BEFORE THE

INDEPENDENT CITIZENS' OVERSIGHT COMMITTEE
AND THE
APPLICATION REVIEW SUBCOMMITTEE
TO THE
CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE
ORGANIZED PURSUANT TO THE
CALIFORNIA STEM CELL RESEARCH AND CURES ACT

REGULAR MEETING

LOCATION:	WESTIN SACRAMENTO MONACO II 4800 RIVERSIDE BLVD. SACRAMENTO, CALIFORNIA
DATE:	MARCH 26, 2026 8:30 A.M.
REPORTER:	BETH C. DRAIN, CA CSR CSR. NO. 7152
FILE NO.:	2026-10

I N D E X

ITEM DESCRIPTION	PAGE NO.
OPEN SESSION	
1. CALL TO ORDER	4
2. ROLL CALL	4
CONSENT CALENDAR	**7**
3. MINUTES FROM THE DECEMBER 11, 2025, ICOC/ARS MEETING, AND JANUARY 29, 2026, ICOC MEETING	
4. APPOINTMENTS/REAPPOINTMENTS OF SCIENTIFIC MEMBERS TO THE GRANTS WORKING GROUP	
5. RECOMMENDATIONS FROM GOVERNANCE SUBCOMMITTEE REGARDING THE ICOC CHAIR, ICOC VICE CHAIR, AND CIRM PRESIDENT/CEO REVIEW: PROCEDURES, TIMELINES, AND SURVEY QUESTIONS	
6. AMENDMENTS TO THE FUNDING MECHANISM FOR CIRM CONFERENCES AND MEETINGS (EDUC1)	
OPEN SESSION	
7. CONSIDERATION OF APPLICATIONS SUBMITTED IN RESPONSE TO DISCOVERY PROGRAM ANNOUNCEMENTS (DISC4)	11
8. CONSIDERATION OF APPLICATIONS SUBMITTED IN RESPONSE TO A CLINICAL PROGRAM ANNOUNCEMENTS (CLIN2)	43
9. CONSIDERATION OF AMENDMENTS TO THE COMMUNITY CARES CENTERS OF EXCELLENCE CONCEPT PLAN	

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I N D E X (CONT'D)

10.	CLOSER TO CURES	NOT REPORTED OR TRANSCRIBED
11.	CONSIDERATION/DISCUSSION OF PROGRAM PREFERENCES AND GUIDING PRINCIPLES	115
12.	CONSIDERATION OF AMENDMENT TO WARRANT CO-FUNDING PROGRAM	107
13.	UPDATE FROM CIRM COMMUNICATIONS TEAM	215
14.	CHAIR'S REPORT	226
15.	VICE-CHAIR'S REPORT	NONE
16.	PRESIDENT'S REPORT	229
CLOSED SESSION		NONE
17.	DISCUSSION OF CONFIDENTIAL INTELLECTUAL PROPERTY OR WORK PRODUCT, PREPUBLICATION DATA, FINANCIAL INFORMATION, CONFIDENTIAL SCIENTIFIC RESEARCH OR DATA, AND OTHER PROPRIETARY INFORMATION RELATING TO APPLICATIONS SUBMITTED IN RESPONSE TO AGENDA ITEMS #7 AND #8 ABOVE. (HEALTH & SAFETY CODE 125290.30(F) (3) (B) AND (C)).	
18.	DISCUSSION OF CONFIDENTIAL INTELLECTUAL PROPERTY OR WORK PRODUCT, PREPUBLICATION DATA, FINANCIAL INFORMATION, CONFIDENTIAL SCIENTIFIC RESEARCH OR DATA, AND OTHER PROPRIETARY INFORMATION RELATING TO AGENDA ITEM #11 ABOVE. (HEALTH & SAFETY CODE 125290.30(F) (3) (B) AND (C)).	
OPEN SESSION		
19.	GENERAL COMMENTS ON THE ARS PROCESS	NONE
20.	PUBLIC COMMENT	234
21.	ADJOURNMENT	235

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MARCH 26, 2026; 8:30 A.M.

CHAIRMAN IMBASCIANI: ALL RIGHT. GOOD MORNING, EVERYONE. WELCOME TO THIS MEETING OF THE INDEPENDENT CITIZEN'S OVERSIGHT COMMITTEE, THE CIRM BOARD, AND THE APPLICATION REVIEW SUBCOMMITTEE. HERE WE ARE IN SACRAMENTO, CALIFORNIA. AND I'M GOING TO ASK THAT WE CALL THE MEETING TO ORDER, AND WE'LL START WITH THE PLEDGE OF ALLEGIANCE IF MR. SCOTT TOCHER WILL DO THE HONORS AND LEAD US. THANK YOU.

MR. TOCHER: SURE. THE FLAG IS BY THE PODIUM. PLEASE STAND IF YOU ARE ABLE.

(THE PLEDGE OF ALLEGIANCE.)

CHAIRMAN IMBASCIANI: THANK YOU, SCOTT. WILL YOU PLEASE CONTINUE AND CALL THE ROLL.

MR. TOCHER: SURE. AYAD ALMASRI.

DR. ALMASRI: PRESENT.

MR. TOCHER: KIM BARRETT.

DR. BARRETT: PRESENT.

MR. TOCHER: DAN BERNAL. GEORGE BLUMENTHAL. MARIA BONNEVILLE.

VICE CHAIR BONNEVILLE: PRESENT.

MR. TOCHER: JOHN CARETHERS.

DR. CARETHERS: PRESENT.

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MR. TOCHER: MONICA CARSON.
DR. CARSON: PRESENT.
MR. TOCHER: THANK YOU VERY MUCH.
MARGUERITE CASILLAS?
MS. CASILLAS: PRESENT.
MR. TOCHER: JUDY CHOU?
DR. CHOU: PRESENT.
MR. TOCHER: LEONDRA CLARK-HARVEY.
DR. CLARK-HARVEY: PRESENT.
MR. TOCHER: SHANNON DAHL.
DR. DAHL: PRESENT.
MR. TOCHER: ANNE-MARIE DULIEGE.
DR. DULIEGE: PRESENT.
MR. TOCHER: YSABEL DURON.
MS. DURON: HERE.
MR. TOCHER: MARK FISCHER-COLBRIE.
MR. FISCHER-COLBRIE: HERE.
MR. TOCHER: ELENA FLOWERS.
DR. FLOWERS: PRESENT.
MR. TOCHER: OH, SORRY. THAT WAS SO QUIET.
JUDY GASSON.
DR. GASSON: HERE.
MR. TOCHER: JEFF GOLDEN.
DR. GOLDEN: PRESENT.

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MR. TOCHER: VITO IMBASCIANI.
CHAIRMAN IMBASCIANI: PRESENT.
MR. TOCHER: RICH LAJARA.
MR. LAJARA: PRESENT.
MR. TOCHER: PAT LEVITT.
DR. LEVITT: PRESENT.
MR. TOCHER: HALA MADANAT.
DR. MADANAT: PRESENT.
MR. TOCHER: LINDA MALKAS.
DR. MALKAS: HERE.
MR. TOCHER: CAROLYN MELTZER. CHRISTINE MIASKOWSKI.
DR. MIASKOWSKI: PRESENT.
MR. TOCHER: ADRIANA PADILLA.
DR. PADILLA: HERE.
MR. TOCHER: JOE PANETTA. JOYCE SACKEY.
DR. SACKEY: HERE.
MR. TOCHER: MARV SOUTHARD.
DR. SOUTHARD: PRESENT.
MR. TOCHER: SHAUNA STARK.
MS. STARK: HERE.
MR. TOCHER: KAROL WATSON.
DR. WATSON: HERE.
MR. TOCHER: YAEL WHITE. KEVIN XU.
MR. XU: HERE.

MR. TOCHER: KEITH YAMAMOTO.

DR. YAMAMOTO: HERE.

MR. TOCHER: GREAT. THANK YOU VERY MUCH.

MR. CHAIR, WE HAVE A QUORUM.

CHAIRMAN IMBASCIANI: WE HAVE A QUORUM. THANK YOU, SCOTT.

THE FIRST ORDER OF BUSINESS IS TO CONSIDER THE CONSENT AGENDA, WHICH IS A LITTLE LONGER THAN USUAL TODAY. IT CONSISTS OF THE MINUTES FROM THE DECEMBER 11TH AND THE JANUARY 29TH MEETING OF THE ICOC, APPOINTMENTS AND REAPPOINTMENTS OF THE SCIENTIFIC MEMBERS TO THE GRANTS WORKING GROUP. AND FOR THOSE -- I PRESUME EVERYONE HAS LOOKED AT THIS. THERE'S ONE NEW APPOINTMENT OF A DR. MARK FITZGERALD, MD.PH.D., FROM THE PERELMAN SCHOOL OF MEDICINE AT THE UNIVERSITY OF PENNSYLVANIA. THERE ARE ONE, TWO, THREE, FOUR, FIVE, SIX REAPPOINTMENTS OF SCIENTISTS.

AND THERE'S ALSO A VERY INTERESTING GRAPH APPENDED TO THIS REPORT THAT QUANTIFIES THE REPRESENTATION OF WOMEN SCIENTIFIC MEMBERS ON THE GRANTS WORKING GROUP. AND YOU'LL SEE THAT THE ATTENDANCE AND PARTICIPATION OF WOMEN SCIENTISTS ON THE GWG HAS NEARLY DOUBLED OVER THE TIME SPAN OF 2020 TO 2025, REACHING A TOTAL OF 50 PERCENT.

THERE ARE OTHER ITEMS ON THE CONSENT AGENDA. ONE IS A RECOMMENDATION FROM THE GOVERNANCE SUBCOMMITTEE REGARDING THE PROCESS OF EVALUATING THE CHAIR, THE VICE CHAIR, AND THE PRESIDENT AND CEO FOR THIS UPCOMING YEAR. AND, FINALLY, THERE ARE SOME AMENDMENTS TO THE FUNDING MECHANISM FOR CIRM RELATED TO THE EDUCATION1 OR EDUC1 PROGRAM.

SO THE WAY THE CONSENT AGENDA WORKS, IF ANYONE WANTS TO DISCUSS ANYTHING THAT I JUST MENTIONED, IT NEEDS TO BE ABSTRACTED BY YOU BY VOICE. AND THEN WE CAN CLOSE OUT THE REST OF THE AGENDA AND THEN PROCEED TO A DISCUSSION OF THE ITEM THAT YOU WOULD LIKE.

DO I HEAR ANY ABSTRACTIONS TO THE CONSENT AGENDA, ITEMS 3, 4, 5, AND 6? NOT IN THE ROOM. AND PERHAPS ANYONE ONLINE? NO. OKAY.

CAN I HAVE A MOTION TO CLOSE THE CONSENT AGENDA PLEASE?

DR. CLARK-HARVEY: SO MOVED.

CHAIRMAN IMBASCIANI: LEONDRA HAS MOVED.

VICE CHAIR BONNEVILLE: SECOND.

CHAIRMAN IMBASCIANI: MARIA SECONDED. SCOTT --

MR. TOCHER: BOARD COMMENT? PUBLIC COMMENT?

ALL THOSE IN THE ROOM IN FAVOR SAY AYE. OPPOSED? ABSTENTIONS? AND I'LL POLL THE MEMBERS ON THE ZOOM.

MONICA CARSON.

DR. CARSON: AYE.

MR. TOCHER: JUDY CHOU.

DR. CHOU: AYE.

MR. TOCHER: YSABEL DURON.

MS. DURON: AYE.

MR. TOCHER: MARK FISCHER-COLBRIE.

MR. FISCHER-COLBRIE: AYE.

MR. TOCHER: JUDY GASSON.

DR. GASSON: YES.

MR. TOCHER: JEFF GOLDEN.

DR. GOLDEN: AYE.

MR. TOCHER: RICH LAJARA.

MR. LAJARA: AYE.

MR. TOCHER: PAT LEVITT.

DR. LEVITT: YES.

MR. TOCHER: HALA MADANAT.

DR. MADANAT: AYE.

MR. TOCHER: CHRIS MIASKOWSKI.

DR. MIASKOWSKI: YES.

MR. TOCHER: MARV SOUTHARD.

DR. SOUTHARD: YES.

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MR. TOCHER: KAROL WATSON.
DR. WATSON: YES.
MR. TOCHER: AND KEVIN XU.
MR. XU: AYE.
MR. TOCHER: OH, AND KEITH YAMAMOTO.
DR. YAMAMOTO: YES.
MR. TOCHER: GREAT. THANK YOU. THAT MOTION CARRIES.
CHAIRMAN IMBASCIANI: THANK YOU, SCOTT. BOARD MEMBER SHANNON DAHL HAS A COMMENT ON THE CONSENT AGENDA.
DR. DAHL: YEAH. I HAD A COMMENT ABOUT THE GRANT WORKING GROUP COMMITTEE. I THINK, JUST LOOKING AT THE NEW APPOINTMENT AND THE REAPPOINTMENTS, AND LOOKING BACK AT THE LIST, I'M REALLY IMPRESSED BY THE GROUP THAT WE HAVE REVIEWING OUR GRANTS. AND THEY'RE SUCH A CRITICAL PIECE OF THE ORGANIZATION AND MOVING THE PROGRAMS FORWARD. I'M EXCITED ABOUT THE NEW APPOINTMENTS AND THE RENEWALS.
AS WE LOOK AT OUR PORTFOLIO AT LARGE AND THE WAY IN WHICH WE'RE ADVANCING MORE PROGRAMS INTO LATER STAGE, I THINK IT WOULD BE HELPFUL TO JUST TAKE A STEP BACK AND SAY DO WE NEED TO ADD ADDITIONAL LATER STAGE EXPERTISE TO THE GROUP TO

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ENSURE THAT EVERY TIME WE'RE GOING FROM PHASE 1 TO BLA, THAT WE HAVE ENOUGH REVIEWERS IN THE ROOM WITH THAT PERSPECTIVE. I SEE WE HAVE SOME ON OUR LIST, WHICH IS GREAT, BUT THEY'RE SMALLER IN NUMBER. SO I WOULD JUST ASK THAT THE TEAM TAKE THAT INTO CONSIDERATION. THANK YOU.

CHAIRMAN IMBASCIANI: THANK YOU, SHANNON.

GOING TO MOVE NOW TO AGENDA ITEM NO. 7, THE CONSIDERATION OF APPLICATIONS THAT HAVE BEEN SUBMITTED TO CIRM IN RESPONSE TO OUR DISCOVERY PROGRAM ANNOUNCEMENTS OR DISC4. AND THIS PRESENTATION IS GOING TO BE LED BY OUR VICE PRESIDENT FOR PORTFOLIO DEVELOPMENT AND REVIEW, DR. GIL SAMBRANO. THANK YOU, GIL.

DR. SAMBRANO: GOOD MORNING, EVERYONE. SO, YES, I'M GOING TO PRESENT TO YOU THE RECOMMENDATIONS FROM THE GRANTS WORKING GROUP AS IT RELATES TO THE DISC4 PROGRAM. SO LET'S GET STARTED WITH THAT.

WE ALWAYS BEGIN WITH OUR MISSION, TO ACCELERATE WORLD-CLASS SCIENCE TO DELIVER TRANSFORMATIVE REGENERATIVE MEDICINE TREATMENTS IN AN EQUITABLE MANNER TO A DIVERSE CALIFORNIA AND WORLD. AND THIS IS IMPORTANT IN SETTING THE STAGE FOR WHAT WE DO AND WHY WE DO IT. OF COURSE, TO HELP

US ACHIEVE THAT MISSION, WE HAVE A STRATEGY WITH VERY SPECIFIC GOALS THAT WE WANT TO ACHIEVE. AS IT RELATES TO DISCOVERY PROGRAMS, THOSE DISCOVERY PROGRAMS ARE SET UP TO SUPPORT COMPREHENSIVE DISCOVERY RESEARCH, AND THEY ALSO ENCOURAGE COLLABORATIVE, MULTIDISCIPLINARY APPROACHES WHERE POSSIBLE.

AND IN PARTICULAR, THE DISC4 AWARDS THAT ARE BASED ON THE ORIGINAL REMIND PROGRAM ARE VERY MUCH INTENDED TO SUPPORT CROSS-DISCIPLINARY, VERY COLLABORATIVE, AND INTEGRATED STUDIES ACROSS A RANGE OF TECHNOLOGIES AND APPROACHES TO ADDRESS BOTTLENECKS AND OTHER KNOWLEDGE GAPS IN HUMAN DISEASE.

SO FOR THE DISC4 AWARDS, ANYBODY WHO APPLIES, WE EXPECT THAT THEY'RE GOING TO ACHIEVE ONE OR MORE OF THE THREE OUTCOMES LISTED, WHICH IS TO DISCOVER NOVEL MECHANISTIC INSIGHTS OR ADVANCE UNDERSTANDING OF HUMAN DISEASE PATHOBIOLOGY, EXTEND UNDERSTANDING OF DISEASE MECHANISMS ACROSS AFFECTED HUMAN POPULATIONS, AND/OR IDENTIFY AND VALIDATE NOVEL THERAPEUTIC STRATEGIES, TARGETS, AND BIOMARKERS.

THE WAY THE DISC4 PROGRAM WAS DESIGNED, IT WAS DESIGNED USING PREFERENCE TOPICS FOR EACH CYCLE.

133 HENNA COURT, SANDPOINT, IDAHO 83864
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AND SO THE BOARD APPROVED PREFERENCE TOPIC FOR THIS PARTICULAR CYCLE WAS NEUROLOGICAL DISEASES. AND SO THAT INCLUDES CONDITIONS AND DISORDERS OF THE BRAIN, SPINAL CORD, AND PERIPHERAL NERVOUS SYSTEM.

ALL RIGHT. SO A LITTLE MORE ABOUT THE PROGRAM STRUCTURE ITSELF. THE DURATION OF THE AWARD IS FOUR YEARS. IT OFFERS 13 OR UP TO 13 MILLION AND AN ADDITIONAL MILLION WITH MATCHING FUNDS FROM THE APPLICANT. THE APPLICANT TEAM ITSELF INCLUDES THE PRINCIPAL INVESTIGATOR ALONG WITH A MINIMUM OF FOUR CO-INVESTIGATORS WHO WORK COLLABORATIVELY TO ACHIEVE, HOPEFULLY, SOMETHING THAT SYNERGIZES AND CAN ACHIEVE MORE THAN EITHER ONE ALONE.

SO THE ALLOCATION THAT WE HAVE FOR THIS PARTICULAR CYCLE IS 84 MILLION TOTAL WHICH SUPPORTS ROUGHLY UP TO SIX AWARDS. AND SO LET ME TELL YOU A LITTLE BIT ABOUT, THEN, THE REVIEW PROCESS THAT'S UTILIZED FOR THE DISC4 APPLICATIONS.

SO THIS UTILIZED A PRESUBMISSION PROCESS AT THE BEGINNING, AT THE ONSET. SO THESE WERE SHORT, THREE-PAGE PRESUBMISSIONS THAT WERE REVIEWED BY THE CIRM STAFF. AND THE SET OF PREFERENCES THAT YOU'VE SEEN BEFORE WERE APPLIED HERE. WE HAD 138 PRESUBMISSIONS, AND OF THOSE 24 WERE INVITED TO COMPLETE A FULL APPLICATION.

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THOSE FULL APPLICATIONS WERE ASSESSED FOR ELIGIBILITY. ALL WERE ELIGIBLE AND WENT ON TO THE MERIT REVIEW STAGE. AND WE ARE GOING TO THEN SHARE WITH YOU THE RECOMMENDATIONS FROM THE GRANTS WORKING GROUP THAT EVALUATED THOSE.

SO THIS IS JUST A REMINDER OF THE COMPOSITION OF THE GRANTS WORKING GROUP PANEL. IT INCLUDES SCIENTIFIC MEMBERS WHO EVALUATE THE APPLICATIONS BASED ON BROAD SUBJECT AREA OR METHODS EXPERTISE, AND THEY ARE THE ONES WHO ENTER THE SCIENTIFIC SCORE FOR EVERY APPLICATION. AND WE ALSO HAVE WHAT WE CALL GRANTS WORKING GROUP BOARD MEMBERS. SO THOSE ARE ICOC PATIENT ADVOCATE MEMBERS WHO SIT ON THE GRANTS WORKING GROUP. THEY OFFER THEIR PATIENT PERSPECTIVE ON THE SIGNIFICANCE AND POTENTIAL IMPACT OF PROJECTS, AND THEY ALSO PROVIDE OVERSIGHT ON THE PROCESS ITSELF. THEY DO NOT ENTER SCORES.

WE ALSO HAVE VISITING SPECIALISTS. THOSE ARE SCIENTIFIC MEMBERS THAT WE INVITE TO FILL KNOWLEDGE GAPS WHEN NECESSARY FOR A PARTICULAR SET OF APPLICATIONS OR EVEN MAYBE ONE APPLICATION AT A TIME. AND THEY PROVIDE THEIR INSIGHT TO THE PANEL ON APPLICATIONS.

THE SCORING SYSTEM THAT WE USE IS ON A

SCALE OF 1 TO 100. A MEDIAN SCORE OF 85 TO 100 MEANS THAT IT HAS EXCEPTIONAL MERIT AND WARRANTS FUNDING. A MEDIAN SCORE OF 1 TO 84 IS NOT RECOMMENDED FOR FUNDING. THE SCORING THAT IS UTILIZED IS HOLISTIC AND BASED UPON ALL FACETS OF THE EXPERT REVIEWS, AND WE DO ENCOURAGE REVIEWERS TO USE THE FULL RANGE.

ALL RIGHT. AND THE CRITERIA THAT ARE THE BASIS FOR THE SCORE ARE HIGHLIGHTED HERE. THESE ARE JUST THE HIGH-LEVEL ELEMENTS OF THE FIVE MAIN CRITERIA, WHICH INCLUDE THE SIGNIFICANCE AND POTENTIAL IMPACT OF THE PROJECT, INNOVATION RELATIVE TO THE CURRENT STATE OF RESEARCH FOR THE PROJECT, THE SCIENTIFIC RATIONALE, THE PROJECT PLAN AND DESIGN, AND THE APPLICANT'S CONSIDERATION OF IMPACT ACROSS AFFECTED POPULATIONS.

THIS TABLE SUMMARIZES THE RECOMMENDATIONS FROM THE GRANTS WORKING GROUP AS IT RELATES TO THIS SET OF APPLICATIONS. SO FOR THOSE 24 APPLICATIONS THAT WERE EVALUATED, EIGHT OF THEM WERE RECOMMENDED BY THE WORKING GROUP, 16 WERE NOT. THE TOTAL BUDGET REQUEST FOR THE EIGHT APPLICATIONS TOTALS 108.5 MILLION. AND AS NOTED EARLIER, THE FUNDS AVAILABLE FOR THE CYCLE IS 84 MILLION. SO THIS EXCEEDS THE AMOUNT THAT WE HAVE AVAILABLE TO SUPPORT ALL THE

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PROJECTS.

SO THE SCORING IN THE REVIEW SOMETIMES RESULTS IN A MINORITY REPORT. AND THAT HAPPENS WHEN ANY APPLICATION THAT'S NOT RECOMMENDED FOR FUNDING BY THE GRANTS WORKING GROUP, BUT HAD 35 PERCENT OR MORE OF THE MEMBERS SCORE IN THE FUNDING RANGE, THOSE INCLUDE A MINORITY REPORT WHICH IS BASICALLY A PARAGRAPH THAT SUMMARIZES THE MINORITY POSITION. AND WE USUALLY CHECK IN WITH THOSE REVIEWERS TO ENSURE IT MIRRORS THEIR PERSPECTIVE. IN THIS PARTICULAR CYCLE THERE WERE NO APPLICATIONS THAT QUALIFIED FOR A MINORITY REPORT.

ALL RIGHT. THIS TABLE SUMMARIZES THE EIGHT APPLICATIONS THAT WERE RECOMMENDED BY THE GRANTS WORKING GROUP. IT SHOWS THEM IN RANK ORDER IN TERMS OF THE MEDIAN SCORE, WHICH RANGES FROM 85 TO 90, ALONG WITH THE BUDGET REQUEST. THE OTHER THING TO MAKE NOTE OF IS YOU SEE THE Y AND THE N IN THE SECOND TO LAST AND THIRD TO LAST COLUMNS. SO THE Y MEANS, YES, THOSE ARE THE NUMBER OF GRANTS WORKING GROUP MEMBERS THAT SCORED 85 OR ABOVE FOR THAT APPLICATION, AND THE N MEANS NO, WHICH THOSE ARE THE ONES THAT SCORED BELOW 85 FOR THAT PARTICULAR APPLICATION.

AND SO YOU WILL NOTICE THAT, IN PARTICULAR

FOR THE LAST TWO WHICH THE CIRM TEAM IS RECOMMENDING NOT TO FUND IN ORDER TO ACCOMMODATE THE BUDGET, HAD A DIFFERENCE OF EIGHT TO SIX. SO EIGHT MEMBERS SCORING 85 OR ABOVE WHILE SIX SCORED BELOW 85. SO IT'S JUST SOMETHING TO TAKE NOTE AS I DESCRIBE THESE.

SO THE CIRM TEAM RECOMMENDATION, JUST TO GIVE YOU A LITTLE BIT MORE ABOUT THE RATIONALE, WE LOOKED AT ALL THE TOP APPLICATIONS AND IN PARTICULAR THOSE THAT HAD A SCORE OF 85. THERE WERE THREE APPLICATIONS THAT I SHOWED YOU ON THAT LIST THAT HAD A SCORE OF 85. AND LOOKING AT THOSE, THE CIRM TEAM IS RECOMMENDING THAT TWO OF THOSE APPLICATIONS NOT BE FUNDED, WHICH IS DISC4-19196 AND DISC4-19226. AND THIS IS SOLELY DUE TO THE FACT THAT WE DON'T HAVE ENOUGH BUDGET TO COVER. I WANT TO EMPHASIZE THE FACT THAT ALL HAVE MERIT. SO WE'RE NOT SUGGESTING THAT ANY OF THESE DO NOT HAVE SCIENTIFIC MERIT AS INDICATED BY THE WORKING GROUP, BUT WE HAD TO DEVELOP A RATIONALE FOR WHY WE WOULD RECOMMEND THE GROUP WE DID.

SO THE DISC4-19391 DID HAVE A GREATER CONSENSUS ON MERIT. SO THAT'S THE ELEVEN MEMBERS SCORING 85 OR ABOVE VERSUS THREE THAT SCORED BELOW WHILE THE OTHER TWO HAD EIGHT TO SIX SPLIT.

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SO A LITTLE BIT MORE ABOUT THE TWO APPLICATIONS THAT ARE NOT RECOMMENDED. SO THIS IS 19196, OR NOT RECOMMENDED BY THE CIRM TEAM. THEY ARE RECOMMENDED BY GRANTS WORKING GROUP JUST TO BE CLEAR. WE'RE NOT RECOMMENDING THIS ONE LARGELY BECAUSE OF THE SCORE. THE APPLICATION ITSELF IN TERMS OF THE TOPIC IS FOCUSED ON NEURODEGENERATIVE DISEASES, PARTICULARLY ALS AND FRONTAL TEMPORAL DEMENTIA, TO UNDERSTAND HOW RNA LOCALIZATION RELATES TO THE DISEASE STATE.

REVIEWERS NOTED AN EXCELLENT TEAM, INNOVATIVE APPROACHES, IMPACT OF THE DATASET TO BE PRODUCED. BUT THERE WAS A RISK THAT WAS NOTED, THAT WHILE THE MISLOCALIZATION OF THE RNA IS A COMMON OBSERVATION IN ALS, THE REVIEWERS DID NOTE THIS SEVERAL TIMES, AND YOU CAN SEE IT IN THE SUMMARY, ABOUT THE UNCERTAINTY OF WHETHER THIS ACTUALLY PLAYS A CAUSAL ROLE IN ALS. AND SO THE RISK IS THAT THE EFFORT EXPENDED HERE MAY BE LIMITED IF IT TURNS OUT THAT THERE IS NO CAUSAL RELATIONSHIP. SO ALSO WE ARE ALREADY MENTIONED THE SCORE OF THE GRANTS WORKING GROUP CONSENSUS BEING EIGHT TO SIX.

SO THEN THE NEXT APPLICATION, 19226, IS THE OTHER ONE THAT WE'RE NOT RECOMMENDING FOR FUNDING. SO THIS APPLICATION IS FOCUSED ON

UNDERSTANDING CYTOKINE RESPONSES IN THE BRAIN AND MICROGLIAL MECHANISMS IN THE CONTEXT OF ALZHEIMER'S DISEASE. AGAIN, REVIEWERS NOTED AN EXCELLENT TEAM, INNOVATIVE APPROACHES, AND THE POTENTIAL CREATION OF A HIGH-VALUE DATASET. FOR SOME REVIEWERS THE ENTHUSIASM WAS OFFSET BY SOME CONCERNS RELATED TO THE LACK OF POWER CALCULATIONS AND OTHER TECHNICAL ELEMENTS. THERE WAS ALSO SOME CONCERN ABOUT THE FACT THAT THE PROJECTS WERE A LITTLE DISJOINTED, DIDN'T SEEM TO RELATE CLEARLY TO ONE ANOTHER AS TO WHY THEY WERE PUT TOGETHER AS PROPOSED. AND, AGAIN, THIS ALSO HAD A GWG GROUP VOTE THAT WAS EIGHT MEMBERS VOTING 85 OR ABOVE AND SIX THAT DID NOT.

ALL RIGHT. SO WITH THIS, THEN WE CAN TRANSITION TO THE EXCEL SPREADSHEET, THE TABLE THAT SHOWS YOU ALL OF THE APPLICATIONS FOR DISCUSSION. AND, CHAIRMAN IMBASCIANI, I'LL JUST TURN IT BACK TO YOU FOR DISCUSSION.

CHAIRMAN IMBASCIANI: DR. SAMBRANO, THANK YOU SO MUCH FOR THAT PRESENTATION AND THE EXPLANATION OF THE DELIBERATIONS YOU WENT THROUGH.

IF I CAN HAVE THE TEMERITY TO SUMMARIZE DR. SAMBRANO'S PRESENTATION, WE HAVE A LOT OF APPLICATIONS, SOME OF WHICH WERE NOT RECOMMENDED FOR FUNDING BY THE GWG. THE GRANTS WORKING GROUP DID

RECOMMEND EIGHT FOR FUNDING, BUT THAT BUDGETARY REQUEST WOULD HAVE EXCEEDED THE $84 MILLION WE HAVE AVAILABLE. IN FACT, IT TOTALED 108 MILLION. AND AS IT HAPPENS, THERE IS A THREE-WAY TIE AT THE BOTTOM. GIL VERY ELOQUENTLY DESCRIBED THE DIFFERENCES BETWEEN THOSE THREE AND WHAT GUIDED THE TEAM TO RECOMMEND ONE OVER THE OTHER. THEREFORE, THERE ARE -- EVEN THOUGH THE GRANTS WORKING GROUP RECOMMENDED EIGHT FOR FUNDING, WE CAN ONLY FUND SIX. AND IT'S GOING TO BE INCUMBENT UPON THE BOARD TO CHOOSE THAT.

SO TO SIMPLIFY THIS FROM A MOTION POINT OF VIEW, I THINK IT WOULD BE EASIEST IF WE HAD A MOTION NOT TO FUND THOSE FROM NO. 9 DOWN. THAT IS, NOT TO FUND THE ONES THAT WERE NOT RECOMMENDED BY THE GRANTS WORKING GROUP. HE'S SHOWING THAT NOW, ALL THE ONES THAT FALL BELOW POSITION EIGHT.

DR. BARRETT: SO MOVED.

MR. TOCHER: FROM A PROCESS STANDPOINT, BECAUSE THE PROGRAM IS WHAT WE CALL OVERSUBSCRIBED AT THE MOMENT, FOR THOSE VOTING MEMBERS OF THE APPLICATION REVIEW SUBCOMMITTEE WHO HAVE A CONFLICT WITH ANY APPLICATION IS CONSIDERED TO HAVE A CONFLICT WITH ALL OF THEM FOR THE PURPOSES OF MAKING A MOTION AND SECONDING A MOTION AND FOR THE

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DISCUSSION. WHEN I CALL YOUR NAME DURING THE ROLL CALL VOTE, YOUR ANSWER WILL BE AYE OR NAY WITH RESPECT TO THE MOTION AND THEN ADD "EXCEPT FOR THOSE APPLICATIONS WITH WHICH I AM IN CONFLICT," SOME VERSION OF THAT.

SO AT THE MOMENT THE VOTING MEMBERS OF THE ARS WITH A CONFLICT AND THUS SHOULD NOT PARTICIPATE IN THE MAKING OF THE MOTION OR DISCUSSION ARE MEMBERS DAHL, BONNEVILLE, DURON, DULIEGE, FLOWERS, FISCHER-COLBRIE, MIASKOWSKI, AND WATSON. THAT MEANS THERE IS A CONFLICT, SO PLEASE REFRAIN FROM --

DR. GOLDEN: THIS IS JEFF GOLDEN. I THINK I HAVE A CONFLICT WITH ONE OF THEM AS WELL, 19444.

MR. TOCHER: YES, 19350 YOU HAVE A CONFLICT.

CHAIRMAN IMBASCIANI: THANK YOU, SCOTT. OKAY. SO THE CHAIR WOULD LIKE TO ENTERTAIN A MOTION NOT TO FUND THOSE APPLICATIONS NOT RECOMMENDED FOR FUNDING BY THE GRANTS WORKING GROUP.

DR. SOUTHARD: SO MOVED.

DR. CARETHERS: I WILL SECOND DR. BARRETT'S MOTION.

MR. TOCHER: SORRY. YOU'RE NOT A VOTING MEMBER OF THE --

CHAIRMAN IMBASCIANI: IT HAS TO BE COMING

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FROM A MEMBER OF THE APPLICATION REVIEW SUBCOMMITTEE.

DR. CARETHERS: MY APOLOGIES.

CHAIRMAN IMBASCIANI: THAT'S QUITE ALL RIGHT.

DR. SOUTHARD: SECOND.

MS. CASILLAS: I'LL MAKE THAT MOTION.

CHAIRMAN IMBASCIANI: OKAY. WE HAVE A MOTION. IT CAN BE SECONDED BY?

DR. SOUTHARD: I WILL SECOND. MARV SOUTHARD.

CHAIRMAN IMBASCIANI: MARV, THANK YOU.

OKAY. ANY DISCUSSION ON THIS EARLY MOTION NOT TO FUND THOSE GRANTS NOT RECOMMENDED BY THE GWG FROM BOARD MEMBERS? BOARD MEMBERS ONLINE? OR ANY MEMBER OF THE PUBLIC LIKE TO SPEAK TO THIS? THERE'S A GENTLEMAN IN THE AUDIENCE THAT MIGHT HAVE --

MS. MORALEZ: ALL RIGHT. SO WE'RE GOING TO NOW OPEN THE FLOOR FOR PUBLIC COMMENT. IF YOU'RE JOINING IN PERSON, PLEASE APPROACH THE PODIUM. IF YOU LIKE, YOU MAY STATE YOUR NAME FOR THE RECORD, AND PLEASE KEEP YOUR REMARKS WITHIN THREE MINUTES.

DR. QI: I'M ACTUALLY DISCUSSING ABOUT PROPOSAL 19196. SHOULD I WAIT UNTIL LATER?

MR. TOCHER: CORRECT. IT'S NOT PART OF

THIS MOTION.

CHAIRMAN IMBASCIANI: THAT'S OKAY. DON'T GO AWAY.

MS. MORALEZ: ANY PARTICIPANTS ON THE PHONE THAT WOULD LIKE TO TALK ABOUT THESE APPLICATIONS, PLEASE PRESS STAR NINE TO RAISE YOUR HAND. ALL RIGHT. WE HAVE ONE MEMBER OF THE PUBLIC NUMBER ENDING IN 3564. IF YOU PRESS STAR SIX TO UNMUTE YOURSELF, IF YOU'D STATE YOUR NAME FOR THE RECORD, AND PLEASE KEEP YOUR COMMENTS WITHIN THREE MINUTES.

MS. MILLER: MY NAME IS LAURA MILLER, AND I AM COMMENTING ON 19391. I AM A PERSON LIVING WITH ALS. ALS BEING A DISEASE THAT SLOWLY TAKES AWAY A PERSON'S ABILITY TO LIVE (INAUDIBLE). FOR MOST OF US ABOUT 90 PERCENT --

MS. MORALEZ: WE'RE NOT ON THAT APPLICATION YET. WE'RE GOING TO SAVE YOUR COMMENTS FOR WHEN WE GET TO THAT APPLICATION NUMBER.

CHAIRMAN IMBASCIANI: THANKS, LANA, FOR THAT CLARIFICATION.

TO THE SPEAKER, WE HAVEN'T -- THE APPLICATION YOU WOULD LIKE TO SPEAK TO HAS NOT BEEN PUT THE TABLE FOR A MOTION, BUT DON'T GO AWAY.

OKAY. IF THERE'S NO OTHER COMMENT, JUST

VERIFYING WITH BOARD SUPPORT, NO. NO OTHER COMMENTS. WE CAN PROCEED TO A ROLL CALL VOTE ON THIS MOTION.

MR. TOCHER: MARIA BONNEVILLE.

VICE CHAIR BONNEVILLE: YES, EXCEPT FOR THOSE WITH WHICH I HAVE A CONFLICT.

MR. TOCHER: MARGUERITE CASILLAS.

MS. CASILLAS: YES.

MR. TOCHER: JUDY CHOU.

DR. CHOU: YES.

MR. TOCHER: LEONDRA CLARK-HARVEY.

DR. CLARK-HARVEY: YES.

MR. TOCHER: SHANNON DAHL.

DR. DAHL: YES, EXCEPT FOR THOSE WITH WHICH I HAVE A CONFLICT.

MR. TOCHER: ANNE-MARIE DULIEGE.

DR. DULIEGE: YES, EXCEPT FOR THOSE WITH WHICH I HAVE A CONFLICT.

MR. TOCHER: YSABEL DURON.

MS. DURON: YES, EXCEPT FOR THOSE WITH WHICH I HAVE A CONFLICT.

MR. TOCHER: MARK FISCHER-COLBRIE.

MR. FISCHER-COLBRIE: YES, EXCEPT FOR THOSE WITH WHICH I HAVE A CONFLICT.

MR. TOCHER: ELENA FLOWERS.

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DR. FLOWERS: YES, EXCEPT FOR THOSE WITH WHICH I HAVE A CONFLICT.

MR. TOCHER: VITO IMBASCIANI.

CHAIRMAN IMBASCIANI: YES.

MR. TOCHER: RICH LAJARA.

MR. LAJARA: YES.

MR. TOCHER: CHRIS MIASKOWSKI.

DR. MIASKOWSKI: YES, EXCEPT FOR THOSE WITH WHICH I HAVE A CONFLICT.

MR. TOCHER: ADRIANA PADILLA.

DR. PADILLA: YES.

MR. TOCHER: MARV SOUTHARD.

DR. SOUTHARD: YES.

MR. TOCHER: KAROL WATSON.

DR. WATSON: YES, EXCEPT FOR THOSE WITH WHICH I HAVE A CONFLICT.

MR. TOCHER: KEVIN XU.

MR. XU: YES.

MR. TOCHER: THANK YOU. THE MOTION CARRIES.

CHAIRMAN IMBASCIANI: THANK YOU, SCOTT. OKAY.

NOW WE ARE LEFT WITH EIGHT APPLICATIONS THAT HAVE BEEN RECOMMENDED FOR FUNDING BY THE GWG. BUT AS DR. SAMBRANO HAS EXPLAINED, OUR BUDGET WILL

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ONLY SUPPORT SIX OF THOSE. WE ARE OVERSUBSCRIBED. SO WE CAN DO THIS IN SEVERAL WAYS. THE SIMPLEST WAY WOULD BE IF SOMEONE MOVED TO ACCEPT THE RECOMMENDATION OF THE CIRM TEAM TO FUND THE SIX THAT HAVE BEEN RECOMMENDED AND NOT TO FUND THE TWO ALTHOUGH THEY TIED IN THAT LOW SCORE.

MS. CASILLAS: SO MOVED.

CHAIRMAN IMBASCIANI: MARGUERITE CASILLAS HAS MOVED.

DR. CARETHERS: I'LL SECOND THE MOTION.

CHAIRMAN IMBASCIANI: THAT'S A SECOND SECOND THERE.

MR. TOCHER: AGAIN, A VOTING MEMBER WITHOUT A CONFLICT. SO THOSE WITH A CONFLICT AT THE MOMENT ARE DAHL, DURON, FISCHER-COLBRIE, FLOWERS, MIASKOWSKI, AND WATSON. SO THE REMAINING VOTING MEMBERS ARE ELIGIBLE.

DR. DULIEGE: I SECOND.

CHAIRMAN IMBASCIANI: THANK YOU. SO ANY DISCUSSION ON THE MOTION FROM BOARD MEMBERS? ANNE-MARIE DULIEGE.

DR. DULIEGE: JUST, GIL, THANK YOU AGAIN FOR THAT GREAT PRESENTATION. WE REALIZE THAT IT'S REALLY A CHALLENGE WHEN WE COME TO AN OVERBUDGET SORT OF SCORING. WE RECEIVED A NUMBER OF LETTERS

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ABOUT THESE APPLICATIONS IN GENERAL TO THESE TWO. CAN YOU SUMMARIZE SOME OF THE CONCERN EXPRESSED IN THE LETTERS AND HOW WE WOULD ADDRESS THEM? I KNOW IT'S A GENERAL QUESTION, BUT MAYBE YOU READ THE LETTERS, I ASSUME.

DR. SAMBRANO: YES. SO WE DID READ THE LETTERS. SO I THINK THEY EACH ADVOCATE FOR THEIR PROJECT HIGHLIGHTING ELEMENTS OF IN SOME CASES THE SCIENTIFIC ELEMENTS THAT THE GRANTS WORKING GROUP HIGHLIGHTED AND HOW THEY'VE ADDRESSED SOME OF THOSE CONCERNS. OF COURSE, WE ALWAYS NOTE THE FACT THAT, UNLESS THE GRANTS WORKING GROUP ACTUALLY SEES THEM, IT'S DIFFICULT TO KNOW WHAT THEY WOULD THINK OF THESE RESPONSES. SO WE DON'T EVALUATE THEM FROM A SCIENTIFIC PERSPECTIVE TO CONFIRM THAT THEY WOULD HAVE CHANGED THE OUTCOME. BUT THEY ARE NOTED THERE.

SOME OF THEM HIGHLIGHT ELEMENTS OF THE FACT THAT THESE ARE AN IMPORTANT AREA. TWO OF THEM IN PARTICULAR THAT ARE ON THE LINE RELATE TO ALS. THEY BOTH HAPPEN TO COME FROM THE SAME INSTITUTION ACTUALLY, BUT THEY ARE BOTH IMPORTANT PROJECTS, BOTH HIGHLIGHTED AS MERITORIOUS BY THE GRANTS WORKING GROUP.

SO I THINK THE DIFFICULTY IS ALSO THAT, EVEN WITH THESE LETTERS, IT BECOMES DIFFICULT TO

DETERMINE WHERE ONE DRAWS A LINE AND HOW ONE RECOMMENDS THEM. SO THAT AT LEAST IS WHAT I CAN OFFER AT THE MOMENT.

CHAIRMAN IMBASCIANI: THANKS, GIL. WE HAVE COMMENT. BOARD MEMBER CASILLAS.

MS. CASILLAS: YEAH. IN ONE OF THE LETTERS ABOUT THOSE TWO APPLICATIONS THAT CAME FROM THE SAME INSTITUTION, THEY PROPOSE LIKE, WELL, TAKE A LITTLE BIT OF MONEY OUT FROM THIS ONE AND PUT IT TO THAT ONE. I MEAN IS THERE EVEN A MECHANISM FOR THAT?

DR. SAMBRANO: IT'S SOMETHING THAT WE DO NOT RECOMMEND. WE DO NOT WANT TO TAKE FUNDS FROM OTHER PROJECTS IN ORDER TO ALLOW, OR EVEN IF THERE ARE FUNDS REMAINING, SO YOU WOULD HAVE ABOUT THREE AND A HALF MILLION REMAINING OUT OF THE 84 IF WE FUND THE TOP SIX, IS NOT SUFFICIENT TO COVER THE SCOPE AND INTENT OF THE PROJECT. THESE PROJECTS WERE REVIEWED WITH THE EXPECTATION THAT, IF THEY WERE TO BE FUNDED, THEY WOULD BE FUNDED IN FULL AND WOULD BE ACCOMPLISHING THE GOALS THAT THEY SET OUT. I THINK PROVIDING ANY LESS WOULD REALLY HAMPER SIGNIFICANTLY THEIR ABILITY TO DO THAT.

MS. CASILLAS: AND THERE'S NO REASON THOSE TWO APPLICATIONS THAT ARE NOT BEING RECOMMENDED

COULDN'T REAPPLY?

DR. SAMBRANO: RIGHT. SO WE ARE GOING TO HAVE ADDITIONAL CYCLES OF DISC4, NOTING, THOUGH, THAT THEY'RE ARE PREFERENCE TOPICS FOR EACH. BUT WE ARE NOT PREVENTING APPLICANTS FROM COMING INTO ANY OF THESE CYCLES. SO THEY CAN REAPPLY.

WE HAVE ACTUALLY IN THE BATCH ONE APPLICATION THAT IS IN THE TOP SIX THAT WAS AN APPLICATION THAT FELL IN THE SAME SITUATION UNDER THE REMIND4 PROGRAM THAT IS NOW BEING FUNDED, ASSUMING THIS GOES FORWARD FOR THAT PROGRAM.

DR. DULIEGE: ONE QUESTION. I THINK I KNOW THE ANSWER, BUT STILL I WILL ASK. THE ENVELOPE FOR THIS CYCLE HAS BEEN FIXED. IS THERE SOME FLEXIBILITY THERE? IS THAT THE BUDGET FOR THIS YEAR WITH AN ADDITIONAL BUDGET FOR THE NEXT CYCLE REVIEW? HOW DO YOU WE CONSIDER THAT?

DR. SAMBRANO: SO THE BUDGET FOR THE NEXT CYCLE HAS NOT BEEN SET. SO THAT WILL COME IN JUNE. SO THIS IS FOR ONE CYCLE PER YEAR. SO THE CYCLE IS -- OR THE BUDGET FOR THIS IS FIXED.

CHAIRMAN IMBASCIANI: I DON'T SEE ANY HANDS FROM BOARD MEMBERS ONLINE. WE CAN GO TO PUBLIC COMMENT. I DO SEE A TELEPHONE CALL, AND WE HAVE A GENTLEMAN IN THE ROOM. YES. SIR, IF YOU

WOULD START AGAIN, TELL US YOUR NAME AGAIN.

DR. QI: NO. IT'S A TIE FOR THE TOP SIX. WE ARE NO. 7.

MR. TOCHER: THE MOTION IS TO FUND THE TOP SIX. SORRY. I ONLY HEARD TO FUND THE TOP SIX. SO NOT FUND THE OTHER TWO.

CHAIRMAN IMBASCIANI: IT'S TO ACCEPT -- THE MOTION IS TO ACCEPT THE RECOMMENDATION OF THE CIRM TEAM ON ALL EIGHT. SO HE IS IN ORDER TO SPEAK.

DR. QI: COULD I START? ALL RIGHT. GOOD MORNING TO MEMBERS OF THE SUBCOMMITTEE. I'M STANLEY QI FROM STANFORD REPRESENTING 19196.

SO ALS IS A DEVASTATING CRISIS FOR CALIFORNIA. DESPITE DECADES OF EFFORTS, THE SURVIVAL RATE REMAINS UNCHANGED. WE ARE HERE TODAY BECAUSE OUR TEAM IS A FIRST-TIME PARTNERSHIP BETWEEN STANFORD AND UCSD, AND WE ARE READY TO BRINGING A NEW THERAPEUTIC SOLUTION TO YOUR PORTFOLIO NAMED SPATIAL RNA MEDICINE.

THE GRANTS WORKING GROUP RAISED A CRITICAL QUESTION. IS RNA LOCALIZATION A CAUSE OR A CONSEQUENCE OF ALS? WE NOW HAVE THE ANSWER. IN RECENT 2025 DATA, WE PROVED THAT RNA BEING IN THE WRONG LOCATION KILL NEURONS. AND CRUCIALLY WE ALSO SHOWN THAT USING OUR TECHNOLOGY TO MOVE ONE KEY RNA

TO THE NEURONS, WE CAN TRIGGER X AMOUNT OF REGROWTH BY 80 PERCENT. WE ARE NOW ABLE TO REWRITE THE RNA GEOGRAPHY TO SAVE THE NEURON.

WE KNOW THE SUBCOMMITTEE IS FACING A DIFFICULT TIE TODAY WITH THE REMAINING FUNDS IN THE ALLOCATION. I WANT TO MENTION THAT OUR TEAM HAS NEVER RECEIVED CIRM FUNDING. WHILE OUR PROPOSAL IS COMPREHENSIVE, WE ARE STILL COMMITTED TO THE MISSION THAT WE HAVE DEVELOPED IN NARROW SCOPE, FLEXIBLE BUDGET MODEL. WE ARE PREPARED TO WORK IMMEDIATELY WITH CIRM TO FIT OUR SCOPE INTO THE AVAILABLE FUNDS. WE BELIEVE THAT IT'S IMPORTANT TO BRING THIS UNIQUE, FIRST-CLASS PLATFORM INTO THE COMMUNITY NOW RATHER THAN WAITING FOR ANOTHER YEAR OF WAITING BECAUSE FOR PATIENTS, WAITING IS NOT AN OPTION.

IF YOU LOOK AT THE CURRENT CIRM PORTFOLIO, YOU WILL FIND MANY WORK IN GENE EDITING AND CELL THERAPY, BUT YOU WILL FIND ZERO PROJECTS ADDRESSING SPATIAL RNA MEDICINE. BY FUNDING 19196, YOU ARE NOT JUST FUNDING ANOTHER STUDY. YOU ARE FILLING A MAJOR GAP IN CALIFORNIA'S PORTFOLIO WITH A TECHNOLOGY THAT DOESN'T EXIST ELSEWHERE. IT'S NOT JUST A TOOL. IT'S A MEDICINE TO STOP ALS.

FINALLY, I WANT TO SHARE WHY THIS PROJECT IS SO URGENT. WE RECEIVED DIRECT AND A MOVING

REQUEST FROM PATIENTS WHO ARE ASKING TO JOIN OUR TEAM, NOT AS SUBJECTS, BUT AS RESEARCHERS TO FUND A CURE FOR THEMSELVES. THEY AREN'T JUST LOOKING FOR A TREATMENT. THEY ARE LOOKING FOR A WAY TO FIGHT BACK. FOR THESE FAMILIES THE FUNDING IS NOT JUST A BUDGET LINE, BUT IT'S THE LITERAL FUEL FOR THEIR HOPE AND THEIR BELIEF THAT A BREAKTHROUGH IS FINALLY WITHIN REACH.

LET'S NOT LEAVE THE HOPE TO CHANCE. SO I HOPE THE COMMITTEE WILL CONSIDER LET'S BREAK THIS TIE IN FAVOR OF INNOVATION AND HELP US MAKE THIS SPATIAL RNA MEDICINE A REALITY FOR CALIFORNIA FAMILIES. THANK YOU.

CHAIRMAN IMBASCIANI: THANK YOU FOR YOUR REMARKS.

MS. MORALEZ: WE HAVE TWO PEOPLE ON THE PHONE. LAURA MILLER ENDING IN 3564. LET'S TRY THIS AGAIN. IF YOU PRESS STAR SIX, AND YOU CAN HAVE THREE MINUTES FOR YOUR PUBLIC COMMENT.

MS. MILLER, ARE YOU AVAILABLE?

MS. MILLER: YES. THANK YOU. AGAIN, MY NAME IS LAURA MILLER. I'M COMMENTING ON 19196. AND I AM LIVING WITH ALS. ALS IS A DEVASTATING DISEASE; AND DESPITE DECADES OF RESEARCH, WE STILL DON'T UNDERSTAND ENOUGH ABOUT HOW THIS DISEASE WORKS.

CONSEQUENTLY, THERE HAVE BEEN NO TREATMENTS DEVELOPED TO STOP THIS PROGRESSING.

THIS PROJECT EXPLORES SOMETHING SCIENTISTS ARE ONLY BEGINNING TO UNDERSTAND, THAT IN ALS MOLECULES INSIDE NERVE CELLS MAY BE GOING TO THE WRONG PLACES. IF WE CAN JUST LEARN HOW TO CORRECT THAT PROCESS, IT CAN OPEN AN ENTIRELY NEW WAY TO TREAT NEURODEGENERATIVE DISEASES.

