

BEFORE 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: AS INDICATED ON THE AGENDA

DATE: OCTOBER 22, 2015
12 P.M.

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

BRS FILE NO.: 98040

BARRISTERS' REPORTING SERVICE

I N D E X

ITEM DESCRIPTION	PAGE NO.
1. CALL TO ORDER	3
2. ROLL CALL	3
CONSENT CALENDAR	
3. CONSIDERATION OF APPOINTMENT OF NEW SCIENTIFIC MEMBERS TO THE GRANTS WORKING GROUP.	5
ACTION ITEMS	
4. CONSIDERATION OF AMENDMENTS TO THE CONFERENCE GRANTS CONCEPT PROPOSAL.	8
5. CONSIDERATION OF ADOPTION OF THE GRANTS ADMINISTRATION POLICY FOR CLINICAL STAGE PROGRAMS, INCLUDING LOAN ELECTION POLICY.	14
DISCUSSION ITEMS	
6. PUBLIC COMMENT	NONE

BARRISTERS' REPORTING SERVICE

1 THURSDAY, OCTOBER 22, 2015; 12 P.M.

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CHAIRMAN THOMAS: GOOD AFTERNOON,
EVERYBODY. THIS IS J.T. SITTING IN CIRM
HEADQUARTERS AMONGST A BUNCH OF GIANTS FANS GETTING
HEARTFELT CONDOLENCES. SENATOR TORRES JUST NOTED
THAT HE HASN'T HEARD ANY HEARTFELT CONDOLENCES.

MR. TORRES: CONDOLENCES FOR THE CUBS.

CHAIRMAN THOMAS: I SEE. SO ANYBODY WHO'D
LIKE TO JOIN IN AND PILE ON OR OFFER SINCERE
CONCERN, I WOULD APPRECIATE IT.

WELCOME TO THE --

DR. PRIETO: LOTS OF HARDSHIP AND WE'RE
ACCUSTOMED TO IT. WE'RE TOUGH.

CHAIRMAN THOMAS: THAT'S A CUBS FAN.
THERE YOU GO. THANK YOU. ANY NEW YORK FANS IN THE
AUDIENCE? DIDN'T THINK SO. NONE HERE EITHER.

OKAY. SO WELCOME TO THE OCTOBER ICOC
BOARD MEETING. THIS IS GOING TO BE A RATHER
ABBREVIATED AGENDA TODAY. SO, MARIA, EVEN THOUGH
EVERYBODY HAS CHIMED IN, WILL YOU OFFICIALLY CALL
THE ROLL?

MS. BONNEVILLE: I SURE WILL.

SUE BRYANT.

DR. BRYANT: HERE.

BARRISTERS' REPORTING SERVICE

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MS. BONNEVILLE: KEN BURTIS.
DR. BURTIS: PRESENT.
MS. BONNEVILLE: JACK DIXON.
DR. DIXON: HERE.
MS. BONNEVILLE: ANNE-MARIE DULIEGE.
DR. DULIEGE: HERE.
MS. BONNEVILLE: ELIZABETH FINI.
DR. FINI: HERE.
MS. BONNEVILLE: MICHAEL FRIEDMAN. JUDY
GASSON. SAM HAWGOOD. DAVID HIGGINS. STEPHEN
JUELSGAARD. SHERRY LANSING.
MS. LANSING: HERE.
MS. BONNEVILLE: KATHY LAPORTE.
DR. LAPORTE: HERE.
MS. BONNEVILLE: BERT LUBIN.
DR. LUBIN: HERE.
MS. BONNEVILLE: SHLOMO MELMED.
DR. MELMED: HERE.
MS. BONNEVILLE: LAUREN MILLER. LLOYD
MINER.
DR. MINER: HERE.
MS. BONNEVILLE: ADRIANA PADILLA.
DR. PADILLA: HERE.
MS. BONNEVILLE: JOE PANETTA.
MR. PANETTA: HERE.

BARRISTERS' REPORTING SERVICE

1 MS. BONNEVILLE: ROBERT PRICE.
2 DR. PRICE: HERE.
3 MS. BONNEVILLE: FRANCISCO PRIETO.
4 DR. PRIETO: HERE.
5 MS. BONNEVILLE: ROBERT QUINT.
6 DR. QUINT: PRESENT.
7 MS. BONNEVILLE: AL ROWLETT.
8 MR. ROWLETT: PRESENT.
9 MS. BONNEVILLE: JEFF SHEEHY.
10 MR. SHEEHY: HERE.
11 MS. BONNEVILLE: OSWALD STEWARD. JONATHAN
12 THOMAS.
13 CHAIRMAN THOMAS: HERE.
14 MS. BONNEVILLE: ART TORRES.
15 MR. TORRES: HERE.
16 MS. BONNEVILLE: KRISTINA VUORI.
17 DR. VUORI: HERE.
18 MS. BONNEVILLE: DONNA WESTON.
19 DR. WESTON: HERE.
20 MS. BONNEVILLE: DIANE WINOKUR.
21 WE HAVE A QUORUM.
22 CHAIRMAN THOMAS: THANK YOU, MARIA. WE
23 MOVE ON TO THE CONSENT CALENDAR, WHICH HAS ONE ITEM,
24 CONSIDERATION OF APPOINTMENT OF NEW SCIENTIFIC
25 MEMBERS TO THE GRANTS WORKING GROUP. THIS IS THE

BARRISTERS' REPORTING SERVICE

1 ONGOING ITEM THAT GIL UPDATES FROM TIME TO TIME.
2 EVEN THOUGH THIS IS A CONSENT ITEM, BECAUSE IT IS A
3 TELEPHONIC CALL, WE NONETHELESS HAVE TO TAKE THE
4 ROLE. MARIA, WILL YOU PLEASE PROCEED.

