

BEFORE THE
INDEPENDENT CITIZENS' OVERSIGHT COMMITTEE
TO THE
CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE
ORGANIZED PURSUANT TO THE
CALIFORNIA STEM CELL RESEARCH AND CURES ACT
REGULAR MEETING

LOCATION: CROWNE PLAZA SFO
1177 AIRPORT BOULEVARD
BURLINGAME, CALIFORNIA

DATE: THURSDAY, MAY 24, 2012
9 A.M.

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

BRS FILE NO.: 91095

BARRISTERS' REPORTING SERVICE

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BARRISTERS' REPORTING SERVICE

1 BURLINGAME, CALIFORNIA; THURSDAY, MAY 24, 2012

2 9 A.M.

3

4 CHAIRMAN THOMAS: GOOD MORNING. I WOULD
5 LIKE TO CALL THIS MEETING OF THE INDEPENDENT
6 CITIZENS OVERSIGHT COMMITTEE TO ORDER ON THIS
7 BEAUTIFUL MAY MORNING IN SAN FRANCISCO. WE WELCOME
8 EVERYBODY WHO IS HERE AND EVERYBODY ON THE PHONE
9 LISTENING TO WHAT WILL BE A MOST INTERESTING AND
10 CHALK FULL AGENDA TODAY.

11 LET'S BEGIN BY TURNING THIS OVER TO MARIA
12 WHO WILL DO THE PLEDGE OF ALLEGIANCE FOLLOWED BY THE
13 ROLL CALL. MARIA.

14 MS. BONNEVILLE: PLEASE STAND IF YOU ARE
15 ABLE.

16 (THE PLEDGE OF ALLEGIANCE.)

17 MS. BONNEVILLE: ROBERT BIRGENEAU. DAVID
18 BRENNER. SUE BRYANT.

19 DR. BRYANT: HERE.

20 MS. BONNEVILLE: KEN BURTIS.

21 DR. BURTIS: HERE.

22 MS. BONNEVILLE: MARCY FEIT. MICHAEL
23 FRIEDMAN.

24 DR. FRIEDMAN: HERE.

25 MS. BONNEVILLE: LEEZA GIBBONS.

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1 MS. GIBBONS: HERE.
2 MS. BONNEVILLE: MICHAEL GOLDBERG.
3 MR. GOLDBERG: HERE.
4 MS. BONNEVILLE: SAM HAWGOOD.
5 DR. HAWGOOD: HERE.
6 MS. BONNEVILLE: STEPHEN JUELSGAARD.
7 DR. JUELSGAARD: HERE.
8 MS. BONNEVILLE: SHERRY LANSING. BERT
9 LUBIN.
10 DR. LUBIN: HERE.
11 MS. BONNEVILLE: MICHAEL MARLETTA.
12 DR. MARLETTA: HERE.
13 MS. BONNEVILLE: SHLOMO MELMED. PHIL
14 PIZZO. FRANCISCO PRIETO. ELIZABETH FINI.
15 DR. FINI: HERE.
16 MS. BONNEVILLE: ROBERT QUINT.
17 DR. QUINT: HERE.
18 MS. BONNEVILLE: DUANE ROTH. JOAN
19 SAMUELSON.
20 MS. SAMUELSON: HERE.
21 MS. BONNEVILLE: DAVID SERRANO-SEWELL.
22 JEFF SHEEHY. JON SHESTACK. OSWALD STEWARD.
23 DR. STEWARD: HERE.
24 MS. BONNEVILLE: JONATHAN THOMAS.
25 CHAIRMAN THOMAS: HERE.

BARRISTERS' REPORTING SERVICE

1 MS. BONNEVILLE: ART TORRES.

2 MR. TORRES: HERE.

3 MS. BONNEVILLE: KRISTINA VUORI.

4 DR. VUORI: HERE.

5 MS. BONNEVILLE: EUGENE WASHINGTON.

6 CHAIRMAN THOMAS: THANK YOU, MARIA. I'D
7 LIKE TO START, AS ALWAYS, WITH OUR CHAIRMAN'S
8 REPORT. FIRST AND FOREMOST WOULD LIKE TO INTRODUCE
9 A NEW MEMBER OF OUR BOARD WHO SORT OF SLIPPED IN THE
10 ROLL CALL THERE UNNOTICED. HE IS DR. MICHAEL
11 MARLETTA SITTING OVER HERE BETWEEN DRS. LUBIN AND
12 STEWARD. MICHAEL IS THE PRESIDENT AND CEO OF THE
13 SCRIPPS RESEARCH INSTITUTE, ALSO THE CECIL H. AND
14 IDA M. GREEN PROFESSOR OF CHEMISTRY AT SCRIPPS.
15 HE'S A MEMBER OF THE NATIONAL ACADEMY OF SCIENCES,
16 THE AMERICAN ACADEMY OF ARTS AND SCIENCES, AND THE
17 INSTITUTE OF MEDICINE, AND IS A FORMER RECIPIENT OF
18 THE PRESTIGIOUS MACARTHUR FELLOWSHIP.

19 MICHAEL, WE ARE DELIGHTED TO HAVE YOU. HE
20 WAS AN APPOINTEE OF TREASURER BILL LOCKYEAR TO
21 REPLACE DR. FLOYD BLOOM ON OUR BOARD. WELCOME, AND
22 I THINK YOU WILL FIND THIS TO BE A MOST INTERESTING
23 UNDERTAKING AS WE PROCEED THROUGH OUR MANY THINGS
24 THAT WE DO OVER THE YEAR. SO THANK YOU AND
25 DELIGHTED TO HAVE YOU HERE.

BARRISTERS' REPORTING SERVICE

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(APPLAUSE.)

CHAIRMAN THOMAS: CONTINUING NOW WITH THE CHAIR'S REPORT, I HAD THE PRIVILEGE OF BEING ABLE TO ATTEND AND SPEAK AT THE OPENING OF OUR ELEVENTH, I BELIEVE, ELEVENTH AND TWELFTH FUNDED FACILITIES, ONE AT THE BUCK INSTITUTE AND ONE AT UC SANTA CRUZ SINCE OUR LAST BOARD MEETING. THE LEVEL OF ENTHUSIASM AND INTEREST FOR THESE TWO FACILITIES AND THE WORK THAT IS GOING TO BE DONE IN THEM WAS PALPABLE AT EACH OF THESE MEETINGS. THEY WERE VERY HIGHLY ATTENDED, MOST ENTHUSIASTICALLY ATTENDED, AND WE WERE DELIGHTED TO BE ABLE TO SAY THAT WE PLAYED A PART IN MAKING THESE BUILDINGS A REALITY AND TO HELP FACILITATE THE EXTRAORDINARY RESEARCH THAT BOTH INSTITUTIONS HAVE GOING NOW AND WILL HAVE IN THE FUTURE.

NEXT WOULD LIKE TO TALK ABOUT OUR FUNDING. THIS IS SOMETHING OF GREAT INTEREST TO US. AS YOU KNOW, HISTORICALLY CIRM HAS BEEN FUNDED ON A SEMIANNUAL BASIS THROUGH BOND PROCEEDS THAT COME FROM STATE GENERAL OBLIGATION BOND ISSUES UNDERTAKEN BY THE STATE TREASURER. THE TREASURER'S OFFICE ACTUALLY HAS TWO WAYS IN WHICH IT CAN FUND PARTICIPATING AGENCIES. ONE IS THROUGH THE BOND MEASURES OR BOND ISSUES, RATHER. THE OTHER IS

BARRISTERS' REPORTING SERVICE

1 THROUGH DRAWING DOWN ON COMMERCIAL PAPER FACILITIES
2 THAT THEY HAVE AVAILABLE TO THEM. AND IN THE CASE
3 OF THE LATTER, THEY WOULD DRAW DOWN FOR THE
4 PARTICIPATING AGENCIES. AND ONCE THE AMOUNT OF
5 OUTSTANDING COMMERCIAL PAPER REACHES A CERTAIN
6 LEVEL, THEY WOULD AGGREGATE THAT TOGETHER AND
7 REFINANCE ALL OF THAT THROUGH A SUBSEQUENT BOND
8 ISSUE.

9 AS YOU KNOW, THE SPRING IS ONE OF THE
10 TIMES OF OUR SEMIANNUAL FUNDING, AND THAT FUNDING IS
11 DESIGNED TO MEET THE AGENCY'S NEEDS THROUGH THE END,
12 IN THIS CASE, THE END OF CALENDAR 2012. WE ARE, AS
13 YOU MAY RECALL, MOSTLY A TAXABLE ENTITY. THAT IS,
14 WE ARE COVERED THROUGH TAXABLE BOND MEASURES, BOND
15 ISSUES WITH SOME EXCEPTION. THIS PARTICULAR SPRING
16 THE TREASURER'S OFFICE HAS DECIDED THAT RATHER THAN
17 INCLUDE US IN THEIR BOND ISSUE, WE'LL BE INCLUDED IN
18 THE COMMERCIAL PAPER OPTION, WHICH WE ARE DELIGHTED
19 THAT THEY HAVE CHOSEN TO DO THIS.

20 WE'RE BASICALLY -- WE DON'T REALLY CARE
21 WHETHER WE'RE FUNDED THROUGH BONDS OR CP. IT'S THE
22 SAME TO US. WE HAVE AS ALWAYS SUBMITTED A LIST OF
23 THE NEEDS THAT WE HAVE AND THE AMOUNT THAT WE NEED
24 TO HAVE FUNDED THROUGH THE END OF THE YEAR IN THIS
25 CASE, AND WE ARE MOST PLEASED THROUGH THE

BARRISTERS' REPORTING SERVICE

1 EXCEPTIONAL HELP OF THE DEPARTMENT OF FINANCE AND
2 THE STATE TREASURER'S OFFICE TO INFORM YOU THAT WE
3 WILL BE RECEIVING ONCE AGAIN THE FULL AMOUNT THAT WE
4 HAVE REQUESTED TO PROCEED FORTH FOR THE REST OF THE
5 CALENDAR YEAR.

6 SO THERE ARE LOTS OF SORT OF
7 TECHNICALITIES AND ISSUES ATTENDANT ON WHEN WE GET
8 IT AND TIMING AND SUBMISSION, ALL THAT STUFF; BUT
9 FOR PURPOSES OF TODAY'S MEETING, JUST KNOW THAT WE
10 ARE FULLY FUNDED AND ARE FULL STEAM AHEAD WITH
11 RESPECT TO BOTH THE DEPARTMENT OF FINANCE AND THE
12 STATE TREASURER'S OFFICE, BOTH OF WHICH REMAIN
13 EXTREMELY SUPPORTIVE OF ALL THAT WE ARE DOING.

14 ANOTHER MATTER, WE ARE GOING TO HEAR
15 TODAY, ONE OF THE AGENDA ITEMS IS THE BUDGET. AND
16 WITH RESPECT TO THAT, OBVIOUSLY WE ARE MINDFUL OF
17 ALL OF THE DISCUSSIONS AT THE STATE LEVEL CONCERNING
18 THE STATE BUDGET, AND WE ARE, I THINK YOU WILL SEE,
19 PROPOSING A VERY PRUDENT BUDGET GOING FORWARD. AND
20 WE WILL CONTINUE TO MONITOR THE SITUATION AT THE
21 STATE AS IT MAY DEVELOP OVER THE NEXT FEW MONTHS AS
22 THEY PROCEED TO NAIL DOWN THE BUDGET THAT THEY ARE
23 CURRENTLY CONSIDERING.

24 ONE OF THE THINGS I WANTED TO BRING TO THE
25 BOARD'S ATTENTION, WE HAVE, AS YOU KNOW, AN RFA OUT

BARRISTERS' REPORTING SERVICE

1 FOR OUR NEW STRATEGIC PARTNERSHIP PROGRAM. IT'S
2 SOMETHING WE'RE VERY EXCITED ABOUT AS YET ANOTHER
3 WAY TO GET BEST-IN-CLASS PROPOSALS IN FOR PROJECTS
4 FROM VARIOUS ENTITIES THROUGHOUT THE STATE OF
5 CALIFORNIA. WE'RE IN THE PROCESS RIGHT NOW, WE HAVE
6 RECEIVED LETTERS OF INTENT FROM A NUMBER OF PARTIES
7 WHO ARE INTERESTED IN APPLYING FOR THIS. THOSE
8 LETTERS OF INTENT CAME IN IN NUMBERS EXCEEDING WHAT,
9 I THINK, WE WERE EXPECTING AND HAVE SOME REAL
10 QUALITY IN THE MIX.

11 PREVIOUSLY THE BOARD HAD AUTHORIZED UP TO
12 \$30 MILLION TO GO TOWARDS THE STRATEGIC PARTNERSHIP
13 PROGRAM. WE WILL BE, THROUGH OUR NORMAL GRANTS
14 WORKING GROUP PROCESS, EVALUATING THE PROPOSALS THAT
15 HAVE COME IN. AND IF IT DEVELOPS THAT THERE ARE
16 MORE THAN WE HAD ORIGINALLY ANTICIPATED THAT WE FEEL
17 AND THE GRANTS WORKING GROUP FEELS ARE WORTHY OF
18 FUNDING, AT THAT TIME WE MAY COME BACK TO THE BOARD
19 TO DISCUSS THE POTENTIAL OF INCREASING THE AMOUNT
20 THAT WE HAD ORIGINALLY ALLOCATED FOR THAT PURPOSE.
21 SO THAT'S SORT OF A STAY TUNED ITEM.

22 EVERYBODY SHOULD HAVE ON THEIR DESKS HERE
23 IN THE ROOM OUR NEW ANNUAL REPORT, WHICH YOU WOULD
24 SEE, I THINK. HOPEFULLY EVERYBODY HAS ONE THERE.
25 WE ARE DELIGHTED TO HAVE THIS. IT IS, AS YOU WILL

BARRISTERS' REPORTING SERVICE

1 SEE, A BIT OF A DIFFERENT FORMAT THAN WHAT WE'VE HAD
2 IN THE PAST. AND IT IS THE PRODUCT OF A GREAT DEAL
3 OF WORK BY OUR STAFF WHO HAS, NOT JUST IN TERMS OF
4 COMING UP WITH THIS DIFFERENT FORMAT, BUT IN PUTTING
5 TOGETHER CONTENT THAT IN A MERE EIGHT PAGES WE THINK
6 CONVEYS THE STORY OF CIRM, THE STATUS OF OUR
7 FUNDING, WHERE WE ARE IN THE PROCESS IN TERMS OF
8 BASIC RESEARCH THROUGH CLINICAL TRIAL FUNDING, THE
9 SUBJECT MATTER OF ALL OF THE DIFFERENT AWARDS, THE
10 MAJOR AWARDS WE HAVE, WHICH AS OF TODAY, AS YOU
11 KNOW, STANDS AT 43.

12 BY THE END OF THE DAY, WHEN WE HAVE VOTED
13 ON THE EARLY TRANSLATION AWARDS, THAT NUMBER WILL
14 INCREASE. BUT WITH RESPECT TO THE ANNUAL REPORT,
15 YOU WILL SEE, AS OF THE SNAPSHOT WHEN THAT WAS
16 FINALIZED A FEW WEEKS AGO, IT CONVEYS VERY NICELY
17 AND UNDERSTANDABLY AND IN PLAIN ENGLISH THE STORY OF
18 CIRM AND THE PROGRESS THAT WE ARE MAKING, WHICH IS
19 CONSIDERABLE ACROSS MANY FRONTS. SO KUDOS TO OUR
20 WHOLE COMMUNICATIONS TEAM ON THAT.

21 IN ADDITION TO THAT, YOU WILL SEE THAT WE
22 HAVE NEW BUSINESS CARDS HERE, BUSINESS CARD-LOOKING
23 CARDS, THAT ARE MEANT TO BE HANDED OUT TO FOLKS TO
24 GIVE THEM A NUMBER OF DIFFERENT WAYS TO CONTACT US,
25 TO GET INFORMATION ABOUT CIRM, AND TO SORT OF GET

BARRISTERS' REPORTING SERVICE

1 THE FULL PICTURE. SO WE ENCOURAGE YOU TO HAND THOSE
2 OUT. AND I THINK YOU'LL FIND THAT THEY ARE VERY
3 WELL RECEIVED AS A NEW SOURCE OF INFORMATION.

4 A WORD ABOUT SORT OF AN INTERESTING
5 DEVELOPMENT THAT HAPPENED AT OUR LAST GRANTS WORKING
6 GROUP, WHICH WAS THE DISEASE TEAM II GRANTS WORKING
7 GROUP. THE ACTUAL RECOMMENDATIONS FROM THAT MEETING
8 WILL BE FORTHCOMING IN OUR JULY BOARD MEETING. BUT
9 AT THE END OF THAT MEETING, WE DID SOMETHING THAT
10 WAS NEW, WHICH WAS WE ASKED THE GRANTS WORKING GROUP
11 WHO HAVE NOW BEEN THROUGH MANY ITERATIONS ACROSS
12 MANY DIFFERENT RFA'S, THIS PARTICULAR GROUP, WE SAID
13 HOW MIGHT WE IMPROVE OUR PROCESS HERE? WHAT ARE
14 SOME IDEAS THAT WE MIGHT USE TO EITHER UNDERTAKE NEW
15 INITIATIVES OR THINGS THAT WOULD BETTER THE WHOLE
16 SEQUENCE THAT WE HAVE IN THESE MEETINGS?

17 AND THAT LED TO A MOST INTERESTING
18 HOUR-AND-A-HALF-LONG DISCUSSION, NOTABLE BOTH FOR
19 THE REAL ENGAGEMENT AS WE HAD SEEN THROUGHOUT THE
20 ENTIRE THREE DAYS OF THE GRANTS WORKING GROUPS BY
21 THE MEMBERS AND A REAL INTEREST IN HELPING US TO
22 DEVELOP NEW IDEAS. AND THIS CAME ON A LATE FRIDAY
23 AFTERNOON WHEN YOU WOULDN'T EXPECT PEOPLE TO BE
24 FULLY ENGAGED, BUT THEY WERE REALLY ENGAGED AND SOME
25 GREAT STUFF CAME OF IT.

BARRISTERS' REPORTING SERVICE

1 WE'VE HAD SOME INTERNAL DISCUSSIONS SINCE
2 THEN, AND WE'RE GOING TO BE BRINGING SOME NEW IDEAS
3 TO THE BOARD AS WE CONTINUE TO REFINE THE
4 SUGGESTIONS THAT CAME OUT OF THAT MEETING SHORTLY.

5 THEN, LET'S SEE HERE, ONE OTHER THING I
6 WANT TO FLAG FOR YOU IS WE HAVE NOT TO DATE, AS FAR
7 AS I KNOW, EVER HAD A BOARD RETREAT. AND WE THINK
8 THAT THIS IS SOMETHING THAT AFTER THE FIRST OF THE
9 YEAR WILL BE SOMETHING THAT WE WOULD BENEFIT FROM
10 GREATLY. TO BEGIN WITH, AS YOU KNOW, AT THE END OF
11 THIS YEAR, A NUMBER OF THE BOARD SEATS ARE UP, AND
12 WE ARE LIKELY TO HAVE SOME ADDITIONAL NEW MEMBERS AT
13 THAT POINT. AND A RETREAT THAT WOULD HELP, AMONG
14 OTHER THINGS, EDUCATE THE NEW BOARD MEMBERS, I
15 THINK, WOULD BE SOMETHING THAT WOULD BE A WELCOME
16 THING.

17 NO. 2, AS YOU KNOW, WE ARE DUE TO HAVE THE
18 FINAL REPORT BY THE IOM AT THE END OF THIS CALENDAR
19 YEAR. THAT REPORT IS SOMETHING THAT WILL BE MUCH
20 ANTICIPATED AND UNDOUBTEDLY VERY INTERESTING AND
21 VERY HELPFUL IN ITS INSIGHTS AND RECOMMENDATIONS.
22 AND THIS WOULD BE SOMETHING WE WOULD ALSO
23 CONTEMPLATE BEING ON THE AGENDA OF THIS RETREAT.

24 AND THEN THE THIRD ITEM WOULD BE
25 CONSIDERATION OF A NUMBER OF THESE IDEAS I JUST

BARRISTERS' REPORTING SERVICE

1 REFERENCED THAT CAME OUT OF THIS DISCUSSION
2 FOLLOWING THE GRANTS WORKING GROUP DISCUSSION. SO
3 ALL OF THIS, I THINK, WOULD BE BENEFICIAL TO HAVE A
4 RETREAT. WE'LL PROBABLY TIME IT TO BE, MARIA,
5 IMMEDIATELY ADJACENT TO THE JANUARY BOARD MEETING.
6 SO IT'S NOT A MATTER OF MAKING EXTRA TIME, AND IT
7 WILL BE A PUBLIC SESSION AS IT WOULD HAVE TO BE. SO
8 MEMBERS OF THE PUBLIC ARE WELCOME. SO JUST STAY
9 TUNED FOR MORE ON THAT, BUT I DID WANT TO FLAG THAT
10 FOR YOU.

11 SO THAT CONCLUDES THE CHAIR'S REPORT. WE
12 HAVE A VERY FULL AGENDA TODAY, SO WE WANT TO MAKE
13 SURE WE MOVE THINGS ALONG. AND I'D LIKE TO NOW TURN
14 THIS OVER TO ALAN FOR THE PRESIDENT'S REPORT.

15 MS. GIBBONS: QUICK QUESTION.

16 CHAIRMAN THOMAS: YES, LEEZA. SORRY.

17 MS. GIBBONS: EXCUSE ME, ALAN. JUST A
18 VERY QUICK QUESTION. FIRST OF ALL, KUDOS AGAIN TO
19 THESE -- FORGIVE ME. JUST A VERY QUICK QUESTION.
20 FIRST OF ALL, IF ANYBODY IS THINKING OF LEAVING THE
21 BOARD, THE ENTICEMENTS OF THAT RETREAT MIGHT MAKE
22 PEOPLE WANT TO STAY, PAJAMA PARTY, GAMES,
23 EVERYTHING. INCREDIBLE.

24 THESE ARE GREAT. I DON'T KNOW WHO ALL WAS
25 INVOLVED IN THIS. THESE ARE ABSOLUTELY FANTASTIC.

BARRISTERS' REPORTING SERVICE

1 MY QUESTION IS CAN WE GET EXTRA COPIES OF THIS
2 PIECE?

3 CHAIRMAN THOMAS: ABSOLUTELY. YES. I
4 WILL SAY THE IDEA OF HAVING THE ANNUAL REPORT IN
5 THAT FORM WAS ORIGINALLY PROPOSED BY AMY ADAMS,
6 WHO'S BEEN ADVOCATING FOR THIS AS SOMETHING THAT WE
7 THOUGHT MIGHT BE A LITTLE BIT EASIER HANDOUT TO GIVE
8 TO FOLKS. THE WHOLE COMMUNICATIONS TEAM LED BY
9 KEVIN MCCORMACK, DON GIBBONS, AND AMY AND TODD,
10 EVERYBODY WORKED EXTENSIVELY ON THAT. AND THERE
11 WERE MANY ITERATIONS. AND IT LOOKS SIMPLE; BUT AS
12 YOU KNOW, SOMETHING LIKE THAT TOOK A LOT OF WORK.
13 SO WOULD LIKE TO THANK THEM FOR THAT.

14 SO, YES, MR. SENATOR.

15 MR. TORRES: YES. I JUST WANT TO ALSO
16 THANK MARIA BONNEVILLE FOR WORKING ON THAT BROCHURE
17 BECAUSE IT HAS RECEIVED GREAT KUDOS FROM MANY
18 FOUNDATIONS THAT I SERVE ON WANTING TO REPLICATE
19 THAT BECAUSE WE SAVE SO MUCH MONEY BY DOING IT IN
20 THIS FORMAT. AND IT'S EASILY ACCESSIBLE, EASILY
21 TRANSFERABLE AT EVENTS OR RALLIES OR WHATEVER,
22 ESPECIALLY FOR PATIENT ADVOCATES. AND I THINK
23 THAT'S WHERE MOST OF THE THING LIES.

24 SECONDLY, I WOULD JUST CAUTION BY USING
25 THE WORD "RETREAT." IF WE CAN NAME IT SOMETHING

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1 ELSE LIKE WORKSHOP, ORIENTATION, OR WHATEVER BECAUSE
2 THE GENERAL PUBLIC OUT THERE THINKS WE'RE GOING TO
3 BE IN A RESORT SOMEWHERE. AND OBVIOUSLY WE'VE NEVER
4 BEEN IN THAT SITUATION. SO I JUST -- LET'S FIND A
5 DIFFERENT WORD OTHER THAN RETREAT.

6 CHAIRMAN THOMAS: SO NOTED. ANY OTHER
7 COMMENTS? YES, MARIA.

8 MS. BONNEVILLE: OH, NO. I WAS JUST GOING
9 TO --

10 CHAIRMAN THOMAS: OKAY. ALL RIGHT. THANK
11 YOU. AND I'D ALSO LIKE, BEFORE I TURN IT OVER TO
12 ALAN, JUST TO NOTE, THANK A COUPLE OTHER MEMBERS OF
13 OUR VERY HARDWORKING STAFF WITH RESPECT TO ALL OF
14 THE WORK ON THE FINANCING THROUGH THE STATE OF
15 CALIFORNIA. LYNN HARWELL AS OUR LEAD ON THAT AND
16 HAS DONE A YEOMAN'S WORK IN HELPING US TO POSITION
17 TO CONTINUE GETTING FULL FUNDING AND ALL THE MANY
18 DIFFERENT ASPECTS ATTENDANT ON THAT EFFORT. SO
19 THANK YOU, LYNN.

20 WITH RESPECT TO OUR BUDGET, MATT PLUNKETT,
21 OUR CFO, AS YOU'VE HEARD FROM PRELIMINARY
22 PRESENTATIONS ON THIS IN PAST BOARD MEETINGS, SPENT
23 AN ENORMOUS AMOUNT OF TIME, HAS RECONFIGURED OUR
24 BUDGET INTO SOMETHING I THINK THAT'S MUCH MORE
25 UNDERSTANDABLE AND LINEAR AND COMPREHENSIVE AND HAS

BARRISTERS' REPORTING SERVICE

1 BEEN VERY WELL RECEIVED BY ALL FOLKS WHO HAVE HEARD
2 IT. SO, MATT, THANK YOU FOR THAT.

3 SO TURN IT OVER TO ALAN.

4 MS. BONNEVILLE: I JUST WANTED TO NOTE FOR
5 THE RECORD THAT FRANCISCO PRIETO, MARCY FEIT, AND
6 JEFF SHEEHY ARE NOW PRESENT. AND I WANTED TO CHECK
7 TO SEE IF DUANE ROTH IS ON THE LINE.

8 MR. ROTH: I AM.

9 MS. BONNEVILLE: AND DR. MELMED. THANK
10 YOU.

11 DR. TROUNSON: SO THANK YOU, CHAIR AND
12 BOARD. AGAIN, STARTING WITH THE SCIENCE SIDE, JUST
13 BEFORE I ACTUALLY START, THERE ARE SOME -- IN THE
14 POCKET OF YOUR FOLDER IS THREE PAPERS THAT WERE
15 PUBLISHED JUST RECENTLY. AND SO I THOUGHT TO
16 INCLUDE THESE BECAUSE SOME OF THESE ARE
17 COMMENTARIES. ONE IS ON CIRM AND DELIVERING CELL
18 THERAPEUTICS IN *NATURE CELL BIOLOGY*. I WAS INVITED
19 TO MAKE THEIR COMMENTARY. THERE'S ONE BY ELLEN
20 FEIGAL AND ELONA BAUM, KEVIN WHITTLESEY, AND JOYCE
21 FREY-VASCONCELLS IN THE JOURNAL THAT WE SUPPORT, THE
22 *STEM CELLS AND TRANSLATIONAL MEDICINE*, REALLY
23 TALKING ABOUT REALLY TAKING ON FOLLOWING ON THE WORK
24 THAT WAS DONE WITH FDA AROUND THE USE OF ANIMAL
25 MODELS IN TRANSLATION. SO IF PEOPLE ARE INTERESTED

BARRISTERS' REPORTING SERVICE

1 IN THAT, I THINK YOU'D FIND THAT INFORMATIVE.
2 THEY'RE IN THE BINDER.

3 AND LASTLY, THERE'S ONE, A COMMENTARY ON
4 STEM CELLS WHICH IS REALLY FOCUSED ON WHAT I WANT TO
5 TELL YOU RIGHT AT THE MOMENT, WHICH IS THE
6 CONVERSION OF CELLS IN THE BODY FROM ONE CELL TYPE
7 TO ANOTHER. SO I WANTED TO TELL YOU A LITTLE BIT
8 ABOUT HEART DISEASE HERE BECAUSE IT'S ALL OF A
9 SUDDEN THERE'S A CASCADE OF WHAT I THINK ARE VERY,
10 VERY IMPORTANT STUDIES.

11 THIS ONE IS THE ONE WE COMMENT ON IN THE
12 JOURNAL *EMBO*, WHICH IS A VERY PRESTIGIOUS JOURNAL,
13 AND WE WERE ASKED TO MAKE A COMMENT ON THE PAPER.
14 AND IT'S OUT OF DEEPAK SRIVASTAVA'S LABORATORY AT
15 GLADSTONE INSTITUTE. AND IF YOU LOOK AT THIS
16 FIGURE, WHICH IS FROM THAT ARTICLE, READ IT BECAUSE
17 IT'S ONLY A COUPLE OF PAGES ANYWAY, WHAT YOU CAN DO
18 WITH FIBROBLASTS OR SKIN CELLS, IF YOU LIKE, THE
19 CELLS WHICH YOU OFTEN GET FROM SKIN AND OTHER
20 TISSUE, VERY COMMON CELL WHICH IS THROUGHOUT THE
21 BODY, YOU CAN ACTUALLY TRANSFECT THEM WITH
22 TRANSCRIPTION FACTORS AND ALTER THEIR FATE INTO IPS
23 CELLS. EVERYBODY KNOWS THAT PRETTY WELL NOW.

24 AND YOU CAN ALSO DO THAT FROM EMBRYONIC
25 STEM CELLS. YOU CAN ALTER THEIR FATE TO

BARRISTERS' REPORTING SERVICE

1 CARDIOMYOCYTES. SO IF YOU HAVE CARDIOMYOCYTES, THE
2 POTENTIAL IS THAT YOU COULD DELIVER THEM TO THE
3 HEART AND TRANSPLANTATION. SO THERE'S SOME VERY
4 INTERESTING WORK GOING IN DERIVING THESE CELLS AND
5 USING THEM FOR TRANSPLANTATION.

6 WHAT'S REALLY MORE INTERESTING, I THINK,
7 WE WILL NOW, AND I THINK IT'S ACTUALLY GOING TO BE A
8 REALLY NEW PLATFORM FOR WORK REALLY ACROSS THE WHOLE
9 STEM CELL SPACE, IS THAT YOU CAN USE A DIFFERENT SET
10 OF TRANSCRIPTION FACTORS, AND YOU CAN ACTUALLY
11 CONVERT THEM DIRECTLY TO CARDIOMYOCYTES WITHOUT
12 HAVING GONE BACK TO THE VERY PRIMITIVE CELLS. THE
13 VERY PRIMITIVE CELLS, OF COURSE, WILL FORM TERATOMAS
14 IF THEY'RE ACTUALLY TRANSPLANTED IN AN
15 UNDIFFERENTIATED STATE. SO HERE YOU BYPASS THAT
16 PARTICULAR ISSUE BY CONVERTING THEM DIRECTLY TO
17 CARDIOMYOCYTES. SO THAT'S EFFECTIVE TECHNOLOGY
18 WHICH REALLY CAME FROM DEEPAK SRIVASTAVA'S
19 LABORATORY.

20 WHAT HE'S JUST RECENTLY SHOWN IS THAT YOU
21 CAN USE A RETROVIRAL VECTOR AND YOU CAN ACTUALLY
22 INJECT THAT INTO THE HEART. YOU CAN CONVERT THE
23 STROMAL OR FIBROBLAST COMPONENTS IN THE HEART IN
24 SITU INTO CARDIOMYOCYTES AND, THEREFORE, REDUCE THE
25 SCAR AND EFFECTIVELY IMPROVE THE OUTPUT OF THE

BARRISTERS' REPORTING SERVICE

1 HEART. SO THIS IS A DIRECT CONVERSION OF THOSE
2 CELLS WHICH ARE STROMAL, WHICH ARE COMPANION CELLS
3 TO CARDIOMYOCYTES, THE HEART MUSCLE CELLS, WHICH ARE
4 THERE IN RELATIVELY LARGE NUMBERS. YOU CAN CONVERT
5 THEM TO HEART MUSCLE CELLS IN SITU.

6 NOW, THIS IS, I THINK, A VERY IMPORTANT
7 OBSERVATION AND ONE WHICH HAS DRAWN A LOT OF
8 INTEREST.

9 NOW, THERE IS SECONDLY ANOTHER PAPER. A
10 PAPER CAME OUT FROM ERIC OLSON'S LAB IN THE
11 UNIVERSITY OF TEXAS ON USING A DIFFERENT SYSTEM.
12 THEY SHOWED THAT FOUR TRANSCRIPTION FACTORS
13 COOPERATE TO REPROGRAM CARDIOMYOCYTES INTO HEART
14 MUSCLE CELLS IN THE LABORATORY. SO THIS STUDY WAS
15 REALLY CONFIRMING THE SRIVASTAVA STUDY, THAT
16 RETROVIRAL FORCED EXPRESSION OF THESE TRANSCRIPTION
17 FACTORS, THESE PARTICULAR FOUR, SO THEY USED FOUR
18 INSTEAD OF THREE, SO THEY ADDED AN EXTRA
19 TRANSCRIPTION FACTOR HERE, BUT THAT'S, I THINK,
20 REALLY BY THE BY WHETHER YOU USE THREE OR FOUR. AND
21 THEY PRODUCED CARDIOMYOCYTES IN THE DIVIDING CELL
22 FRACTION WHICH CARDIOMYOCYTES DON'T DIVIDE. SO IT
23 HAS TO BE IN THE CELLS, THE COMPANION CELLS, THESE
24 STROMAL CELLS IN THE HEART.

25 SO THEY SHOWED THAT IT'S THOSE CELLS WHICH

BARRISTERS' REPORTING SERVICE

1 WERE ACTUALLY TURNED INTO CARDIOMYOCYTES. AND THESE
2 CELLS PRODUCE FUNCTIONAL MYOCYTES, IMPROVING CARDIAC
3 FUNCTION AN ADVERSE VENTRICULAR REMODELING, WHICH
4 MEANS THAT THE PROBLEM AFTER THE HEART ATTACK
5 GENERALLY INCREASES AND INCREASES. WELL, THEY WERE
6 ABLE TO STOP THE CONTINUATION OF THAT VENTRICULAR
7 REMODELING WHICH CAUSES THE BIG SCAR TO OCCUR.

8 SO INDEPENDENT CONFIRMATION, WHICH IS
9 REALLY, REALLY IMPORTANT WHEN YOU GET INTO THIS
10 SCIENTIFIC FIELD. OFTEN, UNFORTUNATELY, THERE'S ONE
11 OBSERVATION AND IT'S NOT REPEATED BY AN INDEPENDENT
12 LABORATORY. SO I'LL JUST SHOW YOU THIS FIGURE
13 BECAUSE ON THE RIGHT-HAND SIDE AS YOU LOOK AT IT,
14 THE INJURED CELLS ARE THE ONES ARE THEY'RE GETTING
15 THE VIRUS WITH THESE TRANSCRIPTION FACTORS ON THE
16 FAR RIGHT-HAND SIDE. AND IT SHOWS THOSE CELLS BEING
17 CONVERTED TO CARDIOMYOCYTES, AND THE GREEN CELL DOWN
18 THERE IS THE ONE WHICH IS ACTUALLY WORKING IN TERMS
19 OF CONTRACTION. SO THEY'RE FUNCTIONAL, THEY'RE
20 EFFECTIVE, THEY'RE THERE IN REASONABLE NUMBERS, AND
21 IT LOOKS LIKE FROM THESE TWO STUDIES ARE A VERY
22 WORTHWHILE AREA TO PURSUE. NOT READY FOR PRIME TIME
23 YET, BUT READY TO PURSUE.

24 NOW, IN ADDITION TO ALL OF THAT, ANOTHER
25 PAPER APPEARED IN APRIL THIS YEAR. AND THIS WAS USE

BARRISTERS' REPORTING SERVICE

1 NOT OF TRANSCRIPTION FACTORS, BUT MICRO-RNA. AND
2 THESE MICRO-RNA'S ARE ABLE TO DO THE SAME JOB AS THE
3 TRANSCRIPTION FACTORS. THEY HAVE TO BE INTRODUCED
4 ALSO INTO THE CELL. YOU HAVE TO INTRODUCE THEM IN
5 THE SAME WAY YOU WOULD INTRODUCE A TRANSCRIPTION
6 FACTOR. SO THERE'S A VIRAL APPROACH TO INTRODUCING
7 THIS.

8 THIS PAPER WAS PUBLISHED IN CIRCULATION
9 RESEARCH FROM THE DUKE CARDIAC RESEARCH CENTER
10 GROUP. AND THEY USED A COMBINATION OF FOUR OF THESE
11 MICRO-RNA'S, NUMBERS 133, 208, AND 499. AND THEY'RE
12 CAPABLE OF INDUCING DIRECT CELLULAR PROGRAM OF THE
13 FIBROBLAST TO CARDIOMYOCYTE-LIKE CELLS IN THE
14 LABORATORY, AND ALSO THEY'RE ABLE TO DEMONSTRATE
15 THAT IN MICE THAT THEY'RE ABLE TO EFFECT THAT CHANGE
16 ALSO WHEN INJECTED INTO MICE IN A LENTIVIRAL VECTOR.
17 OTHER STUDIES HAVE BEEN USING A DIFFERENT APPROACH,
18 BUT LENTIVIRAL APPROACH SEEMS TO BE ONE WHICH IS
19 MUCH MORE ACCEPTABLE TO THE REGULATORY AUTHORITIES.

20 SO HERE WE HAVE NOW TWO DIFFERENT
21 APPROACHES TO CONVERSION OF HEART CELLS FROM THE
22 COMPANION CELLS TO THE WORKING CELLS. NOW, THIS IS
23 A VERY IMPORTANT CHANGE, I THINK, AND A VERY
24 IMPORTANT STEP IN THE WHOLE OF STEM CELL MEDICINE
25 AND SOMETHING THAT WE WANT TO BE THOUGHTFUL ABOUT.

BARRISTERS' REPORTING SERVICE

1 THE PICTURES THERE SHOW THAT THE CONVERSION OF THE
2 CELLS IN THE MOUSE HEART WERE FROM ONE TYPE TO THE
3 WORKING CARDIOMYOCYTES.

4 SO IN ADDITION TO THAT, THERE WAS ANOTHER
5 PAPER THAT JUST CAME OUT ON MAY 22D, WHICH IS NOT
6 VERY LONG AGO, CHAIR, ALSO IN THIS WHOLE AREA. THE
7 PARTICULAR AREA IS INCREDIBLY ALIVE, AND IT'S NOT
8 EXACTLY SYNONYMOUS WITH THOSE OTHER STUDIES. THEY
9 SHOWED THAT IPS CELLS COULD BE REPROGRAMMED FROM
10 SKIN SAMPLES OF PATIENTS WITH ADVANCED HEART
11 FAILURE, DIFFERENTIATED, AND A FUNCTIONAL
12 CARDIOMYOCYTE. SO YOU CAN TAKE PATIENTS WHO ARE
13 VERY ILL WITH ADVANCED HEART FAILURE AND REPROGRAM
14 THEM INTO IPS CELLS. AND THEN THEY COULD SHOW THAT
15 THE CARDIOMYOCYTES THAT THEY'RE ABLE TO DEVELOP IN
16 CULTURE SHOWED SYNCHRONIZED ELECTRICAL ACTIVITY
17 BETWEEN THE HUMAN AND THE NEONATAL RAT MYOCYTES IN
18 CO-CULTURE. AND WHEN THEY WERE TRANSPLANTED IN
19 HEARTS, THEY ENGRAFTED, SURVIVED, AND STRUCTURALLY
20 INTEGRATED INTO RAT CARDIOMYOCYTES.

21 SO YOU CAN ACTUALLY TAKE CELLS FROM THESE
22 PATIENTS AND CONVERT THEM. AND SO WHETHER YOU
23 CONVERT THEM TO THE IPS CELL AND USE THEM AS A
24 TRANSPLANT OR YOU CONVERT THEM IN SITU, WHICH IS
25 VERY ATTRACTIVE, I THINK, AND AVOID SOME OF THE

BARRISTERS' REPORTING SERVICE

1 ISSUES OF CULTURING CELLS AND WHAT YOU MIGHT GET AS
2 A CONSEQUENCE OF HANDLING, MANIPULATING THOSE CELLS.

3 IF WE CAN BUILD A ROBUST TECHNOLOGY IN
4 THIS AREA, I THINK WE'VE GOT SOMETHING VERY SPECIAL
5 IN HEART DISEASE. AND YOU COULD THINK THIS MIGHT
6 APPLY TO A RANGE OF OTHER CONDITIONS. SO I THINK
7 IT'S A VERY INTERESTING SET OF PAPERS AND ONE WHICH
8 I THINK IS GOING TO SET THE FIELD IN THAT DIRECTION
9 FOR SOME TIME. SO I WANTED YOU TO BE AWARE OF THAT.

10 THE OTHER PAPER, THE LAST PAPER I WANT TO
11 DRAW YOUR ATTENTION TO I THINK IS A VERY IMPORTANT
12 PAPER, AND IT'S REALLY ONE THAT I IDENTIFIED OUT OF
13 SCIENCE TRANSLATIONAL MEDICINE. AND IT COMES FROM A
14 LARGE GROUP OF PEOPLE WHO ARE WORKING AT THE
15 UNIVERSITY OF PENN, CELL GENE, UCSF, UCLA, WALTER
16 REED NATIONAL MILITARY MEDICAL CENTER.

17 AND THEY'VE LOOKED AT THE DECADE LONG
18 SAFETY AND FUNCTION OF RETROVIRAL MODIFIED CHIMERIC
19 ANTIGEN RECEPTOR T-CELLS. IMPORTANT PART ABOUT THIS
20 IS THEY'RE STUDYING THE PATIENTS WHO HAVE HAD THESE
21 GENETICALLY MODIFIED CELLS TRANSPLANTED AND WHETHER
22 IN A DECADE LONG EXPERIENCE WHAT IS THE OUTCOME?
23 WHAT ARE THE DANGERS? WHAT ARE THE ISSUES
24 ASSOCIATED WITH USING THESE GENETICALLY MODIFIED
25 CELLS? THERE WAS A LOT OF CONCERN THAT PARTICULARLY

BARRISTERS' REPORTING SERVICE

1 IF YOU USE THE KIND OF RETROVIRAL VECTORS THAT THEY
2 USE IN ORDER TO GET THESE TRANSFORMATIONS, THAT YOU
3 MIGHT END UP WITH ISSUES, PARTICULARLY IF THE
4 INSERTIONS ARE ANYWHERE NEAR GROWTH FACTOR GENES OR
5 GENES RELATED TO GROWTH FACTORS THAT MIGHT INDUCE
6 CLONAL CONVERSION TO CELLS THAT WOULD MULTIPLY IN AN
7 UNREGULATED WAY.

8 SO THESE WERE CONCERNS THAT THE FIELD HAD.
9 THEY STUDIED THREE LARGE CLINICAL TRIALS TO EVALUATE
10 GAMMA RETROVIRAL VECTOR ENGINEERED T-CELLS FOR HIV.
11 AND IN THOSE PATIENTS THEY FOUND THE T-CELLS IN JUST
12 ABOUT EVERY ONE OF THE PATIENTS SAMPLED EVEN AFTER
13 11 YEARS. SO THESE ARE DONOR CELLS WITH THESE
14 RETROVIRAL INSERTIONS. THEY'RE THERE AFTER 11 YEARS
15 AT FREQUENCIES WELL ABOVE T LEVELS FOR MOST VACCINE
16 APPROACHES. SO THAT WAS INTERESTING, THAT THESE
17 CELLS WOULD HANG ON AND WORK FOR THAT LENGTH OF TIME
18 BECAUSE WE'RE ALSO TOLD THAT THESE T-CELLS WILL
19 PROBABLY DECAY VERY QUICKLY.

20 THE TRANSGENE RETAINED EXPRESSION AND
21 FUNCTION IN SITU, AND THERE WAS NO EVIDENCE OF
22 VECTOR INDUCED IMMORTALIZATION; THAT IS, CONVERSION
23 TO THIS UNCONTROLLED GROWTH, WHICH WOULD BE A REAL
24 CONCERN IN PATIENTS IF THAT HAPPENED. SO THESE
25 DONOR T-CELLS HAD STABLE LEVELS OF ENGRAFTMENT, AND

BARRISTERS' REPORTING SERVICE

1 THE DECAY HALF-LIFE WAS GREATER THAN 16 YEARS, WHICH
2 IS TERRIFIC. I THINK THAT'S REALLY -- PERHAPS A
3 LITTLE UNEXPECTED. IF YOU TALK TO MOST T-CELL
4 RESEARCHERS, THEY WOULD HAVE THOUGHT THAT THE DECAY
5 LEVEL WOULD HAVE BEEN MUCH, MUCH QUICKER THAN THAT.

6 SO I'LL SHOW YOU -- THESE RESULTS WILL
7 HAVE, I THINK, A BIG IMPACT IN HUMAN STUDIES BECAUSE
8 IT WILL CREATE A VERY STRONG INTEREST IN UTILIZING
9 THIS APPROACH. AND I'M JUST SHOWING YOU THIS FIGURE
10 BECAUSE THESE ARE THE THREE STUDIES, AND THEY'RE
11 FOLLOWING THE PATIENTS OVER THE 11 YEARS, WHICH IS
12 THE X AXIS THERE. AND YOU CAN SEE THERE'S SOME
13 VARIATION IN THE PATIENTS, BUT THEY'RE MAINTAINING
14 THOSE T-CELL LEVELS PRETTY CONSISTENTLY ACROSS THAT
15 11-YEAR TIME FRAME.

16 SO I THINK THIS IS A VERY NICE PAPER. I
17 THINK IT'S ONE WHICH WILL BE REALLY STRONGLY
18 WELCOMED. AND I HAVEN'T SPOKEN TO PEOPLE LIKE JEFF
19 SHEEHY ABOUT IT, BUT I ACTUALLY THINK THE HIV FIELD
20 WILL FEEL THAT THIS IS A VERY STRONG, POSITIVE
21 PAPER. BUT I THINK IT'S ALSO STRONGLY POSITIVE FOR
22 THE USE OF THIS APPROACH IN A NUMBER OF OTHER
23 CONDITIONS, PARTICULARLY GENETIC DISEASE AND OTHER
24 CONDITIONS WHICH ARE REALLY ON THE VERGE OF ALSO
25 MOVING INTO CLINICAL TRIALS.

BARRISTERS' REPORTING SERVICE

1 SO BACK TO BUSINESS. WE HAVE A NEW HIRE.
2 BILL GIMBEL, OUR I.T. DIRECTOR, HAS COME ON BOARD.
3 BILL HAS BEEN WITH US FOR SOME YEARS, AND BILL IS
4 HERE. SO WELCOME, BILL. THANK YOU VERY MUCH FOR
5 JOINING US.

6 (APPLAUSE.)

7 DR. TROUNSON: SO BILL WAS A CONTRACTOR
8 FOR US, I THINK, NOW FOR TWO YEARS. YES. IT SEEMED
9 LIKE HE'S THERE FOREVER. HE'S ALWAYS ONE OF THE
10 LAST PEOPLE TO LEAVE THE PLACE. HE'S A FANTASTIC
11 PERSON, AND I'M VERY PLEASED HE WAS ABLE TO CONVERT
12 TO BE A FULL-TIME STAFF MEMBER.

13 THE UPCOMING RFA'S, JUST TO REMIND YOU,
14 EARLY TRANSLATIONAL III IS BEING DECIDED HERE AT
15 THIS MEETING. BASIC BIOLOGY IV, THE GRANTS WORKING
16 GROUP REVIEW IS IN JUNE. THE IPS CELL INITIATIVE,
17 WE'RE GOING TO POST PROBABLY LATE JUNE. I HAVE A
18 LITTLE CONCERN, AND I'VE TALKED TO ART AND OTHER
19 MEMBERS OF OUR TEAM ABOUT THIS. THERE'S A BILL
20 THAT'S BEING DISCUSSED IN COMMITTEE AT THIS STAGE,
21 AND IT'S ONE I THINK THAT A LOT OF THE ACADEMIC
22 INSTITUTIONS ARE VERY CONCERNED ABOUT AND SHOULD BE
23 BECAUSE IT RELATES TO WHAT YOU WOULD HAVE TO DO WITH
24 SAMPLES OBTAINED FROM PATIENTS, AND IT MAKES IT
25 ALMOST IMPOSSIBLE TO REALLY DO THE KIND OF STUDIES

BARRISTERS' REPORTING SERVICE

1 THAT WE'RE TALKING ABOUT IN SOME OF OUR RESEARCH
2 PROGRAMS, PARTICULARLY THIS IPS CELL INITIATIVE.

3 SO I'VE TALKED TO ART ABOUT THAT. HE'S
4 ENGAGED ON THIS. WE'RE LOOKING AT IT. WE'RE
5 KEEPING A MONITOR ON IT, BUT THE UNIVERSITIES,
6 MEDICAL CENTERS ARE PRETTY ENGAGED ON IT. IF YOU
7 AREN'T ENGAGED, I THINK MAYBE HAVE A TALK TO ART. I
8 THINK IT'S A VERY IMPORTANT ISSUE FOR MEDICAL
9 RESEARCH. AND I THINK UNFORTUNATELY THE REAL KEY
10 PARTS OF IT HAVE BEEN MISSED BY WHOEVER WAS DRAFTING
11 THE BILL. SO LET'S HOPE THAT WE GET A LITTLE BETTER
12 SENSE HERE FOR THE SAKE OF MEDICAL RESEARCH.

13 SO WE MAY BE PUTTING THIS DOWN A LITTLE
14 BIT, HOPING THAT -- BECAUSE IF THE BILL CAME
15 THROUGH, IT WOULD MAKE LIFE VERY, VERY DIFFICULT FOR
16 US TO DELIVER ON THIS.

17 OUR GENOMICS INITIATIVE, WE EXPECT TO POST
18 THE RFA IN JULY. DISEASE TEAM THERAPY DEVELOPMENT,
19 THERE'S GOING TO BE A FUNDING DECISION IN JULY. SO
20 THAT'S REALLY IMPORTANT, OF COURSE, THAT PROGRAM.
21 NEW FACULTY PHYSICIAN SCIENTIST TRANSLATIONAL
22 RESEARCH AWARD, HECK OF A MOUTHFUL. THAT'S GOING TO
23 BE -- THE GRANTS WORKING GROUP WILL REVIEW THAT IN
24 OCTOBER. AND THE STRATEGIC PARTNERSHIP AWARDS,
25 THOSE APPLICATIONS, THE TENTATIVE REVIEW IN

BARRISTERS' REPORTING SERVICE

1 SEPTEMBER.

2 OUR COLLABORATIVE FUNDING PROGRAMS, WE NOW
3 HAVE 21 COLLABORATIVE FUNDING PARTNERS, WHICH I
4 THINK IS TERRIFIC. WE'VE GONE OVER 20. AND THAT
5 NOW INCLUDES THE MUSCULAR DYSTROPHY ASSOCIATION
6 THAT'S SIGNED AN MOU WITH US. AND THANKS TO MATT
7 FOR HELPING IN THAT PROCESS. MATT AND PARTICULARLY
8 NANCY KOCH, WHO HELPS ME RUN THAT PROGRAM, VERY,
9 VERY EFFICIENT, VERY EFFECTIVE IN THIS COLLABORATIVE
10 PARTNER ARRANGEMENT.

11 THEY'RE THE THIRD FOUNDATION TO JOIN US
12 AFTER THE NEW YORK STEM CELL FOUNDATION AND JDRF.
13 WE HAVE ADDITIONAL FOUNDATION OUTREACH CURRENTLY
14 UNDER WAY. SO WE'RE TRYING TO BRING THOSE
15 FOUNDATIONS INTO THE PROGRAMS SO THEY WOULD FUND
16 OUT-OF-CALIFORNIA COMPONENTS; BUT ALSO, IF THEY
17 CARED TO, THEY COULD FUND IN-CALIFORNIA COMPONENTS
18 TOGETHER WITH US. THAT IS MORE LEVERAGE MONEY FOR
19 WHAT WE DO.

20 BASIC BIOLOGY IV RFA INCLUDES INDIA,
21 FRANCE, CHINA, AND GERMANY PARTICIPATING AS
22 CO-FUNDERS. AND IT'S THE FIRST INVOLVEMENT FOR
23 INDIA AND FRANCE IN THOSE PROGRAMS. AND THE FOURTH
24 ANNUAL FUNDERS MEETING IS GOING TO BE HELD AT THE
25 ISSCR MEETING IN JAPAN. WE HAVE A SCIENTIFIC

BARRISTERS' REPORTING SERVICE

1 RESOURCE WEB PORTAL, AND I THINK IT WOULD BE
2 INTERESTING TO MANY OF THE BOARD MEMBERS. THIS WILL
3 FACILITATE ACCESS AND INFORMATION EXCHANGE AMONGST
4 SCIENTISTS IN CALIFORNIA AND THOSE RESEARCHERS WHO
5 ARE IN THE COLLABORATIVE FUNDING PARTNER
6 JURISDICTIONS. IT ENHANCES OUR ABILITY TO LOCATE
7 RESOURCES WORLDWIDE.

8 SO THIS ENABLES US TO ACTUALLY BE MORE
9 EFFECTIVE AT WHAT WE DO, AND WE'RE DOING IT THROUGH
10 A PARTNER CALLED SCIENCE EXCHANGE. THEY HAVE THE
11 CAPACITY TO DO THIS. WE'RE ADDING THE PORTAL TO THE
12 EXISTING SCIENCE EXCHANGE PLATFORM. CIRM AND THE
13 COLLABORATIVE FUNDING PARTNERS WILL POPULATE THE
14 SITE WITH RELEVANT, NONCONFIDENTIAL INFORMATION FOR
15 ZERO COST.

16 THE TIMING WILL BE THE PROJECT UNDER WAY.
17 THE FIRST WE'RE TRYING TO DO WITH GERMANY AND THAT'S
18 CURRENTLY UNDER WAY. AND WE HOPE TO BE FULLY
19 OPERATIONAL BY THE END OF THE YEAR. SO IN
20 CALIFORNIA, CALIFORNIAN RESEARCHERS WILL BE ABLE TO
21 LOCATE QUALIFIED PARTNER RESEARCHERS ELIGIBLE FOR
22 COLLABORATIVE FUNDING PARTNERING ON SPECIFIC RFA'S
23 AND VICE VERSA. THE COLLABORATIVE FUNDING
24 RESEARCHERS CAN IDENTIFY CALIFORNIAN RESEARCHERS
25 WITH THE DESIRED SKILLS AND EXPERTISE.

BARRISTERS' REPORTING SERVICE

1 WE'VE HAD OUR PERFORMANCE AUDIT, WHICH IS
2 COMPLETE. I THINK YOU WILL HEAR THE RESULTS OF THAT
3 TODAY. YOU'VE GOT SOME INFORMATION IN YOUR FOLDERS.
4 WE WERE FOUND TO BE IN FULL AND ABSOLUTE COMPLIANCE.
5 THERE WERE RECOMMENDATIONS FOR IMPROVED PERFORMANCE,
6 AND STAFF PLAN TO FOLLOW UP, ANALYZE EACH OF THESE
7 RECOMMENDATIONS, TAKE APPROPRIATE ACTION, TRACK THE
8 OUTCOMES, AND PRESENT THE FULL PLAN AT THE NEXT ICOC
9 MEETING. SO IT'S UNDER WAY. MANY OF THE ACTIONS
10 ARE ACTUALLY UNDER WAY, AND THE TEAM IS FULLY
11 ENGAGED IN GETTING THESE RECOMMENDATIONS ACTIVATED
12 UPON.

13 THERE'S A WORKSHOP WITH CHINA. MOST IS
14 THE MINISTRY OF SCIENCE AND TECHNOLOGY IN CHINA
15 FOCUSED ON NETWORKING AND COLLABORATIVE
16 OPPORTUNITIES BETWEEN SCIENTISTS IN CHINA AND
17 CALIFORNIA TO BE HELD JUNE 10TH THROUGH THE 12TH IN
18 SHANGHAI. IT WILL BE ATTENDED BY 10 TO 12
19 CALIFORNIAN SCIENTISTS AND 15 TO 20 CHINESE
20 SCIENTISTS, INCLUDING THE LEADING STEM CELL
21 RESEARCHERS THERE. AND THE FOCUS WILL BE ON
22 NEURODEGENERATIVE DISEASES, SPINAL CORD INJURY, AND
23 BASIC STEM CELL BIOLOGY.

24 WE ALSO HAVE OUR FIRST WORKSHOP WITH OUR
25 SOUTH AMERICAN COLLEAGUES IN SAO PAOLO IN OCTOBER.

BARRISTERS' REPORTING SERVICE

1 WE'VE CONFIRMED 11 SCIENTISTS FROM CALIFORNIA, WHICH
2 INCLUDE THE CITY OF HOPE, KECK GRADUATE INSTITUTE,
3 SALK, STANFORD, UC SAN DIEGO, UC IRVINE, SANTA
4 BARBARA, SAN DIEGO IS THERE, UCSF. THERE ARE PEOPLE
5 COMING FROM ALL OF THESE PLACES. THERE ARE FOUR
6 SCIENTISTS FROM ARGENTINA AND 19 FROM BRAZIL. THE
7 ARGENTINEANS HAVE GOT A CONFERENCE ACTUALLY AT THAT
8 SAME TIME, BUT I WANTED TO TRY AND DRAW SOME OF THE
9 ARGENTINEAN SCIENTISTS INTO THIS MEETING.

10 SO OUR APPROACHES WILL BE AGAIN FOCUSED ON
11 NEURODEGENERATION, CARDIOVASCULAR, EYE, AND LIVER
12 DISEASES.

13 IN TERMS OF INDUSTRY ENGAGEMENT, WE HAVE
14 BIO COMING UP. I THINK ELONA BAUM WILL BE AT BIO.
15 I'M THINKING ELLEN MIGHT BE AT BIO AS WELL. I WON'T
16 BE. THE FOCUS WILL BE ON REGENERATIVE THERAPIES IN
17 THE CLINIC. SO CIRM WILL BE CO-HOSTING WITH THE
18 ALLIANCE FOR REGENERATIVE MEDICINE A WORKSHOP DURING
19 THE BIO CONFERENCE. SO THAT'S THE ONE THAT'S
20 FOCUSED ON REGENERATIVE THERAPIES.

21 THERE'S A STEM CELL MEETING ON THE MESA
22 WHICH HAPPENS EVERY YEAR OCTOBER 30TH TO 31ST. AND
23 THE PLANNING IS UNDER WAY FOR A SECOND INDUSTRY
24 PARTNERING CONFERENCE AS PART OF THE STEM CELL
25 MEETING ON THE MESA. THAT'S STRONGLY SUPPORTED BY

BARRISTERS' REPORTING SERVICE

1 OUR COLLEAGUES DOWN THERE. BUT IT WENT VERY, VERY
2 WELL LAST YEAR.

3 WE HAVE A STRATEGIC PARTNER RFA POSTED
4 WEBINAR. DEADLINE FOR LETTERS OF INTENT ON THE MAY
5 16TH. CIRM WILL BE LED BY -- ELLEN FEIGAL HELD A
6 WEBINAR REGARDING THAT RFA, IN ADDITION TO OUTLINING
7 THE REQUIREMENTS, PROVIDED GUIDANCE ON HOW TO
8 PREPARE A STRONG RFA. SO WE RESPONDED TO INDUSTRY'S
9 NEEDS, TRYING TO GIVE THEM MORE INFORMATION ABOUT
10 HOW TO MORE EFFECTIVELY PREPARE THEIR APPLICATION.
11 AND SO THIS REALLY CAME OUT OF SOME RECOMMENDATIONS
12 FROM THE GRANTS WORKING GROUP. WE LISTENED TO WHAT
13 THE DEFICIENCIES WERE IN SOME OF THE INDUSTRY
14 APPLICATIONS, AND WE'RE TRYING TO GIVE THEM SOME
15 HEADS UP ABOUT THE DOS AND DON'TS OF ACTUALLY
16 APPLYING FOR CIRM FUNDING. AND I THINK IT WENT VERY
17 WELL.

18 ELLEN IS ALSO GOING TO PREPARE A WHITE
19 PAPER FOR US SO THAT IT'S RESIDENT THERE ON OUR
20 WEBSITE AND PEOPLE WILL BE ABLE TO LOOK AT IT, GET
21 THE DOS AND DON'TS, HELP THEM TO PREPARE BETTER
22 APPLICATIONS. AND WE'RE FULLY IN OUTREACH TO BOTH
23 VC'S AND PHARMA AT THE PRESENT TIME. MAYBE A LITTLE
24 TOO EFFECTIVELY PERHAPS. AS THE CHAIRMAN SAID,
25 WE'VE BEEN KIND OF OVERWHELMED WITH RESPONSE FROM

BARRISTERS' REPORTING SERVICE

1 INDUSTRY AT THE MOMENT. I THINK IT WOULD BE A FAIR
2 THING TO SAY THAT WE GOT A LOT MORE INTEREST FROM
3 INDUSTRY THAN WE EXPECTED FOR OUR STRATEGIC
4 PARTNERING RFA.

5 SO I'LL HAND OVER TO MATT NOW TO DO THE
6 FINANCE REPORT. BUT JUST THANKS TO EVERYBODY AGAIN.
7 THE TEAM HERE AT CIRM HAS BEEN WORKING OVERTIME.
8 IT'S BEEN GREAT WORKING WITH THEM ALL, AND IT'S BEEN
9 VERY EFFECTIVE COLLABORATION WITH MARIA AND HER
10 COLLEAGUES AS WELL. THANK YOU.

11 DR. PLUNKETT: THANK YOU, ALAN. SO I WILL
12 RUN THROUGH THE CIRM FINANCES. AS OF APRIL 30TH OF
13 THIS YEAR THROUGH THE END OF LAST MONTH, THE
14 OPERATING EXPENSES TOTALED \$11.0 MILLION. THE PRIOR
15 YEAR PERIOD WAS \$10.1 MILLION. GRANTS DISBURSEMENT,
16 194 MILLION VERSUS THE PRIOR YEAR PERIOD OF 172
17 MILLION. AND THE AVAILABLE BOND CASH AS OF THE END
18 OF LAST MONTH WAS 93 MILLION. THIS IS A DECREASE OF
19 \$65 MILLION FROM THE JANUARY 31ST NUMBERS WHICH I
20 SHARED WITH YOU AT THE MARCH BOARD MEETING IN
21 SACRAMENTO.

22 TO PROVIDE SOME FURTHER DETAIL ON THE
23 OPERATING EXPENSES AS COMPARED TO THE PRIOR YEAR
24 TEN-MONTH PERIOD, THE LARGEST INCREASE WAS DUE TO
25 EMPLOYEE EXPENSES, AN INCREASE OF 14 PERCENT OVER

BARRISTERS' REPORTING SERVICE

1 THE PRIOR YEAR PERIOD. SOME OTHER LARGER VARIANCES
2 THAT I WILL HIGHLIGHT FOR THE ICOC INCLUDE LOWER
3 THAN EXPECTED EXPENSE -- OR LOWER THAN THE PRIOR
4 YEAR PERIOD ON GRANTS REVIEWS, LOWER BY 31 PERCENT;
5 LOWER SPENDING ON INFORMATION TECHNOLOGY BY 33
6 PERCENT; AND AN INCREASE OF \$138,000 IN SCIENTIFIC
7 MEETINGS.

8 THE DRIVER FOR THE INCREASE IN EMPLOYEE
9 EXPENSES WAS THE INCREASE FROM 46 TO 54 FTE'S. THE
10 CONTRACTING INCREASE IN EXPENSE PRIMARILY REFLECTS
11 THE EXPENSES ON THE IOM REVIEW. THE SCIENTIFIC
12 MEETINGS REFLECTS THE WORLD STEM CELL SUMMIT, WHICH
13 WAS \$111,000, AND THEN THE ADDITIONAL FIGURE FOR
14 MEETINGS WAS THE GRANTEE MEETING WAS \$175,000. THIS
15 OCCURS EVERY 18 MONTHS. AND THE COST OF THE GRANTS
16 WORKING GROUP MEETING WHICH WAS HELD IN APRIL IS NOT
17 YET REFLECTED IN ACTUAL EXPENDITURES.

18 IN ADDITION, THIS IS A FORECAST TO FISCAL
19 YEAR-END AS OF JUNE 30TH. AND WHAT I'VE DONE HERE
20 IS HIGHLIGHTED FOR EACH OF THE BUDGET CATEGORIES THE
21 FISCAL YEAR 11-12 BUDGET, A FORECAST TO YEAR-END,
22 AND THEN THE VARIANCE IN BOTH DOLLARS AND PERCENTAGE
23 TERMS.

