

BEFORE THE
INTELLECTUAL PROPERTY AND INDUSTRY 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: AS INDICATED ON THE AGENDA

DATE: MAY 18, 2015
2:15 P.M.

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

BARRISTERS' REPORTING SERVICE

I N D E X

ITEM DESCRIPTION	PAGE NO.
OPEN SESSION	
1. CALL TO ORDER.	3
2. ROLL CALL.	3
3. CONSIDERATION OF ADOPTION OF OPTION TO CONVERT A CLINICAL STAGE PROGRAM AWARD (PA 15-01, 15-02 AND 15-03) FROM A GRANT TO A LOAN	3
4. PUBLIC COMMENT	NONE

BARRISTERS' REPORTING SERVICE

MAY 18, 2015; 2:15 P.M.

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CHAIRMAN JUELSGAARD: WELL, I WILL CALL THE MEETING TO ORDER THEN. SO THIS IS, AGAIN, A MEETING OF THE INTELLECTUAL PROPERTY AND INDUSTRY SUBCOMMITTEE OF THE ICOC. AND I GUESS WE SHOULD START WITH THE ROLL CALL OF THOSE PRESENT. SO, MARIA, ARE YOU AVAILABLE TO DO THAT?

MS. BONNEVILLE: I AM. STEVE JUELSGAARD.

CHAIRMAN JUELSGAARD: PRESENT.

MS. BONNEVILLE: JEFF SHEEHY.

MR. SHEEHY: HERE.

MS. BONNEVILLE: OS STEWARD. JONATHAN THOMAS.

CHAIRMAN THOMAS: HERE.

MS. BONNEVILLE: JOE PANETTA.

MR. PANETTA: HERE.

MS. BONNEVILLE: ANNE-MARIE DULIEGE.

DR. DULIEGE: HERE.

MS. BONNEVILLE: SUE BRYANT.

DR. BRYANT: HERE.

MS. BONNEVILLE: GREAT.

CHAIRMAN JUELSGAARD: ALL RIGHT. WONDERFUL. WELL, WE HAVE ONE AGENDIZED ITEM, AND IT'S THE CONSIDERATION OF THE ADOPTION OF AN OPTION

BARRISTERS' REPORTING SERVICE

1 TO BE ABLE TO CONVERT CLINICAL STAGE PROGRAM AWARDS
2 FROM A GRANT TO A LOAN. THIS IS SOMETHING THAT HAS
3 BEEN IN THE WORKS FOR A LITTLE WHILE AND I THINK IS
4 A REALLY GREAT IDEA. BUT I'M GOING TO TURN THE
5 MEETING OVER TO JAMES HARRISON, WHO CAN WALK US
6 THROUGH THE PROPOSAL. AND THEN WE CAN DISCUSS IT
7 AND GO FROM THERE.

8 MR. HARRISON: THANKS, STEVE. GOOD
9 AFTERNOON, EVERYONE. WHEN OUR NEW PRESIDENT JOINED
10 THE AGENCY, HE TASKED US WITH TAKING A FRESH LOOK AT
11 MANY OF OUR PROGRAMS, INCLUDING THE LOAN
12 ADMINISTRATION POLICY.

13 AS YOU MAY RECALL, THE BOARD ESTABLISHED
14 THE LOAN PROGRAM BACK IN 2009 AFTER A LOT OF
15 CONSIDERATION AND ECONOMIC MODELING. AND AMONG THE
16 GOALS FOR THE LOAN PROGRAM WERE IN SOME WAY
17 EVERGREENING CIRM BY USING THE PROCEEDS OF LOANS TO
18 MAKE NEW RESEARCH AWARDS AND ALSO TO OFFER INDUSTRY
19 AN ALTERNATIVE TO OUR TRADITIONAL GRANT PROGRAM. AT
20 LEAST BASED ON THE ECONOMIC MODELING THAT WAS DONE
21 AT THE TIME, IT WAS ENVISIONED THAT THE LOAN PROGRAM
22 WOULD ULTIMATELY TOTAL APPROXIMATELY 500 MILLION.

23 SINCE THE ADOPTION OF THE LOAN PROGRAM
24 BACK IN 2009, WE HAVE GONE THROUGH MULTIPLE
25 ITERATIONS OF THE LOAN ADMINISTRATION POLICY AND

BARRISTERS' REPORTING SERVICE

1 TWEAKED VIRTUALLY EVERY ASPECT OF THE LOAN PROGRAMS
2 FROM WARRANTS TO THE INTEREST RATE TO WHAT WE CALL
3 THE RISK PREMIUM TO FORGIVENESS. AND EACH OF THESE
4 CHANGES, WHILE SIGNIFICANT, HASN'T FUNDAMENTALLY
5 CHANGED THE PROGRAM ITSELF.

6 TO DATE WE HAVE ISSUED ONLY FIVE LOANS.
7 AND IN YOUR SLIDES, WE HAVE THE STATUS OF THE
8 CURRENT LOAN PROGRAM. OF THOSE FIVE LOANS, ONLY TWO
9 OF THEM ARE OUTSTANDING. WE FORGAVE TWO OF THE
10 LOANS BECAUSE THE PROJECTS WERE UNSUCCESSFUL, AND
11 ONE OF THE LOAN RECIPIENTS, GERON, REPAID CIRM THE
12 AMOUNT THAT IT HAD BEEN DISBURSED PLUS INTEREST WHEN
13 IT DECIDED TO DISCONTINUE ITS STEM CELL PROGRAM FOR
14 BUSINESS REASONS.

15 SO IT'S FAIR TO SAY, AT LEAST AS
16 ORIGINALLY ENVISIONED, THE LOAN PROGRAM HAS NOT MET
17 ALL OF THE GOALS WE SET OUT FOR IT. WE BEGAN TO
18 LOOK AT THE LOAN ADMINISTRATION POLICY ITSELF 2.0
19 SPIRIT AND ACTUALLY WENT THROUGH MULTIPLE REVISIONS
20 OF IT TO TRY TO STREAMLINE IT. I THINK ONE OF THE
21 THINGS WE FOUND WAS THAT IT WAS A VERY COMPLEX
22 PROGRAM. IT WAS HARD TO EXPLAIN TO APPLICANTS, AND
23 MANY OF THE PROVISIONS WERE CHALLENGING TO THEM. IN
24 PARTICULAR, THE WARRANT COVERAGE PROVED TO BE AN
25 OBSTACLE FOR SOME COMPANIES. THE LOAN FORGIVENESS

BARRISTERS' REPORTING SERVICE

1 OPTION, WHILE IMPORTANT, ALSO HAD ONE SIGNIFICANT
2 CAVEAT, WHICH IS THAT IF THE PROGRAM ULTIMATELY WAS
3 RESURRECTED, THE LOAN WOULD AUTOMATICALLY BE
4 REINSTATED. AND WHAT THAT MEANT AS A PRACTICAL
5 MATTER FOR OUR LOAN RECIPIENTS IS THAT THAT LOAN,
6 EVEN IF CIRM FORGAVE IT, REMAINED ON THE COMPANY'S
7 BOOKS ESSENTIALLY IN PERPETUITY BECAUSE THERE'S
8 ALWAYS SOME CHANCE FROM AN ACCOUNTING PERSPECTIVE
9 THAT THE OBLIGATION COULD SPRING BACK TO LIFE.