BREAKTHROUGHS IN ALS RESEARCH DON'T JUST HELP PEOPLE WITH ALS. THEY MAY UNLOCK THE BIOLOGY OF MANY NEURODEGENERATIVE DISEASES.

SO AS SOMEONE LIVING WITH THIS DISEASE, I STRONGLY SUPPORT FUNDING INNOVATIVE RESEARCH LIKE THIS. THANK YOU.

MS. MORALEZ: THANK YOU VERY MUCH. WE HAVE ONE MORE PUBLIC COMMENT -- TWO MORE. LAST FOUR DIGITS IS 6378. IF YOU PRESS STAR SIX AND STATE YOUR NAME, IF YOU WOULD LIKE, AND START YOUR THREE MINUTES.

DR. SNYDER: THIS IS MICHAEL SNYDER. I'M THE CONTACT PI OF 19391, THE ONE THAT WAS RECOMMENDED FOR FUNDING. AND I'D JUST LIKE TO SAY, FIRST OF ALL, THAT WE'RE OBVIOUSLY PLEASED THAT THE REVIEWERS AND CIRM STAFF LIKED OUR APPLICATION AND OVERWHELMINGLY SUPPORTED IT ELEVEN TO THREE IN

FAVOR.

WE DO BELIEVE THIS RESEARCH IS HIGHLY IMPACTFUL, NOT JUST FOR THE SCIENCE, BUT FOR IT'S TRANSLATION POTENTIAL. AND WE HAVE A VERY STRONG AND EXPERIENCED TEAM THAT WE BELIEVE CAN PULL THIS OFF.

THE GENETIC BASIS, AS YOU JUST HEARD, OF SPORADIC ALS IS VERY POORLY UNDERSTOOD. AND WE HAVE NEW, INNOVATIVE AI METHODS THAT PEOPLE REALLY HAVEN'T DONE BEFORE. AND THEY DO FIND NEW GENES AND POTENTIAL ALS TARGETS. AND WE'VE ALREADY FOUND MANY GENES WITH THESE KINDS OF APPROACHES. AND SO WE THINK THESE ARE GOING TO BE VERY, VERY POWERFUL. IN FACT, WE'VE EVEN FOUND ONE POTENTIAL TARGET USING THIS KIND OF APPROACH. SO WE ARE CONFIDENT THAT IT CAN WORK AND BE VERY IMPACTFUL.

THE REVIEWERS DID RAISE SOME CONCERNS. IT SEEMED LIKE THE BIGGEST ONE WAS WHETHER WE WOULD HAVE ACCESS TO SAMPLES. AND WE OBVIOUSLY DO. WE HAVE A MEMBER OF OUR TEAM, HE'S PART OF TARGET ALS, AND EVEN IN HIS OWN BIOBANK, HE HAS MANY POTENTIAL TISSUES THAT WE CAN USE. SO I THINK THEIR MAJOR CONCERN ISN'T REALLY A CONCERN. IT'S TECHNICAL ISSUES AND OTHER TECHNICAL ISSUES AND PRETTY EASILY ADDRESSABLE.

SO THE BOTTOM LINE IS WE DO THINK OUR PROJECT IS HUGELY INNOVATIVE AND CAN EASILY TRANSLATE INTO THINGS THAT WILL BE HIGHLY IMPACTFUL FOR ALS PATIENTS. AND SO WE'RE, AGAIN, QUITE CONFIDENT WE CAN PULL THIS OFF AND HAVE A GREAT IMPACT ON THIS VERY DEVASTATING DISEASE.

CHAIRMAN IMBASCIANI: THANK YOU, DR. SNYDER.

MS. MORALEZ: WE HAVE A PUBLIC COMMENT ENDING IN 4883. PLEASE PRESS STAR SIX TO UNMUTE YOURSELF AND STATE YOUR NAME FOR THE RECORD. YOU HAVE THREE MINUTES.

DR. DOUGHERTY: HELLO, EVERYONE. MY NAME IS SARA DOUGHERTY, AND I'M THE SENIOR DIRECTOR OF RESEARCH WITH THE ALS NETWORK. I'M SPEAKING IN SUPPORT OF TWO APPLICATIONS TODAY, WHICH I REALIZE NOW MIGHT NOT HELP WITH YOUR TIEBREAKER, BUT IT'S REALLY IMPORTANT INFORMATION.

SO REGARDING ITEM 19391, THIS PROPOSAL ADDRESSES AN UNMET NEED AND ONE OF THE MOST CRITICAL CHALLENGES IN ALS RESEARCH, UNDERSTANDING THE GENETIC AND MOLECULAR DRIVERS OF SPORADIC ALS, WHICH WE MENTIONED REPRESENTS THE VAST MAJORITY OF ALS CASES.

BY INTEGRATING MACHINE LEARNING, LARGE

SCALE GENETICS, NEUROPATHOLOGY, AND STEM CELL-BASED FUNCTIONAL SCREENING, THIS PROJECT TAKES A HIGHLY INNOVATIVE AND COMPREHENSIVE APPROACH TO IDENTIFYING NEW THERAPEUTIC TARGETS. WHAT MAKES THIS APPROACH ESPECIALLY POWERFUL IS THAT IT MOVES BEYOND OBSERVATION TO TRUE FUNCTIONAL DISCOVERY, LINKING GENETIC FINDINGS DIRECTLY TO DISEASE MECHANISMS.

THE ULTIMATE GOAL IS TO GENERATE NEW GENETIC TARGETS FOR SPORADIC ALS, AN ESSENTIAL STEP TOWARDS DEVELOPING THERAPIES THAT CAN BENEFIT THE BROADER ALS POPULATION. THIS EXCEPTIONAL MULTIDISCIPLINARY TEAM REPRESENTING LEADING CALIFORNIA INSTITUTIONS HAS THE POTENTIAL TO BUILD A STRONG PIPELINE OF TARGETS THAT COULD MEANINGFULLY IMPACT PATIENTS. FOR THE ALS COMMUNITY, THIS KIND OF DISCOVERY-DRIVEN RESEARCH IS ESSENTIAL TO UNLOCKING NEW TREATMENTS AND ADVANCING THE FIELD TOWARD REAL PROGRESS.

AND THEN PERHAPS UNCONVENTIONALLY IN SUPPORT OF 19196, ALSO AN ALS PROJECT, THIS PROPOSAL REPRESENTS A BOLD, INNOVATIVE APPROACH TO TACKLING ALS. IN THIS INSTANCE, RATHER THAN FOCUSING ON GENES OR PROTEINS, AS DR. QI MENTIONED, THIS WORK EXPLORES HOW THE SPATIAL ORGANIZATION OF RNA WITHIN CELLS CONTRIBUTES TO DISEASE AND SO CRITICALLY HOW

TO CORRECT IT. THIS IS A FUNDAMENTALLY NEW WAY OF THINKING ABOUT NEURODEGENERATION. THIS WORK OPENS THE DOOR TO AN ENTIRELY NEW THERAPEUTIC STRATEGY SPACE THAT GOES BEYOND CURRENT APPROACHES. IMPORTANTLY, THESE MECHANISMS ARE SHARED ACROSS MULTIPLE NEURODEGENERATIVE DISEASES, GIVING BROAD IMPACT.

THIS EXCEPTIONAL TEAM IS GROUNDED IN A HIGHLY COLLABORATIVE ENVIRONMENT. THE PROJECT HAS BOTH SCIENTIFIC RIGOR AND INNOVATIVE EDGE THAT IS NEEDED TO DRIVE MEANINGFUL PROGRESS. FROM A FUNDER'S PERSPECTIVE, THIS KIND OF FORWARD THINKING RESEARCH IS WHAT IS NEEDED TO MOVE FROM INCREMENTAL ADVANCES TOWARD TRULY TRANSFORMATIVE THERAPIES. I THANK YOU FOR YOUR TIME AND TRULY REQUEST THAT YOU CONSIDER BOTH OF THESE PROPOSALS.

CHAIRMAN IMBASCIANI: THANK YOU TO THE SPEAKER. I SEE ANOTHER CALL COMING IN, LANA.

MS. MORALEZ: WE DO. OKAY. THE PHONE NUMBER ENDING IN 7366, IF YOU WOULD PRESS STAR SIX TO UNMUTE YOURSELF AND, IF YOU'D LIKE, STATE YOUR NAME FOR THE RECORD, AND YOU HAVE THREE MINUTES. I SEE THAT YOU'RE UNMUTED. YOU CAN START SPEAKING.

DR. ICHIDA: OH, YES. THANK YOU. THIS IS JUSTIN ICHIDA. I'M ONE OF THE CO-I'S FOR 19391.

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I'M FROM USC. I'VE BEEN WORKING IN THE ALS FIELD FOR OVER A DECADE NOW. AND I THINK WHAT WE'RE BEGINNING TO SEE IS THAT THIS DISEASE IS REVERSIBLE IF YOU IDENTIFY THE RIGHT TARGET. FOR EXAMPLE, THE ASO TARGETING SOD1, WE'VE BEEN SEEING THAT CAN HALT THE DISEASE, IN SOME CASES IMPROVE THE MOTOR FUNCTION OF PATIENTS WITH SOD1 ALS.

I THINK THE CHALLENGE IS THAT MOST OF THE PATIENTS WITH ALS ARE SPORADIC, AND WE DON'T YET KNOW WHAT THE RIGHT GENETIC TARGETS ARE FOR THEIR DISEASE DUE TO THE COMPLEXITY.

AND SO WHAT WE'VE SEEN WITH SOME OF THE NEW TECHNIQUES WITH AI AND MULTI-OM ANALYSIS IS THAT WE CAN ACTUALLY NOW USE THOSE TO BETTER HARNESS THE GENETIC INFORMATION AND SEQUENCING THAT WE HAVE TO FIND THESE NEW GENETIC TARGETS FOR SPORADIC ALS. WE'VE HAD SOME SUCCESS ALREADY WITH ONE OF THEM, AND WE ARE NOW LOOKING TO DO MORE. AND I THINK THIS GRANT WOULD BE PIVOTAL IN ENABLING US TO DO THAT AND COME UP WITH A SERIES OF STRONG GENETIC TARGETS FOR SPORADIC ALS WHERE THERE'S A HUGE UNMET NEED.

THANKS VERY MUCH FOR YOUR CONSIDERATION.

CHAIRMAN IMBASCIANI: THANK YOU. LANA, I THINK I DO NOT SEE ANY MORE HANDS RAISED.

MS. MORALEZ: YOU ARE CORRECT.

CHAIRMAN IMBASCIANI: OKAY. ANY BOARD MEMBER WANT TO MAKE ANY FINAL COMMENTS BEFORE WE PROCEED TO A VOTE?

DR. DULIEGE: GIL, I'M TRYING TO SEE HOW WE CAN OFFER A CREATIVE SOLUTION FOR THE TWO THAT ARE PROPOSED NOT TO BE FUNDED RIGHT NOW BECAUSE OF THE TIE. IS THERE ONLY ONE CYCLE REVIEW FOR DISC4 EVERY FISCAL YEAR, OR ARE THERE MORE THAN THAT? AND DOES IT MEAN THAT IF THESE APPLICANTS WANT TO REAPPLY, THIS WILL BE IN ONE YEAR WITH AN UNKNOWN BUDGET AND UNKNOWN SCOPE OF PROPOSALS? OR IS THERE SOMETHING THAT CAN BE DONE ABOUT THAT?

DR. SAMBRANO: RIGHT. THERE IS ONE CYCLE PER YEAR. AND SO THE SCOPE OF THE NEXT ONE, MAYBE ROSA CAN SPEAK TO IT BECAUSE THAT'S PART OF THE PROPOSAL FOR A LITTLE LATER.

DR. CANET-AVILES: THANK YOU, DR. DULIEGE. CAN YOU HEAR ME.

SO THE NEXT APPLICATION WILL BE OPEN IN APRIL FOR THE DISC4. AND AS WE WILL BE PROPOSING -- OF COURSE, IT'S TO THE PREROGATIVE OF THE BOARD. BUT AS WE WILL BE PROPOSING TODAY, DR. SHEPARD WILL BE PRESENTING THE FOCUS RECOMMENDATION. AND IT'S ACTUALLY A MUCH LARGER SYSTEM SCOPE THAT WE DISCUSS LATER. SO IT WOULD INCLUDE THESE THERAPEUTIC AREAS.

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MOST LIKELY THEY COULD BE ABLE TO REAPPLY. AND WE HAVE ONE A YEAR THAT IS $84 MILLION, BUT WE ALSO HAVE DISC5, WHICH IS $50 MILLION INVESTMENT. SO IN TOTAL WE ARE INVESTING AROUND 135 MILLION IN DISCOVERY EVERY YEAR THROUGH THOSE TWO. AND LIKE SMALLER AWARDS CAN COME THROUGH THE DISC5 WHICH IS ALSO OPEN.

DR. DULIEGE: I THINK WHAT WE'RE SAYING IS THAT THESE TWO APPLICANTS COULD REAPPLY IN APRIL, ALTHOUGH THE REVIEW PROCESS WILL TAKE A YEAR. IS THAT RIGHT? AND IF THEY WERE GRANTED, IF THEY WERE ACCEPTED, THEY WOULD RECEIVE THE MONEY IN?

DR. CANET-AVILES: WHEN IS THE ARS SCHEDULED FOR DISC1?

DR. SAMBRANO: I THINK IT WOULD COME BACK A YEAR FROM NOW. SO IT WOULD BE NEXT MARCH ULTIMATELY TO THE BOARD.

DR. CANET-AVILES: IT'S A LONG PROCESS BECAUSE THERE IS PRESUBMISSION AS WELL. SO WE HAVE LIKE THE PRESUBMISSION, THEY ARE SELECTED, THAT THEY ARE INVITED, THEN THE FULL TEAM PUTS TOGETHER THE PROPOSAL, THEN THAT'S REVIEWED.

CHAIRMAN IMBASCIANI: OKAY. LET ME CLARIFY THIS. A POSITIVE VOTE, A YES VOTE, ON THIS MOTION WILL BE A VOTE TO FUND DISC4-19200, 19271,

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19334, 19371, 19291, AND 19391 AND TO NOT FUND --

DR. SAMBRANO: AND TO NOT FUND 19196 AND 19226.

CHAIRMAN IMBASCIANI: THAT'S CORRECT.

MR. TOCHER: SO FOR THE FOLLOWING MEMBERS, PLEASE VOTE IN THE SAME MANNER THAT I DESCRIBED EARLIER, YES OR NO, EXCEPT FOR THOSE APPLICATIONS WITH WHICH YOU ARE IN CONFLICT. THOSE MEMBERS ARE DAHL, DURON, FISCHER-COLBRIE, FLOWERS, MIASKOWSKI, AND WATSON.

MARIA BONNEVILLE.

VICE CHAIR BONNEVILLE: YES.

MR. TOCHER: MARGUERITE CASILLAS.

MS. CASILLAS: YES.

MR. TOCHER: JUDY CHOU.

DR. CHOU: YES.

MR. TOCHER: LEONDRA CLARK-HARVEY.

DR. CLARK-HARVEY: YES.

MR. TOCHER: SHANNON DAHL.

DR. DAHL: YES, EXCEPT FOR THOSE WITH WHICH I HAVE A CONFLICT.

MR. TOCHER: ANNE-MARIE DULIEGE.

DR. DULIEGE: YES.

MR. TOCHER: YSABEL DURON.

MS. DURON: YES, EXCEPT FOR THOSE WITH

WHICH I HAVE A CONFLICT.

MR. TOCHER: MARK FISCHER-COLBRIE.

MR. FISCHER-COLBRIE: YES, EXCEPT FOR THOSE WITH WHICH I HAVE A CONFLICT.

MR. TOCHER: ELENA FLOWERS.

DR. FLOWERS: YES, EXCEPT FOR THOSE WITH WHICH I HAVE A CONFLICT.

MR. TOCHER: VITO IMBASCIANI.

CHAIRMAN IMBASCIANI: YES.

MR. TOCHER: RICH LAJARA.

MR. LAJARA: YES.

MR. TOCHER: CHRIS MIASKOWSKI.

DR. MIASKOWSKI: YES, EXCEPT FOR THOSE WITH WHICH I HAVE A CONFLICT.

MR. TOCHER: ADRIANA PADILLA.

DR. PADILLA: YES.

MR. TOCHER: MARV SOUTHARD.

DR. SOUTHARD: YES.

MR. TOCHER: KAROL WATSON.

DR. WATSON: YES.

MR. TOCHER: EXCEPT FOR THOSE WITH WHICH YOU ARE IN CONFLICT?

DR. WATSON: EXCEPT FOR THOSE WITH WHICH I'M IN CONFLICT.

MR. TOCHER: THANK YOU VERY MUCH.

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KEVIN XU.

MR. XU: YES.

MR. TOCHER: GREAT. THANK YOU VERY MUCH. THAT MOTION CARRIES.

CHAIRMAN IMBASCIANI: OKAY. ALL RIGHT. THANK YOU, SCOTT. AND THANK YOU, EVERYONE, FOR THE DISCUSSION, AND THANK YOU, GIL.

I'M GOING TO INVITE DR. HAYLEY LAM UP TO THE PODIUM WHERE WE CONSIDER AGENDA ITEM NO. 8, APPLICATIONS SUBMITTED IN RESPONSE TO OUR CLIN2 PROGRAM ANNOUNCEMENT.

DR. LAM: THANK YOU, DR. IMBASCIANI, AND GOOD MORNING TO THE BOARD. GOOD MORNING. IT'S MY PLEASURE TODAY TO PRESENT THE GRANTS WORKING GROUP RECOMMENDATIONS FOR THE CLIN2 CLINICAL TRIAL AWARDS.

AS ALWAYS, WE BEGIN WITH OUR MISSION, ACCELERATING WORLD-CLASS SCIENCE TO DELIVER TRANSFORMATIVE REGENERATIVE MEDICINE TREATMENTS IN AN EQUITABLE MANNER TO A DIVERSE CALIFORNIA AND WORLD.

OUR STRATEGIC GOALS FOR THE CLIN2 PROGRAM FOCUS AROUND GOAL 4, PROPELLING 15 TO 20 THERAPIES TARGETING DISEASES AFFECTING CALIFORNIANS TO LATE STAGE TRIALS. WE'VE BEEN FUNDING CLINICAL TRIAL PROGRAMS FOR A WHILE NOW, AND THE RE-UPDATED CLIN2

PROGRAM HAS A COUPLE OF CHANGES THAT ALLOWED US TO SUPPORT EMERGING NOVEL CLINICAL TRIAL DESIGNS, INCENTIVIZES MARKET ACCESS STRATEGY DEVELOPMENT AND PRECOMMERCIALIZATION ACTIVITIES, AND PRIORITIZES INNOVATIVE THERAPIES FOR DISEASES THAT AFFECT CALIFORNIANS.

THE OVERALL PROGRAM OBJECTIVE IS TO SUPPORT THE COMPLETION OF INTERVENTIONAL TRIALS FOR INNOVATIVE STEM CELL-BASED OR GENETIC THERAPIES ADDRESSING SERIOUS UNMET NEEDS AND WITH THE POTENTIAL FOR TRANSFORMATIVE BENEFITS TO PATIENTS, FAMILIES, AND THE HEALTHCARE SYSTEM.

A LITTLE BIT ABOUT THE PROGRAM STRUCTURE. SO THIS PROGRAM IS OFFERED FOUR TIMES PER YEAR WITH A MAX DURATION OF FOUR YEARS, AND THE FUNDING LIMITS DEPEND ON THE AWARD STAGE AND WHETHER THE APPLICANT IS A FOR-PROFIT OR NONPROFIT. THE PROGRAM EXPECTS AWARDS OF SOMEWHERE RANGING BETWEEN NINE TO 16 AWARDS PER YEAR. AND THE BOARD HAS APPROVED FOR THIS CURRENT FISCAL YEAR A TOTAL OF 135 MILLION. FORTY-TWO OF THAT HAS BEEN EXPENDED THUS FAR.

A LITTLE BIT ABOUT THE REVIEW PROCESS. SO THE CLIN2 PROGRAM ALLOWS APPLICANTS TO SUBMIT A FULL APPLICATION, AND THOSE FULL APPLICATIONS FOR THIS CURRENT ROUND HAD 18 APPLICATIONS GO THROUGH THE

QUALIFICATION PROCESS. THIS ALLOWS THE CIRM TEAM TO APPLY THE PROGRAM PREFERENCES AND FOR THE GRANTS WORKING GROUP TO APPLY THE VALUE PROPOSITION EVALUATION. FROM THIS PROCESS, THE TOP SEVEN APPLICATIONS ADVANCE TO OUR TYPICAL INTERNAL CIRM ELIGIBILITY REVIEW AND GO TO THE SCIENTIFIC MERIT REVIEW BY THE GRANTS WORKING GROUP. FROM THERE THEY GET RECOMMENDATIONS THAT COME TO HERE FOR FINAL FUNDING DECISIONS.

A LITTLE BIT ON HOW THE GRANTS WORKING GROUP EVALUATES THE APPLICATIONS. SO THE COMPOSITION IS UP TO 15 SCIENTIFIC MEMBERS OF THE GRANTS WORKING GROUP THAT PROVIDE EXPERTISE ON DISEASE AREAS, REGULATORY, MANUFACTURING, AND CLINICAL OPERATIONS. WE HAVE OUR ACCESS AND AFFORDABILITY EXPERTS TO PROVIDE AN EVALUATION ALONG THOSE AREAS. WE ALSO HAVE OUR BOARD MEMBERS THAT PROVIDE A PATIENT PERSPECTIVE AND IMPACT AND PROVIDE OVERSIGHT ONTO THE PROCESS. AND WE ALSO HAVE SCIENTIFIC AD HOC SPECIALISTS THAT COME IN AND PROVIDE EXPERTISE ON SPECIFIC AREAS OF THE APPLICATIONS.

THE SCORING SYSTEM FOR THE CLINICAL PROGRAM IS THE SAME AS OUR OTHER SCIENTIFIC PROGRAMS USING A SCALE OF 1 TO 100. A MEDIAN SCORE OF 85 TO

100 IS A RECOMMENDATION FROM THE GROUP TO FUND IF THEY ARE AVAILABLE. AND A MEDIAN SCORE OF 1 TO 84 IS A DO NOT RECOMMEND FOR FUNDING. THE SCORING IS MEANT TO BE HOLISTIC AND BASED ON ALL FACETS OF THE EXPERT REVIEWERS. AND THE GRANTS WORKING GROUP IS ENCOURAGED TO MAKE USE OF THE FULL RANGE OF THE SCORING TO SIGNAL THEIR ENTHUSIASM FOR THE PROJECT OVERALL.

THEY EVALUATE THESE PROJECTS BASED ON FIVE REVIEW CRITERIA. THE FIRST BEING VALUE PROPOSITION; SECOND, RATIONALE; THIRD, THE PROJECT PLAN AND DESIGN; FOURTH, THE PROJECT TEAM AND RESOURCES; AND FINALLY, THE POPULATION IMPACT.

A NOTE ON ACCESS AND AFFORDABILITY. SO ALL APPLICATIONS IN THE CLIN2 PROGRAM ARE EVALUATED BY SUBJECT MATTER EXPERTS IN THIS, AND THEIR REVIEWS ARE PRESENTED AT THE GRANTS WORKING GROUP MEETINGS ALONG WITH THE SCIENTIFIC EVALUATIONS AND THE BOARD MEMBER REVIEWERS. THESE MAY INFORM THE SCORING OF THE REVIEW CRITERIA, AND THERE IS RECOGNITION FOR ESPECIALLY THE EARLY STAGE TRIALS, THAT ANY DEFICIENCIES IN THESE PROGRAMS CAN BE ADDRESSED DURING THE AWARD PERIOD.

SO TO SUMMARIZE, THE GRANTS WORKING GROUP RECOMMENDATIONS FOR THIS RECENT ROUND OF CLINICAL

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APPLICATIONS, SEVEN APPLICATIONS WERE REVIEWED AND THREE ARE RECOMMENDED FOR FUNDING, FOR A TOTAL APPLICANT REQUEST OF 31 MILLION EVEN. AS I MENTIONED BEFORE, SO THERE'S 135 MILLION APPLICATION FOR THE FISCAL YEAR, AND WE CURRENTLY HAVE 92 OF THAT AVAILABLE BASED ON THE PRIOR FIRST ROUND OF CLIN2 APPROVED ABOUT 42 MILLION. SO WE'RE AT 92 FOR THE CURRENT FISCAL YEAR AVAILABLE.

IN TERMS OF MINORITY REPORTS, AS GIL DESCRIBED EARLIER FOR THE DISC4 PROGRAM, THE REQUIREMENTS FOR MINORITY REPORTS IS THE SAME FOR ALL OF OUR PROGRAMS. AND FOR THIS PARTICULAR ROUND OF CLIN2, THERE ARE NO MINORITY REPORTS IN THIS CYCLE.

AND TO PRESENT THE CIRM TEAM RECOMMENDATIONS, THE CIRM TEAM CONCURS WITH THE GRANTS WORKING GROUP RECOMMENDATIONS TO FUND THE THREE APPLICATIONS LISTED HERE: CLIN2-19270, CLIN2-19119, AND CLIN2-19416 FOR A TOTAL OF 31 MILLION.

AND I'LL PASS IT -- CAN WE SHOW THE EXCEL SPREADSHEET? AND I'LL PASS IT TO CHAIR IMBASCIANI. THANK YOU.

CHAIRMAN IMBASCIANI: THANK YOU, HAYLEY. SO WHILE THERE MIGHT BE CHANGES IN THE FUTURE TO HOW

WE CONSIDER CLINICAL APPLICATIONS AT THIS STAGE FOR FUNDING, I'D LIKE TO MAINTAIN THE SYSTEM WE'VE ALWAYS DONE, WHICH IS TO CONSIDER THE CLINICAL APPLICATIONS FOR FUNDING ONE AT A TIME. SO THERE ARE THREE RECOMMENDED BY THE TEAM, AND THE CHAIR WOULD LIKE TO ENTERTAIN A MOTION TO ACCEPT ONE OF THE ONES THAT HAVE BEEN RECOMMENDED FOR FUNDING.

DR. CLARK-HARVEY: SO MOVED.

CHAIRMAN IMBASCIANI: WOULD YOU SPECIFY WHICH ONE, LEONDRA? YOU COULD DO THEM IN ORDER.

DR. CLARK-HARVEY: 19270.

CHAIRMAN IMBASCIANI: IT'S NOT AN EYE TEST. IT'S CLIN2-19270 IS THE MOTION.

DR. CLARK-HARVEY: IT FELT LIKE AN EYE TEST. THANK YOU.

CHAIRMAN IMBASCIANI: DO I HAVE A SECOND?

MS. CASILLAS: I CAN SECOND.

CHAIRMAN IMBASCIANI: THANK YOU. WE HAVE A MOTION AND A SECOND. ANY DISCUSSION FROM BOARD MEMBERS? HAYLEY, YOU MIGHT WANT TO MAYBE SAY SOMETHING -- ANNE-MARIE.

DR. DULIEGE: IT'S SIMPLY A QUESTION. WE HAVE HAD ALL THE DOCUMENTS, BUT FOR THESE THREE, CAN YOU TELL US OR REMIND US WHICH STAGE THEY ARE? IS THERE ENTRY INTO PHASE 1, PHASE 1 TO PHASE 2? WHERE

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ARE THEY ALONG THE LINE WHERE WE'D LIKE TO SEE THEM PROGRESS TOWARDS CLOSE TO PHASE 3?

DR. LAM: THIS PARTICULAR APPLICATION ACTUALLY HAS AN ACTIVE CLIN2 CLINICAL TRIAL RIGHT NOW. AND THIS PROJECT WOULD BE AN EXPANSION OF THAT EXISTING TRIAL BASED ON FDA FEEDBACK.

DR. DULIEGE: OKAY. FOR EACH OF THE THREE?

DR. LAM: I'M JUST SPEAKING OF 19270, WHICH IS THE CURRENT APPLICATION UNDER DISCUSSION.

DR. DULIEGE: OKAY.

DR. LAM: I'M NOT SURE IF I CAN SPEAK TO THE OTHER TWO. IS THAT OKAY?

CHAIRMAN IMBASCIANI: NO ACTUALLY. IT WOULD BE MORE APPROPRIATE TO WAIT. ANY OTHER DISCUSSION ON 19270? ANYONE IN THE AUDIENCE OR IN THE PUBLIC WANT TO SPEAK TO THIS? IF NOT, SCOTT, I THINK WE CAN PROCEED.

MR. TOCHER: JUST ONE MOMENT. ALL RIGHT. I WON'T BE CALLING THE NAMES OF THOSE WHO HAVE A CONFLICT WITH THIS APPLICATION.

MARIA BONNEVILLE.

VICE CHAIR BONNEVILLE: YES.

MR. TOCHER: MARGUERITE CASILLAS.

MS. CASILLAS: YES.

MR. TOCHER: JUDY CHOU.
DR. CHOU: YES.
MR. TOCHER: LEONDRA CLARK-HARVEY.
DR. CLARK-HARVEY: YES.
MR. TOCHER: ANNE-MARIE DULIEGE.
DR. DULIEGE: YES.
MR. TOCHER: SHANNON DAHL.
DR. DAHL: YES.
MR. TOCHER: YSABEL DURON. WAIT. I'M SORRY. I'M READING ACROSS. NO YSABEL. APOLOGIES.
MARK FISCHER-COLBRIE.
MR. FISCHER-COLBRIE: YES.
MR. TOCHER: VITO IMBASCIANI.
CHAIRMAN IMBASCIANI: YES.
MR. TOCHER: RICH LAJARA.
MR. LAJARA: YES.
MR. TOCHER: ADRIANA PADILLA.
DR. PADILLA: YES.
MR. TOCHER: MARV SOUTHARD.
DR. SOUTHARD: YES.
MR. TOCHER: KAROL WATSON.
DR. WATSON: YES.
MR. TOCHER: AND KEVIN XU.
MR. XU: YES.
MR. TOCHER: THANK YOU. THAT MOTION

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CARRIES.

CHAIRMAN IMBASCIANI: THANK YOU. WE CAN NOW CONSIDER ONE OF THE OTHER TWO REMAINING APPLICATIONS THAT HAVE BEEN RECOMMENDED BY THE CIRM TEAM. HAYLEY IS IN PLACE IN CASE ANYONE HAS ANY QUESTIONS. SO IF A BOARD MEMBER WOULD PICK ONE AND NOMINATE IT FOR FUNDING.

MS. CASILLAS: I'LL NOMINATE 19119.

CHAIRMAN IMBASCIANI: YES. THANK YOU VERY MUCH.

VICE CHAIR BONNEVILLE: SECOND.

CHAIRMAN IMBASCIANI: AND WE HAVE A SECOND FROM VICE CHAIR BONNEVILLE. DISCUSSION FROM BOARD MEMBERS? THIS IS THE APPLICATION ON PITT-HOPKINS SYNDROME.

DR. LAM: TO ADDRESS THE QUESTION EARLIER ABOUT THE STAGE OF THE PROGRAM, THIS ONE IS A PHASE 1 FIRST-IN-HUMAN TRIAL.

DR. DULIEGE: FIRST-IN-PATIENT TRIAL; IS THAT RIGHT?

DR. LAM: YES.

CHAIRMAN IMBASCIANI: COMMENTS FROM BOARD MEMBERS OR ONLINE? THANK YOU. IF NOT, ANYONE IN -- ANY MEMBER OF THE PUBLIC WANT TO SPEAK ON THIS? OKAY. SCOTT.

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MR. TOCHER: MARIA BONNEVILLE.
VICE CHAIR BONNEVILLE: YES.
MR. TOCHER: MARGUERITE CASILLAS.
MS. CASILLAS: YES.
MR. TOCHER: JUDY CHOU.
DR. CHOU: YES.
MR. TOCHER: LEONDRA CLARK-HARVEY.
DR. CLARK-HARVEY: YES.
MR. TOCHER: SHANNON DAHL.
DR. DAHL: YES.
MR. TOCHER: ANNE-MARIE DULIEGE.
DR. DULIEGE: YES.
MR. TOCHER: MARK FISCHER-COLBRIE.
MR. FISCHER-COLBRIE: YES.
MR. TOCHER: VITO IMBASCIANI.
CHAIRMAN IMBASCIANI: YES.
MR. TOCHER: RICH LAJARA.
MR. LAJARA: YES.
MR. TOCHER: ADRIANA PADILLA.
DR. PADILLA: YES.
MR. TOCHER: MARV SOUTHARD.
DR. SOUTHARD: YES.
MR. TOCHER: KAROL WATSON.
DR. WATSON: YES.
MR. TOCHER: KEVIN XU.

MR. XU: YES.

MR. TOCHER: THANK YOU. THE MOTION CARRIES.

CHAIRMAN IMBASCIANI: THANK YOU. WE HAVE ONE FINAL APPLICATION RECOMMENDED FOR FUNDING BY THE CIRM TEAM, AND THAT WOULD BE 19416, BLINDING EYE DISEASE.

VICE CHAIR BONNEVILLE: SO MOVED.

MS. CASILLAS: I'LL SECOND.

CHAIRMAN IMBASCIANI: WE HAVE A MOTION AND SECOND. ANY DISCUSSION FROM BOARD MEMBERS?

DR. LAM: AGAIN, TO ADDRESS THE QUESTION EARLIER, THIS IS ALSO A FIRST-IN-HUMAN TRIAL, FIRST IN PATIENT.

CHAIRMAN IMBASCIANI: OKAY. ANY MEMBERS OF THE PUBLIC WANT TO COMMENT? ARE YOU READY TO GO, SCOTT, AGAIN?

MR. TOCHER: UH-HUH.

CHAIRMAN IMBASCIANI: THANKS.

MR. TOCHER: MARIA BONNEVILLE.

VICE CHAIR BONNEVILLE: YES.

MR. TOCHER: MARGUERITE CASILLAS.

MS. CASILLAS: YES.

MR. TOCHER: JUDY CHOU.

DR. CHOU: YES.

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MR. TOCHER: LEONDRA CLARK-HARVEY.
DR. CLARK-HARVEY: YES.
MR. TOCHER: SHANNON DAHL.
DR. DAHL: YES.
MR. TOCHER: ANNE-MARIE DULIEGE.
DR. DULIEGE: YES.
MR. TOCHER: YSABEL DURON.
MS. DURON: YES.
MR. TOCHER: MARK FISCHER-COLBRIE.
MR. FISCHER-COLBRIE: YES.
MR. TOCHER: ELENA FLOWERS.
DR. FLOWERS: YES.
MR. TOCHER: VITO IMBASCIANI.
CHAIRMAN IMBASCIANI: YES.
MR. TOCHER: RICH LAJARA.
MR. LAJARA: YES.
MR. TOCHER: CHRIS MIASKOWSKI.
DR. MIASKOWSKI: YES.
MR. TOCHER: ADRIANA PADILLA.
DR. PADILLA: YES.
MR. TOCHER: MARV SOUTHARD.
DR. SOUTHARD: YES.
MR. TOCHER: AND KEVIN XU.
MR. XU: YES.
MR. TOCHER: THANK YOU. AND THAT CARRIES

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AS WELL.

CHAIRMAN IMBASCIANI: THANKS, SCOTT.

SO THE FINAL PART OF THIS AGENDA ITEM WOULD BE TO CLOSE OUT THE RECOMMENDATIONS. SO CHAIR WOULD LIKE TO ENTERTAIN A MOTION NOT TO FUND THE REMAINING APPLICATIONS.

MS. CASILLAS: I'LL MAKE THAT MOTION.

CHAIRMAN IMBASCIANI: THANK YOU. BOARD MEMBER CASILLAS MOVED.

DR. CLARK-HARVEY: SECOND.

CHAIRMAN IMBASCIANI: LEONDRA SECONDED. THANK YOU.

DR. CARETHERS: MAY I ASK A QUESTION?

MR. TOCHER: LET ME CHECK. OKAY.

DR. CARETHERS: I JUST HAD A GENERAL COMMENT. I NOTICED THAT WITH THESE APPLICATIONS AND I NOTICED THE SCORE CUTOFF, BUT I ALSO NOTICED THE AMOUNT. I WAS WONDERING IF SOMEONE CAN EXPLAIN. WAS THIS THE AMOUNT FOR JUST THIS ROUND, OR IS IT ALL THE CLINICAL APPLICATIONS? AND THEN DOES THAT GO BACK IN THE GENERAL POOL, OR IS THERE GOING TO BE ANOTHER CLINICAL ROUND?

DR. LAM: THERE WILL BE ONE MORE CLINICAL ROUND FOR THIS FISCAL YEAR COMING.

DR. CARETHERS: AND IT'S THE REMINDING

FUNDS THAT GO INTO THIS OR WAS IT --

DR. LAM: WHATEVER IS LEFT AFTER TODAY WILL BE APPLIED TO THE THIRD ROUND FOR THIS FISCAL YEAR.

DR. CARETHERS: OKAY. SO THERE WAS NO LIMIT ON THE AMOUNT ON THIS ROUND. IT'S JUST THAT THAT'S FOR ALL ROUNDS?

DR. LAM: THE 135 APPROVED BY THE BOARD IS FOR THE ENTIRE FISCAL YEAR, WHICH FOR THIS PARTICULAR FISCAL YEAR COVERS THREE CLIN2 ROUNDS. I HOPE THAT MAKES SENSE. AND ONE ROUND HAS ALREADY BEEN VOTED ON AND APPROVED LAST YEAR, AND THEN THIS IS THE SECOND, AND THERE WILL BE ONE MORE COMING.

DR. CARETHERS: OKAY. THANK YOU.

CHAIRMAN IMBASCIANI: THAT WAS GOOD TO CLARIFY. ANY OTHER QUESTIONS FROM BOARD MEMBERS? THERE IS A HAND RAISED FROM THE PUBLIC. LANA, WE COULD TAKE IT NOW.

MS. MORALEZ: ALL RIGHT. WE'RE NOW OPENING THE FLOOR FOR PUBLIC COMMENT. IF YOU ARE JOINING US IN PERSON, WHICH THERE'S QUITE A FEW OF YOU GUYS, ONE AT A TIME, PLEASE APPROACH THE MICROPHONE RIGHT HERE. IF YOU'D LIKE TO STATE YOUR NAME FOR THE RECORD, AND WE WILL KEEP YOU TO THREE MINUTES.

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DR. GAENSLER: GOOD MORNING. I'M KARIN GAENSLER, PI FOR CLIN2 ENTITLED TRILEUKEVAX OR TLV, A FIRST-IN-HUMAN ACUTE MYELOGENOUS LEUKEMIA VACCINE FOR RELAPSE PREVENTION.

WE APPRECIATE THE GRANT REVIEW AND ALSO THE OPPORTUNITY TO SPEAK IN FRONT OF THE ARS TODAY. AML IS THE MOST COMMON LEUKEMIA AFFECTING ABOUT 1800 CALIFORNIANS PER YEAR WHOM I'VE BEEN TREATING FOR THE LAST 35 YEARS. WHILE ABOUT HALF OF PATIENTS ACHIEVE REMISSION, WITHOUT TRANSPLANT, MOST PATIENTS RELAPSE AND DIE.

I WANT TO MAKE THREE POINTS VERY IMPORTANT FOR THE ARS CLIN2 FUNDING THIS MORNING. POINT NO. 1, NEW STRATEGIES TO PREVENT RELAPSE ARE URGENTLY NEEDED. WE DEVELOPED OUR NOVEL IMMUNOTHERAPY TLV -- THANK YOU -- TO ELIMINATE PERSISTING LEUKEMIA AND ADDRESS THIS NEED. BY ENGINEERING PATIENT'S OWN LEUKEMIA CELLS TO MAKE TLV, WE ARE CREATING A PERSONALIZED THERAPY THAT COULD BE USED FOR ANY PATIENT.

THIS STRATEGY IS BASED ON THE ESTABLISHED BIOLOGY OF GRAFT VERSUS LEUKEMIA EFFECTS AFTER STEM CELL TRANSPLANT WHERE DONOR IMMUNE CELLS CAN ELIMINATE RESIDUAL LEUKEMIA. THE GOAL OF TLV ADMINISTRATION IS TO STIMULATE THE PATIENT'S OWN

IMMUNE SYSTEM TO RECOGNIZE AND KILL THE RESIDUAL LEUKEMIA THAT CAUSES RELAPSE. OUR PEER-REVIEWED PRECLINICAL DATA STRONGLY SUPPORTS THIS CONCEPT.

POINT NO. 2, THE PHASE 1 CLINICAL TRIAL IS READY TO GO NOW. WITH SEVEN YEARS OF CIRM FUNDING, WE HAVE BUILT THE INFRASTRUCTURE FOR THE MANUFACTURING OF TLV, WHICH MY COLLEAGUE, DR. DONALD KOHN, WILL DESCRIBE. WE'VE ALSO OBTAINED THE NECESSARY REGULATORY APPROVALS AT OUR INSTITUTIONS AND BY THE FDA.

THE IMPORTANCE OF OUR APPROACH IS SUPPORTED BY THE FACT THAT THE FDA GRANTED TLV BOTH ORPHAN DRUG AND FAST-TRACK DESIGNATIONS IN RECOGNITION OF THE NOVELTY OF OUR IMMUNE THERAPY AND THE CRITICAL NEED THAT IT ADDRESSES.

POINT NO. 3, OUR MAJOR GOAL IS TO MAKE TLV BROADLY AVAILABLE TO ALL CALIFORNIANS. AGAIN, ANY PATIENT CAN POTENTIALLY RECEIVE TLV. THIS IS IN CONTRAST TO STEM CELL TRANSPLANTS WHERE ACCESS FOR OLDER PATIENTS IS LIMITED BY THE NEED FOR MATCHED DONOR, HIGH RISK, AND RIGOROUS HEALTH REQUIREMENTS. ONCE MANUFACTURED, TLV CAN BE AVAILABLE AND SHIPPED TO AN OUTPATIENT THERAPY IN VIRTUALLY ANY COMMUNITY.

THE NINE OPEN LETTERS SUBMITTED TO THE BOARD LAST WEEK STRONGLY SUPPORT OUR SCIENTIFIC

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VALIDATION, REGULATORY AND MANUFACTURING READINESS, AND A CLEAR PATH TO CLINICAL AND COMMERCIAL DEVELOPMENT.

IN SUMMARY, OUR CLINICAL TRIAL IS URGENTLY NEEDED AND CRITICAL TO ADDRESSING THE DEVASTATING ILLNESS. IT IS READY FOR ENROLLMENT NOW AND WILL MAXIMIZE ACCESS AND AVAILABILITY TO PATIENTS ALL OVER CALIFORNIA. I THEREFORE RESPECTFULLY URGE YOU TO PLEASE FUND TLV THIS MORNING. THANK YOU FOR YOUR ATTENTION.

MS. MORALEZ: ALL RIGHT. NEXT PERSON UP, YOU HAVE THREE MINUTES.

MR. HARRINGTON: GOOD MORNING. MY NAME IS KEVIN HARRINGTON. I'M AN AML SURVIVOR. I'M HERE TODAY TO STRONGLY URGE THE BOARD TO CONTINUE FUNDING DR. GAENSLER'S TRILEUKEVAX PROGRAM.

THE TWO WORST DAYS IN AN AML PATIENT'S JOURNEY ARE THE DAY OF DIAGNOSIS AND ALL TOO OFTEN THE DAY THE DISEASE RETURNS OR RELAPSES. THE JOURNEY BETWEEN THOSE TWO EVENTS IS DAUNTING, IN MY CASE AN INTENSIVE CHEMOTHERAPY, INDUCTION CONSOLIDATION, AND IF YOU REACH AND MAINTAIN REMISSION, THE BONE MARROW TRANSPLANT. THAT IN ITSELF CAN BE LETHAL.

AS A SURVIVOR, I KNOW THAT MY RECOVERY WAS

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A BRUTE FORCE MIRACLE OF MODERN MEDICINE. IT DOESN'T END THERE, HOWEVER. POST BMT, MULTIPLE ICU STAYS, INTUBATION, BLOOD CLOTS IN BOTH LEGS, ARMS, LUNGS REQUIRING TWO OPERATIONS, MULTIPLE AMBULANCE RIDES TO SUPPORT THE MOUNTING HOSPITAL STAYS, GI BLEEDING, REPERCUSSIONS OF AN INFECTED BMT DONATION, C DIFF, AND A SIGNIFICANT DECONDITIONING AFTER STEROID TREATMENT FOR GBHD RESULTING IN TIME SPENT IN A REHAB FACILITY TO LEARN HOW TO WALK AGAIN.

WHILE THIS MAY SEEM LIKE WORST CASE SCENARIO AFTER SPENDING SIGNIFICANT OVER THE YEARS IN AML AND BMT ONLINE FORUMS, IT'S NOT UNUSUAL, NOR IS IT UNUSUAL FOR THE LARGE NUMBER OF PATIENTS WHO HAVE SURVIVED BMT OR LESS FORTUNATE WHO WERE TRANSPLANTED AND ELIGIBLE TO FALL INTO RELAPSE. THEIR OPTION, TO GO THROUGH THAT AGAIN OR SIMPLY WAIT.

REMISSION IS NOT THE END OF FEAR. IT'S THE BEGINNING OF A DIFFERENT KIND OF WATCH. EVERY BLOOD TEST, EVERY BRUISE, EVERY FATIGUE TRIGGERS THE SAME RESPONSE: IS IT BACK? TO THIS DAY I STILL POUR OVER AND TREND MY TEST RESULTS.

ALSO WANT TO MENTION THE HOSPITAL STAFF WHO, DESPITE NEVER ENDING REVOLVING DOOR IN AND OUT OF TREATMENT, CONTINUE AN AMAZING LEVEL OF CARE

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WHILE WEARING MULTIPLE HATS, LONG SHIFTS, ON CALL, MAKING ROUNDS, AND IN MANY CASES DEVELOPING THE VERY RESEARCH THAT SAVES OUR LIVES AND FOR THE FIRST TIME DELIVERS REAL HOPE TO OUR COMMUNITY. THEIR DEDICATION TO BOTH PATIENTS AND INNOVATIVE RESEARCH LIKE TLV SHOWS HOW VITAL THE SUPPORT IS FOR PROGRAMS THAT COMBINE COMPASSION AND SCIENTIFIC PROCESS -- PROGRESS.

BY FUNDING INITIATIVES LIKE THIS, WE HONOR NOT JUST THE PATIENTS, BUT ALSO THE STAFF AND THE COMMITMENT THAT DRIVES THESE BREAKTHROUGHS. I ASK ON BEHALF OF ALL AML PATIENTS, PARTICULARLY THE 50 PERCENT THAT WILL RELAPSE, TO FUND THE TRILEUKEVAX PROGRAM. THANK YOU FOR YOUR TIME.

MS. MORALEZ: THANK YOU VERY MUCH. ALL RIGHT. NEXT PERSON UP, PLEASE STEP CLOSE TO THE MICROPHONE AND STATE YOUR NAME, AND YOU HAVE THREE MINUTES.

MR. BROWN: GOOD MORNING. I'M WILLIAM L. BROWN, A RETIRED VENTURE CAPITALIST AND BIOTECH CEO. I WANT TO TALK ABOUT TWO THINGS: TIME AND LEVERAGE.

I HAVE A RARE LEUKEMIA, ONE FOR WHICH THERE'S NOT ENOUGH DATA TO SUGGEST A DEFINITIVE TREATMENT. FOR ALL AML PATIENTS AND FOR ME, THERE'S NO CERTAINTY OF A CURE. WE LIVE IN HOPE EACH DAY

THAT ONE WILL BE ANNOUNCED.

ONE IN THREE LEUKEMIA PATIENTS HAVE AML. OVER 130,000 AML PATIENTS WILL DIE THIS YEAR ALONE. FOR EACH OF THEM, TIME WILL RUN OUT.

THE DEVELOPMENT OF NEW PHARMACEUTICALS EVEN BY THE BEST SCIENTISTS TAKES TIME AND TIME COSTS MONEY. I'VE LEARNED THAT YOU CAN'T HURRY SCIENCE, BUT WE HAVE HERE A DRUG CANDIDATE WHERE THE TIME HAS BEEN INVESTED AND HUMAN TRIALS CAN BEGIN WITHIN THREE MONTHS OF FUNDING. NO OTHER DRUG OR DRUG CANDIDATE REPRODUCES ALL OF THE FEATURES OF TRILEUKEVAX. EXISTING THERAPIES ARE TOXIC, UNPREDICTABLE, AND NOT A RELIABLE CURE.

TRILEUKEVAX IS A PERSONALIZED VACCINE THAT CAN BE MADE FOR ANY AML PATIENT, SHIPPED ANYWHERE, AND ADMINISTERED IN COMMUNITY HEMATOLOGY CLINICS. IT'S TUMOR CELL APPROACH COULD BECOME A GENERALIZED PLATFORM FOR VACCINE DELIVERY. RECOGNIZING THE POTENTIAL FOR A CURE AND THE NEED TO MOVE QUICKLY, THE FDA HAS FAST-TRACKED TRILEUKEVAX FOR PHASE 1 TRIALS.

EACH OF US HERE TODAY IS MOTIVATED TO LEVERAGE THE CIRM'S FUNDS TO TREAT AS MANY PATIENTS AS QUICKLY AS POSSIBLE. SO HOW CAN WE ACHIEVE THIS LEVERAGE? TO DO SO WE NEED TO INVOLVE BIG PHARMA TO

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COMPLETE PHASES 2 AND 3 AND TO DO THE MARKETING AND DISTRIBUTION. BIG PHARMA HAS BECOME VERY PARTICULAR IN WHAT THEY WILL FUND. AND IF YOU DON'T HAVE PHASE 1 DATA, YOUR CANDIDATE WON'T BE CONSIDERED.

MY EXPERIENCE IN THE BIOTECH INDUSTRY TELLS ME THAT POSITIVE PHASE 1 DATA WOULD GENERATE SUFFICIENT BIG PHARMA INTEREST TO COMPLETE THE DEVELOPMENT PROCESS. MAYBE MORE IMPORTANTLY, BIG PHARMA WILL BE INTRIGUED BY THE POSSIBILITY OF A GENERALIZED VACCINE DELIVERY PLATFORM AND THE LEVERAGE IT WILL CREATE FOR NEW DEVELOPMENT. AND THIS LEVERAGE WOULD EXTEND BEYOND TRILEUKEVAX BY EARNING UCSF THE FUNDS TO CONTINUE THE DEVELOPMENT OF NEW DISCOVERIES.

FOR THE OVER 200,000 WORLDWIDE AML PATIENTS, MOST OF WHOM WILL OTHERWISE DIE --

MS. MORALEZ: THANK YOU VERY MUCH. ANYBODY NEXT? ANYBODY ELSE IN PERSON FOR PUBLIC COMMENT? PLEASE STEP UP AND CLOSE TO THE MIC SO WE CAN HEAR YOU AND STATE YOUR NAME, AND WE'LL START YOUR THREE MINUTES.

MR. AINSWORTH: THANK YOU VERY MUCH. I'M SEAN AINSWORTH WITH IMMUSOFT. REALLY I JUST WANT TO EXPRESS MY THANKS TO CIRM AND THE BOARD AND THE GWG FOR THE SUPPORT THAT YOU'VE PROVIDED IMMUSOFT. IT'S

BEEN TRANSFORMATIONAL FOR US. IT'S ALLOWED US TO ACCELERATE OUR LEAD PROGRAM INTO THE CLINIC. WE'VE SEEN SOME GREAT EXCITEMENT FROM THE COMMUNITY AS A RESULT OF THAT. AND WE VERY MUCH APPRECIATE THE CONTINUED SUPPORT.

AND I WOULD ADD THAT WE TAKE THE TRUST THAT CIRM AND THE CALIFORNIA TAXPAYERS PLACED IN US VERY SERIOUSLY. AND WE WILL BE GOOD, DISCIPLINED SHEPHERDS OF THAT TRUST AND BE TRANSPARENT WITH OUR PROGRESS. AND WE'RE VERY HONORED TO BE PART OF THE CIRM PORTFOLIO. SO THANK YOU VERY MUCH.

MS. MORALEZ: ALL RIGHT. IF YOU ARE ON THE PHONE FOR PUBLIC COMMENT, PLEASE PRESS STAR NINE TO RAISE YOUR HAND. ANYBODY ELSE LEFT IN PERSON FOR THESE TWO APPLICATIONS AT THE BOTTOM? ALL RIGHT. I HAVE A PHONE NUMBER ENDING IN 7541. IF YOU WOULD PRESS STAR SIX TO UNMUTE.

