

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
REGULAR MEETING

LOCATION: AS INDICATED ON THE AGENDA

DATE: FEBRUARY 21, 2019
11 A.M.

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

FILE NO.: 2019-06

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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 PARTNERING OPPORTUNITY: QUEST AWARDS.	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 AGENDA ITEMS "4" AND "5" ABOVE. (HEALTH & SAFETY CODE 125290.30(F) (3) (B) AND (C)).	
5. PUBLIC COMMENT.	NONE
6. ADJOURNMENT.	23

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1 ICOC APPLICATION REVIEW SUBCOMMITTEE MEETING

2 THURSDAY, FEBRUARY 21, 2019; 11 A.M.

3

4 CHAIRMAN THOMAS: GOOD MORNING,
5 EVERYBODY. LIKE TO WELCOME YOU TO THE FEBRUARY
6 REGULAR MEETING OF THE ICOC AND THE APPLICATION
7 REVIEW SUBCOMMITTEE. WE CAN PROCEED. MARIA, PLEASE
8 CALL THE ROLL.

9 MS. BONNEVILLE: ANNE-MARIE DULIEGE.
10 DAVID HIGGINS.

11 DR. HIGGINS: HERE.

12 MS. BONNEVILLE: STEVE JUELSGAARD.

13 MR. JUELSGAARD: HERE.

14 MS. BONNEVILLE: SHERRY LANSING. DAVE
15 MARTIN.

16 DR. MARTIN: HERE.

17 MS. BONNEVILLE: LAUREN MILLER.

18 MS. MILLER: HERE.

19 MS. BONNEVILLE: ADRIANA PADILLA. JOE
20 PANETTA.

21 MR. PANETTA: HERE.

22 MS. BONNEVILLE: FRANCISCO PRIETO.

23 DR. PRIETO: HERE.

24 MS. BONNEVILLE: ROBERT QUINT.

25 DR. QUINT: HERE.

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1 MS. BONNEVILLE: AL ROWLETT. JEFF SHEEHY.

2 MR. SHEEHY: HERE.

3 MS. BONNEVILLE: OS STEWARD.

4 DR. STEWARD: HERE.

5 MS. BONNEVILLE: JONATHAN THOMAS.

6 CHAIRMAN THOMAS: HERE.

7 MS. BONNEVILLE: ART TORRES.

8 MR. TORRES: HERE.

9 MS. BONNEVILLE: DIANE WINOKUR.

10 MS. WINOKUR: HERE.

11 MS. BONNEVILLE: ARE THERE ANY OTHER BOARD
12 MEMBERS ON THE LINE WHOSE NAME I DID NOT CALL?

13 DR. SANDMEYER: SUZANNE SANDMEYER.

14 MS. BONNEVILLE: ANYONE ELSE? GREAT.
15 THANK YOU.

16 CHAIRMAN THOMAS: THANK YOU, MARIA.
17 WE'RE GOING TO GO ON TO ITEM 3, CONSIDERATION OF
18 APPLICATION CLIN2-11431. I'D AT THIS POINT LIKE TO
19 TURN THE MEETING OVER TO MR. SHEEHY.

20 MR. SHEEHY: THANK YOU, CHAIRMAN THOMAS.
21 SO I THINK THAT ON THIS PARTICULAR APPLICATION, I
22 THINK THAT THERE'S BEEN A FAIR AMOUNT OF CONSENSUS,
23 THAT THIS IS GOOD SCIENCE AND IS AN IMPORTANT
24 INDICATION. BUT I THINK WHERE WE HAVE GOTTEN KIND
25 OF STUCK IS ON THE FINANCIAL MANAGEMENT OF THIS

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1 PROJECT.

2 AND FOR ME THE POINT THAT I HAD COME TO OR
3 WHERE I COME TO REST ON THIS IS THAT THERE WAS A
4 COMMITMENT TO PROVIDE CO-FUNDING OF JUST OVER TWO
5 MILLION. 550,000 OF THAT HAS BEEN RAISED. THERE'S
6 STILL A REMAINING 1.7 MILLION THAT'S DUE IN APRIL.
7 AND FROM MY PERSPECTIVE, I THINK THIS IS AN
8 IMPORTANT PROJECT, BUT WE CAN'T, IN GOOD FAITH,
9 PROCEED WITHOUT OBTAINING THAT CO-FUNDING, WHICH WE
10 HAVE OTHER INSTITUTIONS AND OTHER PROJECTS WHO HAVE
11 COMMITTED TO CO-FUNDING. AND IT'S HARD FOR ME, AS A
12 PUBLIC AGENCY, TO HAVE TWO DIFFERENT SETS OF
13 STANDARDS, ONE WHERE YOU FULFILL A COMMITMENT THAT
14 YOU HAVE FREELY MADE TO PROVIDE CO-FUNDING, AND THE
15 OTHER WHERE WE RELAX THAT STANDARD ARBITRARILY.

16 SO THE MOTION I WOULD LIKE TO MAKE ABOUT
17 THIS APPLICATION WOULD BE TO FUND, AND I THINK,
18 MR. THOMPSON, CAN YOU KIND OF GIVE US, THERE'S A
19 \$500,000 AMOUNT THAT'S REMAINING, PLUS THE 1.7
20 MILLION, AND THE REQUEST IS AROUND SIX MILLION. SO
21 IS THERE A NUMBER THAT I CAN PENCIL IN FOR THIS?