5 MS. BONNEVILLE: SUE BRYANT.

6 DR. BRYANT: YES.

7 MS. BONNEVILLE: KEN BURTIS.

8 DR. BURTIS: YES.

9 MS. BONNEVILLE: JACK DIXON.

10 CHAIRMAN THOMAS: HOLD ON ONE SECOND. OUR
11 PARLIAMENTARIAN, SENATOR TORRES, NOTES WE, EVEN FOR
12 CONSENT ITEMS, WE DO NEED A MOTION. CAN WE HAVE A
13 MOTION FOR THAT PLEASE?

14 MR. TORRES: SO MOVED.

15 CHAIRMAN THOMAS: THANK YOU, SENATOR
16 TORRES. SECONDED BY?

17 MS. LANSING: SECOND.

18 CHAIRMAN THOMAS: THANK YOU, SHERRY.

19 MS. BONNEVILLE: SUE BRYANT.

20 DR. BRYANT: YES.

21 MS. BONNEVILLE: KEN BURTIS.

22 DR. BURTIS: YES.

23 MS. BONNEVILLE: JACK DIXON.

24 DR. DIXON: YES.

25 MS. BONNEVILLE: ANNE-MARIE DULIEGE.

BARRISTERS' REPORTING SERVICE

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DR. DULIEGE: YES.
MS. BONNEVILLE: ELIZABETH FINI.
DR. FINI: YES.
MS. BONNEVILLE: MICHAEL FRIEDMAN. JUDY
GASSON.
DR. GASSON: YES.
MS. BONNEVILLE: SAM HAWGOOD. DAVID
HIGGINS. STEPHEN JUELSGAARD. SHERRY LANSING.
MS. LANSING: YES, EXCEPT I THINK I HAVE
TO RECUSE MYSELF. I THINK I DO.
MS. BONNEVILLE: KATHY LAPORTE.
DR. LAPORTE: YES.
MS. BONNEVILLE: BERT LUBIN.
DR. LUBIN: YES.
MS. BONNEVILLE: SHLOMO MELMED.
DR. MELMED: YES.
MS. BONNEVILLE: LLOYD MINER.
DR. MINER: YES.
MS. BONNEVILLE: ADRIANA PADILLA.
DR. PADILLA: YES.
MS. BONNEVILLE: JOE PANETTA.
MR. PANETTA: YES.
MS. BONNEVILLE: ROBERT PRICE.
DR. PRICE: YES.
MS. BONNEVILLE: FRANCISCO PRIETO.

BARRISTERS' REPORTING SERVICE

1 DR. PRIETO: AYE.
2 MS. BONNEVILLE: ROBERT QUINT.
3 DR. QUINT: YES.
4 MS. BONNEVILLE: AL ROWLETT.
5 MR. ROWLETT: YES.
6 MS. BONNEVILLE: JEFF SHEEHY.
7 MR. SHEEHY: YES.
8 MS. BONNEVILLE: OSWALD STEWARD. JONATHAN
9 THOMAS.
10 CHAIRMAN THOMAS: YES.
11 MS. BONNEVILLE: ART TORRES.
12 MR. TORRES: AYE.
13 MS. BONNEVILLE: KRISTINA VUORI.
14 DR. VUORI: YES.
15 MS. BONNEVILLE: DONNA WESTON.
16 DR. WESTON: YES.
17 MS. BONNEVILLE: DIANE WINOKUR.
18 MOTION CARRIES.
19 CHAIRMAN THOMAS: MOTION CARRIES. THANK
20 YOU.
21 ON TO ACTION ITEMS, WE HAVE TWO, BOTH
22 FAIRLY QUICK. ITEM 4 ON THE AGENDA HERE,
23 CONSIDERATION OF AMENDMENTS TO THE CONFERENCE GRANTS
24 CONCEPT PROPOSAL. DR. THAKAR WILL PRESENT.
25 DR. THAKAR: THANK YOU, MR. CHAIRMAN,

BARRISTERS' REPORTING SERVICE

1 MEMBERS OF THE ICOC. THIS IS A FOLLOW-UP TO THE MAY
2 2015 ICOC MEETING WHERE A NEW CONCEPT OR A REVISED
3 CONCEPT --

4 CHAIRMAN THOMAS: SORRY. SORRY.

5 DR. THAKAR: THIS IS A MODIFICATION TO THE
6 CONCEPT PLAN FOR THE CONFERENCE GRANT PROGRAM WHICH
7 WAS ORIGINALLY PRESENTED AT THE MAY 2015 ICOC
8 MEETING. THE MEMORANDUM DETAILS WHAT IS BEING
9 PROPOSED; BUT, BRIEFLY, THE CHANGES THAT WERE
10 PROPOSED AT THE MAY 2015 MEETING WERE TO ALIGN THE
11 CONFERENCE GRANT PROGRAM WITH CIRM 2.0. WHAT IT DID
12 WAS REFINE THE ELIGIBILITY REQUIREMENTS AND THE
13 REVIEW CRITERIA SO THAT EVERYTHING ALIGNED TO
14 PRESIDENT MILLS' VISION FOR WHAT CIRM 2.0 SHOULD BE.

