FILING, AND THEY HAVE THAT FOR MARCH OF
16 2024.

17 SO I JUST WANT TO GIVE YOU THE FEELING
18 THAT THIS IS REALLY BECOMING A REALITY FOR CIRM. SO
19 READINESS FOR PRODUCT LAUNCH IS NOT COVERED BY THE
20 CURRENT CLIN2 PA. AND INVARIABLY IN OUR
21 CONVERSATION WITH OUR GRANTEES THAT ARE STARTING TO
22 GET TO THAT STAGE, IT IS REQUIRED TO PLAN FOR
23 READINESS FOR PRODUCT LAUNCH WHILE THE BLA IS BEING
24 PREPARED OR FINALIZING THE TRIAL. AND THAT TAKES
25 ABOUT ONE TO TWO YEARS BEFORE FILING THE BLA.

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1 SO THE GOAL OF A CLIN4 IS TO SUPPORT
2 CIRM-FUNDED PROGRAMS TO ACHIEVE A BLA FILING AND
3 ADVANCEMENT TOWARDS THE GOAL OF OBTAINING A
4 MARKETING APPROVAL.

5 IT IS A VERY IMPORTANT THING TO MENTION
6 AGAIN THAT IT'S A VERY LOGICAL BRIDGE TO THE AAWG,
7 AGAIN, DEMONSTRATING CIRM'S COMMITMENT TO ACCESS AND
8 AFFORDABILITY. THIS IS REALLY AN IMPORTANT KIND OF
9 CONNECTIVITY WITH THE LONG-TERM GOAL OF CIRM MAKING
10 ALL THESE TYPES OF GRANTS AFFORDABLE AND ACCESSIBLE
11 TO PATIENTS.

12 SO WHAT DOES THE NEW CLIN4 INCLUDE AND WHO
13 WILL BE ELIGIBLE FOR THIS GRANT? WE DECIDED TO MAKE
14 SURE THAT WE DON'T HAVE OVERLAPPING CLIN2 REQUESTS
15 AND CLIN4 REQUESTS. SO WE SAID THEY MUST HAVE AN
16 ACTIVE CLIN2 AWARD, OVERLAPPING REQUESTS WHEN I
17 MENTIONED THAT. SO IT MUST HAVE AN ACTIVE CLIN2
18 AWARD. MUST HAVE COMPLETED 50 PERCENT OF THE
19 MILESTONES ON AN ACTIVE CLIN2 AWARD. THAT'S THE
20 FEELING THAT THEY CAN ACTUALLY DO IT, AND THEY HAVE
21 DONE A GOOD JOB ON TIME, WITHIN BUDGET. MUST HAVE
22 COMPLETED AN END-OF-PHASE 2 MEETING OR EQUIVALENT
23 WITH THE FDA AND HAVE CONCURRENCE ON REQUIREMENTS
24 FOR A BLA FILING.

25 AND, AGAIN, FROM EXPERIENCE SO FAR OF TWO

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1 GRANTEES WHO ARE CLOSE TO THAT IS THAT THAT WILL BE
2 VERY HELPFUL FOR THEM.

3 WHAT WILL NEW CLIN4 PROVIDE? WE DEBATED
4 WHETHER WE SHOULD MAKE A CLIN4 A LARGE GRANT, LARGER
5 EVEN THAN THE CLIN2. AND WE CAME TO THE NOTION THAT
6 UP TO \$12 MILLION WILL COVER LATE-STAGE DEVELOPMENT
7 ACTIVITIES NECESSARY FOR BLA FILING, BUT NOT
8 INCLUDED IN THE CLIN2 AWARD.

9 AND LET ME SHOW YOU WHAT THE ACTIVITIES
10 ARE. SO THOSE ACTIVITIES INCLUDE FILING A BLA,
11 CONDUCTING A PRE-BLA MEETING WITH THE FDA. BY THE
12 WAY, FOR SOME OF THOSE, THEY WILL NOT REQUIRE THEM
13 TO PAY THE FEES THAT ARE REQUIRED FOR THAT, BUT MOST
14 OF THEM WILL NEED TO DO THAT. AND THEN COMPILATION
15 OF AN ELECTRONIC COMMON TECHNICAL DOCUMENT, WHICH IS
16 THE FORMULA BY WHICH THE FDA REQUIRES.

17 PRODUCT MANUFACTURING ACTIVITIES NECESSARY
18 TO SUBMIT A BLA. AND THEN COMMERCIAL DEVELOPMENT
19 ACTIVITIES SUCH AS PHARMACOECONOMIC ANALYSIS, BUDGET
20 MODIFICATIONS, BUDGET IMPACT MODIFICATIONS, MANAGED
21 HEALTH-PAYER PERSPECTIVE. THEY HAVE TO HAVE ALL
22 THOSE DISCUSSIONS ONGOING WHILE THEY ARE ACTUALLY
23 PREPARING FOR THIS KEY STEP. DEVELOPMENT OF A
24 SUPPLY CHAIN STRATEGY, KNOWING HOW THEY'RE GOING TO
25 DISTRIBUTE THE DRUG, WHERE IS THE DRUG GOING TO BE

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1 DELIVERED, WHAT IS THE COST OF THAT. THIS ALL HAS
2 TO BE PART OF THE PLANNING.

3 AND THEN INITIATION OF
4 PRECOMMERCIALIZATION ACTIVITIES, SUCH AS PRODUCTION
5 OF PAYOR'S COST-EFFECTIVENESS ANALYSIS REPORT THE
6 INSTITUTE FOR CLINICAL AND ECONOMIC REVIEW REQUIRES,
7 AND THERE IS A NICE GOOD FEE THAT GOES WITH THAT.
8 AND THEN COMPILATION OF AN AMCP DOSSIER. THE AMCP
9 IS THE ACADEMY OF MANAGED CARE PHARMACY DOSSIER.
10 AND, AGAIN, WE ARE TALKING ABOUT MEDICARE, MEDICAID,
11 ET CETERA. AND THEN THE LAST ITEM THAT WE ARE
12 ALLOWING IS A COMPASSIONATE USE OF THE
13 INVESTIGATIONAL THERAPY FOR PATIENTS IN THE PERIOD
14 AFTER ENROLLMENT CLOSED AND MARKET APPROVAL IS AT
15 AWARD STAGE OR IS AWARDED FDA APPROVAL AND AGREEMENT
16 WITH THE DRUG PRODUCT SUPPLIER. AND I'M HAPPY TO
17 DISCUSS THAT IN MORE DETAIL IF NECESSARY.

18 AS A SUMMARY OF WHAT I JUST MENTIONED IN
19 THE LAST FEW SLIDES, I JUST WANT TO HIGHLIGHT THAT
20 WE ARE WITHIN BUDGET. SO THE CLIN1 INCREASE WILL BE
21 6 MILLION TO \$7 MILLION FOR THE NON-PROFIT AND 4
22 MILLION TO 5 MILLION FOR THE PROFIT ORGANIZATIONS.

23 CLIN2 WILL REMAIN UP TO 15 MILLION. AND
24 THE CLIN4, IF APPROVED, IF YOU ALLOW IT TO MOVE
25 FORWARD, THAT WILL BE UP TO 12 MILLION.

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1 SO CIRM REQUESTS KINDLY FROM THE SCIENCE
2 SUBCOMMITTEE TO MOVE FORWARD WITH THE PROPOSED CLIN1
3 AND CLIN2 CONCEPT AMENDMENTS AND THE APPROVAL OF A
4 CLIN4 CONCEPT TO MOVE TO THE ICOC FOR ULTIMATE
5 APPROVAL. WITH THAT, I'M HAPPY TO ANSWER ANY
6 QUESTIONS.

7 CHAIRMAN GOLDSTEIN: MARIA BONNEVILLE.

8 VICE CHAIR BONNEVILLE: I DON'T HAVE ANY
9 QUESTIONS. BUT WHAT I WANTED TO DO IS THANK ABLA SO
10 MUCH. THE CLIN2, JUST A CLARIFICATION OF THE
11 ACTIVITIES THAT ARE ALLOWED, DOVETAILS SO NICELY
12 WITH THE WORK THAT THE AAWG DID WITH THE ROADMAP.
13 AND THANK YOU, ABLA, FOR BRINGING THAT ALL TOGETHER
14 SO THAT WE CAN FURTHER THESE PROJECTS ALONG. SO I
15 REALLY APPRECIATE IT.

16 DR. CREASEY: THANK YOU, MARIA B.

17 CHAIRMAN GOLDSTEIN: MONICA CARSON.

18 DR. CARSON: THANK YOU. THAT WAS A
19 BEAUTIFUL PRESENTATION AND BEAUTIFULLY EXPLAINED.
20 IN GENERAL, IT SOUNDS QUITE RATIONAL.

21 I JUST HAD A QUICK QUESTION ABOUT THE
22 CLIN1 AWARDS. SINCE YOU HAD JUSTIFIED OR JUST HAD
23 PUT IT IN THE CONTEXT OF A 20-PERCENT INCREASE, THE
24 FACT THAT WE ARE GIVING ABOUT, WHAT, APPROXIMATELY
25 17 PERCENT FOR NON-PROFITS AND AN APPROXIMATE

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1 25-PERCENT INCREASE FOR THE PROFITS, THAT MAY BE
2 RATIONALE FOR THAT. I'M JUST CURIOUS ABOUT THE
3 LOGIC OF --

4 DR. CREASEY: WE HAD A DISCUSSION WITH PAT
5 LEVITT, AND I ROUNDED TO \$7 MILLION. IT WAS 7.2
6 MILLION TO BE EQUIVALENT TO THE FOR-PROFIT. AND I
7 ROUNDED DOWN INSTEAD OF UP, INSTEAD OF GOING TO 7.2
8 OR 7.5. AND SO HAVING TO CHANGE IT, WHATEVER WE END
9 UP WITH, WE'D LIKE IT TO BE CONSISTENT BETWEEN THOSE
10 TWO. SO THANKS FOR BRINGING THAT UP.

11 DR. CARSON: SO YOUR ACTUAL PROPOSAL WOULD
12 BE MORE THAT THEY SHOULD BOTH BE 20 PERCENT?

13 DR. CREASEY: CORRECT. CORRECT.

14 DR. CARSON: SO THANK YOU.

15 DR. CREASEY: YOU'RE WELCOME.

16 DR. LEVITT: JUST TO CLARIFY. AS LONG AS
17 IT WAS ROUNDED. ROUNDING IS FINE. I THINK MAKING
18 IT EQUIVALENT, WE COULD EVEN GO A LITTLE HIGHER
19 WOULD BE FINE.

20 DR. CARSON: OKAY, GREAT. THANK YOU, PAT.

21 CHAIRMAN GOLDSTEIN: CHRISTINE.

22 DR. MIASKOWSKI: THANK YOU. ABLA, THANKS
23 FOR YOUR PRESENTATION. ONE OF THE COMMENTS I HAD AS
24 I WAS LISTENING TO IT, I WISH THE NIH HAD THE WISDOM
25 TO INCREASE THEIR BUDGETS, WHICH WE HAVEN'T SEEN IN

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1 A LONG TIME. BUT I DO HAVE TWO QUESTIONS.

2 IN TERMS OF THE CLIN4 PROGRAM, ARE YOU
3 PLANNING A PREAPPLICATION LIKE LETTER OF INTENT TO
4 SCREEN APPLICANTS TO MEET THE MINIMUM CRITERIA?

5 DR. CREASEY: THE TRUTH, CHRISTINE, IS
6 WE'VE BEEN THINKING ABOUT THE CURRENT GRANTEES THAT
7 WE HAVE WHO ARE READY TO MOVE. AND IN ORDER TO HAVE
8 THEM COMPLETE -- EITHER OVERLAP WITH THE CLIN2 AND
9 COME TO APPLY FOR A CLIN4. REMEMBER CIRM IS IN THE
10 ACCELERATION BUSINESS. AND SO IF AN APPLICANT COMES
11 WITH A CLIN2 AND, LET'S SAY, THEY DO ACCOMPLISH A
12 COUPLE OF THEIR MILESTONES AND THEY ARE READY FOR A
13 CLIN4, WE'LL KEEP AN EYE ON THOSE SO AS TO ENCOURAGE
14 THEM TO APPLY.

15 AND SO WE ACTUALLY ARE ACTIVELY WORKING
16 THAT SO THAT WE ARE ACCOMMODATING THE GRANTEES THAT
17 HAVE BEEN WITH US FOR NOW A NUMBER OF YEARS WHO ARE
18 REACHING TO THAT STAGE, BUT IT WILL BE A SHAME IF WE
19 DID NOT ALLOW THEM TO GET THAT STAGE AND NOT FIND
20 ANY FUNDS TO ALLOW THEM TO GET TO THE BLA STAGE AND
21 BE AVAILABLE TO PATIENTS.

22 DR. MIASKOWSKI: YEAH. I THINK IT'S A
23 GREAT IDEA. AND IT SOUNDS LIKE IT'S GOING TO BE AN
24 INVITATIONAL TYPE OF PROCESS.

25 DR. CREASEY: RIGHT. MORE LIKE IT, YEAH.

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1 DR. MIASKOWSKI: THE OTHER POINT, I WAS
2 INTERESTED IN ONE OF YOUR SLIDES WAS THE NOTION OF
3 COLLECTING PATIENT-REPORTED OUTCOMES BECAUSE I THINK
4 THAT IS INCREDIBLY IMPORTANT. AND YOU MADE THE
5 POINT THAT THAT'S REALLY IMPORTANT FOR THE
6 CLINICIANS. I MAKE THE POINT IT'S ALSO REALLY
7 IMPORTANT FOR THE PATIENTS TO KNOW WHAT THEY'RE
8 GETTING INTO AND THE FAMILY MEMBERS.

9 BUT THE QUESTION I HAD WAS IS CIRM IN ANY
10 WAY CONSIDERING STANDARDIZING THESE PRO'S? I KNOW
11 MANY OF THEM HAVE TO BE SPECIFIC TO THE DISEASE OR
12 THE PROCESS THAT'S BEING TREATED. BUT IT WOULD BE
13 INCREDIBLY IMPORTANT, I THINK, FOR US TO TRY TO GET
14 SOME COMMON DATA ELEMENTS ACROSS OUR STUDIES THAT
15 COULD BE METRICS FOR THE LARGER FIELD; FOR EXAMPLE,
16 QUALITY OF LIFE. I THINK THAT SHOULD BE ENDEMIC IN
17 ALL OF THE STUDIES THAT WE ENGAGE IN. AND THERE MAY
18 BE OTHER ONES LIKE FUNCTIONAL OUTCOMES THAT ARE
19 REALLY, REALLY IMPORTANT TO PATIENTS.

20 SO I DON'T KNOW IF YOU'VE HAD DISCUSSIONS
21 OR ARE CONSIDERING THAT. IT SEEMS TO ME ALONG THE
22 SAME LINES AS WHAT WE ARE DOING WITH THE DEI RUBRIC
23 IN TERMS OF BEING UNDER CERTAIN DEMOGRAPHICS. I
24 WONDER IF THAT COULD BE SOMETHING THAT WE COULD HAVE
25 A CONVERSATION ABOUT BECAUSE I THINK IT WOULD SERVE

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1 THE FIELD BROADLY.

2 DR. CREASEY: TOTALLY AGREE, CHRISTINE.
3 RIGHT ON THE MONEY. IN FACT, WE NEED TO COORDINATE
4 ALSO THAT WITH THE AAWG, HOW THEY THINK ABOUT IT, AS
5 WELL AS CREATE POTENTIALLY LIKE A RUBRIC THAT WILL
6 ASSIST US IN MAKING SURE SOME OF THE ELEMENTS ARE
7 GOING TO BE SLIGHTLY DIFFERENT FROM DISEASE ONE TO
8 TWO TO THREE, BUT AT THE SAME TIME I THINK
9 STANDARDIZATION WILL BE HELPFUL TO US. AND SO
10 THAT'S A VERY GOOD SUGGESTION.

11 DR. MIASKOWSKI: YEAH. I THINK I SIT IN
12 ON A LOT OF THE GRANT REVIEWS, AND THE DEI RUBRIC,
13 FROM MY PERSPECTIVE, IS REALLY WORKING, AND WE ARE
14 GETTING SOME METRICS FROM THAT WE'LL BE ABLE TO USE
15 IN THE FUTURE. SO I WOULD REALLY ENCOURAGE YOU TO
16 THINK ABOUT PATIENT-REPORTED OUTCOMES AS WELL.

17 DR. CREASEY: EXCELLENT. THANK YOU. IT
18 WILL BE ON THE LIST.

19 CHAIRMAN GOLDSTEIN: ABLA, I HAVE A COUPLE
20 OF QUESTIONS. ONE I THINK IS PROBABLY SELF-EVIDENT.
21 BUT I'D LIKE TO CONFIRM MY UNDERSTANDING, THAT THESE
22 CHANGES WOULD MAKE IT, IN PRINCIPLE, POSSIBLE TO
23 DEVELOP A THERAPY ENTIRELY IN THE NONCOMMERCIAL
24 SECTOR AND WITH NO INVOLVEMENT OF A COMMERCIAL
25 PARTNER.

