

**BETH C. DRAIN, CA CSR NO. 7152**

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  
EMERGENCY MEETING

LOCATION: VIA ZOOM

DATE: MAY 15, 2020  
11 A.M.

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

FILE NO.: 2020-09

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

I N D E X

ITEM DESCRIPTION	PAGE NO.
<b>OPEN SESSION:</b>	
CALL TO ORDER.	3
ROLL CALL.	3
<b>ACTION ITEMS:</b>	
CONSIDERATION OF APPLICATIONS SUBMITTED IN RESPONSE TO SPECIAL CALL FOR COVID-19 PROJECTS.	12
CONSIDERATION OF APPLICATIONS SUBMITTED IN RESPONSE TO CLINICAL TRIAL STAGE PROJECTS FOR SICKLE CELL DISEASE (CLIN 1 AND 2.).	4
<b>CLOSED SESSION</b>	<b>NONE</b>
DISCUSSION OF CONFIDENTIAL INTELLECTUAL PROPERTY OR WORK PRODUCT, PREPUBLICATION DATA, FINANCIAL INFORMATION, CONFIDENTIAL SCIENTIFIC RESEARCH OR DATA, AND OTHER PROPRIETARY INFORMATION RELATING TO APPLICATIONS SUBMITTED IN RESPONSE TO AGENDA ITEMS "3 AND 4" ABOVE. (HEALTH & SAFETY CODE 125290.30(F) (3) (B) AND (C)).	
<b>DISCUSSION ITEMS:</b>	
PUBLIC COMMENT.	NONE
ADJOURNMENT.	44

**BETH C. DRAIN, CA CSR NO. 7152**

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

MAY 15, 2020; 11:00 A.M.

CHAIRMAN THOMAS: OKAY. THANK YOU,  
EVERYBODY. LIKE TO CALL THE MEETING TO ORDER FOR  
THE MEETING OF THE BOARD AND APPLICATION REVIEW  
SUBCOMMITTEE FOR MAY 15TH. HOPE EVERYBODY IS  
CONTINUING TO STAY SAFE AND HEALTHY WITH THEIR  
FAMILIES. MARIA, WILL YOU PLEASE CALL THE ROLL.

MS. BONNEVILLE: ANNE-MARIE DULIEGE.

DR. DULIEGE: YES, PRESENT.

MS. BONNEVILLE: YSABEL DURON. DAVID  
HIGGINS.

DR. HIGGINS: HERE.

MS. BONNEVILLE: DAVE MARTIN.

DR. MARTIN: HERE.

MS. BONNEVILLE: LAUREN MILLER.

MS. MILLER: HERE.

MS. BONNEVILLE: ADRIANA PADILLA. JOE  
PANETTA.

MR. PANETTA: HERE.

MS. BONNEVILLE: FRANCISCO PRIETO. ROBERT  
QUINT.

DR. QUINT: HERE.

MS. BONNEVILLE: AL ROWLETT.

MR. ROWLETT: HERE.

MS. BONNEVILLE: JEFF SHEEHY.

**BETH C. DRAIN, CA CSR NO. 7152**

1 MR. SHEEHY: HERE.

2 MS. BONNEVILLE: OS STEWARD. JONATHAN  
3 THOMAS.

4 CHAIRMAN THOMAS: HERE.

5 MS. BONNEVILLE: ART TORRES.

6 MR. TORRES: HERE.

7 MS. BONNEVILLE: DIANE WINOKUR.

8 MS. WINOKUR: YES.

9 MS. BONNEVILLE: WE HAVE A QUORUM, AND I'M  
10 GOING TO MUTE MYSELF AND TRY AND GET OS AND  
11 FRANCISCO ON.

12 CHAIRMAN THOMAS: SO TODAY IS THE SECOND  
13 IN OUR SERIES OF MEETINGS TO CONSIDER COVID  
14 APPLICATIONS FROM THIS WEEK'S GWG REVIEW. IN  
15 ADDITION, WE HAVE A SICKLE CELL PROJECT ON THE  
16 AGENDA FOR CONSIDERATION. AND AT THIS POINT WOULD  
17 LIKE TO TURN THE MEETING OVER TO MR. SHEEHY.

18 MR. SHEEHY: THANK YOU, CHAIRMAN THOMAS.

19 I THINK, DR. SAMBRANO, ARE YOU GOING TO  
20 TAKE US THROUGH THIS? WE'RE GOING TO START WITH THE  
21 SICKLE CELL ONE TODAY, AREN'T WE?

22 DR. SAMBRANO: YES, THAT'S CORRECT.

23 CHAIRMAN THOMAS: GREAT. YOU HAVE SLIDES?

24 DR. SAMBRANO: YES. OKAY. THANK YOU.

25 SO GOOD MORNING, EVERYONE. WE ARE GOING

**BETH C. DRAIN, CA CSR NO. 7152**

1 TO TALK ABOUT FIRST THE SICKLE CELL DISEASE PROGRAM  
2 AND THE ONE APPLICATION THAT IS BEING CONSIDERED.  
3 SO IF I COULD HAVE THE NEXT SLIDE, DOUG.

4 THE SICKLE CELL PROGRAM IS ONE, AS YOU  
5 KNOW, THAT IS IN COLLABORATION WITH THE NHLBI TO,  
6 WHERE POSSIBLE, CO-FUND PROGRAMS IN THE CLINICAL  
7 ARENA. SO THAT'S THE LATE STAGE PRECLINICAL  
8 PROJECTS OR CLINICAL TRIALS.

9 IN THIS PARTICULAR CASE WE HAVE AN  
10 APPLICATION THAT IS NOT BEING CO-FUNDED. THIS WOULD  
11 BE AN APPLICATION THAT WAS NOT DEEMED ELIGIBLE FOR  
12 THE NHLBI FUNDING, BUT IS FOR CIRM. SO THIS WOULD  
13 BE A CIRM-ONLY FUNDING.

14 NEXT SLIDE PLEASE. SO THE SCORING AND I  
15 WANT TO JUST EMPHASIZE BECAUSE WE ARE USING TWO  
16 DIFFERENT SCORING METHODS THAT WE'RE GOING TO TALK  
17 ABOUT TODAY. SO FOR THE SICKLE CELL PROGRAM AND FOR  
18 OUR TRADITIONAL CLINICAL PROGRAM, WE USE A SCORING  
19 SCHEME OF 1, 2, AND 3. SO A SCORE OF 1 MEANING IT  
20 HAS EXCEPTIONAL MERIT AND WARRANTS FUNDING; A SCORE  
21 OF 2 MEANING IT NEEDS IMPROVEMENT, AND USUALLY THOSE  
22 GET REVISED AND COME BACK; AND A SCORE OF 3 WHERE  
23 IT'S SUFFICIENTLY FLAWED THAT WE WOULDN'T WANT THAT  
24 TO COME BACK FOR SIX MONTHS.

25 NEXT SLIDE PLEASE. I WANT TO PROVIDE AN

**BETH C. DRAIN, CA CSR NO. 7152**

1 UPDATE ON THE BUDGET STATUS FOR THE SICKLE CELL  
2 DISEASE PROGRAM. SO THERE WAS AN ALLOCATION OF 30  
3 MILLION THAT WAS CREATED AND APPROVED BY THE BOARD  
4 FOR THE PROGRAM. THE AMOUNT THAT IS REQUESTED FOR  
5 TODAY FOR THE ONE APPLICATION IS TWO MILLION. WE  
6 HAVE APPROVED AWARDS THAT HAVE USED UP 2.2 MILLION  
7 OUT OF THE \$30 MILLION BUCKET. AND SO IF THIS  
8 APPLICATION IS APPROVED TODAY, THAT WOULD LEAVE US  
9 WITH 25.8 MILLION. I DO WANT TO NOTE THAT OUT OF  
10 THIS 30 MILLION ALLOCATION, I'M SURE YOU ALL  
11 REMEMBER WE DID BORROW 4.2 MILLION FOR THE COVID-19  
12 PROGRAM THAT'S NOT REFLECTED IN THIS CHART, BUT I  
13 JUST WANT TO MAKE IT CLEAR THAT THAT IS THE CASE.  
14 WE ARE REPLENISHING THAT AMOUNT WITH RECOVERED FUNDS  
15 AS WE GET THEM.

16 NEXT SLIDE PLEASE. OKAY. SO THE PROJECT  
17 THAT WE ARE TALKING ABOUT TODAY IS A THERAPY THAT  
18 USES EXPANDED CORD BLOOD HEMATOPOIETIC STEM CELLS TO  
19 TREAT SEVERE SICKLE CELL DISEASE. AND THE GOAL OF  
20 THIS PROJECT IS TO COMPLETE A PHASE 1 CLINICAL  
21 TRIAL, AND THE AMOUNT REQUESTED IS TWO MILLION, AND  
22 THE APPLICANT IS PROVIDING A CO-FUNDING AMOUNT OF  
23 ABOUT 860,000.

24 NEXT SLIDE PLEASE. SO AS JUST BACKGROUND  
25 INFORMATION ON SICKLE CELL DISEASE AND THE IMPACT OF

**BETH C. DRAIN, CA CSR NO. 7152**

1 THIS THERAPY, AS WE KNOW, SICKLE CELL DISEASE IS ONE  
2 THAT HAS A SEVERE IMPACT ON PATIENTS. THERE ARE  
3 APPROXIMATELY 100,000 AMERICANS THAT THIS DISEASE  
4 AFFECTS. IT IS PARTICULARLY COMMON IN THOSE WITH  
5 SUB-SAHARAN AFRICAN ANCESTRY, AND IT AFFECTS ONE IN  
6 365 AFRICAN-AMERICAN BIRTHS. GLOBALLY THERE ARE  
7 OVER 300,000 BABIES WHO ARE BORN WITH SICKLE CELL  
8 DISEASE EVERY YEAR.

9 THE VALUE PROPOSITION OF THE THERAPY COMES  
10 AROUND IN THE FOLLOWING WAY. SO THE ONLY CURRENT  
11 CURE IS ALLOGENEIC HEMATOPOIETIC STEM CELL  
12 TRANSPLANTATION. IT COMES WITH SOME RISK, BUT IT IS  
13 CURATIVE POTENTIALLY, BUT DONOR AVAILABILITY IS VERY  
14 LIMITED.