10 SO THAT PROVED TO BE AN OBSTACLE AS WELL.
11 SO IN DISCUSSIONS WITH RANDY, WE BATTED AROUND
12 SEVERAL IDEAS, AND ULTIMATELY RANDY CAME UP WITH THE
13 IDEA OF INSTEAD OF OFFERING THIS STAND-ALONE LOAN
14 PROGRAM, INSTEAD OFFERING AN OPTION WHERE AN AWARDEE
15 WOULD CONVERT ITS GRANT TO A LOAN AND ESSENTIALLY
16 HAVE THE OPTION OF OVER THE COURSE OF THE PROGRAM
17 CHANGING THE STATUS OF THE AWARD.

18 WE BELIEVE THAT THIS PROPOSAL WILL HELP US
19 ACHIEVE SOME OF THE AIMS OF CIRM 2.0. SO LET ME
20 JUST WALK YOU BRIEFLY THROUGH SOME OF THE DETAILS.
21 SO REMEMBER THIS WOULD APPLY, AT LEAST FOR NOW, ONLY
22 TO CIRM'S CLINICAL STAGE PROJECT AWARDS, SO THE
23 THREE PROGRAM ANNOUNCEMENTS THAT THE BOARD APPROVED
24 AS PART OF CIRM 2.0: 15-01, 15-02, AND 15-03. AND
25 PURSUANT TO THIS POLICY, WE WOULD ALLOW THE AWARDEE

BARRISTERS' REPORTING SERVICE

1 TO CONVERT THEIR AWARD FROM A GRANT TO A LOAN WITHIN
2 THE EARLIER OF MARKETING APPROVAL BY THE FDA OR
3 SEVEN YEARS FROM THE EFFECTIVE DATE OF THE AWARD.
4 WE WOULD REQUIRE THE AWARDEE TO REPAY CIRM WITHIN
5 TEN DAYS OF MAKING THE ELECTION TO CONVERT FROM A
6 GRANT TO A LOAN UNLESS CIRM AND THE AWARDEE AGREE TO
7 DIFFERENT TERMS. AND WE WOULD SET THE REPAYMENT
8 RATE BASED ON THE DATE OF THE REPAYMENT AND REQUIRE
9 HIGHER RATE THE LATER IN TIME THE REPAYMENT OCCURS.

10 NOW, WE HAVE NOT YET SET THAT RATE OF
11 REPAYMENT. AS YOU WILL SEE IN THE DRAFT POLICY, WE
12 LEFT THAT BLANK. WE ARE IN THE PROCESS OF
13 CONSULTING WITH AN EXPERT TO GET SOME ADVICE ON WHAT
14 THE APPROPRIATE RATE WOULD BE FROM AN ECONOMIC AND
15 FINANCIAL PERSPECTIVE, AND WE WILL COME BACK TO YOU
16 ONCE WE'VE DONE THAT DUE DILIGENCE.

17 IMPORTANTLY, THE CONVERSION FROM A GRANT
18 TO A LOAN WOULD BECOME FINAL ONLY AFTER THE AWARDEE
19 HAS SATISFIED THE TERMS OF THE CONVERSION, MEANING
20 FULL REPAYMENT TO CIRM. AND CIRM'S ACCESS, PRICING,
21 AND MARCH-IN REGULATIONS, WHICH ARE PART OF OUR IP
22 RULES, WOULD CONTINUE TO APPLY TO AN AWARDEE THAT
23 CONVERTED ITS AWARD FROM A GRANT TO A LOAN.

24 WE THINK THAT THIS OPTION WILL HELP
25 ADVANCE CIRM'S MISSION TO ACCELERATE THE DELIVERY OF

BARRISTERS' REPORTING SERVICE

1 STEM CELL THERAPIES TO PATIENTS WITH UNMET MEDICAL
2 NEEDS IN THREE WAYS. ONE, AS WITH THE ORIGINAL LOAN
3 PROGRAM, THIS IS DESIGNED TO ATTRACT INDUSTRY
4 INVOLVEMENT, BUT WE THINK THAT THIS HAS SEVERAL
5 ADVANTAGES TO THE EXISTING PROGRAM. IT'S
6 STREAMLINED, IT'S CLEANER, IT AVOIDS THE HANGING
7 OBLIGATION THAT I REFERENCED EARLIER WHEREBY AN
8 AWARDEE WHO HAS A LOAN THAT'S FORGIVEN CONTINUES TO
9 SHOW THAT AS AN OBLIGATION ON ITS BOOKS INTO
10 PERPETUITY. WE THINK IT ALSO CREATES AN INCENTIVE
11 FOR THE AWARDEES TO REPAY CIRM EARLIER BECAUSE THE
12 EARLIER YOU REPAY, THE LESS YOU WOULD HAVE TO REPAY
13 CIRM. AND WE COULD THEN USE THOSE PROCEEDS TO MAKE
14 NEW RESEARCH AWARDS. AND IT ALSO INCREASES
15 EFFICIENCY SIGNIFICANTLY, ELIMINATING A LOT OF THE
16 COMPLEXITY OF THE STAND-ALONE LOAN ADMINISTRATION
17 POLICY, REDUCING THE BURDEN OF HAVING TO NEGOTIATE
18 EACH LOAN AWARD SEPARATELY, AND THE TIME AND EFFORT
19 OF ENFORCING A SEPARATE ADMINISTRATIVE POLICY
20 COVERING LOANS.

21 SO WE BELIEVE THAT THIS WILL BE AN
22 IMPORTANT ENHANCEMENT TO THE OPTIONS THAT WE
23 CURRENTLY OFFER, AND WE ASK FOR THE SUBCOMMITTEE'S
24 CONSIDERATION OF IT. I'D BE HAPPY TO ANSWER ANY
25 QUESTIONS.

BARRISTERS' REPORTING SERVICE

1 CHAIRMAN JUELSGAARD: ARE THERE ANY
2 QUESTIONS OF ANY MEMBERS OF THE SUBCOMMITTEE?

3 MR. PANETTA: STEVE, THIS IS JOE. I HAVE
4 A QUESTION THAT'S PROBABLY COMPLETELY NAIVE, BUT IF
5 YOU'LL LET ME ASK IT.

6 CHAIRMAN JUELSGAARD: SURE.

7 MR. PANETTA: THANK YOU VERY MUCH. I
8 GUESS WHERE I'M CONFUSED ON THIS IS WHAT IS THE
9 INCENTIVE FOR A COMPANY TO CONVERT A GRANT TO A LOAN
10 IF A GRANT DOES NOT REQUIRE REPAYMENT AND A LOAN
11 DOES?

12 MR. HARRISON: GRANTS COME WITH REVENUE
13 SHARING TERMS, ROYALTIES ESSENTIALLY, .1 PERCENT PER
14 ONE MILLION OF CIRM AWARD.

15 MR. PANETTA: OKAY. SO THE LOAN COULD
16 CONCEIVABLY COST THE COMPANY LESS THAN THE REVENUE
17 SHARING ROYALTY?

18 MR. HARRISON: YEAH. THE COMPANY WOULD
19 HAVE TO DO ITS OWN ECONOMIC ANALYSIS AND SORT THAT
20 OUT, BUT IT DOES PROVIDE AN ALTERNATIVE TO OUR
21 CURRENT OFFERINGS.

