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: VIA ZOOM

DATE: OCTOBER 26, 2023
9 A.M.

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

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I N D E X

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OCTOBER 26, 2023; 9 A.M.

MR. TOCHER: VITO, YOU ARE WELCOME TO OPEN THE MEETING.

CHAIRMAN IMBASCIANI: GOOD MORNING, EVERYONE. WE ARE READY TO START. YES.

MR. TOCHER: GREAT. OKAY. THEN WE'LL ARE TURN TO GIL TO DO THE PRESENTATION ON THESE -- ON THE GRANT APPLICATIONS BEFORE US TODAY.

VICE CHAIR BONNEVILLE: WE NEED A ROLL CALL VOTE, SCOTT?

MR. TOCHER: SORRY.

DAN BERNAL.

MR. BERNAL: PRESENT.

MR. TOCHER: MARIA BONNEVILLE.

VICE CHAIR BONNEVILLE: PRESENT.

MR. TOCHER: LEONDRA CLARK-HARVEY.

DR. CLARK-HARVEY: PRESENT.

MR. TOCHER: YSABEL DURON.

MS. DURON: HERE.

MR. TOCHER: MARK FISCHER-COLBRIE.

DR. FISCHER-COLBRIE: HERE.

MR. TOCHER: FRED FISHER.

DR. FISHER: PRESENT.

MR. TOCHER: ELENA FLOWERS.

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DR. FLOWERS: PRESENT.
MR. TOCHER: DAVID HIGGINS.
DR. HIGGINS: HERE.
MR. TOCHER: VITO IMBASCIANI.
CHAIRMAN IMBASCIANI: PRESENT.
MR. TOCHER: STEVEN JUELSGAARD.
MR. JUELSGAARD: PRESENT.
MR. TOCHER: RICH LAJARA.
MR. LAJARA: PRESENT.
MR. TOCHER: CHRIS MIASKOWSKI. LAUREN MILLER-ROGEN.
MS. MILLER-ROGEN: HERE.
MR. TOCHER: ADRIANA PADILLA.
DR. PADILLA: HERE.
MR. TOCHER: JOE PANETTA.
MR. PANETTA: HERE.
MR. TOCHER: ANNE-MARIE DULIEGE. JUDY CHOU. MARV SOUTHARD. KAROL WATSON. KEVIN XU.
OKAY. GREAT. WE HAVE A QUORUM. GIL.
DR. MELMED: I WASN'T CALLED. I'M SORRY.
MR. TOCHER: HI, SHLOMO. THANK YOU. YES. I WAS JUST TAKING THE POLL OF THE ARS MEMBERS, BUT THANK YOU FOR LETTING ME KNOW YOU'RE HERE.
DR. SAMBRANO: OKAY. GOOD MORNING, EVERYONE. I'M GOING TO START THE PRESENTATION.

SO TODAY I'M GOING TO PRESENT THE RECOMMENDATIONS FROM THE GRANTS WORKING GROUP RELATED TO THE LATEST CYCLE OF THE TRANSLATIONAL PROGRAM. AS ALWAYS, WE BEGIN WITH A STATEMENT OF OUR MISSION, ACCELERATE WORLD-CLASS SCIENCE TO DELIVER TRANSFORMATIVE REGENERATIVE MEDICINE TREATMENTS IN AN EQUITABLE MANNER TO A DIVERSE CALIFORNIA AND WORLD.

AS ALWAYS, THIS REPRESENTS WHAT OUR ULTIMATE GOAL IS. IT IS WHAT WE HELP ALIGN THE GRANTS WORKING GROUP IN THEIR ASSESSMENT OF APPLICATIONS FOR ANY OF OUR PROGRAMS. THE TRANSLATIONAL PROGRAM IN PARTICULAR IS PART OF OUR RECURRING SET OF FUNDING OPPORTUNITIES TO SUPPORT PROGRAMS THAT MIGHT BEGIN WITH A NEW IDEA AND TAKES THEM THROUGH TO THE CLINIC. IN PARTICULAR, THE TRANSLATION PROGRAM OFFERS SUPPORT FOR FOUR DIFFERENT PRODUCT TYPES. THE MAJORITY OF WHICH WE GET ARE THERAPEUTIC PRODUCTS, BUT WE ALSO SUPPORT DIAGNOSTIC, MEDICAL DEVICE, AND TOOLS. AND THE PROGRAM IS SET UP SO THAT IT OFFERS THE APPROPRIATE LENGTH OF TIME FROM 24 TO 30 MONTHS AND THE APPROPRIATE AMOUNT OF FUNDING FOR EACH PRODUCT TYPE TO TAKE THEM THROUGH TRANSLATIONAL ACTIVITIES THAT WILL ALLOW THEM TO GET TO A PRESUBMISSION MEETING OR

TO TRANSFER A TOOL TO BROAD END USE.

AND SO THIS IS AN ILLUSTRATION OF WHAT REQUIREMENTS ARE TO COME IN TO THE TRANSLATION PROGRAM. SO FOR A THERAPEUTIC WE EXPECT APPLICANTS TO HAVE A CANDIDATE, THERAPEUTIC CANDIDATE, WHERE THEY'VE DEMONSTRATED DISEASE-MODIFYING ACTIVITY. AND SIMILARLY FOR THE DIAGNOSTIC, DEVICES, AND TOOLS, THAT THEY HAVE A PROTOTYPE AND A PROOF OF CONCEPT WITH THAT PROTOTYPE WHEN THEY COME IN.

AT THE END OF THE TRANSLATION AWARD, WE EXPECT THAT THE ACTIVITIES WILL ALLOW THEM TO EITHER COMPLETE A PRE-IND MEETING, IF IT'S A THERAPEUTIC, OR ANOTHER PRESUBMISSION MEETING WITH THE FDA FOR THOSE THAT FOLLOW A REGULATORY PATH. AND FOR A TOOL, FOR THEM TO BE AT A STAGE WHERE THEY CAN TRANSFER THE DESIGN TO MANUFACTURING FOR COMMERCIALIZATION OR FOR MAKING AVAILABLE BROADLY TO THE SCIENTIFIC COMMUNITY.

THE SCIENTIFIC REVIEW CRITERIA THAT ARE UTILIZED BY THE GRANTS WORKING GROUP TO ASSESS THESE APPLICATIONS ARE BASED ON FIVE QUESTIONS. DOES THE PROJECT HOLD THE NECESSARY SIGNIFICANCE AND POTENTIAL FOR IMPACT? MEANING WHAT VALUE DOES IT OFFER, AND IS IT SOMETHING THAT'S WORTH DOING? IS THE RATIONALE SOUND? IS IT WELL-PLANNED AND

DESIGNED? IS IT FEASIBLE, INCLUDING HAVING THE APPROPRIATE MEMBERS ON THEIR TEAM AND ALL THE AVAILABLE RESOURCES TO CONDUCT THE PROJECT? AND DOES THE PROJECT UPHOLD THE PRINCIPLES OF DIVERSITY, EQUITY, AND INCLUSION?

THE SCORING SYSTEM THAT'S USED BY THE GRANTS WORKING GROUP IS A SCALE OF 1 TO 100. A SCORE OF 85 TO A 100 MEANS IT'S RECOMMENDED FOR FUNDING IF FUNDS ARE AVAILABLE. ANYTHING BELOW A SCORE OF 85 MEANS THAT IT'S NOT RECOMMENDED FOR FUNDING. AND ALL APPLICATIONS ARE SCORED BY THE SCIENTIFIC MEMBERS OF THE GRANTS WORKING GROUP WITHOUT A CONFLICT. AND WE USE THE MEDIAN OF ALL THE INDIVIDUAL GRANTS WORKING GROUP SCORES TO DETERMINE WHAT THE FINAL SCORE IS.

WE ALSO IN THE TRANSLATION PROGRAM, SIMILAR TO THE CLINICAL PROGRAM, HAVE BEEN UTILIZING ALSO A DEI SCORE. SO THE PATIENT ADVOCATE AND NURSE MEMBERS OF THE BOARD WHO ARE PART OF THE GRANTS WORKING GROUP PROVIDE A DEI SCORE FROM ZERO TO TEN WITH TEN BEING THE BEST OF POSSIBLE SCORE BASED ON THEIR OVERALL ASSESSMENT OF THE APPLICANT'S RESPONSE TO THE DEI QUESTIONS AND ELEMENTS THAT WE POSE. AND THEY USE A RUBRIC, WHICH IS ILLUSTRATED HERE, TO GUIDE THEIR SCORING.

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THE COMPOSITION OF THE GRANTS WORKING GROUP INCLUDES THE SCIENTIFIC MEMBERS THAT, AS I MENTIONED, HAVE THE DIVERSITY OF BACKGROUND TO PROVIDE A SCIENTIFIC SCORE AND MAKE THE SCIENTIFIC ASSESSMENT. OUR GRANTS WORKING GROUP BOARD MEMBERS, WHO ARE THE PATIENT ADVOCATE AND NURSE MEMBERS, PROVIDE THE PATIENT PERSPECTIVE ON THE SIGNIFICANCE AND POTENTIAL FOR IMPACT AS WELL AS OVERSIGHT ON THE PROCESS AND PROVIDE A DEI SCORE ON THE APPLICATION. WE ALSO HAVE AS PART OF THE PANEL SCIENTIFIC SPECIALISTS WHO ARE NONVOTING MEMBERS WHO PARTICIPATE ON AN AD HOC BASIS FOR SPECIFIC APPLICATIONS AS THEIR EXPERTISE IS NEEDED.

ALL RIGHT. SO WE GET TO THE RECOMMENDATIONS OF THE GRANTS WORKING GROUP FOR THIS PARTICULAR CYCLE. THERE WERE 30 APPLICATIONS THAT WERE REVIEWED AND CONSIDERED BY THE WORKING GROUP. TEN WERE RECOMMENDED FOR FUNDING, RECEIVING A SCORE OF 85 OR ABOVE. THE TOTAL REQUEST FOR THOSE TEN APPLICATIONS IS ABOUT 33.5 MILLION. THE FUNDS AVAILABLE ARE 84.6 MILLION. THE FUNDS AVAILABLE ARE INTENDED TO SUPPLY TWO ROUNDS OF TRAN. THIS IS THE FIRST CYCLE. SO WE WILL HAVE ANOTHER CYCLE OF TRAN THAT THAT 84 WILL ALSO HELP COVER.

SO LET ME SPEND A MINUTE ON MINORITY

REPORTS. SO UNDER PROP 14 ANY APPLICATION THAT'S NOT RECOMMENDED FOR FUNDING BY THE GRANTS WORKING GROUP, BUT WHICH HAD 35 PERCENT OR MORE OF THE MEMBERS SCORE IT TO FUND THE APPLICATION MUST INCLUDE A MINORITY REPORT. THE MINORITY REPORT IS INCLUDED IN THE REVIEW SUMMARY. SO WE HAVE PROVIDED THOSE TO YOU, AND IT PROVIDES A BRIEF SYNOPSIS OF THE OPINION OF THE REVIEWERS THAT SCORED THE APPLICATION 85 OR ABOVE.

SO IN THIS PARTICULAR CYCLE, WE HAD ONE APPLICATION THAT QUALIFIED FOR A MINORITY REPORT. THAT WAS TRAN1-15209. THE TITLE IS "CLINICAL DEVELOPMENT OF EXTRACELLULAR VESICLE-BASED THERAPY FOR ALPORT SYNDROME." THE FUNDS REQUESTED IS 5.1 MILLION. AND THE SCORE THAT IT RECEIVED WAS AN 80.

IN THIS PARTICULAR CASE, THE CIRM TEAM SPORTS THE MAJORITY POSITION, MEANING TO NOT FUND, THE APPLICATION FOR TRAN1-15209, AND WE RECOMMEND THAT THE APPLICANTS REVISE AND RESUBMIT FOR THE NEXT TRANSLATIONAL ROUND. AND THE DEADLINE FOR THAT IS UPCOMING DECEMBER 5. AND THE REASON FOR THIS IS THAT THERE WERE PRETTY CLEAR AND SPECIFIC ELEMENTS THAT CAN BE ADDRESSED BY THE APPLICANTS IN A RESUBMISSION. IN PARTICULAR, THE PROJECT WOULD BENEFIT FROM A REVISION THAT ADDRESSES PRELIMINARY

DATA CONCERNS WHERE PARTICULAR DATA RELATED TO USE OF THE SPECIFIC EXTRACELLULAR VESICLES THAT ARE THE CANDIDATE IN A MODEL WOULD BE IMPORTANT TO HAVE AS WELL AS INCORPORATE FEEDBACK FROM REGULATORY AND CMC EXPERTS, WHICH THEY COULD DO AS PART OF A REVISION.

SO THAT'S THE RECOMMENDATION ON THE MINORITY REPORT. THIS IS JUST A REMINDER OF BOARD MEMBERS THAT HAVE A CONFLICT OF INTEREST WITH A TRAN APPLICATION. AND SO, AS MENTIONED EARLIER, PLEASE BE AWARE OF THOSE CONFLICTS AND LOOK TO SCOTT TOCHER FOR WHEN IT MAY BE OKAY TO MAKE A COMMENT IF YOU WANT TO DO THAT.

AND SO NOW LET ME STOP SHARING THIS AND SHARE WITH YOU THE SPREADSHEET THAT SHOWS THE APPLICATIONS IN RANK ORDER. GIVE ME ONE SECOND. OKAY. HERE IS THE APPLICATIONS IN RANK ORDER. THOSE IN GREEN ARE THOSE THAT ARE RECOMMENDED FOR FUNDING. THERE ARE TEN OF THOSE. THE ONE WITH THE MINORITY REPORT IS ACTUALLY A COUPLE OF SLOTS BELOW THAT FUND LINE, WHICH IS HERE. AND WE ARE NOT RECOMMENDING THAT FOR FUNDING. AND HERE ARE THE REMAINDER OF THE APPLICATIONS. SO I TURN IT BACK TO YOU, MR. CHAIR, FOR DISCUSSION.

CHAIRMAN IMBASCIANI: GREAT. SO WE START THIS DISCUSSION ON ALL THESE APPLICATIONS. YOU KNOW

THIS IS THE ONE WHERE WE DO THE FUNNY DANCE. SO I WOULD LIKE TO LOOK AT THOSE THAT ARE RECOMMENDED NOT TO BE FUNDED, THOSE THAT ARE IN TIER II. GIL, COULD YOU TELL US HOW MANY THERE ARE? IT SEEMS TO SCROLL RIGHT OFF THE SCREEN.

DR. SAMBRANO: YEAH. SO THERE'S ABOUT -- THERE WERE 20 THAT WERE NOT RECOMMENDED. SOME WITHDREW, SO THERE MAY BE JUST SLIGHTLY LESS THAN 20 IN THIS FRAME.

CHAIRMAN IMBASCIANI: SO I'D LIKE TO START THE DISCUSSION BY ASKING FOR A MOTION, THAT WE LOOK AT TIER II. AND THE MOTION WOULD BE -- IS THERE ANY APPLICATION IN THIS GROUP THAT YOU WOULD LIKE TO EXCERPT, MEANING YOU WOULD LIKE TO DISCUSS CONSIDERATION OF FUNDING THIS IN SPITE OF THE CIRM TEAM'S RECOMMENDATION NOT TO FUND AND, THEREBY, MOVE IT FROM TIER II UP TO TIER I.

SO I'D LIKE TO ENTERTAIN A MOTION. IN A SENSE THIS IS A CONSENT CALENDAR, AND I'M ASKING YOU TO EXCERPT ANYTHING FROM THE CONSENT CALENDAR FOR DISCUSSION. LET THAT PERCOLATE JUST FOR A LITTLE BIT.

