

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

LOCATION: AS INDICATED ON THE AGENDA

DATE: TUESDAY, JULY 20, 2010
10:30 A.M.

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

BRS FILE NO.: 87839

BARRISTERS' REPORTING SERVICE

I N D E X

ITEM	DESCRIPTION	PAGE NO.
CALL TO ORDER		3
ROLL CALL		3
UPDATE ON PROPOSAL REGARDING POLICY FOR USE OF UNUSED DISEASE TEAM AWARD FUNDS FOR CLINICAL TRIALS		7
UPDATE ON PROPOSAL COMMISSIONING IOM REPORT ON CIRM		30
DISCUSSION AND CONSIDERATION OF CHANGES TO EXTRAORDINARY PETITION AND GRANT ADMINISTRATION APPEALS PROCESSES		40
PUBLIC COMMENT		68

BARRISTERS' REPORTING SERVICE

1 TUESDAY, JULY 20, 2010

2 10: 30 A. M.

3

4 MS. KING: THANK YOU FOR ALL JOINING. WE
5 KNOW SEVERAL OF YOU ARE ALREADY ON THE CALL. I'M
6 GOING TO TURN IT OVER TO OUR CHAIR FOR THE
7 SUBCOMMITTEE, JEFF SHEEHY, AND WE' LL GET STARTED.

8 CHAIRMAN SHEEHY: THANK YOU ALL FOR BEING
9 HERE TODAY. I THINK I' LL CALL THE MEETING TO ORDER.
10 MELISSA, DO YOU WANT TO START THE ROLL CALL.

11 MS. KING: YES. SO SUSAN BRYANT, I KNOW
12 YOU' RE JOINING US AS A MEMBER OF THE PUBLIC. THANK
13 YOU.

14 MARCY FEIT. MICHAEL FRIEDMAN.

15 DR. FRIEDMAN: HERE.

16 MS. KING: ROBERT KLEIN.

17 CHAIRMAN KLEIN: HERE.

18 MS. KING: FRANCISCO PRIETO. ED PENHOET.
19 PHIL PIZZO.

20 DR. PIZZO: HERE.

21 MS. KING: JOHN REED. DUANE ROTH.

22 MR. ROTH: HERE.

23 MS. KING: JOAN SAMUELSON.

24 MS. SAMUELSON: HERE.

25 MS. KING: JEFF SHEEHY.

BARRISTERS' REPORTING SERVICE

1 CHAIRMAN SHEEHY: HERE.

2 MS. KING: OSWALD STEWARD.

3 DR. STEWARD: HERE.

4 MS. KING: AND ART TORRES.

5 CHAIRMAN SHEEHY: I THINK ART IS ON HIS
6 WAY. WILL WE HAVE A QUORUM?

7 MS. KING: ACTUALLY WE NEED MARCY AS WELL,
8 AND I KNOW SHE'S JOINING. I JUST TALKED TO HER
9 OFFICE THIS MORNING.

10 CHAIRMAN SHEEHY: IS JEANNIE ON THE LINE?

11 MS. KING: NO, SHE'S NOT, BUT WE NEED NINE
12 FOR A QUORUM. WE ONLY NEED EIGHT.

13 MS. SAMUELSON: HAS JOHN SLADEK BEEN
14 INCLUDED AS A MEMBER OF THE SUBCOMMITTEE?

15 MS. KING: HE'S NOT A MEMBER OF THE
16 SUBCOMMITTEE SINCE HE'S NOT ON THE BOARD, BUT HE IS
17 ABSOLUTELY MORE THAN WELCOME TO JOIN. I ACTUALLY
18 SENT HIM THE DIAL-IN AND CALLED HIM THIS MORNING AND
19 LEFT HIM A VOICE MAIL, UNDERSTANDING THAT HE MAY BE
20 INTERESTED IN JOINING. I'M NOT SURE WHETHER OR NOT
21 HE'S JOINING.

22 MS. SAMUELSON: THAT MAY HAVE BEEN TOO
23 LATE FOR HIM TO CHANGE SOME OTHER PLANS THAT HE HAD.
24 I'M GLAD YOU DID. I WOULD HOPE WE'D GET WORD TO HIM
25 SOONER IN THE FUTURE IF POSSIBLE.

BARRISTERS' REPORTING SERVICE

1 MS. KING: I CAN DEFINITELY DO THAT. I
2 APOLOGIZE THAT WAS DELAYED. AND I'M HAPPY TO DO
3 THAT. I THINK IT MAKES A LOT OF SENSE.

4 DR. FONTANA: JEANNIE HERE.

5 MS. KING: AND ACTUALLY WE HAVE DR.
6 FONTANA AS WELL. MR. SHEEHY, WE DO HAVE A QUORUM.
7 ART TORRES IS PRESENT AND JEANNIE FONTANA.

8 CHAIRMAN SHEEHY: GREAT. OKAY. THEN I
9 GUESS WE'LL START INTO THE AGENDA, AND I'LL NOTE
10 THAT THE FIRST TWO ITEMS ARE ITEMS THAT ARE SLATED
11 FOR THE AUGUST ICOC MEETING THAT WERE FROM THE
12 PREVIOUS MEETING OF THE SCIENCE SUBCOMMITTEE.

13 THERE WERE OTHER ITEMS THAT WILL BE COMING
14 TO THE BOARD FROM THAT MEETING. ONE IS A
15 PRESENTATION TO GRANTS WORKING GROUP MEMBERS OF
16 INFORMATION ABOUT PROGRAMMATIC REVIEW AMONGST OTHER
17 THINGS. WE HAD A LENGTHY DISCUSSION LAST TIME, SO I
18 DON'T NEED TO REVIEW THAT.

19 HOPEFULLY THE IP TASK FORCE WILL MEET
20 BEFORE AS WAS DETERMINED AT THE LAST SCIENCE
21 SUBCOMMITTEE MEETING, THAT THE IP TASK FORCE WILL
22 MEET TO CONSIDER SUPPLEMENTS TO GRANTS TO ASSIST
23 OFFICES OF TECHNOLOGY AND LICENSING AT UNIVERSITIES
24 SO THAT WE'RE NOT LOSING ANY VALUABLE INTELLECTUAL
25 PROPERTY DUE TO THE SEVERE FUNDING RESTRAINTS THAT

BARRISTERS' REPORTING SERVICE

1 MANY OF THE UNIVERSITIES ARE UNDER AND THE CUTBACKS
2 THAT THEY'RE EXPERIENCING IN THESE OFFICES.

3 I THINK LAST TIME WE DOCUMENTED THAT THIS
4 WAS A PROBLEM THAT OTHER FOUNDATIONS WERE DEALING
5 AND GRAPPLING WITH TO MAKE SURE THAT THERE WAS AN
6 ADEQUATE AMOUNT OF CAPACITY WITHIN THE UNIVERSITIES
7 TO PATENT AND CAPTURE FOR THE PEOPLE OF CALIFORNIA
8 ALL THE POTENTIAL INTELLECTUAL WEALTH THAT MIGHT BE
9 THERE TO PAY BACK THESE BONDS.

10 SO HOPEFULLY STAFF HAS BEEN WORKING ON
11 THIS, PREPARING PROPOSALS. AND, DUANE, THERE IS A
12 PLAN TO HAVE THE IP TASK FORCE MEET BECAUSE I SURE
13 WOULD HATE TO LOSE, YOU KNOW, JUST BECAUSE WE'RE IN
14 THIS TERRIBLE RECESSION, TO HAVE NO PATENT -- TO
15 HAVE LIMITED PATENTING AND LICENSING OF CIRM-FUNDED
16 INVENTIONS.

17 MR. ROTH: RIGHT. SO THAT'S ED PENHOET,
18 RIGHT?

19 MS. KING: YES. HE IS THE CHAIR OF THAT
20 SUBCOMMITTEE, AND I AM HAPPY TO CONTACT HIM ABOUT
21 THAT BASED ON THE INPUT OF THIS SUBCOMMITTEE AT THE
22 LAST MEETING, WHICH HE ATTENDED. I DON'T THINK IT
23 WILL BE A SURPRISE. HE'LL BE ON THIS CALL LATER
24 TODAY. HE JUST COULDN'T JOIN UNTIL ELEVEN.

25 CHAIRMAN SHEEHY: WE'LL JUST REMIND ED.

BARRISTERS' REPORTING SERVICE

1 THAT WAS SOMETHING THAT WAS SUPPOSED TO COME ON AS A
2 REPORT FROM THIS COMMITTEE OR FROM THE IP TASK FORCE
3 FOR THE AUGUST MEETING.

4 AND THEN IS STAFF PREPARED TO GIVE US AN
5 UPDATE ON THE USE OF UNUSED DISEASE TEAM RESEARCH
6 AWARDS FOR CLINICAL TRIALS?

7 MS. FEIT: THIS IS MARCY FEIT. I'VE
8 JOINED THE CONFERENCE.

9 CHAIRMAN SHEEHY: THANK YOU, MARCY.

10 DR. OLSON: YES, MR. CHAIR. I WANTED TO
11 COMMENT ON AN ITEM THAT YOU BROUGHT UP AT A PREVIOUS
12 SCIENCE SUBCOMMITTEE MEETING. AT THAT TIME THE
13 SCIENCE SUBCOMMITTEE ASKED THAT WE LOOK INTO WHAT
14 COULD BE DONE IF THERE WERE EXTRA FUNDS FROM DISEASE
15 TEAMS, FROM OUR CURRENT DISEASE TEAM I.

16 AS YOU ARE ALL AWARE, AWARDS UNDER THE
17 DISEASE TEAM RFA 09-01, THAT IS, DISEASE TEAMS I FOR
18 THE SAKE OF CLARIFICATION, ARE FOR WORK WITHIN THE
19 SCOPE DEFINED BY THAT RFA, WHICH DOES NOT EXTEND
20 BEYOND THE FILING OF AN IND. NOW, AS YOU ARE ALSO
21 AWARE, THAT WE CONTEMPLATE THAT THE UPCOMING DISEASE
22 TEAM II RFA, RFA 10-05, WILL ENCOMPASS MORE ADVANCED
23 WORK FOLLOWING THE FILING OF AN IND.

24 SO WE HAVE BEEN ASKED WHETHER DISEASE TEAM
25 I PROJECTS THAT CAN COMPLETE ITS OBJECTIVES MAY USE

BARRISTERS' REPORTING SERVICE

1 ANY REMAINING FUNDS FOR MORE ADVANCED WORK ON THE
2 CANDIDATE THERAPEUTICS THAT WAS THE SUBJECT OF A
3 DISEASE TEAM I IND FILING. AND STAFF RESPONSE TO
4 THIS IS THAT WE WILL NOTIFY RECIPIENTS OF DISEASE
5 TEAM I AWARDS THAT WE CAN CONSIDER PROPOSALS FROM
6 AWARDEES FOR A CHANGE IN SCOPE.

7 SO IT WOULD FOLLOW UNDER OUR NORMAL
8 PROCEDURES FOR A CHANGE IN SCOPE TO INCLUDE
9 ADDITIONAL WORK THAT WOULD BE WITHIN THE SCOPE OF A
10 DISEASE TEAM II RFA.

11 WE WILL WORK WITH ANY INTERESTED DISEASE
12 TEAM I PI AND THEIR TEAM TO ENSURE THAT ANY MODIFIED
13 RESEARCH PLAN INCLUDES APPROPRIATE MILESTONES,
14 INCLUDING GO/NO-GO EVALUATION POINTS AND TIMELINES.
15 THE MODIFIED RESEARCH PLAN, INCLUDING ANY CLINICAL
16 COMPONENTS, MUST BE FEASIBLE WITHIN THE AMOUNT OF
17 THE AWARD THAT WAS PREVIOUSLY APPROVED BY THE BOARD
18 AND AS STATED IN THE NOTICE OF GRANT AWARD.

19 AND THEN THE OTHER POINT THAT WE WOULD
20 CONSIDER IMPORTANT IS, AS WITH OTHER MAJOR DECISIONS
21 INVOLVING DISEASE TEAM PROJECTS, THE PRESIDENT AND
22 THE VP OF R&D WILL SEEK ADVICE FROM AN EXPERT
23 ADVISORY COMMITTEE AS DESCRIBED IN THE RFA FOR
24 DISEASE TEAM I.

25 SO THOSE ARE MY COMMENTS ON THAT AND THAT

BARRISTERS' REPORTING SERVICE

1 IS OUR PROPOSAL.

2 CHAIRMAN SHEEHY: WELL, I HAD ONE
3 QUESTION, AND THEN I KNOW BOB HAS A QUESTION. IT'S
4 NOT CLEAR TO ME THAT THIS ISSUE ABOUT BEING
5 FEASIBILITY WITHIN THE FUNDING AVAILABLE WILL
6 ACTUALLY CAPTURE THE LEVERAGING OPPORTUNITIES THAT
7 MIGHT BE AVAILABLE. LET'S SAY THAT THERE IS MONEY
8 LEFT OVER. AND SINCE THERE ARE TWO HIV GRANTS, I
9 CAN EASILY IMAGINE EITHER NIH OR GATES OR AMFAR OR
10 ANY OF THE OTHER FUNDERS IN HIV RESEARCH, WE HAVE
11 SOMEBODY WITH AN IND HAS MONEY TO GET HALF OF A
12 CLINICAL TRIAL, AND ONE OF THESE OTHER FUNDERS MIGHT
13 HAVE A WILLINGNESS TO DO THAT. BUT I THINK IF WE
14 BURDEN THE DISEASE TEAMS WITH THE EXPECTATION, IF
15 WE -- LET ME BE MORE CLEAR. IF WE DON'T GIVE THEM
16 THE OPPORTUNITY TO LEVERAGE THESE FUNDS, THEN I
17 THINK WE'RE SETTING THEM UP FOR FAILURE. IT'S NOT
18 CLEAR THAT COMING OUT OF -- AFTER HAVING FINISHED A
19 PROJECT THAT THEY ACTUALLY WROTE A BUDGET FOR IN
20 ORDER TO COMPLETELY DO THE WORK THAT THEY SCHEDULED
21 TO GET THERE FASTER, THAT THEY NECESSARILY THEN HAVE
22 THE COMPLETE FUNDING LEFT OVER TO DO A CLINICAL
23 TRIAL.

24 SO I DON'T WANT US TO GET CAUGHT. THE
25 IDEA IS TO LEVERAGE IN MY MIND.

BARRISTERS' REPORTING SERVICE

1 CHAIRMAN KLEIN: IF I COULD MAYBE FOLLOW
2 ON THIS POINT IS THAT, DR. OLSON, FIRST OF ALL, I
3 THINK EMBEDDED IN WHAT YOU ARE SAYING IS THE STAFF
4 WOULD NEED TO REVIEW THE BUDGET THAT THEY'RE
5 PROPOSING. AND THAT IF IN ADDITION TO THE RESIDUAL
6 FUNDS THEY HAVE FROM DISEASE TEAMS, THEY HAD PRIVATE
7 COMMITMENT OF FUNDS OR NIH COMMITMENT, YOU WILL LOOK
8 AT THE ENTIRE AVAILABLE FUNDS, INCLUDING THE
9 RESIDUAL FUNDS.

10 DR. OLSON: I DON'T THINK WE'RE PRECLUDING
11 LEVERAGING.

12 CHAIRMAN KLEIN: WHAT YOU'RE SAYING IS
13 THAT FEASIBLE GIVEN THE RESIDUAL FUNDS INCLUDING
14 OTHER FUNDS THEY HAVE AVAILABLE TO COMPLETE THAT
15 WORK THEY'RE PROPOSING.

16 DR. OLSON: RIGHT.

17 CHAIRMAN SHEEHY: WE'RE MAKING A CHICKEN
18 AND EGG ARGUMENT. I MEAN IT'S KIND OF LIKE THEY MAY
19 NOT BE ABLE TO GET THE ADDITIONAL FUNDS AND NOT
20 HAVING THE OKAY FROM US TO USE THE FUNDS THAT THEY
21 HAVE AVAILABLE.

22 CHAIRMAN KLEIN: WHAT I UNDERSTAND --

23 CHAIRMAN SHEEHY: I MEAN WOULD WE BE
24 CONTINGENT ON THEM HAVING ATTAINED THE MATCHING
25 FUNDS OR LEVERAGING FUNDS? WOULD WE JUST SAY YOU

BARRISTERS' REPORTING SERVICE

1 DON' T HAVE THE MONEY; WE WANT OUR MONEY BACK?

2 CHAIRMAN KLEIN: SO WHY DON' T WE TAKE THAT
3 AS A SERIES OF QUESTIONS, JEFF, AND BREAKING THEM
4 DOWN. THE FIRST ISSUE IS IF THEY HAD \$3 MILLION OF
5 RESIDUAL FUNDS AND THEY SAID WE HAVE A LIMITED SCOPE
6 HERE, WE' RE GOING TO ASK THAT WE BE ALLOWED TO GO
7 THROUGH AND SPECIFICALLY MANUFACTURE THE CELLULAR
8 PRODUCT TO BE USED IN THE TRIAL AND STOP THERE. SO
9 THEY HAD A LIMITED SCOPE IN MOVING FORWARD ON THEIR
10 PHASE I. WOULD THAT OPTION BE SOMETHING THAT WOULD
11 BE REASONABLE TO PROPOSE?

