

BETH C. DRAIN, CA CSR NO. 7152

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

LOCATION: VIA ZOOM

DATE: NOVEMBER 21, 2024
9 A.M.

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

FILE NO.: 2024-40

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

BETH C. DRAIN, CA CSR NO. 7152

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 CLINICAL TRIAL STAGE PROJECTS PROGRAM ANNOUNCEMENTS (CLIN 1, 2 OR 4)	5
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 AGENDA ITEM 3 ABOVE. (HEALTH & SAFETY CODE 125290.30(F) (3) (B) AND (C)).	
OPEN SESSION	
6. GENERAL COMMENTS ON ARS PROCESS	NONE
7. PUBLIC COMMENT	25
8. ADJOURNMENT	28

BETH C. DRAIN, CA CSR NO. 7152

NOVEMBER 21, 2024; 9 A.M.

CHAIRMAN IMBASCIANI: SCOTT, IT'S MY
PLEASURE TO CALL TO ORDER --

MR. TOCHER: HOLD ONE SECOND. HAVE WE
STARTED THE ZOOM, THE YOUTUBE?

MS. MANDAC: YES.

MR. TOCHER: OKAY.

CHAIRMAN IMBASCIANI: OKAY. I'M GOING TO
CALL TO ORDER NOW THE IF THE 58TH MEETING OF THE
APPLICATION REVIEW SUBCOMMITTEE. AND I'M GOING TO
ASK SCOTT TO START BY TAKING THE ROLL.

MR. TOCHER: THANK YOU, VITO.

DAN BERNAL.

MR. BERNAL: PRESENT.

MR. TOCHER: MARIA BONNEVILLE.

VICE CHAIR BONNEVILLE: HERE.

MR. TOCHER: JUDY CHOU. LEONDRA
CLARK-HARVEY. ANNE-MARIE DULIEGE.

DR. DULIEGE: HERE.

MR. TOCHER: YSABEL DURON.

MS. DURON: HERE.

MR. TOCHER: MARK FISCHER-COLBRIE.

MR. FISCHER-COLBRIE: HERE.

MR. TOCHER: ELENA FLOWERS.

BETH C. DRAIN, CA CSR NO. 7152

1 DR. FLOWERS: PRESENT.
2 MR. TOCHER: DAVID HIGGINS. VITO
3 IMBASCIANI.
4 CHAIRMAN IMBASCIANI: HERE.
5 MR. TOCHER: RICH LAJARA.
6 MR. LAJARA: HERE.
7 MR. TOCHER: CHRIS MIASKOWSKI.
8 DR. MIASKOWSKI: PRESENT.
9 MR. TOCHER: LAUREN MILLER-ROGEN.
10 DR. MILLAN: HERE.
11 MR. TOCHER: ADRIANA PADILLA.
12 DR. PADILLA: HERE.
13 MR. TOCHER: JOE PANETTA.
14 MR. PANETTA: HERE.
15 MR. TOCHER: MARV SOUTHARD.
16 DR. SOUTHARD: HERE.
17 MR. TOCHER: KAROL WATSON.
18 DR. WATSON: HERE.
19 MR. TOCHER: KEVIN XU.
20 MS. MANDAC: ACTUALLY JUST JOINING.
21 MR. TOCHER: OKAY. I SEE THAT
22 CONCERN`KEVIN IS JUST JOINING US.
23 DR. XU: HERE. SORRY.
24 MR. TOCHER: GREAT. THANK YOU, KEVIN.
25 OKAY. WE'RE GOOD TO GO, VITO. WE HAVE A QUORUM.

BETH C. DRAIN, CA CSR NO. 7152

1 CHAIRMAN IMBASCIANI: THANK YOU, SCOTT.

2 SO WE'RE GOING TO CONSIDER THE
3 APPLICATIONS SUBMITTED IN RESPONSE TO CLINICAL STAGE
4 PROJECTS IN THE PROGRAM ANNOUNCEMENT. AND
5 DR. HAYLEY LAM IS GOING TO MAKE THE PRESENTATION OF
6 THE APPLICATIONS. TAKE IT AWAY, HAYLEY.

7 DR. LAM: THANK YOU. GOOD MORNING TO THE
8 BOARD. CAN YOU ALL SEE MY SHARED SCREEN?

9 MS. MANDAC: YEP.

10 DR. LAM: GREAT. THANK YOU.

11 SO I'LL BE TAKING YOU THROUGH THE CLINICAL
12 APPLICATIONS TODAY. AS ALWAYS, WE BEGIN WITH OUR
13 MISSION: ACCELERATING WORLD-CLASS SCIENCE TO
14 DELIVER TRANSFORMATIVE REGENERATIVE MEDICINE
15 TREATMENTS IN AN EQUITABLE MANNER TO A DIVERSE
16 CALIFORNIA AND WORLD.

17 THE CURRENT BUDGET STATUS FOR THE CLINICAL
18 PROGRAM IS AS FOLLOWS: 145.5 WAS APPROVED OR
19 ALLOCATED, RATHER, TO THE CLINICAL BUDGET, AND 14
20 MILLION HAS BEEN APPROVED SO FAR. AND THERE'S JUST
21 UNDER 30 MILLION UP FOR DISCUSSION TODAY.

22 THE SCORING SYSTEM FOR THE CLINICAL
23 PROGRAM REMAINS AS A 1, 2, AND A 3. A 1 IS A
24 RECOMMENDATION FOR FUNDING, WHICH ARE THE
25 APPLICATIONS BEFORE YOU TODAY. A 2, THE APPLICANT

BETH C. DRAIN, CA CSR NO. 7152

1 CAN IMPROVE THE PROJECT AND DOES NOT WARRANT FUNDING
2 AT THIS TIME, BUT THEY CAN RETURN WITH A REVISION
3 SUBMISSION. A SCORE OF A 3 IS A DO NOT RECOMMEND
4 FOR FUNDING, AND THE SAME PROJECT CANNOT RETURN FOR
5 AT LEAST SIX MONTHS.

6 THE REVIEW CRITERIA BY WHICH THESE
7 APPLICATIONS ARE SCORED FOR THE SCIENTIFIC ASPECTS
8 ARE THESE FIVE. SO DOES THE PROJECT HOLD THE
9 NECESSARY SIGNIFICANCE AND POTENTIAL FOR IMPACT? IS
10 THE RATIONALE SOUND? IS THE PROJECT WELL-PLANNED
11 AND DESIGNED? IS THE PROJECT FEASIBLE? AND DOES
12 THE PROJECT UPHOLD PRINCIPLES OF DIVERSITY, EQUITY,
13 AND INCLUSION?

