

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: LUXE HOTEL
11461 SUNSET BOULEVARD
LOS ANGELES, CALIFORNIA

DATE: OCTOBER 28, 2009
8:30 A.M.

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

BRS FILE NO.: 84475

BARRISTERS' REPORTING SERVICE

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CLOSED SESSION

12. A. DISCUSSION OF CONFIDENTIAL INTELLECTUAL PROPERTY OR WORK PRODUCT AND PREPUBLICATION, CONFIDENTIAL SCIENTIFIC RESEARCH OR DATA, AND FINANCIAL INFORMATION RELATING TO APPLICATIONS FOR DISEASE TEAM RESEARCH AWARDS, INCLUDING GRANTS AND LOANS. (HEALTH & SAFETY CODE 125290.30(D) (3) (B) AND (C)).

B. DISCUSSION OF PERSONNEL (GOVERNMENT CODE SECTION 11126, SUBDIVISION (A); HEALTH & SAFETY CODE SECTION 125290.30(D) (3) (D)).

PUBLIC REPORT OF ANY ACTION TAKEN, IF NECESSARY, DURING CLOSED SESSION.

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1 LOS ANGELES, CALIFORNIA; OCTOBER 28, 2009

2 8:30 A.M.

3
4 CHAIRMAN KLEIN: WELCOME. THANK YOU VERY
5 MUCH FOR COMING THIS MORNING FOR WHAT IS AN HISTORIC
6 DAY FOR THIS AGENCY, THE LARGEST RESEARCH GRANT
7 ROUND IN ITS HISTORY THANKS TO THE VISION OF 7
8 MILLION CALIFORNIANS. WE WILL START THE DAY WITH A
9 PLEDGE OF ALLEGIANCE, AND MELISSA KING WILL LEAD US.

10 (THE PLEDGE OF ALLEGIANCE.)

11 CHAIRMAN KLEIN: MELISSA KING, COULD YOU
12 DO THE ROLL CALL, PLEASE.

13 MS. KING: DONALD DAFOE FOR RICARDO AZZIZ.

14 DR. DAFOE: HERE.

15 MS. KING: ROBERT PRICE FOR ROBERT
16 BIRGENEAU.

17 DR. PRICE: HERE.

18 MS. KING: FLOYD BLOOM.

19 DR. BLOOM: HERE.

20 MS. KING: DAVID BRENNER. WILLIAM BRODY.
21 JACOB LEVIN FOR SUSAN BRYANT. MARCY FEIT. MICHAEL
22 FRIEDMAN.

23 DR. FRIEDMAN: HERE.

24 MS. KING: LEEZA GIBBONS. MICHAEL
25 GOLDBERG. SAM HAWGOOD. BOB KLEIN.

BARRISTERS' REPORTING SERVICE

1 CHAIRMAN KLEIN: PRESENT.
2 MS. KING: SHERRY LANSING. GERALD LEVEY.
3 DR. LEVEY: HERE.
4 MS. KING: TED LOVE.
5 DR. LOVE: HERE.
6 MS. KING: ED PENHOET.
7 DR. PENHOET: HERE.
8 MS. KING: PHIL PIZZO.
9 DR. PIZZO: HERE.
10 MS. KING: CLAIRE POMEROY.
11 DR. POMEROY: HERE.
12 MS. KING: FRANCISCO PRIETO. CARMEN
13 PULIAFITO.
14 DR. PULIAFITO: HERE.
15 MS. KING: ROBERT QUINT.
16 DR. QUINT: PRESENT.
17 MS. KING: JEANNIE FONTANA FOR JOHN REED.
18 MS. KING: JOAN SAMUELSON.
19 MS. SAMUELSON: PRESENT.
20 MS. KING: DUANE ROTH.
21 MR. ROTH: HERE.
22 MS. KING: DAVID SERRANO-SEWELL.
23 MR. SERRANO-SEWELL: HERE.
24 MS. KING: JEFF SHEEHY.
25 MR. SHEEHY: HERE.

BARRISTERS' REPORTING SERVICE

1 MS. KING: JONATHAN SHESTACK. OSWALD
2 STEWARD.

3 DR. STEWARD: HERE.

4 MS. KING: ART TORRES.

5 MR. TORRES: HERE.

6 CHAIRMAN KLEIN: WE ARE WAITING FOR ONE OR
7 TWO MEMBERS IN TRANSIT. AND, JENNA PRYNE, COULD YOU
8 PLEASE USE THE HOTEL PHONE, AND THERE MAY BE A
9 COUPLE OF INDIVIDUAL BOARD MEMBERS WHO ARE TIED UP
10 ON CALLS THAT NEED TO BE INTERRUPTED IF THEY COULD
11 PLEASE.

12 WHILE WE'RE WAITING, I'D LIKE TO REVIEW
13 FOR THE BOARD MEMBERS AND THE PUBLIC THE PROTOCOL WE
14 ADOPTED NIGHT. THE PROTOCOL BEGAN WITH THE TIER III
15 DO-NOT-FUND CATEGORY AND WENT THROUGH EACH OF THESE
16 SEQUENTIALLY ASKING FIRST WHETHER ANY BOARD MEMBER
17 WANTED TO MAKE A MOTION TO MOVE ONE OF THOSE TIER
18 III GRANTS TO TIER I. IF THERE WAS A SECOND, THEN
19 WE UNDERTOOK THE PROCESS OF A DISCUSSION INITIATED
20 BY A STAFF SUMMARY WITH BOARD COMMENTS RELATED TO
21 THE EXTRAORDINARY PETITIONS; OR IF THERE WASN'T AN
22 EXTRAORDINARY PETITION, IT COULD HAVE AS WELL BEEN
23 RELATED TO THE SCIENTIFIC MERIT OF THE GRANT.

24 SECONDLY, WE INTEND, AFTER GOING THROUGH
25 ANY AND ALL OF THE APPLICATIONS IN TIER III THAT ANY

BARRISTERS' REPORTING SERVICE

1 BOARD MEMBER WOULD LIKE TO HAVE CONSIDERED TO MOVE
2 TO TIER I, WE STATED OUR INTENTION TO REVIEW THE
3 TIER I GRANTS FOR APPROVAL TO SEE IF THERE WAS ANY
4 PROPOSAL TO MOVE ANY OF THOSE DOWN TO TIER III. AT
5 THAT POINT THERE WOULD BE FINAL VOTES ON THE
6 ALLOCATION OF FUNDS FOR A FINAL DECISION.

7 WITH MICHAEL GOLDBERG JOINING --

8 MS. KING: AND DR. PRIETO. WE NOW HAVE A
9 QUORUM PRESENT IN THE ROOM.

10 CHAIRMAN KLEIN: WE HAVE A QUORUM PRESENT.
11 THANK YOU. I WILL NOT REVIEW THE PROTOCOL BECAUSE I
12 BELIEVE THAT THE TWO MEMBERS THAT JUST JOINED THE
13 BOARD WERE PRESENT LAST NIGHT AND ARE AWARE OF THE
14 PROTOCOL THAT WE HAVE IN EFFECT.

15 LAST NIGHT I BELIEVE WE ENDED, IF I COULD
16 CONFER WITH COUNSEL AND DR. TROUNSON, ASKING IF
17 THERE WERE ANY BOARD MEMBER WHO WANTED TO MAKE A
18 MOTION ON 1487, OR DID I END BEFORE THAT? I ENDED
19 WITH 1487. THERE WAS NO PROPOSAL ON THAT ITEM; IS
20 THAT CORRECT? OKAY.

21 I WOULD LIKE TO GO TO 1450, AND I WOULD
22 LIKE TO KNOW IF THERE'S ANY BOARD MEMBER WHO WOULD
23 LIKE TO MAKE A PROPOSAL TO MOVE 1450 UP. SEEING NO
24 PROPOSAL TO MOVE 1450 UP, I WOULD LIKE TO GO TO
25 1491. IS THERE ANY PROPOSAL ON 1491 TO MOVE IT UP?

BARRISTERS' REPORTING SERVICE

1 MS. SAMUELSON: YES.

2 CHAIRMAN KLEIN: JOAN SAMUELSON WOULD LIKE
3 TO MAKE A MOTION TO MOVE 1450 TO TIER I. IS
4 THERE -- EXCUSE ME -- 1491 TO TIER I. IS THERE A
5 SECOND?

6 DR. PULIAFITO: SECOND.

7 CHAIRMAN KLEIN: SECOND BY DR. PULIAFITO.
8 CAN I HAVE THE CONFLICTS, PLEASE.

9 MR. HARRISON: CONFLICTS ARE DR. DAFOE,
10 FRIEDMAN, AND MR. SHEEHY.

11 CHAIRMAN KLEIN: ALL RIGHT. DR. TROUNSON,
12 WHO YOU WOULD YOU LIKE TO ADDRESS THIS PETITION?

13 DR. TROUNSON: ROSA TO DO IT FOR US,
14 CHAIR.

15 DR. CANET-AVILES: GOOD MORNING, MEMBERS
16 OF THE BOARD, MR. CHAIRMAN, AND THE PUBLIC. SO THIS
17 APPLICATION, THE GOAL OF THIS PROPOSAL WAS TO
18 DEVELOP CLINICAL GRADES OF DOPAMINERGIC NEURONS FROM
19 HUMAN EMBRYONIC STEM CELLS FOR THE TREATMENT OF
20 PATIENTS WITH PARKINSON'S DISEASE. THE REVIEWERS
21 FOUND THAT THIS PROPOSAL HAD SOUND SCIENTIFIC
22 RATIONALE BASED ON DECADES OF TISSUE AND CELL
23 TRANSPLANTATION WORK IN THIS FIELD; HOWEVER, THERE
24 WERE IMPORTANT GAPS. AND MOSTLY THE IMPORTANT GAPS
25 WERE IN THE PRELIMINARY EFFICACY DATA AND THE

BARRISTERS' REPORTING SERVICE

1 RESEARCH PLAN WHICH LOWERED THE PANEL' S EXPECTATION
2 FOR AN IND FILING WITHIN THE FOUR-YEAR TIMEFRAME.

3 IN TERMS OF THE PRELIMINARY DATA EFFICACY,
4 THERE WERE A COUPLE OF MAIN POINTS. ONE OF THEM WAS
5 THAT THERE WERE NOT ENOUGH DETAILS IN TERMS OF THE
6 SCALABILITY OF THE PROCESS. AND ANOTHER ONE WAS THE
7 FACT THAT DESPITE THE APPLICANTS HAVING SHOWN THAT
8 THEY COULD DIFFERENTIATE THE NEURONS TO THE A9
9 PHENOTYPE, WHICH IS WHAT IS LOST IN PARKINSON' S
10 DISEASE, WHEN THEY DID THE LAST PURIFICATION
11 PROCEDURE, WHICH INVOLVES A SPECIFIC TECHNIQUE, THEY
12 DID NOT SHOW THE RATE OF PURIFICATION OF THOSE
13 PARTICULAR NEURONS, AND THAT IS VERY KEY.

14 ANOTHER ISSUE WAS WITH THE ANIMAL MODELS.
15 THEY FOUND THAT THERE WAS A CRITICAL LACK OF
16 SENSORIMOTOR TESTING FOR FUNCTIONAL EFFICACY, AND
17 THERE IS A WELL-ESTABLISHED BATTERY OF SENSORIMOTOR
18 TESTS THAT BETTER REFLECT THE HUMAN CONDITION THAN
19 THE TESTS THAT THEY USE ON ROTATIONAL BEHAVIOR IN
20 THE RODENT MODEL OF PD.

21 FINALLY, THERE WAS ANOTHER LACK IN THE
22 ANIMAL MODELS, WHICH IS ALWAYS VERY IMPORTANT IN
23 ORDER TO GO INTO THE CLINIC. AND IT WAS THAT THEY
24 DID NOT INCLUDE AN ASSESSMENT OF EFFICACY IN THE
25 DYSKINESIA RODENT MODEL. THIS IS IMPORTANT BECAUSE

BARRISTERS' REPORTING SERVICE

1 THERE ARE SEVERE DYSKINESIAS, WHICH IS ONE OF THE
2 MOST SERIOUS SIDE EFFECTS OF EARLY NEURAL TISSUE
3 TRANSPLANTATION IN HUMANS. AND REVIEWERS FOUND THAT
4 THIS WAS CRUCIAL AS WELL.

5 THERE WERE SOME ISSUES IN TERMS OF
6 TIMELINES OF THE NONHUMAN PRIMATE ANIMAL MODELS.
7 THEY FOUND THAT THEY SHOULD HAVE ALLOWED MORE TIME
8 FOR THESE STUDIES, AND THEY WERE STARTED A LITTLE
9 LATE.

10 SO THERE WAS -- IN THIS CASE THERE IS AN
11 EXTRAORDINARY PETITION SUBMITTED BY THE APPLICANTS,
12 AND I COULD RESUME THE POINTS OF THE EXTRAORDINARY
13 PETITION IF YOU WISH ME TO DO SO.

14 MS. SAMUELSON: IN THE REVIEW, WHICH I
15 DON'T HAVE IN FRONT OF ME, ABOUT TWO-THIRDS OF IT
16 WAS POSITIVE FINDINGS OF THE REVIEWERS. I'D
17 APPRECIATE IT IF STAFF COULD GO THROUGH THEM ALL
18 BECAUSE IT WAS JUST ONE AND THEN PROBLEMS. THAT'S
19 NOT MY RECOLLECTION OF THE BALANCE OF THE POSITIVE
20 AND NEGATIVES IN THE REVIEW.

21 DR. CANET-AVILES: THERE WERE MORE
22 NEGATIVES THAN TWO-THIRDS, JOAN. WHAT WAS VERY
23 IMPORTANT IS THAT IN ORDER TO GET INTO PRECLINICAL
24 DEVELOPMENT OF PHASE I, TO FILE AN IND, YOU NEED TO
25 HAVE EFFICACY DATA IN THE PROPER MODELS. AND THEY

BARRISTERS' REPORTING SERVICE

1 DID HAVE SOME MODELS, BUT THERE WAS NOT ENOUGH
2 EFFICACY DATA, THERE WAS NOT ENOUGH DETAIL ON THE
3 SCALABILITY OF THE PROCESS. THOSE WERE TWO MAJOR
4 POINTS THAT THE REVIEWERS CONSIDERED THAT IT WASN'T
5 ENOUGH.

6 CHAIRMAN KLEIN: SO ARE YOU SPECIFICALLY
7 REPORTING TO US ON THE REGULATORY ADVICE WE RECEIVED
8 IN THAT MEETING FROM THE REGULATORY CONSULTANT?

9 DR. CANET-AVILES: THEY ACTUALLY REFLECT
10 THE COMMENTS OF ALL THE REVIEW PANEL. I DO NOT HAVE
11 THE SPECIFIC REVIEWER HERE.

12 CHAIRMAN KLEIN: THANK YOU. THE REQUEST
13 IS THAT YOU TRY AND IDENTIFY THE INDIVIDUAL POINTS
14 THAT WERE POSITIVELY REVIEWED. YOU'VE COVERED
15 CERTAINLY SOME OF THEM ALREADY. IF THERE'S OTHERS
16 THAT YOU HAVEN'T COVERED, IF YOU COULD HIGHLIGHT
17 THOSE AT THE REQUEST OF THE BOARD MEMBER.

18 DR. CANET-AVILES: YES.

19 MS. SAMUELSON: I CAN JUST READ THEM FROM
20 THE REVIEW. I NOW HAVE IT IN FRONT OF ME.

21 DR. CANET-AVILES: MAYBE JOAN WANTS ME TO
22 ADDRESS SPECIFIC.

23 CHAIRMAN KLEIN: HIGHLIGHT THE ONES THAT
24 YOU WOULD LIKE TO.

25 MS. SAMUELSON: IT'S A LITTLE CHALLENGING.

BARRISTERS' REPORTING SERVICE

1 CHAIRMAN KLEIN: IS JOAN'S ASSISTANT HERE
2 AT THIS TIME? IF SHE ISN'T HERE, WE WOULD LIKE TO
3 HAVE A STAFF MEMBER ASSIST HER UNTIL THE ASSISTANT
4 IS HERE.

5 DR. CANET-AVILES: JOAN, IF YOU WANT, I
6 WILL JUST GO ONE BY ONE. I WAS TRYING TO BE
7 PRIORITIZING THE POINTS.

8 MS. SAMUELSON: THAT WILL WORK. SURE. GO
9 AHEAD.

10 DR. CANET-AVILES: THE FIRST, ONE POSITIVE
11 WAS THE RATIONALE AND THE SIGNIFICANCE OF THE
12 PROJECT, WHICH WAS ONE OF THE REVIEW CRITERIA, AND
13 THEY FOUND THIS POSITIVE. THE TWO KEY ASPECTS IN
14 THE PRELIMINARY DATA WAS THE PRODUCTION OF A MORE
15 PURE AND EXPANDABLE SOURCE OF DOPAMINERGIC CELLS
16 THAN HAS BEEN USED PREVIOUSLY. AND THEN -- SO THE
17 FIRST PART WAS THAT THE PROCESS WAS DESCRIBED AS
18 SCALABLE BY THE APPLICANT, BUT INSUFFICIENT DETAILS
19 WERE PRESENTED IN THE APPLICATION REGARDING HOW
20 SCALABILITY COULD BE ACHIEVED.

21 AND WHEN WE TALK ABOUT THE SCALABILITY,
22 JOAN, WE ARE ACTUALLY REFERRING ABOUT DATA SHOWING
23 THAT THEY COULD GO, FOR EXAMPLE, FROM A T25 FLASK TO
24 CELL FACTORY TO DESIRED NUMBERS NEEDED FOR THE
25 CLINICAL DOSE. SO IN OTHER WORDS, THERE SHOULD HAVE

BARRISTERS' REPORTING SERVICE

1 BEEN A PROCESS FLOW DIAGRAM FOR SCALE-UP, AND THAT
2 WAS NOT PROVIDED AND IS PRETTY IMPORTANT.

3 ANOTHER POINT WAS THE EVIDENCE THAT WAS
4 PRESENTED ABOUT THE RATE OF PRODUCTION OF THE
5 DOPAMINERGIC NEURONS OF THE A9 PHENOTYPE. THAT WAS
6 ACTUALLY ADDRESSED YESTERDAY, AND I KIND OF TALKED
7 ABOUT SOME FIGURES DURING OUR CLOSED SESSION. AND I
8 MENTIONED THAT THEY SHOWED AT ONE POINT THAT, BUT
9 NOT IN THE FINAL PURIFICATION STEP, WHICH IS
10 IMPORTANT.

11 THE LACK OF SENSORIMOTOR TESTING WAS ALSO
12 SOMETHING IMPORTANT. ALSO THE TIMING. REVIEWERS
13 FOUND THAT THE TIMING AT WHICH THE 12 AND 16 WEEKS
14 POST TRANSPLANTATION WAS TOO LONG.

15 CHAIRMAN KLEIN: SO, ROSA, I THINK THE
16 REQUEST FROM JOAN WAS, WHILE WE'VE IDENTIFIED AND
17 THE STAFF HAS IDENTIFIED IN THEIR WRITE-UP THE ITEMS
18 THAT THE REVIEWERS TOOK ISSUE WITH, THERE WERE MANY
19 POSITIVE COMMENTS BY THE REVIEWERS. AND SHE WANTS
20 YOU TO HIGHLIGHT FOR US THE POSITIVE COMMENTS SO
21 THAT WE HAVE BOTH SIDES OF THIS.

22 DR. CANET-AVILES: OKAY. SO AS I SAID,
23 THE POSITIVE COMMENTS WAS THAT THE RATIONALE FOR
24 THIS KIND OF THERAPY AND THE SIGNIFICANCE AND THE
25 IMPACT WERE POSITIVE, VERY POSITIVE. SO, AS WE

BARRISTERS' REPORTING SERVICE

1 KNOW, CURRENT THERAPIES ARE EFFECTIVE IN THE CONTROL
2 OF PARKINSON'S DISEASE SYMPTOMS. HOWEVER, LONG-TERM
3 EFFICACY DIMINISHES AS THE DEGENERATION OF
4 DOPAMINERGIC NEURONS, CELLS PROGRESSES. SO THAT WAS
5 ONE POSITIVE.

6 THEY PRAISED THE INCLUSION OF PRECLINICAL
7 STUDIES IN A LARGE ANIMAL MODEL, THE NONHUMAN
8 PRIMATE. THEY PRAISED THE INCLUSION OF THAT;
9 HOWEVER, THEY DIDN'T FIND THAT THERE WAS ENOUGH
10 TIME.

11 FROM THE REGULATORY PERSPECTIVE, THEY
12 FOUND THAT THE PROJECT PLAN WAS PRACTICAL, AND IT
13 WAS TARGETING KEY OBSTACLES IN A LOGICAL ORDER. THE
14 PROPOSED MILESTONES AND THE TIMELINE WERE CLEARLY
15 STATED. THOSE ARE ALL POSITIVE COMMENTS.

16 THEY PRAISED THE PRINCIPAL INVESTIGATOR
17 AND THE TWO CO-PI'S AND THE FACT THAT THE PI WAS
18 COMMITTING 45 PERCENT OF HIS OR HER TIME. AND
19 BASICALLY THOSE WERE THE MAIN POSITIVE FACTS.

20 CHAIRMAN KLEIN: I THINK THERE WAS ALSO A
21 VERY POSITIVE STATEMENT THAT MAHENDRA RAO, WHO HAD
22 TREMENDOUS EXPERIENCE WITH THE FDA, WAS COMMITTING,
23 I BELIEVE, 30 PERCENT.

24 DR. CANET-AVILES: WE DID NOT INCLUDE
25 THAT. WELL, WE DON'T HAVE THAT IN THE SUMMARY.

BARRISTERS' REPORTING SERVICE

1 THAT MIGHT HAVE BEEN IN OUR NOTES.

2 CHAIRMAN KLEIN: IS THAT CORRECT, DR.
3 TROUNSON?

4 DR. TROUNSON: THAT'S CORRECT, CHAIR.
5 JUST TO REMIND THE BOARD THAT WE HAVE A MAJOR STUDY
6 IN THE TRANSLATIONAL, EARLY TRANSLATIONAL PHASE
7 BASICALLY ON THE SAME GROUNDS. THAT'S, AS YOU
8 RECALL, IF I MAY, IS A VERY MAJOR STUDY WITH
9 PRIMATES WHERE WE'RE ACTUALLY TRYING TO DERIVE THE
10 PRIMARY DATA THAT'S REALLY IN CHALLENGE IN THIS
11 PARTICULAR GRANT. THEY BELIEVE THAT THE TIME THAT'S
12 NEEDED TO GET THE ANIMAL STUDIES, PARTICULARLY THE
13 PRIMATE STUDIES, UP IS REALLY -- IT DOESN'T ALLOW
14 YOU TO GET EVEN CLOSE TO AN IND IN THE TIMEFRAME.
15 SO THAT WAS REALLY THE KEY PART OF IT, TO BE HONEST.

16 AND WHILE YOU MIGHT HOPE THAT YOU COULD
17 MAKE PROGRESS, I THINK WE REALLY DO NEED THE TIME
18 WITH THE PRIMATE STUDIES TO GENERATE THAT, AND WE'RE
19 NOT FAR ENOUGH AHEAD.

20 CHAIRMAN KLEIN: THE ISSUE WASN'T THE
21 QUALITY OF THE SCIENCE OR THE SCIENTIFIC
22 INVESTIGATORS. THE ISSUE WAS THE TIME THAT WAS
23 NECESSARY TO MEET THE CONVINCING EVIDENCE THAT THEY
24 COULD GET TO A PHASE I HUMAN TRIAL APPROVAL IN 48
25 MONTHS.

BARRISTERS' REPORTING SERVICE

1 DR. CANET-AVILES: YES. THAT WAS ONE OF
2 THE MAIN CRITERIA.

3 CHAIRMAN KLEIN: SO THERE ARE TWO
4 INDIVIDUALS IN THE AUDIENCE THAT HAVE INDICATED THEY
5 WANT TO MAKE PUBLIC COMMENTS ON THIS GRANT. AND,
6 JOAN, I THINK IT WOULD BE HELPFUL FOR THE BOARD,
7 PRIOR TO THE FULL BOARD DISCUSSION, IF WE HAD THE
8 BENEFIT OF THEIR COMMENTS.

9 MS. SAMUELSON: SURE. I AGREE.

10 CHAIRMAN KLEIN: IS THAT APPROPRIATE? SO
11 I'D LIKE TO, IF WE COULD, AT THIS TIME --

12 DR. PENHOET: CAN WE ASK THE SCORE THAT
13 THIS GRANT RECEIVED?

14 CHAIRMAN KLEIN: YES, WE CAN.

15 DR. CANET-AVILES: THIS ONE WAS 53.

16 DR. PENHOET: 63?

17 DR. CANET-AVILES: 53.

18 DR. PRIETO: CAN WE GET A BREAKDOWN OF THE
19 SCORES, THE SCIENTIFIC REVIEWERS AND THE PROCESS
20 SCORE?

21 DR. CANET-AVILES: I DON'T HAVE IT. WE
22 CAN GET IT. WE WILL GET IT TO YOU.

23 CHAIRMAN KLEIN: OKAY. THAT'S IN PROCESS,
24 DR. PRIETO. I'D LIKE TO HAVE THE PRINCIPAL
25 INVESTIGATOR, IF SHE IS PREPARED, TO MAKE A

BARRISTERS' REPORTING SERVICE

1 PRESENTATION.

2 DR. OLSON: I WILL REMIND YOU THAT THE
3 PROCESS SPECIALISTS WERE GIVEN SPECIFIC INSTRUCTIONS
4 OF HOW TO SCORE THIS. SO WITHIN THE TOP QUARTILE,
5 75 OR ABOVE, THAT INDICATED THAT THEY BELIEVED THERE
6 WAS HIGH PROBABILITY THAT, BASED ON WHAT WAS PRESENT
7 IN THE RESEARCH AND DEVELOPMENT PLAN, THAT, IN FACT,
8 AN IND COULD BE FILED WITHIN THE FOUR YEARS. THE
9 SECOND QUARTILE, POSSIBLY THERE WAS A LOWER
10 PROBABILITY, BUT IT WAS POSSIBLE, BUT, AGAIN, THAT
11 IT COULD HAPPEN. I'D SAY IN THE THIRD AND FOURTH
12 QUARTILE, THAT SIGNIFICANTLY CALLED INTO QUESTION
13 AND THERE HAD TO BE -- IT SIGNIFICANTLY CALLED INTO
14 QUESTION WHETHER AN IND COULD BE FILED.

15 SO THE PROCESS SPECIALIST WITH RESPECT TO
16 THIS PARTICULAR AWARD GAVE IT A 65.

17 CHAIRMAN KLEIN: RIGHT. AND THE PROCESS
18 SPECIALIST SCORE DID NOT ALWAYS RECONCILE WITH THE
19 OVERALL SCORE BECAUSE OF TIME. THE PROCESS
20 SPECIALIST GAVE IT A MUCH HIGHER REGULATORY
21 PROBABILITY SEPARATE FROM THE SCIENTIFIC SCORE.

22 DR. OLSON: RIGHT. AND THEY CONSIDERED
23 ONE SPECIFIC ASPECT OF THE PROPOSAL.

24 CHAIRMAN KLEIN: THANK YOU VERY MUCH.

25 MS. SAMUELSON: THERE WERE OTHER SCORES.

BARRISTERS' REPORTING SERVICE

1 CHAIRMAN KLEIN: DR. ZENG, AM I
2 PRONOUNCING IT CORRECTLY?

3 DR. ZENG: DR. ZENG.

4 CHAIRMAN KLEIN: THANK YOU VERY MUCH. IF
5 YOU COULD -- I THINK GIVEN THE SIZE OF THESE GRANTS,
6 I'M GOING TO MAKE THIS A FIVE MINUTES LIMIT RATHER
7 THAN THREE MINUTES.

8 DR. ZENG: WELL, THANK YOU, MR. CHAIRMAN
9 AND ICOC MEMBERS. I AM XIANMIN ZENG. I'M THE
10 PRINCIPAL INVESTIGATOR ON THIS APPLICATION. SO I
11 REALLY THANK YOU FOR THE OPPORTUNITY TO SPEAK ON
12 BEHALF OF MY APPLICATION AND ALSO PATIENTS WHO
13 SUFFER FROM THE PARKINSON'S DISEASE OR PD.

14 PARKINSON'S DISEASE PATIENTS HAVE PLAYED A
15 PIVOTAL ROLE IN SUPPORTING STEM CELL RESEARCH AND
16 HAVE VOLUNTEERED FOR CELL TRANSPLANT IN LARGE
17 NUMBERS. PD IS ONE OF THE FEW DISEASES WHERE WE
18 ALREADY HAVE POSITIVE DATA AND CLINIC EXPERIENCE
19 WITH CELL TRANSPLANTS IN HUMAN PATIENTS.

20 PD IS SPECIFICALLY MENTIONED IN
21 PROPOSITION 71 AS A TARGET FOR STEM CELL RESEARCH,
22 AND OUR APPLICATION WAS THE ONLY INVITED APPLICATION
23 TO SPECIFICALLY OFFER A PATH TO AN IND FOR THIS
24 DISEASE. SO WE ARE CONFIDENT THAT THE PLAN WE HAVE
25 PROPOSED WILL LEAD TO AN IND AND A CLINIC TRIAL IN

BARRISTERS' REPORTING SERVICE

1 FOUR YEARS. INDEED, THE REVIEWER CONCLUDED THAT OUR
2 PROPOSAL HAS, AND I QUOTE, A SOUND SCIENTIFIC
3 RATIONALE BASED ON DECADE OF TISSUE AND CELL
4 TRANSPLANTATION WORK. THEY STATED THAT WE HAVE
5 DEMONSTRATED OUR ABILITY TO PRODUCE DOPAMINERGIC
6 NEURONS IN SUFFICIENT NUMBERS USING MATERIALS
7 SUITABLE FOR CLINIC USES.

8 THEY AGREE THAT WE HAVE ASSEMBLED A STRONG
9 MULTIDISCIPLINE TEAM AND NOTED THAT THE PI AND THE
10 CO-PI'S HAVE THE EXPERTISE AND TRACK RECORD TO
11 PROVIDE LEADERSHIP FOR THIS PROJECT.

12 THEY ALSO PRAISED THE SIGNIFICANT
13 REGULATORY EXPERTISE IN OUR TEAM, WHICH MR. KLEIN
14 ALREADY SAID. DR. RAO IS THE CO-PI ON OUR
15 APPLICATION, AND HE IS THE FORMER FDA CELL AND GENE
16 THERAPY ADVISORY BOARD'S CHAIRMAN.

17 IN CONTRAST, THE CRITICISMS WRITE BY THE
18 REVIEWERS ARE RELATIVE MINOR AND ARE TECHNICAL IN
19 NATURE. THOSE ARE EITHER EASILY ADDRESSED OR HAVE
20 ALREADY BEEN ADDRESSED, BUT DATA WERE NOT INCLUDED
21 DUE TO THE SPACE LIMITATION IMPOSED BY THE
22 APPLICATION STRUCTURE. FOR EXAMPLE, ONE OF THE
23 MAJOR CRITICISM IS THE LENGTH OF THE SENSORIMOTOR
24 FUNCTIONS IN RODENT MODELS. WE HAVE, INDEED,
25 CONCEIVED AN ENTIRE BATTERY OF FUNCTION TESTS WHICH

BARRISTERS' REPORTING SERVICE

1 ARE STANDARD FOR NEUROLOGIC AND BEHAVIOR ASSESSMENT,
2 AND HAVE RECRUIT JACKSON LAB, THE LEADING VENDOR IN
3 CONDUCTING SUCH STUDIES, AS A PARTNER ON THIS GRANT.
4 UNFORTUNATELY THERE IS NOT ENOUGH SPACE TO
5 DELIMINATE ALL THESE TESTS IN DETAILS, WE THINK THE
6 LIMITATION OF THE APPLICATION.

7 I ALSO WANT TO SAY THE STRENGTHS OF OUR
8 PROPOSAL AND THE ESSENTIAL VALIDITY OF OUR PLAN WERE
9 CONFIRMED BY THE INVITATION TO JOIN WITH THE
10 EUROPEAN CONSORTIUM OF 12 NATIONS LED BY SWEDEN, WHO
11 IS THE PIONEER OF CELL TRANSPLANTATION IN PARKINSON
12 DISEASE. THE EUROPEANS WERE IMPRESSED WITH OUR CGMP
13 MANUFACTURING PLAN WHICH IS OUTLINED IN THIS
14 PROPOSAL. THE URGENCY TO DIRECT CIRM FUNDING TO PD
15 IS COMPOUNDED BY THE CIRM'S TEN-YEAR HORIZON. A
16 DELAY OF EVEN A SINGLE YEAR FOR FUNDING THIS PROJECT
17 WOULD BE DETRIMENTAL TO THE TEAM MEMBER AND THE
18 MOMENTUM WE HAVE BUILT.

19 I'M ASKING ICOC TO CONSIDER FUNDING THIS
20 PROJECT SO THAT WE CAN MAINTAIN THIS STRONG TEAM AND
21 BUILD ON OUR EXTRAORDINARY EFFORT OVER THE PAST
22 YEARS. WITHOUT CIRM SUPPORT, IT WILL BE VERY HARD
23 FOR US TO COLLABORATE WITH THE EUROPEAN CONSORTIUM
24 OR MOVE ANY ASPECT OF THIS PROPOSAL FORWARD OR EVEN
25 ADDRESS THE RELATIVELY MINOR CRITICISMS RAISED BY

BARRISTERS' REPORTING SERVICE

1 THE REVIEWERS. I HOPE THE ICOC WILL GIVE SERIOUS
2 CONSIDERATION TO THIS REQUEST. AND THANK YOU FOR
3 YOUR ATTENTION.

4 CHAIRMAN KLEIN: THANK YOU VERY MUCH. AND
5 THANK YOU FOR YOUR SCIENTIFIC COMMITMENT, DOCTOR. I
6 BELIEVE THAT DR. KOVACH ALSO WANTS TO MAKE A
7 STATEMENT.

8 DR. KOVACH: THANKS, MR. KLEIN, FOR
9 ALLOWING ME TO ADDRESS THE ICOC. I'D LIKE TO THANK
10 THE ICOC FOR ITS HARD WORK. LIKE MANY, IF NOT ALL
11 OF YOU, I'VE SPENT THE LAST 15 YEARS TRYING TO LINE
12 UP THOSE RARE OPPORTUNITIES WHERE WE CAN ACTUALLY
13 TAKE A PRODUCT CANDIDATE AND GET IT INTO THE CLINIC.
14 WHETHER IT'S A PHYSICIAN-SPONSORED IND OR A
15 BIOTECHNOLOGY COMPANY, IT'S REALLY ABOUT LINING UP
16 THREE THINGS; AND THAT IS, PEOPLE, THE TECHNOLOGY OR
17 THE KNOW-HOW, AND THE MONEY. AND WE ALL KNOW THAT
18 OF THE THREE, LINING THE PEOPLE UP IS ACTUALLY THE
19 HARDEST THING TO DO.

20 TO COMPLEMENT WHAT XIANMIN SAID, WE WERE
21 THE ONLY APPLICATION. I THINK PART OF IT DEALT WITH
22 THE FACT THAT WE ASSEMBLED A VERY, VERY STRONG
23 SCIENTIFIC TEAM, INCLUDING THE BUCK INSTITUTE,
24 STANFORD, UCSF, CITY OF HOPE, JACKSON LAB WEST IN
25 SACRAMENTO, AND INVI TROGEN.

BARRISTERS' REPORTING SERVICE

1 AND THE OTHER PART, I THINK, DEALS WITH
2 THE RARITY OF ACTUALLY ASSEMBLING THE COMMITTED
3 INDIVIDUALS TO PULL TOGETHER. AND THIS IS SOMETHING
4 THAT I WITNESSED IN THE OVER 20 FACE-TO-FACE
5 MEETINGS THAT WE HAD TO ACTUALLY DEVELOP AN
6 ENTERPRISE VALUE. SO ONE OF THE THINGS TO EMPHASIZE
7 IS WE HAVE AN EXTRAORDINARY VALUE OF KNOW-HOW THAT
8 HAS BEEN CREATED IN THE LAST YEAR POSITIONED
9 ESSENTIALLY TO CREATE A SHOT-ON GOAL. WE TALK ABOUT
10 OPPORTUNITIES TO GET SOMETHING IN THE CLINIC, HOW
11 RARE THAT ACTUALLY IS IN THE STEM CELL AREA.

12 AND THIS IS IN PARKINSON'S DISEASE WHERE
13 OVER A MILLION PEOPLE SUFFER FROM THIS DISEASE.
14 IT'S MENTIONED IN PROPOSITION 71, SO ONE WOULD THINK
15 THAT THERE'D BE A LOT OF APPLICATIONS. BUT IF YOU
16 REALLY -- MY OBSERVATION HAS BEEN IT'S HARD. AND IN
17 THE TEN-YEAR CYCLE OF CIRM, YOU'RE NOT GOING TO HAVE
18 MANY OPPORTUNITIES LIKE THIS.

19 I WOULD SAY THAT BASICALLY, AS I READ THE
20 APPLICATION VERY CLOSELY, TWO POINTS. ONE, IT DOES
21 COME DOWN, WITH ALL DUE RESPECT TO THE PEOPLE
22 REVIEWING THE GRANT, IT'S REALLY MATTER OF OPINION
23 IN TERMS OF CAN WE GET TO THE CLINIC IN FOUR YEARS.
24 AND SO I LOOK AT THIS, TRY TO BE OBJECTIVE. I'M
25 INVOLVED WITH IT; BUT IF YOU LOOK AT THE -- I JUST

BARRISTERS' REPORTING SERVICE

1 DON' T THINK THAT THE QUALITY OF SCIENTISTS WOULD
2 ASSEMBLE AND DEDICATE THIS EFFORT UNLESS IT WAS --
3 UNLESS THEY FELT THAT THEY COULD GET IT TO THE
4 CLINIC IN FOUR YEARS. AND SO I THINK TO ME THAT
5 IS -- I MEAN IN LAW WE HAVE THE BETTER ARGUMENT. I
6 THINK THE BETTER ARGUMENT IS THE FACT THAT WE'VE
7 ACTUALLY ASSEMBLED THIS ENTERPRISE VALUE AND THE
8 TEAM THAT HAS MADE THE COMMITMENT AND BELIEVES WE
9 CAN DO IT. BUT THAT'S REALLY THE QUESTION IS CAN WE
10 GET TO THE CLINIC IN FOUR YEARS.

11 ONE LAST THING THAT I WOULD MENTION IS IT
12 IS A MILESTONE BASE, AS IT SHOULD BE. I THINK THAT
13 MANY OF THESE PROJECTS ARE GOING TO FALL OUT BECAUSE
14 OF THE DATA. IT SHOULD BE A DATA-DRIVEN PROCESS.
15 WE NOT ONLY ACKNOWLEDGE THAT, WE BELIEVE IN THAT.
16 THAT'S HOW IT SHOULD BE.

17 I WOULD POINT OUT, THOUGH, IN TERMS OF THE
18 VERY ISSUE RELATING TO SCALABILITY AND EFFICACY OF
19 THE CELLS THEMSELVES, SUCCESS BY US THAT WE'LL KNOW
20 EARLY IN THIS PROJECT WOULD LITERALLY RAISE THE TIDE
21 OF KNOWLEDGE. AND THIS GOES TO THE SECOND
22 COMPONENT, WHICH COULD BENEFIT A LOT OF OTHER
23 PROJECTS. THE KNOWLEDGE OF HOW TO DO SCALABILITY IN
24 CELLS, I THINK, WOULD REALLY INURE TO THE BENEFIT OF
25 A LOT OF OTHER PROPOSALS, SO ASK FOR THAT

BARRISTERS' REPORTING SERVICE

1 CONSIDERATION AS WELL. BUT THANKS FOR GIVING ME THE
2 CHANCE TO SPEAK.

3 CHAIRMAN KLEIN: DR. PENHOET.

4 DR. PENHOET: I HAVE A GENERAL QUESTION
5 ABOUT THIS AND ABOUT THE GRANT WHICH IS 1-1485. YOU
6 MENTIONED IN THE 1485 CASE THAT THERE WOULD BE
7 SUPPORT AS WELL FROM THE MRC IN THE UK. IN THIS
8 CASE IT WAS MENTIONED THAT A CONSORTIUM OF EUROPEAN
9 ENTITIES CO-FUND THIS WORK. DO THESE -- IT'S A
10 GENERAL QUESTION YOU CAN ANSWER SPECIFICALLY. BUT I
11 BELIEVE THERE WAS REPRESENTATION MADE THAT THERE
12 WOULD BE FUNDING, MAYBE NOT THROUGH US, BUT THE
13 QUESTION IS IF THERE IS FUNDING FROM AN EXTERNAL
14 AGENCY, DOES IT OFFSET THE FUNDS THAT WE HAVE ON
15 THIS PAGE, OR WOULD THOSE FUNDS BE IN ADDITION TO
16 THE BUDGET WHICH IS INDICATED HERE?

