

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: STANFORD UNIVERSITY
PAUL BREST HALL
STANFORD, CALIFORNIA

DATE: AUGUST 18, 2010, 4 P.M.
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REPORTER: BETH C. DRAIN, CSR
CSR. NO. 7152

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BARRISTERS' REPORTING SERVICE

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BARRISTERS' REPORTING SERVICE

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BARRISTERS' REPORTING SERVICE

1 STANFORD, CALIFORNIA; WEDNESDAY, AUGUST 18, 2010

2 4 P.M.

3
4 CHAIRMAN KLEIN: ALL RIGHT. WE'RE GOING
5 TO CONVENE, AND WE HAVE A COUPLE OF MEMBERS THAT ARE
6 RUNNING LATE, BUT WE DO HAVE A QUORUM. AND THANK
7 YOU, OS, FOR YOUR PARTICULARLY GOOD LOGISTICS THAT
8 GOT YOU HERE.

9 I'D LIKE TO OPEN THIS MEETING OFFICIALLY
10 AT STANFORD UNIVERSITY. WE'RE IN PAUL BREST HALL, A
11 FORMER DEAN -- NAMED AFTER A FORMER DEAN OF THE
12 STANFORD LAW SCHOOL. I'D LIKE TO SAY THAT DOESN'T
13 CREATE ANY CONFLICTS FOR ME. IT WAS ALL A ONE-WAY
14 RELATIONSHIP. I PAID MONEY; THEY HAVEN'T PAID ME
15 ANYTHING, BUT I DID APPRECIATE THE GREAT EDUCATION.

16 WE WANT TO GIVE THANKS IN OPENING THIS
17 MEETING TO JENNIFER PRYNE, AMY CHEUNG, NICK WARSHAW,
18 AND MELISSA KING FOR GETTING US HERE AND READY TO GO
19 WITH ALL OF THE MATERIALS COORDINATION THAT LEADS UP
20 TO EACH OF OUR MEETINGS. AND WE WANT TO THANK THOSE
21 WHO MADE A SPECIAL EFFORT TO JOIN US BY PHONE.

22 WE ARE GOING TO PROCEED WITH A PLEDGE OF
23 ALLEGIANCE LED BY MELISSA KING FOLLOWED BY A ROLL
24 CALL. AND WE WANT TO DRAW YOUR ATTENTION TO LIZZIE
25 CAMPAGLIA, WHO IS HERE WITH US, OUR INTERN, SEATED

BARRISTERS' REPORTING SERVICE

1 OVER ON THE RIGHT WAVING TO YOU, AND PLEASE SAY HI.

2 SHE'S BEEN AN INTERN THIS SUMMER.

3 MS. KING: PLEASE STAND IF YOU ARE ABLE.

4 (THE PLEDGE OF ALLEGIANCE.)

5 MS. KING: CALLING THE ROLL, ROBERT

6 BIRGENEAU.

7 DR. BIRGENEAU: HERE.

8 MS. KING: FLOYD BLOOM. DAVID BRENNER.

9 DR. BRENNER: HERE.

10 MS. KING: KIM WITMER FOR WILLIAM BRODY.

11 DR. WITMER: HERE.

12 MS. KING: SUSAN BRYANT.

13 DR. BRYANT: HERE.

14 MS. KING: MARCY FEIT.

15 MS. FEIT: HERE.

16 MS. KING: MICHAEL FRIEDMAN.

17 DR. FRIEDMAN: HERE.

18 MS. KING: LEEZA GIBBONS. MICHAEL

19 GOLDBERG.

20 MR. GOLDBERG: HERE.

21 MS. KING: SAM HAWGOOD.

22 DR. HAWGOOD: HERE.

23 MS. KING: BOB KLEIN.

24 CHAIRMAN KLEIN: HERE.

25 MS. KING: SHERRY LANSING.

BARRISTERS' REPORTING SERVICE

1 MS. LANSING: HERE.
2 MS. KING: TED LOVE. ED PENHOET.
3 DR. PENHOET: HERE.
4 MS. KING: PHIL PIZZO. CLAIRE POMEROY.
5 DR. POMEROY: HERE.
6 MS. KING: FRANCISCO PRIETO.
7 DR. PRIETO: HERE.
8 MS. KING: ELIZABETH FINI FOR CARMEN
9 PULIAFITO. ROBERT QUINT. JOHN REED. DUANE ROTH.
10 MR. ROTH: HERE.
11 MS. KING: JOAN SAMUELSON.
12 MS. SAMUELSON: HERE.
13 MS. KING: DAVID SERRANO-SEWELL.
14 MR. SERRANO-SEWELL: HERE.
15 MS. KING: JEFF SHEEHY.
16 MR. SHEEHY: HERE.
17 MS. KING: JON SHESTACK. OSWALD STEWARD.
18 DR. STEWARD: HERE.
19 MS. KING: ART TORRES.
20 MR. TORRES: HERE.
21 MS. KING: JAMES ECONOMOU FOR DR.
22 WASHINGTON FROM UCLA.
23 DR. ECONOMOU: HERE.
24 MS. KING: AND WE DO HAVE A QUORUM FOR THE
25 RECORD. THANK YOU, DR. PIZZO. FOR THE RECORD, DR.

BARRISTERS' REPORTING SERVICE

1 PIZZO IS IN THE BUILDING, AND WITH OUR TWO MEMBERS
2 JOINING BY PHONE, CHAIRMAN KLEIN, WE DO HAVE A
3 QUORUM.

4 CHAIRMAN KLEIN: THANK YOU VERY MUCH. I
5 CALL TO EVERYONE'S ATTENTION THE SPOTLIGHT THAT WAS
6 ARRANGED BY LYNN HARWELL AND AMY CHEUNG FOR TOMORROW
7 MORNING ON STROKES. THIS IS GOING TO BE AT THIS
8 SAME LOCATION AT 8:30 IN THE MORNING. SPEAKERS
9 INCLUDE ROBERT QUINT FROM OUR BOARD WITH GARY
10 STEINBERG, DIRECTOR OF STANFORD INSTITUTE FOR
11 NEUROINNOVATION AND TRANSLATIONAL NEUROSCIENCES, AS
12 WELL AS PATIENT ADVOCATE K. MICHAEL COOPER. SO
13 PLEASE, 8:30 SHOULD BE AN EXCELLENT SPOTLIGHT IF
14 EVERYONE MAKES THE EFFORT TO BE THERE RIGHT AT 8:30.

15 WE ARE GOING TO GO INTO EXECUTIVE SESSION
16 ALMOST IMMEDIATELY, BUT THERE ARE A COUPLE OF ITEMS
17 WE'RE GOING TO FIRST COVER GIVEN THAT TED LOVE IS AN
18 IMPORTANT MEMBER OF THE EVALUATION COMMITTEE, BEING
19 CO-CHAIR. AND GIVEN THAT WE'RE WAITING A FEW
20 MINUTES FOR TED TO ARRIVE, I THOUGHT WE COULD FIRST
21 HAVE A VOTE ON A PROPOSED ADDITIONAL AGENDA ITEM.
22 AND THAT PROPOSED ADDITIONAL ITEM SHOULD BE IN YOUR
23 PACKETS AT WHICH TAB, MELISSA?

24 MS. KING: SO RIGHT BEHIND THE AGENDA AT
25 THE FRONT OF YOUR BINDER, THERE IS SOMETHING THAT

BARRISTERS' REPORTING SERVICE

1 LOOKS A LOT LIKE AN AGENDA THAT IS THE PROPOSED
2 ADDITIONAL ITEM. AND THEN THE MATERIALS RELATED TO
3 THAT ITEM ARE IN THE POCKET INSIDE THE COVER ON THE
4 LEFT. THERE'S THE ASSEMBLY BILL ITSELF AND A COUPLE
5 OF OTHER BACKGROUND DOCUMENTS. ASSEMBLY BILL 52 AND
6 A BACKGROUND DOCUMENT ON THAT, AND THEN THERE'S ALSO
7 SB 1064 IN CASE SENATOR TORRES WANTS TO MAKE
8 COMMENTS ABOUT THAT AS WELL.

9 CHAIRMAN KLEIN: CERTAINLY. SO THIS ITEM
10 WE NEED TO ADD TO THE AGENDA BY A TWO-THIRDS VOTE.
11 IT IS NOT AN ITEM THAT WE ANTICIPATED FOR THIS
12 AGENDA. IT WAS A -- THIS BILL IS MOVING FASTER THAN
13 ANTICIPATED, SO IN ORDER TO HAVE A MEANINGFUL
14 POSITION, WE HAVE TO ADDRESS IT AT THIS MEETING.

15 BEFORE I CAN TURN IT OVER TO SENATOR
16 TORRES FOR CONSIDERATION OF THIS ITEM AS CHAIR OF
17 THE LEGISLATIVE COMMITTEE, WE NEED TO HAVE A MOTION
18 AND A VOTE IF WE'RE GOING TO ADD IT TO THE AGENDA.

19 MS. LANSING: SO MOVED.

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

22 MR. GOLDBERG: SECOND.

23 CHAIRMAN KLEIN: SECOND BY MICHAEL
24 GOLDBERG. MR. HARRISON, WOULD YOU LIKE TO MAKE A
25 COMMENT?

BARRISTERS' REPORTING SERVICE

1 MR. HARRISON: JUST TO BE CLEAR, THE
2 MOTION IS TO MAKE A DETERMINATION THAT THE ITEM CAME
3 TO THE BOARD'S ATTENTION, AS THE CHAIR SAID, AFTER
4 THE AGENDA WAS POSTED AND THAT THERE'S A NEED TO
5 TAKE IMMEDIATE ACTION ON IT.

6 CHAIRMAN KLEIN: THANK YOU, MR. HARRISON.
7 ANY DISCUSSION ON THIS ITEM? IS THERE ANY PUBLIC
8 COMMENT ON THIS ITEM?

9 SEEING NONE, SINCE OUR QUORUM INCLUDES
10 MEMBERS ON THE PHONE, MR. HARRISON, DO WE NEED A
11 ROLL CALL OF JUST THE MEMBERS ON THE PHONE? ALL
12 RIGHT. SO WE'RE GOING TO DO A VOICE VOTE OF THOSE
13 PRESENT AND THEN A ROLL CALL OF THE MEMBERS ON THE
14 PHONE.

15 ALL IN FAVOR?

16 (CHORUS OF AYES.)

17 OPPOSED?

18 (NO RESPONSE.)

19 AND THE MEMBERS ON THE PHONE ROLL CALL,
20 PLEASE.

21 MS. KING: KIM WITMER.

22 DR. WITMER: AYE.

23 MS. KING: AND MICHAEL FRIEDMAN.

24 DR. FRIEDMAN: I ALSO ENDORSE IT.

25 CHAIRMAN KLEIN: THANK YOU VERY MUCH.

BARRISTERS' REPORTING SERVICE

1 WITH THAT, I'M GOING TO TURN THIS OVER FOR A
2 DISCUSSION OF THIS ITEM OUT OF ORDER ON THE AGENDA
3 BECAUSE IT IS A LATE ADDED ITEM. AND WE'RE GOING TO
4 TRY AND SEE IF WE CAN GET THIS DONE QUICKLY WHILE
5 WE'RE WAITING FOR ONE OR TWO MORE BOARD MEMBERS.
6 SENATOR TORRES.

7 MR. TORRES: THANK YOU, MR. CHAIRMAN. THE
8 BILL IS PRETTY SELF-EXPLANATORY. IT'S ASSEMBLY BILL
9 52 BY ASSEMBYMEMBER ANTHONY PORTANTINO WITH BOTH
10 REPUBLICAN AND DEMOCRATIC CO-SPONSORS. IT IS
11 CURRENTLY IN A SENATE APPROPRIATIONS SUSPENSE FILE,
12 WHICH MEANS IT WILL COME OUT SHORTLY. AND THEN IT
13 WILL GO TO THE SENATE FLOOR FOR APPROVAL AND THEN
14 BACK TO THE ASSEMBLY FOR CONCURRENCE AND THEN TO THE
15 GOVERNOR'S DESK.

16 IT REQUESTS THE UNIVERSITY OF CALIFORNIA
17 TO DEVELOP A PLAN TO ESTABLISH AND ADMINISTER AN
18 UMBILICAL CORD COLLECTION PROGRAM BY JULY 1, 2011,
19 BY INCREASING THE BIRTH CERTIFICATE FEES BY \$2.
20 THERE'S A SUNSET ON THIS LEGISLATION AS WELL TO
21 JANUARY 1, 2019.

22 AND I WOULD RECOMMEND THAT WE SUPPORT THIS
23 LEGISLATION SO THAT WE MIGHT SEND A LETTER TO THE
24 AUTHOR.

25 CHAIRMAN KLEIN: SO, SENATOR TORRES, FOR

BARRISTERS' REPORTING SERVICE

1 THE PUBLIC AND THE BOARD MEMBERS, IT'S MY
2 UNDERSTANDING THAT THERE'S NO ADMINISTRATIVE BURDEN
3 ON THIS AGENCY FROM THIS BILL. THIS IS MERELY THAT
4 THE AUTHOR, THE PRINCIPAL AUTHORS, BOTH THE SENATE
5 AND THE ASSEMBLY, WANT OUR PERSPECTIVE ON THE VALUE
6 OF PROCEEDING ON THIS PROGRAM; IS THAT A CORRECT
7 STATEMENT?

8 MR. TORRES: CORRECT.

9 DR. PIZZO: THIS IS BASICALLY TO ESTABLISH
10 AN UMBILICAL CORD CELL BANK.

11 MR. TORRES: NO. IT'S A COLLECTION
12 REGISTRY.

13 DR. PIZZO: COLLECTION REGISTRY MEANS
14 WHAT?

15 MR. TORRES: A COLLECTION REGISTRY WHICH
16 WILL THEN PROVIDE FOR DISTRIBUTION TO BANKS ACROSS
17 THE STATE THAT ARE SO LICENSED.

18 MS. SAMUELSON: I MISSED WHAT THE BANK IS
19 FOR.

20 MR. TORRES: CORD BLOOD BANKS. SORRY.
21 ANY OTHER BOARD COMMENTS?

22 DR. PENHOET: QUESTION. WHAT DOES THE
23 UNIVERSITY OF CALIFORNIA THINK ABOUT THIS BURDEN AND
24 \$2 PER?

25 MR. TORRES: THE UNIVERSITY OF CALIFORNIA

BARRISTERS' REPORTING SERVICE

1 IS IN SUPPORT OF THIS LEGISLATION.

2 DR. PENHOET: OKAY.

3 MR. TORRES: IS THERE ANY FURTHER
4 DISCUSSION? ANY COMMENTS FROM THE PUBLIC? IS THERE
5 A MOTION?

6 MR. KLEIN: I MAKE A MOTION.

7 MR. TORRES: MOVED BY MR. KLEIN. SECONDED
8 BY?

9 DR. POMEROY: SECOND.

10 MR. TORRES: MOVED AND SECONDED BY DR.
11 POMEROY. ALL THOSE -- DO YOU WANT TO DO A ROLL CALL
12 ON THIS, JAMES? VOICE ON THE PEOPLE HERE. ALL
13 THOSE IN FAVOR SIGNIFY BY SAYING AYE.

14 (CHORUS OF AYES.)

15 OPPOSED.

16 (NO RESPONSE.)

17 ABSTENTIONS.

18 (NO RESPONSE.)

19 NOW THE ROLL OF THOSE ON THE TELEPHONE.

20 MS. KING: KIM WITMER.

21 DR. WITMER: AYE.

22 MS. KING: MICHAEL FRIEDMAN.

23 DR. FRIEDMAN: AYE.

24 MS. KING: THANK YOU.

25 MR. TORRES: MOTION CARRIES. BACK TO THE

BARRISTERS' REPORTING SERVICE

1 CHAIR.

2 CHAIRMAN KLEIN: SENATOR TORRES, IF YOU
3 COULD THEN UPDATE US ON THE OTHER LEGISLATION THAT
4 IS PROCEEDING AND ITS STATUS AT THIS POINT, SO WE
5 JUST KEEP AS ONE UNIFIED PACKAGE THE LEGISLATIVE
6 ITEMS.

7 MR. TORRES: THANK YOU, MR. CHAIRMAN. AS
8 YOU KNOW, WE'VE BEEN WORKING VERY CLOSELY WITH
9 SENATOR ALQUIST. AND I KNOW DUANE HAS BEEN WORKING
10 AND JAMES WITH THE GOVERNOR'S OFFICE ON SENATE BILL
11 1064, WHICH IS ALSO IN YOUR PACKET. IT HAS BEEN
12 AMENDED IN THE ASSEMBLY AND HAS PASSED THE ASSEMBLY
13 THIS WEEK AND IS NOW CURRENTLY ON THE SENATE FLOOR
14 IN WHAT'S CALLED THIRD READING.

15 THE SENATE WILL TAKE UP THE MEASURE
16 SHORTLY AND CONCUR IN THE ASSEMBLY AMENDMENTS, AND
17 IT WILL BE SENT TO THE GOVERNOR'S DESK FOR
18 SIGNATURE.

19 ANY QUESTIONS? I'LL GIVE YOU ALL AN
20 UPDATE AS SOON AS IT PASSES THE SENATE. DUANE, DO
21 YOU WANT TO ADD ANYTHING?

22 MR. ROTH: NO. I THINK YOU ACCURATELY
23 DESCRIBED THE STATUS OF IT. AND JAMES AND I STILL
24 HAVE SOME CALLS TO MAKE TO THE GOVERNOR'S OFFICE TO
25 MAKE SURE THERE'S COMPLETE UNDERSTANDING OF WHAT'S

BARRISTERS' REPORTING SERVICE

1 IN THIS BILL. SO WE WILL DO THAT.

2 CHAIRMAN KLEIN: ALL RIGHT. SO TRYING TO
3 CLEAR THE DECK OF ADMINISTRATIVE ITEMS WHILE WE'RE
4 PREPARING TO ENTER EXECUTIVE SESSION, ITEM 7 IS
5 CONSIDERATION OF MINUTES FROM PAST BOARD MEETINGS.
6 IS THERE ANY COMMENT ON THOSE MINUTES?

7 DR. POMEROY: MOVE APPROVAL.

8 CHAIRMAN KLEIN: MOVE APPROVAL BY MEMBER
9 POMEROY, DEAN POMEROY. SECOND IS?

10 MS. LANSING: LANSING.

11 CHAIRMAN KLEIN: LANSING. ANY DISCUSSION?
12 ANY DISCUSSION FROM THE PUBLIC? ALL RIGHT. CALL
13 THE QUESTION. ALL IN FAVOR.

14 (CHORUS OF AYES.)

15 OPPOSED.

16 (NO RESPONSE.)

17 ON THE PHONE.

18 MS. KING: KIM WITMER.

19 DR. WITMER: AYE.

20 MS. KING: MICHAEL FRIEDMAN.

21 DR. FRIEDMAN: YES.

22 CHAIRMAN KLEIN: ALL RIGHT. FINAL
23 ADMINISTRATIVE ITEM HERE IS THAT MR. HARRISON HAS
24 INDICATED TO ME THAT TECHNICALLY WE HAVE -- THE
25 EVALUATION SUBCOMMITTEE HAS ACTING CHAIRS AND VICE

BARRISTERS' REPORTING SERVICE

1 CHAIRS, BUT WE HAVEN'T TAKEN THE FINAL ACTION OF
2 CONFIRMING THE VOTE. AND THIS IS ITEM NO. 16 FOR
3 DR. PRIETO AS CHAIR OF THE EVALUATION SUBCOMMITTEE
4 AND DR. LOVE AS THE VICE CHAIR.

5 MR. TORRES: SO MOVED.

6 MS. LANSING: SECOND.

7 CHAIRMAN KLEIN: SECOND BY LANSING. ANY
8 DISCUSSION? ANY DISCUSSION BY THE PUBLIC? CALL THE
9 QUESTION. ALL IN FAVOR.

10 (CHORUS OF AYES.)

11 OPPOSED.

12 (NO RESPONSE.)

13 AND MELISSA.

14 DR. PRIETO: I ABSTAIN.

15 CHAIRMAN KLEIN: FRANCISCO PRIETO
16 ABSTAINS.

17 MS. KING: KIM WITMER.

18 DR. WITMER: AYE.

19 MS. KING: MICHAEL FRIEDMAN.

20 DR. FRIEDMAN: AYE.

21 MS. KING: AND JUST SO EVERYBODY IN THE
22 ROOM HERE WITH US IS AWARE, FOR THE PEOPLE ON THE
23 PHONE, FOR SOME REASON THEY'RE NOT HEARING US THAT
24 WELL. IF YOU CAN SPEAK INTO THE MICROPHONE AND USE
25 YOUR LOUD VOICE INSTEAD OF YOUR QUIET VOICE, PLEASE.

BARRISTERS' REPORTING SERVICE

1 CHAIRMAN KLEIN: WELL, I WANT TO POINT OUT
2 IN THIS PERIOD OF NATIONAL CONFLICT AND TURMOIL IN
3 THE ELECTORAL PROCESS THAT ALL THOSE WHO ARE
4 ELIGIBLE TO VOTE VOTED FOR THESE CANDIDATES. DR.
5 PRIETO, YOU SHOULD BE VERY --

6 (APPLAUSE.)

7 CHAIRMAN KLEIN: -- ENCOURAGED BY THE
8 LEVEL OF SUPPORT OF YOUR PEERS ON THIS COMMITTEE.

9 WHAT IS OUR EXPECTED ARRIVAL TIME HERE?
10 IMMINENT; IS THAT CORRECT?

11 MR. HARRISON: DR. LOVE SHOULD BE HERE ANY
12 MINUTE, SO I WOULD SUGGEST THAT WE MOVE FORWARD AND
13 CONVENE IN CLOSED SESSION IF THE CHAIR IS READY.

14 MS. LANSING: WANT TO DO SOME OF THE
15 GOVERNANCE ONES WHICH ARE PRO FORMA?

16 CHAIRMAN KLEIN: SHERRY, WOULD YOU LIKE TO
17 DO ITEM 15, THE ELECTION OF THE ICOC CHAIR AND VICE
18 CHAIR OF THE PROCESS?

19 MS. LANSING: JAMES, ARE YOU GOING TO DO
20 THOSE?

21 MR. HARRISON: YES.

22 MS. LANSING: OKAY. WHY DON'T YOU DO
23 THOSE BECAUSE THEY'RE PRETTY MUCH FROM OUR CALL. WE
24 COULD DO ITEM 14 AND 15.

25 CHAIRMAN KLEIN: ALL RIGHT. SO I'M GOING

BARRISTERS' REPORTING SERVICE

1 TO PASS THIS TO OUR CHAIR, SHERRY LANSING, TO DO
2 ITEMS 14 AND 15.

3 MS. LANSING: I'M GOING TO TURN IT OVER TO
4 JAMES. MOST OF IT IS IN THE BOOK. JAMES, IF YOU
5 CAN GIVE US A BRIEF SUMMARY OF IT, IT WOULD BE
6 GREAT, AND THEN WE'LL HAVE QUESTIONS.

7 MR. HARRISON: SO THE GOVERNANCE
8 SUBCOMMITTEE MET IN EARLY AUGUST TO CONSIDER
9 AMENDMENTS TO THE BOARD'S BYLAWS. AND THE
10 AMENDMENTS COVER A NUMBER OF DIFFERENT SUBJECTS.
11 THE FIRST, WHICH IS IN ARTICLE 5, SECTION 7 OF THE
12 BYLAWS, WHICH IS AT PAGE 6 OF THE BYLAWS AND TRACK
13 CHANGES, INCORPORATES THE OPEN ROLL VOTING POLICY
14 WHICH THE BOARD ADOPTED IN JUNE 2009 INTO THE
15 BOARD'S BYLAWS. IT WAS PREVIOUSLY A SELF-STANDING
16 POLICY, AND WE THOUGHT IT WAS IMPORTANT TO
17 INCORPORATE IT WITHIN THE BOARD'S BYLAWS.

18 THE ONLY SUBSTANTIVE CHANGE IS A
19 CLARIFICATION OF THE ORIGINAL INTENT OF THE
20 PROVISION WHICH IS TO PROVIDE THAT THE CHAIR HAS THE
21 AUTHORITY TO LEAVE THE ROLL OPEN AFTER DEBATE HAS
22 CONCLUDED IN ORDER TO PERMIT A MEMBER TO PARTICIPATE
23 IN THE VOTE UNDER CIRCUMSTANCES, FOR EXAMPLE, IF THE
24 MEMBER HAD TO LEAVE THE MEETING FOR A TIME AND THEN
25 RETURN OR OTHER SIMILAR CIRCUMSTANCES.

BARRISTERS' REPORTING SERVICE

1 THE NEXT BYLAW AMENDMENT DEALS WITH THE
2 REQUIRED NUMBER OF MEETINGS OF THE GOVERNANCE AND
3 LEGISLATIVE SUBCOMMITTEES. UNDER THE CURRENT
4 BYLAWS, THE GOVERNANCE AND LEGISLATIVE SUBCOMMITTEES
5 ARE REQUIRED TO MEET FOUR AND THREE TIMES PER YEAR
6 RESPECTIVELY. AND WE PROPOSE TO AMEND THE BYLAWS TO
7 REQUIRE THAT BOTH SUBCOMMITTEES MEET AT LEAST ONCE A
8 YEAR, AND GIVE THE CHAIRS OF THOSE SUBCOMMITTEES THE
9 DISCRETION TO CALL ADDITIONAL MEETINGS AS NECESSARY
10 RATHER THAN SETTING AN ARTIFICIAL NUMBER.

11 THE NEXT BYLAW CHANGE IS IN ANTICIPATION
12 OF OUR UPCOMING TRANSITION TO A NEW CHAIR AND VICE
13 CHAIR. AND THE INTENT TO IS TO ESTABLISH IN THE
14 BYLAWS A CLEAR PROCEDURE FOR THE ELECTION OF THE
15 CHAIR AND THE STATUTORY VICE CHAIR.

16 CURRENTLY THE BYLAWS ARE SILENT. WE FELT
17 IT WAS IMPORTANT TO CLARIFY THOSE PROCEDURES TO
18 ANTICIPATE ANY QUESTIONS THAT MIGHT ARISE AT THE
19 TIME OF THE VOTE ITSELF.

20 UNDER THE PROPOSED BYLAW AMENDMENTS, IF
21 THERE ARE TWO OR MORE NOMINEES, THE NOMINEE WHO
22 RECEIVES THE VOTES OF A MAJORITY OF A QUORUM OF THE
23 BOARD WOULD BE ELECTED. HOWEVER, IF NO NOMINEE
24 RECEIVES A MAJORITY OF A QUORUM, THEN THE TOP TWO
25 VOTE-GETTERS WOULD FACE OFF IN A SECOND ROUND OF

BARRISTERS' REPORTING SERVICE

1 VOTING. AND THE PERSON WHO THEN RECEIVED THE VOTES
2 OF A MAJORITY OF A QUORUM WOULD BE ELECTED.

3 MS. LANSING: I HAVE A QUESTION. JUST TO
4 BE CLEAR, SO THE FIRST -- THERE MIGHT BE THREE
5 NOMINEES, WHATEVER. IF EVERY BRANCH HAD A DIFFERENT
6 PERSON, THERE COULD BE MORE. HOW MANY BRANCHES,
7 WHATEVER, FOUR. SO THERE COULD BE FOUR NOMINEES.
8 COULD YOU WIN BY JUST ONE VOTE, OR DO YOU HAVE TO
9 HAVE A TWO-THIRDS, OR WHAT ARE WE SAYING?

10 MR. HARRISON: NO. IT'S A MAJORITY OF A
11 QUORUM. A QUORUM OF THE BOARD IS 19 MEMBERS. SO A
12 PERSON COULD WIN WITH TEN VOTES.

13 MS. LANSING: JUST WANTED TO BE SURE
14 EVERYONE UNDERSTOOD THAT. IF NOBODY DOES, IF
15 THERE'S A TIE, THEN WE GO TO THE TOP TWO.

16 MR. HARRISON: THERE'S A SECOND STEP
17 THERE. IF THERE ARE THREE OR FOUR NOMINEES AND NO
18 SINGLE PERSON RECEIVES THE VOTES OF AT LEAST TEN
19 MEMBERS OF THE BOARD, THEN WHAT WE WOULD DO IS
20 ELIMINATE THE LOWEST VOTE-GETTERS AND HAVE A REVOTE
21 FOR THE TWO INDIVIDUALS WHO RECEIVED THE HIGHEST
22 NUMBER OF VOTES.

23 MR. SERRANO-SEWELL: IT'S A SIMILAR METHOD
24 TO WHEN WE SELECTED OUR HEADQUARTERS.

25 MR. HARRISON: IT IS.

BARRISTERS' REPORTING SERVICE

1 MR. SERRANO-SEWELL: IN THAT RESPECT, THE
2 LOWEST VOTE-GETTER.

3 MR. HARRISON: DAVID IS EXACTLY RIGHT. WE
4 USED A SIMILAR PROCEDURE WITH RESPECT TO THE VOTE ON
5 THE HEADQUARTERS WHEN WE ORIGINALLY HAD FOUR
6 DIFFERENT CITIES VYING FOR THE SELECTION OF
7 HEADQUARTERS. AND WE ULTIMATELY ENDED UP HAVING TWO
8 VOTES, AN INITIAL VOTE AND THEN A SECOND VOTE, AMONG
9 THE TOP TWO CITIES.

10 MR. ROTH: DAVID, DID YOU HAVE TO REMIND
11 ME OF THAT VOTE?

12 DR. POMEROY: WE'RE ALL SUFFERING.

13 MS. LANSING: EVEN THOUGH -- I HAVE TO
14 BRING THIS UP. OKAY. I GUESS -- I JUST WANT US TO
15 DISCUSS FOR A SECOND, EVEN THOUGH I WAS ON THE PHONE
16 CALL AND THOUGHT THIS WAS GREAT, I'M NOW SITTING,
17 YOU KNOW, HOW MANY MONTHS LATER. THE THING THAT
18 BOTHERS ME IS THAT YOU CAN WIN BY ONE VOTE. DO YOU
19 KNOW? IT'S SUCH AN IMPORTANT JOB, AND I WOULD LIKE
20 TO THINK THAT THERE WAS MORE UNANIMITY. AND SO WE
21 CAN ADJUST THIS NOW SHOULD WE WANT TO. ARE WE
22 ALLOWED TO?

23 MR. HARRISON: I BELIEVE THAT YOU COULD.
24 UNDER PROPOSITION 71, THE BOARD CAN ONLY TAKE ACTION
25 BY A MAJORITY OF A QUORUM. SO THAT'S THE MINIMUM.

BARRISTERS' REPORTING SERVICE

1 IN OTHER WORDS, IN ORDER TO ELECT A NEW CHAIR OR
2 VICE CHAIR, YOU'D HAVE TO HAVE AT LEAST TEN VOTES.

3 CHAIRMAN KLEIN: SO THE STATISTICAL ISSUE,
4 SHERRY, IS THAT IF IT WERE A VOTE OF 11 TO 9, TWO
5 VOTES DIFFERENCE, FOR EXAMPLE, IF WE WERE TO SAY YOU
6 HAD TO WIN BY TWO-THIRDS, THE PROBLEM IS WE MAY
7 NEVER RESOLVE THE CONFLICT. SO THE PROBLEM IS THAT
8 STATISTICALLY WE ARE IN A POSITION WHERE THIS IS THE
9 ONLY WAY WE'RE SURE TO RESOLVE THE REFLECT BY AN
10 ACTUAL VOTE BECAUSE WE DON'T HAVE AN ARBITRATION
11 PROVISION OR SOME OTHER RESOLUTION.

12 MS. LANSING: I HEAR YOU. THAT IS, I
13 THINK, WHY I WAS SUPPORTIVE OF IT. I GUESS THEN
14 WHAT I WOULD JUST URGE ALL OF US TO DO, AS HORRIBLE
15 A THOUGHT IT IS THAT BOB IS LEAVING, TO START
16 THINKING OF PEOPLE SO THAT WE CAN AT LEAST NOT JUST
17 HAVE NAMES GIVEN TO US, SO THAT WE CAN BE PART OF
18 THE PROCESS, YOU KNOW, SO THAT THERE WILL BE
19 SOMEBODY THAT WE'RE ALL EXCITED ABOUT.

20 CHAIRMAN KLEIN: AND WE'RE GOING TO ASK
21 THE CONSTITUTIONAL OFFICERS TO TRY AND NOMINATE
22 EARLY, GIVE US THE ADVANTAGE OF HAVING A GOOD
23 DISCUSSION.

24 MS. LANSING: OKAY.

25 MS. SAMUELSON: QUESTION. IS THERE GOING

BARRISTERS' REPORTING SERVICE

1 TO BE AN OPPORTUNITY ON AN AGENDA TO ADDRESS
2 SOMETHING THAT WILL BEGIN INTRODUCING US TO THIS
3 CONCEPT AND REFLECTING ON IT? BECAUSE, YOU KNOW,
4 WHEN, HOW, WHY, ETC., WE HAVEN'T -- WE HAVE BEEN ONE
5 BOARD TO THIS DATE, I THINK, ENTIRELY WITH PEOPLE
6 COMING AND GOING, BUT NOT POSITIONS TURNING OVER.
7 NEVER MIND.

8 CHAIRMAN KLEIN: JOAN, WE CAN AGENDIZE FOR
9 THE OCTOBER BOARD MEETING SPECIFICALLY TO GO THROUGH
10 THE TRANSITION PROCESS AS AN AGENDA ITEM.

11 MR. HARRISON: IN FACT, THE NEXT ITEM ON
12 THIS AGENDA IS OUR FIRST STEP IN THAT PROCESS, WHICH
13 IS TO CONSIDER THE PROCEDURES AT THE REQUEST OF THE
14 GOVERNANCE SUBCOMMITTEE PURSUANT TO WHICH WE
15 ENVISION THE TRANSITION OCCURRING.

16 MS. SAMUELSON: THAT'S WHAT I HAD IN MIND.
17 THANK YOU.

18 MR. SHEEHY: I JUST WANTED TO MAKE CLEAR,
19 AND I THINK THIS GOES A LITTLE BIT WITH WHAT SHERRY
20 WAS SAYING. SO IF THE CANDIDATE DOESN'T GET THE
21 MAJORITY, DO WE HAVE THE -- WE MAY GET A -- LET'S
22 JUST THINK OF THE WORST-CASE SCENARIO. WE GET TWO
23 CANDIDATES WHO DON'T SUPPORT STEM CELL RESEARCH,
24 JUST PUT THAT OUT THERE, BUT IS THERE A REJECTION
25 OPTION? IS IT IMPLICIT THAT WE SEND THEM BACK

BARRISTERS' REPORTING SERVICE

1 BECAUSE THEY SEND US NOMINEES KIND OF LIKE WHAT
2 HAPPENED WITH SENATOR MALDONADO WHEN HE WANTED TO BE
3 LIEUTENANT GOVERNOR, THEY KIND OF SENT IT BACK ONCE.

4 YOU KNOW, DO WE IF THE BOARD -- BECAUSE
5 ULTIMATELY ARE WE -- TO WHAT DEGREE ARE WE BOUND TO
6 SELECT THE NOMINEES THAT ARE PRESENTED TO US, OR CAN
7 WE SAY, YOU KNOW, WITH ALL DUE RESPECT, WE BELIEVE
8 THAT, YOU KNOW -- BECAUSE ULTIMATELY WE CANNOT -- WE
9 WOULD LIKE TO TALK AND HOPEFULLY BUILD THE
10 RELATIONSHIPS WITH INDIVIDUALS TO HAVE APPROPRIATE
11 AND HOPEFULLY THEY'RE WISE AND GOOD LEADERS THAT
12 WILL SEND US GREAT CANDIDATES, BUT JUST MY QUESTION.

13 MR. TORRES: CAN I COMMENT ON THAT POINT,
14 MADAM CHAIR, IF I MAY? THE FOUR CONSTITUTIONAL
15 OFFICERS UNDER THE INITIATIVE WHO ARE ABLE TO
16 NOMINATE FOR CHAIR AND VICE CHAIR OR VICE CHAIRS, AS
17 IT WAS THE CASE EARLIER, IS THE GOVERNOR, THE
18 LIEUTENANT GOVERNOR, ABEL MALDONADO, WHO WILL STILL
19 BE LIEUTENANT GOVERNOR AT THE TIME THIS PROCESS
20 BEGINS AND ENDS, STATE CONTROLLER, JOHN CHEUNG, AND
21 STATE TREASURER BILL LOCKYEAR, ALL OF WHOM ADAMANTLY
22 SUPPORT STEM CELL RESEARCH.

23 SO I DON'T THINK ANY CANDIDATE WOULD
24 EMERGE FROM ANY OF THOSE FOUR THAT WOULD BE OPPOSED
25 TO THEIR INITIAL POSITION ON STEM CELLS.

BARRISTERS' REPORTING SERVICE

1 MS. LANSING: MY UNDERSTANDING IS WE
2 CANNOT REJECT. WE HAVE TO CHOOSE AMONG THE --

3 MR. TORRES: AND THAT'S THE VOTE.

4 DR. PRIETO: I'M NOT SURE THAT THAT IS
5 CORRECT. CAN'T WE SIMPLY VOTE NO? IF NO CANDIDATE
6 GETS A MAJORITY OF A QUORUM, THEN WE HAVE NOT CHOSEN
7 A CHAIR.

8 MR. HARRISON: AS I MENTIONED EARLIER,
9 PROP 71 REQUIRES THAT THE BOARD ACT BY THE VOTE OF A
10 QUORUM. IF THE BOARD CANNOT ACHIEVE A MAJORITY OF A
11 QUORUM ON A SINGLE CANDIDATE, THEN NO PERSON WILL BE
12 ELECTED. IN OTHER WORDS, IT ACTS AS A DE FACTO
13 REJECTION OF THE NOMINEES.

14 CHAIRMAN KLEIN: AND THE WAY THE MECHANICS
15 WORK WHEN I WROTE THE INITIATIVE IS THE EXISTING
16 CHAIR AND VICE CHAIR CONTINUE TO ACT UNTIL THERE IS
17 A MAJORITY OF A QUORUM THAT VOTES IN A NEW CHAIR AND
18 VICE CHAIR.

19 (SIMULTANEOUS DISCUSSION.)

20 DR. STEWARD: I'M SORRY. JUST TO POINT
21 OUT THE OBVIOUS, IF THERE WAS ONLY ONE CANDIDATE, WE
22 WOULD HAVE NO CHOICE BUT TO VOTE FOR THAT CANDIDATE,
23 OR COULD WE VOTE NO?

24 MR. HARRISON: YOU COULD VOTE NO. IF THE
25 CANDIDATE DOESN'T RECEIVE THE NUMBER OF --

BARRISTERS' REPORTING SERVICE

1 MS. LANSING: THAT'S YOUR ANSWER.

2 MR. TORRES: ALSO ON THAT POINT, MADAM
3 CHAIR, AS DR. PIZZO ARTICULATED, THIS PROCESS COULD
4 WELL GO INTO THE TERM OF A NEW GOVERNOR.

5 DR. PIZZO: AND BEYOND.

6 MR. TORRES: AND BEYOND. SO, BOB, BE
7 CAREFUL.

8 MR. SERRANO-SEWELL: VERY QUICKLY, I FULLY
9 ENDORSE THIS. I THINK WE OUGHT TO MOVE ON. WE ARE
10 DOING AS A COMMISSION WHAT I WOULD THINK THE
11 CONSTITUTIONAL OFFICERS WOULD HOPE OTHER COMMISSIONS
12 WOULD DO, WHICH IS ESTABLISH A PROCESS, LET
13 EVERYBODY KNOW ABOUT IT. THE GROUND RULES ARE VERY
14 CLEAR. AND YOU PROCEED AND TAKE A VOTE. WE'VE DONE
15 THAT, AND WE SHOULD BE APPLAUDED FOR IT. AND THE
16 PROCESS WILL PLAY OUT THE WAY THE PROCESS PLAYS OUT.

17 MY POINT IS WE OUGHT NOT TO OVERTHINK IT
18 BECAUSE IT WILL ORGANICALLY HAPPEN. AND WE CAN
19 ADJUST. WE'RE A PRETTY AGILE GROUP OF PEOPLE. WE
20 CAN ADJUST ACCORDINGLY. SO I MOVE ADOPTION.

21 DR. POMEROY: SECOND.

22 DR. PENHOET: SECOND.

23 DR. POMEROY: I DEFER TO MY COLLEAGUE.

24 MR. HARRISON: COULD I ASK FOR A --

25 MS. LANSING: DO I HAVE MORE DISCUSSION ON

BARRISTERS' REPORTING SERVICE

1 THIS? DO I NEED A ROLL CALL VOTE?

2 MR. HARRISON: COULD I ASK FOR ONE
3 CLARIFICATION ABOUT WHETHER THE MOTION COVERS THE
4 OTHER TWO SETS OF AMENDMENTS TO THE AMENDMENT
5 RELATING TO INCORPORATING THE OPEN ROLL VOTING
6 PROCEDURE AND THE AMENDMENT RELATED TO THE MINIMUM
7 NUMBER OF REQUIRED MEETINGS FOR THE GOVERNANCE AND
8 LEGISLATIVE SUBCOMMITTEES?

9 MS. LANSING: I HOPE IT DOES.

10 MR. SERRANO-SEWELL: IT DOES.

11 MS. LANSING: DO I HAVE ANY DISCUSSION
12 FROM THE BOARD MEMBERS? DO I HAVE ANY DISCUSSION
13 FROM MEMBERS OF THE PUBLIC? THEN CAN I HAVE A -- DO
14 I NEED A ROLL CALL VOTE?

15 MS. KING: JUST FOR THE PEOPLE ON THE
16 PHONE.

17 MS. LANSING: ALL IN FAVOR.

18 (CHORUS OF AYES.)

19 OPPOSED?

20 (NO RESPONSE.)

21 OKAY. NOW FOR THE PHONE.

22 MS. KING: THAT WAS DR. FRIEDMAN VOTING ON
23 THE PHONE. HIS VOTE WAS AYE.

24 KIM WITMER, CAN WE HAVE YOUR VOTE, PLEASE?

25 DR. WITMER: AYE.

BARRISTERS' REPORTING SERVICE

1 MS. KING: THANK YOU. FOR THE RECORD,
2 THAT MOTION CARRIES.

3 CHAIRMAN KLEIN: MR. HARRISON, GIVEN THE
4 CONSERVATION OF TIME AND GIVEN THAT WE CAN HANDLE
5 THE NEXT ITEM TOMORROW --

6 MR. HARRISON: IT'S ENTIRELY UP TO YOU.
7 THERE'S ONE ADDITIONAL AMENDMENT TO THE BYLAWS. WE
8 CAN ADDRESS IT NOW OR TOMORROW, WHATEVER IS YOUR
9 PLEASURE.

10 MS. LANSING: IS IT OKAY IF WE TAKE IT?
11 IT'S TWO MINUTES.

12 MR. HARRISON: ALL RIGHT. I WILL TRY TO
13 BE QUICK.

14 THE FINAL AMENDMENT TO THE BYLAWS THAT WE
15 WOULD PROPOSE DEALS WITH A POLICY TO IMPLEMENT SB
16 1064, WHICH, AS VICE CHAIR TORRES NOTED, HAS
17 RECENTLY PASSED THE ASSEMBLY. THIS BYLAW WOULD BE
18 CONTINGENT UPON THE SENATE PASSING SB 1064 AND THE
19 GOVERNOR SIGNING IT. AND IT WOULD ESTABLISH A
20 CONSULTING RATE FOR PATIENT ADVOCATE MEMBERS OF THE
21 BOARD FOR THEIR SERVICE ON THE WORKING GROUPS
22 PERMITTED BY SB 1064.

23 AS YOU ALL KNOW, PROP 71 REQUIRES THE
24 PATIENT ADVOCATES TO MAKE A SUBSTANTIAL COMMITMENT
25 TO CIRM ABOVE AND BEYOND THE COMMITMENT REQUIRED OF

BARRISTERS' REPORTING SERVICE

1 OTHER BOARD MEMBERS BECAUSE IT REQUIRES THEM TO
2 PARTICIPATE NOT ONLY IN BOARD SUBCOMMITTEE AND TASK
3 FORCE MEETINGS, BUT ALSO IN THE WORKING GROUP
4 MEETINGS THEMSELVES. AND BECAUSE THERE ARE THREE
5 WORKING GROUPS AND A LIMITED NUMBER OF PATIENT
6 ADVOCATES, IT MEANS A SUBSTANTIAL COMMITMENT OF TIME
7 WHICH DOES HAVE AN EFFECT ON THEIR ABILITY TO
8 SIMULTANEOUSLY CARRY OUT THEIR OTHER
9 RESPONSIBILITIES, INCLUDING THEIR CURRENT
10 OCCUPATION.

11 THIS PROPOSED BYLAW IS INTENDED TO
12 ESTABLISH A POLICY TO PERMIT THE BOARD TO COMPENSATE
13 THE PATIENT ADVOCATES, EXCLUDING THE CHAIR AND VICE
14 CHAIR OF THE BOARD, FOR THEIR SERVICE ONLY ON THE
15 WORKING GROUPS. AS DUANE ROTH WILL ATTEST, THERE
16 HAVE BEEN SOME CONCERNS RAISED ABOUT THE FACT THAT
17 UNDER SB 1064, THERE IS NO LIMIT EITHER ON THE SCOPE
18 OR ON THE AMOUNT OF COMPENSATION THAT THE BOARD CAN
19 SET.

20 TO ADDRESS THAT, WHAT WE PROPOSE TO DO IS
21 TO AMEND THE BYLAWS TO ADOPT A POLICY THAT PROVIDES
22 THE FOLLOWING. FIRST, THE POLICY WOULD ONLY APPLY
23 TO MEMBERS OF THE GRANTS WORKING GROUP AND TO THE
24 VICE CHAIR OR CO-CHAIRS OF THE STANDARDS AND
25 FACILITIES WORKING GROUP.

BARRISTERS' REPORTING SERVICE

1 SECOND, WE PROPOSE TO LIMIT THE RATE PAID
2 TO PATIENT ADVOCATES TO 75 PERCENT OF THE RATE PAID
3 TO THE SCIENTIFIC MEMBERS OF THE GRANTS WORKING
4 GROUP, AND WE WOULD CAP COMPENSATION ON A YEARLY
5 BASIS AT \$15,000 UNLESS THE BOARD WERE TO APPROVE AN
6 EXCEPTION.

7 FINALLY, THE POLICY WOULD REQUIRE THE
8 BOARD TO DETERMINE ON AN INDIVIDUAL BASIS THAT
9 SERVICE ON THE WORKING GROUPS REQUIRES AN
10 EXTRAORDINARY COMMITMENT OF TIME.

11 AND LET ME JUST MAKE TWO FINAL POINTS.
12 ONE IS THAT THIS IS A POLICY. WE WOULD STILL HAVE
13 TO COME BACK TO THE BOARD WITH GUIDELINES TO
14 IMPLEMENT IT. AND TWO IS THAT THE PATIENT
15 ADVOCATES, OUT OF AN ABUNDANCE OF CAUTION AND TO
16 AVOID EVEN THE APPEARANCE OF A CONFLICT OF INTEREST,
17 WILL NOT PARTICIPATE IN THIS DISCUSSION OR VOTE.

18 MS. LANSING: THEREFORE, I'M GOING TO TURN
19 THIS OVER TO MY CO-CHAIR CLAIRE TO CONDUCT THE
20 DISCUSSION.

21 DR. POMEROY: ARE THERE ANY COMMENTS FROM
22 THE BOARD?

23 MR. ROTH: JUST, JAMES, YOU MAY HAVE SAID
24 THIS, BUT WHAT IS THE CURRENT RATE THAT WE'RE PAYING
25 SCIENTIFIC MEMBERS?

BARRISTERS' REPORTING SERVICE

1 MR. HARRISON: THE CURRENT RATE FOR
2 SCIENTIFIC MEMBERS IS \$750 PER DAY.

3 MR. GOLDBERG: MOVE APPROVAL.

4 DR. POMEROY: A SECOND?

5 MR. ROTH: SECOND.

6 DR. POMEROY: AND ALL IN FAVOR.

7 (CHORUS OF AYES.)

8 DR. POMEROY: OPPOSED.

9 (NO RESPONSE.)

10 DR. POMEROY: ABSTAIN? IF YOU COULD RAISE
11 YOUR HAND IF YOU'RE ABSTAINING SO THAT IT CAN BE
12 RECORDED.

13 MS. LANSING: I THINK WE'RE CONFLICTED.

14 MR. HARRISON: YOU'RE ABSTAINING.

15 DR. POMEROY: KEEP YOUR HANDS, PATIENT
16 ADVOCATES, SO WE CAN COUNT YOU.

17 MS. KING: FOR THE RECORD, THE BOARD
18 MEMBERS ABSTAINING FROM THE VOTE ARE JOAN SAMUELSON,
19 JEFF SHEEHY, SHERRY LANSING, FRANCISCO PRIETO, MARCY
20 FEIT, AND DAVID SERRANO-SEWELL.

21 CHAIRMAN KLEIN: TO CLARIFY THAT, SINCE
22 THE STATUTORY CHAIR AND THE STATUTORY VICE CHAIR ARE
23 PAID, THEY'RE EXCLUDED FROM THOSE THAT QUALIFY.

24 DR. POMEROY: SO THERE'S NO CONFLICT FOR
25 THEM.

BARRISTERS' REPORTING SERVICE

1 CHAIRMAN KLEIN: AND FOR THE RECORD,
2 CLAIRE, I THINK IT WOULD BE GOOD TO NOTE THAT THERE
3 WAS NO PUBLIC HERE THAT WISHED TO SPEAK; IS THAT
4 CORRECT?

5 DR. POMEROY: THANK YOU. AND I THINK WE
6 NEED A ROLL CALL ON THE PHONE.

7 MS. KING: KIM WITMER.

8 DR. WITMER: APPROVE.

9 MS. KING: MICHAEL FRIEDMAN.

10 DR. FRIEDMAN: YES.

11 MS. KING: THANK YOU.

12 DR. PENHOET: OS, AREN'T YOU A PATIENT
13 ADVOCATE?

14 DR. STEWARD: ABSTAIN.

15 MS. KING: OSWALD STEWARD ALSO ABSTAINS
16 FROM THAT VOTE. HE'S AN ALTERNATE.

17 MS. LANDING: AT ANY RATE, I THINK THAT
18 CONCLUDES THE TWO AGENDA ITEMS ON GOVERNANCE, AND
19 WE'LL PICK UP THE THIRD ONE IN THE MORNING.

20 CHAIRMAN KLEIN: THANK YOU VERY MUCH. AND
21 WE WILL ADJOURN TO EXECUTIVE SESSION. MR. HARRISON,
22 WILL YOU READ US THE STATUTORY AUTHORIZATIONS FOR
23 THIS EXECUTIVE SESSION?

24 MR. HARRISON: THE BOARD WILL BE CONVENING
25 IN CLOSED SESSION TO DISCUSS PERSONNEL PURSUANT TO

BARRISTERS' REPORTING SERVICE

1 GOVERNMENT CODE SECTION 11126 AND HEALTH AND SAFETY
2 CODE SECTION 125290.30(D)(3)(D).

3 CHAIRMAN KLEIN: ALL RIGHT. AND WITH
4 THAT, MELISSA, WOULD YOU GIVE US INSTRUCTION ON
5 WHERE WE WILL ADJOURN TO?

6 MS. KING: I WILL, BUT I'M GOING TO DEFER
7 TO MY ESTEEMED COLLEAGUE, JENNIFER PRYNE, FOR THAT.

8 MS. PRYNE: MR. CHAIRMAN, I HAVE ROOM 123
9 RESERVED FOR EXECUTIVE SESSION. THERE ARE
10 DIRECTIONAL SIGNS. IF YOU JUST COME OUT INTO THE
11 HALLWAY, AND ALSO AMY AND I WILL BE ABLE TO LEAD THE
12 BOARD MEMBERS TO THE ROOM.

13 CHAIRMAN KLEIN: THANK YOU VERY MUCH.

14 MS. KING: FOR THE MEMBERS THAT ARE ON THE
15 PHONE, YOU HAVE THE DIAL-IN INFORMATION FOR THE
16 CLOSED SESSION, CORRECT?

17 DR. WITMER: YES, I'VE GOT IT.

18 DR. FRIEDMAN: I THINK I DO, BUT I'LL
19 CHECK WITH MARTHA.

20 MS. KING: IF YOU DON'T, PLEASE CALL ME OR
21 AMY AND WE WILL GET IT TO YOU.

22 CHAIRMAN KLEIN: IT IS NOT ANTICIPATED
23 THAT THERE WILL BE ADDITIONAL BUSINESS TODAY. AND,
24 MR. HARRISON, FOR STATUTORY PURPOSES, IS IT GOING TO
25 BE NECESSARY, GIVEN THERE IS NO EXPECTED BUSINESS,

BARRISTERS' REPORTING SERVICE

1 TO RECONVENE?

2 MR. HARRISON: NO. WE WILL RECONVENE IN
3 THE MORNING IN OPEN SESSION.

4 CHAIRMAN KLEIN: THANK YOU. REMEMBER 8:30
5 IN THE MORNING SHOULD BE AN EXCELLENT SPOTLIGHT ON
6 STROKE. AND HOPE EVERYONE CAN BE THERE.

7 MS. KING: EVEN THOUGH WE WON'T RECONVENE,
8 YOU CAN LEAVE YOUR STUFF HERE, AND YOU'LL COME BACK
9 TO THIS ROOM BEFORE WE LEAVE THE MEETING SITE, SO
10 YOU DON'T HAVE TO TAKE ALL OF YOUR STUFF WITH YOU TO
11 THE CLOSED SESSION ROOM, WHICH IS SMALLER.

12 CHAIRMAN KLEIN: COMPUTERS AND THINGS TAKE
13 WITH YOU. JUST DOCUMENTS COULD BE LEFT.

14 MS. KING: PROBABLY A GOOD IDEA ALTHOUGH
15 THERE WILL BE SEVERAL OF US HERE.

16 (THE BOARD THEN CONVENED IN CLOSED
17 SESSION AT 5 P.M., NOT REPORTED NOR HEREIN
18 TRANSCRIBED. AT THE CONCLUSION OF THE CLOSED
19 SESSION, THE MEETING WAS THEN ADJOURNED FOR THE DAY
20 TO RECONVENE THURSDAY, AUGUST 19, 2010, AT 9:30
21 A.M.)

22

23

24

25 STANFORD, CALIFORNIA; THURSDAY, AUGUST 19, 2010

BARRISTERS' REPORTING SERVICE

1 9:30 A.M.

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CHAIRMAN KLEIN: I'D LIKE TO OPEN THE MEETING THIS MORNING. THANK YOU FOR ALL TURNING OUT FOR THIS TREMENDOUS SPOTLIGHT THIS MORNING ON STROKE. THANK YOU, DR. QUINT, FOR LEADING OFF THAT PROGRAM WITH GARY STEINBERG OF AN EXTREMELY EXCITING DISEASE TEAM PROGRAM, THAT IT WAS VERY ENCOURAGING TO HEAR THEIR PROGRESS AND THE DATA TO DATE.

WHAT I'D LIKE TO DO THIS MORNING IS ASK MELISSA KING TO LEAD US IN THE PLEDGE FOLLOWED BY A ROLL CALL, INCLUDING DO WE HAVE PHONE MEMBERS TODAY?

MS. KING: WE DO.

CHAIRMAN KLEIN: SO WE WILL BEGIN WITH THE PLEDGE OF ALLEGIANCE.

(THE PLEDGE OF ALLEGIANCE.)

MS. KING: ROBERT PRICE FOR ROBERT BIRGENEAU.

DR. PRICE: HERE.

MS. KING: FLOYD BLOOM. DAVID BRENNER.

DR. BRENNER: HERE.

MS. KING: WILLIAM BRODY.

DR. BRODY: HERE.

MS. KING: SUSAN BRYANT.

DR. BRYANT: HERE.

BARRISTERS' REPORTING SERVICE

1 MS. KING: MARCY FEIT. MICHAEL FRIEDMAN.
2 LEEZA GIBBONS. MICHAEL GOLDBERG.
3 MR. GOLDBERG: HERE.
4 MS. KING: SAM HAWGOOD. BOB KLEIN.
5 CHAIRMAN KLEIN: HERE.
6 MS. KING: SHERRY LANSING.
7 MS. LANSING: HERE.
8 MS. KING: TED LOVE. ED PENHOET.
9 DR. PENHOET: HERE.
10 MS. KING: PHIL PIZZO.
11 DR. PIZZO: HERE.
12 MS. KING: CLAIRE POMEROY.
13 DR. POMEROY: HERE.
14 MS. KING: FRANCISCO PRIETO.
15 DR. PRIETO: HERE.
16 MS. KING: ELIZABETH FINI FOR CARMEN
17 PULIAFITO.
18 DR. FINI: HERE.
19 MS. KING: ROBERT QUINT.
20 DR. QUINT: HERE.
21 MS. KING: JOHN REED. DUANE ROTH.
22 MR. ROTH: HERE.
23 MS. KING: AND FOR THE RECORD, TED LOVE
24 HAS JOINED THE MEETING.
25 JOAN SAMUELSON.

BARRISTERS' REPORTING SERVICE

1 MS. SAMUELSON: HERE FOR JUST ABOUT 10, 15
2 MORE MINUTES.

3 MS. KING: DAVID SERRANO-SEWELL.

4 MR. SERRANO-SEWELL: HERE.

5 MS. KING: JEFF SHEEHY.

6 MR. SHEEHY: HERE.

7 MS. KING: JON SHESTACK. OSWALD STEWARD.

8 DR. STEWARD: HERE.

9 MS. KING: ART TORRES.

10 MR. TORRES: HERE.

11 MS. KING: JAMES ECONOMOU FOR EUGENE
12 WASHINGTON.

13 DR. ECONOMOU: HERE.

14 CHAIRMAN KLEIN: AND DURING THE DAY, WILL
15 THOSE ON THE PHONE CHANGE?

16 MS. KING: FIRST OF ALL, WE HAVE A QUORUM
17 RIGHT NOW. AND SECOND OF ALL, IT'S POSSIBLE THAT
18 DR. FRIEDMAN WILL BE ABLE TO JOIN US BY PHONE AGAIN
19 TODAY. DR. BRODY IS ON THE PHONE WITH US ALREADY.

20 JUST A COUPLE OF ANNOUNCEMENTS BEFORE WE
21 GET STARTED. EACH BOARD MEMBER HAS IN FRONT OF YOU
22 FOR ONE OF THE ITEMS ON THE AGENDA A CONFLICTS
23 SHEET. YOU EITHER HAVE A CONFLICT OR DON'T HAVE A
24 CONFLICT; AND IF YOU HAVE A CONFLICT, YOU WILL NOT
25 BE PARTICIPATING IN THE DISCUSSION OR VOTE ON THAT

BARRISTERS' REPORTING SERVICE

1 ITEM. WE WILL NEED YOUR SIGNATURE ON THAT PAGE
2 BEFORE YOU LEAVE TODAY. AND SOME OF YOU ALSO HAVE
3 SOME OTHER SHEETS THAT AMY HAS LEFT FOR YOU THAT WE
4 NEED YOU TO SIGN AS WELL. YOU MAY NOTICE THAT SOME
5 OF THEM ARE FROM PREVIOUS MEETINGS. SO JUST IF YOU
6 COULD BEAR WITH US AS WE CATCH UP ON SOME THINGS AND
7 SIGN EVERYTHING AND HAND IT TO AMY, THAT WOULD BE
8 GREAT.

9 THE OTHER MESSAGE IS THAT I UNDERSTAND
10 PEOPLE ARE LOOKING FOR WATER, AND WE'RE WORKING ON
11 GETTING SOME WATER BROUGHT IN FOR YOU.

12 CHAIRMAN KLEIN: NO LUXURIES FOR THIS
13 GROUP.

14 SO IN OPENING THE MEETING TODAY AT
15 STANFORD, I THINK IT'S APPROPRIATE THAT WE JUST TAKE
16 A MOMENT AND RECOGNIZE THAT SIX YEARS AGO AT THE
17 NATIONAL ACADEMY MEETINGS THAT WERE HELD IN IRVINE
18 WITH A NATIONAL TASK FORCE OF THE NATIONAL ACADEMY
19 TO HELP LEAD US IN THE PROCESS OF SETTING UP THIS
20 AGENCY, WE HAD BETH DRAIN WHO WAS THERE DOING THE
21 TRANSCRIPTS. FROM THAT TIME THROUGH OUR ENTIRE
22 EXISTENCE, THE TRANSCRIPTS OF OUR HISTORY, THE
23 PROGRESS OF THIS AGENCY AT EVERY STEP HAS BEEN
24 RECORDED BY BETH.