15 WHAT THAT DID IS MECHANISM 1, WHICH IS THE
16 OPEN SOLICITATION FOR CONFERENCES, THAT REMAINED
17 UNCHANGED. HOWEVER, MECHANISM 2, WHICH IS THE
18 MECHANISM THAT CIRM USES TO CREATE RFA'S OR RFP'S
19 FOR SPONSORED MEETINGS SPECIFIC ITS MISSION, THERE,
20 THAT IS WHERE THE CHANGES WERE CREATED. NAMELY, THE
21 CO-FUNDING REQUIREMENT WAS REMOVED.

22 IN THE PROCESS THE RESTRICTION OF NOT
23 PERMITTING CONFERENCE GRANT FUNDS OR ANY FUNDS, FOR
24 THAT MATTER, FOR FOOD AND BEVERAGES WAS HELD AND
25 KEPT IN PLACE.

BARRISTERS' REPORTING SERVICE

1 TODAY WE'RE ASKING FOR A MODIFICATION FOR
2 THE CONFERENCE CONCEPT PLAN AND, THUS, THE GAP FOR
3 MECHANISM 2, THE CIRM-INITIATED CONFERENCES. AND
4 THE RATIONALE FOR THIS IS THAT THE NEW CONFERENCE
5 GRANT PLAN DOES NOT HAVE MATCHING FUNDS FOR
6 MECHANISM 2, THE CIRM-INITIATED CONFERENCES. THERE
7 ARE NO REGISTRATION FEES. AND FINALLY, MOST OF
8 THESE MEETINGS ARE AT LEAST ONE DAY, IF NOT MULTIPLE
9 DAYS, AND IT WOULD BE GOOD TO HAVE NOURISHMENT TO
10 KEEP PEOPLE'S ATTENTION AT FULL.

11 AND SO, IF I MAY PERMIT, THE
12 RECOMMENDATION TO THE BOARD IS TO APPROVE THE
13 MODIFICATION OF THE CONCEPT PLAN FOR CONFERENCE
14 GRANT PROGRAM TO ALLOW MECHANISM 2 AWARDEES TO
15 PROVIDE NONALCOHOLIC BEVERAGES AND MEALS AND FOOD TO
16 ATTENDEES AND MAKE CONFORMING CHANGES TO THE GAP.

17 CHAIRMAN THOMAS: THANK YOU, DR. THAKAR.
18 DO I HEAR A MOTION TO THAT EFFECT?

19 MR. TORRES: MOVE IT.

20 MS. LANSING: I'LL SECOND IT.

21 CHAIRMAN THOMAS: THANK YOU, SENATOR
22 TORRES, AND THANK YOU, SHERRY. ANY DISCUSSION BY
23 MEMBERS OF THE BOARD?

24 DR. PRIETO: J.T., THAT IS FRANCISCO. I
25 JUST HAD A QUESTION, AND I DON'T IMAGINE IT'S A VERY

BARRISTERS' REPORTING SERVICE

1 BIG IMPACT TO OUR BUDGET, BUT WHAT'S THE RATIONALE
2 FOR NOT HAVING ANY REGISTRATION FEE?

3 DR. THAKAR: THE RATIONALE FOR NOT HAVING
4 A REGISTRATION FEE IS -- PART OF IT IS INTERNAL
5 CONTROL TO MAKE SURE THAT, IF WE'RE GOING TO BE
6 PROVIDING FOOD, THAT THERE'S NOT EFFECTIVELY A
7 SECOND LEVEL OF CHARGE OR WHATEVER BEING CHARGED
8 BACK ONTO THE CONFERENCE GRANT PROGRAM. THAT'S
9 EFFECTIVELY THE RATIONALE. THE ORIGINAL PROGRAM DID
10 NOT HAVE THAT IN PLACE. IT ALSO MAKES THE MEETINGS
11 AVAILABLE TO ALL GRANTEES.

12 MR. HARRISON: I THINK THAT'S THE MOST
13 IMPORTANT POINT, DR. PRIETO. OFTENTIMES SOME OF
14 THESE CONFERENCES ARE ATTENDED BY CIRM AWARDEES,
15 WHETHER THEY ARE INVESTIGATORS OR BRIDGES STUDENTS.
16 AND IT WOULD BE RATHER OFF TO CHARGE THEM A
17 REGISTRATION FEE TO ATTEND A MEETING THAT CIRM HAD
18 INITIATED AND FROM WHICH THEY'D PROBABLY USE CIRM
19 AWARDS TO PAY THE REGISTRATION FEE IN ANY EVENT. SO
20 IT WOULD BE ADMINISTRATIVELY CUMBERSOME AND WOULD
21 RESTRICT ACCESS IN A WAY THAT IS INCONSISTENT WITH
22 THE GOALS OF THE PROGRAM.