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1 DR. CREASEY: I THINK MANY OF YOU -- I CAN
2 ANSWER THAT, BUT MAYBE LET'S LISTEN TO SHYAM'S
3 PROPOSAL FIRST AND THEN DECIDE TOGETHER ABOUT. YES.
4 THE ANSWER IS YES BECAUSE SINCE WE ARE ELIMINATING
5 CO-FUNDING REQUIREMENTS IN SOME CASES, SO I THINK
6 THAT'S GOING TO BE POSSIBLE.

7 CHAIRMAN GOLDSTEIN: AND THAT MAY BE KEY
8 TO DEVELOPING AFFORDABILITY IF FOR-PROFITS WERE IN
9 THERE.

10 SECOND QUESTION IS ABOUT THE REQUIREMENT
11 OF A CLIN2 TO GET A CLIN4. WHAT ABOUT THE CASE
12 WHERE THERAPEUTIC DEVELOPMENT GETS ABANDONED BY A
13 COMPANY OR ANOTHER ACADEMIC INSTITUTION THAT WAS
14 SUPPORTED WITH NIH FUNDS OR PRIVATE FUNDS? WOULDN'T
15 WE STILL WANT TO BE ABLE TO PICK IT UP WITH A CLIN4
16 IF IT LOOKED LIKE A MERITORIOUS APPROACH?

17 DR. CREASEY: ACTUALLY WE DISCUSSED THAT
18 AT LENGTH. FOR EXAMPLE, FOR SOME INDICATIONS WHERE
19 WE HAVE NO GRANTS AND THEY COME TO US AND ASK FOR A
20 CLIN4, LET'S SAY, IN ANY OF THE PSYCHIATRIC DISEASES
21 OR WHATEVER, WILL WE DO THAT? I THINK WE TALKED
22 ABOUT POTENTIALLY MAKING IT LIKE AN EXCEPTION OR
23 LIKE A VITAL RESEARCH OPPORTUNITY. BUT RIGHT NOW WE
24 ARE TRYING TO KIND OF MOVE ALL THE PROGRAMS THAT WE
25 HAVE, BUT WE'RE GOING TO BE OPEN, WITH YOUR

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1 PERMISSION AND BLESSING, THAT WE ACTUALLY ENTERTAIN
2 SUCH A THING AT SOME POINT.

3 CHAIRMAN GOLDSTEIN: WHEN I WAS AT
4 HARVARD, MANY REGULATIONS AND RULES WERE PRECEDED BY
5 THE WORD "ORDINARILY." ORDINARILY A CLIN2 WOULD BE
6 PROVIDED, BUT THERE'S ALWAYS ROOM FOR GETTING AROUND
7 IT IN SOME REASONABLE WAY IF THERE'S A CONSENSUS.
8 SO THAT MIGHT BE A WAY TO HANDLE THAT. QUITE
9 EFFECTIVE THERE.

10 DR. CREASEY: YES. THANK YOU.

11 CHAIRMAN GOLDSTEIN: ANY OTHER QUESTIONS
12 OR COMMENTS? ALL RIGHT. LET'S HAVE SOMEBODY MOVE
13 FOR APPROVAL.

14 VICE CHAIR BONNEVILLE: SO MOVED.

15 CHAIRMAN GOLDSTEIN: MARIA, THANK YOU.

16 DR. GASSON: SECOND.

17 CHAIRMAN GOLDSTEIN: OKAY. JUDY SECONDED.
18 GREAT. SCOTT, CALL THE ROLL PLEASE.

19 MR. TOCHER: AND I'LL JUST CHECK THAT
20 THERE'S NO PUBLIC COMMENT.

21 MS. MANDAC: THERE IS ONE HAND RAISED.

22 CHAIRMAN GOLDSTEIN: GOOD. YEAH.

23 MR. TOCHER: SO THE 510 NUMBER.

24 VICE CHAIR BONNEVILLE: THEY'RE ON MUTE,
25 SCOTT.

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1 MS. ADELSON: HI THERE. THANK YOU VERY
2 MUCH. THIS IS CELIA ADELSON WITH THE UCLA
3 (UNINTELLIGIBLE). I JUST WANTED TO UNDERSCORE DR.
4 GOLDSTEIN'S COMMENT. IT HAD OCCURRED TO ME THAT
5 CIRM MAY WANT TO GIVE IT SOME FLEXIBILITY ON BOTH
6 THE FIRST PART OF THE CLIN2 REQUIREMENT AND THEN
7 ALSO THE CLIN2 REQUIREMENT AS WELL. I APPRECIATE
8 ABLA'S COMMENTS ABOUT JUST BEING AIMED AT THE
9 CURRENT PORTFOLIO, AND I REALLY UNDERSTAND THE
10 REASONS FOR IT, BUT THAT ALSO INCLUDES A SELECTION
11 BIAS. YOU DON'T KNOW ABOUT THE OTHER PROGRAMS THAT
12 ARE OUT THERE THAT NEED THE FUNDING. SO I JUST
13 WANTED TO MAKE THAT COMMENT.

14 CHAIRMAN GOLDSTEIN: THANK YOU. ABLA,
15 ANYTHING THAT YOU'D LIKE TO RESPOND THERE? YOU
16 DON'T NECESSARILY HAVE TO.

17 DR. CREASEY: I AGREE WITH THE POTENTIAL
18 CONCEPT AWARD SHE MENTIONED AND HAPPY TO ENTERTAIN
19 POTENTIAL -- LIKE WE SAID, WE THOUGHT IT WOULD BE
20 IMPORTANT FOR FOLKS TO KNOW WHAT A CLIN4 IS ALL
21 ABOUT, BUT AT THE SAME TIME FOR US TO ENTERTAIN
22 POTENTIAL ELIGIBILITY AT SOME POINT. BUT RIGHT NOW
23 WE ARE LEAVING IT FOR THE CURRENT PORTFOLIO. AND I
24 UNDERSTAND THERE COULD BE SOME BIAS, BUT AT THE SAME
25 TIME I THINK WE COMMEND ANYONE WHO HAS A PROGRAM

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1 THAT'S REACHED THAT STAGE AND WOULD LIKE TO APPLY TO
2 CIRM, THAT WE WILL DISCUSS IT WITH THIS COMMITTEE
3 AND COME BACK TO THEM.

4 CHAIRMAN GOLDSTEIN: ANY OTHER PUBLIC
5 COMMENT?

6 MR. TOCHER: DOESN'T LOOK LIKE IT. CAN
7 YOU CONFIRM THAT, CLAUDETTE?

8 MS. MANDAC: NO OTHER COMMENTS.

9 CHAIRMAN GOLDSTEIN: GREAT. SO CALL THE
10 ROLL.

11 MR. TOCHER: HAIFAA ABDULHAQ.

12 DR. ABDULHAQ: YES.

13 MR. TOCHER: MARIA BONNEVILLE.

14 VICE CHAIR BONNEVILLE: YES.

15 MR. TOCHER: MONICA CARSON.

16 DR. CARSON: YES.

17 MR. TOCHER: SHLOMO MELMED.

18 DR. MELMED: YES.

19 MR. TOCHER: MARK FISCHER-COLBRIE.

20 DR. FISCHER-COLBRIE: YES.

21 MR. TOCHER: ELENA FLOWERS.

22 DR. FLOWERS: YES.

23 MR. TOCHER: JUDY GASSON.

24 DR. GASSON: YES.

25 MR. TOCHER: LARRY GOLDSTEIN.

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1 CHAIRMAN GOLDSTEIN: YES.

2 MR. TOCHER: DAVID HIGGINS.

3 DR. HIGGINS: YES.

4 MR. TOCHER: VITO IMBASCIANI.

5 DR. IMBASCIANI: YES.

6 MR. TOCHER: PAT LEVITT.

7 DR. LEVITT: YES.

8 MR. TOCHER: AND CHRISTINE MIASKOWSKI.

9 DR. MIASKOWSKI: YES.

10 MR. TOCHER: GREAT. THANKS VERY MUCH.

11 THE MOTION CARRIES.

12 CHAIRMAN GOLDSTEIN: OKAY. NEXT UP ARE
13 SOME PROPOSED CHANGES TO CO-FUNDING REQUIREMENTS
14 FROM INDUSTRY. SHYAM, TAKE IT AWAY.

15 DR. PATEL: I HOPE YOU CAN HEAR AND SEE MY
16 SLIDES OKAY.

17 SO THIS IS A CONTINUATION OF A SET OF
18 CO-FUNDING CHANGES THAT WERE INITIALLY PROPOSED BY
19 THE IP AND INDUSTRY SUBCOMMITTEE. AND SO I'M GOING
20 TO DESCRIBE THOSE TO YOU TODAY. AND THANK YOU FOR
21 YOUR TIME.

22 SO THIS INITIALLY STARTED OFF AS A REQUEST
23 FROM THE IP AND INDUSTRY SUBCOMMITTEE TO EVALUATE
24 WHETHER OUR CO-FUNDING REQUIREMENTS FOR FOR-PROFIT
25 ENTITIES ARE LIMITING THEIR ABILITY TO ACCESS CIRM

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1 FUNDING AND TO PROGRESS THEIR PROJECTS WITH THE USE
2 OF CIRM FUNDS. AND SO WHAT WE HAVE DONE IS WE TOOK
3 THAT AND TOOK A HOLISTIC APPROACH TO ALL THE
4 CO-FUNDING REQUIREMENTS. AND WHAT WE ARE PROPOSING
5 TO YOU IS A CULMINATION OF ALL THAT ACTIVITY IN
6 CLOSE GUIDANCE WITH THE IP SUBCOMMITTEE,
7 PARTICULARLY DR. ABOUSALEM AS WELL AS CHAIRMAN
8 JUELSGAARD.

9 AND SO IT IS GOING TO ADDRESS SEVERAL
10 DIFFERENT CO-FUNDING ELEMENTS. AND I'LL DESCRIBE
11 THOSE TO YOU IN THE NEXT FEW SLIDES.

12 SO, FIRST, TO KIND OF START OFF, I WANT TO
13 DESCRIBE WHAT OUR CURRENT CO-FUNDING REQUIREMENTS
14 ARE. AND AS PART OF THIS EXERCISE, WE WENT BACK AND
15 REEVALUATED THE INTENT OF THE CO-FUNDING
16 REQUIREMENTS. WHEN THE CLINICAL PROGRAM WAS FIRST
17 BEING PROPOSED AS A CONCEPT PLAN, THIS IS BACK IN
18 2014 AND 2015 TIME FRAME, SO SINCE THEN, THE
19 CO-FUNDING REQUIREMENTS HAVE STAYED LARGELY THE SAME
20 WITH MINOR CHANGES HERE AND THERE, BUT THIS IS WHAT
21 THEY ARE AT THE MOMENT.

22 SO FOR A NON-PROFIT ENTITY THAT APPLIES TO
23 CIRM FOR FUNDING, THEY HAVE NO CO-FUNDING
24 REQUIREMENT UP UNTIL THE POINT OF A CLIN2 SUBMISSION
25 THAT IS POST A FIRST-IN-HUMAN CLINICAL TRIAL. ON

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1 THE OTHER SIDE, FOR A FOR-PROFIT ENTITY, THE
2 CO-FUNDING REQUIREMENT ESCALATES FROM TRAN TO CLIN1
3 TO CLIN2. AND I'LL GET INTO THE REASONS FOR WHY
4 THESE CO-FUNDING REQUIREMENTS ARE THERE. BUT I DO
5 WANT TO NOTE THE WAY THE CO-FUNDING IS CALCULATED IS
6 THAT IT'S THE TOTAL PROJECT COSTS OF THAT PARTICULAR
7 STAGE OF ACTIVITY, THE CIRM FUNDING AMOUNT, PLUS THE
8 COMMITMENT FROM THE AWARDEE. THAT'S HOW IT'S
9 CALCULATED.

10 SO WHAT WAS THE INTENT OF THESE CO-FUNDING
11 REQUIREMENTS WHEN THEY WERE FIRST PROPOSED AS PART
12 OF THE INITIAL CLIN2 CONCEPT PLAN? FOR THE
13 FOR-PROFITS, IT WAS TO DEMONSTRATE THAT THEY HAVE A
14 COMMITMENT TO THE PROPOSED PROJECT, THAT THEY ARE
15 COMMITTED TO IT IN THE CURRENT STAGE, AND THEY'RE
16 COMMITTED TO PROGRESSING THAT PROJECT FORWARD, AND
17 THAT IT IS A PRIORITY FOR THEIR PIPELINE.

18 FOR THE NON-PROFITS, THERE IS THAT
19 40-PERCENT CO-FUNDING REQUIREMENT THAT I MENTIONED
20 FOR LATE-STAGE CLINICAL TRIALS. AND THAT WAS
21 INTENDED TO PROMOTE INDUSTRY PARTNERS FOR THOSE
22 LATE-STAGE CLINICAL TRIALS BECAUSE YOU WOULD NEED,
23 IN THE CURRENT TRADITIONAL SORT OF APPROVAL MODEL,
24 THAT YOU WOULD NEED A PARTNER TO TAKE ON THAT
25 PROJECT FOR LATE-STAGE DEVELOPMENT AND

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1 COMMERCIALIZATION.

2 SO HAVING THAT -- IF IT'S A NON-PROFIT
3 THAT'S SPONSORING THAT TRIAL, THEY HAVE A PARTNER IN
4 PLACE TO TAKE THAT PROJECT FORWARD AND TO PROGRESS
5 IT. SO THESE ARE GOING TO BE IMPORTANT -- THE
6 INTENT IS GOING TO BE IMPORTANT AS I DESCRIBE THE
7 CHANGES IN THE NEXT FEW SLIDES.

8 SO THIS SLIDE IS GOING TO OUTLINE WHY WE
9 ARE PROPOSING THE CHANGES TO THE CO-FUNDING
10 REQUIREMENTS, AND THEN IT'S GOING TO DESCRIBE THE
11 CO-FUNDING REQUIREMENTS THEMSELVES. SO, FIRST, I'M
12 GOING TO START OFF BY WHY ARE WE PROPOSING CHANGES.

13 SO FIRST OF ALL, WITH RESPECT TO THE
14 CLINICAL -- THE NON-PROFITS. SO CURRENTLY FOR
15 UNPARTNERED ACADEMIC PROGRAMS THAT HAVE PROMISING
16 FIRST-IN-HUMAN DATA, THE REQUIREMENT TO HAVE
17 40-PERCENT CO-FUNDING FOR THAT NEXT STAGE CLINICAL
18 TRIAL IS ACTUALLY STALLING PROGRESS OF THOSE
19 PROGRAMS BECAUSE THEY HAVE TO FIND SOME WAY TO
20 CREATE -- FIND SOME WAY TO SECURE THAT FUNDING.
21 THIS IS PARTICULARLY RELEVANT FOR PROGRAMS IN THE
22 RARE DISEASE SPACE OR ONES THAT CURRENTLY DON'T HAVE
23 MUCH COMMERCIAL POTENTIAL. AND I THINK WE ALL KNOW
24 OF MANY OF THOSE PROGRAMS. AND THERE ARE SEVERAL
25 PROGRAMS IN OUR OWN PORTFOLIO THAT HAVE EXPERIENCED

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1 THIS SLOWING OR STALLING WHILE THEY'RE TRYING TO
2 FIGURE OUT OTHER MECHANISMS TO FUND THEM. SO THAT'S
3 THE FIRST PART.

4 THE SECOND PART IS THAT THE WAY OUR
5 CURRENT CO-FUNDING REQUIREMENTS ARE DESCRIBED, IF A
6 NON-PROFIT APPLICANT ALREADY HAS A FOR-PROFIT
7 PARTNER, THAT FOR-PROFIT PARTNER IS NOT REQUIRED TO
8 CO-FUND THE CIRM AWARD BECAUSE THE CURRENT
9 CO-FUNDING REQUIREMENTS APPLY TO THE APPLICANT AND
10 SUBSEQUENT AWARDEE AND NOT TO PARTNERS.

11 AND LASTLY, WHICH WAS THE ORIGINAL INTENT
12 OF THESE CHANGES FROM THE IP SUBCOMMITTEE, WAS THAT
13 FOR-PROFITS ARE OPERATING IN A VERY CHALLENGING
14 ECONOMIC ENVIRONMENT. THIS HAS BEEN ONGOING FOR A
15 FEW YEARS NOW. AND ON TOP OF THAT, THEY ARE AT A
16 DISADVANTAGE, RELATIVELY SPEAKING, TO NON-PROFITS
17 FOR CIRM AWARD LEVELS, AND SO IN THE PREVIOUS
18 PRESENTATION, THESE AWARD AMOUNTS FOR CLINICAL AS WELL
19 AS FOR FIRST-IN-HUMAN CLINICAL TRIALS. AND ALSO,
20 UNLIKE NON-PROFITS, FOR-PROFITS CANNOT REQUEST CIRM
21 FUNDING FOR INDIRECT COSTS. THEY CAN REQUEST
22 FUNDING FOR DIRECT FACILITIES COSTS, BUT NOT
23 INDIRECT COSTS, WHICH FOR A NON-PROFIT IS 20
24 PERCENT.

