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:	CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE 1999 HARRISON STREET, SUITE 1650 OAKLAND, CALIFORNIA
DATE:	THURSDAY, OCTOBER 26, 2017 11 A.M.
REPORTER:	BETH C. DRAIN, CSR CA CSR. NO. 7152
FILE NO.:	2017-22

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THURSDAY, OCTOBER 26, 2017; 11 A.M.

CHAIRMAN THOMAS: I'D LIKE TO WELCOME EVERYBODY TO THE REGULAR MEETING OF THE ICOC AND THE APPLICATION REVIEW SUBCOMMITTEE FOR THIS OCTOBER 2017. MARIA, WILL YOU PLEASE CALL THE ROLL.

MS. BONNEVILLE: ANNE-MARIE DULIEGE.

DR. DULIEGE: YES. PRESENT.

MS. BONNEVILLE: DAVID HIGGINS.

DR. HIGGINS: HERE.

MS. BONNEVILLE: STEVE JUELSGAARD. SHERRY LANSING. DAVID MARTIN.

DR. MARTIN: HERE.

MS. BONNEVILLE: LAUREN MILLER.

MS. MILLER: HERE.

MS. BONNEVILLE: ADRIANA PADILLA.

DR. PADILLA: HERE.

MS. BONNEVILLE: JOE PANETTA.

MR. PANETTA: HERE.

MS. BONNEVILLE: FRANCISCO PRIETO. ROBERT QUINT.

DR. QUINT: HERE.

MS. BONNEVILLE: AL ROWLETT. JEFF SHEEHY.

SUPERVISOR SHEEHY: HERE.

MS. BONNEVILLE: OS STEWARD.

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DR. STEWARD: HERE.
MS. BONNEVILLE: JONATHAN THOMAS.
CHAIRMAN THOMAS: HERE.
MS. BONNEVILLE: ART TORRES.
MR. TORRES: HERE.
MS. BONNEVILLE: DIANE WINOKUR.
MS. WINOKUR: HERE.
MS. BONNEVILLE: ARE THERE ANY OTHER BOARD MEMBERS ON THE LINE?
DR. PRIETO: YES, FRANCISCO PRIETO.
MS. BONNEVILLE: THANK YOU, FRANCISCO.
DR. JUELSGAARD: AND THIS IS STEPHAN JUELSGAARD.
MS. BONNEVILLE: THANKS, STEVE.
ARE THERE ANY MEMBERS OF THE PUBLIC AT ANY OF THE LOCATIONS?
OKAY. AND, JEFF, I DO HAVE ONE PUBLIC COMMENT TO READ WHEN IT COMES TIME.
SUPERVISOR SHEEHY: THANK YOU, MARIA.
MS. BONNEVILLE: WE HAVE A QUORUM.
CHAIRMAN THOMAS: THANK YOU, MARIA. AT THIS POINT I'D LIKE TO TURN THE MEETING OVER TO SUPERVISOR SHEEHY FOR CONSIDERATION OF ITEM NO. 3 IN THE AGENDA.
SUPERVISOR SHEEHY: THANK YOU, J.T. I

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THINK DR. PATEL IS GOING TO TAKE US THROUGH THIS; AM I CORRECT?

DR. PATEL: YES, THAT'S CORRECT.

THANK YOU, SUPERVISOR SHEEHY.

SO I'M GOING TO GO THROUGH THE SLIDES THAT ARE ON WEBEX. AND SO BRIEFLY I'M GOING TO START WITH THE OVERVIEW OF OUR CLIN PROGRAMS AND THE THREE CLIN PA'S.

SO AS EVERYONE KNOWS, THE CLIN1 PA IS INTENDED FOR IND- OR IDE-ENABLING ACTIVITIES AND IND/IDE FILING.

CLIN2 PROGRAM IS SPECIFIC FOR PHASE 1, 2, AND 3 CLINICAL STUDIES FOR STEM CELL-BASED TREATMENTS.

AND THE CLIN3 PA IS SPECIFIC FOR ADDITIONAL CLINICAL TRIAL ACTIVITY TO SUPPORT FDA REGISTRATION FOR ACTIVE CLIN2 PROJECTS.

ALL THREE APPLICATIONS UNDER YOUR CONSIDERATION TODAY ARE PART OF THE CLIN2 PROGRAM ANNOUNCEMENT.

SO THE NEXT SLIDE IS A REMINDER OF OUR SCORING SYSTEM. FOR THE CLIN PROGRAM, WE USE THE THREE-TIER SCORING SYSTEM. A TIER I SCORE INDICATES THE GWG RECOMMENDS THIS APPLICATION FOR FUNDING BECAUSE IT HAS EXCEPTIONAL MERIT. A TIER II SCORE

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FROM THE GWG WOULD INDICATE THAT THE APPLICATION HAS MINOR FLAWS AND DOES NOT WARRANT FUNDING AT THIS TIME, BUT THE APPLICANT CAN ADDRESS THESE REVIEWER CONCERNS AND RESUBMIT. TIER II RECOMMENDED APPLICATIONS HAVE BEEN RESUBMITTED BY THE APPLICANT. A TIER III GWG RECOMMENDATION INDICATES THAT THE APPLICATION HAS SIGNIFICANT FLAWS SUCH THAT FUNDING IS NOT WARRANTED AND THAT THE APPLICATION FOR THE SAME PROJECT CANNOT BE RESUBMITTED FOR AT LEAST SIX MONTHS.

AGAIN, A REMINDER THAT ALL APPLICATIONS ARE SCORED BY ALL SCIENTIFIC MEMBERS OF THE GWG WHO HAVE NO CONFLICT OF INTEREST.

SO I'M GOING TO JUMP INTO THE FIRST APPLICATION UNDER CONSIDERATION. AND THIS IS CLIN2-10388. AND THIS A PHASE 1 CLINICAL TRIAL OF A SMALL MOLECULE THERAPY FOR OSTEOARTHRITIS. SO IT'S A SMALL MOLECULE DRUG THAT ACTS ON ENDOGENOUS CARTILAGE PROGENITOR CELLS TO STIMULATE CARTILAGE GROWTH. AND IT'S INDICATED FOR OSTEOARTHRITIS, AND THIS CAN BE FOR KNEE, SHOULDER, AND HIP OSTEOARTHRITIS.