12 DR. OLSON: FIRST, THAT WOULD BE PART OF
13 WHAT I WOULD EXPECT THEM TO HAVE COMPLETED BY THE
14 END OF THE DISEASE TEAM. BUT I DO THINK THAT, YES,
15 THEY COULD PROPOSE AN END POINT THAT WAS COMPATIBLE
16 WITH WHATEVER FUNDS THEY HAD LEFT. IF THEY WERE
17 ABLE TO STATE THAT THEY ANTICIPATED THE ADDITION OF
18 EXTRA FUNDS PENDING THIS, BUT THOSE ARE CONTINGENT
19 FUNDS, RIGHT. YOU DON' T KNOW THAT THEY' RE THERE,
20 BUT THERE WOULD BE SOME ACTIVITIES I' M SURE THAT
21 THEY COULD PROPOSE; I. E. , SITE INITIATION. IT DOES
22 COST MONEY TO SET UP SITES. IT TAKES TIME. AND TO
23 ACTUALLY, ASSUMING THEY' D RECEIVED IND APPROVAL,
24 THEN THEY WOULD PROBABLY GO INTO SITE INITIATION.
25 THEY PROBABLY IDENTIFIED SITES, BUT THEY PROBABLY

BARRISTERS' REPORTING SERVICE

1 HAVE NOT INITIATED SITES.

2 SO I THINK THEY WOULD BE ABLE TO CHOOSE
3 ACTIVITIES THAT MOVED THE PROGRAM FORWARD AND WERE
4 WITHIN THE SCOPE OF WHATEVER REMAINING FUNDS THEY
5 HAD. AND IF THEY HAD ALREADY FUNDS COMMITTED, THEN
6 CERTAINLY THAT COULD PLAY IN. IF THEY HAD THE
7 POTENTIAL FOR COMMITMENT, THAT WE'D HAVE TO THINK
8 ABOUT.

9 DR. TROUNSON: I'M NOT SURE HOW THIS
10 REALLY NEGATIVELY AFFECTS IT BECAUSE THAT'S
11 HAPPENING ALL THE TIME. THERE'S MORE MONEY COMING
12 INTO THESE PROJECTS AS THEY MOVE ALONG. SO IT'S
13 PROBABLY LIKELY THAT THEY'LL GET THERE FASTER
14 BECAUSE THERE'S ADDITIONAL FUNDS COMING INTO THE
15 PROJECT SO THAT THEY'LL MEET THEIR -- PRESUMABLY
16 MEET THEIR MILESTONES MORE QUICKLY OR MORE
17 EFFECTIVELY. AND THE ONLY THING THAT WE NEED TO DO
18 IS ENSURE IF THERE'S MONEY LEFT OVER, THAT IT'S
19 BEING USED APPROPRIATELY.

20 SO I WOULD THINK IT COULD BE USED FOR
21 ESTABLISHMENT OF THEIR CLINICAL PROGRAM, AND THAT
22 SHOULD BE THAT THE FUNDS ARE BEING USED
23 APPROPRIATELY, NOT INAPPROPRIATELY, FOR THAT WORK.

24 AND IF THEY -- IT WILL BE REQUIRED, I'M
25 SURE, TO DO A WHOLE CLINICAL TRIAL, THAT THEY'LL

BARRISTERS' REPORTING SERVICE

1 HAVE TO GET MORE MONEY FROM US IN AN ADDITIONAL
2 PROJECT OR GET MONEY FROM SOME OTHER PLACE. I THINK
3 THAT'S WHAT WOULD BE NORMALLY HAPPENING BECAUSE THE
4 COST OF THOSE CLINICAL PROJECTS ARE GOING TO BE MUCH
5 LARGER THAN THE AMOUNT OF MONEY THAT'S LEFT OVER
6 FROM THE PROJECT, I EXPECT.

7 SO I'M NOT SURE THAT IT REALLY HAS SUCH A
8 NEGATIVE EFFECT ON IT. I THINK WHAT WE'RE SAYING IS
9 THAT THE MONEY THAT'S LEFT OVER NEEDS TO BE
10 APPROPRIATELY UTILIZED FOR THE CLINICAL PROJECT.

11 CHAIRMAN KLEIN: JEFF, COULD WE ASK DUANE
12 OR DR. PIZZO OR ANYONE ELSE ON THE CALL. IT WOULD
13 SEEM IF OUR POSITION IS THAT IF THERE'S LEFT-OVER
14 MONEY AND THAT MONEY IS SUFFICIENT FOR SITE
15 INITIATION, AND IF THEY DEFINE THE TASK AS SITE
16 INITIATION, WOULDN'T THAT, IN FACT, PUT THEM IN A
17 POSITION TO MOVE FORWARD AND ATTRACT MORE FUNDS TO
18 GO FURTHER DOWNSTREAM?

19 MR. ROTH: I'LL COMMENT QUICK BECAUSE I'M
20 IN AN AIRPORT. SO I THINK, JEFF, IT'S INHERENT THAT
21 THEY WOULD LEVERAGE THE MONEY. THEY'RE NOT GOING TO
22 START A TRIAL IF THEY DON'T HAVE MONEY. THAT'S
23 REALLY UNETHICAL. I WORRY MORE ABOUT WHAT HAPPENS
24 TO THE MONEY THAT'S LEFT OVER IF THERE IS NO PATH
25 FORWARD. AND I WOULD THINK THAT THAT WOULD BE

BARRISTERS' REPORTING SERVICE

1 SOMETHING WE NEED TO CONSIDER AS WELL.

2 DR. PIZZO: I AGREE WITH WHAT DUANE SAID
3 AND ACTUALLY WOULD JUST UNDERLINE HIS CAVEAT, WHICH
4 WOULD MEAN THE UNETHICAL PART. WE NEED TO MAKE SURE
5 THAT A TRIAL DOESN'T START IF THERE'S NOT FUNDING TO
6 COMPLETE IT BECAUSE THAT WOULD REALLY BE AN
7 EMBARRASSMENT FOR EVERYONE.

8 CHAIRMAN SHEEHY: DO WE HAVE OTHER BOARD
9 COMMENT?

10 MS. SAMUELSON: THIS IS JOAN WITH A
11 QUESTION. I'M WONDERING HOW THE FOLLOWING FACT
12 SITUATION WOULD FIT IN, WHICH I'VE SEEN IN THE
13 PARKINSON'S COMMUNITY. THAT IS, OBJECTIVES AREN'T
14 ACHIEVED, AND IT'S NOT CLEAR WHY, AND IT IS CLEAR
15 THAT THERE NEEDS TO BE MORE EFFORT APPLIED TO TRYING
16 TO FIGURE THAT OUT, TRYING TO FIGURE OUT WHETHER THE
17 TRANSLATIONAL OBJECTIVE IS APPROPRIATE, WHETHER
18 THERE'S SOMETHING ELSE THAT'S NEEDED, IS THERE NEWER
19 GROWTH FACTOR NEEDED, OR IS THERE SOMETHING ABOUT
20 THE CELLS THEMSELVES, IF YOU'RE IN A CELL
21 REGENERATION, THEIR RESTORATION OBJECTIVE. AND
22 THERE NEEDS TO BE MORE WORK OF A TRANSLATIONAL SORT,
23 BUT IT'S CLEARLY NOT READY FOR CLINICAL TRIAL, BUT
24 THAT THAT DOESN'T MEAN THAT THE PROJECT IS
25 INAPPROPRIATE.

BARRISTERS' REPORTING SERVICE

1 WHERE DO FUNDS COME FROM TO FUND THAT
2 WORK, AND HOW DOES THAT PROCESS FIT INTO THIS?

3 DR. OLSON: SO THIS IS PAT OLSON. IF I
4 UNDERSTAND THE POINT CORRECTLY, THE IDEA IS THAT
5 MILESTONES PERHAPS ARE NOT ACHIEVED BECAUSE IT TURNS
6 OUT THAT MORE RESEARCH WORK NEEDS TO BE DONE. AND I
7 THINK THAT THAT REALLY IS A DISCUSSION WITH THE
8 OVERSIGHT ADVISORY COMMITTEE AS TO WHETHER THE PLAN,
9 THE RESEARCH PLAN, PROPOSED WILL, IN FACT,
10 CONTRIBUTE TO ADVANCING THE FIELD EVEN THOUGH THAT
11 THE OBJECTIVE OF THE RFA WILL NOT BE ACHIEVED. SO I
12 THINK THAT IS ONE OF THE KEY PURPOSES OF HAVING THAT
13 COMMITTEE IS TO UNDERSTAND THAT IF THE TEAM RUNS
14 INTO SOMETHING THAT SUGGESTS THAT THEIR PROPOSAL AS
15 ORIGINALLY CONFIGURED AND THE MILESTONES AS
16 ORIGINALLY LAID OUT IS JUST NO LONGER FEASIBLE OR
17 PRACTICAL, WHAT IS THEIR PLAN FOR MOVING FORWARD AND
18 FOR LEARNING SOMETHING.

19 MS. SAMUELSON: RIGHT. RIGHT. IT'S MORE
20 COMPLICATED THAN WAS INITIALLY UNDERSTOOD. AND THIS
21 HAS FREQUENTLY BEEN THE CASE IN THE CASE OF CELL
22 RESTORATION, CELL REGENERATION EFFORTS IN
23 PARKINSON'S BACK TO THE FIRST FETAL TISSUE DAYS.

24 DR. OLSON: DRUG DEVELOPMENT IS SELDOM
25 LINEAR.

BARRISTERS' REPORTING SERVICE

1 MS. SAMUELSON: EXACTLY. EXACTLY. SO
2 THAT MAY WELL BE AN AREA THAT, ASSUMING THAT THE
3 PROJECTS AREN'T JUST AUTOMATICALLY DEFUNCT AS A
4 RESULT, AND MY HUNCH IS THEY WON'T BE, THAT IT WOULD
5 BE WORTH A FURTHER INVESTMENT. THERE WILL BE FUNDS
6 AVAILABLE FOR THAT.

7 DR. FRIEDMAN: ARE WE LOOKING TO CRAFT --
8 ARE WE JUST GETTING A SENSE OF THE FEELING OF THE
9 COMMITTEE? ARE WE ACTUALLY TRYING TO DRAFT A POLICY
10 AT THIS POINT? HELP ME UNDERSTAND WHAT IT IS YOU'D
11 LIKE TO ACCOMPLISH IN THE DISCUSSION.

12 CHAIRMAN SHEEHY: WELL, STAFF HAS BEEN
13 TASKED TO BRING A POLICY TO BE ADOPTED BY THE BOARD
14 AT THE AUGUST MEETING. SO I WAS JUST GETTING AN
15 UPDATE ON THAT.

16 DR. FRIEDMAN: GOT IT.

17 CHAIRMAN SHEEHY: IF THERE'S ANY FEEDBACK,
18 I THINK IT'S HELPFUL. THIS IS NOT DEFINITIVE.
19 WE'RE NOT GOING TO BE VOTING ON ANYTHING, BUT
20 OBVIOUSLY WE WANT TO -- IF THERE'S INPUT FROM
21 MEMBERS OF THE BOARD ON THIS, IT'S HELPFUL.

22 DR. FRIEDMAN: I THINK THAT'S AN EXCELLENT
23 SUGGESTION, JEFF. AND I'M REALLY GLAD YOU BROUGHT
24 IT BACK FOR THAT REASON. MY OWN RECOMMENDATION TO
25 STAFF IS DON'T TRY AND MAKE A VERY SPECIFIC POLICY

BARRISTERS' REPORTING SERVICE

1 BECAUSE TRYING TO GUESS WHAT THE SPECIFIC
2 CIRCUMSTANCES WOULD BE, I THINK, IS DIFFICULT. EVEN
3 THOUGH IT WILL MAKE MORE WORK FOR US AS A BOARD, I
4 MIGHT RECOMMEND THAT WE LOOK AT THESE ON A
5 CASE-BY-CASE BASIS ABOVE A CERTAIN DOLLAR THRESHOLD
6 OR SOMETHING WITH, OF COURSE, THE RECOMMENDATION OF
7 THE SCIENTIFIC STAFF BECAUSE THAT'S CRITICAL. BUT I
8 CAN IMAGINE SO MANY DIFFERENT SCENARIOS, THAT IT'S
9 HARD TO CRAFT AN OVERALL POLICY RIGHT NOW THAT WON'T
10 TAKE JUST A HELL OF A LOT OF TIME AND ULTIMATELY
11 WON'T BE THAT USEFUL BECAUSE THE CIRCUMSTANCES WILL
12 BE SLIGHTLY DIFFERENT WHEN WE ACTUALLY GET TO IT.

13 CHAIRMAN SHEEHY: AND SO, DR. FRIEDMAN,
14 YOU WOULD ACTUALLY ADVISE BRINGING THESE BACK TO THE
15 BOARD ON A CASE-BY-CASE BASIS, AND REALLY THE
16 INSTRUCTION FROM STAFF BEING TO LET THEM KNOW THAT
17 THE OPTION IS OUT THERE?

18 DR. FRIEDMAN: YES. I KNOW THAT'S SORT OF
19 INEFFICIENT BECAUSE IT MEANS MORE STUFF FOR US TO
20 DO. AND I MAY RUE THIS RECOMMENDATION, BUT MAYBE I
21 WON'T BE ON THE BOARD AT THAT TIME, IN WHICH CASE I
22 WON'T REGRET IT QUITE SO MUCH. BUT I ACTUALLY WOULD
23 SIMPLY STATE WHAT YOU ALL JUST SAID, WHICH THERE IS
24 A FLEXIBILITY AND A RECOGNITION OF THE COMPLEXITY OF
25 WHOLE PROCESS, AND THAT WE AS A FUNDING ORGANIZATION

BARRISTERS' REPORTING SERVICE

1 WOULD BE WILLING TO CONSIDER CIRCUMSTANCES. BUT I'M
2 JUST HAVING A LITTLE TROUBLE GUESSING HOW WELL WE'LL
3 BE ABLE TO WRITE THAT RIGHT NOW.

4 DR. PIZZO: I THINK MIKE MAKES A REALLY
5 IMPORTANT POINT. I AGREE WITH THAT ASSESSMENT THAT
6 YOU JUST PUT FORTH, MIKE. IN REALITY IT'S NOT THAT
7 WE'RE DEALING WITH DOZENS OF THESE THINGS. SO WHILE
8 WE'LL GETTING SOME EXPERIENCE, I THINK YOUR
9 SUGGESTION AND THE CAVEATS THAT YOU POSED ARE REALLY
10 WORTH CAREFUL CONSIDERATION. I CONCUR WITH THAT.

11 MS. FEIT: I AGREE. I THINK WE SHOULD
12 LEAVE OURSELVES AVAILABLE TO CONSIDER EACH AND EVERY
13 OPPORTUNITY ON ITS OWN MERIT SINGULARLY AT THIS
14 TIME.

15 MS. SAMUELSON: SAME HERE. JOAN.

16 CHAIRMAN SHEEHY: ALAN HAD A COMMENT AND
17 THEN BOB, BUT I WOULD LIKE TO KIND OF AGREE WITH
18 THAT TOO BECAUSE I CAN IMAGINE A SITUATION WHERE WE
19 MIGHT DECIDE TO FULLY FUND ONE OF THESE PROJECTS AS
20 A CLINICAL TRIAL. AND TAKING WHAT THEY HAVE LEFT
21 OVER, IF IT LOOKS REALLY GOOD, WHY WOULDN'T WE WANT
22 GET IN THE BALLPARK AND SEE IF WE CAN HIT A HOME
23 RUN?

24 DR. TROUNSON: I THINK THE MOST -- I THINK
25 THE MOST COMMON REQUEST THAT'S GOING TO COME TO US

BARRISTERS' REPORTING SERVICE

1 IS WHETHER THEY CAN USE LEFT-OVER FUNDS IN ADDING TO
2 OTHER FUNDS THAT THEY WOULD BE SEEKING TO DO A
3 CLINICAL TRIAL. WOULD THEY BE ALLOWED TO DO THAT?

4 I THINK THE ANSWER TO THAT QUESTION SHOULD BE YES,
5 AND IT SHOULD BE ALLOWED, ABLE TO FORMULATE A
6 CLINICAL TRIAL. WHAT WE CAN'T SAY, OF COURSE, IS
7 WHETHER EVERYTHING IS IN PERFECT SHAPE UNTIL THEY
8 FIND THAT ADDITIONAL MONEY BECAUSE THAT WILL BE THE
9 FIRST QUESTION THAT WE'RE ASKED. CAN WE USE THE
10 LEFT-OVER MONEY?

11 SO I THINK WE SHOULD BE IN A POSITION TO
12 SAY YES. IT SHOULD BE USED APPROPRIATELY. AND THEN
13 WE HAVE TO HAVE SOME KIND OF REVIEW ABOUT WHETHER
14 THAT CLINICAL TRIAL IS THEN AN APPROPRIATE
15 EXPENDITURE. IF IT'S VERY DIFFERENT, YOU'RE GOING
16 TO HAVE TO GO TO A KIND OF CLINICAL GRANTS WORKING
17 GROUP REVIEW. I THINK WE SHOULD BE ABLE TO SAY,
18 YES, THOSE MONIES CAN BE USED FOR THAT PURPOSE, AND
19 THEN WE SHOULD THEN TAKE IT FROM THERE BECAUSE I
20 THINK PROBABLY EACH AND EVERY ONE OF THEM WILL
21 PROBABLY BE QUITE DIFFERENT.

22 BUT THE FIRST ANSWER THAT WE SHOULD BE
23 ABLE TO GIVE THOSE TEAMS IS, YES, IT SHOULD BE ABLE
24 TO BE USED APPROPRIATELY FOR CLINICAL TRIALS WORK.