22 MR. PANETTA: OKAY.

23 DR. MILLS: BASICALLY, JOE, IT'S SIMILAR
24 TO A ROYALTY BUYOUT PROVISION THAT SOMETIMES EXISTS.
25 WHAT WE FOUND IS THAT ROYALTY ENTANGLEMENTS ALMOST,

BARRISTERS' REPORTING SERVICE

1 IRRESPECTIVE OF THEIR SIZE, ARE DETRIMENTAL TO
2 GETTING PARTNERSHIPS DONE. AND SO EVEN IF IT'S MORE
3 EXPENSIVE, OFTENTIMES LICENSING COMPANIES WOULD
4 RATHER TO BE ABLE TO JUST BUY OUT THE ENTANGLEMENT
5 IN ITS ENTIRETY AND NOT HAVE TO WORRY ABOUT
6 DOWNSTREAM PROVISIONS.

7 MR. PANETTA: GREAT. THANKS A LOT. THAT
8 HELPS ME A LOT. I APPRECIATE IT.

9 CHAIRMAN THOMAS: DO WE WANT TO PROVIDE
10 FOR A ROYALTY BUYOUT OPTION ON TOP OF THIS BECAUSE
11 THERE ARE FIRMS OUT THERE THAT ARE DOING THAT?

12 DR. MILLS: I THINK THE WAY THAT THIS WAS
13 CONSTRUCTED SUFFICIENTLY ADDRESSES THAT NEED. AND
14 IT DOES IT IN A WAY, AND JAMES CAN TALK MORE ABOUT
15 IT, THAT FALLS WITHIN APPROPRIATE CONSTRUCTS FOR
16 WHAT THE STATE OF CALIFORNIA CAN DO. THE IDEA OF
17 ROYALTY BUYOUT WAS ONE OF THE THINGS WE TALKED
18 ABOUT, BUT I THINK THIS MECHANISM MAY DO IT BETTER.

19 CHAIRMAN JUELSGAARD: IT IS THE EQUIVALENT
20 OF A ROYALTY BUYOUT, AS YOU SAID EARLIER, RANDY. IN
21 ESSENCE, WHAT SOMEBODY WILL DO AT THE APPROPRIATE
22 TIME IS LOOK AT THE COST OF ROYALTY VERSUS THE COST
23 OF A BUY-DOWN AND MAKE A DECISION ON WHICH THEY'D
24 RATHER TAKE THE CHANCE ON. SO IT EFFECTIVELY, IN MY
25 EYES, EVEN THOUGH WE CALL IT A LOAN, IT'S A ROYALTY

BARRISTERS' REPORTING SERVICE

1 BUYOUT PROVISION.

2 I DO HAVE ONE QUESTION, AND THAT GOES TO
3 TIMING. SO THIS WEEK WE'RE MEETING, WE HAVE A BOARD
4 MEETING, RIGHT, AND WE'RE GOING TO CONSIDER
5 APPLICATIONS IN RESPONSE TO 15-01 AND 15-02
6 APPLICATIONS. AND SO WE WON'T HAVE COMPLETED THIS
7 YET. WE'RE GOING TO GO TO THE BOARD AND WE'RE GOING
8 TO SAY WE WOULD LIKE YOU TO ADOPT THIS, TO DELEGATE
9 AUTHORITY FOR SETTING THE EXACT TIERING OF THE
10 REPAYMENTS, BACK TO THE SUBCOMMITTEE BECAUSE WE'RE
11 CONSULTING WITH SOME PEOPLE WHO ARE GOING TO HELP US
12 FIGURE OUT WHAT WE THINK IS APPROPRIATE. AND THEN I
13 THOUGHT I SAW A PROVISION THAT WE WOULD GO BACK TO
14 THE BOARD WITH WHAT THE DETERMINATION OF THAT WAS.

15 MR. HARRISON: STEVE, I THINK I CAN CLEAR
16 UP THAT CONFUSION. WHAT WE WOULD REQUEST IS THAT
17 THE SUBCOMMITTEE RECOMMEND APPROVAL OF ADOPTION TO
18 THE BOARD AND ASK THE BOARD TO DELEGATE TO THE
19 SUBCOMMITTEE THE AUTHORITY TO SET THE RATE OF
20 RETURN. BECAUSE THIS IS BEING ADOPTED AS AN INTERIM
21 REGULATION, IT WOULD GO INTO EFFECT IMMEDIATELY.
22 BUT ULTIMATELY, AS WITH THE REMAINDER OF THE GRANTS
23 ADMINISTRATION POLICY FOR 2.0 AWARDS, IT WILL GO
24 THROUGH THE ADMINISTRATIVE PROCEDURE ACT. SO
25 ULTIMATELY WILL COME BACK TO THE BOARD FOR FINAL

BARRISTERS' REPORTING SERVICE

1 ADOPTION.

2 SO THAT WAS THE REFERENCE TO GOING BACK TO
3 THE BOARD, BUT THAT WOULDN'T IMPEDE THE RULE FROM
4 TAKING EFFECT ONCE WE GET SUFFICIENT INFORMATION TO
5 RECOMMEND AN APPROPRIATE RATE OF RETURN AND COME
6 BACK TO THIS SUBCOMMITTEE FOR APPROVAL.

7 CHAIRMAN JUELSGAARD: SO LET ME JUST ASK
8 ABOUT THAT. SO IT'S THAT SECOND STEP THAT'S GOING
9 BACK TO THE BOARD FOR FINALIZATION. SO LET'S ASSUME
10 THAT THIS PROCEEDS -- THIS SUBCOMMITTEE IS DELEGATED
11 THE AUTHORITY TO DEVELOP THE TIERS THAT ARE GOING TO
12 BE USED IN TERMS OF REPAYMENT. AND SO NOW THAT'S
13 DONE AND PEOPLE ARE GRANTED THE FUNDS TO DO
14 PROJECTS, AND WE GET TO THE FINALIZATION STAGE AND
15 THEY'RE FAR DOWN THE ROAD, BUT SOMEWHERE DOWN THE
16 ROAD GOING TO THE BOARD AND THE BOARD SAYS, WELL, WE
17 REALLY DON'T LIKE THE TIERING THAT YOU DID. WE
18 THINK IT'S EITHER TOO HIGH, TOO LOW, OR SOMETHING
19 ELSE. BUT WE'VE ALREADY BEEN OUT THERE, IN ESSENCE,
20 WITH THIS PROGRAM IN PLACE. SO IS THERE A RISK THAT
21 THE BOARD COULD, IN ESSENCE, UNDO WHAT WE WOULD WANT
22 TO HAVE DONE IN THE MEANTIME?

23 MR. HARRISON: NO. BECAUSE ANY CHANGES
24 MADE BY THE BOARD AT THAT POINT IN TIME WOULD APPLY
25 PROSPECTIVELY ONLY.

BARRISTERS' REPORTING SERVICE

1 CHAIRMAN JUELSGAARD: OKAY.

2 MR. HARRISON: SO AWARDS MADE UNDER THE
3 INTERIM RULE, WHICH WOULD HAVE FULL FORCE AND EFFECT
4 UNTIL FINAL ADOPTION, WOULD REMAIN IN EFFECT FOR
5 WHATEVER AWARDS ARE COVERED.