25 SHE SERVES TO CREATE THE TRANSCRIPTS FOR

BARRISTERS' REPORTING SERVICE

1 THE NATIONAL ACADEMY AND FOR OUR AGENCY. SO WE FEEL
2 VERY PRIVILEGED THAT WE HAVE THIS SIX YEARS OF
3 PHENOMENAL DEDICATION TO OUR RECORD OF HOW AN AGENCY
4 THAT IS REALLY MAKING REMARKABLE PROGRESS IN
5 ADVANCING MEDICINE TO REDUCE HUMAN SUFFERING HAS
6 BEEN BORN AND IS MATURING ALL AT THE FINGERTIPS OF
7 BETH DRAIN. SO THANK YOU, BETH.

8 THE REPORTER: THANK YOU VERY MUCH.

9 MS. SAMUELSON: MR. CHAIRMAN, I'M VERY
10 PROUD THAT SEVERAL YEARS AGO BETH AND I JOINED
11 TOGETHER TO LOBBY SUCCESSFULLY FOR LONGER BATHROOM
12 BREAKS.

13 CHAIRMAN KLEIN: NOW THAT WE'VE COMMENTED
14 ON OUR HISTORY, I'D LIKE TO CALL ON THE PRESIDENT
15 FOR THE PRESIDENT'S REPORT. DR. TROUNSON.

16 DR. TROUNSON: THANK YOU VERY MUCH, CHAIR.
17 HAVE WE GOT IT THERE? LOOKS LIKE THE WRONG SIZE TO
18 ME.

19 I THINK IT'S INTERESTING THAT WE'RE
20 ACTUALLY DOING A LOT OF WORK AT THE MOMENT GETTING
21 READY FOR THE EXTERNAL REVIEW AND LOOKING AT SOME OF
22 THE PRODUCTIVITY ELEMENTS. THERE ARE NOW 585
23 PUBLICATIONS THAT HAVE COME OUT OF THE WORK THAT'S
24 BEEN STIMULATED BY CIRM. THAT'S AN ENORMOUS NUMBER
25 OF PAPERS IN A RELATIVELY SHORT TIME. AND RIGHT

BARRISTERS' REPORTING SERVICE

1 NOW, AT THIS PRESENT TIME RIGHT AT THIS MOMENT, THE
2 NUMBER OF PAPERS THAT ARE APPEARING ARE REALLY
3 ASTONISHING, AND THE QUALITY OF THEM ARE
4 EXTRAORDINARY. SO THIS PARTICULAR MONTH I'M
5 COMPLETELY OVERWHELMED ABOUT WHAT I SHOULD SORT OF
6 POINT OUT TO YOU, BUT MOST OF THESE PAPERS THAT HAVE
7 BEEN PUBLISHED, WHICH I THINK ARE TERRIFIC AND
8 FANTASTIC, ARE CIRM-FUNDED OR RELATED VERY MUCH TO
9 CIRM.

10 AND THE FIRST ONE I KNOW WILL BE OF
11 PARTICULAR INTEREST TO SUSAN BRYANT BECAUSE THIS IS
12 A KIND OF AN AREA THAT SHE'S BEEN INTERESTED IN FOR
13 A VERY LONG TIME IS THE TRANSIENT INACTIVATION OF
14 THESE TWO GENES, RB AND ARF, WHICH YIELD
15 REGENERATIVE CELLS FROM POSTMITOTIC MAMMALIAN
16 MUSCLE; THAT IS, CELLS THAT NO LONGER NORMALLY
17 DIVIDE. THEY'RE BEYOND MITOSIS, SO THEY DON'T
18 REALLY DIVIDE. THEY'RE AN END-STAGE CELL.

19 AND AMPHIBIA AND FISH REGENERATE LIMBS,
20 AND THEY REGENERATE PART OF THEIR HEART BY INDUCING
21 CELL CYCLE RE-ENTRY SO THAT THE CELL CYCLE WHICH
22 TURNS AROUND AND PROVIDES FOR DIVISION CAN BE
23 ACTIVATED, THE CELL CYCLE RE-ENTRY FOR THESE CELLS
24 IN THESE ANIMALS BY INACTIVATION OF THIS GENE RB
25 WHICH INDUCES CELL CYCLE RE-ENTRY AND PROLIFERATION

BARRISTERS' REPORTING SERVICE

1 OF SKELETAL MUSCLE IN LIMB FORMATION.

2 NOW, THE QUESTION IS IS THIS RB IN
3 MAMMALS, WHAT DOES IT DO THERE? IT'S NOT PART OF
4 THIS LIMB REGENERATION BECAUSE MAMMALS DON'T
5 REGENERATE LIMBS. ANIMALS DON'T DO THAT. BUT IT'S
6 BEEN ADOPTED AS A TUMOR SUPPRESSOR AS A DIFFERENT
7 FUNCTION. IT ENFORCES MITOTIC ARREST AND STABLE
8 TISSUE-SPECIFIC GENE EXPRESSION AND PREVENTS CELL
9 CYCLE RE-ENTRY AND INHIBITS APOPTOSIS. THAT'S BEEN
10 A TRADE-OFF FOR LIMB REGENERATION AS IN NEWTS. IT'S
11 REALLY INTERESTING THAT THEY'VE TRADED THESE
12 CHARACTERISTICS IN EVOLUTION.

13 AND SO IN MAMMALS ARF, THE OTHER GENE, IS
14 A REGENERATION REPRESSOR. IT'S NOT PRESENT IN THESE
15 MORE PRIMITIVE ANIMALS. AND IF YOU INACTIVATE BOTH
16 RB AND ARF, IT LEADS TO MAMMALIAN MUSCLE
17 REGENERATION BY CELL CYCLE RE-ENTRY. SO YOU CAN
18 ACTUALLY GET CELL RE-ENTRY IF YOU INACTIVATE BOTH
19 THESE. DEDIFFERENTIATION, WHICH IS INTERESTING
20 BECAUSE THAT REALLY HASN'T BEEN DISCUSSED VERY MUCH
21 IN THE LITERATURE, AND UP REGULATION OF WHAT WE CALL
22 THE CYTOKINETIC CELL MACHINERY THAT ALLOWS CELLS TO
23 START DIVISION AGAIN.

24 SO SINGLE POSTMITOTIC MUSCLE CELLS WERE
25 SHOWN BY THE SCIENTISTS IN HELEN BLAU'S LAB AT

BARRISTERS' REPORTING SERVICE

1 STANFORD TO WHEN YOU TRANSIT, SUPPRESS THESE GENES,
2 THEY FORM WHAT ARE CALLED MYOBLAST COLONIES, SO THEY
3 DEVELOP, THEY MULTIPLY, AND DIFFERENTIATE AND FUSE
4 INTO MYOFIBERS WHEN THEY'RE TRANSPLANTED INTO
5 MUSCLES IN ANIMALS. SO HERE WE'VE GOT A SITUATION
6 WHERE WE'VE TURNED POSTMITOTIC CELLS WHICH FORM
7 MUSCLE BACK INTO A TYPE, A MORE PRIMITIVE TYPE THAT
8 ACTUALLY CAN DO THE JOB.

9 THE QUESTION HERE IS CAN THIS PROCESS BE
10 USED FOR AUTOLOGOUS REGENERATIVE THERAPIES IN THE
11 HUMAN? A BIG QUESTION, BUT A BIG START IN THIS
12 AREA. AND I THINK THIS IS ONE OF THE SORT OF
13 PLATFORM PUBLICATIONS.

14 THE NEXT SLIDE WILL GIVE YOU AN IDEA. SO
15 THIS IS IN MOUSE, RIGHT. THERE ARE THE NEWTS WHERE
16 YOU TAKE OFF THE LEGS OR THE TAILS AND THEY CAN
17 REGENERATE THOSE LEGS OR TAILS. BUT IF YOU LOOK UP
18 ON THE RIGHT-HAND SIDE, IT'S DIFFICULT FOR PEOPLE TO
19 SEE FROM THIS SECTION, BUT THESE CELLS, WHEN YOU'VE
20 GOT THAT INHIBITOR, WILL RETURN INTO A CELL CYCLE
21 AND THEN REFORM A WHOLE LOT OF MUSCLES. AND THOSE
22 MUSCLES CAN GO OFF AND FORM MATURE MUSCLE SO THAT
23 YOU GET ACTUALLY REGENERATION OF MUSCLE. IF THIS IS
24 AROUND BONE STRUCTURES, THEN YOU WILL GET
25 REGENERATION OF AT LEAST THE MUSCLE STRUCTURE OF THE

BARRISTERS' REPORTING SERVICE

1 LIMB.

2 IN SOME SENSE I THINK, ALONG WITH ALL THE
3 WORK THAT PEOPLE DO ON BLASTERMAS, WE'RE ON THE WAY
4 TO SOME VERY INTERESTING, I THINK, INDUCTION OF
5 REGENERATION. AND THIS WILL BE, I THINK, COUNTED AS
6 ONE OF THE SORT OF PRIMARY PAPERS IN THE LITERATURE.
7 AND THE TOP, THE GREEN SECTION SHOWS YOU WHEN YOU'VE
8 INHIBITED -- WHEN YOU TRANSPLANT THESE CELLS AND
9 YOU'VE INHIBITED THOSE GENES, YOU GET LOTS OF MUSCLE
10 FIBERS FORMED. MUSCLES IN GREEN AND THE BELOW PART
11 IS WHEN YOU'VE GOT THAT RB GENE PRODUCT TURNED ON.

12 THE NEXT ONE IS ALSO, I THINK, AN
13 ASTONISHING PIECE OF WORK WHICH WAS REPORTED AT THE
14 ISSCR, THE INTERNATIONAL SOCIETY OF STEM CELL
15 RESEARCH, BUT NOW HAS COME OUT IN THE JOURNAL *CELL*,
16 VERY HIGH IMPACT FACTOR JOURNAL, IN AUGUST AGAIN.
17 AND THIS IS A DIRECT REPROGRAMMING OF FIBROBLASTS,
18 WHICH ARE THE HEART STROMAL CELLS, INTO FUNCTIONAL
19 CARDIOMYOCYTES BY DEFINED FACTORS. SO NOT GOING ALL
20 THE WAY BACK TO A PLURIPOTENTIAL STEM CELL NOW,
21 THREE TRANSCRIPTION FACTORS, GATA4, MEF2C, AND TBX5,
22 ARE NEEDED TO RAPIDLY AND EFFICIENTLY REPROGRAM
23 CARDIAC STROMAL CELLS OR DERMAL FIBROBLASTS INTO
24 CARDIOMYOCYTES.

25 I THINK THE DATA IN THE PAPER SHOWS THAT

BARRISTERS' REPORTING SERVICE

1 IT'S MORE EFFICIENT AND YOU GET A BETTER OUTCOME IF
2 YOU USE THE CARDIAC STROMAL CELLS, THE SO-CALLED
3 MESENCHYMAL CELL TYPE THAT'S PRESENT IN THE HEART
4 TISSUE. THESE CELLS WILL EXPRESS CARDIAC-SPECIFIC
5 MARKERS AND HAVE EXPRESSION PROFILES EQUIVALENT TO
6 CARDIAC CELLS AND CONTRACT SPONTANEOUSLY IN CULTURE.
7 AND WHEN TRANSPLANTED IN MOUSE HEARTS ONE DAY AFTER
8 TRANSDUCTION, SO JUST ONE DAY AFTER, THEY
9 DIFFERENTIATE INTO CARDIOMYOCYTE-LIKE CELLS. AND
10 THIS MAY HAVE USEFUL CLINICAL APPLICATIONS FOR
11 CARDIOMYOPATHIES IN THE FUTURE. IT'S A VERY
12 INTERESTING, VERY INTERESTING PAPER BY THE GROUP AT
13 THE GLADSTONE INSTITUTE, A CIRM-FUNDED PAPER.

14 YOU CAN SEE ON THE LEFT-HAND SIDE IF
15 YOU'RE LOOKING AT IT, YOU'VE GOT THE ACTION
16 POTENTIALS ON THE BOTTOM HERE, AND THAT THE
17 CARDIOMYOCYTES THAT ARE FORMED FROM THIS
18 TRANSFORMATION LOOK TO BE BEHAVE JUST LIKE FETAL
19 CARDIOMYOCYTES. AND THEY HAVE RELEASED -- CALCIUM
20 RELEASED PATTERNS VERY SIMILAR INDEED, THE SAME.
21 AND IF YOU LOOK AT THE INTEGRATION OF THESE CELLS
22 INTO THE TISSUES, THEY APPEAR TO BE INTEGRATING IN A
23 VERY PROFOUND WAY.

24 SO THIS IS A VERY ENCOURAGING PIECE OF
25 WORK AND SUGGESTS TO US NOW THAT DIRECT PROGRAMMING

BARRISTERS' REPORTING SERVICE

1 OF CELLS IS GOING TO BECOME REALLY ONE OF THE HOT
2 TOPICS IN THE REGENERATIVE STEM CELL AREA. I DON'T
3 THINK THERE'S ANY DOUBT ABOUT THAT. IT FOLLOWS NOW
4 ON BEHIND DIRECT PROGRAMMING OF NEURONS, AND IT
5 OBVIOUSLY GETS AROUND ONE OF THE PROBLEMS, IF YOU GO
6 BACK TO PLURIPOTENTIAL STEM CELLS, THAT YOU HAVE A
7 TUMOR-FORMING CAPACITY IN THOSE CELLS. YOU NO
8 LONGER HAVE THAT BECAUSE YOU DON'T GO BACK THAT
9 DISTANCE.

10 SO TWO REALLY IMPORTANT PIECES OF WORK
11 THAT I THINK WE NEED TO RECOGNIZE WILL SORT OF SET
12 THE FIELD, AGAIN, ON FIRE, I THINK.

13 THE NEXT PAPER ALSO COMES FROM HELEN
14 BLAU'S LAB. I RARELY DO THAT, SHOW YOU TWO PAPERS
15 FROM THE SAME LAB. IT'S NOT BECAUSE I'M JUST HERE
16 AT STANFORD. I JUST THINK THESE TWO BITS OF WORK
17 ARE REALLY TERRIFIC.

18 THIS LOOKED AT SUBSTRATE ELASTICITY ON
19 WHICH YOU GROW YOUR STEM CELLS. IT'S A VERY
20 IMPORTANT THING. AND THIS WAS A PAPER THAT CAME OUT
21 OF OUR TOOLS AND TECHNOLOGY GRANTS. SO HERE IS
22 SOMETHING THAT'S REALLY VERY SPECIAL.

23 THEY USED A BIOENGINEERED SUBSTRATE AND A
24 NOVEL AUTOMATED CELL TRACKING ALGORITHM TO SHOW THAT
25 THE SUBSTRATE ELASTICITY, THAT'S WHAT THE CELLS ARE

BARRISTERS' REPORTING SERVICE

1 GROWN ON, IS A VERY POTENT REGULATOR OF MUSCLE STEM
2 CELL FATE.

3 IF YOU LOOK AT THE TWO GRAPHS ON THE
4 LEFT-HAND SIDE THERE, THE UPPER GRAPH IS WHERE
5 YOU'VE GOT A PLIANT SURFACE THAT YOU'RE GROWING THE
6 CELLS ON. AND THE ONE ON THE BOTTOM IS RIGID. IF
7 YOU LOOK THE DIFFERENT COLORS, THESE REPRESENT
8 DIFFERENT GENERATIONS OF CELLS, AND YOU CAN SEE ON
9 THE PLIANT SIDE THAT THERE'S MANY MORE CELLS GROWING
10 OVER MANY MORE GENERATIONS. IT LOOKS A MUCH
11 HEALTHIER CULTURE. THE CELLS ARE REALLY MULTIPLYING
12 VERY MUCH BETTER THAN WHEN THEY ARE ON A RIGID
13 SURFACE.

14 AND THEN IF YOU HAVE A LOOK AT THE GRAPH
15 HERE, YOU CAN AGAIN SEE THE PLIANT SURFACE OF THE
16 CELLS ARE PERFORMING MUCH BETTER THAN THE RIGID AND
17 GETTING CLOSER TO THOSE FRESH CELLS WHERE WE'VE JUST
18 TAKEN THEM OUT AND THEN RELOOKED AT THEM AGAIN.

19 AND SO HERE'S SOMETHING THAT'S VERY
20 SPECIAL. IF YOU ARE GOING TO GROW CELLS OF
21 DIFFERENT TYPES, YOU NEED TO BE THOUGHTFUL ABOUT
22 WHAT YOU'RE GROWING THEM ON, THE MATRIX, THE KIND OF
23 SUBSTRATE THAT'S THERE, BUT ALSO THE PHYSICAL NATURE
24 OF THOSE SUBSTRATES BECAUSE THAT'S GOING TO HAVE A
25 VERY PROFOUND EFFECT ON WHAT HAPPENS TO YOUR CELLS.

BARRISTERS' REPORTING SERVICE

1 AND IF YOU'RE GOING TO MULTIPLY CELLS, YOU NEED TO
2 BE THOUGHTFUL ABOUT THAT AS WELL. IF YOU WANT TO
3 EXPAND CELLS IN LARGE QUANTITIES, YOU'RE GOING TO
4 HAVE TO BE THOUGHTFUL ABOUT THE PROPERTIES OF THE
5 MATRIX AND OF THE STRUCTURES THAT YOU GROW THEM ON.

6 I THINK IT'S A VERY IMPORTANT SEMINAL
7 PAPER AGAIN PUBLISHED FROM SUPPORT THAT WE GAVE
8 HELEN AND HER COLLEAGUES HERE AT STANFORD. TERRIFIC
9 COUPLE OF PAPERS FROM THAT LAB, FANTASTIC. AND I
10 THINK, AGAIN, THIS WILL WAKE UP THE FIELD IN TERMS
11 OF HOW THEY PREPARE THEIR CELLS.

12 THE NEXT ONE IS A VERY INTERESTING PAPER,
13 AND SOME PEOPLE HERE WILL KNOW THIS WELL. I'M SURE
14 JEFF SHEEHY WILL KNOW THIS WORK VERY WELL. HE'S NOT
15 HERE. THIS IS THE WORK THAT'S BEEN PUBLISHED BY THE
16 GROUP AT USC. AND IT'S PAULA CANNON'S LAB. AND
17 PAULA IS PART OF THE DISEASE TEAM WHICH IS JOHN
18 ZAIA'S DISEASE TEAM WHERE THEY'RE ACTUALLY
19 INTERFERING WITH THE CCR5 GENE. THE CCR5 GENE IS A
20 CO-RECEPTOR FOR THE VIRUS THAT ALLOWS THE HIV-1
21 VIRUS TO INFECT THE BLOOD CELLS. WITHOUT IT, YOU
22 DON'T GET INFECTION OF BLOOD CELLS.

23 IF YOU DISRUPT THE CCR5 GENE, AND THEY DID
24 THIS IN HUMAN C34 POSITIVE HEMATOPOETIC STEM CELLS
25 USING AN ENGINEERED ZINC-FINGER NUCLEASE, WHICH IS

BARRISTERS' REPORTING SERVICE

1 MADE REALLY -- THIS TECHNOLOGY IS MADE BY SANGAMO, A
2 CALIFORNIA COMPANY. YOU GET A VERY HIGH EFFICIENCY
3 EFFECT OF THAT, AND IT INTERRUPTS THE CCR5 GENE BOTH
4 IN ONE ALLELE AND IN TWO ALLELES. SO YOU GET EITHER
5 MONO- OR BI-ALLELIC DISRUPTION. IT'S IMPORTANT,
6 THAT CHARACTERISTIC, BECAUSE IF YOU GET BI-ALLELIC
7 DISRUPTION, YOU DON'T HAVE A NORMAL GENE PRESENT
8 THERE. YOU CAN'T GET A NORMAL PRODUCT.

9 SO WHEN THEY USE THE HUMAN HEMATOPOIETIC
10 STEM CELLS ENGRAFTED INTO MICE WITH PERMANENTLY
11 DISRUPTED CCR5 AND WHEN CHALLENGED WITH THE TROPIC
12 HIV-1, THERE WAS A RAPID SELECTION FOR THE CCR5
13 NEGATIVE CELLS. AND THESE WERE THE ONES THAT WERE
14 BI-ALLELIC, AND THESE CELLS WERE PRESERVED. THERE
15 WAS A SIGNIFICANTLY LOWER HIV PRESENT IN THOSE
16 ANIMALS AND IN CONTROLS, AND THEY SHOWED A PROFOUND
17 CD35 POSITIVE T-CELL LOSS IN THE CONTROL. SO IF IN
18 YOUR CONTROLS YOU HAD A PROFOUND EFFECT ON YOUR
19 HEMATOPOETIC BLOOD SYSTEM, YOU LOST THOSE BECAUSE OF
20 THE INFECTION BY THE HIV-1 VIRUS; BUT IF YOU
21 DISRUPTED THE CCR5 GENE, THOSE CELLS DOMINATED,
22 BECAME DOMINANT, AND THE ANIMALS LOST THEIR
23 INFECTABILITY AND PRESERVED -- WHAT WAS PRESERVED
24 WAS THE CELLS WHICH HAD THE BI-ALLELIC DISRUPTION.

25 THAT'S A VERY IMPORTANT PROOF OF CONCEPT,

BARRISTERS' REPORTING SERVICE

1 IF YOU LIKE, FOR THAT WORK. THIS WILL ESTABLISH A
2 VERY NICE STEP FORWARD FOR THAT DISEASE TEAM BECAUSE
3 THAT HAS REALLY GIVEN THAT PROOF OF CONCEPT IN AN
4 ANIMAL MODEL AND WILL ACCELERATE, I THINK, THAT
5 PROJECT VERY RAPIDLY.

6 SO I THINK IT WAS A GREAT PIECE OF WORK.
7 PAULA CANNON, AS I SAID, IS PART OF THAT DISEASE
8 TEAM AND OTHERS THAT ARE AUTHORS ON THAT PARTICULAR
9 PAPER, EVEN THOUGH WE DIDN'T FUND SPECIFICALLY THAT
10 WORK, DR. KOHN AND DR. CROOKS, THEY'RE ALSO CIRM
11 GRANTEES. BUT IT IS THE KEY PIECE OF INFORMATION
12 THAT WILL ENABLE THAT DISEASE TEAM.

13 CHAIRMAN KLEIN: DR. TROUNSON, IN THIS
14 PARTICULAR DISEASE TEAM, IS THERE ALSO AN ATTEMPT TO
15 HAVE A CONCURRENT SECOND GENE DISRUPTION IN THIS
16 WORK?

17 DR. TROUNSON: NO. THAT'S NOT THE
18 INTENTION IN THIS PARTICULAR DISEASE TEAM. IT IS IN
19 THE OTHER DISEASE TEAM.

20 I THINK I WANTED TO DRAW YOUR ATTENTION TO
21 JOHN WAGNER'S WORK. JOHN IS AT THE UNIVERSITY OF
22 MINNESOTA, SO HE'S NOT A CALIFORNIAN AND NOT A
23 GRANTEE, BUT HE ACTUALLY WORKS ON THE GRANTS WORKING
24 GROUP. AND IT'S A BEAUTIFUL PIECE OF WORK PUBLISHED
25 IN THE *NEW ENGLAND JOURNAL OF MEDICINE* SHOWING THAT

BARRISTERS' REPORTING SERVICE

1 BONE MARROW TRANSPLANTATION WILL ESSENTIALLY CORRECT
2 RECESSIVE DYSTROPHIC EMPIDERMOLYSIS BULLOSA, THAT
3 DREADFUL DISEASE THAT WE'VE SHOWN YOU IN THE PAST.
4 AND IT IS, AGAIN, ONE OF THE DISEASE TEAM'S TARGETS
5 HERE FROM DR. LANE'S GROUP HERE AT STANFORD.

6 SO THIS IS AN INCURABLE GENETIC DISEASE
7 CAUSED BY MUTATIONS OF THE COLLAGEN 7 GENE AND
8 INTERFERES WITH THE ANCHORING OF THE SKIN OR THE
9 EPIDERMIS TO THE DERMIS. SO YOU'RE JUST ABLE TO
10 EASILY BRUSH THIS DERMIS AWAY. SO PATIENTS LOOK
11 LIKE THEY HAVE DREADFUL BURNS.

12 THEY TREATED SEVEN CHILDREN WITH THIS
13 RECESSIVE DEB WITH IMMUNOMYELOABLATIVE CHEMOTHERAPY
14 AND ALLOGENEIC HLA MATCHED SIBLING BONE MARROW STEM
15 CELL TRANSPLANTATION OR UMBILICAL CORD BLOOD.
16 UNFORTUNATELY ONE PATIENT DIED, AND THAT WAS VERY
17 EARLY IN THE TREATMENT. AND THIS IS VERY PROBABLY
18 BECAUSE OF THE CHEMOTHERAPY THAT WAS INVOLVED.
19 THERE WAS ALSO ONE SEVERE REGIME-RELATED CUTANEOUS
20 TOXICITY ON DAY 17 -- I'LL SHOW YOU THAT IN A
21 MOMENT -- PROBABLY DUE AGAIN TO THE CHEMOTHERAPY.

22 ALL SURVIVING SIX PATIENTS, INCLUDING THAT
23 PARTICULAR PATIENT, HAD IMPROVED WOUND HEALING,
24 REDUCED BLISTER FORMATION AFTER 30 TO 130 DAYS AFTER
25 TRANSPLANTATION. UNFORTUNATELY ONE CHILD DIED AS A

BARRISTERS' REPORTING SERVICE

1 RESULT OF GRAFT REJECTION AND INFECTION AT 183 DAYS.
2 AND THIS WAS THE CHILD THAT RECEIVED THE UNRELATED
3 CORD BLOOD DONOR CELLS, AND THAT HAD TO BE
4 ADMINISTERED TWICE. UNFORTUNATELY THAT CHILD DIED.

5 THE SIX PATIENTS HAVE HAD SUBSTANTIAL
6 PROPORTIONS OF DONOR CELLS IN THE SKIN, AND THIS IS
7 ASTONISHING. SO THEY WERE GIVEN BONE MARROW, YET
8 THEY HAD SKIN CELLS, 20 PERCENT OF THE CELLS IN
9 THEIR SKIN WERE FROM THE DONOR, SO SOMETHING IS ODD
10 HERE BECAUSE IT'S NOT MEANT TO HAPPEN. BONE MARROW
11 IS NOT MEANT TO CHANGE OVER TO SKIN. IT'S JUST NOT
12 MEANT TO DO THAT.

13 SO THIS HAS RAISED A VERY INTERESTING
14 QUESTION, I THINK, ABOUT WHAT CELLS ARE IN THAT BONE
15 MARROW THAT MIGHT DO THAT OR HOW THAT'S ACTUALLY
16 EFFECTED. I THINK IT WILL RAISE A LOT OF INTEREST,
17 AGAIN, IN THE WHOLE FIELD ABOUT WHAT THESE CELLS CAN
18 ACTUALLY DO AND WHETHER THEY CAN ACTUALLY
19 TRANSDIFFERENTIATE. I THINK THE QUESTION WILL BE
20 RAISED CERTAINLY AGAIN FROM THAT. SO --

21 DR. BRYANT: COULD I ASK A QUESTION? SO
22 WHAT KIND OF SKIN CELLS WERE THEY? WERE THEY
23 EPIDERMAL?

24 DR. TROUNSON: YES. THEY HAD EPIDERMAL
25 MARKERS, AND THEY DID THE ELECTRON MICROSCOPY. THEY

BARRISTERS' REPORTING SERVICE

1 LOOKED LIKE SKIN CELLS, EPIDERMAL SKIN CELLS. THEY
2 WERE DEFINITELY DONOR, AND THERE WAS NO EVIDENCE OF
3 FUSION. SO IT'S JUST INTERESTING, AND THEY HAD A
4 LOT OF TROUBLE GETTING THAT PAPER PUBLISHED BECAUSE
5 OF THAT PARTICULAR REASON, I THINK. AND THEY LEFT
6 OUT A LOT OF DISCUSSION ON THIS.

7 I TALKED TO JOHN BECAUSE I SAID THIS IS
8 REALLY, REALLY INTERESTING. AND HE SAID, "WELL, THE
9 VIEW OF THE JOURNAL WAS TO KEEP THAT DOWN." THEY
10 WANTED TO ACTUALLY PUBLISH THIS WORK, BUT IT IS A
11 SOURCE OF REAL INTEREST FOR THE BASIC SCIENTISTS
12 ABOUT WHAT'S HAPPENING THERE.

13 YOU CAN SEE IN THESE STUDIES IT'S JUST
14 SHOWING THE BEFORE AND AFTER OF THESE PATIENTS, AND
15 THE PATIENTS, SEVEN OVER HERE, HAD THAT BAD RESPONSE
16 AT DAY 17, BUT THEN CLEARED UP AFTER DAY 25 AND DAY
17 132. YOU CAN SEE THAT THESE PATIENTS HAVE RESPONDED
18 QUITE DRAMATICALLY IN THEIR SKIN, AND THEY'VE GOT A
19 MUCH BETTER SKIN CONDITION. AND IT'S ESSENTIALLY
20 AROUND 20 PERCENT OF DONOR CELLS THAT ARE PRESUMABLY
21 MAKING ENOUGH NORMAL COLLAGEN 7 THAT ALLOWS THE
22 ANCHORING TO OCCUR.

23 NOW, IF THE POPULATION IS PRESENT THERE
24 FOR LONG ENOUGH, THIS SHOULD BE SUSTAINABLE. AND I
25 DON'T THINK IT'S GOING TO GO AWAY. AT 20 PERCENT IT

BARRISTERS' REPORTING SERVICE

1 APPEARS TO BE SUFFICIENT TO CORRECT THIS DISEASE.
2 SO IT'S A VERY INTERESTING PAPER AND WILL BE
3 CONSIDERED ONE OF THESE LANDMARK PAPERS. SO WE'VE
4 HAD -- THOSE PAPERS, I JUST WAS ASTONISHED AT THE
5 QUALITY OF THESE PAPERS AND HOW THEY'RE CHANGING THE
6 FIELD INCREDIBLY DRAMATICALLY. BUT ALSO FOUR OF
7 THOSE PAPERS -- AND I DON'T SELECT THEM BECAUSE
8 THEY'RE CIRM PAPERS. I SELECT THEM BECAUSE I THINK
9 THEY'RE OUTSTANDING PAPERS. FOUR OF THEM DERIVED
10 FROM CALIFORNIA INITIATIVE. AND, OF COURSE, JOHN IS
11 A VERY CLOSE COLLEAGUE IN THE LAST ONE.

12 SO SHALL WE MOVE ON?

13 I WANT TO INTRODUCE YOU TO TWO MEMBERS OF
14 OUR PERSONNEL, MANI VESSAL. HE EVEN LOOKS LIKE HIS
15 PICTURE. ARIE ABO. MANI IS FROM STANFORD, SO I'M
16 SURE THE DEAN WILL RECOGNIZE HIM AS A PAST MEMBER OF
17 THEIR UNIVERSITY. AND ARIE HAS COME FROM NUVELO,
18 INC. SO VERY IMPORTANT ADDITIONS TO THE SCIENCE
19 TEAM. THANKS, GUYS.

20 MY PRIORITIES, JUST TO GIVE YOU A HEADS-UP
21 OF WHAT I'VE BEEN DOING, A LOT OF TIME AT THE MOMENT
22 IS BEING SPENT ON THIS EXTERNAL REVIEW COMMITTEE AND
23 PREPARING INFORMATION, GETTING US ALL ORGANIZED FOR
24 THAT. I MADE LOTS OF VISITS TO CIRM GRANTEEES,
25 CALIFORNIA INSTITUTES. IT'S ONE OF THE THINGS THAT

BARRISTERS' REPORTING SERVICE

1 I REALLY, REALLY ENJOY DOING. I HAD A GREAT TIME AT
2 BERKELEY AND AT UC SANTA BARBARA. SO I'M GETTING
3 AROUND TO ALL THE INSTITUTES, AS MANY AS I CAN, ALSO
4 VISITING SOME OF THE COMPANIES ON MY WAY.

5 WE'RE STILL INVOLVED IN A VP R&D SEARCH.
6 UNFORTUNATELY LAST COUPLE OF PEOPLE HAVE TURNED US
7 DOWN, SO WE'RE BACK IN THAT SEARCH AND SPENDING
8 QUITE A BIT OF TIME ON THAT. WE'VE BEEN PREPARING
9 FOR THE CLINICAL RFA. AND TO REMIND ME, BOB, WE
10 NEED TO GET THAT DONE IN THE NEXT COUPLE OF DAYS.
11 SO IF YOU AND JAMES COULD SORT OF GET YOUR EYE ON
12 THAT. WE'VE DONE A LOT OF WORK ON IT. I HOPE THAT
13 YOU TWO CAN SORT OF GIVE US THE FEEDBACK PRETTY
14 QUICKLY.

15 THE DISEASE TEAM PROGRAM WHICH WE'RE
16 PRESENTING TO YOU TODAY, SO I'LL SAY NO MORE ABOUT
17 IT.

18 I'VE HAD -- PRESIDENT'S EVALUATION. I'VE
19 HAD TO DO SOME THINGS ON THAT, SOME DOCUMENTS IN
20 SUPPORT OF MYSELF. IT'S NOT THE MOST -- THE THING I
21 ENJOY DOING MOST, I CAN TELL YOU.

22 CALIFORNIA STEM CELL LEADERSHIP AWARDS, I
23 HAD A LOT OF DISCUSSION WITH INSTITUTIONS, ALSO WITH
24 POTENTIAL PEOPLE WHO ARE INTERESTED. BEEN INVOLVED
25 WITH THE ALLIANCE FOR REGENERATIVE MEDICINE.

BARRISTERS' REPORTING SERVICE

1 THEY'RE VERY BUSY AT THE PRESENT TIME. AND WE'RE
2 DOING A LOT OF WORK IN ASSOCIATION WITH THE FDA IN
3 GETTING STANDARDS AND CHARACTERIZATIONS FOR STEM
4 CELLS INTO A MORE SENSIBLE SET OF REGULATIONS. SO
5 WE'RE WORKING TOGETHER WITH THE FDA ON THAT. I'VE
6 BEEN WORKING ON THE ONLINE JOURNAL.

7 CHAIRMAN KLEIN: DR. TROUNSON, THE ONLINE
8 JOURNAL, I BELIEVE, JUST TO BRING EVERYONE TOGETHER
9 IN COMMUNICATIONS, IS COMING BACK TO THE FINANCE
10 COMMITTEE.

11 DR. TROUNSON: FINANCE COMMITTEE. SO IT
12 WILL COME BACK ON THAT. COMMUNICATIONS,
13 COLLABORATIVE FUNDING AGREEMENTS, AND CONTRACTS HAVE
14 BEEN OCCUPYING QUITE A BIT OF TIME. CIRM SCIENTIFIC
15 CREATIVITY INTERNSHIPS AND WORKSHOP REPORTS. SO,
16 AGAIN, IT'S BEEN A BUSY TIME.

17 THE UPCOMING RFA, EARLY TRANSLATIONAL
18 II --

19 CHAIRMAN KLEIN: I THINK SENATOR TORRES
20 HAS A QUESTION.

21 MR. TORRES: JUST A COMMENT ON THE SEARCH
22 FOR VP OF R&D. I MET WITH THE SEARCH FIRM THAT WE
23 HIRED TO ASK THEM TO EXPAND THEIR SEARCH A LITTLE
24 MORE TO INCLUDE MORE CANDIDATES OF COLOR AND WOMEN.
25 AND I KNOW THEY SPOKE TO DR. POMEROY AND DR. LOVE

BARRISTERS' REPORTING SERVICE

1 AND SUBSEQUENTLY SPOKE TO ALAN AFTER THAT MEETING.

2 AND THEY SEEM TO BE COMING UP WITH SOME OTHER
3 CANDIDATES HOPEFULLY FOR US TO BE ABLE TO REVIEW.

4 DR. TROUNSON: UPCOMING RFA'S, EARLY
5 TRANSLATIONAL II, REVIEW IN SEPTEMBER, ICOC EARLY
6 OCTOBER. TOOLS AND TECHNOLOGIES, FULL GRANT
7 APPLICATIONS EXPECTED IN AUGUST THE 26TH, THE REVIEW
8 IN NOVEMBER, TO THE ICOC IN JANUARY. THE CLINICAL
9 PROGRAM WE WANT TO POST AS SOON AS POSSIBLE WITHIN
10 THE NEXT FEW DAYS, IF IT'S POSSIBLE. WE WANT TO GET
11 IT OUT THERE. WE'VE DONE ALL OUR WORK. WE'VE
12 WORKED HARD ON THAT. THE REVIEW FOR FEBRUARY, WHICH
13 SHOULD BE A VERY INTERESTING REVIEW, I THINK, AND
14 THEN THE ICOC IN MAY. BASIC BIOLOGY III WE EXPECT
15 TO RECEIVE PREAPPLICATIONS BY OCTOBER THE 7TH, FULL
16 APPLICATIONS IN JANUARY, REVIEW IN MARCH, AND TO THE
17 ICOC IN MAY. SO A VERY BUSY PROGRAM IN FRONT OF US
18 RIGHT NOW.

19 UPCOMING RFA'S, THE DISEASE TEAM II WE'RE
20 PRESENTING YOU THE CONCEPT TODAY.

21 WORKSHOP REPORTS, WE HAVE A NUMBER OF
22 WORKSHOPS. THIS ONE ON THE MRC WHICH WAS THE
23 SOMATIC CELL NUCLEAR TRANSFER-PARTHENOGENESIS
24 WORKSHOP, WHICH WAS A VERY INTERESTING WORKSHOP,
25 BROUGHT ALL OF THE PEOPLE WORKING IN THE FIELD FROM

BARRISTERS' REPORTING SERVICE

1 AROUND THE WORLD TOGETHER. IT WAS VERY USEFUL
2 WORKSHOP MEETING. THE MAIN QUESTION WAS HOW DOES
3 HUMAN SCNT FIT INTO THE CURRENT STEM CELL FIELD?
4 IT'S A REALLY BURGEONING QUESTION. IT'S ONE OF THE
5 THINGS THAT THIS ORGANIZATIONS WAS SET UPON AS ONE
6 OF THE SORT OF FOUNDING STONES, I THINK.

7 WE HAD A COMPREHENSIVE DISCUSSION WHICH
8 SPANNED TOPICS LIKE TECHNIQUES, STATUS OF THE
9 TECHNOLOGY, COMPARISON TO OTHER METHODOLOGIES,
10 INCLUDING INTERSPECIES SCNT BECAUSE OF THE
11 DIFFICULTY IN IDENTIFYING AND OBTAINING HUMAN
12 OOCYTES, AND PARTHENOGENESIS WHICH DOESN'T INVOLVE A
13 NUCLEAR TRANSFER PROCEDURE. LOOKED AT BARRIERS TO
14 PROGRESS AND THE POTENTIAL APPLICATION.

15 THE WORKSHOP REPORT IS IN ITS FINAL STAGES
16 OF PREPARATION. AND I THINK THE OVERALL CONCLUSIONS
17 FROM THAT WORKSHOP IS THAT HUMAN SCNT WARRANTS
18 FURTHER EXPLORATION, AND THAT A CALL FOR
19 COLLABORATION AMONGST LABS ATTEMPTING THIS WORLDWIDE
20 WOULD BE THE MOST USEFUL WAY OF GOING FORWARD. THE
21 TROUBLE WITH THE SMALL GROUPS OPERATING IN DIFFERENT
22 PARTS OF THE WORLD, THEY'RE REALLY NOT MAKING IT.
23 AND IF WE COULD ALL GET TOGETHER AND HAVE ONE GOOD,
24 DECENT GO AT IT, WE MIGHT BE ABLE TO GENERATE AT
25 LEAST SOME SCNT CELL LINES, WHICH WILL BE VERY

BARRISTERS' REPORTING SERVICE

1 USEFUL FOR COMPARISON PURPOSES, PARTICULARLY
2 COMPARISON PURPOSES WITH IPS CELLS.

3 WE HAD A WORKSHOP WITH OUR COLLABORATIVE
4 FUNDERS, THIS NETWORK THAT WE SET UP. TEN AGENCIES
5 SENT REPRESENTATIVES, INCLUDING GERMANY, THE UNITED
6 KINGDOM, JAPAN, AND KOREA AND INDIA. WE EVALUATED
7 THE CONTRIBUTIONS BY NATIONAL RESEARCH TEAMS TO
8 DATE, HOW WELL WAS IT GOING, WHAT WERE THE
9 CONTRIBUTIONS, WAS IT SATISFYING. WE DISCUSSED
10 CHALLENGES OF JOINT FUNDING, THE BEST PRACTICE FOR
11 ADDRESSING THESE, AND LOOKED AT OPPORTUNITIES FOR
12 NUMEROUS SIDE MEETINGS WITH INTEREST -- THERE
13 REALLY, REALLY WAS A VERY STRONG INTEREST STILL IN
14 WORKING WITH CALIFORNIA SCIENTISTS. SO THAT WAS A
15 REALLY KEY PART OF THE MEETING. THEY REALLY WANT TO
16 WORK WITH CALIFORNIA SCIENTISTS. I THINK THAT IS
17 THE REAL KEY TO THAT PARTICULAR WORKSHOP.

18 WE MET WITH THE NETHERLANDS, AND THEY'RE
19 ATTEMPTING TO SET UP A COLLABORATION WITH US. IT'S
20 A BIT MORE COMPLEX THAN THE NORMAL ONE. WE HAD CIRM
21 PEOPLE AT THE MEETING, DUTCH OFFICIALS, AND STEM
22 CELL SCIENTISTS FROM BOTH CALIFORNIA AND THE
23 NETHERLANDS. WE DISCUSSED THE COOPERATIVE PROGRAMS
24 AND POTENTIAL MOU AND PROPOSED A NETWORKING WORKSHOP
25 TO FACILITATE COLLABORATION. THAT'S IN PART STILL

BARRISTERS' REPORTING SERVICE

1 GENERATING ITS ACTIVITIES, SEEING LATER THIS YEAR
2 WHETHER THERE'S REALLY AN ABILITY TO PUT THAT
3 TOGETHER. SO THE KEY PART OF IT IS CAN WE GET THE
4 FUNDING FROM THE NETHERLANDS TO ADD TO OUR FUNDING
5 TO MAKE IT A PROPER COLLABORATIVE TEAM. SO THAT'S
6 STILL A KEY BIT TO THAT. WE'RE ON OUR WAY, BUT WE
7 HAVEN'T COMPLETED IT TO OUR SATISFACTION, EITHER
8 SIDE, AT THIS STAGE.

9 SO THE BRIDGES PROGRAM, I THINK IT WAS A
10 VERY IMPORTANT TRAINEE MEETING. THAT WAS HELD IN
11 JULY 8TH AND 9TH IN SAN FRANCISCO ATTENDED BY 155
12 BRIDGES TRAINEES. THERE WERE 81 OF THE TRAINEES,
13 155 PEOPLE ALTOGETHER, INCLUDING PROGRAM DIRECTORS,
14 TRAINEE MENTORS, AND CIRM STAFF.

15 AND THE HIGHLIGHTS OF THE PROGRAM INCLUDED
16 POSTER PRESENTATIONS OF INTERNSHIP RESEARCH BY THE
17 TRAINEES AND LECTURES BY LEADING SCIENTISTS,
18 INCLUDING DR. GAYLE MARTIN, LARRY GOLDSTEIN, VICTOR
19 CORCES, TED LOVE, AND AN ANN TSUKAMOTO, AND PROVIDED
20 NETWORKING CAREER OPPORTUNITIES SESSIONS. AND I
21 THINK THEY ENJOYED IT VERY, VERY MUCH. AND
22 EVERYBODY THAT WAS THERE -- EVERYBODY THAT I MET
23 THAT WENT TO THAT HAD A TERRIFIC TIME. SO I THINK
24 IT WAS A CHANCE FOR THEM TO MEET AMONGST EACH OTHER.
25 A MORE PEER-RELATED MEETING WAS VERY, VERY

BARRISTERS' REPORTING SERVICE

1 PRODUCTIVE FOR THEM.

2 I THINK THE NEXT ONE -- ANOTHER WORKSHOP.
3 THERE'S A CIRM IPS CELL WORKSHOP, BANKING WORKSHOP,
4 THAT WE'VE ORGANIZED FOR NOVEMBER 17TH AND 18TH.
5 AND THIS WORKSHOP IS GOING TO BE ATTENDED BY DR.
6 YAMANAKA. HE'S MAKING PREPARATIONS TO BE HERE. AND
7 BY JAMIE THOMSON. IT'S REALLY HARD TO GET THESE TWO
8 GUYS TO COME TO A WORKSHOP, BUT THEY'RE VERY
9 INTERESTED. SO THIS IS A REALLY KEY WORKSHOP TO GET
10 THE SCIENTISTS TOGETHER, CLINICIANS, RESEARCHERS,
11 AND CELL BANKING PROFESSIONALS, AS WELL AS ACADEMIC
12 INDUSTRIES AND AS WELL AS INDUSTRY.

13 WE'RE INTERESTED IN GENERATING
14 PATIENT-SPECIFIC INDUCED IPS CELLS BECAUSE I THINK
15 THEY'VE GOT AN UNPRECEDENTED OPPORTUNITY HERE IN
16 UNDERSTANDING DISEASE AND PERHAPS IN DRUG DISCOVERY
17 AND TOXICOLOGY, BUT IN UNDERSTANDING DISEASE IS WHAT
18 I THINK WOULD DO SOMETHING VERY SPECIAL. SO THE
19 INTEREST HERE HAS INTENSIFIED THE NEED FOR
20 DEVELOPMENT OF A BANK WITH PATIENTS WITH A BROAD
21 GENOTYPE FROM A VARIETY OF DISEASES USING A SINGLE
22 METHOD AND A CENTRALIZED CELL PROCESS SO THAT THEY
23 CAN ACTUALLY TAKE SAMPLES FROM PATIENTS WITH
24 SPECIFIC DISEASES AND CREATE THE HETEROGENEITY OF
25 THAT DISEASE.

BARRISTERS' REPORTING SERVICE

1 YOU CAN'T DO THAT WITH MOUSE MODELS. WHAT
2 YOU CAN ONLY DO WITH A MOUSE MODEL IS CREATE THE
3 MOUSE MODEL OF THE HUMAN DISEASE, BUT NOT THE HUMAN
4 DISEASE. WITH THIS SYSTEM YOU CAN ACTUALLY CREATE
5 THE WHOLE HETEROGENEITY OF THE DISEASE. AND IF YOU
6 CAN THEN DEVELOP DISEASE-IN-A-DISH MODELS, YOU'VE
7 GOT AN INCREDIBLY INTERESTING WAY OF INTERROGATING
8 THAT DISEASE BECAUSE YOU CAN FIND OUT WHETHER THOSE
9 CELLS WILL RESPOND TO DIFFERENT DRUGS OR NOT RESPOND
10 TO THEM, WILL RESPOND ADVERSELY. SO IT TAKES YOU
11 INTO A WHOLE NEW AREA OF MEDICAL RESEARCH WHICH I
12 THINK AS A BASIC RESOURCE WOULD LAST DECADES,
13 DECADES FOR CALIFORNIA AND PROBABLY THE WORLD.

14 SO WE WANT TO HAVE A DISCUSSION WITH
15 SCIENTISTS ABOUT THAT. THE REASON WE'RE MAKING ONE
16 METHOD IS YOU NEED TO REMOVE ALL OF THE VARIABILITY
17 THAT'S CAUSED BY MAKING THEM BY DIFFERENT METHODS
18 AND IN DIFFERENT LABORATORIES. SO WE'RE BRINGING
19 TOGETHER THE THOUGHT LEADERS IN THE FIELD TO DISCUSS
20 THESE ISSUES AND THE CONSIDERATIONS AROUND IT BEFORE
21 WE SORT OF GENERATE SOME RECOMMENDATIONS THAT WE'LL
22 BRING BACK HERE IN DUE COURSE.

23 SO IF I CAN INTRODUCE ELONA BAUM AS CHIEF
24 COUNSEL TO GIVE YOU AN UPDATE ON SEVERAL LEGAL
25 ISSUES.

BARRISTERS' REPORTING SERVICE

1 MS. BAUM: THANK YOU VERY MUCH. I JUST
2 HAVE A FEW SLIDES TO TALK ABOUT SOME OF THE
3 INITIATIVES THAT THE LEGAL OFFICE IS DOING, AND THIS
4 BY NO MEANS IS REPRESENTATIVE OF THE MANY DIFFERENT
5 ACTIVITIES THAT WE HAVE. BUT IN OUR LAST ICOC
6 MEETING, I THINK ONE OF THE REQUESTS WAS THAT WE
7 WOULD DO AN UPDATE OF THE FDA HARMONIZATION-TYPE
8 WORKSHOPS THAT WE'RE DOING. SO I'LL BE TOUCHING ON
9 THAT AND ON SOME OF THE IP ISSUES THAT WE'RE
10 ADDRESSING.

11 THE FIRST TOPIC THAT I WANTED TO TALK
12 ABOUT WAS THE CIRM/ISSCR/ISCT HARMONIZATION WORKSHOP
13 THAT WE DID. IT WAS AN ALL-DAY WORKSHOP THAT
14 OCCURRED ON JUNE 15TH. IT WAS THE DAY BEFORE THE
15 ISSCR CONFERENCE. IT WAS A TERRIFIC TURNOUT. WE
16 ACTUALLY HAD A LOT MORE INTEREST THAN THE ORGANIZERS
17 AT ISSCR ACTUALLY DESIRED, WHICH I THINK SHOWS THAT
18 IT'S A HOT TOPIC. AND WE HAD AN EXCELLENT PANEL OF
19 EXPERTS THAT WE WERE ABLE TO ATTRACT TO THIS
20 WORKSHOP, INCLUDING BOB KLEIN, WHO WAS PART OF THE
21 PANEL FOR THE LUNCHTIME KEYNOTE SPEAKERS, BUT WE
22 ALSO HAD REPRESENTATIVES FROM THE FDA, THE EMA,
23 WHICH IS THE EUROPEAN MEDICINES AGENCY, JAPAN, WE
24 HAD EXPERTS FROM ARGENTINA, CHINA, AND INDIA.

25 I THINK HAVING ALL OF THESE COUNTRIES

BARRISTERS' REPORTING SERVICE

1 REPRESENTED IN A SINGLE ROOM AND TALKING ABOUT THE
2 REGULATORY FRAMEWORKS REALLY HIGHLIGHTED THE FACT
3 THAT THEY ARE DIFFERENT IN MANY WAYS. AND
4 ESPECIALLY THE FACT THAT WE HAD INVITED DR. WISE
5 YOUNG TO TALK ABOUT HIS EXPERIENCES IN CHINA REALLY
6 DROVE HOME THE POINT THAT THERE IS DIFFERENT
7 TOLERANCE, RISK TOLERANCE, ACROSS THE WORLD AND
8 THERE'S DIFFERENT ENFORCEMENT MECHANISMS. SO I WANT
9 TO TOUCH ON A COUPLE POINTS WHICH I THINK YOU'LL
10 FIND INTERESTING.

11 SO DR. WISE YOUNG TALKED ABOUT A PATIENT
12 TRIAL PHASE III THAT HE'S DOING, 400 PATIENTS FOR
13 PROVIDING CORD BLOOD MONONUCLEAR CELLS THAT ARE
14 TRANSPLANTED INTO PATIENTS WITH SPINAL CORD
15 INJURIES. AND HE GIVES HALF OF THEM PLACEBO, HALF
16 OF THEM LITHIUM. THE POINT THAT WAS DRIVEN HOME IN
17 THESE DISCUSSIONS WAS TWOFOLD. ONE, THERE WAS NO
18 PRECLINICAL TESTING DONE PRIOR. SOME PEOPLE IN THE
19 CORRIDORS WERE REALLY APPALLED BY THAT, TO TELL YOU
20 THE TRUTH. OTHERS WERE EXCITED BY THE FACT THAT
21 THERE ARE 400 PATIENTS THAT ARE EASILY ACCEPTABLE
22 AND EASY TO ORGANIZE AVAILABLE IN CHINA FOR THIS
23 STUDY. SO I THINK THAT WAS A TELLING DISCUSSION IN
24 AND OF ITSELF.

25 DR. WISE YOUNG DID SAY THAT HE RECEIVED

BARRISTERS' REPORTING SERVICE

1 ALL OF THE APPROVALS REQUIRED FROM CHINA, IRB
2 APPROVAL, SFDA, AND NOW MOST IS ALSO BECOMING
3 INVOLVED IN REGULATORY ISSUES FOR CLINICAL TRIALS
4 THERE, AND HE OBTAINED ALL APPROVALS THAT HE NEEDED.
5 SO THAT'S JUST A POINT TO CONSIDER WHEN WE'RE
6 LOOKING AT THE BIGGER PICTURE OF HOW TRIALS WILL BE
7 DONE PERHAPS IN COLLABORATIONS.

8 ARGENTINA NOTED, A LOT OF HYPE IN
9 ARGENTINA, THERE'S MEDIA HYPE ABOUT THE PROMISES OF
10 STEM CELL. AND WHAT THEY SAID IS THAT THEY HAVE A
11 VERY IMMATURE REGULATORY OVERSIGHT MECHANISM, AND SO
12 THEY'RE NOT ABLE TO EVEN ENFORCE THESE UNPROVEN
13 TECHNOLOGIES. IRV WEISSMAN TALKED ABOUT WHAT THE
14 ISSCR IS DOING VIS-A-VIS TRYING TO ASSIST PATIENTS
15 TO GET BETTER INFORMED SO THEY CAN MAKE MORE
16 INFORMED DECISIONS ON PROPOSED MEDICAL CURES AS
17 THEY'RE OFTEN TOUTED BY SOME COMPANIES.

18 AND ON A WHOLE DIFFERENT TRACK, WE ALSO
19 PRESENTED, I GUESS, A QUALITATIVE STUDY THAT CIRM
20 HAD UNDERTAKEN TO UNDERSTAND IN THE U.S. WHAT SORT
21 OF DIFFICULTIES CERTAIN COMPANIES ARE FACING AS THEY
22 TRY TO ENTER INTO THE CLINIC FOR STEM CELL
23 THERAPIES.

24 SO IT WOULD TAKE ME, OF COURSE, HOURS AND
25 HOURS TO TELL YOU ALL OF THE GREAT INFORMATION THAT

BARRISTERS' REPORTING SERVICE

1 TRANSPIRED AND WAS EXCHANGED. BUT I WANTED TO SHOW
2 JUST ONE SLIDE SINCE THAT'S ALL THE TIME I HAVE, AND
3 I THINK THIS IS A SLIDE THAT SORT OF SUMS UP THE
4 STUDY THAT MYSELF AND ALAN HAD DONE WHEN WE
5 CONTACTED THESE 17 COMPANIES AND INTERVIEWED THEM.

6 ON THE BOTTOM YOU WILL SEE THE X AXIS, THE
7 TYPES OF DIFFICULTIES THAT THEY HAD INDICATED THAT
8 THEY FACED CHALLENGES ON WHEN THEY WERE TRYING TO
9 GET INTO CLINIC AND THEN HIGH, MEDIUM, OR LOW
10 CONCERN. THE COMPANIES THAT WERE TRYING TO DEVELOP
11 PLURIPOTENT THERAPIES, THEY UNIVERSALLY HAD A LOT OF
12 DIFFICULTY. THAT'S NO SURPRISE. A NUMBER OF THEM,
13 AND THERE'S NOT MANY OF THEM, HAD INDICATED THAT
14 THEY REALLY FELT THAT THE RISK BALANCE THAT THE FDA
15 IS USING IN MAKING ITS DECISIONS EVEN WITH RESPECT
16 TO WHAT CONSTITUTES AN APPROPRIATE PRECLINICAL STUDY
17 DESIGN OR REGIME WAS A LITTLE OFF BASE.

18 THERE WAS A LOT OF UNCERTAINTY, ESPECIALLY
19 AMONG THE PLURIPOTENT STEM CELL COMPANIES, AS TO
20 WHAT AN ANIMAL STUDY SHOULD LOOK LIKE, WHAT WOULD BE
21 ACCEPTABLE. ONE PERSON SAID, "GEE, I REALLY WISH I
22 COULD NAIL THEM DOWN BECAUSE EVERY TIME I GO TO MY
23 INVESTORS AND SAY THIS IS WHAT FDA WILL REQUIRE,
24 THEY COME BACK AND SAY, 'WELL, THEY'LL REQUIRE THAT
25 AND THEN I KNOW YOU'LL NEED MORE MONEY BECAUSE

BARRISTERS' REPORTING SERVICE

1 THEY'LL REQUIRE SOMETHING ELSE.'" THAT'S BEEN A BIG
2 DISCOURAGEMENT FOR SOME OF THESE COMPANIES.

3 AND THEN RELEASE CRITERIA, YOU SEE THAT
4 THE TRANSIENTS IN THE REGENERATIVE MEDICINE
5 COMPANIES DON'T HAVE A WHOLE LOT OF PROBLEM WITH
6 THAT. THOSE ARE SORT OF THE POTENCY ASSAYS AND
7 OTHER TYPES OF RELEASE CRITERIA.

8 WE TALKED A LITTLE BIT THIS MORNING ABOUT
9 TRANSIENT CELL TYPES, SO THOSE ARE MORE LIKE THE
10 MSC'S. AND YOU WILL NOTE THAT THOSE ARE SORT OF
11 BREEZING THROUGH TO THE CLINIC. THEY DON'T SEEM TO
12 HAVE A LOT OF THE PROBLEM BECAUSE THE FDA FIGURES,
13 WELL, THEY DON'T STAY WITHIN THE BODY VERY LONG. SO
14 THAT'S ANOTHER INTERESTING SALIENT POINT THAT WE
15 WERE ABLE TO SORT OF DRAW OUT OF THIS QUALITATIVE
16 STUDY.

17 THE FACT THAT ANIMAL REQUIREMENTS SORT OF
18 RANKS HIGH SORT OF IS TELLING BECAUSE WE ARE GOING
19 TO BE FOCUSING ON THAT ISSUE FROM AN EDUCATION
20 STANDPOINT AND FROM A SORT OF BEST PRACTICES
21 STANDPOINT IN TWO UPCOMING INITIATIVES. SO
22 SEPTEMBER 28TH WE'LL DO A WEBINAR. WE HAVE THE
23 REPRESENTATIVE FROM FDA, MERCEDES SERABIAN, WHO WILL
24 BE GIVING A HALF-HOUR TALK ON OUR WEBINAR, FOLLOWED
25 BY TWO OTHERS. WE HAVE BOB DEANS FROM ATHERSYS AND

BARRISTERS' REPORTING SERVICE

1 MELISSA CARPENTER WHO WILL ALSO BE SPEAKING. AND
2 THERE WILL BE ROOM FOR Q&A AT THE END, PROBABLY 15
3 MINUTES TO A HALF HOUR. AND THAT'S FREE. WE'RE
4 STARTING TO ADVERTISE THAT. THE LAST TIME WE DID
5 THIS, WE HAD ABOUT 150 PEOPLE SIGN UP.

6 AND THEN WE'LL HAVE A ROUNDTABLE THAT WILL
7 HAVE SORT OF THE KEY KNOWLEDGE LEADERS, THOUGHT
8 LEADERS, ON ANIMAL MODELS MEET WITH THE FDA ON
9 OCTOBER 8TH WITH THE GOAL BEING TO REALLY JUST
10 EXCHANGE WHAT THE DIFFICULTIES ARE IN TRYING TO
11 PROVE SAFETY, MOSTLY SAFETY, AND FIGURE OUT BEST
12 PRACTICES, WHAT SOME COMPANIES AND OTHER EMINENT
13 RESEARCHERS BELIEVE IS THE BEST WAY TO GO.

14 MR. SHEEHY: I THINK -- LET ME GIVE A
15 LITTLE BACKGROUND. THERE'S AN ACTIVIST UMBRELLA
16 GROUP, THE AIDS TREATMENT ADVOCATES COALITION, WHICH
17 CONDUCTED A NATIONAL CONFERENCE CALL WITH JOHN ZAIA
18 RELEVANT TO THE PAULA CANNON PAPER THAT WE JUST SAW.
19 AND HE MENTIONED A MEETING WITH THE FDA THAT HE HAD
20 BEEN INFORMED OF THROUGH CIRM. IS THIS WHAT WE'RE
21 TALKING ABOUT?