15 SO THE PROPOSED THERAPEUTIC APPROACH WOULD  
16 BROADEN THE DONOR AVAILABILITY FOR PATIENTS SEEKING  
17 SUCH TRANSPLANTATION. SO THAT IS WHERE THE VALUE  
18 WOULD COME IN.

19 WHY IS THIS A STEM CELL PROJECT? THIS  
20 THERAPY INCLUDES CORD BLOOD-DERIVED HEMATOPOIETIC  
21 STEM CELLS.

22 NEXT SLIDE PLEASE. SO THIS IS JUST A  
23 BIG-PICTURE OVERVIEW OF THE RELATED PROJECTS THAT  
24 EXIST IN OUR PORTFOLIO. SO AT THE VERY TOP IS THE  
25 CURRENT APPLICATION AND HOW THAT WOULD FIT IN.

**BETH C. DRAIN, CA CSR NO. 7152**

1 THERE ARE FOUR OTHER ACTIVE AWARDS THAT ARE IN OUR  
2 CLINICAL PORTFOLIO, TWO THAT ARE AT THE LATE STAGE  
3 PRECLINICAL, AND THEN TWO CLINICAL TRIAL PROJECTS.  
4 MOST OF THESE ARE FOCUSED ON AUTOLOGOUS APPROACHES,  
5 GENE CORRECTION, AND THEN THERE'S ONE THAT'S FOCUSED  
6 ON ACHIEVING IMMUNE TOLERANCE THROUGH MIXED  
7 CHIMERISM.

8 AND SO THE CURRENT APPLICATION THAT WE ARE  
9 CONSIDERING IS UNIQUE AMONG THESE IN THAT IT IS AN  
10 ALLOGENEIC APPROACH THAT USES CORD BLOOD AND EXPANDS  
11 IT IN ORDER TO PROVIDE A TREATMENT.

12 NEXT SLIDE PLEASE. THIS APPLICANT HAS NOT  
13 RECEIVED CIRM FUNDING PREVIOUSLY. SO NOTHING MUCH  
14 TO SAY ON THAT FRONT.

15 AND SO THE LAST SLIDE ON THIS  
16 APPLICATION -- NEXT SLIDE PLEASE, DOUG -- IS THE  
17 RECOMMENDATION AND SCORING FROM THE GWG. SO THIS  
18 RECEIVED A SCORE OF 1, MEANING EXCEPTIONAL MERIT AND  
19 WARRANTING FUNDING. AND SO THIS IS A UNANIMOUS VOTE  
20 BY THE 15 SCIENTIFIC MEMBERS OF THE GWG. THE CIRM  
21 TEAM ALSO RECOMMENDS AND CONCURS WITH THE GWG IN  
22 AWARDEDING THE APPLICANT TWO MILLION.

23 MR. SHEEHY.

24 MR. SHEEHY: THANK YOU, DR. SAMBRANO.

25 COULD I GET A MOTION TO EITHER ACCEPT THE



**BETH C. DRAIN, CA CSR NO. 7152**

1 CIRM TEAM RECOMMENDATION AND FUND THIS PROJECT OR TO  
2 REJECT THE CIRM TEAM RECOMMENDATION AND NOT TO FUND  
3 THIS PROJECT?

4 DR. HIGGINS: THIS IS DAVID IN SAN DIEGO.  
5 I MOVE TO DO JUST THAT.

6 CHAIRMAN THOMAS: TO ACCEPT. GREAT. SO  
7 DO I HAVE A SECOND?

8 MR. TORRES: YES, SECOND.

9 MR. SHEEHY: OKAY. SO DAVID HIGGINS HAD  
10 MOTIONED TO ACCEPT THE RECOMMENDATION, SECONDED BY  
11 SENATOR TORRES. ANY DISCUSSION AMONGST MEMBERS OF  
12 THE BOARD, QUESTIONS, ET CETERA?

13 DR. DULIEGE: MAY I ASK A QUESTION? GIL,  
14 CAN YOU PLEASE CLARIFY WHAT THIS APPROACH WOULD ADD  
15 SPECIFICALLY TO THE CURRENTLY APPROVED APPROACH OF  
16 HEMATOPOIETIC STEM CELLS, IF I'M CORRECT, WHICH IS  
17 ALREADY APPROVED?

18 DR. SAMBRANO: SO THIS IS CORD BLOOD  
19 DERIVED. SO THERE'S ADVANTAGES TO USING CORD BLOOD  
20 THAT INCLUDE MORE TOLERANCE FOR HLA MOLECULE  
21 MISMATCHES. THERE'S LOWER INCIDENCE OF GVHD. ONE  
22 OF THE DIFFICULTIES WITH CORD BLOOD, HOWEVER, IS  
23 THAT OFTEN THERE ISN'T SUFFICIENT IN A SINGLE UNIT  
24 TO TREAT PATIENTS. AND SO WHAT THIS BRINGS FORWARD  
25 IS THE ABILITY TO EXPAND CORD BLOOD UNITS.

**BETH C. DRAIN, CA CSR NO. 7152**

1 SO THERE'S A SMALL MOLECULE THAT THE TEAM  
2 HAS IDENTIFIED AND USES TO EXPAND THE CORD BLOOD IN  
3 ORDER TO CREATE SUFFICIENT MATERIAL FOR THE  
4 TRANSPLANT. AND SO BY VIRTUE OF THAT, IT WOULD  
5 ALLOW THOSE THAT MIGHT NOT OTHERWISE BE ABLE TO  
6 RECEIVE ONE EITHER BECAUSE THERE IS NO GOOD MATCH TO  
7 ACTUALLY BE ABLE TO PURSUE THE TRANSPLANT.

8 DR. DULIEGE: THANK YOU. VERY USEFUL.

9 DR. MARTIN: THIS IS DAVE MARTIN. IS IT  
10 FAIR TO ASK WHY IT'S NOT ELIGIBLE FOR THE  
11 CO-FUNDING?

12 DR. SAMBRANO: BECAUSE I THINK NHLBI  
13 GENERALLY IS FOCUSED ON GENE THERAPY APPROACHES, AND  
14 THEY FELT THIS ONE DID NOT MEET THEIR BAR FOR A GENE  
15 THERAPY APPROACH.

16 DR. MARTIN: THANK YOU.

17 MR. SHEEHY: ADDITIONAL QUESTIONS OR  
18 COMMENTS? IS THERE ANY PUBLIC COMMENT FOR THIS  
19 APPLICATION? IF NOT, MS. BONNEVILLE, COULD YOU  
20 PLEASE CALL THE ROLL.

21 MS. BONNEVILLE: ANNE-MARIE DULIEGE.

22 DR. DULIEGE: YES.

23 MS. BONNEVILLE: DAVID HIGGINS.

24 DR. HIGGINS: YES.

25 MS. BONNEVILLE: DAVE MARTIN.

**BETH C. DRAIN, CA CSR NO. 7152**

1 DR. MARTIN: YES.  
2 MS. BONNEVILLE: LAUREN MILLER.  
3 MS. MILLER: YES.  
4 MS. BONNEVILLE: ADRIANA PADILLA. JOE  
5 PANETTA.  
6 MR. PANETTA: YES.  
7 MS. BONNEVILLE: FRANCISCO PRIETO. ROBERT  
8 QUINT. DR. QUINT?  
9 DR. QUINT: YES.  
10 MS. BONNEVILLE: AL ROWLETT.  
11 MR. ROWLETT: YES.  
12 MS. BONNEVILLE: JEFF SHEEHY.  
13 MR. SHEEHY: YES.  
14 MS. BONNEVILLE: OS STEWARD. YES. HE'S  
15 GIVING ME THE THUMBS UP. I SEE IT.  
16 JONATHAN THOMAS.  
17 CHAIRMAN THOMAS: YES.  
18 MS. BONNEVILLE: ART TORRES.  
19 MR. TORRES: AYE.  
20 MS. BONNEVILLE: DIANE WINOKUR.  
21 MS. WINOKUR: YES.  
22 MS. BONNEVILLE: THE MOTION CARRIES.  
23 MR. TORRES: WHAT'S OUR TOTAL?  
24 MS. BONNEVILLE: TWELVE.  
25 MR. TORRES: THANK YOU.

**BETH C. DRAIN, CA CSR NO. 7152**

1 MR. SHEEHY: THANK YOU. DR. SAMBRANO,  
2 WILL YOU BE TAKING US THROUGH THE COVID  
3 APPLICATIONS?

4 DR. SAMBRANO: YES.

5 MS. BONNEVILLE: REALLY QUICKLY, I WANTED  
6 TO CONFIRM THAT DR. MELMED IS ON THE LINE, I  
7 BELIEVE. HOW ABOUT LINDA MALKAS?

8 DR. MELMED: YES, I'M ON.

9 MS. BONNEVILLE: THANK YOU. AND I JUST  
10 WANTED TO NOTE THE OTHER BOARD MEMBERS THAT HAVE  
11 JOINED. THANK YOU.

12 MR. SHEEHY: THANK YOU. DR. SAMBRANO.

13 DR. SAMBRANO: THANK YOU. NEXT SLIDE  
14 PLEASE, DOUG.

15 OKAY. SO JUST A QUICK REMINDER OF THE  
16 COVID-19 PROGRAM. IT IS ONE THAT WE APPROVED  
17 RECENTLY WITH A \$5 MILLION ALLOCATION, AND IT  
18 ACCEPTS PROJECTS THAT SPAN FROM DISCOVERY THROUGH  
19 CLINICAL TRIALS. NEXT SLIDE PLEASE.

20 AND SO THIS NEXT TABLE JUST SHOWS YOU THE  
21 MAXIMUM AWARD AMOUNTS FROM 150,000 FOR DISCOVERY  
22 PROJECTS UP TO \$750,000 FOR CLINICAL TRIAL PROJECTS.  
23 THE AWARD DURATION IS RELATIVELY SHORT, UP TO A YEAR  
24 FOR ALL EXCEPT THE CLINICAL TRIAL WHICH ALLOWS UP TO  
25 TWO YEARS FOR THE PROGRAM.

