

BEFORE THE
APPLICATION REVIEW TASK FORCE 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: WEDNESDAY, OCTOBER 24, 2012
10 A.M.

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

BRS FILE NO.: 93338

BARRISTERS' REPORTING SERVICE

I N D E X

ITEM DESCRIPTION	PAGE NO.
1. CALL TO ORDER.	3
2. ROLL CALL.	7
3. DISCUSSION OF EXTRAORDINARY PETITION POLICY	9
4. DISCUSSION OF ADDITIONAL ANALYSIS POLICY	9
5. DISCUSSION OF EX PARTE COMMUNICATIONS	NOT HEARD
6. PUBLIC COMMENT.	NONE

BARRISTERS' REPORTING SERVICE

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WEDNESDAY OCTOBER 24, 2012
10 A.M.

CHAIRMAN THOMAS: IN THE JULY BOARD MEETING, WE HAD A NUMBER OF EXTRAORDINARY PETITIONS WHICH WERE THE SUBJECT OF CONSIDERABLE DISCUSSION AND RESULTED IN A REFERRAL BACK TO A SUBSET OF THE GRANTS WORKING GROUP FOR SO-CALLED ADDITIONAL ANALYSIS. THAT PROCEDURE ULTIMATELY RESULTED, OF THE FIVE REFERRED BACK, THREE WERE RECOMMENDED FOR APPROVAL BY THAT SUBGROUP, WHICH SUBGROUP WAS COMPRISED OF THE CHAIR OF THE GRANTS WORKING GROUP SESSION, ANOTHER MEMBER OF THE GRANTS WORKING GROUP WHO WAS PARTICULARLY ATTUNE TO THE SUBSTANTIVE ISSUES IN THE EXTRAORDINARY PETITION, AND ONE OF THE PATIENT ADVOCATE MEMBERS OF THE BOARD. THAT RESULTED IN THREE COMING BACK FROM THAT GROUP FOR APPROVAL. THOSE WERE SUBSEQUENTLY ADOPTED BY THE GROUP AND PASSED.

WHO JUST JOINED?

DR. FEIGAL: ELLEN FEIGAL.

CHAIRMAN THOMAS: J.T. AND BERT. JEFF IS ON HIS WAY AND A NUMBER OF FOLKS ARE ON THE PHONE.

SO THE BOARD ADOPTED THE THREE THAT WERE RECOMMENDED BY THAT GROUP. THEY ALSO PASSED ONE

BARRISTERS' REPORTING SERVICE

1 THAT HAD NOT BEEN RECOMMENDED BY THE GROUP ON
2 RE-REVIEW. AND THAT LED TO A THOUGHT ON THE PART OF
3 THE BOARD -- ALL OF THE PROCESS RESULTED IN THE
4 BOARD FEELING LIKE, BECAUSE THE PROCEDURE WAS A
5 RELATIVELY NEW ONE, WHICH WAS SENDING BACK TO THAT
6 SUBSET OF THE GRANTS WORKING GROUP, THAT IT WOULD BE
7 A GOOD IDEA TO STEP BACK, TAKE A LOOK AT OUR
8 POLICIES WITH REGARD TO PETITIONS, APPEALS, ETC.,
9 AND TO SEE IF THERE WAS A WAY TO FORMULATE A REVISED
10 PROTOCOL FOR DEALING WITH THOSE SORTS OF ISSUES.

11 WE HAVE DISTRIBUTED TO EVERYBODY A REVIEW
12 OF SORT OF THE PAST WAYS THAT APPLICATIONS COULD BE
13 EITHER APPEALED, WHICH IS A TERM OF ART DEALING
14 STRICTLY WITH CONFLICT ISSUES, OR COULD BE THE
15 SUBJECT OF EXTRAORDINARY PETITIONS, WHICH HAVE A
16 HOST OF REQUIREMENTS, SUCH AS SUBMISSION FIVE DAYS
17 IN ADVANCE, LIMITED TO THREE PAGES, ETC. AND
18 EVERYBODY, I THINK, HAS THAT DOCUMENT.

19 WE ALSO DESCRIBED A PREVIOUS WAY TO GO
20 BACK FOR REVIEW TO THE GRANTS WORKING GROUP OR A
21 SUBSET WHICH HAD A SUNSET CLAUSE ATTACHED TO IT THAT
22 HAD EXPIRED BY THE TIME THE JULY BOARD MEETING
23 ROLLED AROUND. BUT IN ALL INSTANCES, THE BOARD HAS
24 HAD THE GENERAL ABILITY TO REFER MATTERS BACK TO THE
25 GRANTS WORKING GROUP IF IT FELT LIKE THERE WERE

BARRISTERS' REPORTING SERVICE

1 ISSUES THAT NEEDED TO BE RESOLVED.

2 IN ADDITION, IT WAS MY SENSE AT THE JULY
3 BOARD MEETING THAT THE PAST PRECEDENT OF HEARING
4 PUBLIC COMMENT ON A PARTICULAR APPLICATION WHICH
5 GAVE EITHER TESTIMONY AS TO THE WHY AN APPLICATION
6 SHOULD BE APPROVED OR OFFER UP, QUOTE, UNQUOTE, NEW
7 INFORMATION OR WHATEVER, IN THE PAST IN MOST
8 INSTANCES THE BOARD HAS DISCUSSED AND ACTED ONE WAY
9 OR ANOTHER ON THE SPOT. IT WAS MY FEELING THAT THAT
10 WASN'T THE OPTIMAL WAY TO GO BECAUSE ALL OF THIS
11 COMMENTARY THAT COMES IN DOES SO, AND THE BOARD,
12 HAVING NOT BEEN IN THE GRANTS WORKING GROUP MEETING,
13 WHICH SPAWNED THE DISCUSSION AND RECOMMENDATION ON
14 THE APPLICATION IN QUESTION, DOESN'T HAVE THE
15 BENEFIT OF REALLY KNOWING WHETHER THE INFORMATION IS
16 NEW OR NOT OR MATERIAL OR NOT OR WHATEVER.

17 SO IT WAS MY SENSE IN JULY THAT IT WOULD
18 BE BEST TO STEP BACK, TO SEND THESE APPLICATIONS FOR
19 WHICH THERE WERE WHAT WE DEEM MATERIAL QUESTIONS
20 BACK TO THE GRANTS WORKING GROUP FOR THE ADDITIONAL
21 ANALYSIS PROCESS. AND THAT LED TO WHAT WE ENDED UP
22 DOING IN JULY.

23 SO THERE'S BEEN A LOT OF FACTORS AT PLAY
24 HERE. WE JUST FELT THAT IT WAS BEST TO SIT DOWN
25 AWAY FROM THE BOARD MEETINGS THEMSELVES AND TO TALK

BARRISTERS' REPORTING SERVICE

1 ABOUT ISSUES THAT BEAR ON BOTH APPELLATE PROCEDURES.
2 TOWARDS THAT END, AT THE SUGGESTION OF VICE CHAIR
3 DUANE ROTH, WE PUT TOGETHER A TASK FORCE WHICH WAS
4 SET UP SPECIFICALLY TO REVIEW PAST PROCEDURES AND TO
5 DISCUSS HOW WE MIGHT PROCEED FROM HERE WITH RESPECT
6 TO THOSE PROCEDURES.

7 THE TASK FORCE IS CHAIRED BY DR. LUBIN.
8 BY THE WAY, I WANTED TO WELCOME JEFF SHEEHY WHO
9 JOINED US A FEW MINUTES AGO. WE HAVE A NUMBER OF
10 MEMBERS OF THE BOARD. WE HAVE A NUMBER OF MEMBERS
11 OF STAFF. WE HAVE SOME MEMBERS OF THE GRANTS
12 WORKING GROUP ALL COMPRISING THIS TASK FORCE.

13 THE AIM OF THE TASK FORCE IS TO DISCUSS
14 THE ISSUES TODAY AND TO TAKE THE THOUGHTS THAT ARE
15 GENERATED, GO OFF AND DEVELOP A SERIES OF
16 RECOMMENDATIONS, WHICH WILL BE DISCUSSED AT THE
17 BOARD RETREAT OR BOARD WORKSHOP WHICH IS SCHEDULED
18 IN JANUARY. AND THEN AS A RESULT OF THAT DISCUSSION
19 BY THE FULL BOARD TO ADOPT PROTOCOLS FOR THESE
20 APPELLATE PROCEDURES.

21 MR. HARRISON, IS THERE ANYTHING YOU'D LIKE
22 TO ADD BEFORE WE GET GOING HERE?

23 MR. HARRISON: NO. I THINK THAT'S A FAIR
24 SUMMARY. I THINK WHAT WE'D LIKE TO DO NOW IS PAUSE
25 AND TO MAKE SURE WE KNOW WHO'S ON THE PHONE OF THE

BARRISTERS' REPORTING SERVICE

1 MEMBERS OF THE TASK FORCE AND THEN WE CAN PROCEED
2 FURTHER.

3 MS. BONNEVILLE: ANNE-MARIE DULIEGE.

4 DR. DULIEGE: YES, I'M HERE.

5 MS. BONNEVILLE: COREY GOODMAN. SHELLY
6 HEIMFELD. BERT LUBIN.

7 DR. LUBIN: HERE.

8 MS. BONNEVILLE: ED PENHOET. DUANE ROTH.
9 JEFF SHEEHY.

10 MR. SHEEHY: HERE.

11 MS. BONNEVILLE: OS STEWARD. JONATHAN
12 THOMAS.

13 CHAIRMAN THOMAS: HERE.

14 MS. BONNEVILLE: KRISTINA VUORI.

15 DR. VUORI: HERE.

16 CHAIRMAN THOMAS: OKAY.

17 DR. TROUNSON: I DO NEED TO SAY THAT
18 THERE'S AN EMPHASIS HERE THAT THE OUTSIDE COMMUNITY
19 AND THE LIFE SCIENCE COMMUNITY IN PARTICULAR IS
20 LOOKING AT THIS QUITE SERIOUSLY BECAUSE, DESPITE THE
21 WAY JON DESCRIBED IT, THE REVIEW REALLY BROUGHT THE
22 SCIENCE -- THAT THE GRANTS WORKING GROUP BROUGHT
23 FORTH SIX PROJECTS. AND THEN THE BOARD FOR WHATEVER
24 REASON ADDED ANOTHER SIX PROJECTS, AND THIS IS A
25 REALLY BIG CONCERN OUT THERE, THAT THE BOARD IS

BARRISTERS' REPORTING SERVICE

1 REALLY IN SOME SORT OF WAY HAS CREATED BY VARIOUS
2 WAYS A GRANT TO BE AWARDED THAT ARE NOT APPROVED BY
3 THE GRANTS WORKING GROUP.

4 I THINK THIS IS A VERY SERIOUS MATTER THAT
5 COULD REALLY BITE US VERY HARD IN A SIMILAR WAY TO
6 WHAT'S HAPPENED IN TEXAS. UNLESS WE COME UP WITH
7 SOME KIND OF PROCESS THAT REALLY ADDRESSES THE
8 SCIENCE, IT'S A VERY LARGE CONCERN. THEY DON'T
9 REALLY SORT OF (UNINTELLIGIBLE) TO THE WORLD OF
10 DETAIL OF EACH AND EVERY PROJECT, BUT THEY SEE A
11 VERY MAJOR CONCERN THERE.

12 SO I WANT TO SAY THIS IS AN ITEM WHICH IS
13 VERY CRITICAL FOR CIRM, THE BOARD, AND US GOING
14 FORWARD. IT'S TOO MUCH AN UNDERSTATEMENT. AND I
15 THINK THERE IS GOING TO BE A GREAT DEAL OF FOCUS ON
16 WHAT COMES OUT OF THIS MEETING.

17 CHAIRMAN THOMAS: ALAN, WE'RE HAVING A
18 HARD TIME HEARING YOU, BUT I THINK WE GOT THE GIST
19 OF WHAT YOU WERE SAYING. THANK YOU FOR YOUR
20 COMMENTS.

21 ARE THERE MEMBERS OF THE PUBLIC AT OTHER
22 SITES? WE HAVE MR. JENSEN HERE WITH US HERE IN THE
23 MEETING HERE. ANY OTHER --

24 DR. VUORI: NONE HERE.

25 CHAIRMAN THOMAS: OKAY. SO THAT IS SORT

BARRISTERS' REPORTING SERVICE

1 OF THE BACKDROP TO THIS DISCUSSION. AND I GUESS THE
2 QUESTION IS, TO START WITH, EVERYBODY HAS THE
3 PROCEDURES THAT YOU HAD THAT WERE SUMMARIZED IN ONE
4 OF THE ATTACHMENTS IN FRONT OF YOU. HOPEFULLY
5 EVERYBODY HAS HAD A CHANCE TO READ. JAMES, WOULD IT
6 WE BEST TO START WITH THOSE, OR HOW WOULD YOU
7 RECOMMEND PROCEEDING?

8 MR. HARRISON: I THINK IT PROBABLY MAKES
9 SENSE TO REMIND EVERYONE THAT THE BOARD AT ITS LAST
10 MEETING DID APPROVE A COUPLE OF AMENDMENTS TO THE
11 EXTRAORDINARY PETITION POLICY AND ADOPTED AN
12 ADDITIONAL ANALYSIS POLICY. AND THOSE COULD AT
13 LEAST SERVE AS A STARTING POINT FOR THE BOARD'S
14 CONSIDERATION OR THE TASK FORCE'S CONSIDERATION OF
15 THE PROTOCOLS THAT THE AGENCY HAS IN PLACE. AND
16 THEN WE CAN PERHAPS USE THOSE AS A LAUNCHING POINT
17 FOR THE DISCUSSION.

18 SO I'LL JUST BRIEFLY SUMMARIZE THE
19 EXISTING PROCESSES. FIRST OF ALL, J.T. REFERRED TO
20 THE APPEALS PROCESS. AND THIS IS A VERY LIMITED
21 PROCESS THAT IS SET FORTH IN THE GRANTS
22 ADMINISTRATION POLICY THAT PROVIDES AN AVENUE FOR AN
23 APPLICANT TO FILE AN APPEAL WITH CIRM FROM A GRANTS
24 WORKING GROUP RECOMMENDATION IF THE APPLICANT
25 BELIEVES THAT A DEMONSTRABLE CONFLICT OF INTEREST ON

BARRISTERS' REPORTING SERVICE

1 THE PART OF ONE OF THE MEMBERS OF THE GRANTS WORKING
2 GROUP HAS AFFECTED THE OUTCOME OF THE REVIEW. SO
3 IT'S LIMITED TO CONFLICTS OF INTEREST.

4 THE PRESIDENT IS VESTED WITH DISCRETION TO
5 CONSIDER A CONFLICT OF INTEREST ALLEGATION AND, IN
6 CONSULTATION WITH THE CHAIR OF THE GRANTS WORKING
7 GROUP, TO MAKE A DETERMINATION, FIRST, AS TO WHETHER
8 OR NOT THERE MAY HAVE BEEN A CONFLICT UNDER CIRM'S
9 CONFLICT OF INTEREST RULES AND THEN, SECONDLY,
10 WHETHER IF SUCH A CONFLICT, IN FACT, EXISTED,
11 WHETHER THAT CONFLICT DETRIMENTALLY AFFECTED THE
12 OUTCOME OF THE REVIEW.