14 IN OUR CLINICAL PROGRAM, IN ADDITION TO
15 THE SCIENTIFIC SCORING, WE ALSO HAVE A DIVERSITY,
16 EQUITY, AND INCLUSION SCORING, WHICH IS A SCALE OF
17 ZERO TO TEN, WITH TEN BEING AN OUTSTANDING RESPONSE.
18 AND THESE ARE SCORED BY ALL MEMBERS OF THE GRANTS
19 WORKING GROUP BOARD MEMBERS WITH NO CONFLICT.

20 THE REVIEW PANEL THAT REVIEWS ALL OF THESE
21 APPLICATIONS IS COMPOSED AS FOLLOWS. THERE'S UP TO
22 15 SCIENTIFIC GROUP MEMBERS, AND THESE FOLKS PROVIDE
23 THE SCIENTIFIC EVALUATION ACROSS THE DISEASE AREA,
24 MANUFACTURING, REGULATORY, PRODUCT DEVELOPMENT THAT
25 PROVIDE THE SCIENTIFIC SCORE FOR ALL APPLICATIONS.

1 OUR GRANTS WORKING GROUP BOARD MEMBERS, WHICH IS OUR
2 PATIENT ADVOCATE AND NURSE MEMBERS OF THE BOARD,
3 WHICH CONDUCT A DEI EVALUATION AND PROVIDE A PATIENT
4 PERSPECTIVE ON THE APPLICATIONS. AND THEY PROVIDE A
5 DEI SCORE ON ALL APPLICATIONS, AND THEY'RE ALSO
6 INVITED TO SUGGEST A SCIENTIFIC SCORE.

7 IN ADDITION, WE HAVE NONVOTING SCIENTIFIC
8 SPECIALISTS THAT WE BRING IN, AS NEEDED, TO PROVIDE
9 EXPERTISE IN AREAS THAT ARE NOT COVERED BY OUR
10 PANELISTS, OUR SCIENTIFIC GRANTS WORKING GROUP
11 MEMBERS.

12 SO WITH THAT, I'LL BE GOING STRAIGHT INTO
13 THE APPLICATIONS. THE FIRST APPLICATION FOR THE
14 COMMITTEE TO CONSIDER IS CLIN2-17078. SO THIS IS A
15 GENE-EDITED STEM CELL PRODUCT FOR ADA-SCID, WHICH
16 I'LL TALK ABOUT A LITTLE BIT MORE. THE GOAL OF THIS
17 PROJECT IS TO ESTABLISH COMMERCIAL MANUFACTURING OF
18 THE PRODUCT IN ANTICIPATION OF FILING FOR LICENSING
19 OF THE PRODUCT. THEY'RE REQUESTING JUST UNDER 15
20 MILLION WITH JUST UNDER 10 MILLION IN CO-FUNDING,
21 AND THIS IS A CALIFORNIA ORGANIZATION.

22 SO A LITTLE BIT ABOUT THE DISEASE. SO
23 ADA-SCID IS AN ADENOSINE DEAMINASE DEFICIENCY.
24 ESSENTIALLY THESE PATIENTS HAVE A NONFUNCTIONING
25 IMMUNE SYSTEM; AND IF IT'S NOT TREATED, IT'S

1 GENERALLY FATAL WITHIN THE FIRST TWO YEARS OF LIFE.

2 THE CURRENT TREATMENT THAT'S IDEAL IS A
3 MATCH-RELATED SIBLING DONOR TRANSPLANT. AND IT
4 USUALLY IS QUITE SUCCESSFUL, BUT IT'S ONLY AVAILABLE
5 FOR ABOUT 20 PERCENT OF PATIENTS.

6 SO THE PROPOSED THERAPY FOR FOLKS THAT
7 DON'T HAVE AN IDEAL DONOR, THERE IS SIGNIFICANT
8 RISKS OF REJECTION AND LONG-TERM SIDE EFFECTS OF THE
9 TREATMENT FROM A TRANSPLANT. AND THE PROPOSED
10 THERAPY IS ESSENTIALLY TO CORRECT THE PATIENT'S OWN
11 COPY OF THAT ADA ENZYME. AND IT'S A POTENTIALLY A
12 CURATIVE TREATMENT THAT IS A ONE-TIME TREATMENT AND
13 HAS LOWER REJECTION RISKS AND LOWER RISK OF
14 LONG-TERM SIDE EFFECTS.

15 AND HOW IT'S RELEVANT TO CIRM IS THAT IT'S
16 A GENE-EDITED STEM CELL PRODUCT.

17 IN TERMS OF THE CIRM PORTFOLIO, THERE IS A
18 CURRENT RUNNING PHASE 2 TRIAL FOR THE SAME PRODUCT.
19 THIS TRIAL HAS BEEN ONGOING FOR A WHILE, BUT STILL
20 HAS SOME FUNDING IN IT AND IS ANTICIPATED TO BE ABLE
21 TO TREAT A FEW MORE PATIENTS WITH THE REMAINING
22 FUNDS.

23 THE APPLICANT TEAM HAS RECEIVED SEVERAL
24 APPLICATION OR SEVERAL AWARDS, RATHER, FROM CIRM
25 PREVIOUSLY. SOME OF THEM ARE ACTIVE AWARDS ACROSS

BETH C. DRAIN, CA CSR NO. 7152

1 ALL THE SPECTRUM ESSENTIALLY OF OUR PRODUCT
2 DEVELOPMENT PIPELINE. SO TRANSLATIONAL AND
3 DISCOVERY AND AS WELL AS SOME AWARDS THAT HAVE BEEN
4 CLOSED. AND ALL OF THESE APPROACHES ARE SIMILAR IN
5 THE SENSE THAT THEY ARE GENE CORRECTING THE
6 PATIENT'S OWN CELLS FOR A GENE THAT HAS A MUTATION
7 IN IT.