MR. TOCHER: VITO, THIS IS SCOTT. CALL AN AUDIBLE HERE. IF I MAY MAKE A SUGGESTION TO THE SUBCOMMITTEE. AS I INDICATED JUST BEFORE WE JOINED,

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BECAUSE THE OVERALL ASK OF THE ENTIRE SLATE OF APPLICATIONS EXCEEDS THE BUDGET, OUR CONFLICT OF INTEREST RULES REQUIRE THAT WE -- THAT MEMBERS WITH A CONFLICT AS TO ANY APPLICATION, WHETHER IT'S IN THE TIER I OR TIER II CATEGORY, SUCH INDIVIDUALS ARE PRECLUDED FROM MAKING A MOTION OR PARTICIPATING IN THE DISCUSSION AS TO ANY APPLICATION UNLESS SUCH TIME AS THE OVERALL DEMAND IS BELOW THAT TOTAL BUDGET, WHICH IS 84 MILLION.

SO THAT WOULD MEAN THAT MEMBERS JUELSGAARD, BERNAL, FLOWERS, PANETTA, AND BONNEVILLE AT THIS MOMENT ARE PRECLUDED FROM MAKING A MOTION OR PARTICIPATING IN ANY DISCUSSION AS TO ANY APPLICATION REGARDLESS OF WHETHER IT IS THE ONE THAT THEY'RE IN CONFLICT WITH. ALL THIS IS A LONG WAY OF SAYING ALL WE NEED TO DO IS GET THE OVERALL BUDGET OF SITTING APPLICATIONS THAT HAVE NOT BEEN DISPENSED WITH, EITHER FUNDED OR UNFUNDED, IS TO GET THAT LINE FROM WHERE IT STANDS, WHICH IS 87.3 MILLION DOWN TO BELOW 84 MILLION.

SO AS I LOOK AT GIL'S LIST, APPLICATION 15279, WHICH, I BELIEVE, IS AT THE BOTTOM OF YOUR SCREEN, HAS A BUDGET AMOUNT THAT, IF THERE WAS A MOTION NOT TO FUND THIS AND IT IS NOT RECOMMENDED FOR FUNDING, AND WE HANDLE THAT DISCRETELY, WE WOULD

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THEN BE ABLE TO OPEN UP THE WHOLE REST OF THE CONSIDERATION OF THE SLATE OF APPLICATIONS UNDER OUR NORMAL PROCESS. SO I APOLOGIZE FOR TAKING UP EVERYONE'S TIME WITH THIS PROCESS POINT, BUT IT WOULD ALLOW GREATER PARTICIPATION BY THE BOARD IF WE HAD A DISCRETE MOTION WITH RESPECT TO THIS APPLICATION.

CHAIRMAN IMBASCIANI: DISCRETE SPELLED C-R-E-T-E, YES?

MR. TOCHER: YES. IN OTHER WORDS, A MOTION NOT TO FUND THIS APPLICATION COULD NOT BE MADE OR SECONDED BY ANY OF THE MEMBERS THAT I JUST IDENTIFIED --

CHAIRMAN IMBASCIANI: RIGHT.

MR. TOCHER: -- FOR DISCUSSION, PUBLIC COMMENT, AND THEN A VOTE. AND IF THAT MOTION PASSED, THEN OUR OVERALL EXPOSURE WOULD BE LESS THAN THE BUDGET AMOUNT AND WE COULD PROCEED AS NORMAL.

CHAIRMAN THOMAS: I THINK THAT'S AN ELEGANT SOLUTION. I DON'T WANT A MOTION TO REMOVE ALL OF THESE, INCLUDING THE ONE WITH THE MINORITY REPORT.

SO THEN I GUESS I SHOULD AMEND MY OWN ASK OF THE BOARD AND ASK FOR A MOTION TO ABSTRACT -- NO, I'M SORRY -- TO SPECIFICALLY NOT FUND TRAN1-15279.

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DR. FISHER: SO MOVED.
MR. TOCHER: CAN YOU IDENTIFY YOURSELF PLEASE?
DR. FISHER: FRED FISHER.
MR. TOCHER: GREAT. THANKS, FRED.
DR. FISCHER-COLBRIE: SECOND.
MR. TOCHER: THANK YOU, MARK.
CHAIRMAN IMBASCIANI: WE HAVE A MOTION AND A SECOND. ANY DISCUSSION FROM THE BOARD MEMBERS FIRST?
MS. DURON: THIS IS YSABEL, VITO. I JUST NEED CLARIFICATION. SCOTT, I THOUGHT I HAD A CONFLICT.
MR. TOCHER: YES.
MS. DURON: AND I DIDN'T HEAR MY NAME, SO I JUST NEED TO CLARIFY THAT BEFORE I SAY ANYTHING.
MR. TOCHER: THAT'S CORRECT. IT'S YSABEL AND STEVE, DAN, ELENA, JOE.
MS. DURON: SORRY, VITO. I CAN'T SAY ANYTHING.
CHAIRMAN IMBASCIANI: NO. THAT'S A VERY WELL TIME COMMENT, YSABEL, CONSIDERING ALL THE PROBLEMS THAT CAN ENSUE IF YOU DIDN'T.
ALL RIGHT. I DON'T HEAR ANY CONVERSATION FROM THE BOARD. IS THERE ANY PUBLIC, ANY MEMBER OF

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THE PUBLIC THAT WOULD LIKE TO COMMENT ON THIS MOTION?

MR. TOCHER: IT DOESN'T APPEAR SO.

CHAIRMAN IMBASCIANI: OKAY. ALL RIGHT. THEN, SCOTT, WOULD YOU PLEASE -- DISCUSSION IS CLOSED -- WOULD YOU PLEASE CALL THE VOTE.

MR. TOCHER: YES. AND THIS IS WHERE -- LEONDRA CLARK-HARVEY.

DR. CLARK-HARVEY: YES.

MR. TOCHER: THANK YOU. MARK FISCHER-COLBRIE.

DR. FISCHER-COLBRIE: AYE.

MR. TOCHER: FRED FISHER.

DR. FISHER: AYE.

MR. TOCHER: ELENA FLOWERS.

DR. FLOWERS: I --

MR. TOCHER: SORRY. DAVID HIGGINS.

DR. HIGGINS: YES.

MR. TOCHER: VITO IMBASCIANI.

CHAIRMAN IMBASCIANI: YES.

MR. TOCHER: RICH LAJARA.

MR. LAJARA: YES.

MR. TOCHER: LAUREN MILLER-ROGEN.

MS. MILLER-ROGEN: YES.

MR. TOCHER: ADRIANA PADILLA.

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DR. PADILLA: YES.

MR. TOCHER: AND I THINK THAT'S EVERYONE.

CHAIRMAN IMBASCIANI: OKAY.

MR. TOCHER: GREAT. THANK YOU.

SO WITH THAT NOW, THE NORMAL PROCESS WOULD APPLY. ANYONE CAN MAKE A MOTION AND PARTICIPATE IN THE DISCUSSION WITH RESPECT TO THE APPLICATION AS LONG AS THEY'RE NOT IN CONFLICT WITH IT. HOWEVER, IT'S AN OMNIBUS MOTION; IN OTHER WORDS, IT'S A MOTION THAT INVOLVES MULTIPLE APPLICATIONS. IT CAN ONLY COME FROM A MEMBER WHO IS NOT IN CONFLICT WITH ANY OF THE SUBJECT APPLICATIONS.

CHAIRMAN IMBASCIANI: SCOTT, THANK YOU FOR SOLVING OUR DILEMMA HERE. CAN I ASK, SCOTT, SHOULD WE FOCUS ON TRAN 15209 NEXT?

MR. TOCHER: IT UP TO THE PLEASURE OF THE COMMITTEE ON HOW IT WOULD LIKE TO PROCEED NEXT. BUT TYPICALLY, YES, WE WOULD DEAL WITH TIER II APPLICATIONS NEXT.

CHAIRMAN IMBASCIANI: WELL, SINCE THERE IS A MINORITY REPORT ON THIS, I THINK WE PROBABLY SHOULD HAVE A SHORT DISCUSSION ON IT. LET'S SEE. DO I HAVE TO ABSTRACT THIS AGAIN AS WE DID THE LAST ONE?

MR. TOCHER: YOU CAN JUST ASK FOR A MOTION

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REGARDING IT.

CHAIRMAN IMBASCIANI: OKAY. BOARD MEMBERS, HAVING HEARD OUR COUNSEL HERE --

DR. FISHER: SO MOVED. I MOVE THAT WE NOT FUND APPLICATION 15209.

CHAIRMAN IMBASCIANI: THANK YOU, FRED. A SECOND PLEASE.

DR. FISCHER-COLBRIE: SECOND. MARK FISCHER-COLBRIE.

CHAIRMAN IMBASCIANI: OKAY. I HEAR THE SECOND. SO THIS 15209 APPLICATION IS OPEN FOR DISCUSSION FOR NOT FUNDING. GIL HAS ALREADY GIVEN US THE CIRM STAFF'S OPINION. IS THERE ANYONE WOULD LIKE TO HAVE MORE INFORMATION ON THAT?

MS. MANDAC: ADRIANA HAS HER HAND RAISED.

CHAIRMAN IMBASCIANI: I CAN'T SEE THAT, BUT THANK YOU, CLAUDETTE. ADRIANA, PLEASE.

DR. PADILLA: YEAH. I JUST WANTED TO HEAR MORE FROM GIL AS TO WHY THE CIRM COMMITTEE AND ACTUALLY WHY IT WAS DEEMED TO NEED TO BE RESUBMITTED. CAN I JUST HEAR THE REASONS WHY?

CHAIRMAN IMBASCIANI: EXCELLENT. THANK YOU. GIL.

DR. SAMBRANO: SURE. ABSOLUTELY. SO GENERALLY I THINK OUR DEFAULT POSITION FOR

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APPLICATIONS THAT ARE NOT RECOMMENDED BY THE GRANTS WORKING GROUP IS THAT THEY HAVE THE OPPORTUNITY TO REVISE THEIR APPLICATION AND RESUBMIT IN THE NEXT CYCLE. SO WE OFFER THESE CYCLES WITH THE GOAL OF TRYING TO MAKE SURE THE APPLICATIONS IMPROVE AND UTILIZE THE CRITIQUES FROM THE GRANTS WORKING GROUP TO MAKE THOSE IMPROVEMENTS.

SO IN THIS PARTICULAR CASE, WE LOOKED AT APPLICATIONS TO SEE IF THERE WERE CONCERNS THAT COULD BE ADDRESSED THROUGH A RESUBMISSION. SO IN PARTICULAR, THE MAJOR CONCERNS THAT WERE RAISED WERE RELATED TO THE EFFICACY DATA. SO SPECIFICALLY, IN THIS PROPOSAL THEIR CANDIDATE IS HUMAN AMNIOTIC FLUID STEM CELL-DERIVED EXTRACELLULAR VESICLES. THEY PROVIDE DATA THAT USES A MOUSE VERSION OF THE CELLS AS WELL AS THE EV'S, BUT NOT WITH THE HUMAN VERSION OF EV'S. SO REVIEWERS THOUGHT IT WOULD BE IMPORTANT TO HAVE THAT PRELIMINARY DATA TO GIVE MORE CONFIDENCE THAT THIS IS LIKELY TO WORK.

AND THERE WERE SOME CONCERNS RAISED RELATED TO THE CMC, THE MANUFACTURING OF THESE EV'S AND THE REGULATORY PATH THAT COULD BE ADDRESSED BY GETTING SOME EXPERT ADVICE. SO WE THOUGHT THAT WAS PRETTY STRAIGHTFORWARD IN TERMS OF WHAT THEY COULD DO THAT COULD BE ADDRESSED THROUGH A REVISION.

SOMETIMES WHEN WE RECOMMEND, AND JUST FOR CONTEXT, AN APPLICATION THAT RECEIVES A MINORITY REPORT, WE LOOK TO SEE IF THE CONCERNS ARE ADDRESSABLE EITHER THROUGH A MILESTONE OR THROUGH SOMETHING THAT AT CIRM WE CAN DO IN TERMS OF MONITORING THE PROJECT VERSUS HAVING THEM MAKE THE REVISIONS. HERE WE FELT THAT MAKING THE REVISIONS WAS THE APPROPRIATE COURSE, AND THAT'S WHY WE MADE THAT RECOMMENDATION.

CHAIRMAN IMBASCIANI: THANK YOU, GIL. ADRIANA, YOU SATISFIED?

DR. PADILLA: YES. I JUST FELT LIKE WE NEEDED TO HEAR THAT.

CHAIRMAN IMBASCIANI: THANK YOU. I AGREE.

ANY OTHER COMMENTS? ANY MEMBER OF THE PUBLIC WHICH TO COMMENT ON FUNDING APPLICATION 15209? CLAUDETTE?

MS. MANDAC: I DO NOT SEE ANY HANDS RAISED.

CHAIRMAN IMBASCIANI: NO HANDS. ALL RIGHT. SCOTT, WE CAN PROCEED TO A VOTE ON THIS. THANK YOU.

MR. TOCHER: ALL RIGHT. THERE ARE NO CONFLICTS, SO EVERYONE IS ELIGIBLE TO VOTE.

DAN BERNAL.

MR. BERNAL: AYE.
MR. TOCHER: MARIA BONNEVILLE.
VICE CHAIR BONNEVILLE: AYE.
MR. TOCHER: LEONDRA CLARK-HARVEY.
DR. CLARK-HARVEY: AYE.
MR. TOCHER: YSABEL DURON.
MS. DURON: YES.
MR. TOCHER: MARK FISCHER-COLBRIE.
MR. FISCHER-COLBRIE: AYE.
MR. TOCHER: FRED FISHER.
DR. FISHER: AYE.
MR. TOCHER: ELENA FLOWERS.
DR. FLOWERS: YES.
MR. TOCHER: DAVID HIGGINS.
DR. HIGGINS: YES.
MR. TOCHER: VITO IMBASCIANI.
CHAIRMAN IMBASCIANI: YES.
MR. TOCHER: STEVE JUELSGAARD.
MR. JUELSGAARD: YES.
MR. TOCHER: RICH LAJARA.
MR. LAJARA: YES.
MR. TOCHER: LAUREN MILLER-ROGEN.
MS. MILLER-ROGEN: YES.
MR. TOCHER: ADRIANA PADILLA.
DR. PADILLA: YES.

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MR. TOCHER: JOE PANETTA.

MR. PANETTA: YES.

MR. TOCHER: THANK YOU. AND THE MOTION CARRIES. SO THAT APPLICATION IS -- WILL NOT BE FUNDED.

CHAIRMAN IMBASCIANI: OKAY. GOOD. HAVING HEARD NO EARLIER MOTION TO ABSTRACT ANYTHING FROM THIS DO NOT FUND CONSENT CALENDAR, I'D LIKE TO HEAR A MOTION FROM THE BOARD NOT TO FUND THE REMAINDER OF TIER II.

DR. FISHER: SO MOVED.

CHAIRMAN IMBASCIANI: MOTION FROM MR. FISHER. THANK YOU. I NEED A SECOND ON THIS.

DR. FISCHER-COLBRIE: SECOND.

CHAIRMAN IMBASCIANI: MARK. THANK YOU, MARK.

ANY FURTHER DISCUSSION FROM THE MEMBERS OF THE BOARD?

MR. TOCHER: STEVE JUELSGAARD HAS HIS HAND.

CHAIRMAN IMBASCIANI: THANK YOU. STEVE.

MR. JUELSGAARD: THIS IS ACTUALLY JUST A QUESTION FOR GIL OF GENERAL INFORMATION. SO THE AMOUNT OF THESE AWARDS IS LIMITED TO $4 MILLION; IS THAT RIGHT, GIL?

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DR. SAMBRANO: YES, IN DIRECT PROJECT COSTS FOR THAT ARE THERAPEUTIC.

MR. JUELSGAARD: ON THE INDIRECT COST THE LIMIT IS 25 PERCENT OF THE AWARD AMOUNT; IS THAT RIGHT?