13 IF THE PRESIDENT DETERMINES THAT THAT HAS
14 OCCURRED, THEN THE APPLICATION IS SENT BACK TO THE
15 GRANTS WORKING GROUP FOR A NEW REVIEW. SO THAT'S
16 THE APPEALS PROCESS.

17 SEPARATELY, AS THE BOARD WELL KNOWS,
18 MEMBERS OF THE PUBLIC ARE FREE TO COMMUNICATE WITH
19 YOU AS MEMBERS OF THE BOARD AT PUBLIC MEETINGS TO
20 EXPRESS THEIR VIEWS ON ANY ITEM THAT IS ON YOUR
21 AGENDA, AND THAT INCLUDES APPLICATIONS FOR FUNDING.
22 SO WHEN THE AGENCY WAS FIRST GETTING ITS FOOTING
23 WITH RESPECT TO GRANT REVIEW, WE BEGAN TO RECEIVE
24 SUBMISSIONS FROM APPLICANTS BOTH IN WRITING AND ORAL
25 COMMENTS AT BOARD MEETINGS. AND THE BOARD DECIDED

BARRISTERS' REPORTING SERVICE

1 THAT IT NEEDED TO ADOPT A POLICY TO PROVIDE SOME
2 PARAMETERS FOR THESE TYPES OF SUBMISSIONS BECAUSE
3 THEY WERE COMING IN A RATHER HAPHAZARD FASHION, AND
4 MANY MEMBERS IN THE SCIENTIFIC COMMUNITY, FRANKLY,
5 WEREN'T EVEN AWARE THAT THEY HAD THE OPPORTUNITY TO
6 COMMUNICATE WITH THE BOARD IN THAT FASHION.

7 SO THE BOARD ADOPTED WHAT IT REFERRED TO
8 AS AN EXTRAORDINARY PETITION POLICY, AND THAT POLICY
9 PROVIDED THAT AN APPLICANT WHO DESIRED TO
10 COMMUNICATE IN WRITING TO THE BOARD REGARDING THE
11 GRANTS WORKING GROUP'S RECOMMENDATION HAD TO DO SO
12 WITHIN FIVE BUSINESS DAYS BEFORE THE BOARD MEETING
13 AT WHICH THE APPLICATION COULD BE CONSIDERED AND HAD
14 TO LIMIT HIS OR HER COMMENTS TO THREE PAGES. THE
15 PROCESS PROVIDED FOR THE PRESIDENT AND THE
16 SCIENTIFIC STAFF TO THEN REVIEW THOSE PETITIONS AND
17 TO MAKE A DETERMINATION AS TO WHETHER OR NOT THEY
18 FELT THAT THE PETITIONS WERE MERITORIOUS OR MADE
19 COMMENTS THAT MERITED BOARD'S FURTHER CONSIDERATION.

20 UNDER THE POLICY THE BOARD WAS ONLY TO
21 CONSIDER AN EXTRAORDINARY PETITION IF A MEMBER OF
22 THE BOARD RAISED HIS HAND OR HER HAND AND SAID I'D
23 LIKE TO HEAR SOME DISCUSSION ABOUT THE EXTRAORDINARY
24 PETITION THAT WAS FILED FOR THIS PARTICULAR
25 APPLICATION. AND AT THAT POINT IN TIME, THERE WOULD

BARRISTERS' REPORTING SERVICE

1 BE A SCIENTIFIC PRESENTATION AND A STAFF DISCUSSION.

2 MR. SHEEHY: COULD I GET SOME
3 CLARIFICATION ON ONE POINT BECAUSE YOU USED THE WORD
4 "HAD TO," ABOUT HAD TO SUBMIT FIVE DAYS IN ADVANCE,
5 AND YOU ALSO SAID THAT THEY HAD TO LIMIT THEMSELVES
6 TO THREE PAGES. THAT REQUIREMENT IS ONLY IN ORDER
7 TO GET SOME REVIEW BY STAFF. WE AS BOARD -- THE
8 PUBLIC STILL HAS ITS RIGHT UNDER OPEN GOVERNMENT
9 LAWS ENSHRINED IN THE CONSTITUTION OF THE STATE OF
10 CALIFORNIA TO WRITE LETTERS TO US, TO COMMUNICATE
11 WITH US EVEN IF IT FALLS OUTSIDE THAT FIVE-DAY
12 WINDOW, EVEN IF IT'S MORE THAN THREE PAGES.

13 I DON'T WANT TO SUGGEST THAT WE'VE LIMITED
14 ANY CONSTITUTIONAL RIGHTS OF THE MEMBERS OF THE
15 CALIFORNIA PUBLIC. BUT THAT THAT REQUIREMENT OF HAD
16 TO IS IN ORDER TO GET FEEDBACK FROM STAFF IN THE
17 EVENT THAT YOU RAISED A POINT THAT STAFF FELT WAS
18 COMPELLING AND TO POTENTIALLY GIVE STAFF SUPPORT FOR
19 THE RECONSIDERATION THAT YOU'RE ASKING FOR.

20 MR. HARRISON: THAT'S CORRECT. MEMBERS OF
21 THE PUBLIC ARE FREE TO COMMUNICATE IN WHATEVER FORM
22 OR FASHION THEY WISH WITH MEMBERS OF THE BOARD. SO
23 THIS POLICY WAS DESIGNED TO PROVIDE AN AVENUE FOR
24 APPLICANTS. IF THEY WANTED TO SUBMIT SOMETHING
25 CALLED AN EXTRAORDINARY PETITION, THEY HAD TO DO SO

BARRISTERS' REPORTING SERVICE

1 IN A MANNER THAT WOULD GIVE THE STAFF AN OPPORTUNITY
2 TO REVIEW IT IN A CONSIDERED FASHION. AND, IN FACT,
3 AT THE BOARD'S LAST MEETING, IT DETERMINED THAT TO
4 THE EXTENT AN APPLICANT SUBMITS SOMETHING IN WRITING
5 REGARDING THE APPLICATION, BUT NOT WITHIN THAT TIME
6 FRAME SPECIFIED BY THE EXTRAORDINARY PETITION
7 POLICY, WE WOULDN'T LABEL IT AN EXTRAORDINARY
8 PETITION. WE WOULD PROVIDE IT TO THE BOARD AS WE DO
9 ALL CORRESPONDENCE WE RECEIVE, BUT WE WOULD LABEL IT
10 AS OTHER CORRESPONDENCE TO GIVE A SIGNAL TO THE
11 BOARD THAT THE APPLICANT DID COMPLY WITH THE POLICY
12 AND THAT STAFF AS A RESULT DIDN'T HAVE SUFFICIENT
13 TIME TO CONSIDER THE INPUT.

14 SO THAT BRIEFLY IS A SUMMARY OF THE
15 EXTRAORDINARY PETITION POLICY. ALTHOUGH IT USES THE
16 TERM "EXTRAORDINARY," IT WAS NEVER DEFINED. AND IN
17 PART THAT WAS BECAUSE OF THE BOARD'S RECOGNITION OF
18 THE FACT THAT AT THE END OF THE DAY ANYONE CAN
19 COMMUNICATE WHATEVER THEY WANT WITH YOU AS MEMBERS
20 OF THE BOARD. SO THAT'S THE EXTRAORDINARY PETITION
21 POLICY.

22 WE HAVE ALSO NOW ADOPTED AN ADDITIONAL
23 ANALYSIS POLICY. AND THIS POLICY IS DESIGNED TO
24 ADDRESS THE SITUATION THAT OUR CHAIR ALLUDED TO THAT
25 AROSE IN JULY. AND THAT IS TO PROVIDE AN

BARRISTERS' REPORTING SERVICE

1 OPPORTUNITY FOR THE BOARD TO SEND AN APPLICATION
2 BACK TO A SUBSET OF THE GRANTS WORKING GROUP FOR
3 VERY LIMITED ADDITIONAL ANALYSIS. AND TO PROVIDE
4 SOME PARAMETERS AROUND THAT POLICY, THE BOARD
5 SPECIFIED THAT IT SHOULD BE LIMITED TO SITUATIONS IN
6 WHICH THERE'S EITHER A MATERIAL DISPUTE OF FACT OR
7 MATERIAL NEW INFORMATION.

8 WITH RESPECT TO A MATERIAL DISPUTE OF
9 FACT, THE CRITERIA THERE INCLUDES THE FOLLOWING:
10 THE APPLICANT DISPUTES THE ACCURACY OF THE STATEMENT
11 IN THE REVIEW SUMMARY; THE DISPUTED FACT IS
12 SIGNIFICANT TO THE GRANTS WORKING GROUP'S SCORING OR
13 RECOMMENDATION; THE DISPUTE RELATES TO AN
14 OBJECTIVELY VERIFIABLE FACT RATHER THAN A DIFFERENCE
15 OF SCIENTIFIC OPINION; AND THAT THE DISCREPANCY WAS
16 NOT RESOLVED THROUGH THE SUPPLEMENTAL INFORMATION
17 PROCESS, WHICH IS A PROCESS THAT IS AVAILABLE TO THE
18 GRANTS WORKING GROUP TO UTILIZE TO RESOLVE A FACTUAL
19 DISPUTE; AND THAT THE ISSUE CANNOT BE RESOLVED AT
20 THE BOARD MEETING ITSELF, THAT IS, THAT IT REQUIRES
21 SOME ADDITIONAL ANALYSIS THAT'S BEYOND THE BOARD'S
22 CAPABILITY TO ENGAGE IN AT A PUBLIC MEETING; AND
23 THEN, FINALLY, THAT THE RESOLUTION OF THE DISPUTE
24 WOULD AFFECT THE BOARD'S DECISION. IN OTHER WORDS,
25 IF THIS IS AN APPLICATION THAT, REGARDLESS OF THE

BARRISTERS' REPORTING SERVICE

1 OUTCOME OF THIS FACTUAL ISSUE, THE BOARD WOULD
2 EITHER APPROVE OR DISAPPROVE, THEN THERE'S NO NEED
3 TO CONSUME ADDITIONAL TIME AND RESOURCES TO ENGAGE
4 IN FURTHER ANALYSIS.

5 THE SECOND PATHWAY WAS WHEN MATERIAL NEW
6 INFORMATION IS PRESENTED. AND, AGAIN, THE BOARD PUT
7 SOME PARAMETERS ON THAT. THE NEW INFORMATION HAS TO
8 BE VERIFIABLE THROUGH EXTERNAL SOURCES. IT HAS TO
9 HAVE ARISEN SINCE GRANTS WORKING GROUP
10 CONSIDERATION. IT SHOULD RESPOND DIRECTLY TO A
11 CRITICISM OR QUESTION THAT AROSE DURING THE GRANTS
12 WORKING GROUP REVIEW. IN OTHER WORDS, WE DON'T WANT
13 APPLICANTS TO USE THIS AS AN OPPORTUNITY TO PUT IN
14 WHATEVER NEW INFORMATION THEY HAVE. IT HAS TO BE
15 SOMETHING MATERIAL; THAT IS, IT HAS TO RESPOND
16 DIRECTLY TO A SPECIFIC CRITICISM OR QUESTION. AND
17 IT SHOULD BE INCLUDED IN AN EXTRAORDINARY PETITION
18 THAT IDENTIFIES THE NEW INFORMATION AND THAT
19 EXPLAINS HOW IT MEETS THE CRITERIA THAT I JUST
20 ALLUDED TO.

21 WITH RESPECT TO THE TYPES OF VERIFIABLE
22 INFORMATION, THIS IS NOT AN EXHAUSTIVE LIST, BUT
23 IT'S INTENDED TO GIVE SOME SENSE OF WHAT WOULD BE
24 CONSIDERED. EXTERNALLY VERIFIABLE INFORMATION, IT
25 COULD BE, FOR EXAMPLE, APPROVAL BY THE FDA TO

BARRISTERS' REPORTING SERVICE

1 INITIATE A CLINICAL TRIAL, A DOCUMENTED AND
2 ENFORCEABLE AGREEMENT BETWEEN THE APPLICANT AND A
3 COMMERCIAL PARTNER, A FINAL COURT DECISION OR
4 ADMINISTRATIVE ACTION, OR DOCUMENTATION CONFIRMING
5 THAT A TRANSCRIPT HAS BEEN ACCEPTED FOR PUBLICATION
6 IN FINAL FORM. AND AGAIN, IT WOULD HAVE TO BE DATA
7 THAT RESPONDED DIRECTLY TO A CRITICISM IN THE GRANTS
8 WORKING GROUP REVIEW.

9 SO THAT'S THE POLICY THAT IS IN PLACE AT
10 THIS POINT IN TIME. AND I'D BE HAPPY TO ANSWER ANY
11 QUESTIONS ABOUT IT. OR IF YOU WOULD LIKE TO BEGIN
12 YOUR DISCUSSION, THAT WOULD BE GREAT AS WELL.

13 DR. LUBIN: THAT'S AN IMPORTANT COMPONENT,
14 I THINK, THAT ADDRESSES A LOT OF THE SCIENTIFIC
15 CONCERNS THAT WE'VE HEARD. JEFF, WHAT DO YOU THINK
16 ABOUT WHAT WAS JUST STATED?

17 MR. SHEEHY: FROM MY PERSPECTIVE WE HAVE A
18 GOOD PROCESS, ACKNOWLEDGING THE REALITY THAT THE
19 PUBLIC HAS THE ABILITY TO CONTACT US, THAT PER PROP
20 71, THE BOARD HAS TO BE FINAL DECISION MAKERS IN
21 DECIDING THESE GRANTS. SO WE CAN'T JUST PASS
22 THROUGH THE GRANTS WORKING GROUP RECOMMENDATIONS
23 WITHOUT TAKING SOME TIME TO DELIBERATE AND TO MAKE
24 OUR OWN INFORMED DECISIONS ABOUT WHETHER TO FUND
25 THESE GRANTS OR NOT. AND ALSO TAKING INTO ACCOUNT

BARRISTERS' REPORTING SERVICE

1 THAT PEER REVIEW IS AN EXTRAORDINARY WAY OF
2 ANALYZING SCIENCE, BUT THAT IT'S NOT ALWAYS PERFECT,
3 AND THAT OUR MISSION REQUIRES US TO ACT WITH URGENCY
4 AND SPEED IN ORDER TO GET CURES AS QUICKLY AS WE CAN
5 TO PATIENTS. AND THE FACT THAT MANY OF OUR CYCLES
6 DON'T COME BACK AGAIN WITHIN A YEAR OR TWO SO THAT
7 APPLICANTS, UNLIKE PERHAPS NIH WHERE THEY DO
8 CRITICISMS, THEY CAN CHALLENGE THOSE, SUBMIT NEW
9 DATA, CREATE ADDITIONAL EXPERIMENTS THAT BUFFERS
10 THEIR APPLICATIONS, AND GET RE-REVIEW WITHIN A
11 FAIRLY SHORT TIME, FOR US IT'S BEEN PRETTY MUCH ONE
12 SHOT OR OUT.