25 CHAIRMAN KLEIN: SO I'D LIKE TO TRY AND

BARRISTERS' REPORTING SERVICE

1 MERGE THESE COMMENTS BECAUSE I DO THINK IT'S
2 IMPORTANT TO BE ABLE TO COMMUNICATE WITH OUR
3 GRANTEES AND CREATE REASONABLE FRAMEWORK FOR
4 EXPECTATIONS. SO I ACTUALLY THINK THAT THE BASIC
5 CRITERIA THAT DR. OLSON LAID OUT, CREATE A SKELETON
6 SO PEOPLE HAVE REASONABLE EXPECTATIONS. THERE'S
7 GOING TO BE ADVISORY BOARD REVIEW. THERE'S GOING TO
8 BE A BUDGET REVIEW. WE'RE GOING TO HAVE MILESTONES.
9 WE NEED TO LAY OUT THAT FRAMEWORK AND THEN EMPOWER
10 THE SCIENTIFIC STAFF AND THE BOARD TO -- SCIENTIFIC
11 STAFF TO MAKE RECOMMENDATIONS, THE BOARD TO HAVE THE
12 POWER TO MAKE MODIFICATIONS AS ADAPT TO THE
13 SITUATION.

14 BUT IT'S HELPFUL TO HAVE THE KIND OF
15 NARRATIVE DISCUSSION WE JUST HAD TODAY INCORPORATED
16 IN HERE THAT GIVES THEM THE UNDERSTANDING THAT, YES,
17 THESE FUNDS CAN BE, SUBJECT TO ALL THESE GUIDELINES,
18 WHICH THE BOARD AND THE STAFF HAVE THE ABILITY TO
19 OVERWRITE IN A SPECIFIC APPROVAL ON A CASE STUDY
20 BASIS, THAT THEY CAN COMBINE THESE FUNDS WITH OTHER
21 FUNDS. THAT INFORMATION, GETTING IT OUT THERE,
22 LETTING PEOPLE UNDERSTAND THE BASIC RULES IS
23 IMPORTANT AND THEN EMPOWERING EXCEPTIONS.

24 MR. TORRES: I THINK I WANT TO ASSOCIATE
25 MYSELF WITH DR. FRIEDMAN'S REMARKS, BUT ALSO I THINK

BARRISTERS' REPORTING SERVICE

1 IT'S IMPORTANT FOR WHOEVER IS LISTENING THAT WE
2 ARTICULATE OUR BASIC DISCUSSION HERE. AS BOB HAS
3 ARTICULATED, WE NEED TO HAVE WHAT THE BASIC RULES
4 ARE GOING TO BE. SO I WOULD LIKE TO HEAR FROM
5 STAFF. I'M A GRANTEE. I GIVE PAT A CALL, LET'S
6 SAY. CAN I USE THESE RESIDUAL FUNDS? WHAT ARE THE
7 STEPS THAT WILL TAKE PLACE AFTER THAT REQUEST IS
8 MADE TO CIRM UNDER ALL OF OUR DISCUSSIONS FROM YOUR
9 PERSPECTIVE?

10 DR. OLSON: IT IS A CHANGE IN SCOPE
11 REQUEST UNDER THE SCOPE THAT WOULD BE ALLOWABLE
12 UNDER DISEASE TEAM II. WE HAVE A FORM THAT, IN
13 FACT, IS USED FOR CHANGE OF SCOPE. THEY WOULD HAVE
14 TO PROVIDE INFORMATION INDICATING WHAT ACTIVITIES.
15 AND SO WE WOULD SAY, ONCE THEY PUT IN, WE WOULD SAY
16 WE WOULD REQUIRE FROM YOU AN UNDERSTANDING OF WHAT
17 MILESTONES YOU SEE IN THE TIME AND HOW YOU WOULD USE
18 THOSE FUNDS GOING FORWARD, WHAT IS THE TIMELINE FOR
19 USE OF THE FUNDS, HOW DOES THIS FIT IN THE OVERALL
20 DEVELOPMENT STRATEGY, WHICH, BY THE WAY, WE WILL
21 HAVE BEEN WORKING WITH WITH THE TEAMS AS PART OF
22 DISEASE TEAM I. WE'LL BE KNOWING THAT ANYHOW. SO
23 ONCE WE HAVE THAT INFORMATION TO UNDERSTAND HOW IT'S
24 A CHANGE OF SCOPE, WE GO AND, AGAIN, THESE PROJECTS
25 WILL HAVE BEEN THROUGH ADVISORY OVERSIGHT COMMITTEE

BARRISTERS' REPORTING SERVICE

1 MEETINGS DURING THE COURSE OF THEIR TENURE. SO IN
2 POINT OF FACT, THE ADVISORY OVERSIGHT COMMITTEE WILL
3 HAVE SOME FAMILIARITY WITH THE PROGRAM, WITH THE
4 PROPOSED CLINICAL PROGRAM, AND IT SHOULD BE NO
5 SURPRISE TO THEM TO SAY THAT THE NEXT STEPS IN
6 DEVELOPMENT ARE STEP X, BRING ON FIVE SITES; STEP Y,
7 START ENROLLMENT AT THIS TARGET.

8 SO IT'S JUST A CONTINUATION OF ACTIVITIES.

9 MR. TORRES: RIGHT. I GET THAT. BUT ONCE
10 THEY GIVE YOU ALL THAT INFORMATION, DOES THAT
11 TRIGGER A SUBSEQUENT OVERSIGHT COMMITTEE REVIEW?

12 DR. OLSON: IT DEPENDS, I THINK, ON THE
13 SCOPE OF WHAT'S TALKED ABOUT. IF IT REALLY IS JUST
14 A -- FIRST, THEY HAVE TO PASS THE 30-DAY IND REVIEW
15 PERIOD. AND ASSUMING THAT THAT IS PASSED AND THEY
16 RECEIVE NO NOTICE OF CLINICAL HOLD, THEN THEY COULD
17 GO AHEAD AND START SITE SELECTION.

18 MR. TORRES: SO THE ADVISORY COMMITTEE
19 THEN RESPONDS TO YOUR INITIATION BASED UPON THE
20 REQUEST FOR WHAT DO WE DO WITH THESE --

21 DR. OLSON: THE CHANGE OF SCOPE, DEPENDING
22 ON WHAT THEY ASK FOR, MIGHT BE SOMETHING THAT MAY OR
23 MAY NOT REQUIRE ADVISORY OVERSIGHT.

24 MR. TORRES: SO YOU DECIDE MAYBE IT
25 DOESN'T REQUIRE IT. AT WHAT POINT DOES DR.

BARRISTERS' REPORTING SERVICE

1 FRIEDMAN'S ANALYSIS COME INTO PLAY WHEN THE BOARD
2 ENTERS THE PICTURE?

3 DR. OLSON: THE BOARD DOES NOT NORMALLY
4 ENTER IN THE CHANGE OF SCOPE REQUESTS. AND SO
5 ACTUALLY THAT WAS A LITTLE BIT OF A NUANCE. I MEAN
6 THE BOARD CERTAINLY COULD BE INFORMED OF UPDATES TO
7 HOW DISEASE TEAMS ARE PROGRESSING OR SUCH, BUT
8 NORMALLY A BOARD DOES NOT PARTICIPATE IN REQUESTS
9 FOR CHANGE OF SCOPE ON PROGRAMS. SO THIS IS A NEW
10 FEATURE.

11 MS. BAUM: I JUST WANTED TO NOTE FOR THE
12 RECORD THAT IT'S NOT JUST A NORMAL PRACTICE. IT'S
13 WHAT'S REQUIRED UNDER THE REGULATIONS IS THE
14 PRESIDENT WOULD NORMALLY OR IS AUTHORIZED TO MAKE
15 THOSE DECISIONS ON CHANGE OF SCOPE. SO I WANTED TO
16 MAKE THAT NOTATION.

17 AND I ALSO WANTED TO NOTE THAT WHEN I WAS
18 LISTENING TO THE CONVERSATION, I THINK I NOTED DR.
19 FRIEDMAN AS SAYING THAT NOT EVERYTHING IN HIS MIND
20 NEEDED TO GO TO THE BOARD EITHER. THERE WAS GOING
21 TO BE SOME CRITERIA BECAUSE OTHERWISE YOU MIGHT BE
22 SLOWING THE PROCESS DOWN UNNECESSARILY.

23 MR. TORRES: I DON'T WANT TO PUT WORDS IN
24 YOUR MOUTH, MIKE. I DON'T THINK YOU WERE SAYING YOU
25 WEREN'T ADVERSE TO REVIEWING MORE WORK, BUT RATHER

BARRISTERS' REPORTING SERVICE

1 WHAT WOULD TRIGGER THAT REVIEW.

2 DR. FRIEDMAN: EXACTLY. AND I HAVE NO
3 DESIRE FOR US TO BE INVOLVED IN THE LARGE NUMBER OF
4 RELATIVELY MINOR REQUESTS THAT YOU GET. I THOUGHT
5 WE WERE MAKING A POLICY FOR SUBSTANTIAL AMOUNTS OF
6 MONEY BEING LEFT OVER OR UNIQUE CONSIDERATIONS. IF
7 WE'RE TALKING ABOUT SOMEBODY OUT OF A \$10 MILLION
8 GRANT ENDS UP WITH \$50,000 AT THE END, THE BOARD
9 DOESN'T WANT TO BE INVOLVED IN THAT. SO I'M ONLY
10 TALKING ABOUT THE BIGGER THINGS OR MORE
11 CONTROVERSIAL THINGS OR MORE COMPLICATED THINGS. I
12 CERTAINLY DON'T WANT TO CREATE A LAYER OF
13 BUREAUCRACY THAT THE STAFF HAS TO DEAL WITH BECAUSE
14 THAT'S COUNTERPRODUCTIVE ALSO.

15 DR. PIZZO: I THINK WE -- I ASSUMED THAT
16 THAT'S WHAT MIKE WAS TALKING ABOUT AS WELL.

17 CHAIRMAN KLEIN: IF THERE'S A \$20 MILLION
18 GRANT, THERE'S 10 MILLION LEFT OVER, AND WE ARE
19 ABOUT TO USE THOSE FUNDS TO START A BREAKTHROUGH
20 HUMAN TRIAL, I THINK IT WOULD BE GOOD TO REVISIT
21 THAT AT THE BOARD LEVEL JUST TO HAVE AN
22 INFORMATIONAL BRIEFING AND MAKE SURE THAT WE CHECK
23 IN TO MAKE CERTAIN THAT WE'RE ALL ON BOARD WITH
24 EXACTLY --

25 MR. TORRES: HOW DO WE CHECK IN? HOW ARE

BARRISTERS' REPORTING SERVICE

1 WE NOTICED THAT THAT'S OCCURRING?

2 CHAIRMAN KLEIN: WELL, LET'S WAIT FOR THE
3 COMMITTEE -- LET'S WAIT FOR THE STAFF TO BRING THIS
4 TO THE BOARD. AND THEY CAN SET SOME GUIDELINES, BUT
5 CERTAINLY I THINK WHAT WE'RE TALKING ABOUT IS A
6 MAJOR EVENT HERE AND MAJOR FUNDING.

7 MS. FEIT: I THINK IN FAIRNESS TO OUR
8 POLICIES AND OUR PROCEDURES, I THINK WE HAVE TO BE
9 CAREFUL THAT WE DON'T GET OURSELVES INTO A POSITION
10 WHERE WE'RE GOING FROM ONE GRANT TO ANOTHER GRANT TO
11 ANOTHER GRANT WITHOUT DUE PROCESS. I THINK WE HAVE
12 TO BE REAL CAREFUL ABOUT THAT GOING FORWARD. IF
13 THERE ARE LEFT-OVER FUNDS, THEN THERE ARE LEFT-OVER
14 FUNDS, BUT WE DON'T WANT TO GET INTO A POSITION
15 WHERE WE'RE GETTING TO A POINT WHERE WE'RE
16 COMFORTABLE WITH JUST GOING FROM ONE PROJECT TO
17 ANOTHER.

18 CHAIRMAN SHEEHY: ANY FURTHER BOARD
19 COMMENTS? SO PAT, DR. TROUNSON, DO YOU HAVE ENOUGH
20 TO KIND OF GET AN OUTLINE BECAUSE YOU'RE GOING TO BE
21 BRINGING A FORMAL POLICY TO THE BOARD IN AUGUST?

22 DR. TROUNSON: SURE. I DON'T THINK
23 THERE'S ANY DOUBT THAT WE HAVE WHAT WE NEED. WE'LL
24 COME BACK TO YOU WITH SOMETHING THAT HOPEFULLY WILL
25 SUIT EVERYBODY.

BARRISTERS' REPORTING SERVICE

1 CHAIRMAN SHEEHY: EVEN THOUGH THIS IS NOT
2 AN ITEM UNDER CONSIDERATION, WE DO HAVE A PUBLIC
3 COMMENT HERE IN SAN FRANCISCO. ALWAYS HAPPY TO TAKE
4 PUBLIC COMMENT. IF AT ANY OF THE OTHER SITES IF
5 THERE ARE PEOPLE FROM THE PUBLIC WHO WOULD LIKE TO
6 SPEAK TO THIS, HAPPY TO HEAR FROM THEM, BUT IT'S NOT
7 FORMALLY NEEDED.

8 MR. REED: THIS IS DON REED. THIS IS VERY
9 EXCITING TO ME. CIRM HAS ALWAYS FOUND WAYS TO GET
10 MORE BANG FOR THE BUCK. AND THIS SEEMS TO ME TO BE
11 ONE. I LIKE THE IDEA OF THE GENERAL FRAMEWORK OF
12 THE PEOPLE BEING TOLD THAT IF YOU CAN FULLY
13 ACCOMPLISH YOUR MISSION AND YOU CAN END UP WITH SOME
14 MONEY LEFT OVER, THAT IT WOULD BE A GENERAL POLICY
15 THAT THAT WOULD BE -- YOU WOULD BE REWARDED FOR YOUR
16 CAREFULNESS BY GIVING STRONG CONSIDERATION TO TAKING
17 THIS TO THE NEXT STEP.

18 ALSO, IF THEY COULD KNOW THAT THEY'RE
19 WORKING TOWARD THIS AND THEY CAN SAY TO OTHER
20 PEOPLE, LOOK, WE'RE BEGINNING WITH A CHUNK OF CHANGE
21 ALREADY, WOULDN'T THAT BE MORE LIKELY TO ATTRACT
22 OUTSIDERS? I THINK THIS COULD BE AN INCENTIVE TO BE
23 CAREFUL, CAUTIOUS RATHER THAN IF THEY KNOW THE MONEY
24 IS ALL GOING TO USED UP, THERE'S A STRONG TEMPTATION
25 TO THINK, WELL, WE CAN ALSO DO THIS, THIS, THIS,

BARRISTERS' REPORTING SERVICE

1 THIS. BUT IF THEY SAY WAIT A MINUTE, THIS COULD
2 ALSO BE PART OF OUR NEXT STEP, I THINK THAT WOULD BE
3 A STRONG INCENTIVE TO BE CAUTIOUS.

4 THIS SEEMED LIKE A VERY EXCITING
5 POSSIBILITY TO ME.

6 CHAIRMAN SHEEHY: I DO THINK WE NEED TO BE
7 CLEAR THAT PEOPLE WHO -- THE INVESTIGATORS WHO COME
8 TO US FOR MONEY FULLY ANTICIPATE USING EVERY DIME IN
9 ORDER TO GET TO THE IND. AND WHAT WE'RE TRYING TO
10 ACCOUNT FOR IS SERENDIPITY BECAUSE IT'S CLEAR THEY
11 SCOPED OUT THE WORK THAT NEEDS TO BE DONE TO GET TO
12 THE IND. IF THERE WAS FAT IN THE BUDGET, I CAN
13 ASSURE YOU STAFF HAS BEEN VERY DILIGENT STEWARDS OF
14 STATE MONEY, AND THEY HAVE GONE THROUGH THESE GRANTS
15 WITH A FINE-TOOTHED COMB, MAKING SURE THAT THE RIGHT
16 SCIENCE IS GETTING DONE TO GET TO THE IND. BUT WHAT
17 WE'RE REALLY TRYING TO ACCOUNT FOR IS THAT
18 EVERYTHING GOES EXACTLY RIGHT, MAYBE IN SOME
19 CIRCUMSTANCES THERE'S SOME OTHER DISCOVERIES THAT
20 ARE NOT RELATED TO THIS TEAM THAT HELPED US JUMP A
21 STEP OR TWO, BUT WE'RE REALLY TALKING ABOUT
22 SERENDIPITY AND EXTREME GOOD FORTUNE. IT'S NOT
23 SOMETHING THAT WE WOULD ANTICIPATE BEING THE NORM.

24 THE BUDGETS ARE WRITTEN, THEY HAVE BEEN
25 EXAMINED, AND THERE'S A CLEAR ANTICIPATION THAT IT

BARRISTERS' REPORTING SERVICE

1 WILL TAKE EVERY DIME THAT THEY HAVE TO GET THROUGH
2 THE WORK THAT THEY HAVE SCHEDULED. I JUST WANTED TO
3 MAKE THAT CLEAR SO PEOPLE DON'T THINK THAT WE'VE SET
4 OUT THESE LAVISHLY PADDED BUDGETS AND WE HAVEN'T
5 GONE OVER THEM CAREFULLY.

6 I THINK WHAT ALL OF US -- I KNOW FROM THE
7 HIV FIELD, WE'VE SEEN SOME REALLY INTERESTING
8 PRELIMINARY PUBLICATIONS -- PUBLICATIONS OF
9 PRELIMINARY WORK THAT LOOKS VERY EXCITING. BUT I
10 FULLY ANTICIPATE THAT THEY'LL NEED EVERY DIME THAT
11 THEY HAVE TO GET TO THE FINISH LINE. JUST IN CASE
12 IS WHAT WE'RE TRYING TO CAPTURE. WE DO WANT TO
13 ENCOURAGE THEM TO GO AS FAST AS THEY CAN OBVIOUSLY
14 BECAUSE THERE ARE PATIENTS THAT ARE WAITING FOR
15 THESE CURES.