8 SO FOR YOUR CONSIDERATION TODAY IS THIS
9 APPLICATION YOU'VE BEEN DISCUSSING, EFFICACY AND
10 SAFETY OF CRYOPRESERVED AUTOLOGOUS CD34+HSC
11 TRANSDUCED WITH EFS-ADA LENTIVIRAL VECTOR ENCODING
12 FOR THE HUMAN ADA GENE IN ADA-SCID SUBJECTS. AND SO
13 THEY'RE REQUESTING 14.798 MILLION, AND THE GWG
14 RECOMMENDATION FOR THIS WAS A UNANIMOUS 15 VOTES IN
15 FAVOR OF FUNDING, AND A DEI SCORE OF 8.5, AND THE
16 CIRM TEAM CONCURS WITH THE RECOMMENDATION OF THE
17 GRANTS WORKING GROUP. THANK YOU.

18 CHAIRMAN IMBASCIANI: THANK YOU, HAYLEY.
19 CHAIR WOULD LIKE TO ENTERTAIN A MOTION TO ACCEPT THE
20 RECOMMENDATION ON THIS APPLICATION.

21 DR. DULIEGE: I MOVE.

22 DR. SOUTHARD: AND MARV SECONDS.

23 CHAIRMAN IMBASCIANI: ANNE-MARIE AND --

24 MR. TOCHER: MARV SOUTHARD.

25 CHAIRMAN IMBASCIANI: THANK YOU, MARVIN.

BETH C. DRAIN, CA CSR NO. 7152

1 OKAY. THE FLOOR IS OPEN FOR DISCUSSION BY BOARD
2 MEMBERS ON APPLICATION 17078.

3 MS. MANDAC: MARIA HAS HER HAND UP.

4 CHAIRMAN IMBASCIANI: YOU CAN SEE THAT
5 BETTER THAN I. THANK YOU. MARIA.

6 VICE CHAIR BONNEVILLE: HI. I JUST HAVE A
7 QUESTION FOR THE TEAM. SO THIS IS AN AWARD THAT WE
8 CURRENTLY FUND, AND THIS IS JUST TO EXTEND THE WORK
9 ALREADY BEING DONE TO BE ABLE TO TREAT MORE PATIENTS
10 WITHIN THE SAME TRIAL IT? IS THAT WHAT I'M
11 UNDERSTANDING?

12 DR. LAM: SO THE PURPOSE OF THIS PROJECT
13 IS TO FUND THE COMMERCIAL MANUFACTURING OF THE
14 PRODUCT. SO -- AND THAT'S A NECESSARY STEP TO BE
15 ABLE TO FILE FOR THE BLA FOR LICENSING IF THAT MAKES
16 SENSE.

17 VICE CHAIR BONNEVILLE: AND IN ORDER TO DO
18 THAT, WE NEEDED TO ADD -- THEY NEEDED TO ADD MORE
19 PEOPLE -- MORE TRIAL PARTICIPANTS?

20 DR. LAM: CORRECT. SO THE --

21 VICE CHAIR BONNEVILLE: GO AHEAD.

22 DR. LAM: YES. SO THE FDA IS REQUESTING
23 FOR THE COMMERCIAL PRODUCT THAT THEY HAVE
24 ESSENTIALLY PROOF THAT THAT COMMERCIAL PRODUCT IS
25 EQUIVALENT TO WHAT THEY'VE BEEN USING.

1 VICE CHAIR BONNEVILLE: IS THAT AN
2 ACTIVITY THAT WE NORMALLY FUND, OR IS THIS SOMETHING
3 THAT -- HAVE WE DONE THIS BEFORE IS, I GUESS, MY
4 QUESTION. AND IS THIS A NECESSARY -- IT IS
5 SOMETHING WE ANTICIPATE WE WILL BE DOING FOR OTHER
6 AWARDS IN ORDER TO GET THEM TO A BLA?

7 DR. LAM: YES. SO IT WOULD BE AN EXPECTED
8 STEP FOR BLA.

9 VICE CHAIR BONNEVILLE: THANK YOU.

10 MS. DURON: SORRY. MY RAISED HAND DOESN'T
11 WORK. SORRY, VITO.

12 WHEN WE TALKED ABOUT GETTING IT TO MARKET
13 OR TO MANUFACTURE IT, REMIND ME, ONE, IF WE GET ANY
14 DOLLARS BACK ONCE IT GETS INTO MANUFACTURING. AND,
15 TWO, DO WE HAVE SOME CONTROL OR SAY OVER PRICING
16 WHICH OFTENTIMES IN THE VERY RARE DISEASES USUALLY
17 IS A REALLY BIG LIFT FOR MOST FAMILIES? SO I'M
18 WONDERING WHERE WE COME IN ON THAT AND WHAT WE CAN
19 SAY ABOUT THAT.

20 DR. LAM: ABOUT YOUR FIRST QUESTION, I'M
21 NOT EXACTLY SURE WHAT -- CAN YOU CLARIFY ON THE
22 MANUFACTURING?

23 MS. DURON: IT'S MY UNDERSTANDING, BASED
24 ON WHAT MARIA JUST SAID -- JUST ASKED, THAT IT IS
25 LEADING TOWARDS MANUFACTURING. IT'S STILL IN TRIAL.

BETH C. DRAIN, CA CSR NO. 7152

1 I'M ASSUMING THAT BECAUSE I KNOW WE TALKED ABOUT
2 GETTING INTO SUPPORTING BUILDING MANUFACTURING AND
3 WORKING WITH MANUFACTURING. SO I'M JUST -- I'M
4 ASSUMING WE'RE MOVING IN THAT DIRECTION TO GET OKAY.
5 AND IF I'M WRONG, PLEASE CLEAR IT UP FOR ME. BUT
6 I'M ACTUALLY MORE CONCERNED ABOUT PRICING AND IMPACT
7 OF THIS AND WHAT KIND OF SAY WE HAVE IN REGULATING
8 PRICING.