22 MR. THOMPSON: SO IF WE TAKE THE REMAINING
23 FUNDS FROM CIRM AND CO-FUNDING ON THE DISEASE TEAM
24 AND SUBTRACT THAT FROM THE \$6 MILLION REQUEST IN A
25 CLIN2, WE ARE LEFT WITH 3,715,031.

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1 MR. SHEEHY: SO I WOULD MOVE TO PROVIDE
2 THIS FUNDING ONCE THE CO-FUNDING HAS BEEN OBTAINED
3 OR TO START AFTER THE CO-FUNDING HAS BEEN OBTAINED
4 AND TO MAKE THIS -- BUT THIS ONLY LASTS TILL MAY
5 1ST. SO THIS OFFER IS OUT THERE. THE OBLIGATION
6 FROM THE APPLICANT AND THE APPLICANT'S INSTITUTION
7 WAS TO COME UP WITH 1.7 MILLION IN APRIL PER THEIR
8 ORIGINAL CONTRACT, IF I'M CORRECT, SO WE'LL GIVE
9 THEM TIME TO DO THAT. ONCE THAT FUNDING IS
10 OBTAINED, THEN THE PROJECT CAN GO FORWARD AS
11 PLANNED. SO THAT WOULD BE MY MOTION; AND IF THERE'S
12 A SECOND --

13 CHAIRMAN THOMAS: SECOND.

14 MR. SHEEHY: -- HAPPY TO HAVE DISCUSSION.
15 SECOND BY CHAIRMAN THOMAS. THIS SEEMS A REASONABLE
16 WAY TO MOVE FORWARD THAT'S FAIR TO OUR PRIOR
17 APPLICANTS AND EVERYONE ELSE. IS THERE ANYBODY WHO
18 WANTS TO CHIME IN? NO BOARD COMMENT?

19 MR. PANETTA: I THINK THAT'S REASONABLE.
20 I'VE GOT JUST ONE SIMPLE QUESTION. I SEE ONE OF THE
21 THINGS THAT WAS INCLUDED HERE IN OUR INFORMATION
22 PACKET WAS A PRESS RELEASE THAT STANFORD PUT OUT
23 RECENTLY, I THINK.

24 MR. SHEEHY: RIGHT.

25 MR. PANETTA: WHAT WAS THE INTENT AND

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1 PURPOSE OF INCLUDING THAT IN THE PACKAGE FOR US?

2 MR. SHEEHY: WELL, IT SPEAKS TO LICENSING
3 OF THIS PRODUCT ALONG WITH ANOTHER PRODUCT. SO IT
4 WAS REALLY ABOUT THE INTELLECTUAL PROPERTY
5 INFORMATION THAT WAS CONTAINED IN THE LAST PARAGRAPH
6 OR ONE OF THE LAST PARAGRAPHS OF THAT PRESS RELEASE.
7 AND SO GIVEN THAT THE APPLICANT INSTITUTION HAS
8 COMMITTED TO CO-FUNDING, THAT WE HAVE NOT ONLY THIS
9 PROJECT, THIS TRAJECTORY, BUT THEY ALSO HAVE AN
10 ADDITIONAL TRAJECTORY IN MIND FOR THIS PRODUCT. IT
11 MADE IT VERY HARD FOR ME TO UNDERSTAND WHY THERE WAS
12 UNWILLINGNESS TO FULFILL THEIR ORIGINAL COMMITMENT
13 TO CIRM.

14 IN OTHER WORDS, THEY HAVE TWO TRACKS FOR
15 THIS PRODUCT. AND WE SPENT JUST OVER 18 MILLION ON
16 IT NOW UP TO DATE. SO THAT'S WHY I THOUGHT IT MIGHT
17 BE RELEVANT.

18 MR. PANETTA: I APPRECIATE IT. WHEN YOU
19 LOOK AT THE IMPRESSIVE LIST OF FOLKS THEY'RE WORKING
20 WITH, IT'S CLEAR TO ME THAT IT SHOULD BE PRETTY
21 STRAIGHTFORWARD OBTAINING THE FUNDING THAT THEY
22 NEED.

23 MR. SHEEHY: THIS REALLY COMES TO THE
24 FAILURE TO -- THE QUESTION ABOUT WHY THEY'RE NOT
25 FULFILLING THEIR CO-FUNDING REQUIREMENT THAT THEY

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1 AGREED TO. NOBODY PUT A GUN TO THEIR HEAD. SO THIS
2 IS SOMETHING THAT WAS NEGOTIATED AND AGREED TO.

3 MR. PANETTA: THANK YOU.

4 MR. SHEEHY: ADDITIONAL COMMENT? ANY
5 PUBLIC COMMENT?

6 MR. JUELSGAARD: SO IN UNDERSTANDING YOUR
7 MOTION, JEFF, I THINK THIS IS MORE DIRECTED TO GABE
8 THAN ANYTHING. SO IN THE MOTION YOU BACKED OUT FROM
9 THE 6 MILLION THE 1.75 ROUGHLY IN CO-FUNDING, BUT
10 YOU ALSO BACKED OUT THE 500,000 THAT'S OUTSTANDING
11 AS PART OF THE CURRENT GRANT.