25 SO WITH THOSE THREE THINGS IN MIND, WE ARE

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1 PROPOSING THE FOLLOWING TABLE OF CHANGES. AND I
2 WILL GO THROUGH THEM ONE STEP AT A TIME.

3 SO FIRST AND FOREMOST, WE DIFFERENTIATED
4 THE NON-PROFIT APPLICANTS TO CIRM INTO TWO
5 CATEGORIES. FIRST IS A NON-PROFIT APPLICANT THAT
6 DOES NOT HAVE A FOR-PROFIT PARTNER WITH A VESTED
7 INTEREST IN COMMERCIALIZING THAT PROJECT. FOR THOSE
8 ENTITIES THERE WILL BE NO CO-FUNDING REQUIREMENT
9 UNDER THIS PROPOSAL AT ANY STAGE OF A CIRM AWARD,
10 DISCOVERY, TRANSLATION, CLINICAL, CLIN2,
11 FIRST-IN-HUMAN, AND THAT SHOULD ALSO, I BELIEVE,
12 EXTEND TO CLIN4 AS WELL.

13 ON THE FLIP SIDE NOW, WITH RESPECT TO THE
14 FOR-PROFIT ELEMENTS THAT ARE INVOLVED THERE, SO FOR
15 A FOR-PROFIT APPLICANT OR WHERE YOU HAVE A
16 NON-PROFIT APPLICANT THAT HAS AN ESTABLISHED
17 FOR-PROFIT PARTNER THAT HAD A VESTED INTEREST IN
18 COMMERCIALIZING THAT PROJECT, THE FOR-PROFIT WOULD
19 BE SUBJECT TO EITHER THE CASH CO-FUNDING REQUIREMENT
20 OR WOULD HAVE THE OPTION FOR A WARRANT-BASED
21 CO-FUNDING REQUIREMENT. AND I'LL DESCRIBE WHAT THIS
22 MEANS.

23 ESSENTIALLY WHAT IT IS IS FLEXIBILITY TO
24 EITHER COMMIT CASH TO CIRM OR TO COMMIT WARRANTS TO
25 CIRM. AND THAT WAS THE ORIGINAL PROPOSAL FROM THE

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1 IP AND INDUSTRY SUBCOMMITTEE WAS TO CREATE THIS
2 WARRANT-BASED CO-FUNDING REQUIREMENT AS AN
3 ALTERNATIVE TO THE CASH-BASED CO-FUNDING REQUIREMENT
4 FOR COMPANIES THAT APPLY TO CIRM.

5 SO I'M GOING TO QUICKLY ADDRESS THE
6 NON-PROFIT SIDE, AND THEN THE REST OF THE
7 PRESENTATION IS GOING TO FOCUS ON WHAT THAT
8 WARRANT-BASED CO-FUNDING REQUIREMENT LOOKS LIKE AND
9 HOW WE DESIGNED IT.

10 SO FIRST AND FOREMOST, AS I ITERATED
11 PREVIOUSLY, THAT 40-PERCENT CO-FUNDING REQUIREMENT
12 IS NOT ACTIVE AS AN INCENTIVE FOR INDUSTRY PARTNERS.
13 THIS IS NOT INCENTIVIZING INDUSTRY PARTNERS TO
14 PARTNER WITH ANY OF THE NON-PROFIT PROGRAMS AT THAT
15 STAGE BY ITSELF. AND WHAT IT INSTEAD IS DOING IS
16 SLOWING THE CLINICAL PROGRESS WHILE THOSE AWARDEES
17 OR THOSE APPLICANTS THAT HAVE PROMISING
18 FIRST-IN-HUMAN CLINICAL DATA WANT TO PROGRESS THAT
19 PROJECT IN A NON-PROFIT SETTING HAVE TO FIND OTHER
20 SOURCES OF FUNDING LIKE NIH, FOUNDATION, AND SO ON.
21 AND AS YOU'VE ALREADY NOTED, NIH FUNDING IS OFTEN
22 NOT SUFFICIENT FOR THESE TYPES OF ACTIVITIES AT THAT
23 LATE STAGE OF DEVELOPMENT.

24 NOW, ON THE FLIP SIDE, IF THAT NON-PROFIT
25 ALREADY HAS A PARTNER, THE CO-FUNDING REQUIREMENT

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1 WOULD APPLY AS STATED IN THE PREVIOUS SLIDE TO THE
2 FOR-PROFIT PARTNER.

3 AND I DO WANT TO QUICKLY REITERATE THAT
4 THESE CLIN2 AWARDS THAT WILL BE GOING TO THE
5 NON-PROFITS WITHOUT A CO-FUNDING REQUIREMENT WOULD
6 STILL HAVE OUR REVENUE SHARING REQUIREMENT AND A
7 LOAN CONVERSION REQUIREMENT ATTACHED TO THEM AS ALL
8 OUR AWARDS DO. SO I JUST WANT TO QUICKLY OUTLINE
9 THAT. IN THE INSTANCE OF A \$15 MILLION CLIN2 AWARD
10 TO A NON-PROFIT FOR A PHASE 2 OR LATER TRIAL, IF
11 THAT DATA IS USED FOR REGULATORY FILING, THEY WOULD
12 BE SUBJECT TO A 1.5 -- THE COMMERCIALIZING ENTITY,
13 WHOEVER THAT MAY BE, WOULD BE SUBJECT TO A
14 1.5-PERCENT ROYALTY ON THAT REVENUE. THIS CAN BE UP
15 TO \$135 MILLION OR TEN YEARS. THAT IS OUR STANDARD
16 REVENUE SHARING REQUIREMENT ATTACHED TO ALL OF OUR
17 AWARDS.

18 ALTERNATIVELY, IF THE AWARDEE OR ITS
19 PARTNER DECIDES TO CONVERT THAT AWARD TO A LOAN,
20 CIRM WOULD AT A MINIMUM HAVE A RETURN OF THE
21 PRINCIPAL AMOUNT, 15 MILLION, AND POTENTIALLY MORE
22 DEPENDING ON WHAT STAGE THEY ELECT. SO THE SORT OF
23 RETURN TO THE STATE AND TO CIRM IS STILL PRESERVED
24 EVEN IF WE REMOVE THE CO-FUNDING REQUIREMENT BECAUSE
25 THOSE ARE SEPARATE INSTANCES.

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1 SO THE REST OF THIS PRESENTATION IS GOING
2 TO FOCUS ON WARRANTS, AND I'M GOING TO GET INTO THE
3 WEEDS A LITTLE BIT. SO I APPRECIATE IT IF YOU HANG
4 WITH ME FOR A LITTLE BIT HERE.

5 SO THE WARRANT-BASED CO-FUNDING
6 REQUIREMENT. SO HOW DOES THIS WORK? SO A
7 FOR-PROFIT AWARDEE WOULD COMMIT WARRANTS. THESE ARE
8 THE RIGHT TO PURCHASE EQUITY IN A COMPANY INSTEAD OF
9 CAPITAL. AND I'LL DESCRIBE THE WARRANTS IN THE NEXT
10 FEW SLIDES. THE AWARDEE WOULD RETAIN CAPITAL FOR
11 OPERATIONAL NEEDS AND VALUE CREATION IN THIS
12 INSTANCE BY NOT HAVING TO COMMIT THAT CO-FUNDING
13 AMOUNT.

14 AND IN ORDER TO MAKE ALL THIS WORK, WHAT
15 WE HAD TO DO WAS THAT WE HAD TO CREATE THIS
16 MECHANISM, AND IT APPLIES IN CERTAIN INSTANCES WHERE
17 CIRM WOULD ACTUALLY COMMIT A HIGHER AWARD AMOUNT UP
18 TO THE AWARD CAP TO MAINTAIN OVERALL FINANCES OF THE
19 CIRM-FUNDED PROJECT. BECAUSE, AS I MENTIONED
20 PREVIOUSLY, THE CO-FUNDING PLUS CIRM FUNDING IS IN
21 TOTALITY ADDRESSING THE TOTAL PROJECT COSTS. IF WE
22 REMOVE THE CO-FUNDING REQUIREMENT, THERE WOULD STILL
23 BE A CASH GAP FOR THOSE PROJECTS. AND SO IN SOME
24 INSTANCES WHERE THE CIRM AWARD CAN FILL THAT GAP IS
25 WHERE THE WARRANT-BASED MECHANISM MAKES THE MOST

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1 SENSE. YOU CAN SEE THAT IN THIS PARTICULAR TABLE.

2 SO FIRST OF ALL, TO WALK YOU THROUGH AN
3 EXAMPLE REALLY QUICKLY, LET'S TAKE, FOR INSTANCE, A
4 TRANSLATIONAL 1 PROJECT THAT HAS A TOTAL PROJECT
5 COST OF \$4 MILLION. SO THE ACTIVITIES TO GET TO A
6 PRE-IND MEETING COST \$4 MILLION IN THIS INSTANCE.
7 THE CIRM AWARD LIMIT FOR THIS IS \$4 MILLION. SO AT
8 THE MOMENT, A FOR-PROFIT APPLICANT COULD AT MOST
9 REQUEST \$3.2 MILLION AND WOULD HAVE TO PUT UP
10 \$800,000 OF ITS OWN MONEY TO CO-FUND THAT PROJECT.

11 UNDER THE WARRANT-BASED CO-FUNDING
12 REQUIREMENT, THIS PARTICULAR SITUATION, THE
13 APPLICANT CAN CHOOSE THE WARRANT-BASED CO-FUNDING
14 INSTEAD OF CASH BASE. IN THAT INSTANCE, THE CIRM
15 AWARDEE CAN REQUEST UP TO \$4 MILLION. AND BECAUSE
16 \$800,000 OF THAT WOULD HAVE BEEN ATTRIBUTED TO THE
17 CO-FUNDING AMOUNT, THAT IS THE AMOUNT OF WARRANT
18 COVERAGE THEY'RE GOING TO HAVE TO GIVE TO CIRM.
19 I'LL DESCRIBE WHAT THAT MEANS IN THE NEXT SLIDE.

20 NOW, AS I MENTIONED, THERE'S A CONSTRAINT
21 HERE OF THE AWARD CAP, AND THAT'S DESCRIBED IN THE
22 NEXT ROW. SO IN INSTANCES WHERE THE PROJECT COST IS
23 SIGNIFICANTLY HIGHER THAN THE CIRM AWARD CAP, THE
24 WARRANT-BASED CO-FUNDING IS ACTUALLY NOT GOING TO BE
25 THAT USEFUL, IF AT ALL. SO IN THIS INSTANCE, LET'S

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1 SAY WE HAVE A \$5 MILLION TOTAL PROJECT COST AND THE
2 CIRM AWARD AMOUNT IS \$4 MILLION. IN THIS INSTANCE,
3 THEY'VE ALREADY HIT THE CAP OF \$4 MILLION AND HAVE
4 TO PUT UP \$1 MILLION OF THEIR OWN MONEY TO ADDRESS
5 CO-FUNDING COSTS. SO THE WARRANT-BASED CO-FUNDING
6 REQUIREMENT IS NOT GOING TO BE HELPFUL BECAUSE THAT
7 \$1 MILLION CASH GAP STILL EXISTS. AND IN THAT
8 INSTANCE THE AWARDEE WOULD BENEFIT FROM JUST TAKING
9 THE CASH-BASED CO-FUNDING REQUIREMENT INSTEAD OF THE
10 WARRANT-BASED.

11 THE LAST ONE I'M GOING TO SKIP, BUT IT
12 JUST DESCRIBES THE SAME SITUATION, BUT FOR A CLIN2
13 AWARD WHERE THE WARRANT-BASED CO-FUNDING REQUIREMENT
14 APPLIED TO THAT.

15 SO WHY WARRANTS? AND SO CIRM HAS A
16 HISTORY WITH WARRANTS IN THE PAST. SO THE PRIOR
17 LOAN PROGRAM THAT CIRM HAD LAUNCHED, AND THERE WERE
18 SEVERAL LOANS THAT WERE GIVEN OUT THAT HAD WARRANTS
19 ATTACHED TO IT. SIMILARLY, THERE WAS AN ATP3
20 PROGRAM THAT WOULD HAVE ALSO HAD WARRANTS ATTACHED
21 TO THAT. SO WHAT ARE WARRANTS?

22 SO WARRANTS BASICALLY ARE ISSUED BY THE
23 COMPANY TO THE HOLDER. AND THIS GIVES THE HOLDER
24 THE RIGHT TO PURCHASE SHARES OF COMPANY STOCK. AND
25 THE WARRANTS ARE EXERCISED BY THE HOLDER AT A SET

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1 EXERCISE PRICE WITHIN A SET AMOUNT OF TIME TO
2 CONVERT THOSE WARRANTS TO SHARES OF COMPANY STOCK.
3 AND PREVIOUSLY AS LAID OUT WAS THAT, AS
4 PART OF THE LOAN PROGRAM, A COMPANY HAD ISSUED
5 WARRANTS TO CIRM AND CIRM HELD THE WARRANTS UNTIL IT
6 MADE A DECISION TO EXERCISE THEM. WHEN THEY
7 EXERCISE THE WARRANTS, IT ASSIGNED THE STOCK SHARES
8 TO A CIRM FUND THAT WAS HELD IN THE SAN FRANCISCO
9 FOUNDATION. IT'S ESSENTIALLY AN ACCOUNT TO
10 AGGREGATE AND HOLD CIRM ASSETS. AND THE FOUNDATION
11 WAS THEN INSTRUCTED TO LIQUIDATE THE SHARES,
12 BASICALLY SELL THE STOCK SHARES IN THE MARKET AND
13 THEN TRANSFER THE PROCEEDS FROM THE FUND BACK TO
14 CIRM. SO THIS WAS SOMETHING THAT WAS DONE IN THE
15 PAST, AND CIRM HAD A PRECEDENT FOR THIS PARTICULAR
16 MECHANISM GOING FORWARD.

17 SO THREE THINGS TO OUTLINE HERE. THEY'RE
18 ISSUED. THE WARRANTS ARE ISSUED TO CIRM AND CIRM
19 HOLDS THOSE WARRANTS. THEN CIRM EXERCISES THOSE
20 WARRANTS TO CONVERT THE WARRANTS INTO SHARES OF
21 COMPANY STOCK WHICH ARE HELD BY THE FUND AT THE SAN
22 FRANCISCO FOUNDATION. AND THEN THEY'RE INSTRUCTED
23 TO LIQUIDATE THE SHARES AND PASS THE MONEY BACK TO
24 CIRM. THAT WAS A PREVIOUS INSTANCE OF HOW THIS
25 WORKED.

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1 SO UNDER THE CURRENT WARRANT-BASED
2 CO-FUNDING REQUIREMENT PROPOSAL, THE APPLICANT WOULD
3 ELECT THE WARRANT-BASED CO-FUNDING REQUIREMENT AT
4 THE TIME OF THE APPLICATION. THEY WOULD HAVE
5 VARIOUS SOURCES OF INFORMATION TO INFORM THIS
6 DECISION, INCLUDING A TERM SHEET, AN FAQ, AND OTHER
7 REFERENCE MATERIALS. AND THE APPLICANT MAY COMBINE
8 WARRANT-BASED AND CASH-BASED CO-FUNDING WHICH UNDER
9 CERTAIN CIRCUMSTANCES COULD MAKE SENSE.

10 THE WARRANTS MUST BE ISSUED AT AWARD
11 START. AND THAT IS A REQUIREMENT FOR US BECAUSE
12 CIRM IS COMMITTING ITS MONEY UP FRONT. AND THERE
13 WILL BE NO MECHANISM FOR BUYING BACK THE WARRANTS.
14 SO THE AWARDEE WILL NOT HAVE A MECHANISM TO BUY BACK
15 THE WARRANTS AT ANY PERIOD, EITHER DURING THE AWARD
16 OR AFTER THE AWARD. CIRM WILL HOLD THOSE WARRANTS
17 UNTIL TIME TO DO SOMETHING WITH IT.

18 SO IN DESIGNING THIS, WE HAD TO CREATE A
19 SET OF TERMS THAT WOULD DERIVE ENOUGH VALUE FOR CIRM
20 FOR, IN ESSENCE, PUTTING OUT ADDITIONAL FUNDING UP
21 TO THE AWARD CAP AND AT THE SAME TIME BEING FAIR TO
22 THE AWARDEES, AND, LASTLY, TO MAKE SURE THAT ALL THE
23 AWARDEES CAN ISSUE THOSE WARRANTS AT AWARD START.

