BEFORE THE SCIENCE SUBCOMMITTEE OF THE INDEPENDENT CITIZENS' OVERSIGHT COMMITTEE TO THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE ORGANIZED PURSUANT TO THE

REGULAR MEETING

CALIFORNIA STEM CELL RESEARCH AND CURES ACT

LOCATION: 210 KING STREET

SAN FRANCISCO, CALIFORNIA

TUESDAY, MAY 25, 2010 DATE:

11 A. M.

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

BRS FILE NO.: 87367

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ITEM	DESCRIF	PTI ON		PAGE	NO
1. CALL TO	ORDER				3
2. ROLL CAL	-L				4
		PRESENTATION G SCIENTIFIC		•	19
REGARDING CI STRUCTURE, F POLICIES, OF AND BEST PRA SCIENTIFIC F	RM, INCL INANCIAL PERATIONS ACTICES, PERFORMAN	COMMISSIONING UDING ORGANI STRUCTURE, STRUCTURE, TO ENHANCE OF CE AND IDENTED THE	ZATIONAL CONFLICTS PERFORMANO PERATIONS A IFY CRITICA	CE, AND	35
E CONSIDED	TION OF	SCODE OF MAT	EDIALS TO I	DE 40	2

- 5. CONSIDERATION OF SCOPE OF MATERIALS TO BE 68 PROVIDED TO GWG MEMBERS IN ADVANCE OF MEETING.
- 6. CONSIDERATION OF POLICY REGARDING USE OF 92 UNUSED DISEASE RESEARCH TEAM AWARD FUNDS FOR CLINICAL TRIALS.
- 7. DISCUSSION OF THE FOLLOWING ITEMS:
 - A. PRE-APPLICATION REVIEW 99
 - B. EXTRAORDINARY PETITION/APPEALS PROCESS 118
 - C. PRE-FUNDING ADMINISTRATIVE REVIEW
 - D. PROGRESS REPORTS
 - E. PRIORITIZATION OF SCIENTIFIC PROGRESS TOWARDS CURES AND MAXIMIZATION OF SCIENTIFIC OPPORTUNITIES TO BEST SERVE PATIENTS (E.G., RECOMMENDATION REGARDING REDUCED FUNDING, BEFORE PRESENTATION TO THE BOARD).
- 8. PUBLIC COMMENT.

ADDITIONAL ITEM:

1. CONSIDERATION OF ALLOCATION OF FUNDS TO 5 CIRM GRANTEES FOR ASSISTANCE IN PATENTING CIRM-FUNDED INVENTIONS AND PROSECUTING THOSE PATENTS.

	DARRISTERS REPORTING SERVICE
1	SAN FRANCISCO, CALIFORNIA; TUESDAY, MAY 25, 2010
2	11 A. M.
3	
4	MS. KING: JEFF SHEEHY IS HERE WITH ME IN
5	SAN FRANCISCO. WE'RE JUST ABOUT TO GET STARTED.
6	AND BEFORE WE DO, JEFF, I JUST WANTED TO LET YOU
7	KNOW DUANE WAS JUST LETTING US KNOW THAT HE NEEDS TO
8	JUMP OFF AT AROUND 10:30, BUT MAY BE ABLE TO DIAL
9	BACK IN LATER IF WE NEED HIM. SO AMY AND I CAN WORK
10	ON THAT IF WE NEED TO.
11	CHAIRMAN SHEEHY: WELCOME, EVERYONE, TO
12	THE FIRST MEETING OF THE SCIENCE SUBCOMMITTEE OF THE
13	ICOC, THE GOVERNING BOARD OF CIRM. WE HAVE
14	PARTICIPANTS IN NINE LOCATIONS ON THE CALL. SO I'M
15	HERE AT CIRM. ARE WE ON THE LINE WITH ALTA
16	PARTNERS?
17	DR. PENHOET: YES.
18	CHAIRMAN SHEEHY: STANFORD? KLEIN
19	FINANCIAL?
20	MR. KLEIN: I'M PRESENT.
21	CHAIRMAN SHEEHY: CITY OF HOPE.
22	DR. CHIU: THIS IS ARLENE. I'M HERE.
23	CHAIRMAN SHEEHY: DR. FONTANA.
24	DR. FONTANA: I'M HERE.
25	CHAIRMAN SHEEHY: UC IRVINE.
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1	DR. STEWARD: WE'RE HERE.
2	CHAIRMAN SHEEHY: DO WE HAVE ANOTHER SITE
3	IN UC IRVINE?
4	MS. KING: THAT WAS DR. STEWARD. AND I
5	KNOW DR. LEVIN IS ALSO ON THE LINE, CORRECT?
6	DR. LEVIN: CORRECT.
7	CHAIRMAN SHEEHY: CONNECT.
8	MR. ROTH: HERE.
9	CHAIRMAN SHEEHY: DID DR. SLADEK GET ON
10	THE LINE?
11	DR. SLADEK: YES. I'M HERE IN DENVER.
12	DR. PRIETO: THIS IS FRANCISCO PRIETO. I
13	JUST GOT ON THE LINE.
14	CHAIRMAN SHEEHY: THANK YOU ALL FOR
15	PARTICIPATING IN THIS CALL. MELISSA, COULD YOU
16	PLEASE CALL THE ROLL.
17	MS. KING: JACOB LEVIN FOR SUSAN BRYANT.
18	DR. LEVI N: HERE.
19	MS. KING: MARCY FEIT. MICHAEL FRIEDMAN.
20	ROBERT KLEIN.
21	MR. KLEIN: HERE.
22	MS. KING: FRANCISCO PRIETO.
23	DR. PRI ETO: HERE.
24	MS. KING: ED PENHOET.
25	DR. PENHOET: HERE.
	4

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1	MS. KING: PHIL PIZZO. JEANNIE FONTANA.
2	DR. FONTANA: HERE.
3	MS. KING: DUANE ROTH.
4	MR. ROTH: HERE.
5	MS. KING: JOAN SAMUELSON.
6	MS. SAMUELSON: HERE.
7	MS. KING: JEFF SHEEHY.
8	CHAIRMAN SHEEHY: HERE.
9	MS. KING: OSWALD STEWARD.
10	DR. STEWARD: HERE. I DO HAVE A MEMBER OF
11	THE PUBLIC.
12	MS. KING: THANK YOU, DR. STEWARD. AND
13	ART TORRES.
14	CHAIRMAN SHEEHY: DO WE HAVE A QUORUM?
15	MR. HARRISON: WE DO.
16	CHAIRMAN SHEEHY: GREAT. SO I'M GOING TO
17	MOVE UP TO THE BEGINNING THE PROPOSED ADDITIONAL
18	ITEM TO THE AGENDA, WHICH IS THE CONSIDERATION OF
19	ALLOCATION OF FUNDS TO CIRM GRANTEES FOR ASSISTANCE
20	IN PATENTING CIRM-FUNDED INVENTIONS AND PROSECUTING
21	THOSE PATENTS.
22	SO MAYBE THE FIRST THING IS COULD WE TAKE
23	A VOTE ON WHETHER OR NOT TO TAKE UP THIS ITEM? AND
24	THEN IF WE DECIDE TO TAKE IT UP, WE CAN MAKE A
25	MOTION TO APPROVE, NOT APPROVE, AND THEN HAVE A
	5

	DARRISTERS REFORTING SERVICE
1	DISCUSSION. SO COULD I GET MOTION TO HEAR IT?
2	MR. KLEIN: I'LL MAKE A MOTION TO ADD IT
3	TO THE AGENDA.
4	CHAIRMAN SHEEHY: SECOND?
5	DR. PRIETO: I'LL SECOND.
6	CHAIRMAN SHEEHY: JAMES.
7	MR. HARRISON: JUST TO BE CLEAR, THE
8	MOTION SHOULD ENCOMPASS A DETERMINATION THAT THE
9	ITEM CAME TO THE SUBCOMMITTEE'S ATTENTION AFTER THE
10	AGENDA WAS POSTED AND THAT THERE IS A NEED TO
11	CONSIDER IT NOW BEFORE THE JUNE BOARD MEETING.
12	CHAIRMAN SHEEHY: OKAY. IS THERE ANY
13	PUBLIC COMMENT? OKAY. MELISSA, CALL THE ROLL.
14	MS. KING: JACOB LEVIN.
15	DR. LEVIN: YES.
16	MS. KING: ROBERT KLEIN.
17	MR. KLEIN: YES.
18	MS. KING: FRANCISCO PRIETO.
19	DR. PRI ETO: AYE.
20	MS. KING: ED PENHOET.
21	DR. PENHOET: YES.
22	MS. KING: JEANNIE FONTANA.
23	DR. FONTANA: YES.
24	MS. KING: DUANE ROTH.
25	MR. ROTH: YES.
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1	MS. KING: JOAN SAMUELSON.
2	MS. SAMUELSON: YES.
3	MS. KING: JEFF SHEEHY.
4	CHAIRMAN SHEEHY: YES.
5	MS. KING: OSWALD STEWARD.
6	DR. STEWARD: YES.
7	MS. KING: THAT MOTION CARRIES.
8	CHAIRMAN SHEEHY: GREAT. SO NOW ON THE
9	ITEM ITSELF, WOULD SOMEONE LIKE TO MAKE A MOTION ON
10	THIS ITEM? AND PERHAPS I KNOW THIS IS SOMETHING
11	THAT YOU WERE INTERESTED IN, BOB. WOULD YOU LIKE TO
12	MAKE THE MOTION AND THEN MAYBE IF I CAN GET A
13	SECOND, WE CAN GET A DISCUSSION.
14	MR. KLEIN: CERTAINLY. SO I WOULD LIKE TO
15	MAKE A MOTION THAT THE BOARD MAKE AVAILABLE TO THE
16	STAFF FUNDS THAT CAN BE USED FOR THE INSTITUTIONS
17	AND THE GRANTS THAT WE HAVE APPROVED TO FILE AND
18	FOLLOW; THAT IS, TO PROSECUTE PATENTS DOMESTICALLY
19	OR INTERNATIONALLY UNDER A PROGRAM TO BE WORKED OUT
20	WITH THE STAFF CONSULTING WITH THE INSTITUTIONS AND
21	THE GRANTEE ORGANIZATIONS.
22	CHAIRMAN SHEEHY: CAN I GET A SECOND?
23	DR. PRIETO: I'LL SECOND.
24	CHAIRMAN SHEEHY: OKAY. DO WE NEED A
25	DISCUSSION OF THIS?
	7
	<i>I</i>

1	MR. KLEIN: I THINK WE DO PROBABLY NEED A
2	DISCUSSION, JEFF. WE SHOULD GIVE PROBABLY EVERYONE
3	THE BACKGROUND THAT A NUMBER OF THE GRANTEE PI'S AND
4	CO-PI'S AND THEIR INSTITUTIONS HAVE INDICATED THAT
5	WITH EXTREME BELT TIGHTENING ON THE UC SYSTEM AND
6	THE IMPACT ON THE PRIVATE ENDOWMENTS FOR STANFORD
7	AND USC AND FOR THE GENERAL IMPACT ON INSTITUTIONS
8	IN CALIFORNIA OF THE ECONOMY, THERE IS A LACK OF
9	SUFFICIENT FUNDS AT TIMES THAT ARE MERITORIOUS AND
10	THE PROSECUTION OF THOSE PATENTS FOR THEY ONLY BE
11	FILED DOMESTICALLY BUT NOT INTERNATIONAL EVEN THOUGH
12	THERE APPEARS TO BE SUBSTANTIAL INTERNATIONAL VALUE.
13	TO PROTECT THE VALUE TO THE STATE OF
14	CALIFORNIA, IT'S IN THE INTEREST OF CALIFORNIA
15	VOTERS AND TAXPAYERS AND THIS AGENCY AS WELL AS
16	PATIENT GROUPS FUNDAMENTALLY THAT WE HAVE THESE
17	PATENTS FILED. THEY REALLY PROVIDE US THE ABILITY
18	TO SECURE OUR ACCESS RIGHTS, OUR ACCESS PLANS FOR
19	PATIENTS AS PART OF PROTECTING INTELLECTUAL PROPERTY
20	AND DISCOVERIES CREATED BY OUR GRANTS AND OUR LOANS.
21	SO THE INTENT WAS TO MAKE A SOURCE OF
22	FUNDING AVAILABLE. RIGHT NOW IN OUR CASH FLOWS WE
23	HAVE ABOUT \$30 MILLION IN OUR CASH FLOW TO BE
24	AVAILABLE FOR THIS PURPOSE, BUT THE INTENT WOULD BE
25	TO WORK OUT A THOUGHTFUL PROGRAM WITH THE SCIENTIFIC

1	STAFF AND WORKING WITH THE GRANTEE ORGANIZATIONS TO
2	MOST EFFECTIVELY USE IT.
3	SO THIS IS NOT TRYING TO FULLY DESIGN THE
4	PROGRAM AT THIS POINT. THIS IS A CONCEPT APPROVAL
5	THAT WOULD THEN BE DELEGATED TO THE STAFF TO DESIGN
6	THAT PROGRAM AND BRING IT TO THE BOARD IF THE BOARD
7	WERE TO APPROVE THE CONCEPT APPROVAL.
8	DR. TROUNSON: I WAS GOING TO ASK JEFF IF
9	ELONA CAN SORT OF FILL IN SOME OF THE BACKGROUND
10	WE'VE BEEN WORKING ON.
11	CHAIRMAN SHEEHY: YEAH. THAT WOULD BE
12	HELPFUL.
13	MS. BAUM: BECAUSE I THINK IT'S
14	APPROPRIATE THAT THIS BE COUCHED AS BOB DID AS
15	EXPLORATORY AND AS A CONCEPT BECAUSE WE HAVE BEEN
16	DOING SOME DUE DILIGENCE, FINDING WHAT OTHER
17	FOUNDATIONS ARE DOING IN THIS REGARD. AND THERE ARE
18	DIFFERENT APPROACHES, AND SOME OF THEM DO JUST
19	PROVIDE IT AS A GRANT. OTHERS ACTUALLY PROVIDE IT
20	WITH CERTAIN REQUIREMENTS THAT THEY ACTUALLY
21	UNDERTAKE THE PATENTING PROCESS. AND THERE'S A LOT
22	OF GOOD REASON FOR THE PATENTING TO OCCUR ON A
23	CENTRALIZED BASIS.
24	SO WHEN WE SPOKE ABOUT THIS YESTERDAY, AND
25	IT JUST CAME TO LIGHT, IT REALLY WAS IN THE

1	EXPLORATION STAGE. AND I THINK IT WOULD BEHOOVE ALL
2	OF US TO HAVE A REALLY THOROUGH DISCUSSION ON WHAT
3	THE NATURE OF THIS PROGRAM WILL LOOK LIKE IN TERMS
4	OF WHAT SORT OF OBLIGATIONS THERE WOULD BE ON THE
5	PARTS OF THE INSTITUTIONS THAT ARE RECEIVING THESE
6	FUNDS, WHETHER IT BE MATCHING, WHETHER OR NOT THERE
7	WOULD BE A REQUIREMENT THAT THERE BE SOME PAYBACK,
8	AND WHAT THAT FORM WOULD BE AND, OF COURSE, WHO
9	WOULD BE UNDERTAKING THE PATENTING APPROACH.
10	MR. KLEIN: ELONA, LET ME UNDERSTAND. ARE
11	YOU SUPPORTING THE CONCEPT APPROVAL, THE DIRECTION
12	OF STAFF TO DEVELOP THIS PROGRAM?
13	MS. BAUM: YES, ABSOLUTELY. I WAS A
14	LITTLE CONCERNED THAT IT MIGHT BE STATING THAT IT
15	WOULD BE JUST AN OUTRIGHT GRANT, AND I JUST DIDN'T
16	WANT THAT.
17	MR. KLEIN: CERTAINLY IT MIGHT BE A GRANT,
18	IT MIGHT BE A LOAN. IT MIGHT BE THERE MIGHT BE
19	APPLICATIONS FOR EITHER. I'M NOT TRYING TO
20	PREJUDICE THE OUTCOME OF THE ACTUAL PROGRAM THAT'S
21	BROUGHT FORWARD.
22	MS. BAUM: AND THE OTHER POINT WAS IS THAT
23	THE PATENTING MIGHT BE UNDERTAKEN BY CIRM BECAUSE
24	THERE WOULD BE ECONOMIES OF SCALE AND OTHER RATIONAL
25	REASONS TO DO IT AS SUCH.