22 MS. BAUM: THAT'S IT. YES, I TALKED TO
23 HIM.

24 MR. SHEEHY: SO THERE'S CONSIDERABLE
25 INTEREST AMONGST AIDS ACTIVISTS. AND FRANKLY HIV

BARRISTERS' REPORTING SERVICE

1 THOUGHT LEADERS ARE NOT SEPARATE FROM THE SCIENTISTS
2 IN THE WAY OTHER DISEASES ARE. IS THAT OPEN TO THE
3 ADVOCACY COMMUNITY BECAUSE -- AND THIS GETS TO SOME
4 OF THE INITIATIVES DUANE HAS BEEN TALKING ABOUT. WE
5 INTEND TO GO MARCHING WITH DR. ZAIA INTO THE CLINIC.
6 AND TO BE ABLE TO GET INTO PATIENTS AT AS SOON AS
7 POSSIBLE TIME, WE NEED THE ADVOCACY COMMUNITY. AND
8 THE ADVOCACY COMMUNITY WILL ACTUALLY DEMAND TO BE AT
9 THE TABLE.

10 SO I'M JUST CURIOUS. I KNOW THAT THEY
11 WERE TALKING TO JOHN ABOUT GETTING THE CIRM CONTACT,
12 PEOPLE FROM THE TREATMENT ACTION GROUP IN NEW YORK,
13 PEOPLE FROM THE AIDS POLICY PROJECT IN PHILADELPHIA,
14 PEOPLE FROM PROJECT INFORM IN SAN FRANCISCO. THE
15 LEADING AIDS ACTIVIST GROUPS HAVE AN INTEREST IN
16 PARTICIPATING IN THESE KINDS OF DISCUSSIONS. WHAT
17 KINDS OF OPPORTUNITIES OR BARRIERS ARE THERE FOR
18 PARTICIPATION?

19 MS. BAUM: I DID TALK TO DR. ZAIA, AND I
20 THINK EVERYONE AGREES THAT PATIENT ADVOCATES ARE
21 JUST A FUNDAMENTAL PART OF THE EQUATION, ESPECIALLY
22 WHEN YOU SEE THAT THERE'S A LITTLE RETICENCE ON THE
23 PART OF THE FDA. I THINK IT ACTUALLY HELPS THE FDA
24 MAKE THESE DECISIONS, TO TELL YOU THE TRUTH.

25 WHEN I WAS TALKING TO DR. ZAIA, I THOUGHT

BARRISTERS' REPORTING SERVICE

1 THAT WHAT YOU DON'T KNOW IS IN THE SPRING WE'RE
2 DOING CLINICAL TRIALS. SO THAT'S WHEN YOU'RE REALLY
3 TALKING ABOUT RISK/BENEFIT DECISION-MAKING. AND I
4 THOUGHT THAT SINCE THIS HAS BEEN SORT OF MARCHING ON
5 ITS WAY AND I HAVEN'T HAD THE CHANCE TO SORT OF
6 BROACH WITH THE FDA THE TOPIC OF PATIENT ADVOCATES
7 AND THE FACT THAT I THOUGHT THAT IN THE CLINICAL
8 TRIAL AND THE DECISION-MAKING THAT'S REQUIRED OF IT,
9 THAT PATIENT ADVOCATES REALLY NEED TO HAVE A VOICE.
10 AND, IN FACT, THEY DO HAVE A VOICE.

11 MR. SHEEHY: IN HIV IT'S NOT ABOUT A
12 VOICE. IT'S ABOUT PARTNERSHIP. IN FACT, THE PAULA
13 CANNON PAPER IS FUNDED BY MONEY THAT ART TORRES AND
14 WILLIE BROWN PROVIDED TO THE CALIFORNIA HIV-AIDS
15 RESEARCH PROGRAM THAT STARTED IN THE EARLY '80S
16 BECAUSE THE ACTIVISTS WENT TO WILLIE BROWN, DIANE
17 FEINSTEIN, AND ART TORRES, AMONGST OTHERS, AND GOT
18 THAT FUNDING.

19 I MEAN JOHN ZAIA IS GETTING FUNDED BECAUSE
20 ADVOCATES GOT THEM FUNDED THROUGH CIRM. YOU CANNOT
21 TELL HIV ACTIVISTS THEY CAN'T BE AT THE TABLE. YOU
22 JUST CAN'T.

23 MS. BAUM: WE'RE NOT SAYING --

24 MR. SHEEHY: THEY'RE ALL FORMER ACT UP
25 PEOPLE. ACT UP NEW YORK IS BEHIND TAG. ACT UP

BARRISTERS' REPORTING SERVICE

1 PHILLY IS WORKING -- HAS MORPHED INTO THE AIDS
2 POLICY PROJECT AND STILL EXISTS. ACT UP GOLDEN GATE
3 IS REPRESENTED IN PROJECT INFORM. WE HAVE ACT UP
4 COME.

5 MS. BAUM: I THINK WE'RE ALL IN AGREEMENT.
6 WE SHOULD TALK. I DON'T KNOW IF WE WANT TO SPEND
7 TIME RIGHT NOW.

8 MR. SHEEHY: I THINK CIRM SHOULD BE
9 PERMISSIVE TO AIDS ACTIVISTS.

10 MS. BAUM: ANY ACTIVISTS, I THINK.

11 CHAIRMAN KLEIN: I THINK OUR GENERAL
12 POLICY IS TO BE INCLUSIVE OF ACTIVISTS, PATIENT
13 REPRESENTATIVES ACROSS THE ENTIRE SPECTRUM.
14 CERTAINLY AIDS ACTIVISTS HAVE BLAZED THE PATHWAY FOR
15 THE COUNTRY AND THE WORLD IN REALLY SHOWING US HOW
16 TO GET TO THE CLINIC QUICKLY. SO THEY'VE REALLY
17 MADE A TREMENDOUS CONTRIBUTION TO ALL OF US.

18 MS. BAUM: I JUST WANT TO REITERATE THAT
19 IN EUROPE THE COMMITTEE FOR ADVANCED THERAPIES, THEY
20 HAVE TWO PATIENT ADVOCATES ON THEIR PANEL. AND I
21 THINK IT'S A GOOD MODEL. LET'S FIGURE OUT SORT OF
22 LOGISTICS.

23 CHAIRMAN KLEIN: SO WE HAVE A SCIENTIFIC
24 SUBCOMMITTEE COMING UP, AND MAYBE, JEFF, YOU COULD
25 REPORT AT THE SCIENTIFIC SUBCOMMITTEE WHAT THE

BARRISTERS' REPORTING SERVICE

1 PROVISION WILL BE.

2 MR. SHEEHY: WE'LL PUT THAT ON THE AGENDA.
3 IT'S HELPFUL BECAUSE IT'S ALSO EMBARRASSING WHEN
4 PEOPLE WANT TO HAVE CONNECTIONS TO CIRM AND, YOU
5 KNOW, THAT DOESN'T HAPPEN. WE HAVE A NATIONAL
6 COALITION OF AIDS ACTIVISTS, VERY DISTINGUISHED
7 INDIVIDUALS, INCLUDING SEVERAL DISTINGUISHED
8 SCIENTISTS WHO ARE PARTICIPATING BECAUSE THEY
9 RECOGNIZE THE VALUE OF SCIENTISTS WORKING WITH
10 ACTIVISTS IN TERMS OF ADVANCING THE SCIENCE. AND IT
11 JUST WOULD BE HELPFUL IF WE HAD A VERY COLLEGIAL
12 INTERFACE WITH OTHER PEOPLE WORKING IN THE FIELD WHO
13 WILL HELP US WITH BOTH THE FDA AND THE NIH.

14 CHAIRMAN KLEIN: I THINK PHILOSOPHICALLY
15 WE'RE ON THE SAME TABLE. SOUNDS LIKE THAT'S THE
16 GOAL, SO LET'S SEE HOW WE CAN GET IT DONE. THANK
17 YOU VERY MUCH FOR THE REPORT.

18 MS. BAUM: I HAVE TWO MORE SLIDES.

19 CHAIRMAN KLEIN: GREAT. GO AHEAD. I
20 DIDN'T MEAN TO INTERRUPT.

21 MS. BAUM: SWITCHING HATS NOW, WE ALSO
22 HAVE BEEN DOING WORKSHOPS RELATED TO AND HAVING
23 MEETINGS RELATED TO CIRM'S INTELLECTUAL PROPERTY
24 REGULATIONS. SO WE MET ON JULY 21ST DOWN AT UCLA.
25 MYSELF, NANCY KOCH, AND ALAN TROUNSON WENT DOWN

BARRISTERS' REPORTING SERVICE

1 THERE, AND IT SORT OF GENERATED BECAUSE THEY HAD
2 BEEN -- ACTUALLY THEY PUBLISHED FOR INTERNAL USE
3 ONLY, BUT IT WAS DISCOVERED ON THE INTERNET, AN
4 ARTICLE THAT CLEARLY SHOWED THAT THEY HAD MAYBE A
5 LITTLE BIT OF CONFUSION ABOUT WHAT OUR REGS ARE. WE
6 CALLED THEM UP, WE CLARIFIED IT, THEN THEY INVITED
7 US DOWN TO SPEAK, NOT ONLY TO THEIR TECH TRANSFER
8 STAFF, BUT ALSO TO THE STAFF SCIENTISTS WHO WERE
9 VERY INTERESTED.

10 SO WE PROVIDED AN OVERVIEW TO THE STAFF
11 SCIENTISTS, AND THE TECH TRANSFER PEOPLE HAD A LOT
12 OF VERY DETAILED QUESTIONS. AND WE SPENT ABOUT AN
13 HOUR GOING THROUGH THOSE QUESTIONS WITH THEM.

14 FOR ALL OF YOU WHO DON'T KNOW, WE'RE IN
15 THE MIDST OF PREPARING A FAQ THAT WE INTEND TO POST
16 ON OUR WEB SITE, WHICH I THINK WILL HELP TO LEND
17 MORE CLARIFICATION AND UNDERSTANDING OF WHAT AND HOW
18 TO IMPLEMENT THESE REGULATIONS. SO I JUST WANTED TO
19 HAVE A FEW WORDS ABOUT THAT.

20 AND ONE LAST MEETING, WHICH WILL BE AT
21 STANFORD, AND THIS WAS ACTUALLY STANFORD'S TECH
22 TRANSFER DEPARTMENT'S IDEA. THEY FELT THAT THEY ARE
23 CREATING THE WHEEL AND DIDN'T WANT TO RECREATE IT
24 WITH RESPECT TO SYSTEMS, PROCESSES THAT OTHER
25 INSTITUTES ARE ENGAGING IN TO IMPLEMENT OUR

BARRISTERS' REPORTING SERVICE

1 REGULATIONS FOR INTELLECTUAL PROPERTY. SO THEY ARE
2 TAKING SORT OF THE LEAD IN RECRUITING TECH TRANSFER
3 FOLKS TO GATHER UP AT STANFORD FOR A DAY TO DISCUSS
4 OUR INTELLECTUAL PROPERTY REGULATIONS.

5 WE'RE PARTNERING WITH THEM. WE WILL
6 CERTAINLY BE THERE TO MAKE SURE THERE'S FULL AND
7 ACCURATE UNDERSTANDING OF WHAT OUR REGULATIONS ARE,
8 HOW THEY SHOULD BE APPLIED. AND WE'RE DOING A
9 LITTLE BIT OF FUNDING TO HELP WITH TRAVEL COSTS IN
10 THESE DIFFICULT ECONOMIC TIMES.

11 CHAIRMAN KLEIN: OKAY.

12 MS. BAUM: THAT'S IT.

13 CHAIRMAN KLEIN: THANK YOU VERY MUCH.
14 WE'RE GOING TO MOVE IMMEDIATELY TO THE BALANCE OF
15 THE GOVERNANCE SUBCOMMITTEE ITEM. SHERRY LANSING IS
16 GOING TO DIRECT THE DISCUSSION ON THESE TWO ITEMS
17 CONCERNING ITEM 13 AND ITEM 15. SHERRY.

18 MS. LANSING: SO THANK YOU, BOB. AND FOR
19 ITEM 13 ACTUALLY, BOB, I'D LIKE YOU TO LEAD THE
20 DISCUSSION ON THE CONSIDERATION OF AMENDMENTS TO OUR
21 CONTRACT POLICY.

22 CHAIRMAN KLEIN: FINE. IAN SWEEDLER, IF
23 YOU COULD MAKE THAT PRESENTATION, PLEASE.

24 MR. SWEEDLER: GOOD MORNING. MY NAME IS
25 IAN SWEEDLER. I'M DEPUTY LEGAL COUNSEL AT CIRM. NO

BARRISTERS' REPORTING SERVICE

1 SLIDES.

2 I PROVIDED A MEMO THAT WENT OUT TO ALL OF
3 YOU AND IS POSTED ON THE WEB SITE OUTLINING THE
4 NATURE OF THE CHANGES THAT ARE HERE. AND WE WENT
5 THROUGH THESE WITH THE GOVERNANCE SUBCOMMITTEE. AND
6 WHAT'S BEFORE YOU IS WHAT THEY RECOMMENDED. IT
7 REFLECTS A COUPLE OF CHANGES THAT HAPPENED AT THE
8 SUBCOMMITTEE.

9 BY WAY OF BACKGROUND, PROPOSITION 71 SAYS
10 THAT CIRM IS SUPPOSED TO ADOPT CONTRACTING
11 PROCEDURES THAT ARE BASED ON THOSE IN USE AT THE
12 UNIVERSITY OF CALIFORNIA. AND THAT'S WHAT WE DID IN
13 APPROXIMATELY 2006 BASED ON CONTRACTING PROCEDURES
14 THAT WERE IN PLACE AT THE UNIVERSITY AT THAT TIME,
15 PRIMARILY SOMETHING THEY PUT OUT CALLED BUSINESS AND
16 FINANCE BULLETIN 34.

17 IN THE INTERVENING PERIOD, THE UNIVERSITY
18 HAS SUBSTANTIALLY REVAMPED ITS CONTRACTING
19 PROCEDURES. SO MOST OF THE CHANGES THAT ARE
20 PROPOSED TODAY ARE CHANGES THAT BRING CIRM'S
21 PROCESSES IN LINE WITH WHAT ARE NOW CURRENT
22 PROCESSES AT THE UNIVERSITY OF CALIFORNIA.

23 AND THEN THERE WERE A COUPLE OF OTHER
24 CHANGES THAT WERE BROUGHT IN REALLY AS
25 CLARIFICATIONS AND ADJUSTMENTS REFLECTING SOME

BARRISTERS' REPORTING SERVICE

1 THINGS THAT WE STUMBLERD ACROSS IN PRACTICE THAT MADE
2 THE POLICY A LITTLE BIT CUMBERSOME.

3 THE MAIN ONE WAS THAT, AS YOU MAY RECALL,
4 THERE ARE VARYING LEVELS OF AUTHORITY TO APPROVE
5 CONTRACTS. A CONTRACT THAT GOES UP TO \$250,000
6 REQUIRES APPROVAL BY THE PRESIDENT. CONTRACTS
7 BETWEEN 250,000 AND 500,000 HAVE TO GO TO THE
8 GOVERNANCE SUBCOMMITTEE FOR APPROVAL. AND ABOVE
9 500,000 THEY HAVE TO GO TO THE FULL BOARD.

10 WE HAD COME ACROSS SITUATIONS IN WHICH A
11 CONTRACT WOULD BE APPROVED BY THE GOVERNANCE
12 SUBCOMMITTEE AT A CERTAIN LEVEL; AND AS WE APPROACH
13 THE END OF THAT CONTRACT, A SMALL INCREASE WOULD BE
14 NEEDED IN ORDER TO CLOSE OUT THE WORK. SO THERE MAY
15 BE A CONTRACT THAT'S \$300,000 AND IT'S APPARENT
16 WE'RE GOING TO NEED 310,000 TO FINISH THE WORK.
17 UNDER THE PRIOR POLICY IT APPEARED THAT WE WOULD
18 HAVE TO COME BACK TO THE GOVERNANCE SUBCOMMITTEE FOR
19 THAT ADDITIONAL AUTHORITY EVEN THOUGH IT WAS A
20 RELATIVELY SMALL CHANGE.

21 SO ONE THING THAT HAS BEEN ADDED TO THIS
22 POLICY, AND IT'S AN APPROACH THAT THE COMMITTEE
23 ITSELF SUGGESTED AT OUR MEETING, WAS THAT UNLESS THE
24 COMMITTEE SPECIFIES OTHERWISE, WHEN THE GOVERNANCE
25 SUBCOMMITTEE APPROVES A CONTRACT, THERE IS A

BARRISTERS' REPORTING SERVICE

1 BUILT-IN APPROVAL FOR THE PRESIDENT TO MAKE A SLIGHT
2 ADJUSTMENT UPWARDS WITHOUT COMING BACK TO THE
3 COMMITTEE, A 15-PERCENT ADJUSTMENT ROOM IN THERE.

4 I'M HAPPY TO ANSWER ANY QUESTIONS OR GO
5 THROUGH THE PARTICULAR CHANGES IN MORE DETAIL IF
6 THAT WOULD BE HELPFUL. WE WENT THROUGH THEM PRETTY
7 MUCH LINE BY LINE WITH THE GOVERNANCE COMMITTEE.

8 MS. LANSING: WE HAD A VERY RIGOROUS
9 MEETING ON THIS, AND THEY REALLY ARE PRETTY MUCH
10 ADJUSTING FROM THE ORIGINAL TIME THAT WE DID THEM TO
11 THE STANDARDS OF THE UNIVERSITY OF CALIFORNIA
12 SYSTEM, WHICH IS HOW WE'VE ALWAYS HELD OURSELVES
13 ACCOUNTABLE, AND THEN MAKING THESE MINOR OTHER
14 ADJUSTMENTS, WHICH WOULD, WE HOPE, MAKE US MORE
15 EFFICIENT IN CARRYING OUT OUR BUSINESS. BUT I'M
16 ANXIOUS TO SEE IF THERE'S ANY QUESTIONS FROM THE
17 BOARD OR ANY DISCUSSION.

18 MR. ROTH: SHERRY, I'D LIKE TO MAKE A
19 MOTION THAT WE ADOPT THE BYLAW CHANGES AS PRESENTED.

20 MS. LANSING: DO I NEED ANY PUBLIC
21 DISCUSSION ON THIS?

22 CHAIRMAN KLEIN: AFTER THE SECOND.

23 MS. LANSING: THE MOTION IS TAKEN. DO I
24 HAVE A SECOND?

25 MR. TORRES: SECOND.

BARRISTERS' REPORTING SERVICE

1 MS. LANSING: FROM ART TORRES, I THINK,
2 WAS THE SECOND AND PHIL PIZZO WAS ALSO THE SECOND,
3 SO THEY'RE TIED. SO THEN CAN I HAVE COMMENTS FROM
4 THE PUBLIC, PLEASE? DO I NEED A ROLL CALL VOTE?
5 ALL IN FAVOR OF THIS PLEASE SAY AYE.

6 (CHORUS OF AYES.)

7 ANY OPPOSED?

8 (NO RESPONSE.)

9 MS. KING: WILLIAM BRODY.

10 DR. BRODY: I'M IN FAVOR.

11 MS. KING: MICHAEL FRIEDMAN, ARE YOU ON
12 THE LINE? NOT YET.

13 MS. LANSING: I THINK WE HAVE A QUORUM, SO
14 THE MOTION CARRIES. THANK YOU ALL VERY MUCH.

15 I'D NOW LIKE TO MOVE ON TO AGENDA ITEM 16.
16 AND, JAMES, CAN YOU LEAD US THROUGH THAT, PLEASE?

17 CHAIRMAN KLEIN: AND THAT WOULD BE ITEM
18 15.

19 MS. LANSING: I'M SORRY. I APOLOGIZE.
20 15. I APOLOGIZE. THESE ARE, AGAIN, MORE
21 CONSIDERATION ABOUT THE PROCESS AND PROCEDURES FOR
22 THE ELECTION OF THE CHAIR AND VICE CHAIR.

23 MR. HARRISON: THAT'S RIGHT. YESTERDAY
24 YOU APPROVED A BYLAW AMENDMENT TO GOVERN THE CONDUCT
25 OF THE ELECTION FOR CHAIR AND VICE CHAIR, AND TODAY

BARRISTERS' REPORTING SERVICE

1 WHAT WE'D LIKE TO DISCUSS ARE THE STEPS THAT LEAD UP
2 TO THAT MEETING.

3 JUST BY WAY OF BRIEF BACKGROUND, THE TERMS
4 OF THE CURRENT CHAIR AND VICE CHAIRS, WHICH ARE SIX
5 YEARS, ARE DUE TO EXPIRE ON DECEMBER 16, 2010, AS
6 WELL AS THE TERMS OF ELEVEN OTHER BOARD MEMBERS WHO
7 WERE APPOINTED AT THE SAME TIME.

8 THE CURRENT BOARD MEMBERS, AS I MENTIONED
9 YESTERDAY, CONTINUE TO SERVE UNTIL THEIR SUCCESSORS
10 ARE EITHER APPOINTED IN THE CASE OF THE MEMBERS OR
11 ELECTED IN THE CASE OF THE CHAIR AND THE VICE CHAIR,
12 AND THEN THEY HAVE TO TAKE THE OATH OF OFFICE BEFORE
13 THEY ARE ACTUALLY QUALIFIED TO SERVE.

14 IT'S ALSO IMPORTANT TO NOTE THAT MEMBERS
15 ARE ELIGIBLE TO SERVE TWO TERMS, AND WE WILL BE
16 CONTACTING THOSE OF YOU WHO WE HAVEN'T YET SPOKEN
17 WITH WHOSE TERMS ARE DUE TO EXPIRE ABOUT YOUR
18 WILLINGNESS TO CONTINUE TO SERVE.

19 LET ME BRIEFLY DESCRIBE THE PROCEDURE
20 UNDER PROP 71 FOR THE NOMINATION OF THE CHAIR AND
21 THE STATUTORY VICE CHAIR. THE GOVERNOR, THE
22 LIEUTENANT GOVERNOR, THE CONTROLLER, AND THE
23 TREASURER EACH HAVE THE AUTHORITY TO MAKE A
24 NOMINATION FOR BOTH CHAIR AND STATUTORY VICE CHAIR.
25 YOU WILL RECALL THAT THE BOARD AMENDED THE BYLAWS

BARRISTERS' REPORTING SERVICE

1 LAST YEAR TO CREATE A NEW OFFICE OF BYLAWS VICE
2 CHAIR. THAT INDIVIDUAL, HOWEVER, IS ELECTED FROM
3 AMONG MEMBERS OF THE BOARD AND IS NOT NOMINATED BY
4 THE CONSTITUTIONAL OFFICERS.

5 THERE'S NO EXPLICIT DEADLINE FOR THE
6 CONSTITUTIONAL OFFICERS TO NOMINATE CANDIDATES, BUT
7 IT IS REASONABLE TO CONSTRUE A PROVISION IN
8 PROPOSITION 71 WHICH REQUIRES APPOINTING AUTHORITIES
9 TO NOMINATE MEMBERS WITHIN 30 DAYS AFTER THE
10 EXPIRATION OF A MEMBER'S TERM TO ALSO APPLY TO THE
11 NOMINATIONS OF CANDIDATES FOR CHAIR AND VICE CHAIR.

12 THE CURRENT CONSTITUTIONAL OFFICERS WILL
13 ALL SERVE THROUGH THE FIRST MONDAY OF JANUARY, SO
14 IT'S REASONABLE TO ASSUME THAT EACH OF THOSE
15 CONSTITUTIONAL OFFICERS WILL MAKE NOMINATIONS
16 REGARDLESS OF THE OUTCOME OF THE ELECTION IN
17 NOVEMBER.

18 IN LIGHT OF THE PENDING TRANSITION, THE
19 GOVERNANCE SUBCOMMITTEE HAS ASKED US TO PRESENT FOR
20 YOUR CONSIDERATION PROCEDURES TO ATTEMPT TO ENSURE
21 AN ORDERLY AND TIMELY TRANSITION OF AUTHORITY. AND
22 WHAT FOLLOWS ARE OUR SUGGESTIONS FOR YOUR
23 CONSIDERATION.

24 FIRST, THE CHAIR, ON BEHALF OF THE BOARD,
25 WOULD REQUEST THAT EACH OF THE CONSTITUTIONAL

BARRISTERS' REPORTING SERVICE

1 OFFICERS MAKES A NOMINATION NO LATER THAN NOVEMBER
2 1ST, 2010, FOR BOTH CHAIR AND VICE CHAIR.

3 THE CHAIRMAN WOULD ALSO REQUEST THAT THE
4 CONSTITUTIONAL OFFICERS PROVIDE BACKGROUND
5 INFORMATION REGARDING THEIR NOMINEES, INCLUDING A
6 BRIEF PERSONAL STATEMENT THAT ADDRESSES THE
7 NOMINEE'S QUALIFICATIONS FOR AND INTEREST IN THE
8 POSITION.

9 THIRD, THE CHAIR WOULD COMMUNICATE TO THE
10 CONSTITUTIONAL OFFICERS THAT THE BOARD INTENDS TO
11 VOTE ON NOMINEES AT ITS MEETING ON DECEMBER 8TH AND
12 9TH UNLESS THE BOARD DESIRES TO TAKE ACTION ON A
13 DIFFERENT DATE. ALSO, IF THE BOARD DESIRES, THE
14 CHAIR WOULD SCHEDULE A MEETING IN ADVANCE OF THE
15 MEETING AT WHICH THE ELECTION IS CONDUCTED IN ORDER
16 TO PROVIDE AN OPPORTUNITY FOR THE NOMINEES TO MAKE
17 BRIEF PRESENTATIONS TO THE BOARD AND FOR THE BOARD
18 TO ASK QUESTIONS OF THE NOMINEES. NOMINEES MAY ALSO
19 BE REQUESTED, OF COURSE, TO MAKE A SIMILAR
20 PRESENTATION AT THE MEETING AT WHICH THE ELECTION IS
21 ACTUALLY CONDUCTED.

22 AND THEN FINALLY, ASSUMING THAT THE BOARD
23 BELIEVES THE MEETING ON THE 8TH AND 9TH IS THE BEST
24 TIME TO TAKE ACTION, THE BOARD WOULD CONVENE IN
25 CLOSED SESSION, HAVE AN OPPORTUNITY TO DISCUSS THE

BARRISTERS' REPORTING SERVICE

1 NOMINEES, AND THEN RECONVENE IN OPEN SESSION TO
2 CONDUCT THE ACTUAL ELECTION.

3 THE NEW CHAIR AND VICE CHAIR WOULD ASSUME
4 THEIR DUTIES AFTER DECEMBER 16TH AND LIKELY BEFORE
5 THE BOARD'S FIRST MEETING IN JANUARY 2011. WE
6 BELIEVE THESE PROPOSED PROCEDURES WOULD PERMIT TIME
7 FOR A BRIEF AND ORDERLY TRANSITION OF AUTHORITY FROM
8 THE CURRENT CHAIR AND VICE CHAIR TO THE NEW
9 OFFICERS. WE'D WELCOME YOUR INPUT AND COMMENTS.

10 MS. LANSING: CAN I HAVE -- THANK YOU,
11 JAMES. THAT'S A VERY CLEAR REPORT. CAN I HAVE SOME
12 INPUT, QUESTIONS BECAUSE WE'RE HERE NOW TO EITHER
13 ACCEPT THIS OR TO RATIFY THAT IT IS WHAT WE'D LIKE
14 TO DO. CLAIRE.

15 DR. POMEROY: JAMES, WHAT THEN HAPPENS IF
16 OUR POLITE REQUEST TO THE NOMINATING OFFICIALS
17 DOESN'T HAPPEN?

18 MR. HARRISON: WELL, WE WOULD COMMUNICATE
19 TWO THINGS TO CONSTITUTIONAL OFFICERS. ONE, THAT
20 WE'D LIKE THEM TO MAKE THEIR NOMINATIONS BY NOVEMBER
21 1ST AND, TWO, THAT WE INTEND TO TAKE ACTION BASED ON
22 THE NOMINATIONS THAT ARE MADE AS OF DECEMBER 8TH OR
23 9TH IF THAT'S THE MEETING AT WHICH THE BOARD THINKS
24 THE ELECTION SHOULD BE CONDUCTED. IN OTHER WORDS,
25 THE BOARD WOULD TAKE ACTION ON THE NOMINEES WHOSE

BARRISTERS' REPORTING SERVICE

1 NAMES ARE BEFORE IT AT THAT POINT IN TIME.

2 MS. LANSING: WAIT A SECOND, BUT THAT
3 DOESN'T ANSWER THE QUESTION. WHAT HAPPENS IF WE
4 DON'T GET FOUR -- WE DON'T GET NOMINATIONS BY
5 NOVEMBER 8TH FROM ALL FOUR OF THE PEOPLE?

6 CHAIRMAN KLEIN: SO, MADAM CHAIRMAN, THE
7 BOARD COULD CHOOSE TO WAIT OR TO TAKE ACTION ON
8 DECEMBER 8TH AND 9TH. WE'RE COMMUNICATING AN
9 INTENT, AND IT'S UP TO THE BOARD TO DECIDE AT THAT
10 POINT. THERE'S ALSO A NATURAL INCENTIVE, BY
11 COMMUNICATING EARLY TO THE CONSTITUTIONAL OFFICERS
12 ABOUT THE NEED FOR AN ORDERLY TRANSITION, THAT THEY
13 WOULD WANT THEIR NOMINEES TO HAVE AN EQUAL ADVANTAGE
14 WITH OTHER NOMINEES. SO THERE'S A NATURAL INCENTIVE
15 FOR THEM TO NOMINATE ON THE SCHEDULE.

16 MS. LANSING: I JUST WANT TO BE CLEAR
17 BECAUSE I THINK CLAIRE HAS ASKED A VERY IMPORTANT
18 QUESTION. SO LET'S SAY WE GET -- ANSWER THESE
19 QUESTIONS. LET'S SAY WE GET NO NOMINATIONS FROM ANY
20 OF THEM. WHAT IS OUR LEGAL OPTION? LET'S SAY WE
21 GET ONE BECAUSE ONE WOULD BE THE SAME AS IF WE GOT
22 TWO OR THREE.

23 CHAIRMAN KLEIN: IF WE DON'T GET ANY
24 NOMINATIONS, THE CURRENT CHAIR AND VICE CHAIRS
25 CONTINUE TO SERVE UNDER THE INITIATIVE UNTIL THEY

BARRISTERS' REPORTING SERVICE

1 ARE THROUGH AN ORDERLY STATUTORY PROCESS REPLACED BY
2 THE BOARD. SO THEY WOULD CONTINUE TO SERVE.

3 IF WE GET ONE NOMINATION IN THE TIME FRAME
4 REQUESTED, THEN THE BOARD WOULD DECIDE WHETHER THE
5 BOARD WISHED TO WAIT OR WHETHER THE BOARD WISHED TO
6 ACT AT THAT POINT.

7 NOW, UNDER THE STATUTORY PROVISIONS,
8 JAMES, MAYBE YOU COULD DRILL DOWN TO THE ISSUE OF IF
9 THE BOARD DECIDED TO WAIT, HOW LONG WOULD THE BOARD
10 HAVE TO WAIT GIVEN A PENDING NOMINATION? WOULD WE
11 HAVE TO TAKE A VOTE ON THE SINGLE ONE BY DECEMBER
12 THE 16TH AND SEE WHETHER THAT FAILED A QUORUM TO
13 DECIDE, OR COULD WE WAIT UNTIL WHAT SPECIFIC DAY?

14 MR. HARRISON: THE BOARD UNDER THAT
15 CIRCUMSTANCE COULD ELECT TO WAIT UNTIL JANUARY 16TH,
16 2011, WHICH WOULD BE THE DATE, THE OUTLYING DATE FOR
17 WHICH NOMINATIONS COULD BE MADE.

18 MS. LANSING: THAT'S THE LAST DATE THE
19 NOMINATIONS CAN BE MADE.

20 MR. HARRISON: CORRECT.

21 DR. PIZZO: SO WHAT HAPPENS, JUST CARRYING
22 THAT LINE OF REASONING, WHAT HAPPENS IF WE GET TO
23 JANUARY 17TH OR 16TH OR 15TH AND DON'T HAVE?

24 MR. HARRISON: AS THE CHAIRMAN SAID, THE
25 CURRENT OFFICERS WOULD CONTINUE TO SERVE UNTIL THEIR

BARRISTERS' REPORTING SERVICE

1 SUCCESSORS.

2 DR. PIZZO: RIGHT. I UNDERSTAND THAT
3 PART. IS THERE THEN A TIME FOR OR IS IT JUST UP TO
4 THE WHIMS?

5 MR. HARRISON: AT THAT POINT IN TIME,
6 THERE'S ONLY ONE ALTERNATIVE OTHER THAN THE POWER OF
7 PERSUASION THAT THE BOARD WOULD HAVE OTHER THAN
8 SIMPLY TO WAIT, WHICH WOULD BE TO FILE A LEGAL
9 ACTION TO COMPEL THE CONSTITUTIONAL OFFICERS TO
10 FOLLOW THEIR STATUTORY DUTIES.

11 MS. LANSING: I DON'T THINK THAT WILL
12 HAPPEN. I THINK THAT -- MY -- WE'VE GONE THROUGH
13 THIS, SO I JUST WANT EVERYONE TO HAVE A FULL
14 DISCLOSURE ABOUT THIS. WOULD YOU EXPLAIN TO THE
15 BOARD WHY WE CAME TO THE CONCLUSION THAT WE WOULD
16 LIKE THE NOMINATIONS BEFORE THE ELECTION, AND THEN
17 ACT ON THEM, OF COURSE, AFTER THE ELECTION, AND WHAT
18 YOU FEEL THE CURRENT -- THAT'S PART 1 -- AND WHAT
19 YOU FEEL THE CURRENT LEGISLATORS, HOW THEY WILL
20 REACT TO THAT BECAUSE THEY COULD SAY, YOU KNOW,
21 "THAT DEADLINE I DON'T LIKE. I LIKE NOVEMBER 8TH TO
22 GIVE YOU MY NOMINATIONS AND YOU VOTE ON THEM
23 NOVEMBER 15TH." THAT TO ME IS THE CRUX OF WHAT WE
24 SHOULD DECIDE.

25 MR. HARRISON: LET ME FIRST START TO

BARRISTERS' REPORTING SERVICE

1 RESPOND TO THAT QUESTION BY NOTING SB 1064, WHICH,
2 AS SENATOR TORRES MENTIONED YESTERDAY, PASSED THE
3 ASSEMBLY, HAS A PROVISION IN IT WHICH REQUIRES THE
4 BOARD TO ENGAGE IN TRANSITION PLANNING FOR THE
5 CHANGE IN LEADERSHIP ON THE BOARD. AND PART OF THE
6 PROCESS THAT YOU'RE GOING THROUGH NOW IS IN
7 ANTICIPATION OF THE ENACTMENT OF SB 1064 AND,
8 FRANKLY, TO ESTABLISH BEST PRACTICES.

9 SO THE LEGISLATURE IS SUPPORTIVE OF THE
10 PROCESS THAT YOU'RE ENGAGING IN NOW AND IS
11 INTERESTED IN A SMOOTH AND ORDERLY TRANSITION OF
12 POWER. SO THAT'S THE FIRST ANSWER.

13 THE SECOND ANSWER IS THAT WITH RESPECT TO
14 CALLING FOR THE NOMINATIONS PRIOR TO THE ELECTION,
15 THE FACT THAT EACH OF THESE CONSTITUTIONAL OFFICERS,
16 INCLUDING THE GOVERNOR WHO IS TERMED OUT, AND
17 INCLUDING THE OTHER THREE CONSTITUTIONAL OFFICERS
18 WHO ARE ALL UP FOR REELECTION, WILL CONTINUE TO
19 SERVE THROUGH THE FIRST MONDAY IN JANUARY; IN OTHER
20 WORDS, THROUGH THE DATE OF THE EXPIRATION OF THE
21 CURRENT CHAIR AND VICE CHAIRS' TERMS.

22 SO IT IS REASONABLE TO EXPECT THAT UNDER
23 THOSE CIRCUMSTANCES THEY WILL HAVE AN INTEREST IN
24 MAKING NOMINATIONS. THEREFORE, REQUESTING THAT THEY
25 DO SO IN A MANNER THAT GIVES THE BOARD AN

BARRISTERS' REPORTING SERVICE

1 OPPORTUNITY TO CONSIDER THE NOMINEES AND TO LEAVE A
2 BRIEF PERIOD OF TIME FOR A TRANSITION FROM THE
3 OUTGOING CHAIR AND VICE CHAIR TO THE INCOMING CHAIR
4 AND VICE CHAIR, WE THINK, WILL BE SUPPORTED BY THE
5 CONSTITUTIONAL OFFICERS THEMSELVES.

6 MS. LANSING: I ACTUALLY WOULD ADD
7 SOMETHING ELSE. I MEAN, YOU KNOW, WHEN YOU'RE
8 ASKING CURRENT OFFICEHOLDERS TO MAKE THEIR
9 NOMINATIONS BEFORE THEY KNOW WHO ARE GOING TO BE
10 POSSIBLY THE NEXT OFFICEHOLDERS, YOU'RE ACTUALLY
11 TAKING IT OUT OF THE POLITICAL ARENA. AND SAYING,
12 YOU KNOW, NO MATTER WHICH PARTY WINS THIS OFFICE OR
13 THAT OFFICE, THAT'S NOT WHAT WE'RE ABOUT. WE'RE
14 GOING TO ASK FOR A PURITY OF RESPONSE. AND SO I
15 THINK THAT'S WHY WE CAME -- ONE OF THE REASONS WE
16 CAME TO THE CONCLUSION.

17 MR. HARRISON: THAT'S CORRECT.

18 MS. LANSING: I JUST WANT TO BE CLEAR
19 BECAUSE THIS TO ME WAS SOMETHING THAT WE SPENT TIME
20 TALKING ABOUT. ANY OTHER DISCUSSION ON THIS?

21 MR. SHEEHY: I JUST WANTED TO HAVE A
22 LITTLE CLARIFICATION ON THE POSSIBLE POTENTIAL
23 MEETING OF THE BOARD BEFORE THE DECEMBER MEETING.
24 THERE'S A LITTLE DIFFERENCE BETWEEN WHAT I HAVE IN
25 MY BOOK AND WHAT YOU PRESENTED. IT'S A SMALL THING,

BARRISTERS' REPORTING SERVICE

1 BUT WE HAVE A TELEPHONIC MEETING STIPULATED IN HERE.
2 AND, YOU KNOW, I WOULDN'T WANT TO PRESAY A
3 TELEPHONIC. I DON'T KNOW IF PEOPLE REMEMBER WAY
4 BACK EARLY, BUT I LIKE TO MEET PEOPLE IN PERSON. I
5 USUALLY DON'T KNOW THEM IN ADVANCE.

6 CHAIRMAN KLEIN: IT WOULD BE AN IN-PERSON
7 MEETING. THAT'S AN IMPORTANT QUESTION.

8 MR. SHEEHY: THERE WERE EARLY APPOINTMENTS
9 THAT WERE MADE, AND WE STARTED TO VOTE ON SOMEONE
10 AFTER A VERY THOROUGH DESCRIPTION, AND I SAID COULD
11 WE PLEASE MEET THIS GUY? I DON'T KNOW IF YOU GUYS
12 REMEMBER. IT'S A SMALL POINT, BUT I'D LIKE THE
13 OPPORTUNITY TO -- YOU KNOW, CERTAINLY OTHER MEMBERS
14 COULD ATTEND BY PHONE, BUT I WOULD LIKE THE
15 OPPORTUNITY FOR AN IN-PERSON.

16 MS. LANSING: WHEN IS THAT?

17 MR. SHEEHY: IF WE DECIDE TO GO THAT WAY.

18 MR. HARRISON: THE POINT OF OFFERING YOU
19 THAT OPPORTUNITY WAS TO GIVE YOU AN OPPORTUNITY TO
20 ACTUALLY MEET THE CANDIDATES AND THEN HAVE SOME TIME
21 TO THINK ABOUT IT BEFORE ACTUALLY TAKING THE VOTE.

22 THE OTHER ALTERNATIVE WOULD SIMPLY BE TO
23 HAVE THE PRESENTATIONS MADE AT THE MEETING AT WHICH
24 THE ELECTION OCCURS. SO WE WERE REALLY LOOKING FOR
25 INPUT FROM YOU ALL AS TO WHETHER YOU WOULD PREFER TO

BARRISTERS' REPORTING SERVICE

1 HAVE AN EARLIER OPPORTUNITY TO MEET THE CANDIDATES.

2 MR. SHEEHY: I ACTUALLY LIKE THIS
3 BIFURCATED PROCESS. I THINK THAT MAKES A LOT OF
4 SENSE.

5 CHAIRMAN KLEIN: LET ME CLARIFY THAT SO
6 THAT THIS MEETING WOULD ALLOW, AS WE ALREADY ALLOW,
7 MEMBERS TO BE ON THE PHONE OR IN PERSON. I THINK IN
8 TERMS OF OUR BYLAWS, WE GENERALLY HAVE A BYLAW
9 LIMITING THE NUMBER WHO CAN ATTEND BY PHONE. IN
10 THAT PARTICULAR CASE, BECAUSE OF THE SHORT TIME
11 FRAMES, I THINK WE'RE GOING TO NEED TO AMEND THAT SO
12 THAT -- BECAUSE THAT'S AN INFORMATIVE MEETING, NOT A
13 MEETING FOR A DECISION, TO MODIFY FOR THAT PURPOSE
14 SO THAT MORE CAN ATTEND BY PHONE IF THAT'S
15 IMPORTANT.

16 MR. SHEEHY: MAYBE THAT'S SOMETHING AS WE
17 ADOPT THIS PROCESS, WE CAN STIPULATE. WE'RE
18 ACTUALLY ADOPTING THIS PROCESS AS A BYLAW.

19 MR. HARRISON: YOU'RE NOT ADOPTING IT AS A
20 BYLAW AMENDMENT. THE ONLY BYLAW AMENDMENT THAT WAS
21 REQUIRED WAS TO SPECIFY A PROCEDURE FOR THE CONDUCT
22 OF THE ELECTION ITSELF.

23 MR. SHEEHY: I THINK WE CAN JUST ADOPT
24 THAT WITHIN THIS PROCEDURE, COULDN'T WE, JAMES,
25 WITHOUT HAVING TO ACTUALLY CHANGE OUR BYLAWS FOR

BARRISTERS' REPORTING SERVICE

1 THIS ONE?

2 MS. LANSING: THIS IS FRIENDLY ADVICE.

3 MR. HARRISON: I SUSPECT THAT IT'S NOT
4 LIKELY TO BE A PROBLEM, CHAIR, BECAUSE ALL THE
5 PATIENT ADVOCATES CAN PARTICIPATE TELEPHONICALLY
6 CURRENTLY. AND THEN WE HAVE PERMISSION FOR UP TO AN
7 ADDITIONAL FIVE TO PARTICIPATE TELEPHONICALLY.

8 CHAIRMAN KLEIN: THAT WILL COVER IT.

9 MR. SHEEHY: I WANT TO MAKE SURE EVERYBODY
10 BECAUSE I KNOW FOLKS ARE BUSY, AND A LOT OF PEOPLE
11 RUN IN A LOT OF DIFFERENT CIRCLES THAN I DO. AND SO
12 MANY TIMES YOU FOLKS KNOW A LOT OF THESE INDIVIDUALS
13 ALREADY AND MAY BE COMFORTABLE JUST PARTICIPATING BY
14 PHONE. AND FOR SOME OF US, YOU KNOW, A LITTLE BIT
15 OF MORE TEXTURE IS ALWAYS HELPFUL.

16 CHAIRMAN KLEIN: IMPORTANT POINT.

17 MS. LANSING: ANY OTHER DISCUSSION? DO I
18 NEED A MOTION? YES. CAN I HAVE A MOTION FOR THIS?

19 DR. PIZZO: SO MOVED.

20 CHAIRMAN KLEIN: SECOND.

21 MS. LANSING: CAN I HAVE ANY DISCUSSION
22 FROM MEMBERS OF THE PUBLIC?

23 MR. REED: THIS IS SUCH A -- ALMOST A
24 TERRIFYING MOMENT FOR ME.

25 MS. LANSING: FOR ALL OF US.

BARRISTERS' REPORTING SERVICE

1 MR. REED: BECAUSE WE HAVE A MAGNIFICENTLY
2 FUNCTIONAL ORGANIZATION AND LEADERSHIP UNPARALLELED.
3 AND THE THOUGHT OF MAJOR CHANGES IS HARD TO DEAL
4 WITH. MY QUESTION IS WHAT -- WILL THE PUBLIC BE
5 ABLE TO PARTICIPATE IN THIS PROCESS AS IT MOVES
6 ALONG AS IS TYPICAL AND HAS BEEN THROUGHOUT OUR
7 HISTORY? I WANT TO KNOW BEFOREHAND WHO ARE THE
8 NOMINEES BEFORE THE VOTE IS TAKEN. I WOULD PREFER
9 TO KEEP EVERYBODY HERE. I DON'T WANT OUTSIDERS
10 COMING IN. WE'VE GOT SOMETHING GREAT HERE. WHAT
11 WOULD BE THE PUBLIC'S PARTICIPATION IN THIS PROCESS?

12 MS. LANSING: JAMES, DO YOU WANT TO ANSWER
13 THAT QUESTION?

14 MR. HARRISON: THE NOMINATIONS THEMSELVES
15 WOULD BE PUBLIC, AND WE WOULD ASK THAT THE
16 CONSTITUTIONAL OFFICERS PROVIDE BACKGROUND
17 INFORMATION, INCLUDING THE PERSONAL STATEMENT, WHICH
18 WOULD BE PROVIDED BOTH TO THE BOARD AND TO THE
19 PUBLIC. AND THE MEETING AT WHICH THE NOMINEES MAKE
20 THEIR PRESENTATIONS WOULD ALSO OCCUR IN PUBLIC.

21 CHAIRMAN KLEIN: AND THERE WOULD BE PUBLIC
22 COMMENT.

23 MS. LANSING: I WAS JUST GOING TO SAY THAT
24 YOU HAVE THE OPPORTUNITY TO HAVE PUBLIC COMMENT AND
25 SPEAK DURING THAT MEETING.

BARRISTERS' REPORTING SERVICE

1 MR. REED: THANK YOU.

2 MR. SHEEHY: COULD I KIND OF FOLLOW UP ON
3 DON'S QUESTION? CAN WE EXTEND THAT JUST AS A
4 CONSIDERATION BEYOND PUBLIC BECAUSE PUBLIC COMMENT
5 IS REALLY A ONE-WAY STREET. COULD WE INCLUDE THE
6 OPPORTUNITY FOR THE PUBLIC TO ASK QUESTIONS?
7 BECAUSE PUBLIC COMMENT DOES NOT NECESSITATE A
8 RESPONSE, BUT ACTUALLY PEOPLE LIKE DON AND OTHER
9 FOLKS WHO HAVE REALLY KEPT US GOING, I DON'T KNOW --

10 MS. LANSING: I WOULD BE VERY SUPPORTIVE
11 OF THAT. I THINK I SPEAK FOR ALL OF US IN SAYING
12 THAT WE SO VALUE DON AND MANY, MANY, MANY OTHER
13 MEMBERS OF THE PUBLIC THAT HAVE BEEN WITH US EVERY
14 STEP OF THE WAY. SO I WOULD BE VERY SUPPORTIVE OF
15 THAT. JAMES, IS THAT POSSIBLE?

16 MR. HARRISON: YES.

17 MS. LANSING: DO I NEED A VOTE FOR THAT?

18 CHAIRMAN KLEIN: JUST AS A SECOND I WOULD
19 ACCEPT THAT AS PART OF THE INTENT OF THE MOTION.

20 DR. PIZZO: SOUNDS GOOD.

21 MS. LANSING: ANY OTHER MEMBERS? THAT WAS
22 A GREAT SUGGESTION, JEFF. THANK YOU. ANY OTHER
23 MEMBERS OF THE PUBLIC? OKAY. ALL IN FAVOR SAY AYE.

24 (CHORUS OF AYES.)

25 ANY OPPOSED?

BARRISTERS' REPORTING SERVICE

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(NO RESPONSE.)

ON THE PHONE?

MS. KING: WILLIAM BRODY. I KNOW YOUR PHONE IS MUTED. ARE YOU VOTING ON THIS ITEM? HE MAY HAVE STEPPED AWAY. WE HAVE A QUORUM WITHOUT HIM, SO THE MOTION CARRIES.

MS. LANSING: THANK YOU ALL AND THANK YOU FOR YOUR INPUT.

DR. BRODY: I'M HERE.

MS. LANSING: YOUR VOTE IS YES; IS THAT CORRECT?

DR. BRODY: YES.

MS. LANSING: THANK YOU, DR. BRODY. THAT CONCLUDES THE GOVERNANCE SUBCOMMITTEE, SO, BOB, I TURN BACK TO YOU.

CHAIRMAN KLEIN: THANK YOU VERY MUCH. SENATOR TORRES.

MR. TORRES: I JUST WANT TO POINT OUT THAT IN OUR CLIPS TODAY IS AN ARTICLE IN THE *HUFFINGTON POST* THAT DON REED WROTE, AND IT'S WELL WORTH READING.

CHAIRMAN KLEIN: ALL RIGHT. SO AS WE MOVE FORWARD TODAY, I'D LIKE TO GO TO THE SCIENCE ITEMS, WHICH ARE VERY SIGNIFICANT HERE. GETTING THEM OUT EARLIER IN THE DAY IS BENEFICIAL TO ANY MEMBERS OF

BARRISTERS' REPORTING SERVICE

1 THE PRESS THAT ARE PART OF THE AUDIO BROADCAST. AND
2 THE FIRST MEMBER -- THE FIRST OF THOSE ITEMS THAT
3 I'M GOING TO PICK UP IS ITEM 10, THE CONSIDERATION
4 OF CONCEPT PROPOSAL FOR DISEASE TEAM II RFA.

5 BEFORE LAUNCHING INTO THAT ITEM, DR.
6 TROUNSON, I'D LIKE TO INDICATE THAT OUR SCIENTIFIC
7 EXPERTISE ON THE BOARD HAS BEEN AUGMENTED ONCE AGAIN
8 BY A GREAT ALTERNATE. DR. JAMES ECONOMOU HAS JOINED
9 US, AS I MENTIONED YESTERDAY. BUT HIS BACKGROUND
10 INCLUDES AN EDUCATION FROM JOHN HOPKINS WITH HIS
11 GENERAL SURGICAL TRAINING AT THE UNIVERSITY OF
12 CALIFORNIA SAN FRANCISCO AND HE JOINED THE UCLA
13 FACULTY IN 1986.

14 IT IS IMPORTANT TO NOTE THAT HE LED FOR 15
15 YEARS THE UCLA HUMAN GENE MEDICINE PROGRAM AND
16 UNDERTOOK THE FIRST GENE THERAPY TRIAL ON THE WEST
17 COAST, A TREMENDOUS CONTRIBUTION OF EXPERTISE AND
18 KNOWLEDGE TO THIS BOARD. HE SERVED AS DEPUTY
19 DIRECTOR OF THE UCLA JOHNSON COMPREHENSIVE CANCER
20 CENTER SINCE 2002. HE IS PRESIDENT ELECT TO THE
21 SOCIETY FOR SURGICAL ONCOLOGY AND A RECIPIENT OF THE
22 JAMES EWING MEDAL. HIS RESEARCH INTERESTS INCLUDE
23 DNA AND DENDRITIC CELL-BASED CANCER VACCINES, T-CELL
24 RECEPTOR ENGINEERING OF LYMPHOCYTES AND HEMATOPOETIC
25 STEM CELLS, AS WELL AS MOLECULAR MECHANISMS OF

BARRISTERS' REPORTING SERVICE

1 RESISTANCE TO APOPTOSIS.

2 HE IS THE VICE CHANCELLOR FOR RESEARCH AND
3 HAS A REFERRAL-BASED CLINICAL PRACTICE IN SURGICAL
4 ONCOLOGY IN TRANSLATIONAL CANCER GENE THERAPY
5 RESEARCH. SO LET US WELCOME HIM WITH A ROUND OF
6 APPLAUSE.

7 (APPLAUSE.)

8 CHAIRMAN KLEIN: THANK YOU. DR. TROUNSON,
9 COULD YOU INDICATE WHO YOU WOULD LIKE TO PRESENT
10 ITEM NO. 10?

11 DR. TROUNSON: DR. BETTINA STEFFEN WILL
12 PRESENT THIS FOR YOU.

13 DR. STEFFEN: MR. CHAIRMAN, BOARD MEMBERS,
14 STAFF, MEMBERS OF THE AUDIENCE, AND GUESTS, TODAY I
15 WOULD LIKE TO PRESENT A CONCEPT PLAN FOR THE DISEASE
16 TEAM II AWARDS FOR YOUR CONSIDERATION.

17 THIS DIAGRAM YOU'VE SEEN MANY TIMES AND
18 REPRESENTS CIRM'S CORE INITIATIVES, THE RESEARCH
19 INITIATIVES. AND THE TOP FOUR BARS IN THIS SLIDE
20 ARE OUR TRANSLATIONAL PROGRAMS DESIGNED TO HELP
21 BRING STEM CELL-BASED THERAPIES TO THE CLINIC.

22 THE DISEASE TEAM II INITIATIVE IS OUR
23 FOCUS OF THE DISCUSSION TODAY. AND THE SECOND ROUND
24 DIFFERS FROM OUR FIRST ROUND PRIMARILY IN THE SCOPE
25 OF DEVELOPMENT ACTIVITIES THAT IT COVERS AND ALSO

BARRISTERS' REPORTING SERVICE

1 THE KEY OUTCOMES FROM THIS PROGRAM.

2 SO IT BEGINS AT A SLIGHTLY LATER
3 DEVELOPMENT STAGE THAN OUR FIRST ROUND WITH
4 NOMINATION OF A DEVELOPMENT CANDIDATE. AND THESE
5 ARE FOR TEAMS WHO FEEL THAT THEY HAVE COMPLETED ALL
6 THE RESEARCH NECESSARY TO BEGIN THE VERY EXPENSIVE
7 PRECLINICAL DEVELOPMENT STAGES. IT'S A STANDARD
8 INDUSTRY TERM, AND WE'VE BEEN WORKING WITH MANY OF
9 OUR ACADEMIC TEAMS TO HELP THEM UNDERSTAND THESE
10 CONCEPTS THROUGH OUR EARLY TRANSLATIONAL PROGRAM.
11 AND, IN FACT, A DEVELOPMENT CANDIDATE IS ONE OF THE
12 VERY IMPORTANT OUTPUTS OF THE EARLY TRANSLATIONAL I
13 AND II PROGRAMS.

14 SO YOU CAN SEE HOW THESE PROGRAMS ARE
15 DESIGNED TO COMPLEMENT ONE ANOTHER AND HOW WE'RE
16 BRINGING TEAMS ALONG TO QUALIFY FOR THESE CLINICAL
17 ORIENTED PROGRAMS.

18 PROJECTS NEED NOT START WITH A DEVELOPMENT
19 CANDIDATE. I ALSO MAKE THE POINT THAT THOSE THAT
20 ARE AT LATER STAGES, SUCH AS BEING READY TO START A
21 PHASE I OR PHASE II TRIAL OR SOMEWHERE IN BETWEEN,
22 WOULD QUALIFY FOR THIS PROGRAM.

23 THIS DISEASE TEAM II AWARD WILL BE A
24 TWO-STAGE PROCESS. IT WILL SUPPORT BOTH A PLANNING
25 AWARD AND A RESEARCH AWARD. AND EACH OF THESE

BARRISTERS' REPORTING SERVICE

1 AWARDS WILL UNDERGO AN APPLICATION, A GRANTS REVIEW
2 PROCESS, AND ICOC APPROVAL. SO YOU WILL SEE THESE
3 TEAMS TWICE. AND IN THIS ROUND, DIFFERENT FROM OUR
4 FIRST DISEASE TEAM AWARD, RECEIVING A PLANNING AWARD
5 WILL BE A PREREQUISITE FOR MOVING ON TO THE SECOND
6 STAGE OF THE APPLICATION PROCESS.

7 I'D LIKE TO SPEND A LITTLE BIT OF TIME
8 TALKING ABOUT WHY WE'RE GOING TO OFFER BOTH OF THESE
9 TYPES OF AWARDS. I'M GOING TO FOCUS ON THE PLANNING
10 AWARD FIRST, WHICH IS ON THE LEFT HAND OF THIS
11 SLIDE.

12 DURING THIS PLANNING PROCESS, WE EXPECT
13 PRINCIPAL INVESTIGATORS TO FORM TEAMS AND DEVELOP
14 THEIR PROPOSALS. AND THERE ARE REALLY THREE REASONS
15 TO DO THIS PLANNING AWARD. FIRST, BASED ON THE
16 FEEDBACK FROM OUR APPLICANTS AND FUNDING PARTNERS,
17 THEY NEED TIME AND FUNDS TO ESTABLISH THE TEAMS WITH
18 THE RIGHT EXPERTISE AND COLLABORATIONS. IN FACT,
19 DR. STEINBERG THIS MORNING AND DR. CARMICHAEL WERE
20 BOTH RECIPIENTS OF PLANNING AWARDS, ONE FROM CIRM
21 AND ONE INTERNALLY FROM STANFORD, AND THEY ACTUALLY
22 FOUND EACH OTHER THROUGH THIS PLANNING PROCESS, HAD
23 THE RESOURCES TO BRING EACH OTHER TO THEIR
24 RESPECTIVE INSTITUTIONS, AND CAME TO THE CONCLUSION
25 THAT THEY WOULD BE A STRONGER TEAM COMBINING THEIR

BARRISTERS' REPORTING SERVICE

1 PRECLINICAL AND CLINICAL EXPERTISE. THIS IS EXACTLY
2 WHAT WE WANT TO HAPPEN AND HOPE TO FACILITATE THAT.

3 THE SECOND THING IS WE THINK THAT THE
4 PLANNING PERIOD WILL IMPROVE THE QUALITY OF THE
5 PROPOSALS. IN OUR PAST ROUND OF DISEASE TEAM
6 AWARDS, RECEIPT OF A PLANNING AWARD WAS HIGHLY
7 CORRELATED WITH A SUCCESSFUL DISEASE TEAM APPLICANT.
8 TEN OF THE 14 GRANTS THAT WERE AWARDED HAD PLANNING
9 AWARDS.

10 AND FINALLY, THE PLANNING AWARDS WILL GIVE
11 THE TEAMS ACCESS TO SOME TYPES OF PERSONNEL,
12 REGULATORY, PROJECT MANAGEMENT, AND CLINICAL
13 PERSONNEL, TO HELP PREPARE NECESSARY SUPPORTING
14 DOCUMENTATION. SO NOT ONLY IS THE RESEARCH PROPOSAL
15 AN IMPORTANT COMPONENT OF THIS, BUT THE TYPES OF
16 DOCUMENTATION, FOR EXAMPLE, A PROJECT TIMELINE, A
17 GANT CHART, SOUNDS SIMPLE, BUT IT'S FAIRLY COMPLEX
18 AND IMPORTANT TO SUCCESS OF THESE PROJECTS,
19 ACTIVITIES-BASED BUDGETS AND CLINICAL PROTOCOL
20 SYNOPSES. SO WE WANT TO GIVE ALL TEAMS ACCESS TO
21 THOSE TYPES OF PERSONNEL TO HELP SUPPORT PREPARING A
22 FULL PROPOSAL.

23 ON THE RIGHT-HAND SIDE, NOW THE RESEARCH
24 AWARD, AS WE'RE SHIFTING DOWNSTREAM, THERE ARE MORE
25 OUTCOMES THAT ARE POSSIBLE UNDER THIS AWARD. SO

BARRISTERS' REPORTING SERVICE

1 JUST LIKE THE FIRST -- SORRY. AND TEAMS NEED NOT
2 ACHIEVE ALL THREE OF THESE GOALS, BUT AT LEAST ONE
3 OF THEM. SO LIKE THE FIRST FOUND OF DISEASE TEAMS,
4 WE WANT TO SEE APPROVABLE IND'S AS A RESULT OF THIS
5 PROGRAM.

6 SECOND, WE HOPE TO SEE TEAMS THAT WILL
7 COMPLETE A PHASE I OR A PHASE I/II COMBINED STUDY
8 DEMONSTRATING PRELIMINARY SAFETY OR PRELIMINARY
9 ACTIVITY IN HUMANS.