**BETH C. DRAIN, CA CSR NO. 7152**

1           NEXT SLIDE PLEASE. SO DESPITE THOSE AWARD  
2 DURATIONS AND AWARD AMOUNT LIMITATIONS, WE DO AND  
3 HAVE SET A PRETTY HIGH BAR FOR A LOT OF THESE  
4 PROJECTS. THERE WAS A CLEAR DELIVERABLE THAT WAS  
5 ESTABLISHED FOR EACH OF THESE TYPES OF PROJECTS  
6 WITHIN SIX MONTHS OF THE PROJECT INITIATION. SO FOR  
7 CLINICAL TRIALS, FOR EXAMPLE, WE EXPECT THAT WITHIN  
8 SIX MONTHS SUCH PROJECTS WOULD INITIATE ENROLLMENT  
9 AND DATA COLLECTION. FOR THE DISC2 OR DISCOVERY  
10 PROJECTS, THAT THEY HAVE DATA FOR A VIABLE CANDIDATE  
11 THAT COULD PROGRESS QUICKLY TO THE CLINIC.

12           AND SO FOR TODAY WE ARE ONLY CONSIDERING  
13 DISC2 AND CLIN2 PROJECTS. THERE ARE NO CLIN1 OR  
14 TRAN PROJECTS THAT ARE IN THE POOL.

15           NEXT SLIDE PLEASE. SO THE RECOMMENDATIONS  
16 FROM THE GWG, WE HAD 16 APPLICATIONS, I BELIEVE,  
17 THAT WERE SUBMITTED, 12 THAT WERE ELIGIBLE AND WERE  
18 REVIEWED. AND SO OUT OF THOSE THERE ARE TWO THAT  
19 ARE RECOMMENDED BY THE GWG. BOTH OF THOSE ARE  
20 DISCOVERY APPLICATIONS, AND SO THE TOTAL AMOUNT  
21 REQUESTED FOR THOSE TWO WOULD BE 300,000. AND THE  
22 FUNDS AVAILABLE ARE 3.9 MILLION.

23           NEXT SLIDE PLEASE. AND SO JUST BRIEFLY,  
24 THE TWO APPLICATIONS THAT ARE RECOMMENDED THAT ARE  
25 DISCOVERY ARE NUMBERS 11811, WHICH RECEIVED A SCORE

**BETH C. DRAIN, CA CSR NO. 7152**

1 OF 90. AND SO THIS APPLICATION IS ENTITLED  
2 "REPURPOSING AMINOADAMANTANE NITRATE COMPOUNDS TO  
3 INHIBIT SARS COV2 VIRAL ACTIVITY AND TO PROTECT THE  
4 BRAIN FROM VIRAL-RELATED DAMAGE."

5 SO THIS IS A PROPOSAL THAT INTENDS TO DO A  
6 SCREEN OF SEVERAL COMPOUNDS TO IDENTIFY THOSE THAT  
7 HAVE THE POTENTIAL TO PROTECT NEURONS FROM VIRAL  
8 DAMAGE AS WELL AS TO INHIBIT THE ACTIVITY OF THE  
9 SARS COV2 VIRUS.

10 THE SECOND PROJECT IS ONE THAT RECEIVED A  
11 SCORE OF 85, AND IT IS ENTITLED "DEVELOPMENT OF A  
12 NOVEL PIKFYVE KINASE INHIBITOR FOR THE TREATMENT OF  
13 COVID-19." THE GOAL OF THIS PROJECT IS TO DETERMINE  
14 IF A NOVEL PIFYVE KINASE INHIBITOR CAN PREVENT SARS  
15 COV2 INFECTION OF TYPE 2 ALVEOLAR LUNG CELLS. AND  
16 SO THAT'S WHAT THIS PROJECT WILL PURSUE.

17 AND, MR. SHEEHY, DOUG IS GOING TO PUT UP  
18 THE DISPLAY OF THE SPREADSHEET THAT SHOWS ALL THE  
19 OTHER APPLICATIONS AS WELL, WHICH MIGHT BE JUST  
20 BENEFICIAL TO GIVE EVERYBODY THE OVERVIEW OF ALL THE  
21 APPLICATIONS. ALL MEMBERS SHOULD ALSO HAVE A COPY  
22 OF THAT SPREADSHEET AVAILABLE IN THE MATERIALS THAT  
23 WERE PROVIDED. SO MR. SHEEHY.

24 MR. SHEEHY: THANK YOU, DR. SAMBRANO.

25 SO THE WAY IN WHICH WE'LL PROCEED IS HOW

**BETH C. DRAIN, CA CSR NO. 7152**

1 WE TYPICALLY PROCEED WITH THESE LARGE GROUPS OF  
2 GRANTS -- OF APPLICATIONS. SO FIRST I'LL TAKE A  
3 MOTION TO MOVE ANY APPLICATION FROM THE UNFUNDABLE  
4 SCORE RANGE INTO THE FUNDABLE SCORE RANGE. THEN  
5 I'LL TAKE A MOTION TO MOVE ANYTHING NOT IN THE  
6 RECOMMENDED RANGE OUT OF THE RECOMMENDED RANGE, AND  
7 THEN WE'LL VOTE ON THE RECOMMENDED AND NOT  
8 RECOMMENDED AS A GROUP.

9 SO, FIRST, IS THERE A MOTION TO MOVE ANY  
10 APPLICATION FROM THE UNFUNDED RANGE INTO THE  
11 FUNDABLE RANGE?

12 CHAIRMAN THOMAS: YES, MR. SHEEHY, I WOULD  
13 LIKE TO, IF I MAY, MOVE 11823 FROM THE CURRENT NOT  
14 FUNDABLE RANGE.

15 DR. MARTIN: I'LL SECOND THAT.

16 MR. SHEEHY: DR. MARTIN. DO WE  
17 HAVE -- FIRST, MIGHT IT BE HELPFUL TO HAVE DR.  
18 SAMBRANO DO A BRIEF REVIEW OF THAT APPLICATION,  
19 CHAIRMAN THOMAS?

20 CHAIRMAN THOMAS: YES. THANK YOU, MR.  
21 SHEEHY.

22 MR. SHEEHY: SURE.

23 DR. SAMBRANO: OKAY. SO APPLICATION  
24 11823, THIS ONE IS ENTITLED "MESENCHYMAL STROMAL  
25 CELLS FOR ARDS COVID POSITIVE AND NEGATIVE

**BETH C. DRAIN, CA CSR NO. 7152**

1 PATIENTS." AND SO THIS IS A CLINICAL TRIAL PROPOSAL  
2 THAT IS INTENDED TO BE AN EXPANSION OF AN EXISTING  
3 BROADER TRIAL THAT IS LOOKING AT THESE MSC CELLS AS  
4 A TREATMENT FOR ARDS, WHICH IS ACUTE RESPIRATORY  
5 DISTRESS SYNDROME.

6 AND SO WITH THE RISE IN THE CRISIS OF  
7 COVID-19, THE IDEA IS TO MOBILIZE THIS TRIAL AND  
8 ALLOW THE TREATMENT OF COVID-19 PATIENTS AND  
9 DETERMINE IF THIS THERAPEUTIC APPROACH MAY ALSO HAVE  
10 AN IMPACT ON SUCH PATIENTS.

11 AND SO THIS IS AN APPLICATION THAT  
12 RECEIVED A SCORE OF 72. THERE WAS ONE MEMBER  
13 THAT -- SCIENTIFIC MEMBER THAT SCORED IT AT 85 OR  
14 ABOVE, 13 MEMBERS THAT SCORED IT BELOW.

15 SO I THINK SOME OF THE REASONS AS TO WHY  
16 THIS APPLICATION DID NOT SCORE IN THE FUNDING RANGE,  
17 I THINK IT WAS UNCLEAR AND FELT THAT THE PIVOT TO  
18 COVID-19 MAY NOT BE ADEQUATE, MEANING THERE WAS THE  
19 BELIEF THAT THERE WERE POTENTIALLY ONLY 20 PATIENTS  
20 THAT WOULD BE PART OF THIS COVID-19 PROJECT. AND SO  
21 THE NUMBER OF PATIENTS WAS ALSO THE RISK THAT NO  
22 PATIENTS WITH COVID-19 WOULD END UP BEING ENROLLED  
23 THE WAY THE PROPOSAL WAS LAID OUT.

24 SO I THINK THAT WAS A KEY CONCERN FROM  
25 REVIEWERS. I THINK THEY FELT THAT THE RATIONALE,



**BETH C. DRAIN, CA CSR NO. 7152**

1 THE TEAM, LARGELY MOST OTHER THINGS WERE FINE AND  
2 APPROPRIATE, AND I THINK THERE WERE CERTAINLY KUDOS  
3 FOR THE TEAM AND THE PI.

4 I THINK THERE WAS ALSO SOME CONCERN THAT  
5 THERE IS ANOTHER TRIAL THAT IS USING A COMMERCIALY  
6 PREPARED PRODUCT THAT IS UNDER WAY. AND SO THERE  
7 MAY BE SOME COMPETITION THERE. BUT I THINK MUCH OF  
8 IT WAS RELATED TO THE NUMBER OF PATIENTS.

9 NOW, SINCE WE PUBLISHED THIS SUMMARY AND  
10 PROVIDED IT TO THE APPLICANT, WE DID GET  
11 CLARIFICATION REGARDING THE COVID-19 PATIENTS. AND  
12 SO IT HAS BEEN MADE CLEAR THAT THIS STUDY WILL  
13 INCLUDE THE BROADER 120 PATIENTS THAT ARE PART OF  
14 THIS STUDY AND WILL ASSESS ANY COVID-19 PATIENTS  
15 ACROSS ALL THE CLINICAL SITES, NOT JUST THE EXPANDED  
16 ONE. SO I THINK THAT IS IMPORTANT INFORMATION THAT  
17 WAS BROUGHT TO LIGHT.

18 SO, MR. SHEEHY.

19 MR. SHEEHY: THANK YOU, DR. SAMBRANO.  
20 FOR DISCUSSION AMONGST BOARD MEMBERS.

21 DR. PRIETO: YES. CAN YOU HEAR ME?

22 MR. SHEEHY: YES, DR. PRIETO.

23 DR. PRIETO: HI.

24 MS. BONNEVILLE: YAY.

25 DR. PRIETO: I WANTED TO RECORD -- I WAS

**BETH C. DRAIN, CA CSR NO. 7152**

1 HAVING SOME TECHNICAL DIFFICULTIES, ALTHOUGH I COULD  
2 HEAR YOU AND SEE YOU ALL, AND WANTED TO RECORD MY  
3 VOTE AS AYE ON THE PREVIOUS APPLICATION.

