

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: MARCH 19, 2026
2 P.M.

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

FILE NO.: 2026-9

**133 HENNA COURT, SANDPOINT, IDAHO 83864
208-920-3543 CACSR7152@OUTLOOK.COM**

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I N D E X

ITEM DESCRIPTION	PAGE NO.
OPEN SESSION	
1. CALL TO ORDER	3
2. ROLL CALL	3
3. DISCUSSION OF PROGRAM PREFERENCES AND GUIDING PRINCIPLES – CONTINUED FROM MEETING OF MARCH 5, 2026	5, 64
4. CONSIDERATION OF AMENDMENTS TO THE CONFERENCE GRANT CONCEPT PLAN (EDUC1)	59
CLOSED SESSION	
5. DISCUSSION OF CONFIDENTIAL INTELLECTUAL PROPERTY OR WORK PRODUCT, PREPUBLICATION DATA, FINANCIAL INFORMATION, CONFIDENTIAL SCIENTIFIC RESEARCH OR DATA, AND OTHER PROPRIETARY INFORMATION RELATING TO THE CIRM PORTFOLIO IN SUPPORT OF AGENDA ITEM 3. (HEALTH & SAFETY CODE 125290.30(F) (3) (B) AND (C)).	
OPEN SESSION	
6. PUBLIC COMMENT	
7. ADJOURNMENT	

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MARCH 19, 2026; 2 P.M.

CHAIRMAN FISCHER-COLBRIE: OKAY. LET'S
GET STARTED. WE HAVE A FULL AGENDA. SO LIKE TO
MOVE EXPEDITIOUSLY. SCOTT, IF YOU CAN CALL THE
ROLL.

MR. TOCHER: SURE. MARIA BONNEVILLE.

VICE CHAIR BONNEVILLE: PRESENT.

MR. TOCHER: MARK FISCHER-COLBRIE.

MR. FISCHER-COLBRIE: HERE.

MR. TOCHER: ELENA FLOWERS.

DR. FLOWERS: PRESENT.

MR. TOCHER: JUDY GASSON.

DR. GASSON: HERE.

MR. TOCHER: VITO IMBASCIANI.

CHAIRMAN IMBASCIANI: HERE.

MR. TOCHER: PAT LEVITT.

DR. LEVITT: HERE.

MR. TOCHER: SHLOMO MELMED. CAROLYN
MELTZER.

DR. MELTZER: HERE.

MR. TOCHER: CHRIS MIASKOWSKI. SHAUNA
STARK.

DR. STARK: HERE.

MR. TOCHER: KAROL WATSON. KEITH

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1 YAMAMOTO.

2 DR. YAMAMOTO: HERE.

3 MR. TOCHER: THANKS VERY MUCH. MARK, WE
4 HAVE A QUORUM.

5 CHAIRMAN FISCHER-COLBRIE: GREAT. AND
6 J.T., IF YOU'D LIKE TO TAKE IT AWAY. THANK YOU.

7 DR. THOMAS: YES. THANK YOU, MARK. RUN
8 OF SHOW HERE, I'M GOING TO GIVE VERY BRIEF
9 INTRODUCTORY COMMENTS, TURN IT OVER TO SHYAM, WHO
10 WILL TURN IT OVER TO GIL.

11 AS EVERYBODY RECALLS, WE HAD OUR SCIENCE
12 SUBCOMMITTEE MEETING ON MARCH 5TH AT WHICH THE TEAM
13 PRESENTED FOR YOUR CONSIDERATION THE NEW APPROACH
14 WHICH WAS INVOLVING GETTING RID OF PREFERENCES,
15 USING GUIDING PRINCIPLES, DOING SELECTION BASED ON
16 SCIENTIFIC MERIT, A NUMBER OF VOLUME CONTROL MOVES,
17 ET CETERA.

18 AT THAT MEETING THERE WERE A NUMBER OF
19 QUESTIONS THAT WERE RAISED AND REQUESTS FOR FURTHER
20 THOUGHT. THE TEAM HAS DILIGENTLY BEEN WORKING ON
21 ALL OF THAT AND HAVE TODAY READY FOR YOUR
22 CONSIDERATION PRESENTATIONS ON THOSE OUTSTANDING
23 QUESTIONS.

24 SO WITHOUT FURTHER ADO, LET ME TURN THINGS
25 OVER TO SHYAM.

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1 CHAIRMAN FISCHER-COLBRIE: THANKS, J.T.

2 DR. PATEL: THANK YOU, J.T. THANK YOU,
3 MARK. AND THANK YOU TO THE SCIENCE SUBCOMMITTEE FOR
4 MEETING AGAIN. I'M GOING TO SHARE MY SCREEN AND GO
5 THROUGH A FEW SLIDES. THEN WE'RE GOING TO PAUSE FOR
6 DISCUSSION, AND THEN WE'LL MOVE ON TO THE SECOND
7 TOPIC.

8 OKAY. SO THIS PRESENTATION IS GOING TO
9 FOCUS ON GUIDING PRINCIPLES AND REVIEW PROCESS
10 UPDATES. AGAIN, I'M SHYAM PATEL, ASSOCIATE VICE
11 PRESIDENT OF PRECLINICAL DEVELOPMENT AT CIRM, AND
12 I'LL BE HANDING IT OFF TO DR. GIL SAMBRANO, VP OF
13 REVIEW AT CIRM.

14 SO THIS IS GOING TO FOCUS ON THE ACCESS
15 STRATEGY DISCUSSION. AND WHAT WE'RE GOING TO GO
16 THROUGH IS WHAT WE'VE HEARD FROM THE BOARD AT THE
17 LAST SCIENCE SUBCOMMITTEE MEETING. THERE WERE A
18 COUPLE OF OUTSTANDING ITEMS THAT WE'RE ADDRESSING
19 TODAY. AND THEN CIRM'S PHILOSOPHY ON PATIENT
20 ACCESS: WHY THIS MATTERS AT THIS STAGE, PROPOSED
21 CHANGES AND QUESTIONS AS WE GO FORWARD. AND THEN
22 THERE'S GOING TO BE A CORRESPONDING PRESENTATION
23 FROM GIL ON THE REVIEW CRITERIA AND THE VOLUME
24 SELECTION PROCESS.

25 SO WITH RESPECT TO ACCESS AND

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1 AFFORDABILITY, WHAT WE HEARD FROM THE SCIENCE
2 SUBCOMMITTEE AT THE LAST MEETING WAS THAT THESE ARE
3 TWO DISTINCT TERMS AND SHOULD NOT BE CONFLATED. AND
4 THE ISSUE WAS WITH THE TERM "AFFORDABILITY" AND HOW
5 THAT CAN BE DEFINED IN DIFFERENT WAYS BY DIFFERENT
6 STAKEHOLDERS.

7 SO A CONCERN ALSO WAS THAT APPLICANTS
8 SHOULD NOT BE EXPECTED TO PROVE THEIR THERAPY WILL
9 BE AFFORDABLE AT A PARTICULAR STAGE, ESPECIALLY IN
10 PRECLINICAL DEVELOPMENT OR AT THE EARLY CLINICAL
11 TRIAL STAGE.

12 THERE WAS ALSO A CONCERN THAT
13 AFFORDABILITY CRITERIA MAY DISCOURAGE INNOVATION,
14 ESPECIALLY AT EARLY STAGES, BECAUSE THE FIRST
15 GENERATION OF A PARTICULAR TECHNOLOGY IS NOT
16 EXPECTED TO BE ALL THAT CHEAP.

17 AND THEN THAT STAGE-APPROPRIATE
18 EXPECTATIONS FOR ANY SORT OF ACCESS AND
19 AFFORDABILITY PLANNING MUST BE VERY CLEAR.

20 AND THEN LASTLY, THAT THERE'S A DESIRE FOR
21 TRANSPARENCY ON WHERE ACCESS AND AFFORDABILITY
22 INFORMS REVIEW VERSUS POST-AWARD PLANNING.

23 AND SO WE WILL BE JUMPING INTO ALL OF
24 THESE ELEMENTS TODAY. AND THANK YOU VERY MUCH FOR
25 YOUR VERY CLEAR AND VERY THOUGHTFUL FEEDBACK AT THE

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1 LAST MEETING AS WELL AS THE VARIOUS PRECALLS.

2 SO FIRST OF ALL, AS THE BOARD IS AWARE,
3 ACCESS AND AFFORDABILITY, BUT PARTICULARLY PATIENT
4 ACCESS, IS A KEY COMPONENT OF PROP 14. IT'S ALSO
5 EMBEDDED IN CIRM'S MISSION, AND IT ALSO WAS A
6 COMPONENT OF THE STRATEGIC ALLOCATION FRAMEWORK AND
7 THE IMPACT GOALS. IN PARTICULAR, WITH PATIENT
8 ACCESS, WHAT WE MEAN IS THAT THERAPIES THAT CIRM
9 FUNDS SHOULD BE ACCESSIBLE TO THE PATIENTS WHO NEED
10 THEM WHERE AND WHEN THEY NEED THEM.

11 AND SO CIRM'S ROLE IN THIS IS TO FUND
12 THERAPIES THAT CAN REACH PATIENTS IN CALIFORNIA,
13 ANTICIPATE BARRIERS TO ACCESS BASED ON THE CURRENT
14 WAVE OF GENE AND CELL THERAPIES THERE ARE IN THE
15 CLINIC OR IN THE MARKETPLACE. AND TO ENSURE AND
16 ENCOURAGE OUR CIRM-FUNDED PROJECTS TO KEEP PATIENT
17 ACCESS IN VIEW DURING DEVELOPMENT.

18 SO IN PRACTICE WHAT THIS MIGHT MEAN IS
19 THAT WE ARE CONSIDERING ACCESS AT THE RIGHT STAGE.
20 SO THERE'S GOING TO BE CERTAIN ASPECTS OF PATIENT
21 ACCESS THAT NEED TO BE FACTORED INTO THE DESIGN,
22 DEVELOPMENT, MANUFACTURING, TESTING, AND DELIVERY OF
23 THE THERAPIES THAT WE FUND. SOME OF THOSE ARE GOING
24 TO BE APPROPRIATE AT THE PRECLINICAL STAGE, SOME AT
25 THE FIRST-IN-HUMAN CLINICAL TRIAL, AND THEN THE

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1 PLANNING AND ACTIVITIES REALLY RAMP UP AS WE GET
2 LATER AND LATER TOWARD BLA FILING.

3 WE ALSO WANT TO MAKE SURE THAT WE ALIGN
4 THE DEVELOPMENT OF THESE THERAPIES WITH THE
5 REAL-WORLD DELIVERY OF THESE THERAPIES TO THE
6 PATIENTS, SUPPORTING THE CLINICAL TRIAL SETTING AS
7 WELL AS IN THE COMMERCIAL SETTING. AND WE WANT TO
8 MAKE SURE THAT WE SUPPORT AND FUND THE READINESS FOR
9 PATIENT ACCESS. AND THAT'S A BIG COMPONENT OF OUR
10 ACCESS AND AFFORDABILITY PLANNING CHECKLIST AS WELL
11 AS IMPLEMENTATION OF THAT, WHICH WE'LL GET INTO IN A
12 LITTLE BIT.

13 SO WHAT ALL THIS DOES MEAN IS THAT WE'RE
14 NOT ACTUALLY EXPECTING A DISCUSSION OR ANY SORT OF
15 REAL LEVERAGE ON THERAPY PRICING AT A VERY EARLY
16 STAGE. WE'RE ALSO NOT EXPECTING OUR AWARDEES TO
17 DRAMATICALLY CHANGE REIMBURSEMENT POLICY, BUT WE ARE
18 EXPECTING THEM TO THINK ABOUT HOW THEIR DECISIONS
19 AND THE DATA THEY GENERATE IS GOING TO EVENTUALLY
20 SUPPORT COVERAGE OR REIMBURSEMENT DECISIONS IF THAT
21 THERAPY WERE TO BE APPROVED.

22 AND LASTLY, AS EXPECTED, WE WANT TO MAKE
23 SURE THAT THERE'S A VIABLE PATH TO ACCESS OF THESE
24 THERAPIES FOR PATIENTS.

25 SO ULTIMATELY TO IMPROVE CLARITY, CIRM

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1 WILL REFER TO ACCESS AND AFFORDABILITY AS PATIENT
2 ACCESS OR ACCESS STRATEGY, EMPHASIZING PLANNING FOR
3 PATIENT ACCESS DURING DEVELOPMENT RATHER THAN DRUG
4 PRICING CONSIDERATIONS OR POLICY CHANGES.

5 SO THIS SLIDE OUTLINES SOME PATIENT ACCESS
6 CONSIDERATIONS THAT MAY BE APPROPRIATE AND THAT CAN
7 MAKE A DIFFERENCE AT BOTH THE PDEV AND CLIN2 STAGE.
8 THE MEMO WE PROVIDED HAS A LITTLE BIT MORE EXAMPLES
9 THAT ARE MORE TANGIBLE, BUT HERE I'M GOING TO KEEP
10 IT RELATIVELY HIGH LEVEL.

11 SO ON THE PDEV SIDE, FOR EXAMPLE, AS I
12 MENTIONED EARLIER, THERE'S CONTROL OF THE AWARDEE IN
13 TERMS OF THE DESIGN, DEVELOPMENT, MANUFACTURING, AND
14 DELIVERY DECISIONS FOR THE THERAPY THAT THEY'RE
15 DEVELOPING. PARTICULARLY, OUR MANUFACTURING WHERE
16 THEY MAY BE DOING SOME OPTIMIZATION AT THE PDEV
17 STAGE AND PLANNING FOR ADDITIONAL OPTIMIZATION WHEN
18 THEY GET CLOSER TO LATE STAGE CLINICAL THAT WOULD
19 IMPACT TIME AND COST FOR DELIVERY.

20 SIMILARLY, HOW THEY DECIDE ON TREATMENT
21 REGIMEN AND TRIAL DESIGN AND HOW THEY ALIGN THAT
22 WITH PATIENT NEEDS AND STANDARD OF CARE IS REALLY
23 IMPORTANT AT THIS STAGE.

24 IF THEY ARE DOING EARLY PATIENT ENGAGEMENT
25 PLANNING, THAT WOULD HELP ACCELERATE ENROLLMENT IF

1 AND WHEN THAT PARTICULAR THERAPY REACHES CLINICAL
2 TRIAL .

3 AND LASTLY, ANY MARKET AND PAYER LANDSCAPE
4 RESEARCH THAT THEY MIGHT DO AT THIS EARLY STAGE
5 WOULD PUT THEM A STEP AHEAD WHEN THEY HAVE TO
6 CONSIDER THOSE ELEMENTS AND HAVE THOSE ELEMENTS
7 FACTORED INTO THEIR ACTIVITIES LATER IN CLINICAL
8 DEVELOPMENT .

9 ON THE CLIN2 SIDE, DURING PHASE 1 TRIAL ,
10 THEY'RE LARGELY FOCUSING ON ACCESS TO PATIENTS IN
11 THE TRIAL ITSELF; BUT AS THEY PLAN FOR LATER STAGE
12 TRIALS, THEY COULD BE INCORPORATING CLINICAL
13 ENDPOINTS INTO THAT TRIAL DESIGN FOR LATER STAGE
14 TRIALS. THAT WILL HELP GENERATE EVIDENCE FOR
15 PAYERS. AND ALSO IF THEY'RE DEVELOPING INCLUSION
16 CRITERIA FOR THOSE LATER STAGE TRIALS, MAKING SURE
17 THAT THOSE ARE GOING TO HELP DRIVE DOWN THE ROAD, IF
18 APPROVED, COVERAGE DECISIONS AND REIMBURSEMENT
19 DECISIONS .

20 THEY CAN ALSO IDENTIFY POTENTIAL BARRIERS
21 TO ADOPTION OVER THE COURSE OF THESE TRIALS BASED ON
22 THEIR EXPERIENCE OF TRIAL OPERATIONS .

23 AND LASTLY, THEY MAY SET UP PATIENT
24 REGISTRIES THAT COLLECT LONG-TERM, REAL-WORLD DATA
25 THAT ULTIMATELY WILL HELP INFORM THEIR DISCUSSIONS

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1 WITH PAYERS IF THAT THERAPY IS APPROVED.

2 WITH ALL THAT IN MIND, WE ARE PROPOSING
3 CHANGES TO THE GUIDING PRINCIPLES FOR BOTH THE PDEV
4 AND CLIN2 PROGRAMS, IN PARTICULAR THE SECOND GUIDING
5 PRINCIPLE. AND IT'S HIGHLIGHTED IN RED HERE AND IS
6 LARGELY THE SAME ACROSS BOTH PROGRAMS.

7 ON THE PDEV SIDE, WE WANT TO ADVANCE
8 STRATEGIES TO IMPROVE PATIENT ACCESS TO STEM
9 CELL-BASED AND GENETIC THERAPIES. AND THE WORD
10 "STRATEGY" HERE IS MEANT TO ENCOMPASS THE FACT THAT
11 THERE COULD BE THINGS THAT THEY COULD BE DOING THAT
12 INFORM THE IMMEDIATE DEVELOPMENT OF THAT THERAPY,
13 BUT ALSO PLANNING FOR HOW THIS THERAPY IS GOING TO
14 BE DELIVERED IN A CLINICAL SETTING AND PLANNING FOR
15 FUTURE ACCESS CONSIDERATIONS AS WELL.

16 ON THE CLIN2 SIDE, THE PROJECTS WILL BE
17 ACTIVELY ADDRESSING KNOWN BARRIERS TO ACCESS OF STEM
18 CELL AND GENETIC THERAPIES, BOTH IN THE CLINICAL
19 TRIAL SETTING, BUT ALSO PLANNING FOR FUTURE ACCESS
20 OF THOSE THERAPIES IF THAT THERAPY IS APPROVED.

21 SO WITH THAT IN MIND, THE CHANGES TO THE
22 PDEV PROGRAM ARE LISTED HERE. THESE ARE CHANGES
23 THAT ARE IN LINE WITH EVERYTHING WE'VE SPOKEN ABOUT
24 SO FAR. SO THE GOAL HERE IS A THERAPY IS DESIGNED
25 AND DEVELOPED WITH PATIENT ACCESS IN MIND. AND WHAT

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1 WE WANT TO DO IS BE ABLE TO TEASE OUT, BOTH IN THE
2 APPLICATION AND THE GRANTS WORKING GROUP REVIEW, A
3 MORE COMPREHENSIVE APPROACH TO HOW PATIENT ACCESS
4 CONSIDERATIONS ARE BEING INCORPORATED INTO THE
5 DEVELOPMENT DECISIONS FOR THAT PARTICULAR THERAPY.

6 SO THE GUIDING PRINCIPLE, AS YOU SAW,
7 FOCUSES ON THAT OVERALL STRATEGY. IN THE
8 APPLICATION WE'RE POSITIONING THE APPLICANT TO
9 PROVIDE A MORE COMPREHENSIVE DISCUSSION OF PATIENT
10 ACCESS BARRIERS AND FEASIBLE, STAGE-APPROPRIATE
11 STRATEGIES FOR THE PROPOSED THERAPY. SO IN THE MEMO
12 WE LISTED OUT WHERE IN THE APPLICATION PROPOSAL
13 TEMPLATE THESE INSTRUCTIONS WILL BE EMBEDDED. AND
14 WE'VE IDENTIFIED SOME AREAS THAT THEY CAN
15 POTENTIALLY ELABORATE ON ON HOW PATIENT ACCESS
16 CONSIDERATIONS MIGHT IMPACT THE DEVELOPMENT OF THAT
17 THERAPY.

18 ON THE GRANTS WORKING GROUP REVIEW SIDE,
19 WE WILL BE ASKING THE REVIEWERS TO ASSESS THE
20 APPLICANT'S OVERALL STRATEGY AND THE
21 STAGE-APPROPRIATE ACTIONS THEY'RE TAKING NOW FOR THE
22 PROPOSED THERAPY FOR THE INTENDED PATIENTS. SO
23 WHAT'S REALLY IMPORTANT HERE IS THAT WE REALLY WANT
24 THEM TO FOCUS ON THIS PARTICULAR THERAPY FOR THIS
25 INTENDED PATIENT POPULATION, WHAT ARE THE ACCESS

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1 CONSIDERATIONS, AND HOW ARE THEY ADDRESSING THEM OR
2 IMPROVING ON THEM.

3 ON THE CLIN2 SIDE, WE ARE PROPOSING A
4 COUPLE OF CLARIFICATIONS. SO THE GOAL, AGAIN, FOR
5 CLIN2 WOULD BE THERAPIES ENTERING LATE STAGE
6 CLINICAL DEVELOPMENT HAVE A VIABLE PATH TO PATIENT
7 ACCESS. SO I ALREADY WENT THROUGH THE GUIDING
8 PRINCIPLE. ON THE APPLICATION, THE APPLICATION WILL
9 ALSO BE POSITIONED SO THAT THE APPLICANT IS
10 PROVIDING A MORE COMPREHENSIVE DISCUSSION OF PATIENT
11 ACCESS BARRIERS AND FEASIBLE STAGE-APPROPRIATE
12 STRATEGIES FOR THE PROPOSED THERAPY. THIS IS PART
13 OF THE ACCESS PLAN DOCUMENT THAT IS INCLUDED IN THE
14 CLIN2 APPLICATION.

15 ON THE GRANTS WORKING GROUP REVIEW SIDE,
16 UNLIKE THE PDEV PROGRAM, THE CLIN2 PROGRAM HAS
17 ACCESS SPECIALISTS THAT ASSESS THE APPLICANT'S
18 ACCESS STRATEGY IN TERMS OF WHAT THEY'RE PLANNING
19 AND HOW THAT PLANNING MIGHT HELP INFLUENCE LATER
20 STAGE DEVELOPMENT AS WELL AS COMMERCIALIZATION OF
21 THAT THERAPY. AND SO HERE THE PATIENT ACCESS
22 STRATEGY FOR THE PROPOSED THERAPY FOR THE INTENDED
23 PATIENTS IS REVIEWED BY THAT ACCESS SPECIALIST AS
24 PART OF THE OVERALL GRANTS WORKING GROUP REVIEW.

25 SO THIS IS GOING TO BE, I THINK, THE LAST

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1 SLIDE ON THIS PARTICULAR TOPIC. I'M GOING TO HAVE
2 THE ANIMATION COME UP. SO THERE IS ONE AREA THAT WE
3 SEEK BOARD INPUT, AND THAT IS ON THAT LAST POINT
4 THAT I JUST MENTIONED, WHICH IS THE ACCESS
5 SPECIALIST REVIEW AND COMMENTS THAT ARE INCORPORATED
6 INTO THE GRANTS WORKING GROUP REVIEW.