17 DR. TROUNSON: NO, ED. IF THERE'S
18 ADDITIONAL FUNDING, WE HAVE NO WRITTEN INFORMATION
19 ON THAT. IT'S NOT PART OF ANY RELATIONSHIP WE HAVE
20 AS AN AGREEMENT WITH ANYBODY. IT'S NOT PART OF THE
21 AGREEMENT WITH MRC, NOR PART OF THE AGREEMENT WITH
22 SPAIN. SO YOU HAVE TO TAKE WHATEVER THAT IS FOR
23 WHAT YOU CAN ASSESS IT AS. I HAVEN'T SEEN ANY
24 DOCUMENTATION THAT WOULD CONFIRM THAT THIS WAS THE
25 CASE.

BARRISTERS' REPORTING SERVICE

1 DR. PENHOET: NEITHER OF THESE TWO HAS
2 FUNDING THROUGH THE PROGRAMS THAT YOU'VE SET UP TO
3 COLLABORATE WITH THESE?

4 CHAIRMAN KLEIN: DR. PENHOET, IF YOU ARE
5 REFERRING TO TWO DIFFERENT GRANTS, THE MRC GRANTS DO
6 HAVE BILATERAL AGREEMENTS IN PLACE AND DO HAVE
7 COMMITTED FUNDS.

8 DR. TROUNSON: BUT NOT IN THIS ONE.

9 DR. PENHOET: NOT IN THIS ONE, BUT IN
10 1485.

11 DR. TROUNSON: WHICH IS?

12 DR. PENHOET: WHICH IS THE THERAPEUTIC
13 ANTIBODIES FOR --

14 DR. TROUNSON: YES, IT DOES AND AGREED TO
15 BE SUPPORTIVE.

16 DR. PENHOET: BUT IF THE GRANT NUMBER HERE
17 IS \$20 MILLION IN 1485, IF MRC PUTS MONEY INTO THIS
18 PROJECT, WILL IT BE DEDUCTED FROM THE 20 MILLION, OR
19 WILL IT BE AVAILABLE ON TOP OF THE 20 MILLION?

20 DR. TROUNSON: IT WILL BE AN ADD-ON. IT
21 WILL BE AN ADD-ON. THE BUDGET REFERS TO THE BUDGET
22 FOR THE CALIFORNIA COMPONENT, AND THE BUDGET FOR THE
23 MRC, WHICH IN THAT PARTICULAR CASE FOR OXFORD IS 4.3
24 MILLION FROM THE MRC TO THE RESEARCHERS IN OXFORD AS
25 PART OF THE JOINT PROGRAM.

BARRISTERS' REPORTING SERVICE

1 DR. PENHOET: THE GRANT WE'RE CURRENTLY
2 DISCUSSING HAS NO COMMITTED FUNDS THROUGH CIRM?

3 DR. TROUNSON: ABSOLUTELY NONE.

4 CHAIRMAN KLEIN: WHAT'S IMPORTANT HERE IS
5 THERE MAY BE REAL OPPORTUNITY THEY'VE IDENTIFIED
6 WITH SWEDEN, BUT WE DON'T HAVE A DOCUMENTED
7 RELATIONSHIP WHERE WE CAN VERIFY THE FUNDING
8 COMMITMENT. SO WHILE THERE IS EVIDENTLY STRONG
9 INTENT, WE DON'T HAVE AN ABILITY HERE TODAY TO
10 VERIFY THIS. UNTIL WE HAVE A BILATERAL AGREEMENT
11 WITH SWEDEN AND A PROTOCOL WHERE WE CAN VERIFY TO
12 YOU, WE'RE IN A SITUATION WHERE WE CAN RECOGNIZE
13 THERE IS AN OPPORTUNITY, BUT WE DON'T KNOW HOW TO
14 EVALUATE ITS TANGIBLE IMMEDIATE NATURE.

15 DR. TROUNSON: I UNDERSTAND, CHAIR, IT'S A
16 CONSORTIUM BASED OUT OF SWITZERLAND.

17 CHAIRMAN KLEIN: OUT OF SWEDEN.

18 DR, TROUNSON: SWITZERLAND. IT INVOLVES
19 SWEDISH RESEARCHERS, BUT IT'S OUT OF SWITZERLAND. I
20 KNOW THE CONSORTIUM, BUT I KNOW NOTHING OF ANY
21 COMMITMENT TO THIS PROJECT HERE. THERE MAY BE, NOT
22 TO MY KNOWLEDGE.

23 CHAIRMAN KLEIN: SO, DR. KOVACH, THAT'S
24 NOT TO SAY THAT WE'RE NOT VERY PLEASED THAT THEY'RE
25 INTERESTED IN THE RESEARCH. IT'S JUST THAT WE DON'T

BARRISTERS' REPORTING SERVICE

1 HAVE THE CURRENT EVIDENCE THAT WE CAN EVALUATE.

2 SO ARE THERE ADDITIONAL QUESTIONS? HAVE
3 YOU FINISHED YOUR COMMENTS, DR. KOVACH?

4 DR. KOVACH: YES. THANK YOU.

5 CHAIRMAN KLEIN: THANK YOU VERY MUCH. AND
6 I UNDERSTAND THAT DR. ARLENE CHIU WOULD LIKE TO
7 ADDRESS.

8 DR. CHIU: THANK YOU FOR THIS OPPORTUNITY.
9 I HAD NO PLANS ON SAYING SOMETHING. AND I JUST
10 WANTED TO COMMENT FIRST TO THANK CIRM FOR PROVIDING
11 US WITH SOME FUNDS TO RUN A CONFERENCE RECENTLY THAT
12 BROUGHT IN SWEDISH INVESTIGATORS TO MEET WITH
13 CALIFORNIA INVESTIGATORS TO EXPLORE OPPORTUNITIES
14 FOR COLLABORATION IN DIABETES AS WELL AS IN
15 NEUROLOGICAL DISORDERS. AND I BELIEVE PERHAPS,
16 CORRECT ME IF I'M WRONG, THAT THESE DISCUSSIONS
17 EMANATED FROM THAT CONFERENCE, AND IT WAS PARTLY
18 FUNDED BY CIRM, AND I THANK YOU FOR THAT. SO IT WAS
19 QUITE RECENT.

20 THE THING THAT I WANTED TO SAY WAS THAT
21 OUT OF THE PANEL DISCUSSION, AND I'M STILL WRITING
22 THE REPORT, SO IT'S NOT PRESENTED TO YOU YET. I WAS
23 GOING THROUGH MY NOTES, AND ONE OF THE COMMENTS WAS
24 FOLLOW-UP. AND THAT IS HOW LONG DO YOU FOLLOW UP ON
25 PATIENTS AND ANIMALS IN ORDER TO SEE LONG-TERM

BARRISTERS' REPORTING SERVICE

1 CONSEQUENCES OF REPLACEMENT THERAPY?

2 AND, AS YOU KNOW, SOME OF THESE QUESTIONS
3 HAVE ARISEN ONLY RECENTLY. AND WE'RE STILL FINDING
4 OUT HOW LONG DO YOU NEED TO FOLLOW UP. AND THE COST
5 OF FOLLOW-UP IS VERY EXPENSIVE, AND THERE WAS SOME
6 DISCUSSION ABOUT WHO'S TO PAY FOR FOLLOW-UP. SO IN
7 SOME CASES, AND I WON'T MENTION ANY NAMES, THEY HAVE
8 PUT ASIDE A COMMITMENT TO FOLLOW UP PATIENTS FOR 15
9 YEARS BECAUSE ONCE YOU PUT CELLS IN, YOU DON'T KNOW
10 EXACTLY WHAT ARE THE SEQUELAE FOR A LONG TIME. SO,
11 THEREFORE, I AGREE, LONGER AND LONGER TERM
12 EXPERIMENTS ARE PROBABLY IN ORDER.

13 BUT THEN YOU TURN THE OTHER SIDE OF THE
14 PAGE AND YOU SAY WHEN DO YOU NEED TO START AND HOW
15 LONG IS ENOUGH FOLLOW-UP? AND IF YOU DON'T GET
16 STARTED SOON, THEN IT WILL DRAG ON AND DELAY ANY
17 POSSIBLE CLINICAL TRIALS FOR DISEASES SUCH AS
18 NEUROLOGICAL DISORDERS BEFORE YOU WANT TO VENTURE
19 AND TRY AND GET AN IND.

20 SO I'M NOT WANTING TO BIAS YOU, BUT THIS
21 IS A CONSIDERATION. EVERY INVESTIGATOR WOULD POINT
22 TO FOLLOW-UP AS AN IMPORTANT ISSUE, BUT NOBODY COULD
23 COME TO A CONCLUSION OF WHAT IS ENOUGH. NOW, RATS,
24 RODENTS, HAVE A LIFE SPAN OF A YEAR OR TWO. SO MANY
25 PEOPLE CHOOSE RODENTS AND FOLLOW UP AS LONG AS THEY

BARRISTERS' REPORTING SERVICE

1 CAN UNTIL THEY DIE. BUT IN TERMS OF PRIMATES, HOW
2 LONG DO YOU FOLLOW UP? SO I JUST WANT TO LEAVE YOU
3 WITH THAT THOUGHT. AND THANK YOU FOR YOUR
4 ATTENTION.

5 CHAIRMAN KLEIN: THANK YOU VERY MUCH. SO
6 THE BOARD HAS HEARD A NUMBER OF POINTS OF VIEW HERE.
7 AND I'D LIKE TO KNOW IF THERE ARE ANY ADDITIONAL
8 BOARD COMMENTS.

9 DR. BLOOM: WE DIDN'T HEAR ANY REBUTTAL TO
10 THE ISSUE OF SCALABILITY.

11 CHAIRMAN KLEIN: THE POINT IS AS TO
12 SCALABILITY, THERE'S NO CURRENT REBUTTAL TO THAT
13 ISSUE. DO WE HAVE ANY ADDITIONAL INFORMATION ON
14 THAT POINT?

15 DR. TROUNSON: THIS IS ONE OF THE ISSUES,
16 AGAIN, WHICH WE'RE TRYING TO ASCERTAIN THROUGH THE
17 TRANSLATIONAL GRANT, CHAIR. IT IS A SERIOUS ISSUE,
18 AND IT IS ONE WHICH EXERCISE THE REVIEWERS IN THEIR
19 THOUGHTS HERE. AND I THINK THE REVIEWERS DID A
20 GENUINE GOOD JOB ON THIS PROJECT. I THINK IT'S
21 FITTED ABOUT WHERE IT SHOULD. IF WE COULD ENCOURAGE
22 THESE STUDIES, WE WOULD. THERE'S NO DOUBT ABOUT IT.
23 BUT TO GO THERE TOO EARLY, OF COURSE, IS TANTAMOUNT
24 TO NOT SUCCEEDING.

25 CHAIRMAN KLEIN: JUST FROM AN INDIVIDUAL

BARRISTERS' REPORTING SERVICE

1 PERSPECTIVE, I THINK WITH ACKNOWLEDGING THE QUALITY
2 OF THE SCIENCE AND THE INVESTIGATORS, THE QUESTION
3 WAS SHOULD THIS BE IN THE EARLY -- IN THE
4 TRANSLATION ROUND NEXT YEAR, OR SHOULD IT BE IN THIS
5 ROUND? WHAT'S APPROPRIATE? THAT'S THE DECISION
6 REALLY BEFORE US.

7 MS. SAMUELSON: I'D LIKE TO ADD A THOUGHT
8 TO THAT, BOB.

9 CHAIRMAN KLEIN: YES. GO AHEAD, JOAN.

10 MS. SAMUELSON: I'M A GREAT DEMONSTRATION
11 OF THE EFFECT OF STRESS ON PARKINSON'S SYMPTOMS AT
12 THE MOMENT. THAT'S PROBABLY ABOUT ALL I'M DOING.
13 I'LL MAKE THIS BRIEF.

14 BUT IT SOUNDS TO ME THAT THE MAIN
15 CRITICISM IS THAT IT'S UNLIKELY THAT IT WOULD MAKE
16 AN IND IN FOUR YEARS. AND MY REACTION TO THAT IS
17 THAT, FIRST OF ALL, THE MAIN AIM OF OUR RESEARCH
18 PROGRAM IS TO GET SIGNIFICANT ADVANCES AS SOON AS
19 POSSIBLE. WHAT IF IT TOOK FIVE YEARS TO GET AN IND?
20 WHAT IF IT TOOK SIX YEARS TO GET AN IND? IF WE
21 COULD GET THAT IN PARKINSON'S RESEARCH, WHICH IS
22 LEADING ALL OF THE OTHER RESEARCH IN CELL
23 TRANSPLANTATION, THAT WOULD BE A TREMENDOUS
24 BREAKTHROUGH. AND IF WE COULD DO IT WITH OUR
25 NICKEL, THAT WOULD BE FABULOUS.

BARRISTERS' REPORTING SERVICE

1 WHY ARE WE GO TO BE ELIMINATING THE
2 POSSIBILITY OF TRYING TO GET TO THE CLINIC SOONER
3 RATHER THAN LATER FOR THAT REASON? IT JUST DOESN'T
4 SEEM SIGNIFICANT IN COMPARISON WITH THE UNMET NEED
5 AND THE IMPORTANCE OF THAT ADVANCE IF WE CAN GET IT.
6 IT SEEMS TO ME THAT PARKINSON'S HAS BEEN DOING MUCH
7 MORE RESEARCH AND DISCOVERING MORE AND MORE
8 BIOLOGICAL COMPLEXITY IN CELL TRANSPLANTATION TO
9 GREAT EFFECT. ALL THE OTHER AREAS OF RESEARCH ARE
10 BENEFITING FROM THAT. BUT BECAUSE ALL OF THAT IS
11 KNOWN, IT'S RAISING LOTS OF QUESTIONS. OF COURSE,
12 THERE ARE MORE QUESTIONS. THAT'S THE POINT OF THE
13 RESEARCH EFFORT. AND THAT'S WHAT WE WOULD BE
14 FUNDING AND EMBRACING, IT SEEMS TO ME, AND TRYING TO
15 MOVE AS FAST AS WE CAN AND NOT BE ONLY CONCERNED TO
16 A PARAMOUNT EXTENT WITH MEETING A 48-MONTH DEADLINE.
17 I'LL LEAVE IT AT THAT. THANKS.

18 CHAIRMAN KLEIN: THANK YOU. DR. PRIETO.

19 DR. PRIETO: TWO QUESTIONS. IF THIS WERE
20 AN EARLY TRANSLATIONAL GRANT, WOULD THIS TEAM BE
21 ABLE TO STAY TOGETHER? WOULD THEY BE ABLE TO KEEP
22 THE PERSONNEL TOGETHER THAT THEY'VE ASSEMBLED FOR
23 THE GRANT? AND THE OTHER IS IF SCALABILITY IS THE
24 STICKING POINT, WHERE WOULD THAT FALL IN OUR
25 GO/NO-GO DECISIONS? AND RELATED TO THAT, HOW ARE WE

BARRISTERS' REPORTING SERVICE

1 GOING TO POLICE THAT FOR ALL OF THESE GRANTS?

2 CHAIRMAN KLEIN: SO, DR. TROUNSON, WOULD
3 YOU LIKE TO ADDRESS THOSE QUESTIONS, PLEASE?

4 DR. TROUNSON: WELL, IT WOULD BE CRITICAL
5 AT SOME POINT CLEARLY. YOU KNOW, I THINK BUILT INTO
6 THE PROJECT IS THE IDEA OF CREATING THE SCALABILITY,
7 BUT ALONG WITH THE SCALABILITY COMES INCREASED RISK.
8 SO IF YOU ARE GOING TO PUSH THESE CELLS REALLY HARD
9 TO MAKE THE NUMBERS, THERE ARE RISKS ASSOCIATED WITH
10 PUSHING THE CELLS THAT HARD. SO YOU'VE GOT TO
11 ACTUALLY ASSESS THAT AS WELL. SO IT IS A COMPLEX
12 QUESTION.

13 YOU'VE GOT TO HAVE A SUFFICIENT SCALE TO
14 ENABLE, AND YOU'VE GOT TO PUSH PRETTY HARD TO DO
15 THAT. BUT THEN THERE'S AN ATTENDANT RISK AS YOU
16 PUSH CELLS HARD TO SCALE THEM UP. SO THAT'S STILL
17 NOT KNOWN. I GOT A FEELING THAT THERE'S PROBABLY
18 SOME -- TIME IS NOT ON OUR SIDE, YOU KNOW, TO DO
19 THAT IN THE TIMEFRAME. SO THESE ARE ALL REALLY
20 IMPORTANT QUESTIONS, AND I THINK THAT'S -- TO GET
21 THE -- YOU CAN GET AN IND IN TWO YEARS IF YOU'VE GOT
22 IT ALL TOGETHER. IN FACT, YOU CAN GET IT IN LESS
23 THAN TWO YEARS IF YOU'VE GOT IT ALL TOGETHER. THE
24 PROBLEM IS THAT IF YOU HAVEN'T GOT IT TOGETHER AND
25 IT COMES APART, THEN YOU DELAY THE TREATMENT. AND

BARRISTERS' REPORTING SERVICE

1 THAT'S WHAT I DON'T WANT TO HAPPEN IN THIS CASE, ANY
2 SIGNIFICANT DELAY.

3 WHETHER THE SCALABILITY WILL CAUSE A
4 DELAY, I'M NOT SURE, BUT IT WILL HAVE TO BE PART OF
5 OUR DETERMINATION OF GO/NO-GO DECISIONS. BUT IT
6 MIGHT WELL BE MORE TOWARDS THE MIDDLE, TOWARDS THE
7 END WHEN WE FINALLY MAKE A JUDGMENT ON THAT BECAUSE
8 THE SCALE PLUS THE RISKS NEED TO BE ASSESSED.

9 CHAIRMAN KLEIN: SO DR -- WELL, LET ME ASK
10 CONFLICTS FIRST.

11 MR. HARRISON: CONFLICTS ARE DAFOE,
12 FRIEDMAN, AND SHEEHY.

13 CHAIRMAN KLEIN: OKAY. DR. PIZZO.

14 DR. PIZZO: SO JUST FOLLOWING UP ON THE
15 CONCEPT OF SCALABILITY AND THE QUESTION THAT YOU
16 RAISED, BOB, WITH REGARD TO WOULD THIS ALSO BE AN
17 APPLICATION FOR A SUBSEQUENT TRANSLATIONAL AWARD. I
18 GUESS THE QUESTION I'D ASK ALAN AND THE SCIENTIFIC
19 TEAM IS WILL THE GUIDANCE OR AT LEAST THE END POINTS
20 THAT WOULD NEED TO BE ACHIEVED BE SUFFICIENTLY
21 DEFINED SO THAT THE INVESTIGATORS WILL UNDERSTAND
22 WHAT HAS TO BE ACCOMPLISHED IN ORDER TO ACHIEVE THAT
23 MILESTONE?

24 DR. TROUNSON: PHIL, I THINK THAT'S A VERY
25 IMPORTANT QUESTION. IT COMES DOWN TO IF YOU GET

BARRISTERS' REPORTING SERVICE

1 YOUR STUDIES FOR AN IND PHASE I TRIAL, AND YOU'VE
2 JUST GOT SUFFICIENT CELLS FOR THAT, YOU'RE GOING TO
3 HAVE TO REDO THE WHOLE THING FOR A PHASE II TRIAL.
4 AND IF YOU HAVEN'T GOT SUFFICIENT CELLS FOR THAT,
5 YOU'RE GOING TO HAVE TO REDO IT FOR THE PHASE III
6 TRIAL. YOU SEE ALL THIS FLOWS BACK ON ITSELF TO
7 CREATE AN EXTRAORDINARILY LONG PERIOD OF TIME.

8 SO THE REASON FOR THE SCALABILITY IS TO
9 SAY, OKAY, THESE ARE THE CELLS THAT EFFECTIVELY GOT
10 THROUGH PHASE I TRIAL, WE CAN TAKE THEM ON TO PHASE
11 II BECAUSE WE'VE STILL GOT THOSE CELLS FROZEN AWAY.
12 AND THEN THE SAME THINGS GOES FOR THE PHASE III
13 TRIAL. THE COMMITMENT IS TO GET A SCALE NECESSARY
14 TO TAKE YOU TO THE CLINIC, OTHERWISE YOU RE-ROTATE
15 ALL THE TIME, AND THAT CAN TAKE YOU, INSTEAD OF FIVE
16 YEARS, IT CAN TAKE YOU 25 YEARS. SO YOU KNOW FROM
17 STEM CELLS, INC. WHAT A REAL PROBLEM THEY HAD WHEN
18 THEY HAD TO REDO THEIR CELLS IN A BATTEN'S TRIAL.
19 IT TOOK THEM, I THINK, TWO YEARS TO RE-GET THE DATA
20 FROM THE CELLS.

21 SO WHAT I'M SAYING IS THE ADVICE THAT WE
22 WILL TAKE WITH THEM IS DEEP ENOUGH TO SAY, WELL,
23 OKAY, IF THE DATA LOOKS GOOD ENOUGH, WE WANT YOU TO
24 HAVE SUFFICIENT CELLS TO MAKE THIS GO TO THE CLINIC
25 IN A MEANINGFUL WAY, NOT IN AN NONMEANINGFUL WAY.

BARRISTERS' REPORTING SERVICE

1 DR. PIZZO: I HAVE TO AGREE WITH THAT.
2 AND JUST, ALTHOUGH NOT IN CELL-BASED THERAPIES, BUT
3 IN OTHER APPROACHES, HAVING MYSELF PARTICIPATED IN
4 FOUR IND'S THAT WENT TO NDA, PRECISELY THE ISSUES
5 THAT YOU'VE DEFINED APPLY.

6 CHAIRMAN KLEIN: THANK YOU. LEEZA
7 GIBBONS.

8 MS. GIBBONS: I KNOW THIS IS WHAT WE'RE
9 TALKING ABOUT IS HOW QUICKLY AND HOW EFFECTIVELY AND
10 EFFICIENTLY AND WITH THE BEST OUTCOME WE CAN GET
11 THESE DRUGS INTO PATIENTS' LIVES. CAN WE TALK SOME
12 MORE ABOUT THE DANGER OF PULLING THE TRIGGER TOO
13 SOON ON THIS BECAUSE OBVIOUSLY WE SAY THIS IS ONE OF
14 OUR TARGET DISEASES, TIME IS OF THE ESSENCE
15 PROPOSITION. WE'VE HEARD THAT. WE'VE HEARD THIS
16 COLLABORATION CAN ONLY BE MADE POSSIBLE IF WE FUND
17 THIS PARTICULAR RESEARCH. THERE ARE A LOT OF
18 COMPELLING REASONS TO GO FORWARD. JOAN'S ARGUMENT
19 CERTAINLY HAS OUR ATTENTION.

20 CAN THE SCIENCE PEOPLE DISCUSS THIS IN
21 LAYMAN'S TERMS WHERE MYSELF AND PERHAPS OTHERS WOULD
22 UNDERSTAND WHAT IS THE DANGER IF WE PULL THE TRIGGER
23 ON THIS ONE TOO QUICKLY? AND IS IT JUST A MATTER OF
24 PROFESSIONAL DISAGREEMENTS WITHIN THE SCIENCE
25 COMMUNITY AND NO ONE REALLY KNOWS FOR SURE?

BARRISTERS' REPORTING SERVICE

1 DR. TROUNSON: MAYBE I SHOULD CALL ON TED
2 LOVE BECAUSE YOU'VE HEARD ENOUGH FROM ME. YOU KNOW,
3 I THINK ESSENTIALLY THERE IS ALWAYS -- THERE COULD
4 ALWAYS TRIGGER AN ADVERSE EVENT THAT COULD SET
5 THINGS BACK. KNOWING WHAT THAT MIGHT BE AND HOW
6 MUCH IT SETS IT BACK, LEEZA, IS REALLY DIFFICULT TO
7 SAY. TED.

8 DR. LOVE: I THINK THAT -- I DON'T THINK
9 THERE'S A LOT OF DANGER INVOLVED HERE BECAUSE THE
10 ASSUMPTION IS THAT THESE MODELS OF SAFETY WILL BE
11 DONE, AND ALL OF THE APPROPRIATE SAFEGUARDS WILL BE
12 IN PLACE. THIS IS PROBABLY, MORE THAN ANYTHING
13 ELSE, AN ISSUE OF STAGE.

14 MS. GIBBONS: NO. I MEANT DANGER IN TERMS
15 OF DELAYING THE TREATMENT LONGER, TO ALAN'S POINT
16 EARLIER, THAT WE DON'T WANT TO ADD MORE YEARS.

17 DR. LOVE: ALAN'S POINT WAS, I THOUGHT,
18 REALLY RELATING TO SCALING THE CELLS. AS YOU SCALE
19 CELLS MORE, YOU RUN MORE RISK THAT THEY BEGIN TO
20 DIFFERENTIATE. AND THOSE CELLS THEN MIGHT, WHEN
21 THEY'RE INJECTED INTO HUMANS, CREATE MORE RISK
22 ISSUES.

23 NOW, ALL OF THAT PRESUMABLY WOULD BE
24 TESTED BEFORE THOSE CELLS WENT INTO HUMANS. I THINK
25 THE SAFEGUARDS SHOULD BE IN PLACE. I DON'T KNOW IF

BARRISTERS' REPORTING SERVICE

1 I WAS MISINTERPRETING SOMETHING.

2 CHAIRMAN KLEIN: I THINK THE QUESTION IS
3 THAT ALAN WENT THROUGH A SCENARIO WHERE IF YOU DON'T
4 HAVE ENOUGH SCALE UP FRONT IN ORDER TO GET THROUGH
5 PHASE I, PHASE II, AND INTO YOUR PRELIMINARY PHASE
6 III, YOU'VE GOT TO GO BACK AND CREATE A MASTER CELL
7 BANK THAT'S LARGE ENOUGH TO GET THERE. OTHERWISE
8 YOU HAVE DIFFERENTIATED CELL CULTURE BASIS THAT
9 YOU'RE NOT USING THE SAME CELLS AT EACH STAGE.

10 DR. LOVE: FROM A REGULATORY PERSPECTIVE,
11 THE CONCERN THERE WOULD BE THAT YOU HAVE A DIFFERENT
12 PRODUCT. AND SO THE FDA WOULD WANT YOU TO GO BACK
13 AND REESTABLISH THE SAFETY OF THAT PRODUCT BEFORE
14 YOU COULD TREAT PATIENTS WITH IT. SO THERE'S NO
15 PATIENT RISK IS WHAT I WAS TRYING TO GET AT.

16 MS. GIBBONS: BUT IT COULD TAKE MORE
17 YEARS.

18 DR. LOVE: BUT THERE IS RISK THAT YOU
19 EFFECTIVELY WASTE MONEY BECAUSE YOU'VE MOVED FORWARD
20 WITH SOMETHING THAT DOESN'T ACTUALLY HAVE THE
21 CAPACITY TO GO ALL THE WAY. AND AS YOU BEGIN TO
22 REENGINEER, YOU, IN THE EYES OF THE FDA, ESSENTIALLY
23 MAKE A DIFFERENT PRODUCT.

24 DR. TROUNSON: AGAIN, IN THAT
25 TRANSLATIONAL STUDY, WE HADN'T DECIDED ON WHAT THE

BARRISTERS' REPORTING SERVICE

1 BEST -- THE FIELD HADN' T DECIDED ON WHAT THE BEST
2 CELLS WERE FOR PARKINSON' S. SO THAT WAS ONE OF THE
3 BIG REASONS FOR DOING THIS PRIMATE STUDY WITH A
4 NUMBER OF DIFFERENT CELL TYPES SO THAT YOU CAN
5 ACTUALLY IDENTIFY THE ONE THAT YOU WANTED TO EXPAND
6 TO THE LEVEL. SO THAT' S WHY WE WERE SUPPORTIVE OF
7 THE TRANSLATIONAL STUDY, OR THAT WAS ONE OF THE
8 REASONS THAT WE WERE SUPPORTIVE OF THE TRANSLATIONAL
9 TO GET THE RIGHT CELL SO THAT WE COULD GET THE
10 EXPANSION AND GET THE CLINICAL TRIAL IN A WAY.

11 IF WE HAPPENED TO DO THE WRONG ONE HERE,
12 OF COURSE, WE WILL HAVE SPENT OUR MONEY DOING
13 SOMETHING THAT WAS INAPPROPRIATE. BUT IT IS -- THE
14 REVIEWERS, THERE WERE SOME REAL EXPERTS ON THE PANEL
15 OF THE REVIEWERS, AND I THINK THEY -- ALL OF THESE
16 COMMENTS CAME OUT IN A WAY, AND THAT' S WHY WE SORT
17 OF SETTLED ON A MARK WHICH WAS PROBABLY NOT AS HIGH
18 AS YOU WOULD HAVE THOUGHT IT WOULD BE GIVEN THE
19 SERIOUS NATURE OF THIS DISEASE. I THINK IT FITTED
20 PRETTY WELL AFTER ALL OF THESE DIFFERENT
21 CONSIDERATIONS.

22 CHAIRMAN KLEIN: ART.

23 MR. TORRES: THANK YOU, MR. CHAIRMAN AND
24 MEMBERS. I WANTED TO, FIRST OF ALL, THE PUBLIC
25 COMMENTS THAT I' VE BEEN MAKING SINCE MARCH,

BARRISTERS' REPORTING SERVICE

1 PARKINSON'S IS ALWAYS PART OF THOSE COMMENTS AS TO
2 WHAT KIND OF COMMITMENTS WE'RE GOING TO MAKE AND HOW
3 WE'RE GOING TO MOVE FORWARD.

4 THE SECOND ISSUE IS THAT FROM WHAT I SEE
5 AS A LAYPERSON, THIS SEEMS TO BE AN EXTRAORDINARY
6 TEAM THAT'S BEEN PUT TOGETHER. IF ANYBODY CAN MOVE
7 FORWARD IN THIS AREA, IT MIGHT VERY WELL BE THIS
8 TEAM.

9 THE THIRD ISSUE THAT I CONCENTRATED IN
10 PUBLIC REMARKS IS THAT PEOPLE SAY THAT, WELL, ARE
11 YOU GOING TO WASTE ALL THIS MONEY WHEN YOU PROVIDE
12 THESE 20-MILLION, 19-MILLION GRANTS? THERE'S ALWAYS
13 THE SAFETY IN THE ESCAPE CLAUSE THAT WE'VE HAD, AND
14 I THINK WE'VE EXERCISED IT ON OCCASION. AND THAT IS
15 IF WE DON'T THINK A PROJECT IS MOVING AS WE THOUGHT
16 IT SHOULD HAVE BEEN MOVING, WE STOP IT. AND WE
17 DON'T WASTE THE MONEY THAT WOULD HAVE GONE FORWARD
18 ON A MAJOR PROJECT LIKE THIS.

19 AND SO I THINK THAT IS GOING TO BE THE
20 PURVIEW. AND I KNOW, ALAN, YOU'VE WORKED VERY HARD
21 ON DETERMINING JUST WHO THESE CANDIDATES OUGHT TO BE
22 TO BE THE NEW VICE PRESIDENT OF RESEARCH AND
23 DEVELOPMENT, AND THAT PERSON IS GOING TO HAVE A VERY
24 TALL RESPONSIBILITY TO MONITOR ALL THE PROJECTS THAT
25 WE APPROVE TODAY, WHETHER IT'S THIS ONE OR ANY

BARRISTERS' REPORTING SERVICE

1 OTHER. BUT I FEEL COMFORTABLE IN MOVING FORWARD
2 BECAUSE THIS HAS BEEN PART OF OUR AGENDA. THIS HAS
3 BEEN PART OF THE VISION. THIS HAS BEEN PART OF THE
4 PUBLIC COMMENTS AS TO WHERE WE'RE MOVING. AND THE
5 ESCAPE CLAUSE, FOR ME, IS THAT AFTER A YEAR, IF WE
6 DETERMINE ALTOGETHER, WITH YOUR VP, WITH THE
7 REVIEWERS, WITH OUR SCIENCE FOLKS, THAT WE'RE NOT
8 MOVING IN THE RIGHT DIRECTION, WE CAN STOP IT
9 WITHOUT WASTING A LOT OF MONEY.

10 CHAIRMAN KLEIN: ALL RIGHT. I THINK WE'VE
11 HAD A HEALTHY DISCUSSION. I'D LIKE TO -- DON REED,
12 YOU HAVE A COMMENT, IF YOU COULD MAKE IT VERY QUICK,
13 PLEASE.

14 MR. REED: THE SCALABILITY ISSUE IS ONE
15 THAT THE FIELD IS GOING TO HAVE TO SOLVE. I THINK
16 IF WE CAN SOLVE IT ALONG THE WAY WITH A TREMENDOUS
17 PROJECT LIKE THIS, I THINK THAT'S VERY VALID. I
18 THINK ALSO WE HAVE TO HAVE THE SAME ATTITUDE TOWARD
19 FUNDING THE RESEARCH THAT THE PARKINSON'S ADVOCATES
20 HAVE FOR FIGHTING FOR THE STRUGGLE. I WORK WITH
21 OTHER STATES. NO GROUP IS MORE CONSISTENTLY
22 RELIABLE IN THE FIGHT THAN PEOPLE IN PARKINSON'S.
23 THEY PUT ASIDE THEIR PERSONAL SUFFERING AND FIGHT
24 HARD FOR THE PROJECTS LIKE THIS ONE. AND I THINK WE
25 SHOULD BEAR THAT IN MIND. IF IT'S A CLOSE THING,

BARRISTERS' REPORTING SERVICE

1 THEN LET'S GO WITH THE PEOPLE WHO HAVE WORKED SO
2 HARD. THEY DESERVE IT.

3 MR. SIMPSON: JOHN SIMPSON WITH THE
4 CONSUMER WATCHDOG. I WOULD ECHO THE VICE CHAIRMAN'S
5 POINT ABOUT SAFEGUARDS. IT SEEMS TO ME THIS
6 DEFINITELY SHOULD BE FUNDED. YOU HAVE APPROPRIATE
7 SAFEGUARDS. IF IT TURNS OUT IT'S NOT GOING AS IT
8 SHOULD, YOU CAN PULL THE PLUG AT A FUTURE DATE. AND
9 YOU'VE ALREADY DEMONSTRATED THAT YOU CAN DO THAT IN
10 SOME OTHER GRANTS, WHICH IS VERY GOOD THING. IT
11 SHOWS THAT YOU ARE MONITORING THE WAY YOU SHOULD BE,
12 AND I THINK WITH THAT BACKGROUND YOU SHOULD FUND
13 THIS.

14 DR. PENHOET: I'D LIKE TO MAKE SURE I
15 UNDERSTAND THE SCORING, DR. OLSON, BASED ON THE
16 PROBABILITY YOU'LL GET TO THE CLINIC WITHIN FOUR
17 YEARS. YOU SAID THIS WAS IN THE MIDDLE OF THE
18 SECOND QUARTILE, IF I UNDERSTOOD YOU CORRECTLY.

19 DR. OLSON: THE SCORING I WAS SPEAKING TO
20 WAS THAT OF THE PROCESS SPECIALIST, WHICH WAS
21 CHARGED DIFFERENTLY FROM THAT OF THE OTHER
22 REVIEWERS. SO YES.

23 DR. PENHOET: AND IT WAS 65 WAS THE SCORE.

24 DR. OLSON: THE PROCESS SPECIALIST GAVE
25 THE 65.

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1 DR. PENHOET: THAT'S WHAT I MEANT. OKAY.

2 DR. PRICE: SO COULD YOU, ONCE AGAIN, GIVE
3 US THE INTERPRETATION? WHAT DO THEY MEAN WHEN THEY
4 SAID IT WAS --

5 DR. PENHOET: AS I UNDERSTOOD HER, FIRST
6 QUARTILE MEANS VERY HIGH PROBABILITY IT WILL GET
7 THERE. SECOND QUARTILE IS A REASONABLE PROBABILITY.
8 THIRD QUARTILE, LESS THAN 50-50 CHANCE, AND BOTTOM
9 QUARTILE PROBABLY HAS NO CHANCE OF MAKING IT. IS
10 THAT CORRECT?

11 DR. OLSON: THAT IS ESSENTIALLY CORRECT.

12 DR. PRICE: SO THE SPECIALIST SAID IT WAS
13 REASONABLE THAT IT WOULD REACH AN IND IN FOUR YEARS.

14 DR. OLSON: THERE WERE SOME OPEN ISSUES,
15 BUT IT WAS POSSIBLE.

16 CHAIRMAN KLEIN: THERE'S REALLY TWO ISSUES
17 HERE. ONE IS THE TIMING. THE OTHER IS THE
18 QUESTION, POINT THAT DR. TROUNSON ADDRESSED, WHICH
19 IS IN THE TRANSLATIONAL GRANT WE HAVE WHERE THEY'RE
20 COMPARING DIFFERENT LINES IN NONHUMAN PRIMATES, TO
21 TRY AND FIGURE OUT WHICH IS THE BEST CELL LINE. HOW
22 IMPORTANT IS THAT INFORMATION IN DEFINING HOW A
23 GREAT TEAM LIKE THIS, WHICH IS SURELY AN EXCELLENT
24 TEAM, DECIDES WHERE TO COMMIT THEIR TREMENDOUS
25 RESOURCES TO TRY AND PUSH PARKINSON'S FORWARD, WHICH

BARRISTERS' REPORTING SERVICE

1 CLEARLY IS AN OBJECTIVE OF THIS GROUP, OF THIS
2 BOARD? THAT'S A QUESTION. DUANE.

3 MR. ROTH: THESE ARE THE VERY DIFFICULT
4 CHALLENGES THAT WE AS A BOARD HAVE TO DEAL WITH.
5 AND WHEN I THINK ABOUT THIS, THERE'S REALLY THREE
6 INTERACTIVE OVERSIGHT RESPONSIBILITIES. THE FIRST
7 IS THE REVIEW PROCESS ITSELF, WHICH WE'RE
8 DISCUSSING. WE HAVE A PROCESS FOR DOING THAT.
9 WE'RE GIVEN THE INFORMATION, AND WE -- SO THE FIRST
10 IS THE REVIEW PROCESS ITSELF, WHICH WE PUT A LOT OF
11 TIME AND ENERGY IN. WE HAVE OVERSIGHT
12 RESPONSIBILITY, AND WE'VE EXERCISED THAT, AND WE
13 WILL CONTINUE TO.

14 THE SECOND IS THE PROGRAMMATIC REVIEW,
15 WHICH IS ANOTHER RESPONSIBILITY. AND THIS
16 PARTICULAR ONE FALLS IN THAT CATEGORY. ARE WE
17 PROPERLY BALANCED IN THE PORTFOLIO?

18 AND THEN THE THIRD IS THE BUDGET, AND THAT
19 WE HAVE THIS FISCAL RESPONSIBILITY, NOT ONLY TO THE
20 OVERALL NUMBER, BUT THE FUTURE GRANTS AND FUTURE
21 THINGS THAT WE PLAN TO DO. SO THESE ARE NOT EASY
22 THINGS TO VOTE ON, BUT I THINK YOU HAVE TO CONSIDER
23 THOSE THREE TOGETHER WHEN YOU MAKE A VOTE.

24 MR. SHESTACK: APROPOS THE BUDGET, YOU
25 HAVE A VERY DIFFERENT POINT OF VIEW THAN CHAIRMAN

BARRISTERS' REPORTING SERVICE

1 KLEIN, AND YOU SHOULD ELUCIDATE YOUR POINT OF VIEW
2 ON THE BUDGET.

3 MS. GIBBONS: I WAS GOING TO ASK WHAT IS,
4 AGAIN, A REMINDER OF OUR FLEXIBILITY AND OUR
5 AUTHORITY?

6 CHAIRMAN KLEIN: SO THE ORIGINAL TARGET
7 BUDGET IS \$210 MILLION. IN FACT, IN MARCH OR APRIL,
8 WHEN DR. TROUNSON AND I AND THE EXECUTIVE COMMITTEE
9 SIGNED OFF ON THE BUDGET TO GO TO THE STATE, WE
10 PROVIDED CONTINGENCIES IN THESE NUMBERS BECAUSE IF
11 THERE WERE CRITICAL OPPORTUNITIES THAT WERE
12 IMMEDIATE, WE WANTED TO BE ABLE ON THE MERITS TO
13 MAKE A DECISION. SO THAT NUMBER IS \$240 MILLION.

14 SO THAT WOULD MEAN THAT WE'D BE USING A
15 SIGNIFICANT PART OF OUR CONTINGENCIES, BUT STILL AT
16 DECEMBER OF 2010 WOULD HAVE A \$70 MILLION
17 CONTINGENCY CARRY-OVER.