1	CHAIRMAN SHEEHY: I THINK WE DECIDED EARLY
2	ON THAT CIRM WAS NOT GOING TO HOLD PATENTS.
3	MS. BAUM: THEY WOULDN'T OWN IT. THEY
4	WOULD JUST UNDERTAKE IT TO MAKE SURE.
5	MR. ROTH: WE'RE GETTING OFF INTO SOME OF
6	THE DETAILS, JEFF. LET ME ASK A TOP-LINE QUESTION.
7	IS THIS THE RIGHT COMMITTEE FOR THIS TO BE
8	CONSIDERED, OR SHOULD IT IN THE IP POLICY COMMITTEE?
9	CHAIRMAN SHEEHY: WELL, I THINK MAYBE WE
10	WOULD TAKE A FRIENDLY AMENDMENT TO THIS MOTION TO
11	HAVE THE PLAN FOR THIS COME BACK TO THE IP
12	COMMITTEE, BUT I THINK IT'S A GOOD IDEA TO GET THIS
13	MOVING FORWARD. I WAS ON A CALL JUST EARLIER THIS
14	WEEK WITH RUSTY BROWN FROM THE MYELIN REPAIR
15	FOUNDATION. AND THIS EXPLICITLY CAME UP, AND THEY
16	ACTUALLY HAVE FACED THE SAME PROBLEM WE'RE FACING,
17	THAT UNIVERSITY AND ACADEMIC RESEARCH CENTERS DO
18	HAVE LIMITED RESOURCES ESPECIALLY IN THIS CURRENT
19	BUDGET ENVIRONMENT TO PATENT INVENTIONS. AND THEY
20	WERE ACTUALLY APPROACHING IT FROM A DIFFERENT
21	PERSPECTIVE THAN WE ARE.
22	WE HAVE A FIDUCIARY OBLIGATION TO THE
23	STATE TO CAPTURE ANY POTENTIAL INCOME THAT MIGHT
24	COME FORWARD AND GET THAT RETURNED TO THE GENERAL
25	FUND, BUT THEY WERE LOOKING AT IT AS THE REALITY
	11

1	THAT UNPATENTED INVENTIONS ARE MUCH HARDER TO GET
2	INDUSTRY TO DEVELOP. AND WITHOUT A CLEAR PATENT
3	TRAIL, IT GETS REALLY MESSY AND CAN ACTUALLY RETARD
4	THE ABILITY TO GET THERAPIES DEVELOPED AND WIDELY
5	AVAILABLE INTO THE CLINIC.
6	SO IF THE MAKER OF THE MOTION AND THE
7	SECOND WOULD ACCEPT THAT FRIENDLY AMENDMENT TO REFER
8	THE FOLLOW-UP ON THIS ISSUE TO THE IP TASK FORCE, I
9	THINK THAT WOULD BE REASONABLE.
10	MR. KLEIN: SO I WOULD CERTAINLY AMEND THE
11	MOTION TO INCORPORATE THE SUGGESTION THAT IF IT IS
12	APPROVED HERE BY CONCEPT, IT WOULD REQUIRE IT
13	WOULD BE COMMITTED TO THE IP COMMITTEE FOR THEIR
14	INPUT BEFORE GOING TO THE BOARD FOR FINAL ACTION.
15	DR. PRIETO: I ACCEPT THAT.
16	CHAIRMAN SHEEHY: DO WE HAVE OTHER BOARD
17	COMMENTS ON THIS ITEM?
18	DR. PRIETO: I WOULD JUST HAVE A QUESTION
19	ABOUT, AND I DON'T KNOW, MAYBE THIS CAN'T BE
20	ANSWERED NOW. I THINK WE'LL NEED MORE BACKGROUND
21	WHEN THIS COMES TO THE IP COMMITTEE, BUT HOW MUCH
22	IMPACT CAN WE HAVE ON DRIVING THESE PATENTS FORWARD?
23	IS IT GOING TO BE SIGNIFICANT? WHAT ARE THE
24	PRECEDENTS? WHO ELSE IS DOING THIS, AND WHAT'S BEEN
25	THE OUTCOME?
	12

MS. BAUM: THE MYELIN REPAIR FOUNDATION
DOES IT, AND I THINK THEY HAVE AN EXCELLENT MODEL.
AND I THINK THE OTHER SIDE OF THE COIN IS WHAT
IMPACT WILL THERE BE IF YOU DON'T DO IT. AND I DO
THINK THAT IT WILL BE VERY DIFFICULT TO ATTRACT THE
FUNDING THAT YOU NEED FOR A PHASE III IF YOU DON'T
HAVE A SOLID IP POSITION.
MR. KLEIN: I WOULD POINT OUT IT'S NOT OUR
INTENT TO STEP IN IN EACH CASE, BUT ONLY IN THE CASE
OF HIGH MERIT WHERE THERE IS NOT SUFFICIENT FUNDS
THAT ARE CURRENTLY AVAILABLE THROUGH THE GRANT OR
THROUGH THE INSTITUTIONS.
DR. TROUNSON: SO, JEFF, THERE'S ALSO THE
ISSUE OF NEED TO PATENT POOL. THIS IS A VERY
COMPLEX AREA WHERE THERE ARE LOTS AND LOTS OF
PATENTS. AND, IN FACT, A LOT OF THE PATENTS ARE NOT
REALLY BEING USED BECAUSE PEOPLE DON'T KNOW THAT
THEY COULD ACTUALLY POOL THEM TOGETHER WITH WORK
THAT WE WOULD BE DOING IN SOME OF THE TRANSLATIONAL
OR DISEASE TEAMS. SO THE OPPORTUNITY OF PATENT
POOLING TO MAKE IT MORE EFFECTIVE AND MORE
ATTRACTIVE TO END USERS TO GET IT INTO ACTUAL PHASE
III, PHASE IV TRIALS IN THE END IS VERY, VERY
IMPORTANT. AND EVEN THE HIGH END UNIVERSITIES ARE
NOT UTILIZING THEIR PATENT PORTFOLIO IN A REALLY
13

1	OPTIMUM WAY.
2	SO WHEN WE'RE FUNDING THIS WORK, WE NEED
3	TO TRY AND OPTIMIZE THAT COMPONENT PART. SO THIS IS
4	A SORT OF WHOLE LOOK AT HOW EFFECTIVELY WE CAN BE
5	HOW MUCH MORE EFFECTIVE WE CAN BE IN TERMS OF
6	GETTING THE WORK TO THE CLINIC, BUT ALSO IN
7	RETURNING FUNDS BACK TO THE STATE OF CALIFORNIA AND
8	TO THE INSTITUTIONS AND RESEARCHERS.
9	DR. KLEIN: DR. TROUNSON, THIS IS AN ISSUE
10	THAT YOU WILL PREPARE A DISCUSSION FOR THE IP TASK
11	FORCE AND THEIR REVIEW.
12	DR. TROUNSON: YEAH. I THINK I WAS JUST
13	MAKING A POINT HERE THAT I THINK IT DOES HAVE A
14	REALLY IMPORTANT FOCUS FOR US IN ENABLING THE
15	CLINICAL TRANSLATION AND EFFECTIVE MOVEMENT OF THE
16	WORK TO THE CLINIC. WITHOUT IT, WE COULD BE
17	SUBSTANTI ALLY HANDI CAPPED.
18	CHAIRMAN SHEEHY: IS THERE FURTHER BOARD
19	DISCUSSION, ALTA PARTNERS?
20	DR. PENHOET: I MOVE APPROVAL TO GO AHEAD
21	AND STUDY THE CONCEPT.
22	MS. KING: THANK YOU, DR. PENHOET. WE DO
23	ACTUALLY ALREADY HAVE A MOTION ON THE TABLE. WE
24	APPRECIATE YOUR VIGOROUS SUPPORT.
25	CHAIRMAN SHEEHY: MAYBE STANFORD IS NOT

1	HERE. JUST ANY ADDITIONAL BOARD COMMENT FROM ANY
2	OTHER SITE?
3	DR. LEVIN: THIS IS JACOB LEVIN AT IRVINE.
4	I'M WONDERING IF THERE'S ANY INTRINSIC CONFLICTS
5	BETWEEN THE PROP 71 TREATMENT OF PATENTS AND THE
6	TREATMENT THAT'S GOING TO BE NECESSARY THROUGH THE
7	UNIVERSITIES. OBVIOUSLY UNIVERSITY OF CALIFORNIA
8	AND ALL THE PUBLICLY SUPPORTED RESEARCH THAT'S
9	SUBJECT TO BAYH-DOLE HAS RESTRICTIONS ON PATENT
10	OWNERSHIP AND LICENSING. I ASSUME THIS IS THE KIND
11	OF ISSUE THAT CAN BE STUDIED ONCE WE GO PAST CONCEPT
12	APPROVAL, RI GHT?
13	CHAIRMAN SHEEHY: YES. AND JUST TO REFER
14	BACK TO SOME OF WHAT I WAS REFERENCING EARLIER, CIRM
15	ITSELF IS NOT HOLDING PATENTS. SO THIS IS REALLY TO
16	FACILITATE THE PATENTING BY THE LOCAL OFFICES OF
17	TECHNOLOGY AT THE VARIOUS UNIVERSITIES. AND THAT'S
18	ALWAYS BEEN OUR MECHANISM, AT LEAST WITH ACADEMIC
19	RESEARCH CENTERS, FOR HANDLING PATENTS. SO I DO NOT
20	BELIEVE THAT WE'RE IN CONFLICT WITH BAYH-DOLE.
21	DR. LEVIN: WE'RE ONLY TALKING ABOUT
22	COVERING THE COSTS?
23	CHAIRMAN SHEEHY: EXACTLY. SOME
24	MECHANISM. YOUR TECHNOLOGY TRANSFER OFFICES, LIKE
25	MOST THINGS AT UC, ARE NOT FARING THE BEST. WE'RE
	45

1	ALL HAVING TOUGH TIMES. I THINK THAT'S WHAT WE'RE
2	TRYING TO GET TO.
3	DR. LEVIN: PROGRAMS TO SOMETHING ALAN WAS
4	MENTIONING ABOUT PATENT POOLING AND THAT THIS IS
5	BEYOND THE SCOPE OF PAYING PATENT COSTS UP FRONT.
6	MR. KLEIN: I THINK THAT'S SOMETHING
7	THAT'S GOING TO BE LOOKED AT BY THE IP COMMITTEE IN
8	TERMS OF THE LEGAL AND FUNCTIONAL ISSUES.
9	CHAIRMAN SHEEHY: YEAH. I THINK THAT'S A
10	LARGER AND SEPARATE DISCUSSION. WE DID HAVE A VERY
11	INTERESTING PRESENTATION ON PATENT POOLS WHEN WE DID
12	THE IP TASK FORCE. AND THAT MAY BE WHEN WE GO BACK
13	TO THAT, WE CAN SEE WHERE THOSE DISCUSSIONS GO. BUT
14	GENERALLY MY UNDERSTANDING OF THE INTENTION OF THIS
15	PARTICULAR CONCEPT IS TO FACILITATE THE ACTUAL
16	PATENTING WORK TAKING PLACE AT ACADEMIC RESEARCH
17	CENTERS THAT THEY'RE CURRENTLY UNDERFUNDED TO DO
18	RIGHT NOW.
19	SO IS THERE ANY PUBLIC COMMENT AT ANY OF
20	THE SITES?
21	MS. KING: I HAVE ONE TO READ HERE IN SAN
22	FRANCISCO WHENEVER YOU'RE READY FOR ME.
23	CHAIRMAN SHEEHY: IF THERE'S NO COMMENT AT
24	ANY OF THE OTHER SITES, THEN, MELISSA.
25	MS. KING: I HAVE A COMMENT THAT WAS
	1/
	16

1	E-MAILED IN BY JOHN SIMPSON, WHO APOLOGIZES FOR NOT
2	BEING ABLE TO ATTEND THE MEETING TODAY, BUT ASKED
3	THAT THIS BRIEF STATEMENT BE READ ABOUT THIS ITEM
4	THAT IS CURRENTLY ON THE TABLE.
5	HIS STATEMENT IS A KEY ELEMENT OF THE
6	CURRENT IP POLICY IS THAT THE RETURN TO THE STATE
7	STARTS ONLY AFTER THE FIRST \$500,000 OF REVENUE IS
8	RECEIVED BY A GRANTEE. THIS \$500,000 THRESHOLD WAS
9	INTENDED TO OFFSET THE COST OF PROSECUTING A PATENT.
10	WHILE ALL THE DETAILS OF THE PROPOSAL TO HELP FUND
11	THE GRANTEES' PATENT PROSECUTION ARE NOT CLEAR TO ME
12	AS I WRITE THIS, ONE ELEMENT SHOULD BE INCLUDED,
13	WHICH IS AS FOLLOWS. IF CIRM FUNDS THE PATENT
14	PROSECUTION, PAYBACK OF THE STATE'S SHARE OF
15	ROYALTIES OR OTHER REVENUE MUST BEGIN AS SOON AS
16	THERE IS REVENUE. THERE SHOULD BE NO \$500,000
17	THRESHOLD BEFORE THE OBLIGATION TO THE STATE BEGINS.
18	THANK YOU FOR YOUR CONSIDERATION. JOHN M. SIMPSON.
19	MR. KLEIN: I THINK THIS IS AN ISSUE THAT
20	REALLY WE SHOULD REFER THAT QUOTE TO THE IP TASK
21	FORCE.
22	CHAIRMAN SHEEHY: ABSOLUTELY. ARE YOU
23	READY TO CALL THE ROLL?
24	MS. KING: I AM.
25	CHAIRMAN SHEEHY: WOULD YOU LIKE COULD
	17