12 IF WE WERE TO APPROVE, JUST SO I'M CLEAR,
13 IF WE WERE INSTEAD TO APPROVE THE \$6 MILLION GRANT
14 THE WAY IT'S BEEN APPLIED FOR, WHICH I'M NOT IN
15 FAVOR OF, BUT IF WE WERE TO DO IT, DOES THAT
16 AUTOMATICALLY TERMINATE THE \$500,000 UNDER THE
17 EXISTING GRANT?

18 MR. THOMPSON: NO.

19 DR. JUELSGAARD: SO WHY ARE WE REMOVING
20 THE \$500,000 THEN FROM THE EXISTING GRANT?

21 MR. THOMPSON: BECAUSE THAT WOULD BE
22 OVERLAPPING ACTIVITY. WE WOULD KEEP THE DISEASE
23 TEAM AWARD OPEN. PER THE MILESTONE SCHEDULE, ONCE
24 SHE RAISES THE CO-FUNDING, WE DISBURSE THE
25 REMAINING -- THE REMAINING CIRM FUNDING. SO THE

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1 REMAINING FUNDS ARE SLOTTED ON TWO REMAINING
2 MILESTONES. SO ONCE SHE RAISES THE FIRST CO-FUNDING
3 TRANCHE, WE WOULD DISBURSE THAT AND ALLOW HER TO
4 FINISH THAT DISEASE TEAM AWARD BEFORE WE WOULD START
5 FUNDING.

6 DR. JUELSGAARD: I JUST WANT TO MAKE SURE
7 WE'RE NOT -- IF WE APPROVE THIS, WE'RE NOT
8 PENALIZING, IN OTHER WORDS, NOT TAKING AWAY MONEY
9 WHICH OTHERWISE UNDER BOTH APPLICATIONS THERE WOULD
10 BE A LEGITIMATE NEED FOR. SEE WHAT I'M SAYING,
11 JEFF?

12 MR. SHEEHY: I DO, BUT I THINK GABE
13 THOMPSON HAS BEEN MANAGING THIS. IT INDICATES THAT
14 THERE'S OVERLAP, AND THIS ELIMINATES THE OVERLAP.

15 MR. TOCHER: IF I CAN JUST INTERJECT. I
16 THINK WHAT YOU'RE SAYING, GABE, IS THAT IN THE EVENT
17 THAT THEY FULFILL THIS CONTINGENCY, BY VIRTUE OF THE
18 FACT THAT IT'S ALREADY A MILESTONE UNDER THE CURRENT
19 DOT AWARD, WHICH WOULD HAVE ENTITLED THEM TO THAT
20 \$500,000 PAYMENT JUST ON THE DISEASE TEAM AWARD,
21 THEN IT'S OBVIOUSLY 500,000 YOU DON'T NEED ON THIS
22 NEW PROPOSED PROJECT, WHICH DOESN'T INCLUDE THAT.

23 MR. SHEEHY: JUST IN TERMS OF PROCESS,
24 THERE IS A BUDGET REVIEW BEFORE THESE APPLICATIONS
25 ARE HEARD BY THE GRANTS WORKING GROUP THAT YOU ARE

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1 PART OF THE TEAM THAT CONDUCTS. AS GRANTS
2 MANAGEMENT AND AS SOMEONE WHO'S LOOKED AT THE
3 CURRENT THE APPLICATION, YOU HAVE A SENSE OF WHAT
4 ACTIVITIES ARE BEING FUNDED BOTH WITH THE ORIGINAL
5 AWARD AND THEN THIS FOLLOW-ON AWARD.

6 IN YOUR UNDERSTANDING OF THE BUDGET, THE
7 ACTIVITIES THAT WOULD BE FUNDED BY THE REMAINING
8 \$500,000 OR 1.7 MILLION WERE INCLUDED IN THE 6
9 MILLION FOR THE NEW AWARD.

10 MR. THOMPSON: CORRECT.

11 MR. SHEEHY: SO BY SPENDING THAT 500,000
12 FROM CIRM AND GETTING THE MATCHING FUNDS, WE'RE LEFT
13 WITH A DELTA OF 3.7 MILLION TO COMPLETE ALL THE
14 ACTIVITIES THAT ARE INCLUDED IN BOTH THE DISEASE
15 TEAM AND THE CURRENT APPLICATION IN FRONT OF US,
16 CORRECT?

17 MR. THOMPSON: THAT'S CORRECT.

18 DR. JUELSGAARD: I'M HAVING A HARD TIME
19 TRYING TO UNDERSTAND THIS. SO LET'S JUST ASSUME FOR
20 A MOMENT THAT THE CO-FUNDING WAS RAISED AND THAT THE
21 \$500,000 WENT TO THE APPLICANT, THEN THE APPLICANT
22 CAME FORWARD AT THAT POINT AND ASKED FOR MORE MONEY.
23 YOU'RE ASSUMING THAT THE APPLICANT IN THAT CASE
24 WOULD HAVE ONLY ASKED FOR 5.5 MILLION. IS THAT WHAT
25 YOU ARE ASSUMING?