7 SO RIGHT NOW AN APPLICANT FOR CLIN2 IS
8 PROPOSING STAGE-APPROPRIATE ACTIVITIES THAT THEY'VE
9 ALREADY COMPLETED ON ACCESS PLANNING AND ACTIVITIES
10 THEY PLAN TO DO AS PART OF THE CLIN2 AWARD. AND
11 THIS IS BASED ON THE ACCESS PLAN CHECKLIST AND
12 RESOURCES THAT WE'VE DEVELOPED IN COORDINATION WITH
13 EXPERTS WHO HAVE EXPERIENCE DIRECTLY IN SUPPORTING
14 THE COMMERCIALIZATION OF CELL AND GENE THERAPIES.
15 THAT ACCESS PLANNING RESOURCES AND CHECKLIST WERE
16 REVIEWED LAST YEAR BY THE AAWG AND THEY WERE
17 APPROVED BY THEM. AND THEY'VE BEEN IMPLEMENTED AND
18 HAVE BEEN IN EXISTENCE THE LAST COUPLE OF CLIN2
19 ROUNDS.

20 SO IN THOSE ROUNDS THE SPECIALISTS WHO ARE
21 EXPERTS IN ACCESS PLANNING AND MARKET ACCESS
22 STRATEGY REVIEW THE ACCESS PLAN OF EVERY CLIN2
23 APPLICATION THAT'S UP FOR GWG REVIEW AND THEY
24 PROVIDE COMMENTS. AND THOSE COMMENTS ARE ACTUALLY
25 PROVIDED DURING THE GRANTS WORKING GROUP REVIEW.

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1 AND SO THIS IS THE CURRENT PROCESS. WE RECOMMEND
2 STAYING WITH THIS PROCESS BECAUSE IT ALLOWS THE
3 GRANTS WORKING GROUP TO FACTOR IN THE ACCESS PLAN
4 READINESS. AND THIS IS PARTICULARLY RELEVANT FOR
5 LATE STAGE TRIALS WHICH ARE GOING TO BE ON A RAPID
6 PATH TO BLA.

7 THE CONS OF THIS APPROACH ARE THAT HOW THE
8 GWG FACTORS IN THE ACCESS SPECIALIST COMMENTS ARE
9 DIFFICULT TO QUANTIFY AS PART OF THEIR OVERALL
10 GRANTS WORKING GROUP RECOMMENDATION SCORE.

11 AN ALTERNATE APPROACH WOULD BE TO HAVE THE
12 SPECIALIST INPUT PROVIDED DIRECTLY TO THE ARS, BUT
13 NOT THE GWG. SO THIS WOULD BE AN ADDITIONAL SUMMARY
14 THAT WOULD GO TO THE ARS ON TOP OF THE GRANTS
15 WORKING GROUP RECOMMENDATION SUMMARY THAT WOULD
16 OUTLINE ALL OF THE ACCESS SPECIALIST COMMENTS FOR
17 THAT PARTICULAR APPLICATION.

18 THE ADVANTAGE OF THIS WOULD BE THAT IT
19 PROVIDES A DISTINCT ACCESS PLAN EVALUATION TO THE
20 ULTIMATE DECIDERS, WHICH IS THE ARS. AND THE
21 DISADVANTAGE IS THAT THERE IS NO IMPACT ON GRANTS
22 WORKING GROUP SCORING. SO THE GRANTS WORKING GROUP
23 WOULD NOT HAVE A VIEW INTO THE ACCESS SPECIALIST
24 COMMENTS AND SCORING AND WOULD NOT BE ABLE TO FACTOR
25 THAT INTO THEIR OWN FUNDING RECOMMENDATION.

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1 SO I'M GOING TO PAUSE THERE -- ACTUALLY
2 THERE'S ONE MORE SLIDE. I APOLOGIZE.

3 SO THIS IS JUST A SUMMARY. I'M GOING TO
4 LET ALL THE ANIMATION COME UP FIRST BEFORE I GET
5 INTO IT. BUT THIS IS BASICALLY A SUMMARY OF
6 EVERYTHING I'VE JUST TALKED ABOUT, WHICH IS TO SAY
7 ON THE PDEV SIDE WE ARE MAKING CHANGES TO THE
8 GUIDING PRINCIPLE, THE SELECTION AND GRANTS WORKING
9 GROUP CRITERIA, AS WELL AS THE APPLICATION TO
10 ACCOUNT FOR A MORE COMPREHENSIVE APPROACH TO PATIENT
11 ACCESS CONSIDERATIONS AND THE PATIENT ACCESS
12 STRATEGY FOR THAT PARTICULAR THERAPY THAT'S BEING
13 PROPOSED FOR THE INTENDED PATIENT POPULATION.

14 DURING THE AWARD WE WILL KEEP THE
15 EXPECTATION THAT THE PDEV AWARDEES ARE USING CIRM
16 FUNDING TO DO MARKET AND REIMBURSEMENT LANDSCAPE
17 RESEARCH TO HELP THEM SET UP FOR A CLINICAL TRIAL
18 DOWN THE ROAD.

19 ON THE CLIN2 SIDE, WE ARE CHANGING THE
20 GUIDING PRINCIPLE. WE'RE NOT MAKING ANY CHANGES TO
21 THE SELECTION CRITERIA. WE DO ASK FOR THE BOARD'S
22 INPUT ON HOW THE ACCESS SPECIALIST COMMENTS SHOULD
23 BE FACTORED INTO THE GRANTS WORKING GROUP REVIEW OR
24 THE ARS REVIEW. AND THEN LASTLY, THERE'S NO CHANGES
25 BEING MADE TO THE AWARD WHICH INVOLVES MANAGEMENT OF

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1 THE ACTIVITIES THAT THE AWARDEE HAS PROPOSED.

2 ALL RIGHT. WE'LL GET TO THE QUESTIONS
3 NOW. I'M HAPPY TO GO BACK TO ANY SLIDES IF NEEDED,
4 BUT WE'RE GOING TO PAUSE HERE AND TAKE THE BOARD'S
5 COMMENTS ON THE PATIENT ACCESS PLANNING STRATEGY.

6 CHAIRMAN FISCHER-COLBRIE: GREAT, SHYAM.
7 AND IF YOU CAN MODERATE THAT BECAUSE I WON'T BE ABLE
8 TO SEE ALL THE HANDS RAISED.

9 DR. PATEL: OF COURSE.

10 MR. TOCHER: LOOKS LIKE PAT.

11 DR. PATEL: PAT.

12 DR. LEVITT: YEAH. SO THANKS, SHYAM. THE
13 EDITS AND THE CHANGES IN TERMS OF WHAT WAS DISCUSSED
14 AT THE LAST MEETING IN TERMS OF FOCUSING ON
15 ACCESSIBILITY AND NOT AFFORDABILITY, WHICH I THINK
16 THERE WAS A LOT OF VOICES ABOUT INVESTIGATORS NOT
17 BEING ABLE TO CONTROL THAT VERY WELL OR EVEN ADDRESS
18 IT, I THINK THOSE ARE ALL GREAT CHANGES. SO THANKS
19 TO THE TEAM FOR WORKING SO QUICKLY TO MAKE THOSE
20 EDITS. AND I THINK THE WAY YOU DESCRIBED THEM, TO
21 ME, SEEMS LIKE VERY APPROPRIATE.

22 THE ACCESSIBILITY COMPONENT IS SOMEWHAT
23 COMPLICATED, BUT THERE ARE COMPLICATIONS WHEN YOU
24 LOOK AT OTHER FUNDING ORGANIZATIONS THAT LOOK AT
25 THINGS LIKE INFRASTRUCTURE AND ENVIRONMENT THAT ARE

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1 NOT NECESSARILY SCORED, BUT ARE TAKEN INTO ACCOUNT.
2 THAT IS, THEY'RE NOT INDIVIDUALLY SCORED, BUT
3 THEY'RE TAKEN INTO ACCOUNT IN SORT OF A HOLISTIC
4 WAY. WHETHER THOSE COMMENTS GO TO THE GWG OR ARS,
5 THERE ARE OTHER PEOPLE ON THIS COMMITTEE THAT CAN
6 SPEAK TO THAT BETTER THAN I, BUT I THINK IT'S NOT
7 UNCOMMON TO HAVE COMMENTS ABOUT COMPONENTS THAT ARE
8 NOT INDIVIDUALLY SCORED, BUT NONETHELESS WILL HAVE
9 AN IMPACT ON RECOMMENDATIONS FOR FUNDING OR NOT. I
10 JUST WANTED TO SAY SO IT'S NOT UNUSUAL. I DON'T
11 THINK IT NEEDS A SCORE, BUT I DO THINK THE COMMENTS
12 CAN BE USED FOR MAKING FINAL DECISIONS ABOUT
13 FUNDING. AND WHETHER THAT'S THE GWG OR THE ARS,
14 MAYBE THE ARS INCORPORATING THAT INTO THEIR FINAL
15 RECOMMENDATIONS MAY BE THE WAY TO GO, BUT OTHERS MAY
16 HAVE BETTER INSIGHT THAN I DO. BUT THANKS FOR THE
17 EDITS.

18 DR. PATEL: THANK YOU SO MUCH, PAT. AND I
19 DO WANT TO ON BEHALF OF THE TEAM ACKNOWLEDGE AND
20 THANK YOU FOR YOUR COMMENTS ON AFFORDABILITY AND
21 YOUR CRITICAL AND CONSTRUCTIVE FEEDBACK ON THAT. I
22 KNOW IT'S BEEN CONSISTENT OVER THE LAST FEW
23 MEETINGS. CAROLYN.

24 DR. MELTZER: YEAH. I'M SHORT BECAUSE I
25 HAD ALSO THOUGHT THAT THESE WERE IMPORTANT CHANGES.

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1 IT'S DEFINITELY APPROPRIATE THAT THE INVESTIGATORS
2 THINK ABOUT ACCESS AND HAVE A PLAN FOR THE THERAPY
3 TO HAVE IMPACT. AGREE WITH THE CHANGES THOUGH.

4 DR. PATEL: THANK YOU, CAROLYN. MARIA HAS
5 HER HAND UP AS WELL.

6 VICE CHAIR BONNEVILLE: I JUST WANTED TO
7 SPEAK TO WHERE THE COMMENTS SHOULD GO AND HOW THE
8 DECISION SHOULD BE MADE. I THINK HAVING IT LIVE IN
9 THE GWG IS WHERE MY TENDENCY GOES. I THINK IT
10 OFFERS A CHANCE FOR ROBUST CONVERSATION AMONGST THE
11 CONSULTANTS THAT ARE PROVIDING THE COMMENTS AND THE
12 PATIENT ADVOCATE GWG MEMBERS AS WELL AS THE
13 SCIENTIFIC MEMBERS OF THAT COMMITTEE.

14 I THINK BYPASSING THAT AND GOING STRAIGHT
15 TO THE ARS WITH THE COMMENTS SORT OF CUTS THAT OUT.
16 AND SO THERE'S NOT A CONTINUED CONVERSATION. I ALSO
17 THINK OFTENTIMES THERE ARE QUESTIONS THAT WE MAY NOT
18 BE ABLE -- THAT ARE CONFIDENTIAL AND WE MAY NOT BE
19 ABLE TO ADDRESS IN PUBLIC. WE'D HAVE TO GO INTO
20 CLOSED SESSION. IT JUST -- IT CREATES MORE OF A
21 LOGISTICAL ISSUE. THAT'S NOT TO SAY IT CAN'T HAPPEN
22 THERE. I JUST DON'T THINK IT'S THE RIGHT PLACE.

23 WE'VE ALSO BEEN TALKING INTERNALLY ABOUT
24 HAVING SOME -- ONE OF THE CRITICISMS IS THAT THE GWG
25 MEMBERS ARE NOT THE EXPERTS IN THIS AND CAN'T JUDGE

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1 WHETHER -- CAN'T WEIGH IN BECAUSE THEY'RE NOT THE
2 EXPERTS. WE'VE TALKED ABOUT, JUST AS WE HAVE SOME
3 EXPERTS WHO SIT AS GWG MEMBERS THAT ARE MORE FOCUSED
4 ON REGULATORY OR MANUFACTURING OR OTHER PARTS OF THE
5 PROGRAM OR THE PROJECT. WE COULD ALSO HAVE GWG
6 MEMBERS THAT ARE SPECIALISTS IN ACCESS IN ADDITION
7 TO THE CONSULTANTS THAT WOULD THEN SORT OF REMEDY
8 THAT ONE THOUGHT THAT PERHAPS THE GWG IS NOT THE
9 RIGHT PLACE.

10 SO I THINK IT SHOULD LIVE THERE, AND THEN
11 THOSE RECOMMENDATIONS GO TO THE ARS. THE TEAM, THE
12 INTERNAL TEAM ALSO WILL HAVE THE OPPORTUNITY TO MAKE
13 RECOMMENDATIONS. SO IF THERE'S SOMETHING THAT'S
14 MISSED, THEY CAN WEIGH IN AND LET THE ARS KNOW. I
15 THINK IT JUST PROVIDES A MORE ROBUST REVIEW OF THIS
16 PROCESS IN TWO PLACES, GWG AND THE ARS. SO THAT
17 WOULD BE MY COMMENT. THANK YOU.

18 DR. PATEL: THANK YOU, MARIA. VITO.

19 CHAIRMAN IMBASCIANI: THANK YOU. MARIA
20 AND I DID NOT COLLABORATE OR PUT OUR HEADS TOGETHER
21 IN THINKING UP A RESPONSE TO THIS. I WAS LISTENING
22 TO SHYAM'S PRESENTATION THINKING I'M AGNOSTIC WHERE
23 THE ACCESS SPECIALIST REPORT GOES, WHETHER TO GWG OR
24 ARS. BUT THEN I REALIZED, SINCE I LEAD THE
25 DISCUSSION AT THE FULL AND OPEN MEETING ON THIS,

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1 THAT I SHOULD NOT BE. AND I AGREE. I THINK FOR
2 DIFFERENT REASONS THAT IT SHOULD RESIDE, CONTINUE TO
3 RESIDE WITH GRANTS WORKING GROUP. BOTH THE ARS AND
4 THE GWG ARE BOTH, WHEN THEY CONVENE, ARE IN THE
5 PROCESS ACTIVELY OF EVALUATING GRANTS. BUT THE GWG
6 IS MORE IN THE BUSINESS OF QUANTIFYING AND GIVING
7 SCORES AND NUMERICAL VALUES. WHERE BY THE TIME IT
8 COMES TO THE ARS, IT'S MORE A RANKING EXERCISE OF
9 WHICH X OUT OF HOW MANY GRANTS CAN BE ACCOMMODATED
10 BY THE BUDGET.

11 AND FOR THAT REASON, I THINK IT HAS A MORE
12 LOGICAL HOME WITH THE GWG. THANKS.

13 DR. PATEL: THANK YOU, VITO. WE'RE NOT
14 SEEING ANY OTHER HANDS UP AT THE MOMENT. WE CAN
15 MOVE ON TO GIL'S PRESENTATION. I'M GOING TO DRIVE
16 THE SLIDES.

17 DR. SAMBRANO: ALL RIGHT. THANK YOU VERY
18 MUCH. YOU CAN GO ON TO THE NEXT ONE.

19 SO I ALSO WANT TO EXTEND MY THANKS TO ALL
20 OF THE COMMITTEE MEMBERS FOR YOUR FEEDBACK AND
21 ADVICE THAT WE'VE GOTTEN OVER THE LAST COUPLE OF
22 WEEKS. IT'S BEEN VERY USEFUL AND HELPFUL IN
23 IMPROVING THE PROCESS. SO I DO APPRECIATE THAT.

24 SO HERE'S JUST A SUMMARY OF WHAT WE HEARD
25 FROM THE LAST MEETING. THERE WERE ELEMENTS THAT

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1 WERE UNCLEAR TO THE COMMITTEE, INCLUDING THAT IT WAS
2 DIFFICULT TO UNDERSTAND HOW REVIEWER SELECTIONS
3 WOULD AFFECT OUTCOMES. THERE WAS A LACK OF CLARITY
4 ON THE COMPOSITE SCORE DETERMINATION AS WELL AS HOW
5 THE CUTOFF ITSELF IS DETERMINED. AND THEN THERE WAS
6 ALSO A QUESTION ABOUT THE ROLE OF PATIENT ADVOCATE
7 MEMBERS IN THE SELECTION PROCESS ITSELF. SO I WILL
8 ADDRESS THOSE ELEMENTS AS WE MOVE FORWARD. SO GO TO
9 THE NEXT SLIDE.

10 AND SO OUR GOAL HERE IS TO CREATE A
11 PROCESS ULTIMATELY THAT IS FOCUSED ON ASSESSING
12 SCIENTIFIC VALUE BASED ON THE GUIDING PRINCIPLES, AS
13 WAS PREVIOUSLY NOTED, BUT ALSO ONE THAT IS FAIR.
14 MEANING THAT IT GIVES AN EQUAL OPPORTUNITY TO ALL
15 APPLICANTS THAT COME IN TO ADVANCE TO A FULL REVIEW.

16 AND SO THE PROCESS THAT I WILL DESCRIBE BY
17 EXAMPLE HERE IS ONE THAT WE WOULD APPLY TO ALL
18 PROGRAMS THAT REQUIRE VOLUME CONTROL. SO IN THIS
19 CASE, DISC4, DISC5, PDEV, CLIN2. THE TARGET NUMBER
20 OF APPLICATIONS, THEN, FOR A FULL GRANTS WORKING
21 GROUP PANEL DISCUSSION IS THE FIRST THING THAT WE
22 ESTABLISHED. AND THAT IS BASED ON ENSURING THAT
23 WHATEVER GOES TO THE GRANTS WORKING GROUP PANEL
24 DISCUSSION ALLOWS FOR A MUCH DEEPER, RIGOROUS REVIEW
25 OF A FULLER SET OF CRITERIA THAN AT THE VOLUME

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1 CONTROL STAGE.

2 SO ONCE WE HAVE THAT TARGET NUMBER AND WE
3 GET SUBMISSIONS FOR A GIVEN CALL, THOSE TWO NUMBERS
4 SET UP WHAT THE PARAMETERS FOR DOING THE GRANTS
5 WORKING GROUP SELECTION WOULD BE. AND SO AS SUCH,
6 AGAIN, WE FOCUS ON A SCIENTIFIC VALUE. AND I'LL
7 SHOW YOU A TABLE IN THE NEXT SLIDE THAT BASICALLY
8 SHOWS YOU THAT ACROSS THE DIFFERENT PROGRAMS, WE
9 HAVE DIFFERENT SIZES IN TERMS OF APPLICATION POOLS,
10 SO THESE ARE JUST APPROXIMATIONS, AND DIFFERENT
11 TARGETS THAT WOULD GO TO THE GRANTS WORKING GROUP
12 PANEL. AND THIS IS WHAT WE WOULD GENERALLY -- AND
13 THESE APPROXIMATE WHAT WE WOULD EXPECT ACROSS THESE
14 FOUR FUNDING PROGRAMS.

15 AND SO THOSE SET UP DIFFERENT TOTAL NUMBER
16 OF APPLICATIONS PER REVIEWER, HOW MANY REVIEWS PER
17 APPLICATION WOULD HAVE TO HAPPEN, AND REVIEWS
18 PER -- WHEN WE TALK ABOUT REVIEWS HERE, IT IS AN
19 INITIAL HIGH LEVEL REVIEW. IT'S NOT AN IN-DEPTH
20 REVIEW OF THE APPLICATION. IT IS WHAT WE'RE ASKING
21 THEM TO DO AT THIS STEP. AND I'LL GO INTO THAT A
22 LITTLE MORE.

23 I WANT TO DO THAT BY EXAMPLE. SO WE'RE
24 GOING TO DO THE PDEV COLUMN HIGHLIGHTED HERE. AND
25 SO IF WE JUST FOLLOW THE NUMBERS HERE, THE

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1 APPLICATION POOL OF ABOUT 75 APPLICATIONS TARGETING
2 ABOUT 30, THIS IS WHAT IT WOULD LOOK LIKE. SO NEXT
3 SLIDE.

4 SO WE START WITH OUR POOL OF ABOUT 75
5 APPLICATIONS. AND SO WE TAKE THAT POOL AND WE SPLIT
6 IT INTO 20 OVERLAPPING BATCHES OF 15 EACH. AND IT'S
7 20 BECAUSE WE'RE GOING TO ASSUME WE HAVE 20
8 REVIEWERS TOTAL THAT ARE GOING TO LOOK AT THESE
9 APPLICATIONS, AND EACH OF THEM IS GOING TO GET
10 EXACTLY 15. AND WE'RE GOING TO ALSO ASK THEM FOR
11 EACH REVIEWER TO SELECT AND RANK THEIR TOP FIVE OUT
12 OF THE 15 THAT WE GIVE THEM. AND SO WE'RE GOING TO
13 FOLLOW THE LITTLE RED EXAMPLE APPLICATION. SO WHAT
14 HAPPENS TO AN APPLICATION, WE'LL TAKE IT THROUGH.
15 THAT APPLICATION IS GOING TO BE CONTAINED IN FOUR
16 DIFFERENT BATCHES OF FOUR DIFFERENT REVIEWERS. AND
17 EACH OF THOSE REVIEWERS WILL LOOK THROUGH THEIR
18 BATCH OF 15. AND IN THIS EXAMPLE, REVIEWER 1
19 SELECTED THAT APPLICATION AND RANKED IT THEIR
20 FAVORITE, NO. 1. REVIEWER 2 ALSO SELECTED IT AND
21 RANKED IT THEIR SECOND BEST. REVIEWER 3 DID NOT
22 SELECT IT. REVIEWER 4 ALSO SELECTED IT AND RANKED
23 IT NO. 1. AND SO THAT'S THE PARAMETERS, THEN, THAT
24 WE WORK OFF OF -- IF YOU GO TO THE NEXT SLIDE -- IN
25 ORDER TO DERIVE A SCORE.

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1 SO BASED ON THE SELECTION AND RANK FROM
2 THOSE FOUR REVIEWERS, WE DEVELOP A COMPOSITE SCORE
3 FOR EACH APPLICATION. AND SO IN THE NEXT SLIDE I'LL
4 SHOW YOU WHAT THE COMPOSITE SCORE LOOKS LIKE.

5 ALL RIGHT. SO EACH APPLICATION IS GOING
6 TO BE GIVEN A COMPOSITE SCORE THAT COMBINES TWO
7 DIFFERENT MEASURES, SELECTION AS WELL AS RANK. AND
8 SO THE SELECTION IS THE FRACTION OF ASSIGNED
9 REVIEWERS THAT PICKED THE APPLICATION. SO AN
10 EXAMPLE WE FOLLOWED, IT WAS THREE OUT OF FOUR, BUT
11 OBVIOUSLY IT COULD BE ANY NUMBER OUT OF FOUR. AND
12 SO WHAT THAT IS MEASURING IS CONSENSUS. IS IT THAT
13 MULTIPLE INDEPENDENT REVIEWERS AGREE THIS
14 APPLICATION DESERVES A FULL REVIEW.

