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

REGULAR MEETING

LOCATION: VIA ZOOM

DATE: JUNE 23, 2022
9 A.M.

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

FILE NO.: 2022-25

I N D E X





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

JUNE 23, 2022; 9 A.M.

CHAIRMAN THOMAS: THANK YOU, MARIA. WELCOME, EVERYBODY, TO TODAY'S MEETING OF THE ICOC AND THE APPLICATION REVIEW SUBCOMMITTEE. MARIA, WILL YOU PLEASE CALL THE ROLL.

MS. BONNEVILLE: DAN BERNAL. LEONDRA CLARK-HARVEY.

MS. CLARK-HARVEY: HERE.

MS. BONNEVILLE: ANNE-MARIE DULIEGE.

DR. DULIEGE: YES.

MS. BONNEVILLE: YSABEL DURON.

MS. DURON: HERE.

MS. BONNEVILLE: MARK FISCHER-COLBRIE.

DR. FISCHER-COLBRIE: HERE.

MS. BONNEVILLE: FRED FISHER.

DR. FISHER: GOOD MORNING.

MS. BONNEVILLE: ELENA FLOWERS. DAVID HIGGINS.

DR. HIGGINS: HERE.

MS. BONNEVILLE: STEVE JUELSGAARD.

MR. JUELSGAARD: PRESENT.

MS. BONNEVILLE: RICH LAJARA.

MR. LAJARA: HERE.

MS. BONNEVILLE: CHRISTINE MIASKOWSKI.



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

LAUREN MILLER-ROGEN.

MS. MILLER-ROGEN: HERE.

MS. BONNEVILLE: ADRIANA PADILLA.

DR. PADILLA: HERE.

MS. BONNEVILLE: JOE PANETTA. AL ROWLETT.

MR. ROWLETT: PRESENT.

MS. BONNEVILLE: MARVIN SOUTHARD.

DR. SOUTHARD: HERE.

MS. BONNEVILLE: JONATHAN THOMAS.

CHAIRMAN THOMAS: HERE.

MS. BONNEVILLE: ART TORRES.

MR. TORRES: PRESENT.

MS. BONNEVILLE: KAROL WATSON.

WE HAVE QUORUM. AND I WANT TO NOTE --

MS. CLARK-HARVEY: THIS IS LEONDRA. I THINK YOU MISSED MY PRESENT. YOU MOVED REALLY FAST. SORRY. I'M HERE.

MS. BONNEVILLE: THANK YOU. AND I NOTED YOU AS PRESENT. THANK YOU SO MUCH.

LARRY -- I WANT TO NOTE OTHER BOARD MEMBERS WHO HAVE JOINED. LARRY GOLDSTEIN. THANK YOU. AND, J.T.

CHAIRMAN THOMAS: THANK YOU, MARIA.

WE WILL NOW MOVE INTO THE MEETING OF THE APPLICATION REVIEW SUBCOMMITTEE. WE HAVE ONE ACTION



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

ITEM WITH MULTIPLE PARTS TODAY. CONSIDERATION OF APPLICATIONS SUBMITTED IN RESPONSE TO DISCOVERY STAGE RESEARCH PROJECT'S PROGRAM ANNOUNCEMENTS OR THE SO-CALLED DISC2. BEGIN WITH A PRESENTATION FROM DR. SAMBRANO. GIL.

DR. SAMBRANO: THANK YOU, MR. CHAIRMAN. SO HOPEFULLY YOU CAN SEE THE PRESENTATION.

GOOD MORNING, EVERYONE. I'M GOING TO PRESENT TO YOU THE RECOMMENDATIONS FROM THE GRANTS WORKING GROUP RELATED TO OUR LATEST CYCLE OF THE DISC2 PROGRAM. AND BEFORE WE START, AS ALWAYS, WE WANT TO REMIND EVERYONE, INCLUDING OURSELVES, ABOUT OUR MISSION AND OUR GOAL AND WHY WE DO ALL OF THIS, WHICH IS TO ACCELERATE WORLD CLASS SCIENCE TO DELIVER TRANSFORMATIVE REGENERATIVE MEDICINE TREATMENTS IN AN EQUITABLE MANNER TO A DIVERSE CALIFORNIA AND WORLD.

AND SO THE DISC2 PROGRAM IS PART OF OUR RECURRING OPPORTUNITIES THAT WE OFFER THROUGHOUT THE YEAR. SO THIS PARTICULAR ONE HAPPENS TWICE A YEAR, AND IT IS AT THE EARLY STAGES OF BRINGING NEW IDEAS TO DEVELOP A SINGLE PRODUCT CANDIDATE. THE SPECIFIC OBJECTIVE OF THE PROGRAM IS TO PROMOTE THE DISCOVERY OF PROMISING NEW STEM CELL-BASED AND GENE THERAPY TECHNOLOGIES THAT COULD BE TRANSLATED TO ENABLE



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

BROAD USE AND ULTIMATELY IMPROVE PATIENT CARE. AND SO WE ARE LOOKING HERE FOR PROJECTS THAT WILL UNIQUELY ENABLE HUMAN STEM CELL/PROGENITOR CELL IN SOME WAY OR ARE UNIQUELY ENABLING FOR THE ADVANCEMENT OF STEM CELL-BASED THERAPIES OR FOR DEVELOPING A GENE THERAPY APPROACH.

AND THE TYPES OF PRODUCTS THAT CAN COME INTO THIS TYPE OF COMPETITION INCLUDES THERAPEUTICS -- THAT'S WHAT WE SEE MOST OF -- BUT ALSO DIAGNOSTIC DEVICES AND TOOLS. IN BOTH CASES WHAT WE'RE LOOKING FOR GENERALLY ALIGN WITH LOOKING FOR DEVELOPING A SINGLE CANDIDATE OR SINGLE PROTOTYPE THAT IS IDENTIFIED BY THE END OF THE AWARD, DEVELOPMENT OF A TARGET PRODUCT PROFILE WHICH IS SORT OF AN IDEALIZED SUMMARY OF WHAT THEY HOPE TO ACHIEVE WITH THEIR PRODUCT IF IT'S SUCCESSFUL, AND THEN A PROOF OF CONCEPT OF SOME TYPE.

SO FOR A THERAPEUTIC, SHOWING THAT DISEASE MODIFYING ACTIVITY OCCURS WITH THE THERAPEUTIC. THAT MEANS IT HAS AN EFFECT ON THE INTENDED DISEASE. OR FOR A TOOL, FOR EXAMPLE, SOME KIND OF PROOF OF CONCEPT THAT THE TOOL WORKS AS INTENDED.

AND SO THIS DISC2 CANDIDATE DISCOVERY PROGRAM FITS IN WITHIN OUR PIPELINE. AND JUST HERE SIMPLY TO SHOW YOU THE APPROXIMATE TIME. SO 24

MONTHS IS WHAT WE CURRENTLY ALLOW FOR THE DISC2 PROGRAM. THAT IS GOING TO CHANGE TO THREE YEARS IN THE NEXT ROUND. FOR THE TRANSLATIONAL PROGRAMS THAT ACHIEVE A SINGLE CANDIDATE AND QUALIFY FOR TRAN, THAT'S ANOTHER 24 TO 30 MONTHS TO GET THEM TO A PRE-IND MEETING, AND THEN SUBSEQUENT TO THAT, IF THEY ARE SUCCESSFUL THERE, THEY CAN QUALIFY FOR POTENTIALLY A CLIN1 AWARD TO DO IND-ENABLING WORK. AND THAT'S ANOTHER 24 MONTHS. SO HERE SIMPLY TO SAY THAT AT THIS STAGE APPLICANTS ARE STILL GOING TO BE AT LEAST SIX YEARS AWAY FROM GETTING TO THE CLINIC FOR THESE PROGRAMS. SO STILL PRETTY EARLY PHASE.

SO AS PERTAINS TO THE REVIEW ITSELF, WE CONDUCT THE REVIEW OF THESE APPLICATIONS IN A TWO-STAGE PROCESS, WHICH WE OFTEN REFER TO AS POSITIVE SELECTION. SO IF YOU HEAR THAT TERM, IT'S RELATED TO THE FIRST STAGE OF THE REVIEW.

AND SO THIS HAPPENS WHEN WE HAVE A TOTAL NUMBER OF APPLICATIONS THAT COME IN THAT EXCEEDS THE CAPACITY OF THE GRANTS WORKING GROUP TO REVIEW IN A SINGLE SESSION. SO THAT'S PRETTY COMMON FOR MOST OF THE DISCOVERY COMPETITIONS THAT WE HAVE. SO IN THIS FIRST STAGE, THE GRANTS WORKING GROUP MEMBERS, INCLUDING THE PATIENT ADVOCATE AND NURSE BOARD MEMBERS, AS A PANEL CONDUCT A PREREVIEW OF



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

APPLICATIONS AND SELECT WHICH ONES TO ADVANCE TO A FULL REVIEW. OF THOSE THAT ARE NOT SELECTED, THE CIRM PRESIDENT AND CIRM TEAM LOOK AND EXAMINE TO SEE IF THERE ARE ANY ADDITIONAL ONES THAT WOULD MERIT A FULL REVIEW, AND THE REMAINDER ARE NOT CONSIDERED.

SO FOR THIS PARTICULAR ROUND, WE HAD A TOTAL OF 75 ELIGIBLE APPLICATIONS THAT WERE SUBMITTED. WE HAD 13 THAT BYPASSED THIS PROCESS BECAUSE ANYTHING THAT SCORES BETWEEN AN 80 AND AN 84 DOESN'T HAVE TO GO THROUGH THIS PROCESS. AND WE ENDED UP WITH A TOTAL OF 54 THAT ADVANCED TO THE FULL REVIEW.

SO THE SCORING SYSTEM FOR THESE APPLICATIONS IS BASED ON A SCALE OF ONE TO A HUNDRED. ANYTHING THAT RECEIVES A SCORE THAT'S GREATER THAN 85 IS RECOMMENDED FOR FUNDING. ANYTHING THAT RECEIVES A SCORE OF, AND THIS IS WRONG, SORRY, 80 TO 84 IS NOT RECOMMENDED, BUT THOSE GET TO THEN BYPASS THE POSITIVE SELECTION PROCESS IF THEY COME IN IN THE NEXT ROUND. AND SO REVIEWERS, WHEN THEY SCORE, KNOW THIS. AND SO THEY GENERALLY TRY TO SCORE APPLICATIONS BETWEEN 80 AND 84 IF THEY WANT TO SEE IT COME BACK AND FEEL THAT THEIR REVISIONS ARE LIKELY TO BE MINOR. ANYTHING THAT SCORES BETWEEN 1 AND 79 IS NOT RECOMMENDED FOR



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

FUNDING. AND SO THIS IS ALL BASED ON THE MEDIAN SCORE FROM ALL INDIVIDUAL GWG SCORES.

THE REVIEW CRITERIA THAT ARE UTILIZED TO GIVE THOSE SCORES ARE BASED ON THESE FIVE QUESTIONS. DOES THE PROJECT HOLD THE NECESSARY SIGNIFICANCE AND POTENTIAL FOR IMPACT IN TERMS OF VALUE THAT IT OFFERS AND IS IT WORTH DOING? IS THE RATIONALE SOUND? IS IT WELL PLANNED AND DESIGNED? IS IT FEASIBLE, INCLUDING WHETHER THEY HAVE THE APPROPRIATE RESOURCES AND A QUALIFIED TEAM? AND DOES THE PROJECT ADDRESS THE NEEDS OF UNDERSERVED COMMUNITIES?

SO WE GET TO THIS SLIDE WHICH IS JUST A REMINDER TO ALL OUR BOARD MEMBERS WHO HAVE A CONFLICT OF INTEREST. IF YOUR NAME IS ON THIS LIST, JUST REMEMBER THAT YOU MAY HAVE A CONFLICT WITH ONE APPLICATION, WHICH MEANS YOU SHOULD REFRAIN FROM PARTICIPATING IN VOTING OR DISCUSSION UNTIL THE VERY END.

HERE ARE THE RECOMMENDATIONS FROM THE GRANTS WORKING GROUP AS IT RELATES TO THIS PARTICULAR CYCLE. SO WE HAD, AS MENTIONED, 54 APPLICATIONS THAT WERE REVIEWED BY THE PANEL. SEVENTEEN OF THOSE APPLICATIONS WERE RECOMMENDED FOR FUNDING BECAUSE THEY RECEIVED A SCORE OF 85 OR



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

GREATER. AND SO THAT TOTAL APPLICANT REQUEST FROM THE 17 APPLICATIONS IS ABOUT 22 MILLION. THE FUNDS AVAILABLE IN THE DISCOVERY PILLAR IS ALMOST 58 MILLION, BUT THAT INCLUDES THE DISC-0 AMOUNT AS WELL. SO THERE'S INTENTIONALLY MORE MONEY HERE BECAUSE WE STILL HAVE ANOTHER COMPETITION FOR THE DISC-0. THAT'S THE NEW EARLY FOUNDATIONAL BIOLOGY YET TO COME TO YOU. AND THEN 37 APPLICATIONS WERE NOT RECOMMENDED FOR FUNDING UNDER THIS CYCLE.