24 SO THIS TABLE DESCRIBES ALL THAT, AND I'M
25 GOING TO OUTLINE A FEW OF THESE POINTS. AND I CAN

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1 GO INTO MORE DETAIL IN THE NEXT ONE.

2 SO ONE THING THAT IS CONSISTENT, THE
3 ECONOMICS OF THE WARRANT IS THAT THE EXERCISE PRICE
4 IS \$.01. SO THIS MEANS THERE'S GOING TO BE A
5 NOMINAL COST TO CIRM TO EXERCISE THOSE WARRANTS.
6 AND THAT REALLY IS KEY TO MAKING SURE THAT THE
7 WARRANTS, THE VALUE OF THESE WARRANTS IS SIMILAR TO
8 THE VALUE OF THE INVESTMENT GOING INTO THAT COMPANY
9 AT THAT STAGE. THE WARRANT TERM IS GOING TO BE TEN
10 YEARS. SO WE HAVE TEN YEARS TO DECIDE WHAT TO DO
11 WITH THOSE WARRANTS.

12 AND THEN IN ORDER TO ENABLE ALL OF THE
13 DIFFERENT TYPES OF COMPANIES THAT APPLY TO CIRM, TO
14 BE ABLE TO ISSUE WARRANTS AT AWARD START FOR VARYING
15 THE SECURITY TYPE AS WELL AS THE NUMBER OF SHARES TO
16 A SPECIFIC COMPANY. SO VERY EARLY-STAGE COMPANIES
17 WOULD GIVE US COMMON STOCK WARRANTS AT A SET FORMULA
18 THOUGH WE RESERVE THE RIGHT TO CONVERT THOSE TO A
19 DIFFERENT SORT OF WARRANT UNDER PREFERRED STOCK AT
20 THE NEXT FINANCING. AND THIS IS FAIRLY COMMON FOR
21 THOSE EARLY-STAGE COMPANIES WHEN THEY'RE GETTING
22 INVESTORS BRINGING IN MONEY AS WELL TO KIND OF
23 DETERMINE THE VALUATION WHEN THERE IS AN ACTIVITY
24 DOWN THE ROAD FOR A FINANCIAL INVESTOR.

25 AND THE PRIVATE AND PUBLIC COMPANY SIDE,

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1 THESE ARE GOING TO BE PREFERRED STOCK OR COMMON
2 STOCK WHICH IS THE EXACT SAME TYPE OF EQUITY THAT
3 THOSE INVESTORS ARE GETTING AT THAT STAGE OF THE
4 COMPANY. AND THERE'S NO OPTIONALITY FOR EACH
5 BECAUSE WE ARE ALREADY GETTING THE SAME VALUE THE
6 INVESTOR IS GETTING AT THAT STAGE.

7 SO LASTLY, I WANT TO TOUCH ON WARRANT
8 ELIGIBILITY REQUIREMENTS FOR COMPANIES APPLYING TO
9 CIRM AND WHAT ADDITIONAL REQUIREMENTS THAT MAY APPLY
10 TO THE WARRANT-BASED MECHANISM. SO AT THE MOMENT
11 ANY FOR-PROFIT APPLICANT WHO APPLIES TO CIRM HAS TO
12 DEMONSTRATE THAT IT HAS AT LEAST SIX MONTHS OF CASH
13 TO MAINTAIN SOLVENCY FROM THE APPLICATION SUBMISSION
14 DATE. AND IT ALSO MUST DEMONSTRATE TO CIRM AT THE
15 TIME OF APPLICATION THAT IT HAS THE ABILITY TO
16 COMMIT THE CO-FUNDING AS WELL AS CONTINGENCY
17 FUNDING. SO HOW IS IT GOING TO BRING IN THE MONEY
18 TO CO-FUND THE PROJECT AND TO HAVE FUNDS SET ASIDE
19 FOR CONTINGENCIES. SO ALL OF THAT IS REQUIRED AT
20 THE APPLICATION STAGE.

21 DURING THE COURSE OF THE AWARD, THE
22 AWARDEE THAT HAS A CO-FUNDING REQUIREMENT IS
23 REQUIRED TO INDICATE THE AMOUNT OF MONEY SPENT ON
24 CO-FUNDING AND ALSO TO DEMONSTRATE THAT IT HAD THE
25 ABILITY TO CO-FUND THAT NEXT MILESTONE. THERE'S

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1 CONTINUOUS CHECKS THAT HAPPEN OVER THE COURSE OF THE
2 AWARD.

3 SO THE WARRANT-BASED CO-FUNDING OPTION
4 CREATES A COUPLE OF ADDITIONAL REQUIREMENTS ON THE
5 ELIGIBILITY SIDE AND THE AWARD REPORTING SIDE THAT
6 I'M GOING TO QUICKLY OUTLINE HERE.

7 SO FIRST, THE VERY, VERY EARLY-STAGE
8 COMPANIES THAT HAVE INSTITUTIONAL FUNDING, THEY
9 WOULD BE REQUIRED TO PROVIDE US THEIR FUND-RAISING
10 PLAN AT THE TIME THEY APPLY TO CIRM. BUT THE
11 PRIVATE COMPANIES THAT HAVE HAD INSTITUTIONAL
12 FINANCING, BASICALLY VENTURE CAPITAL OR BIOPHARMA
13 PARTNERING, THEY HAVE TO TELL US THEIR FUND-RAISING
14 HISTORY TO DATE. AND WE ALSO WANT TO SEE FROM THEIR
15 INVESTOR THAT THEY SUPPORT THIS CIRM PROJECT.

16 THERE WOULD BE NO AWARD PERIOD REPORTING
17 REQUIREMENTS FOR THE LATER-STAGE COMPANIES. BUT FOR
18 THE VERY EARLY-STAGE COMPANIES, THEY WOULD HAVE TO
19 TELL US IF THERE'S A FINANCING EVENT THAT ALLOWS US
20 TO CONVERT -- EXERCISE OUR OPTION TO CONVERT THE
21 WARRANTS, AS I PREVIOUSLY MENTIONED, FROM COMMON
22 STOCK TO PREFERRED STOCK.

23 AND LASTLY, WE'LL ALSO UTILIZE OUR
24 INDUSTRY ALLIANCE PROGRAM TO HELP THESE COMPANIES
25 WHERE NEEDED IN THEIR FUND-RAISING PLANS.

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1 SO THE LAST SLIDE OF THIS PRESENTATION, I
2 WANT TO OUTLINE HOW WE'RE GOING TO MANAGE THIS
3 PORTFOLIO OF WARRANTS IF THIS MECHANISM IS APPROVED
4 BY THE SCIENCE SUBCOMMITTEE AND THE ICOC.

5 SO FIRST AND FOREMOST, THERE'S GOING TO BE
6 THE ISSUANCE OF THE WARRANTS, AND THERE'S ONGOING
7 ROUTINE COMPLIANCE MONITORING. THIS IS GOING TO BE
8 MANAGED BY THE CIRM TEAM WITH SUPPORT FROM AN
9 OUTSIDE COUNSEL.

10 SECONDLY, AS I OUTLINED PREVIOUSLY,
11 THERE'S TWO WAYS THAT THESE WARRANTS CAN CREATE
12 VALUE FOR CIRM. THE FIRST IS WE CAN SELL THE
13 WARRANTS. AND SECONDLY, AND PROBABLY THE MORE
14 LIKELY ONE, IS THAT WE EXERCISE THESE WARRANTS AT AN
15 APPROPRIATE EVENT. SO THIS IS GOING TO BE MANAGED
16 BY THE CIRM TEAM, AND IT'S GOING TO BE FACILITATED
17 BY THE CIRM FUND AT A CALIFORNIA COMMUNITY
18 FOUNDATION. THIS IS A SIMILAR PROCESS TO THE ONE I
19 PREVIOUSLY DESCRIBED THAT HAPPENED THE LAST TIME
20 THAT CIRM HAD WARRANTS.

21 SO THE WAY THIS WOULD WORK IS THE AWARDEE
22 HAS TO ISSUE WARRANTS TO CIRM AT AWARD START. CIRM
23 HOLDS THE WARRANTS UNTIL IT DECIDES TO EXERCISE THEM
24 OR UNTIL CERTAIN AUTOMATIC EXERCISES ARE TRIGGERED,
25 PARTICULARLY IN THE CASE OF THE COMPANY HAVING A

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1 CHANGE IN CONTROL OR GETS ACQUIRED OR IT MERGES OR
2 IT GOES PUBLIC, SO IT ISSUES AN IPO, OR THAT THE
3 WARRANT IS EXPIRING.

4 IN THOSE INSTANCES THE WARRANTS WILL BE
5 EXERCISED, AND THE COMPANY STOCK SHARES ARE GOING TO
6 BE ASSIGNED TO THE CIRM ACCOUNT HELD AT THE
7 CALIFORNIA COMMUNITY FOUNDATION. AND THEN FROM
8 CIRM'S INSTRUCTIONS, THE COMMUNITY FOUNDATION WILL
9 SELL THOSE SHARES OF STOCK AND THEN WILL TRANSFER
10 THE CASH PROCEEDS BACK TO CIRM.

11 SO WITH THAT, I'M GOING TO END MY
12 PRESENTATION. I'M HAPPY TO TAKE ANY QUESTIONS FROM
13 THE COMMITTEE.

14 CHAIRMAN GOLDSTEIN: MARK.

15 DR. FISCHER-COLBRIE: YEAH. I HAVE
16 SEVERAL QUESTIONS. FIRST OF ALL, I VERY MUCH
17 APPLAUD THE NEED AND DESIRE TO FIGURE OUT
18 MODIFICATIONS TO BE ABLE TO PROVIDE FUNDING IN
19 CRITICAL JUNCTURES FOR COMPANIES IN GENERAL. AND
20 SECOND, WITH THE BACKDROP OF THE VERY COMPLICATED
21 AND EXTREMELY DIFFICULT FINANCING ENVIRONMENT IN
22 BIOTECH, THAT MAKES A LOT OF SENSE.

23 SO I APPLAUD THE INITIATIVE. I HAVE A
24 SLEW OF QUESTIONS AROUND HOW THE WARRANTS CAN
25 ACTUALLY HELP TO EFFECT THAT BECAUSE, AS YOU'RE

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1 QUITE FAMILIAR, WARRANTS THAT GO WITH LOANS, THE
2 LOAN OFFERING IS THE PREDOMINANT FINANCIAL MECHANISM
3 FOR PROTECTION FROM OUTSIDE AND HAS QUITE A FEW
4 CLAUSES ASSOCIATED WITH THAT FOR PROTECTION,
5 INCLUDING REPAYMENT PROVISIONS AND A WHOLE HOST OF
6 PROTECTION ELEMENTS.

7 AND THEN IF WARRANTS ARE GIVEN, IT'S ALSO
8 SWEETENER AROUND PREFERRED STOCK, PREFERRED STOCK
9 HAS A WHOLE BUNCH OF BELLS AND WHISTLES AND
10 VALUATION MODELS AND OTHER FEATURES THAT REALLY
11 SWEETEN THE POT, IF YOU WILL, AND WARRANTS ARE SORT
12 OF A NICE OVERLAYER, GRAVY ON TOP OF THAT. AND IF
13 WE ARE IN A SITUATION OF WE ARE DOING WARRANTS, THEN
14 IT'S ACTUALLY PRETTY EASY TO HAVE THAT VALUE OF THE
15 WARRANTS WASH THAT. SO I'M NOT SURE HOW WE'RE GOING
16 TO DEAL WITH THAT PARTICULAR ISSUE.

17 THE OTHER SITUATION I NOTED THAT, WHEREAS
18 THERE'S A BULLET POINT FOR POTENTIAL CONVERSION OF
19 WARRANTS IN THE PREFERRED STOCK, HONESTLY, AS WAS
20 SAID LATER IN THE PRESENTATION, THERE'S A COMMENT
21 AROUND WARRANTS GETTING SWITCHED TO COMMON STOCK.
22 THERE'S RADICAL DIFFERENCES, AS YOU'RE FAMILIAR
23 WITH, WITH WHAT THAT MEANS IN TERMS OF RETURNS.

24 SO MY SENSE IS THERE'S A WHOLE LIST OF
25 QUESTIONS HERE THAT I THINK WE NEED TO GET

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1 ADDITIONAL EXPERTS IN FUNDING AREAS TO MAKE SURE
2 THAT WE'VE GOT THIS BUTTONED UP. THAT'S KIND OF
3 WHERE I'M LEANING TO. BUT I WANTED TO GET YOUR
4 FEEDBACK AND COMMENTS ON THAT TO SEE IF I'M MISSING
5 SOMETHING.

6 DR. PATEL: THANK YOU, MARK. SO THIS WAS
7 VETTED BY THE IP AND INDUSTRY SUBCOMMITTEE OF THE
8 PROPOSAL AS A WHOLE. IN TERMS OF THE WARRANT TERMS,
9 THESE WERE DEVELOPED IN CONJUNCTION WITH OUTSIDE
10 COUNSEL. WE'VE GOT ACCOUNTING IMPLICATIONS FEEDBACK
11 FROM EY, ERNST & YOUNG, AS WELL AS TAX IMPLICATIONS
12 FROM OUR OUTSIDE COUNSEL AS THEY APPLY TO THE
13 COMPANIES.

14 NOW, IN TERMS OF THE PROTECTIONS FOR CIRM,
15 I DO WANT TO NOTE THAT OUR GRANTS AS A WHOLE ARE
16 AT-RISK INVESTMENTS IN THESE COMPANIES. SO THOSE
17 AMOUNTS ARE AT RISK ANYWAY.

18 WITH RESPECT TO WE DID CONSIDER WHETHER IT
19 WOULD BE MORE APPROPRIATE TO CREATE A LOAN MECHANISM
20 AS OPPOSED TO A WARRANT MECHANISM FOR THAT
21 CO-FUNDING REQUIREMENT, THEN GETTING THAT AS AN
22 AWARD, THAT PROPORTION OF THE CO-FUNDING AS A LOAN.
23 AND THERE ARE A LOT OF REASONS WHY THAT PROBABLY
24 WILL NOT BE THAT BENEFICIAL TO THE COMPANIES,
25 PARTICULARLY BECAUSE IN THE PREVIOUS LOAN PROGRAM

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1 THAT CIRM HAD WAS IN AND OF ITSELF NOT ATTRACTIVE TO
2 COMPANIES BECAUSE OF THE TERMS THAT WERE ASSOCIATED
3 WITH THAT. AND SO IT WAS NOT UTILIZED THAT HIGHLY
4 BY THE COMPANIES.

5 SO HERE THE INTENT WAS TO CREATE A
6 MECHANISM THAT WOULD BE FAIR, PROVIDE A RETURN TO
7 CIRM, BUT ALSO BE SOMETHING THAT WOULD HELP THE
8 COMPANIES BE ABLE TO SECURE CIRM FUNDING AND
9 PROGRESS THOSE PROJECTS THAT THEY'RE DEVELOPING.

10 WITH RESPECT TO THE COMMON AND PREFERRED
11 SHARES, SO JUST TO CLARIFY, FOR THE REALLY
12 EARLY-STAGE COMPANIES THAT HAVE NOT HAD A PREFERRED
13 STOCK ISSUANCE AT THE TIME THAT THEY APPLY TO CIRM,
14 WE NEED TO CREATE A MECHANISM THAT ALLOWED THEM TO
15 ISSUE WARRANTS TO CIRM AT THE START OF THE AWARD.
16 AND SO THOSE ARE GOING TO BE COMMON STOCK WARRANTS
17 TO CIRM ALONG THAT PRICING FORMULA.

18 NOW, IN THE EVENT WHEN THAT COMPANY DOES
19 SECURE PREFERRED SHARE FINANCING, CIRM HAS THE
20 OPTION, IF THE ECONOMICS ARE BETTER FOR US, TO
21 CONVERT FROM THAT COMMON STOCK WARRANT TO THE
22 PREFERRED STOCK WARRANT BASED ON THE PRICING OF THE
23 PREFERRED SHARES.

24 NOW, SO THEN WE WOULD HAVE THE OPTION TO
25 DO THAT. IN THE END WE HOPE THESE WARRANTS ARE

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1 EXERCISED; AND EVENTUALLY IF THERE IS AN EVENT THAT
2 IS GOING TO BE EITHER A LIQUIDATING EVENT OR AN IPO,
3 YOU ARE CORRECT, THAT THE PREFERRED SHARES COULD BE
4 CONVERTED. AND THERE'S A CONVERSION PREFERENCE
5 THERE. AND SO THE CONVERSION PREFERENCE WOULD APPLY
6 FOR THE PRIVATE COMPANIES IN THE INSTANCES WHERE WE
7 HAVE TAKEN THOSE COMMON STOCK WARRANTS AND CONVERTED
8 TO PREFERRED SHARES. SO THERE WILL BE A
9 DETERMINATION WHETHER IT MAKES SENSE FOR US TO
10 CONVERT THOSE EARLY-STAGE COMPANIES FROM COMMON
11 STOCK WARRANT TO A PREFERRED STOCK WARRANT.