FOR THIS PARTICULAR PROJECT, THE GOAL IS TO COMPLETE A PHASE 1 CLINICAL TRIAL FOR SAFETY IN PATIENTS WITH A KNEE OSTEOARTHRITIS. THE MAJOR

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ACTIVITIES INCLUDE PHASE 1 CLINICAL STUDY AND DATA ANALYSIS AND REPORTING FOR THAT STUDY, AS WELL AS EVALUATION OF POTENTIAL BIOMARKERS THAT COULD BE USED FOR FUTURE CLINICAL DEVELOPMENT OF THIS PROJECT.

THE FUNDS REQUESTED ARE ROUGHLY $8.4 MILLION, AND THEY'RE NOT REQUIRED TO HAVE ANY CO-FUNDING FOR THIS PARTICULAR PROJECT.

THE GWG GAVE IT A TIER I RECOMMENDATION. THERE ARE ELEVEN SCORES FOR TIER I AND THREE SCORES FOR TIER II. THE CIRM TEAM CONCURS WITH THE GWG RECOMMENDATION FOR THE FULL AWARD AMOUNT OF $8.4 MILLION.

SUPERVISOR SHEEHY: SO DO I HAVE A MOTION TO EITHER ACCEPT THE CIRM TEAM RECOMMENDATION AND FUND THIS APPLICATION OR TO NOT ACCEPT THE RECOMMENDATION AND NOT TO FUND THIS APPLICATION?

MR. TORRES: MOVE TO ACCEPT THE RECOMMENDATION OF THE CIRM TEAM.

SUPERVISOR SHEEHY: DO WE HAVE A SECOND?

DR. JUELSGAARD: I SECOND IT.

SUPERVISOR SHEEHY: WE HAVE DISCUSSION?

ACTUALLY I WAS GOING TO -- SINCE NOBODY ELSE, I ACTUALLY AM GOING TO VOTE AGAINST THIS BECAUSE IT'S A SMALL MOLECULE DRUG IN

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OSTEOARTHRITIS. AND I PERSONALLY -- AND I ACTUALLY COULD PROBABLY USE THIS, TO TELL YOU THE TRUTH; BUT I JUST THINK THIS REALLY KIND OF JUMPS OUT AT ME AS ONE THAT COULD BE FUNDED BY THE PRIVATE SECTOR. WE'RE JUST LOOKING FOR PRODUCTS THAT ACT UPON STEM CELLS. THAT'S SUCH A SLIPPERY SLOPE. WE COULD PROBABLY DO ANYTHING.

SO I DON'T SEE THAT REALLY AS BEING -- THIS IS ONE OF THE LEAST CIRM-Y GRANTS I'VE SEEN. BUT, ANYWAY, THAT'S MY TWO CENTS.

ANYBODY ELSE HAVE ANY COMMENTS? OTHERWISE, WE CAN TAKE PUBLIC COMMENT AND/OR GO TO A VOTE.

DR. DULIEGE: MAYBE WE COULD ASK THE CIRM TEAM TO COMMENT ON YOUR CONCERN AS TO HOW FAR IS IT OR FOR THE SCOPE OF THE CIRM MISSION.

DR. PATEL: I CAN COMMENT ON THAT. FOR THE SMALL MOLECULE DRUG, THE MECHANISM OF ACTION IS TO ACT ON ENDOGENOUS CARTILAGE PROGENITOR CELLS THAT MAY BE PRESENT IN THE TISSUE. AND WHAT IT DOES IS THAT IT STIMULATES THEIR DIFFERENTIATION INTO CARTILAGE CELLS. AND THIS IN TURN WILL LAY DOWN MORE CARTILAGE MATRIX. THIS IS NOT CURATIVE. IT'S DISEASE MODIFYING.

SO THE IDEA IS THAT THE PATIENT WOULD HAVE

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REPEATED TREATMENTS OF THIS PARTICULAR DRUG OVER TIME AND HAVE A DISEASE-MODIFYING EFFECT ON THE PATIENT.

DR. DULIEGE: OKAY.

DR. MARTIN: A QUESTION. IS IT ADMINISTERED LOCALLY RATHER THAN SYSTEMICALLY AT THE SITE OF THE --

CHAIRMAN THOMAS: YES.

DR. MARTIN: I LIKE THE IDEA. WHAT I COULD NOT DETERMINE IS WHETHER THE PRECLINICAL STUDIES DEMONSTRATED IT WAS CLEARLY SOME TYPE OF PRECURSOR STEM CELL THAT WAS THE TARGET OF THE SMALL MOLECULE DRUG. AND IF THAT'S SO, THE ILLUSION OR THE HIT WAS SUCH THAT IT WAS A STEM CELL. IF THAT'S TRUE, THEN I WOULD HAVE NO HESITANCY TO FUND THIS. AND I THINK IT COULD ACTUALLY BE IN CIRM'S ADVANTAGE TO DO THAT. AND THAT IS, GET THE CREDIT FOR FUNDING IT RIGHT OUT OF THE GATE. AND THEN WITH THOSE DATA FROM A PHASE 1B, WHICH PRESUMABLY THIS WOULD BE, A COMMERCIAL ENTITY COULD TAKE IT OVER AND RUN WITH IT. BUT I THINK THE CHANCES OF INCREASING THE INTEREST OF THE PHARMACEUTICAL INDUSTRY IS MUCH GREATER IF YOU HAVE A PHASE 1B POSITIVE RESULT.

DR. STEWARD: MAY I ASK A QUESTION?

SUPERVISOR SHEEHY: YES, PLEASE.

DR. STEWARD: CAN YOU SAY SOMETHING ABOUT THE MILESTONES IN THIS PROJECT AND TIMING OF THOSE MILESTONES? THANK YOU.