13 SO I ACTUALLY THINK, FROM MY PERSPECTIVE,
14 WE HAVE PUT IN PLACE VERY STRONG PROCESSES. WHAT
15 FOR ME THE PROBLEM IS IS THAT AS A BOARD, WE'RE NOT
16 RESPECTING SOME OF THE INPUT WE GET FROM SCIENTISTS.
17 WE ARE AT LEAST ALLOWING THE PERCEPTION TO BE OUT
18 THERE THAT WE CAN BE PERSUADED AGAINST THE JUDGMENT
19 OF SCIENTISTS BECAUSE I THINK FOR ME -- I WAS
20 CONFLICTED ON SOME OF THE APPLICATIONS THAT GOT PUT
21 THROUGH. I FELT LIKE WE HAD A GOOD REVIEW OF THE
22 DISEASE TEAMS. I THINK WE HAVE TO ANTICIPATE THAT
23 WHEN WE DO MAJOR GRANTS, SUCH AS POTENTIALLY \$20
24 MILLION GRANTS, THAT WE WILL GET EXTRAORDINARY
25 PETITIONS, THAT PEOPLE WILL COME AND SPEAK TO THE

BARRISTERS' REPORTING SERVICE

1 BOARD.

2 THAT HAPPENED THE FIRST DISEASE TEAM
3 ROUND. WE HAD JUST AS MANY AS WE HAD THIS TIME. SO
4 I JUST THINK THAT, FIRST OF ALL, WE'RE A PUBLIC
5 AGENCY. THIS IS GOVERNMENT MONEY. PEOPLE CARE. A
6 LOT OF PATIENTS WORKED HARD -- THE PATIENT ADVOCACY
7 GROUPS WORKED HARD TO PASS PROP 71.

8 OUTSIDE OF PERHAPS ASKING OURSELVES TO
9 EXERT MORE DISCIPLINE, I DON'T KNOW WHAT SORTS OF
10 POLICY CHANGES ARE IN ORDER AT THIS POINT. I DO
11 THINK THAT WHEN WE SEND SOMETHING BACK FOR
12 ADDITIONAL ANALYSIS AND IT COMES BACK WITH THE SAME
13 RECOMMENDATION, I THINK WE NEED TO COME UP WITH A
14 FAIRLY STRONG RATIONALE FOR OVERRULING TWO DECISIONS
15 FROM THE WORKING GROUP. AND TO ME, IF I LOOK AT ANY
16 SINGLE PROBLEM THAT IS MOST TROUBLING, THAT IS
17 PROBABLY THE CIRCUMSTANCE THAT WOULD GIVE ME THE
18 GREATEST PAUSE.

19 SO THAT'S MY TWO CENTS.

20 DR. STEWARD: I JUST WANTED TO LET YOU
21 KNOW THAT I HAVE DIALED IN.

22 DR. LUBIN: DO YOU WANT TO HANDLE GETTING
23 THE CALLS.

24 CHAIRMAN THOMAS: OS, I DON'T KNOW HOW
25 MUCH OF WHAT JEFF JUST SAID YOU HEARD OR HOW LONG

BARRISTERS' REPORTING SERVICE

1 YOU'VE BEEN ON, BUT DO YOU HAVE SOME OPENING
2 THOUGHTS ON THE ISSUES HERE?

3 DR. STEWARD: I HEARD BOTH JAMES' SUMMARY
4 AND I HEARD JEFF'S COMMENTS.

5 I THINK MY OPENING THOUGHTS WOULD BE
6 LIMITED TO JUST SAYING THAT I THINK THAT THE PROCESS
7 HAS GOTTEN A LITTLE BIT UNCONTROLLED AND OUT OF HAND
8 AND UNPREDICTABLE, I GUESS. AND THAT I BELIEVE THAT
9 YOU DO NEED TO HAVE CLARITY OF WHAT SHOULD BE
10 CONSIDERED AND WHAT SHOULD NOT BE CONSIDERED. AND
11 OBVIOUSLY THE BOARD, AS A PUBLIC BODY, NEEDS TO HEAR
12 ALL THE PUBLIC COMMENT, BUT WE DON'T NECESSARILY
13 NEED TO ACT ON THEM. AND I THINK JEFF SAID
14 DISCIPLINE, AND I THINK THAT'S EXACTLY RIGHT.

15 BUT HAVING SOMETHING IN PLACE DOES HELP
16 THE APPLICANTS UNDERSTAND THE KINDS OF INFORMATION
17 THAT WE WOULD CONSIDER TO BE APPROPRIATE. THEY CAN
18 ALWAYS COME IN AND SAY WHATEVER THEY WANT, BUT AT
19 LEAST IT'S SOME GUIDANCE THEY'LL UNDERSTAND THAT
20 SOME THINGS ARE CONSIDERED RELEVANT AND SOME THINGS
21 AREN'T.

22 DR. LUBIN: DID YOU WANT TO RESPOND TO
23 THAT?

24 CHAIRMAN THOMAS: GIL, HAS A COMMENT.

25 DR. SAMBRANO: SO I JUST WANTED TO JUST

BARRISTERS' REPORTING SERVICE

1 BRING UP A COUPLE OF POINTS THAT KIND OF REFLECT ON
2 MY READING OF THE NEWEST DOCUMENT ON THE PETITIONS
3 AND ANALYSIS. I THINK, AS MR. SHEEHY AND OTHERS
4 HAVE ALREADY STATED, THE BOARD HAS THE ABILITY TO
5 REALLY CONSIDER ANYTHING THAT COMES FROM THE PUBLIC,
6 AND THE PUBLIC HAS THE RIGHT TO COME TO THE BOARD TO
7 SPEAK ON ANY POINT REGARDING THEIR APPLICATION.

8 I THINK, THOUGH, THAT AS SOMEONE WHO
9 SPEAKS TO THE APPLICANTS SOON AFTER THEY RECEIVE
10 THEIR REVIEW SUMMARIES AND REALLY WANT SOME LEVEL OF
11 GUIDANCE AS TO WHAT TO DO NEXT, THERE IS A BIT OF
12 CONFUSION THAT COMES FROM THE WAY OUR POLICIES ARE
13 STRUCTURED. AND I'LL POINT TO A COUPLE OF THINGS.

14 SO WE HAVE A FORMAL APPEALS PROCESS WHICH,
15 WHEN THAT WAS CREATED, THE POINT OF THAT WAS TO
16 REALLY TRY TO LIMIT THE APPEALS TO A CERTAIN SET OF
17 CIRCUMSTANCES WHICH WERE A DEMONSTRABLE CONFLICT OF
18 INTEREST, WHICH WAS FINE. BUT I THINK THE PETITION
19 POLICY ITSELF IN SOME WAY HAS OPENED UP THE, I
20 GUESS, THE PERCEPTION THAT THERE ARE OTHER FORMS OF
21 APPEAL THAT ONE CAN TAKE.

22 AND SO THE WAY WE'VE STRUCTURED THE
23 ADDITIONAL ANALYSIS OPTION HERE, FOR EXAMPLE, IS
24 REALLY CALLING UPON THE APPLICANT TO INITIATE THE
25 PROCESS BY STATING THAT THEY HAVE A DIFFERENCE, NOT

BARRISTERS' REPORTING SERVICE

1 NECESSARILY SCIENTIFIC OPINION, BUT THEY HAVE A
2 DISPUTE OF MATERIAL FACT WITH WHAT THE GRANTS
3 WORKING GROUP SAYS.

4 SO THAT IS ANOTHER FORM OF APPEAL, IF YOU
5 WILL, THAT NIH TAKES UNDER THE SAME PROCESS, BUT
6 HERE WE'RE SEPARATING AS ONE THAT WAS DISTINCT FROM
7 THE FORMAL APPEAL PROCESS. SO SOMETIMES APPLICANTS
8 DON'T KNOW WHICH WAY TO GO AND THEN WHO NECESSARILY
9 IS RESPONSIBLE FOR REVIEWING THIS KIND OF
10 INFORMATION. IF THERE WERE, FOR EXAMPLE, A SINGLE
11 APPEALS POLICY THAT WAS ALL ENCOMPASSING THAT WOULD
12 SAY THESE ARE THE ITEMS OR ELEMENTS UNDER WHICH WE
13 WILL CONSIDER AN APPEAL, THAT, I THINK, GIVES MORE
14 CLARITY TO THE APPLICANT FOR WHAT AND WHEN THEY
15 SHOULD SUBMIT.

16 I THINK THAT'S ONE THING. THE OTHER THING
17 WITH THE EXTRAORDINARY PETITION POLICY, AGAIN,
18 ALTHOUGH THE PUBLIC HAS A RIGHT TO SUBMIT ANYTHING,
19 I THINK THE POLICY ITSELF IS AN ATTEMPT TO PROVIDE A
20 SET OF GUIDELINES, AGAIN, FOR APPLICANTS. AND SO I
21 DON'T KNOW, AND MAYBE JAMES CAN CORRECT ME ON THIS,
22 THERE'S NOT NECESSARILY ANY LIMIT AS TO HOW ONE CAN
23 DEFINE THOSE GUIDELINES SUCH THAT SOMETHING THAT
24 WOULD BE CONSIDERED A PETITION CAN BE QUITE
25 SPECIFIC. AND AT LEAST IT PROVIDES AN EXAMPLE TO

BARRISTERS' REPORTING SERVICE

1 THE APPLICANTS OF WHAT THE BOARD IS OR FEELS THAT
2 THEY ARE WILLING TO CONSIDER. DOESN'T MEAN THEY
3 CAN'T THEN SUBMIT SOMETHING ELSE, BUT IT PROVIDES
4 BOTH THE BOARD AND THE APPLICANTS A GOOD SENSE OF
5 WHAT WOULD LIKELY BE A MERITORIOUS CONSIDERATION FOR
6 AN APPEAL OR A PETITION, HOWEVER YOU WANT TO CALL
7 IT.

8 DR. TROUNSON: LOOK, I THINK WE ACTUALLY
9 HAVE TO GET TO REALLY ONE OF THE ISSUES THAT HAS
10 BEEN BROUGHT UP. AND IT IS SOMETHING THAT'S
11 CONCERNING. THE FORMAL PROCESS IS IN SOME RESPECT
12 REALLY IN PLACE, BUT WHAT'S CLEARLY HAPPENING IS
13 THAT THE GRANTEES AND SUPPORTERS ARE GOING NOT TO
14 MANAGEMENT OR REALLY THROUGH THE APPROPRIATE
15 PROCESSES, BUT THEY'RE ACTUALLY GOING DIRECT TO THE
16 BOARD MEMBERS. AND THEY'RE CREATING A VERY STRONG
17 ADVOCACY REALLY BY GOING DIRECTLY TO THOSE BOARD
18 MEMBERS.

19 SO THEN IT'S REALLY QUITE DIFFICULT. AND,
20 YOU KNOW, IF YOU CAN'T GET A PROCESS WHICH EVERYBODY
21 RESPECTS, THEN YOU END UP WITH A PROCESS WHICH
22 EVERYBODY WILL USE TO CIRCUMVENT THE PROCESSES THAT
23 ARE PUT IN PLACE.

24 SO WE HAVE TO DISCUSS THAT MATTER, AND WE
25 HAVE TO COME TO GRIPS WITH IT BECAUSE CURRENTLY THIS

BARRISTERS' REPORTING SERVICE

1 IS REALLY ONE OF THE PREFERRED OPTIONS OF GRANTEES
2 OR THEIR SUPPORTERS TO DO THAT. AND THAT REALLY
3 BRINGS A DIFFERENT EMPHASIS TO WHAT'S HAPPENING. SO
4 I'LL ASK YOU REALLY TO ALSO INCLUDE THIS ON YOUR
5 AGENDA FOR CONSIDERATION BECAUSE I THINK IT'S REALLY
6 SERIOUS, AND IN SOME RESPECTS IT REALLY DISRESPECTS
7 THE MORE FORMAL PROCESSES.

8 MR. HARRISON: ALAN, THAT ACTUALLY IS A
9 TOPIC ON THE AGENDA. IT'S ITEM 3, SO WE WILL GET TO
10 THAT LATER THIS MORNING.

11 DR. TROUNSON: OKAY. THANK YOU. I DON'T
12 HAVE IT WITH ME, SO I APOLOGIZE. I'M SOME DISTANCE
13 AWAY AND I DON'T HAVE THAT. OKAY. THANK YOU.

14 DR. VUORI: I THINK IF WE FOCUS ON THE
15 EXTRAORDINARY PETITION IN THIS PART OF THE
16 CONVERSATION, I THINK MY COMMENTS WOULD BE AS
17 FOLLOWS. I THINK THIS EXTRAORDINARY PETITION IS A
18 VERY IMPORTANT MECHANISM TO BE IN PLACE. JEFF HAS
19 ALREADY OUTLINED SOME OF THE REASONS SIMPLY FROM
20 PUBLIC POLICY PERSPECTIVE. HAVING THE OPPORTUNITY
21 TO COME AND GET BACK TO THE ICOC IS SOMETHING THAT
22 IS OBVIOUSLY VERY IMPORTANT IN THE CIRM CONCEPT.

23 FROM ADVANCING SCIENCE PERSPECTIVE, I
24 THINK THE OPPORTUNITY TO MOVE SCIENCE FORWARD FAST
25 IN EXTRAORDINARY CASES WHERE, FOR EXAMPLE, NEW

BARRISTERS' REPORTING SERVICE

1 PERTINENT INFORMATION IS AVAILABLE, I THINK THIS
2 FACT IS VERY IMPORTANT. IT'S SOMETHING THAT, FOR
3 EXAMPLE, NIH DOES NOT HAVE, AND NIH PROCESS IS VERY
4 SLOW. WE HAVE THE OPPORTUNITY TO MOVE MERITORIOUS
5 SCIENCE FORWARD AS FAST AS WE CAN AS LONG AS THE
6 PROCESS IS RESPECTED AND IT WORKS WELL. SO I THINK
7 THE POLICY IS VERY IMPORTANT.

8 AND I THINK EVERYTHING THAT'S WRITTEN IN
9 THIS DOCUMENT IS OUTSTANDINGLY WRITTEN, IT'S VERY
10 CLEAR, AND ON PAPER I DON'T THINK THIS WOULD BE ANY
11 REAL ISSUES AS TO WHAT WARRANTS EXTRAORDINARY
12 PETITION AND WHAT WARRANTS ADDITIONAL ANALYSIS IN MY
13 MIND.

14 GIL'S SUGGESTION OF HAVING SOME TANGIBLE
15 EXAMPLES TO THE GRANT APPLICANTS AS TO WHAT THESE
16 WORDS PRACTICALLY MEAN WOULD PROBABLY BE HELPFUL.
17 SO THAT MIGHT BE ONE THING TO CONSIDER.

18 HOWEVER, I THINK TO SOME EXTENT, KEEPING
19 ALAN'S COMMENTS ON THE SIDE FOR A MINUTE, THERE IS
20 ONE WEAKNESS I SEE IN THE PROCESS. AND THAT IS THAT
21 THE EXTRAORDINARY PETITION DOES COME TO THE BOARD,
22 THE ICOC BOARD. AND THE BOARD IS NOT REALLY IN A
23 POSITION TO MAKE AN EDUCATED DETERMINATION WHETHER A
24 MATERIAL DISPUTE OF FACT TOOK PLACE OR THERE IS
25 MATERIAL NEW INFORMATION. AND THIS COMMENT THAT I

BARRISTERS' REPORTING SERVICE

1 MAKE IS BASED ON THE FACT THAT THE BOARD HAS NOT
2 REVIEWED THOSE GRANT APPLICATIONS AND DO NOT KNOW
3 WHAT THE CONTEXT IS IN THOSE GRANT APPLICATIONS.