18 MS. GIBBONS: WHAT IS THE CHANCE OF THIS
19 ONE COMING BACK TO US IN TRANSLATION WITH THIS
20 CONFIGURATION? IT'S NOT REALLY GOING TO HAPPEN, IS
21 IT?

22 CHAIRMAN KLEIN: NEXT YEAR A TRANSLATIONAL
23 GRANT IS SCHEDULED. AND I BELIEVE THE RFA FOR THE
24 TRANSLATIONAL GRANT GOES OUT WHEN, DR. TROUNSON?

25 DR. OLSON: FEBRUARY.

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1 DR. TROUNSON: THAT'S IN FEBRUARY. AND
2 THERE WILL BE ANOTHER DISEASE TEAMS IN, LETS SAY,
3 12, 13, 14 MONTHS TIME, SO WE WANT TO DO IT YEARLY.
4 SO, YEAH, THESE ARE ROTATING. AND SO THE NEXT
5 OPPORTUNITY IS VERY CLOSE FOR THE TRANSLATION.

6 CHAIRMAN KLEIN: THE FEBRUARY ROUND COMES
7 BACK TO THE BOARD WHEN?

8 DR. TROUNSON: IT WOULD BE JUNE.

9 CHAIRMAN KLEIN: AUGUST, SEPTEMBER PERIOD.
10 SO THAT WOULD MEAN IT WOULD NOT COME BACK TO THE
11 BOARD UNTIL ABOUT OCTOBER.

12 MS. SAMUELSON: AND THAT WOULD BE A
13 TRANSLATIONAL GRANT RATHER THAN THE COMPLEXITY OF
14 THE DISEASE TEAM APPROACH, RIGHT? IT WOULDN'T
15 FIT --

16 CHAIRMAN KLEIN: TEAMS ARE ENCOURAGED IN
17 TRANSLATION AS WELL AS IN DISEASE TEAMS. IN FACT,
18 WE HAVE A NUMBER OF TEAMS WE HAVE FUNDED. DR.
19 QUINT, DO YOU HAVE A QUESTION? DAVID
20 SERRANO-SEWELL.

21 MR. SERRANO-SEWELL: REAL QUICK. BOB, I'M
22 SORRY. I DON'T KNOW IF YOU'RE FINISHED WITH YOUR
23 BUDGET TALK.

24 CHAIRMAN KLEIN: I WAS. THANK YOU.

25 MR. SERRANO-SEWELL: SO JUST IN TERMS OF

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1 MAKING DECISIONS ABOUT WHAT WE HAVE BEFORE US AND
2 HOW I APPROACH IT, I APPROACH IT ON WHAT ARE THE
3 APPLICATIONS WE HAVE NOT ON A FUTURE RFA, RFP,
4 BECAUSE IT'S, IN MY VIEW, SPECULATIVE WHETHER THOSE
5 GROUP OF INDIVIDUALS WILL STAY TOGETHER. IT'S SO
6 FLUID. AND SO I LOOK AT IT AS WHAT'S BEFORE US?
7 WHAT ARE THE FACTS? WHAT'S ALL THE INFORMATION THAT
8 WE HAVE TO MAKE A DECISION? AND NOT THE RFA'S DOWN
9 THE ROAD.

10 DR. POMEROY: SO IT'S BEEN CLARIFIED THAT
11 THIS CAME OUT IN THE SECOND QUARTILE IN TERMS OF THE
12 IND FEASIBILITY. BUT THE OVERALL SCORE WAS 53, AND
13 THAT'S REALLY A REFLECTION OF THE SCIENCE, I'M
14 ASSUMING. IS THAT A CORRECT UNDERSTANDING?

15 DR. OLSON: IT IS A REFLECTION OF ALL THE
16 REVIEW CRITERIA THAT WERE OUTLINED WITH YOU. IT HAS
17 TO DO WITH THE SCIENTIFIC RATIONALE. IT HAS TO DO
18 WITH THE RESEARCH AND PRECLINICAL DEVELOPMENT AND
19 PLAN FEASIBILITY. IT HAS TO DO WITH THE TEAM, THE
20 PI, THE CO-PI, PARTNER PI, AND THE TEAM THAT HAS
21 BEEN PUT TOGETHER. AND IT HAS TO DO WITH THE
22 COLLABORATIONS AND ENVIRONMENT AND WHAT THEY HAVE TO
23 MAKE THIS PROJECT TO SUCCEED. SO ALL OF THOSE
24 PARAMETERS FIGURE INTO THE SCIENTIFIC SCORE.

25 DR. POMEROY: THANK YOU.

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1 CHAIRMAN KLEIN: I THINK WE'VE AT THIS
2 POINT HAD A FULL AND HEALTHY DISCUSSION. I ACCEDE
3 TO ONE LAST COMMENT FROM DR. LOVE, OUR ACTING
4 SCIENTIFIC CHIEF.

5 DR. LOVE: WELL, THIS IS JUST AS A BOARD
6 MEMBER I'M ASKING THIS QUESTION. SO I WANT TO JUST
7 GET A CLEAR ANSWER. WHAT BUDGET NUMBER ARE WE
8 OPERATING TO? IS IT THE 210 THAT WAS DESCRIBED WHEN
9 WE INITIALLY KIND OF STARTED TO LOOK AT THIS RFA, OR
10 IS IT THE 240 NUMBER? WHAT NUMBER SHOULD WE KIND OF
11 BE USING TO SAY THIS IS EXECUTING GOOD FIDUCIARY
12 OBLIGATION OF OUR RESPONSIBILITY IN TERMS OF THE
13 BUDGET? IS IT THE 210 OR THE 240?

14 CHAIRMAN KLEIN: THE STATE HAS
15 SPECIFICALLY FUNDED US BASED ON THE 240 NUMBER, AND
16 THE INITIAL TARGET WAS 210. WE HAVE TO HAVE QUALITY
17 REGARDLESS OF THE NUMBER.

18 DR. ROBSON: MAYBE IF THIS HELPS, THE
19 FINANCIAL PROJECTIONS THAT WE'VE GIVEN YOU OVER THE
20 LAST FEW MONTHS HAVE BEEN BASED ON 210 FOR THIS
21 PARTICULAR PROGRAM. OUR CURRENT SITUATION WITH A
22 210 FIGURE IS WE HAVE ENOUGH MONEY IN OUR CASH-FLOW
23 ACCOUNT TO CARRY US TO THE END OF THE FISCAL YEAR OF
24 2011. THAT'S THE END OF JUNE 2011. IF YOU GO ABOVE
25 210 HERE, THAT WILL SHORTEN, THAT PERIOD WILL

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1 SHORTEN.

2 CHAIRMAN KLEIN: THOSE WERE NOT -- THE
3 REPRESENTATION TO THE STATE WAS THAT WE HAD SET
4 ASIDE CONTINGENCIES FOR SCIENTIFIC OPPORTUNITIES,
5 AND IT WAS ONLY TO GET TO DECEMBER 2010 WITH A
6 CONTINGENCY, NOT TO CARRY THAT CONTINGENCY THROUGH
7 TO JUNE OF 2011.

8 DR. LOVE: I'M TRYING TO BE BINARY. I
9 JUST WANT TO FIGURE OUT WHICH NUMBER DO I THROW OUT.
10 IT SOUNDS LIKE I SHOULD THROW OUT THE 210.

11 DR. PIZZO: COULD I JUST ASK FOR ONE MORE
12 PIECE OF CLARITY AROUND THAT? SO I UNDERSTAND THE
13 210 NUMBER. I UNDERSTAND THE TIMELINES. WHAT'S
14 COMING THAT MAY NOT GET FUNDED IF WE EXCEED 210?
15 WHAT OTHER RFA'S MIGHT GET COMPROMISED?

16 DR. ROBSON: IT'S NOT SO MUCH A QUESTION
17 OF WHAT MIGHT GET COMPROMISED. IT'S JUST A QUESTION
18 OF HOW LONG WOULD OUR MONEY LAST, THE CURRENT MONEY
19 WE HAVE.

20 DR. PIZZO: THOSE ARE THE SAME.

21 DR. ROBSON: WE WORK UNDER THE ASSUMPTION
22 THAT THERE WILL BE ADDITIONAL BOND SALES PRIOR TO
23 JUNE OF 2011. OUR EXPECTATION IS THAT WE'LL HAVE
24 CASH.

25 CHAIRMAN KLEIN: THE ANSWER IS ALL RFA'S

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1 ARE PLANNED INTO THE CASH FLOW AND WE HAVE
2 CONTINGENCY.

3 DR. ROBSON: ARE THERE ANY RFA'S THAT ARE
4 COMING THAT ARE NOT IN OUR MODEL?

5 DR. PIZZO: THAT'S REALLY WHAT I'M ASKING.

6 DR. ROBSON: THE ONLY ONE THAT WOULD BE IS
7 THE EARLY TRANSLATION, WHICH WILL COME UP FOR --
8 IMMUNOLOGY IS IN THERE. ANYTHING THAT'S BEEN
9 THROUGH CONCEPT APPROVAL IS INCLUDED. THOSE THAT
10 HAVE NOT BEEN THROUGH CONCEPT APPROVAL, BUT MIGHT BE
11 APPROVED PRIOR TO JUNE 2011, WILL HAVE AN IMPACT,
12 BUT IT WILL BE A SMALL IMPACT BECAUSE THERE WILL BE
13 A SHORT TIME PERIOD.

14 DR. PENHOET: ONE QUICK POINT. I THINK
15 THAT IRRESPECTIVE OF WHICH GRANTS CONSTITUTE THE
16 PORTFOLIO WE APPROVE TODAY, I BELIEVE THESE NUMBERS
17 ARE A NOT-TO-EXCEED NUMBER BECAUSE WE WILL NOT BE
18 DOING OUR JOB IF WE FUND ALL OF THESE NUMBERS
19 COMPLETE TO THE END. IT MEANS WE WON'T BE
20 TERMINATING ANY PROGRAMS.

21 CHAIRMAN KLEIN: WE DEFINITELY NEED TO
22 MAKE DECISIONS BASED ON CRITERIA WE HAVE BEFORE US.
23 AND IT IS TO THIS BOARD TO MAKE THE JUDGMENT ON
24 WHETHER WE'RE MEETING THOSE CRITERIA.

25 MR. TORRES: I HAVE A MOTION.

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1 CHAIRMAN KLEIN: THE MOTION HAS BEEN
2 CALLED. I'D LIKE TO CALL THE ROLL.
3 MS. KING: ROBERT PRICE.
4 DR. PRICE: NO.
5 MS. KING: FLOYD BLOOM.
6 DR. BLOOM: NO.
7 MS. KING: JACOB LEVIN.
8 DR. LEVIN: ABSTAIN.
9 MS. KING: LEEZA GIBBONS.
10 MS. GIBBONS: YES.
11 MS. KING: MICHAEL GOLDBERG.
12 MR. GOLDBERG: YES.
13 MS. KING: BOB KLEIN.
14 CHAIRMAN KLEIN: NO.
15 MS. KING: GERALD LEVEY.
16 DR. LEVEY: NO.
17 MS. KING: TED LOVE.
18 DR. LOVE: NO.
19 MS. KING: ED PENHOET.
20 DR. PENHOET: NO.
21 MS. KING: PHIL PIZZO.
22 DR. PIZZO: NO.
23 MS. KING: CLAIRE POMEROY.
24 DR. POMEROY: NO.
25 MS. KING: FRANCISCO PRIETO.

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1 DR. PRIETO: YES.
2 MS. KING: CARMEN PULIAFITO.
3 DR. PULIAFITO: NO.
4 MS. KING: ROBERT QUINT.
5 DR. QUINT: NO.
6 MS. KING: DUANE ROTH.
7 MR. ROTH: NO.
8 MS. KING: JOAN SAMUELSON.
9 MS. SAMUELSON: YES.
10 MS. KING: DAVID SERRANO-SEWELL.
11 MR. SERRANO-SEWELL: YES.
12 MS. KING: JONATHAN SHESTACK.
13 MR. SHESTACK: ABSTAIN.
14 MS. KING: OSWALD STEWARD.
15 DR. STEWARD: NO.
16 MS. KING: ART TORRES.
17 MR. TORRES: AYE.
18 CHAIRMAN KLEIN: WHILE IT'S TABULATED, I'D
19 LIKE TO SAY THAT THERE IS TREMENDOUS RESPECT FOR
20 THIS TEAM AND THEIR SCIENTIFIC COMMITMENT AND THE
21 POTENTIAL HERE.
22 I, JUST SPEAKING AS AN INDIVIDUAL, WOULD
23 LIKE TO VERY MUCH SEE THAT APPLICATION FROM THIS
24 TEAM AS EARLY AS POSSIBLE WITH THE TRANSLATIONAL
25 ROUND BEING AVAILABLE IN FEBRUARY. THE PEER REVIEW

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1 WILL HAVE TO JUDGE THIS INDEPENDENTLY AT THAT TIME.
2 THE BOARD WILL HAVE TO JUDGE IT INDEPENDENTLY. THIS
3 IS A TREMENDOUS TEAM OF INDIVIDUALS.

4 MR. SHEEHY: NOW THAT APPLICATION IS OVER,
5 I WENT TO A PRESENTATION AT THE CITY OF HOPE I THINK
6 DR. CHIU HAD ALLUDED TO. I WENT TO A PRESENTATION
7 AT CITY OF HOPE WHERE WE ACTUALLY HAD
8 REPRESENTATIVES FROM THE SWEDISH CONSORTIUM. I
9 DON'T THINK THE DESCRIPTION OF IT THAT WE GOT HERE
10 REALLY CAPTURED THE LEADERSHIP ROLE THAT CONSORTIUM
11 IS MAKING IN TERMS OF TRYING TO GET TO A CURE FOR
12 PARKINSON'S. IT'S LED BY OLLE LINDVALL. I HOPE WE
13 CAN CHARGE STAFF, WE HAVE ALL THESE ARRANGEMENTS
14 WITH ALL THESE OTHER NATIONS. PARKINSON'S IS ONE
15 THE KEY TARGETS. THEY HAVE ALREADY SUBSTANTIAL
16 EXPERIENCE IN CELL THERAPY WITH PARKINSON'S GOING
17 BACK TO THE LATE '80S AND HAVE HAD RESULTS WITH SOME
18 OF THE CELLS THAT THEY HAVE PUT INTO PEOPLE.

19 IT'S KIND OF BEYOND MY COMPREHENSION WHY
20 WE DON'T HAVE A RELATIONSHIP WITH THIS GROUP THAT
21 HAS BEEN FUNDED BY THE EUROPEAN UNION TO REALLY GET
22 TO A CURE IN PARKINSON'S USING CELL THERAPY AS SOON
23 AS POSSIBLE.

24 SO I HOPE GOING FORWARD, AGAIN, THIS
25 APPLICATION IS DEAD, BUT GOING FORWARD, WE WILL TRY

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1 TO TAKE ADVANTAGE OF THIS ENORMOUS MOMENTUM THAT'S
2 HAPPENING IN EUROPE, BUT NOT HERE AND NOT IN
3 CALIFORNIA TO TRY TO REALLY GET TO A CURE FOR
4 PARKINSON'S USING CELL THERAPY.

5 DR. TROUNSON: CHAIR, JUST IN RESPONSE TO
6 THAT, WE'VE BEEN NOW TRYING FOR MORE THAN A YEAR TO
7 GET AN AGREEMENT WITH THE SWEDISH MRC, AND THAT IS
8 STILL ONGOING. WE'RE HAVING REAL TROUBLE IN GETTING
9 ANY GENUINE POSITIVE RESPONSE FROM THE SWEDISH MRC
10 AT THE MOMENT DESPITE HAVING A LOT OF GOOD FRIENDS,
11 LET'S SAY, AMONGST THE SCIENTISTS WHO ACTUALLY DO
12 WORK TOGETHER IN SPECIFIC AGREEMENTS. STANFORD
13 SCIENTISTS WORK WITH THE LUND SCIENTISTS AND SO
14 FORTH. SO WE'VE GOT A LOT OF GOODWILL, BUT AT THIS
15 STAGE, WE HAVEN'T BEEN ABLE TO GET AN AGREEMENT.
16 THE PRIMARY -- ONE OF THE PRIMARY PARKINSON'S
17 DISEASE CONSORTIUMS, AS I SAID, IS RUNNING OUT OF
18 SWITZERLAND, WHICH INCLUDES THE BULK OF THE SWEDISH
19 SCIENTISTS IN PARKINSON'S DISEASE.

20 AND SO WE'VE ALSO MADE APPROACHES TO THAT
21 FUNDING BODY, WHICH IS A SWISS FUNDING BODY, TO SEE
22 WHETHER THERE WOULD BE AN INTEREST IN DOING JOINT
23 WORK WITH US. SO IN ANSWER TO JEFF SHEEHY'S
24 COMMENTS, YES, WE'RE BUSILY TRYING TO DO THAT. AND,
25 OF COURSE, WE'VE ENLISTED THE HELP OF THE SCIENTISTS

BARRISTERS' REPORTING SERVICE

1 THAT WE MET AGAIN AT THE CITY OF HOPE TO TRY AND
2 BRING IT FROM THE GRASS ROOTS UPWARDS AS WELL AS US
3 COMING DOWN.

4 MR. SHEEHY: COULD I JUST MAKE A POINT? I
5 MEAN I FELT LIKE, JUST IN TERMS OF THAT DISCUSSION,
6 THE FACT THAT WE DIDN'T HAVE A FORMAL AGREEMENT,
7 EVEN THOUGH THIS PARTICULAR TEAM HAD MADE THEIR OWN
8 INDEPENDENT ARRANGEMENTS WITH THIS WORLD LEADING
9 ENTERPRISE, WAS A NEGATIVE FACTOR. I WOULD HATE TO
10 SEE ANOTHER SITUATION WHERE AN INDEPENDENT
11 ASSOCIATION WITH A WORLD LEADING CONSORTIUM TRYING
12 TO CURE A DISEASE THAT'S A TARGET DISEASE FOR THIS
13 ENTERPRISE IS SOMEHOW NOT EVALUATED STRONGLY BECAUSE
14 WE HAVEN'T ACTUALLY OBTAINED A FORMAL AGREEMENT WITH
15 THOSE COUNTRIES OR THOSE FUNDING PARTNERS.

16 IF OTHER ARRANGEMENTS HAVE BEEN MADE BY
17 PI'S, BY ENTITIES THAT WE FUND, IT SHOULDN'T BE THAT
18 WE HAVE TO HAVE THESE AGREEMENTS IN PLACE WITH US
19 BEFORE THOSE TYPES OF CONSORTIA GO FORWARD AND
20 BEFORE WE CAN GIVE ANY WEIGHT TO THOSE TYPES OF
21 OTHER ARRANGEMENTS. IT SHOULD BE A LITTLE BIT MORE
22 FLEXIBLE IN HOW WE EVALUATE THAT.

23 CHAIRMAN KLEIN: I THINK IT'S AN IMPORTANT
24 SUBJECT, AND I'LL SCHEDULE IT FOR A DISCUSSION AT
25 THE BOARD. THE KEY ISSUE IS WILL THEY ACCEPT OUR

BARRISTERS' REPORTING SERVICE

1 PEER REVIEW PROCESS, OR DO THEY WANT US TO SUBMIT TO
2 THEIR PEER REVIEW PROCESS?

3 MR. SHEEHY: BOB, THAT'S NOT THE QUESTION.
4 THE QUESTION IS THAT I JUST HEARD A DISCUSSION WHERE
5 WE BASICALLY SAID BECAUSE THIS CONSORTIUM DOESN'T
6 HAVE AN ARRANGEMENT WITH US, WE CAN'T VALUE THE
7 WEIGHT OF THEM INVITING THIS TEAM INTO THAT
8 CONSORTIUM. WE DIDN'T -- HAVING HEARD A VERY
9 LENGTHY DISCUSSION OF WHAT THAT CONSORTIUM WAS DOING
10 AND WHAT THE TYPES OF CELLS, THE AMOUNT OF
11 EXPERIENCE THEY HAVE IN TRYING TO DO CELL THERAPY
12 FOR PARKINSON'S, THE FACT THAT THEY INVITED THIS
13 TEAM IN, WE SHOULD BE ABLE TO CONSIDER THAT AS A
14 FACTOR. WE'RE NOT TALKING ABOUT CO-FUNDING, WHICH
15 IS THESE FORMAL ARRANGEMENTS, BUT I REALLY FELT LIKE
16 WE DID NOT PLACE -- WE DID NOT -- I ALMOST FELT LIKE
17 THAT THAT'S DETRIMENTAL. IN THE DISCUSSION I HEARD,
18 I THOUGHT THAT WAS USED TO THE DETRIMENT OF THIS
19 APPLICATION.

20 CHAIRMAN KLEIN: IF I COULD JUST, AND I'M
21 GOING TO GO TO DR. PIZZO, BUT IF WE HAD A WRITTEN
22 COMMITMENT OF THEIR COLLABORATION AND WHAT IT MEANT
23 AND OUTLINED IT, THAT WOULD HAVE BEEN EXTREMELY
24 HELPFUL. I THINK WE CAN BE FLEXIBLE IN ACCEPTING
25 THOSE KINDS OF WRITTEN COMMITMENTS WITH DETAILS SO

BARRISTERS' REPORTING SERVICE

1 WE KNOW WHAT'S REALLY HAPPENING BECAUSE WE'D LIKE TO
2 ENCOURAGE RELATIONSHIPS WHERE WE CAN LEVERAGE THE
3 SCIENTIFIC VALUES IN THE STATE OF CALIFORNIA. DR.
4 PIZZO.

5 DR. PIZZO: JEFF, JUST FOR THE RECORD, I
6 THINK, OBVIOUSLY I CAN'T SPEAK FOR ANYONE ELSE, BUT
7 I WOULD SAY THAT ISSUE, WHILE IMPORTANT, DIDN'T
8 REALLY AFFECT MY VOTE. I THINK JUST WE'RE LIKELY
9 LOOKING AT THIS IN VARYING WAYS.

10 MR. SHEEHY: I'M NOT SPEAKING TO THE
11 APPLICATION. I'M TALKING ABOUT GOING FORWARD. I
12 HAVE A CONFLICT WITH THAT APPLICATION. I'M VERY
13 COMFORTABLE WITH THE DECISION THAT THE BOARD TOOK.

14 DR. STEWARD: THIS IS A QUESTION. THERE
15 ARE SORT OF TWO GENERAL WAYS THAT ONE CAN IMAGINE
16 THESE KINDS OF COLLABORATIONS GOING FORWARD. ONE IS
17 SORT OF TOP DOWN WHERE CIRM STARTS WITH A
18 COLLABORATIVE AGREEMENT WITH THE PARTICULAR COUNTRY
19 INVOLVED. BUT THE OTHER IS AT THE LEVEL OF THE
20 INDIVIDUAL INVESTIGATOR. IS THERE ANYTHING THAT
21 PROHIBITS ANY OF OUR CIRM APPLICANTS FROM GOING
22 FORWARD, TALKING TO CONSORTIA, MAKING ARRANGEMENTS?

23 DR. TROUNSON: ABSOLUTELY NOT AT ALL, AND
24 IT'S STRONGLY WELCOMED BY ME. IN FACT, I WAS VERY
25 STRONGLY SUPPORTIVE OF HOW WE COULD CREATE LINKAGES

BARRISTERS' REPORTING SERVICE

1 EVEN IF THE GOVERNMENTS WERE UNABLE TO COME TO ANY
2 COMMITMENT, AND THAT WE WOULD ASSIST WITH WORKSHOPS,
3 WE'D ASSIST WITH WHATEVER OTHER ARMORY WE HAVE IN
4 THAT REGARD. BUT UNTIL WE GET, AS BOB SAID, UNTIL
5 YOU GET LETTERS SHOWING YOU THAT YOU'VE GOT
6 AGREEMENTS, IT'S JUST A GOOD THOUGHT.

7 DR. STEWARD: SO I WOULD JUST SAY THAT IT
8 WOULD BE, I THINK, USEFUL FOR THE CIRM APPLICANTS TO
9 KNOW THAT AND THAT WE VALUE THOSE KINDS OF
10 COLLABORATIONS AND ENCOURAGE THEM TO ACTUALLY GO
11 FORWARD AND TRY TO WORK THIS OUT IN ADVANCE.

12 CHAIRMAN KLEIN: ABSOLUTELY.

13 DR. TROUNSON: THE OTHER THING, BOB, I
14 JUST WANT TO REASSURE THE BOARD, THOSE PROJECTS THAT
15 DON'T GET FUNDED, WE WILL CONTINUE TO WORK TOGETHER
16 WITH THOSE GROUPS TO SEE IF WE CAN ACTUALLY TAKE
17 WHATEVER DEFICIENCIES THERE ARE AND HELP THEM WITH
18 MAKING GOOD THOSE DEFICIENCIES; THAT IS, TO KEEP THE
19 TEAMS TOGETHER.

20 IT HAS BEEN CLEAR TO ME THAT IN SOME OF
21 THE INTERNATIONAL ARRANGEMENTS THAT DIDN'T GET
22 FUNDED IN OUR PREVIOUS -- IN SOME OF OUR PREVIOUS
23 APPLICATIONS, THE TEAMS ARE TOGETHER, STILL
24 TOGETHER, WORKING HARD TO GET THEIR APPLICATIONS UP.
25 AND WE'RE GIVING THEM AS MUCH HELP AS WE CAN IN THAT

BARRISTERS' REPORTING SERVICE

1 REGARD. IT WILL BE ONE OF THE CHARGES, AGAIN, FOR
2 THE NEW APPOINTMENT TO HELP IN THIS REGARD, NOT ONLY
3 THOSE PEOPLE THAT ARE FORMED, BUT THOSE THAT ARE
4 NOT -- THAT HAD A DEFICIENCY IN THEIR PROJECT THAT
5 DIDN'T ENABLE THIS TO BE APPROVED HERE.

6 CHAIRMAN KLEIN: IT IS IMPORTANT FOR THE
7 VALUES WE COMMONLY HOLD TO MAKE SURE THE WRITTEN
8 AGREEMENTS ACKNOWLEDGE THE ACCESSIBILITY REQUIREMENT
9 ON JOINT DISCOVERIES FOR CALIFORNIANS AND THE
10 PRICING FOR CALIFORNIA'S NONPROFIT AND PUBLIC SECTOR
11 ENTITIES UNDER THE CALRX PROGRAM. SO IT IS VERY
12 IMPORTANT THAT WE ASSURE PATIENTS IN CALIFORNIA IN
13 THOSE AGREEMENTS THAT THOSE BASIC ISSUES WILL BE
14 RESPECTED.

15 I'D LIKE TO ASK, AS WE GO FORWARD, AT THIS
16 POINT ARE THERE ANY OTHER APPLICATIONS ON WHICH A
17 BOARD MEMBER WOULD LIKE TO MAKE A MOTION TO MOVE IT
18 UP, GOING DOWN FROM 1467 THROUGH THE REST OF THE
19 SCHEDULE?

20 DR. BLOOM: MOVE THAT 1421 BE MOVED UP.

21 MR. SHESTACK: I SECOND.

22 CHAIRMAN KLEIN: IT'S MOVED BY DR. BLOOM,
23 SECOND BY JON SHESTACK. I'D LIKE TO HAVE A
24 PRESENTATION BY DR. STEFFEN. I'D LIKE TO SAY DR.
25 STEFFEN HAS BEEN THE LEAD ON THIS DISEASE TEAM ROUND

BARRISTERS' REPORTING SERVICE

1 AND HAS DONE AN EXTRAORDINARY JOB WITH TREMENDOUS
2 TIME COMMITMENT AND ENERGY COMMITMENT THAT IS REALLY
3 TREMENDOUS. THANK YOU. DOCTOR, COULD ALSO IN YOUR
4 COMMENTS PROVIDE THE SCORE?

5 DR. STEFFEN: THIS APPLICATION 1421
6 RECEIVED A SCORE OF 41. THE APPLICATION PROPOSES TO
7 DEVELOP A HUMAN NEURAL STEM CELL LINE AS A THERAPY
8 FOR MALIGNANT BRAIN TUMOR, SPECIFICALLY RECURRENT
9 HIGH-GRADE GLIOMAS. THE NSC'S WILL BE GENETICALLY
10 ENGINEERED TO DELIVER AN ENZYME, CARBOXYLESTERASE,
11 WHICH I AM GOING TO CALL CE, WHICH CAN CONVERT A
12 SYSTEMICALLY ADMINISTERED PRODRUG CPT-11 TO A POTENT
13 CHEMOTHERAPEUTIC AGENT SN-38.

14 A NUMBER OF PRECLINICAL STUDIES ARE
15 PROPOSED IN RODENT MODELS, INCLUDING EVALUATION OF
16 DELIVERY ROUTES AND DOSES OF NSC'S TO MAXIMALLY
17 TARGET TUMOR DELIVERY, SELECTION OF THE CE ENZYME
18 SOURCE BASED ON DIFFERENT CONVERSION RATES,
19 PHARMACOKINETIC TESTING, OPTIMIZATION OF THE CPT-11
20 DOSING, AND PRECLINICAL SAFETY AND TOXICOLOGY.

21 THE GROUP WILL ALSO DESIGN A CLINICAL
22 HUMAN PROTOCOL AND PREPARE DOCUMENTS FOR AN IND
23 APPLICATION.

24 SO OVERALL WHILE REVIEWERS APPRECIATED THE
25 SCIENTIFIC RATIONALE AND POTENTIAL IMPACT OF THE

BARRISTERS' REPORTING SERVICE

1 PROPOSAL, THERE WERE A NUMBER OF CONCERNS ABOUT THE
2 PRELIMINARY DATA THAT LED THEM TO QUESTION THE
3 PROJECT'S SCIENTIFIC MATURITY AND FEASIBILITY.

4 THE SCIENTIFIC RATIONALE FOR THE PROPOSAL
5 IS SOUND AND DESCRIBED, AND THE REVIEWERS DESCRIBED
6 THE OVERALL STRATEGY AS ELEGANT. THEY APPRECIATED
7 THE ADVANTAGES OFFERED BY LOCAL SELECTIVE DELIVERY
8 OF A CHEMOTHERAPEUTIC AGENT TO BRAIN TUMORS.

9 REVIEWERS DID QUESTION WHY THE CE/CPT-11
10 APPROACH WAS CHOSEN OVER THE OTHER DRUG ENZYME AND
11 WOULD HAVE APPRECIATED A DISCUSSION OF THIS CHOICE.
12 THIS ISSUE WAS RAISED IN AN EXTRAORDINARY PETITION.
13 AND AT THE END OF THE SUMMARY, WE'LL COME BACK AND
14 ADDRESS THE POINTS ON THAT PARTICULAR ISSUE.

15 REVIEWERS ALSO RECOGNIZE THE SIGNIFICANCE
16 OF THE PROPOSAL SINCE THIS IS A DISEASE WHERE THE
17 MAJORITY OF PATIENTS HAVE A FATAL DIAGNOSIS WITHIN
18 ONE YEAR.

19 SO A FEW ISSUES ABOUT THE PRELIMINARY DATA
20 WHICH LED REVIEWERS TO QUESTION THE FEASIBILITY OF
21 THE APPROACH. THEY FOUND THE DATA DEMONSTRATING THE
22 TUMOR TROPISM OF THE NSC'S TO BE COMPELLING. THEY
23 WERE NOT CONVINCED THAT THE DATA SUPPORTING THE
24 PRODRUG CONVERSION STRATEGY WORKED IN THIS SYSTEM
25 COMPARED TO OTHER ENZYME PRODRUG COMBINATIONS THAT

BARRISTERS' REPORTING SERVICE

1 HAVE BEEN STUDIED MORE EXTENSIVELY.

2 REVIEWERS ACKNOWLEDGE THAT THE APPLICANT
3 PRESENTS IN VIVO IMAGING DATA SHOWING TUMOR
4 REGRESSION IN A RODENT GLIOMA MODEL, BUT FOUND IT
5 DIFFICULT TO ASSESS THE RESULTS WITHOUT STATISTICAL
6 ANALYSES OR HISTOLOGIC DATA.

7 REVIEWERS RAISED SOME QUESTIONS ABOUT THE
8 SURVIVAL LENGTH OF THE NSC'S IN VIVO. THE APPLICANT
9 CITED UNPUBLISHED DATA THAT THE NSC'S WILL SURVIVE
10 IN TUMORS AT LEAST TWO WEEKS, AND REVIEWERS WERE
11 UNSURE WHETHER ONE TREATMENT ROUND WOULD BE
12 SUFFICIENT, AND COMMENTED THAT THE PLAN MAY NEED TO
13 ACCOMMODATE THE POSSIBILITY OF MULTIPLE DOSES OF
14 NSC'S.

15 WHILE REVIEWERS QUESTION THE PROPOSAL'S
16 SCIENTIFIC MATURITY, THEY PRAISED THE MATURITY OF
17 THE REGULATORY STRATEGY. THE NSC LINE IN THIS
18 PROPOSAL HAS BEEN FAVORABLY REVIEWED BY THE FDA
19 RECOMBINANT DNA ADVISORY COMMITTEE, OR RAC, AND IS
20 PART OF AN IND CURRENTLY UNDER REVIEW.

21 THE RESEARCH PLAN AND THE MILESTONES WERE
22 GENERALLY REASONABLE AND HAD SOME CONCERNS ABOUT A
23 NUMBER OF IMPORTANT DETAILS. THEY FELT THAT THE
24 MILESTONES SHOULD BE RESET TO ALLOW FOR GENERATION
25 OF THE COMPELLING PRECLINICAL DATA TO SUPPORT THE

BARRISTERS' REPORTING SERVICE

1 OVERALL HYPOTHESIS. REVIEWERS RECOMMENDED
2 PERFORMING IN VITRO POTENCY ASSAYS WITH THE SN-38 ON
3 MODELS OF PRIMARY HUMAN BRAIN TUMOR TISSUE.

4 THEY ALSO FELT THAT THE EFFICACY OF SN-38
5 IN HETEROGENEOUS PATIENT TUMORS SHOULD BE
6 DEMONSTRATED BEFORE PROCEEDING FURTHER.

7 REVIEWERS FOUND THE PI AND THE RESEARCH
8 TEAM TO BE GENERALLY WELL QUALIFIED WITH APPROPRIATE
9 EXPERTISE, INCLUDING GMP MANUFACTURING AND
10 SUCCESSFUL IND FILINGS. THEY WERE, HOWEVER,
11 CONCERNED BY THE NUMBER OF PERSONNEL AND DESCRIBED
12 THE RESEARCH TEAM AS ENORMOUS. THEY RECOMMENDED
13 COMBINING SOME OF THE LOW PERCENT EFFORT POSITIONS
14 TO ENHANCE EFFICIENCY AND CONSERVE RESOURCES.

15 WITH RESPECT TO THE COLLABORATIONS AND
16 RESOURCES AVAILABLE TO THE TEAM, THE REVIEWERS FOUND
17 THESE TO BE MORE THAN ADEQUATE TO COMPLETE THE
18 PROPOSED PROJECT. THE COLLABORATIONS BRING TOGETHER
19 ESSENTIAL INGREDIENTS INCLUDING IMAGING AND
20 STATISTICAL SUPPORT.

21 SO OVERALL WHILE THE REVIEWERS AGREED THAT
22 THE PROPOSAL ADDRESSED AN IMPORTANT MEDICAL NEED AND
23 COULD POTENTIALLY HAVE IMPACT, THEY DID NOT FEEL
24 THAT THE APPLICANT HAD PRESENTED SUFFICIENT
25 PRELIMINARY DATA TO JUSTIFY THE FEASIBILITY OF THE

BARRISTERS' REPORTING SERVICE

1 THERAPEUTIC APPROACH.

2 THAT WAS THE CONCLUSION OF THE WRITTEN
3 SUMMARY STATEMENTS FROM THE REVIEW SESSION IN
4 SEPTEMBER. THERE IS AN EXTRAORDINARY PETITION THAT
5 THE INSTITUTE RECEIVED THAT YOU ALL HAVE IN YOUR
6 BINDERS AND WAS DISCUSSED LAST EVENING. IN THAT
7 EXTRAORDINARY PETITION, I WILL LEAVE IT TO YOU TO
8 READ THE INVESTIGATOR'S COMMENTS, WHICH INCLUDE THE
9 EXPERTISE BROUGHT BY THE TEAM.

10 AND THEN I WANT FOCUS FOR A MINUTE JUST ON
11 THE CHOICE OF THERAPEUTICS. AND THE APPLICANT
12 ARGUES THAT THE CHOICE OF THERAPEUTICS IS WELL
13 FOUNDED AND SHOULD BE TAKEN UNDER CONSIDERATION.

14 THE PRELIMINARY DATA THAT WAS AT THE HEART
15 OF THIS DISCUSSION WAS REVIEWED IN CLOSED SESSION
16 YESTERDAY BECAUSE IT INVOLVED EXAMINING DATA THAT IS
17 PART OF UNPUBLISHED PROPRIETARY WORK.

18 THE CIRM STAFF EVALUATION CAME TO THREE
19 CONCLUSIONS AFTER LOOKING AT THAT DATA. THAT, ONE,
20 THE APPLICANT TEAM HAS AN ASSAY TO SENSITIVELY
21 DETECT IN VIVO THE ACTION OF BOTH THE PRODRUG AND
22 THE METABOLITES LOCALLY AT THE BRAIN TUMOR SITE.
23 AND THESE GO DOWN TO THE LEVEL OF SEVERAL HUNDRED
24 PICOGRAMS OF ACTIVE COMPOUND.

25 THE CIRM STAFF ALSO CONCLUDED THAT THERE

BARRISTERS' REPORTING SERVICE

1 WAS EVIDENCE THAT THE CELLS PRODUCED THE ENZYME, THE
2 CARBOXYLESTERASE, THAT IS ACTIVE AGAINST BRAIN TUMOR
3 CELL LINES.

4 AND THE THIRD CONCLUSION IS THAT THERE IS
5 DATA PROVIDED IN THE APPLICATION BY THE APPLICANT
6 FROM THEIR WORK IN ANOTHER BRAIN TUMOR MODEL THAT
7 SHOWS THAT THE SYSTEM OF NEURAL STEM CELLS
8 DELIVERING THE ENZYME AND ITS ABILITY TO CONVERT THE
9 PRODRUG TO THE ACTIVE METABOLITE IS FUNCTIONAL IN
10 VIVO.

11 THAT CONCLUDES THE STAFF ASSESSMENT ON THE
12 EXTRAORDINARY PETITION.

13 CHAIRMAN KLEIN: AND, DR. STEFFEN, AS TO
14 THE CONCLUSION AS TO THE EFFECTIVENESS OF THIS
15 PARTICULAR CHEMO AGENT. FROM THE STAFF, IS THIS A
16 HIGH QUALITY?

17 DR. TROUNSON: MAYBE I CAN ADDRESS THAT,
18 CHAIR. I THINK A CENTRAL COMPONENT OF THIS PROJECT
19 IS WHETHER THE DRUG THEY'VE CHOSEN IS SUFFICIENT AND
20 ACTIVE TO KILL A GLIOMA. AND IF IT'S NOT, OF
21 COURSE, THEN IT CLEARLY IS A PROBLEM. DR. STEFFEN
22 AND STAFF HAVE BEEN OUT THERE TALKING TO EXPERTS IN
23 THE FIELD, AND WE'D HAVE TO SAY THE BULK OF THE
24 EXPERTS, CERTAINLY THE BULK OF THE EXPERTS BELIEVE
25 THAT THIS COMPOUND IS THE DRUG OF CHOICE FOR GLIOMA.

BARRISTERS' REPORTING SERVICE

1 AND IF YOU COULD DELIVER TO THE SITE OF THE GLIOMA
2 SPECIFICALLY THIS ACTIVE DRUG AT THE KIND OF
3 CONCENTRATIONS THAT THE APPLICANT BELIEVES IS
4 FEASIBLE, AND THEY HAVE SOME EVIDENCE THAT THEY'RE
5 GETTING SUFFICIENT TOXIC DRUG THERE, THEY DO HAVE
6 EVIDENCE THAT THEY ARE, THEN THIS IS A PRETTY
7 IMPORTANT DIFFERENCE, IF YOU LIKE, TO WHAT THE
8 GRANTS WORKING GROUP CONSIDERED WAS THE CENTRAL
9 ISSUE IN THIS PROJECT.

10 SO I'D LIKE TO ASK TED LOVE TO COMMENT AS
11 WELL BECAUSE HE SAT THROUGH THIS, PLUS HE'S AN
12 EXPERT IN THIS AREA, AND HE'S ALSO CONSIDERED ALL
13 THE INFORMATION. BUT WE WANT THE BOARD TO
14 UNDERSTAND IN THIS PARTICULAR INSTANCE THE
15 DISAGREEMENTS WOULD PROBABLY BE PROFOUNDLY IN MAKING
16 A CHOICE OF THIS DRUG RATHER THAN ANOTHER DRUG.
17 AND, OF COURSE, THERE'S ANOTHER PROJECT THAT'S
18 TREATING USING ANOTHER DRUG. SO IT'S A COMPLICATED
19 ISSUE, AS YOU KNOW.