SOME OF THE APPLICATIONS THAT ARE REVIEWED AND SCORED QUALIFY FOR WHAT IS CALLED A MINORITY REPORT. SO UNDER PROP 14 ANY APPLICATION THAT IS NOT RECOMMENDED FOR FUNDING BY THE GRANTS WORKING GROUP, MEANING THAT IT SCORED BELOW 85, BUT WHICH HAD 35 PERCENT OR MORE OF THE MEMBERS SCORE TO FUND THE APPLICATION MUST INCLUDE A MINORITY REPORT. AND SO THE MINORITY REPORT IS INCLUDED IN THE REVIEW SUMMARY AND PROVIDES A BRIEF SYNOPSIS OF THE OPINION OF THE REVIEWERS THAT SCORED THAT APPLICATION 85 OR GREATER.

AND SO FOR THIS ROUND WE HAVE FOUR APPLICATIONS THAT QUALIFIED FOR A MINORITY REPORT, AND I WILL REVIEW THOSE INDIVIDUALLY AND GO INTO MORE DETAIL. BEFORE I DO, I WANT TO JUST MENTION THE CIRM TEAM RECOMMENDATIONS AS IT RELATES TO THE

CYCLE. I WANT TO POINT OUT THAT WHEN WE HAVE APPLICATIONS, PARTICULARLY THOSE THAT QUALIFY FOR A MINORITY REPORT, THE CIRM TEAM EXAMINES THE APPLICATIONS JUST TO DETERMINE IF WE HAVE ANY RECOMMENDATION ONE WAY OR THE OTHER FOR THIS. GENERALLY WHAT WE DO IS WE RECOMMEND THAT APPLICANTS REVISE THEIR APPLICATION TO ADDRESS REVIEWER CONCERNS AND SUBMIT IN THE NEXT CYCLE. WE OFFER THE DISC2 TWICE A YEAR WITH THE GOAL OF BRINGING AND, AS NOTED EARLIER, THERE ARE MANY RESUBMISSIONS THAT COME INTO THE CYCLE, MANY WHO SCORED BETWEEN 80 AND 84, THAT GETS BYPASSED THAT INITIAL STAGE OF REVIEW AND ARE ABLE TO COME IN. SO THE NEXT CYCLE DEADLINE IS GOING TO BE AUGUST 2D. SO ANYONE THAT DOES NOT GET FUNDED IN THIS CYCLE CAN CERTAINLY COME IN AUGUST 2D. AND THOSE THAT SCORED BETWEEN 80 AND 84 GET TO BYPASS THAT FIRST STAGE. THERE'S 11 APPLICATIONS THAT QUALIFY FOR THAT.

NOW, IN SOME CASES WHEN WE REVIEW THE MINORITY REPORTS AND THOSE APPLICATIONS THAT ARE NEAR THAT FUNDING LINE, THERE ARE APPLICATIONS THAT OTHERWISE ARE MERITORIOUS BUT HAVE CONCERNS THAT REALLY CAN'T BE ADDRESSED IN A RESUBMISSION AND WHERE THOSE CONCERNS WOULD NOT NECESSARILY IMPEDE ACHIEVING THE GOALS OF THE DISC2 PROGRAM. AND SO



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

WHEN WE COME ACROSS THOSE TYPES OF APPLICATIONS, WE MAY MAKE A RECOMMENDATION TO GO AHEAD AND FUND THOSE. AND SO WE HAVE TWO THAT MET THOSE CRITERIA FOR US.

SO THOSE ARE APPLICATION 13510 AND 13475, AND SO I WILL GO INTO MORE DETAIL ABOUT EACH OF THESE IN THE NEXT FEW SLIDES.

SO THE FIRST ONE IS RELATED TO APPLICATION DISC2-13510. THIS APPLICATION RECEIVED A SCORE OF 84 AND WE HAD BASICALLY A TIE. THERE WERE SEVEN MEMBERS THAT SCORED 85 OR ABOVE AND SEVEN MEMBERS THAT SCORED BELOW 85 WITH A RANGE OF 80 TO 90.

SO THE TITLE OF THIS APPLICATION IS "A HEMATOPOIETIC STEM CELL-BASED APPROACH TO TREAT HIV EMPLOYING CAR-T CELLS AND ANTI-HIV BROADLY NEUTRALIZING ANTIBODIES." SO CLEARLY THIS IS FOR AN INDICATION OF HIV INFECTION. THE PRODUCT IS A CELL AND GENE THERAPY THAT BASICALLY INVOLVES HEMATOPOIETIC STEM CELLS THAT WOULD BE TRANSPLANTED IN ORDER TO PRODUCE CAR-T CELLS THAT WOULD ACT AGAINST HIV AS WELL AS PRODUCE B-CELLS OR PLASMA CELLS THAT SECRETE BROADLY NEUTRALIZING ANTIBODIES TO ALSO ACT ON ANY FREE HIV VIRUS AND HOPEFULLY SURVEILL AND MAINTAIN THE LATENT RESERVOIR AT BAY.

SO THAT IS THAT APPLICATION. SO LET ME



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

PRESENT TO YOU THE SUMMARY OF THE MINORITY REPORT. SO THE MINORITY REPORT FOR THIS APPLICATION STATES THAT SEVEN GRANTS WORKING GROUP PANELISTS SCORED THE APPLICATION 85 TO 90. SEVEN SCORED THE APPLICATION 80 TO 83. OVERALL MOST OF THE PANELISTS VOTED YES ON WHETHER THE APPLICATION HAD MET EACH OF THE FIVE REVIEW CRITERIA, AND THE SUCCESS OF THE PROJECT WOULD ADDRESS AN UNMET NEED. THE RATIONALE IS SOUND. THE PROJECT IS WELL PLANNED, AND IT'S FEASIBLE AND ADDRESSES NEEDS OF THE UNDERSERVED.

THOSE WHO SCORED BETWEEN 85 AND 90 WERE OPTIMISTIC ABOUT THE DUAL TRANSGENE APPROACH USING BOTH THE CAR-T AND NEUTRALIZING ANTIBODIES, NOTING THAT CAR-T THERAPIES DEVELOPED TO DATE FOR HIV HAD SHOWN SOME EFFECTIVENESS. THESE HIGH SCORING PANELISTS HAD SIMILAR THOUGHTS ABOUT THE RISKS OF FAILURE AS LOWER SCORING PANELISTS, BUT THIS COMBINED WITH ENTHUSIASM FOR THE POTENTIAL PAYOFF FOR PATIENTS. ONE HIGH SCORING PANELIST WROTE, THE PROJECT IS A PRECLINICAL PROOF OF CONCEPT RELEVANT IN IN-VITRO AND IN-VIVO MODELS. IT REPRESENTS AN IMPORTANT STAGE BRIDGING DISCOVERY AND TRANSLATION.

THE PANELISTS WHO SCORED 80 TO 83 TO NOT RECOMMEND FOR FUNDING NOTED THE CONCERNS THAT THE THERAPEUTIC HSC'S WOULD NOT PROPERLY DIFFERENTIATE

INTO AT ALL TYPES OF MATURE T CELLS IN-VIVO, THEREFORE, LIMITING THE SAFETY AND EFFICACY OF THE THERAPY.

SO THIS APPLICATION WAS A RESUBMISSION, MEANING THAT IT'S BEEN SEEN BEFORE BY THE PANEL. AND THE CONCERNS FROM THE REVIEWERS RELATE TO THE POTENTIAL SAFETY OF A FUTURE CANDIDATE IF THE VECTOR AND CONSTRUCT WOULD ULTIMATELY INTERFERE WITH APPROPRIATE MATURATION OF T-CELLS. THAT WAS THE DRIVING CONCERN. NOW, A RESUBMISSION MAY NOT BE ABLE TO ADDRESS THIS SPECIFIC CONCERN AS SUCH WORK MIGHT BE APPROPRIATE FOR LATER STAGE OF RESEARCH WHEN THE FINAL CANDIDATE HAS FINALLY BEEN ACHIEVED. SO MAYBE AT THE TRANSLATIONAL STAGE. SO FOR THIS PARTICULAR STAGE OF RESEARCH, CIRM TEAM BELIEVES THE APPLICANTS HAVE AN APPROPRIATE PROPOSAL THAT WOULDN'T NECESSARILY BE IMPROVED BY TRYING TO ADDRESS THAT CONCERN AND WOULD NOT IMPEDE ACHIEVING THE GOALS OF THE DISC2 PROGRAM. SO FOR THIS ONE WE ARE RECOMMENDING FUNDING.

THE NEXT APPLICATION IS DISC2-13475. THIS RECEIVED A SCORE OF 84. A NUMBER OF 85 OR ABOVE VOTERS WERE SEVEN VERSUS EIGHT WHO SCORED BELOW. THE TITLE IS "DEVELOPING A GENE THERAPY FOR DOMINANT OPTIC ATROPHY USING HUMAN PLURIPOTENT STEM

CELL-DERIVED RETINAL ORGANOID DISEASE MODEL." AND THE DISEASE INDICATION IS AN INHERITED GENETIC DISEASE CALLED DOMINANT OPTIC ATROPHY. IT IS A GENE THERAPY APPROACH THAT WOULD OVERCOME THE GENE DEFECT.

THE PROPOSAL ITSELF IS LOOKING TO DEVELOP THE APPROPRIATE GENE THERAPY AND TEST THIS IN HUMAN RETINAL ORGANOIDS IN ORDER TO DETERMINE IF THEY HAVE AN EFFECTIVE THERAPY.

SO THE MINORITY REPORT FOR THIS ONE READS AS FOLLOWS: SEVEN PANELISTS GAVE THE APPLICATION A SCORE OF 85, RECOMMENDED FOR FUNDING. EIGHT PANELISTS SCORED FROM 79 TO 84. NEARLY ALL GRANTS WORKING GROUP PANELISTS AGREE THAT THE APPLICATION MET FOUR OF THE FIVE REVIEW CRITERIA. THE SUCCESS OF THE PROJECT WOULD ADDRESS AN UNMET NEED. THE PROJECT IS WELL-PLANNED. PROJECT PLAN IS FEASIBLE. AND THE PROPOSAL ADDRESSES NEEDS OF UNDERSERVED GROUPS. HOWEVER, THE GRANTS WORKING GROUP WAS DIVIDED NINE VERSUS FIVE ON WHETHER THE APPLICANT MET THE CRITERION 2, THE PROVISION OF A SOUND RATIONALE FOR THE THERAPEUTIC APPROACH.

THE EIGHT GRANTS WORKING GROUP PANELISTS WHO SCORED THE APPLICATION 79 TO 84 WERE UNIFORMLY CONCERNED ABOUT USING A GENE REPLACEMENT OR

AUGMENTATION THERAPY FOR DOMINANT MENDELIAN DISEASE. IN A DOMINANT MENDELIAN DISEASE SUCH AS DOMINANT OPTIC ATROPHY OR DOA, A PERSON CARRYING A SINGLE MUTANT COPY OF THE TWO COPIES THAT A PERSON HAS IN THEIR GENOME WILL HAVE THE DISEASE. THE MECHANISM OF DOMINANCE VARIES FROM DISEASE TO DISEASE. IT CAN EITHER BE HAPLO INSUFFICIENCY, MEANING THAT ONE HEALTH COPY IS INSUFFICIENT FOR HEALTH OR A DOMINANT NEGATIVE WHERE THE MUTATED COPY IS ACTIVELY HARMFUL. AND SO THE MECHANISM OF MENDELIAN DOMINANCE IN THIS PARTICULAR INDICATION IS NOT KNOWN.

THE SEVEN PANELISTS WHO GAVE THE APPLICATION A SCORE OF 85 AGREED THAT THE RATIONALE FOR GENE REPLACEMENT WILL BE WEAKER IF THE DISEASE INDICATION HAS DOMINANT NEGATIVE MECHANISM; HOWEVER, THESE PANELISTS WERE OPTIMISTIC BASED ON THE ADMIRABLE AMOUNT OF PRELIMINARY DATA FROM THE PATIENT-DERIVED RETINAL ORGANOIDS TRANSDUCED WITH THE CANDIDATE THERAPY IN WHICH THE CELL TYPE THAT DEGENERATES IN DOA APPEAR TO SHOW RECOVERY.

