

BEFORE THE
INDEPENDENT CITIZENS' OVERSIGHT COMMITTEE
AND
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: WEDNESDAY, OCTOBER 19, 2016
11 A.M.

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

BRS FILE NO.: 99020

BARRISTERS' REPORTING SERVICE

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ROLL CALL	3
CONSIDERATION OF APPLICATIONS SUBMITTED IN RESPONSE TO INFR2: PARTNERING OPPORTUNITY TO CREATE A CIRM TRANSLATING CENTER	4
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BARRISTERS' REPORTING SERVICE

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WEDNESDAY, OCTOBER 19, 2016; 11 A.M.

CHAIRMAN THOMAS: GOOD MORNING, EVERYBODY.
WELCOME TO THE OCTOBER MEETING OF THE ICOC AND
APPLICATION REVIEW SUBCOMMITTEE. CALLING THE
MEETING TO ORDER. MARIA, WILL YOU PLEASE CALL THE
ROLL.

MS. BONNEVILLE: DAVID BRENNER. KEN
BURTIS. DEBORAH DEAS. ANNE-MARIE DULIEGE. HOWARD
FEDEROFF. MICHAEL FRIEDMAN. JUDY GASSON. SAM
HAWGOOD. DAVID HIGGINS.

DR. HIGGINS: HERE.

MS. BONNEVILLE: STEPHEN JUELSGAARD.

MR. JUELSGAARD: HERE.

MS. BONNEVILLE: SHERRY LANSING. KATHY
LAPORTE.

DR. LAPORTE: HERE.

MS. BONNEVILLE: BERT LUBIN. SHLOMO
MELMED. LAUREN MILLER.

MS. MILLER: HERE.

MS. BONNEVILLE: LLOYD MINER. ADRIANA
PADILLA.

DR. PADILLA: HERE.

MS. BONNEVILLE: JOE PANETTA. FRANCISCO

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1 PRIETO. CARMEN PULIAFITO. ROBERT QUINT.
2 DR. QUINT: HERE.
3 MS. BONNEVILLE: AL ROWLETT.
4 MR. ROWLETT: HERE.
5 MS. BONNEVILLE: JEFF SHEEHY.
6 MR. SHEEHY: HERE.
7 MS. BONNEVILLE: OSWALD STEWARD.
8 DR. STEWARD: HERE.
9 MS. BONNEVILLE: JONATHAN THOMAS.
10 CHAIRMAN THOMAS: HERE.
11 MS. BONNEVILLE: ART TORRES.
12 MR. TORRES: HERE.
13 MS. BONNEVILLE: KRISTINA VUORI. DIANE
14 WINOKUR.
15 MS. WINOKUR: HERE.
16 MS. BONNEVILLE: THANK YOU.
17 CHAIRMAN THOMAS: THANK YOU, MARIA. GOING
18 ON TO ITEM 3. AS THIS IS THE APPLICATION REVIEW
19 SUBCOMMITTEE, WE'RE NOW GOING TO PROGRAMMATIC
20 REVIEW. SO I WILL TURN THE MEETING OVER TO MR.
21 SHEEHY.
22 MR. SHEEHY: THANK YOU, J.T.
23 SO WE HAVE -- SHALL WE GO INTO A
24 PRESENTATION? IS THAT HOW WE SHOULD START THIS? SO
25 DR. SAMBRANO.

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1 DR. SAMBRANO: THANK YOU, JEFF.

2 SO GOOD MORNING, EVERYONE. I'M GOING TO
3 JUST GIVE AN OVERVIEW ON THE TRANSLATING CENTER
4 REVIEW AND THE RECOMMENDATIONS THAT ARE COMING FROM
5 THE GWG RELATED TO THAT. I'M ALSO GOING TO GO OVER
6 SOME OF THE SLIDES THAT WERE DISTRIBUTED. THEY
7 WON'T BE NECESSARY IN ORDER TO FOLLOW THE
8 PRESENTATION.

