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

I N D E X

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OPEN SESSION	
1. CALL TO ORDER	3
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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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YAMAMOTO.

DR. YAMAMOTO: HERE.

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

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

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

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

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

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

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CHAIRMAN FISCHER-COLBRIE: THANKS, J.T.

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

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

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

SO WITH RESPECT TO ACCESS AND

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

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

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

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

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

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

LAST MEETING AS WELL AS THE VARIOUS PRECALLS.

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

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

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

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

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

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

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

SO ULTIMATELY TO IMPROVE CLARITY, CIRM

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

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

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

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

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

AND WHEN THAT PARTICULAR THERAPY REACHES CLINICAL TRIAL.

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

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

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

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

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WITH PAYERS IF THAT THERAPY IS APPROVED.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

THE ACTIVITIES THAT THE AWARDEE HAS PROPOSED.

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

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

DR. PATEL: OF COURSE.

MR. TOCHER: LOOKS LIKE PAT.

DR. PATEL: PAT.

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

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

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

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

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

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

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

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

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

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

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

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

DR. PATEL: THANK YOU, MARIA. VITO.

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

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

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

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

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

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

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

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

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

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

CONTROL STAGE.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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DOES NOT.

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

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

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

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

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

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

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

DR. SAMBRANO: PAT.

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

DR. YAMAMOTO: NO, GO AHEAD, PAT.

DR. LEVITT: YOU GO. BEAUTY BEFORE AGE.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

DR. YAMAMOTO: YEAH. GOOD.

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

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

DR. LEVITT: YEAH. YEAH. YEAH.

DR. YAMAMOTO: IN THE GRANT MECHANISMS

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

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

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

DR. YAMAMOTO: THAT IS CORRECT.

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

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

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

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

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

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

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

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

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

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

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

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

MS. MANDAC: THERE ARE NO MORE HANDS.

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

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

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

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

CHAIRMAN FISCHER-COLBRIE: OKAY.

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

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

MR. TOCHER: THAT'S CORRECT. A FORMAL

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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TWO-WEEK TO THREE-WEEK PROCESS.

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

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

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

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

CHAIRMAN FISCHER-COLBRIE: OKAY.

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

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APPLICATIONS IN FULL?

CHAIRMAN FISCHER-COLBRIE: WE CAN'T.

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

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

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

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

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

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

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

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

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

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

CHAIRMAN FISCHER-COLBRIE: OKAY.

DR. YAMAMOTO: THAT WOULD BE GREAT.

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

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

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

DR. LEVITT: YES.

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

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

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

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

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

AND TO GET RID OF THOSE TWO BIASES IN THIS

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

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

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

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

DR. LEVITT: YEAH.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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EDUC, RIGHT?

DR. YAMAMOTO: THANKS, SCOTT.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

VICE CHAIR BONNEVILLE: SO MOVED.

(MULTIPLE SECONDS.)

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

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

CHAIRMAN FISCHER-COLBRIE: THANK YOU.

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

MARIA BONNEVILLE.

VICE CHAIR BONNEVILLE: YES.

MR. TOCHER: MARK FISCHER-COLBRIE.

CHAIRMAN FISCHER-COLBRIE: YES.

MR. TOCHER: ELENA FLOWERS.

DR. FLOWERS: YES.

MR. TOCHER: JUDY GASSON.

DR. GASSON: YES.

MR. TOCHER: VITO IMBASCIANI.

CHAIRMAN IMBASCIANI: YES.

MR. TOCHER: PAT LEVITT.

DR. LEVITT: YES.

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MR. TOCHER: CAROLYN MELTZER.
DR. MELTZER: YES.
MR. TOCHER: SHAUNA STARK.
DR. STARK: YES.
MR. TOCHER: KEITH YAMAMOTO.
DR. YAMAMOTO: YES.
MR. TOCHER: GREAT. THANKS VERY MUCH, EVERYONE. THAT MOTION CARRIES.
CHAIRMAN IMBASCIANI: GREAT.
MR. TOCHER: SO WE CAN GO BACK TO THE FIRST ITEM IF YOU'D LIKE, MARK.
CHAIRMAN FISCHER-COLBRIE: LET ME UNDERSTAND SOMETHING. I'M STILL A LITTLE CONFUSED ABOUT THE ONE-PAGER VERSUS THE FULL APPLICATION. I'M NOT TRACKING BECAUSE YOU'RE EITHER GOING TO LOOK AT A FULL APPLICATION AND AT LEAST DO SOME KIND OF A WRITE-UP OR YOU'RE NOT. SO I'M NOT SURE I UNDERSTAND WHAT THE FUNCTION OF THE ONE-PAGER IS BECAUSE IF THEY ONLY EVALUATE OFF THE ONE-PAGER, THEN THAT'S ACTUALLY THE CURSORY REVIEW THAT WE'RE NOT LOOKING FOR. SO I'M NOT UNDERSTANDING THE WORKFLOW. IF SOMEBODY COULD DESCRIBE THAT FOR ME.
DR. YAMAMOTO: MY UNDERSTANDING, AND GIL SAID IT, IS THAT THIS FIRST PROCESS OF SELECTION AND RANKING THAT EVENTUALLY DERIVES THE CUTOFF LINE FOR

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

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

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

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

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

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

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

CHAIRMAN FISCHER-COLBRIE: OH, OKAY.