9 DR. SAMBRANO: HAYLEY, YOU WANT ME TO
10 RESPOND?

11 DR. LAM: SURE.

12 DR. SAMBRANO: YEAH. JUST TO CLARIFY,
13 THESE APPLICANTS ARE IN THEIR LAST STEPS TOWARDS
14 GETTING A BLA. IF THEY DO, AND THEY WOULDN'T
15 NECESSARILY ACHIEVE THAT UNTIL THE END OF THIS
16 AWARD, THEY NEED TO CONDUCT THESE MANUFACTURING
17 ACTIVITIES TO GET TO THAT PLACE. ONCE THEY DO GET A
18 BLA AND BEGIN COMMERCIALIZATION ACTIVITIES, THEN
19 THERE ARE THE REGULATIONS THAT WE HAVE IN PLACE THAT
20 WOULD APPLY IN TERMS OF THE RELATIVE AMOUNT THAT WE
21 PROVIDE TO HOW MUCH THEY MAKE OR IF THEY CHOOSE TO
22 LICENSE THE PRODUCT AND SO ON. SO THOSE RULES
23 WILL -- PROBABLY SCOTT AND RAFAEL KNOW WAY BETTER
24 THAN I DO. BUT THOSE DON'T APPLY UNTIL THEY
25 COMPLETE THOSE ACTIVITIES AND GET TO THIS POINT.

1 BUT THE ACTIVITIES THAT WE WOULD BE
2 FUNDING UNDER THIS AWARD ARE CONSISTENT WITH THE
3 TYPES OF ACTIVITIES THAT WE HAVE FUNDED FOR OTHER
4 PROJECTS. I THINK HERE WE'RE LOOKING AT THE VERY
5 TAIL END OF WHAT WOULD BE THE EQUIVALENT OF A PHASE
6 3 AND INTO BLA.

7 MS. DURON: SO I'M GOING TO BE STUPID
8 AGAIN, GIL, AND ASK ANOTHER QUESTION --

9 DR. SAMBRANO: NO WORRIES.

10 MS. DURON: -- BECAUSE I'M STILL
11 VERY -- WHAT I REALLY WANT TO KNOW IS AT WHAT POINT,
12 AT ANY POINT IN TIME DO WE HAVE A SAY. IF IT GETS
13 INTO MANUFACTURING AND COMMERCIALIZATION, DO WE HAVE
14 ANY SAY ON PRICING OR CONTROL BECAUSE THIS IS THE
15 KIND OF, YOU KNOW, IF IT'S A RARE DISEASE AND IT IS
16 AN INVALUABLE DISCOVERY, IT'S GOING TO BE VERY
17 PRICEY. AND MY CONCERN IS THAT A LOT OF THOSE
18 CHILDREN WHO SUFFER FROM IT, THEIR FAMILIES DON'T
19 NECESSARILY HAVE A TON OF MONEY TO AFFORD IT, AFFORD
20 THIS CURE I WOULD HOPE IT'S CALLED. SO I'M JUST
21 WONDERING IF WE, CIRM, HAVE -- AND MAYBE J.T. CAN
22 ANSWER. BUT I'M JUST KIND OF WONDERING NOW AS WE
23 KEEP TALKING ABOUT COMMERCIALIZATION AND WHO KNOWS
24 WHAT'S GOING TO HAPPEN IN THE CONTEXT OF OUR NEXT
25 ADMINISTRATION. SO I'M -- I'M JUST WONDERING IF WE

BETH C. DRAIN, CA CSR NO. 7152

1 HAVE ANY POWER, SINCE WE FUNDED THINGS LIKE THIS,
2 THAT WE CAN HELP KEEP THE COST DOWN.

3 MR. TOCHER: VITO, THIS IS SCOTT. IF I
4 CAN JUMP IN PERHAPS.

5 CHAIRMAN IMBASCIANI: BECAUSE I HAVE FOUR
6 PEOPLE WITH THEIR HANDS UP, BUT I WANT SOMEONE OUT
7 OF ORDER EVEN WHO WILL RESPOND TO THAT QUESTION. IS
8 THAT YOU, SCOTT?

9 MR. TOCHER: THAT'S RIGHT.

10 CHAIRMAN IMBASCIANI: GO AHEAD.

11 MR. TOCHER: YSABEL, I DON'T WANT
12 TO -- CAN YOU HEAR ME, YSABEL?

13 MS. DURON: YES, SCOTT, I CAN.

14 MR. TOCHER: OKAY. THANK YOU. AND I
15 DON'T WANT TO OVERWHELM EVERYONE WITH A PRIMER IN
16 OUR IP REGS, BUT YOUR QUESTION IS A GREAT ONE AND
17 ONE THAT THE INSTITUTE HAS WRESTLED WITH FOR MANY
18 YEARS AND HAS DEVELOPED A POLICY THAT'S EMBODIED IN
19 OUR INTELLECTUAL PROPERTY REGULATIONS. AND THAT
20 PROVIDES, PURSUANT TO PROP 14 -- 71'S MANDATE, THAT
21 CALIFORNIANS WITH NO OTHER MEANS HAVE ACCESS TO
22 THERAPIES THAT ARE DEVELOPED WITH CIRM FUNDING.

23 SO TO YOUR QUESTION, CALIFORNIANS WHO FALL
24 UNDER 300 PERCENT OF THE FEDERAL POVERTY LINE, A
25 COMMERCIALIZING ENTITY MUST COME WITH AN ACCESS PLAN

BETH C. DRAIN, CA CSR NO. 7152

1 AND PRESENT THAT PLAN TO THIS BOARD FOR APPROVAL
2 THAT WILL ADDRESS ACCESS TO SUCH CALIFORNIANS. AND
3 THE BOARD HAS AN UP-OR-DOWN VOTE ON THAT.

4 IN ADDITION, CALIFORNIA PUBLIC ENTITIES
5 THAT PURCHASE WITH PUBLIC FUNDS ALSO MUST BE
6 PROVIDED ACCESS AND PRICING THAT IS NEGOTIATED WITH
7 THOSE ENTITIES AT A DISCOUNT.

8 AND THEN FINALLY, THERE IS A THIRD LEG.
9 AND, OF COURSE, NATURALLY I'M FORGETTING IT. WE
10 HAVE THE ACCESS PLANS AND THEN CALIFORNIA PRICING.
11 OH, THAT'S RIGHT. AND THIS IS A VESTIGE OF AN
12 EARLIER LAW IN CALIFORNIA, I BELIEVE IT WAS UNDER
13 THE SCHWARZENEGGER ADMINISTRATION, THAT THE
14 CALIFORNIA DISCOUNT PRESCRIPTION DRUG PROGRAM, THE
15 CDPDP, WHICH WAS NEVER FUNDED UNFORTUNATELY, WAS A
16 STATEWIDE, AS IT MAY IMPLY, DISCOUNT PRESCRIPTION
17 DRUG PROGRAM.