9 SO WE HAVE THREE PROGRAMS UNDER
10 INFRASTRUCTURE THAT WE'VE BEEN PUTTING TOGETHER THAT
11 INCLUDE THE ALPHA CLINICS NETWORK, THE ACCELERATING
12 CENTER, WHICH JUST RECENTLY LAUNCHED, AND THE
13 ACCELERATING CENTER, OF COURSE, FOCUSED ON HELPING
14 WITH THE REGULATORY AND LATER STAGE CLINICAL TRIAL
15 MANAGEMENT ASPECT. AND NOW WE'RE LOOKING TO LAUNCH
16 A TRANSLATING CENTER WHICH WILL COMPLEMENT BOTH
17 OTHER INFRASTRUCTURE PROGRAMS WITH THE GOAL OF
18 SHORTENING THE TIME TO GET TO CLINICAL TESTING.

19 AND THE ACTIVITIES THAT THEY PICTURE WILL
20 BE INVOLVED: PROCESS DEVELOPMENT, IND-ENABLING
21 ACTIVITIES, AND PRECLINICAL RESEARCH.

22 THE TRANSLATING CENTER WILL BE A
23 CIRM-FUNDED STEM CELL PRECLINICAL RESEARCH
24 ORGANIZATION THAT WILL HAVE \$15 MILLION OF SUPPORT
25 OVER FIVE YEARS, AND IT WILL OPERATE WITHIN

BARRISTERS' REPORTING SERVICE

1 CALIFORNIA. AND THERE ARE SIX BASIC CORE SERVICES
2 THAT ARE ENCOMPASSED UNDER THE TRANSLATING CENTER,
3 WHICH INCLUDE CONSULTATION SERVICES, PROJECT
4 MANAGEMENT, PRECLINICAL DEVELOPMENT RESEARCH,
5 PROCESS DEVELOPMENT, AND MANUFACTURING, AS WELL AS
6 REGULATORY FILING SUPPORT. AND THESE SERVICES WILL
7 BE PROPORTIONAL TO THE NEEDS OF THE PROJECT, MEANING
8 A CLIENT CAN UTILIZE WHATEVER SERVICES THEY NEED TO
9 ADDRESS WHATEVER GAPS THEY FEEL THEY HAVE AS THEY
10 WORK WITH THESE CENTERS IN ORDER TO ACCELERATE THEIR
11 PROGRAM.

12 THE PROGRAM OR THE TRANSLATING CENTER IS
13 EXPECTED TO BE SUSTAINABLE AS WELL. SO OVER THE
14 COURSE OF THE FIVE YEARS THAT WE WILL PROVIDE
15 SUPPORT, WE HOPE THAT THEY WILL DEVELOP A PROGRAM
16 THAT IS ATTRACTIVE AND THAT BRINGS IN ENOUGH
17 CLIENTELE TO BE SELF-SUPPORTING SO THAT ONCE CIRM
18 FUNDING ENDS, THAT THIS IS A RESOURCE THAT WILL
19 CONTINUE TO BE AVAILABLE TO THE COMMUNITY AND STILL
20 EXIST.

21 ON THE NEXT SLIDE, WHICH IS THE GRANTS
22 WORKING GROUP REVIEW CRITERIA, THIS IS JUST GOING
23 OVER WHAT CRITERIA THE GWG UTILIZED AND HOW WE
24 PRESENTED IT TO THEM IN TERMS OF HOW TO REVIEW THESE
25 APPLICATIONS. AND THEY BOIL DOWN TO THREE BASIC

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1 CRITERIA.