15 THE OTHER MEASUREMENT IS THE RANK. AND
16 HOW IS IT THAT REVIEWERS WHO SELECTED THE
17 APPLICATION FELT THIS COMPARED TO THEIR OTHER
18 SELECTIONS? SO IT MEASURES THE INTENSITY. HOW MUCH
19 DID THEY LIKE THIS APPLICATION RELATIVE TO THE
20 OTHERS? AND SO WE GIVE A DIFFERENT WEIGHTING. SO
21 WE CAN WEIGHT THE COMPOSITE SCORE. IN THIS CASE
22 WE'RE WEIGHTING 60 PERCENT SELECTION AND 40 PERCENT
23 RANK. AND THE REASON FOR THE DIFFERENCE IN THE
24 WEIGHTING IS THAT, IN PART, IT HELPS MITIGATE
25 RANKING DIFFERENCES THAT MAY BE BASED ON DIFFERENCES

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1 IN QUALITY WITHIN THE BATCHES. AND SO THIS IS WHERE
2 WE DERIVE THIS FORMULA.

3 SO IN THE NEXT SLIDE I WILL SHOW YOU HOW
4 THEN IT IS CALCULATED FROM THE EXAMPLE. SO, AGAIN,
5 WE TAKE THAT LITTLE RED APPLICATION IN THE EXAMPLE.
6 AND AS WE KNEW BEFORE, REVIEWER 1 HAD SELECTED IT.
7 SO FOR EACH SELECTION, THIS IS A BINARY ASSIGNMENT
8 OF POINTS SELECTED AGAINST A 1. IF IT ISN'T
9 SELECTED, IT GETS A ZERO. AND SO WE TOTAL THOSE
10 POINTS ACROSS THOSE FOUR REVIEWERS. AND THEN FOR
11 THE RANK, YOU HAVE A POINT SYSTEM BASED ON THE RANK.
12 SO THE TOP APPLICATION, THE FAVORITE, IS 5 POINTS,
13 SECOND FAVORITE, 4 POINTS, AND SO ON. AND SO THAT
14 ALLOWS YOU TO GET A NUMBER OF POINTS FOR THE RANK.

15 AND SO WE PLUG THAT INTO THE COMPOSITE
16 SCORE EQUATION WITH THE RELATIVE WEIGHTING OF 60 TO
17 40. AND SO FOR THIS EXAMPLE, YOU END UP WITH A
18 COMPOSITE SCORE OF 0.73. AND A COMPOSITE SCORE IN
19 TOTAL IS GOING TO RANGE BETWEEN 0 AND 1 WHERE A 1 A
20 PERFECT SCORE AND A 0 MEANS IT WASN'T SELECTED.

21 AND SO THIS IS HOW THE COMPOSITE SCORE MAY
22 AFFECT OUTCOMES JUST FOR EXAMPLE AND UNDER THESE
23 SPECIFIC CONDITIONS THAT WE'RE SHOWING HERE. SO AN
24 EXAMPLE WHERE YOU DO GET A PERFECT SCORE, THAT MEANS
25 IT WAS PICKED FROM FOUR OUT OF FOUR REVIEWERS, THEY

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1 ALL RANKED IT NO. 1. SO THAT GETS A COMPOSITE SCORE
2 OF 1. THAT'S SOMETHING THAT CLEARLY ADVANCES IN
3 THIS SCENARIO.

4 IF YOU GET SOMETHING A LITTLE FURTHER
5 DOWN, SO THE EXAMPLE THAT I SHOWED YOU OF THE .73,
6 THREE OUT OF FOUR WITH SOME MIXED RANKINGS, THAT ONE
7 ALSO WOULD CLEARLY ADVANCE.

8 YOU HAVE TO COME DOWN TO ONLY ONE OUT OF
9 FOUR CHOOSING THE APPLICATION TO FALL BELOW WHERE
10 THE CUTOFF WOULD BE, WHICH GIVES YOU A COMPOSITE
11 SCORE OF ABOUT .25. TYPICALLY THE CUTOFF UNDER
12 THESE SETS OF CONDITIONS IS ABOUT .3 TO .35. AND
13 WE'VE DONE THIS THROUGH A SET -- MONTE CARLO
14 SIMULATIONS WHERE WE RUN MANY ITERATIONS OF THIS
15 USING DATA THAT WE'VE INPUTTED FROM HISTORICAL
16 APPLICATIONS. AND IT ALLOWS US TO PREDICT THE
17 ABILITY OF THIS APPROACH TO ACCURATELY ADVANCE
18 APPLICATIONS THAT ARE HIGH QUALITY VERSUS LOW
19 QUALITY.

20 SO NEXT SLIDE PLEASE. THIS IS WHAT THE
21 DISTRIBUTION OF THAT LOOKS LIKE. SO THIS IS
22 BASICALLY ANOTHER VIEW OF THE SAME THING SO THAT YOU
23 CAN SEE HOW THE APPLICATIONS ACROSS THIS ARE
24 DISTRIBUTED. THERE IS A PRETTY GOOD SPREAD THAT
25 ALLOWS YOU TO ESTABLISH A CUTOFF IN THAT RANGE OF .3

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1 TO .4. YOU CAN GO ON TO THE NEXT SLIDE.

2 ALL RIGHT. SO HOW DO WE EXACTLY ESTABLISH
3 THIS CUTOFF? CUTOFF IS SET AT THE CLOSEST NUMERICAL
4 BREAK, I.E., MEANING WHERE THERE ARE NO TIES, THAT
5 IS CLOSEST TO THE TARGET NUMBER OF APPLICATIONS THAT
6 DOES NOT EXCEED 10 PERCENT MORE OR FEWER THAN THE
7 TARGET. SO THAT GIVES US A RANGE TO WORK WITH IN
8 WHICH WE CAN WORK AROUND ANY POTENTIAL TIES.

9 NOW, THE WAY THE SELECTION AND RANK WORKS,
10 IT ACTUALLY PRODUCES THE FEWEST TIES THAN OTHER
11 APPROACHES THAT WE'VE LOOKED AT AND TESTED. I WILL
12 ALSO NOTE THAT, IN TERMS OF THE PROCESS, WE CAN ALSO
13 INCORPORATE A SCORE IN SOME INSTANCES WHERE IT ALSO
14 HELPS US CREATE A DEGREE OF GRANULARITY THAT MAY BE
15 HELPFUL, PARTICULARLY WHEN THE TOTAL VOLUME OF
16 APPLICATIONS IS ON THE LOWER END.

17 SO WHAT WOULD HAPPEN IN ORDER TO ESTABLISH
18 THE CUTOFF? IF YOU LOOK AT THE TABLE, YOU'RE
19 LOOKING AT RANKINGS FROM NO. 28 TO 32 AND THEIR
20 RESPECTIVE COMPOSITE SCORES, AND YOU HAVE A
21 THREE-WAY TIE OF BETWEEN 29 AND 31 THERE THAT HAVE
22 THE EXACT SAME SCORE. NOW, THE CLOSEST NUMERICAL
23 BREAK IS BETWEEN 31 AND 32. SO THAT'S WHERE WE
24 WOULD DRAW THE LINE. AND SO EVERYTHING THAT'S ABOVE
25 THAT LINE WOULD ADVANCE, EVERYTHING BELOW THAT LINE

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1 DOES NOT.

2 SO AS I MENTIONED, IT'S RARE IF THERE
3 ISN'T A PLACE TO CREATE THAT CUTOFF. BUT IF FOR
4 SOME REASON ALONG THAT 10 PERCENT ABOVE OR BELOW
5 RANGE DOES NOT PRODUCE A CLEAR LINE, THEN WHAT WE
6 WOULD DO IS USE RANDOMIZATION TO SELECT THE TARGET
7 NUMBER AND HELP US AVOID ANY BIASED SELECTION. BUT
8 THAT MEANS THAT WE'RE BASICALLY HAVING A POTENTIALLY
9 FIVE-, SIX-WAY TIE WHERE EVERYTHING OBJECTIVELY FROM
10 THE COMPOSITE SCORE IS THE SAME AND RANDOMIZATION
11 JUST HELPS US SELECT WHICH ONES WOULD ADVANCE TO
12 MAKE SURE THAT WE COMPLETE OUR TARGET OF 30. OKAY.
13 NEXT SLIDE PLEASE.

14 ALL RIGHT. SO THE FINAL STEP, ONCE THE
15 CUTOFF IS MADE, IS THAT THE CIRM PRESIDENT WITH THE
16 CIRM SCIENTIFIC STAFF WILL EXAMINE APPLICATIONS THAT
17 FALL BELOW THE CUTOFF AND MAY ADVANCE A LIMITED
18 NUMBER OF ADDITIONAL APPLICATIONS. OF COURSE,
19 ADVANCEMENT NEEDS TO BE BASED AND JUSTIFIED ON IT
20 REPRESENTING A UNIQUE OPPORTUNITY THAT'S ALIGNED
21 WITH THE GOALS OF THE FUNDING OPPORTUNITY. THE
22 POINT ISN'T TO JUST SIMPLY ALWAYS HAVE SOMETHING TO
23 SELECT, BUT IT'S AN OPPORTUNITY TO ENSURE THAT IF
24 ANYTHING IS MISSED, IF YOU WILL, CAN STILL
25 POTENTIALLY ADVANCE.

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1 AND THEN JUST THE LAST POINT, THAT
2 REVIEWERS MAY UNDER THIS PROCESS PROVIDE BRIEF
3 COMMENTS OR GIVE CATEGORICAL ASSESSMENTS, BUT
4 FEEDBACK TO APPLICANTS IS NOT GUARANTEED AT THIS
5 STAGE OF REVIEW. OF COURSE, WHEN IT GOES TO FULL
6 REVIEW, THERE IS A FULL CRITIQUE THAT IS PROVIDED.
7 NEXT SLIDE PLEASE.

8 ALL RIGHT. SO THE LAST QUESTION WAS
9 RELATED TO THE ROLE OF PATIENT ADVOCATES IN THE
10 PROCESS. AND SO FOLLOWING QUESTIONS AND LOOKING AT
11 THE POSSIBILITIES OF THE ROLE OF PATIENT ADVOCATES
12 HERE, WE SOLICITED FEEDBACK FROM SEVERAL OF THE
13 MEMBERS THAT SERVE ON THE GRANTS WORKING GROUP. AND
14 SO IN DOING SO, WE THOUGHT THAT, GIVEN THE GOAL OF
15 FOCUSING VOLUME CONTROL ON THE SCIENTIFIC VALUE,
16 THAT THE PATIENT ADVOCATE MEMBER'S ROLE, RATHER THAN
17 BEING IN THE VOLUME CONTROL STEP, WOULD INSTEAD BE
18 FOCUSED AND ENHANCED ON THE SUBSEQUENT FULL GRANTS
19 WORKING GROUP PANEL DISCUSSION. AND IN ORDER TO
20 STRENGTHEN THAT ROLE, THE IDEAS THAT WE ARE
21 DEVELOPING AT THE MOMENT ARE TO CREATE AND DEFINE A
22 PATIENT PERSPECTIVE SCORE AND ALSO TO FACILITATE
23 MEETINGS BETWEEN THE PATIENT ADVOCATE MEMBERS AND
24 THE GRANTS WORKING GROUP CHAIR AS WELL AS CIRM STAFF
25 PRIOR TO MEETINGS AKIN TO WHAT WE USED TO DO IN THE

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1 PAST AND WE HAVEN'T DONE IN A WHILE, BUT WHICH I
2 THINK ARE VERY FRUITFUL DISCUSSIONS IN LEVERAGING
3 THE EXPERTISE OF THE CHAIR AS WELL AS THE PATIENT
4 ADVOCATE MEMBERS SO THAT AS WE GO INTO EACH REVIEW,
5 THERE'S A CLEAR UNDERSTANDING OF HOW BOTH CAN
6 CONTRIBUTE TO A FULLER DISCUSSION AND REVIEW OF THE
7 APPLICATIONS.

8 IS THERE A SUBSEQUENT SLIDE? I THINK THAT
9 MAY BE THE LAST ONE. SO AT THIS POINT HAPPY TO TAKE
10 ANY QUESTIONS.

11 DR. PATEL: I'M GOING TO STOP SHARING SO
12 YOU CAN SEE COMMENTERS.

13 DR. SAMBRANO: PAT.

14 DR. LEVITT: I WAS WAITING FOR SOMEBODY
15 ELSE. I'LL LET KEITH GO FIRST. GO AHEAD, KEITH.

16 DR. YAMAMOTO: NO, GO AHEAD, PAT.

17 DR. LEVITT: YOU GO. BEAUTY BEFORE AGE.

18 DR. YAMAMOTO: OKAY. OKAY. THANKS, GIL.
19 AS YOU SAY, THAT I'VE BENEFITED FROM HAVING OFFLINE
20 CONVERSATION ACTUALLY WITH MARIA AND WITH GIL ABOUT
21 THIS. IT'S BEEN, I THOUGHT, RICH AND HOPEFULLY
22 PRODUCTIVE. AND SO GIL WON'T BE SURPRISED TO HEAR
23 ME SAY THAT I THINK THIS IS SUBSTANTIALLY IMPROVED
24 OVER WHAT WAS PROPOSED EARLIER, BUT I HAVE TWO
25 CONCERNS.

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1 ONE IS ABOUT ESTABLISHING A VOLUME CONTROL
2 MECHANISM THAT ELIMINATES 75 TO 80 PERCENT OF THE
3 APPLICATIONS. AND IT'S MY -- I'VE NEVER BEEN ON GWG
4 SO I'M SPEAKING A BIT BLIND HERE. BUT JUST KNOWING
5 ABOUT THE APPLICATIONS THAT COME IN, THE QUALITY OF
6 THE APPLICANT POOL MAKES ME CONCERNED THAT IT WILL
7 BE DRAWING A RATHER ARTIFICIAL CUTOFF LINE BY SIMPLY
8 DECIDING A PRIORI TO ELIMINATE 75 TO 80 PERCENT OF
9 THE APPLICATIONS FROM DETAILED REVIEW, AND THAT WE
10 WOULD FIND OURSELVES IN A SITUATION WHERE
11 REVIEWERS -- SORRY -- RATHER APPLICANTS WHO STRONGLY
12 BELIEVE THAT THEY HAVE COMPLIED WITH THE QUALIFYING
13 ELEMENTS OF THE APPLICATION AND HAVE BROUGHT FORWARD
14 TRULY IMPORTANT SCIENTIFIC APPROACHES ARE EXCLUDED
15 FROM REVIEW AND WE'LL GET -- WE'LL HEAR FROM THE
16 COMMUNITY ABOUT THAT IN SOME DETAIL. IN FACT, AS WE
17 DID PREVIOUSLY. SO THAT'S ONE THING JUST FOR
18 DISCUSSION.

19 AND THE SECOND IS THAT, AS GIL WILL KNOW
20 THAT I WAS GOING TO SAY THIS, THAT I STRONGLY
21 BELIEVE THAT IN THE TWO-STEP RANKING PROCESS, THERE
22 WOULD BE REAL ADVANTAGES IN THE SECOND STEP AFTER
23 SELECTION OF SCORING THE APPLICATIONS RATHER THAN
24 RANKING THEM. BY RANKING THEM, THAT HARDENS THE
25 CONCERN ABOUT A DIFFERENCE OF QUALITY BETWEEN POOLS.

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1 AND SO IF ONE POOL HAD THREE TRULY OUTSTANDING
2 APPLICATIONS OUT OF 15, THOSE WOULD BY NECESSITY
3 MIGHT BE SELECTED, BUT BY NECESSITY ONLY ONE OF THEM
4 COULD BE RANKED THE BEST. AND YOU LOSE ANY KIND OF
5 QUALITATIVE DISTINCTION BETWEEN THE POOLS.

6 AND SO THE RANKING OF NO. 1 IN ONE POOL
7 MAY REFLECT AN APPLICATION THAT IS VERY GOOD, BUT
8 ISN'T NEARLY AS STRONG AS THE TOP APPLICATION IN
9 ANOTHER POOL. AND CONVERSELY, THERE MAY BE, AS I
10 SAID AT THE BEGINNING, THERE MAY BE THREE
11 APPLICATIONS IN A POOL THAT ARE TRULY OUTSTANDING
12 THAT ARE ACTUALLY HIGHER QUALITY THAN ANY OF THE
13 APPLICATIONS THAT ARE IN THE NEXT POOL OVER.

14 SO I WOULD URGE THAT SECOND PARAMETER BE
15 TO SCORE RATHER THAN RANK. I THINK YOU GATE, YOU
16 RECOVER, YOU MAINTAIN DISCRIMINATION IN THE QUALITY
17 OF THE APPLICATIONS THAT YOU LOSE BY SIMPLY RANKING
18 WITHIN A POOL. THOSE ARE THE TWO THOUGHTS I HAD.

19 DR. SAMBRANO: SO CAN I OFFER SOME
20 ADDITIONAL COMMENT HERE? SO THANK YOU, KEITH.
21 YEAH. I THINK, AS YOU AND I DISCUSSED, I THINK
22 SCORING DOES ADD AN ADDITIONAL DIMENSION TO CERTAIN
23 CIRCUMSTANCES. AND AS I HAD MENTIONED, SCORING IS
24 SOMETHING THAT CAN BE INCORPORATED INTO THIS
25 PROCESS, PARTICULARLY IN THE CONDITIONS WHERE YOU

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1 HAVE A SMALLER VOLUME AND SELECTION ISN'T AS
2 EFFECTIVE. COMBINING OR ADDING SCORING IS SOMETHING
3 THAT CERTAINLY CAN BE DONE AND CAN ADD ANOTHER
4 MEASURE.

5 BUT WE ALSO DO TRY TO MITIGATE BECAUSE WE
6 THINK OF THE SAME ISSUE OF WHAT COULD HAPPEN IF YOU
7 HAVE DIFFERENT POOLS THAT ARE OF DIFFERENT QUALITY.
8 AND PART OF MITIGATING THAT IS INCREASING THE NUMBER
9 OF REVIEWERS THAT SEE EACH APPLICATION AND ASSURING
10 THAT THE POOLS ARE NOT IDENTICAL SO THAT YOU HAVE
11 ENOUGH VARIETY IN THE POOLS THAT IT HELPS MAKE UP
12 FOR ANY BATCH VARIABILITY THAT COULD OCCUR.

13 AND WHEN WE DO THE MODELING, IT IS ONE OF
14 THE THINGS THAT'S TAKEN INTO ACCOUNT. SO THE MONTE
15 CARLO USES DATA THAT WE HAVE FROM REAL CIRM
16 APPLICATIONS WHERE WE ASSIGN QUALITY BASED ON THE
17 FACT THAT THEY WERE SCORED HISTORICALLY AN 85 OR
18 ABOVE OR BELOW 85. SO WE ESTABLISH WHAT A GOOD
19 APPLICATION LOOKS LIKE, LOW QUALITY VERSUS HIGH
20 QUALITY, AND THEN RUN THE SIMULATIONS USING THE
21 SELECTION AND RANKING TO SEE WHAT HAPPENS. CAN IT
22 ACCURATELY WORK TO SELECT THE QUALITY APPLICATIONS
23 OVER THE LOW QUALITY?

24 IN THESE DIFFERENT SCENARIOS THE RANGE IN
25 WHICH IT ACCURATELY PREDICTS IS 75 TO 100 PERCENT,

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1 DEPENDING THE VOLUME SIZE. SO IF THE VOLUME SIZE IS
2 EXTREMELY GREAT, 250, 300, THEN YOU'RE LOOKING AT
3 THE PREDICTABILITY BEING ALONG THE 75 TO 80 RANGE.
4 AS IT GETS LOWER, IT GETS CLOSE TO A HUNDRED.

5 SO FROM THAT PERSPECTIVE, IT CAN WORK WELL
6 BASED ON THE SIMULATIONS WE'VE RUN.

7 DR. YAMAMOTO: AND HAVE YOU RUN
8 SIMULATIONS IN WHICH YOU DO SCORING INSTEAD OF
9 RANKING?

10 DR. SAMBRANO: SO FOR SCORING, WE HAVE NOT
11 RUN THE SIMULATION. BUT I THINK IT'S SOMETHING THAT
12 WE SHOULD DO, AND I TAKE YOUR POINT THAT I THINK IT
13 DOES ADD ANOTHER MEASURE. BUT I THINK, AS I
14 MENTIONED, IN THOSE SETTINGS WHERE SELECTION IS NOT
15 AS EFFECTIVE, I THINK SCORING IS AN IMPORTANT THING
16 TO INCLUDE.

17 DR. YAMAMOTO: YEAH. GOOD.

18 DR. LEVITT: SO, KEITH, ARE YOU TALKING
19 ABOUT SCORING OF THE FIVE -- IN THE SCENARIO THAT
20 GIL DESCRIBED, SCORING OF THE FIVE THAT WERE
21 SELECTED. RIGHT?

22 DR. YAMAMOTO: YEAH. I WOULD -- GIL AND I
23 TALKED ABOUT THIS YESTERDAY TOO.

24 DR. LEVITT: YEAH. YEAH. YEAH.

25 DR. YAMAMOTO: IN THE GRANT MECHANISMS

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1 THAT I'M FAMILIAR WITH OR THAT I RUN, WE ASSIGN
2 SCORES BETWEEN 1 AND 7. OURS HAPPENS TO BE ONE TOP
3 AND SEVEN BOTTOM, BUT IT DOESN'T MATTER. BUT THERE
4 HAVE BEEN A LOT OF STUDIES THAT SHOW THAT HUMANS
5 HAVE A HARD TIME DISCRIMINATING BETWEEN -- AMONG
6 MORE THAN SEVEN OR EIGHT DIFFERENT CATEGORIES,
7 SHADES OF QUALITY, SO TO SPEAK. AND SO WE USE
8 SCORES BETWEEN 1 AND 7.

9 WHEN I'VE RUN THE MECHANISMS, I EMPHASIZE
10 THAT WE WANT REVIEWERS TO USE THE WHOLE RANGE, BUT I
11 EMPHASIZE THAT IT DOES NOT MEAN THAT WE'RE LOOKING
12 FOR ONE-SEVENTH OF THE APPLICATIONS TO BE SCORED 1
13 AND ONE-SEVENTH SHOULD BE SCORED 7, BUT TO BE
14 THINKING ABOUT THE QUALITY ACROSS. AND WE PUT IN
15 WORD DESCRIPTORS OF WHAT WE MEAN BY EACH OF THOSE
16 NUMBERS WHERE 1 IS EXCEPTIONAL AND 2 IS OUTSTANDING
17 AND SO FORTH.