DR. SAMBRANO: WELL, THE INDIRECT COST IS 20 PERCENT, BUT THEN THERE ARE DIRECT FACILITIES COSTS WHICH VARY BY THE INSTITUTION.

MR. JUELSGAARD: SO THERE ARE FACILITIES COSTS EMBEDDED IN SOME OF THESE?

DR. SAMBRANO: YES.

MR. JUELSGAARD: SO COULD YOU EXPLAIN TO ME, THEN, THE DIFFERENCE BETWEEN THOSE WITH FACILITIES COSTS THAT ARE EMBEDDED IN THESE AND THOSE WITHOUT? HOW DO FACILITIES COSTS BECOME EMBEDDED IN THESE AWARDS?

DR. SAMBRANO: SO FACILITIES COSTS ARE PART OF WHAT I THINK MOST OF US ARE USED TO HAVING AS AN INDIRECT COST. BUT UNDER PROP 71 AND UNDER PROP 14, THEY ARE DESIGNATED AS DIRECT FACILITIES COSTS. SO INDIRECT COSTS USUALLY HAVE AN ADMINISTRATIVE COMPONENT AND A FACILITIES COMPONENT. WE SEPARATE THEM OUT. SO THE ADMINISTRATIVE COMPONENT IS 20 PERCENT, AND THEN THE FACILITIES COMPONENT IS VARIABLE DEPENDING ON THE INSTITUTION.

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AND SO THOSE ARE COMBINED, IF YOU WILL, TO BE THE OVERHEAD THAT GOES INTO ALL OF THESE APPLICATIONS. SO ALL OF THEM HAVE THE 20 PERCENT AS WELL AS THE ALLOWABLE FACILITIES COSTS.

MR. JUELSGAARD: ALL RIGHT. SO MAYBE I'M MISREADING THE SECTION THAT DEALS WITH INDIRECT COSTS IN TERMS OF HOW IT WORKS. BECAUSE THE WAY I READ IT IS THAT THE AWARD OF ADDITIONAL FACILITIES COSTS ACTUALLY APPLY TO AWARDS FOR FACILITIES, NOT NECESSARILY FOR RESEARCH GRANTS.

DR. SAMBRANO: IT'S DIFFERENT. IT'S A DISTINCT COST CATEGORY. SO THIS IS NOT FOR RENOVATION, CONSTRUCTION, OR BUILDING. THIS IS FOR --

MR. JUELSGAARD: I'LL CONTINUE THIS OFFLINE WITH SCOTT. I JUST -- I'M HAVING A LITTLE BIT OF DIFFICULTY TRANSLATING THE LANGUAGE OF PROP 71 INTO THE PRACTICE. I'LL TALK TO SCOTT.

DR. SAMBRANO: OKAY.

MR. JUELSGAARD: THANK YOU.

CHAIRMAN IMBASCIANI: ANY OTHER COMMENTS FROM BOARD MEMBERS? COMMENTS FROM THE PUBLIC?

MR. TOCHER: WE SHOULD HAVE SUBSTANTIAL PUBLIC COMMENT, I BELIEVE, VITO. SO JUST STAND BY WHILE WE --

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CHAIRMAN IMBASCIANI: THANK YOU, SCOTT.

MR. TOCHER: -- REACH OUT THE MEMBERS OF THE PUBLIC WHO HAVE REACHED OUT DURING THE WEEK AND POSTED LETTERS. I UNDERSTAND THAT THERE ARE FOLKS WHO ARE WAITING TO SPEAK.

CHAIRMAN IMBASCIANI: GOOD.

MR. TOCHER: SO JUST STAND BY. PAUL BRESGE.

DR. BRESGE: YES. CAN YOU HEAR ME?

MR. TOCHER: YES, WE CAN HEAR YOU.

DR. BRESGE: EXCELLENT. SO FIRST, THANK YOU VERY MUCH FOR THE OPPORTUNITY TO ADDRESS YOU TODAY. MY NAME IS PAUL BRESGE, AND I'M THE CEO OF RAY THERAPEUTICS.

I ALSO WANT TO THANK THE REVIEWERS FOR THE EXCELLENT FEEDBACK THAT THEY PROVIDED WITH RESPECT TO OUR TRAN1 GRANT APPLICATION FOR OPTOGENETIC THERAPY FOR THE TREATMENT OF GEOGRAPHIC ATROPHY.

I'M GOING TO ASK THE ICOC TO PLEASE CONSIDER APPROVING OUR APPLICATION GIVEN THE FACT THAT WE HAD SUCH A HIGH SCORE OF 84, ONE BELOW THE REQUIRED THRESHOLD OF 85 FOR FUNDING. WE WERE VERY GRATIFIED BY THE SUPPORT THAT WE RECEIVED FROM THE REVIEWERS FOR THE PROGRAM, AND OVERALL IT WAS VERY STRONG SUPPORT FOR ALL ASPECTS OF OUR APPLICATION.

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IT APPEARS THAT THE ISSUE THAT INFLUENCED OUR SCORE TO RESULT IN THE 84 INSTEAD OF THE 85 IS PRIMARILY GUIDED BY A SINGLE REQUEST THAT WE UTILIZE AN ADDITIONAL ANIMAL MODEL IN OUR PHARMACOLOGY STUDIES. WE AGREE WITH THE RATIONALE TO INCLUDE THIS ANIMAL IN OUR STUDIES, AND WE CAN READILY WORK WITH THE CIRM ADMINISTRATORS TO INCLUDE THIS MODEL IN OUR CIRM GRANT MILESTONES.

WE'VE ALREADY RESEARCHED THE AVAILABILITY OF THESE ANIMALS, AND WE CAN IMPLEMENT IT INTO THE PROGRAM IN PARALLEL WITH OUR OTHER ACTIVITIES, THEREFORE, AVOIDING A DELAY BY BRINGING THIS IMPORTANT THERAPY TO PATIENTS.

BUDGET IMPACT IS NOMINAL, AND WE CAN ACTUALLY FUND IT THROUGH THE COMPANY. SO WE ARE ASKING THIS DECISION TO BE MADE NOW INSTEAD OF HAVING TO RESUBMIT BECAUSE OF PATIENT NEED. THE GEOGRAPHIC ATROPHY FORM OF AGE-RELATED MULTIDISCIPLINARY IS AN ABSOLUTELY DEVASTATING DISEASE THAT CAUSES MAJOR VISION LOSS. THERE ARE MORE THAN A HUNDRED FIFTY ON THE PATIENTS IN CALIFORNIA ALONE THAT CURRENTLY SUFFER FROM BLINDNESS WITH THIS DISEASE, AND THOUSANDS DEVELOP THIS CONDITION EVERY YEAR.

THERE ARE CURRENTLY NO APPROVED THERAPIES

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THAT CAN IMPROVE THEIR VISION. TIME FOR THESE PATIENTS AND THEIR FAMILIES AND CAREGIVERS IS CRITICAL. YOU WILL HEAR MORE ABOUT THE PATIENT EXPERIENCE FROM MY COLLEAGUES, GARY ABRAMS AND PETER FRANCIS.

MY PERSONAL EXPERIENCE WITH CIRM OVER THE LAST 12 YEARS IS TO FOLLOW THE COLLECTIVE ADVICE OF CIRM STAFF, REVIEWERS, AND ADVISORS. AND I HOPE THAT WE CAN TAKE THE SAME COLLABORATIVE APPROACH WITH CIRM TO PROGRESS THIS GEOGRAPHIC ATROPHY PROGRAM AND BRING IT TO PATIENTS.

WE ARE VERY GRATEFUL TO CIRM FOR FUNDING OUR PREVIOUS TRAN1 GRANT APPLICATION FOR DEVELOPMENT OF A THERAPEUTIC FOR RETINITIS PIGMENTOSA, AND WE ARE VERY PLEASED TO ADVISE THAT WE COMPLETED ALL OF OUR ACTIVITIES SUCCESSFULLY AND AHEAD OF SCHEDULE. WE HOPE THAT WE WILL BE ABLE TO DO THE SAME THING WITH THIS APPLICATION. IF APPROVED, WE'LL PARTNER WITH CIRM TO CREATE A SUCCESSFUL AND ROBUST PROGRAM THAT WILL LEAD TO A SUCCESSFUL PRE-IND MEETING WITH FDA AND ULTIMATELY SUCCESSFUL THERAPEUTIC FOR PATIENTS.

I JUST WANT TO CLOSE BY SAYING THAT I HAVE SAID MANY TIMES IN PRIVATE, PUBLIC, AND THROUGH MULTIPLE PRESS RELEASES THAT I HAVE NOTHING BUT

GRATITUDE FOR CIRM AND ALL THAT CIRM DOES FOR PATIENTS IN THE STATE OF CALIFORNIA AND WORLDWIDE. ONE OF THOSE PATIENTS HAPPENS TO BE MY OWN DAUGHTER, TAMAR, WHO LIVES IN CALIFORNIA AND STUDIES IN CALIFORNIA, AND SHE ALSO SUFFERS WITH A BLINDING DISEASE.

WITH THAT, I'LL HAND IT OVER TO GARY ABRAMS.

DR. ABRAMS: THANK YOU, PAUL.

CHAIRMAN IMBASCIANI: MR. ABRAMS.

DR. ABRAMS: YES.

CHAIRMAN IMBASCIANI: GO AHEAD. THE FLOOR IS YOURS. THANK YOU.

DR. ABRAMS: I'D LIKE TO THANK THE MEMBERS OF THE COMMITTEE FOR ALLOWING ME TO SPEAK. MY NAME IS GARY ABRAMS. I AM AN OPHTHALMOLOGIST, AND I'M A RETINA SPECIALIST.

I SEE MANY PATIENTS WITH GEOGRAPHIC ATROPHY ASSOCIATED WITH, MOST OF THEM, WITH AGE-RELATED MACULAR DEGENERATION. GEOGRAPHIC ATROPHY IS LOSS OF THE PHOTORECEPTORS. THESE ARE THE VISION CELLS OF THE RETINA THAT ARE IN THE BACK OF THE EYE IN THE CENTRAL SEEING AREA. IT'S MOST COMMON WITH AGE-RELATED MACULAR DEGENERATION, BUT YOU ALSO FIND IT PRESENT IN SOME INHERITED DISEASES,

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SUCH AS STARGARDT'S DISEASE AND CONE DYSTROPHY.

I WANT TO EMPHASIZE THAT PATIENTS WITH GEOGRAPHIC ATROPHY ARE TRULY DISABLED. IT'S A SERIOUS PROBLEM THAT CAUSES GREAT LOSS OF ABILITY TO PARTICIPATE IN DAILY LIFE. JUST TO GET AN IDEA OF WHAT THESE PEOPLE FACE, I'D LIKE FOR YOU TO ACTUALLY CLOSE ONE EYE AND PUT YOUR FIST IN FRONT OF YOUR OPEN EYE LIKE THIS (INDICATING), AND WHAT DO YOU SEE? WELL, YOU'VE GOT A HUGE CENTRAL BLIND SPOT, AND YOU CAN SEE AROUND THE EDGE OF IT, BUT YOU REALLY CAN'T SEE ANYTHING CENTRALLY.

SO WHAT HAPPENS? YOU CAN'T READ. YOU CAN'T DRIVE. YOU CAN'T SEE YOUR FOOD ON YOUR PLATE. YOU CAN'T COOK. BUT WHAT'S INTERESTING IS MOST -- THE THING THAT SEEMS TO BE MOST DISTURBING TO MANY OF THESE PEOPLE IS THEY CAN'T RECOGNIZE THE FACES OF FRIENDS AND LOVED ONES.

THERE'S NO TREATMENT FOR ESTABLISHED GEOGRAPHIC ATROPHY. WHILE NEW DRUGS MAY SLOW THE PROGRESSION OF GEOGRAPHIC ATROPHY, THERE'S NO CURRENT TREATMENT THAT CAN RESTORE VISION IN THESE FOLKS WHO HAVE LOST THEIR VISION.

RTX021 HAS THE POTENTIAL TO RESTORE VISUAL FUNCTION IN THESE PATIENTS WITH A SINGLE INJECTION INTO THE EYE THAT CAN BE DONE BY ANY TRAINED

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OPHTHALMOLOGIST. AND IT'S LIKELY THIS WILL LAST A LIFETIME.

WITH CIRM'S HELP, WE THINK WE CAN IMPROVE THE LIVES OF THOUSANDS OF PATIENTS IN CALIFORNIA AND THE REST OF THE WORLD WHO SUFFER FROM THIS DEVASTATING DISEASE. ONCE AGAIN, THANK YOU FOR ALLOWING ME TO SPEAK.

CHAIRMAN IMBASCIANI: THANK YOU, MR. ABRAMS. THANK YOU FOR YOUR INPUT AND YOUR CLINICAL EXPERTISE.

DR. ABRAMS: I'M GOING TO TURN THIS OVER TO PETER FRANCIS FOR OUR CONCLUSION.

CHAIRMAN IMBASCIANI: MR. FRANCIS, THE FLOOR IS YOURS.

DR. FRANCIS: GOOD MORNING, EVERYBODY. I'M DR. PETER FRANCIS. I'M AN M.D./PH.D. OPHTHALMOLOGIST. I'M CURRENTLY THE CSO AND CMO OF RAY THERAPEUTICS. AND LIKE DR. ABRAMS, I HAVE MORE THAN 30 YEARS EXPERIENCE AS AN OPHTHALMOLOGIST AND RETINA SPECIALIST PARTICULARLY TREATING PATIENTS WITH AGE-RELATED MACULAR DEGENERATION.

AND I COMMEND PROFESSOR ABRAMS FOR HIS DESCRIPTION OF THE SUBSTANTIAL UNMET MEDICAL NEED IN GEOGRAPHIC ATROPHY. TO ADD TO THAT, ACCORDING TO SURVEYS, JUST TO GIVE YOU A FLAVOR, PATIENTS EQUATE

HAVING GEOGRAPHIC ATROPHY AND THE RESULTING SENSORY LOSS AND PSYCHOLOGICAL IMPACT OF THE DISEASE WITH SEVERE AND ADVANCED SYSTEMIC DISEASES LIKE HEART DISEASE. AT RAY THERAPEUTICS WE HAVE A COMPANY AND MANAGEMENT TEAM WITH AN EXEMPLARY TRACK RECORD OF SUCCESSFUL CIRM GRANT EXECUTION, MEETING MILESTONES AHEAD OF SCHEDULE, ON BUDGET, AND WITH HIGH IMPACT FOR THE CITIZENS OF CALIFORNIA.

IN REGARDS TO THIS CURRENT TRAN1 GRANT, I CAN CONFIRM WE HAVE THE TEAM TO IMPLEMENT, THE FACILITIES TO CONDUCT, AND THE PROGRAM MANAGEMENT CAPABILITIES TO EFFICIENTLY IMPLEMENT THE MILESTONES AS OF NOW.

IN CONCLUSION, AS A TECHNOLOGY OPTOGENETICS IN THE VISION SPACE HAS BEEN SHOWN TO WORK IN RESTORING VISION TO BLIND PATIENTS. SO IT IS SIGNIFICANTLY DERISKED. WHILE THE FIELD HAS LACKED THE OPTOGENETICS METHODS THAT ARE ENGINEERED TO OPTIMIZE THE VISION OUTCOME, AND THAT'S WHAT WE ACTUALLY HAVE HERE AT RAY THERAPEUTICS WITH OUR RTX021 PROGRAM, THE REALISTIC POTENTIAL TO REALIZE THE FULL VISUAL IMPROVEMENT THAT CAN BE GAINED BY OPTOGENETICS IN GEOGRAPHIC ATROPHY.