23 CHAIRMAN THOMAS: ANY OTHER COMMENTS OR
24 QUESTIONS BY MEMBERS OF THE BOARD? ANY COMMENTS BY
25 ANY MEMBERS OF THE PUBLIC AT ANY OF OUR VARIOUS

BARRISTERS' REPORTING SERVICE

1 LOCATIONS? HEARING NONE, MARIA, WILL YOU CALL THE
2 ROLL.

3 MS. BONNEVILLE: SUE BRYANT.

4 DR. BRYANT: YES.

5 MS. BONNEVILLE: KEN BURTIS.

6 DR. BURTIS: YES.

7 MS. BONNEVILLE: JACK DIXON.

8 DR. DIXON: YES.

9 MS. BONNEVILLE: ANNE-MARIE DULIEGE.

10 DR. DULIEGE: YES.

11 MS. BONNEVILLE: ELIZABETH FINI.

12 DR. FINI: YES.

13 MS. BONNEVILLE: MICHAEL FRIEDMAN. JUDY

14 GASSON. SAM HAWGOOD. DAVID HIGGINS. STEPHEN

15 JUELGAARD. SHERRY LANSING.

16 MS. LANSING: YES.

17 MS. BONNEVILLE: KATHY LAPORTE.

18 DR. LAPORTE: YES.

19 MS. BONNEVILLE: BERT LUBIN.

20 DR. LUBIN: YES.

21 MS. BONNEVILLE: SHLOMO MELMED.

22 DR. MELMED: YES.

23 MS. BONNEVILLE: LAUREN MILLER. LLOYD

24 MINER.

25 DR. MINER: YES.

BARRISTERS' REPORTING SERVICE

1 MS. BONNEVILLE: ADRIANA PADILLA.
2 DR. PADILLA: YES.
3 MS. BONNEVILLE: JOE PANETTA.
4 MR. PANETTA: YES.
5 MS. BONNEVILLE: ROBERT PRICE.
6 DR. PRICE: YES.
7 MS. BONNEVILLE: FRANCISCO PRIETO.
8 DR. PRIETO: AYE.
9 MS. BONNEVILLE: ROBERT QUINT.
10 DR. QUINT: YES.
11 MS. BONNEVILLE: AL ROWLETT.
12 MR. ROWLETT: YES.
13 MS. BONNEVILLE: JEFF SHEEHY.
14 MR. SHEEHY: YES.
15 MS. BONNEVILLE: OSWALD STEWARD. JONATHAN
16 THOMAS.
17 CHAIRMAN THOMAS: YES.
18 MS. BONNEVILLE: ART TORRES.
19 MR. TORRES: AYE.
20 MS. BONNEVILLE: KRISTINA VUORI.
21 DR. VUORI: YES.
22 MS. BONNEVILLE: DONNA WESTON.
23 DR. WESTON: YES.
24 MS. BONNEVILLE: DIANE WINOKUR.
25 MS. WINOKUR: YES.

BARRISTERS' REPORTING SERVICE

1 MS. BONNEVILLE: MOTION CARRIES.

2 CHAIRMAN THOMAS: THANK YOU. ON TO ITEM
3 5, CONSIDERATION OF ADOPTION OF A GRANTS
4 ADMINISTRATION POLICY FOR CLINICAL STAGE PROGRAMS
5 INCLUDING LOAN ELECTION POLICY. GABE.

6 MR. THOMPSON: THANK YOU, CHAIRMAN,
7 MEMBERS OF THE BOARD. THIS IS GABRIEL THOMPSON,
8 DIRECTOR OF GRANTS MANAGEMENT, HERE TO PRESENT FOR
9 YOUR CONSIDERATION AMENDMENTS TO AND FINAL ADOPTION
10 OF THE GRANTS ADMINISTRATION POLICY FOR CLINICAL
11 STAGE PROGRAMS.

12 AS YOU MAY RECALL, CIRM USED ITS AUTHORITY
13 LATE LAST YEAR TO ADOPT A GRANTS ADMINISTRATION
14 POLICY FOR CLINICAL STAGE PROGRAMS ON AN INTERIM
15 BASIS SO THAT WE COULD QUICKLY SUPPORT THE AWARDING
16 OF 2.0 AWARDS FOR CLINICAL STAGE PROGRAMS, WHICH WE
17 HAVE BEEN DOING. THE PERIOD BY WHICH THAT INTERIM
18 POLICY IS IN EFFECT IS NOW WINDING DOWN, SO WE ARE
19 PRESENTING SOME FINAL AMENDMENTS TO THAT POLICY,
20 WHICH, IF APPROVED BY THE BOARD TODAY, WOULD THEN GO
21 TO THE OFFICE OF ADMINISTRATIVE LAW FOR FINAL
22 ADOPTION AND APPROVAL.

23 SO I'M GOING TO GO THROUGH THESE FINAL
24 AMENDMENTS, AND FEEL FREE TO ASK QUESTIONS
25 THROUGHOUT, AND THEN I AM GOING TO THEN HAND IT OFF

BARRISTERS' REPORTING SERVICE

1 TO JAMES HARRISON TO DISCUSS THE LOAN ELECTION
2 POLICY AT THE VERY END OF THIS.

3 SO TO START THIS OFF, WE HAVE AN AMENDMENT
4 UNDER THE CONFLICT OF INTEREST MANAGEMENT PLAN. SO
5 FOR CONTEXT, CIRM HAS ALWAYS REQUIRED OUR AWARDEES
6 TO HAVE A CONFLICT OF INTEREST POLICY THAT
7 ESTABLISHES SAFEGUARDS TO PREVENT CIRM-FUNDED
8 INDIVIDUALS OR ORGANIZATIONS TO USE THEIR POSITION
9 TO INFLUENCE ACTIVITIES WHICH THEY KNOW OR HAVE A
10 REASON TO KNOW TO HAVE A FINANCIAL INTEREST. WE'RE
11 ADDING LANGUAGE TO ASK CIRM AWARDEES OR TO REQUIRE
12 CIRM AWARDEES TO NOTIFY CIRM WHEN IT SUSPENDS OR
13 INITIATES SEPARATION ACTION INVOLVING A FINANCIAL
14 CONFLICT OF INTEREST AND TO PROVIDE CIRM WITH A
15 CONFLICT MANAGEMENT PLAN.