16 DR. TROUNSON: JEFF, MAY HAPPEN MORE
17 FREQUENTLY THAN YOU THINK BECAUSE IF IT LOOKS LIKE
18 THERE'S GOING TO BE A SUCCESSFUL PROGRAM, THEN MAYBE
19 INVESTMENTS COME IN EARLIER. AND THEY MAY COME IN
20 THE PRECLINICAL AREA OF THE DISEASE TEAM, AND THAT
21 MIGHT ACCELERATE THE PROJECTS. I THINK THEIR VIEW
22 WOULD BE, THEN, THEY WOULD BE COMFORTABLE DOING THAT
23 IF THEY KNEW THAT THE FUNDS WE WERE ALLOCATING COULD
24 ALSO GO ACROSS TO THE NEXT STAGE.

25 SO I THINK IT'S A VERY IMPORTANT NOTION

BARRISTERS' REPORTING SERVICE

1 THAT WE SAY THAT IF THERE IS A SAVINGS ON THE
2 PROJECT FROM OUR MONEY, AS LONG AS IT'S BEING USED
3 APPROPRIATELY, YES, WE'RE STRONGLY IN FAVOR OF IT.
4 AND SO YOU START WITH THAT UNLESS IT'S
5 INAPPROPRIATE.

6 CHAIRMAN SHEEHY: THANK YOU, DR. TROUNSON.
7 SO UNLESS ANYONE HAS ANY OTHER COMMENTS, I THINK
8 WE'RE READY TO MOVE ON TO AGENDA ITEM NO. 4.

9 MS. SAMUELSON: I'VE GOT A QUICK
10 PROCEDURAL QUESTION, JEFF. DON'T WE NEED TO BE
11 AVAILABLE TO THE PUBLIC AND PROVIDING THEM
12 OPPORTUNITIES TO SEE EVERYTHING THAT WE DO? THAT
13 WAS MY IMPRESSION. AND IT SOUNDED LIKE YOU WERE
14 SAYING -- I'M JUST CURIOUS THAT IT WASN'T NECESSARY
15 IN THIS CONTEXT.

16 CHAIRMAN SHEEHY: FOR THIS PARTICULAR ITEM
17 IN TERMS OF PUBLIC COMMENT?

18 MS. SAMUELSON: I THOUGHT YOU WERE
19 REFERRING TO THE MEETING AS A WHOLE, THAT IT DIDN'T
20 NEED PUBLIC COMMENT.

21 CHAIRMAN SHEEHY: ONLY FOR THAT ITEM
22 BECAUSE IT'S NOT AN ITEM ON WHICH WE'RE TAKING
23 ACTION. IT'S JUST A DISCUSSION ITEM. PUBLIC
24 COMMENT ISN'T REQUIRED, BUT I WANTED TO MAKE CLEAR
25 THAT, NO. 1, WE ARE OPEN TO THE PUBLIC, SO WE'RE

BARRISTERS' REPORTING SERVICE

1 ALWAYS HAPPY TO TAKE PUBLIC COMMENT IF SOMEONE IS
2 INTERESTED IN OFFERING SOME INSIGHT, BUT THAT IT
3 WASN' T A REQUIREMENT THAT WE GO BY EACH SITE, CHECK
4 FOR PUBLIC COMMENT BEFORE WE TAKE A VOTE.

5 MS. SAMUELSON: GOT IT.

6 CHAIRMAN SHEEHY: THAT WAS THE
7 DISTINCTION.

8 SO FOR NO. 4, UPDATE ON CONSIDERATION OF
9 COMMISSIONING AN IOM REPORT ON PERFORMANCE OF CIRM.
10 DID YOU HAVE SOME COMMENTS YOU WANT, INSIGHTS? I
11 JUST WANT -- CAN I REPEAT OUR CONVERSATION FOR
12 BACKGROUND? ONE OF THE THINGS THAT WE HAD DISCUSSED
13 WAS THE POTENTIAL MAYBE OF THIS PARTICULAR REPORT
14 PERHAPS TAKING THE PLACE OF ONE OR TWO OF THE AUDITS
15 THAT HAVE BEEN REQUIRED IN SENATE BILL 1064. AND
16 THAT CLEARLY IS NOT PART OF THE SCOPE. IT WOULD NOT
17 BE PART OF THE SCOPE OF WHAT' S PROPOSED IN 1064.

18 SO THIS IS A SEPARATE REPORT THAT WILL BE
19 COMMISSIONED BY THE INSTITUTE IN ORDER TO GET A
20 COMPLETELY INDEPENDENT ANALYSIS OF OUR PERFORMANCE
21 TO DATE.

22 I THINK CHAIRMAN KLEIN HAS SOME COMMENTS.
23 THE MAIN THING IS JUST TO GET AN UPDATE THAT WE' RE
24 IN DISCUSSIONS WITH THE IOM, AND THIS IS SOMETHING
25 THAT WE CAN BRING UP FOR CONSIDERATION TO THE BOARD

BARRISTERS' REPORTING SERVICE

1 IN AUGUST.

2 CHAIRMAN KLEIN: SO WHAT'S IMPORTANT HERE
3 IS THAT IN REFINING THE VARIOUS STUDIES THAT ARE
4 ONGOING IN EVALUATING THE PERFORMANCE OF THE AGENCY,
5 THE IOM, WE EXPECT TO GET A PROPOSAL FROM THEM. AND
6 THAT PROPOSAL WOULD BE FUNDED, AT LEAST
7 THEORETICALLY, IF ACCEPTED BY THE BOARD, PARTIALLY
8 BY THIS AGENCY AND PARTIALLY BY OUTSIDE DONOR FUNDS
9 TO REDUCE THE COST TO THE STATE. BUT WHAT'S CLEAR
10 HERE IS THAT BECAUSE OF THE PRESTIGE OF THIS
11 ORGANIZATION, IF THEY SUBMIT A PROPOSAL WITH AN
12 EXPECTED TIMELINE OF ABOUT 15 MONTHS, IT WOULD BE
13 DONE ON A TIME FRAME WHERE THERE WAS AN ABILITY FOR
14 THE OUTSIDE PUBLIC TO REVIEW IT, FOR US TO REVIEW
15 ANY RECOMMENDATIONS, FOR THE AGENCY TO BE ABLE TO
16 ADAPT ANY RECOMMENDATIONS TO FURTHER IMPROVE OUR
17 PERFORMANCE. BUT FOR THE PUBLIC LOOKING AT WHETHER
18 DOWNSTREAM THEY WANT TO PROVIDE ADDITIONAL FUNDING
19 BECAUSE OF STRONG SCIENTIFIC PROGRESS, THIS WOULD BE
20 A SOLID MILESTONE, HOPEFULLY, OF INDICATING THE HIGH
21 PERFORMANCE OF THIS AGENCY.

22 SO CLEARLY THIS IS AN INDEPENDENT BODY.
23 CLEARLY IT'S PRESTIGIOUS ON ITS SCIENCE. I
24 SPECIFICALLY HAD A CONVERSATION WITH THEM ABOUT
25 WHETHER THEY WOULD HAVE WITHIN THEIR PROPOSED SCOPE

BARRISTERS' REPORTING SERVICE

1 THE ECONOMIC ANALYSIS OF THE IMPACT OF THIS AGENCY
2 AND THE FUNDING STRUCTURE OF IT IN HELPING
3 CALIFORNIA AND SCIENCE MOVE FORWARD. SPECIFICALLY,
4 WHAT IS THE STRATEGIC VALUE OF HAVING STABLE FUNDING
5 AND ATTRACTING OUTSIDE FUNDS AND ATTRACTING PEOPLE
6 TO THE FIELD? THEY INDICATED THAT THEY HAVE
7 ECONOMISTS, A WHOLE SECTION OF ECONOMISTS, THAT ARE
8 MEMBERS OF THE IOM, AND THAT THEY WOULD HAVE THOSE
9 ECONOMISTS INVOLVED IN THAT PART OF IT SO THAT THEY
10 COULD CERTAINLY LOOK AT THE FUNDING SYSTEM AS BEING
11 IMPORTANT FOR CALIFORNIA AND THE COUNTRY. THEY
12 COULD LOOK AT, IN FACT, THE FUNDING SYSTEM FOR
13 PROVIDING THE STABILITY FOR INSTITUTIONS TO CREATE
14 ENTIRE DEPARTMENTS AND RECRUIT FACULTY AROUND THE
15 FIELD AS WELL AS OUTSTANDING STUDENTS FROM AROUND
16 THE COUNTRY AND AROUND THE WORLD.

17 SO THEY'RE PREPARED IN THIS PROPOSAL,
18 WHICH WE ARE LOOKING FORWARD TO RECEIVING, TO
19 LOOKING AT THE WHOLE SCOPE OF REVIEW AND IN A
20 TIMETABLE THAT I THINK WOULD PROVIDE, AS I SAID, A
21 VERY STRONG MILESTONE FOR THE PUBLIC'S REVIEW OF THE
22 AGENCY'S PERFORMANCE IN LOOKING AT WHETHER THIS
23 AGENCY SHOULD HAVE ADDITIONAL FUNDS IN THE FUTURE.

24 CHAIRMAN SHEEHY: SO ARE THERE ANY OTHER
25 COMMENTS FROM BOARD MEMBERS? I THINK THIS IS MOVING

BARRISTERS' REPORTING SERVICE

1 FORWARD.

2 DR. TROUNSON: THERE'S A COUPLE OF POINTS,
3 ONE OF WHICH I THINK BOB TOUCHED ON, IS THAT THIS IS
4 A VERY COSTLY BUSINESS. SO IT'S GOING TO BE VERY
5 IMPORTANT TO GET SOME ADDITIONAL FUNDS BECAUSE WHEN
6 I SPOKE LAST TIME -- IT'S A POINT AND I THINK IT'S
7 AN IMPORTANT POINT, NO. 1, THAT WE PROBABLY NEED TO
8 GET SOME DONOR MONEY BECAUSE THIS IS GOING TO BE AN
9 EXPENSIVE ISSUE. WE HAVE HAD SOME CONVERSATIONS
10 WITH THE MEMBERS OF IOM, AND WE THINK THAT THAT'S
11 STILL GOING TO BE AROUND THAT KIND OF COST. SO WE
12 NEED TO REFLECT ON THAT. WE NEED TO MAKE SURE THAT
13 WE DO GET THOSE DONOR FUNDS. I THINK THAT'S VERY
14 IMPORTANT.

15 THE OTHER THING IS THAT IT NEEDS TO BE
16 VERY MUCH LINKED TO WHEN WE WANT TO GO FORWARD TO
17 CALIFORNIA OR WHOMEVER FOR GETTING ADDITIONAL FUNDS.
18 AND I THINK WE NEED AS MUCH TIME AS POSSIBLE TO BE
19 ABLE TO DEMONSTRATE THE ECONOMIC BENEFITS OF WHAT
20 WE'RE DOING. ANY LONGER TIME WILL BE MORE AND MORE
21 HELPFUL FOR THAT. WE'VE GOT ONE REPORT, WHICH I
22 THINK JOHN ROBSON IS BRINGING TO THE BOARD SHORTLY
23 ON ONE CLINICAL TRIAL PROGRAM, BUT THAT'S A GOOD
24 START, BUT I THINK WE NEED SEVERAL OF THESE. AND
25 THEY'RE NOT GOING TO HAPPEN FOR A LITTLE WHILE. AND

BARRISTERS' REPORTING SERVICE

1 SO I HOPE IT GIVES US A MAXIMUM OPPORTUNITY TO GET
2 THE MAXIMUM IMPACT FOR THE REPORT.

3 SO I THINK IT'S A VERY IMPORTANT JOB TO BE
4 DONE.

5 CHAIRMAN SHEEHY: JUST TO CLARIFY, SOME OF
6 US HAVE FIDUCIARY RESPONSIBILITIES TO OUR APPOINTING
7 OFFICERS AND OUR APPOINTING BODIES. AND IT WOULD
8 BE, NOTWITHSTANDING THE COST, WHICH \$1 MILLION OUT
9 OF THE BILLION WE'VE ALREADY SPENT, IF WE WANT TO GO
10 THROUGH THE BUDGET, AND REALLY I DON'T KNOW IF THIS
11 WOULD NOT BE ONE OF THE BETTER USES OF FUNDING, TO
12 BE ABLE TO CLEARLY SHOW THE PEOPLE OF CALIFORNIA
13 WHAT THE GOLD STANDARD, OBJECTIVE EVALUATION AGENCY
14 IN THIS COUNTRY, WHAT KIND OF WORK, WHAT KIND OF
15 PROGRESS WE'VE DONE.

16 I CERTAINLY DON'T WANT TO GO OFF THE BOARD
17 IN TWO YEARS WITHOUT THIS REPORT BEING FINISHED. I
18 FEEL VERY STRONGLY. THAT'S WHY I HAVE IT ON THE
19 AGENDA, TO MAKE SURE THAT THIS IS SOMETHING WE CAN
20 APPROVE IN AUGUST, THAT THIS IS SOMETHING THAT GOES
21 FORWARD. I DON'T THINK I COULD GO TO ANY MEMBER OF
22 THE PUBLIC, ANY EDITORIAL BOARD, ANY MEMBER OF THE
23 LEGISLATURE, THE GOVERNOR, ANY ELECTED OFFICIAL
24 WITHOUT SOME SORT OF EXTERNAL REVIEW OF WHAT'S GONE
25 ON WITH A BILLION DOLLARS OF THE TAXPAYERS MONEY,

BARRISTERS' REPORTING SERVICE

1 ESPECIALLY IN THE MIDDLE OF THIS HORRIBLE RECESSION.
2 THERE' S SOME STATE WORKERS THAT ARE WORKING AT
3 MINIMUM WAGE, THANKS TO THE GOVERNOR. AND WE' RE
4 DOING -- AS HAS BEEN NOTED, WE' RE ABLE TO CONTINUE
5 TO DO OUR WORK.

6 I THINK THAT THERE' S A CERTAIN VALUE, AND
7 I THINK CHAIRMAN KLEIN HAS ALLUDED TO THIS, TO THE
8 CONSTANCY OF FUNDING, THE CERTAINTY OF FUNDING IN
9 ADVANCING MEDICAL SCIENCE, TO GETTING CURES FASTER.
10 I THINK WITH THIS REPORT, WE' LL BE ABLE TO SHOW THE
11 VOTERS THAT ACTUALLY THIS WAS A VERY GOOD INVESTMENT
12 AT A CRITICAL TIME FOR THE STATE OF CALIFORNIA, BOTH
13 IN TERMS OF THE FUTURE HEALTH OF CALIFORNIANS AND
14 OTHER PEOPLE IN THIS COUNTRY, BUT ALSO FOR OUR
15 ECONOMY AT A TIME WHEN FUNDS WERE REALLY RESTRICTED
16 FROM A LOT OF OTHER SOURCES.

17 SO I WOULD LIKE US TO BE ABLE TO MAKE THAT
18 ARGUMENT. I KNOW THIS WILL TAKE TIME, BUT I THINK
19 WE SHOULD GET ON WITH IT. AND IF IT COSTS US SOME
20 MONEY, I THINK THE CHAIR SEEMS CONFIDENT THAT WE CAN
21 FIND SOME OUTSIDE FUNDING, BUT WE SHOULD NOT SLOW
22 THIS DOWN. I THINK IT' S IMPORTANT FOR US, FOR OUR
23 CREDI B I L I T Y BOTH AS I N D I V I D U A L S AND AS A BOARD.

24 DR. PIZZO, I KNOW THAT YOU WERE VERY
25 FAMI LI AR WITH THI S.

BARRISTERS' REPORTING SERVICE

1 DR. PIZZO: I AGREE WITH THE POINTS THAT
2 JEFF HAS PUT FORTH. I DO KNOW THE IOM PROCESS, AS
3 OTHERS DO, VERY WELL. I THINK IT'S PROBABLY THE
4 BEST PLACE FOR US TO GO, AND I TOTALLY CONCUR THAT
5 THIS IS A GOOD WAY OF HAVING A REALLY TRULY
6 INDEPENDENT CRITICAL ASSESSMENT. I SUPPORT IT, BUT
7 IT IS GOING TO BE EXPENSIVE AND IT WILL TAKE TIME.

8 CHAIRMAN KLEIN: I'D JUST LIKE TO
9 REEMPHASIZE. I THINK WE CAN FIND SUBSTANTIAL
10 PRIVATE DONATIONS, AS ALAN HAS REFERENCED, AS JEFF
11 HAS REFERENCED, AND THAT I WOULD REALLY SERIOUSLY
12 COMMIT SOME OF MY TIME TO MAKING SURE THAT WE HAVE
13 THAT HAPPEN. IN TIMES OF TIGHT CONSTRAINTS ON
14 BUDGETS EVERYWHERE, I WANT TO MAKE SURE WE HAVE
15 MAJOR PRIVATE CONTRIBUTIONS TO REDUCE THIS COST.

16 MS. BAUM: I JUST WANTED TO FOR THE RECORD
17 JUST ACKNOWLEDGE THE FACT THAT WE DO ALSO HAVE A
18 BLUE RIBBON PANEL OF TOP EXPERTS IN THE FIELD. I
19 DON'T THINK SUGGESTING THAT THE IOM IS ALSO NEEDED
20 SHOULD IN ANY WAY DIMINISH THE SUPPORT AND THE
21 CONTRIBUTIONS THAT THAT PANEL WILL BE MAKING IN
22 OCTOBER. THANK YOU.