DR. PATEL: THE MILESTONES OF THIS PROJECT ARE BEING SET RIGHT NOW BY THE CIRM SCIENCE TEAM. SO ONE OF THE MILESTONES WILL BE TO ENROLL PATIENTS AND THEN TO RECRUIT PATIENTS AND COMPLETE THE STUDY. THERE ARE ALSO MILESTONES GEARED TOWARD BIOMARKER DEVELOPMENT, AND THIS IS TO SPECIFICALLY HAVE SOME EFFICACY END POINTS THAT THEY CAN USE DOWN THE ROAD. SO THE BIOMARKER DEVELOPMENT SHOULD INFORM THEM ON THE LATER STAGE OF THE TRIAL.

SUPERVISOR SHEEHY: OTHER QUESTIONS OR COMMENTS?

THE ONLY THING I WOULD NOTE IS THAT THERE IS OPPORTUNITY COST HERE. THERE WILL BE THINGS THAT WE END UP NOT FUNDING THAT MAY BE MORE RELEVANT TO THE CORE MISSION OF CIRM AND ITS RATIONALE FOR ITS EXISTENCE. BUT THAT'S A PROGRAMMATIC ISSUE FOR ME.

ANYWAY, IF THERE'S NO OTHER COMMENTS.

DR. DULIEGE: JUST ALONG THE LINE OF WHAT YOU MENTIONED, I REALIZE THAT THE MECHANISM OF ACTION HERE OF THE SMALL MOLECULE IS TO STIMULATE THE GROWTH AND MULTIPLICATION OF STEM CELLS. AND THAT'S RELATING TO CIRM'S MISSION.

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ON THE OTHER HAND, AS YOU POINTED OUT, IF THE DEVELOPMENT OF THIS IS THE ONE SMALL MOLECULE, IT HAS THE SAME CHALLENGES OF MANUFACTURING AS ANY OTHER SMALL MOLECULE DEVELOPMENT DONE TYPICALLY BY THE PHARMACY INDUSTRY. IN WORKING IN PHARMACEUTICAL INDUSTRY, I KNOW EXACTLY WHAT THAT IS.

SO I DON'T KNOW THAT IT WOULD REQUIRE THE SAME SUPPORT IN TERMS OF CIRM SUPPORT THERE. AND I TEND TO BE SENSITIVE TO THE COMMENT YOU MADE, WHICH IS, AFTER ALL, IS IT SOMETHING THAT CIRM SHOULD FUND? WE'LL HAVE OTHER PROJECTS THAT WILL REQUIRE MORE OF THE CIRM HELP THAN THIS ONE, I BELIEVE. SO I'D LOVE TO HAVE THE CIRM TEAM, WHETHER IT'S SHYAM OR ANYONE ELSE, COMMENT ON OVERALL THE MISSION AND THIS SPECIFIC PROJECT INDEPENDENTLY OF ITS MODE OF ACTION SIMPLY AS A SMALL MOLECULE DEVELOPMENT.

DR. PATEL: ONE THING I DO WANT TO NOTE IS THAT, WHILE THIS IS A SAFETY STUDY, THEY ALSO PLAN TO GATHER PRELIMINARY EFFICACY IN THIS PHASE 1 TRIAL TO ATTRACT ADDITIONAL INVESTMENT IN THE PROJECT DOWN THE ROAD BECAUSE THEY KNOW THAT THEY'RE GOING TO NEED THAT TO FUND THE PHASE 2 AND PHASE 3 STUDIES AS WELL AS THE OVERALL DEVELOPMENT OF THIS PRODUCT.

DR. DULIEGE: IS IT A PROJECT THAT COULD MORE EASILY THAN OTHERS ATTRACT INDUSTRY FUNDING

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RIGHT FROM THE GET-GO?

DR. JUELSGAARD: COULD I SPEAK TO THE ISSUE?

SUPERVISOR SHEEHY: YEAH, STEVE. DO YOU WANT TO GO AHEAD.

DR. JUELSGAARD: SO, ANNE-MARIE, I THINK YOU KNOW AS WELL AS I THAT IN ORDER FOR OUT-LICENSING TO TAKE PLACE AND THE INDUSTRY TO STEP IN, THERE NEEDS TYPICALLY TO BE SOME DEMONSTRATION OF EFFICACY, SOME HINT OF THE WAY IT'S GOING TO WORK. TO SOME EXTENT, THAT'S DEPENDENT UPON THE INDICATION. SO THE INDUSTRY AROUND CARTILAGE REPAIR IS FAIRLY LIMITED. IT'S NOT LIKE THE ONCOLOGY AREA WHERE THERE ARE SO MANY COMPANIES INVOLVED IN IT. THIS IS A VERY SMALL GROUP OF COMPANIES THAT WOULD BE INTERESTED IN THIS. AND ONE WOULD EXPECT THAT THEY WOULD WANT A LITTLE MORE DEFINITION OF EFFICACY BEFORE THEY DECIDED TO LAUNCH IN.

SO WE IN THE PAST HAVE APPROVED A NUMBER OF SMALL MOLECULE PROJECTS WHERE THE ACTION IS AIMED AT THE STEM CELL THAT'S INVOLVED, WHETHER IT'S UP REGULATING IT OR DOWN REGULATING IT. WE'VE APPROVED THINGS GOING BOTH WAYS, HELPING IT BE ACTIVATED OR, ON THE OTHER HAND, TRYING TO KILL IT OFF. AND SO IT DOESN'T SEEM TO ME, BECAUSE I THINK THE DESCRIPTION

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IN THE CLINICAL STUDY OR THE PUBLIC SUMMARY THAT CAME WITH THIS, SEEMS PRETTY CLEAR THAT THIS DRUG IS AIMED AT WORKING ON THE STEM CELL. I DON'T SENSE MUCH ARGUMENT WITH RESPECT TO THE REVIEWERS ON THAT.

AND SO, JEFF, IT SEEMS TO ME THAT THE ISSUE THAT YOU'RE RAISING, ALTHOUGH I DIDN'T HEAR IT DIRECTLY, MAY BE MORE THE INDICATION, WHICH IS CARTILAGE GENERATION, THAN IT IS ON MECHANISM OF ACTION. SO I WOULD REALLY LIKE TO UNDERSTAND KIND OF WHERE THE PROBLEM IS HERE WITH RESPECT TO SUPPORTING THIS BECAUSE IT'S NOT EXACTLY CLEAR TO ME THAT IT HAS ANYTHING TO DO WITH THE STEM CELL ITSELF, BUT MORE MAYBE OTHER TANGENTIAL ISSUES.