6 CHAIRMAN JUELSGAARD: OKAY. GREAT.
7 PERFECT.

8 HOW LONG WILL IT TAKE BEFORE WE GET TO THE
9 POINT OF BEING FINALIZED BY THE BOARD?

10 MR. HARRISON: PROBABLY ABOUT SIX MONTHS.

11 CHAIRMAN JUELSGAARD: OKAY. GOT IT. THAT
12 ANSWERS MY QUESTIONS.

13 MR. HARRISON: THAT'S JUST A CONSEQUENCE
14 OF THE TIME IT TAKES TO GO THROUGH THE PUBLIC
15 HEARINGS AND PUBLIC COMMENT UNDER THE ADMINISTRATIVE
16 PROCEDURE ACT.

17 CHAIRMAN JUELSGAARD: WHEN DO WE EXPECT
18 THAT WE WILL HAVE FEEDBACK FROM A CONSULTANT AS TO
19 WHAT THEY THINK THE APPROPRIATE TIERING SHOULD BE?

20 MR. HARRISON: WE WOULD HOPE TO HAVE THAT
21 FEEDBACK WITHIN THE NEXT COUPLE OF WEEKS.

22 CHAIRMAN JUELSGAARD: OKAY.

23 MR. HARRISON: SO WE WILL TRY TO SCHEDULE
24 ANOTHER MEETING OF THE SUBCOMMITTEE PERHAPS A MONTH
25 FROM NOW.

BARRISTERS' REPORTING SERVICE

1 CHAIRMAN JUELSGAARD: BUT WHATEVER
2 DECISION GETS MADE A MONTH FROM NOW, LET'S SAY, IS
3 GOING TO BE APPLICABLE TO WHATEVER GRANTS ARE MADE
4 THIS WEEK; IS THAT RIGHT?

5 MR. HARRISON: YES.

6 CHAIRMAN JUELSGAARD: AND AS FAR AS GRANTS
7 THAT HAVE ALREADY BEEN MADE, TO THE TWO THAT ARE
8 STILL OUTSTANDING, WHAT DO WE INTEND IN THAT REGARD?

9 MR. HARRISON: THIS NEW OPTION WOULD HAVE
10 NO EFFECT ON THOSE AWARDEES.

11 I DID RAISE ONE ISSUE EARLIER, WHICH WE
12 MAY WANT TO RECONSIDER FOR THOSE EXISTING PROGRAMS,
13 AND THAT IS THE FACT THAT UNDER OUR CURRENT LOAN
14 ADMINISTRATION POLICY, IF CIRM FORGIVES A LOAN, IT
15 NONETHELESS REMAINS ON THE COMPANY'S BOOKS BECAUSE
16 WE HAVE A TERM IN THE CURRENT LOAN ADMINISTRATION
17 POLICY WHICH PROVIDES THAT THE OBLIGATION SPRINGS
18 BACK TO LIFE IF THE COMPANY SHOULD EVER RESTART
19 THEIR RESEARCH PROGRAM. AND THAT CARRIES BOTH A
20 REPAYMENT OBLIGATION AND INTEREST AT A RATE TO BE
21 SET BY THE SUBCOMMITTEE NOT HIGHER THAN WHATEVER
22 LIBOR IS AT THAT POINT IN TIME PLUS 2 PERCENT. SO
23 WE MAY WANT TO REVISIT THAT POLICY. WE KNOW IT HAS
24 CAUSED SOME CHALLENGES.

25 CHAIRMAN JUELSGAARD: NO, I UNDERSTAND.

BARRISTERS' REPORTING SERVICE

1 SO ONE OF THE SIMPLE FIXES FOR THAT ISSUE IS TO JUST
2 SIMPLY CONVERT THAT GRANT THAT WAS MADE AS A LOAN AT
3 THAT TIME INTO A REGULAR GRANT WITH THIS LOAN OPTION
4 PROVISION ASSOCIATED WITH IT. IN OTHER WORDS, TO
5 GRANT THAT PARTICULAR COMPANY IN.

6 MR. HARRISON: YEAH. WE HAVE BEEN
7 INTERNALLY DISCUSSING SOME OF THOSE OPTIONS, STEVE.
8 AND WE WILL COME BACK TO THE SUBCOMMITTEE WITH SOME
9 IDEAS.

10 CHAIRMAN JUELGAARD: OKAY. GREAT. ARE
11 THERE ANY OTHER QUESTIONS OR DISCUSSION?

12 MR. SHEEHY: YES. I HAVE A QUESTION,
13 STEVE. THIS IS JEFF SHEEHY.

14 CHAIRMAN JUELGAARD: YEAH, JEFF. GO
15 AHEAD.

16 MR. SHEEHY: SO I HAD NOT REALIZED THIS
17 THAT WAS A ROYALTY BUYOUT PROGRAM. SO WHO RECEIVES
18 THE ROYALTIES?

19 MR. HARRISON: SO I'M NOT SURE I WOULD
20 CALL IT A ROYALTY BUYOUT.

21 MR. SHEEHY: HE SAID IT WAS A ROYALTY
22 BUYOUT.

23 MR. HARRISON: SO LET ME TAKE A STEP BACK.
24 WE HAVE AN EXISTING LOAN PROGRAM WHICH IS AUTHORIZED
25 UNDER PROP 71. UNDER THAT PROGRAM AND UNDER OUR

BARRISTERS' REPORTING SERVICE

1 GOVERNING LAW, THE PROCEEDS OF LOANS COME BACK TO
2 CIRM. AND THAT'S ALWAYS BEEN THE CASE SINCE DAY ONE
3 OF OUR EXISTING LOAN PROGRAM. WHAT WE'RE REALLY
4 TRYING TO DO IS ELIMINATE SOME OF THE ADMINISTRATIVE
5 COMPLEXITY OF OUR EXISTING LOAN PROGRAM BY GIVING
6 AWARDEES AN OPTION FOR THESE THREE PROGRAMS TO
7 CONVERT THEIR AWARD FROM A GRANT TO A LOAN WITHIN A
8 SPECIFIED PERIOD OF TIME AND TO REPAY CIRM, AS THEY
9 WOULD WITH A LOAN, NOT A GRANT, WITH AN INTEREST
10 RATE THAT ESCALATES DEPENDING UPON THE DATE OF
11 REPAYMENT. SO THE EARLIER THEY REPAY US, THE LESS
12 THEY PAY. THE LATER THEY PAY, THE MORE THEY PAY.

13 MR. SHEEHY: BUT ROYALTIES THAT ARE DUE
14 UNDER A GRANT PROGRAM, THOSE GO TO THE STATE OF
15 CALIFORNIA TO THE GENERAL FUND.

16 MR. HARRISON: THAT'S CORRECT.

17 MR. SHEEHY: SO WITH A ROYALTY BUYOUT,
18 WE'RE ACTUALLY DIVERTING MONEY FROM THE GENERAL FUND
19 BACK INTO CIRM.

20 DR. MILLS: SO NOT NECESSARILY BECAUSE THE
21 WAY WE STRUCTURED -- SO WE HAVE A LOAN PROGRAM THAT
22 DOES EXACTLY THAT. SO IF WE WERE MODIFYING OUR LOAN
23 PROGRAM TO MAKE IT BETTER, TO MAKE IT MORE USER
24 FRIENDLY, THEN YOU COULD ASSUME THAT PEOPLE WOULD
25 SELECT THE LOAN PROGRAM. WE WOULD ISSUE LOANS.