24 THE OVERALL FIGURES ON OUR FISCAL YEAR
25 11-12 BUDGET IS \$18.5 MILLION. WE'RE FORECASTING A

BARRISTERS' REPORTING SERVICE

1 FIGURE OF 16.5 TO YEAR-END, AND THAT'S \$2 MILLION
2 UNDER BUDGET. THE LARGEST DRIVER IN THIS IS \$1.1
3 MILLION IN UNDERSPENDING IN EMPLOYEE EXPENSES. THIS
4 IS DUE TO THE FACT THAT A NUMBER OF OUR POSITIONS
5 HAVE BEEN EXTREMELY HARD TO FILL, AND WE'VE HAD
6 SEVERAL POSITIONS THAT HAVE BEEN OPEN FOR MUCH OR
7 ALL OF THE YEAR TO DATE.

8 SO AS YOU'RE LOOKING AT THESE FIGURES, IF
9 YOU WANT TO THINK ABOUT WHAT AN ACTUAL RUN RATE
10 EXPENSE WOULD BE, I WOULD SUGGEST ADDING BACK IN
11 THAT VARIANCE. SO IT'S REALLY MORE LIKE A 17.6
12 MILLION PER YEAR SPENDING ON A RUN RATE BASIS.

13 IN ADDITION, SOME OF THE ADDITIONAL
14 SAVINGS THAT HAVE RESULTED IN UNDERSPENDING ON OUR
15 BUDGET, SOME OF THE LARGER ITEMS ARE LOWER THAN
16 EXPECTED SPENDING ON CONTRACTING, LOWER THAN
17 EXPECTED SPENDING ON GRANTS REVIEWS, AND LOWER THAN
18 EXPECTED SPENDING ON SCIENTIFIC MEETINGS.

19 THAT CONCLUDES THE BUDGET REPORT, AND I'D
20 BE HAPPY TO FIELD QUESTIONS FROM ANY MEMBERS OF THE
21 BOARD.

22 CHAIRMAN THOMAS: DR. TROUNSON.

23 DR. TROUNSON: JUST A QUICK UPDATE. I
24 THINK THAT BILL THAT I WAS SPEAKING ABOUT AS FILED
25 IN COMMITTEE AT THIS STAGE, IT MAY NOT HAVE

BARRISTERS' REPORTING SERVICE

1 COMPLETELY GONE AWAY, BUT I THINK THERE IS SOME VERY
2 SOLID OPPOSITION TO IT. SO I THINK PEOPLE OUGHT TO
3 KEEP A WATCHFUL EYE ON IT, BUT IT DIED IN COMMITTEE
4 TODAY, THIS MORNING. SO JUST AN UPDATE FOR YOU.

5 CHAIRMAN THOMAS: THANK YOU. ANY
6 QUESTIONS FOR MATT?

7 MR. TORRES: MR. CHAIRMAN.

8 CHAIRMAN THOMAS: YES, MR. SENATOR.

9 MR. TORRES: WE ARE IN VERY DIFFICULT
10 TIMES, AND I THINK HAVING THE CHANCELLOR HERE, WHO I
11 RESPECT TREMENDOUSLY, UNDERSTANDS THAT MORE THAN
12 ANYBODY GIVEN THE TREMENDOUS IMPACT THAT THIS BUDGET
13 HAS HAD AND THE REVENUE STREAM HAS HAD ON THE
14 UNIVERSITY OF CALIFORNIA.

15 WE SHOULD ALSO BE AWARE THAT AT THE END OF
16 2010, THEN ATTORNEY GENERAL JERRY BROWN REDUCED THE
17 SALARIES OF ALL OF OUR CONSTITUTIONAL OFFICERS AND
18 STATE LEGISLATORS BY 18 PERCENT. THE CONSTITUTIONAL
19 PAY COMMISSION IS NOW CONSIDERING AN ADDITIONAL 5
20 PERCENT REDUCTION IN THEIR SALARIES AS WELL. SO
21 THAT WOULD BE A TOTAL OF 23 PERCENT REDUCTION IN
22 STATE CONSTITUTIONAL OFFICERS FROM THE GOVERNOR ON
23 DOWN TO MEMBERS OF THE LEGISLATURE.

24 SO THE FACT THAT WE ARE TRYING TO SAVE
25 MONEY IS TREMENDOUS AS A STATE AGENCY, NO. 1. NO.

BARRISTERS' REPORTING SERVICE

1 2, AS THE LEGISLATURE AND THE GOVERNOR GRAPPLES WITH
2 THE STATE BUDGET, WHICH THEY HAVE TOLD ME THEY WILL
3 HOPEFULLY PASS BY THE JUNE 15TH DEADLINE, A BALANCED
4 BUDGET REQUIRED BY THE CONSTITUTION, IS GOING TO BE
5 A TREMENDOUS CHALLENGE. AND SO I JUST WANT TO
6 INDICATE THAT THE WORK OF DR. TROUNSON, DR. THOMAS,
7 AND OUR STAFF, INCLUDING OUR CFO, MATT, IS VERY,
8 VERY IMPORTANT THAT IT BECOME AS TRANSPARENT AS
9 POSSIBLE, THAT THE EFFORTS THAT WE ARE UNDERTAKING,
10 ESPECIALLY THE ROLE OF COMMERCIAL PAPER, WHICH WILL
11 BE LESS EXPENSIVE THAN THE DEBT SERVICE ON BONDS, IS
12 ALSO AN EFFORT FOR US TO TRY AND SAVE MONEY AS MUCH
13 AS WE CAN.

14 SO I'M NOT TROUBLED BY PEOPLE NOT
15 ACCEPTING POSITIONS WITHIN THE AGENCY BECAUSE THAT
16 HELPS US SAVE MONEY AS WELL, BUT THE TAXPAYERS NEED
17 TO KNOW THAT THEIR MONEY IS BEING WELL SPENT HERE,
18 THAT WE ARE FISCALLY PRUDENT, THAT WE ARE FISCAL AND
19 CONSERVATIVE OVERSEERS OF THE REVENUES THAT THEY
20 HAVE ENTRUSTED US WITH SINCE 2004 WHEN THIS
21 INITIATIVE PASSED, AND THAT WE WILL CONTINUE AS AN
22 AGENCY TO OVERSEE THE DEVELOPMENTS IN SACRAMENTO
23 BETWEEN NOW AND JUNE 15TH, AND WE WILL RESPOND
24 ACCORDINGLY AS BEST WE CAN IN TERMS OF OUR OWN
25 INITIATIVES, I THINK, WITH THE LEADERSHIP HERE OF

BARRISTERS' REPORTING SERVICE

1 THE INSTITUTE AND THIS BOARD.

2 AND, AGAIN, MY THANKS AGAIN TO MICHAEL
3 GOLDBERG WHO SERVES AS OUR FINANCE CHAIR
4 SUBCOMMITTEE CHAIR WHO HAS BEEN VERY SENSITIVE TO
5 THESE ISSUES. AND I JUST APPLAUD YOUR LEADERSHIP,
6 MICHAEL, IN TERMS OF THE ISSUES THAT YOU'VE BEEN
7 ABLE TO SUSTAIN. THANK YOU.

8 CHAIRMAN THOMAS: THANK YOU FOR THOSE
9 COMMENTS.

10 YES, MR. SERRANO-SEWELL.

11 MR. SERRANO-SEWELL: MY RECOLLECTION IS AT
12 OUR LAST MEETING, FULL COMMISSION MEETING, THERE
13 WERE SOME QUESTIONS AROUND, AND IF MICHAEL AND/OR
14 MARCY CAN SHARE WITH US HOW THAT GOT RESOLVED,
15 ISSUES AROUND OUTSIDE COUNSEL, SPECIFICALLY JAMES
16 HARRISON, TRAVEL, I SEE THERE AN INCREASE, AND THOSE
17 SORTS OF ISSUES, HOW THEY GOT RESOLVED AND THE
18 INTERNAL DISCUSSIONS BETWEEN THE COMMITTEE CHAIRS
19 AND STAFF.

20 CHAIRMAN THOMAS: DAVID, THERE HAS BEEN
21 DISCUSSION ON THAT. THE BUDGET ITSELF IS ON THE
22 AGENDA LATER TODAY, SO WE WILL ADDRESS THAT WHEN WE
23 GET TO THERE. THANK YOU.

24 YES, JOAN.

25 MS. SAMUELSON: I'D JUST LIKE TO ADD A

BARRISTERS' REPORTING SERVICE

1 LITTLE TAG LINE TO THE SENATOR'S STATEMENT WHICH I
2 COMPLETELY AGREE WITH AND I THINK IS EXTREMELY
3 IMPORTANT. I THINK IT'S IMPORTANT THAT THE PUBLIC
4 BE REMINDED THAT WHAT WE HAVE BEEN ASKED TO DO AS
5 OUR MISSION IS SPEND MONEY TO CONDUCT RESEARCH BY
6 ISSUING THE BONDS AND SO ON. AS YOU WERE DESCRIBING
7 EARLIER, WE DON'T PAVE HIGHWAYS, WE DON'T ISSUE
8 DRIVER'S LICENSES, WE DON'T EDUCATE PEOPLE, WHICH
9 THERE MAY BE MANY EFFICIENCIES, BUT IN OUR CASE THE
10 LESS MONEY WE SPEND, POTENTIALLY THE LESS RESEARCH
11 IS DONE. AND SO THERE'S ENORMOUS PRESSURE ON US, I
12 THINK, THAT MIGHT BE REDUCED A BIT IF THE PUBLIC IS
13 CLEAR ABOUT THAT. SO I'M JUST TRYING TO CLEAR THE
14 AIR A LITTLE BIT.

15 MR. TORRES: I THINK THAT'S AN IMPORTANT
16 POINT, BUT MY REFERENCE WAS TO THE 6-PERCENT CAP
17 THAT THIS AGENCY OPERATES UNDER, WHICH NO OTHER
18 STATE AGENCY OPERATES UNDER. AND THE FACT THAT WE
19 WILL BRING IN BETWEEN NOW AND 2012 201 MILLION IN
20 NEW REVENUE TO THE STATE AS A RESULT OF THIS BOARD'S
21 EFFORTS AND THIS AGENCY'S EFFORTS. SO 94 PERCENT
22 GOES DIRECTLY TO RESEARCH. AND OUR INTENT IS NEVER
23 TO DIMINISH THAT APPROPRIATELY, BUT TO CONTINUE THE
24 WORK THAT WE'VE BEEN DOING BECAUSE THAT'S THE
25 MANDATE THAT THE VOTERS GAVE US. BUT MY REFERENCE

BARRISTERS' REPORTING SERVICE

1 WAS TO THE FACT THAT AS A STATE AGENCY, WE ARE
2 OPERATING VERY FISCALLY RESPONSIBLY.

3 MS. SAMUELSON: RIGHT. EXACTLY. THANK
4 YOU.

5 CHAIRMAN THOMAS: OKAY. THANK YOU. ALAN,
6 DO YOU WANT TO COMMENT ON THE LAST SLIDE? WHO'S
7 THAT HANDSOME GUY IN THE MIDDLE THERE?

8 DR. TROUNSON: I ASSURE YOU, CHAIRMAN, I
9 DID NOT DO THIS SLIDE. YOU WILL ALL BE AWARE THAT I
10 NEVER APPEARED IN IT IN THE PAST. SO SOMEBODY'S
11 TAKEN SOME LICENSE TO THIS SLIDE. THEY WILL BE
12 REWARDED.

13 CHAIRMAN THOMAS: PHOTOSHOP IS AN
14 INTERESTING TOOL. OKAY. WE'LL NOW MOVE TO THE NEXT
15 ITEM ON OUR AGENDA. AS YOU KNOW, SB 1064 IN 2010
16 MANDATED THAT WE UNDERTAKE A PERFORMANCE AUDIT EVERY
17 THREE YEARS. THE FIRST OF THOSE IS NOW CONCLUDED
18 AND READY FOR YOUR REVIEW HERE AT THIS MEETING. IT
19 WAS CONDUCTED BY THE FIRM OF MOSS-ADAMS, AND WE HAVE
20 HERE MARK STERANKA AND MARY CASE, WHO ARE GOING TO
21 GIVE A PRESENTATION ON THAT PERFORMANCE AUDIT. SO
22 MARY OR MARK, I TURN IT OVER TO YOU. THANK YOU.

23 MS. CASE: GOOD MORNING, MEMBERS OF THE
24 BOARD. I'M MARY CASE, AUDIT PARTNER FROM
25 MOSS-ADAMS. AND WITH ME TODAY IS MY COLLEAGUE MARK

BARRISTERS' REPORTING SERVICE

1 STERANKA, SENIOR MANAGER. WE WANT TO THANK YOU VERY
2 MUCH FOR HAVING US WITH YOU TODAY TO PROVIDE A BRIEF
3 SYNOPSIS OF OUR PERFORMANCE AUDIT REPORT FOR CIRM.
4 AND WE'RE GOING TO LEAVE TIME AT THE END FOR
5 QUESTIONS, BUT WE WOULD WELCOME YOUR QUESTIONS ALONG
6 THE WAY IF YOU LIKE.

7 FIRST OF ALL, WHAT WE'RE GOING TO DO IS GO
8 THROUGH THE SCOPE OF THE WORK THAT WE DID FOR CIRM
9 AND THE AUDITING STANDARDS THAT WE FOLLOWED FOR OUR
10 WORK, THE SELECTION PROCESS THAT WAS MADE FOR OUR
11 ENGAGEMENT, AND OUR INDEPENDENCE OF CIRM. WE'RE
12 ALSO GOING TO REVIEW THE PROCESS UNDERTAKEN TO
13 PERFORM THE WORK FOR YOU AND TO DRAW OUR CONCLUSIONS
14 AND FORMULATE OUR RECOMMENDATIONS ALONG THE WAY.

15 WE'RE GOING TO SHARE A SUMMARY OF OUR
16 OBSERVATIONS, AND WE'RE GOING TO GO THROUGH OUR
17 FINDINGS FAIRLY BRIEFLY WITH SOME EXAMPLES, AND
18 WE'RE GOING TO DISCUSS OUR RECOMMENDATIONS IN A
19 TIERED FORMAT, IN A TIERED FRAMEWORK BASED ON
20 PRIORITIZATION.

21 SO LAST SUMMER CIRM ENGAGED A FIRM WITH
22 SIGNIFICANT PERFORMANCE AUDIT KNOWLEDGE TO ASSIST
23 THEM WITH THE PROCESS OF SELECTING A FIRM TO PERFORM
24 CIRM'S PERFORMANCE AUDIT. SO MOSS-ADAMS WAS
25 SELECTED BASED ON OUR EXPERIENCE WITH GOVERNMENTAL

BARRISTERS' REPORTING SERVICE

1 AUDITING, WITH PERFORMANCE AUDITS, WITH GRANTS AND
2 CONTRACTING PROCESSES WITH GOVERNMENTS,
3 NOT-FOR-PROFIT ORGANIZATIONS, AND COMMERCIAL
4 ENTITIES, AS WELL AS OUR EXPERIENCE IN CONDUCTING
5 OPERATIONAL AUDITS.

6 THE SCOPE OF OUR WORK INCLUDED EXAMINATION
7 OF THE CORE FUNCTIONS OF CIRM. THESE INCLUDED THE
8 GRANT MAKING, PROCESSES RELATED TO LOANS,
9 CONTRACTING, AND TRACKING AND MONITORING OF
10 INTELLECTUAL PROPERTY. OUR WORK ALSO INCLUDED AN
11 ASSESSMENT OF THE ECONOMY, EFFICIENCY, AND
12 EFFECTIVENESS OF THE SUPPORTING FUNCTIONS AT CIRM.
13 AND THOSE INCLUDED EXECUTIVE LEADERSHIP, FINANCE,
14 HUMAN RESOURCES, INFORMATION TECHNOLOGY, LEGAL,
15 ADMINISTRATIVE SUPPORT, AND COMMUNICATIONS, THE
16 WHOLE SHOOTING MATCH, SO TO SPEAK.

17 OUR WORK SPANNED SIX MONTHS AND
18 ENCOMPASSED NEARLY A THOUSAND HOURS. THE SCOPE OF
19 OUR WORK DID NOT INCLUDE A VERY IMPORTANT ELEMENT,
20 CRITICAL ELEMENT, AND THAT'S AN ASSESSMENT OF THE
21 SCIENTIFIC ASPECTS OF THE CIRM'S WORK. YOU HAVE
22 OTHERS CONDUCTING THAT WORK.

23 THE AUDITING STANDARDS THAT WE FOLLOWED
24 WERE GENERALLY ACCEPTED GOVERNMENT AUDITING
25 STANDARDS WHICH EMANATE FROM THE GAO, GOVERNMENT

BARRISTERS' REPORTING SERVICE

1 ACCOUNTABILITY OFFICE, A FEDERAL AGENCY, WHICH
2 PRESCRIBED THE INDEPENDENCE AND OTHER STANDARDS
3 WHICH WE EMPLOYED IN THE CONDUCT OF OUR WORK. AND
4 SO WE'D, AGAIN, LIKE TO CONFIRM OUR INDEPENDENCE
5 FROM CIRM IN THE WORK THAT WE DID.

6 CIRM IS A VERY -- A RELATIVELY YOUNG
7 ORGANIZATION, AND WE WOULD EXPECT IT TO HAVE A
8 NUMBER OF FINDINGS RELATED TO PERFORMANCE AT THIS
9 STAGE OF ITS EXISTENCE. WE VIEW OUR REPORT AS
10 HAVING A VERY POSITIVE OUTCOME. THE CORE AREAS OF
11 GRANT MAKING, CONTRACTING, AND LENDING REVEALED NO
12 ISSUES WITH CONFORMITY, WITH POLICIES AND
13 PROCEDURES. THERE WERE NO FINDINGS IN THOSE KEY
14 AREAS WHICH ARE ADDRESSED BY THE -- IN THE
15 PERFORMANCE AUDIT; HOWEVER, THERE ARE SOME
16 OPPORTUNITIES FOR INCREASED EFFICIENCIES AND
17 IMPROVED EFFECTIVENESS.

18 OUR PROCESS CONSISTED OF SEVERAL STEPS.
19 THEY INCLUDED INTERVIEWING A SIGNIFICANT NUMBER OF
20 PEOPLE FROM THROUGHOUT THE ORGANIZATION IN A VARIETY
21 OF ROLES ACROSS EVERY FUNCTIONAL AREA INSIDE CIRM.
22 WE REVIEWED HUNDREDS OF DOCUMENTS, IT MAY EVEN
23 APPROACH THOUSANDS, TO UNDERSTAND POLICIES,
24 PROCEDURES, AND PROCESSES. WE THEN PERFORMED
25 STEP-BY-STEP WALK-THROUGHS WITH CIRM PERSONNEL TO

BARRISTERS' REPORTING SERVICE

1 OBSERVE THE PROCESSES AND CONTROLS TO ENSURE
2 COMPLIANCE IN ALL THE AREAS OF THE CORE FUNCTIONS
3 THAT WE WERE REVIEWING.

4 AND THEN FOLLOWING THOSE WALK-THROUGHS, WE
5 SELECTED SAMPLES FROM POPULATIONS WITHIN THE CORE
6 AREAS OF GRANTS, CONTRACTS, AND LOANS. WE EMPLOYED
7 STATISTICAL SAMPLING TECHNIQUES AND TESTED INTERNAL
8 CONTROLS AND COMPLIANCE WITH POLICIES AND
9 PROCEDURES.

10 AMONG THE THINGS THAT WE NOTED DURING THE
11 CONDUCT OF OUR WORK WERE THE PROFESSIONALISM, DRIVE,
12 AND FOCUS OF THE CIRM EMPLOYEES THAT WE INTERACTED
13 WITH. WE SUBJECTED THEM TO CONSIDERABLE RIGOR
14 DURING THE COURSE OF OUR AUDIT, AND WE REALLY
15 APPRECIATED THEIR RESPONSIVENESS AND THEIR CANDOR IN
16 DEALING WITH US ALONG THE WAY. THEY SEEM TO
17 GENERALLY CARE ABOUT THEIR MISSION AND CREATED A
18 DESIRE TO BE EFFICIENT AND EFFECTIVE STEWARDS OF THE
19 PUBLIC FUNDS.

20 IN OUR WORK WE OBSERVED MANY DIFFERENT
21 GOVERNMENT FUNDERS AND FIND THAT CIRM EXHIBITS MORE
22 EFFECTIVE AND APPROPRIATE OVERSIGHT AND MONITORING
23 THAN MANY, PERHAPS MOST THAT WE SEE. SO I'M GOING
24 TO PASS THE BATON TO MARK STRANKA TO DISCUSS FURTHER
25 OUR OBSERVATIONS AND SUMMARIZE SOME OF OUR FINDINGS

BARRISTERS' REPORTING SERVICE

1 AND RECOMMENDATIONS AND THEN WE'LL TAKE SOME
2 QUESTIONS.

3 MR. TORRES: WOULD YOU REPEAT THAT LAST
4 LINE.

5 MS. CASE: PASSING THE BATON TO MARK.

6 MR. TORRES: NO. NO. THE LINE BEFORE
7 THAT.

8 MR. STERANKA: YOU'LL HEAR PLENTY OF GOOD
9 STUFF FROM ME.

10 MR. TORRES: ALL RIGHT.

11 MR. STERANKA: MR. CHAIR, VICE CHAIRS, AND
12 OTHER MEMBERS OF THE BOARD, IT'S A PLEASURE TO BE
13 BACK HERE. I ACTUALLY ATTENDED YOUR DECEMBER BOARD
14 MEETING AT CEDARS-SINAI, AND THAT WAS ACTUALLY QUITE
15 A MOVING EXPERIENCE GETTING TO HEAR ABOUT THE HEART
16 STEM CELL RESEARCH AND FROM THE DOCTORS AND
17 PATIENTS, AND THAT WAS REALLY QUITE EDUCATIONAL FOR
18 ME.

19 I WANT TO DO SOME STAGE SETTING BEFORE
20 TALKING ABOUT FINDINGS AND RECOMMENDATIONS BECAUSE
21 THE CONTEXT FOR DOING A PERFORMANCE AUDIT IS REALLY
22 AS IMPORTANT AS THE AUDIT ITSELF. AND AN AREA TO
23 START IS OUR WORK AND OUR ABILITY TO PROVIDE VALUE
24 TO YOU IS VERY MUCH PREDICATED ON THE EXPERIENCE
25 THAT WE HAVE IN WORKING WITH THE CLIENT FROM BOARD

BARRISTERS' REPORTING SERVICE

1 MEMBERS TO GRANTS WORKING GROUP MEMBERS TO YOUR
2 SENIOR LEADERSHIP TEAM AND STAFF. AND I HAVE TO
3 TELL YOU THEY WERE GREAT TO WORK WITH. THEY WERE
4 COLLABORATIVE. THEY WERE EXTREMELY RESPONSIVE TO
5 OUR NEEDS.

6 AS YOU PROBABLY ALL KNOW, CIRM WE WOULD
7 PUT IN THE CATEGORY AS ONE OF THOSE ORGANIZATIONS
8 THAT GETS POKED AND PRODDED A LOT. OUR STUDY IS NOT
9 THE FIRST. I KNOW IT WON'T BE THE LAST. AND WE
10 KIND OF HATE TO BE A CONTRIBUTING FACTOR TO THAT
11 BECAUSE IT TAKES A LOT OF EFFORT TO RESPOND TO THE
12 INFORMATION NEEDS OF AN ORGANIZATION LIKE OURS TO DO
13 THE WORK THAT WE DID. AND THE STAFF WAS REALLY JUST
14 GREAT IN WORKING WITH US, AND WE REALLY FEEL IT'S
15 INCUMBENT UPON US TO REALLY DELIVER VALUE FOR THE
16 TIME THAT THEY TAKE TO WORK WITH US AND THE MONEY
17 THAT YOU SPEND ON US, AND WE HOPE THAT YOU FIND OUR
18 REPORT DOES, IN FACT, PROVIDE YOU VALUE.

19 SO AS BOARD MEMBERS, I'M GOING TO TRY TO
20 GIVE YOU WHAT I WOULD HOPE WOULD BE YOUR TAKEAWAYS
21 FROM OUR STUDY AND THE RESULTS. AND, AGAIN, A LOT
22 OF IT IS CONTEXTUAL. IT'S IMPORTANT FOR YOU TO KNOW
23 THAT WE HAD FREE REIN TO, WHAT I'D SAY, FOLLOW OUR
24 NOSE. SO WE GET IN, WE DO A LOT OF INTERVIEWS, WE
25 LOOK AT A LOT OF DOCUMENTS, AND WE'RE LOOKING FOR

BARRISTERS' REPORTING SERVICE

1 WHERE WE CAN FIND WAYS FOR IMPROVED ECONOMY,
2 EFFICIENCY, AND EFFECTIVENESS.

3 AND THIS IS A VERY FAVORABLE REPORT. OUR
4 CLIENTS ARE ALWAYS SENSITIVE TO RESULTS OF A
5 PERFORMANCE AUDIT BECAUSE YOU ALWAYS THINK, WELL,
6 YOU'RE SAYING WE'RE NOT DOING SOMETHING RIGHT.
7 WELL, BY DEFINITION OUR JOB IS TO FIND OPPORTUNITIES
8 TO IMPROVE, AND THAT'S WHAT THESE ARE. THEY'RE
9 OPPORTUNITIES TO IMPROVE, TO BUILD UPON THE GOOD
10 WORK THAT YOU DO. THIS IS REALLY MORE OF A BUSINESS
11 FOCUS. IT'S CERTAINLY NOT A SCIENTIFIC FOCUS, AND A
12 LOT OF WHAT WE HAVE TO SAY IS ABOUT HELPING THE
13 ORGANIZATION TO BE MORE EFFICIENT, TO OPERATE EASIER
14 TO MAKE MANAGEMENT AND STAFF BETTER ABLE TO PERFORM
15 THE JOBS THAT THEY DO WITH TOOLS, WITH PROCESSES,
16 WITH TECHNOLOGY, AGAIN, JUST TO ENABLE LIFE TO BE
17 EASIER.

18 AND LASTLY, MAYBE CONTEXTUALLY, AN AUDIT
19 IS SOMETHING DONE AT A POINT IN TIME. AND I'VE
20 ALREADY HEARD TODAY, WE'RE ALREADY AWARE OF ANYWAY,
21 EXAMPLES OF THINGS THAT THE ORGANIZATION IS ALREADY
22 DOING IN RESPONSE TO FINDINGS AND RECOMMENDATIONS WE
23 HAD, THINGS THAT THEY WERE WORKING ON ANYWAY, THINGS
24 THAT HAVE TRANSPIRED DURING THE COURSE OF PREPARING
25 THE REPORT. AND SO WE'RE AT A POINT OF TIME OF

BARRISTERS' REPORTING SERVICE

1 FINDINGS AND RECOMMENDATIONS. YOU KIND OF HAVE TO
2 PUT A STAKE SOMEWHERE, AND I'M NOT EVEN SURE WHAT
3 DATE THAT ACTUALLY IS BECAUSE THINGS ARE ALWAYS
4 MOVING, AND OUR REPORT REFLECTS SOME THINGS THAT
5 HAVE ALREADY HAPPENED, AND IT REFLECTS SOME THINGS
6 THAT -- IT DOESN'T REFLECT SOME THINGS THAT HAVE
7 ALREADY HAPPENED, BUT THIS IS A VERY DYNAMIC
8 PROCESS. IT'S GREAT THAT THE ORGANIZATION IS
9 ALREADY ADDRESSING THINGS THAT ARE IN THE REPORT.
10 THAT'S REWARDING TO US, AND IT SHOULD BE REWARDING
11 TO YOU ALSO AS BOARD MEMBERS.

12 MAYBE ONE LAST THING IN TERMS OF PROCESS.
13 SO THERE'S A LOT OF DELIVERABLES AND STEPS IN THE
14 PROCESS OF A PERFORMANCE AUDIT, AND IT'S IMPORTANT
15 FOR YOU TO KNOW THAT IT BEGINS WITH AN AUDIT PLAN
16 THAT BASICALLY SAYS THIS IS WHAT WE'RE GOING TO LOOK
17 FOR, THIS IS HOW WE'RE GOING TO DO IT. IT'S VERY
18 SPECIFIC. ONCE WE GET IN AND START TO FORM
19 OBSERVATIONS AND FINDINGS, WE GO THROUGH A
20 VERIFICATION OF FACTS. SO ONCE WE HAVE FINDINGS, WE
21 MEET WITH STAFF AND MANAGEMENT AND BOARD CHAIR AND
22 VICE CHAIR AND MAKE SURE THAT WE'VE GOT IT RIGHT,
23 THAT WE HAVEN'T MISSED SOMETHING THAT WE SHOULD HAVE
24 CAUGHT, THAT WE HAVEN'T MISPORTRAYED SOMETHING, AND
25 REALLY MAKING SURE OUR FACTS ARE CORRECT.

BARRISTERS' REPORTING SERVICE

1 ONCE WE'RE THROUGH THAT POINT, WE DEVELOP
2 OUR RECOMMENDATIONS. WE, AGAIN, SORT OF GO THROUGH
3 THE PROCESS OF TESTING THE VIABILITY AND
4 REASONABLENESS OF THOSE RECOMMENDATIONS BECAUSE WE
5 DON'T WANT TO GIVE YOU TEXTBOOK ANSWERS. WE WANT TO
6 GIVE YOU THINGS THAT ARE PRACTICAL, THAT ARE
7 IMPLEMENTABLE FOR YOUR ORGANIZATION.

8 SO I THINK I WANT TO START HERE. THANK
9 YOU. I DIDN'T REALIZE YOU ALREADY GOT ME WHERE I
10 WANTED TO BE.

11 SO SOME OBSERVATIONS. WE WORK WITH
12 BUSINESSES, WE WORK WITH NOT-FOR-PROFITS, WE WORK
13 WITH GOVERNMENTS, LOTS OF ALL OF THE ABOVE,
14 HUNDREDS, IF NOT THOUSANDS. SO WE GET TO SEE A LOT.
15 WE WORK WITH START-UPS WHICH IS KIND OF WHAT CIRM
16 IS. YOU'RE STILL IN TRULY YOUR EARLY YEARS. WE
17 WORK WITH LOTS OF ENTITIES, GOVERNMENTAL ENTITIES,
18 THAT HAVE PROGRAMS THAT SUNSET. WHAT WE DON'T GET
19 TO WORK WITH ARE ORGANIZATIONS, A, AS SORT OF
20 COMPLICATED AS YOU ARE IN TERMS OF THE WORK THAT YOU
21 DO, BUT REALLY UNIQUE IS THE FACT THAT YOU ARE, IN
22 ESSENCE, STILL RAMPING UP YOUR ORGANIZATION, AND
23 THAT'S WHAT OUR STUDY LARGELY INDICATES BECAUSE
24 THERE ARE THOSE OPPORTUNITIES FOR IMPROVED
25 EFFICIENCY, BUT YOU'RE ALSO AT THE SAME TIME HAVING

BARRISTERS' REPORTING SERVICE

1 TO THINK ABOUT TECHNICALLY RAMPING DOWN AND WHAT
2 HAPPENS AT THE END OF THE FUNDING.

3 AND AS YOUR TRANSITION PLAN APPROPRIATELY
4 DOES, IT LOOKS AT ALTERNATIVES, BUT THAT IS A VERY
5 UNIQUE PLACE TO BE AND PROVIDES VERY UNIQUE
6 CHALLENGES TO AN ORGANIZATION TO, IN ESSENCE, BEING
7 RAMPING UP AND THINKING ABOUT RAMPING DOWN ALL AT
8 THE SAME TIME.

9 SO THAT IS VERY MUCH INHERENT IN OUR
10 FINDINGS AND RECOMMENDATIONS AND WHAT IMPACT THAT'S
11 HAVING ON THE ORGANIZATION. AND WHAT WE BELIEVE
12 WE'VE SEEN IS THAT AN ORGANIZATION HAS BEEN HIGHLY
13 FOCUSED, BEING EFFECTIVE ON BEING ABLE TO DO THE
14 BUSINESS THAT YOU DO, TO BE ABLE TO DISTRIBUTE
15 FUNDING TOWARDS YOUR MISSION, AND HAVE WORKED HARD
16 TO BE EFFECTIVELY DOING THAT YEAR IN AND YEAR OUT.
17 AND WHAT YOU SORT OF NOW HAVE A LITTLE BIT OF AN
18 OPPORTUNITY TO DO, ALTHOUGH IT'S NOT LIKE PEOPLE
19 HAVE TIME ON THEIR HANDS, BUT TO BE A LITTLE BIT
20 MORE FOCUSED NOW ON EFFICIENCY, ON HOW DO WE MAKE
21 THE PROCESS BY WHICH WE DO THESE THINGS EASIER. AND
22 YOU'LL HEAR SOME THEMES ABOUT DATA AND INFORMATION
23 AND DECISION-MAKING AND PERFORMANCE, AND THEY'RE ALL
24 TIED TO EFFICIENCY.

25 SO LET'S GO THROUGH SOME SPECIFIC

BARRISTERS' REPORTING SERVICE

1 FINDINGS. I BELIEVE YOU ALL HAVE A COPY OF OUR
2 REPORT. THE REPORT IS ORGANIZED BY THE CATEGORIES
3 REFLECTED ON THIS SLIDE. SO WE FIND COMPLIANCE,
4 PERFORMANCE, EFFICIENCY AND EFFECTIVENESS, HUMAN
5 CAPITAL, AND INFORMATION TECHNOLOGY. AS WE WENT
6 THROUGH OUR ASSESSMENT OF THE ORGANIZATION, THESE
7 ARE SORT OF THE THEMES OR THE BUCKETS IN WHICH WE
8 IDENTIFIED OPPORTUNITIES FOR THE ORGANIZATION TO
9 IMPROVE.

10 SO AS MARY MENTIONED, FROM COMPLIANCE, YOU
11 KNOW, THOSE WERE CHECKS DOWN THE BOX. YOU'RE FULLY
12 COMPLIANT WITH HOW YOU MANAGE YOUR GRANTS, MANAGE
13 YOUR LOANS, DEAL WITH YOUR CONTRACTS, HANDLE
14 INTELLECTUAL PROPERTY. ONE THING THAT WE HAVE FOUND
15 CERTAINLY IS THAT CIRM DOES NOT STAND STILL. THE
16 ORGANIZATION IS CONTINUALLY LOOKING AT HOW TO DO ITS
17 BUSINESS BETTER. A GOOD EXAMPLE OF THAT IS
18 INTELLECTUAL PROPERTY. YOU KNOW, THERE WERE INITIAL
19 THOUGHTS ABOUT HOW WOULD BE THE BEST WAY TO COLLECT
20 INFORMATION RELATIVE TO IP. AND AS YOU'VE STARTED
21 TO GET MORE INTO THE PROCESS AND STILL AT THE VERY
22 NASCENT STAGE OF REALLY DEALING WITH INTELLECTUAL
23 PROPERTY AND CERTAINLY REVENUE ASSOCIATED WITH IT,
24 THE ORGANIZATION HAS LEARNED BETTER WAYS TO COLLECT
25 THAT INFORMATION AND IS, IN FACT, PURSUING THOSE

BARRISTERS' REPORTING SERVICE

1 RELATIVE TO PERFORMANCE AND OUTCOMES.

2 SO THIS IS VERY MUCH A DATA-DRIVEN,
3 OUTCOME-BASED ORGANIZATION. AND CERTAINLY ONE OF
4 YOUR OPPORTUNITIES IS TO BETTER EQUIP MANAGEMENT,
5 BETTER EQUIP THE BOARD TO BE ABLE TO HAVE ACCESS TO
6 KEY PERFORMANCE DATA, OUTCOME-BASED INFORMATION THAT
7 IS JUST MORE READILY AVAILABLE. THE DATA IS THERE.
8 IT'S NOT THAT YOU'RE NOT COLLECTING IT. IT'S THAT
9 IT'S NOT TERRIBLY EASY TO GET YOUR HANDS ON IT. A
10 LOT OF WORK HAS TO GO INTO IT, AND IT REALLY
11 SHOULDN'T HAVE TO BE THAT COMPLICATED, THAT
12 TIME-CONSUMING, THAT MUCH OF AN EFFORT FOR YOUR
13 ORGANIZATION TO BE ABLE TO GENERATE THAT
14 INFORMATION.

15 FROM EFFICIENCY AND EFFECTIVENESS, A
16 COUPLE EXAMPLES. SO FROM AN EFFECTIVENESS
17 STANDPOINT, YOU HAVE A STRONG FOCUS ON DEVELOPING
18 BUSINESS WITH BIOPHARMACEUTICAL. SO ONE OF OUR
19 FINDINGS AND ASSOCIATED RECOMMENDATIONS IS
20 DEVELOPING A VERY SPECIFIC BUSINESS PLAN TO THAT
21 END. THAT'S A TOOL TO HELP YOU BE MORE EFFECTIVE,
22 TO ALIGN YOUR RESOURCES WITHIN THE ORGANIZATION THAT
23 HAVE THE CAPABILITIES TO INFLUENCE AND EFFECT THAT
24 TYPE OF BUSINESS.

25 AN EXAMPLE OF EFFICIENCY WOULD BE, FOR

BARRISTERS' REPORTING SERVICE

1 EXAMPLE, WITHIN YOUR FINANCE DEPARTMENT, YOU'RE
2 RELIANT ON THE STATE FOR A LOT OF YOUR FINANCIAL
3 INFORMATION. YOU DON'T HAVE YOUR OWN ACCOUNTING
4 SYSTEM. THERE'S A TREMENDOUS AMOUNT OF WORK THAT
5 HAS TO GO INTO PRODUCING THE INFORMATION THAT YOU
6 USE ON A DAY-TO-DAY BASIS, AND THAT COULD BE MADE
7 SIMPLER BY USING TECHNOLOGY. AND THAT SHOULD BE
8 SIMPLER. YOU SHOULDN'T GO INTO A ROOM AND SEE
9 STACKS OF PAPER AND KNOWING HOW MANY DIFFERENT
10 SOURCES YOU HAVE TO PULL INFORMATION FROM TO
11 ASSEMBLE A PARTICULAR REPORT. THAT'S NOT A KNOCK ON
12 THE AGENCY. THAT'S AN OPPORTUNITY TO BE ABLE TO BE
13 MORE EFFICIENT.

14 HUMAN CAPITAL, THIS REALLY GOES TO SOME OF
15 THE UNIQUENESS ABOUT YOUR SITUATION. BY DEFINITION,
16 HAVING TO THINK ABOUT RAMPING DOWN REALLY PUTS A
17 STRAIN ON HUMAN RESOURCES. JUST THE FACT THAT YOU
18 HAVE OPEN POSITIONS I THINK IN A WAY IS PARTLY
19 REFLECTIVE OF THAT. RECRUITING AND RETENTION FOR
20 YOUR STAFF IS REALLY A VERY IMPORTANT ISSUE FOR THIS
21 ORGANIZATION. IT WILL BECOME EVER MORE SO WITH EACH
22 YEAR THAT YOU GET CLOSER TO SUNSETTING. I KNOW
23 THERE'S EVERY HOPE THAT THE ORGANIZATION WILL
24 CONTINUE IN SOME FORM OR FASHION, BUT THE FACT OF
25 THE MATTER IS NONE OF US KNOWS WHAT THAT'S GOING TO

BARRISTERS' REPORTING SERVICE

1 LOOK LIKE TODAY. SO IT'S REALLY IMPORTANT TO BE
2 ADDRESSING THE HUMAN CAPITAL ASPECT OF YOUR
3 ORGANIZATION IN THAT CONTEXT.

4 AND THEN, FINALLY, INFORMATION TECHNOLOGY.
5 I'M NOT A TECHNOLOGY GUY, BUT YOU HAVE -- I'LL JUST
6 FINISH AND THEN I'LL TAKE THAT. BUT YOU HAVE LOTS
7 OF OPPORTUNITY TO UTILIZE TECHNOLOGY, AGAIN, TO
8 ENABLE YOU TO BE MORE EFFICIENT. YOU'RE VERY MUCH
9 ON THE RIGHT TRACK. THERE'S A LOT GOING ON. YOU'RE
10 PROBABLY A LITTLE BIT BEHIND THE BALL ON IT BECAUSE
11 YOU COULD BE MAKING GREATER USE OF IT, BUT YOU'RE ON
12 THE RIGHT TRACK.

13 YES, QUESTION.

14 MR. SERRANO-SEWELL: YOU SAID WE COULD ASK
15 ALONG THE WAY. THANK YOU. THE ISSUE OF THE AGENCY
16 HAVING A SHELF LIFE, IF YOU WILL, WHICH YOU JUST
17 ADDRESSED IN TERMS OF RECRUITMENT, AND IT SORT OF
18 IMPACTS A LOT OF OTHER AREAS IN WHAT WE DO AS WELL,
19 SOMEWHAT UNSPOKEN BECAUSE IT'S A BIT OPAQUE WHEN
20 THAT DAY MIGHT HAPPEN, BUT IT WILL HAPPEN BARRING
21 SOMETHING ELSE. SO ASSUMING WE DON'T GET
22 RE-UPPED OR WHATEVER, JUST ASSUMING THAT THE SHELF
23 LIFE IS AND THAT WE WILL EXPIRE, ARE YOUR
24 RECOMMENDATIONS, SORT OF IS THAT EMBODIED WITHIN
25 YOUR REPORT LIKE YOU KNOW YOU WOULD HAVE TO CLOSE?

BARRISTERS' REPORTING SERVICE

1 WE'VE AUDITED OTHER ORGANIZATIONS THAT HAVE HAD A
2 SET TIME FRAME, AND THERE'S SPECIFIC THINGS YOU
3 SHOULD DO, ETC., ETC.

4 MR. STERANKA: THAT'S A GREAT QUESTION.
5 SO THE ANSWER IS KIND OF YES AND NO. YES IN THAT
6 ONE OF OUR RECOMMENDATIONS IS, AND YOU ALREADY HAVE
7 NOW A TRANSITION PLAN, AND THAT WOULD BE NO. 1 AN IS
8 FOR ANY ORGANIZATION THAT WE WORK WITH THAT HAS A
9 SHELF LIFE OR A PROGRAM THAT HAS A SHELF LIFE, WHICH
10 MANY PROGRAMS DO FUNDED BY TASK MEASURES. SO WHAT
11 ARE YOU GOING TO DO WHEN THAT HAPPENS? NO, WE
12 DIDN'T LOOK AT WHAT THOSE PARTICULAR SOLUTIONS
13 SHOULD BE BECAUSE THAT'S FRANKLY PREMATURE.

14 WHAT WE WOULD WANT TO SEE IS THAT THE
15 ORGANIZATION IS PREPARING FOR THAT. AND AS
16 IMPORTANTLY, COMMUNICATING TO YOUR EMPLOYEE BASE HOW
17 YOU'RE APPROACHING THAT, WHAT THE OPTIONS ARE
18 BECAUSE YOU WILL CONTINUE TO HAVE OPTIONS. THERE
19 WILL BE SOME TIME BEFORE SOMETHING IS SETTLED IN ON.

20 AND ONE OF OUR KEY CONCERNS RELATIVE TO
21 PERSONNEL IS THAT BY HUMAN NATURE PEOPLE SORT OF,
22 WHEN THEY HAVE TO FILL A VOID OF INFORMATION, THEY
23 TEND TO ASSUME THE WORST. WHAT'S THE WORST-CASE
24 SCENARIO? SO THE BEST WAY TO ADDRESS THAT IS BEING
25 VERY COMMUNICATIVE, VERY OPEN ABOUT WHAT ARE WE

BARRISTERS' REPORTING SERVICE

1 DOING? WHAT ARE OUR OPTIONS? WHAT WE DO KNOW, WHAT
2 WE DON'T KNOW SO YOU'RE AT LEAST ELIMINATING THE
3 UNCERTAINTY IN TERMS OF GUESSING. YOU CAN'T
4 ELIMINATE THE UNCERTAINTY THAT YOU CAN'T DEVELOP A
5 SOLUTION FOR YET. BUT BEING, AS YOU ARE, BEING OPEN
6 ABOUT IT.

7 AS THAT EVOLVES, COMMUNICATING HOW IT'S
8 EVOLVING AND ALWAYS KEEPING IN MIND THE IMPACT THAT
9 IT CAN AND WILL HAVE ON YOUR PEOPLE, YOUR ABILITY TO
10 ATTRACT AS YOU WILL CONTINUE TO NEED TO, AND
11 CERTAINLY YOUR ABILITY TO RETAIN AS YOU WILL.

12 MR. SERRANO-SEWELL: LASTLY ON THAT TOPIC,
13 ONE WAY -- I MEAN CASE STUDIES, IF YOU WILL, IS THE
14 CLOSURE OF THE STATE'S REDEVELOPMENT AGENCIES. THAT
15 WAS SUDDEN. EVERYBODY KNEW IT. THEY DIDN'T THINK
16 IT WAS GOING TO HAPPEN. THEN IT DID HAPPEN AND MANY
17 AGENCIES, I BET SOME DID A BETTER JOB THAN OTHERS.

18 MR. STERANKA: ABSOLUTELY.

19 MR. SERRANO-SEWELL: AND THEY CERTAINLY
20 HAD TO DOWNSIZE AND KEEP THEIR CORE STAFF IN ONE WAY
21 OR ANOTHER. SO WE MIGHT LEARN FROM THAT.

22 MR. STERANKA: YOU MIGHT, BUT YOU
23 CERTAINLY HAVE THE BENEFIT OF YOU'RE VERY MUCH IN
24 FRONT OF THIS ISSUE. IT'S NOT GOING TO BE A
25 SURPRISE. IT'S JUST HOW IT'S GOING TO UNFOLD.

BARRISTERS' REPORTING SERVICE

1 THAT'S WHAT EVERYONE, I'M SURE, IS INTERESTED TO
2 SEE.

3 SO I'M GOING TO MOVE ON TO
4 RECOMMENDATIONS. AND I'M NOT GOING TO GO THROUGH
5 THESE, AND YOU OBVIOUSLY WOULDN'T EVEN BE ABLE TO
6 READ THEM ON THE SCREEN AS IT IS. WHAT I WANT TO
7 TALK ABOUT IS JUST SOME THEMES, PRIORITIES, HOW WE
8 ADDRESS THEM. SO WE BROKE THEM INTO THREE TIERS.
9 WE BELIEVE THAT ALL 27 RECOMMENDATIONS ARE ALL
10 IMPORTANT. WE HAVE IDENTIFIED WHERE WE THINK THAT
11 THERE IS A POTENTIAL EXTERNAL COST TO THE
12 ORGANIZATION. ALL OF THE CASES WHERE THERE'S A COST
13 IDENTIFIED, THEY'RE TECHNOLOGY RELATED. WITH YOUR
14 NEW HIRING OF AN I.T. DIRECTOR, SOME OF THAT MAY NOT
15 NEED TO BE EXTERNAL COST, WHICH IS GREAT.

16 SOME OF THE THEMES THAT I WOULD HOPE YOU
17 WOULD TAKE AWAY FROM THESE AS A BODY IS, AGAIN,
18 YOU'RE A VERY DATA-DRIVEN, OUTCOME-BASED
19 ORGANIZATION. AND A LOT OF OUR RECOMMENDATIONS ARE
20 REALLY GEARED TOWARDS BEING ABLE TO GENERATE DATA
21 MORE EASILY, HOW YOU COMMUNICATE THAT INFORMATION TO
22 YOUR VARIOUS AUDIENCES, HOW YOU CAN USE TECHNOLOGY
23 TO STREAMLINE THAT PROCESS, HOW YOU CAN INCORPORATE
24 THE USE OF PERFORMANCE METRICS THROUGHOUT YOUR DAILY
25 OPERATIONS FROM USING THEM IN STAFF MEETINGS TO

BARRISTERS' REPORTING SERVICE

1 BEING ABLE TO MAKE DECISIONS AS A BOARD, TO HOW YOU
2 REFLECT THAT IN YOUR ANNUAL PLAN, IN GENERAL HOW YOU
3 COMMUNICATE PERFORMANCE AND PROGRESS TOWARDS THE
4 OUTCOMES TO ALL OF YOUR AUDIENCES. THOSE ARE ALL,
5 OF COURSE, PARAMOUNT TO YOUR BUSINESS.

6 A FEW TO JUST POINT OUT, AND, AGAIN, I
7 APOLOGIZE THAT YOU CERTAINLY CAN'T READ THIS ON
8 SCREEN. AS FAR AS A FEW ITEMS TO TAKE AWAY HERE FOR
9 TIER 1 RECOMMENDATIONS. SO WE TALK ABOUT GRANTS
10 OUTCOME TRACKING, AND THE WORK THAT THE ORGANIZATION
11 IS CURRENTLY DOING TO DEVELOP A DATABASE TO REALLY
12 AT THE FRONT END BE ABLE TO COLLECT THE DATA THAT'S
13 GOING TO TIE BACK TO YOUR OUTCOMES. AND BEING ABLE
14 TO PULL THAT WORK FORWARD AND BUILD IT INTO, WE'VE
15 USED THE TERM, A DIGITAL DASHBOARD, SOMETHING THAT
16 TYPICALLY A BUSINESS WOULD HAVE, AN EXECUTIVE TEAM
17 WOULD BE ABLE TO USE TO SORT OF KEEP THE PULSE ON
18 SOME OF THOSE KEY METRICS THAT YOU'RE, IN ESSENCE,
19 TRACKING CERTAINLY ON AN ANNUAL BASIS, BUT MAKING
20 THAT MORE READILY AVAILABLE ON MORE OF A DAY-TO-DAY
21 BASIS AND TRANSLATING THAT SAME TYPE OF INFORMATION
22 INTO A MORE PERFORMANCE-BASED ANNUAL REPORT.

23 DEVELOPMENT OF A COMMUNICATIONS PLAN,
24 WHICH I BELIEVE HAS ALREADY OCCURRED. SO THAT'S
25 GOING TO BE AN EXAMPLE OF THINGS THAT HAVE

BARRISTERS' REPORTING SERVICE

1 TRANSPIRED DURING THE COURSE OF OUR STUDY.

2 MAKING GRANTS OUTCOME DATA NOT AN OPTION
3 IN TERMS OF PROGRESS REPORTS, BUT A REQUIREMENT.
4 THAT IS ALSO UNDER WAY, AND I BELIEVE INFORMATION
5 EITHER HAS ALREADY OR WILL BE PRESENTED TO THE BOARD
6 RELATIVE TO THAT.

7 ON THE NEXT GROUP OF RECOMMENDATIONS,
8 FIRST ONE ON THE LIST, DOCUMENT MANAGEMENT. SO
9 THIS, AGAIN, GOES BACK TO THIS ORGANIZATION, UNLIKE
10 MANY OTHERS, CERTAINLY UNLIKE MANY STATE AGENCIES,
11 IS GENERATING AN ENORMOUS AMOUNT OF CRITICAL
12 INFORMATION THAT MAYBE ONE COULD ARGUE IS GOING TO
13 BE IMPORTANT FOR GENERATIONS TO COME. PROTECTING
14 THAT INFORMATION, BEING ABLE TO ACCESS THAT
15 INFORMATION BOTH IN THE NEAR TERM AND THE LONG TERM
16 THROUGH A DOCUMENT MANAGEMENT SYSTEM IS QUITE
17 IMPORTANT TO THE ORGANIZATION. IT'S NOT SEXY. IT'S
18 NOT REALLY INTERESTING, DOCUMENT MANAGEMENT, BUT
19 THIS IS SOMETHING THAT WILL HELP YOU PROTECT THE
20 INFORMATION AND IS CERTAINLY SOMETHING WORTH
21 PURSUING.

22 DEALING WITH YOUR ABILITY TO REVIEW
23 PROGRESS REPORTS, YOUR SCIENTIFIC OFFICERS. SO ONE
24 OF OUR FINDINGS WAS YOU'RE REALLY NOT ABLE TO REVIEW
25 PROGRESS REPORTS QUITE AS TIMELY AS THE ORGANIZATION

BARRISTERS' REPORTING SERVICE

1 WOULD HOPE TO GIVEN THE OVERALL WORKLOAD. THAT'S
2 CORE TO YOUR BUSINESS, CORE TO BEING ABLE TO GLEAN
3 PROGRESS CERTAINLY ON THOSE, AND MAKING SURE THAT
4 YOU'RE RESOURCED, THAT YOU'RE USING TOOLS TO
5 OPTIMIZE YOUR ABILITY TO DO THAT.

6 A COUPLE EXAMPLES ON TIER II
7 RECOMMENDATIONS. THE THIRD ONE DOWN, WE TALK ABOUT
8 A FORMAL BUSINESS DEVELOPMENT PLAN, WHICH I
9 MENTIONED EARLIER, AGAIN, WITH A FOCUS TOWARDS THE
10 BIOPHARMACEUTICAL INDUSTRY. YOU HAVE SOME GREAT NEW
11 RESOURCES, NOT MAYBE SO NEW ANYMORE IN YOUR
12 ORGANIZATION, AT THE LEADERSHIP LEVEL WHO BRING
13 GREAT SKILL SETS. THIS IS JUST ALL ABOUT PUTTING A
14 PLAN TOGETHER. WHAT'S OUR GO TO MARKET STRATEGY?
15 WHO HAS WHAT RESPONSIBILITY WITHIN THE ORGANIZATION?
16 THINGS THAT YOU'RE DOING INHERENTLY, BUT
17 CRYSTALLIZING THOSE IN TERMS OF A PLAN.

18 GETTING ACCESS, WHICH YOU'VE ALREADY
19 REQUESTED, TO THE STATE CONTROLLER'S OFFICE FISCAL
20 SYSTEM. SO YOU RELY ON THE STATE FOR FISCAL
21 INFORMATION. YOU DON'T HAVE YOUR OWN FINANCIAL
22 SYSTEM. YOU'VE GOTTEN THAT THROUGH DEPARTMENT OF
23 GENERAL SERVICES RECENTLY READ ONLY ACCESS. THESE
24 ARE THINGS THAT WILL HELP YOUR FINANCE DEPARTMENT TO
25 BE MORE EFFICIENT, HAVE A REDUCED DUAL WORK WITH

BARRISTERS' REPORTING SERVICE

1 DATA.

2 AND MAYBE LAST, BUT NOT LEAST, AN EXAMPLE
3 AT YOUR TIER III LEVEL. I MENTIONED A TRANSITION
4 PLAN AND HOW IMPORTANT THAT IS TO THE ORGANIZATION
5 ONGOING. I KNOW YOU ALREADY HAVE MAYBE WITH YOUR
6 GOVERNANCE BOARD TO ADOPT A BOARD CODE OF CONDUCT.
7 THAT'S NOT RECOMMENDED BECAUSE WE HAVEN'T SEEN ANY
8 ISSUES. IT'S JUST PRUDENT PRACTICE FOR A BOARD TO
9 HAVE A CODE OF CONDUCT IN PLACE. SO THAT'S KIND OF
10 JUST A REGULAR TYPE OF RECOMMENDATION.

11 I THINK WITH THAT MAYBE I'LL STOP TALKING.
12 I DON'T WANT TO GET YOU TOO BEHIND IN YOUR SCHEDULE
13 HERE EARLY. ANY QUESTIONS, ANY OTHER QUESTIONS?

14 CHAIRMAN THOMAS: MR. SENATOR.

15 MR. TORRES: THANK YOU VERY MUCH FOR THAT
16 PRESENTATION. FOR THE NEW MEMBER OF THE BOARD AS
17 WELL AS FOR THE REMAINING MEMBERS OF THE BOARD, I
18 THINK IT'S IMPORTANT TO PUT THIS WHOLE REPORT INTO
19 CONTEXT. THIS WAS NOT A SIMPLE PROCESS TO GET TO.
20 WITH THE HELP OF SCOTT TOCHER, JAMES HARRISON, AND
21 MYSELF, WORKING WITH THE PRESIDENT PRO TEM OF THE
22 SENATE, DARRELL STEINBERG, AND ALSO WITH THE
23 MAJORITY LEADER, DEAN FLOREZ, AND, OF COURSE,
24 SENATOR ELAINE ALQUIST, WHO WAS THE AUTHOR OF THE
25 BILL, AND OBVIOUSLY WORKING WITH THE CONTROLLER OF

BARRISTERS' REPORTING SERVICE

1 THE STATE, IT WAS A VERY ARDUOUS PROCESS TO GET TO
2 THE POINT OF PUTTING A PERFORMANCE AUDIT REQUIREMENT
3 WITHIN SENATE BILL 1064.

4 AND THE REASONS FOR THAT IS THAT MOST
5 PEOPLE MAY NOT KNOW, BUT THIS AGENCY HAS MORE AUDITS
6 THAN ANY OTHER STATE AGENCY IN MY HISTORY AND THE
7 HISTORY OF THE STATE OF CALIFORNIA. WE HAVE AN
8 AUDIT THAT WE DO INTERNALLY. WE HAVE AN AUDIT
9 THAT'S REVIEWED BY THE CONTROLLER. THE CONTROLLER
10 DOES ITS OWN AUDIT REVIEW, AND WE REPORT TO THAT.
11 AND THEN WE REPORT TO THE CONTROLLER'S COMMITTEE,
12 WHICH IS LABELED FINANCIAL ACCOUNTABILITY COMMITTEE.
13 AND I MIGHT ADD THAT REPORT WAS GREETED WITH
14 TREMENDOUS SUPPORT AND A REAL CHANGE IN DIRECTION
15 BECAUSE OF OUR NEW CHAIR AND OBVIOUSLY OUR PRESIDENT
16 WORKING HARD TO MAKE SURE THAT WE ADDRESS THE ISSUES
17 THE CONTROLLER HAD RAISED WITHIN THAT REPORT.

18 SO IMPOSING ANOTHER AUDIT AND A
19 PERFORMANCE AUDIT WAS NOT AN EASY THING TO ACCEPT,
20 BUT WE DID. AND WE NEGOTIATED IT AND ACCEPTED IT
21 BECAUSE WE FELT AT THE END OF THE DAY TRANSPARENCY
22 WAS MUCH MORE IMPORTANT THAN STALLING AROUND OR
23 TRYING TO MAKE THE ARGUMENT THAT IT WOULD COST US
24 MORE. WE ALSO WANTED TO MAKE SURE THAT THIS
25 PERFORMANCE AUDIT WAS DONE ACCORDING TO STATE AND

BARRISTERS' REPORTING SERVICE

1 NATIONAL STANDARDS, WHICH YOU HAVE DONE EXPERTLY.

2 AND THIRDLY, I THINK IT'S IMPORTANT TO
3 POINT OUT THAT THIS PERFORMANCE AUDIT WAS ALSO
4 IMPORTANT TO LAY OUT TO THE REMAINING MEMBERS OF THE
5 LEGISLATURE, NEW AND RETURNING, THAT WE ARE A
6 TRANSPARENT AGENCY, THAT WE BELIEVE IN
7 ACCOUNTABILITY. AND OBVIOUSLY OUR EXPECTATIONS WERE
8 THAT THIS PERFORMANCE AUDIT, INTERNALLY WE KNEW WE'D
9 BE OKAY, AND COMPARATIVELY SPEAKING WE DID VERY WELL
10 IN TERMS OF HOW WE PERFORM AND HOW WE WILL CONTINUE
11 TO PERFORM, AND THE FACT THAT THIS AGENCY HAS ALSO
12 TAKEN VERY SPECIFIC STEPS TO ADDRESS THE ISSUES THAT
13 YOU HAD ALREADY RAISED, THE BOARD OF CONDUCT ISSUE
14 WHICH WAS NOT BASED ON ANY ISSUES THAT WERE RAISED
15 INTERNALLY, BUT A GOOD BEST PRACTICES FOR ANY
16 AGENCY.

17 IN RESPECT TO A COMMUNICATIONS PLAN, IT
18 TOOK US A WHILE TO GET TO THAT POINT, BUT WE'RE
19 THERE NOW WITH A GOOD DIRECTOR OF COMMUNICATIONS AND
20 PATIENT OUTREACH, KEVIN MCCORMACK. SO WE'VE MADE
21 TREMENDOUS STRIDES, BUT I THINK IT'S IMPORTANT FOR
22 THE BOARD TO UNDERSTAND THAT IT WAS NOT AN EASY
23 JOURNEY. AND NEGOTIATING THIS, AS JAMES AND SCOTT
24 WILL TELL YOU, WAS NOT AN EASY TASK, BUT IT WAS
25 DONE. AND I BELIEVE AT THE END OF THE DAY I'M GLAD

BARRISTERS' REPORTING SERVICE

1 IT WAS DONE. AND I WANT TO THANK YOU AND YOUR
2 AGENCY FOR SHOWING THE TAXPAYERS THAT WE HAVE, THAT
3 WE ARE A FISCALLY RESPONSIBLE STATE AGENCY.

4 CHAIRMAN THOMAS: MR. GOLDBERG.

5 MR. GOLDBERG: THANK YOU FOR YOUR REPORT.
6 MY QUESTION IS YOU REFERENCE THAT YOU DO THIS FOR
7 HUNDREDS OF ORGANIZATIONS OF ALL DIFFERENT TYPES.
8 COULD YOU BE QUANTITATIVE AND TAKE A STAB AT WHAT
9 QUARTILE OR DECILE YOU WOULD RATE OUR PERFORMANCE?

10 MR. STERANKA: HOW DID WE KNOW THAT WAS
11 COMING? I WON'T BE QUITE AS COOPERATIVE AS YOU
12 WOULD LIKE. I WOULD SAY THAT YOU FAIRED VERY
13 FAVORABLY. I THINK THAT THAT'S A FAIR, A VERY FAIR
14 RANKING, RATING OF YOU, OF THE ORGANIZATION. I
15 DON'T KNOW THAT I WOULD GO TO QUARTILES NECESSARILY.
16 THIS IS A VERY FAVORABLE REPORT COMPARED TO OTHERS
17 THAT WE HAVE PROVIDED FOR OTHER CLIENTS.

18 MS. CASE: I JUST HAVE TO WEIGH IN ON
19 LITTLE BIT ON THAT. I WOULD SAY IN THE CORE AREAS
20 THAT YOU GUYS WERE SUPERLATIVE COMPARED TO MOST
21 OTHERS. BUT WHEN YOU WEIGH IN THE OPERATIONAL
22 OPPORTUNITIES FOR EFFICIENCY AND EFFECTIVENESS, I
23 THINK MARK'S COMMENT IS EXACTLY RIGHT ON. BUT THE
24 CORE COMPLIANCE AND INTERNAL CONTROL WORK THAT WE
25 DID WAS EXTREMELY GOOD, VERY WELL DESIGNED AND

BARRISTERS' REPORTING SERVICE

1 IMPLEMENTED. NO FINDINGS. AND A GOVERNMENT AGENCY
2 OVERSEEING GRANTEES AND MONITORING PROGRESS AND
3 PROVIDING CONSULTATIONS TO THE GRANTEES, VERY
4 EXCELLENT JOB. AND THAT'S A KEY PIECE OF WHAT YOU
5 DO AND A KEY PIECE OF WHAT'S IN THE REQUIREMENT FOR
6 YOUR PERFORMANCE AUDIT.

7 MR. STERANKA: WAS THAT BETTER?

8 MR. GOLDBERG: NO COMMENT.

9 MR. STERANKA: FAIR ENOUGH.

10 CHAIRMAN THOMAS: DR. TROUNSON.

11 DR. TROUNSON: I'D JUST LIKE TO THANK MARK
12 AND HIS COLLEAGUES FOR BEING A GOOD TEAM TO WORK
13 WITH. AS ART SAID, WE'RE UNDER AN INCREDIBLE
14 PRESSURE TO DELIVER THE PROGRAM FOR CIRM, FOR THE
15 BOARD. AND WE WERE SITTING THROUGH THREE AUDITS
16 GOING ON SIMULTANEOUSLY. AND PARTICULARLY THE
17 PRESSURE ON AMY LEWIS AND GABE THOMPSON AND PAT
18 OLSON AND THE TEAM WAS REALLY, REALLY TOUGH. BUT
19 THEY KEPT UP THE PACE FOR ALL OF THE OTHER
20 ACTIVITIES, AND I THINK IT WAS REALLY HELPFUL THAT
21 MARK UNDERSTOOD THE PRESSURES THAT WE'RE UNDER AND
22 DID IT IN A WAY WHERE IT WAS OKAY TO DO.

23 I MEAN I ACTUALLY THOUGHT WE WERE GOING TO
24 RUN INTO TROUBLE BECAUSE IF IT HADN'T BEEN A
25 THOUGHTFUL GROUP OF PEOPLE, IT MIGHT HAVE HURT

BARRISTERS' REPORTING SERVICE

1 REALLY BADLY.

2 AND I WANT TO THANK IAN SWEEDLER FOR HIS
3 WORK. HE DID A TREMENDOUS JOB ON HELPING MAKE THE
4 CONNECTIONS TO SMOOTH THE WAY AND REALLY HELP GET
5 THE INFORMATION THAT YOU'RE LOOKING FOR. SO I THINK
6 FROM BOTH SIDES, FROM WHAT I THOUGHT MIGHT BE REALLY
7 A DIFFICULT CHORE AND WOULD SET US WAY BEHIND ON
8 SOME OF OUR OTHER ACTIVITIES, WE MANAGED TO KEEP UP
9 OUR OWN PACE AND ADDRESS THE ISSUES THAT YOU NEEDED
10 TO HAVE ADDRESSED. SO I WANT TO THANK YOU FOR THAT
11 AND THANK THE STAFF FOR ACTUALLY DOING IT WITH
12 REALLY GOOD HUMOR AND IN A VERY POSITIVE WAY. AND I
13 THANK GOODNESS BECAUSE IT COULD HAVE BEEN QUITE
14 DIFFICULT. AS I PREDICTED, I THINK, LAST YEAR, THIS
15 WAS GOING TO BE A TOUGH TIME FOR US. BUT THANK YOU
16 FOR BEING SENSITIVE AND BEING HELPFUL TO US, I
17 THINK.

