

BEFORE THE
FINANCE 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 AGENDA

DATE: WEDNESDAY, NOVEMBER 19, 2008
9 A.M.

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

BRS FILE NO. : 83022

BARRISTERS' REPORTING SERVICE

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BARRISTERS' REPORTING SERVICE

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WEDNESDAY, NOVEMBER 19, 2008

9 A.M.

CHAIRMAN GOLDBERG: GOOD MORNING,
EVERYONE. I'D LIKE TO CALL THE MEETING TO ORDER AND
ASK MELISSA TO CONDUCT A ROLL CALL.

MS. KING: OKAY. RICARDO AZZIZ. ROBERT
PRICE.

DR. PRICE: HERE.

MS. KING: FLOYD BLOOM.

DR. BLOOM: HERE.

MS. KING: MARCY FEIT. MICHAEL GOLDBERG.

CHAIRMAN GOLDBERG: HERE.

MS. KING: BOB KLEIN. TED LOVE.

DR. LOVE: HERE.

MS. KING: ED PENHOET.

DR. PENHOET: HERE.

MS. KING: PHIL PIZZO. DUANE ROTH.

MR. ROTH: HERE.

MS. KING: JEFF SHEEHY.

MR. SHEEHY: HERE.

MS. KING: AND OSWALD STEWARD.

DR. STEWARD: HERE.

CHAIRMAN GOLDBERG: WE HAVE A QUORUM?

MS. KING: WE DO HAVE A QUORUM.

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1 CHAIRMAN GOLDBERG: GREAT. I'D LIKE TO
2 NOW PROCEED TO AGENDA ITEM 3(A), CONSIDERATION OF
3 POLICIES AND IMPLEMENTATION PLAN AND PROCESSES FOR
4 THE CIRM LOAN PROGRAM. FIRST BEGINNING WITH A
5 PRESENTATION BY STAFF OF THE CONCEPT PLAN FOR --
6 ACTUALLY LET'S START WITH 3(B), THE DRAFT INTERIM
7 CIRM LOAN ADMINISTRATION POLICY FOR PROFIT
8 ORGANIZATIONS.

9 MR. ROTH: MICHAEL, IT'S DUANE. I'M GOING
10 TO HANG UP AND DIAL BACK IN. I'VE GOT A GUEST HERE
11 FROM THE PUBLIC, SO I'VE GOT TO MOVE. I'LL BE RIGHT
12 BACK.

13 MS. KING: THANK YOU, DUANE.

14 CHAIRMAN GOLDBERG: SO FOR THOSE OF YOU
15 FOLLOWING THE AGENDA AND ATTENDING VIA REMOTE SITES,
16 THERE'S AGENDA ITEM B OF WHICH WE'RE GOING TO BE LED
17 THROUGH BY IAN SWEEDLER. AND, IAN, COULD YOU TELL
18 US, FOR THOSE OF US NOT FAMILIAR WITH YOU, JUST A
19 LITTLE BIT ABOUT YOUR BACKGROUND AND HOW LONG YOU'VE
20 BEEN AFFILIATED WITH THE AGENCY?

21 MR. SWEEDLER: SURE. I'VE BEEN AFFILIATED
22 WITH CIRM SINCE AUGUST. I CAME HERE AS INTERIM
23 GENERAL COUNSEL TO THE PRESIDENT WHEN TAMAR PACHTER
24 WAS LEAVING TO RETURN TO THE ATTORNEY GENERAL'S
25 OFFICE. I CAME HERE ON LOAN FROM THE ATTORNEY

BARRISTERS' REPORTING SERVICE

1 GENERAL' S OFFICE. SO I' VE BEEN ENJOYING THAT EVER
2 SINCE.

3 CHAIRMAN GOLDBERG: WELL, BEING ON LOAN
4 AND SPEAKING ABOUT LOANS, I GUESS, IS A GOOD
5 COMPARISON. SO LET ME DEFER TO YOU. LET ME ASK
6 MEMBERS OF THE COMMITTEE IF WE CAN LET IAN GET
7 THROUGH HIS EXPLANATION OF THE DOCUMENT ONCE AND
8 THEN WE' LL COME BACK AND ASK QUESTIONS AND FOCUS ON
9 SOME OF THE KEY ISSUES, THEN WE' LL FOLLOW THAT WITH
10 QUESTIONS AND/OR COMMENTS FROM THE PUBLIC.

11 MR. SWEEDLER: THANK YOU. THE DOCUMENT
12 THAT WE' LL BE LOOKING AT IS -- HAS THE TITLE "AGENDA
13 ITEM 3(B)" AT THE TOP. THIS IS THE INTERIM LOAN
14 ADMINISTRATION POLICY FOR FOR-PROFIT ORGANIZATIONS.

15 MS. KING: IAN, IF I COULD JUST BRIEFLY
16 ASK. CAN WHOEVER JUST JOINED PLEASE TELL US WHO YOU
17 ARE?

18 MR. ROTH: IT' S DUANE. I' M BACK.

19 MS. KING: OKAY. THANKS, DUANE. JUST SO
20 YOU KNOW, IAN IS WALKING US THROUGH THE DOCUMENT
21 LABELED 3(B), THE LOAN ADMINISTRATION POLICY. JUST
22 STARTED.

23 MR. SWEEDLER: CURRENTLY OUR GRANTEES
24 FOLLOW POLICIES OR EXPECTED TO FOLLOW POLICIES THAT
25 ARE LAID OUT PRIMARILY IN THE DOCUMENT APPROVED BY

BARRISTERS' REPORTING SERVICE

1 THE ICOC AS THE GRANT ADMINISTRATION POLICY FOR
2 ACADEMIC AND NONPROFIT ORGANIZATIONS. WE CREATED AN
3 ADDITIONAL GAP, AS WE CALL IT, FOR FOR-PROFIT
4 ORGANIZATIONS, WHICH TAKES THE FORM OF JUST NOTING
5 THE DIFFERENCES IN TREATMENT BETWEEN FOR-PROFIT
6 GRANTEES AND NONPROFIT GRANTEES. WE ADOPTED A
7 SIMILAR APPROACH HERE.

8 THIS DOCUMENT JUST NOTES THE DIFFERENCES
9 BETWEEN HOW FOR-PROFIT LOAN RECIPIENTS ARE TREATED
10 AS COMPARED TO NONPROFIT GRANT RECIPIENTS. SO,
11 AGAIN, IT JUST READS OFF OF THE NONPROFIT GAP AND
12 ONLY NOTES DIFFERENCES.

13 FOR THE SAME REASON, MANY OF THE
14 CHANGES -- MANY OF THE DIFFERENCES NOTED IN THE
15 FOR-PROFIT GRANTS ADMINISTRATION POLICY WERE SIMPLY
16 REPEATED WITH MODIFICATIONS IN THE FOR-PROFIT LOAN
17 ADMINISTRATION POLICY.

18 SO MY PLAN HERE TODAY IS TAKE YOU THROUGH
19 THIS WITH AN EMPHASIS ON THOSE ITEMS THAT ARE
20 DIFFERENT FROM THE FOR-PROFIT GRANTS ADMINISTRATION
21 POLICY. THE PRIMARY SOURCE FOR THE POLICIES
22 REFLECTED IN HERE WAS THE PACKAGE OF MATERIALS THAT
23 WAS PUT BEFORE THE ICOC AT ITS SEPTEMBER MEETING
24 ABOUT THE LOAN POLICY.

25 SO WITH THAT INTRODUCTION, ON PAGE 2 WE

BARRISTERS' REPORTING SERVICE

1 START WITH A FEW DEFINITIONS. THE THING THAT I
2 WOULD POINT OUT, JUST TO AVOID THINGS THAT WE PUT IN
3 TO ADDRESS SOME CONFUSION, THE TERM "LOAN PERIOD,"
4 JUST TO AVOID CONFUSION, IS DISTINCT FROM THE TERM
5 "PROJECT PERIOD." THE PROJECT PERIOD IS THE TIME IN
6 WHICH THE RESEARCH IS OCCURRING. IT'S WHAT ENDS
7 WITH IN A GRANT SITUATION WHAT WOULD BE CLOSEOUT,
8 AND WE HAVE A SIMILAR CLOSEOUT FOR LOANS; BUT WHEN
9 WE JUST CARRIED THAT TERMINOLOGY OVER, IT COULD HAVE
10 BEEN READ TO MEAN THAT'S ALSO WHEN THE LOAN HAS TO
11 BE REPAID. SO THE LOAN PERIOD REFERS TO THE
12 FINANCIAL ARRANGEMENT, AND IT'S THE PERIOD AT
13 WHICH -- IT ENDS WITH THE PERIOD AT WHICH THE LOAN
14 HAS TO BE REPAID.

15 THE WAY WE'VE CAPTURED DEFINITIONS
16 DISTINGUISHING RECOURSE AND NONRECOURSE LOANS IS
17 SIMPLY ADDRESSING THE CIRCUMSTANCE UNDER WHICH A
18 NONRECOURSE LOAN WOULD NOT HAVE TO BE REPAID, AND
19 THE DETAILS OF THAT ARE PROVIDED FARTHER DOWN IN THE
20 POLICY. WE'LL GET TO THAT.

21 ON PAGE 3, WE LAY OUT THE GENERAL MAP FOR
22 HOW LOANS WILL BE BROUGHT INTO THE PROGRAM. IN
23 REQUEST FOR APPLICATIONS, RFA'S, THAT INCLUDE
24 PRECLINICAL DEVELOPMENT OR CLINICAL INVESTIGATION,
25 WE'LL OFFER LOANS TO FOR-PROFIT ORGANIZATIONS AND

BARRISTERS' REPORTING SERVICE

1 GRANTS TO NONPROFIT ORGANIZATIONS. FOR OTHER RFA'S
2 WE WILL CONTINUE TO OFFER ONLY GRANT FUNDING FOR
3 FOR-PROFIT AND NONPROFIT ORGANIZATIONS.

4 MS. KING: COULD I JUST ASK WHO JUST
5 JOINED THE CALL?

6 MR. KLEIN: THIS IS BOB KLEIN. PREVIOUSLY
7 IT SAID THAT THE CIRCUITS WERE BUSY AND I COULDN'T
8 GET IN, SO I HAD TO INDIRECTLY GET CROSS-CONNECTED
9 IN.

10 MS. KING: OKAY. THANKS. AND JUST SO YOU
11 HAVE THE RIGHT DOCUMENT IN FRONT OF YOU, IAN
12 SWEEDLER IS CURRENTLY WALKING US THROUGH THE
13 DOCUMENT LABELED AGENDA 3(B), WHICH IS THE LOAN --
14 DRAFT LOAN ADMINISTRATION POLICY.

15 MR. KLEIN: AND, IAN, I'D APPRECIATE IT IF
16 YOU COULD JUST REPEAT THE PARAGRAPH YOU JUST WENT
17 THROUGH.

18 MR. SWEEDLER: SURE. SO AT THE TOP OF
19 PAGE 3, SUPPLEMENTING THE DISCUSSION IN THE
20 NONPROFIT GAP ABOUT TYPES OF SUPPORT, WE STATE,
21 "CIRM WILL OFFER LOANS TO FOR-PROFIT APPLICANTS AND
22 GRANTS TO NONPROFIT APPLICANTS IN THOSE RFA'S THAT
23 INCLUDE PRECLINICAL DEVELOPMENT AND/OR CLINICAL
24 INVESTIGATION. OTHER RFA'S WILL CONTINUE TO OFFER
25 ONLY GRANT FUNDING TO FOR-PROFIT AND NONPROFIT

BARRISTERS' REPORTING SERVICE

1 APPLICANTS. "

2 IN THE PART OF THE GAP WHERE WE DEFINE THE
3 DIFFERENT PEOPLE WHO PLAY A ROLE, BOTH AT CIRM AND
4 AT THE ORGANIZATION, THE APPLICANT, WE ALSO ADDED A
5 REFERENCE TO THE FINANCIAL SERVICES PROVIDER, WHICH
6 IS SOMETIMES CALLED A DELEGATED UNDERWRITER, BUT
7 THIS IS TO ENCOMPASS ALL OF THOSE EXTERNAL FINANCIAL
8 SERVICES WE WOULD EXPECT TO BRING IN REGARDING
9 APPROVING AND SERVICING LOANS.

10 PI AND PD ELIGIBILITY IS THE SAME AS THE
11 FOR-PROFIT GAP. ORGANIZATIONAL ELIGIBILITY, WE
12 ADDED AN ADDITIONAL ITEM HERE, AND THAT IS FOR AN
13 RFA THAT OFFERS BOTH GRANT FUNDING AND LOAN FUNDING,
14 FOR-PROFIT ORGANIZATIONS HAVE TO APPLY FOR LOAN
15 FUNDING. THEY'RE NOT ELIGIBLE FOR GRANTS.
16 NONPROFIT ORGANIZATIONS ARE NOT ELIGIBLE FOR LOANS.
17 SO ON RFA'S THAT INCLUDE PRECLINICAL DEVELOPMENT
18 AND/OR CLINICAL INVESTIGATION --

19 MR. KLEIN: AND IF I COULD ASK, WHAT IS
20 THE PROTOCOL HERE? ARE WE GOING TO COMMENT AS YOU
21 GO SECTION BY SECTION OR ONLY AT THE END?

22 CHAIRMAN GOLDBERG: I'M SORRY, BOB. WE
23 DISCUSSED THAT PRIOR TO YOUR JOINING THE CALL.
24 WE'RE GOING TO LET HIM GO THROUGH ONCE AND THEN COME
25 BACK THROUGH WITH QUESTIONS FROM THE COMMITTEE, THEN

BARRISTERS' REPORTING SERVICE

1 THE PUBLIC AND STAFF.

2 MR. KLEIN: OKAY.

3 MR. SWEEDLER: THE NEXT COUPLE OF PAGES
4 SIMPLY CARRY OVER PROVISIONS FROM THE FOR-PROFIT
5 GAP.

6 TURNING TO PAGE 5, INTEREST EARNED ON CIRM
7 FUNDS, IN THE GRANT SITUATION WHERE GRANTEES RECEIVE
8 FUNDS, THEY'RE EXPECTED TO HANDLE THEM IN AN
9 INTEREST-BEARING ACCOUNT, AND THEY'RE EXPECTED TO
10 APPLY THE INTEREST EARNED TOWARDS THE CIRM-FUNDED
11 RESEARCH. WE MADE A COUPLE OF CHANGES HERE, MOSTLY
12 JUST TO REFLECT THE FACT THAT IN A LOAN
13 CIRCUMSTANCE, THERE'S ANOTHER KIND OF INTEREST
14 INVOLVED, AND WE JUST WANTED TO CLARIFY BETWEEN
15 INTEREST THAT'S EARNED AND INTEREST THAT'S ACCRUED
16 ON THE LOAN.

17 THE WAY WE HANDLED THAT IS IN RECOURSE
18 LOANS, RECIPIENTS WILL BE PAYING US INTEREST ON THE
19 FUNDS THEY RECEIVED. IT SEEMED APPROPRIATE THAT
20 THEY WOULD NOT PLACE RESTRICTIONS ON WHAT THEY DO
21 WITH ANY INTEREST THEY EARN ON THOSE FUNDS THAT
22 THEY'RE HOLDING THAT THEY HAVEN'T SPENT YET.
23 NONRECOURSE RECIPIENTS ARE EXPECTED TO HANDLE THEM
24 JUST LIKE GRANT RECIPIENTS DO. THEY'RE EXPECTED TO
25 PUT THEM IN INTEREST-BEARING ACCOUNTS AND APPLY THE

BARRISTERS' REPORTING SERVICE

1 INTEREST TO THE CIRM-FUNDED PROJECT. AND THE
2 INTEREST THAT THEY EARN WILL BEAR ON THEIR REPAYMENT
3 OBLIGATION. THAT'S AN INCREASE OR DECREASE.

4 MS. KING: COULD I JUST, IAN, JUST FOR A
5 MOMENT INTERRUPT AND ASK WHOEVER JUST JOINED, CAN
6 YOU PLEASE LET US KNOW WHO YOU ARE? WHO JUST JOINED
7 THE CALL? DID YOU MUTE YOURSELF IMMEDIATELY? MAYBE
8 IT WAS JUST SOMEONE REJOINING. EXCUSE ME. GO
9 AHEAD, IAN.

10 MR. SWEEDLER: THE NEXT PROVISION, WHICH
11 SAYS "PRIOR APPROVED REQUIREMENTS," IS IN THE PART
12 OF THE NONPROFIT GAP THAT DEALS WITH A VARIETY OF
13 CHANGES THAT OCCUR DURING THE COURSE OF A RESEARCH
14 PROJECT THAT REQUIRE PRIOR APPROVAL FROM CIRM. AND
15 IT'S ALSO AN EXAMPLE OF HOW WE TOOK A BASIC
16 PROCEDURE AND CARRIED IT OVER, BUT HAD TO MAKE SOME
17 ADJUSTMENTS TO ACCOUNT FOR THE FACT THAT IT'S A
18 LOAN. SO UNDER APPROPRIATE CIRCUMSTANCES, A TYPICAL
19 EXAMPLE WOULD BE IF A PI WAS TRANSFERRING
20 ORGANIZATIONS, CIRM WOULD ALLOW THE GRANT TO BE
21 TRANSFERRED FROM ONE ORGANIZATION TO ANOTHER. WE
22 WOULD ALSO ALLOW THAT TO HAPPEN WITH LOANS.

23 FOR THAT TO WORK, THE WAY WE'VE
24 INCORPORATED THIS IS EXPLAINED ON THE NEXT PAGE,
25 PAGE 6, IN THE TWO BOLDED PROVISIONS THERE.

BARRISTERS' REPORTING SERVICE

1 FIRST, WE WOULD HAVE TO EVALUATE THE
2 TRANSFEREE ORGANIZATION UNDER THE SAME FINANCIAL
3 SCRUTINY THAT WE WOULD APPLY TO AN APPLICANT FOR A
4 LOAN BECAUSE WE HAVE THE SAME CONCERNS ABOUT THEIR
5 ABILITY TO MANAGE AND REPAY THE FUNDS. THE SECOND
6 PART IN THE FINAL PARAGRAPH OF THIS SECTION SAYS
7 THAT THE TRANSFEREE ORGANIZATION ASSUMES ALL
8 REPAYMENT OBLIGATION. SO WE ARE NOT LOOKING TO THE
9 ORIGINAL ORGANIZATION TO COLLECT FROM THE FIRST PART
10 AND THE TRANSFEREE ORGANIZATION FOR ANYTHING
11 THAT'S -- FOR FUNDS ADVANCED AFTER THAT. THEY WOULD
12 HAVE TO WORK IT OUT BETWEEN THEMSELVES HOW TO
13 ACCOUNT FOR THAT.

14 PAGE 7, AGAIN, REPORTING REQUIREMENTS,
15 WHICH ARE GENERALLY THE SAME AS THEY ARE FOR
16 FOR-PROFIT GRANT RECIPIENTS. THE ONLY THING THAT WE
17 ADDED HALFWAY DOWN IS REPAYMENT ACCELERATION
18 TRIGGERS. AS WE'LL DISCUSS LATER IN THE POLICY,
19 THERE ARE CERTAIN EVENTS THAT CAUSE THE REPAYMENT
20 OBLIGATION TO BE ACCELERATED, AND WE JUST WANTED TO
21 MAKE SURE IT WAS CLEAR THAT THERE'S AN OBLIGATION TO
22 TELL US THOSE EVENTS OCCUR.

23 ON PAGE 8, JUST CLARIFYING A POINT THAT
24 COMES OVER FROM THE NONPROFIT AND FOR-PROFIT GAP.
25 IN THE EVENT OF FAILURE OF COMPLIANCE IN TERMS OF

BARRISTERS' REPORTING SERVICE

1 THE GRANT, CIRM HAS A VARIETY OF REMEDIES AVAILABLE.
2 AND FAILURE OF COMPLIANCE IS A BROAD TERM THAT COULD
3 RUN THE GAMUT ALL THE WAY UP TO FRAUD OR SCIENTIFIC
4 MISCONDUCT. AND ASIDE FROM WHATEVER REMEDIES THERE
5 MAY BE OUTSIDE OF CIRM FOR LAW ENFORCEMENT PURPOSES,
6 CIRM'S AVAILABLE OPTION IS TO DEMAND RECOVERY OF
7 GRANTED FUNDS.

8 IN A GRANT CIRCUMSTANCE, WE CAN REQUIRE
9 RECIPIENTS TO GIVE BACK THE GRANTED FUNDS. WE JUST
10 WANTED TO MAKE CLEAR HERE THAT A LOAN RECIPIENT
11 FACES EXACTLY THE SAME POTENTIAL OBLIGATION IN THE
12 CIRCUMSTANCE OF MISCONDUCT THAT AMOUNTS TO FAILURE
13 OF COMPLIANCE. AND THAT IS, WHETHER IT'S RECOURSE
14 OR NONRECOURSE, THIS HAS NOTHING TO DO WITH A LOAN
15 REPAYMENT OBLIGATION. THIS IS FOR FAILURE OF
16 COMPLIANCE. AND WE DO NOTE HERE THAT TO THE EXTENT
17 YOU SEEK TO RECOVER ONLY A PORTION OF THE FUNDS THAT
18 WERE DISBURSED AS A LOAN, OF COURSE, THAT REDUCES
19 THE AMOUNT OF LOAN PRINCIPAL TO BE REPAYED. SO THEY
20 DON'T HAVE TO REPAY IT TO US TWICE.