AS YOU HEARD, THE PATIENTS ARE EAGERLY WAITING FOR OUR HIGHLY DIFFERENTIATED AND DERISKED

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TREATMENT. AND I THANK THE CIRM ICOC MEMBERS FOR THEIR ATTENTION AND KIND CONSIDERATION OF OUR REQUEST TO FUND OUR CURRENT TRAN1 APPLICATION. THANK YOU VERY MUCH.

CHAIRMAN IMBASCIANI: THANK YOU, MR. FRANCIS. AND I THANK ALL OF THE SPEAKERS FOR THE CARE WITH WHICH THEY CRAFTED THEIR REMARKS TO THE BOARD. THANK YOU.

MR. TOCHER: VITO, WE HAVE MORE PUBLIC COMMENT.

MS. MANDAC: NEXT ONE IS KAREN CHRISTMAN, IF YOU COULD UNMUTE AND INTRODUCE YOURSELF.

DR. CHRISTMAN: YEAH. HELLO. GOOD MORNING, EVERYONE. SO MY NAME IS KAREN CHRISTMAN. I'M A PROFESSOR OF BIOENGINEERING AT UC SAN DIEGO, AND I'M THE PI OF TRAN1-15291, WHICH IS ON A PRO-REGENERATIVE INFUSIBLE EXTRACELLULAR MATRIX BIOMATERIAL FOR TREATING ACUTE MYOCARDIAL INFARCTION. SO THIS IS A COST-EFFECTIVE REGENERATIVE MEDICINE SOLUTION WHERE YOU CAN ACTUALLY DELIVER AT THE TIME SOMEBODY COMES INTO THE HOSPITAL WITH A HEART ATTACK. IT'S GETTING AN STENT PLACED, AND YOU CAN USE BIOMATERIAL TO REPAIR THE HEART.

SO OUR SCORE WAS AN 83, SO VERY CLOSE.

AND WHILE I KNOW YOU GET A LOT OF PEOPLE ARGUING WHY SCIENTIFICALLY THEY SHOULD BE UP JUST A COUPLE POINTS HIGHER, AND I CAN EASILY DO THAT. BUT WHAT I WANTED TO PROPOSE WHY WE SHOULD BE FUNDED NOW IS ACTUALLY A LITTLE BIT DIFFERENT IN THAT WE HAVE A VERY UNIQUE OPPORTUNITY IF THE CIRM TRAN GRANT IS FUNDED TODAY TO REALLY ACCELERATE THE WHOLE PROJECT TOWARDS AN IND AND INTO PATIENTS, WHICH I THINK EVERYBODY IS WELL AWARE HEART DISEASE IS THE LEADING KILLER IN THE U.S. AND CALIFORNIA.

SO THE UNIQUE OPPORTUNITY IS THAT THE COMPANY I CO-FOUNDED, VENTRIX BIO, JUST RECEIVED AN SBIR GRANT FROM THE NATIONAL INSTITUTE OF HEALTH FROM THE NATIONAL HEART LUNG BLOOD INSTITUTE. AND I'M CO-INVESTIGATOR ON THE GRANT, AND IT PROVIDES COMPLEMENTARY SUPPORT FOR PRECLINICAL DEVELOPMENT OF THE INFUSIBLE EXTRACELLULAR MATRIX PRODUCT.

SO WHAT'S UNIQUE IN THIS SITUATION IS THAT, UNLIKE THE SBIR, CIRM FUNDS MADE A KEY MANUFACTURING DEVELOPMENT IN MAKING INITIAL BATCHES OF MATERIAL. SO WHAT WILL ACCELERATE US IS THAT, IF THE CIRM PROJECT IS FUNDED NOW, WE'LL BE ABLE TO DO THE PRECLINICAL STUDIES UNDER THE SBIR IN ADDITION TO THE ONES WITH THE CIRM GRANT WITH THE MANUFACTURED MATERIAL THAT HAS BEEN SCALED UP AND IS

AT THE SAME CLINICAL GRADE PROCESS THAT WILL BE USED IN PATIENTS.

AND SO WHAT THIS MEANS IS THAT WE'LL BE ABLE TO ACTUALLY REDUCE SOME COSTS ON THE CIRM GRANT ON THINGS THAT WE ARE NOT GOING TO HAVE TO REPEAT WITH THAT MANUFACTURE PROCESS, BUT ALSO OUR MANUFACTURED PRODUCT, BUT ALSO THAT WE CAN REALLY ACCELERATE THIS. SO BASICALLY WE THINK THIS WILL FUND WITH THE SBIR AND THE TRAN GRANT NOW, WE CAN DO IT ON MANUFACTURED MATERIAL AND DO THE MAJORITY OF STUDIES THAT WOULD LEAD TO SUBMISSION OF AN IND. AND WE THINK, BASED ON PREVIOUS EXPERIENCE WITH MYSELF AND VENTRIX, ANOTHER MATERIAL THAT WENT INTO PHASE 1 CLINICAL TRIAL IN HEART FAILURE PATIENTS, THIS WOULD REALLY ALLOW US ACCELERATE BY ABOUT A YEAR AS OPPOSED TO IF IT'S NOT FUNDED NOW AND WE HAVE TO DO A RESUBMISSION, WE ARE NOT GOING TO BE ABLE TO DO THE SBIR STUDIES WITH THE NEW INJECTION MATERIAL WHICH THEN WILL HAVE TO BE REPEATED AND SET US BACK.

SO THAT'S WHY I'D LIKE TO ADVOCATE FOR FUNDING NOW VERSUS IN SIX MONTHS AND REALLY ACCELERATE THIS TECHNOLOGY TO PATIENTS, AGAIN, FOR THE LEADING CAUSE OF DEATH IN CALIFORNIA. SO THANK YOU VERY MUCH.

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CHAIRMAN IMBASCIANI: THANK YOU FOR YOUR COMMENTS, PROFESSOR.

SCOTT, ARE THERE MORE COMMENTS FROM THE GENERAL PUBLIC?

MR. TOCHER: YES, THERE ARE. I BELIEVE DR. IRV WEISSMAN HAS INDIVIDUALS, INCLUDING HIMSELF. IRV, ARE YOU ON THE LINE?

MS. MANDAC: WE DID HAVE A CALLER THAT HAD TRIED TO RAISE A HAND AND THEN DISCONNECTED.

CHAIRMAN IMBASCIANI: IF THAT CALLER WOULD LIKE TO TRY DIALING BACK IN AGAIN.

DR. CHRISTMAN: THAT MIGHT HAVE BEEN ME. I WAS ON MY PHONE EARLIER WHEN I CLOSED IT AND REALIZED I COULD JUST DO IT ON ZOOM. SO THAT WAS PROBABLY ME IF IT WAS A 510 NUMBER.

MS. MANDAC: OKAY. YES, IT WAS.

CHAIRMAN IMBASCIANI: ALL RIGHT. GREAT. THANK YOU, DR. CHRISTMAN.

MR. TOCHER: IS THERE ANY OTHER PUBLIC COMMENT ON THE LINE?

MS. MANDAC: 650.

DR. WEISSMAN: HELLO. CAN YOU HEAR ME?

MR. TOCHER: YES.

DR. WEISSMAN: YES, YOU CAN HEAR ME?

CHAIRMAN IMBASCIANI: YES, WE CAN HEAR

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YOU. CAN YOU IDENTIFY YOURSELF, THEN START?

DR. WEISSMAN: YES. I'M IRV WEISSMAN, PROFESSOR AT STANFORD UNIVERSITY AND FOUNDER OF THE INSTITUTE FOR STEM CELL BIOLOGY AND REGENERATIVE MEDICINE AND CO-AUTHOR OF PROP 71 AND PROP 14.

I'M TALKING TO YOU TODAY ABOUT TRAN4-15225 WE WISH TO BRING PURIFIED HUMAN BLOOD-FORMING STEM CELLS FOR TRANSPLANT TO PATIENTS WITH CANCER AND PATIENTS WITH GENETIC BLOOD DISEASES. WE DEVELOPED A METHOD IN 1992 TO PURIFY BLOOD-FORMING STEM CELLS, WHICH WE CALL CD34+, 90+ HSC. THESE STEM CELLS AS OBTAINED FROM THE PATIENTS OR THE DONORS ARE CANCER FREE AND T-CELL FREE. UNFORTUNATELY, THE GRANTS WORKING GROUP COUNTERED WITH CD34 ONLY SELECTED CELLS.

CD34 SELECTED CELL ISOLATIONS STILL HAVE CANCER CELLS AND T-CELLS IN THEM, AND WE SHOWED THAT DATA IN THE GRANT. WE NEVER PROPOSED CD34. CD34 CELLS WILL NOT WORK IN THE SITUATION WE ARE DEALING WITH, AND THEY ARE NOT COMPARABLE. SO SOMEHOW THAT MISTAKE WAS MADE DURING THE GWG.

IN 1996 SYSTEMIX, A COMPANY I FOUNDED AND STARTED, A TRIAL WITH WOMEN WITH METASTATIC BREAST CANCER. AFTER HIGH DOSE COMBINATION CHEMOTHERAPY, WHICH ELIMINATES NOT ONLY MOST OF THEIR CANCER, BUT

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THEIR WHOLE BLOOD-FORMING SYSTEM, 15 PATIENTS WERE RESCUED WITH THEIR OWN HIGHLY PURIFIED STEM CELLS AND 74 WITH UNPURIFIED STARTING MATERIAL. THIS WAS THE FIRST AND ONLY TIME PURIFIED STEM CELLS WERE TRANSPLANTED TO PATIENTS, BLOOD-FORMING STEM CELLS.

NOW, YEARS LATER THE MEDIAN SURVIVAL OF PATIENTS RESCUED WITH THEIR OWN MOBILIZED BLOOD, THE STANDARD PRACTICE THEN, WAS TWO YEARS AND ALL WERE DEAD OR RELAPSED BY 12 YEARS. THE MEDIAN SURVIVAL, HOWEVER, OF PATIENTS RESCUED WITH THEIR OWN CANCER-FREE STEM CELLS MEDIAN WAS TEN YEARS AND ONE-THIRD OF THEM ARE ALIVE BOTH AT 12 YEARS AND NOW AT 24 YEARS.

THE LARGE PHARMA THAT BOUGHT SYSTEMIX SHUT IT DOWN IN EARLY 2000 WITHOUT SEEING THESE RESULTS. I'M GUESSING IT WAS A BUSINESS DECISION, BUT IT'S JUST A GUESS.

PATIENTS WITH GENETICALLY DEFECTIVE BLOOD AND IMMUNE SYSTEMS CAN BE RESCUED WITH HEALTHY BLOOD-FORMING SYSTEMS OR WITH GENE THERAPY. WE HAVE SHOWN THAT PURE BLOOD-FORMING STEM CELLS LACKING MATURE T-CELLS CAN BE TRANSPLANTED DONOR TO HOST WITHOUT GRAFT VERSUS HOST DISEASE, AND THEY REPLACE THE DISEASE BLOOD-FORMING SYSTEMS. CD34 SELECTED CELLS HAVE T-CELLS, AND WE AND OTHERS HAVE SHOWN

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CAUSE GRAFT VERSUS HOST DISEASE.

WE NEGOTIATED WITH THE LARGE PHARMA THAT BOUGHT US AND RETRIEVED THE RIGHTS TO ISOLATE PURE BLOOD-FORMING STEM CELLS AT STANFORD AT NO ADDED COST IN A NOT-FOR-PROFIT METHOD. WE PROPOSE A BREAST CANCER TRIAL EXTENSIONS FIRST AND HEALTHY DONOR BLOOD-FORMING STEM CELLS FOR SICKLE CELL DISEASE NEXT, HOPEFULLY THROUGH CIRM ALPHA CLINIC STEM CELL CLINICS.

PLEASE RESTORE TRUE STEM CELL TRANSPLANTATION, THE ONLY TRUE, PURE STEM CELL TRANSPLANTATION FOR AN ENORMOUS SET OF UNMET NEED FROM CANCER TO GENETIC BLOOD DISEASES AND FOR ORGAN AND OTHER TISSUE STEM CELL TRANSPLANTS. THANK YOU.

CHAIRMAN IMBASCIANI: THANK YOU, PROFESSOR WEISSMAN.

MR. TOCHER: IRV, THIS IS SCOTT. ARE THERE ANY OTHER MEMBERS OF THE PUBLIC THAT YOU BROUGHT TO THE MEETING? ARE THERE ANY OTHER MEMBERS OF THE PUBLIC?

DR. WEISSMAN: DID JOE GANTZ PROVIDE A DOCUMENT OR THE VIDEO OR AN AUDIO FOR THIS SESSION?

MR. TOCHER: HE PROVIDED THE VIDEO IN HE HAS A LETTER YESTERDAY WHICH WAS DISTRIBUTED TO THE BOARD YESTERDAY.

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DR. WEISSMAN: SO I WOULD URGE EITHER LICENSING TO THE AUDIO PORTION OR ON YOUR OWN PLEASE WATCH THE VIDEO.

CHAIRMAN IMBASCIANI: OKAY.

MR. JUELSGAARD: YES. CALL THE QUESTION.

CHAIRMAN IMBASCIANI: STEVEN, DID YOU SAY CALL THE QUESTION?

MR. JUELSGAARD: YES. PROCEED TO A VOTE.

CHAIRMAN IMBASCIANI: YES. WELL, IT'S A LITTLE COMPLICATED RIGHT NOW. SO WHAT I WOULD LIKE TO DO, IF THE BOARD WILL ALLOW ME, IS TO ABSTRACT THE THREE THAT WERE JUST COMMENTED ON FOR INDIVIDUAL CONVERSATION AND VOTE AND THEN PROCEED TO A MOTION TO CONSIDER ALL THE RESIDUAL APPLICATIONS IN TIER II. TO DO THAT, I NEED THE APPLICATION NUMBER FOR THE GEOGRAPHIC ATROPHY ONE AGAIN PLEASE.

DR. FISHER: WELL, CAN OUR PARLIAMENTARIAN CONFIRM THAT THE BOARD CHAIR CAN DETERMINE TO DO THIS WHEN THERE IS A MOTION AND A SECOND, THEN A CALL FOR THE QUESTION ON THE TABLE?

CHAIRMAN IMBASCIANI: THAT'S A GOOD QUESTION, FRED. I MEAN THE ALTERNATIVE IS TO ASK FOR AMENDMENTS TO THE MOTION.

DR. FISHER: I JUST DON'T WANT YOU TO BE OUT OF COMPLIANCE WITH PARLIAMENTARY PROCEDURE.

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CHAIRMAN IMBASCIANI: THANK YOU. WHO IS OUR PARLIAMENTARIAN?

DR. FISHER: I'M GUESSING IT'S SCOTT.

MR. TOCHER: YES. FRED RAISES THE POINT, AND, VITO, YOU ARE CORRECT, THAT THE APPROPRIATE NEXT STEP WOULD BE A MOTION TO AMEND --

CHAIRMAN IMBASCIANI: OKAY.

MR. TOCHER: -- TO BE TAKEN UP BEFORE THE MOTION ON THE TABLE.

CHAIRMAN IMBASCIANI: THAT'S FINE. WE'LL DO IT BY ROBERTS RULES.

SO MAY I HEAR FROM THE BOARD ANY MOTION TO ABSTRACT ONE OR MORE OF THESE APPLICATIONS FROM THE VOTE? THE VOTE THAT I'M REFERRING TO WILL BE NOT TO FUND ALL THE APPLICATIONS IN TIER II. SO IF YOU WANT TO CONSIDER FUNDING ONE OF THESE IN TIER II, I'M ASKING FOR A MOTION TO ABSTRACT THAT NOW.

DR. HIGGINS: SO MOVED. DAVID IN SAN DIEGO.

MR. JUELSGAARD: WAIT A MINUTE. WHICH ONE, ONE OR ONES? AND BY THE WAY, IT'S NOT REALLY ABSTRACTING THEM. IT'S MOVING THEM FROM TIER II TO TIER I. THAT'S THE MOTION THAT HAS TO BE MADE.