23 MR. TORRES: THAT'S REQUIRED BY THE
24 STRATEGIC PLAN, REFERENCED BY THE INITIATIVE, BUT
25 THAT HAS NOTHING TO DO WITH WHAT THE OTHER ISSUES

BARRISTERS' REPORTING SERVICE

1 ARE THAT WE'RE TALKING ABOUT.

2 DR. PIZZO: COULD SOMEONE --

3 MR. TORRES: THERE ARE TWO SEPARATE TRACKS
4 HERE THAT WE WERE TALKING ABOUT, AND THAT'S WHY I
5 WANTED TO MAKE SURE THAT WE KNEW WHAT WE WERE
6 TALKING ABOUT.

7 DR. PIZZO: COULD SOMEONE PERHAPS SHARE,
8 SINCE I'M NOT SURE THAT I KNOW WHO'S ON THE BLUE
9 RIBBON PANEL, COULD WE TAKE A LOOK AT THAT LIST JUST
10 FOR OUR INFORMATION?

11 CHAIRMAN SHEEHY: SURE. PERHAPS STAFF
12 COULD SEND THAT AROUND TO THE MEMBERS.

13 DR. TROUNSON: SURE. IT'S BEEN OUT THERE
14 BEFORE, PHIL, BUT WE'LL SEND IT.

15 DR. PIZZO: I'M SORRY. I'M SURE IT'S JUST
16 ME.

17 DR. TROUNSON: WE'LL SEND IT TO YOU. I'LL
18 GET PAT TO DO THAT. ANYONE ELSE WHO NEEDS IT,
19 PLEASE LET US KNOW. WE'LL GET IT OUT TO YOU.

20 CHAIRMAN SHEEHY: HOW ABOUT WE JUST SEND
21 IT AROUND TO THE WHOLE COMMITTEE. PROVIDE IT TO
22 MELISSA.

23 DR. OLSON: I JUST WANTED TO MAKE A POINT,
24 AND I THINK ALL THE COMMENTS ARE CERTAINLY TRUE.
25 THE IOM IS CLEARLY RECOGNIZED AS A BLUE RIBBON

BARRISTERS' REPORTING SERVICE

1 INDEPENDENT GROUP. I'M SURE THAT THE COST CAN BE
2 DONE. I APPRECIATE THE VALUE, BUT I DO WANT PEOPLE
3 TO RECOGNIZE THAT THE COST IS NOT JUST IN MONEY.
4 THE COST IS IN STAFF TIME.

5 I HAD THE PLEASURE OF MEETING THE PROGRAM
6 OFFICER WITH, I BELIEVE, WHOM MEMBERS OF THE OFFICE
7 OF THE CHAIR STAFF HAS BEEN TALKING WITH THE IOM.
8 AND THEY DID CONFIRM WITH ME THAT IN POINT OF FACT
9 AN IOM REVIEW IS INCREDIBLY MANAGEMENT AND STAFF
10 TIME INTENSIVE. SO I DO NOT DISPUTE THE VALUE OF
11 THIS. I JUST WANT IT RECOGNIZED AND ACKNOWLEDGED
12 WHAT IT WILL TAKE TO UNDERTAKE SUCH A REPORT.

13 CHAIRMAN KLEIN: I THINK DR. OLSON'S POINT
14 IS CORRECT. AND ONE OF THE BENEFITS OF HAVING IT 15
15 MONTHS OUT IS TO MAKE SURE THAT THERE'S NO OVERLAP
16 WITH THE EXISTING PRESTIGIOUS PANEL THAT'S DOING
17 THEIR SCIENTIFIC REVIEW, WHICH THAT WORK WILL BE
18 DONE ESSENTIALLY IN THE NEXT 90 DAYS. BUT IT WAS
19 VERY IMPORTANT TO RECOGNIZE THAT IT IS A VERY
20 PRESTIGIOUS PANEL. I THINK, DR. PIZZO, YOU'LL SEE
21 WHO'S GOING TO REVIEW THE SCIENTIFIC STRATEGIC PLAN
22 PERFORMANCE. AND THAT WILL BE A GREAT INSTALLMENT
23 THAT WILL CONTRIBUTE TO THE ABILITY OF IOM TO HAVE
24 AN OVERVIEW ON WHAT WE HAVE DONE.

25 MS. SAMUELSON: BOB, THAT WILL ENCOMPASS A

BARRISTERS' REPORTING SERVICE

1 SCIENTIFIC REVIEW AS WELL, OF COURSE, RIGHT, IN
2 ADDITION TO AN ECONOMIC REVIEW AND SO ON. IT SEEMS
3 TO ME THAT THE MOST IMPORTANT THING IS THAT AT EVERY
4 POINT WE KNOW THAT WE'RE ON TRACK AS BEST WE CAN.
5 AND IF WE ARE NOT, HOW WE SHOULD BE TWEAKING WHAT
6 WE'RE DOING SO THAT WE GET THE BEST POSSIBLE
7 RESULTS, AND PRESUMABLY THIS IS A PIECE OF THAT.

8 MY HOPE IS THAT THE PROPOSAL WHEN IT COMES
9 TO THE BOARD WILL SPEAK TO THAT AS BEST IT CAN.

10 MR. TORRES: LET'S KEEP IN MIND AGAIN, NO.
11 1, THAT THE STRATEGIC PLAN REVIEW IS REQUIRED BY THE
12 INITIATIVE. SO WE UNDERSTAND THAT. WE'RE MANDATED
13 TO DO THAT. WE AREN'T MANDATED TO DO THE IOM, WHICH
14 IS WHY THE LEADERSHIP OF CIRM AND THE BOARD IN
15 CONJUNCTION AND WORKING TOGETHER ARE WANTING TO MAKE
16 SURE THAT WE HAVE ANOTHER REVIEW ON TOP OF THAT
17 REVIEW SO THAT WE HAVE A MACRO VIEW OF WHERE WE ARE
18 MOVING AND WHERE WE ARE HEADED.

19 CHAIRMAN SHEEHY: ANY OTHER BOARD
20 COMMENTS? WE HAVE A PUBLIC COMMENT HERE.

21 MR. REED: I THINK EVERYBODY IS THINKING
22 AT THE END OF THE 14 YEARS THAT THIS MUST GO ON,
23 THAT THE CALIFORNIA STEM CELL PROGRAM MUST BE
24 CONTINUED. I THINK THE IOM IS PART OF THAT.

25 NOW, OHIO IS DOING A LOT OF WORK ON

BARRISTERS' REPORTING SERVICE

1 STUDYING THE BENEFITS OF TARGETED FUNDING INTO
2 FORWARD LOOKING RESEARCH PROGRAMS SUCH AS
3 BIOMEDICINE. AND THEY'RE TRYING TO FIND EXACTLY
4 WHAT THE RESULTS WILL BE IN TERMS OF NEW JOBS, NEW
5 REVENUES. I WONDER IF IT WOULD BE POSSIBLE AS PART
6 OF THE IOM REVIEW TO HAVE SOMEBODY THAT'S PART OF
7 THAT PROCEDURE IN OHIO TO LEND US THAT KNOWLEDGE AS
8 PART OF THIS BECAUSE THAT'S WHAT'S GOING TO
9 DETERMINE LONG-TERM SUCCESS OF OUR PROGRAM IS HOW IT
10 AFFECTS PEOPLE. AND JOBS ARE A PART OF THAT
11 PICTURE. SO I THINK OHIO WILL BE GOOD TO CONSULT
12 WITH.

13 CHAIRMAN SHEEHY: THANKS, DON. UNLESS
14 THERE'S ANY OTHER COMMENTS, I'M READY TO MOVE ON TO
15 AGENDA ITEM NO. 5, WHICH IS DISCUSSION OF AND
16 CONSIDERATION OF CHANGES TO THE EXTRAORDINARY
17 PETITION AND GRANT ADMINISTRATION APPEALS PROCESSES.
18 I THINK YOU GUYS, I HOPE EVERYONE HAS A COPY OF THE
19 DOCUMENTS. IT'S A PAGE AND A HALF.

20 I'LL JUST KIND OF GO OVER IT. AND HAPPY
21 FOR ALL COMMENTS AND CHANGES, ETC. I THINK ONE
22 THING THAT CONTINUES TO BEDEVIL US, BUT I THINK
23 WE'RE STUCK WITH, IS THE LINGUISTIC DIFFICULTIES IN
24 DISTINGUISHING BETWEEN THE APPEALS PROCESS AND THE
25 EXTRAORDINARY PETITION PROCESS. BUT THERE IS A

BARRISTERS' REPORTING SERVICE

1 REASON FOR THAT.

2 THE ONLY REASON FOR AN APPEAL OF A
3 SCIENTIFIC SCORE OF A GRANT RECOMMENDATION FROM THE
4 GRANTS REVIEW GROUP IS CONFLICT OF INTEREST. AND SO
5 THE FORMAL APPEALS PROCESS CAPTURES THAT. HOWEVER,
6 AS THE PUBLIC BODY MEETING IN THE STATE OF
7 CALIFORNIA AND GOVERNED BY OPEN GOVERNMENT LAWS THAT
8 ARE ENSHRINED IN CALIFORNIA CONSTITUTION -- BY THE
9 WAY, I WANT STATE UP FRONT I DO NOT FIND THIS A
10 BURDEN. I FIND IT A POSITIVE FEATURE OF CALIFORNIA
11 PUBLIC POLICY PROCESS. BUT ANY MEMBER OF THE PUBLIC
12 CAN ADDRESS THE BOARD, CAN PROVIDE INFORMATION TO
13 THE BOARD REGARDING A MATTER UNDER CONSIDERATION BY
14 US.

15 AND GIVEN THAT, WE HAVE TRIED TO PROVIDE
16 SOME STRUCTURE FOR THAT, WHICH IS WHAT THE
17 EXTRAORDINARY PETITION PROCESS IS. NOW, A COUPLE
18 THINGS I WANT TO DO TODAY IS REINFORCE SOME OF THE
19 POLICIES THAT WE HAVE, SOME OF THE ASPECTS OF THAT
20 POLICY THAT WE'VE KIND OF GOTTEN NEGLIGENT IN
21 APPLYING. ONE IS THAT, AS ORIGINALLY CONCEIVED, THE
22 EXTRAORDINARY PETITION PROCESS DID NOT AUTOMATICALLY
23 GRANT AN APPLICANT REVIEW BY THE BOARD. IT IS
24 CERTAINLY AN OPTION THAT ANY APPLICANT CAN AVAIL
25 THEMSELVES OF, BUT THAT DOES NOT AUTOMATICALLY

BARRISTERS' REPORTING SERVICE

1 QUALIFY FOR DISCUSSION AND CONSIDERATION BY THE
2 BOARD.

3 WE OBVIOUSLY RECEIVE, AND I'M SURE, LIKE
4 MYSELF, ALL THE BOARD MEMBERS READ THE EXTRAORDINARY
5 PETITIONS AND CONSIDER THEM CAREFULLY. BUT UNLESS A
6 BOARD MEMBER SPECIFICALLY ASKS THAT AN EXTRAORDINARY
7 PETITION BE CONSIDERED OR PUBLIC COMMENT FROM A
8 MEMBER OF THE PUBLIC ABOUT INCLUDING AN APPLICANT
9 ABOUT THEIR APPLICATION, CONSIDERATION IS NOT
10 AUTOMATIC.

11 JUST TO REEMPHASIZE, AS A MATTER OF
12 PROCESS, THAT SIMPLY FILING AN EXTRAORDINARY
13 PETITION DOES NOT GUARANTEE ANY ADDITIONAL
14 CONSIDERATION BY THE BOARD.

15 THE SECOND POINT, AND HAVING TALKED TO
16 STAFF ABOUT THIS, ONE OF THE THINGS IS THAT A LOT OF
17 APPLICANTS HAVE DECIDED THAT THERE'S NO DISADVANTAGE
18 TO GOING AHEAD AND FILING AN EXTRAORDINARY PETITION.
19 BOARD STAFF HAS SPENT AN ENORMOUS AMOUNT OF TIME IN
20 RESPONDING TO EACH OF THESE.

21 ONE CHANGE WE ARE PROPOSING TODAY IS TO
22 RESTRICT BOARD COMMENTS TO THOSE EXTRAORDINARY
23 PETITIONS THAT THEY FEEL HAVE MERIT. SO I THINK WE
24 NEED TO BE CLEAR AS BOARD MEMBERS THAT THE STAFF IS
25 READING ALL THE EXTRAORDINARY PETITIONS. THEY'RE

BARRISTERS' REPORTING SERVICE

1 LOOKING AT THE REVIEWS, THEY' RE LOOKING AT THE
2 APPLI CATIONS; BUT RATHER THAN JUST SIMPLY HAVE TO
3 RIGOROUSLY, AS WE' VE BEEN DOING, AND I GIVE STAFF AN
4 ENORMOUS AMOUNT OF CREDIT FOR THE DILIGENCE THAT
5 THEY' VE APPLIED IN THIS PROCESS, BUT RATHER THAN
6 HAVE TO WRITE OUT THESE LONG, EXHAUSTIVE
7 POINT-BY-POINT REBUTTALS, THEY' RE ONLY GOING TO
8 RESPOND TO THOSE EXTRAORDINARY PETITIONS THEY FEEL
9 HAVE SOME MERIT IN THEM.

10 SO I THINK AS BOARD MEMBERS WE NEED TO BE
11 CLEAR THAT WHEN WE GET AN EXTRAORDINARY PETITION
12 WITH NO COMMENT FROM STAFF, THAT STAFF DOES NOT
13 SUPPORT THE EXTRAORDINARY PETITION. AND SO UNLESS
14 WE FIND SOME INTRINSIC MERIT IN THEIR ARGUMENTS THAT
15 WE GET, WE OUGHT NOT TO BE BRINGING THESE UP UNLESS
16 WE' RE PREPARED TO ARGUE FOR THEM.

17 MR. TORRES: SO THERE' S AN APPEAL PROCESS
18 IF WE DON' T AGREE WITH HOW THE STAFF HAS DETERMINED?

19 CHAIRMAN SHEEHY: THE PROCESS IS THAT THE
20 MEMBER OF THE BOARD CAN ASK THAT THAT APPLI CATION BE
21 CONSI DERED.

22 MR. TORRES: SO IT' S AN APPEAL OF THE
23 STAFF DECISION.

24 CHAIRMAN SHEEHY: IT' S NOT AN APPEAL.
25 IT' S RESPONDING TO THE EXTRAORDINARY PETITION. SO

BARRISTERS' REPORTING SERVICE

1 WE CAN HAVE A RESPONSE TO AN EXTRAORDINARY PETITION.
2 I DON'T WANT TO USE THE WORD "APPEAL" IN THE
3 EXTRAORDINARY PETITION PROCESS BECAUSE YOU'RE NOT
4 APPEALING YOUR SCORE OR YOUR RECOMMENDATION FROM THE
5 GRANTS WORKING GROUP. YOU'RE PETITIONING THE BOARD,
6 YOU'RE PROVIDING INFORMATION TO THE BOARD. IF THE
7 BOARD, AS THE DECISION MAKER PER PROP 71, DECIDES TO
8 TAKE UP THAT APPLICATION, CAN LOOK AT THE
9 INFORMATION IN THE EXTRAORDINARY PETITION, THAT'S
10 FULLY WITHIN THE SCOPE OF THE BOARD'S RESPONSIBILITY
11 AND DUTIES. THAT'S THE PREFACE.

12 NOW, WHAT WE'VE KIND OF COME UP WITH, AND
13 I THINK WE MAY NEED SOME DISCUSSION ON SOME POINTS
14 OF THIS, IS MAYBE PROVIDING THE BOARD WITH ANOTHER
15 OPTION BECAUSE I KNOW THAT THERE HAS BEEN -- THERE
16 HAVE BEEN SITUATIONS WHERE I THINK IT GETS VERY
17 DIFFICULT FOR THE BOARD TO COME TO A CLEAR DECISION.
18 AND WHAT WE'RE CALLING THIS IS AN OPTION FOR
19 RESCORING. THIS IS NOT A REREVIEW OPTION. THIS IS
20 AN OPPORTUNITY FOR THE BOARD, AND THIS IS AN OPTION
21 FOR THE BOARD BESIDES DENYING A GRANT AND APPROVING
22 A GRANT, AND TO BE SPECIFIC, THE WAY IN WHICH THIS
23 WOULD BE WORDED, THIS WOULD BE A DENIAL OF A GRANT
24 PENDING -- NOT PENDING, BUT UNLESS THE CHAIR OF THE
25 REVIEW SESSION AND ONE OF THE PRIMARY REVIEWERS

BARRISTERS' REPORTING SERVICE

1 OFFER A HIGHER SCORE THAN INITIALLY RECOMMENDED FOR
2 THE GRANT, THAT THIS GRANT WOULD BE DENIED.

3 THIS DOES GIVE THE BOARD AN OPPORTUNITY IN
4 SOME CIRCUMSTANCES TO IN MOMENTS OF INDECISION WHEN
5 WE CAN'T GET TO A CLEAR CONSENSUS ON A GRANT TO HAVE
6 WHAT SHOULD BE A RARELY EXERCISED, BUT AVAILABLE
7 OPTION FOR HAVING A GRANT RESCORED. A LOT OF
8 DETAILS IN THE PROCESS -- IN THE PROPOSAL FOR THE
9 ACTUAL PROCESS. I CAN GO THROUGH IT, BUT I'M HOPING
10 PEOPLE HAVE READ IT. I THINK CHAIRMAN KLEIN HAS A
11 COMMENT HE WANTED TO MAKE.