4 SO THERE ARE TWO WAYS TO ADDRESS IN MY
5 MIND THIS. ONE IS THAT STAFF IN THIS CASE AS WELL
6 AS THE CHAIR AND THE MEMBERS OF GRANTS WORKING GROUP
7 MAKE AN EXPLICIT STATEMENT WHETHER A MATERIAL
8 DISPUTE OF FACT, IN THEIR OPINION, HAPPENED OR NOT
9 AND THE APPLICANT WHO MADE THE PETITION HAS TO STATE
10 IT VERY CLEARLY WHAT THEY THINK IT IS. AND STAFF,
11 AS WELL AS MEMBERS OF THE GRANTS WORKING GROUP WHO
12 WERE PRESENT, WILL ADVISE THE WHOLE BOARD AS TO
13 THEIR OPINION OF THE MATTER. AND LIKEWISE, THE
14 APPLICANTS WOULD MAKE A VERY CLEAR STATEMENT, ONE OR
15 TWO SENTENCES, WHAT IS THE MATERIAL NEW INFORMATION.
16 AND AGAIN, I THINK THE BOARD HAS TO RELY ON THE
17 STAFF AND THE GRANTS WORKING GROUP MEMBERS'
18 RECOMMENDATION AS TO WHETHER THIS IS REALLY NEW OR
19 WHETHER THIS WAS AVAILABLE AND WHETHER IT AFFECTS
20 THEIR DECISION-MAKING OR NOT.

21 THE OTHER ALTERNATIVE IS THAT THESE
22 EXTRAORDINARY PETITIONS NOT COME TO THE BOARD AS THE
23 FIRST PASS. I DON'T KNOW IF THIS IS FROM A LEGAL
24 PERSPECTIVE EVEN A POSSIBILITY, BUT TO ME THE
25 INDIVIDUALS WHO CAN ASSESS WHETHER THERE IS A

BARRISTERS' REPORTING SERVICE

1 MATERIAL DISPUTE OR FACT OR MATERIAL NEW INFORMATION
2 IS EITHER THE STAFF OR THE REPRESENTATIVES OF THE
3 GRANTS WORKING GROUP.

4 DR. SAMBRANO: SO I ACTUALLY AGREE WITH
5 THAT, AND I THINK ONE OF THE -- I MEAN ONE OF MY
6 COMMENTS RELATED TO THAT WAS THAT THE FORMAL APPEAL
7 PROCESS ALLOWS UP TO 30 DAYS FOR AN APPLICANT TO
8 SUBMIT AN APPEAL REQUEST AND ALLOWS SUFFICIENT TIME
9 TO ACTUALLY DO WHAT YOU JUST DESCRIBED, WHICH IS
10 ALLOW STAFF TO EXAMINE WHETHER THERE IS A MATERIAL
11 DISPUTED FACT, TO THEN CONSULT WITH THE CHAIR, AND
12 THEN BRING A FINDING TO THE PRESIDENT AND THEN TO
13 THE BOARD.

14 CHAIRMAN THOMAS: WHEN YOU SAY CHAIR, YOU
15 MEAN OF THE GRANTS WORKING GROUP?

16 DR. SAMBRANO: OF THE GRANTS WORKING
17 GROUP. RIGHT.

18 THE ISSUE WE CURRENTLY HAVE IS THAT THE
19 PETITIONS COME TOO QUICKLY WHERE WE CANNOT REALLY GO
20 THROUGH SUCH A PROCESS AND THEN BRING A CLEAR
21 RECOMMENDATION TO THE BOARD. ESPECIALLY IF WE DON'T
22 MEET THAT FIVE-BUSINESS DAY DEADLINE. SO I THINK IT
23 BECOMES A CHALLENGE TO ACTUALLY IMPLEMENT IT IN THAT
24 WAY. I AGREE THAT IN ORDER TO DETERMINE WHAT A
25 MATERIAL DISPUTE OF FACT IS WOULD REQUIRE A BIT MORE

BARRISTERS' REPORTING SERVICE

1 IN-DEPTH ANALYSIS.

2 I HAD A SUGGESTION FROM SHELLY HEIMFELD
3 WHO IS ALSO ON THE COMMITTEE, BUT COULDN'T BE HERE.
4 HE RAISED THAT AS ONE CONCERN IN THE DOCUMENT, THAT
5 IT HAS TO BE CLEAR WHO IS MAKING THAT DETERMINATION.

6 MR. HARRISON: CAN I MAKE ONE POINT, WHICH
7 WAS THAT IT WAS CONTEMPLATED, WHEN WE DRAFTED THIS
8 POLICY, THAT STAFF WOULD REVIEW THE CRITERIA WHETHER
9 IT'S A MATERIAL DISPUTE OF FACT OR NEW INFORMATION
10 AND MAKE A RECOMMENDATION TO THE BOARD AS TO WHETHER
11 OR NOT STAFF FELT THAT THE CRITERIA WERE
12 ESTABLISHED. THAT DOESN'T ADDRESS GIL'S QUESTION
13 ABOUT THE AMOUNT OF TIME AVAILABLE TO DO THAT, BUT
14 THAT WAS CONTEMPLATED.

15 ONE APPROACH YOU COULD CONSIDER WOULD BE
16 THAT IF AN APPLICANT SUBMITS A PETITION THAT
17 IDENTIFIES EITHER A MATERIAL DISPUTE OF FACT OR NEW
18 DATA, THAT IT COULD BE DEFERRED IF THERE'S NOT
19 SUFFICIENT TIME FOR STAFF OR GRANTS WORKING GROUP OR
20 WHOMEVER TO CONSIDER IT AND MAKE A RECOMMENDATION.

21 MR. SHEEHY: OUR ORIGINAL PROCESS WAS TO
22 HAVE STAFF OFFER COMMENTS ON ALL EXTRAORDINARY
23 PETITIONS, AND ACTUALLY STAFF ACTUALLY STOPPED DOING
24 IT BECAUSE THEY WERE OVERWHELMED. AND IT ACTUALLY
25 ALMOST MADE IT OBLIGATORY OR AT LEAST GOOD PRACTICE

BARRISTERS' REPORTING SERVICE

1 FOR AN APPLICANT TO SUBMIT AN EXTRAORDINARY PETITION
2 BECAUSE WHY NOT? I MEAN WHAT'S YOUR DOWNSIDE? YOU
3 CAN KNOW YOU'RE GOING TO GET RE-REVIEWED BY STAFF IF
4 YOU SEND IN AN EXTRAORDINARY PETITION.

5 SO THAT'S THE DILEMMA WE HAVE IF WE GO TO
6 A FULL REVIEW. UNLESS WE DO SOMETHING PERHAPS
7 LIKE -- AND PERHAPS IF THEY REALLY DO THINK THERE IS
8 A CREDIBLE MATERIAL FACT IN DISPUTE, THAT THE
9 APPLICANT GETS KICKED OUT OF THE QUEUE. SO THEY
10 WON'T BE REVIEWED AT THAT NEXT MEETING. THERE
11 SHOULD BE SOME ONUS. I MEAN IT SHOULDN'T BE
12 LIKE -- AT LEAST IT DIDN'T WORK BEFORE. I DON'T
13 KNOW. DR. OLSON. I'M TAKING THE CHAIR FROM THE
14 CHAIR.

15 DR. LUBIN: I THINK FINE. THIS IS WHAT WE
16 WANTED TO DO TODAY, AND WE'RE JUST STARTING THE
17 PROCESS.

18 DR. OLSON: I JUST WANT TO MAKE SOME
19 COMMENTS FOR THE CONSIDERATION OF THIS TASK FORCE.
20 I HEAR WHAT JEFF HAS SAID, AND I THINK A LOT OF --
21 AND WHAT GIL HAS SAID AND WHAT VARIOUS MEMBERS ON
22 THE PHONE HAVE SAID. I ACTUALLY THINK -- YOU KNOW,
23 THE EXTRAORDINARY PETITION HAS COME IN WITH
24 OFTENTIMES WHAT I THINK COULD BE MOST OF THE
25 COMMENTS HAVE BEEN ESSENTIALLY DIFFERENCE OF

BARRISTERS' REPORTING SERVICE

1 SCIENTIFIC OPINION.

2 I THINK A VERY IMPORTANT POINT THAT HAS
3 BEEN RAISED IN THIS DOCUMENT IS THAT, ACKNOWLEDGING
4 WHAT MR. SHEEHY AND OTHERS HAVE SAID, THAT, IN FACT,
5 MEMBERS OF THE PUBLIC ALWAYS HAVE A RIGHT TO SUBMIT
6 INFORMATION. AND IT IS A MATTER OF BOARD DISCIPLINE
7 HOW THE BOARD RESPONDS TO THAT INFORMATION.

8 HAVING SAID THAT, I ACTUALLY LIKE THE
9 NOTION THAT THESE CRITERIA, AND I WOULD EMPHASIZE
10 THE POINT OF CRITERIA, FOR WHAT CONSTITUTES MATERIAL
11 DISPUTE OF FACT, FACT VERSUS OPINION, AND WE
12 ACTUALLY HAD A MEMBER OF THE GRANTS REVIEW GROUP,
13 SHELLY HEIMFELD, SPECIFICALLY MAKE THE POINT THAT
14 FOR THE CRITERIA LISTED FOR MATERIAL DISPUTE OF
15 FACT, HE THOUGHT ALL OF THIS SHOULD BE MET BEFORE IT
16 WAS CONSIDERED.

17 AND THERE WERE ALSO PROPOSED BY THIS GROUP
18 AND, I BELIEVE, DISCUSSED THE CRITERIA FOR MATERIAL
19 NEW INFORMATION. WHAT CONSTITUTES AS MATERIAL?
20 BECAUSE IF IT'S NOT GOING TO MAKE A DIFFERENCE IN
21 THE DECISION, IF IT'S NOT FACTUALLY VERIFIABLE, THE
22 CRITERIA THAT HAVE ACTUALLY BEEN PUT IN HERE THAT I
23 THINK THOSE ARE VERY IMPORTANT THINGS. AND IF THAT
24 IS THE PROCESS, FOR THE SAKE OF DISCUSSION, THAT
25 FALLS WITHIN STAFF'S PURVIEW TO DECIDE IF THIS GROUP

BARRISTERS' REPORTING SERVICE

1 AGREES THAT THESE ARE REASONABLE CRITERIA. IF IT
2 FALLS WITHIN STAFF'S PURVIEW TO SAY, YES, THEY HAVE
3 MET THIS, THEN IT'S TRUE. IT WOULD HAVE TO BE
4 DELAYED. THEY WOULD NOT BE CONSIDERED -- THAT
5 APPLICANT WOULD NOT BE CONSIDERED. BUT AT LEAST YOU
6 HAVE ENOUGH INFORMATION THAT IS REALLY WORTH TAKING
7 UP GRANTS WORKING GROUP TIME TO LOOK AT AGAIN OR A
8 SUBGROUP THEREOF.

9 SO I WANT TO REMIND THE GROUP THAT THESE
10 CRITERIA, I THINK, ARE ACTUALLY IMPORTANT. AND I
11 WOULD ASK THE GROUP TO CONSIDER THOSE CRITERIA. AND
12 AS I SAY, YOU'RE NEVER GOING TO BE ABLE TO PRECLUDE
13 ANY APPLICANT FROM SUBMITTING INFORMATION, BUT YOU
14 CAN PRECLUDE WHAT YOU DO WITH IT. YOU CAN DEFINE
15 THE PARAMETERS ON HOW YOU DEAL WITH IT. AND SO
16 THAT'S WHAT I WOULD SUGGEST YOU WOULD CONSIDER.

17 MR. SHEEHY: JUST TO KIND OF -- SO WHAT
18 YOU WOULD SUGGEST IS BASICALLY PERHAPS WE GET RID OF
19 THE EXTRAORDINARY PETITION PROCESS ALTOGETHER AND WE
20 CALL THIS PERHAPS, FOR A POINT OF CLARITY, A
21 SCIENTIFIC APPEAL. AND THE IDEA WOULD BE -- I'M
22 JUST TRYING TO THINK IN TERMS OF PROCESS. THAT YOU
23 LOOK AT THESE CRITERIA AND THAT YOU MEET THESE
24 CRITERIA WHEN YOU SUBMIT THIS WITH THE UNDERSTANDING
25 THAT IT'S LIKELY THE GRANT WILL NOT BE CONSIDERED BY

BARRISTERS' REPORTING SERVICE

1 THE BOARD. THE STAFF WILL TAKE THE FIRST SHOT AT
2 LOOKING TO SEE IF YOU'VE MET THE CRITERIA. IF YOU
3 HAVE, THEN YOU GO TO THE NEXT STEP.

4 THAT'S INTERESTING.

5 DR. LUBIN: THAT SOUNDS LIKE A GOOD
6 PROCESS. WHY DON'T YOU GO AND THEN I WANT TO JUST
7 COMMENT ABOUT ONE ADDITIONAL THING ABOUT WHAT I SEE
8 HAPPENING AT THE MEETINGS THAT HAS A GREAT INFLUENCE
9 ON HOW THE VOTE GOES AND WHETHER SOMETHING IS FUNDED
10 THAT DOESN'T RELATE TO THIS ITEM.

11 CHAIRMAN THOMAS: I THINK THAT'S THE NEXT
12 AGENDA. PAT, I LIKE THIS IDEA A LOT. I THINK THAT
13 THERE'S CERTAIN CIRCUMSTANCES WHICH ARE TRICKY THAT
14 I'LL GIVE ONE EXAMPLE IN WHICH WHAT YOU JUST
15 DESCRIBED, WHICH I THINK MAKES A LOT OF SENSE,
16 WOULDN'T HAVE LED TO A RESULT THAT WE ENDED UP
17 HAVING IN THIS LATEST ROUND OF EXTRAORDINARY
18 PETITIONS. SO I WILL NOTE THAT ALMOST EVERYTHING
19 THAT GOT REFERRED OF THE FIVE, AND MAYBE, GIL, MAYBE
20 YOU CAN REFRESH OUR MEMORY ON THIS, BUT I THINK VERY
21 LITTLE OF IT WAS REFERRED ON THE BASIS OF MATERIAL
22 DISPUTE, THE SCIENTIFIC OPINION ISSUE. ALMOST
23 EVERYTHING THAT WAS REFERRED IS ON THE BASIS OF,
24 QUOTE, UNQUOTE, NEW INFORMATION THAT WE SOUGHT TO
25 HAVE EVALUATED BY THE SUBSET OF THE GRANTS WORKING

BARRISTERS' REPORTING SERVICE

1 GROUP BECAUSE THAT'S WHAT WE WERE NOT ABLE TO -- AS
2 WE SAT THERE, THERE WAS NO WAY THAT THE BOARD COULD
3 DECIDE WHETHER THAT WAS MATERIAL OR WHATEVER OR NOT.

4 AND THAT WAS THE DRIVING FORCE BEHIND, I
5 THINK, ALL OF THE ADDITIONAL ANALYSIS. JUST FOR
6 THOSE ON THE PHONE, GIL'S SHAKING HIS HEAD IN
7 AGREEMENT.

8 IT WOULD BE GREAT TO HAVE CRITERIA UNDER
9 WHICH THOSE COULD BE EVALUATED GOING FORWARD. I
10 THINK ONE OF THE THINGS WE DO NOT WANT TO HAVE,
11 WHICH WE HAD, WAS THE OFFERING OF, QUOTE, UNQUOTE,
12 NEW INFORMATION ON THE SPOT THAT WASN'T IN THE
13 EXTRAORDINARY PETITION OR WHATEVER. WE HAD A COUPLE
14 OF THINGS THAT WERE DEVELOPMENTS OVER THE LAST 48
15 HOURS. AND THAT DOESN'T GIVE YOU ANY TIME TO
16 RESPOND TO ANYTHING. SO WE CAN'T HAVE THAT AGAIN,
17 FOR STARTERS.