18 SO WHAT WE'VE SAID IS WE'VE SORT OF
19 BOOTSTRAPPED TO THAT BODY OF LAW BASICALLY SAID
20 WHENEVER THIS PROGRAM GOES LIVE OR IT'S SUCCESSOR
21 GOES LIVE, THEN A COMMERCIALIZING ENTITY MUST
22 PARTICIPATE IN THAT PROGRAM TO PROVIDE DISCOUNTED
23 PRESCRIPTION DRUGS TO CALIFORNIANS.

24 SO THOSE ARE SORT OF THE THREE PRICING
25 LEGS OF THE STOOL THAT CALIFORNIA HAS FOR

1 COMMERCIALIZING ENTITIES. THANK YOU, VITO.

2 CHAIRMAN IMBASCIANI: THANKS. SO I HAVE
3 ANNE-MARIE AND MARIA. WHICH OF YOU WANTS TO FOLLOW
4 ON TO THIS DISCUSSION? ANNE-MARIE.

5 DR. DULIEGE: OKAY. DOESN'T MATTER. IT'S
6 NOT DIRECTLY RELATED ALTHOUGH I UNDERSTAND THE
7 IMPORTANCE OF THE QUESTION YSABEL WAS ASKING. JUST
8 TO CLARIFY AND FOLLOW UP TO MARIA'S FIRST QUESTION.
9 THIS PROJECT HAS ALREADY BEEN FUNDED. IT'S IN PHASE
10 2. AND I WOULD BE CURIOUS TO KNOW HOW MANY PATIENTS
11 HAVE BEEN ENROLLED OUT OF HOW MANY PATIENTS SHOULD
12 BE ENROLLED JUST TO KNOW WHERE WE ARE.

13 BUT THEN THIS -- IS THIS TO ADD PATIENTS
14 WITH A NEW MARKET COMMERCIAL LEVEL MANUFACTURING
15 PROCESS TO SHOW TO THE FDA THAT THE RESULTS WERE
16 SIMILAR WITH THE UPDATED MANUFACTURING PROCESS?

17 DR. LAM: YES.

18 DR. DULIEGE: OR ARE THESE PURELY
19 MANUFACTURING ACTIVITIES?

20 DR. LAM: NO. THEY WOULD HAVE TO
21 MAN- -- THE FUNDING IS TO MANUFACTURE THE COMMERCIAL
22 PRODUCT AND THEN TREAT PATIENTS AND DEMONSTRATE,
23 HOPEFULLY, IDEALLY, THAT THE TREATMENT HAS SIMILAR
24 RESULTS IN THOSE TRIAL PARTICIPANTS.

25 DR. DULIEGE: SO THIS IS A SECOND STEP,

1 MANUFACTURING, WHICH IS PARALLEL TO THE ONGOING
2 PHASE 2 TRIAL. AND THEN WHEN THE MANUFACTURING IS
3 AVAILABLE, MORE PATIENTS WILL THEN BE ADDED WHICH
4 MAY REQUIRE MORE FUNDING.

5 DR. LAM: CORRECT. I MEAN -- RIGHT. SO
6 THE -- RIGHT.

7 DR. DULIEGE: BRIEFLY, I DO UNDERSTAND HOW
8 THINGS HAPPEN IN CLINICAL DEVELOPMENT AND IT TAKES
9 SUCH A HUGE AMOUNT OF TIME THAT WE GO IN PARALLEL
10 RATHER THAN IN SEQUENTIAL STEPS. IT WOULD HAVE BEEN
11 IDEAL, BUT I THINK JUST SHARING MY KNOWLEDGE HERE TO
12 FIRST HAVE A KNOWLEDGE THAT THIS INTERVENTION IS
13 EFFECTIVE AND THEN DO THE MANUFACTURING PROCESS.
14 BUT I BELIEVE THAT IN REALITY IT WOULD BE -- IT'S A
15 RISK TAKING, BUT PATIENTS CANNOT AFFORD THAT WE TAKE
16 SO MUCH TIME IN THE DEVELOPMENT. I ASSUME THAT
17 THAT'S THE REALITY. THANK YOU.

18 DR. LAM: YEAH. WELL, I MEAN I WILL SAY I
19 BELIEVE THAT THIS GROUP HAS TREATED, I THINK, IT'S
20 OVER 50 PATIENTS WITH THE PRODUCT, WITH THE
21 NONCOMMERCIAL PRODUCT. AND THEY HAD REALLY, I MEAN
22 AS FAR AS I'M CONCERNED, PRETTY GOOD RESULTS, I
23 THINK.

24 DR. DULIEGE: GREAT.

25 DR. LAM: SO IF THEY PUBLISHED, I THINK

BETH C. DRAIN, CA CSR NO. 7152

1 LIKE THE MOST RECENT ONE I THINK WAS THE PUBLICATION
2 WHERE 48 OF THE 50 PATIENTS ACHIEVED LONG-TERM
3 IMMUNE RESTORATION.

4 DR. DULIEGE: GREAT. WELL, VERY USEFUL
5 INFORMATION. THANK YOU.

6 DR. LAM: SO I THINK -- YEAH.

7 CHAIRMAN IMBASCIANI: THANK YOU, HAYLEY,
8 FOR THE CLARIFYING COMMENTS. I SAW SOME HANDS GO
9 DOWN, BUT I WANT TO OFFER THE OPPORTUNITY IF RAFAEL
10 OR MARIA OR ANYONE ELSE TO ADD ANYTHING AT THIS
11 POINT.

12 MR. AGUIRRE-SACASA: NOTHING FROM ME.
13 SCOTT DID A GREAT JOB.

14 CHAIRMAN IMBASCIANI: OKAY. THANK YOU,
15 RAFAEL. ANY OTHER COMMENTS FROM BOARD MEMBERS ON
16 17078?

17 DR. LAM: DR. IMBASCIANI, IF I MAY, I ALSO
18 JUST WANTED TO ADD A COMMENT RELATED TO THIS
19 PARTICULAR APPLICATION WITH REGARDS TO, I THINK,
20 YSABEL'S QUESTIONS.