21 AND THEN CHAPTER 7, FARTHER DOWN ON THE
22 PAGE, IS WHERE WE BEGIN THE PART OF THIS POLICY
23 THAT'S ENTIRELY NEW AND PERTAINS JUST TO LOANS AND
24 IS GENERALLY INTENDED TO INCORPORATE ALL OF THE
25 POLICIES THAT WERE DISCUSSED AT THE MOST RECENT ICOC

BARRISTERS' REPORTING SERVICE

1 MEETING.

2 WE NOTE IN THE INTRODUCTION THERE THAT ONE
3 DIFFERENCE BETWEEN RECOURSE AND NONRECOURSE LOANS IS
4 ELIGIBILITY. EVALUATING APPLICANTS FOR RECOURSE
5 LOANS REQUIRES THAT WE LOOK AT CREDIT ISSUES AND
6 THEIR ABILITY TO REPAY. THE INTEREST RATE WOULD
7 HAVE TO BE STATED IN THE RFA SINCE APPLICANTS WOULD
8 NEED TO KNOW THE TERMS UNDER WHICH THEY'RE APPLYING.
9 THAT WOULD BE DETERMINED BY THE FINANCE
10 SUBCOMMITTEE.

11 WARRANTS, THIS INCORPORATES THE WARRANT
12 POLICY THAT WAS PRESENTED TO THE ICOC. AS WE
13 DISBURSE FUNDS FROM CIRM, WE WOULD EXPECT -- WE
14 WOULD HAVE TO BE ISSUED THE APPROPRIATE WARRANTS FOR
15 THOSE FUNDS DISBURSED. FOR RECOURSE LOANS, THAT
16 WOULD BE WARRANTS WITH A VALUE EQUIVALENT TO 10
17 PERCENT OF THE AMOUNT DISBURSED. FOR NONRECOURSE
18 LOANS, IT'S THE FULL AMOUNT OF THE AMOUNT DISBURSED.
19 THERE IS A CAP, NOT REQUIRE OR ACCEPT WARRANTS THAT
20 EXCEED 20 PERCENT OF THE LOAN RECIPIENT'S SHARES ON
21 A FULLY DILUTED BASIS.

22 TERMS DESCRIBE HOW WE SET THE STRIKE PRICE
23 FOR THE WARRANTS. AND THE LAST SENTENCE THERE IS
24 NOTEWORTHY. THE WARRANTS ARE TRANSFERABLE. THEY
25 MAY BE EXERCISED AT ANY TIME AND THEY DO NOT EXPIRE.

BARRISTERS' REPORTING SERVICE

1 WE OFFER A LOAN PERIOD OF EITHER SIX OR
2 TEN YEARS. THE APPLICANT MAKES THAT ELECTION AT THE
3 TIME THAT THEY SUBMIT THEIR APPLICATION.

4 FOR LOAN REPAYMENT, FOR RECOURSE LOANS,
5 IT'S VERY SIMPLE. LOANS ARE DUE 30 DAYS AFTER THE
6 END OF THE LOAN PERIOD. FOR NONRECOURSE LOANS, THE
7 WAY WE HAVE IMPLEMENTED THAT IN THIS POLICY IS AS
8 FOLLOWS: FOR NONRECOURSE LOANS, THE BASIC
9 OBLIGATION IS THE SAME AS RECOURSE LOANS, TO REPAY
10 WITH INTEREST AT THE END OF THE LOAN PERIOD.
11 HOWEVER, A LOAN RECIPIENT MAY APPLY FOR SUSPENSION
12 OF THE LOAN BASED ON A SHOWING THAT THE PROJECT HAS
13 FAILED. RATHER THAN TRY TO CREATE A GENERIC
14 DEFINITION OF PROJECT FAILURE, WHICH WOULD OBVIOUSLY
15 VARY FROM ONE TYPE OF PROJECT TO ANOTHER, EACH RFA
16 WILL EXPLAIN WHAT WOULD BE PROJECT FAILURE FOR THAT
17 TYPE OF RFA.

18 THIRTY DAYS BEFORE THE END OF THE LOAN
19 PERIOD IS WHEN THE APPLICANT WOULD HAVE TO APPLY FOR
20 SUSPENSION. BASICALLY HERE'S WHAT SUSPENSION
21 AMOUNTS TO. IF THE PROJECT HAS FAILED, THE
22 REPAYMENT OBLIGATION IS SUSPENDED IN ITS ENTIRETY.
23 HOWEVER, WE WANTED TO ACCOUNT FOR THE POSSIBILITY
24 THAT A PROJECT WHICH AT THAT POINT MEETS THE
25 DEFINITION OF FAILURE MAY SUBSEQUENTLY LEAD TO SOME

BARRISTERS' REPORTING SERVICE

1 SORT OF SUBSTANTIAL REVENUE, AND WE WANTED TO MAKE
2 SURE THAT THE STATE WAS BENEFITING APPROPRIATELY
3 FROM THAT.

4 SO THE POLICY IS WRITTEN FROM THAT POINT
5 FORWARD RECIPIENTS OF NONRECOURSE LOANS WOULD HAVE
6 TO FOLLOW THE GENERAL REVENUE SHARING PROVISIONS OF
7 THE INTELLECTUAL PROPERTY POLICY, MAKING THOSE
8 PAYMENTS TO US IN THE FORM OF LOAN PAYMENTS. THE
9 AMOUNT THAT THEY WOULD HAVE TO REPAY TO THE EXTENT
10 REVENUE IS GENERATED WOULD BE CAPPED AT THE BALANCE
11 OF THE LOAN PLUS INTEREST AT THE END OF THE LOAN
12 PERIOD. SO THAT OBLIGATION DOES NOT CONTINUE TO
13 ACCRUE INTEREST AFTER THE END OF THE LOAN PERIOD.

14 PAYMENT ACCELERATION TRIGGERS, AGAIN,
15 THESE COME FROM THE POLICIES PRESENTED TO THE ICOC.
16 THE FIRST THREE THERE ARE THE SAME FOR LOANS OF
17 EITHER SIX OR TEN YEARS, CHANGE OF CONTROL, INITIAL
18 PUBLIC OFFERING, OR, WE THOUGHT IT WAS IMPORTANT TO
19 INCLUDE THIS, IF THEY TERMINATE -- THE RECIPIENT
20 RELINQUISHES THE LOAN, THEY DECIDE TO JUST GIVE UP
21 ON THE PROJECT OR IF CIRM TERMINATES THE LOAN FOR
22 SOME FORM OF MISCONDUCT OR NONCOMPLIANCE.

23 ADDITIONAL TRIGGERS FOR TEN-YEAR LOANS
24 INCLUDE FOLLOW-ON FINANCING OR SUBMITTING AN
25 INVESTIGATIONAL DEVICE EXEMPTION TO THE FDA OR FILED

BARRISTERS' REPORTING SERVICE

1 AN IND APPLICATION. LOAN RECIPIENTS ARE FREE AT ANY
2 TIME TO PREPAY THE FULL AMOUNT OF THE LOAN WITH
3 INTEREST THAT HAD ACCRUED TO THAT POINT WITHOUT ANY
4 PENALTY.

5 THE APPLICATION PROCESS, AT THE TIME OF
6 APPLICATION, WE ASK APPLICANTS TO INDICATE WHETHER
7 THEY WOULD LIKE A SIX- OR A TEN-YEAR LOAN PERIOD AND
8 WHETHER THEY WANT A RECOURSE LOAN OR A NONRECOURSE
9 LOAN. WE RECOGNIZE THAT RECOURSE LOANS HAVE
10 FINANCIAL VETTING REQUIREMENTS THAT NONRECOURSE
11 LOANS DO NOT, SO IT'S POSSIBLE THAT AN APPLICANT
12 WHICH IS RECOMMENDED FOR FUNDING IS NOT RECOMMENDED
13 FOR APPROVAL OF A RECOURSE LOAN FOR FINANCIAL
14 REASONS, AND SO WE'RE ASKING THEM AT THE TIME OF THE
15 APPLICATION TO INDICATE, IF THAT HAPPENS, WOULD YOU
16 ACCEPT A NONRECOURSE LOAN.

17 FINANCIAL FEASIBILITY REVIEW IS THE
18 PROCESS OF REVIEWING THE RANGE OF ISSUES THAT ARISE
19 REGARDING ABILITY TO REPAY FOR A RECOURSE LOAN AS
20 WELL AS GENERAL FEASIBILITY OF THE FINANCIAL PLAN
21 ASSOCIATED WITH THE PROJECT. THAT'S SOMETHING THAT
22 WE WOULD CONTEMPLATE BEING DONE BY AN OUTSIDE
23 FINANCIAL SERVICES PROVIDER. THE KEY THING TO NOTE
24 HERE IS THAT CIRM STAFF WILL NOT DIRECTLY BE
25 INVOLVED IN COLLECTING THAT INFORMATION OR

BARRISTERS' REPORTING SERVICE

1 PROCESSING IT. THE IDEA IS THAT ONCE WE RECEIVE THE
2 APPLICATIONS AND WE SEE WHO IS APPLYING FOR WHAT
3 KIND OF LOANS, WE WOULD DIRECT THEM TO -- WE WOULD
4 CONNECT THEM WITH A FINANCIAL SERVICES PROVIDER, AND
5 THE FINANCIAL SERVICES PROVIDER WOULD HANDLE
6 COLLECTING THE APPROPRIATE INFORMATION AND TIMING
7 ITS OWN PROCESS SO THAT THEY CAN HAVE A
8 RECOMMENDATION TO THE ICOC.

9 WE'VE SAID IN HERE THAT THE FINANCIAL
10 SERVICES PROVIDER WILL COLLECT FROM THE APPLICANT A
11 PROCESSING FEE TO OFFSET THE COST OF FINANCIAL
12 FEASIBILITY REVIEW. THAT WAS THE BEST
13 RECOMMENDATION WE COULD COME UP WITH FOR HOW TO
14 HANDLE THE COST OF THAT REVIEW. AND I KNOW THAT A
15 NUMBER OF DIFFERENT OPTIONS HAVE BEEN DISCUSSED.

16 AND THEN, FINALLY, WE JUST MAKE THE POINT
17 WHICH IS ONE OF THE ESSENTIAL ASPECTS OF LOANS, AND
18 THAT IS LOAN RECIPIENTS ARE NOT SUBJECT TO THE
19 REVENUE SHARING PROVISIONS OF OUR INTELLECTUAL
20 PROPERTY REGULATIONS WITH THE EXCEPTION OF A
21 NONRECOURSE LOAN WHICH HAS BEEN SUSPENDED.

22 SO THAT PRETTY MUCH RUNS THROUGH IT, AND
23 I'D BE HAPPY TO TAKE ANY QUESTIONS.

24 CHAIRMAN GOLDBERG: GREAT. LET ME REMIND
25 EVERYONE THAT THE GOAL WAS OF OUR REVIEW TODAY IS TO

BARRISTERS' REPORTING SERVICE

1 SATISFY OURSELVES OF ANY QUESTIONS WE MAY HAVE,
2 SURFACE ANY ISSUES THAT COME OUT OF PUBLIC COMMENT
3 WITH THE GOAL OF BEING ABLE TO MAKE A RECOMMENDATION
4 TO THE FULL ICOC AT OUR DECEMBER MEETING IN IRVINE.
5 SO THAT'S THE OBJECTIVE. LET ME FIRST ASK MEMBERS
6 OF THE COMMITTEE IF THERE ARE QUESTIONS. I'LL START
7 WITH THIS SITE WITH JEFF SHEEHY, AND THEN WE'LL POLL
8 THE VARIOUS SITES FOR MEMBER QUESTIONS AND ISSUE
9 IDENTIFICATION, THEN WE'LL GO BACK AND GIVE MEMBERS
10 OF THE PUBLIC AN OPPORTUNITY TO ASK QUESTIONS OR
11 MAKE COMMENTS.

12 MR. SHEEHY: SHOULD I START AT THE END OR
13 THE BEGINNING? LET ME JUST -- BECAUSE WE WERE JUST
14 TALKING. I THINK THIS IS CLEAR, AND A LOT OF THESE
15 ARE JUST GOING TO BE CLARIFICATION QUESTIONS. I
16 THINK I GET THIS. I JUST WANT TO CONFIRM.

17 SO THE VERY LAST SENTENCE THAT CLEARLY
18 SHOWS THE COVENANTS.

19 MR. SWEEDLER: YES.

20 MR. SHEEHY: OKAY. THEN GOING BACKWARDS,
21 IN THE EVENT A NONRECOURSE LOAN, SO E(1)(B), ARE
22 THOSE COVENANTS SUSPENDED OR STILL (INAUDIBLE)?

23 MR. SWEEDLER: THEY REMAIN APPLICABLE.

24 MR. SHEEHY: SO THEY REMAIN APPLICABLE.
25 AND IF THEY -- THIS IS THE SITUATION WHERE THEY ARE

BARRISTERS' REPORTING SERVICE

1 ABLE TO PRODUCE REVENUE OFF THE FAILED PROJECT. SO
2 THE QUESTION IS IT DOESN' T FOLLOW --

3 MR. SWEEDLER: YOU' RE REFERRING TO THE
4 ACCESS OF PRICING. THOSE ARE IN PLACE FOR ALL LOAN
5 RECIPIENTS LIKE GRANTS ARE TO THE COVENANTS.

6 MR. SHEEHY: GOING BACKWARDS, SORRY.
7 OKAY. THEN GOING TO D.

8 THE REPORTER: EXCUSE ME. THIS IS THE
9 REPORTER. FOR PEOPLE WHO ARE SPEAKING, COULD THEY
10 GIVE --

11 MS. KING: I THINK THERE' S SOME PAPERS
12 RUSTLING BY ONE OF THE PHONES. IF EVERYBODY COULD
13 PLEASE BE CAREFUL TO KEEP YOUR PAPERS FAR AWAY FROM
14 THE PHONE, IT WOULD BE EASIER FOR EVERYBODY ON THE
15 LINE TO HEAR. THANKS SO MUCH.

16 CHAIRMAN GOLDBERG: FOR THE REPORTER, IT
17 IS MEMBER SHEEHY WHO IS ASKING THE QUESTIONS AND
18 COUNSEL SWEEDLER WHO IS ANSWERING THEM.

19 MR. SHEEHY: OKAY. ON PAGE 6, NOW, SO
20 WHEN WE TALK ABOUT TERMINATING, THERE WAS SOME IDEA
21 THAT WE HAD THAT THERE WOULD BE -- IF THERE WAS
22 FLOATING AROUND IP, THAT WE WOULD HAVE SOME SORT OF
23 CALL ON THAT. THE PROJECT FAILS, YOU KNOW, ON A
24 NONRECOURSE LOAN, WE' RE NOT GOING TO GET REPAYED. IT
25 SEEMS TO ME THAT WE HAD A CONCEPT THAT IF THERE WAS

BARRISTERS' REPORTING SERVICE

1 SOME VALUABLE IP THAT WAS LINGERING, THAT WE HAD
2 SOME SORT OF CLAIM UPON THAT. AM I IMAGINING? DID
3 WE HAVE THAT NOTION? IN A NONRECOURSE LOAN, PROJECT
4 FAILS, THEY DIDN'T HIT THEIR MILESTONES, BUT THEY'RE
5 NOT GOING TO CONTINUE ON IT, WE LOSE ALL OF OUR
6 MONEY; BUT THERE WAS IP INVOLVED, WE HAD SOME
7 SUGGESTION ABOUT MAYBE, YOU KNOW, BEING ABLE TO GET
8 THAT IP, IF I REMEMBER CORRECTLY, HAVING SOME SORT
9 OF CLAIM ON THAT IP EVEN THOUGH THE COMPANY -- IT
10 PROBABLY WOULD BE WORTHLESS, BUT --

11 MR. HARRISON: THERE WAS A QUESTION. I
12 DON'T RECALL WHETHER THERE WAS --

13 MR. SHEEHY: I CAN'T REMEMBER WHAT WE
14 ENDED UP DOING IN OUR POLICY.

15 DR. PENHOET: I HAD STATED EARLIER THAT WE
16 WOULD HAVE SOME CLAIM TO REPAYMENT IF THEY GOT SOME
17 VALUE OUT OF WHAT WE PUT INTO IT DURING THE LOAN
18 PERIOD OR THE ACTIVE PERIOD. SO THAT'S SOMEWHERE IN
19 THIS DOCUMENT ALREADY. BUT DURING THE CONVERSATION
20 WE HAD YESTERDAY AT THE INTELLECTUAL PROPERTY TASK
21 FORCE, I THINK THAT THAT -- THOSE PAYMENTS SHOULD BE
22 LINKED DIRECTLY TO PATENTED INTELLECTUAL PROPERTY,
23 NOT TO KNOW-HOW BECAUSE, YOU KNOW, I THINK INDUSTRY
24 HAS BROUGHT UP SOME VERY LEGITIMATE CONCERNS ABOUT
25 THE PERVASIVE SORT OF NATURE OF KNOW-HOW AND THE

BARRISTERS' REPORTING SERVICE

1 AMBIGUITIES ASSOCIATED WITH CLAIMS THAT THE KNOW-HOW
2 WAS GENERATED DURING THE PERIOD OF TIME OF A FIRM
3 FUNDING.

4 SO, YOU KNOW, WE HAVEN'T REACHED A FINAL
5 CONCLUSION ON THAT ISSUE WITH RESPECT TO THE IP
6 ALWAYS THAT ARE BEING DEVELOPED FOR THE COMBINED
7 NOT-FOR-PROFIT AND FOR-PROFIT, BUT WE HAVE HEARD
8 GREAT CONCERN ABOUT, YOU KNOW, SO-CALLED FUZZY
9 INTELLECTUAL PROPERTY THAT IS NONPATENTED AND,
10 THEREFORE, HARD TO IDENTIFY.

11 SO, YOU KNOW, I WOULD SUPPORT YOUR VIEW,
12 JEFF, THAT IF IT'S PATENTED TECHNOLOGY, THAT WE
13 SHOULD HAVE SOME RIGHT TO RETURN ON IT. BUT FOR
14 NONPATENTED JUST KNOW-HOW, ETC., IT'S GOING TO BE
15 VERY HARD FOR US TO DETERMINE, YOU KNOW, WHAT THOSE
16 INTANGIBLE ASSETS, IF YOU WILL, WERE ACTUALLY USED
17 OR NOT USED OR DEVELOPED WHEN OR NOT DEVELOPED WHEN
18 AND WHO CONTRIBUTED TO IT. IT'S VERY HARD TO
19 DETERMINE.

20 CHAIRMAN GOLDBERG: DR. PENHOET, NANCY
21 KOCH HAS A COMMENT SHE'D LIKE TO MAKE.

22 MS. KOCH: JEFF, ONE THING THAT I RECALL
23 IN THE CONTEXT OF THE LOAN TASK FORCE DISCUSSIONS,
24 AND I THINK DUANE ROTH MAY BE ON THE LINE WITH US,
25 AND, DUANE, YOU MAY REMEMBER THIS AS WELL, WAS WE

BARRISTERS' REPORTING SERVICE

1 HAD A DISCUSSION ABOUT WHAT WOULD HAPPEN IF ONE OF
2 OUR GRANTEES WHO HAD FILED PATENT APPLICATIONS OR
3 ACTUALLY RECEIVED PATENTS WAS ABOUT TO GO UNDER AND
4 IN SO DOING WOULD THREATEN THE ABILITY TO CONTINUE
5 PROSECUTION OF THE APPLICATIONS, ETC.

6 AND WE DISCUSSED IT IN THAT CONTEXT, AND
7 THIS MAY BE WHAT YOU'RE REMEMBERING, THAT WE WOULD
8 ASK THE GRANTEE TO COME TO US BEFORE THEY ABANDONED
9 THE APPLICATIONS AND STOPPED PAYING THE ISSUANCE
10 FEES AND THE LIKE, GIVE US A HEADS-UP IF THIS WERE
11 THE CASE, AND THEN COOPERATE WITH US IN TRYING TO
12 FIND ANOTHER POTENTIAL ENTITY WHO MIGHT WANT TO STEP
13 INTO THE SHOES OF THE GRANTEE, TAKE OVER THE
14 INTELLECTUAL PROPERTY, AND TAKE OVER THE
15 INTELLECTUAL PROPERTY OBLIGATIONS. SO THAT'S WHAT
16 WE DISCUSSED EARLY ON AT THE LOAN TASK FORCE.

17 MR. SHEEHY: I WAS NOT THINKING ABOUT THIS
18 BROADER DEFINITION OF IP. I WAS REALLY FOCUSING ON
19 IF THERE'S A PATENT -- IF THERE'S SOMETHING THAT'S
20 PATENTED. EVEN AT THAT TIME I THINK THE IDEA WAS
21 THAT THEY WERE THINKING MAYBE THE PROJECT DIDN'T
22 WORK, BUT WE WOULDN'T WANT TO LOSE THAT INVENTION
23 THAT WE HAD HELPED PAY FOR JUST BECAUSE THAT COMPANY
24 COULDN'T -- YOU KNOW, WHO KNOWS DOWN THE ROAD. TEN
25 YEARS, FIVE YEARS THERE MIGHT BE SOME VALUE THERE.