CHAIRMAN IMBASCIANI: THANK YOU.

DR. FISHER: I THINK THE MOTION IS -- I

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THINK YOU HAVE TO BASICALLY ASK THE PEOPLE WHO MADE THE ORIGINAL MOTION IF THEY'RE OPEN TO AMENDMENTS TO THEIR MOTION.

CHAIRMAN IMBASCIANI: I DON'T THINK WE NEED TO DO THAT.

MR. TOCHER: SORRY. FRED, ONCE THE MOTION IS MADE AND SECONDED, IT'S -- IT BELONGS TO THE WHOLE FLOOR, TO THE WHOLE COMMITTEE. SO, THEREFORE, PROCEDURALLY THE WAY TO HANDLE THIS IS A MOTION TO AMEND THIS MOTION, WHICH IS THEN PRIVILEGED AND IS VOTED UPON BEFORE THE UNDERLYING MOTION IS TAKEN UP.

SO -- BUT THE POINT IS WELL TAKEN AS TO DAVID'S ATTEMPT TO MAKE A MOTION. IF YOU CAN IDENTIFY, DAVID, TO WHICH APPLICATION YOU'RE SEEKING TO FUND.

DR. HIGGINS: SO WE HAVE TO PICK ONE AS OPPOSED TO --

CHAIRMAN IMBASCIANI: OR SEVERAL.

VICE CHAIR BONNEVILLE: CAN I ASK A QUESTION? I DON'T WANT TO HANDLE ALL THESE THE SAME WAY BECAUSE THEY'RE WILDLY DIFFERENT IN SCORE AND COMMENTS THAT HAVE BEEN MADE BY THE GWG. AND I DON'T THINK THAT THAT'S APPROPRIATE. THAT'S MY PERSONAL OPINION. SO IF WE NEED TO DO IT ON AN INDIVIDUAL BASIS, I WOULD PREFER THAT WE HANDLE IT

THAT WAY. I MAY BE ALONE IN THINKING THAT, BUT I JUST WANTED TO CALL THAT OUT.

CHAIRMAN IMBASCIANI: MARIA, I THINK ULTIMATELY EACH OF THE ONES THAT WE WILL MOVE TO TIER I THROUGH THIS PROCESS WOULD GET THEIR OWN INDIVIDUAL VOTE.

VICE CHAIR BONNEVILLE: NOT IF WE EXTRACT ALL OF THEM AT ONCE.

MR. TOCHER: THE POINT IS TO HANDLE THESE ON A SINGLE BASIS --

CHAIRMAN IMBASCIANI: OKAY.

MR. TOCHER: -- BY MOTION. SO AGAIN, DAVID, CAN YOU IDENTIFY THE APPLICATION THAT YOU WOULD LIKE TO --

DR. HIGGINS: MOST CERTAINLY I CAN. I'M ENTHUSIASTIC ABOUT THIS. FOR 15291, I JUST DON'T FEEL -- WAIT A MINUTE. SORRY. NEXT ONE UP. GEOGRAPHIC ATROPHY, THAT'S 15341. SO THIS COMMENT IS GOING TO BE RELATIVE TO THAT.

I DON'T BELIEVE THAT THERE'S A DIFFERENCE BETWEEN 84 AND 85, NO. 1. AND NO. 2, I THINK THIS IS WORK THAT DESERVES TO BE FUNDED. SO MY MOTION WOULD APPLY TO THAT ONE.

MR. TOCHER: OKAY. SO THE MOTION IS TO MOVE APPLICATION 15341 UP TO TIER I AND TO FUND IT.

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DR. HIGGINS: THAT'S MY MOTION, YES. THANK YOU.

MR. TOCHER: OKAY.

MS. DURON: MR. CHAIR, I SEE THAT ADRIANA PADILLA HAS HAD HER HAND UP FOR SOME TIME.

CHAIRMAN IMBASCIANI: I DO TOO. I'M JUST WONDERING, SCOTT, AS TO A MATTER OF PROCESS HERE. WE'VE GOT A MOTION FOR ONE APPLICATION TO BE REMOVED TO TIER I. SHOULD WE HANDLE THIS ONE DEFINITIVELY NOW AND THEN MOVE ON TO SUBSEQUENT MOTIONS? WE SHOULD. OKAY. WHY DON'T WE DO THAT. ADRIANA, CAN YOU --

MR. TOCHER: CAN I BE HEARD. OKAY. GREAT. WE JUST NEED A SECOND TO DAVID'S MOTION.

VICE CHAIR BONNEVILLE: I SECOND.

MR. TOCHER: THANK YOU.

CHAIRMAN IMBASCIANI: ADRIANA.

DR. PADILLA: YES. I WAS AGREEING WITH THE MOTION ON THE FLOOR. I ALSO WANTED TO CONSIDER MOVING THE TRAN 15291 ALSO FOR CONSIDERATION FOR FUNDING.

THEIR SCORE, IF YOU LOOK AT THE NUMBER OF GWG VOTES, IT WAS JUST RIGHT UP THERE. AND ACTUALLY THEY HAD FIVE PEOPLE WHO ULTIMATELY WERE WILLING TO FUND IT VERSUS TEN NOT. AND THAT'S PRETTY

SIGNIFICANT NUMBERS THAT I SEE.

MR. JUELSGAARD: I THINK WE NEED TO DEAL WITH THIS ONE FIRST. WE HAVE A MOTION AND THEN WE CAN MOVE TO WHATEVER ELSE WE MIGHT BE INTERESTED IN MOVING FORWARD. LET'S JUST DO THIS SO WE DON'T ALL GET CONFUSED.

CHAIRMAN IMBASCIANI: I AGREE. SO, ADRIANA, WOULD YOU HOLD THAT IN RESERVE?

DR. PADILLA: SURE.

CHAIRMAN IMBASCIANI: JOE PANETTA. HELLO.

MR. PANETTA: HELLO, MR. CHAIRMAN. I HEARD SOME PRETTY COMPELLING TESTIMONY ABOUT 15341 FROM THE THREE PRESENTERS, BUT I SEE THAT IT HAS A SCORE OF ONE YES AND 13 NOS. AND SO MAY I ASK A QUESTION OF GIL?

CHAIRMAN IMBASCIANI: I THINK, YES. GO AHEAD, GIL.

MR. PANETTA: SO, GIL, I THINK THE FIRST PRESENTER COMMENTED THAT THERE WAS A SINGLE DEFICIENCY THAT THEY CORRECTED IN THE PROPOSAL AND THAT THAT SHOULD THEN MAKE IT APPROPRIATE FOR APPROVAL. BUT WHAT I'M CURIOUS ABOUT IS WERE THOSE 13 NO VOTES RELATIVE TO THAT DEFICIENCY?

DR. SAMBRANO: YEAH. NO, THAT'S A GREAT QUESTION. IT'S HARD TO KNOW EXACTLY IF THAT IS WHY.

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I THINK WE CAN SURMISE THAT THAT IS PROBABLY THE CASE BECAUSE THAT WAS THE MOST OUTSTANDING ISSUE THAT WAS RAISED RELATED TO THIS APPLICATION. MEANING THAT THERE WAS A MODEL THAT REVIEWERS WOULD LIKE TO HAVE SEEN DONE IN THE PRELIMINARY DATA THAT WAS NOT USED.

I THINK THE QUESTION HERE IS IS THIS SOMETHING THAT WE WOULD WANT NOT JUST SIMPLY FOR THE APPLICANTS TO DO, BUT ALSO WHETHER THE GRANTS WORKING GROUP COULD SEE THE OUTCOME OF THAT BEFORE MOVING FORWARD OR WHETHER THERE IS A MILESTONE THAT WE COULD PUT IN PLACE, IF WE DECIDE TO FUND IT, THAT WOULD HAVE THEM DO THAT STUDY BEFORE MOVING FORWARD.

MR. PANETTA: OKAY. THANKS. BECAUSE I JUST WANT TO BE SURE THAT IF IT WERE THAT SINGLE DEFICIENCY AND THAT WERE THE DECISION TO BE MADE, THAT THERE WERE NOT OTHER DEFICIENCIES THAT WE SHOULD CONSIDER IN THIS BECAUSE ONE YES AND 13 NOS IS PRETTY LOPSIDED.

DR. SAMBRANO: YEAH. I AGREE. I THINK THAT THE MAJOR CONCERN WAS THE USE OF THAT MODEL.

CHAIRMAN IMBASCIANI: LET ME REMIND THE BOARD MEMBERS. WE ARE NOW WORKING ON THE MOTION TO MOVE APPLICATION 15341, THE ONE DEALING WITH GEOGRAPHIC ATROPHY, FROM TIER II TO TIER I. SO

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LET'S CONTINUE THAT DISCUSSION.

MR. FISHER.

DR. FISHER: I HAD A SIMILAR QUESTION. I'LL ASK IT IN A DIFFERENT WAY. I'M WONDERING IF GIL AGREES WITH THE APPLICANT'S CHARACTERIZATION OF THE DEFICIENCIES AND THEIR CONCLUSION THAT IT WAS THAT SOLE DEFICIENCY THAT WAS THE RESULT OF THEIR SCORE OR THEIR VOTES. AND DO THE STAFF AGREE THAT, WITH THAT DEFICIENCY CORRECTED, THIS BECOMES A FUNDABLE PROPOSAL?

DR. SAMBRANO: SO, FRED, I DO AGREE THAT THE MAJOR CONCERN WAS CONDUCTING THE PRECLINICAL EXPERIMENTS USING A MODEL THAT WAS NOT USED AND THAT REVIEWERS WOULD LIKE TO HAVE SEEN IT. I DO THINK THAT WAS THE MAJOR CONCERN.

I THINK ADDRESSING THAT WOULD IMPROVE THE APPLICATION OR WOULD HAVE IMPROVED THE APPLICATION, BUT I WOULD HESITATE TO SPEAK FOR THE GRANTS WORKING GROUP IN TERMS OF ULTIMATELY WHAT DROVE THEIR SCORE AND WHETHER THERE WERE ADDITIONAL CONCERNS THAT WERE NOT VOICED OR NOT REPRESENTED IN THE SUMMARY. BUT BASED ON THE SUMMARY THAT WE HAVE AND WHAT WE HEARD FROM THE GRANTS WORKING GROUP, I THINK THAT WAS THE MAJOR CONCERN.

DR. FISHER: GIVEN MY EXPERIENCE ON THE

GRANTS WORKING GROUP, I AM TYPICALLY RELUCTANT TO OVERTURN THEIR DECISIONS GIVEN MY EXPERIENCE OF THE THOROUGHNESS AND THE SERIOUSNESS WITH WHICH THEY TAKE THEIR REVIEWS. SO IF, IN FACT, THIS IS THE SOLE DEFICIENCY, THEN I WOULD HOPE THAT IF WE ULTIMATELY RECOMMEND FUNDING THIS PROPOSAL, THAT THAT FUNDING WOULD BE CONDITIONAL UPON A RESULT OF THIS ADDITIONAL REQUIRED EXPERIMENT.

CHAIRMAN IMBASCIANI: OKAY. ANY FURTHER DISCUSSION FROM BOARD MEMBERS?

VICE CHAIR BONNEVILLE: STEVE HAS HIS HAND RAISED.

MR. TOCHER: STEVE, YOU'RE IN CONFLICT WITH THIS APPLICATION UNLESS IT'S A PROCESS QUESTION.

MR. JUELSGAARD: NO. I WAS -- I'M TRYING TO THINK WHETHER IT'S A PROCESS POINT OR NOT. NO, IT WASN'T. OKAY. SO I'M IN CONFLICT. ALL RIGHT.

CHAIRMAN IMBASCIANI: THANK YOU. THANKS, SCOTT. ANY OTHER MEMBERS OF THE BOARD WANT TO COMMENT ON THIS 15341? ANY MEMBERS OF THE PUBLIC WE HAVEN'T HEARD FROM YET? AFTER YOUR CHECK, SCOTT, I THINK YOU CAN PROCEED TO A VOTE. AN AYE VOTE, MAYBE YOU CAN CLARIFY WHAT THE AYE VOTE MEANS.

MR. TOCHER: YES. AN AYE VOTE WOULD BE TO

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FUND APPLICATION 15341.

CHAIRMAN IMBASCIANI: EXCUSE ME. I THINK YOU MEAN TO PUT INTO TIER I, YES?

MR. TOCHER: THE MOTION WAS TO FUND.

CHAIRMAN IMBASCIANI: OKAY. ALL RIGHT.

MR. TOCHER: DAN BERNAL.

MR. BERNAL: AYE.

MR. TOCHER: MARIA BONNEVILLE.

VICE CHAIR BONNEVILLE: YES.

MR. TOCHER: LEONDRA CLARK-HARVEY.

DR. CLARK-HARVEY: AYE.

MR. TOCHER: YSABEL DURON.

MS. DURON: YES.

MR. TOCHER: MARK FISCHER-COLBRIE.

MR. FISCHER-COLBRIE: AYE.

MR. TOCHER: FRED FISHER.

DR. FISHER: AYE.

MR. TOCHER: ELENA FLOWERS.

DR. FLOWERS: YES.

MR. TOCHER: DAVID HIGGINS.

DR. HIGGINS: YES.

MR. TOCHER: VITO IMBASCIANI.

CHAIRMAN IMBASCIANI: YES.

MR. TOCHER: RICH LAJARA.

MR. LAJARA: YES.

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MR. TOCHER: LAUREN MILLER-ROGEN.
MS. MILLER-ROGEN: YES.
MR. TOCHER: ADRIANA PADILLA.
DR. PADILLA: YES.
MR. TOCHER: AND JOE PANETTA.
MR. PANETTA: YES.
MR. TOCHER: ALL RIGHT. THAT MOTION CARRIES. THAT APPLICATION IS FUNDED AND IS NOT PART OF TIER II.
CHAIRMAN IMBASCIANI: ALL RIGHT. NOW I WOULD LIKE TO OPEN THE FLOOR TO MOTIONS TO MOVE TO TIER I OR TO FUND ANY OF THE OTHER TWO APPLICATIONS THAT WE TALKED ABOUT.
MR. TOCHER: I BELIEVE ADRIANA HAS HER HAND UP.
CHAIRMAN IMBASCIANI: YES, ADRIANA.
DR. PADILLA: I WANTED TO RETURN BACK TO MY MOTION PREVIOUSLY TO MOVE UP THE TRAN 15291 AGAIN FOR THE REASON THAT THE SCORING WAS FAVORABLE WITH THE FINAL VOTES FOR THE GWG GROUP FIVE FOR FUNDING AND TEN FOR NOT AND A DEI SCORE THAT WAS VERY REASONABLE AND FOR THE HEALTH PROBLEM THAT IS VERY SIGNIFICANT TO MAJOR POPULATIONS HERE IN CALIFORNIA.
CHAIRMAN IMBASCIANI: THANK YOU. WE NEED A SECOND FOR THIS MOTION OR DO WE ALREADY HAVE ONE?

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MR. TOCHER: WE DON'T HAVE ONE YET.

DR. HIGGINS: I'LL SECOND.

CHAIRMAN IMBASCIANI: THAT WAS DAVID HIGGINS. THANK YOU. FURTHER DISCUSSION?

MS. MANDAC: FRED HAS HIS HAND RAISED.

CHAIRMAN IMBASCIANI: FRED. YES, I SEE IT NOW.

DR. FISHER: I THINK IT WOULD BE HELPFUL TO HEAR FROM GIL ABOUT THIS PROPOSAL AND THE STAFF'S THOUGHTS ABOUT APPROVING IT IN ITS CURRENT STATE.