21 CHAIRMAN IMBASCIANI: PLEASE DO.

22 DR. LAM: THIS PARTICULAR APPLICANT IS
23 WORKING WITH A PUBLIC BENEFIT CORPORATION AND THE
24 COMMERCIAL MANUFACTURING PARTNER. AND THIS
25 PARTICULAR PARTNERSHIP, THEY ARE -- ONE OF THEIR

BETH C. DRAIN, CA CSR NO. 7152

1 MAIN FOCUSES, THE INTENT IS, AT LEAST, TO BE PATIENT
2 FOCUSED IN TERMS OF ACCESS TO THIS THERAPY.

3 CHAIRMAN IMBASCIANI: UH-HUH.

4 MS. DURON: THANK YOU, HAYLEY. MAY I JUST
5 SAY THIS KIND OF COSTS, EVEN WITH HELP, CAN
6 SOMETIMES BREAK THE BACK OF EVEN MIDDLE INCOME
7 FAMILIES AND EVEN UPPER INCOME FAMILIES. SO I'M
8 JUST -- I WAS JUST WONDERING ABOUT IT. BUT THANKS,
9 EVERYBODY, FOR THE CLARIFICATIONS. I APPRECIATE IT.

10 CHAIRMAN IMBASCIANI: OKAY, YSABEL. I
11 DON'T SEE ANY OTHER COMMENT. I'LL ASK IF THERE'S
12 ANY MEMBER OF THE PUBLIC THAT WOULD LIKE TO COMMENT
13 ON THIS APPLICATION.

14 MS. MANDAC: THERE ARE NO HANDS RAISED.

15 CHAIRMAN IMBASCIANI: THERE ARE NO HANDS
16 RAISED. SCOTT, I THINK WE ARE READY TO GO TO A ROLL
17 CALL VOTE.

18 MR. TOCHER: GREAT. AND THE MOTION IS TO
19 FUND CLIN2-17078.

20 MARIA BONNEVILLE.

21 VICE CHAIR BONNEVILLE: YES.

22 MR. TOCHER: JUDY CHOU. LEONDRA
23 CLARK-HARVEY. ANNE-MARIE DULIEGE.

24 DR. DULIEGE: YES.

25 MR. TOCHER: YSABEL DURON.

BETH C. DRAIN, CA CSR NO. 7152

1 MS. DURON: YES.
2 MR. TOCHER: MARK FISCHER-COLBRIE.
3 MR. FISCHER-COLBRIE: YES.
4 MR. TOCHER: DAVID HIGGINS.
5 DR. HIGGINS: YES.
6 MR. TOCHER: VITO IMBASCIANI.
7 CHAIRMAN IMBASCIANI: YES.
8 MR. TOCHER: RICH LAJARA.
9 MR. LAJARA: YES.
10 MR. TOCHER: LAUREN MILLER-ROGEN.
11 MS. MILLER-ROGEN: YES.
12 MR. TOCHER: ADRIANA PADILLA.
13 DR. PADILLA: YES.
14 MR. TOCHER: JOE PANETTA.
15 MR. PANETTA: YES.
16 MR. TOCHER: MARV SOUTHARD.
17 DR. SOUTHARD: YES.
18 MR. TOCHER: KEVIN XU.
19 DR. XU: YES.
20 MR. TOCHER: THANK YOU VERY MUCH. THE
21 MOTION CARRIES.
22 CHAIRMAN IMBASCIANI: THANK YOU, SCOTT.
23 WE CAN NOW PROCEED TO CONSIDERATION OF CLIN2-17127.
24 DR. LAM.
25 DR. LAM: THANK YOU. SO ON TO THE SECOND

1 APPLICATION. THIS IS A GENE-MODIFIED STEM CELL
2 THERAPY FOR ARTEMIS SCID, ART-SCID. AND THE GOAL OF
3 THIS PROJECT IS TO COMPLETE A PHASE 2 TRIAL AND ALSO
4 SUBMIT A BLA. AND THEY'RE REQUESTING JUST UNDER 15
5 MILLION WITH NO CO-FUNDING, AND THIS IS A CALIFORNIA
6 ORGANIZATION.

7 SO BACKGROUND ON THIS DISEASE. SO IT IS
8 ALSO A DIFFERENT VARIETY, I SUPPOSE, OF THE SCID.
9 SO ESSENTIALLY NO FUNCTIONING IMMUNE SYSTEM. AND,
10 AGAIN, THIS IS ALSO FATAL IF NOT TREATED. AND THIS
11 PARTICULAR VARIATION OF THE SCID DISPROPORTIONATELY
12 IMPACTS NATIVE AMERICAN POPULATIONS. AND THE
13 CURRENT STANDARD OF CARE TRANSPLANT HAS MORE
14 COMPLICATIONS IN ARTEMIS SCID COMPARED TO OTHER
15 TYPES OF SCID. AND THEY OFTENTIMES NEED FREQUENT
16 EXPENSIVE TREATMENTS, ONGOING TREATMENTS, BECAUSE
17 THE IMMUNE SYSTEMS CANNOT BE FULLY RESTORED EVEN
18 WITH A SUCCESSFUL TRANSPLANT.

19 SO THE PROPOSITION VALUE OF THE PROPOSED
20 THERAPY IS TO MODIFY THE PATIENT'S OWN BLOOD STEM
21 CELLS WITH A FUNCTIONAL COPY OF THE DEFECTIVE GENE
22 AND WITH THE GOAL OF RESTORING A HEALTHY IMMUNE
23 SYSTEM. AND, AGAIN, THE PATIENT'S OWN CELLS WILL
24 REDUCE THE RISK OF TRANSPLANTATION SUCH AS THE GRAFT
25 REJECTION. AND ALSO THE DATA TO DATE HAS SHOWN THAT

1 THERE'S MORE COMPLETE RESTORATION OF THE IMMUNE
2 SYSTEM WITH THIS METHOD.

3 AND THIS IS A CIRM PROJECT AS IT'S DERIVED
4 FROM STEM CELLS AND IS A GENE THERAPY.

5 THE CIRM PORTFOLIO PROJECTS, SO THERE IS A
6 PHASE 1 TRIAL THAT IS CLOSING FOR THE SAME PRODUCT
7 AND PROJECT. AND THIS IS, AGAIN, A PHASE 2 TRIAL.
8 SO A CONTINUATION.