DR. MILLER: THANK YOU AND HELLO. MY NAME IS WES MILLER. I'M A CHIEF MEDICAL OFFICER AT EPICRISPR BIOTECHNOLOGY. THANK YOU FOR ALLOWING ME TO PUBLICLY COMMENT ON THE REVIEWER RESPONSES TO OUR APPLICATION 19378.

AS A CALIFORNIA-BASED START-UP, WE VIEW OURSELVES AS A CRUCIAL PARTNER IN HELPING CIRM REALIZE ITS MISSION TO DEVELOP NOT ONLY A DIVERSE

PORTFOLIO OF EFFECTIVE AND TRANSFORMATIVE THERAPIES, BUT ALSO TO MAKE SUCH MEDICINES ACCESSIBLE AND AFFORDABLE TO PATIENTS.

OUR APPLICATION IS FOCUSED ON EPI-321, THE FIRST AND ONLY EPIGENETIC EDITING THERAPY IN THE U.S. BEING EVALUATED IN AN ONGOING FIRST-IN-HUMAN AND FIRST-IN-PATIENT CLINICAL STUDY.

EPI-321 WAS DEVELOPED AS A POTENTIAL CURE FOR FSHD, ONE OF THE MOST COMMON FORMS OF MUSCULAR DYSTROPHY AFFECTING ABOUT ONE MILLION PEOPLE GLOBALLY AND APPROXIMATELY 5,000 CALIFORNIANS ALONE. CURRENTLY NO DISEASE MODIFYING OPTIONS ARE AVAILABLE FOR PATIENTS, REPRESENTING A MAJOR UNMET MEDICAL NEED. EPI-321 IS A POTENTIAL ONE-TIME TREATMENT FOR PATIENTS WHO DESPERATELY NEED A TREATMENT FOR THIS CHRONIC DISEASE AND HAS BEEN GRANTED ORPHAN DRUG FAST-TRACK, AND RARE PEDIATRIC DESIGNATIONS BY THE FDA.

SEVERAL REVIEWERS EXPRESSED CONCERNS THAT PLANNED EPI-321 CLINICAL DOSES IN THE LOW 10 TO THE 13TH VECTOR GENOME PER KILOGRAM I.V. RANGE WOULD BE INSUFFICIENT FOR BIOLOGICAL EFFECT AND CLINICAL BENEFIT FOR FSHD. HOWEVER, THREE LINES OF EVIDENCE SUPPORT THE CONTRARY AND MUST BE STRESSED. FIRST, PEOPLE WITH FSHD EXHIBIT CLINICALLY ATTENUATED TO

133 HENNA COURT, SANDPOINT, IDAHO 83864
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ABSENT DISEASE IN THE SETTING OF 30 TO 50 PERCENT NORMAL NUCLEI. THIS SUGGESTS THAT DEFINITIVE AND DURABLE SILENCING OF DUX4 IN ONLY THIS FRACTION OF NUCLEI MAY BE SUFFICIENT TO ABROGATE CLINICAL FSH.

SECOND, IN ALIGNING WITH THESE NATURAL HISTORY OBSERVATIONS, EPI-321 NONCLINICAL EFFICACY DATA FROM VARIOUS UNIQUE FSHD PATIENT MUSCLE CELL LINES SHOWED DEEP SUPPRESSION OF THE DUX4 PATHWAY, REDUCED APOPTOSIS, AND RESCUED MUSCLE CONTRACTUAL FUNCTION AT BIODISTRIBUTION LEVELS IN THIS RANGE OF .3 TO .6 SECTOR GENOMES PER DIPLOID GENOME.

THIRD, PUBLISHED CLINICAL DATA FROM OVER 80 INDIVIDUALS ADMINISTERED VARIOUS I.V. DOSES OF AVRH 74 PREDICT THAT THESE PLANNED EPI-321 CLINICAL DOSES WILL EXCEED THIS MUSCLE BIODISTRIBUTION THRESHOLD, AND PRELIMINARY DATA FROM THE ONGOING FIRST-IN-HUMAN STUDY ARE BEGINNING TO CONFIRM THIS PREDICTION.

FINALLY, THE COMPANY IS DEDICATED TO DEVELOPING NOVEL THERAPIES THAT CAN BE ACCESSIBLE AND AFFORDABLE TO PATIENTS WHO CURRENTLY HAVE NO THERAPEUTIC OPTIONS. RECENT IMPROVEMENTS IN PROCESS DEVELOPMENT HAVE BROUGHT DOWN THE COST OF MANUFACTURING BY UPWARDS OF 60 PERCENT ALREADY. HOWEVER, CONTINUED EFFORTS TO IMPROVE THE

133 HENNA COURT, SANDPOINT, IDAHO 83864
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MANUFACTURING PROCESS ARE NEEDED TO BRING DOWN THE COST IN LATE STAGE CLINICAL IN EVENTUAL COMMERCIAL SETTINGS.

WE STRONGLY BELIEVE THIS SQUARELY ALIGNS WITH CIRM'S MISSION. I HOPE THIS HELPS ADDRESS THE REMAINING REVIEWER CONCERNS AND THAT CIRM WILL STRONGLY CONSIDER OUR APPLICATION FOR FUNDING THIS CYCLE AND HELP TO BRING EPI-321 TO PATIENTS WHO NEED IT MOST. THANKS SO MUCH FOR YOUR TIME.

MS. MORALEZ: GREAT. THANK YOU SO VERY MUCH. IS THERE ANY OTHER PUBLIC COMMENT? I THINK WE'RE GOOD, CHAIR.

CHAIRMAN IMBASCIANI: OKAY. SO CLEARLY THERE'S A LOT OF INTEREST IN THE TWO APPLICATIONS THAT WERE NOT RECOMMENDED BY THE TEAM. IF THERE IS INTEREST ON THE PART OF BOARD MEMBERS IN FUNDING ONE OF THOSE, WE NEED TO DEFEAT THE MOTION ON THE TABLE. AND PREPARATORY TO THAT AND WITH RESPECT TO THE CLOSENESS OF THE SCORES AND OUR REMAINING BUDGET, I'M GOING TO ASK DR. LAM IF YOU WOULD COMMENT A LITTLE FURTHER ON YOUR DELIBERATIONS, ON YOUR RECOMMENDATIONS.

DR. LAM: THANK YOU. SO THE CIRM TEAM DID AN INTERNAL CHECK OF BOTH OF THESE APPLICATIONS. I WILL NOTE FOR JUST ADDITIONAL INFORMATION FOR THE

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BOARD. LET'S SEE. SO ADDRESSING BOTH OF THEM SEPARATELY, 19378, THE FSHD APPLICATION, THIS APPLICATION DOES NOT HAVE -- OR THIS INDICATION, THE CIRM PORTFOLIO DOES NOT HAVE ANY ACTIVE AWARDS IN THE PDEV OR THE CLIN2 PORTFOLIO.

AND THEN REGARDING 19191, THIS IS THE AML APPLICATION. THIS ONE, THE CIRM ACTIVE PORTFOLIO HAS NO PDEV AWARDS, BUT THERE ARE TWO CLIN2 ACTIVE AWARDS IN AML, BUT WITH A DIFFERENT MODALITY FROM THE CURRENT APPLICATION. JUST FOR ADDITIONAL INFORMATION FOR FOLKS IF THAT'S HELPFUL AT ALL.

CHAIRMAN IMBASCIANI: THANKS, HAYLEY. BOARD MEMBERS PROBABLY HAVE SOME QUESTIONS FOR HAYLEY.

DR. DULIEGE: YES. FIRST, IN GENERAL, I WANTED TO THANK THE MEMBERS OF THE PUBLIC, SCIENTISTS AND PATIENTS, WHO HAVE SINCE THIS MORNING, INCLUDING FOR DISC4, HAVE THE COURAGE TO COME TO THE MICROPHONE OR TO THE PHONE TO THE EXPLAIN THE URGENCY AND THE IMPORTANCE OF THE PROGRAM. AND I WANT TO ASSURE THAT THE BOARD AT LARGE IS VERY SENSITIVE TO THAT. AND THANK YOU FOR THIS.

SECOND, I WANTED TO KNOW IF YOU COULD TELL US A LITTLE BIT ABOUT THE COMMENTS THAT WERE MADE BY

THE GRANTS WORKING GROUP PARTICULARLY IN REGARD TO APPLICATION 19191, THE AUTOLOGOUS AML VACCINE, BECAUSE THIS ONE HAD RELATIVELY A LOW SCORE COMPARED TO WHAT'S THE MINIMUM THRESHOLD TO BE CONSIDERED, 80 VERSUS 85? CAN YOU TELL US ABOUT WHAT JUSTIFY THIS LOW SCORE WHEN WE HEAR OTHERWISE THAT THIS IS AN INTERVENTION THAT IS READY, THAT HAS BEEN APPROVED IN ESSENCE BY THE FDA TO START? THERE'S A LOT OF POSITIVE THINGS ABOUT THAT.

DR. LAM: YES. I THINK THE REVIEWERS AGREED ON THOSE POINTS. IT'S A NEEDED OPTION FOR AML FOR THOSE THAT ARE INELIGIBLE FOR THE STANDARD OF CARE OR TRANSPLANTS AND CANNOT UNDERGO THE HIGH DOSE CHEMOS.

I THINK THE CONCERNS FROM THE GRANTS WORKING GROUP MAINLY WERE AROUND THE DESIGN OF THE CLINICAL TRIAL. SO THE CONCERNS -- I THINK THE PRIMARY DRIVER OF THE SCORING, I GUESS, THERE WERE SOME MINOR CONCERNS AROUND THE MANUFACTURING, JUST IT BEING COMPLEX, AND POSSIBLE CONCERNS WITH THE YIELD OF THE PRODUCT. BUT I THINK THE MAJOR CONCERN GOING BACK FROM THE -- TO SPEAK TO THE TRIAL DESIGN WAS THEY BELIEVE THAT THE DESIGN OF THE TRIAL WOULD ULTIMATELY BE SAFE AS A PHASE 1 TRIAL, BUT IT WOULD BE DIFFICULT TO INTERPRET THE DATA AND UNDERSTAND

133 HENNA COURT, SANDPOINT, IDAHO 83864
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WHETHER IT WOULD GO FORWARD AS A GO/NO-GO DECISION.

THAT KIND OF SUMMARIZES THE GRANTS WORKING GROUP SENTIMENT IN TERMS OF HOW THEY VOTED. BASICALLY IT WOULD BE -- THEY WOULD BE ABLE TO DETERMINE WHETHER THE PRODUCT WAS SAFE, BUT NOT WHETHER -- THEY WOULDN'T BE ABLE TO UNDERSTAND WHETHER IT WORKS AND WHETHER TO MOVE FORWARD TO THE NEXT STAGE OF PHASE TRIALS.

DR. DULIEGE: ISN'T THAT THE MAIN GOAL FOR PHASE 1 STUDY, TO DETERMINE SAFETY, BUT NOT NECESSARILY TO HAVE A SIGNAL TO MOVE AHEAD? THE SIGNAL IS GIVEN BY A PHASE 2 TRIAL WITH A MORE COMPLEX DESIGN. SO IT'S HARD TO EXPECT SUBSTANTIAL EFFICACY INFORMATION AT THE END OF A PHASE 1 IN PATIENT STUDIES.

DR. LAM: YES.

DR. DAHL: COULD YOU PROVIDE THE SAME PERSPECTIVE ON THE OTHER AWARD AS WELL, OTHER GRANT?

DR. LAM: JUST SO WE'RE CLEAR, 19378, FOR THE FSHD. SO FOR THIS ONE ALSO HIGH UNMET NEED, AND IT'S POTENTIALLY A ONE-TIME TREATMENT WITH A NOVEL APPROACH ON THE EPIGENETIC SIDE.

THE CONCERN FROM THE GRANTS WORKING GROUP HERE FOCUSED MAINLY ON THE TOXICITY OF THE -- POTENTIAL TOXICITY OF THE TREATMENT, WHICH WAS ALSO

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COMMENTED BY THE PUBLIC COMMENT AS WELL. AND, AGAIN, THEY THOUGHT THAT THE PROPOSED DOSES FOR THE TRIAL WERE, AGAIN, LIKELY TO BE SAFE, BUT NOT LIKELY TO MAKE A DIFFERENCE IN TERMS OF DISEASE MODIFICATION.

DR. DAHL: I GUESS IT'S THE SAME COMMENT ANNE-MARIE MADE ABOUT THE OTHER ONE. SAFETY IS THE GOAL OF PHASE 1.

CHAIRMAN IMBASCIANI: SCOTT, COULD I ASK YOU TO REPEAT THE MOTION OR BETH?

MR. TOCHER: THE MOTION IS TO NOT FUND THE REMAINING TWO CLIN'S. SO THOSE WOULD BE 19378 AND 19191.

DR. DULIEGE: VITO, ASKING FELLOW BOARD MEMBERS OR MEMBERS OF THE CIRM TEAM TO HELP US, HOW CAN WE ADDRESS THE ISSUE WHERE THE COMMENTS FROM THE GRANTS WORKING GROUP WAS THAT THERE WOULD BE INSUFFICIENT DATA AT THE END OF THIS TRIAL TO GIVE AN INDICATION OF EFFICACY, NOT PROOF, BUT INDICATION AND RECOGNIZE THAT THE DESIGN OF PHASE 1 TRIAL IS NOT -- CANNOT GENERATE THAT?

DR. LAM: YES. I THINK THAT IS THE UNDERSTANDING FROM THE GRANTS WORKING GROUP, THAT IT IS A SAFETY TRIAL. I THINK THEIR HOPE IS THAT -- THE HOPE WOULD BE THAT THERE COULD BE SOME SIGNAL

133 HENNA COURT, SANDPOINT, IDAHO 83864
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AND SOME DATA FROM SOME OF THESE TRIALS, ESPECIALLY FOR THE MORE RARE CONDITIONS. BUT I THINK I WOULD ALSO SAY THAT IT'S -- THE APPLICATIONS ARE SCORED IN THESE CLINICAL REVIEWS ACROSS ALL SEVEN APPLICATIONS. SO THERE IS SOME CONSIDERATION FOR THE RELATIVE ENTHUSIASM THAT THEY MIGHT HAVE FOR PROJECTS ACROSS THE COHORT.

DR. SAMBRANO.

DR. SAMBRANO: SO I THINK ONE OTHER THING TO NOTE IS ONE OF THE THINGS THAT WE STRESS WITH THE GRANTS WORKING GROUP IS THAT WE'RE LOOKING FOR NOVEL, TRANSFORMATIVE THERAPIES. SO PART OF IT IS THAT IT IS NOT NECESSARILY, AS WAS NOTED, THAT AN INITIAL PHASE 1 TRIAL SHOW ANY EFFICACY OR NECESSARILY ANY SIGNAL. THEY'RE OFTEN DESIGNED TO ASSESS SAFETY. BUT I THINK THEY ARE ALSO LOOKING AT IS THIS A THERAPY THAT'S LIKELY TO, EITHER WHEN IT GOES BEYOND THE PHASE 1, TO BE EFFECTIVE AND TO HAVE A MEANINGFUL IMPACT ON THE PATIENT POPULATION.

AND SO I THINK THAT IS PART OF THE CALCULUS THAT IS IN THERE. AND SO THE REASON THEY LOOK FOR AT LEAST A HOPE FOR SOME SIGNAL EFFICACY IS THAT IT'S GOING TO ALSO SIGNAL THAT THIS IS REALLY, TRULY A TRANSFORMATIVE THERAPY.

NOW, THAT DOESN'T MEAN THAT, OF COURSE,

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THAT WE CAN'T FUND A PROPOSAL THAT IS FOCUSED ON SAFETY. I THINK THAT IS OKAY.

I THINK THE OTHER THING TO CONSIDER IN TERMS OF JUST THE BUDGET, SO THAT YOU'RE AWARE, I THINK HAYLEY NOTED, THE BUDGET IS AT 92 MILLION CURRENTLY. THIS WOULD BRING US DOWN TO ABOUT 60 MILLION -- IS THAT CORRECT, HAYLEY? -- IF WE FUNDED THE TOP THREE FOR ONE MORE CYCLE. SO I THINK IN TERMS OF IS THERE FLEXIBILITY IN THE BUDGET TO INCLUDE AN ADDITIONAL OR TWO ADDITIONAL, YOU COULD KNOWING THAT THE NEXT CYCLE COULD BE IMPACTED, BUT AT THE MOMENT EACH CYCLE IS USING UP ABOUT MAYBE 40 MILLION PER CYCLE. SO THE REMAINDER WOULD STILL LIKELY BE ADEQUATE. SO I THINK THAT IS SOMETHING THAT YOU CAN ALSO TAKE INTO ACCOUNT.

DR. LAM: JUST TO LOOK AT THE NUMBERS, IF THESE TWO APPLICATIONS WERE FUNDED, THAT WOULD BE AN ADDITIONAL 20 MILLION FOR THIS ROUND. AND THAT WOULD BRING THE TOTAL AWARDED FOR THIS ROUND TO 51 MILLION OUT OF THE 92 REMAINING. SO THAT WOULD BE 41 REMAINING FOR THE LAST ROUND IF THESE TWO APPLICATIONS WERE FUNDED.

CHAIRMAN IMBASCIANI: THANK YOU, HAYLEY. IN ORDER TO, IN A SENSE, PROMPT OR FORCE FURTHER DISCUSSION AMONG BOARD MEMBERS, I'D LIKE TO AMEND

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THE MOTION. I'D LIKE TO AMEND THE MOTION TO INCLUDE FUNDING APPLICATION CLIN2-19191.

MR. TOCHER: ONLY THAT ONE?

CHAIRMAN IMBASCIANI: YEAH. WE CAN DO THEM ONE AT A TIME. I THINK IT WOULD BE CLEANER TO DO IT ONE AT A TIME.

MR. TOCHER: SO THE MOTION IS TO AMEND THE MOTION ON THE TABLE TO FUND 19191. IS THERE A SECOND?

DR. DULIEGE: I SECOND.

CHAIRMAN IMBASCIANI: MARK FISCHER-COLBRIE. MARK, YOU NEED TO UNMUTE I THINK.

MR. FISCHER-COLBRIE: SORRY ABOUT THAT. IS IT OKAY TO MAKE A COMMENT?

MR. TOCHER: IT IS.

CHAIRMAN IMBASCIANI: THE FLOOR IS YOURS.

MR. FISCHER-COLBRIE: I JUST WANTED TO COMMENT THAT THE REVIEWERS ARE EXTREMELY FAMILIAR WITH THE FACT THAT PHASE 1 IS INTENSELY FOCUSED ON SAFETY, AND THERE'S ALMOST NEVER GOING TO BE A DETERMINATION OR EVEN A NOD IN TERMS OF WHETHER OR NOT THERE'S A SIGNAL BECAUSE OF THE HIGHLY LIMITED NUMBER OF PATIENTS. SO THE REVIEWERS VERY MUCH FACTOR THAT INTO THEIR CONSIDERATION. THAT'S PART OF THE DNA OF THE REVIEW CYCLE.

133 HENNA COURT, SANDPOINT, IDAHO 83864
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SO I DIDN'T WANT THERE TO BE AN INTIMATION THAT THERE IS A CLEAR WAIT FOR A SIGNAL OUT OF A PHASE 1 TRIAL BECAUSE EVERYONE KNOWS THAT'S HIGHLY UNLIKELY. AND THIS IS IN A CIRCUMSTANCE, JUST TO GIVE NUANCE TO THE PREVIOUS COMMENTS, IN THE CONTEXT THAT PEOPLE ARE LOOKING AT WHAT'S NEXT AND WHAT IS THE RISK PROFILE FOR ACHIEVING THE PHASE 2 TRIAL WORK AND WHAT ARE THE CHARACTERISTICS IN THE PHASE 2 WHERE A SIGNAL MIGHT BE ABLE TO BE DETERMINED, COME INTO PLAY. I JUST WANTED TO CLARIFY SOME OF THE COMMENTS RELATED TO HOW PEOPLE MAKE THEIR DETERMINATIONS ON THE SCORING. THANKS.

CHAIRMAN IMBASCIANI: THANK YOU, MARK. JOHN CARETHERS.

DR. CARETHERS: YES. THANK YOU. I THOUGHT YOU WERE GOING TO MAKE THE MOTION ON 19378 AS THE ONE BECAUSE THE SCORES WERE SO CLOSE. SO I WAS WONDERING IF ROSA COULD ADD -- SOMEONE CAN ADD COMMENTS. MY UNDERSTANDING THAT 191, THE SCORE WAS LOWER FROM SOME OF THE PREVIOUS COMMENTS. I WAS WONDERING IF THERE WAS SOME ADDITIONAL DETAIL. I GOT CONFUSED.

CHAIRMAN IMBASCIANI: THE DOOR IS NOT CLOSED, NOT AT ALL.

DR. CARETHERS: I DON'T THINK I CAN MAKE A

MOTION, BUT IT COULD SEEM LIKE 19378 WOULD BE THE ONE I WOULD INCLUDE, NOT 191.

DR. CANET-AVILES: THANK YOU, DR. CARETHERS. SO FOR 19191, IN OUR VIEW THAT'S HOW WE AGREED WITH THE GRANTS WORKING GROUP RECOMMENDATION IS THAT IT'S HARD TO JUSTIFY FUNDING AS SUBMITTED. THE APPLICATION AS IT WAS PROVIDED BY THE VERY GOOD PUBLIC SPEAKERS, IT ADDRESSES A VERY REAL NEED. BUT THE RECORD SUPPORTS THE GRANTS WORKING GROUP VIEW THAT THE TRIAL IS NOT SUFFICIENTLY DIFFERENTIATING ACTUALLY OR INTERPRETABLE FOR A 12 MILLION FIRST-IN-HUMAN AWARD BECAUSE ISSUES ARE NOT THAT THE BIOLOGY IS NOT PLAUSIBLE. THE REVIEWERS DID SAY THAT THE RATIONALE IS SOUND AND THE PRECLINICAL DATA ARE SUPPORTED.

THE PROBLEM IS THAT THE APPLICATION DIDN'T CONVINCINGLY SHOW THAT THIS VACCINE IS MEANINGFULLY BETTER THAN PRIOR AML VACCINE EFFORTS. AND THE PROPOSED TRIAL MAY NOT GENERATE THE CLEAR GO/NO-GO ANSWERS.

SO WITH THAT, OUR STRONG RECOMMENDATION IS THEY CAN COME BACK AND ADDRESS THE REVIEWERS' COMMENTS AND REAPPLY.

ONE OF THE THINGS THAT WE WILL HAVE TODAY IN THE DISCUSSION THAT WE WILL BE PROVIDING WITH

REGARDS TO THE PREFERENCES GOING INTO GUIDING PRINCIPLES IS WHAT ARE OUR GUIDING PRINCIPLES. AND WE'RE GOING TO REVIEW WHAT THE GUIDING PRINCIPLES FOR CLIN2 ARE. WE WANT TRANSFORMATIVE THERAPIES THAT DIFFERENTIATE FROM WHAT'S ALREADY OUT THERE. RIGHT. AND WE HAVE A LIMITED AMOUNT OF FUNDING AND TIME. RIGHT.

SO WITH THAT, OUR RECOMMENDATION COULD BE WHAT THE GRANTS WORKING GROUP SAID, ADDRESS THOSE ISSUES AND COME BACK. AND THERE ARE FOUR INSTANCES OF CLINICAL APPLICATIONS A YEAR.

DR. CARETHERS: THANK YOU. VERY HELPFUL.

CHAIRMAN IMBASCIANI: ANY OTHER QUESTIONS FROM BOARD MEMBERS? I PRESUME WE'RE GOING TO HEAD TO A VOTE ON THE AMENDMENT FIRST BEFORE THE MAIN MOTION. ANY MEMBER OF THE PUBLIC WANT TO COMMENT ON THE AMENDMENT? PLEASE. IF I REMEMBER, DR. GAENSLER, YES?

DR. GAENSLER: I'M PERMITTED?

CHAIRMAN IMBASCIANI: YES. FLOOR IS YOURS.

DR. GAENSLER: THANK YOU VERY MUCH FOR ALL THIS DISCUSSION. I THINK WHAT HAS GOTTEN BURIED IS THE VERY PROMISING DATA THAT WE DO HAVE. IN OUR PROOF OF CONCEPT DATA, WE LOOKED AT THE ABILITY OF

THIS VACCINE TO ERADICATE ACTIVE, AGGRESSIVE LEUKEMIA, WHICH IT DID IN 80 PERCENT OF MODELS OF THE VERY AGGRESSIVE DISEASE. I KNOW THAT'S A MOUSE MODEL. HOWEVER, IN OUR IN VIVO DATA, WE WERE ABLE TO TAKE PATIENT IMMUNE CELLS AFTER REMISSION INDUCTION AND CO-CULTURE THEM WITH THE VACCINE AND SEE SPECIFIC LEUKEMIALYTIC EFFECTS THAT DID NOT TARGET THE NORMAL BONE MARROW IN MOST PATIENTS. AND WHILE THESE WERE VARIABLE, THEY WERE STRIKING BECAUSE THE IMMUNE EFFECTS WERE SEEN IN REMISSION PATIENT CELLS WHO HAD RECEIVED LYMPHODEPLETING THERAPY.

SO I THINK THIS IS VERY STRONG EVIDENCE THAT THIS COULD HAVE ACTIVITY. AND IT IS VERY DIFFERENT, AND I'LL NOW BE A LITTLE BIT SCIENTIFIC, FROM OTHER VACCINES BECAUSE WE HAVE PROVIDED THE COAST IMMULATORY SIGNAL, CD 80, TO ACTUALLY TRIGGER CYTOLYTIC T-CELL EFFECTS. AND FOR THAT REASON, IT IS DIFFERENT FROM EVERY OTHER VACCINE ON THE MARKET AND CAN BE MADE FOR ANY PATIENT EXCLUSIVE OF HLA ETHNIC OR OTHER DESCRIPTORS OF PATIENTS.

SO THIS IS A UNIVERSALLY APPLICABLE VACCINE THAT WE KNOW HOW TO MAKE. UNFORTUNATELY, DON KOHN WAS NOT ABLE TO GET ON AND TELL YOU THAT THE MANUFACTURING IS HIGHLY DEVELOPED AND EFFICIENT.

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AND SO IT IS VERY ATTRACTIVE TO HAVE A THERAPY THAT REALLY ANY PATIENT COULD GET IN THEIR OWN COMMUNITY WITHOUT TRAVELING TO A MAJOR MEDICAL CENTER WITH THE FINANCIAL COST AND DIFFICULTIES ATTENDANT. THANK YOU FOR LETTING ME SPEAK.

CHAIRMAN IMBASCIANI: THANK YOU. OUR PRESIDENT AND CEO, J.T.

DR. THOMAS: YES. THANK YOU, MR. CHAIRMAN. THANK YOU, EVERYBODY, FOR YOUR COMMENTARY TODAY. I JUST WANT TO, AS A GENERIC MATTER, NOTE TO THE BOARD THAT THE GRANTS WORKING GROUP IN ANY APPLICATION SEES ALL OF THE DATA THAT IS SUBJECT MATTER OF COMMENTARY ON PARTICULAR APPLICATIONS AND THROUGH RIGOROUS PROCESS COMES TO CONCLUSION, WHICH IS EITHER TO FUND OR NOT FUND. IT'S IMPOSSIBLE AS THE BOARD SITS HERE TODAY TO HEAR COMMENTARY THAT ADDRESSES THE SCIENCE THAT YOU CAN EVALUATE AS TO WHETHER THAT IS PERSUASIVE OVER AND ABOVE WHAT THE GRANTS WORKING GROUP IN RIGOROUS AND ROBUST DEBATE HAS ALREADY CONTEMPLATED.

SO I JUST MAKE THAT POINT, NOT WITH SPECIFICITY TO ANY PARTICULAR APPLICATION, BUT JUST GENERICALLY AS YOU CONSIDER MOTIONS LIKE THIS. THANK YOU, MR. CHAIRMAN.

CHAIRMAN IMBASCIANI: THANKS, JONATHAN.

YES, ADRIANA.

DR. PADILLA: DURING THE GWG DELIBERATIONS, DID THE QUESTIONS GO OUT TO THE PROJECT COORDINATORS ABOUT THE CHALLENGES THAT WERE BEING NOTED SO THAT THEY COULD RE-DELIBERATE?

DR. LAM: SO THE REVIEW PROCESS ALLOWS REVIEWERS TO ASK QUESTIONS TO THE APPLICANT AND RESPOND IF THERE ARE ANY. I AM NOT A HUNDRED PERCENT SURE ON THIS PARTICULAR APPLICATION, BUT I WOULD HAVE TO DOUBLE-CHECK.

DR. PADILLA: I ALSO FEEL THERE'S A LOT OF SCIENCE HERE THAT I CAN'T ASSESS. I REALLY NEED THE GWG TO ASSESS THAT.

DR. LAM: THE GRANTS WORKING GROUP ALSO HAS THE OPTION, IF THERE ARE SORT OF SCORED DRIVING QUESTIONS, ALLOWS US TO CALL OUT LIVE DURING THE MEETINGS TO THE APPLICANT IF THERE'S AN OUTSTANDING QUESTION THAT THE ANSWER TO WHICH WOULD INFLUENCE HOW THEY RECOMMEND THE APPLICATION IN THE FINAL SCORING AS WELL.

DR. DAHL: I HAVE A QUESTION. CAN YOU ALSO CLARIFY IF THERE'S ANOTHER -- YOU MENTION THERE IS ANOTHER ROUND OF REVIEWS FOR THIS CLIN2 PROGRAM THIS YEAR WITH THE BUDGET. WHAT IS THE TIMELINE FOR THAT? SO IF SOMEBODY WAS GOING TO RESUBMIT SO THAT

THE GWG COULD REVIEW AGAIN WITH THESE RESPONSES, WHEN WOULD THAT UNFOLD?

DR. LAM: RIGHT. SO FROM THIS COHORT, IF, FOR EXAMPLE, THERE WERE APPLICATIONS THAT ARE NOT RECOMMENDED, THEY COULD COME IN AT THE END OF APRIL. THERE'S A DEADLINE AT THE END OF APRIL FOR NEW APPLICATIONS FOR WHICH THESE WOULD BE ELIGIBLE OR ANY PROJECTS THAT AREN'T FUNDED ARE ELIGIBLE TO SUBMIT AT THE END OF APRIL. I THINK IT'S APRIL 28TH.

DR. DULIEGE: THE DURATION OF THE REVIEW CYCLE BECAUSE WHAT MATTERS IS WHEN THEY COULD -- IF A GROUP REAPPLIES, WHEN WOULD BE THE REVIEW AND THE DURATION OF THE PROCESS AND WHEN THEY WOULD HEAR ABOUT A POTENTIAL OUTCOME OF THE REAPPLICATION?

DR. LAM: RIGHT. SO FOR THE APRIL, I BELIEVE IT WOULD BE COMING TO SEPTEMBER ARS. I MEAN IT WOULD COME TO THE BOARD IN SEPTEMBER.

DR. DULIEGE: OKAY.

CHAIRMAN IMBASCIANI: MARGUERITE.

MS. CASILLAS: JUST TO ADRIANA'S QUESTION. SO I'M A PATIENT REVIEWER. WE ARE NOTIFIED OF WHEN QUESTIONS ARE DUE. I FEEL LIKE THE CIRM TEAM DOES A GOOD JOB TO ENCOURAGE US TO ASK QUESTIONS. EVERY TIME I HAVE, I HAVE GOTTEN GOOD RESPONSES FROM

APPLICANTS. SO THAT PIECE IS WORKING, I THINK.

CHAIRMAN IMBASCIANI: I DON'T SEE ANY MORE COMMENTS FROM BOARD MEMBERS INCLUDING THOSE OUTSIDE THE ROOM. ANY MEMBER OF THE PUBLIC WANT TO COMMENT? NO. WE CAN PROCEED TO A VOTE ON THE AMENDMENT, SCOTT.

MR. TOCHER: SO TO BE CLEAR, THIS IS A MOTION TO AMEND THAT WE'RE VOTING ON. SO THERE WILL STILL BE ANOTHER STEP ULTIMATELY. YOU WILL STILL BE TAKING A VOTE ON THE UNDERLYING MOTION ASSUMING THERE ISN'T ANOTHER MOTION TO AMEND WITH REGARD TO THE OTHER APPLICATION. SO THE RESULTS OF THIS VOTE, I'M NOT GOING TO CALL ON THOSE MEMBERS WHO HAVE A CONFLICT AS TO EITHER OF THE APPLICATIONS BECAUSE THIS AFFECTS THAT PENDING MOTION.

SO, AGAIN, THIS WILL JUST BE A MOTION TO WHETHER THE ORIGINAL WILL BE AMENDED. SO AN AYE VOTE WILL ESSENTIALLY BE TO FUND APPLICATION 19191 AND THEN NOT FUND 19378. THAT WILL BE THE NEW SHAPE OF THE UNDERLINING MOTION.

CHAIRMAN IMBASCIANI: I SEE KEITH'S HAND UP.

DR. YAMAMOTO: YES. I DON'T KNOW IF I CAN --

MR. TOCHER: WAIT. WAIT. KEITH HAS A

CONFLICT.

CHAIRMAN IMBASCIANI: THANK YOU. KEITH, I'M SORRY, BUT I THINK YOU'RE CONFLICTED ON THIS. SORRY TO INTERRUPT.

MR. TOCHER: SO I'LL TAKE THE VOTE NOW.

MARGUERITE CASILLAS.

MS. CASILLAS: NO.

MR. TOCHER: JUDY CHOU.

DR. CHOU: YES.

MR. TOCHER: LEONDRA CLARK-HARVEY.

DR. CLARK-HARVEY: NO.

MR. TOCHER: SHANNON DAHL.

DR. DAHL: NO.

MR. TOCHER: ANNE-MARIE DULIEGE.

DR. DULIEGE: YES.

MR. TOCHER: MARK FISCHER-COLBRIE.

MR. FISCHER-COLBRIE: NO.

MR. TOCHER: VITO IMBASCIANI.

CHAIRMAN IMBASCIANI: YES.

MR. TOCHER: RICH LAJARA.

MR. LAJARA: NO.

MR. TOCHER: ADRIANA PADILLA.

DR. PADILLA: NO.

MR. TOCHER: MARV SOUTHARD.

DR. SOUTHARD: NO.

MR. TOCHER: AND KEVIN XU.

MR. XU: NO.

MR. TOCHER: THE MOTION TO AMEND DOES NOT PASS.

CHAIRMAN IMBASCIANI: OKAY. DISCUSSION AGAIN ON THE ORIGINAL MOTION. ARE WE FINISHED WITH THE DISCUSSION ON THAT? IF ANY BOARD MEMBER WANTS TO MAKE A COMMENT OR A MEMBER OF THE PUBLIC. DO YOU SEE ANY HANDS, CLAUDETTE? NO. OKAY. SCOTT, WE CAN GO TO THE ORIGINAL MOTION UNLESS THERE'S ANOTHER.

DR. DULIEGE: CAN YOU REPEAT THE ORIGINAL MOTION FOR CLARITY PLEASE?

MR. TOCHER: CERTAINLY. THE MOTION IS TO NOT FUND APPLICATIONS 19378 AND 19191.

SO FOR THE FOLLOWING MEMBERS, BONNEVILLE, DURON, FLOWERS, MIASKOWSKI, AND WATSON, YOU HAVE A CONFLICT. SO PLEASE INDICATE YOUR VOTE, AGAIN, WITH THE EXCEPTION OF THOSE WITH WHICH YOU HAVE A CONFLICT.

MARIA BONNEVILLE.

VICE CHAIR BONNEVILLE: YES, EXCEPT FOR THOSE WITH WHICH I HAVE A CONFLICT.

MR. TOCHER: MARGUERITE CASILLAS.

MS. CASILLAS: YES.

MR. TOCHER: JUDY CHOU.

DR. CHOU: YES.
MR. TOCHER: LEONDRA CLARK-HARVEY.
DR. CLARK-HARVEY: YES.
MR. TOCHER: SHANNON DAHL.
DR. DAHL: YES.
MR. TOCHER: ANNE-MARIE DULIEGE.
DR. DULIEGE: NO.
MR. TOCHER: YSABEL DURON.
MS. DURON: YES, EXCEPT FOR THOSE WITH WHICH I HAVE A CONFLICT.
MR. TOCHER: MARK FISCHER-COLBRIE.
MR. FISCHER-COLBRIE: YES.
MR. TOCHER: ELENA FLOWERS.
DR. FLOWERS: YES, EXCEPT FOR THOSE WITH WHICH I HAVE A CONFLICT.
MR. TOCHER: VITO IMBASCIANI.
CHAIRMAN IMBASCIANI: YES.
MR. TOCHER: RICH LAJARA.
MR. LAJARA: YES.
MR. TOCHER: CHRIS MIASKOWSKI.
DR. MIASKOWSKI: YES, EXCEPT FOR THOSE WITH WHICH I HAVE A CONFLICT.
MR. TOCHER: ADRIANA PADILLA.
DR. PADILLA: YES.
MR. TOCHER: MARV SOUTHARD.

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DR. SOUTHARD: YES.
MR. TOCHER: KAROL WATSON.
DR. WATSON: YES, EXCEPT FOR THOSE WITH WHICH I HAVE A CONFLICT.
MR. TOCHER: KEVIN XU.
MR. XU: YES.
MR. TOCHER: THANK YOU. AND THAT MOTION CARRIES.
CHAIRMAN IMBASCIANI: GREAT. THANK YOU AND THANK YOU, HAYLEY. YOU WANT A BREAK?
MR. TOCHER: WE WOULD LOVE A TEN-MINUTE BREAK.
CHAIRMAN IMBASCIANI: YES. YOU MAY HAVE.
MR. TOCHER: THANK YOU. SO WE'LL SEE YOU AT 10:30.
(A RECESS WAS TAKEN.)
CHAIRMAN IMBASCIANI: I PRESUME WE CAN CONVENE AGAIN. OKAY. WE'RE GOING TO START IMMINENTLY. OKAY. WE'RE GOING TO TAKE UP WHERE WE LEFT OFF AND DIRECT EVERYONE'S ATTENTION TO AGENDA ITEM NO. 9. THIS IS GOING TO BE A DISCUSSION OF AMENDMENTS TO THE COMMUNITY CARE CENTER OF EXCELLENCE CONCEPT PLAN OR INFRASTRUCTURE 8. AND THE PRESENTATION WILL BE LED BY THE ASSISTANT DIRECTOR OF PATIENT ACCESS, DR. GEOFF LOMAX.

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DR. LOMAX: THANK YOU, MR. CHAIRMAN. BETH, ARE WE OKAY SOUNDWISE?

THE REPORTER: YES.

DR. LOMAX: THANK YOU. I'D LIKE TO THANK THE CIRM LEADERSHIP FOR GIVING US THE OPPORTUNITY TO PRESENT THIS ITEM AND ACKNOWLEDGE THE PATIENT ACCESS TEAM FOR THEIR EFFORT IN PULLING THESE MATERIALS TOGETHER AND ALL THE THOUGHT BEHIND IT.

SO, AGAIN, THIS IS FOR YOUR CONSIDERATION THE REOPENING OF OUR INFR8 PROGRAM, WHICH IS MORE COMMONLY KNOWN AS THE COMMUNITY CARE CENTERS OF EXCELLENCE PROGRAM. JUST A BRIEF REMINDER OF THE CONTOURS OF THIS PROGRAM. IT IS MANDATED BY PROPOSITION 14 TO ESTABLISH THE COMMUNITY CARE CENTERS OF EXCELLENCE.

THE AIM OF THE PROGRAM IS TO EXPAND THE CAPACITY OF OUR EXISTING CLINICAL TRIAL NETWORK WHICH IS EMBODIED IN THE ALPHA CLINICS NETWORK WITH THE AIM OF PROMOTING ACCESS TO BOTH HUMAN CLINICAL TRIALS AND TREATMENTS THAT ARISE FROM THOSE TRIALS, PARTICULARLY INSTITUTE-FUNDED PROGRAMS.

AND A MAIN CRITERIA FOR PRIORITIZING FOR THE PROGRAM ITSELF IS TO ENSURE THERE'S GEOGRAPHIC DIVERSITY IN THOSE CENTERS. AND SO WE KNOW THAT GEOGRAPHIC DIVERSITY IS CRITICAL TO MAKING

TREATMENTS BROADLY AVAILABLE TO PATIENTS AS WE HEARD FROM A NUMBER OF COMMENTS, THAT PROXIMITY AND ACCESS GO HAND IN HAND. SO THIS PROGRAM IS INTENDED TO ACHIEVE THAT OUTCOME.

I'M GOING TO UPDATE YOU ON THE STATUS OF THE PROGRAM AS IT STANDS AT THE MOMENT. IN OCTOBER OF 2025, YOU APPROVED THREE AWARDS PURSUANT TO THE INFR8 PROGRAM. THOSE AWARDS TOTALED A $27 MILLION COMMITMENT. THE ORIGINAL BUDGET THAT YOU AUTHORIZED IN THE CONCEPT PLAN WAS 36 MILLION. SO THERE WAS REMAINING FUNDS AVAILABLE THROUGH YOUR INITIAL AUTHORIZATION FOR THIS PROGRAM. THOSE FUNDS ARE STILL REMAINING.

ALSO WANT TO GIVE YOU A PERSPECTIVE OF THE CURRENT STATUS OF OUR CLINICAL INFRASTRUCTURE PROGRAM AS IT STANDS RIGHT NOW. AND THAT'S ILLUSTRATED BY THE MAP ON THE RIGHT SIDE OF THIS SLIDE. WE'VE GOT THE ALPHA CLINICS IN RED AND THE COMMUNITY CARE CENTERS IN BLUE. AND I THINK WHAT WE'RE TRYING TO GET ACROSS AND THAT MAP ILLUSTRATES QUITE NICELY IS OUR CURRENT FOOTPRINT IS WITHIN THE STATE, BUT SOUTH OF SACRAMENTO. SO THERE'S ABOUT ONE-THIRD OF THE AREA OF THE STATE THERE IS NO CLINICAL FOOTPRINT TO SERVE PATIENTS.

AND DURING THE OCTOBER MEETING, THE ICOC

EXPRESSED CONCERNS ABOUT THIS GEOGRAPHIC GAP. AND POINTING OUT THAT THIS REGION IS NOT SERVED BY ANY CURRENT CLINICAL INFRASTRUCTURE. THAT REPRESENTS A POPULATION OF ABOUT 3 MILLION CALIFORNIANS. AND SO THE BOARD DIRECTED THE TEAM TO IDENTIFY OPTIONS TO EXPAND THE REACH OF OUR CLINICAL INFRASTRUCTURE INTO NORTHERN CALIFORNIA. AND SO WE SET ABOUT DOING THAT.

WE'VE ACTUALLY ENGAGED WITH CENTERS -- WE KNOW THERE IS CAPACITY IN THAT REGION. AND BECAUSE THERE IS SUCH CAPACITY, WHAT WE'RE RECOMMENDING IS THAT WE REOPEN THE COMMUNITY CARE CENTER OF EXCELLENCE REQUEST FOR APPLICATIONS. THAT WOULD REQUIRE SOME VERY MINOR TECHNICAL AMENDMENTS. WE'RE ASKING THE AUTHORIZATION OF $9 MILLION WHICH WOULD FUND ONE AWARD. AND THAT 9 MILLION REPRESENTS THE UNCOMMITTED FUNDS FROM THE PREVIOUS CONCEPT PLAN YOU APPROVED LAST YEAR. WE WOULD OBVIOUSLY HAVE TO MODIFY OUR DEADLINES AS WE HAVE TO HAVE NEW DATES. AND WE WOULD LIMIT ELIGIBILITY TO APPLICANT ORGANIZATIONS WITH CLINICAL OPERATIONS IN THOSE NORTHERN COUNTIES WHICH WERE ILLUSTRATED IN THE PREVIOUS SLIDE IN THE BOX.

WE WOULD ALSO PROPOSE A SOMEWHAT EXPEDITED TIMELINE. SO THE LAUNCH, IF THERE IS AN APPLICATION

THAT'S RECOMMENDED FOR FUNDING AND APPROVED BY THIS BOARD, THAT THE START-UP WOULD COINCIDE AS QUICKLY AS POSSIBLE WITH THE EXISTING AWARDS WHICH WE'VE ACTUALLY JUST FINALIZED THE CONTRACT OF TWO OF THE PROGRAMS YOU APPROVED IN OCTOBER. AND JUST AS A SIDEBAR NOTE, THE EXCITEMENT AND THE ENTHUSIASM IS PALPABLE. THOSE PROGRAMS ARE JUST SO EXCITING, AND IT'S JUST A PLEASURE TO BE A PART OF THAT.

SO WE'D LIKE ANY NEW AWARD TO BE AS CLOSE AS POSSIBLE TO THAT PROGRAM. SO WE'RE RECOMMENDING THE PROGRAM WOULD CLOSE AT THE END OF JUNE, AND IT WOULD COME TO THE APPLICATION REVIEW SUBCOMMITTEE IN SEPTEMBER.

I'M GOING TO HAVE TO TAKE A CLASS IN CLICKER. THERE WE GO. SO THE REQUEST IS THAT THE BOARD REOPEN THE COMMUNITY CARE CENTERS OF EXCELLENCE PROGRAM, WHICH IS INFR8, AND THAT THE APPROVED CONCEPT PLAN, WHICH IS PART OF THE MATERIALS NOTICED FOR THIS MEETING, THAT IT INCLUDES THOSE MINOR MODIFICATIONS WHICH I COVERED IN THE PREVIOUS SLIDE. SO WITH THAT, I TURN IT BACK TO THE CHAIR.

CHAIRMAN IMBASCIANI: VICE CHAIR BONNEVILLE.

VICE CHAIR BONNEVILLE: I'D LIKE MAKE A

MOTION TO REOPEN THE COMMUNITY CARE CENTERS OF EXCELLENCE FUNDING OPPORTUNITY WITH THE MODIFIED CONCEPT PLAN.

DR. BARRETT: SECOND.

CHAIRMAN IMBASCIANI: OKAY. MOTION IS ON THE TABLE. WE HAVE THE OPPORTUNITY TO DISCUSS. ANNE-MARIE.

DR. DULIEGE: JUST CAN YOU GIVE US A LITTLE BIT OF HISTORY OR PERSPECTIVE? YOU MAKE TO REOPEN THIS CCE. WHEN THEY OPENED BEFORE, DID THEY CLOSE? WHAT'S THE REOPENING?

DR. LOMAX: JUST TO BE CLEAR, SO THIS IS A NEW PROGRAM. WE'VE JUST GONE THROUGH THE FIRST FUNDING CYCLE AND APPROVED THREE AWARDS. AND THE REOPENING IS NOT -- IS TO ALLOW -- WHEN WE APPROVED THOSE AWARDS, ONE OF THE ELEMENTS OF THE APPROVAL WAS TO TAKE THE MONEY OFF THE TABLE, SO TO SPEAK, THAT 8 MILLION. SO THE REOPENING, IF YOU WILL, IS A CONFUSING WAY OF SAYING CAN WE RE-ACCESS THAT 8 MILLION SO WE CAN ALLOW THE RFA TO OPEN AND ACCESS THOSE FUNDS IF THERE IS A SUCCESSFUL APPLICANT PURSUANT TO THAT RFA.

DR. DULIEGE: GREAT. THANK YOU.

VICE CHAIR BONNEVILLE: I WANT TO THANK THE PATIENT ACCESS TEAM AND ALSO THE BOARD FOR

DIRECTING THAT WE EXPLORE MORE IN THIS PART OF THE STATE BECAUSE IT WAS CLEAR THAT WE NEEDED TO GO BACK OUT AND ASSESS WHETHER OR NOT THERE WERE COMMUNITY CARE CENTERS IN THAT REGION THAT COULD APPLY TO EXPAND OUR FOOTPRINT. SO I REALLY APPRECIATE IT. AND THERE'S BEEN A LOT OF WORK THAT'S BEEN DONE WITH OUTREACH AND VISITING DIFFERENT SITES. AND SO THANK YOU. I APPRECIATE IT. AND THANKS TO THE BOARD FOR UNDERSTANDING HOW IMPORTANT THIS IS.

DR. SACKEY: SIMILARLY, I WANT TO THANK YOU FOR THE WORK. THIS IS REALLY EXCITING AND IT IS IMPORTANT. I ALSO WANT TO THANK THE BOARD FOR MAKING THE CALL THAT THIS WAS NOT SERVING THE WHOLE STATE.

SO I GUESS MY QUESTION IS GOING FORWARD -- AND I'M ENTIRELY SUPPORTIVE OF REALLY REOPENING IT TO ENSURE THAT WE HAVE GEOGRAPHIC DIVERSITY HERE. BUT I GUESS MY QUESTION IS GOING FORWARD, WHEN WE HAVE NEW INITIATIVES, WHAT WILL BE THE PROCESS THAT WE WILL TAKE SO THAT FROM THE GET-GO WE'RE LOOKING AT THIS DATA AS A WHOLE? I MEAN I KNOW THAT THESE THINGS ARE ITERATIVE, BUT IT JUST SEEMS TO ME THAT NOW THAT YOU'RE SHOWING THE GRAPH, IT SEEMS QUITE OBVIOUS THAT WE HAD A GAP. SO WHAT STEPS WOULD WE TAKE IN THE FUTURE TO ENSURE THAT IT WOULDN'T TAKE

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THE BOARD REACTING TO HAVE SOMETHING THAT IS COMPREHENSIVE AND INCLUSIVE?

DR. LOMAX: THANK YOU FOR THAT QUESTION. SO WHILE THE GAP COULD BE INTERPRETED AS WE WERE REMISS AND MISSED SOMETHING, WE HAVE IN THE PRIOR ROUND, WE DID ENGAGE APPLICANTS. AND I WOULD NOTE -- AND THERE WERE A NUMBER OF AWARDS THAT WEREN'T RECOMMENDED FOR FUNDING. LET'S SAY HAD ALL THE AWARDS IN THE ORIGINAL ROUND BEEN RECOMMENDED FOR FUNDING, THAT MAP WOULD HAVE LOOKED A BIT DIFFERENT.

SO AT THE END OF THE DAY, WE AIM TO FULFILL THE OBJECTIVES OF THE PROGRAM. BUT, AGAIN, WE'RE STILL DEPENDENT ON THE APPLICANT TO SUBMIT AN APPLICATION THAT IS DEEMED MERITORIOUS. AND SO IT WASN'T A QUESTION OF NOT RECOGNIZING THE NEED. IT WAS A QUESTION OF APPLICATIONS THAT WERE ULTIMATELY FUNDED WHEN AT THE END OF THE DAY WE WERE LEFT WITH THAT GAP.

SO THE PROCESS WORKED. AND WE'RE JUST TRYING TO RESTART IT AGAIN NOW WITH THAT MORE NARROW SET OF CONDITIONS TO ENSURE WE ACHIEVE THAT OUTCOME AS BEST WE CAN PROVIDED THERE'S A FUNDABLE APPLICATION THAT COMES THROUGH THE PROCESS.

DR. SACKEY: THANK YOU FOR THE

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208-255-5453 208-920-3543 DRAIBE@HOTMAIL.COM

CLARIFICATION. SO ESSENTIALLY WHAT YOU'RE SAYING IS THAT IT WAS THE CALIBER OF THE APPLICATIONS YOU RECEIVED THAT LED TO WHAT APPEARED TO BE A GAP IN NORTHERN CALIFORNIA?

DR. LOMAX: THAT'S CORRECT.

DR. SACKEY: AND SO WHAT STEPS ARE WE TAKING THEN NOW THAT WE'RE GOING TO FOCUS ON THEM? I WOULD IMAGINE WE STILL WANT TO HAVE HIGH CALIBER APPLICATIONS. SO DOES CIRM HAVE AN OPPORTUNITY TO MAYBE HELP BUILD THE CAPACITY SO THAT THE APPLICATIONS THAT COME FORWARD ARE, IN FACT, STRONG ENOUGH THAT WE WERE ABLE TO FUND THEM?

DR. LOMAX: SO WE ALWAYS ENCOURAGE APPLICANTS TO CONTACT THE CIRM TEAM AND ASK QUESTIONS TO STRENGTHEN THEIR APPLICATION. AND IN ADDITION, THERE ARE -- WITHIN THE NETWORK ITSELF, WE SAW THIS IN THE FIRST ROUND AND I HAVE EVERY EXPECTATION THIS WOULD OCCUR IF YOU WERE TO REOPEN THIS APPLICATION, THAT THE APPLICANT ORGANIZATIONS THEMSELVES WILL REACH OUT TO THE EXISTING CIRM NETWORK OF ALPHA CLINICS AND IN THIS CASE COMMUNITY CARE CENTERS AND ENGAGE WITH THOSE CENTERS AND DEVELOP THE APPLICATION IN SUCH A WAY WHERE IT WILL BE AS COMPETITIVE AS POSSIBLE. AND WE VERY MUCH ENCOURAGE AND WILL FACILITATE THOSE COLLABORATIONS

OR COMMUNICATIONS DURING THE PROCESS.