10 AND THE THIRD GOAL IS TO COMPLETE A
11 CONTROLLED PHASE II STUDY. AND YOU CAN SEE HOW
12 THESE THREE WRAPPED TOGETHER BEGIN TO SUPPORT THAT
13 CIRM TEN-YEAR ASPIRATIONAL GOAL OF HAVING PROOF OF
14 CONCEPT FOR STEM CELL-BASED THERAPIES. AND AS
15 ALWAYS, WE WANT TO SEE THERAPEUTICS DEVELOPED FOR
16 UNMET MEDICAL NEEDS.

17 WE'VE TALKED A LITTLE BIT ABOUT THE TYPE
18 OF ACTIVITIES THAT WILL BE FUNDED UNDER THIS AWARD
19 FROM PRECLINICAL DEVELOPMENT AND THE CONDUCT OF
20 EARLY TRIALS IN THE FIRST TWO BULLETS. BUT I THINK
21 IT'S REALLY IMPORTANT TO NOTE THAT CIRM IS ONE OF
22 THE FEW ORGANIZATIONS THAT WILL ACTUALLY FUND ALL
23 THE ACTIVITIES THAT ARE NECESSARY TO BOTH FILE AN
24 IND AND TO RUN A CLINICAL STUDY. AND THESE ARE
25 EXEMPLIFIED IN THE THIRD AND FOURTH BULLETS.

BARRISTERS' REPORTING SERVICE

1 SO A SUPPORTING STUDY, THESE ARE THINGS
2 THAT ARE NOT NECESSARILY THE PHASE I OR II STUDY,
3 BUT MIGHT PROVIDE CLARIFICATION THAT'S IMPORTANT TO
4 DESIGNING TRIALS THAT GET BETTER OUTCOMES. SO YOU
5 MIGHT DO MORE PHARMACODYNAMIC STUDIES TO IMPROVE
6 YOUR DOSING CALCULATIONS. CIRM WILL ALSO SUPPORT
7 THE GMP, GOOD MANUFACTURING PRACTICE, ACTIVITIES AND
8 OPTIMIZATION THAT ARE NECESSARY TO CONDUCT THE
9 TRIALS THAT ARE PROPOSED UNDER THE AWARD.

10 WE HAVE SEVERAL EXAMPLES FROM
11 INVESTIGATORS THAT THEY SAY THEY SIMPLY WOULDN'T BE
12 ABLE TO DO THESE KINDS OF PROJECT IF IT WEREN'T FOR
13 THE COMPREHENSIVE, CONTINUOUS SUPPORT THAT COMES
14 FROM THESE CIRM PROJECTS.

15 WHILE WE'RE ON THIS, I THINK WE SHOULD
16 MENTION THAT WHAT WE WILL NOT FUND ARE PHASE III
17 PIVOTAL STUDIES.

18 SO AS ALWAYS, THE USE OF A STEM CELL
19 EITHER FOR DEVELOPMENT OR AS THE THERAPEUTIC
20 CANDIDATE ARE IMPORTANT FOR THESE PROJECTS. THE
21 TYPES OF CELLS THAT WE'RE INTERESTED IN THIS SECOND
22 ROUND INCLUDE THOSE LISTED, THE PLURIPOTENT-DERIVED
23 CELLS, GENETICALLY MODIFIED STEM CELLS, WHICH MIGHT
24 BE, FOR EXAMPLE, A HEMATOPOETIC STEM CELL THAT IS
25 GENETICALLY CORRECTED TO ADDRESS A DISEASE

BARRISTERS' REPORTING SERVICE

1 PHENOTYPE, NEURAL STEM CELLS, AND NEURAL PROGENITOR
2 CELLS. THERE'S A LONG HISTORY AND A LOT OF EXCITING
3 WORK IN THAT AREA. STEM CELL ENGINEERED FUNCTIONAL
4 TISSUES, THIS IS WHERE WE'RE THINKING ABOUT AN
5 EXAMPLE MIGHT BE A COMPLEX TUBULAR STRUCTURE LIKE A
6 VASCULAR GRAFT OR A NEOBLADDER WHERE CELLS ARE PART
7 OF THE TISSUE ENGINEERING, AND THEY ARE INTENDED FOR
8 TRANSPLANTATION INTO INDIVIDUALS.

9 WE'RE ALSO INTERESTED IN NOVEL
10 REGENERATIVE THERAPIES DIRECTED IN ENDOGENOUS STEM
11 CELLS AND ALSO DIRECTLY REPROGRAMMED CELLS. THESE
12 ARE THE CONCEPTS THAT DR. TROUNSON TALKED ABOUT, THE
13 LAST ONE IN HIS SCIENTIFIC PRESENTATION TODAY.
14 THERE'S A LOT OF BASIC WORK STILL TO BE DONE, BUT WE
15 THOUGHT WE'D AT LEAST PUT IT ON THE LIST.

16 OUR STANDARD ELIGIBILITY CRITERIA THAT
17 WERE AGREED TO WITH MEMBERS OF A TASK FORCE OF THIS
18 BOARD APPLY TO THIS RFA. SO SAME ELIGIBILITY. WE
19 EXPECT TEAMS OR WILL ALLOW FOR ONE PRINCIPAL
20 INVESTIGATOR AND UP TO AN ADDITIONAL CO-PRINCIPAL
21 INVESTIGATOR AND WANT TO SEE THE CONSISTENT
22 30-PERCENT MINIMUM EFFORT FROM THE PI AND THE 20
23 PERCENT FROM THE CO-PI.

24 I HOPE YOU ALL HEARD DR. STEINBERG THIS
25 MORNING, WHO SAID, AND I WROTE IT DOWN, "THIS IS A

BARRISTERS' REPORTING SERVICE

1 HUGUE AMOUNT OF WORK AND MORE THAN I EXPECTED
2 INITIALLY." BUT ALSO IN THAT SAME BREATH HE SAID,
3 "WE WANT TO BE ONE OF THOSE TEAMS WHO DELIVERS THAT
4 IND." SO I THOUGHT THAT WAS ILLUSTRATIVE OF THAT
5 COMMITMENT TO THE PROJECTS.

6 PI OR CO-PI'S ON EXISTING DISEASE TEAM
7 AWARDS ARE NOT ELIGIBLE TO APPLY TO THIS ROUND.

8 FINALLY, EITHER NONPROFIT OR FOR-PROFIT
9 INSTITUTIONS MAY APPLY.

10 THE PLANNING AWARD AS WE HAVE PROPOSED IT
11 WOULD BE 20 GRANTS OF UP TO \$110,000 FOR SIX MONTHS
12 OF PLANNING. SO THIS IS AN INCREASE OVER THE LAST
13 TIME, AND IT INCLUDES A 10-PERCENT ALLOTMENT FOR
14 INDIRECT COSTS. THE TOTAL PLANNING AWARD COSTS
15 WOULD BE UP TO \$2.2 MILLION.

16 FOR THE RESEARCH AWARD, WE PROPOSE SIX
17 PROJECTS WITH UP TO FOUR YEARS OF TOTAL JUSTIFIABLE
18 COSTS NOT TO EXCEED \$20 MILLION, FOR A TOTAL
19 RESEARCH AWARD BUDGET OF \$120 MILLION. MATCHING
20 FUNDS FOR THIS ONE, UNLIKE THE TARGETED CLINICAL
21 DEVELOPMENT, WE WILL NOT REQUIRE; BUT IF PROJECTS
22 HAVE ACTIVITIES THAT WOULD EXCEED THE \$20 MILLION,
23 WE WILL EXPECT TEAMS TO JUSTIFY IN THEIR PROPOSAL
24 THEIR PLAN TO SECURE THESE FUNDS.

25 THE AWARD INSTRUMENT WOULD BE A GRANT FOR

BARRISTERS' REPORTING SERVICE

1 A NONPROFIT ORGANIZATION AND A LOAN FOR A
2 FOR-PROFIT, AND THE TOTAL PROGRAM COST THAT WE'RE
3 ASKING YOU TO APPROVE TODAY FOR BOTH THE PLANNING
4 AND THE RESEARCH AWARD WOULD BE \$122.2 MILLION.

5 OUR PROVISIONAL TIMETABLE IS LISTED HERE.
6 THE RFA RELEASE WE WOULD EXPECT BY NOVEMBER OF THIS
7 YEAR, AND THE RECEIPT OF THE PLANNING APPLICATIONS
8 WOULD BE IN MARCH 2011. THAT'S IN RED BECAUSE IN
9 YOUR BINDERS IN THE CONCEPT PROPOSAL THAT WAS STATED
10 AS FEBRUARY. WE HAD TO ADJUST. THIS IS ACTUALLY
11 GOING TO BE AN ONLINE APPLICATION, AND YOU ARE GOING
12 TO HEAR FROM AMY LEWIS IN GRANTS MANAGEMENT TODAY A
13 LITTLE BIT ABOUT THAT ONLINE SYSTEM. WE WANT TO
14 SUPPORT MOVING THE INVESTIGATORS TO AN ONLINE
15 APPLICATION PROCESS. THOSE WOULD BE REVIEWED IN MAY
16 AND APPROVED BY THIS BOARD IN AUGUST, AND THEN THE
17 PLANNING PERIOD WOULD OCCUR AT THE LATTER HALF OF
18 2011. WE WOULD RECEIVE THE FULL APPLICATIONS IN
19 JANUARY OF 2012, BE REVIEWED IN SPRING, AND COME TO
20 THIS BOARD FOR CONSIDERATION IN JUNE OF 2012.

21 SO THAT CONCLUDES MY PRESENTATION, AND I'D
22 BE HAPPY TO TAKE QUESTIONS.

23 CHAIRMAN KLEIN: DR. STEFFEN, JUST AS A
24 CLARIFICATION, WE HAVE AN EARLY TRANSLATION AWARD
25 PROCESS THAT IS ONGOING AT THIS POINT. WE ARE GOING

BARRISTERS' REPORTING SERVICE

1 TO APPROVE THIS YEAR A SECOND EARLY TRANSLATION
2 GROUP. IF THERE IS A CANDIDATE IN THE EARLY
3 TRANSLATION PROCESS THAT IS GOING FASTER THAN
4 ANTICIPATED, I WOULD HOPE THAT THEY COULD APPLY IN
5 THE DISEASE TEAM PROCESS IF THEY ESTIMATED THEY
6 WOULD BE THROUGH THEIR EARLY TRANSLATION CRITERIA IN
7 A TIME FRAME SUFFICIENT TO MEET THE DISEASE TEAM
8 SCHEDULE BECAUSE WE'VE ALREADY PRESELECTED THEM FOR
9 EXCELLENCE. AND IF THEY'RE MOVING FASTER, I HOPE WE
10 DON'T HAVE ANYTHING IN OUR PRIOR QUALIFICATIONS THAT
11 SAID IF YOU'RE IN EARLY TRANSLATION, YOU CAN'T ALSO
12 APPLY FOR DISEASE TEAM. SO, DR. TROUNSON, WOULD YOU
13 LIKE TO COMMENT?

14 DR. TROUNSON: NO. I THINK THAT'S
15 PERFECTLY CLEAR TO ME, CHAIR. WHAT THEY SHOULD DO
16 IS COME IN ON IT BECAUSE WHAT WE WANT TO DO IS TO
17 GET THAT PLANNING PROCESS DONE. SO IF THEY COULD
18 COME IN ON THAT PLANNING PROCESS, IF THEY'RE THAT
19 ADVANCED, WE WOULD SEE THAT AS A VERY COMPETITIVE
20 GRANT IF THEY'RE AT AN ADVANCED STAGE. SO MY OWN
21 VIEW, WITHOUT TALKING WITH THE STAFF, I WOULD HAVE
22 THOUGHT THAT THAT WOULD BE PERFECTLY APPROPRIATE.
23 BUT I CAN'T REALLY SEE ANY REASON TO NOT ALLOW THEM
24 TO DO THAT. PERFECTLY OKAY.

25 CHAIRMAN KLEIN: I THINK, JEFF, DID YOU

BARRISTERS' REPORTING SERVICE

1 HAVE A POINT?

2 MR. SHEEHY: I HAVE A LOT OF POINTS.

3 CHAIRMAN KLEIN: DR. BRENNER AND THEN JEFF
4 SHEEHY.

5 DR. BRENNER: JUST A FOLLOW-UP TO WHAT YOU
6 SAID. ONE THING TO THINK ABOUT IS IF SOMEONE HAS AN
7 EARLY GRANT AND THEN WANTS TO APPLY FOR THIS GRANT,
8 THERE SHOULD BE A MECHANISM IN WHICH THEY LOSE THE
9 RESIDUAL PART OF THE OLD GRANT.

10 DR. TROUNSON: THAT'S RIGHT. IF THERE WAS
11 A RESIDUAL ON THAT, IT WOULD BE -- THAT WOULD BE
12 COMPLETED. OBVIOUSLY IT MIGHT DEPEND ON HOW MUCH
13 TIME IS REQUIRED BEFORE THEY LINK INTO THE NEXT ONE
14 IF THEY'RE AWARDED, BUT ABSOLUTELY.

15 CHAIRMAN KLEIN: TO CLARIFY THAT, IT'S
16 ONLY IF THEY DID RECEIVE THE NEXT GRANT.

17 MR. SHEEHY: I THINK THIS IS AN
18 OUTSTANDING PROPOSAL. THANK YOU, DR. STEFFEN. BUT
19 I DID HAVE -- SO, FIRST, WHEN YOU TALK ABOUT UNMET
20 MEDICAL NEEDS, I KNOW THAT THAT'S KIND OF A TERM OF
21 ART; BUT WHEN WE WENT THROUGH THE LAST DISEASE TEAM
22 PROCESS, SOME OF THE WORKING GROUP MEMBERS
23 INTERPRETED THAT TO BE IF THERE'S A PERFECTLY
24 ADEQUATE THERAPY; I.E., IN HIV THERE ARE PILLS THAT
25 TO THE OUTSIDE WORLD SEEM VERY TOLERABLE AND

BARRISTERS' REPORTING SERVICE

1 ADEQUATE, THAT THE NEED FOR CELL THERAPY IS NOT
2 NECESSARILY -- YOU KNOW, THERE'S NOT AN UNMET
3 MEDICAL NEED. I THINK WE WORKED THAT OUT, BUT I
4 HOPE GOING INTO THE REVIEW THAT WE CAN KIND OF
5 CLARIFY THAT THEY CAN HAVE AN IMPACT ON DIABETES,
6 THEY CAN HAVE AN IMPACT ON HIV, OTHER CHRONIC LIFE
7 THREATENING DISEASES THAT PEOPLE KIND OF STUMBLE
8 ALONG WITH THAT TO OUTSIDE OBSERVERS DON'T SEEM TO
9 BE PARTICULARLY BURDENSOME, BUT TO MANY PEOPLE
10 LIVING WITH THESE DISEASES AND CONDITION, ACTUALLY
11 IT DOES REPRESENT QUITE A BIT OF UNMET MEDICAL NEED.

12 THAT'S JUST -- WE'VE TALKED ABOUT THIS
13 BEFORE. JUST SO THAT WE DON'T HAVE PEOPLE COMING IN
14 SAYING THEY GOT THE PILLS.

15 MY NEXT QUESTION. THERE IS NOT A PREAP
16 PROCESS ON THIS, CORRECT?

17 DR. STEFFEN: THERE IS NOT A PREAP
18 PROCESS.

19 MR. SHEEHY: ANYBODY WILL BE ABLE -- IN
20 FACT, MY UNDERSTANDING IS THAT THE PLANNING AWARD
21 PROCESS IS GOING TO BE THE PREAP PROCESS, SO THE
22 WORKING GROUP WILL BE THE --

23 DR. STEFFEN: SO BASED ON FEEDBACK THAT WE
24 GOT FROM THE GRANTS WORKING GROUP AND APPLICANTS AND
25 SO FORTH, IF THEY DO A PLANNING AWARD AND WE GO TO

BARRISTERS' REPORTING SERVICE

1 THE EFFORT OF SEATING A FULL GRANTS WORKING GROUP,
2 THEY SPEND THEIR TIME REVIEWING THE PROPOSALS, AND I
3 THINK WE HEARD THIS ACROSS THE BOARD, THAT THAT
4 SHOULD BE THE PREREQUISITE THEN TO APPLY FOR THE
5 FULL AWARD.

6 MR. SHEEHY: BUT I MEANT IN TERMS OF
7 APPLYING FOR THE PLANNING GRANT.

8 DR. STEFFEN: IT'S OPEN TO ALL ELIGIBLE
9 APPLICANTS.

10 MR. SHEEHY: SO IF WE GOT A HUNDRED
11 APPLICATIONS, THEN WE WOULD SEAT THE WORKING GROUP.

12 DR. STEFFEN: WE WOULD REVIEW A HUNDRED.

13 MR. SHEEHY: THAT'S GREAT.

14 DR. STEFFEN: AND IT WOULD BE OVER SEVERAL
15 EXTRA DAYS. THEY'LL BE A LITTLE BIT DIFFERENT
16 FLAVOR THAN LAST TIME. THERE WILL BE MORE
17 SCIENTIFIC MEAT, IF YOU WILL, IN THEM. THE LAST
18 TIME THEY WERE REALLY ABOUT PLANNING AND HOW ARE YOU
19 GOING TO PLAN. THIS WILL ACTUALLY CONTAIN
20 COMPONENTS OF THE SCIENTIFIC PROPOSAL, NOT FULLY
21 FLESHED OUT, BUT MUCH MORE FOCUSED ON WHAT IS THE
22 INDICATION, WHAT IS THE PROPOSED THERAPEUTIC, HOW
23 ARE YOU GOING TO GET THERE, CLINICAL DEVELOPMENT
24 PLAN, AND SO FORTH.

25 MR. SHEEHY: AND THEN MY OTHER QUESTION,

BARRISTERS' REPORTING SERVICE

1 AND ACTUALLY I WOULD LIKE THE BOARD TO CONSIDER
2 THIS, IS I'D REALLY LIKE TO INCREASE THE INPUTS.
3 FRANKLY, I'D LIKE TO DOUBLE AT LEAST THE NUMBER OF
4 PLANNING AWARDS AND AT LEAST GO TO 14 OR 15
5 POTENTIAL DISEASE TEAMS BECAUSE IF YOU LOOK AT OUR
6 TIMELINE, THIS IS REALLY KIND OF -- IF YOU LOOK HOW
7 WE ORIGINALLY STRUCTURED THIS PROGRAM OR WE TALKED
8 ABOUT IT, WE'RE GOING TO DO A DISEASE TEAM ROUND
9 EVERY YEAR. AND THIS IS REALLY -- OUR LAST DISEASE
10 TEAM APPROVAL WAS OCTOBER OF '09. THE NEXT DISEASE
11 TEAM APPROVAL IS GOING TO BE IN JUNE OF 2012. AND I
12 WORRY ABOUT US HAVING ENOUGH INPUT TO GIVE US ENOUGH
13 RESULTS. WE EXPECT MOST OF THESE PROGRAMS TO FAIL.
14 THIS HAS BEEN A CONSTANT THEME IN ALL OF OUR
15 DISCUSSIONS ABOUT DISEASE TEAMS.

16 OBVIOUSLY I DON'T WANT TO FUND ANYTHING
17 THAT'S NOT MERITORIOUS, BUT I WANT TO SET OUT A
18 PRIORI IF WE FUNDED 14 DISEASE TEAMS LAST TIME, WHY
19 WOULD WE ONLY FUND SIX THIS TIME? AND THE KEY
20 FUNNEL, IF YOU LOOK AT THE METRICS, IS GOING TO BE
21 HOW MANY PLANNING AWARDS WE DO. AND IN ORDER TO
22 GET, YOU KNOW, 10 TO 15 DISEASE TEAMS, WHICH I THINK
23 WE SHOULD THINK OF A MINIMUM, THESE ARE MILESTONE
24 DRIVEN, AGAIN, I BELIEVE. AND IF THEY DON'T MAKE
25 THEIR MILESTONES, WE'RE GOING TO EXPECT SOME

BARRISTERS' REPORTING SERVICE

1 ATTRITION FROM OUR CURRENT DISEASE TEAM ROUND. WE
2 SHOULD EXPECT -- IF WE ONLY HAVE SIX AND WE LOSE
3 TWO-THIRDS OF THOSE, WE DON'T HAVE VERY MUCH IN THE
4 PIPELINE GOING FORWARD. AND I THINK THAT WE SAW 14
5 REALLY GOOD PROPOSALS AND THE SCIENCE IS GOING
6 PRETTY GOOD, AND WE FUNDED A LOT OF REALLY SMART
7 PEOPLE. I THINK WE'RE ALL IMPRESSED WITH WHAT WE'RE
8 DOING. AND CERTAINLY WE HAD BUDGETED ANOTHER \$250
9 MILLION DISEASE TEAM ROUND.

10 PERSONALLY I WOULD SUGGEST THAT WE DO UP
11 TO 45 PLANNING AWARDS. IF WE DON'T GET THE SCIENCE,
12 WE DON'T DO THEM. AND THAT WOULD GIVE US THE
13 OPPORTUNITY TO DO UP TO 15 DISEASE TEAMS BECAUSE WE
14 HAD PLANNED TO ACTUALLY SPEND, I THINK, 400 MILLION
15 ON DISEASE TEAMS WITHIN THE NEXT TWO YEARS WHEN YOU
16 LOOK AT OUR ORIGINAL WAY IN WHICH WE WERE THINKING
17 ABOUT THE DISEASE TEAMS ROLLING OUT THE LAST TIME WE
18 LOOKED AT THIS.

19 SO THAT WOULD BE MY AMENDMENT TO THIS.
20 AND I DON'T THINK -- I MEAN STAFF RIGHT NOW IS
21 HANDLING 14 DISEASE TEAMS. THE BILL HAS PASSED THE
22 ASSEMBLY, RIGHT, SO WE CAN STAFF UP MORE. SOME OF
23 THOSE DISEASE TEAMS WILL NOT BE HERE BY THE TIME
24 THIS COMES THROUGH, I HAVE A FEELING, BECAUSE THEY
25 ALL STARTED. SO I WANT TO MAKE SURE WE HAVE A GOOD

BARRISTERS' REPORTING SERVICE

1 PIPELINE SO THAT WE HAVE SOMETHING TO SHOW THE
2 VOTERS IN 2012, 2013, 2014, 2015. SO THAT WOULD BE
3 MY RECOMMENDATION, UP TO 45 PLANNING AWARDS AND UP
4 TO 15 DISEASE TEAMS.

5 CHAIRMAN KLEIN: SO, DR. TROUNSON, THIS IS
6 CLEARLY A POINT THAT WE'VE TALKED ABOUT BEFORE IS
7 GETTING A LARGE ENOUGH PORTFOLIO SO THAT WE ENHANCE
8 OUR ABILITY TO HAVE POSITIVE OUTCOMES. BUT COULD
9 YOU PLEASE ADDRESS THIS? OF COURSE, JEFF'S
10 STATEMENT IS CONDITIONED ON THE QUALITY OF THE
11 SCIENCE BEING THERE TO MERIT THE AWARD.

12 I WOULD ADD ONE POINT TO, JEFF, WHAT
13 YOU'VE SAID IS THAT TO THE EXTENT WE SET THE TARGET
14 AT A LOWER LEVEL FOR PLANNING GRANTS OR FOR THE
15 FINAL AWARDS, PARTICULARLY FOR FINAL AWARDS, IT
16 DISCOURAGES OR COULD DISCOURAGE APPLICATIONS BECAUSE
17 IF THEY THINK ONLY A VERY SMALL AMOUNT COULD
18 POSSIBLY BE FUNDED, THE ODDS BECOME TOO GREAT TO
19 MAKE A MASSIVE EFFORT. AND CERTAINLY THIS IS A
20 MASSIVE EFFORT. SO THAT BY HAVING HIGHER TARGETS
21 EXPLICITLY CONDITIONED ON THE QUALITY OF THE
22 SCIENCE, YOU CAN POTENTIALLY ELICIT A MORE ROBUST
23 RESPONSE FROM THE APPLICANTS BECAUSE THEY HAVE THESE
24 MASSIVE TEAM EFFORTS TO PUT TOGETHER.

25 MR. SHEEHY: CAN I JUST MAKE ONE MORE

BARRISTERS' REPORTING SERVICE

1 POINT REALLY QUICKLY, BOB? IN THAT THE LOAN PROGRAM
2 IS PART OF THIS, AND THIS IS REALLY THE MAIN
3 COMPONENT OF OUR LOAN PROGRAM WAS THE DISEASE TEAM
4 PROCESS, IF YOU'RE TALKING ABOUT SUSTAINED, VIABLE,
5 FUTURE FUNDING, HOW MANY LOANS DO WE HAVE OUT NOW?

6 DR. TROUNSON: ONE.

7 MR. SHEEHY: ONE. SO WE DO SIX AWARDS, WE
8 GOT ONE OUT OF 14, I MEAN I THINK WE ALSO NEED A
9 PORTFOLIO OF LOAN APPLICANTS. I THINK IF WE DO IT
10 AT THAT SCALE, AND HOPEFULLY, AND DR. PENHOET HAS
11 REFERENCED THIS BEFORE, BUT HOPEFULLY THE MARKET IS
12 MORE PERMISSIVE OR WILL BE MORE PERMISSIVE IN 2012
13 TO PEOPLE PARTICIPATING IN THE LOAN PROGRAM. AND IF
14 WE HAVE A MUCH BROADER PORTFOLIO WITH A LOT -- IF
15 INDUSTRY SEES WE'RE GOING INTO THIS AT THIS SCALE,
16 WE MAY GET MORE PARTICIPANTS FROM INDUSTRY THAT ARE
17 FURTHER DOWN IN THE DEVELOPMENT PIPELINE IN PHASE I,
18 PHASE II, PHASE III WHERE THEY HAVE MORE INTEREST IN
19 INVOLVING THEMSELVES IN THE LOAN PROGRAM. AND WE
20 CAN REALLY -- IF WE DON'T GET SOMETHING IN THE
21 PIPELINE IN TERMS OF LOANS BY 2012, WE'RE NOT GOING
22 TO SEE ANY MONEY COME IN FOR A LONG TIME.

23 CHAIRMAN KLEIN: WE DO HAVE SOME
24 INCENTIVES FOR EARLY PAYOFFS, BUT YOUR POINT IS
25 QUITE WELL TAKEN. LET'S ASK DR. TROUNSON.

BARRISTERS' REPORTING SERVICE

1 DR. TROUNSON: YOU NEED TO BACK IT BACK
2 FROM WHAT WE CAN ACTUALLY HANDLE, I GUESS. IT'S
3 VERY HARD TO PREDICT THE NUMBER OF GRANTS THAT WILL
4 REALLY BE THERE. WE HAVE TO FOCUS ON THE GRANTS
5 THAT WILL GET INTO THIS NEXT ROUND. SO IT'S EARLY.
6 IT'S BASICALLY EARLY NEXT YEAR, RIGHT, THAT WE'LL
7 RECEIVE THESE APPLICATIONS. SO IT'S NOT LATER ON.
8 IT'S WHETHER THEY'RE THERE NOW.

9 OUR OWN FEELING IS THAT WE'RE NOT
10 OVERWHELMED. BUT ANYWAY, THE ONLY WAY YOU REALLY
11 FIND OUT IS IF YOU PUT OUT THE APPLICATION AND SEEK
12 THE NUMBERS. BUT THE FIRST TIME AROUND, OF COURSE,
13 YOU WOULD GATHER KIND OF EVERYBODY WHO REALLY HAD
14 SOMETHING. AND SO THEN YOU SHOULD LOGICALLY -- I
15 WOULD HAVE THOUGHT IT SHOULD COME DOWN AS YOU START
16 TO SATISFY. THERE'S A STRONG BUILDUP, AS YOU SAY,
17 FROM THE TRANSLATIONAL COMPONENT PART.

18 THE NUMBER THAT WE NEED TO FOCUS ON IS
19 WHAT WE CAN ACTUALLY HANDLE IN REVIEW. I DON'T
20 THINK YOU CAN HANDLE 40 OF THESE CLINICAL REVIEWS AT
21 THE ONE SITTING, SO YOU WOULD HAVE TO HAVE A MUCH
22 LONGER TIME. I THINK THE LAST TIME WE HAD -- CAN
23 YOU REMEMBER, BETTINA, HOW MANY WE HAD FOR LAST TIME
24 WHEN WE CONSIDERED THE FINAL GRANTS?

25 DR. STEFFEN: THERE WERE 31 DISEASE TEAM

BARRISTERS' REPORTING SERVICE

1 APPLICATIONS, AND THE COMPLEXITY, BECAUSE THESE
2 INVOLVE CLINICAL STUDIES, THE TARGETED CLINICAL
3 DEVELOPMENT, THIS WILL LOOK A LOT MORE LIKE THE
4 TARGETED CLINICAL DEVELOPMENT. AND THAT APPLICATION
5 ALMOST DOUBLES IN TERMS OF THE INFORMATION THAT WE
6 HAVE TO COLLECT AND REVIEW, DATA SAFETY MONITORING.

7 DR. TROUNSON: THEY'RE VERY LARGE.

8 CHAIRMAN KLEIN: COULD WE UNDERSTAND THAT
9 FIGURE? IN THE FINAL DISEASE TEAM APPLICATIONS, HOW
10 MANY WERE INVITED FOR APPLICATION?

11 DR. STEFFEN: THIRTY-TWO AND WE RECEIVED
12 AND REVIEWED 31.

13 CHAIRMAN KLEIN: RIGHT.

14 DR. STEFFEN: OF AN APPLICATION THAT'S
15 ABOUT HALF THE SIZE OF WHAT WE ANTICIPATE.

16 DR. TROUNSON: SO THIS IS GOING TO BE MUCH
17 LARGER, SO TO PUT IT AT 40 WOULD -- I JUST DON'T
18 KNOW HOW YOU'D DO THAT. YOU WOULD HAVE TO HAVE A
19 VERY LONG PROCESS OR DOUBLE SESSION, AT LEAST A
20 DOUBLE SESSION, TO HANDLE THAT. THAT'S A PRETTY BIG
21 BITE. WE LOOKED AT IT FROM THAT SIDE BACKWARDS WHAT
22 WE COULD HANDLE AT THIS POINT AND WHAT WE WERE THEN
23 GOING TO ENCOURAGE GOING FORWARD.

24 PART OF THE TROUBLE IS YOU DON'T WANT A
25 MASSIVE NUMBER OF PEOPLE WRITING THESE VERY BIG

BARRISTERS' REPORTING SERVICE

1 GRANT APPLICATIONS BECAUSE THAT'S -- THEY DON'T GET
2 THEM, OF COURSE, THE WRITTEN GRANT APPLICATION, BUT
3 THEY'VE TAKEN A LOT OF TIME AND EFFORT TO DO THAT.
4 SO THIS IS ALSO A BIT OF A DOWNER. SO WHAT WE
5 WANTED TO DO IS TRY AND CONTROL THOSE NUMBERS SO
6 THAT IT WAS ENOUGH -- WE HAD ENOUGH TO CONSIDER AND
7 THEN ENOUGH TO -- NOT TOO MANY THAT WERE WRITING
8 THESE VERY LARGE APPLICATIONS THAT WOULDN'T GET
9 THEM.

10 SO MAYBE MY FEELING IS NOT TO GO OUT AS
11 FAR AS JEFF HAS SUGGESTED. THAT SEEMS LIKE IT'S
12 OVERWHELMING AND WE'RE UNLIKELY TO BE ABLE TO COPE.
13 IT'S A HUGE AMOUNT OF WORK.

14 BUT IT DEPENDS ON THE BOARD AND THE
15 FEELING FOR HOW MUCH YOU WANT TO REALLY INCREMENT
16 THIS IN A WAY WITHOUT BUSTING OUR CAPACITY.

17 CHAIRMAN KLEIN: DR. PIZZO AND THEN I'M
18 GOING TO GO TO OS STEWARD AND THEN DUANE ROTH.

19 DR. PIZZO: A COUPLE OF VERY QUICK
20 COMMENTS AND THEN A QUESTION AND PROPOSAL. THE
21 QUICK COMMENT, FOLLOWING UP TO WHAT GARY STEINBERG
22 SAID THIS MORNING, IN ADDITION TO THE POINTS THAT
23 WERE MADE IS HE A COUPLE TIMES REFERENCED THAT THE
24 RESULTS, THE FRUIT OF RESULTS, MIGHT TAKE 10 TO 20
25 YEARS. NONE OF US KNOW EXACTLY WHEN THAT'S GOING TO

BARRISTERS' REPORTING SERVICE

1 BE, BUT HE WAS BEING REASONABLY CONSERVATIVE.

2 I THINK WE WANT TO DO THE FOLLOWING. WE
3 RECOGNIZE THE INCREDIBLE AMOUNT OF PROGRESS THAT'S
4 BEEN MADE. IF WE JUST THINK ABOUT WHERE WE'VE BEEN
5 OVER THE LAST SIX YEARS TO WHERE WE ARE TODAY, IT'S
6 REALLY EXTRAORDINARY. AND WE WANT TO SEE THIS
7 EFFORT BE SUSTAINED OVER TIME. SO THAT IF PROP 71
8 AND CIRM WERE TO COMPLETE ITS DECADE CYCLE AND, IN
9 ESSENCE, DISAPPEAR, WE WOULD HAVE LOST OUR
10 INVESTMENT AS A STATE AND AS A NATION.

11 SO THINKING ABOUT HOW TO PREPARE FOR THAT,
12 WHICH IS, I THINK, ONE OF JEFF'S MAJOR DRIVING
13 ISSUES, IS HOW DO WE FEED THIS PIPELINE IN A WAY
14 THAT BOTH PROMOTES GOOD SCIENCE AND APPLICATION, BUT
15 ALSO CREATES A PATHWAY TO CONTINUED SUPPORT SO THAT
16 OVER TIME WE CAN REALIZE THIS.

17 AND I, THEREFORE, LIKE THE CONCEPT OF
18 PRIMING THAT PIPELINE MORE. I DON'T KNOW WHAT THE
19 RIGHT NUMBER IS, BUT I THINK SOMETHING MORE THAN WE
20 HAVE NOW MAKES SENSE.

21 HERE'S THE ADDITIONAL CAVEAT. I THINK
22 IT'S IMPORTANT TO LOOK AT THE DISEASE TEAMS AS
23 THEY'VE BEEN CONSTRUCTED, BUT TO LOOK AT THEM AS
24 LEARNING LABORATORIES. WE DON'T KNOW WHETHER THE
25 CURRENT MODEL IS GOING TO ACHIEVE THE KIND OF

BARRISTERS' REPORTING SERVICE

1 OUTCOME THAT WE WANT. IN FACT, YOU STATED, AND I
2 THINK CORRECTLY, THAT LOTS OF IT WILL FAIL. AND IF
3 IT FOLLOWS THE RULES OF SCIENCE, LOTS OF THINGS WILL
4 FAIL BEFORE WE GET SUCCESSES ANYWAY. AND I WOULD
5 LIKE TO SEE THE DISEASE TEAM CONCEPT EXPLORE SOME
6 UNCHARTED WATERS AS WELL. SO BEFORE WE PUT ALL OF
7 OUR INVESTMENTS IN MORE OF THE SAME, I'D LIKE TO
8 THINK ABOUT WAYS OF CREATING OTHER PARTNERSHIPS.

9 SO, FOR EXAMPLE, SHOULD WE BE THINKING
10 ABOUT MORE ACADEMIC INDUSTRY RELATIONSHIPS SUPPORTED
11 RESULTS THAT WILL FOSTER THE TRANSLATION MORE
12 RAPIDLY? THIS IS A NEW TERRITORY. I'M NOT SURE
13 THAT -- THERE'S LOTS OF ISSUES THAT WE NEED TO GET
14 RESOLVED FROM IP TO CONFLICT AND ALL THE REST; BUT
15 IF WE COULD THINK ABOUT WAYS OF USING FUNDS TO SEED
16 CONNECTIONS, WE MIGHT BE MORE ABLE TO DO WHAT WE ALL
17 WANT TO DO.

18 WHAT I'M GETTING AT IS, A, I AGREE THAT WE
19 SHOULD PRIME MORE ROBUSTLY THAN WE SEEM TO BE RIGHT
20 NOW; BUT, B, WE SHOULDN'T PUT ALL OF OUR EGGS IN ONE
21 BASKET. WE COULD THINK ABOUT OTHER VENUES THAT
22 MIGHT STIMULATE NEW APPROACHES THAT WE'RE NOT YET
23 THINKING ABOUT THAT WILL MOVE THE AGENDA FORWARD
24 WITH THE PREMISE, THE IMPORTANT PREMISE, THAT WHAT
25 WE WANT TO DO IS TO MAKE SURE THAT THE FIRST SIX

BARRISTERS' REPORTING SERVICE

1 YEARS' INVESTMENT THAT WILL ULTIMATELY BE TEN IS
2 CARRIED FORTH FOR YEARS BEYOND THAT SO THAT WE
3 REALLY DO ACHIEVE THE RESULTS THAT WE'RE ALL AIMING
4 AND SEEKING.

5 CHAIRMAN KLEIN: SO IN THE TIMELINE HERE
6 THAT WE'RE ALL TALKING ABOUT, BY JUNE OF 2012, IF WE
7 GO OUT FOUR YEARS FROM THAT TO 2016, IN FACT, IT'S
8 VERY IMPORTANT THAT IN JUNE OF 2012 WE FAST TRACK
9 GETTING FROM APPROVAL TO AUTHORIZATIONS FOR FUNDING.
10 IN FACT, PERHAPS LENGTHEN THE TIME THAT A TEAM CAN
11 WORK AND GET REIMBURSEMENT TO THE TIME THEIR FINAL
12 DOCUMENTATION IS DONE AS LONG AS THEY ARE PROCEEDING
13 ONLY AFTER THE PROPER COMMITTEE APPROVALS FROM THEIR
14 OWN INSTITUTION. BECAUSE 2016 JUNE WE MAY HAVE ON
15 THE NOVEMBER BALLOT OF 2016 ANOTHER \$4 BILLION UNDER
16 CONSIDERATION AT THAT TIME. SO THE TIMING OF THIS
17 PORTFOLIO BUILDUP IS VERY IMPORTANT.

18 IT IS ALSO ENCOURAGING THAT OF THE FIRST
19 DISEASE TEAM GROUP THAT WE FUNDED IN PORTFOLIO, IT
20 APPEARS THAT SOME OF THEM WILL GET TO A PHASE I
21 TRIAL IN LESS THAN FOUR YEARS, WHICH IS HELPFUL, BUT
22 ONLY WITH A LARGER PORTFOLIO THAT WE HAVE A CHANCE
23 FOR THAT REALLY OCCURRING WITH ANY REAL POSSIBILITY
24 GOING FORWARD.

25 SO, OS, YOU HAD A COMMENT.

BARRISTERS' REPORTING SERVICE

1 DR. PIZZO: CAN I JUST MAKE ONE FOLLOW-UP?
2 AND THAT IS JUST TO REMIND OURSELVES THAT PHASE I IS
3 A NICE END POINT, BUT MOST THINGS FAIL AT PHASE I.
4 SO WE NEED TO BE THINKING ABOUT A BIGGER PHASE I
5 PORTFOLIO IF WE'RE GOING TO HIT INTO WHAT WE
6 ULTIMATELY WANT TO GET TO IS SOMETHING THAT WILL
7 LEAD TO AN IND. THAT'S A WHOLE DIFFERENT SET OF
8 ISSUES FOR US.

9 DR. STEWARD: TWO COMMENTS. I ALWAYS
10 WORRY A LITTLE BIT ABOUT CLOSING DOORS. AND ONE CAN
11 IMAGINE -- I CERTAINLY UNDERSTAND THE RATIONALE FOR
12 HAVING A REQUIREMENT FOR A PLANNING GRANT BEFORE THE
13 MAIN GRANT BECAUSE IT CERTAINLY, MAYBE NOT
14 GUARANTEES, BUT ENHANCES THE LIKELIHOOD THAT YOU
15 WILL GET A BETTER APPLICATION. ON THE OTHER HAND,
16 YOU CAN IMAGINE SITUATIONS WHERE SOMETHING MIGHT NOT
17 BE IN PLACE AT THE TIME THE PLANNING GRANT WAS DUE
18 AND MIGHT BE IN PLACE AT THE TIME THAT THE REGULAR
19 PROPOSAL WAS DUE. I JUST WOULD ENCOURAGE YOU TO
20 THINK ABOUT WHETHER THAT RIGID REQUIREMENT FOR
21 HAVING A PLANNING GRANT BEFORE PUTTING IN THE MAIN
22 GRANT MIGHT NOT SHUT OFF SOME THINGS THAT ARE
23 POTENTIALLY QUITE IMPORTANT.

24 THE SECOND THING I THINK RELATES TO WHAT
25 JEFF WAS TALKING ABOUT AND A LITTLE BIT WHAT DR.

BARRISTERS' REPORTING SERVICE

1 PIZZO WAS TALKING ABOUT IN TERMS OF SCOPE AND HOW
2 MANY GRANTS SHOULD WE FUND. AND JUST TO REMIND
3 EVERYBODY, THE BIG DIFFERENCE BETWEEN WHAT WE DO AND
4 WHAT NIH DOES IS THAT WE HAVE NEVER GIVEN ANYBODY A
5 SECOND BITE OF THE APPLE, SO TO SPEAK. IF A GRANT
6 COMES IN AND THERE ARE FLAWS WITH IT, THERE REALLY
7 ISN'T ANY WAY FOR THE PROPOSAL TO BE FIXED AND
8 RESUBMITTED. THEY ESSENTIALLY JUST LOSE OUT.

9 I WONDER IF, GIVEN HOW IMPORTANT THIS IS,
10 I WONDER IF THIS MIGHT BE THE ONE WHERE WE WOULD
11 MAKE THAT AN OPPORTUNITY FOR PEOPLE TO COME BACK IN
12 WITH A REVISED PROPOSAL, MAYBE HAVE REALLY TWO
13 SEPARATE ROUNDS DEVOTED TO THIS WHOLE THING WHERE
14 SOME OF THE REALLY HIGH QUALITY PROPOSALS THAT HAD
15 SOMETHING WRONG WITH THEM MIGHT BE ABLE TO COME BACK
16 AND BE RECONSIDERED.

17 CHAIRMAN KLEIN: ONE OF THE CONSIDERATIONS
18 IN ADDRESSING THAT, BETTINA, IS IF YOU COULD ADDRESS
19 THE ADDITIONAL TIME AND WHAT THAT DOES IN TERMS OF
20 WHAT THE TIME SCHEDULE MIGHT BE.

21 DR. STEFFEN: SORRY. THE ADDITIONAL TIME?

22 CHAIRMAN KLEIN: IF, IN FACT, WE ALLOW --

23 DR. STEFFEN: I THINK THAT YOUR LAST POINT
24 ABOUT INCORPORATING FEEDBACK FROM THE GRANTS WORKING
25 GROUP IS EXACTLY THE CONCEPT BEHIND THIS PLANNING

BARRISTERS' REPORTING SERVICE

1 AWARD WITH THE SEATED GRANTS WORKING GROUP AND THEN
2 A FULL APPLICATION. SO IN ASKING FOR THE SCIENTIFIC
3 PROPOSAL IN THIS PLANNING AWARD, WHICH WE DID NOT DO
4 IN THE LAST ROUND, THEY WILL HAVE AN OPPORTUNITY TO
5 RECEIVE THE GRANTS WORKING GROUP FEEDBACK, BE
6 PROVIDED THAT FEEDBACK, AND INCORPORATE THAT INTO
7 THEIR PROPOSAL AT A FULL APPLICATION.

8 SO THE GRANTS WORKING GROUP COULD SAY AT
9 THE PLANNING STAGE, PLANNING APPLICATION STAGE, WE
10 LIKE IT, IT'S MISSING THIS, WE'LL LOOK AT A FULL
11 PROPOSAL IF THEY CAN ADDRESS THIS ISSUE, AND SO
12 FORTH. SO THAT WAS OUR CONCEPT AND OUR PLAN TO USE
13 THE SPECIFIC INPUT FROM THE GRANTS WORKING GROUP.
14 SO THEY WOULD HAVE TO VOTE TO APPROVE AND GIVE THAT
15 TEAM A PLANNING AWARD TO FLESH OUT THE REST OF THE
16 DETAILS.

17 CHAIRMAN KLEIN: DUANE.

18 MR. ROTH: THANK YOU. I WANTED TO SPEAK
19 TO WHAT JEFF AND PHIL WERE TALKING ABOUT A LITTLE
20 BIT AND TO SUGGEST THAT WE NEED TO PUT IN CONTEXT
21 WHAT WE ALL ARE TRYING TO DO HERE. WE'RE ALL
22 FAVORING MOVING THINGS FROM DISCOVERY TO TRANSLATION
23 IN THE CLINIC. BUT I THINK THE CONSIDERATION SHOULD
24 BE WHETHER THE DISEASE TEAMS ARE THE ONLY INSTRUMENT
25 THAT WE WANT TO USE HERE. THEY ARE COMPLEX

BARRISTERS' REPORTING SERVICE

1 INSTRUMENTS. AND THEY DON'T LEAVE YOU A LOT OF
2 FLEXIBILITY ONCE YOU'VE MADE A DECISION TO GO.

3 SO ONE SUGGESTION MAY BE TO CONSIDER
4 AUGMENTING THE DISEASE TEAM AS OUTLINED WITH A
5 CLINICAL GRANT OR LOAN TO MOVE PRODUCTS THAT DON'T
6 REQUIRE MULTIPLE INSTITUTIONS AND COMPANIES TO COME
7 TOGETHER, BUT RATHER ADVANCE THOSE EARLY CLINICAL
8 TRIALS ON A ONE-BY-ONE BASIS. SO I THINK WE SHOULD
9 PROBABLY LOOK AT IT IN THAT CONTEXT, NOT SO MUCH IN
10 IF WE DOUBLE THIS NUMBER, WE HAVE DOUBLE THE CHANCE,
11 BUT A SECOND LAYER, WHICH IS TO ALLOW THAT
12 FLEXIBILITY TO FUND INDIVIDUAL PROJECTS WHICH ALSO,
13 BY THE WAY, ADDRESSES THE LOAN ISSUE.

14 WE LEARNED IN THIS LAST DISEASE TEAM THE
15 COMPLEXITY AND THE INCENTIVES AND DISINCENTIVES THAT
16 PEOPLE WENT THROUGH TRYING TO FIGURE OUT WHETHER
17 THEY SHOULD COME IN ON A GRANT OR A LOAN. AND I
18 WOULD HAVE GUESSED, AND IT PROVED TO BE TRUE, THAT
19 MOST OF THEM WOULD COME FOR THE GRANT BECAUSE THAT'S
20 GOING TO BE MORE DESIRABLE.

21 SO IF YOU REALLY WANT TO GET LOANS OUT,
22 YOU NEED SORT OF A LOAN ONLY RFP. THEN PEOPLE WILL
23 APPLY KNOWING FULL WELL THAT'S HOW THE MONEY WILL BE
24 DISTRIBUTED. BUT I THINK AS LONG AS YOU HAVE THIS
25 OPTIONAL THING, YOU WILL SEE A LOT -- I KNOW SOME

BARRISTERS' REPORTING SERVICE

1 PEOPLE WENT THROUGH THIS PROCESS WHICH WAS
2 EXTRAORDINARILY COMPLEX. COMPANIES THAT WERE
3 PROVIDING REAGENTS OR EVEN DRUGS WERE TREMENDOUSLY
4 WORRIED ABOUT THE REACH-THROUGH PROVISIONS, AND WE
5 HAVE TO DEAL WITH SORT OF LAW FIRM AFTER LAW FIRM
6 AND COMPANY AFTER COMPANY.

7 SO IF WE COULD SIMPLIFY THAT, I THINK IT
8 WOULD ACCOMPLISH WHAT JEFF IS LOOKING FOR AND WHAT
9 PHIL WAS TALKING ABOUT.

10 CHAIRMAN KLEIN: DR. TROUNSON AND THEN I'M
11 GOING TO GO TO JEFF SHEEHY AND THEN ED PENHOET.

12 DR. TROUNSON: YOU KNOW, YOU CAN ACTUALLY
13 COME IN AS A SINGLE ENTITY AS A COMMERCIAL ENTITY ON
14 THIS. THERE'S NOTHING THAT PREVENTS THAT. THE
15 DISEASE TEAMS, THE IDEA WAS TO BUILD TEAMS THAT WERE
16 CAPABLE. IF YOU'RE CAPABLE WITHOUT ADDING ON, THEN
17 IT'S NOT IN ANY WAY -- THAT IN THE REVIEW PROCESS
18 DOES NOT SORT OF STOP ANY OF THAT.

19 SO I THINK THAT THAT'S ACCOMMODATED WITHIN
20 THIS. YOU CAN ACTUALLY ENTER WITH AN IND IN THIS
21 PARTICULAR ONE IF THAT'S WHAT YOU HAVE, OR YOU CAN,
22 AS A SINGLE ENTITY, COME IN. YOU JUST HAVE TO BE --
23 YOU KNOW, YOU HAVE TO GET THROUGH THE GRANTS WORKING
24 GROUP TO BE SCORED HIGHLY ENOUGH.

25 CHAIRMAN KLEIN: DR. TROUNSON, REMIND THE

BARRISTERS' REPORTING SERVICE

1 BOARD ABOUT THE CLINICAL TRIAL ROUND AS WELL. I'M
2 GOING TO GO -- AFTER ED PENHOET, DR. PIZZO, I'LL
3 COME BACK TO YOU.

4 DR. TROUNSON: THERE'S A CLINICAL TRIAL
5 ROUND THAT WE'RE GOING TO RELEASE THAT RFA WITHIN
6 THE NEXT FEW DAYS, WE HOPE. THAT'S CONFINED TO
7 PLURIPOTENTIAL STEM CELLS, SO THERE'S POSSIBLY NOT A
8 LOT OF APPLICANTS THAT ARE HOLDING IND'S THAT WOULD
9 BE IN THAT SPACE. BUT WE KNOW THAT THERE A NUMBER,
10 A NUMBER OF 3+, AND WE DON'T KNOW WHO'S GOING TO
11 COME FORWARD. THERE'S BEEN A LOT OF INTEREST.

12 AND SO LOOKING AT THIS PARTICULAR
13 PORTFOLIO THERE, GIVE YOU SOME IDEA OF WHERE THE
14 DIFFERENT PROJECTS ARE. THIS HAS BEEN CONSTRUCTED
15 BY DR. OLSON WHO'S HAD SOME EXPERIENCE IN THIS
16 SPACE. AND SO THE LEADING EDGE, YOU CAN SEE, IS UP
17 THERE AT DIABETES. THEY'RE IN THIS PRECLINICAL
18 DEVELOPMENT PART OF IT, BUT A LOT OF THE OTHERS ARE
19 JUST -- YOU KNOW, THEY'RE A FAIR WAY BACK. SO WE
20 ARE IN THIS PROCESS SORT OF STILL BUILDING OUR
21 CAPACITY. SO IT'S VERY CLEAR TO ME THAT THERE'S NOT
22 A LOT IN THIS SORT OF LATE PHASE AT THE PRESENT TIME
23 OR NOT OBVIOUS TO ME. MAYBE IT WILL COME OUT OF THE
24 APPLICATION PROCESS, BUT IT WILL BE -- I THINK WILL
25 BE SURPRISING IF THERE'S THE NUMBER THAT JEFF IS

BARRISTERS' REPORTING SERVICE

1 TALKING ABOUT AT THIS POINT IN TIME BECAUSE I'M OUT
2 THERE IN THE INSTITUTIONS AND WITH THE COMPANIES.

3 SOME OF THE COMPANIES HAVE NOT INDICATED
4 WHETHER THEY WOULD COME IN OR NOT. I THINK IT
5 DEPENDS A LOT ABOUT WHAT THEY DO WHEN THEY READ
6 ABOUT THE LOANS, TO BE HONEST, AND THERE'S A WHOLE
7 LOT OF NEGOTIATIONS WHICH RELATE TO THAT BEFORE
8 THEY'LL COME IN. SO IT'S POSSIBLE THAT -- I THINK
9 YOU'RE THINKING THERE'S PROBABLY A LOT MORE THERE
10 THAN ACTUALLY WILL BE, BUT I GUESS WE'LL HAVE TO
11 FIND OUT IN DUE COURSE. BUT THAT IS A REALISTIC
12 ESTIMATE OF WHERE THESE PROJECTS ARE AT THE PRESENT
13 TIME BECAUSE THE STAFF HAVE REALLY BEEN VERY CLOSE
14 AND LINKED UP AT THE MOMENT.

15 DR. STEFFEN: MAY I JUST CLARIFY ONE
16 POINT? TO DUANE'S POINT, SO THERE'S NOTHING IN THIS
17 THAT PRECLUDES A FOR-PROFIT WALKING UP AS A SINGLE
18 ENTITY APPLICANT. THERE ARE NO COMPLEX TRANSFERS.
19 THEY CAN BE A ONE-STOP SHOP, WALK UP, APPLY FOR A
20 LOAN.

21 MR. ROTH: I UNDERSTAND THAT. MY POINT IS
22 THAT THE ONES WE FUNDED WERE COMPLEX INSTRUMENTS,
23 AND THAT'S THE PERCEPTION. IF YOU ADVERTISE AND
24 PROMOTE IT AS STANDALONE, THAT'S FINE, BUT THOSE
25 FAVORED MULTIPLE INSTITUTIONS AND EVEN INTERNATIONAL

BARRISTERS' REPORTING SERVICE

1 STUDIES OR PARTNERS BEING ASSOCIATED WITH THOSE.
2 AND FROM MY STANDPOINT, THE FACT THAT WE ONLY FUNDED
3 ONE COMPANY OUT OF THE 14 OR WHATEVER IT WAS DISEASE
4 TEAMS TELLS ME YOU DON'T THINK OF INSTITUTIONS AS
5 BEING THE DRIVERS OF IND'S AND PHASE I AND PHASE
6 II'S. YET THAT'S WHO WE GOT DRIVING THE BUS RIGHT
7 NOW.

8 THAT'S ALL I'M GETTING AT IS IF YOU CAN
9 POSITION PROPERLY SO THAT INDIVIDUAL COMPANIES DON'T
10 THINK THEY'RE GOING TO NEED TO HAVE A PI WITH A BIG
11 NAME OR AN INSTITUTION BEHIND IT AND THEY THINK
12 THEY'LL HAVE A FAIR OPPORTUNITY, THEN I THINK IT'S
13 FINE. BUT IT'S PERCEPTION AND REALITY. I REALIZE
14 BY THE LETTER OF THE LAW YOU CAN DO THIS, BUT THAT
15 DOESN'T MEAN IT'S GOING TO BE WORTH THE EFFORT TO
16 WIN IF YOU THINK YOU CAN'T GET THROUGH REVIEW
17 PROCESS BECAUSE THERE WILL BE A BIAS TOWARDS THESE
18 MULTIFACTORIAL PARTNERS.

19 CHAIRMAN KLEIN: IN ENHANCING COMPANIES
20 AND COMPANY-ACADEMIC PARTICIPATIONS, I THINK, DUANE,
21 IT MAY BE IMPORTANT TO QUICKLY LOOK AT OUR LOAN
22 TERMS. OUR PERFECT MODEL MAY BE THE ENEMY OF THE
23 PRACTICAL. AND I THINK UNTIL COMPANIES GET MORE
24 EXPERIENCE WITH THE LOAN PROGRAM, I THINK WE MAY
25 NEED TO MAKE THOSE TERMS LESS AGGRESSIVE TO REALLY

BARRISTERS' REPORTING SERVICE

1 GET SOME MOMENTUM IN THAT LOAN PROGRAM AND INDUCE
2 MORE COMPANY PARTICIPATION SO THAT WE REALLY CAN
3 MOVE THAT MODEL FORWARD. THAT'S A SUBJECT FOR THE
4 FINANCE COMMITTEE IN A DIFFERENT DISCUSSION.

5 JEFF SHEEHY.

6 MR. SHEEHY: WELL, I HAD A COUPLE OF
7 POINTS. ONE, AS TO THE BURDEN ON THE APPLICANTS WHO
8 GO TO THE DIFFICULTY OF PREPARING THESE
9 APPLICATIONS, WE BASICALLY FUNDED THEM TO DO IT. SO
10 I DON'T THINK IT'S PARTICULARLY ONEROUS. WE'VE
11 GIVEN FUNDING TO PREPARE THE APPLICATIONS THAT THEY
12 TURN THEM IN AND THEY DON'T GET THEM.

13 THE OTHER THING --

14 CHAIRMAN KLEIN: YOU'RE REFERRING TO THE
15 FACT THAT IF THEY GET A PLANNING GRANT, IT WILL FUND
16 THE VERY THOUGHTFUL AND INTENSIVE PROCESS THAT DR.
17 TROUNSON WAS REFERRING TO.

18 MR. SHEEHY: YEAH. THE OTHER THING IS I
19 ACTUALLY THINK THAT A LARGER GROUP OF GRANTS AND A
20 MORE DIFFICULT REVIEW WILL ACTUALLY SOLVE ONE OF THE
21 PROBLEMS IN THE FIRST DISEASE TEAM REVIEW IN THAT WE
22 SHOULD HAVE A DIFFERENT REVIEW FOR CERTAIN AREAS OF
23 INQUIRY. ONE OF THE REASONS WE HAD THE PROBLEM WITH
24 THE ABOODY GRANT IS THAT THE MAJORITY OF THE PEOPLE
25 SITTING AROUND THAT TABLE WERE NOT NEUROLOGISTS. SO

BARRISTERS' REPORTING SERVICE

1 YOU HAD A COUPLE OF EXPERTS AND THEY GOT IT WRONG.
2 AND SO WE'RE REALLY -- WE'VE GOT
3 HEMATOPOETIC, ADULT STEM CELLS, AND WE'VE GOT STROKE
4 USING EMBRYONIC STEM CELLS, WE'VE GOT IPS CELLS
5 GOING FOR EPIDERMOLYSIS BULLOSA, AND THAT'S A LOT,
6 AND YOU END UP WITH ONLY A VERY SMALL NUMBER OF
7 PEOPLE ON THE ACTUAL VOTING WORKING GROUP WHO
8 UNDERSTAND THE UNDERLYING SCIENCE, AND THEY'RE
9 RELYING ON A SMALL SET OF SPECIALISTS. AND THAT
10 BECOMES -- SO YOU REALLY LOSE THE TEXTURE OF A FULL
11 REVIEW GIVEN THE COMPLEXITY OF THE SCIENCE WE'RE
12 REVIEWING.

13 AND SO I WOULD ACTUALLY SAY -- I MEAN WE
14 CAN EITHER DO A LOT OF SMALLER REVIEWS, OR WE CAN DO
15 A BIG REVIEW AND DO A LOT OF THINGS. THIS SEEMS
16 LIKE THIS IS DOING A LOT OF THINGS. WE'RE GOING
17 IND, WE'RE GOING PHASE I, WE'RE GOING PHASE II,
18 COMPANIES, COMPANY-ACADEMIC PARTNERSHIPS. LET'S TRY
19 TO HAVE A REALLY GOOD REVIEW PROCESS, AND MAYBE IT
20 IS A SERIES OF REVIEWS OVER SPECIFIC DISCRETE
21 SCIENTIFIC -- ALL THE NEUROLOGICAL ONES IN ONE ROOM,
22 BUT THINK OF NATURAL -- ONCE WE KNOW WHAT WE HAVE,
23 WHICH THE GREAT THING ABOUT THE PLANNING AWARD
24 MECHANISM IS THAT WHATEVER NUMBER WE DECIDE ON, WE
25 WILL HAVE AN IDEA, WE WILL KNOW EXACTLY WHAT WE'RE

BARRISTERS' REPORTING SERVICE

1 GOING TO HAVE FOR BIG REVIEW. WE HAVE A LOT OF TIME
2 TO PUT TOGETHER MAYBE A WEEK OF REVIEW OR A REVIEW
3 ONE WEEK AND THE NEXT WEEK INVOLVING DIFFERENT SETS
4 OF INDIVIDUALS WITH DIFFERENT SETS OF EXPERTISE.