12 CHAIRMAN KLEIN: IF I COULD JUST COMMENT
13 ON THE POINTS YOU JUST MADE, JEFF, IS THAT THE
14 MESSAGE TO APPLICANTS IS THAT THIS IS A RARE
15 OCCURRENCE WHERE THE BOARD WOULD LOOK TO THIS. THIS
16 IS NOT AN OPEN DOOR. YOU POINTED OUT IN THE SCRIPT
17 HERE THAT IN THE NARRATIVE THAT IF THE SCIENTIFIC
18 STAFF RECOGNIZES THERE'S AN ERROR AND MAKES A
19 RECOMMENDATION TO THE BOARD, THE BOARD RESOLVES THE
20 ISSUE. IF THE BOARD BRINGS UP AN ISSUE WHERE IT IS
21 A PROGRAMMATIC ISSUE, THEY MAKE A DECISION, THEY
22 MOVE ON.

23 THIS IS A VERY, VERY RARE, AS YOU SAID,
24 SITUATION WHERE THE SCIENTIFIC STAFF AND THE BOARD
25 FEEL, AND THE BOARD MAKES A DECISION THAT THEY'D

BARRISTERS' REPORTING SERVICE

1 LIKE TO HAVE THIS VERY LIMITED RESCORING OPTION.
2 SO THE BOARD WOULD MAKE A MOTION TO DENY EXCEPT IF
3 IN THAT SITUATION THIS PARTICULAR GRANT HAD A SCORE
4 RAISED IN THIS PROCESS YOU'RE DESCRIBING.

5 MS. SAMUELSON: COULD IT EVER BE USED IN
6 THE SITUATION WHERE THE BOARD WAS INTERESTED IN
7 RESCORING BECAUSE IT THOUGHT THAT IT MIGHT BE
8 APPROPRIATE?

9 CHAIRMAN SHEEHY: THAT WOULD BE THE
10 CIRCUMSTANCE IN WHICH THE BOARD WOULD USE THIS.

11 MS. SAMUELSON: WHAT I MEAN BY THAT IS
12 THAT IT IS INTERESTED IN A DECISION TO FUND THE
13 GRANT, SO AGAINST THE WORKING GROUP RECOMMENDATION,
14 BUT IT WANTS THE FEEDBACK OF THE WORKING GROUP
15 SCORING PERHAPS WITH SOME PREMISE PRESENTED FOR
16 THEM. IT WANTS INPUT, IN OTHER WORDS.

17 CHAIRMAN SHEEHY: RIGHT. WE DON'T
18 PRECLUDE -- THE GOAL OF THIS PROCESS IS NOT TO END
19 THE PROGRAMMATIC REVIEW OF GRANTS BY THE BOARD. SO
20 IF THE BOARD HAS A STRONG PROGRAMMATIC BASIS FOR
21 WANTING TO APPROVE A GRANT, THAT SHOULD NOT BE
22 GROUNDS FOR RESCORING. BUT I CAN TELL YOU A
23 CIRCUMSTANCE WHERE I WOULD VISUALIZE THIS IS A GRANT
24 THAT DID NOT GET A FUNDABLE SCORE. BASED ON MY
25 EXPERIENCE AND MY KNOWLEDGE OF HIV, HIV GRANT, I'M

BARRISTERS' REPORTING SERVICE

1 READING THE EXTRAORDINARY PETITION AND I SEE
2 SOMETHING THAT I FEEL IS REALLY COMPELLING.

3 THE DISCUSSION AT THE BOARD, OTHER BOARD
4 MEMBERS FEEL HIGHLY UNCOMFORTABLE ABOUT VOTING
5 THROUGH A GRANT WITH THIS SCORE; BUT MAYBE AS A
6 COURTESY TO ME, THEY WOULD ALLOW THIS GRANT TO HAVE
7 THE OPTION FOR RESCORING. WE DON'T ALL HAVE PERFECT
8 KNOWLEDGE ACROSS ALL AREAS OF SCIENCE. CERTAINLY
9 FOR PATIENT ADVOCATES WE HAVE A LOT OF EXPERIENCE
10 WITHIN THE CONTEXT OF THE DISEASES WITH WHICH WE'RE
11 CONFRONTED. CERTAINLY THE WORKING GROUP COVERING A
12 WHOLE HOST OF DISEASES AND CONDITIONS MAY NOT HAVE
13 TOTAL UNDERSTANDING OF ALL ASPECTS OF THE DISEASE.

14 I WOULD EXPECT THIS OPTION TO BE USED VERY
15 RARELY. I WOULD NOT EXPECT IT TO BE USED IN EVERY
16 GRANT ROUND. AND I WOULD EXPECT IT TO ONLY BE USED
17 IN THE MOST EXTRAORDINARY CIRCUMSTANCES.

18 DR. TROUNSON: JEFF, I'M JUST WONDERING
19 ABOUT WHEN YOU ARE TALKING ABOUT RESCORING, YOU
20 REALLY ARE GOING TO HAVE TO PROVIDE SOME ADDITIONAL
21 INFORMATION TO THE REVIEWERS. OTHERWISE,
22 THEORETICALLY AT LEAST, THEY'LL COME UP WITH EXACTLY
23 THE SAME SCORE BECAUSE NOTHING SCIENTIFICALLY HAS
24 CHANGED.

25 WHAT I WAS WONDERING IS THE PROCESS REALLY

BARRISTERS' REPORTING SERVICE

1 SHOULD INVOLVE TAKING WHATEVER MATTERS THAT WERE IN
2 SCIENTIFIC DEBATE, IF THEY WERE RAISED, GETTING SOME
3 WORK DONE ON THEM SO THAT THERE IS SOME FURTHER
4 INFORMATION FROM EXPERTS IN THE AREA. AND THEN I
5 KIND OF THINK FOR A RESCORE, IT WOULD BE PROBABLY
6 BEST TO GET THE WHOLE GRANTS REVIEW TEAM BACK TO
7 RESCORE IT BECAUSE ESSENTIALLY YOU'RE GOING TO GIVE
8 THEM SOME REVISED INFORMATION THAT MIGHT BE DERIVED
9 FROM SOME OTHER PLACE BECAUSE THE RESCORE, THE SCORE
10 IS A SCIENTIFIC SCORE. SO I THINK YOU HAVE TO
11 ACTUALLY GO TO SOME CHANGE IN THE SCIENCE, WHETHER
12 THEY REALLY GOT IT CORRECTLY IN THE FIRST PLACE OR
13 IT WAS A DIFFERENT PERSPECTIVE ON SOME OF THE
14 SCIENTIFIC ISSUES THAT WERE RAISED.

15 SO I WONDERED IF YOU'RE GOING TO RESCORE,
16 YOU PROBABLY HAVE TO GET THE INFORMATION, DO SOME
17 ANALYSIS ON IT, GET IT BACK TO THE REVIEWERS, AND
18 THEN ASK THEM TO RELOOK AT IT IN THE LIGHT OF THE
19 NEW INFORMATION.

20 CHAIRMAN SHEEHY: I GUESS I'M CONFUSED
21 HERE BECAUSE I DISCUSSED THIS PROCESS WITH STAFF
22 BEFORE WE BROUGHT IT TO THE BOARD, AND EXPLICITLY
23 THE REQUEST WAS NOT TO INVOLVE THE ENTIRE WORKING
24 GROUP. SO IF STAFF IS IN AGREEMENT WITH THE
25 PRESIDENT, I DON'T KNOW WHAT KIND OF PROCESS WE HAVE

BARRISTERS' REPORTING SERVICE

1 FOR RESOLVING THESE TYPES OF ISSUES.

2 CHAIRMAN KLEIN: LET ME ASK THIS QUESTION,
3 JEFF. THIS IS BOB KLEIN. IS IT POSSIBLE WE HAVE
4 TWO DIFFERENT FACT PATTERNS? ONE, THERE'S A *NATURE*
5 ARTICLE THAT COMES OUT THAT'S, YOU KNOW, A
6 BREAKTHROUGH ARTICLE THAT HAPPENS TO VALIDATE THIS
7 RIGHT BEFORE THE BOARD MEETS. AND SO I'D ASK DR.
8 TROUNSON, IN THAT PARTICULAR CASE MAYBE THE
9 SCIENTIFIC STAFF IS COMFORTABLE WITH, GIVEN THE
10 BLATANT NATURE OF THE CHANGE, JUST HAVING A LIMITED
11 CATEGORY.

12 I THINK WHAT JEFF IS REFERRING TO IS PRIOR
13 TO DISCUSSIONS THAT MAYBE EVEN OCCURRED AT THE BOARD
14 LEVEL WHERE THERE'S CONCERN ON CONSERVING THE TIME
15 OF THE GRANTS REVIEW WORKING GROUP, AND IS IT
16 POSSIBLE THAT WE COULD HAVE A DICHOTOMOUS CHOICE
17 HERE, THAT IF IT WAS A CLEAR PUBLICATION OR
18 SOMETHING THAT CAME OUT WHERE THEY WANTED A
19 RESCORING OF IT IN LIGHT OF THIS PUBLICATION TO SEE
20 IF IT ACTUALLY DIRECTLY RELATED TO THIS GRANT OR
21 NOT, THAT YOU COULD HAVE A MORE LIMITED CHOICE OF
22 JUST GOING TO A COUPLE OF PEOPLE. AND IF IT WERE A
23 MORE COMPLICATED, BROADER ISSUE, THAT MAYBE YOU
24 COULD USE THE FULL REVIEW BOARD, BUT TRY AND,
25 THEREFORE, ACCOMPLISH JEFF'S GOAL OF RESPONDING TO

BARRISTERS' REPORTING SERVICE

1 THE STAFF'S GENERAL CONCERN OF NOT BURDENING THE
2 WHOLE BOARD WITH A REVIEW.

3 DR. TROUNSON: I DIDN'T GET ANY DISCUSSION
4 OF THIS ISSUE PRIOR TO STAFF, SO IT'S MY OWN VIEW.
5 SO I'M NOT SUGGESTING THAT I'M REPRESENTING STAFF'S
6 VIEW. IT'S JUST THAT IF YOU'RE GOING TO RESCORE,
7 YOU PROBABLY HAVE SOME BASIS TO RESCORE. OTHERWISE
8 I WOULD JUST COME UP WITH THE SAME SCORE, IF I WAS A
9 REVIEWER.

10 CHAIRMAN SHEEHY: THAT'S THE EXPECTATION,
11 AND THE INFORMATION WILL BE THAT THEY PROVIDED
12 PUBLICLY TO THE EXTRAORDINARY PETITION PROCESS, AND
13 IT'S JUST AN OPTION FOR THE BOARD. THE IDEA IS NOT
14 TO PROVIDE A PATH TO REREVIEW. I PERSONALLY HAVE
15 TENDED TO AGREE WITH STAFF, THAT REREVIEW IS NOT
16 PART OF OUR PROCESS AT LEAST AT THIS TIME. WE MAY
17 WANT TO TAKE IT UP LATER. HOWEVER, I THINK THE
18 OPPORTUNITY -- YOU KNOW, WE'VE BEEN IN SITUATIONS
19 WHERE WE'VE BEEN AT --

20 MS. SAMUELSON: THERE HAVE BEEN CHANGES IN
21 CIRCUMSTANCES.

22 CHAIRMAN SHEEHY: -- NOT ABLE TO REALLY
23 COME TO A CONSENSUS. AND I THINK THAT OUR DECISIONS
24 AT THAT POINT GET REALLY ARBITRARY. AND I DON'T
25 THINK IT HAPPENS THAT OFTEN. BUT CERTAINLY, YOU

BARRISTERS' REPORTING SERVICE

1 KNOW, THERE ARE TIMES WHEN THERE'S AN EXTRAORDINARY
2 AMOUNT OF PRESSURE ON US AS BOARD MEMBERS TO MAKE
3 DECISIONS ONE WAY OR THE OTHER. I THINK THAT THIS
4 JUST GIVES US ANOTHER OPTION TO MAKE THE DECISION.

5 OTHER BOARD MEMBERS WANT TO MAKE COMMENTS?

6 DR. BRYANT: I WOULD LIKE TO MAKE A
7 COMMENT AT SOME POINT AS A MEMBER OF THE PUBLIC.
8 THIS IS SUE.

9 MS. SAMUELSON: GO AHEAD, SUE.

10 DR. BRYANT: I WOULD SAY THERE ARE TWO
11 THINGS. THERE'S THE FAIRNESS OF THE PROCESS, BUT
12 THERE'S PROTECTING THE GRANTS REVIEW COMMITTEE FROM
13 HAVING EXCESSIVE WORKLOAD. I THINK YOU HAVE TO HAVE
14 VERY TIGHT GUIDELINES. AND I THINK PRODUCING
15 EVIDENCE THAT HAS APPEARED IN PRESS THAT DIRECTLY
16 REFUTES THE DECISION IS ABOUT AS FAR AS YOU WANT TO
17 GO BECAUSE IF YOU LEAVE IT MORE BROAD THAN THAT,
18 ANYBODY WHO GETS TURNED DOWN COULD COME BACK WITH
19 ANYTHING. IT WOULD JUST LIKE OPEN IT UP FOR
20 COMPLETE CHAOS IN A WAY IF YOU DON'T MAKE IT REALLY
21 SPECIFIC.

22 SO THAT'S MY OPINION ON THAT, BUT I'M
23 WILLING TO LISTEN TO OTHER THINGS. I THINK
24 EVERYBODY -- I THINK THE OPPORTUNITY FOR A REREVIEW
25 UNDER CIRCUMSTANCES WHERE THE DECISION CAN CLEARLY

BARRISTERS' REPORTING SERVICE

1 BE SHOWN TO BE MISGUIDED AND UNINFORMED BECAUSE THE
2 INFORMATION WASN'T THERE OR THE PERSON DIDN'T KNOW
3 ABOUT IT, DOESN'T MATTER WHETHER IT'S RECENTLY
4 PUBLISHED OR PUBLISHED AT AN EARLIER TIME, IT'S NOT
5 NECESSARILY THE CASE THAT EVERYBODY KNOWS EVERYTHING
6 ALL THE TIME. I THINK THAT WOULD BE A CAUSE FOR
7 HAVING A REREVIEW.

8 MR. ROTH: GET ME IN WHEN YOU CAN, JEFF.

9 DR. STEWARD: I'D LIKE TO SAY SOMETHING
10 TOO WHEN I SHOW UP IN THE ORDER HERE.

11 CHAIRMAN SHEEHY: WE'LL DO JOAN, DUANE,
12 AND OS RIGHT AFTER GIL MAKES A COMMENT.

13 MS. SAMUELSON: IT SEEMS TO ME THERE HAVE
14 BEEN SITUATIONS WHERE THE BOARD HAS FOUND EITHER
15 FACTUAL ERROR OR SOME KIND OF -- THAT THEIR
16 ASSESSMENT OF THE GRANT IS INCONSISTENT WITH THE
17 SCORE, AND THERE'S BEEN CURIOSITY ABOUT WHY THERE IS
18 THAT INCONSISTENCY. IT WOULD BE NICE TO HAVE THAT
19 INPUT.

20 CHAIRMAN SHEEHY: GIL HAD A COMMENT.

21 DR. SAMBRANO: I HAVE JUST A COUPLE OF
22 POINTS. I THINK, IN GENERAL, I THINK STAFF
23 CERTAINLY AGREES WITH THE IDEA OF HAVING AND
24 CREATING AN OPTION THAT'S AVAILABLE TO THE BOARD. I
25 THINK THAT WE CAN IMAGINE, HOWEVER, A VARIETY OF

BARRISTERS' REPORTING SERVICE

1 SITUATIONS WHERE SOME MIGHT BE EASILY RESOLVED BY
2 SIMPLY TAKING MORE TIME AND HAVING STAFF LOOK INTO A
3 SITUATION AND RESOLVING IT THERE.

4 ON THE OTHER EXTREME, IT MIGHT REQUIRE
5 ADDITIONAL EXPERTISE IN ORDER TO RESOLVE IT IF IT'S
6 A SCIENTIFIC ISSUE THAT NEEDS TO BE MORE FULLY
7 VETTED. I THINK THE POTENTIAL DANGER OF HAVING THE
8 ENTIRE GRANTS WORKING GROUP INVOLVED WOULD TEND TO
9 IMPLY THAT YOU'RE NOW ENGAGED IN A COMPLETE REREVIEW
10 OF AN APPLICATION WHICH WE REALLY WANT TO TRY TO
11 AVOID.

12 THE OTHER THING I WANTED TO POINT OUT IS
13 THAT IN TERMS OF WHAT TRIGGERS THIS KIND OF EVENT,
14 WE ALREADY HAVE A POLICY IN PLACE THAT ALLOWS
15 APPLICANTS TO SUBMIT SUPPLEMENTAL INFORMATION AFTER
16 THE APPLICATION IS IN. AND IT'S DESIGNED SO THAT
17 THE GRANTS WORKING GROUP HAS THE OPPORTUNITY TO
18 COMMENT ON IT BEFORE THE REVIEW AND CAN INCORPORATE
19 THAT NEW INFORMATION INTO THEIR SCORE AND INTO THEIR
20 ASSESSMENT.