9 THE APPLICANT TEAM HAS RECEIVED PRIOR CIRM
10 FUNDING FOR SEVERAL STAGES ALONG THE DEVELOPMENT OF
11 THE SAME PRODUCT AS YOU CAN SEE HERE. SO THEY'VE
12 BEEN FUNDED FROM PRECLINICAL THROUGH IND-ENABLING AT
13 THE PHASE 1 TRIAL.

14 SO FOR THE APPLICATION REVIEW
15 SUBCOMMITTEE'S CONSIDERATION IS CLIN2-17127, GENE
16 THERAPY FOR ARTEMIS DEFICIENT SEVERE COMBINED
17 IMMUNODEFICIENCY USING A CELL INACTIVATING
18 LENTIVIRAL VECTOR.

19 THE GRANTS WORKING GROUP RECOMMENDATION
20 WAS A UNANIMOUS RECOMMENDATION TO FUND, AND THE DEI
21 SCORE FOR THIS APPLICATION IS AN 8, AND THE CIRM
22 TEAM CONCURS WITH THE GRANTS WORKING GROUP
23 RECOMMENDATION TO FUND FOR THE AWARD AMOUNT OF JUST
24 UNDER 15 MILLION. SO I'LL HAND IT BACK TO CHAIR
25 IMBASCIANI.

BETH C. DRAIN, CA CSR NO. 7152

1 CHAIRMAN IMBASCIANI: THANK YOU, HAYLEY.
2 THANK YOU FOR THE RECOMMENDATION FROM THE REVIEW
3 TEAM. I WOULD LIKE TO HAVE A MOTION TO OPEN UP
4 DISCUSSION PLEASE.

5 DR. SOUTHARD: MARV SOUTHARD MOVES.

6 CHAIRMAN IMBASCIANI: YES. MARVIN, THAT
7 WAS A MOTION TO FUND, YES?

8 DR. SOUTHARD: YES.

9 CHAIRMAN IMBASCIANI: OKAY. AND WE HAVE A
10 SECOND?

11 MR. TOCHER: NOT AT THE MOMENT.

12 MR. FISCHER-COLBRIE: SECOND, MARK
13 FISCHER-COLBRIE.

14 MR. TOCHER: THANK YOU, MARK.

15 CHAIRMAN IMBASCIANI: THANK YOU, MARK.
16 OKAY. I'D LIKE TO OPEN THE FLOOR TO DISCUSSION FROM
17 BOARD MEMBERS. I DON'T SEE ANY HANDS. OKAY. IS
18 THERE ANY MEMBER OF THE PUBLIC THAT WOULD LIKE TO
19 ADDRESS THIS APPLICATION?

20 MS. MANDAC: NO HANDS RAISED.

21 CHAIRMAN IMBASCIANI: AND THERE ARE NONE
22 RAISED. OKAY. SCOTT, I KNOW YOU JUST DID, BUT YOU
23 NEED TO DO IT AGAIN. ROLL CALL VOTE.

24 MR. TOCHER: ALL RIGHT. JUST ONE MOMENT.
25 AND THIS IS A MOTION TO FUND CLIN2-17127.

BETH C. DRAIN, CA CSR NO. 7152

1 CHAIRMAN IMBASCIANI: YES.
2 MR. TOCHER: JUDY CHOU. LEONDRA
3 CLARK-HARVEY. ANNE-MARIE DULIEGE.
4 DR. DULIEGE: YES.
5 MR. TOCHER: MARK FISCHER-COLBRIE.
6 MR. FISCHER-COLBRIE: YES.
7 MR. TOCHER: DAVID HIGGINS.
8 DR. HIGGINS: YES.
9 MR. TOCHER: VITO IMBASCIANI.
10 CHAIRMAN IMBASCIANI: YES.
11 MR. TOCHER: RICH LAJARA.
12 MR. LAJARA: YES.
13 MR. TOCHER: LAUREN MILLER-ROGEN.
14 MS. MILLER-ROGEN: YES.
15 MR. TOCHER: ADRIANA PADILLA.
16 DR. PADILLA: YES.
17 MR. TOCHER: JOE PANETTA.
18 MR. PANETTA: YES.
19 MR. TOCHER: MARV SOUTHARD. MARV, I THINK
20 YOU MAY BE ON MUTE.
21 DR. SOUTHARD: I DON'T THINK SO. YES.
22 MR. TOCHER: OKAY. THANK YOU. MAYBE IT
23 WAS JUST ME. KAROL WATSON.
24 DR. WATSON: YES.
25 MR. TOCHER: KEVIN XU.

BETH C. DRAIN, CA CSR NO. 7152

1 DR. XU: YES.

2 MR. TOCHER: IT'S LIKE WE'RE ON A RADIO
3 PROGRAM. GREAT. THAT MOTION CARRIES. THANKS VERY
4 MUCH. I THINK I HAVE EVERYONE'S VOTE RECORDED.
5 AND, VITO, THE MOTION CARRIES.

6 CHAIRMAN IMBASCIANI: THANK YOU VERY MUCH.
7 OKAY. SO WE'RE COMING NOW TO THE PART OF THE
8 MEETING FOR PUBLIC COMMENT. AND I WOULD LIKE TO ASK
9 GIL -- I SEE WE HAVE A MEMBER OF THE PUBLIC IN
10 ATTENDANCE WHO WOULD LIKE TO MAKE A COMMENT. I'D
11 ASK THE GENTLEMAN PLEASE STATE YOUR NAME, AND YOU
12 HAVE THREE MINUTES TO ADDRESS THE BOARD.