BARRISTERS' REPORTING SERVICE

1 THOSE LOANS WOULD BE REPAID TO US. CIRM WOULD THEN
2 TAKE THAT MONEY, REINVEST IT INTO OTHER THINGS WHERE
3 THE LOAN PROGRAM (INAUDIBLE), BUT THE GRANT AND
4 ROYALTY PROVISION RECYCLED WAS DONE, THEN THE STATE
5 OF CALIFORNIA WOULD GET REPAID. BUT THE STATE OF
6 CALIFORNIA ISN'T LOSING OUT ON THAT MONEY. IT'S
7 COMING BACK TO CIRM, NOT TO BE EVAPORATED, BUT TO BE
8 REINVESTED IN THINGS THAT HAVE FUTURE ROYALTY
9 GENERATING OPPORTUNITIES.

10 MR. SHEEHY: I APOLOGIZE FOR BEING
11 DIFFICULT, BUT PART OF THE COMMITMENT OF PROP 71 WAS
12 TO RETURN MONEY TO THE GENERAL FUND, AND THIS IS ONE
13 OF THE KEY WAYS. AND I GUESS I HAD NOT THOUGHT OF
14 THIS AS A ROYALTY BUYOUT PROGRAM. I HAD THOUGHT OF
15 IT AS SUBSTITUTION FOR A CURRENT LOAN PROGRAM. AT
16 LEAST THE INDUSTRY PEOPLE CLEARLY SEE THIS AS A
17 ROYALTY BUYOUT PROGRAM, AND I DON'T KNOW THAT I FEEL
18 COMFORTABLE IN TAKING ACTION TO BUY OUT ROYALTIES
19 THAT WOULD BE DUE TO THE GENERAL FUND TO REPAY THE
20 BONDS THAT WERE ISSUED AND THE INTEREST THAT WAS
21 ISSUED ON THOSE BONDS -- THAT IS BEING PAID ON THOSE
22 BONDS.

23 CHAIRMAN JUELSGAARD: JEFF, I'M SORRY IF I
24 ADDED TO THE CONFUSION. SO I THINK YOU HAVE TO
25 DIVORCE WHAT IS ACTUALLY HAPPENING FROM THE

BARRISTERS' REPORTING SERVICE

1 PERSPECTIVE THAT IS ASSOCIATED WITH THIS. BUT TO GO
2 BACK TO WHAT I SAID, I DO THINK THAT FROM THE
3 PERSPECTIVE OF SOMEBODY IN INDUSTRY, WHEN THEY WOULD
4 LOOK AT THIS AND THINK ABOUT WHAT TO DO, DO I
5 CONVERT THIS INTO A LOAN OR DO I JUST SIMPLY STAY
6 WITH THE EXISTING GRANT AND THE ROYALTY OBLIGATIONS
7 THAT GO WITH IT, IT IS VERY MUCH IN MY MIND, IF I'M
8 ON THE INDUSTRY SIDE, TANTAMOUNT TO LOOKING AT
9 BUYING OUT MY ROYALTY STREAM, WHICH IN THE
10 VERNACULAR IS CALLED A ROYALTY BUY-DOWN OR BUYOUT.

11 SO WHILE LEGALLY IT'S SET UP AS A LOAN,
12 SOME PEOPLE MIGHT WELL HAVE THE VIEW THAT IT WAS A
13 WAY OF ELIMINATING ROYALTIES WITH CREATING A
14 CERTAINTY OF A PAYMENT THAT'S TO BE MADE.

15 SO IF THAT'S A CONCERN OF YOURS, IT'S NOT
16 THE LEGAL ISSUE. IT'S THE PERSPECTIVE ISSUE.

17 CHAIRMAN THOMAS: IF SOMEBODY EXERCISES
18 OPTION, WHAT IF YOU HAD A CERTAIN PERCENTAGE THAT
19 WOULD HAVE CORRESPONDED TO WHAT THE STATE MIGHT BE
20 GETTING BACK UNDER THE ROYALTY STREAM GO TO THE
21 STATE AND THE BALANCE GO BACK TO CIRM?

22 CHAIRMAN JUELSGAARD: WELL, WE WOULDN'T
23 KNOW WHAT THE STATE WOULD BE RECEIVING IN TERMS OF A
24 ROYALTY, RIGHT? IS THAT WHAT YOU'RE SAYING, J.T.?
25 I'M SORRY.

BARRISTERS' REPORTING SERVICE

1 CHAIRMAN THOMAS: I'M TRYING TO FIGURE OUT
2 HOW YOU CAN PLACE -- I UNDERSTAND WHAT JEFF IS
3 SAYING.

4 CHAIRMAN JUELSGAARD: I JUST DON'T KNOW
5 HOW YOU CAN DIVINE WHAT'S WHAT. I MEAN, YOU KNOW,
6 PAYING A LUMP SUM IS VERY STRAIGHTFORWARD. YOU KNOW
7 EXACTLY WHAT YOU ARE GETTING. TRYING TO FIGURE OUT
8 IF SOME OF THAT MONEY IS PARTIALLY ONE THING AND
9 ANOTHER I THINK IS NIGH NEAR IMPOSSIBLE.

10 IS THERE FURTHER DISCUSSION?

11 DR. DULIEGE: THIS IS ANNE-MARIE. FOR ME
12 IT WAS PRETTY CLEAR. I KNOW THE CHANGES THAT ARE
13 BEING MADE IS VERY MUCH STILL WITHIN THE INTENT OF
14 THE GRANTS, AND SO I'M COMFORTABLE WITH IT.

15 CHAIRMAN JUELSGAARD: ALL RIGHT. OTHERS?

16 DR. BRYANT: I'M COMFORTABLE WITH WHAT
17 I'VE BEEN LISTENING TO. I THINK THIS IS A WISE MOVE
18 AT THIS STAGE OF THE GAME.

19 MR. PANETTA: I JUST WANT TO GIVE YOU MY
20 PERSPECTIVE ON THIS BUYOUT, THE APPEARANCE OF A
21 BUYOUT. FROM MY STANDPOINT, IT'S A TRADE-OFF IN THE
22 SENSE THAT THE LOAN IN A WAY PROVIDES CIRM WITH THE
23 ASSURANCE THAT THE DOLLARS ARE GOING TO BE PAID
24 BACK; WHEREAS, THE GRANT KIND OF ASSUMES THAT IF
25 THERE'S SUCCESS, THE DOLLARS WILL BE PAID BACK, BUT

BARRISTERS' REPORTING SERVICE

1 THERE ISN'T THE ASSURANCE THERE. SO I THINK IT'S
2 KIND OF A TRADE-OFF IN WHETHER IT'S A ROYALTY BUYOUT
3 OR NOT. LEGALLY THAT'S NOT A LEVEL OF EXPERTISE.
4 TO ME IT'S KIND OF A TRADE-OFF ON RISK DECISION THAT
5 THE COMPANY MAKES TOO.

6 MR. SHEEHY: I WOULD NOTE THAT ONE OF THE
7 TRIGGERS FOR THIS IS MARKETING APPROVAL BY THE FDA.
8 SO THAT INDICATES THAT A REVENUE STREAM IS
9 ANTICIPATED THAT WOULD BE GOING TO THE GENERAL FUND.
10 THAT IS A TRIGGER TO NOT ALLOW THIS TO HAPPEN.