5 SO I THINK IF WE'D HAD TEN NEUROLOGISTS
6 AROUND THE TABLE, I THINK THE ABOODY GRANT WOULD
7 HAVE GOTTEN APPROVED BECAUSE THEY WOULD HAVE SAID,
8 OH, SHE'S USING -- THIS IS THE DRUG THAT'S REALLY
9 THE HOT DRUG RIGHT NOW, WHICH WAS REALLY THE THING
10 THAT THEY WERE DELIVERING AND HAD NOT PERMEATED TO
11 THOSE PARTICULAR SETS OF SPECIALISTS THAT THIS WAS
12 WHAT MANY PEOPLE IN THE FIELD WERE CONSIDERING THE
13 BEST CHEMICAL TO DELIVER TO THE BRAIN TO KILL THESE
14 TUMORS.

15 SO I DISCUSSED WITH GIL THAT THE BREADTH
16 OF THE APPLICATIONS THAT WE'RE REVIEWING IN DISEASE
17 TEAMS PUTS AN ENORMOUS BURDEN ON A VERY SMALL NUMBER
18 OF PEOPLE TO MAKE A LOT OF DECISIONS.

19 AND THE OTHER POINT I'D MAKE IS THAT I
20 UNDERSTAND WHAT DUANE AND DR. PIZZO HAVE SAID ABOUT
21 TRYING TO DO SOMETHING DIFFERENT, BUT WE'RE KIND OF
22 LOCKED INTO -- I LOOK AT THIS SCHEDULE. WE'RE
23 LOCKED. THIS IS THE NEXT THING COMING UP, SO
24 WHATEVER YOU WANT TO FIT IN, THINK ABOUT WHEN THAT'S
25 GOING TO BE, HOW THAT'S GOING TO BE DESIGNED. WE

BARRISTERS' REPORTING SERVICE

1 HAVE A NEW STRATEGIC PLANNING PROCESS THAT'S JUST
2 NOW BEGINNING WITH AN EXTERNAL REVIEW WHICH SHOULD
3 BE THE POINT AT WHICH WE START TO DISCUSS AND
4 CONSTRUCT THESE DIFFERENT TYPES OF RFA'S, WHICH I'M
5 VERY SUPPORTIVE OF. BUT I DON'T SEE THE MECHANISM
6 TO GET THOSE CONSTRUCTED, INTRODUCED INTO OUR
7 SYSTEM, PUT ON OUR SCHEDULE BEFORE THIS HAPPENS.

8 AND THEN I STILL HAVE THE PIPELINE
9 PROBLEM. I WANT TO HAVE ENOUGH STUFF IN THE
10 PIPELINE SO THAT WHEN YOU GO IN 2016, WE'VE ACTUALLY
11 GOT SOMETHING TO SHOW THE VOTERS. THAT'S WHERE I'M
12 COMING FROM.

13 CHAIRMAN KLEIN: OKAY. THANK YOU VERY
14 MUCH. DR. PENHOET.

15 DR. PENHOET: A COMMENT AND A QUESTION TO
16 YOUR ISSUE, JEFF. I THINK YOU'VE PUT YOUR FINGER ON
17 A VERY IMPORTANT ISSUE. IF THESE WERE NIH GRANTS,
18 THEY WOULD ALL GO TO DIFFERENT STUDY SECTIONS TO BE
19 EVALUATED. EARLY ON IN OUR PROCESS, WE WERE
20 EVALUATING BASIC RESEARCH AND STEM CELL BIOLOGY
21 BASICALLY, AND WE ASSEMBLED THE GROUP TO DO THAT.
22 HERE YOU REALLY, BY DEFINITION, REQUIRE EXPERTISE IN
23 THESE DISEASES IN ORDER TO MAKE RATIONAL DECISIONS
24 ABOUT WHAT GETS FUNDED. I DON'T KNOW HOW WE'RE
25 GOING TO SOLVE THAT PROBLEM NECESSARILY, BUT I THINK

BARRISTERS' REPORTING SERVICE

1 IT'S A VERY IMPORTANT ISSUE THAT YOU BRING UP
2 BECAUSE IT'S AN ENTIRELY DIFFERENT SET.

3 THE QUESTION I HAD WAS IF YOU PARSE THIS
4 PROBLEM INTO THE NUMBER OF PLANNING GRANTS AND THE
5 NUMBER OF ACTUAL GRANTS, YOU SAID THAT THE PLANNING
6 GRANT LIMITATION WAS DESIGNED PRIMARILY TO ADDRESS
7 THE ISSUE OF INTERNAL CAPACITY. BUT THE NUMBER THAT
8 YOU WOULD ACTUALLY FUND BEING SIX, WAS THAT DRIVEN
9 BY FINANCIAL CONSIDERATIONS? WAS IT DRIVEN BY ALSO
10 CAPACITY TO MANAGE THOSE GRANTS? HOW DID YOU CHOOSE
11 SIX AND \$120 MILLION? WHAT WAS THE BASIS FOR THAT
12 CHOICE?

13 DR. TROUNSON: THAT WAS CHOSEN FROM THE
14 NUMBERS ESSENTIALLY FROM IF YOU HAD 20 FULL GRANTS,
15 YOU'D EXPECT A HIGH ORDER OF EXPECTATION OUT OF
16 THOSE WOULD BE A THIRD THAT WOULD REALLY BE
17 WORTHWHILE FUNDING. SO THAT'S THE KIND OF
18 COMPUTATION THAT WE WERE MAKING.

19 CHAIRMAN KLEIN: OKAY.

20 DR. PENHOET: THAT'S A PREDICTION. BUT IF
21 YOU DOUBLE, YOU COULD DO 12, YOU STILL MIGHT SAY IF
22 WE AUTHORIZE UP TO 12, FOR EXAMPLE, YOU COULD STILL
23 ONLY FUND SIX IF THERE ARE ONLY GOOD ONES -- IF YOUR
24 PREDICTION THAT THERE WILL ONLY BE SIX GOOD ONES
25 TURNS OUT TO BE THE CASE.

BARRISTERS' REPORTING SERVICE

1 DR. TROUNSON: YEAH. A LOT DEPENDS,
2 CLEARLY DEPENDS ON WHAT IS CLASSIFIED AS GOOD
3 PROJECTS, AS YOU SAY. WE DO USE A RANGE OF
4 SPECIALISTS. SO IN THE SENSE -- I DON'T THINK IT'S
5 NECESSARILY A GOOD IDEA TO TALK ABOUT ONE GRANT
6 WHERE SOMEONE GOT IT WRONG. THERE WAS AN EXPERT WHO
7 GOT SOMETHING WRONG, AND WE WENT AND SORT OF
8 CORRECTED THAT. BUT WE HAVE THE ABILITY TO BRING IN
9 EXPERTS AND A NUMBER OF THEM IN THESE GRANT AREAS.

10 SO I THINK IF -- THERE'S ALSO THE WORKLOAD
11 IS NOT ONLY ON THE GRANTEES -- SORRY -- ON THE
12 GRANTS REVIEW TEAM MEMBERS, BUT IT'S ALSO ON STAFF
13 BECAUSE THEY'VE GOT TO PRODUCE A HECK OF LOT OF
14 WRITTEN MATERIAL IN A RELATIVELY SHORT TIME. SO IF
15 YOU HAVE LARGE NUMBERS OF THESE REPORTS THAT YOU'VE
16 GOT TO DO, YOU REALLY DO SUBMERGE THE STAFF AS WELL.
17 WE'RE TRYING TO SORT OF FIGURE OUT WITH OUR STAFF
18 WHAT WE CAN DO. WE'RE HAVING A LOOK AT WHAT WE
19 THINK IS OUT THERE. AND THE SENSE OF IT IS THAT
20 WE'RE ON THE UNDER SIDE OF THIS BY THE SOUND FROM
21 THE BOARD, BUT OUR FEELING WHEN WE'RE OUT THERE IS
22 THAT THERE'S PROBABLY -- RIGHT AT THE MOMENT THERE'S
23 NOT A VERY LARGE NUMBER OF THEM UNLESS SOME OF THE
24 BIGGER COMPANIES SUDDENLY CHANGE THEIR MIND ABOUT
25 COMING INTO THIS SPACE AND COME IN WITH A NUMBER OF

BARRISTERS' REPORTING SERVICE

1 PRODUCTS, THAT THEY'VE ACTUALLY GOT UP CLOSE TO THIS
2 PIPELINE, BUT THEY HAVEN'T SHOWN A LOT OF INTEREST
3 AT THIS POINT.

4 CHAIRMAN KLEIN: DR. TROUNSON, I THINK
5 UNDERLYING THIS DISCUSSION IS THE HOPE BY THE BOARD
6 THAT THE BILL THAT'S CURRENTLY PENDING WILL GIVE YOU
7 STAFF RELIEF AND ADDITIONAL STAFF RESOURCES TO HELP
8 MEET THIS GOAL. AND WE'LL BE OPTIMISTIC ABOUT THAT
9 FOR THE MOMENT. IT'S GONE A LONG WAY THROUGH THE
10 PROCESS.

11 DR. BRYANT: THE MOMENT HAS PAST, BUT I
12 WAS JUST GOING TO SUPPORT THE DISCUSSION WE WERE
13 HAVING ABOUT THE MISCELLANY THAT WE HAVE UP HERE OF
14 DIFFERENT TOPICS. SOMEHOW IF WE COULD ORGANIZE
15 EITHER THE CALL FOR PROPOSALS OR THE REVIEW OF THEM
16 INTO SUBGROUPS THAT WERE MORE TOPIC FOCUSED, YOU
17 COULD GATHER PEOPLE THAT ARE MORE LIKELY TO BE
18 INTERESTED AND MOTIVATED AND EXPERT IN THOSE AREAS.

19 CHAIRMAN KLEIN: IN TOOLS AND TECHNOLOGY,
20 PREVIOUSLY WE'VE HAD BACK-TO-BACK SESSIONS WITH TWO
21 OVERLAPPING ACTUALLY PEER REVIEW MEMBERSHIP TO
22 EXPAND THE EXPERTISE. THIS IS SOMETHING, I THINK,
23 WE LOOK TO THE SCIENTIFIC STAFF TO DETERMINE, BUT
24 CERTAINLY THERE'S AT TIMES UP TO 50 OUTSIDE
25 SPECIALISTS THAT COME IN AND HELP US. AS JEFF

BARRISTERS' REPORTING SERVICE

1 POINTS OUT, YOU HEAR THE EXPERTS, BUT THE PEOPLE WHO
2 ARE SCORING, IT'S GOOD TO HAVE A DIVERSITY OF THE
3 PEOPLE WHO ARE SCORING THAT IS ALIGNED WITH THE POOL
4 OF GRANTS TO THE EXTENT THAT YOU CAN.

5 ON THE OTHER HAND, THERE'S A LIMIT ON WHO
6 WE CAN RECRUIT, AND THERE'S A LIMIT ON THE STAFF TO
7 BE ABLE TO MOVE THIS THROUGH THE SYSTEM.

8 DR. STEFFEN, YOUR PRESENTATION IS SO
9 POPULAR, I'VE GOTTEN A COUPLE NOTES FROM THE BOARD
10 TO ASK THAT YOU E-MAIL IT TO THE BOARD BECAUSE THEY
11 LIKED YOUR PRESENTATION SO WELL.

12 WOULD YOU OR DR. OLSON LIKE TO MAKE A
13 COMMENT IN RESPONSE TO THE BOARD COMMENTS THAT HAVE
14 BEEN MADE?

15 DR. STEFFEN: I THINK I WOULD JUST LIKE TO
16 ADD THAT THE NUMBER SIX THAT WE ARRIVED AT IS A
17 CONSIDERATION OF MANY FACTORS. AND IF YOU LOOK AT
18 THIS PORTFOLIO AND THE STATE OF THE PROJECTS THAT WE
19 GOT IN THE FIRST ROUND, AND, GRANTED, IT DOES NOT
20 REPRESENT EVERY POSSIBLE PROJECT THAT IS OUT THERE,
21 BUT WE'RE STARTING LATER THAN THE FIRST ROUND OF
22 DISEASE TEAMS, SO WE'RE STARTING BETWEEN THAT
23 PRECLINICAL RESEARCH AND PRECLINICAL DEVELOPMENT
24 WHERE THERE IS EXACTLY ONE PROJECT THAT IS AT THAT
25 STAGE.

BARRISTERS' REPORTING SERVICE

1 SO THE STATE OF SCIENCE ITSELF MAY
2 INDICATE THAT THERE MAY NOT BE THAT MANY PROJECTS.
3 WE FELT LIKE SIX WAS A HEALTHY NUMBER TO CONSIDER
4 WHO WOULD BE READY FOR THOSE. SO IT'S JUST ONE
5 OTHER FACTOR THAT WENT INTO CONSIDERING THE NUMBER
6 OF PROPOSALS.

7 CHAIRMAN KLEIN: THANK YOU. DR. OLSON,
8 DID YOU HAVE A COMMENT?

9 DR. OLSON: THANK YOU. I JUST WANTED TO
10 ADD AN ADDITIONAL CONSIDERATION. I THINK THE
11 RELEVANT NUMBER TO SOME EXTENT IS THE 20, AND I
12 THINK WE'VE EMPHASIZED THAT AT THE PREVIOUS DISEASE
13 TEAM AWARDS, WHICH WAS CONSIDERABLY EARLIER AND HAD
14 A LARGE RESEARCH COMPONENT, THERE'S NO QUESTION THAT
15 I THINK DISCOVERY AND EARLY TRANSLATIONAL
16 PRECLINICAL RESEARCH YOU SEE UP THERE IS A LARGE --
17 HAS A LARGE RESEARCH ELEMENT TO IT.

18 THOSE PROPOSALS WERE 31 OF THEM CAME TO A
19 GRANTS WORKING GROUP FOR A THREE-DAY MEETING. WE'RE
20 TALKING ABOUT SOMETHING THAT'S DOUBLE -- THE
21 APPLICATION IS LIKELY TO BE CLOSE TO DOUBLE IN SIZE,
22 AND WE'RE -- I APPRECIATE THE POINT ABOUT OBVIOUSLY
23 WE ALWAYS WILL TRY AND GET RELEVANT EXPERTISE. I
24 THINK THESE KINDS OF PROJECTS FALL IN WHAT I CALL
25 THE DEVELOPMENT STAGE OF THE PIPELINE. SO THE KINDS

BARRISTERS' REPORTING SERVICE

1 OF PEOPLE WHO ARE REALLY IMPORTANT TO THAT ARE NOT
2 JUST THE DISEASE EXPERTS, THEY'RE THE REGULATORY
3 EXPERTS, THEY'RE THE PROCESS EXPERTS, THEY'RE ALSO
4 THE BIOLOGISTS TO SOME EXTENT BECAUSE YOU HAVE TO
5 ALWAYS REMEMBER IT'S THE SCIENCE THAT UNDERLIES ALL
6 OF THIS THAT MAKES THIS IMPORTANT.

7 BUT IT IS TRUE THAT THE EXPERTS IN ANY
8 PARTICULAR DISEASE AREA, IT WILL BE VERY IMPORTANT
9 TO HAVE THEM THERE AS WE DID IN THE DISEASE TEAM I.
10 AND SO WE NEED TO MAKE SURE. BUT I THINK THAT THE
11 NUMBER 20, WHETHER THERE ARE SIX OR TEN THAT COME
12 OUT OF THAT, I DON'T KNOW IF THEY'RE GOOD PROJECTS,
13 BUT I'M LOOKING AT MORE OF WHAT WE WANT TO TAKE TO
14 THE DISEASE TEAM, WHAT WE WANT TO GET THROUGH IT IN
15 A REASONABLE AMOUNT OF TIME, WHAT WE ACTUALLY DO
16 BELIEVE IS OUT THERE, AS DR. TROUNSON HAS SAID AND
17 AS REITERATED BY DR. STEFFEN.

18 SO THOSE ARE JUST POINTS THAT I WANTED TO
19 MAKE AS WELL IS THAT WE'RE TRYING TO THINK OF THE
20 GRANTS WORKING GROUP, WE'RE TRYING TO THINK OF THE
21 SOMEWHAT TIMELY THING. YOU KNOW, WE WILL -- IF THE
22 BOARD WANTS TO DO FAR MORE THAN THAT, THEN WE WILL
23 ADJUST THE PROGRAM ACCORDINGLY, AND WE WILL NOT
24 PROBABLY DO OTHER THINGS BECAUSE WE CAN ONLY CONVENE
25 GRANTS WORKING GROUPS -- WE CAN ONLY GET PEOPLE OUT

BARRISTERS' REPORTING SERVICE

1 HERE SO OFTEN.

2 CHAIRMAN KLEIN: I THINK DUANE HAD A
3 QUESTION, THEN JEFF HAS A QUESTION.

4 MR. ROTH: SO JUST ONE SUGGESTION, AFTER
5 LISTENING TO THIS CONVERSATION, THAT YOU CONSIDER A
6 REBRANDING OF WHAT THIS IS AND NOT HAVE IT FEEL LIKE
7 IT'S JUST A SECOND ROUND OF DISEASE TEAMS WHEN, IN
8 FACT, YOU'RE TALKING ABOUT SOMETHING THAT'S MORE
9 UPSTREAM. I THINK THAT WILL SOLVE MY PROBLEM OF THE
10 PERCEPTION THAT YOU'VE PUT THIS MULTIFACTORIAL TEAM
11 TOGETHER IN ORDER TO WIN ONE OF THESE AWARDS. SO IT
12 WOULD BE NICE IF WE COULD FIGURE OUT THE RIGHT WORDS
13 ABOUT CLINICAL, TRANSLATIONAL, WHATEVER TO BRAND IT.

14 CHAIRMAN KLEIN: MR. HARRISON IS NOT HERE,
15 BUT I THINK IT WOULD BE GOOD TO KEEP THE WORD
16 "DISEASE TEAM" FOR LEGAL REASONS INTO THIS TITLE
17 BECAUSE OF OUR HISTORICAL DEVELOPMENT OF OUR PROCESS
18 AND OUR LEGAL STRUCTURE, AND IT COULD BE DISEASE
19 TEAM SLASH SOMETHING ELSE, SO IT COULD AUGMENT -- IT
20 COULD HAVE SOMETHING IN IT OTHER THAN SOLELY DISEASE
21 TEAMS, BUT IT'S IMPORTANT TO SHOW THAT WE HAVE A
22 CONTINUING PROCESS WITH A REPEAT OF SOME OF THESE SO
23 THAT THOSE INDIVIDUALS THAT MAY NOT HAVE QUALIFIED
24 IN THE FIRST ROUND FOR THIS -- OF DISEASE TEAMS HAVE
25 AN ABILITY TO GO INTO THE SECOND ROUND OF DISEASE

BARRISTERS' REPORTING SERVICE

1 TEAMS, IN QUOTES, BUT THAT'S SOMETHING TO BE
2 CONSIDERED INTERNALLY.

3 SO WHAT IS THE PLEASURE OF THE BOARD ON
4 THIS ISSUE? DR. PRICE.

5 DR. PRICE: PEOPLE HAVE COMMENTED ON THE
6 TRADE-OFF WITH RESPECT TO DOUBLING, LET'S SAY, THE
7 NUMBER OF -- POTENTIALLY THE NUMBER OF AWARDS AT THE
8 SECOND PHASE OF THIS IN TERMS OF WORKLOAD TRADE-OFF,
9 BUT NOBODY SAID ANYTHING ABOUT THE FINANCIAL
10 TRADE-OFFS. WHAT ARE THE THINGS THAT WE WERE
11 PLANNING AND WOULD LIKE TO DO BEYOND THIS ROUND OF
12 DISEASE TEAM PROJECTS THAT WE WOULD HAVE TO -- THAT
13 THE FINANCIAL CONSTRAINTS WOULD MAKE IT IMPOSSIBLE
14 FOR US TO DO IF WE SHOULD DOUBLE THE OUTLAY ON THESE
15 PROJECTS?

16 DR. TROUNSON: CLEARLY IT WOULD PROBABLY
17 REQUIRE AN ANALYSIS WITH SOME OF THE REQUIREMENTS
18 THAT YOU HAVE, BOB, TO DO THAT SATISFACTORILY FOR
19 YOU. BUT, YOU KNOW, WE TRIED TO PROVIDE YOU WITH
20 SOME INFORMATION ON WHAT WE HAVE IN OUR OVERALL \$3
21 BILLION AND HOW FAR THAT WILL GO AT THE LAST BOARD
22 MEETING AND GAVE YOU SOME IDEA OF THE SPEND RATE
23 NEEDED TO BE REDUCED, OTHERWISE WE'RE OUT OF
24 BUSINESS BY 2014. THAT'S FOUR YEARS AWAY. WE
25 WOULDN'T BE GIVING MORE PROJECTS ON THE CURRENT

BARRISTERS' REPORTING SERVICE

1 SPEND RATE. IF WE KEPT ON THAT RATE, WE'D BE
2 FINISHED AT 2014. SO WE THINK FOR THE MISSION YOU
3 HAVE TO GO LONGER THAN THAT TO REALLY ACHIEVE THOSE
4 ENDS.

5 SO WE'VE ACTUALLY STRETCHED THIS BECAUSE
6 WE'VE PUT TWO GRANTS WORKING REVIEWS INTO THIS
7 PARTICULAR PROPOSAL, SO WE'VE STRETCHED IT OUT
8 ANOTHER EIGHT, NINE MONTHS, NINE OR EVEN TEN MONTHS
9 TO ACCOMMODATE A DOUBLE GRANTS -- DOUBLE REVIEW
10 THERE. SO THAT HAS SOME ACCOMMODATION ON THAT
11 TIMELINE. SO TO GET THE OUTCOME TO YOU, WE WOULD
12 HAVE TO FIGURE THAT OUT.

13 IF YOU SPEND \$240 MILLION VERSUS 150
14 MILLION, THERE'S \$100 MILLION DIFFERENCE THAT WON'T
15 GO TO SOMETHING ELSE. THAT'S SELF-EVIDENT. BUT
16 WHAT THAT MIGHT NOT GO TO, I SUPPOSE, KIND OF
17 DEPENDS ON HOW WE CONSTRUCT THE WHOLE PROPOSAL VIA
18 THE BOARD OVER THE NEXT THREE OR FOUR YEARS. BUT
19 THERE IS A TRADE-OFF, AS YOU SAY, ONE AGAINST THE
20 OTHER.

21 BUT I THINK WHAT'S THE REALLY IMPORTANT
22 PART IS TO BE ABLE TO GET TO FUND THE REALLY GOOD
23 PROJECTS THAT GET TO THE CLINIC. THAT'S WHAT --
24 THAT'S MY AIM AND THAT'S WHAT I'M ABOUT. AND IF
25 THERE'S SIX OR THERE'S EIGHT, IT HAPPENED 14, I'D

BARRISTERS' REPORTING SERVICE

1 COME BACK HERE PERSUADING YOU TO DO THAT. BUT IF
2 THERE IS ONLY SIX, I DON'T WANT TO ACTUALLY FUND IN
3 THIS -- WITH THESE PARAMETERS SOMETHING THAT OUGHT
4 TO BE IN TRANSLATION AND TAKE THE TIME TO GET
5 MATURE. THAT'S REALLY WHAT WE'RE TRYING TO ACHIEVE.
6 SO IF IT TURNED OUT TO BE 14 AND THAT'S WHAT IT WAS,
7 I'D HAVE NO HESITANCY RECOMMENDING IT TO YOU. KNOW
8 THAT I WILL GO, AND I'M AN OPTIMISTIC PERSON, I WILL
9 GO WITH THAT.

10 BUT I HEAR WHAT WE'VE GIVEN YOU, I
11 SUPPOSE, THE LEAN DOWN, THE LEAN APPROACH, AND I'M A
12 LITTLE WORRIED ABOUT HAVING TO DO 40 FULL
13 APPLICATIONS. IF WE CUT THE DIFFERENCE SOMEWHERE,
14 THAT MIGHT WORK IT OUT FOR ME. BUT 40 SEEMS
15 OVERWHELMING. THIRTY IS A TOUGH JOB AND WILL
16 PROBABLY REQUIRE TWO SITTINGS. AND, YES, WE CAN
17 HAVE MORE SPECIALISTS INVOLVED. AND WE'RE LIMITED
18 TO THE PEOPLE YOU APPOINT AS GRANTS REVIEWERS, SO
19 WE'RE GATHERING THEM AS QUICKLY AS WE CAN THAT ARE
20 APPROPRIATE, BUT WE HAVE GOT SOME LIMITATIONS ON THE
21 ACTUAL GRANTS WORKING GROUP PEOPLE THAT WE HAVE.

22 CHAIRMAN KLEIN: SO IT'S IMPORTANT IN THE
23 FRAMEWORK FOR THIS, DR. TROUNSON, THAT WE UNDERSTAND
24 THE WORST-CASE ASSUMPTIONS AND COMPOUNDING
25 NEGATIVES. I THINK IN THE OCTOBER MEETING, WE

BARRISTERS' REPORTING SERVICE

1 SHOULD LOOK AT A MORE REALISTIC FUNDING TRAJECTORY
2 BECAUSE THE PRIOR PROJECTION WE GOT IN THE LAST
3 MEETING WAS COMPOUNDING ON ALL NEGATIVES IN THE
4 SENSE THAT -- OR WE COULD LOOK IT AS ALL POSITIVES,
5 THAT EVERY DISEASE TEAM WOULD MAKE EVERY MILESTONE
6 AND GET EVERY FUNDING, WHICH IS HARD. I WOULD LOVE
7 TO BELIEVE THAT THAT'S TRUE, BUT I FIND IT DIFFICULT
8 TO BELIEVE IT. IT ASSUMED NO MATCHING FUNDS. THERE
9 WERE SO MANY COMPOUNDING ASSUMPTIONS, I THINK THE
10 REALISTIC PROJECTION IS PROBABLY CLOSER TO 2016 WITH
11 A BLENDED ANALYSIS OF THESE NUMBERS. AND I THINK IN
12 OCTOBER WE SHOULD TAKE A LOOK AT THAT.

13 DR. TROUNSON: HAPPY TO DO THAT, CHAIR.
14 WE BUILT IN SOME OF THOSE ASSUMPTIONS, BUT GIVEN
15 THAT WE'VE HAD A LITTLE TIME NOW TO REFLECT, AND
16 PARTICULARLY THESE DISEASE TEAMS REALLY DRIVE THOSE
17 OUTCOMES DRAMATICALLY BECAUSE THEY'RE THE VERY BIG
18 DOLLAR COMPONENTS, WE'LL HAPPILY DO THAT. I'LL ASK
19 DR. ROBSON TO REDO IT. I'LL ASK HIM TO MEET WITH
20 YOU TO TAKE A LOOK AT THOSE ASSUMPTIONS. WE HAD
21 BUILT SOME OF THOSE IN. WHETHER THEY'RE REALISTIC
22 OR NOT, I THINK WE WON'T CUT OFF PROJECTS AFTER ONE
23 YEAR, TWO YEARS MAYBE, BUT I THINK WHERE WE GET
24 CUTOFFS IS PROBABLY MAYBE THE THIRD YEAR. AND IT
25 WILL BE PRETTY DEMANDING TO CUT THEM OFF. I KNOW

BARRISTERS' REPORTING SERVICE

1 THAT. THAT'S JUST LIFE.

2 CHAIRMAN KLEIN: LOOK FORWARD TO THAT. I
3 WAS JUST RELYING ON DR. ROBSON'S STATEMENT OF
4 ASSUMPTIONS FROM THE LAST MEETING. AND IT'S GOOD TO
5 KNOW THAT THERE ARE SOME OF THOSE ASSUMPTIONS BUILT
6 IN. BUT THE KEY HERE IS A STRATEGIC BALANCE OF
7 WHETHER WE'RE MORE LIKELY TO GET A RENEWAL OF OUR
8 FUNDING IF WE HAVE A BIGGER PORTFOLIO AND A HIGHER
9 CHANCE OF SUCCESS AT THE TIME THE VOTERS HAVE TO
10 LOOK AT THIS AS VERSUS FUNDING IN THE OUT-YEAR
11 PERIOD.

12 SO I THINK THAT'S AN IMPORTANT STRATEGIC
13 CONSIDERATION. JEFF, DID YOU HAVE ANOTHER COMMENT?

14 MR. SHEEHY: WELL, I DID. I MEAN I DON'T
15 KNOW IF PEOPLE REMEMBER THE PRESENTATION AT THE END
16 OF THE LAST MEETING, AND WE WERE PRESENTED WITH TWO
17 DIFFERENT PROJECTIONS. AND ONE ASSUMED A
18 \$200-MILLION DISEASE TEAM ROUND ANNUALLY. AND THE
19 OTHER ONE PROJECTED A \$100-MILLION DISEASE TEAM
20 ROUND ANNUALLY, AND WHAT WE'VE DONE IS WE'RE DOING
21 \$120 MILLION DISEASE TEAM ROUND BIANNUALLY. SO I
22 THINK THAT WE'VE GONE BELOW THE LOWEST PROJECTION
23 THAT WE GOT LAST TIME. AND I THINK IF WE WENT EVEN
24 TO MY SUGGESTION, WE WOULD BE BELOW THE HIGH
25 PROJECTION, THE NORMATIVE PROJECTION, WHICH HAS BEEN

BARRISTERS' REPORTING SERVICE

1 OUR STRATEGIC PLAN, WHICH IS TO DO TRANSLATION,
2 DISEASE TEAMS, BASIC BIOLOGY ON AN ANNUAL BASIS, AND
3 DOING DISEASE TEAMS AT 200 MILLION.

4 SO I JUST MAKE THAT POINT. THE NUMBERS
5 THING I DON'T THINK IS THE ISSUE. EVEN IF WE WERE
6 TO TAKE THE HIGHEST NUMBER, AND I'M WILLING TO SHIFT
7 THAT DOWN, BUT WE WERE TO TAKE THE HIGHEST NUMBER,
8 THAT'S LESS THAN WHAT WE PUT OUT -- WHAT DR. ROBSON
9 PRESENTED LAST MEETING AS THE NORMATIVE RATE OF
10 FUNDING FOR THE AGENCY GOING FORWARD ACCORDING TO
11 OUR STRATEGIC PLAN.

12 NOW, MY SECOND POINT IS THAT I DON'T
13 ACCEPT THAT THERE'S NO PHASE I, PHASE II PRODUCTS.
14 OUR CLINICAL TRIAL ROUND THAT WE'RE DOING IS
15 PLURIPOTENT WITH MATCHING FUNDS. FROM THE MINUTE
16 I'VE BEEN ON THIS AGENCY I'VE HEARD, I REMEMBER
17 STEVE SHERWIN, ALL THE INDUSTRY MEETINGS I'VE HEARD
18 IS WE'VE GOT PRODUCTS WAITING FOR MONEY, BUT NOBODY
19 WANTS TO INVEST IN CELL THERAPY BECAUSE THERE'S NOT
20 A BUSINESS MODEL. AND THE FUNDING CAN DRIVE THE
21 BUSINESS MODEL. PERHAPS THAT ENDS UP LEADING US
22 INTO THE ALPHA CLINIC REALM.

23 BUT RIGHT NOW I KNOW IN HIV, NIH WON'T
24 FUND CELL THERAPIES. I TALKED TO CARL DIFFENBACH,
25 AND HE JUST IS VERY UNENTHUSIASTIC ABOUT GENE AND

BARRISTERS' REPORTING SERVICE

1 CELL THERAPIES AND DOESN'T WANT TO FUND THEM. I'M
2 NOT COMPLETELY SURE THAT THAT'S NOT TRUE IN OTHER
3 DISEASES. WE HAVE ADULT STEM CELLS WITH A LOAN OR A
4 GRANT THAT DOESN'T REQUIRE MATCHING FUNDS. I THINK
5 THERE ARE PRODUCTS OUT THERE MYSELF, AND I'D LIKE TO
6 FIND OUT. AND I'D RATHER BE WRONG ON THAT SIDE, NOT
7 HAVING THE APPLICATIONS, THAN ON THE OTHER SIDE WE
8 HAVE APPLICATIONS THAT WE WERE NOT PREPARED TO FUND.

9 SO, YOU KNOW, THE OTHER QUESTION I HAVE,
10 AND I WOULD CONSIDER MAYBE HYPHENATING AND CAPTURING
11 DUANE'S POINT. COMPANY EARLY PHASE -- DISEASE TEAM
12 SLASH INDUSTRY EARLY PHASED CLINICAL TRIAL ROUND.
13 BUT SOMEHOW WORDSMITHING IT TO SAY TO INDUSTRY WE
14 WANT THESE PRODUCTS IN ADULT STEM CELLS THAT YOU
15 THINK ARE FEASIBLE FOR GOING FORWARD.

16 AND THE OTHER QUESTION I HAVE IS IS IT
17 FEASIBLE TO REVIEW THESE OVER SEVERAL ROUNDS? WE
18 HAVE A LOT OF REVIEWERS. WE MUST HAVE CLOSE TO A
19 HUNDRED PEOPLE, SOMEWHERE BETWEEN 50 AND A HUNDRED
20 PEOPLE WE'VE APPROVED EITHER AS PERMANENT OR
21 ALTERNATE MEMBERS FOR THE GRANTS WORKING GROUP.

22 CHAIRMAN KLEIN: I THINK, JEFF, ONE OF THE
23 CONSTRAINTS IS THAT WE DON'T HAVE A BIG SUPPLY OF
24 INDUSTRY MEMBERS, WHICH WE REALLY TRIED TO GET ONTO
25 THE DISEASE TEAM ROUNDS TO MAKE SURE THAT WE HAD

BARRISTERS' REPORTING SERVICE

1 THAT PERSPECTIVE. WE HAVE THE TREMENDOUS BENEFIT OF
2 DR. OLSON HAS IMPLEMENTED A REGULATORY SPECIALIST
3 WHO'S PRESENT AT THE PEER REVIEW ROUNDS, BUT HAVING
4 INDUSTRY MEMBERS IS DIFFICULT AND GETTING PEOPLE
5 WITH TRANSLATIONAL DOWNSTREAM DEVELOPMENT EXPERIENCE
6 IS IMPORTANT.

7 YOUR POINT AND DUANE'S POINT ABOUT THE
8 COMMUNICATION I THINK IS VERY IMPORTANT. AND WE
9 SHOULD TRY AND CRAFT THAT, BUT I WOULD ASK YOU. DR.
10 TROUNSON IN KIND OF THE STRETCH NUMBER HERE IS
11 SAYING WHAT IF WE SAID IN A MOTION APPROXIMATELY 30
12 AND WE SAID UP TO 14 IS THE NUMBER I HEARD IN TERMS
13 OF THE DISEASE TEAM, HOW WOULD THAT FEEL IN TRYING
14 TO PROVIDE A BALANCE HERE BETWEEN CAPACITY AND THE
15 REACH WE NEED TO HAVE A BIGGER PORTFOLIO?

16 MR. SHEEHY: I STILL THINK YOU HAVE THE
17 RATIO ISSUE. IF YOU DON'T TAKE IT UP TO AT LEAST
18 35, YOU'RE UNLIKELY TO GET 14. I WOULD SAY IF YOU
19 DO 35, THEN I THINK YOU'VE GOT A SHOT AT GETTING 12,
20 WHICH SEEMS WITHIN THE REALM. IF YOU WANT TO BRING
21 ME DOWN FROM 40 TO 35 SO THAT WE GET AT LEAST A
22 DOZEN, I THINK THAT'S REASONABLE. I WOULD BE HAPPY
23 WITH THAT JUST OPERATING OFF -- IT'S BEEN MY
24 EXPERIENCE, AND I THINK THAT'S WHAT PEOPLE HAVE
25 ALLUDED TO, FOR EVERY THREE GRANTS YOU REVIEW, IT'S

BARRISTERS' REPORTING SERVICE

1 A HIGH RATE OF APPROVAL TO GET ONE.

2 DR. TROUNSON: IT SHOULD BE DRIVEN REALLY
3 BY THE QUALITY. AND THE GRANTS REVIEW WILL LOOK AT
4 THAT, SO THEY WILL COME UP WITH A NUMBER, I THINK,
5 AT THAT POINT. SO THAT WILL BE EVIDENT BY WHAT THEY
6 THINK THE QUALITY IS.

7 CHAIRMAN KLEIN: I THINK JEFF IN ALL THESE
8 DISCUSSIONS ARE UP TO 14 UNLESS THE QUALITY IS
9 THERE.

10 MR. SHEEHY: I DON'T WANT TO FUND BAD
11 SCIENCE, AND OUR REVIEWS ARE RIGOROUS.

12 DR. PIZZO: SO I DON'T KNOW WHAT THE RIGHT
13 NUMBER IS. I THINK WE'RE GRAPPLING WITH THAT
14 CHALLENGE, AND I AGREE WITH YOU THAT IT HAS TO BE
15 GOOD SCIENCE. MAYBE WHAT I'M GOING TO ASK HAS
16 ALREADY BEEN DONE MULTIPLE TIMES, IN WHICH CASE IT'S
17 NOT RELEVANT. BUT WE HAVE BEEN WORKING, AND I'M
18 SURE OTHER INSTITUTIONS, OTHER ACADEMIC CENTERS ARE
19 DOING THIS AS WELL, IS WE'VE GOT A PROCESS IN PLACE
20 WHERE WE BRING IN BIOTECH INDUSTRY LEADERS, VENTURE
21 CAPITALISTS, SCIENTISTS TOGETHER WHO HAVE BEEN
22 MEETING ON A REGULAR BASIS TO REVIEW PRODUCTS THAT
23 COME OUT OF OUR OTL FOR POTENTIAL TRANSLATION AND
24 APPLICATION. THIS HAS TURNED OUT TO BE AN
25 ENORMOUSLY FRUITIVE ACTIVITY. IT'S HAD A GREAT

BARRISTERS' REPORTING SERVICE

1 EDUCATIONAL CONTENT, BUT IT ALSO IS MAKING THINGS
2 MOVE FORWARD.

3 AND SO THE QUESTION IS, AND IT KEYS OFF
4 OF, ALAN, WHAT YOU STATED AND, DUANE, WHAT YOU
5 ALLUDED TO. IF INDUSTRY HAS GOT THINGS IN THE
6 PIPELINE AND THEY'RE NOT THERE, ARE THERE WAYS THAT
7 WE COULD SEED THIS TO HAPPEN IN MORE NOVEL MANNERS?
8 HAVE WE HAD, FOR EXAMPLE, AS PART OF OUR STRATEGIC
9 PLANNING EFFORT, AN OFF-THE-RECORD KIND OF THINK
10 TANK BETWEEN INDUSTRY LEADERS, ACADEMIC, VENTURE
11 CAPITALISTS IN THE SAME ROOM AT THE SAME TIME, NOT
12 SEPARATE, WOULD YOU BUY INTO THIS, YOU KNOW,
13 APPROACH, BUT REALLY COMING TOGETHER AND SAY IF WE
14 COULD CREATE THE WORLD DIFFERENTLY, HOW MIGHT WE
15 THINK ABOUT NOVEL WAYS OF APPROACHING THESE KINDS OF
16 BOTH RESEARCH AND TRANSLATION EFFORTS? BECAUSE I
17 THINK AT THE END OF THE DAY, WHAT WE'RE ALL AIMING
18 FOR IS SUCCESS. WE WANT TO OPTIMIZE SUCCESS.
19 WHETHER WE DO IT BY MORE NUMBERS, WHICH IS A RISKY
20 BUSINESS FOR ALL THE REASONS THAT WERE STATED
21 BECAUSE WE MAY BE JUST REPRODUCING MORE OF THE SAME
22 VERSUS SOMETHING NEW AND NOVEL, IS WHAT I THINK WE
23 SHOULDN'T MISS OUT ON.

24 SO IF YOU'VE DONE IT, GREAT. IF NOT, I'D
25 SUGGEST THAT WE MAYBE TALK SEPARATELY ABOUT OTHER

BARRISTERS' REPORTING SERVICE

1 WAYS OF THINKING ABOUT THIS SO THAT WE MIGHT COME UP
2 WITH NOVEL OR DIFFERENT WAYS OF APPROACHING
3 SOLUTIONS.

4 DR. TROUNSON: PART OF WHAT ELONA BAUM IS
5 TALKING ABOUT IS TRYING TO GET THE INSTITUTIONS
6 TOGETHER AND SAY WE'VE GOT IP HERE AND IP THERE.
7 AND SOME OF THIS IS NOT KNOWN TO ONE ANOTHER AND TO
8 CREATE THE OPPORTUNITIES FOR COMPANIES TO SEE, NOT
9 ONLY WHAT IS GOOD RESEARCH, BUT WHAT IP IS
10 ATTRACTIVE BECAUSE THE PARTNERSHIPS ARE OFTEN
11 DERIVED REALLY --

12 DR. PIZZO: BUT IT'S A DIFFERENT QUESTION
13 THAT I'M ASKING. BECAUSE I KNOW WHEN WE GO TO OTL,
14 YOU KNOW, WE HAVE A GREAT OTL, BUT THEY HAVE CERTAIN
15 LIMITATIONS WHAT THEY'RE WILLING TO DO. AND WE'VE
16 BROUGHT TOGETHER PEOPLE FROM DIFFERENT WAYS OF
17 LOOKING AT THE WORLD. VC PEOPLE GET TO KNOW EACH
18 OTHER BECAUSE THEY'RE DOING IT ON A REGULAR BASIS.
19 AND INDUSTRY LEADERS, AND WE'VE GOT REPRESENTATIVES
20 OF THAT IN THIS ROOM, BUT, YOU KNOW, WE DON'T TALK
21 TOGETHER ABOUT SOLVING THE PROBLEM. WE TEND TO TALK
22 IN OUR SEPARATE SILOS.

23 AND I'M ASKING AS PART OF THE STRATEGIC
24 PLANNING PROCESS, IF YOU'RE DOING IT, FINE; BUT IF
25 NOT, LET'S THINK ABOUT THE OTHER WAYS OF "SEEDING"

BARRISTERS' REPORTING SERVICE

1 SOME OF THESE INTERACTIONS.

2 DR. TROUNSON: I'LL BE REALLY HAPPY TO
3 TALK TO YOU AND OTHER MEMBERS ABOUT THAT, PHIL. I'M
4 INTERESTED IN YOUR THOUGHTS THERE.

5 DR. PENHOET: I JUST WANT -- IN RESPONSE
6 TO JEFF'S COMMENT, I THINK THE RATIO OF FUNDABLE
7 APPLICATIONS TO TOTAL APPLICATIONS IS NOT A FIXED
8 NUMBER. AND THE BIGGER YOU MAKE THE NUMBER OF
9 APPLICATIONS, THE YIELD CURVE IS GOING TO GO DOWN.
10 SO YOU WON'T GET ONE-THIRD OF A HUNDRED OR YOU --
11 IT'S NOT LIKELY. WE HAVE A FINITE POOL OF POTENTIAL
12 APPLICANTS THAT WE CAN DEAL WITH. I'M NOT SURE
13 WE'VE SOLVED THE QUALITY PROBLEM ON THE EVENTUAL
14 NUMBER BY INCREASING THE DENOMINATOR, IF YOU WILL.
15 I THINK WE DO HAVE TO BE SENSITIVE TO THE BURDEN OF
16 THIS ALSO.

17 SO IF I COULD INTRODUCE A FRIENDLY
18 AMENDMENT, WE'VE HEARD THAT THEY'VE HANDLED 30
19 BEFORE, THEY THINK THEY CAN HANDLE 30, IT'S A
20 STRETCH, IF THERE'S A NUMBER LIKE 30 AND 10, FOR
21 EXAMPLE, WHICH WOULD BE MAYBE A COMPROMISE POSITION.

22 CHAIRMAN KLEIN: I DON'T THINK THE
23 DOWNSTREAM NUMBER IS THE PROBLEM. HOW ABOUT MERGING
24 THESE FOR 30 AND APPROXIMATELY 30. AS DR. TROUNSON
25 HAS SAID, IF THE SCIENTIFIC STAFF SEES GREATER

BARRISTERS' REPORTING SERVICE

1 QUALITY, YOU KNOW THEY'RE GOING TO COME AND
2 RECOMMEND 32 OR 33 OR WHATEVER, 35, IF IT'S THERE.
3 SO IF WE SAID APPROXIMATELY 30 AND UP TO 12, THAT
4 KIND OF BLENDS THE GROUPS TOGETHER. IS THAT --
5 WOULD YOU BE WILLING TO MAKE THAT MOTION FOR
6 DISCUSSION?

7 DR. PENHOET: SO MOVED.

8 CHAIRMAN KLEIN: IS THERE A SECOND?

9 DR. BRENNER: SECOND.

10 CHAIRMAN KLEIN: SECOND, DR. BRENNER.

11 JEFF, I'M GOING TO LET YOU BE THE FIRST ONE TO
12 COMMENT IF YOU WOULD LIKE.

13 MR. SHEEHY: IN THE SPIRIT OF COMPROMISE,
14 THE ONLY THING THAT I WOULD LIKE TO ADD TO THAT IS
15 DUANE'S POINT. IF YOU WILL ACCEPT A FRIENDLY
16 AMENDMENT. WHILE MAINTAINING THE DISEASE TEAMS
17 MONIKER, TO SOMEHOW INCORPORATE BOTH IN THE TITLE
18 AND SOMEHOW IN THE COMMUNICATION OF THIS RFA THAT WE
19 ARE ACTIVELY SEEKING INDUSTRY PARTICIPATION, THAT
20 THIS IS INDUSTRY SPACE THAT WE'RE GOING IN, YOU
21 DON'T HAVE TO BRING ANY MATCHING FUNDS. I'D ALSO
22 LIKE US TO THINK ABOUT IF THE WORKING GROUPS SENDS
23 UP A BUNCH OF REALLY -- YOU KNOW, OVER 30 GOOD
24 APPLICATIONS, THAT WE REALLY ARE VERY THOUGHTFUL
25 ABOUT IT. WE DON'T KNOW. THEY MAY ONLY SEND US

BARRISTERS' REPORTING SERVICE

1 TEN, BUT I WANT US -- I WOULD BE HAPPY TO ACCEPT
2 LIKE THAT.

3 CHAIRMAN KLEIN: AND SO, JEFF, I THINK WE
4 NEED TO LEAVE OUT THE ISSUE ON MATCHING FUNDS
5 BECAUSE IF THEY PROPOSE AN EXPENSIVE PHASE I, THERE
6 WOULD BE SOME MATCHING FUNDS.

7 MR. SHEEHY: WELL, I MEAN WITHIN THE
8 CONTOURS OF WE JUST DESCRIBED. IT'S LIMITED TO 20
9 MILLION. IF YOUR PROJECT COSTS MORE THAN 20 MILLION
10 AS THE CONCEPT IS DESCRIBED, YOU HAVE TO PROVIDE
11 MATCHING FUNDS, BUT A PRIORI. I MEAN AN ADULT STEM
12 CELL PRODUCT GENETICALLY MODIFIED TO GO INTO A
13 HANDFUL OF PATIENTS DOESN'T REQUIRE \$30 MILLION.

14 CHAIRMAN KLEIN: THAT'S RIGHT.

15 MS. SHEEHY: AT LEAST MY CONVERSATIONS
16 WITH SOME OTHER FOLKS.

17 CHAIRMAN KLEIN: DR. PENHOET, WOULD YOU
18 ACCEPT THE COMMUNICATIONS MODIFICATION TO THAT
19 PROPOSAL?

20 DR. PENHOET: IN THE INTEREST OF BOARD
21 HARMONY, I WILL.

22 CHAIRMAN KLEIN: OKAY. AND THE SECOND,
23 DOES THE SECOND ACCEPT THAT? ACCEPTED. ADDITIONAL
24 DISCUSSION?

25 IS THERE -- DR. TROUNSON, WOULD YOU LIKE

BARRISTERS' REPORTING SERVICE

1 TO COMMENT ON THE PROPOSAL?

2 DR. TROUNSON: THANK YOU, CHAIR. AND
3 THANKS FOR THE CONSIDERATION, BOARD MEMBERS. I
4 THINK, AS I SAID BEFORE, WE SEE WHAT WE DO AS OUR
5 MISSION. AND SO WE'RE DETERMINED TO BRING YOU THE
6 BEST THAT WE CAN FIND, AND WE WORK HARD AT ALSO
7 CREATING THESE PARTNERSHIPS. I THINK A NUMBER OF
8 THESE PARTNERSHIPS HAVE BEEN CREATED OUT OF OUR
9 SUGGESTIONS OR ADDITIONS ON THAT MAKE THEM EVEN
10 BETTER.

11 SO WE'RE WORKING HARD TO DO THAT, AND WE
12 REALLY WANT THIS TO SUCCEED. SO I THINK WE CAN
13 ACCOMMODATE THOSE NUMBERS. IT WILL PRESS US HARD,
14 AND I'M ALWAYS A LITTLE RELUCTANT TO PRESS THE STAFF
15 EVEN HARDER, BUT I THINK THEY WILL ACCOMMODATE THIS.
16 AND LET'S HOPE THAT WE GET SOME FANTASTIC
17 APPLICATIONS THROUGH TO THE FINAL STAGE, AND THAT'S
18 REALLY WHAT IT'S ALL ABOUT.

19 CHAIRMAN KLEIN: I THINK WE'RE GOING TO
20 REALIZE WE HAVE TO REALLY INCREASE THE STAFF TO DEAL
21 WITH OUR MISSION OBJECTIVE HERE BECAUSE THE STAFF IS
22 REALLY PUTTING IN A HUGE AMOUNT OF EFFORT TO MOVE
23 THESE FORWARD. IS THERE PUBLIC COMMENT?

24 MR. REED: FIRST, IT'S WONDERFUL, AS
25 ALWAYS, THAT STAFF IS ALWAYS WILLING TO TAKE ON THE

BARRISTERS' REPORTING SERVICE

1 EXTRA BURDEN, GO THE EXTRA MILE. IT'S TYPICAL OF
2 HOW THEY'VE TAKEN ON EVERYTHING. I'M VERY GLAD THAT
3 1064 MAY ALLEVIATE SOME OF THAT BURDEN, AND LET'S
4 HOPE IT COMES SOON.

5 SHAKESPEARE SAID SOMETHING TO THE EFFECT
6 THAT THERE IS A TIME IN THE TIDES OF THE LIVES OF
7 MEN WHICH, IF TAKEN AT THE FULL, ADVANCES THE CAUSE
8 AND WHICH, IF NEGLECTED, NEVER COMES AGAIN. I DON'T
9 WANT TO LOOK BACK IN 2016 AND SAY IF ONLY WE'D BEEN
10 A LITTLE BOLDER. I REALLY APPRECIATE THE FACT THAT
11 EVERYBODY HAS TAKEN THAT CAREFUL, BUT BOLDER NEXT
12 STEP. THANK YOU.

13 CHAIRMAN KLEIN: ADDITIONAL PUBLIC
14 COMMENT?

15 DR. POMEROY: SINCE THE COST OF THIS
16 PROPOSAL IS NOW 243 MILLION, UP TO 243 MILLION, I
17 WOULD JUST REQUEST THAT AT OUR NEXT MEETING, WE GET
18 AN UNDERSTANDING OF WHAT THE IMPLICATIONS ARE IF THE
19 FULL NUMBER WERE FUNDED.

20 CHAIRMAN KLEIN: THANK YOU VERY MUCH. I
21 THINK DR. TROUNSON SUGGESTED WE COULD GET TOGETHER
22 WITH DR. ROBSON BEFOREHAND AND WORK THOSE NUMBERS
23 OUT AND BRING YOU THE ASSUMPTIONS TOO SO YOU CAN
24 LOOK AT DIFFERENT ASSUMPTIONS IN THAT.

25 DR. TROUNSON: I THINK IT'S VERY IMPORTANT

BARRISTERS' REPORTING SERVICE

1 THAT WE DO THIS ON A REASONABLY REGULAR BASIS
2 BECAUSE THINGS ARE CHANGING. AND THINGS THAT WE HAD
3 IN THOSE ASSUMPTIONS INCLUDED US DOING SOME ADD-ON
4 CLINICAL OPTIONS TO TAKE SOME OF THE DISEASE TEAMS
5 AND TRANSLATIONS THROUGH, AND THAT'S NOT EMBEDDED IN
6 ANY WAY IN THE ICOC DECISION. SO I THINK IT'S
7 REALLY IMPORTANT THAT WE GET TO UNDERSTAND EXACTLY
8 WHAT THOSE PREDICTIONS ARE AND WHAT DEGREE OF
9 ELASTICITY EXISTS. AND WE SHOULD DO THAT AS A
10 CONTINUING PROCESS.

11 CHAIRMAN KLEIN: THANK YOU, DR. TROUNSON.
12 SO I'M GOING TO CALL THE QUESTION. ALL IN
13 FAVOR.

14 (CHORUS OF AYES.)

15 MR. HARRISON: I JUST WANTED TO MAKE SURE
16 THAT I UNDERSTOOD AND FOR THE RECORD THAT THE MOTION
17 WAS CLEAR. AS I UNDERSTAND IT, IT'S TO APPROVE THE
18 CONCEPT PLAN, BUT TO MODIFY IT TO PERMIT UP TO
19 APPROXIMATELY 30 PLANNING GRANT AWARDS AND UP TO
20 APPROXIMATELY 12 AWARDS AND TO INCORPORATE IN THE
21 COMMUNICATIONS REGARDING THE RFA THAT WE ARE
22 ACTIVELY SEEKING INDUSTRY PARTICIPATION.

23 CHAIRMAN KLEIN: AND IT WAS THE -- BOTH UP
24 TOS INCLUDE THE QUALIFIER APPROXIMATELY SO THAT
25 SCIENTIFIC STAFF CAN GUIDE US ON THE QUALITY.

BARRISTERS' REPORTING SERVICE

1 SO WITH THAT CLARIFICATION, I'M GOING TO
2 TAKE THAT VOICE VOTE AGAIN JUST FOR THE RECORD. ALL
3 IN FAVOR.

4 (CHORUS OF AYES.)

5 OPPOSED?

6 (NO RESPONSE.)

7 AND ON THE -- MELISSA, PLEASE ASK FOR THE
8 TELEPHONIC.

9 MS. KING: WILLIAM BRODY. ARE YOU THERE,
10 DR. BRODY?

11 DR. FRIEDMAN, I BELIEVE YOU'VE ALREADY
12 CAST YOUR VOTE, CORRECT?

13 DR. FRIEDMAN: YES.

14 MS. KING: JUST CHECKING ONE MORE TIME ON
15 DR. BRODY. LOOKS LIKE HE STEPPED AWAY, BUT THE
16 MOTION DOES CARRY.

17 CHAIRMAN KLEIN: THANK YOU. AT THIS POINT
18 I THINK IT'S APPROPRIATE TO BREAK.

19 DR. TROUNSON: CHAIR, JUST --

20 DR. BRODY: I GOT DISCONNECTED AND IT TOOK
21 FOREVER TO GET BACK ON. DID I MISS A VOTE?

22 CHAIRMAN KLEIN: THE VOTE WAS -- LET ME
23 HAVE MR. HARRISON REPEAT THE MOTION. AT THIS POINT
24 WE HAVE A UNANIMOUS VOTE, BUT WE WANT TO MAKE SURE
25 WE GET YOUR VOTE. MR. HARRISON, WOULD YOU REPEAT

BARRISTERS' REPORTING SERVICE

1 THE MOTION?

2 MR. HARRISON: THE MOTION, DR. BRODY, IS
3 TO APPROVE THE CONCEPT PLAN FOR THE DISEASE TEAM II
4 RFA, BUT TO MODIFY IT TO PERMIT UP TO APPROXIMATELY
5 30 PLANNING GRANT AWARDS AND UP TO APPROXIMATELY 12
6 GRANT AWARDS, GRANT OR LOAN, I SHOULD SAY, AND TO
7 INCORPORATE IN THE COMMUNICATION REGARDING THE RFA
8 THAT CIRM IS ACTIVELY SEEKING INDUSTRY
9 PARTICIPATION.

10 DR. BRODY: OKAY. I GIVE MY APPROVAL.

11 CHAIRMAN KLEIN: THANK YOU VERY MUCH.

12 MELISSA KING, IS IT APPROPRIATE --

13 DR. TROUNSON: JUST BEFORE YOU BREAK, AT
14 THE END OF THE PRESIDENT'S PRESENTATION, WE'D ASKED
15 AMY LEWIS AND AMY ADAMS TO VERY BRIEFLY FILL YOU IN
16 ON A COUPLE OF SMALL THINGS, BUT I'D ASKED THEM BOTH
17 TO COME. AND IF IT'S POSSIBLE EITHER NOW OR AFTER
18 LUNCH TO HEAR THEM BRIEFLY JUST TO --

19 CHAIRMAN KLEIN: WE WILL ABSOLUTELY HEAR
20 THEM. LET ME ASK FOR YOUR ADVICE ON HOW LONG THOSE
21 ITEMS ARE.

22 DR. TROUNSON: I THINK THEY WOULD TAKE NO
23 LONGER THAN TEN MINUTES.

24 CHAIRMAN KLEIN: IS IT ACCEPTABLE THAT
25 THEY DO IT AFTER LUNCH BECAUSE WE'VE GOT -- MELISSA

BARRISTERS' REPORTING SERVICE

1 KING, WHAT'S OUR FLEXIBILITY HERE WITH THE CATERING?

2 MS. KING: WE CAN BREAK FOR LUNCH AS SOON
3 AS WE'RE READY, BUT WHAT I SUGGEST, BECAUSE WE HAVE
4 COUPLE OF ITEMS THAT ARE GOING TO POTENTIALLY TAKE
5 CONSIDERABLE TIME, BUT YET A COUPLE OF OTHER ITEMS
6 THAT WE COULD PROBABLY DEAL WITH VERY QUICKLY, AND
7 THESE ARE ACTION ITEMS. I KNOW WE HAVE A NUMBER OF
8 BOARD MEMBERS THAT NEED TO LEAVE BY 2:30. I'D LIKE
9 US TO DO THE TWO ITEMS THAT WE CAN DO QUICKLY NOW,
10 BREAK FOR LUNCH, AND COME BACK AND DEAL WITH THE
11 SUBSTANTIVE ITEMS LEFT ON THE AGENDA, AND FOLLOW
12 THAT WITH ANYTHING ELSE WE HAVE LEFT.

13 CHAIRMAN KLEIN: I'VE NEVER BEEN ABLE TO
14 ASSUME THAT WE WOULD DO AN ITEM QUICKLY.

15 MS. KING: THE ITEMS ARE NO. 9,
16 CONSIDERATION OF PROPOSED NEW SCIENTIFIC MEMBERS FOR
17 THE WORKING GROUP. IT'S ALWAYS IMPORTANT TO MAKE
18 SURE THAT WE ACTUALLY DO THAT FOR THEM, ESPECIALLY
19 AHEAD OF A WORKING GROUP MEETING. AND WHAT'S THE
20 OTHER ONE I THOUGHT WAS QUICK? POTENTIALLY NO. 11,
21 ALTHOUGH I'M NOT SURE, BUT IT HAS GONE THROUGH THE
22 SCIENCE SUBCOMMITTEE AT THIS POINT. AND THIS IS A
23 STAFF PROPOSAL REGARDING THE USE OF UNUSED DISEASE
24 TEAM FUNDS FOR CLINICAL TRIALS. THE BOARD HAS
25 DISCUSSED IT A NUMBER OF TIMES OVER THE YEAR OR TWO,

BARRISTERS' REPORTING SERVICE

1 I THINK, AND IT'S NOW COME THROUGH THE SCIENCE
2 SUBCOMMITTEE AND THERE'S AN ACTUAL PROPOSAL.

3 CHAIRMAN KLEIN: JEFF, WHAT'S YOUR ADVICE?
4 DO YOU THINK WE COULD RUN THROUGH THAT QUICKLY?

5 MR. SHEEHY: WE COULD WITH ONE AMENDMENT
6 TO THAT PROPOSAL, WHICH IS THAT IT COME TO THE BOARD
7 FOR APPROVAL. I WOULD NOT WANT US TO FUND A
8 CLINICAL TRIAL WITHOUT THE BOARD HAVING APPROVED IT.
9 I THINK THE POLICY AS STATED IS FINE, BUT THE
10 CLINICAL TRIAL SHOULD COME BACK TO THE BOARD.

11 MS. KING: SO, CHAIRMAN KLEIN, WHAT I'M
12 GOING TO SUGGEST IS THAT WE JUST DEAL WITH ITEM NO.
13 9 AND THEN BREAK FOR LUNCH.

14 MS. LANSING: I WOULD LIKE TO MOVE -- I'VE
15 READ THIS. I THINK EVERYBODY HAS. I THINK THEY ARE
16 EXTRAORDINARILY DISTINGUISHED ADDITIONS. AND SO I
17 WOULD LIKE TO MOVE APPROVAL OF NO. 9.