18 BUT HERE, PAT, HERE'S WHERE I JUST THROW
19 THIS OPEN FOR THOUGHT. THE STAFF IN EVALUATING THE
20 EXTRAORDINARY PETITIONS HAVE CERTAIN OF THOSE
21 PETITIONS THEY THOUGHT WARRANTED FURTHER DISCUSSION.
22 ONE OF THEM WAS NOT THE RP PROPOSAL. STAFF DID NOT
23 FEEL THAT THAT WAS AMONG THE INFORMATION SUBMITTED
24 WARRANTED FURTHER REVIEW. AND YET THERE WAS NEW
25 INFORMATION GIVEN, QUOTE, UNQUOTE, AT THE MEETING,

BARRISTERS' REPORTING SERVICE

1 AND THAT LED TO A REFERRAL FOR ADDITIONAL ANALYSIS.
2 AND THE SUBSET OF THE GRANTS WORKING GROUP IN THAT
3 INSTANCE, HEARING THE NEW INFORMATION, VOTED TO
4 RECOMMEND APPROVAL TO THE BOARD FOR THAT
5 APPLICATION.

6 SO HOW DO WE DEAL WITH FACTS LIKE THAT?

7 DR. SAMBRANO: I DON'T WANT TO DISCUSS ANY
8 SPECIFIC APPLICATION HERE, BUT I CAN SAY THAT THERE
9 ARE DIFFERENT CIRCUMSTANCES THAT WE MIGHT ENCOUNTER.
10 SO THERE MIGHT BE NEW DATA OR INFORMATION THAT IS OF
11 ENOUGH SUBSTANCE WHERE IT REALLY REQUIRES A FULL
12 GRANTS WORKING GROUP REVIEW WHERE BASICALLY THE
13 ANALYSIS WE DID WITH A COUPLE OF REVIEWERS AND THE
14 CHAIR MAY NOT BE SUFFICIENT. SO IF THE INFORMATION
15 IS SUCH THAT IT REALLY ALTERS THE PROPOSAL OVERALL,
16 I THINK THAT ALMOST DESERVES A NEW FULL REVIEW.

17 I THINK THERE IS INFORMATION THAT IS VERY
18 FOCUSED AND NARROW THAT MAYBE ADDRESSES A SPECIFIC
19 CONCERN THAT THE GRANTS WORKING GROUP HAD. IN SUCH
20 A CASE, THEN THE ADDITIONAL ANALYSIS AS WE HAVE
21 CONSTRUCTED IT IS FINE AND APPROPRIATE.

22 I THINK IT CAN ALSO HAPPEN THAT IF IT'S
23 NOT CLEAR THAT THE NEW INFORMATION IS ADDRESSING A
24 SPECIFIC CONCERN OF THE GRANTS WORKING GROUP, THEN
25 THERE IS THE DANGER OF GIVING THAT ASPECT SO MUCH

BARRISTERS' REPORTING SERVICE

1 VALUE THAT THE BOARD MAY THEN VOTE SIMPLY ON THAT
2 AND THEN ARE APPROVING A PROPOSAL ONLY ON THAT ONE
3 QUESTION AND THEN FORGETTING ABOUT ALL THE OTHER
4 POINTS THAT WERE REALLY RELEVANT IN THE OVERALL
5 REVIEW.

6 SO I THINK WE DON'T WANT TO GET AWAY FROM
7 WHAT WAS THE OVERALL REVIEW BY A LARGE GROUP OF
8 SCIENTISTS BECAUSE IT SHOULD BE RECOGNIZED THAT,
9 ESPECIALLY THE CLINICAL REVIEW, IS NOT ONLY DO WE
10 HAVE THE FINISH SCIENTISTS, OFTEN WE HAVE ABOUT AN
11 EQUAL NUMBER OF SPECIALISTS PARTICIPATING ON THE
12 PHONE. SO WE HAVE 25 TO 30 SCIENTISTS CONTRIBUTING
13 TO ALL THESE APPLICATIONS. WHEN YOU DO AN
14 ADDITIONAL ANALYSIS, YOU JUST DON'T HAVE THAT LEVEL
15 OF IN-DEPTH REVIEW. AS A RESULT IT'S GOING TO BE
16 LIMITED IN TERMS OF WHAT YOU CAN CONSIDER.

17 SO I THINK IN ASSESSING WHAT, THEN, SHOULD
18 GO FOR AN ADDITIONAL ANALYSIS REVIEW, I THINK ONE
19 HAS TO POINT TO A VERY SPECIFIC ELEMENT THAT NEEDS
20 TO BE ADDRESSED, AND IT'S ONE THAT CAN BE ADDRESSED
21 BY A SMALL SET OF REVIEWERS.

22 CHAIRMAN THOMAS: ALL RIGHT. I THINK
23 THAT'S WHAT WE DID. WE CONFINED THE REVIEW TO VERY
24 SPECIFIC QUESTIONS, DID WE NOT?

25 DR. SAMBRANO: WE DID. I THINK IN SOME

BARRISTERS' REPORTING SERVICE

1 CASES THE QUESTION WAS ACTUALLY RATHER OPEN-ENDED.
2 AND I THINK IT WAS NOT NECESSARILY RELATED TO WHAT
3 WAS A MAJOR CONCERN OF THE GRANTS WORKING GROUP.
4 AND I THINK THAT'S WHERE WE HAVE TO BE CAREFUL.

5 MR. HARRISON: JUST TO BE CLEAR, PART OF
6 THE NEW CRITERIA BOTH FOR NEW INFORMATION AS WELL AS
7 MATERIAL DISPUTE OF FACT IS THAT IT ADDRESSES A
8 SPECIFIC CONCERN OR QUESTION IDENTIFIED IN THE GWG'S
9 REVIEW AND IS MATERIAL TO THE BOARD'S CONSIDERATION
10 OF IT. SO I THINK WE'VE THROUGH THE NEW POLICIES
11 ARTICULATED A NARROWER STANDARD.

12 DR. OLSON: YES.

13 DR. DULIEGE: I'M SORRY. I'M TRYING TO
14 INTERVENE HERE AND I DON'T KNOW WHEN IT'S NOT
15 INTERRUPTING. THE ONE THING IS WHEN YOU INTERVENE,
16 YOU COULD SAY YOUR FIRST NAME. THAT ALLOWS FOR US
17 ON THE PHONE TO HAVE THE CONVERSATION A LITTLE BIT
18 MORE EASILY.

19 IF I COULD MAKE THEN TWO COMMENTS ABOUT
20 WHAT I'VE HEARD. ONE, I THINK, GIL, YOU ADVOCATED
21 FOR VOTING CONFUSION AND SIMPLIFYING THE PROCESS TO
22 SOME EXTENT. AND EVEN IF -- FOR US WHEN WE REVIEW
23 THE ORIGINAL INFORMATION, THAT'S EXTREMELY CLEAR AND
24 SPECIFIC. IF THIS IS THE FEEDBACK THAT YOU'RE
25 GETTING FROM APPLICANTS, WE NEED TO LISTEN TO IT.

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1 AND IF THERE WAS ONE WAY TO MAKE IT A SINGLE APPEAL
2 PROCESS, I THINK THAT WOULD BE A GOOD THING.

3 SECOND, I CERTAINLY AGREE STRONGLY WITH
4 THE COMMENTS THAT WERE MADE THAT WE SHOULD AVOID
5 PUTTING THE BOARD IN SITUATIONS TO ACT OR TO BE
6 TEMPTED TO ACT IMMEDIATELY UPON COMMENTS FROM THE
7 AUDIENCE, WHETHER THESE ARE ADVOCATES OR SCIENTISTS
8 OR BOTH. BUT RATHER GET ANY COMMENTS BACK TO THE
9 STAFF FOR FURTHER ANALYSIS AND THEN BACK TO THE
10 BOARD.

11 IN REGARDS TO THE POTENTIAL CONCERN THAT
12 WE SHOULD ACT RAPIDLY, YES, IT IS TIME TO VOTE
13 RAPIDLY, BUT I SHOULD SAY THAT THIS BOARD, IT SEEMS
14 TO ME, VERY FREQUENTLY IN GETTING A MONTH OR A
15 COUPLE OF MONTHS OF ADDITIONAL REVIEW BY THE
16 SCIENTIFIC STAFF IS VERY WELL WORTH THE QUALITY OF
17 THE DECISION IN THE END.

18 DR. LUBIN: THANK YOU, ANNE-MARIE. WELL,
19 I THINK THESE ARE OBVIOUSLY VERY IMPORTANT POINTS.
20 I JUST WANT TO HAVE SOME CLARIFICATION IN TERMS OF
21 AN APPLICANT IS INFORMED OF THE DECISION THAT'S MADE
22 BY THE GRANTS WORKING GROUP AND THE RECOMMENDATIONS
23 AND THE SCORE. IS THAT CORRECT?

24 DR. SAMBRANO: THAT'S CORRECT.

25 DR. LUBIN: AND ALSO WHETHER THEY FIT INTO

BARRISTERS' REPORTING SERVICE

1 TO A FUNDABLE OR NOT A FUNDABLE CRITERIA?

2 DR. SAMBRANO: YES. THEY GET THE
3 RECOMMENDATION TO THE BOARD.

4 DR. LUBIN: AND THEY'RE TOLD WHY THAT'S
5 DONE?

6 DR. SAMBRANO: RIGHT. SO THAT'S IN THE
7 SUMMARY OF THE REVIEW. SO THE SUMMARY OF REVIEW --

8 DR. LUBIN: HOW FAR IN ADVANCE OF THE --

9 DR. SAMBRANO: IT'S ABOUT TWO WEEKS PRIOR
10 TO THE BOARD MEETING.

11 DR. LUBIN: OKAY. SO ARE WE SAYING THAT
12 IF YOU'RE WORKING IN A LABORATORY AND SINCE THE TIME
13 YOU SUBMITTED THIS, YOU'VE GENERATED NEW DATA, WE
14 WANT TO BE SURE THAT ALL THAT NEW DATA IS AVAILABLE
15 FOR YOU TO PRESENT BACK TO OUR WORKING GROUP?
16 BECAUSE IF SO AND I WAS A SCIENTIST AND THAT'S ONE
17 OF THE GROUPS WE'VE TALKED ABOUT, BOY, I'D BE RIGHT
18 ON TOP OF GETTING -- I'D PUT MY WHOLE STAFF ON A
19 COUPLE ITEMS THAT ADDRESS THE CONCERNS HERE AND
20 BRING IT BACK AGAIN. BECAUSE IF YOU LOOK AT THE
21 TRACK RECORD OF WHAT'S HAPPENED, THIS IS A
22 SUCCESSFUL AVENUE. AND I WOULDN'T GIVE UP ON IT AND
23 ESPECIALLY BECAUSE OF WHAT JEFF SAID, THAT THE
24 OPPORTUNITY TO DO THE SAME THING NEXT YEAR MAY NOT
25 EXIST OR IS UNLIKELY TO EXIST.

BARRISTERS' REPORTING SERVICE

1 YOU WANT TO COMMENT ON THAT, GIL?

2 DR. SAMBRANO: YES. I AGREE THAT
3 CERTAINLY IF WE PROVIDE AN INCENTIVE FOR AN
4 APPLICANT -- I MEAN I THINK ANY APPLICANT WHO IS NOT
5 RECOMMENDED IS GOING TO TAKE WHATEVER CHANCE THERE
6 IS, EVEN IF IT'S A SMALL CHANCE THAT THEY MIGHT GET
7 FUNDED, TO DO SO. SO IF A PETITION OR APPEAL
8 PRESENTS A MECHANISM FOR DOING THAT, FOR GETTING
9 THEIR APPLICATION RECONSIDERED, IT ONLY MAKES SENSE
10 FOR THEM TO DO THAT. AND SO I THINK IN THAT SENSE
11 IT WOULD ENCOURAGE PETITIONS.

12 ON THE OTHER HAND, IF THERE ARE CLEAR
13 GUIDELINES AS TO WHAT EXACTLY THEN CONSTITUTES
14 MERITORIOUS APPEAL OR PETITION, I THINK THAT MAKES
15 IT CLEARER TO BOTH THE BOARD AND THE APPLICANT.
16 THEY CAN CONSIDER DO I REALLY HAVE ENOUGH OF A CASE
17 TO MAKE BEFORE THE BOARD OR CIRM. AND IF THEY
18 DON'T, THEN MAYBE WE WON'T HEAR ABOUT IT.

19 DR. LUBIN: ONE LAST QUESTION, I'M SORRY,
20 BEFORE WE GO TO YOU, PAT. DOES THE SCIENTIFIC
21 REVIEW GROUP, BOTH THE ONES THAT ARE STANDARD AND
22 THE ONES YOU BRING IN OUTSIDE, DO THEY KNOW ABOUT
23 THIS PROCESS THAT GOES ON, WHAT THE APPLICANT'S
24 OPPORTUNITIES ARE? ARE THEY FAMILIAR WITH THAT
25 PART? ALAN BROUGHT THIS UP A LITTLE BIT AT THE

BARRISTERS' REPORTING SERVICE

1 BEGINNING, CONCERN ABOUT IF I WERE A REVIEWER AND
2 SPENT SEVERAL DAYS HERE REVIEWING THINGS AND THEN
3 ALL OF A SUDDEN THIS THING CAME IN AND THAT CHANGED
4 THE WHOLE OUTCOME OF WHAT I AND MAYBE WHOEVER ELSE
5 REVIEWED A GRANT RECOMMENDED, THAT WOULD BOTHER ME
6 TO BE A REVIEWER. AND I SENSE THAT AS A CONCERN.

7 DR. SAMBRANO: YES. SO WHAT WE NORMALLY
8 DO IS FOLLOWING A BOARD MEETING WHEN THE BOARD HAS
9 MADE A DETERMINATION ON WHICH APPLICATIONS TO MOVE
10 FORWARD, WE REPORT BACK TO THE MEMBERS OF THE GRANTS
11 WORKING GROUP WHO PARTICIPATED IN THAT REVIEW TO
12 JUST FOLLOW UP AND LET THEM KNOW WHAT THE RESULT OF
13 THEIR RECOMMENDATIONS WERE. AND SO CERTAINLY IF
14 THERE ARE SIGNIFICANT CHANGES FROM WHAT WAS
15 RECOMMENDED, THERE'S GOING TO BE QUESTION AS TO WHY
16 THAT WAS. AND I THINK MANY OF THEM WILL, NOT ALL OF
17 THEM, BUT MANY WILL LOOK AT WHAT HAS HAPPENED OR
18 OCCURRED AT EACH OF THE BOARD MEETINGS, AND THEY
19 EITHER OBSERVE BECAUSE THEY EITHER READ THE
20 TRANSCRIPTS OR READ THE NEWSPAPERS AS TO WHAT HAS
21 OCCURRED. AND SOME OF THEM HAVE INDEED EXPRESSED
22 CONCERN ABOUT IT.

23 SO I THINK FROM THEIR PERSPECTIVE, IT'S
24 NOT AN ISSUE OF UNDERSTANDING THE PROCESS, BUT I
25 THINK REALLY A CALL FOR US TO HAVE A PROCESS THAT IS

BARRISTERS' REPORTING SERVICE

1 CLEAR, UNDERSTANDABLE AND THAT I THINK WOULD BRING
2 MERITORIOUS APPLICATIONS UP. AND IF THERE IS AN
3 APPEAL PROCESS, THAT IT'S ONE THAT MAKES SENSE.