11 MR. HARRISON: THE EARLIER OF SEVEN YEARS
12 OR MARKETING APPROVAL BY THE FDA.

13 DR. MILLS: THAT KIND OF PROVISION IS IN
14 THERE. SO IF YOU'RE ALREADY PAYING OR YOU'RE
15 IMMINENTLY GOING TO PAY ROYALTIES, YOU CAN'T DO IT
16 THEN. YOU HAVE TO DO IT WHEN THERE'S BASICALLY
17 RISK. YOU HAVE NO CHANCE OF GETTING READY, THERE'S
18 A PROBABILITY THAT AT LEAST EXISTS THAT ZERO MIGHT
19 BE THE FOREVER ROYALTY REPAYMENT.

20 CHAIRMAN JUELSGAARD: WELL, SO FDA
21 APPROVAL WAS THE THING THAT'S BEEN PLUGGED IN THERE.
22 THIS IS AN APPEARANCES ISSUE, AND WE'RE GETTING
23 CLOSER TO THE POINT OF REVENUE REALIZATION.
24 IRRESPECTIVE OF WHAT PEOPLE MIGHT THINK THE AMOUNT
25 OF REVENUE MIGHT BE, YOU MIGHT, INSTEAD, BACK UP THE

BARRISTERS' REPORTING SERVICE

1 REPAYMENT OBLIGATION TO THE POINT OF SUBMISSION OF A
2 BLA OR NDA OR WHATEVER THIS GOES UNDER TO THE FDA.
3 SO THE SUBMISSION OF AN APPLICATION FOR APPROVAL OF
4 THE PRODUCT TO THE FDA DRIVES. SO IT'S NOT THE
5 APPROVAL ITSELF, BUT THE SUBMISSION. APPROVALS TEND
6 TO BE 18 MONTHS OUT DEPENDING ON HOW LONG THE FDA IS
7 GOING TO TAKE TO REVIEW THESE THINGS. SO THERE
8 WOULD STILL BE UNCERTAINTY OF FDA APPROVAL AT THAT
9 POINT.

10 IS THERE ANY REACTION TO THAT AS A
11 THOUGHT?

12 MR. SHEEHY: ALL I CAN SAY --

13 CHAIRMAN JUELSGAARD: NEGATIVE, POSITIVE,
14 I DON'T CARE.

15 MR. SHEEHY: STEVE, I THINK I'M GOING TO
16 BE AN OUTLIER ON THIS ONE. I HAD NOT HEARD THE TERM
17 "ROYALTY BUYOUT." AND GIVEN THE TWO DIFFERENT
18 DIRECTIONS THAT -- GIVEN THE TWO DIFFERENT
19 DIRECTIONS THAT INCOME FROM CIRM'S OUTLAYS CAN GO,
20 ONE IS IF IT'S A GRANT, IT RETURNS TO THE GENERAL
21 FUND OF THE STATE OF CALIFORNIA. AND THE OTHER, IF
22 IT'S A LOAN, IT'S RETURNED TO CIRM. IT FEELS LIKE
23 ROYALTY BUYOUT, AND THAT IS NOT SOMETHING I'M
24 COMFORTABLE WITH. I MEAN WALKS LIKE A DUCK, IT
25 SOUNDS LIKE A DUCK, I THINK IT'S A DUCK.

BARRISTERS' REPORTING SERVICE

1 DR. MILLS: CAN I TRY IT ONE MORE TIME?
2 BECAUSE I THINK IT HAS TO DO WITH THE DESTINATIONS
3 OF THE MONIES THAT MATTERS HERE. AND SO WHEN WE
4 INVEST MONEY INTO A PROGRAM, THAT MONEY -- THE MONEY
5 THAT COMES BACK TO US HAS RIGHT NOW TWO POTENTIAL
6 DESTINATIONS. ONE OF THEM IS TO THE STATE GENERAL
7 FUND. THAT IS A TERMINAL DESTINATION, RIGHT? WHEN
8 THAT MONEY GOES BACK TO THE STATE'S GENERAL FUND, IT
9 ENDS THERE. IT DOESN'T COME BACK TO US. THERE'S NO
10 RECYCLING. THE OTHER DESTINATION IS EITHER UNDER
11 THE LOAN PROGRAM OR AS PROPOSED HERE IS A RECYCLING
12 VERSION. AND THAT IS THAT MONEY COMES BACK. IT
13 DOESN'T COME INTO THE ADMINISTRATIVE BUCKET TO GET
14 USED UP BY EXPENSES AND SALARIES AND THINGS LIKE
15 THAT. IT JUST GETS RECYCLED INTO THE SEND IT BACK
16 OUT AGAIN FOR DOING WORK BUCKET.

17 AND SO I THINK THAT DISTINCTION IS WE'RE
18 NOT DIVERTING THEM -- WE'RE NOT DIVERTING THE MONEY
19 FROM ONE TERMINAL DESTINATION TO ANOTHER TERMINAL
20 DESTINATION. WE'RE TAKING MONEY AND EITHER IT GOES
21 TO A TERMINAL DESTINATION OR IT COMES BACK AND GETS
22 RECYCLED TO ACCOMPLISH CIRM'S MISSION AGAIN. HOW
23 ABOUT THAT? IT'S A RECYCLING ARGUMENT IN CALIFORNIA
24 THAT WORKS LIKE --

25 CHAIRMAN JUELSGAARD: LET ME ADDRESS THAT

BARRISTERS' REPORTING SERVICE

1 I AGREE WITH YOU. SO, JEFF, IT SEEMS TO ME THAT WE
2 HAVE TWO DIFFERENT OBLIGATIONS AS A BODY. ONE IS TO
3 TRY AND ADVANCE OUR STEM CELL RESEARCH AND
4 DEVELOPMENT TO GET THERAPEUTIC PRODUCTS THAT WILL DO
5 GOOD FOR PEOPLE. RIGHT? THEN THE OTHER ONE IS TO
6 TRY AND MAKE MONEY FOR THE STATE. NOW, YOU KNOW,
7 SOMETIMES THOSE THINGS ARE GOING TO BE IN OPPOSITION
8 TO EACH OTHER. SOMETIMES WE'RE GOING TO DO
9 THINGS -- I THINK WE PROBABLY MAKE DECISIONS ALL THE
10 TIME WHERE THE ODDS ARE A RETURN TO THE STATE MIGHT
11 BE REALLY LOW BECAUSE THE HURDLE IS SO HIGH TO GET
12 OVER WITH RESPECT TO THE DISEASE WE'RE TALKING
13 ABOUT, THAT THERE'S MORE LIKELY TO BE FAILURE THAN
14 SUCCESS, BUT WE MAKE THOSE DECISIONS BECAUSE WE
15 THINK THAT THE FIRST PURPOSE, THE ONE WHERE WE
16 INVEST MONEY TO TRY AND USE THIS AREA OF THERAPY FOR
17 THE BETTERMENT OF THE CITIZENS OF THE STATE OF
18 CALIFORNIA, THAT THAT'S A HIGHER PURPOSE THAN
19 CYCLING MONEY TO THE STATE FUNDS.