BARRISTERS' REPORTING SERVICE

1 AND WE WOULDN' T WANT IT BURIED WITH THAT COMPANY.
2 IT' S NOT NECESSARILY ABOUT GETTING A RETURN, JUST
3 KEEPING THAT SCIENCE, BEING ABLE TO MAKE SURE THAT
4 THAT SCIENCE COULD GET BACK INTO THE FLOW, I THINK,
5 IS WHERE WE WERE TRYING TO HAVE THE DISCUSSION.

6 AND THAT' S A QUESTION THAT I DON' T THINK
7 IS ADDRESSED IN THIS DRAFT. IS THAT SOMETHING MAYBE
8 WE COULD --

9 MR. SWEEDLER: LET ME JUST SAY THAT
10 RECOURSE AND -- NONRECOURSE LOANS HAVE EXACTLY THE
11 SAME REPAYMENT OBLIGATION AS RECOURSE LOANS UP UNTIL
12 THE POINT AT WHICH AN APPLICATION FOR SUSPENSION IS
13 GRANTED. SO IF THEY TERMINATE THE PROJECT, UNLESS
14 THE REPAYMENT IS SUSPENDED, THEY HAVE TO REPAY IT.
15 IF THEY -- IF IT IS SUSPENDED IN TERMS OF THEIR
16 REPAYMENT OBLIGATION, THEY BASICALLY SWITCH OVER TO
17 BE THE SAME AS A GRANT RECIPIENT. AS THE IP
18 EVOLVES, WE' LL HAVE TO MAKE SURE THAT WE' RE
19 CAPTURING THE RIGHT ASPECTS OF THE IP POLICY.

20 MR. SHEEHY: YEAH, BUT ON A RECOURSE LOAN,
21 THEY' RE GOING TO PAY US BACK. SO WE HAVEN' T PAID
22 FOR SOMETHING AND THEN LOST ACCESS TO THE IP. BUT
23 IN THIS THING, WE DON' T HAVE ANY CLAIM ON THEIR IP.
24 BUT ON THIS ONE THEY HAVEN' T PAID US, THE PROJECT
25 FAILS, THERE' S SOME VALUABLE IP, BUT SHOULDN' T WE

BARRISTERS' REPORTING SERVICE

1 HAVE SOME SORT OF LINGERING -- IT SEEMS TO ME WE
2 HAVE SOME INTEREST IN AT LEAST MAKING SURE THAT IP,
3 AS NANCY WAS SAYING, GETS FURTHER DEVELOPED IF
4 THERE'S ANY VALUE IN HAVING IT DEVELOPED.

5 MR. HARRISON: AND I THINK PERHAPS THE WAY
6 THAT YOU CAN ADDRESS THAT IS IN THE CONTEXT OF THE
7 APPLICATION FOR SUSPENSION OF REPAYMENT. IF THERE
8 IS A PATENT APPLICATION PENDING AT THAT TIME, ONE OF
9 THE CONDITIONS THAT COULD BE IMPOSED UPON GRANTING
10 THE APPLICATION FOR SUSPENSION OF REPAYMENT FOR A
11 NONRECOURSE LOAN WOULD BE TO TRY TO ADDRESS THE
12 INTEREST IN THAT PENDING INTELLECTUAL PROPERTY
13 RIGHT.

14 MS. KOCH: I THINK THAT'S RIGHT. IT WAS
15 STAFF'S HOPE THAT AFTER WE HAD YESTERDAY'S MEETING
16 OF THE IP TASK FORCE AND TODAY'S MEETING OF YOUR
17 COMMITTEE, WE WOULD TAKE BACK THE SENTIMENTS OF BOTH
18 OF THOSE ENTITIES AND TRY AND CRAFT A SPECIFIC IP
19 POLICY FOR THE LOAN CONTEXT.

20 MR. ROTH: MICHAEL, IT'S DUANE ROTH. I
21 HAVE JUST A LITTLE BIT DIFFERENT THOUGHT ON THIS
22 SECTION E AND IN PARTICULAR ON B. SO THE THOUGHT
23 WAS THAT THE LOAN, THE NONRECOURSE LOAN, FOLLOWS THE
24 PRODUCT OR PROJECT WHEREVER IT GOES UP UNTIL THE
25 POINT THAT THE LOAN RECIPIENT WOULD DECLARE THAT

BARRISTERS' REPORTING SERVICE

1 THEY' RE ABANDONING THE PROJECT. INSTEAD OF
2 SUSPENDING, ABANDON. AND THE CONCEPT THERE WAS WE
3 HAVE STOPPED, WE' RE NOT GOING TO LICENSE, WE' RE NOT
4 GOING TO DO ANYTHING WITH THE IP, WE' RE DONE. AND
5 THEY WOULD HAVE THE RESPONSIBILITY TO TELL US THEY
6 HAVE DONE SUCH.

7 AT THAT POINT, THEN, WE SHOULD DISCUSS HOW
8 WE MIGHT WORK WITH THEM IF THERE IS IP THAT WE THINK
9 IS OF VALUE TO DO SOMETHING WITH IT. THAT' S KIND OF
10 A SEPARATE ISSUE.

11 BUT THIS CONCEPT OF SUSPENSION, I THINK I
12 WOULD PROBABLY MOVE TOWARDS MAKING THEM DECLARE
13 THEY' RE ABANDONING THE PROJECT BECAUSE SUSPENSION
14 MEANS IF THEY GO ON TO LICENSE IT, WHATEVER IT IS,
15 THE TECHNOLOGY OR THE PRODUCT, THE LOAN WOULD FOLLOW
16 THAT. AND THE LOAN SHOULD STAY WITH THAT UP UNTIL
17 THE POINT THAT IT' S CLEARLY ABANDONED BY SOMEBODY.

18 MS. KING: COULD I JUST ASK --

19 MR. ROTH: WE COULD ALWAYS NEGOTIATE AT
20 THE POINT OF THAT ABANDONMENT. WE SHOULD HAVE, I
21 THINK, THE RIGHT TO NEGOTIATE WITH THEM TO GET THE
22 INTELLECTUAL PROPERTY TO SOMEBODY ELSE.

23 MR. SHEEHY: THAT' S MY RECOLLECTION. MY
24 RECOLLECTION IS YOU LED THAT DISCUSSION, DUANE.
25 THAT' S EXACTLY HOW I REMEMBER. IT WAS A NONRECOURSE

BARRISTERS' REPORTING SERVICE

1 LOAN WAS TO FOLLOW A PROJECT, SO THERE WOULD HAVE
2 BEEN SOME SPECIFIC IP INVOLVED. THEY ABANDON IT.
3 WE WANTED TO MAKE SURE THAT IT DIDN'T JUST
4 COMPLETELY DISAPPEAR AND SOMEBODY ELSE COULD DO
5 SOMETHING WITH IT AND WE COULD MEDIATE THAT.

6 MR. KLEIN: THIS IS BOB KLEIN. IF I COULD
7 COMMENT ON THIS SECTION AS WELL. I DON'T THINK THE
8 CONCEPT WE WANT HERE IS A FAILED PROJECT BECAUSE
9 JUST BECAUSE THEY CANNOT PAY THE MONEY BACK AT THE
10 END OF THE TERM DOES NOT MEAN IT IS A FAILED
11 PROJECT. SO I THINK WHAT WE NEED TO DO IS CREATE
12 SOME OTHER CLASSIFICATIONS.

13 THEY MAY HAVE REFINANCING IN PROCESS.
14 THEY MAY BE DOING SOME MODIFIED TRIALS TO TRY AND
15 FIND ALTERNATIVE USES. SO FROM A REPORTING PURPOSE,
16 IF WE'RE REPORTING ALL THESE THINGS ARE FAILED, THE
17 PROCESS IN MANY CASES MAY BE THAT THEY JUST HAVE
18 REACHED AN OBSTACLE. THEY CAN'T GET A NEW -- THEY
19 CAN'T GET A VENTURE CAPITAL ROUND. THEY CAN'T GET
20 FINANCING AT THAT POINT, BUT THEY ARE WORKING ON IT.
21 AND THAT SHOULD NOT END UP HAVING THE INTEREST
22 CAPPED AT THE AMOUNT OF THE OUTSTANDING LOAN.

23 SO I THINK WE'RE GOING TO NEED TO REWORK
24 THIS SECTION BECAUSE THERE'S SOME MULTIPLE
25 CONDITIONS HERE THAT ARE DIFFERENT THAN, AS DUANE

BARRISTERS' REPORTING SERVICE

1 AND JEFF HAVE JUST SAID, ABANDONMENT, WHICH IS A
2 VERY DIFFERENT CLASSIFICATION. AND WE CERTAINLY
3 DON'T WANT TO LIMIT OUR RETURN JUST BECAUSE SOMEONE
4 DOESN'T HAVE A CURRENT ABILITY TO PAY US BACK AND
5 HAS SUSPENDED ACTIVITY WHILE THEY'RE TRYING TO
6 RESTRUCTURE.

7 SO I DO THINK THAT WE DO NEED TO
8 SPECIFICALLY ADDRESS VARIOUS CERTAIN DIFFERENT FACT
9 PATTERNS HERE WHICH ARE DIFFERENT THAN TERMINATION.

10 MS. KING: THIS IS MELISSA. I JUST VERY
11 BRIEFLY WANT TO CHECK. WHO JOINED THE CALL IN THE
12 LAST COUPLE OF MINUTES? I KNOW SOMEBODY NEW JOINED
13 THE CALL.

14 MR. ROTH: MELISSA, THAT WAS ME. I HIT
15 THE OFF BUTTON INSTEAD OF MUTE AND HAD TO DIAL BACK
16 IN.

17 DR. AZZIZ: MELISSA, I DON'T KNOW IF YOU
18 ARE AWARE. THIS IS RICARDO WITH BILL ADAMS FROM THE
19 PUBLIC AT OUR PLACE IN CEDARS. I DON'T KNOW IF MY
20 STAFF TOLD YOU THAT OR NOT.

21 MS. KING: NOT YET. MAYBE I JUST HAVEN'T
22 CHECKED. SO THANK YOU, DR. AZZIZ. JUST SO YOU KNOW
23 THERE, WE'RE GOING THROUGH AGENDA ITEM NO. 3(B), THE
24 LOAN ADMINISTRATION POLICY. THAT'S ACTUALLY THE
25 FIRST ITEM WE'RE GOING THROUGH. WE'RE GOING TO GO

BARRISTERS' REPORTING SERVICE

1 BACK TO ITEM 3(A). SO WE'RE IN THE MIDDLE OF A
2 CONVERSATION ON THAT DOCUMENT, DR. AZZIZ, IN CASE
3 YOU WANT TO --

4 DR. AZZIZ: WE'VE ACTUALLY BEEN ON THE
5 CALL FOR ABOUT 40 MINUTES.

6 MR. KLEIN: THIS IS BOB KLEIN. I'D JUST
7 LIKE TO SAY WE ALL STARTED CRITICALLY ANALYZING
8 THIS; BUT, IAN, I CERTAINLY BELIEVE ALL OF US
9 RECOGNIZE A HUGE AMOUNT OF EFFORT WAS PUT IN THIS.
10 IT'S A VERY GOOD STARTING POINT HERE, AND WE
11 APPRECIATE ALL OF THE EFFORT AND ENERGY THAT'S GONE
12 INTO THIS.

13 CHAIRMAN GOLDBERG: SO LET ME SUGGEST AS
14 AN ACTION FROM THE DISCUSSION THUS FAR THAT WE ASK
15 STAFF TO HARMONIZE THE INTELLECTUAL PROPERTY POLICY
16 WITH THE LOAN ADMINISTRATION POLICY AND GIVE SOME
17 CONSIDERATION AND PROPOSE SOME LANGUAGE TO ADDRESS
18 THE SITUATION CHAIRMAN KLEIN DESCRIBES WHERE THERE
19 MAY BE AN INTERMEDIATE ZONE BETWEEN AN ACTIVE
20 PROPOSAL, AN INTACT LOAN, AND TERMINATION AND WHAT
21 HAPPENS IN THE EVENT OF TERMINATION.

22 SO IS THAT SATISFACTORY ON THAT POINT?
23 LET ME CONTINUE THROUGH THE SITES. JEFF SHEEHY HAS
24 ANOTHER QUESTION BEFORE WE GO TO YOUR SITE, DR.
25 AZZIZ.

BARRISTERS' REPORTING SERVICE

1 MR. SHEEHY: YEAH. MY NEXT QUESTION WAS
2 ON RELINQUISHMENT. SO I KNOW IN THE OTHER ONES
3 WE'VE TIED THIS TO PI'S. DO WE WANT TO TIE THIS SO
4 STRONGLY TO PI'S AS OPPOSED TO -- AND THIS IS
5 JUST --

6 DR. AZZIZ: JEFF, I'M SORRY. COULD YOU
7 TELL US THE SECTION YOU'RE LOOKING AT?

8 MR. SHEEHY: I'M SORRY. I'M ON PAGE 5, D.
9 SO THIS SEEMS -- THE RELINQUISHMENT OF AWARD AND
10 AWARD TRANSFER SEEMS TO BE CONSISTENT WITH OUR OTHER
11 POLICIES WHERE WE TIE THESE VERY STRONGLY TO A PI.
12 AND I JUST WANT -- AND THIS IS JUST A POINT OF
13 CLARIFICATION -- WANT TO ASK DO WE -- IN THIS
14 PARTICULAR CIRCUMSTANCE, DO WE WANT TO TIE THIS TO
15 THE PI, OR IS THIS MORE RELEVANT TO THE COMPANY?

16 MR. SWEEDLER: THIS IS AN AREA WHERE THE
17 NONPROFIT GAP ACTUALLY ALREADY COVERS THAT. AT SOME
18 POINT IN THE COURSE OF A GRANT PROJECT, EITHER THE
19 PI MIGHT CHANGE OR THE INSTITUTION MIGHT CHANGE, BUT
20 THE GRANT IS TO THE INSTITUTION. IF THE PI CHANGES,
21 IT'S NOT A NEW GRANT AND IT WOULDN'T BE A NEW LOAN.
22 THAT WOULD JUST BE A CHANGE OF THE TERM.

23 IF THE INSTITUTION CHANGES, WE HAVE TO
24 ISSUE A NEW GRANT OR A NEW LOAN. SO THAT'S WHY WE
25 HAVE TO HANDLE IT SOMEWHAT DIFFERENTLY WITH A LOAN

BARRISTERS' REPORTING SERVICE

1 BECAUSE THE REPAYMENT OBLIGATION IS INSTITUTIONAL.
2 THE SAME OPTION IS THERE FOR A CHANGE IN PI WHILE IT
3 STAYS WITH AN INSTITUTION. THAT'S ALSO A
4 POSSIBILITY. IT'S JUST THAT WOULD BE HANDLED THE
5 SAME AS IT IS WITH A GRANT.

6 DR. AZZIZ: I'M SORRY. THIS IS RICARDO.
7 I ALSO -- I MEAN SO IT'S A LITTLE UNCLEAR. IS THIS
8 JUST A POTENTIAL OPTION? THE WAY IT'S WRITTEN IT'S
9 AS IF THE PI ACTUALLY TRANSFERS, THEN THIS KICKS IN,
10 BUT THAT MAY OR MAY NOT BE THE CASE. SO HOW DO WE
11 PHRASE IT SO THAT WE UNDERSTAND THAT THESE ARE JUST
12 POSSIBILITIES?

13 CHAIRMAN GOLDBERG: DR. OLSON WOULD LIKE
14 TO COMMENT ON THIS POINT.

15 DR. OLSON: I JUST WANT TO MAKE A
16 CLARIFICATION, AND THIS SPEAKS TO JEFF'S POINT, THAT
17 IN POINT OF FACT THE ORGANIZATION WHO HAS THE LOAN
18 HAS TO RELINQUISH IT. IF THE ORGANIZATION DOES NOT
19 RELINQUISH THE LOAN, THE LOAN CANNOT POSSIBLY FOLLOW
20 THE PI. SO, THEREFORE, THE ORGANIZATION HAS THE
21 OPPORTUNITY TO NAME ANOTHER PI. AND SO IT, IN FACT,
22 ADDRESSES, I'D SAY, WHAT IS COMMON INDUSTRY
23 PRACTICE.

24 MR. KLEIN: AND, DR. OLSON, THIS IS BOB
25 KLEIN. WOULD IT BE APPROPRIATE TO HAVE A PROVISION

BARRISTERS' REPORTING SERVICE

1 THAT IF THE ORGANIZATION IS GOING TO NAME ANOTHER
2 PI, THAT THERE IS -- THAT THE AGENCY WILL NOT
3 UNREASONABLY WITHHOLD APPROVAL, BUT HAVE SOME
4 APPROVAL RIGHT OF THE SUBSTITUTE PI?

5 DR. OLSON: THE AGENCY HAS PRIOR APPROVAL
6 RIGHTS UNDER THOSE CIRCUMSTANCES. SO THEY WOULD
7 HAVE TO PRESENT THE OTHER PI TO US AND THEIR
8 QUALIFICATIONS, AND WE WOULD HAVE TO REVIEW THEM.
9 SO WE DO HAVE PRIOR APPROVAL. AND, YOU KNOW, WE
10 LIKE TO THINK OF OURSELVES AS REASONABLE, SO,
11 THEREFORE, IT WOULD NOT BE UNREASONABLY WITHHELD.

12 MR. KLEIN: WELL, I'M TRYING TO SEE WHERE
13 IN THIS DOCUMENT DOES IT, IN FACT, GIVE YOU THAT
14 RIGHT TO PRIOR APPROVAL OF CHANGE IN THE PI?

15 MR. SWEEDLER: IT'S NOT IN THIS DOCUMENT
16 BECAUSE THIS DOCUMENT INCORPORATES THE NONPROFIT
17 GAP. THAT'S A PROVISION THAT APPLIES ACROSS THE
18 BOARD TO ALL GRANTS AND LOANS. IT RUNS OFF THE
19 POLICY IN THE NONPROFIT GAP.

20 MR. KLEIN: ALL RIGHT. AND THAT
21 CROSS-REFERENCE IS CLEAR AS TO THAT SPECIFIC POINT?

22 DR. AZZIZ: THIS IS RICARDO. I HAVE
23 TO -- IT JUST WASN'T CLEAR, SO A LITTLE BIT OF TEXT
24 IN HERE REFERRING TO THAT WOULD BE SORT OF HELPFUL.

25 MR. KLEIN: I THINK TO THE EXTENT THAT WE

BARRISTERS' REPORTING SERVICE

1 HAVE TOO MUCH OF A GENERAL INCORPORATION OF THE
2 NONPROFIT GAP, SOMEONE READS THIS DOCUMENT AND THEY
3 DON'T HAVE THE WHOLE PICTURE. I THINK RICARDO'S
4 SUGGESTION IS VERY GOOD.

5 MR. SWEEDLER: THAT IS A PERSISTENT
6 PROBLEM WITH THE DOCUMENT, AND THAT IS IT'S HARD TO
7 READ IT AS A STAND-ALONE DOCUMENT. THERE ARE ALSO
8 DRAWBACKS TO TRYING TO RESTATE THE SAME POLICY
9 ACROSS THREE DOCUMENTS WITH POTENTIAL CONFUSION AND
10 CARRY-OVER. SO WE CAN TRY TO MAKE A POINT OF MAKING
11 MORE EXPLICIT CROSS-REFERENCES SO THAT SOMEONE
12 READING THIS DOCUMENT UNDERSTANDS WHERE THE POLICY
13 IS ON ANOTHER PARTICULAR POINT.

14 MR. KLEIN: I THINK THAT WOULD BE VERY
15 HELPFUL.

16 CHAIRMAN GOLDBERG: ANOTHER POINT FOR JEFF
17 SHEEHY.

18 MR. SHEEHY: SORRY. THIS IS JUST BECAUSE
19 I WENT FIRST. THIS IS MY LAST ONE, AND THIS IS,
20 AGAIN, ON PI'S AND PI ELIGIBILITY. AND I JUST
21 WANT -- YOU KNOW, WE HAVE THIS GREATER THAN 50
22 PERCENT, AND THAT SEEMS THAT THAT MUST BE A PURE
23 CARRY-OVER. DOES THAT STILL MAKE SENSE? AGAIN, I
24 TEND TO THINK THAT WE'RE FUNDING COMPANIES IN THIS
25 PARTICULAR INSTANCE MORE THAN PI'S, AND SO I'M

BARRISTERS' REPORTING SERVICE

1 WONDERING, YOU KNOW, IF IN THIS PARTICULAR INSTANCE
2 WE WANT TO CONTINUE TO HAVE THIS AT THIS LEVEL.

3 CHAIRMAN GOLDBERG: DR. OLSON.

4 DR. OLSON: I WOULD JUST COMMENT THAT THAT
5 IS REGARDING EMPLOYMENT, NOT TO PERCENT OF TIME ON
6 THE PROJECT. AND I THINK THAT IN A FOR-PROFIT
7 ORGANIZATION, A 50-PERCENT EMPLOYMENT COMMITMENT IS
8 NOT UNREASONABLE FOR -- A REQUIREMENT ON OUR PART IS
9 NOT UNREASONABLE FOR SOMEONE WHO WE HAVE LEADING A
10 FIRM-FUNDED PROJECT.