16 NEXT AMENDMENT IS UNDER OUR DEFINITION OF
17 OPERATIONAL MILESTONES. WE'RE ADDING ONE SMALL
18 AMENDMENT TO ESTABLISH A FINAL OPERATIONAL MILESTONE
19 PER PROJECT THAT DEFINES THE END DATE FOR THE
20 CIRM-FUNDED AWARD AND DEFINES THE END DATE BY WHICH
21 THEY CAN USE CIRM FUNDING. WE PREVIOUSLY DIDN'T
22 HAVE A DEFINED END DATE, SO WE'RE GOING TO ESTABLISH
23 A FINAL OPERATIONAL MILESTONE THAT DEFINES THE END
24 OF THE AWARD AND THE TIME BY WHICH THEY CAN USE CIRM
25 FUNDING.

BARRISTERS' REPORTING SERVICE

1 WE HAVE A NEW SECTION REGARDING USE OF THE
2 CIRM LOGO. SO WHAT THIS AMENDMENT IS DOING IS
3 INDICATING RULES REGARDING USE OF THE LOGO SO THAT
4 WHEN CIRM IS ACTUALLY DIRECTLY FUNDING A CLINICAL
5 TRIAL, THE SPONSOR MAY USE CIRM'S LOGO; BUT WHEN
6 CIRM IS NOT DIRECTLY FUNDING A TRIAL, THE SPONSOR
7 MAY NOT USE THE CIRM LOGO. AND THIS HAS ACTUALLY
8 COME UP NOW THAT CIRM IS FUNDING THE ALPHA STEM
9 CELLS CLINIC. THE ALPHA STEM CELLS CLINIC CAN USE
10 THE LOGO TO SHOW CIRM'S ENDORSEMENT OF THE CLINIC
11 ITSELF, BUT CANNOT USE THAT LOGO TO SHOW ENDORSEMENT
12 OF ANY TRIALS RUN THROUGH THE CLINIC THAT AREN'T
13 DIRECTLY FUNDED BY CIRM.

14 NEXT AMENDMENT IS CLARIFYING ALLOWABLE
15 FACILITIES COST. WE'VE ADDED TWO CLARIFICATIONS
16 HERE TO INDICATE THAT CIRM WILL ACCEPT THE
17 APPLICANT'S FINAL FEDERALLY NEGOTIATED FACILITIES
18 RATE IN PLACE AT THE TIME THAT THEY APPLIED TO CIRM.
19 AND WE'VE ALSO CLARIFIED THAT IF THEY DON'T HAVE A
20 FINAL FEDERALLY NEGOTIATED RATE AT THE TIME THEY
21 APPLIED, THEY MAY USE PROVISIONALLY APPROVED RATES.
22 AND THEN ONCE THEY HAVE THE FEDERALLY -- FINAL
23 FACILITIES RATE APPROVED, THEY CAN COME BACK TO CIRM
24 AND CIRM WILL ENSURE THAT WE'RE FUNDING NO MORE THAN
25 THEIR FINAL FEDERALLY APPROVED RATE OR THE MAXIMUM

BARRISTERS' REPORTING SERVICE

1 BOARD-APPROVED AWARD AMOUNT.

2 NEXT AMENDMENT UNDER PRIOR APPROVAL

3 REQUIREMENTS, THESE ARE INSTANCES -- WHEN CIRM HAS
4 FUNDED AN AWARD, THIS IS WHERE AN AWARDEE HAS TO
5 SEEK CIRM'S PRIOR APPROVAL BEFORE ENGAGING IN ANY
6 CHANGE TO AN AWARD. AND SO UNDER PRIOR APPROVAL, WE
7 HAVE A CHANGE OF RESEARCH PLAN, AND WE'RE CLARIFYING
8 SCENARIOS THAT QUALIFY AS A CHANGE OF RESEARCH PLAN,
9 INCLUDING CHANGE IN PATIENT ENROLLMENT CRITERIA AND
10 A CHANGE IN AN AWARD'S TARGETED DISEASE INDICATION,
11 AS WELL AS A CHANGE IN A TRIAL'S SPONSORSHIP. SO
12 WE'RE CLARIFYING THOSE ARE SCENARIOS ON WHICH AN
13 AWARDEE WOULD HAVE TO SEEK CIRM'S APPROVAL BEFORE
14 MAKING SUCH CHANGES.

15 WE'VE ALSO CLARIFIED UNDER THIS SECTION
16 THAT CIRM PROPOSED CHANGES IN THE RESEARCH PLAN
17 WOULD GO BEYOND CIRM'S AUTHORITY TO APPROVE GIVEN
18 WHAT WAS ORIGINALLY RECOMMENDED BY THE GWG AND
19 APPROVED BY THE BOARD. AND THAT UNDER SUCH
20 CIRCUMSTANCES, THE AWARDEE WOULD HAVE TO REAPPLY TO
21 CIRM WITH A NEW PROJECT. WE'VE GIVEN AN EXAMPLE
22 HERE OF A CASE WHERE A CHANGE IN A PROJECT THAT
23 WOULD ACTUALLY REQUIRE THE RESUBMISSION OF AN IND
24 WITH THE FDA COULD BE SUCH AN EXAMPLE THAT WOULD SO
25 MATERIALLY AFFECT THE PROJECT THAT CIRM WOULD NOT BE

BARRISTERS' REPORTING SERVICE

1 ABLE TO APPROVE SUCH A CHANGE UNDER THE CURRENT
2 AWARD AND WOULD ASK THE AWARDEE TO WIND DOWN THAT
3 AWARD AND REAPPLY WITH THE NEW PROJECT.