18 AND I THINK THE RECOMMENDATIONS THAT YOU
19 MAKE ARE VERY USEFUL. SO SOME OF THEM ARE UNDER
20 CONSIDERATION ABOUT HOW WE CAN ACTUALLY DO THEM, BUT
21 MOST OF THEM ARE IN PROCESS ALREADY, AND WE'VE
22 IDENTIFIED THE KEY STAFF THAT WILL ACTUALLY DELIVER
23 ON THEM.

24 SO WE FEEL VERY GOOD ABOUT THIS AUDIT, AND
25 WE FEEL THAT WE'VE BEEN DONE OVER BY A REAL

BARRISTERS' REPORTING SERVICE

1 PROFESSIONAL GROUP OF PEOPLE IN A WAY THAT'S BEEN
2 VERY HELPFUL. SO THANK YOU TO YOU AND YOUR
3 COLLEAGUES.

4 MR. STERANKA: THANK YOU. YOU HAVE QUITE
5 A HIGH CALIBER GROUP HERE, SO WE HAD TO HAVE OUR ACT
6 TOGETHER TO KEEP UP WITH YOU.

7 CHAIRMAN THOMAS: THANK YOU FOR THOSE
8 COMMENTS, ALAN. I'D LIKE TO ADD TO THAT ON TOP OF
9 EVERYTHING ELSE. AS EVERYBODY KNOWS, THIS IS AN
10 EXTRAORDINARY YEAR IN TERMS OF NUMBERS OF RFA'S THAT
11 WE HAVE OUTSTANDING, THINGS TO EVALUATE, THINGS TO
12 REVIEW. SO WHEN YOU OVERLAY THREE AUDITS ON TOP OF
13 THAT, IT DOES POSE SOME SIGNIFICANT LOGISTICAL
14 CHALLENGES. AND I WANT TO ECHO WHAT ALAN SAID IN
15 CONGRATULATING EVERYBODY FOR COMPLETELY RISING TO
16 THE OCCASION ON THIS AND EVERYTHING ELSE WE'RE DOING
17 TO MAKE WHAT IS A VERY CHALLENGING YEAR GO
18 SEAMLESSLY. AND, MARK, THANK YOU VERY MUCH AS WELL.

19 DO WE HAVE ANY COMMENTS, CLOSING THOUGHTS?
20 WE REALLY APPRECIATE THIS. WE ARE DELIGHTED WITH
21 THE RESULTS. IT'S ALWAYS NICE TO HEAR THAT WE'RE ON
22 THE RIGHT TRACK AND ACTUALLY BETTER THAN THAT.

23 JAMES. THANK YOU. JAMES IS GIVING ME THE
24 EYE OVER THERE. SO DO WE HAVE ANY PUBLIC COMMENT ON
25 THIS PARTICULAR TOPIC? WELCOME, DON REED.

BARRISTERS' REPORTING SERVICE

1 MR. REED: MY PLEASURE. I THINK THERE'S
2 SOMETHING THAT GOES A LITTLE BEYOND THAT. THIS
3 ORGANIZATION HAS BEEN AUDITED SO MANY TIMES, AND
4 EVERY TIME COMING UP SQUEAKY CLEAN. AND I FELT THAT
5 THERE'S SOMETHING MORE THAN THAT THAT NEEDED TO BE
6 SAID. AND THAT WAS WHY I WROTE THE FOLLOWING LETTER
7 WHICH WILL MAKE SENSE WHEN I GET TO THE END OF IT.

8 AS THE FATHER OF A PARALYZED YOUNG MAN,
9 I'M REMINDED EVERY DAY WHY CALIFORNIA APPROVED
10 PROPOSITION 71 AUTHORIZING THE SALE OF STATE BONDS
11 TO FUND THE PROGRAM OF STEM CELL RESEARCH. ROMAN
12 REED WAS 19 WHEN HIS NECK WAS BROKEN AT A COLLEGE
13 FOOTBALL GAME. TODAY AT 36 HE'S REMARKABLY
14 INDEPENDENT, DRIVING AN ADAPTED VAN, GRADUATE OF UC
15 BERKELEY, AND A FATHER OF THREE, BUT HE'S STILL
16 PARALYZED, AMONG THE 100 MILLION AMERICANS AFFLICTED
17 WITH A CHRONIC DISEASE DISABILITY.

18 CONSIDER THOSE AUDITS. ONE IN THREE U.S.
19 CITIZENS HAS AN INCURABLE ILLNESS OR INJURY. THIS
20 IS A PROBLEM WHICH COULD CRUSH A COUNTRY'S ECONOMY.
21 IN 2009 AMERICA SPENT 1.65 TRILLION ON CHRONIC
22 DISEASE, EXCEEDING THE ENTIRE NATIONAL DEBT FOR THAT
23 PERIOD OF TIME. AND FOR ALL THAT COLOSSAL
24 EXPENDITURE, NOT A SINGLE PERSON GOT WELL.

25 CHRONIC MEANS INCURABLE. THAT IS WHY

BARRISTERS' REPORTING SERVICE

1 CALIFORNIA INVESTED IN THE \$6 BILLION STEM CELL
2 PROGRAM BECAUSE WE WANT TO HEAL OUR LOVED ONES, NOT
3 JUST MAINTAIN THEM IN THEIR MISERY. TODAY 12
4 SHINING NEW STEM CELL RESEARCH CENTERS ARE FOSTERING
5 A SYSTEMATIC QUEST FOR CURE, FORMING BIOMEDICAL
6 CLUSTERS UP AND DOWN THE STATE. WAS THIS EXPENSIVE?
7 OF COURSE. A WAR CANNOT BE FOUGHT FOR PENNIES, BUT
8 CALIFORNIA WAS CAREFUL TOO. WE DO NOT WANT TO
9 OVERSPEND ON CONSTRUCTION COST. THE GOVERNING BOARD
10 ADDED A CREATIVE FINANCIAL REQUIREMENT THAT
11 POTENTIAL SITES SHOULD COMPETE TO BRING OUTSIDE
12 MONEY WITH THEM. THIS LEVERAGED CIRM'S 271 MILLION
13 INTO 1.15 BILLION, FOUR TIMES OUR INVESTMENT, NEW
14 MONEY FOR THE GOLDEN STATE.

15 ALREADY THE PROGRAM HAS BENEFITED
16 CALIFORNIA BY EXPANDING BIOMEDICAL, ONE OF OUR
17 STATE'S FOUNDATIONAL INDUSTRIES. YOUNG PEOPLE CAN
18 LEARN A NEW TRADE AT THEIR LOCAL HIGH SCHOOLS AND
19 STATE COLLEGES BECAUSE OF A CIRM PROGRAM AVAILABLE
20 ONLINE AS PART OF THEIR EDUCATIONAL CURRICULA.

21 ADDITIONALLY, THE BRIDGES PROGRAM OFFERS A
22 WAY FOR TOPNOTCH, OFTEN FINANCIALLY DISADVANTAGED
23 STUDENTS TO WORK IN STEM CELL LABORATORIES GETTING
24 PRICELESS PRACTICAL EXPERIENCE TO BEGIN WHAT MIGHT
25 BECOME A FRUITFUL CAREER.

BARRISTERS' REPORTING SERVICE

1 THE CIRM HAS TRIED TO ANTICIPATE EVERY
2 NEED OF A NEW AND DEVELOPING FIELD ESTABLISHING
3 BASIC STEM CELL BIOLOGY PROGRAMS, BRINGING BOTH NEW
4 AND EXPERIENCED SCIENTISTS TO OUR FIELD, REACHING
5 OUT TO MAKE COOPERATIVE EFFORTS ACROSS THE COUNTRY
6 AND THE WORLD, DEVELOPING NEW TOOLS AND TECHNOLOGY,
7 FINDING WAYS TO ELIMINATE BOTTLENECKS, STUDYING
8 REGULATORY MINE FIELDS, LOAN PROGRAMS FOR BIOMEDICAL
9 MEDICINE, ESPECIALLY EXPENSIVE AND DIFFICULT
10 CLINICAL TRIALS, INVESTIGATING THE ENDLESS STRUGGLE
11 OVER INTELLECTUAL PROPERTY AND MUCH MORE.

12 CIRM'S CROWNING JEWEL IS A DISEASE TEAM
13 GRANT. EVERYTHING IS PREPARATION OF THESE HUGE AND
14 AMBITIOUS GRANTS UP TO \$20 MILLION EACH WITH THE
15 AMBITIOUS GOAL OF BRINGING HUMAN THERAPY TO CLINICAL
16 TRIALS WITHIN FOUR YEARS, AND WE HAVE 14 OF THEM.
17 WE ARE MAKING REALISTIC STEP-BY-STEP PROGRESS TOWARD
18 THIS GIGANTIC GOAL. ALREADY CIRM HAS ACHIEVED 1,000
19 PUBLISHED BREAKTHROUGHS, SCIENTIFIC PAPERS, EACH A
20 PIECE OF THE PUZZLE OF THE CURE. THIS LIBRARY OF
21 DOCUMENTATION THAT ONLY OFFERS PATIENT ADVOCATES FOR
22 PROGRESS, BUT ALSO CAUTIONS THOUGH IT DOES NOT WORK,
23 SO THAT RESEARCHERS CAN AVOID WASTING TIME AND
24 MONEY.

25 COLLABORATIONS ARE BEING FORGED. ALREADY

BARRISTERS' REPORTING SERVICE

1 130 TOP STEM CELL SCIENTISTS HAVE MOVED TO
2 CALIFORNIA, PERHAPS DRAWN BY THE CIRM PROGRAM.
3 BIOMEDICAL CLASSES ARE DEVELOPING. AND WHILE EVERY
4 CALIFORNIA DOLLAR MUST BE SPENT IN THE HOME STATE,
5 WE'RE GETTING MORE BANG FOR THE BUCK BY PARTNERING
6 WITH OTHER STATES AND COUNTRIES, 16 OF THEM.
7 ALREADY THESE NEW PARTNERS HAVE CONTRIBUTED MORE
8 THAN \$60 MILLION OF ADD-ON FUNDING AS WELL AS
9 INTELLECTUAL STRENGTH. THE JOB IS NOT DONE, BUT IT
10 IS WELL DONE. IT IS WELL BEGUN. LIKE FARMERS
11 BATTLING THE WILDERNESS, THE CIRM HAS CLEARED
12 GROUND, REMOVED BOULDERS, PLOWED AND PLANTING,
13 IRRIGATED AND WEEDED. TODAY'S SEEDS ARE BURSTING
14 OPEN BELOW GROUND. NEW SHOOTS ARE PUSHING UPWARDS
15 THROUGH THE SOIL, REACHING FOR THE SUN. THE
16 CALIFORNIA STEM CELL PROGRAM IS THE PRIDE OF THE
17 STATE, THE GLORY OF A NATION, AND A FRIEND TO ALL
18 THE WORLD.

19 AND THAT'S WHY IT IS AN HONOR AND DELIGHT
20 TO NOMINATE THE CALIFORNIA INSTITUTE FOR
21 REGENERATIVE MEDICINE FOR THE PAUL G. ROGERS
22 DISTINGUISHED ORGANIZATION LEGACY AWARD FROM
23 RESEARCH AMERICA WHICH WAS PREVIOUSLY WON BY THE
24 MARCH OF DIMES. THANK YOU.

25 (APPLAUSE.)

BARRISTERS' REPORTING SERVICE

1 RECONVENING. BEFORE WE START WITH THE NEXT ITEM, I
2 JUST WANTED TO NOTE FOR THE RECORD THAT WITH RESPECT
3 TO THE PERFORMANCE AUDIT, WE WILL BE BRINGING
4 BACK -- IAN SWEEDLER, SPEARHEADING THE EFFORT, WILL
5 BE BRINGING BACK TO THE BOARD A GAME PLAN AT OUR
6 JULY BOARD MEETING AS TO HOW TO IMPLEMENT THE
7 RECOMMENDATIONS SET FORTH IN THE PERFORMANCE AUDIT,
8 AND THAT WE WILL BE PERIODICALLY AFTER THAT COMING
9 BACK TO THE BOARD WITH SPECIFIC UPDATES. AND WE'LL,
10 OF COURSE, HAVE THAT AVAILABLE TO THE PUBLIC AS WELL
11 SO THAT EVERYBODY CAN TRACK HOW WE FOLLOW ALONG WITH
12 THE MANY RECOMMENDATIONS.

13 SO WITH THAT, LET'S TURN THIS OVER TO THE
14 NEXT ITEM, WHICH IS THE THIRD ROUND OF EARLY
15 TRANSLATION AWARDS. AS YOU KNOW, WE'VE HAD A NUMBER
16 OF THESE IN THE PAST THAT COMPRISES A SIGNIFICANT
17 PORTION OF THE 43 MAJOR AWARDS THAT WE'VE GIVEN TO
18 DATE. THIS IS, AS NOTED, THE THIRD ROUND OF EARLY
19 TRANSLATION AWARDS. AND I'D LIKE TO TURN THIS OVER
20 TO DR. SAMBRANO TO GIVE US CONTEXT ON THIS PROCESS.

21 DR. SAMBRANO: MR. CHAIR, THANK YOU VERY
22 MUCH. MEMBERS OF THE BOARD, MEMBERS OF THE PUBLIC,
23 I WANT TO JUST VERY BRIEFLY, I HAVE ABOUT TWO
24 MINUTES, AND I WILL TRY TO DO THIS WITHIN THAT TIME
25 IF I CAN, TO GIVE YOU A VERY BRIEF BACKGROUND AND

BARRISTERS' REPORTING SERVICE

1 OVERVIEW OF THE PROCESS AND JUST TO PROVIDE SOME
2 CONTEXT. THIS WILL NOT BE COMPREHENSIVE IN ANY WAY,
3 BUT I CAN ADDRESS ANY QUESTIONS SHOULD YOU HAVE
4 THEM.

5 SO IT'S IMPORTANT TO KNOW THAT AS WE BRING
6 THESE APPLICATIONS TO YOU, THAT ALL OF THE
7 APPLICATIONS UNDER CONSIDERATION BY THE ICOC, THE
8 GRANTS WORKING GROUP HAS CONDUCTED ALREADY A
9 THOROUGH SCIENTIFIC EVALUATION OF EACH APPLICATION
10 BASED ON THE REVIEW CRITERIA THAT ARE OUTLINED IN
11 THE RFA. AND ADDITIONALLY, IT HAS PERFORMED A
12 PROGRAMMATIC ASSESSMENT TO ARRIVE AT THE FUNDING
13 RECOMMENDATIONS MADE TO YOU.

14 AS YOU KNOW, THE GRANTS WORKING GROUP
15 ITSELF IS COMPOSED OF FIFTEEN SCIENTIFIC MEMBERS AND
16 SEVEN PATIENT ADVOCATE MEMBERS WHO ALSO SERVE ON
17 THIS BOARD. THE FIFTEEN SCIENTIFIC MEMBERS ARE
18 ASSIGNED BASED ON THE MOST RELEVANT EXPERTISE TO
19 THIS RFA. THAT EXPERTISE IS ENHANCED BY RECRUITMENT
20 OF ADDITIONAL SPECIALIST REVIEWERS WHO PROVIDE
21 EVALUATIONS, BUT DO NOT PROVIDE FINAL SCORES OR
22 VOTES.

23 SO IN THIS PARTICULAR RFA, WE HAD A TOTAL
24 OF 28 DIFFERENT SCIENTIFIC EXPERTS WHO CONTRIBUTED
25 TO THE REVIEW OF THE 41 APPLICATIONS COMING TO YOU.

BARRISTERS' REPORTING SERVICE

1 DURING THE GRANTS WORKING GROUP REVIEW
2 MEETING, ALL APPLICATIONS ARE DISCUSSED AND SCORED.
3 THERE IS NO TRIAGE. CIRM SCIENTIFIC STAFF TAKES
4 EXTENSIVE NOTES OF THE DISCUSSION WHICH, WHEN
5 COMBINED WITH THE REVIEWER CRITIQUES, HELPS
6 FORMULATE THE SUMMARIES THAT YOU SEE IN YOUR BOOKS.

7 NOW, EACH APPLICANT FOLLOWING THE REVIEW
8 AND THE GENERATION OF THE SUMMARIES RECEIVES A
9 REVIEW REPORT, AND THAT'S ABOUT TWO WEEKS BEFORE
10 THIS MEETING. THAT INCLUDES THE SCIENTIFIC SCORES,
11 THE RECOMMENDATION, THE SUMMARY OF THE REVIEW WHICH
12 WILL HIGHLIGHT THE STRENGTHS AND WEAKNESSES OF THE
13 PROPOSAL, AND THEN PRESENTS ANY SUGGESTED CONDITIONS
14 OR MODIFICATIONS.

15 THE REVIEW REPORT THAT IS SENT BY E-MAIL
16 ALSO DESCRIBES THE BASIC PROCESS FOR ADDRESSING
17 CONCERNS ABOUT THE REVIEW. SO APPLICANTS ARE
18 INSTRUCTED TO CONTACT THE SENIOR REVIEW OFFICER AS
19 THEIR FIRST STEP, BUT WE ALSO PROVIDE LINKS TO THE
20 GRANTS ADMINISTRATION POLICY WHICH DESCRIBES THE
21 FORMAL APPEALS PROCESS AND THE EXTRAORDINARY
22 PETITION POLICY. IT'S IMPORTANT TO REMEMBER THAT
23 THE FORMAL APPEALS PROCESS IS SEPARATE AND DISTINCT
24 FROM THE EXTRAORDINARY PETITION PROCESS.

25 FOR APPEALS, OR FORMAL APPEALS, IF THE

BARRISTERS' REPORTING SERVICE

1 APPLICANT BELIEVES THAT A CONFLICT OF INTEREST AS
2 DEFINED UNDER THE GRANTS WORKING GROUP CONFLICT OF
3 INTEREST POLICY MIGHT HAVE HAD A NEGATIVE IMPACT ON
4 THE REVIEW, THE APPLICANT MAY CHOOSE TO PURSUE A
5 FORMAL APPEAL. DEMONSTRATION THAT A CONFLICT OF
6 INTEREST HAD A NEGATIVE IMPACT ON THE REVIEW PROCESS
7 AND RESULTED IN A FLAWED REVIEW IS THE ONLY GROUND
8 FOR A FORMAL APPEAL. AND THOSE APPEALS ARE MANAGED
9 BY THE CIRM PRESIDENT, LEGAL COUNSEL, SCIENTIFIC
10 STAFF, AND THE GRANTS WORKING GROUP REVIEW CHAIR.

11 NOW, ON THE OTHER HAND, IF THE APPLICANT
12 WISHES TO PETITION THE ICOC, THE APPLICANT MAY
13 SUBMIT AN EXTRAORDINARY PETITION. THE PETITION
14 POLICY DOES NOT LIMIT OR SPECIFY CIRCUMSTANCES UNDER
15 WHICH A PETITION CAN BE MADE, BUT IT IS INTENDED TO
16 AFFORD APPLICANTS AN OPPORTUNITY TO COMMUNICATE WITH
17 THE BOARD ABOUT THE REVIEW BASED ON WHAT THE
18 APPLICANT WOULD DEEM TO BE AN EXTRAORDINARY
19 CIRCUMSTANCE.

20 THE ICOC ESTABLISHED THIS POLICY TO MANAGE
21 AS BEST ONE CAN APPLICANT REQUESTS THAT MAY COME
22 FROM REVIEW. AND APPLICANTS ARE ASKED TO SUBMIT NOT
23 LESS THAN FIVE BUSINESS DAYS OF AN ICOC MEETING.
24 WHEN THEY ARE NOT, THEN WE LABEL THEM AS LATE.

25 NOW, IF AN EXTRAORDINARY PETITION HAS BEEN

BARRISTERS' REPORTING SERVICE

1 SUBMITTED BY THE APPLICANT, THE ICOC IS NOT REQUIRED
2 TO DISCUSS IT UNLESS A BOARD MEMBER HAS A SPECIFIC
3 QUESTION OR FEELS THAT THE PETITION MAY HAVE MERIT.
4 THE ICOC SCIENCE SUBCOMMITTEE PROVIDED THAT THE CIRM
5 STAFF SHOULD NOT PREPARE WRITTEN REBUTTALS TO
6 PETITIONS AND SHOULD PROVIDE WRITTEN RESPONSES ONLY
7 IN CASES WHERE CIRM STAFF BELIEVES THE PETITION HAS
8 MERIT. IN ALL CASES, HOWEVER, CIRM STAFF WILL BE
9 PREPARED TO ADDRESS ANY QUESTIONS OR CONCERNS THAT
10 BOARD MEMBERS MAY HAVE.

11 NOW, AS WE BRING THESE APPLICATIONS TO
12 YOU, WE'RE GOING TO BRING THE RECOMMENDATIONS OF THE
13 GRANTS WORKING GROUP FOR YOUR CONSIDERATION. YOU
14 CAN ALREADY CONSIDER OBVIOUSLY OTHER THINGS THAT MAY
15 IMPACT YOUR DECISION TO FUND OR NOT FUND
16 APPLICATIONS, SUCH AS THE AVAILABILITY OF FUNDS, THE
17 OVERALL GRANT PORTFOLIO, ANY STRATEGIC
18 CONSIDERATIONS, OR THE MISSION OF CIRM. AND SO WHAT
19 WE TRY TO DO IS PROVIDE YOU TOOLS THAT WILL HELP YOU
20 IN FORMULATING YOUR DECISION.

21 SO IN YOUR BINDERS YOU WILL FIND SEVERAL
22 THINGS. YOU WILL FIND A TABLE THAT LISTS THE
23 APPLICATIONS IN RANK ORDER. THAT TABLE SHOWS THE
24 APPLICATION NUMBER, THE TITLE OF THE PROJECT, THE
25 SCIENTIFIC SCORE, WHICH INCLUDES THE AVERAGE, THE

BARRISTERS' REPORTING SERVICE

1 MEDIAN, STANDARD DEVIATION, AND RANGE OF INDIVIDUAL
2 SCORES, BY THE SCIENTIFIC MEMBERS OF THE WORKING
3 GROUP, THE AMOUNT REQUESTED FROM THE APPLICANT. AND
4 IF APPROPRIATE, WE'VE INCLUDED INFORMATION ABOUT THE
5 DISEASE AREA OR THE TARGET INDICATION THAT MIGHT
6 HELP YOU ASSESS THE OVERALL APPLICATIONS FROM THAT
7 PERSPECTIVE.

8 WE ALSO PROVIDE A COPY OF THE REVIEW
9 REPORT FOR EACH APPLICATION THAT HIGHLIGHTS THE
10 STRENGTHS AND WEAKNESSES. WE HAVE A COMPILATION OF
11 THE PROGRAMMATIC DISCUSSION, SECTIONS FROM THE
12 REVIEW REPORTS FOR YOUR QUICK REFERENCE. THAT WAY
13 YOU KNOW THAT THESE WERE DISCUSSED DURING THE
14 PROGRAMMATIC PORTION OF THE REVIEW. A COPY OF THE
15 CURRENT PORTFOLIO OF THE CIRM GRANTS FOR YOUR
16 REFERENCE SO THAT YOU CAN UTILIZE THAT AS A TOOL TO
17 COMPARE THE CURRENT PROPOSALS WITH WHAT CIRM IS
18 ALREADY FUNDING. AND THEN ANY EXTRAORDINARY
19 PETITIONS THAT WERE SUBMITTED BY APPLICANTS AND ANY
20 CIRM STAFF ASSESSMENTS, WHERE APPROPRIATE.

21 FOR THIS PARTICULAR RFA, WE RECEIVED THREE
22 EXTRAORDINARY PETITIONS. ONE OF THEM WAS LABELED
23 LATE, JUST FOR YOU TO NOTE. YOU SHOULD ALSO NOTE
24 THAT THERE ARE TWO AWARD CATEGORIES FOR THIS
25 PARTICULAR RFA, A DC AND DCF, WHICH DR. ARIE ABO

BARRISTERS' REPORTING SERVICE

1 WILL DETAIL A LITTLE MORE, BUT JUST NOTE THAT THAT
2 MEANS THAT THERE ARE ACTUALLY TWO TABLES IN YOUR
3 BINDERS, ONE FOR EACH OF THESE CATEGORIES, BECAUSE
4 THEY WERE REVIEWED SEPARATELY BY THE GRANTS WORKING
5 GROUP.

6 SO TO GET US STARTED, DR. ARIE ABO IS
7 GOING TO PRESENT AN OVERVIEW THAT REMINDS US OF THE
8 OBJECTIVES AND FEATURES OF THE RFA. AND ONCE HE IS
9 DONE WITH THAT, WE ARE GOING TO SHOW YOU A DISPLAY
10 OF THE RANK ORDER ON THE OVERHEAD WHICH ESSENTIALLY
11 MIRRORS WHAT YOU HAVE IN YOUR BINDERS. FOR ANY OF
12 THE APPLICATIONS THAT ARE LISTED, MEMBERS OF THE
13 BOARD MAY REQUEST DISCUSSION OF THE APPLICATION TO
14 INFORM YOUR DECISION. AND SO SCIENCE OFFICERS WILL
15 BE PREPARED TO PROVIDE A SYNOPSIS OF THE APPLICATION
16 THAT INCLUDES A SUMMARY OF THE STRENGTHS AND
17 WEAKNESSES NOTED BY REVIEWERS AND ADDRESS ANY OF
18 YOUR QUESTIONS.

19 IF THERE ARE ANY CONFIDENTIAL OR PROPRIETY
20 INFORMATION, WE CAN DISCUSS THAT WITHIN A CLOSED
21 SESSION. SO I WILL STOP THERE AND I WILL LET DR.
22 ABO TAKE OVER HERE.

23 DR. ABO: THANK YOU, GIL. MR. CHAIRMAN,
24 MEMBERS OF THE ICOC, MEMBERS OF THE PUBLIC, CIRM
25 STAFF, I'M HERE TO REPORT THE RECOMMENDATION OF THE

BARRISTERS' REPORTING SERVICE

1 GRANT WORKING GROUP FOR EARLY TRANSLATION III.
2 BEFORE I GO THROUGH THE RECOMMENDATION, I'D LIKE TO
3 REMIND YOU THAT FOCUS ON THE INITIATIVE OF THE EARLY
4 TRANSLATION PROGRAMS. THIS IS THE THIRD CYCLE OF
5 THE EARLY TRANSLATION III, AND I WAS HERE
6 APPROXIMATE A YEAR AGO, PRESENTED YOU THE CONCEPT.
7 AND FOR THOSE OF YOU THAT ARE NOT FAMILIAR WITH THIS
8 PROGRAM, THIS IS A PROGRAM THAT WAS DESIGNED TO
9 BRIDGE BASIC BIOLOGY TO CLINICAL TO IND-ENABLING
10 STUDIES. AS YOU CAN SEE HERE, IT FITS PERFECTLY IN
11 THE SPECTRUM OF OTHER PROGRAMS THAT WE HAVE AT CIRM
12 FROM STEM CELL BIOLOGY, BASIC RESEARCH PROGRAMS TO
13 DISEASE TEAM AND CLINICAL DEVELOPMENT PROGRAMS.

14 UNDER THIS INITIATIVE, WE DESIGNED TWO
15 TYPE OF AWARDS, THE DEVELOPMENT CANDIDATE AWARD, THE
16 DC AWARD, AND THE DEVELOPMENT CANDIDATE FEASIBILITY
17 AWARDS. AND THE REASON FOR THAT, WE WANTED TO
18 CREATE A SPACE TO PROJECT AN INVESTIGATOR THAT WANTS
19 TO TAKE THEIR EARLY HYPOTHESIS AND EARLY SCIENCE AND
20 BASIC RESEARCH TO BRING IT TO THERAPEUTIC
21 DEVELOPMENT TO ENTER TO THE TRANSLATIONAL SPACE.

22 SO TO TAKE A THERAPEUTIC CANDIDATE UNDER
23 THE DEVELOPMENT CANDIDATE FEASIBILITY, THE DCF, TO
24 IDENTIFY THE THERAPEUTIC CANDIDATE THAT COULD NOT
25 NECESSARILY MOVE ALL THE WAY TO CLINICAL

BARRISTERS' REPORTING SERVICE

1 DEVELOPMENT, BUT WILL BRING IT ALL THE WAY TO PROOF
2 OF CONCEPT.

3 SO SINCE A LOT OF THE APPLICANTS THAT WE
4 HAVE ARE ACADEMIC SCIENTISTS AND NOT A LOT OF THEM
5 ARE ENGAGED IN TRANSLATIONAL SCIENCE, THIS IS AN
6 OPPORTUNITY FOR THEM TO BE ENGAGED IN THIS PROCESS
7 AND REALLY BE PART OF THE MISSION OF CIRM.

8 UNDER THE DEVELOPMENT CANDIDATE AWARD,
9 WHICH IS A BIGGER TYPE OF AWARD, WE DESIGNED THE
10 PROCESS THAT ALLOWS INVESTIGATORS OR PROJECT TO TAKE
11 A THERAPEUTIC CANDIDATE ALL THE WAY TO IND-ENABLING
12 STAGE AND POTENTIALLY COULD MOVE IN THE LATER RFA,
13 IN THE DISEASE TEAM, TO CLINICAL DEVELOPMENT.

14 WE SET UP A FEW PRIORITIES FOR THIS RFA
15 WHERE WE WERE ASKING PROJECTS THAT ARE USING EITHER
16 STEM CELLS, PLURIPOTENT STEM CELLS FOR CELL
17 THERAPIES OR USING PLURIPOTENT STEM CELLS FOR
18 IDENTIFYING THERAPEUTIC CANDIDATES, ESSENTIALLY
19 CELLS, PLURIPOTENT DERIVATIVE CELLS THAT COULD BE
20 USED FOR DRUG SCREEN TO IDENTIFY THERAPEUTIC AGENT
21 THAT COULD BECOME DRUGS.

22 AND IN ADDITION, WE ADDED A CONSIDERATION
23 FOR THE PORTFOLIO. WE WILL ENCOURAGE APPLICATIONS
24 TO -- EXCUSE ME -- THE REVIEWERS TO ASSESS SOME OF
25 THE APPLICATION BASED ON THE PORTFOLIO

BARRISTERS' REPORTING SERVICE

1 CONSIDERATION; AND IF THERE IS AN APPLICATION THAT
2 IS ALREADY REPRESENTED IN CIRM'S PORTFOLIO, WE
3 REQUESTED IT TO BE COMPELLING AND INTERESTING
4 PROJECT.

5 WE DEFINED THE SCOPE OF ACTIVITIES TO THE
6 INVESTIGATORS AND THE REVIEWERS. AND CLEARLY OUT OF
7 SCOPE OF ACTIVITY WE DID NOT REALLY SEEK TO SUPPORT
8 UNDER THIS RFA STUDIES THAT SUPPORT IND-ENABLING
9 STUDIES SUCH AS GMP PRODUCTION OR GLP TOXICOLOGY ON
10 CLINICAL STUDIES. WE HAVE OTHER PLACES, OTHER RFA
11 TO SUPPORT THESE KIND OF STUDIES. AND WE DEFINED
12 VERY TIGHTLY THE SCOPE OF ACTIVITIES THAT WE WISH TO
13 SUPPORT, WHICH IS INCLUDING, AS YOU CAN SEE HERE IN
14 THE LEFT-HAND SIDE, CHARACTERIZATION OF THERAPEUTIC
15 CANDIDATES, RESEARCH PRODUCTION SCALE OF THERAPEUTIC
16 CANDIDATES, AND PROJECTS SUCH AS DISEASE IN THE DISH
17 AS WELL.

18 AND WE DEFINED A SET OF SIX REVIEW
19 CRITERIA THAT I WILL GO VERY BRIEFLY THROUGH THEM.
20 THEY WERE PART OF THE RFA, AND WE PROVIDED THIS AND
21 DISCUSSED THIS VERY CLOSELY WITH THE REVIEWERS THE
22 CRITERIA THAT WE REALLY WANT TO FOCUS IN ORDER TO
23 IDENTIFY THE BEST APPLICANTS.

24 AND SO THE FIRST ONE, THE OBJECTIVE AND
25 MILESTONES, WE CLEARLY WERE LOOKING FOR PROJECTS OR

BARRISTERS' REPORTING SERVICE

1 APPLICATIONS THAT COULD ACHIEVE DEVELOPMENT
2 CANDIDATES AND DEVELOPMENT CANDIDATE FEASIBILITY.
3 WE ARE LOOKING FOR THE TARGET PRODUCT PROFILE THAT'S
4 SCIENTIFICALLY AND CLINICALLY REASONABLE AND DEFINED
5 MILESTONES THAT COULD BE TRACKED AND SUPPORT THE
6 STUDIES.

7 UNDER THE RATIONALE AND SIGNIFICANCE, WE
8 WERE LOOKING FOR PROJECTS THAT ADDRESS UNMET MEDICAL
9 NEEDS AND COULD LEAD TO SIGNIFICANT IMPROVED THERAPY
10 FOR THE PROPOSED DISEASE AND INJURY.

11 UNDER REVIEW CRITERIA NO. 3, THE RESEARCH
12 PROJECT AND FEASIBILITY AND DESIGN, WE ASKED
13 REVIEWERS TO PAY ATTENTION TO PRELIMINARY RESULTS TO
14 SEE IF THERE'S ANY COMPELLING DATA SUPPORTING THE
15 PROPOSED RESEARCH.

16 AND UNDER THE RESEARCH PLANS WE WERE
17 LOOKING FOR A FOCUSED PROPOSAL WITH WELL DESIGNED
18 AND ACHIEVE MILESTONES AND OBJECTIVES WITHIN THREE
19 YEARS PERIOD.

20 FOR REVIEW CRITERIA NO. 4, THE
21 QUALIFICATION OF THE TEAM, THE PI, THE CO-PI, AND
22 PARTNER PI, WE WERE LOOKING FOR A TEAM THAT IS
23 COMMITTED TO TRANSLATIONAL SCIENCE AND THEY HAVE THE
24 RELEVANT EXPERIENCE FOR THE TRANSLATION SCIENCE.
25 ESPECIALLY WE ASKED THE REVIEWERS TO PAY ATTENTION

BARRISTERS' REPORTING SERVICE

1 FOR THE TRACK RECORD FOR THE PI AND THE CO-PI, THAT
2 THEY HAVE SUCCESSFUL RECORD IN PROPOSED
3 TRANSLATIONAL PROJECT BECAUSE THIS IS VERY IMPORTANT
4 AS SOME OF THE ACTIVITIES ARE DIFFERENT FROM BASIC
5 SCIENCE, AND WE'RE LOOKING FOR INVESTIGATOR THAT
6 COULD BRING THIS TO THE TABLE.

7 UNDER REVIEW CRITERIA NO. 5, THERE IS A
8 NUMBER OF THINGS LISTED HERE, BUT MOST IMPORTANTLY I
9 WOULD LIKE TO EMPHASIZE THAT WE WERE LOOKING FOR A
10 PROJECT THAT WOULD COME WITH A SET OF DOCUMENTS THAT
11 ALREADY SUPPORT THAT THEY HAVE THE MATERIAL TRANSFER
12 AGREEMENT, THE IP POSITION, THAT THEY COULD HAVE THE
13 REAGENTS THAT ARE NECESSARY TO DEVELOP FOR THE
14 PROJECT.

15 AND LASTLY, THEIR RESPONSIVENESS FOR THE
16 RFA, THE REVIEWER CRITERIA NO. 6. WE WERE ASKING
17 FOR REVIEWER TO ASSESS THE PROJECT BEST IF THEY
18 ADDRESS THE RFA OBJECTIVES, NAMELY, ACHIEVING A DC
19 AND DCF, AND THE USE OF STEM CELL FOR PROOF OF
20 CONCEPT FOR DEVELOPMENT CANDIDATE, AND IDENTIFY A
21 TARGET OF INTERVENTION IN CASE OF THE DC, AND
22 PORTFOLIO CONSIDERATIONS.

23 SO HAVING SAID THAT, I'M GOING TO SHOW YOU
24 NOW THE SCORE DISTRIBUTION FOR THE DC AWARDS. AS
25 YOU CAN SEE HERE FROM THIS HISTOGRAM, THE GRANT

BARRISTERS' REPORTING SERVICE

1 WORKING GROUP DREW THE LINE AT SCORE OF 75 AND
2 DEFINED THAT TIER NO. 1 ABOVE 75 AND TIER NO. 2 WAS
3 DEFINED BETWEEN SCORE 45 TO 75. EVERYTHING -- THAT
4 WAS THE INITIAL LINE THAT WAS DRAWN ON 75.
5 EVERYTHING THAT WAS IN TIER II WAS DISCUSSED IN THE
6 PROGRAMMATIC DISCUSSION DURING THE GRANTS WORKING
7 GROUP AND WAS DECIDED EITHER TO MOVE TO TIER I OR
8 TIER III.

9 SIMILARLY, FOR THE DC SCORE DISTRIBUTION,
10 THE LINE FOR TIER I WAS DRAWN IN 75 AND TIER II WAS
11 DEFINED BETWEEN 56, SCORE 56 TO FIVE. AND
12 SIMILARLY, PROGRAMS THAT WERE IN TIER II WERE
13 DISCUSSED IN PROGRAMMATIC EITHER TO BE MOVED TO TIER
14 I OR TO TIER III.

15 SO MY LAST SLIDE IS SHOWING THE
16 RECOMMENDATION FOR THE GRANTS WORKING GROUP. AND AS
17 YOU CAN SEE FROM THIS TABLE, INITIALLY THE TARGET
18 NUMBER OF APPLICATIONS THAT WE WERE TARGETED AS
19 APPROVED BY THE BOARD WAS 95 MILLION, 50 DC AND 10
20 DCF AWARDS. AND THE RECOMMENDED FOR FUNDING WERE
21 NINE DC AND TEN DCF WITH THE EXCEPTION OF ONE DC
22 THAT WILL BE CONVERTED TO A DCF.

23 THANK YOU. IF YOU HAVE ANY QUESTIONS,
24 I'LL BE HAPPY TO ADDRESS THEM.

25 CHAIRMAN THOMAS: ANY QUESTIONS FOR DR.

BARRISTERS' REPORTING SERVICE

1 ABO? JAMES.

2 MR. HARRISON: BEFORE WE BEGIN DISCUSSING
3 INDIVIDUAL APPLICATIONS, I'D LIKE TO JUST REMIND THE
4 BOARD OF TWO THINGS. ONE, YOU SHOULD EACH HAVE A
5 LIST OF THE APPLICATIONS BY APPLICATION NUMBER OF
6 THE APPLICATIONS IN WHICH YOU HAVE A CONFLICT OF
7 INTEREST. SO IF THE BOARD BEGINS TO DISCUSS AN
8 APPLICATION IN WHICH YOU HAVE AN INTEREST, PLEASE
9 REFRAIN FROM PARTICIPATING IN THE DISCUSSION AS WELL
10 AS THE VOTE. WE WILL NOT CALL YOU IF THERE'S A
11 MOTION ON THOSE APPLICATIONS DURING THE ROLL CALL
12 VOTE.

13 THE SECOND THING I WOULD LIKE TO REMIND
14 YOU, AS DR. SAMBRANO MENTIONED, THE BOARD DOES HAVE
15 THE OPPORTUNITY TO CONVENE IN CLOSED SESSION IF
16 NECESSARY TO DISCUSS PROPRIETARY INFORMATION. AND
17 ALTHOUGH IT'S SOMETIMES DIFFICULT TO KNOW IN THE
18 ABSTRACT WHAT INFORMATION WOULD CONSTITUTE
19 PROPRIETARY INFORMATION IN ANY PARTICULAR
20 APPLICATION, GENERALLY SPEAKING, WITH RESPECT TO
21 THESE APPLICATIONS, THE TYPE OF INFORMATION THAT
22 WOULD QUALIFY WOULD BE INFORMATION LIKE
23 PREPUBLICATION DATA OR OTHER INFORMATION WHICH IF
24 KNOWN TO AN APPLICANT'S COMPETITORS WOULD TEND TO
25 GIVE THE COMPETITORS AN ADVANTAGE. AND THAT COULD

BARRISTERS' REPORTING SERVICE

1 INCLUDE, FOR EXAMPLE, SPECIFIC DETAILS REGARDING THE
2 THERAPEUTIC CANDIDATE OR THE RESEARCH PLAN; FOR
3 EXAMPLE, THE TIMELINES.

4 SO IF A BOARD MEMBER ASKS A QUESTION THAT
5 REQUIRES THE DISCLOSURE OF CONFIDENTIAL INFORMATION,
6 STAFF WILL MAKE A NOTE OF THAT, AND WE'LL HAVE AN
7 OPPORTUNITY TO DISCUSS THAT IN A CLOSED SESSION
8 SETTING.

9 CHAIRMAN THOMAS: THANK YOU, JAMES. I
10 BELIEVE ALL BOARD MEMBERS HAVE A CONFLICT OF
11 INTEREST SHEET. JAMES? MARIA?

12 MS. BONNEVILLE: THEY DO.

13 CHAIRMAN THOMAS: WHICH AT THE CONCLUSION
14 OF THE DISCUSSION ON THE ET AWARDS, WE NEED TO SIGN
15 AND MARIA WILL PICK THEM UP FROM EVERYBODY.

16 SO WITH THAT PROCEDURALLY IN PLACE, I'D
17 LIKE TO OPEN THE DISCUSSION ON THE PROPOSED AWARDS.
18 JOAN.

19 MS. SAMUELSON: I HAVE A QUESTION FIRST
20 FOR MAYBE ARIE. I'M NOT SURE. IT'S TO CLARIFY THE
21 TRANSLATIONAL PORTFOLIO. THIS IS EVERY GRANT THAT
22 WE HAVE OR ARE CURRENTLY FUNDING THAT ARE ATTEMPTING
23 TO MOVE TOWARD A THERAPEUTIC RESULT; IS THAT RIGHT?

24 DR. ABO: IT DEPENDS ON WHICH CATEGORY.
25 SO THE DC OR DCF, YEAH, YOU'RE TALKING ABOUT THE

BARRISTERS' REPORTING SERVICE

1 APPLICATION THAT WERE RECOMMENDED OR ANY
2 APPLICATIONS?

3 MS. SAMUELSON: BOTH. YEAH. YEAH.
4 BECAUSE THIS GOES TO THE QUESTION OF PROGRAMMATIC
5 CONSIDERATIONS.

6 DR. OLSON: PERHAPS I COULD COMMENT ON
7 THAT. THE SET OF -- THE TRANSLATIONAL PORTFOLIO
8 THAT WAS PROVIDED TO YOU AS PART OF THE MATERIALS
9 INCLUDES ALL THE EARLY TRANSLATIONAL, ALL THE
10 DISEASE TEAM, ALL THE AWARDS THAT ARE ESSENTIALLY
11 TARGETING -- ARE ATTEMPTING TO ADDRESS A THERAPEUTIC
12 OPTION. IN THE PARTICULAR HANDOUT THAT YOU
13 RECEIVED, IN WHITE ARE THOSE THAT ARE CURRENTLY PART
14 OF OUR PORTFOLIO. IN GRAY ARE THE ET III
15 APPLICATIONS, WHETHER DC -- TARGETING EITHER A
16 DEVELOPMENT CANDIDATE OR A PROOF OF CONCEPT THAT
17 WERE NOT RECOMMENDED BY THE GRANTS WORKING GROUP.
18 AND IN GREEN ARE THE ET III EITHER DC OR DCF
19 APPLICATIONS THAT WERE RECOMMENDED BY THE GRANTS
20 WORKING GROUP.

21 SO IT'S A CURRENT PORTFOLIO PLUS WHAT THE
22 FUTURE MIGHT LOOK LIKE DEPENDING ON THE BOARD'S
23 DECISIONS AS BASED ON THIS PARTICULAR SET OF
24 APPLICATIONS.

25 MS. SAMUELSON: AND THE MAJORITY,

BARRISTERS' REPORTING SERVICE

1 SIGNIFICANT MAJORITY, OF THOSE ET III APPLICATIONS
2 THAT ARE NOW BEFORE US ARE NOT RECOMMENDED FOR
3 FUNDING, RIGHT? THIS IS SOUNDING LIKE A CROSS
4 EXAMINATION. I DON'T MEAN IT TO. I'M JUST TRYING
5 TO BE CLEAR.

6 DR. OLSON: I JUST SHOWED YOU THE FINAL
7 SLIDES THAT ARIE SHOWED YOU INDICATED, WHAT, ABOUT
8 HALF -- NO. IT'S 19. 19 TOTAL? IT'S ABOUT HALF OF
9 THEM. ABOUT HALF OF THEM ARE RECOMMENDED FOR
10 FUNDING, SO I DON'T THINK IT'S A FAIR STATEMENT TO
11 SAY THAT THE VAST MAJORITY.

12 MS. SAMUELSON: OKAY. YEAH. OKAY.
13 THANKS.

14 CHAIRMAN THOMAS: I'D LIKE TO OPEN THE
15 DISCUSSION. PERHAPS MR. SHEEHY, AS CHAIR OF THE
16 SCIENCE SUBCOMMITTEE, IF YOU COULD JUST GIVE A FEW
17 THOUGHTS ON THE GRANTS WORKING GROUP PROCESS FOR
18 THIS APPLICATION.

19 MR. SHEEHY: SURE. AND I THINK IT WAS A
20 ROBUST DISCUSSION THAT WE HAD IN PROGRAMMATIC
21 REVIEW. I DO THINK AS PEOPLE LOOK AT THIS, THEY'LL
22 SEE SOME MOVEMENT. AND I DON'T KNOW IF, FOR
23 EXAMPLE -- GIL, IS THERE A SEPARATE SHEET IN HERE
24 WITH THE PROGRAMMATIC? I KNOW THAT YOU HAVE A
25 SYNOPSIS OF THE PROGRAMMATIC.

BARRISTERS' REPORTING SERVICE

1 DR. SAMBRANO: YES. RIGHT. THERE SHOULD
2 BE A SHEET THAT'S A SUMMARY OF ALL THE PROGRAMMATIC
3 DISCUSSION. SO IT COMPILES IT FROM EACH OF THE
4 REVIEW REPORTS.

5 MR. SHEEHY: YEAH. PEOPLE SHOULD LOOK AT
6 THAT. I COULDN'T FIND IT IN MINE, BUT NONETHELESS,
7 THE PROGRAMMATIC PIECE IS ALSO APPENDED TO THE END
8 OF EACH APPLICATION. I DO THINK IT MIGHT SAVE SOME
9 DISCUSSION ON SOME OF THE OUTLIERS THAT GOT MOVED UP
10 TO TAKE A MINUTE AND LOOK AT THE PROGRAMMATIC
11 DISCUSSION. THIS WAS A GROUP OF REVIEWERS THAT TOOK
12 PROGRAMMATIC REVIEW VERY SERIOUSLY. AND THEY DID
13 MAKE A COUPLE OF RECOMMENDATIONS THAT INCLUDED
14 CONDITIONS.

15 NOW, IT'S UP TO STAFF TO ENSURE THAT THOSE
16 CONDITIONS ARE FOLLOWED. BUT WE DID NOT WANT TO
17 STOP SCIENCE THAT MIGHT HAVE A MEASURABLE IMPACT ON
18 DISEASE FROM GOING FORWARD BECAUSE THERE WAS A
19 SINGLE DEFECT THAT WAS READILY CURABLE BASED ON THE
20 ADVICE OF THIS, I THINK, VERY STRONG GROUP OF
21 REVIEWERS.

22 SO I DO HOPE THAT FOLKS WILL LOOK AT THE
23 PROGRAMMATIC DISCUSSION. IN GENERAL, THE SCORES
24 WERE REALLY GOOD. THIS IS A REALLY GOOD GROUP OF
25 APPLICATIONS. BUT I DON'T KNOW THAT WE NEED TO --

BARRISTERS' REPORTING SERVICE

1 IF WE ARE GOING TO DISCUSS THOSE, I THINK PEOPLE
2 SHOULD FIRST LOOK AND SEE WHAT THE GRANTS REVIEW
3 GROUP DID IN PROGRAMMATIC REVIEW, WHY THEY DID IT,
4 IT MAKES SENSE, AND START FROM THAT BASIS BECAUSE
5 SOME OF THEM DID MAKE FAIRLY LARGE JUMPS, BUT THAT
6 WAS NOT BASED ON THE APPLICATION WITHOUT SOME
7 ADDITIONAL CONDITIONS BEING IMPOSED UPON THE
8 GRANTEE.

9 AND, AGAIN, WE CAN COUNT ON STAFF, I
10 THINK, DR. TROUNSON, YOU WOULD AGREE, TO MAKE SURE
11 THOSE CONDITIONS ARE FULFILLED IF THE GRANTS ARE
12 GOING TO GO FORWARD.

13 DR. TROUNSON: SURE, JEFF. WE CERTAINLY
14 HAVE HIGHLIGHTED THAT. AND SUBJECT TO THE DECISION
15 OF THE BOARD, WE WILL IMPLEMENT THOSE UNDER YOUR
16 INSTRUCTION. IF THERE'S FURTHER INSTRUCTION, WE'LL
17 TAKE THAT AS WELL.

18 MR. SHEEHY: AND JUST TO BE CLEAR, THERE'S
19 ACTUALLY ANOTHER CHART. SO YOU'RE LOOKING AT THIS
20 ONE AND THERE'S ALSO -- I DON'T KNOW IF YOU WANT TO
21 THROW THE OTHER ONE UP NOW. ARE WE GOING TO TAKE
22 THESE IN SEPARATE PILES?

23 CHAIRMAN THOMAS: YES. WE'RE GOING TO
24 ADDRESS THEM IN THE TWO TRANCHES HERE. SO THIS IS
25 THE DCF AWARDS.

BARRISTERS' REPORTING SERVICE

1 MR. SHEEHY: SO I WAS SPEAKING GENERICALLY
2 ACROSS BOTH CATEGORIES.

3 DR. SAMBRANO: I CAN SHOW YOU THE -- THIS
4 IS THEN THE DC.

5 MR. SHEEHY: YEAH. IF YOU LOOK, THE DC
6 HAD SOME -- IF YOU SHOW THE WHOLE THING, A COUPLE OF
7 MOVE-UPS. AND THAT'S JUST TO GIVE YOU A SENSE.
8 AGAIN, THIS WAS A VERY ROBUST DISCUSSION BY THE
9 GRANTS WORKING GROUP IN PROGRAMMATIC REVIEW. THAT'S
10 WHY WE HAD THAT DEGREE OF ACTIVITY, AND THIS IS A
11 GOOD PLACE FOR THAT KIND OF TO TAKE SOME RISK, I
12 THINK.

13 DR. SAMBRANO: JUST TO NOTE, THE
14 PROGRAMMATIC SUMMARIES WERE E-MAILED TO YOU. I
15 DON'T KNOW IF THAT WAS JUST NOW OR PREVIOUSLY. SO
16 IT SHOULD BE --

17 MS. BONNEVILLE: IF YOU DON'T HAVE THEM,
18 WE'LL GET COPIES TO YOU.

19 MR. SHEEHY: AND YOU CAN LOOK AT THE
20 APPLICATION. THERE'S ACTUALLY A CATEGORY
21 "PROGRAMMATIC REVIEW," AND THAT GIVES YOU THAT
22 DISCUSSION THERE AS WELL.

23 CHAIRMAN THOMAS: GIL, DO I REMEMBER
24 CORRECTLY THAT IN ONE INSTANCE THERE WAS A DC THAT
25 WAS MOVED DOWN TO A DCF?

BARRISTERS' REPORTING SERVICE

1 DR. SAMBRANO: SO THERE IS A
2 RECOMMENDATION ON ONE OF THE DC APPLICATIONS TO
3 CONVERT IT TO A DCF. AND SO THAT ONE, WHEN WE GET
4 TO THE DC, OR I CAN JUST SHOW YOU, IT'S APPLICATION
5 5617. SO IT'S THIS ONE HERE. SO PART OF THE
6 DISCUSSION IN THE RECOMMENDATION WAS THAT IT WAS
7 RECOMMENDED IN PART BASED ON A CONVERSION TO A
8 DCF-TYPE AWARD.

9 CHAIRMAN THOMAS: OKAY. SO ARE THERE --
10 WHICH DO WE HAVE UP HERE? OKAY. WE HAVE THE DCF
11 FIRST. ARE THERE ANY QUESTIONS OR COMMENTS WITH
12 RESPECT TO EITHER ANY OF THE RECOMMENDED AWARDS OR
13 WITH RESPECT TO ANY THAT ARE CURRENTLY NOT BEING
14 RECOMMENDED FOR FUNDING? YES, JOAN.

15 MS. SAMUELSON: DO WE HAVE THE RANGE OF
16 SCORES FOR THOSE NOT RECOMMENDED FOR FUNDING?

17 CHAIRMAN THOMAS: I THINK THAT WE SAW THEM
18 ON THE CHARTS.

19 DR. SAMBRANO: SO YOU HAVE SCORES SHOWN
20 FOR 60 AND ABOVE AND ANYTHING THAT'S IN TIER I. SO
21 NORMALLY WE DON'T SHOW THE SCORES FOR ANYTHING
22 THAT'S BELOW 60.

23 MS. SAMUELSON: DO YOU HAVE THAT RANGE?

24 DR. SAMBRANO: WE HAVE THE RANGE, BUT
25 WE -- I MEAN THAT GOES ALONG WITH THE SCORE. SO IF

BARRISTERS' REPORTING SERVICE

1 YOU HAVE ONE IN PARTICULAR THAT YOU WANT TO KNOW
2 ABOUT, WE CAN PROVIDE THAT TO YOU.

3 I THINK THE OTHER THING TO KNOW IS THAT
4 THESE ARE IN RANK ORDER BY AVERAGE SCORE. SO
5 BASICALLY THE ONES AT THE VERY BOTTOM ARE
6 ESSENTIALLY THE ONES THAT SCORED THE LOWEST. AND SO
7 THEY ARE IN THAT ORDER.

8 MS. SAMUELSON: I'M INTERESTED IN THE
9 SCORE FOR -- IT'S THE SPINAL CORD INJURY APPLICATION
10 THAT'S THE HIGHEST RANKING DCF, 5606.

11 DR. SAMBRANO: OKAY. SO THAT ONE THE
12 AVERAGE SCORE WAS A 54, THE MEDIAN IS A 55, THE
13 STANDARD DEVIATION IS 5, AND THE RANGE WAS 40, THE
14 LOWEST, AND 60, THE HIGHEST.

15 MS. SAMUELSON: SORRY. WHAT WAS THE
16 LOWEST?

17 DR. SAMBRANO: FORTY.

18 MS. SAMUELSON: ARE WE TAKING UP HEARING
19 THE EXTRAORDINARY PETITIONS NOW?

20 CHAIRMAN THOMAS: NO. WE'RE GOING TO DO
21 THAT AT THE CONCLUSION. ANY OTHER COMMENTS,
22 QUESTIONS ON THE DCF APPLICATIONS? DR. STEWARD.

23 DR. STEWARD: SO A QUESTION. AT WHAT
24 POINT WOULD YOU LIKE TO HAVE REQUESTS FOR
25 CONSIDERATION OF PROPRIETARY INFORMATION?

BARRISTERS' REPORTING SERVICE

1 CHAIRMAN THOMAS: MR. HARRISON.

2 MR. HARRISON: THE PROCEDURE THAT WE TRY
3 TO FOLLOW IS TO IDENTIFY THOSE APPLICATIONS IN WHICH
4 BOARD MEMBERS HAVE AN INTEREST, ASK SCIENTIFIC STAFF
5 TO MAKE A PRESENTATION. ALL OF THE INFORMATION THAT
6 CAN BE PROVIDED IN PUBLIC SESSION WILL BE PROVIDED
7 AT THAT POINT IN TIME, AND STAFF WILL ANSWER AS MANY
8 QUESTIONS AS THEY CAN. TO THE EXTENT THAT THE
9 QUESTIONS CALL FOR PROPRIETARY INFORMATION, WE'LL
10 MAKE A NOTE OF THAT. AND THEN AFTER WE COMPLETE THE
11 PUBLIC SESSION, WE'LL CONVENE IN CLOSED SESSION TO
12 DISCUSS THAT PARTICULAR INFORMATION.

13 DR. STEWARD: SO WOULD IT, THEN, BE
14 APPROPRIATE TO RAISE APPLICATIONS FOR CONSIDERATION
15 AT THIS POINT IN TIME?

16 MR. HARRISON: YES.

17 DR. STEWARD: OKAY. SO JUST TO CONTINUE
18 DOWN JOAN'S TRACK, 5606.

19 CHAIRMAN THOMAS: DR. YAFFE.

20 DR. YAFFE: MR. CHAIRMAN, MEMBERS OF THE
21 BOARD, APPLICATION 5606, AS YOU HEARD, THIS RECEIVED
22 A SCORE OF 54 AND WAS NOT RECOMMENDED FOR FUNDING.
23 THIS DEVELOPMENT CANDIDATE FEASIBILITY AWARD
24 APPLICATION PROPOSES TO EVALUATE TRANSPLANTATION OF
25 HUMAN EMBRYONIC STEM CELL-DERIVED INHIBITORY NEURON

BARRISTERS' REPORTING SERVICE

1 PRECURSORS AS A TREATMENT FOR BLADDER SPASTICITY AND
2 NEUROPATHIC PAIN ASSOCIATED WITH CHRONIC SPINAL CORD
3 INJURY.

4 THE APPLICANT HAS DEMONSTRATED THAT MURINE
5 INHIBITORY NERVE CELLS INTEGRATE INTO ADULT SPINAL
6 CORD AND IMPROVE SYMPTOMS IN AN ANIMAL MODEL OF
7 CHRONIC SPINAL CORD INJURY AND HAS RECENTLY
8 DEVELOPED METHODS TO CREATE HUMAN INHIBITORY
9 INTERNEURONS FROM EMBRYONIC STEM CELLS. THIS
10 PROPOSAL WILL CAPITALIZE ON RECENT DEVELOPMENTS AND
11 DETERMINE WHETHER HUMAN EMBRYONIC STEM CELL-DERIVED
12 INHIBITORY NERVE CELLS CAN BE SUCCESSFULLY
13 TRANSPLANTED INTO THE GRAY MATTER OF THE INJURED
14 SPINAL CORD IN A MOUSE MODEL OF SPINAL CORD INJURY
15 AND REDUCE NEUROGENIC BLADDER DYSFUNCTION AND
16 NEUROPATHIC PAIN.

17 MAJOR STRENGTHS IDENTIFIED BY THE
18 REVIEWERS IN THIS APPLICATION INCLUDE THE IMPORTANCE
19 AND SIGNIFICANCE OF THE GOAL AND THE RECOGNIZED
20 MEDICAL NEED, PROMISING PRELIMINARY DATA FROM MOUSE
21 STUDIES, AND AN EXCELLENT PI AND RESEARCH TEAM.

22 KEY WEAKNESSES IDENTIFIED BY REVIEWERS
23 INCLUDE SERIOUS CONCERNS ABOUT THE THERAPEUTIC
24 STRATEGY, IN PARTICULAR THE PROPOSED SITE OF CELL
25 TRANSPLANTATION, AND SERIOUS CONCERNS ALSO ABOUT

BARRISTERS' REPORTING SERVICE

1 ASPECTS OF PROJECT FEASIBILITY, INCLUDING TIMING OF
2 POTENTIAL TREATMENTS, SURVIVAL AND ASSESSMENT OF
3 TRANSPLANTED CELLS, AND THE PURITY OF PROPOSED CELL
4 POPULATIONS.

5 THIS PROPOSAL WAS CONSIDERED DURING
6 PROGRAMMATIC DISCUSSION ALSO WHEN IT WAS RAISED
7 BECAUSE OF THE RECOGNIZED IMPORTANCE OF THE SPINAL
8 CORD INJURY AS AN IMPORTANT AREA FOR THE DEVELOPMENT
9 OF NEW THERAPIES. REVIEWERS REITERATED THE PROPOSED
10 STRENGTHS AND WEAKNESSES, AND A MOTION TO PROMOTE
11 THIS TO TIER I FAILED. BE HAPPY TO TAKE QUESTIONS
12 OR PROVIDE MORE DETAILS.

13 CHAIRMAN THOMAS: DR. STEWARD.

14 DR. STEWARD: IS IT APPROPRIATE TO ASK FOR
15 THE DISTRIBUTION OF VOTES ON THE MOTION TO MOVE IT
16 TO TIER I? IS THAT SOMETHING THAT WE CAN DO?

17 DR. YAFFE: DURING PROGRAMMATIC REVIEW?

18 DR. STEWARD: DURING PROGRAMMATIC.

19 DR. YAFFE: WE'RE LOOKING IT UP.

20 DR. STEWARD: OKAY. I REALIZE IT DIDN'T
21 HIT THE THRESHOLD.

22 DR. YAFFE: IT DID NOT HIT THE THRESHOLD
23 FOR A MINORITY REPORT.

24 CHAIRMAN THOMAS: WE'RE WAITING ON THAT
25 ANSWER.

BARRISTERS' REPORTING SERVICE

1 DR. STEWARD: SO IN THE MEANTIME, CAN YOU
2 EXPAND ANY ON THE ISSUE OF -- I'M LOOKING AT
3 THIS -- THE STRINGENCY OF THE LINEAGE MARKERS. IS
4 THERE ANYTHING MORE THAT CAN -- IT SEEMS LIKE
5 THAT --

6 DR. YAFFE: THERE'S CONCERN ABOUT THAT. I
7 THINK TO DISCUSS SPECIFIC LINEAGE MARKERS, WE WOULD
8 HAVE TO DO THAT IN CLOSED SESSION.

9 DR. STEWARD: THAT'S WHAT I THOUGHT. AND
10 SO I'D LIKE TO ACTUALLY DO THAT.

11 DR. YAFFE: I SUSPECT THAT'S PROPRIETARY
12 INFORMATION.

13 ON THE MOTION TO ADVANCE TO TIER I, THERE
14 WERE 3 YESES AND 16 NAYS.

15 DR. STEWARD: THANK YOU.

16 CHAIRMAN THOMAS: ANY OTHER QUESTIONS FOR
17 DR. YAFFE? WE HAVE A PUBLIC COMMENT. MR. REED.

18 MR. REED: OBVIOUSLY IF THIS WAS -- IF I
19 WAS ON THE BOARD, I WOULD BE ONE OF THE ONES
20 DISQUALIFIED BECAUSE I HAVE A DEFINITE CONFLICT OF
21 INTEREST. THE INHIBITORS ARE NOT ONLY FOR PAIN.
22 THEY'RE FOR SPASTICITY WHICH I'VE SEEN FLING MY SON
23 OUT OF HIS WHEELCHAIR. THE PAIN THAT SOME PEOPLE GO
24 THROUGH WITH CHRONIC SPINAL CORD INJURY HAS BEEN
25 DESCRIBED AS HAVING YOUR SKIN SCRAPED OFF AND

BARRISTERS' REPORTING SERVICE

1 GASOLINE POURED ONTO YOUR FLESH.

2 I DON'T KNOW MUCH ABOUT THIS, THE
3 PROPOSAL, BUT THE NEED IS GIGANTIC. AND IF WE ARE
4 WELL UNDER BUDGET ON THIS, I WOULD HOPE THAT IT
5 WOULD BE CONSIDERED.

6 CHAIRMAN THOMAS: THANK YOU, DON. DR.
7 STEWARD.

8 DR. STEWARD: I THINK AT THIS POINT WHAT I
9 WOULD RECOMMEND IS THAT WE DEFER UNTIL WE CONSIDER
10 THE PROPRIETARY INFORMATION. IS THAT APPROPRIATE OR
11 WE COULD DISCUSS IT MORE NOW? WHAT WOULD BE THE
12 APPROPRIATE --

13 MR. HARRISON: UNLESS MEMBERS HAVE OTHER
14 QUESTIONS APPROPRIATE FOR PUBLIC SESSION, WE'LL NOTE
15 THAT ITEM. AND WHEN WE CONVENE IN CLOSED SESSION,
16 WE'LL ADDRESS IT AT THAT POINT IN TIME. I'D SUGGEST
17 NOW THAT WE MOVE ON TO OTHER APPLICATIONS THAT
18 MEMBERS MIGHT HAVE AN INTEREST IN DISCUSSING.

19 CHAIRMAN THOMAS: ARE THERE ANY OTHER DCF
20 APPLICATIONS THAT ANY MEMBER OF THE BOARD WOULD LIKE
21 TO DISCUSS? HEARING NONE, PROCEDURALLY, MR.
22 HARRISON, DO WE WAIT ON A MOTION TO APPROVE ALL THE
23 DCF AWARDS PENDING DISCUSSION IN CLOSED SESSION ON
24 THIS ONE ITEM?

25 MR. HARRISON: YES. I'D RECOMMEND THAT WE

BARRISTERS' REPORTING SERVICE

1 GO THROUGH A PUBLIC SESSION DISCUSSION OF ALL THE
2 APPLICATIONS IN WHICH MEMBERS HAVE AN INTEREST.
3 THEN WE'LL KNOW WHAT ITEMS OF A CONFIDENTIAL NATURE
4 THAT WE NEED TO DISCUSS IN CLOSED SESSION. WE'LL
5 CONVENE IN CLOSED SESSION, AND THEN WE'LL RETURN TO
6 OPEN SESSION AND ENTERTAIN MOTIONS.