20 BUT THE EXPERT ADVICE IS IN THE CASE OF
21 THE GLIOMA, THIS WOULD BE THE MOST IDEAL DRUG THAT
22 IS CURRENTLY AVAILABLE. BUT, TED, CAN YOU REALLY
23 SORT OF PUT SUBSTANCE TO THAT? OR I'M HAPPY FOR YOU
24 TO SAY THAT REALLY I EXPRESSED THE VIEWS OF WHAT
25 WE'VE BEEN TRYING TO GET AT IN THIS PROJECT.

BARRISTERS' REPORTING SERVICE

1 DR. LOVE: WELL, I'LL BE FAIRLY BRIEF, BUT
2 I THINK THE THING THAT I WOULD SAY IS THAT, AS ALAN
3 SAID, THERE IS A SIGNIFICANT AMOUNT OF SYMMETRY
4 BETWEEN THIS GRANT AND A GRANT THAT'S ALREADY IN
5 TIER I, AND THERE WAS A SIZABLE DIFFERENCE IN THE
6 SCORE. AND I THINK IT'S FAIR TO SAY THAT AT LEAST I
7 PERSONALLY HAVE STRUGGLED TO UNDERSTAND
8 SCIENTIFICALLY WHY THAT DIFFERENCE EXISTS.

9 WE PLOWED INTO DATA AND THE INFORMATION,
10 PARTICULARLY ABOUT THE USE OF THE VARIOUS
11 CHEMOTHERAPEUTICS, I THINK YOU WALK AWAY AND FEEL
12 LIKE THAT CERTAINLY DOESN'T EXPLAIN THE DIFFERENCE
13 IN SCORE. IN FACT, IF ANYTHING, CPT-11 MIGHT BE A
14 MORE ATTRACTIVE EXPERIMENTAL APPROACH HERE.

15 SO THAT'S A CHALLENGE, QUITE FRANKLY, IS
16 THAT I DON'T THINK WE WERE EVER ABLE TO REALLY
17 UNDERSTAND THAT, AND WE TRIED VERY HARD TO
18 UNDERSTAND THAT. AND AS I DUG INTO IT DEEPER AND
19 DEEPER, I JUST PERSONALLY HAVE TO SAY THAT I THINK
20 THAT TECHNICALLY THIS GRANT LOOKS AS GOOD AS ONE
21 THAT'S VERY SIMILAR THAT HAD A SCORE OF 71.

22 MR. SHESTACK: ISN'T THIS A SITUATION OF
23 HUMAN ERROR WHERE THE PROCESS SPECIALIST AT OUR
24 REVIEW SESSION HAD A VERY SPECIFIC POINT OF VIEW,
25 THAT THIS WAS NOT THE RIGHT THERAPEUTIC AGENT AND

BARRISTERS' REPORTING SERVICE

1 SUBSEQUENTLY HAS BEEN DISAGREED WITH?

2 MR. SHEEHY: ACTUALLY THE PROCESS
3 SPECIALIST SCORED IT HIGH, BUT THERE WAS A
4 DISAGREEMENT.

5 CHAIRMAN KLEIN: HE'S TALKING ABOUT ONE OF
6 THE TECHNICAL SPECIALISTS, NOT THE REGULATORY
7 SPECIALIST.

8 MR. SHESTACK: RIGHT.

9 MR. SHEEHY: THE REGULATORY SPECIALIST
10 ACTUALLY GAVE IT A TOP QUARTILE.

11 MR. SHESTACK: MY UNDERSTANDING WAS THAT
12 THERE WAS SOMEONE WHO HAD A VERY SPECIFIC POINT OF
13 VIEW THAT SUBSEQUENTLY -- EVERYONE WHO IS
14 KNOWLEDGEABLE SAID IT WAS JUST A MISTAKE. THEY WERE
15 MISINFORMED. AND, HENCE, THIS GRANT GOT A LOW SCORE
16 WHEN MANY PEOPLE WHO SEEM TO KNOW ABOUT IT BELIEVE
17 IT DESERVES A HIGHER SCORE.

18 CHAIRMAN KLEIN: DR. LOVE SAID THAT THAT'S
19 RIGHT. HE WAS NOT IMMEDIATELY AT THE MICROPHONE.

20 MR. SHEEHY: HAVING BEEN IN THE
21 DISCUSSION, I MEAN BASICALLY THEY SAID YOU USED THE
22 WRONG DRUG. IT'S LIKE, DUH. YOU CAN IMAGINE WHY
23 THE WHOLE THING KIND OF COLLAPSED AFTER THAT. SO
24 WHAT WE'RE HEARING IS --

25 MR. SHESTACK: IS THAT THEY USED THE RIGHT

BARRISTERS' REPORTING SERVICE

1 DRUG.

2 MR. SHEEHY: I LEAVE THAT TO STAFF AND TO
3 DR. LOVE WHO HAVE MORE EXPERIENCE ON WHAT THE
4 APPROPRIATE THERAPEUTIC TO DELIVER MIGHT BE. YOU
5 KNOW, THE WHOLE THING FALLS APART IF YOU'RE NOT
6 USING THE APPROPRIATE THERAPEUTIC.

7 CHAIRMAN KLEIN: EXCUSE ME, DR. PRIETO.
8 I'M GOING TO TAKE YOUR COMMENT, AND THEN I'D LIKE TO
9 LET THE BOARD KNOW THERE'S THREE MEMBERS IN THE
10 PUBLIC, DR. ABOODY, DR. MOATS, AND DR. BARISH, WHO
11 WOULD LIKE TO MAKE COMMENTS.

12 DR. PRIETO: I WAS ALSO IN THIS REVIEW,
13 AND IT SEEMS TO ME THAT THIS CHOICE OF TREATMENT WAS
14 A SUBSTANTIAL FACTOR IN BRINGING DOWN THE SCORE OF
15 THIS APPLICATION, AND IT TURNS OUT THAT THAT
16 CRITICISM APPEARS TO BE INVALID.

17 CHAIRMAN KLEIN: THANK YOU.

18 DR. TROUNSON: DR. PRIETO, YOU HAVE TO BE
19 A BIT CLEAR THAT THE USE OF THIS DRUG IN GLIOMA,
20 THAT NO DRUGS WORK VERY WELL IN IT. SO WHAT WE'RE
21 SAYING IS REALLY DOES THIS DELIVERY SYSTEM WITH THIS
22 DRUG PROVIDE YOU WITH SOME CONFIDENCE THAT IT IS --
23 IT COULD BE EFFECTIVE. SO WHAT I WANT TO MAKE SURE
24 IS THAT THIS TERRIBLE DISEASE DOESN'T HAVE A VERY
25 GOOD TREATMENT AT ALL, AND THE DRUG DELIVERED ISN'T

BARRISTERS' REPORTING SERVICE

1 VERY EFFECTIVE. BUT IF IT WAS DELIVERED TO THE SITE
2 WITH A VERY ACTIVE CONCENTRATION OF THE ACTIVE
3 MOLECULE, MAYBE YOU'D FEEL CONFIDENT THAT IT WAS A
4 LITTLE BETTER.

5 DR. PRIETO: IS THE DELIVERY SYSTEM -- IN
6 THE OTHER GRANT WHICH SCORED HIGH, WHICH IS IN THE
7 FUNDABLE CATEGORY CURRENTLY, HOW DOES THEIR DELIVERY
8 SYSTEM DIFFER?

9 DR. TROUNSON: IT'S ESSENTIALLY THE SAME
10 DELIVERY SYSTEM, ESSENTIALLY THE SAME.

11 DR. PRIETO: WE'VE ALREADY -- WE ARE
12 LIKELY TO APPROVE A GRANT USING THE SAME DELIVERY
13 SYSTEM, AND IT TURNS OUT THAT THESE PEOPLE USING THE
14 SAME DELIVERY SYSTEM HAVE, IN FACT, CHOSEN WHAT IS
15 PROBABLY THE BEST POTENTIAL DRUG.

16 DR. TROUNSON: I THINK IT IS IN THE PUBLIC
17 DOMAIN, CHAIR, AND IT'S NOT SOMETHING THAT WE KNEW,
18 BUT IN TERMS OF THE INFORMATION THAT WAS PUT TO YOU
19 IS THAT THIS APPLICANT HAS AN IND ON THE DRUG, ON
20 ONE OF THE TWO DRUGS PROPOSED TO BE USED BY THE
21 OTHER APPLICANT, ALREADY HAS, SO IT DOESN'T HAVE AN
22 IND, BUT HAS AN IND IN PROCESS OR CONSIDERATION.

23 DR. PRIETO: SO THIS APPLICANT IS ACTUALLY
24 FURTHER ALONG.

25 DR. TROUNSON: ARGUABLY FURTHER ALONG.

BARRISTERS' REPORTING SERVICE

1 CHAIRMAN KLEIN: I THINK THE OTHER --

2 MR. SHESTACK: THAT DOESN'T CONCERN THIS
3 GRANT.

4 CHAIRMAN KLEIN: WE'RE NOT GOING INTO THIS
5 GRANT AT THIS TIME, THE OTHER GRANT AT THIS TIME,
6 BECAUSE IT IS A MORE COMPLEX FACT PATTERN.

7 MS. GIBBONS: THIS IS MY QUESTION. SO
8 PROCEDURALLY WE'RE LOOKING AT THIS ONE.

9 CHAIRMAN KLEIN: WE'RE ONLY ADDRESSING
10 THIS GRANT.

11 MR. SHESTACK: WHETHER TO MOVE IT UP.

12 CHAIRMAN KLEIN: WHETHER TO MOVE IT UP.
13 AND I BELIEVE DR. ABOODY HAS SOME COMMENTS IF WE
14 COULD HEAR FROM HER. AND MY UNDERSTANDING IS THAT
15 DR. ABOODY IS ONE OF THE ORIGINAL AUTHORS ON THIS
16 DELIVERY SYSTEM AND HAS PUBLISHED SINCE THEN ON THIS
17 DELIVERY SYSTEM.

18 DR. ABOODY: CHAIRMAN KLEIN AND MEMBERS OF
19 THE BOARD, I'M DR. KAREN ABOODY, PRINCIPAL
20 INVESTIGATOR ON THE GRANT IN DISCUSSION. I GREATLY
21 APPRECIATE THIS OPPORTUNITY TO PRESENT OUR PETITION
22 IN SUPPORT OF FUNDING OUR PROPOSAL.

23 AS YOU'VE HEARD, HIGH-GRADE GLIOMAS ARE
24 DEVASTATING BRAIN TUMORS THAT CAN STRIKE PEOPLE AT
25 ANY AGE. AND UNFORTUNATELY THE PROGNOSIS IS VERY

BARRISTERS' REPORTING SERVICE

1 POOR WITH AVAILABLE THERAPIES, WITH SURVIVAL AT
2 RECURRENCE MEASURED IN MONTHS. AND THERE'S A
3 CRITICAL NEED FOR NEW AND INNOVATIVE TREATMENT
4 STRATEGIES.

5 OUR APPROACH HARNESSSES THE UNIQUE ABILITY
6 OF NEURAL STEM CELLS TO TARGET TUMORS. WE PROPOSE
7 TO USE THESE TUMOR TARGETING CELLS TO DELIVER CANCER
8 KILLING AGENTS SPECIFICALLY TO BRAIN TUMORS. OUR
9 TEAM ALREADY HAS A PROVEN TRACK RECORD FOR BRINGING
10 A NEURAL STEM CELL-MEDIATED BRAIN CANCER TREATMENT
11 TO IND SUBMISSION WITHIN FOUR YEARS. I BELIEVE WE
12 HAVE THE EXPERIENCE, EXPERTISE, INFRASTRUCTURE, AND
13 TECHNOLOGY TO FILE A NEW IND FOR A MORE EFFECTIVE
14 NEURAL STEM CELL BRAIN TUMOR TREATMENT IN THE NEXT
15 FOUR YEARS FOR THE FOLLOWING REASONS.

16 FIRST, I HAVE BEEN WORKING AT THE LEADING
17 EDGE OF THIS FIELD FOR THE PAST 14 YEARS BOTH IN
18 ACADEMICS AT HARVARD AND IN INDUSTRY. MY SEMINAL
19 PAPER IN *PNAS* WAS THE FIRST TO SHOW THAT NEURAL STEM
20 CELLS HOME TO INVASIVE BRAIN TUMOR SITES.

21 SECOND, OUR TEAM HAS ALREADY RECEIVED
22 UNANIMOUS CONSENT FROM THE NIH RECOMBINANT DNA
23 ADVISORY COMMITTEE TO USE OUR ENGINEERED HUMAN
24 NEURAL STEM CELL LINES IN CLINICAL TRIALS.

25 THIRD, WE HAVE ALREADY ESTABLISHED AN FDA

BARRISTERS' REPORTING SERVICE

1 COMPLIANT MASTER CELL BANK AT CITY OF HOPE GMP
2 FACILITY FOR USE OF THESE CELLS IN PATIENTS. OF
3 IMPORTANCE, THIS MASTER CELL BANK IS ESTABLISHED AND
4 EXPANDABLE TO MAKE FURTHER WORKING CELL BANKS, AND
5 THE LINE ITSELF IS APPROVED BY THE NIH FOR HUMAN
6 USE. THUS, WE DO NOT NEED TO SEEK OUT A NEW SOURCE
7 OF NEURAL STEM CELLS. THE STEM CELL DELIVERY
8 VEHICLE IS ALREADY IN HAND.

9 FOURTH, WE HAVE ALREADY COMPLETED THE
10 NECESSARY SAFETY AND PRECLINICAL STUDIES AND
11 RECEIVED REGULATORY APPROVALS FROM THE IRB AND
12 INSTITUTIONAL BIOSAFETY COMMITTEE REQUIRED FOR THIS
13 INITIAL IND SUBMISSION.

14 MOST IMPORTANTLY, OUR TEAM IS THE FIRST IN
15 THE WORLD TO FILE AN IND WITH THE FDA FOR NEURAL
16 STEM CELL-MEDIATED CANCER THERAPY WHICH IS FOR
17 RECURRENT GLIOMA PATIENTS. SPECIFICALLY, OUR FIRST
18 IND CURRENTLY UNDER REVIEW WITH THE FDA IS FOR USE
19 OF OUR CELLS, THIS CELL LINE, TO DELIVER CYTOSINE
20 DEAMINASE, WHICH COMBINED WITH THE ORAL PRODRUG
21 5-FC, PRODUCES THE CHEMOTHERAPEUTIC AGENT 5-FU
22 LOCALLY AT THE TUMOR SITE.

23 THE PRIMARY GOAL OF THIS FIRST IN HUMAN
24 TRIAL IS TO DEMONSTRATE SAFETY AND FEASIBILITY OF
25 OUR NEURAL STEM CELL-MEDIATED APPROACH USING THESE

BARRISTERS' REPORTING SERVICE

1 SAME MASTER CELL BANK CELLS. OUR CIRM PROPOSAL
2 SEEKS TO IMPROVE THE THERAPEUTIC POTENTIAL OF OUR
3 TECHNOLOGY SO THAT WE CAN DELIVER CE TO CONVERT
4 SYSTEMICALLY ADMINISTERED CPT-11 TO SN-38. THIS IS
5 A CHEMOTHERAPEUTIC AGENT SHOWN BY OUR STUDIES AND
6 OTHERS TO BE A THOUSANDFOLD MORE EFFECTIVE AT TUMOR
7 KILLING THAN 5-FU. IN FACT, OUR PRECLINICAL STUDIES
8 USING THIS APPROACH WITH OUR CELLS AND THE CE/CPT-11
9 APPROACH IN NEUROBLASTOMA MODELS DEMONSTRATED
10 90-PERCENT CURE AT ONE YEAR AS OPPOSED TO ZERO
11 PERCENT IN THE UNTREATED GROUP.

12 SO OUR PRELIMINARY DATA AND CITED DATA
13 STRONGLY SUPPORT THIS APPROACH FOR GLIOMA TREATMENT
14 AS WELL. CPT-11 IS IN PHASE I TRIALS WITH GLIOMA.
15 OUR TECHNOLOGY WILL LOCALIZE THE EFFECT OF THE
16 CPT-11 TO THE BRAIN TUMOR SITES AND INCREASE THE
17 EFFECT A THOUSANDFOLD.

18 FINALLY, CITY OF HOPE IS AN EXEMPLARY
19 INSTITUTION FOR TRANSLATIONAL STUDIES WITH OVER 40
20 PERCENT OF THEIR PATIENTS IN CLINICAL TRIALS. WE
21 KNOW THE PROCESS, WE KNOW THE ISSUES, AND WE HAVE
22 THE CELLS, REGULATORY AND PRECLINICAL TIMELINE, AND
23 THERAPEUTIC VECTORS IN HAND AND READY FOR
24 DEVELOPMENT TO SUCCESSFULLY FILE AN IND AND A SECOND
25 IND WITHIN THE NEXT FOUR YEARS.

BARRISTERS' REPORTING SERVICE

1 I BELIEVE THAT OUR TEAM IS CURRENTLY IN
2 THE MOST ADVANCED POSITION FOR TRANSLATING NEURAL
3 STEM CELL-MEDIATED CANCER THERAPY FROM THE
4 LABORATORY TO PATIENT TRIALS AND FIRMLY COMMITTED TO
5 BRINGING THIS NOVEL APPROACH INTO THE CLINIC WITH
6 FIRM SUPPORT.

7 WE SINCERELY APPRECIATE YOUR COMMITMENT TO
8 SUPPORTING THE BEST, MOST ADVANCED SCIENCE FOR
9 TRANSLATION TO CLINICAL APPLICATION. AND I THANK
10 YOU FOR CONSIDERING OUR EXTRAORDINARY PETITION AND
11 SUPPORT OF FUNDING OUR APPLICATION. THANK YOU VERY
12 MUCH.

13 CHAIRMAN KLEIN: THANK YOU, DR. ABOODY.
14 AND DR. MOATS.

15 DR. MOATS: SHE ENDED A LITTLE MORE
16 QUICKLY THAN I EXPECTED. THANK YOU, BOARD MEMBERS,
17 FOR CONSIDERING OUR PETITION.

18 I WOULD JUST LIKE TO SAY FROM A SISTER
19 INSTITUTION THAT WE SUPPORT THIS APPLICATION VERY
20 STRONGLY. I'M FROM CHILDREN'S HOSPITAL LOS ANGELES
21 USC. WE HAVE BEEN WORKING WITH KAREN ON THE IND AND
22 THE PRE-IND MEETINGS, AND WE'RE DOING A LOT OF THE
23 SAFETY AND EFFICACY STUDIES FOR AMENDMENTS THAT WE
24 HAVE IN MIND. SHE'S BEEN A GREAT COLLABORATOR, AND
25 SHE'S FOCUSED VERY SPECIFICALLY ON THE CLINICAL

BARRISTERS' REPORTING SERVICE

1 APPLICATION OF THIS RATHER THAN ON THE HARD CORE
2 BASIC SCIENCE SIDE.

3 AND I WOULD LIKE TO POINT OUT THAT I AM
4 FROM THE CLINICAL DEPARTMENTS AT CHILDREN'S, NOT THE
5 BASIC SCIENCE DEPARTMENTS AT CHILDREN'S. SO I
6 REPRESENT NEURAL ONCOLOGY, NEUROSURGERY, AND
7 NEURORADIOLOGY, WHICH IS AN INTERESTING DISTINCTION
8 IN THE TRANSLATIONAL WORLD BECAUSE I FOCUS ON TOPICS
9 THAT WE REALLY BELIEVE ARE GOING TO IMMEDIATELY BE
10 TRANSLATABLE.

11 AND AS YOU PROBABLY KNOW, GLIOMA IN
12 CHILDREN IS AN EXTREMELY BAD DISEASE AND THAT WE'RE
13 LOOKING FOR THERAPIES THAT CAN SHARE NEURONS
14 PARTICULARLY. SO THE FOCUS OF CHILDREN'S HOSPITAL
15 LOS ANGELES AND THE NEURAL TUMOR PROGRAMS IS TO
16 SPARE NEURONS. AND WE THINK THAT STEM CELL THERAPY
17 HAS THE MAJOR ADVANTAGE OF THAT. AND I APPRECIATE
18 YOU GUYS TAKING THE TIME TO REVIEW OUR PROCESS.
19 THANK YOU VERY MUCH.

20 CHAIRMAN KLEIN: THANK YOU, DR. MOATS.
21 AND DR. BARI SH.

22 DR. BARI SH: THANK YOU FOR THE OPPORTUNITY
23 TO SPEAK IN SUPPORT OF THIS PROPOSAL. MY NAME IS
24 MICHAEL BARI SH. I'M PROFESSOR OF NEUROSCIENCES AT
25 CITY OF HOPE. I'M CHAIR OF THE DEPARTMENT. I'M

BARRISTERS' REPORTING SERVICE

1 ASSOCIATE DEAN FOR ACADEMIC AFFAIRS IN OUR GRADUATE
2 SCHOOL. I'M ALSO A HANDS-ON SCIENTIST.

3 ON THIS PROJECT I'M TEAM LEADER FOR
4 MICROSCOPY AND FOR QUANTITATIVE ANALYSES. I'M
5 SPEAKING SIMPLY TO EMPHASIZE THE ACTIVE INVOLVEMENT
6 OF SENIOR LEADERSHIP AT CITY OF HOPE IN SUPPORTING
7 THIS PROPOSAL. THIS IS ONE OF THE MOST EXCITING
8 PROJECTS I'VE EVER BEEN INVOLVED WITH, AND I THINK
9 IT'S POTENTIALLY THE MOST SIGNIFICANT. THANK YOU
10 VERY MUCH.

11 CHAIRMAN KLEIN: THANK YOU VERY MUCH. AND
12 COULD I HAVE CONFLICTS, PLEASE.

13 MR. HARRISON: CONFLICTS ARE DAFOE,
14 FRIEDMAN, GOLDBERG, POMEROY, AND PULIAFITO.

15 CHAIRMAN KLEIN: YES. THANK YOU. DUANE.

16 MR. ROTH: YES. THIS IS ONE WHERE I THINK
17 EVEN THOUGH THE EXTRAORDINARY PETITION WAS LATE,
18 WHICH IS ANOTHER SUBJECT, BUT THE EXTRAORDINARY
19 PETITION CAME IN LATE, WHICH I THINK WE HAVE TO
20 ADDRESS IN THE FUTURE; BUT SETTING THAT ASIDE, IT'S
21 THE ONE OF ALL THE EXTRAORDINARY PETITIONS THAT
22 SUPPORTED FACTUAL INFORMATION THAT WAS NOT CORRECT.
23 AND SO IN ON THIS ONE I'LL BE VOTING IN FAVOR FOR
24 THAT REASON.

25 CHAIRMAN KLEIN: THANK YOU. ART.

BARRISTERS' REPORTING SERVICE

1 MR. TORRES: AM I ASKING A SILLY QUESTION
2 THEN? ON THE OTHER PROPOSAL THAT IT'S IN THE TOP
3 TIER, ARE WE GOING TO REMOVE THAT BECAUSE IT'S THE
4 SAME?

5 CHAIRMAN KLEIN: THAT'S NOT -- THAT'S
6 SOMETHING THAT'S GOT TO BE SEPARATELY CONSIDERED,
7 AND THERE ARE SEPARATE CONFLICTS.

8 MR. SHESTACK: AND IT'S NOT QUITE A DIRECT
9 CORRELATION.

10 CHAIRMAN KLEIN: THE OTHER PROPOSAL HAS
11 ALSO A SEPARATE THERAPY THAT'S UNDER CONSIDERATION
12 AS WELL.

13 MR. TORRES: IN ADDITION TO WHAT WE'VE
14 SEEN.

15 MR. SHESTACK: AND THE BOARD MAY WANT TO
16 SEPARATELY MAKE A COMMENT ABOUT THAT FOR THE RECORD.

17 CHAIRMAN KLEIN: WE ARE FOCUSING ONLY ON
18 THIS APPLICATION AT THIS TIME. ADDITIONAL COMMENTS?

19 MR. SHESTACK: I WOULD JUST LIKE TO SECOND
20 WHAT DUANE ROTH SAID, THAT THIS PROPOSAL SEEMS LIKE
21 THE EXACT TEXTBOOK EXAMPLE OF WHAT THE EXTRAORDINARY
22 PETITION PROCESS IS SUPPOSED TO DISCOVER WHEN THERE
23 WAS PERHAPS A TRUE MISINTERPRETATION OF FACT. SO I
24 THINK IT DESERVES SERIOUS CONSIDERATION.

25 CHAIRMAN KLEIN: THANK YOU. ANY

BARRISTERS' REPORTING SERVICE

1 ADDITIONAL COMMENTS? DR. TROUNSON.

2 DR. TROUNSON: JUST A COUPLE OF POINTS.
3 WE DID RECEIVE A CONFIDENTIAL NOTE FROM THE PI
4 BEFORE THE FIVE DAYS. WE ASKED HER TO RECONSIDER
5 SOME OF THE MATTERS THAT SHE HAD IN HER NOTE TO US.
6 SO WE DID ACTUALLY RECEIVE A CORRESPONDENCE OF A
7 CONFIDENTIAL NATURE BEFORE AND ASKED HER TO
8 RECONSIDER HER SUBMISSION BECAUSE IT WAS A PUBLIC
9 SUBMISSION, WHICH SHE DID. SO I THINK WE STILL
10 DIDN'T RECEIVE THE PUBLIC SUBMISSION WITHIN THE FIVE
11 DAYS, BUT WE HAD HAD CORRESPONDENCE. I DON'T KNOW
12 IF THAT HELPS.

13 THE OTHER THING IS TO JUST TO REMIND YOU
14 THAT PERHAPS WHERE THERE MAY BE -- WHERE I MAY HAVE
15 SOME DISAGREEMENT WITH THE PI IN THIS MATTER IS THAT
16 DEMONSTRATING THE EFFECTIVENESS ON NEUROBLASTOMA
17 ISN'T -- BY THE EXPERTS ISN'T A GOOD TEST FOR
18 DECIDING THAT IT WORKS FOR GLIOMA. SO JUST TO SAY
19 THAT THAT PIECE OF INFORMATION THAT THE REVIEWERS
20 REALLY DID NOTE AND THE EXPERTS AGREE ISN'T PROBABLY
21 THE APPROPRIATE TEST. THAT IS NOT TO SAY THAT THEY
22 CAN'T DO THE APPROPRIATE TEST OR IT HASN'T BEEN
23 DONE, BUT IT WASN'T IN THE SUBMISSION.

24 CHAIRMAN KLEIN: THANK YOU. OKAY. I'D
25 LIKE TO GET A ROLL CALL UNLESS THERE'S OTHER

BARRISTERS' REPORTING SERVICE

1 COMMENTS. DR. STEWARD.

2 DR. STEWARD: CAN I JUST ASK ONE QUESTION
3 BEFORE I VOTE? SO IN THINKING ABOUT THIS, ONE OF
4 THE COMMENTS THAT DUANE MADE LAST TIME OR MAYBE TIME
5 BEFORE THAT WAS OUR RESPONSIBILITIES TO BE FISCALLY
6 SOUND. AND THE QUESTION IS ARE WE GOING TO GO BACK
7 TO THE TIER I GRANTS AND ASK ABOUT RECONSIDERING
8 THOSE?

9 CHAIRMAN KLEIN: WE ARE GOING THROUGH THE
10 TIER I GRANTS AFTER THIS TIER.

11 DR. STEWARD: AND WILL THAT INCLUDE THE
12 TWO GRANTS THAT WE MOVED UP LAST NIGHT, OR HAVING
13 VOTED ON THOSE, ARE THOSE ALREADY IN THAT TIER?

14 CHAIRMAN KLEIN: THEY'RE IN TIER I. AND
15 WE ARE GOING TO LOOK AT TIER I OVERALL, AND ANY
16 GRANT THAT ANYONE WANTS TO TAKE OUT OF TIER I IS
17 OPEN TO A MOTION.

18 MR. SERRANO-SEWELL: I HAVE A COMMENT.

19 CHAIRMAN KLEIN: DAVID SERRANO-SEWELL.

20 MR. SERRANO-SEWELL: I'M INCLINED TO
21 SUPPORT THIS. I JUST -- THE CHALLENGE I'M HAVING IS
22 WHETHER THIS MISTAKE, AND NO ONE HAS DISPUTED THAT A
23 MISTAKE HAD HAPPENED AND IT WAS POINTED OUT IN THE
24 RESPONSE. THUS FAR, I THINK THE LOWEST WE'VE MOVED
25 TO TIER I IS A 65 SCORE; IS THAT RIGHT?

BARRISTERS' REPORTING SERVICE

1 CHAIRMAN KLEIN: THAT'S CORRECT.

2 MR. SERRANO-SEWELL: WAS THIS MISTAKE THAT
3 KIND OF POINT DIFFERENCE?

4 CHAIRMAN KLEIN: THIS WAS A PIVOTAL ISSUE,
5 AS JEFF SHEEHY HAS SAID, IF THE CHEMO AGENT IS WRONG
6 AND IS NOT EFFECTIVE, WHY WOULD YOU FUND IT? THE
7 PROPONENT HAS ALSO ADDRESSED OTHER ISSUES THAT WERE
8 RESPONSIVE.

9 MR. SERRANO-SEWELL: I NEEDED THAT
10 ASSURANCE. THANK YOU.

11 CHAIRMAN KLEIN: WE HAVE A REQUEST FOR ONE
12 MORE PUBLIC COMMENT, AND I WILL TAKE ONE MORE PUBLIC
13 COMMENT IF YOU COULD MAKE IT BRIEF, PLEASE.

14 MR. COLE: VERY BRIEFLY. I'M MARK COLE
15 FROM THE NATIONAL BRAIN TUMOR SOCIETY. AND I JUST
16 WANT TO THANK THE BOARD FOR YOUR CONSIDERATION OF
17 THIS PROPOSAL AND THE OTHER ONE AS WELL TO ASSIST IN
18 DEVELOPING NEW TREATMENTS FOR THIS DEVASTATING
19 DISEASE. SO THANK YOU.

20 CHAIRMAN KLEIN: THANK YOU VERY MUCH.
21 APPRECIATE YOUR PRESENCE VERY MUCH. ALL RIGHT.

22 MS. SAMUELSON: MR. CHAIRMAN, AT SOME
23 POINT I'D LIKE TO UNDERSTAND BETTER WHAT SORT OF THE
24 NOTICE WE GIVE TO APPLICANTS ABOUT THE FIVE. WE
25 DON'T HAVE TO DO IT NOW, BUT IT WASN'T APPROPRIATE

BARRISTERS' REPORTING SERVICE

1 LAST NIGHT.

2 CHAIRMAN KLEIN: WE WILL ADDRESS THAT
3 LATER. AND IN DECEMBER WE'LL COME BACK WITH, I
4 THINK, SOME DISCUSSION OF SUGGESTIONS ON WHEN YOU
5 CAN SUBMIT MATERIALS AND SOME OTHER ISSUES TO TRY
6 AND IMPROVE IT, BUT WE WANT TO GIVE THE STAFF SOME
7 TIME FOR SOME SUGGESTIONS AND EVALUATION.

8 COULD WE HAVE A ROLL CALL, PLEASE?

9 MS. KING: ROBERT PRICE.

10 DR. PRICE: YES.

11 MS. KING: FLOYD BLOOM.

12 DR. BLOOM: YES.

13 MS. KING: JACOB LEVIN.

14 DR. LEVIN: YES.

15 MS. KING: LEEZA GIBBONS.

16 MS. GIBBONS: YES.

17 MS. KING: BOB KLEIN.

18 CHAIRMAN KLEIN: YES.

19 MS. KING: GERALD LEVEY.

20 DR. LEVEY: YES.

21 MS. KING: TED LOVE.

22 DR. LOVE: YES.

23 MS. KING: ED PENHOET.

24 DR. PENHOET: YES.

25 MS. KING: PHIL PIZZO.

BARRISTERS' REPORTING SERVICE

1 DR. PIZZO: YES.
2 MS. KING: FRANCISCO PRIETO.
3 DR. PRIETO: YES.
4 MS. KING: ROBERT QUINT.
5 DR. QUINT: YES.
6 MS. KING: DUANE ROTH.
7 MR. ROTH: YES.
8 MS. KING: JOAN SAMUELSON.
9 MS. SAMUELSON: YES.
10 MS. KING: DAVID SERRANO-SEWELL.
11 MR. SERRANO-SEWELL: YES.
12 MS. KING: JEFF SHEEHY.
13 MR. SHEEHY: YES.
14 MS. KING: JON SHESTACK.
15 MR. SHESTACK: YES.
16 MS. KING: OSWALD STEWARD.
17 DR. STEWARD: YES.
18 MS. KING: ART TORRES.
19 MR. TORRES: AYE.
20 MS. KING: AND FOR THE RECORD THAT MOTION
21 CARRIES.
22 CHAIRMAN KLEIN: THANK YOU VERY MUCH.
23 DOES THE BOARD, DOES ANY BOARD MEMBER IN TIER III
24 HAVE ANY OTHER MOTION THEY'D LIKE TO MAKE? SEEING
25 NONE, BEFORE WE GO TO THE TIER I AND OUR FINAL

BARRISTERS' REPORTING SERVICE

1 CONSIDERATIONS AND VOTES, I'D LIKE TO GIVE THE BOARD
2 FIVE MINUTES, BUT I'D LIKE TO KEEP IT VERY CLEARLY
3 AT FIVE MINUTES AND THE STAFF AS A BREAK.

4 (A RECESS WAS TAKEN.)

5 CHAIRMAN KLEIN: ALL RIGHT. WE'RE GOING
6 TO RECONVENE. IF THE STAFF COULD PLEASE ASK BOARD
7 MEMBERS TO TAKE THEIR SEATS. THERE ARE EVIDENTLY
8 THREE COMMENTS FROM THE PUBLIC ON 1478 THAT I WAS
9 UNAWARE OF. I THINK IN THE INTEREST OF FAIRNESS, IF
10 THE BOARD COULD TAKE THEIR SEATS, PLEASE. DR.
11 FRIEDMAN. DAVID SERRANO-SEWELL. THANK YOU VERY
12 MUCH.

13 WE HAVE THREE SPEAKERS ON 1478 THAT I WAS
14 UNAWARE OF. IN THE INTEREST OF FAIRNESS, I'M GOING
15 TO OPEN IT TO THOSE SPEAKERS TO SEE IF THE BOARD
16 WOULD LIKE TO TAKE ANY ACTION RELATED TO THAT ITEM.
17 THE FIRST SPEAKER IS DR. CHIA SOO.

18 DR. SOO: THANK YOU. GOOD MORNING. I
19 WANT TO THANK THE COMMITTEE FOR ALL THEIR
20 THOUGHTFULNESS, DEDICATION, AND HARD WORK. I AM THE
21 PI OF THIS GRANT.

22 AND, FIRST, I JUST WANT TO GO THROUGH SOME
23 OF THE STRENGTHS. NO. 1, WE HAVE AN OSTEOINDUCTIVE
24 MOLECULE NELL-1 THAT'S UNIQUE IN ITS ABILITY TO
25 STIMULATE STEM CELLS TO PROMOTE OSTEOBLASTIC

BARRISTERS' REPORTING SERVICE

1 DIFFERENTIATION AND TO INHIBIT ADIPOGENIC
2 DIFFERENTIATION. AND NOT ONLY THAT, THIS IS A
3 PROTEIN THAT IS ALREADY VERY MATURE IN TERMS OF ITS
4 DEVELOPMENT. WE HAVE CGMP-COMPLIANT PROTEIN
5 PRODUCTION UNDER WAY. WE HAVE ALREADY COMPLETED
6 EFFECTIVE DOSING STUDIES IN NONHUMAN PRIMATES, WHICH
7 IS NO SMALL FEAT BECAUSE WHAT GROWS BONE IN A MOUSE
8 OR A RAT WILL NOT NECESSARILY GROW BONE IN HUMANS.

9 WE HAVE BEEN WORKING WITH REGULATORY
10 AGENCIES OR WITH FDA CONSULTANTS FOR THE PAST TWO
11 YEAR TO SET UP A MATURE IND PATHWAY FOR THE PROTEIN.

12 AND, LASTLY, THIS PROTEIN WAS ORIGINALLY
13 ISOLATED IN CRANIOSYNOSTOSIS PATIENTS FORMING EXCESS
14 BONE, SO WE KNOW THIS PROTEIN WORKS IN HUMANS. AND
15 THE OTHER STRENGTH OF THE PROPOSAL, BESIDES THE
16 OSTEOINDUCTIVE FACTOR NELL-1, IS THE FACT THAT WE'RE
17 USING WHAT WE CALL PERIVASCULAR STEM CELLS. MY
18 COLLEAGUE, DR. BRUNO PEULT, WILL TALK MORE ABOUT
19 THEM, BUT REALLY THE MAIN IMPORTANT THING ABOUT
20 THESE CELLS IS THAT THEY CAN BE PROSPECTIVELY
21 ISOLATED. FOR INSTANCE, RIGHT NOW MOST MESENCHYMAL
22 STEM CELLS USED ARE IDENTIFIED IN CULTURE
23 RETROSPECTIVELY, AND THEY'RE A HETEROGENEOUS
24 POPULATION.

25 REALLY FROM THE FDA STANDPOINT, TO GET A

BARRISTERS' REPORTING SERVICE

1 MESENCHYMAL STEM CELL-TYPE PRODUCT APPROVED WITH
2 EXOGENOUS SIGNALS TO GET TO DIFFERENTIATE INTO WHAT
3 YOU ULTIMATELY WANT TO DIFFERENTIATE INTO, YOU
4 REALLY NEED TO START OUT WITH A WELL-DEFINED
5 HOMOGENEOUS CELL POPULATION BECAUSE IF YOU DON'T
6 EVEN KNOW WHAT YOUR STARTING CELL POPULATION IS, IT
7 IS VERY HARD TO DO DOSING STUDIES ON PROTEINS OR
8 OTHER DIFFERENTIATION FACTORS YOU'RE GOING TO ADD
9 WITH IT.

10 SO THE STRENGTH OF OUR PROPOSAL IS REALLY
11 WE COMBINE -- WE HAVE A UNIQUE OSTEOINDUCTIVE FACTOR
12 AND WE HAVE A UNIQUE STEM CELL POPULATION THAT DR.
13 BRUNO PEULT IDENTIFIED.

14 AND THE NEXT THING I JUST WANTED TO JUST
15 SPEND AND TALK ABOUT VERY BRIEFLY ON IS REALLY WHAT
16 IS THE ADVANTAGE OF A COMBINATION NELL-1 PROTEIN
17 STEM CELL PRODUCT? THAT IS REALLY, IF YOU LOOK AT
18 THE PRESENT GOLD STANDARD OF BONE GRAFT, IT'S
19 AUTOGRAFT BONE. AND THEN IF YOU LOOK AT WHAT'S NEXT
20 IN EFFICACY, IT'S BMP. BUT BMP'S COME NOWHERE NEAR
21 AUTOGRAFT BONE IN TERMS OF SAFETY. SO AUTOGRAFT
22 BONE HAS SIDE EFFECTS IN TERMS OF THERE'S
23 SIGNIFICANT DONOR MORBIDITY IN HARVESTING, AND YOU
24 ONLY HAVE A LIMITED SUPPLY. AND FOR OSTEOPOROTIC
25 PATIENTS WHO ARE BASICALLY OSTEOPENIC IN THE FIRST

BARRISTERS' REPORTING SERVICE

1 PLACE, THEY'RE NOT REALLY A GOOD DONOR TO TAKE MORE
2 BONE FROM BECAUSE THEY CAN ITSELF CAUSE FRACTURES.

3 AND THE OTHER THING IS WITH RESPECT TO
4 BMP, THE OTHER THING THAT'S CURRENTLY SIMILAR IN
5 EFFICACY TO AUTOGRAFT BONE IS THAT BMP HAS
6 SIGNIFICANT SIDE EFFECTS. THE FDA RECENTLY SENT OUT
7 A WARNING ABOUT LIFE-THREATENING COMPLICATIONS IN
8 CERVICAL FUSION CASES WITH BMP. AND SO BMP'S CAN
9 CAUSE AIRWAY COMPROMISE. THEY CAN ALSO CAUSE
10 HETEROTOPIC BONE FORMATION. FOR INSTANCE, A
11 POSTERIOR FUSION STUDY USING BMP'S WAS HALTED
12 BECAUSE IT FORMED ECTOPIC BONE NEXT TO THE NERVE
13 ROOTS. AND BMP HAS OTHER PROBLEMS IN TERMS OF IT
14 ACTIVATES OSTEOCLASTS WHICH CAN CAUSE SIGNIFICANT
15 BONE RESORPTION WHICH IN OSTEOPOROSIS PATIENTS ARE
16 ANOTHER FACTOR THAT WOULD ADVISE AGAINST THEIR USE.

