

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: MAY 21, 2024
3 P.M.

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

FILE NO.: 2024-24

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MAY 21, 2024; 3 P.M.

CHAIRMAN FISCHER-COLBRIE: DO THE CALL TO
ORDER AND GET STARTED AND DO THE ROLL CALL.

MS. MANDAC: MARIA BONNEVILLE.

VICE CHAIR BONNEVILLE: PRESENT.

MS. MANDAC: MONICA CARSON.

DR. CARSON: HERE.

MA. MANDAC: MARK FISCHER-COLBRIE.

CHAIRMAN FISCHER-COLBRIE: HERE.

MS. MANDAC: ELENA FLOWERS.

DR. FLOWERS: PRESENT.

MS. MANDAC: JUDY GASSON.

DR. GASSON: HERE.

MS. MANDAC: LARRY GOLDSTEIN. DAVID
HIGGINS. VITO IMBASCIANI.

CHAIRMAN IMBASCIANI: YEAH.

MS. MANDAC: PAT LEVITT. SHLOMO MELMED.

DR. MELMED: HERE.

MS. MANDAC: CHRISTINE MIASKOWSKI. KAROL
WATSON. KEITH YAMAMOTO.

BACK TO YOU, MARK.

CHAIRMAN FISCHER-COLBRIE: GREAT. AND IF
YOU CAN LET ME KNOW, DO WE CURRENTLY HAVE A QUORUM?
OR I THINK WE'RE ANTICIPATING MORE TO COME IN, BUT

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1 HOW IS OUR STATUS CURRENTLY?

2 MS. MANDAC: WE ARE TWO SHORT OF QUORUM.
3 WE'RE EXPECTING A COUPLE MORE TO JOIN A LITTLE
4 LATER.

5 CHAIRMAN FISCHER-COLBRIE: OKAY. WELL, IN
6 THIS CONTEXT THEN, BECAUSE I THINK THERE IS A TON OF
7 MATERIAL THAT WE NEED TO GET THROUGH, I'D LIKE TO GO
8 AHEAD AND GET STARTED. FROM THAT PERSPECTIVE, THE
9 FIRST ITEM ON THE AGENDA IS CONSIDERATION OF THE
10 CIRM INTERM RESEARCH BUDGET FOR THE FISCAL YEAR 2024
11 AND 2025. AND WITH THAT, I'LL TURN IT OVER TO THE
12 CIRM TEAM TO LAUNCH THAT AGENDA ITEM.

13 MS. LEWIS: THIS IS JENNIFER LEWIS. I'M
14 THE VICE PRESIDENT OF OPERATIONS AT CIRM, AND IT'S
15 MY PLEASURE TODAY TO SHARE WITH THE SUBCOMMITTEE THE
16 FISCAL YEAR 24/25 RESEARCH BUDGET.

17 SO AS YOU ALL KNOW, WE START ALL OUR
18 PRESENTATIONS WITH OUR MISSION STATEMENT:

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TO ACCELERATE WORLD-CLASS SCIENCE TO DELIVER
TRANSFORMATIVE REGENERATIVE MEDICINE TREATMENTS IN
AN EQUITABLE MANNER TO A DIVERSE CALIFORNIA AND
WORLD.

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1 SO BEFORE I KICK OFF WITH THE AGENDA FOR
2 TODAY, I WANTED TO SHARE TWO INFORMATIONAL SLIDES
3 WITH THE SUBCOMMITTEE. THIS GIVES YOU CONTEXT OF
4 OUR GRANT FUNDS AS A WHOLE AS WELL AS IT RELATES TO
5 PROP 14. THIS SLIDE DISPLAYS GRANT FUNDS AVAILABLE
6 FOR BOTH PROP 71 AND 14. AND THE TOTAL IS \$7.64
7 BILLION IN GRANTS FUNDS AS OF APRIL 30, 2024. THE
8 BREAKDOWN OF THIS, AS OF APRIL 2024, OF WHAT HAS
9 BEEN ENCUMBERED AND UNENCUMBERED IS SHOWN HERE. SO
10 TO DATE 3.8 BILLION HAS BEEN ENCUMBERED, WHICH MEANS
11 THESE ARE ACTUAL FUNDS THAT HAVE BEEN PAID OUT BY
12 CIRM OR HAVE BEEN COMMITTED IN THE FORM OF A GRANT
13 CONTRACT THAT HAS BEEN APPROVED BY THIS BOARD. THE
14 UNENCUMBERED GRANT FUNDS TOTALS 3.86. AND I WOULD
15 NOTE, AS MANY OF THIS COMMITTEE KNOWS AS YOU'VE HAD
16 DISCUSSIONS ABOUT THE STRATEGIC ALLOCATION
17 FRAMEWORK, THIS NUMBER VARIES SLIGHTLY TO WHAT HAS
18 BEEN PRESENTED OVER THE PAST FEW MONTHS FOR TWO
19 REASONS AS THE NUMBER THAT MY COLLEAGUE DR.
20 CANET-AVILES HAS BEEN SHARING WAS A PROJECTION WHILE
21 THIS IS ACTUAL NUMBERS. SO THIS IS THE TOTAL AS OF
22 TODAY OF UNENCUMBERED, 3.86. SO WE'RE ROUGHLY
23 HALFWAY THROUGH THE RESEARCH FUNDS.

24 THIS NEXT SLIDE IS ANOTHER VISUAL THAT IS
25 FOCUSING ON PROP 14 FUNDS. SO THESE ARE RESEARCH

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1 FUNDS ALLOCATIONS DETERMINED BY THE PROPOSITION.
2 THIS FIRST COLUMN IS FOR RESEARCH, THERAPY
3 DEVELOPMENT, AND THERAPY DELIVERY. THIS IS WHAT'S
4 SPECIFIED IN THE PROPOSITION OF \$3.4 BILLION. AND
5 AS YOU CAN SEE, AS OF TODAY WE HAVE \$764 MILLION
6 COMMITTED. AND THIS ARROW ON THE SIDE, WHAT THAT'S
7 SHOWING IS JUST THE PROPOSITION DOES CALL OUT TWO
8 AREAS THAT ARE EARMARKED AS UP TO AMOUNTS FOR
9 BUILDING AND EQUIPPING SHARED RESOURCE LABS, WHICH
10 TOTALS 26 MILLION AND THEN BUILD, EQIP, AND
11 OPERATING COMMUNITY CARE CENTERS OF EXCELLENCE,
12 WHICH TOTALS 78 MILLION.

13 THE MIDDLE COLUMN IS SHOWING DISEASES OF
14 THE BRAIN AND CENTRAL NERVOUS SYSTEM. PROP 14 CALLS
15 OUT 1.38 BILLION TOWARDS THIS TYPE OF PROGRAM AND
16 GRANTS. 243 MILLION HAS BEEN COMMITTED TO DATE.

17 AND THE LAST BUCKET IS ACCESS AND
18 AFFORDABILITY, WHICH 96 MILLION IS ALLOCATED IN THE
19 PROP 14 OF WHICH ABOUT 2.4 BILLION HAS BEEN APPROVED
20 BY THE BOARD TO DATE.

21 SO IN THE NEXT FEW SLIDES, WHAT I'LL BE
22 GOING OVER TODAY IS THE FISCAL YEAR 23/24 APPROVED
23 RESEARCH BUDGET RESULTS AND THEN GO INTO THE FISCAL
24 YEAR 24/25 PROPOSED INTERIM RESEARCH BUDGET, THE
25 MAJOR DRIVERS, AND ANY CONSIDERATIONS.

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1 SO LET ME WALK YOU THROUGH THE APPROVED
2 RESEARCH BUDGET AND THE ACTUAL RESULTS. AS YOU CAN
3 SEE HERE, THE FIRST COLUMN DISPLAYS THE FISCAL YEAR
4 23/24 APPROVED RESEARCH BUDGET, WHICH TOTALS \$519
5 MILLION. THE SECOND COLUMN IS DISPLAYING THE
6 COMMITMENTS TO DATE WHICH TOTAL \$297 MILLION.

7 SINCE THIS PRESENTATION WAS PREPARED AS OF
8 APRIL 2024, WE HAVE MANY STILL PENDING REVIEWS AND
9 ACTIVITIES FOR THE NEXT TWO MONTHS. SO THE THIRD
10 COLUMN IS DISPLAYING ANY PENDING COMMITMENTS THAT
11 ARE COMING TO AN ARS MEETING THIS MONTH OR BY JUNE.
12 THIS INCLUDES FOR CLINICAL 11.9 MILLION THAT WILL BE
13 COMING NEXT WEEK TO THE MAY APPLICATION REVIEW
14 SUBCOMMITTEE MEETING, 441 MILLION FOR THE
15 TRANSLATIONAL PROGRAM THAT WILL ALSO BE COMING TO
16 THE MAY APPLICATION REVIEW SUBCOMMITTEE MEETING.

17 NO PENDING DISCOVERY APPLICATIONS.
18 250,000 IN EDUCATION CONFERENCE GRANTS THAT ARE
19 PENDING APPROVAL BY THE END OF THE FISCAL YEAR. AND
20 THEN NO PENDING INFRASTRUCTURE APPROVALS BY THE END
21 OF THE FISCAL YEAR.

22 SO THIS IS A TOTAL OF 53 MILLION IN
23 PENDING ACTIVITIES THAT WILL BE PRESENTED FOR
24 APPROVAL BEFORE THE END OF THE FISCAL YEAR.

25 SO THE FOURTH COLUMN IS WHAT WE CALL

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1 ESTIMATED TO FINISH, MEANING THAT IT TOTALS THE
2 PREVIOUS TWO COLUMNS. AND THAT TOTAL IS 351 MILLION
3 IS WHERE WE EXPECT TO LAND AT THE END OF THE FISCAL
4 YEAR.

5 THE ONE CAVEAT I WILL SAY IS THAT FOR
6 CLINICAL, WE STILL HAVE ONE PENDING GWG THAT IS
7 OCCURRING THIS WEEK WHERE WE ANTICIPATE THAT THE
8 APPLICATIONS THAT HAVE BEEN SUBMITTED COULD LIKELY
9 DEplete THE REMAINING FUNDS IN THE CLINICAL BUDGET.

10 SO THE LAST COLUMN IS WHAT WE LIKE TO SHOW
11 IS THE VARIANCE. THIS IS THE VARIANCE BETWEEN THE
12 23/24 APPROVED BUDGET AND THE ESTIMATED TO FINISH.
13 AND I'D LIKE TO GO LINE BY LINE ON THIS BECAUSE
14 THERE'S SOME EXPLANATIONS THAT I THINK WILL BE
15 USEFUL FOR THE SUBCOMMITTEE AS WELL AS IT RELATES TO
16 THE 24/25 BUDGET.

17 SO THE FIRST IS THERE'S 41 MILLION
18 REMAINING IN THE CLINICAL VARIANCE BETWEEN THE
19 APPROVED BUDGET AND ESTIMATED TO FINISH. THIS MAY
20 BE DEPLETED FURTHER AS THERE IS ONE PENDING GWG AND
21 APPLICATION REVIEW SUBCOMMITTEE THAT WOULD COME IN
22 JUNE WITH THE TOTALS STILL UNKNOWN.

23 THE NEXT IS 1 MILLION REMAINING VARIANCE
24 BETWEEN THE TRANSLATION APPROVED BUDGET AND
25 ESTIMATED TO FINISH. 93 MILLION VARIANCE BETWEEN

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1 THE APPROVED BUDGET AND ESTIMATED TO FINISH FOR
2 DISCOVERY. AND THE REASON FOR THIS LARGE VARIANCE
3 IS DUE TO TWO PROGRAMS. THE QUEST DISC2 PROGRAM AND
4 THE REMIND-L PROGRAMS WERE POSTPONED DURING THE
5 FISCAL YEAR DUE TO VARIOUS OPERATIONAL REASONS,
6 EXTENDING AN APPLICATION DATE OR JUST ADJUSTING THE
7 REVIEW SCHEDULE BASED ON SOME OF THE FLOW CONTROL
8 CONSIDERATIONS OF THE ORGANIZATION. THEREFORE, THE
9 ACTUAL, ALTHOUGH WE'RE ACCEPTING APPLICATIONS OR
10 THEY'RE PENDING REVIEW, THE ACTUAL APPROVAL FOR
11 THOSE TWO PROGRAMS WILL NOT OCCUR UNTIL 24/25.
12 THEREFORE, WE HAVE A LARGER VARIANCE IN THAT PROGRAM
13 AND PILLAR.