DR. DULIEGE: SPECIFICALLY HERE THIS IS NOT TO DO WITH THE INDICATION ITSELF, WHICH I THINK IS VERY VALUABLE. THERE'S STILL NOT A GOOD TREATMENT FOR OSTEOARTHRITIS, AND MANY PEOPLE, INCLUDING MANY CALIFORNIANS, STILL SUFFER FROM IT.

MY CONCERN TO SOME EXTENT IS I UNDERSTAND THE MECHANISM OF ACTION, BUT IT IS THE DEVELOPMENT OF A SMALL MOLECULE WHICH IN ITSELF, IN TERMS OF MANUFACTURING AND CONTROL CHEMISTRY, IS VERY WELL KNOWN AND IS EASIER, CLEARLY EASIER, THAN DEVELOPMENT OF A PURE STEM-CELL PRODUCT. AND SO THAT'S WHERE I HAVE TO THINK A BIT AS TO WHETHER,

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GIVEN THAT WE WANT TO BE CAREFUL ABOUT OUR MONEY AND WANT TO EXTEND THE DURATION OF OUR MONEY AS MUCH AS POSSIBLE, WHETHER SUCH PROJECT IS MORE AKIN TO A SMALL MOLECULE DEVELOPMENT THAN TO A TRUE STEM-CELL PROJECT DEVELOPMENT EVEN IF ITS MECHANISM IS THROUGH STEM CELLS.

SUPERVISOR SHEEHY: STEVE, IF I CAN ADDRESS YOUR POINT TOO. SO, FIRST, AS I UNDERSTAND, IT'S NOT A CURE. SO THIS IS MULTIPLE INJECTIONS OVER TIME. BUT, SECOND, IT IS THE SMALL MOLECULE PIECE OF IT THAT I HAVE TROUBLE WITH. WE TYPICALLY, AND I MAY BE WRONG -- MY MEMORY OF THE PORTFOLIO IS NOT WHAT IT USED TO BE -- BUT WE HAVEN'T REALLY DONE SMALL MOLECULES EXCEPT IN ONCOLOGY, TARGETING CANCER STEM CELLS. IN THIS ONE I MEAN IT FEELS TO ME LIKE -- I'M JUST NOT FEELING THAT SENSE OF URGENCY HERE. AND, AGAIN, IF THERE WASN'T AN OPPORTUNITY COST HERE, I WOULD FEEL MUCH DIFFERENTLY. BUT REALLY COMING OUT OF THE LAST APPLICATION REVIEW SUBCOMMITTEE, I REALLY STARTED TO ASK MYSELF IS THIS SOMETHING THAT REALLY IS MORE ALIGNED WITH CIRM'S MISSION? TO ME IN SOME PART IT'S FUNDING STUFF THAT IS VERY HARD TO FUND, AND IT'S HARD FOR ME TO SEE -- I MEAN THERE IS NEED FOR RELIEF FOR PEOPLE WITH KNEE OSTEOARTHRITIS. I GUESS I CAN'T UNDERSTAND WHY

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THERE'S NOT INDUSTRY BACKING IF THE DATA THAT THEY'RE USING TO GET INTO THE PHASE 1 CLINICAL TRIAL IS SHOWING SUFFICIENT EFFICACY TO BE PERSUASIVE TO THE FDA AND SAFETY.

SO IF THEY HAVE SAFETY AND EFFICACY IN A SMALL MOLECULE FOR SOMETHING THAT IS NOT -- LIKE I SAID, I NEED A KNEE REPLACEMENT AT SOME POINT DUE TO OSTEOARTHRITIS. I GET WHAT IT'S ABOUT. AND, AGAIN, IT'S LIKE SAND IS FALLING THROUGH THE HOURGLASS. AND I JUST REALLY WOULD LIKE TO SEE US FOCUS ON THOSE THINGS WHERE WE CAN HAVE REALLY CELL THERAPIES AND MULTIPLE CELLS. THAT'S JUST WHERE I THINK WE CAN HAVE A GREAT IMPACT AND WHERE THERE'S REALLY A CURE AT THE END OF IT OR SOMETHING APPROACHING A CURE OR SIGNIFICANT RELIEF FOR A SIGNIFICANT UNMET MEDICAL NEED.

I DON'T WANT TO BELABOR THE POINT, BUT THAT'S JUST MY PERSPECTIVE. IT IS PROGRAMMATIC. IT'S NOT A SCIENTIFIC DECISION AND WAS PURELY A PROGRAMMATIC DECISION.

MR. TORRES: SPEAKING OF THAT, MR. CHAIRMAN, IF I MAY, I HAVE HAD ONE KNEE REPLACED AND I'M PROBABLY GOING TO HAVE TO HAVE ANOTHER ONE REPLACED. IT IS NOT A PRETTY PICTURE. SO IF WE CAN DEAL WITH THE LARGE NUMBERS OF PEOPLE IN MY AGE

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GROUP, AND OBVIOUSLY YOUR AGE GROUP NOW TOO, JEFF, THIS IS A MAJOR IMPACT ON TAXPAYERS IN CALIFORNIA THAT ARE AFFECTED BY THIS DISEASE. AND IF WE CAN SHOW THAT WE'RE AT LEAST TRYING TO FIND SOME TREATMENT, MAYBE IT'S NOT A CURE, BUT AT LEAST SOME TREATMENT THAT WILL ALLEVIATE THE PAIN, WHICH IS SUBSTANTIAL FOR OSTEOARTHRITIS VICTIMS, WE MAY BE MOVING FORWARD TO GETTING SUPPORT FOR OUR EFFORTS IN OTHER AREAS AS WELL. AND THAT'S WHY I WAS SO STRONGLY IN SUPPORT OF THIS EFFORT AS I WAS THE CHINESE CLINICAL STUDY THAT WE FUNDED AWHILE BACK AT USC, WHICH STILL HASN'T BEGUN BECAUSE OF ICE REGULATIONS UNDER THE TRUMP ADMINISTRATION.