11 CHAIRMAN GOLDBERG: IN FACT, IT'S
12 GENERALLY A THRESHOLD FOR BEING CONSIDERED AN
13 EMPLOYEE.

14 DR. OLSON: CORRECT.

15 MR. SHEEHY: I'M JUST PUTTING IT OUT
16 THERE. AGAIN, IT'S JUST --

17 MR. KLEIN: JEFF, ARE YOU ASKING THAT IN
18 THE CONTEXT THAT A NUMBER OF THESE START-UPS MAY
19 HAVE CRITICAL INVESTIGATORS OR PI'S THAT ARE, IN
20 FACT, ALSO WORKING FOR A UNIVERSITY OR SOMETHING,
21 AND SO THEY ARE A PART-TIME EMPLOYEE, NOT A
22 FULL-TIME, AND LEAVING THE ABILITY OF THE SCIENTIFIC
23 TEAM TO MAKE A DISCRETIONARY JUDGMENT IF THAT PERSON
24 IS CRITICAL TO THE GRANT AND IT'S A HIGH RANKING
25 GRANT, NOT FORECLOSING OUR ABILITY TO CONSIDER

BARRISTERS' REPORTING SERVICE

1 SOMETHING LESS.

2 MR. SHEEHY: YOU KNOW, I KNOW BILL ADAMS
3 IS THERE AT CEDARS-SINAI, AND HE HAS MADE
4 REPRESENTATIONS THAT CIRCUMSTANCES RELATIVELY
5 SIMILAR TO WHAT YOU'RE DESCRIBING MIGHT BE POSSIBLE.
6 AGAIN, I'M NOT ADVOCATING FOR ANY POSITION OR
7 ANOTHER. I JUST KNOW THAT THIS HAS BEEN AN ISSUE,
8 PI ELIGIBILITY. AND, AGAIN, BECAUSE WE'RE REALLY
9 FOCUSED ON COMPANIES, I WANT TO MAKE SURE THAT WE
10 GET IT RIGHT.

11 CHAIRMAN GOLDBERG: THANK YOU, JEFF.
12 WE'LL GO TO THE CEDARS-SINAI SITE FOR ANY QUESTIONS
13 OR COMMENTS FROM THE MEMBERS PRESENT.

14 DR. AZZIZ: THIS IS RICARDO. I'VE MADE MY
15 COMMENTS. OVERALL IT LOOKS LIKE A GREAT STARTING
16 DOCUMENT. I MEAN I REALLY CONGRATULATE YOU ON THAT.
17 OF COURSE, WE'VE CLARIFIED IT. BILL, DO YOU
18 HAVE --

19 CHAIRMAN GOLDBERG: RICARDO, WE'RE GOING
20 TO HOLD --

21 DR. AZZIZ: READY FOR PUBLIC COMMENTS,
22 CORRECT?

23 CHAIRMAN GOLDBERG: WE'RE GOING --
24 CORRECT. WE'RE GOING TO HOLD PUBLIC COMMENTS AFTER
25 WE POLL THE COMMITTEE.

BARRISTERS' REPORTING SERVICE

1 DR. AZZIZ: VERY GOOD.

2 CHAIRMAN GOLDBERG: OKAY. NEXT SITE IS
3 CONNECT. DUANE.

4 MR. ROTH: SO JUST A COUPLE OF THINGS. I
5 AGREE WITH MANY OF THE THINGS THAT WE TALKED ABOUT.
6 JEFF MENTIONED COMPANIES VERSUS PEOPLE. AND I THINK
7 WE MIGHT WANT TO GIVE SOME CONSIDERATION TO MAKE
8 THIS PRIMARILY A COMPANY RESPONSIBILITY VERSUS A PI
9 RESPONSIBILITY. THAT WE CAN DISCUSS A LITTLE LATER.

10 I WANTED TO GO TO PAGE 9, AND I WANT TO
11 RETURN TO THIS END OF LOAN PERIOD. WHEN BOB KLEIN
12 WAS SPEAKING, IT JUST OCCURRED TO ME THAT THIS
13 NONRECOURSE LOAN ABANDONMENT CONCEPT HAS -- IT
14 SHOULD NOT BE TIED TILL THE END OF THE LOAN PERIOD,
15 THE SIX OR TEN YEARS. IT SHOULD BE AT THE TIME THEY
16 ABANDON. SO HOW WE RECTIFY THAT IN THIS DOCUMENT I
17 THINK NEEDS TO BE CONSIDERED. BUT IF SOMEBODY IS
18 WORKING ON A PROJECT AND THEY DECIDE IT'S DEAD, WE
19 WANT TO BE NOTIFIED OF THAT. OBVIOUSLY THE LOAN
20 AMOUNTS SHOULD BE RETURNED IF THERE'S ANY LEFT. AND
21 WE THEN MOVE TO THE INTELLECTUAL PROPERTY PART OF
22 THAT. THAT'S ON THE NONRECOURSE SIDE.

23 I THINK JUST CONSIDERATION. RIGHT NOW IT
24 SAYS WITHIN 30 DAYS AFTER THE END OF THE LOAN
25 PERIOD. THAT WOULD NOT BE APPROPRIATE FOR SOMETHING

BARRISTERS' REPORTING SERVICE

1 THAT'S ABANDONED IN YEAR THREE OF A SIX-YEAR PERIOD.
2 SO THAT IS ONE.

3 CHAIRMAN GOLDBERG: IAN SWEEDLER WOULD
4 LIKE TO COMMENT ON THAT.

5 MR. SWEEDLER: I JUST WANTED TO POINT OUT
6 ON PAGE 10, IF SOMEBODY ABANDONS THE PROJECT DURING
7 THE PROJECT PERIOD, THEN THAT RESULTS IN -- THAT'S
8 AN ACCELERATION TRIGGER. SO --

9 MR. ROTH: ALL RIGHT. AND I WAS LOOKING
10 FOR THAT. SO IT'S RELINQUISHMENT OR TERMINATION, C
11 ON PAGE 10.

12 MR. SWEEDLER: RIGHT.

13 CHAIRMAN KLEIN: THANK YOU. YOU HAVE
14 ANOTHER POINT, DUANE?

15 MR. ROTH: THE ONLY OTHER ONE THAT I WANT
16 TO RAISE, BECAUSE I THINK IT WILL BE RAISED LATER,
17 DEALS WITH -- I'LL TRY AND FIND IT HERE REAL QUICK.
18 IT DEALS WITH THE WARRANTS AS NEVER EXPIRING. AND,
19 MICHAEL, THIS IS MORE A QUESTION FOR YOU. THAT'S
20 UNUSUAL IN MY EXPERIENCE.

21 CHAIRMAN GOLDBERG: YEAH. THERE WAS --
22 I'M NOT CLEAR ON RECONCILING TWO DIFFERENT THINGS ON
23 THE WARRANTS. ONE WAS WE TALKED ABOUT THE ELECTION
24 OF THE SIX-YEAR WARRANT OR A TEN-YEAR WARRANT, AND
25 THEN WE TALKED ABOUT SEPARATELY THE WARRANTS HAVING

BARRISTERS' REPORTING SERVICE

1 ESSENTIALLY A PERPETUAL LIFE. I'M NOT FAMILIAR WITH
2 ANY WARRANTS THAT COMPANIES ISSUE THAT HAVE
3 PERPETUAL LIFE. IT'S EITHER A FIXED TERM, AND
4 SOMETIMES THAT FIXED TERM IS TRIGGERED BY EVENTS
5 SUCH AS A CHANGE OF CONTROL OR A PUBLIC OFFERING OF
6 A CERTAIN SIZE, WHAT HAVE YOU. IS THAT THE
7 POINT --

8 MR. ROTH: YEAH. IT'S MORE THIS -- YOU
9 KNOW, IT'S ON PAGE 9, NO. 2, WARRANT TERMS. THE
10 LOAN TERM IS SIX OR TEN YEARS. I UNDERSTAND THAT.
11 BUT THE WARRANTS --

12 CHAIRMAN GOLDBERG: THE WARRANTS OUGHT TO
13 BE -- I THINK THE SIMPLEST THING TO SAY, AND IN
14 GENERAL PRACTICE, WOULD BE TEN-YEAR WARRANTS.

15 MR. ROTH: I'M OPEN TO DISCUSS THAT. IT'S
16 WONDERFUL IF WE COULD GET THEM FOREVER, BUT I THINK
17 THAT MIGHT CREATE SOME ISSUES WITH THE COMPANIES
18 THEMSELVES.

19 CHAIRMAN GOLDBERG: YEAH, I AGREE. I
20 THINK TEN-YEAR WARRANTS SHOULD BE GENERALLY
21 ACCEPTABLE.

22 DR. LOVE: I THINK YOU'LL END UP PAYING
23 FOREVER FOR ACCOUNTANTS TO FIGURE OUT HOW TO VALUE
24 WARRANTS THAT NEVER EXPIRE.

25 CHAIRMAN GOLDBERG: THAT'S TED LOVE.

BARRISTERS' REPORTING SERVICE

1 THANK YOU FOR THAT COMMENT. WE' LL GET TO YOU
2 SHORTLY.

3 MR. ROTH: OKAY. THAT' S IT FOR ME.

4 CHAIRMAN GOLDBERG: OKAY. WE' RE NOW GOING
5 TO UC IRVINE.

6 DR. STEWARD: NO COMMENTS. I THINK THIS
7 IS A VERY WELL-DESIGNED WORKING DOCUMENT.

8 CHAIRMAN GOLDBERG: THANK YOU, OS. TED
9 LOVE, WE' RE NOW AT NUVELO.

10 DR. LOVE: AS USUAL, DUANE CAUGHT MY POINT
11 ABOUT THE WARRANTS. I DID WANT TO ASK A QUESTION
12 ABOUT ON PAGE 3 IN TERMS OF ORGANIZATIONAL
13 ELIGIBILITY. IAN, COULD YOU REMIND US WHY WE MAKE
14 THE POINT THAT, IF THE RFA OFFERS BOTH GRANT FUNDING
15 AND LOAN FUNDING, FOR-PROFIT ORGANIZATIONS COULD
16 ONLY APPLY FOR LOANS? I' M SURE WE TALKED ABOUT
17 THAT, BUT WOULD YOU REMIND US AGAIN WHY WE DECIDED
18 THAT THEY COULD ONLY APPLY FOR LOANS?

19 CHAIRMAN GOLDBERG: I' M GOING TO ASK DR.
20 OLSON TO ADDRESS THAT SINCE SHE HAS A DOG IN THIS
21 HUNT.

22 DR. OLSON: YOU MAY RECALL THAT THIS WAS A
23 VERY LIVELY DISCUSSION, I BELIEVE, AT THE PREVIOUS
24 TASK FORCE MEETING. AND THE IDEA WAS THAT WE -- YOU
25 KNOW, WE DO WANT TO ENCOURAGE LOANS. AND THERE' S

BARRISTERS' REPORTING SERVICE

1 BEEN VARIOUS PROPOSALS AS TO HOW WE COULD DO THAT.
2 AND ONE OF THE PROPOSALS WAS OFFER DIFFERENT AMOUNTS
3 OF FUNDING IN A GIVEN RFA TO EITHER AN ORGANIZATION
4 THAT WOULD CHOOSE TO TAKE A LOAN VERSUS AN
5 ORGANIZATION THAT WOULD CHOOSE TO TAKE A GRANT.

6 TO MY MIND THAT'S BASICALLY ENCOURAGING
7 PEOPLE TO PAD BUDGETS OR THINGS LIKE THAT. SO I
8 THINK SINCE WE ALSO LOOKED AT THIS AS BEING
9 PARTICULARLY APPROPRIATE FOR THE EXPENSIVE STAGES OF
10 RESEARCH, PRECLINICAL DEVELOPMENT AND CLINICAL
11 DEVELOPMENT, THAT WE CONSIDERED IT WOULD BE
12 PARTICULARLY -- AND THAT THAT'S WHERE WE REALLY
13 WANTED TO ENCOURAGE FOR-PROFIT COMPANIES TO
14 PARTICIPATE, THAT BY REQUIRING FOR-PROFIT
15 ORGANIZATIONS TO TAKE A LOAN, WE ESSENTIALLY SAY,
16 YOU KNOW, GIVE THEM -- WE SERVE OUR GOALS OF TRYING
17 TO HAVE LOANS AVAILABLE. TO SOME EXTENT, I THINK IT
18 SERVES THE FOR-PROFIT ORGANIZATION'S GOALS AS WELL
19 AND REMOVE INCENTIVES FOR GAMING.

20 MR. KLEIN: TED, THIS IS BOB KLEIN. IF I
21 COULD COMMENT. ONE OF THE MOTIVATIONS IN, AS DR.
22 OLSON REFERENCED, IS WITH LOANS, WE HAVE A PLAN FOR
23 RECOVERY OF THOSE. AND WE'RE GOING TO HAVE MORE
24 FUNDS AVAILABLE FOR LOANS. AND AS WE GO INTO THE
25 PRECLINICAL AND CLINICAL AND THE DOLLAR AMOUNTS ARE

BARRISTERS' REPORTING SERVICE

1 HIGHER IN THOSE AWARDS, IT'S IMPORTANT, IF WE'RE
2 GOING TO BE ABLE TO OFFER A SIGNIFICANT NUMBER OF
3 AWARDS IN EACH OF THOSE ROUNDS, TO HAVE A VERY LARGE
4 NUMBER OF LOANS AS VERSUS GRANTS BECAUSE WE JUST
5 DON'T HAVE THE FUNDS OTHERWISE TO FUND A PROGRAM OF
6 SCALE.

7 NOW, THE OTHER SIDE OF THAT, THOUGH, IS
8 THAT I DO BELIEVE THAT WE SHOULD RETAIN AT THE BOARD
9 AND WITH THE RECOMMENDATION OF THE SCIENTIFIC STAFF
10 OR PLACE IT ON THE SCIENTIFIC STAFF THE ABILITY TO
11 HAVE GRANTS FOR FOR-PROFITS BECAUSE YOU CAN HAVE AN
12 ORPHAN DISEASE WITH A VERY SMALL POPULATION WHERE
13 IT'S JUST NOT GOING TO BE FEASIBLE TO HAVE A LOAN
14 PROGRAM AND SUPPORT THE FINANCIAL INCENTIVES TO
15 ADDRESS A SMALL POPULATION ORPHAN DISEASE.

16 SO I DO BELIEVE THAT WHILE THERE CAN BE A
17 BURDEN OF PROOF ON THE COMPANY TO APPLY FOR A LOAN
18 AND PRESUMPTIONS THAT ONLY A LOAN WOULD GENERALLY
19 APPLY, THAT WE SHOULD DEFINITELY RETAIN THE ABILITY
20 TO HAVE GRANTS. THIS IS PARTICULARLY TRUE IN THE
21 STAGE THAT WE'RE IN BECAUSE SOME OF THE EARLY
22 BREAKTHROUGHS, WE MAY GET A FASTER FDA APPROVAL
23 BECAUSE WE HAVE THESE ORPHAN DISEASES THAT ARE FATAL
24 AND THAT HAVE VERY SMALL POPULATIONS AND JUST DON'T
25 HAVE A GOOD ECONOMIC MODEL TO DRIVE THEM.

BARRISTERS' REPORTING SERVICE

1 SO I DON'T THINK WE SHOULD FORECLOSE THE
2 ABILITY TO HAVE GRANTS, BUT HAVE A PRESUMPTION FOR
3 LOANS.

4 CHAIRMAN GOLDBERG: DR. OLSON.

5 DR. OLSON: I APPRECIATE THE COMMENTS. I
6 WOULD -- THERE'S USUALLY NOT AN ECONOMIC RETURN
7 ARGUMENT THAT FIGURES INTO THE SCIENTIFIC REVIEW OF
8 ANY GRANT OR LOAN. SO, IN FACT, I THINK IT IS THE
9 RECOGNITION OF THE MANY WHO HAVE PARTICIPATED IN
10 DRUG DEVELOPMENT THAT, IN FACT, AN ORPHAN CASE IS
11 OFTEN A VERY POSITIVE ENTRY. I DON'T THINK THAT
12 REALLY IMPACTS ON A COMPANY'S ABILITY TO
13 EITHER -- THAT WOULD NOT BE A CONSIDERATION IN
14 REPAYMENT OF A LOAN, NOR WOULD IT BE A SCIENTIFIC
15 CONSIDERATION NECESSARILY IN EVALUATING A LOAN OR A
16 GRANT.

17 SO I GUESS I WOULD JUST RESPECTFULLY
18 SUBMIT THAT IT'S NOT OBVIOUS TO ME THAT AN ORPHAN
19 DISEASE OR NOT WOULD BE DISADVANTAGED IN A LOAN
20 SETTING.

21 MR. KLEIN: OKAY. COULD I GET -- THIS IS
22 BOB. COULD I GET, TED, YOUR COMMENTS ON THAT
23 BECAUSE FROM A FINANCIAL PERSPECTIVE, IF I WERE
24 TRYING TO ATTRACT, PUTTING MYSELF IN THE PLACE OF
25 SOMEONE WITH A SMALL COMPANY THAT'S TRYING TO

BARRISTERS' REPORTING SERVICE

1 ADDRESS AN ORPHAN DISEASE, I WOULD THINK THAT WITH
2 VERY LIMITED FEASIBILITY, STARTING OUT WITH A LOAN
3 WOULD REALLY ENCUMBER MY ABILITY TO ATTRACT MINIMAL
4 CAPITAL NECESSARY TO ADVANCE THIS TO A THERAPEUTIC
5 STAGE.

6 DR. LOVE: I ACTUALLY THINK I KIND OF COME
7 OUT WHERE DR. OLSON SUGGESTED, AND THAT IS I THINK
8 THAT EVEN FOR ORPHAN DISEASE WHERE YOU'RE HAVING A
9 DRAMATIC IMPACT, WE'VE SEEN OVER AND OVER AND OVER
10 AGAIN THAT THERAPIES WHICH ESSENTIALLY TAKE A SMALL
11 GROUP OF PEOPLE WHO WOULD ORDINARILY DIE OR SUFFER
12 ENORMOUS MORBIDITY AND ESSENTIALLY CORRECTING THAT
13 PROBLEM, WHICH IS WHAT OUR GOAL WOULD BE HERE,
14 ACTUALLY CAN BE VERY LUCRATIVE FOR A COMPANY. SO I
15 MEAN I COULD IMAGINE A SITUATION WHERE THERE ARE
16 REALLY ONLY A HANDFUL OF PEOPLE IN THE WORLD; BUT
17 CERTAINLY WHEN YOU GET INTO TENS OF THOUSANDS OF
18 PEOPLE ON A WORLDWIDE BASIS, ORPHAN HAS BEEN VERY
19 ATTRACTIVE IF YOU CAN HAVE A MAJOR IMPACT.

20 MR. KLEIN: WELL, THEN, ON THAT SIDE OF
21 IT, GIVEN THAT WE'RE TRYING TO GET TO ACCESSIBILITY
22 AND AFFORDABILITY FOR THE STATE, IF WE HAVE A LOAN
23 PROGRAM FOR AN ORPHAN DISEASE WITH A RAPID MORBIDITY
24 PATTERN, I WOULD HOPE THAT WE WOULD INCORPORATE IN
25 OUR THINKING THE ABILITY TO WRITE OFF OR WRITE DOWN

BARRISTERS' REPORTING SERVICE

1 THAT LOAN AS A PART OF GETTING TO THE ACCESSIBILITY
2 WE NEED.

3 CHAIRMAN GOLDBERG: JEFF SHEEHY.

4 MR. SHEEHY: I ACTUALLY AM NOT COMFORTABLE
5 WITH THE RATIONALE FOR THIS. IT SEEMS LIKE THAT WE
6 WENT FROM LOOKING AT DIFFERENT WAYS TO MOTIVATE
7 PEOPLE TO TAKE LOANS, AND I DON'T THINK THAT'S A
8 VALID REASON FOR DISCRIMINATION ON THIS BASIS. AND
9 I THINK WE SHOULD GO BACK TO OUR ORIGINAL IDEA,
10 WHICH IS THAT A COMPANY COULD ELECT FOR A GRANT OR A
11 LOAN. THE ONLY DISTINCTION IS WHO THE ULTIMATE
12 RECIPIENT OF THE FUNDS FOR SUCCESS IS. AND IF A
13 COMPANY ACTUALLY TAKES A GRANT AND THEN HAS SUCCESS,
14 THE FRUIT OF THAT SUCCESS GOES TO THE GENERAL FUND.
15 AND IF THE COMPANY TAKES A LOAN AND THEN IS ABLE TO
16 PAY BACK THAT LOAN, WE GET TO KEEP THE MONEY.