12 DR. FISCHER-COLBRIE: THANK YOU FOR THOSE
13 CLARIFICATIONS. IN ALL, I THINK YOU'VE DONE A GOOD
14 JOB ON GETTING THE HOMEWORK DONE RELATED TO LEGAL
15 AND ACCOUNTING AND TAX IMPLICATIONS.

16 HAVE YOU HAD AN OPPORTUNITY TO TALK TO
17 PEOPLE WHO ARE DOING CURRENT ROUNDS OF FUNDING TO
18 UNDERSTAND THE PARAMETERS AND VALUATION
19 PERSPECTIVES? THERE'S QUITE A FEW DIFFERENT
20 ELEMENTS HERE. AND, AGAIN, WARRANTS ARE TYPICALLY A
21 SWEETENER ON ATTRACTION AS OPPOSED TO A PRIMARY
22 FUNDING MECHANISM. SO HAVE WE TALKED TO FOLKS WHO
23 HAVE BEEN DOING DEALS AND WALKING THROUGH THE ISSUES
24 AND OPPORTUNITIES ASSOCIATED WITH THAT?

25 DR. PATEL: YES. SO WE SOUGHT FEEDBACK

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1 FROM OUR -- SO ON THE POINT OF THE DEMAND, WE SOUGHT
2 FEEDBACK FROM OUR AWARDEES AS WELL AS WE SOUGHT
3 FEEDBACK FROM OUR INVESTMENT PARTNERS ON THE
4 INDUSTRY ALLIANCE. THESE ARE VENTURE CAPITAL
5 FRIENDS THAT WE WORK WITH. IN THOSE INSTANCES, WE
6 OUTLINED THE TERMS. AND ONE OF THE THINGS THAT IS
7 PROVIDED IN THEM IS THAT THEY'RE PREFUNDED WARRANTS.
8 SO THESE ARE GOING TO BE -- AND THAT'S THE EXERCISE
9 PRICE OF A PENNY. SO THAT'S WHERE THE VALUE REALLY
10 COMES FROM IS THAT WE ARE NOT PAYING ADDITIONAL TO
11 EXERCISE THESE WARRANTS WHEN IT COMES TIME TO DO
12 THAT. AND THOSE WERE THINGS THAT WE DISCUSSED AS
13 WELL AS THE PREFERRED SHARE WARRANTS FOR THOSE
14 PRIVATE COMPANIES.

15 AND BOTH OF THOSE, THE FEEDBACK FROM THE
16 INVESTORS WAS THAT SEEMS APPROPRIATE GIVEN THE SORT
17 OF VALUE THAT WE ARE PROVIDING TO THE COMPANY
18 INVESTING.

19 DR. FISCHER-COLBRIE: AND DID THEY POINT
20 TO THE FACT THE COMPANIES NEED TO FUND THE VALUE OF
21 WARRANTS AT 409A VALUATION? DID THAT COME UP IN THE
22 DISCUSSION? BECAUSE A LOT OF TIMES THEY'RE PRESET.
23 IF IT'S A PREFERRED WARRANT, FOR EXAMPLE, IT CAN'T
24 PRESET THAT.

25 DR. PATEL: YES, WE DID. WE WALKED

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1 THROUGH THAT WITH BOTH ERNST & YOUNG ON THE
2 ACCOUNTING SIDE AS WELL AS WITH THE OUTSIDE COUNSEL
3 ON THE LEGAL SIDE AS TO WHAT THOSE IMPLICATIONS
4 WOULD BE FOR THE COMPANIES. AND THEY HAD SEVERAL
5 OPTIONS TO ACCOUNT FOR THAT. AND IT WAS NOT GOING
6 TO BE, FROM OUR PERSPECTIVE, A MAJOR CONCERN FOR
7 THOSE COMPANIES TO BE ABLE TO DO THAT.

8 CHAIRMAN GOLDSTEIN: SATISFIED, MARK?

9 DR. FISCHER-COLBRIE: OKAY. I THINK
10 THERE'S SOME QUESTIONS, BUT I'LL LET OTHER PEOPLE
11 JUMP IN.

12 CHAIRMAN GOLDSTEIN: SHLOMO.

13 DR. MELMED: THANK YOU. I THINK THAT,
14 SHYAM, YOUR OUTLINE IS GREAT, VERY ELEGANT. THANK
15 YOU.

16 IT'S CLEAR THAT THE WARRANT OPTION REALLY
17 ALLOWS CIRM TO ENJOY THE BENEFITS IF THE PRODUCT IS
18 SUCCESSFUL. BUT THE CONCERN, I THINK, THAT WE WOULD
19 HAVE AS A PUBLIC AGENCY REPRESENTING THE CITIZENS IS
20 ARE WE, IN FACT, DIMINISHING THE RISK WHICH THE
21 FOR-PROFIT IS TAKING? AND THE ELEMENT OF RISK IS
22 REALLY THE DRIVER OF THE FOR-PROFIT WORLD. AND BY
23 REMOVING THAT ELEMENT OF RISK, ARE WE, IN FACT,
24 DOING OURSELVES A DISSERVICE AS A PUBLIC AGENCY WHEN
25 WE EXPECT THE FOR-PROFITS TO ASSUME SOME DEGREE OF

1 RISK?

2 DR. PATEL: YEAH. I APPRECIATE THAT
3 QUESTION. SO I'LL SPEAK TO THIS FROM MY OWN
4 EXPERIENCE OF BEING SORT OF HERE IN THE PAST AND
5 RUNNING THAT. SO THERE ARE RISKS FOR ANY PROJECT
6 THAT A SMALL COMPANY, THE TYPES OF COMPANIES THAT
7 APPLY TO CIRM, ARE TAKING ON. SO HERE THERE'S A
8 FEW. FIRST OF ALL IS THAT ALL OF THE OVERHEAD COSTS
9 FOR THAT PROJECT, INDIRECT COSTS, ARE BEING BORNE BY
10 THE COMPANY BECAUSE WE ARE NOT PAYING FOR THOSE.
11 SECONDLY, THERE IS THE RISK OF OPPORTUNITY COST TO
12 THIS PROJECT. THEY'RE COMMITTING THEIR RESOURCES,
13 THEIR PERSONNEL, THEIR TIME TO THIS PROJECT.

14 DR. MELMED: NOW WE ARE NOT. NOW WE ARE
15 TELLING THEM THAT THEY'RE NOT ENTITLED TO COMMIT.

16 DR. PATEL: SORRY.

17 DR. MELMED: WE ARE TELLING THEM THAT THEY
18 DON'T HAVE TO COMMIT. THEY'RE ONLY COMMITTING ONCE.

19 DR. PATEL: THEY'RE COMMITTING ONCE, BUT
20 THE OPPORTUNITY COSTS COME FROM THE FACT THAT THESE
21 COMPANIES HAVE LIMITED STAFF, THEY HAVE LIMITED
22 RESOURCES, AND THEY'RE COMMITTING THOSE TO THE
23 PROJECT AS OPPOSED TO ANY OTHER PROJECTS. AND THEY
24 ARE PUTTING THEIR OWN SKIN IN THE GAME FOR THE
25 PROJECT BECAUSE THEY COULD BE SUPPORTING SOME OTHER

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1 PROJECT. AND SO THAT OPPORTUNITY COST DOES EXIST
2 WITH THE LIMITED SORT OF PERSONNEL RESOURCES AND
3 ABILITIES THAT THEY HAVE AS A SMALL COMPANY.

4 DR. MELMED: OKAY. I THINK IT'S VERY
5 IMPORTANT THAT WE ARTICULATE VERY CLEARLY, IT MIGHT
6 BE IN A SEPARATE PARAGRAPH, THAT WE DO EXPECT THE
7 COMPANIES TO ASSUME RISK AND RISK WILL BE ASSUMED BY
8 AND DELINEATE WHAT YOU JUST SAID NOW IN YOUR ANSWER
9 BECAUSE THAT'S GOING TO BE A CONCERN BY THE PUBLIC.
10 THANK YOU. I CAN'T QUANTIFY. I'M NOT AN EXPERT IN
11 QUANTIFYING RISK, BUT I HOPE WHAT YOU SAID WILL BE
12 SUFFICIENT TO SATISFY THE PEOPLE WHO UNDERSTAND
13 RISK.

14 CHAIRMAN GOLDSTEIN: VITO.

15 DR. IMBASCIANI: THANK YOU. A COMMENT AND
16 A QUESTION. FIRST OF ALL, I WANT TO COMPLIMENT
17 SHYAM. THAT WAS A BRILLIANT PRESENTATION, VERY
18 COMPLICATED SUBJECT. YOU DID A GREAT JOB, AND YOU
19 PRESENTED WITH A LOT OF CLARITY.

20 SO THIS IS A QUESTION. MAYBE IT GOES TO
21 THE LAWYER. I'M NOT SURE. IT GOES BACK TO LAW
22 SCHOOL 101 AND TORTS. I'M JUST CURIOUS ABOUT THE
23 LEGAL BASIS FOR OUR CLAIM TO A WARRANT. ARE ALL
24 CIRM GRANTS CONTRACTS AND THEY HAVE THE FORCE OF
25 CONTRACT?

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1 MR. AGUIRRE-SACASA: YES.

2 DR. IMBASCIANI: SO IT'S NOT JUST A
3 CONGRATULATIONS. HERE YOU ARE. THEY ACTUALLY SIGN
4 A CONTRACT WITH US?

5 MR. AGUIRRE-SACASA: CORRECT.

6 DR. IMBASCIANI: OKAY. AND THAT GIVES US
7 THE LEGAL CLAIM IF IT EVER COMES TO THAT.

8 MR. AGUIRRE-SACASA: YES, SIR.

9 DR. IMBASCIANI: OKAY.

10 CHAIRMAN GOLDSTEIN: OTHER QUESTIONS FROM
11 THE COMMITTEE? PUBLIC COMMENT? OOPS, SORRY.
12 SHLOMO.

13 DR. MELMED: YEAH. QUESTION WE ASKED, I
14 THINK, A COUPLE OF YEARS AGO IN A DIFFERENT CONTEXT.
15 WHO'S GOING TO MAKE THE DECISION ON SELLING THE
16 WARRANTS? IS IT GOING TO BE THIS BOARD OR THE
17 FOUNDATION? ARE WE GOING TO MAKE THAT DECISION?
18 AND HOW WILL WE KNOW THAT IT'S TIME TO SELL? WHO'S
19 GOING TO MAKE THE BUSINESS DECISION?

20 DR. PATEL: SO THERE ARE A COUPLE
21 ELEMENTS. FIRST IS EXERCISING THE WARRANTS AND
22 CONVERT IT INTO THE COMPANY SHARES OF STOCK. AND SO
23 THAT WOULD BE A CIRM EXECUTIVE DECISION TO DO THAT.
24 SO --

25 DR. MELMED: WHEN YOU SAY EXECUTIVE, A

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1 BOARD DECISION OR A STAFF DECISION?

2 DR. PATEL: STAFF DECISION TO DO THAT.
3 AND SO NOW WE COME DOWN -- IT PARTICULARLY WOULD
4 APPLY IF WE HAVE PUBLIC COMPANY WARRANTS. FOR THE
5 PRIVATE COMPANIES, MOST OF THE TIME THE EXERCISE OF
6 THOSE WARRANTS WOULD BE TRIGGERED BY A CHANGE IN THE
7 COMPANY, EITHER THROUGH A CHANGE OF CONTROL OR AN
8 IPO. AND SO THAT'S THE FIRST PART, TO EXERCISE THE
9 WARRANTS INTO COMPANY SHARES OF STOCK.

10 THEN THE SHARES OF STOCK ARE ASSIGNED TO
11 THE CIRM FUND. THOSE SHARES ARE GOING TO BE SOLD BY
12 THE FOUNDATION, BUT THOSE ARE GOING TO BE DICTATED
13 BY THE INSTRUCTIONS FROM CIRM.

14 DR. MELMED: WHEN YOU SAY FROM CIRM, FROM
15 THE BOARD OR FROM THE STAFF?

16 DR. PATEL: AGAIN, THAT WOULD BE FROM THE
17 STAFF.

18 DR. MELMED: CLEARLY THE DECISION TO SELL
19 PUBLIC SHARES SHOULD BE A BOARD DECISION. I'M NOT
20 SURE THAT IT SHOULD BE A STAFF DECISION. I'M
21 NOT -- WE HAVE FIDUCIARY RESPONSIBILITY. I'M NOT
22 SURE THAT WE SHOULD BE ASSIGNING STAFF THE DECISION
23 ON SELLING OR BUYING STOCK.

24 VICE CHAIR BONNEVILLE: WELL, NO. I THINK
25 FROM A PRACTICAL STANDPOINT, IN THE PAST THE BOARD

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1 HAS GIVEN THE CEO THE AUTHORITY TO MAKE THIS
2 DECISION. FROM A PRACTICAL STANDPOINT, IT TAKES TEN
3 DAYS TO GET EVERYBODY ON A CALL TO THEN COORDINATE A
4 DECISION ABOUT EXERCISING OR SELLING STOCK, WHICH
5 COULD CHANGE THINGS VERY DRASTICALLY WITHIN TEN
6 DAYS. SO IN THE PAST THE BOARD HAS GIVEN THE
7 AUTHORITY TO THE CEO TO MAKE THAT DECISION AND WORK
8 WITH THE INTERNAL TEAM, THE LAWYERS AND BUSINESS
9 DEVELOPMENT AND OTHER FOLKS, TO BE ABLE TO MOVE
10 FORWARD IN THAT DIRECTION. THAT'S TO THE PAST. IF
11 THERE'S DECISION THAT'S CHANGED, THAT'S FINE. I
12 JUST WANTED TO GIVE YOU SOME CONTEXT.

13 DR. MELMED: THE QUESTION IS WHETHER THE
14 BOARD IS COMFORTABLE IN ABROGATING THAT OBLIGATION.
15 I MEAN IT COULD BE TENS OF MILLIONS OF DOLLARS IN
16 THAT DECISION FOR CIRM OR MORE. COULD BE HUNDREDS
17 OF MILLIONS. I DON'T KNOW WHETHER WE AS A BOARD WHO
18 HAVE FIDUCIARY RESPONSIBILITY FOR CIRM CAN ABROGATE
19 THAT AMOUNT OF RESPONSIBILITY. THAT'S A LEGAL
20 QUESTION AND ALSO A MORAL QUESTION.

21 VICE CHAIR BONNEVILLE: FROM A LEGAL
22 STANDPOINT, IT COULD GO EITHER WAY. SO THAT'S A
23 DECISION THAT THE BOARD NEEDS TO MAKE IS WHETHER OR
24 NOT THEY WANT TO HAVE THAT AS PART OF THE WAY IT
25 WORKS OR IF THEY WANT TO, AGAIN, GIVE THE CEO THE

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1 AUTHORITY TO DO IT. SO I DEFER TO THE BOARD ON THAT
2 MATTER.

3 DR. MELMED: THANK YOU.

4 CHAIRMAN GOLDSTEIN: CAN I JUST INSERT A
5 RELATED QUESTION HERE AND THEN WE'LL GO TO MARK.

6 ORDINARILY IF SOME EMPLOYEE OF THE COMPANY
7 OR INVESTOR TAKES STOCK OPTIONS, THEY'RE PROHIBITED
8 FROM SELLING THOSE OPTIONS FOR SEVERAL MONTHS
9 POST-IPO. WOULD WE HAVE THAT RESTRICTION, OR WOULD
10 WE BE ABLE TO SELL AT THE MOMENT OF THE IPO IF THE
11 STOCK PRICE IS SUFFICIENTLY HIGH?

12 DR. PATEL: IT DEPENDS ON THE IPO TERMS
13 AND HOW THAT MIGHT APPLY TO OTHER HOLDERS OF STOCK.

14 CHAIRMAN GOLDSTEIN: MARK.

15 DR. FISCHER-COLBRIE: LARRY, WITH RESPECT
16 TO THAT, THAT'S USUALLY ARRANGED BY THE BANKS AT THE
17 TIME OF THE IPO. AND WHAT HAPPENS IS THEY WILL
18 REQUEST A PROHIBITION ON SALES FOR AT LEAST SIX
19 MONTHS POST-IPO AND THEY'LL CERTAINLY REQUEST THAT.
20 SO FYI.