4 BUT I WANTED TO ASK DR. SAMBRANO WASN'T  
5 THERE ALSO A CONCERN THAT THIS APPLICATION WAS ONLY  
6 GOING TO LOOK AT PATIENTS WHO HAD RECOVERED FROM THE  
7 ACUTE PHASE OF COVID-19 INFECTION AND LOOKING AT THE  
8 PULMONARY SEQUELAE RATHER THAN PERHAPS THE MORE  
9 URGENT TREATMENT OF THE ACUTE INFECTION? I THOUGHT  
10 I SAW THAT.

11 DR. SAMBRANO: I DON'T RECALL THAT FOR  
12 THIS PARTICULAR APPLICATION. I DO RECALL IT FOR  
13 ANOTHER ONE, BUT I DON'T --

14 DR. PRIETO: OKAY.

15 DR. SAMBRANO: -- RECALL THAT WAS THE CASE  
16 HERE.

17 DR. PRIETO: OKAY. THANK YOU.

18 DR. STEWARD: I'M JUST CURIOUS IF YOU CAN  
19 HEAR ME.

20 MS. BONNEVILLE: YES, OS, WE CAN HEAR YOU.

21 DR. STEWARD: FANTASTIC.

22 MS. BONNEVILLE: A DOUBLE WIN. THANK YOU.

23 MR. SHEEHY: DR. STEWARD, DID YOU HAVE A  
24 QUESTION OR COMMENT?

25 DR. STEWARD: NO. I'VE BEEN HAVING

**BETH C. DRAIN, CA CSR NO. 7152**

1 TROUBLE CONNECTING, AND I WAS JUST DOING A VOICE  
2 CHECK. THANK YOU.

3 MR. SHEEHY: OH, GREAT. THANK YOU.

4 IS THERE ANOTHER --

5 MR. ROWLETT: AL ROWLETT.

6 MR. SHEEHY: PLEASE.

7 MR. ROWLETT: I WAS THE PATIENT ADVOCATE  
8 THAT REVIEWED THIS PARTICULAR PROPOSAL. AND WITHOUT  
9 TALKING ABOUT MY SCORE, THE CONCERNS THAT I HAD WERE  
10 REFLECTED IN THE COMMENTS GIVEN BY MR. SAMBRANO AND  
11 IN THE RESPONSE BY THE PI WHO I BELIEVE IS ON THIS  
12 CALL. AND SO I'M FORESHADOWING MY VOTE, BUT I WAS  
13 FAVORABLY DISPOSED GIVEN THE RESPONSE. SO THANK  
14 YOU, MR. SAMBRANO.

15 MR. SHEEHY: THANK YOU, MR. ROWLETT. IS  
16 THERE ANOTHER ADDITIONAL BOARD COMMENT?

17 DR. DULIEGE: I DON'T SEE HOW I CAN RAISE  
18 MY HAND OTHER THAN IN FRONT OF THE SCREEN.

19 GIL, GIVEN YOUR CLARIFICATION THAT IN FACT  
20 THE ACTUAL SAMPLE SIZE IN THIS CLINICAL TRIAL IS  
21 LARGER THAN WHAT THE REVIEWERS APPARENTLY INITIALLY  
22 UNDERSTOOD, DO YOU THINK THE RESPONSE ADDRESSED MOST  
23 OF THE COMMENTS AND POTENTIAL CONCERNS FROM THE  
24 REVIEWERS? AND DO THEY ACTUALLY LIFT THOSE CONCERNS  
25 THAT IN FACT THE SCORE SHOULD BE HIGHER?

**BETH C. DRAIN, CA CSR NO. 7152**

1 DR. SAMBRANO: SO I HESITATE TO SPEAK FOR  
2 THE GRANTS WORKING GROUP AND EXACTLY WHAT THEY WOULD  
3 BELIEVE, BUT I CAN TELL YOU THAT THAT WAS A MAJOR  
4 CONCERN. I THINK IT WAS UNCLEAR WHETHER ADEQUATE  
5 NUMBERS OF PATIENTS WITH COVID-19 WOULD BE AVAILABLE  
6 IN ORDER TO GET ANY MEANINGFUL OUTPUT FROM THE  
7 TRIAL. BUT IN ADDITION TO LEARNING THAT THE NUMBER  
8 OF PATIENTS WHICH WOULD BE DRAWN FROM INCLUDES THE  
9 BROADER TRIAL, I THINK IT WAS ALSO MADE CLEAR THAT  
10 COVID-19 PATIENTS HAVE ALREADY BEEN ENROLLED. SO I  
11 THINK THOSE TWO THINGS WOULD CERTAINLY HAVE MADE A  
12 DIFFERENCE IN THE GENERAL VIEW OF THIS APPLICATION.  
13 I CANNOT TELL YOU NECESSARILY WHETHER IT WOULD HAVE  
14 PUT IT OVER THE FUNDING LINE.

15 DR. DULIEGE: I UNDERSTAND. THANK YOU.

16 MR. SHEEHY: THANK YOU, DR. SAMBRANO.

17 AND JUST, BY THE WAY, IF YOU DO WANT  
18 TO -- IT'S FINE FOR PEOPLE TO CHIME IN; BUT IF YOU  
19 DO WANT TO RAISE YOUR HAND, YOU NEED -- YOU CAN GO  
20 TO THE PARTICIPANTS WINDOW, AND THEY DO HAVE THE  
21 OPTION THERE, BUT IT'S FINE FOR PEOPLE TO CHIME IN.  
22 SO I DON'T WANT TO DISCOURAGE THAT.

23 ARE THERE OTHER COMMENTS OR QUESTIONS FROM  
24 BOARD MEMBERS?

25 DR. MARTIN: I WOULD JUST LIKE TO MAKE THE

**BETH C. DRAIN, CA CSR NO. 7152**

1 COMMENT, ALTHOUGH I'VE BEEN SUFFICIENTLY FORTUNATE  
2 NOT TO TAKE CARE OF A COVID ID PATIENT, THE ARDS  
3 SEEMS TO BE -- THAT AND CRS SEEM TO BE TWO OF THE  
4 MAJOR LIFE-THREATENING PHENOMENON IN THE SEVERELY  
5 AFFECTED AND INTUBATED PATIENTS. AND THIS IS AN  
6 APPLICATION THAT IS SO FAR ALONG IN TERMS OF HAVING  
7 A PRODUCT CANDIDATE IN THE CLINIC THAT HAPPENS TO BE  
8 STEM-CELL BASED AND IS TREATING THE LIFE-THREATENING  
9 ASPECT OF COVID ID 19. SO I THINK THAT THIS ONE,  
10 FOR ME, IS, GIVEN THAT THE CONCERNS OF THE WORKING  
11 GROUP WERE AT LEAST ADDRESSED BY THE PRINCIPAL  
12 INVESTIGATOR, IT SEEMS TO ME ONE THAT IS RIGHT AND  
13 ON TARGET BECAUSE THEY'RE TREATING THE CLINICAL  
14 ASPECT WITH A NOVEL APPROACH WITH A GROUP OF CENTERS  
15 THAT ARE WELL EXPERIENCED IN THIS PARTICULAR  
16 CLINICAL SYNDROME ASSOCIATED WITH THIS PARTICULAR  
17 INFECTION. SO I WOULD CERTAINLY ENCOURAGE US TO  
18 SERIOUSLY CONSIDER SUPPORTING THIS, PARTICULARLY  
19 SINCE IT'S SO FAR ALONG. AND TO GET A CLINICAL  
20 TRIAL FOR THIS PRICE THAT ALREADY HAS MOMENTUM I  
21 THINK IS AN IMPORTANT OPPORTUNITY FOR US.

22 MR. SHEEHY: THANK YOU, DR. MARTIN.  
23 ADDITIONAL COMMENTS OR QUESTIONS FROM BOARD MEMBERS?

24 CHAIRMAN THOMAS: MR. SHEEHY, JUST ONE  
25 LAST POINT FOR ME. I WANT TO ECHO WHAT DR. MARTIN

**BETH C. DRAIN, CA CSR NO. 7152**

1 SAID, AND I'D ALSO MAKE THE POINT THAT IT'S  
2 PIGGYBACKING OFF OF A PREVIOUSLY, THIS IS  
3 REITERATION, PREVIOUSLY FUNDED CIRM PROJECT THAT IT  
4 ITSELF HAD GONE THROUGH THE GWG PROCESS FAVORABLY.  
5 AND SO I THINK THAT HAVING THIS AS AN EXTENSION OF  
6 THAT TO FURTHER THE BALL HERE MAKES IMMINENT SENSE.

7 MR. SHEEHY: THANK YOU, CHAIRMAN THOMAS.  
8 ADDITIONAL COMMENTS, QUESTIONS? THANK YOU. DO WE  
9 HAVE PUBLIC COMMENT?

10 MS. BONNEVILLE: I BELIEVE -- YEAH, I  
11 THINK THERE WILL BE PUBLIC COMMENT.

12 DR. MATTHAY: THIS IS DR. MATTHAY. DOES  
13 THAT MEAN ME?

14 MS. BONNEVILLE: YES.

15 MR. SHEEHY: DR. MATTHAY.

16 MS. BONNEVILLE: IF YOU HAVE COMMENTS,  
17 PLEASE.

18 DR. MATTHAY: ALL RIGHT. SO THANK YOU  
19 VERY MUCH FOR CONSIDERING THIS PROPOSAL. I WON'T  
20 BELABOR, BECAUSE IT'S ALREADY BEEN DISCUSSED, SOME  
21 OF THE RESPONSES TO THE REVIEW. I'M SORRY THAT IT  
22 WAS NOT CLEAR IN THE WAY WE EXPLAINED THE  
23 APPLICATION THAT THIS REALLY IS A 120-PATIENT TRIAL.  
24 AND SO IT'S BASED STATISTICALLY ON THE 120 PATIENTS,  
25 NOT THE PROPOSED 20 ADDITIONAL PATIENTS. AND IT IS

**BETH C. DRAIN, CA CSR NO. 7152**

1 DOUBLE BLIND, RANDOMIZED PLACEBO CONTROLLED.

2 AND IN TERMS OF THE COVID-19 ISSUE, I  
3 WOULD LIKE TO REASSURE THE REVIEW BOARD THAT WE ARE  
4 DOING EVERYTHING TO ENROLL THESE PATIENTS. IN FACT,  
5 I THINK I POINTED OUT IN THE RESPONSES THAT WE HAVE  
6 ENROLLED IN SAN FRANCISCO AT UCSF AND ZUCKERBERG 11  
7 OF 13 PATIENTS WITH ACUTE RESPIRATORY DISTRESS  
8 SYNDROME WHO ARE COVID POSITIVE. AND SINCE I  
9 SUBMITTED THAT YESTERDAY, WE ENROLLED ANOTHER  
10 PATIENT JUST YESTERDAY AFTERNOON. SO IT'S 12 OF 14.