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1 MR. THOMPSON: YES.

2 DR. JUELSGAARD: SO 5.5, WHATEVER THEY'RE
3 GOING TO ASK FOR, IT WOULD BE \$6 MILLION LESS THE
4 \$500,000, THEN YOU'RE ASSUMING LESS THE CO-FUNDING.
5 SO YOU THINK THAT'S WHAT THE APPLICANT WOULD HAVE
6 DONE, JUST SORT OF SAID WE REALLY DON'T NEED THAT
7 500,000 BECAUSE THAT WAS FULFILLED BY THE FIRST
8 GRANT?

9 MR. THOMPSON: YES.

10 MR. SHEEHY: AND THIS GRANT WAS WRITTEN
11 WITH THE ASSUMPTION THAT THEY WOULD NOT BE ABLE TO
12 FULFILL THE OBLIGATION AND WOULD NOT HAVE ACCESS TO
13 THE \$500,000 THAT WAS STILL REMAINING ON THE
14 ORIGINAL GRANT.

15 DR. JUELSGAARD: WE KNOW THAT HOW, THAT
16 THAT'S WHAT THEIR ASSUMPTION WAS?

17 MR. SHEEHY: BECAUSE WE'VE BEEN MANAGING
18 THE FIRST GRANT AND WE'VE EXAMINED CLOSELY THE
19 BUDGET OF THE SECOND GRANT AS PART OF THE DUE
20 DILIGENCE PROCESS BEFORE AN APPLICATION WAS EVEN
21 HEARD AT THE GRANTS WORKING GROUP.

22 DR. JUELSGAARD: HOW CONFIDENT THAT THAT'S
23 THE ASSUMPTION THAT THE APPLICANT MADE, THAT HELPS
24 ANSWER THE QUESTION FOR ME.

25 CHAIRMAN THOMAS: DID THEY BUMP UP WHAT

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1 THEY WOULD HAVE ASKED FOR BY 500,000 BECAUSE, UNDER
2 THE NEW APPLICATION, THEY WOULD NOT HAVE BEEN
3 GETTING ACCESS TO THE FIRST 500?

4 MR. THOMPSON: THE WAY THE APPLICATION,
5 JUST IN GENERAL, WORK IS THAT THEY ASSUME A PROJECT
6 START. THEIR CLOCK CAN START ON THE NEW FUNDING
7 ABOUT FOUR MONTHS AFTER APPLICATION SUBMISSION. AND
8 SO THEY JUST ASSUME EVERYTHING CAN START AT THAT
9 POINT. IN THIS CASE, THE CONTINUATION, IT'S
10 EVERYTHING STARTING AROUND THIS TIME OF APPROVAL.
11 OUR ALLOWABLE COSTS ALLOW THEM TO START INCURRING
12 FUNDS THE DAY OF THE BOARD APPROVAL OF THAT
13 APPLICATION. AND SO ALL THOSE ACTIVITIES WOULD
14 BE -- IN THIS CASE ALL THOSE ACTIVITIES IN THE NEW
15 ONE WOULD BE THINGS THAT WERE ACTIVITIES COVERED BY
16 THE DISEASE TEAM AWARD.

17 DR. JUELSGAARD: JUST FOR MY EDIFICATION,
18 SCOTT, CAN YOU REPEAT THE MOTION, AND THEN I GUESS
19 WE SHOULD ASK FOR PUBLIC COMMENT, ETC.

20 MR. TOCHER: SURE. I HAVE IT AS THE
21 MOTION IS TO APPROVE THIS AWARD IN THE AMOUNT OF 3
22 MILLION, APPROXIMATELY \$3 MILLION CONTINGENT ON THE
23 APPLICANT RAISING THE CO-FUNDING AMOUNT AGREED TO
24 AND REMAINING UNDER THE DISEASE TEAM AWARD, WHICH
25 MUST BE ACCOMPLISHED BY MAY 1ST OF THIS YEAR.

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1 MR. SHEEHY: PUBLIC COMMENT?

2 DR. SHIZURU: I'M DR. SHIZURU. I'M THE
3 PI. I UNDERSTAND I HAVE THREE MINUTES OR DO I JUST
4 DISCUSS IT? I HAD A PREPARED STATEMENT, BUT I THINK
5 I HAVE TO ADDRESS DIRECTLY THE ISSUE OF THE
6 CO-FUNDING.

7 I THINK -- I AM A PHYSICIAN SCIENTIST. I
8 AM THE PI ON THIS AWARD. THE ONUS IS ON ME TO RAISE
9 THE CO-FUNDING FOR THIS STUDY. GIVEN -- AND I THINK
10 THAT GIVEN THAT, I'M DOING EVERYTHING I POSSIBLY CAN
11 GIVEN THE POSITIVE RESULTS THAT WE'RE SEEING, AND I
12 THINK IT IS SUPPORTED BY THE LETTERS THAT WERE SENT
13 TO US IN JUST A FEW DAYS WHEN WE ASKED FOR IT. BUT
14 THE ONUS IS ON ME TO RAISE THE CO-FUNDING, AND
15 THAT'S BEEN VERY DIFFICULT.