20 SO I DO THINK THAT THEY DON'T ALWAYS
21 OPERATE TOGETHER. THEY SOMETIMES OPERATE IN
22 CONFLICT, AND THAT THIS MAY BE ONE OF THEM. BUT
23 THAT'S ALL RIGHT FROM MY POINT OF VIEW BECAUSE IT'S
24 HAVING TO CHOOSE BETWEEN THE TWO, TRYING TO IMPROVE
25 HUMAN HEALTH VERSUS RETURNING MONEY TO THE STATE

BARRISTERS' REPORTING SERVICE

1 COFFERS. IF I'M FORCED TO CHOOSE BETWEEN THOSE TWO,
2 I'M MORE LIKELY TO COME DOWN ON THE FORMER THAN ON
3 THE LATTER.

4 DR. MILLS: OR THE RECYCLING ARGUMENT.

5 CHAIRMAN JUELSGAARD: OTHER COMMENTS,
6 OTHER DISCUSSION? ACTUALLY THIS HAS BEEN A GREAT
7 DISCUSSION. JEFF, I APPRECIATE YOU'RE RAISING YOUR
8 CONCERNS ABOUT THIS. DON'T MEAN TO PUT THEM DOWN AT
9 ALL. THEY'RE VERY REAL.

10 CHAIRMAN THOMAS: STEVE, I JUST WANT TO
11 ASK JAMES A QUESTION. WHAT WERE THE PROVISIONS OF
12 PROP 71 WITH RESPECT TO LOANS IN THE FIRST INSTANCE?
13 THE REASON I'M ASKING IS OBVIOUSLY PROP 71
14 CONTEMPLATED ONE SET OF FACTS THAT WOULD HAVE MONEY
15 COMING BACK TO CIRM AS OPPOSED TO SAYING WE WANT
16 EVERYTHING TO RESULT IN MONEY GOING DIRECTLY TO THE
17 STATE. SO THERE WAS A PROVISION IN THERE. SO WHAT
18 EXACTLY, JUST FOR OUR BENEFIT HERE, DID IT SAY?

19 MR. HARRISON: PROP 71 AUTHORIZED CIRM TO
20 MAKE GRANTS OR LOANS AND REQUIRES THE BOARD TO
21 ESTABLISH POLICIES FOR GRANTS THAT BALANCE THE STATE
22 OPPORTUNITY FOR A RETURN ON ITS INVESTMENT WITH THE
23 NEED TO ENSURE THAT THE MEDICAL RESEARCH AND
24 COMMERCIALIZATION IS NOT UNNECESSARILY HINDERED.
25 WITH RESPECT TO THE LOANS, IT INCLUDES A PROVISION

BARRISTERS' REPORTING SERVICE

1 THAT SPECIFIES THAT THE PROCEEDS OF LOANS, INCLUDING
2 PRINCIPAL AND INTEREST, GET REPAID TO CIRM FOR USES,
3 AS RANDY SAID, IN MAKING NEW RESEARCH AWARDS. SO
4 THAT MONEY BY STATUTE CANNOT BE USED TO PAY CIRM'S
5 ADMINISTRATIVE COSTS. IT HAS TO BE USED TO MAKE NEW
6 RESEARCH AWARDS. AND THAT'S THE SUM TOTAL OF WHAT
7 PROP 71 SAYS WITH RESPECT TO LOANS.

8 CHAIRMAN JUELSGAARD: ALL RIGHT. ANY MORE
9 COMMENTS, DISCUSSION, ETC., FROM THE MEMBERS OF THE
10 SUBCOMMITTEE?

11 MR. SHEEHY: WELL, DO WE WANT TO TRY TO
12 FIGURE A WAY OFF THIS CLIFF?

13 CHAIRMAN JUELSGAARD: IT DEPENDS ON IF YOU
14 THINK WE'RE ON A CLIFF.

15 MR. SHEEHY: I HAVE TO SAY THIS ISN'T
16 SOMETHING THAT I CAN SUPPORT.

17 CHAIRMAN JUELSGAARD: I UNDERSTAND THAT,
18 JEFF. I GOT THAT.

19 MR. SHEEHY: BUT IT MAY JUST BE A QUESTION
20 OF SEMANTICS. SO THAT'S THE ONLY THING -- BECAUSE
21 WHEN WE CALL IT A GRANT, IN MY MIND, JUST BEING A
22 SIMPLE PERSON AND NOT AN ATTORNEY, IF IT'S A GRANT
23 AND PROPOSITION 71 IS FAIRLY EXPLICIT ABOUT WHAT
24 HAPPENS WITH GRANTS, AND THERE'S A WHOLE BACKLOG OF
25 POLICY RELATING TO WHAT HAPPENS WITH GRANTS, THEN

BARRISTERS' REPORTING SERVICE

1 IT'S HARD FOR ME TO BE SUPPORTIVE OF SOMETHING THAT,
2 EVEN WITH THE BEST INTENTIONS, DIVERTS REVENUE
3 STREAM FROM THE STATE, WHICH ALSO IS TRYING TO HELP
4 HUMAN HEALTH BY HAVING SUFFICIENT FUNDS FOR
5 MEDI-CAL, ALSO HAS OTHER VERY LAUDABLE GOALS LIKE
6 EDUCATION THAT ARE VERY MUCH PUBLIC GOODS AND CARE
7 FOR LOW-INCOME FOLKS AND FOR THE ELDERLY. IT'S JUST
8 HARD FOR ME TO TRY TO PUT MY -- MY PARTICULAR
9 INTEREST IN CIRM AHEAD OF THOSE OTHER INTERESTS AND
10 DECIDE UNILATERALLY TO REDIRECT THOSE FUNDS BACK TO
11 CIRM. THE LOAN PROGRAM WAS CLEARLY ENVISIONED IN
12 PROP 71 AS THEY MOVE FORWARD TO PROVIDE FOR
13 EVERGREENING OF CIRM. SO IT'S A SEMANTIC ISSUE WITH
14 REGARDS TO GRANTS AND LOANS, GRANTS AND LOANS THAT
15 PROVIDE AN EXTREME CHALLENGE.

16 MR. HARRISON: JEFF, MAYBE I CAN HELP YOU
17 BECAUSE I AT LEAST HAVE THOUGHT OF THIS DIFFERENTLY.
18 AND SOMETIMES THE NOMENCLATURE HAS KIND OF GOTTEN US
19 A LITTLE BIT TIED UP.

20 I THINK OF CIRM AS MAKING AWARDS. AND
21 THOSE AWARDS ARE GOVERNED BY A SET OF POLICIES. YOU
22 CAN ALMOST THINK OF IT AS EVERY AWARD UNDER 15-01
23 THROUGH 15-03 IS BY DEFAULT A LOAN BECAUSE THE
24 AWARDEE WOULD HAVE THE OPTION OF SAYING I'M GOING TO
25 MAKE THIS A LOAN, I'M GOING TO REPAY CIRM WITH A

BARRISTERS' REPORTING SERVICE

1 RATE OF RETURN, WHATEVER IT IS. BY MAKING THIS
2 DECISION TO TREAT IT AS A LOAN, I WILL CONTINUE TO
3 BE COVERED BY THE OTHER OBLIGATIONS, THE PRICING AND
4 THE MARCH-IN RIGHTS, BUT AS LONG AS I MAKE THAT
5 DECISION THE EARLIER OF SEVEN YEARS, AND WHETHER
6 IT'S THE DATE OF MARKET AUTHORIZATION BY THE FDA OR,
7 AS STEVE SUGGESTED, AN APPLICATION IS SUBMITTED FOR
8 MARKETING AUTHORIZATION, I THINK WE CAN PLAY WITH
9 THOSE DATES, BUT AN OUTER LIMIT ON IT. BUT AT THAT
10 POINT IN TIME, I'M TREATING THIS AS A LOAN. I REPAY
11 CIRM. CIRM GETS TO USE THOSE FUNDS PER PROP 71 TO
12 MAKE ADDITIONAL RESEARCH AWARDS.