14 FOR EDUCATION THERE IS A VARIANCE OF
15 \$914,000. AND THEN FOR INFRASTRUCTURE THERE'S \$30
16 MILLION VARIANCE FROM THE APPROVED BUDGET TO
17 ESTIMATED TO FINISH. THIS IS ALSO DUE TO AN
18 OPERATIONAL CHANGE WHICH, NOT CHANGE, BUT THE SHARED
19 RESEARCH LAB PROGRAM. AS YOU MAY RECALL, THAT
20 PROGRAM HAD APPLICATIONS COME TO THE BOARD IN MARCH
21 FOR APPROVAL. AND IN THAT APPROVAL, THE TIER I
22 APPLICATIONS, THERE WERE SEVERAL TIER II
23 APPLICATIONS THAT WERE RECOMMENDED TO GO BACK TO THE
24 RESPECTIVE GWG OR FACILITIES WORKING GROUP TO BE
25 RE-REVIEWED AND CONSIDERED. AND SO THOSE

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1 APPLICATIONS ARE BEING RE-REVIEWED, BUT THE ACTUAL
2 APPROVALS FOR THOSE TIER II APPLICATIONS WILL NOT
3 OCCUR UNTIL THE 24/25 FISCAL YEAR. SO THE TOTAL
4 VARIANCE AT THE END OF 23/24 THAT WE'RE ANTICIPATING
5 IS 168 MILLION.

6 THIS NEXT SLIDE WAS AT THE REQUEST OF DR.
7 GOLDSTEIN AS WE REVIEWED THE BUDGETS. IT'S SHOWING
8 THE HISTORICAL RESEARCH BUDGET PERFORMANCE. AND HE
9 FELT IT WAS IMPORTANT AND THE CIRM TEAM AGREED TO
10 SHOW, NOW THAT WE'RE SEVERAL YEARS INTO PROP 14 AND
11 WE'RE REACHING OUR OPERATIONAL HEIGHT OF DEMAND AND
12 REVIEWS, TO ALSO SHOW OUR PERFORMANCE OF WHAT THE
13 ICOC APPROVED AS OUR TOTAL BUDGET EACH YEAR AND WHAT
14 WAS ACTUALLY COMMITTED AND UNCOMMITTED AT THE END OF
15 EACH YEAR.

16 AND SO ALL THIS GRAPH IS SHOWING IS THE
17 FOUR YEARS THAT WE HAVE HAD IN PROP 14. YOU WILL
18 NOTICE THE FIRST YEAR IS SIX MONTHS WHICH WAS DUE TO
19 A RAMP-UP OF THE ORGANIZATION, BUT YOU WILL SEE THAT
20 THE FIRST COLUMN, THE FIRST NUMBER IN THAT COLUMN,
21 352 MILLION IS SHOWING THE TOTAL APPROVED BUDGET
22 COMMITTED, THEN THE COMMITTED FUNDS AND UNCOMMITTED
23 UNDERNEATH THAT. AND THAT'S INFORMATIONAL PURPOSES
24 FOR THIS COMMITTEE AS WE CONSIDER FUTURE RESEARCH
25 BUDGET APPROVALS AND FORECASTING.

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1 SO BEFORE I GO FURTHER, I'LL PAUSE IF
2 THERE'S ANY QUESTIONS ON THE HISTORICAL. IF NOT,
3 I'LL KEEP GOING TO THE 24/25 BUDGET. OKAY.

4 SO NOW I'LL DIG INTO THE 24/25 INTERIM
5 BUDGET. AND AS MENTIONED, THIS IS A SIX-MONTH
6 INTERIM BUDGET THAT SUPPORTS APPLICATION REVIEW
7 SUBCOMMITTEE APPROVALS FROM JULY THROUGH DECEMBER OF
8 2024. AND THE RATIONALE BEHIND THIS WAS THAT THE
9 CIRM TEAM, AS WE'RE GOING UNDER STRATEGIC ALLOCATION
10 EVALUATION AND COMING TO THE BOARD IN SEPTEMBER WITH
11 RECOMMENDATIONS, THEN FOLLOWING THAT THIS TEAM WOULD
12 COME IN DECEMBER WITH ANY REVISIONS THAT NEEDED TO
13 BE MADE TO THE RESEARCH BUDGET FOR THE NEXT SIX
14 MONTHS.

15 SO THIS BUDGET THAT I'LL PRESENT TO YOU
16 SHORTLY IS ONLY SUPPORTING ACTIVITIES OVER THE NEXT
17 SIX MONTHS, WHICH INCLUDE MONTHLY CLINICAL
18 APPROVALS, SUCH AS THE TIER II RESUBMISSIONS THAT
19 WE'VE BEEN TAKING IN OVER THE PAST SEVERAL MONTHS,
20 AS WELL AS ALIGNS WITH MY COLLEAGUE DR. SAMBRANO'S
21 REVIEW PROCESS CHANGES THAT HE'LL BE PRESENTING
22 SHORTLY FOR THE CLINICAL PROGRAM AND REOPENING THAT
23 PROGRAM.

24 IT ALSO INCLUDES APPROVALS FOR A
25 TRANSLATION ROUND, A QUEST ROUND, THE REMIND-L ROUND

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1 THAT I MENTIONED, COMMUNITY CARE CENTERS, AND TIER
2 II APPLICATION REVIEWS FOR SHARED RESOURCE LABS.

3 SO TO GIVE YOU A LITTLE BIT MORE DETAIL
4 INTO HOW WE DETERMINE THE ALLOCATIONS FOR EACH OF
5 THE PROGRAMMATIC BUDGETS, THE CLINICAL BUDGET WE ARE
6 REQUESTING 145.5 MILLION. THIS IS BASED ON THE
7 NUMBER OF AWARDS DETERMINED BY THE GOALS OF THE
8 THERAPEUTIC DEVELOPMENT TEAM FOR FISCAL YEAR 2024,
9 AND WE'RE TAKING THAT IN ACCOUNT FOR THE SIX-MONTH
10 PERIOD. WHEN WE CALCULATED THIS NUMBER, WE DID THIS
11 BY THE MAXIMUM TOTAL AWARD AMOUNT FOR THE VARIOUS
12 PROGRAMS IN CLIN1 AND CLIN2 AND THE NEW CLIN4
13 OPPORTUNITY.

14 FOR THE TRANSLATIONAL BUDGET, WE ARE
15 REQUESTING \$60 MILLION. THIS IS BASED ON THE
16 AVERAGE NUMBER OF AWARDS IN FISCAL YEAR 23/24 AS
17 WELL AS THE AVERAGE AWARD AMOUNT DURING THE PAST
18 FISCAL YEAR.

19 FOR THE DISCOVERY BUDGET, WE'RE REQUESTING
20 \$116.2 MILLION. THIS IS THE REQUEST FOR THE TWO
21 PROGRAMS THAT I MENTIONED PREVIOUSLY, THE QUEST
22 PROGRAM FOR 28 MILLION AND REMIND-L OF 88.2 MILLION,
23 FOR THE TWO PROGRAMS THAT WE HAVE OPENED UP
24 APPLICATIONS FOR AND ARE IN VARIOUS STAGES OF THE
25 PROCESS, BUT WILL NOT HAVE APPROVALS UNTIL THE 24/25

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1 FISCAL YEAR.

2 FOR EDUCATION WE ARE NOT REQUESTING A
3 BUDGET FOR THE SIX-MONTH PERIOD. THE RATIONALE FOR
4 THIS IS THERE ARE TWO MECHANISMS FOR EDUCATION
5 CONFERENCE GRANT PROGRAMS. SO EDUC1 IS OUR
6 CONFERENCE GRANT PROGRAM. ONE MECHANISM IS WHAT WE
7 CALL UNSOLICITED PROPOSALS WHERE WE OFFER ABOUT
8 \$50,000 PER AWARD TO VARIOUS CONFERENCES THAT ARE
9 RELATED TO THE REGENERATIVE MEDICINE AREA.

10 DUE TO THE STRATEGIC ALLOCATION FRAMEWORK,
11 THE CIRM TEAM IS RECOMMENDING THAT WE DO NOT OFFER
12 THIS PROGRAM FOR THESE SIX MONTHS AS WE REALLY WANT
13 TO, ONCE WE HAVE THOSE RECOMMENDATIONS, ALIGN THAT
14 PROGRAM ANNOUNCEMENT TO REALLY CALL FOR THOSE THINGS
15 THAT ALIGN WITH OUR STRATEGY AND THE GOALS THAT THIS
16 SUBCOMMITTEE AND THE BOARD APPROVE.

17 ADDITIONALLY, WE HAVE ANOTHER MECHANISM
18 THAT'S MORE OF A CIRM-DRIVEN SPECIFIC, SUCH AS
19 EDUCATION CONFERENCE AND THINGS OF THAT NATURE. AND
20 WE DON'T ANTICIPATE ANY RFA'S DURING THAT PERIOD.
21 SO, AGAIN, SUPPORTING THE NOT REQUESTING FOR ANY
22 BUDGET FOR THAT CATEGORY FOR THIS SIX-MONTH PERIOD.

23 AND THEN LASTLY, THERE'S AN INFRASTRUCTURE
24 BUDGET. WE ARE REQUESTING 88.8 MILLION. THIS IS
25 FOR THE SHARED RESEARCH LAB TIER II APPLICATIONS

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1 THAT I MENTIONED, THE 28.6 MILLION. AND THEN IN
2 ADDITION, WE ARE ACCEPTING APPLICATIONS RIGHT NOW
3 FOR THE COMMUNITY CARE CENTERS OF EXCELLENCE
4 PROGRAM, WHICH IS A TOTAL OF \$60 MILLION.

5 SO WHAT THIS SLIDE IS SHOWING IS A SIDE BY
6 SIDE OF THE FISCAL YEAR 23/24 APPROVED BUDGET AND
7 THE ESTIMATED TO FINISH AND THEN THE PROPOSED FISCAL
8 YEAR 24/25 BUDGET FROM JULY THROUGH DECEMBER, WHICH
9 TOTALS \$410.5 MILLION.

10 THE LAST COLUMN, THE FOURTH COLUMN IS
11 SHOWING WHAT ESSENTIALLY IS A REALLOCATION FROM
12 FISCAL YEAR 23/24. THESE ARE THE THREE PROGRAMS I
13 IDENTIFIED, WHICH WERE TWO IN DISCOVERY AND AS WELL
14 AS ONE IN THE INFRASTRUCTURE SHARED LABS THAT, DUE
15 TO SCHEDULES AND JUST OPERATIONS, WE WON'T HAVE
16 ACTUAL APPROVALS UNTIL 24/25.

17 AND THEN LASTLY, SO THE REQUEST TODAY FOR
18 THIS SUBCOMMITTEE IS TO RECOMMEND APPROVAL OF THE
19 FISCAL YEAR 24/25 RESEARCH BUDGET TO THE ICOC. AND
20 I CAN ENTERTAIN ANY QUESTIONS. AND I'LL HAND IT
21 OVER TO YOU, CHAIR.

22 CHAIRMAN FISCHER-COLBRIE: SO GREAT
23 DISCUSSION. ARE THERE QUESTIONS ABOUT WHAT'S
24 ANTICIPATED HERE WITH RESPECT TO THE SIX MONTHS
25 SEQUENCING AND WITH RESPECT TO ANY QUESTIONS OF THE

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1 PRESENTATION? ANY OTHER COMMENTS FROM CIRM STAFF
2 RELATED TO WHAT'S UNDER REVIEW HERE? OKAY. HEARING
3 NONE, NOW I THINK WE NEED TO PROCEED TO A VOTE, IF
4 I'M NOT MISTAKEN; AND IF THAT'S THE CASE, DO WE
5 CURRENTLY HAVE A QUORUM?

6 MR. TOCHER: MARK, WE'RE JUST ONE SHY OF A
7 QUORUM. FORTUNATELY, WE HAVE AN OPTION AVAILABLE
8 WHICH IS WE CAN PASS ALONG TO THE BOARD IN JUNE WHAT
9 A SENSE OF THE SUBCOMMITTEE MEMBERS ARE THAT ARE
10 HERE.

11 CHAIRMAN FISCHER-COLBRIE: OKAY.

12 MR. TOCHER: WHAT WE WOULD NORMALLY DO AT
13 THIS POINT IS YOU MIGHT ASK IF THERE'S ANY OBJECTION
14 TO FORWARDING THIS PROPOSED BUDGET TO THE BOARD.
15 AND WE'LL LISTEN TO SEE IF THERE ARE ANY QUESTIONS
16 OR CONCERNS THAT MEMBERS HAVE.

17 CHAIRMAN FISCHER-COLBRIE: THANK YOU FOR
18 THAT CLARIFICATION, SCOTT. WITH THAT IN MIND, ARE
19 THERE ANY OBJECTIONS OR CONSIDERATIONS RELATED TO
20 GIVING A SENSE OF THE BOARD OF WHAT THE SCIENCE
21 SUBCOMMITTEE WOULD LIKE TO DO WITH RESPECT TO THE
22 DISCUSSION OF THE SIX-MONTH BUDGET? I'M NOT SEEING
23 ANY FLAGS OR HANDS UP.