	BARRISTERS' REPORTING SERVICE
1	YOU RESTATE THE MOTION?
2	MR. HARRISON: SURE. AS I UNDERSTAND IT,
3	THE MOTION IS TO REQUEST THAT STAFF PREPARE A PLAN
4	FOR THE ALLOCATION OF FUNDS FOR THE PURPOSE OF
5	SUPPORTING THE PATENTING OF CIRM-FUNDED INVENTIONS
6	AND PRESENT THAT PLAN TO THE IP TASK FORCE.
7	MS. KING: JACOB LEVIN.
8	DR. LEVIN: YES.
9	MS. KING: ROBERT KLEIN.
10	MR. KLEIN: YES.
11	MS. KING: FRANCISCO PRIETO.
12	DR. PRI ETO AYE.
13	MS. KING: ED PENHOET.
14	DR. PENHOET: YES.
15	MS. KING: JEANNIE FONTANA.
16	DR. FONTANA: YES.
17	MS. KING: DUANE ROTH.
18	MR. ROTH: YES.
19	MS. KING: JOAN SAMUELSON.
20	MS. SAMUELSON: YES.
21	MS. KING: JEFF SHEEHY.
22	CHAIRMAN SHEEHY: YES.
23	MS. KING: OSWALD STEWARD.
24	DR. STEWARD: YES.
25	MS. KING: AND ART TORRES.
	18

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1	MR. TORRES: AYE.
2	MS. KING: AND THAT MOTION CARRIES.
3	CHAIRMAN SHEEHY: OKAY. AGENDA ITEM 3,
4	CONSIDERATION OF PRESENTATION OF INFORMATION
5	REGARDING SCIENTIFIC SCORES. AND I'D LIKE TO ASK
6	BOB KLEIN TO INTRODUCE THIS ITEM.
7	MR. KLEIN: CERTAINLY, JEFF. SO IN THE
8	LAST BOARD MEETING, A NUMBER OF THE BOARD MEMBERS
9	AFTER THE MEETING ASKED THAT THE IMPLICATION THAT
10	HAD BEEN GIVEN UPON REQUEST RELATED TO THE PEER
11	REVIEW STANDARD DEVIATION ON A PARTICULAR GRANT AS
12	WELL AS THE HIGH AND LOW SCORE ON THAT GRANT ALONG
13	WITH MEDIAN SCORE OR, IF APPROPRIATE, THE MEAN SCORE
14	BE AVAILABLE WHEN GRANTS WERE DISCUSSED THAT WERE
15	NOT RECOMMENDED IN THE TOP TIER, TIER I.
16	IN SUBSEQUENT DISCUSSIONS WITH VARIOUS
17	BOARD MEMBERS, IN TRYING TO PROVIDE THIS AND PROVIDE
18	GREATER INFORMATION FOR THE PUBLIC AND THE BOARD,
19	WHAT HAS BEEN SUGGESTED IS THAT WHEN THE PEER REVIEW
20	GROUP PROVIDES A TIER I, A TIER II, AND TIER III,
21	THE TIER II BEING RECOMMENDED FOR FUNDING IF FUNDS
22	ARE AVAILABLE, THAT WITHIN TIER II THE STANDARD
23	DEVIATIONS BE PROVIDED. WHEN THEY ONLY PROVIDE A
24	TIER I AND A TIER III, WITH TIER III BEING NOT
25	RECOMMENDED, THAT THE STAFF HAVE AVAILABLE UPON
	10

1	REQUEST FOR ANY INDIVIDUAL GRANT THE STANDARD
2	DEVIATIONS ON THAT GRANT AND THE HIGH AND LOW SCORES
3	AS WELL AS THE MEAN AND/OR MEDIAN SCORE.
4	THE INTENT OF THE BOARD MEMBERS WAS TO
5	UNDERSTAND IF, IN FACT, THERE IS SOME SIGNIFICANT
6	POLARIZATION AND IF BASIC INFORMATION REFLECTED IN
7	THE NOMINAL AVERAGE SCORE IS NOT AS REPRESENTATIVE
8	OF THE DIVERSITY IN THE SCORING AS THE OTHER
9	INFORMATION MIGHT INDICATE.
10	SO THE MOTION IN THIS CASE WOULD BE THAT
11	THE STAFF WORK WITH THE VICE CHAIR OF THE PEER
12	REVIEW GROUP, THE VICE CHAIRS OF THE PEER REVIEW
13	GROUP, AND THE EXECUTIVE COMMITTEE TO BRING TO THE
14	BOARD A SYSTEM OF PROVIDING ADDITIONAL INFORMATION
15	ON THE RECOMMENDED FOR APPROVAL IF FUNDS ARE
16	AVAILABLE THAT WOULD BECOME A STANDARD PART OF THE
17	SCORING INFORMATION THAT MIGHT BE POSTED SUCH AS THE
18	STANDARD DEVIATION, AND THAT ON THE THIRD TIER WHAT
19	INFORMATION THE BOARD WOULD WANT TO HAVE AVAILABLE
20	FOR THE PUBLIC DISCUSSION IF BOARD MEMBERS THOUGHT
21	TO RAISE THE THIRD TIER FOR CONSIDERATION.
22	CHAIRMAN SHEEHY: BOB, WOULD YOU ACCEPT A
23	FRIENDLY AMENDMENT TO THAT MOTION?
24	MR. KLEIN: ABSOLUTELY.
25	CHAIRMAN SHEEHY: I THINK WHERE WE'RE IN
	20

1	ONLY A TWO-TIER SETTING, MAYBE WE COULD AMEND SO
2	THAT TREATMENT OF TIER II THAT YOU RECOMMEND FOR
3	TIER II ALSO HAPPEN TO ALL GRANTS WITH A SCORE ABOVE
4	60 SO THAT WE CREATE A DE FACTO TIER II. RATHER
5	THAN JUST THE ONES THAT THE BOARD WILL WANT, MAY OR
6	MAY NOT WANT TO LOOK AT, THE SAME TYPE OF
7	INFORMATION THAT YOU WOULD PROVIDE FOR GRANTS IN
8	TIER II, IN THE ABSENCE OF A TIER II, THEY BE
9	PROVIDED FOR GRANTS OVER 60, BUT UNDER THE FUNDING
10	LI NE.
11	MR. KLEIN: OKAY. THAT IS ACCEPTABLE TO
12	ME. DR. PENHOET HAD SOME SIMILAR DISCUSSIONS. ED,
13	WOULD THAT ADDRESS THE QUESTION THAT YOU RAISED WITH
14	ME?
15	DR. PENHOET: LIKELY. I JUST WANTED TO BE
16	SURE THAT IF WE'RE GOING TO USE CRITERIA WHICH ARE
17	OTHER THAN STANDARD CRITERIA FOR ANY GRANTS, THAT WE
18	LOOK MORE COMPREHENSIVELY AT THE TOTAL RATHER THAN
19	JUST SELECTING ONE OR TWO OUT AND, THEREFORE, NOT
20	GIVE OTHERS IN THE SAME RANGE BENEFIT OF THE SAME
21	ANALYSIS.
22	MR. KLEIN: I THINK JEFF'S PROPOSAL DOES
23	THAT, AND I WOULD ACCEPT THAT AS AN AMENDMENT IF
24	THERE'S A SECOND TO SUPPORT THIS MOTION.
25	DR. LEVIN: I'LL SECOND THAT.
	21

1	MR. ROTH: JEFF, I'M GOING TO HAVE TO HOP
2	OFF. I WONDER IF I COULD INDULGE JUST TO MAKE TWO
3	QUICK COMMENTS BEFORE I LEAVE?
4	CHAIRMAN SHEEHY: SURE. PLEASE.
5	MR. ROTH: SO ONE THING IS THAT I THINK
6	THE SCOPE OF THE WORK OF THIS COMMITTEE SHOULD BE A
7	MORE COMPREHENSIVE OVERVIEW, AND I THINK THAT'S
8	COMING UP IN NO. 4. WE'VE BEEN DOING THIS AWHILE.
9	NOW IS PROBABLY THE TIME TO REFLECT ON WHAT WORKS
10	WELL AND WHAT DOESN'T, THIS BEING ONE OF THOSE
11	ISSUES THAT NEEDS TO COME FORWARD.
12	THE SECOND THING, AS A REVIEWER OF THESE,
13	I FIND PARTICULARLY USEFUL THE, WHAT DO YOU CALL,
14	THE ALLOCATION WHAT IS THE REVIEW YOU GIVE THE
15	PEER REVIEW?
16	MR. KLEIN: PROGRAMMATIC REVIEW.
17	MR. ROTH: PROGRAMMATIC REVIEW. I FIND
18	VERY HELPFUL TO US TO MAKE SURE THAT SOMEBODY SPENDS
19	REAL TIME ON THE PROGRAMMATIC REVIEW SO WE DON'T GET
20	IN THE SITUATION WHERE SOMEBODY IS LOBBYING US, AND
21	WE DECIDE AS A PROGRAMMATIC THING WE SHOULD DO IT.
22	AND THAT HAPPENED LAST TIME.
23	AND THEN FINALLY, I THINK IT WOULD BE
24	REALLY HELPFUL IF, IN ADDITION TO THE PROGRAMMATIC
25	REVIEW, YOU ASK THE REVIEWERS TO PICK THE ONE OR TWO
	22

1	GRANTS THAT WERE, QUOTE, TOO INNOVATIVE OR LACKED
2	SUFFICIENT PRELIMINARY DATA TO BE FUNDED, BUT WERE
3	CONSIDERED TO BE VERY, VERY INNOVATIVE. I'D LIKE
4	PERSONALLY, AS A REVIEWER AT THE BOARD LEVEL, TO SEE
5	THOSE, HAVE THOSE DISCUSSED IN ADDITION TO THE
6	PROGRAMMATIC ONES. AND MY WORRY HERE IS WE'RE
7	LEAVING SOME REALLY INTERESTING, NOVEL, NEW
8	APPROACHES BECAUSE WE DON'T HAVE ANY PRELIMINARY
9	DATA. THAT WOULD BE HELPFUL TO ME TO SORT OUT ONE
10	OR TWO GRANTS THAT WE WOULD TAKE A LOOK AT LIKE
11	THAT.
12	WITH THAT, I'M GOING TO SEND OFF.
13	MR. KLEIN: DO WE LOSE OUR QUORUM WITH
14	DUANE?
15	MS. KING: NO, WE DON'T.
16	MR. ROTH: I'LL COME BACK. ALL YOU HAVE
17	TO DO IS CALL LAUREN AND I'LL STEP OUT OF THE
18	MEETING, BUT I'VE GOT TO GO START A MEETING HERE.
19	MS. KING: THANKS SO MUCH, DUANE. WE HAVE
20	SENATOR TORRES WITH US NOW. HE'S ACTUALLY BEEN HERE
21	FOR QUITE SOME TIME. HE WAS NOT HERE FOR THE
22	INITIAL ROLL CALL. WE HAVE A QUORUM WITH HIM, BUT I
23	ALSO WANTED TO CHECK IN. HAS ANY MEMBER OF THE
24	SUBCOMMITTEE JOINED SINCE THE ROLL CALL AND,
25	THEREFORE, NOT HAVING BEEN TAKEN ACCOUNTED FOR? IF

1	NOT, WE CAN PROCEED. WE STILL HAVE A QUORUM.
2	CHAIRMAN SHEEHY: DO WE HAVE ADDITIONAL
3	BOARD DISCUSSION ON THIS?
4	DR. LEVIN: I THINK THIS IS A GREAT IDEA.
5	THE MORE INFORMATION WE CAN GET ABOUT THESE GRANTS
6	DURING BOARD REVIEW THE BETTER. I THINK THAT IT'S
7	VERY DIFFICULT TO MAKE DECISIONS WITHOUT BEING ABLE
8	TO READ THE WHOLE GRANT. SO IF WE KNOW THE MORE
9	INFORMATION WE CAN GET ABOUT WHAT THE REVIEWERS
10	THEMSELVES HAVE DECIDED AND THE DISTRIBUTION OF THE
11	SCORE, THE EASIER IT'S GOING TO BE TO MAKE INFORMED
12	DECI SI ONS.
13	DR. STEWARD: CAN I ASK A QUESTION? GIVEN
14	THE STANDARD DEVIATION, FOR EXAMPLE, IS JUST ANOTHER
15	KEYSTROKE IN EXCEL. WHY NOT JUST HAVE THE STANDARD
16	DEVIATION AND MEANS AVAILABLE FOR ALL THE GRANTS?
17	MR. KLEIN: I THINK THAT BELOW A CERTAIN
18	LEVEL, BECAUSE THE STANDARD DEVIATION IN ALL
19	PROBABILITY CAN CHANGE THE OUTCOME, BELOW A CERTAIN
20	LEVEL WAS CHOSEN BY JEFF AT 60. AND IN THIS
21	PROPOSED PROPOSAL IT'S MUCH AT LEAST MUCH LESS
22	LIKELY THAT A STANDARD DEVIATION BY POLARIZATION OF
23	SCORES WOULD DRAG IT BELOW 60.
24	DR. STEWARD: ACTUALLY I'M ASKING IN TERMS
25	OF THE UPPER TIER. IT ACTUALLY WOULD BE INTERESTING
	2.4

1	TO KNOW IF THERE WERE GRANTS AT THE BORDERLINE OF
2	THE UPPER TIER THAT ALSO HAVE THE SAME KIND OF LARGE
3	STANDARD DEVIATION INDICATING A DISAGREEMENT AMONGST
4	THE REVIEWERS. AND, AGAIN, WE DON'T REPORT THE
5	LOWER TIER ANYWAY.
6	MR. KLEIN: MR. CHAIRMAN, I WOULD ACCEPT
7	AS A FRIENDLY AMENDMENT HAVING STANDARD DEVIATIONS
8	SHOWN FOR THE UPPER TIER AS WELL IF MY SECOND WOULD
9	AGREE TO THAT. THE SECOND WAS DR. PRIETO.
10	DR. PRIETO: I'M NOT SURE I WAS SECOND.
11	MS. KING: I BELIEVE THE SECOND FOR THIS
12	MOTION WAS DR. PENHOET.
13	MR. KLEIN: DR. PENHOET, WOULD THAT BE
14	ACCEPTABLE TO YOU?
15	DR. PENHOET: YES.
16	DR. PRIETO: IF I CAN SPEAK AGAIN, I THINK
17	THAT'S AN EXCELLENT IDEA.
18	CHAIRMAN SHEEHY: WE HAVE A COMMENT FROM
19	JAMES HARRISON.
20	MR. HARRISON: I JUST WANTED TO MAKE SURE
21	FOR THE RECORD THAT I UNDERSTOOD THE MOTION. AS I
22	UNDERSTAND IT, THE MOTION IS TO REQUEST THAT STAFF
23	PRESENT THE FOLLOWING INFORMATION: STANDARD
24	DEVIATION, MEDIAN, AND THE RANGE OF THE SCORES FOR
25	ALL APPLICATIONS IN TIER I AND TIER II WHEN THERE
	0.5