18 DR. PRICE: SECOND.

19 CHAIRMAN KLEIN: THAT SPECIFICALLY IS
20 CONSIDERATION OF PROPOSED NEW SCIENTIFIC MEMBERS TO
21 THE GRANTS WORKING GROUP. AND FOR THE RECORD, I
22 THINK IT WOULD BE IMPORTANT TO READ THE NAMES OF THE
23 CANDIDATES INTO THE RECORD IF WE COULD DO THAT,
24 PLEASE.

25 MR. SHEEHY: DR. ANTHONY HOLLANDER FROM

BARRISTERS' REPORTING SERVICE

1 THE UNIVERSITY OF BRISTOL, DR. ROSSER FROM THE
2 CARDIFF BRAIN REPAIR GROUP, AND DR. STEER, CLIFFORD
3 STEER FROM UNIVERSITY OF MINNESOTA.

4 CHAIRMAN KLEIN: IS THERE A SECOND?

5 MR. ROTH: SECOND.

6 CHAIRMAN KLEIN: OKAY. DISCUSSION?

7 PUBLIC COMMENT? ALL IN FAVOR.

8 (CHORUS OF AYES.)

9 OPPOSED?

10 (NO RESPONSE).

11 TELEPHONIC?

12 MS. KING: DR. WILLIAM BRODY.

13 DR. BRODY: AYE. AYE.

14 MS. KING: MICHAEL FRIEDMAN.

15 DR. FRIEDMAN. YES.

16 MS. KING: THANK YOU. AND FOR THE RECORD,
17 THAT MOTION CARRIES.

18 CHAIRMAN KLEIN: OKAY. AND AMY LEWIS IS
19 HERE. AMY, COULD YOU QUICKLY GIVE YOUR
20 PRESENTATION, AND THEN WE ARE GOING TO GO TO LUNCH.

21 MS. KING: IT'S BEEN SUGGESTED BY DR.
22 POMEROY, AND IT IS A POSSIBILITY, THAT WE COULD DO A
23 WORKING LUNCH. THE LUNCH ARE IN BOXES, SO WE COULD
24 GO GET LUNCH AND PEOPLE COULD HAVE LUNCH NOW.

25 CHAIRMAN KLEIN: THAT'S A VERY GOOD

BARRISTERS' REPORTING SERVICE

1 SUGGESTION. AMY, WITH YOUR PATIENCE WITH US, WE
2 WILL GO GET LUNCH AND BRING IT BACK AND RECONVENE.
3 THANK YOU.

4 (A RECESS WAS TAKEN.)

5 MS. KING: I'D LIKE TO INTRODUCE AMY
6 LEWIS, OUR GRANTS MANAGEMENT OFFICER, WHO WILL BEGIN
7 HER PRESENTATION. THANK YOU.

8 MS. LEWIS: THANK YOU. I'M TOLD I HAVE
9 KIND OF A QUIET VOICE, SO I'LL TRY TO SPEAK LOUDLY
10 SO YOU CAN HEAR ME. I AM HERE TODAY JUST TO GIVE
11 YOU A LITTLE UPDATE ON OUR GRANTS MANAGEMENT SYSTEM.
12 I'M GOING TO GIVE YOU SORT OF A SNAPSHOT, A 30,000
13 FOOT VIEW OF OUR CURRENT SYSTEM, AND THEN SHOW YOU
14 WHAT WE'RE AIMING TO DO, WHAT OUR FUTURE SYSTEM WILL
15 LOOK LIKE, AND THEN I ALSO WOULD LIKE TO SHOW YOU,
16 JUST TO GIVE YOU A QUICK VIEW OF OUR PROGRESS REPORT
17 SYSTEM. THIS IS A WEB-BASED SYSTEM THAT OUR
18 GRANTEES ARE CURRENTLY USING THAT WE THINK IS PRETTY
19 GREAT, AND SO WE WANTED TO SHOW YOU THAT.

20 I'M GLAD EVERYONE HAS FOOD AND DOESN'T
21 HAVE LOW BLOOD SUGAR ANYMORE AS I GO THROUGH THIS
22 PRESENTATION.

23 SO FIRST, I ALSO THOUGHT I WOULD MENTION,
24 JUST REMINDING FOLKS, WHAT A GRANTS MANAGEMENT
25 SYSTEM IS. THIS IS A SYSTEM THAT ALLOWS US TO

BARRISTERS' REPORTING SERVICE

1 MONITOR AND TRACK A GRANTS AWARD THROUGH ITS ENTIRE
2 LIFE CYCLE. THAT'S FROM APPLICATION TO AWARD ALL
3 THE WAY TO CLOSEOUT. SOUNDS KIND OF BORING, BUT
4 IT'S ACTUALLY QUITE IMPORTANT. IT'S WHERE WE KEEP
5 ALL OF THE DATA ASSOCIATED WITH OUR GRANTS. THAT'S
6 HOW WE TRACK AND MONITOR THE RESEARCH PROGRESS.
7 IT'S HOW WE MAKE SURE THAT WE ARE MONITORING AND
8 TRACKING COMPLIANCE. AND THIS IS ALL QUITE
9 IMPORTANT FOR A STATE AGENCY.

10 SO THIS IS WHAT OUR CURRENT GRANTS
11 MANAGEMENT SYSTEM LOOKS LIKE. THE DATA COMES IN IN
12 VARIOUS WAYS. YOU CAN SEE THAT WE HAVE DATA COMING
13 IN ALL ALONG THE LEFT. THE GRANTEE APPLICATIONS ARE
14 PAPER OR PDF FILES. IN OUR REVIEW MODULE, DATA
15 COMES IN THROUGH A WEB-BASED SYSTEM. AND THEN, AS I
16 MENTIONED, OUR GRANTEE PROGRESS REPORTS, GRANTEES
17 SUBMIT THEIR DATA USING A WEB-BASED SYSTEM.

18 WHAT I'D REALLY LIKE FOR YOU TO NOTICE IS
19 THAT THE STARS ON THIS GRAPHIC REPRESENT A STEP
20 WHERE THERE'S MANUAL DATA TRANSFER. SO THERE'S A
21 LOT OF OPPORTUNITY FOR SOMEONE TO TAKE DATA OUT OF
22 ONE SYSTEM AND ACCIDENTALLY MAKE A MISTAKE WHEN
23 THEY'RE ENTERING IT INTO THE NEXT SYSTEM.

24 I THOUGHT I'D GIVE YOU AN EXAMPLE JUST TO
25 ILLUSTRATE IT. SO GRANTEE APPLICATIONS COME IN,

BARRISTERS' REPORTING SERVICE

1 PAPER OR PDF FILES. THERE'S ACTUALLY A MANUAL STEP
2 THAT WE HAVE TO DO TO GET THAT DATA INTO WHAT WE'RE
3 CALLING OUR MASTER DATABASE. AND THEN THE NEXT
4 STEP, LET'S SAY, FOR EXAMPLE, AFTER WE'VE RECEIVE
5 THOSE APPLICATIONS, WE NEED TO DO SOME FINANCIAL
6 FORECASTING. THE STATE TREASURER'S OFFICE HAS ASKED
7 US FOR DATA.

8 SO WE NEED TO TAKE THAT DATA OUT OF OUR
9 MASTER DATABASE, A MANUAL STEP, TO TRANSFER THE
10 DATA. WE NEED TO FORMAT IT IN A WAY THAT MICROEDGE
11 GIFTS, OUR OFF-THE-SHELF GRANTS MANAGEMENT SYSTEM
12 THAT WE'RE USING RIGHT NOW FOR POSTAWARD TRACKING,
13 WILL ACTUALLY ACCEPT IT. SO WE FORMAT IT INTO A
14 VERSION THAT GIFTS WILL ACCEPT. WE PUT IT INTO
15 GIFTS. AND THEN WE NEED TO PRODUCE THE DATA FOR OUR
16 FINANCIAL TEAM TO CHECK AND THEN SEND ON TO THE
17 STATE TREASURER'S OFFICE. SO THE DATA COMES OUT OF
18 MICROEDGE GIFTS. WE REFORMAT IT ONE MORE TIME, AND
19 THEN WE CAN SEND IT ON TO THE TREASURER'S OFFICE TO
20 TELL THEM WHAT WE FORECAST WE'LL BE SPENDING.

21 IT'S A LOT OF TIMES THAT YOU CAN SEE,
22 THREE TIMES THERE, THAT THE DATA IS TOUCHED BY A
23 PERSON. AND THAT'S THREE TIMES THAT WE HAVE AN
24 OPPORTUNITY FOR USER ERROR, HUMAN ERROR, WHICH
25 UNFORTUNATELY THAT TENDS TO HAPPEN. ERROR TENDS TO

BARRISTERS' REPORTING SERVICE

1 HAPPEN WHEN HUMANS ARE INVOLVED IN TOUCHING DATA.
2 SO WHAT OUR SYSTEM, WHAT WE REALLY WOULD
3 LIKE OUR SYSTEM TO LOOK LIKE IN THE FUTURE IS NOT
4 THIS HYBRID, PAPER-BASED, PARTIALLY AUTOMATED
5 SYSTEM. WE'RE LOOKING TO MOVE TO THE STREAMLINED,
6 ROBUST, CRADLE-TO-GRAVE SYSTEM THAT WILL ALLOW US TO
7 FULLY SUPPORT OUR GRANTEES AND ALL OF THEIR
8 REPORTING ACTIVITIES, AND IT WILL ALLOW US TO
9 PROVIDE REAL-TIME DATA INFORMATION ON OUR GRANTS TO
10 ALL OF OUR STAKEHOLDERS, THE STATE TREASURER'S
11 OFFICE, OUR CONSTITUENTS WHO ARE LOOKING AT OUR WEB
12 SITE, AND ACTUALLY ALL THE STAFF INTERNALLY WHO NEED
13 TO USE THE DATA ON CURRENT GRANTS TO MAKE STRATEGIC
14 DECISIONS.

15 THAT'S SORT OF OUR GOAL WITH OUR GRANTS
16 MANAGEMENT SYSTEM. WHAT I WANTED TO SHOW YOU NEXT
17 IS THE PROGRESS REPORT MODULE. THIS IS JUST ONE
18 PIECE OF THE SYSTEM, BUT THIS IS THE MODULE THAT WE
19 JUST RELEASED ABOUT SIX MONTHS AGO THAT ALLOWS OUR
20 GRANTEES TO SUBMIT PROGRESS REPORT DATA TO US ONLINE
21 RATHER THAN USING A PIECE OF PAPER.

22 SO I'M LOGGED IN HERE IN OUR BETA SITE TO
23 SHOW YOU AS IF I'M JEANNE LORING. YOU CAN SEE HER
24 NAME UP AT THE TOP OF THE SCREEN HERE. SHE HAS A
25 TOOLS AND TECHNOLOGIES AWARD AND AN EARLY

BARRISTERS' REPORTING SERVICE

1 TRANSLATIONAL AWARD. FOR THE SAKE OF THIS
2 DEMONSTRATION, WE'LL SAY SHE HAS A PROGRESS REPORT
3 DUE FOR BOTH AWARDS. IT'S REALLY SIMPLE FOR DR.
4 LORING TO KNOW WHAT SHE HAS TO TURN IN TO US. SHE
5 DOESN'T HAVE TO CHECK HER E-MAIL, LOOK FOR DOCUMENTS
6 THAT WERE SENT TO HER BY GRANTS MANAGEMENT STAFF.
7 SHE LOGS IN HERE TO HER PORTFOLIO, AND HERE IT IS
8 RIGHT IN FRONT HER. SHE HAS A PROGRESS REPORT DUE
9 FOR THESE TWO GRANTS.

10 SO SHE CLICKS ON HER EARLY TRANSLATIONAL
11 AWARD, AND HERE WE ACTUALLY GIVE HER A LITTLE MORE
12 INFORMATION, THE ACTIVITIES SHE NEEDS TO COMPLETE IS
13 A PROGRESS REPORT. THIS IS FOR THE YEAR ONE, AND
14 THIS IS FOR THE REPORTING PERIODS DATED SEPTEMBER 1,
15 2009, TO AUGUST 31, 2010.

16 SO I'LL CLICK INTO THE PROGRESS REPORT
17 PAGE. I HOPE YOU'VE NOTICED AS WE'VE CLICKED
18 THROUGH HERE THAT WE HAVEN'T HAD TO GO THROUGH AN
19 INSTRUCTIONS PAGE. A LOT OF TIMES PEOPLE CAN GET
20 BOGGED DOWN BY LONG INSTRUCTIONS PAGES. AND WHAT
21 WE'VE LEARNED OVER THE YEARS IS THAT IT'S MUCH
22 EASIER AND MUCH FASTER FOR OUR GRANTEES IF WE BUILD
23 A SYSTEM THAT'S VERY INTUITIVE AND TAKES THEM STEP
24 BY STEP THROUGH THE PROCESS AND ALL THE ACTIVITIES
25 THAT THEY NEED TO COMPLETE.

BARRISTERS' REPORTING SERVICE

1 SO A PROGRESS REPORT IS SOMETHING THAT'S
2 REQUIRED BY OUR GRANTS ADMINISTRATION POLICY. FOR
3 THIS PARTICULAR GRANT, IT WOULD BE REQUIRED
4 ANNUALLY, AN ANNUAL PROGRESS REPORT. YOU CAN SEE
5 HERE WE PROVIDE A TEMPLATE FOR THE SCIENTIFIC
6 PROGRESS REPORT. IT'S RIGHT HERE ON THE SYSTEM.
7 AGAIN, DR. LORING DOESN'T HAVE TO GO CHECK HER
8 E-MAIL AND FIND THE DOCUMENT THAT SHE'S SUPPOSED TO
9 USE. SHE JUST CLICKS ON THE FILE HERE, SHE CAN OPEN
10 IT UP, AND SAVE HER DATA IN IT.

11 AND THEN THE OTHER REALLY EXCITING PIECE
12 OF FUNCTIONALITY THAT WE HAVE IS THAT ONCE SOMEONE
13 HAS ACTUALLY FILLED OUT THEIR SCIENTIFIC PROGRESS
14 REPORT, THEY CAN UPLOAD THEIR DOCUMENTS TO OUR
15 SYSTEM. SO IF YOU ARE ON THE UPLOAD DOCUMENTS PAGE,
16 DR. LORING OR ANOTHER GRANTEE COULD UPLOAD THEIR
17 SCIENTIFIC PROGRESS REPORT. THEY CAN ALSO UPLOAD
18 OTHER REQUIRED DOCUMENTS THAT THEY NEED TO SUBMIT
19 WITH THEIR PROGRESS REPORT. WE THINK THIS IS A HUGE
20 EFFICIENCY FOR US BECAUSE GRANTEES CAN JUST UPLOAD
21 EVERYTHING HERE TO THIS PAGE. THEY DON'T HAVE TO
22 FIND ALL THE DOCUMENTS, TRY TO E-MAIL THEM TO US,
23 PRINT THEM OUT, SEND THEM TO US. IT'S REALLY
24 FANTASTIC FOR GRANTEES, AND WE THINK IT'S ALSO QUITE
25 EFFICIENT FOR STAFF BECAUSE ALL THE DOCUMENTS LIVE

BARRISTERS' REPORTING SERVICE

1 IN ONE PLACE. WHEN IT'S TIME FOR OUR SCIENTIFIC
2 STAFF TO LOOK AT A PROGRESS REPORT, THEY CAN JUST
3 LOOK AT THIS ONE SECTION.

4 SO WE HAVE OTHER SECTIONS HERE THAT ARE
5 REQUIRED BY OUR GRANTS ADMINISTRATION POLICY.
6 GRANTEES HAVE TO TELL US ABOUT THE PUBLIC SUMMARY OF
7 SCIENTIFIC PROGRESS. I MENTION THIS BECAUSE AMY
8 ADAMS WILL TOUCH ON THIS WHEN SHE GIVES HER
9 PRESENTATION IN JUST A MOMENT. RIGHT NOW THAT
10 PUBLIC SUMMARY COMES INTO US, HAS BEEN COMING INTO
11 US IN A FORMAT THAT'S BEEN VERY DIFFICULT FOR US TO
12 PROVIDE TO THE PUBLIC. WE WANT TO MAKE THIS DATA
13 AVAILABLE QUICKLY AND EASILY TO THE PUBLIC. THIS
14 SYSTEM IS GOING TO HELP US DO THAT.

15 THE OTHER AREA THAT'S IMPORTANT TO MENTION
16 IS THE LIST OF PUBLICATIONS. IT'S IMPORTANT THAT
17 OUR GRANTEES' PUBLICATIONS ARE AVAILABLE FOR THE
18 PUBLIC. THEY CAN SEARCH OUR GRANTS AND SEE WHO'S
19 PUBLISHED WHAT. THIS SYSTEM WILL HELP US MAKE THAT
20 INFORMATION AVAILABLE QUICKLY TO OUR STAKEHOLDERS AS
21 WELL.

22 I ALSO WANT TO JUST MENTION A NEW SECTION
23 FOR US IN OUR PROGRESS REPORTS IS THIS OUTCOMES
24 SECTION. SO IN ADDITION TO THE INFORMATION THAT I
25 SPOKE TO YOU ABOUT, WHICH IS REQUIRED BY OUR

BARRISTERS' REPORTING SERVICE

1 POLICIES, WE'RE ASKING OUR GRANTEES TO HELP US
2 MEASURE OUTCOMES OF OUR CIRM-FUNDED RESEARCH BY
3 PROVIDING ADDITIONAL INFORMATION. AND SO THE
4 ADDITIONAL INFORMATION YOU CAN SEE HERE. IT'S
5 BASICALLY TO REPORT NOTEWORTHY OUTCOMES THAT HAVE
6 COME FROM THE PROJECT LIKE FILING AN IND OR
7 GENERATING A NEW STEM CELL LINE.

8 THIS INFORMATION IS ALSO GOING TO BE
9 HELPFUL FOR US IN THE FUTURE TO CODE GRANTS. AND
10 AMY ADAMS WILL SHOW YOU IN HER PRESENTATION THAT
11 THAT CODING ACTUALLY CAN BE USED TO ORGANIZE AND
12 FILTER GRANTS ON OUR WEB SITE.

13 FINALLY, WE ASK OUR GRANTEES WHERE THEY'RE
14 DOING THEIR WORK. WE'D LIKE TO KNOW IF THEY'RE
15 WORKING IN THE CIRM-SHARED LABS AND MAJOR
16 FACILITIES. WE ALSO ASK THEM FOR SOME DETAIL ON USE
17 OF HUMAN PLURIPOTENT STEM CELL LINES. SO THE GREAT
18 PART ABOUT THIS PROGRESS REPORT IS ONCE A GRANTEE IS
19 DONE, THEY JUST CLICK DONE WITH PROGRESS REPORT,
20 IT'S SUBMITTED TO US, THEY ALSO HAVE A RECORD OF
21 WHAT THEY'VE SUBMITTED IN THEIR PORTFOLIO. THEY
22 DON'T HAVE TO GO BACK AND SEARCH THEIR RECORDS TO
23 SEE WHAT THEY'VE SUBMITTED. WE THINK IT REALLY
24 STREAMLINES THE PROCESS. WE'VE GOTTEN GREAT
25 FEEDBACK FROM GRANTEES.

BARRISTERS' REPORTING SERVICE

1 WE'VE RECEIVED OVER A HUNDRED PROGRESS
2 REPORTS THROUGH THIS ONLINE SUBMISSION. WE'VE HAD
3 ZERO PHONE CALLS FROM GRANTEES ASKING HOW TO USE THE
4 SYSTEM, WHICH WE THOUGHT WAS REALLY A GOOD SIGN.

5 (APPLAUSE.)

6 MS. LEWIS: SO THIS IS JUST A QUICK LITTLE
7 PEEK INTO OUR CUSTOM SYSTEM, JUST ONE PIECE OF IT.
8 AND I LOOK FORWARD, HOPEFULLY IN THE FUTURE, OF
9 SHOWING YOU MORE OF THE FUNCTIONALITY THAT WE'RE
10 BUILDING. SO AMY ADAMS IS GOING TO TALK TO YOU NEXT
11 ABOUT HOW THE DATA THAT WE'RE TAKING IN IN THE
12 SYSTEM IS GOING TO BE DISPLAYED TO THE PUBLIC. AND
13 THEN IF YOU HAVE ANY QUESTIONS, I'LL BE HAPPY TO
14 ANSWER THEM AFTERWARDS.

15 CHAIRMAN KLEIN: I'D LIKE TO RECOGNIZE
16 THAT AMY LEWIS HAS BEEN COMMITTED TO THIS MISSION
17 FOR SEVEN YEARS, SINCE 2003. SO I THINK WE SHOULD
18 GIVE HER A GREAT ROUND OF APPLAUSE.

19 (APPLAUSE.)

20 MS. ADAMS: SO AMY LEWIS TALKED TO YOU
21 ABOUT HOW WE GET DATA INTO THE SYSTEM, AND WHAT I'M
22 GOING TO SHOW YOU IS HOW WE'RE TRYING TO DISPLAY
23 SOME OF THAT DATA TO OUR CONSTITUENTS, SO THE
24 PATIENTS, THE FAMILIES, THE TAXPAYERS, THE
25 LEGISLATORS, WHO WANT TO KNOW WHAT WE'RE FUNDING.

BARRISTERS' REPORTING SERVICE

1 SO THE IMPORTANT THING I WANT YOU TO
2 NOTICE HERE IS HERE'S THE WEB SITE, AND HERE ARE THE
3 TWO PLACES WE GET DATA INTO THE WEB SITE, AND THEY
4 BOTH INVOLVE A MANUAL STEP.

5 I'LL COME BACK TO THAT. RIGHT NOW I AM
6 THAT MANUAL STEP, AND IT'S BEEN LIMITING IN TERMS OF
7 WHAT WE PULL IN ACCURATELY.

8 NOW I WANT TO GO -- SO WE'VE BEEN
9 COLLECTING A LOT OF DATA AS AMY SHOWED YOU. AND DON
10 GIBBONS AND I HAVE BEEN VERY EAGER TO START TELLING
11 THE PUBLIC MORE ABOUT WHAT THIS DATA SAYS, WHAT
12 WE'RE FUNDING. THE FIRST STEP OF THIS CAME A COUPLE
13 MONTHS AGO WHEN WE RELEASED 18 DISEASE PAGES ONTO
14 THE WEB SITE, AND SEVERAL MEMBERS OF THE BOARD WERE
15 VERY INSTRUMENTAL IN MAKING SURE THOSE WERE ACCURATE
16 AND PRETTY DETAILED. THAT'S NICE. WE'RE TALKING
17 ABOUT HOW STEM CELL RESEARCH COULD IMPROVE THOSE
18 DISEASES, BUT IT DOESN'T QUITE SAY WHAT WE'RE REALLY
19 FUNDING.

20 SO WHAT I'M GOING TO PREVIEW FOR YOU HERE,
21 THIS IS ACTUALLY A NEW FEATURE. YOU'RE LOOKING AT
22 THE DEMO SITE RIGHT NOW, BUT IT SHOULD BE LIVE ON
23 OUR REAL SITE LATER TODAY. FOR ANYONE WHO'S
24 LISTENING IN ON THE AUDIOCAST, THE PAGE YOU'RE
25 LOOKING AT YOU'LL BE ABLE TO SEE LATER TODAY. EVERY

BARRISTERS' REPORTING SERVICE

1 PAGE OF OUR SITE HAS A BLUE BUTTON AT THE BOTTOM
2 RIGHT THAT SAYS "SEARCH CIRM GRANTS." IF YOU CLICK
3 ON THAT, YOU WILL BE ABLE TO SEE WHAT I'M TALKING
4 ABOUT RIGHT NOW.

5 SO WE'VE -- WHAT THIS PAGE SHOWS IS A
6 COMPLETE LIST OF ALL AWARDS GIVEN OUT BY CIRM. THIS
7 LIST EXISTS ON OUR CURRENT SITE. CURRENTLY ALL YOU
8 CAN DO, THOUGH, IS SORT THAT BY DIFFERENT
9 INSTITUTIONS YOU MIGHT BE INTERESTED IN OR BY THE
10 DIFFERENT ROUNDS OF FUNDING. WHAT WE'RE NOW ABLE TO
11 PROVIDE TO PEOPLE IS THE ABILITY TO SORT BY THE
12 DISEASE FOCUSED ON IN THAT AWARD, BY THE TYPE OF
13 STEM CELL LINE BEING USED IN THAT AWARD, STEM CELL
14 LINES BEING GENERATED IN THE AWARD, AND WHETHER OR
15 NOT THEY HAVE COLLABORATIVE FUNDERS.

16 LET'S JUST LOOK AT THIS. WHEN YOU CLICK
17 ON THE DISEASE FOCUSED, YOU SEE A LONG LIST OF
18 DISEASES. I WANT TO SAY HERE THIS LOOKS PRETTY
19 STRAIGHTFORWARD. IT'S A LIST OF DISEASES, BUT THAT
20 DIDN'T ARISE OUT OF NOWHERE. IT WAS DR. KELLY
21 SHEPHERD IN OUR SCIENCE OFFICE WHO REALLY LED THE
22 EFFORT TO DEVELOP A CODING MECHANISM THAT WE COULD
23 USE TO CODE OUR GRANTS AND THEN DEVELOPED THE
24 MECHANISM BY WHICH THEY WOULD DO THE CODING AND
25 WORKED WITH THE SCIENCE OFFICERS TO MAKE SURE THAT

BARRISTERS' REPORTING SERVICE

1 WE'RE CODING THINGS ACCURATELY. SO IT LOOKS PRETTY
2 STRAIGHTFORWARD. IT REPRESENTS A LOT OF TIME ON THE
3 PART OF DR. KELLY SHEPHERD.

4 LET'S SAY I AM SOMEONE WHO VOTED FOR
5 PROPOSITION 71 BECAUSE I CARE ABOUT PARKINSON'S
6 DISEASE. LET'S SEE WHAT WE FIND. WE SELECT
7 PARKINSON'S DISEASE, HIT APPLY, AND IT TAKES A
8 SECOND, AND HERE YOU SEE A LIST OF ALL OF THE AWARDS
9 WE FUNDED THAT APPLY TO PARKINSON'S DISEASE.
10 THERE'S A RANGE FROM THE REALLY BASIC SCIENCE TO THE
11 EARLY TRANSLATIONAL AWARDS. THE DIFFERENT FILTER
12 CATEGORIES ALLOW YOU TO CONTINUE FILTERING.

13 SO LET'S SAY I CARE DEEPLY ABOUT EMBRYONIC
14 STEM CELLS. HOW MANY OF THESE PARKINSONS' AWARDS
15 USE EMBRYONIC STEM CELLS? LOOKS LIKE MOST OF THEM
16 DO, BUT YOU CAN CONTINUE FILTERING. YOU COULD LOOK
17 AT WHO'S USING IPS, WHO'S GENERATING IPS, WHETHER
18 THEY HAVE INTERNATIONAL COLLABORATORS.

19 I THINK THIS IS GOING TO BE A VERY
20 VALUABLE WAY OF ALLOWING THE PUBLIC TO UNDERSTAND
21 MORE ABOUT WHAT WE'RE FUNDING.

22 ONE THING I WANT TO SAY -- ACTUALLY LET ME
23 SHOW YOU WHAT WE DISPLAY ABOUT THOSE AWARDS. SO IF
24 YOU CLICK ON THE TITLE OF THE GRANT, WHAT YOU SEE IS
25 INFORMATION ABOUT THAT AWARD. SO YOU SEE THE TITLE,

BARRISTERS' REPORTING SERVICE

1 WHAT KIND OF AWARD IT IS, WHO THE AWARD WENT TO.
2 AND THEN THE PUBLIC ABSTRACT AND STATEMENT OF
3 BENEFIT, THESE COME IN WITH THE APPLICATIONS.
4 THAT'S GREAT. WE'RE TELLING THE PUBLIC WHAT THESE
5 PEOPLE SAID THEY WERE GOING TO DO. WHAT WOULD BE
6 BETTER IS IF WE CAN TELL THE PUBLIC WHAT THEY'VE
7 ACTUALLY DONE WITH OUR MONEY.

8 AND THAT'S WHERE AMY'S TALK COMES IN. NOW
9 THAT WE'RE COLLECTING DATA IN AN AUTOMATED MANNER
10 AND ABLE TO GET THE PROGRESS REPORTING, THE
11 PUBLICATIONS, AND OTHER OUTCOMES OF THESE AWARDS,
12 WE'RE GOING TO BE ABLE TO SET IT UP SO THAT THERE IS
13 NO HUMAN INVOLVED. WE CAN HAVE THE WEB SITE TALK
14 DIRECTLY WITH THE DATABASE AND START PULLING THAT
15 INFORMATION IN.

16 AND ONCE WE DO THAT, WE WILL BE ABLE TO
17 ALSO PROVIDE REAL-TIME DATA. RIGHT NOW, BECAUSE
18 THERE IS THE HUMAN STEP AND A LOT OF DATA CLEANUP
19 AND SIGNIFICANT POSSIBLE HUMAN ERROR, WE ARE ONLY
20 GOING TO BE UPDATING THIS CHART PROBABLY AFTER EVERY
21 TIME THE BOARD VOTES ON A ROUND OF FUNDING. WE
22 WON'T DO IT MORE OFTEN THAN THAT. ONCE WE HAVE THIS
23 MASTER DATABASE SET UP, WE CAN DO IT IN REAL-TIME,
24 WHICH I THINK WILL BE A REALLY NICE WAY OF SHOWING
25 THE PUBLIC WHAT WE'RE FUNDING.

BARRISTERS' REPORTING SERVICE

1 CHAIRMAN KLEIN: SO, AMY, I THINK THIS IS
2 EXTREMELY HELPFUL, AND I'D ALSO LIKE TO CALL THE
3 BOARD'S ATTENTION THAT AS WE GO INTO THIS PERIOD
4 WHERE WE'RE HAVING RETIRING BOARD MEMBERS, IT'S
5 CRITICAL THAT PEOPLE WHO WOULD WANT TO APPLY TO BE
6 BOARD MEMBERS AND THE PUBLIC REALLY UNDERSTAND WHAT
7 THE BOARD DOES. UNTIL ABOUT EIGHT WEEKS AGO, THERE
8 WERE ONLY FOUR PARAGRAPHS ON THE ENTIRE WEB SITE
9 ABOUT WHAT THE BOARD DID. AMY HAS BEEN WORKING WITH
10 US AND HAS DEVELOPED KIND OF A STAGE-ONE BROADER
11 DESCRIPTION OF WHAT THE GOVERNING BOARD DOES. AND
12 WE'RE GOING TO BE WORKING WITH HER BETWEEN NOW AND
13 THE END OF THE YEAR ON DEVELOPING PROFILES OF ALL
14 THE RETIRING MEMBERS OF THE BOARD OF WHAT THEY HAVE
15 DONE. SO SOMEONE LOOKING AT PROSPECTIVE SERVICE ON
16 THIS BOARD CAN SEE WHAT THEY COULD ACCOMPLISH, THE
17 KINDS OF CONTRIBUTIONS THAT ARE BEING MADE.

18 SINCE NONE OF THE PATIENT ADVOCATE TERMS
19 ARE UP, WE'RE GOING TO HAVE TO ALSO START DOING SOME
20 PATIENT ADVOCATE PROFILES BECAUSE FROM TIME TO TIME
21 PATIENT ADVOCATES RETIRE EVEN THOUGH THEIR TERMS ARE
22 NOT UP. IT'S IMPORTANT THAT THE PUBLIC REALLY
23 UNDERSTAND, HAVE SOME INSIGHT ABOUT THE
24 CONTRIBUTIONS THAT ARE MADE, THE IMPACT ON DISEASES
25 THAT ARE MADE SO PROSPECTIVE APPLICANTS CAN SEE WHY

BARRISTERS' REPORTING SERVICE

1 IT'S IMPORTANT TO COMMIT THE KIND OF QUALITY TIME
2 THAT'S NECESSARY TO SERVE ON THE BOARD.

3 SO I REALLY THINK WE SHOULD THANK AMY
4 ADAMS. THIS IS VERY HELPFUL TO US AS WE GO THROUGH
5 THIS PROCESS OF REBUILDING THE BOARD AND EDUCATING
6 THE PUBLIC.

7 MS. LANSING: I DON'T WANT TO COMMENT TILL
8 YOU ARE DONE WITH YOUR REPORT. SO DO YOU HAVE MORE
9 TO SAY?

10 MS. ADAMS: I'M DONE.

11 MS. LANSING: I WILL COMMENT. I THINK
12 THAT UPDATING THIS WEB SITE, YOU JUST ARE DOING
13 TERRIFIC WORK, ALL OF YOU. AND THANK YOU FOR
14 EVERYTHING THAT YOU ARE DOING.

15 THIS IS PART OF THIS, AND IT'S A PART OF A
16 BIGGER ISSUE AS WELL. SO LET ME FRAME THIS, AND
17 THEN I'M GOING TO MAKE A SUGGESTION. I THINK THAT
18 THE PUBLIC IS -- THIS IS NO ONE'S FAULT. I JUST
19 WANT TO SAY THIS UP FRONT. THE PUBLIC IS NOT AS
20 AWARE AS THEY SHOULD BE OF THE AMAZING PROGRESS
21 THAT'S BEING MADE. I LIVE IN A LIMITED WORLD. I
22 DON'T LIVE IN A SCIENTIFIC WORLD. BUT I HAVE TO SAY
23 OVER AND OVER AND OVER AGAIN I HEAR, "SO WHAT'S
24 HAPPENING?" DO YOU KNOW? AND THE IDEA THAT A
25 REPORT LIKE THIS MORNING, WHICH I KNOW FOR ALL OF US

BARRISTERS' REPORTING SERVICE

1 AND ALAN'S REPORT JUST MAKES ALL OF US GO WOW. AND
2 THAT HAPPENS AT EVERY MEETING. SO I THINK THAT WE
3 HAVE AN OBLIGATION TO EDUCATE THE PUBLIC IN A VERY,
4 VERY COST-EFFECTIVE WAY.

5 I'M TELLING YOU THAT THIS COSTS NOTHING.
6 I'M TELLING YOU WE COULD DO EVERYTHING WE WANTED TO
7 DO PROBABLY FOR TENS OF THOUSANDS DOLLARS. WE CAN
8 SHOOT, AND WE PROBABLY CAN FIND PRO BONO PEOPLE THAT
9 ARE DEDICATED TO OUR MISSION, FILMMAKERS LITTLE WEB
10 PODS THAT WE CAN PUT ON OUR SITE. AND THOSE WEB
11 PODS ARE SO EFFECTIVE. AND I URGE YOU. YOU CAN
12 LOOK ON THE STAND UP TO CANCER. WE'RE DOING THIS
13 ALL THE TIME, BUT IT REALLY COSTS NOTHING. I'M
14 TELLING YOU HUNDREDS OF DOLLARS TO DO ONE, THOUSANDS
15 OF DOLLARS TO DO A COUPLE OF THEM. AND YOU COULD
16 HAVE, FOR EXAMPLE, A SHORTER VERSION OF WHAT'S GOING
17 ON WITH SOME OF THE DISEASE TEAMS. AND YOU COULD
18 INTERVIEW THE DOCTORS. AND I'M REALLY DOING THIS
19 NOT FOR THE SCIENTIFIC COMMUNITY, WHICH CAN READ AND
20 UNDERSTAND IT, BUT I'M DOING IT FOR PEOPLE LIKE
21 MYSELF THAT WOULD GO, WOW, DO YOU KNOW, FOR THE
22 PUBLIC.

23 AND I THINK IT'S REALLY IMPORTANT THAT
24 THEY HEAR THE DOCTOR TALKING, MAYBE THERE'S A
25 PATIENT, MAYBE THERE'S A VISUAL TO SEE, AND YOU CAN

BARRISTERS' REPORTING SERVICE

1 ALSO INTERVIEW THE PATIENT ADVOCATES, YOU CAN
2 INTERVIEW BOARD MEMBERS. AND ALL OF THIS BECOMES A
3 MUCH MORE INTERACTIVE AND DYNAMIC WAY TO GET THE
4 INFORMATION ACROSS IN ADDITION TO WHAT YOU READ.

5 AND I JUST CAN'T BEGIN TO TELL YOU HOW
6 MANY PEOPLE I THINK ARE OUT THERE, FILMMAKERS THAT
7 WOULD LOVE TO DO THIS PRO BONO. THERE'S FIRMS THAT
8 DO IT PRO BONO. AND EVEN IF WE HAD TO PAY, WE'RE
9 TALKING ABOUT SUCH LITTLE MONEY. YOU'RE TALKING
10 ABOUT A DIGITAL CAMERA. EVERY ONE OF YOU HAS ONE OF
11 THESE FLIP CAMS, AND I'M TELLING YOU YOU CAN DO IT
12 YOURSELF. IT'S NOT THAT HARD.

13 SO I JUST URGE US. I'M SERIOUS. I
14 CONSTANTLY HAVE PEOPLE DOING IT, AND I SHUDDER TO
15 THINK WHAT IT'S GOING TO DO TO THE FILM INDUSTRY
16 BECAUSE THEY'RE VERY GOOD. I BEG US TO LOOK AT
17 USING VISUALS AND REALLY HAVING THEM. I GUESS
18 YOU'RE GOING TO SHOW ME ONE THAT YOU ALREADY HAVE.

19 MS. ADAMS: I THINK JEFF SHEEHY CAN TELL
20 YOU ABOUT THIS. HE CAN TELL YOU ABOUT THE CUTE
21 LITTLE GIRL IN THIS ONE.

22 SO I TOTALLY AGREE WITH YOU, SHERRY. SO
23 WE -- AND CLEARLY SINCE YOU DON'T KNOW ABOUT THESE,
24 WE NEED TO WORK ON MAKING THEM MORE ACCESSIBLE AND
25 MORE VISIBLE ON THE WEB SITE. WE'VE ACTUALLY BEEN

BARRISTERS' REPORTING SERVICE

1 DOING A SERIES OF VIDEOS ABOUT DIFFERENT DISEASES
2 BEING TARGETED BY CIRM AWARDS. WE'VE KIND OF BEEN
3 FOCUSING ON THE DISEASE TEAMS ALTHOUGH WE'VE DONE
4 SOME OTHER DISEASES AS WELL. AND IN EACH ONE WE
5 FEATURE A PATIENT ADVOCATE AND THEN THE PI, USUALLY
6 THE PI, ON A CIRM AWARD. DR. STEWARD FILMED ONE FOR
7 US RECENTLY. THEY'RE ALL THREE TO FIVE MINUTES
8 LONG. THEY'RE POSTED HERE AND ON YOUTUBE. ACTUALLY
9 ON YOUTUBE WE GET MANY MORE VIEWS ON YOUTUBE THAN ON
10 OUR WEB SITE. IT'S FANTASTIC.

11 WE'VE HAD, LAST I LOOKED, ABOUT 83,000
12 VIEWS TO OUR VIDEOS ON YOUTUBE. I DON'T KNOW IF
13 YOU'VE SEEN THIS, BUT YOUTUBE PROVIDES REALLY
14 ASTOUNDING INFORMATION ABOUT WHO IS WATCHING YOUR
15 VIDEOS AND HOW ATTENTIVE THEY ARE. AND ALL BUT, I
16 THINK, TWO OR THREE OF OUR VIDEOS HAVE SIGNIFICANTLY
17 ABOVE AVERAGE VIEWER RATINGS AND IN-VIEWER ATTENTION
18 STATISTICS, WHICH I THINK EXACTLY MAKES YOUR POINT,
19 THAT PEOPLE REALLY CARE ABOUT THIS.

20 MS. LANSING: THEN I APOLOGIZE FOR NOT
21 KNOWING.

22 MS. ADAMS: THAT'S FINE. IT MEANS THAT I
23 HAVEN'T DONE MY JOB AND MADE IT VISIBLE.

24 MS. LANSING: THEN I WILL SAY THIS TO ALL
25 OF THE PATIENT ADVOCATES AND BOARD MEMBERS. WHEN

BARRISTERS' REPORTING SERVICE

1 YOU HAVE THESE VIDEOS, IT'S SO EASY FOR US TO SHOOT
2 AN E-MAIL OUT TO OUR BASE TO JUST SAY THERE'S A
3 WONDERFUL VIDEO. JUST LIKE YOU SAID, THERE'S A
4 WONDERFUL THING ON *HUFFINGTON POST*. I'M JUST
5 SUGGESTING THAT WE HAVE A VERY COORDINATED EFFORT
6 BECAUSE NOW -- BEFORE WE WERE A DREAM, WE ADVOCATED
7 FOR THAT DREAM, AND IT WAS PATIENT ADVOCATES AND
8 SCIENTISTS AND THE CITIZENS THAT GOT THIS
9 PROPOSITION PASSED. SO NOW WE NEED TO HAVE A
10 COORDINATED EFFORT ON BEHALF OF ALL OF US, ON BEHALF
11 OF ALL OF OUR ACTIVIST GROUPS TO MAKE SURE THAT
12 THESE ARE SEEN AND READ. BUT SEEN IS TO ME WHERE
13 THE EMOTIONAL THING IS REALLY THERE.

14 MR. SHEEHY: JUST TO -- I ALSO WANT TO
15 REMARK THAT WE KEEP THE, WHICH ARE JUST AS VALUABLE,
16 THE SPOTLIGHTS. AND SO THE ZAIA SPOTLIGHT IS THE
17 REASON WHY WE HAVE ALL THESE AIDS ACTIVISTS, WHICH
18 I'VE DISTRIBUTED, AND THEY WATCHED THAT AND THEN
19 THEY READ THE WHOLE CANNON PAPER. THAT'S WHY
20 THEY'RE LIKE, OKAY. LET'S GET OUR CLINICAL TRIAL.
21 LET'S GO TO THE FDA. WHERE IS CIRM? LET'S GET
22 GOING. AND THE GREAT VIDEO THEY DID.

23 ACTUALLY, YOU KNOW, AT LEAST I HAVE, I'VE
24 BEEN GETTING IT OUT THERE. AND A LOT OF PEOPLE HAVE
25 STOPPED SAYING WHAT'S CIRM.

BARRISTERS' REPORTING SERVICE

1 MS. LANSING: I APOLOGIZE BECAUSE I
2 HAVEN'T BEEN.

3 CHAIRMAN KLEIN: SHERRY, YOUR FUNDAMENTAL
4 POINT IS ABSOLUTELY RIGHT. EVERY MEMBER OF THIS
5 BOARD GETS THE QUESTION WHAT ARE YOU ARE DOING. WE
6 REALLY, FOR ACCOUNTABILITY AND REPORTING TO THE
7 PUBLIC, HAVE A COMPLETELY DIFFERENT LEVEL OF
8 OUTREACH WE NEED. WHEN YOU REALIZE THAT IN THE LAST
9 TEN DAYS BEFORE THE ELECTION, THERE WERE THREE
10 MILLION AFFINITY GROUP E-MAILS. THE POTENTIAL IS
11 THERE, THE INTEREST IS THERE. WE HAVE AN OBLIGATION
12 TO REPORT ON A DIFFERENT SCALE TO THE PUBLIC, AND
13 IT'S VERY IMPORTANT WE REPORT BECAUSE THERE'S AN
14 OPPOSITION THAT IS TRYING TO MISLEAD THE PUBLIC
15 ABOUT SOME OF THESE CELLULAR THERAPIES. AND THERE
16 IS, IN FACT, ANOTHER GROUP THAT'S TRYING TO SELL
17 OFFSHORE THERAPIES THAT ARE NOT PROPERLY VALIDATED
18 AND APPROVED.

19 SO IT HELPS THE PUBLIC KNOW STUDY PROGRESS
20 IS BEING MADE TO PROPERLY WAIT FOR FDA-APPROVED
21 THERAPIES. WE HAVE A NUMBER OF LEVELS OF
22 RESPONSIBILITY HERE, AND YOU'RE RIGHT. THE
23 SUBCOMMITTEE ON COMMUNICATION HAS BEEN DEFERRED
24 UNTIL THE SCIENTIFIC SUBCOMMITTEE CAN HAVE ITS
25 MEETINGS. IT NOW NEEDS TO MEET, BUT CERTAINLY WE'VE

BARRISTERS' REPORTING SERVICE

1 MADE SOME SUBSTANTIAL PROGRESS.

2 MS. LANSING: THANK YOU. I JUST THINK
3 THIS IS PART OF OUR MISSION. AND I THINK THAT IF
4 OUR SUBCOMMITTEE ON COMMUNICATIONS MEETS OR EVEN IF
5 WE HAD A RETREAT OF THE WHOLE BOARD TO REALLY FIGURE
6 OUT, AFTER THE SUBCOMMITTEE, WHAT WE COULD DO.

7 JEFF, YOU'VE BEEN DOING IT. I GUESS FOR THE REST US
8 WE HAVEN'T EITHER THE TOOLS OR HAVEN'T BEEN CALLED
9 ON OR DIDN'T KNOW HOW TO DO IT.

10 CHAIRMAN KLEIN: IN TERMS OF REPORTING,
11 MELISSA HAS HAD SOME INTERNS WHICH VOLUNTEERED THEIR
12 TIME ALL SUMMER TO BUILD THE LIST OF THE PATIENT
13 ADVOCACY ORGANIZATIONS AND PATIENT SUPPORT GROUPS SO
14 THAT WE WOULD KNOW THE NETWORK THAT NEEDS THIS
15 INFORMATION SO WE COULD, IN FACT, CREATE AN
16 EFFECTIVE DISTRIBUTION MECHANISM. SO THIS IS
17 SOMETHING THAT IS IN PROGRESS, OVERDUE, BUT IT'S A
18 VERY HIGH PRIORITY.

19 MS. LANSING: I'LL END WITH ONE SENTENCE.
20 EVERY CITIZEN IS A PATIENT ADVOCATE WHETHER THEY
21 IDENTIFY THEMSELVES AS ONE OR NOT BECAUSE EVERYBODY
22 HAS BEEN TOUCHED BY ONE OF THE DISEASES THAT WE
23 REPRESENT. I THINK DON REED IN HIS BLOG WAS VERY
24 ELOQUENT IN MAKING THAT CLEAR. SO I'M VERY EXCITED
25 TO HELP IN ANY WAY I CAN.

BARRISTERS' REPORTING SERVICE

1 CHAIRMAN KLEIN: MELISSA, COULD WE GET
2 FROM THE TRANSCRIPT WHAT SHERRY JUST SAID, EVERY
3 CITIZEN IS A PATIENT ADVOCATE BECAUSE EVERYONE HAS
4 BEEN TOUCHED BY A DISEASE THAT OUR THERAPIES CAN
5 TREAT. LET'S PUT THAT ON OUR WEB SITE, ON THE BOARD
6 PORTION OF THE WEB SITE. AND, DON, YOU HAVE SOME
7 COMMENTS.

8 MR. GIBBONS: CAN I JUST TAKE ONE SECOND
9 TO LET YOU KNOW WHAT'S COMING YOUR WAY. THE TIMING
10 OF THIS IS GREAT. WE, AMY AND I, WANTED TO BUILD A
11 ROBUST CONTENT THAT ANY PATIENT ADVOCATE COULD SAY
12 THERE'S SOMETHING HERE FOR ME BECAUSE YOU HAD TO BE
13 VERY DISEASE SPECIFIC BECAUSE PEOPLE CARE ABOUT
14 THEIR DISEASE AND THEIR LOVED ONE. UNTIL WE COULD
15 DO THIS SORT, WE WEREN'T READY FOR A BIG ROLLOUT.
16 WE ARE NOW ABSOLUTELY READY AND NEED A BIG ROLLOUT.

17 I MENTIONED TO YOU BACK IN FEBRUARY THAT I
18 WAS DOING A BOARD SLIDE DECK. WE'RE WAITING FOR THE
19 FINAL ECONOMIC IMPACT DATA TO COME IN. WE FINALLY
20 HAVE THAT. SO EACH BOARD MEMBER WILL BE GETTING A
21 JUMP DRIVE WITH AN INDIVIDUALIZED SLIDE DECK THAT
22 HAS SLIDES PERTAINING TO YOUR DISEASE OF INTEREST,
23 YOUR REGION IN TERMS OF THE GRANTS IN YOUR LOCAL
24 AREA, AND LINKS TO VIDEOS THAT WE'VE DONE ABOUT
25 THAT. SO IT WILL MAKE IT MUCH EASIER FOR YOU TO DO

BARRISTERS' REPORTING SERVICE

1 YOUR JOB OF BEING ADVOCATES FOR US.

2 MS. LANSING: HELP US, AS YOU DO, IN
3 SAYING, OKAY, SEND THIS, IF YOU WISH -- WE'RE NOT
4 GOING TO FORCE ANYONE -- TO THIS GROUP AND HERE'S
5 HOW YOU DO IT.

6 MR. GIBBONS: PERFECT. SO EACH OF YOU
7 WILL BE GETTING A JUMP DRIVE. WE ALSO ARE ABOUT TO
8 HIRE A PATIENT ADVOCATE COORDINATOR THAT WILL BE
9 GOING OUT TO THESE DISEASE GROUPS, SHOWING THEM WHAT
10 WE HAVE FOR THEM THAT IS PERSONALIZED, IS ABOUT
11 THEIR CONDITION, AND GETTING THEM ACTIVATED TO GET
12 SOME OF THIS STUFF GOING MORE VIRAL AND GET THESE
13 EXCELLENT VIDEOS THAT WE'RE MAKING MORE WIDELY SEEN
14 AND USED.

15 MS. LANSING: CONGRATULATIONS.

16 CHAIRMAN KLEIN: DON, IT'S VERY IMPORTANT
17 TO BRING THAT TO THE CHAIR'S EXECUTIVE COMMITTEE SO
18 WE GET SOME INPUT FROM PEOPLE LIKE ART WHO HAVE
19 TREMENDOUS INSIGHT IN COMMUNICATIONS, PUBLIC
20 COMMUNICATIONS, AND WE CAN MAKE SURE WE'RE GETTING
21 ACROSS THE THINGS THAT THE PUBLIC IS GOING TO FIND
22 MOST IMPORTANT. SO WHEN WE SEND IT OUT TO THE
23 BOARD, WE WANT TO MAKE SURE THAT WE'VE GONE THROUGH
24 THAT REFINEMENT.

25 MR. GIBBONS: I HAVE BEEN COORDINATING

BARRISTERS' REPORTING SERVICE

1 WITH ART THROUGH THIS ENTIRE PROCESS.

2 CHAIRMAN KLEIN: THE CHAIR'S EXECUTIVE
3 COMMITTEE, LET'S JUST SCHEDULE THAT REVIEW.

4 MR. GIBBONS: SURE.

5 MS. ADAMS: CAN I MAKE ONE RESPONSE TO
6 SHERRY? I JUST WANT TO SAY I WOULD BE HAPPY TO PUT
7 TOGETHER A LIST OF THE RESOURCES WE HAVE ON THE WEB
8 SITE IN TERMS OF WHAT VIDEOS WE HAVE AND WHAT
9 FEATURE STORIES WE HAVE ON THE SITE. AND MAYBE
10 MELISSA CAN MAIL IT TO THE BOARD. AND THAT WAY YOU
11 AT LEAST HAVE THAT LIST AT YOUR DISPOSAL.

12 MS. LANSING: GREAT. THANK YOU VERY, VERY
13 MUCH.

14 DR. STEWARD: ACTUALLY THIS IS GOING BACK
15 TO THE EARLIER ONE. AND MAYBE I WON'T START THIS
16 UNTIL YOU ARE FINISHED TALKING ABOUT THE PUBLIC
17 OUTREACH.

18 CHAIRMAN KLEIN: YOU WANT TO GO BACK TO
19 AMY'S PRESENTATION?

20 DR. STEWARD: YEAH. I REALLY HATE TO DO
21 THIS BECAUSE THIS HAS BEEN A WONDERFUL AND REALLY
22 EXCITING, FUN DISCUSSION. WHAT I'M ABOUT TO SAY IS
23 NOT FUN, AND I GUESS I'D JUST LIKE TO MAYBE ASK FOR
24 A REPORT ON THIS LATER ON.

25 I GUESS I RECENTLY RECEIVED A SOMEWHAT

BARRISTERS' REPORTING SERVICE

1 PAINFUL EDUCATION ABOUT NIH'S NEW POLICIES ON I.T.
2 SECURITY. AND IT REALLY IS QUITE REMARKABLE THE
3 DEGREE TO WHICH THEY'RE RAMPING UP THEIR SECURITY
4 REQUIREMENTS. I GUESS AT SOME POINT I'D REALLY LIKE
5 TO HEAR A REPORT ON I.T. SECURITY ON THE AGENCY.
6 THERE'S A LOT OF DATA THERE THAT WOULD BE SENSITIVE
7 IN MANY, MANY WAYS.

8 CHAIRMAN KLEIN: DR. STEWARD, LET'S BOOK
9 THAT AS A REPORT. WE'VE GOT AN HOUR. WE'VE GOT
10 SOME CRITICAL ISSUES. WE WANT TO MAKE SURE WE
11 MAINTAIN THE ITEMS. AND LET'S GIVE A ROUND OF
12 APPLAUSE TO BOTH PRESENTERS.

13 (APPLAUSE.)

14 CHAIRMAN KLEIN: SO WHAT I'D LIKE TO DO
15 HERE IS GO TO ITEM NO. 12, IF WE COULD, PLEASE.
16 AND, JAMES HARRISON, COULD YOU DISCUSS THE CONFLICTS
17 ISSUES RELATED TO -- ITEM 11 IS THE ITEM I WANT TO
18 GO TO. WOULD YOU DISCUSS THE CONFLICTS ISSUES AND
19 HOW WE'RE TREATING POLICY DISCUSSIONS AS SEPARATE
20 FROM A MOTION THAT WOULD IMPLEMENT THIS ITEM?

21 MR. HARRISON: YES. THERE ARE IN A SENSE
22 TWO SEPARATE QUESTIONS ADDRESSED BY THIS ITEM. ONE
23 IS WHETHER, AS A POLICY MATTER, THE BOARD WOULD LIKE
24 TO AFFIRM IN A SPECIFIC CASE OF THE DISEASE TEAM
25 AWARDS THE EXISTING GRANTS MANAGEMENT POLICY WHICH

BARRISTERS' REPORTING SERVICE

1 PERMITS A CHANGE IN SCOPE OF A GRANT AWARD. IN THIS
2 PARTICULAR CASE, THE CHANGE IN SCOPE WOULD BE TO
3 PERMIT A GRANTEE TO USE UNUSED DISEASE TEAM AWARD
4 FUNDS FOR A CLINICAL TRIAL IF THE GRANTEE WAS ABLE
5 TO REACH AN IND AT AN AMOUNT LESS THAN THE GRANT
6 AWARD.

7 THE SECOND ISSUE IS ONCE THAT POLICY IS
8 APPROVED, WHAT IS THE MECHANISM FOR ACCOMPLISHING
9 THAT. AS I REFERENCE, WE HAVE AN EXISTING GRANTS
10 MANAGEMENT POLICY WHICH PERMITS THE PRESIDENT TO
11 APPROVE A CHANGE IN SCOPE OF A GRANT AWARD, BUT AT
12 THE SCIENCE SUBCOMMITTEE MEETING, MEMBERS EXPRESSED
13 AN INTEREST, GIVEN THE SIGNIFICANCE OF MOVING
14 FORWARD WITH A CLINICAL TRIAL, OF HAVING THE MATTER
15 BROUGHT BACK TO THE BOARD ON AN INDIVIDUAL BASIS TO
16 APPROVE THE USE OF THOSE FUNDS FOR A PARTICULAR
17 AWARD IN A CLINICAL TRIAL.

18 CHAIRMAN KLEIN: SO PROCEDURALLY HERE WHAT
19 WE'RE GOING TO DO IS DR. OLSON; IS THAT CORRECT, DR.
20 TROUNSON, IS GOING TO MAKE A PRESENTATION?

21 DR. TROUNSON: DR. OLSON IS.

22 CHAIRMAN KLEIN: AND THEN WHAT WE'RE GOING
23 TO DO IS HAVE A GENERAL DISCUSSION OF THIS ITEM.
24 THEN THERE'S TO BE A MOTION. ONCE THAT MOTION IS
25 MADE IN TERMS OF -- THIS IS THE INTEGRATED APPROACH,

BARRISTERS' REPORTING SERVICE

1 JAMES. I SEE HIS CONSTERNATION AT AN INTEGRATED
2 APPROACH. LET'S HAVE A GENERAL POLICY DISCUSSION.
3 THE WAY I WAS APPROACHING THIS, JAMES, IS THEN IF
4 THERE'S A SPECIFIC MOTION THAT WOULD AFFECT THIS
5 DISEASE TEAM ROUND, THERE ARE NONE OF THOSE
6 INSTITUTIONS THAT WERE PARTICIPANTS DIRECTLY OR
7 INDIRECTLY IN THIS DISEASE TEAM ROUND WOULD THEN
8 PARTICIPATE IN THE DISCUSSION OF THAT MOTION. IS
9 THAT APPROACH ACCEPTABLE?

10 MR. HARRISON: THAT APPROACH IS
11 ACCEPTABLE. STANDARDS AND THE CONSIDERATION OF
12 STANDARDS ARE TREATED DIFFERENTLY THAN THE
13 DISCUSSION OF ACTUAL AWARDS OR AWARD PROGRAMS.

14 CHAIRMAN KLEIN: FINE. SO INSTEAD OF
15 DESCRIBING THIS AS INTEGRATED, LET'S CALL IT
16 BIFURCATED. DR. OLSON.

17 DR. OLSON: MR. CHAIRMAN, MEMBERS OF THE
18 BOARD, MEMBERS OF THE AUDIENCE, AND STAFF, I WOULD
19 LIKE TO DISCUSS TODAY THE DISEASE TEAM I AWARDS AND
20 ACTIVITY EXPANSION OPPORTUNITY. WHAT I WOULD LIKE
21 FIRST TO DO IS PROVIDE A BIT OF BACKGROUND TO THIS
22 PROGRAM. AND THE BOARD AND ALSO THE SCIENCE
23 SUBCOMMITTEE OF THE BOARD HAS ASKED STAFF TO ADDRESS
24 HOW DISEASE TEAM I PROJECTS THAT FILE A COMPLETE IND
25 AHEAD OF SCHEDULE AND WITHIN THE FOUR-YEAR TERM OF

BARRISTERS' REPORTING SERVICE

1 THE PERIOD AND THAT HAVE UNSPENT CIRM FUNDS, WOULD
2 STAFF -- HOW WOULD STAFF ENABLE THE USE OF THOSE
3 UNSPENT FUNDS FOR POST-IND ACTIVITIES, INCLUDING
4 CLINICAL TRIALS?

5 SO LET ME JUST REMIND YOU THAT THE DISEASE
6 TEAM I RESEARCH AWARDS, THE SCOPE OF FUNDABLE
7 ACTIVITIES AS DEFINED IN THE RFA INCLUDED THOSE TO
8 FILE A COMPLETE IND WITHIN THE FOUR-YEAR PERIOD.

9 SO WHAT WE WOULD -- IF I HAVE THE NEXT
10 SLIDE. WHAT WE WOULD SUGGEST IS THAT WE WOULD
11 UTILIZE APPROVED PROCESSES THAT WE ALREADY HAVE TO
12 ENABLE THIS. SO ONE OF THOSE IS THE PRIOR APPROVAL
13 REQUEST OR SHORTENED HERE TO PAR. THIS IS THE --
14 IT'S PART OF THE RULES THAT WERE ADOPTED BY THE
15 BOARD THAT SAY THAT SIGNIFICANT CHANGES TO A
16 BOARD-APPROVED PROJECT REQUIRE CIRM APPROVAL. AND
17 THESE CAN BE FINANCIAL CHANGES, IN WHICH CASE
18 TYPICALLY THE GRANTS MANAGEMENT OFFICE ADDRESSES
19 THEM, SOMETIMES WITH INPUT FROM THE SCIENCE OFFICE
20 IF THEY HAVE A SCIENTIFIC IMPACT, AND THEY CAN
21 INCLUDE SCIENTIFIC CHANGES BECAUSE I THINK, AS WE
22 ALL KNOW, SCIENCE CHANGES AS IT GOES ALONG, AND
23 SCIENTISTS WANT TO BE ABLE TO RESPOND TO THAT. SO
24 IF THE CHANGE IS WITHIN THE GOAL OF THE RFA AND THE
25 GOAL OF CIRM'S MISSION, THAT'S SOMETHING WE DO. WE

BARRISTERS' REPORTING SERVICE

1 PROCESS HUNDREDS OF THESE EVERY YEAR. WE DEAL WITH
2 THEM.

3 THE OTHER THING THAT WE WOULD LIKE TO
4 SUGGEST IS THAT A PRIOR APPROVAL REQUEST THAT IS
5 INFORMED BY ADVICE FROM AN OVERSIGHT ADVISORY
6 COMMITTEE. YOU MAY RECALL THAT AS PART OF THE
7 CONCEPT PROPOSED FOR DISEASE TEAM I AND IS
8 INCORPORATED INTO THE RFA, THAT FOR THESE DISEASE
9 TEAM RESEARCH AWARDS, BECAUSE OF THE MAGNITUDE OF
10 THE AWARDS, BECAUSE OF THE TYPE OF PROJECTS WE'RE
11 DEALING WITH, WE ARE GOING TO HAVE EXPERT OVERSIGHT
12 ADVISORY COMMITTEES THAT ADVISE THE PRESIDENT AND
13 STAFF AT MAJOR SCIENTIFIC DECISION POINTS ON THE
14 PROJECT. SO, FOR EXAMPLE, IN DISEASE TEAM I, THE
15 GO/NO-GO FOR A DEVELOPMENT CANDIDATE TO MOVE INTO
16 IND-ENABLING DEVELOPMENT.