7 CHAIRMAN THOMAS: THANK YOU. OKAY. LET'S
8 MOVE ON NOW TO THE DC AWARDS. ARE THERE ANY
9 SPECIFIC APPLICATIONS THAT ANY MEMBERS OF THE BOARD
10 WOULD LIKE TO DISCUSS, EITHER THOSE MARKED AS
11 RECOMMENDED FOR FUNDING OR THOSE NOT RECOMMENDED?

12 MS. SAMUELSON: MR. CHAIRMAN?

13 THE COURT: YES, JOAN.

14 MS. SAMUELSON: NO. 5567, THE RETINAL
15 PROGENITOR CELLS FOR MACULAR DEGENERATION.

16 CHAIRMAN THOMAS: YES. WOULD YOU LIKE TO
17 HAVE STAFF PRESENT ON THAT?

18 MS. SAMUELSON: PLEASE.

19 CHAIRMAN THOMAS: YES. DR. SAMBRANO, WHO
20 IS THE --

21 DR. SAMBRANO: IT'S DR. ABO.

22 CHAIRMAN THOMAS: DR. ABO WILL PRESENT.
23 THANK YOU.

24 DR. ABO: THIS PROJECT IS A DC
25 APPLICATION. THEY PROPOSE TO USE EMBRYONIC STEM

BARRISTERS' REPORTING SERVICE

1 CELLS-DERIVED RPE AND PHOTORECEPTORS PROGENITORS
2 GROWN TOGETHER AS A RETINAL SHEET. THEY WANT TO USE
3 THIS AS A COMBINATION THERAPY.

4 THE OBJECTIVE AND MILESTONES OF THIS
5 PROJECT WAS THE REVIEWERS SAID THAT THIS WORK IS IN
6 EARLY STAGE OF DEVELOPMENT. THEY WERE CONCERNED
7 ABOUT THE INABILITY TO SHOW EXPRESSION OF MATURE
8 RETINAL MARKERS AS DIFFERENTIATED CELLS. AND THEY
9 DID NOT HAVE A PLAN TO ASSESS DISTANCE MIGRATION OF
10 TRANSPLANTED CELLS BESIDE THE RETINA.

11 ALTHOUGH THEY FELT, ON THE RATIONALE AND
12 SIGNIFICANCE, THAT THIS PROPOSAL TARGETED UNMET
13 MEDICAL NEEDS FOR AMD.

14 THE REVIEWERS FELT THAT THE RESEARCH
15 PROJECT FEASIBILITY AND DESIGN WAS NOT SUFFICIENTLY
16 DEVELOPED AND LACK OF CRITICAL DETAILS, INSUFFICIENT
17 DESCRIPTIONS OF THE VISUAL ACUITY TEST WHICH IS
18 ESSENTIAL TO ASSESS SUCCESS OF TRANSPLANT, RETINAL
19 TRANSPLANT. NO ELECTROPHYSIOLOGY MEASUREMENT
20 INCLUDED, WHICH IS ESSENTIAL COMPONENT TO ASSESS
21 FUNCTIONALITY OF THE CELLS. THERE WAS NO PLAN TO
22 ASSESS POTENTIAL NEGATIVE EFFECTS SUCH AS PAIN. IT
23 WAS NOT CONSIDERED IN THIS PROPOSAL. AND IT WAS NOT
24 CLEAR HOW THEY ARE GOING TO INTERPRET THE
25 DESCRIPTIVE DATA.

BARRISTERS' REPORTING SERVICE

1 THE PI, THEY FELT, IS STRONG, AND THERE
2 WAS SOME CONCERNS ABOUT 40 PERCENT USE OF THE
3 EFFORTS BY THE PI WAS NOT JUSTIFIABLE. THAT'S WHAT
4 THE REVIEWER FELT. AND THERE WAS CONCERNS
5 REGARDING --

6 MS. SAMUELSON: WHAT WAS THAT LAST
7 COMMENT? SORRY.

8 DR. ABO: YOU KNOW, THE PI EFFORTS IN THE
9 PROJECT WAS 40 PERCENT, AND REVIEWERS FELT IT'S NOT
10 JUSTIFIABLE. AND THERE WERE CONCERNS --

11 MS. SAMUELSON: UNJUSTIFIABLY LOW?

12 DR. ABO: NO. IT WAS TOO HIGH, THE
13 EFFORT. THAT'S WHAT THEY FELT. CONCERNS, AGAIN,
14 ABOUT THE BUDGET. THERE WERE ISSUES ASSOCIATED WITH
15 BUYING EQUIPMENT THAT SHOULD BE ALREADY IN PLACE.
16 AND THERE WAS NOT DEFINED ROLES FOR NUMEROUS OF THE
17 STAFF UNDER THIS PROPOSAL. SO THERE WAS A LOT OF
18 ISSUES.

19 AND OVERALL THEY FELT THAT THIS PROPOSAL
20 WAS NOT -- IN AN EARLY STAGE AND WAS NOT READY FOR
21 TO BE SUPPORTED BECAUSE IT NEEDS A LOT OF OTHER
22 ISSUES, AS I READ YOU ALL OF THIS.

23 CHAIRMAN THOMAS: JOAN, DO YOU HAVE ANY
24 OTHER QUESTIONS ON THIS ONE?

25 MS. SAMUELSON: NOT THAT ARE POPPING UP

BARRISTERS' REPORTING SERVICE

1 RIGHT THIS SECOND. I'M SURE I WILL IF I REFLECT ON
2 IT. BUT OUR COMMENTS, RESPONSE OF COMMENTS COME
3 LATER; IS THAT RIGHT?

4 CHAIRMAN THOMAS: I THINK WE WANT TO
5 DISCUSS NOW, IF WE CAN, WHILE WE'RE ON THE TOPIC.

6 MS. SAMUELSON: OKAY. I GUESS THE FIRST
7 POINT TO MAKE IS THAT THERE'S VERY LITTLE IN THE
8 PORTFOLIO. I'M TRYING TO FIND IT.

9 DR. ABO: WE HAVE TWO PROJECTS ON AMD IN
10 THE PORTFOLIO.

11 MS. SAMUELSON: PARDON? COULD YOU SPEAK
12 UP A LITTLE BIT?

13 DR. ABO: UNDER THE EYE DISEASES IN THE
14 PORTFOLIO, WE HAVE TWO PROGRAMS IN AMD. ONE IS AN
15 IND-ENABLING DISEASE TEAM I AGE-RELATED MACULAR
16 DEGENERATION, AND THE OTHER ONE IS EARLY TRANSLATION
17 1 DC AWARD. AND THERE IS A THIRD ONE. IT'S A DC
18 AWARD AS WELL. SO THERE'S THREE APPROACHES IN THE
19 TRANSLATIONAL PORTFOLIO TARGETING THE SAME DISEASE
20 WITH SIMILAR APPROACHES USING RPE CELLS AND TO CELL
21 TRANSPLANT.

22 MS. SAMUELSON: IS THAT REGARDED BY STAFF
23 AS A PROBLEM, THAT THEY'RE SIMILAR?

24 DR. ABO: THE APPROACH IN THIS PROPOSAL
25 WAS NOT IDENTICAL. AS I RECALL FROM THE REVIEW,

BARRISTERS' REPORTING SERVICE

1 DURING THE REVIEW SESSION, THE FACT THAT THEY WANT
2 TO USE A COMBINATION OF PHOTORECEPTORS AND RPE WAS
3 ATTRACTIVE AS PART OF THE APPROACH, ALTHOUGH THE
4 REVIEWERS, AS I SAID, FELT THAT THE SCIENCE WAS NOT
5 THERE AND THAT THE PROPOSAL WAS TOO EARLY STAGE.
6 THEY WERE MISSING LOT OF DETAIL, THE RIGHT TEST TO
7 REALLY ASSESS THE SUCCESS OF THIS APPROACH. THAT
8 WAS THE MAIN CRITICISM.

9 BUT AS I SAID, THE APPROACH IS DIFFERENT
10 THAN JUST TAKING WHAT WE HAVE ON THE PORTFOLIO, JUST
11 RPE CELLS TRANSPLANTED IN THE RETINA. HERE THERE IS
12 A COMBINATION OF PRODUCT OF A COMBINATION OF RPE
13 PLUS PHOTORECEPTOR CELLS.

14 MS. SAMUELSON: AND THAT WOULD BE THE WAY
15 IT ENDS UP WORKING AS OPPOSED TO THE OTHERS WHICH
16 ARE DIFFERENT, RIGHT?

17 DR. ABO: IT COULD BE. IF IT WAS -- IF
18 THE SCIENCE WAS READY, AS THE REVIEWERS SAID, THIS
19 PROBABLY COULD BE A VERY ATTRACTIVE PROJECT.

20 MS. SAMUELSON: AND GIVEN THAT THIS IS
21 EARLY TRANSLATION AND IT'S JUST A FEASIBILITY AWARD,
22 ISN'T THIS --

23 DR. ABO: NO. THIS IS A DC AWARD.

24 MS. SAMUELSON: EVEN SO, THIS IS THE FIRST
25 EFFORT TO TRY TO TAKE BASIC SCIENCE AND COME UP WITH

BARRISTERS' REPORTING SERVICE

1 A HYPOTHESIS THAT CAN LEAD TO SOMETHING. ISN'T THAT
2 WHAT THIS PART OF OUR GRANT PORTFOLIO IS TRYING TO
3 DO WITH THE EARLY TRANSLATION AWARD? THAT'S MY
4 UNDERSTANDING OF IT. AND I SHOULDN'T BE
5 INTERROGATING YOU ABOUT IT.

6 DR. ABO: NO. THE REVIEWER IS THE ONE
7 THAT MADE THE DECISION. I'M JUST COMMUNICATING
8 THEIR MESSAGE.

9 MS. SAMUELSON: I'M NOT GOING TO SHOOT THE
10 MESSENGER. THIS IS OBVIOUSLY AN ENORMOUSLY
11 IMPORTANT PART OF OUR PORTFOLIO. I SPENT LAST
12 WEEKEND WITH A WOMAN WITH MACULAR DEGENERATION, AND
13 SHE CAN SEE A LITTLE BIT OUT OF THE FAR RIGHT CORNER
14 OF HER EYE AND THAT'S ALL. IT DESERVES ROBUST
15 ATTENTION, AND I DON'T THINK THAT'S WHAT WE HAVE IN
16 OUR PORTFOLIO NOW. SO IMPORTANT NEW IDEAS DESERVE
17 FUNDING, AND IT SEEMS TO ME THAT THIS HAS THAT, AND
18 THAT IN EARLY TRANSLATION WE SHOULDN'T BE EXPECTING
19 PERFECTION. THAT IS A POINT AT WHICH WE'RE TAKING A
20 SERIES OF UNKNOWNNS AND TRYING TO TURN THEM INTO A
21 KNOWN COMMODITY THERAPY.

22 AND SO TO CRITICIZE IT AS NOT REALLY READY
23 FOR PRIME TIME IS NOT TO ACCEPT THIS PART OF THE
24 PORTFOLIO, I THINK. I THINK IT'S IMPORTANT TO PUT
25 THE FUNDING TO IT. AND SO I THINK WE SHOULD BE

BARRISTERS' REPORTING SERVICE

1 DOING IT.

2 CHAIRMAN THOMAS: DR. PRIETO AND THEN DR.
3 TROUNSON.

4 DR. PRIETO: I'M TRYING TO REMEMBER SOME
5 OF THE DISCUSSION AROUND THIS APPLICATION. BUT
6 THERE ARE A COUPLE OF POINTS ON THE FEASIBILITY AND
7 DESIGN THAT WERE BROUGHT UP AS CRITICISMS THAT YOU
8 WOULD QUESTION. THE FIRST POINT, THAT OUTCOME
9 MEASURES WERE INSUFFICIENTLY DESCRIBED. AND THEN
10 RELATED TO THAT, THERE'S INSUFFICIENT DESCRIPTION OF
11 THE VISUAL ACUITY TEST WHICH IS PARTICULARLY
12 IMPORTANT FOR EVALUATING THE SUCCESS OF THE
13 TRANSPLANTS. I THINK THAT'S OBVIOUS, BUT IT SEEMS
14 TO ME THAT VISUAL ACUITY TESTING AND THE ASSESSMENT
15 OF VISUAL ACUITY IS A VERY WELL ESTABLISHED AND
16 MATURE TECHNOLOGY WITH VALIDATED INSTRUMENTS THAT
17 HAVE BEEN IN USE FOREVER.

18 I'M NOT SURE THAT I WOULD NECESSARILY
19 EXPECT THAT TO BE LAID OUT IN GREAT DETAIL,
20 PARTICULARLY GIVEN THAT WE GIVE SOME SPACE
21 CONSTRAINTS TO AN APPLICANT.

22 CHAIRMAN THOMAS: DR. TROUNSON.

23 DR. TROUNSON: WELL, I THINK THE IMPORTANT
24 PART IS TO REALLY REFLECT ON WHAT THEY'RE TRYING TO
25 ACHIEVE WITH WHAT TOOLS THEY'VE GOT. I THINK THIS

BARRISTERS' REPORTING SERVICE

1 STUDY PROBABLY DESERVES A LITTLE BIT MORE -- A BIT
2 MORE DEVELOPMENT. YOU'VE GOT TO ACTUALLY PRODUCE
3 RETINAL EPITHELIAL CELLS, WHICH ARE GENERALLY WHERE
4 THE FIELD IS REASONABLY COMFORTABLE. AND THEN ON
5 TOP OF THAT, YOU GOT TO DEVELOP PHOTORECEPTOR CELLS.
6 AND THE CONCERNS REALLY ARE THE SCIENTISTS BELIEVE
7 THAT THERE REALLY WASN'T -- IT DIDN'T REALLY HAVE
8 THE TOOLS TO GET TO THOSE ENDPOINTS. AND PERHAPS A
9 LITTLE MORE TIME MIGHT MAKE IT MORE PERSUASIVE.

10 BUT I THINK WHEN YOU LOOK AT THE SCIENCE
11 OF SOME OF THESE PROJECTS, YOU'VE GOT TO BE
12 COMFORTABLE THAT THEY CAN ACTUALLY DO SOMETHING AS
13 COMPLEX AS THIS IN THE TIME FRAME. AND THE
14 SCIENTISTS CLEARLY DIDN'T THINK THAT THE TOOLS WERE
15 THERE IN THIS PARTICULAR STUDY TO COMPLETE IT.

16 SO I MEAN IT'S REALLY MORE ABOUT THE
17 SCIENCE BEING READY. IN SOME OF THE OTHER STUDIES
18 THAT WE'VE ALREADY GOT GOING IN THIS AREA, THEY'RE
19 WELL AND TRULY MATURE AND THEY'RE IN GOOD
20 DEVELOPMENT PHASES. BUT THIS ONE SOUNDED LIKE IT
21 REALLY DID NEED A LITTLE BIT MORE TIME TO SORT OF BE
22 PERSUASIVE THAT YOU COULD GET BOTH THESE CELL TYPES
23 TO DEVELOP IN SITU WITH THIS PARTICULAR APPLICATION.

24 CHAIRMAN THOMAS: JOAN.

25 MS. SAMUELSON: THE APPLICATION DID GET A

BARRISTERS' REPORTING SERVICE

1 63, WHICH IS HIGHER THAN SOME OF THE OTHER GRANTS
2 THAT ARE RECOMMENDED FOR FUNDING. SO IT SEEMS TO ME
3 IT'S NOT STRICTLY A DEFICIT IN SCIENTIFIC MERIT, BUT
4 MORE A REFLECTION OF THE CHALLENGES THAT FACE THESE
5 INVESTIGATORS AS THEY'RE TRYING TO SOLVE AN
6 INTRACTABLE PROBLEM THAT HAS NO THERAPEUTIC
7 TREATMENT NOW. THAT'S THE HIGH BAR THAT THE
8 INITIATIVE GIVES US TO ACHIEVE, TO SUCCEED, TO TAKE
9 INCURABLE DISORDERS AND MAKE THEM CURABLE.

10 AND I KNOW IN PARKINSON'S MOST OF THE TIME
11 IT TAKES LONGER THAN THREE YEARS TO ADDRESS A
12 PROPOSED THERAPY AND FIGURE OUT HOW TO DEVELOP IT
13 ENOUGH THAT IT IS READY FOR A CLINICAL TRIAL. AND
14 WE'VE PUT THIS LIMIT OF THREE YEARS ON THESE GRANTS,
15 AND I DON'T THINK IT'S ALWAYS REFLECTIVE OF THE
16 TOUGH WORK THAT'S GOT TO BE DONE, AND THAT THAT MAY
17 BE THE CASE IN THIS CASE, AND THAT THAT'S WHAT'S
18 GOING ON WITH THE SCORE, THAT IT IS JUST UNDULY
19 DIFFICULT AND THAT IT DOESN'T REFLECT THE QUALITY OF
20 THE IDEA AND OF THE INVESTIGATORS AND OF HOW HARD
21 THEY'RE GOING TO WORK. AND IF WE CAN BENEFIT FROM
22 WHATEVER SCIENTIFIC ADVANCES COME FROM THOSE THREE
23 OR MORE YEARS OF WORK, TERRIFIC. IT WILL BE GREAT
24 USE OF OUR FUNDS.

25 DR. ABO: I JUST WANT TO EMPHASIZE THAT

BARRISTERS' REPORTING SERVICE

1 THIS WAS AN AWARD THAT WAS SUBMITTED UNDER OUR
2 DEVELOPMENT CANDIDATE AWARDS. WE HAVE THE SPACE FOR
3 THIS KIND OF STUDY WHICH IS A DCF AWARDS. IT'S A
4 LOWER EARLY STAGE PROJECT THAT COULD BE DEVELOPED
5 INTO THE DEVELOPMENT CANDIDATE. SO IT'S NOT JUST
6 THREE YEARS PROGRAM. ONE COULD ENTER INTO THE DCF,
7 GENERATE SOME DATA, AND AFTER A YEAR, TWO YEARS, OR
8 EVEN DURING THE PROCESS USE THE DATA AS PRELIMINARY
9 DATA TO APPLY FOR A DC AWARD. SO IT'S ABOUT SIX
10 YEARS PROGRAM. YOU CAN LOOK AT IT AS THAT'S WHAT WE
11 TRY TO ACHIEVE.

12 SO WE ASKED THE REVIEWERS TO ASSESS THIS
13 PROJECT AS A DEVELOPMENT CANDIDATE AWARD, NOT AS A
14 PROOF OF CONCEPT TYPE OF AWARD. AND THAT'S THE
15 RESPONSIBILITY OF THE APPLICANT TO UNDERSTAND THE
16 DIFFERENCES BETWEEN THESE TWO TYPE OF AWARDS WHEN
17 THEY APPLY FOR IT.

18 MS. SAMUELSON: RIGHT. AND I GUESS AT
19 THIS POINT WATCHING HOW THOSE TWO CATEGORIES WORK,
20 SOMETIMES THERE ARE THINGS THAT FALL THROUGH THE
21 CRACKS. I THINK IT'S TERRIFIC THAT THEY ARE
22 SUFFICIENTLY AMBITIOUS AND CONFIDENT ABOUT THEIR
23 HYPOTHESIS THAT THEY REALLY WANT TO BE AGGRESSIVE
24 ABOUT WORKING IT. AND IT'S A LOT MORE MONEY, AND
25 THE DIFFICULTY OF THE WORK IS SUFFICIENTLY -- IS

BARRISTERS' REPORTING SERVICE

1 SUFFICIENT TO JUSTIFY THAT MUCH MONEY. MAYBE
2 THEY'RE UNDULY AMBITIOUS IN THAT TIME FRAME, BUT IT
3 MAY MEAN THAT THAT EXTRA MONEY AND THE DEMANDS OF A
4 DC AS OPPOSED TO A DCF WILL GET MORE WORK DONE. AND
5 THAT'S ALL A GOOD THING.

6 CHAIRMAN THOMAS: PROCEDURALLY, DR. ABO,
7 FOR PURPOSES OF DISCUSSION, IS ONE OPTION HERE TO
8 PROPOSE THAT THE AWARD POTENTIALLY WOULD BE REDUCED
9 TO A DCF AWARD, WHICH WOULD THEN INVOLVE
10 REDEFINITION OF SCOPE, FUNDING, ETC.? DO WE HAVE
11 THAT AS AN OPTION HERE?

12 MR. SHEEHY: JUST AS A POINT, THE GRANTS
13 WORKING GROUP HAD THAT OPTION IN THE PROGRAMMATIC
14 REVIEW. SO THAT -- YEAH. THEY COULD HAVE DONE THAT
15 IF THEY THOUGHT THAT THAT PROPOSAL COULD HAVE
16 MERITED THAT TYPE OF APPROACH.

17 DR. SAMBRANO: SO THE OPTION WAS
18 AVAILABLE, AS MR. SHEEHY SAYS, WITH THE GRANTS
19 WORKING GROUP. AND THEY ACTUALLY DID MAKE THAT
20 RECOMMENDATION IN ONE CASE. AS WE ALSO ALERTED THE
21 GRANTS WORKING GROUP, ON DOING THIS, ONE HAS TO BE
22 VERY CAUTIOUS ABOUT MAKING SUCH A CHANGE. NOT ONLY
23 IS THE AWARD AMOUNT DIFFERENT, YOU WANT TO MAKE SURE
24 THAT BY REDUCING THE AWARD AMOUNT AND PUTTING IT
25 INTO A DIFFERENT CATEGORY, THAT IT IN SOME WAY

BARRISTERS' REPORTING SERVICE

1 DOESN'T THEN PREVENT APPLICANTS FROM BEING ABLE TO
2 PURSUE THE STUDIES GIVEN THE SIGNIFICANT DIFFERENCES
3 IN THE AWARD TYPE. SO ONE HAS TO, I THINK, JUST
4 TREAD VERY CAREFULLY IN DOING THAT.

5 CHAIRMAN THOMAS: THANK YOU. DR. FEIGAL.

6 DR. FEIGAL: YEAH. I JUST WANT TO MAKE A
7 COMMENT. IT'S NOT SPECIFIC TO THIS PROPOSAL, BUT
8 JUST IN GENERAL. I THINK IT'S REALLY HARD IF WE
9 MAKE SUGGESTIONS TO CHANGE THE BUDGET, CHANGE THE
10 SCOPE, GREATLY REVISE WHAT THE APPLICANT INTENDED TO
11 PRESENT. AND I THINK THERE'S NOT JUST THIS ONE, BUT
12 PROBABLY MULTIPLE ONES THAT THAT COULD BE SUGGESTED
13 FOR. BUT I THINK THAT'S A VERY DIFFERENT WAY OF
14 APPROACHING HOW TO LOOK AT THESE APPLICATIONS THAT
15 COME IN.

16 I THINK, AS JEFF POINTED OUT, THERE IS A
17 PROGRAMMATIC DISCUSSION THAT TAKES PLACE WHERE SOME
18 OF THESE OPTIONS ARE DISCUSSED. AND YOU HEARD WHAT
19 THE PROPOSAL WAS AND THE REASONS WHY THEY MAY OR MAY
20 NOT HAVE WANTED TO DO IT. BUT I JUST THINK FOR THE
21 BOARD TO SUGGEST -- IT'S CERTAINLY AN OPTION YOU CAN
22 SUGGEST, BUT I WOULD JUST CAUTION YOU THAT I THINK
23 THAT'S A VERY HARD ROAD TO GO DOWN IF THE BOARD IS
24 SUGGESTING REVISING THE SCOPE AND REVISING THE
25 BUDGET. JUST AN OPINION. I JUST WANTED TO PUT THAT

BARRISTERS' REPORTING SERVICE

1 OUT.

2 MS. SAMUELSON: AND THAT IS NOT WHAT I'M
3 SUGGESTING. I'M SUGGESTING THAT THE FACT THAT THIS
4 GRANT APPLICATION MAY NOT SEEM PERFECT AND AN OVERLY
5 DEMANDING SET OF CRITERIA IN THE CONTEXT OF THE
6 DIFFICULTY OF SCIENTIFIC ADVANCES IN THIS VERY
7 DIFFICULT FIELD AND THAT THE MISSION OF OUR
8 PROGRAMMATIC DISCUSSION IS TO LOOK FOR SITUATIONS
9 WHERE IMPORTANT ADVANCES COULD BE MADE THAT AREN'T
10 NECESSARILY SATISFYING THE LETTER OF THE LAW IN
11 EVERY INSTANCE. THAT'S WHERE WE ARE SUPPOSED TO BE
12 ACTING.

13 CHAIRMAN THOMAS: MR. SHEEHY.

14 MR. SHEEHY: YOU KNOW, MAYBE ONE WAY TO
15 KIND OF BRING THIS DISCUSSION TO A CLOSE MIGHT JUST
16 BE TO HAVE A VOTE. I MEAN A MOTION AND A VOTE. I
17 JUST DON'T -- I DON'T KNOW. I MEAN JUST AS A
18 SUGGESTION TO THE CHAIR AND TO JOAN, MAYBE THAT'S A
19 GOOD WAY.

20 CHAIRMAN THOMAS: I THINK WHAT WE DECIDED
21 TO DO WAS TO WITHHOLD ANY MOTIONS OR ANY VOTES UNTIL
22 WE HAVE OUR CLOSED SESSION AND THEN COME BACK AND
23 CAN ENTERTAIN ANY MOTIONS AND VOTES AT THAT POINT.
24 SO ARE THERE ANY OTHER COMMENTS ON ANY OF THE
25 AWARDS? DR. VUORI.

BARRISTERS' REPORTING SERVICE

1 DR. VUORI: I HAVE A QUESTION ON THE
2 APPLICATION 5541. ACTUALLY I HAVE READ THE
3 COMMENTARY IN THE BOOKLET, AND I HAVE ONE SPECIFIC
4 QUESTION THAT I THINK HELPS ME TO PUT THE COMMENTS
5 IN PERSPECTIVE. AND THAT IS WHAT TYPE OF SOLID
6 TUMOR IS PROPOSED TO BEING STUDIED HERE?

7 DR. ABO: I THINK IT'S PANCREATIC CANCER.
8 THE FIRST ONE DISCUSSES PANCREATIC CANCER.

9 DR. VUORI: 5541 FOCUSES ON PANCREATIC
10 CANCER SPECIFICALLY?

11 DR. ABO: I HAVE TO LOOK. IS THAT
12 CONFIDENTIAL INFORMATION BECAUSE IT'S NOT IN THE
13 PUBLIC ABSTRACT?

14 DR. OLSON: I THINK THAT'S OKAY.

15 DR. ABO: STRONG ACTIVITY IN PRECLINICAL
16 MODEL FOR PANCREATIC CANCER. THAT'S THE AREA THAT
17 THEY FEEL THAT THEY CAN GO FORWARD WITH THIS
18 APPROACH.

19 DR. VUORI: SO I WOULD LIKE TO MOVE THIS
20 APPLICATION TO BE DISCUSSED IN THE CLOSED SESSION
21 REGARDING ITS STUDY DESIGN.

22 DR. PRIETO: ANOTHER APPLICATION WHEN
23 WE'RE READY FOR THAT.

24 CHAIRMAN THOMAS: IS THERE ANY OTHER
25 COMMENTS ON THIS PARTICULAR APPLICATION? HEARING

BARRISTERS' REPORTING SERVICE

1 NONE, DR. PRIETO.

2 DR. PRIETO: YEAH. I'D ALSO LIKE TO BRING
3 UP 5660.

4 CHAIRMAN THOMAS: PLEASE PROCEED.

5 DR. CANET-AVILES: I WOULD LIKE TO REVIEW
6 THE SUMMARY FIRST. THIS APPLICATION IS FOR THE
7 DEVELOPMENT CANDIDATE, AND IT'S FOCUSED ON HUMAN
8 EMBRYONIC STEM CELL-DERIVED NEUROPROGENITOR CELL
9 THERAPY FOR STROKE. THE APPLICANT PROPOSED TO
10 TRANSIENTLY AND EX VIVO GENETICALLY MODIFY HUMAN
11 EMBRYONIC STEM CELLS TO DERIVE NEURAL PRECURSOR
12 CELLS, PROGENITOR CELLS, TO IMPROVE SURVIVAL AND
13 DIFFERENTIATION INTO NEURONS FOLLOWING TRANSPLANT
14 INTO THE STROKE BRAIN.

15 HE PROPOSED FOUR MILESTONES. THE FIRST
16 ONE WAS TO TRANSDUCE THE HUMAN EMBRYONIC STEM
17 CELL-DERIVED NEUROPROGENITOR CELLS WITH A VIRAL
18 VECTOR AND VERIFY NEUROGENESIS IN VITRO.

19 THE SECOND ONE WAS TO TRANSPLANT THESE
20 CELLS INTO IN ANIMAL MODELS OF A STROKE.

21 THE THIRD ONE WAS TO ANALYZE THESE ANIMALS
22 TO VERIFY NEURONAL DIFFERENTIATION AND INTEGRATION
23 IN VIVO. AND LASTLY, THE FOURTH MILESTONE WAS TO
24 ANALYZE THE BEHAVIOR OF THESE ANIMALS TO DETERMINE
25 IF THESE CELLS COULD AMELIORATE THE STROKE-INDUCED

BARRISTERS' REPORTING SERVICE

1 DEFICITS.

2 THE MAJOR KEY CON OF THIS APPLICATION, IT
3 WAS THE STRONG OPINION OF THE GRANTS WORKING GROUP,
4 IT WAS UNDER THE OBJECTIVE AND MILESTONES, WAS THAT
5 THE PROJECT COULD BE READY TO ADVANCE INTO
6 IND-ENABLING STUDIES IN THE THREE YEARS. BASED ON
7 THE APPLICATION, AND THIS IS KEY, THEY DID NOT
8 PROPOSE THE KEY ACTIVITIES LISTED IN THE RFA FOR
9 ACHIEVING DEVELOPMENT CANDIDATE. IF YOU LOOK AT THE
10 RFA, YOU CAN FIND THIS ON PAGE 3 OF THE RFA.
11 BASICALLY THERE WERE NO STUDIES PROPOSED TO
12 CHARACTERIZE THIS POPULATION THAT THEY ARE PROPOSING
13 TO DERIVE.

14 IN TERMS OF RATIONALE AND SIGNIFICANCE,
15 IT'S INDEED A VERY SIGNIFICANT PROBLEM THAT SOCIETY
16 FACES. STROKE CAUSES IRREVERSIBLE DAMAGE TO THE
17 BRAIN, AND THERE ARE CURRENTLY FEW TREATMENTS, FEW
18 EFFECTIVE TREATMENTS. ANY STEM CELL-BASED
19 RESTORATION OF THE CENTRAL NERVOUS SYSTEM COULD BE A
20 MAJOR ADVANCEMENT IN STROKE THERAPY.

21 IN TERMS OF FEASIBILITY AND DESIGN, THE
22 GRANTS WORKING GROUP FOUND THAT THE PRECLINICAL
23 ANIMAL STUDIES, WHICH ARE THE BULK OF THIS PROPOSAL,
24 ARE NOT FEASIBLE OVER THE COURSE OF THE THREE-YEAR
25 AWARD. BASICALLY THEY PROPOSED TO CONDUCT THE

BARRISTERS' REPORTING SERVICE

1 STUDIES WITH RESOURCES -- IN THE TIME AND WITH THE
2 RESOURCES THEY HAVE ALLOTTED, THEY ARE NOT FEASIBLE.
3 AND I DON'T KNOW IF IT'S PROPRIETARY INFORMATION THE
4 AMOUNT OF ANIMALS PROPOSED. THEY PROPOSE TO DO
5 THESE STUDIES IN TWO YEARS AND IT WAS A HUGE NUMBER.
6 AND IF IT'S CONSIDERED CONFIDENTIAL, I CAN TALK
7 ABOUT IT IN CLOSED DOORS LATER. BUT THAT WAS ONE OF
8 THE MAJOR CONS.

9 A MOTION WAS MADE TO MOVE THIS APPLICATION
10 TO TIER III, NOT RECOMMENDED FOR FUNDING, AND THE
11 MOTION CARRIED. ARE THERE ANY QUESTIONS SPECIFIC?

12 MS. SAMUELSON: QUESTION, ROSA. THE
13 NUMBER OF ANIMALS TO BE TESTED AT A CERTAIN TIME
14 FRAME WAS REGARDED AS REALLY AMBITIOUS?

15 DR. CANET-AVILES: SO THE NUMBER OF
16 ANIMALS WAS GOING TO BE -- IN TWO YEARS WAS GOING TO
17 COME UP TO APPROXIMATELY 10,000 ANIMALS, WHICH MEANT
18 THAT YOU WERE GOING TO BE WORKING WITH ABOUT AN
19 AVERAGE OF 15 ANIMALS PER DAY. AND YOU HAVE TO DO
20 ALL THE, LIKE, SURGERY IN ORDER TO INDUCE THE STROKE
21 AND EVERYTHING. SO THAT WAS NOT SEEN AS FEASIBLE.
22 BUT MORE THAN THAT -- IF YOU JUST GIVE ME A MOMENT.

23 DR. STEWARD: I'M SORRY. COULD I SUGGEST
24 THAT THE DISCUSSION OF ANIMAL USE AND NUMBERS, THAT
25 REALLY STRIKES ME AS BEING PROPRIETARY.

BARRISTERS' REPORTING SERVICE

1 CHAIRMAN THOMAS: MR. HARRISON.

2 MR. HARRISON: WE CAN DISCUSS THAT FURTHER
3 IN CLOSED SESSION.

4 CHAIRMAN THOMAS: THANK YOU. ANY OTHER
5 QUESTIONS OF ROSA ON THIS APPLICATION? IT NOW
6 SOUNDS LIKE THREE --

7 DR. PRIETO: IT IS A QUESTION. BUT THIS
8 IS THE SUBJECT OF AN EXTRAORDINARY PETITION WHICH
9 ADDRESS SEVERAL OF THESE POINTS DIRECTLY. SO WE'LL
10 DISCUSS THAT IN CLOSED SESSION, INCLUDING THE
11 QUESTIONS OF THE ANIMAL USAGE AND FEASIBILITY OF
12 THAT.

13 DR. CANET-AVILES: THAT'S ONE OF THE
14 POINTS RAISED.

15 CHAIRMAN THOMAS: IS THAT OKAY, MR.
16 HARRISON?

17 MR. HARRISON: WITH RESPECT TO THE STUDY
18 DESIGN AND THE USE OF ANIMALS, YES. IF THERE ARE
19 OTHER POINTS THAT YOU'D LIKE TO DISCUSS IN THE
20 EXTRAORDINARY PETITION THAT DON'T FALL INTO THE
21 CATEGORY OF BEING PROPRIETARY, THEY CAN BE ADDRESSED
22 NOW.

23 DR. PRIETO: WELL, THE EXTRAORDINARY
24 PETITION DOES CALL INTO QUESTION FACTUAL ERRORS OR
25 POTENTIAL FACTUAL ERRORS IN THE REVIEW, INCLUDING

BARRISTERS' REPORTING SERVICE

1 THAT IN OUR SUMMARY HERE THE RESEARCH PLAN DOES NOT
2 INCLUDE A THOROUGH INVESTIGATION OF SAFETY ENDPOINTS
3 AND, IN PARTICULAR, THE POTENTIAL FOR NEWLY
4 TRANSPLANTED NEURONS TO CAUSE ABNORMAL ACTIVITY, AND
5 SEIZURE SHOULD BE EXAMINED.

6 I THINK I CAN MENTION THE REVIEWER'S NAME
7 IF THERE'S AN EXTRAORDINARY PETITION. THE
8 INVESTIGATOR'S NAME, IT'S STUART LIPTON FROM THE
9 SANFORD-BURNHAM, AND HE DOES DIRECTLY ADDRESS THAT
10 QUESTION, THAT THIS IS NOT FACTUALLY CORRECT, THAT
11 THERE'S AN ENTIRE SECTION IN THE GRANT ABOUT
12 MONITORING ELECTRICAL ACTIVITY IN THESE CELLS
13 USING -- HE DESCRIBES THE TECHNIQUES. IN THE THIRD
14 MILESTONE THERE'S A WHOLE SECTION OF THE PRELIMINARY
15 DATA ON THOSE EXPERIMENTS.

16 IT KIND OF BRINGS INTO QUESTION: DO WE
17 ALWAYS HAVE THE APPROPRIATE EXPERTISE IN OUR REVIEW
18 SESSION, PEOPLE WITH FAMILIARITY OF THE CLINICAL
19 ISSUES AND SUCH?

20 CHAIRMAN THOMAS: DR. STEWARD.

21 DR. STEWARD: JUST IN PRINCIPLE AND SORT
22 OF IRRESPECTIVE OF THIS APPLICATION, I WOULD SUGGEST
23 THAT IF THERE ARE CLAIMS OF DISCREPANCIES OF FACT,
24 THAT THAT REQUIRES US TO REALLY DRILL DOWN A LITTLE
25 BIT MORE INTO THE DETAILS OF THE APPLICATION AND,

BARRISTERS' REPORTING SERVICE

1 THEREFORE, IT IS PROPRIETARY, AND THAT THAT SHOULD
2 BE SOMETHING THAT WE COULD DO IN CLOSED SESSION.

3 CHAIRMAN THOMAS: MR. HARRISON IS NODDING
4 IN THE AFFIRMATIVE. ANY OTHER COMMENTS ON THIS
5 PARTICULAR APPLICATION?

6 DR. STEWARD: JUST IF WE COULD GET THE
7 DISTRIBUTION OF VOTES ON THE MOTION TO MOVE TO TIER
8 I. MAYBE LATER, BUT AT SOME POINT.

9 CHAIRMAN THOMAS: WE CAN GET THAT NOW.
10 THAT'S AN OPEN SESSION QUESTION.

11 DR. CANET-AVILES: SORRY. THERE WAS NO
12 MOTION TO TIER I. IT WAS TO TIER III.

13 DR. STEWARD: OKAY.

14 DR. CANET-AVILES: IT WAS FROM TIER II TO
15 TIER III.

16 DR. STEWARD: WELL, PROBABLY IT WOULD BE
17 USEFUL TO HAVE THAT.

18 DR. CANET-AVILES: I WILL GET IT TO YOU.

19 MR. SWEEDLER: I HAVE THAT INFORMATION.
20 IT WAS MOVED DOWN BY A VOTE OF 18 AYE VOTES TO TWO
21 NO VOTES.

22 DR. STEWARD: THANK YOU.

23 CHAIRMAN THOMAS: THANK YOU, ROSA. ARE
24 THERE ANY COMMENTS OR QUESTIONS ABOUT OTHER
25 APPLICATIONS? MR. SHEEHY.

BARRISTERS' REPORTING SERVICE

1 MR. SHEEHY: COULD WE TAKE A LOOK AT 5626?
2 JUST LOOKING AT THE NUMBERS, IT HAS A HIGH STANDARD
3 DEVIATION, AND THEN ITS MEDIAN SCORE IS 75, WHICH IS
4 ACTUALLY HIGHER IN A MEDIAN SENSE THAN THE THREE
5 ABOVE IT. AND IT SEEMS AS THOUGH -- I MEAN I LOOK
6 AT THE REVIEW, AND THE REVIEW SEEMS TO FOCUS ON
7 PROBABLY THE 40, AND I DON'T KNOW IF IT REALLY
8 ADDRESSES WHY THE MEDIAN WAS 75. I MEAN THERE SEEMS
9 TO BE SOME DISPUTE AS TO WHETHER THESE CELLS ARE THE
10 BEST CELLS IN HEART DISEASE, BUT THAT SEEMS TO BE A
11 LIVE DEBATE. AND ARE WE PREMATURELY KIND OF FALLING
12 ON ONE SIDE OF THAT DEBATE, THAT THE MESENCHYMAL
13 STEM CELLS ARE NOT GOING TO BE THE GREAT CELLS TO
14 PUT IN FOR HEART DISEASE? ARE WE KIND OF
15 ARBITRARILY MAKING THAT DECISION WHEN IT SEEMS LIKE
16 A SUBSTANTIAL NUMBER OF THE REVIEWERS WERE
17 COMFORTABLE WITH US MAKING THAT BET?

18 AND IT SEEMS LIKE THE KEY THING HERE IS
19 THE MATRIX THAT'S GOING TO HOLD THEM IN PLACE. WE
20 REALLY MIGHT NOT KNOW THE ANSWER UNTIL WE PUT IN
21 SOMETHING THAT HOLDS THOSE CELLS IN PLACE AND WE CAN
22 SEE WHAT HAPPENS.

23 WE DID HAVE THAT GREAT PRESENTATION AT
24 CEDARS-SINAI, SO WE DO KNOW THAT CELLS GOING INTO
25 THE HEART DO SEEM TO BE DOING SOME STUFF. SO MAYBE

BARRISTERS' REPORTING SERVICE

1 INSIGHTS.

2 CHAIRMAN THOMAS: YES, PLEASE PROCEED.

3 DR. COLLINS: GOOD MORNING, MR. CHAIRMAN
4 AND MEMBERS OF THE BOARD AND PUBLIC. I'D LIKE TO
5 JUST BRIEFLY PRESENT TO YOU A SYNOPSIS OF THIS
6 APPLICATION, AND THEN I WILL GO THROUGH THE KEY
7 POINTS THAT CAME UP IN THE REVIEW.

8 SO THIS IS A DEVELOPMENT CANDIDATE
9 PROPOSAL, AND I MAY SAY DC LATER, BUT I'LL TRY TO
10 STICK WITH DC, WITH DEVELOPMENT CANDIDATE, TO
11 EVALUATE DONOR-DERIVED BONE MARROW MESENCHYMAL STEM
12 CELLS ON AN FDA-APPROVED BIOLOGICAL SCAFFOLD OR CELL
13 CARRIER FOR THE TREATMENT OF CHRONIC HEART ATTACKS.
14 AND THE RATIONALE BEHIND ADDING THIS CARRIER IS TO
15 KEEP THE CELLS AT THE DESIRED TRANSPLANT SITE AND
16 ENHANCE THE THERAPEUTIC IMPACT OF THE STEM CELLS BY
17 RETAINING THEM IN PLACE.

18 SO JUST BRIEFLY, THE PLAN IS TO DEVELOP
19 AND CHARACTERIZE THIS DEVICE IN VITRO AND THEN
20 PERFORM IN VIVO SAFETY AND EFFICACY TESTING. AND AS
21 FAR AS THE EVALUATION OF THE GRANTS WORKING GROUP,
22 THIS IS A PROPOSAL FROM AN ACCOMPLISHED CARDIAC
23 SURGEON, THAT'S ONE OF THE STRENGTHS, WITH CLINICAL
24 EXPERIENCE USING THE PROPOSED SCAFFOLD. THE TEAM
25 ITSELF IS TRANSLATIONALLY FOCUSED AND HAS STEM CELL

BARRISTERS' REPORTING SERVICE

1 AND MANUFACTURING EXPERTISE.

2 AND THE PANEL DID NOTE THAT THE
3 APPLICATION WAS CLEARLY WRITTEN WITH APPROPRIATE
4 MILESTONES AND SUCCESS CRITERIA. SO THOSE WERE THE
5 STRENGTHS. AND IN ADDITION, THE UNMET MEDICAL NEED
6 IN HEART FAILURE IS OBVIOUSLY COMPELLING.

7 HOWEVER, THE GRANTS WORKING GROUP HAD
8 THREE MAIN CONCERNS REGARDING THE PROPOSAL THAT
9 RESULTED IN THE RECOMMENDATION NOT TO FUND THE
10 PROGRAM. AND THE FIRST, I THINK, AND KEY
11 RESERVATION WAS THAT THEY FOUND THE PROGRAM TO BE
12 PREMATURE. AS ALREADY MENTIONED, PRELIMINARY DATA
13 AND FEASIBILITY ARE IMPORTANT FOR THESE DEVELOPMENT
14 CANDIDATE AWARDS. AND THIS WAS PART OF THE REVIEW
15 CRITERIA.

16 AND THE PANEL NOTED THAT THE PROPOSAL --
17 THE APPLICATION LOOKED AT PRELIMINARY DATA USING THE
18 PROPOSED CANDIDATE IN THE CHRONIC HEART DISEASE
19 MODEL. SO THEY WERE A LITTLE BIT CONCERNED THAT THE
20 DATA THERE TO SHOW THAT PERHAPS THIS PRODUCT WOULD
21 BE MORE EFFECTIVE THAN EITHER COMPONENT ALONE WAS
22 LACKING.

23 AND THIS CONCERN MAY HAVE BEEN MAGNIFIED
24 BY UNCERTAINTY THAT YOU MENTIONED, MR. SHEEHY, THAT
25 MSC'S ARE THE BEST CHOICE FOR REPAIRING CHRONICALLY

BARRISTERS' REPORTING SERVICE

1 DAMAGED HEARTS GIVEN THAT THIS IS A WELL-STUDIED
2 CELL TYPE IN THIS DISEASE AND THE DATA HAVE BEEN A
3 BIT CONFLICTING TO DATE.

4 AND FINALLY, THERE WAS DISCUSSION THAT THE
5 PANEL DIDN'T FIND THAT THE DC WAS PARTICULARLY
6 NOVEL. AGAIN, I MENTIONED THAT IT WAS WELL STUDIED.
7 AND THE PANEL WAS NOT CLEAR THAT ATTEMPTS TO RETAIN
8 THE CELLS AT THAT TIME THE TRANSPLANTATION SITE
9 WOULD REALLY IMPROVE THEIR EFFECT. AND I THINK
10 REALLY THAT DATA WAS WHAT THEY WOULD HAVE LIKED TO
11 SEE TO FEEL MORE COMFORTABLE WITH RECOMMENDING IT.

12 SO THOSE WERE THE KEY REASONS FROM THE
13 REVIEW THAT IT WASN'T RECOMMENDED FOR FUNDING.

14 CHAIRMAN THOMAS: MR. SHEEHY.

15 MR. SHEEHY: WELL, JUST A COUPLE OF
16 POINTS. ONE, IT DOESN'T SEEM LIKE WE HAVE ANY
17 CARDIAC MSC WORK GOING ON. I THINK I'M CORRECT IN
18 THAT. AND I THINK, I MEAN I'M NOT AN EXPERT ON
19 THIS, BUT MSC'S SEEM TO BE MOVING FAIRLY -- I MEAN
20 HAVING SAT THROUGH THESE REVIEWS, SEEM TO BE VERY
21 TRANSPLANTABLE RIGHT NOW. THEY'RE NOT IMMUNOGENIC.
22 THEY'RE NOT TUMOROGENIC. SO IT DOES ADDRESS PERHAPS
23 A GAP IN OUR PORTFOLIO. AND I WONDER TO WHAT DEGREE
24 THE NOVELTY WAS A NEGATIVE AND THAT MAYBE OTHER
25 PEOPLE ARE DOING THIS. MAYBE THIS IS SOMETHING WE

BARRISTERS' REPORTING SERVICE

1 MIGHT WANT TO DO. MAYBE WE COULD GET THERE FIRST.

2 BE A NICE HOME RUN FOR US IF WE DID, I THINK.

3 DR. COLLINS: I THINK THE POINT WITH THE
4 NOVELTY -- I'M SORRY.

5 MR. SHEEHY: NO. GO AHEAD, PLEASE.

6 DR. COLLINS: I THINK THE POINT WITH THE
7 NOVELTY WAS THAT IT'S NOT JUST WHO'S DOING IT, THAT
8 THIS HAS BEEN WELL STUDIED TO THE POINT THERE HAVE
9 BEEN A NUMBER OF CLINICAL TRIALS, INCLUDING -- WELL,
10 ANYWAYS, I THINK THAT WAS THE KEY POINT.

11 MR. SHEEHY: BUT ISN'T THE DATA KIND OF
12 CONFLICTING? SOME SHOW SOME EFFECT FROM HAVING THE
13 MSC'S THERE AND SOME SHOW NO EFFECT.

14 DR. COLLINS: EXACTLY.

15 MR. SHEEHY: AND SO THEIR HYPOTHESIS IS IF
16 WE JUST KEEP THE CELLS THERE, WE MIGHT GET AN
17 EFFECT. SO HE'S GOT A RELATIVELY SAFE CELL
18 POPULATION, GOOD BIOMATERIAL TO HOLD THEM THERE. I
19 THINK THIS IS A SAFE, APPROVED PRODUCT.

20 DR. COLLINS: THE MATERIAL IS APPROVED.

21 MR. SHEEHY: AND THEN I LOOK AT THE MEDIAN
22 SCORE OF 75, AND TO ME THIS SUGGESTS ONE WHERE WE
23 MIGHT -- PERSONALLY, AND WE'RE NOT MAKING MOTIONS
24 NOW, BUT WE MIGHT WANT TO TAKE A LOOK AT PERHAPS
25 TAKING A RISK ON THIS. AND THE CELL TYPE WE DON'T

BARRISTERS' REPORTING SERVICE

1 HAVE IN OUR PORTFOLIO FOR THIS PARTICULAR APPROACH.

2 CHAIRMAN THOMAS: DR. TROUNSON.

3 DR. TROUNSON: JUST IN A GENERAL SENSE,

4 JEFF, THE MSC'S USUALLY DON'T LAST VERY LONG.

5 THEY'RE GONE IN A COUPLE OF DAYS. AND SO I THINK

6 ONE OF THE CONCERNS OF THE REVIEWERS WAS SAYING,

7 WELL, WOULDN'T THAT BE THE SAME IN THIS SITUATION?

8 TELL US THAT THE SCAFFOLD SEEDED WITH THIS IS

9 BETTER. AND THAT'S WHAT WE DIDN'T HAVE. YOU PUT

10 THE SCAFFOLD ON, MIGHT BE JUST AS GOOD AS ADDING THE

11 CELLS. SO THAT WAS -- IT WAS DEFICIENT IN THAT

12 REGARD.

13 SO I THINK THE INJECTION FRACTION STUDIES

14 WITH DIFFERENT COMPANIES IS UP AND DOWN, YES, BUT

15 THERE'S USUALLY SOME MERIT FOR HAVING THOSE MSC'S.

16 WE HAVE NO IDEA WHAT THAT MECHANISM IS, OF COURSE,

17 WHICH IS A LITTLE CONCERNING, BUT I THINK THE REAL

18 ISSUE WHERE THE REVIEWERS WERE REALLY SORT OF

19 STRUGGLING WAS, WELL, IS IT REALLY BETTER THAN JUST

20 HAVING THE SCAFFOLD. THE SCAFFOLD THERE WOULD

21 ATTRACT ENDOGENOUS CELLS AS WELL, AND SO WONDERED

22 WHERE THE BENEFIT WAS. AND IF THEY COULD SHOW THEM

23 THE BENEFIT, I THINK, IT WOULD HAVE HELPED

24 CONSIDERABLY. THAT'S THE WAY I RECALL THE

25 DISCUSSION.

BARRISTERS' REPORTING SERVICE

1 MR. SHEEHY: MIGHT NOT HAVING THOSE MSC'S
2 WITH THEIR KIND OF SOMEWHAT MAGIC PROPERTY IN THE
3 ENDOGENOUS CELLS, WHICH SEEMS LIKE IF MSC'S ARE
4 DOING SOMETHING, THEY'RE DOING SOMETHING ON THE
5 ENDOGENOUS CELLS HAVING THAT TRAFFICKING AND THEN
6 THE MSC'S WITH THEIR KIND OF PRESENCE THERE, EVEN IF
7 THEY'RE NOT THERE FOR A LONG TIME. I MEAN JUST --

8 DR. TROUNSON: THAT'S TRUE. JUST TO
9 REMIND YOU, ALSO, THAT THE GROUP AT CEDARS-SINAI
10 COMPARED MSC'S AND MONONUCLEOCYTES WITH THE CARDIAC
11 CELLS, AND THERE WAS REALLY A VERY BIG DIFFERENCE IN
12 THEIR STUDIES. I'D LIKE TO SEE THAT REPEATED BY
13 OTHERS, BUT IT LOOKS LIKE, IF WE'RE ON THE TRACK,
14 WE'RE KIND OF ON THE TRACK WITH A BETTER COMPOUND
15 GIVEN THAT PARTICULAR STUDY. AS I SAID, I'D LIKE TO
16 SEE THAT REPEATED. BUT IT LOOKED MUCH BETTER TO
17 UTILIZE THE HEART -- THE HEART-TYPE CELLS RATHER
18 THAN THE MSC'S.

19 MR. SHEEHY: THOSE DON'T PERSIST EITHER,
20 RIGHT?

21 DR. TROUNSON: NO. NO. THAT'S TRUE. NO,
22 THAT'S RIGHT. THAT I AGREE. THAT I AGREE.

23 CHAIRMAN THOMAS: DR. STEWARD.

24 DR. STEWARD: COULD YOU REMIND US, THERE'S
25 ONE COMMENT IN HERE ABOUT LACKS LETTERS OF SUPPORT

BARRISTERS' REPORTING SERVICE

1 FROM CO-INVESTIGATORS. COULD I COMMENT? I DON'T
2 REMEMBER THE DEGREE TO WHICH THAT INFLUENCED THE
3 OVERALL SCORE.

4 DR. COLLINS: SO THAT WAS DISCUSSED. I
5 DON'T RECALL IT BEING A KEY CRITICISM. ARE YOU
6 GETTING TO ANY OTHER DOCUMENT OR JUST THE --

7 DR. STEWARD: WELL, YEAH, BECAUSE
8 ACTUALLY -- SO I REALIZE THAT WE'RE NOT OFFICIALLY
9 CONSIDERING THE EXTRAORDINARY PETITIONS, BUT THE
10 EXTRAORDINARY PETITION THAT RELATES TO THIS GRANT
11 DOES HAVE THAT, AND I JUST WANTED TO RAISE THAT AS
12 AN ISSUE IF THAT WAS A MAJOR FACTOR.

13 DR. COLLINS: SO I THINK REALLY THE KEY
14 FACTOR WAS THAT THE PROPOSAL WAS A BIT PREMATURE AND
15 THERE WERE SOME CONCERNS ABOUT, AS WE DISCUSSED, THE
16 SELECTED THERAPEUTIC CELL TYPE.

17 BUT TO THE PETITION, A PETITION WAS
18 RECEIVED, IT WAS RECEIVED LATE, BUT IT WAS
19 DOCUMENTING BOTH SUPPORT FROM MANUFACTURER OF THE
20 SCAFFOLD AS WELL AS MATERIAL TRANSFER AGREEMENT FROM
21 THE PRODUCER OF THE SCAFFOLD TO PROVIDE THIS
22 MATERIAL AS WELL AS TECHNICAL EXPERTISE FOR THE
23 PROPOSED PROGRAM. AND THAT WAS RECEIVED.

24 DR. STEWARD: IF I COULD JUST COMMENT. I
25 WILL CONFESS THAT I NORMALLY DON'T LIKE THE

BARRISTERS' REPORTING SERVICE

1 EXTRAORDINARY PETITIONS BECAUSE THEY VERY OFTEN
2 ARGUE WITH THE REVIEWERS ABOUT POINTS THAT REALLY
3 ARE VERY DIFFICULT TO ADJUDICATE IN A SETTING LIKE
4 THIS. IN THIS CASE, HOWEVER, THE EXTRAORDINARY
5 PETITION PERTAINS TO SOMETHING THAT ACTUALLY DID
6 SHOW UP IN THE REVIEW AND REALLY IS AN MTA THAT
7 WASN'T EXECUTED AT THE TIME. SO I JUST WANTED TO
8 POINT THAT OUT JUST TO SAY IF IT WAS A KEY FACTOR,
9 THAT THAT APPEARS TO BE IN PLACE NOW. IS THAT
10 CORRECT?

11 DR. COLLINS: YES, THAT'S CORRECT.

12 DR. STEWARD: OKAY.

13 CHAIRMAN THOMAS: ANY OTHER COMMENTS ON
14 THIS APPLICATION? THANK YOU. ANY OTHER COMMENTS ON
15 ANY OTHER DC APPLICATION NOT YET DISCUSSED? HEARING
16 NONE, MR. HARRISON, PERHAPS YOU COULD DESCRIBE THE
17 NEXT STEP WITH RESPECT TO CLOSED SESSION.

18 MR. HARRISON: YES. BUT BEFORE WE GO TO
19 CLOSED SESSION, I UNDERSTAND THAT THERE IS A MEMBER
20 OF THE PUBLIC PRESENT IN SAN DIEGO WITH DUANE ROTH
21 WHO WOULD LIKE TO OFFER A COMMENT ABOUT AN
22 APPLICATION THAT HAS NOT YET BEEN DISCUSSED. SO
23 PERHAPS WE COULD OFFER THAT OPPORTUNITY FIRST AND
24 THEN CONVENE IN CLOSED SESSION SO WE MAKE SURE THAT
25 WE'VE COVERED EVERYTHING WE NEED TO.

BARRISTERS' REPORTING SERVICE

1 CHAIRMAN THOMAS: CERTAINLY.

2 MR. ROTH: SO I HAVE SOME MEMBERS OF THE
3 PUBLIC THAT DID SUBMIT AN EXTRAORDINARY PETITION,
4 AND THEY WOULD LIKE TO MAKE A COMMENT. SO I'LL TURN
5 IT OVER TO THEM.

6 DR. CHU: GOOD MORNING, EVERYONE. THIS IS
7 DR. PETER CHU AND THE PRESIDENT AND CO-FOUNDER OF
8 ECLIPSE THERAPEUTICS. WE SUBMITTED GRANT NUMBER
9 TR3-05730. IT RECEIVED A BORDERLINE SCORE AND WAS
10 NOT APPROVED FOR FUNDING. SO WE DID SUBMIT A
11 PETITION WHICH IS, I THINK, ON THE AGENDA AS ONE OF
12 THE THREE PETITIONS.

13 I'D JUST LIKE TO SORT OF SUMMARIZE SORT OF
14 OUR ARGUMENT HERE. SO ECLIPSE IS A SAN DIEGO
15 BIOTECH COMPANY FOCUSED ON DEVELOPING A VERY
16 PROMISING DRUG TARGETING CANCER STEM CELLS THAT CAN
17 TREAT NOT ONLY COLON CANCER, BUT MOST OTHER SOLID
18 CANCERS, SUCH AS BREAST, PROSTATE, PANCREATIC, AND
19 LUNG CANCER. THESE ARE DISEASES THAT AFFECT
20 MILLIONS OF AMERICANS EVERY YEAR. WE'RE A SPIN-OUT
21 OF BIOGEN IDEC, A MAJOR BIOTECH COMPANY THAT CHOSE
22 TO EXIT CANCER R&D AND CLOSE ITS SAN DIEGO SITES.

23 SO AT ECLIPSE WE'RE ACTUALLY CAPITALIZING
24 ON MILLIONS OF DOLLARS AND SEVEN YEARS AT BIOGEN
25 IDEC PREVIOUSLY INVESTED IN THIS CANCER STEM CELL

BARRISTERS' REPORTING SERVICE

1 AND ANTIBODY PROGRAM. SO AS A RESULT WE ACTUALLY
2 HAVE A VERY ADVANCED PRECLINICAL STAGE CANCER STEM
3 CELL DRUG POISED TO ENTER THE CLINIC WITHIN 18
4 MONTHS. SO WE BELIEVE THIS WOULD BE AN EXCELLENT
5 OPPORTUNITY FOR CIRM TO PARTNER WITH AND BE
6 ASSOCIATED WITH A VERY EXCITING, VERY PROMISING DRUG
7 THAT WOULD BE TESTED IN PATIENTS IN THE VERY NEAR
8 FUTURE.

9 SO WE HAVE PRECLINICAL STUDIES THAT HAVE
10 SHOWN VERY GOOD RESULTS, SIGNIFICANT INHIBITION OF
11 PRIMARY COLORECTAL TUMOR MODELS. THESE ARE TUMORS
12 DIRECTLY FROM THE PATIENTS. AND MORE IMPORTANTLY,
13 WE HAVE SHOWN SIGNIFICANTLY INCREASED SURVIVAL OF
14 THE ANIMALS IN THESE STUDIES. VERY IMPORTANTLY,
15 WE'VE RECENTLY SHOWN THAT OUR DRUG ACTUALLY DOES
16 REDUCE THE FREQUENCY OF CANCER STEM CELLS IN THESE
17 MODELS. SO, IN FACT, WHEN WE TREAT THESE TUMORS,
18 TAKE THEM OUT AND REIMPLANT THEM INTO THE MICE, THEY
19 EITHER DO NOT GROW OR GROW VERY POORLY. IN
20 CONTRAST, THE CONTROL OR CHEMO-TREATED TUMORS GROW
21 IN A HUNDRED PERCENT OF THE ANIMALS AND, IN FACT,
22 THEY GROW MUCH, MUCH FASTER.

23 SO WE FILED THIS PETITION, AS I MENTIONED,
24 BECAUSE WE HAD THE BORDERLINE SCORE. SO AS YOU WILL
25 READ IN OUR PETITION LETTER, SINCE WE SUBMITTED THIS

BARRISTERS' REPORTING SERVICE

1 APPLICATION, WE'VE MADE VERY GOOD PROGRESS ON OUR
2 DRUG PROGRAM. WE'VE ACTUALLY MOVED FASTER THAN WE
3 HAD EXPECTED. WE HAVE SELECTED A LEAD DRUG
4 CANDIDATE ALREADY. SO WE'VE BEEN ABLE TO MOVE UP
5 OUR TIMELINES. AND AS I MENTIONED, WE'RE ON TRACK
6 TO BE IN THE CLINIC WITHIN 18 MONTHS. SO WE'VE
7 ACTUALLY COMPLETED MILESTONE ONE IN THIS GRANT AND
8 WILL ACTUALLY NOT BE NEEDING THE FULL BUDGET THAT WE
9 ORIGINALLY REQUESTED.

10 SOMETHING OF NOTE, MENTIONING THAT WE HAD
11 A STRONG LETTER OF SUPPORT FROM PROFESSOR HANS
12 CLEAVERS ON THIS GRANT. HE'S THE WORLD'S EXPERT ON
13 COLON STEM CELL BIOLOGY. I KNOW HE'S WELL-KNOWN AND
14 HIGHLY RESPECTED BY MANY OF THOSE AT CIRM. AND HE
15 ONLY AGREED TO JOIN OUR ADVISORY BOARD AFTER SEEING
16 OUR DATA. HE'S ACTUALLY NOT ON ANY OTHER CANCER
17 ADVISORY BOARDS. WE'RE THE ONLY ONE. SO I THINK
18 THAT SPEAKS VERY HIGHLY OF THE PROMISE OF OUR DRUG.

19 SO WE DO BELIEVE THERE'S --

20 MR. ROTH: GO AHEAD, J.T.

21 CHAIRMAN THOMAS: SORRY, DUANE.

22 MR. ROTH: OH, I THOUGHT SOMEBODY WAS
23 TRYING TO INTERRUPT.

24 CHAIRMAN THOMAS: NO.

25 DR. CHU: SO WE DO BELIEVE WE HAVE AN

BARRISTERS' REPORTING SERVICE

1 EXTRAORDINARY CIRCUMSTANCE HERE WHICH IS A VALID
2 REASON TO HAVE OUR GRANT APPROVED, WHICH IS SORT OF
3 THE FINAL RECOMMENDATION OF THE REVIEW COMMITTEE WAS
4 THAT WE HAD NOT DEMONSTRATED THAT WE WERE ABLE TO
5 REDUCE THE CANCER STEM CELLS WITH OUR DRUG IN VIVO,
6 AND THEY RECOMMENDED THAT THEY WOULD HAVE LIKED TO
7 HAVE SEEN THAT DATA. WE ACTUALLY, AS I MENTIONED,
8 HAVE GENERATED THAT DATA IN THE LAST -- SINCE THE
9 GRANT WAS SUBMITTED, WE ACTUALLY ATTEMPTED TO SUBMIT
10 THIS DATA LAST MONTH TO CIRM ALTHOUGH WE WERE TOLD
11 THAT OUR GRANT HAD ALREADY BEEN REVIEWED. AND
12 ESSENTIALLY SINCE WE SUBMITTED THE GRANT, WE ARE IN
13 THE PROCESS OF TRANSFERRING ALL OUR ASSETS FROM
14 BIOGEN IDEC FROM THEIR FREEZERS TO OUR NEW LAB IN
15 SAN DIEGO. SO WE WEREN'T ABLE TO DO THESE
16 EXPERIMENTS AT THE TIME; BUT, AS I MENTIONED, SINCE
17 THE GRANT HAS BEEN SUBMITTED, WE HAVE DONE THOSE
18 EXPERIMENTS, AND THE DATA HAS BEEN VERY POSITIVE.