16 IT POTENTIALLY CANNOT HAPPEN. AND IN THAT
17 CASE, I WOULD NEED TO PAUSE THE STUDY AND CONTINUE
18 TO DO WHATEVER I CAN TO RAISE MONEY FOR THE STUDY.
19 SO IT IS MY RESPONSIBILITY TO RAISE MONEY AND TO DO
20 WHATEVER I CAN TO BRING THIS TREATMENT FORWARD TO
21 THESE CHILDREN WITH SCID AND FOR OTHER PEOPLE WHO
22 HAVE NEED OF THIS KIND OF ANTIBODY THERAPY.

23 I DO HAVE A WRITTEN STATEMENT. I CAN GO
24 AHEAD AND READ IT, BUT I JUST NEED TO ADDRESS, I
25 THINK, SPECIFICALLY THE ISSUE OF THE CO-FUNDING.

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1 DR. JUELSGAARD: YOU WORK AT STANFORD?

2 DR. SHIZURU: I DO.

3 DR. JUELSGAARD: WHEN THIS COMMITMENT WAS
4 MADE TO CO-FUND, IT WASN'T JUST YOUR SIGNATURE ON
5 THE CONTRACT THAT RELATED TO THAT. THERE WAS A
6 SIGNATURE THAT CAME FROM AN OFFICE AT STANFORD
7 UNIVERSITY AS WELL. THEY'RE VERY AWARE OF THIS
8 COMMITMENT.

9 SO IN TERMS OF THE INTERNAL WORKINGS OF
10 STANFORD, HAVE THEY BASICALLY SAID TO YOU, "YES, WE
11 SIGNED OFF ON THIS, BUT THIS IS REALLY YOUR PROBLEM,
12 NOT OURS." IS THAT WHAT'S HAPPENED? OTHERWISE I
13 WOULD EXPECT -- STANFORD UNIVERSITY, IT'S AN
14 INSTITUTION I'VE GONE TO SCHOOL THERE, I UNDERSTAND
15 THEY'RE FAIRLY WELL TAKEN CARE OF IN TERMS OF THEIR
16 ECONOMICS. SO I'M JUST CURIOUS AS TO WHY THEY
17 WOULDN'T BE WILLING TO PROVIDE THAT CO-FUNDING IN
18 EXCHANGE FOR A DOWN THE ROAD, IF EVERYTHING WORKS
19 OUT, KIND OF REPAYMENT OF A LOAN OR SOMETHING.

20 SO, ANYWAY, I DO SEE THAT THERE'S A
21 SOLUTION HERE. IF STANFORD'S PUT ITS OWN SIGNATURE
22 ON THIS AGREEMENT IS WHEN THEY STEP INTO THIS AND
23 WORK WITH YOU.

24 DR. SHIZURU: I THINK THAT WHEN WE WERE
25 AGREEING TO THIS, WE KNOW THAT THERE'S A PATH TO GO

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1 FORWARD TO RAISE MONEY FROM INVESTORS AND WE
2 PROVIDED THAT. THE LENGTH OF TIME, THOUGH, HAS
3 TAKEN AWHILE LONGER THAN I HAD HOPED. I UNDERSTAND
4 YOUR POINT, BUT I HAVE NOT GONE BACK TO THEM AND
5 SAID, "LOOK, I NEED THE \$1.7 MILLION." BECAUSE THE
6 MONEY THAT WAS RAISED MONEY SO FAR WAS MONEY WHICH I
7 RAISED FROM MY GIFT FUNDS AND SOME OTHER
8 PHILANTHROPY FOR THIS PROJECT SPECIFICALLY.

9 MR. SHEEHY: THIS GOES TO THE PROBLEM I
10 HAVE. IT'S ALL GREAT TO PRODUCE PRODUCTS, BUT IF WE
11 CAN'T PRODUCTS TO PATIENTS, AS I'VE SAID MULTIPLE
12 TIMES, THE BOTTLES OF PILLS THAT I TAKE EVERY DAY
13 HAVE COMMERCIAL ENTITIES ON IT. SO THIS IS AN
14 ORIGINAL PROBLEM WHEN THE DISEASE TEAM WAS FIRST
15 APPROVED WITH THE SCORE OF 53, AND THERE WASN'T
16 ANYTHING THAT SAID THERE WASN'T THE CAPABILITY TO
17 REALLY DEVELOP A PRODUCT LIKE THIS. SO THAT'S WHERE
18 THE RUBBER IS KIND OF HITTING THE ROAD. WE CANNOT,
19 AS A STATE AGENCY, FORGIVE AN OBLIGATION THAT WAS
20 MADE BY AN INSTITUTION THAT HAS RECEIVED \$380
21 MILLION FROM US WITH 70 MILLION IN INDIRECTS ON A
22 PROJECT THAT'S GOTTEN ALMOST \$3 MILLION IN
23 INDIRECT'S WITH AN ENDOWMENT OF ALMOST 27 BILLION
24 THAT PASSED OUT LAST YEAR 1.2 BILLION WITHIN THE
25 INSTITUTION. IT BOGGLES THE MIND, AND IT'S NOT

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1 SOMETHING I CAN DO. IT'S NOT -- SOMEBODY HAS TO
2 HAVE THE CONVERSATION WITH THE INSTITUTION WHICH
3 BINDS AGREEMENTS.