SO THIS ALSO IS A RESUBMISSION, MEANING THE GRANTS WORKING GROUP HAS LOOKED AT THIS APPLICATION NOW TWICE. THE CONCERNS FROM REVIEWERS RELATE TO, AS EXPLAINED, THE POSSIBILITY THAT DOA MIGHT BE A DOMINANT NEGATIVE MECHANISM AND,

THEREFORE, MAKING THE THERAPEUTIC MUCH LESS LIKELY TO WORK.

NOW, A RESUBMISSION WOULD NOT BE ABLE TO REALLY ADDRESS THIS CONCERN, BUT STUDIES PERFORMED UNDER THE PROPOSAL WOULD CERTAINLY DETERMINE IF THE THERAPEUTIC APPROACH WOULD BE EFFECTIVE OR NOT EVEN IN THE ABSENCE OF KNOWING THE UNDERLYING DOMINANCE MECHANISM. SO, THEREFORE, CIRM TEAM BELIEVES THAT THE BEST WAY TO KNOW IS TO ADVANCE THIS PROJECT, AND WE WOULD RECOMMEND THIS ONE TO MOVE FORWARD AS WELL.

THE THIRD MINORITY REPORT IS FOR APPLICATION DISC2-13413. THIS ALSO RECEIVED A SCORE OF 84. THERE WERE SIX MEMBERS WHO SCORED 85 OR GREATER, EIGHT THAT SCORED BELOW 85, WITH A RANGE OF 70 TO 85. THE APPLICATION IS ENTITLED, "IN UTERO TREATMENT OF DUCHENNE MUSCULAR DYSTROPHY WITH NONVIRAL GENE EDITING FOR PATIENTS WITH DUCHENNE MUSCULAR DYSTROPHY."

SO THIS IS GENERALLY A GENE THERAPY APPROACH. MORE SPECIFICALLY, IT'S A LIPID NANOPARTICLE M-RNA COMPLEX THAT WOULD BE INTRODUCED IN UTERO AND HOPEFULLY REACH ALL DIFFERENT AFFECTED ORGANS AND TISSUES IN ORDER TO CORRECT THE DYSTROPHIN MUTATION IN SUCH PATIENTS.

AND SO THE MINORITY REPORT FOR THIS ONE



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

READS AS FOLLOWS: SIX PANELISTS GAVE THIS APPLICATION A SCORE OF 85, EIGHT PANELISTS SCORED BETWEEN 70 AND 84. THE GREAT MAJORITY OF PANELISTS VOTED YES AS TO WHETHER EACH OF THE FIVE CRITERIA WERE MET. OVERALL REVIEWERS IN FAVOR OF FUNDING THE APPLICATION THOUGHT THERE WAS A SIGNIFICANT UNMET NEED FOR DUCHENNE MUSCULAR DYSTROPHY TREATMENTS AND THOUGHT THAT THE APPROACH OF USING LIPID NANOPARTICLES FOR TARGETED GENE EDITING IN UTERO MADE SENSE. THESE REVIEWERS ALSO THOUGHT THE PRELIMINARY DATA WAS STRONG, THE PROPOSED PROJECT WAS HIGHLY INNOVATIVE, AND THE TEAM WAS WELL QUALIFIED TO COMPLETE THE WORK.

ONE SUPPORTIVE REVIEWER NOTED THAT THE DEPENDENCY ON AIM 3, ON THE SUCCESS OF AIM 2 WAS A POTENTIAL RISK FOR THE PROJECT AS NO ALTERNATIVES WERE PRESENTED. GREATEST DIVERGENCE BETWEEN THE HIGH SCORING AND LOW SCORING PANELISTS IS IN THE COMMENTS FOR CRITERION 4, FEASIBILITY OF THE PROJECT. REVIEWERS IN FAVOR OF FUNDING THOUGHT THE TIMELINE WAS FEASIBLE AND THE TEAM WAS QUALIFIED. REVIEWERS NOT IN FAVOR OF FUNDING SAID THE PROJECT WAS TOO AMBITIOUS, UNCERTAIN, OR HAD TOO MANY MILESTONES. NO REVIEWER EXPRESSED DOUBTS OF THE PROPOSED TEAM.



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

SO, NOW, FOR THIS APPLICATION, THIS IS A FIRST-TIME APPLICANT. SO IT'S NOT A RESUBMISSION. THE APPLICANT, BASED ON THE CRITICISMS, HAS THE OPPORTUNITY TO ADDRESS THE CONCERNS IN A REVISED APPLICATION BY REEVALUATING THE PROPOSED ACTIVITIES AND DESIGN OF THE PROJECT IN ORDER TO MAKE IT CONFORM BETTER TO THE GOALS OF THE DISC2 PROGRAM.

NOW, THE APPLICANT WOULD, BECAUSE OF THE SCORE THEY RECEIVED, BYPASS THE FIRST STAGE OF REVIEW. AND THEN THE NEXT CYCLE OF DISC2, AS I MENTIONED EARLIER, DOES OFFER AN ADDITIONAL YEAR OF FUNDING AS WELL AS MORE FUNDS FOR THAT ADDITIONAL YEAR. THAT WOULD HELP, PARTICULARLY IN THIS CASE, ADDRESS THE CONCERNS RELATED TO HAVING TOO MANY ACTIVITIES. SO BASICALLY IT WOULD GIVE THE APPLICANT MORE WIGGLE ROOM TO WORK WITH. SO WE ARE NOT RECOMMENDING THIS PARTICULAR APPLICATION FOR FUNDING.

THE LAST MINORITY REPORT RELATES TO THE DISC2-13442. THIS ONE SCORED 83 WITH SIX MEMBERS SCORING 85 OR ABOVE AND EIGHT SCORING BELOW. THE TITLE IS "MICROGEL ENCAPSULATED IPSC-DERIVED NOTOCHORDAL CELLS TO TREAT INTERVERTEBRAL DISC DEGENERATION AND LOW BACK PAIN."

SO THIS IS FOR A DISEASE INDICATION WHERE

INTERVERTEBRAL DISC DEGENERATES WITH THE HOPE TO USE A CELL THERAPY THAT WOULD ALLOW SUCH PATIENTS TO GAIN SOME RECOVERY OF TISSUE AND HOPEFULLY AVAIL THEM OF LOW BACK PAIN AS WELL AS ANY FURTHER DAMAGE TO THEIR DISC.

SO THE MINORITY REPORT FOR THIS ONE READS AS FOLLOWS: SIX PANELISTS GAVE THIS APPLICATION A SCORE OF 85 TO 86, EIGHT PANELISTS SCORED 80 TO 83. ALL 14 SCORING GRANTS WORKING GROUP PANELISTS AGREED WITH A YES VOTE THAT THE APPLICATION MEETS FOUR OF THE FIVE REVIEW CRITERIA. SUCCESS OF THE PROJECT WOULD ADDRESS AN UNMET NEED. THE RATIONALE FOR THE APPROACH IS SOUND. THE PROJECT IS FEASIBLE. AND THE PROPOSAL ADDRESSES THE NEEDS OF UNDERSERVED GROUPS. PANELIST VOTES WERE SPLIT NINE TO FIVE ON WHETHER THE APPLICATION MEETS REVIEW CRITERION 3 FOR A WELL-PLANNED AND WELL-DESIGNED PROJECT. PANELISTS WHO SCORED THE APPLICATION 80 TO 83 EMPHASIZED THE IMPORTANCE OF ADDITIONAL PRELIMINARY DATA DEMONSTRATING THE CELL PRODUCT FUNCTIONALITY IN ITS FINAL FORMULATION.

THE PANELISTS THAT SCORED 85 OR 86 WERE FAVORABLY IMPRESSED WITH THE STUDY RATIONALE AND THE APPLICANT'S PUBLISHED STUDY RESULTS SHOWING DERIVATION OF NOTOCHORDAL CELLS FROM IPSC'S. THESE

PANELISTS ALSO MADE POSITIVE COMMENTS ABOUT THE STRENGTH OF THE PRELIMINARY DATA GENERALLY AND THE FEASIBILITY OF THE PROJECT. HIGH SCORING PANELISTS ACKNOWLEDGED THE NEED FOR SUPPORTIVE DATA FROM STUDIES USING THE FINAL CANDIDATE PRODUCT, BUT THOUGHT THAT THE PRODUCT PLAN PUT THE APPLICANT IN GOOD STEAD TO COLLECT THIS DATA DURING THE PROJECT PERIOD.

SO HERE WE HAVE AN APPLICATION, THIS IS NOT A RESUBMISSION. THIS IS A FIRST-TIME APPLICATION. THE APPLICANT HAS, BASED ON THE CRITIQUE, CONCERNS THAT COULD BE ADDRESSED IN A REVISED APPLICATION BY PROVIDING ADDITIONAL DATA AS WELL AS RESPONDING TO SOME OF THE CONCERNS RAISED BY REVIEWERS, INCLUDING THE FORMULATION OF THE CANDIDATE. SO WE ARE NOT RECOMMENDING THIS APPLICATION FOR FUNDING.

AND THAT CONCLUDES THE MINORITY REPORT SUMMARIES. GIVE ME JUST ONE SECOND. I WILL PUT UP THE EXCEL SHEET THAT SHOWS ALL OF THE APPLICATIONS. SO THIS IS ALSO SHOWN IN YOUR MATERIALS. THIS IS THE RANK ORDER OF ALL THE APPLICATIONS. THERE ARE 17 IN GREEN THAT ARE RECOMMENDED BY THE GRANTS WORKING GROUP. THE FOUR APPLICATIONS THAT RECEIVED A MINORITY REPORT, THE TWO THAT THE CIRM TEAM IS

RECOMMENDING ARE THESE TWO HERE, 13510, 13475, AND THEN BELOW ALL THAT ARE THE ONES THAT SCORED -- THAT DID NOT RECEIVE A MINORITY REPORT OR SCORED BELOW 80. ALL RIGHT. SO, MR. CHAIRMAN, BACK TO YOU.

CHAIRMAN THOMAS: THANK YOU VERY MUCH, GIL. SO HERE'S HOW THIS IS GOING TO WORK, EVERYBODY. THE FIRST THING I'M GOING TO DO IS ASK IF THERE ARE ANY MOTIONS TO MOVE ANY OF THE PROJECTS CURRENTLY IN THE NOT RECOMMENDED FOR FUNDING LIST UP TO THE RECOMMENDED FOR FUNDING GROUP. IF THERE ARE NONE, WE WILL PROCEED IMMEDIATELY TO ENTERTAIN AN OMNIBUS MOTION TO APPROVE THOSE IN THE TOP TIER. IF THERE ARE SOME THAT ARE MOVED TO MOVE UP TO THE TOP TIER, WE WILL FIRST VOTE ON WHETHER OR NOT TO MOVE THEM UP AND THEN PROCEED TO THE OMNIBUS MOTION ON ALL OF THE GRANTS IN THE TOP TIER. AND FOLLOWING THAT VOTE, WE WILL CLOSE OUT THE VOTING BY A VOTE TO NOT RECOMMEND FOR FUNDING THE REMAINING PROJECTS IN THE NOT RECOMMENDED FOR FUNDING RANGE.

SO THE FIRST --

MS. BONNEVILLE: J.T., REALLY QUICKLY, JUST AS A REMINDER, YOU MIGHT WANT TO ALSO ASK IF THERE ANY IN THE FUNDED THAT PEOPLE FEEL SHOULD NOT BE FUNDED. SO THAT'S AN EXTRA STEP. SORRY ABOUT THAT.



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

CHAIRMAN THOMAS: THANK YOU. YES.

SO FIRST QUESTION. WOULD ANYBODY LIKE TO MOVE ANY OF THOSE PROJECTS CURRENTLY NOT RECOMMENDED FOR FUNDING UP TO THE RECOMMENDED FOR FUNDING TIER?

DR. SOUTHARD: I MOVE WE FOLLOW THE STAFF RECOMMENDATION AND MOVE THE TWO THAT THEY RECOMMEND TO THE FUNDED CATEGORY.

CHAIRMAN THOMAS: MOVED BY MARV SOUTHARD. DO WE HAVE A SECOND?

MR. ROWLETT: I SECOND.

CHAIRMAN THOMAS: AL, THAT WAS YOU?

MR. ROWLETT: YES, IT WAS.

CHAIRMAN THOMAS: WE GOT A LITTLE FEEDBACK THERE. OKAY. THANK YOU. OKAY.