11 SO WE ARE REALLY DOING WELL ON THE  
12 COVID-19 POSITIVE ARDS PATIENTS. I THINK I CAN  
13 ASSURE CIRM THAT THAT WILL CONTINUE AND THAT IS A  
14 MAJOR SUPPORTED PART OF OUR PROGRAM.

15 AND I THINK I WON'T GO THROUGH THE OTHER  
16 RESPONSES. I THINK IN INTEREST OF TIME, I WILL ALSO  
17 EMPHASIZE THAT WE HAVE A STRONG TRACK RECORD OF  
18 ENROLLING IN PRIOR TRIALS IN BOTH CALIFORNIA AND  
19 NATIONAL TRIALS. I INDICATED THAT IN THE RESPONSE  
20 NO. 8. AND I DO THINK ACTUALLY THAT IT IS HEALTHY  
21 FOR US TO INTEGRATE WITH ACADEMIC AND INDUSTRY FOR  
22 THESE TRIALS. AND I HAVE BEEN SUPPORTIVE OF, FOR  
23 EXAMPLE, OTHER EFFORTS IN THE PRIVATE DOMAIN SUCH AS  
24 ATHERSYS, THE MULTISTEM THERAPY IN CLEVELAND, OHIO.  
25 THEY'RE TRYING TO START A TRIAL, AND I THINK THAT'S

**BETH C. DRAIN, CA CSR NO. 7152**

1 VERY GOOD. WE NEED MORE THAN ONE EFFORT IN THIS  
2 AREA.

3 AND SO I THINK THAT'S PART OF CIRM'S  
4 MISSION; AND ALTHOUGH I'M ACADEMICALLY ORIENTED AND  
5 I HAVE NO FINANCIAL CONNECTION TO ATHERSYS, I STILL  
6 ENCOURAGE EFFORTS IN BOTH AREAS. THAT DOES CONFORM  
7 WITH WHAT DR. FRANCIS COLLINS HAS RECOMMENDED FROM  
8 THE NIH.

9 AND I WOULD LIKE TO EMPHASIZE TWO OTHER  
10 POINTS. WE ARE REALLY FOCUSED ON UNDERSERVED  
11 POPULATIONS, WHICH WAS THE THEME OF OTHER ALPHA STEM  
12 CELL APPLICATIONS AND FUNDING FROM CIRM AT UCSF, AND  
13 WE FULFILLED THAT COMMITMENT BY ENROLLING THE VAST  
14 MAJORITY, FOR EXAMPLE, OF OUR COVID-19 PATIENTS WITH  
15 ARDS IN SAN FRANCISCO GENERAL HOSPITAL. AND  
16 UNIVERSITY OF CALIFORNIA DAVIS WOULD INCREASE THE  
17 OPPORTUNITY TO SERVE AND ENROLL PATIENTS WITH AN  
18 UNDERSERVED BACKGROUND.

19 AND I LAID OUT THE STRENGTH OF THE  
20 APPLICATION, I THINK, IN TERMS OF THE INVESTIGATORS  
21 AT UC DAVIS WITH WHOM I'VE WORKED FOR MANY YEARS AND  
22 HAVE A PARTICULARLY TALENTED YOUNG ASSOCIATE  
23 PROFESSOR, DR. CALLCUT, WHO WAS WITH US AT UCSF AND  
24 MOVED TO A MAJOR POSITION AT UC DAVIS IN MARCH. SO  
25 I THINK WE HAVE ALL THAT WOULD BE NEEDED TO DO THIS



**BETH C. DRAIN, CA CSR NO. 7152**

1 VERY WELL, AND THERE'S STRONG SUPPORT FROM THE  
2 DEPARTMENT OF DEFENSE AND THE NIH.

3 SO WHY DON'T I STOP THERE SO I DON'T TAKE  
4 TOO MUCH OF YOUR TIME. BUT IF THERE ARE ANY  
5 QUESTIONS, I'D BE HAPPY TO TAKE THEM.

6 MR. SHEEHY: THANK YOU, DR. MATTHAY. I  
7 THINK WE HAVE ANOTHER PUBLIC COMMENT, RIGHT?

8 MS. BONNEVILLE: YES. IT'S FROM PHONE NO.  
9 (626) 340-5600.

10 DR. SHI: SO IS THAT ME? HELLO.

11 MS. BONNEVILLE: YOU HAVE PUBLIC COMMENT  
12 ABOUT THIS PARTICULAR AWARD OR APPLICATION?

13 DR. SHI: I HAVE COUPLE COMMENTS FOR  
14 COVID-19 11813.

15 MR. SHEEHY: GREAT. GREAT. IF YOU DON'T  
16 MIND, COULD YOU STATE YOUR NAME FOR THE PERSON  
17 TAKING --

18 DR. SHI: MAY I START?

19 MR. SHEEHY: PLEASE.

20 DR. SHI: HELLO, CHAIRMAN THOMAS AND THE  
21 MEMBERS OF THE BOARD. I'M YANHONG SHI, A PROFESSOR  
22 FROM CITY OF HOPE. I'M HERE TO ASK YOU TO CONSIDER  
23 FUNDING MY APPLICATION DUE TO COVID-19, 11813,  
24 "COMBATING COVID-19 USING HUMAN PSC-DERIVED NK  
25 CELLS." THIS PROPOSAL RECEIVED A SCORE OF 78, ONLY

**BETH C. DRAIN, CA CSR NO. 7152**

1 A FEW POINTS BELOW THE FUNDING LINE. BECAUSE  
2 MULTIPLE REVIEWERS FEEL THAT THIS PROPOSAL COULD  
3 YIELD SIGNIFICANT IMPACT ON THE FIELD, I ASK THAT  
4 YOU CONSIDER FUNDING THIS STUDY.

5 TODAY THERE ARE NO APPROVED PROPHYLACTIC  
6 OR THERAPEUTIC OPTIONS FOR COVID-19. AND MORE  
7 IMPORTANTLY, IT IS LIKELY THAT COVID-19 WILL BE WITH  
8 US FOR THE FORESEEABLE FUTURE. EVEN WITH A FUTURE  
9 VACCINE, PATIENTS WHO ARE SEVERELY AFFECTED BY THIS  
10 DISEASE WILL CONTINUE TO APPEAR. THUS, HAVING  
11 TREATMENT OPTIONS AVAILABLE COULD BE LIFESAVING.

12 NK CELLS PLAY AN IMPORTANT ROLE IN  
13 REGULATING A DEFENSE AGAINST THE VIRALLY INFECTED  
14 CELLS AND THE TUMOR CELLS. DEPLETION AND EXHAUSTION  
15 OF NK CELLS HAS BEEN SHOWN TO CAUSE DISEASE  
16 PROGRESSION AND A POOR CLINICAL OUTCOME ASSOCIATED  
17 WITH VIRAL INFECTION AND CANCER. IN THIS REGARD,  
18 IMMENSE ADVANCEMENT HAS BEEN MADE IN CELL-BASED  
19 IMMUNOTHERAPY TO ENHANCE PATIENT'S IMMUNE SYSTEMS  
20 THROUGH ADOPTIVE TRANSFER.

21 WE PROPOSE TO USE GENETICALLY ENGINEERED  
22 PLURIPOTENT STEM CELLS TO MAKE AN UNLIMITED SUPPLY  
23 OF NK CELLS WITH ENHANCED KILLING EFFECT TO TREAT  
24 COVID-19. THESE NK CELLS COULD EFFECTIVELY KILL  
25 VIRALLY INFECTED CELLS AND RESIST VIRUS-INDUCED

1 EXHAUSTION.

2 THE REVIEWERS ACKNOWLEDGED THAT THIS  
3 PROJECT IS STRAIGHTFORWARD AND STREAMLINED. IF  
4 SUCCESSFUL COULD BE MOVED INTO PATIENTS QUICKLY.

5 ONE POTENTIAL CONCERN WAS THAT AN NK  
6 TREATMENT COULD HAVE TOXIC SIDE EFFECTS, BUT TO DATE  
7 NK THERAPY FOR CANCER HAS HAD MINIMAL TOXICITY. AN  
8 ADDED ADVANTAGE OF NK-BASED IMMUNOTHERAPY IS THAT NK  
9 CELLS DON'T HAVE THE SIDE EFFECTS OFTEN ASSOCIATED  
10 WITH IMMUNOTHERAPY SUCH AS CYTOKINE STORM. MULTIPLE  
11 CLINICAL TRIALS HAVE DEMONSTRATED THAT NK CELLS ARE  
12 SAFE. THE HUMAN PLURIPOTENT STEM CELL APPROACH  
13 PROPOSED IN THIS STUDY WILL ALLOW US TO GENERATE NK  
14 CELL THERAPY FOR COVID-19.

15 NUMEROUS COVID-19 PATIENTS DESPERATELY  
16 NEED TREATMENT. WE HOPE THAT THROUGH OUR RESEARCH  
17 THESE PATIENTS CAN BE SAVED TO LEAD A NORMAL AND  
18 FULFILLING LIFE. THANK YOU FOR YOUR ATTENTION. ON  
19 BEHALF OF COVID-19 PATIENTS AND THEIR FAMILIES, I'M  
20 HOPING YOU WILL APPROVE OUR PROPOSAL FOR FUNDING.  
21 THANK YOU.