2 THE FIRST IS DOES THE PROPOSED CENTER HOLD
3 THE NECESSARY SIGNIFICANCE AND POTENTIAL FOR IMPACT;
4 THAT IS, HOW LIKELY IS THE PROPOSED CENTER TO
5 ACCELERATE PROGRESSION OF STEM CELL PROJECTS FROM
6 LATE PRECLINICAL STAGE TO IND FILING AND CONDUCT OF
7 THE CLINICAL TRIAL? DOES IT OFFER A SUFFICIENT
8 IMPACTFUL AND PRACTICAL VALUE PROPOSITION FOR
9 RESEARCHERS, FOR PATIENTS, OR HEALTHCARE PROVIDERS
10 BY INCREASING THE SPEED AND QUALITY OF THE
11 PRECLINICAL STAGE PROJECT. SO THAT'S THE FIRST ONE.

12 SECOND ONE, HAS THE APPLICANT DEVELOPED A
13 PLAN TO SUCCESSFULLY ESTABLISH AND OPERATIONALIZE
14 THE CENTER? THEN WE WANT TO KNOW HOW WELL THEY
15 INTEGRATE WITH THE ACCELERATING CENTER THAT WE'VE
16 ALREADY SUPPORTED. ARE THE OPERATIONS APPROPRIATELY
17 PLANNED AND DESIGNED TO EXECUTE MEANINGFUL,
18 ACCELERATING, AND IMPACTFUL RESOURCES; THAT IS, THE
19 CORE SERVICES THAT I PREVIOUSLY DESCRIBED. DO THEY
20 HAVE AN APPROPRIATE PROJECT PLAN AND TIMELINE FOR
21 ESTABLISHING THE CENTER? AND DO THEY HAVE A GOOD
22 PLAN FOR COMPETITIVE PRICING WHILE ENSURING
23 SUSTAINABILITY OF THE CENTER BEYOND FIVE YEARS.

24 AND THEN THE THIRD, IS THE PROPOSAL
25 FEASIBLE; THAT IS, IS THE CENTER LIKELY TO BE

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1 ESTABLISHED WITHIN THE PROPOSED TIMELINE? IS THE
2 TEAM APPROPRIATELY QUALIFIED AND STAFFED? DO THEY
3 HAVE ALL THE NECESSARY RESOURCES TO ACCOMPLISH WHAT
4 THEY PROPOSE? AND DO THEY HAVE A VIABLE CONTINGENCY
5 PLAN TO MITIGATE -- TO MANAGE RISK AND DELAYS? SO
6 THAT'S THE REVIEW CRITERIA.

7 THE OTHER THING THAT WE UTILIZED IN THIS
8 REVIEW, WHICH WE INTRODUCED IN THE ACCELERATING
9 CENTER, WAS THE PITCH. SO THAT MEANS THAT APPLICANT
10 TEAMS WERE INVITED TO BE FACE TO FACE WITH THE GWG
11 AND GIVE A 15-MINUTE PRESENTATION TO ADDRESS THE
12 BIG-PICTURE POINTS OF THEIR PROPOSAL, THE VISION,
13 HOW THEY WILL MAINTAIN AND ESTABLISH SUSTAINABILITY,
14 AND WHAT THE OVERALL VALUE PROPOSITION OF THE
15 TRANSLATING CENTER IS GOING TO BE. THE GWG HAD AN
16 OPPORTUNITY TO ASK QUESTIONS DIRECTLY OF TEAM
17 MEMBERS, AND SO THAT WAS EXTENSIVELY UTILIZED AS WE
18 WERE HAPPY TO SEE.

19 THE NEXT SLIDE IS THE DESCRIPTION OF THE
20 SCORING SYSTEM, WHICH IS, JUST BRIEFLY, THE 1 TO 100
21 SCALE, WITH 85 BEING THE CUTOFF. EIGHTY-FIVE OR
22 ABOVE MEANING EXCEPTIONAL MERIT AND WARRANTS
23 FUNDING. IN THIS CASE, BECAUSE IT'S AN
24 INFRASTRUCTURE PROGRAM UNDER THE RULES THAT WERE
25 ESTABLISHED FOR THIS PARTICULAR ONE, ONLY THE

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1 APPLICATION WITH THE HIGHEST AVERAGE SCORE IS
2 RECOMMENDED FOR FUNDING.