SO I THINK THAT'S WHY I VOTED FOR THIS PROPOSAL.

SUPERVISOR SHEEHY: THE ONLY THING I MIGHT NOTE IS THAT WE DO HAVE PROJECTS IN THE PORTFOLIO USING VARIOUS TYPES OF STEM CELLS DIRECTLY; BUT, AGAIN, I TAKE YOUR POINT, SENATOR.

ANY OTHER COMMENTS?

DR. MARTIN: I WOULD SAY THAT IF IT'S FEASIBLE, IF IT ACTUALLY WORKS OR COULD WORK, STIMULATING RESIDENTIAL STEM CELLS WITHIN THE JOINT, IF THERE ARE ANY LEFT, THE EXCESS OF SMALL MOLECULE ENDOGENOUS STEM CELLS IS PROBABLY GREATER THAN

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TRYING TO GO THROUGH THE PROCESS OF CREATING THOSE STEM CELLS, WHETHER THEY BE AUTOLOGOUS OR ALLOGENEIC, AND THEN INJECT THEM INTO THE JOINT AND HAVE THEM ESSENTIALLY NOT CURE THE DISEASE, BUT, AGAIN, REPLACE SOME OF THE CARTILAGE. I LIKE THE IDEA OF USING RESIDENTIAL ENDOGENOUS CELLS AND DIFFERENTIATING THOSE INTO CARTILAGE-PRODUCING CELLS RATHER THAN HAVING TO DO CELL THERAPY IN THIS SITUATION.

MS. WINOKUR: AND I HAVE OSTEOARTHRITIS IN THE HIP WHICH I HAD COMPLETELY REPLACED BY SURGERY. AND ONCE THAT WAS DONE, I NO LONGER AM IN PAIN, CAN STILL GET MYSELF AROUND. AND I WOULD RATHER DO THAT THAN HAVE TO CONTINUOUSLY GO IN FOR NEW VERSIONS OF THIS TREATMENT.

SUPERVISOR SHEEHY: THANK YOU, DIANE. DO WE HAVE OTHER COMMENTS, QUESTIONS?

DR. DULIEGE: I WANT TO SAY I DEFINITELY BELIEVE THAT THE INDICATION IS IMPORTANT. BESIDES THAT IT'S REPEATING INJECTIONS, NO ONE KNOWS HOW FREQUENTLY IT MAY BE IN THE END IN FREQUENT INJECTIONS, WHICH WOULD BE QUITE CONVENIENT FOR THE PATIENT, WHERE I BELIEVE THAT, GIVEN THE AMOUNT OF MONEY WE HAVE, THIS PROJECT IN MY MIND DOESN'T RAISE TO A PROJECT THAT WE SHOULD HELP BECAUSE THE

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DEVELOPMENT OF THE SMALL MOLECULE, AS I INDICATED, IT'S MUCH EASIER TO DO THAN THE DEVELOPMENT OF A PURE STEM CELL-BASED PROJECT. AND IT'S MUCH AKIN TO WHAT INDUSTRY DOES IN GENERAL REALLY BASED ON PRECLINICAL DATA. SO IN MY CASE THAT'S THE REASON WHY I WILL VOTE NO.

DR. JUELSGAARD: LET ME JUST RESPOND TO THAT. NOWHERE IN THE ASK IN THE APPLICATION I'VE SEEN HAVE THEY ASKED ABOUT DEVELOPMENT OF THE SMALL MOLECULE, ABOUT THE ORGANIC CHEMISTRY THAT GOES WITH THAT. RATHER, THIS IS AIMED AT DETERMINING WHETHER OR NOT IT'S SAFE AND SOME HINT OF EFFICACY. SO THEY'VE NOT ASKED FOR ANY CMC-RELATED EFFORTS THAT I CAN SEE IN THIS.

SO IT SEEMS TO ME TO BE RELATIVELY CLEAN. IT'S REALLY JUST LOOKING AT THE EFFECT OF THE MOLECULE ON THE ENDOGENOUS STEM CELLS.

SUPERVISOR SHEEHY: OTHER QUESTIONS, COMMENTS?

DR. STEWARD: I'M JUST GOING TO ANNOUNCE THAT I'M LEANING TOWARD NO. SO JUST TO SAY THAT AND FOR ALL THE REASONS THAT EVERYONE ELSE HAS EXPRESSED. MAINLY THE FACT THAT TO ME THE LINK TO STEM CELLS SEEMS UNCLEAR. AND IN COMPARISON TO SO MANY OF THE OTHER THINGS THAT WE'RE DEALING WITH,

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THIS IS TO ME LESS OF AN URGENT UNMET MEDICAL NEED. THANK YOU.

DR. HIGGINS: CAN I ASK A FOLLOW-UP QUESTION ON THAT TO OS? OS, YOUR STATEMENT JUST NOW IS ACTUALLY PRETTY PROFOUND, THAT ITS LINK TO STEM CELLS IS NOT VERY CLEAR. IS THAT TRUE, THAT THERE'S REALLY NO CLEAR LINK TO THE STIMULATION OF STEM CELLS TO PRODUCE CARTILAGE?

DR. PATEL: I'M SORRY. DO YOU MIND REPEATING THAT QUESTION AGAIN?

DR. HIGGINS: I THINK I JUST HEARD OS SAY THAT THE LINK TO THE STIMULATION BY THE SMALL MOLECULE OF STEM CELLS IS UNCLEAR. IS THAT TRUE? BECAUSE THAT'S A GAME CHANGER FOR ME, IF THERE'S ANY LACK OF CLARITY, IS THAT THAT'S THE MECHANISM.

DR. PATEL: SO THE REVIEWERS NOTED THAT THE PRECLINICAL STUDIES TEND TO SUPPORT THAT THERE IS SOME ACTIVITY ON ENDOGENOUS STEM PROGENITOR CELLS. WHETHER THAT TRANSLATES TO HUMANS, IT NEEDS TO BE DISCOVERED IN THIS CLINICAL TRIAL.