IS THERE ANY DISCUSSION BY MEMBERS OF THE BOARD ON THIS MOTION?

MS. BONNEVILLE: ANNE-MARIE HAS HER HAND RAISED.

CHAIRMAN THOMAS: ANNE-MARIE AND THEN FRED. ANNE-MARIE.

DR. DULIEGE: THANK YOU. FIRST, GIL AND THE CIRM TEAM, CONGRATULATIONS AGAIN FOR AN EXCELLENT PROCESS. I WON'T BELABOR THE POINT, JUST GO RIGHT TO THE POINT AND MAXIMIZE OUR TIME AND EXPERTISE AND YOUR TIME AND EXPERTISE.



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

FOR THESE TWO THAT ARE RECOMMENDED, I'M A LITTLE PUZZLED BY THE FACT THAT THE DISCUSSION FROM THE GWG WAS ABOUT, IF I UNDERSTOOD CORRECTLY, THE SCIENTIFIC RATIONALE. AT LEAST FOR THE SECOND ONE, THE BLINDNESS ONE, COULD YOU EXPAND ON IT A LITTLE BIT? IS THERE ENOUGH RATIONALE IN THE MIDST OF THE UNCERTAINTY, SCIENTIFIC UNCERTAINTY, TO THINK THAT THIS WOULDN'T BE WASTED MONEY? DO YOU THINK THAT THE POWER OF GENETICS IS ENOUGH? THAT'S MY FIRST QUESTION FOR THE BLINDNESS ONE. I CAN'T REMEMBER THE EXACT TERM HERE, THE RETINAL ORGANOID DISEASE MODEL.

AND THE SECOND IS BACK TO THE HIV ONE. WHAT IS THE GOAL OF THIS PROJECT? IS IT TO CURE HIV, OR IS IT TO PERFORM BETTER THAN ANTIRETROVIRALS? IN THE FIRST CASE I THINK THERE'S A SCIENTIFIC RATIONALE. IN THE SECOND CASE I'M A LITTLE LESS CLEAR. THANK YOU FOR YOUR CLARIFICATION, GIL.

DR. SAMBRANO: SURE. ABSOLUTELY. SO FOR THE DOMINANT OPTIC ATROPHY, YES, THERE WERE CONCERNS RAISED AS IT RELATES TO THE RATIONALE OF SOME REVIEWERS, STATING, FOR EXAMPLE, "I DON'T FEEL THERE'S SUFFICIENT JUSTIFICATION FOR USING A RETINAL ORGANOID MODEL INSTEAD OF FURTHER DEVELOPING ANIMAL

MODELS." I THINK THE RATIONALE WAS NOT RELATED TO THE THERAPY ITSELF, BUT GENERALLY THE APPROACH FOR USING THE ORGANOID MODELS VERSUS USING IN VIVO MODEL.

WE DON'T HAVE AN OPINION ON THE CIRM TEAM ONE WAY OR THE OTHER. I THINK THEY WERE SPLIT IN TERMS OF THAT OPINION. THE MAJORITY OF THE GRANTS WORKING GROUP FELT IT WAS FINE TO USE THE ORGANOID MODELS. OUR ASSESSMENT OF THIS IN TERMS OF WHY WE ARE RECOMMENDING WAS REALLY FOCUSED ON WHETHER, ASSUMING THAT THINGS WORK OUT, WOULD THEY BE ABLE TO ACHIEVE THE GOALS OF THE DISC2. THERE'S OBVIOUSLY A RISK FOR ALL PROJECTS, BUT WE THOUGHT, YES, THEY COULD ASSUMING THEY WOULD SUCCEED IN THESE STUDIES, AND THAT IT WOULD BE DIFFICULT TO ADDRESS THE MOST SIGNIFICANT CONCERN FROM REVIEWERS, WHICH WAS RELATED TO THE UNDERLYING DOMINANCE MECHANISM WHICH WE THOUGHT THE APPLICANTS REALLY WOULD NOT BE ABLE TO ADDRESS IN THEIR RESUBMISSION. SO THOSE ARE THE TWO THINGS THAT REALLY DROVE THAT ONE.

FOR THE HIV, SO THE GOAL FOR THAT ONE IS TO DEVELOP A THERAPY THAT WOULD PREVENT THE LATENT RESERVOIR FROM EMERGING. SO AS PRO VIRUS EMERGES FROM THAT LATENT RESERVOIR, THERE WOULD BE BASICALLY A MECHANISM OF ONGOING SURVEILLANCE IN ORDER TO

PREVENT THE VIRUS FROM REPLICATING. SO IT WOULDN'T NECESSARILY BE A CURE, MEANING IT WOULDN'T NECESSARILY ELIMINATE THE LATENT RESERVOIR BECAUSE IT DOESN'T SPECIFICALLY TARGET IT, BUT THE IDEA WOULD BE THAT IT WOULD PREVENT IT FROM ADVANCING OR EMERGING.

DR. DULIEGE: THANK YOU.

DR. CANET-AVILES: GIL, CAN I ADD ONE THING?

DR. SAMBRANO: YES, PLEASE.

DR. CANET-AVILES: SO WITH REGARDS TO THE APPLICATION WITH -- THE FIRST APPLICATION, ONE OF THE COMMENTS FROM THE REVIEWERS WAS THAT EVEN IF THE PROJECT FAILED, THE MODEL, THE ORGANOID MODEL, WOULD BRING A LOT OF VALUE BECAUSE THERE IS ACTUALLY NOT -- THERE'S KIND OF A BELIEF IN THE FIELD AS TO WHETHER AN ORGANOID MODEL CAN WORK FOR TESTING IN THIS DISEASE BECAUSE THE ANIMAL MODELS ARE NOT GOOD. SO IT COULD BE REASONABLE SPENDING AT THIS LEVEL OF FUNDING, ESPECIALLY IN DISC, TO HAVE AS AN OUTCOME A REALLY GOOD ORGANOID MODEL THAT SUPERSEDES WHAT THE ANIMAL MODELS CAN PROVIDE.

SO NO MATTER WHAT, WE THOUGHT THAT THIS COULD BRING VALUE TO THE FIELD, AND THAT WAS ANSWERING DR. DULIEGE'S QUESTION AS WELL.



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

DR. DULIEGE: VERY HELPFUL. THANK YOU.

CHAIRMAN THOMAS: FRED.

DR. FISHER: AGAIN, JUST TO BE CLEAR, THE SCORES THAT WE'RE LOOKING AT, THE 15 PEOPLE THAT VOTED FOR 13475 AND THE 14 PEOPLE THAT VOTED FOR 13510, THOSE WERE ALL THE SCIENTIFIC REVIEWERS. THOSE DON'T INCLUDE THE VOTES OF ANY ADVOCATES OR NONSCIENTISTS; IS THAT RIGHT?

DR. SAMBRANO: SO THE SEVEN VERSUS EIGHT IN TERMS OF THE SCORE IS ONLY THE SCIENTIFIC MEMBERS. HOWEVER, THE GRANTS WORKING GROUP VOTES AGAINST EACH CRITERION MAY INCLUDE SOME OF THE PATIENT ADVOCATE AND NURSE MEMBER VOTES.

DR. FISHER: SO, AGAIN, I'M IN NO POSITION TO EVALUATE THE SCIENCE; BUT AS A LAYPERSON IN THIS PROCESS, I'M PLEASED TO SEE THAT OF THE SEVEN PEOPLE THAT SCORED 13510 AT 85 OR ABOVE, THAT THE RANGE WENT AS HIGH AS 90. AND HAVING BEEN THROUGH THESE MEETINGS NOW, SEEING THAT THE PROJECTS THAT HAVE GREAT ENTHUSIASM SCORE WELL ABOVE 85, AND 85 IS LIKE THE BOTTOM IN TERMS OF CONFIDENCE LEVEL, BUT PEOPLE WANT TO SEE IT HAPPEN.

AND SO WHEN I'M LOOKING AT THIS, BEING ASKED FOR MY OPINION ABOUT IT, SEEING THAT THE RANGE INCLUDED AT LEAST A 90 IS HELPFUL TO SEE. AND THE

CIRM TEAM'S PERSPECTIVE ABOUT IT IS SUPER HELPFUL.

FOR 13475 THE RANGE GOT NO HIGHER THAN 85, AND THE MAJORITY OF THE SCIENTIFIC VIEWERS, A SLIM ONE ALBEIT, VOTED LESS THAN 85. SO I'M HAVING JUST, AGAIN, FROM A LAY POINT OF VIEW BECAUSE I DON'T UNDERSTAND THE SCIENCE THAT WE ARE TALKING ABOUT, FROM A LAY POINT OF VIEW, I'M JUST CAUTIOUS ABOUT GOING AGAINST THE SCIENTIFIC REVIEWERS, MAJORITY OF WHOM VOTED THAT IT SHOULD NOT BE FUNDED, AND EVEN THOSE THAT VOTED TO FUND IT VOTED WITH THE LOWEST AMOUNT OF ENTHUSIASM FOR FUNDING POSSIBLE.

SO I JUST WANTED TO PUT THAT OUT THERE. AGAIN, I'LL RELY ON THE RECOMMENDATIONS OF THE CIRM TEAM ABOUT THIS. OBVIOUSLY THEY BROUGHT IT TO US AND ARE RECOMMENDING IT FOR REASONS. AND I WILL, IF THIS BODY AGREES THAT THESE SHOULD BE FUNDED, I'LL CERTAINLY VOTE IN FAVOR OF THAT, BUT I JUST WANTED TO EXPRESS WHAT IT'S LIKE AS A LAYPERSON LOOKING AT THIS AND MAKING THE DECISION BASED ON THE INFORMATION THAT WE HAVE AVAILABLE.

CHAIRMAN THOMAS: THANK YOU, FRED.

ANY OTHER COMMENTS FROM MEMBERS OF THE BOARD? I WOULD JUST LIKE TO ADD A COUPLE. ONE WITH RESPECT TO THE HIV PROJECT, THE ISSUE OF LATENT RESERVOIR HAS ALWAYS BEEN PARTICULARLY VEXING, AND I



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

THINK THAT SOMETHING THAT AIMS TO DO SOMETHING ABOUT THAT VERY SERIOUS CONCERN IS SOMETHING THAT WE SHOULD BE BEHIND, IN ADDITION TO THE OTHER REASONS ARTICULATED BY GIL.

ON THE DOMINANT OPTIC ATROPHY PROPOSAL, FROM A PROGRAMMATIC NOTE, GIL, CORRECT ME IF I'M WRONG, BUT WE DON'T HAVE ANYTHING ANYWHERE IN THE CIRM PORTFOLIO ON THIS PARTICULAR INDICATION; IS THAT CORRECT?

DR. SAMBRANO: YES, THAT'S CORRECT.

CHAIRMAN THOMAS: SO THAT TO ME, IN ADDITION TO THE REASONS THAT GIL REFERENCED AS TO WHY THE TEAM RECOMMENDS FUNDING THAT PARTICULAR PROJECT, IS SOMETHING THAT LEADS ME TO SUPPORT THAT NOTION.

ANY OTHER COMMENTS? DO WE HAVE ANY COMMENTS FROM MEMBERS OF THE PUBLIC? OKAY.

MS. BONNEVILLE: THERE ARE NO HANDS RAISED.

CHAIRMAN THOMAS: OKAY. THANK YOU, MARIA.

DR. MARKS: J.T., IF I MAY, JUST FOR A POINT OF CLARITY. THE ORIGINAL MOTION DID NOT STATE THE SPECIFIC APPLICATIONS THAT WE ARE CONSIDERING. IT WAS JUST GENERICALLY WHAT THE CIRM STAFF RECOMMENDED. SO FOR CLARITY, CAN WE JUST SPECIFY

THAT THE TWO ARE DISC2-13510 AND DISC2-13475?

CHAIRMAN THOMAS: YES. THANK YOU, KEVIN.

MS. BONNEVILLE: J.T., WE DO HAVE PUBLIC COMMENT NOW. I JUST WANT TO CONFIRM THAT THIS IS PUBLIC COMMENT ABOUT THE TWO APPLICATIONS THAT ARE CURRENTLY BEING CONSIDERED AND NOT GENERAL PUBLIC COMMENT ON OTHER APPLICATIONS.

CHAIRMAN THOMAS: OKAY. THANK YOU.

MS. BONNEVILLE: SO JENNIFER ROSLYN. SO WE'LL START WITH YOU. AND IT'S LIMITED TO THREE MINUTES. SO THANK YOU.

DR. WANG: I THINK YOU WERE JUST CONFIRMING IF THE COMMENT RELATED TO THE TWO --

MS. BONNEVILLE: THAT ARE CURRENTLY BEING VOTED ON, CORRECT.