3 ON THE NEXT SLIDE IS JUST THE FINAL VOTE
4 THAT WE TAKE AT THE END OF EACH REVIEW FOR THE RIGOR
5 OF THE PROCESS AND THE OVERALL FAIRNESS. AND THE
6 VOTE TAKEN BY THE GWG AND PATIENT ADVOCATE MEMBERS
7 WAS UNANIMOUS IN TERMS OF HAVING AN APPROPRIATE
8 PROCESS.

9 AND THEN THE NEXT SLIDE SHOWS A TABLE OF
10 THE APPLICATIONS THAT WERE RECEIVED AND REVIEWED.
11 SO WE HAD A TOTAL OF FOUR APPLICATIONS THAT WERE
12 ACCEPTED FOR REVIEW AND UNDERWENT REVIEW. THERE WAS
13 ONE APPLICATION THAT SCORED BETWEEN 85 AND 100; AND,
14 THEREFORE, IT WAS RECOMMENDED FOR FUNDING, AND THERE
15 WERE THREE THAT WERE NOT OF THE THREE TO HAVE
16 WITHDRAWN. AND SO WHAT IS AVAILABLE TO YOU IN TERMS
17 OF REVIEW SUMMARIES ON THE SUMMARIES FOR THE TWO
18 THAT REMAIN, ONE WAS THAT RECOMMENDED AND ONE THAT
19 WAS NOT.

20 AND ON THE NEXT SLIDE WE HAVE THE OVERVIEW
21 OF THE FIRST APPLICATION, WHICH IS THE RECOMMENDED
22 ONE, 9298, WHICH RECEIVED A SCORE OF 89 WITH A
23 MEDIAN OF 90. THE CIRM TEAM ALSO RECOMMENDS THIS
24 APPLICATION FOR FUNDING WITH AN AWARD AMOUNT OF 15
25 MILLION. AND I WILL STOP THERE FOR ANY QUESTIONS.

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1 MR. SHEEHY: SO DO WE HAVE ANY QUESTIONS?
2 SO DO WE HAVE A MOTION TO ACCEPT THE TEAM
3 RECOMMENDATION AND FUND THE APPLICATION 09298?

4 MR. TORRES: SO MOVED.

5 DR. STEWARD: SECOND.

6 CHAIRMAN THOMAS: SECONDED BY DR. STEWARD.
7 ANY ADDITIONAL DISCUSSION?

8 MS. HARRISON: IT'S JAMES. JUST ONE
9 CLARIFICATION. DOES THIS MOTION INCORPORATE NOT
10 APPROVING THE SECOND APPLICATION, 9233?