DR. SAMBRANO: SO THIS APPLICATION IS PRO-REGENERATIVE INFUSIBLE ECM BIOMATERIAL FOR TREATING ACUTE MYOCARDIAL INFARCTION. SO THE CANDIDATE IS AN INJECTABLE BIOMATERIAL THAT'S DERIVED FROM SCAFFOLDING OF PIG HEART THAT'S USED TO FOLLOW TREATMENT OF MYOCARDIAL INFARCTION.

SO THE APPLICATION RECEIVED A SCORE OF 83. AND AS MENTIONED, THERE WERE FIVE MEMBERS WHO SCORED 85 OR ABOVE AND TEN THAT SCORED BELOW.

THE MAJOR CONCERN THAT WAS HIGHLIGHTED BY REVIEWERS WAS THE NEED FOR THE APPLICANT TEAM TO SEEK ADVICE FROM THE FDA. THEY WERE CONCERNED THAT THE STUDIES THAT ARE PROPOSED, WHICH IN GENERAL PRESENT A GOOD RATIONALE, ARE WELL-PLANNED AND DESIGNED MAY NOT BE THE CORRECT STUDIES TO DO. AND

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THAT DEPENDING ON THE SPECIFIC REGULATORY ROUTE THAT THIS GOES THROUGH, WHETHER IT'S THROUGH CBIR OR WHETHER IT IS CONSIDERED A DEVICE MAY IMPACT ON WHAT THOSE STUDIES SHOULD BE AND HOW THEY'RE DONE.

THE APPLICANTS HAVE PUT THROUGH A VERY SIMILAR OR SAME PRODUCT THROUGH THE REGULATORY PROCESS IN THE PAST, BUT THERE WERE SOME KEY DIFFERENCES NOTED BY REVIEWERS RELATED TO THE TIMING AND THE SPECIFIC APPLICABILITY OF THIS PARTICULAR CASE USE THAT MAY MAKE IT DIFFERENT. AND SO I THINK THAT WAS THE PRIMARY CONCERN FROM REVIEWERS TO ENSURE THAT THE STUDIES THAT ARE BEING PROPOSED HERE HAVE HAD A LOOK BY THE FDA TO MAKE SURE THAT THEY ARE ON THE RIGHT PATH TO AVOID HAVING TO EITHER DO THEM AGAIN OR DO THEM DIFFERENTLY.

SO I THINK THAT WAS THE OVERLYING CONCERN.

DR. FISHER: AND DID THE APPLICANT, HEARING THAT FEEDBACK, HAVE A RESPONSE? I DIDN'T HEAR THEM ADDRESS THAT IN THE COMMENTS.

DR. SAMBRANO: CORRECT. I DID NOT SEE THAT EITHER.

DR. FISHER: I THINK IT SOUNDS TO ME LIKE IF WE ARE NOT SURE THAT THIS IS ON THE RIGHT PATH, THEN WE COULD BE SPENDING THIS MONEY ONLY TO FIND THAT IT WAS WASTED BECAUSE IT WAS ON THE WRONG PATH

TOWARD FDA APPROVAL, WHICH IS WHAT WE ALL ULTIMATELY SEEK, INCLUDING THE APPLICANT. IT SEEMS LIKE THEY WOULD WANT THAT FEEDBACK BEFORE MOVING FORWARD ALSO.

AGAIN, IF PEOPLE ARE MOTIVATED TO FUND THIS PROPOSAL, THEN IS IT POSSIBLE FOR US TO MAKE FUNDING CONDITIONAL ON THE FDA AGREEING THAT THIS APPLICATION IS ACTUALLY ON THE RIGHT TRACK TOWARD APPROVAL?

DR. SAMBRANO: WE COULD DO THAT. I THINK THE QUESTION IS TO WHAT EXTENT DOES THE PROPOSAL POTENTIALLY CHANGE IN TERMS OF WHAT STUDIES HAVE TO BE CONDUCTED WITH THE BUDGET AS THEY LAID OUT. IF IT'S SIGNIFICANTLY DIFFERENT, THAT COULD POSE A PROBLEM MOVING FORWARD. IF IT SOLIDIFIES AND VALIDATES WHAT THEY HAVE ALREADY PROPOSED, THEN IT WOULD NOT BE AN ISSUE.

DR. FISHER: YEAH. I WOULD SUGGEST THAT IF THE FDA DOES NOT AGREE THAT THIS IS ON THE RIGHT PATH, THEN THE APPLICANT WOULD HAVE TO COME BACK WITH A NEW APPLICATION BECAUSE THE -- THEY WOULDN'T BE ELIGIBLE FOR THE FUNDING BASED ON THAT CONCLUSION BY THE FDA.

CHAIRMAN IMBASCIANI: THANK YOU, FRED. I HAVE NEXT STEPHEN JUELSGAARD WHO'S GOING TO BE FOLLOWED BE DAN BERNAL AND THEN MARIA BONNEVILLE.

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STEPHEN.

MR. TOCHER: STEVE, YOU'RE MUTED.

MR. JUELSGAARD: SORRY. MUTED AND OFF SCREEN. THERE WE GO.

A QUESTION, THEN A POINT. SO THE QUESTION IS REALLY OF GIL. SO FRED ASKED YOU THE QUESTION ABOUT THE STAFF'S VIEW OF THIS AND THE IMPORTANCE OF HAVING A MEETING WITH THE FDA AHEAD OF TIME TO MAKE SURE THAT YOU'RE ON THE RIGHT TRACK WITH RESPECT TO THE EXPECTED CLINICAL -- PRECLINICAL ENDPOINTS THAT YOU'RE LOOKING AT. SO I TAKE IT BECAUSE YOU HAVEN'T APPROVED -- YOU'RE NOT RECOMMENDING THIS FOR APPROVAL, THAT YOU AGREE WITH ESSENTIALLY THE POINT OF VIEW THAT IT WOULD BE BEST FOR THIS PARTICULAR APPLICANT TO HAVE A MEETING WITH THE IND, A PRE, PRE-IND MEETING IS ESSENTIALLY WHAT IT RELATES TO, BUT AN EARLY MEETING TO MAKE SURE THAT THEY'RE ON THE RIGHT PATH. SO THAT'S A QUESTION. I'M GOING TO LET YOU ANSWER THAT IN JUST A SECOND. SO LET ME JUST MAKE THE POINT.

THE POINT IS IN THE LETTER THAT WAS SUBMITTED THAT WE HAD A CHANCE TO READ, I DIDN'T SEE ANYTHING REALLY ADDRESSING THAT POINT THAT WAS PICKED UP ON BY THE REVIEWERS. THE LETTER, INSTEAD, FOCUSED ON THE FACT THAT WE HAVE APPROVED

APPLICATIONS IN THE PAST THAT HAD LOWER THAN 85 SCORES, WHICH I DON'T FIND PARTICULARLY HELPFUL. IT'S TRUE, BUT I'M NOT SURE WHY THAT SHOULD MATTER HERE. THEY DIDN'T REALLY ADDRESS THE ISSUE OF WHY IT'S NOT IMPORTANT TO HAVE A MEETING WITH THE -- AN EARLY MEETING WITH THE FDA.

SO ANYWAY, BACK TO YOU, GIL. WHAT'S YOUR VIEW OR THE STAFF'S VIEW OF THIS WHAT I'LL CALL A PRE, PRE-IND FDA MEETING?

DR. SAMBRANO: YEAH. THANK YOU. SO OUR RECOMMENDATION FOR ALL OF THESE APPLICATIONS THAT WERE IN HERE DO WAS TO ALIGN WITH THE GRANTS WORKING GROUP RECOMMENDATION. AGAIN, WE BELIEVE THAT THE PROCESS THAT WE HAVE IN PLACE THAT ALLOWS A RESUBMISSION AND A REVISION TO ADDRESS THE CONCERNS IS SOMETHING THAT LEADS TO IMPROVED AND BETTER APPLICATIONS. SO WE ARE GENERALLY COMFORTABLE WITH THAT RECOMMENDATION, AND WE DIDN'T SEE ANYTHING SPECIFIC ABOUT THIS ONE THAT WOULD PROMPT US TO SPECIFICALLY FUND IT NOW.

MR. JUELSGAARD: THANK YOU.

CHAIRMAN IMBASCIANI: THANK YOU, STEPHEN. THAT MEANS DAN IS NEXT.

MR. BERNAL: THANK YOU, MR. CHAIR. QUESTION FOR GIL. AND, GIL, FIRST OF ALL, THANK YOU

SO MUCH FOR ALWAYS BEING SO WELL PREPARED AND ABLE TO ANSWER ALL OF OUR QUESTIONS DURING THESE MEETINGS.

IT SEEMS THAT THIS APPLICATION WAS SCORED JUST BELOW THE THRESHOLD FOR A MINORITY REPORT. THAT BEING SAID, IS THERE ANYTHING THAT STANDS OUT FROM ANY OF THE COMMENTS FROM THE REVIEWERS THAT MIGHT HAVE BEEN RELEVANT OR PARTICULARLY COMPELLING FROM WITHIN THOSE COMMENTS THAT MIGHT HAVE LED TO A MINORITY REPORT THAT WOULD SWAY THIS VOTE?

DR. SAMBRANO: YEAH. I THINK IN GENERAL THIS IS A VERY GOOD APPLICATION. AND I THINK REVIEWERS THINK THIS IS SOMETHING THAT ULTIMATELY CAN GO FORWARD. AND I THINK THERE'S ENTHUSIASM BEHIND TAKING THIS APPROACH AND HAVING THE APPLICANT MOVE FORWARD WITH THIS PATH.

I THINK THE CONCERN WAS, AGAIN, THAT WITHOUT HAVING DIRECTION FROM THE FDA, THEY MAY BE EMBARKING ON STUDIES THAT ARE EITHER INAPPROPRIATE OR MAY BE JUST A WASTE OF TIME. AND THAT THEY MAY ACTUALLY BE ABLE TO DO THIS FOR LESS, PARTICULARLY IF THIS IS CONSIDERED A DEVICE, AND MAY NOT HAVE TO GO THROUGH THE ROUTE AS PROPOSED.

SO I THINK FOR A MINORITY REPORT, IF THIS HAD QUALIFIED, I THINK THE SAME POINTS STAND. AND I

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DON'T SEE ANYTHING IN PARTICULAR BEYOND THAT THAT I THINK WOULD BE HIGHLIGHTED IN THE MINORITY REPORT.

MR. BERNAL: THANKS, GIL.

CHAIRMAN IMBASCIANI: MARIA, YOU HAD YOUR HAND UP. WHERE DID YOU GO?

VICE CHAIR BONNEVILLE: I LOWERED IT. MY QUESTION WAS ANSWERED. THANK YOU.

CHAIRMAN IMBASCIANI: OKAY. ADRIANA.

DR. PADILLA: JUST CLARIFICATION FROM GIL. THE POINT THAT WAS IN THE LETTER AS FAR AS A PREVIOUS AWARDED GRANT, WAS THAT PART OF THE APPLICATION OR WAS THAT AN AFTER FACT ISSUE THAT WASN'T TAKEN INTO CONSIDERATION?

DR. SAMBRANO: I'M SORRY. I DIDN'T UNDERSTAND THE QUESTION.

DR. PADILLA: THERE WAS A POINT IN THE LETTER ON THE REBUTTAL FROM THE GRANT PERSON THAT THEY HAD RECEIVED AN AWARD THAT WAS ON A TIME FRAME IMPORTANCE ISSUE. WAS THAT PART OF THE APPLICATION? WAS THAT A KNOWN ISSUE AT THE TIME OF THE REVIEW?

DR. SAMBRANO: I DON'T BELIEVE IT WAS.

DR. PADILLA: WOULD THAT HAVE MADE A DIFFERENCE?

DR. SAMBRANO: YOU KNOW, GENERALLY THE WAY WE ADVISE THE GRANTS WORKING GROUP IS TO FOCUS ON

THE MERIT OF THE APPLICATION BEFORE THEM. THE TIMING OF OTHER FUNDING AND OTHER OPPORTUNITIES THAT MAY CONTRIBUTE TO THAT EASILY ISN'T A PART OF THE REVIEW. SO I THINK GENERALLY WE WOULD HAVE ADVISED THEM TO FOCUS ON THE MERIT OF THE APPLICATION ON ITS OWN.

DR. PADILLA: THANK YOU.

CHAIRMAN IMBASCIANI: SHLOMO MELMED.

DR. MELMED: THANKS. I'M NOT ADDRESSING THE MERITS OR NOT FOR THIS APPLICATION. JUST A GENERAL COMMENT. WE HAVE AN OUTSTANDING GRANTS REVIEW GROUP. WE HAVE A VERY PROFESSIONAL AND WELL-OILED STAFF SUPPORT OF THE PROCESS. AND I GET VERY NERVOUS WHEN WE START TRYING TO DO OUR OWN PEER REVIEW ON LIMITED INFORMATION. AND I THINK THAT AS A COMMITTEE, OUR ROLE IS NOT TO DO PEER REVIEW, AND SOMETIMES WE CROSS THAT BORDER. AND I WOULD CAUTION ALL OF US, THAT ABSENT A FULL PEER REVIEW PROCESS, IT'S VERY DIFFICULT FOR US TO SECOND-GUESS THE VOTING. AND I PERSONALLY TRUST OUR GRANTS WORKING GROUP AND I TRUST OUR STAFF. AND, AGAIN, I'M NOT EXPRESSING AN OPINION EITHER WAY FOR THIS MOTION. THANK YOU.

CHAIRMAN IMBASCIANI: THANK YOU, SHLOMO. WELL SAID.

HELP ME WITH THIS SCREEN HERE. I DON'T SEE ANY OTHER HANDS FROM BOARD MEMBERS. ALL RIGHT. THE FLOOR IS OPEN FOR ANY MEMBER OF THE PUBLIC TO COMMENT.

MS. MANDAC: DR. CHRISTMAN HAS HER HAND RAISED.

CHAIRMAN IMBASCIANI: YES. DR. CHRISTMAN.

DR. CHRISTMAN: YES. THANK YOU VERY MUCH FOR THE DISCUSSION. JUST WANT TO MAKE TWO QUICK COMMENTS. PER THE LAST REVIEWER'S COMMENT, I WAS KIND OF GIVEN ADVICE BY CIRM STAFF THAT THE BOARD DOES NOT DEAL WITH KIND OF THE SCIENTIFIC REVIEW, TO ACTUALLY NOT MAKE THOSE COMMENTS IN MY LETTER. SO THAT'S WHY THEY WERE ABSENT.

AND I WILL -- AND MY SECOND POINT IS THAT WE KNOW FOR CERTAIN THAT THIS IS A BIOLOGIC. I THINK THERE WERE SOME MEMBERS OF THE REVIEW COMMITTEE THAT THOUGHT IT WAS A DEVICE, AND THAT LED TO MANY OF THOSE COMMENTS ABOUT WHETHER WE ARE ON THE WRONG PATHWAY AND WRONG STUDIES. BUT IF YOU LOOK AT OUR DESIGNATION LETTER FOR OUR PREVIOUS PROJECT, BASICALLY ANY DECELLULARIZED BIOMATERIAL THAT CANNOT GO 5, 10K, THE FDA IS REGULATING ALL AS BIOLOGICS. IF YOU LOOK AT HUMACYTE'S TUBE OF A DECELLULARIZED SCAFFOLD, WHICH IS A PHYSICAL TUBE,

YOU SEE THAT IT'S ALSO REGULATED AS A DEVICE.

SO WE KNOW FOR CERTAIN, ALTHOUGH I WOULD LOVE IT TO BE A DEVICE, THAT SHIP SAILED ABOUT A DECADE AGO. SO WE KNOW FOR CERTAIN IT IS A BIOLOGIC, AND I THINK THERE WAS SOME CONFUSION ON THE WORKING GROUP, THAT THEY THOUGHT IT WAS A DEVICE AND, THEREFORE, THOUGHT WE WERE NOT GOING ON THE RIGHT PATH. BUT WE ARE CERTAIN THAT IT IS A BIOLOGIC. AND OF COURSE (UNINTELLIGIBLE). THANK YOU.