1	ARE THREE TIERS, AND WHERE THERE ARE JUST TWO TIERS,
2	FOR ALL APPLICATIONS WITH A SCORE OF 60 AND OVER.
3	DR. STEWARD: I ACTUALLY THOUGHT THAT WE
4	WERE JUST TALKING ABOUT MEAN AND STANDARD DEVIATION
5	WITH HAVING THE OTHER INFORMATION AVAILABLE ON
6	REQUEST. STANDARD DEVIATION ACTUALLY
7	MR. KLEIN: THE OTHER INFORMATION WOULD BE
8	AVAILABLE ON REQUEST.
9	MR. HARRISON: STANDARD DEVIATION AND
10	MEDIAN AND MEAN.
11	MR. KLEIN: YES. JUST TO BE CLEAR,
12	STANDARD DEVIATION AND MEAN, SO WE WOULD NOT INCLUDE
13	THE MEDIAN?
14	DR. STEWARD: THAT WOULD BE SUFFICIENT AS
15	FAR AS I'M CONCERNED. THIS IS OS. WITH THE MEDIAN
16	BEING AVAILABLE IF REQUESTED.
17	DR. PENHOET: IT'S EASY TO CALCULATE IT.
18	WHY NOT HAVE IT THERE?
19	CHAIRMAN SHEEHY: I THINK THE MEDIAN,
20	MEDIAN AND THE MEAN MAKES SENSE.
21	DR. LEVIN: WHY DO WE NOT WANT TO REPORT
22	THE HIGH AND LOW SCORES?
23	CHAIRMAN SHEEHY: I THINK THAT THAT WOULD
24	BE REASONABLE TOO, BUT I LEAVE IT TO THE MAKERS OF
25	THE MOTION.
	24

	DARRISTERS REPORTING SERVICE
1	DR. PENHOET: I WOULD.
2	DR. KLEIN: IS THAT ED?
3	DR. PENHOET: YEAH. WHAT'S YOUR CONCERN,
4	0S?
5	MR. KLEIN: I GOT TO FOLLOW THE LEADERSHIP
6	OF MY SECOND AND HAVE HIGH AND LOW SCORES AVAILABLE
7	T00.
8	CHAIRMAN SHEEHY: SO WE HAVE MEDIAN, MEAN,
9	STATISTICAL DEVIATION, HIGH AND LOW.
10	MR. KLEIN: RIGHT.
11	DR. STEWARD: I HAVE NO OBJECTION TO IT.
12	IT'S JUST MORE OR LESS YOU CAN GET A SENSE OF THE
13	REST WITH THE STANDARD DEVIATION, BUT IT'S FINE TO
14	HAVE IT. THE MORE THE BETTER.
15	CHAIRMAN SHEEHY: OKAY. DO WE HAVE
16	ADDITIONAL DISCUSSION OF THIS ITEM?
17	DR. SLADEK: THIS IS JOHN SLADEK. I JUST
18	WANT TO ASK IF YOU ARE GOING TO FOLLOW UP ON DUANE'S
19	COMMENT BEFORE HE LEFT ABOUT PICKING ONE OR TWO
20	PROPOSALS THAT ARE, AS HE PUT IT, TOO INNOVATIVE. I
21	KNOW IT'S NOT PART OF THIS MOTION, BUT IT MIGHT BE
22	RELEVANT, ESPECIALLY FROM WHAT I'VE SEEN AS A
23	REVI EWER.
24	MR. KLEIN: DR. SLADEK, THE ISSUE IS THAT
25	ON A NOTICE PROVISION, OUR MOTIONS CAN ONLY ADDRESS
	27
	27

1	WHAT WE PROVIDED, ALTHOUGH IT'S HIGHLY MERITORIOUS
2	WHAT HE'S RAISED AS AN AREA FOR STUDY. WE CAN'T
3	ADDRESS IT WITHIN THIS MOTION.
4	CHAIRMAN SHEEHY: WHAT I MIGHT SUGGEST,
5	DR. SLADEK, IS MAYBE INTRODUCING THAT WITHIN ITEM 5,
6	THE SCOPE OF MATERIALS TO BE PROVIDED TO GRANT
7	WORKING GROUP MEMBERS. AND I THINK IT WOULD FIT IN
8	THERE AS AN INSTRUCTION. AS ADMINISTRATIVE CHAIR OF
9	THE WORKING GROUP, YOU WOULD HAVE THE OPPORTUNITY TO
10	OPERATIONALIZE THAT, AS WOULD BOTH JOAN AND I AS
11	VICE CHAIRS OF THE WORKING GROUP. AND SO MAKE THAT
12	PART OF THE INSTRUCTIONS TO ACTUALLY MAKE WE
13	COULD INCLUDE THAT IN THAT ITEM AS PART OF THE
14	INSTRUCTIONS THAT ARE GIVEN TO THE WORKING GROUP
15	DURING PROGRAMMATIC REVIEW.
16	MR. KLEIN: JEFF, I WOULD HOPE THAT IN
17	ORDER TO GET THIS WORKED OUT, THAT WE HAVE A FULL
18	DISCUSSION WITH SCIENTIFIC STAFF SO THAT WE REALLY
19	REFINE THIS NUGGET OF AN IDEA BEFORE WE INCORPORATE
20	IT IN THE LATER MOTION AS A SPECIFIC DIRECTION. BUT
21	I'LL LEAVE THAT TO THE LATER DISCUSSION.
22	CHAIRMAN SHEEHY: MY MAIN POINT WAS THAT
23	THAT COULD EASILY FIT WITHIN THAT ITEM.
24	MR. KLEIN: RIGHT. CERTAINLY WE COULD FIT
25	THAT INTO THAT DISCUSSION OF THAT ITEM.

1	DR. SLADEK: THANK YOU BOTH.
2	CHAIRMAN SHEEHY: OKAY. NOW, DO WE HAVE
3	PUBLIC COMMENT AT ANY SITE ON THIS ITEM?
4	MR. KLEIN: IS THERE COMMENT FROM THE
5	SCIENTIFIC STAFF?
6	MS. KING: WE HAVE SEVERAL MEMBERS OF THEM
7	HERE IN SAN FRANCISCO, AND NO ONE HAS MADE A MOVE
8	FOR THE MICROPHONE YET. DR. TROUNSON WOULD LIKE TO
9	MAKE A COMMENT AT THIS POINT.
10	DR. TROUNSON: WELL, I THINK THE STAFF ARE
11	QUITE COMFORTABLE WITH PROVIDING THE INFORMATION
12	THAT'S REQUESTED. I THINK IT'S A BETTER IDEA TO
13	HAVE MORE INFORMATION EVEN IN UP THE UPPER ECHELON
14	BECAUSE I THINK YOU'RE GOING TO LOOK AT THAT AND
15	THEN SEE THAT THERE IS A RANGE IN VARIATION THERE.
16	AND I THINK THERE'S ACTUALLY A LOT OF VALUE IN
17	HAVING SOME VARIATION AS DISTINCT FROM PUSHING THE
18	REVIEWERS TO ALL COME TOGETHER IN A SINGLE NUMBER.
19	THAT, I DON'T THINK, IS THAT INFORMATIVE, AND IT'S
20	NOT THAT GOOD FOR DISCUSSION.
21	SO I THINK BEING ABLE TO USE THE BROADER
22	RANGE WILL GIVE YOU SOME IDEA OF WHAT'S HAPPENING
23	RIGHT THROUGH THE SCOPE, AND I THINK IT'S A BETTER
24	VIEW OF THE DATA THAN JUST HAVING IT APPLIED TO A
25	FEW GRANTS AND THEN SORT OF CHOOSING WHETHER HIGH

1	VARIATION OR NO VARIATION IS A POSITIVE OR A
2	NEGATIVE. I'M NOT SURE WHETHER IT'S A POSITIVE OR
3	NEGATI VE ANYWAY.
4	BUT IF THERE IS WHAT I THINK I WAS
5	TRYING TO FIND OUT AT SOME POINT WAS THERE DEEPER
6	INTEREST ON THE BOARD WHERE WE COULD HAVE THE
7	STATISTICIAN SORT OF HELP FRAME EVEN OTHER
8	STATISTICS. BUT WE WOULD BE QUITE COMFORTABLE WITH
9	PROVIDING WHAT YOU'RE REQUESTING.
10	CHAIRMAN SHEEHY: ANOTHER CALL FOR PUBLIC
11	COMMENT.
12	DR. CHIU: THIS IS ARLENE FROM CITY OF
13	HOPE. AND I JUST WONDERED, PERHAPS I DIDN'T
14	UNDERSTAND DR. SLADEK'S COMMENT, BUT WILL THESE
15	PIECES OF INFORMATION BE PROVIDED TO THE GRANTS
16	WORKING GROUP MEMBERS PRIOR TO OR DURING
17	PROGRAMMATIC REVIEW SO THAT THEY TOO CAN SEE THE
18	RANGE AND THE MEDIAN AND MEAN BECAUSE NOW THEY'RE
19	GIVEN THE MEANS BEFORE DISCUSSION? AND IT MIGHT
20	PROVOKE INTERESTING DISCUSSIONS, PARTICULARLY FOR
21	PROGRAMMATI C.
22	MR. KLEIN: THIS IS BOB KLEIN, ARLENE.
23	THAT'S AN EXCELLENT SUGGESTION. I THINK UNDER AS
24	A SEPARATE ITEM FOR THE TWO ON THE TABLE FOR THE
25	SCIENTIFIC COMMITTEE, HOPEFULLY, JEFF, FOR YOU TO

1	BRING BACK, AND HOPEFULLY WITH ADVICE FROM OUR
2	SCIENTIFIC STAFF, I WOULD THINK THAT WOULD BE VERY
3	BENEFICIAL. BUT IT'S NOT PART OF THE AGENDIZED
4	ITEM, BUT CERTAINLY IS A VERY HIGH MERIT SUGGESTION
5	WHICH COULD BE VERY HELPFUL TO THE PEER REVIEWERS.
6	DR. CHIU: THE ONLY REASON I BRING IT UP
7	IS I UNDERSTAND WE COULD HAVE ANOTHER DISCUSSION
8	WHEN YOU COME TO ITEM NO. 5, BUT ITEM NO. 5
9	SPECIFICALLY STATES SCOPE OF MATERIALS TO BE
10	PROVIDED TO GRANTS WORKING GROUP MEMBERS IN ADVANCE
11	OF MEETING. AND THIS WOULD BE INFORMATION DURING
12	THE MEETING.
13	MR. KLEIN: COULD WE, JEFF FIRST OF
14	ALL, JAMES, LOOKING BACK, EVEN THOUGH THE WORDING IS
15	GENERAL ENOUGH, SO I GUESS WE COULD ADDRESS HER
16	QUESTION UNDER THIS ITEM; IS THAT CORRECT?
17	MR. HARRISON: YES, THAT'S CORRECT.
18	MR. KLEIN: SO WITH THAT CORRECTION TO MY
19	PREVIOUS STATEMENT, DR. TROUNSON, COULD YOU COMMENT
20	ON ARLENE'S POSITION?
21	MS. KING: WE ACTUALLY HAVE DR. OLSON HERE
22	WAITING PATIENTLY TO MAKE A COMMENT.
23	DR. OLSON: I JUST WANTED TO COMMENT THAT,
24	IN FACT, GENERALLY IN ALL REVIEWS LATELY THAT, AND
25	I'D SAY ALL THE REVIEWS FOR THE LAST YEAR OR SO, WE

1	HAVE MADE AVAILABLE TO THE GRANTS WORKING GROUP, WE
2	LET THEM KNOW THOSE APPLICATIONS THAT HAVE A LARGER
3	STANDARD DEVIATION TO, IN FACT, GIVE THEM THE
4	OPPORTUNITY TO PROGRAMMATICALLY DISCUSS THEM.
5	CHAIRMAN SHEEHY: AS VICE CHAIR OF THE
6	WORKING GROUP, I WOULD GREATLY APPRECIATE HAVING
7	THIS ADDED TO THE MOTION, TO BE HONEST. I FIND IT
8	HARD IN THE WORKING GROUP IT'S KIND OF ON AN AD
9	HOC BASIS WHEN PEOPLE REQUEST IT, AND IT WOULD
10	CERTAINLY ENLIVEN AND FACILITATE A MORE ROBUST
11	PROGRAMMATIC DISCUSSION, WHICH I THINK WAS PART 1 OF
12	WHAT DUANE WAS ASKING FOR WAS A MORE INFORMATIVE
13	PROGRAMMATIC REVIEW.
14	PROGRAMMATIC REVIEW HAS SUFFERED RECENTLY
15	AND HAS HAD THE SAME SUPPORT THAT IT HAS
16	HISTORICALLY HAD WITHIN THE REVIEW SYSTEM. SO THIS
17	BE MIGHT BE SOME WAY TO ENHANCE, FACILITATE, AND
18	
	REVIVE THE PROGRAMMATIC REVIEW OF THE GRANTS WORKING
19	GROUP. SO I WOULD BE VERY SUPPORTIVE OF HAVING THE
20	GROUP. SO I WOULD BE VERY SUPPORTIVE OF HAVING THE
20 21	GROUP. SO I WOULD BE VERY SUPPORTIVE OF HAVING THE SAME SORT OF INFORMATION PROVIDED FOR PROGRAMMATIC
20 21 22	GROUP. SO I WOULD BE VERY SUPPORTIVE OF HAVING THE SAME SORT OF INFORMATION PROVIDED FOR PROGRAMMATIC REVIEW AT THE GRANTS WORKING GROUP.
20212223	GROUP. SO I WOULD BE VERY SUPPORTIVE OF HAVING THE SAME SORT OF INFORMATION PROVIDED FOR PROGRAMMATIC REVIEW AT THE GRANTS WORKING GROUP. MR. KLEIN: DR. PENHOET, AS THE SECOND ON
19 20 21 22 23 24 25	GROUP. SO I WOULD BE VERY SUPPORTIVE OF HAVING THE SAME SORT OF INFORMATION PROVIDED FOR PROGRAMMATIC REVIEW AT THE GRANTS WORKING GROUP. MR. KLEIN: DR. PENHOET, AS THE SECOND ON THIS MOTION, WHAT IS YOUR VIEW?