24 SCOTT, IF WE NEED TO DO ANY PUBLIC COMMENT
25 AT THIS POINT OR NOT?

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1 MR. TOCHER: IT'S FINE TO INVITE PUBLIC
2 COMMENT TO THIS AGENDA ITEM SINCE WE'LL BE CLOSING
3 OUT THIS AGENDA ITEM AND GETTING READY TO MOVE ON TO
4 THE NEXT. SO IT IS APPROPRIATE TO INVITE PUBLIC
5 COMMENT, IF ANY.

6 CHAIRMAN FISCHER-COLBRIE: GREAT. THEN
7 WITH THAT IN MIND, ARE THERE ANY QUESTIONS OR
8 COMMENTS FROM THE PUBLIC?

9 MS. MANDAC: THERE ARE NO HANDS RAISED.

10 CHAIRMAN FISCHER-COLBRIE: OKAY. WELL, I
11 GUESS IN SUMMARY, THEN, WITHOUT REQUIRING A FORMAL
12 VOTE, THE SENSE OF THE SCIENCE COMMITTEE IS TO GO
13 FORTH WITH THE RECOMMENDATIONS FROM THE CIRM TEAM
14 RELATED TO THE INTERIM RESEARCH BUDGET AND PRESENT
15 THAT TO THE BOARD. SO THANK YOU. GREAT.

16 I THINK THAT CLOSES OUT THAT AGENDA ITEM.
17 WE CAN MOVE ON TO THE NEXT AGENDA ITEM, WHICH DR.
18 SAMBRANO WILL BE PRESENTING FOR OUR REVIEW AND
19 CONSIDERATION. AND I'LL TURN IT OVER TO GIL.

20 DR. SAMBRANO: OKAY. THANK YOU VERY MUCH,
21 MARK. LET ME JUST SHARE THE SLIDES.

22 SO THANK YOU ALL FOR COMING TO THIS
23 MEETING AND FOR YOUR ATTENTION TODAY. I WANT TO
24 PRESENT TO YOU WHERE WE ARE IN THE FLOW CONTROL
25 DEVELOPMENT PROCESS AND WHAT IDEAS WE HAVE THAT WE

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1 WANT TO BRING TO THE BOARD ULTIMATELY IN JUNE.

2 I WANT TO START OFF WITH JUST A TIMELINE
3 THAT YOU HAVE SEEN AT OTHER SCIENCE SUBCOMMITTEE
4 MEETINGS THAT ROSA HAS PRESENTED WHICH ARE RELATED
5 TO THE STRATEGIC ALLOCATION FRAMEWORK. BUT WITHIN
6 IT, THERE IS THE FLOW CONTROL, WHICH WE ARE DOING
7 CONCURRENTLY. AND JUST SO THAT YOU GET A SENSE OF
8 THE TIMING OF WHAT WE'RE PROPOSING TO DO AND
9 ASSUMING THAT EVERYTHING MOVES AS WE EXPECT, THE
10 HOPE IS TO PRESENT OUR EVALUATION AND ASSESSMENT OF
11 WHERE WE ARE IN THE FLOW CONTROL ALONG WITH A
12 PROPOSAL THAT I'M SHARING WITH YOU NOW AND
13 POTENTIALLY RESUME CLINICAL APPLICATION SUBMISSIONS
14 WITH THE FIRST DEADLINE BEING AT THE END OF JULY.

15 IF WE DO THAT, I EXTEND THE TIMELINE HERE
16 IN THIS NEXT SLIDE INTO THE LATTER PART OF THE YEAR.
17 SO IF THE JULY DEADLINE IS THE FIRST ONE, THEN THE
18 EARLIEST CLINICAL APPLICATION APPROVAL WOULD BEGIN
19 IN NOVEMBER OF THIS YEAR IN ORDER TO ACCOUNT FOR THE
20 REVIEW CYCLE TO COMPLETE. I'LL GO INTO DETAIL OF
21 WHAT WE'RE PROPOSING TO DO. BUT ASSUMING THAT THAT
22 WORKS, THAT'S WHEN THE EARLIEST DATE WOULD COME.

23 AS YOU KNOW, WE ARE ALSO WORKING ON
24 DEVELOPING WHAT MAY BE A NEW SET OF PRIORITIES AND
25 THINKING STRATEGICALLY AS WELL. AND SO

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1 RECOMMENDATIONS IN RELATION TO THE STRATEGIC
2 ALLOCATION FRAMEWORK WILL COME TO THE BOARD IN
3 SEPTEMBER. SO FROM THAT MAY EMANATE, WITH THOSE
4 RECOMMENDATIONS, NEW CONCEPTS, NEW IDEAS THAT WOULD
5 LEAD TO NEW OPPORTUNITIES, INCLUDING CHANGING THE
6 CLINICAL PROGRAM. WHATEVER THOSE CHANGES MAY BE
7 WOULD BEGIN IN JANUARY OF NEXT YEAR, THE NEXT
8 CALENDAR YEAR 2025. AND SO THE EARLIEST APPROVAL OF
9 ANY CLIN APPLICATIONS THAT ARE RESPONDING TO THOSE
10 NEW OPPORTUNITIES WOULD HAPPEN IN MAY OF NEXT YEAR.
11 SO WE'RE LOOKING AT A YEAR AHEAD. AND THAT'S JUST
12 SOMETHING TO KEEP IN THE BACK OF YOUR MIND IN TERMS
13 OF THE TIMING OF WHAT WE'RE TALKING ABOUT NOW.

14 THE OTHER THING I WANTED TO STRESS IS THAT
15 THESE TWO EFFORTS, THE CLINICAL FLOW CONTROL PROCESS
16 THAT I'M GOING TO FOCUS IN ON TODAY AND THE
17 STRATEGIC ALLOCATION FRAMEWORK, ARE TWO PARALLEL
18 EFFORTS. WE ARE COORDINATING TO KEEP THEM ALIGNED,
19 BUT THEY ARE AND HAVE SEPARATE GOALS. THE FOCUS OF
20 THE STRATEGIC ALLOCATION FRAMEWORK IS STRATEGIC
21 WHILE THE CLINICAL FLOW CONTROL PROCESS IS REALLY
22 FOCUSED ON RESPONDING TO THE INCREASING NUMBERS OF
23 APPLICATIONS THAT WE HAVE OBSERVED IN THE CLINICAL
24 PROGRAM. AND IT'S NOT MEANT TO ADDRESS ANY FUNDING
25 STRATEGIES. IT IS ALSO INTENDED TO ADDRESS THE

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1 CHALLENGES BASED ON WHAT THE EXISTING CLINICAL
2 PROGRAM ELIGIBILITY AND STRUCTURE IS. MEANING WE'RE
3 NOT NECESSARILY WORKING WITH SOMETHING THAT WE DON'T
4 KNOW WHAT THE PRIORITIES WILL BE, SAY, COME
5 SEPTEMBER.

6 HOWEVER, WE DO WANT TO KEEP AN EYE TOWARDS
7 WHAT WE'RE WORKING ON. AND SO THEREFORE WHATEVER WE
8 COME UP WITH IN TERMS OF A NEW PROCESS, WE WANT IT
9 TO BE ADAPTABLE AND WE WANT IT TO BE APPLICABLE EVEN
10 BEYOND WHAT WE PRESENT AS FAR AS STRATEGIC
11 ALLOCATION FRAMEWORK AFTER SEPTEMBER BECAUSE WE
12 DON'T WANT TO HAVE TO STOP AGAIN IN ORDER TO REBUILD
13 SOMETHING ELSE AND CREATE MORE DELAYS. SO THE IDEA
14 IS THAT IT WOULD BE FLEXIBLE.

15 THE OTHER THING I WANT TO HIGHLIGHT, AND
16 THIS IS NOW GETTING INTO THE CREATION OF THE PROCESS
17 ITSELF, IS A LITTLE BIT OF THE HISTORICAL BACKGROUND
18 ON HOW THE CURRENT CLINICAL PROCESS CAME TO BE AND
19 THE CONTEXT UNDER WHICH IT WAS CREATED.

20 SO THIS WAS IN 2014 WHEN WE LAUNCHED CIRM
21 2.0. IT IS WHEN WE LAUNCHED THE CLINICAL, TRAN, AND
22 DISCOVERY PROGRAMS AS THE PILLARS THAT WE WOULD BE
23 SPECIFICALLY FUNDING ON A CONTINUOUS BASIS. BEFORE
24 2014 WE HAD SUPPORTED UP TO, I THINK, 16 CLINICAL
25 TRIALS THAT WE HAD AT THE TIME. AND THOSE CAME

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1 ABOUT THROUGH AD HOC REVIEWS THAT WERE SET UP. THEY
2 WERE NOT VERY PREDICTABLE. THEY WERE KIND OF AS
3 BEST WE COULD, MAYBE ONCE A YEAR. AND AT THE TIME
4 THE FIELD OF REGENERATIVE MEDICINE HAD NOT YET
5 ADVANCED MANY CANDIDATES TO THE CLINICAL TRIAL
6 STAGE.

7 SO THE PHILOSOPHY BEHIND OUR PROGRAM WAS
8 REALLY TO FUND ANY MERITORIOUS PROJECT THAT
9 ULTIMATELY REACHED THIS STAGE BECAUSE IF WE HAD A
10 CELL THERAPY THAT HAD REACHED THAT STAGE, WHY
11 WOULDN'T WE FUND IT? AND AS SUCH, WHEN WE
12 CONSIDERED THE PROJECTS, WE WERE ASSESSING THEM
13 INDEPENDENTLY OF EACH OTHER BECAUSE EACH CYCLE WAS
14 LOOKING AT ONE OR TWO PROPOSALS. SO IN THE CASE
15 WHERE YOU HAVE JUST ONE PROPOSAL, THERE WAS NOTHING
16 TO COMPARE IT TO. AND SO RANKING PROPOSALS DIDN'T
17 MAKE SENSE. AND SO THAT'S WHERE WE STARTED, AND WE
18 STARTED EVOLVING AND CREATING THE PROCESS AROUND
19 THAT. AND OVER TIME IT BECAME A PRETTY ROBUST
20 PROCESS THAT I WILL GIVE YOU A LITTLE MORE DETAIL
21 ON.

22 I WANTED TO SHOW YOU A COUPLE OF ELEMENTS
23 THAT I THINK ARE IMPORTANT TO KNOW ABOUT THE
24 EXISTING PROCESS. IT HAS BEEN ALIGNED OVER THE
25 YEARS WITH THE TARGET NUMBER OF AWARDS THAT WE HAVE

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1 FOR CLIN2. THOSE ARE THE CLINICAL TRIAL LEVEL
2 AWARDS AND THE CLIN1S WHICH ARE THE IND ENABLING.
3 GIVEN THE SUCCESS RATE THAT WE HAVE OBSERVED OVER
4 THE YEARS, THE NUMBER OF APPLICATIONS THAT WE NEED
5 TO REVIEW IS SHOWN IN THAT FOURTH COLUMN. FOR
6 CLIN2, 28 TO 32 APPLICATIONS IN ORDER TO GET YOU 16
7 AWARDS IN A GIVEN YEAR. WE HOLD ELEVEN CYCLES PER
8 YEAR. AND SO WHAT YOU NEED IS ABOUT THREE
9 APPLICATIONS TO COME IN FOR EACH CYCLE IN ORDER TO
10 ACHIEVE THAT GOAL FOR CLIN1. IT'S SIMILAR WITH
11 ABOUT TWO NEW APPLICATIONS COMING IN EACH CYCLE.

12 AND SO IT'S CLEAR FROM THAT THAT AT LEAST
13 WHAT WE'RE TARGETING AND THE GENERAL NUMBER OF
14 AWARDS THAT WE EXPECT TO GIVE OUT ALIGNS WELL WITH
15 THE PROCESS.

16 BUT AS WE HAVE SEEN MORE RECENTLY, THE
17 PROCESS FAILS WHEN YOU GET MANY MORE APPLICATIONS
18 BECAUSE WE CAN'T SUPPORT. IT DOESN'T SCALE UP
19 HIGHER THAN HAVING FIVE OR SO NEW APPLICATIONS PER
20 CYCLE. BUT THE EXISTING PROCESS IS QUITE A RIGOROUS
21 ONE. SOME FOLKS HAVE POINTED OUT THE HIGH SUCCESS
22 RATE. BUT I WANT TO EXPLAIN THAT HIGH SUCCESS RATE
23 AS BEING ONE THAT IS THE RESULT OF SEVERAL ELEMENTS.
24 MOST APPLICANTS GO THROUGH ONE APPLICATION REVISION
25 AND SOMETIMES MORE BEFORE THEY GET A RECOMMENDATION

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1 TO FUND. MEANING THAT THE GRANTS WORKING GROUP
2 LOOKS AT THEIR APPLICATION A LOT OF TIMES TWO OR
3 MORE TIMES. WITH FEW APPLICATIONS PER CYCLE, WE
4 HAVE THE FULL PARTICIPATION OF THE GRANTS WORKING
5 GROUP PANEL THAT MEANINGFULLY CONTRIBUTES TO EACH OF
6 THE EVALUATIONS. WE HAVE 15 SCIENTISTS THAT OUR
7 PANELS ARE LIMITED TO. BUT WITH HAVING ONE TO FIVE
8 APPLICATIONS, ALL OF THE PANELISTS CAN LOOK AT ALL
9 THE APPLICATIONS AND CONTRIBUTE TO THE DISCUSSION AS
10 OFTEN HAPPENS.