17 ANOTHER ONE OF THOSE WOULD ACTUALLY BE
18 GO/NO-GO TO ACTUALLY FILE THE IND. THIS IS
19 TYPICALLY WHAT WOULD HAPPEN WHEN YOU'VE COMPLETED
20 YOUR TOXICOLOGY STUDIES. YOU'VE PROBABLY HAD YOUR
21 PRE-IND -- ASSUREDLY YOU'VE HAD YOUR PRE-IND
22 MEETING. YOU HAVE MANUFACTURED YOUR CLINICAL
23 THINGS. YOU'RE PRETTY MUCH READY TO THINK ABOUT
24 FILING THE IND. I WILL REMIND YOU FILING AN IND
25 MEANS YOU ARE REQUESTING PERMISSION OF THE FDA TO GO

BARRISTERS' REPORTING SERVICE

1 TREAT PATIENTS. SO YOU ARE ACTUALLY -- YOU SUBMIT A
2 CLINICAL PROTOCOL, YOU SUBMIT ALL THE PRECLINICAL
3 AND TOXICOLOGY DATA. SO THAT'S ACTUALLY ANOTHER BIG
4 MILESTONE.

5 AND AT THAT POINT THAT'S WHERE WE THINK IT
6 WOULD BE OBVIOUS FOR THE TEAM, BECAUSE THE TEAM
7 WOULD CLEARLY RECOGNIZE BY THAT POINT IF THEY HAD
8 UNEXPENDED FUNDS AVAILABLE, AND THEY COULD PROPOSE
9 AN EXPANDED PROJECT AS PART OF THAT GO/NO-GO FOR IND
10 FILING DECISION.

11 OBVIOUSLY A PART OF THIS IS NOTIFYING THE
12 DISEASE TEAM I GRANTEES THAT THIS PROCESS WOULD BE
13 AVAILABLE TO THEM. AND SO IF WE AGREE ON ALL THIS,
14 THIS IS WHAT WE WOULD DO. WE WOULD NOTIFY THE
15 DISEASE TEAM I GRANTEES THAT WE WOULD ACCEPT A PRIOR
16 APPROVAL REQUEST FROM AWARDEES FOR A CHANGE IN SCOPE
17 TO INCLUDE ADDITIONAL WORK THAT FALLS WITHIN THE
18 SCOPE OF DISEASE TEAM II RFA. SO YOU'VE ALREADY
19 HEARD FROM DR. STEFFEN THAT THE DISEASE TEAM II RFA
20 WOULD INCLUDE ALL THOSE ACTIVITIES, POST-IND
21 ACTIVITIES. SOMETIMES HAVE YOU TO RESPOND TO THE
22 FDA. THE FDA DOESN'T NOT SAY ANYTHING FOR 30 DAYS.
23 IF YOU DON'T HEAR FROM THE FDA IN 30 DAYS, YOU'RE
24 GOOD TO GO, DO WHATEVER THE NEXT ACTIVITIES ARE:
25 START THE CLINICAL SITE CONTRACTS, GO THROUGH IRB

BARRISTERS' REPORTING SERVICE

1 APPROVALS. THERE'S ACTUALLY USUALLY QUITE A BIT OF
2 LEAD-UP WORK TO ACTUALLY INITIATING A TRIAL.

3 SO THOSE ARE THE KINDS OF THINGS THAT THE
4 TEAM WOULD KNOW ABOUT. IF YOU DID HEAR FROM THE
5 FDA, IT'S POSSIBLE YOU MIGHT HAVE GO BACK AND DO
6 ANOTHER STUDY. SO THESE ARE THE KINDS OF ACTIVITIES
7 THAT ONE COULD CONTEMPLATE. AND THAT WOULD BE
8 PRESUMABLY IN THE TEAM'S EXPANDED PROJECT PROPOSAL.

9 SO THAT'S WHAT WE WOULD SUGGEST. AND I
10 THINK, AS WITH ANY OTHER MAJOR EVENT ON PROGRAMS WE
11 HAVE, WE WOULD EXPECT TO UPDATE THE ICOC AS PART OF
12 THE PRESIDENT'S REPORT ON THESE KINDS OF SIGNIFICANT
13 ACTIVITIES. SO IT WOULD BE -- THAT WOULD BE WHAT WE
14 WOULD SUGGEST. SO IF THERE ARE ANY COMMENTS OR
15 QUESTIONS, I WOULD BE HAPPY TO FURTHER DISCUSS.

16 CHAIRMAN KLEIN: THANK YOU. THANK YOU
17 VERY MUCH, DR. OLSON. IN TERMS OF THE ICOC
18 INVOLVEMENT, DR. TROUNSON, I HAD JUST A MOMENT TO
19 SPEAK WITH YOU EARLIER. I THINK THERE IS, JUST AS A
20 POLICY ISSUE AS A MODIFICATION OF THE FINAL STEP,
21 THE THOUGHT WAS THAT IT'S IMPORTANT THAT THE BOARD
22 TAKE RESPONSIBILITY AS WE GO INTO ANY CLINICAL TRIAL
23 AND MAKE CERTAIN THAT BEFORE THAT TRIAL STARTS, THE
24 BOARD HAS AN ABILITY TO SIGN OFF ON IT. SO THAT
25 IT'S BEEN SUGGESTED THAT WHEN THE SCIENTIFIC STAFF,

BARRISTERS' REPORTING SERVICE

1 WHEN THERE'S A REQUEST, THE SCIENTIFIC STAFF WILL
2 COME TO THE BOARD WITH THE REQUEST, THEIR SCIENTIFIC
3 ADVICE ON THAT REQUEST, SO THE BOARD CAN MAKE AN
4 EXPLICIT DECISION TO EFFECTIVELY ENDORSE THAT OR ASK
5 FOR ADDITIONAL STEPS.

6 BUT OUR POLICY IS TO HELP MOVE THESE
7 FORWARD. SO HOPEFULLY IT WOULD BE TO ENDORSE THE
8 SCIENTIFIC ADVICE, INCLUDING THE EFFECTS OF THE
9 ADVISORY COMMITTEE ADVICE; BUT I THINK IT IS
10 IMPORTANT, AS ARTICULATED BY SOME MEMBERS OF THE
11 BOARD PREVIOUSLY, THAT THE BOARD TAKE RESPONSIBILITY
12 WHENEVER WE'RE GOING INTO A CLINICAL TRIAL. AND
13 THAT PROVIDES PROTECTION FOR THE MISSION, THE STAFF,
14 KNOWING THAT WE'RE ALTOGETHER AND WE KNOW WHAT WE'VE
15 UNDERTAKEN. DR. TROUNSON, DOES THAT SEEM
16 ACCEPTABLE?

17 DR. TROUNSON: I HAVEN'T DISCUSSED IT WITH
18 STAFF, BUT IT SEEMS PERFECTLY ACCEPTABLE TO ME,
19 CHAIR.

20 MR. ROTH: CAN WE HAVE A THRESHOLD ON
21 THAT, JUST SOME POINT AT WHICH YOU WOULD BRING
22 THINGS TO THE BOARD AS OPPOSED TO A COUPLE HUNDRED
23 THOUSAND OR WHATEVER IS LEFT OVER? I DON'T THINK WE
24 NEED TO SEE EVERY SPECIFIC CHANGE, BUT SOME MINIMUM
25 THAT IT WOULD COME TO THE BOARD. I THINK, YOU KNOW,

BARRISTERS' REPORTING SERVICE

1 IF IT'S OVER A MILLION DOLLARS --

2 DR. OLSON: YES. I WOULD PICK A MILLION.

3 MR. ROTH: -- IN A \$20 MILLION, THEN I
4 WOULD LIKE TO LOOK. I THINK UNDER THAT IT'S REALLY
5 WITHIN THE POLICY WE ALREADY HAVE. IT'S JUST IT'S
6 REAL MONEY AND MAYBE IT SHOULD COME BACK.

7 CHAIRMAN KLEIN: LET ME ASK THIS QUESTION.
8 THERE'S A LOT OF THE EXPENDITURES BEFORE YOU GET
9 INTO HUMAN SUBJECTS. SO ARE YOU SAYING LESS THAN A
10 MILLION DOLLARS AND YOU'RE NOT STARTING WITH HUMAN
11 SUBJECTS?

12 DR. OLSON: IF I UNDERSTOOD HIM -- I'M
13 SORRY. PERHAPS YOU WOULD EXPLAIN IT.

14 MR. ROTH: I DON'T THINK IT REALLY MATTERS
15 ON THE HUMAN SUBJECT ISSUE. I WOULD JUST SAY IF
16 THERE'S A REDEPLOYMENT OF A MILLION OR MORE, YOU'D
17 FIRST GO THROUGH YOUR SCIENTIFIC REVIEW AND SAY
18 YOU'RE BEHIND IT OR DON'T BRING IT TO US, BUT THEN
19 YOU BRING IT TO US IF IT'S A MILLION JUST FOR
20 CONFIRMATION.

21 CHAIRMAN KLEIN: LET'S GET BOARD INPUT ON
22 THIS BECAUSE THERE ARE SOME BOARD MEMBERS I'M AWARE
23 OF THAT THINK THAT IF WE'RE GOING TO GO INTO HUMANS,
24 WE SHOULD BRING IT BACK AND THE BOARD SHOULD BE
25 AWARE AND MAKE A DECISION. ANYONE WANT TO COMMENT

BARRISTERS' REPORTING SERVICE

1 ON THAT? GO AHEAD, JAMES.

2 MR. HARRISON: I JUST WANTED TO POINT OUT,
3 AGAIN, THERE ARE REALLY TWO SEPARATE QUESTIONS HERE.
4 WITH RESPECT TO THE POLICY OF WHETHER UNUSED FUNDS
5 FROM THE DISEASE TEAM I AWARDS SHOULD BE ABLE TO BE
6 USED FOR CLINICAL TRIAL WORK IF THE GRANTEE HAS BEEN
7 SUCCESSFUL IN FILING AN IND WITHIN LESS THAN THE
8 FOUR-YEAR TIME PERIOD AND HAS LEFT-OVER FUNDS IS A
9 QUESTION THAT ONLY CERTAIN MEMBERS OF THE BOARD CAN
10 PARTICIPATE IN BECAUSE OF THE FACT THAT MEMBERS ARE
11 FROM INSTITUTIONS THAT ARE PARTICIPATING IN SOME OF
12 THESE AWARDS.

13 THE SECOND ISSUE THAT'S BEEN IDENTIFIED BY
14 DUANE ROTH, IF THAT, IN FACT, IS THE POLICY, WHAT
15 PROCEDURE WOULD THE BOARD LIKE TO EMPLOY TO GET
16 THERE? WE HAVE AN EXISTING POLICY, WHICH DR. OLSON
17 DESCRIBED, AND SOME BOARD MEMBERS HAVE EXPRESSED
18 INTEREST IN HAVING THOSE DECISIONS COME TO THE
19 BOARD. IN ORDER TO PERMIT BOARD MEMBERS TO
20 PARTICIPATE, IT MIGHT MAKE SENSE TO BIFURCATE THE
21 QUESTION SO THAT IF THERE'S CONSENSUS AMONG THOSE
22 MEMBERS WHO CAN PARTICIPATE ON THE POLICY OF
23 PERMITTING THE FUNDS TO BE USED, WE COULD THEN HAVE
24 A BROADER DISCUSSION AND INCORPORATE MORE MEMBERS IN
25 THE DISCUSSION OF WHAT PROCEDURE IS APPROPRIATE.

BARRISTERS' REPORTING SERVICE

1 CHAIRMAN KLEIN: SINCE THIS IS SO
2 IMPORTANT THAT WE ALLOW THESE TRIALS TO GO ON, I
3 THINK I WOULD PREFER TO DEFAULT TO A MORE
4 CONSERVATIVE POSITION. I THINK IT'S IMPORTANT
5 BECAUSE KNOWING THE OPPOSITION TO SOME OF OUR
6 RESEARCH WILL TAKE ANY TECHNICAL GROUNDS EVEN WITH
7 THE COLORING OF AN ISSUE TO CHALLENGE US. IF YOU
8 COULD TELL US WHO HAS THE CONFLICTS, AND THEN WE
9 WILL LIMIT THAT DISCUSSION SO THAT WE HAVE AN
10 ABSOLUTE, UNASSAILABLE POSITION THAT WE RESTRICTED
11 THIS DISCUSSION BECAUSE IT HAS BEEN POSITIONED
12 PROPERLY INVOLVING THE PHASE I DISEASE TEAMS, AS WE
13 REQUESTED. SO I THINK IT'S IMPORTANT THAT YOU TELL
14 US WHAT THOSE ARE.

15 MR. HARRISON: MEMBERS WHO CAN PARTICIPATE
16 IN THIS DISCUSSION ARE KLEIN, TORRES, ROTH, PRICE,
17 BRYANT, GIBBONS, LOVE, PENHOET, QUINT, SAMUELSON,
18 SERRANO-SEWELL, AND SHESTACK.

19 MS. LANSING: COULD YOU READ THE LIST
20 AGAIN?

21 MR. ROTH: BOB, JUST TO ANSWER THE
22 QUESTION ABOUT HUMAN SUBJECTS AND CLINICAL TRIALS,
23 THAT'S WHAT THESE THINGS ARE ALL ABOUT. IT'S TO GET
24 TO AN IND AND TO CONTINUE ON. AND TO ME THERE ARE
25 SAFEGUARDS BUILT IN ALREADY. FIRST YOU HAVE FDA'S

BARRISTERS' REPORTING SERVICE

1 CONCURRENCE. SECOND, YOU'VE GOT AN IRB. THAT'S
2 THEIR JOB TO LOOK AT THE SAFETY AND EFFECTIVENESS OF
3 THIS. AND THIRD, YOU'VE GOT OUR OWN STAFF WHO'S
4 LOOKING AT IT AS WELL. WHY IT NEEDS TO COME TO US,
5 I DON'T SEE ANY BENEFIT OF THAT OTHER THAN THE
6 FINANCIAL.

7 DR. TROUNSON: IT ALSO TAKES A VERY LONG
8 TIME BETWEEN SUBMISSION OF THE APPLICATION AND THEIR
9 APPROVAL, UNFORTUNATELY VERY LONG TIME. BUT WE
10 WOULD BE ADVISING THE BOARD ON ANY APPLICATIONS THAT
11 ARE COMING FROM THESE TEAMS ANYWAY. SO I THINK YOU
12 WILL BE WELL AWARE OF IT PRIOR TO. AND WE WOULD
13 CLEARLY -- I WOULD DO MY BEST TO ENSURE THAT THE
14 BOARD ABSOLUTELY KNEW WHAT THE PROSPECTS WERE AND,
15 NEEDS BE, BRING IT TO THE BOARD BEFORE ANY IND IS
16 AGREED TO HAPPEN BECAUSE THAT'S KIND OF THREE, FOUR,
17 FIVE, SIX, SEVEN, EIGHT, NINE MONTHS. IT CAN BE A
18 VERY LONG TIME.

19 CHAIRMAN KLEIN: SO WE'LL HAVE THE TIME,
20 DUANE. AND THE KEY IS THAT I THINK THIS BOARD, IF
21 WE'RE GOING TO GO INTO HUMAN SUBJECTS, SHOULD BE
22 MAKING A DECISION THAT WE HAVE THE RECOMMENDATIONS
23 FROM THE SCIENTIFIC STAFF AND WE'VE GONE ON RECORD
24 ON THIS. BUT THAT'S UP TO THE BOARD'S DECISION. I
25 CERTAINLY DON'T HAVE ANY PROBLEM WITH THE MILLION

BARRISTERS' REPORTING SERVICE

1 DOLLAR FIGURE FOR ALL THE PRELIMINARY WORK PRIOR TO
2 GOING INTO HUMANS.

3 DR. PENHOET: BOB, DOES THAT POLICY SAY
4 THAT IF WE DO DISEASE TEAM II --

5 CHAIRMAN KLEIN: ON DISEASE TEAM II, ED,
6 WE'RE APPROVING THE AWARD INCLUDING GOING FORWARD ON
7 A TRIAL.

8 DR. PENHOET: YEAH. GOING FORWARD AND
9 APPROVING IT ONCE THEY GET THEIR IND APPROVED, IT'S
10 A DIFFERENT ISSUE. WE CAN GIVE THEM A BLANKET
11 APPROVAL. IF WE APPROVE YOUR PROJECT, YOU'RE FREE
12 TO GO INTO THE CLINIC WHENEVER YOU CAN GET THERE. I
13 HEARD WHAT YOU JUST SAID IS THIS BOARD WANTS TO
14 OPINE SORT OF WITH ALL THE INFORMATION IN HAND
15 BEFORE PEOPLE GO INTO HUMANS.

16 CHAIRMAN KLEIN: DISEASE TEAM I WAS NOT
17 INITIALLY JUDGED ON THIS BASIS.

18 DR. PENHOET: I UNDERSTAND THAT. SO WE'RE
19 JUST MAKING A DECISION TODAY. THE ARGUMENT TO BRING
20 IT BACK TO THE BOARD YOU'RE MAKING FOR DISEASE TEAM
21 I --

22 CHAIRMAN KLEIN: ONLY.

23 DR. PENHOET: -- IS THAT WE SHOULD -- WE
24 HAVE NOT IN THE COURSE OF APPROVING DISEASE TEAM I,
25 WE HAVE NOT APPROVED A CLINICAL TRIAL. THEREFORE,

BARRISTERS' REPORTING SERVICE

1 THAT'S A SPECIAL CASE BECAUSE WE HAVE IT. BUT IN
2 DISEASE TEAM II, THERE WILL BE AN IMPLICIT PRIOR
3 APPROVAL TO WHATEVER CLINICAL TRIALS COME OUT OF
4 DISEASE TEAM?

5 CHAIRMAN KLEIN: I'M JUST TELLING YOU MY
6 PERSONAL VIEW AND WHAT I'VE HEARD FROM SOME OTHER
7 BOARD MEMBERS.

8 MS. BAUM: I HAVE A QUESTION. SO THAT
9 STAFF KNOWS HOW TO BEST PREPARE FOR ANY
10 PRESENTATION, WHAT WOULD BE THE BASIS FOR APPROVING
11 OR NOT APPROVING? IRB'S ARE LOOKING AT THIS, FDA IS
12 LOOKING AT IT. THEY HAVE A HUGE DATA PACKAGE.
13 WOULD YOU WANT THE SAME LEVEL OF REVIEW FOR
14 SOMETHING LIKE THAT?

15 CHAIRMAN KLEIN: NO. SO THE SCIENTIFIC --
16 I THINK DR. OLSON HAS OUTLINED A VERY GOOD PROCESS.
17 AND THE SCIENTIFIC TEAM WILL HAVE THE BENEFIT OF AN
18 ADVISORY GROUP. IT'S JUST A QUESTION OF MAKING
19 CERTAIN THAT THE BOARD KNOWS WHEN WE'VE GONE INTO A
20 HUMAN TRIAL IS, FROM MY PERSPECTIVE, A KEY ISSUE OR
21 IF IT'S MORE THAN A MILLION DOLLARS.

22 MS. BAUM: SO IT'S JUST A GENERAL SUMMARY.
23 YOU DON'T NEED A VERY IN-DEPTH DISCUSSION.

24 CHAIRMAN KLEIN: WELL, A GENERAL SUMMARY,
25 BUT THE STAFF WOULD BE AVAILABLE TO ANSWER

BARRISTERS' REPORTING SERVICE

1 QUESTIONS, BUT IT'S NOT MEANT TO BE A HUGE
2 UNDERTAKING.

3 DR. TROUNSON: CHAIR, COULD YOU OUTLINE
4 WHAT YOU MIGHT -- WHERE YOU MIGHT CONSIDER NOT
5 AGREEING TO A CLINICAL TRIAL IF THE FDA HAD AGREED?

6 CHAIRMAN KLEIN: MY PERSONAL PERSPECTIVE
7 IS THAT IF WE HAVE THE APPROVALS AND YOU HAVE AN
8 ADVISORY COMMITTEE THAT'S CONCURRING AND THE FDA HAS
9 APPROVED IT, I PERSONALLY WOULD BE VERY SUPPORTIVE.
10 THIS HAS COME UP AS A GENERAL POLICY ISSUE BEFORE
11 FROM OTHER BOARD MEMBERS THAT THEY WOULD LIKE TO
12 KNOW IF WE'RE UNDERTAKING A HUMAN CLINICAL TRIAL.

13 DR. TROUNSON: I THINK WE WOULD GUARANTEE
14 THAT WE WOULD BRING THAT TO THE BOARD IN GOOD TIME
15 BEFORE ANYTHING WAS OPERATIVE BECAUSE THERE IS SUCH
16 AN AMOUNT OF TIME THERE. I WAS JUST INTERESTED
17 WHETHER YOU HAD A SCENARIO. I WAS TRYING TO THINK
18 OF A SCENARIO WHERE YOU WOULD DENY THAT IF THEY HAD
19 APPROVAL TO GO AHEAD. I'M NOT SURE I CAN IMAGINE
20 THAT.

21 CHAIRMAN KLEIN: WELL, YOU MAY COME TO US
22 WITH A SPLIT ISSUE. YOU CAN SAY THERE'S AN FDA
23 APPROVAL, THERE'S AN ADVISORY COMMITTEE THAT THINKS
24 THAT THERE'S THINGS THAT HAVE NOT BEEN MET OR NEED
25 TO BE MET, THE STAFF IS SPLIT ON THIS. WHAT'S YOUR

BARRISTERS' REPORTING SERVICE

1 POSITION? THERE'S SO MANY DETAILED FACT PATTERNS I
2 CAN'T ANTICIPATE. THE KEY ISSUE THAT HAS BEEN
3 BROUGHT UP AS A GENERAL POLICY MATTER IS JUST A
4 QUESTION OF, AND IT'S AN OPEN QUESTION, DOES THIS
5 BOARD ON PHASE I, WHERE WE DID NOT APPROVE IT AND
6 HAVE IT PEER REVIEWED AS A CLINICAL TRIAL, WANT TO
7 HAVE AN APPROVAL BEFORE WE START CLINICAL TRIALS.

8 DR. PIZZO: I CAN'T TALK.

9 DR. LOVE: CAN I TALK? I'VE BEEN OUT OF
10 THE ROOM FOR A LITTLE BIT OF THIS.

11 DR. PIZZO: NOT EVEN CONCEPTUALLY? CAN I
12 MAKE A CONCEPTUAL COMMENT THAT HAS NOTHING TO DO?

13 CHAIRMAN KLEIN: NO. DR. LOVE CEDES HIS
14 POSITION TO DR. BRYANT.

15 DR. BRYANT: I WAS JUST GOING TO SAY ISN'T
16 WHAT WE REALLY WANT JUST TO BE INFORMED IF THERE'S
17 ALREADY FDA APPROVAL?

18 CHAIRMAN KLEIN: WELL --

19 DR. LOVE: LET ME ASK THIS. I'M KIND OF
20 GOING THE SAME DIRECTION. BEING INFORMED IS A VERY
21 EASY THING. YOU CAN SEND AN E-MAIL TO US. IT'S
22 PROBABLY LIKE WE'D KNOW ANYWAY. I'M JUST NOT SURE
23 IF THE BOARD WANTS TO BE IN A POSITION OF APPROVING
24 SOMETHING WHEN THERE'S ALREADY A VERY HIGH INTEGRITY
25 SYSTEM THAT EXISTS FOR APPROVING THIS. COMPANY

BARRISTERS' REPORTING SERVICE

1 BOARDS DON'T APPROVE PEOPLE GOING INTO HUMAN
2 CLINICAL TRIALS, AND THEY PROBABLY HAVE AN EASIER
3 CAPACITY TO DO THAT IF THEY WANTED TO DO, BUT NO ONE
4 DOES THAT.

5 SO IF WE THINK IT'S DISCHARGING FIDUCIARY
6 OBLIGATION, MAYBE. I'M JUST NOT SURE WE REALLY WANT
7 TO PUT OURSELVES IN THAT POSITION.

8 CHAIRMAN KLEIN: WHAT HAPPENS, WHAT'S YOUR
9 VIEW IF SOMEONE REQUESTS TO USE THE FUNDS AND
10 THERE'S A SPLIT ISSUE BECAUSE THE ADVISORY BOARD AND
11 THE STAFF HAVE A SPLIT POSITION?

12 DR. LOVE: THERE REALLY ISN'T A SPLIT
13 DECISION. THE FDA WILL DENY IT IF THEY CAN'T AGREE.
14 THEY DON'T GIVE YOU A VOTE. THEY EITHER GIVE YOU
15 APPROVAL OR NOT. IRB'S DON'T SPLIT. THEY GIVE YOU
16 AN APPROVAL OR NOT.

17 CHAIRMAN KLEIN: WE HAVE AN ADVISORY
18 COMMITTEE THAT'S SEPARATE FROM THOSE STRUCTURES.

19 DR. LOVE: I UNDERSTAND THAT, BUT THOSE
20 ARE NOT THE PEOPLE AT THE END OF THE DAY THAT ARE
21 GUARDED WITH THE PROTECTION AND SAFETY OF THE
22 PATIENT, WHICH I THINK IS WHAT PROBABLY WOULD
23 CONCERN US THE MOST. IS SOMETHING GOING ON AND THEN
24 PATIENTS GET INJURED, AND THERE'S A VERY RIGOROUS
25 PROCESS OUT THERE THAT DOESN'T VOTE, BUT RATHER

BARRISTERS' REPORTING SERVICE

1 REACHES CONSENSUS ABOUT WHETHER OR NOT YOU CAN GO
2 FORWARD.

3 CHAIRMAN KLEIN: ALL RIGHT. YES, DR.
4 BRYANT.

5 DR. BRYANT: I WAS JUST GOING TO FOLLOW
6 UP. SO IF WE ARE GOING TO GIVE APPROVAL TO SUCH
7 CASES, WHAT ABOUT THE COST OF THE TRIAL? WHAT IF
8 THERE ISN'T ENOUGH MONEY LEFT OVER IN THE GRANT TO
9 FUND THE WHOLE THING? WHAT WILL OUR RESPONSIBILITY
10 BE THERE?

11 CHAIRMAN KLEIN: WELL, THAT WOULD BE ONE
12 OF THE THINGS WE REVIEW WHEN THE SCIENTIFIC STAFF
13 BROUGHT US THE INFORMATION. YOU KNOW, THIS IS A \$10
14 MILLION TRIAL. YOU CAN MOVE DOWNSTREAM WITH THREE,
15 BUT YOU GET THROUGH IT. THEY THINK THEY CAN GET
16 MONEY IF THEY GET PAST THIS MILESTONE, BUT THEY'RE
17 NOT SURE. WHAT DO YOU WANT TO DO?

18 DR. TROUNSON: I THINK IN EVERY
19 CIRCUMSTANCE THEY WILL HAVE HAD TO RAISE MONEY
20 BECAUSE THERE'S NO CHANCE THAT WHAT'S LEFT OVER WILL
21 REALLY COVER THE COST OF THE CLINICAL TRIAL. SO
22 WHAT THEY'LL BE ASKING IS CAN THEY USE THE FUNDS TO
23 SUPPLEMENT WHAT THEY'VE GOT. I THINK THAT WILL BE
24 THE CASE 99 PERCENT OF THE TIME AND NOT THAT THEY
25 WOULD JUST USE, SAY, THE \$2 MILLION THAT WAS LEFT OR

BARRISTERS' REPORTING SERVICE

1 THREE MILLION OR FIVE MILLION TO DO A CLINICAL
2 TRIAL. I DON'T THINK IT WOULD COVER THE COST THAT I
3 CAN IMAGINE IN SUCH A THING. IT WILL HAVE TO BE CAN
4 THAT BE USED TO SUPPLEMENT WHATEVER FUNDS THEY'VE
5 GOT.

6 DR. BRYANT: THEY CAN USE IT AS LEVERAGE.

7 CHAIRMAN KLEIN: OR THE FDA COULD HAVE
8 SOME SUPPLEMENTAL PROCEDURES THEY WANT BEFORE THE
9 TRIAL COULD REALLY START, AND OUR MONEY MIGHT
10 ADDRESS THOSE SUPPLEMENTAL POINTS.

11 DR. OLSON: I WAS JUST GOING TO SAY THAT
12 AS PART OF THE PLAN, THAT THEY WOULD BRING, SAY, IF
13 THE GO/NO-GO DECISION TO FILE THE IND, THEY BELIEVE
14 THEY WOULD HAVE EXCESS FUNDS, I WOULD EXPECT THEM TO
15 SAY HOW MIGHT THEY SEE THEM BEING SPENT, HOW MIGHT
16 THEY COVER THE REST OF THE COST OF THE TRIAL BECAUSE
17 USUALLY YOU DON'T WANT TO ENROLL ONE PATIENT AND
18 STOP. THAT'S NOT A GOOD THING TO DO. SO I WOULD
19 THINK THAT THAT WOULD BE PART OF THE PLAN. AND I
20 THINK ALAN IS RIGHT. AND I BELIEVE, AS MR. SHEEHY
21 POINTED OUT AT THE SCIENCE SUBCOMMITTEE MEETING,
22 THIS IS -- THE LIKELIHOOD OF LOTS OF MONEY BEING
23 LEFT OVER IN MANY OF THESE PROJECTS IS PROBABLY NOT
24 HIGH.

25 CHAIRMAN KLEIN: I THINK WE DO ENHANCE THE

BARRISTERS' REPORTING SERVICE

1 ABILITY TO HAVE SOME OF IT LEFT OVER BY HAVING THIS
2 EXPLICIT POLICY THAT WE CAN MOVE THINGS FORWARD, AND
3 THAT COULD BE QUITE HELPFUL. SO I'M VERY SUPPORTIVE
4 OF THIS POLICY.

5 I THINK WE'VE HAD A GOOD DISCUSSION HERE.
6 TED, WOULD YOU LIKE TO MAKE A MOTION?

7 DR. LOVE: I WOULD MOVE THAT WE NOT PUT --

8 MR. HARRISON: BEFORE ANYONE MAKES A
9 MOTION, I JUST WANTED TO POINT OUT TO THE BOARD THAT
10 IF THEY'RE INCLINED TO AGREE WITH THE STAFF
11 PROPOSAL, NO ACTION IS NECESSARY BECAUSE THE GRANTS
12 ADMINISTRATION POLICY ALREADY PERMITS THE STAFF --

13 CHAIRMAN KLEIN: I'D LIKE A MOTION ON THIS
14 FOR THE RECORD BECAUSE I DON'T WANT THIS CHALLENGED
15 IF WE GO FORWARD.

16 DR. LOVE: WELL, I MEAN I THINK I'M
17 PERSONALLY VERY COMFORTABLE WITH THE IDEA OF
18 NOTIFICATION. I THINK BOARD MEMBERS WOULD WANT TO
19 KNOW WHEN WE'RE ABOUT TO BEGIN. I THINK STAFF WOULD
20 WANT TO TELL US, QUITE FRANKLY. SO I'M HAPPY TO
21 MOVE THAT WE WOULD BE NOTIFIED WITHIN SOME WARNING,
22 APPROPRIATE WARNING TIME, AT 30 DAYS BEFORE PATIENTS
23 ARE EXPOSED IN CLINICAL TRIALS.

24 CHAIRMAN KLEIN: AS A FRIENDLY AMENDMENT,
25 THIS IS MONTHS OF A PROCESS. THEY'RE GOING TO NEED

BARRISTERS' REPORTING SERVICE

1 TO KNOW SUBSTANTIALLY MORE IN ADVANCE, IF POSSIBLE.

2 DR. LOVE: I WAS SETTING A MINIMUM. I WAS
3 SAYING MINIMUM 30 DAYS.

4 DR. TROUNSON: AS SOON AS POSSIBLE.

5 CHAIRMAN KLEIN: WITH A GOAL OF HAVING
6 THREE OR FOUR MONTHS OF ADVANCE NOTICE.

7 MR. ROTH: CAN WE POSSIBLY TIE THESE TWO
8 THINGS TOGETHER, THE MILLION-DOLLAR THRESHOLD, THAT
9 YOU WOULD COME BACK WITH TWO THINGS: ONE, ANYTHING
10 OVER A MILLION DOLLARS REDIRECTED AND, TWO, THAT
11 THERE WOULD BE AN INFORMATIONAL NOTICE THAT WE'D
12 MOVE MONEY FROM PRECLINICAL TO CLINICAL.

13 MS. BAUM: DOES THAT MEAN THAT YOU'RE
14 SAYING APPROVAL IS REQUIRED ABOVE A MILLION OR JUST
15 INFORMATIONAL?

16 MR. ROTH: THE MILLION DOLLARS, I THINK,
17 SHOULD COME TO THE BOARD AND BE PROBABLY APPROVED OR
18 COULD GO TO THE SUBCOMMITTEE IF YOU PREFER. THAT
19 WAS MY UNDERSTANDING.

20 DR. PENHOET: YOU KNOW, THE BARRIERS TO
21 GETTING AN APPROVED IND ALREADY IS SO GREAT, THEY'RE
22 ENORMOUS. SO IT'S A HORRENDOUS EFFORT TO GET AN
23 APPROVED IND AND AN APPROVED IRB AND ALL OF THE
24 THINGS THAT GO WITH IT. AND I THINK WE SHOULD DO
25 EVERYTHING WE CAN TO REWARD GOOD BEHAVIOR AND NOT

BARRISTERS' REPORTING SERVICE

1 THROW MORE ROADBLOCKS IN THE WAY. SO I DON'T LIKE
2 YOUR PROPOSAL. I BELIEVE WHAT TED HAS PROPOSED, IS
3 IT A MOTION, TED, IS THAT WE APPROVE THE STAFF
4 RECOMMENDATION WITH THE ADDITION THAT STAFF WILL
5 COME TO US AS SOON AS POSSIBLE TO NOTIFY US THAT
6 THEY HAVE BEEN REQUESTED TO MAKE THIS MODIFICATION.

7 MR. ROTH: I AM FINE WITH THAT. IT WAS
8 MORE -- MY DOING IT WAS MORE TO PROTECT THE
9 INTEGRITY OF THE STAFF IF THEY WERE CONCERNED ABOUT
10 MOVING MONEY LIKE THAT, BUT I HAVE NO OBJECTIONS AT
11 ALL TO DOING IT THIS WAY.

12 CHAIRMAN KLEIN: IS THAT A SECOND, DR.
13 PENHOET?

14 DR. PENHOET: YES.

15 CHAIRMAN KLEIN: WE HAVE TWO SECONDS. DR.
16 LOVE. AND IS THERE PUBLIC COMMENT? I'M GOING TO DO
17 A ROLL CALL VOTE HERE BECAUSE OF THE CONFLICTS
18 ISSUES, AND WE'LL ONLY CALL ON THOSE WITHOUT A
19 CONFLICT; IS THAT CORRECT, MR. HARRISON?

20 MR. HARRISON: YES. AS I UNDERSTAND IT,
21 THE MOTION IS TO ENDORSE THE STAFF POLICY, BUT TO
22 REQUIRE THE STAFF TO NOTIFY THE BOARD WHEN A REQUEST
23 IS MADE.

24 CHAIRMAN KLEIN: RIGHT. WELL, MADE AND
25 GRANTED.

BARRISTERS' REPORTING SERVICE

1 MR. HARRISON: MADE AND GRANTED.
2 CHAIRMAN KLEIN: MADE AND/OR GRANTED, SO
3 THAT WE WOULD KNOW IF IT'S DENIED AS WELL.
4 MR. HARRISON: MADE AND CONSIDERED.
5 MS. KING: ROBERT PRICE.
6 DR. PRICE: YES.
7 MS. KING: SUSAN BRYANT.
8 DR. BRYANT: YES.
9 MS. KING: BOB KLEIN.
10 CHAIRMAN KLEIN: YES.
11 MS. KING: TED LOVE.
12 DR. LOVE: YES.
13 MS. KING: ED PENHOET.
14 DR. PENHOET: YES.
15 MS. KING: ROBERT QUINT.
16 DR. QUINT: YES.
17 MS. KING: DUANE ROTH.
18 MR. ROTH: YES.
19 MS. KING: DAVID SERRANO-SEWELL.
20 MR. SERRANO-SEWELL: PASS.
21 MS. KING: ART TORRES.
22 MR. TORRES: AYE.
23 MR. SERRANO-SEWELL: I ABSTAINED.
24 MR. HARRISON: MOTION PASSES.
25 MR. SHEEHY: I WOULD JUST LIKE TO SAY HOW

BARRISTERS' REPORTING SERVICE

1 PROFOUNDLY DISAPPOINTED I AM WITH THIS PROCESS, HOW
2 DISEMPOWERED AND HOW WASTEFUL THE SCIENCE
3 SUBCOMMITTEE HAS BEEN. I SPECIFICALLY ASKED THAT
4 THIS ITEM COME FORWARD FROM STAFF WITH A PROPOSAL
5 THAT WOULD ALLOW FOR BOARD APPROVAL.

6 THE WAY THAT THIS WAS WRITTEN PREVENTED ME
7 FROM HAVING ANY IMPACT ON THIS DISCUSSION. THE REST
8 OF MY BOARD MEMBERS HAVE DONE ME A DISSERVICE TODAY.
9 THE SCENARIO IN WHICH I IMAGINED THIS IS NOT UPON AN
10 APPROVAL OF AN IND AND THE GO DECISION, BUT WHERE
11 THE SCIENTIFIC ADVISORY BOARD, THIS EXTERNAL GROUP,
12 THE MEMBERSHIP OF WHOM I HAVE NO CONTROL, NO
13 CONTACT, DECIDES NOT PROCEED, EVEN THOUGH AN IND HAS
14 BEEN GRANTED.

15 I WILL GIVE YOU A SCENARIO. JOHN ZAIA
16 GETS AN IND FOR HIS HIV EXPERIMENT, OKAY, USING
17 GENETICALLY ALTERED HEMATOPOETIC STEM CELLS. IN
18 ORDER TO PUT THAT INTO PATIENTS TO REPLICATE WHAT WE
19 JUST SAW THIS MORNING IN THE MOUSE EXPERIMENT THAT
20 PAULA CANNON HAS DONE, HE HAS TO DO SOME
21 CONDITIONING. THERE ARE PEOPLE ON THAT EXTERNAL
22 ADVISORY BOARD, AND I'VE HEARD PAT SAY THIS, WHO
23 DON'T BELIEVE THAT IT'S APPROPRIATE TO DO THE
24 CONDITIONING. YET I HAVE TALKED TO PEOPLE IN THE
25 PATIENT COMMUNITY, IN FACT, I HAVE TALKED TO PEOPLE

BARRISTERS' REPORTING SERVICE

1 WHO HAVE EXPERIENCED CONDITIONING AS PART OF EFFORTS
2 TO TREAT HIV BEFORE THERE WERE THERAPIES, AND THAT
3 IS A PATIENT DECISION. AND IF THAT GETS TURNED
4 DOWN, THEY CANNOT ROLL OVER THAT MONEY AND DO THAT
5 TRIAL, THEN I HAVE BEEN DEFRAUDED.

6 AND THE FACT THAT YOU HAVEN'T BROUGHT THAT
7 DECISION TO THIS BOARD IS NOT APPROPRIATE. AND
8 WHAT -- LET ME FINISH TALKING.

9 CHAIRMAN KLEIN: CAN I UNDERSTAND THE
10 MOTION THAT WAS MADE? CAN I RELATE BECAUSE I THINK
11 YOU HAVE IN THE MOTION THE NOTICE YOU NEED.

12 MR. SHEEHY: WE HAVE NOTICE, BUT WE DON'T
13 HAVE POWER TO APPROVE OR DISAPPROVE.

14 CHAIRMAN KLEIN: IF IT'S --

15 MR. SHEEHY: AND I THINK THIS A SYSTEMIC
16 ATTEMPT TO DISEMPOWER THIS BOARD. I ASKED THIS AT
17 THE SCIENTIFIC SUBCOMMITTEE. I ASKED FOR A PROCESS
18 THAT LISTENS TO MY CONCERNS AND MY INPUT. I HAVE MY
19 COMMUNITY ENGAGED THIS PROCESS. I KNOW WHAT IT
20 TAKES TO GET THIS, I KNOW OBSTACLES WE'RE GOING TO
21 TAKE TO GET THIS INTO PATIENTS. WE HAVE BEEN
22 TALKING WITH SCIENTISTS AND ADVOCATES AND ACTIVISTS
23 FROM ALL OVER THE COUNTRY. WE'RE WAITING FOR THIS
24 TO HAPPEN. THE NIH WILL NOT FUND IT, WHICH IS WHY
25 PAULA CANNON'S WORK IS FUNDED IN CALIFORNIA AND WHY

BARRISTERS' REPORTING SERVICE

1 JOHN ZAIA'S WORK IS IN CALIFORNIA, BECAUSE THEY ARE
2 PEOPLE WHO DO NOT BELIEVE THAT THE RISK IS
3 APPROPRIATE. BUT THAT IS A DECISION THAT PEOPLE
4 WITH HIV HAVE THE RIGHT TO MAKE.

5 AND SO I AM JUST ENTIRELY DISAPPOINTED.
6 MOST PROFOUNDLY I AM DISAPPOINTED WITH THIS PROCESS
7 THAT DOES NOT RESPECT MY DIRECTION AND MY INPUT AT A
8 SUBCOMMITTEE THAT'S BEEN EMPOWERED BY THIS BOARD. I
9 DON'T THINK IT SHOULD MEET AGAIN BECAUSE NONE OF THE
10 RECOMMENDATIONS OF THAT SUBCOMMITTEE ARE MET WITH
11 ANY SENSE OF COOPERATION FROM THE STAFF.

12 CHAIRMAN KLEIN: OKAY. JEFF, MY
13 UNDERSTANDING OF THE MOTION THAT PASSED WAS THERE BE
14 A NOTIFICATION WHETHER IT'S APPROVED OR DENIED. IF
15 IT'S DENIED, THEN THE BOARD COULD CONSIDER WHY IT
16 WAS DENIED AND CONSIDER TAKING A DIFFERENT ACTION.
17 IF WE HAVE NOTIFICATION THAT SOMETHING HAS BEEN
18 DENIED, THE BOARD WOULD HAVE THE POWER TO REQUEST A
19 FULL REPORT OF WHY AND TAKE A DIFFERENT ACTION. SO
20 DOESN'T THAT PUT YOU IN THE POSITION THAT YOU WANTED
21 FOR A POLICY BASIS TO BE ABLE TO KNOW IF SOMETHING
22 HAS BEEN DENIED, WHY IT'S BEEN DENIED, AND THIS
23 BOARD TO BE ABLE TO TAKE A DIFFERENT POSITION IF IT
24 CHOSE TO? DOESN'T THAT ACCOMPLISH THE GOAL?

25 MR. SHEEHY: NOTIFICATION DOES NOT ALLOW

BARRISTERS' REPORTING SERVICE

1 FOR ACTION. IN ORDER TO HAVE ACTION AT THIS BOARD,
2 THERE HAS TO BE NOTICE CONSIDERATION THAT ALLOWS FOR
3 ACTION. INFORMING US DOES NOT ALLOW US THE
4 OPPORTUNITY TO TAKE ACTION, AM I NOT CORRECT?

5 CHAIRMAN KLEIN: NO. MR. HARRISON, IF WE
6 WERE NOTICED THAT IT HAD BEEN DENIED, WE'D BE FULLY
7 EMPOWERED TO TAKE A DIFFERENT ACTION; IS THAT
8 CORRECT?

9 MR. HARRISON: UNDER THE GRANT
10 ADMINISTRATION POLICY, THE PRESIDENT HAS THE
11 AUTHORITY TO APPROVE CHANGES IN SCOPE. THE BOARD
12 COULD CERTAINLY TAKE A MOTION TELLING THE PRESIDENT
13 THAT IT HAD A DIFFERENT VIEW THAN THE ONE REACHED BY
14 STAFF AND DIRECTING THEM TO TAKE ACTION.

15 MR. SHEEHY: WOULD THAT HAVE TO BE AN
16 AGENDAD ITEM? HOW WOULD THAT BE PRESENTED TO US?

17 CHAIRMAN KLEIN: WE WOULD GET NOTICE.

18 MR. SHEEHY: I UNDERSTAND THIS IS GOING TO
19 BE AN ITEM THAT'S INCLUDED IN THE PRESIDENT'S
20 REPORT. WE CANNOT TAKE ACTION ON ITEMS IN THE
21 PRESIDENT'S REPORT, CAN WE?

22 MR. HARRISON: WELL, IT DEPENDS UPON HOW
23 IT'S AGENDIZED, BUT WE CAN CERTAINLY AGENDIZE THESE
24 ITEMS TO PERMIT THE BOARD TO HAVE THE OPPORTUNITY TO
25 TAKE ACTION.

BARRISTERS' REPORTING SERVICE

1 DR. TROUNSON: WE'RE GOING TO ADVISE YOU
2 WHENEVER WE HEAR THAT SOMEBODY IS GOING TO PUT IN AN
3 IND. WE'RE GOING TO ADVISE YOU IF THE IND ALSO HAS
4 BEEN APPROVED BY THE FDA. THE ADVISORY COMMITTEE IS
5 ONLY AN ADVISORY COMMITTEE. IT HAS NO FORMAL
6 DECISION-MAKING. I ACTUALLY, AS I SAID TO YOU,
7 CHAIR, I CAN'T IMAGINE WHAT WE WOULD DO NOT TO
8 SUPPORT AN IND. THIS IS THE MISSION OF CIRM. IT'S
9 JUST NOT FEASIBLE TO ME TO IMAGINE THAT WE WOULDN'T
10 GO AHEAD WITH AN IND ATTACHED TO ANY OF THESE
11 PROJECTS, BUT YOU WOULD HAVE THAT INFORMATION AS
12 SOON AS WE HEAR THEY'RE GOING TO OR THEY'VE
13 SUBMITTED, GOING TO SUBMIT AN IND, AND THEN DURING
14 SOME TIME LATER, USUALLY MONTHS, WHETHER THE FDA HAS
15 APPROVED IT.

16 CHAIRMAN KLEIN: JEFF, LET ME MAKE A
17 SUGGESTION JUST TO MAKE IT VERY CLEAR. BRING BACK
18 ON THE OCTOBER BOARD MEETING AN ITEM THAT IF THERE
19 IS, IN FACT, A DENIAL, THERE WILL BE A CONSIDERATION
20 OF AN ITEM TO MAKE IT A FORMAL CONSIDERATION ITEM IN
21 THE AGENDA. THAT WILL BE OUR POLICY. IT WILL BE
22 CONSIDERED AT THE OCTOBER MEETING BECAUSE WE DO WANT
23 TO CLOSE THE LOOP AND PROVIDE INDEPENDENTLY -- FOR
24 THIS BOARD TO INDEPENDENTLY ACT IF THERE'S A
25 DIFFERENT DECISION TO BE MADE.

BARRISTERS' REPORTING SERVICE

1 MR. SHEEHY: THAT WOULD BE HELPFUL.

2 CHAIRMAN KLEIN: THANK YOU VERY MUCH.

3 DR. POMEROY: BOB, CAN I MAKE A COMMENT AS
4 WELL? OBVIOUSLY WE ALL HAVE THE GOAL OF GETTING AN
5 IND, AND WE'LL ALL CELEBRATE THE DAY THAT WE GET AN
6 IND. BUT THE OTHER THING THIS DOES CUT OUT, IT
7 MEANS WE'RE GOING TO BE FUNDING CLINICAL TRIALS THAT
8 HAVE NOT UNDERGONE PEER REVIEW. AND BECAUSE THE
9 PEER REVIEW WAS UP TO A CERTAIN POINT, FROM WHAT I
10 UNDERSTAND, AND WE'RE PROPOSING DOING RESEARCH THAT
11 GOES BEYOND THE POINT THAT WAS PEER REVIEWED. AND
12 SO I JUST WANT TO POINT OUT WHAT WE HAVE JUST
13 DECIDED TO DO, WHICH IS PUT THE ONUS ON THE BOARD
14 NOW OF BEING NOTIFIED AND, I GUESS, APPROVING
15 CLINICAL RESEARCH IN A CONTROVERSIAL AREA THAT'S NOT
16 UNDERGONE PEER REVIEW. JUST A STATEMENT OF FACT.

17 CHAIRMAN KLEIN: DR. POMEROY, THAT WAS MY
18 POINT IN THE DISCUSSION, BUT DIDN'T SEEM LIKE I WAS
19 GOING TO PREVAIL ON THAT POINT.

20 DR. POMEROY: I WASN'T ALLOWED TO SPEAK
21 BEFORE THE VOTE, SO I DID NOT. I WAS TRYING TO BE
22 COMPLIANT.

23 CHAIRMAN KLEIN: I SEE. OKAY. ALL RIGHT.
24 SO --

25 MR. SHEEHY: AND INTERESTINGLY, IF THIS

BARRISTERS' REPORTING SERVICE

1 HAD BEEN BROUGHT IN THE MANNER DIRECTED BY THE
2 SCIENCE SUBCOMMITTEE WITH THE BOARD APPROVAL IN IT,
3 YOU WOULD HAVE BEEN ABLE TO HAVE A CONVERSATION.

4 CHAIRMAN KLEIN: FROM A POLICY VIEWPOINT,
5 WE CAN AGENDIZE AS A SEPARATE ITEM WHERE WE CAN GET
6 FULL PARTICIPATION, WHICH WE ALWAYS WANT FROM THE
7 BOARD, HOW WE DEAL WITH THIS SPECIFIC ISSUE.

8 MR. SHEEHY: IT'S JUST ASTOUNDING THAT
9 THIS PERCENTAGE OF THE BOARD HAS MADE A DECISION
10 ABOUT CLINICAL TRIALS.

11 CHAIRMAN KLEIN: OKAY.

12 MR. SHEEHY: THAT IS JUST OUTRAGEOUS AND
13 HIGHLY INAPPROPRIATE THAT MOST OF THE MEMBERS OF
14 THIS BOARD HAVE HAD NO INPUT ON THIS.

15 DR. LOVE: BOB, CAN I MAKE ONE OTHER
16 COMMENT?

17 MR. SHEEHY: YOU HAVE HIJACKED US.

18 DR. LOVE: TO YOUR POINT, CLAIRE, I THINK
19 MOST CLINICAL TRIALS DON'T UNDERGO PEER REVIEW IN
20 THE WAY THAT OUR GRANTS USUALLY DO, BUT THEY DO
21 UNDERGO PEER REVIEW AT THE FDA BECAUSE THE FDA
22 DOESN'T ALLOW YOU TO DO ANYTHING TO HUMANS WITHOUT
23 THEIR INTERNAL PEER REVIEW PROCESS.

24 AND THEN I WOULD ALSO SAY THAT I THINK
25 THAT IN REALITY ANY KIND OF GROUP THAT'S DOING A

BARRISTERS' REPORTING SERVICE

1 TRIAL OF INVESTIGATORS HAS A PROCESS FOR DOING PEER
2 REVIEW. SO I UNDERSTAND THAT WE WOULD NOT BE DOING
3 THE PEER REVIEW, BUT I WOULD SAY THAT I THINK THERE
4 IS PEER REVIEW GOING ON.

5 DR. POMEROY: I DON'T OBJECT TO THESE
6 TRIALS BEING DONE, BUT THE FDA IS NOT -- DOES NOT
7 HAVE THE RESPONSIBILITY FOR OVERSEEING THE
8 EXPENDITURES OF CIRM MONEY. WE DO. IT IS OUR -- IN
9 MY OPINION, IT IS OUR PEER REVIEW GROUP. THE POINT
10 OF FDA REVIEW IS NOT TO DETERMINE THAT CIRM DOLLARS
11 ARE BEING APPROPRIATELY ALLOCATED. IT'S ABOUT
12 SAFETY.

13 CHAIRMAN KLEIN: SO WE'RE GOING TO HAVE A
14 SEPARATE AGENDIZED ITEM IN THE OCTOBER MEETING, AND
15 HOPEFULLY IT WILL ADDRESS THIS ISSUE IN TERMS OF
16 POLICY AND PROVIDE FOR AN OPPORTUNITY FOR BROADER
17 DISCUSSION.

18 IF WE LOOK AT THIS FROM A PERSPECTIVE THAT
19 WE'RE NOT LIMITED TO ONE MEETING, BUT WE HAVE MORE
20 THAN ONE MEETING TO ACCOMPLISH THE GOAL
21 INCREMENTALLY, ALWAYS AS A BOARD WE'VE SHOWN
22 OURSELVES DEDICATED TO ALWAYS IMPROVING OUR POSITION
23 AS WE LEARN, AS WE GET MORE COMMENTS, IMPROVING OUR
24 PROCESS. AND BY HAVING DISCUSSION IN OCTOBER, WE
25 WILL IMPROVE THAT PROCESS AND GET A BROADER

BARRISTERS' REPORTING SERVICE

1 PERSPECTIVE.

2 THE NEXT ITEM THAT WE NEED TO GO TO IS
3 ITEM 12, AND WE COULD LOOK AT THAT ITEM, PLEASE.
4 THE MATERIALS THAT YOU HAVE BEFORE YOU HAVE BEEN
5 DEVELOPED WITH THE INSTITUTE OF MEDICINE. THESE
6 MATERIALS ANTICIPATE BOTH COVERING THE ECONOMIC
7 IMPACT ISSUES WITH ECONOMISTS THAT ARE MEMBERS OF
8 THE INSTITUTE OF MEDICINE AS WELL AS THE SCIENTIFIC
9 ISSUES AS WELL AS CONFLICTS ISSUES. WE HAVE A
10 RESPONSIBILITY TO THE PUBLIC FOR AN INDEPENDENT
11 REVIEW OF THE NATIONAL BODY THAT IS WELL UNDERSTOOD
12 ON ISSUES SUCH AS CONFLICTS SO IT'S VERY CLEAR TO
13 THE PUBLIC THAT WE HAVE DONE THE VERY BEST JOB
14 POSSIBLE, HOPEFULLY IMPROVING ON THE STANDARDS OF
15 THE NATION IN CREATING A NEW AND IMPROVED MODEL ON
16 HOW WE PROTECT FROM CONFLICTS IN WHAT WE'RE DOING.

17 IT IS VERY IMPORTANT FOR THE PUBLIC TO
18 HAVE AN INDEPENDENT REVIEW OF THIS KIND SO THAT WHEN
19 THERE ARE THOSE THAT BRING UP ISSUES OF CONFLICTS AS
20 A SMOKE SCREEN TO OUR POLICIES, THEY REALLY OPPOSE
21 THE RESEARCH, BUT THEY ASSERT CONFLICTS ISSUES, FOR
22 EXAMPLE, THAT THE PUBLIC HAS A WAY TO INDEPENDENTLY
23 GET A BENCHMARK ON OUR PERFORMANCE. WHEN THOSE WHO
24 ARE OPPOSED TO OUR RESEARCH CHALLENGE OUR PEER
25 REVIEW PROCESS AND THE CONFIDENTIAL NATURE OF PEER

BARRISTERS' REPORTING SERVICE

1 REVIEW SO WE HAVE A BLUNTLY, INSIGHTFUL PEER REVIEW,
2 IT'S IMPORTANT THAT THE PUBLIC BE ABLE TO LOOK AT A
3 NATIONAL GROUP LIKE THE NATIONAL ACADEMIES INSTITUTE
4 OF MEDICINE TO LOOK AT A VALIDATION OR CRITICISM OR
5 SUGGESTIONS FOR IMPROVEMENTS.

6 SO THE INTENT HERE IS FOR ACCOUNTABILITY
7 TO THE PUBLIC TO BE ABLE TO HAVE A PROGRAM THAT'S
8 RESPONSIVE.

9 THE MATERIALS HERE TALK ABOUT A PERIOD OF
10 12 TO 14 MONTHS. IN CONSIDERATION OF STAFF LOADS
11 AND WORKING WITH THE STAFF, IT IS SUGGESTED THAT WE
12 DO 22 TO 26 MONTHS, BUT WITH THE GOAL THAT DURING
13 2012 WE HAVE THE FINAL PRODUCT. THAT'S THE PERIOD
14 IN WHICH THE LONGEST SERVING MEMBERS OF THIS BOARD
15 WILL HAVE BEEN SERVING, AND IT'S VERY IMPORTANT WE
16 GET THIS REPORT BACK IN THAT TIME PERIOD.

17 IT'S ALSO IMPORTANT TO NOTE THAT THIS
18 PROCESS FOR CALIFORNIA EXAMINES THE VALUE OF
19 LONG-TERM FUNDING, FOR THE VALUE OF STABILITY IN
20 FUNDING FROM APPROPRIATIONS FUNDING THAT CERTAINLY
21 DEMONSTRATED BY THIS ECONOMY IS UNPREDICTABLE AND
22 VERY UNEVEN, DISRUPTING PLANS, CREATING --
23 UNDERMINING THE CERTAINTY THAT SOMEONE NEEDS TO COME
24 INTO THIS AREA FROM A RELATED DISCIPLINE TO
25 CONTRIBUTE TO A TEAM WHERE IT'S NOT CERTAIN THAT

BARRISTERS' REPORTING SERVICE

1 THERE WILL BE FUNDING DOWNSTREAM TO REALLY FULFILL
2 ON A COMMITMENT THAT COULD MOVE A THERAPY TO
3 PATIENTS.

4 WE HAVE DISCUSSED THIS IN THE SCIENTIFIC
5 SUBCOMMITTEE. JEFF, WOULD YOU LIKE TO ADDRESS THIS
6 ITEM?

7 MR. SHEEHY: SURE.

8 DR. PENHOET: CAN I ASK A PROCEDURAL
9 QUESTION FIRST OF JAMES? FOR THOSE OF US WHO ARE
10 MEMBERS OF THE INSTITUTE OF MEDICINE, DO WE HAVE A
11 CONFLICT BECAUSE THIS WILL PROVIDE REVENUES TO THE
12 INSTITUTE?

13 MR. HARRISON: YOU DO NOT HAVE A CONFLICT
14 UNDER THE POLITICAL REFORM ACT. HOWEVER, UNDER
15 GOVERNMENT CODE SECTION 1090, EVEN WHEN THERE IS NO
16 FINANCIAL BENEFIT OR CIRCUMSTANCES WHERE THE
17 ATTORNEY GENERAL'S OFFICE HAS DETERMINED THAT
18 BECAUSE THERE MAY BE SOME REPUTATIONAL BENEFIT TO AN
19 INDIVIDUAL FLOWING FROM A DECISION, THAT IT COULD BE
20 DEEMED TO BE A FINANCIAL INTEREST. SO OUT OF AN
21 ABUNDANCE OF CAUTION, I WOULD RECOMMEND THAT YOU
22 ABSTAIN.

23 DR. PIZZO: CAN WE JUST HAVE A QUICK HANDS
24 RAISED OF HOW MANY PEOPLE ARE AFFECTED, SO WE'LL
25 KNOW. JUST MINOR VOICES.