19 SO WE BELIEVE THAT THAT'S A VERY VALID
20 REASON FOR THIS PETITION. I'D JUST LIKE TO CLOSE BY
21 SAYING THAT WE ALSO HAVE A VERY STRONG TEAM THAT
22 WE'VE ASSEMBLED AT ECLIPSE. OUR EMPLOYEES HAVE LED
23 PROGRAMS THAT HAVE LED TO EIGHT FDA DRUG APPROVALS
24 AND OVER 15 IND APPROVALS, SO WE BELIEVE WE HAVE THE
25 TRACK RECORD AND THE CREDIBILITY TO SUCCEED IN THIS

BARRISTERS' REPORTING SERVICE

1 DRUG. AND WE REALLY WOULD LIKE TO WORK WITH CIRM ON
2 THIS DRUG PROGRAM.

3 MR. ROTH: OKAY, J.T.

4 CHAIRMAN THOMAS: OKAY. THANK YOU, DR.
5 CHU. THANK YOU, DUANE. MR. HARRISON.

6 MR. HARRISON: I BELIEVE WE HAVE ONE
7 MEMBER OF THE PUBLIC PRESENT WITH US HERE WHO WOULD
8 LIKE TO MAKE A COMMENT BEFORE WE CONVENE IN CLOSED
9 SESSION. JUST A REMINDER, COMMENTERS SHOULD LIMIT
10 THEMSELVES TO THREE MINUTES PLEASE.

11 DR. BOYD: THANK YOU VERY MUCH. MR.
12 CHAIRMAN, MEMBERS OF THE BOARD, I'M DR. DOUGLAS
13 BOYD. I'M THE PRINCIPAL INVESTIGATOR OF GRANT
14 NUMBER 05626, EXTRACELLULAR MATRIX BY SCAFFOLDS
15 AUGMENTED WITH HUMAN STEM CELLS FOR CARDIOVASCULAR
16 REPAIR. I'D JUST LIKE TO ADDRESS THE BOARD
17 ESSENTIALLY WITH THREE ISSUES THAT I HAD AND TO
18 CLARIFY WITH REGARDS TO THIS GRANT APPLICATION.

19 SO ONE OF MY COLLEAGUES THAT ARE CLOSE,
20 SANDRA GUARD (PHONETIC) AND MY OTHER COLLEAGUE JAN
21 NOLTA, THEY'RE HERE PRESENT WITH ME TODAY. I'D
22 FIRST LIKE TO THANK THE COMMITTEE FOR THEIR
23 INVOLVEMENT AND ALL THE TIME THEY'VE SPENT IN THIS
24 UNIQUE AND VISIONARY ORGANIZATION. IT ENABLES
25 RESEARCHERS LIKE US TO REALLY GET THE JOB DONE, BUT,

BARRISTERS' REPORTING SERVICE

1 MORE IMPORTANTLY, IT BRINGS PROMISE TO THE 16
2 MILLION AMERICANS THAT HAVE CARDIOVASCULAR DISEASE.

3 I'M JUST A SIMPLE CARDIAC SURGEON. SO
4 WHEN I SPEAK TO OTHER ESTEEMED SCIENTISTS AND
5 BRILLIANT PEOPLE, I'M JUST REALLY A PLUMBER. THE
6 FACT IS THAT ONE THING I DO HAVE THE ADVANTAGE OF IS
7 BEING IN THE OPERATING ROOM EVERY DAY AND DEALING
8 WITH THESE PATIENTS. I CAN TELL YOU THAT THE GAP
9 BETWEEN BASIC SCIENCE AND CLINICAL UTILITY IS
10 ENORMOUS. BUT I CAN TELL YOU THAT EVERY DAY THAT --
11 SIX YEARS AGO I IMPLANTED THE FIRST HUMAN BY
12 SCAFFOLD FOR CARDIOVASCULAR REPAIR AND REGENERATION.
13 I USE THAT IN MY PRACTICE REGULARLY, AND I HAVE
14 GREAT FAMILIARITY WITH THAT. WHAT I CAN TELL YOU IS
15 THAT IT BRINGS GREAT PROMISE TO THE MILLIONS OF
16 PEOPLE THAT DO HAVE HEART DISEASE.

17 THE OTHER THING IS REGARDING THE THREE
18 ISSUES REGARDING OUR APPLICATION. THE FIRST THING,
19 ONE OF THE MAIN CRITICISMS OF OUR GRANT WAS THAT OUR
20 APPLICATION LACKED LETTERS OF SUPPORT FROM INDUSTRY.
21 AND THAT WAS REALLY MY SHORTFALL. WHAT I'D LIKE TO
22 MAKE CLEAR TO THE BOARD IS THAT OUR INDUSTRY PARTNER
23 IS COOK BIOTECH, A \$500 MILLION INDUSTRY. COOK
24 BIOTECH PRODUCED THE WORLD'S FIRST BIOLOGICS ECM
25 BIOSCAFFOLD AND HAS THE MOST EXPERIENCE IN PRODUCING

BARRISTERS' REPORTING SERVICE

1 THIS, AND IS FULLY ENDORSED AND IS EXCITED AND
2 BACKING US IN THIS ENDEAVOR. THEY ARE A HUNDRED
3 PERCENT BEHIND US. AND WE HAVE DOCUMENTED THAT IN
4 OUR RECENT LETTER.

5 OF CONCERN TO ME WAS THAT IT WAS MENTIONED
6 IN THE REVIEWER'S REPORT THAT THIS LACK OF
7 COLLABORATION INCREASED THE RISK OF THIS PROJECT. I
8 WANT TO ASSURE THE BOARD THAT WE HAVE FULL AND
9 UNYIELDING SUPPORT BY THE WORLD'S NO. 1 PRODUCER OF
10 BIOLOGIC SCAFFOLDS.

11 THE SECOND THING I'D LIKE TO ADDRESS IS I
12 UNDERSTAND THERE'S A PANEL DEBATE ABOUT THE CHOICE
13 OF MESENCHYMAL STEM CELLS FOR THE DEVELOPMENT
14 CANDIDATE AND HOW THAT THERE'S A PLUS-MINUS EFFECT
15 MENTIONED ON THE EFFICACY. I COULDN'T AGREE MORE.
16 AND THE REASON WHY IS THAT THE IDEA OF A PARADIGM OF
17 CELLS ALONE FOR CARDIAC REGENERATION IN OUR OWN
18 EXPERIENCE AND IN OUR OWN PRELIMINARY RESULTS SHOW
19 THAT CELLS ALONE FOR CARDIAC REGENERATION ARE
20 PROBABLY NOT THE RIGHT WAY TO GO. AND THE
21 COMBINATION WITH A SCAFFOLD, WE BELIEVE, HAS GREAT
22 PROMISE AND, THEREFORE, IS THE FOCUS OF OUR
23 INVESTIGATIVE EFFORTS.

24 SO WE FEEL THAT THE COMBINATION OF STEM
25 CELLS AND SCAFFOLDS IS REALLY A VERY, VERY NOVEL

BARRISTERS' REPORTING SERVICE

1 APPROACH THAT REALLY SHOULD BE GIVEN STRONG
2 CONSIDERATION BY THE BOARD.

3 I CAN TELL YOU THAT THREE MONTHS AGO I HAD
4 A PATIENT THAT I WAS CALLED TO SEE IN THE INTENSIVE
5 CARE UNIT. SHE WAS DYING. SHE'S A 31-YEAR-OLD
6 MOTHER WITH TWO CHILDREN. SHE HAD INFECTIONS IN HER
7 LUNGS BECAUSE SHE HAD A MASSIVELY INFECTED VALVE
8 SEEDING HER LUNGS. I BROUGHT HER TO THE OPERATING
9 ROOM AS A LAST HOPE. HER HEART PUMP WAS FAILING.
10 THE ONLY OPPORTUNITY TO SAVE HER LIFE WAS TO PUT IN
11 AN ARTIFICIAL VALVE. UNFORTUNATELY, IF YOU PUT AN
12 ARTIFICIAL VALVE INSIDE AN INFECTED SITE, THEY
13 IMMEDIATELY GET REINFECTION AND THE PATIENT IS
14 DOOMED TO DIE.

15 BECAUSE OF OUR RESEARCH IN REGENERATIVE
16 MEDICINE, I CHOSE TO DO A VERY, VERY NOVEL AND
17 RADICAL PROCEDURE. AND THAT WAS OUR TEAM REBUILT A
18 HUMAN HEART VALVE IN THE OPERATING ROOM AND
19 IMPLANTED IT. THIS WAS THREE MONTHS AGO. THE
20 PATIENT IS NOW HOME AND ECHO SHOWS THAT SHE'S
21 COMPLETELY REGENERATED HER VALVE. AND THIS IS GOING
22 TO BE REPORTED IN THE NEXT SIX WEEKS AT AN
23 INTERNATIONAL CONFERENCE.

24 THESE KIND OF THINGS ALSO THAT MAY HAVE
25 BEEN OVERLOOKED IN OUR REPORT WAS THAT OUR

BARRISTERS' REPORTING SERVICE

1 PRELIMINARY STUDIES DID, IN FACT, SHOW A DECREASE IN
2 INFLAMMATION SURROUNDING THE REGENERATIVE PROCESS
3 WHEN YOU ADD MESENCHYMAL STEM CELLS TO MATRIX. AND
4 I THINK THIS IS VERY, VERY IMPORTANT. AS WE ALL
5 KNOW, INFLAMMATION IS ONE OF THE ACHILLES HEELS OF
6 REGENERATION.

7 IN SUMMARY, I'D LIKE TO SAY THAT OUR GRANT
8 ADDRESSES THE NO. 1 CAUSE OF DISEASE AND CAUSE OF
9 DEATH IN CALIFORNIA AND THE UNITED STATES. WE HAVE
10 DIRECTLY ADDRESSED THE REVIEW PANEL'S CONCERN
11 REGARDING OUR COLLABORATIVE SUPPORT. AND, IN FACT,
12 WE HAVE THE STRONGEST INDUSTRY SUPPORT POSSIBLY
13 AVAILABLE IN THIS BIOSCAFFOLD STEM CELL EFFORT.

14 WE HAVE THE TOOLS TO GET THE JOB DONE. WE
15 HAVE THE FACILITIES, WE HAVE WORLD-CLASS FACILITIES,
16 WE HAVE THE SURGEONS AND THE STAFF TO DO THE SURGERY
17 AND GET THE RESEARCH DONE, BUT ALSO WE HAVE THE
18 EXPERIENCE IN USING THIS SCAFFOLD EVERY DAY. I
19 REALLY HOPE THAT THE BOARD WILL RECONSIDER FUNDING
20 FOR OUR PROJECT. THANK YOU.

21 CHAIRMAN THOMAS: THANK YOU, DR. BOYD.
22 DR. OLSON.

23 DR. OLSON: I JUST WANTED TO BRING ONE
24 THING TO THE BOARD'S ATTENTION BECAUSE IT HAS NOT
25 COME UP IN DISCUSSION. AND IF YOU WILL NOTE ON THE,

BARRISTERS' REPORTING SERVICE

1 AND I BELIEVE DR. ABO BROUGHT THIS UP IN HIS
2 PRESENTATION, IT'S ALSO OBVIOUS UP THERE THAT
3 APPLICATION NO. TR3-05617 WAS ACTUALLY RECOMMENDED
4 IN PROGRAMMATIC REVIEW BY THE GRANTS WORKING GROUP
5 TO BE FUNDED AS A DEVELOPMENT CANDIDATE FEASIBILITY
6 AWARD.

7 I WOULD LIKE TO OFFER A STAFF
8 RECOMMENDATION INSTEAD. NOW, IF YOU WOULD LIKE ME
9 TO GO INTO THIS, BUT THE REASON -- AND MAYBE I'D
10 BETTER GIVE YOU A BIT OF BACKGROUND SO YOU
11 UNDERSTAND THE BASIS FOR THE STAFF RECOMMENDATION.
12 SO WHAT THIS AWARD IS, IT'S A DEVELOPMENT CANDIDATE
13 AWARD FOCUSED ON IDENTIFYING SMALL MOLECULE DRUGS
14 FOR THE TREATMENT OF MULTIPLE SCLEROSIS.

15 THE APPLICANT PROPOSES TO IDENTIFY SMALL
16 MOLECULE DRUGS THAT REMYELINATE AXONS. THEY'VE
17 PROPOSED SIX MILESTONES, BUT BASICALLY THESE
18 MILESTONES FALL IN TWO CLASSES. THEY HAVE SCREENED
19 USING THEIR ASSAY A SET OF BIOLOGICALLY ACTIVE
20 COMPOUNDS INCLUDING KNOWN DRUGS AND HAVE IDENTIFIED
21 SEVERAL, ONE OF WHICH IS A DRUG FDA APPROVED IN
22 CLINICAL USE. AND MUCH OF THEIR PRELIMINARY DATA IS
23 DIRECTED TO THAT DRUG.

24 OKAY. THEY HAVE ALSO CONDUCTED A SCREEN
25 WITH WHOLLY NOVEL COMPOUNDS AND HAVE IDENTIFIED A

BARRISTERS' REPORTING SERVICE

1 NUMBER OF WHAT I'LL CALL HITS, NEW SCAFFOLDS. AND
2 SO THE PROPOSAL ESSENTIALLY IS BIFURCATED IN TWO
3 SENSES. IT'S BASICALLY DOING THE WORK ON THE
4 ALREADY APPROVED DRUGS THAT HAVE SHOWN TO BE
5 POSITIVE IN THIS INDICATION, SO CONDUCTING THE
6 PRECLINICAL STUDIES, MOVING THEM FORWARD, OR DOING
7 THE OPTIMIZATION ON THE HITS, WHICH INVOLVES SAR
8 STUDIES. IN OTHER WORDS, THOSE ARE MUCH FURTHER
9 BEHIND. THEY'RE NOT APPROVED FOR ANOTHER
10 INDICATION. THEY DON'T HAVE A RECORD OF TOXICITY.

11 SO ESSENTIALLY WHAT THE GRANTS WORKING
12 GROUP WAS EXCITED ABOUT AND WHAT THEY WANTED TO DO
13 IS THEY WANTED THEM TO MOVE FORWARD WITH ESSENTIALLY
14 THE APPROVED DRUG CANDIDATE, THE APPROVED COMPOUNDS.
15 AND THAT'S WHERE THE RECOMMENDATION WAS FOCUSED.

16 SO ALTHOUGH I THINK STAFF, IF YOU LOOK AT
17 THE PROGRAMMATIC DISCUSSION, YOU CAN SEE THAT STAFF
18 TRIED TO INDICATE THAT THE DCF AWARD WAS FOCUSED ON
19 ESSENTIALLY PROOF OF CONCEPT; WHEREAS, THIS INITIAL
20 CLASS OF APPROVED DRUGS THAT ARE ACTIVE IN THIS
21 INDICATION CLEARLY ALREADY SHOW PROOF OF CONCEPT.
22 SO WHAT THE STAFF MODIFICATION THAT I JUST WANT TO
23 OFFER FOR YOUR CONSIDERATION, AND THE REASON I'M
24 OFFERING IT NOW IS IF THERE WOULD WANT TO BE ANY
25 FURTHER DISCUSSION OF THIS, IS THAT, IN FACT, THIS

BARRISTERS' REPORTING SERVICE

1 STAY AS A DC AWARD, BUT THAT THE FOCUS WOULD BE ON
2 THE DRUG ALREADY IDENTIFIED AND THE SET OF
3 BIOLOGICALLY -- I MEAN THIS DRUG ALREADY IDENTIFIED
4 HAS GOOD PHARMACOLOGIC PROPERTIES. IT'S GOT
5 EVERYTHING YOU'D EXPECT. OKAY. AND THE FOCUS WOULD
6 BE ON MOVING THAT FORWARD AS A DC, AND THE BUDGET
7 WOULD BE ADJUSTED ACCORDINGLY.

8 NOW, AS I SAY, IF YOU READ THE
9 PROGRAMMATIC, THERE ARE OTHER ISSUES WITH REVIEWERS
10 WERE PLUS AND MINUS ON THE DCF RECOMMENDATION, BUT
11 THAT IS THE STAFF AMENDMENT, TO CONSIDER IT AS A DC
12 AWARD RATHER THAN A DCF WITH A REDUCED BUDGET.

13 CHAIRMAN THOMAS: DR. BRYANT.

14 DR. BRYANT: I'M SORRY. I MISSED THE
15 NUMBER OF THE AWARD, AND I'VE GOT SEVERAL CONFLICTS,
16 SO I WANT TO MAKE SURE I DON'T COMMENT ON SOMETHING
17 INAPPROPRIATE.

18 DR. OLSON: 5617.

19 DR. BRYANT: THANK YOU.

20 CHAIRMAN THOMAS: DR. LUBIN.

21 DR. LUBIN: SO JUST SUMMARIZE ONCE MORE
22 WHY YOU'RE MAKING THIS SUGGESTION TO US.

23 DR. OLSON: BECAUSE THE GOAL OF A
24 DEVELOPMENT CANDIDATE FEASIBILITY AWARD IS SIMPLY TO
25 GET INITIAL PROOF OF CONCEPT OF A HYPOTHESIS. THEY

BARRISTERS' REPORTING SERVICE

1 ARE PAST THAT STAGE. THEY COULD PRETTY -- THIS
2 COULD PROBABLY BE PRETTY EASILY MOVED INTO THE
3 CLINIC IN A COUPLE OF YEARS.

4 MR. SERRANO-SEWELL: (INAUDIBLE).

5 DR. OLSON: IF YOU LOOK AT THE -- I THINK
6 THEY WERE JUST LOOKING AT THE MONEY ISSUE. AND THEY
7 WERE SAYING, WELL, YOU WON'T NEED ALL THE FUNDING
8 NECESSARY FOR A DC AWARD TO DO THIS REDUCED SET OF
9 ACTIVITIES. AND WE DID TRY -- IT WAS BROUGHT UP AT
10 THE GRANTS WORKING GROUP MEETING AND IS CAPTURED IN
11 THE PROGRAMMATIC DISCUSSION. AND SO AS I SAY, THE
12 INTENT WAS TO MOVE WITH ALL SPEED TOWARDS VALIDATING
13 IT.

14 NOW, THERE ARE OTHER -- THERE ARE OTHER
15 POINTS. I'VE NOT GONE INTO THE WHOLE DISCUSSION.
16 BUT THE RECOMMENDATION I THINK I WOULD SAY I
17 CAPTURED THE SPIRIT OF WHAT THE GRANTS WORKING GROUP
18 WANTED THROUGH THIS PROPOSED MODIFICATION.

19 DR. BRYANT: I WAS JUST GOING TO ASK IF
20 THERE WERE ANY SPECIFIC CRITICISMS THAT WERE MADE OF
21 THE OTHER PART OF THE PROPOSAL.

22 DR. OLSON: I WOULD BE HAPPY TO GO THROUGH
23 THE SUMMARY IF YOU WOULD LIKE. SO I THINK I'VE
24 OUTLINED WHAT THE PROPOSAL IS ABOUT.

25 I THINK THE MAIN -- FIRST, LET ME SAY THAT

BARRISTERS' REPORTING SERVICE

1 THE RESEARCH TEAM WAS PERCEIVED TO BE STRONG,
2 PARTICULARLY IN THE AREA OF SMALL MOLECULE DRUG
3 DISCOVERY AND OPTIMIZATION. THAT'S CLEARLY --
4 THAT'S WHAT THEY DO. THAT'S A STRENGTH OF THEIRS.
5 THEY'RE DEFINITELY TRANSLATIONALLY FOCUSED. THEY'VE
6 DONE THIS KIND OF THING BEFORE.

7 WITH RESPECT TO THE TEAM, THE GRANTS
8 WORKING GROUP DID HAVE -- SO THIS DRUG IS FOR THE
9 TREATMENT OF MS. I BELIEVE I SAID THAT. THEY WOULD
10 HAVE LIKED TO SEE A CLINICAL MS PHYSICIAN ON THE
11 TEAM BECAUSE OF THE ISSUES ASSOCIATED WITH THE
12 DIFFERENT TYPES OF MS AND THE KINDS OF DRUGS, AND
13 THAT GETS TO PROBABLY THE OTHER ISSUE.

14 SO THERE WAS SOME QUESTION ABOUT THE --
15 THEY CONSIDERED THAT THE OBJECTIVE OF TARGETING
16 OPC -- SO WHAT THIS DRUG THAT THEY'RE SCREENING FOR
17 IS DIFFERENTIATION OF AN OLIGODENDROCYTE PROGENITOR
18 POPULATION INTO MATURE OLIGODENDROCYTES. SO THEY'RE
19 LOOKING FOR A SMALL MOLECULE THAT WILL ESSENTIALLY
20 SAY PROGENITOR BECOME A FULLY MATURE CELL. BECAUSE
21 ONE OF THE KEY ISSUES IN MULTIPLE SCLEROSIS IS YOU
22 GET OLIGODENDROCYTE PROGENITORS AT THE SITE OF
23 LESION, BUT THEY DON'T DIFFERENTIATE. AND SO THEY
24 SAID, WELL, OKAY, IF WE DEVELOPED A SCREEN TO SELECT
25 FOR SMALL MOLECULES THAT DID THAT, THAT WOULD BE

BARRISTERS' REPORTING SERVICE

1 GOOD.

2 THEY, HOWEVER, WERE CONCERNED ABOUT DRUGS
3 THAT, IN FACT, STIMULATE OPC DIFFERENTIATION
4 BECAUSE, IF YOU THINK ABOUT IT, WHEN YOU GIVE A
5 SMALL MOLECULE, WHAT YOU DO IS YOU TARGET THE
6 PROGENITORS NO MATTER WHERE THEY ARE. AND SO THERE
7 WAS SOME CONCERN ABOUT DO YOU RUN THE RISK OF
8 DEPLETING A PROGENITOR POPULATION BY GIVING THIS
9 DRUG? SO THERE WERE A BIT OF ISSUES WITH THE
10 RATIONALE, AND THAT REALLY WAS THE MAIN CONCERN WITH
11 THE RATIONALE IS THAT IS THIS HYPOTHESIS POTENTIALLY
12 DANGEROUS, AND THAT'S JUST SOMETHING THAT YOU CAN'T
13 KNOW RIGHT OFF THE BAT.

14 BUT THE PRECLINICAL DATA, AT LEAST IN
15 SUPPORT OF THIS, THEY CONSIDERED TO BE GOOD. THEY
16 WERE -- I MEAN THE TREATMENT OPTIONS FOR MULTIPLE
17 SCLEROSIS ARE NOT GOOD. AND SO I THINK IT WAS A
18 BALANCE IN THEIR MIND AS WANTING TO MOVE FORWARD
19 WITH SOMETHING THAT MIGHT OFFER AN OPTION VERSUS
20 CONCERNS ABOUT ESSENTIALLY THE SCIENTIFIC RATIONALE
21 BEHIND THIS.

22 CHAIRMAN THOMAS: DR. STEWARD.

23 DR. STEWARD: PAT, I WAS ACTUALLY JUST
24 LOOKING AT THIS. AND SO I GUESS THE BIG DIFFERENCE
25 BETWEEN A DF AND A DCF IS REALLY THE BRINGING THIS

BARRISTERS' REPORTING SERVICE

1 TO THE CLINIC. AND THE ONE COMMENT --

2 DR. OLSON: IT'S BRINGING IT TO -- SO IT
3 MOVES INTO THE REGULATED DEVELOPMENT ENVIRONMENT.

4 DR. STEWARD: RIGHT. AND JUST TO SAY, THE
5 COMMENT HERE, THAT SPECIFIC EXPERTISE IN MS WOULD BE
6 REQUIRED FOR THE SUCCESSFUL EXECUTION, THEY WANT
7 SOMEBODY WHO'S REALLY A CLINICIAN IN MS, RIGHT?

8 DR. OLSON: THEY WOULD LIKE SOMEONE LIKE
9 THAT TO ADVISE ON, I THINK, SORT OF MS BIOLOGY OR
10 CLINICAL THINGS. THEY THINK THAT THERE ARE
11 SUBTLETIES ASSOCIATED WITH THAT THAT WAS IMPORTANT
12 IN THIS CONTEXT.

13 DR. STEWARD: WAS THAT PART OF THE REASON
14 THAT IT WAS RECOMMENDED AS A DCF, THAT THEY DIDN'T
15 REALLY HAVE THAT EXPERTISE IN PLACE AND, THEREFORE,
16 IT WAS A VERY RISKY THING TO MOVE FORWARD IN THE WAY
17 THAT THEY WERE PLANNING?

18 DR. OLSON: THAT EXPERTISE WOULD BE LESS
19 RELEVANT AS A DCF THAN AS A DC.

20 DR. STEWARD: OKAY.

21 DR. PIZZO: I JUST WANT TO FOLLOW UP ON
22 THE POINT THAT WAS JUST MADE. FROM OTHER STUDIES AT
23 LEAST I'VE BECOME AWARE OF, THE ISSUE OF MS IS A
24 VERY COMPLICATED STORY, AS YOU KNOW.

25 DR. OLSON: YES. ALSO TRUE.

BARRISTERS' REPORTING SERVICE

1 DR. PIZZO: AND I THINK TO THE POINT THAT
2 WAS JUST BEING MADE, IT'S VERY HETEROGENEOUS.

3 DR. OLSON: YES.

4 DR. PIZZO: THE DEFINITION IS VERY
5 VARIEGATED. AND I THINK THAT IT'S REALLY IMPERATIVE
6 TO MAKE SURE THAT THERE IS EXPERTISE ON THE CLINICAL
7 TEAM. OTHERWISE IT CAN BECOME A VERY ALTERED
8 RESPONSE.

9 DR. OLSON: YES. I'M SORRY. THAT IS PART
10 OF THE -- I DID NOT CHANGE THAT PART OF THE
11 RECOMMENDATION. I THINK THAT BOTH THE STAFF
12 RECOMMENDATION AS WELL AS THE RECOMMENDATION OF THE
13 GRANTS WORKING GROUP WOULD BE THAT THAT TYPE OF
14 EXPERTISE SHOULD BE PART OF THE TEAM IF THIS MOVES
15 FORWARD IN WHATEVER FORM.

16 DR. PIZZO: CAN WE SAY MUST?

17 DR. OLSON: WE CAN SAY MUST.

18 CHAIRMAN THOMAS: MR. SHEEHY.

19 MR. SHEEHY: I WOULD JUST LIKE TO SAY, PER
20 MY RECOLLECTION, DR. OLSON'S RECOMMENDATION IS VERY
21 CONSISTENT WITH THE SPIRIT OF WHAT THE GRANTS
22 WORKING GROUP WAS TRYING TO ACCOMPLISH. I MEAN YOU
23 HAVE BASICALLY AN OFF-THE-SHELF DRUG THAT SEEMS TO
24 HAVE SOME MEASURABLE IMPACT ON MS WHERE WE'RE NOT
25 REALLY INVESTED AT ALL AT THIS POINT. AND THE IDEA

BARRISTERS' REPORTING SERVICE

1 WAS TO GET THAT AS QUICKLY INTO THE CLINIC AS
2 POSSIBLE. AND SO I THINK WHAT DR. OLSON IS
3 PROPOSING IS QUITE IN LINE WITH THAT.

4 CHAIRMAN THOMAS: DR. BRYANT.

5 DR. BRYANT: I JUST HAVE ONE MORE COMMENT
6 ON THAT, ON THE REASON FOR NOT PREFERRING THE SECOND
7 PART, THE MORE EXPLORATORY PART. AND THAT IS ARE
8 THERE NO ANIMAL STUDIES THAT ADDRESS THE ISSUE OF
9 WHEN YOU GIVE THESE KIND OF DRUGS TO ANIMALS, THAT
10 IT DEPLETES THE STEM CELL POPULATION OR NOT? IF
11 NOT, THEN I COMPLETELY AGREE WITH IT. BUT I MEAN
12 SURELY THERE MUST BE SOME.

13 DR. OLSON: I CAN STATE THAT TWO COMMON
14 PRECLINICAL MS MODELS WERE PERFORMED WITH ONE OF THE
15 LEAD COMPOUNDS. NOW, THEY DID NOT -- I CAN ALSO
16 STATE THAT THEY DID NOT SPECIFICALLY ADDRESS THAT
17 ISSUE. I'M NOT SURE HOW READILY THAT COULD BE
18 ADDRESSED IN A MODEL, NOR CAN I SPEAK TO THE FACT
19 HOW EXTRAPOLATABLE IT WOULD BE, BUT THAT'S ALWAYS
20 TRUE.

21 CHAIRMAN THOMAS: OKAY. SEEING NO FURTHER
22 COMMENT, ARE THERE ANY COMMENTS ABOUT ANY OTHER DC
23 AWARDS? SEEING NONE, I THINK WE'RE NOW READY TO
24 ADJOURN INTO CLOSED SESSION. WE HAVE BOX LUNCHES
25 AVAILABLE IN THE OTHER ROOM ACROSS THE HALL AND

BARRISTERS' REPORTING SERVICE

1 WOULD REQUEST THAT BOARD MEMBERS EAT THEIR LUNCH
2 OVER THERE. WE'LL DO A WORKING LUNCH CLOSED
3 SESSION. MR. HARRISON.

4 MR. HARRISON: THE BOARD WILL BE CONVENING
5 IN CLOSED SESSION TO CONSIDER PROPRIETARY
6 INFORMATION RELATED TO APPLICATIONS FOR CIRM EARLY
7 TRANSLATION III AWARDS PURSUANT TO HEALTH AND SAFETY
8 CODE SECTION 125290.30(F)(3)(B) AND (C). AND
9 HOPEFULLY WE WILL TRY TO LIMIT OUR CLOSED SESSION TO
10 APPROXIMATELY 45 MINUTES AT A MAXIMUM BECAUSE WE
11 HAVE A LOT OF WORK TO ACCOMPLISH THIS AFTERNOON.

12 CHAIRMAN THOMAS: THANK YOU. SO IF
13 EVERYBODY COULD PROCEED ACROSS THE HALL WITH ALL
14 DELIBERATE SPEED, THAT WOULD BE APPRECIATED.

15 (A RECESS WAS TAKEN.)

16 CHAIRMAN THOMAS: OKAY. WE ARE NOW
17 RECONVENING IN OPEN SESSION. WE HAVE CONCLUDED THE
18 CLOSED SESSION DISCUSSION ON THE THREE APPLICATIONS
19 IDENTIFIED IN THE EARLIER SESSION AND ARE NOW BACK,
20 FOLLOWING WHAT I THINK HAS BEEN A DETAILED AND
21 ROBUST CONSIDERATION OF ALL OF THE AWARDS, READY TO
22 HAVE MOTIONS WITH RESPECT TO APPROVAL.

23 FIRST OF ALL, ARE THERE -- IS THERE A
24 MOTION TO APPROVE -- YES, JAMES. YOU'RE LOOKING AT
25 ME.

BARRISTERS' REPORTING SERVICE

1 MR. HARRISON: I WAS JUST GOING TO SUGGEST
2 THAT YOU REQUEST ANY MOTIONS TO MOVE APPLICATIONS
3 FROM TIER III TO TIER I. AND THEN ONCE WE'VE
4 EXHAUSTED THOSE MOTIONS, YOU CAN ASK FOR MOTIONS TO
5 MOVE APPLICATIONS OUT OF TIER I TO TIER III. AND
6 THEN WE'LL TAKE OMNIBUS MOTIONS ON THE AWARDS.

7 CHAIRMAN THOMAS: THAT WAS PRECISELY WHERE
8 I WAS HEADED, MR. HARRISON.

9 MR. HARRISON: I'M SORRY I INTERRUPTED
10 YOU.

11 CHAIRMAN THOMAS: LET THE RECORD REFLECT.
12 SO DO WE HAVE ANY MOTIONS TO MOVE ANY OF THE
13 CURRENTLY TIER III PROPOSALS? YES, DR. SAMBRANO.

14 DR. SAMBRANO: I DON'T KNOW IF YOU WANT TO
15 DO THEM IN THAT ORDER, DCF FIRST AND DC.

16 CHAIRMAN THOMAS: YES. WHY DON'T WE DO
17 THAT. IT'S A GOOD IDEA. OKAY. ARE THERE ANY
18 RECOMMENDATIONS TO MOVE ANY OF THE CURRENTLY TIER
19 III PROPOSALS ON THE DCF LIST UP TO TIER I?

20 MS. SAMUELSON: MR. CHAIRMAN, WOULD IT BE
21 POSSIBLE TO JUST, SO WE'RE ALL ON THE SAME PAGE, GET
22 A BRIEF LIST OF THOSE THAT ARE ELIGIBLE FOR FURTHER
23 DISCUSSION? WE'RE DOWN TO A SHORT LIST, AREN'T WE?

24 CHAIRMAN THOMAS: WELL, IF WE ARE
25 CONFINING THAT TO THE PROPOSALS THAT WERE DISCUSSED

BARRISTERS' REPORTING SERVICE

1 IN CLOSED SESSION.

2 MS. SAMUELSON: I THINK IN COMBINATION
3 WITH THE DISCUSSION BEFORE.

4 CHAIRMAN THOMAS: YES. AND THOSE THAT
5 WERE THE SUBJECT OF EXTRAORDINARY PETITIONS THAT
6 WERE NOT DISCUSSED IN CLOSED SESSION. COULD WE HAVE
7 SOMEBODY GIVE US THAT LIST? YES. MR. HARRISON.

8 MR. HARRISON: THE APPLICATIONS THAT WERE
9 DISCUSSED IN OPEN SESSION WERE 5606, 5567.

10 MS. GIBBONS: IS THERE A TWO- OR
11 THREE-WORD DESCRIPTION THAT WOULD TRIGGER IT FOR US
12 BECAUSE --

13 DR. SAMBRANO: SO I CAN READ THE TITLE FOR
14 5606. THAT WAS HUMAN ES CELL-DERIVED MGE INHIBITORY
15 INTERNEURON TRANSPLANTATION FOR SPINAL CORD INJURY.

16 DR. STEWARD: AND COULD WE ACTUALLY
17 CONSIDER THEM DCF BY CATEGORY? AND THEN IF YOU
18 COULD DO THE SAME THING WHEN WE COME TO THE DC?

19 MS. SAMUELSON: AND THE PRINCIPAL
20 INVESTIGATOR OR THE INSTITUTION.

21 DR. SAMBRANO: WE CAN'T REVEAL THAT
22 INFORMATION IN PUBLIC. SO THAT WAS DCF. SO, JAMES,
23 I WILL READ THE TITLE IF YOU READ THE APPLICATION
24 NUMBER.

25 MR. HARRISON: THE NEXT WAS 5567.

BARRISTERS' REPORTING SERVICE

1 DR. SAMBRANO: SO I THINK THAT WAS A DCF.
2 I'M SORRY. DC. 5567 IS TRANSPLANTATION OF STEM
3 CELL-DERIVED RETINAL PROGENITOR AND RPE SHEETS TO
4 RESTORE VISION.

5 DR. STEWARD: ISN'T THAT A DC?

6 DR. SAMBRANO: YES. SORRY. IT WAS A DC.

7 CHAIRMAN THOMAS: LET'S TRY TO CONFINE
8 THIS FIRST TO THE DCF LIST.

9 DR. PRIETO: ARE THERE ANY OTHER DCF'S
10 THAT ANYONE ELSE WANTS TO BRING UP OR DISCUSS?
11 THAT'S, I THINK, THE QUESTION OS IS ASKING AND I'M
12 CURIOUS.

13 DR. STEWARD: SO I DO --

14 CHAIRMAN THOMAS: DR. STEWARD.

15 DR. STEWARD: IF I MAY. I DO WANT TO
16 RAISE 5606, AND I GUESS IN ORDER TO DO THAT, I'M
17 GOING TO MOVE THAT IT BE MOVED TO TIER I. I'LL SAY
18 THAT AT THE END OF THE DISCUSSION -- I WANT TO HEAR
19 REALLY WHAT EVERYBODY HAS TO SAY ABOUT THAT; BUT AT
20 THE END OF THE DISCUSSION, I MAY VERY WELL VOTE
21 AGAINST MY OWN MOTION, BUT JUST TO SAY THAT.

22 DR. PRIETO: I'LL SECOND.

23 CHAIRMAN THOMAS: THANK YOU. DISCUSSION
24 ON THE TOPIC? DR. STEWARD.

25 DR. STEWARD: SO THIS IS A GRANT TO TEST A

BARRISTERS' REPORTING SERVICE

1 DEVELOPMENT CANDIDATE FOR SPINAL CORD INJURY. THE
2 TARGET IS BLADDER SPASTICITY AND NEUROPATHIC PAIN.
3 AND THE IDEA IS THAT THESE DISORDERS THAT ARE VERY,
4 VERY CRITICAL AFTER SPINAL CORD INJURY ARE DUE, IN
5 PART, TO THE LOSS OF INHIBITORY INTERNEURONS. SO
6 THE IDEA HERE IS THAT AS A CONSEQUENCE OF LOSS OF
7 THESE NEURONS, THE SPINAL CORD IS FIRING WILDLY.
8 AND THAT IS THE REASON FOR THESE NEUROPATHIC PAIN
9 SYNDROMES IN PART AND ALSO THE CAUSE OF BLADDER
10 SPASTICITY WHICH IS A MAJOR DEBILITATING PART OF
11 SPINAL CORD INJURY.

12 THE ISSUE IS THAT PEOPLE WITH SPINAL CORD
13 INJURY CAN'T CONTROL THEIR BLADDER; BUT MORE THAN
14 THAT, THERE'S SOMETHING CALLED DETRUSOR SPHINCTER
15 DYSSYNERGIA. SO BASICALLY THE SPHINCTER STAYS
16 CLOSED AND THE BLADDER IS PUMPING AWAY AND YOU CAN'T
17 EXPEL URINE. AND AS A CONSEQUENCE, THE URINE IS
18 PROPELLED BACK UP INTO THE KIDNEYS. AND THAT IS A
19 MAJOR CAUSE OF URINARY TRACT INFECTIONS AND OTHER
20 URINARY DISORDERS.

21 SO HAVING SOMETHING TO SOLVE THESE ISSUES,
22 AND ESPECIALLY BLADDER, WOULD REALLY BE A HUGE
23 THING.

24 THE MAJOR CRITICISMS WERE, NO. 1, THERE
25 REALLY WASN'T ANY PRELIMINARY EVIDENCE INDICATING

BARRISTERS' REPORTING SERVICE

1 THE FEASIBILITY OF THE BLADDER STUDIES. AND WHAT WE
2 CONSIDERED IN THE CLOSED SESSION WAS ONE OF THE
3 COMMENTS THAT THE MARKERS FOR THE CELLS WERE NOT
4 SUFFICIENTLY STRINGENT TO BE ABLE TO IDENTIFY THE
5 CELL POPULATIONS THAT WERE BEING TRANSPLANTED. THEY
6 REPORTED THAT THERE WAS A LEVEL OF CONTAMINATION.
7 MY MEMORY IS IT'S AROUND 30 PERCENT. AND THE ISSUE
8 IS HOW MANY -- WHAT ARE THESE CELLS AND WHAT ARE
9 THEY LIKELY TO DO?

10 AND SO IDENTIFYING THESE NONTARGET CELLS,
11 NONINHIBITORY NEURONS, IS IMPORTANT, BUT IT'S ALSO
12 IMPORTANT TO IDENTIFY THE INHIBITORY NEURONS. AND
13 SO THE REVIEWER'S COMMENT WAS THAT THE MARKERS WERE
14 NOT SUFFICIENTLY STRINGENT.

15 WE DID LOOK AT THAT IN CLOSED SESSION.
16 THE MARKERS ARE PROPRIETARY INFORMATION, AND WE
17 FOUND NO BASIS TO ARGUE WITH THE REVIEWER'S
18 CONCLUSIONS REGARDING THOSE MARKERS.

19 DR. PIZZO: CAN I JUST MAKE ONE ADDENDUM
20 TO THAT, WHICH IS SOME OF THE MARKERS ARE NOT
21 NEUROSPECIFIC AS WELL.

22 CHAIRMAN THOMAS: ANY OTHER COMMENTS ON
23 THIS APPLICATION? SO DO -- WE NEED A ROLL CALL
24 VOTE. FIRST OF ALL, WE HAVE COMMENT FROM A MEMBER
25 OF THE PUBLIC. MR. REED. NO. THANK YOU.

BARRISTERS' REPORTING SERVICE

1 MS. SAMUELSON: ISN'T THERE AN
2 EXTRAORDINARY PETITION ON THIS ONE?

3 DR. STEWARD: THERE WAS NO EXTRAORDINARY
4 PETITION.

5 CHAIRMAN THOMAS: NOT ON THIS ONE. SO,
6 MARIA, WOULD YOU PLEASE CALL THE ROLL.

7 MR. HARRISON: JUST TO RESTATE THE MOTION
8 IS TO MOVE APPLICATION 5606 TO TIER I.

9 DR. STEWARD: I'M SORRY. IF I MAY. DON
10 REED ALREADY HAD PUBLIC COMMENT REGARDING THIS
11 BEFORE THE BREAK, AND THIS WAS THE APPLICATION ON
12 WHICH HE WAS MAKING --

13 CHAIRMAN THOMAS: YES, I'M AWARE OF THAT.
14 I WAS JUST WONDERING IF HE WANTED TO REITERATE
15 ANYTHING. THANK YOU. OKAY. MARIA.

16 MS. BONNEVILLE: ROBERT BIRGENEAU.

17 DR. BIRGENEAU: YES.

18 MS. BONNEVILLE: DAVID BRENNER. SUSAN
19 BRYANT.

20 DR. BRYANT: YES.

21 MS. BONNEVILLE: KEN BURTIS.

22 DR. BURTIS: YES.

23 MS. BONNEVILLE: MICHAEL FRIEDMAN.

24 DR. FRIEDMAN: YES.

25 MS. BONNEVILLE: LEEZA GIBBONS.

BARRISTERS' REPORTING SERVICE

1 MS. GIBBONS: YES.
2 MS. BONNEVILLE: MICHAEL GOLDBERG.
3 MR. GOLDBERG: YES.
4 MS. BONNEVILLE: STEVE JUELSGAARD.
5 DR. JUELSGAARD: NO.
6 MS. BONNEVILLE: BERT LUBIN.
7 DR. LUBIN: NO.
8 MS. BONNEVILLE: MICHAEL MARLETTA.
9 DR. MARLETTA: NO.
10 MS. BONNEVILLE: SHLOMO MELMED. PHIL
11 PIZZO.
12 DR. PIZZO: NO.
13 MS. BONNEVILLE: FRANCISCO PRIETO.
14 DR. PRIETO: YES.
15 MS. BONNEVILLE: ELIZABETH FINI. ROBERT
16 QUINT.
17 DR. QUINT: NO.
18 MS. BONNEVILLE: DUANE ROTH. JOAN
19 SAMUELSON.
20 MS. SAMUELSON: YES.
21 MS. BONNEVILLE: DAVID SERRANO-SEWELL.
22 MR. SERRANO-SEWELL: YES.
23 MS. BONNEVILLE: JONATHAN SHESTACK. OS
24 STEWARD.
25 DR. STEWARD: YES.

BARRISTERS' REPORTING SERVICE

1 MS. BONNEVILLE: JONATHAN THOMAS.

2 CHAIRMAN THOMAS: YES.

3 MS. BONNEVILLE: ART TORRES.

4 MR. TORRES: AYE.

5 MS. BONNEVILLE: CHRISTINA VUORI.

6 DR. VUORI: YES.

7 MS. BONNEVILLE: EUGENE WASHINGTON.

8 CHAIRMAN THOMAS: MR. HARRISON.

9 MR. HARRISON: JUST GIVE US ONE MOMENT TO
10 MAKE SURE WE HAVE THE CORRECT TABULATION. THANK
11 YOU. SO THAT MOTION PASSES BY A VOTE OF 13 TO FIVE.

12 CHAIRMAN THOMAS: THANK YOU, MR. HARRISON.
13 DOES THAT EXHAUST THE LIST OF DCF CANDIDATES? OKAY.
14 COULD YOU NOW RECITE IN ORDER HERE THE DC CANDIDATES
15 FOR POSSIBLE CONSIDERATION TO MOVE FROM TIER III TO
16 TIER I.

17 MR. HARRISON: THE FIRST THAT WAS
18 DISCUSSED WAS 5567.

19 DR. SAMBRANO: SO 5567 WAS TRANSPLANTATION
20 OF STEM CELL-DERIVED RETINAL PROGENITOR AND RPE
21 SHEETS TO RESTORE VISION.

22 CHAIRMAN THOMAS: IS THERE A MOTION TO
23 MOVE THIS FROM TIER III TO TIER I?

24 MS. SAMUELSON: YES.

25 CHAIRMAN THOMAS: MOVED BY JOAN SAMUELSON.

BARRISTERS' REPORTING SERVICE

1 IS THERE A SECOND?

2 DR. PRIETO: WELL, JUST TO KEEP THE
3 DISCUSSION GOING, I'LL SECOND.

4 CHAIRMAN THOMAS: SECOND BY DR. PRIETO.
5 SO DISCUSSION. JOAN.

6 MS. SAMUELSON: IT WOULD BE REPEATING
7 EVERYTHING I SAID BEFORE THE CLOSED SESSION.
8 THINKING OF -- SORRY. I THOUGHT I'D HAVE A SECOND
9 TO GET BACK TO THIS ONE. AND I DON'T KNOW WHERE MY
10 NOTES ON IT ARE.

11 CHAIRMAN THOMAS: PERHAPS DR. PRIETO COULD
12 STEP IN WHILE YOU'RE --

13 MS. SAMUELSON: THAT WOULD BE NICE.

14 DR. PRIETO: WAS THIS DISCUSSED DURING --
15 WAS THERE ANY PROPRIETARY INFORMATION BROUGHT UP IN
16 THE CLOSED SESSION? I DIDN'T THINK I HEARD ANY.

17 ONE OF THE ISSUES MAY BE SCIENTIFIC STAFF
18 COULD TALK A LITTLE BIT MORE ABOUT THIS BECAUSE IT
19 APPLIES TO ANOTHER APPLICATION THAT WE'LL BE VOTING
20 ON -- EXCUSE ME A SECOND -- THE CHARACTERIZATION
21 WORK THAT HAS BEEN DONE AND WHETHER THAT'S REALLY
22 ADEQUATE FOR THEM TO MEET THEIR TIMELINES.

23 DR. ABO: SO JUST TO REMIND YOU, PART OF
24 THE DISCUSSION THAT JOAN BROUGHT UP, THERE WERE
25 THREE OTHER AMD PROJECTS IN THE PORTFOLIO, BUT THE

BARRISTERS' REPORTING SERVICE

1 MAIN CONCERN OF THE REVIEWERS WERE THAT THEY FELT
2 THIS IS AN EARLY STAGE, UNDERDEVELOPED PROPOSAL.
3 THERE WAS CONCERN ASSOCIATED WITH EXPRESSION MARKERS
4 FOR THE RETINAL MARKERS. THEY DID NOT CONSIDER
5 POSSIBILITY OF SURVIVAL OF ENDOGENOUS NEURONS. BUT
6 THE MAIN CONCERNS WERE NOT SUFFICIENT, AS I SAID,
7 DEVELOPED AND LACK OF CRITICAL DETAILS, INSUFFICIENT
8 DESCRIPTION OF VISUAL ACUITY TESTS IN ANIMALS. THAT
9 WAS ALL PRECLINICAL STUDIES. NO ELECTROPHYSIOLOGY
10 MEASUREMENT, WHICH IS VERY IMPORTANT TO CELL
11 CHARACTERIZATION. AND POTENTIAL NEGATIVE EFFECT AND
12 PAIN WAS NOT CONSIDERED AND OTHER ISSUES.

13 AND SOME ISSUES ON QUALIFICATION OF THE
14 PI, AS I MENTIONED, THAT IT SEEMS UNJUSTIFIABLE TO
15 CHARGE 40-PERCENT EFFORT FOR THE PI. AND THERE'S
16 SOME ISSUES WITH BUDGET ASSOCIATED WITH EQUIPMENT
17 AND THE ROLE OF SOME OF THE STAFF THAT WERE PROPOSED
18 TO BE PART OF THIS STUDY.

19 DR. PRIETO: JUST REMEMBERING THIS, AS I
20 RECALL, ACTUALLY THE QUALIFICATIONS OF THE PI WERE
21 THOUGHT TO BE PRETTY STRONG. SOMEONE WHO'S A
22 WELL-KNOWN LEADER IN THE FIELD, BUT THERE WERE
23 SIGNIFICANT QUESTIONS IN THE GRANTS REVIEW ABOUT THE
24 BUDGET AND THE AMOUNT ALLOCATED TO SOME OF THE
25 EFFORTS.

BARRISTERS' REPORTING SERVICE

1 MR. TORRES: THE ITEM NUMBER AGAIN?

2 DR. PRIETO: 5567, MACULAR DEGENERATION.

3 MS. SAMUELSON: AND THIS HAD A SCORE OF
4 63; IS THAT RIGHT? I THINK. IN WHICH CASE --

5 DR. ABO: RPE WAS THE PHOTORECEPTOR SHEET
6 WHICH BRINGS A DIFFERENT LEVEL OF COMPLEXITY AND
7 POTENTIALLY COULD BE AN IMPORTANT UNMET NEED. THE
8 APPROACH IS NOVEL AND IS DIFFERENT THAN WHAT WE HAVE
9 IN THE PORTFOLIO RIGHT NOW.

10 MS. SAMUELSON: AND AS I'M HEARING IT, I'M
11 SCRAMBLING MY METAPHORS HERE, I'M LISTENING THROUGH
12 THE LENS OF PROP 71, WHICH SAYS THAT OUR MISSION IS
13 TO DEVELOP REGENERATIVE MEDICAL TREATMENTS AND CURES
14 SO THAT WE CAN SWITCH AWAY FROM MAINTENANCE TOWARD
15 PREVENTION AND CURES. AND THIS IS A CASE WHERE I
16 SUPPOSE MOST OF THE PEOPLE HAVE NO THERAPEUTIC
17 ALTERNATIVE AND SIMPLY BECOME BLIND. AND SO THERE'S
18 GREAT URGENCY PER OUR PROGRAMMATIC MISSION, AND
19 THAT'S WHAT WE NEED TO BE THINKING ABOUT AT THE END
20 OF EVERY DISCUSSION PER PROP 71, NOT IS EVERY BOX
21 CHECKED, BUT IS THERE A REASONABLE POSSIBILITY THAT
22 THIS WILL PRODUCE THIS TREATMENT OR EVEN JUST
23 ADVANCE THE SCIENCE IN SOME SIGNIFICANT WAY SO THAT
24 SOMETHING WILL, WHICH IS PROBABLY THE MOST FREQUENT
25 WAY THAT STUFF DEVELOPS, RIGHT. THAT'S MY

BARRISTERS' REPORTING SERVICE

1 PERSPECTIVE WITH PARKINSON'S, THAT THERE'S SOME
2 ADVANCE MADE BY A TEAM SOMEWHERE IN THE UNITED
3 STATES AND THEN BY ONE IN EUROPE AND SO ON AND THEY
4 BUILD OFF EACH OTHER'S WORK. AND WE WANT TO GET
5 THERE AS SOON AS HUMANLY POSSIBLE. THAT'S THE OTHER
6 LANGUAGE FROM THE STATUTE.

7 SO HERE WE'RE TRYING TO ADDRESS BLINDNESS,
8 AND THEY'RE TRYING TO BE AMBITIOUS ABOUT IT AND GO
9 AT IT FROM A DC PERSPECTIVE SO THEY'LL GET MORE
10 MONEY. AND IT'S AN INTRACTABLE PROBLEM. SO IT MAY
11 TAKE LONGER THAN THREE YEARS. THAT JUST DOESN'T
12 STRIKE ME AS A FATAL FLAW, NOR DO ANY OF THE OTHER
13 CRITICISMS WHEN AT THE SAME TIME THEY'RE SAYING THAT
14 THESE IDEAS ARE IMPORTANT AND NEW AND THAT THE TEAM
15 IS EFFECTIVE. THEN THAT SOUNDS LIKE THE ELEMENTS OF
16 SUCCESS. IT MAY NOT BE EXACTLY THE RESULT THAT THEY
17 ORIGINALLY PREDICT, BUT HOW OFTEN IS IT? THAT SEEMS
18 TO BE THE WAY SCIENCE WORKS FROM MY PERCH. SO I
19 RECOMMEND FUNDING, MOVING IT TO TIER I.

20 DR. MARLETTA: COULD I MAKE A COMMENT?

21 CHAIRMAN THOMAS: CERTAINLY. DR.

22 MARLETTA.

23 DR. MARLETTA: IT'S AGAINST WHAT I SAID I
24 WOULD DO TODAY. I PROMISED MYSELF. BUT THOSE THAT
25 KNOW ME KNOW THAT IT'S ALMOST IMPOSSIBLE FOR ME TO

BARRISTERS' REPORTING SERVICE

1 SIT HERE WITH A MICROPHONE IN FRONT OF ME AND NOT
2 SAY SOMETHING. SO I JUST WANT TO -- YOU KNOW, WHAT
3 WE DON'T HAVE, WHAT I FIND THAT I DON'T HAVE THAT I
4 WOULD NEED IS I DIDN'T READ THE PROPOSAL. I CAN
5 ONLY LOOK AT THE REVIEWER REPORT. AND WHAT I READ
6 IN THE REVIEWER REPORT, THE VERY FIRST COMMENT IS A
7 SERIOUS -- I'M READING FROM IT -- A SERIOUS CONCERN
8 IS THE INABILITY TO SHOW ANY EXPRESSION OF MATURE
9 RETINAL MARKERS IN THE COMPOSITE HSEC-DERIVED
10 RETINAL SHEETS. IT'S UNCLEAR WHETHER ADDITIONAL
11 OPTIMIZATION WILL SUCCESSFULLY ACCOMPLISH THE GOAL
12 OF THIS DIFFERENTIATION AND HOW LONG IT WILL TAKE.

13 SO TO ME THIS SOUNDS LIKE A FATAL FLAW.
14 THEY CAN'T EXPRESS MARKERS ON THE CELLS TO KNOW THAT
15 THEY HAVE CELLS THEY CAN DO ANYTHING WITH. SO WITH
16 ALL DUE RESPECT TO THE UNMET MEDICAL NEED, I'M
17 AFRAID THAT STEP ONE, THEY'RE NOT EVEN ON THE MAP.
18 AND THEY WON'T BE ABLE TO DO ANY OF THE EXPERIMENTS
19 THAT THEY PROPOSE TO DO. SO IT JUST SOUNDS TO ME
20 LIKE A SERIOUS FATAL FLAW.

21 MS. SAMUELSON: MY QUESTION IN RESPONSE IS
22 THAT I THINK THIS IS AN IMPORTANT DISCUSSION. I
23 APPRECIATE YOU JUMPING IN BECAUSE THIS IS WHAT WE
24 FACE EVERY TIME, IT SEEMS TO ME. HOW MUCH OF THAT
25 IS SIMPLY THE PROCESS OF SCIENTIFIC EXPERIMENTATION,

BARRISTERS' REPORTING SERVICE

1 WHICH IS IN THE NATURE OF HOW CURES AND EFFECTIVE
2 TREATMENTS ARE REACHED? THEY'VE GOT A HYPOTHESIS
3 AND THEY DON'T HAVE ALL THE DATA YET.

4 DR. MARLETTA: MY CONCERN IS I APPRECIATE
5 THE HYPOTHESIS AND THEY HAVE A SERIES OF EXPERIMENTS
6 PROPOSED THAT ARE BOTH RISKY AND COULD BE QUITE
7 INFORMATIVE, BUT MY POINT IS, FROM WHAT I READ IN
8 FRONT OF ME, AS LIMITED AS THAT IS, THAT THEY CANNOT
9 EVEN BEGIN THE EXPERIMENTS.

10 CHAIRMAN THOMAS: DR. STEWARD.

11 DR. STEWARD: YEAH. I'D GO BACK, I THINK,
12 TO YOUR COMMENTS BEFORE LUNCH, JOAN. I MEAN -- AM I
13 IN CONFLICT ON THIS? OOPS. SORRY.

14 CHAIRMAN THOMAS: LEEZA.

15 MS. GIBBONS: JOAN, I THINK YOU HIT IT.
16 THIS REPRESENTS THAT CONFLICT THAT WE HAVE BETWEEN
17 BEING RESPONSIBLE AND BEING AGGRESSIVE, RECOGNIZING
18 THE VERY NATURE OF SCIENCE FOR, I'LL SPEAK FOR
19 MYSELF, BEING A LAYPERSON, MEANING SO MANY TIMES IT
20 ENDS UP IN A DEAD END WHICH ULTIMATELY THE NO IS THE
21 ANSWER THAT GETS US TO THE BREAKTHROUGH. AND THEN
22 WANTING TO MAKE SURE THAT WE TAKE SERIOUSLY, AS WE
23 DO, THE GREAT RESPECT THAT WE HAVE FOR STAFF AND THE
24 REVIEWERS AND ALL THE EXTRAORDINARY AMOUNT OF WORK
25 THAT GOES INTO THESE RECOMMENDATIONS BEFORE THEY GET

BARRISTERS' REPORTING SERVICE

1 TO US.

2 CAN WE BE REMINDED OF THE SCORES FOR THIS
3 ONE AGAIN, PLEASE?

4 DR. SAMBRANO: SO THE SCORES ARE UP ON THE
5 SCREEN. THE SCORE WAS A 63.

6 MS. GIBBONS: OKAY. WAS THAT A DIG AT MY
7 EYESIGHT RIGHT THERE?

8 DR. SAMBRANO: NO, IT WAS NOT INTENDED AS
9 SUCH.

10 MR. TORRES: NOT LEEZA IN THIS CATEGORY,
11 BUT I'M CHRONOLOGICALLY GIFTED. AND I STILL CAN'T
12 SEE THESE NUMBERS. IT'S VERY DIFFICULT.

13 DR. SAMBRANO: LET'S RETRACT THAT LAST
14 STATEMENT OF MINE. AND I WILL JUST READ TO YOU THE
15 SCORES. SO THE SCORE, THE AVERAGE SCORE WAS A 63,
16 THE MEDIAN WAS A 60, THE STANDARD DEVIATION IS A 5,
17 AND THE RANGE IS FROM 55 TO 75.

18 CHAIRMAN THOMAS: SEEING NO FURTHER
19 DISCUSSION, MARIA, WILL YOU PLEASE -- DO WE HAVE ANY
20 PUBLIC COMMENT ON THIS? SEEING NONE, MARIA, PLEASE
21 CALL THE ROLL.

22 MS. BONNEVILLE: ROBERT BIRGENEAU.

23 DR. BIRGENEAU: NO.

24 MS. BONNEVILLE: DAVID BRENNER. KEN
25 BURTIS.

BARRISTERS' REPORTING SERVICE

1 DR. BURTIS: NO.
2 MS. BONNEVILLE: MARCY FEIT.
3 MS. FEIT: NO.
4 MS. BONNEVILLE: MICHAEL FRIEDMAN.
5 DR. FRIEDMAN: NO.
6 MS. BONNEVILLE: LEEZA GIBBONS.
7 MS. GIBBONS: NO.
8 MS. BONNEVILLE: MICHAEL GOLDBERG.
9 MR. GOLDBERG: NO.
10 MS. BONNEVILLE: SAM HAWGOOD.
11 DR. HAWGOOD: NO.
12 MS. BONNEVILLE: STEVE JUELSGAARD.
13 DR. JUELSGAARD: NO.
14 MS. BONNEVILLE: BERT LUBIN.
15 DR. LUBIN: NO.
16 MS. BONNEVILLE: MICHAEL MARLETTA.
17 DR. MARLETTA: NO.
18 MS. BONNEVILLE: SHLOMO MELMED. PHIL
19 PIZZO.
20 DR. PIZZO: NO.
21 MS. BONNEVILLE: FRANCISCO PRIETO.
22 DR. PRIETO: NO.
23 MS. BONNEVILLE: ELIZABETH FINI.
24 DR. FINI: NO.
25 MS. BONNEVILLE: ROBERT QUINT.

BARRISTERS' REPORTING SERVICE

1 DR. QUINT: NO.
2 MS. BONNEVILLE: DUANE ROTH.
3 MR. ROTH: NO.
4 MS. BONNEVILLE: JOAN SAMUELSON.
5 MS. SAMUELSON: YES.
6 MS. BONNEVILLE: DAVID SERRANO-SEWELL.
7 MR. SERRANO-SEWELL: NO.
8 MS. BONNEVILLE: JEFF SHEEHY.
9 MR. SHEEHY: NO.
10 MS. BONNEVILLE: JONATHAN SHESTACK.
11 JONATHAN THOMAS.
12 CHAIRMAN THOMAS: NO.
13 MS. BONNEVILLE: ART TORRES.
14 MR. TORRES: NO.
15 MS. BONNEVILLE: CHRISTINA VUORI.
16 DR. VUORI: NO.
17 MS. BONNEVILLE: EUGENE WASHINGTON.
18 MR. HARRISON: THAT MOTION FAILS BY A VOTE
19 OF ONE YES VOTE AND 20 NO VOTES.
20 CHAIRMAN THOMAS: JAMES, DO WE HAVE
21 ANOTHER DC CANDIDATE?
22 MR. HARRISON: APPLICATION NO. 5541.
23 DR. SAMBRANO: SO THAT ONE WAS SELECTION
24 OF ANTI-R-SPONDIN ANTIBODY FOR TARGETING CANCER STEM
25 CELLS.

BARRISTERS' REPORTING SERVICE

1 CHAIRMAN THOMAS: IS THERE A MOTION THAT
2 WE MOVE IT FROM TIER III TO TIER I? HEARING NONE,
3 JAMES, ARE THERE ANY OTHERS?

4 MR. HARRISON: THE NEXT APPLICATION IS NO.
5 5660.

6 DR. SAMBRANO: THAT WAS PROGRAMMING HUMAN
7 ESC-DERIVED NEURAL STEM CELLS WITH MEF2C4
8 TRANSPLANTATION IN STROKE.

9 CHAIRMAN THOMAS: IS THERE A MOTION TO
10 MOVE THIS FROM TIER III TO TIER I?

11 DR. PRIETO: SO MOVED.

12 CHAIRMAN THOMAS: SECOND? I'LL SECOND FOR
13 PURPOSES OF DISCUSSION. DR. PRIETO.

14 DR. PRIETO: SO THIS ONE, AS I EXPECT MOST
15 OF YOU HAVE READ BY NOW, IS THE SUBJECT OF AN
16 EXTRAORDINARY PETITION. THE PETITIONER, LET ME TURN
17 TO THE LETTER, STUART LIPTON AT THE SANFORD BURNHAM,
18 QUESTIONS SOME OF THE FACTUAL POINTS MADE OR
19 ASSERTED BY THE REVIEWERS DURING THE REVIEW.
20 QUESTIONS WERE RAISED IN CLOSED SESSION ABOUT SOME
21 OF THE TECHNICAL ASPECTS OF THIS AND WHETHER
22 PRELIMINARY WORK HAS BEEN DONE THAT REALLY WOULD
23 ALLOW THEM TO DO WHAT HE SAYS HE CAN DO.

24 I WAS IMPRESSED THAT IF ANYONE CAN DO THIS
25 WORK THIS AMBITIOUS AND DIFFICULT, IT WOULD HAVE

BARRISTERS' REPORTING SERVICE

1 HUGE CLINICAL SIGNIFICANCE AND THAT HE IS PROBABLY
2 OR HIS GROUP IS PROBABLY A GROUP THAT COULD DO IT IF
3 ANYONE CAN.

4 ONE OF THE ISSUES THAT WAS RAISED IS A
5 CLINICAL ONE, SO I WANTED TO SPEAK TO THAT A LITTLE
6 BIT ABOUT THE TIMING. AND THIS DID COME UP IN THE
7 REVIEW. THEY'RE PROPOSING TO INTERVENE A WEEK AFTER
8 THE STROKE, IN THEIR CASE THE STROKE THAT THEY
9 CREATE IN THEIR ANIMAL MODEL. QUESTION WAS RAISED
10 WHETHER THAT'S APPROPRIATE BECAUSE STROKE HAS A HUGE
11 VARIABILITY IN ITS CLINICAL OUTCOME AND EXPRESSION,
12 AND THAT CAN TAKE QUITE A WHILE TO BE APPARENT. I
13 READ THIS AS THEY'RE TRYING TO BALANCE THE ATTEMPT
14 TO INTERVENE AT A POINT THAT'S EARLY ENOUGH WHERE
15 YOU COULD MAKE A DIFFERENCE, BUT FAR ENOUGH ALONG
16 THAT THE STROKE IS IN SOME SENSE ESTABLISHED.

17 AND AS HE POINTS OUT, THAT CLINICALLY,
18 QUOTING FROM HIS PETITION, CLINICALLY MOST STROKES
19 ARE COMPLETED BY THE END OF ONE WEEK. AND THAT'S
20 CERTAINLY TRUE ANATOMICALLY AND IN TERMS OF JUST THE
21 IMMEDIATE PHYSICAL EFFECT OF THE STROKE. THE
22 EXPRESSION OF THE STROKE IN TERMS OF THE ACTUAL
23 CLINICAL OUTCOME CAN VARY TREMENDOUSLY DEPENDING ON
24 THE PREEXISTING HEALTH OF THE PERSON WHO SUFFERS THE
25 STROKE, THEIR OWN MOTIVATION, PSYCHOLOGICAL FACTORS,

BARRISTERS' REPORTING SERVICE

1 AND THERE'S A HUGE NUMBER OF VARIABLES. BUT I THINK
2 THAT THIS IS AS VALID A TIME POINT AS ANY OTHER TO
3 PICK, AND I THINK HE MAKES A GOOD ARGUMENT FOR IT.

4 THE NUMBERS OF ANIMALS THAT THEY HAVE TO
5 USE AND THE SIZE OF THEIR PROJECT IS LARGE, AND SOME
6 OF THE PRELIMINARY WORK HAS PERHAPS NOT BEEN CARRIED
7 AS FAR AS ALONG AS WE'D LIKE TO SEE IN THE
8 PRELIMINARY DATA, BUT I THINK THAT THIS IS A
9 MERITORIOUS APPLICATION, AND I WOULD URGE US TO MOVE
10 IT UP TO TIER I.