17 AND IN ADDITION, BMP'S ACTIVATE ADIPOGENIC
18 PROGRAMS, BUT THE BONE MARROW AND IN OSTEOPOROSIS
19 PATIENTS THAT CAN ALSO BE A SIGNIFICANT PROBLEM
20 BECAUSE ONE OF THE PROBLEMS IS IN OSTEOPOROTIC
21 PATIENTS, THE BONE CELLS TEND TO FORM FAT CELLS
22 RATHER THAN BONE CELLS, AND THAT'S ONE OF THE
23 REASONS THEY GET OSTEOPOROTIC IN THE FIRST PLACE.

24 CHAIRMAN KLEIN: SO, DR. SOO, IN TERMS OF
25 TIME, IF DR. PEULT OR DR. TING COULD ADDRESS SOME

BARRISTERS' REPORTING SERVICE

1 OF THE OTHER ISSUES. AND I'D ASK TOO WHEN THEY COME
2 UP, IF THEY COULD FOCUS ON WHAT ARE THE ISSUES THAT
3 THEY HAVE WITH THE REVIEW BECAUSE YOU'VE GIVEN US A
4 VERY GOOD FOUNDATION SUMMARY. BUT IN TERMS OF TIME,
5 I'D LIKE TO KEEP EACH OF THEM TO FIVE MINUTES.

6 DR. SOO: SURE. THANK YOU.

7 DR. PEULT: GOOD MORNING, LADIES AND
8 GENTLEMEN. I AM BRUNO PEULT. I AM A PROFESSOR IN
9 THE DEPARTMENT OF ORTHOPEDIC SURGERY AT UCLA, AND I
10 PARTICIPATED IN THIS GRANT APPLICATION PRINCIPALLY
11 AS THE STEM CELL PROVIDER. WE CHOOSE TO USE IN THIS
12 PROPOSAL A NOVEL POPULATION OF HUMAN STEM CELLS THAT
13 WE AND OTHERS HAVE RECENTLY CHARACTERIZED,
14 IDENTIFIED, PURIFIED A LARGE NUMBER OF HUMAN ORGANS,
15 INCLUDING THE MOST ACCESSIBLE ONES, LIKE THE FAT
16 TISSUE, FOR EXAMPLE.

17 SO THESE CELLS ARE NOT HETEROGENEOUS LIKE
18 MESENCHYMAL STEM CELLS ARE. THEY HAVE NOT BEEN
19 ARTIFICIALLY DERIVED LIKE EMBRYONIC STEM CELLS.
20 THEY EXHIBIT A VERY, VERY ROBUST DEVELOPMENTAL
21 POTENTIAL IN TERMS OF APPLICATIONS, BONE, CARTILAGE,
22 MUSCLE. THESE CELLS CAN BE PURIFIED TO HOMOGENEITY
23 ALSO.

24 SO WE LARGELY PLANNED THIS APPLICATION ON
25 THESE VERY ORIGINAL, NOVEL STEM CELL POPULATIONS AND

BARRISTERS' REPORTING SERVICE

1 ALSO ASSUMED THAT IT MAKES A GOOD CASE FOR AN EASY
2 AND FAST APPROVAL BY THE FDA SINCE IT IS SUCH A
3 PRECISELY IDENTIFIED CHARACTERIZED STEM CELL
4 POPULATION.

5 SO TO ADDRESS VERY DIRECTLY THE ISSUES, AS
6 MR. CHAIRMAN JUST SUGGESTED, WE HAD TWO MAIN
7 CRITICISMS REGARDING THIS STEM CELL POPULATION. THE
8 FIRST ONE WAS THAT THE REFEREES SAY THAT WE ARE NOT
9 VERY CLEAR IN TERMS OF HOW MANY OF SUCH STEM CELLS
10 COULD BE PURIFIED FROM THE PATIENT. SO PROBABLY
11 WASN'T VERY, VERY CLEAR IN THE APPLICATION, BUT WE
12 HAVE NOW MORE THAN FOUR YEARS EXPERIENCE OF SORTING
13 THESE CELLS FROM ADIPOSE TISSUE. AND WE HAVE
14 ALREADY PUBLISHED THESE NUMBERS. SO WE HAVE VERY
15 PRECISE NUMBERS REGARDING WHAT COULD BE INDEED
16 PURIFIED FROM PATIENTS FOR THERAPEUTIC PROPOSALS.

17 THE SECOND ISSUE WAS THE APPLICANT SHOULD
18 THINK OF DEVELOPING A MORE ROBUST ISOLATION
19 PROCEDURE. IN FACT, WE HAVE BEEN PROPOSING AND WE
20 ARE COMMONLY USING THE MOST STRINGENT, THE MOST
21 SENSITIVE, IF NOT THE CHEAPEST, SORTING PROCEDURE,
22 WHICH IS PHOTOCYTOLOGY.

23 WHAT I WOULD LIKE TO SAY HERE IS THAT I
24 WAS INVOLVED VERY DIRECTLY A FEW YEARS AGO WITH IRV
25 WEISSMAN IN THE PROSPECTIVE PURIFICATION OF HUMAN

BARRISTERS' REPORTING SERVICE

1 HEMATOPOIETIC STEM CELLS. AND AT SYSTEMIX
2 INCORPORATED, OUR COMPANY AT THAT TIME, THESE CELLS
3 WERE RAPIDLY USED IN A LARGE, LARGE COHORT OF CANCER
4 PATIENTS IN FORM OF BREAST CANCER. AND HOW DID IT
5 PURIFY THE CELLS? BY PHOTOCYTOLOGY, AND IT
6 PERFORMED EXTREMELY WELL AND IS QUITE SUCCESSFUL.
7 SO WE ARE CONFIDENT THAT PHOTOCYTOLOGY CAN BE USED
8 RELIABLY TO PURIFY THESE CELLS.

9 CHAIRMAN KLEIN: LET ME ASK TWO QUESTIONS.
10 ONE, ON THE PUBLISHED SPECIFIC DESCRIPTION OF THE
11 CELL NUMBERS, WAS THAT IN THE APPLICATION?

12 DR. PEULT: IT WAS IN THE APPLICATION.
13 MAYBE IT WAS NOT CLEARLY DESCRIBED. BUT, YES, WE
14 MENTIONED THE CELL TO CELL NUMBER THAT CAN BE
15 PURIFIED, THE YIELD AFTER PURIFICATION.

16 CHAIRMAN KLEIN: AND THE PUBLICATION WAS
17 CITED?

18 DR. PEULT: YES.

19 CHAIRMAN KLEIN: AND AS TO THE SECOND
20 POINT, WAS THIS COVERED IN THE APPLICATION?

21 DR. PEULT: YES. WE MENTIONED THAT WE DO
22 HAVE ACCESS TO COMPLIANT FACILITY AT UCLA.

23 CHAIRMAN KLEIN: WITH DATA? THE DATA WERE
24 PRESENTED.

25 DR. PEULT: THE DATA?

BARRISTERS' REPORTING SERVICE

1 CHAIRMAN KLEIN: WERE THE DATA ON THIS
2 POINT PRESENTED?

3 DR. PEULT: WELL, THE PURIFICATION BY
4 FACTS OF THE CELLS, WE EXTENSIVELY PRESENTED THE
5 PRIMARY RESOURCE, OF COURSE. AND WE ADDED THAT WE
6 DO HAVE ACCESS TO A GMP-COMPLIANT FACILITY AT UCLA,
7 WHICH WE HAVE NOT YET STARTED USING, OF COURSE. WE
8 ARE BEFORE THAT STAGE, BUT WE DO HAVE ACCESS.

9 CHAIRMAN KLEIN: OKAY. AND I'D LIKE TO
10 GET THE COMMENTS FROM DR. KANG TING.

11 DR. TING: SO I'M A PROFESSOR IN THE
12 BIOENGINEERING DEPARTMENT AND THE DEPARTMENT OF
13 ORTHOPEDIC SURGERY. I'M ALSO THE FIRST FEW
14 RESEARCHERS DISCOVER NELL-1 AS A NOVEL, POTENT
15 GROWTH FACTORS TO STIMULATE MSC CELLS. WE HAVE DONE
16 STUDY UP TO THE LARGE ANIMAL FROM SHEEP TO GOAT TO
17 MONKEY, PRIMATE STUDIES, TO SHOW THE EFFICACY IN
18 SPINAL FUSIONS. I WILL ADDRESS THREE ISSUES FOR THE
19 REVIEWERS.

20 FIRST ISSUE IS THAT WHILE THE REVIEWERS,
21 THEY'RE VERY EXCITED AND POSITIVE ABOUT NELL-1, THEY
22 WONDER WHETHER NELL-1 WORKS WITH MSC IS BETTER THAN
23 NELL-1 ALONE. I WILL ADDRESS THE ISSUE BY THREE
24 ASPECTS.

25 FIRST OF ALL, WE SHOW THE PRELIMINARY

BARRISTERS' REPORTING SERVICE

1 DATA. SECONDLY, WE HAVE TWO PUBLICATIONS CITED THAT
2 WE PUBLISHED, ONE IN (UNINTELLIGIBLE) THERAPY, ONE
3 IN THE JPMR THAT WE SHOW THAT NELL-1, WHEN WE ADDED
4 WITH BMSC, WE SHOW MUCH BETTER BONE FORMATION THAN
5 BMC ALONE, THAN NELL-1 ALONE, AND THEN BMC PLUS
6 BMP2. SO WE HAVE TWO APPLICATIONS IN GOOD JOURNALS
7 THAT SHOW THAT. SO I THINK THAT SHOULD BE ABLE TO
8 ADDRESS THE CONCERN FROM THE REVIEWERS.

9 AND THE SECOND ASPECT IS THE MIXING
10 DEVICE. I THINK THE REVIEWER CONCERNED ABOUT
11 WHETHER WE CAN COME UP -- MAKE A DEVICE IN TWO
12 YEARS. AND THAT IN THE PROPOSAL WE MENTION THAT WE
13 USE AN OFF-THE-SHELF MIXING DEVICE, AND WE DESIGN IT
14 TO MAKE IT FIT TO THE PROPER VOLUME. AS MY
15 COLLEAGUE AND INVESTIGATOR, DR. PEULT, HE'S THE
16 VICE CHAIR OF ENGINEERING AND MY ENGINEERING
17 BACKGROUND, WE'LL ABLE TO DO THAT EASILY. ACTUALLY
18 IT'S ONE OF THE LEAST PROBLEMATIC THINGS.

19 I'M GOING TO SHOW YOU A PROTOTYPE WHAT WE
20 DO HERE. BASICALLY WE SCALE DOWN THE CARTRIDGE.
21 THIS IS AROUND 75 ML DOWN TO AROUND 10 ML THAT GOES
22 THROUGH A SIMPLE SPIRAL SYRINGE METHOD. WE CONNECT
23 THIS TO THIS COMPONENT WITH ANOTHER KIND OF A GUN WE
24 PUT TOGETHER. AND THIS IS VERY SIMPLE. ACTUALLY
25 FROM MY EXPERTISE, IT'S A PROJECT FOR A GRADUATE

BARRISTERS' REPORTING SERVICE

1 STUDENT AT MOST. SO I DO NOT SEE THAT AS A MAJOR
2 PROBLEM.

3 AND THE THIRD CONCERN IS THE ENVIRONMENT.
4 I THINK THE REVIEWERS MENTIONED THAT OUR ENVIRONMENT
5 NOT THE OPTIMAL FOR PRODUCT ENVIRONMENT. I THINK,
6 FIRST OF ALL, OUR TEAM, THE CIRM TEAM, WE LOCATED IN
7 THE LATEST BUILDINGS IN THE RESEARCH BUILDING AND
8 THE BIOENGINEERING BUILDINGS. AND WE HAVE CLOSE
9 COLLABORATION WITH GCRC, WHICH IS A COUPLE OF
10 INVESTIGATOR, AND WE ALSO LEVERAGE WITH THE UC DAVIS
11 WHO HAS AN GMP/GLP FACILITY FOR THE PRIMATE STUDY.

12 AND I THINK DR. GERALD LEVEY IS HERE TOO,
13 SO I THINK HE CAN ASSURE YOU THAT WE DO HAVE ALL THE
14 FACILITY WE NEED TO CONDUCT -- TO FINISH THE STUDY.
15 AS A MATTER OF FACT, WITH THE GCRC WE HAVE HERE, WE
16 ARE READY TO DO THE PHASE II ONCE THIS IS DONE
17 PROBABLY.

18 SO IN SUMMARY, NO ONE IS A MATURE CLINICAL
19 PROJECTS. NO. 1, WE CARRY ALL THE WAY TO PRIMATE
20 STUDY ALREADY, SHOWED A GOOD EFFICACY WITH DOSING.
21 THE PART 2, THE MSC CELLS WITH DR. BRUNO PEULT, WE
22 HAVE DONE ALREADY THE RODENT MODEL THAT WE SHOW THAT
23 IT WORKS PERFECTLY WELL EXCEPT THE DOSING. WE'RE
24 NOT DOWN TO LARGE ANIMAL STUDY YET, BUT I THINK THIS
25 IS THE LIMIT WE CAN GO TO. SO IN THE NEXT STAGE, WE

BARRISTERS' REPORTING SERVICE

1 DO REQUIRE THE CIRM TO GIVE US THE SUPPORT TO CARRY
2 OUT THE PROJECT. SO IT'S A MATURE PROJECT. WE
3 SPENT TEN YEARS ON IT. FOR THE PAST TWO YEARS WE
4 SPENT ACTIVE TIME TO DO THE CRO, WITH MTF, THE U.S.
5 THE LARGEST TISSUE BANK TO HELP US ON THIS PROJECT
6 WITH SUPPORT OF NIH, UC, AND, OF COURSE, THE
7 CALIFORNIA, THE UC DISCOVERY GRANT, AND ALSO FROM
8 THE NONPROFIT FOUNDATION TO PUSH THIS PROJECT
9 FORWARD. SO I THINK THIS PROJECT IS MORE THAN READY
10 TO GO THE NEXT STEP. THANK YOU VERY MUCH.

11 CHAIRMAN KLEIN: THANK YOU. I'D LIKE
12 INDICATE THERE'S A LOT OF INFORMATION YOU'VE JUST
13 PRESENTED. IT'S VERY DIFFICULT FOR THE BOARD TO
14 ABSORB THIS ON THE DAY OF THE MEETING. AND TO THE
15 EXTENT IT'S SUBMITTED TO THE STAFF IN ADVANCE, THEN
16 WE CAN HAVE A STAFF EVALUATION, WHICH WOULD HAVE
17 BEEN VERY, VERY HELPFUL. WE DO GREATLY APPRECIATE
18 YOUR WORK. AND CLEARLY YOU HAVE SOME EXCELLENT
19 SCIENTISTS ON THIS TEAM.

20 I'D LIKE TO ASK IS THERE ANY BOARD MEMBER
21 WHO WOULD LIKE TO BRING THIS UP AS A MOTION OR NOT.
22 I DON'T SEE ANY BOARD MEMBER WHO WOULD LIKE TO BRING
23 THIS UP AT THIS TIME.

24 WE DO HAVE A PUBLIC COMMENT, I'VE BEEN
25 INFORMED, ON THE PHONE FROM THE KATHLEEN CODY; IS

BARRISTERS' REPORTING SERVICE

1 THAT CORRECT? AND SHE IS IN MARCY FEIT'S OFFICE
2 WHO'S TELEPHONICALLY CONNECTED.

3 MS. KING: THAT'S CORRECT. KATHLEEN, CAN
4 YOU HEAR US? WE CAN BARELY HEAR YOU. I'M HOPING
5 THAT WE CAN CHANGE THAT.

6 MS. CODY: YES. I'M VERY SORRY THAT I
7 CAN'T BE WITH YOU THERE TODAY.

8 MS. KING: THAT'S ACTUALLY PERFECT VOLUME.
9 I'M JUST GOING TO ASK YOU TO WAIT JUST TEN SECONDS
10 FOR CHAIRMAN KLEIN TO RETURN TO HIS SEAT BEFORE YOU
11 MAKE YOUR COMMENT. ALL RIGHT, KATHLEEN. THANK YOU.
12 WHY DON'T YOU GO AHEAD.

13 MS. CODY: THANK YOU VERY MUCH. MY NAME
14 IS KATHLEEN CODY, AND I AM THE EXECUTIVE DIRECTOR OF
15 AMERICAN (UNINTELLIGIBLE). WE'RE A PATIENT
16 EDUCATION AND ADVOCACY ORGANIZATION, AND WE'RE BASED
17 IN OAKLAND IN NORTHERN CALIFORNIA. AND THE PROPOSAL
18 BEFORE YOU FROM UCLA REPRESENTS FOR US A POTENTIALLY
19 LIFESAVING RESEARCH INTO WHAT WE VIEW AS A POSSIBLE
20 CURE FOR OSTEOPOROSIS.

21 SO I WANTED TO JUST EXPLAIN THAT I'M
22 REPRESENTING 44 MILLION AMERICANS WHO ARE AT RISK
23 FOR FRACTURE BECAUSE OF OSTEOPOROSIS. MOST OF THEM
24 DON'T EVEN KNOW THAT THEY ARE AT RISK FOR A
25 POTENTIALLY LIFE-CHANGING FRACTURE. THAT'S ONE

BARRISTERS' REPORTING SERVICE

1 THING OUR ORGANIZATION IS WORKING ON. IT'S HARD TO
2 BELIEVE THIS BECAUSE THE DISEASE WILL TOUCH THE
3 LIVES OF PROBABLY EVERYBODY AT THIS MEETING. AND IT
4 MAY NOT BE ONE OF YOU IN THE ROOM, BUT CERTAINLY IT
5 WILL BE A FRIEND OF YOURS, YOUR MOTHER, YOUR SISTER,
6 YOUR GRANDMOTHER OR GRANDFATHER. AND OSTEOPOROSIS
7 IS STILL A TERRIBLY OVERLOOKED AND UNDERTREATED
8 DISEASE BY MOST PATIENTS AND DOCTORS.

9 SO I OFTEN ASK MYSELF, BECAUSE THE
10 PATIENTS ARE GENERALLY OLDER, IS IT BECAUSE MOST OF
11 THEM ARE FEMALE? OR IS IT THAT THE PATIENTS
12 THEMSELVES THINK THAT IT'S KIND OF NORMAL TO SHRINK
13 SEVERAL INCHES AS THEY AGE? SO IF WE HAVE SO MUCH
14 OSTEOPOROSIS, THEN WHY ARE WE NOT MAKING BETTER
15 PROGRESS? SO WE KNOW THAT THERE'S A GOOD TEST THAT
16 CAN HELP IDENTIFY OSTEOPOROSIS AND IDENTIFY PEOPLE
17 WHO ARE AT RISK FOR FRACTURE. A BONE DENSITY TEST
18 IS PRETTY SIMPLE, AND YET IN 2008 ONLY 13 PERCENT OF
19 THE WOMEN WHO ARE OF MEDICARE AGE WERE TESTED. SO
20 WE HAVE A REAL PROBLEM IN TERMS OF THE
21 IDENTIFICATION OF PATIENTS WHO ARE AT RISK FOR
22 HAVING A FRACTURE BECAUSE OF OSTEOPOROSIS.

23 SO WHEN A BONE DOES BREAK, WE KNOW THAT
24 OSTEOPOROSIS IS THE LEADING CAUSE OF FRACTURES AND
25 ONLY RESULT IN BAD OUTCOMES, AN ENORMOUS AMOUNT OF

BARRISTERS' REPORTING SERVICE

1 IMMOBILITY, DISABILITY, AND EVEN DEATH AS A RESULT
2 OF A FRACTURE. AND IT'S STILL SURPRISING TO ME THAT
3 78 PERCENT OF THE PATIENTS IN THIS COUNTRY WHO HAVE
4 A FRACTURE ARE NEVER EVALUATED FOR OSTEOPOROSIS AS
5 AN UNDERLYING CAUSE AND TREATED FOR IT SO THEY CAN
6 PREVENT MORE FRACTURES. IN FACT, THERE ARE SO MANY
7 FRACTURES IN THIS COUNTRY IT'S UNBELIEVABLE. THERE
8 HAVE BEEN TWO MILLION IN 2007. AND DURING THIS
9 MEETING, WHILE YOU'RE DISCUSSING THIS PROPOSAL,
10 THERE WILL PROBABLY BE ABOUT 2,000 FRACTURES THAT
11 OCCUR.

12 SO DISABILITY, PAIN, AND DEATH ARE
13 CERTAINLY A CONCERN AMONG THOSE OF US WHO ARE TRYING
14 TO DO SOMETHING ABOUT OSTEOPOROSIS.

15 CHAIRMAN KLEIN: KATHLEEN, THIS IS
16 CHAIRMAN BOB KLEIN. I THINK WE'RE HIGHLY SUPPORTIVE
17 OF YOUR GOALS AND REALIZE IT'S A MAJOR SCIENTIFIC
18 AND CLINICAL ISSUE WE HAVE TO DEAL WITH. THE KEY
19 HERE IS, A, WE HAVE A LIMITED TIME TO SPEAK. BUT
20 ALSO THE ISSUE IS IN TERMS OF THE REVIEW, WHAT
21 SHOULD CHANGE OUR OPINION BASED UPON THE REVIEW THAT
22 WAS MADE. AND WITH THE FUNDAMENTAL BACKGROUND
23 YOU'VE GIVEN US, WE CERTAINLY HAVE REINFORCED
24 EXTREMELY WELL THE IMPORTANCE OF THIS AREA. AND WE
25 DO HAVE A TRANSLATIONAL ROUND THAT CERTAINLY THIS

BARRISTERS' REPORTING SERVICE

1 COULD REAPPLY FOR. THIS IS A GRANT THAT HAD AN
2 APPLICATION TO APPLY, IT'S A VERY SERIOUS GRANT, WE
3 RESPECT THAT. BUT IF YOU COULD CONCLUDE YOUR
4 REMARKS ON THE POINT OF WHY SHOULD WE CHANGE THE
5 RECOMMENDATION.

6 MS. CODY: I THINK UCLA AND UCI ARE DOING
7 BREAKTHROUGH RESEARCH THAT COULD BE THE BEGINNING OF
8 A CURE FOR OSTEOPOROSIS AND FRACTURES. AND WE HAVE
9 SUCH A DIFFICULT TIME JUST TRYING TO PREVENT THOSE,
10 THAT HAVING AN OPTION OF ACTUALLY TREATING A
11 FRACTURE AND PREVENTING FURTHER FRACTURES IS A REAL
12 BREAKTHROUGH FOR THIS DISEASE THAT AFFECTS SO MANY
13 MILLIONS OF AMERICANS.

14 CHAIRMAN KLEIN: OKAY. I THINK WE ALL
15 AGREE WITH THIS GOAL. IT'S A TERRIBLY IMPORTANT
16 ISSUE. AT THIS POINT WE DO NOT HAVE A BOARD MEMBER
17 PREPARED TO MOVE THIS ITEM. AND I THINK IT IS
18 IMPORTANT THAT WE HAVE TO MOVE FORWARD, BUT WE
19 DEEPLY APPRECIATE YOUR COMMENTS. WE DEEPLY
20 APPRECIATE THE SCIENCE OF THE TEAM BEFORE US.
21 CERTAINLY WE HOPE THEY REAPPLY AND CAN FURTHER
22 ADVANCE THEIR MEDICAL APPLICATIONS. I'D LIKE --

23 MR. ROTH: MR. CHAIRMAN, I'D LIKE TO MAKE
24 A MOTION THAT WE APPROVE TIER I AS SPECIFIED ON THE
25 CHART FOR \$229,772,918.

BARRISTERS' REPORTING SERVICE

1 MR. TORRES: SECOND.

2 CHAIRMAN KLEIN: MOTION HAS BEEN MADE AND
3 SECONDED. DR. OLSON.

4 DR. OLSON: I DO NEED TO BRING SOMETHING
5 TO THE ATTENTION OF THE BOARD REGARDING ONE OF THE
6 APPLICATIONS IN TIER I. YOU NEED TO KNOW THIS
7 BEFORE YOU VOTE JUST BECAUSE IT'S IMPORTANT.

8 ONE OF THE APPLICATIONS THAT IS
9 RECOMMENDED FOR FUNDING IN TIER I, APPLICATION
10 DR101471 WAS SUBMITTED AS A PROPOSAL FOR
11 COLLABORATIVE FUNDING FROM THE CIRM AND THE MRC.
12 VERY SHORTLY BEFORE THE GRANTS WORKING GROUP REVIEW
13 MEETING IN SEPTEMBER, THE MRC AND CIRM WERE INFORMED
14 OF A CHANGE IN THE PARTNER PI'S EMPLOYMENT STATUS.

15 THE GRANTS WORKING GROUP WAS MADE AWARE OF
16 THIS INFORMATION AND THAT THE CONTINUED ROLE OF THE
17 PARTNER PI IN THIS PROPOSAL WAS IN QUESTION. THE
18 GRANTS WORKING GROUP MADE ITS RECOMMENDATION BASED
19 ON THE APPLICATION AS SUBMITTED BECAUSE OBVIOUSLY
20 THERE WAS NOTHING TO PROCESS OTHERWISE.

21 SO THAT IS THE SUMMARY. THE SUMMARY IS
22 BASED ON THE APPLICATION AS SUBMITTED, AND THE
23 RECOMMENDATION WAS MADE ON THE APPLICATION AS
24 SUBMITTED. WHAT THE GRANTS WORKING GROUP AGREED WAS
25 AGREED THAT CIRM AND THE MRC, CONSISTENT WITH THEIR

BARRISTERS' REPORTING SERVICE

1 PROCESSES, WOULD ADDRESS WHAT HAD OCCURRED AND THAT
2 THE PRESIDENT, IN CONJUNCTION WITH THE GRANTS
3 WORKING GROUP CHAIR AND OTHER MEMBERS AS
4 APPROPRIATE, WOULD MAKE A THOROUGH EVALUATION OF ANY
5 PROPOSED CHANGES THAT WOULD RESULT FROM THIS.

6 SUBSEQUENTLY, THE MRC IN ACCORDANCE WITH
7 ITS PROCESSES REQUESTED SPECIFIC ASSURANCES FROM THE
8 PARTNER PI THAT THEY WOULD BE ABLE TO CARRY OUT THE
9 UK PART OF THE PROPOSED RESEARCH AS DESCRIBED.
10 THOSE ASSURANCES WERE NOT FORTHCOMING, AND THE MRC
11 HAS, THEREFORE, DECIDED NOT TO FUND THE UK PART OF
12 THE PROPOSAL.

13 DESPITE THE MRC'S DECISION, THE ICOC MAY
14 CHOOSE TO MOVE THE ENTIRE PROJECT FORWARD USING ONLY
15 CIRM FUNDS. THEY CAN DO THIS BECAUSE THE TOTAL
16 PROJECT BUDGET, INCLUDING THE MRC PORTION OF THE
17 BUDGET, WAS LESS THAN 20 MILLION. THEREFORE, THE
18 FORMER UK PORTION OF THIS PROJECT COULD BE PERFORMED
19 IN CALIFORNIA USING CIRM FUNDS IF THE ICOC SO
20 DECIDED AND IF THEY WERE TO ACCEPT THE GRANTS
21 WORKING GROUP FUNDING DECISION.

22 IF THE ICOC CHOOSES TO APPROVE THE GRANT
23 ON THOSE TERMS, AND THESE ARE CONSISTENT WITH OUR
24 POLICIES AND PROCESSES, IT WILL BE UP TO THE PI TO
25 SUBMIT AN AMENDED PROPOSAL TO SHOW TO THE

BARRISTERS' REPORTING SERVICE

1 SATISFACTION OF THE CIRM PRESIDENT AND THE CHAIR OF
2 THE GRANTS WORKING GROUP AND OTHER PEOPLE THAT THE
3 CIRM PRESIDENT MAY CHOOSE TO INVOLVE THAT THE ENTIRE
4 PROJECT PLAN AS DESCRIBED IN THE APPLICATION CAN BE
5 COMPLETED IN CALIFORNIA. SO THE DOLLARS THAT ARE
6 CURRENTLY UP THERE FOR THAT PROJECT, IN FACT, HAVE
7 BEEN ADJUSTED. THE \$4.8 MILLION, WHICH WAS THE MRC
8 PORTION OF THE PROJECT, HAS BEEN ADDED TO THE NUMBER
9 FOR 1471 IN TIER I.

10 SO I WANTED TO MAKE SURE THAT YOU WERE
11 AWARE OF THE POINTS REGARDING THIS. SO THIS IS THE
12 RECOMMENDATION OF US AS TO HOW YOU MIGHT PROCEED.

13 CHAIRMAN KLEIN: DR. OLSON, IT'S MY
14 UNDERSTANDING, CERTAINLY I WAS IN THE PEER REVIEW
15 SESSION, THIS WAS BROUGHT TO THE ATTENTION OF THE
16 PEER REVIEW COMMITTEE, AND THE PEER REVIEW COMMITTEE
17 DECIDED THAT IN THAT PARTICULAR CASE THE MRC PORTION
18 WAS NONESSENTIAL AND COULD BE EASILY ACCOMPLISHED
19 WITHIN CALIFORNIA. AND THEY WERE WILLING TO
20 RECOMMEND THIS WITH THAT KNOWLEDGE AND WITH A
21 DELEGATION, IF THE BOARD WERE TO APPROVE IT, TO THE
22 PRESIDENT AND THE SCIENTIFIC STAFF TO WORK WITH THE
23 PI TO REPLACE THAT COMPONENT WHICH THEY VIEWED AS A
24 SMALL SUPPORTING COMPONENT OF THIS GRANT; IS THAT
25 CORRECT, DR. TROUNSON?

BARRISTERS' REPORTING SERVICE

1 DR. TROUNSON: THAT'S EXACTLY CORRECT.
2 THE PI'S BELIEVE THAT THERE'S NO REAL DIFFICULTY.
3 THEY CAN ACCESS THE CELL LINE FROM THE UK IF THEY
4 WISH. BUT THEY FEEL THAT THEY WILL HAVE NO
5 DIFFICULTY IN MEETING THE OVERALL REQUIREMENTS OF
6 THE GRANT WITHOUT HAVING THE UK COMPONENT BY MAKING
7 SOME ADJUSTMENTS THAT WOULD BE ACCEPTABLE TO US.

8 CHAIRMAN KLEIN: AND SO, AGAIN, TO
9 EMPHASIZE WHAT DR. TROUNSON JUST SAID, ONE OF THE
10 KEY COMPONENTS FROM THE UK WAS A PARTICULAR CELL
11 LINE WHICH IS, IN FACT, ACCESSIBLE EVEN THOUGH THE
12 MRC GROUP IS NOT THERE. AND THEY SPECIFICALLY
13 APPROVED IN THE PEER REVIEW GROUP THIS
14 RECOMMENDATION WITH THE DELEGATION OF THAT
15 SUPPORTING ROLE.

16 DR. TROUNSON: THAT'S CORRECT.

17 CHAIRMAN KLEIN: ADDITIONAL QUESTIONS?

18 DR. LEVEY: IS THERE ANY WAY WE CAN GET --

19 CHAIRMAN KLEIN: WHAT ARE THE CONFLICTS?

20 MR. HARRISON: THE CONFLICTS ARE BLOOM,
21 FRIEDMAN, AND SHEEHY.

22 CHAIRMAN KLEIN: THANK YOU. DOCTOR.

23 DR. LEVEY: YEAH. IS THERE ANY WAY WE CAN
24 THOUGHTFULLY RECONSIDER THIS AND MAKE A FINAL
25 DECISION NEXT MEETING? I DON'T QUITE FOLLOW A LOT

BARRISTERS' REPORTING SERVICE

1 OF WHAT'S GOING ON WITH THIS.

2 DR. OLSON: AS WE INDICATED, WE WOULD
3 NEED -- THE PI HAS BEEN ALERTED TO THIS. THE PI HAS
4 BEEN ALERTED TO THE PROPOSAL THAT IS BEING MADE AND
5 WILL BE SUBMITTING TO US A REVISED PROPOSAL. SO
6 THEN THE PRESIDENT WOULD SEEK INPUT FROM PEOPLE AS
7 APPROPRIATE. BUT THAT'S THE BOARD'S DECISION.

8 DR. PRIETO: COULD WE DEFER DECISION ON
9 THIS GRANT?

10 CHAIRMAN KLEIN: WE CAN. THAT'S WITHIN
11 OUR POWER. IT'S UP TO THE BOARD.

12 DR. PRIETO: I'LL MAKE SUCH A MOTION.

13 DR. LEVEY: I'LL SECOND IT.

14 CHAIRMAN KLEIN: SO YOU'RE SUGGESTING A
15 SUBSTITUTE MOTION. AND LET ME ASK THE MAKERS OF THE
16 MOTION THAT'S PENDING, WOULD YOU ACCEPT THE
17 SUBSTITUTION MOTION?

18 MR. ROTH: SO LET ME ASK THE QUESTION
19 AGAIN. SO I WANT TO MAKE SURE THAT THERE IS
20 COMPLETE UNDERSTANDING ABOUT HOW IT WAS PROCESSED.
21 IT WAS PROCESSED BY OUR REVIEW GROUP WITH THIS
22 KNOWLEDGE?

23 DR. TROUNSON: IT'S NOT THE FULL REVIEW
24 GROUP THAT IT WAS RECOMMENDED. SO THE GRANTS
25 WORKING GROUP RECOMMENDED THAT THE PRESIDENT AND THE

BARRISTERS' REPORTING SERVICE

1 CHAIRMAN OF THE GRANTS WORKING GROUP WITH PERHAPS
2 ONE OF THE REGULATORY SPECIALISTS EXAMINE THE
3 PROJECT TO SEE IF THE CALIFORNIA COMPONENT WAS
4 INCREASED TO COVER THAT ASPECT THAT THE UK WAS
5 DOING, THAT IT WAS THE SAME PROJECT OR ESSENTIALLY
6 THE SAME.

7 MR. ROTH: I GUESS WHILE I'M VERY
8 SYMPATHETIC TO THE MOTION AND THE SECOND, WHAT I
9 THINK -- YOU CAN HANDLE IT TWO WAYS. WE CAN WAIT
10 AND COME BACK IN DECEMBER, OR WE CAN SAY THIS IS
11 LIKE ANY OTHER GRANT UP THERE. ADMINISTRATIVELY
12 IT'S GOT TO MEET EVERYTHING IT WAS SAID TO MEET, AND
13 THIS JUST HAPPENED. I WISH WE WOULD HAVE HAD THIS
14 INFORMATION SOONER; BUT, NEVERTHELESS, I THINK I
15 WOULD LEAN TOWARDS HANDLING IT ADMINISTRATIVELY.

16 DR. PRIETO: MEANING WHAT?

17 MR. ROTH: MEANING THAT IT'S BEING
18 PROPERLY PROCESSED WHERE YOU'VE GOT A CHANGE THAT
19 MAY AFFECT THE OVERALL WHERE IT WOULD BE BROUGHT
20 BACK AS A RECOMMENDATION NOT TO FUND. THAT'S WITHIN
21 STAFF'S POWER TO DO THAT.

22 MR. SERRANO-SEWELL: IF WE DELEGATE IT TO
23 STAFF.

24 MR. ROTH: THAT'S WHAT I'M SUGGESTING. IT
25 WOULD BE DELEGATED TO THEM TO DEAL LIKE ANY OTHER

BARRISTERS' REPORTING SERVICE

1 GRANT UP HERE WHERE A KEY COMPONENT FALLS OUT.

2 DR. OLSON: THAT IS CORRECT. IT IS WITHIN
3 THE SCOPE OF OUR ADMINISTRATIVE PROCESSES TO DEAL
4 WITH CHANGES THAT OCCUR. PI, SCOPE, WE HAVE
5 PROCESSES TO ADDRESS THAT.

6 CHAIRMAN KLEIN: SO DR. STEWARD.

7 DR. STEWARD: I DON'T WANT TO DELAY
8 THINGS, BUT I GUESS I'M FEELING UNCOMFORTABLE ABOUT
9 THIS BECAUSE IT ISN'T NECESSARILY THE CASE THAT YOU
10 CAN JUST THROW MONEY AT SOMETHING AND MAKE IT
11 HAPPEN. THIS COMPONENT WAS BASED ON THE EXPERTISE
12 OF THE PEOPLE IN THE MRC COMPONENT. WE MAY OR MAY
13 NOT BE ABLE TO RECRUIT PEOPLE WITH SUFFICIENT
14 EXPERTISE. IT MAY NOT COST THE SAME AMOUNT. IT MAY
15 COST MUCH MORE IN CALIFORNIA. SO I'M JUST
16 UNCOMFORTABLE MOVING FORWARD ON THIS BASIS.

17 I GUESS IN TERMS OF THE MOTION THAT IS ON
18 THE FLOOR, I'D RATHER VOTE WITH A LEVEL OF
19 ENTHUSIASM AND NOT HAVE A LOT OF NAGGING CONCERNS
20 ABOUT THIS PROJECT, FOR EXAMPLE, GOING FORWARD.
21 ALREADY WE'RE SIGNIFICANTLY OVER BUDGET AND AGAIN
22 LOOKING AT THAT.

23 MR. ROTH: JUST THE PROCESS THAT COULD BE
24 SUGGESTED HERE WOULD BE A REREVIEW ALMOST.

25 CHAIRMAN KLEIN: I THINK THAT THIS PROCESS

BARRISTERS' REPORTING SERVICE

1 THAT'S SUGGESTED IS BRINGING BACK TO THE BOARD THE
2 SOLUTION THAT THE PRESIDENT WITH THE CHAIR AND VICE
3 CHAIRS OF THE PEER REVIEW GROUP IS ABLE TO WORK OUT
4 TO PROVIDE MORE TANGIBLE EVIDENCE THAT, IN FACT, THE
5 OBJECTIVES CAN BE MET.

6 MR. SERRANO-SEWELL: LET ME TRY TO
7 ARTICULATE IT, BOB, IF THAT'S OKAY. THIS IS MAYBE
8 WHAT YOU ARE SAYING, DUANE. SO IF I UNDERSTAND IT,
9 IT'S SORT OF A MODIFICATION OF MAYBE WHAT FRANCISCO
10 HAD PROPOSED. I'M NOT SURE. AND THAT IS, WITH THIS
11 MOTION WE DELEGATE TO THE PRESIDENT AND WHOMEVER HE
12 SELECTS TO CONSULT WITH IN REVIEWING THE
13 PROPOSERS -- THE APPLICANTS' AMENDED APPLICATION
14 SUBJECT TO THE BOARD'S APPROVAL AT ITS DECEMBER
15 MEETING. IS THAT ACCEPTABLE?

16 MR. ROTH: I WOULD ACCEPT THAT. WHAT I
17 DON'T WANT TO DO IS GO THROUGH -- I DON'T THINK A
18 REREVIEW HERE IS APPROPRIATE.

19 MR. SERRANO-SEWELL: BUT IT'S COMING BACK
20 TO THE BOARD, AND WE HAVE THE DISCRETION AND CAN
21 APPROVE IT AT THAT TIME.

22 MR. ROTH: SCIENTIFIC REVIEW IS WHAT I WAS
23 TALKING ABOUT.

24 MR. SERRANO-SEWELL: WITH THE SPECIFIC
25 PLAN IN PLACE, AND WE'LL HAVE STAFF'S -- WE'LL HAVE

BARRISTERS' REPORTING SERVICE

1 THE PRESIDENT'S THOUGHTS ON THE MATTER.

2 MR. ROTH: SO WHY DON'T I MAKE THAT AS AN
3 AMENDMENT TO MY MOTION, THAT WE WILL APPROVE ALL OF
4 THESE GRANTS WITH THE CAVEAT THAT THAT PARTICULAR
5 GRANT WILL BE BROUGHT BACK IN DECEMBER FOR FINAL
6 APPROVAL BY THIS BOARD.

7 DR. TROUNSON: I THINK THAT WOULD BE
8 ACCEPTABLE, CHAIR. I THINK AN INDICATION THAT THE
9 PROJECT TO THE PI, THAT IT'S LIKELY TO BE FUNDED IF
10 IT MEETS THOSE CRITERIA WOULD BE AN IMPORTANT
11 INDICATION FROM THE BOARD. AND IT'S NECESSARY THAT
12 WE WORK HARD TO ACHIEVE A SUITABLE ADJUSTMENT. I
13 DON'T BELIEVE IN THIS CASE THAT'S HONESTLY TOO
14 DIFFICULT. SO WE WILL WORK WITH THE PI TO ENSURE
15 THAT THE PROJECT IS EQUIVALENT.