22 MR. SHEEHY: THANK YOU. SENATOR TORRES, I  
23 SEE THAT YOU HAVE YOUR HAND UP.

24 MR. TORRES: SO THIS IS NOT ON THE MOTION,  
25 WHICH I SUPPORT, THAT'S BEFORE US, BUT ON ANOTHER

**BETH C. DRAIN, CA CSR NO. 7152**

1 APPLICATION WHICH I SAT THROUGH AS WELL WHERE THE  
2 SCORE --

3 MR. SHEEHY: SO, SENATOR TORRES, CAN WE  
4 WAIT AND GET THROUGH PUBLIC COMMENT?

5 MR. TORRES: OH, OKAY. SURE. I THOUGHT  
6 WE WERE DONE.

7 MR. SHEEHY: NO. NO. NOT QUITE. THANK  
8 YOU.

9 I HAVE ANOTHER PUBLIC COMMENT FROM  
10 (925) 818-8797. AND COULD I REQUEST THAT YOU SPEAK  
11 SPECIFICALLY TO THE MOTION THAT WE HAVE BEFORE US,  
12 WHICH IS ON THE APPLICATION -- I CAN'T SEE THE  
13 NUMBERS BECAUSE OF THE WAY THIS SHOWS UP ON MY  
14 SCREEN.

15 MS. BONNEVILLE: 11823.

16 MR. SHEEHY: RIGHT. RIGHT. SO IF YOU  
17 HAVE A COMMENT ON A DIFFERENT APPLICATION, CAN I  
18 PLEASE ASK THAT YOU WOULD HOLD FOR THAT?

19 DR. LI: YES. I HAVE A COMMENT ON OTHER  
20 APPLICATION, NOT THIS ONE. I CAN WAIT.

21 MR. SHEEHY: LET US GO FORWARD WITH THIS  
22 ONE. SO IS THERE ANY OTHER PUBLIC COMMENT ON THIS  
23 APPLICATION? GREAT. COULD WE THEN CALL THE ROLL ON  
24 THE MOTION TO MOVE THIS INTO THE FUNDABLE RANGE  
25 PLEASE?

**BETH C. DRAIN, CA CSR NO. 7152**

1 MS. BONNEVILLE: YES. ANNE-MARIE DULIEGE.  
2 DR. DULIEGE: YES.  
3 MS. BONNEVILLE: YSABEL DURON. DAVID  
4 HIGGINS.  
5 DR. HIGGINS: YES.  
6 MS. BONNEVILLE: STEVE JUELSGAARD.  
7 MR. JUELSGAARD: YES.  
8 MS. BONNEVILLE: DAVE 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: AL ROWLETT.  
21 MR. ROWLETT: YES.  
22 MS. BONNEVILLE: JEFF SHEEHY.  
23 MR. SHEEHY: YES.  
24 MS. BONNEVILLE: OS STEWARD. OS, YOU'RE  
25 ON MUTE. AFTER ALL THAT. THANK YOU.

**BETH C. DRAIN, CA CSR NO. 7152**

1 MR. TORRES: YOU SAW HIS THUMB?  
2 MS. BONNEVILLE: UH-HUH. JONATHAN THOMAS.  
3 CHAIRMAN THOMAS: YES.  
4 MS. BONNEVILLE: ART TORRES.  
5 MR. TORRES: AYE.  
6 MS. BONNEVILLE: DIANE WINOKUR.  
7 MS. WINOKUR: YES.  
8 MS. BONNEVILLE: THANK YOU. THE MOTION  
9 CARRIES.  
10 MR. SHEEHY: GREAT. SO, SENATOR TORRES, I  
11 THINK YOU WANTED TO MAKE A MOTION ABOUT ANOTHER  
12 APPLICATION OR A COMMENT ON ANOTHER APPLICATION?  
13 MR. TORRES: YES. I JUST WANTED TO ASK  
14 GILBERT REGARDING THE APPLICATION BY DR. SONG FROM  
15 CELULARITY, 11857. THE REVIEWERS DURING THE  
16 EXAMINATION, WE ALL GAVE IT PRETTY HIGH MARKS, IN  
17 THE HIGH 80S AND TWO 80S. I WAS WONDERING WHAT WERE  
18 THE OTHER SCORES BECAUSE I CAN'T GET THAT ON MY  
19 SCREEN BECAUSE THE TEXT IS TOO BIG FOR TRANSMISSION?  
20 DR. SAMBRANO: SURE. SO THIS IS  
21 APPLICATION 11857. AND SO THIS WAS A PHASE 1/2 OF  
22 HUMAN PLACENTAL HEMATOPOIETIC STEM CELL-DERIVED  
23 NATURAL KILLER CELLS FOR TREATMENT OF ADULTS WITH  
24 COVID-19. SO THIS HAD A MEDIAN SCORE OF 84. SO  
25 IT'S JUST ONE POINT BELOW THE FUNDING LINE. THERE

**BETH C. DRAIN, CA CSR NO. 7152**

1 WERE FIVE MEMBERS THAT SCORED BASICALLY 85 BECAUSE  
2 THAT WAS THE HIGHEST SCORE GIVEN, AND THEN THERE  
3 WERE NINE MEMBERS THAT SCORED BELOW THAT. AND THAT  
4 WOULD BE BETWEEN 70 AND 84.

5 MR. TORRES: AND CAN YOU TELL US WHAT THE  
6 APPLICATION DID?

7 DR. SAMBRANO: SURE. SO THIS IS A  
8 PROPOSAL FOR TAKING HUMAN PLACENTAL-DERIVED  
9 HEMATOPOIETIC STEM CELLS THAT ARE CULTURED INTO  
10 NATURAL KILLER CELLS. AND SO THIS IS A PROPOSAL TO  
11 DO A CLINICAL TRIAL TO STUDY THEIR IMPACT ON  
12 COVID-19 PATIENTS. SO THE NK CELL POPULATION IS  
13 ALLOGENEIC AND EXPANDED IN CULTURE IN ORDER TO HAVE  
14 SUFFICIENT CELLS TO TREAT PATIENTS.

15 I THINK THE CONCERNS RELATED TO THIS  
16 APPLICATION WERE, I THINK, THE UNKNOWN ABOUT  
17 NATURAL KILLER CELLS AS A THERAPEUTIC AND THE  
18 POTENTIAL RELEVANCE FOR COVID-19. THERE IS SOME  
19 DATA THAT SUGGEST THAT CELLS SUCH AS NATURAL KILLER  
20 CELLS AND T-CELLS BECOME EXHAUSTED BECAUSE OF  
21 CHRONIC STIMULATION IN COVID-19 PATIENTS. AND SO  
22 THAT IS THE REASON FOR TRYING TO PURSUE THIS AND  
23 OTHER SIMILAR STUDIES, BUT IT IS UNKNOWN WHAT THE  
24 EFFECT OF THE NATURAL KILLER CELLS IN A COVID-19  
25 PATIENT ENVIRONMENT WOULD BE.

**BETH C. DRAIN, CA CSR NO. 7152**

1 I THINK SOME OF THE FEARS FROM WORKING  
2 GROUP MEMBERS IS THAT IT COULD POTENTIALLY  
3 EXACERBATE THE CONDITION, BUT IT IS AN UNKNOWN. SO  
4 IT IS JUST A RISK.

5 MR. TORRES: WELL, EVERYTHING IS AN  
6 UNKNOWN RIGHT NOW IN THIS ENVIRONMENT. AND I THINK  
7 THAT I DON'T KNOW WHETHER WE SHOULD TAKE A RISK IN  
8 SEEING WHETHER THIS PROCESS WORKS OR NOT. THAT WAS  
9 THE ONLY ISSUE THAT I HAD RAISED BECAUSE I WAS  
10 INTRIGUED BY THE REVIEWERS AND WHAT THEY WERE  
11 HINTING AT, BUT ALSO A CONCERN ABOUT THE  
12 EXACERBATION THAT MANY OF THEM SAID AS WELL. SO I'M  
13 REAL -- I'M ON THE FENCE. I THINK I'M JUST NOT  
14 GOING TO MAKE A MOTION AND JUST LEAVE IT AT THAT  
15 UNLESS THERE ARE OTHER MEMBERS OF THE BOARD THAT  
16 WANT TO OPINE ON THIS ISSUE.

17 MR. SHEEHY: OTHER COMMENTS, QUESTIONS  
18 FROM BOARD MEMBERS ON THIS? OKAY. IS THERE  
19 ANY -- IS THERE A MOTION TO MOVE ANY OTHER  
20 APPLICATIONS FROM TIER II INTO TIER I?

21 THEN IS THERE A MOTION TO MOVE ANY  
22 APPLICATION FROM TIER I INTO TIER II?

23 THEN COULD I GET A MOTION TO APPROVE ALL  
24 THE APPLICATIONS IN TIER I, INCLUDING 11823, WHICH  
25 WE HAVE MOVED INTO TIER I?



**BETH C. DRAIN, CA CSR NO. 7152**

1 MR. TORRES: SO MOVED.

2 MR. SHEEHY: SO MOVED BY SENATOR TORRES.

3 SECOND?

4 DR. DULIEGE: I SECOND.

5 MR. SHEEHY: BY DR. DULIEGE.

6 IS THERE -- ARE THERE ANY COMMENTS -- ANY  
7 BOARD COMMENTS AND QUESTIONS ON THIS? ANY PUBLIC  
8 COMMENT? I THINK 925, I THINK THIS IS PROBABLY AS  
9 GOOD A PLACE AS ANY TO CHIME IN IF YOU'D LIKE TO  
10 MAKE YOUR COMMENTS.

11 DR. LI: OKAY. CAN YOU HEAR ME?

12 MR. SHEEHY: YES.

13 DR. LI: OKAY, GREAT. THANK YOU VERY  
14 MUCH. THIS IS DR. SONG LI CALLING FROM UCLA  
15 BIOENGINEERING. SO WE REALLY APPRECIATE THIS  
16 OPPORTUNITY TO RESPOND TO THE REVIEW. THIS IS  
17 REGARDING THE APPLICATION DISCOVERY GRANT 11838 WITH  
18 A SCORE OF 82. IT'S VERY CLOSE TO THE CUTOFF LINE.

19 WE APPRECIATE THE APPLICATION REVIEW  
20 COMMITTEE'S COMMENTS. AND BASICALLY WE HAVE  
21 UNANIMOUS SUPPORT FOR THE SIGNIFICANCE AND IMPACT OF  
22 THIS PROJECT FROM THE COMMITTEE AND IN THE COMMENTS  
23 ON THE UNIQUENESS AND ALSO THE PROMISING AND NOVEL  
24 APPROACH FOR HIGH RISK, HIGH REWARD PROJECT. SO  
25 THAT'S THE COMMENT.

