

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

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25

I N D E X

ITEM DESCRIPTION	PAGE NO.
OPEN SESSION	
1. CALL TO ORDER.	3
2. ROLL CALL.	3
3. CONSIDERATION OF APPLICATIONS SUBMITTED IN RESPONSE TO CLIN 2: PARTNERING OPPORTUNITY FOR CLINICAL TRIAL STAGE PROJECTS.	4
CLOSED SESSION	NONE
4. DISCUSSION OF CONFIDENTIAL INTELLECTUAL PROPERTY OR WORK PRODUCT, PREPUBLICATION DATA, FINANCIAL INFORMATION, CONFIDENTIAL SCIENTIFIC RESEARCH OR DATA, AND OTHER PROPRIETARY INFORMATION RELATING TO APPLICATIONS SUBMITTED IN RESPONSE TO CLIN 2: PARTNERING OPPORTUNITY FOR CLINICAL TRIAL STAGE PROJECTS (HEALTH & SAFETY CODE 125290.30(F) (3) (B) AND (C)).	
5. PUBLIC COMMENT.	NONE
6. ADJOURNMENT.	31

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25

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.

1 DR. STEWARD: HERE.
2 MS. BONNEVILLE: JONATHAN THOMAS.
3 CHAIRMAN THOMAS: HERE.
4 MS. BONNEVILLE: ART TORRES.
5 MR. TORRES: HERE.
6 MS. BONNEVILLE: DIANE WINOKUR.
7 MS. WINOKUR: HERE.
8 MS. BONNEVILLE: ARE THERE ANY OTHER BOARD
9 MEMBERS ON THE LINE?
10 DR. PRIETO: YES, FRANCISCO PRIETO.
11 MS. BONNEVILLE: THANK YOU, FRANCISCO.
12 DR. JUELSGAARD: AND THIS IS STEPHAN
13 JUELSGAARD.
14 MS. BONNEVILLE: THANKS, STEVE.
15 ARE THERE ANY MEMBERS OF THE PUBLIC AT ANY
16 OF THE LOCATIONS?
17 OKAY. AND, JEFF, I DO HAVE ONE PUBLIC
18 COMMENT TO READ WHEN IT COMES TIME.
19 SUPERVISOR SHEEHY: THANK YOU, MARIA.
20 MS. BONNEVILLE: WE HAVE A QUORUM.
21 CHAIRMAN THOMAS: THANK YOU, MARIA. AT
22 THIS POINT I'D LIKE TO TURN THE MEETING OVER TO
23 SUPERVISOR SHEEHY FOR CONSIDERATION OF ITEM NO. 3 IN
24 THE AGENDA.
25 SUPERVISOR SHEEHY: THANK YOU, J.T. I

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

3 DR. PATEL: YES, THAT'S CORRECT.

4 THANK YOU, SUPERVISOR SHEEHY.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

20 SUPERVISOR SHEEHY: DO WE HAVE A SECOND?

21 DR. JUELGAARD: I SECOND IT.

22 SUPERVISOR SHEEHY: WE HAVE DISCUSSION?

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

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

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

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

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

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

25 SO THE IDEA IS THAT THE PATIENT WOULD HAVE

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

4 DR. DULIEGE: OKAY.

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

8 CHAIRMAN THOMAS: YES.

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

24 DR. STEWARD: MAY I ASK A QUESTION?

25 SUPERVISOR SHEEHY: YES, PLEASE.

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

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

13 SUPERVISOR SHEEHY: OTHER QUESTIONS OR
14 COMMENTS?

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

20 ANYWAY, IF THERE'S NO OTHER COMMENTS.

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

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

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

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

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

1 RIGHT FROM THE GET-GO?

2 DR. JUELSGAARD: COULD I SPEAK TO THE
3 ISSUE?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

20 ANY OTHER COMMENTS?

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

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

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

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

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

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

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

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

18 SUPERVISOR SHEEHY: OTHER QUESTIONS,
19 COMMENTS?

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

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

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

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

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

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

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

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

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

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

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

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

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

23 "IN 2003 THE COST OF ARTHRITIS AND OTHER
24 RHEUMATIC CONDITIONS WAS ESTIMATED AT \$128 BILLION,
25 80 BILLION DIRECT, 40 BILLION INDIRECT, AS IN TIME