DR. PADILLA: THANK YOU. THAT WAS ONE OF MY QUESTIONS. I WAS GOING TO ASK IS CIRM GOING TO BE NURTURING SOME OF THE ORGANIZATIONS THAT APPLIED DURING THE FIRST ROUND AND TO ASSIST THEM TO MOVE INTO A MORE SUCCESSFUL SELECTION?

DR. LOMAX: AGAIN, WE OBVIOUSLY DO EVERYTHING WE CAN TO MAKE THIS OPPORTUNITY VISIBLE TO ORGANIZATIONS THAT APPEAR TO BE POSITIONED TO APPLY. WE HELP FACILITATE THE NETWORKING COMMUNICATIONS AS I HAD JUST INDICATED. AND AS CO-CHAIR BONNEVILLE INDICATED AS WELL, WE'VE BEEN OUT INTO THE REGION AND RECOGNIZE THERE ARE ORGANIZATIONS THAT WOULD APPEAR TO BE ELIGIBLE FOR THIS PROGRAM. AND SO, AGAIN, SHOWING THAT VISIBILITY, GIVING THEM INFORMATION ABOUT THE PROCESS. AND, AGAIN, I ANTICIPATE WE WILL HAVE QUALITY APPLICANTS IN THIS ROUND.

I THINK WE HAVE TO BE VERY CAREFUL, I THINK, ONCE WE OPEN AN APPLICATION, THAT WE'RE BEING FAIR AND OBJECTIVE AND NOT GOING BEYOND OUR REMIT AS WHAT WE CAN DO IN TERMS OF THE APPLICATIONS THEMSELVES.

DR. PADILLA: ONLY BECAUSE THESE SITES ALSO HAVE LIMITED RESOURCES TO PULL FROM, THEY MAY

NOT HAVE THE EXPERTISE TO BUILD A ROBUST APPLICATION PROCESS. AND IT WOULD BE INCUMBENT ON THE MAJOR UNIVERSITY INSTITUTIONS IN NORTHERN CALIFORNIA TO ALSO REALIZE THAT AND REACH OUT FROM THIS CALL OF THIS NEW PROPOSAL.

DR. LOMAX: YEAH. AGAIN, I THINK THAT INTEREST IS THERE WITH THE EXISTING CENTERS. AND THERE'S CERTAINLY HEADROOM WITHIN OUR EXISTING CLINICAL NETWORK FOR THOSE TEAMS TO SUPPORT SOME OF THESE EFFORTS. SO I THINK IF THE INTEREST AND THE TEAMS AND THE BRAIN POWER IS THERE, WE JUST NEED TO GET -- PULL THOSE APPLICATIONS THROUGH.

CHAIRMAN IMBASCIANI: GOOD. BOARD MEMBER ALMASRI.

DR. ALMASRI: SO I UNDERSTAND THAT WE MISSED A BIG PART OF THE GEOGRAPHY, BUT DO WE HAVE AT LEAST ROUGH ESTIMATE OF WHAT'S THE POPULATION OF THIS AREA? IS IT 5 PERCENT OR 10 PERCENT OF THE STATE? BECAUSE OBVIOUSLY WE ARE AFTER THE HUMAN SO I TOTALLY UNDERSTAND BECAUSE ALSO LIMITING THE REMAINING FUND TO ONLY SMALL GEOGRAPHIC AREA WHO MAY NOT HAVE THE EXPERTISE AND RESOURCES TO CONDUCT WHAT WE ARE TRYING TO DO CAN BE ALSO RESTRICTIVE.

DR. LOMAX: I'LL MAKE THIS COMMENT ON A COUPLE OF REALITIES WE'VE SURFACED DURING OUR NEEDS

133 HENNA COURT, SANDPOINT, IDAHO 83864
208-255-5453 208-920-3543 DRAIBE@HOTMAIL.COM

ASSESSMENT AND LEAVE IT TO THE BOARD TO DETERMINE HOW COMPELLING THEY ARE IN TERMS OF YOUR DECISION. AGAIN, AS I INDICATED, WE'RE ROUGHLY ABOUT 3 MILLION RESIDENTS. THAT AREA IS -- TWO OF THE EXISTING MAJOR MEDICAL CENTERS IN THAT REGION ARE UNDER, AS WE UNDERSTAND IT, TREMENDOUS STRAIN LARGELY BECAUSE OF FEDERAL FUNDING CUTS. SO I WON'T CALL THEM OUT BECAUSE I DON'T WANT TO SORT OF REPRESENT THEM, BUT THAT AREA IS EXPERIENCING SUBSTANTIAL STRAIN IN TERMS OF PATIENT ACCESS TO HEALTHCARE IN GENERAL. THESE ARE MAJOR MEDICAL FACILITIES.

SO TO THE EXTENT THERE'S A NEED, IT'S AMPLIFIED IN THAT REGION GIVEN CUTS TO FEDERAL HEALTH FUNDING. THEY'RE ALSO, INTERESTINGLY ENOUGH, LOOKING AT SORT OF THE EPIDEMIOLOGY OF THE REGION. THERE ARE COMPARATIVELY HIGH INCIDENCE OF CANCERS THROUGHOUT THE NORTHERN PART OF THE STATE. ACTUALLY I HAD AN EARLIER MAP OF THAT. I'M SORRY I DON'T HAVE IT IN THE APPENDIX OR I WOULD SHOW IT. THOSE ARE CONDITIONS WHICH ARE SORT OF UNIQUELY ALIGNED WITH REGENERATIVE MEDICINE TREATMENTS.

SO IN TERMS OF THE BURDEN OF DISEASE, THAT REGION IS SOMEWHAT UNUSUAL IN TERMS OF WHAT WE'RE SEEING IN THE CANCER REGISTRY IN PARTICULAR. SO THERE'S PERHAPS A UNIQUE OPPORTUNITY TO REALLY HELP

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208-255-5453 208-920-3543 DRAIBE@HOTMAIL.COM

PATIENTS IN THAT REGION. SO WITHIN THOSE NUMBERS, HAVING A LARGER PROPORTION OF PATIENTS THAT COULD POTENTIALLY BENEFIT IS A REAL POTENTIAL VALUE PROPOSITION FOR THIS PROGRAM.

AND I THINK, FINALLY, JUST OVERALL CIRM'S, WITH THE EXCEPTION OF A COUPLE OF CENTERS, OUR FOOTPRINT IS SOMEWHAT LIMITED IN THAT REGION. AND IF WE GO BACK TO THE PROPOSITION AND THE MANDATE FOR SORT OF GEOGRAPHIC DIVERSITY AND ACCESS, OUR INTERPRETATION WAS THAT WHAT WE'RE BRINGING FORWARD TODAY DOES ALIGN WITH WHAT THE PROPOSITION IS ASKING FOR. SO I HOPE THAT'S HELPFUL IN TERMS OF HOW YOU WEIGH THE BENEFITS OR THE VALUE PROPOSITION OF WHAT WE'RE PROPOSING.

DR. SACKEY: QUESTION.

CHAIRMAN IMBASCIANI: JOYCE.

DR. SACKEY: A LOT OF WHAT YOU JUST SAID, THAT THE MAJOR INSTITUTIONS IN THE REGION ARE UNDER SUCH CONSTRAINTS, I WONDER, I WONDER WHETHER LIMITING THIS EXTENDED DEADLINE TO ONLY THAT REGION MIGHT, IN FACT, ACHIEVE WHAT WE'RE LOOKING FOR. IS THERE A WAY IN WHICH WE MIGHT ENCOURAGE COLLABORATION BETWEEN INSTITUTIONS IN THE CENTRAL REGION, IN THE SOUTHERN SIDE OF CALIFORNIA WHO MIGHT ACTUALLY HAVE THE CAPACITY AND ARE NOT AS DISTRACTED

BY THE FUNDING CUTS TO SUPPORT THE APPLICANTS WHO ARE GOING TO COME FROM THIS REGION?

DR. LOMAX: SO, AGAIN, JUST TO GIVE YOU A LITTLE BIT OF A SENSE OF HOW WE TRY THROUGH A NEEDS ASSESSMENT PROCESS LOOK AT ISSUES LIKE FEASIBILITY, CAPACITY, AND IN TERMS OF THEN INFORMING THE TIMELINES. SO IN DISCUSSIONS, AND I'LL ACKNOWLEDGE BECAUSE THERE IS NO -- IN DISCUSSIONS, FOR EXAMPLE, WITH FRESNO, WHO WE'VE JUST FUNDED IN THE FIRST ROUND, THEY WERE EXTREMELY OPEN AND MOTIVATED TO ENGAGE APPLICANTS AS A SORT OF PEER TO PEER BECAUSE THEY'RE A CENTER THAT THEY HAVE A LOT OF CHARACTERISTICS OF THE TYPE OF APPLICANT THAT WOULD COME INTO THIS PROGRAM.

SO IN TERMS OF THE COLLABORATIONS YOU'RE ALLUDING TO, I THINK THERE'S VERY MUCH A WILLINGNESS AMONGST THE EXISTING CENTERS TO DRIVE THOSE COLLABORATIONS, SUPPORT THOSE APPLICANTS. AND THEY'RE FRESH OFF OF COMING THROUGH IN OCTOBER.

SO OUR SENSE IS THAT THAT SUPPORT WILL BE THERE, BUT ACKNOWLEDGE THAT THESE CENTERS CAN HAVE MORE LIMITED CAPACITY. I THINK IT GOES BACK TO THE COMMENT PREVIOUSLY. BUT WE DO TRY TO MATCHMAKE AND SORT OF PROVIDE THOSE SUPPORT STRUCTURES BECAUSE OBVIOUSLY OUR MISSION IS TO GET -- OUR GOAL IS TO

GET THE BEST APPLICATIONS POSSIBLE. SO IT'S STRIKING THAT BALANCE.

CHAIRMAN IMBASCIANI: OKAY. BOARD MEMBER PAT LEVITT IS NEXT. UNMUTE PLEASE.

DR. LEVITT: I AM UNMUTED. CAN YOU HEAR ME?

DR. SOUTHARD: YES, WE CAN HEAR YOU.

DR. LEVITT: ALL RIGHT. THANK YOU. I JUST WANTED TO SAY THAT THE COMMUNITY CARE CENTERS OF EXCELLENCE ARE REALLY CRITICAL IN TERMS OF THEIR OPERATIONS LOCALLY. AND THAT RIGHT NOW 3 MILLION PEOPLE IN THAT PART OF THE STATE, IF THEY WANT TO GET ACCESS TO THE PROGRAMS THAT WOULD FACILITATE AND IMPROVE EVEN REFERRALS FOR WHAT WE'RE TRYING TO DO FOR CLINICAL TRIALS AND FOR OTHER KINDS OF TREATMENTS, WE NEED THEM LOCALLY IN THAT REGION. IT'S 3 MILLION PEOPLE.

I'VE TALKED TO GEOFF ABOUT THIS. THERE IS A LOT OF COLLABORATION ALREADY AMONGST THOSE THAT HAVE BEEN FUNDED AND A WILLINGNESS TO SHARE THEIR STRATEGIES FOR HOW THEY IMPROVE ACCESS AND ENGAGE WITH THE COMMUNITIES. SO I THINK THIS IS A REALLY POSITIVE MOVE. I THINK THE CIRM TEAM HAS DONE A LOT OF DUE DILIGENCE IN TERMS OF UNDERSTANDING WHAT THE OPPORTUNITIES ARE IN THAT REGION FOR FUNDING REALLY

133 HENNA COURT, SANDPOINT, IDAHO 83864
208-255-5453 208-920-3543 DRAIBE@HOTMAIL.COM

STRONG APPLICATIONS. THANKS.

CHAIRMAN IMBASCIANI: THANK YOU, PAT. YES, KIM.

DR. BARRETT: YEAH. I JUST WANTED TO COMMENT ON WHAT I SEE AS THE GREAT IMPORTANCE OF THIS PROPOSAL. AS THE ACADEMIC MEDICAL CENTER THAT IS THE FURTHEST NORTH IN CALIFORNIA, AT UC DAVIS WE HAVE A LOT OF INTERACTIONS WITH MEDICAL FACILITIES IN THIS PART OF THE STATE. THERE'S CERTAINLY A HUGE AMOUNT OF NEED. BUT ALSO SOME VERY ENERGETIC AND ENTHUSIASTIC PARTNERS THAT WE'VE HAD DISCUSSIONS WITH ABOUT OTHER TYPES OF COLLABORATION. BUT THOSE CONVERSATIONS LET US KNOW HOW MUCH THIS IS NEEDED. AND WHEN WE'RE TALKING ABOUT ALL THE WAY UP TO THE BORDER WITH OREGON, THOSE PEOPLE ARE WAY TOO FAR FROM THE EXISTING CENTERS TO HAVE THE ABILITY TO ACCESS.

CHAIRMAN IMBASCIANI: THANK YOU, KIM. ANNE-MARIE.

DR. DULIEGE: JUST TO SAY THAT I'M ALSO VERY MUCH IN FAVOR OF THIS PROPOSAL. BUT MAYBE A MORE BASIC QUESTION FOR SOME OF US WHO MAY NOT HAVE BEEN PART OF THE BOARD FOR A LONG TIME, CAN YOU REMIND US THE MANDATE OF THE COMMUNITY CARE CENTERS OF EXCELLENCE? WHAT DEFINES A GREAT CENTER? AND

FOR THOSE CENTERS THAT HAVE BEEN OPEN FOR SOME TIME NOW, HOW HAVE THEY HELPED THE MISSION OF THE CIRM? WHAT DIFFERENCE THEY HAVE MADE. I'M SURE IT WOULD BE GREAT TO HAVE THAT.

DR. LOMAX: THANK YOU FOR THAT. I JUST WANT IT TO GO BACK AS A REMINDER. SO THIS PROGRAM WE HAVE -- THIS PROGRAM IS THREE DAYS OLD. WE HAVE JUST -- WE'VE JUST SIGNED OUR FIRST CONTRACT. SO THIS IS A NEW PROGRAM. YOUR OCTOBER DECISION WAS THE INITIAL ROUND OF FUNDING FOR THIS PROGRAM. AND SO WE DON'T -- WE CAN'T GIVE YOU OUTCOMES AT THIS TIME. SO THIS IS AN EXPERIMENT, BUT IT'S PROBABLY ONE OF THE COOLEST EXPERIMENTS IN REGENERATIVE MEDICINE RIGHT NOW. EVERYONE, AGAIN, I THINK TWO YEARS OF NEEDS ASSESSMENTS, INTERACTING BOTH WITH COMMERCIAL PROVIDERS WHO HAVE APPROVED THERAPIES AND OUR CLINICAL TRIALISTS WHO ARE TRYING TO REACH PATIENTS, EVERYONE COMES BACK TO THE VALUE AND THE IMPORTANCE OF WORKING OUTSIDE OF THE ACADEMIC CENTERS TO ENGAGE THESE PATIENTS.

AND SO WE THINK, BASED ON THAT SORT OF COLLECTIVE WISDOM, WE'VE REALLY LINED UP A PROGRAM THAT'S GOING TO BE FIT FOR PURPOSE, BUT WE JUST CAN'T ANSWER AT THIS TIME.

I DO WANT TO COME BACK TO THE POINT THAT

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208-255-5453 208-920-3543 DRAIBE@HOTMAIL.COM

IF WE CAN GET THEM ALL WORKING AT THE SAME CADENCE, WHICH IS WHAT WE'RE TRYING TO DO HERE, IS TO ALLOW THIS FIRST COHORT TO MOVE AT ROUGHLY THE SAME CADENCE, WE SEE A LOT OF VALUE IN THAT BECAUSE THERE'S A LOT CO-LEARNING AND LEARNING IN THAT SORT OF INITIAL UPTAKE PROCESS, ACCREDITATION, THE CLINICAL RESEARCH ASPECTS OF IT. IF THEY CAN SORT OF WORK WITH EACH OTHER IN A PARTNERED ENVIRONMENT, WE THINK WE CAN GET THAT ONE PLUS ONE EQUALS THREE IN THE VALUE OF THE NETWORK. BUT, LIKE I SAY, THIS IS ONE OF THOSE GREAT CIRM EXPERIMENTS.

CHAIRMAN IMBASCIANI: I THINK PART OF THAT QUESTION WAS THE MANDATE.

DR. LOMAX: I'VE JUST COME BACK TO THE SLIDE TO KIND OF REMIND US OF HOW PROP 14 PUT FORWARD THIS REQUEST OR PUT FORWARD THIS MANDATE IN THE PROPOSITION.

CHAIRMAN IMBASCIANI: YES. GOOD. NO OTHER COMMENTS FROM BOARD MEMBERS OR QUESTIONS FOR GEOFF? WE'LL OPEN IT UP TO MEMBERS OF THE PUBLIC. THERE ARE NONE. OKAY.

SO WE HAVE A REQUEST OF THE BOARD TO -- PUT THE REQUEST BACK UP AGAIN -- TO ALTER THE INFRASTRUCTURE 8 PROGRAM WITH AMENDMENTS THAT GEOFF HAS GONE THROUGH AND APPROVE THE MODIFIED CONCEPT

PLAN. SO I THINK WE CAN GO TO A VOTE.

MR. TOCHER: OKAY. SO I'LL TAKE A VOICE VOTE IN THE ROOM, AND THEN I MUST POLL MEMBERS INDIVIDUALLY ON THE ZOOM. SO ALL THOSE IN THE ROOM IN FAVOR SAY AYE. THOSE OPPOSED NAY. ANY ABSTENTIONS? AND I'LL POLL THE MEMBERS ON THE ZOOM.

MONICA CARSON.

DR. CARSON: AYE.

MR. TOCHER: JUDY CHOU.

DR. CHOU: AYE.

MR. TOCHER: YSABEL DURON.

MS. DURON: AYE.

MR. TOCHER: MARK FISCHER-COLBRIE.

MR. FISCHER-COLBRIE: AYE.

MR. TOCHER: JUDY GASSON.

DR. GASSON: AYE.

MR. TOCHER: JEFF GOLDEN.

DR. GOLDEN: AYE.

MR. TOCHER: RICH LAJARA.

MR. LAJARA: AYE.

MR. TOCHER: PAT LEVITT.

DR. LEVITT: YES.

MR. TOCHER: HALA MADANAT. CHRIS MIASKOWSKI.

DR. MIASKOWSKI: YES.

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MR. TOCHER: MARV SOUTHARD.
DR. SOUTHARD: YES.
MR. TOCHER: KAROL WATSON.
DR. WATSON: YES.
MR. TOCHER: KEVIN XU.
MR. XU: AYE.
MR. TOCHER: AND KEITH YAMAMOTO.
DR. YAMAMOTO: YES.
MR. TOCHER: GREAT. THANK YOU VERY MUCH. THAT MOTION CARRIES.
CHAIRMAN IMBASCIANI: THAT CARRIES. THANK YOU, SCOTT. SO GOOD. HAPPY TO MOVE ON TO AGENDA ITEM NO. 10, WHICH WILL TAKE US UP TO OUR LUNCH BREAK. THIS IS THE SECOND INSTALLMENT OF A NEW AND REGULARLY OCCURRING AGENDA ITEM THAT FEATURES RESEARCHERS AND PATIENTS WHO HAVE BENEFITED FROM CIRM'S ACTIVITIES. AND TO LEAD THE DISCUSSION, OUR DIRECTOR OF COMMUNICATIONS, AMY ADAMS.
MS. ADAMS: THANK YOU, EVERYONE. I'M EXCITED TO ANNOUNCE TWO SPEAKERS TODAY. YOU'RE FIRST GOING TO HEAR FROM DR. JAMES DEKLOE, WHO IS DISTINGUISHED PROFESSOR OF BIOTECHNOLOGY AND BIOMANUFACTURING AT SOLANO COLLEGE, WHICH IS IN FAIRFIELD. HE RUNS OUR COMPASS PROGRAM IN FAIRFIELD, AND THEY'VE DONE SOME INCREDIBLY

INNOVATIVE STUFF THERE.

JIM WILL INTRODUCE SOME STUDENTS FROM THE PROGRAM WHO WILL ALSO PRESENT. AND I JUST WANT TO POINT OUT JIM IS SO DEDICATED TO THIS PROGRAM. AND TALKING ABOUT IT WITH ALL OF YOU, HE TOOK A RED EYE. IN THIS FLIGHT ENVIRONMENT, HE TOOK A RED EYE TO GET HERE. SO I'M JUST INCREDIBLY GRATEFUL FOR THAT.

FOLLOWING THAT PRESENTATION, YOU'RE GOING TO HEAR FROM DIANA FARMER. SHE IS SURGEON IN CHIEF AT THE CHILDREN'S HOSPITAL OF THE UNIVERSITY OF CALIFORNIA DAVIS AND CHIEF OF PEDIATRIC SURGERY AT SHRINER'S CHILDREN'S NORTHERN CALIFORNIA.

SHE'S GOING TO PRESENT RESULTS FROM HER WORK DEVELOPING A STEM CELL TREATMENT FOR SPINA BIFIDA. CIRM HAS SUPPORTED SEVERAL STAGES OF HER WORK AND IS CURRENTLY SUPPORTING A CLINICAL TRIAL.

SO, JIM, I'LL TURN IT OVER TO YOU.

(THE CLOSER TO CURES PRESENTATIONS WERE THEN HEARD, NOT REPORTED NOR HEREIN TRANSCRIBED.)

(A RECESS WAS TAKEN.)

CHAIRMAN IMBASCIANI: WE'RE COMING BACK INTO LIVE SESSION HERE. THANK YOU, EVERYONE. I HOPE YOU ENJOYED YOUR LUNCH.

WE ARE GOING TO JUST JUMP AHEAD

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TEMPORARILY TO AGENDA ITEM NO. 12. WE'LL COME BACK TO 11 IN A MINUTE. THIS IS THE CONSIDERATION OF AN AMENDMENT TO OUR WARRANT CO-FUNDING PROGRAM. THE DISCUSSION WILL BE LED CHIEF COUNSEL RAFAEL AGUIRRE-SACASA. RAFAEL.

MR. AGUIRRE-SACASA: THANK YOU, DR. IMBASCIANI. GOOD AFTERNOON, EVERYONE. MY NAME IS RAFAEL AGUIRRE-SACASA, AND I'M THE GENERAL COUNSEL. AND I'M HERE TO UPDATE YOU ON THE WARRANT PROGRAM. I'D ALSO LIKE TO THANK DR. SHYAM PATEL AND J.T. WHO'VE ALSO BEEN HELPING ME WITH THE STRUCTURE AND THE UPDATES HERE TO THIS PROGRAM.

WHAT WE'RE TALKING ABOUT TODAY IS A TARGETED REFINEMENT TO THE CIRM WARRANT PROGRAM WHICH WAS APPROVED BY THE ICOC IN DECEMBER OF 2023. BEFORE WE GET TO THE SLIDES, I WANT TO GIVE YOU A QUICK UPDATE ON THE STATUS OF THE PROGRAM.

AT A HIGH LEVEL, THE PROGRAM IS WORKING AS IT'S INTENDED. IT PERMITS COMPANIES TO SATISFY THEIR CO-FUNDING OBLIGATIONS THROUGH WARRANTS INSTEAD OF CASH. AND THIS ALLOWS CIRM TO PARTICIPATE IN THE UPSIDE OF ANY SUCCESSFUL PROGRAMS.

WHERE WE'VE ENCOUNTERED CHALLENGES IS WITH EARLY STAGE COMPANIES THAT HAVE NOT YET COMPLETED A

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PRICED EQUITY FINANCING. IN THOSE CASES THE CURRENT STRUCTURE USES AN ASSIGNED PLACEHOLDER VALUATION OF $1 WHICH WE FOUND CAN CREATE DISTORTIONS AND MAKE PARTICIPATION IN THE WARRANT PROGRAM MORE DIFFICULT.

SO WHAT WE'RE PROPOSING TODAY IS A NARROW, PRACTICAL FIX BY INTRODUCING A SAFE WARRANT HYBRID. WE'LL TALK ABOUT SAFE IN A MINUTE. AND THAT DEFERS VALUATION UNTIL THERE'S A REAL MARKET FINANCING WHICH PRESERVES THE SAME UPSIDE FOR CIRM IN THE FUTURE. NOW TO THE SLIDES.

OUR ORIGINAL CO-FUNDING WARRANT STRUCTURE, APPLICANTS COULD, AGAIN, SATISFY THE CO-FUNDING REQUIREMENT BY ISSUING WARRANTS TO CIRM IN LIEU OF CASH. AS A POINT OF REFERENCE, UNDER STATE LAW, WE, CIRM, CANNOT HOLD EQUITY. AND THAT'S WHY WE STRUCTURED THIS AS A WARRANT PROGRAM. THE CORE STRUCTURE IS THAT CIRM RECEIVES A STOCK WARRANT EQUAL TO THE WAIVED CO-FUNDING AMOUNT, AND THE SHARES ARE DETERMINED BY DIVIDING THE CO-FUNDING AMOUNT BY A REFERENCE PRICE.

FOR THE REFERENCE PRICE DETERMINATION, IT DEPENDS ON THE CAPITALIZATION AND STRUCTURE OF THE APPLICANT COMPANY. IF PREFERRED FINANCING EXISTS, WE RECEIVE A PREFERRED WARRANT WITH A REFERENCE PRICE EQUAL TO THE PRICE PER SHARES OF THE MOST

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RECENT PREFERRED STOCK FINANCING. FOR PUBLIC COMPANIES, PRETTY STRAIGHTFORWARD. COMMON WARRANT, REFERENCE PRICE IS THE AVERAGE OF THE CLOSING BID ASK PRICES OR THE CLOSING PRICE FOR THE TEN-DAY TRADING PERIOD ENDING FIVE TRADING DAYS BEFORE THE ISSUE DATE. IN BOTH THOSE CASES, IT'S EASY TO DETERMINE THE REFERENCE PRICE.

IN THE LAST SITUATION WHERE THERE IS NO PREFERRED FINANCING, UNDER THE CURRENT STRUCTURE WE RECEIVE A COMMON WARRANT, AND THE REFERENCE PRICE IS THE DEFAULT $1 PER SHARE SUBJECT TO ADJUSTMENT AND NEGOTIATION. THE OTHER KEY WARRANT TERMS ARE AN EXERCISED PRICE OF A PENNY PER SHARE, TEN-YEAR TERM FOR THE WARRANT, ANTI-DILUTION PROTECTIONS THAT NOW AUTOMATICALLY EXERCISES UPON IPO AND ACQUISITION, WHICH ARE PRETTY STANDARD FOR WARRANT TERMS.

AS I MENTIONED, THE IMPLEMENTATION CHALLENGE HAS ARISEN WHEN COMPANIES HAVE NOT YET COMPLETED A PRICED EQUITY FINANCING, AND THAT MAKES IT HARD TO DETERMINE THE RIGHT REFERENCE PRICE UNDER THE ORIGINAL WARRANT STRUCTURE. WE INITIALLY USED A $1 REFERENCE PRICE, WHICH WE HAVE FOUND, AND WE'VE HEARD FROM OUR APPLICANTS, SO THIS IS BASED ON FEEDBACK THAT WE HAVE RECEIVED, THAT IT RAISES ARBITRARY EVALUATION ASSUMPTIONS WHICH CAN CREATE

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POTENTIAL DISTORTIONS TO OWNERSHIP PERCENTAGES AND OBVIOUSLY CAN CREATE UNCERTAINTY FOR FUTURE INVESTORS.

TO ADDRESS THESE VALUATION CHALLENGES, WE ARE PROPOSING A WARRANT PROGRAM THAT INTRODUCES THE SAFE WARRANT HYBRID STRUCTURE, WHICH WE'LL TALK ABOUT IN A MINUTE. AND, AGAIN, THIS WOULD ONLY APPLY TO COMPANIES WHERE A PUBLIC MARKET DOES NOT EXIST FOR ITS COMMON STOCK AND NO SHARES OF PREFERRED STOCK HAVE BEEN ISSUED. ANY QUESTIONS SO FAR? OKAY. WE'LL CONTINUE WITH THE SECURITIES LAW UPDATE.

THE UPDATED STRUCTURE, TO ADDRESS THESE VALUATION CHALLENGES, WE'RE PROPOSING THE WARRANT PROGRAM INTRODUCE A SAFE WARRANT STRUCTURE. THE SAFE STANDS FOR A SIMPLE AGREEMENT FOR FUTURE EQUITY. HOW THIS WORKS IS THAT WE WOULD RECEIVE A SAFE WARRANT -- WE WOULD ENTER INTO A SAFE AGREEMENT WITH THE APPLICANT. THE SAFE WOULD BE CONVERTIBLE INTO WARRANTS EQUAL TO THE WAIVED CO-FUNDING AMOUNT, SO SIMILAR TO WHAT WE HAD BEFORE. THE SAFE WOULD CONVERT INTO PREFERRED STOCK WARRANT.

NOW, THE DIFFERENCE HERE IS THAT THE WARRANT SHARES WOULD BE DETERMINED ON THE PREFERRED FINANCING ROUND, WHENEVER THAT HAPPENS AT A FUTURE

DATE. PART OF THAT IS THAT WE, CIRM, WOULD GET AN ECONOMIC EQUIVALENT OF A 20-PERCENT DISCOUNT TO NEW INVESTORS ON THE SALES PRICE, GIVING US 20 PERCENT MORE RETURN ON THE SHARES OBVIOUSLY.

THERE WOULD ALSO BE A SIDE LETTER PROVIDING FOR INFORMATION RIGHTS TO MAKE SURE THAT CIRM IS APPRISED OF ALL SITUATIONS AND INFORMATION THAT APPLY TO THE APPLICANT. AND THERE'S ALSO A MOST FAVORED NATION CLAUSE THAT MEANS THAT WE WOULD GET THE SAME TERMS AS OTHER INVESTORS IF THEY ARE BETTER TERMS THAN WHAT HAPPENED AT THE MOST RECENT FINANCING. SO WE ARE PROTECTED MOVING FORWARD.

THE KEY ADVANTAGES IS IT ALLOWS START-UPS WITHOUT A PRICED EQUITY ROUND TO PARTICIPATE IN THE PROGRAM. WE'VE RECEIVED DIRECT FEEDBACK FROM SOME APPLICANTS THAT THEY WOULD NOT BE ABLE TO PARTICIPATE UNDER THE CURRENT STRUCTURE BECAUSE THEY FEEL IT WOULD CAUSE THEM PROBLEMS IN THE INVESTOR COMMUNITY.

USING THE SAFE PRICE MECHANICS, WHICH ARE WIDELY USED IN THE VALLEY AND ACROSS THE COUNTRY, THIS ALIGNS WITH VENTURE MARKET PRACTICES. OF COURSE, IT STILL PRESERVES OUR UPSIDE PROTECTION AS WE WOULD HAVE HAD WITH THE ORIGINAL WARRANT STRUCTURE. AND MOST IMPORTANTLY, IT AVOIDS A LOT OF

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FRICTION IN THE WHOLE PROCESS BECAUSE IT AVOIDS THE NEED TO ASSIGN AN ARBITRARY VALUATION TO EARLY STAGE COMPANIES WHICH CAN CREATE THOSE DISTORTIONS I'VE TALKED ABOUT.

SO TO SUMMARIZE, THE UPDATED STRUCTURE MAINTAINS OUR ABILITY TO CAPTURE VALUE, IT PRESERVES OUR WARRANT-BASED UPSIDE PARTICIPATION, SIMPLIFIES THE PARTICIPATION FOR EARLY STAGE COMPANIES BY DEFERRING VALUATION UNTIL REAL FINANCING OCCURS, AND, FINALLY, IT ALIGNS THE PROGRAM WITH CURRENT VENTURE FINANCING PRACTICES.

AND THEN THE REQUEST IS THAT THE ICOC APPROVE THE PROPOSED SAFE WARRANT STRUCTURE FOR USE IN APPLICABLE FUNDING PROGRAMS WHERE A COMPANY HAS NOT YET COMPLETED A PRICED EQUITY FINANCING. I'M HAPPY TO ANSWER ANY QUESTIONS AT THIS TIME.

CHAIRMAN IMBASCIANI: THANK YOU, RAFAEL. I'M GOING TO MOVE THAT THE BOARD ACCEPT THE REQUEST, THAT WE APPROVE THIS CHANGE TO THE SAFE WARRANT STRUCTURE. I'M MAKING A MOTION, YES.

VICE CHAIR BONNEVILLE: SECOND.

CHAIRMAN IMBASCIANI: SO THAT WILL OPEN THE FLOOR TO DISCUSSION. THANKS FOR THAT LUCID PRESENTATION. I KNOW THIS IS DENSE MATERIAL. ANYONE HAVE ANY QUESTIONS OF THE -- J.T.

DR. THOMAS: I WANT TO THANK RAFAEL AND SHYAM FOR PUTTING THIS TOGETHER AND FOR SORTING OUT THAT THIS IS SOMETHING THAT WE SHOULD BE DOING. THIS IS JUST FOR MEMBERS OF THE BOARD. THIS IS AN EXTREMELY CONVENTIONAL INSTRUMENT IN THE FINANCING SPACE FOR EARLY STAGE COMPANIES AND SOMETHING THAT'S -- WE'RE NOT REINVENTING ANYTHING HERE. WE'RE JUST SORT OF TAKING THINGS MORE INTO THE MAINSTREAM. SO STRONGLY ENDORSE THIS.

CHAIRMAN IMBASCIANI: THANK YOU, J.T. SCOTT.

MR. TOCHER: NOT SURE WHERE THE FEEDBACK IS COMING FROM. THE TEAM HAD THE OPPORTUNITY TO PRESENT THIS TO CO-CHAIRS, KIM BARRETT'S ALTERNATE, DON TAYLOR, AND HALA MADANAT, AND WALKED THROUGH IT AS WELL, AND THEY ENDORSED THE APPROACH THAT YOU SEE HERE.

CHAIRMAN IMBASCIANI: OKAY. THAT'S IMPORTANT NEWS. THANK YOU.

MS. MANDAC: HALA HAS HER HAND RAISED.

CHAIRMAN IMBASCIANI: HALA. YES, I SEE IT. HI, HALA. THANK YOU. THE FLOOR IS YOURS.

DR. MADANAT: I HAD MY HAND RAISED. I WAS GOING TO SAY EXACTLY THE SAME THING, THAT WE MET AND BOTH DON AND I AGREED THAT THIS WAS REALLY A GOOD

IDEA. SO THAT'S ALL I WAS GOING TO SAY. THAT'S WHY I LOWERED MY HAND.

MR. AGUIRRE-SACASA: THANK YOU, HALA.

CHAIRMAN IMBASCIANI: ANYONE ELSE HAVE ANY -- QUESTIONS OR COMMENTS FROM ANYONE ELSE? OKAY. MOTION, COMMENT, ANYONE? ANY COMMENTS FROM THE PUBLIC EITHER IN THE AUDIENCE OR REMOTE? YOU DON'T SEE ANY. ALL RIGHT. SCOTT, WE CAN PROCEED TO A VOTE.

MR. TOCHER: ALL THOSE IN THE ROOM IN FAVOR SAY AYE. THOSE OPPOSED SAY NAY. ANY ABSTENTIONS? AND I'LL POLL THE MEMBERS ON THE ZOOM.

MONICA CARSON.

DR. CARSON: AYE.

MR. TOCHER: JUDY CHOU.

DR. CHOU: AYE.

MR. TOCHER: YSABEL DURON.

MS. DURON: YES.

MR. TOCHER: MARK FISCHER-COLBRIE.

MR. FISCHER-COLBRIE: YES.

MR. TOCHER: JUDY GASSON.

DR. GASSON: YES.

MR. TOCHER: JEFF GOLDEN.

DR. GOLDEN: YES.

MR. TOCHER: RICH LAJARA.

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MR. LAJARA: YES.
MR. TOCHER: PAT LEVITT.
DR. LEVITT: YES.
MR. TOCHER: HALA MADANAT.
DR. MADANAT: YES.
MR. TOCHER: CHRIS MIASKOWSKI.
DR. MIASKOWSKI: YES.
MR. TOCHER: MARV SOUTHARD.
DR. SOUTHARD: YES.
MR. TOCHER: KAROL WATSON.
DR. WATSON: YES.
MR. TOCHER: KEVIN XU.
MR. XU: AYE.
MR. TOCHER: AND KEITH YAMAMOTO.
DR. YAMAMOTO: YES.
MR. TOCHER: GREAT. THANK YOU VERY MUCH. THAT MOTION CARRIES.
MR. AGUIRRE-SACASA: THANK YOU, BOARD.
CHAIRMAN IMBASCIANI: THANK YOU, RAFAEL.
WE'RE GOING NOW BACK TO AGENDA ITEM NO. 11. WE'VE DEDICATED A SUBSTANTIAL AMOUNT OF TIME ON THE AGENDA FOR THIS LENGTHY DISCUSSION HERE. THE CONSIDERATION OF PROGRAM PREFERENCES AND GUIDING PRINCIPLES. AND I WOULD LIKE TO INVITE J.T.
DR. THOMAS: I THINK WE'RE GOING TO MARK

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FIRST AND THEN TO ME. MARK WANTED TO GIVE SOME OPENING COMMENTS.

CHAIRMAN IMBASCIANI: OKAY.

MR. FISCHER-COLBRIE: THANK YOU, J.T. JUST AS A REMINDER TO SET THE STAGE A LITTLE BIT, AND I'M SURE J.T. WILL AMPLIFY THIS AS WELL, WE'RE IN AN ENVIRONMENT WHERE, DUE TO LACK OF FUNDING IN BIOTECH AND WITH THE IMPACT OF WHAT'S GOING ON AT NIH AND OTHER FUNDING SOURCES, THERE HAS CONTINUED TO BE A MASSIVE INCREASE IN THE NUMBER OF APPLICATIONS SUBMITTED TO CIRM ACROSS THE BOARD FOR ADVANCING RESEARCH. THAT'S POINT NO. 1.

POINT NO. 2 IS THAT, AS CIRM HAS CONTINUED ITS GOALS OF IMPROVEMENT AND ACCELERATION, THE STRATEGIC ALLOCATION FRAMEWORK THAT'S BEEN IMPLEMENTED THAT HAS BEEN SUCH AN INCREDIBLY STRONG PROCESS BECAUSE OF THE FACT THAT IT IS DERIVED ON DEEP DATA, DEEP THOUGHT, AND ELEMENTS THAT A LOT OF PEOPLE HAVE NOT BEEN ABLE TO CONSIDER IN THE PAST, IT'S ACTUALLY IN MY VIEW WORTHY OF PUBLICATION AS A ROADMAP FOR OTHER ORGANIZATIONS FOR CONSIDERATION.

WITH THOSE TWO ACTIVITIES HAVING KICKED OFF THE ALLOCATION OF FUNDING IN MIND, THAT'S A CONDITION WHERE THE MECHANISMS FOR DETERMINING HOW DO YOU MAKE THE PROPER DECISIONS RELATED TO BOTH THE

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STRATEGIC ALLOCATION FRAMEWORK AND THE VOLUME OF APPLICATIONS COMING IN? AND OUR FIRST ATTEMPT AT THAT WAS CLEARLY BASED ON DOING THE BEST JOB WE COULD TO CREATE COMPLETELY OBJECTIVE CRITERIA THAT WE CALL PREFERENCES THAT HAVE A NUMERICAL SCORE ASSOCIATED WITH THAT; AND, WHEREAS, THAT HAD SOME EFFECT IN TERMS OF ENSURING THAT IT WAS NOT SUBJECT TO DEBATE ABOUT WHAT DO THOSE NUMBERS MEAN AND HOW DOES THAT WORK IN TERMS OF THE CRITERIA THAT WENT INTO THAT?

IT CAUSED A NUMBER OF ISSUES THAT A LOT OF PEOPLE THEN RESPONDED TO AND SAID, HEY, WE NEED TO MAKE CHANGES IN TERMS OF HOW WE MAKE THAT TRIAGE DECISION. WITH THAT IN MIND THEN, YOU WILL SEE IN THE PRESENTATION TWO PRIMARY TOPIC AREAS AROUND THAT. THE FIRST HAS TO DO WITH WHAT WE CALL THE VOLUME CONTROL, WHICH WILL GET COVERED IN DETAIL, AS TO HOW TO MAKE THOSE DECISIONS WITH A FULL SCIENTIFIC REVIEW. THAT IS A REVIEW CYCLE THAT IS A MODIFICATION OF WHAT THE GWG DOES. AS AN INITIAL STEP, IT IS LOOSELY CALLED POSITIVE SELECTION, BUT FOR THE DEEP INSIDE BASEBALL PEOPLE, IT'S NOT THE SAME AS THE POSITIVE SELECTION AS WHAT'S BEEN DONE PREVIOUSLY IN OTHER AREAS IN THE PERSPECTIVE THAT THERE ARE A DEDICATED NUMBER OF PEOPLE WITH

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SCIENTIFIC BACKGROUND WHO HAVE TO REVIEW ALL THE APPLICATIONS. YOU WILL HEAR MORE ABOUT THAT IN THE DECISION PROCESS.

THERE'S A MECHANISM, THEN, AROUND VOLUME CONTROL. THE OTHER ONE IS THE REMOVAL OF THE PREFERENCES, SCORING, AND CRITERIA, BUT RATHER A SHIFT TO WHAT IS CALLED GUIDING PRINCIPLES. AND THAT IS HELPING TO FRAME THE OBJECTIVES OF THE STRATEGIC ALLOCATION FRAMEWORK WITH DIRECTIONS ABOUT HOW TO LOOK AT THINGS. AND SO THE KEY ELEMENTS THAT PEOPLE SHOULD BE TAKING INTO CONSIDERATION AS THE TRIAGING IS BEING DONE ARE TRANSFORMATIONAL ELEMENTS AND OTHER CHARACTERISTICS ALONG WITH A REFRAMING OF THE COMMUNICATION OF THE WORD "AFFORDABILITY" IN THE CONTEXT THAT THAT CAUSED A LOT OF PROBLEMS FOR PEOPLE BECAUSE THE PRESUMPTION WAS AFFORDABILITY JUST MEANT LOW COST.

AND THERE'S AN UPDATE ON THE FRAMING FOR THAT DISCUSSION AROUND ACCESS AND AFFORDABILITY WHERE THE FOCUS IS ON HOW CAN ACCESS BE ACHIEVED WITH THE VIEW OF LOOKING AT ACCESS AS WHAT ARE THE CHARACTERISTICS THAT ARE GOING TO BE HELPFUL FOR SOMEBODY LOOKING AT A CLINICAL TRIAL DESIGN AND OTHER ELEMENTS TO BE ABLE TO ACCELERATE AND ENABLE COMMERCIALIZATION OF THE CLINICAL TRIAL WORK AS

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POSITIVE RESULTS COME IN.

SO WITH THAT IN MIND, YOU WILL HEAR THE SPECIFICS AND THE DETAILS ABOUT HOW THE GUIDING PRINCIPLES AND HOW THE VOLUME CONTROL IS BEING MANAGED. WE'VE HAD FOUR TO FIVE HOURS OF DISCUSSION ON THE SCIENTIFIC COMMITTEE MARCH 5TH AND MARCH 19TH AROUND THIS. THERE'S A VERY STRONG CONSENSUS THAT THERE'S A REAL NEED FOR CHANGING OUR VOLUME CONTROL SYSTEM AND PROCESS, AND THERE'S A STRONG CONSENSUS THAT THE NEW MECHANISMS THEY PROPOSED ARE FULLY SUPPORTED BY THE SCIENCE SUBCOMMITTEE.

SO I WANT TO MAKE SURE TO GET THAT OUT THERE FRONT AND CENTER, THAT WE'RE ALL BEHIND WHAT THE PROPOSALS ARE RELATED TO THIS. THERE WERE A COUPLE OF OPEN ISSUES THAT WE FELT WERE RELATIVELY SMALL IN SCALE FOR FURTHER CONSIDERATION. FOR EXAMPLE, ONE WOULD BE THERE'S A NUMERICAL ELEMENT TO THE SCIENTIFIC REVIEW FOR THE FIRST PASS BEFORE LEADING TO THE FULL GRANT WORKING GROUP REVIEW ON DO YOU LOOK AT A TRUE SCORING SYSTEM, OR DO YOU LOOK AT A RANKING OF THE PROPOSALS THAT THOSE SCIENTISTS ARE REVIEWING? YOU WILL SEE SOME INFORMATION ABOUT THAT AS WELL. SO WE DIDN'T COME TO A FINAL DETERMINATION ON THAT, BUT WE FELT THAT WAS VERY MUCH ON THE MARGIN RELATED TO WHAT THE UNDERLYING PROPOSALS ARE.

SO BASICALLY THE SCIENCE COMMITTEE THEN IS IN FAVOR OF THIS. THERE ARE OTHER NUANCES OF CLARIFICATION OF THE PATIENT ADVOCATE ROLE IN THIS ELEMENT AND OTHER THINGS THAT YOU WILL HEAR IN THE PRESENTATION, BUT THE SCIENCE COMMITTEE IS IN SUPPORT OF THE OVERALL PROPOSAL. AND WE JUST WANTED TO GIVE SOME CHARACTERIZATION OF THAT SO THAT WE DIDN'T NECESSARILY WANT TO GET INTO A LONG, EXTENDED DEBATE ABOUT PARTICULAR WORDING OR OTHER THINGS. BUT I WANT TO ENSURE THAT THERE'S ADEQUATE DISCUSSION FOR THE BOARD TO MAKE SURE THAT THE BIG MOVING PARTS IN HOW THIS IS GOING TO WORK IS UNDERSTOOD. SO WITH THAT, I'LL TURN IT OVER TO J.T. AND I KNOW THE TEAM WILL DO A GREAT JOB, MUCH BETTER THAN I CAN, OF PRESENTING THE INFORMATION GOING FORWARD HERE. SO J.T.

DR. THOMAS: THANKS VERY MUCH, MARK. THAT WAS A VERY GOOD, CONCISE SUMMARY OF MANY THINGS THAT YOU ALL ARE GOING TO HEAR ABOUT TODAY. AND I DON'T HAVE ANY INTRODUCTORY REMARKS THAT COULD DO BETTER THAN THAT OTHER THAN TO NOTE THAT THE RUN OF SHOW THAT YOU ARE GOING TO HAVE, ROSA IS GOING TO START WITH THE PRESENTATION ON THE SWITCH FROM PREFERENCES TO GUIDING PRINCIPLES. GIL WILL FOLLOW THAT WITH A NUMBER OF REMARKS ABOUT VOLUME CONTROL. DR. KELLY

133 HENNA COURT, SANDPOINT, IDAHO 83864
208-255-5453 208-920-3543 DRAIBE@HOTMAIL.COM

SHEPARD WILL -- ACTUALLY, SORRY, AFTER GIL, ROSA WILL COME BACK AND TALK ABOUT HOW THIS SHIFT IN THE GUIDING PRINCIPLES WILL INFORM PROGRAMMATIC DISCUSSION AT THE ARS. THEN AFTER THAT WILL BE DR. KELLY SHEPARD TALKING BRIEFLY ABOUT THE ISSUE OF THE FOCUS OF THE NEXT DISC4. AND THEN, FINALLY, WE'LL CLOSE WITH DR. SHYAM PATEL TALKING ABOUT THE QUESTION OF GOING FROM TWO PDEV ROUNDS A YEAR TO ONE.

SO THAT'S WHAT YOU ARE GOING TO HEAR. ALL OF THIS, OF COURSE, KEEP IN MIND, IS IN OUR NEVER ENDING QUEST TO PRODUCE THE BEST POSSIBLE PRODUCT TO BENEFIT PATIENTS IN THE STATE OF CALIFORNIA. AND WE THINK THAT ALL OF WHAT YOU ARE ABOUT TO HEAR IS A MAJOR STEP FORWARD WITH RESPECT TO ALL OF THE TOPICS TO BE DISCUSSED AS WE PROCEED. SO WITHOUT FURTHER ADO, ROSA.

DR. CANET-AVILES: THANK YOU, J.T. AND THANK YOU, MARK, FOR THE VERY GOOD SUMMARY OF -- AND ONE POINT THAT YOU MADE, YOU'VE MADE IT SEVERAL TIMES, I WANT TO ACKNOWLEDGE IT IS THAT WE SHOULD PUBLISH THE STRATEGIC ALLOCATION FRAMEWORK, THE PROCESS AND THE OUTCOMES AND THE LEARNINGS. THIS IS PART OF THE LEARNINGS. AND I PROMISE YOU WE'LL DO THIS.

SO AS J.T. MENTIONED AND AS MARK MENTIONED, THIS ITEM DEALS WITH THE RESPONSE THAT THE CIRM TEAM HAS AROUND THE DISCUSSION THAT WE HAD ABOUT THE PREFERENCES. THAT STARTED ALREADY IN DECEMBER.

BEFORE I GO INTO THIS, I HAVE TO THANK A LOT OF PEOPLE. SO I WOULD LIKE TO START WITH THANKING THE FULL SCIENCE SUBCOMMITTEE FOR ALL THEIR TIME, SUPPORT, THE DISCUSSIONS, THE EXTRA HOURS BACK AND FORTH THAT HAS BEEN VERY IMPORTANT.

SECONDLY, I WANT TO THANK MY COLLEAGUES, ESPECIALLY DR. SHYAM PATEL -- SHYAM, YOU CAN SAY HI -- BUT SHYAM STEPPED UP TO PRESENT DURING BOTH SCIENCE SUBCOMMITTEES WHEN I WAS NOT AVAILABLE. AND HE'S BEEN A GREAT PARTNER IN CRIME IN DEVELOPING THIS. I ALSO WANT TO THANK THE TWO OTHER LEADS OF TEAMS, DR. KELLY SHEPARD, WHO LEADS DISCOVERY AND EDUCATION, AND DR. JOE GOLD, WHO LEADS THE CLINICAL DEVELOPMENT TEAM, FOR THEIR JOINED FORCES IN DEVELOPING THESE ANSWERS AND GOING THROUGH GUIDING PRINCIPLES, ETC. DR. SARA TAYLOR AND DR. LIZ NOBLIN, AS YOU CAN SEE, THERE IS A 50-PAGE SUMMARY AND MEMO THAT REQUIRES A LOT OF COORDINATION. AND I WANT TO THANK THEM FOR WRANGLING EVERYBODY AS WELL. MY PARTNER IN CRIME IS GIL, DR. GIL SAMBRANO, WHO WE

ARE GOING TO TAG TEAM IN THIS PRESENTATION, BUT HIM AND HIS TEAM ALSO I WANT TO THANK. MY COLLEAGUES AT THE EXECUTIVE TEAM AND REALLY EVERYBODY ELSE AND OBVIOUSLY J.T. FOR HIS LEADERSHIP.

AM I MISSING ANYBODY? HOPEFULLY NOT.

SO WITHOUT FURTHER ADO, I'M JUST GOING TO GET STARTED. SO THE FIRST THING I WANT TO START MENTIONING IS THAT WE ARE NOT STEPPING AWAY FROM, AS MARK SAID, FROM THE STRATEGIC ALLOCATION FRAMEWORK. WE ARE ACTUALLY PROVIDING A REFINEMENT OF HOW WE IMPLEMENT THIS.

AS J.T. NOTED, IN THE LAST FEW MONTHS THE BOARD HAS PROVIDED EXTENSIVE FEEDBACK AROUND THE PREFERENCES AND THE PREFERENCES-BASED EVALUATION PROCESS. SOME OF THE THINGS THAT WE'VE HEARD IS THAT WE CANNOT FUND ALL PROJECTS AND THAT THE USER PREFERENCES CAN FILTER AND EXCLUDE SOME MODALITIES, CLASSES, OR INNOVATIVE PROJECTS, AND THAT APPLICATIONS AS A CONSEQUENCE ARE BEING TRIAGED WITHOUT ANY SCIENTIFIC EVALUATION. THESE ARE SOME OF THE THINGS THAT WE'VE HEARD.

WE'VE ALSO GOTTEN FEEDBACK THAT WE SHOULD TAILOR THE GUIDING PRINCIPLES FOR EACH PROGRAM. AND ONE OF THE THINGS THAT WE HEARD WAS THE BEGINNING IN JANUARY WE PRESENTED THE START OF THE GUIDING

PRINCIPLES. AND IN THE WORK THAT WE'VE DONE IN PARTNERSHIP WITH THE SCIENCE SUBCOMMITTEE, WHAT WE'VE DONE IS WE'VE BEEN REFINING THEM TO ADAPT TO EACH ONE OF THE PROGRAMS.