11 CHAIRMAN THOMAS: DEAN HAWGOOD.

12 MS. SAMUELSON: DOES IT NEED A SECOND?

13 DR. HAWGOOD: I THINK ONE OF THE CONCERNS
14 THAT THE REVIEWERS ALSO RAISED THAT IS IMPORTANT IS
15 LACK OF COMPELLING PRELIMINARY DATA FOR THE
16 PARTICULAR CELL TYPE AND THE PARTICULAR VIRAL VECTOR
17 THAT IS BEING USED. THE PROOF OF PRINCIPLE WORK IS
18 DONE WITH A MURINE EMBRYONIC STEM CELL LINE AND A
19 LENTI VECTOR, AND THE PROPOSAL IS HUMAN CELLS WITH
20 AN ADENOVIRAL VECTOR. AND FOR A THREE-YEAR PROJECT,
21 THE CELL CHARACTERIZATION IS NOT YET COMPLETE. AND
22 SO I THINK THAT RAISED QUESTIONS OF FEASIBILITY AS
23 WELL.

24 CHAIRMAN THOMAS: IS THERE ANY OTHER
25 DISCUSSION BY MEMBERS OF THE BOARD? ANY PUBLIC

BARRISTERS' REPORTING SERVICE

1 COMMENT? DON REED.

2 MR. REED: THIS RAISES TO ME A VERY
3 INTERESTING QUESTION ON THE TIMING. WHEN MY SON WAS
4 FIRST INJURED, WE TRIED TO GET HIM INTO A CLINICAL
5 STUDY ON SYGEN, A GANGLIOSIDE GM1 OF DRIED-UP COW
6 BRAINS. AND IT WAS DONE UNDER FDA AUSPICES, BUT WE
7 MISSED THE DEADLINE BY ONE HOUR. WE HAD TO BE 72
8 HOURS. WE GOT THERE 73. SO THE TIMING EVER SINCE
9 HAS STRUCK ME AS HUGELY IMPORTANT TO A LOT OF
10 NEUROLOGICAL CONDITIONS. AND IF THE TIMING IS AN
11 ESSENCE OF THIS AND STROKE IS SUCH AN ENORMOUS
12 PROBLEM AND SO DEVASTATING, I WONDER IF THE
13 SCIENTIFIC KNOWLEDGE THAT WE MIGHT GAIN MIGHT BE
14 VIABLE TO MORE PROJECTS THAN JUST THIS ONE ALONE.

15 CHAIRMAN THOMAS: THANK YOU. ANY FURTHER
16 DISCUSSION? MARIA, PLEASE CALL THE ROLL.

17 MR. HARRISON: AND, AGAIN, FOR THE RECORD,
18 THIS IS A MOTION TO MOVE APPLICATION 5660 TO TIER I.

19 MS. BONNEVILLE: ROBERT BIRGENEAU.

20 DR. BIRGENEAU: NO.

21 MS. BONNEVILLE: DAVID BRENNER. SUSAN
22 BRYANT.

23 DR. BRYANT: YES.

24 MS. BONNEVILLE: KEN BURTIS.

25 DR. BURTIS: NO.

BARRISTERS' REPORTING SERVICE

1 MS. BONNEVILLE: MARCY FEIT.
2 MS. FEIT: NO.
3 MS. BONNEVILLE: MICHAEL FRIEDMAN. LEEZA
4 GIBBONS.
5 MS. GIBBONS: YES.
6 MS. BONNEVILLE: MICHAEL GOLDBERG.
7 MR. GOLDBERG: YES.
8 MS. BONNEVILLE: SAM HAWGOOD.
9 DR. HAWGOOD: NO.
10 MS. BONNEVILLE: STEVE JUELSGAARD.
11 DR. JUELSGAARD: NO.
12 MS. BONNEVILLE: SHERRY LANSING. BURT
13 LUBIN.
14 DR. LUBIN: NO.
15 MS. BONNEVILLE: MICHAEL MARLETTA.
16 DR. MARLETTA: NO.
17 MS. BONNEVILLE: SHLOMO MELMED.
18 DR. MELMED: NO.
19 MS. BONNEVILLE: PHIL PIZZO.
20 DR. PIZZO: NO.
21 MS. BONNEVILLE: FRANCISCO PRIETO.
22 DR. PRIETO: YES.
23 MS. BONNEVILLE: ELIZABETH FINI.
24 DR. FINI: NO.
25 MS. BONNEVILLE: ROBERT QUINT.

BARRISTERS' REPORTING SERVICE

1 DR. QUINT: NO.
2 MS. BONNEVILLE: JOAN SAMUELSON.
3 MS. SAMUELSON: YES.
4 MS. BONNEVILLE: DAVID SERRANO-SEWELL.
5 MR. SERRANO-SEWELL: YES.
6 MS. BONNEVILLE: JEFF SHEEHY.
7 MR. SHEEHY: NO.
8 MS. BONNEVILLE: JON SHESTACK. OS
9 STEWARD.
10 DR. STEWARD: NO.
11 MS. BONNEVILLE: JONATHAN THOMAS.
12 CHAIRMAN THOMAS: YES.
13 MS. BONNEVILLE: ART TORRES.
14 MR. TORRES: NO.
15 MS. BONNEVILLE: EUGENE WASHINGTON.
16 MR. HARRISON: MOTION FAILS BY A VOTE OF 8
17 YES VOTES TO 14 NO VOTES.
18 CHAIRMAN THOMAS: THANK YOU. MR.
19 HARRISON, ARE THERE OTHER DC CANDIDATES?
20 MR. HARRISON: YES. THE NEXT APPLICATION
21 THAT WAS DISCUSSED WAS 5626.
22 DR. SAMBRANO: OKAY. THAT WAS
23 EXTRACELLULAR MATRIX BY SCAFFOLD AUGMENTED WITH
24 HUMAN STEM CELLS FOR CARDIOVASCULAR REPAIR.
25 CHAIRMAN THOMAS: AND THIS WAS THE SUBJECT

BARRISTERS' REPORTING SERVICE

1 OF AN EXTRAORDINARY APPEAL.

2 DR. SAMBRANO: YES.

3 MR. SHEEHY: I WOULD LIKE TO MOVE THAT
4 INTO TIER I.

5 MS. GIBBONS: SECOND.

6 CHAIRMAN THOMAS: MOVED BY MR. SHEEHY,
7 SECONDED BY LEEZA GIBBONS. DISCUSSION FROM MEMBERS
8 OF THE BOARD. MR. SHEEHY.

9 MR. SHEEHY: SURE. SO TO BEGIN WITH, I
10 THINK THE SCORE JUSTIFIES IT. THE MEDIAN SCORE ON
11 THIS IS 75. I THINK THAT THERE WERE A COUPLE OF
12 OUTLIERS THAT BROUGHT THAT DOWN. IT HAS THE HIGHEST
13 STANDARD DEVIATION. 75 WAS APPROXIMATELY WHERE WE
14 SET THE GREEN LINE. I THINK WE ACTUALLY SET IT AT
15 76 IN THIS REVIEW. SO WITHOUT THE OUTLIERS, I THINK
16 IT WOULD HAVE BEEN FUNDABLE ANYWAY.

17 I THINK WE'RE TALKING ABOUT A PRODUCT THAT
18 COULD HAVE ENORMOUS IMPACT QUICKLY. YOU HAVE TWO
19 THINGS THAT ARE ALREADY IN THE CLINIC, WHICH IS THIS
20 MATRIX, WHICH IS ALREADY BEING PUT INTO PATIENTS,
21 AND MESENCHYMAL STEM CELLS, WHICH ARE ALSO BEING PUT
22 INTO PATIENTS, SO IT MAKES SENSE TO PUT THEM
23 TOGETHER. IT'S LIKE AN OREO. WHAT WOULD WE DO IF
24 WE HADN'T MADE THAT? SORRY. I HAVE A
25 SEVEN-YEAR-OLD.

BARRISTERS' REPORTING SERVICE

1 BUT, YOU KNOW, THE OTHER THING IS I DO
2 THINK THE SAFETY IMPLIED HERE IS VERY STRONG, AND I
3 KNOW THAT WE TALKED ABOUT THE CEDARS-SINAI PRODUCT,
4 BUT THAT'S STILL AN AUTOLOGOUS PRODUCT. AND WE'RE
5 ASSUMING THAT WHEN WE DO IT ALLOGENEICALLY, WE HAVE
6 NO DATA IN HUMANS THAT IT WORKS -- THAT IT'S SAFE
7 ALLOGENEICALLY. SO WE'RE JUST KIND OF GUESSING THAT
8 IT'S GOING TO BE OKAY AS AN ALLOGENEIC PRODUCT. THE
9 ONLY CELLS, I THINK, THAT HAVE BEEN SHOWN TO BE SAFE
10 RIGHT NOW FOR HEART DISEASE IN HUMANS IS STILL
11 MESENCHYMAL STEM CELLS AS AN ALLOGENEIC PRODUCT, I
12 THINK.

13 THEY HAVE THE ANIMAL DATA TO SUGGEST THAT
14 THE ALLOGENEIC THING WILL WORK, BUT NOT -- YOU KNOW,
15 WHAT THEY WENT INTO PATIENTS WITH WAS AUTOLOGOUS,
16 AND SO I THINK THE FACT THAT WE ARE SEEING SOME SORT
17 OF IMPACT FROM PUTTING CELLS INTO PATIENTS, EVERYONE
18 SEEMS TO AGREE WE DON'T KNOW WHAT THEY ARE,
19 EVERYBODY SEEMS TO AGREE THEY DON'T STAY FOR A LONG
20 TIME, SO I THINK THIS PARTICULAR CELL TYPE, WHICH IS
21 VERY SAFE, GETTING IT TO STAY THERE FOR A LONG TIME
22 AND SEEING IF THAT MAKES A BIG DIFFERENCE IN
23 PATIENTS, I THINK, IS A PRETTY GOOD IDEA. I THINK
24 THERE'S BEEN SOME BENEFIT DEMONSTRATED FROM THE
25 PATCH. SOME STUDIES, NOT ALL THE STUDIES, HAVE

BARRISTERS' REPORTING SERVICE

1 SHOWN SOME BENEFIT FROM MESENCHYMAL STEM CELLS. SO
2 WE'RE NOT IN THIS SPACE AT ALL FOR CARDIOVASCULAR
3 DISEASE. IT SEEMS TO ME LIKE THIS IS AN EASY ONE
4 FOR US TO TAKE A BET ON.

5 CHAIRMAN THOMAS: LEEZA.

6 MS. GIBBONS: I WAS REALLY JUST SAYING I
7 THINK IT'S A VERY COMPELLING ARGUMENT, AND I
8 APPRECIATE YOU FOR ARTICULATING IT SO BEAUTIFULLY AS
9 YOU ALWAYS DO, JEFF.

10 CHAIRMAN THOMAS: ANY OTHER COMMENTS ON
11 THIS APPLICATION FROM MEMBERS OF THE BOARD? YES,
12 DR. FRIEDMAN.

13 DR. FRIEDMAN: I TOO FIND THIS REALLY
14 INTERESTING AND CREATIVE. AND THE COMPETITION WITH
15 OTHER PRODUCTS DOESN'T BOTHER ME AT ALL. I AM -- I
16 DO HAVE A CONCERN, AND LET ME JUST SHARE WHAT THAT
17 CONCERN IS, THAT WE'RE DOING TWO THINGS
18 SIMULTANEOUSLY, EITHER ONE OF WHICH COULD BE VERY
19 INTERESTING AND VERY POSITIVE. AND BY COMMINGLING
20 IT, I'M GUESSING, BECAUSE I WANT TO SEE THIS BE
21 PRACTICALLY AVAILABLE TO PEOPLE, I'M GUESSING THAT
22 THIS IS GOING TO CAUSE SOME REGULATORY ISSUES THAT
23 ARE GOING TO HAVE TO BE WORKED OUT LATER. THAT MAY
24 NOT BE A REASON TO -- THAT MAY NOT BE A FLAW RIGHT
25 NOW THAT STOPS IT, BUT IT IS SOMETHING THAT CAUSES

BARRISTERS' REPORTING SERVICE

1 ME CONCERN. AND I FIND THE WHOLE IDEA VERY
2 INTRIGUING. I'M NOT SURE THAT IT'S READY AT THIS
3 MOMENT.

4 CHAIRMAN THOMAS: JOAN.

5 MS. SAMUELSON: AS I RECALL, THE OTHER
6 VARIABLE IN THE PARTICULAR CASE THAT THE PRIMARY --
7 THE PRINCIPAL INVESTIGATOR WAS CONCERNED WITH WAS A
8 35-YEAR-OLD WOMAN WITH HEART FAILURE. I MAY NOT
9 HAVE THAT EXACTLY RIGHT, BUT THAT'S MY RECOLLECTION
10 OF THE DISCUSSION THIS MORNING, WHICH SHOULD BE
11 BROUGHT INTO THE BALANCE WITH ANY EFFICACY QUESTIONS
12 AS WELL AS SAFETY.

13 CHAIRMAN THOMAS: DR. STEWARD.

14 DR. STEWARD: I JUST WANT TO RAISE --
15 REMIND EVERYONE OF THE ISSUE OF THE LETTER, AND I
16 DON'T MEAN THE APPEAL. I MEANT THE LETTER OF
17 AGREEMENT THAT WAS STRUCK AND THAT WAS CERTIFIED.
18 THAT DID COME UP AS A NEGATIVE FACTOR IN THE REVIEW,
19 AND YOU CAN'T -- I THINK IT'S VERY DIFFICULT TO
20 JUDGE HOW MUCH OF A DIFFERENCE THAT MADE IN TERMS OF
21 THE POINTS IN THE REVIEW, BUT IT DID COME UP. AND
22 JUST TO REMIND EVERYBODY THAT THIS WAS REALLY CLOSE
23 TO THE BOUNDARY TO BEGIN WITH. SO EVEN THAT POINT
24 OR TWO COULD HAVE PUSHED IT OVER THE EDGE.

25 CHAIRMAN THOMAS: OTHER COMMENTS?

BARRISTERS' REPORTING SERVICE

1 COMMENTS FROM MEMBERS OF THE PUBLIC. MR. REED.

2 MR. REED: I JUST REALLY LIKE THE IDEA OF
3 REACHING OUT TO THE MEDICAL COMMUNITY, PEOPLE THAT
4 ARE ON THE FRONT LINE TRYING TO SAVE LIVES. AND I
5 THINK THAT WOULD BE A GOOD WAY FOR US TO GET CLOSE
6 TO THAT QUICKLY.

7 CHAIRMAN THOMAS: THANK YOU. ANY OTHER
8 COMMENTS FROM MEMBERS OF THE BOARD? MARIA, PLEASE
9 CALL THE ROLL.

10 MR. HARRISON: AGAIN, THIS IS A MOTION TO
11 MOVE APPLICATION 5626 TO TIER I.

12 MS. BONNEVILLE: ROBERT BIRGENEAU.

13 DR. BIRGENEAU: NO.

14 MS. BONNEVILLE: DAVID BRENNER. SUSAN
15 BRYANT.

16 DR. BRYANT: YES.

17 MS. BONNEVILLE: MICHAEL FRIEDMAN.

18 DR. FRIEDMAN: NO.

19 MS. BONNEVILLE: LEEZA GIBBONS.

20 MS. GIBBONS: YES.

21 MS. BONNEVILLE: MICHAEL GOLDBERG.

22 MR. GOLDBERG: YES.

23 MS. BONNEVILLE: SAM HAWGOOD.

24 DR. HAWGOOD: NO.

25 MS. BONNEVILLE: STEVE JUELGAARD.

BARRISTERS' REPORTING SERVICE

1 DR. JUELSGAARD: YES.
2 MS. BONNEVILLE: BERT LUBIN.
3 DR. LUBIN: NO.
4 MS. BONNEVILLE: MICHAEL MARLETTA.
5 DR. MARLETTA: NO.
6 MS. BONNEVILLE: SHLOMO MELMED.
7 DR. MELMED: NO.
8 MS. BONNEVILLE: PHIL PIZZO.
9 DR. PIZZO: YES.
10 MS. BONNEVILLE: ELIZABETH FINI.
11 DR. FINI: NO.
12 MS. BONNEVILLE: ROBERT QUINT.
13 DR. QUINT: NO.
14 MS. BONNEVILLE: DUANE ROTH.
15 MR. ROTH: YES.
16 MS. BONNEVILLE: JOAN SAMUELSON.
17 MS. SAMUELSON: YES.
18 MS. BONNEVILLE: DAVID SERRANO-SEWELL.
19 JEFF SHEEHY.
20 MR. SHEEHY: YES.
21 MS. BONNEVILLE: JONATHAN SHESTACK. OS
22 STEWARD.
23 DR. STEWARD: YES.
24 MS. BONNEVILLE: JONATHAN THOMAS.
25 CHAIRMAN THOMAS: YES.

BARRISTERS' REPORTING SERVICE

1 MS. BONNEVILLE: ART TORRES.

2 MR. TORRES: AYE.

3 MS. BONNEVILLE: CHRISTINA VUORI.

4 DR. VUORI: YES.

5 MS. BONNEVILLE: EUGENE WASHINGTON.

6 DAVID.

7 MR. SERRANO-SEWELL: YES.

8 MR. HARRISON: THAT MOTION CARRIES BY A
9 VOTE OF 13 TO 8.

10 CHAIRMAN THOMAS: THANK YOU. MR.
11 HARRISON, I BELIEVE THERE'S ONE OTHER.

12 MR. HARRISON: YES. THERE WAS AN
13 APPLICATION RAISED IN PUBLIC COMMENT. IT'S
14 APPLICATION NO. 5730.

15 DR. SAMBRANO: SO THAT WAS MONOCLONAL
16 ANTIBODY THERAPEUTIC TARGETING A, REDACTED,
17 MONOCLONAL EXPRESSED ON HUMAN CANCER STEM CELLS.

18 CHAIRMAN THOMAS: AND THIS WAS THE SUBJECT
19 OF AN EXTRAORDINARY APPEAL, CORRECT?

20 DR. SAMBRANO: YES.

21 CHAIRMAN THOMAS: DO WE HAVE A MOTION TO
22 APPROVE MOVING THIS FROM TIER III TO TIER I?

23 MS. SAMUELSON: COULD YOU REPEAT WHAT THAT
24 NUMBER WAS?

25 MR. HARRISON: 5730.

BARRISTERS' REPORTING SERVICE

1 CHAIRMAN THOMAS: DO I HEAR A MOTION TO
2 MOVE THIS FROM TIER III TO TIER I? HEARING NONE, I
3 BELIEVE THAT THAT CONCLUDES OUR DISCUSSION. NO,
4 THERE WAS ONE MORE.

5 MR. HARRISON: YOU WILL RECALL THAT STAFF
6 RAISED A PROPOSAL WITH RESPECT TO APPLICATION 5617,
7 AND THAT REQUEST WAS TO MODIFY THE GRANTS WORKING
8 GROUP'S RECOMMENDATION SO THAT THE AWARD WOULD
9 REMAIN A DC AWARD, BUT FOCUS ON THE DRUG THAT WAS
10 ALREADY IDENTIFIED AND ADJUST THE BUDGET
11 ACCORDINGLY. AND I BELIEVE THE BOARD REQUESTED ALSO
12 THAT WE BE SURE TO REQUIRE CLINICAL EXPERTISE.

13 CHAIRMAN THOMAS: DO WE HEAR A MOTION TO
14 THAT EFFECT?

15 MR. SHEEHY: SO MOVED.

16 CHAIRMAN THOMAS: MOVED BY MR. SHEEHY.

17 MR. TORRES: SECOND.

18 CHAIRMAN THOMAS: SECONDED BY SENATOR
19 TORRES. IS THERE DISCUSSION? ANY PUBLIC COMMENT?
20 OKAY. MARIA, PLEASE CALL THE ROLL.

21 MS. BONNEVILLE: ROBERT BIRGENEAU.

22 DR. BIRGENEAU: YES.

23 MS. BONNEVILLE: DAVID BRENNER. SUSAN
24 BRYANT.

25 DR. BRYANT: YES.

BARRISTERS' REPORTING SERVICE

1 MS. BONNEVILLE: KEN BURTIS.
2 DR. BURTIS: YES.
3 MS. BONNEVILLE: MARCY FEIT.
4 MS. FEIT: YES.
5 MS. BONNEVILLE: MICHAEL FRIEDMAN.
6 DR. FRIEDMAN: YES.
7 MS. BONNEVILLE: LEEZA GIBBONS.
8 MS. GIBBONS: YES.
9 MS. BONNEVILLE: MICHAEL GOLDBERG.
10 MR. GOLDBERG: YES.
11 MS. BONNEVILLE: SAM HAWGOOD.
12 DR. HAWGOOD: YES.
13 MS. BONNEVILLE: STEVE JUELSGAARD.
14 DR. JUELSGAARD: YES.
15 MS. BONNEVILLE: SHERRY LANSING. BERT
16 LUBIN.
17 DR. LUBIN: YES.
18 MS. BONNEVILLE: SHLOMO MELMED.
19 DR. MELMED: YES.
20 MS. BONNEVILLE: PHIL PIZZO.
21 DR. PIZZO: YES.
22 MS. BONNEVILLE: FRANCISCO PRIETO.
23 DR. PRIETO: YES.
24 MS. BONNEVILLE: ELIZABETH FINI.
25 DR. FINI: YES.

BARRISTERS' REPORTING SERVICE

1 MS. BONNEVILLE: ROBERT QUINT.
2 DR. QUINT: YES.
3 MS. BONNEVILLE: DUANE ROTH.
4 MR. ROTH: YES.
5 MS. BONNEVILLE: JOAN SAMUELSON.
6 MS. SAMUELSON: YES.
7 MS. BONNEVILLE: DAVID SERRANO-SEWELL.
8 MR. SERRANO-SEWELL: YES.
9 MS. BONNEVILLE: JEFF SHEEHY.
10 MR. SHEEHY: YES.
11 MS. BONNEVILLE: JONATHAN SHESTACK. OS
12 STEWARD.
13 DR. STEWARD: YES.
14 MS. BONNEVILLE: JONATHAN THOMAS.
15 CHAIRMAN THOMAS: YES.
16 MS. BONNEVILLE: ART TORRES.
17 MR. TORRES: AYE.
18 MS. BONNEVILLE: CHRISTINA VUORI.
19 DR. VUORI: YES.
20 MS. BONNEVILLE: EUGENE WASHINGTON.
21 CHAIRMAN THOMAS: I THINK WE DON'T REALLY
22 NEED TO TABULATE THAT ONE.
23 MR. HARRISON: BUT IT CARRIES BY A VOTE OF
24 23 TO ZERO.
25 CHAIRMAN THOMAS: YES. THANK YOU. OKAY.

BARRISTERS' REPORTING SERVICE

1 SO NOW THAT DOES EXHAUST THE APPLICATIONS WE HAD TO
2 TAKE ON AN INDIVIDUAL BASIS. I WOULD NOW ENTERTAIN
3 A MOTION THAT WE APPROVE THE AWARDS AS AMENDED IN
4 THEIR ENTIRETY.

5 MR. TORRES: SO MOVED.

6 MS. GIBBONS: SECOND.

7 CHAIRMAN THOMAS: MOVED BY SENATOR TORRES,
8 SECOND BY LEEZA GIBBONS. ANY DISCUSSION? COMMENTS
9 BY MEMBERS OF THE PUBLIC? HEARING NONE, MARIA, WILL
10 YOU CALL THE ROLL.

11 MR. HARRISON: I'D LIKE TO REMIND MEMBERS
12 TO VOTE YES, NO, OR ABSTAIN, IF YOU CHOOSE, EXCEPT
13 WITH RESPECT TO THOSE APPLICATIONS IN WHICH YOU HAVE
14 A CONFLICT. YOU HAVE A LIST IN FRONT OF YOU THAT
15 IDENTIFIES ANY APPLICATION NUMBERS.

16 MS. BONNEVILLE: ROBERT BIRGENEAU.

17 DR. BIRGENEAU: YES, WITH THE EXCEPTION OF
18 TR3-05556 AND TR3-05565.

19 MS. BONNEVILLE: DAVID BRENNER. SUSAN
20 BRYANT.

21 DR. BRYANT: YES, WITH THE EXCEPTION OF
22 THOSE FOR WHICH I HAVE A CONFLICT.

23 MS. BONNEVILLE: KEN BURTIS.

24 DR. BURTIS: YES, WITH THE EXCEPTION OF
25 THOSE WITH WHICH I HAVE A CONFLICT.

BARRISTERS' REPORTING SERVICE

1 MS. BONNEVILLE: MARCY FEIT.

2 MS. FEIT: YES, EXCEPT FOR THOSE FOR WHICH
3 I HAVE A CONFLICT.

4 MS. BONNEVILLE: MICHAEL FRIEDMAN.

5 DR. FRIEDMAN: YES, EXCEPT FOR THOSE FOR
6 WHICH I HAVE A CONFLICT.

7 MS. BONNEVILLE: LEEZA GIBBONS.

8 MS. GIBBONS: I HAVE NO CONFLICTS. YES.

9 MS. BONNEVILLE: MICHAEL GOLDBERG.

10 MR. GOLDBERG: YES, EXCEPT FOR THOSE FOR
11 WHICH I HAVE A CONFLICT.

12 MS. BONNEVILLE: SAM HAWGOOD.

13 DR. HAWGOOD: YES, EXCEPT FOR THOSE FOR
14 WHICH I HAVE A CONFLICT.

15 MS. BONNEVILLE: STEVE JUELSGAARD.

16 DR. JUELSGAARD: YES.

17 MS. BONNEVILLE: SHERRY LANSING. BERT
18 LUBIN.

19 DR. LUBIN: YES.

20 MS. BONNEVILLE: MICHAEL MARLETTA.

21 DR. MARLETTA: YES, EXCEPT FOR THOSE FOR
22 WHICH I HAVE A CONFLICT.

23 MS. BONNEVILLE: SHLOMO MELMED.

24 DR. MELMED: YES, EXCEPT FOR THOSE FOR
25 WHICH I HAVE A CONFLICT.

BARRISTERS' REPORTING SERVICE

1 MS. BONNEVILLE: PHIL PIZZO.

2 DR. PIZZO: YES, EXCEPT FOR THOSE FOR
3 WHICH I HAVE A CONFLICT.

4 MS. BONNEVILLE: FRANCISCO PRIETO.

5 DR. PRIETO: YES, EXCEPT FOR THOSE FOR
6 WHICH I HAVE A CONFLICT.

7 MS. BONNEVILLE: ELIZABETH FINI.

8 DR. FINI: YES, EXCEPT FOR THOSE FOR WHICH
9 I HAVE A CONFLICT.

10 MS. BONNEVILLE: ROBERT QUINT.

11 DR. QUINT: YES. AND I HAVE NO CONFLICTS.

12 MS. BONNEVILLE: DUANE ROTH.

13 MR. ROTH: YES, EXCEPT FOR THOSE FOR WHICH
14 I HAVE A CONFLICT.

15 MS. BONNEVILLE: JOAN SAMUELSON.

16 MS. SAMUELSON: NO CONFLICTS. YES.

17 MS. BONNEVILLE: DAVID SERRANO-SEWELL.

18 MR. SERRANO-SEWELL: YES.

19 MS. BONNEVILLE: JEFF SHEEHY.

20 MR. SHEEHY: YES, EXCEPT FOR THOSE FOR
21 WHICH I HAVE A CONFLICT.

22 MS. BONNEVILLE: JONATHAN SHESTACK. OS
23 STEWARD.

24 DR. STEWARD: YES, EXCEPT FOR THOSE FOR
25 WHICH I HAVE A CONFLICT.

BARRISTERS' REPORTING SERVICE

1 MS. BONNEVILLE: JONATHAN THOMAS.

2 CHAIRMAN THOMAS: YES.

3 MS. BONNEVILLE: ART TORRES.

4 MR. TORRES: AYE.

5 MS. BONNEVILLE: CHRISTINA VUORI.

6 DR. VUORI: YES, EXCEPT FOR THOSE FOR
7 WHICH I HAVE A CONFLICT.

8 MS. BONNEVILLE: EUGENE WASHINGTON.

9 MR. HARRISON: THE MOTION CARRIES.

10 CHAIRMAN THOMAS: WELL, THANK YOU,
11 EVERYBODY, FOR A LENGTHY AND CONSIDERED DISCUSSION
12 ON VERY IMPORTANT TOPICS. I THINK WE'VE GOT SOME
13 TERRIFIC PROJECTS HERE AND CONGRATULATE ALL
14 INVOLVED.

15 LET'S NOW MOVE ON TO THE NEXT ITEM ON THE
16 AGENDA, WHICH IS CONSIDERATION OF APPOINTMENT OF NEW
17 SCIENTIFIC MEMBERS OF THE GRANTS WORKING GROUP. DR.
18 SAMBRANO.

19 DR. SAMBRANO: THANK YOU. SO TODAY WE'RE
20 BRINGING FOR YOUR CONSIDERATION THREE NOMINEES FOR
21 GRANTS WORKING GROUP MEMBERS THAT BRING KEY
22 SCIENTIFIC EXPERTISE IN THE AREAS OF NEUROBIOLOGY,
23 NEURO-ONCOLOGY, AND CARDIOLOGY. THE NOMINEES AND
24 THEIR BRIEF BIOS ARE IN YOUR BINDERS. THEY INCLUDE
25 DR. JANE JOHNSON FROM UT SOUTHWESTERN, DR. JOHN SKUO

BARRISTERS' REPORTING SERVICE

1 FROM THE UNIVERSITY OF WISCONSIN, AND DR. HESHAM
2 SADEK FROM UT SOUTHWESTERN.

3 WE REQUEST YOUR APPROVAL AND APPOINTMENT
4 OF THESE NOMINEES AS MEMBERS OF THE GRANTS WORKING
5 GROUP.

6 CHAIRMAN THOMAS: DO I HEAR A MOTION?

7 DR. FRIEDMAN: SO MOVED.

8 CHAIRMAN THOMAS: MOVED BY DR. FRIEDMAN.

9 DR. VUORI: SECOND.

10 CHAIRMAN THOMAS: SECOND BY DR. VUORI.

11 ANY DISCUSSION? COMMENTS BY MEMBERS OF THE PUBLIC?

12 MR. HARRISON, DOES THIS REQUIRE A ROLL
13 CALL VOTE OR JUST A SENSE OF THE --

14 MR. HARRISON: IT REQUIRES A VOICE VOTE
15 EXCEPT FOR THOSE WHO ARE ON THE TELEPHONE, AND WE
16 NEED A ROLL CALL VOTE FOR THEM.

17 CHAIRMAN THOMAS: OKAY. SO WITH RESPECT
18 TO THOSE IN THE ROOM, ALL THOSE IN FAVOR OF THIS
19 MOTION PLEASE SAY AYE. OPPOSED? MARIA, PLEASE
20 CANVASS THOSE MEMBERS ON THE PHONE.

21 MS. BONNEVILLE: SHLOMO MELMED.

22 DR. MELMED: YES.

23 MS. BONNEVILLE: DUANE ROTH.

24 MR. ROTH: YES, EXCEPT WHICH I HAVE A
25 CONFLICT. SORRY, GUYS. I WAS LATE. I WAS TRYING

BARRISTERS' REPORTING SERVICE

1 TO GET AROUND THE CORNER HERE.

2 CHAIRMAN THOMAS: SOUNDED LIKE A
3 PRERECORDED MESSAGE.

4 MR. ROTH: IT IS. I WISH I COULD PLAY IT
5 OFTEN.

6 CHAIRMAN THOMAS: YES. NOW, THANK YOU.
7 THAT'S, MR. HARRISON, UNANIMOUSLY APPROVED.

8 MR. HARRISON: CORRECT.

9 MS. SAMUELSON: MR. CHAIRMAN, I NEED TO
10 ABSTAIN BECAUSE AT THIS POINT I DON'T THINK IT'S
11 ACCURATE TO CHARACTERIZE THESE PEOPLE AS SCIENTIFIC
12 MEMBERS. I THINK IT'S CONFUSING TO THE BOARD AND
13 DOESN'T REFLECT THE FACT THAT THERE ARE NOW OVER A
14 HUNDRED WHO ARE PARTICIPANTS AND IMPORTANT, BUT WE
15 DON'T AT THIS POINT HAVE A WORKING GROUP WITH
16 MEMBERS PER SE. AND I THINK THAT SHOULD BE
17 REMEMBERED. THANK YOU.

18 CHAIRMAN THOMAS: OKAY. MR. HARRISON,
19 PLEASE REFLECT THAT IN THE FINAL TALLY.

20 NEXT, ITEM NO. 10, CONSIDERATION OF
21 RECOMMENDATIONS OF THE IP AND INDUSTRY SUBCOMMITTEE.
22 I'LL TURN THIS OVER TO MR. JUELSGAARD.

23 DR. JUELSGAARD: WELL, I'M GOING TO TURN
24 THIS OVER TO ELONA IN JUST A MOMENT. BUT REAL
25 QUICKLY, WE HAVE SINCE THE LAST MEETING DISCUSSED

BARRISTERS' REPORTING SERVICE

1 TWO TOPICS. AND THAT'S AMENDMENTS TO THE LOAN
2 ADMINISTRATION POLICY AND THE OTHER IS THE INDUCED
3 PLURIPOTENT STEM CELL BANKING INITIATIVE THAT WAS
4 APPROVED AT A BOARD MEETING, I THINK, IN DECEMBER.
5 SO I HAVE NOTHING MORE TO SAY BECAUSE ELONA HAS IT
6 ALL.

7 MS. BAUM: I THINK MY EYESIGHT IS GOING AS
8 WELL, SO DON'T FEEL BAD. THIS IS BIG PRINT AND I
9 CAN STILL BARELY SEE IT.

10 I AM GOING TO TRY TO GO THROUGH THESE
11 ITEMS FAIRLY QUICKLY BECAUSE IT'S LATE IN THE
12 AFTERNOON AND I KNOW WE HAVE A LOT OF BUSINESS TO
13 CONDUCT. IF I AM GOING TOO FAST, PLEASE JUST
14 INTERRUPT AND ASK QUESTIONS ALONG THE WAY.

15 AND JUST FOR PRELIMINARY MATTERS, I WANTED
16 TO NOTE THAT THE AGENDA SAYS THAT THREE ITEMS WILL
17 BE DISCUSSED THAT ARISE FROM THE IP AND INDUSTRY
18 SUBCOMMITTEE. IN FACT, THERE'S TWO. WE JUST PLACED
19 THE LAST ONE, THE UPDATE ON SOME PROPOSED IP
20 REGULATIONS, AS SORT OF A PLACEHOLDER IN CASE WE
21 WERE ABLE TO ADDRESS THAT EARLIER THIS MORNING,
22 WHICH WE DID NOT, BUT KEEP YOUR EYES OUT. WE WILL
23 BE DOING THAT SOON, I HOPE.

24 SO LET ME DO THIS AS QUICKLY AS POSSIBLE,
25 BUT WITHOUT LOSING ANY OF THE CONTENT. WHAT YOU

BARRISTERS' REPORTING SERVICE

1 HAVE IN TAB 10 IS SOME DOCUMENTATION OF SOME VERY
2 MARKED-UP REGULATIONS FROM OUR LOAN ADMINISTRATION
3 POLICY. THEY ARE HIGHLY MARKED UP BECAUSE THEY
4 ACTUALLY REFLECT TWO SETS OF CHANGES. THE FIRST SET
5 WAS ALREADY APPROVED, AND THEN THERE'S A SECOND SET.
6 THE SECOND SET IS WHAT YOU ARE FOCUSING ON TODAY.
7 THEY ARE HIGHLIGHTED. AND SINCE THESE WERE POSTED,
8 I THINK, WITHIN THE TEN-DAY OR CERTAINLY THE
9 SEVEN-DAY TIME FRAME BEFORE THIS MEETING, HOPEFULLY
10 YOU'VE HAD A CHANCE TO TAKE A LOOK AT THEM.

11 SO WHAT I THOUGHT THAT I WOULD DO IS, ONE,
12 LET YOU KNOW THAT THE IP AND INDUSTRY SUBCOMMITTEE
13 LOOKED AT THESE PROPOSED REGULATIONS IN EXTREME
14 DETAIL. WE HAD A SUBCOMMITTEE MEETING THAT WAS
15 NEARLY AN HOUR AND A HALF LONG, AND WE DID A VERY
16 DETAILED PAGE-TURNING EXERCISE LOOKING AT ALL OF THE
17 LANGUAGE THAT WAS CHANGED. SO WHAT I THOUGHT THAT I
18 WOULD DO IS JUST HIGHLIGHT THE TEN OR SO SUBSTANTIVE
19 ISSUES THAT I THINK DESERVES YOUR ATTENTION TODAY.

20 I WANT TO REMIND YOU THAT ON MAY 8TH, THE
21 SUBCOMMITTEE DID BY UNANIMOUS VOTE OF ALL THOSE
22 PRESENT AGREE TO RECOMMEND THE APPROVAL OF THESE
23 REGULATIONS TODAY.

24 SO, AGAIN, I'LL GO VERY QUICKLY BECAUSE I
25 HAVE TO COVER A LOT OF GROUND. BUT THE FIRST CHANGE

BARRISTERS' REPORTING SERVICE

1 I WANTED TO DRAW YOUR ATTENTION TO IS ON PAGE 1, IF
2 YOU CARE TO LOOK AND FOLLOW WITH ME. THAT JUST
3 INCLUDED A PURPOSE SECTION FOR THE LAP OR THE LOAN
4 REGULATIONS. IT WAS IMPORTANT, WE THOUGHT, TO
5 PROVIDE CONTEXT FOR THOSE WHO ARE LOOKING AT OUR
6 REGULATIONS SO THAT THEY UNDERSTOOD THAT WE'RE
7 TRYING TO STRIKE A BALANCE BETWEEN ACCEPTING
8 FINANCIAL RISK AND NOT UNDULY TRYING TO HINDER THE
9 GRANTING PROCESS WITH REGULATIONS THAT SEEK A LOT OF
10 REVENUE RETURN FROM CIRM, BUT STILL CAN PROGRESS THE
11 SCIENCE FORWARD AND ACKNOWLEDGE THAT WE UNDERSTAND
12 WE'RE NOT ONLY TAKING SCIENTIFIC RISK IN THESE
13 ENDEAVORS, BUT ALSO FINANCIAL.

14 SO MOVING ON, THE SECOND POINT OF NOTE IS
15 A CHANGE OR PROPOSED CHANGE TO THE DEFINITION OF NET
16 COMMERCIAL REVENUE. WHAT WE'RE DOING THERE IS
17 EXCLUDING PRECOMMERCIAL PAYMENTS; IN ESSENCE,
18 UP-FRONT MILESTONES OR PRECOMMERCIAL DEVELOPMENT
19 MILESTONES FROM THE DEFINITION OF REVENUE. THIS
20 WILL ALLOW THOSE WHO ARE ENGAGED IN THE RESEARCH TO
21 HAVE A BETTER ABILITY TO REINVEST THAT TYPE OF
22 FUNDING IN THE DEVELOPMENT PROCESS.

23 THIRD, WE JUST ADDED A LITTLE CHANGE TO
24 THE SECTION RELATING TO FINANCIAL SERVICES PROVIDER
25 SUCH THAT WE DIDN'T HAVE TO HAVE THAT DUE DILIGENCE

BARRISTERS' REPORTING SERVICE

1 CONDUCTED BY A THIRD PARTY. WE COULD, IF WE CHOSE,
2 HAVE A THIRD PARTY DO THE DUE DILIGENCE, OR IN THE
3 ALTERNATIVE, WE CAN USE OUR OWN INTERNAL RESOURCES.
4 WE WANTED TO PROVIDE THE FLEXIBILITY SO THAT IN THE
5 FUTURE IF WE DID DECIDE TO DO THIS IN-HOUSE, WE
6 WOULDN'T HAVE TO CHANGE REGULATIONS THEN. SO THIS
7 WAS JUST LOOKING FORWARD AND TRYING TO ADDRESS IT IN
8 THAT WAY.

9 NEXT, WE JUST ELIMINATED A LOT OF
10 TERMINOLOGY AND REGULATIONS THAT WERE EITHER
11 OVERLAPPING WITH THE IP REGULATIONS OR WERE
12 REDUNDANT WITHIN THE BODY OF THE LAP. WE AT ONE
13 POINT THOUGHT IT WAS A GOOD IDEA TO HAVE A LOT OF
14 BELT AND SUSPENDER-TYPE LANGUAGE. AND THEN WE
15 REALIZED WHEN WE WERE GETTING A LOT OF INQUIRIES,
16 THAT WE WERE CREATING A LOT OF CONFUSION BECAUSE
17 THEY WOULD READ A CLAUSE ONE PLACE AND THEN IT SEE
18 IT SOMEWHAT WORDED DIFFERENTLY SOMEWHERE ELSE WHEN,
19 IN FACT, IT ALL MEANT THE SAME THING. AND SO I JUST
20 WANTED TO BRING YOUR ATTENTION THAT ON PAGES 7, 8,
21 AND 9 WE MADE SOME CHANGES THAT WERE BASICALLY TO
22 MAKE SURE THAT ALL OF OUR REGULATIONS WERE IN LINE
23 WITH THE IP REGULATIONS IN PARTICULAR AND, OF
24 COURSE, INTERNALLY. AND I'VE OUTLINED WHAT SOME OF
25 THOSE REGULATION CHANGES ARE IN THESE SLIDES AND IN

BARRISTERS' REPORTING SERVICE

1 MY MEMO.

2 IN ADDITION, WE ALSO CHANGED ON PAGE 10,
3 AND YOU'LL SEE WHERE IT'S MARKED ON THE SLIDES, IT'S
4 SECTION VII B., THE NOTION THAT IF YOUR LOAN WAS
5 FORGIVEN BECAUSE IT WAS NOT DEEMED SUCCESSFUL, THAT
6 IN THE EVENT THAT YOU HAD RECEIVED SOME INTERIM OR
7 WOULD RECEIVE SOME INTERIM REVENUE FROM LICENSING,
8 THAT INSTEAD OF PAYING BACK CIRM A HUNDRED PERCENT,
9 YOU ONLY NEEDED TO PAY BACK 50 PERCENT OF
10 THIRD-PARTY COSTS OR 50 PERCENT TO EQUAL AND TO PAY
11 FOR THE THIRD-PARTY COSTS WHICH WERE INCURRED IN
12 GENERATING SUCH REVENUE. THE NOTION BEING THAT
13 THERE IS THIS OBLIGATION TO MAKE ANY INVENTIONS AND
14 DISCOVERIES AND DATA USEFUL; BUT IN DOING SO,
15 SOMETIMES IT COSTS ATTORNEY TIME AND IN-HOUSE TIME
16 TO INCUR THE LICENSE OR WHATNOT. SO WE'RE ALLOWING
17 THE LOAN RECIPIENT TO RECOUP ITS ATTORNEY FEE COSTS
18 OR THIRD-PARTY COSTS.

19 MOVING FORWARD, WE MADE A NUMBER OF TWEAKS
20 TO THE WARRANTS LANGUAGE THAT IS IN YOUR
21 REGULATIONS. A LOT OF THIS CAME FROM SOME QUESTIONS
22 THAT WE FIELDDED. SO INSTEAD OF HAVING TO DO AN FAQ
23 THAT EXPLAINS WHAT OUR REGULATIONS MEANT, WE JUST
24 FIGURED WE'D MAKE THE CHANGES THAT, QUOTE, FIX THEM.
25 SO WE HAD A CLARIFICATION OF THE DEFINITION OF WHAT

BARRISTERS' REPORTING SERVICE

1 FULLY DILUTED MEANS. IN OTHER WORDS, WE STATED THAT
2 IT INCLUDES STOCK OPTIONS. WE CLARIFIED THAT
3 WARRANTS ARE DUE NOT JUST UPON SORT OF THE SIGNING
4 OF A NOTICE OF LOAN AGREEMENT, BUT UPON EACH
5 DISBURSEMENT, AND THEY'RE CALCULATED BASED ON EACH
6 DISBURSEMENT. WE ALSO STATED THAT THE BORROWER MAY
7 ELECT TO PROVIDE THE WARRANTS IN THE FORM OF COMMON
8 OR PREFERRED STOCK. AND WE CLARIFIED, IT WASN'T
9 NECESSARY, BUT TO MAKE IT IN BLACK AND WHITE AND
10 CRYSTAL CLEAR, WE CLARIFIED THAT CIRM IS ENTITLED TO
11 RETAIN WARRANTS WHEN THEY'RE DUE AND OWING
12 REGARDLESS OF WHAT THE ULTIMATE DISPOSITION OF THE
13 LOAN IS OR THE SUCCESS OF THE PROJECT.

14 MOVING ON, I THINK I JUST HAVE A FEW MORE
15 OF THESE. WITH RESPECT TO THE MULTIPLE RISK
16 PREMIUM, YOU MIGHT RECALL THAT WAS AN ALTERNATIVE TO
17 PROVIDING WARRANTS UNDER OUR LAP. WE CHANGED THE
18 FIRST TRIGGER POINT. YOU MIGHT RECALL THAT UNDER
19 THE RISK PREMIUM, THERE WERE THREE TRIGGER POINTS AT
20 WHICH THREE TIMES THE LOAN AMOUNT WOULD BE OWED.
21 WELL, THE FIRST ONE STARTED AT 10 MILLION, AND IT
22 DOESN'T REALLY WORK WHEN YOU HAVE A \$20 MILLION LOAN
23 AND YOU'VE JUST EARNED 10 MILLION. YOU'LL BE IN
24 DEFAULT. SO WE WANTED TO FIX THAT, AND WE SAID,
25 THEREFORE, THAT THE FIRST TRIGGER PAYMENT IS 50

BARRISTERS' REPORTING SERVICE

1 MILLION. AND INSTEAD OF PAYING IT OVER 12 MONTHS,
2 WHICH IS WHAT WAS INITIALLY PROVIDED FOR, SINCE IT
3 IS SORT OF THE FIRST SET OF REVENUE, WE SAID PAY IT
4 OVER 18 MONTHS.

5 WE ALSO DID A NUMBER OF CHANGES WITH
6 RESPECT TO CHANGE OF CONTROL AND LOAN ACCELERATION.
7 AND BASICALLY WE STATED THAT CIRM MAY ACCELERATE A
8 LOAN UPON A CHANGE OF CONTROL EXCEPT IN A CERTAIN
9 CIRCUMSTANCE TO MAKE IT CLEAR PEOPLE KNEW WHEN THAT
10 CIRCUMSTANCE WAS. AND AS DEFINED IN THESE PROPOSED
11 AMENDMENTS, IT IS IN THE EVENT THAT THE SURVIVING
12 ENTITY ASSUMES THE LOAN OBLIGATIONS. THAT'S AN
13 ESSENTIAL REQUIREMENT AND SHOULD ALWAYS BE. AND, OF
14 COURSE, HERE'S WHERE THERE'S A LITTLE SORT OF
15 NUANCE. THEY HAVE TO HAVE SHAREHOLDER EQUITY EQUAL
16 TO OR GREATER THAN THE LOAN RECIPIENT PRIOR TO THE
17 CHANGE OF CONTROL.

18 MOVING ON, THIS IS THE ONE TIME WITH
19 ASSIGNEES THAT WE HAD SOME BELT-AND-SUSPENDER
20 LANGUAGE. WE SAID THAT ASSIGNEES HAVE THE SAME
21 OBLIGATIONS AS THE LOAN RECIPIENT UNDER THE IP
22 REGULATIONS. I THINK THAT WOULD BE BY ORDER OF LAW
23 ANYWAY.

24 AND THIS IS MY LAST ONE BEFORE I SWITCH
25 OVER TO THE NEXT SET OF REGULATIONS. I KNOW I'M

BARRISTERS' REPORTING SERVICE

1 TALKING FAST; AND IF THERE'S ANY QUESTIONS, PLEASE
2 DO INTERRUPT ME.

3 SUBORDINATION. THE OLD SET OR ACTUALLY
4 THE PENDING AND THE SET OF REGULATIONS IN EFFECT
5 PROVIDE FOR SUBORDINATION IN CERTAIN CIRCUMSTANCES
6 FOR PRODUCT-BACKED LOANS. IT'S SILENT ON
7 COMPANY-BACKED LOANS. AND WE JUST DECIDED THAT
8 BECAUSE WE ACTUALLY HAD A LOT OF QUESTIONS ON IT
9 ANYWAY, BECAUSE IT WAS SILENT ON COMPANY-BACKED
10 LOANS, THAT WE WOULD TAKE THIS ON A CASE-BY-CASE
11 BASIS. THIS WAS THE INSTRUCTION AND DIRECTION THAT
12 WE GOT FROM THE IP AND INDUSTRY SUBCOMMITTEE. AND
13 ON A CASE-BY-CASE BASIS, WE WOULD UNDERSTAND WHAT
14 THE DIFFERENT FINANCIAL STRENGTHS WERE AND A LOT
15 MORE ABOUT THE PROJECT, AND THEN INTERNALLY WE COULD
16 USE OUR EXPERTISE TO MAKE THE DECISION WHETHER OR
17 NOT TO SUBORDINATE.

18 SO THOSE ARE THE TEN MAJOR SUBSTANTIVE
19 CHANGES TO THE LAP, AND REST ASSURED THAT THE IP AND
20 INDUSTRY SUBCOMMITTEE SPENT A LONG TIME LOOKING AT
21 THIS IN DETAIL, AND WHAT YOU SEE BEFORE YOU
22 INCORPORATES THEIR SUGGESTED CHANGES. AND WITH
23 THAT, I WOULD JUST ASK YOU TO APPROVE THE PROPOSED
24 AMENDMENTS.

25 CHAIRMAN THOMAS: DO WE HAVE -- BEFORE WE

BARRISTERS' REPORTING SERVICE

1 ASK FOR MOTIONS HERE, MR. GOLDBERG, WOULD YOU LIKE
2 TO COMMENT AT ALL?

3 MR. GOLDBERG: I THINK THIS HAS BEEN FULLY
4 DISCUSSED AND DEBATED BY THE INTELLECTUAL PROPERTY
5 AND INDUSTRY SUBCOMMITTEE, AND I'M VERY COMFORTABLE
6 MOVING IT TO A VOTE PENDING ANY FURTHER QUESTIONS.

7 CHAIRMAN THOMAS: MR. JUELSGAARD.

8 DR. JUELSGAARD: NO, I DON'T HAVE ANYTHING
9 TO ADD OTHER THAN I MOVE THAT THIS BE APPROVED.

10 CHAIRMAN THOMAS: IS THERE A SECOND?

11 DR. FRIEDMAN: SECOND.

12 CHAIRMAN THOMAS: SECONDED BY DR.
13 FRIEDMAN. ANY FURTHER DISCUSSION? SENATOR TORRES.

14 MR. TORRES: YES. I THINK IT'S IMPORTANT
15 TO NOTE HOW THIS WILL IMPROVE POTENTIAL REVENUE TO
16 THE STATE OF CALIFORNIA.

17 MS. BAUM: WELL, THE LOAN PROGRAM IN
18 PARTICULAR IS VERY ADVANTAGEOUS BECAUSE AMONG SOME
19 POTENTIAL GRANTEES, THEY MIGHT WANT A LOAN VERSUS A
20 GRANT, BUT NOW WE ALLOW BOTH ASPECTS AND ALLOW THE
21 GRANTEES TO CHOOSE BETWEEN GRANTS AND LOANS.

22 MR. TORRES: THE WARRANT CONCEPT.

23 MS. BAUM: WELL, THE WARRANT CONCEPT, OF
24 COURSE, ALLOWS US TO PARTICIPATE IN THE SUCCESS OF A
25 COMPANY IN THAT WE END UP HOLDING RIGHTS OF VALUE

BARRISTERS' REPORTING SERVICE

1 THAT ALLOW US TO, I GUESS, SHARE IN SORT OF THE
2 INCREASED VALUE OF THE VERY COMPANIES THAT WE ARE
3 FUNDING.

4 MR. TORRES: SO THAT IN TURN INCREASES
5 REVENUE TO -- POTENTIAL REVENUE TO THE STATE OF
6 CALIFORNIA.

7 MS. BAUM: WELL, TO BE FRANK WITH YOU, THE
8 LOAN PROGRAM IS A PROGRAM WHERE THE PROCEEDS GO
9 DIRECTLY TO CIRM, WHICH I THINK COULD BE SAID
10 BENEFITS THE STATE AS WELL.

11 MR. TORRES: EXACTLY. THANK YOU.

12 CHAIRMAN THOMAS: DR. PRIETO.

13 DR. PRIETO: YES. QUESTION ABOUT THE
14 DEFINITION OF NET COMMERCIAL REVENUE AND THE CHANGE
15 THERE. YOU MENTIONED THAT THE REASONING BEHIND THAT
16 WAS THAT FUNDS WOULD BE REINVESTED. IF YOU COULD
17 EXPAND ON THAT A LITTLE BIT. AND DO WE HAVE ANY
18 GUARANTEE OR ASSURANCES THAT, IN FACT, THAT'S WHAT
19 WOULD HAPPEN?

20 MS. BAUM: THE THOUGHT WAS IS THAT IF WE
21 DIDN'T TRY TO CAPTURE THAT INCOME, THAT IT WOULD
22 LIKELY BE REINVESTED INTO THE PRODUCT OR PROJECT.
23 TO BE FRANK AGAIN, WE THOUGHT ABOUT PUTTING A
24 CONDITION THAT IT WOULD BE REINVESTED AS A
25 CONDITION, BUT WE FELT THAT THE ECONOMICS AND THE

BARRISTERS' REPORTING SERVICE

1 DRIVERS WOULD MOST LIKELY ALLOW THIS TO OCCUR
2 ANYWAY. AND THAT BY MAKING IT AN ABSOLUTE
3 REQUIREMENT, IT WOULD CAUSE SOME COMPANIES ACTUALLY
4 NOT TO WANT TO ENGAGE WITH CIRM AT ALL. AND THE
5 REASON BEING IS THAT SOMETIMES PEOPLE RECEIVE THESE
6 UP-FRONTS OR ESPECIALLY THESE DEVELOPMENT
7 MILESTONES, AND IT'S NOT REAL CLEAR FROM WHAT
8 PROJECT THEY ARE DERIVED FROM BECAUSE THEY'LL HAVE,
9 FOR INSTANCE, A MOLECULE OR AN ANTIBODY OR WHATNOT,
10 A THERAPEUTIC, AND WITH MANY DIFFERENT INDICATIONS,
11 AND WE FUND ON AN INDICATION-BY-INDICATION BASIS.
12 SO SOMETIMES IT'S SORT OF THE FIRST TO GET INTO A
13 CLINICAL TRIAL ENDS UP TRIGGERING A DEVELOPMENT
14 MILESTONE.

15 WELL, IF CIRM SORT OF FUNDED THAT, THE
16 INDICATION THAT CREATED THAT, THERE ARE A LOT OF
17 OTHER INDICATIONS THAT MAY HAVE BEEN IN THE WORKS
18 AND BEEN SUBJECTED TO A LOT OF R&D EXPENDITURES
19 BEFOREHAND. SO IT BECAME VERY COMPLICATED IN THE
20 WAY THAT THE COMPANIES ARE DOING BUSINESS TO REALLY
21 UNDERSTAND IN ALL CIRCUMSTANCES WHEN IT WOULD BE
22 DERIVED STRICTLY FROM CIRM TO REQUIRE THEM TO
23 REINVEST IT IN THE CIRM-FUNDED PROJECT. AND
24 SOMETIMES IT'S A PAYMENT IN ARREARS AGAIN; AND
25 BECAUSE OF THE COMPLICATED WAY THAT THESE BUSINESS

BARRISTERS' REPORTING SERVICE

1 DEALS ARE MADE, IT WAS A LITTLE TROUBLESOME TO
2 FIGURE OUT EXACTLY WHEN THAT WOULD HAVE BEEN
3 TRIGGERED STRICTLY BY CIRM. SO WE DECIDED THAT WE
4 WOULD JUST EXCLUDE THIS WITH THE MOTION THAT THAT'S
5 SORT OF THE WAY BUSINESS IS OPERATED. THEY REINVEST
6 IT. THEY'RE NOT A PUBLIC COMPANY GIVING OUT
7 DIVIDENDS.

8 DR. PRIETO: OR REIMBURSING THEIR OWN
9 OFFICERS OR -- I'M JUST WORRIED THAT, YOU KNOW, IS
10 THIS SOME SORT OF AN ESCAPE VALVE, AND COULD THIS BE
11 MISUSED? COULD THEY BE SUBJECT TO ABUSE?

12 DR. JUELSGAARD: WELL, IN MY EXPERIENCE
13 THESE PAYMENTS OF MILESTONES ARE, IN ESSENCE, ARREAR
14 PAYMENTS FOR INCURRING RISK. SO COMPANIES GO AT
15 RISK SPENDING THEIR OWN MONEY, TIME, AND EFFORT TO
16 DETERMINE IF YOU CAN REACH A PARTICULAR GOAL.
17 SHOULD THAT GOAL NOT BE REACHED, THOSE PAYMENTS ARE
18 NOT MADE. BUT IF THE GOAL IS REACHED, THEY ARE
19 PAID. AND, IN ESSENCE, IT'S MAKING UP FOR WHAT
20 YOU'VE SPENT IN THE INTERIM BOTH IN TERMS OF MONEY
21 AND TIME THAT WOULD HAVE BEEN SPENT DOING SOMETHING
22 ELSE HAD YOU NOT SPENT IT ON THIS.

23 SO I DON'T THINK WE WANT TO DISCOURAGE
24 COMPANIES FROM DOING THAT. AND SO TO, IN ESSENCE,
25 ADDRESS THOSE MILESTONES AS PART OF SOMETHING THAT

BARRISTERS' REPORTING SERVICE

1 WE SHOULD REACH THROUGH TO, I THINK, WILL BE
2 DISCOURAGING WITH RESPECT TO COMPANIES WANTING TO
3 OTHERWISE BE INVOLVED WITH THIS PROGRAM FROM MY
4 POINT OF VIEW.

5 CHAIRMAN THOMAS: ANY OTHER DISCUSSION?
6 COMMENTS FROM MEMBERS OF THE PUBLIC? HEARING NONE,
7 MR. HARRISON, VOICE VOTE SUFFICES HERE?

8 MR. HARRISON: CORRECT. AND AGAIN, THE
9 MOTION IS TO APPROVE THE PROPOSED AMENDMENTS TO THE
10 LOAN ADMINISTRATION POLICY.

11 CHAIRMAN THOMAS: BEFORE THE VOTE, DO YOU
12 WANT TO REITERATE ELONA AND MATT AND MANY OTHERS
13 SPENT A LOT OF TIME ON THIS. SO THIS IS THE PRODUCT
14 OF A GREAT DEAL OF THOUGHT AND ATTENTION.

15 MS. BAUM: I WANT TO ACKNOWLEDGE SCOTT TOO
16 WHO SPENT A CONSIDERABLE AMOUNT OF TIME AS WELL.
17 IT'S VERY MUCH APPRECIATED.

18 CHAIRMAN THOMAS: YES. THANK YOU VERY
19 MUCH. SO ALL THOSE IN FAVOR OF THE MOTION, PLEASE
20 SAY AYE. OPPOSED? ABSTENTIONS?

21 MR. HARRISON: NOW WE'LL DO A ROLL CALL OF
22 THOSE ON THE PHONE.

23 CHAIRMAN THOMAS: YES.

24 MS. BONNEVILLE: DUANE ROTH.

25 MR. ROTH: YES.

BARRISTERS' REPORTING SERVICE

1 MS. BONNEVILLE: SHLOMO MELMED.

2 DR. MELMED: YES.

3 CHAIRMAN THOMAS: OKAY. PASSES
4 UNANIMOUSLY.

5 BEFORE WE GET TO THE NEXT AGENDA TOPIC, WE
6 ACTUALLY HAVE A MOST IMPORTANT ANNOUNCEMENT, WHICH
7 IS TODAY, I BELIEVE, IS DR. BRYANT'S BIRTHDAY. AND
8 TO COMMEMORATE, WE HAVE CUPCAKES IN THE BACK ROOM
9 THERE WHICH, MARIA, SOMEBODY IS GOING TO PASS OUT.
10 IN THE INTEREST OF TIME, WE ARE GOING TO HAVE A
11 WORKING DESSERT.

12 DR. PIZZO: JON, WOULD YOU PLEASE LEAD US
13 IN A SONG.

14 (HAPPY BIRTHDAY WAS THEN SUNG.)

15 (APPLAUSE.)

16 CHAIRMAN THOMAS: OKAY. NOW, ELONA, DO
17 YOU HAVE ITEM NO. 2?

18 MS. BAUM: OKAY. ITEM NO. 2, THIS REGARDS
19 THE INTERIM REGULATIONS FOR THE IPS REPOSITORY. SO
20 I'LL JUST KEEP GOING. YOU ALL MIGHT RECALL THAT IN
21 DECEMBER 8TH OF 2011, THE ICOC APPROVED A CONCEPT
22 FOR THIS REPOSITORY. WHAT WILL OCCUR IS WE WILL
23 SEE, HOPEFULLY SOON, THE POSTING OF THREE RFA'S, ONE
24 FOR DISEASE MODELING, ANOTHER FOR CELL LINE
25 DERIVATION UP TO \$16 MILLION AS INITIALLY

BARRISTERS' REPORTING SERVICE

1 ENVISIONED, AND THEN THE REPOSITORY DISTRIBUTION ARM
2 OF \$10 MILLION.

3 AS WE STARTED THIS, AS I STARTED TO SORT
4 OF SINK MY TEETH INTO WHAT THIS INITIATIVE IS ALL
5 ABOUT, IT BECAME VERY SELF-EVIDENT THAT OUR IP
6 REGULATIONS WOULD ACTUALLY DETER IN MANY RESPECTS
7 THE SUCCESS OF THIS VERY INITIATIVE. AND I'LL TELL
8 YOU WHY IN A SECOND. AND EITHER THAT OR THEY JUST
9 WEREN'T APPLICABLE, BUT IT SEEMED LIKE WE NEEDED
10 OTHER MECHANISMS TO MAKE SURE THAT WE WOULD BE ABLE
11 TO ENJOY THE RESULTS OF OUR FUNDED RESEARCH.

12 SO LET ME TELL YOU A LITTLE BIT ABOUT WHY
13 THE IP REGULATIONS DON'T WORK BECAUSE YOU'LL SEE
14 WHAT I'M RECOMMENDING IS THAT THEY NOT APPLY IN THIS
15 PARTICULAR SITUATION. SO, FOR INSTANCE, THE IP
16 REGULATIONS STATE THAT THE GRANTEE OWNS ALL OF THE
17 IP, BUT HERE WE WANT TO REMAIN -- WE WANT TO
18 MAINTAIN ULTIMATE CONTROL OF THESE CELL LINES, IN
19 PARTICULAR BECAUSE WE WANT THE ABILITY TO ENSURE
20 THAT THEY ARE FREELY AVAILABLE TO ALL RESEARCHERS
21 WHO CAN BENEFIT FROM THEIR USE, WHICH GETS ME TO MY
22 NEXT POINT.

23 THE IP REGULATIONS REQUIRE AND ALLOW
24 EXCLUSIVE LICENSING. WELL, WE DON'T WANT THESE CELL
25 LINES TO EVER BE EXCLUSIVELY LICENSED. AND AS I

BARRISTERS' REPORTING SERVICE

1 WENT THROUGH EACH OF THE DIFFERENT REQUIREMENTS THAT
2 ARE SET FORTH IN THE IP REGS, I EITHER REALIZED THAT
3 THEY PROBABLY DON'T APPLY ON POINT OR THEY SHOULD BE
4 TWEAKED IN SOME WAY. AND SO WHAT I'M ADVOCATING
5 HERE, AND, AGAIN, THIS IS WHAT THE IP AND INDUSTRY
6 SUBCOMMITTEE HAS ALREADY REVIEWED AND DISCUSSED AT
7 OUR MARCH 8TH MEETING AND HAS CONCLUDED TO RECOMMEND
8 APPROVAL, BUT I THINK APPROVAL WHICH WOULD NOT GO
9 INTO EFFECT UNTIL SOMETIME INTO DECEMBER WHEN WE
10 WILL PURSUE THROUGH THE OFFICE OF ADMINISTRATIVE LAW
11 A NEW SET OF REGULATIONS, INTERIM REGULATIONS, WHICH
12 WOULD LOOK AS FOLLOWS.

13 SO FIRST OF ALL, CIRM WOULD OWN ALL OF THE
14 CELL LINES. WE WOULD THEN THROUGH WHAT WE CALL A
15 DEPOSIT AGREEMENT HAVE THEM IN THE POSSESSION OF A
16 REPOSITORY THAT DISTRIBUTES THEM.

17 WITH RESPECT TO PUBLICATION, WE SIMPLY
18 JUST WANT THE ACKNOWLEDGEMENT OF CIRM'S FUNDING, AND
19 ALSO IT'S VERY IMPORTANT THAT THE ACTUAL NAME OF THE
20 REPOSITORY BE IDENTIFIED. SO WHEN THE RESEARCH IS
21 OUT THERE, PEOPLE KNOW WHERE TO FIND THE ACTUAL CELL
22 LINE.