21 JUST A QUICK QUESTION. I'M WALKING
22 THROUGH THE WARRANT COVERAGE. IF WE GO TO THE
23 EXAMPLE OF, I THINK THERE WAS A REFERENCE ON ONE OF
24 THE CHARTS FOR \$2.4 MILLION IN WARRANTS. COULD YOU
25 JUST WALK ME THROUGH HOW WE ARE THINKING ABOUT THAT

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1 2.4 MILLION IN TERMS OF SHARE CONVERSION? I WASN'T
2 REALLY TRACKING HOW THAT GETS CALCULATED. WHAT DOES
3 THAT MEAN IN TERMS OF NUMBER OF SHARES?

4 DR. PATEL: GOOD POINT. SO THE WAY WE ARE
5 DOING THAT -- AND I'LL DESCRIBE IT FOR ALL THREE
6 INSTANCES OF THE DIFFERENT COMPANIES. SO IF WE ARE
7 TRYING TO GET COVERAGE FOR 2.4 MILLION, AND I'M
8 GOING TO KEEP IT SIMPLE AND SAY A MILLION DOLLARS
9 JUST TO KEEP THE MATH SIMPLE SO I DON'T MESS IT UP.

10 DR. FISCHER-COLBRIE: SURE.

11 DR. PATEL: SO FOR \$1 MILLION, LET'S SAY
12 THE EXAMPLE FIRST OF A PUBLIC COMPANY. FOR THE
13 PUBLIC COMPANY, WHAT WE'LL NEED TO FIGURE OUT IS HOW
14 MANY SHARES WE'RE GOING TO GET FOR THAT MILLION
15 DOLLARS AND WHAT WE ARE USING AS THE MARKET PRICE OF
16 THEIR COMMON STOCK. SO IT'S GOING TO BE AN AVERAGE
17 CLOSING PRICE OVER THE LAST TEN DAYS. AND BASED ON
18 THAT, WE WOULD TAKE THE AMOUNT OF CIRM FUNDING THAT
19 COULD BE ATTRIBUTED TO CO-FUNDING, SO THAT'S A
20 MILLION DOLLARS, DIVIDED BY THE SHARE PRICE TO GIVE
21 US THE NUMBER OF SHARES. THAT WOULD THE WARRANTS.

22 FOR THE PRIVATE COMPANY THAT HAS HAD AN
23 INSTITUTIONAL FINANCING ROUND, WE WILL TAKE THE
24 PREFERRED STOCK PRICE OF THE MOST RECENT ROUND. AND
25 SO THAT WOULD BE A CALCULATION FOR THE DENOMINATOR

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1 OF THAT EQUATION THAT I PREVIOUSLY MENTIONED.

2 FOR THE VERY EARLY-STAGE COMPANIES THAT
3 HAVE NOT HAD A PREFERRED SHARE FINANCING TO DATE, WE
4 WILL IN INSTANCES WHERE POSSIBLE USE A FORMULA OF A
5 \$1 OF CIRM CO-FUNDING DIVIDED BY \$1 OF COMMON STOCK
6 TO GET THAT PARTICULAR FORMULA. BUT WE DO RESERVE
7 THE RIGHT TO MAKE MODIFICATIONS TO THAT FORMULA
8 BASED ON THE CAP STRUCTURE OF THAT COMPANY.

9 NOW, WHEN THAT WOULD CONVERT TO A
10 PREFERRED STOCK WARRANT, THAT WOULD BE THE PRICE OF
11 THE PREFERRED STOCK SHARES. SO IN THAT INSTANCE,
12 WHEN WE HAVE THAT OPTIONALITY TO GO FROM THAT COMMON
13 STOCK GOING TO PREFERRED STOCK WARRANT, WE WOULD BE
14 LOOKING AT WHAT IS THE ADDITIONAL SHARES THAT CIRM
15 WOULD BE GETTING AS WELL AS WHETHER IT'S MORE
16 PREFERABLE TO HAVE PREFERRED STOCK OR COMMON STOCK
17 WARRANTS AT THAT TIME. I HOPE THAT'S HELPFUL.

18 DR. FISCHER-COLBRIE: YES. THANK YOU.
19 THAT'S VERY HELPFUL IN TERMS OF THE MATH. JUST ONE
20 BIG CAVEAT. A LOT OF COMPANIES TODAY, WHATEVER THEY
21 DID ON THEIR LAST ROUND OF FUNDING SERIES A OR
22 SERIES B ARE OFTEN SEEING DRAMATICALLY LOWER VALUES
23 IF THEY'RE TRYING TO BE IN THE MARKET TODAY. SO
24 THERE WOULD BE -- THAT WOULD BE AN EXTREMELY
25 GENEROUS AMOUNT RELATED TO THAT CONVERSION

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1 CALCULATION.

2 DR. PATEL: NOTED. WE DID THINK ABOUT
3 OTHER WAYS IN TERMS OF USING (UNINTELLIGIBLE) AND
4 WHATNOT, BUT THIS WAS MEANT TO BE A MORE CONSISTENT
5 WAY ACROSS ALL OF THE AWARDEES.

6 CHAIRMAN GOLDSTEIN: OKAY. IF THERE ARE
7 NO FURTHER QUESTIONS, PUBLIC COMMENT PLEASE.

8 MR. TOCHER: I'M NOT SEEING ANY, LARRY.
9 CLAUDETTE.

10 MS. MANDAC: CONFIRMING THERE ARE NO HANDS
11 RAISED.

12 CHAIRMAN GOLDSTEIN: GREAT. WOULD
13 SOMEBODY LIKE TO MOVE APPROVAL TO RECOMMEND TO THE
14 ICOC THAT THEY CONSIDER THIS?

15 DR. MIASKOWSKI: SO MOVED.

16 CHAIRMAN GOLDSTEIN: THERE WE GO.

17 DR. HIGGINS: I'LL SECOND.

18 CHAIRMAN GOLDSTEIN: OKAY. THANK YOU.
19 SCOTT, PLEASE CALL THE ROLL.

20 MR. TOCHER: HAIFAA ABDULHAQ.

21 DR. ABDULHAQ: YES.

22 MR. TOCHER: MARIA BONNEVILLE.

23 VICE CHAIR BONNEVILLE: YES.

24 MR. TOCHER: MONICA CARSON.

25 DR. CARSON: YES.

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MR. TOCHER: SHLOMO MELMED.
DR. MELMED: YES.
MR. TOCHER: MARK FISCHER-COLBRIE.
DR. FISCHER-COLBRIE: NO.
MR. TOCHER: ELENA FLOWERS.
DR. FLOWERS: MAY I ABSTAIN?
MR. TOCHER: SURE. JUDY GASSON.
DR. GASSON: YES.
MR. TOCHER: LARRY GOLDSTEIN.
CHAIRMAN GOLDSTEIN: YES.
MR. TOCHER: DAVID HIGGINS.
DR. HIGGINS: YES.
MR. TOCHER: VITO IMBASCIANI.
DR. IMBASCIANI: YES.
MR. TOCHER: PAT LEVITT.
DR. LEVITT: YES.
MR. TOCHER: CHRISTINE MIASKOWSKI.
DR. MIASKOWSKI: YES.
MR. TOCHER: GREAT. THANKS VERY MUCH,
LARRY. THE MOTION CARRIES.
CHAIRMAN GOLDSTEIN: OKAY. FINAL PROPOSAL
IN FRONT OF US TODAY COMES FROM GEOFF LOMAX
REGARDING THE COMMUNITY CARE CENTERS AND A CONCEPT
PLAN.
DR. LOMAX: THANK YOU, CHAIRS. GEOFF

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1 LOMAX REPRESENTING THE MEDICAL AFFAIRS AND POLICY
2 TEAM. I'M GOING TO BE A LITTLE BIT SENSITIVE TO
3 TIME AND TRY TO MOVE THIS FASTER THAN I WOULD, BUT
4 FEEL FREE TO STOP ME IF YOU HAVE QUESTIONS. SO I'M
5 GOING TO DESCRIBE THE COMMUNITY CARE CENTERS OF
6 EXCELLENCE CONCEPT PLAN. AND AS A REMINDER, FOR
7 COMPLETENESS, YOU DO HAVE A MEMO AND A DRAFT PLAN
8 NOTICED AS PART OF THIS MEETING SO WE HAVE A
9 COMPLETE RECORD.

10 A REMINDER, THIS IS A PLAN THAT'S BEEN
11 UNDER DEVELOPMENT SINCE THE LATER PART OF 2022. WE
12 HAD A NEEDS ASSESSMENT PHASE THAT INCLUDED A SERIES
13 OF LISTENING SESSIONS AND STATEWIDE PUBLIC WORKSHOP.
14 AND IN ADDITION TO THOSE MEETINGS, WE WERE HAVING
15 ONGOING CONSULTATION WITH THE ACCESS AND
16 AFFORDABILITY WORKING GROUP WHO ARE ALSO PROVIDING
17 FEEDBACK AND RECOMMENDATIONS TO THE NEEDS ASSESSMENT
18 PROCESS AS WE WERE MOVING THROUGH THAT PHASE. AND
19 AS A REMINDER, THE MEMO DESCRIBING THIS ITEM
20 INCLUDES A LINK TO ITEMS -- THE DOCUMENTATION THAT
21 WE CREATED AS PART OF THAT NEEDS ASSESSMENT PHASE.
22 THAT REALLY SERVED TO INFORM THE DRAFT CONCEPT WHICH
23 YOU NOW HAVE BEFORE YOU.

24 IT WAS PRESENTED TO THE ACCESS AND
25 AFFORDABILITY WORKING GROUP THREE WEEKS AGO, AND WE

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1 HAVE INCORPORATED SOME ADDITIONAL FEEDBACK FROM
2 THEM. AND I'LL SUMMARIZE THAT FOR YOU TODAY. THE
3 AIM WOULD BE TO MOVE THE CONCEPT PLAN TO THE BOARD
4 AT THE NEXT DECEMBER BOARD MEETING SO WE COULD ENTER
5 THE APPLICATION PHASE EARLY NEXT YEAR.

6 ALSO WANTED TO REMIND YOU THE COMMUNITY
7 CARE CENTERS OF EXCELLENCE ARE OUR INFRASTRUCTURE
8 PROGRAM. THEY'RE DESCRIBED IN PROPOSITION 14 AS AN
9 INFRASTRUCTURE HUB FOR EXPANDING ACCESS TO CLINICAL
10 TRIALS AND REGENERATIVE MEDICINE TREATMENTS IN
11 ADDITION TO CIRM EDUCATION AND TRAINING PROGRAMS.
12 AND I JUST WANT TO -- IT'S NOT IN THE SLIDE, BUT I
13 DID WANT TO REMIND YOU OF THE LANGUAGE IN
14 PROPOSITION 14 WHICH INCLUDES ESTABLISHING
15 GEOGRAPHICALLY DIVERSE CENTERS OF EXCELLENCE TO
16 CONDUCT CLINICAL TRIALS AND/OR TO SEEK TO MAKE THE
17 RESULTING TREATMENTS AND CURES BROADLY AVAILABLE TO
18 CALIFORNIA PATIENTS. SO THAT'S THE MANDATE
19 VIS-A-VIS THE PROPOSITION.

20 ONE OF THE SORT OF COMMON QUESTIONS WE HAD
21 ALONG THE PROCESS: WHAT DO THESE CENTERS LOOK LIKE?
22 THESE CENTERS OFTEN, WHEN YOU SAY COMMUNITY CARE
23 CENTERS, I THINK ONE ENVISIONS BUILDINGS. THEY'RE
24 REALLY PEOPLE. THIS IS FROM OUR ALPHA CLINICS
25 MEETING. AND REALLY WHAT WE ARE SUPPORTING ARE

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1 TEAMS TO GO OUT AND SUPPORT THE CLINICAL RESEARCH
2 AND SUBSEQUENT TREATMENT OF PATIENTS.

3 AND SO WHAT DO THESE TEAMS LOOK LIKE?
4 THIS IS SORT OF A TYPICAL TEAM AT A CENTER THAT
5 WOULD BE TREATING PATIENTS. AS WE ARE AWARE, CELL
6 AND GENE THERAPY CLINICAL RESEARCH HAS A RANGE OF
7 VERY SPECIALIZED NEEDS, STARTING WITH WORKING
8 DIRECTLY WITH A SPONSOR, EDUCATING AND NAVIGATING
9 THE PATIENTS, CONSIDERING ISSUES RELATED TO COVERAGE
10 ANALYSIS AND THE FINANCING OF THE TRIAL, THE
11 MANAGEMENT OF PRODUCTS, WHICH COULD BE QUITE UNIQUE
12 AND INCLUDE MANUFACTURING, AND THEN, OF COURSE, THE
13 DATA MANAGEMENT.

14 SO IF ONE WERE TO LOOK AT WHAT THESE TEAMS
15 LOOK LIKE, THERE ARE INDIVIDUALS THAT MANAGE PATIENT
16 REGISTRIES SO WE CAN IDENTIFY PATIENTS AND DEVELOP
17 THOSE COHORTS. THE RESEARCH NURSES ARE SPECIALIZED
18 AND HAVE A SPECIALIZED SET OF SKILLS BECAUSE THIS
19 INVOLVES NOT JUST BEDSIDE MANNER, BUT DATA
20 COLLECTION. THE LABORATORY AND PHARMACY PIECE MAY
21 INCLUDE, AGAIN, POTENTIALLY THE MANUFACTURING OF
22 PRODUCTS, BUT THE HANDLING MAY BE QUITE SPECIALIZED.
23 PATIENT NAVIGATORS WHO CAN EXPLAIN AND HELP CONSENT
24 THOSE PATIENTS, AND THEN THE RESEARCH COORDINATORS
25 AND THE CLINICIANS. SO THIS IS SORT OF THE PROFILE

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1 OF AN ALPHA CLINIC TEAM. AND IMAGINE THAT FOR SOME
2 OF THESE CENTERS SUCH TEAMS WOULD BE SUBSTANTIALLY
3 SIMILAR.

4 MOVING TO SORT OF HOW WE ENVISION THIS
5 FITTING THE BROAD SET OF CIRM INFRASTRUCTURE, IN
6 THIS GRAPHIC WE REALLY WANT TO SORT OF CREATE THE
7 IDEA THAT WE'VE GOT THE PATIENTS IN THE MIDDLE OF A
8 WRAPAROUND SUPPORT NETWORK THAT, AGAIN, INCLUDES THE
9 ALPHA CLINICS NETWORK, WHICH AT THIS TIME INCLUDES
10 TEN MEDICAL CENTERS, NINE AWARDS, THE VAST MAJORITY
11 OF CIRM-FUNDED CLINICAL TRIALS, WHICH IS 96 THAT ARE
12 SUPPORTED WITHIN THAT NETWORK. SO THESE ARE THE
13 ACTIVE AND ONGOING ELEMENTS OF OUR CLINICAL TRIALS
14 PROGRAMS THAT ARE RIPE FOR FURTHER EXPANSION AND
15 PARTNERSHIP.

16 THE FIRST STAGE OF THAT EXPANSION WILL BE
17 EARLY NEXT YEAR AS WE ANTICIPATE THE ROLLOUT OF THE
18 PATIENT SUPPORT PROGRAM. AS A REMINDER, THAT
19 PROGRAM AIMS TO COMPLEMENT THE CHARGE OF PROPOSITION
20 14 ON THE ACCESS SIDE, SPECIFICALLY TO IMPROVE OR TO
21 ADDRESS FINANCIAL AND LOGISTICAL BARRIERS RELATED TO
22 PARTICIPATION IN TRIALS. SO HELPING PATIENTS
23 IDENTIFY TRIALS, GETTING THEM CONNECTED TO CLINICAL
24 SITES, AND, FOR CERTAIN PATIENTS THAT WOULD BE
25 ELIGIBLE, SUPPORT THE COSTS THEY MIGHT INCUR,

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1 PARTICULARLY OUT-OF-POCKET COSTS, TO PARTICIPATE IN
2 THOSE TRIALS.

3 AND THE FINAL PIECE ARE THE COMMUNITY CARE
4 CENTERS. AND WHAT YOU HAVE BEFORE YOU TODAY IS THE
5 DRAFT CONCEPT PLAN FOR THAT PROGRAM.

6 MAYBE TO SORT OF BRING THIS INTO A FLOW
7 DIAGRAM. AND, AGAIN, THIS IS AS WE WENT THOROUGH
8 THE NEEDS ASSESSMENT AND HAD DISCUSSIONS OUT IN THE
9 COMMUNITY, WE HAD ENVISIONED AND THE PLAN IS
10 DESIGNED TO ACCOMMODATE THIS. THE CONCEPT PLAN IS
11 THAT THERE BE A CAPACITY TO PERFORM
12 COMMUNITY-CENTERED ENGAGEMENTS. SO THE PATIENT
13 WOULD BE ABLE TO INTERACT WITHIN THEIR COMMUNITY TO
14 UNDERSTAND OR LEARN ABOUT THESE TRIALS AND
15 POTENTIALLY GET CONNECTED TO A COMMUNITY CARE
16 CENTER, WHICH WOULD THEN HAVE THE ABILITY TO
17 NAVIGATE THE PATIENT TO, IN THIS PARTICULAR
18 SCENARIO, TO AN ALPHA CLINIC WHERE PATIENT TREATMENT
19 COULD OCCUR. AND THEN IDEALLY A MAJORITY OF THE
20 FOLLOW-UP AND HOPEFULLY EVEN THE PRETREATMENT
21 CLINICAL ACTIVITY COULD OCCUR IN A COMMUNITY SETTING
22 IF THE PATIENT LIVED DISTANT FROM AN ALPHA CLINIC.
23 AND, AGAIN, THE PATIENT SUPPORT PROGRAM REALLY
24 ESTABLISHES AN OVERLAY THERE TO PROVIDE ADDITIONAL
25 SUPPORT TO THE PATIENT.