13 MS. MANDAC: DR. RAMKUMAR, I DON'T KNOW IF
14 YOU CAN HEAR US.

15 CHAIRMAN IMBASCIANI: DR. RAMKUMAR, CAN
16 YOU HEAR ME?

17 DR. RAMKUMAR: CAN YOU HEAR ME?

18 MS. MANDAC: YES. TURN OFF THE YOUTUBE,
19 DR. RAMKUMAR.

20 CHAIRMAN IMBASCIANI: DR. RAMKUMAR, CAN
21 YOU HEAR ME?

22 DR. RAMKUMAR: I CAN HEAR YOU, BUT I KEEP
23 HEARING AN ECHO.

24 MS. MANDAC: IF YOU HAVE IT OPEN ON
25 YOUTUBE, COULD YOU PLEASE TURN OFF THE BROWSER?

BETH C. DRAIN, CA CSR NO. 7152

1 SORRY. WE CAN'T -- DR. RAMKUMAR, WE CAN SEE YOUR
2 LIPS MOVING, BUT UNFORTUNATELY THERE'S NO AUDIO.

3 DR. RAMKUMAR: HOW ABOUT NOW?

4 CHAIRMAN IMBASCIANI: YES.

5 MS. MANDAC: YES.

6 CHAIRMAN IMBASCIANI: GREAT.

7 DR. RAMKUMAR: OKAY. SORRY FOR THE
8 TECHNICAL ISSUES.

9 CHAIRMAN IMBASCIANI: THAT'S OKAY. THE
10 CLOCK HAS NOT STARTED YET. GO AHEAD.

11 DR. RAMKUMAR: OKAY, GREAT. HI. MY NAME
12 IS RAM. I'M THE COO FOR OCULOGENEX. AND WE ARE
13 DEVELOPING A PROMISING GENE THERAPY FOR AN UNMET
14 NEED IN THE OCULAR SPACE THAT WILL BENEFIT OVER TWO
15 MILLION CALIFORNIANS WITH AMD. A PRE-IND MEETING
16 PAVED A REALLY CLEAR PATH FOR US TO GET TO
17 FIRST-IN-HUMAN TRIALS WITH STRONG FDA SUPPORT OF OUR
18 PLANS.

19 WE SUBMITTED A CLIN1 GRANT PROPOSAL IN
20 JULY AND WERE NOTIFIED IN OCTOBER THAT WE WILL NOT
21 PROCEED TO THE GWG MERIT REVIEW PRIOR TO MAKING OUR
22 FUNDING DECISIONS. AND WE DIDN'T RECEIVE ANY
23 DETAILS AT THAT TIME. I DID ATTEND THE JUNE ARS
24 MEETING WHERE DR. SAMBRANO PRESENTED THE NEW
25 QUALIFYING PROCESS THAT WAS APPROVED BY THE ICOC.

BETH C. DRAIN, CA CSR NO. 7152

1 AND I DID LISTEN IN TO THE DETAILS OF THE QUALIFYING
2 PROCESS THAT BROUGHT AN OBJECTIVE ELEMENT AND A
3 SUBJECTIVE ELEMENT. AND WHEN I COORDINATED OUR
4 INPUT WITH CIRM, I DID GET A REPLY YESTERDAY THAT
5 KIND OF SAID THAT DURING THE QUALIFYING PROCESS, WE
6 RECEIVED A SCORE OF 3 OUT OF 6 ON THE OBJECTIVE
7 PORTION AND 13 OUT OF 20 ON THE SUBJECTIVE PORTION.
8 AND DR. LAM WAS KIND ENOUGH TO ATTACH THE TWO GWG
9 REVIEWER COMMENTS ALONG WITH THE SCORES.

10 WHEN WE REVIEWED THAT, I REALIZED THAT
11 THIS PROCESS DID NOT WORK TO OUR ADVANTAGE PRIMARILY
12 BECAUSE I BELIEVE AS A NONPIPELINE PROPOSAL WE ARE
13 DISADVANTAGED FROM THE FIRST ELEMENT OF THE PROCESS,
14 THE OBJECTIVE PORTION. AND UNDER THE SUBJECTIVE
15 PORTION, OF THE TWO REVIEWERS, IT WAS OBVIOUS TO US
16 THAT ONE REVIEWER EITHER DID NOT HAVE THE BACKGROUND
17 TO EVALUATE THE PROPOSAL OR MADE COMMENTS AGAINST
18 THE SCORE THAT WERE WRONG IN THREE OF THE FOUR
19 CATEGORIES. SO YOU GET A SCORE OF FIVE FOR EACH OF
20 FOUR CRITERIA IN THE SECOND CATEGORY THAT'S CALLED
21 SUBJECTIVE. AND WE FOUND THAT THREE OUT OF THE FOUR
22 WERE BASED ON ASSUMPTIONS THAT WERE ALL WRONG.

23 SO WE SAID WE NEEDED TO BRING THIS TO YOUR
24 ATTENTION AND SEE HOW WE COULD, AS A CALIFORNIA
25 CORPORATION WITH A PROMISING THERAPY IN OUR HANDS,

BETH C. DRAIN, CA CSR NO. 7152

1 GET SUPPORT FROM CIRM AND WORK THROUGH THIS PROCESS.

2 I UNDERSTAND IT'S --

3 MS. MANDAC: THANK YOU SO MUCH, DR.

4 RAMKUMAR.

5 CHAIRMAN IMBASCIANI: THANK YOU, DR.

6 RAMKUMAR. DOES THAT REQUIRE A RESPONSE? I DON'T

7 THINK SO. THANK YOU FOR YOUR REMARKS. THEY'RE DULY

8 NOTED.

9 ANY OTHER MEMBER OF THE PUBLIC WISH TO

10 ADDRESS THE BOARD ON THE APPLICATIONS THAT HAVE BEEN

11 SUBMITTED OR ON ANY OTHER ITEM NOT ON THE AGENDA?

12 NO. OKAY.

13 FOLKS, I THINK WE'VE COME TO THE END OF

14 THE AGENDA THEN. THANK YOU VERY MUCH FOR YOUR

15 PARTICIPATION. ANY FINAL COMMENTS FROM ANYONE? IF

16 NOT, WE ARE ADJOURNED.

17 MR. TOCHER: THANKS, EVERYONE, FOR MAKING

18 IT TO THE MEETING.

19 (THE MEETING WAS THEN CONCLUDED AT 9:30 A.M.)

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 VIRTUAL PROCEEDINGS BEFORE THE APPLICATION REVIEW SUBCOMMITTEE OF THE INDEPENDENT CITIZEN'S OVERSIGHT COMMITTEE OF THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE IN THE MATTER OF ITS REGULAR MEETING HELD ON NOVEMBER 21, 2024, WAS HELD AS HEREIN APPEARS AND THAT THIS IS THE ORIGINAL TRANSCRIPT THEREOF AND THAT THE STATEMENTS THAT APPEAR IN THIS TRANSCRIPT WERE REPORTED STENOGRAPHICALLY BY ME AND TRANSCRIBED BY ME. I ALSO CERTIFY THAT THIS TRANSCRIPT IS A TRUE AND ACCURATE RECORD OF THE PROCEEDING.

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