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

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

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

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

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DIFFERENCES.

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

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

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

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

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

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

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

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

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

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

DR. YAMAMOTO: THAT'S RIGHT.

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

DR. YAMAMOTO: YEAH. YEAH.

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

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

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

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

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

CHAIRMAN FISCHER-COLBRIE: WELL, MY BIAS

IS TO HAVE THE FULL APPLICATION AND PEOPLE GO THROUGH IT. THEY ARE GOING TO MAKE THEIR DETERMINATIONS AROUND IMPACT. KEITH IS RIGHT. THEY'RE ALSO GOING TO BE KIND OF HAVE THEIR HEAD LEANING IN A CERTAIN DIRECTION DEPENDING ON THEIR FIRST INITIAL PASS. BUT FROM MY PERSPECTIVE, AT LEAST THERE'S SUFFICIENT DETAIL AND INFORMATION THERE FOR THEM TO MAKE AN INFORMED DECISION. AND BASED ON, FOR EXAMPLE, WHAT I SAW FROM PDEV TODAY, PEOPLE DO WORK AT IT. THEY DO TAKE A LOOK AT IT.

SO IT DOESN'T GET THE FULL GWG REVIEW, BUT YOU'RE STILL GETTING A NUMBER OF RESEARCHERS BASED ON SCIENCE TO MAKE A DETERMINATION. IT'S JUST A LITTLE HARD FOR ME TO -- IF SOMEBODY SAID, WELL, YOU'RE GOING TO BASE THESE ON A ONE-PAGER, I'M CONCERNED IT DOESN'T ADDRESS THE ISSUES THAT PEOPLE BROUGHT UP BEFORE ABOUT, WELL, WAIT. WHY WAS MINE NOT SELECTED? IT'S LIKE I DON'T KNOW IF A ONE-PAGER --

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

CHAIRMAN FISCHER-COLBRIE: UH-HUH.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

DR. YAMAMOTO: THAT'S HOW GATES WORKS.

CHAIRMAN FISCHER-COLBRIE: OKAY. YEAH. OKAY. IT'S INTERESTING BECAUSE I'VE SEEN SEVERAL OF THESE WHERE PEOPLE MAKE THESE INCREDIBLE STATEMENTS OF IMPACT. AND THEN YOU LOOK AT, WELL, HOW'S THE MAGIC HAPPEN? AND IT'S LIKE NOT REALLY, BUT OKAY. INTERESTING.

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

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

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

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

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

CHAIRMAN FISCHER-COLBRIE: SURE.

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

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

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

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

CHAIRMAN FISCHER-COLBRIE: IS THAT YOU, JUDY?

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

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

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

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

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

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

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

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

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

SO --

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

DR. SAMBRANO: IF I CAN JUST RESPOND TO

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

DR. YAMAMOTO: AH.

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

(INTERRUPTION IN PROCEEDINGS.)

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

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

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UNFORTUNATELY, WE DON'T HAVE THAT ABILITY.

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

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

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

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

DR. YAMAMOTO: YEAH.

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

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

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

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

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

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

DR. MELTZER: I GOT TO GO TOO.

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

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

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

CHAIRMAN IMBASCIANI: SURE.

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

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

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

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

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

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

DR. YAMAMOTO: YEAH.

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

DR. YAMAMOTO: YEAH.

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

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

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

MR. AGUIRRE-SACASA: CORRECT.

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

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

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

MR. AGUIRRE-SACASA: CLAUDETTE.

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

MR. AGUIRRE-SACASA: HELLO, CALLER 310.

MR. CHEN: CAN YOU HEAR ME?

MR. AGUIRRE-SACASA: YES.

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

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

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

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

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

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

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

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

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

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

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RESUBMISSION IN THE IMMEDIATE NEXT CYCLE.

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

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

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

CHAIRMAN FISCHER-COLBRIE: NO.

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

PREVIEW OF WHAT'S TO COME NEXT WEEK.

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

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

DR. GASSON: THANK YOU, MARK.

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

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

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

(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.

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