4 NEXT AMENDMENT IS JUST CLARIFYING UNDER
5 RELINQUISHMENT OR TERMINATION OF AN AWARD THAT SUCH
6 A DECISION TO RELINQUISH DOES NOT EXTINGUISH THE
7 AWARDEE'S REQUIREMENT UNDER THE CIRM'S INTELLECTUAL
8 PROPERTY POLICY AND REVENUE SHARING REQUIREMENT.

9 AND THE LAST ONE HERE IS AN AMENDMENT
10 UNDER FAILURE OF COMPLIANCE TO CLARIFY THAT IF CIRM
11 DECIDES TO TERMINATE OR THE AWARDEE DECIDES TO
12 RELINQUISH, THAT ALL UNSPENT CIRM FUNDS SHOULD BE
13 RETURNED TO CIRM WITHIN 120 DAYS OF THE DATE OF THE
14 TERMINATION.

15 SO THOSE ARE ALL THE AMENDMENTS MINUS THE
16 ADDITION OF THE LOAN ELECTION POLICY THAT I'M
17 PRESENTING. AND IF YOU HAVE ANY QUESTIONS, LET ME
18 KNOW. OTHERWISE, I'LL TURN IT OVER TO JAMES.

19 CHAIRMAN THOMAS: ANY QUESTIONS BY MEMBERS
20 OF THE BOARD? SENATOR TORRES.

21 MR. TORRES: PART D WHERE IT TALKS ABOUT
22 THE CIRM LOGO, WHAT ABOUT THE CLINICAL TRIALS THAT
23 WE ARE NOT FUNDING, BUT MAY HAVE BEEN A PRIOR CIRM
24 RESEARCH FUND? ARE WE GOING TO MAKE A NOTE OF THAT
25 OR JUST LEAVE IT BLANK?

BARRISTERS' REPORTING SERVICE

1 MR. THOMPSON: AS FAR AS USE OF THE CIRM
2 LOGO, I DON'T THINK WE WOULD ALLOW USE OF THE CIRM
3 LOGO FOR THOSE TYPES OF TRIALS.

4 MR. TORRES: NOT EVEN AFTER THIS TRIAL
5 BENEFITED FROM FUNDING IN THE PAST?

6 MR. HARRISON: WE COULD CERTAINLY PERMIT
7 THE ALPHA STEM CELL CLINIC TO INDICATE THE TRIALS
8 THAT WE'RE FUNDING AS WELL AS PROGRAMS THAT MAY HAVE
9 RECEIVED PRIOR CIRM SUPPORT AS LONG AS IT'S CLEAR
10 THAT WE'RE NOT FUNDING THAT PARTICULAR TRIAL.

11 MR. TORRES: I WOULD FEEL VERY COMFORTABLE
12 WITH THAT. DOES THAT REQUIRE AN AMENDMENT?

13 MR. HARRISON: NO. WE'LL MAKE THAT
14 ADJUSTMENT.

15 CHAIRMAN THOMAS: FURTHER QUESTIONS FROM
16 MEMBERS OF THE BOARD? OKAY. MR. HARRISON.

17 MR. HARRISON: SO AS YOU MAY RECALL, CIRM
18 ESTABLISHED A LOAN POLICY IN 2009 WHICH WE RECENTLY
19 AMENDED SUBSTANTIALLY WITH THE BOARD'S APPROVAL IN
20 MAY OF THIS YEAR. THE POINT OF THE AMENDMENT WAS TO
21 STREAMLINE THE PROGRAM AND MAKE IT MORE ATTRACTIVE
22 TO POTENTIAL INDUSTRY PARTNERS. AND THE GIST OF THE
23 AMENDMENT WAS TO ATTEMPT TO ELIMINATE SOME OF THE
24 ADMINISTRATIVE BURDEN ASSOCIATED WITH THE LOAN
25 PROGRAM. SO RATHER THAN FORCING AN AWARDEE TO MAKE

BARRISTERS' REPORTING SERVICE

1 AN ELECTION BEFORE THE AWARDEE SUBMITTED AN
2 APPLICATION, UNDER THE REVISED PROGRAM, AN AWARDEE
3 COULD ELECT TO TREAT ITS AWARD AS A LOAN ANY TIME
4 BETWEEN THE END OF THE PROGRAM AND SEVEN YEARS FROM
5 THE DATE OF THE AWARD OR THE FILING OF AN
6 APPLICATION FOR MARKETING AUTHORIZATION WITH THE
7 FOOD AND DRUG ADMINISTRATION, WHICHEVER WAS EARLIER.