1	AS A FRIENDLY AMENDMENT WITH THE SUPPORT OF THE
2	SECOND.
3	MS. SAMUELSON: I AGREE WITH JEFF. I HAD
4	ASSUMED THAT THIS INFORMATION WOULD BE GOING TO THE
5	WORKING GROUP AS WELL. I CAN'T IMAGINE WE WOULD
6	WANT THEIR DISCUSSION TO HAVE LESS THE
7	AVAILABILITY OF LESS INFORMATION THAN THE BOARD HAS
8	BECAUSE WE BENEFIT A LOT FROM THEIR SCORES AND THEIR
9	FINAL VOTES. SO WE SHOULD HAVE THAT INFORMATION.
10	I ALSO AM ASSUMING THAT AT SOME POINT WHEN
11	WE'RE TALKING ABOUT THE MISSION OF THIS
12	SUBCOMMITTEE, WE'LL TALK ABOUT THE RELATIONSHIP
13	BETWEEN THE SUBCOMMITTEE AND THE WORKING GROUP.
14	DR. PIZZO: I'M SORRY THAT I'M LATE IN
15	JOINING THE CALL. BEFORE YOU TAKE A VOTE, IF
16	SOMEONE COULD JUST JUST CATCHING UP, IF YOU JUST
17	REPEAT THE MOTION AT SOME POINT.
18	MS. KING: DR. PIZZO, THANK YOU FOR
19	JOINING US.
20	DR. PIZZO: I'M SORRY THAT I COULDN'T GET
21	HERE TILL JUST NOW.
22	CHAIRMAN SHEEHY: JAMES.
23	MR. HARRISON: DR. PIZZO, THE MOTION,
24	PLEASE CORRECT ME IF I'VE GOT IT INCORRECT, IS TO
25	REQUEST THAT STAFF PRESENT STANDARD DEVIATION,
	22

MEDIAN, MEAN, AND THE RANGE, THE HIGH AND LOW
SCORES, TO THE BOARD AND THE GRANTS WORKING GROUP
FOR ALL APPLICATIONS IN TIER I AND TIER II WHEN
THERE ARE THREE TIERS AND FOR ALL APPLICATIONS WITH
A SCORE OF 60 AND ABOVE WHEN THERE ARE ONLY TWO
TI ERS.
DR. PI ZZO: GOOD.
MR. KLEIN: ADDITIONALLY, JAMES, WITH THE
AMENDMENT THAT THE SAME INFORMATION WOULD BE
AVAILABLE TO THE PEER REVIEW GROUP FOR THE
PROGRAMMATIC PORTION OF THE PEER REVIEW.
MR. HARRISON: THAT WAS INCLUDED IN THE
MOTION, TO THE BOARD AND TO THE GRANTS WORKING
GROUP.
DR. PI ZZO: THANK YOU.
CHAIRMAN SHEEHY: OKAY. AGAIN, SINCE
WE'VE HAD AN AMENDMENT, IS THERE ANY PUBLIC COMMENT?
MELISSA, COULD YOU CALL THE ROLL.
MS. KING: JUST A QUICK CHECK. I KNOW DR.
FRIEDMAN WAS HOPING TO JOIN US AS WELL. DR.
FRIEDMAN, BY ANY CHANCE, ARE YOU ON THE LINE?
CALLING THE ROLL: JACOB LEVIN.
DR. LEVIN: YES.
MS. KING: ROBERT KLEIN.
MR. KLEIN: YES.
2.4

34

1	MS. KING: FRANCISCO PRIETO.
2	DR. PRI ETO YES.
3	MS. KING: ED PENHOET.
4	DR. PENHOET: YES.
5	MS. KING: PHIL PIZZO.
6	DR. PI ZZO: YES.
7	MS. KING: JEANNIE FONTANA.
8	DR. FONTANA: YES.
9	MS. KING: JOAN SAMUELSON.
10	MS. SAMUELSON: YES.
11	MS. KING: JEFF SHEEHY.
12	CHAIRMAN SHEEHY: YES.
13	MS. KING: OSWALD STEWARD.
14	DR. STEWARD: YES.
15	MS. KING: AND ART TORRES.
16	MR. TORRES: AYE.
17	MS. KING: FOR THE RECORD, THAT MOTION
18	CARRI ES.
19	CHAIRMAN SHEEHY: SO AGENDA ITEM 4,
20	CONSIDERATION OF COMMISSIONING AN IOM STUDY
21	REGARDING CIRM INCLUDING ORGANIZATIONAL STRUCTURE,
22	FINANCIAL STRUCTURE, CONFLICTS POLICIES, OPERATIONS,
23	SCIENTIFIC PERFORMANCE AND BEST PRACTICES TO ENHANCE
24	OPERATIONS AND SCIENTIFIC PERFORMANCE AND IDENTIFY
25	CRITICAL SCIENTIFIC OPPORTUNITIES IN THE NEAR TERM.
	35

1	SO I'LL INTRODUCE THIS ITEM. AND FIRST
2	LET ME JUST KIND OF INTRODUCE US TO THE INSTITUTE OF
3	MEDICINE. IT MAY NOT BE WIDELY KNOWN WHAT IT DOES.
4	THE INSTITUTE OF MEDICINE IS AN INDEPENDENT
5	NONPROFIT ORGANIZATION THAT WORKS OUTSIDE GOVERNMENT
6	TO PROVIDE UNBIASED AND AUTHORITATIVE ADVICE TO
7	DECISION MAKERS AND THE PUBLIC. ESTABLISHED IN
8	1870, THE IOM IS THE HEALTH ARM OF THE NATIONAL
9	ACADEMY OF SCIENCES, WHICH WAS CHARTERED UNDER
10	PRESIDENT ABRAHAM LINCOLN. THE IOM ASKS AND ANSWERS
11	THE NATION'S MOST PRESSING QUESTIONS ABOUT HEALTH
12	AND HEALTHCARE. AND THE AIM IS TO HELP THOSE IN
13	GOVERNMENT AND THE PRIVATE SECTOR MAKE INFORMED
14	HEALTH DECISIONS BY PROVIDING EVIDENCE UPON WHICH
15	THEY CAN RELY.
16	MANY OF THE STUDIES THAT THE IOM
17	UNDERTAKES BEGIN AS SPECIFIC MANDATES FROM CONGRESS.
18	OTHERS ARE REQUESTED BY FEDERAL AGENCIES AND
19	INDEPENDENT ORGANIZATIONS. SO THAT'S BASICALLY WHAT
20	THE IOM DOES. AND IT SEEMS TO ME THAT ALMOST SIX
21	YEARS INTO OUR EXISTENCE A STUDY BY THE INSTITUTE OF
22	MEDICINE WOULD PROVIDE AN OPPORTUNITY FOR AN
23	ABSOLUTELY OBJECTIVE, INDEPENDENT, UNBLASED
24	EVALUATION OF WHAT WE'VE DONE TO DATE AND PROVIDE AN
25	OPPORTUNITY TO GET RECOMMENDATIONS FOR MOVING

1	FORWARD.
2	HAVING SPENT AT THIS POINT A BILLION
3	DOLLARS IN CALIFORNIA TAXPAYERS' MONEY, WE HAVE YET
4	TO UNDERTAKE THIS KIND OF INDEPENDENT SCIENTIFIC
5	ANALYSIS BY THE BEST EXPERTS IN THE MEDICAL AND
6	RESEARCH FIELD IN THE COUNTRY. AND I THINK WE HAVE
7	AN OBLIGATION BOTH TO THE LEGISLATURE AND TO THE
8	PUBLIC TO COMMISSION SUCH A REPORT.
9	I THINK IN SOME WAYS, AND I DO SUPPORT AND
10	WE REITERATED OUR SUPPORT FOR SENATE BILL TODAY FOR
11	A PERFORMANCE AUDIT, THAT THE ABILITY TO ACTUALLY
12	EVALUATE OUR SCIENTIFIC WORK AND HOW WE DO OUR
13	SCIENTIFIC WORK AND TO MAKE SUGGESTIONS ON HOW WE
14	CAN MOVE FORWARD LIES BEYOND THE SCOPE OF SOMETHING
15	THAT THE LEGISLATURE COULD RECOMMEND USING STATE
16	RESOURCES. THERE'S SIMPLY NO BODY AT A STATE LEVEL
17	THAT POSSESSES THE TYPE OF SCIENTIFIC EXPERTISE WE
18	NEED TO DO THIS KIND OF REPORT.
19	SO I THINK THAT I WOULD BE VERY SUPPORTIVE
20	OF THIS GOING FORWARD. AND I WOULD LIKE TO MAKE A
21	MOTION TO MOVE THIS ITEM. CAN I GET A SECOND?
22	MR. KLEIN: JEFF, I WILL SECOND THAT. I
23	WOULD LIKE TO MAKE A FRIENDLY AMENDMENT THAT IT BE
24	RECOMMENDED TO THE BOARD AND TO WORK WITH THE
25	SCIENTIFIC STAFF AND THE IOM ON A MORE DETAILED

1	BUDGET AND SCOPE BEFORE IT IS BROUGHT TO THE BOARD
2	FOR FINAL DECISION. IS THAT ACCEPTED?
3	CHAIRMAN SHEEHY: AS LONG AS IT'S COMING
4	TO THE BOARD AT THE JUNE MEETING.
5	MR. KLEIN: ALL RIGHT. I WILL ACCEPT THAT
6	AS A PROVISION.
7	CHAIRMAN SHEEHY: OKAY. DO OTHER
8	MEMBERS
9	DR. PIZZO: JEFF, I'D LIKE TO COMMENT WHEN
10	THERE'S A MOMENT.
11	MR. KLEIN: JEFF, COULD MR. HARRISON
12	COMMENT ABOUT THE ALQUIST BILL AND THE REQUIREMENT
13	IN THAT BILL? PHIL WAS NOT ON FOR THE EARLIER
14	DISCUSSION, AND IT WOULD BE GOOD FOR PHIL OR ANYONE
15	ELSE WHO'S JOINED TO UNDERSTAND HOW THIS WOULD
16	FULFILL THE REQUIREMENTS IN THE LEGISLATIVE BILL
17	THAT'S GOING TO THE LEGISLATURE AT THIS TIME WITH
18	THE SUPPORT FROM THE PRIOR VOTE WE MADE TODAY AS IT
19	HAS BEEN NARROWED TO THE REMAINING POINT.
20	MR. TORRES: ON THAT POINT, MR. CHAIRMAN.
21	YES. UNDER THE PROPOSITION OUR PRESIDENT HAS
22	UNDERTAKEN THE INITIATIVE TO ASSEMBLE WHAT I
23	CONSIDER AN INCREDIBLE GROUP OF SCIENTISTS TO HELP
24	REVIEW OUR STRATEGIC PLAN. I THINK IT'S IMPORTANT
25	FOR US TO HAVE ON THE TABLE JUST HOW MANY PROPOSALS

1	WE ARE GOING TO UNDERGO OR PROPOSE TO UNDERGO SO
2	THAT WE HAVE A CLEAR UNDERSTANDING OF WHERE WE'RE AT
3	AND THE WORKLOAD OF THAT THAT IS INVOLVED ACROSS THE
4	BOARD. THANK YOU.
5	CHAIRMAN SHEEHY: IT SEEMS TO ME THAT THEY
6	WOULD BE COMPLEMENTARY. THE SAME TYPE OF SCIENTIFIC
7	INFORMATION THAT MIGHT BE PROVIDED FOR THE INTERNAL
8	SCIENTIFIC REVIEW COULD ALSO BE MADE AVAILABLE
9	FAIRLY EASILY TO THE INSTITUTE OF MEDICINE. SO
10	RATHER THAN HAVE TO DO THIS TWICE IN THE NEXT YEAR
11	WHERE YOU MIGHT DO AN INTERNAL REVIEW AND THEN SIX
12	MONTHS LATER
13	MR. TORRES: THIS IS NOT AN INTERNAL
14	REVIEW I WAS REFERENCING. IT'S WHAT'S MANDATED
15	UNDER THE PROPOSITION TO HAVE A REVIEW OF OUR
16	STRATEGIC PLAN.
17	MR. KLEIN: SENATOR TORRES, I THINK IT
18	WOULD BE HELPFUL, THOUGH, IF MR. HARRISON RELATED
19	HOW THIS IOM STUDY WOULD WORK IN TERMS OF FULFILLING
20	THE REQUIREMENTS UNDER THE LEGISLATION AND THE
21	SCIENTIFIC STUDY, WHICH YOU VERY APPROPRIATELY POINT
22	OUT IS SOMETHING THAT'S GOING TO HAPPEN AND BE
23	COMPLETED STRATEGIC PLAN EVALUATION IS GOING TO
24	BE COMPLETED BY DECEMBER OF THIS YEAR.
25	AND, MR. HARRISON, IF YOU COULD COMMENT ON
	20

1	THE TIMING SPECIFICALLY THAT WE WOULD HAVE UNDER THE
2	LEGISLATION, WHEN WE'D HAVE TO COMMISSION THE STUDY
3	AND THE TIME WE'D HAVE TO COMPLETE ANOTHER STUDY TO
4	BE CONSISTENT WITH THE LEGISLATION, THAT WOULD BE
5	HELPFUL TO US.
6	MR. HARRISON: SURE. WHAT CHAIRMAN KLEIN
7	IS REFERRING TO A PROVISION IN SB 1064 WHICH THE
8	BOARD ENDORSED AT A MEETING EARLIER THIS MORNING AND
9	WHICH WOULD REQUIRE CIRM TO COMMISSION AN
10	INDEPENDENT PERFORMANCE AUDIT OF ITS OPERATIONS ONCE
11	EVERY THREE YEARS BEGINNING IN THE FISCAL YEAR
12	2010-2011. THERE'S NO DEADLINE FOR THE COMPLETION
13	OF THAT PERFORMANCE REVIEW. AND THE PERFORMANCE
14	REVIEW IS NOT REQUIRED TO INCLUDE A REVIEW OF
15	SCIENTIFIC PERFORMANCE. IT IS REQUIRED TO INCLUDE A
16	REVIEW OF THE OPERATIONS OF THE AGENCY, ITS BEST
17	PRACTICES, AND A REVIEW TO DETERMINE WHETHER OR NOT
18	THE AGENCY IS COMPLYING WITH ITS OWN POLICIES AND
19	PROCEDURES.
20	THE EXTERNAL AUDIT THAT VICE CHAIR TORRES
21	REFERRED TO A MOMENT AGO IS SPECIFIED IN THE
22	SCIENTIFIC STRATEGIC PLAN, WHICH WAS FIRST ADOPTED
23	IN 2006 AND LATER UPDATED, WHICH CALLS FOR AN
24	EXTERNAL REVIEW WHICH IS SCHEDULED TO OCCUR THIS
25	FALL AND TO BE CONCLUDED BY DECEMBER, I UNDERSTAND.
	40