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1 I THINK WE JUST -- EARLIER ON I THINK THE
2 DISCUSSION OF PATIENT-REPORTED OUTCOMES WAS REALLY
3 EXCITING. I THINK IN TERMS OF THAT WAS A TOPIC
4 WITHIN THE NEEDS ASSESSMENT FROM THE ACCESS AND
5 AFFORDABILITY WORKING GROUP, THE IDEA THAT WE DO
6 NEED ROBUST PATIENT-REPORTED OUTCOMES, NOT JUST IN
7 TERMS OF CLINICAL EFFICACY, BUT THOSE OUTCOMES CAN
8 ALSO DRIVE THE ABILITY TO REIMBURSE THESE PRODUCTS
9 BECAUSE ON THE REIMBURSEMENT SIDE THAT EVIDENCE IS
10 ALSO CRITICAL. WE COULD REALLY SEE THE COMMUNITY
11 CARE CENTERS PERFORMING A VERY UNIQUE ROLE IN
12 DEVELOPING ROBUST DATA IN THAT CONTEXT. SO JUST TO
13 CONNECT IT UP TO PRIOR DISCUSSIONS.

14 SO LET ME NOW JUMP INTO A COUPLE OF THE
15 KEY ASPECTS OF THE CONCEPT PLAN ITSELF. THIS IS NOW
16 SORT OF ELIGIBILITY. I WANT TO SORT OF FOCUS ON
17 SORT OF A THREE-PART TEST IN TERMS OF THE APPLICANT
18 BEING ELIGIBLE, A THREE-PART TEST ON THE CLINICAL
19 SIDE. PART 1 WOULD BE A CAPACITY TO SUPPORT HUMAN
20 SUBJECTS PROTOCOLS IN A HEALTH RESEARCH CONTEXT.
21 JUST TO BE CLEAR, HUMAN SUBJECTS EQUALS IRB
22 OVERSIGHT. IT'S THAT FUNDAMENTAL REGULATORY PART
23 THAT CIRM EXPECTS TO EXIST IN ANY RESEARCH WE ARE
24 CONDUCTING THAT INVOLVES INTERACTIONS WITH PEOPLE.

25 IN ADDITION, THE CENTER WOULD HAVE TO HAVE

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1 THE CAPACITY, BE IN THE PROCESS OF DEVELOPING
2 CAPACITY TO SUPPORT CLINICAL RESEARCH PROTOCOLS
3 INVOLVING CELL, GENE, OR REGENERATIVE MEDICINE
4 TREATMENTS. AND FINALLY, WE WANTED TO HAVE SOME
5 PROTECTIONS IN THERE. WE DO NOT WANT TO BE FUNDING
6 SITES THAT WOULD BE ADMINISTERING UNAUTHORIZED STEM
7 CELL TREATMENTS. AND I'LL TOUCH ON IN A LATER SLIDE
8 SORT OF MORE SPECIFICALLY HOW WE'VE TRIED TO ADDRESS
9 THAT.

10 THIS PROGRAM, YOU ALSO HAVE TO HAVE THE
11 CAPACITY TO SUPPORT CAREER DEVELOPMENT ACTIVITIES.
12 THAT'S EDUCATION, TRAINING OF PHYSICIANS, NURSES,
13 RESEARCH COORDINATORS, COMMUNITY HEALTH WORKERS, OR
14 OTHER HEALTH PROFESSIONALS. ACTUALLY WE ARE
15 FOCUSING ON CAREER DEVELOPMENT AS WE VIEW THESE
16 SITES AS EXCELLENT LOCATIONS FOR PLACING CIRM
17 TRAINEES THAT HAVE ALREADY PARTICIPATED IN CIRM
18 PROGRAMS OR ARE PARTICIPATING IN CIRM PROGRAMS.
19 AND, AGAIN, I'LL TOUCH ON THAT ON THE FOLLOWING
20 SLIDE.

21 AND IN THIS CASE WE ARE ALSO LOOKING FOR A
22 THIRD PART, THAT THEY'VE GOT A TRACK RECORD OF
23 CONDUCTING OR COORDINATING WITH COMMUNITY-BASED
24 ORGANIZATIONS TO CONDUCT HEALTH EDUCATION ACTIVITIES
25 IN THE COMMUNITY. AND, AGAIN, THIS IS SOMETHING

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1 THAT, BASED ON THE NEEDS ASSESSMENT AND INTERACTIONS
2 WE HAVE HAD WITH CENTERS THAT PARTICIPATED IN THE
3 NEEDS ASSESSMENT, THESE ARE FAIRLY COMMON
4 ACTIVITIES. AND THE AIM OF THIS PROGRAM WOULD BE TO
5 FURTHER RESOURCE THOSE ACTIVITIES TOWARDS THE AIMS
6 OF THE CIRM MISSION.

7 SO I'M GOING TO NOW SORT OF DESCRIBE HOW
8 WE THEN SUPPORT THOSE ACTIVITIES. SO SORT OF BREAK
9 THEM OUT. THERE'S A LITTLE BIT OF NUANCE HERE.
10 FIRST OF ALL, IN TERMS OF CLINICAL OPERATIONS, WHAT
11 WE LEARNED IS THERE ARE A NUMBER OF SITES WITHIN
12 CALIFORNIA THAT ARE CLEARLY CAPABLE OF SUPPORTING
13 REGENERATIVE MEDICINE CLINICAL TRIALS. AND BY
14 SUPPORTING, THEY ARE ENGAGING PATIENTS, THEY ARE
15 EDUCATING PATIENTS, AND THEY ARE BOTH DOING
16 PRESCREENING AND FOLLOWING UP WITH PATIENTS IN
17 CLINICAL TRIALS. BUT THE ACTUAL INVESTIGATIONAL
18 PRODUCT, THAT INTERVENTION IS OCCURRING AT A PARTNER
19 SITE. AND SO THAT'S A MODEL THAT ALREADY EXISTS,
20 AND THERE ARE A NUMBER OF SITES THAT WE INTERACTED
21 WITH THAT APPEAR VERY INTERESTED IN DEVELOPING THAT
22 MODEL OF SUPPORT, BUT DON'T VIEW THEMSELVES AS
23 NECESSARILY AIMING TO MANAGE THE ACTUAL
24 INVESTIGATIONAL PRODUCT.

25 THE OTHER SIDE OF THAT COIN IS THERE ARE

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1 SITES OUT THERE THAT ARE REALLY ON THE CUSP OF BEING
2 ABLE TO DELIVER THESE PRODUCTS. AND SO WHAT WE'VE
3 TRIED TO DO ON THE PROPOSAL ON THE CLINICAL SIDE IS
4 TO HAVE TWO FUNDING OPPORTUNITIES, ONE FOR A SUPPORT
5 SITE AND ONE FOR A SUPPORT AND DELIVERY SITE. THE
6 IDEA ON THE DELIVERY SITE IS THAT OVER THE AWARD
7 PERIOD, THEY WOULD THEN DEVELOP THE CAPACITY TO
8 MANAGE THOSE INVESTIGATIONAL PRODUCTS.

9 IN TERMS OF CAREER DEVELOPMENT, AGAIN, THE
10 AIM HERE IS TO ADAPT, APPLY, OR OTHERWISE UTILIZE
11 CIRM EDUCATION AND TRAINING RESOURCES. THEY WOULD
12 SERVE AS A PLACEMENT SITE FOR SCHOLARS AND TRAINEES,
13 AND THEY WOULD REALLY INTEGRATE REGENERATIVE
14 MEDICINE INTO OTHER NAVIGATION AND COMMUNITY HEALTH
15 WORKER CERTIFICATION PROGRAMS. THESE ARE IMPORTANT
16 PROGRAMS BECAUSE THEY'RE ELIGIBLE FOR -- IT ALLOWS
17 US TO TAP INTO AN EXISTING WORKFORCE THAT ALREADY
18 HAS A ROBUST TOUCHPOINT WITH PATIENTS. AND THESE
19 ACTIVITIES ARE ALSO REIMBURSED THROUGH VARIOUS
20 HEALTH FINANCING MECHANISMS. SO WE VIEW IT AS AN
21 EXCELLENT OPPORTUNITY TO UTILIZE IN THIS PROGRAM.

22 ONE OF THE THINGS TO POINT OUT, BECAUSE
23 THIS WILL BE A BOARD MEETING, BECAUSE ONE OF THE
24 QUESTIONS THAT CAME UP IS IT SEEMS CHALLENGING. HOW
25 DO WE CONNECT CIRM APPLICANTS TO A LOT OF THESE CIRM

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1 EDUCATION PROGRAMS? AND AT THE BOARD MEETING,
2 THERE'S GOING TO BE A PRESENTATION FROM THE
3 DISCOVERY TEAM IN TERMS OF A VERY ROBUST SYSTEM
4 THEY'RE DEVELOPING AROUND EDUCATION PORTALS AND A
5 WHOLE SYSTEM TO CONSOLIDATE AND CONNECT PEOPLE WITH
6 OUR EDUCATION PROGRAMS. SO THIS PIECE IS INTENDED
7 TO REALLY DOVETAIL WITH THAT WORK. AND, AGAIN,
8 YOU'LL HEAR MORE ABOUT IT IN THE DECEMBER BOARD
9 MEETING.

10 AND FINALLY, THERE WILL BE SPECIFIED
11 BUDGET ITEMS FOR A BUDGET COMMITMENT FOR OUTREACH
12 AND ENGAGEMENT AND PARTNERSHIPS WITH COMMUNITY-BASED
13 ORGANIZATIONS. THAT'S WHAT WE ARE PROPOSING THERE.

14 GOING TO JUST DO A QUICK COMPARE AND
15 CONTRAST BECAUSE, AGAIN, THESE ARE QUESTIONS WE GOT
16 FROM SOME OF THE OTHER WORKING GROUPS. COMPARING,
17 ON THE CLINICAL SIDE, THE ELIGIBILITY FOR AN ALPHA
18 CLINIC WAS THAT THEY ALREADY HAVE DEMONSTRATED
19 CAPACITY TO HANDLE CLIN2 PROGRAMS AND MANAGE AND
20 DELIVER AND TREAT PATIENTS WITH INVESTIGATIONAL
21 PRODUCTS.

22 FOR A COMMUNITY CARE CENTER, AT A MINIMUM
23 THEY NEED TO BE ABLE TO SUPPORT THOSE TRIALS. AND,
24 AGAIN, CERTAIN CENTERS ARE IN THE PROCESS OR WOULD
25 LIKE TO BE IN THE PROCESS OF DEVELOPING THE CAPACITY

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1 TO CONDUCT THOSE TRIALS AS WELL. SO WE HAVE AN
2 OPPORTUNITY FOR BOTH THOSE CONTINGENCIES.

3 ALPHA CLINICS HAVE REALLY CREATED A NUMBER
4 OF VERY EFFECTIVE TRAINING PROGRAMS, EVERYTHING FROM
5 CLINICAL FELLOWS TO RESEARCH COORDINATORS, NURSE
6 TRAINING. IN THE CONTEXT OF THE COMMUNITY CARE
7 CENTERS, WE REALLY AIM TO APPLY THOSE PROGRAMS AND
8 ALSO SERVE AS A PLACEMENT SITE FOR THOSE TRAINEES.

9 AND THEN, AGAIN, THE ALPHA CLINICS DO HAVE
10 STRONG ENGAGEMENT AND NAVIGATION CAPACITIES. THEIR
11 CTSA'S ARE OFTEN BEING LEVERAGED TO MEET WITH
12 PATIENTS. IN TERMS OF THE COMMUNITY CARE CENTERS,
13 WE WOULD OBVIOUSLY WANT TO REPLICATE THOSE
14 ACTIVITIES, BUT ALSO ALLOW THEM TO MOVE DOWN THROUGH
15 MORE COMMUNITY-BASED ORGANIZATIONS, FAITH-BASED
16 ORGANIZATIONS, A SET OF ORGANIZATIONS THAT HAVE A
17 RICHER OR DEEPER TOUCHPOINT WITH THE COMMUNITY.

18 AND REALLY THAT COMES DOWN TO THE
19 RATIONALE. THERE IS ONE OF THE MOST -- THE TERM WE
20 HEARD MOST FREQUENTLY IN TERMS OF A NEEDS ASSESSMENT
21 WAS TRUST. AND THAT IN ORDER TO DEVELOP THOSE SORT
22 OF TRUST-BUILDING SCENARIOS, THERE NEEDS TO BE A
23 BROADER REACH THAN WE CURRENTLY HAVE WITH OUR
24 EXISTING CLINICAL TRIAL AWARDS.

25 A COUPLE OF CONSIDERATIONS, AND I FLAG

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1 THESE BECAUSE, AGAIN, THEY WERE EITHER RAISED BY
2 OTHER WORKING GROUPS, AND THEY COME UP AS QUESTIONS
3 ALREADY. SO WANT TO SORT OF COVER THEM FOR YOUR
4 BENEFIT. IN TERMS OF ETHICS POLICY, AGAIN, HOW DO
5 WE KNOW WE GET THE ETHICS RIGHT IS REALLY THE
6 QUESTION HERE. AND, AGAIN, WE ARE STARTING WITH THE
7 CONTEXT THAT APPLICANTS MUST HAVE EXPERIENCE
8 IMPLEMENTING HUMAN SUBJECTS PROTOCOLS, THAT THEY'RE
9 FORMALLY IN THE -- THE FORMAL HUMAN SUBJECT
10 PROTECTION PROGRAM IS IN PLACE OR THAT THEY'VE HAD
11 EXPERIENCE IMPLEMENTING SUCH PROGRAMS, WHICH WOULD
12 INCLUDE INSTITUTIONAL REVIEW BOARDS.

13 UNAUTHORIZED STEM CELL TREATMENTS, WE HAVE
14 THE BENEFIT OF CALIFORNIA LAW THAT REQUIRES
15 NOTIFICATION OF ANYONE RECEIVING A TREATMENT FROM A
16 PROVIDER. IF THAT TREATMENT IS DESCRIBED AS A STEM
17 CELL THERAPY AND HAS NOT BEEN AUTHORIZED BY THE FOOD
18 AND DRUG ADMINISTRATION, THEN A NOTIFICATION MUST BE
19 PROVIDED. IF THE SITE IS PROVIDING TREATMENTS THAT
20 REQUIRE THAT NOTIFICATION, THEY WOULD NOT BE
21 ELIGIBLE TO APPLY FOR THIS PROGRAM.

22 AND THEN FINALLY, IN TERMS OF RESEARCH
23 ETHICS TRAINING, WE HAVE HAD A LOT OF DISCUSSION
24 WITH GROUPS THAT HAVE DEVELOPED COMMUNITY ENGAGEMENT
25 PROGRAMS IN SUPPORT OF, SAY, RARE DISEASE AND

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1 CLINICAL TRIALS. AND WHAT WE'VE LEARNED IS THERE IS
2 A NUMBER OF ETHICS TRAINING PROGRAMS THAT HAVE BEEN
3 ADAPTED TO TRAIN THOSE INDIVIDUALS PERFORMING THAT
4 TYPE OF ENGAGEMENT ON THE RESEARCH ETHICS FRAMEWORK
5 AND GET THEM ACTUALLY CERTIFIED, HAVE THEM GET
6 CERTIFICATIONS THAT WOULD BE EQUIVALENT TO, SAY,
7 SOMEONE DOING PATIENT RECRUITMENT OR PATIENT
8 ENROLLMENT IN A CLINICAL TRIAL. SO WE PROVIDE THE
9 SUPPORT WITHIN THIS PROGRAM TO HAVE THOSE PEOPLE
10 TRAINED UP SO EVERYONE IS OPERATING AT A BASE LEVEL
11 IN TERMS OF RESEARCH ETHICS.