18 DR. LEVITT: THE SCORING WOULD BE DONE ON
19 THOSE THAT WERE SELECTED, NOT ON ALL APPLICATIONS?

20 DR. YAMAMOTO: THAT IS CORRECT.

21 DR. LEVITT: OKAY. SO I THOUGHT ABOUT
22 THAT AS WELL. AND MY SUSPICION IS -- GIL RAN MONTE
23 CARLOS, THE TEAM RAN MONTE CARLOS. MY SUSPICION IS
24 THAT IT PROBABLY MAY MAKE THE DIFFERENCE ON THE
25 FRINGES. BUT IF THERE'S, LIKE I HAVE -- I SELECTED

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1 FIVE AND I THINK THEY'RE ALL ONES. YOU SELECT FIVE
2 AND YOU THINK THEY'RE ALL THREES. I THINK BOTH OF
3 THOSE BECAUSE THEY'VE BEEN SELECTED BY THREE OTHER
4 REVIEWERS ARE GOING TO GET IN, RIGHT, BASED ON THE
5 CUTOFF. SO I THINK IT MAY MAKE A LITTLE BIT OF A
6 DIFFERENCE. I'M NOT SURE, BUT I CAN GO EITHER WAY.

7 THE THING ABOUT 75, 80 PERCENT OF THESE
8 APPLICATIONS ARE GOING TO BE TRIAGED ESSENTIALLY,
9 IT'S ACTUALLY WORSE WHEN YOU LOOK AT ARPA-H, WHICH
10 ALL OF US -- OUR ARPA-H IS AN HHS ADVANCED
11 INNOVATION, LARGE DOLLAR AMOUNT FUNDING MECHANISM
12 THAT TENS OF THOUSANDS OF APPLICATIONS WERE
13 SUBMITTED. AND BASICALLY IN THAT CONTEXT A HANDFUL
14 WERE SELECTED. THE DIRECTORS' PIONEER AWARDS, THE
15 SAME THING. IT'S LIKE 10 PERCENT MAYBE, 5 PERCENT
16 OR 10 PERCENT GET ADVANCED BASED ON A SELECT
17 COMMITTEE THAT NOBODY KNOWS WHO IS EVEN ON THE
18 COMMITTEE MAKES THOSE SELECTIONS. THE BRAIN
19 BEHAVIORAL RESEARCH FOUNDATION IS THE SAME THING.
20 LIKE FOR POST-DOC AWARDS, THERE COULD BE A THOUSAND
21 APPLICATIONS, AND THEY END UP SELECTING AND FUNDING
22 A HUNDRED OR A HUNDRED FIFTY.

23 SO I DON'T THINK IT'S THAT UNUSUAL FOR
24 INVESTIGATORS TO UNDERSTAND THAT FOR CERTAIN
25 AGENCIES, GOVERNMENT LEVEL AND CERTAIN PRIVATE

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1 SECTOR, THAT THIS IS SORT OF WHAT IT IS, THAT THERE
2 ARE A LOT OF APPLICATIONS AND A LIMITED AMOUNT OF
3 MONEY AND ALSO LIMITED ABILITY TO REVIEW HUNDREDS OF
4 APPLICATIONS.

5 SO I SEE YOUR POINT FOR THE POINT 2, AND
6 MAYBE SCORING OF THOSE FIVE WOULD BE BETTER. BUT I
7 DO THINK IT'S JUST -- THERE WILL BE INVESTIGATORS
8 THAT WILL BE UPSET NO MATTER WHAT. I JUST THINK
9 THERE'S NO WAY AROUND IT, AND WE'RE NOT THE FIRST
10 AGENCY TO HAVE TO DEAL WITH THIS. THERE ARE MANY
11 OTHER AGENCIES AND NON-PROFITS THAT HAVE TO DEAL
12 WITH THIS ON A DAILY BASIS. AND, OF COURSE, IT'S
13 SAD FOR REASONS THAT WE UNDERSTAND. BUT I DON'T
14 THINK THERE'S ANY WAY AROUND IT. I'LL STOP THERE.

15 DR. YAMAMOTO: IT'S INTERESTING THAT THIS
16 TURNED INTO A DEBATE BETWEEN PAT AND ME. BUT THE
17 CONCERNS -- SO I UNDERSTAND THAT THERE ARE
18 MECHANISMS AND PROCESSES AND AGENCIES THAT ARE
19 REQUIRED TO BE EXTREMELY HIGHLY SELECTIVE IN THE
20 AWARDS THAT THEY GIVE. BUT I THINK THAT THOSE
21 AGENCIES CERTAINLY GIVE THE IMPRESSION THAT THE
22 PROPOSAL WAS REVIEWED. AND HERE WE'RE TELLING 80
23 PERCENT OF THE PEOPLE THAT HAVE GONE TO A LOT OF
24 WORK TO PREPARE AN APPLICATION, THANK YOU VERY MUCH,
25 BUT WE'RE NOT GOING TO REVIEW YOUR APPLICATION. AND

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1 THAT'S PRETTY DIFFICULT. THAT'S THE CONCERN I HAVE.
2 AND IT'S WHAT I PREDICT WE WOULD HEAR FROM
3 APPLICANTS IF WE WERE TO USE THIS MECHANISM.

4 DR. LEVITT: I THINK THERE'S A WAY OF
5 COMMUNICATING THAT BECAUSE THEY ARE
6 GETTING -- THEY'RE ALL GETTING REVIEWED AND THEY'RE
7 ALL USING THE SCIENTIFIC -- THIS IS ALL BASED ON THE
8 SCIENCE. THEY MAY DISAGREE WITH THE OUTCOME. AND,
9 OF COURSE, I SUBMITTED A PIONEER AWARD AND I
10 DISAGREED WITH THE OUTCOME. AND SUBMITTED AN ARPA-H
11 GRANT AND I DISAGREED WITH THE OUTCOME. AND BY THE
12 WAY, I DIDN'T GET ANY FEEDBACK FROM EITHER OF THEM.

13 I THINK, GIL, YOU MAY WANT TO CONSIDER
14 LIKE IF THERE'S ANY ROOM FOR SOME SHORT FEEDBACK TO
15 THE APPLICANTS, NOT ADDING A TON OF WORK TO THE GWG
16 MEMBERS. BUT THEY'RE PROBABLY TAKING NOTES, WHICH
17 MEANS THE NOTES COULD BE ASSIMILATED INTO SOME
18 COMMENTS BACK WHICH WOULD HELP THE INVESTIGATORS.

19 DR. SAMBRANO: YEAH. I THINK THAT THAT'S
20 CERTAINLY SOMETHING THAT WE WANT TO EXPLORE.

21 DR. LEVITT: AND WE HAVE AN EXPERT
22 COMMUNICATOR WHO CAN SORT OF FIGURE OUT HOW TO TALK
23 ABOUT THAT, DISCUSS THIS WITH THE FIELD OF
24 INVESTIGATORS APPLYING.

25 MS. MANDAC: THERE ARE NO MORE HANDS.

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1 CHAIRMAN FISCHER-COLBRIE: OTHER
2 QUESTIONS, OTHER CONSIDERATIONS? ANY OTHER
3 COMMENTS? I SEE THERE'S SOMEBODY HAS A PHONE NUMBER
4 THERE. I'M NOT SURE WHO THAT IS.

5 MS. MANDAC: IT'S A PUBLIC MEMBER, MARK,
6 SO NOT YET.

7 CHAIRMAN FISCHER-COLBRIE: OKAY. SO DO WE
8 HAVE A CONSENSUS OR A RECOMMENDATION FOR WHAT WE
9 WANT TO DO HERE FOR BOTH THESE ELEMENTS IN HOW WE
10 MIGHT CONSIDER THIS?

11 VICE CHAIR BONNEVILLE: MARK, I WOULD LIKE
12 TO SUGGEST THAT WE -- THAT THE SCIENCE SUBCOMMITTEE
13 MAKES A DETERMINATION FOR THE FIRST ONE OF WHERE THE
14 ACCESS FEEDBACK, WHERE THAT LIVES, WHETHER IT'S GWG
15 OR GOES STRAIGHT TO THE ARS, AND HAVE IT BE THAT IT
16 GOES TO THE GWG AS A RECOMMENDATION FROM US FIRST.

17 CHAIRMAN FISCHER-COLBRIE: OKAY.

18 VICE CHAIR BONNEVILLE: AND THEN TO THE
19 SECOND ITEM, I LEAVE THAT TO PAT AND KEITH TO WORK.

20 CHAIRMAN FISCHER-COLBRIE: WITH THE FIRST
21 ONE, SCOTT, I DON'T THINK WE NEED A MOTION OR DO WE
22 RELATED TO THE FIRST ELEMENT. JUST GIVE OUR ASSENT
23 THAT THE SCIENCE SUBCOMMITTEE IS IN FAVOR OF TAKING
24 THAT APPROACH.

25 MR. TOCHER: THAT'S CORRECT. A FORMAL

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1 MOTION AND VOTE ISN'T REQUIRED SO LONG AS THERE'S A
2 CONSENSUS OF THE COMMITTEE. THE TEAM CAN TAKE THIS
3 FORWARD TO THE BOARD.

4 CHAIRMAN FISCHER-COLBRIE: I THINK I CAN
5 EXPRESS CONFIDENTLY THAT THAT'S THE CONSENSUS OF THE
6 COMMITTEE UNLESS ANYBODY WANTS TO INTERVENE AT THIS
7 POINT. THAT'S ONE LAST SHOT TO DO SO.

8 DR. LEVITT: I'M OKAY WITH HAVING IT SIT
9 IN THE GWG. I THINK THE SCIENCE -- I THINK THIS
10 COMMITTEE SHOULD MAKE A RECOMMENDATION THAT THE
11 BOARD WILL HEAR ABOUT. I'M FINE WITH THAT. MARIA'S
12 CASE WAS WELL MADE.

13 CHAIRMAN FISCHER-COLBRIE: LET'S MOVE
14 FORWARD IN THAT REGARD AND GET THAT SQUARED AWAY.
15 AND THEN WITH RESPECT TO THE SECOND ITEM, GIL, YOU
16 WERE INDICATING THAT YOU MIGHT WANT TO TAKE A LOOK
17 AT A NUMERICAL VERSUS A RANKING SIMULATION? IS
18 THAT --

19 DR. SAMBRANO: SO OUR PROPOSAL WAS TO USE
20 THE OVERALL APPROACH THAT USES DIFFERENT MEASURES.
21 AND TYPICALLY THAT WOULD BE SELECTION AND RANK. BUT
22 AS NOTED, I THINK PARTICULARLY FOR WHEN YOU HAVE A
23 LOW VOLUME, SCORING IS SOMETHING THAT WE HAD ALSO
24 PROPOSED. I THINK WE HAD THAT PROPOSED IN THE MEMO.
25 SO SCORING IS A PART OF IT, BUT I THINK THE QUESTION

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1 OF WHETHER YOU APPLY SCORING ACROSS THE BOARD
2 REGARDLESS OF THE VOLUME IS SOMETHING THAT WE
3 HAVEN'T, BUT WE CAN CERTAINLY DO THAT IF THAT'S
4 DESIRED.

5 CHAIRMAN FISCHER-COLBRIE: OKAY. SO I
6 WANT TO MAKE SURE WE UNDERSTAND WHAT WE'RE TALKING
7 ABOUT WITH SCORING. AND PAT KIND OF ASKED THAT
8 QUESTION, BUT I WANT TO MAKE SURE IT'S CLEAR TO
9 EVERYBODY BECAUSE ALL APPLICATIONS ARE GETTING
10 REVIEWED BY AT LEAST FIVE REVIEWERS; ISN'T THAT
11 CORRECT? RIGHT?

12 DR. SAMBRANO: DEPENDS ON THE VOLUME,
13 RIGHT. SO IT'S AT LEAST -- EACH APPLICATION IS
14 BEING LOOKED AT BY THREE, FOUR, FIVE, OR SIX
15 REVIEWERS DEPENDING ON THE VOLUME. AND SO THEY GET
16 A COMPOSITE SCORE, EACH APPLICATION, THAT'S BASED ON
17 IT BEING SELECTED OR NOT AS ONE PARAMETER. AND THE
18 OTHER PARAMETER IS THE RANK THEY RECEIVE. AND THE
19 RANK THAT THEY RECEIVE IS JUST PART OF THAT
20 COMPOSITE SCORE THAT ALLOWS US TO RANK THEM ALL.

21 INSTEAD OF DOING A RANK, WE CAN DO A
22 NUMERICAL SCORE, SAY, 1 TO 7, 1 TO 10, THAT WOULD BE
23 GIVEN TO EACH OF THOSE SELECTED APPLICATIONS.

24 I THINK IN DOING EITHER ONE, YOU GET A
25 RELATIVELY SIMILAR OUTCOME EVEN THOUGH I THINK THE

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1 SCORE CAN POTENTIALLY GIVE YOU MORE GRANULARITY IN
2 CERTAIN CIRCUMSTANCES. SO I THINK IT'S JUST A
3 QUESTION OF IS THERE A DESIRE FOR US TO DO IT ONE
4 WAY VERSUS THE OTHER OR TO APPLY IT DEPENDING ON
5 WHAT THE VOLUME IS AND WHERE IT MIGHT BE MOST
6 APPROPRIATE.

7 CHAIRMAN FISCHER-COLBRIE: I THINK -- GO
8 AHEAD, KEITH.

9 DR. YAMAMOTO: IN ALL THESE DISCUSSIONS
10 YOU AND I HAVE HAD, GIL, I HAVEN'T HEARD A
11 DISADVANTAGE TO DOING THE SCORING. IT'S NOT MORE
12 COMPLEX AND IT MAINTAINS INFORMATION THAT YOU
13 OTHERWISE LOSE BY RANKING. AND SO I JUST DON'T
14 SEE -- I DON'T THINK IT ADDS COMPLEXITY, AND I
15 HAVEN'T HEARD A DISADVANTAGE TO DOING IT. SO I
16 GUESS I'M A LITTLE BIT CONCERNED THERE.

17 AND ON PAT'S POINT, SINCE I HAVE THE
18 MICROPHONE HERE, THAT THERE ARE MECHANISMS THAT HE'S
19 APPLIED FOR AND NOT GOTTEN. I WON'T MAKE ANY JOKES
20 ABOUT THAT. I'LL JUST SAY THAT THAT'S TRUE. I'M
21 VERY FAMILIAR WITH THOSE MECHANISMS. I WORK VERY
22 HARD TO HAVE ARPA-H INSTITUTED AS A SEPARATE
23 APPROACH TO BEING ABLE TO SORT THROUGH APPLICATIONS
24 AND CHOOSE HIGH QUALITY APPLICATIONS. AND SO I'M
25 FAMILIAR WITH THAT.

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1 BUT WHAT WE'RE DOING -- SO THE FACT
2 THAT -- MARK, THE POINT THAT YOU MADE, THE FACT THAT
3 EVERY APPLICATION IS EXAMINED IS TRUE. BUT AS GIL
4 TOLD US, THAT THE EXAMINATION OF THE APPLICATIONS AT
5 THE SELECTION LEVEL IS RELATIVELY CURSORY. SO IN
6 THAT SENSE, IT'S SIMILAR TO WHAT THE NIH DOES. IT'S
7 NOT A FORMALIZED MECHANISM, BUT ACROSS ALL THE STUDY
8 SECTIONS, IT'S VERY COMMON FOR THE STAFF TO LOOK AT
9 THE SCORES THAT HAVE BEEN GIVEN BEFORE THE MEETING
10 AND TO ESSENTIALLY ESTABLISH A TRIAGE LINE THAT
11 ELIMINATES APPROXIMATELY 50 PERCENT OF THE
12 APPLICATIONS FROM DISCUSSION.

13 AND SO THOSE APPLICANTS RECEIVE A NOTE
14 FROM THE STUDY SECTION, NIH ACTUALLY, THAT SAYS THAT
15 YOUR APPLICATION WAS NOT SELECTED FOR DISCUSSION.
16 SO THAT'S THE TRIAGE THAT NIH APPLICANTS ARE
17 FAMILIAR WITH. AND THEY'RE NOT HAPPY ABOUT THAT
18 BECAUSE THEY FEEL LIKE THEIR APPLICATION WAS GOOD
19 AND FOR SOME REASON IT GOT ELIMINATED FROM
20 DISCUSSION. BUT THAT SOME REASON IS THAT THE
21 OVERALL EVALUATION OF THE STUDY SECTION MEMBERS SAID
22 THAT THOSE THINGS SHOULD NOT ADVANCE FORWARD.

23 SO THAT TRIAGE LINE, FIRST OF ALL, IS
24 ESTABLISHED ABOUT 50 PERCENT. I THINK IT'S HARD TO
25 DISCRIMINATE. LET ME PUT IT THE OTHER WAY. IT'S

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1 RELATIVELY EASY TO DISCRIMINATE THE TOP HALF FROM
2 THE BOTTOM HALF, BUT IT'S VERY HARD -- I THINK
3 IT'S -- I QUESTION WHETHER IT'S POSSIBLE TO REALLY
4 DISCRIMINATE THE TOP 20 PERCENT FROM THE BOTTOM 80
5 PERCENT BECAUSE WHAT YOU'RE DOING IS YOU'RE SAYING I
6 CAN DISCRIMINATE THE TOP 20 PERCENT FROM THE NEXT 2
7 PERCENT, THE NEXT 5 PERCENT BELOW THAT 20 PERCENT.
8 THAT IS VERY TOUGH. I'M NOT REALLY CONVINCED THAT A
9 CURSORY GLANCE AT AN APPLICATION CAN MAKE THAT
10 JUDGMENT WELL. AND I THINK THAT WE'RE GOING TO
11 REALLY HEAR FROM THE APPLICANTS IF WE TRY TO DO
12 THAT.

13 CHAIRMAN FISCHER-COLBRIE: KEITH -- GO
14 AHEAD, GIL.

15 DR. SAMBRANO: I JUST WANTED TO ADD MAYBE
16 A LITTLE MORE TO THE CONCERNS ABOUT THE SCORE VERSUS
17 THE RANKING JUST TO POINT OUT THAT THE POTENTIAL
18 DISADVANTAGE OF A SCORE IS IN TERMS OF THE FACT THAT
19 YOU STILL HAVE REVIEWERS THAT MAY END UP BEING
20 EITHER MORE SEVERE OR LENIENT IN THEIR APPROACH. IT
21 DOESN'T ACCOUNT FOR THAT ELEMENT ACROSS REVIEWERS.
22 SO YOU'RE STILL FACED WITH THE ISSUE OF POTENTIAL
23 DIFFERENCES.

24 I THINK THE ONLY WAY TO MITIGATE THAT IS
25 REALLY BY INCREASING THE NUMBER OF REVIEWERS THAT

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1 SEE EACH APPLICATION, WHICH I THINK FOR US THE
2 NUMBERS THAT I SHOWED YOU ARE SORT OF MINIMUM. AND
3 BY INCREASING IT, IT ACTUALLY HELPS.

4 I THINK THE OTHER THING THAT'S IMPORTANT
5 TO NOTE ABOUT RANKING VERSUS SCORING IS THAT IT IS
6 SIMPLER IN TERMS OF A REVIEWER DECIDING, ONCE THEY
7 HAVE CLARITY ON WHAT THEY'RE LOOKING FOR, THAT THIS
8 IS MY FAVORITE, THIS IS MY SECOND FAVORITE, OR MY
9 THIRD FAVORITE VERSUS TO GIVE A SCORE THAT IS --
10 THAT'S GOING TO ACTUALLY WORK THE SAME WAY ACROSS
11 ALL REVIEWERS, ACROSS ALL THE POOLS. MEANING THAT
12 THERE'S A RUBRIC BEHIND THAT SCORE. IT'S
13 MORE -- IT'S A HARDER CALCULUS TO MAKE WHEN WE GIVE
14 THEM THE BATCH OF 15. I MEAN THOSE ARE JUST
15 CONSIDERATIONS, BUT, AGAIN, I THINK BOTH ARE GOOD
16 MEASURES. IT IS JUST SOME SLIGHT DIFFERENCES IN HOW
17 WE MAY HAVE TO IMPLEMENT.

18 CHAIRMAN FISCHER-COLBRIE: YEAH. SO
19 THERE'S TWO ISSUES HERE. ONE IS SCORE VERSUS
20 RANKING. AND THEY BOTH HAVE DIFFERENT CONSEQUENCES.
21 IF ONE PRESUPPOSES PEOPLE ARE RELATIVELY CONSISTENT
22 IN SCORING, THEN OBVIOUSLY THERE'S ADVANTAGES TO
23 INFORMATION GAINED THERE BECAUSE SOMEBODY MIGHT RANK
24 SOMETHING 3, 4, AND 5, BUT IN THEIR MINDS THOSE ARE
25 ALL -- WOULD BE RANGED 60, 50, AND 40 KIND OF

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1 SITUATION, RIGHT? VERSUS SOMEBODY ELSE WHO'S
2 RANKING 3, 4, AND 5, IT MIGHT BE 90, 85, AND 80 KIND
3 OF CONVERSATION MAYBE. SO I THINK THERE'S --
4 OBVIOUSLY THAT REQUIRES SOME THOUGHT.

5 THE OTHER QUESTION, THOUGH, GETS BACK TO
6 THE HEART OF THE TRIAGE ISSUE. BECAUSE ONE MIGHT BE
7 ABLE TO MAKE THE ARGUMENT THAT EVEN A VERY DETAILED
8 REVIEW, IT'S GOING TO BE REALLY HARD TO DO THE TOP
9 20 VERSUS THE TOP 80 OR THE BOTTOM 80 JUST BECAUSE
10 OF THE FACT THAT THERE'S PROBABLY 40 PERCENT OF THE
11 APPLICATIONS ARE FRANKLY OUTSTANDING IN THEIR OWN
12 RIGHT. RIGHT? SO I DON'T REALLY KNOW HOW TO GET
13 AROUND THAT PARTICULAR ISSUE. I THINK WE CAN LOOK
14 AT HAVING GIL TAKE A LOOK AT THE NUMERICAL SCORING
15 AND MAKE SOME ASSESSMENTS. I THINK SOME THINGS WILL
16 POP OUT IN THAT CONVERSATION.

17 WHAT IS A LITTLE MORE DIFFICULT TO COME TO
18 GRIPS WITH IS WHAT ARE WE SAYING WITH RESPECT TO
19 REVIEW OF THE APPLICATION. I DON'T KNOW HOW CURSORY
20 THE INITIAL CUT IS RELATED TO THAT. GIL, MAYBE YOU
21 WANT TO COMMENT ON WHAT THE INITIAL REVIEW TIME
22 SEQUENCE IS OR CYCLE IS.