16 CHAIRMAN KLEIN: AND AS AN ADDITIONAL JUST
17 TECHNICAL UPDATE, I'D LIKE TO SAY THAT AS TO GRANT
18 1480, WHERE YESTERDAY THE DISCUSSION WAS THAT OUR
19 ETHICAL STANDARDS WOULD PREVENT NONHUMAN PRIMATES,
20 IT APPEARS THAT IT MAY BE THE ANIMAL REGULATORY
21 STANDARDS THAT WOULD NEED TO BE ADDRESSED IN DEALING
22 WITH NONHUMAN PRIMATES ON THE PARTICULAR STROKE
23 MODEL. SO IT STILL IS A BARRIER, BUT NOT AN ETHICAL
24 BARRIER OF OUR REGULATIONS. DR. POMEROY.

25 DR. POMEROY: I HAVE SOME CONCERNS ABOUT

BARRISTERS' REPORTING SERVICE

1 THIS DISTINCTION BETWEEN APPROVAL AND FINAL
2 APPROVAL. I JUST DON'T KNOW WHAT THAT MEANS.

3 MR. SERRANO-SEWELL: IT'S CONTINGENT
4 SUBJECT TO OUR ACTION IN DECEMBER. WHAT'S UNCLEAR
5 ABOUT THAT?

6 DR. POMEROY: WHAT'S UNCLEAR IS I HEARD
7 DR. TROUNSON SAY WE WOULD BE REASSURING THE PI THAT
8 THIS WAS LIKELY TO GET FUNDED. I WOULD NOT LIKE TO
9 PREDETERMINE WHAT THE OUTCOME OF THIS REVIEW WOULD
10 BE. AND I WOULD LIKE IT TO BE VERY CLEAR TO THE PI
11 THAT THIS IS NOT MERELY AN ADMINISTRATIVE HOOP THAT
12 THEY'RE RUNNING THROUGH. THIS IS \$4.8 MILLION PART
13 OF A GRANT IN WHICH THE PI IS NOT GOING TO BE
14 AVAILABLE. AND THAT IS MORE THAN JUST A PRO FORMA
15 ADMINISTRATIVE REVIEW AND SHOULD NOT BE ACCOMPANIED
16 BY A REASSURANCE THAT THIS IS LIKELY TO WORK OUT IN
17 THEIR FAVOR. I THINK WE HAVE TO HAVE A FAIR,
18 OPEN-MINDED REVIEW OF IT WHEN IT COMES BACK IN
19 DECEMBER.

20 MR. SERRANO-SEWELL: THAT WAS THE INTENT
21 MY SUGGESTION.

22 MR. ROTH: I AGREE WITH WHAT YOU JUST
23 SAID.

24 CHAIRMAN KLEIN: WE APPRECIATE THE
25 CLARIFICATIONS. ANY ADDITIONAL COMMENTS? ANY

BARRISTERS' REPORTING SERVICE

1 PUBLIC COMMENTS ON THE MOTION?

2 MR. ROTH: WE HAVE A MOTION.

3 MR. TORRES: SECOND.

4 MR. ROTH: WITH THE MODIFICATION.

5 CHAIRMAN KLEIN: WITH THE MODIFICATION AND
6 SECOND. AND I'M GOING TO HAVE THE MOTION RESTATED
7 BEFORE WE VOTE ON IT, BUT I'D LIKE TO KNOW IF
8 THERE'S ANY PUBLIC COMMENT. SEEING NO PUBLIC
9 COMMENTS, COULD WE RESTATE THE MOTION.

10 MR. HARRISON: THE MOTION MADE BY MEMBER
11 ROTH AND SECONDED BY MEMBER TORRES IS TO APPROVE FOR
12 FUNDING ALL APPLICATIONS IN TIER I EXCEPT FOR
13 APPLICATION 1471, WHICH WILL BE DEFERRED UNTIL
14 DECEMBER.

15 CHAIRMAN KLEIN: I DON'T THINK THAT'S THE
16 MOTION. I THINK THE MOTION WAS TO CONDITIONALLY
17 APPROVE IT, BUT WITH A FULL -- COMING BACK TO THE
18 BOARD, UNDERSTANDING THAT IT WOULD COME UNDER A FULL
19 REVIEW AT THE BOARD AT THAT TIME. IS THAT CORRECT?

20 MR. ROTH: THAT'S CORRECT. THAT'S WHAT I
21 INTENDED BY THE MODIFICATION IS THAT IT WILL COME
22 BACK FOR FINAL APPROVAL AFTER ALL THE ADDITIONAL
23 ADMINISTRATIVE REVIEW TAKES PLACE TO MAKE SURE THAT
24 THIS CAN BE PERFORMED.

25 CHAIRMAN KLEIN: WHICH WILL BE A FULL

BARRISTERS' REPORTING SERVICE

1 REVIEW OF THAT AT THE BOARD. ALL RIGHT. I'D LIKE
2 TO CALL THE ROLL, PLEASE. AND REMEMBER YOU ARE
3 VOTING IN FAVOR OR AGAINST EXCEPT FOR THOSE IN WHICH
4 YOU ARE IN CONFLICT.

5 MS. KING: DONALD DAFOE.

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

8 MS. KING: ROBERT PRICE.

9 DR. PRICE: YES.

10 MS. KING: FLOYD BLOOM.

11 DR. BLOOM: YES, EXCEPT FOR THOSE FOR
12 WHICH I HAVE A CONFLICT.

13 MS. KING: JACOB LEVIN.

14 DR. LEVIN: YES, EXCEPT FOR THOSE FOR
15 WHICH I HAVE A CONFLICT.

16 MS. KING: MICHAEL FRIEDMAN.

17 DR. FRIEDMAN: YES, EXCEPT FOR THOSE FOR
18 WHICH I HAVE A CONFLICT.

19 MS. KING: LEEZA GIBBONS.

20 MS. GIBBONS: YES.

21 MS. KING: MICHAEL GOLDBERG.

22 MR. GOLDBERG: YES, EXCEPT FOR THOSE FOR
23 WHICH I HAVE A CONFLICT.

24 MS. KING: BOB KLEIN.

25 CHAIRMAN KLEIN: YES.

BARRISTERS' REPORTING SERVICE

1 MS. KING: I S MEMBER LANSING PREPARED TO
2 VOTE IN THIS.

3 MS. LANSING: GIVE ME A FEW MORE MINUTES
4 BECAUSE I WAS IN CONFLICT FOR SO MUCH AND I WAS HERE
5 LAST NIGHT.

6 MS. KING: I 'LL COME BACK TO YOU.
7 GERALD LEVEY.

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

10 MS. KING: TED LOVE. TED, I WILL CIRCLE
11 BACK TO YOU AS WELL.

12 ED PENHOET.

13 DR. PENHOET: YES.

14 MS. KING: PHIL PIZZO.

15 DR. PIZZO: YES, EXCEPT FOR THOSE FOR
16 WHICH I HAVE A CONFLICT.

17 MS. KING: CLAIRE POMEROY.

18 DR. POMEROY: YES, EXCEPT FOR THOSE FOR
19 WHICH I HAVE A CONFLICT.

20 MS. KING: FRANCISCO PRIETO.

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

23 MS. KING: CARMEN PULIAFITO.

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

BARRISTERS' REPORTING SERVICE

1 MS. KING: ROBERT QUINT.

2 DR. QUINT: YES.

3 MS. KING: DUANE ROTH.

4 MR. ROTH: YES.

5 MS. KING: JOAN SAMUELSON.

6 MS. SAMUELSON: YES.

7 MS. KING: DAVID SERRANO-SEWELL.

8 MR. SERRANO-SEWELL: YES.

9 MS. KING: JEFF SHEEHY.

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

12 MS. KING: OSWALD STEWARD.

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

15 MS. KING: ART TORRES.

16 MR. TORRES: AYE.

17 MS. KING: TED LOVE.

18 DR. LOVE: AYE.

19 MS. KING: SHERRY LANSING.

20 MS. LANSING: YES, EXCEPT FOR THOSE FOR
21 WHICH I HAVE A CONFLICT.

22 MS. KING: FOR THE RECORD THAT MOTION
23 CARRIES.

24 (APPLAUSE.)

25 CHAIRMAN KLEIN: SO WE ARE GOING TO

BARRISTERS' REPORTING SERVICE

1 ADJOURN FOR ABOUT 45 MINUTES. I'D LIKE TO IN
2 ADJOURNING, THOUGH, AGAIN, THANK THE SCIENTIFIC
3 STAFF UNDER THE LEADERSHIP OF DR. TROUNSON, DR.
4 OLSON, DR. SAMBRANO, AND DR. STEFFEN, WHO WAS
5 PERSONALLY RESPONSIBLE FOR THIS, FOR THEIR
6 TREMENDOUS WORK. IT IS A HUGE INVESTMENT OF THE
7 TIME AND INTENSE COMMITMENT. AND WHILE ALL OF THE
8 STAFF WAS CRITICAL TO THIS EFFORT, THE SCIENTIFIC
9 LEADERSHIP WAS MAGNIFICENT ON THIS. AND WE DEEPLY
10 APPRECIATE IT. LET'S GIVE THEM A HAND OF APPLAUSE.

11 (APPLAUSE.)

12 CHAIRMAN KLEIN: WE STAND ADJOURNED. FOR
13 THOSE WHO WANT TO PARTICIPATE, THERE IS A PRESS --
14 WE STAND RECESSED. FOR THOSE WHO WANT TO
15 PARTICIPATE, THERE'S A PRESS CONFERENCE NEXT DOOR.
16 AND, DON, WOULD YOU GIVE US ANY DIRECTION?

17 MR. GIBBONS: YOU'RE ALL WELCOME TO
18 ATTEND, AND WE HOPE IT GOES WELL.

19 (A RECESS WAS TAKEN.)

20 CHAIRMAN KLEIN: I'M GOING TO ASK THAT MR.
21 HARRISON, COULD YOU DO A ROLL CALL, AND WE'RE GOING
22 TO START PROCEEDING WITH REPORTS.

23 DR. LOMAX, IF YOU COULD BEGIN THE ITEM 17
24 BECAUSE WE HAVE SEEN THIS ITEM TWICE, AND SO THIS IS
25 A THIRD VIEW OF THIS ITEM. WHILE PEOPLE ARE COMING

BARRISTERS' REPORTING SERVICE

1 IN, I DON'T THINK THEY'RE GOING TO MISS ANYTHING.
2 WE'RE SUMMARIZING PRIOR ACTIONS. PLEASE CALL TO OUR
3 ATTENTION ANY ITEM THAT IS A CHANGE FROM PRIOR
4 APPROVALS FROM OTHER COMMITTEES BECAUSE WE'LL WANT
5 TO MAKE SURE, WHEN EVERYONE ARRIVES BEFORE THE VOTE,
6 THAT WE HIGHLIGHT THAT ITEM.

7 DR. TROUNSON: CHAIR, REALLY THE STRATEGIC
8 PLAN HAS ALREADY BEEN BASICALLY APPROVED. I THINK
9 YOU SAW THE COMPLETE VIEW OF IT LAST TIME.

10 CHAIRMAN KLEIN: SO, MR. LOMAX, IF YOU
11 COULD BE VERY TERSE.

12 DR. LOMAX: THANK YOU, MR. CHAIRMAN,
13 MEMBERS OF THE BOARD. A VERY QUICK REVIEW OF
14 TIMELINE. YOU ARE CORRECT, THESE ARE NOT
15 PARTICULARLY NEW ITEMS. IN MARCH OF THIS 2008, WE
16 BROUGHT TO YOU A SET OF AMENDMENTS TO OUR
17 REGULATIONS DESIGNED TO ADDRESS ISSUES OF IPS
18 RESEARCH AND PROCUREMENT OF EMBRYOS. THOSE ITEMS
19 WENT INTO THE OFFICE OF ADMINISTRATIVE LAW IN MAY,
20 AND WE RECEIVED EXTENSIVE PUBLIC COMMENTS. AND
21 WE'VE TAKEN THOSE PUBLIC COMMENTS, THEY WERE
22 COMPILED, AND BROUGHT TO THE STANDARDS WORKING GROUP
23 IN OCTOBER FOR THEIR CONSIDERATION.

24 AND AS A RESULT OF THAT MEETING, WE HAVE
25 BROUGHT FORWARD A SET OF AMENDMENTS TO THE

BARRISTERS' REPORTING SERVICE

1 AMENDMENTS, IF YOU WILL. THE STANDARDS WORKING
2 GROUP, IT WAS A SENSE OF THE COMMITTEE THAT WE
3 SHOULD REVISE THE OVERSIGHT REQUIREMENTS BASICALLY
4 TO PROVIDE BETTER FLEXIBILITY, PARTICULARLY FOR IPS
5 EXPERIMENTS, TO AUTHORIZE THE USE OF CERTAIN EMBRYOS
6 THAT WERE CREATED FOR IN VITRO FERTILIZATION FOR
7 RESEARCH PURPOSES.

8 THIS IS TO BE MORE CONSISTENT WITH THE
9 NATIONAL INSTITUTES OF HEALTH'S REVISED GUIDELINES.
10 AUTHORIZE THE USE OF CELLS AND TISSUES PROCURED BY
11 AN IRB. THIS IS JUST ADDRESSING SOME DETAIL ISSUES
12 AROUND PAYMENT FOR SOMATIC CELLS, NOT EMBRYOS.

13 AND, FINALLY, IT WAS A SENSE OF THE
14 COMMITTEE THAT WE WOULD STILL MAINTAIN RESTRICTIONS
15 ON PAYMENTS USING CIRM FUNDS. I CAN GO INTO A BIT
16 MORE DETAIL THERE.

17 CHAIRMAN KLEIN: I THINK THIS HAS BEEN
18 FULLY REVIEWED TWICE NOW, AND THIS HAS GONE BACK
19 THROUGH THE STANDARDS WORKING GROUP DISCUSSIONS.

20 DR. LOMAX: THAT'S CORRECT.

21 CHAIRMAN KLEIN: SO IS THERE A MOTION TO
22 MOVE ON THIS ITEM?

23 DR. STEWARD: SO MOVED.

24 DR. BLOOM: SECOND.

25 CHAIRMAN KLEIN: SECOND BY DR. BLOOM. CAN

BARRISTERS' REPORTING SERVICE

1 COUNSEL OR MELISSA KING PLEASE INDICATE WHETHER WE
2 HAVE A QUORUM? DR. LOVE INDICATED HE'S RETURNING
3 IMMEDIATELY.

4 MR. HARRISON: WE HAVE A QUORUM.

5 CHAIRMAN KLEIN: PUBLIC COMMENT? SEEING
6 NONE, CALL THE QUESTION. ALL IN FAVOR? OPPOSED?
7 ABSTAIN? THANK YOU.

8 I'D LIKE TO GO, NOW THAT WE HAVE A QUORUM,
9 TO ITEM 8, WHICH IS CRITICAL TO MAKE SURE WE HAVE
10 THE LOAN THAT'S PART OF WHAT WE APPROVED FUNDED.
11 CAN WE HAVE A REPORT ON ITEM 8, PLEASE.

12 MR. GOLDBERG: THANK YOU, CHAIRMAN KLEIN.
13 WE HELD A FINANCE SUBCOMMITTEE TO REVIEW THE VARIOUS
14 ASPECTS OF THE LOAN MATERIALS THAT YOU'VE GOT IN
15 YOUR PACKAGES. A TRANSCRIPT WAS PREPARED, AND I'D
16 LIKE TO INCORPORATE IT IN THE RECORD IN FULL FROM
17 OUR MEETING OF FRIDAY, OCTOBER 23D.

18 WE ARE VERY MUCH ALIGNED AS A FINANCE
19 SUBCOMMITTEE ABOUT HOW TO PROCEED HERE. I THINK
20 WE'RE ALSO ALIGNED WITH CIRM STAFF. AND IN SHORT,
21 WE'RE VERY EXCITED ABOUT THE PROCESS OF INITIATING
22 OUR FIRST LOAN IN CONNECTION WITH THIS OUTSTANDING
23 DIABETES GRANT. AND WE ARE ALSO VERY MINDFUL THAT
24 THIS IS A WORK IN PROGRESS, THAT ALTHOUGH WE'RE
25 PROVIDING CLEAR GUIDANCE AS BEST WE CAN, THIS IS THE

BARRISTERS' REPORTING SERVICE

1 FIRST LOAN THAT AN AGENCY OF THIS SORT HAS EVER
2 PROVIDED AS FAR AS WE KNOW.

3 IT'S MODELED EXTENSIVELY OFF OF BEST
4 PRACTICES BOTH IN INDUSTRY AND OTHER NONPROFIT
5 PROGRAMS. AND WE ARE HOPEFUL THAT THE WAY WE'RE
6 IMPLEMENTING IT IS GOING TO BE IN THE BEST INTERESTS
7 OF ALL THE DIVERSE PARTIES INVOLVED.

8 BY THE SAME TOKEN, WE ALSO ARE RECOGNIZING
9 THAT WE MAY CHOOSE TO OPTIMIZE CERTAIN FEATURES,
10 THAT WE MAY CHOOSE TO ALLOCATE MORE LATITUDE AND
11 DISCRETION TO THE STAFF OVER TIME; BUT FOR THE TIME
12 BEING, WE VIEW IT AS OUR FIDUCIARY DUTY AS A FINANCE
13 SUBCOMMITTEE AND AS THE ICOC TO STILL REMAIN HEAVILY
14 INVOLVED.

15 SO STAFF HAS DONE A MAGNIFICENT JOB IN
16 SUPPORTING THE EFFORTS OF THE LOAN PROGRAM LED BY
17 DUANE ROTH, THE LOAN TASK FORCE, THAT IS, AND HAS
18 CONTINUED TO SUPPORT THE FINANCE SUBCOMMITTEE. AND
19 I'LL HAND IT OVER TO DUANE TO MAKE ANY REMARKS HE'D
20 LIKE TO.

21 MR. ROTH: SO I HAVE VERY FEW REMARKS. I
22 THINK YOU SAID IT PERFECTLY, MICHAEL. AND WE
23 WILL -- YOU USED THE WORD "OPTIMIZE." I THINK
24 THAT'S A GOOD WORD. AS WE LEARN, INTERACTING WITH
25 THE LOAN RECIPIENTS, ABOUT CERTAIN TERMS AND

BARRISTERS' REPORTING SERVICE

1 CONDITIONS, WE' LL NEED TO ADJUST THOSE. LI KEWI SE,
2 THROUGH THE SUBCOMMITTEE, WE MAY MAKE
3 RECOMMENDATIONS FOR CHANGES TO THE TERMS AND
4 CONDI TIONS.

5 CHAIRMAN KLEIN: THANK YOU VERY MUCH.
6 ADDITIONAL COMMENTS? PUBLIC COMMENTS?

7 CALL THE QUESTION. ALL IN FAVOR?
8 OPPOSED? WE'VE GOT TO HAVE A MOTION HERE. IN THE
9 LOAN PROGRAM, WHO WOULD LIKE TO MAKE A MOTION?

10 MR. TORRES: SO MOVED.

11 CHAIRMAN KLEIN: THIS IS FOR APPROVING
12 ITEM NO. 8. THIS IS THE RECOMMENDATION OF THE
13 FINANCE SUBCOMMITTEE REGARDING CRITERIA FOR
14 EVALUATION OF ELIGIBILITY FOR RECOURSE LOANS AND
15 PROCESS FOR FINANCIAL REVIEW OF LOAN APPLICATIONS.
16 AND THAT IS TO APPROVE THAT ITEM AS SHOWN AT TAB 8
17 IN THE BINDER; IS THAT A CORRECT STATEMENT?

18 MR. HARRISON: WITH ONE EXCEPTION, MR.
19 CHAIR. A PRIOR VERSION OF THE PROCESS MEMO WAS
20 INCLUDED IN THE BOARD' S PACKET RATHER THAN THE
21 VERSION OF THE MEMO THAT WAS RECEIVED AND
22 RECOMMENDED BY THE FINANCE SUBCOMMITTEE, WHICH
23 INCLUDES AN ADDITIONAL EXCEPTION PURSUANT TO WHICH
24 THE FINANCE SUBCOMMITTEE CAN REVIEW THE TERMS OF A
25 LOAN.

BARRISTERS' REPORTING SERVICE

1 CHAIRMAN KLEIN: YES. AND IS THAT
2 AMENDMENT ACCEPTED BY THE MAKER OF THE MOTION?

3 MR. TORRES: YES.

4 CHAIRMAN KLEIN: DOES THE SECOND ACCEPT
5 IT?

6 MR. GOLDBERG: YES.

7 CHAIRMAN KLEIN: MAKER AND THE SECOND
8 ACCEPT THE AMENDMENT. I'M SORRY. I HAD THOUGHT
9 THAT THE MATERIALS UNDER TAB 8 HAD REFLECTED THAT
10 UPDATE. THANK YOU VERY MUCH. APPRECIATE COUNSEL'S
11 FOCUS.

12 ALL RIGHT. SO ADDITIONAL PUBLIC COMMENT
13 WITH THAT AMENDMENT? SEEING NONE, ALL IN FAVOR?
14 OPPOSED? ALL RIGHT.

15 GOING ON TO ITEM NO. 9, THIS IS AN
16 AMENDMENT TO THE LOAN ADMINISTRATION POLICY,
17 INCLUDING, BUT NOT LIMITED TO, A PROPOSAL TO
18 ELIMINATE THE REQUIREMENT THAT APPLICANTS IDENTIFY
19 WHETHER THEY WOULD ACCEPT A NONRECOURSE LOAN IF THEY
20 ARE NOT ELIGIBLE FOR A RECOURSE LOAN.

21 THE PRIOR FACT PATTERN WAS THAT THE
22 APPLICANT WAS PUT IN A POSITION OF HAVING TO MAKE A
23 CHOICE BETWEEN A RECOURSE LOAN AND A NONRECOURSE
24 LOAN BEFORE THEY REALLY KNEW THEIR STANDING AND
25 BEFORE THEY REALLY KNEW WHAT THE EVALUATION WAS OF

BARRISTERS' REPORTING SERVICE

1 THEIR BUSINESS CONDITION BY THE DELEGATED
2 UNDERWRITING; IS THAT CORRECT, MR. GOLDBERG?

3 MR. GOLDBERG: THAT IS CORRECT. IT WAS
4 THE VIEW OF THE FINANCE SUBCOMMITTEE THAT THIS
5 AMENDMENT AS PROPOSED BY ELONA BAUM AND STAFF BE
6 APPROVED.

7 CHAIRMAN KLEIN: AND, DUANE, DID YOU WANT
8 TO MAKE A COMMENT?

9 MR. ROTH: NO.

10 CHAIRMAN KLEIN: OKAY. ADDITIONAL
11 COMMENTS FROM THE BOARD? IS THERE A MOTION?

12 MR. TORRES: MOVE IT.

13 DR. LOVE: SECOND.

14 CHAIRMAN KLEIN: MOVED BY ART TORRES,
15 SECOND BY DR. LOVE. IS THERE PUBLIC COMMENT? AND
16 CAN I ASK, TO BE CAREFUL HERE, DO WE HAVE ANYONE
17 TELEPHONICALLY PARTICIPATING?

18 MS. KING: NOT RIGHT NOW.

19 CHAIRMAN KLEIN: NOT AT THIS MOMENT. I
20 JUST WANTED TO MAKE SURE THEIR THOUGHTS WERE TAKEN
21 IN CONSIDERATION IF I MIGHT NOT FULLY HEAR THEM.

22 ALL RIGHT. AND THERE'S NO PUBLIC COMMENT;
23 IS THAT CORRECT? CALL THE QUESTION. ALL IN FAVOR?
24 OPPOSED? THANK YOU.

25 ITEM NO. 10 IS AN EXTENSION OF THE

BARRISTERS' REPORTING SERVICE

1 EXISTING LEGAL SERVICES CONTRACT WITH NANCY KOCH.
2 THERE ARE PUBLIC DOCUMENTS AVAILABLE ON THIS ITEM;
3 IS THAT RIGHT?

4 MS. KING: YES. IT'S IN THE -- DUE TO THE
5 TIMING WITH WHICH WE RECEIVED THE MEMO, IT'S IN THE
6 POCKET IN THE LEFT FRONT COVER OF YOUR BINDER
7 LABELED ITEM NO. 10. IT IS OUT FOR THE PUBLIC AND
8 HAS BEEN POSTED ON THE WEB SITE.

9 CHAIRMAN KLEIN: THIS IS THE ITEM THAT WE
10 PREVIOUSLY WENT THROUGH.

11 MS. KING: IT'S A ONE-PAGE DOCUMENT THAT
12 HAS HOLES.

13 CHAIRMAN KLEIN: ELONA BAUM, WOULD YOU
14 GIVE US A STATUS REPORT ON THIS ITEM, PLEASE?

15 MS. BAUM: CHAIR, MEMBERS OF THE BOARD,
16 THIS IS AN ITEM TO ENTER INTO A NEW AGREEMENT WITH
17 NANCY KOCH. AS YOU MAY RECALL, THE SCIENCE TEAM HAS
18 APPLAUDED HER EFFORTS, AND SHE'S DONE TERRIFIC WORK
19 WITH RESPECT TO OUR COLLABORATION FUNDING PROGRAM,
20 BIOSIMILARS PROGRAM IN THE PAST. HER CURRENT
21 CONTRACT HAS BEEN AMENDED AND ENDS ON THE 31ST OF
22 OCTOBER. SO WE ARE PROPOSING TO ENTER INTO A NEW
23 SIX-MONTH CONTRACT. AND I'M HAPPY TO PROVIDE OTHER
24 TERMS AND CONDITIONS IF YOU WANT THE HOURLY RATE.

25 CHAIRMAN KLEIN: CAN YOU GIVE US THE TOTAL

BARRISTERS' REPORTING SERVICE

1 DOLLAR AMOUNT OF THIS AUTHORIZATION, PLEASE?

2 MS. BAUM: THE MAXIMUM CONTRACT AMOUNT
3 WOULD BE A HUNDRED THOUSAND FOR SIX MONTHS.

4 CHAIRMAN KLEIN: AND THE REASON THIS IS
5 COMING TO THE BOARD IS BECAUSE WE'RE AGGREGATING
6 THAT WITH PRIOR CONTRACTS; AND, THEREFORE, THE BEST
7 PRACTICE HAS BEEN TO BRING THIS TO THE BOARD IN THAT
8 CASE.

9 MS. BAUM: RIGHT.

10 CHAIRMAN KLEIN: ANY DISCUSSION OF THIS
11 ITEM?

12 DR. POMEROY: WHAT IS THE LONG-TERM PLAN
13 HERE? WE EXTENDED THIS EVERY SIX MONTHS SINCE, I
14 GUESS, APRIL 2008. SO WE JUST -- IS THE PLAN TO
15 JUST KEEP DOING THAT, OR DO WE HAVE A LONG-TERM
16 PLAN?

17 CHAIRMAN KLEIN: TO ADDRESS THE ISSUE,
18 THIS IS A CONSULTANT TO THE CHAIR'S OFFICE THAT'S
19 BEEN WORKING WITH THE PRESIDENT'S OFFICE A GREAT
20 DEAL AS WELL AS THE CHAIR'S OFFICE. AND THE KEY
21 ISSUE HERE IS THAT THIS -- WE DO NOT HAVE THE STAFF
22 POSITIONS TO, IN FACT, INCREASE THIS TO A FULL-TIME
23 POSITION WITHIN THE OFFICES. AND WE'RE TRYING TO
24 STAY FLEXIBLE AND NOT COMMIT KEY POSITIONS WE NEED
25 FOR SCIENTIFIC APPOINTMENTS. SO WE ARE, IN FACT,

BARRISTERS' REPORTING SERVICE

1 FINDING THAT HER SPECIFIC BACKGROUND AND HER WORK TO
2 DATE HAS BEEN TREMENDOUSLY VALUABLE WITH THE
3 INTERNATIONAL COMMUNITY AND WITH, FOR EXAMPLE, THE
4 BILATERAL AGREEMENT WITH THE STATE OF MARYLAND. BUT
5 THIS IS NOT NECESSARILY A LONG-TERM NEED.

6 SO WE'RE TRYING TO KEEP THIS CONTRACT IN
7 PLACE WHILE WE CAN OPTIMIZE THE SERVICE OF THE NEEDS
8 THAT HAVE BEEN IDENTIFIED WITHOUT MAKING A MULTIYEAR
9 COMMITMENT.

10 DR. TROUNSON: MR. CHAIR, JUST ON BEHALF
11 OF THE INSTITUTION, THE INSTITUTE, I'VE ASKED THE
12 GENERAL COUNSEL TO RESOLVE THIS MATTER BECAUSE I
13 THINK IT DOES NEED TO BE ADDRESSED AND RESOLVED.
14 AND SO I'VE ASKED HER TO COME BACK TO ME, AT LEAST,
15 WITH SOME RESOLUTION ABOUT WHETHER THIS NEEDS TO BE
16 CONTINUED OR THERE WOULD BE AN ALTERNATIVE. SO WE
17 WILL -- THAT WILL BE HAPPENING IN-HOUSE.

18 CHAIRMAN KLEIN: I WILL TELL YOU FROM THE
19 CHAIR'S OFFICE NEEDS, WE'RE NOT FULLY UP TO STAFF.
20 WE'RE MISSING A DIRECTOR FINANCE, LEGAL, AND
21 GOVERNMENTAL AFFAIRS, AND ANOTHER POSITION. AND
22 RIGHT NOW FOR THE NEXT YEAR, IT'S GOING TO BE VERY
23 DIFFICULT TO REPLACE SOMEONE WITH THIS EXPERIENCE.
24 IT IS VERY -- SO THE HOURS MAY REDUCE IN A FUTURE
25 PERIOD SIGNIFICANTLY BASED UPON THE PRESIDENT'S

BARRISTERS' REPORTING SERVICE

1 NEEDS. BUT FOR THE NEXT 12 MONTHS AT LEAST, THE
2 CHAIR'S OFFICE HAS SOME VERY SIGNIFICANT NEEDS IN
3 THIS AREA. AND IT'S COVERING OVER SOME GAPS IN OUR
4 STAFFING.

5 MS. BAUM: IF I COULD POINT OUT THAT I
6 THINK THAT THERE'S A LOT OF HEAVY LIFTING THAT NEEDS
7 TO BE DONE IN TERMS OF ENTERING THE OTHER MOU'S THAT
8 WE'RE TARGETING. BUT I THINK THAT WE'LL GET CLOSE
9 TO COMPLETING A LOT OF THAT WORK IN THE NEXT SIX
10 MONTHS, AND THIS WILL BUY THE TIME TO FIGURE OUT HOW
11 WE CAN OR IF WE SHOULD END UP USING IN-HOUSE
12 RESOURCES TO ACCOMPLISH THE REST OF THE ALLIANCE
13 MANAGEMENT TASK.

14 DR. PULIAFITO: I MOVE THAT WE APPROVE
15 THIS CONTRACT.

16 CHAIRMAN KLEIN: IS THERE A SECOND?

17 MR. SERRANO-SEWELL: SECOND.

18 CHAIRMAN KLEIN: DAVID SERRANO-SEWELL IS
19 THE SECOND. MOTION WAS MADE BY DR. PULIAFITO.
20 ADDITIONAL DISCUSSION?

21 MR. SERRANO-SEWELL: VERY BRIEFLY,
22 CHAIRMAN. WHEN WE WERE IN BALTIMORE AT THE WORLD
23 STEM CELL SUMMIT TOGETHER, I GOT TO WITNESS NANCY
24 FIRS THAND. AND HER INTERACTIONS WITH HER
25 COLLEAGUES, AND THIS IS THE HIGHEST DEGREE OF LEGAL

BARRISTERS' REPORTING SERVICE

1 SERVICES WE'RE GETTING FROM SOMEONE, SHE IS A
2 PROFESSIONAL. SHE IS DEDICATED TO THE MISSION. AND
3 THIS IS A BARGAIN.

4 CHAIRMAN KLEIN: OKAY. SO ADDITIONAL
5 COMMENTS? PUBLIC COMMENT? CALL THE QUESTION. ALL
6 IN FAVOR? OPPOSED? THANK YOU VERY MUCH.

7 I'D LIKE TO MOVE DOWN -- I'M GOING TO VERY
8 QUICKLY COVER AN ITEM, HOPEFULLY WITHOUT READING IT
9 FULLY, WHICH ARE THE RESOLUTIONS FOR ALTA CHARO AND
10 DON FISHER, BOTH OF WHOM HAVE INDIVIDUALLY IN VERY
11 DIFFERENT ROLES MADE TREMENDOUS CONTRIBUTIONS TO
12 THIS AGENCY.

13 DON FISHER, OF COURSE, BEING A PRIME MOVER
14 ON OUR HEADQUARTERS. DON FISHER, UNFORTUNATELY
15 DIED. SO WE HAVE RESOLUTIONS THAT ARE IN YOUR BOOKS
16 THAT I'M SURE YOU'VE READ, AND I'D LIKE TO SEE IF WE
17 CAN GET A MOTION.

18 MS. LANSING: I'D LIKE TO MOVE IT.

19 CHAIRMAN KLEIN: MOVED BY SHERRY LANSING.
20 IS THERE A SECOND?

21 MR. TORRES: SECOND.

22 CHAIRMAN KLEIN: SECOND BY ART TORRES. IS
23 THERE DISCUSSION?

24 MS. LANSING: I JUST WANT TO SAY, AS A
25 MEMBER OF THE GRANTS WORKING COMMITTEE, THAT ALTA

BARRISTERS' REPORTING SERVICE

1 CHARO WAS EXTRAORDINARY. WE WILL MISS HER DEEPLY,
2 AND IT'S REALLY A CONFLICT OF INTEREST FOR HER TO
3 CONTINUE, WHICH IS WHY SHE'S NOT DOING SO. BUT HER
4 CONTRIBUTION HAS BEEN EXTRAORDINARY.

5 AND I KNOW YOU PROBABLY -- SOMEONE WANT TO
6 SPEAK TO DON FISHER WHO KNEW HIM AS I UNFORTUNATELY
7 DID NOT.

8 CHAIRMAN KLEIN: DON FISHER, AS A FORMER
9 PRESIDENT OF THE GAP, MADE TREMENDOUS CONTRIBUTIONS
10 TO MEDICAL RESEARCH FOR YEARS ALONG WITH MANY OTHER
11 CHARITABLE CONTRIBUTIONS TO THE CALIFORNIA NONPROFIT
12 AND CHARITABLE COMMUNITIES. AND HIS FINANCIAL
13 SUPPORT REALLY MADE IT POSSIBLE TO HAVE THE \$20
14 MILLION OF SUPPORT THAT WENT INTO THE HEADQUARTERS
15 BID IN SAN FRANCISCO. A REMARKABLE INDIVIDUAL. HE
16 AND HIS WIFE NEED TO BE RECOGNIZED. THE RESOLUTION
17 SPECIFICALLY, SINCE HE HAS PASSED AWAY, IS MEANT FOR
18 THE FAMILY TO CONVEY OUR THANKS AND GOES THROUGH
19 SOME OF THE CRITICAL DETAILS THAT RECITE THE
20 PROGRESS THAT HAS BEEN MADE BECAUSE OF HIS
21 GENEROSITY.

22 I THINK WE HAVE A RESOLUTION PENDING. ANY
23 ADDITIONAL COMMENTS? PUBLIC COMMENT? I CALL THE
24 QUESTION. ALL IN FAVOR? OPPOSED?

25 ITEM 7 IS APPOINTMENTS TO THE GRANTS

BARRISTERS' REPORTING SERVICE

1 WORKING GROUP, BUT NOT LIMITED TO APPOINTMENT OF NEW
2 SCIENTIFIC MEMBERS. I THINK WE SHOULD HANDLE THESE
3 ITEMS INDIVIDUALLY. 7 A, DR. SAMBRANO, WOULD YOU
4 LIKE TO ADDRESS THAT?

5 DR. SAMBRANO: JUST VERY BRIEFLY, MR.
6 CHAIR AND MEMBERS OF THE BOARD, MEMBERS OF THE
7 PUBLIC, TODAY WE ARE BRINGING FOR YOUR CONSIDERATION
8 NINE NOMINEES FOR ALTERNATE GRANTS WORKING GROUP
9 MEMBERS WHO WILL SPECIFICALLY EXPAND OUR OVERALL
10 EXPERTISE IN THE AREAS OF IMMUNOLOGY, CANCER STEM
11 CELLS, AND RETINAL DISEASE. AND FOR MANY OF THESE,
12 WE'RE LOOKING FORWARD TO THE REVIEW FOR
13 TRANSPLANTATION IMMUNOLOGY.

14 AND I WILL JUST REMIND YOU THAT AS
15 ALTERNATE GRANTS WORKING GROUP MEMBERS, THESE
16 INDIVIDUALS MAY BE CALLED UPON TO PARTICIPATE IN A
17 GRANTS WORKING GROUP MEETING AS AN AD HOC REVIEWER
18 OR ASKED TO BECOME A REGULAR MEMBER OF THE GRANTS
19 WORKING GROUP TO REPLACE CURRENT MEMBERS AS
20 NECESSARY.

21 ALTERNATE GRANTS WORKING GROUP MEMBERS ARE
22 SUBJECT TO AND MUST AGREE TO ABIDE BY THE SAME
23 CONFLICT OF INTEREST AND FINANCIAL DISCLOSURE POLICY
24 AS REGULAR WORKING GROUP MEMBERS. AND SO THE
25 NOMINEES INCLUDE DRs. MICHAEL BOULTON, ANNE COOKE,

BARRISTERS' REPORTING SERVICE

1 ALAN FLAKE, MARK JENKINS, WILLIAM MATSUI, JAMES
2 SCHWOB, HERMAN WALDMANN, HARTMUT WEKERLE, THERESA
3 WHITESIDE. AND THIS WOULD BRING THE NUMBER OF
4 ALTERNATE MEMBERS OF THE WORKING GROUP TO A TOTAL OF
5 105.

6 SO WE REQUEST YOUR APPROVAL AND
7 APPOINTMENT OF THESE NOMINEES AS ALTERNATE MEMBERS
8 OF THE WORKING GROUP.

9 DR. PULIAFITO: MR. CHAIRMAN, I'D LIKE TO
10 MOVE THAT WE ACCEPT THESE AS MEMBERS OF THE WORKING
11 GROUP.

12 CHAIRMAN KLEIN: ALL RIGHT. IS THERE A
13 SECOND?

14 MS. LANSING: SECOND.

15 CHAIRMAN KLEIN: SECOND BY SHERRY LANSING.
16 MOTION WAS MADE BY DR. PULIAFITO.

17 JOAN SAMUELSON, I THINK ON THIS ITEM YOU
18 HAD SUGGESTED TO ME THAT YOU WANTED TO HAVE
19 CONSIDERATION OF AN AMENDMENT TO THIS ITEM WHEREBY
20 AN EXISTING ALTERNATE WOULD -- YOU HAD AN INDIVIDUAL
21 IN MIND WHO IS AN EXISTING ALTERNATE THAT YOU WANTED
22 TO HAVE THAT ALTERNATE BE THE NEXT PERSON TO BE
23 ELEVATED IN THE EVENT OF A VACANCY TO THE WORKING
24 GROUP; IS THAT CORRECT?

25 MS. SAMUELSON: THAT IS CORRECT.

BARRISTERS' REPORTING SERVICE

1 CHAIRMAN KLEIN: WHO IS THE INDIVIDUAL?

2 MS. SAMUELSON: IT'S DR. SLADEK.

3 CHAIRMAN KLEIN: IS THAT CORRECT, THAT DR.
4 SLADEK IS A CURRENT ALTERNATE?

5 DR. SAMBRANO: YES, THAT'S CORRECT.

6 CHAIRMAN KLEIN: AND THE REQUEST FROM
7 MEMBER SAMUELSON IS THAT THERE BE AN AMENDMENT TO
8 THIS MOTION, AS I UNDERSTAND IT, SUCH THAT DR.
9 SLADEK, WHO HAS BEEN A LONG-TERM ALTERNATE, IF THERE
10 IS AN OPENING ON THE REGULAR WORKING GROUP, BECOME A
11 REGULAR MEMBER OF THAT WORKING GROUP; IS THAT
12 CORRECT?

13 MS. SAMUELSON: THAT'S RIGHT. HE'S BEEN A
14 VERY VALUABLE RESOURCE TO THE WORKING GROUP AND HAS
15 FUNCTIONED IN THE CAPACITY SEVERAL TIMES, I THINK,
16 AS ACTING CHAIR.

17 CHAIRMAN KLEIN: OKAY. SO DISCUSSION?

18 MR. SHEEHY: I THINK DR. SLADEK HAS DONE A
19 TREMENDOUS JOB ON THE WORKING GROUP, SO I'M VERY
20 SUPPORTIVE OF WHAT JOAN IS SUGGESTING. I THINK IT'S
21 APPROPRIATE.

22 DR. PULIAFITO: I ACCEPT THE AMENDMENT.

23 CHAIRMAN KLEIN: AMENDMENT IS ACCEPTED BY
24 THE FIRST AND SECOND. ANY ADDITIONAL COMMENTS?
25 YES.

BARRISTERS' REPORTING SERVICE

1 DR. SAMBRANO: JUST A POINT OF
2 CLARIFICATION. THERE IS A VACANCY AVAILABLE, SO DR.
3 SLADEK WOULD, BASED ON YOUR VOTE, AUTOMATICALLY
4 BECOME A REGULAR MEMBER OF THE WORKING GROUP.