17 SO I WOULD PREFER GOING BACK TO THE
18 ORIGINAL IDEA OF LETTING THE COMPANY ELECT. IT
19 SEEMS LIKE THAT WE HAD THIS CONCEPT, AND I CAN
20 REMEMBER DISCUSSIONS ABOUT IT. ON A GIVEN RFA WE
21 MAY SAY THAT A GRANT -- YOU CAN APPLY FOR A GRANT OF
22 15 MILLION; BUT IF YOU TAKE A LOAN, YOU CAN GET 20
23 MILLION, AND THAT WAY WE WOULD INCENTIVIZE THE
24 COMPANIES. BUT INCENTIVIZING COMPANIES TO TAKE
25 LOANS SO WE CAN MAKE MONEY ISN'T REALLY TO ME

BARRISTERS' REPORTING SERVICE

1 PARAMOUNT TO OUR MISSION.

2 AND A COMPANY SHOULD BE ABLE TO CHOOSE
3 WHETHER TO TAKE A GRANT OR A LOAN BECAUSE IF A
4 COMPANY HAS A BIG SUCCESS, THERE'S THE POTENTIAL FOR
5 A LARGE PAYBACK TO THE STATE OF CALIFORNIA, WHICH
6 COULD HELP US IN THESE DIRE BUDGET TIMES. AND I
7 REALLY DON'T THINK THAT OUR PRIMARY MOTIVATION HERE
8 SHOULD BE TO MAKE MONEY. WE'RE TRYING TO OFFER
9 SOMETHING TO COMPANIES THAT CAN ENABLE THEM TO DO
10 MORE WORK, TO GET FUNDS TO CONTINUE IN THESE TOUGH
11 TIMES. BUT I'M NOT COMFORTABLE WITH THIS PROVISION.
12 I'D RATHER GO BACK TO OUR ORIGINAL DECISION, WHICH
13 WAS THE OPTION.

14 MR. KLEIN: JEFF, OUR MOTIVATION IS NOT TO
15 MAKE MONEY. IN THE ORIGINAL DEBATE WE WENT THROUGH
16 THE FACT THAT YOU'RE GOING TO TAKE AN IMMEDIATE HIT
17 OF ABOUT 40 PERCENT TO YOUR DISEASE TEAM GRANTS IF
18 YOU DON'T HAVE A MAJOR LOAN PROGRAM COMPONENT WHERE
19 YOU HAVE THE ABILITY TO RECOVER LOAN PROCEEDS AND
20 THEN BE ABLE TO PUT THEM OUT ON A PROGRAMMATIC
21 BASIS. PURPOSE OF THE LOAN PROGRAM IS, IN FACT,
22 DRIVEN BY THE ABILITY TO FUND MORE THERAPY
23 DEVELOPMENT. TO GO FURTHER INTO CLINICAL FUNDING AT
24 LARGER DOLLARS, AS YOU MENTIONED, WITHOUT THE
25 ABILITY TO RECOVER FUNDS, WE HAVE TO REALLY SCALE

BARRISTERS' REPORTING SERVICE

1 DOWN WHAT WE'RE GOING TO DO, HOW MANY RESEARCH
2 PROGRAMS WE'RE GOING TO REACH, AND WHAT THE SIZE OF
3 OUR CLINICAL SUPPORT FOR FUNDING TO GET TO PATIENTS
4 IS GOING TO BE.

5 SO IT'S DEFINITELY NOT THAT. AND THE
6 RECOVERIES ON ROYALTIES ARE DE MINIMIS COMPARED TO
7 THE POTENTIAL FOR THE STATE IF WE HAVE A BROADER
8 PORTFOLIO TO HAVE LOWER HEALTHCARE COST FOR PATIENTS
9 AND FAMILIES SUFFERING FROM CHRONIC DISEASE.

10 MR. SHEEHY: I'M JUST NOT COMFORTABLE WITH
11 THIS AS A BASIS FOR MAKING THIS DISCRIMINATION. I
12 THINK A COMPANY SHOULD BE ABLE TO ELECT A LOAN OR A
13 GRANT. THAT IS THE POSITION I WOULD SUPPORT. I
14 WOULD NOT SUPPORT GOING FORWARD REQUIRING
15 FOR-PROFITS TO TAKE LOANS IN AN RFA WHERE LOANS ARE
16 OFFERED. THEY SHOULD HAVE THE SAME OPTION AS A
17 NOT-FOR-PROFIT TO TAKE A GRANT.

18 CHAIRMAN GOLDBERG: DR. OLSON, WOULD YOU
19 LIKE TO ADDRESS STAFF'S VIEW ON THAT POINT?

20 DR. OLSON: I THINK STAFF'S OPINION --
21 STAFF IS NOT NECESSARILY AGAINST THAT WHILE
22 RECOGNIZING THE DESIRE TO ESSENTIALLY BE ABLE TO
23 CONTINUE TO FUND PROGRAMS SUCH AS THE DISEASE TEAM
24 AND THAT A LOAN DOES PROVIDE A MECHANISM. STAFF
25 DOES HAVE ISSUES WHERE THE NOTION OF INCENTIVIZING

BARRISTERS' REPORTING SERVICE

1 LOANS BY PROVIDING DIFFERENTIAL AMOUNTS OF MONEY
2 AVAIL ABLE IN ANY GIVEN RFA. BUT A PRIORI STAFF DOES
3 NOT DISAGREE WITH MR. SHEEHY' S POINT, BUT RECOGNIZES
4 THE DESIRABILITY OF HAVING ADDITIONAL FUNDS
5 AVAIL ABLE THROUGH A LOAN PROGRAM.

6 MR. SHEEHY: WE WERE RIGHT IN THE MIDDLE
7 OF AN RFA PHASE WITH THE TOOLS AND TECHNOLOGY
8 WHERE -- I MEAN I JUST -- YOU KNOW, COMPANIES WOULD
9 APPLY, NONPROFITS WOULD APPLY, THEY' RE BOTH APPLYING
10 FOR GRANTS. I WOULD HATE TO THINK THAT SOMEBODY
11 WHO -- YOU KNOW, THIS SEEMS LIKE THAT THERE ARE
12 COMPANIES THAT ARE INTERESTED IN TAKING GRANTS FROM
13 US. AND I DON' T WANT TO TELL THEM THAT THEY CAN NO
14 LONGER TAKE GRANTS WITHIN CERTAIN RFA' S UNLESS --
15 THAT THEY HAVE TO TAKE LOANS. I JUST DON' T THINK
16 THAT THERE' S ANY -- I DON' T THINK THE POLICY
17 RATIONALE FOR DOING SO IS SUFFICIENT TO MAKE THAT
18 DISCRIMINATION.

19 CHAIRMAN GOLDBERG: I' M GOING TO GO TO
20 DR. OLSON AND THEN TO YOU, DUANE.

21 DR. OLSON: AGAIN, I JUST WANTED TO REMIND
22 THE COMMITTEE OF ONE OTHER ASPECT OF THE STAFF
23 RECOMMENDATION THAT ATTEMPTS TO RECONCILE ALL THESE,
24 YOU KNOW, RELEVANT VIEWPOINTS. AND THAT IS THAT
25 BASICALLY THE LOANS WOULD ONLY BE IN THOSE RFA' S

BARRISTERS' REPORTING SERVICE

1 WHERE PRECLINICAL DEVELOPMENT AND CLINICAL
2 DEVELOPMENT WERE PART OF THE RFA. SO THE
3 PARTICULARLY LARGE PROGRAMS, SUCH AS DISEASE TEAMS
4 OR, YOU KNOW, IF WE HAVE INDEPENDENT CLINICAL RFA'S
5 OR DISEASE TEAMS STARTS TO INCORPORATE CLINICAL
6 INVESTIGATIONS, THOSE ARE THE ONLY TYPES OF RFA'S
7 WHERE WE WOULD REQUIRE COMPANIES TO TAKE A LOAN.

8 IN OTHER SITUATIONS COMPANIES WOULD HAVE
9 THE FULL -- WOULD HAVE A GRANT.

10 CHAIRMAN GOLDBERG: THANK YOU. DUANE.

11 MR. ROTH: SO THIS IS THE VERY REASON THAT
12 THE TASK FORCE RECOMMENDED NOT INCLUDING THIS IN THE
13 POLICY. AND IT WAS TO GIVE FLEXIBILITY TO MAKE IT
14 ON AN RFA -- MAKE A DECISION ON AN RFA-BY-RFA BASIS.
15 AND SO I WOULD STRONGLY SUPPORT THAT WE NOT LOCK
16 OURSELVES IN ON POLICY THAT'S THIS ABSOLUTE. AND
17 LET'S HAVE THIS DISCUSSION BASED ON WHAT THE RFA IS,
18 AND THEN WE CAN DETERMINE WHETHER WE WANT TO, YOU
19 KNOW, FORCE PEOPLE ONE WAY OR THE OTHER OR IF WE
20 WANT TO LET THEM CHOOSE OR IF WE WANT TO PUT
21 DIFFERENTIAL AMOUNTS IN THE TWO -- IN THE TWO SIDES
22 OF IT.

23 DR. AZZIZ: SO, MICHAEL, YOU WANT TO
24 JUST -- DO I SPEAK OR DO YOU WANT TO JUST GO AROUND
25 THE TABLE?

BARRISTERS' REPORTING SERVICE

1 CHAIRMAN GOLDBERG: PLEASE GO AHEAD.

2 DR. AZZIZ: I JUST WANTED TO SUPPORT THAT.

3 I MEAN WE WENT BACK AND FORTH THROUGH THIS, AND I
4 THINK WE ALL UNDERSTAND THAT WE'D LIKE TO
5 INCENTIVIZE LOANS AS A PARTIALLY RETURNABLE
6 RESOURCE, BUT THE REALITY IS IT WILL VARY ACCORDING
7 TO THE RFA. AND SOME RFA'S MAY BE ABLE TO ALLOW A
8 GRANT TO A COMPANY WHO THEN GETS A LOAN FOR THE
9 LARGER AMOUNT, ETC. SO I JUST THINK I AGREE THAT WE
10 NEED TO LEAVE IT OPEN AND DECIDE IT ON AN RFA
11 INDIVIDUAL BASIS.

12 CHAIRMAN GOLDBERG: GREAT. LET ME ASK THE
13 UC BERKELEY SITE FOR MEMBER COMMENTS. HEARING
14 NONE --

15 DR. PRICE: NO COMMENTS.

16 CHAIRMAN GOLDBERG: STANFORD.

17 MR. KLEIN: YEAH. THIS IS BOB KLEIN. ON
18 AN RFA BASIS I THINK THAT MAKES SOME GOOD SENSE
19 WHILE REALIZING THAT WE'RE GOING TO, IF WE DON'T
20 HAVE A VERY STRONG PREFERENCE FOR COMPANIES TAKING
21 LOANS, WE'RE GOING TO RADICALLY CUT PROJECTIONS OF
22 THE SCALE OF THESE PRECLINICAL PROGRAMS AND CLINICAL
23 PROGRAMS.

24 CHAIRMAN GOLDBERG: WASHINGTON, D. C.

25 DR. BLOOM: I HAVE NO FURTHER COMMENTS.

BARRISTERS' REPORTING SERVICE

1 I'VE ENJOYED THE DISCUSSION. I THINK IT WAS A GOOD
2 DOCUMENT TO START WITH, AND THE DISCUSSION WILL
3 IMPROVE IT.

4 CHAIRMAN GOLDBERG: THANK YOU, FLOYD.
5 BERKELEY SITE.

6 DR. PENHOET: NO FURTHER COMMENTS.

7 CHAIRMAN GOLDBERG: OKAY. SO WHY
8 DON'T -- DO YOU HAVE ANY FURTHER COMMENTS, DR.
9 OLSON?

10 DR. OLSON: I GUESS I JUST WANTED TO ASK
11 ONE QUESTION OF THE COMMITTEE, AND IT'S FOR MY OWN
12 CLARIFICATION. ON PAGE 11 OF THE DOCUMENT AT THE
13 TOP OF THE PAGE, ESSENTIALLY THE PAYMENT
14 ACCELERATION, I WOULD JUST -- IF IT WAS THE INTENT
15 OF THE COMMITTEE TO HAVE A LOAN COME DUE UPON IND
16 FILING, I WOULD NOTE THAT IND FILING IS WHEN YOU
17 ENTER CLINICAL TRIALS. IT'S TYPICALLY PART OF WHAT
18 I WOULD CALL THE VALLEY OF DEATH. ENTERING PIVOTAL
19 TRIAL, I DISTINGUISH COMPLETELY, THAT I THINK THE
20 LOAN SHOULD BECOME DUE UPON ENTERING PIVOTAL
21 CLINICAL TRIALS. BUT I WOULD JUST ASK THE COMMITTEE
22 IF IT WAS ITS INTENT TO HAVE A LOAN PAYMENT TRIGGER
23 AT THESE EARLY STAGES?

24 CHAIRMAN GOLDBERG: I THINK NOT. I THINK
25 THAT'S A GOOD CATCH. DUANE, YOU HAD A COMMENT?

BARRISTERS' REPORTING SERVICE

1 MR. ROTH: YEAH. THAT SHOULD NOT BE IND.
2 THAT SHOULD BE THE MEDICAL DEVICE, THE APPLICATION
3 OR FILING OF A MEDICAL DEVICE APPLICATION. IT'S NOT
4 IND. NANCY, WHAT IS IT? I FORGET THE TERM.

5 DR. OLSON: SO IS IDE THE FILING FOR
6 MARKETING FOR A DEVICE?

7 MR. ROTH: THAT'S IDE IS WHAT IT'S
8 SUPPOSED TO BE.

9 DR. OLSON: OKAY. SO THAT'S -- YEAH.
10 THAT'S, I THINK, FILING FOR MARKETING APPROVAL FOR A
11 DEVICE, AND THAT'S AN ACCEPTABLE TRIGGER AS WELL.

12 DR. LOVE: IT'S LIKE A PMA OR SOMETHING
13 LIKE THAT.

14 DR. OLSON: YEAH.

15 MR. ROTH: MICHAEL, I NEED TO MAKE ONE
16 MORE SUGGESTION ON PAGE 10.

17 CHAIRMAN GOLDBERG: CERTAINLY.

18 MR. ROTH: SO UNDER THESE PAYMENT
19 ACCELERATION TRIGGERS, THE ONES THAT APPLY TO BOTH,
20 WE HAVE CHANGE OF CONTROL, INITIAL PUBLIC OFFERING,
21 RELINQUISHMENT, OR TERMINATION. I WOULD LIKE TO
22 SUGGEST THAT WE ELIMINATE (B) UNDER THAT AND CATCH
23 IT UNDER THE ADDITIONAL TRIGGERS, (D) BELOW. IN
24 THINKING ABOUT AN IPO OF 20 MILLION WHERE THEY COULD
25 HAVE A LOAN FOR FIVE MILLION FROM US, THAT'S A

BARRISTERS' REPORTING SERVICE

1 SIGNIFICANT AMOUNT OF THEIR NEW CAPITAL --

2 CHAIRMAN GOLDBERG: YEAH.

3 MR. ROTH: -- THAT WE WOULD BE SUCKING
4 OUT. TWENTY MILLION IS KIND OF AN ARBITRARY NUMBER.
5 IT DEPENDS ON WHO YOU ARE. YOU KNOW, IF YOU'RE A
6 SMALL COMPANY AND 20 MILLION TO DO A CLINICAL TRIAL
7 OR TO FINISH ONE, GIVING US BACK FIVE MILLION OUT OF
8 THAT WOULD BE A BIG HIT.

9 MR. KLEIN: DUANE, THIS IS BOB. INSTEAD
10 OF JUST ELIMINATING IT, WHY DON'T YOU -- WHY DON'T
11 YOU CREATE A PROPORTIONALITY STANDARD BECAUSE IN
12 EXCESS OF 20 MILLION. SO IF YOU ELIMINATE IT, IF
13 THEY HAVE A \$100 MILLION IPO OR A \$50 MILLION IPO
14 AND THEY HAVE A \$5 MILLION LOAN --

15 MR. ROTH: LET ME TRY SOMETHING, BOB. I
16 WOULD SUGGEST THAT YOU TAKE UNDER (D), LITTLE (I)
17 THE LOAN RECIPIENT SECURES FOLLOW-ON FINANCING, AND
18 THAT MEANS ANY KIND OF FINANCING, IN AN AMOUNT AT
19 LEAST 20 TIMES OUR LOAN AMOUNT, THE LOAN WOULD
20 BECOME DUE WITHIN 30 DAYS. I'D MOVE THAT UP TO
21 REPLACE THE IPO.

22 DR. LOVE: I THINK THAT'S A GOOD IDEA,
23 DUANE. I WROTE A QUESTION MARK BEHIND THE IPO AS
24 WELL FOR ALL THE SAME REASONS YOU MENTION.

25 MR. KLEIN: SO IN TERMS OF -- INSTEAD

BARRISTERS' REPORTING SERVICE

1 OF -- CAN WE TALK ABOUT FOLLOW-ON FUNDING INSTEAD OF
2 FINANCING SO WE'RE NOT IMPLYING A LOAN?

3 MR. ROTH: YEAH. THAT'S FINE. JUST
4 TERMINOLOGY-WISE, BUT I THINK WE CAN GET RID OF THE
5 INITIAL PUBLIC OFFERING AND JUST PUT IF THEY REACH A
6 POINT WHERE THEY'VE GOT 20 TIMES MORE FUNDING IN
7 FOLLOW-ON FUNDING THAN THE AMOUNT WE HAVE A LOAN,
8 THAT WOULD BE A TRIGGER.

9 CHAIRMAN GOLDBERG: I AGREE. ANY -- I
10 THINK THAT CONCLUDES COMMENTS FROM THE MEMBERS --

11 MR. KLEIN: MICHAEL, I HAVE SOME IF YOU
12 ARE READY TO GO TO STANFORD.

13 CHAIRMAN GOLDBERG: WE'VE BEEN TO
14 STANFORD, BUT IF WE DIDN'T COMPLETE YOUR LIST OF
15 POINTS, PLEASE GO AHEAD.

16 DR. STEWARD: JUST BEFORE YOU START, THIS
17 IS OS. I HAVE TO SIGN OFF HERE. SO HOPE YOU HAVE A
18 GOOD CONTINUING MEETING.

19 CHAIRMAN GOLDBERG: THANK YOU, OS.

20 DR. PRICE: YEAH. THIS IS BOB PRICE. I'M
21 IN THE SAME POSITION. DO YOU HAVE ANY QUORUM
22 PROBLEMS THERE?

23 MS. KING: NO.

24 DR. PRICE: OKAY.

25 MS. KING: AS OF RIGHT NOW. THANK YOU,

BARRISTERS' REPORTING SERVICE

1 DR. PRICE.

2 CHAIRMAN GOLDBERG: BOB, ON ITEM 3(B) IN
3 THE AGENDA, YOU HAVE SOME MORE POINTS YOU' D LIKE TO
4 MAKE?

5 MR. KLEIN: YEAH, DEFINITELY. IF YOU GO
6 TO PAGE 10, YOU' VE GOT LOAN APPLICATION PROCESS,
7 YOU' VE GOT FINANCIAL FEASIBILITY REVIEW, AND WE
8 HAVEN' T SEEMED TO ADDRESSED THE LOAN ADMINISTRATION
9 POLICY -- THE LOAN ADMINISTRATION PERIOD. AND I
10 THINK WE SHOULD -- WE NEED TO ADD A PROVISION THAT
11 DEALS WITH THE LOAN ADMINISTRATION PERIOD AND
12 REFERENCE THAT THERE WILL BE A COMPENSATION POLICY
13 SET BY THE BOARD BASED UPON REVIEW OF COMPETITIVE
14 RFA' S. BUT DURING THE LOAN ADMINISTRATION PERIOD,
15 YOU' RE GOING TO HAVE POTENTIALLY PROPOSALS THAT
16 DON' T HAVE FEES FOR ANNUAL ADMINISTRATION. THEY MAY
17 HAVE INTEREST SPREADS BECAUSE OF BANK REGULATORY
18 PREFERENCES OR CAPITAL IMPACTS OF DIFFERENT
19 REPORTING OF INCOME.

20 BUT YOU ALSO ARE GOING TO HAVE A SPECIAL
21 ADMINISTRATIVE FEE FOR SPECIAL SERVICES LIKE DEALING
22 WITH THE WARRANTS. SO UNLESS WE' VE DEALT WITH IT
23 SOMEWHERE ELSE, WE SHOULD CONTEMPLATE AS A
24 SUBSECTION HERE THAT WE DON' T HAVE THE COMPENSATION
25 OF THE EXTERNAL FINANCIAL SERVICE PROVIDER DURING

BARRISTERS' REPORTING SERVICE

1 THE LOAN ADMINISTRATION PERIOD.

2 CHAIRMAN GOLDBERG: DR. OLSON.

3 DR. OLSON: MR. KLEIN, IT WAS MY
4 UNDERSTANDING THAT WE WERE GOING TO DEAL WITH THOSE
5 KINDS OF CONSIDERATIONS IN THE RFP AS OPPOSED TO IN
6 THE POLICY. I JUST PUT THAT FORTH FOR YOUR
7 CONSIDERATION.

8 MR. KLEIN: SURE. I'M NOT DICTATING
9 WHAT -- THE SETTING OF FEES IS NOT WHAT I'M
10 SUGGESTING, BUT WE DON'T HAVE ANY PROVISION IN HERE
11 AS A POLICY TO ESSENTIALLY PROVIDE COMPENSATION
12 DURING THE LOAN ADMINISTRATION PERIOD. JUST DON'T
13 ADDRESS IT AT ALL.

14 CHAIRMAN GOLDBERG: IAN SWEEDLER.

15 MR. SWEEDLER: IF I UNDERSTAND WHAT YOU'RE
16 SAYING, YOU HAVE A FEE. WE HAVE A PROVISION IN HERE
17 FOR A FEE TO COVER THE COST OF EVALUATING AN
18 APPLICATION. TO THE EXTENT FINANCIAL SERVICES ARE
19 NEEDED AFTER A LOAN IS BEING ADMINISTERED, WE
20 HAVEN'T YET GIVEN AUTHORITY IN HERE TO CHARGE A FEE
21 TO COVER THAT. AND YOU'RE SUGGESTING THAT WE
22 INCLUDE THAT OPTION; IS THAT CORRECT?