11 ONCE YOU START HAVING MORE APPLICATIONS
12 THAN THAT, THEN THE REVIEWERS START FOCUSING SIMPLY
13 ON THOSE THAT THEY ARE ASSIGNED TO. MOST OF THE
14 SUCCESSFUL APPLICANTS THAT WE HAVE RECEIVED
15 SIGNIFICANT GUIDANCE FROM OUR THERAPEUTICS
16 DEVELOPMENT TEAM. SO THEY PROVIDE ADVICE ON WHAT
17 MAKES A COMPETITIVE APPLICATION AND WHAT ELEMENTS
18 SHOULD BE INCLUDED WITHIN THEIR APPLICATION FOR THEM
19 TO BE SUCCESSFUL. AND SO CERTAINLY THOSE THINGS
20 CONTRIBUTE TO A HIGH SUCCESS RATE AS WELL AS ALSO
21 THE FACT THAT EACH OF THE PANELS ARE TAILORED TO THE
22 NEEDS OF EACH REVIEW CYCLE. SO DEPENDING ON WHAT
23 GROUP OF APPLICATIONS WE GET IN A GIVEN CYCLE, WE'RE
24 GOING TO TAILOR THE GRANTS WORKING GROUP MEMBERS
25 BASED ON THE EXPERTISE REQUIREMENTS THAT ARE NEEDED

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1 TO COVER THOSE APPLICATIONS.

2 SO THERE'S A LOT OF ELEMENTS FROM THIS
3 PROCESS AS IT HAS BEEN BUILT OUT THAT WE WOULD LIKE
4 TO KEEP IN CONSIDERING HOW WE SCALE IT UP OR HOW WE
5 ACCOUNT FOR NOW AN INCREASED NUMBER OF APPLICATIONS.
6 WE WANT TO CONTINUE TO HAVE THE MAXIMUM CONTRIBUTION
7 FROM THE FULL GRANTS WORKING GROUP PANEL ON EACH
8 APPLICATION TO THE EXTENT POSSIBLE. WE WANT TO
9 CONTINUE TO HAVE A TIER II PROCESS THAT ALLOWS
10 PROJECTS TO IMPROVE BECAUSE THEY DO. THEY RESPOND
11 POSITIVELY TO THE COMMENTS THAT THEY GET FROM THE
12 GRANTS WORKING GROUP, BUT IT ALSO HAS THE EFFECT OF
13 PREVENTING APPEALS, MEANING THE APPLICANTS DON'T
14 FEEL THAT THEY DON'T HAVE THAT OPPORTUNITY TO
15 RESPOND TO COMMENTS. AND ULTIMATELY WHEN AN
16 APPLICANT APPEALS, THEY SIMPLY WANT THE REVIEW PANEL
17 TO LOOK AGAIN. AND THEY TYPICALLY LOOK AT THAT
18 OPPORTUNITY WITH A TIER II SCORE.

19 WE WANT THESE TO CONTINUE TO BE FREQUENT
20 AND PREDICTABLE AND QUICK TO THE EXTENT THAT WE CAN
21 IN ORDER TO ALLOW APPLICATIONS TO COME IN WHEN
22 THEY'RE READY. AND THAT'S IMPORTANT BECAUSE IN THE
23 PAST WE HAD APPLICATIONS THAT WOULD, WHEN WE HAD A
24 REVIEW, SAY, ONCE A YEAR OR ON AN AD HOC BASIS,
25 APPLICATIONS WOULD COME IN THAT DIDN'T REALLY HAVE A

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1 COMPLETE DATASET, REALLY DIDN'T HAVE ALL THE
2 ELEMENTS THAT WOULD BE REQUIRED TO HAVE A
3 COMPETITIVE APPLICATION BECAUSE THEY WERE REALLY TOO
4 EARLY, BUT THEY FELT COMPELLED TO SUBMIT BECAUSE
5 OTHERWISE THEY'D MISS THEIR OPPORTUNITY.

6 SIMILARLY, WE HAD APPLICATIONS WHO WERE
7 SITTING FOR A FEW MONTHS WAITING FOR A DEADLINE TO
8 COME UP BEFORE THEY COULD SUBMIT EVEN THOUGH THEY
9 WERE MORE THAN READY. SO HAVING THAT FREQUENCY AND
10 THE PREDICTABILITY OF IT CERTAINLY HELPS US CAPTURE
11 PROJECTS WHEN THEY ARE READY AND AVOIDS UNNECESSARY
12 DELAYS.

13 WE WANT TO CONTINUE TO OFFER OPPORTUNITIES
14 FOR CLARIFICATION. THERE'S DIFFERENT WAYS IN WHICH
15 WE DO THAT THAT ALLOWS THE REVIEWERS AND THE
16 APPLICANTS TO -- WELL, IT ALLOWS THE REVIEWERS TO
17 BETTER UNDERSTAND WHAT THE APPLICANTS INTEND BY
18 HAVING THEM ASK QUESTIONS OF THE APPLICANTS THROUGH
19 OUR STAFF. I THINK THAT HELPS IN THE OVERALL REVIEW
20 PROCESS. WE WANT TO CONTINUE HAVING THE
21 PARTICIPATION OF THE GRANTS WORKING GROUP PATIENT
22 ADVOCATES PARTICIPATING IN THE EVALUATION OF THE
23 PROJECTS, PARTICULARLY THE DEI ELEMENTS. HAVING
24 THEM BE A PART OF THE GROUP IS SOMETHING THAT WE ALL
25 AGREE IS QUITE ESSENTIAL TO THE REVIEW. THE

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1 SCIENTIFIC MEMBERS VIEW IT AS A VALUABLE
2 CONTRIBUTION TO THE REVIEWS, AND WE FEEL THAT IT
3 PROVIDES OUR PATIENT ADVOCATE BOARD MEMBERS A VERY
4 MEANINGFUL WAY OF PARTICIPATING IN THESE REVIEWS.

5 WE WANT THE ALIGNMENT IN TERMS OF THE
6 TARGETED NUMBER OF PROPOSALS THAT WE WANT TO FUND TO
7 ALIGN WITH THE PROCESS ITSELF. AND WE WANT TO
8 MAINTAIN THE OVERALL RIGOR THAT WE'VE BEEN TRYING TO
9 UPHOLD OVER THE LAST SEVERAL YEARS THAT THIS
10 CLINICAL PROGRAM HAS EXISTED.

11 SO WITH THAT IN MIND, WE LOOKED AT A
12 COUPLE OF OVERALL DIFFERENT APPROACHES. ONE WAS TO
13 CREATE A PRELIMINARY FILTERING OR QUALIFYING PROCESS
14 THAT FEEDS INTO WHAT IS LARGELY THE EXISTING
15 CLINICAL REVIEW PROCESS. SO A WAY OF DETERMINING
16 WHAT ULTIMATELY COMES IN AND HAVING SOME KIND OF
17 SELECTION THAT HAPPENS BEFOREHAND. THE OTHER OPTION
18 WAS TO JUST COMPLETELY RETHINK THIS TO TOSS THAT
19 AWAY AND THINK OF A NEW CLINICAL PROGRAM OR ADOPT
20 WHAT WE DO FOR DISCOVERY AND TRANSLATIONAL
21 APPLICATIONS WHERE WE CERTAINLY RECEIVE A LOT MORE
22 APPLICATIONS.

23 DOING SO, HOWEVER, WOULD RISK HAVING A
24 GREATER NUMBER OF APPLICATIONS THAT NEED TO BE
25 REVIEWED IN A CYCLE, AND THE LEVEL OF RIGOR AND

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1 ATTENTION THAT WE CAN DEDICATE TO THEM WOULD
2 INEVITABLY HAVE TO DECREASE. THE FREQUENCY WILL
3 ALSO NEED TO BE LESS IN ORDER TO ACCOMMODATE THE
4 CHANGES, AND WE THINK THOSE WOULD REQUIRE MORE
5 EXTENSIVE POLICY CHANGES AND CHANGES TO THE
6 APPLICATIONS AND PROGRAM.

7 SO WE WENT WITH REALLY TRYING TO CREATE A
8 FILTERING OR QUALIFYING PROCESS AS THE APPROACH WE
9 WOULD TRY TO SEE HOW THAT WOULD WORK.

10 THIS IS AN ILLUSTRATION OF THE CURRENT
11 CLINICAL APPLICATION AND REVIEW PROCESS WHICH WE
12 DIVIDE INTO IN THREE PHASES THAT BEGIN WITH THE
13 APPLICATION SUBMISSION, WE ASSESS APPLICATIONS FOR
14 ELIGIBILITY, THOSE THAT ARE ACCEPTED GO INTO THE
15 MERIT REVIEW BY THE GRANTS WORKING GROUP. AND THEN
16 THOSE RECOMMENDATIONS FROM THE GRANTS WORKING GROUP
17 GO TO THE BOARD. AND OVERALL, ASSUMING AN
18 APPLICATION IS SUCCESSFUL IN GETTING A POSITIVE
19 RECOMMENDATION, THE CYCLE IS ABOUT THREE MONTHS.

20 WHAT WE ARE PROPOSING NOW IS TO CREATE A
21 PROCESS THAT ADDS A COMPETITIVE QUALIFICATION STEP
22 AT THE ONSET. SO APPLICATIONS ARE SUBMITTED, AND AT
23 THIS STEP THEY GO THROUGH A RANK SCORING BASED ON
24 SPECIFIC CRITERIA THAT I'LL DESCRIBE IN JUST A
25 SECOND. AND WE SELECT THE TOP FIVE APPLICATIONS

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1 THAT THEN ADVANCE INTO THE NONRANKED SCORING THAT WE
2 ALREADY HAVE IN THE EXISTING PROCESS. NOW, THAT
3 WOULD ADD ABOUT A MONTH TO THE CYCLE. SO WE ARE NOW
4 HAVING OVERLAPPING FOUR-MONTH CYCLES INSTEAD OF
5 THREE-MONTH CYCLES.

6 SO LET ME GO INTO A LITTLE MORE DETAIL ON
7 WHAT THAT QUALIFICATION PROCESS WOULD LOOK LIKE.
8 THIS WOULD APPLY ONLY TO THE CLIN1S, THAT'S THE
9 IND-ENABLING, AND THE CLIN2S, THE CLINICAL TRIAL
10 PROPOSALS, BUT NOT CLIN4. THE CLIN4 ARE THE NEW BLA
11 STAGE PROJECTS. THE CLIN4 ALREADY GOES THROUGH A
12 PROCESS THAT IS EQUIVALENT TO THAT ALMOST BECAUSE
13 THEY HAVE TO HAVE A CLIN2 IN ORDER TO QUALIFY FOR A
14 CLIN4. AND BEFORE ANYBODY SUBMITS AN APPLICATION
15 FOR CLIN4, THEY HAVE TO GO THROUGH CONVERSATIONS
16 WITH THE THERAPEUTICS DEVELOPMENT TEAM TO ENSURE
17 THAT THEY ARE READY.

18 WE'RE NOT EXPECTING TO GET MORE THAN TWO
19 OR THREE IN A YEAR FOR CLIN4. SO WE'RE NOT TALKING
20 ABOUT LARGE NUMBERS THERE.

21 FOR THIS PROCESS, WE'RE CREATING A
22 QUALIFYING SCORE THAT IS BASED ON SEVERAL OBJECTIVE
23 CRITERIA AS WELL AS SOME SUBJECTIVE. AND I WILL
24 GIVE YOU SOME EXAMPLES AND SOME SPECIFICS ON THAT IN
25 A SECOND. BASED ON THOSE CRITERIA AND HOW THEY

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1 SCORE, WE WOULD RANK THE SUBMISSION AND, AS
2 MENTIONED, ADVANCE THE TOP FIVE INTO THAT CYCLE, BUT
3 WE WOULD RETAIN THE SUBMISSIONS IN THAT COMPETITIVE
4 POOL FOR A COUPLE OF CYCLES, MEANING THAT ANY GIVEN
5 APPLICATION HAS MULTIPLE OPPORTUNITIES TO ADVANCE
6 INTO THE REVIEW CYCLE.

7 NOW, IF A POOL HAS FIVE APPLICATIONS OR
8 LESS, WELL, THEN ALL OF THEM WOULD ADVANCE AND THERE
9 WOULD BE NO NEED TO QUALIFY.