4 DR. TROUNSON: JUST TO AMPLIFY SOMETHING
5 THERE IS THAT IF IT GETS SENT BACK BY THE BOARD, WE
6 ACTUALLY DON'T INVOLVE THE WHOLE GRANTS WORKING
7 GROUP. WE INVOLVE REALLY ONLY THREE MEMBERS. SO
8 THIS IS A GRANTS WORKING GROUP WHICH HAS 15
9 SCIENTISTS SITTING PLUS SEVEN PATIENT ADVOCATES,
10 PLUS SOME SPECIALISTS. SO THEY MAY NOT COME OUT
11 WITH THE SAME VIEW THAT THE THREE MEMBERS DID.

12 SO THEY MAY STILL FEEL THAT, DESPITE
13 WHATEVER THAT NEW INFORMATION WAS, THEY'RE STILL NOT
14 FEELING VERY GOOD. SO WE CAN'T BE CERTAIN THAT THE
15 DECISION WOULD REALLY REFLECT ACCURATELY WHAT THE
16 WHOLE GRANTS WORKING GROUP WOULD THINK, BUT WE'RE
17 TRYING TO GET A SAMPLE THAT MIGHT BE REFLECTIVE OF
18 IT. BUT ALL YOU CAN SAY WAS THAT IT MIGHT BE
19 REFLECTIVE OF IT.

20 AND I THINK TO BE FAIR, I DON'T THINK WE
21 WERE REALLY EVER ASKED, BUT I ACTUALLY DON'T THINK
22 STAFF, AND THAT'S KIND OF REPRESENTING MYSELF AND
23 ELLEN AS A SPOKESPERSONS, REALLY FELT THAT OUR
24 RECOMMENDATIONS WERE REALLY DIFFERENT OURSELVES FROM
25 THE ORIGINAL ONES THAT GO TO THE BOARD.

BARRISTERS' REPORTING SERVICE

1 YOU TAKE IT AS WHATEVER YOU WISH, BUT
2 THERE IS THIS PROCESS OF REPRESENTING THE VIEWS AND
3 THAT THE BOARD REVIEW IS PROBABLY THE BEST REVIEW
4 WHERE THERE ARE MULTIPLE INPUTS WHERE YOU CAN
5 ACTUALLY GET AT THE VIEWS, BUT, OF COURSE, IT'S VERY
6 DIFFICULT TO RECONSTITUTE A WHOLE GRANTS WORKING
7 GROUP. SO THERE'S SOME PROBLEMS IN THE PROCESS, I
8 THINK, THAT ARE REALLY NOT ALL THAT EASY TO RESOLVE.

9 CHAIRMAN THOMAS: ALAN, WHAT WOULD YOU,
10 AND I WAS GOING TO ASK GIL THE SAME QUESTION, WHAT
11 WOULD YOU RECOMMEND IN TERMS, TO THE EXTENT
12 SOMETHING IS SENT BACK, WHAT'S THE IDEAL NUMBER OF A
13 RECONSTITUTED ADDITIONAL ANALYSIS GROUP?

14 DR. TROUNSON: WELL, WHEN I WAS REALLY
15 SORT OF PROPOSING THAT, I THINK, TO THE BOARD A
16 THREE-MEMBER ONE, I THINK IT WAS ON THE VERY NARROW
17 ISSUE OF DOES THIS NEW PIECE OF INFORMATION
18 REPRESENT ANYTHING SIGNIFICANT. AND SO I THINK
19 THAT'S PROBABLY THE BEST YOU CAN DO, BUT IT'S THE
20 NARROWNESS OF THE QUESTION THAT NEEDS TO BE ASKED.
21 OTHERWISE, IF YOU ASK THE BROAD QUESTION, THEN I
22 THINK YOU'VE GOT A REAL PROBLEM ABOUT THAT SMALL
23 NUMBER OF PEOPLE BEING ADEQUATELY ABLE TO ADDRESS
24 IT.

25 LOOK, I DON'T HAVE AN OFF-THE-CUFF

BARRISTERS' REPORTING SERVICE

1 RECOMMENDATION HERE BECAUSE IF IT'S BEING SENT BACK
2 IN SUBSTANTIAL NUMBERS, AS THEY WERE ON THAT ONE
3 OCCASION, IT'S VERY DIFFICULT TO CONSTITUTE EVEN THE
4 NUMBERS OF PEOPLE THAT WE NEEDED TO ADDRESS THAT
5 FROM THE WHOLE BOARD -- FROM THE WHOLE GRANTS
6 WORKING GROUP. SO TO GET THE WHOLE LOT OF THEM TO
7 COME BACK EITHER TELEPHONICALLY, I WOULD THINK, GIL,
8 THAT WOULD BE REALLY, REALLY DIFFICULT. SO WE WOULD
9 PROBABLY NEED TO CONTINUE TO DO THAT, BUT MAKE SURE
10 THAT THE QUESTION BEING ADDRESSED THAT'S RETURNED TO
11 THEM IS AT ARE THE NARROWEST POSSIBLE QUESTION SO
12 THAT YOU'RE NOT TRYING TO ADDRESS ALL THE OTHER
13 ISSUES THAT WERE UNDER CONSIDERATION.

14 DR. STEWARD: COULD I JUST RAISE A
15 POSSIBILITY AND MAYBE ASK STAFF TO RESPOND? I THINK
16 WE BOUNCED THIS AROUND MAYBE CASUALLY WITH A FEW OF
17 US EARLIER ON. AND RECOGNIZING EVERYTHING THAT YOU
18 JUST SAID, ALAN, WHICH IS ABSOLUTELY CORRECT, THERE
19 IS ANOTHER OPTION. AND THAT WOULD BE TO SIMPLY MAKE
20 IT PART OF THE REVIEW PROCESS, TO ARRANGE FOR THE
21 GRANTS WORKING GROUP TO REMEET TELEPHONICALLY AT
22 SOME PERIOD OF TIME AFTER THE REVIEW PROCESS AND
23 AFTER THE ICOC MEETING OR BEFORE THE ICOC MEETING.
24 THE TIMING MIGHT NOT MATTER. I THINK THAT THE ISSUE
25 HERE HAS BEEN SORT OF THIS AD HOC UNCERTAIN NATURE

BARRISTERS' REPORTING SERVICE

1 IT TO.

2 BUT IF YOU SIMPLY SAID IN ADVANCE THE
3 GRANTS WORKING GROUP MEETING IS GOING TO BE THE
4 FOLLOWING DAYS AND THERE WILL BE A FOLLOW-UP
5 MEETING, ONE-DAY TELEPHONIC, ON ANOTHER DAY SOME
6 MONTHS IN ADVANCE TO CONSIDER ALL OF THIS STUFF.
7 THAT WAY YOU WOULD REALLY BE ABLE TO HAVE THE FULL
8 CONSIDERATION OF THE GRANTS WORKING GROUP. IT WOULD
9 ALL BE PREPLANNED IN ADVANCE. IT WOULDN'T BE AD
10 HOC. AND IT WOULD THEN PROVIDE THE BOARD WITH THE
11 RICHEST INFORMATION ACTUALLY IN TERMS OF HOW THE
12 APPLICANTS WERE RESPONDING TO THE SPECIFIC CONCERNS
13 THAT THE GRANTS WORKING GROUP RAISED.

14 SO MY QUESTION IS TO BOTH YOU AND GIL AND
15 WHOMEVER ELSE. WHAT DO YOU THINK ABOUT THIS IN
16 TERMS OF FEASIBILITY?

17 DR. TROUNSON: GIL, DO YOU WANT TO ADDRESS
18 THAT?

19 DR. OLSON: I WANT TO MAKE A COMMENT ABOUT
20 THAT TO SOME EXTENT. FIRST, IF YOU THOUGHT
21 EXTRAORDINARY PETITIONS AND THE EXTRAORDINARY
22 PETITION POLICY INVITED SUBMISSIONS, GUARANTEEING A
23 FOLLOW-UP GRANTS WORKING GROUP, I THINK, GUARANTEE
24 THAT. SO I THINK YOU WOULD HAVE TO LOOK AT THAT AS
25 HOLDING TWO GRANTS WORKING GROUP MEETINGS FOR EVERY

BARRISTERS' REPORTING SERVICE

1 RFA TO SOME EXTENT. I THINK YOU WOULD REALLY HAVE
2 TO CONSIDER THAT, AND YOU WOULD HAVE TO CONSIDER
3 THAT IN THE CONTEXT OF WHAT CIRM, THE BOARD, AND
4 WHAT OUR MISSION IS. SO THAT'S A COMMENT.

5 SO I GO BACK TO THE POINT THAT I THINK
6 MANY HAVE MADE. AND DEFINE CRITERIA, DEFINE GOOD
7 CRITERIA FOR MATERIAL NEW INFORMATION. THIS SPEAKS
8 TO DR. LUBIN'S POINT OF, BOY, IF I GET MY REVIEW
9 SUMMARY, I'M GOING TO PUT MY LAB ON THIS LIKE CRAZY
10 FOR ONE WEEK AND GENERATE THIS DATA.

11 BUT I THEN HARK ALSO BACK TO A POINT GIL
12 MADE. VERY SELDOM IS A SCORE OR A DECISION DUE TO
13 ONE POINT. AND SO IT IS A LITTLE BIT DANGEROUS TO
14 SAY INFORMATION ADDRESSING THIS MAKES THAT MUCH OF A
15 DIFFERENCE.

16 SO I DO THINK ALL OF THESE THINGS NEED TO
17 BE CONSIDERED AND ARE WORTH DISCUSSING BY THIS
18 COMMITTEE IN THE CONTEXT OF MATERIAL NEW INFORMATION
19 OR THE OTHER CRITERIA HERE, MATERIAL DISPUTE OF
20 FACT. AND THEN THE PROCESS BY WHICH, ONCE THERE IS
21 SOME AGREEMENT ON THE CRITERIA, THE PROCESS BY WHICH
22 THAT COULD BE HANDLED IS ALSO AN IMPORTANT POINT OF
23 DISCUSSION, WHETHER IT'S GETTING THE CHAIR PLUS OR
24 WHETHER IT'S MORE THAN THAT, BUT I WOULD NOT OPEN UP
25 RIGHT OFF THE BAT A TWO REVIEW PER RFA SITUATION.

BARRISTERS' REPORTING SERVICE

1 DR. STEWARD: PAT --

2 DR. FEIGAL: WHEN APPROPRIATE, I'D LIKE TO
3 BE CALLED ON.

4 DR. STEWARD: PAT, THIS IS OS. IF YOU
5 COULD JUST CLARIFY. I DEFINITELY WASN'T SUGGESTING
6 THAT. WHAT I WAS SUGGESTING WAS THAT WHATEVER
7 ADDITIONAL INFORMATION THAT WAS CONSIDERED TO BE
8 PERTINENT WOULD BE OPTIMALLY REVIEWED IF IT REALLY
9 COULD BE REVIEWED BY THE FULL WORKING GROUP. AND I
10 TOTALLY AGREE. YOU WOULDN'T WANT TO HAVE TWO
11 MEETINGS PER ROUND NECESSARILY, BUT IF IT COULD JUST
12 BE A PREPLANNED THING.

13 IF I COULD JUST THROW ONE MORE LITTLE
14 THING IN. THE OTHER POSSIBILITY IS THAT THERE MAY
15 VERY WELL BE ROUNDS WHERE WE ESSENTIALLY PAY OUT
16 EVERYBODY WHO WAS RECOMMENDED FOR FUNDING. AND THEN
17 ALL OF THIS KIND OF BECOMES OF MOOT. SO THERE'S AN
18 INTERESTING IMPLICATION OF THAT. WHETHER WE PAY OUT
19 OR NOT DEPENDS A LOT ON WHAT WE SET THE THRESHOLD
20 FOR FUNDING, THE FUNDING LIMITS FOR THAT PARTICULAR
21 ROUND. I JUST SAY ALL THAT WITHOUT COMMENTING ON IT
22 ONE WAY OR THE OTHER.

23 CHAIRMAN THOMAS: GIL'S HAD HIS HAND UP
24 FOR A WHILE.

25 DR. FEIGAL: AND THEN MAYBE AFTER GIL, IF

BARRISTERS' REPORTING SERVICE

1 I COULD MAKE A COMMENT.

2 CHAIRMAN THOMAS: SURE.

3 DR. SAMBRANO: SO I WANTED TO ADDRESS THE
4 INITIAL POINT, AND YOU ASKED WHETHER THERE WOULD BE
5 FEASIBILITY ISSUES. AND I THINK THERE CERTAINLY
6 WOULD IN TRYING TO ASSEMBLE THE FULL PANEL AGAIN TO
7 RECONSIDER SOMETHING. I THINK PART OF THE REASON
8 FOR THAT -- WELL, THERE ARE SEVERAL REASONS. BUT
9 ONE OF THEM IS THAT WE ARE POTENTIALLY SETTING UP A
10 REVIEW PANEL FOR SOMETHING THAT MAY OR MAY NOT
11 HAPPEN. AND IT'S REALLY HARD TO GET COMMITMENT OF
12 PEOPLE TO DO THAT.

13 THE OTHER THING IS THAT WE ARE, I MEAN I
14 THINK AT THIS POINT, QUITE, I DON'T WANT TO SAY
15 OVERWHELMED, BUT WE HAVE QUITE A BIT ON OUR PLATE
16 WITH EVERY RFA THAT IS BEING RUN IN PARALLEL AND
17 OVERLAPPING. SO BASICALLY ONCE WE ARE DONE WITH A
18 REVIEW AND MOVE TO THE BOARD, WE KIND OF ARE WORKING
19 ON THE NEXT ONE AND MOVING ON VERY QUICKLY AND
20 FOCUSING ON THAT NEXT REVIEW. I THINK HAVING TO PUT
21 TOGETHER A PANEL FOR WHAT MAY BE ONE APPLICATION
22 WOULD PROBABLY BE MORE WORK THAN IT MIGHT ACTUALLY
23 WARRANT.

24 AND SO I GUESS ONE WAY TO LOOK AT IT AND
25 THE WAY I TEND TO LOOK AT IT, IF THERE IS A QUESTION

BARRISTERS' REPORTING SERVICE

1 WHERE IT IS SPECIFIC, AS WE OUTLINED IN THIS
2 DOCUMENT, AND NARROW ENOUGH THAT BASICALLY HAVING
3 THE GRANTS WORKING GROUP CHAIR AND A COUPLE OF
4 REVIEWERS THAT CAN ADDRESS IT AND IT SPEAKS TO A
5 SPECIFIC CRITICISM, THEN I THINK THAT'S FINE. IF
6 THE CHANGES ARE SUCH THAT WE'RE REALLY LOOKING AT
7 WHAT SHOULD BE A NEW APPLICATION, THEN LET'S MAKE IT
8 A NEW APPLICATION AND COME INTO A DIFFERENT ROUND.

9 I KNOW THERE ARE CHALLENGES WITH THAT
10 BECAUSE, UNLIKE NIH, WE DON'T HAVE JUST ANOTHER
11 STUDY SECTION THAT WE CAN TOSS IT OVER TO AND SAY,
12 WELL, WHY DON'T YOU REVIEW IT BECAUSE WE'RE RFA
13 DRIVEN. AND SO IT'S A LITTLE DIFFERENT. AND RFA'S
14 ARE A LITTLE DIFFERENT EACH TIME. BUT I THINK IT'S
15 JUST A BALANCE OF BEING ABLE TO MANAGE EVERYTHING
16 THAT WE'RE HANDLING AND WHETHER WE WANT TO ACTUALLY
17 DEDICATE THAT MUCH EFFORT AND TIME TO WHAT COULD BE
18 JUST ONE APPLICANT.