12 SO SOME ADDITIONAL PROGRAM CONSIDERATIONS.
13 I ALLUDED TO THIS EARLIER. JUST TO BE A BIT MORE
14 SPECIFIC, WE TRIED TO IDENTIFY WAYS WE CAN BUILD
15 SUSTAINABILITY INTO THESE PROGRAMS. AND, AGAIN, I
16 MENTIONED COMMUNITY HEALTH WORKER CERTIFICATION
17 PROGRAMS. AND NOW THERE ARE PATIENT NAVIGATION
18 CERTIFICATION PROGRAMS. THOSE CERTIFICATIONS ARE
19 VERY IMPORTANT BECAUSE THERE ARE NOW MECHANISMS,
20 EITHER STATE OR NATIONAL PROGRAMS, THAT ALLOW FOR
21 THE REIMBURSEMENT OF THOSE SERVICES. SO WE VIEW
22 THIS PROGRAM AS AN OPPORTUNITY TO CREATE A
23 REGENERATIVE MEDICINE MODULE THAT COULD THEN BE
24 APPLIED IN THESE CERTIFICATION PROGRAMS AND GO ON TO
25 SUPPORT THE ONGOING -- THIS WORK ON AN ONGOING BASIS

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1 INDEPENDENT OF CIRM FUNDING AND SIMPLY BECOME
2 REIMBURSABLE.

3 I NOTED, AGAIN, THAT THIS IS COORDINATION
4 WITH CIRM EDUCATION PROGRAMS. I WON'T SAY A LOT
5 HERE, BUT AS I INDICATED, THERE WILL BE SUBSTANTIAL
6 BACKGROUND AT THE DECEMBER MEETING.

7 AND I THINK STILL ANOTHER CHALLENGE, AND
8 THIS CAME FROM THE ACCESS AND AFFORDABILITY WORKING
9 GROUP. I THINK THE QUOTE IS FOR MANY OF OUR TRIALS,
10 WE ARE STILL LOOKING FOR A NEEDLE IN A HAYSTACK IN
11 TERMS OF SOME OF THESE MORE RARE DISEASE
12 INDICATIONS. SO WE HAVE BEGUN TO INTERACT WITH
13 GROUPS THAT HAVE SUCCESSFULLY WORKED WITH RARE
14 DISEASES COHORTS AND DISEASE ADVOCACY GROUPS. AND
15 THE PLAN WOULD BE MOVING FORWARD, ONCE WE ISSUE THE
16 APPLICATION, TO HOLD A SERIES OF WEBINARS TO CONNECT
17 APPLICANTS TO THESE GROUPS TO CONSIDER WAYS THEY CAN
18 PARTNER AND COLLABORATE TO REACH THE PATIENT
19 POPULATIONS OF INTEREST.

20 SO FINALLY, I WILL GET TO THE NUMBERS. WE
21 ARE REQUESTING A BUDGET ALLOCATION OF 60.2 MILLION.
22 AND THE BUDGET IS DESIGNED TO SUPPORT, AGAIN, THE
23 CORE OPERATIONS, WHICH I DESCRIBED PREVIOUSLY. THAT
24 COULD BE A SUPPORT OR SUPPORT AND DELIVERY SITE.
25 COMMUNITY PARTNERSHIPS ARE CALLED OUT SEPARATELY.

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1 IT'S A SEPARATE BUDGET LINE ITEM. AND, AGAIN, THAT
2 WAS REINFORCED BY THE ACCESS AND AFFORDABILITY
3 WORKING GROUP, THAT WE REALLY WANT TO GUARANTEE
4 THOSE FUNDS ARE THERE AND THAT THEY DON'T GET LOST
5 OVER THE AWARD PERIOD AND DON'T FLOW INTO THE
6 COMMUNITY. SO WE REALLY SEPARATE THAT OUT AS A
7 SEPARATE LINE ITEM.

8 AND ONE THING I HAVEN'T MENTIONED, AGAIN,
9 THIS IS VIS-A-VIS PROPOSITION 14, THERE ARE FUNDS
10 AVAILABLE FOR BUILDING RENOVATION, EQUIPMENT, AND
11 FACILITIES. SO THERE WOULD BE A FACILITIES
12 COMPONENT PROPOSED FOR THIS PROGRAM.

13 AS WE MODELED IT OUT, BASED ON THE 60.2
14 MILLION, WE CAN ENVISION THAT COULD DISTRIBUTE WHERE
15 WE'D HAVE THREE SUPPORT AND DELIVERY AWARDS ON THE
16 ORDER OF ABOUT 10 MILLION PER AWARD AND 4 SUPPORT
17 SITES AWARDS ON THE ORDER OF ABOUT 7.5 MILLION PER
18 AWARD.

19 SO WITH THAT, I WILL -- I'VE STILL GOT A
20 BIT OF TIME. SO I'LL SEE IF THERE'S ANY QUESTIONS.
21 OBVIOUSLY, WE ARE REQUESTING RECOMMENDATION FROM YOU
22 ALL TO APPROVE THE CONCEPT PLAN FOR ICOC
23 CONSIDERATION. THANK YOU FOR YOUR TIME AND
24 CONSIDERATION.

25 CHAIRMAN GOLDSTEIN: THANKS, GEOFF. THAT

1 WAS REALLY TERRIFIC. GOOD JOB.

2 QUESTIONS? PAT.

3 DR. LEVITT: SO THAT'S REALLY A TON TO
4 UNPACK. AND I DON'T -- FROM MY PERSPECTIVE, I'M
5 REALLY KIND OF QUEASY ABOUT DOING THIS IN FIVE
6 MINUTES. ONE OF THE THINGS I'M REALLY CONCERNED
7 ABOUT IS THE ENTRY POINT BECAUSE ALL THIS IS SO
8 CRITICALLY IMPORTANT. I DON'T REALLY HAVE THE DATA
9 ABOUT THE COMMUNITY CARE CENTERS, LIKE WHAT IS
10 THE -- WHAT ARE THE NUMBERS ABOUT THOSE THAT SEEM TO
11 BE ABLE TO ACTUALLY CARRY OUT HUMAN SUBJECTS
12 STUDIES. BECAUSE IT'S ONE THING TO PROVIDE
13 HEALTHCARE. IT'S ANOTHER TO ACTUALLY RUN A CLINICAL
14 TRIAL. SO THAT'S ONE ISSUE.

15 THE SECOND IS THAT COMMUNITY ENGAGEMENT,
16 FROM MY PERSPECTIVE, REALLY HAS TO BE CRYSTALLIZED
17 AND REALLY WELL ARTICULATED IN TERMS OF WHAT CIRM
18 EXPECTS TO SEE BECAUSE SEVERAL OF US HAVE BEEN
19 ENGAGED AND ACTIVE IN OUR OWN CTSI'S. AND THOSE
20 NUMBERS SOMETIMES ARE JUST HOLLOW, THAT THEY'RE NOT
21 MEANINGFUL, REALLY MEANINGFUL COMMUNITY ENGAGEMENTS
22 WHERE THERE'S ACTUAL ACTIVITY THAT OCCURS THAT
23 DEMONSTRATES THE TRANSLATION OF ENGAGEMENT TO
24 PARTICIPATION. AND THAT'S GOING TO DEFINE --
25 WHATEVER THE ENGAGEMENT MECHANISM IS, IT'S GOING TO

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1 DEFINE THE SUCCESS OF THIS PROGRAM.

2 SO THE CONCEPT, I THINK, IS GREAT, BUT I
3 THINK THERE'S SOME REALLY IMPORTANT COMPONENTS THAT
4 CIRM HAS TO ARTICULATE SO THAT THE AWARDS THAT WILL
5 BE GIVEN OUT ARE GOING TO BE GIVEN TO ORGANIZATIONS
6 THAT UNDERSTAND WHAT THEIR RESPONSIBILITIES ARE IN
7 DEMONSTRATING SUCCESS. SO I'LL STOP THERE BECAUSE
8 THERE'S A WHOPPING THREE MINUTES LEFT TO DISCUSS.

9 DR. LOMAX: MAYBE BRIEFLY, WHEN YOU SAY
10 COMMUNITY CARE CENTER, I THINK WHAT COMES INTO --
11 WHAT ONE IMAGINES IS, I THINK AS YOU ALLUDED TO, IN
12 FACT THE CENTERS THAT REALLY ENGAGE IN THIS PROCESS,
13 I THINK, ARE MORE ON THE ORDER OF REGIONAL
14 HOSPITALS, BUT THEY'RE WELL AWAY FROM THE ALPHA
15 CLINICS. SO, FOR EXAMPLE, WITHOUT NAMING IT, ONE OF
16 THE CENTERS IS IN THE SORT OF -- MUCH FURTHER EAST
17 OF THE COAST. AND THEY'RE WORKING WITH CANCER
18 PATIENTS TO ENROLL THEM IN ALPHA CLINIC CLINICAL
19 TRIALS ALREADY. IT'S THAT LEVEL OF CAPACITY THAT I
20 THINK, WHEN ONE LOOKS AT WHAT'S IT GOING TO TAKE TO
21 APPLY FOR THIS PROGRAM, THOSE ARE THE SORT OF TYPES
22 OF APPLICANTS. NOW, WE INCENTIVIZE, THEN,
23 PARTNERSHIPS WITH MAYBE MORE COMMUNITY-BASED
24 PROVIDERS. BUT AT A BASELINE, THAT'S THE SCALE OF
25 CAPACITY THAT AN APPLICANT WOULD NEED TO BRING TO

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1 THIS PROGRAM.

2 DR. LEVITT: SO THE REFERRAL FROM
3 COMMUNITY-BASED PROVIDERS IS REALLY IMPORTANT. I
4 THINK THAT'S IMPORTANT. THAT'S HOW THEY GET
5 REFERRED TO A REGIONAL CENTER. AND WE KNOW -- I'M
6 NOT AN EXPERT IN THIS, BUT I READ THE JOURNALS,
7 PUBLICATION AFTER PUBLICATION, DATA AFTER DATA,
8 ABOUT THE CHALLENGES, PARTICULARLY FOR
9 UNDERREPRESENTED GROUPS, OF EVEN BEING CONSIDERED TO
10 GET A REFERRAL, THAT THERE'S MAJOR PROBLEMS THAT WE
11 HAVE GOING FROM COMMUNITY TO THESE REGIONAL CENTERS,
12 WHICH IS WHY I SAY IT'S NOT IMPOSSIBLE TO DO. I
13 JUST THINK THERE HAS TO BE SOME LEVEL OF
14 UNDERSTANDING THAT THESE MAJOR PROBLEMS EXIST. AND
15 IF WE ARE TALKING ABOUT ACCESS AND AFFORDABILITY, WE
16 HAVE TO -- THAT THOSE WHO ARE GOING TO APPLY FOR
17 THIS NEED TO HAVE A REAL PLAN THAT'S GOING TO CHANGE
18 THE DYNAMIC.

19 DR. MELMED: LARRY, SORRY. I HAVE TO GET
20 OFF. I HOPE THE QUORUM IS STILL INTACT.

21 MR. TOCHER: IT IS. WE ARE JUST AT QUORUM
22 WITH YOUR ABSENCE.

23 DR. LEVITT: I HAVE A MEETING AT NOON AS
24 WELL TO MY EXECUTIVE LEADERSHIP GROUP HERE IN THE
25 HOSPITAL. BUT I THINK THIS IS, TO ME, THE MOST

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1 COMPLICATED COMPONENT THAT WAS PRESENTED TODAY. AND
2 I LOVE THE CONCEPT, BUT I THINK -- I HAVE TO HAVE
3 SOME MORE TIME TO UNDERSTAND THE DETAILS OF HOW THIS
4 IS GOING TO BE DONE.

5 CHAIRMAN GOLDSTEIN: SO, PAT AND GEOFF, IN
6 VIEW OF THE TIME, CAN I MAKE THE FOLLOWING
7 SUGGESTION, WHICH IS I THINK WE SHOULD GO AHEAD AND
8 SEND THIS TO THE ICOC BECAUSE THERE'S ADDITIONAL
9 EXPERTISE AT THE ICOC LEVEL ON SOME OF THESE ISSUES.
10 AND COULD I ASK PAT AND GEOFF TO WORK TOGETHER PRIOR
11 TO THAT MEETING TO TRY TO ADDRESS SOME OF PAT'S
12 ISSUES EXPLICITLY? WOULD THAT BE --

13 VICE CHAIR BONNEVILLE: LARRY, IT'S
14 SCHEDULED RIGHT NOW TO GO TO THE DECEMBER 14
15 MEETING. SO IT WOULD HAVE TO GO TO THE JANUARY
16 MEETING INSTEAD, ALLOWING FOR MORE TIME TO WORK
17 THESE THINGS OUT. SO I LEAVE IT TO SCOTT TOCHER,
18 GEOFF, AND PAT TO SORT OF DETERMINE THAT.

19 DR. LEVITT: I AGREE. I'M HAPPY TO SEE IT
20 GO TO THE ICOC, BUT IS IT GOING TO GO WITH APPROVAL
21 OF THE SCIENCE SUBCOMMITTEE? OR IS IT JUST GOING TO
22 GO THERE? I MEAN I DON'T KNOW THE APPROPRIATE
23 PROTOCOL. BUT RIGHT NOW I COULDN'T VOTE YES ON IT.
24 I WOULD ABSTAIN.

25 DR. LOMAX: CAN I JUST ADD THAT IN TERMS

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1 OF THE TIMELINE CHECK, UP UNTIL NOW WE ARE ON OUR
2 TIMELINE, AND WE BUILT SOME SLACK INTO THAT
3 TIMELINE. AND SO I THINK, TO THE EXTENT THIS
4 COMMITTEE ISN'T FULLY SATISFIED AND THERE'S
5 MODIFICATIONS THAT WOULD BE MADE, I WOULD PREFER TO
6 SEND THAT TO THE BOARD WITH THAT ENDORSEMENT RATHER
7 THAN NOT HAVING IT. SO A DELAY OF ONE MONTH IS
8 COMPLETELY -- WE CAN ACCOMMODATE THAT BECAUSE,
9 AGAIN, WE ARE ON TRACK WITH THIS PROJECT.

10 VICE CHAIR BONNEVILLE: I AGREE WITH
11 GEOFF. I THINK THIS SHOULD HOLD UNTIL THE JANUARY
12 MEETING AND PERHAPS GET THE SCIENCE SUBCOMMITTEE
13 BACK IN JANUARY TO DISCUSS THE SUBJECT WITH MORE
14 INFORMATION THAT PAT'S REQUESTED.

15 CHAIRMAN GOLDSTEIN: PAT, ARE YOU
16 COMFORTABLE WITH THAT?

17 DR. LEVITT: YEAH. I'M FINE WITH THAT.
18 SORRY TO THROW A WRENCH IN THIS, BUT I JUST THINK
19 THIS IS ONE OF THE MOST IMPORTANT THINGS THAT WE ARE
20 DOING. AND WE SPENT A TON OF TIME WITH STAFF GOING
21 OUT TO VARIOUS LOCATIONS IN THE STATE. AND I THINK
22 WE SHOULD HONOR ALL THE TIME THAT WAS PUT IN TO MAKE
23 SURE WE GET THIS RIGHT.

24 VICE CHAIR BONNEVILLE: I AGREE.

25 DR. LEVITT: OKAY.

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1 CHAIRMAN GOLDSTEIN: SO WE'LL DEFER TO
2 JANUARY. AND IN THE MEANTIME, PAT, GET TOGETHER
3 WITH GEOFF AND WORK SOME OF THIS OUT PLEASE.

4 DR. LEVITT: ABSOLUTELY. I'VE GOT LOTS OF
5 FREE TIME.

6 CHAIRMAN GOLDSTEIN: I KNOW. CLAUDETTE
7 AND LANA, SORRY, BUT YOU'RE GOING TO HAVE TO
8 SCHEDULE ANOTHER SCIENCE SUBCOMMITTEE MEETING TO
9 DEAL WITH THESE ISSUES.

10 MARIA, YOUR HAND IS -- THAT'S YOUR TREE,
11 NOT YOUR HAND. LET'S SEE. SCOTT, ANYTHING ELSE WE
12 NEED TO DO IN ORDER TO ADJOURN?

13 MR. TOCHER: ABSOLUTELY NOT. YOU'VE HAD A
14 FULL DAY, SO YOU CAN JUST CLOSE THE MEETING AND
15 THANK EVERYONE.

16 CHAIRMAN GOLDSTEIN: OKAY. SEE YOU AGAIN
17 SOON, EVERYBODY.

18 (THE MEETING WAS THEN CONCLUDED AT 12:03 P.M.)

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REPORTER'S CERTIFICATE

I, BETH C. DRAIN, A CERTIFIED SHORTHAND REPORTER IN AND FOR THE STATE OF CALIFORNIA, HEREBY CERTIFY THAT THE FOREGOING TRANSCRIPT OF THE VIRTUAL PROCEEDINGS BEFORE THE SCIENCE SUBCOMMITTEE OF THE INDEPENDENT CITIZEN'S OVERSIGHT COMMITTEE OF THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE IN THE MATTER OF ITS REGULAR MEETING HELD ON NOVEMBER 30, 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.

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