10 IF WE NOW GO FURTHER IN ASSESSING WHAT THE
11 QUALIFICATION PROCESS LOOKS LIKE, WE WOULD START
12 WITH STEP ONE IN WHICH WE WOULD ASSESS APPLICATIONS
13 BASED ON OBJECTIVE CRITERIA THAT ARE SCORED BY THE
14 CIRM TEAM. AND SO WE WOULD ASSIGN POINTS FOR EACH
15 CRITERION MET. THE APPLICATIONS WOULD BE RANKED;
16 TOP FIVE WOULD QUALIFY FOR REVIEW. HOWEVER, THERE
17 IS THE LIKELIHOOD THAT THERE ARE GOING TO BE
18 INSTANCES WHERE WE HAVE TIES AND WHERE WE CAN'T
19 SELECT WHAT THE TOP FIVE WOULD BE THROUGH THE
20 OBJECTIVE CRITERIA ALONE. IF THAT IS THE CASE, THEN
21 WE MOVE TO STEP TWO WHICH WOULD INVOLVE SUBJECTIVE
22 CRITERIA THAT ARE SCORED BY GRANTS WORKING GROUP
23 MEMBERS.

24 AND SO WE WOULD RECRUIT GRANTS WORKING
25 GROUP MEMBERS TO HELP US SCORE APPLICATIONS BASED ON

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1 FOUR TO FIVE KEY ELEMENTS. AND I'LL GIVE YOU SOME
2 EXAMPLES OF THOSE. BUT THE IDEA IS TO KEEP IT HIGH
3 LEVEL AND SHORT. WE DON'T WANT THEM TO GO INTO AN
4 EXTENSIVE REVIEW. WE WANT THEM TO HELP US HIGHLIGHT
5 WHICH ONES THEY FEEL ARE OF POTENTIAL VALUE AND
6 WORTH DIGGING INTO MORE.

7 THE APPLICATIONS WOULD THEN BE RANKED BY
8 THEIR SCORE. AND THEN, OF COURSE, WE WOULD BREAK --
9 THE SCORES WOULD BREAK THOSE TIES. AN APPLICATION
10 THAT DOES NOT QUALIFY CAN EITHER BE WITHDRAWN BY THE
11 APPLICANT OR IT CAN BE RERANKED FOR UP TO TWO
12 ADDITIONAL CYCLES AS I MENTIONED BEFORE. BUT AFTER
13 THAT, THEY COME OUT OF CONSIDERATION, AND THEY CAN'T
14 BE RESUBMITTED FOR SIX MONTHS. AND THAT IS
15 NECESSARY IN ORDER TO AVOID JUST HAVING APPLICATIONS
16 CONSTANTLY IN THE COMPETITIVE POOL WITHOUT AT LEAST
17 MAKING SOME SIGNIFICANT CHANGE.

18 SO HERE IS SOME EXAMPLES OF THE OBJECTIVE
19 CRITERIA, AND I'LL GO INTO A LITTLE MORE DETAIL. SO
20 EXAMPLES OF THE CRITERIA THAT WOULD BE SCORED BY
21 CIRM ARE, FOR EXAMPLE, IF THIS IS A CALIFORNIA
22 ORGANIZATION OR NOT, WE WOULD, FOR EXAMPLE, FAVOR
23 ORGANIZATIONS THAT ARE CALIFORNIA BASED. THE
24 PERCENT EXPENDITURES IN CALIFORNIA IS ANOTHER
25 EXAMPLE, WHETHER IT'S A PIPELINE PROJECT, MEANING IT

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1 REPRESENTS A PROGRESSION EVENT, SOMETHING THAT'S
2 ADVANCING FROM A CIRM-FUNDED TRAN PROGRAM INTO A
3 CLIN1 OR A CLIN1 INTO CLIN2 AND SO ON.

4 BASED ON THE THERAPEUTIC TYPE, FOR
5 EXAMPLE, WE WOULD ADVANCE CELL THERAPIES OVER SMALL
6 MOLECULE APPROACHES GIVEN OUR MANDATE AS A STEM CELL
7 AGENCY. SOME EXAMPLES OF SUBJECTIVE CRITERIA THAT
8 WOULD BE SCORED BY THE GRANTS WORKING GROUP
9 EXPERT ARE RELATED TO THE OVERALL VALUE PROPOSITION
10 OF THE PROJECT. THESE THAT I LIST HERE ARE PART OF
11 THE REVIEW CRITERIA THAT THEY ALREADY UTILIZE, BUT
12 THESE ARE THE HIGH LEVEL ONES THAT WOULD ALLOW THEM
13 TO DISTINGUISH AMONG PROJECTS MORE QUICKLY THAN
14 DIGGING INTO THE APPLICATION TO ASSESS THINGS AS
15 FEASIBILITY AND SO ON. HERE WE WOULD ASK THEM IS
16 THIS SOMETHING THAT ADDRESSES AN UNMET NEED? HOW
17 WELL THEY THINK IT IMPACTS ON PATIENTS IF THE
18 APPROACH IS SUCCESSFUL. WHAT KIND OF IMPROVEMENT
19 OVER STANDARD OF CARE THEY WOULD EXPECT TO SEE AND
20 PERHAPS WHETHER THEY HAVE A SOUND RATIONALE. AND,
21 AGAIN, THE SUBJECTIVE CRITERIA WOULD BE APPLIED ONLY
22 IF THE OBJECTIVE CRITERIA DON'T ALLOW US TO DISCERN
23 BETWEEN THE APPLICATIONS.

24 SO IN THINKING OF THE PROCESS THIS WAY,
25 AND I DO WANT TO JUST REITERATE THAT WE ARE

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1 PRESENTING THIS WITH THE IDEA OF GETTING INPUT AND
2 FEEDBACK FROM YOU, PARTICULARLY IF YOU HAVE IDEAS
3 FOR OTHER CRITERIA THAT WE COULD USE. NONE OF THESE
4 ARE SET IN STONE OR FINALIZED IN ANY WAY. OUR GOAL
5 WAS TO BRING THEM TO YOU WITH THE IDEA THAT WE WOULD
6 GET SOME FEEDBACK AND PERHAPS ADDITIONAL IDEAS.

7 SO THE WAY WE THOUGHT OF THESE CRITERIA,
8 WE WANT TO CHOOSE THINGS THAT ARE GENERALLY
9 SUPPORTED BY PROP 14 OR THE CLINICAL PROGRAM CONCEPT
10 OR ANNOUNCEMENT. THEY OBVIOUSLY DO HAVE
11 PROGRAMMATIC VALUE. AND SO THAT'S WHY WE NEED YOUR
12 OKAY TO MOVE FORWARD WITH WHAT WE CHOOSE AND LIKELY
13 WOULD INCLUDE IN THE CONCEPT. BUT THE IDEA IS IF
14 WE'RE COMPARING OTHERWISE ELIGIBLE APPLICATIONS,
15 WHAT SHOULD WE ADVANTAGE? WE WOULD RECOMMEND
16 SUPPORTING THINGS SUCH AS CALIFORNIA-BASED
17 ORGANIZATIONS OVER NON-CALIFORNIA, CELL THERAPIES
18 AND GENE THERAPIES THAT HAS BEEN LARGELY OUR FOCUS
19 OVER OTHER APPROACHES SUCH AS SMALL MOLECULES. WE
20 WOULD ALSO SUGGEST ADVANTAGING PROJECT ADVANCEMENTS,
21 THOSE THAT HAVE RECEIVED PREVIOUS FUNDINGS AND THAT
22 ARE ADVANCING TO A MORE ADVANCED STAGE OF
23 DEVELOPMENT OVER NEW PROJECTS. ADVANCING TRIALS
24 THAT ARE AT A GREATER LATER STAGE. SO A PIVOTAL
25 PHASE 3 OVER A PHASE 1 OR OVER A CLIN1. AND PERHAPS

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1 PROJECTS THAT ARE LESS LIKELY TO RECEIVE FUNDING
2 FROM OTHER SOURCES.

3 NOW, IN THINKING ABOUT THESE CRITERIA, THE
4 IDEA IS, TO THE EXTENT POSSIBLE, IN ORDER TO MAKE
5 THEM AS OBJECTIVE AS POSSIBLE, IS THAT THESE ARE
6 CRITERIA THAT ARE NOT UNLIKELY TO CHANGE OVER TIME,
7 THAT THESE ARE JUST INTRINSIC TO THE PROPOSAL TO THE
8 APPLICANTS IN SOME WAY IN ORDER TO ALLOW US TO
9 REALLY DISCERN THOSE THAT WE WANT TO MOVE FORWARD.

10 SO THAT'S THE PROPOSAL FOR THE QUALIFYING
11 PROCESS. I WANT TO JUST VERY BRIEFLY MOVE INTO SOME
12 OTHER CHANGES THAT WE WANT TO MAKE THAT WE THINK ARE
13 IMPORTANT TO STREAMLINE THE PROCESS. AND THIS IS
14 RELATED TO THE CHANGES IN THE NONRANKED PROCESS. WE
15 WANT TO LIMIT THE TIER II RESUBMISSIONS THAT WE
16 CURRENTLY HAVE TO ONE TIME. WE HAVE HAD MORE
17 RECENTLY RESUBMISSIONS THAT HAPPENED SEVERAL TIMES,
18 BUT WE DON'T KNOW THAT IT OFFERS ANY MORE OF AN
19 OPPORTUNITY FOR IMPROVING THE APPLICATION.

20 SO THE IDEA WOULD BE TO LIMIT THEM TO ONE
21 OPPORTUNITY TO MAKE THE CHANGES AND FIXES. AND SO
22 RESUBMISSIONS WOULD BE SCORED A 1 OR A 3 THEREAFTER.

23 THE SECOND THING THAT WE THINK WOULD BE
24 IMPORTANT TO DO IS TO TIGHTEN OUR INTERNAL DEADLINES
25 FOR RESOLVING ELIGIBILITY ISSUES AND OTHER RELATED

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1 ELEMENTS THAT COME UP. WE DO A LOT OF WORK TO WORK
2 WITH APPLICANTS AND SOMETIMES HAVE EXTENSIVE BACK
3 AND FORTH TO GET THEIR ELIGIBILITY ELEMENTS
4 STRAIGHTENED OUT. BUT WE WANT TO JUST AT THIS POINT
5 OUT OF EFFICIENCY IN ORDER TO BE ABLE TO MOVE MORE
6 QUICKLY HAVE A SINGLE ELIGIBILITY NOTICE, A CHANCE
7 TO RESOLVE. IF THEY CAN'T RESOLVE IT, THEY MOVE OUT
8 OF THE CYCLE SO THAT WE CAN MOVE ON WITH THOSE THAT
9 ARE GOING TO BE ELIGIBLE AND BE ABLE TO MOVE FORWARD
10 INTO THE REVIEW.

11 THIS SLIDE IS JUST HIGHLIGHTING SOME OF
12 THE THINGS THAT WE HAVE TO CHANGE IN TERMS OF OUR
13 POLICIES OR REGULATIONS IN ORDER TO MOVE FORWARD
14 WITH THIS PROCESS. THE MOST OBVIOUS ONE IS THE
15 GRANTS WORKING GROUP BYLAWS WHICH DESCRIBES IN A LOT
16 OF DETAIL THE SCORING AS WELL AS THE TIER I, II, AND
17 III PROCESS FOR CLINICAL REVIEWS AS WELL AS OTHER
18 REVIEWS. BUT IN ORDER TO RESTRICT THE TIER II
19 PROCESS IN THE CLINICAL REVIEWS TO ONE INSTANCE, WE
20 NEED TO CHANGE SOME LANGUAGE IN THE BYLAWS. AND I
21 THINK THAT WAS INCLUDED IN THE MATERIALS THAT WERE
22 PROVIDED TO YOU SO YOU CAN LOOK AT THAT. IT'S JUST
23 A VERY -- I THINK IT'S JUST ONE SENTENCE THAT NEEDS
24 TO BE ADDED.

25 WE ALSO EXPECT THAT WE WOULD UPDATE THE

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1 CONCEPT AND THE PROGRAM ANNOUNCEMENT IN ORDER TO
2 DEFINE THE QUALIFICATION STEP ITSELF AND THE
3 SPECIFIC SELECTION CRITERIA THAT ARE USED. WE WANT
4 THE SELECTION CRITERIA TO BE TRANSPARENT TO
5 EVERYONE, INCLUDING THE APPLICANT, SO THAT THEY
6 UNDERSTAND THAT WE'RE USING IT IN ORDER TO ADVANTAGE
7 SOME APPLICATIONS OVER OTHERS. IT DOESN'T PREVENT
8 THEM FROM BEING REVIEWED BECAUSE IT'S NOT
9 ELIGIBILITY, MEANING EACH OF THE QUALIFICATION
10 CRITERIA ALONE ARE NOT ENOUGH TO PREVENT SOMEBODY
11 FROM MOVING FORWARD. IT IS REALLY THE COMBINATION
12 OF FACTORS THAT CONTRIBUTE TO A SCORE BASED ON THESE
13 CRITERIA.