13 MR. SHEEHY: MAYBE, AGAIN, MAYBE THIS IS
14 SEMANTICS. MAYBE WHEN WE TALK ABOUT THIS, WE CAN
15 STOP SAYING CONVERTING LOANS FROM -- AWARDS FROM
16 GRANTS TO LOANS.

17 MR. HARRISON: RIGHT.

18 MR. SHEEHY: THAT THEY HAVE THE OPTION TO
19 RECEIVE THEIR AWARD AS A GRANT OR LOAN OR SOME WAY
20 OF -- WHAT YOU'RE DESCRIBING IS WHAT I HAD
21 UNDERSTOOD THIS TO BE, WHICH I'M COMFORTABLE WITH.
22 WHAT I'M NOT COMFORTABLE WITH IS BUYING OUT
23 ROYALTIES TO THE STATE. THAT RAISES ISSUES WITH ME.

24 MR. HARRISON: SO MAYBE WE CAN REFRAME IT
25 A LITTLE BIT. AT LEAST I HAD IT IN MY MIND THAT

BARRISTERS' REPORTING SERVICE

1 IT'S AN AWARD. IT'S AN AWARD, AND THE AWARDEE HAS
2 THE OPTION TO REPAY THAT AWARD. AND IF THE AWARDEE
3 DECIDES WITHIN A CERTAIN PERIOD OF TIME, SET THE
4 OUTER BOUNDARIES OF THAT --

5 DR. MILLS: IF NOT, IT DEFAULTS TO A
6 GRANT.

7 MR. HARRISON: EXACTLY.

8 MR. SHEEHY: THAT'S SOMETHING -- SORRY,
9 STEVE. I THOUGHT WE MIGHT BE ABLE TO GET THERE
10 BECAUSE I THINK WE'RE ON SEMANTICS. THE SEMANTICS
11 WE'RE REALLY CHALLENGING. THIS LANGUAGE IS VERY
12 CHALLENGING HERE FOR ME. I APOLOGIZE.

13 CHAIRMAN JUELGAARD: THAT'S ALL RIGHT.

14 MR. HARRISON: STEVE, IF IT'S OKAY FOR
15 JEFF AND THE REST OF THE MEMBERS, MAYBE I COULD TAKE
16 A CRACK AT REFORMULATING THE MEMO AND THE POWERPOINT
17 TO MAKE THAT SEMANTIC DISTINCTION MORE CLEAR. AND
18 IF YOU'D AUTHORIZE ME TO DO THAT AS PART OF THE
19 MOTION RECOMMENDING BOARD APPROVAL, THAT MIGHT BE
20 THE QUICKEST WAY TO MOVE FORWARD GIVEN THE FACT THAT
21 WE HAVE A BOARD MEETING THIS WEEK.

22 MR. SHEEHY: I'M COMFORTABLE WITH THAT AND
23 MAYBE THE OTHER MEMBERS ARE.

24 DR. BRYANT: I'D BE COMFORTABLE WITH THAT.

25 DR. DULIEGE: OF COURSE, ME TOO.

BARRISTERS' REPORTING SERVICE

1 MR. PANETTA: I AM TOO.

2 CHAIRMAN JUELSGAARD: ALL RIGHT. WELL,
3 THEN, CAN WE HAVE -- JAMES, WHY DON'T YOU FRAME THE
4 MOTION, AND THEN SOMEBODY CAN MAKE THE MOTION BASED
5 ON THE LANGUAGE YOU FRAMED.

6 MR. HARRISON: AS I UNDERSTAND IT, THE
7 MOTION IS TO RECOMMEND IN CONCEPT APPROVAL OF AN
8 OPTION TO CONVERT OR MAKE AN AWARD A LOAN WITH A
9 DEFAULT THAT IF THE GRANT WITHIN A SPECIFIED PERIOD
10 OF TIME AND TO DELEGATE TO THE CIRM TEAM THE TASK OF
11 WRITING THAT MORE CLEARLY AND SUCCINCTLY. AND
12 ASSUMING THE BOARD APPROVES IT, TO ASK THE BOARD TO
13 DELEGATE TO THE SUBCOMMITTEE THE RESPONSIBILITY TO
14 APPROVE A RATE OF RETURN BASED ON THE RECOMMENDATION
15 FROM THE CIRM TEAM.

16 CHAIRMAN JUELSGAARD: THANK YOU. THAT WAS
17 VERY CLEAR. WOULD ANYONE LIKE TO MAKE A MOTION TO
18 THAT EFFECT?

19 MR. SHEEHY: I WOULD MAKE THAT MOTION.

20 CHAIRMAN JUELSGAARD: THANK YOU, JEFF. IS
21 THERE A SECOND?

22 DR. DULIEGE: I SECOND.

23 CHAIRMAN JUELSGAARD: ALL RIGHT. GREAT.
24 ANY MORE DISCUSSION FROM MEMBERS OF THE
25 SUBCOMMITTEE? IF NOT, ANY DISCUSSION FROM MEMBERS

BARRISTERS' REPORTING SERVICE

1 OF THE PUBLIC WHO MIGHT BE ON THE LINE OR OTHERWISE
2 PRESENT? ALL RIGHT. IF THERE'S NO DISCUSSION ON
3 EITHER FRONT, THEN, MARIA, WOULD YOU CALL THE ROLL
4 PLEASE.

5 MS. BONNEVILLE: SURE. STEVE JUELSGAARD.

6 CHAIRMAN JUELSGAARD: YES.

7 MS. BONNEVILLE: JEFF SHEEHY.

8 MR. SHEEHY: YES.

9 MS. BONNEVILLE: OS STEWARD. JONATHAN
10 THOMAS.

11 CHAIRMAN THOMAS: YES.

12 MS. BONNEVILLE: JOE PANETTA.

13 MR. PANETTA: YES.

14 MS. BONNEVILLE: ANNE-MARIE DULIEGE.

15 DR. DULIEGE: YES.

16 MS. BONNEVILLE: SUE BRYANT.

17 DR. BRYANT: YES.

18 CHAIRMAN JUELSGAARD: WONDERFUL. IT'S
19 BEEN APPROVED. THANK YOU, EVERYONE.

20 THERE WASN'T ANYTHING ELSE ON THE AGENDA
21 AS IT WAS SENT OUT, BUT IS THERE ANYTHING ELSE THAT
22 ANY OTHER MEMBER OF THE SUBCOMMITTEE WOULD LIKE TO
23 RAISE AT THIS POINT, ANY OTHER ISSUES OR CONCERNS OR
24 ITEMS? ANY PUBLIC COMMENT OUTSIDE OF WHAT WE JUST
25 DID? WELL, IF NOT, THEN THIS MEETING STANDS

BARRISTERS' REPORTING SERVICE

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ADJOURNED.

MS. BONNEVILLE: THANK YOU.

(THE MEETING WAS THEN CONCLUDED.)

BARRISTERS' REPORTING SERVICE

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 INTELLECTUAL PROPERTY AND INDUSTRY SUBCOMMITTEE OF THE INDEPENDENT CITIZEN'S OVERSIGHT COMMITTEE OF THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE IN THE MATTER OF ITS REGULAR MEETING HELD MAY 18, 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
BARRISTERS' REPORTING SERVICE
160 S. OLD SPRINGS ROAD
SUITE 270
ANAHEIM, CALIFORNIA
(714) 444-4100