AND SPECIFICALLY, WHAT MARK WAS MENTIONING ABOUT ACCESS AND AFFORDABILITY, ONE OF THE ITEMS THAT CAME OUT OF THE DISCUSSION ON MARCH 5TH THAT WENT INTO MARCH 19 WAS THE FOCUS ON PDEV AND CLIN2, THAT THEY SHOULD -- THAT THERE WAS A TERMINOLOGY ISSUE, THAT WE SHOULD FOCUS ON ACCESS RATHER THAN AFFORDABILITY WITH CLEAR EXPECTATIONS FOR APPLICANTS, STAGE-APPROPRIATE EXPECTATIONS. RIGHT.

AND THEN THERE WERE CONCERNS AROUND THE GUIDING PRINCIPLES AND PREFERENCES FOR DISCOVERY PROGRAMS. THE MESSAGE WAS THAT WE NEED TO BE SPECIFIC TO THE DISCOVERY. AND, AS YOU WILL SEE, WE'VE BEEN SPECIFIC. AND THEN, AS YOU CAN SEE, MORE TRANSPARENCY AND STRONGER COMMUNICATION OF PREFERENCES NEEDED. MY COLLEAGUE AMY ADAMS HAS BEEN AT THE HELM NOW FOR THE PAST -- IS IT SIX MONTHS, AMY? -- AND SHE'S LIKE BREAKING GROUND. AS YOU CAN SEE WITH THE MEMO AND ALL THE LETTERS AND EVERYTHING, THERE IS ACTUALLY A COMMUNICATIONS PLAN AS WELL. AND WE WILL BE -- DEPENDING ON WHAT COMES OUT OF TODAY, THERE WILL BE COMMUNICATION TO THE

APPLICANTS AND POTENTIAL APPLICANTS IN THE UPCOMING CHANGES.

AND THEN THE REQUEST FOR DATA TO INFORM THE DISCUSSION. THE MEMO HAS APPENDICES THAT CONTAIN THE DATA OF HOW THE PREFERENCES APPLY TO THE PROGRAMS FOR WHAT WERE THE OUTCOMES OF APPLYING THE PREFERENCES. AND THERE'S ALSO PORTFOLIO ANALYSIS IN THAT MEMO.

SO AS A RECAP OF THE PREFERENCES, THE PREFERENCES FLOAT FROM THE GUIDING PRINCIPLES. AND THE GUIDING PRINCIPLES ARE BASICALLY HOW -- THEY DELINEATE HOW WE WILL FUND -- WHAT OUR PROGRAMS WILL FUND. BASICALLY A GUIDING PRINCIPLE WILL TELL US WHETHER HOW ARE WE GOING TO GET TO ACCELERATE LATER STAGE CLINICAL TRIALS IN OUR PORTFOLIO OR TO DISCOVER NOVEL MECHANISMS. THE WAY THAT WE DO THAT IS THROUGH SHAPING OUR PROGRAMS THROUGH THESE GUIDING PRINCIPLES. RIGHT.

SO WHEN WE PRESENTED THE PREFERENCES, THEY HAD TWO GOALS. THERE WERE TWO SEPARATE OBJECTIVES. THE FIRST ONE IS THAT THEY WERE GOING TO HELP US TO PRIORITIZE WHAT WE FUND. AND THE SECOND WAS THAT THEY WERE GOING HELP US CONTROL VOLUME AS WELL. HOWEVER, IT KIND OF BACKFIRED BECAUSE THE VOLUME CONTROL LED TO SOME LIMITATIONS, AS WE PRESENTED AND

WHAT WE HEARD, BY APPLYING PRIOR TO SCIENTIFIC REVIEW, THERE WAS SOME UNWANTED FILTERING THAT HAPPENED, AND IT'S REFLECTED IN THE ANALYSIS OF THE DATA THAT WE GOT THROUGH APPLYING THE PREFERENCES.

AND THEN BY HAVING PREFERENCES, WE WERE ALSO GOING TO REQUIRE ITERATIVE CYCLE, TWO-CYCLE CHANGES WHICH WAS NOT GOING TO BE FEASIBLE IN THE LONG TERM.

SO WHAT WE PROPOSE IS TO REMOVE THE PREFERENCES THEMSELVES AND ALSO AS THEY APPLY TO VOLUME CONTROL MEASURE. INSTEAD, THE INTENT IS TO GO BACK TO THE GUIDING PRINCIPLES, WHICH WE HAVE ALWAYS BEEN IN THE BACKGROUND SHAPING OUR STRATEGY. WE JUST NEVER LIKE SPECIFICALLY SPOKE ABOUT THEM IN THE WAY THAT WE ARE TALKING ABOUT TODAY.

SO THE GOAL TODAY IS TO ENSURE THAT THE BOARD HAS AGREEMENT ON HOW THESE PRINCIPLES SHAPE WHAT WE FUND FOR EACH OF THE PROGRAMS AND HOW DO THEY APPLY AT EACH STEP OF THE APPLICATION LIFE CYCLE. THROUGHOUT THE PRESENTATION TODAY WITH GIL AND I, WE ARE GOING TO REFERENCE TO THE STEPS IN THIS SLIDE, THE VOLUME CONTROL, THE MERIT REVIEW, AND THE FUNDING DECISIONS. THE GUIDING PRINCIPLES ARE EMBEDDED IN EACH ONE OF THE STEPS, AND THE PRESENTATION IS REALLY ABOUT HOW ARE WE APPLYING

THESE GUIDING PRINCIPLES IN EACH STEP.

SO JUST FOR A REFERENCE IN TERMS OF THE TERMINOLOGY, I WANT TO GO THROUGH EACH ONE OF THE STEPS. THE VOLUME CONTROL STEP FOCUSES AS WELL AS REDUCES THE NUMBER OF APPLICATIONS TO ALLOW MEANINGFUL SCIENTIFIC REVIEW FOR EACH ONE OF THESE PROGRAMS, THE DISC4, THE PDEV, AND THE CLIN2.

THE SECOND STEP, THE MERIT REVIEW, IS THAT ONCE THOSE APPLICATIONS HAVE BEEN FORWARDED TO SCIENTIFIC REVIEW, THE GRANTS WORKING GROUP WILL REVIEW THOSE APPLICATIONS AND WILL PROVIDE RECOMMENDATIONS TO THE BOARD.

AND THE THIRD STEP IS HOW THE BOARD MAKES THOSE FUNDING DECISIONS BASED ON THE RECOMMENDATIONS FROM THE GRANTS WORKING GROUP, BUT ALSO FROM PROGRAMMATIC FACTORS THAT WILL BE PROVIDED TO THE BOARD. AND OTHER INFORMATION LIKE BUDGET AVAILABLE, ETC., AS YOU'VE SEEN TODAY IN THE DISC4, WE HAD TO MAKE SOME TOUGH DECISIONS. RIGHT.

SO TODAY WE ARE GOING TO GO THROUGH EACH ONE OF THE STEPS AND DISCUSS HOW THE GUIDING PRINCIPLES HELP US SHAPE WHAT WE FUND.

SO WE ARE SEEKING TODAY FROM THE BOARD TWO THINGS. THE FIRST ONE IS FEEDBACK AS WELL AS AGREEMENT ON WHAT WE SHOULD FUND FOR EACH ONE OF

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THESE THREE PROGRAMS, THE DISC4, THE PDEV, AND THE CLIN2. EFFECTIVELY WHAT ARE THE GUIDING PRINCIPLES UNDERLYING THESE PROGRAMS? AND WE ARE GOING TO PRESENT THEM FOR EACH ONE OF THE PROGRAMS.

SECONDLY, WE ARE SEEKING BOARD FEEDBACK ON ENSURING THAT THE GUIDING PRINCIPLES ARE APPLIED BY THE RIGHT PARTY WITH THE RIGHT INFORMATION AND AT THE RIGHT TIME. AND THEN AS J.T. MENTIONED, WE ARE GOING TO HAVE SOME UPDATES THAT ARE SEPARATE FROM THESE GUIDING PRINCIPLES DISCUSSION WITH REGARDS TO THE DISC4 AND THE PDEV PROGRAM THAT WILL BE PRESENTED BY OUR COLLEAGUES.

SO I'M GOING STOP IN THE MIDDLE AS WE ARE PRESENTING. AND IF THERE ARE QUESTIONS, PLEASE FEEL FREE TO INTERRUPT ME AS I'M PRESENTING. BEFORE WE GO AND JUMP RIGHT INTO THE GUIDING PRINCIPLES FOR PDEV AND CLIN2, WHICH IS THE NEXT SLIDE, WE ARE GOING TO JUST GOING JUMP RIGHT IT, THOSE PROGRAMS ARE THE ONES THAT MOVE THERAPIES FROM PRECLINICAL UP TO CLINICAL DEVELOPMENT AND HOPEFULLY COMMERCIALIZATION EVENTUALLY.

BUT BEFORE WALKING THROUGH THEM, JUST A LITTLE BIT OF FRAMING. THE CELL AND GENE THERAPY FIELD HAS MADE REAL PROGRESS WITH THE FIRST GENERATION OF CELL AND GENE THERAPIES OUT IN THE

MARKET. WE HAVE CAR-T THERAPIES, WE HAVE AV THERAPIES LIKE ZOLGENSMA AND LUXTURNA, AND WE ALSO HAVE GENE-MODIFIED CELL THERAPIES FOR SICKLE CELL DISEASE. RIGHT.

ONE OF THE THINGS THAT WE'VE LEARNED, AND DR. FARMER WAS ALSO TALKING ABOUT THAT, IS THAT THESE THERAPIES, WE ARE LEARNING NOW THERE ARE ISSUES WITH ACCESS IN TERMS OF MANUFACTURABILITY AND OTHER ISSUES THAT ARE PRECLUDING SOMETIMES FROM MAXIMIZING THE ACCESS TO THESE THERAPIES FROM PATIENTS. SO WE DO NEED TO TAKE THIS INTO ACCOUNT, AND THAT WILL BE REFLECTED IN THE GUIDING PRINCIPLES. AND THIS COMMENT CAME FROM THE MARCH 19TH DISCUSSION IN TERMS OF MAKING SURE WE DON'T CONFLATE ACCESS AND AFFORDABILITY, THAT ACCESS IS VERY NECESSARY AND WE HAVE TO TAKE IT INTO ACCOUNT.

SO GIVEN WHAT I JUST MENTIONED ABOUT THE OVERALL LANDSCAPE OF THE CELL AND GENE THERAPIES, THE GUIDING PRINCIPLES FOR THE PDEV PORTFOLIO AND THE CLIN2 PORTFOLIO ARE VERY SIMILAR IN SCOPE AS YOU CAN SEE. WE BELIEVE THAT OVERALL, AND THAT'S WHAT I WAS MENTIONING THIS MORNING, FOR THE PDEV PORTFOLIO AND THE CLIN2, THE THERAPIES THAT WE FUND SHOULD OFFER THE POTENTIAL FOR TRANSFORMATIVE PATIENT OUTCOMES. AND SPECIFICALLY, ON THE PDEV SIDE, THEY

SHOULD BE LEVERAGING CUTTING EDGE THERAPEUTIC TECHNOLOGIES TO SERVE THAT PURPOSE OF TRANSFORMING THESE PATIENT OUTCOMES.

ACROSS THE PORTFOLIO WE EXPECT ALSO THAT PROJECTS TO ALSO LEARN FROM THIS FIRST GENERATION OF CGT BY TAKING PRACTICAL, STAGE-APPROPRIATE STEPS TO ADDRESS PATIENT ACCESS BARRIERS. THAT'S THE SECOND GUIDING PRINCIPLE. AND THAT MEANS THAT THEY NEED TO TAKE DELIBERATE STAGE-APPROPRIATE STEPS TO ADDRESS THOSE BARRIERS RATHER THAN TREATING THEM AS AN AFTERTHOUGHT.

CONSISTENT WITH OUR PATIENT ACCESS FRAMEWORK AND REVIEW PROCESSES, THIS ALSO INCLUDES CHOICES FOR THERAPEUTIC DESIGN, DEVELOPMENT STRATEGY, AND CLINICAL PLANNING THAT MAY AFFECT THE ABILITY OF PATIENTS TO ULTIMATELY RECEIVE THESE THERAPIES.

AND LASTLY, THE THERAPIES, AS THE MANDATE OF OUR PROPOSITION MANDATE MAKES IT, THEY NEED TO BROADLY ADDRESS BOTH PREVALENT AND RARE DISEASES AFFECTING CALIFORNIANS.

I'M GOING TO STOP HERE FOR A SECOND IN CASE THAT THERE ARE ANY COMMENTS OR QUESTIONS WITH REGARDS TO PDEV, CLIN2. AND I DON'T KNOW IF, MARK, IF YOU WANT TO MAKE ANY COMMENTS.

MR. FISCHER-COLBRIE: PLEASE CONTINUE. THAT'S EXCELLENT.

MR. TOCHER: KEITH YAMAMOTO HAS A QUESTION.

DR. CANET-AVILES: KEITH. DR. YAMAMOTO.

DR. YAMAMOTO: SORRY. ON THE THIRD ONE, I WONDER IF YOU WANT TO SAY BROADLY ADDRESS PREVALENT OR RARE DISEASES AFFECTING CALIFORNIANS. I DON'T KNOW IF YOU WANT TO ASK THE APPLICANTS TO COME FORWARD WITH IDEAS THAT WOULD ADDRESS BOTH PREVALENT AND RARE.

DR. CANET-AVILES: THANK YOU, DR. YAMAMOTO. ACTUALLY, THE GUIDING PRINCIPLE REFERS TO THE PORTFOLIO. IT'S NOT SO MUCH AN INDIVIDUAL APPLICATION. SO WHAT THE GUIDING PRINCIPLE IS REFERRING TO IS THAT CIRM, WHAT WE WANT TO FUND, WE DO NOT REMOVE EITHER/OR. WE WILL FUND BOTH TYPES OF DISEASES BECAUSE BOTH TYPES, RARE AND PREVALENT, DO AFFECT CALIFORNIA POPULATION. MAYBE I WASN'T EXPLICIT. SORRY ABOUT THAT.

DR. YAMAMOTO: THAT'S GOOD. THANKS.

DR. CANET-AVILES: DR. DULIEGE.

DR. DULIEGE: FIRST OF ALL, THANK YOU. IT'S ACTUALLY VERY INTERESTING TO HAVE THIS DIALOGUE. AND THANK YOU FOR ALL THE WORK THAT WENT

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TO THAT.

CAN YOU OUTLINE WHAT'S DIFFERENT IN WHAT YOU'RE PROPOSING VERSUS THE UNDERLYING PHILOSOPHY THAT THE CIRM ALWAYS HAS HAD TO FUND CUTTING-EDGE SCIENCE TO IMPROVE ACCESS TO PATIENTS? WHAT'S SPECIFICALLY NEW IN THESE PRINCIPLES?

DR. CANET-AVILES: I THINK IT'S THE WAY THAT WE ARE APPLYING AND IMPLEMENTING THIS. THE PHILOSOPHY WAS THERE. BUT I BELIEVE THAT WHEN THE RUBBER HITS THE ROAD, IT'S IN THE WAY THAT WE IMPLEMENT IT THROUGH OUR PROGRAMS. SO WHAT'S SPECIFIC NOW IS THAT, FOR EXAMPLE, AT THE VOLUME CONTROL, AS DR. SAMBRANO WILL EXPLAIN, WE HAVE DEVELOPED A SELECTION CRITERIA THAT DERIVE DIRECTLY FROM THESE GUIDING PRINCIPLES. AND THEY HELP THE GRANTS WORKING GROUP REVIEW DELINEATE WHAT WILL MAKE -- GET THROUGH TO REVIEW, RIGHT, OF ALL THE AWARDS.

FOR THE REVIEW CRITERIA, WE'VE ALWAYS HAD THE REVIEW CRITERIA BASED ON THOSE GUIDING PRINCIPLES AND THEY HAVEN'T CHANGED. WE'VE REFINED A LITTLE BIT BECAUSE WE ARE NOT ADDING -- THERE WAS A WHOLE NOMENCLATURE TERMINOLOGY BETWEEN CONFLATING ACCESS AND AFFORDABILITY AND NOW IT'S BEEN REFINED.

AND THEN AT THE ARS, YOU JUST ASKED THE

KEY QUESTION, ANNE-MARIE, BECAUSE IT'S WHAT WE ARE GOING TO GO THROUGH, BUT AT THE ARS WE ARE GOING TO BE MORE EXPLICIT AND TRANSPARENT IN THE WAY THAT WE PROVIDE THE RECOMMENDATIONS TO THE ARS THAT HIT THOSE GUIDING PRINCIPLES.

DOES THAT ANSWER YOUR QUESTION?

DR. DULIEGE: YEAH.

DR. CANET-AVILES: SO I WILL GO NOW TO THE DISC4. SO DISC4 OPERATES UNDER DIFFERENT STRUCTURAL LOGIC. IT IS PART OF OUR DISCOVERY ENGINE WHICH LEADS TO ELUCIDATING DISEASE MECHANISMS AND SEEDING THE FIELD WITH NEW PATHWAYS, DISCOVERING NEW TARGETS AND BIOMARKERS. SO THE GUIDING PRINCIPLES REFLECT THAT DESIGN. THE DISC4 PORTFOLIO IS INTENDED TO CREATE MULTIDISCIPLINARY RESEARCH APPROACHES THAT INTEGRATE DIVERSE SOURCES OF EVIDENCE, DIFFERENT COMPUTATIONAL BIOLOGY, CLINICAL DATA, ANIMAL MODEL DATA. THAT'S WHAT WE MEAN BY THAT. THAT THEY INNOVATE THROUGH COLLABORATION NETWORK SYNERGY AND DATA LEVERAGE. AND ULTIMATELY, THE GUIDING PRINCIPLE ALSO REFLECTS THE MANDATE OF OUR PROPOSITION THAT HAS BEEN MATERIALIZED THROUGH THE NEURO TASK FORCE AS WELL AS OTHER ORGANIZATIONAL PRIORITIES THAT WE MIGHT FIND AND WE LEFT IT AS A MORE OPEN THING THERE.

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SO DISC4 PRINCIPLES ARE MORE ABOUT CATALYZING THE ECOSYSTEM LEVEL IMPACT WHICH IS A DIFFERENT TYPE OF APPROACH.

I WILL STOP HERE BECAUSE WE ARE GOING TO BE SWITCHING GEARS A LITTLE BIT TO FOCUS ON ENSURING THAT THE GUIDING PRINCIPLES ARE APPLIED TO THE RIGHT PARTY WITH THE RIGHT INFORMATION AND AT THE RIGHT TIME. SO BEFORE I GET THERE, ANY OTHER QUESTIONS? AM I GOING TOO SLOW? FEEL FREE TO TELL ME. IT'S THE POSTPRANDIAL TIME. I JUST WANT TO MAKE SURE WE ALL KEEP THE CONVERSATION.

DR. DULIEGE: ONE THING ABOUT THAT. WILL YOU SOME POINT OR GIL TALK ABOUT REMOVING THE POINT-BASED PREFERENCES?

DR. CANET-AVILES: YES. SLIDE NO. -- WE'VE REMOVED THEM. THEY ARE REMOVED. YES. SLIDE NO. 3, I BELIEVE IT WAS, CAN WE GO BACK? LET ME SEE. HERE. SO THE SLIDE SAYS WE PROPOSE REMOVING POINT-BASED PREFERENCES. SO WHAT ALL THIS IS ABOUT IS, INSTEAD OF THE PREFERENCES, WE ARE GOING TO UTILIZE THE GUIDING PRINCIPLES. AND I THINK I PROBABLY WENT DOWN TOO MUCH INTO DETAIL OF WHAT THESE GUIDING PRINCIPLES ARE. BUT NOW WE ARE GOING TO TALK ABOUT HOW ARE THOSE GUIDING PRINCIPLES APPLIED AT THOSE THREE DIFFERENT STEPS.

FOR THE MERIT REVIEW AND THE FUNDING DECISIONS, THEY'VE ALWAYS BEEN APPLIED. AND WE WILL REVISIT THAT, AND GIL WILL GO INTO DETAIL OF HOW WE DO THIS. FOR THE VOLUME CONTROL, I'M GOING TO SHOW IT IN A MINUTE HOW IT CHANGES. BUT THANK YOU. YOU'RE ON TOP OF IT, WHICH IS HELPFUL, BECAUSE IT MAKES ME THEN HAVE THE DISCUSSION.

DR. DAHL: ONE QUESTION ABOUT YOU MENTIONED THE PORTFOLIO REVIEW. IT MIGHT BE HELPFUL FOR US AS A BOARD OVER TIME TO SEE WHAT THAT LOOKS LIKE IN FIVE YEARS. JUST SOMETHING TO THINK ABOUT.

DR. CANET-AVILES: EXCELLENT. THAT'S AN EXCELLENT QUESTION. AND WE ARE COMING -- THANK YOU FOR ASKING THAT. I THINK IT COULD BE VERY GOOD FOR US TO COME IN JUNE AS WE WERE PLANNING AND TO FRAME IT IN THE CONTEXT OF, IF OTHER MEMBERS AGREE, TO FRAME IT IN THE CONTEXT OF THIS IS WHAT WE HAVE NOW, THIS IS HOW WE SEE IT EVOLVING IN FIVE YEARS, AND THEN THE BOARD CAN ENTERTAIN LIKE, WELL, MAYBE THIS MEANS THAT WE NEED TO PUSH SOMETHING ELSE OR WE SHOULD STOP. IT WILL HELP WITH FRAMING THINGS. SO THANK YOU FOR THE QUESTION.

SO TO FRAME THE PROPOSAL, WE'VE CLARIFIED ROLES ACROSS THREE STAGES, AS I WAS SAYING: VOLUME CONTROL, MERIT REVIEW, AND FUNDING DECISIONS, WHICH

WE ARE GOING TO BE SHOWING ONE BY ONE. ON THIS LEFT COLUMN, WE HAVE WHO IS GOING TO APPLY THE GUIDING PRINCIPLES. AND HOPEFULLY THIS WILL ANSWER DR. DULIEGE'S QUESTION. HOW THESE GUIDING PRINCIPLES ARE APPLIED THROUGH SELECTION CRITERIA, THROUGH MERIT REVIEW, OR THROUGH RECOMMENDATIONS, AND WHAT HAPPENS WHEN WE DO THAT. SO I'M GOING TO GO STEP BY STEP.

FOR THE FIRST ONE, THE VOLUME CONTROL, WE ARE PROPOSING A CHANGE FROM THE PREFERENCE-BASED APPROACH THAT'S CURRENTLY DRIVEN BY CIRM STAFF TO ONE THAT'S GOING TO BE LED BY THE GRANTS WORKING GROUP WHO COULD SELECT APPLICATIONS, NOT BASED ON PREFERENCES, BUT BASED ON THE SELECTION CRITERIA THAT ARE DEFINED AND ACTUALLY THEY ARE IN THE MEMO. SOMETHING VERY IMPORTANT THAT'S REFLECTED IN THE MEMO IS HOW THESE SCIENTIFIC CRITERIA ARE BEING DEVELOPED, AND THEY ARE DERIVED FROM THE GUIDING PRINCIPLES. WE CAN GO IN-DEPTH AND WE COULD PULL THE MEMO IF YOU WANT.

AT THE NEXT STEP, WE HAVE THE MERIT REVIEW WHICH IS THE RESPONSIBILITY OF THE GRANTS WORKING GROUP AND HAS ALWAYS BEEN GROUNDED IN ESTABLISHED REVIEW CRITERIA ALIGNED WITH THE GUIDING PRINCIPLES.

AND FINALLY, AS I WAS MENTIONING, THE

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FUNDING DECISIONS CONTINUE TO REST, AS ALWAYS, IN THE APPLICATION REVIEW SUBCOMMITTEE OF THE ICOC. AS YOU CAN SEE, THE GUIDING PRINCIPLES ARE APPLIED DIRECTLY INTO THE CRITERIA USED AT EACH ONE OF THE STEPS, SELECTION CRITERIA, REVIEW CRITERIA THAT HAS ALWAYS BEEN THERE, AND THE PROGRAMMATIC FACTORS, WHICH HAS BEEN THERE, BUT IT HASN'T BEEN STREAMLINED AND IT HAD NOT BEEN AS TRANSPARENT AS WE ARE GOING TO MAKE IT HAPPEN MOVING FORWARD.

UNDER ALL OF THIS IS THE ROLE OF THE CIRM TEAM, WHICH OUR ROLE IS TO DESIGN AND SUPPORT THE PROCESS, DEFINING THE CRITERIA, ASSEMBLING THE RIGHT EXPERTISE, AND MAKING SURE THAT EACH GROUP HAS THE INFORMATION NEEDED TO MAKE SOUND DECISIONS. AND THIS INCLUDES PROVIDING MORE TRANSPARENT AND STRUCTURED INFORMATION PACKAGE TO THE BOARD, INCLUDING HOW EACH APPLICATION ALIGNS WITH THE GUIDING PRINCIPLES ALONGSIDE WITH THE GRANTS WORKING GROUP RECOMMENDATION.

AND WITH THAT OVERVIEW, I WILL TURN IT OVER TO MY COLLEAGUE, DR. SAMBRANO, TO WALK THROUGH THE DETAILS, PARTICULARLY OF THE VOLUME CONTROL.

DR. SAMBRANO: THANK YOU VERY MUCH. AND I ALSO WANT TO EXTEND MY THANKS TO THE SCIENCE SUBCOMMITTEE AND BOARD MEMBERS THAT WE HAVE HAD

CONVERSATIONS ABOUT THIS PROCESS. I THINK IT HAS BEEN VERY HELPFUL IN OUR THINKING AND IN WHAT WE ARE PROPOSING. THANK YOU. ESSENTIAL PIECE OF EQUIPMENT HERE.

SO WHAT I WANT TO SPEAK ABOUT TODAY IS THE PROCESS THAT WE WOULD LIKE TO UTILIZE FOR THE VOLUME CONTROL STEP. AND AS ROSA MENTIONED, THE VOLUME CONTROL STEP COMES IN IMMEDIATELY AFTER APPLICATION SUBMISSION BUT BEFORE THE FULL GRANTS WORKING GROUP REVIEW. AND NOW THIS HAPPENS AND THE REASON WE NEED TO HAVE IT HAS ALSO ALREADY BEEN MENTIONED. WE DO GET A LARGE FLOOD OF APPLICATIONS ACROSS THE MANY PROGRAMS, AND THAT HAS CONTINUED TO INCREASE OVER TIME. AND OVER THE YEARS WE HAVE UTILIZED DIFFERENT MECHANISMS. SO THIS IS NOT THE FIRST TIME THAT WE ARE DEALING WITH THIS ISSUE. WE HAVE DEALT WITH IT FOR MANY YEARS. WE'VE USED PREAPPLICATIONS, WE HAVE EVEN LIMITED THE NUMBER OF APPLICATIONS THAT COULD BE SUBMITTED BY AN INSTITUTION, WHICH, OF COURSE, DID NOT WORK WELL. I THINK THERE ARE MANY REASONS WHY THAT DOESN'T WORK. NEVERTHELESS, WE'VE TRIED DIFFERENT THINGS. THE LATEST WAS THE USE OF THE PREFERENCES AS A METHOD BY WHICH WE COULD DO THE VOLUME CONTROL.

AND SO, AS WAS ALSO MENTIONED, WE WANT TO

STEP AWAY FROM THOSE PREFERENCES AND PROPOSE SOMETHING DIFFERENT. IN THE END THE PURPOSE OF VOLUME CONTROL IDEALLY IS TO REMOVE OUT OF A POOL OF APPLICATIONS THOSE THAT CLEARLY ARE NOT GOING TO BE COMPETITIVE TO ENRICH THE POOL FOR THOSE THAT BEST ALIGN WITH OUR GOALS AND TO ALLOW A MORE RIGOROUS REVIEW OF THAT GROUP THAT IS MOST COMPETITIVE.

ALL RIGHT. SO IN GOING INTO WHAT THE PROPOSED PROCESS LOOKS LIKE AND THE GOALS THAT WE SET OUT TO ACHIEVE, THE VERY FIRST ONE IS TO REFOCUS THE SELECTION OF APPLICATIONS ON THE SCIENCE RATHER THAN ON STRICT PREFERENCES. WE LEARNED THAT THE STRICT PREFERENCES DID NOT ALLOW FOR A NUANCED ASSESSMENT OF THE SCIENTIFIC VALUE OF APPLICATIONS. AND SO WE REALLY WANT TO MOVE AWAY FROM THOSE AND BACK TO A MORE SCIENTIFIC-BASED REVIEW.

WE WANT TO ALIGN THE PROGRAMS ACROSS THE BOARD SO THAT THEY ARE MORE CONSISTENT IN TERMS OF HOW THE VOLUME CONTROL PROCESS IS IMPLEMENTED. THIS ALLOWS A BETTER AND EASIER WAY OF COMMUNICATING IT AND UNDERSTANDING IT FROM THE PERSPECTIVE OF APPLICANTS. AND THEN WE ALSO WANT TO LEVERAGE, AND AS YOU WILL SEE, LONG-STANDING LEARNINGS FROM OUR POSITIVE SELECTION PROCESS THAT WAS IMPLEMENTED IN 2015, AGAIN, FOR THE SAME PURPOSE OF VOLUME CONTROL.

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AND SO WHAT WE PROPOSE IS A MODIFICATION OF THIS.

ONE OF THE THINGS THAT WE HAVE DONE WITH POSITIVE SELECTION IS THAT THE PROCESS HAS EVOLVED. WE HAVE A CONTINUED COLLECTION OF DATA AND ANALYSIS TO ENSURE THAT THE PROCESS IS WORKING AS WE THINK IT SHOULD. AND WHERE IT'S NOT, WE TRY TO MAKE TWEAKS AND IMPROVEMENTS ALONG THE WAY. AND AS A RESULT, I THINK HAVING A UNIFIED PROCESS ALLOWS INCREASED EFFICIENCY IN THAT OPPORTUNITY TO LEARN AND IMPLEMENT THOSE IMPROVEMENTS.

ALL RIGHT. SO THIS TABLE IS JUST A DEPICTION OF WHAT FOR THE FOUR PROGRAMS SHOWN IN THIS TABLE, DISC5, DISC4, PDEV, AND CLIN2, WHAT THE CURRENT PROCESS IS. AND AS YOU SEE, IT VARIES. IT'S POSITIVE SELECTION IN ONE CASE, PRESUBMISSION IN A COUPLE, AND WHAT WE CALL QUALIFICATION IN CLIN2. AND THEN ALSO IMPORTANTLY WHO MAKES THE SELECTION IS ALSO VARIABLE. SO IN SOME CASES, IT'S THE GRANTS WORKING GROUP, IN SOME CASES IT'S CIRM OR A COMBINATION OF. AND THEN, LASTLY, THE BASIS FOR THAT SELECTION HAS BEEN IN MANY CASES THE OBJECTIVE PREFERENCES, BUT IN OTHER CASES IT HAS BEEN MORE THE WHAT WE CALL SCIENTIFIC VALUE OR VALUE PROPOSITION.

NOW, THE VARIABILITY MAKES IT, AS MENTIONED, HARD TO TRACK AND UNDERSTAND BY

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208-255-5453 208-920-3543 DRAIBE@HOTMAIL.COM

APPLICANTS AND ALSO VERY INEFFICIENT.

MR. TOCHER: I'M SORRY. YSABEL DURON HAS HER HAND RAISED.

DR. SAMBRANO: SORRY. YSABEL.

MS. DURON: LET ME MAKE SURE. THANKS, GIL. AND I MAY HAVE SHOULD HAVE PERHAPS ASKED ROSA EARLIER BECAUSE WHAT I AM NOT SEEING IN ANY WAY, SHAPE, OR FORM IS ANY -- WHEN YOU TALK ABOUT SCIENTIFIC VALUE VERSUS STRICT PREFERENCES, I AM VERY CONCERNED ABOUT WHERE WE HAVE BURIED DEI. I KNOW HOW HARD YOU WORKED ON THAT. I KNOW HOW MUCH WE WORKED AROUND THIS WHOLE ISSUE. AND I'M VERY FEARFUL THAT IF WE PLAY LANGUAGE GAMES HERE, THAT WE'RE GOING TO MISS THE TOTAL INTENT OF MAKING SURE THAT THERE IS REPRESENTATION FROM ACROSS THIS STATE WITHIN THE SCIENCE AND WITHIN THE CLINICAL TRIALS, ET CETERA, ET CETERA.

I KNOW WE TALK, BUT PART OF ME NEEDS TO SEE IT ON PAPER EXPRESSED SOMEWHERE SOMEHOW SO THAT THE SCIENTIFIC APPLICANTS THEMSELVES ALSO KNOW WE ARE STILL VERY COMMITTED TO THAT PRINCIPLE. AND I'M NOT HEARING IT OR SEEING IT. AND I THINK, AS PEOPLE KEEP PRAISING CIRM FOR BEING THE ONE GOOD GO-TO PLACE, I'M HOPING WE'RE NOT LOSING ONE OF THE MOST IMPORTANT CRITERIA, AND THAT WAS THE TURN TOWARDS

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DEI.

SO CAN YOU TELL ME WHERE WITHIN ALL OF THIS WE ARE KEEPING OUR EYE ON THE PRIZE OF DEI WHEN POINTS HAVE BEEN TAKEN AWAY, NOT BEING CONSIDERED, ET CETERA, ET CETERA.

DR. SAMBRANO: RIGHT. SO THANK YOU, YSABEL, FOR YOUR QUESTION. SO THE ELEMENTS OF DEI CONTINUE TO EXIST IN WHAT WE CALL POPULATION IMPACT. AND SO THAT IS STILL A CORE CRITERION THAT EXISTS THROUGHOUT OUR DIFFERENT PROGRAMS AND SOMETHING THAT IS EVALUATED BY THE GRANTS WORKING GROUP AS PART OF THE SCORE THAT THEY DERIVE FOR THE APPLICATIONS BEFORE IT COMES TO THE BOARD. SO THOSE KEY ELEMENTS ARE THERE. THEY WILL CONTINUE TO BE THERE. AND SO THAT, AT LEAST IN THIS WHOLE PROCESS, IS WHERE WE CURRENTLY HAVE THEM.

MS. DURON: I'LL JUST SAY, GIL, I APPRECIATE EVERYBODY'S BEST INTENTIONS. I DON'T KNOW THAT I FEEL BETTER ABOUT IT RIGHT NOW. THANK YOU.

DR. SAMBRANO: OKAY. UNDERSTOOD. THANK YOU.

SO LET ME TRANSITION FROM THIS TABLE THAT DESCRIBES OUR CURRENT PROCESS TO WHAT WE INTEND TO DO FOR THE VOLUME CONTROL STEP. SO WE PROPOSE WHAT

WE CALL GWG SELECTION JUST TO DISTINGUISH IT FROM THE PREVIOUSLY KNOWN POSITIVE SELECTION BECAUSE IT DOES DEVIATE IN TERMS OF THE METHODOLOGY A LITTLE BIT AND UNIFYING THAT AROUND WHO IS MAKING THESE SELECTIONS. SO IT'S THE GRANTS WORKING GROUP MEMBERS THAT DO THE SELECTION. IN ALL CASES IT'S BASED ON WHAT WE'RE CALLING THE SCIENTIFIC VALUE. SO THAT SCIENTIFIC VALUE OR THE SELECTION CRITERIA, AS ROSA MENTIONED, ARE DEFINED IN MORE DETAIL IN THE MEMO BECAUSE THEY DIFFER FROM PROGRAM TO PROGRAM. BUT THEY ARE ALIGNED WITH THE GUIDING PRINCIPLES, PARTICULARLY THE FIRST OFTEN BULLET OF THE GUIDING PRINCIPLES THAT IS LOOKING FOR THE MOST IMPACTFUL, TRANSFORMATIVE PROJECTS, PARTICULARLY FOR PDEV AND CLIN2, AND THOSE THAT OFFER A MEANINGFUL ADVANCE COLLABORATION AND INNOVATION FOR PROJECTS LIKE DISC5 AND DISC4.

AND SO WITH THAT, I'M GOING TO GO OVER THE PROCESS SO THAT YOU GET A SENSE OF WHAT THIS WOULD LOOK LIKE. AND SO THIS IS A PROCESS THAT WE WOULD APPLY TO ALL PROGRAMS THAT REQUIRE VOLUME CONTROL. AND IT ALL BEGINS WITH ESTABLISHING A TARGET NUMBER. SO FOR EACH OF THE DIFFERENT PROGRAMS, WE TARGET A NUMBER OF APPLICATIONS THAT ALLOWS US TO HAVE A FULL, ROBUST DISCUSSION WITH THE GRANTS WORKING

133 HENNA COURT, SANDPOINT, IDAHO 83864
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GROUP PANEL AND ENSURE THAT EACH APPLICATION IS VERY WELL CONSIDERED AND WE CAN BRING, THEREFORE, APPROPRIATE RECOMMENDATIONS TO THE BOARD.

SO THE TARGET NUMBER -- AND THEN, OF COURSE, THE NUMBER OF SUBMISSIONS WE GET WILL DETERMINE THE NECESSARY PARAMETERS THAT WE HAVE TO SET UP FOR HOW THAT SELECTION OCCURS. NOW, OF COURSE, IF THE TARGET NUMBER IS THE SAME AS THE NUMBER OF SUBMISSIONS WE GET, THEN THERE'S NO NEED FOR VOLUME CONTROL. BUT, OF COURSE, THAT IS RARELY THE CASE THESE DAYS.

SO IN THAT PROCESS, WHICH I WILL DESCRIBE, SCIENTIFIC REVIEWERS ARE GOING DO TWO THINGS. THEY'RE GOING TO SELECT AND RANK APPLICATIONS BASED ON THE ASSESSMENT OF THE SCIENTIFIC VALUE THAT IS APPROPRIATE FOR THAT SPECIFIC PROGRAM.

AND THIS IS JUST A TABLE THAT GIVES YOU A SENSE ACROSS THESE FOUR DIFFERENT PROGRAMS WHAT THE RELATIVE APPLICATION POOL MIGHT LOOK LIKE. SO SOMETHING LIKE DISC5 WILL OFTEN GET IN THE ORDER OF ABOUT 200, SOMETIMES MORE APPLICATIONS. WE DID HAVE A RECENT DISC-0, I BELIEVE, THAT HAD 350 SUBMISSIONS. SO IT IS VARIABLE, BUT IN THE RANGE OF THE COUPLE HUNDREDS. AND PDEV MAY BE AROUND 75. WE USED ONLY PRESUBMISSIONS. SO THIS IS STILL A LITTLE

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BIT OF A GUESS. WE HAD, IN TERMS OF, PRESUBMISSIONS ABOUT 130 OR SO THAT WE GOT. SO FOR APPLICATIONS IT MIGHT BE A LITTLE LESS.

SO WHEN YOU LOOK AT THE POOLS AND THE TARGET THAT WE WOULD TAKE TO A FULL PANEL REVIEW, THAT HELPS US SET UP, THEN, THE NUMBER OF REVIEWERS THAT WE MAY NEED, THE NUMBER OF APPLICATIONS EACH REVIEWER NEEDS TO SEE IN THIS SELECTION PROCESS TO ENSURE THAT EACH GETS ENOUGH VIEWS AND THE NUMBER OF REVIEWS THAT EACH APPLICATION IS GOING TO RECEIVE.

AND SO WE'RE GOING TO FOLLOW ONE OF THESE. SO WE'RE GOING TO TAKE THE PDEV AS AN EXAMPLE TO FOLLOW THIS THROUGH. SO LET'S IMAGINE AN APPLICATION POOL OF ABOUT 75 APPLICATIONS WHERE WE'RE GOING TO USE 20 REVIEWERS AND WE'RE TARGETING 30 TO ADVANCE.

AND SO IN THAT SCENARIO, WE START WITH OUR POOL OF 75 APPLICATIONS. AND SO THE FIRST THING WE DO IS WE TAKE THE POOL AND SPLIT IT INTO 20 OVERLAPPING BATCHES OF 15 EACH. AND SO WITH THOSE 20 REVIEWERS, EACH REVIEWER GETS A BATCH OF 15. AND WE'RE GOING TO FOLLOW WHAT HAPPENS TO ONE APPLICATION. SO THAT APPLICATION THAT'S IN RED IS GOING TO APPEAR IN FOUR DIFFERENT BATCHES THAT FOUR DIFFERENT REVIEWERS WILL LOOK AT. AND SO EACH OF

THOSE REVIEWERS WILL LOOK THROUGH THEIR BATCH OF 15, AND THEY WILL SELECT WHAT THEY BELIEVE ARE THEIR BEST FIVE APPLICATIONS AND THEN RANK THEM.

AND SO IN THIS EXAMPLE, REVIEWER NO. 1 SELECTED THE APPLICATION AND RANKED IT NO. 1. THE SECOND REVIEWER ALSO SELECTED IT AND RANKED IT NO. 2. REVIEWER 3 DID NOT SELECT IT. SO THAT ONE IS STILL SITTING IN THEIR PILE BETWEEN 6 AND 15. AND THEN REVIEWER 4 ALSO PICKED IT AND RANKED IT NO. 1. ALL RIGHT.

AND SO IF WE MOVE FORWARD WITH THAT, WE TAKE THE VALUES OF SELECTION AND RANK IN ORDER TO CREATE A COMPOSITE SCORE FOR THAT SPECIFIC APPLICATION. AND SO WHAT THE COMPOSITE SCORE DOES IS THAT EACH APPLICATION COMBINES TWO MEASUREMENTS, THE SELECTION AND THE RANK FOR THAT APPLICATION. AND WE WEIGHT THEM A LITTLE DIFFERENTLY. SO LET ME FIRST TELL YOU WHAT THE SELECTION AND RANK IS MEASURING.

SO THE SELECTION RANKS WHAT FRACTION OF THE ASSIGNED REVIEWERS PICKED THE APPLICATIONS, AND MEANING IS IT THAT MULTIPLE INDEPENDENT REVIEWERS AGREE THIS APPLICATION SHOULD BE ADVANCED? THE RANK MEASURES THE INTENSITY. HOW MUCH AMONG THE APPLICATIONS THAT THEY SAW, DID THEY LIKE THIS

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APPLICATION COMPARED TO THEIR OTHER SELECTIONS? AND SO WE WEIGHT THEM 60/40 PERCENT. WE WANT TO PRIORITIZE SELECTION OVER RANK BECAUSE SELECTION IS MORE PREDICTIVE OF APPLICATIONS THAT DO WELL IN REVIEW OVER RANK. AND SO WE CREATE AN EQUATION FROM THAT.

AND THEN ON THE NEXT SLIDE, I WILL SHOW YOU HOW THAT CALCULATION HAPPENS. SO FOR OUR EXAMPLE APPLICATION THAT I SHOWED YOU THAT HAD THOSE FOUR REVIEWERS, BASED ON THEIR SELECTION AND RANK, REVIEWER 1 SELECTED IT. AND SO THE APPLICATION GETS A POINT FOR THAT SELECTION. IF IT'S NOT SELECTED, LIKE REVIEWER 3, THEN THERE IS NO POINT. SO THIS IS A BINARY CALCULATION. THEY EITHER GET ONE POINT OR NO POINTS FOR FOUR REVIEWERS.

AND THEN BASED ON THE RANK, SO THE NO. 1 RANK GETS CONVERTED TO POINTS. NO. 1 RANK GETS FIVE POINTS, NO. 2 GETS FOUR, NO. 3 GETS THREE AND SO ON. SO WE PLUG THOSE INTO THE EQUATION SO THAT WE CAN GET A COMPOSITE SCORE THAT'S BALANCED 60/40 PERCENT. IF YOU DO THE CALCULATION, THAT GIVES YOU A COMPOSITE NUMBER OF .73. AND SO WHAT DOES THAT MEAN?

FOR A COMPOSITE SCORE, THE BEST POSSIBLE COMPOSITE SCORE, MEANING EVERY REVIEWER SELECTED IT

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AND EVERY REVIEWER RANKED IT NO. 1, THE BEST POSSIBLE SCORE IS A 1. THE WORST POSSIBLE SCORE NOBODY SELECTED, THEREFORE, IT DIDN'T GET RANKED IS A ZERO. SO THE COMPOSITE SCORE WILL ALWAYS BE SOMEWHERE BETWEEN 0 AND 1. AND SO EACH APPLICATION THEN GETS ITS COMPOSITE SCORE. AND IF YOU LOOK AT THE DISTRIBUTION OF THE COMPOSITE SCORES FROM 0 TO 1 ACROSS THE EXAMPLE, 75 APPLICATIONS, THIS IS WHAT IT WOULD LOOK LIKE.

AND SO THE DISTRIBUTION HERE AND THE EXAMPLES THAT I'M SHOWING YOU, WE RAN THESE THROUGH MONTE CARLO SIMULATIONS THAT ALLOWED US TO DO MANY ITERATIONS OF THIS. SO ABOUT A HUNDRED RUNS FOR EACH OF THE DIFFERENT PROGRAMS THAT WE HAVE IN ORDER TO GET THE AVERAGES OF WHERE THE CUTOFF WOULD GENERALLY FALL AND WHICH FRACTION WOULD ADVANCE AND WHICH ONES ARE FILTERED OUT.

AND AS YOU SEE THE DISTRIBUTION, BECAUSE THE REVIEWERS ARE DOING FIRST AS THEIR STEP IS A SELECTION. THEY'RE FIRST DETERMINING, OUT OF THE THESE 15 I HAVE, WHAT ARE MY TOP FIVE? SO THEY'RE FIRST PICKING THEIR TOP THIRD. AND IN DOING SO, THE LARGE FRACTION, THE LOWER TWO-THIRDS, IS FILTERED OUT. AND THEN THEY ARE RANKING THEIR THEN TOP SELECTIONS IN ORDER TO GET A SPREAD AND ESTABLISH A

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CUTOFF. AND SO THAT'S WHY YOU SEE THE DISTRIBUTION AS IT SHOWS HERE.

DR. CARETHERS: BEFORE YOU GO ON, CAN I JUST ASK A QUESTION? I JUST WONDER THOUGH WHY WAS IT 60/40 THE WEIGHT PICKED VERSUS LIKE 50-50? I'M JUST CURIOUS.

DR. SAMBRANO: YEAH. IT IS SIMPLY BECAUSE WE WANT TO PRIORITIZE SELECTION OVER THE RANK. BECAUSE THE SELECTION IS ACROSS DIFFERENT REVIEWERS. SO THE MORE AN APPLICATION IS SELECTED, THE MORE PREDICTIVE IT IS OF ITS SUCCESS. THE RANK IS REALLY NOW LIMITED ONLY TO THAT TOP FRACTION, AND IT'S GIVING YOU MORE LIMITED INFORMATION. IT'S TELLING YOU ONLY WITHIN THE ONES THAT THEY LIKE, DID IT HAPPEN TO BE THEIR NO. 1, THEIR NO. 2, AND NO. 3. SO IT'S REALLY PRIORITIZING THE SELECTION OVER THE VERY SPECIFIC RANK.

DR. CARETHERS: SO WHY NOT 75/25? I'M JUST --

DR. SAMBRANO: IT COULD BE.

DR. CARETHERS: SO IT'S JUST WHERE TO START.

DR. SAMBRANO: SO IT'S WHERE WE STARTED, BUT IT'S ALSO WHAT THE MODEL SUGGESTED MIGHT BE THE BEST, BUT THAT CAN BE TWEAKED. SO WE COULD DO A

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75/25 AND TRY THAT OUT.

DR. BARRETT: STOP TO TAKE QUESTIONS BRIEFLY. I ALSO WONDERED HOW YOU SELECTED THE NUMBER OF REVIEWERS FOR THE DIFFERENT PROGRAMS. WAS THAT ALSO ARBITRARY?

DR. SAMBRANO: SO THE NUMBER OF REVIEWERS THAT WE SELECT FOR THE OVERALL POOL IS NOT NECESSARILY ARBITRARY. YOU CAN WORK WITHIN THE RANGE. YOU HAVE TO HAVE ENOUGH REVIEWERS WHERE YOU GET COVERAGE OF THE ENTIRE POOL AND THAT EVERY APPLICATION GETS AT LEAST A THREE, FOUR, OR FIVE VIEWS FROM THOSE REVIEWERS.

WHAT STARTS TO HAPPEN IF YOU HAVE TOO MANY REVIEWERS IS THAT THEY DON'T GET ENOUGH REPRESENTATION OF THE POOL. SO YOU WANT TO BALANCE IT SO THAT EACH REVIEWER HAS ENOUGH POOL REPRESENTATION WITHIN THEIR BATCHES, BUT AT THE SAME TIME YOU HAVE ENOUGH REVIEWERS THAT YOU HAVE GOOD OVERLAP AND ARE ABLE TO GET SUFFICIENT NUMBER OF REVIEWS FOR EACH APPLICATION.

DR. BARRETT: BUT TO GET FIVE PEOPLE TO LOOK AT EACH, I CAN'T REMEMBER WHICH PROGRAM, A CLIN PROGRAM, RIGHT, YOU'RE TALKING ABOUT A LOT OF EXTRA WORKLOAD. IS THAT FEASIBLE?

DR. SAMBRANO: YES. BECAUSE FOR THAT ONE,

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THE POOL NUMBER IS NOT AS BIG. AND SO THE NUMBER -- I MEAN WE WANT TO START WITH A MINIMUM OF 15 REVIEWERS. AND SO WITH THAT, THAT'S EASILY ACHIEVABLE FOR CLIN.

DR. BARRETT: BUT THIS IS ADDING ADDITIONAL WORKLOAD TO THE REVIEWERS TO DO THIS UP-FRONT SELECTION, RIGHT?

DR. SAMBRANO: YES. IN SOME OF THE PROGRAMS. BUT THIS IS SOMETHING THAT THEY'VE BEEN DOING FOR OVER TEN YEARS IN SOME OF OUR OTHER PROGRAMS THAT HAVE USED POSITIVE SELECTION.

DR. BARRETT: OKAY. THANKS.

DR. SACKEY: THANK YOU FOR THIS OVERVIEW, AND I LIKE THE EXERCISE YOU JUST WALKED US THROUGH PICKING ONE APPLICATION AND WALKING IT THROUGH. I GUESS MY QUESTION HAS TO DO WITH WHAT HAPPENS UPSTREAM TO THIS STAGE. IT STRIKES ME THAT WE ARE ASSUMING THAT -- I LIKE THE FACT WE'RE BEING PRINCIPLED, BUT WE'RE ASSUMING THAT THE FOUR REVIEWERS OR FIVE REVIEWERS ARE INTERPRETING THE GUIDING PRINCIPLES THE SAME WAY IN TERMS OF HOW THEY ARE ASCRIBING SCIENTIFIC VALUE. AND IT BRINGS TO ME THE QUESTION THAT YSABEL HAD BEFORE BECAUSE WHEN YOU DESCRIBED WHERE DEI HAS LANDED, YOU ACTUALLY USED LANGUAGE THAT I THINK THERE MAY BE REVIEWERS WHO MAY

NOT NECESSARILY INTERPRET SCIENTIFIC VALUE AS INCLUDING POPULATION IMPACT.

SO I'M WONDERING IF MAYBE THERE NEEDS TO BE SOMETHING MORE EXPLICIT TO ENSURE THAT WE KNOW THAT THOSE REVIEWERS ARE IN FACT APPLYING THE PRINCIPLES SIMILARLY. DO YOU SEE WHAT I'M TRYING TO SAY?

DR. SAMBRANO: YES. AND THOSE ARE THINGS WE WORRY ABOUT TOO. AND SO PART OF ADDRESSING THAT AND MITIGATING THAT IS THAT WE HAVE A LOT OF MEETINGS WITH REVIEWERS WHERE WE DO WHAT IS ESSENTIALLY TRAINING. WE GO OVER THE REVIEW CRITERIA, ADDRESS QUESTIONS TO ENSURE THAT THEY UNDERSTAND THEM IN SIMILAR WAYS AND KNOW THAT THERE ARE TWO DIFFERENT TASKS. SO THEY'RE GOING TO HAVE THE TASK OF DOING THE SELECTION AND WHAT THE SELECTION CRITERIA ARE, HOW THEY DIFFER FROM THE REVIEW CRITERIA THAT THEY WOULD UTILIZE IN A FULL DISCUSSION AND IN THE PANEL, AND HOW TO APPLY THEM.