19 CHAIRMAN THOMAS: I THINK, GIL, IN JAMES'
20 LANGUAGE THERE IT DOES SAY THAT IF IT'S TANTAMOUNT
21 TO A NEW APPLICATION, IT WON'T BE CONSIDERED THROUGH
22 THE APPELLATE PROCESS IN ANY EVENT.

23 DR. SAMBRANO: RIGHT.

24 CHAIRMAN THOMAS: WHICH I THINK IS WHAT
25 YOU'RE SAYING.

BARRISTERS' REPORTING SERVICE

1 DR. SAMBRANO: RIGHT. AND I THINK THAT'S
2 WHAT WOULD CONSTITUTE HAVING A FULL GRANTS WORKING
3 GROUP.

4 CHAIRMAN THOMAS: ABSOLUTELY. I ALSO JUST
5 WANT TO SAY JUST FOR THE RECORD THAT WHEN WE HAD
6 FIVE ADDITIONAL ANALYSES IN BETWEEN THE JULY AND
7 SEPTEMBER BOARD MEETINGS, THAT GIL DID AN INCREDIBLE
8 JOB OF PULLING THEM ALTOGETHER IN A TIMELY MANNER
9 THAT ALLOWED FOR THEM TO DO THEIR ANALYSIS AND
10 INFORM THE BOARD IN ADVANCE OF THAT SEPTEMBER BOARD
11 MEETING AND DID SO IN AUGUST, WHICH IS PARTICULARLY
12 TOUGH TO GET PEOPLE. SO I JUST WANT TO COMMEND GIL
13 ON A TERRIFIC JOB IN A VERY DIFFICULT LOGISTICAL
14 SITUATION.

15 ELLEN.

16 DR. FEIGAL: THE ONLY OTHER COMMENT I
17 WANTED TO MAKE IS PROBABLY REITERATING THE OTHER TWO
18 SPEAKERS IN THAT I DON'T THINK IT WOULD BE A WISE
19 PROCESS TO PUT IN PLACE A SECOND RECONVENING OF THE
20 ORIGINAL GRANT REVIEW GROUP TO GO OVER ANY
21 UNRESOLVED ISSUES AT A SEPARATE POINT IN TIME. SO
22 IT'S JUST REITERATING THAT FOR A VARIETY OF REASONS.

23 THE SECOND, I GUESS, IS JUST THE PRINCIPLE
24 THAT PEER REVIEW, I THINK WE ALL RECOGNIZE, IS A
25 RIGOROUS, BUT IMPERFECT PROCESS. AND I GUESS I SEE

BARRISTERS' REPORTING SERVICE

1 THESE APPEALS AS MORE EXTRAORDINARY OPPORTUNITIES
2 FOR CIRM TO MOVE A PROJECT FORWARD IN A MORE
3 ACCELERATED FASHION. SO I WOULD THINK ONE OF THE
4 PRINCIPLES WE WANT TO LAY DOWN THERE IS THAT THESE
5 SHOULD BE FINITE, RARE EVENTS, NOT COMMON EVENTS,
6 THAT MOVE FORWARD.

7 AND I THINK SOME OF THE CRITERIA THAT HAVE
8 BEEN PUT IN PLACE WILL HELP MAKE THAT FINITE SORT OF
9 EXCEPTIONAL CIRCUMSTANCE MORE OF A REALITY. RIGHT
10 NOW THESE AREN'T EXTRAORDINARY PETITIONS THAT ARE
11 COMING THROUGH. THESE ARE ALMOST COMMON EVENTS THAT
12 ARE COMING THROUGH. SO I THINK LAYING DOWN THESE
13 MORE SPECIFIC CRITERIA SHOULD HOPEFULLY TRIAGE OUT
14 SOME OF THE ONES THAT REALLY SHOULDN'T BE COMING
15 FORWARD AS EXTRAORDINARY.

16 CHAIRMAN THOMAS: GOOD POINT. I'M GOING
17 TO CALL ON JEFF. AND I ALSO, BERT, WANT TO NOTE
18 THAT WE'VE ONLY GOT ABOUT 15 MINUTES LEFT.

19 DR. LUBIN: THAT'S WHAT I WAS THINKING AS
20 WELL. GO AHEAD.

21 MR. SHEEHY: I JUST WANT TO MAKE TWO
22 POINTS. IN TERMS OF OUR CURRENT CONSTRUCT, I THINK
23 THAT I'VE HEARD A COUPLE OF INTERESTING IDEAS FOR
24 TWEAKING. ONE IS TO SIMPLIFY THE APPEALS PROCESS
25 AND TRY TO LIMIT THAT, MAYBE DO AWAY WITH THE

BARRISTERS' REPORTING SERVICE

1 EXTRAORDINARY PETITION PROCESS AND LIMIT THAT TO
2 MATERIAL NEW FACTS. AND PEOPLE CAN WRITE US OR
3 SUBMIT WHATEVER THEY WANT IF IT'S JUST ARGUING WITH
4 THE REVIEW.

5 BUT I ALSO WANTED TO MAYBE LOOK A LITTLE
6 MORE BLUE SKY BECAUSE WHAT WE'RE REALLY TALKING
7 ABOUT IS NOT A PROBLEM THAT EXISTS IN MOST OF OUR
8 GRANT ROUNDS. THIS HAS REALLY BEEN LIMITED TO
9 DISEASE TEAMS.

10 AND PART OF THE PROBLEM IS THAT -- THERE'S
11 POSSIBLY TWO WAYS TO ADDRESS THIS. ONE OF THE
12 THINGS THAT WE'VE TALKED ABOUT, AND I KNOW THAT
13 STAFF HAS NOT BEEN SUPPORTIVE OF THIS, BUT I'M STILL
14 GOING TO PUT IT OUT THERE, IS ACTUALLY HAVING THE
15 GRANTEES HAVE THEIR ARGUMENTS WITH THE REVIEWERS IN
16 SOME REAL-TIME WAY DURING THE REVIEW LIKE THE WAY
17 NIH USED TO DO WHEN THEY WOULD DO BIG GRANTS.
18 THERE'D BE SOME SORT OF EITHER TELEPHONIC OR
19 IN-PERSON SITE VISIT. BECAUSE IT REALLY IS
20 SOMETHING, WHEN YOU HAVE -- THE COMPLEXITY AND SIZE
21 OF THESE GRANTS DO KIND OF ASK FOR AN ITERATIVE
22 PROCESS BETWEEN THE GRANTEE AND THE REVIEWERS.
23 THERE'S NOT ALWAYS COMPLETE CLARITY, AND WE TRY TO
24 GIVE THEM A PROCESS TO SUBMIT QUESTIONS, THE
25 REVIEWERS TO SUBMIT QUESTIONS THAT THE GRANTEES CAN

BARRISTERS' REPORTING SERVICE

1 ANSWER. I STILL THINK IT LEAVES GRANTEES FEELING
2 LIKE THAT WITHIN THEIR APPLICATION CONSTRUCT THAT
3 THEY'RE NOT ABLE TO HAVE THE DIALOGUE WITH THE
4 REVIEWERS WHERE THEY FEEL LIKE THAT THEIR SCIENCE
5 HAS BEEN REVIEWED IN A WAY THAT THEY AGREE WITH. SO
6 THEY'RE GOING TO DISPUTE THAT WITH \$20 MILLION ON
7 THE LINE.

8 SO THAT'S ONE BLUE SKY IDEA TO KIND OF
9 MAYBE PERHAPS GET US OUT OF THIS CIRCLE.

10 THE OTHER ONE IS SOMETHING THAT I HEARD IN
11 THE LAST DISEASE TEAM ROUND. WHAT WE DO NOW IS WE
12 BASICALLY SAY HERE'S THE BIG POT OF GOLD AT THE END
13 OF THE RAINBOW. HERE'S \$20 MILLION. THERE'S NOT A
14 LOT OF GRANTS THAT CAN BE WRITTEN THAT ACCOMPLISH
15 THAT. THERE'S SOME GOOD IDEAS THAT IF PEOPLE HIT
16 THEIR MILESTONES AND MAYBE TWEAK THEIR WORK AS THEY
17 GO ALONG MIGHT BE GOOD PROJECTS AND COULD ACTUALLY
18 BE DRAMATICALLY GOOD PROJECTS.

19 AND WE DO HAVE -- PARALLEL TO OUR REVIEW
20 PROCESS WE DO HAVE -- WHICH I WANT TO COMMEND DR.
21 FEIGAL AND STAFF FOR THEIR INCREDIBLE WORK IN THE
22 CLINICAL DEVELOPMENT ADVISORY PANEL PROCESS. WE DO
23 HAVE A WAY -- WE ARE IN REAL-TIME MAKING SURE
24 GRANTEES HIT THEIR MILESTONES, PROVIDING WHAT I
25 THINK IS EXTRAORDINARY ADVICE, ASSISTANCE TO THEM AS

BARRISTERS' REPORTING SERVICE

1 THEY MOVE THEIR PROJECTS THROUGH THE TRANSLATIONAL
2 AND CLINICAL SPACE.

3 AND PERHAPS THE IDEA IS MAYBE NOT TO BE
4 SAYING, "OKAY, YOU'RE COMING IN FOR \$20 MILLION
5 HERE. DO YOU HAVE IT SOUP TO NUTS TO GO ALL THE
6 WAY, SAY, FOR INSTANCE, TO AN IND OR TO COMPLETION
7 OF A PHASE I CLINICAL TRIAL?" AS OPPOSED TO SAYING
8 AT THE END OF THE DAY, YOU COULD GET THIS MUCH
9 MONEY, BUT WHAT IS YOUR IDEA? WHAT ARE YOUR FIRST
10 STEPS? IT'S INCREDIBLE. WHAT DO YOU NEED TO
11 ACCOMPLISH THAT TO MOVE THROUGH THIS SPACE? YOU'LL
12 BE REVIEWED BY THE CDAP SO THAT YOUR MONEY IS
13 METERED AS OPPOSED TO PREEMPTIVELY GIVING \$20
14 MILLION AND THEN BUILDING ALL YOUR EXPECTATIONS
15 AROUND THAT.

16 AND THEN AS YOU MAKE YOUR JUMPS, WE REALLY
17 KIND OF GET MARRIED TO THESE FOLKS WHICH WE'RE KIND
18 OF DOING IN A MORE -- IN A LESS DELIBERATE WAY, BUT
19 I THINK VERY SOPHISTICATED WAY. WE ARE MARRYING
20 THESE PROJECTS. WE ARE WALKING WITH THEM WHEN THEY
21 GET THEIR DISEASE TEAMS. SOME OF THEM AREN'T MAKING
22 IT, BUT WE ARE TRYING TO WALK WITH THEM. AND KIND
23 OF ACKNOWLEDGING THAT AND SAYING, OKAY, WE'RE
24 GOING -- WE LIKE YOUR IDEA. WE LIKE WHERE YOU'RE
25 GOING. YOU CAN GET X AMOUNT OF MONEY TO GET

BARRISTERS' REPORTING SERVICE

1 STARTED.

2 IT'S KIND OF LIKE WHAT WE DID WITH THE
3 DUCHENNE THING ACTUALLY. WE PUT THEM IN THE
4 APPROPRIATE SPACE. THEY CAN COME BACK -- YOU GET
5 REGULAR INTERACTIONS WITH THE CLINICAL DEVELOPMENT
6 ADVISORY PANEL. WHEN YOU WANT TO MAKE A BIG JUMP,
7 YOU WOULD GET RE-REVIEWED. SO, FOR INSTANCE, IF
8 YOU'RE GOING TO AN IND BEFORE YOU GET TO CLINICAL
9 TRIAL FUNDING FROM US, YOU WOULD GO TO ANOTHER
10 GRANTS WORKING GROUP REVIEW.

11 BUT MAYBE LOOKING AT HOW WE'RE DOING OUR
12 FUNDING AND TAKING A 30,000 FEET LOOK AT ALL THE
13 THINGS THAT WE'RE DOING, WHICH I THINK WE'RE DOING A
14 LOT OF STUFF INCREDIBLY WELL, AND MAYBE TRYING TO
15 TWEAK THAT SO THAT WE DON'T HAVE -- IT'S LIKE THE
16 LOTTERY. FOLKS ARE COMING IN. I GOT 20 -- THE
17 EXPECTATIONS FOR GRANTEES ARE JUST SO HIGH, AND I
18 THINK THAT THERE IS A SIGNIFICANT AMOUNT OF
19 OVERAMBICTION IN SOME OF THESE PROJECTS THAT ISN'T
20 JUSTIFIED BY THE SCIENCE.

21 AND WHERE WE GET THE RUB IS THAT THERE ARE
22 SOME GOOD IDEAS, THERE IS SIGNIFICANT PROGRESS THAT
23 COULD BE MADE IN SOME CRITICAL DISEASES, BUT IT'S
24 JUST OUR CONSTRUCT IS NOT REALLY APPROPRIATE FOR
25 MOST OF THE APPLICATIONS WE'RE GETTING.

BARRISTERS' REPORTING SERVICE

1 DR. LUBIN: CAN I ASK RELATED TO THAT,
2 JEFF. APPRECIATE THAT REMARK. ISN'T THERE AN
3 ANNUAL PROGRESS REPORT AND EVALUATION WHETHER WE'RE
4 GOING TO CONTINUE THE FUNDING?

5 DR. FEIGAL: ACTUALLY COULD I COMMENT ON
6 THAT?

7 DR. LUBIN: YES, PLEASE. GO AHEAD.

8 DR. FEIGAL: SO WE HAVE NOT JUST AN
9 ANNUAL, WE HAVE QUARTERLY PROGRESS REPORTS FOR THE
10 DEVELOPMENT TEAMS. AND IN ADDITION, WE HAVE
11 IN-PERSON MEETINGS WHERE THE TEAM COMES IN PERSON
12 AND MEETS WITH THE CIRM SCIENTIFIC STAFF AND WITH
13 OUR PANEL OF CLINICAL DEVELOPMENT ADVISORS. AND
14 THEY PRESENT THEIR PROGRESS, THEY PRESENT THEIR
15 CHALLENGES, THEY PRESENT THEIR QUESTIONS WHERE THEY
16 WANT ADVICE ON HOW TO MOVE FORWARD.

17 SO WE HAVE A VERY INTERACTIVE DISCUSSION
18 WITH THE TEAM, WITH THE DIFFERENT TEAMS AT REGULAR
19 INTERVALS IN ADDITION TO AN ANNUAL PROGRESS REPORT.