23 DR. SAMBRANO: SO IN TERMS OF THE TIMING
24 FOR THE REVIEW ITSELF, I MEAN ONCE WE HAVE THE
25 APPLICATIONS, ASSIGN THEM TO REVIEWERS, IT'S ABOUT A

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1 TWO-WEEK TO THREE-WEEK PROCESS.

2 CHAIRMAN FISCHER-COLBRIE: I MEANT HOW
3 LONG WILL A REVIEWER SPEND REVIEWING AN APPLICATION
4 FOR CONSIDERATION FOR THE RANKING OR SCORING? HOW
5 LONG WILL THEY TAKE TO REVIEW THAT APPLICATION?

6 DR. SAMBRANO: WELL, THEY WILL -- I MEAN
7 WE GIVE THEM TYPICALLY TWO TO THREE WEEKS TO WORK
8 WITH THE BATCH THEY HAVE. BUT THE ACTUAL TIME THAT
9 EACH REVIEWER TAKES IS PROBABLY QUITE VARIABLE, BUT
10 A DAY OR TWO. SO WE GIVE THEM TO TWO- TO THREE-WEEK
11 PERIOD SO THAT THEY CAN FIND TIME WITHIN THEIR
12 SCHEDULE TO DO IT. BUT THEY CAN DO IT IN A DAY OR
13 TWO.

14 CHAIRMAN FISCHER-COLBRIE: SO, KEITH, I'M
15 WONDERING WHAT YOUR THINKING IS SORT OF WHAT IS IN
16 EFFECT A REQUIREMENT FOR A REVIEW TIME OR CYCLE OR
17 THOROUGHNESS FROM YOUR PERSPECTIVE. YOU'VE BEEN
18 THROUGH A MILLION OF THESE.

19 MR. TOCHER: MARK, KEITH HAD TO DROP OFF
20 AT THREE.

21 CHAIRMAN FISCHER-COLBRIE: OKAY.

22 DR. LEVITT: SO THAT'S THE ISSUE IS THAT I
23 UNDERSTAND KEITH'S CONCERNS, BUT HE HASN'T PRESENTED
24 A SOLUTION, WHICH I TOLD HIM SEVERAL TIMES. WHAT'S
25 THE SOLUTION TO THIS? ARE WE GOING TO REVIEW 300

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1 APPLICATIONS IN FULL?

2 CHAIRMAN FISCHER-COLBRIE: WE CAN'T.

3 DR. LEVITT: SO WHEN YOU DO TRIAGING, THE
4 PSYCHOLOGY AROUND IT, SOME OF US ON THIS CALL HAVE
5 DONE A LOT OF PREREVIEW BEFORE IT GOES TO A FULL
6 REVIEW, IT'S NOT LIKE READING THE ABSTRACT AND
7 DECIDING I DON'T LIKE THIS, SO I'M NOT GOING TO
8 SELECT IT. I DON'T KNOW ANY REVIEWER WHO DOESN'T
9 SPEND AT LEAST -- LIKE TO DO A FULL REVIEW OF A
10 REGULAR NIH GRANT APPLICATION, 12 PAGES, SINGLE
11 SPACE, ET CETERA, ET CETERA, EVEN FOR AN EXPERIENCED
12 REVIEWER, YOU'RE TALKING ABOUT TEN HOURS TO GO
13 THROUGH THAT. IT'S ABOUT TEN HOURS BECAUSE YOU HAVE
14 TO GO AND YOU LOOK AT SOME OF THE LITERATURE THAT
15 THEY CITED AND ET CETERA, ET CETERA, PROTOCOLS.
16 IT'S NOT A LOT OF THE WORDS. IT SOUNDS LIKE A LOT
17 OF WORDS, BUT IT'S NOT.

18 FOR DOING WHAT GIL IS TALKING ABOUT, IT'S
19 PROBABLY SEVERAL HOURS PER APPLICATION. BUT AS
20 YOU'RE READING THE ABSTRACTS, SPECIFIC AIMS, YOU'RE
21 READING THE GOALS, YOU'RE READING SOME OF THE
22 METHODS TO SEE AND YOU'RE CERTAINLY READING ABOUT
23 THE INVESTIGATORS AND THE INFRASTRUCTURE TO
24 DETERMINE WHETHER THEY CAN DO WHAT THEY'RE DOING.
25 IF IT'S A CLIN GRANT, FOR EXAMPLE, OR A PDEV GRANT,

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1 DO THEY HAVE THE RESOURCES TO BE ABLE TO DO IT AND
2 WHAT'S THEIR EXPERIENCE? THERE'S KEITH NOW. BUT I
3 DON'T SEE A WAY AROUND THE TRIAGE PROCESS. THERE
4 HAS TO BE SOME TRIAGE PROCESS BECAUSE WE CAN'T
5 REVIEW 300 APPLICATIONS. AND THEY'RE GETTING THE
6 FULL APPLICATION AS OPPOSED TO A THREE-PAGE OR
7 FIVE-PAGE SUMMARY, WHICH SEEMS TO ME LIKE FOR SOME
8 REVIEWERS WHO ARE OBSESSIVE COMPULSIVE, THEY MAY
9 ACTUALLY PUT IN A LOT OF TIME FOR THE PREREVIEW AND
10 OTHERS I DON'T THINK THEY'RE JUST GOING TO READ THE
11 ABSTRACT. WE HAVE THE FAITH -- AND DIRECT THEM THAT
12 THEY HAVE TO BE SUBSTANTIVE. YOU HEAR MY DOG IS
13 UPSET WITH KEITH AND ALL HIS COMMENTS. I'LL STOP
14 THERE.

15 DR. YAMAMOTO: FIRST OF ALL, LET ME
16 APOLOGIZE FOR DISAPPEARING. WE HAVE GUESTS HERE,
17 AND SO I'M NOT IN MY OFFICE. I'M IN MY WIFE'S
18 OFFICE. AND WHAT I DISCOVERED IN THE COURSE OF THIS
19 MEETING IS THAT THIS PLUG NEXT TO HER DESK IS NOT
20 HOT. AND SO MY COMPUTER DIED. SO APOLOGIES.

21 AND THE TAIL END OF THESE COMMENTS, I
22 CERTAINLY AGREE WITH GIL AND THE COMMITTEE AND WITH
23 PAT THAT A VOLUME CONTROL MECHANISM IS ESSENTIAL. I
24 THINK -- SO IF WE'RE STUCK WITH THE SITUATION WHERE
25 WE'RE GOING TO HAVE A VOLUME CONTROL MECHANISM THAT

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1 ELIMINATES, BY NECESSITY, 75 TO 80 PERCENT OF THE
2 APPLICATIONS, WE BETTER MAKE THAT FIRST SCREENING
3 PROCESS AS GOOD AS WE CAN MAKE IT. AND I THINK THAT
4 BY SCORING IT IMPROVES IT. SO MAYBE NOT A LOT,
5 MAYBE NOT ENOUGH TO PREVENT APPLICANTS WHO SUBMIT
6 VERY HIGH QUALITY APPLICATIONS FROM COMPLAINING
7 ABOUT THE WAY THAT WE'RE GOING ABOUT THE VOLUME
8 CONTROL. MAYBE THERE'S NO WAY TO AVOID THAT, BUT I
9 SUBMIT THAT SCORING WILL HELP.

10 CHAIRMAN FISCHER-COLBRIE: I'M NOT -- I
11 THINK THAT'S A REASONABLE THING TO LOOK AT FRANKLY.
12 I THINK THAT CAN BE A SITUATION WHERE WE CAN ASK GIL
13 TO TAKE A LOOK AT THAT AND UNDERSTAND THE MATH
14 BEHIND IT AND WHAT ARE THE PROS AND THE CONS. SO I
15 THINK THAT FOUNDATIONALLY WHAT WE CAN THEN DO, AT
16 LEAST AS THE SCIENCE COMMITTEE, IS TO SAY, HEY,
17 LOOK. THE OVERALL PROCESS OF THE MECHANISM WE AGREE
18 TO. WE'RE GOING TO FINE-TUNE WHETHER IT'S RANKING
19 OR SCORING. AND WE CAN BRING THAT INFORMATION
20 FORWARD, AND WE CAN HAVE A DISCUSSION ABOUT THAT AT
21 THE BOARD MEETING RELATED TO THAT.

22 SO EVEN THOUGH WE'RE NOT FULLY CENTERED ON
23 A RECOMMENDATION FROM THE SCIENCE COMMITTEE, THE
24 REST OF THE PROCESS WE CAN SAY, HEY, THIS HAS NOW
25 BEEN SET UP TO MITIGATE THE CLEAR PROBLEMS THAT WE

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1 HAVE RIGHT NOW THAT WE HAVE TO FIX AND MOVE ON WITH
2 BECAUSE WE'VE GOT REAL-TIME, CURRENT ISSUES WITH THE
3 CURRENT SELECTION PROCESS. SO THAT WOULD BE MY
4 RECOMMENDATION, BUT I'M THROWING THAT OUT THERE FOR
5 OTHER PEOPLE TO OPINE ON.

6 DR. SAMBRANO: SO I'M HAPPY TO RUN THROUGH
7 THE MATH, IF YOU WILL, AND SIMULATIONS THAT COMPARE
8 THE SCORING TO THE RANKING. SO WE CAN DO THAT
9 RELATIVELY QUICKLY AND MAYBE PROVIDE SOME OF THAT
10 DATA FOR NEXT WEEK.

11 CHAIRMAN FISCHER-COLBRIE: OKAY.

12 DR. YAMAMOTO: THAT WOULD BE GREAT.

13 DR. LEVITT: I WOULD SAY THE OTHER THING
14 IS TO MAYBE WE CAN TALK OFF LINE WITH GIL ABOUT HOW
15 TO COMMUNICATE WHAT'S EXPECTED OF THE GWG IN TERMS
16 OF THE INITIAL PROCESS OF SELECTION. AND I WOULD
17 ACTUALLY RECOMMEND THAT THERE NEEDS TO BE AT LEAST A
18 PARAGRAPH WRITTEN WHICH IN SOME WAYS FORCES THE
19 MEMBERS OF THE GWG TO TAKE THE TRIAGE PROCESS LIKE
20 THEY'RE NOT JUST PUTTING NOTES DOWN, LIKE THEY WRITE
21 A PARAGRAPH BASICALLY SAYS HERE'S THE RATIONALE.
22 IT'S NOT A DETAILED REVIEW LIKE THEY DO WHEN THEY DO
23 THE FULL REVIEW, BUT IT'S ENOUGH TO BASICALLY SAY
24 I'M WRITING THIS. HERE'S THE WEAKNESSES I SAW, AND
25 I DON'T RECOMMEND THIS FOR MOVING FORWARD OR HERE'S

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1 THE STRENGTHS AND HERE'S WHY I WANT TO MOVE IT
2 FORWARD.

3 CHAIRMAN IMBASCIANI: I THINK THAT'S A
4 GREAT IDEA BECAUSE THEN WE CAN ENSURE THERE IS A
5 REVIEW AND THAT THERE'S SUFFICIENT --

6 DR. LEVITT: YES.

7 CHAIRMAN FISCHER-COLBRIE: -- THOUGHT
8 GIVEN TO IT. AND BY AND LARGE PEOPLE ARE DOING
9 THAT. JUST EVEN ON THE PDEV TODAY, FOR EXAMPLE,
10 THERE WAS A LOT OF WORK THAT WENT INTO JUST THE
11 SELECTION PROCESS. SO, ANYWAY, I THINK THAT'S A
12 GREAT RECOMMENDATION. AND THAT ALSO ADDRESSES THE
13 QUESTION ABOUT, WELL, IS IT A CURSORY REVIEW OR NOT.
14 AT LEAST THERE IS A CERTAINTY SOMEBODY HAS GIVEN
15 THOUGHT TO THE REVIEW BECAUSE, AS WE KNOW, A LOT OF
16 THE TRIAGE PROCESS GETS BIASED BY AN INSTITUTION OR
17 SOME OTHER TOPIC THAT DISTRACTS THEM AND THEY DO A
18 THUMBS UP AND OTHER ONES DON'T EVEN GET DISCUSSED.

19 DR. LEVITT: AND THE TEAM WILL HAVE A
20 RECORD, AND THEY CAN DECIDE WHETHER THERE ARE
21 CERTAIN REVIEWERS IN GWG THAT ARE NOT TAKING IT
22 QUITE AS SERIOUSLY AS OTHERS. I THINK IT WILL HELP
23 THE TEAM ANYWAY TO HAVE SOMETHING LIKE THAT.

24 DR. YAMAMOTO: I THINK THIS IS A VERY GOOD
25 SUGGESTION, PAT.

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1 AND SO I'LL JUST ADD ANOTHER WRINKLE,
2 SOMETHING THAT GIL AND I TALKED ABOUT AND THAT I'VE
3 USED IN A COUPLE OF MECHANISMS THAT I OVERSEE. AND
4 I MENTIONED IT IN A PREVIOUS MEETING, SO I'LL DO IT
5 QUICKLY.

6 AND THAT IS TO HAVE AS PART OF THE
7 APPLICATION A ONE-PAGE SUMMARY WHICH IS ESSENTIALLY,
8 IF IT'S AN NIH GRANT, IT'S AN ABSTRACTION OF THE
9 ABSTRACT PLUS THE SPECIFIC AIMS PAGE. THOSE ARE
10 EACH A PAGE LONG OR PAGE AND A HALF, I GUESS. AND
11 WE ASK THE APPLICATIONS TO REDUCE THAT TO ONE PAGE
12 THAT IS CLEANSED OF ANY IDENTIFIERS OF WHO THE
13 APPLICANT IS OR WHERE THE APPLICATION IS COMING FROM
14 TO ELIMINATE IN THIS FIRST ROUND OF REVIEW TWO
15 COMPONENTS THAT EVENTUALLY BECOME ESSENTIAL FOR THE
16 REVIEW PROCESS, BUT ELIMINATE IN THE FIRST ROUND TO
17 ELIMINATE OR REDUCE TWO BIASES THAT WE KNOW ARE
18 BUILT INTO OUR REVIEW PROCESSES AND THAT IS
19 INDIVIDUAL REPUTATIONAL BIAS. BIG SHOT VERSUS A NEW
20 COMER YOU'VE NEVER HEARD OF. AN INSTITUTIONAL BIAS
21 COMING FROM A TOP-FLIGHT, LONG ESTABLISHED, HIGH
22 PRODUCTIVITY RESEARCH INSTITUTION AND A MODEST, A
23 COMMUNITY COLLEGE THAT WE HAVEN'T HEARD OF BECAUSE
24 IT'S NOT FROM OUR REGION OF THE STATE.

25 AND TO GET RID OF THOSE TWO BIASES IN THIS

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1 FIRST STEP, I THINK IS SOMETHING THAT IS, FIRST OF
2 ALL, EASY TO DO AND SECOND IS ESSENTIAL. IF WE WANT
3 OUR MECHANISMS TO BE AS TIGHTLY FOCUSED ON QUALITY
4 AS POSSIBLE AND NOT HAVE THESE OTHER BIASES CRAWL
5 IN. THIS IS NOT A VERY WELL FLESHED OUT
6 APPLICATION, BUT IT'S FROM THIS FAMOUS GUY AND I'M
7 SURE HE'LL FIGURE IT OUT. SO LET'S MOVE AHEAD AS
8 OPPOSED TO THE VERY SAME APPLICATION COMING FROM
9 SOMEBODY THAT YOU'RE NOT FAMILIAR WITH OR FROM AN IN
10 INSTITUTION THAT DOES NOT HAVE A LONG REPUTATION.
11 SO ANYWAY, YOU HAVE THIS ONE PAGE. AND FOR PEOPLE
12 WHO HAVE DONE A LOT OF REVIEWING OF LONG
13 APPLICATIONS, PROGRAM PROJECT GRANTS AND LONG
14 COMPLEX R1 APPLICATIONS, YOU KNOW THAT IT DOESN'T
15 TAKE VERY MUCH READING FOR YOU TO KIND OF KNOW WHAT
16 YOU'RE GOING TO DO IN YOUR REVIEW.

17 AND MY EXPERIENCE IN USING THIS MECHANISM
18 IS THAT THE REVIEWERS FEEL VERY CONFIDENT THAT THEY
19 CAN MAKE THAT ASSESSMENT WITHOUT HAVING TO PLOW
20 THROUGH ALL THE DETAILS. AND I THINK IF WE HAD THAT
21 COUPLED WITH WHAT PAT IS SUGGESTING, ASKING THE
22 REVIEWERS TO WRITE A SHORT PARAGRAPH, I WOULD SAY
23 ONE SENTENCE TO ONE PARAGRAPH, THAT PROVIDES A
24 RATIONALE FOR THIS DECISION OF WHETHER THE
25 APPLICATION SHOULD MOVE FORWARD OR NOT, THEN I THINK

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1 IT WOULD BE REALLY QUITE SIMPLE AND WOULD ALLOW THIS
2 FIRST LOOK TO BE ONE THAT IS RELATIVELY WELL
3 INFORMED RATHER THAN HAVING THE REVIEWER KIND OF
4 HAVE TO KIND OF DECIDE HOW MUCH DETAIL AM I GOING TO
5 PLOW THROUGH THIS LONG APPLICATION BEFORE I FEEL
6 CONFIDENT THAT I'M MAKING THE RIGHT RECOMMENDATION.

7 CHAIRMAN FISCHER-COLBRIE: SO I'M NOT A
8 HUNDRED PERCENT CLEAR, KEITH, BECAUSE, GIL, CORRECT
9 ME IF I'M WRONG, THE APPLICATION IS A FULL
10 APPLICATION, RIGHT?

11 DR. LEVITT: YEAH.

12 CHAIRMAN FISCHER-COLBRIE: SO IT'S REALLY,
13 REALLY, REALLY HARD TO DISGUISE WHERE IT'S COMING
14 FROM BECAUSE THEY'RE LISTING --

15 DR. YAMAMOTO: NO. NO. NO. NO. NO, ALL
16 YOU GET FOR THIS FIRST ROUND REVIEW IS THAT ONE
17 PAGE.

18 CHAIRMAN FISCHER-COLBRIE: FOR A FIRST
19 ROUND REVIEW TO GET A ONE-PAGER?

20 DR. YAMAMOTO: YEAH. YEAH. WE'VE DONE
21 THIS -- THE GATES GRAND CHALLENGES, WHICH ARE LONG
22 APPLICATIONS --

23 CHAIRMAN FISCHER-COLBRIE: OKAY. SO
24 YOU'RE NOT SUGGESTING THEN A FULL APPLICATION?

25 DR. YAMAMOTO: NO. I'M SUGGESTING A WAY

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1 FOR REVIEWERS TO FEEL CONFIDENT ABOUT MAKING
2 RECOMMENDATION WITHOUT HAVING TO PLOW THROUGH THE
3 LONG APPLICATION.

4 DR. SAMBRANO: SO IF I MAY, I THINK,
5 KEITH, THESE ARE, AS YOU SAID, SUGGESTIONS WE'VE
6 TALKED ABOUT. I THINK THEY'RE IDEAS THAT ARE GOOD.
7 WE HAVE THOUGHT OF THOSE AS WELL.

8 IN THE DISC5, DISC-0 WE HAVE WHAT WE CALL
9 THE PREVIEW PAGE, WHICH IS SORT OF THE EQUIVALENT OF
10 THE ONE-PAGER, IF YOU WILL, THAT REVIEWERS ARE ASKED
11 TO LOOK AT AS A SUMMARY OF WHAT THE AIMS AND MAIN
12 ELEMENTS ARE. SO THAT IS A COMPONENT.

13 WE HAVE ALSO TRIED THE ANONYMOUS APPROACH
14 IN DIFFERENT SCENARIOS. SO THROUGH POSITIVE
15 SELECTION, WE ALSO ARE ABLE TO DO AN ANONYMOUS TYPE
16 OF REVIEW.

17 WHAT WE HAVE FOUND WHEN WE HAVE HAD TO DO
18 THE ANONYMOUS APPROACH IS THAT APPLICANTS FIND WAYS,
19 EVEN IF IT'S WITH ONE PAGE, TO IDENTIFY THEMSELVES,
20 WHICH GAVE US A VERY HARD TIME IN FIGURING OUT WHAT
21 DO WE DO WITH THOSE WHERE THEY ACTUALLY DID IDENTIFY
22 THEMSELVES VERSUS THOSE WHERE THE APPLICANT WAS
23 QUITE TRUE TO THE GOAL OF NOT IDENTIFYING
24 THEMSELVES. SO IT DOES INTRODUCE SOME CHALLENGES IN
25 DOING IT, BUT I DO -- I AGREE AND APPRECIATE THE

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1 IDEA THAT IF WE COULD TRULY DO AN ANONYMOUS
2 APPROACH, IT MIGHT HAVE SOME BENEFIT.

3 AT LEAST IN THE TIMES AND THE WAYS IN
4 WHICH WE'VE TRIED IT, IT HAS PROVED THAT THERE ARE
5 WAYS TO GET AROUND THAT UNFORTUNATELY.

6 DR. YAMAMOTO: I GUESS MY JUDGMENT WOULD
7 BE TO DO WHAT GATES DOES, AND THAT SAYS YOU JUST
8 WRITE BACK TO THE APPLICANT AND SAY YOUR APPLICATION
9 IS NOT GOING TO BE REVIEWED BECAUSE YOU'VE LOOKED
10 FOR WAYS TO SNEAK IN WHO YOU ARE. ALL IT TAKES IS
11 ONE SENTENCE. WE HAVE SHOWN PREVIOUSLY THAT AND
12 IT'S ALL OVER. AND SO THOSE THINGS ARE EASY TO DO,
13 BUT THEY'RE ALSO EASY TO CATCH.

14 MR. TOCHER: HEY, MARK. THIS IS SCOTT
15 BACK AT HQ. I WONDER IF FROM A PROCESS STANDPOINT I
16 THINK SOME MEMBERS, WE MAY LOSE A QUORUM HERE IN
17 JUST A COUPLE MINUTES. WE DO HAVE ONE MORE ITEM.
18 I'M WONDERING IF PERHAPS WE COULD JUST HIT THE PAUSE
19 BUTTON ON THIS AGENDA ITEM, TAKE UP THE SECOND ONE
20 BECAUSE WE'RE HOPING TO GET THAT ONE THROUGH TO THE
21 BOARD NEXT WEEK, AND THEN WE CAN COME BACK TO THIS
22 ITEM AND HAVE ANY FURTHER DISCUSSION AND RECEIVE
23 PUBLIC COMMENT AS WELL.

24 CHAIRMAN FISCHER-COLBRIE: ALL RIGHT.
25 SOUNDS GOOD. LET'S ROCK AND ROLL. THIS IS ON THE

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1 EDUC, RIGHT?