SO THAT IS AN IMPORTANT ELEMENT BECAUSE YOU WANT TO MAKE SURE, TO THE EXTENT POSSIBLE, THAT ALL REVIEWERS ARE LOOKING AT THE APPLICATIONS IN THE SAME WAY IN ORDER TO ENSURE THAT WE'RE ON THE SAME PAGE OF WHY THEY'RE SELECTING THEM. BECAUSE ESPECIALLY WHEN YOU HAVE SO MANY APPLICATIONS THAT

IN GENERAL DO HAVE MERIT, FROM A SCIENTIFIC PERSPECTIVE THEY MAY BE INTERESTING, THEY ARE GOOD IDEAS, BUT NOT ALL GOOD IDEAS ARE THE ONES THAT WE WANT TO HAVE WITHIN OUR PROGRAM. SO IT'S HOW WE DEFINE THAT VERY SPECIFIC VALUE TO CIRM THAT WE WANT TO MAKE SURE THEY UNDERSTAND. SO I THINK YOU'RE VERY RIGHT, THAT THAT IS A KEY ELEMENT.

CHAIRMAN IMBASCIANI: GIL, WE HAVE BOARD MEMBER YAMAMOTO FOLLOWED BY DR. LEVITT AND THEN ANNE-MARIE.

DR. YAMAMOTO: GIL, THANK YOU FOR THIS. CAN I ASK YOU TO GO BACK TO THE TABLE WHERE YOU TALKED ABOUT THE DIFFERENT MECHANISMS AND THE NUMBER OF APPLICATIONS THAT COME IN AND THE GOAL TO GET DOWN TO A CERTAIN NUMBER. I'M SORRY. THIS ONE.

SO FIRST OF ALL, YOU SAID THAT -- I'M SORRY. TWO QUESTIONS ABOUT THIS. THE FIRST IS THAT YOU TOLD US THAT YOU WOULD APPLY THE VOLUME CONTROL TO THE MECHANISMS THAT REQUIRE IT; THAT IS, WHERE THE NUMBER OF -- THE APPLICANT POOL IS SO LARGE THAT YOU REALLY NEED TO CUT DOWN TO SOME TARGET NUMBER, WHICH YOU HAVE HERE. BUT NOW YOU'VE SHOWN US FOUR MECHANISMS IN WHICH THE APPLICATION POOL RANGES OVER AN ORDER OF MAGNITUDE. BUT FOR EACH OF THEM, IT LOOKS LIKE YOU'RE STILL APPLYING THIS VOLUME CONTROL

133 HENNA COURT, SANDPOINT, IDAHO 83864
208-255-5453 208-920-3543 DRAIBE@HOTMAIL.COM

MECHANISM, IF I'M UNDERSTANDING THE SECOND LINE, THE TARGET FOR ADVANCEMENT. IS THAT TRUE? SO IS THE GOAL TO ACTUALLY APPLY THE VOLUME CONTROL MECHANISMS TO EVERY MECHANISM NO MATTER WHAT THE NUMBER OF APPLICATIONS THAT COMES IN? YOU GET 20 APPLICATIONS COMING IN, WHY NOT JUST REVIEW THEM?

DR. SAMBRANO: RIGHT. FOR EXAMPLE, IF WE CONTINUE TO FOLLOW THE PDEV, IF THE TARGET IS 30 AND THE APPLICATION POOL THAT COMES IN IS 30, THEN THERE IS NO VOLUME CONTROL. THERE'S NO NEED TO GO THROUGH THIS STEP. BUT IF IT EXCEEDS THAT --

DR. YAMAMOTO: RIGHT. RIGHT.

DR. SAMBRANO: SO LIKE IN THIS EXAMPLE 75, THEN YES. THEN WE WOULD IMPLEMENT IT.

DR. YAMAMOTO: WHAT DETERMINES THE TARGET FOR ADVANCEMENT? I THOUGHT IT WAS THE CAPACITY OF REVIEWERS THAT YOU HAVE.

DR. SAMBRANO: IT IS. IT IS HOW WE CONDUCT THE REVIEW. AND SO WHY IS IT SO DIFFERENT, SAY, BETWEEN CLIN2 AND DISC5? WELL, IT'S BECAUSE THE NATURE OF THE REVIEW AND THE NUMBER OF REVIEWERS THAT WE ASSIGN TO APPLICATIONS IN THE FULL REVIEW IS VERY DIFFERENT. THE CONTENT OF THE APPLICATIONS DIFFERS GREATLY. AND, FOR EXAMPLE, WITH CLIN2, WE BRING DISEASE AREA EXPERTS, REGULATORY EXPERTS, CMC,

WE HAVE THE ACCESS AND AFFORDABILITY REVIEW. SO THE REVIEWS ARE MUCH MORE INVOLVED AND TAKE MORE TIME.

AND SO IN ORDER TO ALLOW FOR A FULL, RIGOROUS DISCUSSION, THE TARGET NUMBER OF ABOUT TEN IS WHAT WE THINK ALLOWS FOR A ROBUST DISCUSSION. WHEREAS, I THINK FOR A DISC5, WE CAN DO AS MANY AS 50 WITH THAT TYPE OF APPLICATION.

DR. YAMAMOTO: OKAY. GOT IT. GOOD. THANK YOU.

SO MY SECOND QUESTION. SO THANKS FOR THAT. MY SECOND QUESTION IS HOW IS THE COMPOSITE NUMBER USED TO ARRIVE AT THE TARGET TO REACH THE TARGET FOR ADVANCEMENT?

DR. SAMBRANO: YEAH. OKAY. SO I WILL -- I HAVE MORE SLIDES IN WHICH I CAN SHOW YOU SOME OF THAT. BUT I MEAN IN BRIEF, SO THE WAY WE DID THESE SIMULATIONS, THEY INCLUDE THAT TARGET NUMBER IN TERMS OF WHAT WE WOULD WANT, WHERE WE WOULD WANT TO DO THE CUTOFF. SO IN MOST CASES THE COMPOSITE NUMBER ENDS UP BEING SOMEWHERE BETWEEN .3 AND .4 WHERE THIS DISTRIBUTION LANDS WHERE THE 30TH APPLICATION FALLS IN THAT GRAY ZONE AREA. AND SO I WILL SHOW YOU A TABLE THAT SHOWS YOU THE RANK ORDER OF HOW THEN WE WOULD DETERMINE THAT CUTOFF.

DR. YAMAMOTO: OKAY. SO THE GOAL OF

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THE -- WHEN WE TALK ABOUT VOLUME CONTROL, WHAT YOU'RE TALKING ABOUT IS ARRIVING AT A REASONABLE NUMBER OF APPLICATIONS THAT WILL BE DISCUSSED, NOT ARRIVING AT A REASONABLE NUMBER OF APPLICATIONS THAT WILL BE REVIEWED. SO ALL OF THE 200 APPLICATIONS GET A FULL REVIEW?

DR. SAMBRANO: NO.

DR. YAMAMOTO: BUT ONLY A CERTAIN NUMBER OF THEM WILL BE DISCUSSED; IS THAT CORRECT?

DR. SAMBRANO: NO. NO. SO THE SELECTION PROCESS IS NOT THE SAME AS A FULL GRANTS WORKING GROUP REVIEW. IT IS A TRIAGE STEP BASICALLY THAT WHERE YOU LOOK AT THE APPLICATIONS ONLY AT A VERY HIGH LEVEL. YOU'RE LOOKING AT THEM FROM WHAT ARE THE SELECTION CRITERIA, NOT THE REVIEW CRITERIA. SO THE SELECTION CRITERIA IN THESE TYPES OF PROGRAMS ARE GOING TO BE IS THIS A TRANSFORMATIVE PROJECT THAT IS GOING TO HAVE A MEANINGFUL IMPACT TO PATIENTS? AND SO LOOKING AT THAT, NOT LOOKING AT WHAT IS THEIR PLAN AND DESIGN, NOT LOOKING AT DO THEY HAVE THE PRELIMINARY DATA AND APPROPRIATE RATIONALE, NOT LOOKING AT THOSE DETAILS. IT IS LOOKING AT WHAT WE FEEL IS THE MOST IMPORTANT AND ALIGNED WITH THE GUIDING PRINCIPLES. IS THIS SOMETHING THAT'S WORTH FUNDING TO START OFF WITH

BEFORE YOU DIVE INTO THE DETAIL. AND IF IT IS, THEN WE CAN DIVE IN DEEPER AND DISCUSS DOES THE PLAN AND DESIGN, DOES THE TEAM AND ALL THAT SUPPORT THIS IDEA THAT WE DETERMINED WAS A VALUABLE ONE?

DR. YAMAMOTO: SO ARE THE APPLICATIONS SET UP IN SUCH A WAY THAT THE REVIEWERS CAN DO A SCAN OF SOME SUMMARY LEVEL THING THAT FOCUSES ON THE GUIDING PRINCIPLES AND MAKE SOME ASSESSMENT? IF I WAS A REVIEWER, I WOULD FEEL I HAVE A RESPONSIBILITY TO LOOK AT THESE THINGS PRETTY CAREFULLY KNOWING WHAT THE CONSEQUENCES OF MY DECISION IS. AND SO I'M JUST WONDERING, IT JUST SEEMS LIKE YOU MAY BE ASKING THE REVIEWERS, UNLESS YOU PROVIDE THEM WITH SOME PAGE THAT FOCUSES ON GUIDING PRINCIPLES THAT THE REVIEWER CAN LOOK AT WITHOUT PLOWING THROUGH THE WHOLE APPLICATION, THEN I WOULD THINK MANY REVIEWERS WOULD FEEL IT'S THEIR RESPONSIBILITY IN FAIRNESS TO THE APPLICANT TO LOOK AT THE APPLICATION VERY CAREFULLY. THEN YOU'D BE IN A SITUATION WHERE EVERY APPLICATION IS BEING REVIEWED WHERE THAT DOESN'T REALLY FIT WITH THE VOLUME CONTROL PRINCIPLE.

DR. SAMBRANO: RIGHT. SO THE APPLICATIONS, AS MENTIONED, ARE EACH KIND OF TAILORED TO THE DIFFERENT TYPE OF PROGRAM. FOR THE DISC5, BECAUSE WE HAVE HAD A LONG-STANDING USE OF

THE POSITIVE SELECTION PROCESS, INCLUDE A PREVIEW PAGE, WHICH IS A SUMMARY OF THEIR OVERALL AIMS, WHAT THE GOALS ARE, AND WHAT THE ULTIMATE IMPACT OF THEIR PROJECT, IF SUCCESSFUL, WOULD ACHIEVE. AND SO THERE IS SORT OF THAT KIND OF FRONT-PAGE PREVIEW THAT REVIEWERS CAN FOCUS ON, BUT HAVE THE FULL APPLICATION AVAILABLE, AND WHICH THEY OFTEN UTILIZE, IN ORDER TO CONFIRM OR TO REFERENCE ANY OF THE ELEMENTS THAT THEY FEEL ARE IMPORTANT TO ASSESSING WHETHER THIS PRESENTS A GOOD SCIENTIFIC VALUE.

FOR THE OTHER APPLICATIONS, LIKE THE CLINICAL, THERE ARE CLEAR SECTIONS THAT ARE FOCUSED SPECIFICALLY ON THE VALUE PROPOSITION OF THE PROPOSAL THAT SUMMARIZES THE KEY ELEMENTS OF WHAT THIS PROPOSED THERAPY INTENDS TO DO, WHAT THE COMPLETION OF THE TRIAL WOULD ACHIEVE, AND, OF COURSE, THE LONG-TERM IMPACT OF THE PROPOSED THERAPY SHOULD IT BE SUCCESSFUL.

SO THOSE ELEMENTS ARE EASILY POINTED TO IN THE APPLICATION. AND WE DO THAT AS PART OF OUR TRAINING WITH REVIEWERS IN TERMS OF ADVISING OF WHERE TO FIND THE INFORMATION AND HOW TO BEST ACCESS IT. BUT WE ALSO DON'T WANT TO NECESSARILY LIMIT WHERE THEY LOOK BECAUSE SOME OF THAT INFORMATION CAN BE FOUND IN DIFFERENT PARTS OR ELEMENTS OF THE

133 HENNA COURT, SANDPOINT, IDAHO 83864
208-255-5453 208-920-3543 DRAIBE@HOTMAIL.COM

APPLICATION AS SOME REVIEWERS HAVE POINTED OUT TO US.

SO IT IS SOMETHING WHERE PROVIDING THE APPLICATION AS A WHOLE GIVES THEM THE OPPORTUNITY TO LOOK WHERE NECESSARY TO FEEL COMFORTABLE THAT THEY ARE MAKING AN APPROPRIATE SELECTION.

DR. YAMAMOTO: OKAY. WE CAN TALK ABOUT THIS MORE AS YOU GO THROUGH THIS, BUT I HAVE CONCERNS. AND WE'LL GET BACK TO THAT, THE CAPACITY TO CUT DOWN 200 APPLICATIONS TO 50 BASED ON A RELATIVELY CURSORY ASSESSMENT WHERE YOU'RE MAKING A CLAIM THAT YOU ARE MAKING JUDGMENTS BASED ON SCIENTIFIC MERIT. BUT WHY DON'T YOU GO AHEAD AND WE'LL GET BACK TO IT.

CHAIRMAN IMBASCIANI: THANKS, KEITH. PAT'S NEXT FOLLOWED BY ANNE-MARIE AND THEN CHRISTINE.

DR. LEVITT: SO WE HAD LOTS OF DISCUSSIONS ABOUT THIS, HOURS. FIRST, I WOULD SAY HAVING A SINGLE PAGE SUMMARY ADDRESSING THE GUIDING PRINCIPLES IS NOT GOING TO BE ANY BETTER THAN A SPECIFIC AIMS PAGE THAT ALWAYS HAS TO HAVE A RATIONALE SECTION FOR THE SPECIFIC AIMS THAT ARE BEING PROPOSED.

SECOND IS THAT THE GUIDING PRINCIPLES

DON'T GO AWAY WITH THE REVIEW. THEY'RE STILL PART OF THE REVIEW, WHICH INCLUDES ACCESS AND ACCESSIBILITY, WHICH IS REALLY NOW EMPHASIZED. WHEN IT WAS COMBINED WITH AFFORDABILITY, AT LEAST FROM MY PERSPECTIVE, IT GOT DILUTED. ACCESS IS REALLY SOMETHING THAT THE INVESTIGATORS CAN ADDRESS IN RELEVANT WAYS THAT INCLUDE DIVERSITY AND EQUITABILITY OF ACCESS.

WE HAD DISCUSSIONS ABOUT HOW IT WAS SO DIFFICULT FOR A STEM CELL BIOLOGIST DOING TRANSPLANTS INTO A SPINA BIFIDA, PHYSICIAN, WOULD BE ABLE TO ADDRESS AFFORDABILITY WHEN POLICYMAKERS AND HEALTH ECONOMISTS CAN'T DO IT WELL. SO ACCESS IS A KEY TO THE PRINCIPLE. AND IF I UNDERSTAND WHAT'S BEEN DISCUSSED, THESE ARE GOING TO BE COMMUNICATED VERY CLEARLY TO APPLICANTS. AND IF THEY UNDERSTAND THAT THE GUIDING PRINCIPLES ARE BEING USED TO MAKE SELECTIONS ABOUT FINALISTS AND IT'S STILL GOING TO BE PART OF THE APPLICATION REVIEW PROCESS, IF THEY DON'T ADDRESS THE GUIDING PRINCIPLES WITHIN A FULL APPLICATION ITSELF, IT'S NOT GOING TO DO WELL. SO I DON'T SEE IT GOING AWAY AND VANISHING.

THE OTHER IS THAT IT'S NOT A TERRIBLE BURDEN TO READ A SPECIFIC AIMS PAGE AND ABSTRACT, WHICH ARE ALL INCLUDED IN A FULL APPLICATION, AS

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WELL AS A SIGNIFICANT SECTION WHICH REALLY GIVES THE REVIEWER A COMPLETE PICTURE OF WHY THIS IS SO IMPORTANT FOR CIRM TO CONSIDER INDEPENDENT OF THE DETAILS AND THE METHODS SECTION AND THE STATISTICS AND OTHER THINGS THAT ARE GOING TO BE EVALUATED IN THE FULL APPLICATION.

SO I WOULD ARGUE THAT A SINGLE PAGE IN ADDITION TO WHAT THEY'RE ALREADY DOING OR JUST HAVING A SINGLE PAGE IS NOT GOING TO SATISFY THOSE WHO COMPLAIN THAT THERE WASN'T SCIENTIFIC MERIT FOR THE INITIAL PROCESS THAT WAS USED FOR MAKING SELECTION.

FINALLY, SOMETHING I LEARNED ALONG THE WAY, I DIDN'T KNOW THIS WHEN I JOINED THE BOARD, THERE'S A LIMITED NUMBER OF REVIEWERS ON THE GWG. ONE SOLUTION WOULD BE JUST TO ADD MORE REVIEWERS, BUT WE CAN'T. I GUESS THAT WAS THE SECOND TO FINAL THING.

THE FINAL THING I WOULD SAY, IF YOU SHIFT FROM 60/40 TO 75 TO 25, BASED ON GIL'S GRAY AREA, THAT'S WHERE THE SHIFTS WOULD OCCUR. IT'S UNLIKELY, IF YOU RUN MONTE CARLO, TO SEE SHIFTS GOING INTO EITHER THE LOW RED AREA OR THE HIGHER AREA. IT'S GOING TO BE WITHIN THAT RANGE, AND IT'S NOT GOING TO MAKE REALLY A WHOLE LOT OF DIFFERENCE. SO WE COULD

QUIBBLE ABOUT 75/25, 80/20, 60/40, BUT I DO DEGREE WITH GIL THAT THE SELECTION ITSELF SHOULD BE THE MOST IMPORTANT THING BECAUSE ONCE YOU START RANKING, YOU'RE RANKING AGAINST FIVE. WHEN YOU'RE SELECTING, YOU'RE SELECTING AGAINST THE WHOLE BATCH THAT YOU'VE BEEN ASSIGNED. THANKS.

CHAIRMAN IMBASCIANI: THANKS, PAT.

DR. YAMAMOTO: CAN I INTERRUPT YOU? I WANT TO SAY ONE THING ABOUT WHAT PAT TALKED ABOUT AND -- BECAUSE IT'S WHAT'S WORRYING ME. YOU ARE REALLY CONSTRAINED, GIL, YOU'RE TRYING TO WORK WITHIN A VERY DIFFICULT CONSTRAINT, AND THAT IS THE LIMITED NUMBER OF PEOPLE ON GWG. SO I'LL JUST REMIND PEOPLE THAT WHEN THE NIH STARTED ITS PEER REVIEW SYSTEM IN 1946, IT STARTED WITH TEN STUDY SECTIONS. AND THE WAY THEY DEALT WITH VOLUME CONTROL WAS TO ADD MORE STUDY SECTIONS. NOW THERE'S 240. STARTED WITH TEN, AND NOW THERE'S 240 IN ORDER TO MANAGE THE VOLUME OF APPLICATIONS THAT COMES IN. SO THAT WAS THEIR PRIMARY VOLUME CONTROL SYSTEM.

AND NOW THEY DO A TRIAGE IN WHICH THE GOAL OF THE TRIAGE IS NOT TO LIMIT THE NUMBER OF APPLICATIONS THAT HAVE TO BE READ BY A GIVEN REVIEWER, BUT TO LIMIT THE NUMBER OF APPLICATIONS THAT WILL BE REVIEWED IN THE STUDY SECTION MEETING.

AND THAT CUTOFF, THAT TRIAGE LINE IS SET AT ROUGHLY 50 PERCENT, NOT EXACTLY, BUT ROUGHLY 50 PERCENT OF THE APPLICATIONS THAT ARE ACTUALLY REVIEWED -- ACTUALLY DISCUSSED. AND THAT GIVES THE STUDY SECTION THE TIME TO BE ABLE TO PUT THE KIND OF FOCUS THAT'S DESERVED INTO THE APPLICATIONS THAT ARE JUDGED AS BEING IN THE UPPER HALF. BUT THAT KIND OF TRIAGE LINE DRAWING, IN MY VIEW, I'VE SAID THIS BEFORE, IT'S VERY HARD TO DRAW A TRIAGE LINE THAT IS MORE THAN A THUMBS UP AND THUMBS DOWN, MORE THAN A 50-PERCENT LINE THAT SAYS, NO, THIS ISN'T REALLY, THIS DOESN'T REALLY DO IT. THAT'S NOT -- 50 PERCENT IS NOT SO HARD, BUT THE 75 PERCENT, 80 PERCENT YOU'RE TRYING TO DO WITH SOME OF THESE MECHANISMS, I THINK IT'S VERY HARD.

SO JUST ACKNOWLEDGING, GIL, YOU'RE STUCK WITH THIS CONSTRAINT WHERE YOU DON'T GET TO DEAL WITH VOLUME CONTROL SIMPLY BY ADDING MORE REVIEWERS. AND SO NOW WE'RE STRUGGLING ALL OF US TOGETHER TO TRY TO COME UP WITH A SYSTEM THAT IS SCIENCE BASED, AS YOU SAID, BUT STILL ALLOWS THE REVIEWERS TO BE ABLE TO MOVE THROUGH THIS LARGE NUMBER OF APPLICATIONS EFFICIENTLY. AND THE CRITERIA BY WHICH IT'S DONE, THE STRUCTURE OF THE APPLICATION THAT ALLOWS THEM TO DO THAT EFFICIENTLY IN WAYS THAT

133 HENNA COURT, SANDPOINT, IDAHO 83864
208-255-5453 208-920-3543 DRAIBE@HOTMAIL.COM

IDEALLY ALL THE REVIEWERS WILL BE LOOKING AT THE SAME STUFF, NOT SOME REVIEWERS FEELING LIKE THEY HAVE TO READ THE WHOLE APPLICATION, OTHERS THAT KIND OF PICK AND CHOOSE WHICH PARTS THEY'RE GOING TO FOCUS ON, AND OTHERS THAT ARE JUST READING ABSTRACTS. YOU DON'T REALLY WANT THAT, AND I THINK THAT'S THE PROBLEM WE'RE STUCK WITH.

DR. LEVITT: I'LL JUST ADD, KEITH, THAT THE NIH HAS NOW GONE TO TRIAGING 67 PERCENT, THE TOP THIRD. THE TOP THIRD ONLY GET DISCUSSED AT STUDY SECTION, TOP THIRD.

DR. YAMAMOTO: THAT'S NOT -- I'M NOT A FAN OF THAT.

DR. LEVITT: I'M NOT JUSTIFYING IT, BUT THAT'S THE NAME OF THE GAME.

AND THE OTHER THING IS THAT, FOR THOSE WHO HAVE DONE REVIEWS ON STUDY SECTIONS, YOU KNOW THAT EACH STUDY SECTION MEMBER HAS A DIFFERENT VIEW ON WHAT INNOVATION IS AND HOW THEY DEFINE IT.

DR. YAMAMOTO: OF COURSE. OF COURSE.

DR. LEVITT: WHAT RIGOR IS, ET CETERA, ET CETERA. SO THERE'S NO WAY OF GETTING AROUND ALL THIS. I AGREE WITH YOU, THAT THE CIRM TEAM HAS A REALLY CHALLENGING PROBLEM THAT IS TOUGH TO GET OUT OF.

CHAIRMAN IMBASCIANI: THANK YOU, GENTLEMEN. ANNE-MARIE.

DR. DULIEGE: SO TWO QUESTIONS, GIL. ONE IS ABOUT THE TOTAL NUMBER OF APPLICATION THAT WILL GO TO THE REVIEW, THE GRANTS WORKING GROUP. SO MY UNDERSTANDING OF THE CURRENT SYSTEM, THAT THE CIRM TEAM WAS LOOKING AT THE APPLICATION WHEN THEY'RE REVIEWED AND LOOKING AT BASIC COMPLETENESS AND OVERALL COMPLETENESS BEFORE THEY WOULD SEND IT TO THE GRANT WORKING GROUP. WILL THAT STILL APPLY?

DR. SAMBRANO: YES. WE WILL STILL LOOK -- ESSENTIALLY THAT'S THE ELIGIBILITY STAGE AS WE CALL IT, ENSURE THAT THE APPLICATIONS ARE COMPLETE, ELIGIBLE, AND SO ON. SO THAT'S A PROCESS THAT WE DO IN PARALLEL AND CERTAINLY BEFORE THEY GO TO THE PANEL.

DR. DULIEGE: GREAT. THANK YOU. THAT'S REASSURING.

SECOND, ARE THERE A LIST OF GUIDING PRINCIPLES? AND ARE THEY THE SAME? I ASSUME THEY WILL BE DIFFERENT BETWEEN A DISC APPLICATION 4, 5 VERSUS, LET'S SAY, A CLINICAL APPLICATION?

DR. SAMBRANO: YES. THEY'RE EACH DESIGNED AROUND THE DIFFERENT PROGRAMS. AND, AGAIN, I KNOW WE KEEP USING THE GUIDING PRINCIPLES. THE GUIDING

133 HENNA COURT, SANDPOINT, IDAHO 83864
208-255-5453 208-920-3543 DRAIBE@HOTMAIL.COM

PRINCIPLES IS THE UMBRELLA TERM THAT WE USE FOR WHAT WE WANT THE PORTFOLIO TO LOOK LIKE. AND SO IF YOU LOOK AT THE FIRST BULLET, IN A LOT OF THESE IS WE WANT SOMETHING THAT'S IMPACTFUL, SIGNIFICANT, TRANSFORMATIVE. AND SO THAT'S GOING TO ALIGN WITH ALSO, THEN, THE SELECTION CRITERIA THAT WE WOULD USE AT THIS STEP AS WELL AS THE REVIEW CRITERIA.

ONE OF THE OTHER GUIDING PRINCIPLES IS HAVING A BALANCE BETWEEN THE RARE AND PREVALENT DISEASES. THAT'S NOT ONE THAT YOU WOULD APPLY NECESSARILY AS A SELECTION CRITERIA OR AS A REVIEW CRITERIA. THAT'S FOR US, CIRM, TO HAVE A PORTFOLIO THAT INCLUDES ALL OF THOSE ELEMENTS.

SO I JUST WANT TO MAKE SURE WE'RE CAREFUL IN TERMS OF LIKE HOW WE TRANSITION THE GUIDING PRINCIPLES TO EACH OF THE SELECTION CRITERIA AND REVIEW CRITERIA. THE SELECTION CRITERIA ARE GOING TO BE REALLY FOCUSED ON IS THIS PROJECT FOR THOSE FIRST BULLETS THE TRANSFORMATIVE, SIGNIFICANT TYPE OF PROJECT THAT'S GOING TO MAKE A DIFFERENCE AND THAT'S ALIGNED WITH OUR GOALS?

CHAIRMAN IMBASCIANI: FINALLY, CHRISTINA.

DR. MIASKOWSKI: I'D LIKE TO SPEAK IN SUPPORT OF THIS PROCESS IN ITS TOTALITY. SELECTION IS HARD. AND WE'RE FACED, AS I THINK KEITH SAID,

WITH DIFFICULT DECISIONS. I'M INVOLVED IN A NUMBER OF ORGANIZATIONS THAT ARE DOING THIS PROCESS, AND I CAN ATTEST TO THE FACT THAT WHAT CIRM IS PROPOSING AND THE LEADERSHIP IS PROPOSING IS RIGOROUS.

THE OTHER THING, HAVING SERVED ON THE GWG, I DON'T KNOW NOW, FIVE YEARS, I WANT TO ACKNOWLEDGE THAT THE STAFF, GIL'S GROUP, DOES VERY RIGOROUS TRAINING OF THE REVIEWERS. SO IT IS TOP OF MIND WHAT OUR PRIORITIES ARE. AND FROM MY PERSPECTIVE, IN TERMS OF THE WAY THE APPLICATIONS ARE CONSTRUCTED ACROSS OUR DIFFERENT MECHANISMS, IT'S VERY EASY TO FIGURE OUT IF THE APPLICANT WHO'S PUTTING THE APPLICATION UNDERSTANDS WHAT WE'RE TRYING TO ACHIEVE. AND I'M SURE ALL OF US THAT HAVE READ GRANTS KNOW THAT THERE ARE PEOPLE THAT DO THAT REALLY, REALLY WELL AND FOLLOW THE DIRECTIONS AND HIT ALL THE BULLET POINTS, AND THEN THERE ARE OTHER PEOPLE THAT ARE COMPLETELY OFF THE PAGE.

I WANT TO REASSURE YSABEL AND OTHERS THAT THE DEI ELEMENTS ARE STILL VIEWED AS VERY, VERY IMPORTANT IN CIRM'S MISSION. AND THEY'RE NOT CALLED OUT DEI FOR ALL THE REASONS WE KNOW ABOUT IN RELATIONSHIP TO THE FEDERAL LANDSCAPE, BUT THE APPLICANTS ARE ASKED TO PROVIDE US WITH CLEAR INFORMATION ABOUT HOW THEY'RE VIEWING, IN TERMS OF

133 HENNA COURT, SANDPOINT, IDAHO 83864
208-255-5453 208-920-3543 DRAIBE@HOTMAIL.COM

MOVING A PRODUCT OR A THERAPY INTO THE CLINICAL AREA, HOW THEY'RE VIEWING THE UNMET NEEDS, THE DIVERSITY OF THE POPULATION THAT HAS THE PROBLEM THAT'S UNDER CONSIDERATION, THE ECONOMIC VALUE PROPOSITION IN TERMS OF WHAT THEY'RE DOING TO SUPPORT INDIVIDUALS TO COME AND RECEIVE THIS THERAPY.

I JUST WANT TO SPEAK OF HOW RIGOROUS THIS PROCESS IS AND HOW, AS SOMEONE WHO'S A NURSE, HAS A BACKGROUND IN CLINICAL TRIALS, BUT IS THERE AS AN ADVOCATE FOR PATIENTS, EVERY COMMENT THE PATIENT ADVOCATES MAKE ABOUT DEI ARE VALUED AND WE'RE PART OF THE DISCUSSION.

AND THE LAST REVIEW THAT WE DID WITH PDEV, EVERY APPLICATION GOT A FAIR REVIEW IN TERMS OF THE SCIENCE, IN TERMS OF ITS POTENTIAL TO MOVE INTO THE CLINIC, WAS IT A VALUE PROPOSITION, WAS IT SOMETHING THAT SOCIETY NEEDED. AND WE HAD SOME APPLICATIONS THAT WERE FOR RARE DISEASES. WE HAD APPLICATIONS THAT WERE MORE FOR COMMON CONDITIONS. EACH ONE OF THEM WAS VALUED AND DISCUSSED.

SO I JUST WANT TO SPEAK HIGHLY IN FAVOR OF THIS EVEN THOUGH IT'S A VERY, VERY HARD THING THAT WE HAVE TO DO. IT'S THE BEST WE HAVE AT THE TIME WITH THE RESOURCES THAT WE HAVE, AND I JUST WANT TO

133 HENNA COURT, SANDPOINT, IDAHO 83864
208-255-5453 208-920-3543 DRAIBE@HOTMAIL.COM

APPLAUD THE STAFF FOR PUTTING IT TOGETHER. I THINK YOU HAVE TO TRUST THAT THE GWG IS WELL EDUCATED, WELL INFORMED TO MAKE INFORMATIVE DECISIONS. AND VIRTUALLY EVERY MEETING GOES OVER BECAUSE WE SPEND TIME -- THE AMOUNT OF TIME THAT APPLICATIONS NEED TO GIVE THEM A FAIR REVIEW. AND I'LL STOP THERE.

CHAIRMAN IMBASCIANI: THANK YOU, CHRISTINE. MARVIN, YOU'RE NEXT AND THEN LEONDRA WILL FOLLOW.

DR. SOUTHARD: I JUST WANTED TO SUPPORT EVERYTHING THAT CHRISTINE JUST SAID, SUPPORTING THIS CHANGE. AS SOMEONE WHO HAS SPENT HOURS AND HOURS REVIEWING, I HAVE TO SAY THAT THE CHANGE ON DEI TO ACCESS AND AFFORDABILITY, IF THE APPLICANT GETS IT, THEY GET IT REALLY WELL. AND IF THEY MISS IT, WE KNOW THAT THEY MISSED IT. SO I THINK THE PROCESS IS FULLY SUPPORTED. THANK YOU.

DR. CLARK-HARVEY: WHEW. I DID THAT FOR EVERYONE. THAT'S AN IMPORTANT BREATH BECAUSE I FEEL VERY PRIVILEGED HERE AS A PATIENT ADVOCATE TO BE SURROUNDED WITH COLLEAGUES THAT HAVE SUCH DEEP AND INTENSE SUBJECT MATTER EXPERTISE. THAT'S WHY WE ARE HERE. AND WITH THAT SAID, I THINK WE ALL BRING OUR VARIOUS PERSPECTIVES ON THE SUBJECT MATTER AT HAND. WE ALSO HAVE PERSPECTIVES ON THE PROCESS. BUT WE

133 HENNA COURT, SANDPOINT, IDAHO 83864
208-255-5453 208-920-3543 DRAIBE@HOTMAIL.COM

ARE A BOARD, AND WE HAVE A VERY CAPABLE STAFF. AND I DO THINK THAT SOMETIMES WE CAN TEND TO DANCE ON THE LINE BETWEEN EXPERTISE AND PROCESS. PROCESS FALLS WITHIN THE HANDS AND THE PURVIEW OF THE STAFF. OF COURSE, WE AS A BOARD CAN COMMENT ON THAT IF THERE ARE CONCERNS, BUT I THINK WE HAVE REACHED A POINT WHERE WE HAVE TO MOVE FORWARD. AND I AM VERY COMFORTABLE WITH THE PROCESS THAT HAS BEEN PUT FORTH. I APPRECIATE. I FEEL LIKE WE'VE HAD RIGOROUS DEBATE. AND I ALSO TRUST AND WANT TO HONOR MY COLLEAGUES THAT SPENT HOURS AND HOURS AND HOURS POURING OVER THESE APPLICATIONS AND TRYING TO DO WHAT'S RIGHT. SO THOSE ARE MY COMMENTS BASED ON WHAT I'VE OBSERVED AND HOW I'D LIKE TO MOVE FORWARD.

CHAIRMAN IMBASCIANI: THANK YOU. GIL, I DON'T SEE ANY OTHER HANDS RAISED.

DR. SAMBRANO: ALL RIGHT. THANK YOU VERY MUCH FOR THE COMMENTS AND QUESTIONS.

SO LET ME JUST GO OVER THE NEXT FEW SLIDES WHICH ADDRESS A PARTICULAR ELEMENT THAT CAME UP AT THE LAST SCIENCE SUBCOMMITTEE OF OUR USE OF SELECTION WITH RANKING VERSUS USING SELECTION WITH SCORING AND WHETHER THAT MAY MAKE A DIFFERENCE IN THE OUTCOMES. AND SO WE LOOKED AT THIS AND RAN SOME MONTE CARLO SIMULATIONS UTILIZING BOTH RANK AND

SCORE.

AND SO JUST TO SHOW YOU WHAT THE POTENTIAL DIFFERENCES ARE, I'M GOING TO WALK YOU THROUGH SOME OF THESE SLIDES. SO THIS IS AN EXPANSION OF THE SLIDE I PREVIOUSLY SHOWED YOU WHERE SELECTION MEANS A BINARY DECISION YES OR NO AND, THEREFORE, A POINT OR NO POINT. THAT WOULD REMAIN. AND THEN THE RANK, AS I ALSO SHOWED YOU, GETS CONVERTED TO POINTS. WELL, IF YOU LOOK AT A SCORE INSTEAD OF A RANK, AND IF YOU HAVE A SCALE OF 1 TO 5, THAT CAN MIRROR ALMOST EXACTLY A RANK BECAUSE YOU ARE CONVERTING THINGS TO POINTS OR A SCORE.

IN THIS TABLE I'M JUST SHOWING YOU THE ASSUMPTION THAT THE SCORE IS GOING TO BE EQUIVALENT TO THE RANK. IT DOESN'T HAVE TO BE. AND ONE OF THE THINGS WITH A SCORE IS THAT IT ALLOWS YOU TO SCORE MANY APPLICATIONS THE SAME OR A RANK FORCES YOU TO SEPARATE THEM. WE LOOKED AT A DIFFERENT SCALE. SO LIKE 1 TO 10 GIVES YOU MORE GRANULARITY IN TERMS OF WHAT THE OUTCOME MAY BE IN TERMS OF ASSIGNING AN APPLICATION SOME DIFFERENCES. SO IN THIS EXAMPLE, THE TOP AND THE BOTTOM ROW WHERE REVIEWER 1 AND REVIEWER 4 GAVE THAT APPLICATION EITHER A SCORE OF 5 OR IT GOT 5 POINTS BECAUSE IT WAS RANKED NO. 1 IN THEIR PILE. THERE MAY BE DIFFERENCES THAT A GREATER

SCALE COULD OFFER OF DISTINGUISHING IT AS A 10 VERSUS A 9 IN THAT PARTICULAR CASE. OF COURSE, THERE CAN BE MORE THAN THAT.

DIDN'T FINISH MAKING MY POINT. SORRY. AND THEN AT THE BOTTOM YOU SEE WHAT THE COMPOSITE SCORE WOULD LOOK LIKE FOR ALL OF THESE, AND THEY'RE PRETTY MUCH IN THE SAME BALLPARK.

IF YOU LOOK AT AN EXAMPLE HERE OF FIVE APPLICATIONS THAT ARE RANKED OR SCORED BY A GIVEN REVIEWER, YOU SEE APPLICATIONS A, B, C, D, E. AND SO IN THE RANKING, THEY ARE RANKED AND THEY ARE FORCED TO BE RANKED AND GIVEN A UNIQUE VALUE. SO 1, 2, 3, 4, 5. BUT IF YOU SCORE, YOU CAN GET A MORE VARIABLE OUTCOME IN TERMS OF WHAT A REVIEWER MAY DECIDE TO SCORE THESE APPLICATIONS. BECAUSE REMEMBER THESE TEND TO BE, IN THE EXAMPLE OF 5 OUT OF 15, THESE ARE GOING TO BE LIMITED TO THE TOP THIRD OF APPLICATIONS THAT THEY'RE LOOKING AT.

SO BY VIRTUE OF THAT, THE RANGE OF SCORES THAT THEY'RE GOING TO UTILIZE ARE GOING TO TEND TOWARDS THE TOP BECAUSE IT'S GOING TO COMPRESS THE SCALE. AND SO IT IS LIKELY THAT YOU ARE GOING GET MORE ASSIGNMENTS OF THE SAME SCORE TO MULTIPLE APPLICATIONS. AND SO I IDENTIFIED AND KIND OF JUST READ THE POSSIBILITY THAT YOU COULD GET MULTIPLE

133 HENNA COURT, SANDPOINT, IDAHO 83864
208-255-5453 208-920-3543 DRAIBE@HOTMAIL.COM

SCORES OF 5 OR 4 IN A SCALE OF 1 TO 5 OR MULTIPLE 8S AND 10S AND SO ON IN A SCALE OF 1 TO 10.

SO WHAT DOES ALL THAT MEAN? WELL, IT MEANS THAT YOU HAVE THE POTENTIAL FOR HAVING MORE TIES. THE POSSIBILITY IS THAT YOU MAY END UP GETTING MORE CLUMPING OF SCORES.

BUT WHEN WE RAN THE DISTRIBUTIONS ACROSS THIS, THEY STILL LOOK LARGELY THE SAME. AND ALTHOUGH THERE IS THE POSSIBILITY OF HAVING SOME CLUMPING HERE OR THERE, IT DIDN'T NECESSARILY PAN OUT IN ALL OF THE ITERATIONS THAT WE DID. BUT, OF COURSE, THESE ARE JUST SIMULATIONS. THEY'RE NOT ACTUAL VALIDATED, IN-PRACTICE SESSIONS. SO WE DON'T KNOW EXACTLY WHAT WE WILL FIND IN TERMS OF IN REAL PRACTICE WHETHER RANK AND SCORE ULTIMATELY MAKE A SIGNIFICANT DIFFERENCE. BUT AT LEAST IN THE SIMULATIONS, THEY SEEM TO BEHAVE VERY MUCH THE SAME.

AND SO THE SUMMARY OF THE ANALYSIS LOOKING AT RANKING VERSUS SCORING SUGGESTS THAT WE END UP WITH SIMILAR COMPOSITE SCORES, SIMILAR DISTRIBUTIONS, AND GRAY ZONES OR CUTOFF. AND, OF COURSE, KEY DIFFERENCES ARE THAT RANKING FORCES SEPARATION OF APPLICATIONS WHILE SCORING CAN RESULT IN SCORE COMPRESSION, WHICH COULD CREATE MORE TIES. SCORING, HOWEVER, DOES PROVIDE COMPARABILITY ACROSS

133 HENNA COURT, SANDPOINT, IDAHO 83864
208-255-5453 208-920-3543 DRAIBE@HOTMAIL.COM

BATCHES, AND THAT MAY BE IMPORTANT, BUT IT IS DIFFICULT TO KNOW IF, WHEN YOU SEE ANY DIFFERENCE, IT'S DUE TO BATCHES ACTUALLY BEING DIFFERENT FROM ONE ANOTHER IN TERMS OF QUALITY OR IF IT'S DIFFERENCES IN THE REVIEWER THEMSELVES IN THAT ONE REVIEWER WAS MORE LENIENT, ANOTHER ONE WAS MORE STRICT. AND SO THAT'S NOT SOMETHING THAT YOU CAN ASSESS.

SO WHEN COMPARING THESE, I THINK THE CIRM TEAM, IN GENERAL, PREFERS THE USE OF RANKING BECAUSE WE FEEL, AT LEAST AT THE ONSET TO TEST THIS OUT, WE THINK IT WILL PROVIDE CONSISTENT SEPARATION OF SCORES, PARTICULARLY AT THE CUTOFF. BUT LIKE ANYTHING ELSE, THIS IS SOMETHING THAT WE WANT TO CONTINUE TO COLLECT DATA ON AND MAKE SURE THAT WHAT WE'RE EXPECTING IN PRACTICE IS WORKING AS WE THINK.

ALL RIGHT. SO HOW DO YOU ESTABLISH THE CUTOFF? SO THIS IS THE TABLE I HAD MENTIONED EARLIER. SO THE WAY WE WOULD ESTABLISH THE SPECIFIC CUTOFF IS WE WOULD SET IT AT THE CLOSEST NUMERICAL BREAK WHERE THERE ARE NO TIES TO THE TARGET NUMBER OF APPLICATIONS THAT WOULD NOT EXCEED 10 PERCENT MORE OR FEWER THAN THE TARGET NUMBER.

AND SO IN THIS EXAMPLE, YOU HAVE THE APPLICATIONS THAT RANKED FROM 28 TO 32, AND YOU SEE

133 HENNA COURT, SANDPOINT, IDAHO 83864
208-255-5453 208-920-3543 DRAIBE@HOTMAIL.COM

THAT APPLICATIONS 29, 30, AND 31 HAVE THE EXACT SAME COMPOSITE SCORES. THOSE ARE TIED. AND SO WE WOULD LOOK FOR IS WHERE IS THE CLOSEST NUMERICAL BREAK WITH NO TIES THAT OCCURS BETWEEN 31 AND 32. SO THAT'S WHERE THE CUTOFF WOULD BE ESTABLISHED. AND SO ANYTHING THAT IS .32 OR GREATER ADVANCES, AND EVERYTHING ELSE BELOW THAT DOES NOT.

NOW, IF FOR SOME REASON AND, AGAIN, THE MODELING SUGGESTS THAT IT WOULD BE A RARE OCCURRENCE IF YOU CAN'T ESTABLISH THIS KIND OF CUTOFF, BUT IF FOR SOME REASON WE CANNOT, THEN WE WILL TAKE THE ENTIRE RANGE THAT OCCURS, WHICH IS LIKELY TO BE, SAY, FIVE, SIX APPLICATIONS IN AN EXAMPLE LIKE THIS, AND RANDOMIZE THEM IN ORDER TO SELECT THE TARGET NUMBER IN ORDER TO AVOID ANY SPECIFIC SELECTION BIAS IN DETERMINING WHAT ADVANCES.

ALL RIGHT. SO THEN THE LAST STEP IN THE PROCESS IS THAT ONCE A CUTOFF IS ESTABLISHED, THEN THE CIRM PRESIDENT, WITH RECOMMENDATION FROM THE CIRM STAFF, WILL EXAMINE THE APPLICATIONS THAT FALL BELOW THE CUTOFF AND MAY ADVANCE A LIMITED NUMBER OF THOSE APPLICATIONS THAT COULD REPRESENT A UNIQUE OPPORTUNITY ALIGNED WITH THE GOALS OF THE PARTICULAR CYCLE. AND SO THIS IS, IF YOU WILL, SORT OF A RESCUE PROCESS THAT'S BUILT INTO THIS.

133 HENNA COURT, SANDPOINT, IDAHO 83864
208-255-5453 208-920-3543 DRAIBE@HOTMAIL.COM

NOW, THE OTHER QUESTION THAT WE ADDRESSED DURING THE SCIENCE SUBCOMMITTEE, WHICH IS A VERY IMPORTANT ONE, IS THE ROLE OF PATIENT ADVOCATES IN TERMS OF THIS PROCESS. SO ALTHOUGH NOT INVOLVED DIRECTLY IN THE VOLUME CONTROL SELECTION, WHAT WE WANT TO DO IS HAVE THE ROLE OF THE PATIENT ADVOCATE STRENGTHENED AT THE GWG PANEL DISCUSSION. SO FOR THOSE APPLICATIONS THAT ADVANCE, ONE OF THE IDEAS THAT CAME THROUGH OUR ONGOING DISCUSSIONS WAS TO DEFINE AND INCLUDE A PATIENT PERSPECTIVE SCORE. AND SO THIS SCORE WOULD ALLOW US TO DEFINE SOME SPECIFIC CRITERIA THAT COME FROM THE PATIENT PERSPECTIVE AND UTILIZE A SCORE THAT THEN REPRESENTS THAT, THAT WE WOULD BRING TO THE BOARD AS PART OF THE APPLICATION. THIS IS AN ELEMENT THAT WE ARE STILL DISCUSSING WITH THE PATIENT ADVOCATE MEMBERS THAT SERVE ON THE GRANTS WORKING GROUP TO BETTER DEFINE IT BECAUSE IT CERTAINLY NEEDS MORE DEFINITION AND SOMETHING THAT WE WANT TO BRING BACK IDEALLY IN JUNE TO PRESENT TO YOU AS PART OF THIS PACKAGE.

AND ONE OF THE OTHER ELEMENTS THAT WE THOUGHT WOULD BE IMPORTANT WAS TO HAVE A PREDISCUSSION ORIENTATION THAT INCLUDES THE PATIENT ADVOCATES ALONG WITH THE GRANTS WORKING GROUP CHAIR TO TALK ABOUT HOW TO LEVERAGE THE RESPECTIVE

EXPERTISE GOING INTO THESE REVIEWS AND MAKING SURE THAT THE PATIENT PERSPECTIVE IS SOMETHING THAT IS INCLUDED IN THE DISCUSSION WHEN THESE APPLICATIONS ARE BROUGHT TO THE TABLE.

SO THAT'S MY SLIDE, AND I THINK, ROSA, IT COMES BACK TO YOU.

DR. YAMAMOTO: CAN WE DISCUSS?

CHAIRMAN IMBASCIANI: WHO'S SPEAKING?

VICE CHAIR BONNEVILLE: KEITH IS.

CHAIRMAN IMBASCIANI: KEITH, THERE YOU ARE. YES.

DR. YAMAMOTO: SO I APOLOGIZE, GIL. I'M STILL NOT CLEAR WHAT THE -- WHAT IS THE CUTOFF -- WHAT HAPPENS TO THE THINGS THAT ARE ABOVE AND BELOW THE CUTOFF? THIS IS FOR FURTHER DISCUSSION TO THEN DECIDE ON WHAT GETS FUNDED, WHAT WE RECOMMEND FOR FUNDING?

DR. SAMBRANO: RIGHT. SO THE ONES THAT ARE ABOVE THE CUTOFF ADVANCE TO, THEN, THE FULL GRANTS WORKING GROUP REVIEW. AND SO THEY ARE ASSIGNED A FULL SET OF REVIEWERS. SO IF IT'S CLINICAL, FOR EXAMPLE, THE FULL SET OF DISEASE AREA EXPERTS, CMC, AND SO ON, TO HAVE THAT FULL REVIEW AND DISCUSSION. THE ONES THAT FALL BELOW THE CUTOFF DO NOT ADVANCE, AND THAT'S SORT OF THE END FOR THOSE

133 HENNA COURT, SANDPOINT, IDAHO 83864
208-255-5453 208-920-3543 DRAIBE@HOTMAIL.COM

APPLICATIONS.

DR. YAMAMOTO: RIGHT. RIGHT. RIGHT. SO BEING ABOVE OR BELOW THE CUTOFF IS VERY CRITICAL OR GETTING THE ATTENTION OF THE PRESIDENT IF YOU'RE BELOW THE CUTOFF IS REALLY CRITICAL. IT'S REALLY THE BALLGAME OF WHETHER YOU'RE GOING TO BE IN THE RUNNING FOR GETTING FUNDED OR NOT. AND SO THAT'S WHY I THINK IT'S PARTICULARLY IMPORTANT TO SORT OF TRY TO GET THIS RIGHT. AND SO WHEN YOU SAY THAT THE NICE THING ABOUT RANKING, AND YOU'RE CERTAINLY CORRECT, THE NICE THING ABOUT RANKING IS THAT YOU GET GOOD SEPARATION OF THE APPLICATIONS.

THE PROBLEM IS THAT THAT SEPARATION IS A FALSE ONE. WHEN YOU'RE RANKING FIVE APPLICATIONS THAT YOU'VE SELECTED, THE RANKINGS BY DEFINITION SAY THAT YOU BELIEVE THAT THE QUALITY OF THEM, THE SCIENTIFIC VALUE OF THEM DIFFERS BY 20 PERCENT AS YOU GO FROM 1 TO 2 TO 3 TO 4 TO 5. THAT THE NO. 1 ONE IS 20 PERCENT BETTER THAN THE NO. 2 ONE.

IF YOU'RE SCORING, THAT ARTIFICIALNESS, YOU'RE LIBERATED FROM THAT ARTIFICIALNESS. SO A STRONG POOL COULD HAVE FIVE SELECTED APPLICATIONS IN WHICH THREE OF THEM GET A 1 AND TWO OF THEM GET A 2. IN A WEAK POOL, YOU COULD HAVE THE TOP RANKING ONE COULD GET A 6. AND SO YOU'RE ABLE TO REALLY INSERT

133 HENNA COURT, SANDPOINT, IDAHO 83864
208-255-5453 208-920-3543 DRAIBE@HOTMAIL.COM

AN ASSESSMENT OF THE QUALITY -- THE SCIENTIFIC VALUE IS WHAT WE'RE CLAIMING THAT WE'RE DOING IN THIS PROCESS. AND I JUST THINK THAT -- AND SO WHEN YOU RAN THE SIMULATIONS AND CAME UP WITH THE TWO PROCESSES, RANKING AND SCORING, THEY WERE RELATIVELY SIMILAR IS BECAUSE YOU ESSENTIALLY ASSIGNED THE SCORES TO REFLECT THE RANKS. BUT WHAT I'M SAYING IS THAT HOPEFULLY THAT WOULDN'T BE TRUE. THERE'S NO REVIEWER THAT WOULD ACTUALLY BELIEVE THAT THE FIVE THAT THEY'VE SELECTED DIFFER EACH FROM THE OTHER BY 20 PERCENT. THAT'S NOT TRUE. NOBODY WOULD BELIEVE THAT.

AND SO IF YOU LIBERATE THE REVIEWERS TO ACTUALLY ASCRIBE WHAT THEY THINK THE RELATIVE SCIENTIFIC VALUE OF THE APPLICATIONS IS, THEN YOU GET MUCH MORE INFORMATION. AND AS YOU SAID, YOU ALSO GAIN INTERPOOL INFORMATION. SO I THINK THE TWO ARE REALLY NOT AT ALL EQUIVALENT AND THAT THE SCORING IS SUBSTANTIALLY SUPERIOR. AND THIS MAY SOUND A LOT LIKE I'M QUIBBLING OVER DETAILS, AND I APOLOGIZE TO THE GROUP FOR THAT, BUT BECAUSE ESTABLISHING PRIORITY ABOVE AND BELOW THE CUTOFF IS SO CRITICAL AND IT'S REALLY THE BALLGAME, I THINK WE REALLY WANT TO TRY TO GET THIS RIGHT. AND WE OWE IT TO THE APPLICANTS WHO HAVE DONE SO MUCH WORK

133 HENNA COURT, SANDPOINT, IDAHO 83864
208-255-5453 208-920-3543 DRAIBE@HOTMAIL.COM

PREPARING THEIR APPLICATIONS TO BE ABLE TO DO THAT.