1	MR. KLEIN: MR. HARRISON, WOULD YOU
2	INDICATE THAT IF WE DO NOT SELECT AN EXTERNAL AUDIT
3	TO SATISFY THE LEGISLATION, COULD YOU EXPLAIN THE
4	BUREAU OF STATE AUDITS POWER AT THAT POINT?
5	MR. HARRISON: I'M SORRY. COULD YOU
6	REPEAT THE QUESTION?
7	MR. KLEIN: UNDER THE LEGISLATION WE HAVE
8	THE REQUIREMENT THAT WE EITHER CHOOSE THE BUREAU OF
9	STATE AUDITS, THE STATE AGENCY THAT PREVIOUSLY
10	AUDITED US, OR WE HAVE THE OPTION OF CHOOSING AN
11	EXTERNAL ENTITY LIKE THE IOM; IS THAT CORRECT?
12	MR. HARRISON: YES. THE BILL SPECIFIES
13	THAT THE AGENCY HAS THE AUTHORITY TO RETAIN AN
14	OUTSIDE ORGANIZATION TO CONDUCT THIS PERFORMANCE
15	REVIEW, AND IT MENTIONS THAT THAT COULD BE DONE BY
16	THE BUREAU OF STATE AUDITS, BUT IT DOESN'T TIE THE
17	AGENCY'S HANDS. THAT IS, CIRM WOULD BE FREE TO
18	SELECT ANOTHER OUTSIDE REVIEWER PROVIDED THAT THEY
19	CONDUCT THE REVIEW PURSUANT TO GOVERNMENT AUDITING
20	STANDARDS.
21	CHAIRMAN SHEEHY: DR. PIZZO.
22	DR. PIZZO: THANK YOU, JEFF. JUST A
23	COUPLE OF COMMENTS. THERE MAY BE OTHERS ON THE CALL
24	WHO ARE IN THE SAME SITUATION, BUT JUST FOR A LITTLE
25	BIT OF BACKGROUND, I HAVE BEEN A MEMBER OF THE IOM
	41
	1 1

1	FOR MANY YEARS NOW. AND I ACTUALLY WAS CHAIR OF THE
2	HEALTH SCIENCE POLICY BOARD FOR SOME PERIOD AND A
3	MEMBER OF THE COUNCIL OF THE IOM NOW. AND I WOULD
4	SAY THAT THE ATTRIBUTES THAT YOU DESCRIBED ARE
5	CERTAINLY APPROPRIATE. IT IS ONE OF THE VERY FEW
6	TRULY INDEPENDENT AUTHORITIES. AND REALLY THAT IS
7	ONE OF THE MOST EXTRAORDINARY PARTS OF THE ROLE THAT
8	IT PLAYS. IT DOES BRING TOGETHER LEADING FIGURES TO
9	LOOK AT AN IMPORTANT QUESTION.
10	THE TWO CAVEATS THAT I THINK NEED TO BE
11	PUT FORTH, AND THESE ARE DETAILS, BUT THEY'RE
12	RELEVANT. ONE IS THAT IT TAKES TIME. THE IOM IS
13	DELIBERATIVE AND DELIBERATE, METHODICAL, BUT NOT THE
14	MOST RAPIDLY MOVING OF ORGANIZATIONS. SO STUDIES
15	WHEN COMMISSIONED ARE NOT OFTEN DONE RAPIDLY. AND
16	THAT IS ONE FACTOR.
17	THE SECOND IS IT ALMOST INVARIABLY
18	REQUIRES SOME EXTERNAL SOURCE OF FUNDING FOR A WORK
19	GROUP OR EVALUATION OR STUDY TO BE DONE. SO THERE
20	WOULD NEED TO BE SOME CONSIDERATION AS TO WHERE THAT
21	WOULD COME FROM IF THE IOM WAS GOING TO BE INVOLVED.
22	THIRDLY, ALTHOUGH THERE ARE MANY WAYS OF
23	GAINING ENTRY, I'D BE HAPPY TO HELP FACILITATE THIS
24	IF THERE'S A DECISION TO GO FORWARD. BUT I THINK
25	THE ICOC NEEDS TO BE, A, AWARE OF THE TIME ISSUE

1	AND, B, THE EXPECTATION OF COVERING COST, BUT ALSO
2	OBVIOUSLY THE BENEFIT THAT COMES FROM A TRULY
3	INDEPENDENT AND CAREFULLY CALIBRATED REVIEW.
4	MR. KLEIN: ABSOLUTELY ALL OF YOUR POINTS
5	I'M IN TOTAL AGREEMENT WITH. DR. HARVEY FEINBERG I
6	TALKED TO STARTING ABOUT A YEAR AGO AND DR. TROUNSON
7	ABOUT. GIVEN THE COST LEVELS AT THE IOM, DISCUSSION
8	HAS BEEN TO TRY AND FIND AN OUTSIDE FUNDING SOURCE
9	TO CONTRIBUTE APPROXIMATELY HALF OR A LITTLE BIT
10	MORE THAN HALF OF THOSE COSTS. BUT THE AGENCY WOULD
11	STILL HAVE A COST OF FOUR TO \$500,000 ONCE EVERY
12	THREE YEARS IF THEY CHOSE TO REPEAT THIS REVIEW WITH
13	THE IOM.
14	THE KEY HERE IS THAT, AS I DISCUSSED THIS
15	WITH DR. PENHOET, IT COULD TAKE 18 MONTHS, IT COULD
16	TAKE TWO YEARS BECAUSE ALL OF THE PEOPLE ON THE
17	PANELS HAVE MANY OTHER IMPORTANT THINGS TO DO. AND
18	WE MUST ONLY COMMISSION IT UNDER THE LEGISLATION.
19	THE FACT THAT IT TAKES TIME TO ACCOMPLISH
20	APPROPRIATELY WITH THE INDEPENDENCE THAT'S SO
21	IMPORTANT IS NOT AN IMPOSITION OF THE LEGISLATION.
22	IN TERMS OF POSITIONING THE AGENCY FOR FUTURE BOND
	IN TERMS OF POSTITONING THE AGENCY FOR FUTURE DOND
23	AUTHORIZATION, IF IT WERE DONE IN TWO YEARS AND IF
23 24 25	AUTHORIZATION, IF IT WERE DONE IN TWO YEARS AND IF

1	THAT BLUE RIBBON INDEPENDENT VALIDATION COULD BE A
2	VERY, VERY VALUABLE ASSET TO THE PUBLIC, TO THE
3	TRANSPARENCY FOR THE LEGISLATURE, AND FOR THE BOARD.
4	IF IT'S POSSIBLE THEY WOULD RECOMMEND,
5	WITHIN THE CONFINES OF THE INITIATIVE AND STATUTORY
6	AUTHORITY, SOME REFINEMENTS COULD GIVE US THE TIME
7	TO CONSIDER THOSE THOUGHTFULLY AND ADOPT THEM. BUT
8	BEFORE THE NEXT THREE-YEAR AUDIT WOULD BE REQUIRED,
9	WE WOULD HAVE TO HAVE THE PUBLIC VOTE ON THE BOND
10	ISSUE. SO THIS IS REALLY, GIVEN THE LEAD-TIME, OUR
11	OPPORTUNITY TO UNDERTAKE A VERY SERIOUS INDEPENDENT
12	STUDY, HAVE IT FINISHED IN TIME THAT THE PUBLIC CAN
13	ANALYZE IT BEFORE WE GO BACK AND PUT FORTH THE
14	QUESTION ABOUT WHETHER WE'RE ENTITLED TO MORE BONDS
15	OR THE PUBLIC WOULD LIKE TO GIVE US THE PRIVILEGE OF
16	DEALING WITH MORE BONDS.
17	DR. PIZZO: RIGHT. I THINK THAT'S
18	IMPORTANT. FOR THOSE WHO DON'T KNOW, THE PERSON
19	THAT BOB REFERRED TO, HARVEY FEINBERG, IS THE
20	PRESIDENT OF IOM. AND I WOULD SAY THAT OF ANY
21	ORGANIZATION THAT I'M FAMILIAR WITH ON A NATIONAL
22	LEVEL, THERE ISN'T ANY OTHER THAT CARRIES THE WEIGHT
23	OF INDEPENDENCE AND CRITICAL REVIEW THAN THE IOM AND
24	THE NATIONAL ACADEMY OF SCIENCES.
25	MR. KLEIN: AND, AGAIN, I'D LIKE THE
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1	OPPORTUNITY WITH THE VICE CHAIRS OF THE PEER REVIEW
2	GROUP AND WITH THE VICE CHAIRS OF THE BOARD,
3	CONSULTING WITH OTHER INDIVIDUAL BOARD MEMBERS, TO
4	TRY AND WORK WITH THE SCIENTIFIC STAFF AND DR.
5	TROUNSON AND THE SCIENTIFIC LEADERSHIP IN THE AGENCY
6	TO TRY AND CREATE A HIGHLY ARTICULATED, MORE HIGHLY
7	ARTICULATED OUTLINE OF THE SCOPE WORKING WITH JAMES
8	HARRISON AND SCOTT TOCHER AND ELONA BAUM AND IAN
9	SWEEDLER AS WELL ON THE LEGAL SIDE TO KIND OF
10	DESCRIBE THE SCOPE OF THIS AND WORKING ON THE BUDGET
11	ISSUES SO THAT WHEN IT COMES TO THE BOARD, WE HAVE
12	THE DETAILS BEHIND THE CONCEPT AVAILABLE.
13	MS. SAMUELSON: QUESTION. THIS IS JOAN.
14	I GUESS I HAVE A QUESTION FOR THE MAKERS OF THE
15	MOTION IN TERMS OF WHAT THEY ACTUALLY ARE TRYING TO
16	ACCOMPLISH WITH THIS. AND IT MAY BE THAT IT IS TO
17	SERVE THE NEEDS FOR SOME OF THE SUBPARTS OF OUR
18	MISSION, SUCH AS HAVING OUR BOND FINANCING IN PLACE
19	AND SO ON. AND IF IT'S TO HAVE BLUE RIBBON KIND OF
20	APPROVAL OF OUR MECHANISMS OF THOSE VARIOUS SUBSETS
21	THAT I'M SEEING IN NO. 4, LIKE OUR FINANCIAL
22	STRUCTURE, OUR ORGANIZATIONAL STRUCTURE, AND SO ON,
23	MAYBE IT DOESN'T MATTER. SPEED ISN'T AS IMPORTANT
24	AND MAYBE IT'S NOT IN CONFLICT WITH THE WORK OF THE
25	STRATEGIC PLAN COMMITTEE.

1	BUT IF THERE'S ANY INTENTION FOR THIS TO
2	ALSO GUIDE US IN FIGURING OUT WHETHER WE ARE
3	STRUCTURED TO SPEND THE \$3 BILLION AS EFFECTIVELY AS
4	POSSIBLE AND TO SERVE THE GOALS OF OUR MISSION, THAT
5	IS, TO GET CURES AS SOON AS IT'S HUMANLY POSSIBLE,
6	THEN MAYBE THIS ISN'T THE RIGHT MECHANISM. SO
7	THAT'S MY QUESTION, I GUESS.
8	MR. KLEIN: SO, JEFF, COULD I ASK JOAN A
9	QUESTI ON?
10	CHAIRMAN SHEEHY: SURE. BE MY GUEST.
11	MR. KLEIN: SO WHY WOULDN'T IT BE THE
12	RIGHT MECHANISM TO HELP US LOOK AT OUR STRUCTURE AND
13	SEE IF IT'S THE MOST EFFECTIVE PROCESS WITHIN THE
14	INITIATIVE CONSTRAINTS TO MOVE THERAPIES FORWARD AS
15	SAFELY AND RAPIDLY AS POSSIBLE?
16	MS. SAMUELSON: WELL, BECAUSE IF WE ARE
17	NOT DOING THIS RIGHT NOW, I WANT TO KNOW THAT SOONER
18	THAN TWO YEARS FROM NOW.
19	MS. KING: LET ME JUST SEE IF I CAN
20	CLARIFY, BOB. I THINK YOU MISUNDERSTOOD JOAN'S
21	QUESTION. WHAT SHE'S SAYING IS SHE DOESN'T SEE IN
22	THE DESCRIPTION OF THE ITEM THAT THAT WOULD BE PART
23	OF THE REVIEW. AND SHE'S SAYING THAT IF IT'S NOT
24	PART OF THE REVIEW, MAYBE THIS ISN'T THE RIGHT
25	REVIEW TO DO. AM I CORRECT, JOAN?
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1	MS. SAMUELSON: ACTUALLY IT DEPENDS ON
2	WHAT THE MAKERS OF THE MOTION ARE TRYING TO
3	ACCOMPLI SH.
4	MR. KLEIN: JOAN, THERE'S TWO PRINCIPAL
5	OBJECTIVES HERE. ONE IS TO FULFILL THE TRANSPARENCY
6	AND PUBLIC INSIGHTS TO AN EVALUATION THAT THE VOTERS
7	AND THE LEGISLATURE DESERVE AND THE LEGISLATION IS
8	CALLING FOR. AND SECONDLY, TO GIVE US AN
9	INDEPENDENT EVALUATION THAT VOTERS CAN LOOK TO IN
10	CONSIDERING FUTURE BOND AUTHORITY. WHILE I THINK
11	THAT THE REVIEW OF THE SCIENTIFIC STRATEGIC PLAN IS
12	POPULATED BY TREMENDOUS INDIVIDUALS THAT HAVE GREAT
13	CREDENTIALS AND CAN PROVIDE TREMENDOUS VALUE, THE
14	VOTERS IT'S HARD TO TRANSLATE THAT REPORT'S
15	FINDINGS TO THE VOTERS BECAUSE IT DOESN'T HAVE
16	INDEPENDENT NATIONAL PRESTIGE AND REPUTATION.
17	SO YOU CAN'T JUST KIND OF READ OFF TO THE
18	VOTERS THE CREDENTIALS OF EACH MEMBER OF THE
19	SCIENTIFIC STRATEGIC PLAN, BUT THE VOTERS ARE AWARE
20	BROADLY OF THE NATIONAL ACADEMY OF SCIENCE AND
21	INSTITUTE OF MEDICINE. AND CERTAINLY CHAMBERS OF
22	COMMERCE AND OTHER LEADERSHIP GROUPS ARE AWARE OF
23	THAT GROUP, SO THERE'S AN ABILITY TO LOOK AT THEIR
24	FINDINGS AND RECOMMENDATIONS AND THE VOTERS TAKE
25	SOME COMFORT THAT WE'RE ON THE RIGHT COURSE.
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1	CHAIRMAN SHEEHY: AND, JOAN, FROM MY
2	PERSPECTIVE, I THINK WHAT YOU'RE LOOKING FOR IS AN
3	UPDATE ON THE STRATEGIC PLAN. I THINK THAT'S
4	MANDATED IN PROP 71 THAT THE BOARD UPDATE THE
5	STRATEGIC PLAN. THE PRESIDENT HAS STARTED A
6	PROCESS. WE'VE HAD ONE UPDATE TO THE STRATEGIC
7	PLAN. I THINK THAT I THINK YOU'RE RIGHT. THESE
8	ARE TWO DIFFERENT THINGS. I THINK WE HAVE AN
9	OBLIGATION FOR SOME ACCOUNTABILITY TO THE VOTERS AND
10	FOR A TOTAL OBJECTIVE ANALYSIS OF WHERE WE ARE, WHAT
11	WE'VE DONE. IT MAY BE INFORMATIVE AND IT MOST
12	LIKELY WILL BE INFORMATIVE IN TERMS OF GOING
13	FORWARD; BUT FOR THE IMMEDIATE ISSUES IN TERMS OF
14	WHAT WE SHOULD BE DOING NEXT STRATEGICALLY, I THINK
15	THAT THAT IS A SEPARATE DISCUSSION.
16	MR. TORRES: MR. CHAIRMAN, I JUST WANT TO
17	BE VERY CLEAR WHAT MY POSITION IS. AND THAT IS THAT
18	I SUPPORT IN CONCEPT MR. SHEEHY'S MOTION OR CONCEPT.
19	BUT I ALSO WANT TO MAKE CLEAR THAT IN
20	REPRESENTATIONS THAT I MAKE TO THE LEGISLATURE,
21	BECAUSE OF THEIR CONCERNS OF THE COST FACTORS AND
22	HOW WE ARE SPENDING MONEY OR NOT SPENDING MONEY, I
23	MADE IT VERY CLEAR TO THEM THAT WE WANT TO HAVE AS
24	TIGHT A BUDGET AS POSSIBLE, NO. 1.
25	NO. 2, IN RESPONSE TO THE CONCERN THAT WE