CHAIRMAN IMBASCIANI: OKAY. I THINK -- ARE WE AT THE POINT, SCOTT, WHERE WE CAN TAKE A VOTE ON THIS? I THINK WE ARE.

MR. TOCHER: YEAH. JUST CHECKING TO SEE IF THERE'S ANY OTHER PUBLIC COMMENT.

CHAIRMAN IMBASCIANI: THANK YOU.

MR. TOCHER: IT DOESN'T APPEAR SO. IS THAT CORRECT?

MS. MANDAC: YES. THERE'S NO ADDITIONAL HANDS RAISED.

CHAIRMAN IMBASCIANI: SO IT MIGHT BE HELPFUL IF YOU JUST CLARIFIED AGAIN WHAT A YES OR A NO VOTE MEANS HERE.

MR. TOCHER: YES. THE MOTION IS TO MOVE APPLICATION 15291 UP TIER I. SO A YES VOTE WOULD

MOVE THIS UP TO TIER I AND THEN PRESUMABLY BE FINALLY DISPENSED WITH WHEN ALL THE MOTIONS TO FUND TIER I IS MADE.

DAN BERNAL.

MR. BERNAL: AYE.

MR. TOCHER: MARIA BONNEVILLE.

VICE CHAIR BONNEVILLE: YES.

MR. TOCHER: LEONDRA CLARK-HARVEY.

DR. CLARK-HARVEY: NO.

MR. TOCHER: WAS THAT A NO?

DR. CLARK-HARVEY: THAT WAS A NO.

MR. TOCHER: YSABEL DURON.

MS. DURON: YES.

MR. TOCHER: MARK FISCHER-COLBRIE.

MR. FISCHER-COLBRIE: YES.

MR. TOCHER: FRED FISHER.

DR. FISHER: NO.

MR. TOCHER: ELENA FLOWERS.

DR. FLOWERS: NO.

MR. TOCHER: DAVID HIGGINS.

DR. HIGGINS: YES.

MR. TOCHER: VITO IMBASCIANI.

CHAIRMAN IMBASCIANI: NO.

MR. TOCHER: STEVE JUELSGAARD.

MR. JUELSGAARD: NO.

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MR. TOCHER: RICH LAJARA.
MR. LAJARA: YES.
MR. TOCHER: LAUREN MILLER-ROGEN.
MS. MILLER-ROGEN: YES.
MR. TOCHER: ADRIANA PADILLA.
DR. PADILLA: YES.
MR. TOCHER: JOE PANETTA.
MR. PANETTA: YES.
MR. TOCHER: THE MOTION CARRIES NINE AYE VOTES TO FIVE NO VOTES. SO THAT APPLICATION IS NOW IN TIER I.
CHAIRMAN IMBASCIANI: OH, GREAT. THANK YOU VERY MUCH, MEMBERS OF THE BOARD. I THINK WE ARE NOW READY TO HEAR A MOTION ON 15225, IF I HAVE THAT ONE RIGHT, PURIFICATION OF HUMAN HEMATOPOIETIC STEM CELLS. THE MOTION WOULD BE TO EXTRACT THIS FROM TIER II AND MOVE IT TO TIER I. OKAY. I DO NOT HEAR A MOTION. AM I MISSING ANYTHING? THE SCREEN GOES ON FOR MANY --
MR. TOCHER: I DON'T SEE ANY HANDS RAISED.
CHAIRMAN IMBASCIANI: OKAY.
DR. FISCHER-COLBRIE: SORRY. I WAS HAVING TROUBLE RAISING MY HAND. JUST A QUICK QUESTION FOR GIL WITH RESPECT TO THE COMMENT THAT WAS MADE EARLIER BY DR. WEISSMAN.

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CHAIRMAN IMBASCIANI: I CAN'T SEE WHO'S SPEAKING. I'M SORRY.

DR. FISCHER-COLBRIE: MARK FISCHER-COLBRIE.

CHAIRMAN THOMAS: THANK YOU.

DR. SAMBRANO: YES, MARK. WHAT IS YOUR QUESTION?

DR. FISCHER-COLBRIE: I THINK HIS COMMENT WAS, IF I'M NOT MISTAKEN, THAT THERE WAS A FUNDAMENTAL MISCONCEPTION WITH RESPECT TO THE MODELING SELECTION AND WAS THE PRIMARY BASIS FOR THE OBJECTION. AND JUST WANTED TO FOLLOW UP ON THAT COMMENT.

DR. SAMBRANO: SURE. SO BASED ON WHAT WE HEARD FROM REVIEWERS AND ON THE REVIEWER COMMENTS, I CERTAINLY UNDERSTAND THAT INTERPRETATION, BUT I DON'T AGREE THAT THE REVIEWERS VIEWED THIS AS A CD34 ONLY FOCUS OR THAT CD34 SHOULD BE THE ONLY OR APPROPRIATE WAY OF PURIFYING OR SELECTING HEMATOPOIETIC STEM CELLS; BUT, RATHER, THAT THERE ARE NOW MANY DIFFERENT APPROACHES FOR ISOLATING HEMATOPOIETIC STEM CELLS AND HEMATOPOIETIC STEM CELL CD34 POSITIVE CELL POPULATIONS, MANY THAT REMOVE T-CELLS, SOME THAT ADD BACK REGULATORY T-CELLS, AND THERE ARE OTHER ANTIBODIES THAT ALSO CAN BE UTILIZED

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FOR THE SAME PURPOSE.

SO I DO THINK THAT THE REVIEWERS UNDERSTOOD WHAT THE DIFFERENCE BETWEEN THE CD34 POSITIVE CELLS AND THEN THE SPECIFIC CD34 POSITIVE 90 -- CD90 POSITIVE CELLS ARE. I THINK THEY WERE LOOKING FOR MORE EXPLANATION FROM THE APPLICANT ON WHY SPECIFICALLY REDEVELOPING THESE ANTIBODIES AND HOW THEY IN THE CURRENT SETTING OF WHAT EXISTS TODAY WOULD BE A BENEFIT AND ADDRESS AN UNMET MEDICAL NEED. SO I THINK THAT'S WHERE REVIEWERS WERE COMING FROM ON THAT POINT.

DR. FISCHER-COLBRIE: TERRIFIC. THANK YOU FOR THE CLARIFICATION. THANK YOU.

CHAIRMAN IMBASCIANI: HEARING NO MOTION FROM THE FLOOR, I THINK WE ARE NOW TO THE POINT WHERE WE ARE GOING TO ENTERTAIN A MOTION TO NOT FUND --

DR. FISHER: I MADE THE MOTION.

MR. TOCHER: THERE'S ALREADY A MOTION ON THE TABLE THAT'S BEEN MADE AND SECONDED.

CHAIRMAN IMBASCIANI: THANK YOU, SCOTT. YES. THANK YOU. SO WE CAN PROCEED, IF THERE'S NO FURTHER DISCUSSION ON TIER II, WE ARE ABOUT TO VOTE ON NOT VOTING AT THIS PRESENT TIME ALL THE APPLICATIONS REMAINING IN TIER II.

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MR. TOCHER: THAT'S RIGHT. AND FOR MEMBERS BONNEVILLE, BURRON, AND JUELSGAARD, IF YOU WOULD GIVE YOUR VOTE AND THEN STATE EXCEPT WITH REGARD TO THOSE APPLICATIONS WITH WHICH YOU HAVE CONFLICT.

CHAIRMAN IMBASCIANI: THAT'S GREAT. GO AHEAD, SCOTT. YOU CAN PROCEED TO THE VOTE.

DAN BERNAL.

MR. BERNAL: AYE.

MR. TOCHER: MARIA BONNEVILLE.

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

MR. TOCHER: LEONDRA CLARK-HARVEY.

DR. CLARK-HARVEY: AYE.

MR. TOCHER: YSABEL DURON.

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

MR. TOCHER: MARK FISCHER-COLBRIE.

MR. FISCHER-COLBRIE: AYE.

MR. TOCHER: FRED FISHER.

DR. FISHER: AYE.

MR. TOCHER: ELENA FLOWERS.

DR. FLOWERS: YES.

MR. TOCHER: DAVID HIGGINS.

DR. HIGGINS: YES.

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MR. TOCHER: VITO IMBASCIANI.
CHAIRMAN IMBASCIANI: YES.
MR. TOCHER: STEVE JUELSGAARD.
MR. JUELSGAARD: YES.
MR. TOCHER: EXCEPT FOR THOSE WITH WHICH YOU HAVE A CONFLICT?
MR. JUELSGAARD: EXCEPT FOR THOSE WITH WHICH I HAVE A CONFLICT.
MR. TOCHER: THANK YOU. RICH LAJARA.
MR. LAJARA: YES.
MR. TOCHER: LAUREN MILLER-ROGEN.
MS. MILLER-ROGEN: YES.
MR. TOCHER: ADRIANA PADILLA.
DR. PADILLA: YES.
MR. TOCHER: JOE PANETTA.
MR. PANETTA: YES.
MR. TOCHER: THANK YOU VERY MUCH. AND THAT MOTION CARRIES.
CHAIRMAN IMBASCIANI: GREAT. THANK YOU. NOW WE CAN DIRECT OUR ATTENTION AS A BOARD TO TIER I. BUT, OF COURSE, IT'S NEVER THAT EASY. SO WE'RE GOING TO START WITH IS THERE ANY APPLICATION IN ALL OF TIER I, INCLUDING -- THAT BOARD MEMBERS WOULD LIKE TO REMOVE, AND THAT WOULD MEAN NOT TO FUND? SO THERE ARE TEN, NOW PLUS TWO, 12, ENTRANTS INTO TIER

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I. ANY MOTIONS ON ABSTRACTING ANY OF THESE TO REMOVE THEM FROM FUNDING?

NOT HEARING ANY MOTION, WE CAN PROCEED TO ENTERTAIN A MOTION TO ACCEPT FOR FUNDING ALL APPLICATIONS IN TIER I.

MR. BERNAL: SO MOVED.

CHAIRMAN IMBASCIANI: DAN BERNAL MOVED. I NEED A SECOND.

MR. TOCHER: JUST A SECOND. FOR THOSE -- UNFORTUNATELY, DAN, --

MR. BERNAL: OH, THAT'S RIGHT. THANK YOU.

DR. CLARK-HARVEY: SO MOVED. SO MOVED.

DR. FISHER: SECOND.

CHAIRMAN IMBASCIANI: WE HAVE A MOVEMENT AND A SECOND. SO THE FLOOR IS NOW OPEN TO DISCUSSION ON THESE APPLICATIONS.

MS. DURON: YSABEL HERE. COULD I GET AN EXPLANATION ON 15298 WHY THE DEI SCORE IS SO LOW?

CHAIRMAN IMBASCIANI: THANK YOU, YSABEL. ONE FIVE -- SAY THE NUMBER AGAIN. 298.

MS. DURON: I BELIEVE THERE ARE TWO THAT ARE ACTUALLY SIXES THAT I SEE ON THIS. SO 15253 AND 15298.

CHAIRMAN IMBASCIANI: SO I'M GOING TO DIRECT THIS QUESTION TO GIL, MAYBE STARTING WITH

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298.

DR. SAMBRANO: YEAH, THANK YOU. SO I THINK BOTH OF THEM, IT'S A VERY GOOD OBSERVATION, YSABEL. THEY BOTH HAPPEN TO ALSO BE TOOL APPLICATIONS. THEY'RE THE TRAN4.

SO THE FIRST ONE, THE ONE THAT YOU ASKED ABOUT, IS TO DEVELOP AND IPSC MEDIUM. SO THIS IS A CULTURE MEDIUM THAT IS USED FOR IPSC STEM CELLS AND TO MAINTAIN THEM AND TO DEVELOP THIS FOR GMP MANUFACTURING.

SO I THINK PART OF THE CHALLENGE THAT BOTH APPLICATIONS HAVE IS IN MAKING A CLEAR CASE OF HOW THIS MEDIUM IS GOING TO INCORPORATE PRINCIPLES OF DIVERSITY, EQUITY, AND INCLUSION. AND I THINK FOR SOME OF THESE IT'S DIFFICULT BECAUSE THEY DON'T HAVE 1, SAY, SPECIFIC DISEASE WHERE THEY CAN SPEAK TO THE DISEASE BURDEN OR THE SPECIFIC POPULATION OF INDIVIDUALS THAT WOULD BENEFIT FROM, SAY, A THERAPY GIVEN THAT THIS IS A TOOL. I THINK, IN GENERAL, REVIEWERS THOUGHT THAT THIS WAS SOMETHING THAT WAS BROADLY APPLICABLE AND THAT THERE WAS NO SPECIFIC CONCERN ABOUT A MEDIUM NOT BEING APPLICABLE TO CERTAIN OR SPECIFIC POPULATIONS.

I THINK IN BOTH CASES THIS OTHER SECOND ONE IS ABOUT IPSC CELLS THEMSELVES AND CREATING A

UNIVERSAL DONOR CELL LINE. I THINK THERE MORE SO A DISCUSSION ABOUT HOW EITHER THE MEDIUM OR IN THIS CASE THE UNIVERSALITY OF THE IPSC CELLS THAT ARE GENERATED WOULD IMPACT ON DIFFERENT PATIENT POPULATIONS WOULD HAVE BEEN APPRECIATED. I THINK THERE WAS A LACK OF DISCUSSION, BUT I DON'T THINK THERE WAS ANY CONCERN FROM THE WORKING GROUP RELATED TO THIS.

GENERALLY A SCORE OF SIX, OUR PATIENT ADVOCATE AND NURSE MEMBERS HERE ON THE BOARD CAN SPEAK TO THIS, IS A PASSING GRADE, IF YOU WILL. THE SIX IS SORT OF LOW ON THE SCORES THAT THEY STILL BELIEVE IS ADEQUATE TO MOVE FORWARD; BUT IF THERE ARE MAYBE SPECIFIC COMMENTS OR OTHER CONCERNS THAT THE PATIENT ADVOCATE MEMBERS WHO GAVE THESE SCORES WOULD LIKE TO SPEAK TO, CERTAINLY WOULD INVITE THEIR VIEWS.

CHAIRMAN IMBASCIANI: THANK YOU, GIL. FRED FISHER.

DR. FISHER: I NEVER CEASE TO BE AMAZED BY GIL'S ABILITY TO RECOUNT THE DETAILS OF ALL OF THESE GRANTS AND HAVE IT AT YOUR FINGERTIPS AND ARTICULATE IT SO WELL. SO THANK YOU FOR THAT, GIL.

AND I HAD RAISED MY HAND TO BASICALLY STATE WHAT YOU STATED. A SIX IS ESSENTIALLY THE

EQUIVALENT OF AN 85, THE BOTTOM SCORE THAT THE GRANT WORKING GROUP WOULD CONSIDER IN TERMS OF A FUNDABLE APPLICATION. SO I JUST WANTED TO CLARIFY THAT FOR BOARD MEMBERS WHO DON'T PARTICIPATE ON THE GWG.

CHAIRMAN IMBASCIANI: THANK YOU, FRED. THANKS FOR YOUR COMMENT. I THINK THE ONLY THING THESE GRAPHS LACK IS A COLUMN THAT SCORES GIL'S ABILITY TO RECALL.