DR. WANG: NO, MY COMMENT WAS NOT RELATED TO THOSE TWO.

MS. BONNEVILLE: OKAY. IF YOU COULD WAIT UNTIL OTHER PUBLIC COMMENT. WE JUST WOULD LIKE TO HEAR FROM MEMBERS OF THE PUBLIC ON THIS SPECIFICALLY. TIFFANY.

DR. PERRY: YES.

MS. BONNEVILLE: IS YOUR PUBLIC COMMENT RELATED TO THESE TWO APPLICATIONS?

DR. PERRY: SO SORRY. IF YOU COULD REPEAT



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

THE QUESTION.

MS. BONNEVILLE: IS YOUR PUBLIC COMMENT RELATED TO EITHER OF THESE TWO APPLICATIONS? IF NOT, THERE WILL BE OTHER PUBLIC COMMENT AVAILABLE.

DR. PERRY: NO.

MS. BONNEVILLE: THERE WILL BE OPPORTUNITY FOR OTHER PUBLIC COMMENT.

AND ANNE-MARIE HAS HER HAND RAISED AS WELL.

CHAIRMAN THOMAS: ANNE-MARIE.

DR. DULIEGE: THANK YOU VERY MUCH. VERY USEFUL CONVERSATION.

MARIA MILLAN, I WANTED TO ASK YOU A QUESTION IN REGARDS TO THE COMMENT THAT FRED FISHER JUST MADE ABOUT THE APPLICATION ON THE RETINAL ORGANOID DISEASE MODEL, THE ONE THAT IS A LITTLE BIT MORE ON THE CUSP REALLY, AND THAT WOULD HELP ME FOR MY VOTE.

DO YOU THINK THAT IT IS JUSTIFIED WITH THE CIRM THAT WE SUPPORT AN APPLICATION, NOT SO MUCH BECAUSE WE BELIEVE THAT IT'S LIKELY TO BE SUCCESSFUL, BUT BECAUSE WE BELIEVE THAT, BY DOING THIS EXPERIMENT, THE ENTIRE FIELD AND THAT PARTICULAR DISEASE, WE'LL UNDERSTAND BETTER THE MECHANISM OF DISEASE, IN THIS CASE THE ROLE OF THE

GENETICS IN THE ONSET OF THE DISEASE? CAN YOU HELP US, GUIDE OUR JUDGMENT HERE? THANK YOU.

DR. MILLAN: SO, ANNE-MARIE, IN RESPONSE TO THE COMMENT WHICH I THINK I UNDERSTAND FRED'S QUESTION, GIVEN THE RANGE OF THE SCORES AND THE PATTERN OF THE SCORES, DOES THAT SPEAK TO THE STRENGTH OF THE APPLICATION, AND SHOULD THAT BE CONSIDERED OR WAS IT CONSIDERED, MAYBE I'M PARAPHRASING, WHEN WE MADE THE RECOMMENDATION TO RECOMMEND THIS APPLICATION UNDER THE MINORITY REPORT CATEGORY. I WILL JUST START BY SAYING THAT IT'S AN IMPERFECT SCIENCE. WE DO OUR VERY BEST TO GIVE GUIDANCE TO REVIEWERS, AND GIL AND TEAM REALLY DO A GREAT JOB WITH IT. BUT WHEN YOU'RE IN THAT KIND OF A GRAY ZONE FOR SCORES, IT'S NOT REALLY QUANTITATIVE. SO IT REALLY DOES RELY ON THE AGGREGATE INFORMATION BOTH FROM THE SCIENTIFIC REVIEW AND PUTTING THAT TOGETHER.

I THINK BOTH GIL AND ROSA, WHO, BY THE WAY, THE ENTIRE SCIENCE TEAM COMES TOGETHER IN THIS, REALLY LOOK AT THE INPUT OF THE GWG WITH REGARDS TO THE APPLICATION. IN AGGREGATE WE DO BELIEVE THAT THIS SHOULD BE FUNDED BASED ON THE REVIEWERS' COMMENTS AND UNDER THE MINORITY REPORT UMBRELLA. SO WITHOUT GOING INTO THAT RATIONALE AGAIN FOR THE

RATIONALE THAT WAS PROVIDED BY DR. SAMBRANO AND REINFORCED BY DR. AVILES, HOPEFULLY THAT'S ENOUGH. WHENEVER WE HAVE SCORES, I THINK WHAT HAPPENS, IT PUTS THEM IN A CATEGORY SO IT ALLOWS FOR THE DISCUSSION AND THEN IT ALLOWS THE BOARD TO MAKE THEIR PROGRAMMATIC DISCUSSION. AGAIN, IT'S NOT AN EXACT SCIENCE. IT'S A GUIDE TO HAVE THOSE DISCUSSIONS IS THE BEST WAY I CAN KIND OF REPRESENT HOW SCORES ARE USED.

ANNE-MARIE, I DON'T KNOW IF THAT COMPLETELY ANSWERS YOUR QUESTION.

DR. DULIEGE: IT DOES, MARIA, AND IT HELPS ME PUT TOGETHER THE COMMENTS FROM ROSA, GIL, YOU, AND OTHERS, THAT IN THAT PARTICULAR CASE, MORE THAN IN OTHERS, WHILE THERE'S A LOT OF UNCERTAINTY ABOUT THE VALUE OF THE EXPERIMENT TO FIND A CURE, IT'S ALWAYS THE CASE, PARTICULARLY IN STEM CELL RESEARCH, THERE'S EVEN MORE SO A VALUE OF THIS EXPERIMENT TO HELP SCIENTISTS UNDERSTAND THE FIELD BETTER. AND FOR ME THAT COUNTS AS WELL. I'LL VOTE YES FOR THIS REASON TO APPROVE IT.

CHAIRMAN THOMAS: STEVE.

MR. JUELSGAARD: SO LET ME MAKE AN ADDITIONAL COMMENT REGARDING ONE THAT INVOLVES THE CELL-DERIVED RETINAL ORGANOID MODEL.

SO ON JUNE 9TH THE HOUSE OF REPRESENTATIVES, THE U.S. HOUSE OF REPRESENTATIVES, VOTED TO APPROVE THE FDA MODERNIZATION ACT. THE SENATE HAS ALREADY APPROVED THAT. I'M NOT EXACTLY SURE WHEN IT GOES TO BIDEN FOR HIS SIGNATURE. BUT IN THAT ACT IS A REQUIREMENT, WELL, I WOULDN'T SAY IT'S A REQUIREMENT, BUT A STRONG PUSH TO HAVE THE FDA BASICALLY CHANGE THE MODELS THAT IT REQUIRES USING FOR TESTING FOR IND PURPOSES TO MOVE AWAY FROM THE ANIMAL MODEL TESTING AND TO OTHER MECHANISMS OF TESTING. ONE OF THOSE POTENTIAL MODELS IS GOING TO BE THE AREA OF ORGANOIDS. IT'S AN UP AND COMING AREA.

SO SORT OF ALA WHAT ANNE-MARIE WAS TALKING ABOUT, BUT FROM A DIFFERENT POINT OF VIEW, IF IT DOESN'T ACTUALLY WORK IN THIS CASE, BUT HELPS SUPPORT THE DEVELOPMENT OF ORGANOIDS AS A MODEL, I THINK JUST FOR THAT REASON ALONE IT'S WORTH FUNDING BECAUSE WE ARE HEADED IN THAT DIRECTION, AWAY FROM THE USE OF ANIMAL MODELS. AND I KNOW THAT WAS A CRITIQUE IN THE ASSESSMENT, BUT UNFORTUNATELY OR FORTUNATELY ANIMAL MODELS ARE AT SOME POINT GOING TO BECOME A THING OF PAST, PARTICULARLY WHEN IT GOES FOR FDA REGULATORY PURPOSES IN TERMS OF ANIMAL TESTING LEADING UP TO AN IND.



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

CHAIRMAN THOMAS: THANK YOU, STEVE.

ANY OTHER COMMENTS FROM MEMBERS OF THE BOARD?

MS. BONNEVILLE: I JUST WANT TO MAKE ONE QUICK COMMENT. WE ARE AT QUORUM RIGHT NOW. IF ANYONE NEEDS TO LEAVE EARLY, WE RUN THE RISK OF NOT BEING ABLE TO TAKE A VOTE. SO I JUST WANT TO MAKE SURE EVERYONE IS CLEAR.

CHAIRMAN THOMAS: OKAY. THANK YOU. SEEING NO MORE COMMENTS FROM MEMBERS OF THE BOARD AND, MARIA, I ASSUME NO MORE MEMBERS OF THE PUBLIC EITHER WITH RESPECT TO THESE TWO PARTICULAR GRANTS, LET'S PROCEED NOW TO A VOTE ON WHETHER OR NOT TO ELEVATE THESE TWO GRANTS AS NUMBERED BY KEVIN UP TO THE RECOMMENDED FOR FUNDING RANGE. MARIA, WILL YOU PLEASE CALL THE ROLL.

MS. BONNEVILLE: LEONDRA CLARK-HARVEY.

MS. CLARK-HARVEY: YES.

MS. BONNEVILLE: ANNE-MARIE DULIEGE.

DR. DULIEGE: YES.

MS. BONNEVILLE: MARK FISCHER-COLBRIE.

DR. FISCHER-COLBRIE: YES.

MS. BONNEVILLE: FRED FISHER.

DR. FISHER: YES.

MS. BONNEVILLE: DAVID HIGGINS.

DR. HIGGINS: YES.
MS. BONNEVILLE: STEVE JUELSGAARD.
MR. JUELSGAARD: YES.
MS. BONNEVILLE: RICH LAJARA.
MR. LAJARA: YES.
MS. BONNEVILLE: LAUREN MILLER-ROGEN.
MS. MILLER-ROGEN: YES.
MS. BONNEVILLE: ADRIANA PADILLA.
DR. PADILLA: YES.
MS. BONNEVILLE: AL ROWLETT. MARVIN SOUTHARD.
DR. SOUTHARD: YES.
MS. BONNEVILLE: JONATHAN THOMAS.
CHAIRMAN THOMAS: YES.
MS. BONNEVILLE: ART TORRES.
MR. TORRES: AYE.
MS. BONNEVILLE: THE MOTION CARRIES.
CHAIRMAN THOMAS: OKAY. THANK YOU.
SO WE NOW HAVE THOSE TWO ADDED. WE NOW HAVE A TOTAL OF 19 IN THE GROUP RECOMMENDED FOR FUNDING. WE DO HAVE TWO COMMENTS ON OTHER GRANTS IN THE NOT RECOMMENDED FOR FUNDING RANGE. I THINK THIS WOULD BE A TIME TO HEAR THOSE. SO, MARIA, WILL YOU PLEASE INVITE THOSE PUBLIC COMMENTERS TO SPEAK TO THE BOARD.



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

MS. BONNEVILLE: I THINK YOU JUST DID. SO IF YOU HAVE PUBLIC COMMENT, NOW IS YOUR OPPORTUNITY. AND, AGAIN, IT'S LIMITED TO THREE MINUTES. AND PLEASE JUST RAISE YOUR HAND AND WE CAN CALL ON YOU. I KNOW YOU'RE NOT JENNIFER ROSLYN, SO WE'RE GOING TO CALL YOU JENNIFER FOR NOW.

DR. WANG: THANK YOU, MARIA. THANK YOU, BOARD, AND THANK YOU, EVERYBODY. SO MY NAME IS AIJUN WANG. I'M THE PI FOR ONE OF THE 84S, NO. 3 ON THE LIST WITH THE MINORITY REPORT, 13413.

I JUST HAVE A VERY BRIEF COMMENT ABOUT THIS PROJECT. ACTUALLY, FIRST OF ALL, I WANT TO EXPRESS MY GREAT GRATITUDE TO THE REVIEWERS AND ALSO OUR CIRM TEAM RECOGNIZING THE IMPORTANCE AND THE INNOVATION OF THE PROJECT.

WHAT WE ARE TRYING TO DO, I REALLY ECHO WHAT BOARD MEMBER ANNE-MARIE JUST MENTIONED, TRYING TO FIND A CURE. SO WHAT WE'RE TRYING TO DO IN THIS PROJECT IS REALLY TO FIND A CURE FOR A VERY BAD DISEASE, DUCHENNE MUSCULAR DYSTROPHY. AND WHAT WE ACTUALLY HAVE SHOWN, VERY EXCITED ABOUT, FOR THE PRELIMINARY DATA WE HAVE GATHERED, AND MANY OF THE REVIEWERS HAVE ALSO RECOGNIZED THAT WE FOUND SOME TECHNOLOGY ELEMENTS THAT CAN BE UTILIZED TO TARGET THE HEART AND DIAPHRAGM IN THE FETUS, ACTUALLY



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

BEFORE THE BABY IS BORN. WE CAN EDIT THOSE CELLS IN THE DIAPHRAGM AND HEART.