DR. CARETHERS: THIS IS JOHN CARETHERS. I JUST WANT TO SAY I SUPPORT THIS PROCESS. IN ESSENCE, YOU'RE TAKING A PROCESS THAT APPLY TO THE DIFFERENT PROGRAMS AND MORE STANDARDIZING ACROSS THE PROGRAMS, AND YOU'RE JUST USING A DIFFERENT, SLIGHTLY DIFFERENT WAY TO GET THE CUTOFF FOR THE FINAL REVIEW. SO YOU'RE TAKING A HUNDRED APPLICATIONS. YOU SHOWED THE DISTRIBUTION BETWEEN THE TWO. THEY DON'T LOOK HORRIBLY DIFFERENT. I KNOW THESE WERE MODELS. BUT I THINK THE PROCESS WILL BE THE PROCESS.

I AM LESS WORRIED ABOUT ORDINAL RANKING BECAUSE I THINK IT HELPS DIFFERENTIATE EVENTUALLY WHICH ONES GET FUNDED BECAUSE WE DO HAVE LIMITED FUNDING. IT'S ALWAYS HARD WHEN YOU SEE SCORES THAT ARE ALL VERY TIGHTLY, EVEN THOUGH THAT REFLECTS THE SCIENTIFIC RIGOR, AND MAYBE THERE COULD BE AN OPTION FOR TWO SCORES, BUT THE ORDINAL RANKING PUTS THEM IN ORDER BASED ON THE RIGOROUS REVIEW ON HOW SOMEONE IS GOING TO MOVE FORWARD BASED ON THE LIMITATIONS OF THE RESOURCES THAT ARE HAD FOR THAT ROUND. AND SO YOU HAVE TO DIFFERENTIATE SOMEHOW.

I GUESS THE ONLY THING THAT I WOULD POSSIBLY AGREE WITH KEITH ON THE ORDINAL VERSUS A

133 HENNA COURT, SANDPOINT, IDAHO 83864
208-255-5453 208-920-3543 DRAIBE@HOTMAIL.COM

SCORE RANKING IS HOW DO YOU COMPARE SOMEONE FROM ROUND 1 TO SAY ROUND 5 IN THE CLINICAL ROUND WHEN THE RULES HAVE CHANGED SLIGHTLY. I'M LESS WORRIED ABOUT THE INDIVIDUAL ROUNDS, BUT THAT WOULD BE THE ONLY THING I WOULD ASK.

DR. BARRETT: YEAH. THIS HAS BEEN A REALLY USEFUL DISCUSSION, AND I DO APPLAUD THE TEAM FOR WORKING VERY HARD ON THIS. AT THE RISK OF SORT OF TRYING TO REINVENT THE WHEEL, DID YOU CONSIDER A MODEL JUST BASED ON THE YES OR NO, IS IT IN THE TOP THIRD? BECAUSE WHEN I WAS AT THE NSF, WE HAD A SIMILAR PROBLEM WITH A VERY LARGE APPLICATION PRESSURE AND A NEED TO VOLUME CONTROL ON THE FRONT END. AND BEFORE I GOT THERE, THEY HAD A VERY SIMILAR PROCESS WHERE PEOPLE WOULD PICK THEIR TOP, I THINK IN THIS CASE IT WAS SEVEN, AND THEN THEY HAD TO RANK THEM.

AND WE WERE ADVISED BY THE THEN DIRECTOR OF THE SOCIAL AND BEHAVIORAL SCIENCES DIRECTORATE THAT IT IS ACTUALLY VERY DIFFICULT FROM A SOCIAL SCIENCE PERSPECTIVE FOR PEOPLE TO PUT THINGS IN ORDER. IN THAT CASE IT WAS FOR SEVEN. BUT IT FELT NOT TO REALLY ADD MEANINGFULLY TO THE PROCESS.

AND PERHAPS IF YOU ARE ONLY ASKING PEOPLE TO PUT THEM IN THE TOP THIRD, YOU COULD ACTUALLY

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HAVE MORE REVIEWERS DO THAT AND MAKE THAT A SORT OF MORE ROBUST NUMBER AND PRESUMABLY STILL HAVE A SPREAD ACROSS A LARGE NUMBER OF REVIEWERS.

DR. SAMBRANO: SO WE DID THE MODELING. SO THAT'S WHAT WE CALL SORT OF JUST A BINARY SELECTION, WHICH IS SIMILAR TO WHAT WE HAVE DONE WITH POSITIVE SELECTION. AND SO WE'VE ESSENTIALLY DONE THAT KIND OF BINARY MODEL. BUT WHAT HAPPENS IS THAT YOU END UP WITH A VERY LARGE GRAY AREA BECAUSE THE SELECTION IS LIMITED IN TERMS OF ITS LEVEL OF GRANULARITY. ADDING RANK OR SCORING, EITHER ONE, GIVES YOU ANOTHER LEVEL OF GRANULARITY BECAUSE YOU HAVE ANOTHER MEASURE THAT YOU CAN USE IN ORDER TO DISTINGUISH APPLICATIONS, AND IT ALLOWS THAT GRAY ZONE, THAT CUTOFF, TO NARROW SIGNIFICANTLY. AND SO IT ALLOWS A BETTER CUTOFF.

BUT WE DID LOOK AT DIFFERENT APPROACHES IN TERMS OF THE MODELING. AGAIN, A LOT OF THIS IS IN PRACTICE WHAT'S GOING TO HAPPEN. I THINK KEITH MAY BE ABSOLUTELY RIGHT, THAT SCORING WORKS BETTER. FROM OUR PERSPECTIVE, WE THINK THAT RANKING MAY WORK BETTER; BUT UNTIL WE DO IT, WE'RE NOT REALLY GOING TO KNOW. SO WE WANT TO COLLECT THAT DATA, MAKE SURE THAT IT'S WORKING AS WE EXPECT.

I ALSO JUST WANT TO CLARIFY IN TERMS OF A

COUPLE OF THE POINTS MADE, WHEN WE DID THE MODELING, WE DID NOT ASSUME THAT THEY WOULD HAVE UNIQUE SCORES. THE SCORES WERE ALLOWED TO BE THE SAME. AND THAT'S WHY YOU END UP GETTING THE ISSUE OF SCORE COMPRESSION. AND SO IT MAKES THE USE OF THE SCALE, IT JUST REALLY TIGHTENS IT. SO, FOR ME, THAT IS SOMETHING THAT WE WANT TO BE CAREFUL ABOUT. BUT, AGAIN, IT IS LOOKING AT A NUANCED ELEMENT. IT'S A SECOND MEASURE. WHETHER SCORE OR RANK, I THINK THEY WOULD BOTH ULTIMATELY WORK. BUT I CAN GET THIS POINT, RANKING FOR US IS WHAT WE PREFER.

DR. BARRETT: I MEAN I'M WILLING TO SUPPORT THE PROPOSAL NO MATTER WHAT, BUT YOU MIGHT WANT TO CONSULT WITH A SOCIAL SCIENTIST WHO WORKS ON VOTING PREFERENCES OR SOMETHING LIKE THAT JUST TO MAKE SURE THAT YOU'RE NOT INTRODUCING AN ELEMENT THAT'S NOT DEFENSIBLE FROM A HUMAN PSYCHOLOGY STANDPOINT.

DR. SAMBRANO: SURE. THANK YOU.

CHAIRMAN IMBASCIANI: PAT LEVITT IS ON THE LINE.

DR. LEVITT: YEAH. I WAS GOING TO SAY WHEN YOU -- BECAUSE I'VE BEEN ON NSF PANELS AS WELL, AND THE GRAY AREA IS VERY LARGE. IT'S ACTUALLY OUT OF FOUR BINS, IT OCCUPIES TWO BINS WHEN THEY DEFINE

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THE BINS AS MUST FUND, AND THEN YOU HAVE TWO BINS WHERE YOU'RE NOT SURE WHICH BIN IT SHOULD GO IN, TWO OR THREE, AND THEN YOU HAVE FOUR YOU'RE NOT GOING TO FUND AT ALL. SO YOU HAVE A VERY LARGE NUMBER OF APPLICATIONS THAT ARE SITTING IN THE MIDDLE. SO THAT TO ME IS A PROBLEM, BUT THAT'S HOW IT'S RUN A AT THE NATIONAL SCIENCE FOUNDATION.

THE OTHER THING I WOULD SAY IS I AGREE TO KEITH'S POINT, THAT IT WILL -- SCORING WILL DEAL WITH INTERGROUP BATCH ISSUES. BUT THE PROBLEM WITH SCORING HAS ALWAYS BEEN, AND THIS IS TRUE AT NIH AND EVERY OTHER ORGANIZATION THAT USES SCORING, IS THAT THERE'S SCORING COMPRESSION. THAT IS A SOCIAL SCIENCE FACT. AND YOU NEED A THIN GRAY AREA HERE AND YOU NEED SOME WAY OF DIFFERENTIATING WHICH THE RANK DOES. SO I WOULD REALLY SUPPORT TRYING TO RANK FIRST AND SEEING WHAT HAPPENS. AS YOUR GRAY ZONE, AS YOU PREDICTED BASED ON YOUR MONTE CARLO, IS THERE A CLEAR BREAK? AND THEN IF THERE'S SOME ISSUES, GOING TO SCORING IS CERTAINLY WORTH A TRY, BUT I DO THINK THAT REVIEWERS TEND TO COMPRESS. AND NIH HAS GONE TO EXTREMES TO TRY TO GET REVIEWERS TO USE THE WHOLE RANGE AND THEY NEVER DO. SO CONGRATULATIONS, AND MAYBE WE'RE DONE WITH THIS.

CHAIRMAN IMBASCIANI: OKAY. SCOTT, WE'RE

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TAKING A BREAK.

MR. TOCHER: IF WE ARE FINISHED WITH THIS PORTION.

CHAIRMAN IMBASCIANI: DO YOU WANT TO GO TO A POINT WHERE YOU CAN PAUSE?

DR. SAMBRANO: THIS IS A POINT WHERE WE CAN PAUSE.

MR. TOCHER: WE WILL TAKE A QUICK FIVE, AND I KNOW THAT MEANS TEN, BIOBREAK. AND SO PLEASE HURRY BACK AS SOON AS YOU CAN.

(A RECESS WAS TAKEN.)

DR. CANET-AVILES: SO, LET'S ROCK AND ROLL. SO I'M NOW GOING TO FOCUS ON HOW THE GUIDING PRINCIPLES ARE APPLIED IN THE LAST STEP IN THE APPLICATION LIFE CYCLES, WHICH IS THE FUNDING DECISIONS WHICH THE APPLICATION REVIEW SUBCOMMITTEE OF THE BOARD MAKES.

AND SO, AGAIN, JUST TO ITERATE, WE ARE ON THAT TARGET, THE GREEN PART RIGHT THERE. THAT'S THE FUNDING DECISION. AND HISTORICALLY, JUST FOR CONTEXT, THE CIRM TEAM HAS PROVIDED RECOMMENDATIONS TO THE ARS BY PROVIDING AN ANALYSIS, A PROGRAMMATIC ANALYSIS, TOGETHER WITH THE GRANTS WORKING GROUP SUMMARIES AND THE PUBLIC COMMENT. BUT ULTIMATELY THE ARS CONSIDERS MANY DIFFERENT THINGS IN HOW IT

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CHOOSES TO FUND WHICH APPLICATION.

SO WHAT WE ARE GOING TO DO NOW IS PROPOSE A REFINEMENT. IT'S NOT A HUGE CHANGE. IT'S JUST A REFINEMENT ON HOW THE CIRM TEAM RECOMMENDATIONS ASSIST THE ARS IN MAKING THESE DECISIONS, WHICH IS BASICALLY A MORE TRANSPARENT WAY TO PROVIDE PROGRAMMATIC RECOMMENDATIONS BASED ON THE GUIDING PRINCIPLES. SO THIS IS THE LAST STAGE, HOW TO APPLY GUIDING PRINCIPLES TO THE RECOMMENDATIONS.

SO WHAT DOES THE CIRM TEAM RECOMMENDATIONS INCLUDE? THE FIRST THING THAT THEY INCLUDE ARE -- SO WE'RE GOING FOCUS, JUST TO FOCUS THE ATTENTION, THE PROGRAMMATIC FACTORS IS WHERE THE GUIDING PRINCIPLES WILL GO. BUT WHEN WE PROVIDE RECOMMENDATIONS TO THE ARS OF THE BOARD, WE PROVIDE THE AVAILABLE PROGRAM BUDGETS OR SOMETIMES, LIKE TODAY, WE DIDN'T HAVE ENOUGH MONEY TO FUND THE EIGHT DISC4. SO WE HAD TO PROVIDE THE BUDGET AVAILABLE, THE BUDGET ASK, AND THEN THE BOARD COULD MAKE THEIR DECISIONS.

WE ALSO PROVIDE THE GRANTS WORKING GROUP A SCORE AND THE COMMENTS, THE SUMMARY OF THE COMMENTS FROM THE GRANTS WORKING GROUP, THE PROGRAMMATIC FACTORS, WHICH IS WHERE THE GUIDING PRINCIPLES WILL COME INTO PLAY AT THAT PORTFOLIO LEVEL. AND I'LL GO

INTO SPECIFICS IN THE NEXT SLIDES. AND THEN PRIOR AWARDEE PERFORMANCE LIKE IF THEY HAVE STRONG EXECUTION, THAT BUILDS CONFIDENCE. RIGHT? BUT IF THERE ARE PERSISTENT DELAYS, WE MIGHT BRING THIS UP SO THAT THE BOARD IS AWARE THAT THOSE THINGS HAPPEN. AND THEN ANY NEW INFORMATION, SCIENTIFIC OR ADMINISTRATIVE INFORMATION, THAT COMES TO THE ATTENTION OF CIRM STAFF THROUGH DIRECT COMMUNICATION WITH APPLICANTS OR INSTITUTIONS OR PUBLICATIONS OR OTHER.

SO IN THE NEXT SLIDES, WHAT I'M GOING TO DESCRIBE IS HOW THESE GUIDING PRINCIPLES APPLY AND ARE ASSESSED AND LEVERAGED IN THE CIRM TEAM RECOMMENDATIONS AT THE PROGRAMMATIC LEVEL. SO PROGRAMMATIC FACTORS FOR PDEV AND CLIN2, THERE ARE THE THREE GUIDING PRINCIPLES THAT APPLY ON HOW THEY ARE ASSESSED. THE FIRST ONE IS TRANSFORMATIVE CLINICAL IMPACT. THE KIND OF INFORMATION THAT WE LOOK AT ONCE THERE IS A GRANTS WORKING GROUP RECOMMENDATION FOR US TO PROVIDE TO THE BOARD IS THAT WE COMPARE THAT AWARD TO ACTIVE AWARDS AND EXTERNAL LANDSCAPE WITHIN THE SAME INDICATION.

THE SECOND ASPECT IS PATIENT ACCESS, AND THERE IS A DIFFERENCE HERE BETWEEN CLIN2 AND PDEV. SO FOR CLIN2, BEYOND PROVIDING ANY KNOWLEDGE OF THE

MODALITY AND ROUTE OF ADMINISTRATION WHICH DOES HAVE AN EFFECT ON THE PATIENT OR HOW THE PATIENTS WILL BE ABLE TO ACCESS THIS, WE ALSO PROVIDE A SUMMARY OF THE ACCESS SPECIALIST REVIEWER COMMENTS. THERE WILL BE ACCESS SPECIALISTS REVIEWERS IN THE GRANTS WORKING GROUP OF CLIN2. AND THEN THE DISEASE REPRESENTATION. WE COMPARE TO OUR ACTIVE AWARD PORTFOLIO BY DISEASE AREA.

SO THE NEXT ONE IS THE DISC4. SO FOR DISC4, THE THREE PRINCIPLES. THE FIRST ONE, THE MULTIDISCIPLINARY RESEARCH APPROACH, DOES NOT APPLY. WE DO NOT PROVIDE ANYTHING EXTRA. THERE IS AN ASSESSMENT THAT'S ALREADY PROVIDED BY THE GRANTS WORKING GROUP REVIEW SUMMARY, AND THAT'S WHAT THE ARS WILL RECEIVE IN TERMS OF THAT PRINCIPLE.

BUT THEN FOR THE COLLABORATION NETWORK SYNERGY AND DATA LEVERAGE, WE ARE GOING TO EVALUATE HOW THE RESEARCH APPROACHES AND THE TOPIC AREA COMPARE TO ACTIVE DISC4 PORTFOLIO AND PENDING AWARDS TO FIGURE OUT IF THERE ARE WAYS THAT BY FUNDING THAT AWARD WE COULD BE ABLE TO INCREASE THE NETWORK SYNERGY, FOR EXAMPLE. SO THOSE KIND OF ELEMENTS WILL BE IN CONSIDERATION IN THAT PROGRAMMATIC RECOMMENDATION.

AND THEN THE NEURO TASK FORCE AND OTHER

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ORGANIZATIONAL PRIORITIES, BECAUSE, AS KELLY WILL DESCRIBE, THE DISC4 IS OPEN TO ALL COMERS. WE JUST HAVE A FOCUS AREA THAT WILL BE IN PLAY AT THE SELECTION CRITERIA. SO IF THERE IS ONE THAT'S NOT WITHIN THE ANNUAL FOCUS AREA, BUT IT MAKES IT TO REVIEW, AND THEN WE CAN ONLY FUND, AGAIN, SIX OF EIGHT, THOSE THAT ARE NOT WITHIN THE ANNUAL FOCUS AREA, THAT WOULD BE A CONSIDERATION AND THEN ANY ADDITIONAL CONSIDERATIONS CONCERNING EVOLVING RESEARCH LANDSCAPE AND FUNDING NEEDS.

SO FINALLY, THE CIRM TEAM RECOMMENDATION MEMO, THIS IS WHAT WE WILL PROVIDE TO THE ARS FOR THE MEETING FOR CONSIDERATION. AND, AGAIN, THEY CAN -- IT'S UP TO THE PREROGATIVE OF THE APPLICATION REVIEW SUBCOMMITTEE TO CONSIDER THIS. SO WE WILL INCLUDE, AND THERE IS AN EXAMPLE IN THE MEMO, A SUMMARY TABLE AND RATIONALE FOR ALL THE APPLICATIONS. ACTUALLY WE PUT RECOMMENDATIONS THERE, BUT IT'S CONFUSING. SO ALL THE APPLICATIONS THAT CAME IN, WE WILL HAVE A SUMMARY TABLE AND THE RATIONALE. AND WE WILL HAVE GRANTS WORKING GROUP WHETHER THEY RECOMMENDED FOR FUNDING AND THEN WHAT THE TEAM, LIKE IF WE DISAGREE WITH THAT OR NOT. RIGHT?

AND THEN BASED ON ALL THAT, THE ANALYSIS

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OF PROGRAMMATIC FACTORS FOR THE MINORITY REPORTS, APPLICATIONS WHERE THE CIRM RECOMMENDATION DIFFERS FROM GRANTS WORKING GROUP, ALL OF THOSE WILL HAVE AN ANALYSIS OF THE FACTORS THAT WE JUST SAW. AND THEN ANY APPLICATION, AND THIS IS A HANDFUL OF AN EXPRESSION, BUT IF WE THINK ABOUT IT, ANY APPLICATION WITH A GRANTS WORKING GROUP SCORE HIGHER THAN OR TIED WITH THE LOWEST SCORING CIRM RECOMMENDED APPLICATIONS.

SO LET'S IMAGINE THAT WE HAD AN 80 AND THERE IS AN 83 THAT'S NOT RECOMMENDED, BUT WE RECOMMEND FOR FUNDING THE 80 BECAUSE MAYBE IT HAS AN ACCESS PATH THAT'S AMAZING AND WE THINK THAT IT WILL MAKE IT, AND IT WILL BE A LOT OF VALUE FOR PATIENTS. SO WE COULD ACTUALLY BE MAKING -- ANYTHING THAT'S OVER THAT 80 COULD BE COMING WITH A PROGRAMMATIC AS WELL BECAUSE WE NEED TO EXPLAIN TO THE BOARD HOW THEY DIFFER. YOU NEED TO HAVE THOSE DETAILS. SO THAT'S IT.

AND NOW OTHER UPDATES TO FUNDING PROGRAMS. AND I WANT TO SAY SOMETHING ABOUT KELLY.

DR. SHEPARD -- SORRY.

VICE CHAIR BONNEVILLE: IT'S OKAY. I WANTED TO MAKE A COMMENT ABOUT THE ARS AND THE RECOMMENDATIONS THAT ARE GOING TO BE COMING AND HOW

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THOSE ARE COMING BECAUSE I THINK THAT'S WONDERFUL. I THINK IT IS REALLY IMPORTANT TO HAVE ALL OF THAT INFORMATION AS OUR FUNDING DOLLARS GET FEWER AND THE DEMAND STAYS THE SAME AND MORE THINGS ARE RECOMMENDED THAN WE CAN FUND. I THINK IT'S -- I THINK HOW WE APPROACH THE ARS IS GOING TO HAVE TO CHANGE A BIT OR AT LEAST BE CONSIDERED DIFFERENTLY AND HOW THE PRESENTATIONS ARE DONE AND WHAT INFORMATION IS GIVEN DURING THE PRESENTATION VERSUS WHAT IS IN OUR BOARDABLE OR BOARD PACKETS IS ALSO REALLY IMPORTANT. AND SO I THINK IT'S SOMETHING THAT VITO HAS TO FIGURE OUT AS CHAIR OF THE ARS IS HOW WE ARE GOING TO GO TO APPROACH THE APPLICATION REVIEW SUBCOMMITTEE.

CHAIRMAN IMBASCIANI: YOU'RE ABSOLUTELY RIGHT, MARIA. WE'VE JUST BEGUN TO HAVE CONVERSATIONS ON THIS. IT IS GOING TO PUT A SLIGHTLY, I EXPECT, LARGER ONUS, BURDEN, ON MEMBERS OF THE ARS TO BE -- YOU'VE ALWAYS BEEN DILIGENT, OF COURSE, IN COMING TO THESE MEETINGS, BUT AN EXTRA DEGREE OF DILIGENCE IS GOING TO BE REQUIRED BECAUSE YOU ARE GOING TO HAVE A MORE POWERFUL ROLE IN SELECTING APPLICATIONS FOR FUNDING BASED ON THE INFORMATION, THE REPORT CARDS, THE REVIEW CARDS THAT ARE GOING TO BE COMING FROM THE TEAM. SO MORE

HOMEWORK WILL HAVE TO BE DONE.

VICE CHAIR BONNEVILLE: IS THAT SOMETHING THAT WE CAN START TO DISCUSS IN JUNE, WHAT THAT PROCESS WILL BE? I KNOW THIS WON'T TAKE EFFECT -- WILL IT START FOR THE JUNE MEETING? NO. IT WILL PROBABLY BE SEPTEMBER IS WHEN THE FIRST BUNCH OF APPLICATIONS.

DR. CANET-AVILES: THE FIRST CLIN2 WILL BE IN SEPTEMBER BECAUSE IT'S THE APRIL CLIN2.

VICE CHAIR BONNEVILLE: GREAT. SO WE SHOULD START TALKING ABOUT THIS IN JUNE SO THAT BY SEPTEMBER WE UNDERSTAND WHAT THE ASK IS.

CHAIRMAN IMBASCIANI: I'LL START TALKING TODAY IF YOU WANT.

DR. CANET-AVILES: THANK YOU. I JUST WANTED TO MENTION WE HEARD JIM DEKLOE TODAY. THE EDUCATION AND THE WORKFORCE DEVELOPMENT HAS BEEN A SET OF STAR PROGRAMS AT CIRM. AND I FEEL IT'D BE REMISS TO NOT MENTION THE ROLE THAT DR. SHEPARD HAS HAD IN THE DEVELOPMENT OF OUR WORKFORCE EDUCATION PROGRAMS. SHE'S ALSO THE LEAD FOR THE DISCOVERY PROGRAM. SO I JUST WANT TO THANK KELLY FOR ALL THE WORK BECAUSE FOR THE LONGEST TIME SHE WAS HOLDING THEM ON HER OWN. NOW SHE HAS A TEAM DOING THAT WITH HER. AND THEY ARE POSSIBLE BECAUSE OF HER EFFORTS

AND HER MENTORSHIP AS WELL OF THOSE DIRECTORS. SO THANK YOU, KELLY.

AND NOW COME ON OVER. YOU HAVE THE DISC4 FOCUS.

DR. SHEPARD: GOOD AFTERNOON, MEMBERS OF THE BOARD, MEMBERS OF THE PUBLIC. GOOD AFTERNOON, EVERYONE, MEMBERS OF OUR BOARD, MEMBERS OF THE PUBLIC, CIRM TEAM. IT'S MY PLEASURE TO COME HERE BEFORE YOU TODAY TO PROPOSE TO YOU THE ANNUAL FOCUS AREA FOR OUR NEXT DISC4 FUNDING OPPORTUNITY.

SO THIS IS JUST A QUICK REMINDER THAT WHEN YOU APPROVED THE DISC4 CONCEPT LAST MARCH, IT INCLUDED A ROTATING AREA FOCUS. THE FIRST OR PILOT VERSION OF THIS PROGRAM WAS OUR REMIND PROGRAM, AND IT HAD A FOCUS ON NEUROPSYCHIATRIC AND NEURODEVELOPMENT PROGRAMS.

THE SECOND ITERATION WAS ALSO NEURO TASK FORCE RECOMMENDED AREA FOCUS, WHICH WAS NEUROLOGICAL DISORDERS. AND THE CULMINATION OF THAT ROUND OF FUNDING IS THE SLATE OF OUTSTANDING DISC4 APPLICATIONS THAT YOU APPROVED THIS MORNING. AND WE ARE REALLY THRILLED TO SEE THE INNOVATIVE SCIENCE THAT CAME OUT OF THIS INITIATIVE.

SO TODAY WE'RE HERE TO TALK ABOUT WHAT THE AREA FOCUS WILL BE FOR OUR NEXT CYCLE THAT WE WOULD

BRINGING TO YOU NEXT MARCH.

SO WE'VE CONSIDERED A LOT OF DIFFERENT POSSIBILITIES ON OUR TEAM, CONSULTING LITERATURE AND LOOKING AT THE TRENDS THAT WE'VE BEEN SEEING IN OUR DISCOVERY PROGRAMS AND KIND OF SOME OF THE OPPORTUNITIES THAT ARE OUT THERE. AND WHAT WE HAVE DECIDED TO PROPOSE AS OUR FIRST SUGGESTION FOR THE NEXT AREA OF FOCUS CAN BE DESCRIBED AS IMMUNE TISSUE INTERACTIONS OR INTERPLAY IN THE CONTEXT OF DISEASE AND REPAIR.

SO THIS IS SORT OF A SYSTEMS FOCUS RATHER THAN A DISEASE OR TISSUE-SPECIFIC FOCUS BECAUSE, AS YOU ALL KNOW, THE IMMUNE SYSTEM PLAYS A ROLE IN A LOT OF OUR TISSUES AND PROCESSES IN OUR BODY. IT'S NOT JUST ABOUT FIGHTING INFECTION. IT MAKES CONTRIBUTIONS AT ALL LEVELS AND STAGES OF OUR HEALTH AND OUR LIFETIME.

AND SO THIS FOCUS AREA IS APPLICABLE TO A BROAD SPECTRUM OF DISEASES THAT AFFECT CALIFORNIANS. SO THAT'S WHAT IS MEANT TO BE DEPICTED IN THAT LITTLE FIGURE WE PUT TOGETHER. IT'S SHOWING THAT ALL THESE DIFFERENT ORGAN SYSTEMS, THERE ARE DISEASES THAT AFFECT THOSE ORGANS THAT SUFFER WHEN THERE ARE DYSREGULATION OF IMMUNE FUNCTION. SO IT'S APPLICABLE TO A BROAD SPECTRUM OF DISEASES. IT'S A

PROBLEM THAT IS WELL-SUITED FOR THE DISC4 INITIATIVE.

THE DISC4, AS YOU RECALL, IS THE LARGE, MULTIDISCIPLINARY TEAM-BASED APPROACH, TAKING ADVANTAGE OF CUTTING-EDGE NEW TOOLS AND OMICS-DRIVEN APPROACHES. AND SO THIS IS THE PERFECT TYPE OF APPLICATION OF AN INVESTMENT TO BEGIN TO UNRAVEL THE COMPLEXITY OF HOW IMMUNE-TISSUE INTERACTIONS AFFECT OUR DEVELOPMENT AND HOW THEY GO AWRY IN SITUATIONS OF DISEASE AND HOW THEY CONTRIBUTE TO OUR BODY'S ABILITY TO REPAIR ITSELF AFTER SICKNESS OR DISEASE.

THIS APPROACH, BECAUSE IT IS COMPLEX AND INTERDISCIPLINARY AND INTERSYSTEMS APPROACH, IT WILL ENABLE IDENTIFICATION OF NOVEL TARGETS AND BIOMARKERS; FOR EXAMPLE, SUCH AS THOSE THAT DISTINGUISH BETWEEN MALADAPTIVE VERSUS PRODUCTIVE REPAIR. THIS IS PARTICULARLY USEFUL FOR IDENTIFYING NOVEL TARGETS BECAUSE YOU NEED TO DO YOUR STUDIES IN A SYSTEM WHERE THERE ARE MULTIPLE DIFFERENT TYPES OF CELL TYPES WORKING TOGETHER TO IDENTIFY A POTENTIAL PATHWAY TO TARGET, WHICH IS SOMETHING THAT WOULD BE MISSED IN A SYSTEM WHERE YOU'RE ONLY LOOKING AT ONE CELL TYPE FOR ONLY CELL AUTONOMOUS DEFECTS.

SO THERE'S POSSIBILITIES TO TAKE ADVANTAGE OF THESE REALLY NEW TECHNOLOGIES TO UNDERSTAND

SPATIAL OMICS IN CELLS, CELL/CELL INTERACTIONS, CELL STATES, DIFFERENCES IN CELL STATES. THOSE ARE ALL OPEN FIELDS OF INVESTIGATION THAT MIGHT LEAD TO NEW AND INTERESTING TARGETS AND BIOMARKERS THAT COULD BE OF BENEFIT AND PERHAPS RELEVANT IN MORE THAN ONE DISEASE CONTEXT.

THIS IS ALSO AN AREA THAT REALLY SUPPORTS AND TAKES ADVANTAGE OF THE IMPROVED HUMAN STEM CELL AND ORGANOID MODELS THAT A LOT OF OUR GRANTEES ARE WORKING ON, BUILDING THE NEXT GENERATION OF ASSEMBLOIDS THAT INCLUDE IMMUNE CELLS IN ADDITION TO THE TISSUE CELLS OF A PARTICULAR ORGANOID AND OTHER SUPPORT CELLS.

AND, FINALLY, WE THINK THAT FOCUSING AROUND SYSTEMS LIKE THIS WILL CREATE STRONG OPPORTUNITIES FOR NETWORK SYNERGY ACROSS FUNDED PROGRAMS. AND, INDEED, SOME OF THE TYPES OF PROPOSALS WE SAW IN THE CYCLE THAT YOU DISCUSSED THIS MORNING, WE WERE SEEING QUITE A FEW PROJECTS THAT WERE ADDRESSING NEURAL IMMUNE INTERACTIONS. AND SO THOSE TYPES OF PROGRAMS WILL FIND A HOME IN THIS AREA FOCUS AS WELL.

SO THIS IS OUR RECOMMENDATION. AND I'D BE HAPPY TO TAKE ANY QUESTIONS IF YOU ANY OF YOU HAVE QUESTIONS BEFORE WE ASK FOR YOUR VOTE ON THIS.

CHAIRMAN IMBASCIANI: I DON'T SEE ANY.

DR. DULIEGE: IS THAT STILL IN CYCLE OF ONE PER YEAR, OR WILL THERE BE -- ARE THERE ANY OPTION? I KNOW IT'S A LOT OF WORK AND DEPENDS OF THE MONEY WE HAVE TO HAVE TWO CYCLES PER YEAR. I'M SAYING THAT BECAUSE IF PEOPLE WANT TO BE GIVEN A CHANCE TO REAPPLY, BASED ON SOME COMMENTS, ONE CYCLE PER YEAR REALLY IS NOT PRACTICAL. SO I'M JUST CURIOUS.

DR. SHEPARD: WELL, CURRENTLY THE WAY OUR BUDGET REQUEST HAS BEEN IS IT HAS BEEN SET FOR ONE CYCLE PER YEAR. AND I KNOW THAT WE COME AND DISCUSS BUDGET WITH YOU EVERY YEAR. BUT THIS PARTICULAR CYCLE IS READY. ASSUMING WE GET AN APPROVAL TODAY, WE'LL BE READY TO POST THE PA IN APRIL AND BEGIN TO START ACCEPTING THE PRESUBMISSIONS THAT WOULD BE DUE LATER THIS SUMMER.

SO WE WOULD HAVE THAT GOING BEFORE ANY DISCUSSIONS ABOUT THIS NEXT CYCLE AFTER THAT. BUT AS DR. CANET-AVILES POINTED OUT THIS MORNING, WE ALSO HAVE ANOTHER DISCOVERY OPPORTUNITY CALLED DISC5 WHICH SUPPORTS SIMILAR TYPES OF METHODOLOGICAL STUDIES JUST WITH SMALLER TEAMS. AND WE'RE REALLY HOPING THAT SOME OF THE PROJECTS THAT MIGHT BE SUITABLE FOR THESE LARGE MULTIDISCIPLINARY

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APPROACHES COULD INDEED ALSO CHOOSE TO PARTICIPATE FOR A SUBSET OF THOSE ACTIVITIES UNDER A FUTURE DISC5. AND THEY WOULD STILL HAVE THE BENEFIT, IF RECEIVING A DISC5 GRANT, OF INTERACTING WITH AND JOINING PART OF THE NETWORK THAT WE'RE BUILDING FOR OUR DISCOVERY PROGRAMS SO THAT THEY CAN LEVERAGE DATA AND BUILD ON EACH OTHER'S FINDINGS TO THE EXTENT THAT WE CAN LEVERAGE THAT.

VICE CHAIR BONNEVILLE: ALSO THIS DID COME THROUGH THE SCIENCE SUBCOMMITTEE, AND EVERYONE -- AND THIS ISN'T ABOUT ONE OR TWO CYCLES, BUT PRIMARILY THE FOCUS RECOMMENDATION WAS SOMETHING THAT THE SCIENCE SUBCOMMITTEE READILY ENDORSED AND THOUGHT WAS A GREAT IDEA. SO THANKS, KELLY.

THE QUESTION ABOUT TWO CYCLES VERSUS ONE WOULD BE SOMETHING ROSA CAN ADDRESS IN FURTHER DETAIL, ANNE-MARIE.

DR. CANET-AVILES: THANK YOU, DR. DULIEGE.

SO ONE OF THE -- THIS PROGRAM, THE DISC4, WAS MODELED AFTER PUBLIC/PRIVATE PARTNERSHIPS LIKE THE ACCELERATED MEDICINES PARTNERSHIPS. THOSE PROGRAMS ARE ACTUALLY MULTIDISCIPLINARY COLLABORATIONS. IT TAKES A LONG TIME TO PUT TOGETHER, REVIEW. AS YOU SAW, WE GET LIKE A HUNDRED PREAPPLICATIONS, PRESUBMISSIONS. RIGHT? SO THE

PROCESS IS LONG. WE CAN ONLY DO ONE A YEAR.

BUT ALSO, IT WAS MODELED THROUGH -- THE NIH FUNDING FOR THIS KIND OF PROGRAMS IS 80 MILLION EVERY FIVE YEARS. SO WE ARE ACTUALLY HAVING 84 EVERY YEAR WHICH IS -- AND THAT'S WHY WE COMPLEMENT WITH THE DISC5. RIGHT? SO THERE'S A DIFFERENT NATURE TO THESE KIND OF PROGRAMS, AND HOPEFULLY THAT HELPS ALSO WITH THE CONTEXT. THANK YOU.

DR. DULIEGE: THANK YOU.

CHAIRMAN IMBASCIANI: KELLY, MARK FISCHER-COLBRIE IS ON THE LINE.

DR. SHEPARD: YES. THANK YOU, MARK.

MR. FISCHER-COLBRIE: THANK YOU, KELLY. I'M VERY EXCITED ABOUT THIS OPPORTUNITY HERE BECAUSE THIS FURTHER EXPANDS UPON OUR STRATEGIC DIRECTION WITH RESPECT TO LOOKING AT THINGS AS SYSTEMS. AND HAVING THAT KIND OF BROAD PERSPECTIVE HAS THE OPPORTUNITY TO MAKE DRAMATIC IMPROVEMENTS ABOUT KNOWLEDGE AND ABOUT HOW THINGS WORK. AND SO WITH THIS KIND OF APPROACH AND WITH THIS PARTICULAR TOPIC AREA, I THINK THERE IS INCREDIBLE OPPORTUNITIES FOR ACCELERATION OF DISCOVERY. SO THANK YOU.

DR. SHEPARD: THANK YOU, MARK.

WELL, IF THERE ARE NO FURTHER QUESTIONS, THANK YOU FOR YOUR ATTENTION. AND I THINK WE'LL

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HAVE DR. SHYAM PATEL PRESENT THE FINAL SLIDE HERE.

DR. PATEL: GOOD AFTERNOON. I HOPE THIS IS WORKING. ALL RIGHT. GREAT. GOOD AFTERNOON. I'M SHYAM PATEL, ASSOCIATE VICE PRESIDENT OF PRECLINICAL DEVELOPMENT AT CIRM. I'M GETTING THE EAR SIGNAL FROM MY COLLEAGUES. SO I'M GOING TO TRY A LITTLE HARDER HERE.

SO BEFORE I BEGIN, I DO ALSO WANT TO SECOND ROSA'S COMMENT ABOUT DR. KELLY SHEPARD AND THE TEAM'S DEDICATION TO EDUC PROGRAMS. I CAN SEE ON A DAILY BASIS HOW MUCH HEART THEY POUR INTO THAT. AND I'VE SAID IT BEFORE AND I'LL SAY IT AGAIN. ON A WEEKLY BASIS, WE COME ACROSS PEOPLE WHO ARE ALUMNI OF THOSE PROGRAMS. TO GIVE YOU A EXAMPLE, DR. DIANA FARMER EARLIER TODAY SPOKE ABOUT HER PROGRAM. SHE MENTIONED DR. AIJUN WANG AS HER COLLABORATOR. HE WAS A CIRM SCHOLAR.

SHE ALSO MENTIONED THAT THE ONE BIG ADVANTAGE THAT THEY HAVE IS THE GMP MANUFACTURING FACILITY AT UC DAVIS. THE DIRECTOR OF THAT FACILITY, BRIAN FURY, WAS ONE OF THE FIRST BRIDGES SCHOLARS. AND SO NOT ONLY ARE THEY BEING TRAINED THROUGH THESE DIFFERENT INSTITUTIONS, THEY'RE GOING ON TO HAVE CAREERS THAT DIRECTLY IMPACT CIRM PROJECTS.

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OKAY. SO WITH THAT OUT OF THE WAY, I'M GOING TO TALK ABOUT THE PDEV CYCLE RECURRENCE. SO JUST A REMINDER, THE PDEV PROGRAM IS A PRECLINICAL DEVELOPMENT PROGRAM. IT'S DESIGNED TO TAKE EVERY SINGLE PROJECT THAT IT FUNDS TO IND CLEARANCE. SO REGARDLESS OF WHAT STAGE IT'S AT, THEY GET FUNDING TO GET ALL THE WAY TO IND CLEARANCE. THEY CAN COME IN HAVING JUST DECLARED A CANDIDATE, OR THEY COULD COME IN MIDSTREAM WITH THE PRE-IND MEETING OR AFTER THEIR PRE-IND MEETING. SO AT ANY POINT ALONG THAT SPECTRUM, THE TRANSLATIONAL VALLEY OF DEATH, THEY CAN SUBMIT AN APPLICATION TO CIRM, GET FUNDED, AND GET THE FUNDING THEY NEED TO GET ALL THE WAY TO IND CLEARANCE.

SO WHEN WE FIRST DESIGNED THIS PROGRAM AND WE BROUGHT IT TO THE BOARD FOR APPROVAL LAST YEAR, WE HAD INCORPORATED TWO APPLICATION CYCLES PER FISCAL YEAR FOR THAT PROGRAM. HOWEVER, HAVING GONE THROUGH THE EXERCISE OF DOING THOSE TWO CYCLES, WE'RE REALIZING THAT THE KEY BENEFITS OF HAVING TWO CYCLES IS ACTUALLY NOT BEING REALIZED FOR THIS PARTICULAR PROGRAM. AND WE ARE RECOMMENDING THAT THE BOARD APPROVE MOVING TO ONE CYCLE. I'LL EXPLAIN THAT IN A LOT OF EXCRUCIATING DETAIL BECAUSE IT'S IMPORTANT.

133 HENNA COURT, SANDPOINT, IDAHO 83864
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BUT I'LL START OFF FIRST BY SAYING THAT OUR REASON TO HAVE MULTIPLE CYCLES IS THAT, IF YOU HAVE SOME SORT OF KEY READINESS REQUIREMENT, THAT THE PROJECTS HAVE THE ABILITY TO APPLY WHEN THEY ARE READY. IN THIS PARTICULAR INSTANCE, WE DELIBERATELY DESIGNED THIS PROGRAM TO ALLOW FOR ENTRY AT ANY STAGE ACROSS THAT PRECLINICAL SPECTRUM. SO WE HAVE PROJECTS WHO ARE APPLYING MIDSTREAM OF A PRE-IND MEETING, OR THEY'RE APPLYING RIGHT WHEN THEY HAVE DECLARED A CANDIDATE.

SO IN THAT SENSE, WHEN AN APPLICATION DUE DATE IS AVAILABLE, IF A PROGRAM IS WITHIN THAT SPECTRUM OF PRECLINICAL DEVELOPMENT, IT SHOULD BE ABLE TO SUBMIT AN APPLICATION. SO THAT WAS ONE ASPECT OF WHAT WE CONSIDERED HERE.

ANOTHER ASPECT WAS IF YOU HAVE MULTIPLE CYCLES, WHAT THAT USUALLY DOES IT ADVANTAGES RESUBMISSION SO THAT YOU CAN GET A CLOSE TO FUNDABLE SCORE OR MAYBE YOU GOT A FUNDABLE SCORE AND YOU WERE NOT FUNDED, YOU CAN COME BACK IN FOR A CYCLE THAT MAY BE A COUPLE MONTHS DOWN THE ROAD. HOWEVER, BECAUSE OF THE WAY WE HAVE TO LINE UP THESE TWO CYCLES TO FIT WITHIN ONE FISCAL YEAR, THE CYCLES HAVE OVERLAP. SO SOMEBODY WHO SUBMITS IN THAT FIRST PDEV CYCLE ACTUALLY CAN'T APPLY IN THE SECOND ONE.

133 HENNA COURT, SANDPOINT, IDAHO 83864
208-255-5453 208-920-3543 DRAIBE@HOTMAIL.COM

THEY WOULD HAVE TO WAIT FOR THE THIRD CYCLE. SO IN THAT SENSE, THAT RESUBMISSION BENEFIT WITH MULTIPLE CYCLES IS NOT FULLY REALIZED WITH THESE TWO CYCLES.

LASTLY, THE ALLOWANCE OF HAVING TWO CYCLES ALLOWS FROM AN ADMINISTRATIVE PERSPECTIVE TO BE ABLE TO BATCH APPLICATIONS. YOU PRESUMABLY CAN GET HALF THE APPLICATIONS GOING THROUGH REVIEW AND FUNDING IN THAT FIRST CYCLE AND THE OTHER HALF IN THE SECOND CYCLE. HOWEVER, WHAT WE'RE SEEING RIGHT NOW IS THAT, BECAUSE OF THE REALLY HIGH VOLUME AND THE HIGH SCIENTIFIC MERIT ACROSS THE BOARD, THAT WE'RE EXHAUSTING A SIGNIFICANT AMOUNT OF THE PROGRAM BUDGET IN THE FIRST CYCLE. AND THAT HAPPENED IN THE FIRST CYCLE OF PDEV WHERE WE SPENT ABOUT 120 MILLION, LEAVING ABOUT 40 MILLION FOR THE SECOND CYCLE.

AND SO IN THAT SENSE, IT'S JUST GOING TO INCENTIVIZE APPLICANTS TO WANT TO SUBMIT THAT FIRST CYCLE ANYWAY BECAUSE THEY GET A HIGHER SHOT AT A BIGGER BUDGET THAT THEY CAN FUND.

SO WITH ALL THAT IN MIND, PLUS CONSIDERING A LOT OF OTHER FACTORS, WE ARE RECOMMENDING MOVING TO ONE CYCLE PER YEAR. SO WHAT THIS DOES IS THAT -- NOW, JUST TO BE CLEAR, ONE CYCLE PER YEAR DOES NOT MEAN THAT THE PROGRAM BUDGET IS HALVED. THE PROGRAM

133 HENNA COURT, SANDPOINT, IDAHO 83864
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BUDGET STAYS THE SAME. SO ONE CYCLE. EVERYBODY APPLIES. THEY ALL HAVE ACCESS TO THE FULL PROGRAM BUDGET. EVERYBODY COMPETES AT THE SAME TIME FOR THE FULL PROGRAM BUDGET.

TO DO THIS, WE HAVE TO HAVE A HIGHER VOLUME OF APPLICATIONS TO BE REVIEWED FOR THAT FULL PROGRAM BUDGET. SO NUMBER OF APPLICATIONS ACTUALLY REVIEWED WILL GO UP BECAUSE WE HAVE TO MAKE SURE THAT WE CAN EXHAUST THE ENTIRE BUDGET. ANY UNFUNDED APPLICATIONS WOULD HAVE TO RESUBMIT IN THE NEXT FISCAL YEAR APPLICATION CYCLE. I KNOW ON PAPER IT SOUNDS REALLY BAD; BUT ACTUALLY, IF YOU GO THROUGH THE WHOLE CYCLE, THE NEXT APPLICATION CYCLE IS PROBABLY ABOUT FOUR TO SIX MONTHS AWAY.

AND THEN LASTLY, THIS ALLOWS US TO OPTIMIZE THE TIMELINES FOR ALL THE PROGRAM UPDATES IN THE APPLICATION LIFE CYCLES AS WELL. RIGHT NOW ONE OF THE THINGS THAT WE WERE STRUGGLING WITH WITH HAVING TWO CYCLES WAS HOW DO WE LINE UP THE APPLICATION LEAD-TIME, THE REVIEW LEAD-TIME, AND THE ARS DATES. AS YOU ALL KNOW, WE HAVE AN ADDITIONAL FACTOR WE HAVE TO WORRY ABOUT, WHICH THAT THE ARS DATES NOW HAVE TO LINE UP WITH THE IN-PERSON ICOCS PUTTING FOR ADDITIONAL CONSTRAINT. AND TO PUT TWO CYCLES IN THERE, WE ACTUALLY HAD THE ISSUE WHERE ONE

133 HENNA COURT, SANDPOINT, IDAHO 83864
208-255-5453 208-920-3543 DRAIBE@HOTMAIL.COM

APPLICATION CYCLE OVERLAPPED ACROSS THE ENTIRE HOLIDAY PERIOD. AND SO WE HAD TO MAKE IT MUCH LONGER BECAUSE WE HAD TO GIVE APPLICANTS ENOUGH TIME TO BE ABLE TO SUBMIT AN APPLICATION AND NOT WORRY ABOUT STAFF BEING ON VACATION OR THE UNIVERSITIES CLOSING DOWN DURING THE HOLIDAY PERIOD.

AT THE SAME TIME, ON THE FLIP SIDE, WE HAD AN ISSUE WHERE THE APPLICATIONS WERE AWARDED BY THE ARS, AND THE CONTRACTING PERIOD OVERLAPPED WITH THE HOLIDAY PERIOD. SO WE HAD TO EXTEND THE TIMELINE FOR CONTRACTING THOSE AWARDS. SO THOSE TYPES OF THINGS IN TRYING TO MAKE TWO APPLICATION CYCLES FIT INTO ONE FISCAL YEAR, WE CAN AVOID THAT BY OPTIMIZING THAT ONE CYCLE. SO ULTIMATELY WITH THIS ONE CYCLE, WHAT WE HOPE WE CAN DO IS LINE IT ALL UP SO THE APPLICANTS HAVE ADEQUATE TIME TO MAKE THEIR APPLICATION, THE GWG HAS ENOUGH TIME TO DO THE SELECTION AND THE REVIEW, AND WE HAVE THE ADEQUATE URGENCY AND APPROPRIATENESS TO MAKE IT -- TO GET IT CONTRACTED. ULTIMATELY, IT HELPS US FUND AND LAUNCH THE AWARDS THAT THE GWG RECOMMENDS AND THE ARS APPROVES IN AN OPTIMAL MANNER WITH A SINGLE CYCLE.

HAPPY TO TAKE ANY QUESTIONS ON THAT IF THERE ARE ANY.

CHAIRMAN IMBASCIANI: ANY QUESTIONS FROM

IN THE ROOM? I DON'T SEE ANYONE. MARGUERITE.

MS. CASILLAS: HI. THANK YOU SO MUCH FOR ADDRESSING THIS ISSUE. AS HAVING JUST GONE THROUGH THE SECOND PDEV SESSION, IT WAS REALLY TOUGH TO SEE ALL THOSE GREAT APPLICATIONS AND NOT VERY MUCH MONEY LEFT. SO I AGREE SOMETHING REALLY NEEDS TO BE DONE.

THERE WAS A LETTER THAT WAS SUBMITTED. I DIDN'T QUITE UNDERSTAND HOW THE CONCERNS THAT WERE RAISED THERE WOULD REALLY -- WELL, HOW THIS CHANGE WOULD RESULT IN THOSE CONCERNS THAT THAT WRITER MENTIONED. DOES THE CIRM TEAM FEEL THAT THERE'S ANY VALIDITY THERE IN TERMS OF THE ISSUES THAT WERE RAISED?

DR. PATEL: SO IT'S A GOOD POINT. THERE ARE A COUPLE OF QUESTIONS THAT WERE RAISED BY APPLICANTS AND AWARDEES IN THE SENSE THAT IF THERE ARE MULTIPLE APPLICATION DEADLINES, THEY WOULDN'T BE ABLE TO HAVE AS MUCH LAG WITH A CIRM AWARD ENDING AND THE NEXT ONE STARTING. AND IN THAT SENSE WE CAN'T FULLY ACCOUNT FOR THE FINANCIAL SITUATION OR THE AWARD LIFE CYCLES OF EVERY SINGLE AWARDEE. BUT AT THE SAME TIME, BECAUSE WE DESIGNED THIS PROGRAM TO ALLOW APPLICANTS TO SUBMIT AT ANY POINT IN THEIR CYCLE, AS YOU'VE NOTICED, WE'VE HAD SEVERAL ACTIVE TRAN AWARDEES ACTUALLY SUBMIT FOR A PDEV

APPLICATION. AND SO IN THAT SENSE, THERE IS A WAY TO OVERCOME SOME OF THAT, BUT THOSE ARE CONCERNS THAT ARE VALID FROM THE APPLICANTS, THAT I'M GOING TO HAVE A CIRM AWARD END. AND IF I HAVE MULTIPLE DEADLINES, THEN I CAN REDUCE THE LAG TIME TO GET FUNDED. WE RECOGNIZE THAT, BUT WE CAN'T FULLY ACCOUNT FOR THAT IN ALL CIRCUMSTANCES.

CHAIRMAN IMBASCIANI: JOYCE.

DR. SACKEY: THANK YOU FOR THE PRESENTATION. I'M ALSO INFERRING, AND CORRECT ME IF I'M WRONG, THAT AS WE ARE GETTING HIGHER AND HIGHER VOLUME OF APPLICATIONS AND WE ARE TRYING TO, THEREFORE, NOT BURN OUT OUR REVIEWERS, THAT THIS MIGHT ALSO BE GOOD FOR WELL-BEING. IT WASN'T ONE OF THE BULLET POINTS, BUT I WOULD IMAGINE EVERYBODY'S TALKED ABOUT INCREASED NUMBER OF APPLICATIONS MAKES SENSE. FEDERAL FUNDS ARE GETTING TRICKIER AND TRICKIER. AND WE HAVE HUMAN BEINGS THAT WE'RE RELYING ON TO REVIEW THESE APPLICATIONS. AND SO I THINK IT'S A VALID THING IF THAT IS ACTUALLY -- THAT INFERENCE IS CORRECT.