8 THE BOARD APPROVED THE PROPOSED AMENDMENT
9 AND DELEGATED TO THE I.T. AND INDUSTRY SUBCOMMITTEE
10 THE AUTHORITY TO ESTABLISH AN APPROPRIATE RATE OF
11 RETURN FOR THOSE AWARDEES WHO ELECTED TO TREAT THEIR
12 AWARD AS A LOAN. AFTER APPROVAL OF THE POLICY, THE
13 CIRM TEAM, IN CONSULTATION WITH CHAIR JUELSGAARD,
14 THE CHAIR OF THE I.T. AND INDUSTRY SUBCOMMITTEE, DID
15 SOME ADDITIONAL DUE DILIGENCE AND DETERMINED THAT
16 THERE WERE SIMPLY TOO MANY VARIABLES ASSOCIATED WITH
17 THE RISK OF DEVELOPMENT, THE TYPE OF THERAPEUTIC
18 CANDIDATE, AND THE STAGE OF AWARD TO SET AN
19 APPROPRIATE RATE OF RETURN THAT APPLIED BOTH TO AN
20 ELECTION THAT WAS MADE EARLY ON AS WELL AS AN
21 ELECTION THAT WAS MADE BEFORE FILING MARKETING
22 AUTHORIZATION APPROVAL WITH THE FDA.

23 SO WHAT WE'VE DONE IS TO GO BACK AND TAKE
24 A DIFFERENT APPROACH. AND WHAT YOU HAVE IN FRONT OF
25 YOU TODAY IS OUR PROPOSED APPROACH WHICH HAS BEEN

BARRISTERS' REPORTING SERVICE

1 REVIEWED BOTH BY CHAIR JUELGAARD OF THE I.T. AND
2 INDUSTRY SUBCOMMITTEE AS WELL AS THE FINANCE
3 SUBCOMMITTEE WHICH RECOMMENDED ITS APPROVAL.

4 SO UNDER THIS APPROACH, THERE WOULD BE
5 THREE VARIABLES ASSOCIATED WITH AN ELECTION TO TREAT
6 AND AWARD AS A LOAN. THE TYPE OF AWARD, WHETHER
7 IT'S FOR PRECLINICAL RESEARCH OR CLINICAL RESEARCH,
8 THE STAGE OF RESEARCH AT WHICH THE ELECTION TO
9 CONVERT IS MADE, WHETHER IT IS DURING PHASE I, PHASE
10 II, PHASE III, OR REGISTRATION, AS WELL AS THE TYPE
11 OF THERAPEUTIC. CELLULAR THERAPIES OBVIOUSLY HAVE A
12 GREATER RISK PROFILE THAN SMALL MOLECULES AND
13 ANTIBODIES WHICH HAVE A CLEARER REGULATORY PATHWAY.

14 WITH THOSE VARIABLES, WHAT WE WOULD DO
15 WOULD BE TO ESTABLISH A RATE OF RETURN THAT IS
16 CONTINGENT UPON EACH OF THOSE VARIABLES. AND WHAT
17 YOU'LL SEE IN THE PROPOSAL IS A TABLE WHICH SETS
18 FORTH THE RATE OF RETURN. AND JUST AS AN EXAMPLE,
19 IF WE WERE TO AWARD AN AWARD FOR PRECLINICAL
20 RESEARCH AND THE AWARDEE WERE TO ELECT BEFORE THE
21 FIRST READOUT OF DATA IN A PHASE I CLINICAL TRIAL
22 FOR THAT PROGRAM, AND IF IT WERE A CELL THERAPY, THE
23 RATE OF RETURN WOULD BE 60 PERCENT OF THE AMOUNT OF
24 THE AWARD. AND THE REASON FOR THAT IS THAT, GIVEN
25 THE EARLY STAGE OF THE PROGRAM AND THE RISK INVOLVED

BARRISTERS' REPORTING SERVICE

1 AND THE NET PRESENT VALUE, 60 PERCENT, THOUGH IT'S
2 LESS THAN THE FULL AMOUNT OF THE AWARD, WOULD STILL
3 RETURN FUNDS TO CIRM THAT COULD BE USED TO MAKE
4 ADDITIONAL AWARDS FOR RESEARCH.

5 ON THE OTHER HAND, IF YOU HAD AN AWARD FOR
6 A PHASE II CLINICAL TRIAL FOR A SMALL MOLECULE AND
7 THE AWARDEE WERE TO DECIDE WITHIN TEN DAYS OF FILING
8 AN APPLICATION FOR MARKETING AUTHORIZATION FROM THE
9 FDA TO CONVERT ITS AWARD TO A LOAN, OBVIOUSLY THE
10 AWARD WOULD HAVE BEEN SUBSTANTIALLY DERISKED BY THAT
11 POINT IN TIME. SO THE RATE OF RETURN THAT WOULD BE
12 OWED TO CIRM FOR AN ELECTION THEN WOULD BE THE FULL
13 VALUE OF THE LOAN PLUS AN INTEREST RATE AT 30
14 PERCENT PLUS LIBOR.

15 SO WE BELIEVE THAT THIS APPROACH ALLOWS US
16 TO DISTINGUISH BETWEEN THESE VARIABLES AND TO SET A
17 RATE OF RETURN CONTINGENT ON THESE VARIABLES THAT
18 MORE APPROPRIATELY REFLECTS THE RISK INVOLVED IN THE
19 NET PRESENT VALUE OF MONEY.