DR. DULIEGE: JUST TO CLARIFY, AND I'M REVIEWING THE INFORMATION THAT WE RECEIVED, I THINK THE LINK IS PRETTY CLEAR. IN MY MIND, IT'S SIMPLE. IT'S SIMPLE. IT'S A SMALL MOLECULE REFERRED TO AS KA34 THAT PROMOTES THE DIFFERENTIATION OF CARTILAGE

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ENDOGENOUS STEM CELLS THROUGH INCREASED GENE EXPRESSION. SO THE LINK IS THERE. THE MECHANISM OF ACTION IS THERE. FOR ME THAT'S CLEAR. AGAIN, I SAID THE REASON WHY I WILL VOTE NO.

DR. HIGGINS: THAT HELPS ME A LOT. JUST WHEN OS SPEAKS, I LISTEN.

DR. STEWARD: THANK YOU, DAVID. I GUESS TO ME, YES, THERE IS EVIDENCE. IS THE EVIDENCE COMPELLING? I WASN'T COMPELLED. I'M PREPARED TO LISTEN, BUT IT ISN'T AS CLEAR TO ME AS SOME OF THE OTHER THINGS THAT WE LOOK AT. THAT'S ALL. SO I'M NOT ABSOLUTELY NO. I'M STILL THINKING, BUT I AM LEANING TOWARD A NO ON THIS ONE. THANK YOU.

SUPERVISOR SHEEHY: OTHER COMMENTS? DISCUSSION? QUESTIONS? PUBLIC COMMENT?

MS. BONNEVILLE: I HAVE A LETTER THAT DON REED WANTED ME TO READ INTO THE RECORD.

FROM DON REED: "EVERY SCIENTIFIC GOAL CIRM TAKES ON IS A WORTHY ONE FROM BOTH HUMANITARIAN AND ECONOMIC REASONS, BUT SELDOM ARE THOSE TWO REASONS MORE WOVEN TOGETHER THAN THE POSSIBILITY OF ALLEVIATING ARTHRITIS.

"IN 2003 THE COST OF ARTHRITIS AND OTHER RHEUMATIC CONDITIONS WAS ESTIMATED AT $128 BILLION, 80 BILLION DIRECT, 40 BILLION INDIRECT, AS IN TIME

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LOST FROM WORK. THE PAIN CANNOT BE QUANTIFIED. EVERY TIME I FOLLOW MY WIFE DOWNSTAIRS, SHE WILL SAY, 'PASS ME UP,' BECAUSE SHE CANNOT GO TOO FAST. JUST TO WATCH HER GOING UP OR DOWNSTAIRS IS PAINFUL BECAUSE EACH STEP FOR HER IS A SMALL SEPARATE AGONY. SHE BRACES HERSELF HOLDING ONTO THE RAILING, FULLY EXTENDS THE FOOT, AND THEN GRADUALLY SHIFTS HER WEIGHT. HER FACE CONTORTS WITH THE PAIN. SHE PLANS HER DAY SO SHE DOES NOT HAVE TO GO UP THE STAIRS UNTIL NIGHTFALL. AND THIS IS JUST ONE SMALL PHYSICAL ACTIVITY FOR THE FORMER ATHLETE NOW SEVERELY LIMITED BY HER ARTHRITIS.

"IF CLIN2-10388 IS SUCCESSFUL, IT IS THE THING THAT WILL BE CHEERED FOR BY MILLIONS, THOSE WHO SUFFER THE PAIN OF WALKING WITHOUT PROPER KNEE CARTILAGE AND ALSO WE WHO FETCH AND CARRY FOR THEM. THANK YOU FOR CONSIDERING WHAT MAY BRING RELIEF TO MANY. BEST, DON REED."

SUPERVISOR SHEEHY: THANK YOU, MARIA. DO WE HAVE ANY OTHER -- I GUESS THAT'S WHERE WE ARE. WE'RE DONE WITH PUBLIC COMMENT. CAN WE CALL THE ROLL THEN.

MS. BONNEVILLE: ANNE-MARIE DULIEGE.

DR. DULIEGE: NO.

MS. BONNEVILLE: DAVID HIGGINS.

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DR. HIGGINS: YES.
MS. BONNEVILLE: STEVE JUELSGAARD.
MR. JUELSGAARD: YES.
MS. BONNEVILLE: DAVID MARTIN.
DR. MARTIN: YES.
MS. BONNEVILLE: LAUREN MILLER.
MS. MILLER: YES.
MS. BONNEVILLE: ADRIANA PADILLA.
DR. PADILLA: YES.
MS. BONNEVILLE: JOE PANETTA.
MR. PANETTA: YES.
MS. BONNEVILLE: FRANCISCO PRIETO.
DR. PRIETO: AYE.
MS. BONNEVILLE: ROBERT QUINT.
DR. QUINT: NO.
MS. BONNEVILLE: JEFF SHEEHY.
SUPERVISOR SHEEHY: NO.
MS. BONNEVILLE: OS STEWARD.
DR. STEWARD: NO.
MS. BONNEVILLE: JONATHAN THOMAS.
CHAIRMAN THOMAS: YES.
MS. BONNEVILLE: ART TORRES.
MR. TORRES: AYE.
MS. BONNEVILLE: DIANE WINOKUR.
MS. WINOKUR: NO.

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MS. BONNEVILLE: MOTION CARRIES. NINE TO FIVE: 9 YES, 5 NOES.

SUPERVISOR SHEEHY: THANKS, MARIA.

SO, DR. PATEL, CAN WE PROCEED TO THE NEXT PROJECT.

DR. PATEL: YES. SO THE NEXT ONE IS CLIN2-10392. THIS IS PHASE 1-2 TRIAL OF A CELL THERAPY FOR VIRAL INFECTION.

SO THE THERAPY HERE IS PARTIALLY HLA-MATCHED VIRUS-SPECIFIC T CELLS, WHICH IS QUITE A MOUTHFUL. THE INDICATION HERE IS FOR PERSISTENT VIRAL INFECTIONS IN PATIENTS WITH IMMUNODEFICIENCY. AND THEY'RE TARGETING THREE DIFFERENT VIRAL INFECTIONS HERE: CYTOMEGALOVIRUS, CMV, EPSTEIN-BARR, AND ADENOVIRUS. AND THE GOAL FOR THIS PARTICULAR PROJECT IS TO COMPLETE A PHASE 1/2 CLINICAL TRIAL TO ASSESS BOTH SAFETY AND EFFICACY OF THIS T-CELL THERAPY IN PATIENTS.