**BETH C. DRAIN, CA CSR NO. 7152**

1 THE MAJOR CONCERN FOR THIS COMMENT WAS THE  
2 FEASIBILITY OF THE PRODUCT AND THE COMPLEXITY OF  
3 THIS DRUG (UNINTELLIGIBLE). SO THIS PROPOSAL, WHILE  
4 TRYING TO ADDRESS A MAJOR ISSUE FOR THIS COVID-19  
5 PANDEMIC, WE KNOW THAT ELDERLY POPULATION IS HIGHLY  
6 SUSCEPTIBLE AND VULNERABLE TO INFECTION AND THERE'S  
7 A HIGH DEATH RATE. SO THAT'S WELL-KNOWN.

8 THERE'S NO SOLUTION TO THIS PROBLEM. AND  
9 FOR THESE OLD PEOPLE, AND WE KNOW FOR ALL THE  
10 PREVIOUS INFECTIOUS DISEASE STUDIES, PEOPLE KNOW  
11 THAT EVEN VACCINE MAY BE MUCH LESS EFFECTIVE  
12 (UNINTELLIGIBLE) OTHER VIRUS VACCINES.

13 SO WHAT I'M TRYING TO PROPOSE IS TO BOOST  
14 THE T-MEMORY STEM CELLS, WHICH IS VERY IMPORTANT FOR  
15 THE LONG-TERM MEMORY OF THE IMMUNITY WHICH IS  
16 MISSING IN THE ELDERLY POPULATION.

17 SO WE HAVE A DRUG DELIVERY SYSTEM  
18 PROPOSED. SO REGARDING THE FEASIBILITY, I WOULD SAY  
19 IT'S NOT AS COMPLEX AS PEOPLE THOUGHT. WE HAVE  
20 THREE MAJOR COMPONENTS. AND ALL OF THESE COMPONENTS  
21 ACTUALLY HELPING AND USED IN OTHER CLINICAL TRIAL  
22 APPROVED AS PRODUCTS BY FDA. SO THESE THREE  
23 COMPONENTS, ONE IS THE SCAFFOLD MATERIAL, WHICH IS  
24 ALGINATE, IN A FEW THOUSANDS CLINICAL TRIAL OF  
25 PRODUCT APPROVED ALREADY. AND THE SECOND COMPONENT

**BETH C. DRAIN, CA CSR NO. 7152**

1 IS THIS ARTIFICIAL ANTIGEN PRESENT IN CELLS. AND  
2 THERE ARE AT LEAST SIX CLINICAL TRIAL INCLUDING ONE  
3 FOR T-CELL EXPANSION WITH ANTIBODY PRESENTATION AND  
4 EXPANDED T-CELLS AND USE THAT TO KILL CANCER. SO  
5 THAT'S IN CLINICAL TRIAL. SEVERAL OF THESE  
6 EXAMPLES. AND THE THIRD COMPONENT IS CYTOKINES.  
7 AND THESE CYTOKINES ACTUALLY ARE PROVIDED BY NIH FOR  
8 PRECLINICAL TRIAL WITH LARGE QUANTITY IN RESEARCH,  
9 GOOD QUALITY.

10 SO ALL OF THIS THREE COMPONENTS ALREADY  
11 HAVE A CLEAR PATHWAY FOR NIH APPROVAL. SO WE DON'T  
12 THINK IT'S A BIG ISSUE.

13 IN ADDITION, AS PART OF PROPOSED STUDIES,  
14 WE ARE GOING TO DO A STUDY TO EVALUATE THE EFFECTS  
15 OF EACH OF THESE COMPONENTS AND TRYING TO SIMPLIFY  
16 IT AND SEE WHICH IS NECESSARY AND SUFFICIENT TO  
17 INDUCE THE T-MEMORY STEM CELLS IN ELDERLY.

18 SO I THINK THIS IS FEASIBLE AND OUR TEAM  
19 REALLY INCLUDES INTERDISCIPLINARY EXPERTISE ON STEM  
20 CELL ENGINEERING, BIOMATERIALS, DRUG DELIVERY, AND  
21 VIROLOGY. AND WE HAVE ALL THESE MATERIALS READY.  
22 WE HAVE TESTED IT IN T-CELLS, ACTIVATION AND  
23 REGULATION WITH DRUG DELIVERY PLATFORM. SO WE THINK  
24 WE CAN MOVE QUICKLY WITH WHAT WE PROPOSE TO DO  
25 (UNINTELLIGIBLE) ON FEASIBILITY.

**BETH C. DRAIN, CA CSR NO. 7152**

1 I WILL STOP HERE AND BE HAPPY TO ANSWER  
2 ANY QUESTIONS.

3 MR. SHEEHY: THANK YOU, DR. LI.

4 DO WE HAVE ANY MORE PUBLIC COMMENT ON THE  
5 MOTION BEFORE US?

6 MS. BONNEVILLE: JEFF, I BELIEVE DR. SONG  
7 HAS A COMMENT. HE MIGHT BE ON MUTE RIGHT NOW. SO  
8 I'M LOOKING. I'M SCANNING. I DON'T SEE A HAND  
9 RAISED, SO I'M NOT SURE. JUST ONE SECOND. OKAY.  
10 DR. CASPER APPARENTLY IS WHO WILL BE SPEAKING, AND I  
11 DON'T KNOW, WE NEED A PHONE NUMBER FROM WHICH THEY  
12 ARE SPEAKING IN ORDER TO GIVE THEM THE ABILITY TO  
13 GIVE A PUBLIC COMMENT.

14 MR. SHEEHY: OKAY.

15 MR. GUILLEN: DIAL STAR NINE AND YOU WILL  
16 RAISE YOUR HAND IF YOU WANT TO MAKE PUBLIC COMMENT.  
17 PLEASE DIAL STAR NINE ON YOUR TELEPHONE.

18 MS. BONNEVILLE: SO WE HAVE TWO. WE HAVE  
19 (206) 381-0883.

20 DR. CASPER: YEAH, HI. THAT'S ME. THIS  
21 IS DR. CASPER. CAN YOU HEAR ME?

22 MS. BONNEVILLE: YES.

23 DR. CASPER: THANK YOU VERY MUCH FOR  
24 GIVING ME THE OPPORTUNITY TO SPEAK. THIS IS DR.  
25 CORY CASPER. I'M THE CHIEF EXECUTIVE OFFICER OF THE

**BETH C. DRAIN, CA CSR NO. 7152**

1 INFECTIOUS DISEASE RESEARCH INSTITUTE AND A  
2 PROFESSOR OF MEDICINE AND INFECTIOUS DISEASE AT THE  
3 UNIVERSITY OF WASHINGTON. I'M SPEAKING, I GUESS, ON  
4 BEHALF OF APPLICATION 857, WHICH IS THE CELULARITY  
5 TRIAL THAT WAS JUST DISCUSSED.

6 THIS STUDY RECEIVED WHAT I THOUGHT WERE  
7 VERY FAVORABLE REVIEWS. SO THANK YOU VERY MUCH FOR  
8 YOUR CAREFUL CONSIDERATION.

9 AS WAS NOTED, THEY WERE GENERALLY  
10 FAVORABLE AND THERE WERE SOME CONCERNS ABOUT  
11 POTENTIAL SAFETY ISSUES OF THE NK CELL INFUSION IN  
12 PATIENTS WITH COVID-19. SO ULTIMATELY YOU'RE RIGHT.  
13 IT'S IMPOSSIBLE TO KNOW WHETHER THESE CELLS WILL BE  
14 SAFE IN THIS CLINICAL CONDITION. IT'S OBVIOUSLY A  
15 NOVEL VIRUS AND THE NOVEL CLINICAL CONSTELLATION OF  
16 SYMPTOMS THAT WE ARE STILL LEARNING ABOUT. BUT I DO  
17 THINK THAT IT IS IMPORTANT TO TAKE A CHANCE AND TO  
18 DO THIS INVESTIGATION. I THINK THERE ARE  
19 APPROPRIATE SAFEGUARDS THAT HAVE BEEN BUILT INTO THE  
20 STUDY IN A VERY CAREFUL STUDY DESIGN, AND I CAN  
21 OUTLINE THOSE IN A MOMENT.

22 AND ALSO I THINK THAT, ALTHOUGH YOU CAN'T  
23 HAVE ANY PRELIMINARY DATA FOR THIS VIRUS, GIVEN THAT  
24 IT'S SO NEW, THE FACT THAT THIS PRODUCT HAS BEEN  
25 USED IN PHASE 1 STUDIES FOR CANCER IN 25 INDIVIDUALS

**BETH C. DRAIN, CA CSR NO. 7152**

1 WITH NO SIGNIFICANT SAFETY SIGNAL, I THINK, IS VERY  
2 IMPORTANT.

3 WITH RESPECT TO THE CLINICAL TRIAL DESIGN,  
4 THE INCLUSION CRITERIA FOR THE ELIGIBILITY OF  
5 PATIENTS IN THE TRIAL IS SUCH THAT PATIENTS ONLY  
6 WITH MODERATE DISEASE ARE ALLOWED TO ENTER. SO IT  
7 SAFEGUARDS AGAINST ENROLLING PATIENTS WHO ALREADY  
8 HAVE LUNG INJURY. AND THERE ARE ADDITIONAL  
9 SAFEGUARDS THAT ARE PROVIDED.

10 SO ONE SAFEGUARD IS THAT THERE'S A REDUCED  
11 DOSE OF THE CELLS THAT ARE PROVIDED AT THE FIRST  
12 INFUSION WITH CLOSE OBSERVATION BEFORE THE FULL DOSE  
13 IS PROVIDED IN THE SECOND AND THIRD INFUSION.

14 THERE'S CAREFUL MONITORING, AND IT'S MANDATED THAT  
15 THE DRUG WHICH IS CURRENTLY USED IN MY INSTITUTION  
16 AND OTHERS FOR DEFENDING AGAINST THIS CYTOKINE  
17 RELEASE SYNDROME, THESE ARE IL6 RECEPTOR BLOCKERS,  
18 ARE AVAILABLE FOR RESCUE SHOULD PATIENTS BEGIN TO  
19 DEVELOP ANY OF THESE CLINICAL CONDITIONS.