14 AND TO THE EXTENT POSSIBLE, WE WANT TO
15 CREATE CLEARER ELIGIBILITY CRITERIA IF WE NEED TO OR
16 REFINE OUR REVIEW CRITERIA.

17 I BELIEVE -- YEAH. THAT'S THE END OF THE
18 SLIDE DECK. AGAIN, JUST WANT TO INVITE YOUR
19 FEEDBACK ON THIS OVERALL PROCESS. MARK, I'LL TURN
20 IT BACK TO YOU FOR ANY QUESTIONS.

21 CHAIRMAN FISCHER-COLBRIE: THANKS, GIL,
22 FOR AN EXCELLENT PRESENTATION. AND BEFORE WE LAUNCH
23 INTO QUESTIONS, I JUST WANT TO COMPLIMENT THE CIRM
24 STAFF FOR A GREAT PROCESS TO DATE IN TERMS OF THE
25 EFFORT AND THE QUALITY OF WHAT'S BEEN DONE ON THE

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1 GWG PROCESS FOR ALL THIS ACTIVITY CURRENTLY WITH THE
2 ACKNOWLEDGEMENT THAT THE TIDAL WAVE OF NEW
3 APPLICATIONS IS ONE OF THE DETERMINANTS FOR
4 REQUIRING A CHANGE HERE IN ORDER TO KEEP UP OUR
5 QUALITY LEVEL AND SUPPORT. BUT THE CIRM TEAM HAS
6 BEEN OUTSTANDING AT PROGRESSING WITH A VERY STRONG
7 EFFORT. SO THANK YOU FOR YOUR EFFORTS THERE.

8 WITH THAT IN MIND, THOUGH, I WOULD LIKE TO
9 SEE IF THERE ANY QUESTIONS OUT THERE. I'M SCANNING
10 THROUGH THE LIST HERE. I'M NOT SEEING ANYTHING, BUT
11 DOES ANYBODY HAVE QUESTIONS ABOUT WHAT'S BEING
12 CONSIDERED HERE? I GUESS THAT TERRI JONES. I'M NOT
13 SURE WHO WAS FIRST, TERRI OR VITO. I'LL GO WITH
14 TERRI.

15 MS. MANDAC: VITO FIRST. WE'RE NOT READY
16 FOR PUBLIC COMMENT.

17 CHAIRMAN FISCHER-COLBRIE: MY MISTAKE.
18 THANK YOU. VITO.

19 CHAIRMAN IMBASCIANI: THANK YOU. SORRY.
20 THANKS, MARK. AND, GIL, COMPLIMENTS ON THE LUCIDITY
21 OF THE PRESENTATION. IT'S NOT REALLY A QUESTION.
22 I'M ANTICIPATING MAYBE A MORE GENERAL REACTION FROM
23 THE BOARD. AND IF YOU WANTED TO PULL UP THE SLIDE,
24 IT'S THE ONE THAT TALKS ABOUT THE OBJECTIVE AND THE
25 SUBJECTIVE CRITERIA. I HAVE NO PROBLEMS AT ALL WITH

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1 ANY OF THE CRITERIA. I AGREE THAT THE OBJECTIVE
2 ONES ARE INTRINSIC AND SORT OF IMMUTABLE. THEY JUMP
3 OUT OF THE PAGE. AND THE SAME THING WITH THE
4 SUBJECTIVE ONES.

5 WHAT I WOULD ASK YOU TO DO FOR ME, COULD
6 YOU REHEARSE THE DISCUSSION THAT MUST HAVE HAPPENED
7 AMONG THE TEAM AS TO WHY THE SUBJECTIVE CRITERIA
8 WERE RELEGATED TO A TIE-BREAKING LOCATION IN THIS
9 PROCESS? YOU CAN MAKE AN ARGUMENT THAT SOME OF THE
10 SUBJECTIVE CRITERIA WERE THEMSELVES PROGRAMMATIC,
11 UNMET MEDICAL NEED, EXCEEDING STANDARD OF CARE, AND
12 SO ON. SO WAS THERE ANY DISCUSSION TO INCORPORATING
13 SOME OF THE SUBJECTIVE CRITERIA IN THE INITIAL
14 SCREENING CRITERIA BEFORE THE CONSIDERATION OF ANY
15 TIE OR TIE-BREAKING?

16 DR. SAMBRANO: YES. AND SO THANKS FOR THE
17 QUESTION. I THINK PART OF IT WAS THINKING ABOUT HOW
18 TO STREAMLINE THIS TO THE EXTENT POSSIBLE AND
19 THINKING ABOUT WHAT WE WOULD NEED TO DO. SO LET'S
20 SAY WE WERE LOOKING AT 10 OR 20 APPLICATIONS THAT
21 WOULD THEN NEED TO BE SCREENED BY GRANTS WORKING
22 GROUP MEMBERS WITH THE SUBJECTIVE CRITERIA ALONG
23 WITH THEN THE CIRM TEAM LOOKING AT THE OBJECTIVE
24 CRITERIA. WE FELT THAT IT WOULD BE EASIER IF WE
25 FOCUSED THE GRANTS WORKING GROUP EFFORT BECAUSE

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1 RECRUITING THE RIGHT NUMBER OF INDIVIDUALS AND
2 NARROWING THE NUMBER OF APPLICATIONS THAT WOULD
3 REQUIRE THE TIE-BREAKING ELEMENT WOULD BE FEWER IF
4 WE DID THE STEPS SEQUENTIALLY RATHER THAN AT THE
5 SAME TIME AND WOULD ONLY BE NECESSARY IF, IN FACT,
6 WE ENDED UP WITH A TIE. SO IT WAS REALLY ABOUT
7 THINKING ABOUT EFFICIENCY IN PROCESS AS TO WHY WE
8 MADE IT A SEQUENTIAL TWO STEP.

9 CHAIRMAN IMBASCIANI: GOOD. THANK YOU.

10 CHAIRMAN FISCHER-COLBRIE: KEITH.

11 DR. YAMAMOTO: JUST FOLLOWING VITO, I HAVE
12 THE SAME KIND OF CONCERN. AND MY FEELING, GIL -- SO
13 THANKS FOR THIS. IT WAS A TERRIFIC PRESENTATION,
14 AND YOU CLEARLY HAVE THOUGHT IT THROUGH VERY
15 CAREFULLY. SO THANK YOU FOR ALL OF THAT.

16 I HAVE A SIMILAR RESPONSE AS VITO'S. IT
17 SEEMED TO ME THAT GETTING THE GWG TO WEIGH IN ON
18 THESE AND MAYBE OTHER SUBJECTIVE CRITERIA THAT I CAN
19 THINK OF WOULD NOT ACTUALLY BE INEFFICIENT. HAVING
20 SERVED ON MANY, MANY REVIEW PANELS OVER THE YEARS, I
21 CAN SAY THAT IT REALLY IS VERY SIMPLE TO MAKE THIS
22 ASSESSMENT FOR CRITERIA SUCH AS THIS OR, IN FACT, IN
23 KIND OF SCANNING THE SPECIFIC -- I DON'T KNOW HOW
24 THE APPLICATIONS ARE STRUCTURED, BUT IN NIH GRANTS,
25 SCANNING THE ABSTRACT AND SPECIFIC AIMS, AND IT'S

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1 QUITE SIMPLE TO REACH THE CONCLUSION THAT THIS IS
2 SOMETHING THAT SHOULD GO FORWARD TO FULL REVIEW,
3 THAT IT'S SUFFICIENTLY MERITORIOUS ON ITS FACE TO BE
4 ABLE TO DO THAT.

5 AND SO IN THE NIH PROCESS, WE WERE FACED
6 WITH A LONG GRANT APPLICATION. IT'S ALWAYS BEEN A
7 BIT OF SOURCE OF FRUSTRATION TO ME THAT YOU HAVE TO
8 GO THROUGH THE WHOLE PROCESS OF REVIEW HAVING LOOKED
9 AT THE AIMS, MAYBE A BIT ABOUT THE METHODS, BUT MORE
10 THE AIMS, THE VALUE OF THE QUESTION, THE VALUE OF AN
11 ANSWER IF THE PROJECT IS COMPLETED. THAT ASSESSMENT
12 CAN REALLY BE MADE IN A FEW MINUTES. AND SO IT'S
13 FRUSTRATING TO HAVE TO GO THROUGH AND DO A FULL
14 REVIEW WHERE YOU REALLY KNOW WHAT THE FATE OF THIS
15 IS GOING TO BE AT LEAST IN YOUR HANDS AS A REVIEWER.

16 I THINK IT WOULDN'T BE HARD. IT'S NOT A
17 TOUGH TASK. AND WHAT WE HAD DISCUSSED EARLIER WHEN
18 WE WERE INFORMALLY DISCUSSING IS REALLY MOVING
19 TOWARD THE NIH PROCESS OF TRIAGING HALF OF THE
20 APPLICATIONS IS WHAT THE NIH USES, BUT YOU CAN PICK
21 A DIFFERENT LEVEL BASED ON THE WAYS THAT THE
22 APPLICATIONS SEEM TO BE COMING IN, THE QUALITY OF
23 THE APPLICATIONS THAT ARE COMING IN. AND SO I
24 REGARD THE SUBJECTIVE CRITERIA AS FINE, BUT, IN
25 FACT, I BELIEVE THAT IT WOULDN'T BE A TALL TASK TO

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1 ASK THE GWG TO LOOK AT THE SUBSTANCE OF THE PROPOSAL
2 ITSELF AND MAKE A JUDGMENT ABOUT WHETHER THIS SHOULD
3 OR SHOULDN'T MOVE FORWARD, APPLYING A TRIAGE-TYPE OF
4 PROCESS THAT WOULD SHORTEN THE LIST OF PROPOSALS TO
5 BE EXAMINED.

6 I GUESS MAYBE THE PRELIMINARY QUESTION I
7 SHOULD HAVE ASKED IS IF THE EXPERIENCE THAT SCORING
8 THE CIRM STAFF'S WORK OF SCORING THESE OBJECTIVE
9 CRITERIA WILL BE SUFFICIENT IN GENERAL TO BE ABLE TO
10 SORT OUT AND IDENTIFY THE TOP FIVE WITH OR WITHOUT
11 TIES. IS THERE GOING TO BE A BIG RANGE OF PEOPLE
12 THAT ARE STICKING WITH THESE OBJECTIVE CRITERIA OR
13 NOT THAT ALLOW YOU TO DO THIS SEPARATION? AND SO IS
14 IT -- DO YOU EXPECT THAT REALLY ONLY A FEW WOULD
15 ADVANCE BASED ON TIES, ONLY A FEW WOULD ADVANCE TO
16 BEING SCRUTINIZED BY THE GRANTS WORKING GROUP? OR
17 IS IT SORT OF AN EXPECTATION THAT MOST OF THEM WOULD
18 DO WELL ON THESE OBJECTIVE CRITERIA, AND YOU'D END
19 UP WITH LOTS OF TIES ESSENTIALLY, MEANING THAT MOST
20 OF THE LIST WOULD GO TO THE GRANTS WORKING GROUP?
21 SO I GUESS IT'S REALLY TWO QUESTIONS. THAT MAY BE
22 THE FIRST ONE.

23 AND THE SECOND IS A COMMENT THAT IT'S MY
24 VIEW FROM PERSONAL EXPERIENCE THAT BEING ABLE TO ASK
25 THE GRANTS WORKING GROUP TO MAKE THESE ASSESSMENTS

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1 THAT WOULD END UP RANKING THE APPLICATIONS
2 SUFFICIENTLY TO CUT DOWN THE NUMBER THAT HAVE TO BE
3 EXAMINED FOR FULL REVIEW WOULD BE STRAIGHTFORWARD
4 AND, IN FACT, WOULD YIELD EXAMINATION OF THE BEST
5 APPLICATIONS IN A GIVEN ROUND.

6 DR. SAMBRANO: THANK YOU, KEITH. WE DID
7 SORT OF A MOCK TRIAL, IF YOU WILL, OF THE
8 QUALIFICATION PROCESS WITH THE OBJECTIVE CRITERIA
9 BASED ON SEVERAL OF THE RECENT CYCLES THAT WE'VE HAD
10 TO SEE HOW THE APPLICATIONS WOULD. IN GENERAL USING
11 CRITERIA LIKE WE'VE SELECTED FOR THE OBJECTIVE
12 CRITERIA IN MOST CASES ALLOW US TO PICK THE TOP
13 FIVE, BUT YOU DO END UP IN SOME CASES WITH TIES THAT
14 NEED TO BE ADDRESSED. SO IT'S NOT SOMETHING WHERE
15 YOU MIGHT AS WELL GIVE IT TO THE GRANTS WORKING
16 GROUP BECAUSE YOU'RE GOING TO NEED TO DO IT ANYWAY.
17 IT KIND OF JUST DEPENDS ON THE COHORT OF
18 APPLICATIONS, BUT IN MOST CASES THE OBJECTIVE
19 CRITERIA ALONE CAN HELP YOU IDENTIFY THE TOP FIVE.