4 CHAIRMAN THOMAS: IT GOES BEYOND THAT.
5 IT'S ALSO THAT WE HAVE A NUMBER OF ENTITIES THAT
6 HAVE MADE COMMITMENTS TO RAISE CO-FUNDING THAT HAVE
7 MET THOSE. AND THAT IS NOT SOMETHING THAT WE CAN
8 SUDDENLY OVERLOOK HERE. WE NEED TO HAVE THAT
9 COMMITMENT UPHOLD BEFORE WE'RE GOING TO PROCEED.
10 WE'RE NOT GOING TO SET PRECEDENT BY DEVIATING FROM
11 THE PRACTICE THAT WE'VE HAD ALL THE WAY ALONG HERE.
12 SO THAT IS SOMETHING THAT WE FEEL VERY STRONGLY
13 ABOUT BELIEVE THAT IT'S SOMETHING YOU SHOULD BE ABLE
14 TO WORK OUT WITH THE INSTITUTION.

15 DR. SHIZURU: I'M NOT -- I'VE NOT HAD THAT
16 CONVERSATION RECENTLY WITH THE INSTITUTION WITH
17 REGARD TO THIS PARTICULAR AWARD. I WAS HESITANT TO
18 APPLY FOR THIS AWARD BECAUSE OF THE ISSUE THAT'S
19 COMING UP RIGHT NOW. BUT I THINK THAT IN MY
20 DISCUSSIONS WITH CIRM, IT SEEMED IT WOULD BE
21 REASONABLE SINCE WE SPENT AND WAS BUDGETED -- THE
22 CLINICAL TRIAL WAS BUDGETED FOR \$5 MILLION OR \$5.5
23 MILLION. AND WE KNOW THAT IN ORDER TO BE ABLE TO
24 TAKE THE TRIAL TO COMPLETION AND REALLY WELL AND BE
25 ABLE TO TAKE IT TO AN APPROVAL, THAT IT'S GOING TO

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1 COST MORE.

2 WITH REGARD TO THE CO-FUNDING ISSUE AND
3 STANFORD, I WOULD HAVE TO GO BACK TO STANFORD AND
4 ASK THEM IF THEY'RE WILLING TO TAKE ON THIS
5 COMMITMENT.

6 CHAIRMAN THOMAS: I THINK THAT'S VERY
7 REASONABLE. WE VERY MUCH LIKE THE SCIENCE. I THINK
8 IT'S GOT GREAT PROMISE. WE THINK IT'S A PLATFORM
9 TECHNOLOGY THAT'S APPLICABLE TO A NUMBER OF
10 INDICATIONS. ALL OF THAT IS PLAUSIBLE, BUT WE'VE
11 GOT FISCAL CONSTRAINTS AND PRECEDENTS HERE THAT WE
12 HAVE TO OBSERVE. SO THAT'S THE REASON FOR THE
13 MOTION.

14 DR. SHIZURU: MY ONLY RESPONSE TO THAT IS
15 I KNOW MY RESPONSIBILITY AS A PHYSICIAN SCIENTIST IS
16 THAT I DO WHATEVER I CAN TO RAISE MONEY FOR THIS
17 PROJECT SO THAT IT GOES FORWARD. AND THAT EVEN
18 MEANS COMING BACK TO CIRM AND ASKING FOR YOU TO
19 BREAK PRECEDENT. THAT'S ALL I CAN SAY. IT'S MY
20 RESPONSIBILITY. I'VE SEEN THE POSITIVE BENEFITS IT
21 HAS ON PATIENTS. I'M JUST DOING WHAT I CAN DO. I
22 WILL GO BACK TO THE UNIVERSITY. I DON'T KNOW THE
23 ANSWER TO THAT. I DO KNOW THAT THE FUNDING ISSUE IS
24 A MAJOR ONE FOR THIS TRIAL. IT IS EXPENSIVE TO A
25 RUN A TRIAL, THEN FROM THE ACADEMIC INSTITUTION OR A

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1 TRIAL THAT'S GOING TO GO FORWARD TO THE FDA AND
2 LIKELY TO APPROVAL. THE ONE THING I DON'T WANT TO
3 HAPPEN IS TO NOW DO THIS TRIAL SORT OF ON A LOWER
4 BUDGET AND THEN HAVE TO REPEAT THE TRIAL AS A DOSE
5 ESCALATION BECAUSE WE HAVEN'T HAD THE NECESSARY AND
6 APPROPRIATE OVERSIGHT, REGULATORY OVERSIGHT THAT'S
7 REQUIRED TO BE ABLE TO GET A TRIAL APPROVED, A DRUG
8 APPROVED THROUGH THE FDA.

9 MR. JUELSGAARD: LET ME JUST REPEAT WHAT I
10 SAID BEFORE, THAT STANFORD SIGNED THE SAME AGREEMENT
11 YOU SIGNED. AND IF THEY WEREN'T WILLING TO BACKSTOP
12 THE COMMITMENT OF CO-FUNDING, THEY SHOULD NEVER HAVE
13 SIGNED AN AGREEMENT THAT CONTAINED THAT. FROM MY
14 POINT OF VIEW, THEY'RE EQUALLY AS OBLIGATED AS YOU
15 ARE TO FULFILL THIS FUNDING REQUIREMENT. THAT'S HOW
16 I VIEW IT. THEY MAY VIEW IT DIFFERENTLY. BUT THEN
17 FROM MY POINT OF VIEW, THEY SHOULD NEVER HAVE SIGNED
18 A DEAL THAT INCLUDED A REQUIREMENT FOR CO-FUNDING.