MS. DURON: VITO, CAN I SAY, FIRST OF ALL, THANK YOU, GIL. I APPRECIATE THAT. SECOND OF ALL, I OBVIOUSLY HAVE TO GO BACK TO SCHOOL FOR A VERY LONG TIME TO REALLY UNDERSTAND THIS STUFF. BUT I'M ALWAYS CONCERNED BECAUSE MAYBE SIX LOOKS GOOD ON AN AVERAGE, BUT I ALWAYS WORRY THAT, UNLESS THERE'S REAL INTENTION AT WHATEVER STAGE WE ARE AT TO MEASURE ITS IMPACT OR LACK OF IMPACT OR ACCESS, THAT WE LET IT GO. EVEN THE QUESTION ABOUT WHETHER OR NOT, BECAUSE A VERY SMART GROUP OF SCIENTISTS SAY IT'S A GOOD THING OR A BAD THING NOT TO HAVE, THAT PEOPLE IN GENERAL, PATIENT ADVOCATES, CONSUMERS ON THE STREET ALSO HAVE A VERY GOOD OPINION. AND SOMETIMES IT MIGHT COUNTER WHAT THE SCIENTISTS THINK OR SAY.

AND BECAUSE WE HAVE SEEN DISPARITIES FOR SO LONG OVER A LONG PERIOD OF TIME AND WE ARE STILL

VERY FAR FROM REACHING SOME KIND OF EQUITY AND WE HAVE TO KEEP BRINGING THIS UP OVER AND OVER AND OVER AGAIN, I JUST DARE TO QUESTION SOMETHING AT A SIX BECAUSE I SAY, YOU KNOW, DO YOU HAVE A LATINO MOUSE? OR DO YOU HAVE A LATINO SPIT? OR IS THAT CELL LINE REALLY REPRESENTATIVE OF ALL OF US? AND SO I JUST WANT TO QUESTION IT, AND I WANT THE BOARD MEMBERS ALWAYS TO CONSIDER THAT WE HAVE YET TO REALLY, REALLY, REALLY, REALLY ADDRESS DISPARITIES WHEN IT COMES TO UNDERRESEARCHED, UNDERREPRESENTED GROUPS, RACIAL, ETHNIC, AND VULNERABLE POPULATIONS. SO WE SHOULD NEVER TAKE FOR GRANTED AVERAGE. AVERAGE IS NOT GOOD ENOUGH AS FAR AS I'M CONCERNED WHEN IT COMES TO ADDRESSING DISPARITIES. SO WE NEED TO BE VERY CLUED IN AND VERY ON TOP OF THIS ISSUE. THANK YOU, VITO.

CHAIRMAN IMBASCIANI: THANK YOU, YSABEL, VERY MUCH FOR THOSE COMMENTS.

FRED, BACK TO YOU AND THEN MR. STEVE REES.

DR. FISHER: FIRST, I'D LIKE TO ASK THE STAFF TO FORWARD TO YSABEL THE DEI RUBRIC SO SHE CAN SEE THE DIFFERENCE BETWEEN A SCORE OF SIX -- I THINK IT'S SIX, SEVEN, AND EIGHT VERSUS EIGHT, NINE, AND TEN, HOWEVER IT'S LAID OUT. AND, YSABEL, ANY INSIGHTS OR FEEDBACK THAT YOU HAVE, THE RUBRICS ARE

A WORK IN PROGRESS. SO IF YOU THINK THAT THERE'S SOMETHING MISSING OR THERE'S SOMETHING YOU'D LIKE TO SHARE, WE ARE OPEN TO HEARING IT.

THE SECOND POINT IS THAT THE APPLICATION PROCESS IS TRAINING APPLICANTS TO BE MORE SENSITIVE TO THE ISSUES THAT YOU'RE DISCUSSING. IF I LOOK AT THE APPLICATIONS I LOOKED AT A YEAR AGO AND THEIR RESPONSES TO THE DEI SECTIONS VERSUS THE RESPONSES NOW, THEY ARE MARKEDLY IMPROVED.

AND THE FINAL POINT IS THAT WHILE YOUR COMMENTS ARE ALWAYS IMPORTANT, HAVE CONFIDENCE IN THOSE OF US THAT ARE ON THE GWG TO BE TAKING SERIOUSLY THE DEI COMPONENT. AND WHAT WE ARE ACTUALLY STARTING TO HEAR MORE OF NOW, USED TO BE JUST THE BOARD MEMBERS, GWG WOULD COMMENT ON DEI, AND NOW WE ARE HAVING THE SCIENTISTS ACTUALLY COMMENTING THOROUGHLY ON THE DEI SECTIONS. SO THIS IS AN ACCULTURATION PROCESS, IF THAT'S THE RIGHT WORD -- NO PUN INTENDED -- ON THE PART OF THE SCIENTIFIC COMMUNITY AND CERTAINLY A WORK IN PROGRESS ON THE GWG IN TERMS OF GETTING RIGHT HOW WE SCORE THESE PROPOSALS.

MS. DURON: MAY I RESPOND?

CHAIRMAN IMBASCIANI: PLEASE, YSABEL.

MS. DURON: THANK YOU VERY MUCH FOR THAT,

FRED. I REALLY DO APPRECIATE IT. YOU SHOULD KNOW THAT I HAVE BEEN TOUTING THAT RUBRIC ALL OVER TOWN, IF YOU WILL, INCLUDING SHARING IT WITH THE NATIONAL ADVISORY -- THE CANCER ADVISORY BOARD AND THE NCI AS A MODEL FOR MEASURING AND ACCOUNTABILITY FOR THE RESEARCH GRANTS THAT THEY'RE GIVING OUT, WHICH NUMBER IN THE BILLIONS. SO, YES, I REALLY APPRECIATE THE RUBRIC AND GLAD THAT WE ARE STILL WORKING ON IT, DEVELOPING IT, AND, AS YOU SAID, WE ARE ALL BECOMING VERY SENSITIZED TO IT. I JUST REALLY APPRECIATE WHAT CIRM HAS DONE AND THANK YOU EVERY DAY FOR SUPPORTING THE WHOLE IDEA OF DEI. THAT'S WHERE IT STARTED. SO THANK YOU.

CHAIRMAN IMBASCIANI: THANK YOU. I WANT TO SAY TO MR. REES. I'M SORRY I CALLED ON YOU NEXT, BUT YOU HAVE TO WAIT. BY OUR RULES I NEED TO CALL ON BOARD MEMBERS FIRST. SO HOLD ON. DON'T GO AWAY. MARIA BONNEVILLE.

VICE CHAIR BONNEVILLE: I WAS JUST GOING TO MENTION TO YSABEL AND TO THE REST OF THE BOARD MEMBERS. WE HAD ASKED A DEI CONSULTANT TO COME ON BOARD AND TAKE A LOOK AT THE RUBRIC, THE GWG PROCESS, THINGS LIKE THAT. THEY'VE ISSUED -- THEY WILL BE PRESENTING TO THE BOARD IN DECEMBER SORT OF THEIR FEEDBACK ON THE PROCESS AND THE USE OF THE

RUBRIC AND ANY RECOMMENDATIONS THAT THEY MIGHT HAVE. SO JUST AS A HEADS UP, THAT'S COMING TO THE BOARD IN DECEMBER. SO YOU WILL HEAR MORE ABOUT IT THERE, YSABEL, AND THEN THE BOARD MEMBERS ON SORT OF HOW WE ARE DOING AND ANY RECOMMENDATIONS THEY MAY HAVE.

CHAIRMAN IMBASCIANI: THANK YOU, MARIA. ANY OTHER BOARD MEMBERS HAVE THEIR HANDS RAISED? I DON'T SEE ANY. NOW WE ARE GOING TO TURN TO MEMBERS OF THE PUBLIC. I'M SORRY IF IT'S MR. OR PROFESSOR REES. I DON'T HAVE YOUR TITLE HERE. THE FLOOR IS YOURS.

DR. REES: SURE. THANK YOU. SO THIS IS STEVE REES. I'M THE CEO OF DEFINED BIOSCIENCE, AND WE'RE THE ONES THAT ASSEMBLED APPLICATION 15298 THAT WE ARE DISCUSSING NOW.

I SHOULD TELL YOU DURING OUR REVIEW PROCESS AND IN REWRITING THIS APPLICATION, DEI WAS AT THE FOREFRONT OF OUR MINDS WHEN IT CAME TO FIGURING OUT HOW DO WE BEST ADDRESS THIS FOR A TECHNOLOGY THAT SHOULD BE BROADLY APPLICABLE ACROSS DISEASE STATES AND NEEDS FOR STEM CELL CULTURE. AND THE POINTS THAT THE BOARD HAS ALREADY RAISED IN REGARDS TO CELL LINE AVAILABILITY AND HOW REPRESENTATIVE, GIVEN THE FEW NUMBER OF CELL LINES THAT WE HAVE FOR THESE UNDERREPRESENTED GROUPS, IT'S

VERY HARD TO KNOW BECAUSE THERE'S VERY FEW CELL LINES AVAILABLE.

SO IN OUR RESEARCH WE FOUND THAT EVEN AS OF JUST A FEW YEARS AGO, IT WAS ABOUT A THIRD AS LIKELY TO FIND A CELL LINE OF AFRICAN DESCENT OR HALF AS LIKELY FOR ASIAN OR PACIFIC ISLANDER DESCENT, AND EVEN ONLY 5 PERCENT OF HUMANS STEM CELL LINES AVAILABLE FOR PRECLINICAL WORK WAS OF AFRICAN DESCENT AS WELL. AND WE KEPT SEEING THESE NUMBERS AND LOOKING FOR CELL LINES AND REALIZED THAT THERE'S JUST A VERY FEW NUMBER AVAILABLE FOR US TO EVEN KNOW IF WHAT WE HAVE IS REPRESENTATIVE.

SO FOR US IT WAS A BALANCE BETWEEN -- WITH A STUDY LIKE THIS, HAVING A LIMITED NUMBER OF CELL LINES WE CAN CONCEIVABLY TEST GIVEN THAT THIS STUDY FOCUSES ON IN-DEPTH STUDIES OF A MEDIA, YOU CAN ONLY COVER SO MANY LINES. AND WE WANTED TO BE CAREFUL TO CHOOSE LINES THAT WERE AS REPRESENTATIVE OF A LARGER COMMUNITY AS WE COULD MAKE THEM WHILE NOT SACRIFICING WHAT WE COULD LEARN FROM THE RESULTS OF THOSE STUDIES.

SO TO US WE KEPT THINKING THIS NEEDS TO BE ANOTHER PROPOSAL AND EFFORT FROM CIRM TO EXPAND THE NUMBER OF THESE CELL LINES THAT ARE AVAILABLE. IT'S CERTAINLY SOMETHING THE TEAM IS INTERESTED IN, AND

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WE JUST TRIED TO BALANCE THAT. AND THAT SEEMED TO BE RECEIVED WELL BY THE REVIEWERS, THAT THERE WAS JUST REALITIES OF LIMITATION THAT WE COULD FOCUS ON HERE. BUT IT'S AT THE FOREFRONT OF OUR MINDS, AND I'M SURE MANY RESEARCHERS. THANKS FOR THE CHANCE TO SPEAK HERE.

CHAIRMAN IMBASCIANI: THANK YOU, MR. REES, FOR YOUR COMMENTS AND YOUR SUGGESTION. SCOTT.

MR. TOCHER: JUST CHECKING TO SEE IF THERE'S ANY MORE.

CHAIRMAN IMBASCIANI: THANK YOU.

MR. TOCHER: THERE DOESN'T APPEAR TO BE.

CHAIRMAN IMBASCIANI: ALL RIGHT. THEN I CAN WE CAN PROCEED TO A VOTE ON ACCEPTING FOR FUNDING ALL THE APPLICATIONS IN TIER I.

MR. TOCHER: AND MEMBERS BERNAL, BONNEVILLE, FLOWERS, JUELSGAARD, AND PANETTA, THE SAME ADMONITION WHEN YOU GIVE YOUR VOTE.

DAN BERNAL.

MR. BERNAL: YES, EXCEPT FOR THOSE WITH WHICH I HAVE A CONFLICT.

MR. TOCHER: MARIA BONNEVILLE.

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

MR. TOCHER: LEONDRA CLARK-HARVEY.

DR. CLARK-HARVEY: YES.
MR. TOCHER: YSABEL DURON.
MS. DURON: YES, EXCEPT. YOU DIDN'T MENTION MY NAME AGAIN. EXCEPT FOR THOSE WITH WHICH I HAVE A CONFLICT.
MR. TOCHER: THAT'S ALWAYS SAFE.
MARK FISCHER-COLBRIE.
MR. FISCHER-COLBRIE: YES.
MR. TOCHER: FRED FISHER.
DR. FISHER: YES.
MR. TOCHER: ELENA FLOWERS.
DR. FLOWERS: YES, EXCEPT FOR THOSE WITH WHICH I HAVE A CONFLICT.
MR. TOCHER: DAVID HIGGINS.
DR. HIGGINS: YES.
MR. TOCHER: VITO IMBASCIANI.
CHAIRMAN IMBASCIANI: YES.
MR. TOCHER: STEVE JUELSGAARD.
MR. JUELSGAARD: YES, EXCEPT FOR THOSE WITH WHICH I HAVE A CONFLICT.
MR. TOCHER: RICH LAJARA.
MR. LAJARA: YES.
MR. TOCHER: LAUREN MILLER-ROGEN.
MS. MILLER-ROGEN: YES.
MR. TOCHER: ADRIANA PADILLA.

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DR. PADILLA: YES.

MR. TOCHER: JOE PANETTA.

MR. PANETTA: YES, EXCEPT FOR THOSE WITH WHICH I HAVE A CONFLICT.

MR. TOCHER: THANK YOU, JOE. AND THAT DOES IT. THE MOTION CARRIES.

CHAIRMAN IMBASCIANI: OKAY. THANK YOU, SCOTT. I DON'T HAVE THE AGENDA IN FRONT OF ME. IT'S ON A DIFFERENT SCREEN. WHAT IS NEXT?

MR. TOCHER: IF THERE ARE ANY PUBLIC COMMENT ABOUT ANY MATTERS NOT AGENDIZED.

CHAIRMAN IMBASCIANI: OKAY. WE ARE AT THAT FINAL POINT OF THE MEETING. IS THERE ANY MEMBER OF THE PUBLIC OUT THERE THAT WOULD LIKE TO MAKE SOME COMMENT ON A SUBJECT THAT WE HAVE NOT BROUGHT UP YET THIS MORNING?

MR. TOCHER: NOT SEEING ANY HANDS.

CHAIRMAN IMBASCIANI: IF NOT, ALL GOOD THINGS COME TO AN END. I THINK ANY FINAL COMMENTS FROM BOARD MEMBERS? IF NOT, I DON'T THINK WE NEED MOTIONS TO ADJOURN, CORRECT?

MR. TOCHER: THAT'S CORRECT.

CHAIRMAN IMBASCIANI: OKAY. BOARD MEMBERS, THANK YOU SO MUCH FOR YOUR PARTICIPATION THIS MORNING. I REALLY APPRECIATE IT. WE DID GOOD

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WORK. THANK YOU VERY MUCH.

VICE CHAIR BONNEVILLE: THANK YOU, EVERYONE.

(THE MEETING WAS THEN CONCLUDED AT 10:43 A.M.)

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REPORTER'S CERTIFICATE

I, BETH C. DRAIN, A CERTIFIED SHORTHAND REPORTER IN AND FOR THE STATE OF CALIFORNIA, HEREBY CERTIFY THAT THE FOREGOING TRANSCRIPT OF THE VIRTUAL PROCEEDINGS BEFORE THE 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 OCTOBER 26, 2023, WAS HELD AS HEREIN APPEARS AND THAT THIS IS THE ORIGINAL TRANSCRIPT THEREOF AND THAT THE STATEMENTS THAT APPEAR IN THIS TRANSCRIPT WERE REPORTED STENOGRAPHICALLY BY ME AND TRANSCRIBED BY ME. I ALSO CERTIFY THAT THIS TRANSCRIPT IS A TRUE AND ACCURATE RECORD OF THE PROCEEDING.

BETH C. DRAIN, CA CSR 7152
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