5 CHAIRMAN KLEIN: ALL RIGHT. THANK YOU.
6 AND PUBLIC COMMENT? SEEING NO PUBLIC COMMENT, I
7 WILL CALL THE QUESTION. ALL IN FAVOR? OPPOSED?

8 APPOINTMENT OF THE CO-VICE CHAIR, DR.
9 SAMBRANO.

10 DR. SAMBRANO: I THINK THAT ITEM COMES
11 BACK TO YOU, MR. CHAIR. I DON'T HAVE ANY SPECIFIC
12 RECOMMENDATION OTHER THAN WHAT MIGHT BE BROUGHT BY
13 THE BOARD.

14 CHAIRMAN KLEIN: CERTAINLY. SO WE HAVE
15 HAD THE TREMENDOUS BENEFIT ON THE GRANTS WORKING
16 GROUP OF BOTH JOAN SAMUELSON AND JEFF SHEEHY ACTING
17 AS VICE CHAIR. AND THAT HAS BEEN VERY EFFECTIVE FOR
18 US OVER TIME, MAKING SURE WE HAVE BOTH OF THEIR
19 CONTRIBUTIONS. AND WITH A HIGH DEGREE OF
20 COORDINATION FOR THE SPEED FOR THE GROUP'S MOVEMENT
21 THROUGH DOCUMENTS, JOAN AND JEFF HAVE WORKED OUT AN
22 ARRANGEMENT WHERE JEFF HANDLES THE PROCEDURAL
23 ISSUES, BUT JOAN IS A VERY CRITICAL SOURCE OF INPUT
24 AND INSPIRATION TO THE GRANTS WORKING GROUP.

25 SO WE'D LIKE TO FORMALLY DESIGNATE THEM BY

BARRISTERS' REPORTING SERVICE

1 THE BOARD AS CO-VICE CHAIRS IF THERE IS A MOTION.

2 MR. TORRES: SO MOVED.

3 DR. LOVE: SECOND.

4 CHAIRMAN KLEIN: MOTION BY ART TORRES,
5 SECOND BY DR. LOVE. DISCUSSION?

6 MS. SAMUELSON: I'D LIKE TO SAY A COUPLE
7 WORDS. JEFF HAS DONE AN EXTRAORDINARY JOB IN
8 PROVIDING CONSTANT LEADERSHIP AND INSPIRATION
9 HIMSELF IN OUR WORK AGENDA. AND I OWE HIM A
10 PERSONAL DEBT OF GRATITUDE BECAUSE THE LAST YEAR
11 WITH THE DIFFICULTY AND MY PARENTS' ILLNESSES HAS
12 MADE IT VERY HARD FOR ME TO BE ABLE TO BE HERE AND
13 DO THE JOB THAT THE WORKING GROUP HAS NEEDED IN OUR
14 MANY MEETINGS. AND JEFF HAS JUST DONE AN
15 EXTRAORDINARY JOB OF MAKING IT POSSIBLE FOR ME TO
16 NOT BE HERE WHEN I COULDN'T, AND YET HAVE THE WORK
17 PRODUCT THAT WE'VE HAD.

18 SO I THINK HE IS OWED ALL SORTS OF THINGS,
19 AND CERTAINLY THIS TITLE IS THE LEAST OF THEM.

20 CHAIRMAN KLEIN: MAYBE WE CAN GIVE A HAND
21 OF APPLAUSE BOTH TO JOAN AND TO JEFF.

22 (APPLAUSE.)

23 MR. TORRES: HE MAY PREFER A CHECK.

24 CHAIRMAN KLEIN: THAT'S BEYOND MY
25 AUTHORITY.

BARRISTERS' REPORTING SERVICE

1 ALL RIGHT. SO WE HAVE A MOTION ON THE
2 FLOOR, AND DO WE HAVE ANY OTHER COMMENTS?

3 DR. PRICE: SOMEBODY REPEAT THE MOTION.

4 CHAIRMAN KLEIN: THE MOTION IS FOR JEFF
5 SHEEHY AND JOAN BOTH TO BE FORMALLY APPOINTED AS
6 CO-VICE CHAIRS OF THE GRANTS WORKING GROUP.

7 ALL RIGHT. ANY ADDITIONAL COMMENTS BY
8 PUBLIC? CALL THE QUESTION. ALL IN FAVOR? OPPOSED?
9 ABSTAIN? THANK YOU.

10 7 C I THINK WE NEED TO TAKE SOME TIME
11 WITH. IT'S IMPORTANT THE BOARD ALL UNDERSTAND THIS.
12 THIS IS NOT SOMETHING THAT HAS BEEN DISCUSSED WITH
13 MANY MEMBERS OF THE BOARD. SO, DR. SAMBRANO, COULD
14 YOU PLEASE PRESENT 7 C.

15 DR. SAMBRANO: CERTAINLY. SO ON SEPTEMBER
16 9TH THE GRANTS WORKING GROUP MET RIGHT BEFORE THE
17 DISEASE TEAM REVIEW AND CONSIDERED AND RECOMMENDED
18 THAT THE ICOC AMEND THE GRANTS WORKING GROUP BYLAWS
19 TO REFLECT SOME CHANGES THAT ARE PROPOSED FOR
20 SELECTING AND APPOINTING THE CHAIR OF THE GRANTS
21 WORKING GROUP.

22 THE PROPOSED CHANGES INCLUDE MODIFICATIONS
23 IN ARTICLE 4, SECTION 9 AND THE ADDITION OF SECTION
24 9.5, WHICH ARE BOTH RELATED TO THE PROCESS OF
25 APPOINTMENT OF AN ADMINISTRATIVE CHAIR AS WELL AS AN

BARRISTERS' REPORTING SERVICE

1 ACTING CHAIR OF THE GRANTS WORKING GROUP WITH THEIR
2 RESPECTIVE DUTIES. AND SO THESE CHANGES WOULD
3 IMPLEMENT THE RECOMMENDATIONS OF THE WORKING GROUP,
4 WHICH ARE THE FOLLOWING.

5 IT IS RECOGNIZED THAT CIRM IS BROADENING
6 ITS RFA PROFILE TO INCLUDE TRANSLATIONAL,
7 PRECLINICAL, AND CLINICAL TRIAL RESEARCH, WHICH
8 REQUIRES VERY DIFFERENT REVIEWER EXPERTISE FROM THE
9 BASIC RESEARCH AND TRAINING. SO CONSEQUENTLY
10 THERE'S AN IMPORTANT NEED TO HAVE CHAIRS OF THE CIRM
11 REVIEW PANELS WITH THE APPROPRIATE EXPERTISE AND
12 SENIORITY THAT COMPLEMENTS THOSE TYPES OF RFA'S THAT
13 ARE BEING CONSIDERED.

14 THE ROLE OF THE CHAIR OF THE GRANTS
15 WORKING GROUP, BY WAY OF OUR CURRENT POLICY, RESTS
16 ON ONE SINGLE APPOINTED INDIVIDUAL. BUT IN PRACTICE
17 IT REALLY REQUIRES THE BREADTH AND EXPERTISE OF
18 SEVERAL INDIVIDUALS. SO OVERALL THE CHAIR LEADS THE
19 GRANTS WORKING GROUP IN PROVIDING ADVICE AND
20 RECOMMENDATIONS TO THE ICOC ON BOTH SCIENTIFIC MERIT
21 OF APPLICATIONS SUBMITTED TO CIRM AND ON POLICY
22 ISSUES THAT RELATE TO THE MANAGEMENT OF AWARDS.

23 AND AS WE EXPECT TO BE CONDUCTING FIVE TO
24 SEVEN GRANTS WORKING GROUP REVIEWS PER YEAR IN SAN
25 FRANCISCO, IT BECOMES IMPRACTICAL TO HAVE A SINGLE

BARRISTERS' REPORTING SERVICE

1 INDIVIDUAL CHAIR ALL OF THESE REVIEWS. THEREFORE,
2 THE GRANTS WORKING GROUP IS RECOMMENDING THAT THE
3 ICOC AMEND THE GRANTS WORKING GROUP BYLAWS TO ALLOW
4 THE APPOINTMENT OF ONE SCIENTIFIC MEMBER AS THE
5 STANDING ADMINISTRATIVE CHAIR OF THE GRANTS WORKING
6 GROUP AND THEN ALSO TO AUTHORIZE THE CIRM PRESIDENT
7 TO APPOINT AN APPROPRIATE GRANTS WORKING GROUP
8 SCIENTIFIC MEMBER OR ALTERNATE MEMBER AS THE ACTING
9 CHAIR FOR EACH OF THE REVIEW MEETINGS TO REFLECT THE
10 SPECIFIC EXPERTISE REQUIRED FOR THAT RFA.

11 THE ROLE OF THE ACTING CHAIR OF THE GRANTS
12 WORKING GROUP WILL BE TO PRESIDE OVER THE SCIENTIFIC
13 EVALUATION OF GRANT AND LOAN APPLICATIONS SUBMITTED
14 TO CIRM IN RESPONSE TO A SPECIFIC RFA. THE ACTING
15 CHAIR WOULD HAVE THE KNOWLEDGE AND BACKGROUND THAT'S
16 NECESSARY TO LEAD THE REVIEW OF PROPOSALS UNDER THAT
17 RFA. AND THEIR DUTIES WOULD COMMENCE UPON THE
18 PRESIDENT'S APPOINTMENT TO THE REVIEW AND ENCOMPASS
19 ANY GRANTS WORKING GROUP BUSINESS RELATED TO THE
20 SCIENTIFIC REVIEW OF THAT RFA, INCLUDING
21 CONSIDERATION OF FORMAL APPEALS AFTER THE REVIEW.

22 NOW, THE ROLE OF THE ADMINISTRATIVE CHAIR
23 OF THE GRANTS WORKING GROUP WOULD BE TO PRESIDE OVER
24 GENERAL GRANTS WORKING GROUP BUSINESS, WHICH
25 INCLUDES RECOMMENDATIONS TO THE ICOC OF STANDARDS OF

BARRISTERS' REPORTING SERVICE

1 SCIENTIFIC OVERSIGHT, GRANT APPLICATIONS OR AWARDS,
2 AS WELL AS THE SCIENTIFIC EVALUATION OF GRANT OR
3 LOAN APPLICATIONS THAT HAVE NOT SPECIFICALLY BEEN
4 DESIGNATED TO ONE RFA OR REVIEW MEETING.

5 SO WE ARE REQUESTING THE APPROVAL OF THE
6 HIGHLIGHTED CHANGES WHICH SHOULD BE SHOWN IN YOUR
7 TAB NO. 7 C. AND SO WE REQUEST THE APPROVAL OF
8 THOSE CHANGES TO IMPLEMENT THIS PROCESS FOR
9 SELECTING AND APPOINTING GRANTS WORKING GROUP
10 CHAIRS.

11 CHAIRMAN KLEIN: DR. SAMBRANO WHAT ARE THE
12 WORDS "INCLUDING THE CONSIDERATION OF FORMAL APPEALS
13 AFTER THE REVIEW MEETING"?

14 DR. SAMBRANO: SO IT'S IN REFERENCE TO THE
15 SPECIFIC RFA. THIS IS THE ACTING CHAIR. IS THAT
16 WHAT YOU WERE REFERRING TO?

17 CHAIRMAN KLEIN: YES.

18 DR. SAMBRANO: SO THIS IS THE
19 CONSIDERATION OF FORMAL APPEALS AFTER REVIEWS. PART
20 OF THE APPEAL PROCESS FOR FORMAL APPEALS IS TO
21 CONSULT THE GRANTS WORKING GROUP CHAIR TO DETERMINE
22 THE MERIT OF THE APPEAL.

23 CHAIRMAN KLEIN: SO THE WORD "APPEAL" HERE
24 IS USED IN THE NARROW CONTEXT OF OUR DEFINITION OF
25 APPEALS AS RESTRICTED TO CONFLICTS?

BARRISTERS' REPORTING SERVICE

1 DR. SAMBRANO: THAT'S CORRECT, IN THE GAP.

2 CHAIRMAN KLEIN: I UNDERSTAND. SO THIS IS
3 ONLY DEALING WITH THE APPEALS ON A CONFLICT HAVING
4 EXISTED AT THE PEER REVIEW SESSION. I JUST WANTED
5 TO CLARIFY THAT FOR EVERYONE.

6 ARE THERE ADDITIONAL QUESTIONS ABOUT THIS
7 PROCESS? DR. PRICE.

8 DR. PRICE: JUST FOLLOWING UP ON YOUR
9 CLARIFICATION, SHOULD THERE NOT BE SOME LANGUAGE IN
10 THIS TO MAKE IT CLEAR THAT WHAT WE'RE TALKING ABOUT
11 ARE THE NARROW BAND OF APPEALS?

12 MR. SHEEHY: IT'S BEING PROVIDED AS AN
13 AMENDMENT TO THE BYLAWS. SO IF YOU LOOK IN YOUR
14 BINDER, WHAT HE'S DOING IS GIVING YOU A NARRATIVE
15 SUMMARY OF ACTUAL FORMAL LANGUAGE THAT'S GOING INTO
16 THE BYLAWS OF THE GRANTS WORKING GROUP, IF I'M
17 CORRECT.

18 DR. SAMBRANO: THAT'S CORRECT.

19 MR. SHEEHY: AND THE ONLY APPEAL PROCESS
20 THAT IS RELEVANT TO THE GRANTS WORKING GROUP BYLAWS
21 IS THAT SPECIFIC APPEAL PROCESS THAT'S LIMITED TO
22 CONFLICTS OF INTEREST.

23 CHAIRMAN KLEIN: FOR OUTSIDE READERS,
24 HOWEVER, WHO MAY BE CONFUSED BY THIS, IF WE WERE TO
25 CAPITALIZE "FORMAL APPEAL" AND HAVE THE DEFINITION

BARRISTERS' REPORTING SERVICE

1 BE CLEAR. MR. HARRISON, IF WE WERE TO CAPITALIZE
2 FORMAL APPEAL AND HAVE A DEFINITION THAT'S CLEAR,
3 THEN THE READER WOULD BE ON NOTICE THAT THIS IS A
4 DEFINED TERM BECAUSE WE DON'T WANT PEOPLE TRYING TO
5 ACCESS THIS OUT OF CONFUSION. DOES THAT SOUND LIKE
6 A REASONABLE CLARIFICATION?

7 MR. HARRISON: I THINK WE CAN ALSO
8 CROSS-REFERENCE THE SECTION OF THE GAP THAT DEFINES
9 THE APPEALS PROCESS.

10 CHAIRMAN KLEIN: SO THAT WOULD BE VERY
11 HELPFUL. SO, DR. SAMBRANO, DO YOU HAVE ADDITIONAL
12 POINTS TO COVER?

13 DR. SAMBRANO: NO.

14 CHAIRMAN KLEIN: OKAY. THANK YOU. JOAN
15 SAMUELSON.

16 MS. SAMUELSON: I'M SEEING THIS FOR THE
17 FIRST TIME, WHICH MAY WELL BE MY FAULT HAVING BEEN
18 SO BUSY WITH FAMILY AFFAIRS OF LATE. SO I'M NOT
19 COMPLAINING ABOUT THAT, BUT I HAVE SOME QUESTIONS
20 ABOUT IT. AND I'M NOT SURE HOW MUCH OF IT COULD GET
21 RESOLVED IN THIS MEETING, AND WHETHER WE MIGHT PUT
22 IT OVER TO THE NEXT MEETING.

23 FOR EXAMPLE, LOOKING AT PAGE 7 AT THE TOP
24 OF THAT PAGE, FUNDING RECOMMENDATIONS, IT TALKS
25 ABOUT THE PROCESS FOLLOWING THE SETTING OF THE

BARRISTERS' REPORTING SERVICE

1 SCIENTIFIC SCORE AND THE PROCESS OF RANKING THE
2 GRANTS IN THE FUNDING TIERS AND SO ON. AND MY
3 RECOLLECTION IS THAT IN THE INITIATIVE IT PROVIDES
4 THAT THAT PROCESS BE RUN BY THE VICE CHAIR, WHICH
5 JEFF HAS CONDUCTED THAT PART OF THE REVIEW VERY
6 ABLY, I MUST SAY. I'M NOT SEEING ANY REFERENCE TO
7 THAT HERE.

8 SO I'M WONDERING, FOR ONE THING, HOW, IF
9 THIS ESTABLISHES NEW PROCEDURE, AND HOW IT
10 INTERSECTS WITH THE PROCEDURES IN THE LAW NOW.

11 CHAIRMAN KLEIN: MR. SAMBRANO, COULD YOU
12 RESPOND TO THE MEMBER'S QUESTION?

13 DR. SAMBRANO: SO I THINK THE SECTION THAT
14 YOU ARE REFERENCING IS OLD LANGUAGE THAT HAS EXISTED
15 IN THE BYLAWS. I THINK THE LAST APPROVAL WHICH WAS
16 DONE LAST YEAR MADE CHANGES SUCH AS INDICATING
17 PROVISIONALLY RECOMMENDED FOR FUNDING, WHICH IS NOW
18 IN THE GRANTS ADMINISTRATION POLICY, BUT NO OTHER
19 CHANGES HAVE BEEN MADE TO THIS PARTICULAR SECTION OF
20 THE BYLAWS. AND WHAT WE'RE PROPOSING, AT LEAST
21 UNDER THIS ITEM, ARE CHANGES THAT ARE UNDER SECTION
22 4, SECTION 9 AND THEY ARE HIGHLIGHTED IN RED.

23 MS. SAMUELSON: IS IT SOMEWHERE ELSE THAT
24 THE VICE CHAIR ROLE IS PROVIDED FOR? IS IT
25 SOMEWHERE ELSE?

BARRISTERS' REPORTING SERVICE

1 MR. SHEEHY: I THINK, JOAN, WHEN I SAW
2 THIS, I HAD THE SAME QUESTION. I ACTUALLY WENT
3 BACK, I WANT TO SAY, TO 2005 AND LOOKED AT OUR
4 INITIAL ADOPTION OF THE BYLAWS. I DON'T THINK WE'VE
5 EVER ADOPTED THE -- WE'VE EVER -- AT LEAST WITHIN
6 THE BYLAWS, I DON'T THINK IT'S -- NOTHING'S BEEN
7 CHANGED, SO DR. SAMBRANO IS RIGHT. BUT THAT THE
8 PROGRAMMATIC REVIEW, I DON'T THINK, HAS BEEN ADOPTED
9 AS A BYLAWS PROCESS. IT MAY EXIST IN SOME OTHER WAY
10 WITHIN OUR RATHER LABYRINTH OF PROCEDURAL AND
11 REGULATORY STUFF. BUT IN OTHER WORDS, NO ONE IS
12 TRYING TO CHANGE SOMETHING HERE INADVERTENTLY. AND
13 IT MAY JUST BE THAT AT SOME POINT WE NEED TO INCLUDE
14 THAT -- PUT THAT -- INCLUDE THAT PROCESS IN THE
15 BYLAWS. THIS MAY HAVE JUST BEEN -- THIS MAY HAVE
16 BEEN TOTALLY EVOLUTIONARY IN THAT IT NEVER REALLY
17 GOT FORMALLY CODIFIED INTO THE BYLAWS OR ANYWHERE
18 ELSE. WE'VE REALLY KIND OF FOCUSED ON APPROVING THE
19 GRANTS.

20 DR. LEVIN: IT ACTUALLY DOES SAY ON THE
21 BOTTOM OF PAGE 3, THE OLD LANGUAGE, THE VICE CHAIR
22 OF THE GRANTS WORKING GROUP SHALL PRESIDE OVER THE
23 GRANT AND LOAN RECOMMENDATION PROCEDURES DESCRIBED
24 HERE WITHIN ARTICLE 6, SECTION 2(B). I THINK THAT'S
25 WHAT YOU WERE REFERRING TO, THAT THAT IS THE ROLE OF

BARRISTERS' REPORTING SERVICE

1 THE VICE CHAIR AND HAS BEEN IN THE BYLAWS FOR QUITE
2 SOME TIME.

3 CHAIRMAN KLEIN: THANK YOU. YOU CAN JOIN
4 THE RANKS OF OUR GREAT LEGAL REPRESENTATIVES.

5 MS. SAMUELSON: SO THAT RAISES ONE
6 QUESTION TO ME IN WHAT IS THE ROLE OF THE, NOT THE
7 ADMINISTRATIVE CHAIR, IT'S THE ACTING --

8 DR. SAMBRANO: SO THE ACTING CHAIR WOULD
9 HAVE ESSENTIALLY THE SAME ROLE THAT THE CURRENT
10 CHAIR HAS HAD FOR ANY SPECIFIC REVIEW. SO THEY
11 WOULD PRESIDE OVER THE SCIENTIFIC PORTION OF THE
12 REVIEW. THE CO-VICE CHAIRS OF THE GRANTS WORKING
13 GROUP WOULD PRESIDE OVER THE PROGRAMMATIC PORTION,
14 SO THAT WOULD STILL BE THE SAME. THE ADMINISTRATIVE
15 CHAIR, THEN, FOR EXAMPLE, MIGHT PRESIDE OVER THE
16 PUBLIC SESSIONS IN WHICH THERE ARE GRANTS WORKING
17 GROUP BUSINESS BEING CONSIDERED, FOR EXAMPLE, LIKE
18 CHANGES IN BYLAWS AND PUTTING FORTH THOSE
19 RECOMMENDATIONS.

20 CHAIRMAN KLEIN: SO LET ME ASK THIS
21 QUESTION.

22 MS. SAMUELSON: THAT'S ANOTHER ROLE WHICH
23 I THINK THE VICE CHAIR HAS HAD IN THE PAST.

24 MR. SHEEHY: THE VICE CHAIR HAS NOT BEEN
25 CHAIR OF THE PUBLIC SESSION. TO GO BACK TO THE

BARRISTERS' REPORTING SERVICE

1 OTHER POINT, I ACTUALLY DO THINK THERE' S A MI SPRINT.
2 I THINK IT' S SUPPOSED TO BE ARTICLE 6, SECTION 2(C)
3 IN THAT REFERENCE THAT DR. LEVIN JUST NOTED. SO
4 MAYBE OVER THE COURSE OF TIME, WE HAVE A MISPRINT
5 BECAUSE IT SAYS 2(B), AND ACTUALLY 2(B) IS THE
6 SCIENTIFIC EVALUATION AND SCORING, SO I THINK THAT
7 THERE' S A TYPO THAT ENTERED INTO IT.

8 CHAIRMAN KLEIN: WE DEFINITELY WANT TO
9 MAKE SURE WE GET THIS RIGHT. SO LET ME ASK THIS
10 QUESTION. DR. TROUNSON, YOU HAVE A COUPLE OF GRANTS
11 WORKING GROUP CHAIRS YOU NEED TO APPOINT SHORTLY FOR
12 OR RECRUIT IS PROBABLY THE BETTER WORD; IS THAT
13 CORRECT?

14 DR. TROUNSON: I THINK YOU' RE REFERRING TO
15 US TRYING TO FIND PEOPLE WHO ARE SUITABLE FOR
16 PARTICULAR GRANTS, SUCH AS THE IMMUNOLOGY --

17 CHAIRMAN KLEIN: THAT' S EXACTLY RIGHT.

18 DR. TROUNSON: -- FOR WHOM THERE ARE NO
19 REAL GENUINE CHAIRS AVAIL ABLE FROM WITH IN THE
20 CURRENT PORTFOLIO. SO IN THAT CIRCUMSTANCE, YES, WE
21 WILL BE LOOKING FOR SOMEBODY SPECIFIC. AND WE' VE
22 ACTUALLY IDENTIFIED SOMEONE AT OXFORD UNIVERSITY AT
23 THE MOMENT WHO WOULD BE PREPARED TO DO IT.

24 CHAIRMAN KLEIN: AND SO LET ME ASK THE
25 SECOND QUESTION. ALSO WE HAVE A BASIC SCIENCE

BARRISTERS' REPORTING SERVICE

1 COMING UP THAT YOU NEED TO RECRUIT A CHAIR FOR; IS
2 THAT CORRECT?

3 DR. TROUNSON: YES. AS YOU WOULD BE
4 AWARE, STU ORKIN HAS RESIGNED AS CHAIR. HE'S
5 DONE -- HE FEELS HE'S DONE SUFFICIENT TIME FOR US.
6 AND SO WE WOULD LIKE TO FIND AN APPROPRIATE CHAIR
7 FOR THAT. IT WOULDN'T NECESSARILY BE THE SAME
8 PERSON WHO CONDUCTED OR CHAIRED OUR DISEASE TEAM
9 PROGRAM, WHO'S A MUCH MORE TRANSLATIONAL, EARLY
10 CLINICAL PERSON. I THINK YOU NEED A MORE BASIC
11 PERSON WHO IS PROBABLY STEEPED IN SOME MOLECULAR
12 GENETICS STEM CELL BIOLOGY THAT WOULD BE MORE
13 APPROPRIATE FOR MANAGING THOSE GRANTS WORKING
14 GROUPS.

15 SO WITHOUT IDENTIFYING SOMEBODY AT THIS
16 STAGE, I HAVE -- WE HAVE SOME PEOPLE IN MIND, BUT WE
17 WANTED TO SEE WHETHER YOU WERE COMFORTABLE IN DOING
18 THIS.

19 CHAIRMAN KLEIN: LET ME ASK THIS. IT'S
20 IMPORTANT THAT THE VICE CHAIRS AND THE OTHER MEMBERS
21 BE COMFORTABLE WITH THE PROVISIONS HERE. IT SEEMS
22 THAT THERE'S SOME REFERENCES AND SOME AMBIGUITIES
23 THAT WE WANT TO MAKE SURE WE GET RIGHT. WHAT WOULD
24 THE MEMBERS THINK ABOUT POSTPONING THIS PARTICULAR
25 ITEM TO THE DECEMBER MEETING TO GIVE EVERYONE A

BARRISTERS' REPORTING SERVICE

1 CHANCE TO BE COMFORTABLE, BUT IMMEDIATELY
2 AUTHORIZING THE PRESIDENT IN A SUBSTITUTE MOTION TO
3 RECRUIT THE CHAIRS FOR IMMUNOLOGY AND BASIC SCIENCE
4 WHICH HAVE LEAD-TIME ISSUES ASSOCIATED WITH THEM SO
5 THAT THAT IS NOT HELD UP.

6 MR. TORRES: SO MOVED.

7 CHAIRMAN KLEIN: THAT'S MOVED BY ART
8 TORRES. IS THERE A SECOND?

9 DR. BLOOM: SECOND.

10 CHAIRMAN KLEIN: IS THERE DISCUSSION?

11 DR. STEWARD: SO JUST FOR CLARIFICATION,
12 ARE THE INCONSISTENCIES IN THE PART OF THIS THAT IS
13 UNDER REVISION, THE REVISIONS THAT WE'RE CONSIDERING
14 OR THE REST OF THE DOCUMENT.

15 CHAIRMAN KLEIN: I THINK THE INTENT HERE
16 IS TO GET EVERYTHING RIGHT AT ONCE INSTEAD OF
17 PIECEMEALING IT. OKAY? DR. TROUNSON, WOULD THAT BE
18 ACCEPTABLE?

19 DR. TROUNSON: THAT IS. I'VE JUST
20 INSTRUCTED THE GENERAL COUNSEL, SHE DIDN'T SEE THIS
21 MATTER BEFOREHAND, THAT SHE AND THE DEPUTY GENERAL
22 COUNSEL NEED TO GET THIS INTO AN APPROPRIATE STATE
23 FOR THE NEXT MEETING.

24 CHAIRMAN KLEIN: THANK YOU VERY MUCH. IS
25 THERE PUBLIC COMMENT ON THIS? SEEING --

BARRISTERS' REPORTING SERVICE

1 MS. SAMUELSON: I WOULD APPRECIATE
2 CONSULTATION WITH THE VICE CHAIRS.

3 CHAIRMAN KLEIN: I THINK, AS THE PRESIDENT
4 HAS ALWAYS DONE, ON THESE ITEMS WHEN IT'S BEEN
5 MENTIONED THAT THE BOARD HAS AN INTEREST OR
6 PARTICULAR BOARD MEMBERS HAS AN INTEREST, I'M SURE
7 HE'LL BE REACHING OUT TO YOU.

8 SO I'D LIKE TO CALL THE QUESTION. ALL IN
9 FAVOR? OPPOSED? THANK YOU.

10 SO THE COUNSEL HAS PROPERLY BROUGHT TO MY
11 ATTENTION THAT IN OUR CELEBRATION OF THE DISEASE
12 TEAM AWARDS THAT WE DID NOT FINISH THE SECOND VOTE,
13 WHICH IS THE VOTE ON ITEM 11 TO VOTE TO NOT FUND THE
14 BALANCE OF TIER III.

15 MS. LANSING: SO MOVED.

16 CHAIRMAN KLEIN: MOVED BY SHERRY LANSING.
17 IS THERE A SECOND?

18 MS. LANSING: I CAN'T MOVE IT.

19 DR. LOVE: I'LL MOVE IT.

20 MR. TORRES: SECOND.

21 CHAIRMAN KLEIN: TED LOVE DOES NOT HAVE
22 CONFLICTS. HE IS MOVING IT, AND IT'S SECONDED BY
23 ART TORRES.

24 SO IS THERE DISCUSSION? IS THERE PUBLIC
25 COMMENT? SO I REMIND YOU THAT YOU WILL BE VOTING

BARRISTERS' REPORTING SERVICE

1 FOR OR AGAINST EXCEPT FOR THOSE IN WHICH YOU ARE IN
2 CONFLICT. CALL THE QUESTION, AND IF WE COULD HAVE A
3 THE ROLL CALL VOTE, PLEASE.

4 MS. KING: DONALD DAFOE.

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

7 MS. KING: ROBERT PRICE.

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

10 MS. KING: FLOYD BLOOM.

11 DR. BLOOM: YES, EXCEPT FOR THOSE FOR
12 WHICH I HAVE A CONFLICT.

13 MS. KING: JACOB LEVIN.

14 DR. LEVIN: YES, EXCEPT FOR THOSE FOR
15 WHICH I HAVE A CONFLICT.

16 MS. KING: MICHAEL FRIEDMAN.

17 DR. FRIEDMAN: YES, EXCEPT FOR THOSE FOR
18 WHICH I HAVE A CONFLICT.

19 MS. KING: LEEZA GIBBONS.

20 MS. GIBBONS: YES.

21 MS. KING: MICHAEL GOLDBERG.

22 MR. GOLDBERG: YES, EXCEPT FOR THOSE FOR
23 WHICH I HAVE A CONFLICT.

24 MS. KING: BOB KLEIN.

25 CHAIRMAN KLEIN: YES.

BARRISTERS' REPORTING SERVICE

1 MS. KING: SHERRY LANSING.

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

4 MS. KING: GERALD LEVEY.

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

7 MS. KING: TED LOVE.

8 DR. LOVE: YES.

9 MS. KING: ED PENHOET.

10 DR. PENHOET: YES.

11 MS. KING: PHIL PIZZO.

12 DR. PIZZO: YES, EXCEPT FOR THOSE FOR
13 WHICH I HAVE A CONFLICT.

14 MS. KING: CLAIRE POMEROY.

15 DR. POMEROY: YES, EXCEPT FOR THOSE FOR
16 WHICH I HAVE A CONFLICT.

17 MS. KING: FRANCISCO PRIETO.

18 DR. PRIETO: YES, EXCEPT FOR THOSE FOR
19 WHICH I HAVE A CONFLICT.

20 MS. KING: CARMEN PULIAFITO.

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

23 MS. KING: ROBERT QUINT.

24 DR. QUINT: YES.

25 MS. KING: DUANE ROTH.

BARRISTERS' REPORTING SERVICE

1 MR. ROTH: YES.

2 MS. KING: JOAN SAMUELSON.

3 MS. SAMUELSON: YES.

4 MS. KING: DAVID SERRANO-SEWELL.

5 MR. SERRANO-SEWELL: YES.

6 MS. KING: JEFF SHEEHY.

7 MR. SHEEHY: YES, EXCEPT FOR THOSE FOR
8 WHICH I HAVE A CONFLICT.

9 MS. KING: OSWALD STEWARD.

10 DR. STEWARD: YES, EXCEPT FOR THOSE FOR
11 WHICH I HAVE A CONFLICT.

12 MS. KING: ART TORRES.

13 MR. TORRES: AYE.

14 MS. KING: THAT MOTION CARRIES.

15 CHAIRMAN KLEIN: SO WE HAVE AS OUR NEXT
16 ITEM CONSIDERATION OF NEW MEMBERS TO THE STANDARDS
17 WORKING GROUP, ITEM 16. GEOFF LOMAX, I KNOW YOU ARE
18 UNDER A TIGHT SCHEDULE, IF YOU COULD MAKE, AGAIN, A
19 TERSE PRESENTATION.

20 DR. LOMAX: THIS IS THE MEMBER WHICH WE
21 HAVE BROUGHT TO YOUR CONSIDERATION TO REPLACE ALTA
22 CHAR. AGAIN, I WILL MISS HER DEEPLY. SHE'S BEEN A
23 TREMENDOUS ASSET. BUT PATRICK TAYLOR IS THE DEPUTY
24 GENERAL COUNSEL AND CHIEF COUNSEL FOR RESEARCH
25 AFFAIRS AT CHILDREN'S HOSPITAL BOSTON. AND

BARRISTERS' REPORTING SERVICE

1 BASICALLY PAT TAYLOR BRINGS EXPERIENCE ON THE
2 REGULATORY SIDE, THE LEGAL SIDE, INFORMED CONSENT,
3 ALL THE LEGAL AND REGULATORY ASPECTS OF HUMAN
4 SUBJECTS RESEARCH, AS WELL AS PARTICIPATION WITH
5 ISSCR. SO WE FEEL WE'RE GETTING SOMEBODY WHO BRINGS
6 A SUBSTANTIAL EQUIVALENT IN TERMS OF RESEARCH TO THE
7 WORKING GROUP.

8 MR. TORRES: SO MOVED.

9 MS. SAMUELSON: SECOND.

10 CHAIRMAN KLEIN: SECOND BY JOAN SAMUELSON.
11 MOTION IS BY ART TORRES. COMMENT? SOUNDS LIKE AN
12 INDIVIDUAL WE'RE VERY FORTUNATE TO HAVE.

13 MS. LANSING: JUST TO SAY THAT BERNIE LO
14 AND I WERE VERY, VERY EXCITED ABOUT THIS INDIVIDUAL.
15 AND EVEN THOUGH NO ONE CAN REPLACE ALTA, WE FEEL WE
16 HAVE A VERY GOOD PERSON.

17 CHAIRMAN KLEIN: THANK YOU VERY MUCH,
18 SHERRY LANSING.

19 DR. PIZZO: THAT'S MY FORMER HOME BEFORE I
20 CAME TO CALIFORNIA. GREAT INSTITUTION.

21 CHAIRMAN KLEIN: PUBLIC COMMENT? ALL IN
22 FAVOR? OPPOSED? ABSTENTIONS? MOTION PASSES.
23 THANK YOU, GEOFF LOMAX, FOR YOUR TREMENDOUS WORK, AS
24 ALWAYS.

25 AND, GEOFF, I KNOW YOU HAVE TO MAKE A

BARRISTERS' REPORTING SERVICE

1 PLANE. AND SO YOUR COMMENTS ON COMPLIANCE ARE VERY
2 IMPORTANT. AND IF YOU COULD SUBMIT THOSE IN WRITING
3 SO THAT THE PUBLIC CAN HAVE THOSE COMMENTS IN
4 ADDITION TO THE BOARD, AND WE WILL REVISIT THAT ITEM
5 IN DECEMBER.

6 DR. LOMAX: LOOK FORWARD TO IT. THANK YOU
7 VERY MUCH, MR. CHAIRMAN. THANK YOU, MEMBERS OF THE
8 BOARD.

9 MS. LANSING: THANKS, GEOFF.

10 CHAIRMAN KLEIN: WE HAVE AN ITEM NO. 18,
11 WHICH IS A VERY IMPORTANT ITEM TO OUR BRIDGES
12 PROGRAM. I'D LIKE DR. YAFFE TO MAKE THAT
13 PRESENTATION.

14 DR. YAFFE: MR. CHAIRMAN, MEMBERS OF THE
15 BOARD, I BRING TO YOU FOR YOUR CONSIDERATION TRAVEL
16 SUPPLEMENTS FOR THE BRIDGES TO STEM CELL RESEARCH
17 AWARDS. THIS WAS RFA 08-104. THE PURPOSE OF THIS
18 SUPPLEMENT IS TO SUPPORT TRAINEE TRAVEL TO AN ANNUAL
19 CIRM-SPONSORED BRIDGES AWARDS TRAINING MEETING. WE
20 DID NOT INCLUDE REQUESTS FOR THESE FUNDS IN THE
21 ORIGINAL AWARD.

22 IMPORTANCE OF THIS WILL BE THAT THE
23 TRAINEES WILL BE BROUGHT TOGETHER WITH PROGRAM
24 DIRECTORS AND SOME OF THE INTERN HOSTS FOR A TIME TO
25 LEARN ABOUT EACH OTHER'S WORK, SHARE COMMON

BARRISTERS' REPORTING SERVICE

1 PRACTICE, AND GENERALLY TO HAVE AN ACTIVITY THAT
2 SUPPORTS AND COMPLEMENTS THE INTERNSHIPS AND OTHER
3 TRAINING ACTIVITIES.

4 THE FUNDS WILL BE USED ONLY TOWARD PAYING
5 ACTUAL TRAVEL COSTS FOR TRAINEES FOR TRAVEL AND
6 LODGING TO THE ANNUAL MEETING. FUNDS REQUESTED ARE
7 UP TO \$750 PER TRAINEE PER YEAR.

8 THESE ARE THE GRANTS THAT WERE AWARDED
9 PREVIOUSLY BY YOU. THE SAME AMOUNT OF MONEY EXCEPT
10 FOR ONE GRANT THAT HAS A REDUCED AMOUNT BECAUSE THEY
11 HAVE FEWER TRAINEES IN THE FIRST YEAR. THE TOTAL IS
12 \$243,000.

13 SO VERY BRIEFLY, IN SUMMARY, THE FUNDS
14 REQUESTED TO SUPPORT TRAVEL COSTS FOR TRAINEES IN
15 THE CIRM BRIDGES TO STEM CELL RESEARCH AWARDS
16 PROGRAM TO ATTEND ANNUAL CIRM-SPONSORED BRIDGES
17 TRAINING MEETING, TOTAL REQUEST HERE IS \$243,000.
18 THIS IS RELATIVE TO THE 17.5 MILLION THAT YOU
19 ALLOCATED TO THIS PROGRAM, AND WE CERTAINLY ENSURE
20 OUR TRAINEES HAVE THE OPPORTUNITY TO COME TO THIS
21 WHAT WE THINK IS A VERY VALUABLE EXPERIENCE.

22 CHAIRMAN KLEIN: BEFORE DISCUSSION, I WANT
23 TO POINT OUT THE SIGNIFICANT CONFLICTS BECAUSE OF
24 THE RELATED INSTITUTIONS. MR. HARRISON, COULD YOU
25 STATE THE CONFLICTS?

BARRISTERS' REPORTING SERVICE

1 MR. HARRISON: IT MIGHT BE EASIER FOR ME
2 TO STATE WHO CAN PARTICIPATE IN THE DISCUSSION.
3 AND, AGAIN, THIS IS A VERY INDIRECT CONFLICT BECAUSE
4 THE INSTITUTIONS THAT ARE RECEIVING THESE FUNDS ARE
5 NOT INSTITUTIONS THAT EMPLOY MEMBERS ON THIS BOARD,
6 BUT BECAUSE THERE ARE RELATIONSHIPS BETWEEN THOSE
7 INSTITUTIONS AND THE INSTITUTIONS TO WHICH THE
8 BRIDGES AWARDS WERE MADE. WE'RE BEING VERY CAREFUL.

9 SO THE FOLLOWING MEMBERS CAN PARTICIPATE
10 IN THIS DISCUSSION: AZZIZ, GIBBONS, KLEIN, LEVEY,
11 LOVE, QUINT, ROTH, SAMUELSON, SERRANO-SEWELL,
12 SHESTACK, AND TORRES.

13 CHAIRMAN KLEIN: ARE YOU SURE AZZIZ CAN
14 PARTICIPATE?

15 MR. HARRISON: DAFOE, I'M SORRY.

16 CHAIRMAN KLEIN: DAFOE. UCLA
17 RELATIONSHIP. CEDARS, HE'S AT CEDARS, BUT HE HAS AN
18 ASSOCIATION WITH UCLA FROM CEDARS.