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

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

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

23 MS. BONNEVILLE: ANNE-MARIE DULIEGE.

24 DR. DULIEGE: NO.

25 MS. BONNEVILLE: DAVID HIGGINS.

1 DR. HIGGINS: YES.
2 MS. BONNEVILLE: STEVE JUELSGAARD.
3 MR. JUELSGAARD: YES.
4 MS. BONNEVILLE: DAVID MARTIN.
5 DR. MARTIN: YES.
6 MS. BONNEVILLE: LAUREN MILLER.
7 MS. MILLER: YES.
8 MS. BONNEVILLE: ADRIANA PADILLA.
9 DR. PADILLA: YES.
10 MS. BONNEVILLE: JOE PANETTA.
11 MR. PANETTA: YES.
12 MS. BONNEVILLE: FRANCISCO PRIETO.
13 DR. PRIETO: AYE.
14 MS. BONNEVILLE: ROBERT QUINT.
15 DR. QUINT: NO.
16 MS. BONNEVILLE: JEFF SHEEHY.
17 SUPERVISOR SHEEHY: NO.
18 MS. BONNEVILLE: OS STEWARD.
19 DR. STEWARD: NO.
20 MS. BONNEVILLE: JONATHAN THOMAS.
21 CHAIRMAN THOMAS: YES.
22 MS. BONNEVILLE: ART TORRES.
23 MR. TORRES: AYE.
24 MS. BONNEVILLE: DIANE WINOKUR.
25 MS. WINOKUR: NO.

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

3 SUPERVISOR SHEEHY: THANKS, MARIA.

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

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

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

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

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

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

4 SUPERVISOR SHEEHY: THANK YOU, DR. PATEL.

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

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

11 SUPERVISOR SHEEHY: DO I HAVE A SECOND?

12 DR. JUELSGAARD: I SECOND.

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

16 MS. BONNEVILLE: ANNE-MARIE DULIEGE.

17 DR. DULIEGE: AYE.

18 MS. BONNEVILLE: DAVID HIGGINS.

19 DR. HIGGINS: YES.

20 MS. BONNEVILLE: STEVE JUELSGAARD.

21 MR. JUELSGAARD: YES.

22 MS. BONNEVILLE: DAVID MARTIN.

23 DR. MARTIN: YES.

24 MS. BONNEVILLE: LAUREN MILLER.

25 MS. MILLER: YES.

1 MS. BONNEVILLE: ADRIANA PADILLA.
2 DR. PADILLA: YES.
3 MS. BONNEVILLE: JOE PANETTA.
4 MR. PANETTA: YES.
5 MS. BONNEVILLE: FRANCISCO PRIETO.
6 DR. PRIETO: AYE.
7 MS. BONNEVILLE: ROBERT QUINT.
8 DR. QUINT: YES.
9 MS. BONNEVILLE: JEFF SHEEHY.
10 SUPERVISOR SHEEHY: YES.
11 MS. BONNEVILLE: OS STEWARD.
12 DR. STEWARD: YES.
13 MS. BONNEVILLE: JONATHAN THOMAS.
14 CHAIRMAN THOMAS: YES.
15 MS. BONNEVILLE: ART TORRES.
16 MR. TORRES: AYE.
17 MS. BONNEVILLE: DIANE WINOKUR.
18 MS. WINOKUR: YES.
19 MS. BONNEVILLE: MOTION CARRIES.
20 SUPERVISOR SHEEHY: THANK YOU, MARIA.
21 SO, DR. PATEL, CAN WE GO TO THE NEXT AND
22 FINAL PROJECT PLEASE.
23 DR. PATEL: SO THE LAST ONE IS A
24 CLIN2-10395 APPLICATION. THIS IS FOR A PHASE 1
25 CLINICAL TRIAL OF A CELL THERAPY FOR MULTIPLE