THE REASON THIS IS IMPORTANT, BECAUSE ALSO THE DUCHENNE MUSCULAR DYSTROPHY PATIENTS WOULD DIE VERY EARLY PRIMARILY BECAUSE OF THE CARDIAC DYSFUNCTION AND ALSO RESPIRATORY FUNCTION LOSS.

SO THIS IS A VERY -- AS ONE OF THE REVIEWERS ACTUALLY POINTED OUT, IT COULD BE A -- IT'S A VERY SMALL POPULATION OF RARE DISEASE, BUT I THINK GOES ALONG VERY WELL WITH THE CIRM'S MOTION. FOR EXAMPLE, CIRM ANNOUNCED THE PARTNERSHIP WITH THE NIH AND FDA AND PRIVATE SECTOR TO FIND CURES FOR RARE DISEASES. SO I THINK THIS PROJECT, WE ARE REALLY EXCITED ABOUT THE NEW FINDING. WE JUST DON'T WANT TO GET ANY DELAY ON THIS PROJECT, BUT I REALLY APPRECIATE WHAT GIL JUST MENTIONED, THAT EVEN THOUGH WE WERE AMBITIOUS, WE'RE TRYING TO COMPLETE THE WHOLE THING FROM THE IN VITRO CULTURE CELL MODEL TO ANIMAL MODEL TO HUMAN DISEASE MODEL. IT'S A REALLY AMBITIOUS TEAM PROJECT, BUT WE HAVE A VERY WONDERFUL TEAM AND WE ALSO HAVE EXPERTISE IN LEADING TRANSLATIONAL RESEARCH INTO CLINICAL TRIAL.

SO ACTUALLY THE TEAM AT UC DAVIS LED BY DR. DANA FARMER AND MYSELF ARE ACTUALLY CONDUCTING AN ONGOING CLINICAL TRIAL USING IN UTERO TREATMENT



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

FOR SPINA BIFIDA. I KNOW MANY OF YOU MAY REMEMBER THIS PROJECT.

ANYWAY, I WANT TO SAY THANK YOU TO THE TEAM. AND IF YOU COULD SUPPORT THIS ROUND FOR OUR PROJECT, WE CAN MOVE FASTER, BUT I WOULD APPRECIATE ANY COMMENT OR FURTHER CONSIDERATION EVEN IF WE HAVE TO COME BACK NEXT ROUND. IT WOULD JUST BE A LITTLE BIT DELAYED, BUT THANK YOU VERY MUCH.

CHAIRMAN THOMAS: THANK YOU. TIFFANY.

DR. PERRY: THANK YOU SO MUCH. SO OUR PROJECT IS PROJECT NO. 13442, "MICROGEL ENCAPSULATED ISPC-DERIVED NOTOCHORDAL CELLS TO TREAT INTERVERTEBRAL DISC DEGENERATION, LOW BACK PAIN."

JUST TO GIVE SORT OF FROM THE CLINICAL SIDE OF THINGS SOME HISTORY AND WHY THIS IS A HUGE PROJECT. IN MARCH OF 2018 IN THE *LANCET*, DR. HARLIGSON (PHONETIC) STATED THAT LOW BACK PAIN IS THE NO. 1 CAUSE OF DISABILITY WORLDWIDE WITH OVER 60.1 MILLION YEARS LIVED WITH DISABILITY IN 2015 ALONE. OVER A 25-YEAR INTERVAL, THE INCIDENCE OF LOW BACK PAIN DISABILITY INCREASED 54 PERCENT WORLDWIDE MOST LIKELY DUE TO OUR AGING POPULATION.

STUDIES HAVE FOUND THAT IN HIGHER INCOME COUNTRIES THE INCIDENCE OF BACK PAIN IS 33 PERCENT, AND HEALTHCARE APPROACHES FOR BACK PAIN CONTRIBUTE

TO THE OVERALL BURDEN OF DISEASE AND COST RATHER THAN REDUCING IT. IN LOWER INCOME WORKING COUNTRIES, FARMERS DECREASE THEIR WORKLOAD TO DIMINISHING EFFECTS OF BACK PAIN CAUSED BY MANUAL LABOR, WHICH ALSO CAN INCREASE THAT CYCLE OF POVERTY IN THOSE AREAS.

THE GOAL OF OUR PROJECT IS TO FIGURE OUT THE ULTIMATE ISSUE WITH LOW BACK PAIN AND DEGENERATIVE DISC. OUR PROJECT WANTS TO ADDRESS THE LOW BACK PAIN RELATED TO DEGENERATIVE DISC BY USING PLURIPOTENT STEM CELLS TO REVITALIZE AND REPOPULATE THE NUCLEUS PULPOSUS.

SO WHAT IS THE BURDEN OF LOW BACK PAIN IN SOCIETY? THE COST. THE COST OF MEDICAL CARE, INDIRECT COST, PRODUCTIVITY LOSS, STAYING OUT OF WORK, ALTERNATIVE MEDICINE AND MEDICATION, AND TIME TO AND FROM APPOINTMENTS. THE U.S. ALONE HAS THE HIGHEST COST FOR DIRECT MEDICAL TREATMENT IN LOW BACK PAIN PRIMARILY DUE TO OUR MEDICALLY INTENSIVE APPROACH. DEPRESSION, CHRONIC PAIN, OPIOID CRISIS, HALF A MILLION DEATHS OVER A 20-YEAR PERIOD ATTRIBUTABLE TO PRESCRIPTION AND ILLICIT DRUG USE OF OPIOIDS.

IF WE COULD FIND A STEM CELL TREATMENT FOR LOW BACK PAIN CAUSED BY DEGENERATIVE DISC, THE



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

EFFECTS COULD BE ENDLESS AND SEEN WORLDWIDE. PSYCHOLOGICAL AND MENTAL IMPROVEMENT, ATTENDANCE IN WORKPLACE, COST OF HEALTHCARE DRIVEN DOWN INSTEAD OF UP, PRODUCTIVITY BY FARMERS GLOBALLY, AND LONGEVITY OF LIFE ACCOMPANIED BY QUALITY OF LIFE.

JUST THIS WEEK AT CEDARS-SINAI MEDICAL CENTER, WHERE WE ARE, THE FIRST HUMAN EXPERIMENTAL INJECTION OF STEM CELLS INTO THE MOTOR CORTEX FOR AMYOTROPHIC LATERAL SCLEROSIS OCCURRED. THIS IS THE FIRST PATIENT IN HUMAN TRIALS WITH CRANIAL INJECTION OF STEM CELLS FOR ALS. CEDARS-SINAI IS COMMITTED TO STEM CELL RESEARCH. OUR TEAM WANTS TO FOLLOW IN LEADING THIS GLOBAL QUEST FOR STEM CELL THERAPIES IN SPINE.

OUR PROJECT IS FUNDAMENTALLY ORIENTED AT USING MINIMALLY INVASIVE STEM CELL BIOLOGICAL SOLUTIONS TO RECREATE THE NUCLEUS PULPOSUS AND REJUVENATE THE INTERVERTEBRAL DISC PREVENTING THE CASCADE OF EVENTS THAT WE'VE TALKED ABOUT. THANK YOU FOR YOUR TIME.

CHAIRMAN THOMAS: THANK YOU, TIFFANY.

OKAY. SO DO WE HAVE, MARIA, ANY MORE PUBLIC COMMENT ON ANY APPLICATIONS THAT ARE CURRENTLY NOT IN THE RECOMMENDED FOR FUNDING RANGE?

MS. BONNEVILLE: YES. WE HAVE A HAND

RAISED, AND THAT IS LANA.

DR. ZHOLUDEVA: YES. HI. GOOD MORNING. I WANTED TO CLARIFY THAT THE CALL FOR PUBLIC COMMENTS WAS ONLY FOR THE GRANTS THAT RECEIVED A MINORITY REPORT, OR IS IT ANY OF THE PROJECTS THAT WERE NOT RECOMMENDED FOR FUNDING?

MS. BONNEVILLE: ANY OF THE PROJECTS.

DR. ZHOLUDEVA: GREAT. I WOULD LIKE TO TAKE AN OPPORTUNITY MAKE A COMMENT, THEN, ON PROJECT 13502. AND IT'S JUST THE ONE BELOW THE ONES THAT RECEIVED A MINORITY REPORT TITLED "EXCITATORY SPINAL INTERNEURONS FROM HUMAN PLURIPOTENT STEM CELLS TO TREAT SPINAL CORD INJURY." IS IT OKAY IF I MAKE THE COMMENT?

MS. BONNEVILLE: YES.

DR. ZHOLUDEVA: OKAY. THANK YOU FOR THE OPPORTUNITY TO SPEAK WITH YOU ALL TODAY AND BRIEFLY DISCUSS MY DISC PROPOSAL TO CIRM. I WOULD FIRST LIKE TO EXPRESS MY GRATITUDE FOR THE REVIEWERS OF OUR PROPOSAL. I WAS VERY HONORED BY A NUMBER OF POSITIVE COMMENTS OF THEIR RECOGNITION THAT THE PROPOSAL HAS POTENTIAL FOR HIGH SCIENTIFIC IMPACT, WAS BUILT ON A SOLID RATIONALE BASED ON THE WORK THAT WE HAVE PREVIOUSLY PUBLISHED. AND IN LINE WITH THE DISC2 PROGRAM, THE RESEARCH DESCRIBED IN OUR

PROPOSAL AIMS TO IDENTIFY A THERAPEUTIC CANDIDATE THAT COULD POTENTIALLY HELP NOT ONLY THE THOUSANDS OF CALIFORNIANS CURRENTLY LIVING WITH A SPINAL CORD INJURY, BUT THE HUNDREDS OF THOUSANDS OF AMERICANS LIVING THROUGHOUT THE COUNTRY AND, OF COURSE, MANY THAT ARE OVERSEAS.

WHILE THE MEAN SCORE OF THE PROPOSAL WAS 83, IT'S JUST BELOW THE FUNDING. MY PURPOSE HERE TODAY IS REALLY JUST TO TAKE THE OPPORTUNITY TO ADDRESS WHAT LOOKS TO BE THE ONLY ONE KEY SCORE DRIVING FACTOR THAT DAMPENS ENTHUSIASM FOR OUR PROPOSAL AND NOT A SINGLE CONCERN FROM A COUPLE OF THE REVIEWERS FOR MY PERSONAL PROFESSIONAL EXPERIENCE TO DATE. I'M GLAD TO HAVE THIS OPPORTUNITY TO TRY AND CLARIFY THIS FOR THE DISCUSSION.

SO THERE WAS ONE COMMENT THAT I WAS NOT A CONTRIBUTING FACTOR ON PAPER THAT LED TO THE PROPOSAL, WHICH IS NOT ENTIRELY ACCURATE. AND TO CLARIFY, THE PRESENT PROPOSAL IS BUILT IN PRIOR WORK BY MYSELF AND PARALLEL WORK FROM MY PRIOR MENTOR, DR. TODD MCDEVITT, OF WHICH THIS IS A RESUBMISSION. AND I WAS ACTUALLY RECRUITED INTO THE MCDEVITT TEAM AT GLADSTONE INSTITUTES AND TOOK OVER THE SPINAL CORD INJURY PROGRAM TO GATHER PILOT DATA FOR THE



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

PRESENT PROPOSAL, AND I'VE BEEN LEADING THIS PROGRAM FOR SEVERAL YEARS NOW AND IN CHARGE OF THE DEDICATED FUNDS AND PERSONNEL.

THERE WAS SOME CONCERN THAT I HAD LITTLE EXPERIENCE MANAGING A RESEARCH PROGRAM OF THIS SIZE. AND I REALLY JUST WANTED TO NOTE THAT, IN TAKING OVER THE SPINAL CORD INJURY PROGRAM AT GLADSTONE INSTITUTES, I HAVE HELPED BRING IN AROUND $400,000 IN FUNDING TO SUPPORT AND BUILD THE PROGRAM. AND IT IS NOW FROM THIS THAT I WOULD LIKE TO BUILD FURTHER WITH THE PRESENT PROPOSAL OF IDENTIFYING A POSSIBLE THERAPEUTIC TARGET THAT WE'RE VERY EXCITED ABOUT AND I FEEL PREPARED TO MANAGE.