THE MAJOR PROPOSED ACTIVITIES INCLUDE TO ASSESS THE SAFETY OF ADMINISTERING THIS PRODUCT TO THE PATIENT AND TO ASSESS THE EFFICACY OF THE PRODUCT AND OVERALL PATIENT SURVIVAL AT SIX AND TWELVE MONTHS.

THE FUNDS REQUESTED ARE ROUGHLY 4.8 MILLION. AND THE GWG RECOMMENDATION HERE WAS TIER

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I. THERE WERE NINE TIER I SCORES AND ONE TIER II SCORE. CIRM TEAM CONCURS WITH THE RECOMMENDATION FOR THE FULL AWARD AMOUNT OF 4.8 MILLION.

SUPERVISOR SHEEHY: THANK YOU, DR. PATEL.

DO I HAVE A MOTION TO EITHER ACCEPT THE TEAM RECOMMENDATION AND FUND THIS PROJECT, OR DO I HAVE A MOTION TO NOT ACCEPT THE TEAM RECOMMENDATION AND NOT FUND IT?

DR. DULIEGE: I CAN MAKE THE MOTION TO ACCEPT.

SUPERVISOR SHEEHY: DO I HAVE A SECOND?

DR. JUELSGAARD: I SECOND.

SUPERVISOR SHEEHY: THANK YOU. DO WE HAVE ANY BOARD DISCUSSION? DO WE HAVE ANY PUBLIC COMMENT? MARIA, COULD YOU CALL THE ROLL PLEASE.

MS. BONNEVILLE: ANNE-MARIE DULIEGE.

DR. DULIEGE: AYE.

MS. BONNEVILLE: DAVID HIGGINS.

DR. HIGGINS: YES.

MS. BONNEVILLE: STEVE JUELSGAARD.

MR. JUELSGAARD: YES.

MS. BONNEVILLE: DAVID MARTIN.

DR. MARTIN: YES.

MS. BONNEVILLE: LAUREN MILLER.

MS. MILLER: YES.

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MS. BONNEVILLE: ADRIANA PADILLA.
DR. PADILLA: YES.
MS. BONNEVILLE: JOE PANETTA.
MR. PANETTA: YES.
MS. BONNEVILLE: FRANCISCO PRIETO.
DR. PRIETO: AYE.
MS. BONNEVILLE: ROBERT QUINT.
DR. QUINT: YES.
MS. BONNEVILLE: JEFF SHEEHY.
SUPERVISOR SHEEHY: YES.
MS. BONNEVILLE: OS STEWARD.
DR. STEWARD: YES.
MS. BONNEVILLE: JONATHAN THOMAS.
CHAIRMAN THOMAS: YES.
MS. BONNEVILLE: ART TORRES.
MR. TORRES: AYE.
MS. BONNEVILLE: DIANE WINOKUR.
MS. WINOKUR: YES.
MS. BONNEVILLE: MOTION CARRIES.
SUPERVISOR SHEEHY: THANK YOU, MARIA.
SO, DR. PATEL, CAN WE GO TO THE NEXT AND FINAL PROJECT PLEASE.
DR. PATEL: SO THE LAST ONE IS A CLIN2-10395 APPLICATION. THIS IS FOR A PHASE 1 CLINICAL TRIAL OF A CELL THERAPY FOR MULTIPLE

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MYELOMA. AND THE THERAPY HERE IS STEM CELL MEMORY CHIMERIC ANTIGEN RECEPTOR CAR-T CELLS. AND THEY'RE TARGETING THE B CELL MATURATION ANTIGEN BCMA IN MYELOMA CELLS. AND THE INDICATION HERE IS MULTIPLE MYELOMA.

AND THE GOAL OF THIS PROJECT IS TO COMPLETE A PHASE 1 CLINICAL TRIAL TO ASSESS SAFETY OF THE CAR-T CELL THERAPY. AND THEY HAVE MAJOR ACTIVITIES HERE TO MANUFACTURE THE PRODUCT AS AN AUTOLOGOUS T-CELL PRODUCT, AND THEY'RE GOING TO ENROLL, TREAT, AND FOLLOW UP THE PATIENTS. AND, FINALLY, THEY'RE GOING TO CONDUCT NONCLINICAL SAFETY STUDIES, AND THIS IS FOR AN IND AMENDMENT TO USE THE SAFETY SWITCH.

THE FUNDS REQUESTED ARE ROUGHLY $20 MILLION, AND THEY'RE CO-FUNDING $8.6 MILLION. THE GWG RECOMMENDATION HERE WAS A TIER I, AND IT WAS A UNANIMOUS TIER I RECOMMENDATION WITH ALL TEN REVIEWERS GIVING IT A TIER I SCORE. THE CIRM TEAM CONCURS WITH THIS RECOMMENDATION, BUT FOR THE AWARD AMOUNT THAT IS REDUCED BY THE GRANTS MANAGEMENT OFFICE TO $19,813,407. SUPERVISOR SHEEHY.

SUPERVISOR SHEEHY: THANK YOU, DR. PATEL.

COULD I GET A MOTION TO EITHER ACCEPT THE TEAM RECOMMENDATION AND FUND THIS APPLICATION, OR TO

NOT ACCEPT THE TEAM RECOMMENDATION AND TO NOT FUND THIS APPLICATION?

DR. PRIETO: I'LL MOVE TO ACCEPT.

SUPERVISOR SHEEHY: DO I HAVE A SECOND?

DR. DULIEGE: I SECOND IT.

SUPERVISOR SHEEHY: ANY BOARD COMMENTS, QUESTIONS, DISCUSSION?

DR. DULIEGE: I HAVE ONE QUESTION. CLEARLY THE SCIENTIFIC ENDEAVOR IS EXTREMELY IMPORTANT. MY QUESTION IS ABOUT THE AMOUNT OF FUNDING. ARE WE ASKED TO SUPPORT FUNDING OF $19 MILLION INDEED? WERE THERE ANY REDUCTIONS IN FUNDING, OR CAN WE CLARIFY THAT POINT? THANK YOU.