11 MR. TORRES: YES.

12 MR. SHEEHY: YES. OS?

13 DR. STEWARD: YES FROM THE SECOND.

14 MR. SHEEHY: YES, IT DOES. ANY PUBLIC
15 COMMENT AT ANY OF THE SITES? COULD WE CALL THE ROLL
16 THEN, PLEASE.

17 MS. BONNEVILLE: ANNE-MARIE DULIEGE.
18 DAVID HIGGINS.

19 DR. HIGGINS: YES.

20 MS. BONNEVILLE: STEVE JUELSGAARD.

21 MR. JUELSGAARD: YES.

22 MS. BONNEVILLE: SHERRY LANSING. KATHY
23 LAPORTE.

24 MS. LAPORTE: YES.

25 MS. BONNEVILLE: LAUREN MILLER.

BARRISTERS' REPORTING SERVICE

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MS. MILLER: YES.
MS. BONNEVILLE: ADRIANA PADILLA.
DR. PADILLA: YES.
MS. BONNEVILLE: JOE PANETTA. FRANCISCO
PRIETO. ROBERT QUINT.
DR. QUINT: YES.
MS. BONNEVILLE: AL ROWLETT.
MR. ROWLETT: YES.
MS. BONNEVILLE: JEFF SHEEHY.
MR. SHEEHY: YES.
MS. BONNEVILLE: OS STEWARD.
DR. STEWARD: YES.
MS. BONNEVILLE: JONATHAN THOMAS.
CHAIRMAN THOMAS: YES.
MS. BONNEVILLE: ART TORRES.
MR. TORRES: AYE.
MS. BONNEVILLE: DIANE WINOKUR.
MS. WINOKUR: YES.
MS. BONNEVILLE: MOTION CARRIES.
MR. SHEEHY: GREAT. THANK YOU.
I WANT TO CONGRATULATE THE CIRM TEAM ON
PUTTING IN PLACE THIS LAST PIECE OF CRITICAL
INFRASTRUCTURE TO ACCELERATE US INTO THE CLINIC.
AND CONGRATULATE QUINTILES WHICH I THINK WILL GIVE
US A SEAMLESS PRODUCT ALL THE WAY FROM TRANSLATION

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1 THROUGH CLINICAL TRIALS.

2 THANK YOU TO EVERYBODY ON THE CALL TODAY.
3 IT'S BACK TO YOU, CHAIRMAN THOMAS.

4 CHAIRMAN THOMAS: THANK YOU, MR. SHEEHY.
5 I ECHO YOUR COMMENTS. AND CONGRATULATIONS TO
6 EVERYBODY WORKING ON THIS. I THINK THIS WILL BE A
7 TERRIFIC PROGRAM AND BETWEEN IT AND THE ACCELERATING
8 CENTER WILL PROVIDE WORLD-CLASS SERVICE FOR ALL
9 THOSE WORKING ALONG THE RESEARCH SPECTRUM IN
10 CELLULAR THERAPY.

11 WE HAVE NO OTHER ITEMS ON THE AGENDA.
12 WE'RE NOW AT PUBLIC COMMENT.

13 MS. CHEUNG: I JUST WANTED TO SAY
14 SOMETHING AFTER YOU WERE DONE.

15 CHAIRMAN THOMAS: NOW PUBLIC COMMENT. IS
16 THERE ANY MEMBERS OF THE PUBLIC AT ANY OF THE
17 VARIOUS SITES WHO WOULD LIKE TO GIVE COMMENT ON
18 ANYTHING AT THIS POINT? HEARING NONE, AMY.

19 MS. CHEUNG: SO OUR NEXT APPLICATION
20 SUBCOMMITTEE MEETING IS NOVEMBER 17TH, AND IT'S
21 GOING TO BE SCHEDULED FOR TWO HOURS. CURRENTLY IT'S
22 SCHEDULED FROM ELEVEN TO TWELVE, BUT WE WILL GO FROM
23 ELEVEN TO ONE. SO I WILL SEND AN E-MAIL ABOUT THAT.
24 YOU'LL SEE AN E-MAIL FROM ME SHORTLY.

25 CHAIRMAN THOMAS: THANK YOU VERY MUCH.

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1 THAT CONCLUDES THIS MEETING. THANK YOU, EVERYBODY.
2 AND, LADIES AND GENTLEMEN, HAVE A PLEASANT REST OF
3 YOUR DAY. WE STAND ADJOURNED.

4 (THE MEETING WAS THEN CONCLUDED AT
5 11:16 AM.)

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REPORTER'S CERTIFICATE

I, BETH C. DRAIN, A CERTIFIED SHORTHAND REPORTER IN AND FOR THE STATE OF CALIFORNIA, HEREBY CERTIFY THAT THE FOREGOING TRANSCRIPT OF THE TELEPHONIC PROCEEDINGS BEFORE THE INDEPENDENT CITIZEN'S OVERSIGHT COMMITTEE AND THE APPLICATION REVIEW SUBCOMMITTEE OF THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE IN THE MATTER OF ITS REGULAR MEETING HELD ON OCTOBER 19, 2016, 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, CSR 7152
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