20 SO WE DO HAVE MILESTONES IN PLACE, BOTH
21 SUCCESS, PROGRESS, AND SUCCESS CRITERIA. IN
22 ADDITION, I THINK WHAT JEFF IS REFERRING TO, AND I
23 THINK HE'S CORRECT, WHEN THE POT IS LARGE, THERE'S A
24 LOT AT STAKE AND PEOPLE ARE PROBABLY WILLING TO GO
25 FOR THAT EXTRA MILEAGE BECAUSE IT'S A VERY

BARRISTERS' REPORTING SERVICE

1 ATTRACTIVE POT OF DOLLARS TO HAVE TO GET YOUR
2 PROJECT DONE.

3 WHAT WE ARE SUGGESTING BOTH AT THE
4 UPCOMING BOARD, AND I GUESS THAT WILL BE TOMORROW,
5 IS SOME INCREASED SCRUTINY IN TERMS OF THE BUDGETS
6 THAT COME IN FOR THESE DIFFERENT PROJECTS. AND IT
7 MAY BE THAT WE PUT FINANCIAL MILESTONES IN PLACE AND
8 THAT WE HAVE SORT OF CEILINGS OF THE BUDGET SO THAT
9 THE BOARD HAS APPROVED UP TO A CEILING OF 20, BUT WE
10 METER IT OUT AT THE APPROPRIATE TIMES IF THEIR
11 ACTIVITIES AND THEIR PROGRESS IS SUFFICIENT.

12 SO I THINK WE HAVE THE TOOLS IN HANDS TO
13 DO THAT. IT MAY BE THAT WE NEED TO MODIFY SOME OF
14 OUR PROCESSES TO MAKE IT MORE SMOOTH, BUT I THINK WE
15 DO HAVE THE ABILITY TO DO THAT.

16 DR. LUBIN: ELLEN, LET ME JUST ASK A
17 QUESTION. IF AT THE END OF THE FIRST YEAR OF A \$20
18 MILLION APPLICATION THAT HAD FIVE MILLION IN THE
19 FIRST YEAR OR FOUR MILLION, WHATEVER THE BUDGET WAS,
20 YOU FELT PROGRESS WASN'T MADE ON ALMOST ANYTHING
21 THAT WAS IN THE APPLICATION, WOULD WE STOP FUNDING?

22 DR. FEIGAL: WE HAVE THE ABILITY, AND WE
23 HAVEN'T DONE IT IN THE FIRST YEAR, BUT WE'VE DONE IT
24 IN THE SECOND YEAR, WHERE IF THEY'VE DONE THE
25 EXPERIMENTS AND THEY'VE MET A NO-GO MILESTONE, WE DO

BARRISTERS' REPORTING SERVICE

1 HAVE THE OPPORTUNITY AND WE HAVE TERMINATED AN AWARD
2 WITH SOME RUNDOWN TIME FOR THEM TO COMPLETE WHAT
3 THEY NEED TO DO. SO WE DO RIGHT NOW HAVE THE
4 OPPORTUNITY TO DO THAT.

5 DR. LUBIN: SO ESSENTIALLY AN AMOUNT IS
6 AWARDED, BUT IT'S CONTINGENT UPON MEETING THE
7 CRITERIA FOR ANNUAL REVIEW. AND SO THAT'S A LITTLE
8 DIFFERENT. IN THE PUBLIC'S VISION, 20 MILLION WAS
9 GIVEN, BUT IT'S GOING TO BE EVALUATED REGULARLY.
10 AND IF PROGRESS ISN'T THERE, THEN A DISCUSSION
11 REGARDING CONTINUING THE FUNDING WILL BE MADE. I
12 THINK THAT'S A VERY IMPORTANT THING. IF I'M PART OF
13 A PUBLIC THAT CONTRIBUTED TO THE 20-MILLION
14 APPLICATION, THEN I KNOW. IT'S NOT, WELL, NOW YOU
15 HAVE 20 MILLION AND THEN YOU CAN GO DO WHATEVER YOU
16 WANT TO DO. HOPEFULLY AT THE END OF THAT 20
17 MILLION, THERE WILL BE SOMETHING THAT IS GOING INTO
18 PATIENTS TO IMPROVE THEIR LIVES.

19 DR. FEIGAL: YEAH. LET ME TELL YOU,
20 THOUGH, IT'S A CHALLENGING PROCESS TO GO THROUGH
21 BOTH FOR THE TEAM THAT'S GOING THROUGH IT FROM THE
22 OUTSIDE AND FOR INTERNAL AND OUR EXTERNAL ADVISORS.
23 SO IT'S CERTAINLY SOMETHING THAT WE DO WITH GREAT
24 CARE.

25 SO I GUESS MY CAVEAT TO YOU IS IF THE

BARRISTERS' REPORTING SERVICE

1 GRANT REVIEW GROUP, THEY HAVE VERY STRONG
2 RECOMMENDATION NOT TO FUND SOMETHING BECAUSE OF THE
3 SCIENCE, PEOPLE SHOULD NOT THINK, OH, WELL, IF WE
4 PUT CERTAIN CONDITIONS IN PLACE, WE CAN LET THIS ONE
5 GO FORWARD BECAUSE STAFF ARE GOING TO CATCH IT AT
6 THOSE CONDITIONS. I'M JUST SAYING THAT IT'S NOT
7 JUST HERE'S SOME MONEY AND WE JUST LOOK AT WRITTEN
8 REPORTS ON A PERIODIC BASIS. WE ACTUALLY DO MORE
9 INTENSE SCRUTINY ABOUT THEIR PROGRESS, AND WE REACH
10 MUTUALLY AGREED-UPON MILESTONES WITH THE
11 INVESTIGATORS SO THAT THEY KNOW WHAT TO EXPECT AND
12 WE HAVE COMMUNICATED THAT TO THEM.

13 SO WE WORK TOGETHER WITH THEM, AND WE
14 EVALUATE IT AT INTERVALS.

15 DR. LUBIN: I UNDERSTAND THAT, BUT I GUESS
16 WHEN THE AWARD IS MADE, IS IT CLEAR TO THE PERSON
17 RECEIVING THE AWARD THAT THIS IS NOT AUTOMATIC FOR
18 THE NEXT FOUR OR FIVE YEARS?

19 DR. FEIGAL: WELL, IT IS IN THE RFA. AND
20 WHAT WE'RE DOING WITH THE NEXT COHORT OF DISEASE
21 TEAMS IS WE'RE ACTUALLY GOING TO MEET WITH THEM AT
22 OUR UPCOMING GRANTEE MEETING IN MARCH, EARLY NEXT
23 YEAR, WHERE WE'LL HAVE THE ALUMNI AND THEN WE'LL
24 HAVE THE NEW COHORT OF DISEASE TEAMS AND STRATEGIC
25 PARTNERSHIP TEAMS MEET. AND WE'LL GO OVER

BARRISTERS' REPORTING SERVICE

1 EXPECTATIONS AND LESSONS LEARNED AND WHAT WE MIGHT
2 DO TO IMPROVE, BUT WE PLAN TO HAVE AN IN-PERSON
3 MEETING WITH ALL OF THEM TO GO OVER THIS.

4 DR. LUBIN: SOUNDS GOOD. PAT, YOU WANTED
5 TO ADD SOMETHING.

6 DR. OLSON: I WILL REITERATE WHAT ELLEN
7 SAID. IT'S IN THE RFA. IT'S IN THE NGA. IT'S
8 IMPLICIT IN THE MILESTONE DISCUSSION. AND AS SHE
9 SAID, SHE'S HAVING THIS.

10 BUT I ALSO WANT TO REITERATE ANOTHER POINT
11 SHE MADE. I WOULD ENCOURAGE THE BOARD TO RECOGNIZE
12 THAT IT IS DIFFICULT -- IT IS DIFFICULT TO STOP AN
13 AWARD THAT PERHAPS SHOULDN'T HAVE BEEN STARTED. I
14 MEAN YOU'VE COMMITTED RESOURCES, YOU'VE COMMITTED
15 PERSONNEL. SO IF THE SCIENCE REALLY DOESN'T JUSTIFY
16 IT, YOU REALLY DO NEED TO THINK TWICE ABOUT, WELL,
17 LET'S FUND THIS FOR A YEAR OR 18 MONTHS OR SOMETHING
18 AND SEE WHAT THEY CAN DO.

19 SO I JUST -- IT'S NOT EASY TO -- IT'S A
20 LOT OF WORK FOR STAFF AND FOR EVERYBODY INVOLVED.

21 DR. LUBIN: I'D LIKE TO COMMENT ON THAT.
22 FIRST OF ALL, I COMPLETELY AGREE WITH YOU. AND I
23 THINK THE EMOTIONAL EVENT FOR THE DAY SHOULD NOT
24 SWAY PEOPLE TO SAY THIS IS A BAD DISEASE. WE ALL
25 KNOW THESE DISEASES ARE BAD. WE DON'T NEED TO HEAR

BARRISTERS' REPORTING SERVICE

1 THAT THEY'RE BAD. BUT WE SHOULD GIVE THE FUNDING
2 BECAUSE YOU'RE GOING TO SEE WHETHER THIS WORKS OR
3 NOT. IT'S NOT A TRIAL BALLOON. THAT ISN'T WHAT WE
4 SHOULD BE SUPPORTING. IT SHOULD BE SCIENTIFICALLY
5 BASED, AND THAT'S WHAT I THINK THE BOARD WANTS AND
6 IS DOING THEIR BEST TO ACHIEVE.

7 DR. SAMBRANO: I JUST WANTED TO ADD
8 SOMETHING TO WHAT YOU JUST SAID. I THINK ONE OF
9 THE -- ALL OF WHAT WE'VE BEEN DISCUSSING IN THE LAST
10 FEW MINUTES, I THINK, MAY IN SOME WAY BE HELPFUL IN
11 TERMS OF BOTH THE APPLICANT UNDERSTANDING, THE BOARD
12 UNDERSTANDING WHAT THE PARAMETERS OF AN APPLICATION
13 MAY BE OR WHAT THE GRANT WILL LOOK LIKE. I THINK
14 THOSE ARE MORE ABOUT THE REVIEW PROCESS ITSELF
15 RATHER THAN THE PETITION OR ANALYSIS OF SUCH BECAUSE
16 THE DRIVER FOR AN APPEAL OR A PETITION IS SIMPLY THE
17 FACT THAT THEY'RE NOT RECOMMENDED FOR FUNDING.
18 THAT'S IT.

19 AND IF THEY'RE NOT RECOMMENDED, WE'RE
20 GOING TO GET A REBUTTAL OR APPEAL OR ANYTHING ELSE.
21 WE DON'T GET THEM FROM ANYONE WHO'S RECOMMENDED. SO
22 IT'S SOMETHING THAT'S GOING HAPPEN REGARDLESS OF
23 WHAT WE DO BEFORE THAT RECOMMENDATION IS MADE. AND
24 SO I THINK, CLEAR, WE ARE ABOUT WHAT WE ARE WILLING
25 TO DO OR NOT, I THINK THAT'S THE FOCUS HERE IN TERMS

BARRISTERS' REPORTING SERVICE

1 OF WHAT WE SHOULD TRY TO ACCOMPLISH.

2 DR. LUBIN: I AGREE. WELL, ONE OF THE
3 PROBLEMS WE HAVE IS THAT IT IS 11:30. THESE ARE
4 REALLY GREAT COMMENTS, AND I THINK THIS IS GOING TO
5 ADVANCE WHAT WE'VE BEEN ASKED TO DO. BUT I THINK
6 WE'RE GOING TO NEED TO SPEND ADDITIONAL MEETING TIME
7 BECAUSE THERE ARE TWO, AT LEAST TWO ADDITIONAL ITEMS
8 THAT WE ALL KNOW WE WANT TO HAVE DISCUSSION. I
9 THINK WE'VE MADE A LOT OF PROGRESS ON THIS ONE.

10 I THINK MAYBE FROM MY PERSPECTIVE I LIKE
11 THE IDEA OF THESE CRITERIA THAT HAVE TO BE MET IN
12 ORDER FOR REBUTTAL, AND MAYBE WE NEED TO LOOK AT
13 WHAT WE CURRENTLY HAVE AND IF WE WANT TO ADD SOME
14 MORE ONTO THAT. AND WE COULD DISCUSS THAT BRIEFLY
15 TOMORROW, A COUPLE OF US AT A BREAK, OR WHATEVER.

16 AND THEN, J.T., HOW WOULD YOU LIKE TO
17 HANDLE WHEN WE GET TOGETHER AGAIN OR WHAT'S THE
18 PLAN?

19 MS. BONNEVILLE: I THINK, BASED ON YOUR
20 SCHEDULE, MID-DECEMBER IS OUR NEXT MEETING. AND I'M
21 GOING TO CONFIRM THAT WITH TANYA AND THEN I'LL SEND
22 OUT AN E-MAIL.

23 DR. LUBIN: THAT SEEMS LATE. DO WE WANT
24 TO WAIT UNTIL THEN? BECAUSE IN JANUARY --

25 MS. BONNEVILLE: I WILL DOUBLE-CHECK WITH

BARRISTERS' REPORTING SERVICE

1 TANYA.

2 DR. LUBIN: I WOULD LIKE TO KEEP THE
3 MOMENTUM GOING. OTHERWISE, WE'LL FORGET ABOUT WHAT
4 WE DID OR DOING OVER AGAIN WHAT WE'VE ALREADY TALKED
5 ABOUT, AND THEN NOT TO GET TO THE REST OF THE ISSUES
6 AND COMPLETE THIS, WHICH I THINK IS REALLY IMPORTANT
7 FOR THE CREDIBILITY OF OUR WHOLE OPERATION AND FOR
8 THE VALUE THAT WE BRING AS A CONSEQUENCE OF THE
9 RESOURCES THAT ARE AVAILABLE IN THIS STATE. WE WANT
10 TO USE THEM AS WISELY AS WE CAN.

11 CHAIRMAN THOMAS: I JUST THINK IT'S BEEN A
12 GREAT DISCUSSION. WE GREATLY VALUE EVERYBODY'S
13 INPUT AND UNDERSTAND THAT THE PROCESS MAY BE THERE,
14 BUT IT CAN ALWAYS BE IMPROVED. SO ALL OF THESE
15 COMMENTS ARE VERY USEFUL IN HELPING US TO DO THAT.

16 MR. CHAIR, I THINK IT'S BEEN A VERY
17 VALUABLE DISCUSSION, AND WE'LL CONTINUE IN OUR NEXT
18 MEETING.

19 DR. LUBIN: GREAT.

20 CHAIRMAN THOMAS: JEFF, DO YOU HAVE ANY
21 THOUGHTS? ANY OTHER COMMENTS BY ANYBODY ON THE
22 PHONE?

23 DR. DULIEGE: APPRECIATE THE DISCUSSION.
24 VERY USEFUL.

25 CHAIRMAN THOMAS: THANK YOU THEN, MR.

BARRISTERS' REPORTING SERVICE

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CHAIR.

DR. LUBIN: MEETING IS ADJOURNED.

CHAIRMAN THOMAS: MEETING IS ADJOURNED.

THANKS VERY MUCH.

(THE MEETING WAS THEN CONCLUDED AT
11:30 A.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 TELEPHONIC PROCEEDINGS BEFORE THE APPLICATION REVIEW TASK FORCE OF THE INDEPENDENT CITIZEN'S OVERSIGHT COMMITTEE OF THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE IN THE MATTER OF ITS REGULAR MEETING ON OCTOBER 24, 2012, WAS HELD AS HEREIN APPEARS AND THAT THIS IS THE ORIGINAL TRANSCRIPT THEREOF AND THAT THE STATEMENTS THAT APPEAR IN THIS TRANSCRIPT WERE REPORTED STENOGRAPHICALLY BY ME AND TRANSCRIBED BY ME. I ALSO CERTIFY THAT THIS TRANSCRIPT IS A TRUE AND ACCURATE RECORD OF THE PROCEEDING.

BETH C. DRAIN, CSR 7152
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