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

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

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

23 SUPERVISOR SHEEHY: THANK YOU, DR. PATEL.

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

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

3 DR. PRIETO: I'LL MOVE TO ACCEPT.

4 SUPERVISOR SHEEHY: DO I HAVE A SECOND?

5 DR. DULIEGE: I SECOND IT.

6 SUPERVISOR SHEEHY: ANY BOARD COMMENTS,
7 QUESTIONS, DISCUSSION?

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

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

25 THIS IS ALSO A MILESTONE-BASED PROJECT.

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

4 DR. DULIEGE: THANK YOU VERY MUCH.

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

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

21 DR. MARTIN: THESE ARE AUTOLOGOUS T-CELLS?

22 DR. PATEL: YES.

23 DR. MARTIN: THANK YOU.

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

1 PLEASE.
2 MS. BONNEVILLE: ANNE-MARIE DULIEGE.
3 DR. DULIEGE: YES, I SUPPORT.
4 MS. BONNEVILLE: DAVID HIGGINS.
5 DR. HIGGINS: YES.
6 MS. BONNEVILLE: STEVE JUELSGAARD.
7 MR. JUELSGAARD: YES.
8 MS. BONNEVILLE: DAVID MARTIN.
9 DR. MARTIN: YES.
10 MS. BONNEVILLE: LAUREN MILLER.
11 MS. MILLER: YES.
12 MS. BONNEVILLE: ADRIANA PADILLA.
13 DR. PADILLA: YES.
14 MS. BONNEVILLE: JOE PANETTA.
15 MR. PANETTA: YES.
16 MS. BONNEVILLE: FRANCISCO PRIETO.
17 DR. PRIETO: AYE.
18 MS. BONNEVILLE: ROBERT QUINT.
19 DR. QUINT: YES.
20 MS. BONNEVILLE: JEFF SHEEHY.
21 SUPERVISOR SHEEHY: YES.
22 MS. BONNEVILLE: OS STEWARD.
23 DR. STEWARD: YES.
24 MS. BONNEVILLE: JONATHAN THOMAS.
25 CHAIRMAN THOMAS: YES.

1 MS. BONNEVILLE: ART TORRES.

2 MR. TORRES: AYE.

3 MS. BONNEVILLE: DIANE WINOKUR.

4 MS. WINOKUR: YES.

5 MS. BONNEVILLE: MOTION CARRIES.

6 SUPERVISOR SHEEHY: THANK YOU, MARIA.

7 SO, CHAIRMAN THOMAS, THIS CONCLUDES THE
8 BUSINESS OF THE APPLICATION REVIEW SUBCOMMITTEE.

9 CHAIRMAN THOMAS: THANK YOU, MR.
10 SUPERVISOR.

11 DO WE HAVE ANY GENERAL PUBLIC COMMENT ON
12 ANY MATTERS WHATSOEVER? HEARING NONE, I THINK THAT
13 CONCLUDES TODAY'S AGENDA. WANT TO THANK EVERYBODY.
14 WE --

15 MR. TORRES: JUST ONE POINT. I JUST WANT
16 TO SAY HOW THANKFUL WE ARE THAT STEVE JUELSGAARD IS
17 WITH US TODAY AFTER WHAT HE AND HIS LOVELY WIFE HAD
18 TO ENDURE IN THE LAST FEW WEEKS. SO, STEVE, WELCOME
19 BACK.

20 CHAIRMAN THOMAS: HERE. HERE.

21 MR. JUELSGAARD: THANK YOU, ART.
22 APPRECIATE IT.

23 CHAIRMAN THOMAS: THANK YOU. AND OUR
24 THOUGHTS WERE WITH YOU, STEVE, AND CONTINUE TO BE.
25 AND, ART, TO YOU AS WELL FOR WHAT YOU HAD TO ENDURE

1 DURING THAT PERIOD.

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

6 (THE MEETING WAS THEN CONCLUDED AT
7 11:39 A.M.)

8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25

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
133 HENNA COURT
SANDPOINT, IDAHO
(208) 255-5453