DR. PATEL: YES. TO DO IT AT A SINGLE CYCLE, WE COULD ENSURE THAT THE FULL PROGRAM BUDGET IS BEING REVIEWED ALL AT ONCE AND THAT WE'RE DEPLOYING IT. AND SO THE GWG HAS ALL THE

133 HENNA COURT, SANDPOINT, IDAHO 83864
208-255-5453 208-920-3543 DRAIBE@HOTMAIL.COM

INFORMATION TO DEPLOY THAT FULL BUDGET AND SO DOES THE ARS.

DR. SACKEY: AND WELLNESS.

DR. PATEL: YES. WELLNESS IS IMPORTANT, YES, ESPECIALLY FOR THE PATIENT ADVOCATE REVIEWERS WHO HAVE TO REVIEW ACROSS MULTIPLE PROGRAMS.

DR. SACKEY: HUNDRED PERCENT SUPPORTIVE OF THIS PROPOSAL.

CHAIRMAN IMBASCIANI: THANK YOU, JOYCE. ANYONE ELSE IN THE ROOM WANT TO ASK SHYAM QUESTIONS? ANYONE ONLINE? OR ANYONE IN THE PUBLIC? OKAY.

MS. MORALEZ: WE DO HAVE ONE PUBLIC COMMENT ON THE PHONE.

CHAIRMAN IMBASCIANI: THERE IS ONE. I'M SORRY. I DIDN'T SEE IT. NOW I SEE IT.

DR. PATEL: WOULD YOU LIKE TO WAIT FOR THE PUBLIC COMMENT UNTIL THE MOTION IS MADE?

CHAIRMAN IMBASCIANI: THERE'S NO MOTION YET. SO, ROSA, DO YOU WANT TO COME UP AND LAY THIS OUT AS A MOTION TO THE BOARD? AND I PRESUME IT'S GOING TO BE AN OMNIBUS MOTION.

DR. CANET-AVILES: THANK YOU. THANK YOU, SHYAM.

SO TO FINALIZE, WE HAVE KIND OF AN OVERALL MOTION FOR ALL WHAT WE PRESENTED TODAY. THE CIRM

STAFF REQUESTS, WITH THE RECOMMENDATION OF THE SCIENCE SUBCOMMITTEE, FOR THE BOARD TO APPROVE THE FOLLOWING: FIRST, AMENDMENTS TO THE DISC4, PDEV, AND CLIN2 CONCEPT PLANS THAT ARE ALSO IN THE DOCUMENTS THAT WE APPENDED WITH THIS ITEM. THERE ARE TRACK CHANGES ON HOW THE GUIDING PRINCIPLES APPLY TO THE OBJECTIVES OF THE PROGRAMS. IMPLEMENTATION OF THE PROPOSED GRANTS WORKING GROUP SELECTION PROCESS IN ALL PROGRAMS REQUIRING VOLUME CONTROL. AND THEN, FINALLY, THE LAST TWO ITEMS THAT WERE JUST PRESENTED BY KELLY AND SHYAM, THE DISC4 PROGRAM FOCUS AREA FOR THE FISCAL YEAR 26/27 FUNDING CYCLE AND ONCE PER YEAR PDEV FUNDING CYCLE.

CHAIRMAN IMBASCIANI: OKAY. BOARD WOULD ENTERTAIN A MOTION TO APPROVE THE FOLLOWING.

VICE CHAIR BONNEVILLE: SO MOVED.

DR. MALKAS: SECOND.

CHAIRMAN IMBASCIANI: WE HAVE A MOTION AND LEONDRA SECONDED. SHE DID NOT. OH, SORRY, LINDA.

DR. MALKAS: I'M LIKE INVISIBLE.

CHAIRMAN IMBASCIANI: ACOUSTICALLY IT CAME FROM THE LEFT. SO DISCUSSION?

PUBLIC SPEAKER: ARE YOU READY FOR MY PUBLIC COMMENT?

VICE CHAIR BONNEVILLE: IT'S NOT TIME FOR

PUBLIC COMMENT.

CHAIRMAN IMBASCIANI: WE'RE GOING TO HAVE COMMENT FROM BOARD MEMBERS FIRST, AND THEN WE'LL INVITE THE PUBLIC TO COMMENT. WE'LL START WITH MONICA CARSON.

(INTERRUPTION IN PROCEEDINGS DUE TO AUDIO ISSUES.)

CHAIRMAN IMBASCIANI: MONICA IS GOING TO BE FOLLOWED BY A NUMBER OF PEOPLE, AND I'LL READ THE LIST OFF SHORTLY. MONICA, THE FLOOR IS YOURS.

(CONTINUED INTERRUPTION IN PROCEEDINGS.)

MR. TOCHER: OKAY. MONICA CARSON, LONG AWAITED. YOU ARE FIRST UP FOR COMMENT.

DR. CARSON: I WAS JUST TRYING TO GET ORIGINAL ATTENTION ABOUT THE LACK OF SOUND.

VICE CHAIR BONNEVILLE: IS THERE ANY OTHER BOARD COMMENT? IS THERE ANY PUBLIC COMMENT?

MS. MORALEZ: I DO SEE A HAND RAISED THAT NOW WENT AWAY. NOW IT'S RAISED AGAIN. OKAY. SO THE NUMBER ENDING IN 3158, IF YOU CAN UNMUTE YOURSELF BY PRESSING STAR SIX, YOU'LL HAVE THREE MINUTES.

MR. SYNDER: HI. THIS IS EVAN SNYDER FROM SBP. THANKS FOR LETTING ME VOICE MY CONCERN ABOUT THE PROPOSED REDUCTION IN FREQUENCY OF PDEV GRANT

CYCLES, WHICH I FEAR WILL HAVE UNINTENDED AND UNDESIRED CONSEQUENCES FOR CIRM'S MISSION AND BREADTH OF CALIFORNIA SCIENTISTS, CLINICIANS, BUSINESSES, AND PATIENTS WHO BENEFIT FROM CIRM.

I'VE UPLOADED A LETTER TO ICOC, SO I'LL NOT READ THAT. I UNDERSTAND THE WORK AND FINANCIAL BURDEN THE OLD FUNDING MODEL PRESENTED. I'LL USE MY TIME SIMPLY TO SUGGEST WE FIGURE OUT OTHER CREATIVE SOLUTIONS. CIRM WAS INITIALLY CONCEIVED TO IMMUNIZE CALIFORNIANS FROM THE POLITICALLY DRIVEN VAGARIES OF WASHINGTON, D.C. THAT THREAT IS NO LESS NOW THAN IT WAS THEN, PROBABLY WORSE.

THE PRINCIPLES AND APPROACHES, TOPICS AND PATIENT POPULATIONS WE HOLD DEAR ARE UNDER ATTACK. THE SURGE IN APPLICATIONS TO CIRM IS A SYMPTOM OF THAT. I FEAR THAT REDUCING THE NUMBER OF CYCLES WILL SOFTEN OUR CORE MISSION. ROBUST PRECLINICAL DEVELOPMENT HAS DEFINED CIRM. WHILE I APPRECIATE THE IMMENSE BURDEN THIS EMPHASIS PLACES ON CIRM, ITS MENU AND TIMELINE OF FUNDING OPPORTUNITIES HAS SO ACCURATELY BEEN IN TUNE WITH THE TEMPO AND DYNAMICS OF CUTTING-EDGE PRECLINICAL DEVELOPMENT. SUCH PRECLINICAL AND CLINIC RESEARCH, PARTICULARLY IN ACADEMIA AND SMALL COMPANIES, CANNOT LANGUISH UNFUNDED AND UNACTUALIZED FOR AN ENTIRE YEAR.

133 HENNA COURT, SANDPOINT, IDAHO 83864
208-255-5453 208-920-3543 DRAIBE@HOTMAIL.COM

I KNOW WE CANNOT GO BACK TO THE OLD MODEL. I WOULD SIMPLY SUGGEST, BEFORE WE MAKE SUCH A CHANGE, THAT CIRM, IN CONJUNCTION WITH OTHER CALIFORNIA SCIENTISTS, CLINICIANS, BUSINESSES, PATIENTS, RETHINK CREATIVE WAYS NOT TO LEAD TO SOME OF THE UNINTENDED CONSEQUENCES I FEAR.

SOME SUGGESTIONS MIGHT BE GIVING SMALLER DOLLAR AMOUNTS PER GRANT WHILE MAINTAINING FREQUENCY. MANY PDEV PROJECTS ARE NOT READY TO GO THE FULL 13 MILLION. EARLY PDEV ONLY IS AN OPTION. LATE PDEV ONLY IS AN OPTION, PARTICULARLY IF YOU'VE BEEN IN THE CIRM PIPELINE. COMBINED EARLY AND LATE PDEV WOULD BE A MINORITY OF PROJECTS MOSTLY FROM PHARMA AND HOSPITAL-BASED ENTITIES. A SHORTER MERIT-BASED LOI PRESELECTION PROCESS WOULD HELP STREAMLINE THINGS. SHORTENING APPLICATIONS FOR REVIEWERS TO READ TO ELIMINATE REDUNDANT SECTIONS OR DETAILED APPROPRIATE ONLY AFTER A MERIT-BASED FUNDABLE SCORE.

THANKS FOR CONSIDERING SOLUTIONS OTHER THAN REDUCING PDEV GRANTING FREQUENCY.

CHAIRMAN IMBASCIANI: GREAT. THANK YOU VERY MUCH. THE CHAIR RECOGNIZES HIMSELF FOR A COMMENT WHICH I HAVEN'T HAD A CHANCE TO DO.

I SPEAK IN SUPPORT OF ALL FOUR COMPONENTS

133 HENNA COURT, SANDPOINT, IDAHO 83864
208-255-5453 208-920-3543 DRAIBE@HOTMAIL.COM

OF THIS MOTION. AND I'M GOING TO JUST FOCUS IN ON ONE TO MAKE A COMMENT ON VOLUME CONTROL. I AM, I THINK, THE ONLY EX OFFICIO MEMBER OF THE GRANTS WORKING GROUP ALONG WITH ALL OUR PATIENT ADVOCATES AND OUR NURSE REPRESENTATIVES. SO I HAVE EXPERIENCE OF THE PROCESS. EVERY ONE OF THOSE MEETINGS I ATTEND. SO I AGREE THAT WE HAVE TO IMPOSE A PROCESS THAT WILL ALLOW OUR REVIEWERS TO ASSESS SCIENTIFIC MERIT, BUT TO DO SO IN A REASONABLE FORMAT GIVEN THAT THE NUMBER OF REVIEWERS WE HAVE ACCESS TO IS BY LAW LIMITED.

THE PROPOSED SYSTEM IN THIS MOTION GIVES THE LARGEST POSSIBLE EXPOSURE TO EACH APPLICATION -- GIVES THE LARGEST POSSIBLE EXPOSURE OF EACH APPLICATION TO THE GREATEST NUMBER OF REVIEWERS WITHOUT PHYSICALLY EXHAUSTING THEM OR DILUTING THEIR CRITICAL APPARATUS. I TRUST THE GRANTS WORKING GROUP TO GIVE GREAT EFFORT IN REVIEWING ALL COMPONENTS OF AN APPLICATION, AND I TRUST THEIR RECOMMENDATIONS. THANK YOU.

SCOTT, IF THERE'S NO MORE COMMENT EITHER PUBLIC OR BOARD MEMBER, WE CAN PROCEED.

MR. TOCHER: ALL RIGHT. FOR THE RECORD, DON TAYLOR, ALTERNATE FOR KIM BARRETT, HAS JOINED THE MEETING.

133 HENNA COURT, SANDPOINT, IDAHO 83864
208-255-5453 208-920-3543 DRAIBE@HOTMAIL.COM

SO ALL THOSE IN THE ROOM IN FAVOR SAY AYE. THOSE OPPOSED SAY NAY. ANY ABSTENTIONS? AND I'LL POLL THE MEMBERS ON THE ZOOM.

MONICA CARSON.

DR. CARSON: AYE.

MR. TOCHER: JUDY CHOU.

DR. CHOU: AYE.

MR. TOCHER: YSABEL DURON.

MS. DURON: YES.

MR. TOCHER: MARK FISCHER-COLBRIE.

MR. FISCHER-COLBRIE: YES.

MR. TOCHER: JUDY GASSON.

DR. GASSON: YES.

MR. TOCHER: JEFF GOLDEN.

DR. GOLDEN: YES.

MR. TOCHER: RICH LAJARA.

MR. LAJARA: YES.

MR. TOCHER: PAT LEVITT.

DR. LEVITT: YES.

MR. TOCHER: HALA MADANAT.

DR. MADANAT: YES.

MR. TOCHER: CHRIS MIASKOWSKI.

DR. MIASKOWSKI: YES.

MR. TOCHER: MARV SOUTHARD.

DR. SOUTHARD: YES.

133 HENNA COURT, SANDPOINT, IDAHO 83864
208-255-5453 208-920-3543 DRAIBE@HOTMAIL.COM

MR. TOCHER: KEVIN XU.
MR. XU: AYE.
MR. TOCHER: AND KEITH YAMAMOTO.
DR. YAMAMOTO: NO.
MR. TOCHER: THANK YOU. THE MOTION CARRIES.
CHAIRMAN IMBASCIANI: OKAY. THANK YOU VERY MUCH. AND THANK YOU, ROSA, NOT JUST FOR TODAY'S PRESENTATION.
WE NOW HAVE AN UPDATE, AGENDA ITEM NO. 13, FROM THE COMMUNICATIONS TEAM LED BY DIRECTOR OF COMMUNICATIONS, AMY ADAMS.
MS. ADAMS: OKAY. SO I WANT TO START BY SAYING YOU DON'T HAVE TO VOTE ON ANYTHING IN WHAT I'M ABOUT TO SAY. SO YOU CAN ALL SIT BACK. THERE'S SOME POPCORN IN BACK OF THE ROOM. I'M GOING TO TRY TO KEEP THIS EASY AND HOPEFULLY SHORT BECAUSE I THINK I'M ALL THAT STANDS BETWEEN YOU AND THE TRAFFIC.
SO LET'S START. FIRST OF ALL, THANK YOU, BOARD MEMBERS, MEMBERS OF THE CIRM TEAM, AND IMPORTANTLY ANY MEMBERS OF THE PUBLIC WHO ARE ON THE CALL.
OKAY. I ALWAYS LIKE TO START MY PRESENTATION WITH A REMINDER OF OUR MISSION.

OBVIOUSLY WE ALL KNOW WHAT OUR MISSION IS, BUT IT IS FRONT AND CENTER IN EVERYTHING WE DO IN COMMUNICATIONS. AND THE WAY THAT THE COMMUNICATIONS AND OUTREACH TEAM HELPS MOVE THAT MISSION FORWARD IS BY DRIVING AWARENESS OF AND SUPPORT FOR CIRM'S PROGRESS AND ACCOMPLISHMENTS.

A REMINDER. SO MY COMMUNICATION AND OUTREACH STRATEGY HAS FOUR PILLARS. AND AS WITH MOST OF MY PRESENTATIONS, WE ARE GOING TO GO THROUGH THESE FOUR PILLARS AND TALK ABOUT WHAT WE'RE DOING WITHIN EACH.

SO WE'RE GOING TO START WITH CREATING THE STORY. AND THIS IS A REMINDER. I'M TAKING THIS ALL THE WAY BACK, WAY, WAY BACK TO DECEMBER WHEN I PRESENTED ALL OF YOU MY STRATEGY. SO WHAT I'M GOING TO GO THROUGH TODAY IS FOR EACH OF THE PILLARS WHAT I SAID I WAS GOING TO DO WITHIN THAT PILLAR IN THE STRATEGY, AND THEN WE'RE GOING TO TALK ABOUT WHAT WE'VE STARTED TO DO. OBVIOUSLY THAT WAS DECEMBER. IT IS NOW MARCH. WE HAVE NOT DONE A LOT ON THE STRATEGY, BUT WE ARE MAKING PROGRESS IN SEVERAL PLACES.

SO YOU'LL SEE FOR EVERY -- THIS IS THE ACTUAL SLIDE YOU SAW IN DECEMBER. UNDER WHAT WE'LL DO, THERE'S A HANDFUL OF TACTICS. THE GREEN

CHECKMARK, I THINK WE ALL KNOW WHAT THAT MEANS. THE LITTLE PURPLE THING, THAT MEANS WE'RE WORKING ON IT. AND THE RED X, THAT WILL BE THE NEXT BOARD MEETING. SO THIS WILL BE THE FORMAT FOR EVERY PILLAR.

SO FIRST OF ALL, WITHIN CREATING THE STORY, THIS IS THE ONE PLACE WHERE I THINK WE'VE REALLY STARTED TO MAKE PROGRESS ALREADY. YOU'VE ALREADY SEEN A VERSION OF THE CIRM STORY PRESENTED BY J.T. AND WE'RE STARTING TO DEVELOP MANY VERSIONS OF THAT. OBVIOUSLY ONE STORY DOESN'T WORK FOR ALL AUDIENCES. THE ONE YOU SAW I THINK WAS REALLY COMPELLING AND EMOTIONAL, BUT IT'S NOT RIGHT FOR EVERYONE. SO WE'RE STARTING TO BUILD OUT DIFFERENT VERSIONS OF THAT STORY AND MAKE IT EASY FOR EVERYONE TO HAVE RESOURCES THEY NEED TO TELL CIRM'S STORY.

AND I'M GOING TO SHOW A COUPLE OF EXAMPLES. WE'RE CREATING A NEW DECK, SOME NEW DECK MATERIALS. AND WE'RE TRYING TO MAKE IT EASIER FOR PEOPLE WITHIN CIRM TO HAVE ACCESS TO REALLY VISUAL AND EMOTIONAL SLIDES EVEN FOR WHEN THEY'RE TALKING ABOUT THE SCIENCE. AND I'M JUST GOING TO KIND GO THROUGH A FEW JUST NICE EXAMPLES OF WAYS THAT I THINK WE CAN BE LOOKING AT OUR STORY. OBVIOUSLY WE DO SCIENCE AS WELL AS PATIENTS. SO WE'VE GOT SOME GREAT SCIENCE IMAGES AS WELL.

133 HENNA COURT, SANDPOINT, IDAHO 83864
208-255-5453 208-920-3543 DRAIBE@HOTMAIL.COM

AND I'M JUST GOING TO LEAVE CREATE THE STORY THERE AND MOVE ON TO SOME OF THE OTHER STUFF WE'RE DOING.

SO TELL THE STORY. WHAT I TOLD YOU WE WOULD DO IS A WHOLE BUNCH OF THINGS. ONE OF THEM I'M GOING TO TALK ABOUT IS MAKE THE WEBSITE FULLY ACCESSIBLE. SO WE HAVE AN ACCESSIBLE WEBSITE. WE DID THAT. ACTUALLY THE PREVIOUS COMMUNICATIONS TEAM DID THAT, AND I THINK THEY SHOULD BE REALLY PROUD OF IT. THERE ARE SOME DOCUMENTS ON THE WEBSITE THAT WERE NOT YET ACCESSIBLE, AND WE MADE THEM ACCESSIBLE. SO THIS IS THE KIND OF THING THAT'S HAPPENING BEHIND THE SCENES THAT I THINK IS INCREDIBLY IMPORTANT AS A PUBLIC-FACING ORGANIZATION, THAT WE BE ACCESSIBLE TO ALL PEOPLE WHO MIGHT WANT TO ACCESS INFORMATION.

THE TWO THINGS I'M REALLY GOING TO TALK ABOUT TODAY IS SOME OF OUR EXPANDED WRITTEN AND VIDEO STORYTELLING. I'M NOT GOING TO TALK ABOUT VIDEO. A STORYTELLING TOOLKIT THAT WE'RE TO BUILD OUT TO HELP PEOPLE TALK ABOUT THE ORGANIZATION. SO HERE'S SOME OF THE STORYTELLING THAT WE'RE DOING.

THE TWO CLOSER TO CURES IMAGES THERE, THAT SHOULD LOOK FAMILIAR. THOSE ARE THE CLOSER TO CURES THAT YOU HEARD AT THE LAST BOARD MEETING. SO AS WE

133 HENNA COURT, SANDPOINT, IDAHO 83864
208-255-5453 208-920-3543 DRAIBE@HOTMAIL.COM

ALL SEE, THIS IS REALLY FANTASTIC CONTENT AND WE'RE TAKING ADVANTAGE OF IT. SO WE'VE WRITTEN STORIES ABOUT EACH OF THE CLOSER TO CURES. WE'VE GOT THE VIDEOS FROM THOSE EMBEDDED IN THE STORY. WE'RE ROLLING THEM OUT OVER SOCIAL MEDIA. AND I WILL SAY THEY ARE DOING EXTRAORDINARILY WELL ACROSS PLATFORMS. I DON'T THINK IT HURTS THAT THESE SCIENTISTS ARE WELL-KNOWN AND LIKED AND ARE PROMOTING IT AND THEIR ORGANIZATIONS ARE DOING THE SAME. SO I THINK IT REALLY HELPS GET OUR WORD OUT WHEN WE'RE ALSO ABLE TO TAKE ADVANTAGE OF OTHER ORGANIZATIONS THAT HAVE A GREAT PRESENCE. WE'RE KIND OF PIGGYBACKING ON SOME GIANTS HERE.

AND THEN THE BEAUTIFUL PICTURE -- I VOID RIGHT LEFT. THE BEAUTIFUL PICTURE ON THE RIGHT. SO THIS IS A FAMILY THAT PARTICIPATED IN ONE OF THE CIRM-FUNDED TRIALS. IT'S JUST AN INCREDIBLE STORY. THE OLDER GIRLS WERE BOTH BORN WITH A DISEASE CALLED LAD-1. IT'S AN IMMUNE DISORDER. PARENTS DIDN'T KNOW THAT. THEY WERE JUST GETTING SICK A LOT. AND THE PARENTS FINALLY GOT THESE GIRLS DIAGNOSED WITH THIS INCREDIBLY RARE DISEASE THAT HAS NO CURE ASIDE FROM A BONE MARROW TRANSPLANT, WHICH IS NOT AN EASY ROAD. THE MOTHER WAS PREGNANT WITH THAT LITTLE BOY THERE WHEN THEY FOUND THAT OUT.

133 HENNA COURT, SANDPOINT, IDAHO 83864
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SO THE PARENTS -- THIS FAMILY CAME TO THE ATTENTION OF OUR GRANTEE DOWN AT UCLA THAT WAS RUNNING THIS TRIAL, DON KOHN. HE REACHED OUT TO THEM AND INVITED THEM TO SEE IF THEY WERE ELIGIBLE, BUT THEN THIS FAMILY WENT TO L.A., PARTICIPATED IN THAT TRIAL, AND HERE THEY ARE AT DISNEYLAND, LIKE THE WORLD'S GERMIEST PLACE. AND THESE LITTLE KIDS BORN WITH AN IMMUNE DISORDER ARE SMILING WITH THEIR LITTLE MOUSE EARS ON. SO THIS STORY ALSO DID VERY WELL ACROSS CHANNELS BECAUSE IT'S SUCH A GREAT STORY.

I WANT TO MOVE ON TO DELIVER THE STORY. THE THING IS TELLING THE STORY IS ONE THING. IT'S GREAT. SO WE WROTE A GREAT STORY. YAY. REALLY CUTE KIDS AND IT'S A GREAT STORY. IT DOESN'T DO YOU ANY GOOD UNLESS YOU GET THAT STORY TO THE PEOPLE WHO NEED TO SEE THAT STORY. THAT'S A WHOLE SEPARATE PART OF A STRATEGY. AND THAT REALLY IS EMAIL LISTS AND SOCIAL MEDIA AND LEVERAGING OUR GRANTEES AND ALL OF THAT WORK. SO I SEPARATE THOSE TWO OUT BECAUSE I THINK THEY ARE TWO DIFFERENT ACTIVITIES.

WITHIN DELIVERING THE STORY, A HANDFUL OF THINGS THAT WE'RE DOING. ONE I'VE MENTIONED PREVIOUSLY. WE'VE HIRED A PR FIRM, AND I'M GOING TO TALK A LITTLE BIT ABOUT SOME OF THE WORK THEY'RE

133 HENNA COURT, SANDPOINT, IDAHO 83864
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DOING.

WE HAVE STARTED TRAINING, I SAY, ADVOCATES. IN THIS CASE THE ADVOCATES ARE OUR INTERNAL CIRM TEAM. SO WE'RE STARTING TO TRAIN THE CIRM TEAM ON HOW TO USE OUR MESSAGING AND OTHER MATERIALS TO BE ABLE TO TALK ABOUT CIRM.

ONE OF THE ITEMS ON HERE IS CREATE A STRATEGY FOR COMMUNICATING ABOUT CIRM, WHICH WE DID.

SO LET'S TALK ABOUT THE MESSAGING TRAINING BECAUSE THIS WAS A LOT OF FUN, I THOUGHT. SO WE INVITED EVERYONE IN CIRM TO THIS TRAINING. AND THIS IS A SCREENSHOT FROM ONE OF THE TRAININGS. THERE WERE ABOUT 60 ATTENDEES FROM WITHIN CIRM, WHICH IS A GOOD PORTION OF THE ORGANIZATION. WE BROKE PEOPLE INTO TEAMS, AND THEY WERE GIVEN SCENARIOS AND TOLD HERE'S YOUR SCENARIO, AND WHAT WOULD YOU TELL THIS PERSON ABOUT CIRM. SO THERE WERE ELEVEN SCENARIOS, AND EACH TEAM CAME UP WITH MULTIPLE CHOICE, MANY OPTIONS OF HOW THEY WOULD TALK TO THAT PERSON BECAUSE THERE WERE A LOT OF THE IDEAS ABOUT HOW WE SHOULD BE TELLING STORIES.

THIS IS STEP 1. I THINK THERE'S A LOT OF MORE STEPS TO BE DONE TO HELP PEOPLE TALK ABOUT THE ORGANIZATION, BUT IT'S ONE OF THE THINGS WE'VE BEEN DOING.

133 HENNA COURT, SANDPOINT, IDAHO 83864
208-255-5453 208-920-3543 DRAIBE@HOTMAIL.COM

AND THEN I WANT TO TALK A BIT ABOUT THE PR TEAM IS JUST DOING A FANTASTIC JOB. SO THE AT LAST BOARD MEETING, YOU ALL APPROVED THE CONCEPT PLAN FOR RAPID. THE PR TEAM PITCHED THAT PRETTY EXTENSIVELY. AND I WILL SAY THAT DR. SHYAM PATEL DID HARD LABOR. HE DID A LOT OF INTERVIEWS IN BETWEEN EVERYTHING ELSE HE IS ALSO DOING. SO THAT WAS GREAT. AND THEN BOTH J.T. AND ROSA HAVE DONE QUITE A FEW INTERVIEWS ON RAPID. I HAVE A COUPLE OF EXAMPLES HERE.

GENETIC ENGINEERING AND BIOTECHNOLOGY NEWS, WHICH IS AN OUTLET THAT REACHES A LOT OF THE PEOPLE WHO WE REALLY WANT TO REACH, DID A NICE STORY. STAT DID A STORY, AND I'VE GOT A QUOTE HERE FROM J.T. THAT'S A RIGHT-ON MESSAGE ABOUT WHO CIRM IS AND WHAT WE'RE TRYING TO DO. ALSO, CNBC CURES, WHICH IS FOCUSED ON TELLING RARE DISEASE STORIES. CNBC CURES, THEIR MAIN VEHICLE IS THEY PUT OUT A NEWSLETTER. AND THAT'S WHERE MOST OF THEIR STORYTELLING HAPPENS. AND THE TOP OF THE NEWSLETTER WAS A LONG STORY ALL ABOUT RAPID WITH SOME REALLY NICE QUOTES FROM DR. PATEL. I THINK J.T. IS GOING TO TALK ABOUT AN INTERVIEW HE DID THAT HASN'T PUBLISHED YET.

OKAY. THEN I WANT TO TALK ABOUT OUTREACH. I'VE GOT A COUPLE -- I WANT TO LOOK AT MY NOTES

BECAUSE I'VE GOT SOME NUMBERS HERE. SO SINCE THE LAST BOARD MEETING, THE OUTREACH TEAM, THEY DID TEN OUTREACH EVENTS REACHING ABOUT 250 PEOPLE. AND AT THOSE OUTREACH EVENTS, EIGHT DIFFERENT STUDENTS FROM OUR EDUCATION PROGRAMS PARTICIPATED IN THOSE EVENTS. AND IN ADDITION, TWO PEOPLE FROM MY TEAM RECENTLY MET WITH STUDENTS AT SAN JOSE STATE UNIVERSITY TO TRAIN THEM IN HOW TO DO OUTREACH. SO THAT REACHED AN ADDITIONAL SET OF STUDENTS.

THE IMAGES HERE, JUST TO GO THROUGH THEM, SO YOU'VE GOT DR. JOE GOLD AND YSABEL DURON DOING TWO DIFFERENT PRESENTATIONS AT ROTARY CLUBS. AND THEN WE HAVE ADITI, VICE CHAIR BONNEVILLE, AND THEN GEOFF LOMAX HERE. THAT WAS AT THE -- WHAT WAS THAT, MARIA? -- THE ALAMEDA --

VICE CHAIR BONNEVILLE: COUNTY PUBLIC HEALTH COMMISSION.

MS. ADAMS: EXACTLY. SO THESE ARE JUST SOME EXAMPLES OF THE KINDS OF OUTREACH THAT ARE GOING ON.

AND THEN I'M GOING TO ONLY BRIEFLY TOUCH ON MEASURE THE IMPACT. SO WE MEASURE THINGS ALL THE TIME. HERE'S THE THING. WE JUST STARTED REALLY -- WE JUST ROLLED OUT A NEW STRATEGY. SO ALL OF OUR MEASUREMENTS ARE BASELINE. SO I CAN STAND HERE AND

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208-255-5453 208-920-3543 DRAIBE@HOTMAIL.COM

GIVE YOU BASELINE NUMBERS, BUT THEY'RE NOT GOING TO MEAN A LOT. SOME NUMBER OF THOUSANDS OF PEOPLE SAW A POST ON FACEBOOK. SO WHAT I PLAN TO DO IS START REPORTING OUT ON MEASUREMENTS ONCE WE'VE GOT THE BASELINE, AND THEN WE CAN REPORT OUT INCREASES OVER TIME.

AND WITH THAT, I THANK YOU ALL. I'LL TAKE QUESTIONS, OR I'LL LET YOU ALL JUMP IN YOUR CARS AND GET IN TRAFFIC. ALL RIGHT. PAT. HI, PAT.

DR. LEVITT: HOW ARE YOU?

MS. ADAMS: I'M GOOD. THANK YOU.

DR. LEVITT: GOOD.

MS. ADAMS: YOU'RE COMING FROM THE SKY.

DR. LEVITT: YEAH. WELL, I'M GETTING OVER MY COLD, AND THIS MEETING IS NOT HELPING. THAT WAS JUST A JOKE. I LOVE THIS MEETING.

GETTING OUT THE STORY IS LIKE REALLY IMPORTANT. AND I THINK I'D BE INTERESTED AT ANOTHER TIME TO HEAR ABOUT HOW TO DO THIS IN A BROADER WAY. BECAUSE PRESENTATIONS TO SMALL GROUPS ARE IMPORTANT, PARTICULARLY KEY GROUPS; BUT FOR IT TO BECOME VIRAL, AS YOU KNOW, NEEDS A DIFFERENT KIND OF STRATEGY. AND IT'S NOT EASY, BUT I THINK THERE ARE MECHANISMS THROUGH THAT. SO I JUST WANT TO MAKE THE COMMENT THAT THING YOU EMPHASIZED, HAVING A GREAT STORY IS

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WONDERFUL EXCEPT THAT IT'S A SECRET UNTIL IT GETS OUT THERE.

AND SO GREAT PROGRESS REALLY. AND THIS NEXT STEP, I THINK, WILL BE REALLY CRITICAL. I'M HAPPY TO TALK ABOUT IT WITH YOU BETWEEN MEETINGS.

MS. ADAMS: THANK YOU, PAT. I AGREE COMPLETELY.

DR. TAYLOR: THANK YOU. PHENOMENAL WORK IN PROGRESS. WHAT'S THE BIGGEST OBSTACLE THAT YOU LOOK FORWARD TO OVERCOMING IF YOU COULD JUST PICK ONE?

MS. ADAMS: OH, MY GOSH. THAT'S A REALLY HARD QUESTION FOR LATE IN THE DAY. IT'S THE SIZE AND DIVERSITY OF THE STATE. ACTUALLY I'M GOING TO TAKE IT BACK. AND I'M SAYING THE SAME THING WHEN I'M COMING IN FROM A DIFFERENT ANGLE. THE FRAGMENTATION OF THE COMMUNICATIONS INFRASTRUCTURE RIGHT NOW.

THERE WAS A PERIOD OF TIME EARLIER IN MY CAREER WHERE YOU COULD LIKE PUT SOMETHING ON FACEBOOK AND PEOPLE WOULD SEE IT. AND NOW IT TAKES A LOT OF WORK. YOU HAVE TO REWRITE THINGS EACH TIME. YOU HAVE TO PUT IT ON THE WEBSITE AND ON THE BLOG AND IN AN EMAIL AND ON INSTAGRAM AND ON FACEBOOK AND ON WHATEVER WE'RE CALLING THOSE OTHER

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THINGS NOW. AND GO TO CLUBS AND THINK ABOUT -- PAT'S EXACTLY RIGHT. IT'S GREAT TO REACH THESE HIGH IMPACT PLACES, BUT HOW DO YOU SPEAK TO LARGER AUDIENCES?

IT'S REALLY FRAGMENTED, AND EACH ONE OF THOSE AUDIENCES REQUIRES SOMEONE TO TAKE THE TIME TO DO THAT. SO I THINK IT'S EASY TO SAY TIME, MONEY, PEOPLE, BUT I THINK IT'S REALLY THE FRAGMENTATION THAT MAKES IT HARD FOR A REASONABLE -- WE HAVE A REASONABLE STAFF, BUT IT JUST MAKES IT HARD RIGHT NOW. I THINK THAT'S HARD NOT JUST FOR ME. THAT IS WHERE WE ARE RIGHT NOW IN THE COMMUNICATIONS LANDSCAPE.

CHAIRMAN IMBASCIANI: OTHER COMMENTS OR QUESTIONS? I'M GOING TO THANK YOU AGAIN, AMY. ONE OF THE HIGHLIGHTS OF OUR MEETING.

LISTEN, I OWE THE BOARD A VERY, VERY SHORT CHAIR'S REPORT, WHICH I'M GOING TO DO, REALIZING THAT I'M THE ONLY THING SEPARATING THE BOARD FROM HEARING FROM OUR PRESIDENT WHO HAS SOME LATE BREAKING NEWS. SO LET ME DO THIS VERY QUICKLY. THIS WILL TAKE TWO MINUTES, J.T.

IT'S VERY APPROPRIATE, BOARD MEMBERS, THAT I FOLLOW AMY'S TALK ON HOW TO TELL CIRM'S STORY. I WOULD LIKE TO REPORT TO YOU OF A NEW INITIATIVE I'VE

UNDERTAKEN WITH THE AIM OF BRINGING KNOWLEDGE OF CIRM'S WORK AND ACCOMPLISHMENTS TO A WIDER CALIFORNIA AUDIENCE. AND BY THAT I MEAN AUDIENCES OUTSIDE THE TYPICAL SCIENTIFIC AND BIOTECHNOLOGY WORLDS.

CAPITALIZING ON SOME LONGSTANDING RELATIONSHIPS THAT I'VE DEVELOPED OVER THE YEARS, I'VE BEGUN REACHING OUT TO SOME OF THE LARGEST VETERAN ORGANIZATIONS IN THE STATE. MANY OF THESE ASSOCIATIONS HAVE LARGE CONVENTIONS EACH YEAR THAT ATTRACT MEMBERS FROM EVERY CORNER OF THE STATE. AS A MATTER OF BACKGROUND, THERE ARE NOW PRESENTLY ABOUT 1.6 MILLION VETERANS IN CALIFORNIA, MORE THAN ANY OTHER STATE.

TO ADVOCATE FOR THEM, CONGRESS HAS CHARTERED OVER 50 VETERAN SERVICE ORGANIZATIONS, THE MOST FAMILIAR BEING THE VFW, VETERANS OF FOREIGN WARS, AND THE AMERICAN LEGION. WHAT MEMBERS OF ALL THESE ORGANIZATIONS HAVE IN COMMON VARIES. SOME ATTRACT MEMBERS WHO SERVED IN A SPECIFIC WAR, LIKE KOREA, VIETNAM, OR IN MY CASE THE TWO GULF WARS. OTHERS ATTRACT MEMBERS OF SPECIFIC ETHNIC GROUPS. SOME REQUIRE A DISTINGUISHING CHARACTERISTIC RESULTING FROM THEIR COMBAT EXPERIENCE, SUCH AS THE SOCIETY FOR THE PURPLE HEART, THE DISABLED VETERANS

133 HENNA COURT, SANDPOINT, IDAHO 83864
208-255-5453 208-920-3543 DRAIBE@HOTMAIL.COM

OF AMERICA. PARALYZED VETERANS HAVE THEIR OWN ORGANIZATION AS DO THOSE EXPOSED TO IONIZING RADIATION FROM HIROSHIMA, BIKINI ATOLL, OR THE NEVADA TEST SITES. THE NAVY, THE MARINES, THE COASTGUARD, THE OTHER SERVICE BRANCHES HAVE THEIR OWN ORGANIZATIONS, AND SO ON.

THE TWO LARGEST AND OLDEST ORGANIZATIONS, THE AMERICAN LEGION AND THE VFW, HAVE INVITED ME TO ADDRESS THEIR ANNUAL CONVENTIONS THIS SUMMER. GIVEN THAT ALL VETERANS GROUPS ARE CHARTERED TO FOSTER THEIR MEMBERS' WELL-BEING, AND THAT ONE OF THEIR LEADING CONCERNS IS HEALTH, MY OFFER TO ACQUAINT THEM WITH CIRM'S WORK WAS SEEN AS CONSONANT WITH THEIR NATIONAL MISSION.

ONE OF THE REASONS I THINK THAT THIS IS AN IDEAL AUDIENCE TO EDUCATE IS THAT, AS A GROUP, THEY ARE INVOLVED ACTIVELY IN THE AFFAIRS OF THEIR COMMUNITIES. THEY ARE ALSO AMONG THE MOST INTERESTED CITIZEN GROUPS IN LEARNING ABOUT ADVANCES IN MEDICINE AND BIOLOGICAL SCIENCE PRECISELY BECAUSE, AS A GROUP, THEY HAVE BEEN SO DISPROPORTIONATELY AFFECTED BY WAR, WHETHER BY EXPOSURE TO TOXIC ENVIRONMENTS, THINK AGENT ORANGE, DEPLETED URANIUM, AND OTHER CARCINOGENS, OR TO BLAST INJURIES THAT CAUSE CHRONIC AND TRAUMATIC

133 HENNA COURT, SANDPOINT, IDAHO 83864
208-255-5453 208-920-3543 DRAIBE@HOTMAIL.COM

ENCEPHALOPATHIES.

I'M EXPECTING SEVERAL HUNDRED VETERANS AND THEIR AUXILIARIES TO BE IN EACH OF THESE AUDIENCES. AND WHEN IT'S DONE, THEY WILL RETURN TO THE CITIES, TOWNS, AND HAMLETS IN EVERY COUNTY IN THE STATE. TAKE ALPINE COUNTY, IF YOU RECALL THE MAP THAT GEOFF LOMAX SHOWED EARLIER. POPULATION OF ALPINE COUNTY IS 1200 PEOPLE, BUT THEY TOO HAVE AN AMERICAN LEGION AND A VFW POST. SO IT'S MY HOPE THAT ALL OF THESE VETERANS WILL CARRY SOME KNOWLEDGE OF CIRM AND OUR MISSION AND OUR SUCCESSES TO DATE BACK HOME WITH THEM.

THANK YOU. NO QUESTIONS OR COMMENTS. I AM EAGERLY AWAITING THE PRESIDENT'S REPORT. J.T., YOU WANT TO COME UP OR YOU'RE GOING TO STAY THERE?

PUBLIC SPEAKER: I'M ONE OF THE PUBLIC MEMBERS. BEFORE WE --

MS. MORALEZ: NO, WE'RE NOT TAKING PUBLIC COMMENT RIGHT NOW. THANK YOU.

DR. THOMAS: MR. CHAIR, MADAM VICE CHAIR, MEMBERS OF THE BOARD, MEMBERS OF THE PUBLIC, AND MEMBERS OF OUR ESTEEMED TEAM, WE HAVE A VERY SIGNIFICANT, HOT-OFF-THE PRESS ANNOUNCEMENT TO MAKE, WHICH IS THAT ROCKET PHARMACEUTICALS, WHICH IS A CIRM AWARDEE, JUST HAD THEIR PRODUCT FOR ADDRESSING

SEVERE LEUKOCYTE ADHESION DEFICIENCY TYPE 1, OR LAD-1 OR LAD-1 FOR SHORT, APPROVED BY THE FDA, JUST RECEIVED CLEARANCE ON THEIR BLA. SO THIS MARKS THE FIRST PRODUCT THAT CIRM HAS HELPED FUND THAT IS NOW PROCEEDING INTO COMMERCIALIZATION.

THIS IS A VERY LARGE EVENT FOR ROCKET AND A VERY LARGE EVENT FOR CIRM. AND I WOULD LIKE JUST TO READ TO YOU BRIEFLY FROM THE FDA WEBSITE ON WHICH THIS NEWS IS POSTED. THE OFFICIAL WORD FROM THE FDA: U.S. FOOD AND DRUG ADMINISTRATION TODAY APPROVED KRESLADI, THE FIRST GENE THERAPY FOR THE TREATMENT OF LAD-1. KRESLADI IS INDICATED FOR THE TREATMENT OF PEDIATRIC PATIENTS WITH SEVERE LEUKOCYTE ADHESION DEFICIENCY DUE TO A VARIETY OF THINGS THAT AREN'T WORTH GETTING INTO EXTREME DETAIL HERE, BUT JUST TO NOTE THAT THIS IS A VERY SERIOUS CONDITION. THE FAMILY THAT AMY WAS REFERRING TO, WHOSE EXTREMELY CUTE PICTURE WAS AT DISNEYLAND WEARING ALL THE MOUSE EARS, WAS THE FAMILY THAT SHE WROTE ABOUT THAT HAD THIS CONDITION. AND SO THIS IS FOR THAT FAMILY AND FOR OTHERS WITH THIS CONDITION A VERY MAJOR DEVELOPMENT.

SO I THOUGHT EVERYBODY WOULD BE MOST INTERESTED TO HEAR THAT BECAUSE WE'VE BEEN WAITING FOR OUR FIRST EVER BLA APPROVED PRODUCT TO COME OUT

133 HENNA COURT, SANDPOINT, IDAHO 83864
208-255-5453 208-920-3543 DRAIBE@HOTMAIL.COM

OF CIRM. DAVID, YOU HEAR THAT?

MR. LARSEN: YES, I DID. THANK YOU VERY MUCH. HOW MUCH DID CIRM INVEST IN THIS ENTERPRISE?

DR. THOMAS: JOE, DO YOU KNOW THE ANSWER TO THAT QUESTION?

MS. ADAMS: I HAVE THE ANSWER RIGHT HERE. 5,867,085.

MR. LARSEN: THANK YOU. AFTER ALL, MONEY IS THE MOTHER'S MILK OF SCIENCE.

DR. THOMAS: THAT'S RIGHT. SO THAT IS THE BIG NEWS.

WE HAVE OTHER PIECES OF NEWS THAT, BECAUSE THIS SORT OF DWARFS EVERYTHING ELSE, I THINK WE'RE GOING TO KEEP, IN THE INTEREST OF TIME, FOR THE NEXT PRESIDENT'S REPORT OTHER THAN TO MENTION TWO QUICK THINGS. ONE IS ANOTHER PATIENT STORY, WHICH I THINK IS VERY IMPORTANT FOR YOU ALL TO HEAR, WAS INTERVIEWED BY *U.S.A. TODAY* A NUMBER OF WEEKS AGO. AND ON THAT CALL WAS A FAMILY WITH TWO CHILDREN THAT HAD SCID, ONE OF WHICH WAS TEN YEARS BEFORE THE OTHER. THAT ONE AT THAT POINT THE ONLY TREATMENT AVAILABLE WAS A BONE MARROW TRANSPLANT, AND THAT CHILD WHO HAD THAT TREATMENT HAS HAD NUMEROUS ISSUES, WAS IN THE HOSPITAL FOR, I BELIEVE, A YEAR. THE FAMILY WENT BANKRUPT AS A RESULT OF DEALING WITH

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208-255-5453 208-920-3543 DRAIBE@HOTMAIL.COM

THE HEALTHCARE ISSUES. IT WAS A VERY, VERY DIFFICULT STORY TO HEAR IN THE COURSE OF THIS INTERVIEW. AND YOUR HEART WENT OUT TO THE FAMILY.

THE SECOND CHILD, BY THE TIME THAT CHILD WAS SIMILARLY DIAGNOSED, WHICH IS TERRIBLE IN AND OF ITSELF, IF YOU CAN IMAGINE HAVING TWO CHILDREN WITH THE SAME CONDITION. AND, OH, BY THE WAY, THE HUSBAND'S UNCLE, I BELIEVE, HAD TWO OTHER CHILDREN THAT HAD SCID AS WELL. BY THE TIME THE YOUNGEST OF THE TWO IN THIS FAMILY THAT WAS BEING INTERVIEWED DEVELOPED THE CONDITION, THEY WERE ABLE TO USE DON KOHN'S APPROACH TO SCID TO GET TREATMENT AT UCLA. AND THAT CHILD IS NOW THRIVING AND HAS NONE OF THE LINGERING SIDE EFFECTS THAT THEIR OLDER CHILD HAD.

AND IT SHOWS -- FIRST OF ALL, IT WAS GREAT NEWS TO HEAR, BUT MORE THAN ANYTHING, THAT'S THE PRIMARY POINT, BUT CERTAINLY OF GREAT SIGNIFICANCE IS THE DEMONSTRATION OF THIS AS THE HOPE THAT CELL AND GENE THERAPY PRESENTS TO PATIENTS OF ALL SORTS OF CURRENTLY INCURABLE DISEASE. SO THAT *U.S.A. TODAY* ARTICLE IS GOING TO BE COMING OUT SHORTLY. WE WILL DISTRIBUTE WHEN THE TIME COMES.

THE LAST THING I WANT TO MENTION IS, JUST TO CLOSE ON A VERY POSITIVE NOTE, THAT I'D LIKE TO HAVE EVERYBODY WISH JENN LEWIS OF THE OAKLAND

133 HENNA COURT, SANDPOINT, IDAHO 83864
208-255-5453 208-920-3543 DRAIBE@HOTMAIL.COM

LEWISES AND DR. LIZ NOBLIN A VERY HAPPY BIRTHDAY TODAY. MR. CHAIR, I'M GOING TO CLOSE ON THAT. AND THANK YOU, EVERYBODY.

CHAIRMAN IMBASCIANI: THANK YOU, J.T. WHERE ARE YOU, JENN? HAPPY BIRTHDAY AND LIZ. OKAY. THANK YOU. AND, J.T., WE'LL LOOK FORWARD TO THE ADDENDUM TO THE REPORT AT A FUTURE DATE.

WE'RE AT THE POINT OF THE MEETING WHERE WE ASK --

MR. TOCHER: WE HAVE A COMMENT BY MARK FISCHER-COLBRIE.

CHAIRMAN IMBASCIANI: OH, THANK YOU.

MR. FISCHER-COLBRIE: THIS IS INCREDIBLY EXCITING NEWS ABOUT ROCKET. AND PARALLELING THE CONVERSATION AROUND SCID IS THE FACT THAT THERE ARE A WHOLE SLEW OF VERY SUCCESSFUL PATIENT SOLUTIONS AND TREATMENTS THAT HAVE BEEN ACHIEVED THROUGH CIRM-SUPPORTED FUNDING. AND JUST WANTED TO EXPAND UPON THAT CONCEPT WITH THE PERSPECTIVE OF WE'VE HAD A LOT OF SUCCESSES, BUT WE DO WANT TO BALLYHOO AND SUPPORT A BROADER COMMUNICATION AROUND ROCKET AND WHAT'S HAPPENING SPECIFICALLY AROUND THE BLA PROCESS. SO THANKS.

CHAIRMAN IMBASCIANI: THANK YOU, MARK. BEFORE WE GO THE PUBLIC, ARE THERE ANY MEMBERS OF

THE BOARD WHO WANT TO MAKE ANY COMMENT ON OUR ARS PROCESS OR ON ANY ITEM THAT WASN'T ON THE AGENDA? IF NOT, I KNOW WE HAVE A MEMBER OF THE PUBLIC THAT'S ON THE PHONE. SO WE CAN LET THEM SPEAK.

MS. MORALEZ: ALL RIGHT. THE NUMBER ENDING IN 3427, IF YOU WOULD UNMUTE YOURSELF, AND YOU HAVE THREE MINUTES.

MR. BHATNAGER: MY NAME IS PARIJAT BHATNAGER. I WOULD LIKE TO MAKE -- I WOULD LIKE TO BRING SOMETHING IMPORTANT TO THE NOTICE OF THE BOARD. I BROUGHT THIS TO YOUR NOTICE TWICE IN THE PAST, BUT I HAVE BEEN WAITING FOR SOME ACTION ON YOUR BEHALF. BASICALLY THE ISSUE IS THAT I HAVE STARTED A NEW NONPROFIT. IT HAS BEEN ABOUT SIX MONTHS OR ABOUT A YEAR. AND SOME OF THE -- ONE OF THE REQUIREMENTS, ELIGIBILITY CONDITIONS, FOR APPLYING FOR CIRM GRANT HAVE MADE US INELIGIBLE. AND I'M SURE THAT IT WAS NOT INTENDED TO BE LIKE THIS, BUT I WAS TOLD THAT SOMEBODY WOULD GET BACK TO ME. I HAVE NOT BEEN CONTACTED ABOUT THIS SO FAR.

AND BASICALLY THERE IS A REQUIREMENT THAT THE INSTITUTE NEEDS TO HAVE AT LEAST ONE W-2 EMPLOYEE. I HAVE PUT A LETTER TO THE BOARD ON THE WEBSITE, AND I WAS HOPING YOU COULD HAVE A DISCUSSION ON HOW THIS COULD BE ADDRESSED. WE HAVE

ALL HEARD TODAY THAT HOW IMPORTANT THE FUNDING FROM CIRM IS IN BRINGING GROUNDBREAKING TREATMENTS TO THE PUBLIC, TO THE BENEFIT OF THE PUBLIC. AND I BELIEVE THAT WE SHOULD ALSO GET A CHANCE TO HELP CALIFORNIA WITH GROUNDBREAKING TREATMENT, AS WELL AS INCREASING EMPLOYMENT OPPORTUNITIES FOR THOSE WHO WOULD BE HELPING US ACCOMPLISH THIS GOAL. THANK YOU. I'M LOOKING FORWARD TO A RESPONSE.

CHAIRMAN IMBASCIANI: OKAY. WE KNOW WHO THIS IS THAT'S SPEAKING AND CONTACT INFORMATION? WE DO. OKAY. THANK YOU, SPEAKER. WE'VE GOT YOUR CONTACT INFORMATION, AND WE'LL LOOK INTO IT. I APPRECIATE YOUR REMARKS.

I JUST WANT TO LET EVERYONE KNOW THAT THE NEXT MEETING OF THE ICOC WILL BE ON THURSDAY 25 JUNE 2026 AT THE HYATT HOTEL IN BURLINGAME, CALIFORNIA. IT WILL START AT NINE IN THE MORNING, NOT AT 8:30. AND THIS MEETING IS NOW ADJOURNED.

(THE MEETING WAS THEN ADJOURNED AT 4:32 P.M.)

133 HENNA COURT, SANDPOINT, IDAHO 83864
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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 PROCEEDINGS BEFORE THE INDEPENDENT CITIZEN'S OVERSIGHT COMMITTEE AND THE APPLICATION REVIEW SUBCOMMITTEE OF THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE IN THE MATTER OF ITS REGULAR MEETING HELD ON MARCH 26, 2026, WAS HELD AS HEREIN APPEARS AND THAT THIS IS THE ORIGINAL TRANSCRIPT THEREOF AND THAT THE STATEMENTS THAT APPEAR IN THIS TRANSCRIPT WERE REPORTED STENOGRAPHICALLY BY ME AND TRANSCRIBED BY ME. I ALSO CERTIFY THAT THIS TRANSCRIPT IS A TRUE AND ACCURATE RECORD OF THE PROCEEDING.

BETH C. DRAIN, CA CSR 7152
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