23 MR. KLEIN: WELL, YEAH, BECAUSE IT WILL BE
24 A FUNDAMENTAL RESPONSIBILITY OF THE FINANCIAL
25 SERVICES PROVIDER TO ADMINISTER THESE LOANS

BARRISTERS' REPORTING SERVICE

1 INCLUDING, FOR EXAMPLE, MONITORING THE WARRANT
2 PROVISIONS OR OTHER FUNCTIONS. AND SO WE NEED TO BE
3 ABLE TO HAVE THAT UNDER OUR POLICIES TO AUTHORIZE
4 COMPENSATION DURING THAT PERIOD.

5 MR. SWEEDLER: I THINK THAT'S A GOOD
6 POINT.

7 CHAIRMAN GOLDBERG: ANYTHING ELSE ON 3(B),
8 BOB?

9 MR. KLEIN: QUESTION FOR YOU AND, DUANE,
10 MAYBE YOU CAN COMMENT ON THIS. I THINK DURING THE
11 PREVIOUS DISCUSSIONS, ON PAGE 8 WHEN WE DISCUSSED
12 THE LOAN PERIODS OF SIX OR TEN YEARS, TWO POINTS.
13 ONE IS WE ARE CONTEMPLATING DIFFERENT INTEREST RATES
14 FOR THE DIFFERENT LOAN PERIODS; IS THAT CORRECT?

15 MR. ROTH: I DON'T THINK NECESSARILY, BOB,
16 THAT WE WOULD DO THAT. IT'S AN OPTION, BUT I DID
17 NOT THINK THERE WOULD BE. IT'S SIMPLY THE TERMS ARE
18 SHORTER. AND ON THE TEN-YEAR, THERE'S ACCELERATION
19 OPTIONS THAT WE WOULD HAVE THE APPLICANTS HAVE TO
20 ABIDE BY. BUT I DID NOT ANTICIPATE THERE WOULD BE
21 DIFFERENT INTEREST RATES.

22 MR. KLEIN: OKAY. I THINK WE SHOULD HAVE
23 THAT CAPACITY BECAUSE AS A BASIC INCENTIVE FOR
24 PEOPLE TO HAVE A SHORTER PERIOD, IF THEY CAN LIVE
25 WITH IT, HAVING DIFFERENT INTEREST RATES IS ONE OF

BARRISTERS' REPORTING SERVICE

1 THE TOOLS I THINK WE SHOULD HAVE AVAILABLE TO US
2 BECAUSE CLEARLY FROM OUR PROGRAMMATIC GOALS OF
3 TURNING MONEY OVER AND PUTTING OUT MORE PROGRAMMATIC
4 FUNDING, TO THE EXTENT WE CAN INCENTIVIZE
5 WITHOUT -- INCENTIVIZE SHORTER TERMS, WE'RE MUCH
6 BETTER OFF IN ACCOMPLISHING OUR GOAL OF HAVING MORE
7 PROGRAM FUNDS TO PUT OUT.

8 MR. ROTH: BOB, PERHAPS THE BEST ANSWER IS
9 THAT THE INTEREST RATE WILL BE DETERMINED AS PART OF
10 THE RFA, WHICH IT IS NOW, AND THAT WE COULD HAVE THE
11 FLEXIBILITY TO SAY NONRECOURSE IS 6 PERCENT AND
12 RECOURSE LOANS ARE 4 PERCENT.

13 MR. KLEIN: RIGHT. SO I THINK --

14 MR. ROTH: TEN-YEAR TERM IS 8 PERCENT,
15 WHATEVER WE WANT TO DO, WE'D HAVE THE FLEXIBILITY TO
16 DO IT.

17 MR. KLEIN: I THINK THAT'S GOOD. AND THEN
18 THE QUESTION IS WHY IS IT SIX OR TEN? WHY DON'T WE
19 SAY SIX TO TEN SO THAT WE CAN HAVE THE FLEXIBILITY
20 OF SETTING THESE BASED UPON THE RFA AND THE
21 STRUCTURE OF THE TASK THAT THESE COMPANIES ARE
22 LOOKING AT ON A SPECIFIC RFA AT THE RIGHT TERMS?

23 MR. ROTH: YEAH. I'M THINKING ABOUT WHAT,
24 YOU KNOW, THE COMPLEXITY OF THAT.

25 MR. KLEIN: WELL, THE LOAN ADMINISTRATOR

BARRISTERS' REPORTING SERVICE

1 IS GOING TO DEAL WITH THE REASON. IT TAKES THE
2 SAME -- THE SAME TRANSACTION COST TO ORIGINATE A
3 LOAN AT SIX, SEVEN, EIGHT, NINE, OR TEN YEARS. AND
4 SO THE QUESTION IS GIVING OURSELVES THE FLEXIBILITY,
5 WHY WOULDN'T WE DO THAT INSTEAD OF JUST GIVING
6 OURSELVES A DICHOTOMOUS OPTION?

7 MR. ROTH: I THINK WE STARTED OUT WITH ALL
8 THE LOANS BEING TEN YEARS, AND THEN WE SAID, WELL,
9 WE'D LIKE TO GET PEOPLE REPAYING US SOONER IF
10 THEY'RE ABLE TO. SO WE SAID IF YOU TAKE A SIX-YEAR
11 LOAN, YOU HAVE NO OBLIGATIONS OTHER THAN CHANGE OF
12 CONTROL AND NOW THE 20 TIMES FOLLOW-ON FINANCING.
13 BUT IF YOU TAKE A TEN-YEAR, A LONGER TERM LOAN, THEN
14 IF YOU GET IN A PIVOTAL TRIAL OR YOU FILE AN
15 APPLICATION FOR A MEDICAL DEVICE APPROVAL, THINGS
16 LIKE THAT WOULD TRIGGER EARLY REPAYMENT. BUT I
17 DON'T KNOW HOW YOU WOULD DEAL WITH THE FLEXIBILITY
18 AND WHAT THE DIFFERENCES WOULD BE ON THOSE POLICIES
19 IF YOU DID A SEVEN-YEAR OR AN EIGHT-YEAR OR A
20 NINE-YEAR.

21 CHAIRMAN GOLDBERG: IAN SWEEDLER HAS A
22 POINT HE'D LIKE TO MAKE HERE.

23 MR. SWEEDLER: JUST TWO ITEMS. FIRST OF
24 ALL, IF THE IDEA IS TO HAVE THIS COMMITTEE SET
25 DIFFERENTIAL INTEREST RATES FOR SIX-YEAR AND

BARRISTERS' REPORTING SERVICE

1 TEN-YEAR LOANS, THEN HAVING AN INFINITE NUMBER OF
2 DIFFERENT LOAN TERMS WOULD COMPLICATE THAT TASK.

3 MR. KLEIN: INFINITE IS NOT -- SIX, SEVEN,
4 EIGHT, NINE, AND TEN IS NOT INFINITE.

5 MR. SWEEDLER: BUT I WOULD ALSO POINT OUT
6 THAT BECAUSE OF THE OPTION FOR PREPAYMENT WITHOUT
7 PENALTY, SOMEONE WHO TAKES A TEN-YEAR LOAN, IT MAKES
8 ECONOMIC SENSE TO REPAY IT AFTER EIGHT YEARS, GOES
9 INTO THE TEN-YEAR LOAN KNOWING THAT THEY'LL BE ABLE
10 TO DO THAT IF THEY WANT TO AND ONLY PAYING INTEREST
11 THAT'S ACCRUED FOR THE EIGHT YEARS.

12 MR. KLEIN: I'M NOT LOOKING AT THEIR
13 INTEREST. I'M LOOKING AT OUR INTEREST. BUT LET ME
14 JUST MAKE A SUGGESTION. WHY DON'T WE JUST SAY MAY
15 ELECT A LOAN PERIOD OF SIX OR TEN YEARS AT THE TIME
16 OF THE APPLICATION OR SUCH OTHER TERM AS THIS
17 COMMITTEE MAY -- AS THE BOARD MAY DETERMINE AT THE
18 TIME OF THE RFA AND JUST RETAIN OUR OPTION HERE?

19 CHAIRMAN GOLDBERG: DR. OLSON WOULD LIKE
20 TO MAKE A COMMENT TO THAT.

21 DR. OLSON: I GUESS I JUST HAVE ONE
22 COMMENT IS THAT THIS WILL HAVE TO BE PART OF OUR
23 APPLICATION PROCESS. IT WILL HAVE TO BE -- IF WE
24 ALLOW DIFFERENT OPTIONS, IT WILL BE A DIFFERENT
25 PROGRAM EVERY TIME. SO THAT JUST I WOULD PUT FORTH

BARRISTERS' REPORTING SERVICE

1 FOR YOUR CONSIDERATION.

2 MR. KLEIN: AND HOW DO WE -- WELL, LET ME
3 SAVE -- I HAVE ANOTHER COMMENT I WILL SAVE FOR A
4 LATER DATE, I GUESS. GENERALLY SPEAKING, YOU DON'T
5 HAVE TO USE FLEXIBILITY. IF YOU DON'T USE
6 FLEXIBILITY, YOU GET DOWNSTREAM TO A POINT THAT YOU
7 NEED IT AND YOUR JAMMED AGAINST THE WALL. SO HAVING
8 AN OPTION TO HAVE ANOTHER TERM, I THINK, IS
9 VALUABLE. BUT BEING SENSITIVE TO DR. OLSON'S
10 COMMENT, YOU DON'T NEED -- YOU DON'T USE IT UNLESS
11 YOU REALLY NEED IT.

12 CHAIRMAN GOLDBERG: OKAY. BOB, ANY OTHER
13 POINTS ON 3(B) BECAUSE WE NEED TO COVER 3(A)?

14 MR. KLEIN: NO.

15 CHAIRMAN GOLDBERG: OKAY. WE'RE GOING TO
16 QUICKLY GO THROUGH FOR COMMENTS. COULD YOU INDICATE
17 TO ME WHERE WE HAVE MEMBERS OF THE PUBLIC WHO WOULD
18 LIKE TO MAKE COMMENTS AND I'LL MAKE A LIST. WE HAVE
19 ONE HERE.

20 DR. AZZIZ: I THINK BILL ADAMS HERE WOULD
21 LIKE TO MAKE A COMMENT ON 3(B) THAT WE JUST
22 DISCUSSED.

23 CHAIRMAN GOLDBERG: OKAY. ANY OTHER
24 SITES?

25 MR. ROTH: YES, SAN DIEGO.

BARRISTERS' REPORTING SERVICE

1 CHAIRMAN GOLDBERG: OKAY. WHY DON'T WE
2 START IN THE SOUTH AND MOVE NORTH. SAN DIEGO.

3 MR. ESMAELI -AZAD: THIS IS BABAK
4 ESMAELI -AZAD, THE CEO OF DNA MICROARRAY, INC. JUST
5 A QUICK COMMENT THAT HAVING BEEN INVOLVED WITH THE
6 PROCESS, I WANT TO FIRST THANK EVERYONE INVOLVED FOR
7 GENERATING THE PROGRAM AND REALLY APPRECIATE THIS
8 AND LOOK FORWARD TO BEING ABLE TO APPLY FOR THE
9 LOANS.

10 NOW, I TOOK A LOT OF NOTES THROUGHOUT THE
11 DISCUSSION ON THIS DOCUMENT, AND I THINK IN THE
12 INTEREST OF TIME, I SHOULD NOT GO THROUGH ALL OF
13 THEM. AND WANT TO FIND OUT IF WE COULD MAYBE DRAFT
14 A TRANSCRIPT AND SUBMIT IT TO YOU FOR YOUR
15 CONSIDERATION THAT WOULD BE COVERING ALL THE
16 CONCERNS WE MIGHT HAVE?

17 CHAIRMAN GOLDBERG: YEAH. YOU'RE WELCOME
18 TO SUBMIT YOUR COMMENTS IN WRITING TO THE CIRM
19 STAFF. AND I'D ASK YOU TO DIRECT THEM TO IAN
20 SWEEDLER, WHO WILL CIRCULATE THEM TO MEMBERS OF THE
21 COMMITTEE.

22 MR. ESMAELI -AZAD: WELL, I APPRECIATE
23 THAT. JUST A QUICK, AGAIN, COMMENT THAT THE
24 MIND-SET THAT WE COME FROM, THAT WE WOULD LIKE TO
25 SEE A LOAN PROGRAM THAT'S VERY INDUSTRY FRIENDLY AND

BARRISTERS' REPORTING SERVICE

1 IT IS VERY ATTRACTIVE. AND THE WAY I THINK OF IT IS
2 THAT THE GRANTS PROGRAM IS ZERO COST CAPITAL WHERE
3 THE LOAN PROGRAM HAS A COST ASSOCIATED WITH IT. SO
4 THE PROCESS HAS TO BE SUCH THAT IT WOULD PROMOTE
5 COMPANIES TO BE VERY MUCH INTERESTED IN GOING FOR
6 THE LOAN APPLICATIONS.

7 CHAIRMAN GOLDBERG: WE SUPPORT THAT AS AN
8 OBJECTIVE.

9 MR. ESMAELI -AZAD: OKAY. SO WE' LL DRAFT
10 ALL THE COMMENTS AND FORWARD THEM TO YOU WITHIN
11 COUPLE OF DAYS, AND I APPRECIATE THE OPPORTUNITY.

12 CHAIRMAN GOLDBERG: THANK YOU VERY MUCH.
13 LOS ANGELES.

14 MR. ADAMS: HI , IT' S BILL ADAMS. ON THE
15 ISSUE OF PI 'S WITH A 50 PERCENT, YOU KNOW, ONE OF
16 THE PROBLEMS WE HAD WITH THE PAST RFA IS THAT, AS A
17 FOR-PROFIT COMPANY, WE WERE NOT ABLE TO IDENTIFY A
18 PI FROM OUTSIDE OF OUR OWN STAFF, WHICH I THINK PUT
19 US AT A SUBSTANTIAL DISADVANTAGE AND WAS A LOSS FOR
20 US AND CERTAINLY A LOSS FOR CIRM. I AM NOT GOING TO
21 GET A TOP ACADEMIC OUT OF STANFORD OR UCI OR
22 SOMEWHERE ELSE THAT WOULD BE ABLE TO WORK FOR US 50
23 PERCENT OF THE TIME.

24 I THINK THEY SHOULD -- THE LIMITS SHOULD
25 BE THE TIME THAT THE PI IS PUTTING INTO THE GRANT.

BARRISTERS' REPORTING SERVICE

1 SO IF THEY'RE PUTTING 10 PERCENT INTO THE GRANT,
2 THAT SHOULD BE THE BENCHMARK FOR COMPANIES LIKE
3 OURS.

4 I THINK I HAD QUESTIONS ABOUT SIX TO TEN
5 YEARS ON LOANS. MY ONLY SUGGESTION ON LOANS WOULD
6 BE THAT THERE SHOULD BE A REAL INCENTIVE FOR
7 COMPANIES OR FOR THE BORROWERS TO PAY OFF EARLY,
8 EITHER REDUCE INTEREST RATES OR MAYBE EVEN A REDUCED
9 WARRANT COVERAGE BECAUSE IF I -- IF WE'RE VERY
10 SUCCESSFUL AND WE CAN PAY BACK A SIX- OR A TEN-YEAR
11 LOAN IN TWO YEARS, THAT'S DEFINITELY TO THE
12 ADVANTAGE OF CIRM. AND NEEDLESS TO SAY, I'D LIKE
13 THE LOAN OFF MY BOOKS.

14 LAST THING IS ON WARRANTS, YOU DO NEED A
15 TIME LIMIT. PRICE WATERHOUSE, MY AUDITORS FOR A
16 PUBLIC COMPANY, WILL GO NUTS AND TELL ME THAT
17 THERE'S NO TIME LIMIT ON THOSE WARRANTS. WE'RE
18 ALREADY DEALING WITH WHAT'S CALLED A BLACK-SCHOLES
19 FORMULA, WHICH IS MORE COMPLICATED THAN I EVEN WANT
20 TO TRY TO DESCRIBE TO ANYBODY HERE. BUT I
21 APPRECIATE YOUR -- OUR DOCUMENT IS GETTING VERY
22 CLOSE. THANK YOU.

23 CHAIRMAN GOLDBERG: THANK YOU. DON REED
24 IN SAN FRANCISCO.

25 MR. REED: YES. I HAD A QUESTION ON PAGE

BARRISTERS' REPORTING SERVICE

1 9 OF THE NONRECOURSE LOAN. IT SAYS THE LOAN
2 RECIPIENT MAY APPLY FOR SUSPENSION OF ALL OR PART OF
3 THE LOAN BASED ON SHOWING THAT THE PROJECT FUNDED
4 HAS FAILED. I HAVE TWO QUESTIONS. NO. 1, HOW IS
5 THAT DECIDED WHETHER IT GETS ALL OF IT OR NONE OF IT
6 FORGIVEN?

7 AND SECONDLY, THERE WAS A COMMENT MADE
8 EARLIER ABOUT THE FLOATING IP. IN OTHER WORDS, IF
9 THERE'S STILL SOME VALUE THERE, EVEN THOUGH THE
10 PROJECT FAILED, WHO HANGS ONTO THAT? ARE WE AT
11 CROSS PURPOSES WITH THEM? DO WE WANT TO LIKE SAY,
12 WELL, YOU KEEP IT AND WE ENCOURAGE YOU TO GO FURTHER
13 AND DEVELOP IT IF YOU CAN? OR WE LIKE THIS, WE WANT
14 TO KEEP IT SO WE CAN GET SOMETHING OF VALUE? COULD
15 YOU GUYS COMMENT ON THAT A LITTLE BIT?

16 MR. SWEEDLER: I THINK THOSE ARE GOOD
17 POINTS, AND THOSE ARE AREAS WHERE PARTLY IT'S AN
18 AREA WHERE WE'LL BE ADDRESSING IT IN OUR EFFORTS TO
19 HARMONIZE THIS POLICY WITH THE IP POLICY. THE
20 NOTION BEHIND PARTIAL SUSPENSION, YOU WOULD SEE A
21 SITUATION WHERE THE STATUS OF THE PROJECT IS SUCH
22 THAT SOME REASONABLENESS SHOULD BE JUSTIFIED AND
23 WARRANTED WHERE THEY WOULD WANT TO GET THAT OFF
24 THEIR BOOKS.

25 IN TERMS OF WHAT IS FAILURE OF A PROJECT,

BARRISTERS' REPORTING SERVICE

1 CHAIRMAN KLEIN ALREADY RAISED SOME ISSUES ABOUT
2 THAT, AND IT DOES LOOK LIKE WE'LL NEED TO, FIRST OF
3 ALL, MAYBE CHANGE THAT TERM TO SOMETHING ELSE AND
4 THEN TERM IT IN THE RIGHT WAY TO MAKE THAT
5 DETERMINATION. THE ACTUAL STANDARD WOULD PROBABLY
6 STILL HAVE TO BE SET PER RFA BECAUSE IT WILL RELATE
7 TO THE TYPE OF RESEARCH INVOLVED. BUT I THINK THOSE
8 ARE GOOD POINTS THAT WE WILL BE TRYING TO ADDRESS IN
9 THE NEXT DRAFT.

10 CHAIRMAN GOLDBERG: THANK YOU, MR. REED.
11 HEARING NO OTHER COMMENTS FROM THE PUBLIC, I'D LIKE
12 TO PROCEED TO A DISCUSSION OF ITEM 3(A), THE CONCEPT
13 PLAN FOR REQUESTS FOR PROPOSALS FOR DELEGATED
14 UNDERWRITERS. WE'VE DISCUSSED THIS IN PART IN PRIOR
15 COMMITTEE SESSIONS. AND I THINK WHAT WE'RE
16 INTERESTED IN OBTAINING RECOMMENDATIONS FOR IS TO
17 DIRECT STAFF TO GO FORWARD AND PUT TOGETHER AN RFP
18 FOR DELEGATED UNDERWRITERS WHICH WE WOULD THEN HAVE
19 AN OPPORTUNITY TO REVIEW. BUT THIS PROVIDES THE
20 GUIDANCE THAT WOULD ENABLE THEM TO INITIATE THAT
21 EFFORT.

22 ARE THERE ANY QUESTIONS FROM MEMBERS OF
23 THE COMMITTEE ON THE CONCEPT PIECE OR WHAT WE'RE
24 PROPOSING TO DO HERE?

25 MR. ROTH: MICHAEL, IT'S DUANE IN SAN

BARRISTERS' REPORTING SERVICE

1 DIEGO. THE ONLY -- I THINK IT'S FINE. I HAVE NO
2 COMMENTS SPECIFICALLY TO THE DOCUMENT IN TERMS OF
3 WHAT'S HERE, BUT I WANT TO RAISE THE ISSUE OF HOW
4 WE'RE GOING TO HANDLE CONFLICT OF INTEREST OF
5 POTENTIAL UNDERWRITERS. AND I'M THINKING ABOUT
6 THINGS LIKE, YOU KNOW, COMPETITIVE -- THEY HAVE A
7 CLIENT THAT'S COMPETITIVE WITH THE COMPANY THAT'S
8 ASKING FOR A LOAN OR THEY'RE FUNDING SOMEBODY THAT
9 IS ASKING FOR A LOAN. THERE ARE MANY THINGS I CAN
10 THINK OF THAT PROBABLY SHOULD BE THOUGHT OUT NOW
11 INSTEAD OF WAITING TILL WE PUT IT OUT THERE AND THEN
12 DECIDE THERE ARE PARTIES THAT ARE DISINTERESTED
13 PARTIES THAT ARE CAPABLE OF DOING THIS, BUT NOT
14 FUNDING EARLY STAGE.