21 AND SO I WOULD WANT TO BE CAREFUL ABOUT
22 THE TYPE OF ALLOWANCE THAT'S MADE IN TERMS OF NEW
23 DATA OR INFORMATION BECAUSE THAT ITSELF MIGHT ALSO
24 TRIGGER A NEED FOR A REREVIEW AS OPPOSED TO LOOKING
25 AT SPECIFIC INFORMATION OR A SCIENTIFIC QUESTION

BARRISTERS' REPORTING SERVICE

1 THAT JUST NEEDS TO BE CLARIFIED TO HELP THE BOARD
2 MAKE A DECISION.

3 CHAIRMAN SHEEHY: DUANE, I THINK YOU WERE
4 UP NEXT.

5 MR. ROTH: YES. I'M SORRY ABOUT THIS. I
6 HAVE THREE CELL PHONES AND THEY'RE ALL GOING OUT AT
7 THE SAME TIME.

8 SO I WANT TO ALIGN WITH THE COMMENTS ABOUT
9 REREVIEW AND NEW INFORMATION. I THINK YOU HAVE TO
10 HAVE A REALLY IMPEACHABLE PROOF STANDARD THERE.
11 OTHERWISE EVERYBODY HAS NEW INFORMATION AND THEY'LL
12 BRING IT TO YOU. AND WHILE THIS IS CRAFTED TO BE
13 VERY NARROW, MY CONCERN WILL BE, LIKE OUR OTHER
14 OPTIONS FOR PETITIONS AND CONFLICT OF INTEREST, IT
15 WILL GROW THE FIRST TIME WE APPROVE ONE OF THESE
16 UNDER THIS PROCEDURE. SO WHATEVER WE DO, LET'S MAKE
17 SURE THAT WE'RE AS TIGHT AS WE POSSIBLY CAN BE.

18 AND I'M PARTICULARLY BOTHERED BY NEW
19 INFORMATION. THAT IMPLIES TO ME THAT YOU REALLY
20 DON'T HAVE A LEVEL PLAYING FIELD BECAUSE, AS I SAID,
21 THERE'S CONSTANT UPDATES TO THESE SCIENTIFIC
22 PROGRESSES. AND THIS WOULD REALLY SEEM TO ME TO ADD
23 ANOTHER COMPLEXITY.

24 FINALLY, THE REVIEWERS, I CAUGHT THE SAME
25 THING, IF YOU'VE GOT THE SAME PEOPLE REVIEWING THE

BARRISTERS' REPORTING SERVICE

1 SAME INFORMATION, WHICH IS REALLY WHAT IT SHOULD BE,
2 THEY' RE PROBABLY GOING TO COME TO THE SAME IDEA. SO
3 MAYBE AN OUTSIDE REVIEW BY A DIFFERENT GROUP TO SEE
4 IF THERE' S VALIDITY MIGHT BE IMPORTANT. THANKS.

5 CHAIRMAN SHEEHY: AND THEN OS.

6 DR. STEWARD: THANKS. SO I JUST HAVE TO
7 SHARE THE CONCERNS THAT BOTH SUE STARTED WITH AND
8 DUANE RAISED. I THINK THIS IS A REALLY SLIPPERY
9 SLOPE, AND I GUESS I AM CONCERNED ABOUT THE WHOLE
10 PROCESS IN GENERAL. I THINK THIS CAN JUST EXPLODE.

11 HAVING SAID THAT, THERE ARE REALLY TWO KEY
12 THINGS THAT I' D LIKE TO RAISE. FIRST OF ALL IS THE
13 QUESTION OF WHETHER THE BOARD REALLY ALREADY HAS
14 THIS OPTION. AND JUST REALLY THINKING ABOUT WHAT
15 GIL SAID, WE CAN IMAGINE A MULTITUDE OF DIFFERENT
16 SCENARIOS HERE THAT THE BOARD MAY WANT TO CONSIDER.
17 AND I KIND OF THINK THAT THE BOARD REALLY ALREADY
18 HAS THE ABILITY TO REQUEST A REREVIEW, A REANALYSIS,
19 WHATEVER, AT ITS DISCRETION. WE DON' T NEED A
20 POLICY.

21 NO. 2, AND THIS IS A MORE FUNDAMENTAL
22 THING, AND I' VE BEEN THINKING ABOUT THIS IN TERMS OF
23 THIS WHOLE ISSUE OF EXTRAORDINARY PETITIONS. THE
24 THING THAT WE MOST OFTEN RUN INTO IS AN INVESTIGATOR
25 WHO, FIRST OF ALL, IDENTIFIES THEMSELVES, WHICH IS

BARRISTERS' REPORTING SERVICE

1 REALLY, I GUESS, I THINK ONE OF THE FUNDAMENTAL
2 PROBLEMS WITH THIS PROCESS, BECAUSE IF THIS IS
3 SOMEBODY WE ALL KNOW, WE SAY, "OH, WELL, THIS PERSON
4 DESERVES SOME REALLY EXTRA ATTENTION." AND IF IT'S
5 NOT SOMEBODY WE KNOW, THEN MAYBE WE PAY LESS
6 ATTENTION TO IT. IT REALLY IS A FUNDAMENTAL, I
7 GUESS, UNLEVELING OF THE PLAYING FIELD.

8 AND THE PROBLEM THAT WE MOST OFTEN RUN
9 INTO IS THAT WHOEVER SAYS, YOU KNOW, THE REVIEWER
10 MISSED THIS OR THERE'S A MISTAKE OR WHATEVER, AND WE
11 HAVE IN FRONT OF US THE LETTER FROM THE
12 INVESTIGATOR, BUT WE'RE STILL UNABLE TO LOOK AT THE
13 GRANT ITSELF OR THE COMMENTS OF THE REVIEW PANEL.

14 SO MY SPECIFIC PROPOSAL THAT NOW I'M GOING
15 TO MAKE FOR ALL OF THE EXTRAORDINARY PETITIONS IS
16 THAT IF AN INVESTIGATOR WANTS TO MAKE AN
17 EXTRAORDINARY PETITION, THEY SHOULD VOLUNTEER
18 THEMSELVES TO PROVIDE THE ICOC WITH A COPY OF THE
19 ORIGINAL PROPOSAL AND A COPY OF THE REVIEW. IN
20 OTHER WORDS, LET'S GET ALL THE ISSUES OUT ON THE
21 TABLE FOR OUR CONSIDERATION.

22 CHAIRMAN KLEIN: CAN I MAKE A LEGAL
23 COMMENT HERE?

24 CHAIRMAN SHEEHY: OKAY. THE CHAIR HAS A
25 LEGAL.

BARRISTERS' REPORTING SERVICE

1 CHAIRMAN KLEIN: IF WE NEED ADDITIONAL
2 SUPPORT OF CALLING COUNSEL, BUT WE SACRIFICE ALL THE
3 PROPRIETARY INFORMATION IF IT'S SUPPLIED TO ALL THE
4 BOARD MEMBERS AS THE FULL APPLICATION.

5 DR. STEWARD: BOB, I'M SORRY. I HAVE BEEN
6 THINKING ABOUT THIS AND I FORGOT TO SAY THAT. THERE
7 CAN BE TRULY PROPRIETARY INFORMATION IN THE PROPOSAL
8 THAT COULD BE REDACTED. BUT, IN FACT, 99 PERCENT OF
9 THE PROPOSAL AND CERTAINLY THE PART THAT THE
10 REVIEWER -- OR THE APPLICANT IS CHALLENGING ALREADY
11 IS PUBLIC. SO BASICALLY THE APPLICANT CAN SAY I'D
12 LIKE PAGE 8, LINES 15 THROUGH 35 REDACTED FOR
13 PROPRIETARY REASONS. EVERYTHING ELSE GOES PUBLIC.

14 CHAIRMAN SHEEHY: SO ARE YOU MAKING A
15 MOTION?

16 DR. STEWARD: I WILL. LET'S ACTUALLY
17 START WITH POINT NO. 1. POINT NO. 1 IS DON'T WE AS
18 THE BOARD ALREADY HAVE THE CAPACITY TO REQUEST AN
19 EXTRAORDINARY ANYTHING WE WANT IN TERMS OF REREVIEW,
20 RECONSIDERATION, WHATEVER? IF SO, THEN I DON'T
21 THINK A FORMAL POLICY IS NECESSARY.

22 CHAIRMAN SHEEHY: I WOULD SAY THAT WE
23 POSSIBLY DO. IT'S NOT PART OF OUR NORMAL PROCESS.
24 WE DON'T HAVE THE ABILITY TO DO A TWO-PERSON REVIEW.
25 THAT DOESN'T EXIST. LET ME JUST MAKE A POINT ABOUT

BARRISTERS' REPORTING SERVICE

1 THIS.

2 I KIND OF WANT US TO GET AWAY FROM
3 THINKING ABOUT THE FAIRNESS OF THE PROCESS. THIS
4 HAS KIND OF COME UP A COUPLE OF TIMES. AND THIS IS
5 A NUANCE, AND I'VE GOTTEN IN TROUBLE FOR TRYING TO
6 ADDRESS THIS, BUT I THINK JOAN WILL PROBABLY AGREE
7 WITH ME ON THIS. WHAT IS IMPORTANT IS THAT WE FUND
8 THE BEST SCIENCE AND THAT WE DON'T RUN A GREAT HORSE
9 RACE. WE RUN A HORSE RACE BECAUSE THAT'S HOW YOU
10 DETERMINE WHAT THE BEST SCIENCE IS, BUT EVERY NOW
11 AND THEN THERE'S A GOOD HORSE THAT DIDN'T MAKE THE
12 FINISH LINE. AND WE'VE TAKEN ADVANTAGE OF THAT
13 BEFORE. THE ABOUDI GRANT IS A GREAT EXAMPLE OF A
14 GOOD HORSE THAT DIDN'T MAKE THE FINISH LINE.

15 AS A PATIENT ADVOCATE, I'M LESS
16 INTERESTED -- I DON'T WANT TO FUND BAD SCIENCE. SO
17 THAT'S MY PRIORITY OFF THE TOP. I DON'T WANT TO
18 FUND BAD SCIENCE. BUT IF SOMETHING EMERGES THAT
19 SHOWS THAT THIS WAS GOOD SCIENCE, AND THE ABOUDI
20 CASE IS A GREAT EXAMPLE, I DON'T WANT TO SAY, WELL,
21 YOU KNOW, YOU LOST THE RACE. YOU'RE NOT GOING TO
22 GET FUNDED TILL TWO YEARS FROM NOW WHEN WE COME BACK
23 TO THIS GRANT ROUND. PEOPLE WILL HAVE DIED WITHOUT
24 A SUCCESSFUL THERAPY.

25 SO WHAT I REALLY WANT TO FOCUS ON, AT

BARRISTERS' REPORTING SERVICE

1 LEAST PERSONALLY, IS CAPTURING GOOD SCIENCE. AND IF
2 THERE IS SOME INFORMATION RELEVANT TO A GRANT THAT
3 COMES UP IN THE CONTEXT OF AN EXTRAORDINARY
4 PETITION, I WOULD LIKE TO FIGURE OUT SOMEHOW TO DO
5 THAT. I KNOW THAT A LOT OF BOARD MEMBERS DON'T FEEL
6 COMFORTABLE MAKING DECISIONS ON THESE GRANTS
7 SOMETIMES. I DON'T THINK REREVIEW IS AN OPTION WE
8 OUGHT TO GO INTO, BUT I'M OPEN TO ANY IDEA. THIS
9 WAS JUST ONE IDEA, BUT WHAT WE HAVE RIGHT NOW IS A
10 BROKEN SYSTEM. AND I THINK IT'S INCUMBENT ON US TO
11 SET THE CONTOURS FOR THE SYSTEM.

12 IF WE DON'T ALLOW A LOT OF RESCORING, IT'S
13 NOT GOING TO BE ADVANTAGEOUS TO PEOPLE. THEY CAN'T
14 COME IN AND ASK FOR A RESCORE. THAT'S NOT PART OF
15 THE EXTRAORDINARY PETITION PROCESS. REMEMBER THE
16 RESCORING IS DENIAL. I THINK THE CRITICISM THAT'S
17 BEEN MADE IS THAT THE SAME REVIEWERS ARE HIGHLY
18 LIKELY TO GIVE IT THE SAME SCORE. YES. IT'S ALMOST
19 WHENEVER WE PUT IN THESE CONTROL FEATURES, THERE'S
20 RESISTANCE. SO A FEATURE WHERE THE BOARD DOESN'T
21 LOOK AT AN EXTRAORDINARY PETITION UNLESS AN
22 INDIVIDUAL MEMBER THINKS IT HAS MERIT HAS KIND OF
23 DEGRADED EVEN THOUGH THAT WAS ONE OF OUR BIG CONTROL
24 POINTS, THAT PEOPLE WOULD RECOGNIZE THAT IT DIDN'T
25 AVAIL THEM IN MOST INSTANCES TO DO AN EXTRAORDINARY

BARRISTERS' REPORTING SERVICE

1 PETITION. INSTEAD, WE CONSIDER EVERY ONE, SO NOW
2 IT'S BECOME A FEATURE OF GAMESMANSHIP OR
3 GRANTSMANSHIP ALWAYS TO DO AN EXTRAORDINARY
4 PETITION.

5 IF WE ASSERT SOME DISCIPLINE AS A BOARD
6 AND ONLY EXERCISE THIS OPTION WHEN WE FEEL LIKE
7 THERE'S COMPELLING EVIDENCE, WITH THE UNDERSTANDING
8 THAT FOR SOME GRANTEES THEY MAY HAVE HAD A BETTER
9 SHOT UP AND DOWN ON THEIR GRANT, THIS ACTUALLY MAY
10 DISADVANTAGE SOME GRANTS BECAUSE THE BOARD IS GOING
11 TO PASS ON ACTUALLY CONSIDERING THEM. WITH THE
12 UNDERSTANDING THAT THE SAME REVIEWER WHO GAVE YOU A
13 65 IS STILL GOING TO GIVE YOU A 65 AND THAT'S IT, I
14 THINK WE DON'T -- WE'RE NOT TRYING TO CREATE MORE
15 OPEN DOORS; BUT FOR THE REALLY GOOD PIECE OF
16 INFORMATION THAT'S REALLY COMPELLING TO A BOARD
17 MEMBER THAT MIGHT BE COMPELLING TO A REVIEWER WHO HAS
18 ALREADY LOOKED AT THE GRANT, WHO KNOWS THE GRANT,
19 WHO CAN TAKE A LITTLE BIT OF TIME TO LOOK AT THIS
20 PIECE OF INFORMATION AND SAY, NAH, DOESN'T PERSUADE
21 ME, OR SAY, IF I THOUGHT OF THAT, I'D HAVE GIVEN
22 THIS AN 80, THAT'S WHAT WE'RE TRYING TO ACCOMPLISH.

23 BUT WE'RE NOT TRYING TO CREATE A BIG OPEN
24 DOOR; BUT IF THERE ARE OTHER OPTIONS OUT THERE, I'M
25 WILLING TO HEAR THEM. ART HAS A COMMENT AND I THINK

BARRISTERS' REPORTING SERVICE

1 JOAN.

2 DR. PIZZO: PHIL WOULD LIKE TO MAKE A
3 COMMENT TOO.

4 MR. TORRES: QUICKLY. I AGREE WITH WHAT
5 ALAN SET OUT AT THE OUTSET, AND THAT IS THAT YOU'RE
6 GOING TO PROBABLY GET THE SAME SCORE IF YOU GO BACK
7 TO THE REVIEWERS WHO REVIEWED THE GRANT INITIALLY.
8 I ALSO LIKE OSSIE AND DUANE'S PERSPECTIVE, AND THAT
9 IS, WELL, IF THAT'S THE CASE, WHAT ABOUT AN OUTSIDE
10 REVIEW.

11 SO MY QUESTION IS WHAT TRIGGERS THAT AND
12 IS THAT PRACTICAL? I THINK BEST TO HEAR FROM DR.
13 TROUNSON ON THAT.

14 MS. KING: BEFORE WE GO ON TO OTHER
15 COMMENTS, I JUST WANT TO POINT OUT TO MR. SHEEHY
16 THAT IT'S ACTUALLY NOON RIGHT NOW. WE MAY START TO
17 LOSE PEOPLE. YOU NEED TO THINK ABOUT IN THE NEXT
18 COUPLE MINUTES AFTER THESE COMMENTS WHAT WE WANT TO
19 DO WITH THE RECOMMENDATIONS VIS-A-VIS THE BOARD.

20 MR. TORRES: OSSIE, YOU CAN CHIME IN AS
21 WELL.

22 DR. TROUNSON: YOU CAN USE THE EXAMPLE OF
23 THE ABOUDI GRANT BECAUSE IT WAS RAISED BY JEFF, THAT
24 WE WENT OUT TO A WHOLE LIST OF PEOPLE THAT I THOUGHT
25 WAS EXPERT IN THE AREA, AND WE GOT A DIFFERENT VIEW

BARRISTERS' REPORTING SERVICE

1 TO ONE OF THE PRIMARY CONCLUSIONS OF THE REVIEWERS.
2 I FELT THAT THAT INFORMATION NEEDED TO BE BROUGHT TO
3 THE BOARD BECAUSE I THOUGHT IT WAS WRONG. I
4 ACTUALLY THOUGHT IT WAS WRONG WHEN I LISTENED TO THE
5 REVIEW, SO I WENT TO EXPLORE THAT EVEN BEFORE WE GOT
6 THE PETITION. SO YOU DO NEED A BIT OF TIME IF
7 YOU'RE GOING TO GET HOLD OF AN EXTERNAL REVIEWER AND
8 DO ALL OF THAT SORT OF THING. SO THAT'S REALLY
9 QUITE DIFFICULT UNLESS THERE'S ENOUGH SPACE BETWEEN
10 THE TIME YOU RECEIVE A PETITION AND YOU CAN ACTUALLY
11 ADDRESS THAT FOR THE BOARD. SO SORT OF FIVE DAYS
12 REALLY STRETCHES US TO DO THAT. AND IF IT'S LESS
13 THAN THAT, IT'S IMPOSSIBLE, AS JEFF SAID.