20 I AGREE WITH YOU THAT THE ASSESSMENT BY
21 GRANTS WORKING GROUP MEMBERS TO VERY QUICKLY LET US
22 KNOW THIS IS SOMETHING THAT IS WORTH LOOKING AT
23 FURTHER OR NOT IS SOMETHING THAT CAN BE VERY SIMPLE.

24 WHAT I THINK WE WERE CHALLENGED BY IS MORE
25 WHO THOSE EXPERTS SHOULD BE THAT ARE GOING TO ASSESS

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1 WHETHER THERE IS AN UNMET NEED, WHETHER THIS TRULY
2 REPRESENTS SOMETHING THAT'S AN IMPROVEMENT OVER A
3 STANDARD OF CARE FOR EACH OF THE APPLICATIONS. WE
4 REALLY DO NEED AN EXPERT IN THAT ARENA, IN THAT AREA
5 WHO IS LIKELY A CLINICIAN TO BE ABLE TO MAKE THAT
6 ASSESSMENT.

7 SO THAT MEANS, FROM OUR PERSPECTIVE, WE
8 NEED TO MAKE SURE THAT FOR EVERY LARGE GROUP OF
9 APPLICATIONS THAT WE IDENTIFY THE RIGHT REVIEWERS
10 WHO CAN MAKE THAT ASSESSMENT AND GIVE US BACK A
11 SCORE. SO THAT'S WHERE IT BECOMES MORE DIFFICULT,
12 PARTICULARLY IF WE HAVE A LOT OF APPLICATION THAT
13 CUT ACROSS MANY DIFFERENT DISEASE INDICATIONS AND
14 MANY DIFFERENT APPROACHES.

15 WE THOUGHT OF DIFFERENT POTENTIAL WAYS OF
16 DOING THAT TO HAVE A SET OF WHAT WE WOULD CALL
17 GENERALIST GRANTS WORKING GROUP MEMBERS WHO HAVE
18 BROAD VIEWS OF THINGS AND CAN GIVE US THOSE OPINIONS
19 OR IN CASES WHERE WE CAN'T HAVE EXPERTS THAT ARE
20 WELL VERSED IN THE DISEASE TO BE ABLE TO GIVE US THE
21 OPINION. SO I THINK IN THE END WE THOUGHT, IF WE'RE
22 LIMITING THIS TO ONLY A SELECT NUMBER, THOSE WHERE
23 WE END UP HAVING A TIE, IT ALLOWS US TO ACTUALLY
24 RECRUIT AND IDENTIFY THOSE THAT HAVE THE MOST
25 EXPERTISE TO BE ABLE TO GIVE US A CLEARER ASSESSMENT

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1 OF THE UNMET NEED AND IMPROVEMENT OR IMPACT ON
2 PATIENTS THAN IF WE LET SORT OF A STANDING PANEL
3 GIVE US THEIR OPINION ACROSS SO MANY DIFFERENT
4 POTENTIAL DISEASE INDICATIONS.

5 SO THAT WAS OUR THINKING ABOUT IT AND SOME
6 OF THE CONSIDERATIONS THAT WENT INTO THAT --

7 CHAIRMAN FISCHER-COLBRIE: OKAY. KEITH, I
8 DON'T KNOW IF YOU HAVE FOLLOW-UP COMMENT OR QUESTION
9 ON THAT. OTHERWISE, MARIA, YOU HAD YOUR HAND UP AND
10 THEN PULLED IT BACK DOWN AGAIN. BUT GO AHEAD,
11 KEITH.

12 DR. YAMAMOTO: IF I CAN JUST MAKE ONE
13 QUICK FOLLOW-UP. THANK YOU, GIL, FOR THAT.

14 DR. SAMBRANO: YOU BET.

15 DR. YAMAMOTO: WHAT I WOULD SAY IN
16 RESPONSE IS THAT YOU SAID TO ME THE KEYWORD, WHICH
17 IS GENERALIST. AND MY EXPERIENCE IN REVIEW IS
18 REALLY OF BASIC SCIENCE NIH APPLICATIONS MOSTLY, BUT
19 ALSO LOTS OF -- I'VE SAT ON SEVERAL POST-DOC
20 FELLOWSHIP PANELS WHERE YOU GET A HUGE DIVERSITY OF
21 DIFFERENT KINDS OF SCIENCE COMING IN. AND THE REAL
22 KEY TO BEING ABLE TO MAKE GOOD DECISIONS IS HAVING
23 EXACTLY WHAT YOU SAID, HAVING GENERALISTS IN THE
24 ROOM.

25 AND SO IN MY VIEW THAT'S THE MAIN THING

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1 THAT YOU WANT THROUGHOUT THE WHOLE PROCESS. HAVING,
2 AT LEAST IN BASIC SCIENCE, HAVING CONTENT EXPERTS,
3 PEOPLE WHO ARE ACTUALLY RESPONSIBLE FOR CREATING A
4 GIVEN PARADIGM, THOSE PEOPLE ARE BIASED AGAINST
5 ANYTHING THAT RUNS AGAINST THEIR PARADIGM. AND SO
6 WHEN YOU ASK IF THIS IS, IN BASIC SCIENCE
7 TERMINOLOGY, ADDRESSING AN UNMET NEED, THE CONTENT
8 EXPERTS ARE GOING TO SAY, NO, WE'VE GOT THIS
9 COVERED. IF SOMEBODY COMES IN AND SAYS WE NEED TO
10 BE DOING SOMETHING IN A DIFFERENT WAY, APPROACH,
11 THINKING ABOUT THE PROBLEM IN A DIFFERENT WAY. SO
12 GENERALIST IS THE KEY. AND I THINK FINDING PEOPLE
13 LIKE THAT TO SERVE ON THESE PANELS AND THEN
14 OBLIGATING THE APPLICANTS TO TALK ABOUT WHAT, IN
15 THIS CASE WITH CLINICAL APPLICATIONS, TO TALK ABOUT
16 THE UNMET NEED, TO TALK ABOUT IMPROVEMENT OVER
17 STANDARD OF CARE IS ESSENTIAL. AND THE GENERALISTS
18 CAN THEN MAKE AN ASSESSMENT OF WHETHER THIS WOULD
19 CREATE A MEANINGFUL ADVANCE.

20 SO I THINK AT LEAST THERE IS ANOTHER WAY
21 TO THINK ABOUT THE POINT THAT YOU'VE RAISED.

22 DR. SAMBRANO: THANK YOU, KEITH.

23 CHAIRMAN FISCHER-COLBRIE: OKAY. MARIA,
24 DID YOU HAVE A FOLLOW-UP?

25 VICE CHAIR BONNEVILLE: NO. I'M GOOD.

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1 CHAIRMAN FISCHER-COLBRIE: MONICA.

2 DR. CARSON: FOLLOWING UP ON WHAT WAS JUST
3 DISCUSSED, I THINK THE UNSPOKEN FEAR IS THAT THE
4 NEXT BREAKOUT IDEA OF AN UNMET NEED IMPACT ON
5 PATIENTS OR ONE OF THESE OTHER THINGS SOMEHOW DIDN'T
6 PASS THE OBJECTIVE CRITERIA.

7 SO I HAVE TWO QUESTIONS ON THAT SINCE IT
8 SOUNDS LIKE YOU MIGHT PARTLY HAVE THIS ANSWER.
9 YOU'VE MOCKED UP RETROSPECTIVELY ON THE GRANTS THAT
10 HAVE COME THROUGH. WAS THERE A SENSE -- YOU SAID
11 MOST OF THEM WOULD HAVE GOTTEN THROUGH. IS THERE A
12 SENSE THAT YOU WOULD HAVE LOST SOME THINGS THAT HAVE
13 PROGRESSED WELL OVER THE CYCLES OR AS THEY'VE
14 DEVELOPED? SO YOU MUST HAVE SOME INFORMATION ON
15 THAT, AND THAT MIGHT ADDRESS PEOPLES' FEARS ON THIS.

16 AND THEN SECONDLY, IT MIGHT BE SOMETHING
17 THAT IT'S THE FIRST PASS ON THE EXAMPLES, BUT YOU
18 HAVE SOME EITHER GENERALIST OR SOMETHING THAT JUST
19 DOES A LOOK OVER TO SEE IN A SENSE SHOULD ANYTHING
20 BE PULLED OUT OF TRIAGE. IN THE SOMETHING THAT WAS
21 TRIAGED BY THIS OBJECTIVE CRITERIA, WAS SOMEBODY
22 JUST LOOKING OVER THAT AND JUST SAYING WE WOULD --
23 SHOULD THIS BE LOOKED AT AGAIN. SO THAT'S THE TWO
24 QUESTIONS. ONE, WHAT'S THE DATA FROM YOUR MOCK
25 LOOKING BACK USING THIS CRITERIA? WOULD ANYTHING

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1 SIGNIFICANT HAVE BEEN LOST THAT ACTUALLY WAS
2 SUCCESSFUL?

3 AND THEN TWO, HAVE YOU THOUGHT ABOUT
4 SOMEBODY LOOKING AT WHAT WAS TRIAGED JUST AS A FIRST
5 PASS, MAYBE TWO OR THREE PEOPLE THAT YOU HAVE AS A
6 PANEL? IT DOESN'T HAVE TO BE AS ACCURATE. IT'S
7 JUST A HEADS UP.

8 DR. SAMBRANO: THAT'S A GREAT QUESTION.
9 I THINK THE DIFFICULTY IN ANSWERING THE QUESTION IS
10 THAT WE DIDN'T -- THE OBJECTIVE CRITERIA ARE
11 DIFFERENT FROM THE SCIENTIFIC REVIEW CRITERIA. SO
12 YOU CAN HAVE, FOR EXAMPLE, A NON-CALIFORNIA
13 ORGANIZATION THAT MAYBE HAS A GREAT PROJECT. AND WE
14 WOULD SAY, YEAH, IT DID WELL IN GRANTS WORKING GROUP
15 REVIEW AND MAYBE ULTIMATELY IT LEADS TO SOMETHING
16 SIGNIFICANT, BUT THESE OBJECTIVE CRITERIA ARE REALLY
17 PRIORITIZING THE THINGS THAT WE THINK WE SHOULD FUND
18 OR THE KINDS OF PROJECTS THAT WE THINK SHOULD MOVE
19 FORWARD OVER OTHERS, NOT BASED NECESSARILY ON THE
20 SCIENTIFIC ELEMENTS, BUT ON THE MORE PROGRAMMATIC
21 LEVEL.

22 AND SO I THINK IT'S DIFFICULT TO KNOW
23 WHETHER ULTIMATELY IT'S GOING TO NOT SELECT A
24 PROJECT THAT MIGHT BE SUCCESSFUL DOWN THE LINE. WE
25 DON'T HAVE THE DATA FOR THAT BECAUSE THAT WOULD BE A

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1 LONG-TERM QUESTION. BUT ON THE OTHER HAND, WHEN WE
2 COMPARED WHAT GOT SELECTED TO, SAY, WHAT GOT
3 ULTIMATELY RECOMMENDED, IT ALIGNED DECENTLY WELL,
4 NOT IN ALL CASES. A LOT OF WHAT WAS RECOMMENDED BY
5 THE GRANTS WORKING GROUP ULTIMATELY ARE THINGS THAT
6 WE SAW MOVE FORWARD.

7 SO IT SUGGESTED THAT IT WASN'T DOING
8 ANYTHING HARMFUL NECESSARILY ACROSS THE BOARD IF YOU
9 LOOK AT THE TOTAL NUMBER; BUT IF YOU LOOK AT IT FROM
10 THE PERSPECTIVE OF ONE GIVEN APPLICATION, IN SOME
11 CASES THEY MOVE FORWARD AND OTHERS THEY DIDN'T. BUT
12 I THINK OVERALL IT DIDN'T REALLY DO ANYTHING THAT WE
13 WOULD CONSIDER TO BE SELECTING AGAINST THE THINGS
14 THAT WE WOULD WANT.

15 DR. CARSON: THANK YOU.

16 CHAIRMAN FISCHER-COLBRIE: OTHER
17 QUESTIONS? COMMENTS? SCANNING THROUGH HERE, I
18 DON'T SEE ANY. ANY OTHER QUESTIONS AT ALL? OKAY.

19 DR. THOMAS: THANK YOU. I JUST WANTED TO
20 MAKE A COUPLE OF COMMENTS HERE. ONE WAS WANTED TO
21 REITERATE THE POINTS MADE ABOUT THE EXCELLENCE OF
22 THE PRESENTATIONS BY JENN AND GIL. PUTTING THE
23 BUDGET TOGETHER IS A VERY COMPLEX EFFORT THAT
24 REQUIRES A LOT OF COOPERATION BY MEMBERS OF THE
25 SCIENTIFIC TEAM ACROSS CIRM AND TO BE ABLE TO PULL

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1 IT ALL TOGETHER IN A FASHION THAT RESULTS IN THE
2 PRESENTATION TODAY IS A REAL SKILL. AND I JUST
3 WANTED TO THANK JENN AND EVERYBODY WHO'S INVOLVED IN
4 THAT FOR ALL THE EFFORT THAT WENT INTO THAT.