23 I ALSO WANT TO HAVE A STATEMENT WITHIN
24 THESE INTERIM REGULATIONS, AND, AGAIN, THEY'RE IN
25 YOUR BINDER AND YOU CAN SEE THE ACTUAL LANGUAGE,

BARRISTERS' REPORTING SERVICE

1 THAT SAYS THE IP REGULATIONS DO NOT APPLY. BUT, OF
2 COURSE, THERE'S A PROVISION WITHIN THESE PROPOSED
3 REGULATIONS THAT STATE THE GRANTS ADMINISTRATION
4 POLICY WOULD APPLY AND SO TOO WOULD THE SCIENCE AND
5 MEDICAL ACCOUNTABILITY STANDARDS.

6 I DON'T WANT YOU TO THINK THAT THOSE ARE
7 THE ONLY WAYS THAT WE CAN CONTROL THIS RESOURCE.
8 THERE WILL BE A DEPOSIT AGREEMENT BETWEEN CIRM AND
9 THE REPOSITORY, AND THROUGH THAT WE WILL BE ABLE TO
10 NEGOTIATE THE TYPES OR THE LEVEL OF FEES THAT THEY
11 CHARGE RESEARCHERS. WE'LL BE ABLE TO ENSURE THAT
12 THERE'S FAVORABLE PRICING FOR CALIFORNIA RESEARCHERS
13 IN PARTICULAR. WE WILL BE ABLE TO INCLUDE
14 PROVISIONS BARRING THEM FROM EXCLUSIVELY LICENSING
15 THE LINES. WE MAY BE ABLE TO NEGOTIATE SOME
16 POSSIBLE REVENUE SHARING WITH THEM. I KNOW THAT
17 THERE ARE OTHER REPOSITORIES OUT THERE THAT HAVE OR
18 STARTING TO FIND THAT THEY CAN NEGOTIATE SOME
19 REVENUE SHARING AFTER A CERTAIN LEVEL IS MET. THE
20 MOST IMPORTANT THING IS THAT WE DON'T REACH TOO FAR
21 INTO THE REVENUE SUCH THAT THIS WILL NOT BE A
22 SELF-SUSTAINING OPERATION. THAT'S THE MOST
23 IMPORTANT ASPECT, SO WE DON'T WANT TO TIP THE
24 BALANCE IN THE WRONG DIRECTION.

25 AND, OF COURSE, WE WILL REQUIRE THEM TO BE

BARRISTERS' REPORTING SERVICE

1 IN COMPLIANCE WITH ALL PRIVACY LAWS, NOT JUST HIPAA.
2 SO THERE WILL BE ADEQUATE CONTROLS VIA CONTRACT AND
3 THEN, OF COURSE, BY THESE INTERIM SET OF
4 REGULATIONS.

5 WITH THAT SAID, WE ARE JUST REQUESTING
6 THAT THE BOARD APPROVE THOSE REGULATIONS. I THINK,
7 SCOTT, YOU HAD A SUGGESTION THAT THEY NOT BECOME
8 EFFECTIVE UNTIL DECEMBER OF THIS YEAR.

9 CHAIRMAN THOMAS: DO WE HEAR A MOTION TO
10 THAT EFFECT? MR. JUELSGAARD.

11 DR. JUELSGAARD: SO MOVED.

12 CHAIRMAN THOMAS: THANK YOU. DO WE HEAR A
13 SECOND?

14 MS. SAMUELSON: SECOND.

15 CHAIRMAN THOMAS: MULTIPLE SECONDS. JOAN
16 WE'LL GIVE THE SECOND TO.

17 MS. SAMUELSON: I WILL AND I HAVE A
18 CLARIFYING QUESTION.

19 CHAIRMAN THOMAS: YES.

20 MS. SAMUELSON: HOW IS THIS DIFFERENT, IF
21 AT ALL, FROM THE STATUS QUO IF THERE'S ANYTHING
22 COMPARABLE TO THIS? AND WHAT DO WE KNOW ABOUT
23 WHETHER THAT WOULD CREATE DISINCENTIVES TO THE
24 DEVELOPERS?

25 MS. BAUM: WHEN YOU REFER TO STATUS QUO,

BARRISTERS' REPORTING SERVICE

1 ARE YOU REFERRING TO THE WAY OTHER REPOSITORIES?

2 THAT'S WHAT I'M TRYING TO DO.

3 MS. SAMUELSON: THE OWNERSHIP RIGHTS.

4 MS. BAUM: WELL, THAT'S A VERY GOOD POINT,
5 AND I HAVE IT IN MY MEMO AND I FORGOT TO MENTION IT
6 HERE. WE ARE ALIGNING OURSELVES WITH THE WAY THAT
7 NIH AND IN PARTICULAR MAHENDRA RAO'S CENTER FOR
8 REGENERATIVE MEDICINE IS OPERATING. AND WE'VE
9 CONSULTED WITH THEM, AND THAT CENTER IS GOING TO OWN
10 THE LINES THAT THEY'RE PAYING TO BE DEVELOPED AS
11 WELL. SO WE'RE COMPLETELY ALIGNED OR TRYING TO BE
12 ALIGNED WITH BEST PRACTICES THAT WE KNOW OF.

13 AND HOW WILL THAT IMPACT? I DON'T THINK
14 THERE WILL BE ANY IMPACT AT ALL IN TERMS OF THE
15 RESEARCHERS' INTEREST IN ACCESSING THESE LINES
16 BECAUSE THIS IS PRETTY MUCH THE WAY IT WORKS ANYWAY.
17 THEY KNOW THAT THEY HAVE TO GO BACK IF THEY WANT A
18 COMMERCIAL RELATIONSHIP AND NEGOTIATE WITH THE OWNER
19 THAT PLACED THE SAMPLES OR THE CELL LINES IN THESE
20 REPOSITORIES ANYWAY. SO THEY'RE USED TO THAT.

21 CHAIRMAN THOMAS: FURTHER DISCUSSION?
22 COMMENTS FROM MEMBERS OF THE PUBLIC? HEARING NONE,
23 MR. HARRISON, RESTATE THE MOTION FOR A VOICE VOTE.

24 MR. HARRISON: THE MOTION IS TO APPROVE
25 THE INTERIM IPSC REGULATIONS WITH AN EFFECTIVE DATE

BARRISTERS' REPORTING SERVICE

1 OF DECEMBER 1, 2012.

2 CHAIRMAN THOMAS: ALL THOSE IN FAVOR
3 PLEASE SAY AYE. HOLD ON ONE SECOND. THAT WAS AN
4 AYE. VERY TRICKY, DR. FRIEDMAN. YOU WOULDN'T BE
5 GOOD AT AUCTIONS. ALL THOSE IN FAVOR PLEASE SAY
6 AYE. OPPOSED? ABSTENTIONS? POLLING ON THE PHONE,
7 MARIA.

8 MS. BONNEVILLE: DUANE ROTH.

9 MR. ROTH: YES.

10 MS. BONNEVILLE: SHLOMO MELMED.

11 DR. MELMED: YES.

12 CHAIRMAN THOMAS: UNANIMOUSLY APPROVED.
13 THANK YOU, ELONA. THANK YOU, SCOTT. THANK YOU,
14 MEMBERS OF THE IP AND INDUSTRY SUBCOMMITTEE ON THIS
15 ITEM. VERY EXCITING AS WE MOVE FORWARD IN BREAKING
16 NEW GROUND YET AGAIN.

17 MOVING ON TO THE NEXT ITEM, CONSIDERATION
18 OF RECOMMENDATION FROM THE FINANCE SUBCOMMITTEE
19 INCLUDING CIRM BUDGET AND THE FINANCE SUBCOMMITTEE
20 MISSION STATEMENT. WE'LL START WITH MR. GOLDBERG.

21 MR. GOLDBERG: THANK YOU, CHAIRMAN THOMAS.
22 SO WE'RE GOING TO HAVE A KUMBAYA MOMENT HERE AND
23 DISCUSS THE MISSION OF THE FINANCE SUBCOMMITTEE.

24 DR. PIZZO: MICHAEL, THIS COULD BE A
25 FIRST, THE MISSION OF THE FINANCE SUBCOMMITTEE.

BARRISTERS' REPORTING SERVICE

1 MR. GOLDBERG: SO IF YOU TURN TO ITEM NO.
2 11 IN YOUR BINDERS, THERE ARE JUST A COUPLE OF QUICK
3 MODIFICATIONS THAT HAVE BEEN PROPOSED BY OUR
4 SUBCOMMITTEE IN TERMS OF ITS MISSION STATEMENT. THE
5 FIRST IS THAT SINCE THE SUBCOMMITTEE, AS A MATTER OF
6 PRACTICE, WAS ALREADY REVIEWING THE BUDGET AND COST
7 CONTROL PROGRAMS, WE THOUGHT THAT SHOULD BE INCLUDED
8 IN THE MISSION STATEMENT.

9 SECONDLY, WE VOTED TO ENLARGE THE MISSION
10 OF THE INTELLECTUAL PROPERTY AND INDUSTRY
11 SUBCOMMITTEE TO INCORPORATE OVERSIGHT OF THE CIRM
12 LOAN PROGRAM. SO THAT HAD PREVIOUSLY BEEN WITHIN
13 THE SCOPE OF THE FINANCE SUBCOMMITTEE, AND THE
14 MISSION NEEDS TO BE MODIFIED SO IT REFLECTS THAT IT
15 NO LONGER SHOULD BE.

16 AND FINALLY, THE COMMITTEE WOULD LIKE TO
17 DESIGNATE THE VICE CHAIR OF THE SUBCOMMITTEE AS THE
18 CO-CHAIR OF THE SUBCOMMITTEE. IN THAT CONNECTION,
19 MY ABLE COLLEAGUE MARCY FEIT SHOULD RECEIVE, NOT
20 ONLY A PROMOTION, BUT A SALARY INCREASE.

21 MS. FEIT: THEY DID THAT WHEN I WASN'T IN
22 ATTENDANCE.

23 MR. GOLDBERG: SO WITH THAT, WE CAN OPEN
24 IT FOR DISCUSSION OR A MOTION.

25 DR. PIZZO: I WOULD RECOMMEND THAT WE

BARRISTERS' REPORTING SERVICE

1 INCREASE MARCY'S SALARY FROM ZERO -- BY 5 PERCENT OF
2 ZERO.

3 CHAIRMAN THOMAS: TAKE THAT AS A FRIENDLY
4 AMENDMENT. IS THERE A MOTION TO APPROVE THE MISSION
5 STATEMENT?

6 DR. JUELSGAARD: SO MOVED.

7 CHAIRMAN THOMAS: MR. JUELSGAARD.

8 DR. FRIEDMAN: SECOND.

9 CHAIRMAN THOMAS: SECONDED BY DR.
10 FRIEDMAN. ANY FURTHER DISCUSSION? COMMENTS FROM
11 MEMBERS OF THE PUBLIC. EXCUSE ME. HEARING NONE,
12 ANOTHER VOICE VOTE TO APPROVE THE MISSION STATEMENT.
13 ALL THOSE IN FAVOR PLEASE SAY AYE. OPPOSED?
14 ABSTENTIONS? MARIA.

15 MS. BONNEVILLE: DUANE ROTH.

16 MR. ROTH: YES.

17 MS. BONNEVILLE: SHLOMO MELMED.

18 DR. MELMED: YES.

19 CHAIRMAN THOMAS: ANOTHER UNANIMOUS VOTE.
20 WE LIKE THOSE.

21 MR. GOLDBERG: CONGRATULATIONS, CO-CHAIR
22 FEIT.

23 CHAIRMAN THOMAS: SPEND THE RAISE VERY
24 WISELY.

25 OKAY. NOW WE PROCEED TO CONSIDERATION OF

BARRISTERS' REPORTING SERVICE

1 THE BUDGET FOR APPROVAL. TURN IT OVER TO MATT.

2 DR. PLUNKETT: THANK YOU. SO ON SLIDE 2,
3 FOR THOSE WHO ARE AT REMOTE SITES, WE HAVE THE GOALS
4 FOR THE COMING FISCAL YEAR FOR CIRM. AND THIS IS
5 THE FIRST TIME THAT WE'VE REALLY DIRECTLY COUPLED
6 ANNUAL GOALS FOR THE ORGANIZATION TO OUR BUDGETING
7 PROCESS. AND THE REASON FOR THIS IS WE WANT TO BE
8 ABLE FOR EVERY SINGLE LINE ITEM IN THE BUDGET TO BE
9 ABLE TO POINT BACK TO ONE OF OUR GOALS AND TALK
10 ABOUT HOW A PARTICULAR EXPENDITURE HELPS US ACHIEVE
11 ONE OF THESE VERY IMPORTANT THINGS THAT WE'RE TRYING
12 TO ACHIEVE IN THE COMING FISCAL YEAR.

13 I WON'T READ EVERY SINGLE WORD HERE, BUT
14 REALLY JUST WANT TO HIT THE HIGHLIGHTS. AND THAT'S
15 THAT WE'RE GOING TO CONTINUE TO BE GOOD STEWARDS OF
16 PUBLIC DOLLARS AS WE SEEK TO GET TWO OR MORE
17 PROGRAMS IN OUR PORTFOLIO WITH AN OPEN IND, ACHIEVE
18 \$50 MILLION IN NEW OUTSIDE FINANCIAL COMMITMENTS FOR
19 CIRM PROGRAMS, ENSURE THE FUNDING OF POTENTIALLY
20 HIGH IMPACT PROJECTS, EDUCATE AND ENGAGE THE
21 CALIFORNIA COMMUNITY, AND OPTIMIZE CIRM'S WORKFORCE,
22 STAFFING, AND PROCESSES IN LIGHT OF OUR 6-PERCENT
23 EXPENSE CAP.

24 SLIDE 3 IS A RECAP OF OUR PROCESS TO DATE.
25 AND I WOULD JUST LIKE TO REMIND EVERYBODY THAT THIS

BARRISTERS' REPORTING SERVICE

1 HAS BEEN BOTH A VERY EXTENSIVE AS WELL AS PUBLIC
2 PROCESS. WE DID PREVIEW THIS BUDGET WITH THE ICOC
3 AT OUR BOARD MEETING IN MARCH IN SACRAMENTO. WE DID
4 HAVE A VERY EXHAUSTIVE REVIEW OF THE BUDGET AT THE
5 APRIL FINANCE SUBCOMMITTEE MEETING, AND WE DID HAVE
6 SOME FURTHER INTERNAL REFINEMENT THROUGHOUT THE
7 MONTH OF APRIL, AND I WILL COMMENT ON A COUPLE OF
8 KEY CHANGES IN A COUPLE OF SLIDES DOWN THE ROAD.

9 ANOTHER THING WHICH I WOULD LIKE TO REMIND
10 THE ICOC MEMBERS OF IS THAT WE HAVE DONE A BIT OF A
11 REARRANGEMENT OF THE PRESENTATION OF THE BUDGET.
12 AND THAT'S TO REALLY HAVE SOME COST CENTERS, THE
13 COLUMNS, IN THE BUDGET REFLECT THE FUNCTIONAL AREAS
14 AND NOT REPORTING RELATIONSHIPS. AND YOU CAN SEE
15 THOSE LISTED ON THE LEFT-HAND SIDE OF THE SCREEN.

16 IN ADDITION, WE'VE TRIED TO MAKE FOR A
17 LITTLE BIT GREATER SPECIFICITY --

18 MS. LANSING: HI. THIS IS SHERRY LANSING.
19 I JUST WANT YOU TO KNOW I'M NOW ONLINE. IS THAT
20 OKAY?

21 DR. PLUNKETT: WE CAN ALL HEAR YOU. THANK
22 YOU.

23 MS. LANSING: THANK YOU.

24 CHAIRMAN THOMAS: HI, SHERRY. WELCOME.

25 DR. PLUNKETT: ON THE RIGHT-HAND SIDE YOU

BARRISTERS' REPORTING SERVICE

1 CAN SEE THE ROWS WHICH WE BELIEVE GIVES GREATER
2 SPECIFICITY AND CLARITY FOR THE BUDGET.

3 ONE MORE POINT AS FAR AS THE BUDGET DETAIL
4 IS THAT THE ALLOCATIONS AGAINST OUR EXPENSE CAP,
5 GRANTS ADMINISTRATION, GENERAL AND ADMINISTRATIVE
6 AND LEGAL, ALL REMAIN UNCHANGED.

7 SO THIS IS ON SLIDE 6 IS THE ROLL-UP OF
8 THE FISCAL 12-13 BUDGET. AFTER I'M DONE WITH THIS
9 SLIDE, THIS WILL BE A GOOD POINT TO PAUSE FOR
10 DISCUSSION AND QUESTIONS. I WOULD LIKE TO REMIND
11 EACH OF THE MEMBERS OF THE ICOC THAT THERE IS
12 DETAILED LINE ITEM BACKUP THAT WAS PROVIDED TO YOU
13 IN THE BOARD PACKAGE. I CAN CERTAINLY FIELD
14 QUESTIONS ON THAT, BUT WON'T GO THROUGH THAT IN
15 SPECIFIC DETAIL UNLESS REQUESTED.

16 I WOULD LIKE TO HIGHLIGHT TWO CHANGES
17 WHICH WE DID MAKE BETWEEN THE MARCH BOARD MEETING
18 AND TODAY. IN MARCH YOU RECALL THAT WE DID HAVE A
19 PROPOSAL TO ADD AN ADDITIONAL FTE IN THE LEGAL GROUP
20 TO DO CERTAIN CONTRACTS AND INTELLECTUAL
21 PROPERTY-RELATED WORK. AFTER SOME EXTENSIVE REVIEW
22 AND DISCUSSION, WE'VE DECIDED NOT TO ADD THAT FTE TO
23 THE LEGAL GROUP AND, INSTEAD, REPLACE SOME AMOUNT OF
24 THAT WORK WITH SOME EXTERNAL SERVICES.

25 AND THE OTHER THING I WOULD LIKE TO

BARRISTERS' REPORTING SERVICE

1 COMMENT ON IS LAST WEEK CALPERS DETERMINED THAT THEY
2 NEEDED TO RAISE THE EMPLOYER CONTRIBUTION FROM 18.2
3 PERCENT OF GROSS SALARY TO 19.7 PERCENT OF GROSS
4 SALARY. THAT WAS AN \$89,000 IMPACT IN OUR EMPLOYEE
5 EXPENSES, AND THAT WAS WHAT GENERATED THE GENESIS OF
6 THE UPDATE TO THE BUDGET MATERIALS WHICH YOU GOT AT
7 THE END OF LAST WEEK.

8 SO I THINK I CAN JUST PAUSE AT THIS POINT
9 AND SEE IF THERE'S ANY QUESTIONS ABOUT ANY OF THE
10 EITHER BIG PICTURE DETAIL, HOW THINGS ARE MOVING
11 OVERALL, OR ANY OF THE SPECIFIC LINE ITEMS WHICH YOU
12 HAVE ALREADY RECEIVED.

13 SO OUR TRAVEL AND EMPLOYEE OUT-OF-POCKET
14 BUDGET FOR THE COMING FISCAL YEAR IS \$527,000. THIS
15 IS IN LINE WITH THIS YEAR'S BUDGET OF \$520,000 IN
16 AGGREGATE. I'LL NOTE THAT THIS ALSO INCLUDES AN
17 OUT-OF-STATE TRAVEL BUDGET OF 298,000. YOU WOULD
18 SEE THAT MANY OF THE LINE ITEM EXPENSES YEAR ON YEAR
19 DID GO DOWN ON A DEPARTMENTAL LEVEL. AND THE THING
20 THAT I WOULD LIKE TO EMPHASIZE HERE IS THE TRAVEL IS
21 REALLY DIRECTLY COUPLED TO THE \$50 MILLION IN
22 FINANCIAL LEVERAGE WHICH WE'RE SEEKING TO ACHIEVE
23 OVER THE COMING FISCAL YEAR.

24 SO THIS REFLECTS EVERYTHING FROM WORK
25 WHICH ELONA AND I ARE DOING WITH THE INVESTMENT AND

BARRISTERS' REPORTING SERVICE

1 PHARMACEUTICAL COMMITTEE COMMUNITY, WORK WHICH ALAN
2 IS DOING WITH POTENTIAL COLLABORATIVE FUNDING
3 PARTNERS, AS WELL AS WORK WITH THE REGULATORY
4 AGENCIES AND OTHERS IN WASHINGTON, D.C., WHICH ELLEN
5 AND OTHERS ARE SEEKING TO ACHIEVE. AND, OF COURSE,
6 THERE'S ALL OF THE IN-STATE WORK THAT WE DO IN TERMS
7 OF AUDITS OF OUR GRANTEES, SITE VISITS, COMPLIANCE
8 VISITS, BOARD MEETINGS FOR STAFF MEMBERS TO TRAVEL
9 AND SO FORTH.

10 DOES THAT ANSWER THE QUESTION?

11 SO THE OTHER THING ON SLIDE 7, THEN, JUST
12 MOVING ON, IS TO TOUCH BRIEFLY UPON THE EXPENSE
13 FORECASTING. AND AS WE HAD A DISCUSSION ON THE
14 MOSS-ADAMS REPORT THIS MORNING, WE CERTAINLY ARE
15 LOOKING AT BOTH SIDES OF THE COIN HERE. AND IN
16 TERMS OF FISCAL PRUDENCE, IT'S VERY IMPORTANT FOR US
17 TO MAKE SURE THAT THROUGHOUT THE ENTIRE LIFE OF THE
18 AGENCY THAT WE STAY WITHIN OUR EXPENSE CAPS.

19 WHAT WE'VE DONE IN TERMS OF MODELING THIS
20 OUT IS PROJECTING MODEST EXPENSE GROWTH THROUGH JUNE
21 2017 AND THEN ANNUAL DECREASES THROUGH JUNE 2022.
22 AND AS WE'VE RUN THESE PROJECTIONS, WE HAVE A LIST
23 OF ABOUT 20 WHAT I WOULD CALL IRREGULAR EXPENSES.
24 AS JUST ONE EXAMPLE, WE'VE ADDED IN RENT OF A
25 MILLION DOLLARS A YEAR STARTING NOVEMBER 2015. AND

BARRISTERS' REPORTING SERVICE

1 ALL OF THOSE DIFFERENT ADJUSTMENTS WE'VE USED TO
2 CREATE A LONG-TERM EXPENSE FORECAST FOR THE
3 ORGANIZATION.

4 ON SLIDE 8, AND I APOLOGIZE THAT THE
5 COLORS HERE APPEAR A LITTLE BIT WASHED OUT, WHAT YOU
6 CAN SEE IS THE SOLID AND THE DASHED LINES ARE -- THE
7 SOLID LINES ARE THE CUMULATIVE EXPENSES FOR THE
8 ORGANIZATION. THE DASHED LINES ARE THE STATUTORY
9 EXPENSE CAPS CONTAINED IN PROPOSITION 71. AND THE
10 BARS WITH THE RIGHT-HAND AXIS ARE THE ANNUAL
11 EXPENSES FOR EACH OF THE TWO EXPENSE CATEGORIES
12 WHICH WE TRACK AGAINST THE EXPENSE CAPS.

13 AND THE GOOD NEWS FOR EACH OF THESE IS
14 THAT THEY'RE BOTH \$90 MILLION BASED ON THE
15 PROJECTIONS HERE. THIS IS SOMETHING THAT I WOULD
16 CHARACTERIZE AS PRECISE, BUT NOT NECESSARILY HIGHLY
17 ACCURATE. IT MAY BE A LITTLE MORE THAN THAT; IT MAY
18 BE A LITTLE LESS THAN THAT OVER TIME. AND WHAT
19 WE'LL CONTINUE TO DO EVERY YEAR IS MONITOR THESE
20 PROJECTIONS AND MAKE SURE THAT WE STAY WITHIN THESE
21 EXPENSE CAPS.

22 SO ARE THERE ANY QUESTIONS ABOUT TRACKING
23 THE LONG-TERM EXPENSES AND THE MODELING?

24 MR. GOLDBERG: I JUST WANT TO THANK YOU,
25 MATT, FOR YOUR EXTENSIVE WORK ON THIS AND THE

BARRISTERS' REPORTING SERVICE

1 COORDINATION OF YOUR TEAM AND THE COOPERATION YOU
2 GOT FROM THE ENTIRE STAFF IN BEING ABLE TO BRING A
3 BUDGET TOGETHER AS THOUGHTFULLY AND IN AS TIMELY A
4 MANNER AS YOU WERE ABLE TO DO IT. CERTAINLY SET A
5 NEW HIGH BAR FOR US IN TERMS OF WHAT WE'VE BEEN
6 ACCUSTOMED TO. AND THANK YOU, ALAN, FOR ALL YOUR
7 SUPPORT IN BEING ABLE TO ACCOMMODATE THAT FOR US.

8 CHAIRMAN THOMAS: MARCY FEIT.

9 MS. FEIT: I ALSO WANT TO ECHO MICHAEL'S
10 COMMENTS TO YOU, MATT. MATT KEEPS US UPDATED
11 ALMOST, IF NOT DAILY, WEEKLY ON ANY FINANCIAL ISSUES
12 OR CONCERNS OR UPDATES THAT ARE NECESSARY. AND IT'S
13 REALLY NICE TO HAVE THAT COMMUNICATION. HE DOES A
14 GREAT JOB. SO THANK YOU, MATT, FOR THAT.

15 DR. PLUNKETT: THANK YOU. THIS WAS TRULY
16 A COLLABORATIVE EFFORT OF HONESTLY EVERY PERSON IN
17 THE ORGANIZATION.

18 MR. SERRANO-SEWELL: SO AM I -- FORGIVE ME
19 IF I'M LOOKING AT THE WRONG THING. YOU CAN KIND OF
20 SEE IT FROM HERE. SO EACH -- AND THIS IS THE -- YOU
21 SEE I'M LOOKING AT THE SUMMARY PAGE. SO FOR THE
22 TRAVEL AND OUT-OF-POCKET, THAT'S EACH DIVISION
23 WITHIN CIRM?

24 DR. PLUNKETT: THAT'S RIGHT.

25 MR. SERRANO-SEWELL: OKAY. SO, FOR

BARRISTERS' REPORTING SERVICE

1 EXAMPLE, WITHIN THAT LINE ITEM, SCIENCE RESEARCH IS
2 86.

3 DR. PLUNKETT: CORRECT.

4 MR. SERRANO-SEWELL: 86,000, PROBABLY.

5 DR. PLUNKETT: CORRECT.

6 MR. SERRANO-SEWELL: OKAY. SO I SEE IN
7 LEGAL IS 80,000.

8 DR. PLUNKETT: CORRECT.

9 MR. SERRANO-SEWELL: WHAT WAS THEIR LAST
10 YEAR TRAVEL BUDGET? OR MORE TO THE POINT, I'M JUST
11 SPEAKING OUT LOUD NOW, AND IT'S MAYBE BECAUSE OUR
12 LEGAL DEPARTMENT, WE DON'T GET TO GO ON AS MANY
13 TRIPS AS WE'D LIKE, BUT WHAT IS THE JUSTIFICATION
14 FOR THAT NUMBER? IT SEEMS HIGH TO ME.

15 DR. PLUNKETT: SURE. SO FOR THE LEGAL
16 TRAVEL BUDGET NUMBER, SO I THINK, AS EVERYBODY
17 KNOWS, ELONA'S POSITION IS VICE PRESIDENT -- I'M
18 SORRY -- GENERAL COUNSEL AND VICE PRESIDENT OF THE
19 BUSINESS DEVELOPMENT. AND ELONA AND I EACH HAVE A
20 NUMBER OF TRIPS PLANNED BOTH SEPARATELY AND TOGETHER
21 OVER THE COMING YEAR TO BIOTECHNOLOGY AND
22 PHARMACEUTICAL INDUSTRY MEETINGS WHERE WE INTEND TO
23 MEET WITH BOTH LARGE AND MIDSIZE COMPANIES WHO COULD
24 POTENTIALLY OFFER CO-FUNDING FOR CIRM-FUNDED
25 RESEARCH.

BARRISTERS' REPORTING SERVICE

1 IN ADDITION, ELONA HAS BEEN WORKING QUITE
2 EXTENSIVELY WITH THE ALLIANCE FOR REGENERATIVE
3 MEDICINE ON REGULATORY AND OTHER MATTERS THAT ARE
4 VERY IMPORTANT TO OUR GRANTEES IN TERMS OF
5 CLARIFYING AND STREAMLINING THE REGULATORY PATHWAY.
6 AND SO THERE ARE A NUMBER OF TRIPS TO THE
7 WASHINGTON, D.C. AREA WITH A REGULATORY FDA FOCUS.

8 CHAIRMAN THOMAS: DO WE HAVE A MOTION ON
9 THE TABLE TO APPROVE?

10 DR. FRIEDMAN: SO MOVED.

11 CHAIRMAN THOMAS: MOVED BY DR. FRIEDMAN.

12 DR. VUORI: SECOND.

13 CHAIRMAN THOMAS: SECONDED BY DR. VUORI.
14 ANY FURTHER DISCUSSION BY MEMBERS OF THE BOARD? ANY
15 PUBLIC COMMENT? MR. HARRISON, ANOTHER VOICE VOTE.

16 MR. HARRISON: CORRECT. WITH ROLL CALL
17 FOR THOSE ON THE PHONE.

18 CHAIRMAN THOMAS: THANK YOU. ALL THOSE IN
19 FAVOR OF THIS BUDGET FOR FISCAL 12-13 PLEASE SAY
20 AYE. OPPOSED? ABSTENTIONS? MARIA.

21 MS. BONNEVILLE: DUANE ROTH.

22 MR. ROTH: YES.

23 MS. BONNEVILLE: SHLOMO MELMED.

24 DR. MELMED: YES.

25 MS. BONNEVILLE: SHERRY LANSING.

BARRISTERS' REPORTING SERVICE

1 MS. LANSING: YES.

2 MS. BONNEVILLE: THANK YOU.

3 CHAIRMAN THOMAS: OKAY. ANOTHER UNANIMOUS
4 VOTE. THANK YOU VERY MUCH, MATT, FOR CONSIDERABLE
5 EFFORT AND HARD WORK.

6 OKAY. THE NEXT ITEM WHICH WILL BE THE, I
7 BELIEVE, THE FINAL INSTALLMENT OF THE SAGA IS DR.
8 FEIGAL PRESENTING FOR YOUR CONSIDERATION THE FINAL
9 VERSION OF THE STRATEGIC PLAN.

10 DR. FEIGAL: HI. THANKS VERY MUCH. AND
11 THE FIRST THING I WANT TO THANK IS REALLY THE
12 TREMENDOUS NUMBER OF INPUTS THAT WE RECEIVED FROM
13 PATIENTS, FROM PATIENT ADVOCATES, FROM COMPANIES,
14 FROM RESEARCHERS, CLINICIANS, FROM THE CIRM STAFF,
15 FROM THE LEADERSHIP LEVEL TO PEOPLE WORKING REALLY
16 IN THE TRENCHES TO GET THE WORK DONE, AND
17 PARTICULARLY ALAN TROUNSON, PAT OLSON, ELONA BAUM,
18 MATT PLUNKETT, AND WITH PARTICULAR HELP, I THINK, IN
19 TERMS OF PUTTING TOGETHER SOME OF THESE APPENDICES
20 FROM KELLY SHEPHERD AND FROM RAUL THAKKAR. IN
21 ADDITION, I REALLY WANT TO THANK THE BOARD FOR ALL
22 THEIR INPUTS AND PARTICULARLY UNDER THE LEADERSHIP
23 OF THE CHAIRMAN, JONATHAN THOMAS.

24 SO THIS IS A LIVING DOCUMENT, AND THIS
25 WILL GUIDE ALL OF OUR WORK. AND THIS PLAN THAT

BARRISTERS' REPORTING SERVICE

1 WE'RE PUTTING TOGETHER NOW, CIRM'S ORIGINAL
2 STRATEGIC PLAN WAS PUT TOGETHER IN 2006. IT WAS
3 UPDATED IN 2009-2010 IN PREPARATION FOR A PANEL OF
4 EXPERTS THAT CAME TO REVIEW OUR AGENCY. SO THIS
5 2012 UPDATE REALLY REFLECTS THE RECOMMENDATIONS FROM
6 THAT PANEL OF EXTERNAL REVIEW EXPERTS FROM 2010. IT
7 ALSO REFLECTS OTHER SHIFTS IN THE SCIENTIFIC FIELD
8 AND REFLECTS THE INPUTS FROM ALL OF OUR
9 STAKEHOLDERS, PATIENTS, INDUSTRY, RESEARCHERS,
10 CLINICIANS, AND THIS BOARD.

11 WE'VE HAD A LOT OF DIFFERENT INPUTS WHICH
12 I'LL JUST VERY QUICKLY SUMMARIZE HERE. INTERNALLY
13 WE HAD A CIRM SENIOR STAFF RETREAT AND A SCIENCE
14 TEAM RETREAT THAT STARTED BACK IN AUGUST OF 2011. I
15 DON'T MEAN IT STARTED BACK IN 2011. WE HAD A
16 RETREAT BACK THEN TO HAVE THAT KIND OF DISCUSSION.
17 WE'VE HAD UPDATES AT EACH OF THE ICOC BOARD MEETINGS
18 SINCE AUGUST OF 2011. SO WE'VE WALKED YOU THROUGH
19 IT STEP BY STEP AT EACH BOARD MEETING. WE MET WITH
20 THE STEM CELL RESEARCH LEADERS IN SEPTEMBER OF 2011.
21 AND IN ADDITION, WE HAD A VARIETY OF PUBLIC OR
22 PRIVATE TYPE OF MEETINGS FROM SEPTEMBER THROUGH
23 DECEMBER OF 2011 WITH INDUSTRY, WITH PATIENT
24 ADVOCATES, WITH ALL OF OUR COLLABORATIVE FUNDING
25 PARTNERS, WITH THE CLINICAL DEVELOPMENT ADVISORS.

BARRISTERS' REPORTING SERVICE

1 THOSE ARE THE PANEL OF ADVISORS THAT HELP GIVE US
2 INPUT ON OUR DISEASE TEAM RESEARCH AWARDS. WITH
3 PROFESSIONAL SOCIETIES AND WITH THE ALLIANCE FOR
4 REGENERATIVE MEDICINE.

5 IN ADDITION, WE PROVIDED ALL OF THE
6 STRATEGIC PLAN UPDATES WITH THE INSTITUTE OF
7 MEDICINE REVIEW COMMITTEE WHO IS REVIEWING CIRM AND
8 WILL COME UP WITH A FINAL REPORT AT THE END OF THIS
9 CALENDAR YEAR.

10 WE USED A THREE-STEP APPROACH TO REVISE
11 THIS STRATEGIC PLAN FOR 2012. AS MENTIONED, IT
12 STARTED WITH AN INTERNAL DISCUSSION OF WHERE WE'VE
13 BEEN, WHERE WE ARE, WHERE WE WANT TO GO, WHY WE WANT
14 TO GET THERE, AND HOW ARE WE GOING TO DO IT.

15 WE SOUGHT IN STEP TWO ALL THE VARIETY OF
16 INPUTS FROM THE BOARD, FROM THE PUBLIC, THE
17 INDUSTRY, AND FROM PATIENTS. AND WE'RE NOW AT THE
18 FINAL STEP, STEP 3, WHERE WE'RE FOCUSING ON THIS
19 FINAL STRATEGIC PLAN FOR YOUR CONSIDERATION.

20 IT STARTS WITH A MISSION AND A VISION. WE
21 HAVE A VERY AMBITIOUS MISSION, AND WE HAVE A VERY
22 CHALLENGING MISSION BECAUSE THERE'S A TIME URGENCY
23 AND A TIMELINE FOR IT. SO WE'RE REALLY HERE TO
24 SUPPORT AND ADVANCE STEM CELL RESEARCH AND
25 REGENERATIVE MEDICINE. WE'RE REALLY HERE TO ADVANCE

BARRISTERS' REPORTING SERVICE

1 THAT SCIENCE TO THE DISCOVERY AND THE DEVELOPMENT OF
2 CURES, THERAPIES, THE DIAGNOSTICS, AND THE RESEARCH
3 TECHNOLOGIES THAT CAN HELP PATIENTS. SO AT THE END
4 OF THE DAY AND AT THE BEGINNING OF THE DAY, WE'RE
5 HERE TO ACTUALLY DEVELOP THERAPIES AND POTENTIAL
6 CURES FOR PATIENTS.

7 THE FIRST STAGE OF CIRM WAS REALLY SET IN
8 EXPLORING THE FIELD. WE HAD TO CULTIVATE THE FIELD.
9 WE HAD TO BRING IN THE RESEARCH LEADERSHIP. WE
10 ACTUALLY HAD TO PHYSICALLY BUILD -- WE FUNDED THE
11 BUILDING OF THESE STEM CELL FACILITIES. AND IN
12 ADDITION, SEEDED THE FIELD WITH RESEARCH WITH OUR
13 FUNDING INITIATIVES. SO THIS WAS REALLY AN
14 EXPLORATION PHASE AND TO ESTABLISH THAT FOUNDATION
15 FOR LEADERSHIP IN STEM CELL RESEARCH IN THE FIELD.

16 THE NEXT FIVE YEARS, WHICH WE'RE IN NOW,
17 IS REALLY A PERIOD THAT WE BELIEVE SHOULD BE ONE OF
18 MORE FOCUS WHERE WE REALLY HAVE A TIME OF
19 PRIORITIZING OUR PROJECTS AND INVESTMENT. WE'RE NOW
20 AT A STAGE OF MATURATION AND SOPHISTICATION OF THE
21 STEM CELL FIELD WHERE WE'RE ABLE TO DRIVE AT LEAST A
22 COMPONENT OF THE SCIENCE INTO CLINICAL TRIALS TO
23 GENERATE SOME PRELIMINARY EVIDENCE OF THERAPEUTIC
24 BENEFIT. IT'S ALSO A TIME OF REALLY FORGING NEW AND
25 STRONGER PARTNERSHIPS WITH PATIENT ADVOCATES, WITH

BARRISTERS' REPORTING SERVICE

1 INDUSTRY, WITH DIFFERENT SCIENTIFIC DISCIPLINES BOTH
2 WITHIN CALIFORNIA, ACROSS THE UNITED STATES, AND
3 INTERNATIONALLY.

4 IN ADDITION, WE HAVE A LOT OF
5 COLLABORATIONS AND COOPERATION WITH PROFESSIONAL
6 SOCIETIES, WITH DIFFERENT ALLIANCES, AND ALSO WITH
7 THE FOOD AND DRUG ADMINISTRATION BECAUSE WE REALLY
8 NEED TO HELP FORGE THAT PATHWAY FOR THIS TYPE OF
9 INNOVATIVE TECHNOLOGY SO THAT IT REALLY CAN GET INTO
10 THE CLINIC. SO WE'RE NOT JUST A FUNDING AGENCY
11 ALONE. WE ALSO DO A LOT OF WORK IN PARALLEL TO
12 ESTABLISH THESE TYPES OF INTERACTIONS AND
13 RELATIONSHIPS TO HELP THE FIELD MOVE FORWARD.

14 AND WE'RE DOING ALL OF THIS SO THAT BY
15 2017 AND BEYOND WE CAN REALLY FACILITATE THE
16 COMMERCIALIZATION OF THESE THERAPIES. WE KNOW THAT
17 WE'RE NOT GOING TO DO IT ALONE. WE'RE NOT GOING TO
18 COMMERCIALIZE THE THERAPIES. THAT'S WHY WE HAVE TO
19 SET UP THESE COLLABORATIONS AND INTERACTIONS. WE
20 WANT TO ADVANCE THESE THERAPIES TO PATIENTS FROM
21 2017 AND BEYOND AND ALSO TO ENABLE A BUSINESS MODEL
22 SO THAT THESE STEM CELL COMPANIES AND DIFFERENT
23 AGENCIES THAT ARE GOING TO BE SUPPORTING THESE
24 THERAPIES CAN EXIST AND BE VIABLE.

25 SO WE DEVELOPED OBJECTIVES AND ALSO THE

BARRISTERS' REPORTING SERVICE

1 SINGLEMOST IMPORTANT KEY OUTCOMES OVER THE NEXT FIVE
2 YEARS. AND THESE OBJECTIVES AND OUTCOMES ALIGN WITH
3 OUR MISSION. AND WE DIVIDED THESE INTO FOUR
4 CATEGORIES: SCIENTIFIC, CLINICAL, ECONOMIC, AND
5 COMMUNITY.

6 UNDER SCIENTIFIC, THE MAJOR OBJECTIVE BY
7 2017 IS REALLY TO ACCELERATE THE UNDERSTANDING OF
8 STEM CELL SCIENCE AND ITS APPLICATION SO THAT WE
9 HAVE A BETTER UNDERSTANDING OF HUMAN DISEASES AND
10 INJURY WITH THE SINGLEMOST IMPORTANT KEY OUTCOME
11 SCIENTIFICALLY IS TO ACHIEVE TRANSFORMATIVE RESEARCH
12 DISCOVERIES. SOME OF OUR WORK MAY BE INCREMENTAL,
13 BUT WE THINK WHAT WE REALLY NEED TO DO IS ACHIEVE
14 SOME TRANSFORMATIVE RESEARCH ADVANCEMENT.

15 UNDER CLINICAL, OVER THE NEXT FIVE YEARS,
16 WE'LL ADVANCE STEM CELL SCIENCE INTO CLINICAL TRIALS
17 WITH THE PURPOSE OF ACHIEVING EVIDENCE OF
18 THERAPEUTIC BENEFIT FOR PATIENTS WITH OUR KEY MOST
19 IMPORTANT OUTCOME TO ACHIEVE CLINICAL PROOF OF
20 CONCEPT FOR STEM CELL THERAPIES. DO THESE WORK IS
21 REALLY OUR BIG QUESTION. CAN WE ESTABLISH SOME OF
22 THAT PRELIMINARY EVIDENCE TO SHOW THAT?

23 ECONOMICALLY, WE ARE GOING TO BE DRIVING
24 ECONOMIC DEVELOPMENT FOR CALIFORNIA FROM THE STEM
25 CELL SCIENCE AND FROM THE THERAPIES THAT WE'RE

BARRISTERS' REPORTING SERVICE

1 PUTTING OUT THERE. SOME OF THIS COULD BE REALIZED
2 WITHIN THE NEXT FIVE YEARS. PROBABLY MOST OF IT IS
3 WELL BEYOND THE NEXT FIVE YEARS. THE BIGGEST SINGLE
4 KEY OUTCOME WILL BE ONE OF LEVERAGING. CIRM HAS 3
5 BILLION WITHIN ITS DOMAIN TO WORK WITH. ALTHOUGH
6 THAT SOUNDS LIKE A VERY LARGE AMOUNT OF MONEY AND IT
7 IS, WE KNOW THAT MUCH MORE IS NEEDED TO REALLY MAKE
8 IT COME TO FRUITION. AND WHAT WE'RE REALLY TRYING
9 TO DO ECONOMICALLY IS TO LEVERAGE, TO ENTICE, TO
10 MULTIPLY THAT FUNDING FROM OTHERS OUTSIDE OF CIRM,
11 WHETHER IT BE FROM PRIVATE DONORS, VENTURE
12 CAPITALISTS, INDUSTRY, MATCHING FUNDS FROM
13 INSTITUTIONS, BUT REALLY LEVERAGE OUR INVESTMENT.

14 AND FOR THE COMMUNITY, TO MAINTAIN
15 CALIFORNIA AS THE WORLD STEM CELL LEADER SO THAT THE
16 COMMUNITY RECOGNIZES CALIFORNIA AS WELL AS IT HAVING
17 GLOBAL RECOGNITION AS THE STEM CELL STATE.

18 THESE ARE OUR STRATEGIES TO ACHIEVE OUR
19 OBJECTIVES AND GOALS. THEY'RE SET BY THE DIFFERENT
20 BINS THAT I'VE JUST OUTLINED: SCIENTIFIC, CLINICAL,
21 ECONOMIC, AND COMMUNITY, AND JUST CLEARLY TALKS
22 ABOUT WHAT OUR STRATEGIES ARE.

23 SCIENTIFICALLY WE KNOW WE'RE GOING TO NEED
24 TO CONTINUE THAT ENGINE OF DISCOVERY. WE'RE GOING
25 TO CONTINUE TO INVEST IN BASIC AND FUNDAMENTAL

BARRISTERS' REPORTING SERVICE

1 RESEARCH. WE KNOW WE NEED TO CONTINUE TO CREATE A
2 COLLABORATIVE RESEARCH COMMUNITY THAT ENHANCES
3 CALIFORNIA'S LEADERSHIP. AND WE KNOW THAT WE NEED
4 TO THINK ABOUT OUR FUNDING STRATEGY AND HOW TO
5 REALIGN OUR FUNDING PROGRAMS, OUR REVIEW, AND OUR
6 DECISION-MAKING WITH OUR STRATEGIC OBJECTIVES.

7 UNDER CLINICAL, WE'RE GOING TO HAVE TO
8 THINK ABOUT ARE THERE SOME NEAR-TERM OPPORTUNITIES
9 PERHAPS IN PARTICULAR TYPES OF DISEASES OR INJURIES
10 THAT WE MAY NEED TO BE THINKING ABOUT. IN THE
11 PREVIOUS FIVE YEARS, WE'VE BEEN VERY EXPLORATORY.
12 SHOULD WE NOW BE THINKING PERHAPS OF SOME MORE
13 SPECIFIC TYPES OF OPPORTUNITIES BASED ON EITHER THE
14 TECHNOLOGY OR THE DISEASE OR THE INJURY TO REALLY
15 EXPAND OUR COLLABORATIVE EFFORTS, TO REALLY, AS I
16 SAID, REALLY FOSTER DEVELOPING THAT REGULATORY PATH
17 FOR STEM CELL THERAPIES, AND TO HAVE PLANS IN PLACE
18 TO REALLY BOOST THE BIOTECHNOLOGY SECTOR IN
19 CALIFORNIA.

20 ONCE AGAIN, THIS IS GOING TO TAKE FOCUS,
21 PRIORITIZATION, AND EVALUATION SO THAT WE'RE MOVING
22 THE MOST PROMISING RESEARCH PROJECTS, PROGRAMS
23 FORWARD, AND THAT THIS IS GOING TO TAKE SOME VERY
24 HARD DECISION-MAKING FROM US INTERNALLY, FROM OUR
25 BOARD, FROM OUR GRANTS REVIEWERS, AND TO REALLY

BARRISTERS' REPORTING SERVICE

1 ENHANCE OUR INTERACTIONS WITH PATIENTS AND WITH
2 ADVOCATES.

3 ECONOMICALLY I THINK THE BIG KEY HERE, AS
4 I SAID, IS STRATEGIES TO IMPROVE OUR LEVERAGING OF
5 CIRM'S INVESTMENT. AND IN TERMS OF THE COMMUNITY,
6 IT'S REALLY PUTTING OUT STRATEGIES THAT WE'RE MORE
7 COMMUNICATING THE VALUE PROPOSITION OF CIRM AND OF
8 THE STEM CELL FIELD, WHY PEOPLE SHOULD CARE ABOUT
9 IT, AND REALLY CREATE AN AWARENESS AMONG
10 STAKEHOLDERS OF CIRM'S ROLE IN MAKING CALIFORNIA A
11 LEADER IN THE FIELD.

12 THESE ARE SOME OF THE TANGIBLE ONE-YEAR
13 GOALS THAT WE ARE SETTING OUT TO ACHIEVE BY JULY OF
14 2013, SO APPROXIMATELY A YEAR FROM NOW. SOME OF
15 THESE ARE QUALITATIVE, SOME OF THESE ARE
16 QUANTITATIVE. IT'S A MIX. BUT WHAT WE TRIED TO DO
17 IS HAVE A GOAL THAT ADDRESSES EACH OF THE BINS I'VE
18 JUST GONE THROUGH: SCIENTIFIC, CLINICAL, ECONOMIC,
19 AND COMMUNITY.

20 SO THE FIRST ONE HERE IS THAT WE WILL HAVE
21 WITHIN THE NEXT YEAR AT LEAST TWO PROGRAMS WITHIN
22 OUR PORTFOLIO THAT WILL HAVE AN APPROVED
23 INVESTIGATIONAL NEW DRUG FILED WITH THE U.S. FOOD
24 AND DRUG ADMINISTRATION TO ENTER HUMAN CLINICAL
25 TRIALS. WITHIN THE NEXT YEAR WE WILL HAVE ACHIEVED

BARRISTERS' REPORTING SERVICE

1 50 MILLION IN NEW OUTSIDE FINANCIAL COMMITMENT.
2 THIS COULD COME FROM COLLABORATIVE FUNDING PARTNERS,
3 FROM INDUSTRY, VENTURE CAPITALISTS, OR MATCHING
4 FUNDS FROM INSTITUTIONS. THIRDLY, THAT WE WILL HAVE
5 PRIORITIZED OUR SOLICITATIONS SO THAT WE HAVE A
6 HIGHER LIKELIHOOD OF ENSURING THAT POTENTIALLY HIGH
7 IMPACT PROJECTS THAT COULD RESULT IN TRANSFORMATIVE
8 RESEARCH ARE FUNDED. AND THAT WE WILL STRENGTHEN
9 THE EDUCATION EFFORTS AND MAKE A STRONGER EFFORT TO
10 ENGAGE THE CALIFORNIA COMMUNITY IN CIRM'S MISSION
11 AND ACHIEVEMENTS AND, IN PART, DOING THIS BY
12 INCREASING THE NUMBER OF MONTHLY ONLINE ENGAGEMENTS
13 FROM WHAT WE ARE NOW TO A LARGER NUMBER.

14 AND AS YOU HEARD EARLIER, WE'RE RAMPING UP
15 SOME THINGS, BUT THEN WE NEED TO KEEP IN MIND THE
16 EVENTUALITIES PERHAPS OF AT LEAST THE CURRENT
17 SITUATION WITH CIRM ENDING AT SOME POINT IN THE
18 FUTURE HOW TO OPTIMIZE OUR WORKFORCE, STAFFING, AND
19 PROCESSES SO THAT WE CAN MEET THE CHANGING
20 PRIORITIES, BUT STILL STAY WITHIN THE 6-PERCENT
21 CEILING.

22 THOSE ARE OUR ONE-YEAR GOALS FOR NEXT
23 YEAR. OUR FIVE-YEAR GOALS FOR JULY OF 2017, THERE'S
24 TEN OF THEM. AND ONCE AGAIN, THEY FOCUS ON THE
25 SCIENTIFIC, THE CLINICAL, THE ECONOMIC, AND THE

BARRISTERS' REPORTING SERVICE

1 COMMUNITY.
2 SO THE FIRST HERE IS THINKING ABOUT THE
3 FACTORS REGULATING THE SELF-RENEWAL AND
4 TUMOR-CAUSING POTENTIAL OF STEM CELLS AND THEIR
5 DERIVATIVES AND THAT THEY WILL BE IDENTIFIED AND
6 CHARACTERIZED. IN FIVE YEARS WE'LL HAVE A MORE
7 THOROUGH DESCRIPTION OF THE STEPS OF DIFFERENTIATION
8 THAT LEAD TO THE PRODUCTION OF THE CRITICAL CELLS IN
9 THE BODY THAT ARE NEEDED FOR TRANSPLANTATION. THAT
10 WE WILL HAVE FUNDED NEW APPROACHES FOR ENSURING
11 THERE CAN BE SUCCESSFUL ALLOGENEIC CELL
12 TRANSPLANTATION IN CLINICAL DEVELOPMENT. THAT WE
13 WILL HAVE ESTABLISHED PROOF OF PRINCIPLE IN
14 PRECLINICAL ANIMAL MODELS -- THIS IS A CRITICAL STEP
15 IN TERMS OF MOVING FORWARD INTO HUMANS -- IN
16 PRECLINICAL ANIMAL MODELS FOR THE TREATMENT OF MORE
17 THAN TEN DISEASES. AND IN ADDITION TO ANIMAL
18 MODELS, WE'RE WORKING ON THE NEW TECHNOLOGY WITH
19 DISEASE IN THE DISH AND THE IPS STEM CELL-BASED
20 TECHNOLOGY WHERE WE'LL CREATE DISEASE-SPECIFIC CELL
21 LINES FOR 20 TO 30 DIFFERENT DISEASES AND USE THEM
22 TO GAIN NEW INFORMATION ABOUT THE UNDERLYING
23 PATHOGENESIS OF DISEASE, BUT, IN ADDITION, USE THIS
24 STEM CELL-BASED TECHNOLOGY HERE AS A TOOL RATHER
25 THAN AS THERAPY TO IDENTIFY NEW DRUG TARGETS FOR

BARRISTERS' REPORTING SERVICE

1 DISCOVERY OF NEW THERAPEUTICS.

2 IN ADDITION, IN THE NEXT FIVE YEARS WE'LL
3 HAVE DEVELOPED NEW PROCEDURES FOR THE PRODUCTION OF
4 A VARIETY OF STEM OR PROGENITOR CELLS THAT CAN MEET
5 THE REQUIREMENTS FOR GOING INTO CLINICAL
6 APPLICATION. SO HERE WE ARE TALKING ABOUT IT BEING
7 USED FOR THERAPY.

8 AND THAT WE WILL HAVE 20 CIRM-FUNDED
9 PROGRAMS WITH OUTSIDE CAPITAL COMMITMENTS FOR
10 FUNDING DEVELOPMENT WORK. THAT WE'LL HAVE TEN
11 THERAPIES IN PHASE I OR II CLINICAL TRIALS IN AT
12 LEAST FIVE DIFFERENT THERAPEUTIC AREAS BASED ON STEM
13 CELL RESEARCH. AND THAT WE WILL HAVE SHOWN CLINICAL
14 PROOF OF CONCEPT, THAT TRANSPLANTED CELLS DERIVED
15 FROM PLURIPOTENT OR PROGENITOR CELLS CAN BE USED TO
16 RESTORE FUNCTION IN DISEASE OR INJURY. THAT'S
17 PROBABLY OUR MOST AMBITIOUS GOAL. AND THAT WE WILL
18 HAVE EDUCATED AND ENGAGED THE CALIFORNIA COMMUNITY
19 IN CIRM'S MISSION AND ACHIEVEMENTS. AND ONCE AGAIN,
20 WE'RE TRYING TO QUANTITATE IT WITH SPECIFYING THE
21 NUMBER OF INCREASE OF MONTHLY ONLINE ENGAGEMENTS.

22 SO WHAT WE TRIED TO DO IS GIVE YOU SOME
23 VERY TANGIBLE ONE- AND FIVE-YEAR GOALS AND OUTCOMES,
24 HOW THEY TIE TO OUR STRATEGIC OBJECTIVES, AND HOW
25 THEY ALIGN WITH OUR VISION AND MISSION. AND NONE OF

BARRISTERS' REPORTING SERVICE

1 THIS IS GOING TO WORK UNLESS WE ALIGN OUR RESEARCH
2 FUNDING STRATEGY WITH OUR STRATEGIC PLAN. SO THE
3 INTENT IS THAT DOCUMENT WON'T BE SOMETHING THAT WE
4 PUT ON THE SHELF, BUT WE WILL USE IT. AND IT SHOULD
5 BE GUIDING THE DEVELOPMENT OF OUR CONCEPTS, OUR
6 SOLICITATIONS. IT SHOULD BE INFORMING THE GRANT
7 REVIEW GROUP RECOMMENDATIONS. IT SHOULD BE
8 INFORMING THE ICOC BOARD DECISIONS. AND IT SHOULD
9 INFORM HOW WE PRIORITIZE WHERE WE PUT OUR RESOURCES
10 AND HOW WE ALLOCATE THEM.

11 IN ADDITION, I SAID AT THE BEGINNING THIS
12 IS A LIVING DOCUMENT. STUFF HAPPENS. SO WE'RE
13 GOING TO HAVE RESEARCH TAKING PLACE, PROGRESS
14 UPDATES, OUTCOMES, CHANGES IN THE FIELD. THESE TOO
15 ARE GOING TO INFORM OUR ACTIONS. AND WE'LL BE
16 PROVIDING THE BOARD AS WELL AS THE PUBLIC REGULAR
17 INTERVAL UPDATES OF PROGRESS AND OF OUTCOMES AND OF
18 CHANGES IN THE FIELD. SO IT MAY BE WE NEED TO
19 REFINE THE PLAN ACCORDING TO THE REALITY AROUND US.

20 I WANT TO REMIND YOU OF SOME OF THE
21 FUNDING THAT YOU'VE HEARD IN PREVIOUS MEETINGS JUST
22 SO YOU CAN SEE HOW IT FITS AT THIS PARTICULAR
23 SNAPSHOT IN TIME AND REALIZING IT'S GOING TO CHANGE.
24 THIS WAS A SNAPSHOT AT ABOUT FEBRUARY, A FEW MONTHS
25 AGO, WITH A NUMBER OF AWARDS AND ALLOCATION OF

BARRISTERS' REPORTING SERVICE

1 DOLLARS AT THAT PARTICULAR MOMENT IN TIME. SO THIS
2 IS FLUID. THESE PIE CHARTS ARE GOING TO LOOK
3 SLIGHTLY DIFFERENT. BUT WE GAVE YOU TWO DIFFERENT
4 SCENARIOS THAT MIGHT HAPPEN IN THE FUTURE, POTENTIAL
5 SCENARIOS.

6 SO IF WE LOOK AT THE END OF THE \$3 BILLION
7 OF FUNDING, THIS IS THE WAY THE PROPORTION OF
8 FUNDING COULD LOOK BASED ON WHERE THE FUNDING GOES
9 OVER THE LIFESPAN OF CIRM. AT THE END OF THAT 3
10 BILLION OF SPENDING, IT WOULD BE APPROXIMATELY 30
11 PERCENT SPENT IN FACILITIES, CORE RESOURCES,
12 TRAINING, AND CAREER DEVELOPMENT. ABOUT 30 PERCENT
13 IN BASIC RESEARCH AND TRANSLATIONAL RESEARCH, AND A
14 LITTLE MORE THAN A THIRD DEVELOPMENT RESEARCH.

15 SCENARIO TWO, VERY SIMILAR. WE HAVE A
16 LITTLE BIT MORE IN FACILITIES, CORE RESOURCES,
17 TRAINING, AND CAREER DEVELOPMENT. BUT THE
18 PROPORTIONS ARE RELATIVELY SIMILAR.

19 WHAT WE DO KNOW IS THAT WE DO ANTICIPATE,
20 BASED ON OUR STRATEGIC PLAN, THAT THE PROPORTION OF
21 THE MONEY THAT WE EXPEND ON TRANSLATIONAL AND
22 DEVELOPMENT, IF WE'RE TO FOLLOW OUR STRATEGIC PLAN,
23 WILL INCREASE. RIGHT NOW OUR TRANSLATIONAL AND
24 DEVELOPMENT PROGRAMS REPRESENT ABOUT 9 PERCENT BY
25 NUMBER AND ABOUT 31 PERCENT OF THE 1.28 BILLION

BARRISTERS' REPORTING SERVICE

1 THAT'S ALLOCATED TO FUNDED PROGRAMS TODAY. WHAT
2 I'VE SHOWN HERE IS THE CHEVRON OF PRODUCT
3 DEVELOPMENT FROM BASIC RESEARCH IN PHASE II, AND
4 UNDER THIS I'VE SHOWN THE DIFFERENT TRANSLATIONAL
5 AND DEVELOPMENT INITIATIVES THAT COVER THE SPECTRUM
6 OF WHAT WE FUND RIGHT NOW.

7 SOME OF THESE HAVE ALREADY COME TO YOU.
8 SOME OF THESE WILL COME TO YOU IN JULY OR BY THE END
9 OF THE YEAR. FOR EXAMPLE, DISEASE TEAM II
10 INITIATIVE WILL COME TO YOU IN JULY, AND THE
11 STRATEGIC PARTNERSHIP FUND WILL COME TO YOU LATER
12 THIS YEAR. THE REASON I'M BRINGING THIS UP IS YOU
13 LOOK AT INITIATIVES ONE AT A TIME, BUT WE ALWAYS
14 HAVE TO KEEP IN MIND WHERE WE'RE TRYING TO GO. AND
15 THE FACT THAT IF A CERTAIN NUMBER OF MERITORIOUS
16 PROGRAMS AREN'T MET AT ONE POINT IN TIME, IT DOESN'T
17 MEAN THAT THERE COULDN'T BE SOME FUNGIBILITY IN
18 TERMS OF WHERE THOSE DOLLARS THAT MAYBE DON'T GET
19 ALLOCATED TODAY MIGHT BE ABLE TO BE USED IN THE
20 FUTURE. SO EVERYBODY KNOWS THAT. I'M JUST
21 EXPLICITLY STATING THAT.

22 WHAT I DID WITH THESE PIE CHARTS IS
23 ACTUALLY SHOW YOU THE PERCENTAGE AND ALLOCATION OF
24 FUNDING ON THE BUCKETS OF WHAT'S ALREADY BEEN
25 FUNDED, WHAT'S BEEN CONCEPT APPROVED, AND WHAT THE

BARRISTERS' REPORTING SERVICE

1 POTENTIAL FUTURE SCENARIOS COULD BE JUST TO SHOW YOU
2 IN A NUTSHELL HOW THE PROPORTIONS WILL BE EXPECTED
3 TO CHANGE.

4 IF WE LOOK AT THE FACILITIES, CORE
5 RESOURCES, TRAINING, AND CAREER DEVELOPMENT, IT
6 REPRESENTS WITH THE CURRENT FUNDED ABOUT 25 PERCENT
7 RIGHT NOW -- I'M SORRY -- 25 PERCENT FOR FACILITIES
8 AND CORE RESOURCES, ABOUT 25 PERCENT FOR TRAINING
9 AND CAREER DEVELOPMENT, ABOUT 33 PERCENT FOR BASIC
10 AND TRANSLATIONAL RESEARCH, AND ABOUT 18 PERCENT
11 RIGHT NOW FOR DEVELOPMENT.

12 IF WE LOOK AT CONCEPT APPROVED, WE CAN SEE
13 THAT THE DEVELOPMENT SLICE OF THE PIE IS INCREASING
14 FROM ABOUT 18 PERCENT ALMOST TO 50 PERCENT. SO
15 YOU'RE GOING TO SEE THESE PROPORTIONS CHANGE OVER
16 TIME. AND THEN IF YOU LOOK AT THE FUTURE, YOU CAN
17 SEE IT CHANGING AGAIN. I THINK FOR PURPOSES OF
18 TIME, I WON'T SPEND MUCH MORE ON THAT. BUT IT'S
19 JUST TO SHOW YOU THE PREVIOUS PIE SHOWED YOU OVERALL
20 THE 3 BILLION WHAT THE PROPORTIONS WOULD LOOK LIKE.
21 WHAT THIS IS TRYING TO SHOW YOU IS, ACCORDING TO THE
22 DIFFERENT POINTS IN TIME OF CIRM, HOW THE
23 PROPORTIONS ARE GOING TO CHANGE.

24 SO ONCE AGAIN, IF WE PUT OUR BETS RIGHT
25 AND STRATEGICALLY THINK ABOUT OUR ALLOCATION AND OUR

BARRISTERS' REPORTING SERVICE

1 PRIORITIES, WE HAVE ABOUT 1.5 BILLION LEFT OF CIRM
2 FUNDING TO ACHIEVE OUR KEY OUTCOMES. THIS IS NOT
3 TAKING INTO ACCOUNT, OF COURSE, THE LEVERAGING OF
4 CIRM INVESTMENTS FROM OTHER TYPES OF ENTITIES. BUT
5 WHAT REMAINS TO BE ACHIEVED ARE OUR KEY STRATEGIC
6 OUTCOMES WHICH INCLUDE ACHIEVING TRANSFORMATIVE
7 RESEARCH DISCOVERIES, ACHIEVING CLINICAL PROOF OF
8 CONCEPT FOR STEM CELL THERAPIES, LEVERAGING OUR
9 INVESTMENT, AND HAVING CALIFORNIA BE GLOBALLY
10 RECOGNIZED AS THE STEM CELL STATE.

11 SO THAT'S GIVING YOU, I THINK, JUST THE
12 KEY POINTS OF WHAT WE'VE BEEN TALKING ABOUT SINCE
13 AUGUST OF LAST YEAR AND JUST PUT IT ALTOGETHER IN
14 ONE PACKAGE FOR YOU.

15 AND I ALSO NEGLECTED TO ALSO THANK, I
16 MEANT TO DO THIS, DON GIBBONS WHO ACTUALLY SPENT
17 QUITE A BIT OF TIME WITH THE WRITING AND THE
18 EXECUTIVE SUMMARY, AND I ALSO WANTED TO THANK ANKA
19 URBAN WHO'S DONE A LOT OF WORK JUST PUTTING THE
20 MANUSCRIPT TOGETHER, PUTTING ALL THE APPENDICES
21 TOGETHER FOR YOU, MAKING SURE ALL THE LINKS WORK
22 WHEN YOU TRY TO GO TO THOSE DIFFERENT PAPERS.