1	SHOULD HAVE A PERFORMANCE AUDIT, A SCIENTIFIC
2	PERFORMANCE AUDIT, I ALWAYS FELL BACK AND SAID THAT
3	OUR PRESIDENT WAS PURSUING A REVIEW OF OUR STRATEGIC
4	PLAN BASED ON SCIENTIFIC REVIEW BY SOME OF THE BEST
5	IN THE WORLD TO COME BACK TO US AND TO THE PUBLIC
6	AND TO THE LEGISLATURE AS TO HOW WE ARE PROCEEDING.
7	WHAT I DON'T WANT TO SEE IS TO HAVE THEN
8	TWO AUDITS, IOM AND THEN THE LEGISLATIVE RESPONSE,
9	BECAUSE WE'RE TALKING ABOUT 800,000 AT THAT POINT,
10	400 WHICH IT COST US IN '06, 200,000, 200,000 FROM
11	THE STATE BOARD OF AUDITS, THAT'S IN '06 MONEY,
12	400,000. NOW I'M HEARING THAT THIS MAY REQUIRE US
13	TO PUT FORWARD ANOTHER 400,000. THAT'S GETTING
14	CLOSE TO A MILLION BUCKS ON AUDITS. SO WE NEED TO
15	EXPLORE TO SEE WHETHER THE IOM CAN FULFILL THE
16	LEGISLATIVE INTENT THAT WE PUT INTO 1064, WHICH
17	REQUIRES US TO PETITION FOR AN AUDIT. IT DOESN'T
18	PUT A TIMEFRAME ON COMPLETION. SO DR. PIZZO'S
19	REMARKS THAT IT MIGHT TAKE TWO YEARS WOULD BE
20	APPROPRIATE UNDER THE LEGISLATION AS YOU AND I HAVE
21	READ IT AND SO OPINED.
22	SO I JUST WANT TO MAKE SURE THAT IF WE
23	MOVE IN THE DIRECTION OF THE LOM, THAT THAT
24	DIRECTION ENCOMPASSES THE MANDATE WITHIN THE
25	LEGISLATION SO WE'RE NOT CAUGHT IN THE PUBLIC VIEW

1	THAT WHY ARE YOU DOING TWO AUDITS.
2	DR. FONTANA: ART, COULD YOU PLEASE
3	CLARIFY THAT FOR ME? DID YOU SAY THAT THERE IS A
4	SCIENTIFIC PERFORMANCE AUDIT ALREADY UNDERGOING?
5	MR. TORRES: NO. NO. WHAT I SAID WAS
6	THAT PROPOSITION 71 REQUIRES US TO HAVE A STRATEGIC
7	REVIEW OF HOW WE'RE DOING. I INTERPRETED THAT, AND
8	CORRECT ME IF I'M WRONG BECAUSE I'M A LAYPERSON
9	HERE, I INTERPRETED THAT TO MEAN THAT THAT'S REALLY
10	A SCIENTIFIC PERFORMANCE REVIEW, NOT AN AUDIT, A
11	REVIEW OF HOW WE'RE DOING STRATEGICALLY AS MANDATED
12	BY PROP 71. AND THE PRESIDENT HAS BEGUN TO
13	IMPLEMENT, THAT WE WILL ANNOUNCE THE CHAIR AND THE
14	FINAL MEMBERSHIP TO THE LEGISLATURE WHEN I RECEIVE
15	SUCH.
16	BUT THE SECOND ISSUE IS THAT IN OUR
17	NEGOTIATIONS ON SENATE BILL 1064, WE MINIMIZED AND
18	REALLY STREAMLINED THE EFFORT TO HAVE AN AUDIT THAT
19	WE COULD COMMISSION THE AUDITORS ON AS LONG AS IT
20	COMPLIED WITH STATE MANDATED REQUIREMENTS. IT COULD
21	BE BSA, IT COULD BE SOMEBODY ELSE. IT COULD BE THE
22	IOM. I JUST WANT TO MAKE SURE THAT IN PETITIONING
23	THIS CONCEPT, THAT IF WE'RE GOING TO MOVE IN THE IOM
24	DIRECTION, WHICH I'M NOT OPPOSED TO, BUT ONLY IF IT
25	INCLUDES THE MANDATE THAT WE'RE TALKING ABOUT SO WE

1	JUST HAVE ONE. THAT'S ALL I'M SAYING.
2	MR. KLEIN: MY INTENTION INCLUDING THE
3	REFERENCE EARLIER WORKING WITH THE SCIENTIFIC STAFF
4	AND ALL OF THE COUNSEL TO THE BOARD AND THE
5	ORGANIZATION WAS TO MAKE CERTAIN THAT, IN FACT, THIS
6	IS MEETING THE LEGISLATIVE REQUIREMENTS. THE
7	INITIAL DISCUSSIONS THAT I'VE HAD WITH MR. HARRISON
8	ARE THAT THIS SHOULD MEET THE REQUIREMENTS. THERE
9	IS SPECIFIC LANGUAGE I WANT TO CHECK ON WHICH SAYS
10	ACCORDING TO GOVERNMENT AUDITING STANDARDS, AND I
11	WANT TO MAKE SURE THAT LANGUAGE DOESN'T HAVE SOME
12	PARTICULAR SENSITIVITY AS RELATES TO THE IOM. MY
13	INTENTION OF THIS MOTION IS TO BRING IT FORWARD WITH
14	A LEGAL REVIEW OF THOSE ISSUES AS WELL AS A BUDGET
15	AND AN OUTLINE OF SCOPE.
16	MR. TORRES: ON THAT FINAL POINT, I JUST
17	WANT TO MAKE CLEAR WHERE I'M COMING FROM. NO. 1,
18	THE REPRESENTATIONS THAT I PERSONALLY MADE AS WELL
19	AS OTHERS TO THE LEGISLATURE, THAT WE ARE VERY COST
20	CONSCIOUS AND WE HAVE BEEN, WE HAVE BEEN, NO. 1.
21	AND NO. 2, BEING HERE DAY TO DAY I ALSO SEE THE
22	TREMENDOUS WORKLOAD ON OUR SCIENTIFIC STAFF. AND
23	THE LAST THING I WANT TO SEE IS THEM DOING ANOTHER
24	AUDIT THAT THEY DON'T HAVE TO DO IF WE CAN MAKE SURE
25	THAT WE PROGRAM YOUR CONCEPT WITHIN THE LEGISLATIVE

1	MANDATE FOR AN AUDIT.
2	MR. KLEIN: EXACTLY THE INTENT OF THE
3	MOTION.
4	MR. TORRES: ALL RIGHT.
5	DR. FONTANA: I GUESS I HAVE TWO
6	QUESTIONS. IS IT POSSIBLE I THINK THE IOM IS A
7	GREAT STAMP OF APPROVAL. THERE'S NO DOUBT. CAN WE
8	INCREASE THE COMPREHENSION OF THAT IOM REVIEW OF US
9	TO INCLUDE AT THAT TIME HOW THE SCIENCE WORKING
10	GROUP IS DOING?
11	AND A SEPARATE NOTE, I THINK WHAT JEFF WAS
12	ADDRESSING AND JOAN'S CONCERNS WERE IS WE WANT SOME
13	INDEPENDENT REVIEW NOW SO THAT IN THE EVENT THAT WE
14	ARE DOING SOMETHING LESS EFFICIENT THAN WE COULD BE
15	DOING, THAT WE CAN MAKE ALTERATIONS NOW, NOT IN TWO
16	YEARS FROM NOW, BECAUSE OF OUR FIDUCIARY
17	RESPONSIBILITY AND OUR TRYING TO MEET OUR GOALS.
18	MR. KLEIN: THIS IS BOB, DR. FONTANA. TO
19	PROVIDE FURTHER CLARITY TO YOUR PRIOR QUESTION, AS
20	MANDATED BY THE STRATEGIC PLAN, THERE IS A
21	SCIENTIFIC STRATEGIC PLAN REVIEW THAT'S IN PROCESS
22	THAT WILL BE CONCLUDED BY THE END OF THIS YEAR,
23	WHICH INVOLVES THE SCIENTIFIC STAFF AND INVOLVES
24	INTERVIEWING BOARD MEMBERS AS TO THE SCIENTIFIC
25	ISSUES. AND SO WE WILL ESSENTIALLY BE GETTING AN

1	INTERIM FEEDBACK ON THE SCIENTIFIC PLAN AND COULD
2	ADDRESS ISSUES LIKE THE PEER REVIEW, INCLUDING ITEMS
3	LIKE THIS NEW INITIATIVE FOR ADDITIONAL TRANSPARENCY
4	ON SCORES. THAT INTERIM FEEDBACK THERE, SEPARATE
5	FROM THE LEGISLATIVE MANDATE AUDIT ON THE OVERALL
6	OPERATIONS OF THE AGENCY, THAT WILL BE LATER.
7	DR. FONTANA: RI GHT.
8	CHAIRMAN SHEEHY: JEANNIE, I DO THINK THAT
9	THE IOM STUDY WOULD LOOK AT THE SCIENTIFIC WORKING
10	GROUP AMONGST OTHER THINGS.
11	DR. FONTANA: THAT WOULD BE GREAT. SO I
12	THINK MY CONCERNS ARE ADDRESSED IF, BOB, YOU'RE
13	SUGGESTING THAT WE WOULD GET SOME INTERIM FEEDBACK
14	NOW OR THE END OF THE YEAR THAT WE COULD MAKE
15	ADJUSTMENTS GOING FORWARD. AND THEN THE IOM STUDY
16	COMES IN IN TWO YEARS, THAT MAKES A LOT OF SENSE.
17	JOAN, I DON'T KNOW HOW YOU FEEL ABOUT THAT.
18	DR. PENHOET: INTERIM COMING FROM WHERE?
19	MR. KLEIN: THE INTERIM IS THE SCIENTIFIC
20	STRATEGIC PLAN REVIEW.
21	DR. PENHOET: THAT'S ALREADY IN PROGRESS,
22	RI GHT.
23	MR. KLEIN: EXACTLY.
24	DR. TROUNSON: I JUST HAVE A FEW CONCERNS
25	IN LISTENING TO THIS. ONE OF THEM IS REALLY ON
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1	ART'S POINT. IF IT'S GOING TO TAKE SOME TIME FOR
2	THIS OPERATION TO PERFORMANCE AUDIT, WHICH I THINK
3	THEY GENUINELY REQUESTED FROM THE LEGISLATURE, NO.
4	1, IS THIS THE BEST GROUP TO DO THAT? THESE ARE
5	CLINICIANS AND SCIENTISTS, SO THEY'RE PRIMARILY
6	CLINICIANS. SO WOULD THEY BE THE BEST GROUP TO DO
7	THIS, AND WOULD THE STATE LEGISLATURE FEEL THAT
8	THEIR REQUIREMENTS FOR AN ACTUAL PERFORMANCE AUDIT,
9	NOT SCIENCE, HAS REALLY BEEN DEALT WITH?
10	BECAUSE I THINK THE THOUGHT IS HERE THAT
11	IF WE GET MIXED UP IN THE TWO, WE ARE GOING TO HAVE
12	BASICALLY AN EXTERNAL REVIEW COMING UP WHICH IS
13	GOING TO DEMAND A LOT OF TIME. AND I THINK WHATEVER
14	AUDIT PROCESS DOES TAKE A LOT OF STAFF TIME, A LOT
15	OF IN-DEPTH WORK WITH WHOEVER IS DOING THE AUDIT.
16	OF COURSE, IF YOU'RE GOING TO DO A PROGRAM WITH THE
17	IOM, PARTICULARLY TO GET THE DEPTH TO BE PERSUASIVE
18	TO THE COMMUNITY THAT IT'S WORTH TAKING CIRM ON
19	AGAIN FOR ANOTHER TRANCHE, THAT'S GOING TO BE A VERY
20	DEEP, I THINK A VERY DEEP AND TIME-CONSUMING
21	PROCESS.
22	SO I JUST WANT TO MAKE SURE THAT WE DON'T
23	GET MIXED UP IN THE REQUIREMENTS. AND I THINK THE
24	POINT HAS TO BE VERY STRONGLY THAT THE PERFORMANCE
25	AUDIT HAS TO BE DEALT WITH WITHIN THE TIMEFRAME THAT

1	THE LEGISLATURE IS REQUESTING. THEY MIGHT HAVE
2	SAID THEY'VE SAID THAT WE HAVE TO DO IT IN
3	2010-11.
4	MR. TORRES: WE HAVE TO BEGIN.
5	DR. TROUNSON: TO PUT IT OFF FOR TWO AND A
6	HALF YEARS, SO I THINK WE HAVE TO ACTUALLY GET THAT
7	DONE. AND WE HAVE TO MAKE SURE THAT WHOEVER IS
8	DOING IT WILL DO IT APPROPRIATELY SO THAT WE DON'T
9	HAVE TO REDO IT AGAIN.
10	CHAIRMAN SHEEHY: I ACTUALLY THINK THAT
11	THE WAY MEMBER TORRES POSED THIS IS APPROPRIATE, AND
12	I THINK WE CAN COME BACK WITH AN IOM REPORT THAT
13	ENCOMPASSES BOTH ASPECTS. I PERSONALLY COULD NOT
14	REPRESENT TO ANY MEMBER OF THE LEGISLATURE THAT WE
15	ARE SPENDING OUR MONEY WISELY WITHOUT THE IMPRIMATUR
16	OF AN INDEPENDENT SCIENTIFIC EVALUATION OF THE WORK
17	WE'VE DONE. WHAT WE PRODUCE I WILL NOT REPRESENT TO
18	ANY MEMBER OF THE PUBLIC, TO THE PRESS, TO ANY
19	MEMBER OF THE LEGISLATURE IS OF ANY VALUE UNLESS I
20	GET AN INDEPENDENT IMPRIMATUR.
21	MR. TORRES: THERE'S NO DISAGREEMENT
22	THERE. WE JUST WANT TO MAKE SURE THAT WE FULFILL
23	THE IMPACT OF THE LEGISLATION WITHOUT DUPLICATING.
24	MR. KLEIN: THIS IS SPECIFICALLY AN INTENT
25	TO MAKE SURE THAT THIS FITS THE LEGISLATIVE