14 I THINK IT DEPENDS ON WHAT THE ISSUE IS,
15 AND I THINK SOMETIMES YOU MIGHT NEED TO GET A
16 DIFFERENT KIND OF PERSON TO DO THAT BECAUSE THE
17 EXPERTISE MAY NOT BE DWELLING IN THE ORIGINAL
18 REVIEWER. IT MIGHT BE SOMETHING THAT'S OUT OF THE
19 BOX. IT'S NOT EXACTLY. BUT ON THE OTHER HAND,
20 THOSE ARE THE PEOPLE THAT HAVE READ THROUGH, THEY'VE
21 LISTENED TO ALL THE ARGUMENT, AND THEY'VE GOT A
22 KNOWLEDGE OF THAT PROJECT WITH RESPECT TO THE OTHER
23 PROJECTS. THE PEOPLE WHO HAVE BEEN THROUGH THE
24 REVIEW HAVE BEEN WELL SCHOOLED GENERALLY. I'M JUST
25 STRUGGLING TO TRY AND FIND MYSELF WHAT'S THE BEST

BARRISTERS' REPORTING SERVICE

1 THING TO DO. I THINK IT'S A COMBINATION OF MAYBE
2 ALL OF THESE THINGS, AND PROBABLY NOT EVERY ONE FITS
3 EXACTLY INTO THE SAME CATEGORY, THAT WE MIGHT NEED
4 SOME FLEXIBILITY TO ADDRESS THIS.

5 I UNDERSTAND -- I BETTER UNDERSTAND WHAT
6 JEFF'S ISSUE IS, AND I BETTER UNDERSTAND ACTUALLY
7 WHAT GIL'S POINT IS, AND I HAVEN'T HAD THIS
8 OPPORTUNITY OF DISCUSSION BEFORE TODAY. I'M SORRY.
9 WE SHOULD TRY AND FIX THAT. BUT I THINK WE NEED A
10 LITTLE BIT OF FLEXIBILITY, AND IT'S SOMETHING WHICH
11 THEN IS CONCERNING AND IS VERY DEEP AND MIGHT
12 ACTUALLY REQUIRE A WHOLE REREVIEW IF IT'S DEEP AND
13 IT HAS TO BE PLOWED THROUGH RIGHT AGAIN. I THINK
14 THERE'S GOING TO BE VARIANCE; BUT IF IT'S USED
15 SPARINGLY AND IT'S USED VERY SPARINGLY, I THINK IT
16 CAN BE HANDLED IN A WAY THAT YOU GET THE REQUIRED
17 OUTCOME. IF IT BECOMES A THING WHICH PEOPLE USE
18 FREQUENTLY, THEN I THINK IT'S GOING TO BE AN
19 ENORMOUS BURDEN FOR US ALL.

20 MS. SAMUELSON: I THINK BACK TO WHAT WE'RE
21 TRYING TO ACCOMPLISH, WHICH I THINK IS TO IMPROVE
22 UPON THE EXTRAORDINARY PETITION PROCESS THAT'S JUST
23 BEING IMPLEMENTED NOW. AND IT MAY BE THAT IT'S -- I
24 DON'T SEE IT AS A BROKEN SYSTEM EXACTLY. THERE ARE
25 CONCERNS ABOUT IT. BUT MAYBE IT'S LIKE DEMOCRACY.

BARRISTERS' REPORTING SERVICE

1 WE'RE NOT NUTS ABOUT IT, BUT IT'S THE BEST WE'VE
2 GOT. AND MAYBE SOMETHING LIKE OS' SUGGESTION MIGHT
3 ASSIST THE BOARD IN FEELING IT'S GOT THE FAIREST
4 POSSIBLE SYSTEM IT CAN HAVE UNDER THE CIRCUMSTANCES
5 AND IT HAS THE INFORMATION THAT CAN BE MOST USEFUL
6 TO COMING TO A CONCLUSION WHERE IT MAY BE, AND WE'VE
7 HAD EXAMPLES OF IT, WHERE THERE HAVE BEEN SITUATIONS
8 WHERE THE BOARD FOUND THAT THE SCORES JUST REALLY
9 DIDN'T REFLECT ACCURATELY WHAT IT WAS SEEING IN THE
10 INFORMATION THAT WAS BEING GIVEN, AND THAT AT TIMES
11 THERE WERE FACTUAL ERRORS.

12 SO WE WANT THE BOARD TO HAVE THE BENEFIT
13 OF THAT. AND I HAVE FOUND THE CRITIQUES TO BE THE
14 MOST USEFUL DOCUMENTS MYSELF. AND IF THOSE COULD BE
15 FURNISHED AS WELL AS WHATEVER OTHERS, OS OR OTHERS
16 THINK IS APPROPRIATE.

17 DR. PIZZO: YOU KNOW, I THINK, AS OTHERS
18 ARE STATING, I ALSO AGREE, EVEN THOUGH IT MIGHT BE
19 MORE CUMBERSOME, THAT OS' RECOMMENDATION MAKES
20 SENSE. AND THERE'S ONE OTHER VARIABLE THAT I
21 HAVEN'T HEARD, BUT WHICH HAS CERTAINLY COME TO MY
22 OWN ATTENTION WHEN I'M AT THE MEETINGS AND THESE
23 THINGS ARE BEING DISCUSSED, WHICH IS THE EMOTIONAL
24 OVERTONE THAT UNDERSTANDABLY TAKES PLACE. I HAVE
25 WATCHED AND WE'VE ALL WITNESSED WHEN SOMEONE SPEAKS

BARRISTERS' REPORTING SERVICE

1 WITH DEEP CONCERN AND PASSION, PARTICULARLY ABOUT A
2 MEMBER OF THEIR OWN FAMILY, THAT UNDERSTANDABLY WE
3 RESPOND TO THAT AND WE'RE RESPONDING IN THE MOMENT.
4 AND I THINK THERE'S A BENEFIT TO LISTENING IN THE
5 MOMENT, BUT THEN HAVING AN OPPORTUNITY TO BE SURE
6 THAT WE'RE REACTING WITH THE MOST CRITICAL DATA THAT
7 WE CAN.

8 CHAIRMAN SHEEHY: TO BE PERFECTLY HONEST,
9 DR. PIZZO, THAT WAS ONE OF THE DRIVING FORCES FOR
10 THIS POLICY BECAUSE A LOT OF TIMES I FIND MYSELF
11 COMPELLED BY EMOTION AND I'VE LOST THE SCIENCE. SO
12 MY THOUGHT WAS THAT THIS GAVE ME AN OPTION AS A
13 BOARD MEMBER WITH REALLY THE APPLICATION
14 FUNDAMENTALLY DENIED UNLESS IT WAS COMPELLING TO THE
15 CHAIR OF THE REVIEW GROUP AND ONE OF THE PRIMARY
16 REVIEWERS THAT SOME OF THE NEW INFORMATION, WHICH
17 HAS BEEN PRESENTED IN THESE EMOTIONAL ATMOSPHERES,
18 IF IT'S COMPELLING TO A REVIEWER, FAIRLY OBJECTIVELY
19 IN AN ATMOSPHERE WHERE THERE'S NO EMOTION, THEN I'M
20 HAPPY TO HAVE THE GRANT COME BACK AND CONSIDER IT
21 AND FUND IT. BUT THIS WAS A WAY TO ACTUALLY --

22 DR. PIZZO: FAIR ENOUGH.

23 CHAIRMAN SHEEHY: -- GIVE THE BOARD A WAY
24 TO DEAL WITH THESE WITH A LITTLE LESS EMOTION, SO
25 RETHINKING THAT THERE MIGHT HAVE BEEN VALUABLE

BARRISTERS' REPORTING SERVICE

1 INFORMATION IN THERE. THAT WAS ONE OF THE DRIVERS
2 FOR THIS.

3 DR. PIZZO: THANKS FOR THAT, JEFF.

4 CHAIRMAN SHEEHY: I ALSO DIDN'T WANT TO
5 MAKE THAT THE ONLY REASON FOR THIS PROPOSAL.

6 DR. PIZZO: NO, IT'S NOT. OF COURSE, IT
7 SHOULD NEVER BE, BUT IT CERTAINLY HAD AN IMPACT.

8 CHAIRMAN SHEEHY: SO, AGAIN, AS YOU THINK
9 ABOUT IT AS A BOARD MEMBER, YOU CAN SAY I'M VERY
10 SYMPATHETIC TO WHAT YOU'RE TALKING ABOUT. LET'S SEE
11 WHAT THE REVIEWERS CHANGE. WE HAVE YOUR PETITION,
12 WE HAVE ALL THE INFORMATION YOU PROVIDED US. WE'LL
13 SEND IT ON AND IF THEY AGREE. THAT'S WHERE I WAS
14 GOING.

15 BUT I WAS ALSO GOING TO THAT OTHER ASPECT
16 WHERE I AS A PATIENT ADVOCATE SOMETIMES WILL HAVE
17 AND OTHER BOARD MEMBERS, BASED ON THEIR SPECIFIC
18 SCIENTIFIC EXPERIENCE, MAY FEEL LIKE THAT THEY READ
19 THE PETITION, THEY MAY FEEL LIKE THEY HAVE ENOUGH
20 INFORMATION AND OTHER BOARD MEMBERS, RATHER THAN GET
21 SO CONTENTIOUS, WHY DON'T YOU SUPPORT MY GRANT, TO
22 SAY, WELL, LET'S RESCORE IT. IF THE INFORMATION
23 REALLY IS VALUABLE SCIENTIFICALLY, THEN THE
24 REVIEWERS WILL RECOGNIZE IT BECAUSE WE HAVE
25 OUTSTANDING REVIEWERS AND THEY KNOW THE SCIENCE, AND

BARRISTERS' REPORTING SERVICE

1 IT WOULDN'T BE A BIG BURDEN ON THEM TO LOOK AT THIS
2 LIMITED AMOUNT OF INFORMATION AND COME TO A QUICK
3 DECISION ON WHETHER IT AFFECTS THEIR SCORES OR NOT.

4 THAT'S WHAT WAS DRIVING THE FORMULATION OF
5 THIS POLICY. BUT I THINK WE'RE AT A POINT WHERE
6 WE'RE RUNNING OUT OF TIME, PEOPLE NEED TO MOVE ON.
7 WE CAN HAVE ANOTHER MEETING TO LOOK AT THIS. UNLESS
8 SOMEONE WANTS TO MAKE A MOTION TO ADOPT THIS OR IF
9 OS WOULD LIKE TO MAKE A MOTION ON THE IDEA THAT HE
10 HAS, MAYBE WHAT WE COULD DO, IF PEOPLE COULD SEND
11 MELISSA ANY IDEAS THAT YOU HAVE AND SHE CAN SEND
12 THEM SPECIFICALLY TO ME. IF I DON'T SHARE THEM WITH
13 ANYBODY ELSE, I DON'T VIOLATE BAGLEY-KEENE AND WE
14 CAN TALK TO STAFF AND COME UP WITH PERHAPS ANOTHER
15 BITE AT THE APPLE OR IS THAT PROBLEMATIC?

16 MR. TORRES: ON THAT POINT, I JUST WANT TO
17 REITERATE. I THINK WE HEARD WHAT TOOK PLACE BEFORE
18 IN THE ABOUDI SITUATION THAT ALAN ARTICULATED. IT
19 SEEMS TO BE THE ALTERNATIVE, AND THAT IS IF THERE'S
20 AN OPPORTUNITY TO DO THAT, SEARCH OUT THE EXPERTISE,
21 GET AN OUTSIDE REVIEW, LIKE DUANE AND DR. PIZZO AND
22 OS HAVE INDICATED, AND LET'S GO WITH IT, BUT ALLOW
23 ENOUGH FLEXIBILITY TO DO THAT. SO I THINK WE STILL
24 NEED TO THINK IT THROUGH TO SEE HOW THAT WOULD BE
25 WORDED.

BARRISTERS' REPORTING SERVICE

1 MR. ROTH: I WANT TO JUST FOLLOW UP ON
2 THAT AND SUGGEST THAT THIS HAS BEEN A VERY GOOD
3 DISCUSSION, BUT I DON'T THINK IT'S TIME TO TAKE
4 ACTION TODAY. BECAUSE THE PUBLIC HASN'T HAD A LOT
5 OF TIME TO LOOK AT THIS, MAYBE WE'LL GET SOME GOOD
6 INPUT FROM THE PUBLIC ON HOW WE MIGHT HANDLE THIS.

7 DR. STEWARD: I WOULD NOT MAKE A MOTION
8 FORMALLY ON MY PROPOSAL EITHER, BUT I WOULD LIKE TO
9 PROPOSE IT AS SOMETHING THAT WE ALL THINK ABOUT.
10 I'D BE HAPPY TO WRITE UP A LITTLE THING OR PERHAPS
11 IF STAFF WANTED TO DO THAT, THAT'S GREAT, WHICHEVER.

12 DR. PIZZO: THAT WOULD BE GREAT.

13 CHAIRMAN SHEEHY: WE WOULD NOT VIOLATE
14 BAGLEY-KEENE. SINCE THIS HAS BEEN DISCUSSED IN
15 PUBLIC AS OS FLESHED OUT HIS PROPOSAL, AND WE WERE
16 ABLE TO WORK WITH ATTORNEYS AND STAFF TO MAKE IT A
17 MORE FULLY REALIZABLE PROPOSAL FOR A FUTURE MEETING
18 OF THE SCIENCE SUBCOMMITTEE.

19 DR. PIZZO: OKAY. SIGNING OFF.

20 CHAIRMAN SHEEHY: I'D LIKE TO NOT FORMALLY
21 ADJOURN YET. SO IF MEMBERS NEED TO GO, WE'RE NOT
22 GOING TO CONSIDER ANYTHING ELSE TODAY, BUT I WANTED
23 TO GIVE ANY MEMBER OF THE PUBLIC OR ANYONE ELSE A
24 CHANCE TO MAKE ANY OTHER COMMENTS. DON REED.

25 MR. REED: THIS IS LIKE WINSTON CHURCHILL

BARRISTERS' REPORTING SERVICE

1 SAID. THE TOUGH DECISIONS ARE 51 PERCENT AND 49
2 PERCENT. THIS IS A VERY TOUGH ONE. EVERYONE IS
3 GOING THE EXTRA MILE TO FIND THE BEST POSSIBLE WAY.
4 I DO LIKE THE IDEA OF WHEN THINGS ARE SO CLOSE, TO
5 HAVE OUTSIDE AUTHORITY BROUGHT IN, BUT IT IS A TOUGH
6 DECISION.

7 CHAIRMAN SHEEHY: CHAIRMAN KLEIN.

8 CHAIRMAN KLEIN: I'D JUST LIKE TO CLARIFY
9 FOR THE RECORD THAT, JEFF, YOU'VE SPOKEN MANY TIMES
10 ABOUT HOW EFFECTIVE THE PEER REVIEW SYSTEM IS. AND
11 CERTAINLY THE EXTRAORDINARY PETITION PROCESS HAS
12 GIVEN US THE ABILITY, WORKING WITH THE STAFF, THAT
13 HAD THE HIGH POTENTIAL WHERE THERE WAS AN ERROR LIKE
14 THE ABOUDI GRANT. SO I THINK THAT WHAT WE'RE REALLY
15 DOING IS A VERY HIGH STANDARD. WE'RE REACHING TO
16 TRY AND IMPROVE THE SYSTEM, TO FIND THAT
17 BREAKTHROUGH GRANT WE MIGHT OTHERWISE PASS OVER.
18 BUT I WOULD IDENTIFY WITH WHAT JOAN SAID. WE'RE
19 TRYING TO DO IMPROVEMENTS HERE, AND WE HAVE A BROKEN
20 CAPACITY TO GET THAT LAST GRANT, BUT THAT'S WHAT
21 WE'RE REACHING FOR IN A SYSTEM THAT OTHERWISE IS
22 WORKING PRETTY WELL.

23 CHAIRMAN SHEEHY: DO WE HAVE ANY OTHER
24 COMMENTS FROM MEMBERS OF THE BOARD OR FROM ANYONE AT
25 ANY OTHER SITE?

BARRISTERS' REPORTING SERVICE

1 MR. TORRES: JUST TO THANK YOU FOR THE
2 DI SCUSSION.

3 CHAIRMAN SHEEHY: THEN WE' RE ADJOURNED.
4 THANK YOU.

5 (THE MEETING WAS THEN ADJOURNED AT
6 12:05 P. M.)

7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25

BARRISTERS' REPORTING SERVICE

REPORTER' S CERTIFICATE

I, BETH C. DRAIN, A CERTIFIED SHORTHAND REPORTER IN AND FOR THE STATE OF CALIFORNIA, HEREBY CERTIFY THAT THE FOREGOING TRANSCRIPT OF THE TELEPHONIC PROCEEDINGS BEFORE THE SCIENCE SUBCOMMITTEE OF THE INDEPENDENT CITIZEN' S OVERSIGHT COMMITTEE OF THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE IN THE MATTER OF ITS REGULAR MEETING HELD ON TUESDAY, JULY 20, 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
BARRISTER' S REPORTING SERVICE
1072 BRISTOL STREET
SUITE 100
COSTA MESA, CALIFORNIA
(714) 444-4100