20 SO WITH THAT, I'D BE HAPPY TO ANSWER ANY
21 QUESTIONS.

22 CHAIRMAN THOMAS: ANY QUESTIONS FROM
23 MEMBERS OF THE BOARD.

24 MS. LANSING: SO DO YOU NEED APPROVAL?

25 CHAIRMAN THOMAS: YES, SHERRY. IF THERE

BARRISTERS' REPORTING SERVICE

1 ARE NO QUESTIONS, WE NEED TO MOVE APPROVAL.

2 MR. TORRES: SO MOVED.

3 CHAIRMAN THOMAS: MOVED BY SENATOR TORRES.

4 MS. WINOKUR: SECOND.

5 CHAIRMAN THOMAS: SECOND BY MS. WINOKUR.

6 THANK YOU VERY MUCH. MARIA, WILL YOU CALL THE ROLL.

7 PUBLIC COMMENT. DO WE HAVE PUBLIC COMMENT ON ANY OF

8 THE ASPECTS OF THIS ITEM? HEARING NONE, MARIA, WILL

9 YOU CALL THE ROLL.

10 MS. BONNEVILLE: SUE BRYANT.

11 DR. BRYANT: YES.

12 MS. BONNEVILLE: KEN BURTIS.

13 DR. BURTIS: YES.

14 MS. BONNEVILLE: JACK DIXON.

15 DR. DIXON: YES.

16 MS. BONNEVILLE: ANNE-MARIE DULIEGE.

17 DR. DULIEGE: YES.

18 MS. BONNEVILLE: ELIZABETH FINI.

19 DR. FINI: YES.

20 MS. BONNEVILLE: MICHAEL FRIEDMAN. JUDY

21 GASSON. SAM HAWGOOD. DAVID HIGGINS. STEPHEN

22 JUELGAARD. SHERRY LANSING. KATHY LAPORTE.

23 DR. LAPORTE: YES.

24 MS. BONNEVILLE: BERT LUBIN.

25 DR. LUBIN: YES.

BARRISTERS' REPORTING SERVICE

1 MS. BONNEVILLE: SHLOMO MELMED.
2 DR. MELMED: YES.
3 MS. BONNEVILLE: LAUREN MILLER. LLOYD
4 MINER.
5 DR. MINER: YES.
6 MS. BONNEVILLE: ADRIANA PADILLA.
7 DR. PADILLA: YES.
8 MS. BONNEVILLE: JOE PANETTA.
9 MR. PANETTA: YES.
10 MS. BONNEVILLE: ROBERT PRICE.
11 DR. PRICE: YES.
12 MS. BONNEVILLE: FRANCISCO PRIETO.
13 DR. PRIETO: AYE.
14 MS. BONNEVILLE: ROBERT QUINT.
15 DR. QUINT: YES.
16 MS. BONNEVILLE: AL ROWLETT.
17 MR. ROWLETT: YES.
18 MS. BONNEVILLE: JEFF SHEEHY.
19 MR. SHEEHY: YES.
20 MS. BONNEVILLE: OSWALD STEWARD. JONATHAN
21 THOMAS.
22 CHAIRMAN THOMAS: YES.
23 MS. BONNEVILLE: ART TORRES.
24 MR. TORRES: AYE.
25 MS. BONNEVILLE: KRISTINA VUORI.

BARRISTERS' REPORTING SERVICE

1 DR. VUORI: YES.

2 MS. BONNEVILLE: DONNA WESTON.

3 DR. WESTON: YES.

4 MS. BONNEVILLE: DIANE WINOKUR.

5 MS. WINOKUR: YES.

6 MOTION CARRIES.

7 CHAIRMAN THOMAS: MOTION CARRIES. THANK
8 YOU VERY MUCH. THAT CONCLUDES THE ACTION ITEMS FOR
9 THE AGENDA. WE'RE NOW IN THE PUBLIC COMMENT SECTION
10 WHEREIN ANY MEMBERS OF THE PUBLIC ARE FREE TO
11 COMMENT ON ANYTHING THEY WISH, KEEPING SUCH COMMENTS
12 TO THREE MINUTES. DO WE HAVE ANY MEMBERS OF THE
13 PUBLIC AT ANY OF OUR SITES WHO WOULD LIKE TO SPEAK?
14 HEARING NONE, I THINK MARIA HAS ONE ANNOUNCEMENT TO
15 MAKE HERE.

16 MS. BONNEVILLE: JUST AS A REMINDER, OUR
17 NEXT IN-PERSON BOARD MEETING IS DECEMBER 17TH IN LOS
18 ANGELES. AND WE'LL BE SENDING OUT DETAILS LATER
19 THIS WEEK, ACTUALLY TOMORROW, FRIDAY. SO WE'LL SEND
20 YOU ALL THE INFORMATION TOMORROW.

21 CHAIRMAN THOMAS: THANK YOU MARIA; THANK
22 YOU, MEMBERS OF THE BOARD; THANK YOU, MEMBERS OF THE
23 CIRM TEAM. I BELIEVE WITH THAT, WE WILL ENTERTAIN A
24 MOTION TO ADJOURN. SENATOR TORRES.

25 MR. TORRES: SO MOVED.

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CHAIRMAN THOMAS: IS THERE A SECOND?

(MULTIPLE SECONDS.)

CHAIRMAN THOMAS: A LOT OF SECONDS. OKAY.

THANKS, EVERYBODY. WE'LL TALK TO YOU NEXT MONTH.

(THE MEETING WAS THEN CONCLUDED AT
12:30 2 P.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 OF THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE IN THE MATTER OF ITS REGULAR MEETING HELD ON OCTOBER 22, 2015, 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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