19 DR. DAFOE: I HAVE AN ACADEMIC
20 APPOINTMENT.

21 MR. HARRISON: I BELIEVE DR. LEVEY CAN
22 PARTICIPATE AS WELL.

23 DR. PIZZO: BOTH DR. LEVEY AND DR. DAFOE
24 ARE LOOKING BLANK ON THIS ONE. JERRY --

25 CHAIRMAN KLEIN: UCLA IS NOT ONE OF THE

BARRISTERS' REPORTING SERVICE

1 COLLABORATING INSTITUTIONS IN THE BRIDGES PROGRAM;
2 IS THAT CORRECT? THAT'S NOT THE WAY I REMEMBER.

3 MR. HARRISON: WE WILL DOUBLE-CHECK IT,
4 BUT BASED ON OUR RECORDS, IT WAS NOT ONE OF THE
5 APPROVED PROGRAMS.

6 DR. PIZZO: SINCE HE'S NOT HERE, LET'S NOT
7 ASK HIM.

8 CHAIRMAN KLEIN: OUT OF CAUTION, I WOULD
9 ASK THAT WE NOT VOTE UNTIL WE DO THE RESEARCH,
10 PLEASE.

11 SO ANY DISCUSSION AMONG THOSE WHO CAN MAKE
12 COMMENTS?

13 DR. LOVE: SOUNDS LIKE A GREAT IDEA, AN
14 IMPORTANT THING TO DO.

15 CHAIRMAN KLEIN: I THINK HISTORICALLY
16 WE'VE SEEN A TREMENDOUS VALUE BY THE SYNERGY OF
17 HAVING THESE INDIVIDUALS GO TO THE GRANT MEETING AND
18 BE INSPIRED BY THE MORE SENIOR SCIENTISTS AND THEIR
19 PROJECTS. IT IS SOMETHING THAT REALLY CAN HELP THEM
20 MAKE A DECISION ABOUT DEDICATING THEMSELVES TO THIS
21 AS A CAREER OR, IN FACT, IN THE CASE OF SOME OF
22 THESE THAT ARE MASTERS PROGRAM SEEKING A PH.D. DOING
23 FURTHER WORK IN THE FIELD.

24 MR. ROTH: SO I'D LIKE TO MAKE A MOTION TO
25 APPROVE.

BARRISTERS' REPORTING SERVICE

1 CHAIRMAN KLEIN: IS THERE A SECOND?

2 DR. LOVE: SECOND.

3 CHAIRMAN KLEIN: SECOND BY DR. LOVE. SO I
4 THINK WE CAN CARRY THIS WITHOUT THOSE VOTES. IF
5 THERE'S ANY CONCERN, I WOULD RATHER NOT HAVE THOSE
6 VOTES UNLESS SOMEONE FEELS REALLY COMPELLED TO VOTE.
7 SO IF WE COULD READ THE ROLL CALL WITHOUT THOSE TWO
8 VOTES, PLEASE.

9 MS. KING: THIS IS THE ROLL CALL OF THE
10 PEOPLE WHO CAN --

11 CHAIRMAN KLEIN: CAN PARTICIPATE, YES.

12 MS. KING: LEEZA GIBBONS.

13 MS. GIBBONS: YES.

14 MS. KING: BOB KLEIN.

15 CHAIRMAN KLEIN: YES.

16 MS. KING: TED LOVE.

17 DR. LOVE: YES.

18 MS. KING: ROBERT QUINT.

19 DR. QUINT: YES.

20 MS. KING: JOAN SAMUELSON.

21 MS. SAMUELSON: YES.

22 MS. KING: DAVID SERRANO-SEWELL.

23 MR. SERRANO-SEWELL: YES.

24 MS. KING: ART TORRES.

25 MR. TORRES: AYE.

BARRISTERS' REPORTING SERVICE

1 MS. KING: THERE ARE NO MORE VOTES TO BE
2 TAKEN. IF THAT'S THE LIST, THE MOTION CARRIES.

3 CHAIRMAN KLEIN: OKAY. ALL RIGHT. I
4 APPRECIATE TAKING A MORE CAUTIOUS APPROACH.

5 I WOULD LIKE TO FOCUS ON A VERY IMPORTANT
6 TOPIC HERE THAT WAS --

7 MS. KING: DUANE ROTH, CAN YOU VOTE ON
8 THAT?

9 MR. ROTH: I VOTE YES.

10 CHAIRMAN KLEIN: I WOULD LIKE TO FOCUS ON
11 A VERY IMPORTANT TOPIC HERE THAT WAS PART OF THE
12 CHAIRMAN'S REPORT THAT I DEFERRED BECAUSE OF THE
13 CRITICAL NATURE OF GETTING THROUGH ITEMS THAT NEEDED
14 A QUORUM, BUT IT IS OF SIGNIFICANT IMPORTANCE TO US.
15 I'D LIKE OUR OWN SENATOR TORRES, OUR VICE CHAIR, TO
16 LOOK AT THE RISKS IN THE INITIATIVE AND LEGISLATIVE
17 CALENDAR THAT ARE COMING UP IN NEXT YEAR AND GIVE US
18 A HEADS-UP ON THOSE ISSUES.

19 MR. TORRES: THANK YOU VERY MUCH, MR.
20 CHAIRMAN. I'M SORRY DUANE IS LEAVING. I WANTED TO
21 THANK HIM FOR THE WORK HE DID ON BIOSIMILARS IN
22 WASHINGTON THIS PAST MONTH ON LEGISLATION. AND ALSO
23 TO THANK RETIRED CONGRESSMEMBER THOMAS HERMSDORFER
24 FROM GERMANY, WHO IS A VERY DEAR FRIEND OF MINE AND
25 HELPED US GET THROUGH THE GERMAN-CIRM AGREEMENT WITH

BARRISTERS' REPORTING SERVICE

1 HIS INPUT, AND ALSO TO PAT BECKER WHO HELPED
2 TREMENDOUSLY ON THE DREW UNIVERSITY MEETING THAT WE
3 HAD YESTERDAY, WHICH WAS VERY SUCCESSFUL. AGAIN,
4 KUDOS TO ALAN AND BOB TODAY ON THAT PRESS
5 CONFERENCE, WHICH I THOUGHT WAS VERY, VERY
6 IMPRESSIVE IN TERMS WHAT WE WERE DOING.

7 I'M GOING TO BE VERY QUICK BECAUSE I'M
8 GOING TO SEND YOU EACH AN E-MAIL TO AVOID THE
9 DESTRUCTION OF TREES BECAUSE IT'S A VERY LENGTHY
10 E-MAIL.

11 WE ARE IN SERIOUS JEOPARDY WITH THE
12 INITIATIVES THAT ARE NOW BEING CIRCULATED TO BE
13 PLACED ON THE JUNE OR NOVEMBER BALLOT OF 2010. THE
14 FIRST ONE IS CALLED PERSONHOOD INITIATIVE, WHICH IS
15 NOW PENDING IN THE AG'S OFFICE FOR TITLE AND SUMMARY
16 TO BE CIRCULATED. I KNOW JAMES PROVIDED ME A MEMO
17 ON THAT ISSUE. BASICALLY, IF PASSED, THIS
18 INITIATIVE WOULD READ: THE TERM "PERSON" APPLIES TO
19 ALL LIVING HUMAN ORGANISMS FROM THE BEGINNING OF
20 THEIR BIOLOGICAL DEVELOPMENT REGARDLESS OF THE MEANS
21 BY WHICH THEY WERE PROCREATED, METHOD OF
22 REPRODUCTION, AGE, RACE, SEX, GENDER, PHYSICAL
23 WELL-BEING, FUNCTION OR CONDITION OF PHYSICAL OR
24 MENTAL DEPENDENCY, AND/OR DISABILITY.

25 IT'S CALLED THE CALIFORNIA HUMAN RIGHTS

BARRISTERS' REPORTING SERVICE

1 AMENDMENT. AND IT WILL BE CIRCULATED SHORTLY, MY
2 FRIENDS.

3 THE SECOND ISSUE, OF COURSE, IS AN
4 INITIATIVE THAT WAS WITHDRAWN, BUT NOW THE SECRETARY
5 OF STATE JUST INFORMED ME TODAY THAT IT WAS
6 SUBMITTED AGAIN OCTOBER 23D TO CREATE A TOBACCO
7 CANCER COMMISSION IN CALIFORNIA. AND READING THE
8 INITIATIVE, AS I JUST DID MOMENTS AGO, IT'S VERY
9 SIMILAR TO CIRM. AND IT WOULD APPLY 50 CENTS TAX ON
10 EVERY CIGARETTE SOLD IN CALIFORNIA. AND THAT MONEY
11 WOULD BE DEPOSITED IN A FUND WHICH WOULD BE CALLED
12 THE CALIFORNIA CANCER RESEARCH ACT, AND IT WOULD
13 DISTRIBUTE GRANTS TO ALL TOBACCO-RELATED DISEASES
14 THAT ARE CAUSED BY TOBACCO, 60 PERCENT, INTO THEIR
15 2010 RESEARCH FUND FOR THE PURPOSE OF GRANTS AND
16 LOANS TO SUPPORT RESEARCH IN EARLY DETECTION
17 TREATMENTS, COMPLEMENTARY TREATMENTS, CURES OF LUNG
18 CANCER AND OTHER TYPES OF CANCER, CARDIOVASCULAR
19 DISEASE, EMPHYSEMA.

20 I DON'T KNOW WHO'S REALLY GOING TO FUND
21 THIS CAMPAIGN. THE LAWYER HAS NOT RETURNED MY CALL
22 AS OF YET. THERE'S NOTHING LIKE AN EX-CHAIRMAN THAT
23 USED TO BE IN MY LAW FIRM, THE LANCE OLSON FIRM IN
24 SACRAMENTO, BUT THAT'S GOING TO BE -- HAS BEEN
25 RESUBMITTED TO THE SECRETARY OF STATE AGAIN. COULD

BARRISTERS' REPORTING SERVICE

1 VERY WELL IMPACT US. PARENTAL CONSENT --

2 MS. LANSING: CAN I ASK A QUESTION ABOUT
3 THAT? I HONESTLY DON'T KNOW ABOUT IT. I FEEL I
4 MUST ASK THE QUESTION. SO THE INITIATIVE THAT
5 THEY' RE PUTTING PUTS 50 PERCENT TAX.

6 MR. TORRES: FIFTY CENTS.

7 MS. LANSING: FIFTY-CENT TAX ON CIGARETTES
8 THAT BASICALLY GOES INTO CANCER AWARENESS,
9 PREVENTION, AND RESEARCH.

10 MR. TORRES: CORRECT.

11 MS. LANSING: AGAIN, WHY IS THAT A
12 CONFLICT WITH US?

13 MR. TORRES: NO. NO. I JUST WANTED YOU
14 TO BE AWARE OF IT.

15 MS. LANSING: AM I WRONG? IS THAT A
16 PROBLEM FOR US?

17 DR. PRIETO: I THINK THE DEVIL IS IN THE
18 DETAILS, BUT I DON'T SEE A CONFLICT. I DON'T THINK
19 IT WOULD BE JUST CANCER IF IT'S TOBACCO RELATED.

20 MS. LANSING: IT'S EMPHYSEMA, IT'S
21 EVERYTHING. SO THAT --

22 MR. TORRES: IT'S NOT A CONFLICT.

23 MS. LANSING: -- SOUNDS VERY MUCH LIKE
24 CIRM. I'M CONFUSED.

25 MR. TORRES: BECAUSE IT IS CREATED ON THE

BARRISTERS' REPORTING SERVICE

1 MODEL OF CIRM AS AN AGENCY. IT WILL BECOME A STATE
2 AGENCY ACCORDING TO THIS INITIATIVE MODELED
3 BASICALLY ON OUR FORMULA.

4 MS. LANSING: BUT --

5 MR. TORRES: THERE'S NOTHING WRONG WITH
6 THAT. I JUST WANTED YOU TO BE AWARE OF IT.

7 MS. LANSING: BUT THE PERSONHOOD ONE IS
8 QUITE DIFFERENT.

9 MR. SERRANO-SEWELL: SHERRY, I THINK THAT
10 THE VICE CHAIRMAN WAS SPEAKING TO THE FIRST
11 INITIATIVE AND NOT BOTH.

12 MS. LANSING: THANK YOU FOR THE
13 CORRECTION.

14 MR. TORRES: NOW, INITIATIVE WHICH WILL
15 HAVE AN IMPACT ON US IS THIS CONSTITUTIONAL
16 CONVENTION INITIATIVE. AND IT WOULD REQUIRE THREE
17 SEPARATE STATE ELECTIONS AT A COST OF ABOUT 75
18 MILLION PER ELECTION TO CREATE A CONSTITUTIONAL
19 CONVENTION TO REVISE THE CONSTITUTION OF CALIFORNIA.
20 THAT'S US.

21 SO IT WOULD REQUIRE A FIRST STEP TO HAVE A
22 CONSTITUTIONAL CONVENTION, THEN A SECOND ELECTION TO
23 ELECT THE 400 CONVENTION DELEGATES WHO CANNOT BE
24 COMMUNICATED WITH, NOR THEIR NAMES RELEASED UNTIL
25 THE ELECTION WERE OVER. AND NO. 3, IF THAT WERE TO

BARRISTERS' REPORTING SERVICE

1 BE APPROVED BY THE VOTERS, THE TAXPAYERS WOULD HAVE
2 TO USE PUBLIC MONEY FOR THE CAMPAIGN FINANCING OF
3 ALL CONVENTION DELEGATE CANDIDATES.

4 I KNOW THERE'S A TENDENCY OUT THERE WE NEED A
5 CONSTITUTIONAL CONVENTION TO RESOLVE ALL THESE OTHER
6 ISSUES. LET'S BE VERY CLEAR ABOUT WHAT A
7 CONSTITUTIONAL CONVENTION WOULD DO IN CALIFORNIA.
8 IT WOULD AFFECT ANYTHING THAT'S IN THE STATE
9 CONSTITUTION AS IT'S CURRENTLY CONSTITUTED.

10 THE OTHER INITIATIVES ON THE BALLOT THAT
11 WOULD HAVE SORT OF AN IMPACT OBVIOUSLY IS THE
12 PART-TIME LEGISLATURE. THAT MIGHT BE GOOD FOR US.
13 I DON'T KNOW. THAT'S ALSO GOING TO BE CIRCULATED ON
14 THE BALLOT AS WELL AS A CHANGE IN THE TERM LIMITS
15 AND ALSO THE REQUIREMENT ON THE BUDGET, WHICH GEORGE
16 LAYKOFF, WHO'S A PROFESSOR AT BERKELEY AND OTHERS,
17 IN FACT, SOMEONE BY THE NAME OF JAMES HARRISON IS
18 ALSO WORKING ON AN INITIATIVE TO REDUCE THE
19 THRESHOLD FOR PASSING OF OUR STATE BUDGET, WHICH
20 WOULD CONCEIVABLY BE ON THE BALLOT.

21 ALSO, LASTLY, THIS DOES NOT AFFECT US, BUT
22 THERE'S ALSO AN INITIATIVE TO ALLOW THE LISTENING
23 AND PERFORMING OF CHRISTMAS MUSIC DURING THE HOLIDAY
24 SEASON IN OUR CALIFORNIA CLASSROOMS. ALSO
25 INITIATIVE WOULD MAKE THE BIBLE'S CONTENT AS

BARRISTERS' REPORTING SERVICE

1 AUTHORITY FOR ALL OF CALIFORNIA TO SECURE AND
2 PERPETUATE THE BLESSINGS OF ALMIGHTY GOD FOR THE
3 PEOPLE OF CALIFORNIA. I WANT GOD'S BLESSING, THAT'S
4 FOR SURE.

5 BUT THE MOST IMPORTANT ONE FOR THOSE OF US
6 THAT ARE CHRONOLOGICALLY GIFTED, THERE IS AN
7 INITIATIVE BEING CIRCULATED TODAY IN CALIFORNIA THAT
8 WOULD REMOVE ALL STATE OR PROPERTY TAXES ON
9 RESIDENTS 55 OR OVER. I'M SIGNING THAT ONE.

10 (SIMULTANEOUS DISCUSSION.)

11 CHAIRMAN KLEIN: JUST THREE POINTS ON THIS
12 SUMMARY PRESENTATION. FIRST OF ALL, TO THE EXTENT
13 THAT WE ARE WELL REPRESENTED IN THE LEGISLATURE,
14 IT'S BY INDIVIDUALS WHO HAVE COMMITTED THEMSELVES
15 FULL TIME AND HAVE REALLY STUDIED WHAT WE'RE DOING.
16 IT'S TAKEN US A LONG TIME TO BUILD UP THAT KNOWLEDGE
17 AND SUPPORT. AND A PART-TIME LEGISLATURE HAS A
18 DEFINITE RISK FOR US IN PEOPLE WORKING AT THE
19 PERIPHERY OF UNDERSTANDING OF WHAT WE ARE ABOUT.

20 A SEPARATE ITEM IS THE 50-PERCENT VOTE, I
21 BELIEVE, IS ALSO JOINED WITH THE PROVISION, ART,
22 THAT IF THE LEGISLATORS DON'T PASS A BUDGET BY A
23 SPECIFIC DATE, THEY LOSE THEIR SALARIES UNTIL IT IS
24 PASSED; IS THAT CORRECT?

25 MR. TORRES: YES.

BARRISTERS' REPORTING SERVICE

1 CHAIRMAN KLEIN: AND THAT MAKES IT A VERY
2 POPULAR PROPOSAL POTENTIALLY. BUT THAT WOULD REALLY
3 HELP CREATE A STABLE, REGULAR BUDGET PROCESS FOR US
4 TO HAVE A 50-PERCENT VOTE.

5 THE THIRD ITEM IS THAT THE INITIATIVE ON
6 PERSONHOOD, THE GOAL BY THE CIRCULATORS, ONE WOULD
7 GUESS STRATEGICALLY IS TO GET IT OUT BY THANKSGIVING
8 SO IN THANKSGIVING AND CHRISTMAS SEASON IN THE
9 CHURCHES, THE INITIATIVE SIGNATURES ARE GATHERED.
10 SO IT IS VERY IMPORTANT THAT GOVERNMENT RELATIONS
11 OFFICERS WITH THE VARIOUS INSTITUTIONS BE AWARE OF
12 THIS, BE AWARE OF ITS SIGNIFICANCE TO RESEARCH. AND
13 WE HAVE SOME GENERAL INFORMATION THAT GOES OUT WHICH
14 IS MERELY INFORMATIVE, NOT SUGGESTING A PARTICULAR
15 POSITION. LET EVERYONE MAKE THEIR DECISION ON THE
16 THEIR POSITION, BUT THE PUBLIC NEEDS TO BE INFORMED
17 OF THE IMPLICATIONS OF THIS FOR THE MISSION.

18 MR. TORRES: LASTLY, I JUST WANT TO SAY
19 THANK YOU TO THE GOVERNOR OF THIS STATE, TO THE
20 DEPARTMENT OF FINANCE, AND TREASURER LOCKYEAR.
21 THOSE THREE OFFICES HAVE JUST BEEN ABSOLUTELY
22 INCREDIBLE FOR US. AND THE COOPERATIVE SPIRIT BY
23 THE GOVERNOR, THE TREASURER, AND THE DEPARTMENT OF
24 FINANCE, WE OWE THEM A GREAT DEBT OF GRATITUDE.

25 (APPLAUSE.)

BARRISTERS' REPORTING SERVICE

1 CHAIRMAN KLEIN: SO WE HAVE TWO MORE ITEMS
2 THAT I'M AWARE OF, BUT I DO NOT BELIEVE THEY REQUIRE
3 A VOTE, BUT I WANT TO BE CLEAR ABOUT THIS. FIRST OF
4 ALL, ITEM 19 IS REPORT ON THE RESULTS OF THE SURVEY
5 OF THE GRANTS WORKING GROUP. AND ITEM 15 IS
6 CONSIDERATION OF THE UPDATE TO THE STRATEGIC PLAN.
7 DOES THAT REQUIRE A VOTE TODAY?

8 DR. TROUNSON: I UNDERSTOOD IT DOES,
9 CHAIR. IT'S HERE FOR APPROVAL.

10 CHAIRMAN KLEIN: WE CERTAINLY -- LET ME
11 ASK. WHAT IS OUR STATUS ON QUORUM?

12 MS. KING: WE STILL HAVE A QUORUM EVEN IF
13 DR. PULIAFITO -- SINCE MICHAEL GOLDBERG IS BACK,
14 WE'RE FINE.

15 MS. LANSING: WE'VE ALL READ IT, SO MAYBE
16 WE CAN JUST HAVE QUESTIONS.

17 CHAIRMAN KLEIN: SHERRY LANSING HAS
18 SUGGESTED THAT SINCE WE'VE ALL READ IT, MAYBE WE
19 COULD ADDRESS QUESTIONS. IS THAT ACCEPTABLE, DR.
20 TROUNSON?

21 DR. TROUNSON: SURE.

22 CHAIRMAN KLEIN: WOULD YOU LIKE TO TAKE
23 THE PODIUM? IT'S BETTER THERE. SO ARE THERE
24 QUESTIONS ON THE STRATEGIC PLAN AS PRESENTED, OR ARE
25 THERE MEMBERS THAT WOULD LIKE TO GO THROUGH ANY

BARRISTERS' REPORTING SERVICE

1 PARTICULAR SECTION OF THE STRATEGIC PLAN UPDATE AT
2 THIS TIME?

3 MS. SAMUELSON: MR. CHAIRMAN, I WOULD LOVE
4 TO DO THAT. AND AFTER THE GRANTS PROCESS RAISED
5 SEVERAL MORE THAT I WROTE DOWN AS WE WERE PROCEEDING
6 THROUGH ALL OF THOSE VOTES, I DON'T FEEL CAPABLE NOW
7 OF GIVING IT THE ATTENTION AND DEPTH OF THOUGHT THAT
8 I THINK IT DESERVES. AND I WOULD REALLY LIKE TO
9 ADDRESS THAT AT THE NEXT MEETING WHETHER OR NOT WE
10 COVER PART OF IT NOW AND ANSWER QUESTIONS OR NOT.

11 CHAIRMAN KLEIN: SO THERE'S BEEN A REQUEST
12 THAT WE GO THROUGH THE KEY SECTIONS IN THE STRATEGIC
13 PLAN. DR. TROUNSON, DO YOU HAVE SLIDES THAT ADDRESS
14 IT?

15 DR. TROUNSON: WE WENT THROUGH THIS LAST
16 TIME. THAT'S PART OF THE PROBLEM. I HAVE ONE
17 SLIDE. WE TOOK THE COMMENTS FROM THE BOARD LAST
18 TIME, AND WE MADE ADJUSTMENTS TO THE PLAN ON THE
19 COMMENTS. SO WE'RE REALLY GIVING YOU THE FINAL.

20 I GUESS THE PRIMARY COMPONENTS OF THIS
21 PLAN ARE TO REVIEW THE PRIORITIES AND ASSESS
22 PROGRESS, AND SO WE'VE DONE THAT WITHIN THE PLAN.
23 INCREASE THE TRANSLATIONAL PIPELINE TO THE CLINIC,
24 AND TODAY IS PART OF -- THAT PART OF THE PROCESS.
25 WE'RE ACTUALLY MOVING MORE AGGRESSIVELY TOWARDS THE

BARRISTERS' REPORTING SERVICE

1 TRANSLATIONAL PIPELINE COMPONENT. REORGANIZE TO
2 BETTER CHAPERONE THE APPLICATION OF THERAPEUTIC BASE
3 STEM CELLS, SO THAT REALLY REFERS PARTICULARLY TO
4 APPOINTMENT OF A VP R & D AND SUPPORT STAFF TO
5 ACTUALLY MONITOR AND ASSIST IN THE TRANSLATIONAL AND
6 EARLY CLINICAL PHASES OF OUR PROGRAMS.

7 CREATING GLOBAL SCIENCE PARTNERSHIP TO
8 LEVERAGE BOND FUNDS AND ENHANCE DELIVERY OF THE
9 MISSION. THIS IS MUCH LARGER THAN WAS EVER
10 ENVISAGED IN THE ORIGINAL PLAN. WE'RE NEARING
11 ALMOST SATURATION POINT, I THINK, OF THAT. WE'RE
12 JUST COLLECTING A NUMBER OF THE STATES WHO ARE
13 RELEVANT TO THE RESEARCHERS CURRENTLY. THERE ARE A
14 FEW OUTSTANDING COUNTRIES THAT WE'RE STILL HAVING
15 DISCUSSIONS WITH THAT INCLUDES ISRAEL, INDIA,
16 SWEDEN, FOR EXAMPLE.

17 ENGAGING THE CAPACITY TO ADDRESS MAJOR
18 ROADBLOCKS, FOR EXAMPLE, GET INTO TRANSPLANTATION
19 IMMUNOLOGY IN A VERY SERIOUS WAY BECAUSE WE FEEL
20 THAT IS A MAJOR ROADBLOCK THAT WE YET HAVEN'T
21 OVERCOME IN AN ACCEPTABLE WAY BECAUSE THE PATIENTS
22 HAVE TO BE IMMUNE SUPPRESSED ESSENTIALLY IF THEY'RE
23 GOING TO HAVE CELL THERAPIES THAT ARE NOT CELLS FROM
24 THEMSELVES. WE DON'T KNOW THE CAPACITY OF IPS CELLS
25 TO BE THERAPEUTICALLY AVAILBLE AT THIS POINT.

BARRISTERS' REPORTING SERVICE

1 AND ENGAGING BIOTECHNOLOGY, PHARMA
2 INVESTMENT SECTORS AS SIGNIFICANT PARTNERS. WE
3 BELIEVE THAT ONCE WE'RE IN THIS PIPELINE, IT IS
4 ESSENTIAL TO HAVE SIGNIFICANT PARTNERSHIPS WITH THE
5 BIOTECHNOLOGY INDUSTRY AND WITH THE PHARMACEUTICAL
6 INDUSTRY, BOTH OF WHOM HAVE EXPRESSED STRONG
7 INTEREST AND YET FEEL THAT WE HAVE NOT BEEN ABLE TO
8 CONSUMMATE OUR RELATIONSHIPS IN THIS RESPECT TO THE
9 LEVEL THAT'S REALLY REQUIRED IF WE'RE GOING TO
10 ENABLE THAT PIPELINE TO FUNCTION.

11 SO THEY'RE THE PRIMARY ASPECTS OF THE
12 REVISION OF THE PLAN THAT CONCENTRATE ON THOSE
13 MATTERS, A RECONCENTRATION, IF YOU LIKE.

14 CHAIRMAN KLEIN: ALL RIGHT.

15 MS. LANSING: I'D LIKE TO MOVE ADOPTION OF
16 THE PLAN.

17 CHAIRMAN KLEIN: SHERRY LANSING WOULD LIKE
18 TO MOVE ADOPTION OF THE PLAN. IS THERE A SECOND?

19 MR. GOLDBERG: SECOND.

20 CHAIRMAN KLEIN: SECOND BY MICHAEL
21 GOLDBERG. ADDITIONAL DISCUSSION BY THE MEMBERS?

22 MR. GOLDBERG: I JUST WANT TO CONGRATULATE
23 YOU, ALAN, AND YOUR ENTIRE TEAM. IT'S A GREAT
24 DOCUMENT.

25 MS. LANSING: SECOND THAT.

BARRISTERS' REPORTING SERVICE

1 CHAIRMAN KLEIN: OKAY. I THINK, JOAN, THE
2 POSITION OF THE BOARD MEMBERS IS THAT BECAUSE
3 THEY'VE SEEN THIS AT SEVERAL MEETINGS, THEY'RE --

4 MS. LANSING: CAN I MAKE A SUGGESTION IN
5 RESPECT TO MY COLLEAGUE, JOAN, WHO DESERVES THE
6 TIME. I THINK WE HAVE A QUORUM. PERHAPS, ALAN, YOU
7 AND JOAN COULD MEET AND YOU COULD GO THROUGH IT IN
8 MORE DETAIL IF THAT WOULD MAKE YOU COMFORTABLE.

9 MS. SAMUELSON: I'D LOVE THAT. I THINK WE
10 ALSO NEED, AS A BOARD, TO FOCUS ON THE STRATEGIC
11 PLAN AND WHAT IT IS. I THINK WE NOW HAVE A VERY
12 COMPREHENSIVE, MAYBE COMPLETELY COMPREHENSIVE, FOR
13 ALL I KNOW, LIST OF TODOS, BUT I DON'T SEE IT AS A
14 STRATEGIC PLAN. I DON'T SEE IT AS A CLEAR GOAL WITH
15 MEANS FOR HOW TO GET THERE THAT TELL US HOW OUR
16 FUNDING PORTFOLIO IS GETTING US THERE AND HOW EACH
17 PIECE OF IT, WHAT THE ROLE OF EACH PIECE OF IT IS IN
18 THAT PROCESS, AND WHAT WE THINK WE'RE GOING TO
19 ACCOMPLISH WHEN. I DON'T THINK WE HAVE ANYTHING
20 LIKE THAT, MY UNDERSTANDING OF WHAT A STRATEGIC PLAN
21 SHOULD BE.

22 AND MAYBE WE HAVE IT IN SOME OTHER FORM
23 THAT I'M JUST NOT SUFFICIENTLY APPRECIATIVE OF. BUT
24 AS WE WERE DEBATING THE GRANTS, I FELT THE ABSENCE
25 OF THAT IN THE DISCUSSION. AND I THINK IT WOULD

BARRISTERS' REPORTING SERVICE

1 BEHOOVE US TO HAVE A SESSION WHERE WE FOCUS ON IT.
2 AND THAT'S NOT TO SAY THIS WORK ISN'T VALUABLE TO
3 US, BUT I THINK WE HAVE TO DO THAT.

4 CHAIRMAN KLEIN: MAYBE I COULD ASK THIS
5 QUESTION.

6 DR. TROUNSON: WE'VE HAD SEVERAL -- A
7 NUMBER OF PUBLIC MEETINGS, BOTH WITH THE COMMUNITY
8 AND THE INDUSTRY. WE'VE HAD A LOT OF SESSIONS HERE.
9 WE HAVE TO HAVE A REVIEW NEXT YEAR BY AN INDEPENDENT
10 GROUP OF SCIENTISTS TO RESHAPE THE STRATEGIC PLAN.
11 SO THIS WAS A REVISION TO THE CURRENT ONE SINCE WE
12 HAD HAD SUCH A LOT OF CHANGES TO THE KEY STAFF. SO
13 YOU ARE GETTING A FLAVOR, IF YOU LIKE, OF MY
14 PRESIDENCY COMING IN.

15 I THINK WE'RE IN A BETTER POSITION NOW TO
16 KNOW WHAT WE'RE LOOKING FOR IN AN EXAMINATION BY AN
17 INDEPENDENT GROUP OF PEOPLE ABOUT OUR STRATEGIC PLAN
18 THAT'S SCHEDULED FOR NEXT YEAR.

19 CHAIRMAN KLEIN: SO LET ME --

20 MS. SAMUELSON: THEN MAYBE WE'RE ALL ON
21 THE SAME PAGE BECAUSE THAT SOUNDS GREAT. WE'RE NOT
22 ASSUMING THAT THIS IS, AS IT'S STATED NOW, THE FINAL
23 DOCUMENT FOR SOME SIGNIFICANT AMOUNT OF TIME.

24 CHAIRMAN KLEIN: JOAN, WE'RE CHARGED WITH
25 UPDATING THIS. THE PRESIDENT HAS PUT A GREAT DEAL

BARRISTERS' REPORTING SERVICE

1 OF EFFORT WITH THE STAFF INTO IT. THEY'VE GONE
2 THROUGH A NUMBER OF PUBLIC HEARINGS. THIS IS AN
3 ORGANIC DOCUMENT, CONTINUES TO EVOLVE. AND I THINK
4 THAT'S THE KEY YOU'RE NOW FOCUSED ON IS THAT IN
5 ADOPTING THIS, THERE IS SCHEDULED REVIEW COMING UP.
6 AND IN THAT MOVING TOWARDS THAT SCHEDULED REVIEW, I
7 THINK YOU'RE FOCUSED ON WHEN DO WE FUND CLINICAL
8 TRIALS? IS IT EARLIER THAN WE THOUGHT? THOSE TYPES
9 OF QUESTIONS DON'T END TODAY. THEY ARE ORGANIC AND
10 CONTINUE.

11 SO EACH TIME THE PRESIDENT IS TRYING TO
12 GET A SNAPSHOT IN TIME AND GIVE US AN UPDATE AND
13 GIVE AN UPDATE TO THE OUTSIDE WORLD THAT THEY CAN
14 COMPREHENSIVELY UNDERSTAND WHERE WE ARE. BUT THE
15 STRATEGIC ISSUES WILL CONTINUE TO BE ON THE AGENDA
16 TO ADDRESS OPPORTUNITIES THAT ARISE AS WE DEVELOP
17 THIS PIPELINE. I THINK IT WOULD BE VALUABLE TO
18 ADOPT THIS STRATEGIC PLAN AND REALIZE THAT WE'RE
19 GOING TO CONTINUE IN AN ORGANIC FASHION TO GROW AS
20 WE MOVE FORWARD. DOES THAT MAKE SENSE TO THE BOARD?

21 MS. LANSING: YES.

22 CHAIRMAN KLEIN: ADDITIONAL COMMENTS?
23 PUBLIC COMMENTS? I'D LIKE TO CALL THE QUESTION.
24 ALL IN FAVOR? OPPOSED? ABSTAIN?

25 THANK YOU. COULD WE HAVE A REPORT ON THE

BARRISTERS' REPORTING SERVICE

1 SURVEY THAT OCCURRED? IT'S ITEM NO. 19, DR.
2 SAMBRANO.

3 DR. SAMBRANO: MR. CHAIR, MEMBERS OF THE
4 BOARD, AT THE LAST GRANTS WORKING GROUP REVIEW,
5 SCIENTIFIC MEMBERS OF THE WORKING GROUP WERE
6 INFORMALLY SURVEYED AT THE REQUEST OF THE BOARD
7 REGARDING THEIR OPINION ABOUT PUBLIC ACCESS TO THEIR
8 FINANCIAL DISCLOSURE STATEMENTS. DURING THE COURSE
9 OF THE REVIEW MEETING, WE APPROACHED EIGHT DIFFERENT
10 MEMBERS WHO WERE EACH GIVEN A SURVEY FORM TO
11 COMPLETE ANONYMOUSLY. THEY WERE REMINDED THAT THEY
12 ARE CURRENTLY SUBJECT TO DISCLOSURE OF THEIR
13 FINANCIAL, PROFESSIONAL, AND PERSONAL INTEREST TO
14 CIRM. THEY EACH ARE REQUIRED TO COMPLETE AND SUBMIT
15 A FINANCIAL DISCLOSURE FORM THAT SUMMARIZES THEIR
16 INTEREST IN REAL PROPERTY OR INVESTMENTS OVER \$5,000
17 IN CALIFORNIA. AND THESE DOCUMENTS ARE
18 CONFIDENTIAL.

19 WE ALSO REMINDED THEM THAT CIRM ALLOWS
20 STATE AUDITORS TO REVIEW THESE DISCLOSURE STATEMENTS
21 TO VERIFY THAT CIRM IS COMPLYING WITH CONFLICT
22 POLICIES.

23 WE EXPLAINED THAT CIRM HAS BEEN ASKED TO
24 TAKE AN INFORMAL, ANONYMOUS POLL OF THE GRANTS
25 WORKING GROUP MEMBERS TO DETERMINE HOW DIFFERENT

BARRISTERS' REPORTING SERVICE

1 DISCLOSURE REQUIREMENTS WOULD AFFECT THEIR
2 WILLINGNESS TO SERVE AS A GRANTS WORKING GROUP
3 MEMBER. AND WE ASKED THEM THREE QUESTIONS.

4 THE FIRST QUESTION IS INTRODUCED IN THIS
5 WAY. CURRENTLY YOU COMPLETE AND SUBMIT A FINANCIAL
6 DISCLOSURE FORM THAT SUMMARIZES YOUR INTEREST IN
7 REAL PROPERTY OR INVESTMENTS OVER \$5,000 IN
8 CALIFORNIA. THESE DOCUMENTS ARE CONFIDENTIAL AND
9 AVAILABLE ONLY TO STATE AUDITORS THAT OVERSEE CIRM
10 ACTIVITIES. WOULD YOU REMAIN WILLING TO SERVE AS A
11 GRANTS WORKING GROUP MEMBER IF YOUR FINANCIAL
12 DISCLOSURE FORM WAS AVAILABLE TO THE GENERAL PUBLIC?

13 FOUR MEMBERS RESPONDED YES, FOUR MEMBERS
14 RESPONDED NO.

15 THE SECOND QUESTION: OFFICERS AND
16 EMPLOYEES OF THE STATE OF CALIFORNIA ARE REQUIRED TO
17 COMPLETE AN ANNUAL FORM 700, WHICH IS A
18 COMPREHENSIVE DISCLOSURE OF ALL ECONOMIC INTERESTS,
19 INCLUDING INCOME EARNED BY YOU, YOUR SPOUSE,
20 INVESTMENTS, TRUSTS, BUSINESS ENTITIES, HONORARIA,
21 GIFTS, AND TRAVEL PAYMENTS FROM THIRD PARTIES. THE
22 COMPLETED FORMS ARE AVAILABLE FOR PUBLIC INSPECTION.
23 CURRENTLY GRANTS WORKING GROUP MEMBERS ARE NOT
24 REQUIRED TO COMPLETE FORM 700. WOULD YOU REMAIN
25 WILLING TO SERVE AS A GRANTS WORKING GROUP MEMBER IF

BARRISTERS' REPORTING SERVICE

1 YOU WERE REQUIRED TO COMPLETE A CALIFORNIA FORM 700
2 FOR PUBLIC DISCLOSURE?

3 TWO RESPONDED YES, SIX RESPONDED NO.

4 THE LAST QUESTION: BEYOND SPECIFICALLY
5 DESIGNATED CIRM STAFF AND STATE AUDITORS, TO WHOM DO
6 YOU FEEL IT APPROPRIATE TO PROVIDE ACCESS TO YOUR
7 FINANCIAL DISCLOSURE INFORMATION? SEVEN RESPONDED
8 NO ONE ELSE AND ONE NO RESPONSE.

9 CHAIRMAN KLEIN: THANK YOU VERY MUCH. I
10 THINK THAT IT'S EVIDENCE THAT WE'VE GONE REALLY AS
11 FAR AS WE CAN. WE'RE TRYING TO BE AS TRANSPARENT AS
12 POSSIBLE. WE DID WORK OUT WITH THE LEGISLATURE
13 SEVERAL YEARS AGO AN AGREEMENT THAT WAS A JOINT
14 AGREEMENT WITH THE SENATE AND THE ASSEMBLY, THAT THE
15 GOVERNOR'S OFFICE WAS COMFORTABLE WITH, THAT WE
16 ADOPTED THAT PROVIDED REALLY TREMENDOUS TRANSPARENCY
17 AND AUDIT OVERSIGHT, AND WE CANNOT AFFORD TO LOSE
18 HALF OR MORE OF OUR PEER REVIEW GROUP.

19 I THINK THE MEMBERS THEY POLLED ARE FAIRLY
20 REPRESENTATIVE OF THE REST OF THE GROUP, AND SO IT'S
21 IMPORTANT FOR US TO FOLLOW THROUGH AND PROVIDE THIS
22 INFORMATION BACK TO THE LITTLE HOOVER COMMISSION.
23 BUT I THINK WE REALLY HAVE, AS INDICATED BY THIS
24 INFORMAL POLL, DONE AS MUCH AS WE CAN WITHOUT LOSING
25 INDIVIDUAL, CRITICAL TALENT FROM OUT OF STATE THAT'S

BARRISTERS' REPORTING SERVICE

1 ON A VOLUNTEER BASIS THAT'S VITAL TO ADVANCING THE
2 BEST SCIENCE AND CLINICAL PRACTICES FOR THE BENEFIT
3 OF PATIENTS IN CALIFORNIA.

4 SO, COUNSEL, MELISSA KING, DR. TROUNSON,
5 IS THERE ANY OTHER ITEM THAT WE NEED TO ADDRESS
6 TODAY?

7 MS. KING: PUBLIC COMMENT IF THERE ARE
8 ANY.

9 CHAIRMAN KLEIN: GENERAL PUBLIC COMMENTS
10 IF THERE ARE ANY.

11 MS. LANSING: WE WILL THANK OUR CHAIRMAN
12 FOR AN EXTRAORDINARILY GOOD JOB.

13 (APPLAUSE.)

14 CHAIRMAN KLEIN: THANK YOU ALL. WE STAND
15 ADJOURNED.

16 (THE MEETING WAS THEN ADJOURNED AT
17 02:25 P. M.)

18
19
20
21
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24
25

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

LUXE HOTEL
11461 SUNSET BOULEVARD
LOS ANGELES, CALIFORNIA
ON
OCTOBER 28, 2009

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.



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