2 DR. YAMAMOTO: THANKS, SCOTT.

3 MR. TOCHER: YES. YOU BET. WE'LL COME
4 BACK TO IT.

5 CHAIRMAN FISCHER-COLBRIE: SO, LIZ, YOU
6 GET THE WHOPPING THREE MINUTES, RIGHT?

7 DR. NOBLIN: LET'S GO. THANK YOU SO MUCH,
8 MARK AND SCOTT. I'M GOING TO VERY, VERY QUICKLY
9 GIVE THE SCIENCE SUBCOMMITTEE AN UPDATE ON SOME
10 FUNCTIONAL CHANGES THAT CIRM WOULD LIKE TO MAKE TO
11 THE EDUC1 CONCEPT.

12 SO AS A REMINDER AND AN ORIENTATION FOR
13 ANY NEW COMMITTEE MEMBERS, EDUC1 IS THE MECHANISM BY
14 WHICH CIRM SUPPORTS MISSION CRITICAL SCIENTIFIC AND
15 PROGRAMMATIC MEETINGS AND CONFERENCES. THIS
16 INCLUDES THINGS LIKE ANNUAL TRAINING MEETINGS OR
17 MEETINGS THAT BRING TOGETHER AWARDEES IN A SPECIFIC
18 PROGRAM LIKE REMIND OR MANUFACTURING.

19 SO THESE EDUC1 MEETINGS ADDRESS A RANGE OF
20 TOPICS AND THEN CORRESPONDINGLY HAVE A RANGE OF
21 STRUCTURES AND BUDGETS. WE HAVE AT THE LOWER END
22 INDIVIDUAL PROGRAM NETWORK MEETINGS WHICH CAN BE
23 MANAGED FOR AS LITTLE AS \$50,000. AND THEN OUR
24 LARGEST MEETING, THE PAN TRAINING NETWORK MEETING
25 COSTS ABOUT \$450,000 TO MANAGE. AND EACH YEAR THE

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1 ICOC APPROVES AN EDUC1 PROGRAM BUDGET AS PART OF THE
2 RESEARCH BUDGET THAT'S PRESENTED.

3 SO THE CHANGES THAT WE ARE REQUESTING
4 TODAY ARE EXACTLY RELATED TO THE RANGE OF MEETINGS
5 AND FLEXIBILITY TO OPERATE WITHIN THE VARIOUS
6 OBJECTIVES AND STRUCTURES.

7 SO TO EXPLAIN THOSE CHANGES, I WILL
8 QUICKLY JUST SAY THAT THIS IS A REQUEST TO MOVE FROM
9 ISSUING GRANTS FOR EDUC1 MEETINGS, TO ESTABLISHING
10 MASTER SERVICE AGREEMENTS WITH MEETING PLANNING
11 VENDORS, AND THEN ESTABLISHING -- APPROVING SCOPES
12 OF WORK TO COVER THE REQUIREMENTS FOR EACH SPECIFIC
13 MEETING.

14 THIS IS A CHANGE THAT WE THINK IS GOING TO
15 BRING EFFICIENCY, COST SAVINGS, AND RETAIN THE
16 FLEXIBILITY THAT WE NEED FOR EDUC1. EFFICIENCY IN
17 THE EXECUTING AND SOW UNDER AN MSA IS EXPECTED TO BE
18 VERY RAPID AND EFFICIENT. IF WE HAVE ONE VENDOR
19 THAT'S MANAGING MULTIPLE EDUC1 MEETINGS, THAT'S
20 WHERE WE EXPECT TO SEE COST SAVINGS. AND, AGAIN,
21 THE FLEXIBILITY IS THROUGH THE ABILITY TO DESIGN
22 EACH SCOPE OF WORK SPECIFIC TO THE NEEDS AND
23 REQUIREMENTS FOR EACH MEETING.

24 SO IN ORDER TO IMPLEMENT THAT SHIFT FROM A
25 GRANT TO A CONTRACT, THERE IS A REQUEST THAT WE

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1 WOULD LIKE TO MAKE, THAT THE ICOC APPROVE A LIMITED
2 EXEMPTION TO CIRM'S PURCHASING POLICY. AND I
3 IMPORTANTLY WANT TO SAY THAT THIS EXEMPTION MIRRORS
4 WHAT IS CURRENTLY DELEGATED TO CIRM'S PRESIDENT
5 TODAY UNDER EDUC1, WHICH IS THE ABILITY TO AWARD --
6 TO ISSUE AWARDS OF UP TO \$500,000. SO, AGAIN, THIS
7 IS THAT SAME DELEGATION, BUT NOW JUST APPLIED ON THE
8 CONTRACTING SIDE.

9 SO WHAT THE PURCHASING POLICY REQUIRES IS
10 THAT GOVERNANCE SUBCOMMITTEE APPROVE CONTRACTS UP TO
11 \$250,000 ANNUALLY AND THAT ICOC APPROVES CONTRACTS
12 OVER \$500,000 ANNUALLY. SO THE EXEMPTION FOR EDUC1
13 WOULD BE TO ALLOW THE CIRM PRESIDENT TO EXECUTE
14 SOW'S OF UP TO \$500,000 PER SOW.

15 SOME OF THE OVERSIGHT THAT WE WOULD RETAIN
16 WITH THIS EXEMPTION IS THAT, AGAIN, THIS IS LIMITED
17 TO EDUC1 SOW'S. WE WOULD CONTINUE REGULAR REPORTING
18 ON CONTRACTS TO GOVERNANCE SUBCOMMITTEE AND THEN
19 ANNUALLY TO THE ICOC. AND, AGAIN, WHEN THE ICOC
20 APPROVES RESEARCH BUDGETS EACH JUNE, THAT WOULD
21 INCLUDE THE PROPOSED EDUC1 OVERALL PROGRAM BUDGET.

22 SO ASSUMING THAT WE HAVE ICOC APPROVAL OF
23 THESE CONCEPT UPDATES IN MARCH, WE WOULD MOVE
24 QUICKLY TO GET SOME OF OUR INITIAL MEETING
25 ORGANIZING VENDORS, POSTING OUR RFP AT THE END OF

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1 MARCH, PROPOSALS DUE ON MAY 14TH, AND THEN VENDOR
2 SELECTION BY THE END OF JUNE. THIS IS OUR INITIAL
3 RUN-THROUGH OF THIS PROCESS, AND THIS TIMELINE LET'S
4 US CONDUCT OUR FIRST EDUC1 MEETINGS IN EITHER LATE
5 2026 OR EARLY 2027. WE'RE SPECIFICALLY THINKING
6 ABOUT THE NEXT REMIND NETWORK MEETING IN THIS CASE.

7 I WILL JUST VERY BRIEFLY MENTION THAT THE
8 2026 TRAINEE MEETINGS, BOTH SPARK AND PAN TRAINEE,
9 ARE ALREADY UNDER PLANNING. WE HAVE GRANTS ISSUED
10 FOR THOSE MEETINGS, AND THAT WAS JUST TO ENSURE THAT
11 WE COULD START THE PLANNING PROCESS IN TIME FOR
12 THOSE MEETINGS THIS SUMMER.

13 OKAY. SO I THINK THAT WAS MAYBE A BIT
14 OVER THREE MINUTES, BUT OUR REQUEST FOR A MOTION
15 TODAY IS THAT WE REQUEST SCIENCE SUBCOMMITTEE
16 ENDORSEMENT FOR THE REVISED EDUC1 CONCEPT, INCLUDING
17 THE DELEGATION OF AUTHORITY TO THE CIRM PRESIDENT
18 AND TO EXECUTE THE MSA AND MEETING SPECIFIC SOW'S OF
19 UP TO \$500,000.

20 CHAIRMAN FISCHER-COLBRIE: GREAT, THANK
21 YOU, LIZ. THIS IS A SITUATION WHERE THIS IMPROVES
22 ADMINISTRATIVE COSTS AND MAKES THINGS WAY EASIER TO
23 ORGANIZE THESE EVENTS. SO I THINK THIS IS
24 INCREDIBLY POSITIVE AND BENEFICIAL FOR CIRM AND FOR
25 SAVING MONEY.

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1 SO WITH THAT, I'D LIKE TO GET A MOTION FOR
2 ENDORSEMENT.

3 VICE CHAIR BONNEVILLE: SO MOVED.

4 (MULTIPLE SECONDS.)

5 CHAIRMAN FISCHER-COLBRIE: OKAY. ALL
6 THOSE IN FAVOR --

7 MR. TOCHER: EXCUSE ME. ACTUALLY THE LAW
8 REQUIRES US TO DO A ROLL CALL JUST TO MAKE IT SUPER
9 SLOW.

10 CHAIRMAN FISCHER-COLBRIE: THANK YOU.

11 MR. TOCHER: SURE. I'M NOT SEEING ANY
12 PUBLIC COMMENT ON THIS ITEM. SO LET'S MOVE TO ROLL
13 CALL VOTE.

14 MARIA BONNEVILLE.

15 VICE CHAIR BONNEVILLE: YES.

16 MR. TOCHER: MARK FISCHER-COLBRIE.

17 CHAIRMAN FISCHER-COLBRIE: YES.

18 MR. TOCHER: ELENA FLOWERS.

19 DR. FLOWERS: YES.

20 MR. TOCHER: JUDY GASSON.

21 DR. GASSON: YES.

22 MR. TOCHER: VITO IMBASCIANI.

23 CHAIRMAN IMBASCIANI: YES.

24 MR. TOCHER: PAT LEVITT.

25 DR. LEVITT: YES.

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1 MR. TOCHER: CAROLYN MELTZER.

2 DR. MELTZER: YES.

3 MR. TOCHER: SHAUNA STARK.

4 DR. STARK: YES.

5 MR. TOCHER: KEITH YAMAMOTO.

6 DR. YAMAMOTO: YES.

7 MR. TOCHER: GREAT. THANKS VERY MUCH,
8 EVERYONE. THAT MOTION CARRIES.

9 CHAIRMAN IMBASCIANI: GREAT.

10 MR. TOCHER: SO WE CAN GO BACK TO THE
11 FIRST ITEM IF YOU'D LIKE, MARK.

12 CHAIRMAN FISCHER-COLBRIE: LET ME
13 UNDERSTAND SOMETHING. I'M STILL A LITTLE CONFUSED
14 ABOUT THE ONE-PAGER VERSUS THE FULL APPLICATION.
15 I'M NOT TRACKING BECAUSE YOU'RE EITHER GOING TO LOOK
16 AT A FULL APPLICATION AND AT LEAST DO SOME KIND OF A
17 WRITE-UP OR YOU'RE NOT. SO I'M NOT SURE I
18 UNDERSTAND WHAT THE FUNCTION OF THE ONE-PAGER IS
19 BECAUSE IF THEY ONLY EVALUATE OFF THE ONE-PAGER,
20 THEN THAT'S ACTUALLY THE CURSORY REVIEW THAT WE'RE
21 NOT LOOKING FOR. SO I'M NOT UNDERSTANDING THE
22 WORKFLOW. IF SOMEBODY COULD DESCRIBE THAT FOR ME.

23 DR. YAMAMOTO: MY UNDERSTANDING, AND GIL
24 SAID IT, IS THAT THIS FIRST PROCESS OF SELECTION AND
25 RANKING THAT EVENTUALLY DERIVES THE CUTOFF LINE FOR

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1 REVIEW IS NOT IF APPLICATIONS ARE FULLY REVIEWED.
2 AND SO THEN THE QUESTION IS CAN WE GIVE -- WHAT'S
3 THE BEST RESOLUTION THAT WE CAN GIVE TO THE
4 REVIEWERS SO EVERYBODY IS DOING THE EQUIVALENT
5 THING?

6 YOU CAN IMAGINE SOME REVIEWERS SAYING,
7 "WELL, I'LL KIND OF SKIM IT OVER. I KNOW WHAT TO
8 LOOK FOR. AND I'LL MAKE A DECISION." AND OTHERS
9 WHO SAY, "I'M NOT BEING RESPONSIBLE TO THE POOR
10 APPLICANT UNLESS I REALLY EXAMINE THIS THING IN
11 DETAIL." THESE ARE LONG APPLICATIONS. AND SO
12 THOSE -- IT WOULD BE NICE TO EVEN OUT THOSE
13 DIFFERENCES.

14 AND WHAT I'M ARGUING FROM EXPERIENCE IS
15 THAT ONE WAY TO EVEN THEM OUT IS TO ASK THE
16 APPLICANT -- MAKE PART OF THE APPLICATION, MAKE AS
17 PART OF THE APPLICATION THIS ONE-PAGE REVIEW. IN
18 THE FIRST ROUND OF EVALUATION WHERE THE TRIAGE LINE
19 IS BEING DRAWN, ALL THAT IS PROVIDED TO THE
20 REVIEWERS IS THE ONE-PAGERS DEIDENTIFIED, AND THEY
21 MAKE THEIR ASSESSMENT BASED ON THAT.

22 I DON'T KNOW WHETHER IT'S POSSIBLE BY ANY
23 PROCESS TO FAIRLY ELIMINATE 80 PERCENT OF THE
24 APPLICATIONS FROM DETAILED DISCUSSION OR EVALUATION,
25 BUT AT LEAST THIS ONE-PAGE THING EVENS THE PLAYING

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1 FIELD FOR THE REVIEWERS SO THEY'RE ALL LOOKING AT
2 THE SAME THING, EVALUATING THE SAME LEVEL OF
3 INFORMATION, AND THOSE ARE ABSTRACTED INTO ONE PAGE
4 DEIDENTIFIED. AND THEN ONCE THAT TRIAGE LINE IS
5 DRAWN, THEN THE FULL APPLICATIONS ARE THEN PROVIDED
6 TO THE REVIEWERS FOR THOSE APPLICATIONS THAT SURVIVE
7 THE FIRST ROUND.

8 CHAIRMAN FISCHER-COLBRIE: SO YOU'RE
9 ACTUALLY SAYING YOU LIKE A MORE CURSORY REVIEW
10 INITIALLY FOR THE TRIAGE? I'M NOT SURE --

11 DR. YAMAMOTO: I DON'T KNOW HOW MORE
12 CURSORY IT IS.

13 CHAIRMAN FISCHER-COLBRIE: OH, OKAY.

14 DR. YAMAMOTO: I'VE NEVER BEEN ON THE GWG
15 SO I DON'T KNOW.

16 CHAIRMAN FISCHER-COLBRIE: I JUST MEANT
17 RELATED TO EVALUATING A FULL APPLICATION VERSUS
18 EVALUATING A ONE-PAGER.

19 DR. YAMAMOTO: SO, GIL, CORRECT ME IF I'M
20 WRONG, BUT I THINK WHAT HE SAID AT THE BEGINNING IS
21 THAT THIS IS NOT AN EVALUATION -- A FULL-BLOWN
22 EVALUATION OF THE WHOLE REVIEW. OTHERWISE, IT SORT
23 OF TAKES AWAY FROM --

24 CHAIRMAN IMBASCIANI: GIL, IF YOU COULD
25 CLARIFY. I THINK THERE'S SOME REAL TERMINOLOGY

1 DIFFERENCES.

2 DR. SAMBRANO: MAYBE. BUT IT REALLY ISN'T
3 ABOUT THE APPLICATION ITSELF. IT'S ABOUT THE
4 CRITERIA THAT ARE USED TO SELECT IT. SO THE POINT
5 IS THE INITIAL REVIEW IS TO ASSESS AT A VERY HIGH
6 LEVEL, AND THAT'S WHY WE USE THE SCIENTIFIC VALUE
7 AND WE DEFINE IT BASED ON THE GUIDING PRINCIPLE, IS
8 THIS A TRANSFORMATIVE PROJECT OR NOT?

9 BEFORE YOU GET INTO THE DETAILS OF THE
10 PLAN, THE DESIGN, THE TEAM, ALL OF THE ELEMENTS THAT
11 MIGHT BE ASKED IN A FULL SET OF CRITERIA WHERE WE
12 ASK FOR RATIONALE, WE ASK FOR PLANNING AND DESIGN,
13 WE ASK FOR THE TEAM, WE ASK FOR POPULATION IMPACT,
14 WE'RE NOT ASKING FOR ALL THAT. WE'RE JUST ASKING AT
15 A HIGH LEVEL IS THIS SOMETHING THAT CAN MAKE THE
16 DIFFERENCE IN PATIENTS' LIVES? IS THIS SOMETHING
17 THAT WILL MAKE A DIFFERENCE BECAUSE IT'S A
18 TRANSFORMATIVE THERAPY THAT'S GOING TO BE BETTER
19 THAN ANYTHING THAT'S CURRENTLY OUT THERE? THAT'S
20 THE FOCUS OF THE REVIEW.

21 NOW, WHETHER THEY DO IT AND DERIVE THAT
22 ASSESSMENT FROM A ONE-PAGE OR IF IT TAKES THEM MORE,
23 WE'RE NOT KIND OF DISTINGUISHING THAT. WE DO
24 PROVIDE AN EASIER WAY OF LOOKING AT THE APPLICATION
25 THROUGH A PREVIEW PAGE. BUT FOR REVIEWERS IT'S

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1 REALLY LOOK AT THIS PROPOSAL AND TELL US FROM THAT
2 LENS IS THIS ONE THAT SHOULD AND DESERVES A DEEPER
3 AND FURTHER LOOK. AND THAT'S THE TASK THAT THEY
4 HAVE WHEN DOING THAT INITIAL SELECTION.

5 CHAIRMAN FISCHER-COLBRIE: AND THAT'S OFF
6 A FULL APPLICATION THOUGH, RIGHT, GIL?

7 DR. SAMBRANO: THEY HAVE THE FULL
8 APPLICATION AVAILABLE TO THEM, CORRECT.

9 DR. YAMAMOTO: THEY JUST HAVE TO SORT
10 THROUGH AND FIND THOSE THINGS -- THOSE COMPONENTS.
11 AND WHAT I'M ARGUING, GIL, IS THAT IF YOU TOLD THE
12 APPLICANTS WE WANT A ONE-PAGER THAT DOES THIS, THAT
13 IS RESPONSIVE TO THESE PARTICULAR ELEMENTS THAT THE
14 REVIEWERS NEED TO MAKE, AND IT'S GOING TO BE ON THAT
15 BASIS THAT YOUR APPLICATION IS SELECTED FOR FULL
16 REVIEW, I THINK YOU'LL GET GOOD RESPONSES.

17 DR. LEVITT: I GUESS I'M CONFUSED AS WELL
18 BECAUSE THE CRITICISMS ABOUT THE INITIAL APPROACHES
19 WITH THAT IS THAT THERE WAS NO SCIENTIFIC REVIEW.
20 THERE WERE RELATIVELY SHORT FORMS THAT WERE BEING
21 USED. THERE WERE FORMS BEING USED, IT WASN'T FULL
22 APPLICATIONS, AND THERE WAS A LOT OF COMPLAINTS.
23 AND SO I THINK THERE'S HETEROGENEITY ACROSS THE
24 BOARD IN EVERY STUDY SECTION. SOME ARE GOING TO BE
25 MORE DETAILED AND OBSESSIVE ABOUT LOOKING AT THE

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1 WHOLE APPLICATION. IT'S NOT HARD TO FIND RATIONALE
2 SECTIONS AND SPECIFIC AIMS SECTIONS AND METHOD
3 SECTIONS, ET CETERA. I MEAN THE ONLY THING THAT IT
4 DOES WITH ONE PAGE AND IT'S DEIDENTIFIED IS IT GETS
5 RID OF INSTITUTIONAL AND INVESTIGATOR BIAS. I'M NOT
6 ARGUING FOR OR AGAINST THAT.

7 BUT I DO THINK THAT WE'VE ALREADY HEARD
8 FROM OUR SCIENTISTS THAT THEY WANT SELECTIONS BASED
9 ON THE SCIENCE.

10 DR. YAMAMOTO: THAT'S RIGHT.

11 DR. LEVITT: AND I DON'T THINK YOU CAN DO
12 IT ON ONE PAGE BECAUSE, ESPECIALLY IF THE
13 INSTRUCTIONS ARE SOMETHING NEW, SOMETHING NOVEL, ET
14 CETERA, ET CETERA, THEN YOU GO BACK TO THE SAME
15 ARGUMENT THAT, WELL, WE FUNDED SO MUCH CANCER, WE'RE
16 NOT GOING TO SELECT CELL-BASED THERAPIES BECAUSE,
17 WELL, WE ALREADY HAVE A BUNCH OF CELL-BASED
18 THERAPIES. AND THAT WAS THE ARGUMENT FROM A NUMBER
19 OF THE INVESTIGATORS WHO HAD PUBLIC COMMENT ABOUT
20 THIS IS THAT IT WASN'T BASED ON THE SCIENCE. IT WAS
21 BASED ON SOMETHING ELSE, WHATEVER THAT WAS.

22 DR. YAMAMOTO: YEAH. YEAH.

23 DR. LEVITT: I DON'T SEE HOW THIS SOLVES
24 ANYTHING. AND WE JUST HAVE TO RELY ON THE REVIEWERS
25 TO BASICALLY DO AN EFFICIENT JOB. THEY HAVE THE

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1 WHOLE APPLICATION, THEY CAN LOOK AT THE WHOLE THING,
2 THE ABSTRACT IS -- ESSENTIALLY 30 LINES IS HALF A
3 PAGE. AND SO YOU'RE ASKING FOR ANOTHER HALF A PAGE.
4 AND REVIEWING, TO ME, AN ABSTRACT TO DECIDE WHETHER
5 IT'S THUMBS UP OR THUMBS DOWN, TO ME, IS JUST NOT
6 ADEQUATE. BUT THAT'S JUST ME.

7 DR. THOMAS: MARK, CAN I OFFER A DATA
8 POINT HERE FOR WHAT IT'S WORTH?

9 CHAIRMAN FISCHER-COLBRIE: YEAH. J.T., GO
10 AHEAD.

11 DR. THOMAS: SO I DON'T PRETEND TO HAVE
12 BORNE WITNESS TO EVEN A FRACTION OF THE REVIEWS THAT
13 KEITH HAS PARTICIPATED IN PERSONALLY OVER HIS
14 CAREER. BUT I DO WANT TO NOTE, AND HAVING SAT
15 THROUGH 14 YEARS WORTH OF GWG, ON THIS ISSUE OF
16 INSTITUTIONAL OR PERSONAL BIAS, THERE ARE FREQUENTLY
17 COMMENTS ABOUT THE STRENGTH OF THE TEAM, THE
18 INSTITUTION, ET CETERA. BUT NONETHELESS, THE
19 LANDSCAPE IS STREWN WITH APPLICATIONS THAT WERE NOT
20 RECOMMENDED FOR FUNDING REGARDLESS OF THAT. SO I'M
21 NOT ENTIRELY SURE HOW MUCH INSTITUTIONAL AND
22 INDIVIDUAL BIAS ENTERS INTO THE ANALYSIS. I
23 WELCOME -- MARK, YOU'VE BEEN ON A LOT OF THESE.
24 VITO, WHAT ARE YOUR VIEWS ON THAT?