BARRISTERS' REPORTING SERVICE

1 MR. SHEEHY: I THINK THAT THIS IS
2 ABSOLUTELY ESSENTIAL IF, AS A MATTER OF FIDUCIARY
3 RESPONSIBILITY, THAT BEFORE ALL OF THE MEMBERS OF
4 THE FIRST BOARD LEAVE, WE HAVE AN ASSESSMENT BY AN
5 ENTITY SUCH AS THE INSTITUTE OF MEDICINE, WHICH I
6 THINK MOST OF US KNOW IS THE PREMIERE ANALYTICAL --
7 ONE OF THE PREMIERE, NOT THE PREMIERE, ANALYTICAL
8 FORCE IN BIOMEDICINE, PART OF THE NATIONAL ACADEMY
9 OF SCIENCES AROUND SINCE ESTABLISHED BY ABRAHAM
10 LINCOLN. THE OFFER INDEPENDENT ADVICE TO
11 REPUBLICANS AND DEMOCRATS, TO THE CONGRESS, TO EACH
12 ADMINISTRATION. I'VE READ REPORTS THAT WERE OFFERED
13 TO PRESIDENT BUSH, I'VE READ REPORTS THAT WERE
14 OFFERED TO PRESIDENT CLINTON, PRESIDENT OBAMA.
15 EVERYONE RELIES ON THE IOM FOR EXPERT ADVICE.

16 AND SO I THINK THIS GIVES US AN
17 OPPORTUNITY TO GET AN OBJECTIVE, UNVARNISHED LOOK AT
18 THE WORK WE'VE DONE SO THAT WE CAN TELL THE PEOPLE
19 OF CALIFORNIA WHAT WE'VE DONE WITH THEIR MONEY.

20 THE ONLY THING I WOULD LIKE TO SEE IS IN
21 TERMS OF THE STATEMENT OF TASK IS, AND I WOULD LIKE
22 TO MOVE TO ADOPT THIS, BY THE WAY, IS TO ADD AN
23 ANALYSIS OF THE OUTPUT, MEANING THE GRANTS WE FUNDED
24 AND THEIR SCIENTIFIC AND ECONOMIC IMPACT. I THINK
25 WE SHOULD HAVE SOME METRICS, WE SHOULD HAVE SOME

BARRISTERS' REPORTING SERVICE

1 PUBLICATIONS, WE MAY HAVE SOME EARLY CLINICAL TRIAL
2 WORK. THERE ARE ECONOMISTS WITHIN THE INSTITUTE OF
3 MEDICINE THAT CAN GIVE US AN OBJECTIVE VIEW OF THE
4 ECONOMIC IMPACT OF THIS FUNDING THAT THIS AGENCY HAS
5 MADE THAT, I THINK, FOR ONCE WILL NOT GET ATTACKED.

6 CHAIRMAN KLEIN HAS BEEN DOING ECONOMIC
7 ANALYSIS GOING BACK TO THE CAMPAIGN, AND IT SEEMS
8 LIKE EVERY TIME WE DO ONE, PEOPLE CARP ON IT. BUT I
9 ACTUALLY BELIEVE THAT THIS TIME FROM THE INSTITUTE
10 OF MEDICINE, THE NUMBERS WE GET WILL SHOW THE PEOPLE
11 OF CALIFORNIA THAT THEY MADE A WISE INVESTMENT THAT
12 IS ALREADY BEGINNING TO PAY OFF IN TERMS OF JOBS, IN
13 TERMS OF INFRASTRUCTURE, IN TERMS OF PEOPLE MOVING
14 HERE AND DOING GREAT SCIENCE, AND THE POTENTIAL IN
15 THE NOT TOO DISTANT FUTURE OF CURES FOR PATIENTS AND
16 IMPROVEMENTS IN THEIR LIVES AND FOR THEIR FAMILIES.

17 SO I WOULD LIKE TO MOVE TO ADOPT THAT WITH
18 THAT ONE ADDITION.

19 CHAIRMAN KLEIN: AND, JEFF SHEEHY, ON YOUR
20 MOTION, DR. PRIETO, I THINK YOU HAD A SUGGESTION
21 THAT PERHAPS WE SHOULD LOOK AT PART OF THE 3.5
22 MILLION OR MORE OF FUNDS THAT I AND ED PENHOET AND
23 OTHERS RAISED FOR STUDIES AND CONFERENCES THAT IS
24 NOT COMING FROM THE TAXPAYER, BUT DONOR FUNDS, TO
25 PAY FOR THIS STUDY. SO IN THIS TIME OF ECONOMIC

BARRISTERS' REPORTING SERVICE

1 CONSTRAINTS IN CALIFORNIA, WE'RE USING DONOR FUNDS
2 TO PAY FOR THAT STUDY; IS THAT CORRECT?

3 DR. PRIETO: YEAH. THAT WAS THE MOTION I
4 INTENDED TO MAKE.

5 MR. SHEEHY: I'LL TAKE IT AS A FRIENDLY
6 AMENDMENT.

7 DR. PRIETO: IF YOU WOULD ACCEPT THAT AS A
8 FRIENDLY AMENDMENT.

9 MR. SHEEHY: WOULD YOU BE MY SECOND?

10 DR. PRIETO: I'LL BE HAPPY TO SECOND.

11 MR. SHEEHY: ART WAS THE SECOND. I'M
12 SORRY.

13 CHAIRMAN KLEIN: LET ME ASK AS WELL -- SO
14 I TALKED TO DR. POPE SPECIFICALLY ABOUT THIS ISSUE
15 OF WHETHER THEY WILL HAVE ECONOMISTS WHO WILL DO
16 ECONOMIC ANALYSIS --

17 MR. TORRES: MY QUESTION IS WHETHER
18 THEY'RE ABLE TO FORECAST IN THESE ECONOMIC TIMES.

19 CHAIRMAN KLEIN: THE RESPONSE THAT WE HAVE
20 TO DATE IS, IN FACT, THAT THEY CAN DO AN ECONOMIC
21 ANALYSIS FROM DR. POPE. BUT I WILL RECONFIRM THAT
22 WITH HIM. AND DR. BRYANT.

23 DR. BRYANT: I THINK IT'S AN EXCELLENT
24 IDEA. THE ONLY THING THAT I'M SLIGHTLY CONCERNED
25 ABOUT IS THAT THIS WILL COME OFF AS A NATIONAL --

BARRISTERS' REPORTING SERVICE

1 THE BENEFIT TO THE NATION; WHEREAS, WE'RE IN THE
2 POSITION OF TRYING TO EXPLAIN WHY CALIFORNIA SHOULD
3 HAVE SPENT ALL THIS MUCH MONEY. IF THERE IS A WAY
4 TO GET THAT ASPECT OF IT TOO, I THINK IT MIGHT --
5 OTHERWISE, I CAN SEE IT MIGHT BACKFIRE A LITTLE BIT
6 ON US.

7 CHAIRMAN KLEIN: SO, IN FACT, DR.
8 TROUNSON, WHILE YOU WERE OUT, I EXPLAINED THE RANGE
9 OF 22 TO 26 MONTHS INCLUDING WITH A GOAL THAT IT HAS
10 TO BE FINISHED, HOWEVER, IN 2012. AND IN TERMS OF
11 THIS, IF THEY DESIRE TO HAVE NATIONAL PROJECTIONS
12 AND WE WANT A SUBSET OF PROJECTIONS FOR CALIFORNIA,
13 I WOULD SUGGEST THAT WE PROVIDE PERHAPS, SINCE WE'RE
14 SPECIFICALLY PAYING FOR IT OUT OF DONOR FUNDS, WE
15 HAVE SUBSTANTIAL UNUSED FUNDS OVER THE LAST FIVE
16 YEARS, WE HAVE SOME FLEXIBILITY OF APPROXIMATELY 20
17 PERCENT IN CASE WE NEED A SEPARATE SUBSET OF
18 PROJECTIONS. IS THAT A REASONABLE AMENDMENT, THAT
19 IF WE DO -- IF THEIR APPROACH HAD BEEN TO DO
20 NATIONAL PROJECTIONS, BECAUSE THAT'S THEIR GENERAL
21 CHARGE, TO GET SEPARATE CALIFORNIA PROJECTIONS THAT
22 WE HAVE SOME FLEXIBILITY IN THE TOTAL DOLLAR AMOUNT
23 BY A 20-PERCENT AMOUNT?

24 MR. SHEEHY: THAT SOUNDS REASONABLE. I
25 WOULD LIKE TO INCLUDE IN THE MOTION THAT THIS IS

BARRISTERS' REPORTING SERVICE

1 COMPLETED BEFORE NOVEMBER 2012. WE CAN'T TELL THAT
2 THEM THAT THEY HAVE TO DO IT, BUT OUR REQUEST THAT
3 THIS -- WE WOULD LIKE THIS AT THE EIGHT-YEAR
4 ANNIVERSARY OF THE PASSAGE OF PROP 71 SO THAT WE CAN
5 TELL FOLKS WHAT WE'VE DONE.

6 CHAIRMAN KLEIN: WE WILL WORK TO THAT
7 GOAL.

8 MR. SHEEHY: AS AN OBJECTIVE.

9 DR. TROUNSON: SOME FLEXIBILITY, CHAIR,
10 WOULD BE VERY HELPFUL BECAUSE THE PROBLEM OF BSA AND
11 OTHER AUDITS FALLING AT THE SAME TIME, WE NEED TO
12 MAKE SURE WE'RE NOT SORT OF, YOU KNOW, IN THAT KIND
13 OF SITUATION. SO SOME FLEXIBILITY TO DO THIS.

14 CHAIRMAN KLEIN: RIGHT. SO 22 TO 26
15 MONTHS WOULD PUT IT ALL IN 2012, BUT ALSO WITH A
16 GOAL IN THE CENTER OF THAT TIME FRAME BEING NOVEMBER
17 OF 2010, BUT NO LATER THAN NOVEMBER OF 2012 AS A
18 GOAL.

19 MR. TORRES: ON THAT POINT, IN RESPONDING
20 TO PRESIDENT TROUNSON, UNDER THE SENATE BILL WHICH
21 IS ON THE SENATE FLOOR AS WE SPEAK, IT WILL PROVIDE
22 FOR A PERFORMANCE AUDIT, WHICH YOU'RE REFERENCING,
23 NOT NECESSARILY WOULD THE BSA COULD OR WE COULD
24 CHOOSE ANOTHER AGENCY -- ANOTHER ACCOUNTING FIRM AS
25 LONG AS THEY COMPLY WITH GOVERNMENT STANDARDS, AND

BARRISTERS' REPORTING SERVICE

1 THAT THAT WOULD HAVE TO GO OUT FOR BID FROM US NO
2 LATER THAN JULY 1 WHEN THE END OF THE FISCAL YEAR OF
3 2010-2011 HAS BEEN COMPLETED. SO THAT WOULD BEGIN
4 AT THAT POINT.

5 I WASN'T HERE AT THE TIME, BUT I
6 BELIEVE --

7 CHAIRMAN KLEIN: JULY 1, END OF THE FISCAL
8 YEAR OF?

9 MR. TORRES: 2010-11. SO I WAS NOT HERE
10 DURING THE FIRST BSA. HOW LONG DID THAT AUDIT TAKE?

11 DR. TROUNSON: SIX MONTHS.

12 MR. TORRES: SIX MONTHS. SO THAT'S THE
13 TIME.

14 DR. TROUNSON: IT WAS VERY TIME DEMANDING.
15 WE CHECKED WITH ARLENE CHIU, AND IT WAS A HUGE
16 AMOUNT OF TIME. WE KNOW THESE THINGS TAKE A LOT OF
17 TIME, SO WE NEED TO BE PRETTY CLEAR THAT WE DON'T
18 SORT OF FALL WITH TWO OF THEM ON US BECAUSE THAT'S
19 JUST IMPOSSIBLE.

20 CHAIRMAN KLEIN: THAT'S WHY WE AMENDED THE
21 TIME FRAME ON THIS PROPOSAL.

22 MR. SHEEHY: TO BE CLEAR ABOUT THE BURDEN,
23 WE'RE NOT COMMISSIONING THE SPANISH INQUISITION
24 HERE. I MEAN THE BSA IS A COMPLIANCE AUDIT, SO THEY
25 WANT TO SEE EVERY SINGLE CONFLICT OF INTEREST

BARRISTERS' REPORTING SERVICE

1 DOCUMENT FROM EVERY SINGLE WORKING GROUP MEETING TO
2 MAKE SURE THAT THEY WERE COMPLIED WITH. THAT IS
3 ONEROUS. I THINK HERE THEY'RE LOOKING AT OUR
4 STANDARDS AND SEEING WHETHER WE HAVE ACCEPTABLE
5 STANDARDS, WHICH IS NOT THE SAME LEVEL OF
6 DIFFICULTY. AND SO I THINK TO ANALOGIZE BETWEEN
7 THIS REPORT, WHICH IS LOOKING REALLY AT OUR
8 PROCESSES AND OUR OUTPUT, AND THE AUDIT THAT
9 LEGISLATURE IS COMMISSIONING, RIGHTLY, TO MAKE SURE
10 THAT WE ARE FULLY COMPLYING WITH ALL OF OUR
11 PROCESSES IN EVERY SINGLE INSTANCE ARE TWO DIFFERENT
12 THINGS AND WILL NOT PLACE THE SAME BURDEN.

13 DR. TROUNSON: BUT WE'RE USING 2,000,
14 ABOUT 2,000 HOURS ON THIS CURRENT ONE THAT WE'RE
15 JUST DOING IN OCTOBER. WE DO KNOW THAT WHATEVER IT
16 IS, THEY WILL ASK FOR DIFFERENT INFORMATION, OTHER
17 INFORMATION, UPDATED INFORMATION. WE'VE GOT TO
18 GENERATE THAT. WE KNOW THAT. WE GOT TO DO A PROPER
19 JOB ON IT. SO WE JUST WANT TO MAKE SURE THAT WE'RE
20 ABLE TO DO THAT, AND THAT'S WHY WE'RE JUST SAYING --

21 CHAIRMAN KLEIN: THAT'S WHY WE'VE MODIFIED
22 THE TIME FRAMES.

23 MR. ROTH: SO I HAVE A NUMBER OF COMMENTS
24 ON THIS. FIRST, I HAVE GREAT RESPECT FOR THE
25 INSTITUTE OF MEDICINE, AND THEY'D BE A FINE AGENCY

BARRISTERS' REPORTING SERVICE

1 TO LOOK AT SOMETHING LIKE THIS EXCEPT FOR THE FACT
2 THAT WE HAVE A LOT OF OTHER REVIEWS GOING ON,
3 INCLUDING THE SCIENTIFIC REVIEW. WE JUST HEARD
4 ABOUT THE FINANCIAL REVIEWERS THAT WE HAVE. AND
5 THEN THE NEW BILL CONTEMPLATES A PERFORMANCE REVIEW.
6 WE'VE DONE AN ECONOMIC IMPACT STUDY, WHICH WE'VE
7 ALREADY COMMISSIONED, AND I'M REALLY -- IT'S OKAY TO
8 SAY THAT THIS ISN'T GOING TO REQUIRE MUCH STAFF
9 TIME, BUT I'VE BEEN THROUGH THESE THINGS. THEY
10 REQUIRE A CONSIDERABLE AMOUNT OF BRINGING THEM UP TO
11 SPEED AND EDUCATING THEM ON THESE POLICIES.

12 I COULD GO ON AND ON ABOUT THAT. THE TIME
13 FRAME, REALLY I DON'T FIND THAT A PERSUASIVE
14 ARGUMENT. THIS AGENCY IS GOING TO GET BUSIER, NOT
15 LESS BUSY IN THAT PERIOD OF TIME. AND IF YOU START
16 A STUDY LIKE THIS AND IT TAKES 24 MONTHS TO BE DONE,
17 BECAUSE YOU'RE GOING TO GO SLOW OR STRING IT OUT,
18 THE DATA IS GOING TO BE STALE BY THE TIME YOU GET TO
19 THE END, AND YOU ALMOST HAVE TO START OVER.

20 THE THIRD IS I WOULD JUST CAUTION THAT THE
21 OUTCOME ON SOMETHING LIKE THIS CAN CUT BOTH WAYS.
22 AND TO GO IN JUST SORT OF BLIND TRUST THAT THEY'RE
23 GOING REACH THE CONCLUSION YOU WANT THEM TO REACH, I
24 DON'T THINK IS A FOREGONE CONCLUSION. SO YOU AT
25 LEAST OUGHT TO THINK ABOUT THE DOWNSIDE OF A RATHER

BARRISTERS' REPORTING SERVICE

1 CRITICAL ONE.

2 AND FINALLY, THE FUNDS, I UNDERSTAND THAT
3 THE MONEY WOULD COME FROM A DIFFERENT SOURCE, BUT
4 THAT'S THE ONLY MONEY WE HAVE RIGHT NOW TO DO THINGS
5 THAT WE CAN'T DO WITH THE STATE FUNDS. SO EVERY
6 TIME YOU DEplete THAT, YOU TAKE AWAY A LITTLE BIT OF
7 YOUR ABILITY TO HAVE SOME MONEY TO DO THINGS YOU
8 MIGHT WANT TO DO.

9 SO I HAVEN'T MADE A DECISION YET ABOUT
10 WHICH WAY I'D LIKE TO GO, BUT I THINK IT NEEDS SOME
11 MORE THOUGHT BEFORE WE JUST GO AHEAD AND SIGN UP FOR
12 YET ANOTHER STUDY.

13 CHAIRMAN KLEIN: DUANE, IN TERMS OF THE
14 FUNDING, WE'VE HAD OVER THREE AND A HALF MILLION
15 SITTING THERE FOR THE LAST FIVE YEARS SINCE I RAISED
16 THIS MONEY. IT WAS RAISED FOR THIS PARTICULAR
17 PURPOSE, AND IT'S NOT A NONRENEWABLE RESOURCE. ANY
18 BOARD MEMBER, JUST LIKE I DID, COULD GO OUT AND
19 RAISE CONTRIBUTIONS FOR THIS. BUT I RAISED THE
20 MONEY SO THAT WE COULD HAVE ACCOUNTABILITY STUDIES,
21 AND WE OWE ACCOUNTABILITY TO THE PUBLIC. AND
22 CERTAINLY WE CAN'T ANTICIPATE THAT WE KNOW EXACTLY
23 HOW IT COMES OUT. WE HAVE GREAT CONFIDENCE, BUT
24 HOPEFULLY WE'LL LEARN SOMETHING FROM THIS STUDY.
25 AND THEN WE'LL HAVE ENOUGH TIME DURING OUR TIME

BARRISTERS' REPORTING SERVICE

1 PERIOD OF THIS INITIATIVE TO FOLLOW THEIR
2 RECOMMENDATIONS AND FURTHER IMPROVE THIS
3 INSTITUTION.

4 WE OWE THE ACCOUNTABILITY AND THE RIGOR OF
5 SUBMITTING OURSELVES TO A TRULY INDEPENDENT BODY --
6 AS YOU POINT OUT, THEY ARE -- AND BEING RESPONSIVE
7 TO THAT BODY SO THAT THE PUBLIC KNOWS WE'VE REALLY
8 FULFILLED OUR OBLIGATIONS.

9 ARE THERE OTHER COMMENTS?

10 DR. BRENNER: I JUST WANTED TO SORT OF
11 EXPAND A LITTLE BIT. FIRST OF ALL, I THINK IT'S
12 ALWAYS A GOOD EXERCISE TO HAVE AN EXTERNAL REVIEW.
13 I THINK IT REALLY HELPS THE INSTITUTIONS TO HAVE A
14 COMPLETELY OBJECTIVE GROUP COME IN AND LOOK VERY
15 CAREFULLY AT WHAT YOU ARE DOING. I THINK THAT'S THE
16 BASE I WANT TO START WITH.

17 I DO THINK, THOUGH, WE HAVE TO BE REALLY
18 CAREFUL TO DEFINE CLEARLY WHAT THE DELIVERABLES ARE.
19 WHAT EXACTLY DO WE WANT THEM TO LOOK AT AND WHAT WE
20 WANT THEM TO ASSESS BECAUSE THERE ARE MANY, MANY
21 TOPICS THEY CAN LOOK INTO. ONE OF MY FEARS IS THAT
22 IT'S A VERY INTERESTING, AGGRESSIVE ORGANIZATION.
23 AND ONCE YOU ASK THEM TO, IF YOU DON'T CLEARLY
24 DEFINE WHAT YOU WANT, THEY'LL LOOK AT SOMETHING THAT
25 YOU'RE NOT INTERESTED IN THAT'S NOT REAL IMPORTANT

BARRISTERS' REPORTING SERVICE

1 TO US. AND THAT'S THE RESULT YOU'LL GET, AND WE'LL
2 BE A MILLION DOLLARS POORER.

3 AND THE THIRD THING I WANT TO KNOW, IS
4 THERE ANY POSSIBILITY TO GET BUY-IN FROM WHOEVER --
5 WHATEVER CONSTITUENTS WE THINK ARE REALLY IMPORTANT
6 THAT THEY AGREE THAT THIS IS REALLY IMPORTANT AND
7 THAT IT WILL BE A DEFINING REVIEW AND IT WON'T BE
8 THROWN OUT LIKE SO MANY OTHER IMPORTANT THINGS HAVE
9 BEEN DONE SO THAT WE CAN SAY WE AGREE THAT THE
10 INSTITUTE OF MEDICINE IS THE LAST WORD IN THESE
11 THREE TOPICS THAT WE THINK ARE REALLY IMPORTANT AT
12 THIS POINT IN OUR ORGANIZATION SO THAT IT WILL HAVE
13 STAYING POWER AND IT WILL NOT BE DISMISSED EASILY.

14 CHAIRMAN KLEIN: TWO THINGS, IN TAB 12,
15 THE FIVE AREAS OF FOCUS ARE THE SCOPE.

16 DR. BRENNER: IT OUGHT TO BE MORE
17 PRECISE.

18 CHAIRMAN KLEIN: AND IN THE CONTRACT, WE
19 CAN REFINE THAT DOWN, INCLUDING SOME OF THE COMMENTS
20 THAT HAVE BEEN MADE HERE TODAY. BUT THERE ARE MANY
21 CONSTITUENCIES. SO SOME CONSTITUENCIES ARE GOING TO
22 LOOK TO THE BSA AUDIT BECAUSE THAT'S THEIR
23 ORIENTATION. SOME CONSTITUENCIES WILL LOOK TO THE
24 NATIONAL ACADEMIES INSTITUTE OF MEDICINE BECAUSE
25 THEY UNDERSTAND THAT GOLD STANDARD. SOME

BARRISTERS' REPORTING SERVICE

1 CONSTITUENCIES WILL LOOK TO SOME OF THE OTHER
2 REVIEWS THAT ARE DONE. THERE WON'T BE A DEFINITIVE
3 FINAL PROGRAM BECAUSE DIFFERENT CONSTITUENCIES HAVE
4 DIFFERENT REFERENCE POINTS.

5 BUT HAVING DEALT WITH A COUPLE OF HUNDRED
6 DIFFERENT CONSTITUENT GROUPS, I CAN TELL YOU THAT
7 THERE'S -- FROM MY PERSONAL EXPERIENCE, I WAS, AS A
8 BOARD MEMBER, I WOULD SAY THAT THERE'S A VERY HIGH
9 CREDIBILITY IN A CONTRIBUTION TO OUR ABILITY TO
10 MESSAGE TO THE PUBLIC ABOUT OUR PERFORMANCE.
11 SPECIFICALLY IS OUR PEER REVIEW AND THE
12 CONFIDENTIALITY OF THAT IMPORTANT? IT IS A RIGOROUS
13 SYSTEM? WE HAVE DEFENDED AGAINST CONFLICTS OF
14 INTEREST. ARE WE DOING IT PROPERLY? IS OUR
15 CONFLICTS POLICIES THAT WE'RE CONSTANTLY ATTACKED
16 ON, ARE THEY, IN FACT, THE BEST IN THE NATION OR THE
17 WORLD, FOR THAT MATTER?

18 FOR THIS GROUP TO COME OUT AND GIVE US AN
19 OPINION ON THAT IS A VERY VALUABLE POINT.

20 DR. PRICE: BOB, I UNDERSTAND THAT, YET IF
21 YOU THINK ABOUT THE GROUPS THAT HAVE BEEN HAMMERING
22 US ON THOSE VERY THINGS, THE INSTITUTE OF MEDICINE
23 IS NOT GOING TO HAVE ANY PARTICULAR WEIGHT WITH
24 THEM. AND, INDEED, THEY'VE ALREADY SPOKEN, AT LEAST
25 ONE OF THEM HAS, OUR FRIENDLY BLOGGER, *THE*

BARRISTERS' REPORTING SERVICE

1 CALIFORNIA REPORT, WHO HAS JUST RECENTLY BLOGGED AND
2 SAYS, "OH, THIS IDEA IS JUST FOR CIRM TO HIRE SOME
3 OF THEIR ACADEMIC BUDDIES TO GIVE THEM AN A+ SO THAT
4 WE CAN GET ANOTHER \$6 BILLION FROM THE TAXPAYERS OF
5 CALIFORNIA." THAT'S THE MESSAGE FROM JOHN Q.
6 PUBLIC.

7 CHAIRMAN KLEIN: NO. THAT'S NOT FROM JOHN
8 Q. IT'S FROM -- WE WILL NEVER CONVINCING THOSE
9 THAT --

10 DR. PRICE: EXACTLY.

11 CHAIRMAN KLEIN: -- NEVER CONVINCING THE
12 PEOPLE THAT ARE ADAMANT AGAINST US. BUT FOR THE
13 PUBLIC AND FOR THE CONSTITUENT GROUPS THAT ARE
14 REASONED AND PREPARED TO LOOK AT EVIDENCE, THIS IS A
15 VERY IMPORTANT VALIDATION THAT THEY CAN LOOK TO TO
16 SEPARATE OUT WHAT IS A FALSE CLAIM FROM REAL
17 PERFORMANCE.

18 WHAT I'D LIKE TO DO IS SEE IF WE HAVE
19 OTHER COMMENTS.

20 MR. SHEEHY: JUST I THINK, NOTWITHSTANDING
21 DAVE JENSEN, I BELIEVE THE MEDIA -- I BELIEVE IF
22 THIS REPORT, EDITORIAL BOARDS OF MAJOR CALIFORNIA
23 NEWSPAPERS WOULD BE TAKEN SERIOUSLY FOR THE VERY
24 REASON THAT DUANE'S WORRIED ABOUT IT BECAUSE YOU
25 CAN'T CONTROL THE OUTPUT. I'VE WORKED WITH

BARRISTERS' REPORTING SERVICE

1 JOURNALISTS. I'VE TALKED TO JOURNALISTS ABOUT IOM
2 REPORTS. AND TO A PERSON THEY VIEW THIS AS AN
3 OBJECTIVE, POWERFUL ANALYSIS THAT IS COMPLETELY
4 UNBIASED.

5 SO IT MAY NOT CONVINCING SOME OF OUR
6 NAYSAYERS, BUT FOR A VERY IMPORTANT CONSTITUENCY,
7 WHICH ARE THE EDITORIAL BOARDS AND THE PEOPLE WHO
8 REALLY UNDERSTAND HOW MEDICAL SCIENCE IS DONE, AND I
9 THINK IT'S GOING TO BE AN INCREDIBLY POWERFUL TOOL
10 FOR US TO REALLY EXPLAIN WHAT WE'VE BEEN DOING. I
11 THINK MANY MEMBERS OF THE LEGISLATURE RECOGNIZE
12 THIS. AND I'M CERTAIN MEMBERS IN CONGRESS RECOGNIZE
13 THE VALUE OF AN IOM ANALYSIS BECAUSE THEY USE IT TO
14 INFORM THEIR OWN DECISION-MAKING PROCESS.

15 CHAIRMAN KLEIN: DR. BRYANT.

16 DR. BRYANT: YES. I WAS JUST WONDERING IF
17 PEOPLE FEEL THAT IT WOULD BE A VALUABLE TOOL TO
18 COUNTERBALANCE THE LITTLE HOOVER COMMISSION, WHICH
19 IS STILL AROUND AND MAY NOT -- I KNOW THE TIMING IS
20 A LITTLE OFF BECAUSE IT'S GOING TO BE DELAYED IN
21 TIME.

22 CHAIRMAN KLEIN: I THINK IT IS A --

23 DR. BRYANT: THEY'RE GOING TO ADDRESS SOME
24 OF THE SAME ISSUES.

25 CHAIRMAN KLEIN: EXACTLY. SO UNLESS

BARRISTERS' REPORTING SERVICE

1 THERE'S MORE BOARD COMMENT, I'D LIKE TO SEE IF
2 THERE'S PUBLIC COMMENT.

3 MR. REED: IN OHIO THE THIRD FRONTIER WAS
4 A VERY CAREFULLY PLANNED STRUCTURE TO PUT \$700
5 MILLION INTO FUTURE-ORIENTED ENTERPRISES LIKE
6 BIOMEDICINE, AND THEY HAD IMPORTANT OBJECTIVE
7 REPORTS AS BACKUP FOR THEM. I THINK A LOT OF
8 PEOPLE -- WE LIVE THIS, BUT FOR A LOT OF PEOPLE,
9 THEY WILL WAIT TILL THE NEXT INCIDENT REALLY TOUCHES
10 THEIR LIVES, LIKE A VOTE. THAT'S WHEN THEY'LL
11 DECIDE. I THINK IT'S CRUCIAL THAT WE HAVE, WHATEVER
12 THE RISKS ARE, A UNIVERSALLY RESPECTED BODY GIVE AN
13 OBJECTIVE OVERVIEW OF THE WORK THAT HAS BEEN DONE.

14 CHAIRMAN KLEIN: THANK YOU. SO UNLESS
15 THERE'S ADDITIONAL COMMENT, I'D LIKE TO CALL THE
16 QUESTION HERE. AND COULD I HEAR ALL THOSE IN FAVOR.

17 (CHORUS OF AYES.)

18 OPPOSED?

19 MR. ROTH: NO.

20 MS. KING: JUST IN CASE WE HAVE PEOPLE ON
21 THE PHONE, WILLIAM BRODY. MICHAEL FRIEDMAN.

22 WE HAVE A QUORUM WITHOUT THEM, SO THE
23 MOTION CARRIES WITH ONE NO VOTE FROM MR. ROTH.

24 DR. POMEROY: AND THREE ABSTAINS.

25 DR. PRICE: NO.

BARRISTERS' REPORTING SERVICE

1 CHAIRMAN KLEIN: DR. TROUNSON, WE HAVE
2 ITEM 8, AND COULD YOU PLEASE -- MR. HARRISON.

3 MR. HARRISON: JUST FOR THE RECORD, CHAIR,
4 COULD WE ASK THOSE MEMBERS WHO ABSTAINED IN THE
5 VOICE VOTE TO RAISE THEIR HANDS. PIZZO, HAWGOOD,
6 PENHOET, AND BRENNER FOR THE RECORD.

7 CHAIRMAN KLEIN: ALL RIGHT.

8 DR. TROUNSON: SO DR. ROBSON IS TO PRESENT
9 THIS, CHAIR.

10 DR. ROBSON: SIGNING BACK IN. OKAY.
11 THANK YOU VERY MUCH. THIS IS SOMETHING COMPLETELY
12 DIFFERENT AND DOESN'T REQUIRE A VOTE. YOU'VE
13 ALREADY PASSED THE POLICY ON THIS ISSUE.

14 CHAIRMAN KLEIN: THIS IS A VERY IMPORTANT
15 INFORMATIONAL ITEM. IT SAYS CONSIDERATION, MR.
16 HARRISON.

17 MR. HARRISON: CHAIR, WE FAVOR PHRASING
18 AGENDA ITEMS WITH THE WORD "CONSIDERATION" JUST TO
19 PRESERVE THE BOARD'S AUTHORITY TO TAKE ACTION IF IT
20 SO CHOOSES. THIS IS AN INFORMATIONAL ITEM. WE
21 DON'T EXPECT TO ASK THE BOARD TO TAKE ANY ACTION.
22 AND IT'S ALSO AN ITEM AS TO WHICH CERTAIN MEMBERS
23 HAVE TO RECUSE THEMSELVES BECAUSE IT PERTAINS TO THE
24 MAJOR FACILITIES AWARDS.

25 CHAIRMAN KLEIN: BEFORE THERE ARE

BARRISTERS' REPORTING SERVICE

1 QUESTIONS AS RELATED TO THIS ADMINISTRATION, WE'LL
2 NEED TO CLEAR THOSE QUESTIONS.

3 DR. ROBSON: SO I'M REPORTING ON THE
4 STAFF'S IMPLEMENTATION PLAN OF THE POLICY THAT WAS
5 APPROVED BY THE BOARD IN OCTOBER OF 2007 REGARDING
6 REDUCTIONS FOR FACILITIES PART B PAYMENTS FOR
7 INSTITUTIONS -- CIRM GRANTS TO INSTITUTIONS THAT
8 HAVE MAJOR FACILITIES.

9 THIS IS A BIT OF AN ESOTERIC TOPIC, SO I
10 THOUGHT MAYBE I WOULD GO BACK THROUGH THE RATIONALE
11 AND THE HISTORY JUST VERY BRIEFLY. YOU HAVE A
12 COUPLE OF DOCUMENTS IN YOUR BINDER ABOUT THIS. IF
13 YOU GO BACK TO PROPOSITION 71, PROPOSITION 71 ALLOWS
14 CIRM GRANTS TO PAY FOR THE MAINTENANCE AND
15 OPERATIONS OF THE FACILITIES THAT ARE USED FOR THE
16 RESEARCH, AND IT ALSO ALLOWS FOR A RESEARCH FUNDING
17 SHALL INCLUDE AN ALLOWANCE FOR MARKET LEASE RATE OR
18 REIMBURSEMENT FOR THE FACILITY. IN OTHER WORDS, WE
19 CAN ESSENTIALLY PAY TO RENT THE RESEARCH SPACE. AND
20 THAT'S DONE IN DIFFERENT WAYS.

21 THE EXCEPTION TO THIS IS IN THE CASE OF
22 MAJOR FACILITIES. WE SHOULD NOT -- THE PROPOSITION
23 71 FORBIDS US FROM PAYING FOR RENTING SPACE THAT
24 ESSENTIALLY WE PAY TO BUILD.

25 LET ME JUST GO THROUGH HOW THIS IS HANDLED

BARRISTERS' REPORTING SERVICE

1 RIGHT NOW, HOW WE PAY FOR THESE FACILITIES COSTS.
2 WE FOLLOW A MODEL THAT WAS DEVELOPED BY THE NIH, AND
3 WE USE REIMBURSEMENT RATES THAT WERE NEGOTIATED
4 BETWEEN THE VARIOUS INSTITUTIONS AND THE NIH. WE
5 DON'T HAVE THE CAPACITY TO DO THAT OURSELVES, SO
6 WE'VE JUST ADOPTED THE NIH POLICIES.

7 SO NIH PAYS THESE COSTS AS DIRECT COSTS ON
8 RESEARCH GRANTS IN TWO WAYS. PART A IS FOR
9 OPERATIONS AND MAINTENANCE AND LIBRARY COSTS, SO
10 THAT'S ELECTRICITY, LIGHT, JANITORIAL SERVICE, AND
11 SO FORTH. AND THE RANGE OF THAT RATE FROM THE
12 VARIOUS INSTITUTIONS THAT WE FUND IS BETWEEN 10 AND
13 46 PERCENT. PART B IS THE COST OF WHAT I WAS
14 REFERRING TO EARLIER, THE SORT OF MARKET-GOING LEASE
15 RATE OR COULD BE DEPRECIATION OR RENT. IT'S
16 CALCULATED DIFFERENT WAYS AT DIFFERENT INSTITUTIONS.
17 AND THAT PERCENTAGE RANGES FROM 5 TO 49 PERCENT.
18 AND THAT'S THE ONE WE'RE FOCUSED ON HERE TODAY.

19 I SHOULD MENTION THAT ON AVERAGE THE TWO
20 TOGETHER FOR OUR INSTITUTIONS IS ABOUT 35 TO 36
21 PERCENT ON TOP OF OUR GRANTS. WHAT WE'RE SAYING
22 HERE IS THAT WHAT PROPOSITION 71 STIPULATES IS THAT
23 FOR RESEARCH CONDUCTED IN A MAJOR FACILITY, THAT
24 FACILITIES PART B PAYMENT IS NOT ALLOWED, AND IT'S
25 NOT ALLOWED BECAUSE CIRM PAID FOR THE FACILITY. AND

BARRISTERS' REPORTING SERVICE

1 IF WE PAID THAT, WE'D ESSENTIALLY BE PAYING TWICE
2 FOR THOSE RESEARCH FACILITIES.

3 JUST TO GIVE YOU AN EXAMPLE OF WHAT THE
4 IMPACT OF THIS IS ON A GRANT, I'VE JUST DONE THIS
5 SORT OF HYPOTHETICALLY. I'VE JUST GIVEN TWO
6 EXAMPLES HERE OF A MILLION DOLLARS IN RESEARCH
7 FUNDS, DIRECT RESEARCH FUNDS, FACILITIES. IF IT'S
8 DONE OUTSIDE OF A CIRM FACILITY, THERE WOULD BE
9 \$200,000 ADDED. I'VE JUST USED A 20-PERCENT RATE AS
10 AN AVERAGE RATE AND A 16-PERCENT RATE AS AN AVERAGE
11 RATE FOR FACILITIES B. THERE WOULD BE AN ADDITIONAL
12 \$200,000 FOR FACILITIES PART A, 160,000 FOR
13 FACILITIES PART B, AND THEN WE PAY AN OVERHEAD RATE,
14 WHICH IS 20 PERCENT ON TOP OF THOSE THREE DIRECT
15 RATES, WHICH WOULD BRING THE TOTAL OF THAT AWARD TO
16 1,632,000.

17 FOR THE SAME INSTITUTION, IF THE RESEARCH
18 WAS DONE IN THE MAJOR FACILITY, THERE WOULD BE NO
19 FACILITIES PART B RATE, AND THEN THE OVERHEADS WOULD
20 BE REDUCED COMMENSURATE, SO THE REDUCTION WOULD BE
21 ABOUT \$200,000 IN THAT CASE.

22 NOW, THIS IS A SUMMARY OF THE POLICY THAT
23 WAS APPROVED BY THE ICOC UNANIMOUSLY IN OCTOBER OF
24 2007. AND WHAT IT STIPULATES IS THAT MAJOR
25 FACILITIES SHALL BE USED ONLY FOR STEM CELL

BARRISTERS' REPORTING SERVICE

1 RESEARCH. STEM CELL RESEARCH MUST BE HOUSED IN A
2 MAJOR FACILITY AS DESCRIBED IN THE APPLICATION FOR
3 THAT FACILITY. SO IN OTHER WORDS, YOU HAVE TO
4 BASICALLY DO THE RESEARCH IN THE FACILITY YOU
5 PROMISED YOU WOULD DO. CIRM WILL NOT PAY FOR
6 FACILITIES PART B FOR ANY RESEARCH IN THE MAJOR
7 FACILITY. SO IF THERE'S ADDITIONAL RESEARCH THAT
8 COMES INTO THE MAJOR FACILITY IN ADDITION TO WHAT
9 WAS DESCRIBED IN THE APPLICATION, WE WOULDN'T PAY
10 FOR FACILITIES PART B ON THAT RESEARCH.

11 FINALLY, CIRM WILL TRACK THE FACILITIES
12 PART B REDUCTION. AND ONCE, FOR ANY INSTITUTION,
13 THE AGGREGATE OF ALL THE REDUCTIONS WERE TO REACH
14 THE AMOUNT OF THE GRANT THAT WAS AWARDED, AT THAT
15 POINT WE WOULD BEGIN TO PAY FACILITIES PART B AGAIN.

16 SO THIS IS HOW WE'LL BE IMPLEMENTING THIS.
17 WE HAD TO COME UP WITH A WAY TO DO THIS THAT WAS
18 PRACTICAL AND EASY FOR THE STAFF AND FOR THE
19 GRANTEES. WE TRIED TO COME UP WITH A POLICY, BUT
20 ALSO THAT WAS PERFECTLY CONSISTENT WITH THE POLICY
21 ITSELF. SO THE PLAN THAT YOU HAVE OUTLINED IN YOUR
22 BINDER IS SUMMARIZED HERE. SO AN INSTITUTION WITH A
23 CIRM MAJOR FACILITY WILL NOT RECEIVE FACILITIES PART
24 B FROM CIRM FOR RESEARCH DESCRIBED IN ITS MAJOR
25 FACILITIES APPLICATION OR FOR ANY RESEARCH BEING

BARRISTERS' REPORTING SERVICE

1 CONDUCTED IN THE MAJOR FACILITY.

2 DR. PENHOET: JOHN, WHAT ABOUT THE CASE
3 WHERE WE ONLY PAID FOR HALF THE FACILITY? MATCHING
4 FUNDS WERE USED FROM SOME OTHER SOURCE.

5 DR. ROBSON: WELL, MATCHING FUNDS WERE
6 REQUIRED FOR ALL OF THE FACILITIES, BUT PROPOSITION
7 71 DOESN'T MENTION MATCHING FUNDS, NOR DOES THE
8 POLICY MENTION MATCHING FUNDS IN THIS CONTEXT. IT
9 JUST SAYS IF WE PAID FOR PART OF THE FACILITY, IF
10 IT'S IN THAT APPLICATION, WE CAN'T FUND THAT
11 FACILITIES PART B ON THOSE.

12 DR. PENHOET: EVEN THOUGH WE DIDN'T FUND
13 THE WHOLE FACILITY, WE ONLY FUNDED PART OF THE
14 FACILITY.

15 DR. ROBSON: CORRECT. BUT THEY'RE ONLY ON
16 THE HOOK FOR THE AMOUNT THAT WE PROVIDED.

17 CHAIRMAN KLEIN: SO IT'S IMPORTANT HERE
18 THAT -- MR. HARRISON, COMMENT ON THE PARAMETERS OF
19 THIS DISCUSSION.

20 MR. HARRISON: SINCE DR. PENHOET JUST
21 POSED A QUESTION FOR INFORMATIONAL PURPOSES, IT'S
22 OKAY. BUT THE MEMBERS WHO CAN PARTICIPATE IN THE
23 DISCUSSION OF THIS ITEM ARE GIBBONS, KLEIN, LOVE,
24 QUINT, ROTH, SAMUELSON, SERRANO-SEWELL, SHESTACK,
25 AND TORRES.

BARRISTERS' REPORTING SERVICE

1 CHAIRMAN KLEIN: THANK YOU. QUESTION IS
2 GOOD FOR EVERYONE'S BENEFIT. THANK YOU.

3 DR. ROBSON: OKAY. SO NOW, THERE WOULD BE
4 CASES IN WHICH AN INSTITUTION COULD RECEIVE
5 FACILITIES PART B IF THEY HAVE A MAJOR FACILITY, AND
6 THAT'S OUTLINED HERE. SO IT COULD RECEIVE
7 FACILITIES PART B IF THE INSTITUTION WAS TO CERTIFY
8 THAT THE PI WAS NOT IDENTIFIED IN THE MAJOR
9 FACILITIES APPLICATION AS BEING SOMEONE WHO WOULD BE
10 DOING THEIR RESEARCH WITHIN THE FACILITY. MANY OF
11 THESE APPLICATIONS INCLUDED THE NAMES OF PEOPLE WHO
12 WOULD BE INVOLVED WITH THE RESEARCH, BUT THAT THEY
13 WOULDN'T BE HOUSED WITHIN THE FACILITIES. SO IT'S
14 JUST THOSE WHO ARE IDENTIFIED AS BEING HOUSED IN THE
15 FACILITY. THE PI WAS NOT IDENTIFIED IN THE SPACE
16 PLAN FOR THE MAJOR FACILITY, WHICH IS SOMETHING
17 WE'RE RECEIVING FROM THESE FACILITIES AS THEY OPEN.
18 TWO YEARS HAVE PASSED OR MORE SINCE THEY SUBMITTED
19 THE APPLICATION, SO THEY'RE GIVING US REVISED SPACE
20 PLANS.

21 FINALLY, THAT THE PI WILL BE HOUSED --
22 WILL BE DOING THEIR RESEARCH OUTSIDE THE INSTITUTE
23 AND WILL NOT BE USING THE MAJOR FACILITY EXCEPT
24 OCCASIONALLY FOR SHARED SPECIALIZED RESOURCES.

25 NOW, JUST AS A COUPLE OF OTHER ADDITIONAL

BARRISTERS' REPORTING SERVICE

1 DETAILS, IF THERE'S A CO-PI ON A GRANT, WE WOULD
2 TREAT THE BUDGET FOR THE CO-PI AND THE BUDGET FOR
3 THE PI SEPARATELY IN APPLYING THIS POLICY.

4 FINALLY, THE TIMING. THIS WOULD TAKE
5 EFFECT WHEN THE FACILITIES ARE READY FOR OCCUPANCY.
6 IT WOULD APPLY TO ALL NEW GRANTS SUBSEQUENT TO THAT
7 DATE, AND IT WOULD ALSO BE APPLIED TO GRANTS THAT
8 WERE ONGOING BEGINNING AT THE NEXT ANNUAL BUDGET
9 RENEWAL YEAR.

10 CHAIRMAN KLEIN: SO, DR. ROBSON, JUST TO
11 FURTHER EXPLICATE THIS, IF, IN FACT, A PI IN THE
12 FACILITY HAS A CO-PI WHO'S IN THE CHEMISTRY
13 BUILDING, MY UNDERSTANDING IS THAT CO-PI WOULD HAVE
14 A SEPARATE BUDGET, AND THEY WOULD STILL GET PART B;
15 IS THAT CORRECT?

16 DR. ROBSON: IF THE CO-PI WAS AT THE SAME
17 INSTITUTION, USUALLY WHEN THEY'RE IN ONE
18 INSTITUTION, IT'S NOT A CO-PI. IT'S A
19 CO-INVESTIGATOR, IF I'M CORRECT, PAT?

20 DR. OLSON: IT COULD BE A CO-PI IN THAT
21 SITUATION.

22 DR. ROBSON: OKAY. IT COULD BE. THAT
23 WOULD BE THE CASE. IT WAS A CO-PI IN THE SAME
24 INSTITUTION OR IN A DIFFERENT INSTITUTION, THEIR
25 BUDGETS ARE EACH HANDLED SEPARATELY. BUT IF THAT

BARRISTERS' REPORTING SERVICE

1 CO-PI IN THE CHEMISTRY DEPARTMENT WAS DOING A GOOD
2 PART OF THEIR WORK WITHIN THE MAJOR FACILITY, THEN
3 THEY WOULD NOT GET FACILITIES PART B. BUT IF THE
4 INSTITUTION CERTIFIED THAT, NO, THE CHEMIST IS DOING
5 ALL OF HIS OR HER WORK IN THE CHEMISTRY DEPARTMENT,
6 THEN THEY WOULD GET IT.

7 CHAIRMAN KLEIN: BECAUSE WE WANTED TO MAKE
8 SURE WE DIDN'T HAVE A DISINCENTIVE FOR COLLABORATION
9 FROM DEPARTMENTS OUTSIDE OF THE CENTRAL FACILITY.
10 SO, DR. HAWGOOD, I'M NOT SURE THAT YOU CAN --

11 DR. HAWGOOD: MY QUESTION IS CAN I ASK AN
12 INFORMATIONAL OR A CLARIFICATION QUESTION?

13 MR. HARRISON: YOU CAN ASK AN
14 INFORMATIONAL QUESTION.

15 DR. HAWGOOD: COULD YOU GO BACK TWO
16 SLIDES?

17 DR. ROBSON: NEXT QUESTION.

18 DR. HAWGOOD: SO IF AN INVESTIGATOR WAS
19 NAMED IN THE GRANT AS TO GO INTO THE BUILDING, BUT
20 IN THE TWO YEARS THAT HAVE ELAPSED, FOR VARIOUS
21 PROGRAMMATIC REASONS, NOW THE DECISION IS THAT
22 PERSON'S LAB WILL NOT GO INTO THE BUILDING AND,
23 THEREFORE, WOULD NOT APPEAR ON THE SPACE PLAN,
24 THEY'LL GET PART B?

25 DR. ROBSON: SO OUR INTERPRETATION OF THE

BARRISTERS' REPORTING SERVICE

1 POLICY IS THAT THE POLICY WAS FAIRLY CLEAR THAT SAID
2 THAT WHAT YOU PROPOSED TO DO IN THE APPLICATION THE
3 INSTITUTIONS ARE OBLIGATED TO DO. SO IN THAT CASE
4 THE PERSON WAS PROPOSED TO BE IN THE BUILDING.
5 PRESUMABLY PART OF THE REASON THAT THE APPLICATION
6 WAS FUNDED WAS BASED ON THAT PERSON'S PROGRAM AS
7 PARTICIPATING, SO THEY WOULD NOT GET FACILITIES PART
8 B.

9 CHAIRMAN KLEIN: SO CAN I ASK DR. TROUNSON
10 A QUESTION? SO, DR. TROUNSON, LET'S ASSUME THAT THE
11 BUILDING IS COMPLETELY OCCUPIED, BUT ONE OF THE
12 PEOPLE WHO WAS ORIGINALLY NAMED TO BE IN THE
13 BUILDING CAN'T BE IN THE BUILDING BECAUSE THERE'S
14 NOT ENOUGH SPACE FOR THEM. IS THERE A WAY THAT THE
15 PRESIDENT CAN MAKE A REALISTIC DECISION THAT THE
16 INTENT HAS BEEN FOLLOWED, AND THAT THERE JUST WASN'T
17 SUFFICIENT SPACE TO ACCOMMODATE THIS PERSON? HOW
18 WOULD YOU APPROACH THIS QUESTION?

19 DR. TROUNSON: WELL, I THINK I PROBABLY
20 HAVE TO TAKE THAT ON ADVICE, CHAIR. MY
21 UNDERSTANDING IS THAT THAT WAS A COMMITMENT,
22 ESSENTIALLY A CONTRACTUAL COMMITMENT IN THE GRANT
23 APPLICATION PROCESS. AND IF SO, IF THEY HADN'T BEEN
24 INCLUDED IN THERE, THE SPACE DESIGN WOULD HAVE
25 INCLUDED THEM BEING IN IT. SO THAT WOULD BE THEN --

BARRISTERS' REPORTING SERVICE

1 THEY WOULD HAVE BEEN DISPLACED BY SOMEONE ELSE.

2 AND SO I THINK IT'S A FAIRLY DIFFICULT ONE
3 TO RULE ON WITHOUT GOING BACK TO SOME LEGAL ADVICE.
4 AND I WANT THE TIME TO DETERMINE THAT BECAUSE
5 EVERYTHING THAT I KNOW ABOUT THIS FACILITIES IS THAT
6 WE'VE KEPT AS CLEAR AS WE CAN TO THE ORIGINAL
7 APPLICATIONS AND INTENT.

8 CHAIRMAN KLEIN: ABSOLUTELY. BUT, FOR
9 EXAMPLE, IN THE PARADIGM CASE, IF THE PERSON WAS
10 NAMED TO BE IN THE FACILITY AND THEY'RE NOW AT A
11 DIFFERENT INSTITUTION, THAT WOULD SEEM TO BE A
12 MATTER OF IMPOSSIBILITY.

13 DR. TROUNSON: THEY WON'T BE PART OF THAT
14 INSTITUTION CLEARLY, SO THEY'LL BE AT SOME OTHER
15 PLACE. SO IF THEY'VE LEFT, CLEARLY IT'S THE CASE
16 THEY WON'T BE -- IF THEY'VE GONE INTERSTATE.

17 DR. ROBSON: WE WOULDN'T BE PAYING THEM
18 FACILITIES PART B.

19 CHAIRMAN KLEIN: SO LOOK FORWARD TO YOUR
20 ABILITY TO HAVE SOME TIME TO THINK ABOUT THIS, BUT
21 CERTAINLY IT WAS NOT OUR ORIGINAL INTENT IF WE HAVE
22 THE FACILITY FULL OF STEM CELL RESEARCHERS AND WE'RE
23 NOT PAYING ANY OF THEM THEIR PART B AND SOMEONE HAS
24 BEEN -- PERHAPS EVEN GIVEN UP THEIR SPOT IN THAT
25 BECAUSE THEY'VE GOT A NEW FACULTY AWARD TO BRING IN

BARRISTERS' REPORTING SERVICE

1 SOME GREAT RESEARCHER THAT HADN'T BEEN IDENTIFIED,
2 WE WOULDN'T WANT TO DOUBLE PENALIZE SOMEONE FOR
3 MOVING OUT OF THE FACILITY TO ACCOMMODATE A GREAT
4 NEW RESEARCHER THAT HAD BEEN RECRUITED BECAUSE
5 THAT'S THE MOST ATTRACTIVE PLACE TO DO RESEARCH.

6 SO IF YOU WOULD PLEASE TAKE A LOOK AT
7 THAT, AND LET'S JUST THINK ABOUT HOW WE MIGHT
8 ADDRESS IT.

9 DR. TROUNSON: I WILL. THE ONLY THING I
10 WOULD SAY IS THE SCIENTIFIC COMPONENT PART OF THE
11 MAJOR FACILITIES REALLY DID INCLUDE SOME
12 CONSIDERATION OF THE QUALITY OF THE PEOPLE THAT
13 WOULD BE CONGREGATING.

14 CHAIRMAN KLEIN: ABSOLUTELY. FOR EXAMPLE,
15 IT MIGHT COME BACK AND SAY, LOOK, IF HE GAVE UP HIS
16 SLOT BECAUSE THEY'RE RECRUITING A WORLD LEADER AND
17 YOU DECIDE THAT IT'S AN EQUAL OR SUPERIOR SCIENTIFIC
18 CONTRIBUTION, I JUST WANT YOUR CONSIDERED OPINION.

19 MR. ROTH: I HAVE SPENT QUITE A BIT OF
20 TIME TALKING WITH JOHN ABOUT THIS AND WITH OTHERS.
21 I THINK THE MOST IMPORTANT PART OF THIS POLICY IS
22 NOT TO CREATE A DISINCENTIVE FOR PEOPLE NOT TO BE
23 AFFILIATED WITH OUR INSTITUTE AND THAT WE SHOULD
24 BEND OVER BACKWARDS TO MAKE SURE WE DON'T DO THAT
25 UNINTENTIONALLY. AS A WAY TO GET STARTED, LET'S

BARRISTERS' REPORTING SERVICE

1 START WITH THIS AND SEE IF THE POLICY WORKS. IF WE
2 FIND THAT THE PEOPLE ARE BEING CREATIVE AND ARE NOT
3 MOVING IN OR BEING AFFILIATED, THEN I THINK WE NEED
4 TO REVISIT IT.

5 AND JUST TO ADD ONE PROPOSAL I MADE AND
6 COULD BE REVISITED WAS THAT THERE BE A DISCOUNT
7 BASED ON THE TOTAL COST OF THE FACILITY AND WHAT WE
8 PAID. SO IF A FACILITY COSTS A HUNDRED MILLION AND
9 WE PUT IN 40, THEY WOULD STILL GET 60 PERCENT OF THE
10 PART B BECAUSE THE TOTAL COST -- IN OTHER WORDS, WE
11 WOULDN'T BE PAYING TWICE ON OUR MONEY, WHICH WAS
12 ALWAYS THE INTENT HERE. SO THAT'S ANOTHER OPTION.
13 THERE'S SOME MORE COMPLICATIONS WITH THAT.

14 DR. ROBSON: THERE ARE COMPLICATIONS WITH
15 THAT, AND THAT WOULD REQUIRE A CHANGE IN THE POLICY.

16 MR. ROTH: I UNDERSTAND. BUT THAT'S WHAT
17 I'M SUGGESTING IS WE KEEP AN OPEN MIND THAT WE MAY
18 NEED TO CHANGE THIS POLICY BECAUSE WE MAY CREATE
19 DISINCENTIVES FOR PEOPLE TO BE AFFILIATED WITH OUR
20 INSTITUTES BECAUSE THERE'S REAL MONEY IN THIS CASE
21 THAT YOU GAVE, 160,000 --

22 DR. ROBSON: WE'VE SPENT HOURS AND HOURS
23 DISCUSSING THAT VERY PROBLEM. BUT WITHIN THE POLICY
24 THAT'S IN EXISTENCE, THIS WAS --

25 CHAIRMAN KLEIN: DR. ROBSON, ONE OF THE

BARRISTERS' REPORTING SERVICE

1 THINGS THAT WAS MOST IMPORTANT IS THAT THE WAY
2 COMPETITION OCCURRED IS PEOPLE HAD TO PUT UP
3 MATCHING FUNDS. SO THOSE MATCHING FUNDS HAVE
4 ALREADY BEEN TAKEN INTO CONSIDERATION. AND SO --

5 DR. TROUNSON: THE OTHER THING, CHAIR, IT
6 WOULD APPEAR TO PENALIZE THOSE FROM -- THE LESS
7 WELL-TO-DO INSTITUTIONS WOULD END UP PAYING A MUCH
8 HIGHER PROPORTION, AND THAT WOULDN'T REALLY LOOK
9 VERY GOOD FOR US. WE'VE GONE THROUGH THAT AND WE'VE
10 LOOKED AT WHATEVER OPTIONS ARE THERE. LET'S CHECK
11 IT OUT BECAUSE IN THE INSTITUTIONS THAT I'VE VISITED
12 ON THIS MATTER, THE DECISION ABOUT WHO GOES IN IS
13 TOTALLY UNCONNECTED TO THIS MATTER. AND THE
14 INSTITUTIONS ARE ESSENTIALLY FILLING UP OR FILLED UP
15 FAIRLY QUICKLY. AND WHERE THEY'RE NOT FILLED,
16 THEY'RE BEING KEPT BY THE INSTITUTIONS TO BRING IN
17 SOME ADDITIONAL OUTSIDE LEADERSHIP PEOPLE.

18 CHAIRMAN KLEIN: DR. ROBSON AND DR.
19 TROUNSON AND THE STAFF CERTAINLY SPENT A GREAT DEAL
20 OF TIME TRYING TO LOOK AT THESE OPTIONS AND TRYING
21 TO FOLLOW POLICY, BUT I THINK, AS DUANE SAYS, WE
22 HAVE ABILITY AS WE GO FORWARD TO LOOK AT THIS AGAIN
23 IF THERE'S SOME DISTORTION BECAUSE WE'RE MISSION
24 DRIVEN AND WE NEED TO BE OPEN TO ANALYZING ANY
25 DISTORTIONS IN MISSION ACHIEVEMENT. WE HAVE THE

BARRISTERS' REPORTING SERVICE

1 ABILITY TO OPEN HERE AND GO FORWARD, BUT THANK YOU,
2 DR. ROBSON AND DR. TROUNSON, FOR ALL THE TIME YOU'VE
3 PUT INTO THIS WITH ELONA BAUM AND OTHER MEMBERS OF
4 YOUR STAFF.

5 ARE THERE OTHER ITEMS THAT WE HAVE BEFORE
6 US TODAY?

7 MS. KING: PUBLIC COMMENT.

8 CHAIRMAN KLEIN: RIGHT. I KNOW THAT, BUT
9 I THINK WE HAVE OTHERWISE HANDLED ALL OF OUR ITEMS.
10 IS THERE CLOSING PUBLIC COMMENT? SEEING NONE, I
11 THANK THE BOARD FOR ANOTHER VIBRANT, ROBUST SESSION.
12 THANK YOU.

13 LET US AGAIN, THE STAFF PUTS IN HUGE HOURS
14 PREPARING FOR THIS MEETING. LET US THANK IN THE
15 CHAIRMAN'S STAFF MELISSA KING, JENNA PRYNE, LYNN
16 HARWELL. LET'S THANK NICK, SCOTT TOUCHER. AND ON
17 THE PRESIDENT'S STAFF ELONA BAUM, JOHN ROBSON, AND
18 JOAN AND AMY, PATRICIA OLSON. I THINK I MENTIONED
19 JENNA. DR. BETTINA STEFFEN FOR THIS VERY IMPORTANT
20 MOVE FORWARD AND DRAMATIC NEW PROGRAM FOR DISEASE
21 TEAMS. IT'S A PHENOMENAL TEAM OF PEOPLE. LET US
22 PLEASE GIVE ALL OF THEM A ROUND OF APPLAUSE. AMY
23 CHEUNG AS WELL.

24 (APPLAUSE.)

25 (THE MEETING WAS THEN ADJOURNED AT 2:55 P.M.)

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

STANFORD UNIVERSITY
PAUL BREST HALL
STANFORD, CALIFORNIA
ON
AUGUST 18, 2010
AUGUST 19, 2010

WAS HELD AS HEREIN APPEARS AND THAT THIS IS THE ORIGINAL TRANSCRIPT THEREOF AND THAT THE STATEMENTS THAT APPEAR IN THIS TRANSCRIPT WERE REPORTED STENOGRAPHICALLY BY ME AND TRANSCRIBED BY ME. I ALSO CERTIFY THAT THIS TRANSCRIPT IS A TRUE AND ACCURATE RECORD OF THE PROCEEDING.

BETH C. DRAIN, CSR 7152
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