15 CHAIRMAN GOLDBERG: RIGHT. THIS IS AN
16 IMPORTANT POINT. I'M GLAD YOU BROUGHT IT UP, DUANE.
17 I'M GOING TO ASK COUNSEL TO ADDRESS IT.

18 MR. HARRISON: THIS IS JAMES HARRISON. I
19 THINK YOU'RE RIGHT. THOSE ARE ISSUES THAT WE WILL
20 HAVE TO ADDRESS AS WE DEVELOP THE RFP ITSELF BECAUSE
21 WE WILL CLEARLY NEED TO SET OUT GUIDELINES SO THAT
22 THE DELEGATED UNDERWRITERS ARE AWARE OF THE POLICIES
23 THAT WE WOULD IMPOSE UPON THEM TO PREVENT CONFLICTS
24 OF INTEREST.

25 AND I SHOULD ADD THAT ONE OF THE RATIONALE

BARRISTERS' REPORTING SERVICE

1 BEHIND SEEKING MULTIPLE CONTRACTORS IN THIS CASE IS
2 TO ENABLE US TO AVOID THOSE SORTS OF CONFLICTS OF
3 INTEREST BY USING A DELEGATED UNDERWRITER THAT
4 DOESN'T HAVE A CONFLICT WITH RESPECT TO A PARTICULAR
5 APPLICANT. SO THOSE ARE POLICIES THAT WE WILL
6 DEVELOP AS PART OF THE RFP ITSELF.

7 MR. ROTH: GREAT. THANK YOU.

8 CHAIRMAN GOLDBERG: JEFF SHEEHY HAS A
9 COMMENT.

10 MR. SHEEHY: YEAH. WHAT'S THE DECISION
11 POINT ON THIS?

12 MS. KING: ON WHO GETS THE CONTRACT, YOU
13 MEAN?

14 MR. SHEEHY: YEAH. I MEAN I WOULD HOPE
15 THAT WE'D HAVE -- IDEALLY IT SEEMS LIKE WE GET A
16 RECOMMENDATION FROM THIS COMMITTEE IN A PUBLIC
17 HEARING, AND THEN IT GOES TO THE BOARD FOR --

18 MR. KLEIN: IT WILL GO TO THE BOARD, JEFF.
19 THIS IS A BOARD DECISION.

20 MR. SHEEHY: IT SAYS -- JUST BECAUSE IN
21 THE FIRST PARAGRAPH IT SAYS THAT CIRM WILL SELECT,
22 BUT I JUST WANT TO BE CLEAR THAT THE -- AND I THINK
23 WE SHOULD, YOU KNOW, BECAUSE OF ISSUES LIKE COI, IT
24 MIGHT BE EASIER TO HAVE -- I DON'T KNOW IF YOU WANT
25 TO DO IT IN THE SUBCOMMITTEE, BUT IF THERE IS SOME

BARRISTERS' REPORTING SERVICE

1 DISCUSSION TO DO THAT AND NOT BURDEN THE BOARD, THE
2 PEOPLE IN THE PUBLIC WANT TO WEIGH IN OR SOMETHING;
3 BUT AS LONG AS IT COMES TO THE BOARD EVENTUALLY, I'M
4 FINE.

5 CHAIRMAN GOLDBERG: I THINK IT'S
6 CONTEMPLATED THAT RESPONSES FROM THE RFA, THE RFP,
7 RATHER, THAT WOULD LEAD TO POTENTIAL DESIGNATED
8 UNDERWRITERS WOULD THEN COME TO US SO THAT WE CAN
9 UNDERSTAND WHO THEY ARE. BUT I THINK WITH RESPECT
10 TO SELECTION OF A SPECIFIC DESIGNATED UNDERWRITER OR
11 A SPECIFIC LOAN APPLICATION, THAT IS A STAFF JOB.

12 MR. SHEEHY: YEAH. I WOULD THINK WE'D
13 HAVE WHATEVER NUMBER OF BROAD CONTRACTORS, BUT THEN
14 THE STAFF WOULD ASSIGN INTERNALLY PER PROJECT.

15 CHAIRMAN GOLDBERG: RIGHT.

16 MR. SHEEHY: I THINK THE CONTRACTORS
17 THEMSELVES WHO ARE GOING TO DO THIS SHOULD BE
18 SELECTED BY THE ICOC AND, YOU KNOW, THERE SHOULD BE
19 SOME OPPORTUNITY FOR SOME PUBLIC TO WEIGH IN WITH
20 SOME SUBSTANCE IF PEOPLE HAVE CONCERNS. IT MAY BE
21 VERY PRO FORMA, BUT I JUST WANT TO MAKE SURE.
22 PEOPLE HAVE RAISED SOME CONCERNS IN THE PAST.

23 CHAIRMAN GOLDBERG: IAN SWEEDLER.

24 MR. SWEEDLER: I THINK -- I DON'T KNOW
25 THAT WE DISCUSSED THIS AMONG THE STAFF. MY

BARRISTERS' REPORTING SERVICE

1 ASSUMPTION IS THAT CIRM WOULD FOLLOW THE CONTRACTING
2 POLICIES WE'RE SUPPOSED TO FOLLOW, WHICH PROVIDE
3 THAT CONTRACTS AT A CERTAIN LEVEL ARE DECIDED BY THE
4 PRESIDENT AND THEN SO ON UP TO THE GOVERNANCE
5 COMMITTEE AND THE ICOC. IF THE BOARD WANTS TO
6 CHANGE THAT POLICY OR HAVE US TREAT IT DIFFERENTLY
7 HERE, WE JUST WOULD NEED DIRECTION ABOUT THAT.

8 MR. KLEIN: MICHAEL, THIS IS BOB. CAN I
9 COMMENT ON THAT?

10 CHAIRMAN GOLDBERG: CERTAINLY.

11 MR. KLEIN: I THINK YOUR CLARIFICATION WAS
12 GOOD, MICHAEL. IN THE NORMAL COURSE OF CONTRACTING,
13 THE DESIGNATION OF A LOAN GOING TO ONE CONTRACTOR OR
14 ANOTHER IS VERY APPROPRIATE. BUT THIS IS AN
15 INNOVATIVE PROGRAM; AND AS JEFF POINTS OUT, THE
16 PUBLIC HAS A REAL INTEREST IN UNDERSTANDING IT. AND
17 SO THE INTENTION, I THINK, AT THE BOARD LEVEL HAS
18 BEEN FOR THE BOARD TO APPROVE THE ACTUAL
19 CONTRACTORS. THE BOARD MAY WELL SEE THAT WHEN THE
20 RFA COMES IN, THERE ARE SOME POLICY QUESTIONS THAT
21 ARE BURIED IN THOSE PROPOSALS THAT NEED TO BE
22 DECIDED AND DISCUSSED PUBLICLY AT THE TIME OF THE
23 DECISION ON THE CONTRACTORS. SO I PUT THIS INTO A
24 DIFFERENT CATEGORY, IAN, THAN NORMAL CONTRACTING FOR
25 RATHER CUSTOMARY SERVICES.

BARRISTERS' REPORTING SERVICE

1 MS. KING: LIKE WE DID WITH PRESIDENTIAL
2 SEARCH.

3 CHAIRMAN GOLDBERG: ARE THERE ANY OTHER
4 COMMENTS ON THIS AGENDA ITEM? ANY PUBLIC COMMENTS
5 ON THIS AGENDA ITEM? HEARING NONE, I'D LIKE TO ASK
6 CHAIRMAN KLEIN, GIVEN THE LIMITED AMOUNT OF TIME WE
7 HAVE, AND WE HAVE TWO REMAINING AGENDA ITEMS AND
8 BOTH OF THEM ARE, I KNOW, VERY IMPORTANT TO HIM, IF
9 HE WOULD PREFER TO SEQUENCE THEM IN THE ORDER THAT
10 HE THINKS ARE MOST IMPORTANT TO THE AGENCY.

11 MS. KING: BOB, THOSE ARE AGENDA ITEMS NO.
12 4 AND 5. AND FOR NO. 4 WE HAVE A DOCUMENT. AND
13 WHAT CHAIR GOLDBERG IS SUGGESTING IS THAT YOU CAN
14 CHOOSE TO START WITH EITHER FOUR OR FIVE GIVEN THAT
15 WE HAVE 20 MINUTES LEFT FOR THE MEETING. YOU MIGHT
16 WANT TO TAKE THAT UNDER ADVISEMENT. THANK YOU.

17 DR. AZZIZ: MELISSA, THIS IS RICARDO. I
18 APOLOGIZE TO EVERYBODY. I HAVE ANOTHER MEETING THAT
19 I HAVE TO BE OUT. SO I'M LEAVING OFF. BILL ADAMS
20 WILL REMAIN HERE ON THE PHONE AS A MEMBER OF THE
21 PUBLIC HERE AT CEDARS.

22 MS. KING: THANK YOU, DR. AZZIZ, AND
23 THANKS FOR BEING HERE.

24 DR. AZZIZ: THANK YOU VERY MUCH. QUORUM
25 IS OKAY FOR YOU?

BARRISTERS' REPORTING SERVICE

1 MS. KING: I WAS JUST ABOUT TO ASK. DID
2 DR. PIZZO END UP JOINING WITH YOU, BOB?

3 MR. KLEIN: HE HAS NOT JOINED YET.

4 MS. KING: SO, DR. AZZIZ, WE KNOW YOU HAVE
5 TO GO.

6 DR. AZZIZ: LET ME PUT IT THIS WAY. I
7 WILL BE IN A MEETING IN AN ADJACENT OFFICE. IF YOU
8 HAVE SOMETHING TO VOTE ON THAT YOU NEED AN ELECTION,
9 MY STAFF WILL GET ME. HOW ABOUT THAT?

10 MS. KING: THANK YOU.

11 MR. KLEIN: LET ME ASK THIS QUESTION.
12 MICHAEL, BEFORE DR. AZZIZ LEAVES, DID YOU WANT TO
13 TAKE ANY ACTION ON A FORMAL RECOMMENDATION ON THE
14 TWO ITEMS WE'VE JUST GONE OVER?

15 CHAIRMAN GOLDBERG: I GUESS I LEAVE THAT
16 TO YOU. I DON'T THINK WE NEED A RECOMMENDATION
17 FORMALLY TO TAKE THIS FORWARD TO THE ICOC IN
18 DECEMBER. THAT'S MY UNDERSTANDING.

19 MR. HARRISON: ACTUALLY I THINK WITH
20 RESPECT TO THE LOAN ADMINISTRATION POLICY THAT WE
21 PLANNED TO BRING IT TO THE BOARD IN JANUARY BECAUSE
22 OF THE CROWDED AGENDA WE HAVE IN DECEMBER. AND I
23 THINK THE SUBCOMMITTEE HAS COMMUNICATED ITS CLEAR
24 DESIRE WITH RESPECT TO THE PROPOSED MODIFICATIONS TO
25 THE LOAN ADMINISTRATION POLICY, AND I THINK STAFF

BARRISTERS' REPORTING SERVICE

1 CAN MAKE THOSE AND THEN BRING THEM TO THE FULL ICOC
2 WITH THE SENSE OF THE SUBCOMMITTEE.

3 MR. KLEIN: OKAY. THANK YOU. I JUST
4 DIDN'T WANT YOU TO LOSE THE OPPORTUNITY IF YOU SO
5 ELECTED.

6 CHAIRMAN GOLDBERG: THANK YOU.

7 MR. KLEIN: OKAY. SO ON ITEM 4, IS THE
8 STAFF CURRENTLY PRESENT THAT WOULD BE ABLE TO
9 DESCRIBE FOR THE BOARD BEYOND WHAT IS WRITTEN IN
10 THIS SHORT SUMMARY BASICALLY THE GOAL OF THIS
11 ACCELERATED FUNDING PROGRAM FOR FOCUSING ON TRYING
12 TO EXPEDITIOUSLY GET FUNDS TO THE BIOTECH SECTOR
13 THAT IS UNDER SUCH SEVERE FINANCIAL STRESS?

14 CHAIRMAN GOLDBERG: DR. OLSON IS PRESENT
15 IF DR. OLSON CARES TO TAKE THIS UP. I'M NOT SURE
16 THAT SHE IS, BUT SHE'S PROCEEDING TO THE MICROPHONE.

17 DR. OLSON: I THINK THAT WE ALL RECOGNIZE
18 THAT THIS IS A TOUGH TIME FOR BIOTECH IN GENERAL,
19 AND THAT, YOU KNOW, WE ARE TRYING TO ESSENTIALLY DO
20 WHAT WE CAN TO HELP THOSE -- HELP THOSE
21 ORGANIZATIONS WHO ARE CONDUCTING RESEARCH THAT WOULD
22 BE VALUABLE TO OUR EFFORTS.

23 SO THE PROPOSAL IS, AS I UNDERSTAND IT,
24 AND I'M SURE PEOPLE WILL CORRECT ME IF I'M WRONG, IS
25 THAT NORMALLY WHEN WE HAVE -- WE RECEIVE

BARRISTERS' REPORTING SERVICE

1 RECOMMENDATIONS FROM THE GRANTS WORKING GROUP, WE
2 RECEIVE RECOMMENDATIONS THAT ARE RECOMMENDED FOR
3 FUNDING, RECOMMENDED IF FUNDS ARE AVAILABLE, AND
4 THEN NOT RECOMMENDED FOR FUNDING. IN ORDER TO HELP
5 GET THE MONEY TO QUALIFIED -- TO SCIENTIFICALLY
6 MERITORIOUS APPLICANTS -- FOR-PROFIT APPLICANTS MORE
7 QUICKLY, WE WOULD NOTIFY ALL APPLICANTS OF WHICH
8 TIER THEY WERE IN. WE WOULD ALSO NOTIFY THOSE
9 APPLICANTS IN TIER 1 THAT IF THEY COMPLETED THEIR
10 REQUIRED DOCUMENTATION IN TERMS OF ASSURANCES, IF
11 THEY WERE TO HAVE THOSE COMPLETED, THAT WE WOULD
12 MAKE ALL POSSIBLE EFFORTS -- PARDON ME. WE WOULD
13 ALSO HAVE THE DELEGATED UNDERWRITER DO THE FINANCIAL
14 REVIEW IF THIS, IN QUOTES, INCLUDED A LOAN PROGRAM.

15 SO I WOULD NOTE THAT THIS IS TRUE FOR BOTH
16 GRANTS OR LOANS. WE ARE PROPOSING TO DO THIS FOR
17 BOTH GRANTS OR LOANS, THAT THOSE PEOPLE IN TIER 1
18 WOULD BE NOTIFIED TO GET THEIR ASSURANCES TOGETHER.
19 WE WOULD THEN IMMEDIATELY FOLLOWING ICOC APPROVAL
20 AND PENDING RECEIPT OF ASSURANCES FOR WHERE THE
21 RESEARCH REQUIRED THOSE ASSURANCES TO EVEN BE
22 PERFORMED, WE WOULD BE ABLE TO DEFINITELY ACCELERATE
23 NOTICE OF GRANT AWARD AND MAKE FUNDS AVAILABLE. SO
24 THAT IS THE PROPOSAL.

25 MR. KLEIN: THANK YOU, DR. OLSON. SO,

BARRISTERS' REPORTING SERVICE

1 MICHAEL, THIS IS IN RESPONSE TO A REQUEST THAT I
2 MADE TO TRY AND IN REAL-TIME COME UP WITH A MORE
3 ACCELERATED FUNDING. AND I'D EMPHASIZE AGAIN THIS
4 IS FOR THOSE BIOTECH COMPANIES, IT'S BEEN SAID
5 BEFORE, BUT I WANT TO EMPHASIZE IT, THAT ARE IN THE
6 TOP TIER ONLY, RECOMMENDED FOR FUNDING, WHO WOULD
7 GET A PRIORITIZATION ESSENTIALLY BETWEEN THE PEER
8 REVIEW AND THE BOARD MEETING OF THEIR PROCESSING FOR
9 FUNDING SO THEY COULD BE FUNDED IMMEDIATELY.

10 WHAT WE'RE TRYING TO DO IS IF YOU LOOK AT
11 THE LAST TWO FUNDING ROUNDS, THE ONLY -- WELL, THE
12 LAST TWO FUNDING ROUNDS WE SEE A THREE-AND-A-HALF OR
13 FOUR-AND-A-HALF MONTH TIME PERIOD FOR FUNDING
14 BECAUSE WE HAVE A GAP BETWEEN PEER REVIEW AND THE
15 BOARD AND A MAJOR GAP, THEN, FROM THE BOARD TO
16 POTENTIALLY HAVING ALL OF THE POST-BOARD PROCESSING
17 ON COMPLIANCE IN PLACE. AND THE ATTEMPT HERE IS TO
18 SEE, FOR THE LIMITED NUMBER OF PRIVATE COMPANIES
19 THAT ARE COMING UP IN THESE VERY IMPORTANT CLINICAL
20 AND PRECLINICAL ROUNDS, TO PROCESS THEM, AS
21 DR. OLSON SAYS, ON A PRIORITY BASIS IMMEDIATELY
22 AFTER PEER REVIEW AND BEFORE THE BOARD MEETING.

23 WE WOULD ALSO IN OUR SETTING OF BOARD
24 MEETINGS FOR NEXT YEAR TRY AND LOOK AT IT AND SEE
25 WHAT THE GAP IN TIMING IS BETWEEN PEER REVIEW AND

BARRISTERS' REPORTING SERVICE

1 THE BOARD MEETING TO MINIMIZE THAT. IDEALLY WE'D
2 LIKE TO GET SOMEWHERE WHERE WE HAVE NO MORE THAN
3 FOUR OR FIVE WEEKS RATHER THAN THREE AND A HALF OR
4 FOUR AND A HALF MONTHS IN BETWEEN SO THAT WHEN WE
5 HAVE -- WHEN WE REALIZE THAT 60 PERCENT OF PRIVATE
6 BIOTECH COMPANIES MAY ONLY HAVE SIX TO NINE MONTHS
7 OF WORKING CAPITAL, THERE'S A HUGE DIFFERENCE FOR
8 THEM BETWEEN A FOUR OR FIVE WEEKS FUNDING PERIOD AND
9 A THREE-AND-A-HALF OR FOUR-AND-A-HALF MONTH FUNDING
10 PERIOD.

11 SO THAT'S THE GOAL, TRYING TO BE
12 RESPONSIVE TO THE FINANCIAL ENVIRONMENT. AND I
13 GREATLY APPRECIATE THE SCIENTIFIC STAFF COMING UP
14 WITH THIS RESPONSE.

15 CHAIRMAN GOLDBERG: EXCELLENT. THANK YOU.
16 JEFF SHEEHY HAS A COMMENT AND WE'LL TAKE IT FROM
17 THERE. I THINK THE MEMBERS OF THE COMMITTEE
18 GENERALLY SHARE THE SENTIMENTS EXPRESSED BY DR.
19 OLSON AND CHAIRMAN KLEIN.

20 MR. SHEEHY: IN GENERAL I SUPPORT THIS;
21 HOWEVER, I DO HAVE A CONCERN ABOUT THE FACT THAT
22 WE'RE SPECIFICALLY SEGMENTING OUT APPROVALS, ETHICAL
23 APPROVALS. I ASSUME SCRO WOULD ALSO INCLUDE IRB. I
24 MEAN I GUESS I HAVE TO HAVE FURTHER UNDERSTANDING
25 BECAUSE I HATE -- YOU KNOW, I'M NOT COMPLETELY

BARRISTERS' REPORTING SERVICE

1 CERTAIN THAT I'M COMFORTABLE WITH RELEASING MONEY
2 WITHOUT THE PROPER -- YOU KNOW, WE'LL DO A FINANCIAL
3 REVIEW, BUT WE WON'T DO ETHICAL REVIEW BEFORE WE'LL
4 GIVE OUT MONEY. AND WHAT IF THERE ARE ETHICAL
5 ISSUES? AND WE ARE TALKING ABOUT BEING IN AN AREA
6 OF RESEARCH WHERE HUMANS ARE INVOLVED WHERE THERE
7 COULD BE SIGNIFICANT ETHICAL QUESTIONS. AND I'M NOT
8 COMFORTABLE.

9 MR. KLEIN: JEFF, THERE MAY BE A
10 MISIMPRESSION. THERE WON'T BE MONEY GIVEN OUT FOR
11 CLINICAL WORK OR PRECLINICAL IN EITHER CATEGORY
12 UNTIL THE PROPER APPROVALS HAVE BEEN DONE FOR THAT
13 WORK. SO IF THEY NEED AN IRB, THEY CAN'T BEGIN THE
14 WORK WITH OUR FUNDS BEFORE THAT IRB IS ISSUED. AND
15 THAT'S CONSISTENT WITH CURRENT PRACTICE.