I AM VERY PLEASED TO HAVE SUPPORT FROM MANY SENIOR SCIENTISTS AT GLADSTONE, INCLUDING THE PRESIDENT OF OUR INSTITUTE, DR. DEEPAK SRIVASTAVA, WHO PROVIDED A LETTER OF SUPPORT FOR MYSELF AND THIS PROPOSAL, MY PRIOR MENTOR WHO NOW HAS LEFT GLADSTONE, AND HE IS AT SANAX THERAPEUTICS, LEAVING ME IN CHARGE.

MY COLLEAGUES IN THE FIELD OF SPINAL CORD INJURY AND TRANSPLANTATION RESEARCH ARE CLINICAL PROFESSIONALS THAT VOLUNTEER THEIR TIME TO MEET REGULARLY AND INDIVIDUALS LIVING WITH A SPINAL CORD INJURY SUCH AS ROMAN REED, WHO'S AN ONGOING



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

SUPPORTER OF OUR WORK AND WHO ALSO MEETS REGULARLY WITH US. I REALLY HOPE THAT I COULD CLARIFY SOME POINTS AND NOW ALLEVIATE SOME OF THE MINOR CONCERNS THAT SOME OF THE REVIEWERS HAD. AND I THANK YOU FOR THIS OPPORTUNITY TO MEET AND SPEAK WITH YOU. AND THANK YOU FOR THE WORK THAT YOU ARE DOING.

CHAIRMAN THOMAS: SORRY. THANK YOU. DEEPAK, YOU'RE NEXT.

DR. SRIVASTAVA: THANK YOU, JON. MY NAME IS DEEPAK SRIVASTAVA. AS LANA MENTIONED, I DO SERVE AS PRESIDENT OF THE GLADSTONE INSTITUTES. I THOUGHT I WOULD JUST COMMENT, MAKE A COMMENT ON LANA'S SUGGESTIONS.

THE MAJOR FEATURE THAT LOWERED THE SCORE OUT OF THE FUNDABLE RANGE WAS, IN FACT, THIS CONCERN ABOUT EXPERIENCE. I SHOULD SAY THAT LANA, IT SEEMS TO ME, TO BE AN EXTRAORDINARY TALENT WHO I'VE BEEN IMPRESSED WITH HOW PROMINENT HER RECOGNITION IS ALREADY IN THE SPINAL CORD INJURY FIELD, AS I'VE COME TO UNDERSTAND IT. AND IF THERE WERE, AFTER DR. MCDEVITT THAT LEFT GLADSTONE TO GO TO SANA, LANA HAS REALLY SINGLE-HANDEDLY LED THE EFFORT, AND WE'VE BEEN ABLE TO RAISE PHILANTHROPIC DOLLARS THAT SHE HAS DIRECTED TO GET TO THIS POINT FOR THIS APPLICATION.

FUNDING THIS APPLICATION, I THINK, WOULD REALLY ACCELERATE THE WORK IN SPINAL CORD INJURY THAT HAD VERY POSITIVE SCIENTIFIC RECOMMENDATIONS. IN ADDITION, IF THERE'S ANY CONCERN ABOUT INSTITUTIONAL COMMITMENT, THEN I CAN CERTAINLY ADDRESS THAT FROM MY ROLE IN THAT WE ARE COMMITTED TO THIS AREA, THE STEM CELL AREA IN GENERAL, AS YOU ALL KNOW, BUT LANA SPECIFICALLY AND THE SPINAL CORD INJURY WORK THAT SHE'S DOING, I COULDN'T BE MORE EXCITED ABOUT IT. AT GLADSTONE WE ARE COMMITTED TO SUPPORTING IT. THANK YOU SO MUCH.

CHAIRMAN THOMAS: THANK YOU, DEEPAK. MARIA, DO YOU WANT TO CALL THE NEXT GUEST PLEASE.

MS. BONNEVILLE: IT IS JEANNE PAZ.

MS. PAZ: CAN YOU HEAR ME?

MS. BONNEVILLE: YES.

CHAIRMAN THOMAS: YES.

MS. PAZ: SO I WOULD LIKE TO THANK CIRM AND ALL THE REVIEWERS FOR A CAREFUL REVIEW OF OUR PROPOSAL. THE PROPOSAL NUMBER IS DISC2-13533, ENTITLED "GENE THERAPY VECTOR CORRECTING ENDOPLASMIC RETICULUM STRESS AND GABA UPTAKE DEFECT IN MYOCLONIC ATONIC EPILEPSY."

OUR DISC2 PROPOSAL FOCUSES ON THE DESPERATELY NEEDED TREATMENT FOR A RARE, DEVASTATING

NEURODEVELOPMENTAL DISORDER CALLED SLC6A1 SYNDROME. THIS GENE REGULATES BRAIN DEVELOPMENT AND EXCITABILITY IN CHILDREN WITH MUTATIONS IN THIS GENE WHO SUFFER FROM AUTISM, DEBILITATING EPILEPTIC SEIZURES, SLEEP, ATTENTION, AND MOTOR DEFICITS.

SLC6A1 MUTATIONS CAN CAUSE DEATH IN CHILDREN. MY INVESTIGATOR, N. MATHARU, AND I ARE ACTUALLY INVOLVED WITH THE SLC6A1 PATIENT ORGANIZATION, AND WE KNOW THE KIDS FOR WHOM WE ARE DEVELOPING THESE THERAPIES. DEVELOPING AND VALIDATING TREATMENTS FOR FDA APPROVAL REQUIRES AN ANIMAL MODEL. SLC6A1 RECENTLY DEVELOPED THE FIRST MOUSE MODEL THAT OUR LAB WAS THE FIRST TO CHARACTERIZE.

THIS MOUSE MODEL HAS SEVERE SEIZURES. MY CO-INVESTIGATOR AND I, DR. MATHARU, WERE APPROACHED BY CIRM IN 2021 TO SUBMIT A PROPOSAL ON DEVELOPING A GENE THERAPY FOR THIS DISORDER.

AFTER DISCUSSING THE PROJECT, WE WERE ADVISED TO APPLY FOR THE DISC2 FUNDING OPPORTUNITY, DEFINED AS AN OPPORTUNITY FOR EARLY STAGE PROJECTS THAT ARE HIGH RISK, HIGH REWARD. AND WE SUBMITTED A PROPOSAL TO GET FUNDS TO DEVELOP A NEW VECTOR DURING THE FIRST SIX MONTHS OF THE PROPOSAL, AND THEN TO USE THIS VECTOR IN OUR MOUSE MODEL THAT HAS A



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

MUTATION THAT WAS DISCOVERED IN A CHILD WITH THE DISORDER.

IN THE PROPOSAL WE DOCUMENTED THE FEASIBILITY OF THE APPROACH AND A CAREFUL CHARACTERIZATION OF THE FIRST MOUSE MODEL OF THIS DISORDER. AGAIN, I WANT TO EMPHASIZE THAT THIS DISORDER CANNOT BE STUDIED IN ORGANOIDS OR CELLS. YOU DO NEED A MOUSE MODEL THAT HAS SEIZURES IN ORDER TO GET AN FDA APPROVAL LATER ON. SO WE HAVE THAT FIRST MOUSE MODEL.

SO DURING THE FIRST REVIEW, WE GOT A SCORE OF 80. THE REVIEWERS EXPRESSED A SIGNIFICANT ENTHUSIASM, AND THEY ALL EMPHASIZED THAT THIS COULD BE REALLY LIFE CHANGING IF THIS WORKED AND THAT IT WAS A GOOD PROPOSAL FOR A HIGH RISK, HIGH REWARD PROGRAM. HOWEVER, THE MAIN CONCERN WAS THAT WE DIDN'T HAVE THE VECTOR YET, BUT WE NEEDED FUNDING TO GET THE VECTOR. AFTER DISCUSSING WITH CIRM IN 2121, WE WERE TOLD THAT IF WE ALREADY HAD VALIDATED THE VECTOR, WE WOULD NOT BE APPLYING FOR DISC2. WE WOULD BE APPLYING FOR THE NEXT STEP, WHICH WOULD BE THE PRECLINICAL TRANSLATIONAL STEP. SO WE WERE GETTING --

MS. BONNEVILLE: YOU'VE EXCEEDED THE THREE MINUTES. IF YOU COULD WRAP THAT UP, THAT WOULD BE

GREAT.

DR. PAZ: SO WE WERE GIVEN THREE WEEKS TO REVISE, WHICH WAS NOT SUFFICIENT TO MAKE THE VECTOR. AND WE FEEL LIKE THE GRANT WAS REVIEWED AS AN RO1 GRANT FROM THE NIH RATHER THAN HIGH RISK, HIGH REWARD. AND I THINK MY COLLABORATOR N. MATHARU, IS HERE. SO MAYBE SHE CAN SAY A FEW WORDS TOO. THANK YOU.

MS. BONNEVILLE: NEXT PUBLIC COMMENT IS FROM MICHAEL LANE. AGAIN, AS A REMINDER, YOU HAVE THREE MINUTES.

DR. LANE: THANK YOU VERY MUCH FOR GIVING ME THE CHANCE TO TALK TODAY. I'M JUST GOING TO BE MAKING A COMMENT ON DR. ZHOLUDEVA'S PROPOSAL, WHICH IS, JUST LOOKING AT THE NUMBER REAL QUICK, I DON'T SEE IT ON THE LIST ANYMORE, BUT TO FOLLOW UP ON THE COMMENTS THAT BOTH DR. ZHOLUDEVA AND DR. SRIVASTAVA MADE, I WANTED TO FIRSTLY SAY I'M A COLLABORATOR ON THIS PROPOSAL. AND IT GIVES ME A GREAT DEAL OF PLEASURE TO BE PART OF THIS WORK.

THE WORK THAT DR. ZHOLUDEVA HAS PROPOSED IN THIS PROPOSAL IS ESSENTIALLY BUILDING AN IPS CELL THERAPY FOR SPINAL CORD INJURY AS SHE ALLUDED TO, BUT THIS IS ACTUALLY SOMETHING THAT SHE HAS DEVELOPED OVER THE LAST SEVERAL YEARS, WHICH HAS

RESHAPED THE WAY THAT CELL THERAPIES ARE BEING USED TO TREAT NEURAL INJURY AND DISEASE.

AND THERE'S A BIG SHIFT IN THE FIELD OF SPINAL CORD INJURY, ALS, AND TRANSPLANTATION FOR TREATING NEURAL INJURIES AND DISEASE WHICH HAS ESSENTIALLY RESULTED FROM LANA'S PRIOR WORK, WHICH SHE'S NOW DEVELOPING CELLULAR ENGINEERING STRATEGIES TO MAKE CELLS SPECIFIC FOR REPAIRING INJURED SUBSTRATES. THIS IS SOMETHING THAT HAS NOT BEEN DONE IN THE HUGE AMOUNT OF WORK THAT'S BEEN DONE OVER THE LAST SEVERAL DECADES.

I MYSELF HAVE BEEN WORKING IN THE FIELD OF SPINAL CORD INJURY FOR MORE THAN 20 YEARS NOW, AND THIS RECENT SHIFT IN THINKING AS HOW WE CAN USE CELLS TO MORE EFFECTIVELY REGENERATE INJURED NERVOUS TISSUE IS ESSENTIALLY BUILDING OFF THE WORK THAT TODD MCDEVITT HAS DONE AND IN THE WORK THAT LANA ZHOLUDEVA DID IN PARALLEL.

I ALSO WANT TO COMMEND THE GLADSTONE INSTITUTES FOR PROVIDING A GREAT DEAL OF SUPPORT FOR UP AND COMING, RISING SUPERSTARS IN THE FIELD OF SPINAL CORD INJURY AND THE FIELD OF NEURAL INJURY LIKE DR. ZHOLUDEVA, AND THE SUPPORT THAT GLADSTONE ESSENTIALLY HAS GIVEN HER HAS POSITIONED HER TO BECOME A FUTURE LEADER IN THE FIELD OF SPINAL CORD



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

INJURY. AND ESSENTIALLY IN NOW RUNNING THE SPINAL CORD INJURY PROGRAM AT GLADSTONE, I LOOK FORWARD TO BEING ABLE TO WORK WITH THEIR TEAM AND ASSIST THEM ANY WAY I CAN. THANK YOU AGAIN.

CHAIRMAN THOMAS: THANK YOU VERY MUCH. MARIA, DO WE HAVE AN ADDITIONAL COMMENT?

MS. BONNEVILLE: DMITRIY, I THINK, IS NEXT PLEASE. AND AS A REMINDER, YOU HAVE THREE MINUTES.

DR. SHEYN: I JUST WANT TO MENTION A FEW POINTS THAT WERE IN MY LETTER TO THE BOARD. AND I'M TALKING ABOUT THE APPLICATION THAT PARTICULARLY DESCRIBED 13442 FOR THE INTERVERTEBRAL DISC REGENERATION.