25 CHAIRMAN FISCHER-COLBRIE: WELL, MY BIAS

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1 IS TO HAVE THE FULL APPLICATION AND PEOPLE GO
2 THROUGH IT. THEY ARE GOING TO MAKE THEIR
3 DETERMINATIONS AROUND IMPACT. KEITH IS RIGHT.
4 THEY'RE ALSO GOING TO BE KIND OF HAVE THEIR HEAD
5 LEANING IN A CERTAIN DIRECTION DEPENDING ON THEIR
6 FIRST INITIAL PASS. BUT FROM MY PERSPECTIVE, AT
7 LEAST THERE'S SUFFICIENT DETAIL AND INFORMATION
8 THERE FOR THEM TO MAKE AN INFORMED DECISION. AND
9 BASED ON, FOR EXAMPLE, WHAT I SAW FROM PDEV TODAY,
10 PEOPLE DO WORK AT IT. THEY DO TAKE A LOOK AT IT.
11 SO IT DOESN'T GET THE FULL GWG REVIEW, BUT
12 YOU'RE STILL GETTING A NUMBER OF RESEARCHERS BASED
13 ON SCIENCE TO MAKE A DETERMINATION. IT'S JUST A
14 LITTLE HARD FOR ME TO -- IF SOMEBODY SAID, WELL,
15 YOU'RE GOING TO BASE THESE ON A ONE-PAGER, I'M
16 CONCERNED IT DOESN'T ADDRESS THE ISSUES THAT PEOPLE
17 BROUGHT UP BEFORE ABOUT, WELL, WAIT. WHY WAS MINE
18 NOT SELECTED? IT'S LIKE I DON'T KNOW IF A
19 ONE-PAGER --

20 DR. YAMAMOTO: I'LL JUST SAY TWO THINGS
21 THAT ADDRESS THIS POINT.

22 CHAIRMAN FISCHER-COLBRIE: UH-HUH.

23 DR. YAMAMOTO: ONE IS THAT THE MECHANISM
24 THAT I HAVE THE MOST EXPERIENCE WITH WITH THESE
25 ONE-PAGERS IS THE GATES GRAND CHALLENGES. SOME OF

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1 YOU MAY HAVE SAT ON THOSE PANELS. AND IT WAS MY
2 EXPERIENCE -- I ONLY DID IT TWICE. AND IN THE TWO
3 TIMES YOU GOT BETWEEN 250 AND 300 PAGES, ONE-PAGERS.
4 AND EVERYBODY ON THE REVIEW COMMITTEE GOT THE SAME
5 250 TO 300 PAGES. MAYBE IT WAS 200 TO 250. ANYWAY,
6 IN EXCESS OF 200 PAGES IN WHICH THE APPLICANTS WERE
7 DIRECTED TO FOCUS ON THE IDEA, THE QUALITY OF THE
8 IDEA AND THE PROJECTED IMPACT IF THE IDEA WERE TO BE
9 TRUE -- TO BE PROVEN CORRECT. AND THAT OFTEN THEY
10 WOULD ALSO POINT OUT THAT IF THE IDEA IS NOT PROVEN
11 CORRECT, THE APPROACHES THAT THEY'RE TAKING WILL
12 REVEAL INFORMATION OF GREAT VALUE.

13 AND WE DISCOVERED -- IN THOSE TWO ROUNDS I
14 PERSONALLY DISCOVERED TWO IMPORTANT THINGS. ONE IS
15 THAT IT WAS ACTUALLY EASY TO DRAW A DISTINCTION
16 BETWEEN -- AND THE GATES SAID WE'LL REVIEW HALF OF
17 THESE IN DETAIL. AND IT WAS ACTUALLY EASY TO MAKE
18 AN ASSESSMENT OF THE TOP HALF FROM THE BOTTOM HALF.
19 THAT WAS DISCOVERY ONE.

20 DISCOVERY TWO WAS TRUE FOR ME AND FOR
21 EVERYONE I TALKED WITH ABOUT GOING THROUGH THIS
22 PROCESS. THAT IS THAT WE DISCOVERED THAT WE ARE
23 CARRYING AROUND THESE BIASES. WE LIKE TO THINK THAT
24 WE'RE NOT BIASED. BUT YOU GO THROUGH AND YOU PICK
25 THE APPLICATIONS THAT YOU THINK ARE TERRIFIC AND

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1 THOSE THAT YOU THINK ARE NOT, AND WHAT YOU FIND IS
2 THAT THE APPLICATION THAT YOU ARE MOST EXCITED ABOUT
3 IS COMING FROM AN INVESTIGATOR YOU'VE NEVER HEARD
4 OF. THE GATES GRAND CHALLENGES ARE GLOBAL, SO
5 SOMETIMES THEY'RE COMING FROM INSTITUTIONS YOU'VE
6 NEVER HEARD OF. AND YOU THINK, OH, MY GOD. WHAT
7 WOULD I HAVE DONE IF I KNEW THAT INFORMATION GOING
8 IN? AND EVERYBODY I TALKED TO WENT THROUGH THE SAME
9 PROCESS.

10 WE'RE ALL CARRYING THESE BIASES AROUND,
11 AND WOULDN'T IT BE NICE TO HAVE A SCIENTIFIC
12 APPLICATION PROCESS, EVALUATION PROCESS, THAT
13 DOESN'T HAVE THESE BIASES BECAUSE WE'RE LOSING
14 IMPORTANT IDEAS AND ACTUALLY INVESTIGATORS FROM THE
15 COMMUNITY BY CARRYING THESE BIASES AROUND. SO ALL
16 I'M SAYING IS THAT I THINK THERE'S VALUE IN DOING
17 THAT IN A DEIDENTIFIED WAY JUST FROM MY OWN ON
18 PERSONAL EXPERIENCES.

19 SO WE KNOW THAT -- WE ALL HAVE TO ADMIT
20 THAT WE'RE INFLUENCED BY AN APPLICATION COMING FROM
21 A NOBEL LAUREATE. THIS IS NOT TO SAY THAT THAT
22 INFORMATION IS NOT IMPORTANT. IT'S THERE IN THE
23 FULL APPLICATION. YOU'D LIKE TO KNOW WHO'S THIS
24 COMING FROM AND IS THE INSTITUTION AT A LEVEL WHERE
25 THEY CAN SUPPORT THE WORK, WHERE THEY CAN PROVIDE

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1 INFORMATIVE, COLLABORATIVE INFORMATION, SUGGESTIONS,
2 ADVICE, COUNSEL IF THE APPLICANT HERSELF IS NOT
3 FULLY QUALIFIED COMING OUT OF THE GATES TO BE ABLE
4 TO CARRY OUT THE WORK. AND SO THAT INFORMATION IS
5 THERE. BUT IN THAT FIRST ROUND OF BASICALLY THUMBS
6 UP OR THUMBS DOWN, AS GATES HAS IT AT THE 50-PERCENT
7 CUTOFF LINE, THAT IT WOULD BE NICE TO RID OURSELVES
8 OF THOSE BIASES. AND I WOULD SUBMIT THAT THE ONLY
9 WAY WE CAN RID OURSELVES OF IT IS NOT TO PROVIDE
10 THAT INFORMATION.

11 CHAIRMAN FISCHER-COLBRIE: OKAY, KEITH.
12 IF I CAN MAKE SURE I UNDERSTAND IT, YOU'RE PROPOSING
13 THAT, RATHER THAN A FULL APPLICATION, AN APPLICANT
14 TURNS IN A ONE-PAGER --

15 DR. YAMAMOTO: NO. IT'S PART OF THE
16 APPLICATION.

17 CHAIRMAN FISCHER-COLBRIE: IT'S PART OF
18 THE APPLICATION.

19 DR. YAMAMOTO: YEAH. AND IN THIS INITIAL
20 ROUND, ALL THAT'S PROVIDED IS THAT ONE PAGE. AND
21 THEN THE TOP 50 PERCENT A FULL APPLICATION IS
22 PROVIDED.

23 CHAIRMAN FISCHER-COLBRIE: OKAY. SO
24 THEY'RE PROVIDING THE FULL APPLICATION WITH A
25 ONE-PAGER, BUT THE REVIEWERS INITIALLY ONLY SEE THE

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1 ONE-PAGER. THEY DON'T SEE THE FULL APPLICATION.

2 DR. YAMAMOTO: THAT'S HOW GATES WORKS.

3 CHAIRMAN FISCHER-COLBRIE: OKAY. YEAH.

4 OKAY. IT'S INTERESTING BECAUSE I'VE SEEN SEVERAL OF
5 THESE WHERE PEOPLE MAKE THESE INCREDIBLE STATEMENTS
6 OF IMPACT. AND THEN YOU LOOK AT, WELL, HOW'S THE
7 MAGIC HAPPEN? AND IT'S LIKE NOT REALLY, BUT OKAY.
8 INTERESTING.

9 DR. YAMAMOTO: WELL, BY INCLUDING THE
10 ABSTRACT AND THE SPECIFIC AIMS, YOU GET A VIEW IN
11 THE AIMS WHETHER THEY THINK THAT THEIR APPROACH IS
12 REALLY GOING TO GET THEM THERE.

13 CHAIRMAN FISCHER-COLBRIE: PRESUMPTIVELY
14 WHAT YOU'RE SAYING, KEITH, IS YOU TRY TO LOOK FOR
15 STUFF THAT MASSIVELY MOVE THE NEEDLE. WHAT ARE
16 THINGS THAT ARE MASSIVE UPGRADES --

17 DR. YAMAMOTO: GIL GAVE A VERY GOOD
18 RECOUNTING OF WHAT HE WANTS THE REVIEWERS TO BE
19 LOOKING FOR IN THIS INITIAL ROUND WHERE THE TRIAGE
20 LINE IS ESTABLISHED. AND SO WHY SHOULDN'T GIL
21 REVEAL THAT TO THE APPLICANTS AND SAY REDUCE TO ONE
22 PAGE YOUR ANSWERS TO THESE POINTS.

23 CHAIRMAN FISCHER-COLBRIE: OTHERS ON THE
24 COMMITTEE WANT TO COMMENT OR OTHER THOUGHTS OR
25 VIEWS?

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1 DR. THOMAS: CAN I JUST MAKE A POINT HERE?

2 CHAIRMAN FISCHER-COLBRIE: SURE.

3 DR. THOMAS: KEITH, I DON'T KNOW IF I JUST
4 HEARD YOU CORRECTLY, BUT IF WE DID, WE NEED TO SORT
5 OF RESPOND TO IT. YOU SAID YOU'RE RECOMMENDING A
6 ONE-PAGER IN ADDITION TO THE FULL REVIEW. THE
7 ONE-PAGER IS THE ONLY DOCUMENT THAT GOES TO THE
8 SELECTION PROCESS. AND THEN YOU SAID THE TOP 50
9 PERCENT PROCEED. I ASSUME YOU'RE NOT RECOMMENDING
10 THAT 50 PERCENT OF ALL APPLICATIONS GO TO REVIEW
11 BECAUSE THE BANDWIDTH ISSUE WITH OUR GWG MEMBERS,
12 PATIENT ADVOCATES, ET CETERA IS SO SUBSTANTIAL, THAT
13 JUST ISN'T GOING TO WORK.

14 DR. YAMAMOTO: ABSOLUTELY, J.T. AND GIL
15 AND I DISCUSSED THIS ALREADY. I THINK IT'S REALLY
16 HARD TO DO A TRIAGE WHERE YOU'RE ELIMINATING 80
17 PERCENT OF THE APPLICATIONS. I DON'T KNOW IF THAT'S
18 POSSIBLE TO BE DONE EQUITABLY. I THINK IT'S EASY TO
19 ELIMINATE HALF. IT'S RELATIVELY -- IT'S QUITE
20 SIMPLE. THERE'S LOTS OF REVIEWER AGREEMENT WHEN
21 THAT 50-PERCENT LINE IS DRAWN. OBVIOUSLY THE
22 APPLICANTS BELOW IT DON'T AGREE, BUT THE REVIEWERS
23 FIND IT RELATIVELY EASY TO TRIAGE HALF. I THINK
24 IT'S A HUGE CHALLENGE EQUITABLY TO ELIMINATE 80
25 PERCENT WHEN YOU REALLY ARE TRYING TO FIND A LINE

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1 BETWEEN 80 TO 100 PERCENT LEVEL OF QUALITY AND LET'S
2 JUST SAY TO FIND THE BORDER, THE 75 TO 80 PERCENT
3 QUALITY. THAT'S TOUGH GOING.

4 I DON'T KNOW IF THAT'S EVEN POSSIBLE, BUT
5 I KNOW THAT THAT IS WHAT -- THERE'S GENERAL
6 AGREEMENT THAT YOU ARE KIND OF OBLIGATED TO LOOK FOR
7 A WAY TO BE ABLE TO ESTABLISH THAT LINE. I THINK
8 IT'S HARD TO DO, BUT YES. AND SO I'M NOT ARGUING IN
9 ANY WAY THAT THE PROCESS THAT I'VE DESCRIBED WOULD
10 ALLOW RELATIVELY EASY DISCRIMINATION TO BE DRAWN
11 WHERE 80 PERCENT OF THE APPLICANTS ARE EXCLUDED FROM
12 BEING ABLE TO LOOK AT THAT FULL APPLICATION. I
13 THINK IT'S VERY HARD.

14 CHAIRMAN FISCHER-COLBRIE: IS THAT YOU,
15 JUDY?

16 DR. GASSON: YEAH. SO COUPLE COMMENTS. I
17 COMPLETELY AGREE WITH KEITH THAT IT'S HARD TO PICK
18 THE TOP 20 PERCENT. I'VE ALWAYS HAD A THIRD, A
19 THIRD, A THIRD RULE THAT IS RELATIVELY
20 STRAIGHTFORWARD TO PICK THE TOP THREE, THE BOTTOM
21 THIRD, AND THEN THERE'S ALWAYS THOSE IN THE MIDDLE.
22 SO, AGAIN, I UNDERSTAND THE CHALLENGE WITH THE GWG,
23 BUT I DO THINK THAT THAT'S REALLY DIFFICULT.

24 I ALSO AGREE WITH KEITH, THAT WE ALL HAVE
25 A BIAS THAT WE CARRY AROUND, WHICH IS REALLY

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1 UNFORTUNATE. AND TRY AS HARD AS WE MIGHT TO BE
2 EQUITABLE AND SO ON AND SO FORTH, IT'S THERE. I
3 ADMIRE THE GATES FOUNDATION FOR GIVING THIS A TRY.
4 I THINK IT'S A REALLY INTERESTING IDEA. BUT AT THE
5 END OF THE DAY, I'M REALLY AFRAID THE SCIENTIFIC
6 COMMUNITY WILL BE EXTREMELY UNHAPPY IF THEY ARE
7 LIMITED TO A ONE-PAGE SUBMISSION OF THEIR ENTIRE
8 GRANT APPLICATION. THAT'S ALL I HAVE TO SAY.

9 DR. MELTZER: I AGREE WITH THAT CONSENSUS
10 AS WELL.

11 DR. YAMAMOTO: I'LL JUST SAY THAT I
12 HAVEN'T SEEN THAT THERE'S BEEN A BIG PUSHBACK FOR
13 THE GATES APPLICANTS AND THAT I MYSELF WOULD BE
14 PERFECTLY WILLING TO DO THAT IF THE CRITERIA THAT
15 WILL BE THE FOCUS ARE MADE CLEAR IN THE WAY THAT I
16 THINK GIL MADE IT HALF AN HOUR AGO.

17 CHAIRMAN FISCHER-COLBRIE: JUDY, ARE YOU
18 BACK WITH ANOTHER COMMENT THERE? I SEE YOUR HAND
19 RAISED.

20 OTHER QUESTIONS, COMMENTS? OKAY. I'M NOT
21 EXACTLY SURE WHERE TO GO FROM HERE. IT SOUNDS LIKE
22 THIS IS A NEW PROPOSAL FOR GETTING APPLICATIONS
23 THROUGH. I'M NOT EVEN -- THE 50 PERCENT, I DON'T
24 EVEN KNOW HOW WE WOULD MAKE THAT WORK. I'M NOT SURE
25 WHAT THE NEXT STEPS CAN BE HERE GOING FORWARD

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1 BECAUSE OUR PROCESS NEEDS TO GET FIXED NOW. WE'VE
2 GOT PROBLEMS RIGHT NOW TODAY THAT CAN'T WAIT.

3 SO I'M NOT SURE IF THIS IS SOMETHING WE
4 FIX THE THINGS WE KNOW WE HAVE TO FIX AND THEN WORK
5 ON THIS SOME MORE AROUND SOME OF THESE IDEAS AND
6 CONCEPTS AND SEE IF THERE'S A PRACTICAL SOLUTION FOR
7 BOTH STAFFING AND OTHER CONDITIONS. I THINK THE
8 REALITY IS THAT'S ACCURATE IT'S GOING TO BE
9 IMPOSSIBLE TO BE WITH A FINE-TOOTHED COMB PICKING
10 THE TOP 20 PERCENT. BUT THE REALITY IS WITH THE
11 FLOOD OF APPLICATIONS, MANY OF THE APPLICANTS WOULD
12 BE MORE THAN WELL DESERVING. AND MAKING SOME FINITE
13 DIFFERENCE BETWEEN ONE VERSUS THE OTHER IS GOING TO
14 BE A PROBLEM NO MATTER WHAT WE DO KIND OF THING.

15 SO --

16 DR. YAMAMOTO: GIL, HOW HARD WOULD IT BE
17 TO INCREASE THE SIZE OF THE REVIEW COMMITTEES? IS
18 THAT -- IT'S GOT TO BE ALREADY A CENTRAL CHALLENGE
19 TO FIND REVIEWERS OUTSIDE OF CALIFORNIA THAT ARE
20 WILLING TO PUT IN THIS KIND OF EFFORT FOR ALL OF OUR
21 BENEFITS. AND MAYBE IT'S JUST NOT FEASIBLE TO
22 INCREASE THE SIZE OF THE REVIEWER POOL IN ORDER TO
23 ADDRESS SOME OF THESE PROBLEMS. MAYBE YOU CAN
24 COMMENT ON THAT.

25 DR. SAMBRANO: IF I CAN JUST RESPOND TO

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1 THAT. SO, KEITH, WE ARE LIMITED BY THE PROPOSITION,
2 THAT THE GRANTS WORKING GROUP CANNOT BE MORE THAN 15
3 SCIENTIFIC MEMBERS AND SEVEN PATIENT ADVOCATE
4 MEMBERS.

5 DR. YAMAMOTO: AH.

6 DR. SAMBRANO: SO WE ARE VERY LIMITED IN
7 THAT CAPACITY. WE HAVE, HOWEVER, EXPLORED WAYS IN
8 WHICH WE CAN EXPAND THE GROUP. SO WE HAVE AND USE
9 SPECIALISTS. THEY'RE NONSCORING, BUT THEY PROVIDE
10 ADDITIONAL EXPERTISE. WE HAVE USED WHAT WE CALL
11 SORT OF THE ROTATING PANEL WHERE WE --

12 (INTERRUPTION IN PROCEEDINGS.)

13 DR. SAMBRANO: -- WHERE WE BRING MEMBERS
14 IN AND OUT OF THE PANEL SO THAT IT'S NEVER MORE THAN
15 15 AT A TIME IN ORDER TO INCREASE THE EXPERTISE.
16 AND WE DID THAT WITH THE LAST DISC-0 OPPORTUNITY,
17 AND WE MADE THAT WORK. IT ALLOWED US TO INCREASE
18 THE PANEL TO, I THINK IT WAS, 20 TO 22 PEOPLE WHO
19 WERE ABLE TO SCORE.

20 BUT I THINK ASIDE FROM THAT, WHAT WE
21 CANNOT DO IS WHAT ESSENTIALLY NIH DOES, WHICH HAS
22 ABOUT 250 DIFFERENT STUDY SECTIONS THAT HAS
23 RELATIVELY LARGER PANELS THAN OUR OWN WHERE YOU CAN
24 FLIP AN APPLICATION IN ONE FIELD TO THIS PANEL AND
25 ANOTHER APPLICATION TO A DIFFERENT PANEL.

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1 UNFORTUNATELY, WE DON'T HAVE THAT ABILITY.

2 DR. YAMAMOTO: YEAH. SO I'LL JUST SAY
3 THAT I DON'T KNOW WHETHER IT'S GOING TO BE POSSIBLE
4 FOR US WITH CONFIDENCE TO BE ABLE TO DRAW THE TRIAGE
5 LINE AS THE TOP 20 PERCENT, BUT I THINK IT MAKES IT
6 ALL THE MORE IMPORTANT TO DO THE VERY BEST WE CAN.
7 AND I FEEL THAT MANDATING AS PART OF THE APPLICATION
8 THIS ONE-PAGE SUMMARY THAT ADDRESSES DIRECTLY THE
9 POINTS THAT GIL OUTLINED AWHILE BACK WOULD BE
10 SOMETHING THAT THE APPLICANTS WOULD BE WILLING TO
11 DO. OF COURSE, THEY'LL DO IT BECAUSE YOU'RE TELLING
12 THEM THAT THIS IS WHERE THE WAY THE LINE IS GOING TO
13 BE DRAWN. SO THEY'RE GOING TO PUT A PRETTY GOOD
14 EFFORT IN.

15 I TAKE PAT'S POINT, THAT HE AS A REVIEWER
16 DOESN'T THINK THAT HE COULD RESPONSIBLY MAKE A
17 CONCLUSION BASED ON THAT, BUT I THINK FROM WHAT GIL
18 SAID, YOU'RE ALREADY ASKING THE REVIEWERS TO MAKE
19 THIS ASSESSMENT AND NOT ASKING THEM TO PLOW THROUGH
20 THE WHOLE THING, THAT THERE'S HUGE ELEMENTS OF THESE
21 LARGE APPLICATIONS THAT YOU'RE KIND OF LIBERATING
22 THE REVIEWERS FROM EVALUATING AT ALL. SO I THINK WE
23 COULD GO ONE STEP BETTER BY TELLING THE APPLICANTS
24 AND THE REVIEWERS EXACTLY WHAT WE'RE LOOKING FOR,
25 WHAT THAT INITIAL ROUND REVIEW IS GOING TO LOOK LIKE

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1 FROM WHICH THAT LINE WILL BE DERIVED. AND SO
2 THEY'RE GOING TO WORK AS HARD AS THEY POSSIBLY CAN
3 TO BE ABOVE IT.