16 SO UNDER CURRENT PRACTICE, FOR EXAMPLE, MY
17 UNDERSTANDING IS THEY CAN ACTUALLY GET FUNDS ON A
18 GRANT RIGHT NOW IF THEY NEED AN IRB APPROVAL, THEY
19 CAN USE THOSE FUNDS FOR THE PROCESSING OF THAT
20 APPROVAL, BUT THEY CAN'T START THE WORK WITHOUT ALL
21 OF THE REQUIREMENTS. THAT IS CONSISTENT WITH WHAT
22 WILL BE MAINTAINED UNDER THIS POLICY. SO THERE'S
23 NO --

24 MR. SHEEHY: STAFF IS SHAKING THEIR HEAD
25 NO.

BARRISTERS' REPORTING SERVICE

1 DR. OLSON: I JUST WANTED TO CLARIFY.
2 GETTING APPROVALS IS ACTUALLY -- IT'S USUALLY JUST
3 PUTTING SOME DETAIL AROUND THE PARTICULAR PROPOSAL
4 AND SUBMITTING IT TO THE APPROPRIATE REVIEW
5 COMMITTEE. I DO WANT TO EMPHASIZE CHAIRMAN KLEIN'S
6 POINT, HOWEVER, THAT WE HAVE NO INTENTION OF
7 PROVIDING ANY KIND OF FUNDING TO ORGANIZATIONS THAT
8 HAVE NOT SUBMITTED THE -- THAT WOULD ALLOW THEM TO
9 CONDUCT RESEARCH WHERE THEY DON'T HAVE THE REQUIRED
10 ASSURANCES IN PLACE. ASSURANCES INCLUDE ASSURANCES
11 FOR CONDUCTING RESEARCH ON ANIMAL STUDIES, FOR GOING
12 THROUGH SCRO COMMITTEES TO CONDUCT RESEARCH ON
13 PLURIPOTENT STEM CELL LINES, AND IRB APPROVAL WHEN
14 HUMAN SUBJECTS ARE INVOLVED. SO WE WOULD NOT DO
15 THAT. WE DON'T DO THAT NOW. IT WOULD BE ILLEGAL
16 FOR US TO DO THAT UNDER PROPOSITION 71.

17 MR. SWEEDLER: MAY I ADD A CLARIFICATION
18 TO THAT? AS I UNDERSTAND IT, IT MAY BE THAT IN A
19 PARTICULAR PROPOSAL RIGHT NOW, FOR EXAMPLE, THE WORK
20 PLANNED AND BUDGETED FOR YEAR ONE DOESN'T REQUIRE
21 THOSE APPROVALS BECAUSE IT DOESN'T COME WITHIN THAT
22 PURVIEW. SO WE WOULD NOT ASK FOR APPROVALS
23 PREMATURELY NECESSARILY. SO WE MIGHT RELEASE FUNDS
24 FOR YEAR ONE, LIMITED TO THAT WORK THAT DOES NOT
25 REQUIRE THOSE APPROVALS, AND THAT WOULD BE A

BARRISTERS' REPORTING SERVICE

1 CONDITION IN THE GRANT, THAT THEY COULDN'T PROCEED
2 FORWARD UNTIL THEY HAD THE APPROPRIATE PROPOSALS.

3 IN SOME INSTANCES, IT WOULD BE POINTLESS
4 TO SEEK APPROVALS THAT WOULD ACTUALLY JUST EXPIRE
5 BEFORE THEY WERE NEEDED ANYWAY. SO WHAT WOULD BE
6 DIFFERENT HERE IS THAT WE WOULD CONSIDER THAT FOR AN
7 INITIAL PERIOD OF LESS THAN A YEAR. IF THE PROJECT
8 BUDGETED WORKED FOR THE FIRST THREE MONTHS THAT
9 DIDN'T REQUIRE THOSE APPROVALS, WE WOULD CONSIDER A
10 RELEASE OF LESS THAN A FULL YEAR'S FUNDS. BUT ONE
11 THING SHOULD BE ABSOLUTELY CLEAR. CIRM WILL NOT
12 RELEASE FUNDS TO PAY FOR RESEARCH FOR WHICH ALL
13 ETHICAL APPROVALS ARE NOT IN PLACE. AND FUNDS THAT
14 ARE RELEASED UNDER A CIRCUMSTANCE LIKE THAT WILL BE
15 RELEASED SUBJECT TO AN EXPLICIT CONDITION THAT THEY
16 CAN'T PROCEED.

17 CHAIRMAN GOLDBERG: THANK YOU FOR THAT
18 CLEAR CLARIFICATION. COMMENTS FROM THE PUBLIC AT
19 ANY SITE?

20 MR. ROTH: HERE IN SAN DIEGO.

21 MR. ESMAELI-AZAD: THIS IS BABAK
22 ESMAELI-AZAD, DNA MICROARRAY AGAIN. ONCE AGAIN, I
23 WANT TO START BY THANKING YOU FOR BEING SENSITIVE TO
24 THE BIOTECH'S NEEDS AND REALITIES, AND I FULLY
25 SUPPORT THIS PROPOSAL.

BARRISTERS' REPORTING SERVICE

1 I WANTED TO ADD AN ADDITIONAL REQUEST IF I
2 MAY, THAT RIGHT AFTER THE REVIEW OF THE GRANTS, IT
3 WOULD BE EXTREMELY HELPFUL FOR -- I THINK ACTUALLY I
4 SPEAK ON BEHALF OF BOTH FOR-PROFITS AND
5 NONPROFITS -- THAT WE GET ACCESS TO THE SCORES THAT
6 ARE ISSUED BY THE REVIEWERS. AND, OF COURSE,
7 PRIVATELY AND ONLY CONFIDENTIALLY TO THE PI OR THE
8 COMPANIES OR THE UNIVERSITIES THAT ARE APPLICANTS.
9 I'VE DISCUSSED THIS EARLIER IN OTHER MEETINGS WITH
10 THE STAFF THAT THIS WILL BE VERY, VERY BENEFICIAL
11 BOTH IN TERMS OF OUR PLANNING AND STRATEGIC
12 DECISIONS MADE FOR THE YEARS AND MONTHS AHEAD.

13 AND, OF COURSE, NO ONE IS GOING TO TAKE
14 THAT RANKING -- SCORE RANKING AND MAKE ANY
15 ASSUMPTIONS ON THE BASIS OF IT, BUT IT'S EXTRA
16 INFORMATION THAT CIRM HAS THAT, IF YOU COMMUNICATE
17 WITH US, IT WOULD BE VERY MUCH APPRECIATED. AND
18 THIS IS A MODEL USED BY NIH AS YOU ARE ALL AWARE OF,
19 AND THERE'S A REASON FOR THAT.

20 CHAIRMAN GOLDBERG: THANK YOU FOR THAT
21 COMMENT. LET ME NOW PROCEED TO THE FINAL AGENDA
22 ITEM, TO THE EXTENT THAT YOU'D LIKE FEEDBACK TO YOUR
23 SUGGESTION, BOB, THAT WE MAY WISH TO PROVIDE SOME
24 INPUT FROM CALIFORNIA WITH RESPECT TO THE U. S.
25 PRESIDENTIAL TRANSITION TEAM FOR CIRM PROGRAMS.

BARRISTERS' REPORTING SERVICE

1 MR. KLEIN: OKAY. I'LL TRY AND BE SUMMARY
2 HERE. AT SOME POINT IN THE FUTURE, WE'RE GOING TO
3 TRY AND BRING TOGETHER A LEGISLATIVE SUBCOMMITTEE,
4 BUT I WANTED, BECAUSE OF THE FINANCIAL IMPLICATIONS,
5 TO SPECIFICALLY BRING TO THE ATTENTION OF THIS
6 COMMITTEE.

7 FIRST OF ALL, WE OBVIOUSLY WELCOME AND
8 APPLAUD THE PRESIDENT-ELECT'S DECISION TO MOVE
9 FORWARD ON AN EXECUTIVE ORDER THAT REVERSES
10 PRESIDENT BUSH'S POSITION THAT PROHIBITED USING NIH
11 FUNDS ON NON-PRESIDENTIAL STEM CELL LINES, EMBRYONIC
12 STEM CELL LINES. I WOULD INDICATE THAT FROM A
13 CONGRESSIONAL POINT OF VIEW, THERE IS GOING TO BE A
14 NEED TO CLARIFY FOR THEM THAT WE STILL NEED THE
15 DICKEY-WICKER AMENDMENT. THE DICKEY-WICKER
16 AMENDMENT IS A RIDER ON ANNUAL APPROPRIATION BILLS
17 THAT NEEDS TO BE REMOVED, AND THAT EFFECTIVELY SAYS
18 YOU CANNOT USE FEDERAL FUNDS TO DESTROY EMBRYOS. SO
19 YOU COULDN'T USE FEDERAL FUNDS WHILE THAT AMENDMENT
20 IS IN PLACE.

21 IN SUMMARY, TO CREATE NEW CELL LINES, BUT
22 WITH THE REMOVAL OF THE EXECUTIVE ORDER, YOU COULD
23 USE NIH FUNDS ON NON-PRESIDENTIAL LINES THAT WERE IN
24 EXISTENCE. THERE IS AN OPINION PREVIOUSLY FROM
25 HEALTH AND HUMAN SERVICES GENERAL COUNSEL THAT SCNT

BARRISTERS' REPORTING SERVICE

1 IS NOT CONSIDERED CREATED THROUGH AN EMBRYO PROCESS
2 BECAUSE THERE IS NO SPERM UTILIZED. AND I ASSUME
3 THE SAME OPINION WOULD APPLY TO IPS CELLS, SO
4 THEORETICALLY WITH THE EXECUTIVE ORDER BEING
5 REMOVED, YOU COULD USE FEDERAL FUNDS FOR SCNT OR IPS
6 CREATION OF NEW CELL LINES.

7 THE OTHER KEY OBVIOUSLY BLATANT POINT IS
8 THAT WE NEED THE SPECIFIC AUTHORIZATION FOR FUNDING
9 FOR EMBRYONIC STEM CELLS AND THE PROHIBITION FOR
10 HUMAN REPRODUCTIVE CLONING TO BE PASSED. THE BILL
11 THAT WAS PREVIOUSLY VETOED IN THE LAST TWO YEARS IS
12 AN IMPORTANT SIGNAL TO ALL THE OTHER STATES IN THE
13 COUNTRY THAT THEY WILL HAVE STABILITY IN THIS POLICY
14 AND THERE WILL BE FUNDING THAT WILL PROCEED TO
15 INCLUDE EMBRYONIC STEM CELL RESEARCH.

16 IN TERMS OF OUR FINANCIAL INTEREST, THE
17 LOAN GUARANTEES THAT ARE BEING CONSIDERED FOR A
18 NUMBER OF SECTORS OF THE ECONOMY COULD INCLUDE THE
19 BIOTECH SECTOR. AND HERE, IF THERE WERE A
20 50-PERCENT LOAN GUARANTEE PROVISION FOR GOVERNMENTAL
21 LOAN BIOTECH PROGRAMS, IT WOULD MEAN THAT IF WE HAD
22 ALLOCATED CONCEPTUALLY, AND ONLY CONCEPTUALLY,
23 BECAUSE IT'S SUBJECT TO APPROVAL OF EVERY LOAN AT
24 THAT TIME AT THE BOARD LEVEL, BUT IF WE CONCEPTUALLY
25 APPROVED A \$500 MILLION ALLOCATION FOR A LOAN

BARRISTERS' REPORTING SERVICE

1 PROGRAM AND THERE WERE A GOVERNMENT PROGRAM FOR
2 50-PERCENT GUARANTEE, WE'D HAVE THE POSSIBILITY,
3 SUBJECT TO A LOT OF DETAILED WORK AND LEGAL REVIEW,
4 TO CREATE A BILLION DOLLAR PROGRAM WITH THAT. SO IT
5 WOULD SUBSTANTIALLY EXPAND OUR CAPACITY FOR FUNDING.

6 IN ADDITION, THERE ARE CURRENT
7 RESTRICTIONS THAT EXIST ON THE USE OF SBIC, SMALL
8 BUSINESS INVESTMENT CORPORATION, LOANS FOR BIOTECH.
9 AND I BELIEVE IT WOULD BE BENEFICIAL IF SOME OF
10 THOSE RESTRICTIONS WERE CHANGED TO MAKE IT MORE
11 POSSIBLE FOR COMPANIES THAT HAVE RECEIVED VENTURE
12 CAPITAL FUNDING IN THE PAST TO GET SBIC LOANS
13 BECAUSE WITH FALLING STOCK PRICES, DOING ANOTHER
14 ROUND OF STOCK OFFERINGS IS NOT FEASIBLE UNLESS
15 YOU'RE GOING TO HEDGE FUNDS, WHICH ARE
16 EXTRAORDINARILY DIFFICULT TO DEAL WITH AND CREATE
17 TREMENDOUS PRESSURE ON THESE SMALL COMPANIES TO THE
18 EXTENT HEDGE FUND MONEY IS AVAILABLE AT ALL.

19 AND FINALLY, IN TERMS OF THE FUTURE CHOKE
20 POINTS FOR MOVING CELLULAR THERAPIES FORWARD, IT'S
21 GOING TO BE IMPORTANT THAT THERE BE FUNDS FOR STAFF
22 EXPANSION OF THE FDA. THE STAFF EXPANSION OF THE
23 FDA, AS STATES ALL OVER THIS COUNTRY START TO MOVE
24 THERAPIES DOWNSTREAM TOWARDS IND'S, EVERYONE IS
25 GOING TO NEED EXPERT ADVICE ON EXACTLY WHAT KIND OF

BARRISTERS' REPORTING SERVICE

1 DATA AND WHAT KIND OF PRECLINICAL WORK IS GOING TO
2 BE REQUIRED FOR AN IND TO BE APPROVED FOR A PHASE I
3 HUMAN TRIAL. THAT ADVICE IS REQUIRED THREE YEARS OR
4 MORE IN ADVANCE BECAUSE THIS IS AN INNOVATIVE AREA.

5 AND SO IT'S GOING TO BE AN EARLY PRIORITY
6 WITH A LOT OF LEAD-TIME IMPORTANCE TO GET FDA
7 EXPANSION THAT CAN DEAL WITH CELLULAR THERAPIES AS
8 THEY ADVANCE.

9 THE FINAL POINT, I GUESS, OUTSIDE OF THE
10 STEM CELL FOCUSED AREAS IS THAT WE HAVE A GENERAL
11 INTEREST IN MAKING SURE THAT NIH FUNDING GENERALLY
12 IS EXPANDED BEYOND JUST STEM CELL FUNDING AS WE KNOW
13 THE STEM CELL AREA IS HIGHLY INTERDEPENDENT WITH
14 CHEMISTRY AND MANY OTHER AREAS OF BIOCHEMISTRY AND
15 MANY OTHER AREAS OF NIH FUNDING. SO IT IS, I THINK,
16 VERY IMPORTANT THAT EARLY ON IT BE CLEAR THAT WE ARE
17 NOT JUST ISOLATING OUR POSITION ON STEM CELL FUNDING
18 AT THE NIH, BUT NIH FUNDING BEING RESTORED TO
19 REASONABLE LEVELS IN REAL DOLLAR TERMS GENERALLY.

20 SO THOSE ARE THE FIVE AREAS IN SUMMARY.
21 AND I'D LIKE TO SEE, MICHAEL, IF WE HAD ANY SPECIFIC
22 BOARD INPUT TO THIS TO MAKE SURE IN TERMS OF
23 PRIORITIES AND DIRECTION OF FOCUS IF THERE'S OTHER
24 AREAS THE BOARD WOULD LIKE TO SEE INITIAL
25 DISCUSSIONS ON. WE WILL BRING A FORMAL POSITION TO

BARRISTERS' REPORTING SERVICE

1 THE BOARD LATER, BUT I'D LIKE TO GET EARLY INPUT
2 FROM THE BOARD.

3 CHAIRMAN GOLDBERG: EXCELLENT. IN LIGHT
4 OF IT BEING 11 O'CLOCK AND MANY OF THE PARTICIPANTS
5 ON THIS CALL HAVE HAD TO HOLD THEIR SCHEDULES TO THE
6 FULL EXTENT THAT WE HAD ASKED, LET ME SUGGEST THAT
7 WE CIRCLE BACK ON THIS ISSUE EITHER, YOU KNOW,
8 THROUGH A LEGISLATIVE SUBCOMMITTEE MEETING OR A
9 SUBSEQUENT MEETING OF THIS COMMITTEE, AND ALL OF US
10 CAN CONTACT YOU INDEPENDENTLY WITH ANY ADDITIONAL
11 POINTS THAT MAY BE RELEVANT FOR INTEGRATION INTO
12 YOUR OVERALL EFFORTS.

13 MR. KLEIN: THAT WOULD BE GREAT. AND IN
14 TERMS OF REAL-TIME SIGNIFICANCE, INDIVIDUAL COMMENTS
15 AND SUGGESTIONS FROM THE BOARD AND, FRANKLY, FROM
16 THE BIOTECH COMMUNITY ARE WELCOMED. AND IF THEY'RE
17 DIRECTED TO MELISSA KING, EXECUTIVE DIRECTOR FOR THE
18 BOARD, SHE CAN COMMUNICATE THEM TO ME OR GET A PHONE
19 CALL TOGETHER WITH ME, BUT I WOULD DEEPLY APPRECIATE
20 INPUT.

21 CHAIRMAN GOLDBERG: GREAT. I'M GOING TO
22 PROVIDE ONE FINAL COMMENT OPPORTUNITY TO THE PUBLIC.
23 DON REED HERE AND THEN I'M GOING TO PROCEED TO
24 ADJOURN THE MEETING.

25 MR. REED: JUST ON THE NIH FUNDING,

BARRISTERS' REPORTING SERVICE

1 PRESIDENT-ELECT OBAMA MADE A COMMENT EARLY IN THE
2 CAMPAIGN THAT HE WOULD LIKE TO DOUBLE THE NIH. AND
3 I THINK THAT'S A REALLY GOOD THING FOR US TO KEEP
4 HIM REMINDED OF. THANK YOU.

5 MR. KLEIN: I WOULD SAY, DON, THAT GIVEN
6 THERE'S A TRILLION DOLLARS THAT'S GONE OUT THE DOOR
7 SINCE THEN OR BEEN COMMITTED TO OTHER USES SINCE
8 THEN, IT'S GOING TO BE IMPORTANT HOW WE ALL MARSHAL
9 OUR ARGUMENTS TO SHOW THE CRITICAL LEAD-TIME IN NIH
10 FUNDING TO LIMITING THE GROWTH OR REDUCING FUTURE
11 MEDICAL COSTS IN THIS COUNTRY. AND THAT'S GOING TO
12 BE, YOU KNOW, A TOUGH ADVOCACY BECAUSE THE OTHER
13 COMPETITION FOR FUNDS HAVE LEGITIMATE PURPOSES AS
14 WELL.

15 MR. REED: ABSOLUTELY. BUT IF THE NO. 1
16 CAUSE OF HOME BANKRUPTCY IS INABILITY TO PAY
17 HEALTHCARE COSTS, THE STEM CELL MUST BE REGARDED AS
18 PART OF THE ANSWERS TO FINANCIAL MELTDOWN, AND IT
19 MUST BE TAKEN HUGELY SIGNIFICANTLY. WE MUST ASK FOR
20 A LOT. THEY CAN ALWAYS TELL US NO, BUT WE MUST ASK
21 FOR A LOT.

22 CHAIRMAN GOLDBERG: OKAY. THIS IS ANOTHER
23 GREAT OPPORTUNITY FOR CALIFORNIA TO DEMONSTRATE ITS
24 LEADERSHIP BECAUSE ITS CITIZENS HAVE ALLOCATED THE
25 \$3 BILLION FOR THAT PURPOSE HERE. WE CAN ALL FEEL

BARRISTERS' REPORTING SERVICE

1 GOOD ABOUT IT FOR A NANOSECOND AND THEN GET BACK TO
2 MAKING THIS ALL HAPPEN. THANK YOU TO ALL THE STAFF
3 WHO MAKES THIS ALL POSSIBLE FOR US, AND PARTICULARLY
4 TO IAN SWEEDLER AND JAMES HARRISON FOR ALL THE WORK
5 IN PREPARATION OF THE MEETING, IN ADDITION TO
6 MELISSA AND LYNN AND TO ALL THE SCIENTIFIC STAFF.
7 THANK YOU ALL VERY MUCH. MEETING ADJOURNED.

8 (THE MEETING WAS THEN ADJOURNED AT
9 11:05 A. M.)

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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 PROCEEDINGS BEFORE THE FINANCE SUBCOMMITTEE OF THE INDEPENDENT CITIZEN' S OVERSIGHT COMMITTEE OF THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE IN THE MATTER OF ITS REGULAR MEETING HELD ON WEDNESDAY, NOVEMBER 19, 2008, 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 AND TRANSCRIBED BY ME. I ALSO CERTIFY THAT THIS TRANSCRIPT IS A TRUE AND ACCURATE RECORD OF THE PROCEEDING.



BETH C. DRAIN, CSR 7152
BARRISTER' S REPORTING SERVICE
1072 BRISTOL STREET
SUITE 100
COSTA MESA, CALIFORNIA
(714) 444-4100