DR. PATEL: SO THE MAJOR DRIVERS FOR THIS BUDGET ARE THE MANUFACTURING COSTS AS WELL AS THE TRIAL SIZE ITSELF COULD BE UP TO 40 PATIENTS BECAUSE THEY HAVE MULTIPLE COHORTS. IT'S A DOSE ESCALATION STUDY. GIVEN THAT, THEY COULD REACH THE FINAL OUTCOME WITH A LOWER COHORT OF LESS PATIENTS THAN THE PROJECTED 40. IN THAT PARTICULAR INSTANCE, CIRM DOES HAVE A CALL-BACK THAT THEY CAN PUT INTO THE CONTRACT ALLOWING US TO CLAIM BACK SOME OF THE MONEY IF THEY ARE ABLE TO REACH THEIR TRIAL CONCLUSION WITHOUT ENROLLING ALL 40 PATIENTS.

THIS IS ALSO A MILESTONE-BASED PROJECT.

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SO IF THE PERFORMANCE OF THE PROJECT IS NOT PROGRESSING AS EXPECTED, THAT COULD REDUCE THE MILESTONE PAYMENTS GOING FORWARD.

DR. DULIEGE: THANK YOU VERY MUCH.

DR. MARTIN: I HAVE A QUESTION ABOUT THE EVIDENCE WHICH I'M SURE THE REVIEWERS LOOKED AT, THAT THE T-CELLS BEING USED ARE ACTUALLY STEM CELLS AND CENTRAL MEMORY STEM CELLS BECAUSE THAT IS, IN MY EXPERIENCE, AND I HAPPEN TO WORK IN THIS FIELD A BIT, IS SOMETIMES RATHER VAGUELY DEFINED. ARE THESE REALLY SCM'S?

DR. PATEL: SO THE ACCEPTED WAY OF DETERMINING THAT IS TO LOOK AT THE CELL MARKERS. IN THIS PARTICULAR INSTANCE, WHEN THEY ENRICH FOR THE CELLS AT THE END OF THE MANUFACTURING PROCESS, THERE IS A VERY HIGH PROPORTION OF STEM CELL MEMORY T-CELLS PRESENT, AND THE REVIEWERS AGREED WITH THIS IN THEIR REVIEW OF THE APPLICATION. WHETHER THOSE T-CELLS WILL LEAD TO CLINICAL BENEFIT NEEDS TO BE FIGURED OUT IN THIS PARTICULAR TRIAL.

DR. MARTIN: THESE ARE AUTOLOGOUS T-CELLS?

DR. PATEL: YES.

DR. MARTIN: THANK YOU.

SUPERVISOR SHEEHY: OTHER QUESTIONS OR COMMENTS? ANY PUBLIC COMMENT? MARIA, CALL THE ROLL

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PLEASE.

MS. BONNEVILLE: ANNE-MARIE DULIEGE.

DR. DULIEGE: YES, I SUPPORT.

MS. BONNEVILLE: DAVID HIGGINS.

DR. HIGGINS: YES.

MS. BONNEVILLE: STEVE JUELSGAARD.

MR. JUELSGAARD: YES.

MS. BONNEVILLE: DAVID MARTIN.

DR. MARTIN: YES.

MS. BONNEVILLE: LAUREN MILLER.

MS. MILLER: YES.

MS. BONNEVILLE: ADRIANA PADILLA.

DR. PADILLA: YES.

MS. BONNEVILLE: JOE PANETTA.

MR. PANETTA: YES.

MS. BONNEVILLE: FRANCISCO PRIETO.

DR. PRIETO: AYE.

MS. BONNEVILLE: ROBERT QUINT.

DR. QUINT: YES.

MS. BONNEVILLE: JEFF SHEEHY.

SUPERVISOR SHEEHY: YES.

MS. BONNEVILLE: OS STEWARD.

DR. STEWARD: YES.

MS. BONNEVILLE: JONATHAN THOMAS.

CHAIRMAN THOMAS: YES.

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MS. BONNEVILLE: ART TORRES.
MR. TORRES: AYE.
MS. BONNEVILLE: DIANE WINOKUR.
MS. WINOKUR: YES.
MS. BONNEVILLE: MOTION CARRIES.
SUPERVISOR SHEEHY: THANK YOU, MARIA.
SO, CHAIRMAN THOMAS, THIS CONCLUDES THE BUSINESS OF THE APPLICATION REVIEW SUBCOMMITTEE.
CHAIRMAN THOMAS: THANK YOU, MR. SUPERVISOR.
DO WE HAVE ANY GENERAL PUBLIC COMMENT ON ANY MATTERS WHATSOEVER? HEARING NONE, I THINK THAT CONCLUDES TODAY'S AGENDA. WANT TO THANK EVERYBODY. WE --
MR. TORRES: JUST ONE POINT. I JUST WANT TO SAY HOW THANKFUL WE ARE THAT STEVE JUELSGAARD IS WITH US TODAY AFTER WHAT HE AND HIS LOVELY WIFE HAD TO ENDURE IN THE LAST FEW WEEKS. SO, STEVE, WELCOME BACK.
CHAIRMAN THOMAS: HERE. HERE.
MR. JUELSGAARD: THANK YOU, ART. APPRECIATE IT.
CHAIRMAN THOMAS: THANK YOU. AND OUR THOUGHTS WERE WITH YOU, STEVE, AND CONTINUE TO BE. AND, ART, TO YOU AS WELL FOR WHAT YOU HAD TO ENDURE

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DURING THAT PERIOD.

SO I THINK IF THERE'S NO OTHER BUSINESS, I THINK THAT CONCLUDES TODAY'S MEETING. LOOK FORWARD TO OUR NEXT APPLICATION REVIEW SUBCOMMITTEE IN NOVEMBER. AND WITH THAT, WE STAND ADJOURNED.

(THE MEETING WAS THEN CONCLUDED AT 11:39 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 TELEPHONIC 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, 2017, 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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