SO THANK YOU, GIL, FOR THE SUMMARY OF THE MINORITY REPORT. JUST ONE POINT FROM THAT REPORT, THAT LOW SCORING PANELISTS WERE TALKING ABOUT LACK OF OR INSUFFICIENT AMOUNT OF PRELIMINARY DATA. WHAT I JUST WANT TO MENTION IS THAT IN OUR PREVIOUS CIRM GRANT ON THIS TOPIC, WE WERE ABLE TO SHOW FEASIBILITY OF NOTOCHORDAL CELL DIFFERENTIATION AND SHOW THEM IN A VERY TRANSLATABLE AND LARGE ANIMAL MODEL. AND IN THIS PROPOSAL WE ARE ACTUALLY TRYING TO IMPROVE THE FORMULATION OF THE DELIVERY SYSTEM. THE GOAL OF THIS STUDY IS TO FIND A CANDIDATE WITH THESE CELLS AND IN THE FINAL FORMULATION.

SO WHEN THE REVIEWERS ARE ASKING FOR FINAL FORMULATION, I THINK THIS DIRECTLY SPEAKS TO THE TARGET OF THIS PROBLEM TO FIND THE FINAL CANDIDATE. THANK YOU.

CHAIRMAN THOMAS: THANK YOU, DMITRIY. ARE THERE ANY OTHER PUBLIC COMMENTS, MARIA?

MS. BONNEVILLE: NO. THERE ARE NO HANDS RAISED.

CHAIRMAN THOMAS: OKAY. I'M GOING TO ENTERTAIN A MOTION THAT WE APPROVE THE 19 PROJECTS CURRENTLY IN THE RECOMMENDED FOR FUNDING RANGE. AND IF THERE'S ANYBODY WHO DOESN'T THINK THAT LIST IS COMPLETE OR WHATEVER, THIS IS THE TIME TO SAY SOMETHING. I'LL REMIND YOU THAT THE TWO THAT WERE ADDED WERE THE ONLY TWO THAT THE TEAM RECOMMENDED WE CURRENTLY MOVE UP. AND ALSO NOTE THAT THE NEXT SUBMISSION DATE FOR THE NEXT ROUND, WHICH WILL BE A THREE-YEAR ROUND, IS GOING TO BE AUGUST 2D. SO IT IS IN THE RELATIVELY NEAR FUTURE.

SO CAN I HAVE A MOTION THAT WE APPROVE THE 19 PROJECTS CURRENTLY IN THE RECOMMENDED FOR FUNDING RANGE?

DR. CLARK-HARVEY: SO MOVED.

DR. FISHER: SECONDED.

CHAIRMAN THOMAS: MARIA, DID YOU GET THAT?



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

THERE WERE ABOUT FIVE SO MOVES IN THERE.

MS. BONNEVILLE: NO, I DID NOT.

CHAIRMAN THOMAS: LEONDRA MOVED.

DR. FISHER: FRED SECONDED.

CHAIRMAN THOMAS: OKAY. THANK YOU.

IS THERE DISCUSSION BY MEMBERS OF THE BOARD ON THIS MOTION? OKAY. IS THERE DISCUSSION BY MEMBERS OF THE PUBLIC? AND REMEMBER THIS IS ABOUT APPROVING THE 19 PROJECTS LISTED IN THE RECOMMENDED FOR FUNDING RANGE? MARIA.

MS. BONNEVILLE: LET ME GO TO THE VOTE. I WANT TO MAKE SURE I CAPTURE EVERYTHING. OKAY. AS A REMINDER --

CHAIRMAN THOMAS: MARIA, BEFORE YOU SAY ANYTHING, YOU REMINDED ME PREVIOUSLY, WHICH I WAS REMISS IN DOING, IS THERE ANY MOTION TO REMOVE ANY OF THE PROJECTS RECOMMENDED FOR FUNDING FROM THE RECOMMENDED FOR FUNDING RANGE?

MS. BONNEVILLE: THAT'S A DIFFERENT MOTION, J.T. DO YOU WANT TO ENTERTAIN THAT MOTION FIRST?

CHAIRMAN THOMAS: WELL, I JUST WANTED TO SEE IF THERE WAS A MOTION. DOESN'T SOUND LIKE THERE IS ONE.

MS. BONNEVILLE: KEVIN, FROM A PROCEDURAL



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

STANDPOINT, I LEAVE THIS UP TO YOU.

DR. MARKS: FROM A PROCEDURAL STANDPOINT, WE HAVE A MOTION ON THE FLOOR. IF THAT MOTION WERE TO BE WITHDRAWN, THAT'S WITH THE PERMISSION OF THE MOVER AND THE SECOND.

CHAIRMAN THOMAS: I DON'T THINK THAT'S NECESSARY BECAUSE THERE WAS NO INDICATION OF ANY INTEREST IN THE SUBSEQUENT MOTION, IF THAT'S OKAY, KEVIN.

MR. MARKS: THAT'S FINE.

CHAIRMAN THOMAS: MARIA, WILL YOU PLEASE CALL THE ROLL ON THE MOTION TO APPROVE THE 19 PROJECTS CURRENTLY IN THE RECOMMENDED FOR FUNDING RANGE.

MS. BONNEVILLE: YES. AND AS A REMINDER, YOU CAN VOTE YES OR NO EXCEPT FOR THOSE WITH WHICH YOU HAVE A CONFLICT.

LEONDRA CLARK-HARVEY.

MS. CLARK-HARVEY: YES.

MS. BONNEVILLE: ANNE-MARIE DULIEGE.

DR. DULIEGE: YES.

MS. BONNEVILLE: YSABEL DURON.

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

MS. BONNEVILLE: MARK FISCHER-COLBRIE.



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

DR. FISCHER-COLBRIE: YES.
MS. BONNEVILLE: FRED FISHER.
DR. FISHER: YES.
MS. BONNEVILLE: DAVID HIGGINS.
DR. HIGGINS: YES.
MS. BONNEVILLE: STEVE JUELSGAARD.
MR. JUELSGAARD: YES.
MS. BONNEVILLE: RICH LAJARA.
LAUREN MILLER-ROGEN.
MS. MILLER-ROGEN: YES.
MS. BONNEVILLE: ADRIANA PADILLA.
DR. PADILLA: YES.
MS. BONNEVILLE: AL ROWLETT.
MR. ROWLETT: YES.
MS. BONNEVILLE: MARVIN SOUTHARD.
DR. SOUTHARD: YES.
MS. BONNEVILLE: JONATHAN THOMAS.
CHAIRMAN THOMAS: YES.
MS. BONNEVILLE: ART TORRES.
MR. TORRES: AYE, EXCEPT FOR THOSE WITH WHICH I AM CONFLICTED.
MR. LAJARA: THIS IS RICH. ARE YOU GUYS ABLE TO HEAR ME?
MS. BONNEVILLE: NOW WE CAN.
MR. LAJARA: YES.



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

MS. BONNEVILLE: THANK YOU. THE MOTION PASSES.

CHAIRMAN THOMAS: THANK YOU. OKAY. THE ONLY REMAINING ORDER OF BUSINESS ON THE VOTES IS DO I HAVE A MOTION TO NOT APPROVE THOSE PROJECTS THAT REMAIN IN THE NOT RECOMMENDED FOR FUNDING RANGE?

DR. DULIEGE: I MOTION.

CHAIRMAN THOMAS: MOVED BY ANNE-MARIE. DO I HAVE A SECOND?

DR. SOUTHARD: SECOND.

CHAIRMAN THOMAS: IS THERE ANY DISCUSSION BE MEMBERS OF THE BOARD? ANY DISCUSSION BY MEMBERS OF THE PUBLIC? AND I WOULD REMIND THOSE WHO SPOKE -- FIRST OF ALL, THANK YOU VERY MUCH FOR THAT, BUT THIS WOULD NOT BE A TIME TO SPEAK AGAIN ON THAT JUST TO REITERATE THOSE POINTS. YES, FRED.

DR. FISHER: APOLOGIES. COULD YOU JUST REPEAT THE MOTION?

CHAIRMAN THOMAS: THE MOTION IS TO NOT APPROVE FOR FUNDING THOSE PROJECTS THAT REMAIN IN THE NOT RECOMMENDED FOR FUNDING RANGE, WHICH ARE THOSE IN THE WHITE ON THE POSTED SPREADSHEET ON THE SCREEN.

DR. FISHER: THANK YOU.

CHAIRMAN THOMAS: ANY OTHER COMMENTS OR

QUESTIONS BY MEMBERS OF THE BOARD? ANY COMMENT FROM MEMBERS OF THE PUBLIC? MARIA, WILL YOU PLEASE CALL THE ROLL.

MS. BONNEVILLE: YES. AGAIN, IF YOU COULD SAY YES OR NO EXCEPT FOR THOSE WITH WHICH YOU HAVE A CONFLICT.

LEONDRA CLARK-HARVEY.

MS. CLARK-HARVEY: YES.

MS. BONNEVILLE: ANNE-MARIE DULIEGE.

DR. DULIEGE: YES.

MS. BONNEVILLE: YSABEL DURON.

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

MS. BONNEVILLE: MARK FISCHER-COLBRIE.

DR. FISCHER-COLBRIE: YES.

MS. BONNEVILLE: FRED FISHER.

DR. FISHER: YES.

MS. BONNEVILLE: DAVID HIGGINS.

DR. HIGGINS: YES.

MS. BONNEVILLE: STEVE JUELSGAARD.

MR. JUELSGAARD: YES.

MS. BONNEVILLE: RICH LAJARA.

MR. LAJARA: YES.

MS. BONNEVILLE: LAUREN MILLER-ROGEN.

MS. MILLER-ROGEN: YES.



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

MS. BONNEVILLE: ADRIANA PADILLA.
DR. PADILLA: YES.
MS. BONNEVILLE: AL ROWLETT.
MR. ROWLETT: YES.
MS. BONNEVILLE: MARVIN SOUTHARD.
DR. SOUTHARD: YES.
MS. BONNEVILLE: JONATHAN THOMAS.
CHAIRMAN THOMAS: YES.
MS. BONNEVILLE: ART TORRES.
MR. TORRES: AYE, EXCEPT FOR THOSE WITH WHICH I AM IN CONFLICT.
MS. BONNEVILLE: THE MOTION CARRIES.
CHAIRMAN THOMAS: THANK YOU VERY MUCH, MARIA. THANK YOU, EVERYBODY, FOR THAT ROBUST DISCUSSION AND CONSIDERATION. THANK YOU TO ALL THOSE WHO COMMENTED.
I WOULD ENCOURAGE THOSE OF YOU THAT DID NOT GET AWARDS TODAY TO REAPPLY, IF THAT'S THE APPROPRIATE MOVE, ON AUGUST 2D.
THAT CONCLUDES THE APPLICATION REVIEW SUBCOMMITTEE PORTION OF THE MEETING. IS THERE ANY PUBLIC COMMENT ON ITEMS IN GENERAL?
MS. BONNEVILLE: THERE IS NONE.
CHAIRMAN THOMAS: OKAY. HEARING THAT, THAT CONCLUDES TODAY'S BUSINESS. THANK YOU ALL. I



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

WANT TO REMIND EVERYBODY WE HAVE A MEETING OF THE FULL BOARD ON NEXT MONDAY AND LOOK FORWARD TO SEEING YOU ALL THEN. TILL THEN, HAVE A GREAT REST OF YOUR WEEK AND WEEKEND. AND, MARIA, THANK YOU FOR ALL YOUR WORK IN NAVIGATING THROUGH THIS, AS ALWAYS, AND TO EVERYBODY ON THE TEAM FOR THEIR HELP.

ALL RIGHT. WE STAND ADJOURNED. THANKS VERY MUCH.

(THE MEETING WAS THEN CONCLUDED AT 10:25 A.M.)



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

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 APPLICATION REVIEW SUBCOMMITTEE OF THE INDEPENDENT CITIZEN'S OVERSIGHT COMMITTEE OF THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE IN THE MATTER OF ITS REGULAR MEETING HELD ON JUNE 23, 2022, WAS HELD AS HEREIN APPEARS AND THAT THIS IS THE ORIGINAL TRANSCRIPT THEREOF AND THAT THE STATEMENTS THAT APPEAR IN THIS TRANSCRIPT WERE REPORTED STENOGRAPHICALLY BY ME AND TRANSCRIBED BY ME. I ALSO CERTIFY THAT THIS TRANSCRIPT IS A TRUE AND ACCURATE RECORD OF THE PROCEEDING.

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