4 DR. LEVITT: I THINK WE RESPONDED -- GIL
5 AND HIS TEAM, THE WHOLE TEAM RESPONDED WELL IN TERMS
6 OF INTRODUCING IMPORTANT UNDERSTANDING OF WHAT THE
7 CRITERIA ARE GOING TO BE --

8 DR. YAMAMOTO: YEAH.

9 DR. LEVITT: -- AND THAT'S THE SCIENTIFIC
10 COMPONENTS. TO ME THAT'S THE MOST IMPORTANT THING.
11 THE SECOND IS THAT THEY'VE IDENTIFIED MATHEMATICALLY
12 WHAT THEY NEED TO BE ABLE -- WHAT THEY CAN REVIEW
13 REASONABLY WELL IN THE CONTEXT OF THE LIMITATIONS
14 THAT CIRM HAS IN TERMS OF HOW THEY OPERATE THEIR
15 GRANT REVIEW COMMITTEES.

16 I WOULD SAY THAT WE GO WITH THAT, AND THEN
17 WE CAN COLLECT DATA, KEITH, ABOUT BIASES AND OTHER
18 THINGS WITH WHAT THEY'RE RECOMMENDING. YOU CAN MAKE
19 THE ARGUMENT THAT THE NARROWER YOU HAVE TO MAKE YOUR
20 GROUP, THE MORE INFORMATION YOU NEED. 50 PERCENT,
21 EASY. I DON'T NEED AS MUCH INFORMATION AS IF I'M
22 GOING TO HAVE TO ELIMINATE 80 PERCENT. SO I WOULD
23 MAKE THE ARGUMENT THE OPPOSITE WAY, THAT YOU NEED
24 MORE INFORMATION IN ORDER TO NOT SCREW SOMETHING UP
25 AND EXCLUDE SOMEBODY WHO WOULD HAVE BEEN INCLUDED IF

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1 IT WAS 50 PERCENT, BUT IT'S NOT. AND SO I THINK WE
2 HAVE SOMETHING IN FRONT OF US. WE HAVE GRANT
3 DEADLINES THAT COMING UP. WE HAVE GRANT APPLICATION
4 DEADLINES THAT ARE COMING UP. WE HAVE PUBLIC
5 COMMENT IN LETTERS THAT HAVE WRITTEN THAT BASICALLY
6 SAY USE THE SCIENCE TO DECIDE. AND I THINK THAT'S
7 WHAT WE SHOULD DO WITH THE RUBRIC THAT WE HAVE.

8 AND I THINK THE ONLY -- FROM MY
9 PERSPECTIVE, THE ONLY THING LEFT IS TO DECIDE. AND
10 GIL SAID HE WOULD RUN IT LIKE SCORING OR RANKING. I
11 SEE ARGUMENTS ON BOTH SIDES. AND GIL CAN RUN
12 ANOTHER SET OF MONTE CARLOS OR WHATEVER PERMUTATIONS
13 HE WANTS TO RUN, AND THEN LEAVE IT UP TO THE TEAM TO
14 DECIDE WITH THEY'RE GOING TO DO IN TERMS OF THE NEXT
15 APPLICATIONS THAT ARE COMING IN.

16 THEN WE CAN GATHER DATA ON, OH, IS IT ALL
17 SENIOR PI'S THAT MADE IT THROUGH? IS IT ALL UCSF
18 INVESTIGATORS, FOR EXAMPLE, THAT MADE IT THROUGH?
19 AND NOBODY FROM CHILDREN'S HOSPITAL OF LOS ANGELES?
20 WE CAN MAKE -- WE CAN GET THAT DATA TO SEE WHAT THE
21 BIASES ACTUALLY ARE; BUT WITH THE CUTOFF THAT WE'RE
22 TALKING ABOUT, WHICH IS REALLY WE HAVE NO OTHER
23 CHOICE, I DON'T SEE THE POINT OF HAVING LESS
24 INFORMATION IN THAT INITIAL CUT. I WOULD REALLY --
25 I WOULD HAVE A LOT OF ANXIETY. I WOULD NEED ZOLOFT

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1 BEFORE I WAS ABLE TO FEEL COMFORTABLE DOING THAT.
2 AND I HAVE TO GO BECAUSE MY CHAIRMAN IS WAITING FOR
3 ME. AND CAROLYN KNOWS THAT I CAN'T DISAPPOINT MY
4 CHAIRMAN.

5 DR. MELTZER: I GOT TO GO TOO.

6 CHAIRMAN FISCHER-COLBRIE: ALL RIGHT.
7 WELL, THANK YOU, GUYS. APPRECIATE ALL THE FEEDBACK.
8 I THINK THE RECOMMENDATION I WANT TO PROPOSE OUT
9 THERE IS THE FOLLOWING. ONE IS THAT GIL TAKE A LOOK
10 AT THE SCORING VERSUS THE RANKING. I KNOW THERE'S A
11 LOT OF MERIT TO THE SCORING. WE'LL TAKE A LOOK AT
12 THAT, COME BACK WITH FEEDBACK.

13 I THINK THIS IS ALSO A SITUATION OF I
14 WOULD RECOMMEND, BECAUSE OF THE NECESSITY TO FIX
15 WHAT WE HAVE AND THIS IS NOT AN UNREASONABLE
16 APPROACH, THAT WE MOVE AHEAD WITH THE PROPOSED
17 METHODOLOGY WITH THE VIEW THAT WE'RE JUST GOING TO
18 HAVE TO KEEP TAKING A LOOK AT THIS TO SEE IF WE CAN
19 CREATE THE BEST SYSTEM WE POSSIBLY CAN AND COLLECT
20 DATA AND COLLECT INFORMATION. UNDOUBTEDLY, WHATEVER
21 MECHANISM WE PICK, THERE'S GOING TO BE SOME ISSUE OR
22 PROBLEM WE'RE GOING TO NEED TO DEAL WITH IN ANY
23 CASE, BUT I HAVE A STRONG SENSE OF URGENCY, THAT
24 WHAT WE'RE DOING NOW IS NOT THE RIGHT APPROACH AND
25 WE'VE GOT TO FIX THAT NOW.

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1 DR. YAMAMOTO: WELL SAID, MARK. I DON'T
2 DISAGREE WITH ANYTHING YOU JUST SAID. AND I THINK
3 THAT -- SO I AGREE. I THINK THIS IS THE WAY WE
4 SHOULD PROCEED, BUT I THINK WE SHOULD REVEAL TO THE
5 APPLICANT COMMUNITY THAT THIS IS TOUGH GOING. THIS
6 IS A HARD THING. AND SOME OF THE DIFFICULTIES ARE
7 NOT SELF-INFLICTED. WHAT'S HAPPENED TO THE FEDERAL
8 BUDGET OR THE THREATS TO IT ARE SUBSTANTIAL.
9 THEY'RE KIND OF EVER WITH US.

10 CHAIRMAN IMBASCIANI: SURE.

11 DR. YAMAMOTO: CONGRESS IN ONE VIEW SOLVED
12 THE PROBLEM WITH THE PRESIDENT'S BUDGET BY SAYING,
13 "NO, WE'RE GOING TO GIVE THE NIH IN FACT A LITTLE
14 BIT OF AN INCREASE INSTEAD OF A DECREASE." BUT THEN
15 RUSS VOUGHT TURNS AROUND AND SAYS, "I'M THE DIRECTOR
16 OF THE OMB AND WE'RE THE PEOPLE WITH THE REAL POWER.
17 AND I'LL RELEASE THE MONEY WHEN I WANT TO, AND I'LL
18 RELEASE AS MUCH AS I WANT TO. I DON'T CARE WHAT YOU
19 APPROPRIATED." THAT BATTLE IS STILL TO BE FOUGHT.
20 AND SO CIRM GETS STUCK TRYING TO ADDRESS THESE
21 PROBLEMS NO MATTER WHAT.

22 AND I THINK IT WOULD NOT BE UNFAIR TO SAY
23 TO THE APPLICANT COMMUNITY THESE ARE COMPLEX TIMES
24 THE LIKES OF WHICH WE'VE NEVER SEEN BEFORE, AND
25 WE'RE DOING THE BEST WE CAN. WE'RE MAKING THESE

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1 PROCESSES AS HIGH QUALITY AS POSSIBLE IN ADDRESSING
2 REALLY THE QUALITY OF THE APPLICATIONS YOU PUT
3 FORWARD, BUT DON'T BE SURPRISED. SO WE'RE
4 INSTITUTING THESE CHANGES, BUT DON'T BE SURPRISED IF
5 IN THE FUTURE THERE ARE MORE CHANGES. SO I THINK
6 THAT WOULD BE RELIEF TO THE COMMUNITY IN TERMS OF
7 JUST BEING HONEST, BUT ALSO IT WILL BE A RELIEF TO
8 THEM TO SAY, "WE THINK YOU STILL DIDN'T GET IT
9 RIGHT, BUT IT'S A RELIEF TO SEE THAT YOU SEE THIS AS
10 AN EVOLVING PROCESS, AND LOOK FORWARD TO FUTURE
11 CHANGES AND WE'LL MAKE SUGGESTIONS OF OUR OWN." AND
12 SO THEY WON'T THINK THAT THIS IS A DONE DEAL. WE
13 DON'T CARE WHAT YOU SAY IN THE FUTURE.

14 SO I WOULD SUGGEST THAT WE ADOPT THE
15 PROCESS AS IT'S BEEN PROPOSED EXACTLY AS YOU SAID,
16 MARK, BUT MAKE -- REVEAL TO THE APPLICANTS THAT WE
17 SEE THIS AS AN EVOLVING PROCESS.

18 CHAIRMAN FISCHER-COLBRIE: YOU'RE SPOT ON,
19 KEITH. AND I THINK THIS IS A CRITICAL ELEMENT
20 AROUND THE COMMUNICATIONS PLAN BECAUSE COMMUNICATION
21 OF WHAT THE CHANGES ARE AND HOW THEY IMPACT THINGS
22 AND FURTHER HEIGHTENING OF, HEY, WHEN YOU'RE WRITING
23 YOUR APPLICATION, GUYS, HERE ARE THE KEY THINGS THAT
24 WE'RE GOING TO BE BANGING ON FROM A REVIEW
25 PERSPECTIVE. WHETHER IT'S THE INITIAL TRIAGE OR

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1 NOT, THESE ARE THE CRITERIA THAT YOU'VE GOT TO BE
2 HOMED IN ON YOUR APPLICATION.

3 DR. YAMAMOTO: YEAH.

4 CHAIRMAN FISCHER-COLBRIE: SO IF YOU HAVE
5 BENEFITS OF ATTRIBUTES OF THE VALUE PROPOSITION AND
6 INNOVATION AND ALL THOSE OTHER ELEMENTS, THEN YOU
7 BETTER MAKE SURE TO DRAG THOSE OUT FRONT AND CENTER,
8 NOT HAVE IT GET LOST IN SOME ARCANE ISSUE. SO THE
9 COMMUNICATION PLAN IS GOING TO HAVE TO BE CRITICAL,
10 AND I KNOW THE TEAM IS ALREADY WORKING ON THAT, BUT
11 THAT'S GOING TO REQUIRE KIND OF AD NAUSEUM
12 COMMUNICATION BECAUSE IT TAKES A LOT OF TIME AND
13 EFFORT TO REACH PEOPLE OUT THERE. AND WE HAVE TO
14 ASSURE THAT WE'RE DOING AS MUCH AS WE POSSIBLY CAN.

15 DR. YAMAMOTO: YEAH.

16 CHAIRMAN FISCHER-COLBRIE: SO PART OF THAT
17 WHAT YOU'RE TALKING ABOUT IS A CRITICAL PART.

18 RAFAEL.

19 MR. AGUIRRE-SACASA: NO, MARK. SORRY FOR
20 INTERRUPTING, BUT WHENEVER THE CONVERSATION IS DONE,
21 I JUST WANTED TO NOTE WE HAVE ONE PUBLIC COMMENT
22 THAT HAS BEEN WAITING PATIENTLY. SO I JUST WANT TO
23 MAKE SURE THAT BEFORE WE DROP-OFF --

24 CHAIRMAN FISCHER-COLBRIE: I THINK WE'RE
25 NOT MAKING A MOTION, BUT --

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1 MR. AGUIRRE-SACASA: CORRECT.

2 CHAIRMAN FISCHER-COLBRIE: WE HAVE A SENSE
3 FOR THE COMMITTEE. AND I THINK WE CAN TAKE THE
4 PUBLIC COMMENT NOW. IS THAT FAIR?

5 MR. AGUIRRE-SACASA: THAT'S EXACTLY WHAT I
6 WOULD PROPOSE.

7 CHAIRMAN FISCHER-COLBRIE: LET'S DO THAT.
8 THANK YOU.

9 MR. AGUIRRE-SACASA: CLAUDETTE.

10 MS. MANDAC: SO WE DO HAVE THE CALLER WITH
11 AREA CODE 310. THE CLOCK STARTS NOW. THE FLOOR IS
12 YOURS. YOU WILL SEE A TIMER OR YOU WILL HEAR A
13 TIMER OFF AS SOON AS YOUR THREE MINUTES IS OVER.
14 THE FLOOR IS YOURS. IF YOU COULD PLEASE UNMUTE.

15 MR. AGUIRRE-SACASA: HELLO, CALLER 310.

16 MR. CHEN: CAN YOU HEAR ME?

17 MR. AGUIRRE-SACASA: YES.

18 MR. CHEN: THANK YOU VERY MUCH FOR THE
19 OPPORTUNITY TO MAKE A COMMENT DURING THIS IMPORTANT
20 DISCUSSION. AND I KNOW THAT THERE'S A LONG
21 CONVERSATION ALREADY. I'LL TRY TO MAKE IT SHORT.

22 MY NAME IS JOHN (PHONETIC) CHEN, AND I'M
23 AN ADMINISTRATIVE DIRECTOR OF A RESEARCH CENTER AT
24 UCLA THAT IS DEVELOPING CELL/GENE THERAPY CLINICAL
25 TRIALS FOR CANCER PATIENTS. IN MY ROLE I SUPPORT

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1 RESEARCHERS TAKING THEIR PROMISING CLINICAL RESEARCH
2 RESULTS TO APPLYING AN IND WITH THE FDA AND THEN
3 RUNNING THE PHASE 1 USUALLY FIRST-IN-HUMAN CLINICAL
4 TRIALS.

5 I WANT TO RAISE A QUESTION TODAY REGARDING
6 THE PROPOSED CHANGE TO REDUCE THE PDEV FROM TWICE TO
7 ONCE A YEAR, WHICH WAS DISCUSSED IN THE PRIOR
8 SCIENCE SUBCOMMITTEE MEETING, BUT NOT TODAY.
9 PROJECTS THAT ARE APPLYING TO THE PDEV PHASE,
10 PARTICULARLY THE LATE STAGE PDEV PROGRAM, USUALLY
11 ALREADY RECEIVE DIRECT FEEDBACK FROM THE FDA OR
12 OTHER PRACTICAL GUIDANCE TO ADDRESS SPECIFIC R & D
13 BEFORE REALISTICALLY ESTABLISHING A CLINICAL TRIAL
14 FOR THE TREATMENT. THESE WELL-DEFINED R & D PATHS
15 ARE HIGHLY TIME SENSITIVE BECAUSE OF HOW RAPIDLY THE
16 FIELD OF CELL/GENE THERAPY IS MOVING.

17 IN THE PAST THE LATE STAGE PDEV APPLICANTS
18 WOULD HAVE BEEN ABLE TO SUBMIT APPLICATIONS TO CIRM
19 AT A MONTHLY BASIS. THE RECENT CHANGE TO TWICE A
20 YEAR IS CHALLENGING, BUT CAN BE MANAGED WITH SOME
21 NON-CIRM FUNDING IN BETWEEN. HOWEVER, ANNUAL RFA
22 CYCLES WOULD MAKE CIRM NOT A RELIABLE PARTNER FOR
23 RESEARCHERS WHO MUST PLAN AN AGGRESSIVE R & D
24 TIMELINE TO MOVE THE PROJECT TO CLINIC AS QUICKLY AS
25 POSSIBLE.

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1 THE LATE STAGE PDEV IS A CRITICALLY TIME
2 SENSITIVE PHASE IN DEVELOPING A NOVEL TREATMENT.
3 AND I HOPE CIRM WOULD CONTINUE TO SUPPORT RESEARCH
4 GROUPS THAT HAVE AGGRESSIVE R & D TIMELINES IN
5 DEVELOPING NEW TREATMENTS AND SUPPORT THEM WITH MORE
6 FREQUENT PDEV RFA CYCLES THAT BETTER MATCH THE TIME
7 SENSITIVITY OF THESE APPLICATIONS. THIS IS ALL I
8 HAVE. THANK YOU AGAIN FOR YOUR ATTENTION.

9 CHAIRMAN FISCHER-COLBRIE: THANK YOU.
10 J.T. OR GIL, I DON'T KNOW IF YOU WANT TO MAKE ANY
11 COMMENTS OR HOLD OFF ON THAT EITHER WAY.

12 DR. THOMAS: ROSA, DO YOU WANT TO COMMENT?

13 DR. CANET-AVILES: I'M HAPPY TO COMMENT.
14 WE HAVE A PRESENTATION PREPARED FOR THE 26TH. THE
15 PROPOSED CHANGE, INITIALLY HAD SPECIFIED TWO
16 APPLICATION CYCLES PER YEAR WITH SOME EXPECTED
17 BENEFITS OF THE TWO CYCLES THAT HAVE NOT BEEN
18 REALIZED. THE PDEV RIGHT NOW ALLOWS ENTRY ALSO AT
19 ANY POINT ACROSS THE CLINICAL DEVELOPMENT LIFE
20 CYCLE.

21 SO ONE OF THE IMPORTANT POINTS IS THAT THE
22 APPLICATION RESUBMISSION, WE WERE SUPPOSED -- WE
23 WERE EXPECTING THAT IT COULD REDUCE THE DELAY
24 BETWEEN CYCLES. AND IN REALITY WHAT'S HAPPENING IS
25 THAT THE PDEV CYCLE OVERLAPPED, PREVENTS

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1 RESUBMISSION IN THE IMMEDIATE NEXT CYCLE.

2 AND THEN THERE IS A HIGH CHANCE OF THE
3 FIRST FISCAL YEAR CYCLE EXHAUSTING THE MAJORITY OF
4 AVAILABLE PROGRAM FUNDS AS IT'S HAPPENED IN THIS
5 YEAR AND AS WE KNOW IT'S A REALITY. SO BASED ON
6 THAT, WE COULD BE HAVING -- WE WOULD BE PROPOSING
7 THIS AND IT HAS SOME PRACTICAL IMPLICATIONS. IN
8 SOME WAYS ALL SUBMITTED APPLICATION COMPETE FOR THE
9 FULL PROGRAM BUDGET. THERE IS A HIGHER VOLUME OF
10 APPLICATIONS REVIEWED TO ACCOUNT FOR THE FULL
11 PROGRAM BUDGET. ALL UNFUNDED APPLICATIONS MAY
12 RESUBMIT IN THE NEXT FISCAL YEAR APPLICATION CYCLE,
13 AND THE TIMELINES FOR PROGRAM UPDATES AND
14 APPLICATION LIFE CYCLES WILL BE OPTIMIZED.

15 SO OVERALL THAT WOULD BE ONE OF THE
16 REASONS THAT WE WILL PROPOSE THIS TO THE ICOC, AND
17 THAT WAS PROPOSED BACK IN MARCH 5TH AND WILL COME IN
18 THE MARCH 26TH.

19 DR. THOMAS: MARK, -- THANK YOU, ROSA.
20 THIS ISN'T A GOOD PLACE TO GET INTO A DEBATE ON
21 THIS.

22 CHAIRMAN FISCHER-COLBRIE: NO.

23 DR. THOMAS: WE APPRECIATE THE PUBLIC
24 COMMENT VERY MUCH, BUT THIS IS A TOPIC PROPERLY
25 TAKEN UP BY THE FULL BOARD. SO THAT WAS JUST A

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1 PREVIEW OF WHAT'S TO COME NEXT WEEK.

2 CHAIRMAN FISCHER-COLBRIE: RIGHT. THANK
3 YOU, J.T. I THINK THAT'S APPROPRIATE. AND I JUST
4 WANT TO MAKE SURE THAT IF YOU HAD CHOSEN TO, THAT
5 YOU'D WANT TO RESPOND. SO THANK YOU.

6 OKAY. SOME MORE DISCUSSION OF THE BOARD?
7 HEY, THANKS, GUYS, SCIENCE COMMITTEE. IT WILL BE
8 NICE TO GET THIS MOSTLY BEHIND US AND MOVE ON
9 BECAUSE THE STRATEGIC ALLOCATION FRAMEWORK HAS TAKEN
10 A HUGE AMOUNT OF WORK. THE TEAM HAS DONE AN
11 INCREDIBLE JOB OF ITERATING ON THE CURRENT APPROVAL
12 PROCESSES. UNDOUBTEDLY, THERE ARE GOING TO BE
13 FUTURE CHANGES REQUIRED. IT'S JUST GOING TO HAPPEN.
14 AND THERE'S COMMUNICATION WORK TO BE DONE, BUT IT
15 WILL BE NICE TO GET INTO MORE A STEADY STATE AND BE
16 ABLE TO FOCUS IN ON OUR OTHER ISSUES THAT WE HAVE TO
17 DEAL WITH. SO THANK YOU FOR ALL THE HARD EFFORT BY
18 EVERYBODY, THE SCIENCE COMMITTEE AND THE TEAM. SO
19 WE VERY MUCH APPRECIATE WHAT YOU'VE BEEN ABLE TO GET
20 ACCOMPLISHED. SO THANK YOU.

21 DR. GASSON: THANK YOU, MARK.

22 DR. THOMAS: YEAH. THANK YOU, MARK, AND
23 THANK YOU, MEMBERS OF THE BOARD. THESE DISCUSSIONS,
24 AS YOU CAN SEE, ARE EXTREMELY HELPFUL. THE WORK
25 PRODUCT HAS INTEGRATED COMMENTS THROUGHOUT, AND WE

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1 REALLY APPRECIATE THE AMOUNT OF ATTENTION TO DETAIL
2 AND SUGGESTION AND ALL THE EXPERTISE BROUGHT TO THE
3 TABLE TO HELP US REFINE THIS AND HONE IT DOWN TO THE
4 BEST PRODUCT POSSIBLE. SO THANK YOU ALL OF YOU.

5 CHAIRMAN FISCHER-COLBRIE: MORE TO COME.
6 THANK YOU ALL.

7 (THE MEETING WAS THEN CONCLUDED.)
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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 MARCH 19, 2026, WAS HELD AS HEREIN APPEARS AND THAT THIS IS THE ORIGINAL TRANSCRIPT THEREOF AND THAT THE STATEMENTS THAT APPEAR IN THIS TRANSCRIPT WERE REPORTED STENOGRAPHICALLY BY ME AND TRANSCRIBED BY ME. I ALSO CERTIFY THAT THIS TRANSCRIPT IS A TRUE AND ACCURATE RECORD OF THE PROCEEDING.

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