23 SO YOU'VE GOT THE FINAL PLAN IN YOUR
24 BINDER. YOU'VE SEEN THE KEY POINTS FROM THIS
25 PRESENTATION. SO REALLY THE CONSIDERATION TODAY IS

BARRISTERS' REPORTING SERVICE

1 OF THIS FINAL VERSION. AND PERHAPS BEFORE THE VOTE,
2 IF YOU HAVE ANY QUESTIONS, I'D BE HAPPY TO ANSWER
3 THEM.

4 CHAIRMAN THOMAS: SENATOR TORRES.

5 MR. TORRES: ELLEN, I JUST WANT TO THANK
6 YOU FOR ALL THE HARD WORK THAT YOU AND THE PEOPLE
7 THAT YOU MENTIONED ALREADY, I WON'T MENTION THEM
8 AGAIN, FOR THEIR INPUT AND THEIR TRANSPARENCY TO
9 THOSE OF US THAT ARE THERE IN THE OFFICE, BUT ALSO
10 OTHER BOARD MEMBERS AS WELL TO SEEK THE INPUT. AND
11 ALSO THE FACT THAT YOU ALL TOOK THE TIME TO SEEK THE
12 INPUT OF PATIENT ADVOCATES. THAT'S EXTREMELY
13 IMPORTANT AS WE MOVE FORWARD BECAUSE WE HAVE TO MOVE
14 FORWARD TOGETHER. SO I MOVE THAT WE ADOPT THE
15 REPORT.

16 DR. LUBIN: SECOND.

17 CHAIRMAN THOMAS: SECOND BY DR. LUBIN. IS
18 THERE FURTHER DISCUSSION? MR. SHEEHY.

19 MR. SHEEHY: FIRST, I DO WANT TO
20 COMPLIMENT DR. FEIGAL AND STAFF, EVERYBODY INVOLVED
21 IN THIS. THIS IS A GREAT PRODUCT.

22 I HAD ONE -- AND THE PROCESS I THINK HAS
23 BEEN OUTSTANDING. I HAD ONE QUESTION. TWO
24 SCENARIOS ARE POSED. AND WHEN DOES THAT DECISION
25 POINT COME TO US? BECAUSE I WOULD BE RELUCTANT TO

BARRISTERS' REPORTING SERVICE

1 VOTE ON THIS WITH THAT BEING LEFT OUT THERE. I
2 PERSONALLY FEEL THE TRAINING ASPECT OF WHAT WE DO IS
3 VERY IMPORTANT. THE BRIDGES PIECE OF IT, TO ME, IS
4 ABSOLUTELY CRITICAL. BUT I KNOW OTHERS MAY NOT FEEL
5 THE SAME WAY, BUT AT SOME POINT WE SHOULD KIND OF
6 REACH THAT DECISION POINT.

7 CHAIRMAN THOMAS: DR. TROUNSON.

8 DR. TROUNSON: SO I THINK THAT'S A VERY
9 IMPORTANT POINT BECAUSE THERE WAS NO FINAL DECISION
10 ON IT, JEFF. AND SO I THINK WHAT WE SHOULD DO MAYBE
11 IS BRING IT FORWARD AS A SEPARATE ITEM BECAUSE THERE
12 WAS A LOT OF MATERIAL IN HERE. AND SO WITH YOUR
13 INDULGENCE, BOARD, I THINK IF WE COME FORWARD AT THE
14 NEXT BOARD MEETING AND CREATE A LITTLE SPOT ABOUT
15 DISCUSSING WHICH IS THE BEST SCENARIO, GIVE YOU A
16 LITTLE BIT MORE INFORMATION ON IT, AND THEN HAVE YOU
17 GIVE YOUR VIEWS BACK TO US. I THINK WE OUGHT TO
18 THINK THAT THAT OUGHT TO BE ABLE TO BE CHANGED IN
19 TIME BECAUSE THINGS WILL CHANGE IN TIME FOR US. BUT
20 IF YOU COULD GIVE US -- I THINK THE NEXT TIME, IF
21 YOU CAN GIVE US A CITE ABOUT WHETHER YOU PREFER ONE
22 OR THE OTHER, THEN WE'LL WORK TOWARDS THAT, BUT BE
23 UNDERSTANDING THAT WE COULD ALTER THAT AS WE MOVE
24 FORWARD, BUT THAT BEING THE POSITION THAT WE TAKE AT
25 THAT POINT IN TIME. IS THAT OKAY?

BARRISTERS' REPORTING SERVICE

1 MR. SHEEHY: YEAH. I THINK THAT'S
2 REASONABLE. I JUST THINK WE NEED TO -- BECAUSE
3 THOSE PROGRAMS HAVE BEEN GOING TOO, THEY'LL NEED
4 TO -- IF THOSE ARE GOING TO GO AWAY, I THINK THOSE
5 PEOPLE WHO ARE DOING THAT WILL NEED TO KNOW THAT.

6 DR. FEIGAL: THE WAY I ARTICULATED IN THE
7 PLAN IS THOSE ARE JUST POTENTIAL SCENARIOS. SO I
8 DON'T THINK IT LOCKED IN.

9 CHAIRMAN THOMAS: DR. OLSON, DID YOU HAVE
10 A COMMENT?

11 DR. OLSON: I JUST WANTED TO ELABORATE ON
12 THAT POINT. I MEAN SO, FOR EXAMPLE, AS ELLEN SAID,
13 THAT WAS A SNAPSHOT IN TIME, THOSE FINANCIAL
14 SCENARIOS. BASED ON THE DECISIONS THIS BOARD MADE
15 TODAY AS FAR AS VOTING FOR AN EARLY TRANSLATION,
16 THERE'S SUDDENLY \$30 MILLION APPROXIMATELY THAT WAS
17 CONCEPT APPROVED THAT WE ASSUMED WAS ALLOCATED THAT
18 NOW COULD BE AVAILABLE FOR BEING ALLOCATED
19 DIFFERENTLY. SO I THINK THE POINT WAS THAT THE
20 BOARD NEEDS TO -- WHAT I THINK I WAS TRYING TO GET
21 ACROSS AT THE MEETING WAS THAT THE BOARD HAS TO
22 RECOGNIZE THAT TO ACHIEVE THE MOST COSTLY OBJECTIVE,
23 ESSENTIALLY THE DEVELOPMENT OBJECTIVE, THE CLINICAL
24 DEVELOPMENT PROOF OF CONCEPT, THAT A SUBSTANTIAL
25 AMOUNT OF MONEY WILL HAVE TO BE SPENT ON

BARRISTERS' REPORTING SERVICE

1 DEVELOPMENT-TYPE PROGRAMS, PARTICULARLY CLINICAL
2 STAGE PROGRAMS, BUT THAT THERE WILL ALWAYS BE THE
3 OPPORTUNITY FOR A DISCUSSION AT EVERY CONCEPT
4 APPROVAL AND PERHAPS A SUMMARY DISCUSSION ON AN
5 ANNUAL BASIS AT THE BOARD'S WHAT THEY WANT TO DO.
6 BUT IT WAS NOT INTENDED TO SAY THIS IS A DECISION
7 THAT HAS TO BE MADE NOW.

8 DR. FEIGAL: YEAH. THAT'S ABSOLUTELY
9 RIGHT. I MEAN THIS IS GOING TO CHANGE. THESE PIE
10 CHARTS ARE GOING TO BE DIFFERENT TOMORROW BASED ON
11 DECISIONS.

12 MR. SHEEHY: I THINK IT'S HELPFUL BECAUSE
13 I THINK, LIKE OUR DISCUSSION WE HAD EARLIER, AND
14 WE'RE GOING TO BE THINKING ABOUT HOW FAR TO STRETCH
15 OURSELVES, AND YOU KIND OF ALLUDED TO THIS WHEN WE
16 WERE HAVING THE CONVERSATION. WE'RE NOW IN THE
17 REALM OF TRADE-OFFS. SO IF WE DECIDE TO PICK UP
18 THAT EXTRA DC PROJECT AND THEN WE'RE GOING TO TURN
19 AROUND AND SAY WE ALSO WANT TO DO TRAINING AND THEN
20 WE ALSO WANT TO DO A STRATEGIC PARTNERSHIP, I MEAN
21 AT SOME POINT WE NEED TO HAVE THESE CHOICES A LITTLE
22 BIT FURTHER IN THE FOREFRONT OF OUR BRAINS AND NOT
23 NECESSARILY BACK THERE LIKE WE HAVE AN INFINITE
24 AMOUNT OF MONEY TO SPEND.

25 SO THAT'S AS MUCH AS ANYTHING WHY I WOULD

BARRISTERS' REPORTING SERVICE

1 LIKE PEOPLE TO BE THINKING SERIOUSLY ABOUT THIS AS
2 WE GO THROUGH BOTH TODAY, AND THEN NEXT MONTH WE'RE
3 GOING THROUGH A BIG ROUND WHERE WE MAY HAVE PEOPLE
4 WITH PETITIONS AND A LOT OF COMPELLING ARGUMENTS TO
5 SPEND ANOTHER \$20 MILLION HERE, ANOTHER \$20 MILLION
6 THERE. WE SHOULD BE VERY CAUTIOUS AND THINK ABOUT
7 WHAT THE COST IS DOWN THE ROAD.

8 DR. TROUNSON: WHAT I'D LIKE TO DO IS
9 MAYBE EVEN HAVE IT AS A COMPONENT PART THAT JUST
10 MOVES ALL THE TIME JUST SO THAT THE AWARENESS IS
11 THERE, SO THAT YOUR AWARENESS IS THERE. AND THEN IF
12 YOU WANT TO CHANGE SOMETHING, THEN WE CAN LOOK AT
13 THE WAY IT MIGHT CHANGE IT. BUT IF WE CAN BRING
14 THAT BACK TO YOU THE NEXT MEETING, I THINK IT WOULD
15 BE GOOD FOR US TO THINK ABOUT HOW BEST TO SORT OF
16 HAVE IT AS AN ONGOING PROCESS IF YOU WILL INDULGE US
17 IN THAT.

18 MR. SHEEHY: I THINK THAT'S A GREAT IDEA.
19 THANKS, DR. TROUNSON.

20 CHAIRMAN THOMAS: ANY OTHER COMMENTS BY
21 MEMBERS OF THE BOARD?

22 MS. SAMUELSON: I'VE GOT A COUPLE
23 QUESTIONS. I'M WONDERING ABOUT THE CHOICE OF
24 QUANTITY, THE 30 PROJECTS IN CLINICAL DEVELOPMENT OR
25 WORDS TO THAT EFFECT. IT SOUNDS TO ME LIKE IT COULD

BARRISTERS' REPORTING SERVICE

1 BE SUPPLANTING SOME SIGNIFICANT BREAKTHROUGH IN A
2 VERY, VERY GNARLY DISORDER, ONE OF THE
3 NEURODEGENERATIVE ONES, FOR EXAMPLE.

4 DR. FEIGAL: WELL, I MEAN ANY TARGET
5 IS -- YOU KNOW, WHAT WE DID IS LANDSCAPE WHERE WE
6 ARE, WHAT WE KNOW WE HAVE IN THE PIPELINE, AND I
7 THINK WHAT WE PUT TOGETHER ARE NOT FANTASY NUMBERS.
8 I THINK WE ACTUALLY TRIED TO BASE IT AT LEAST ON
9 PROJECTED DATA AND WHERE WE THOUGHT THE FIELD COULD
10 TAKE US. SO WE TRIED TO ARRIVE AT WHAT WE THOUGHT
11 WERE ACHIEVABLE NUMBERS.

12 MS. SAMUELSON: HOW MANY OF THOSE INCLUDED
13 THOSE?

14 DR. FEIGAL: EXCUSE ME?

15 MS. SAMUELSON: HOW MANY INCLUDED THOSE
16 VERY DIFFICULT TO ACHIEVE DISORDERS?

17 DR. FEIGAL: WELL, I MEAN WE DIDN'T
18 SPECIFY WHICH DISEASES THEY HAD TO BE. WE DIDN'T
19 PROSCRIBE WHAT WAS IN THAT LIST, BUT WE DID LOOK AT
20 A VARIETY OF THINGS. AND WE THOUGHT ON AVERAGE
21 THAT'S WHERE IT COULD BE. I CAN'T TELL YOU IF IT
22 WILL BE IN HEMOPHILIA OR IF IT WILL BE IN HIV. I
23 MEAN I DON'T KNOW WHAT THOSE 20 TO 30 DIFFERENT
24 PRECLINICAL DISEASES WILL BE.

25 ALSO, THE TEN THERAPY, THE CLINICAL

BARRISTERS' REPORTING SERVICE

1 TRIALS, PART OF IT IS GOING TO DEPEND, I THINK, ON
2 OUR PRIORITIZATION OF THE SCIENCE AND THE
3 OPPORTUNITIES WITH WORKSHOPS THAT WE'RE GOING TO BE
4 HAVING THAT WILL HELP DETERMINE WHERE THOSE -- WHAT
5 DISEASES WE MAY WANT TO INVEST IN. SO WE HAVEN'T
6 PROSCRIBED WHICH DISEASES THEY NEED TO BE AT THIS
7 POINT IN TIME, BUT WE MAY WORK THAT OUT OVER THE
8 NEXT FIVE YEARS.

9 MS. SAMUELSON: IT WOULD SEEM TO ME AT
10 SOME POINT YOU'D NEED TO THINK ABOUT THAT.

11 DR. FEIGAL: YES. I AGREE.

12 MS. SAMUELSON: AND WE WOULD. THIS IS
13 SUPPOSED TO BE OUR DOCUMENT, I THINK.

14 DR. FEIGAL: CORRECT. WE'RE ALL IN THIS
15 TOGETHER. I AGREE.

16 MS. SAMUELSON: YEP. YEP.

17 CHAIRMAN THOMAS: ANY OTHER COMMENTS?

18 MS. SAMUELSON: I DIDN'T SEE ANY -- ONE
19 MORE QUESTION. I DIDN'T SEE ANY REFERENCE TO A
20 FUTURE ROLE FOR THE GRANTS WORKING GROUP AS OPPOSED
21 TO THE EXTERNAL ADVISORY BOARD. THERE WAS ONE
22 REFERENCE ABOUT ITS ROLE AND COMPARING IT TO THE
23 GRANTS WORKING GROUP, BUT I DIDN'T SEE A FUTURE ROLE
24 FOR THE GRANTS WORKING GROUP.

25 DR. FEIGAL: WELL, ACTUALLY I HAVE --

BARRISTERS' REPORTING SERVICE

1 MS. SAMUELSON: THE STATUTE, OF COURSE,
2 DOES CREATE ONE.

3 DR. FEIGAL: WELL, I MEAN GRANTS WORKING
4 GROUP WILL REMAIN A PART OF THIS. WE HAVEN'T
5 REDEFINED THEIR ROLE, BUT WE JUST -- WE HAVE
6 INCLUDED THEM IN THE FUTURE. I GUESS I'M NOT SURE I
7 UNDERSTAND YOUR QUESTION.

8 MS. SAMUELSON: IN ANYTHING BEYOND GRANTS
9 REVIEW, SUCH AS THE INPUT THAT WE GOT AT THE END OF
10 THE LAST --

11 DR. FEIGAL: I DIDN'T GO INTO TACTICS
12 HERE. SO WE CAN DISCUSS WHAT KIND OF ADDITIONAL
13 ROLES WE THINK WOULD BE APPROPRIATE TO HAVE.

14 CHAIRMAN THOMAS: OKAY. IT'S BEEN MOVED
15 AND SECONDED. I WOULD LIKE TO ECHO THE COMMENTS.
16 ELLEN AND EVERYBODY WHO WORKED ON THIS, THIS IS A
17 THOROUGHLY PROFESSIONAL, HIGHLY CONSIDERED, REASONED
18 DOCUMENT, AND I THINK WE SHOULD ALL BE VERY PROUD OF
19 THIS, AND IT SETS THE REAL TONE FOR THE NEXT FIVE
20 YEARS. SO THANK YOU TO EVERYBODY.

21 DO WE HAVE ANY COMMENTS FROM MEMBERS OF
22 THE PUBLIC?

23 (APPLAUSE.)

24 CHAIRMAN THOMAS: HEARING NONE -- YES.
25 DR. TROUNSON.

BARRISTERS' REPORTING SERVICE

1 DR. TROUNSON: JUST VERY BRIEFLY, WE'VE
2 ASKED KEVIN TO PREPARE A VERY LAY SHORT DESCRIPTION
3 SO THAT THAT CAN BE EASILY DIGESTED BY PEOPLE IN A
4 VERY QUICK TIME. SO WE'LL HAVE THAT AVAILABLE OVER
5 THE NEXT FEW WEEKS AND MAKE SURE YOU GET TO SEE
6 THAT, BUT IT WILL BE A SHORT LAY DESCRIPTION OF JUST
7 ONE AND A HALF PAGES. SO IF YOU'RE ASKED, YOU GET
8 THE KEY ELEMENTS IN A VERY LAY WAY FROM IT IF THAT'S
9 OKAY WITH YOU.

10 CHAIRMAN THOMAS: THAT'S GREAT. ALWAYS
11 ANYTHING IN PLAIN ENGLISH IS ALWAYS VERY HELPFUL.
12 NOT TO SAY THIS ISN'T, ELLEN. MORE SUCCINCT PLAIN
13 ENGLISH.

14 ANYWAY, ALL THOSE IN -- MR. HARRISON,
15 ANOTHER VOICE VOTE PRESUMABLY.

16 MR. HARRISON: YES. EXCEPT FOR THOSE ON
17 THE PHONE.

18 CHAIRMAN THOMAS: YES. ALL THOSE IN FAVOR
19 PLEASE SAY AYE. OPPOSED? ABSTENTIONS? MARIA.

20 MS. BONNEVILLE: I SEE WE'RE GETTING
21 PUNCHY. DUANE ROTH.

22 MR. ROTH: YES. ANY MORE SINGING, I'M NOT
23 GOING TO VOTE. MY CONGRATULATIONS TO THE WHOLE
24 GROUP. THEY DID A TERRIFIC JOB ON THIS.

25 MS. BONNEVILLE: SHLOMO MELMED. SHERRY

BARRISTERS' REPORTING SERVICE

1 LANSING.

2 MS. LANSING: YES.

3 CHAIRMAN THOMAS: THANK YOU. AND, ELLEN,
4 CONGRATULATIONS.

5 OKAY. WE'RE NOW GOING TO MOVE TO ITEM 13,
6 WHICH IS CONSIDERATION OF THE CONTRACT OF THE REMCHO
7 FIRM. THIS IS ONE I DON'T THINK NEEDS A WHOLE LOT
8 OF INTRODUCTION. AS EVERYBODY KNOWS, THE REMCHO
9 FIRM, AND JAMES IN PARTICULAR, HAVE BEEN AN INTEGRAL
10 PART OF EVERYTHING CIRM HAS DONE STARTING BEFORE THE
11 OUTSET. AND THEY HAVE BEEN INVOLVED IN BASICALLY
12 EVERY IMPORTANT ASPECT OF WHAT CIRM HAS ACCOMPLISHED
13 SINCE THAT POINT. SPECIFICALLY MATTERS THAT THE
14 FIRM ARE INVOLVED IN INCLUDE GOVERNING BOARD AND ITS
15 SUBCOMMITTEES, IOM REVIEW, IP AND LOAN PROGRAM,
16 CONFLICTS AND STATUTORY COMPLIANCE, INTERACTING WITH
17 LEGISLATORS AND VARIOUS OTHERS IN SACRAMENTO, AND
18 MULTIPLE TIMES A DAY CONSULTATION WITH THE CHAIR AND
19 WITH MEMBERS OF THE CIRM STAFF, AND BASICALLY JUST
20 VERY, VERY CENTRAL ROLE IN EVERYTHING.

21 I KNOW THAT MY FIRST YEAR HERE I GREATLY
22 VALUED JAMES' INPUT. I KNOW HE'S TRYING TO, LIKE,
23 NOT LISTEN TO THIS AND PAY ATTENTION TO ALL THE
24 ACCOLADES, BUT IT IS A FACT. HE'S BEEN AN
25 INVALUABLE RESOURCE TO ME AND TO EVERYBODY HERE AT

BARRISTERS' REPORTING SERVICE

1 CIRM.

2 THE CONTRACT CALLS FOR APPROVAL OF
3 REMCHO'S WORK FOR FISCAL 12-13 IN THE AMOUNT OF
4 \$550,000. I VERY MUCH MOVE APPROVAL OF THAT IF
5 SOMEBODY WOULD LIKE TO MAKE THAT MOTION.

6 MR. TORRES: SO MOVED.

7 CHAIRMAN THOMAS: SO MOVED BY SENATOR
8 TORRES.

9 MS. SAMUELSON: SECOND.

10 CHAIRMAN THOMAS: WHERE WAS THE SECOND?
11 FROM JOAN. THANK YOU, JOAN. ANY DISCUSSION ON THE
12 TOPIC?

13 MS. SAMUELSON: QUESTION ABOUT THE AMOUNT.
14 IS THIS A PERCENTAGE INCREASE OR BASED ON A
15 CALCULATION? THE NEED FOR THE SERVICES OF THIS FIRM
16 ARE GREAT, TO SAY THE LEAST. AND I WOULD WANT TO BE
17 SURE THAT IT'S FINANCED SUFFICIENTLY.

18 CHAIRMAN THOMAS: YES. AS I UNDERSTAND,
19 JAMES, IT'S ROUGHLY COMPARABLE TO LAST YEAR.

20 MR. HARRISON: CORRECT.

21 MS. SAMUELSON: WAS THERE OR IS THERE
22 ANTICIPATED TO BE ANY INFLATION, AND WAS THAT TAKEN
23 INTO CONSIDERATION IN THE RESPONSIBILITIES OR THE
24 ECONOMY?

25 CHAIRMAN THOMAS: RIGHT. I THINK THE

BARRISTERS' REPORTING SERVICE

1 AMOUNT CAME ABOUT AFTER CONSIDERED THOUGHT BY MR.
2 HARRISON ON THIS. YES. TO THE EXTENT THERE IS A
3 NEED FOR ADDITIONAL OR EXTRAORDINARY SERVICE, WE
4 HAVE A CONTINGENCY AS WELL FACTORED INTO THE BUDGET.

5 MS. SAMUELSON: GOOD. CAN THE MOTION
6 INCLUDE REFERENCE TO THAT AND APPROVAL OF IT SO THAT
7 THERE'S NO CONFUSION ABOUT IT?

8 CHAIRMAN THOMAS: YES. SO AT THE RISK OF
9 ASKING A HIGHLY SELF-SERVING QUESTION, MR. HARRISON,
10 WOULD YOU LIKE TO STATE THE MOTION? MR. TOCHER,
11 WOULD YOU LIKE TO STATE THE MOTION?

12 MR. TOCHER: THE MOTION IS TO APPROVE THE
13 REMCHO CONTRACT FOR FISCAL YEAR 2012-2013 WITH THE
14 ADDITIONAL CONTINGENCY ALREADY INCLUDED IN THE
15 BUDGET.

16 CHAIRMAN THOMAS: OKAY. THANK YOU. WOULD
17 THE AUTHOR AND SECOND OF THE ORIGINAL MOTION TAKE
18 THAT AS A FRIENDLY AMENDMENT?

19 MR. TORRES: YES.

20 MS. SAMUELSON: YES.

21 CHAIRMAN THOMAS: OKAY. ANY FURTHER
22 DISCUSSION? ANOTHER VOICE VOTE. ALL THOSE IN FAVOR
23 OF THIS ITEM, PLEASE SAY AYE. OPPOSED?
24 ABSTENTIONS? MARIA, I'LL SAY IT WITHOUT SINGING,
25 DUANE.

BARRISTERS' REPORTING SERVICE

1 MS. BONNEVILLE: DUANE ROTH.

2 MR. ROTH: YES.

3 MS. BONNEVILLE: SHLOMO MELMED. SHERRY
4 LANSING.

5 MS. LANSING: YES.

6 CHAIRMAN THOMAS: OKAY. THANK YOU VERY
7 MUCH.

8 JUST VERY QUICKLY, LET'S SEE, SHERRY,
9 WE'RE GOING TO COME BACK TO YOU IN ONE MINUTE HERE.
10 JUST WANTED TO GET TO ITEM 15 VERY QUICKLY, IF YOU
11 WILL BEAR WITH US, WHICH IS CONSIDERATION OF
12 RECOMMENDATIONS FROM THE STANDARDS WORKING GROUP
13 REGARDING REVIEW AND OVERSIGHT OF THE CIRM-FUNDED
14 RESEARCH. MR. LOMAX.

15 DR. LOMAX: THANK YOU VERY MUCH, MR.
16 CHAIRMAN, MEMBERS OF THE ICOC. I'D LIKE TO GIVE YOU
17 A REPORT BACK ON TWO ITEMS FROM THE APRIL STANDARDS
18 WORKING GROUP MEETING FOR YOUR CONSIDERATION. THESE
19 ARE AMENDMENTS FOR CONSIDERATION TO THE MEDICAL AND
20 ETHICAL STANDARDS.

21 BRIEFLY IN CONTEXT, AS I'M SURE YOU'RE
22 WELL AWARE BY NOW, OUR MEDICAL AND ETHICAL STANDARDS
23 MEET OR EXCEED ALL NATIONAL STANDARDS FOR OVERSIGHT
24 OF RESEARCH. IN ADDITION, WE HAVE EXTREMELY STRONG
25 LANGUAGE IN TERMS OF GUARDING AGAINST CONFLICTS, AS

BARRISTERS' REPORTING SERVICE

1 WE'RE ALL VERY FAMILIAR.

2 AFTER THE BENEFIT OF SIX YEARS OF
3 EXPERIENCE AND EXTENSIVE POLICY EVALUATION, WE'VE
4 IDENTIFIED SOME AREAS WHERE WE CAN STILL MAINTAIN
5 THESE HIGH STANDARDS, BUT OFFER OUR GRANTEES SOME
6 ADDED FLEXIBILITY. I'D LIKE TO RUN THROUGH THOSE
7 TWO AREAS FOR YOU.

8 FIRST IS THE OVERSIGHT COMMITTEE
9 MEMBERSHIP. WHEN WE ORIGINALLY PUT FORTH THE
10 STANDARDS, WE ASKED THAT INSTITUTIONS AND THEIR
11 OVERSIGHT COMMITTEES INCLUDE A LAY MEMBER OF THE
12 PUBLIC, AND THAT LAYPERSON COULD RECEIVE NO MONEY
13 WHATSOEVER. SO THAT WOULD EVEN INCLUDE THINGS LIKE
14 NOT BEING ABLE TO PAY FOR PARKING OR A MODEST
15 STIPEND FOR COMING TO A MEETING AND SPENDING HOURS
16 AT AN INSTITUTION. THIS IS TYPICAL PROCEDURE.
17 INSTITUTIONS LIKE TO DO THIS FOR INDIVIDUALS WHO
18 SERVE ON INSTITUTIONAL REVIEW BOARDS, ANIMAL REVIEW
19 COMMITTEES; BUT BASED ON OUR STANDARDS, THEY HAD TO
20 HAVE A COMPLETELY SEPARATE POLICY FOR CIRM RESEARCH.

21 SO THE SUGGESTION IS THAT THE NONSCIENTIST
22 PUBLIC MEMBER, WE STRIKE THIS PROHIBITION AND JUST
23 ALLOW FLEXIBILITY, ALLOW INSTITUTIONS TO APPLY THEIR
24 POLICIES AS THEY WOULD WITH ANY OTHER COMMITTEE. SO
25 THAT'S THE FIRST PROPOSED AMENDMENT.

BARRISTERS' REPORTING SERVICE

1 THE SECOND ONE CONCERNS THE OVERSIGHT OF
2 RESEARCH, IN PARTICULAR IN VITRO RESEARCH INVOLVING
3 IDENTIFIABLE CELLS. NOW, THIS RESEARCH IS ALWAYS
4 REVIEWED BY AN INSTITUTIONAL REVIEW BOARD. AND IN
5 OUR REGULATIONS WE REQUIRED THAT THE STEM CELL
6 RESEARCH OVERSIGHT COMMITTEE FOR A PARTICULAR
7 GRANTEE INSTITUTION ALSO BE INFORMED THAT THIS
8 RESEARCH IS GOING ON. SO IT'S WHAT WE CALL A
9 NOTIFICATION REQUIREMENT. AND THE PURPOSE IS THAT
10 WE WANT THE STEM CELL RESEARCH OVERSIGHT COMMITTEE
11 TO BE AWARE OF ANY HUMAN SUBJECTS RESEARCH GOING ON
12 IN A CIRM GRANT.

13 UNFORTUNATELY A NUMBER OF OUR GRANTEES NO
14 LONGER HAVE ACCESS TO THESE COMMITTEES. THERE WAS A
15 COMMITTEE AVAILABLE THAT COULD BE USED ON CONTRACT,
16 BUT THOSE SERVICES ARE NO LONGER AVAILABLE. THIS
17 CREATES A ROADBLOCK FOR IN VITRO RESEARCH FOR SOME
18 OF OUR GRANTEE INSTITUTIONS. AND SO WHAT WE'RE
19 PROPOSING IS THAT WE APPLY A SECOND STANDARD WHICH
20 WE USE WHICH IS THAT AN INSTITUTIONAL OFFICIAL AT
21 THE GRANTEE INSTITUTION CAN PROVIDE -- THAT
22 INDIVIDUAL CAN BE NOTIFIED IN LIEU OF THE STEM CELL
23 RESEARCH OVERSIGHT COMMITTEE.

24 AND WHAT THIS WOULD ALLOW, AGAIN, WE'VE
25 HAD QUITE A BIT OF EXPERIENCE WITH THIS PROCESS.

BARRISTERS' REPORTING SERVICE

1 THE INSTITUTIONAL OFFICIAL HAS TO BE SOMEONE, FOR
2 EXAMPLE, IN THE OFFICE OF GENERAL COUNSEL WHO'S
3 FAMILIAR WITH APPLICABLE LAWS AND REGULATIONS, BUT
4 THAT INDIVIDUAL WOULD BE RESPONSIBLE FOR CERTIFYING
5 THAT THE RESEARCH IS DONE IN ACCORDANCE WITH CIRM
6 REQUIREMENTS OR ANY OTHER APPLICABLE REQUIREMENTS,
7 BUT, AGAIN, WOULDN'T NECESSITATE A FULL COMMITTEE
8 FOR THIS TYPE OF RESEARCH WHICH IS DEEMED -- IN
9 VITRO RESEARCH, WE'VE NOT ENCOUNTERED ANY ETHICAL
10 PROBLEMS, ANY TYPES OF PROBLEMS THAT WOULD REQUIRE A
11 FULL OVERSIGHT COMMITTEE.

12 SO THE RECOMMENDATION HERE, AGAIN, IS TO
13 ALLOW NOTIFICATION OF RESPONSIBLE INSTITUTIONAL
14 OFFICIAL IN LIEU OF SCRO COMMITTEE NOTIFICATION.

15 AND THE MOTION BEFORE THE BOARD WOULD BE
16 TO, MR. HARRISON.

17 MR. HARRISON: THE MOTION WOULD BE TO
18 APPROVE THE RECOMMENDATIONS FROM THE STANDARDS
19 WORKING GROUP REGARDING THE REVIEW AND OVERSIGHT OF
20 CIRM-FUNDED RESEARCH IN THE FORM OF THE PROPOSED
21 AMENDMENTS TO THE REGULATIONS.

22 MS. LANSING: I'D LIKE TO MOVE THIS.

23 CHAIRMAN THOMAS: THANK YOU. IS THERE A
24 SECOND BEFORE WE GET --

25 MR. TORRES: SECOND.

BARRISTERS' REPORTING SERVICE

1 CHAIRMAN THOMAS: SECOND BY SENATOR

2 TORRES. DR. BRYANT AND THEN DR. LUBIN.

3 DR. BRYANT: SO I THINK IT WOULD BE A GOOD
4 IDEA TO SPECIFY THE INSTITUTIONAL OFFICIAL BECAUSE
5 IF IT WENT TO THE LEGAL DEPARTMENT, FOR INSTANCE, IT
6 MIGHT NOT BE APPROPRIATE. SO MOST PLACES THAT DO
7 RESEARCH HAVE AN OFFICE OF RESEARCH WITH A VICE
8 CHANCELLOR OR SOME OTHER PERSON LIKE THAT IN CHARGE.
9 AND SO I THINK THEY WOULD BE THE ONE. AND ALL THOSE
10 COMPLIANCE COMMITTEES REPORT IN THROUGH THAT OFFICE,
11 SO IT WOULD BE THE MOST APPROPRIATE ENTITY.

12 DR. LOMAX: WE DO IN THE -- IN OUR
13 REGULATIONS WE DO DEFINE THAT INDIVIDUAL AS SOMEONE,
14 I BELIEVE THE LEGAL TERM IS, SOMEONE WITH PLENARY
15 AUTHORITY. SO THERE IS SOME -- WELL --

16 DR. BRYANT: IT SHOULD BE THE HEAD
17 RESEARCH AUTHORITY OF THE CAMPUS.

18 DR. LOMAX: THAT'S RIGHT. BUT IN SOME
19 CASES, PARTICULARLY WITH THE NONCAMPUS GRANTEES, IT
20 WILL BE SOMEONE -- THEY WON'T HAVE A VICE -- THEY
21 DON'T HAVE A VICE CHANCELLOR OF RESEARCH. IT HAS TO
22 BE WITH AUTHORITY FOR THE ORGANIZATION. SO WE HAVE
23 DEFINED IT THAT WAY, BUT IT WOULDN'T SAY -- THEY
24 DON'T SPECIFY, FOR EXAMPLE, THE VICE CHANCELLOR OF
25 RESEARCH.

BARRISTERS' REPORTING SERVICE

1 DR. BRYANT: BUT I THINK, BECAUSE THINGS
2 LIKE THIS CAN GET LOST IN INSTITUTIONS, I WOULD SAY
3 IT SHOULD BE THE VICE CHANCELLOR FOR RESEARCH OR
4 THEIR EQUIVALENT OR THE CHANCELLOR AND LET THEM TAKE
5 CARE OF IT OR THE HEAD OF THE INSTITUTION. I'M JUST
6 WORRIED THAT THESE THINGS, IF IT GOES TO LIKE THE
7 CAMPUS LAWYER OR SOMETHING, IT WOULD NOT GET TO THE
8 RIGHT PLACE NECESSARILY. SO I THINK IT NEEDS TO GO
9 TO THE -- ANYWAY, SORRY.

10 CHAIRMAN THOMAS: I THINK DR. LUBIN WAS
11 FIRST.

12 DR. LUBIN: I'M SECONDING THE MOTION.

13 CHAIRMAN THOMAS: OH, I SEE. OKAY. THANK
14 YOU. DR. STEWARD.

15 DR. STEWARD: I THINK THIS IS REALLY SORT
16 OF FOLLOWING UP ON DR. BRYANT'S COMMENT. COULD YOU
17 UNPACK A LITTLE BIT WHAT THE PROBLEMS ARE? YOU
18 MENTIONED, YOU KNOW, INSTITUTIONS THAT DON'T HAVE
19 THE SCRO COMMITTEES AND THEN DON'T HAVE SOMEBODY WHO
20 WOULD BE THE -- WHAT ARE WE TALKING ABOUT HERE?

21 DR. LOMAX: SO THIS PARTICULAR CASE,
22 AGAIN, IN VITRO RESEARCH INVOLVING TYPICALLY SOME
23 KIND OF PLURIPOTENT STEM CELL LINE. WE HAVE AN
24 EXTENSIVE SET OF REQUIREMENTS THAT SAY THAT STEM
25 CELL LINE HAS TO HAVE HAD PROPER INFORMED CONSENT,

BARRISTERS' REPORTING SERVICE

1 KNOWN WAS PAID FOR THE USE OF THOSE CELLS. WE HAVE
2 A SERIES OF VERY SPECIFIC REQUIREMENTS.

3 AND SO THE POINT -- THE PURPOSE OF THE
4 NOTIFICATION REQUIREMENT WAS TO TELL THE COMMITTEE
5 THIS RESEARCHER IS INTENDING TO USE THESE MATERIALS.
6 BY OUR REGULATIONS YOU'RE ON THE HOOK, YOU'RE
7 OBLIGATED TO CONFIRM OR KNOW THAT THOSE MATERIALS
8 MEET ALL OF OUR REQUIREMENTS. AND IT'S A FAIRLY
9 STRAIGHT LIST OF REQUIREMENTS.

10 SO WHAT THIS IS INTENDED TO DO IS
11 SAY -- AND TYPICALLY THE WAY THE OVERSIGHT
12 COMMITTEES DO THAT IS THEY DON'T HAVE A FULL
13 COMMITTEE MEETING. THEY HAVE WHAT THEY CALL AN
14 EXPEDITED PROCESS WHERE THE CHAIRPERSON OR THEIR
15 DESIGNATED PERSON GOES AND DOES THAT CHECKING. WHAT
16 THIS AMENDMENT WOULD ALLOW IS SOMEBODY TO DO THAT
17 SAME PROCESS, BUT NOT AS A REPRESENTATIVE OF THE
18 STEM CELL RESEARCH OVERSIGHT COMMITTEE, BUT SOMEONE
19 WHO HAS EXPERIENCE, TRAINING, THE ABILITY TO MAKE
20 THAT DETERMINATION. AND, AGAIN, TYPICALLY SOMEONE
21 IN A SORT OF GENERAL COUNSEL OFFICE OR SOMEONE WHO
22 UNDERSTANDS THE REGULATORY REQUIREMENTS. SO IT'S
23 FUNCTIONALLY EQUIVALENT. IT'S JUST BEING PERFORMED
24 BY SOMEONE OTHER THAN THE ADMINISTRATIVE OR THE
25 CHAIR OF THE OVERSIGHT COMMITTEE. DOES THAT MAKE

BARRISTERS' REPORTING SERVICE

1 SENSE? DOES THAT CLARIFY?

2 DR. STEWARD: YES. EXCEPT I STILL DON'T
3 QUITE UNDERSTAND WHY -- WHAT SORT OF ORGANIZATION
4 WOULDN'T HAVE THE KIND OF PERSON THAT DR. BRYANT IS
5 TALKING ABOUT. SOMEONE WHOSE ROLE IT IS IN THE
6 INSTITUTION TO OVERSEE COMPLIANCE?

7 DR. LOMAX: SO OUR UNDERSTANDING IS
8 EVERYONE HAS THAT -- ALL OF OUR GRANTEES HAS SOMEONE
9 AT THAT LEVEL. WHAT ALL OF OUR GRANTEES DO NOT HAVE
10 IS A STEM CELL RESEARCH OVERSIGHT COMMITTEE, WHICH
11 IS A COMMITTEE FORMED IN ACCORDANCE WITH OUR
12 REGULATIONS. AND THERE'S REQUIREMENTS FOR THAT.
13 THERE'S CERTAIN TYPES OF EXPERTISE, CERTAIN TYPES OF
14 REPRESENTATION. IN ORDER TO PUT TOGETHER ONE OF
15 THOSE COMMITTEES, THAT IS A FAIRLY LABORIOUS AND
16 IT'S A MAJOR ENDEAVOR WHICH IF YOU'RE NOT OF A
17 CERTAIN SCALE, IN ORDER TO ACCOMPLISH THAT, IF YOU
18 HAVE ONE OR TWO CIRM GRANTS AND YOU'RE A SMALL
19 INSTITUTION, THAT CAN BE A VERY HIGH BAR TO GET
20 OVER.

21 SO WHAT WE'RE TRYING TO DO IN THIS CASE IS
22 GIVE THOSE INSTITUTIONS A SECOND PATH SO THEY CAN
23 MAKE THAT DETERMINATION THROUGH, LIKE I SAY, SOMEONE
24 WITH LEGAL RESPONSIBILITY, SOMEONE OF THAT NATURE.

25 DR. STEWARD: SO I GUESS, JUST TO AMPLIFY

BARRISTERS' REPORTING SERVICE

1 THEN, I THINK THAT THERE NEEDS TO BE A PRETTY CLEAR
2 DEFINITION OF WHAT THAT PERSON ACTUALLY IS AND THEIR
3 QUALIFICATIONS. YOU COULD IMAGINE THIS BEING
4 REVIEWED BY SOMEBODY WHO REALLY DIDN'T KNOW WHAT
5 THEY WERE LOOKING AT. I THINK THAT WAS DR. BRYANT'S
6 POINT. AND SO I DON'T KNOW HOW TO LAY THOSE OUT,
7 BUT IT SEEMS LIKE THERE OUGHT TO BE SOME SPECIFICITY
8 THERE.

9 DR. BRYANT: I THINK IF YOU WANT TO
10 DESIGNATE IT TO THE CHIEF COMPLIANCE OFFICER OF THE
11 INSTITUTION, THAT WOULD BE THE WAY TO DO IT. THEN
12 IT WOULD END UP IN THE RIGHT PLACE, BUT IT WOULDN'T
13 NECESSARILY BE THE HEAD LAWYER OR ANYTHING LIKE THAT
14 OR EVEN THE LEGAL DEPARTMENT.

15 CHAIRMAN THOMAS: DEAN PIZZO.

16 DR. PIZZO: I THINK WE'RE GETTING -- IN
17 ALL FAIRNESS, I UNDERSTAND WHERE YOU'RE GOING, BUT
18 I'D BE A LITTLE CAREFUL ABOUT SPECIFYING THE ACTUAL
19 JOB DESCRIPTION. THE REALITY IS OUR OFFICE OF
20 GENERAL COUNSEL, I CAN SPEAK TO THIS AT LEAST AT
21 STANFORD, IS CERTAINLY INVOLVED IN COMPLIANCE
22 ISSUES. THERE'S NO QUESTION ABOUT THAT. WE DO HAVE
23 A DEAN OF RESEARCH, BUT WE ALSO HAVE AUTHORITY
24 WITHIN, IN OUR CASE, THE MEDICAL SCHOOL THAT
25 OVERSEES COMPLIANCE ALMOST INDEPENDENTLY OF WHAT

BARRISTERS' REPORTING SERVICE

1 TAKES PLACE. SO INSTITUTIONS VARY, WHICH IS WHY I
2 LIKED YOUR -- WELL, I THINK CHIEF COMPLIANCE OFFICER
3 MAY BE IT. I JUST THINK THAT PERSON COULD BE A
4 LAWYER, SO I THINK WE WANT TO BE JUDICIOUS ABOUT
5 THAT.

6 I THOUGHT YOUR OTHER RECOMMENDATION, WHICH
7 CERTAINLY WOULD ALLOW THE AUTHORITY, IS THAT IT CAN
8 GO THROUGH, IF YOU WILL, CHANCELLOR OR THE PRESIDENT
9 OR WHOMEVER IS THE INSTITUTIONAL LEADER JUST TO BE
10 SURE IT'S APPROPRIATELY DELEGATED.

11 DR. LOMAX: JUST ONE SORT OF PROCESS. IN
12 A NUMBER OF CASES, EVERY CASE I'M AWARE OF WHERE
13 INSTITUTIONS HAVE USED THIS MECHANISM, THERE'S
14 ACTUALLY BEEN -- I'VE ACTUALLY SAT DOWN WITH THE
15 CIRM SCIENCE OFFICER, AND IT'S BEEN THROUGH A VERBAL
16 CONVERSATION. SO I ALSO WANT TO SORT OF REMIND YOU
17 THAT WE ARE -- WE DON'T SORT OF TURN A BLIND EYE.
18 WE'RE VERY ACTIVE IN TERMS OF THIS PROCESS, AND
19 THERE'S BOTH THE SCIENCE OFFICER AND MYSELF ALWAYS
20 SORT OF COMMUNICATING. AND OFTEN THAT'S AN EXTERNAL
21 COMMUNICATION TO THE GRANTEE ORGANIZATION. SO IT'S
22 NOT A PIECE OF PAPER SHOWS UP AND THAT'S IT.

23 CHAIRMAN THOMAS: ANY OTHER COMMENTS BY
24 MEMBERS OF THE BOARD? I WILL SAY THAT THIS IS THE
25 FIRST STANDARDS WORKING GROUP MEETING THAT I HAVE

BARRISTERS' REPORTING SERVICE

1 ATTENDED, FIRST ONE SINCE I'VE BEEN ON BOARD. AND
2 IT WAS, AS WITH ALL OF OUR GROUPS, A HIGHLY
3 IMPRESSIVE AGGREGATION OF PEOPLE VERY DEDICATED TO
4 DISCUSSING THESE AND OTHER TOPICS. AND I WOULD LIKE
5 TO JUST CONGRATULATE GEOFF FOR SPEARHEADING THE
6 WHOLE THING. IT'S VERY, VERY WELL DONE.

7 COMMENTS BY MEMBERS OF THE PUBLIC? MR.
8 HARRISON, RESTATE THE MOTION.

9 MR. HARRISON: THE MOTION IS TO APPROVE
10 THE RECOMMENDATIONS FROM THE STANDARDS WORKING GROUP
11 REGARDING THE REVIEW AND OVERSIGHT OF CIRM-FUNDED
12 RESEARCH AS REFLECTED IN THE PROPOSED AMENDMENTS TO
13 THE REGULATIONS.

14 CHAIRMAN THOMAS: ALL THOSE IN FAVOR
15 PLEASE SAY AYE. OPPOSED? ABSTAINING? MARIA.

16 MS. BONNEVILLE: DUANE ROTH.

17 MR. ROTH: YES.

18 MS. BONNEVILLE: SHLOMO MELMED. SHERRY
19 LANSING.

20 MS. LANSING: YES.

21 CHAIRMAN THOMAS: THANK YOU. WE WILL NOW
22 GO TO ITEM 14.

23 MS. LANSING: THAT'S ME, RIGHT?

24 CHAIRMAN THOMAS: WHICH IS SHERRY.

25 MS. LANSING: CAN YOU HEAR ME?

BARRISTERS' REPORTING SERVICE

1 CHAIRMAN THOMAS: WE CAN HEAR VERY
2 CLEARLY. WHICH IS CONSIDERATION OF THE
3 RECOMMENDATIONS OF THE GOVERNANCE SUBCOMMITTEE.

4 MS. LANSING: OKAY. ON MAY 3D WE HAD A
5 MEETING OF THE GOVERNANCE SUBCOMMITTEE TO DISCUSS
6 THREE ITEMS: AMENDMENTS TO THE GOVERNING BOARD
7 BYLAWS, ADOPTION OF A CODE OF CONDUCT, AND
8 CONSIDERATION OF CHANGES TO THE CONFLICT OF INTEREST
9 CODE.

10 I'D LIKE TO ASK JAMES TO PLEASE DESCRIBE
11 EACH ITEM AND THE RECOMMENDATION FROM THE
12 SUBCOMMITTEE. AFTER EACH ITEM IS INTRODUCED, WE
13 WILL TAKE QUESTIONS FROM BOARD MEMBERS AND THE
14 PUBLIC. I WILL THEN ASK FOR A MOTION ON EACH
15 INDIVIDUAL ITEM.

16 JAMES, CAN YOU PLEASE START WITH THE
17 PROPOSED CHANGES TO THE BOARD BYLAWS.

18 MR. HARRISON: ABSOLUTELY. THANK YOU,
19 SHERRY. AND MICHAEL GOLDBERG TOUCHED ON THIS
20 EARLIER TODAY, BUT WHEN THE BOARD FIRST ADOPTED ITS
21 BYLAWS, THERE WERE ONLY TWO STANDING COMMITTEES, THE
22 GOVERNANCE AND THE LEGISLATIVE SUBCOMMITTEES. AND
23 THE GOVERNANCE SUBCOMMITTEE HAD RESPONSIBILITY FOR
24 CIRM'S BUDGET AND COST CONTROL PROGRAMS.

25 WHEN THE FINANCE SUBCOMMITTEE WAS CREATED

BARRISTERS' REPORTING SERVICE

1 IN 2007, IT UNDERTOOK RESPONSIBILITY FOR REVIEW OF
2 THE BUDGET AND THE COST CONTROL PROGRAMS, BUT WE
3 HAVE NOT UNTIL NOW CONFORMED OUR BYLAWS TO REFLECT
4 THE FACT THAT FINANCE CARRIES OUT THIS
5 RESPONSIBILITY. YOU'VE APPROVED THE CHANGE TO THE
6 FINANCE SUBCOMMITTEE MISSION STATEMENT TO MAKE ITS
7 JURISDICTION OVER THE BUDGET EXPLICIT TODAY, AND
8 WE'D ASK FOR YOUR APPROVAL TO AN AMENDMENT TO
9 ARTICLE 6, SECTION 4 OF THE BYLAWS TO CONFORM THE
10 BYLAWS TO CURRENT PRACTICE.

11 THERE IS ONE OTHER ISSUE IN THE BYLAWS
12 THAT WE ARE SEEKING YOUR APPROVAL OF. IN 2010 THE
13 BOARD ADOPTED A NEW PROVISION IN THE BYLAWS TO
14 ADDRESS AND IMPLEMENT A PROVISION IN SB 1064 WHICH
15 PROVIDED FOR THE PATIENT ADVOCATE MEMBERS OF THE
16 GRANTS WORKING GROUP AND THE PATIENT ADVOCATE
17 LEADERSHIP OF THE STANDARDS AND FACILITIES WORKING
18 GROUP TO RECEIVE COMPENSATION ON CONSULTING RATE FOR
19 THEIR SERVICE ON THE WORKING GROUPS. THE BYLAWS
20 REFLECTED THIS AND INCLUDED A CAP ON THAT
21 COMPENSATION, BUT DID NOT SPECIFY WHETHER IT WAS ON
22 A FISCAL YEAR OR CALENDAR YEAR BASIS. AND WE'RE
23 PROPOSING SIMPLY TO CLARIFY THAT THE CAP APPLIES TO
24 A FISCAL YEAR BASIS CONSISTENT WITH CIRM'S BUDGET
25 YEAR. AND WE WOULD, THEREFORE, ASK FOR YOUR

BARRISTERS' REPORTING SERVICE

1 APPROVAL OF THE PROPOSED AMENDMENTS TO BOTH ARTICLE
2 6, SECTION 4 AND ARTICLE 4, SECTION 7 OF THE BOARD'S
3 BYLAWS.

4 CHAIRMAN THOMAS: DO I HEAR A MOTION TO
5 THAT EFFECT?

6 MR. GOLDBERG: SO MOVED.

7 CHAIRMAN THOMAS: MOVED BY MR. GOLDBERG.

8 DR. MARLETTA: SECOND.

9 CHAIRMAN THOMAS: SECONDED BY DR.
10 MARLETTA. ANY DISCUSSION? COMMENTS FROM MEMBERS OF
11 THE PUBLIC? WE'LL PROCEED TO VOTE ON THE
12 RECOMMENDATION AS SET FORTH ON THE SCREEN UP THERE.
13 ALL THOSE IN FAVOR PLEASE SAY AYE. OPPOSED?
14 ABSTENTION? MARIA.

15 MS. BONNEVILLE: DUANE ROTH.

16 MR. ROTH: YES.

17 MS. BONNEVILLE: SHLOMO MELMED. SHERRY
18 LANSING.

19 MS. LANSING: YES.

20 OKAY. SO THE MOTION PASSES. SO THE NEXT
21 ITEM CONSIDERED WAS A CODE OF CONDUCT. AND, JAMES,
22 CAN YOU PLEASE DESCRIBE THE BOARD CODE OF CONDUCT
23 AND THE RECOMMENDATION FROM THE SUBCOMMITTEE.

24 MR. HARRISON: YES. AT THE CHAIR OF THE
25 GOVERNANCE SUBCOMMITTEE'S DIRECTION, WE PREPARED A

BARRISTERS' REPORTING SERVICE

1 CODE OF CONDUCT. AND WE DID SO AFTER SURVEYING THE
2 CODES OF CONDUCT OF NUMEROUS OTHER ORGANIZATIONS,
3 INCLUDING THE UNIVERSITY OF CALIFORNIA REGENTS,
4 OTHER STATE AGENCIES, AND NONPROFITS.

5 THE CODE THAT YOU WILL SEE INCLUDES A
6 STATEMENT OF EXPECTATIONS FOR BOARD MEMBERS
7 INCLUDING ATTENDANCE AT MEETINGS, THE PROTECTION OF
8 CONFIDENTIAL INFORMATION, INTERACTION WITH THE MEDIA
9 ON BEHALF OF CIRM, AS WELL AS THE PROTOCOLS FOR
10 MAKING REQUESTS OF CIRM STAFF. AS THE PERFORMANCE
11 AUDITORS MENTIONED THIS MORNING, CODES OF CONDUCT
12 ARE CONSIDERED BEST PRACTICE. SO WE WOULD ASK THE
13 BOARD FOR YOUR APPROVAL OF THE PROPOSED CODE OF
14 CONDUCT.

15 CHAIRMAN THOMAS: MOTION TO THAT EFFECT?

16 MR. TORRES: SO MOVED.

17 CHAIRMAN THOMAS: MOVED BY SENATOR TORRES.

18 SECONDED BY --

19 DR. PIZZO: SECOND.

20 CHAIRMAN THOMAS: -- DEAN PIZZO. ANY
21 DISCUSSION? COMMENTS FROM MEMBERS OF THE PUBLIC?
22 HEARING NONE, PROCEED TO A VOICE VOTE ON THAT ITEM.
23 ALL THOSE IN FAVOR PLEASE SAY AYE. OPPOSED?
24 ABSTENTIONS? MARIA.

25 MS. BONNEVILLE: DUANE ROTH.

BARRISTERS' REPORTING SERVICE

1 MR. ROTH: YES.

2 MS. BONNEVILLE: SHLOMO MELMED. SHERRY
3 LANSING.

4 MS. LANSING: YES.

5 SO THAT CARRIES. AND, JAMES, NOW IF YOU
6 WOULD WALK US THROUGH THE CONSIDERATION OF CHANGES
7 TO THE CONFLICT OF INTEREST CODE.

8 MR. HARRISON: THANK YOU, SHERRY. THE
9 POLITICAL REFORM ACT REQUIRES EVERY STATE AGENCY TO
10 ADOPT A CONFLICT OF INTEREST CODE AND TO CONDUCT A
11 BIENNIAL REVIEW OF THAT CODE. CIRM'S CONFLICT OF
12 INTEREST CODE, LIKE THE CODES OF EVERY STATE AGENCY,
13 IDENTIFY WHO WITHIN THE AGENCY HAS TO DISCLOSE THEIR
14 FINANCIAL INTERESTS BY FILING FORM 700 AND WHAT THEY
15 HAVE TO DISCLOSE. AND RECENTLY THE FAIR POLITICAL
16 PRACTICES COMMISSION, WHICH IS RESPONSIBLE FOR
17 REVIEWING AND APPROVING CIRM'S CONFLICT OF INTEREST
18 CODE, HAS RECOMMENDED THAT CIRM AS WELL AS OTHER
19 STATE AGENCIES NARROW THE DISCLOSURE CATEGORIES SO
20 THAT THEY CLOSELY REFLECT THE NATURE OF THE WORK
21 THAT THE AGENCY PERFORMS.

22 CURRENTLY CIRM BOARD MEMBERS AND HIGH
23 LEVEL STAFF HAS THE BROADEST DISCLOSURE CATEGORY.
24 WE PRESENTED THE FAIR POLITICAL PRACTICES
25 RECOMMENDATION TO THE GOVERNANCE SUBCOMMITTEE, AND

BARRISTERS' REPORTING SERVICE

1 CHAIR LANSING, I THINK, SAID IT BEST WHEN SHE
2 EXPRESSED HER THANKS FOR THE FPPC'S ADVICE, BUT
3 RECOMMENDED THAT CIRM SHOULD CONTINUE TO SET AN
4 EXAMPLE BY REQUIRING THE BROADEST DISCLOSURE OF
5 MEMBERS OF THE BOARD AS WELL AS EXECUTIVE STAFF BOTH
6 BECAUSE OF CIRM'S UNIQUE MISSION, AS WELL AS THE
7 AGENCY'S LONG-STANDING COMMITMENT TO TRANSPARENCY.

8 THE GOVERNANCE SUBCOMMITTEE UNANIMOUSLY
9 AGREED WITH CHAIR LANSING AND REPRESENTED THAT THE
10 BOARD MAINTAIN DISCLOSURE CATEGORY ONE IN THE
11 CONFLICT OF INTEREST CODE FOR BOARD MEMBERS AND
12 EXECUTIVE STAFF, BUT PROCEED WITH THE TECHNICAL
13 AMENDMENTS TO THE CODE, INCLUDING CONSIDERATION OF
14 THE APPROPRIATE LEVEL OF DISCLOSURE FOR NONEXECUTIVE
15 STAFF. AND WE WOULD ASK THE BOARD TO APPROVE THAT
16 RECOMMENDATION.

17 CHAIRMAN THOMAS: DO I HEAR A MOTION TO
18 THAT EFFECT?

19 DR. STEWARD: SO MOVED.

20 CHAIRMAN THOMAS: DR. STEWARD. SECONDED
21 BY --

22 DR. PIZZO: SECOND.

23 CHAIRMAN THOMAS: -- DEAN PIZZO. ANY
24 DISCUSSION ON THIS TOPIC? COMMENTS FROM MEMBERS OF
25 THE PUBLIC? HEARING NONE, A VOICE VOTE. ALL THOSE

BARRISTERS' REPORTING SERVICE

1 IN FAVOR PLEASE SAY AYE. OPPOSED? ABSTAINING?

2 MARIA.

3 MS. BONNEVILLE: DUANE ROTH.

4 MR. ROTH: YES.

5 MS. BONNEVILLE: SHLOMO MELMED. SHERRY

6 LANSING.

7 MS. LANSING: YES.

8 AND THAT CONCLUDES THE GOVERNANCE

9 SUBCOMMITTEE AND OUR RECOMMENDATIONS. SO THANK YOU.

10 CHAIRMAN THOMAS: THANK YOU, MADAM CHAIR.

11 AND THANK YOU, MR. HARRISON.

12 THE NEXT ITEM ON THE AGENDA WE'RE ACTUALLY

13 DEFERRING UNTIL JULY BECAUSE TED WAS TIED UP TODAY

14 AND UNABLE TO MAKE IT. SO WE'LL HAVE THE OFFICIAL

15 PRESENTATION OF THE RESOLUTION TO HIM FOR HIS MANY

16 YEARS OF SERVICE AT THE JULY MEETING.

17 LAST, BUT NOT LEAST, ON THE VOTING AGENDA

18 IS THE ALWAYS CONTROVERSIAL CONSIDERATION OF THE

19 MINUTES.

20 MS. LANSING: I MOVE THE MINUTES.

21 MS. GIBBONS: SECOND.

22 CHAIRMAN THOMAS: BEEN MOVED AND SECONDED.

23 ANY DISCUSSION ON THIS TOPIC? I DON'T THINK WE NEED

24 ANY COMMENTS FROM MEMBERS OF THE PUBLIC IF I'M NOT

25 MISTAKEN. SO ALL THOSE IN FAVOR PLEASE SAY AYE.

BARRISTERS' REPORTING SERVICE

1 OPPOSED? ABSTAINING? MARIA.

2 MS. BONNEVILLE: DUANE ROTH.

3 MR. ROTH: YES.

4 MS. BONNEVILLE: SHLOMO MELMED. SHERRY
5 LANSING.

6 MS. LANSING: YES.

7 CHAIRMAN THOMAS: OKAY. SO THAT CONCLUDES
8 THE VOTING MEMBERS OF THE AGENDA. NOW, WE'RE GOING
9 TO TAKE A SHORT BREAK, FIVE MINUTES, AND HAVE
10 TODAY'S SPOTLIGHT, WHICH, AS ALWAYS, WILL BE SORT OF
11 UNDER THE CATEGORY OF WHAT IT'S ALL ABOUT, AND WOULD
12 INVITE EVERYBODY TO COME BACK IN FIVE MINUTES TO
13 HEAR THAT. THANK YOU.

14 (A RECESS WAS TAKEN.)

15 (THE SPOTLIGHT WAS THEN PRESENTED,
16 BUT NOT REPORTED NOR HEREIN TRANSCRIBED.)

17 CHAIRMAN THOMAS: WELL, LADIES AND
18 GENTLEMEN, I BELIEVE THAT THAT CONCLUDES THE AGENDA
19 FOR THIS MEETING. THANK YOU, EVERYBODY. WE GOT
20 THROUGH AN AWFUL LOT OF HIGHLY SUBSTANTIVE STUFF,
21 AND I THINK WE'VE DEMONSTRATED AGAIN HOW HARDWORKING
22 OUR STAFF IS IN PUTTING TOGETHER ALL OF THESE MANY
23 INITIATIVES THAT ARE ONGOING SIMULTANEOUSLY. SO WE
24 WILL ADJOURN THE MEETING. OUR NEXT MEETING WILL BE
25 IN JULY. AND EVERYBODY HAVE A VERY HAPPY HOLIDAY

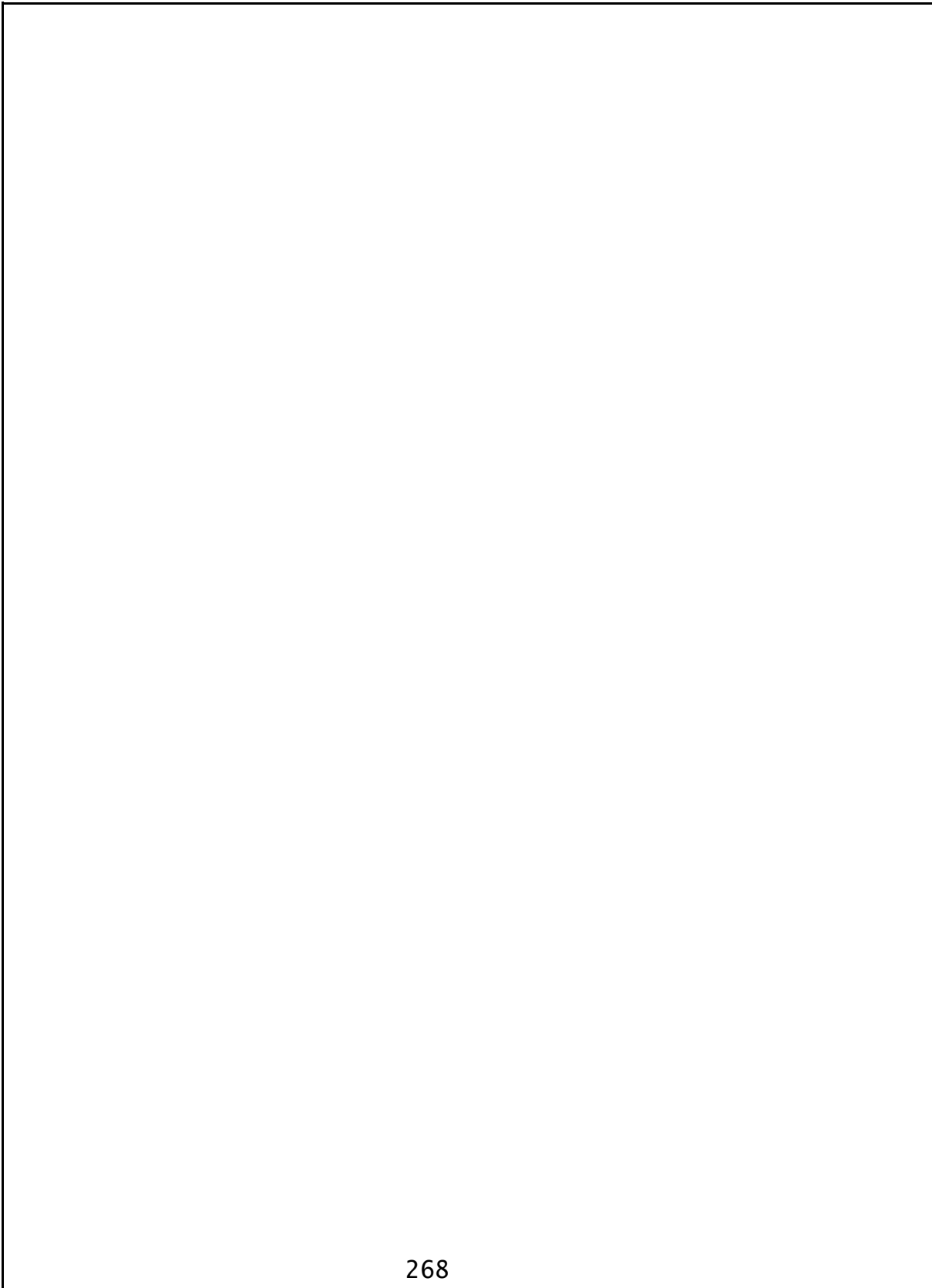
BARRISTERS' REPORTING SERVICE

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WEEKEND, AND WE'LL SEE YOU SOON. THANK YOU.

(THE MEETING WAS THEN CONCLUDED AT
4:45 P.M.)

BARRISTERS' REPORTING SERVICE



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 INDEPENDENT CITIZEN'S OVERSIGHT COMMITTEE OF THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE IN THE MATTER OF ITS REGULAR MEETING HELD AT THE LOCATION INDICATED BELOW

CROWNE PLAZA SFO
1177 AIRPORT BOULEVARD
BURLINGAME, CALIFORNIA
ON
MAY 24, 2012

WAS HELD AS HEREIN APPEARS AND THAT THIS IS THE ORIGINAL TRANSCRIPT THEREOF AND THAT THE STATEMENTS THAT APPEAR IN THIS TRANSCRIPT WERE REPORTED STENOGRAPHICALLY BY ME AND TRANSCRIBED BY ME. I ALSO CERTIFY THAT THIS TRANSCRIPT IS A TRUE AND ACCURATE RECORD OF THE PROCEEDING.

BETH C. DRAIN, CSR 7152
BARRISTERS' REPORTING SERVICE
160 S. OLD SPRINGS ROAD
SUITE 270
ANAHEIM, CALIFORNIA
(714) 444-4100