19 DR. SHIZURU: I'VE NEVER BEEN IN THIS
20 POSITION BEFORE. I HAVE TO SAY THAT I HAVE ALWAYS
21 VIEWED THIS AS MY RESPONSIBILITY. I DO VIEW IT THAT
22 WAY.

23 MR. SHEEHY: THEY GET INDIRECTS. IN THIS
24 NEW AWARD, THEY'RE GOING TO GET 25 PERCENT
25 INDIRECTS. WE GAVE THEM \$50 MILLION FOR A BUILDING.

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1 IT'S NOT LIKE THE UNIVERSITY ISN'T MAKING MONEY EVEN
2 ON THE 3.7, THEY GET 25 PERCENT FOR INDIRECTS.

3 DR. STEWARD: CAN I ASK A QUESTION?

4 MR. SHEEHY: SURE, OS.

5 DR. STEWARD: I JUST WANT TO UNDERSTAND A
6 LITTLE BIT MORE ABOUT THE DETAILS OF YOUR MOTION,
7 JEFF. YOU THINK THAT THE COMMITMENTS MADE TO
8 RECEIVE THE ORIGINAL REWARD ARE MET, MEANING THAT
9 STANFORD COME UP WITH THE CO-FUNDING, OR IS IT THAT
10 SOMEONE COME UP WITH THE CO-FUNDING?

11 MR. SHEEHY: IT'S MERELY THAT THE
12 CO-FUNDING BE COME UP WITH. THAT'S THE REQUIREMENT.
13 THERE WAS AN AGREEMENT FOR CO-FUNDING. THE
14 INSTITUTION SIGNED IT. SO THAT'S WHY I DON'T
15 FEEL -- WHY I'M A BIT CONFUSED WHY THE INSTITUTION
16 ISN'T IDENTIFYING TO DO THIS. IT'S DUE IN APRIL.

17 DR. STEWARD: MY QUESTION, I GUESS, IS
18 REALLY WHY WOULDN'T THE MOTION BE, IN FACT, THE
19 OTHER WAY? THAT CIRM, AS A STATE AGENCY, REQUIRE
20 THE INSTITUTION TO MEET ITS OBLIGATIONS THAT WERE,
21 IN FACT, VOLUNTARILY CONFIRMED BY THEIR SIGNATURE?
22 IT SEEMS TO ME THAT THIS IS NOW BEING PUT -- THE
23 PI'S BASICALLY SAID, "WELL, IT'S MY RESPONSIBILITY."
24 WELL, I'M QUESTIONING THAT ACTUALLY BECAUSE THERE
25 WAS A SIGNATURE, A COMMITMENT, AND APPARENTLY THAT

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1 SIGNATURE AND COMMITMENT ARE NOT BEING FULFILLED.

2 SO THAT'S MY QUESTION. THANK YOU.

3 MR. SHEEHY: FROM MY PERSPECTIVE, I DON'T
4 WANT TO BE TOO PRESCRIPTIVE. WE HAVE AN OBLIGATION
5 THAT'S DUE IN APRIL. IF THAT OBLIGATION IS
6 FULFILLED IN APRIL, NOT ONLY WILL THE \$1.7 MILLION
7 COME IN, BUT THEN THE ALREADY BUDGETED \$500,000 WILL
8 COME IN, AND THEN THE NEW CIRM FUNDING OF 3.7
9 MILLION WILL FLOW. AND SO THAT'S ALL I'M TRYING TO
10 DO. THE COMMITMENT OF THE INSTITUTION CONTRACTUALLY
11 REASSURES ME THAT THIS IS NOT AN UNREASONABLE ASK.
12 IF STANFORD CHOOSES NOT TO ENSURE THAT THEIR
13 CONTRACTUAL COMMITMENT IS MADE, THEN THAT RAISES
14 DEEP QUESTIONS ABOUT THE PROJECT AS A WHOLE AND ITS
15 VIABILITY, BUT THERE MAY BE THINGS THAT I'M NOT
16 PRIVY TO THAT MAKES STANFORD UNWILLING TO FULFILL
17 ITS COMMITMENT. SO I THINK THE MOTION TO ME IS
18 PRETTY STRAIGHTFORWARD.

19 DR. SHIZURU: I AS THE PI HAVE NOT GONE
20 BACK TO STANFORD AND TOLD THEM THAT THIS IS THE KIND
21 OF DISCUSSION THAT WE'RE GOING TO BE HAVING. SO,
22 AGAIN, I DON'T KNOW THAT STANFORD IS THAT AWARE THAT
23 THEY WOULD BE ASKED TO DO THIS.