20 THERE'S A VERY CAREFUL PHASE 1 AND PHASE 2  
21 DESIGN. THE FIRST THREE PATIENTS THAT ARE ENROLLED  
22 WILL BE EVALUATED RIGOROUSLY BY DATA SAFETY  
23 MONITORING BOARD; AND THEN AFTER 11 ADDITIONAL  
24 PATIENTS ARE ENROLLED, THEY WILL ALSO BE REVIEWED BY  
25 THE DATA SAFETY COMMITTEE. SO I THINK THAT THERE

**BETH C. DRAIN, CA CSR NO. 7152**

1 ARE AMPLE OPPORTUNITIES TO SURVEY, PREVENT, AND  
2 ANALYZE ANY ADVERSE EVENTS THAT COME FROM THIS  
3 TRIAL.

4 SO IN SUM, I THINK THAT WE HAVE A PRODUCT  
5 THAT I THINK IS -- HAS A BIOLOGIC PLAUSIBILITY FOR  
6 BEING VERY IMPORTANT AND VERY UNIQUE IN ITS  
7 TREATMENT FOR COVID DISEASE. I THINK THAT WE HAVE  
8 ADEQUATE SAFEGUARDS THAT HAVE BEEN PUT INTO THE  
9 TRIAL TO REALLY ASSURE THE SAFETY OF THE  
10 PARTICIPANTS. AND, AGAIN, WE APPRECIATE THE  
11 ENTHUSIASM THAT WAS VOICED BY THE REVIEWERS.

12 MR. SHEEHY: THANK YOU. ADDITIONAL PUBLIC  
13 COMMENT?

14 MS. BONNEVILLE: WE HAVE TWO HANDS RAISED.  
15 I BELIEVE -- I THINK IT'S SONG LI HAS THE HAND  
16 RAISED.

17 MR. SHEEHY: PUBLIC COMMENT?

18 DR. LI: CAN I MAKE A QUICK COMMENT?

19 MR. SHEEHY: QUICK. I MEAN GENERALLY WE  
20 ONLY ONE -- YOU GET ONE SHOT KIND OF IN PUBLIC  
21 COMMENT, BUT GO AHEAD.

22 DR. LI: TEN SECONDS. I JUST WANTED TO  
23 ADD THAT INDEED THE REVIEW COMMITTEE POINTED OUT  
24 THIS DISCOVERY STAGE PROJECT. IT'S A CHALLENGE, BUT  
25 IT'S WORTH THE RISK FOR SMALL INVESTMENT. INDEED,

**BETH C. DRAIN, CA CSR NO. 7152**

1 THE IMPACT IS HUGE, I THINK, TO TRACK THE ELDERLY  
2 POPULATION'S VULNERABILITY TO THE DISEASE. I HOPE  
3 THE BOARD CAN SEE THIS FAVORABLE AND MOVE THIS TO  
4 CATEGORY ONE.

5 MR. SHEEHY: THANK YOU. NO MORE PUBLIC  
6 COMMENT?

7 MS. BONNEVILLE: I DON'T SEE ANY.

8 MR. SHEEHY: OKAY. SO COULD WE CALL THE  
9 ROLL ON THIS MOTION TO FUND THE APPLICATIONS IN TIER  
10 I INCLUDING THE ONE WE ADDED, 11823?

11 MS. BONNEVILLE: YES.

12 ANNE-MARIE DULIEGE.

13 DR. DULIEGE: NO FOR ME.

14 MS. BONNEVILLE: DAVID HIGGINS.

15 DR. HIGGINS: YES.

16 MS. BONNEVILLE: STEVE JUELSGAARD.

17 MR. JUELSGAARD: YES.

18 MS. BONNEVILLE: DAVE MARTIN.

19 DR. MARTIN: YES.

20 MS. BONNEVILLE: LAUREN MILLER.

21 MS. MILLER: YES.

22 MS. BONNEVILLE: JOE PANETTA.

23 MR. PANETTA: YES.

24 MS. BONNEVILLE: FRANCISCO PRIETO.

25 DR. PRIETO: AYE.



**BETH C. DRAIN, CA CSR NO. 7152**

1 MS. BONNEVILLE: ROBERT QUINT.  
2 DR. QUINT: YES.  
3 MS. BONNEVILLE: AL ROWLETT.  
4 MR. ROWLETT: YES.  
5 MS. BONNEVILLE: JEFF SHEEHY.  
6 MR. SHEEHY: YES.  
7 MS. BONNEVILLE: OS STEWARD.  
8 DR. STEWARD: YES.  
9 MS. BONNEVILLE: WE HEARD YOU.  
10 JONATHAN THOMAS. J.T.?  
11 CHAIRMAN THOMAS: YES.  
12 MS. BONNEVILLE: ART TORRES.  
13 MR. TORRES: AYE, ALL THREE.  
14 MS. BONNEVILLE: DIANE WINOKUR.  
15 MS. WINOKUR: YES.  
16 MS. BONNEVILLE: THANK YOU. THE MOTION  
17 CARRIES.  
18 MR. SHEEHY: THANK YOU.  
19 NOW WHAT WE WOULD NEED IS A MOTION TO NOT  
20 FUND THE REMAINING APPLICATIONS.  
21 DR. DULIEGE: I MAKE THIS MOTION.  
22 MR. SHEEHY: MADE BY DR. DULIEGE. IS  
23 THERE A SECOND?  
24 DR. STEWARD: SECOND.  
25 MR. SHEEHY: SECONDED BY DR. STEWARD. ANY

**BETH C. DRAIN, CA CSR NO. 7152**

1 BOARD COMMENT OR DISCUSSION?

2 MR. TORRES: YES, MR. CHAIRMAN, IT'S  
3 TORRES AGAIN.

4 MR. SHEEHY: SURE.

5 MR. TORRES: A QUESTION OF GILBERT. IF WE  
6 CHOOSE TO REJECT ALL THE REMAINING APPLICATIONS, DO  
7 ANY OF THEM HAVE AN OPPORTUNITY TO MODIFY OR REFORM  
8 THEIR PROPOSAL IN TIME FOR ANOTHER ROUND THAT WE  
9 MIGHT HAVE IN THE VERY NEAR FUTURE?

10 DR. SAMBRANO: SO THE NEXT APPLICATION  
11 DEADLINE IS THIS COMING TUESDAY. SO ALL APPLICANTS  
12 HAVE AN OPPORTUNITY TO REVISE AND RESUBMIT.

13 MR. TORRES: EVEN IF THEY WERE REJECTED  
14 TODAY, THEY CAN REVISE AND RESUBMIT?

15 DR. SAMBRANO: YES, ABSOLUTELY.

16 MR. TORRES: ALL RIGHT. THANK YOU, MR.  
17 CHAIRMAN.

18 MR. SHEEHY: OKAY. THANK YOU, SENATOR  
19 TORRES. ANY OTHER BOARD COMMENTS OR QUESTIONS? DO  
20 WE HAVE ANY PUBLIC COMMENT ON THIS MOTION? IF NOT,  
21 COULD WE CALL THE ROLL PLEASE, MS. BONNEVILLE.

22 MS. BONNEVILLE: ANNE-MARIE DULIEGE.

23 DR. DULIEGE: YES.

24 MS. BONNEVILLE: DAVID HIGGINS.

25 DR. HIGGINS: YES.

**BETH C. DRAIN, CA CSR NO. 7152**

1 MS. BONNEVILLE: STEVE JUELSGAARD.  
2 MR. JUELSGAARD: YES.  
3 MS. BONNEVILLE: DAVE MARTIN.  
4 DR. MARTIN: YES.  
5 MS. BONNEVILLE: LAUREN MILLER.  
6 MS. MILLER: YES.  
7 MS. BONNEVILLE: JOE PANETTA.  
8 MR. PANETTA: YEP.  
9 MS. BONNEVILLE: FRANCISCO PRIETO.  
10 DR. PRIETO: AYE.  
11 MS. BONNEVILLE: ROBERT QUINT.  
12 DR. QUINT: YES.  
13 MS. BONNEVILLE: AL ROWLETT.  
14 MR. ROWLETT: YES.  
15 MS. BONNEVILLE: JEFF SHEEHY.  
16 MR. SHEEHY: YES.  
17 MS. BONNEVILLE: OS STEWARD.  
18 DR. STEWARD: YES.  
19 MS. BONNEVILLE: JONATHAN THOMAS.  
20 CHAIRMAN THOMAS: YES.  
21 MS. BONNEVILLE: ART TORRES.  
22 MR. TORRES: AYE.  
23 MS. BONNEVILLE: DIANE WINOKUR.  
24 MS. WINOKUR: YES.  
25 MS. BONNEVILLE: THANK YOU. THE MOTION

**BETH C. DRAIN, CA CSR NO. 7152**

1 CARRIES.

2 MR. SHEEHY: THANK YOU, MS. BONNEVILLE.  
3 CHAIRMAN THOMAS, THIS CONCLUDES THE BUSINESS OF THE  
4 APPLICATION REVIEW SUBCOMMITTEE.

5 CHAIRMAN THOMAS: THANK YOU VERY MUCH, MR.  
6 SHEEHY AND ALL PARTICIPANTS.

7 WE HAVE ONE OTHER ITEM ON THE AGENDA,  
8 WHICH IS PUBLIC COMMENT ON ANY TOPICS IN GENERAL.  
9 DO WE HAVE ANY MEMBERS OF THE PUBLIC WHO WOULD LIKE  
10 TO SAY ANYTHING AT THIS POINT? HEARING NONE, I  
11 AGAIN WANT TO THANK EVERYBODY. IT'S AN ADDITIONAL  
12 THREE COVID AWARDS. WE HAVE BEEN DEFINITELY DOING  
13 OUR PART TO CONTRIBUTE TO THIS UNPRECEDENTED,  
14 WORLDWIDE EFFORT TO FIND TREATMENTS AND THERAPIES  
15 FOR THIS NOVEL DISEASE.

16 WE WILL HAVE ANOTHER MEETING OF THE GRANTS  
17 WORKING GROUP IN A COUPLE WEEKS TO CONSIDER THE NEXT  
18 ROUND OF APPLICATIONS, AND WE'LL RECONVENE THIS BODY  
19 SHORTLY THEREAFTER. PLEASE, EVERYBODY, YOU AND YOUR  
20 FAMILIES STAY SAFE. WITH THAT, WE STAND ADJOURNED.

21 (THE MEETING WAS THEN CONCLUDED AT 12:09 P.M.)  
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 PROCEEDINGS VIA ZOOM 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 MAY 15, 2020, 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