5 WITH RESPECT TO GIL'S PROGRAM, A NUMBER OF
6 YOU HAVE NOTED HOW GOOD A JOB WAS DONE ON THAT.
7 THAT TOO TOOK A GREAT DEAL OF TIME AND EFFORT BY GIL
8 AND THE REVIEW TEAM, MEMBERS OF THE LEADERSHIP TEAM.
9 AND AS I MADE THE COMMENT IN THE PAST, WE ASKED AT
10 THE BEGINNING OF THE YEAR A LOT OF THE TEAM TO PUT
11 TOGETHER A NUMBER OF VERY TRANSFORMATIVE CHANGES TO
12 WHAT CIRM IS DOING. FLOW CONTROL WAS THE FIRST
13 DOMINO TO HIT HERE AS IT'S COMING TO THE BOARD.
14 MORE WILL FOLLOW AND WILL CONVERGE INTO A UNIFIED
15 CRESCENDO IN SEPTEMBER. BUT I WANTED TO
16 CONGRATULATE GIL AND THE TEAM AND EVERYBODY WHO'S
17 WORKED ON THIS FOR A GREAT EFFORT HERE. THIS IS THE
18 FIRST TIME WE'VE DONE THIS IN 20 YEARS, AND IT'S A
19 BIG DEAL. SO WANT THE BOARD TO KNOW THAT.

20 LASTLY, I JUST WANTED TO MAKE A POINT THAT
21 SORT OF TIES JENN'S BUDGET AND GIL'S FLOW CONTROL
22 PRESENTATION TOGETHER. SO YOU RECALL THAT JENN HAS
23 ASKED FOR THE SENSE OF THE COMMITTEE WITH RESPECT TO
24 A \$410 MILLION SIX-MONTH BUDGET. AND YOU WILL
25 NOTICE THAT THAT'S A QUITE SIGNIFICANT NUMBER FOR

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1 SIX MONTHS. BUT THE POINT I WANT TO MAKE IS, FIRST
2 OF ALL, TO REITERATE THAT THERE WERE \$148 MILLION
3 INCLUDED IN THAT 410 THAT WERE ROLLED OVER FROM LAST
4 YEAR. SO IF YOU TOOK THOSE OUT, THE ASK WOULD HAVE
5 BEEN 260 PLUS.

6 BUT BEYOND THAT, WITH RESPECT TO FLOW
7 CONTROL, ONCE WE BRING TO THE BOARD THE
8 RECOMMENDATIONS FOR THE STRATEGIC ALLOCATION
9 FRAMEWORK IN SEPTEMBER, DEPENDING ON HOW THE BOARD
10 CHOOSES TO GO WITH THOSE, WHAT WILL RESULT IN ANY
11 EVENT WILL BE A NUMBER OF CHANGES TO WHAT WE'VE DONE
12 IN THE PAST. AND THE CHANGES WILL REQUIRE SEVERAL
13 MONTHS TO IMPLEMENT. AND AS SUCH, THE BUDGET FOR
14 THE SECOND HALF OF THE FISCAL YEAR WILL BE
15 SIGNIFICANTLY LOWER THAN WHAT HAS BEEN ASKED FOR THE
16 FIRST SIX MONTHS. WHEN YOU SORT OF ADD THE TWO
17 THINGS TOGETHER, YOU'RE GOING TO END UP WITH A
18 TYPICAL YEAR'S ASK. AND I THOUGHT THAT THAT WAS A
19 POINT THAT WAS SOMETHING WORTH HIGHLIGHTING TO THE
20 BOARD AS IT KIND OF NEATLY TIES, AGAIN, THE BUDGET
21 AND THE FLOW CONTROL RECOMMENDATIONS TOGETHER.

22 SO, AGAIN, THANK YOU, TEAM. EXCELLENT
23 JOB. AND BACK TO YOU, MR. CHAIRMAN.

24 CHAIRMAN FISCHER-COLBRIE: GREAT. THANK
25 YOU SO MUCH. THOSE ARE GREAT, HELPFUL COMMENTS

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1 HERE. AND THEN CURRENTLY THEN, SCOTT, IF YOU CAN
2 ADVISE ME AGAIN. DO WE WANT TO PROVIDE A SENSE OF
3 THE COMMITTEE OF THE COMMUNICATIONS TO THE BOARD?
4 IS THAT THE PROPER NEXT STEP HERE?

5 MR. TOCHER: THAT'S RIGHT, MARK. I WOULD
6 SEE IF THERE'S ANY OR I SHOULD SAY ANY PUBLIC
7 COMMENT. I THINK WE HAD ONE PERHAPS EARLIER, AND
8 THEN, YES, JUST TO SURVEY THE COMMITTEE AND SEE IF
9 THERE'S ANY OBJECTION TO MOVING FORWARD WITH IT AT
10 THE BOARD.

11 CHAIRMAN FISCHER-COLBRIE: OKAY. WITH
12 THAT IN MIND THEN, LET ME GET A SENSE FROM THE
13 BOARD -- I MEAN THE SCIENCE SUBCOMMITTEE, AND THEN
14 MOVE TO THE PUBLIC COMMENT QUESTION.

15 SO WITH THAT IN MIND, JUST WANTED TO BE
16 ABLE TO ENSURE THAT WE'VE TAKEN PROPER CONSIDERATION
17 AROUND THE COMMENTS THAT BE HAVE MADE SO FAR. I
18 WANTED TO FOLLOW UP AND SEE IF THERE ARE ANY
19 OBJECTIONS TO TAKING FORWARD AS A SENSE OF THE
20 COMMITTEE IN PROVIDING THESE COMMUNICATIONS TO THE
21 BOARD, AND OBVIOUSLY THERE WILL BE A FURTHER
22 DISCUSSION AT THE BOARD AS WELL.

23 ANY QUESTIONS OR CONCERNS? OKAY. WITH
24 THAT IN MIND, THEN, I THINK THERE'S AN OPPORTUNITY
25 FOR PUBLIC COMMENT IF I'M NOT MISTAKEN. I'M NOT

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1 SURE WHO IS FIRST RELATED TO THAT.

2 MS. MANDAC: OKAY. SO THERE ARE TWO HANDS
3 RAISED FOR PUBLIC COMMENT. TERRI FIRST AND THEN
4 KATE. EACH OF YOU WILL GET THREE MINUTES EACH. I
5 AM KEEPING TIME. SO ONCE YOU HEAR THE CLOCK, I WILL
6 MUTE YOU. SO, TERRI.

7 DR. JONES: THANK YOU. I ALSO WANT TO
8 NOTE MY APPRECIATION BE KNOWN TO THE COMMITTEE FOR
9 ALL THE WORK THAT THEY DID FOR THIS. AND I JUST
10 WANT TO CLARIFY SOMETHING. I DON'T KNOW IF YOU CAN
11 ANSWER THIS OR NOT, BUT I WANT TO CONFIRM THAT I
12 HEARD THAT THE DEADLINE IS RIGHT FOR SUBMITTING A
13 CLIN2 GRANT IS NOW -- YOU THINK IT'S GOING TO BE AT
14 THE END OF JULY.

15 AND THE SECOND FOLLOW-UP TO THAT IS WOULD
16 YOU KNOW WHEN THE PORTAL WILL ACTUALLY OPEN?

17 DR. SAMBRANO: YES. OUR INTENT, ASSUMING
18 THAT WE GET APPROVAL BY THE BOARD IN JUNE, THAT THE
19 FIRST DEADLINE WOULD BE THE END OF JULY. AND OUR
20 GOAL WOULD BE TO OPEN THE PORTAL BY THE BEGINNING OF
21 JULY. SO IT GIVES YOU A SHORT WINDOW TO PUT AN
22 APPLICATION TOGETHER. WE NEED TO CREATE NEW
23 APPLICATIONS FOR THIS, BUT THAT IS OUR ESTIMATE AT
24 THE MOMENT.

25 DR. JONES: OKAY. THANK YOU. THAT'S ALL

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1 FOR ME.

2 MS. MANDAC: THANK YOU SO MUCH, TERRI.
3 KATE, YOU HAVE THE FLOOR.

4 DR. MASIUK: HI. THIS IS KATE MASIUK.
5 I'M A PROJECT SCIENTIST AT UCLA. I WANTED TO MAKE A
6 COMMENT ABOUT THE OBJECTIVE CRITERIA SCORING SYSTEM
7 AND SPECIFICALLY ABOUT THE CRITERIA THAT PRIORITIZES
8 APPLICATIONS WITH A GREATER PERCENTAGE OF CALIFORNIA
9 SPEND.

10 SO I KNOW FOR OUR PROGRAM, AND THIS
11 PROBABLY APPLIES TO MANY OF THE OTHER PROGRAMS AT
12 THESE LATER STAGES, A HUGE PERCENTAGE OF THE GRANT
13 BUDGET IS SPENT ON CELL AND POTENTIALLY VIRUS
14 MANUFACTURING. AND OFTEN THESE FACILITIES THAT MAKE
15 THESE PRODUCTS ARE VERY SPECIALIZED AND LOCATED
16 OUTSIDE OF CALIFORNIA. SO I JUST WORRY THAT THIS
17 CRITERIA COULD POTENTIALLY INCENTIVIZE APPLICANTS TO
18 PICK CALIFORNIA-BASED ORGANIZATIONS THAT MAY NOT
19 NECESSARILY BE THE BEST CHOICE FOR THEIR PROGRAM AND
20 COULD POTENTIALLY COMPROMISE THE SUCCESS OF THE
21 PROGRAM BY NOT BEING ABLE TO USE WELL-VETTED
22 MANUFACTURING FACILITIES OUTSIDE OF CALIFORNIA THAT
23 HAVE A GOOD TRACK RECORD. THAT'S MY COMMENT.

24 DR. SAMBRANO: WOULD YOU LIKE ME TO
25 RESPOND, MARK?

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1 CHAIRMAN FISCHER-COLBRIE: PLEASE.

2 DR. SAMBRANO: SO THANK YOU FOR THAT
3 COMMENT. AND IT IS SOMETHING THAT WE CONSIDERED. I
4 INCLUDED IT IN THE SLIDE AS ONE OF THE IDEAS THAT WE
5 INITIALLY HAD FOR OBJECTIVE CRITERIA. BUT YOU
6 PRESENTED ONE OF THE POTENTIAL REASONS WHY WE DON'T
7 WANT TO CONSIDER THAT, AND WE HAVE THOUGHT OF
8 ACTUALLY A COUPLE OF OTHERS. AND SO IN THE
9 SUBSEQUENT SLIDE, ON SLIDE 15, YOU MAY NOTICE THAT I
10 DIDN'T INCLUDE IT AS ONE OF THE ONES WE RECOMMENDED.
11 IT WAS ONE OF THE THINGS WE CONSIDERED, BUT THERE
12 ARE A LOT OF ELEMENTS THAT MAY MAKE IT DIFFICULT FOR
13 US TO ACTUALLY TRULY ASSESS OBJECTIVELY AND
14 SOMETHING THAT IS SUBJECT TO CHANGING OVER TIME. SO
15 WE CHOSE NOT TO INCLUDE IT AS ONE OF THE ONES WE
16 RECOMMENDED.

17 DR. MASIUK: THANK YOU FOR THE RESPONSE.

18 CHAIRMAN FISCHER-COLBRIE: OKAY. GREAT.
19 OKAY. WITH THAT, I BELIEVE THAT CONCLUDES THE
20 MEETING FOR TODAY UNLESS THERE ARE OTHER QUESTIONS
21 OR COMMENTS THAT THE CIRM STAFF WOULD LIKE TO BRING
22 UP.

23 OKAY. WITH THAT, WE CAN BE ADJOURNED.
24 THANK YOU SO MUCH FOR YOUR PARTICIPATION. MASSIVE
25 AMOUNT OF WORK HERE GOING ON BY THE CIRM TEAM. I'M

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1 IN AWE OF WHAT THEY'RE ABLE TO GET ACCOMPLISHED. SO
2 THANK, GUYS.

3 VICE CHAIR BONNEVILLE: THANKS, EVERYONE.
4 APPRECIATE IT.

5 (THE MEETING WAS THEN CONCLUDED AT 4:19 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 MAY 21, 2024, WAS HELD AS HEREIN APPEARS AND THAT THIS IS THE ORIGINAL TRANSCRIPT THEREOF AND THAT THE STATEMENTS THAT APPEAR IN THIS TRANSCRIPT WERE REPORTED STENOGRAPHICALLY BY ME AND TRANSCRIBED BY ME. I ALSO CERTIFY THAT THIS TRANSCRIPT IS A TRUE AND ACCURATE RECORD OF THE PROCEEDING.

BETH C. DRAIN, CA CSR 7152
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