24 MR. SHEEHY: THAT WAS THE CONVERSATION WE
25 HAD AT THE LAST APPLICATION REVIEW SUBCOMMITTEE WAS

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1 THAT OUR QUESTIONS WERE FINANCIAL. AND I GOT
2 BARRAGED WITH A LOT OF ISSUES THAT WERE NOT RELEVANT
3 TO THAT DISCUSSION. AGAIN, THAT GOES TO CORE
4 COMPETENCE. IF THERE'S NOT THE ABILITY TO HEAR WHAT
5 PEOPLE ARE TELLING YOU, THEN IT MAKES ME QUESTION
6 WHETHER WE'LL ACTUALLY HAVE A PRODUCT AT THE END OF
7 THE DAY BECAUSE CORE COMPETENCE --

8 DR. JUELSGAARD: REMEMBER THIS MOTION
9 CONTAINS A DROP-DEAD DATE OF MAY 1. TODAY IS
10 FEBRUARY 21. SO WE HAVE A FEW DAYS LEFT IN
11 FEBRUARY, THEN TWO FULL MONTHS, MARCH AND APRIL,
12 BEFORE WE GET TO MAY 1. IT WOULD SEEM TO BE THAT
13 STANFORD CAN MAKE A DECISION WITHIN THAT PERIOD OF
14 TIME MOST CERTAINLY ABOUT WHAT IT WANTS TO DO,
15 WHETHER IT'S WILLING TO BACKSTOP ITS COMMITMENT.

16 MR. TORRES: I JUST WANTED TO THANK YOU
17 FOR THE MOTION. I THINK IT'S A REASONABLE STEP, AND
18 I HAVE SUCH HIGH REGARD FOR JUDY AND THE WORK THAT
19 SHE'S BEEN DOING TIRELESSLY OVER THE YEARS. BUT I
20 DO THINK THAT WE HAVE PUT FORWARD THIS MOTION IN
21 ORDER TO GET STANFORD'S ATTENTION AS TO WHAT THEIR
22 COMMITMENT HAS BEEN IN THE PAST AND WHAT IT WILL
23 CONTINUE TO BE GIVEN THE NATURE OF THE ARRANGEMENT
24 THAT WE MADE WITH THEM. SO I WOULD LIKE TO CALL FOR
25 THE QUESTION.

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1 MR. SHEEHY: DO WE HAVE ANY OTHER PUBLIC
2 COMMENT? OKAY. MS. BONNEVILLE, COULD YOU CALL THE
3 ROLL PLEASE.

4 MS. BONNEVILLE: ANNE-MARIE DULIEGE.
5 DAVID HIGGINS.

6 DR. HIGGINS: YES.

7 MS. BONNEVILLE: STEVE JUELSGAARD.

8 MR. JUELSGAARD: YES.

9 MS. BONNEVILLE: DAVE MARTIN. I'LL COME
10 BACK. LAUREN MILLER.

11 MS. MILLER: YES.

12 MS. BONNEVILLE: ADRIANA PADILLA. JOE
13 PANETTA.

14 MR. PANETTA: YES.

15 MS. BONNEVILLE: FRANCISCO PRIETO.

16 DR. PRIETO: AYE.

17 MS. BONNEVILLE: ROBERT QUINT.

18 DR. QUINT: YES.

19 MS. BONNEVILLE: JEFF SHEEHY.

20 MR. SHEEHY: YES.

21 MS. BONNEVILLE: OS STEWARD.

22 DR. STEWARD: YES.

23 MS. BONNEVILLE: JONATHAN THOMAS.

24 CHAIRMAN THOMAS: YES.

25 MS. BONNEVILLE: ART TORRES.

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1 MR. TORRES: AYE.

2 MS. BONNEVILLE: DIANE WINOKUR.

3 MS. WINOKUR: YES.

4 MS. BONNEVILLE: MOTION CARRIES.

5 MR. SHEEHY: SO I BELIEVE THAT'S THE ONLY
6 THING LEFT ON THE AGENDA. MR. CHAIRMAN, BACK TO
7 YOU.

8 MR. TORRES: THANK YOU GUYS. I HAVE TO GO
9 BACK TO ANOTHER BOARD MEETING. TAKE CARE.

10 CHAIRMAN THOMAS: THANK YOU, MR. TORRES.
11 THANK YOU, DR. SHIZURU.

12 ANY GENERAL PUBLIC COMMENT ON ANY TOPICS
13 OF ANY KIND ANYWHERE? HEARING NONE, THAT CONCLUDES
14 TODAY'S AGENDA. WE WILL SEE YOU IN PERSON IN MARCH,
15 AND THIS MEETING STANDS ADJOURNED.

16 (THE MEETING WAS THEN CONCLUDED AT
17 11:34 A.M.)

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REPORTER'S CERTIFICATE

I, BETH C. DRAIN, A CERTIFIED SHORTHAND REPORTER IN AND FOR THE STATE OF CALIFORNIA, HEREBY CERTIFY THAT THE FOREGOING TRANSCRIPT OF THE TELEPHONIC PROCEEDINGS BEFORE THE INDEPENDENT CITIZEN'S OVERSIGHT COMMITTEE AND THE APPLICATION REVIEW SUBCOMMITTEE OF THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE IN THE MATTER OF ITS REGULAR MEETING HELD ON FEBRUARY 21, 2019, 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.

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