1	REQUIREMENTS, AND WE HAVE TO COMMISSION IT BY THE
2	END OF THIS YEAR OR IN 2011, SO THE TIMEFRAME FOR
3	WORKING ON THE STRATEGIC SCIENTIFIC PLAN REVIEW IS A
4	SEPARATE TIMEFRAME FROM THE IOM BECAUSE THE IOM WILL
5	TAKE, AS DR. PENHOET AND DR. PIZZO AND OTHERS KNOW,
6	WILL TAKE A NUMBER OF MONTHS TO CONSTITUTE THEIR
7	ACTUAL REVIEW COMMITTEE, MAYBE EVEN FIVE OR SIX
8	MONTHS. THE TIMEFRAME WILL NOT OVERLAP, WILL NOT
9	CREATE A BURDEN ON THE STAFF IN 2010 WHEN WE'RE
10	TRYING TO COMPLETE THE SCIENTIFIC STRATEGIC PLAN
11	REVI EW.
12	CHAIRMAN SHEEHY: I REALLY LIKE I SAID,
13	I SEE THEM AS BEING COMPLEMENTARY. YOU WOULD HAVE
14	THE ONE ALREADY COMPLETED, WHICH COULD SERVE AS AN
15	EXCELLENT BASIS FOR THE INITIATION OF THE SECOND.
16	AND IT'S HARD FOR ME TO SEE THE LEGISLATURE WOULD
17	OBJECT TO A BODY THAT IS COMMISSIONED TO DO
18	PRECISELY THESE TYPES OF EXAMINATIONS BY CONGRESS
19	AND BY FEDERAL AGENCIES. I THINK THAT THIS
20	SHOULDN'T BE TOO HARD OF A STRETCH TO MAKE THIS
21	BECOME THE PERFORMANCE AUDIT THAT THE LEGISLATURE
22	WOULD FEEL COMFORTABLE WITH.
23	MR. TORRES: THAT'S WHAT WE HAVE TO
24	EXPLORE, AND I THINK WE HAVE ROOM TO DO THAT.
25	CHAIRMAN SHEEHY: WE HAVE THE ROOM TO DO
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1	THAT. SO DO WE HAVE OTHER COMMENTS?
2	MS. SAMUELSON: THIS IS JOAN. IN RESPONSE
3	TO JEANNIE'S QUESTION. I GUESS IT SEEMS TO ME THE
4	QUESTION IS WHAT THE QUESTIONS ARE WE'RE GOING TO BE
5	ASKING THEM TO EXPLORE. IF THEY LOOK AT THE GRANTS
6	THAT WE'VE FUNDED AND THE SCIENCE THAT IT'S PRODUCED
7	AND ASK ARE THEY WELL CONCEIVED AND HAVE THEY
8	EXPLORED IMPORTANT QUESTIONS AND HAVE THEY PRODUCED
9	IMPORTANT DATA, ARE THEY PUBLISHED IN THE RIGHT
10	JOURNALS, ARE THEY MOVING THINGS ALONG, THAT MIGHT
11	GET A LOT OF WONDERFUL FEEDBACK, BUT IT MAY NOT, IN
12	FACT, BE THE QUESTION THAT I THINK WE ALSO NEED TO
13	BE ASKING, WHICH IS IS THE MONEY WE'RE PUTTING INTO
14	GRANTS GOING TO FUND THE WORK THAT IS AT THE MOST
15	RAPID PACE POSSIBLE, NOT FASTER, BUT AT THE MOST
16	RAPID PACE POSSIBLE, FUNDING WORK THAT IS PRODUCING
17	HYPOTHESIS-DRIVEN EXPERIMENTS THAT ARE GOING TO
18	RESULT IN BREAKTHROUGHS THAT ARE GOING TO TELL THE
19	PHARMACEUTICAL COMMUNITY, LET'S SAY, OR THE BIOTECH
20	COMMUNITY WHAT TO PRODUCE THAT WILL, IN FACT, HAVE
21	CURATIVE INVENTIONS AT SOME REASONABLE POINT IN THE
22	FUTURE. THAT'S WHAT WE'VE PROMISED.
23	AND THAT SEEMS TO ME TO BE A DIFFERENT SET
24	OF QUESTIONS POTENTIALLY. AND MAYBE QUESTIONS WOULD
25	BE ASKED TO THE IOM OR MAYBE THE LATTER ONES WOULD,

1	I DON'T KNOW. I'D LIKE TO HEAR MORE ABOUT WHO WOULD
2	BE ANSWERING THEM.
3	MR. KLEIN: JOAN, THIS IS BOB KLEIN. IN
4	MAKING THE MOTION, I SPECIFICALLY REFERENCED WORKING
5	WITH BOTH VICE CHAIRS OF THE WORKING GROUP IN
6	ADDITION TO THE LEADERSHIP OF THE SCIENTIFIC STAFF
7	AND DR. TROUNSON AND OUR LEGAL COUNSEL AND OTHER
8	BOARD MEMBERS WITH QUESTIONS SO WE COULD REFINE THE
9	SCOPE. AND I'M GOING TO BE ASKING YOU FOR YOUR
10	CONTRIBUTION, WHICH YOU JUST MADE ON THE RECORD, FOR
11	WHAT THE PROPER SCOPE SHOULD BE, IN ADDITION TO
12	OTHER BOARD MEMBERS. AND THEN WE WILL, OF COURSE,
13	HAVE A FULL DISCUSSION AT THE BOARD MEETING ON THE
14	PROPOSED SCOPE.
15	MS. SAMUELSON: IS THIS QUESTION, THEN,
16	GOING TO BE A PART OF THAT BECAUSE THAT SOUNDS
17	GREAT, BOB. BUT IF IN VOTING FOR THIS, WE WILL HAVE
18	SELECTED, IN EFFECT, THE IOM AS THE APPROPRIATE
19	GROUP AND THE STUDY AS DESCRIBED IN THE MOTION, THAT
20	MAY FEEL PREMATURE.
21	MR. KLEIN: UNTIL THE BOARD VOTES ON IT,
22	THIS IS JUST A RECOMMENDATION TO THE BOARD WITH A
23	PROCESS FOR INPUT BEFORE IT GETS TO THE BOARD.
24	CHAIRMAN SHEEHY: EXACTLY, JOAN.
25	MS. SAMUELSON: OKAY. IF THE MOTION IS
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1	UNDERSTOOD THAT WAY, I THINK THIS IS A VERY
2	IMPORTANT THING TO BE DISCUSSING.
3	CHAIRMAN SHEEHY: WELL, THIS COMMITTEE
4	CAN'T BE THE FINAL ACTOR. IT HAS TO GO TO THE
5	BOARD.
6	MS. SAMUELSON: SURE. WE WANT TO KNOW
7	WHAT IT IS WE THINK WE WANT THEM TO DO. AND I THINK
8	THIS IS AN IMPORTANT AREA TO EXPLORE AND TO DO IT
9	RIGHT NOW AND THAT WE SHOULD BE STUDYING THE VARIOUS
10	OPTIONS. I'M NOT I HAVEN'T HEARD ANYTHING THAT
11	TELLS ME WHETHER THE IOM APPROACH IS THE RIGHT ONE.
12	I'M HEARING SOME POTENTIAL CONFLICT BETWEEN THE
13	NECESSITY OF SPEED AND THEIR PROCESS IN TERMS OF
14	SOME OF THE QUESTIONS THAT THEY'VE ANSWERED.
15	CHAIRMAN SHEEHY: LIKE WE'VE SAID ALREADY,
16	THE IMMEDIATE REVIEW THAT'S GOING TO PROVIDE THE
17	INFORMATION THAT YOU ARE ASKING FOR IS THE CURRENT
18	ONGOING SCIENTIFIC REVIEW THAT THE PRESIDENT IS
19	CONDUCTING. AND I THINK THAT THAT WILL BE MUCH MORE
20	USEFUL FOR GIVING YOU THE TYPES OF ANSWERS THAT YOU
21	NEED IN THE NEAR TERM. AND WE'VE ALREADY APPROVED
22	THAT. THAT'S ALREADY GOING FORWARD AS FAR AS I
23	KNOW.
24	MS. SAMUELSON: THEN I'M FEELING THE SAME
25	CONCERN THAT I HEARD FROM ART TORRES, AS I
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_	INDEPOTOR IT THE LETTER OF THE LOW STUDY
1	UNDERSTOOD IT, THAT IF THAT'S NOT WHAT THE IOM STUDY
2	WOULD BE DOING, THEN IT'S DUPLICATIVE.
3	CHAIRMAN SHEEHY: FINE. DO WE HAVE OTHER
4	BOARD COMMENT?
5	DR. FONTANA: I GUESS I'M A LITTLE
6	CONFUSED AGAIN.
7	CHAIRMAN SHEEHY: I JUST I DON'T
8	KNOW I MEAN TO ME IT'S REALLY A QUESTION DO WE
9	WANT AN INDEPENDENT GOLD STANDARD EVALUATION OF WHAT
10	WE'RE DOING. AND ESPECIALLY IF WE CAN MERGE THAT
11	WITH THE REQUIREMENT FROM THE LEGISLATURE, THAT WE
12	HAVE A PERFORMANCE AUDIT, TO ME IT'S JUST A
13	NO-BRAINER. I DO THINK WE HAVE TO HAVE AN INTERNAL
14	SCIENTIFIC STRATEGIC PLAN. WE'RE AT A POINT WHERE
15	WE NEED A NEW ONE. THOSE TO MY MIND ARE NOT
16	PROCESSES THAT ARE AT ODDS WITH EACH OTHER, BUT
17	THEY'RE COMPLEMENTARY. ONE WILL BE COMPLETED BEFORE
18	THE OTHER. THE ONE WILL NECESSARILY INFORM THE
19	OTHER. BUT I THINK THAT IT WOULD BEHOOVE ALL OF US
20	VIS-A-VIS OUR OBLIGATIONS TO THE TAXPAYERS, WE'VE
21	BEEN THROUGH A BILLION DOLLARS OF THEIR MONEY, TO
22	HAVE THE LOW OR SOMEONE WITH THAT LEVEL OF
23	CREDIBILITY LOOK AT THE WORK WE'VE DONE AND VALIDATE
24	IT.
25	I PERSONALLY AM PROUD OF THE WORK WE'VE
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1	DONE. I THINK THEY'RE GOING TO COME BACK AND SAY
2	FABULOUS THINGS ABOUT US. I THINK WE'RE MORE NIMBLE
3	THAN NIH. WE'VE DONE SOME INNOVATIVE PROGRAMS, BUT
4	IN TERMS OF THE IMMEDIATE STRATEGIC ISSUES THAT WE
5	NEED TO ADDRESS, WHICH I THINK IS WHAT JOAN IS
6	TALKING ABOUT, THAT IS WHAT THE PRESIDENT IS WORKING
7	ON RIGHT NOW AND WE NEED TO TAKE UP IN THE NEAR TERM
8	WITHIN THE NEXT SIX TO NINE MONTHS. THE IOM REPORT
9	CANNOT FEASIBLY BE COMPLETED TO ANSWER THOSE
10	QUESTIONS IN THAT TIMEFRAME. THAT'S HOW I
11	UNDERSTAND IT.
12	DR. PIZZO: JEFF, I THINK YOU'VE
13	SUMMARIZED IT VERY WELL. AND I AGREE WITH THE
14	CONCLUSIONS THAT YOU PUT FORWARD. I WOULD HOPE THAT
15	WE CAN MOVE THE QUESTION.
16	MS. KING: BEFORE WE DO THAT, I THINK IT
17	MIGHT BE HELPFUL TO HAVE MR. HARRISON RESTATE THE
18	MOTION. AND ALSO JUST TO POINT OUT THAT ONE OF THE
19	THINGS THAT CAN BE BROUGHT BACK TO THE BOARD IN JUNE
20	IS AN ACTUAL TIMELINE FROM THE IOM INSTEAD OF JUST A
21	GUESSTI MATE.
22	DR. PIZZO: LET ME JUST BE CLEAR ABOUT
23	THAT. HAVING BEEN PART OF THAT ORGANIZATION FOR
24	ALMOST 15 YEARS, I THINK THAT'S GOING TO BE HARD TO
25	DO. EACH OF THOSE WORK GROUPS OPERATE PRETTY

1	AUTONOMOUSLY, AND THEY CAN SAY THAT THEY'LL HAVE IT
2	IN TWO YEARS, BUT I THINK IT'S HARD TO GET THAT
3	DEFINITIVELY SUCH.
4	MS. KING: IF WE COULD JUST ASK MR.
5	HARRISON TO RESTATE THE MOTION FOR US.
6	MR. KLEIN: HAVE WE HAD PUBLIC COMMENT?
7	CHAIRMAN SHEEHY: AFTER HE RESTATES THE
8	MOTION, BOB. I ALWAYS THINK IT'S HELPFUL TO HAVE
9	PUBLIC COMMENT SO THAT PEOPLE KNOW WHAT THEY'RE
10	COMMENTING ON.
11	MR. KLEIN: ABSOLUTELY.
12	MR. HARRISON: THE MOTION, AS I UNDERSTAND
13	IT, IS TO REQUEST THAT STAFF, IN CONSULTATION WITH
14	THE VICE CHAIRS OF THE GRANTS WORKING GROUP AND
15	BOARD LEADERSHIP, PRESENT A PLAN FOR AN IOM STUDY TO
16	THE BOARD AT ITS JUNE MEETING.
17	MR. KLEIN: SPECIFICALLY I CALLED OUT THE
18	CHAIR WILL WORK WITH BOTH VICE CHAIRS AND THE VICE
19	CHAIRS OF THE GRANTS WORKING GROUP AS WELL AS THE
20	LEGAL TEAM SO WE HAVE A FULL SPECTRUM OF REVIEW WITH
21	THE SCIENTIFIC LEADERSHIP OF THE AGENCY LED BY DR.
22	TROUNSON.
23	DR. TROUNSON: CAN THAT REALLY BE DONE BY
24	JUNE?
25	MR. KLEIN: WELL, I'M CONCERNED ABOUT THE
	/ 2
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1	TIMETABLE, DR. TROUNSON, PARTICULARLY BECAUSE OF THE
2	ISSCR MEETING, BUT I'M PREPARED TO SEE WHAT PROGRESS
3	WE CAN MAKE ON IT IN A GOOD-FAITH EFFORT TO MEET
4	JEFF'S REQUEST.
5	CHAIRMAN SHEEHY: I WOULD ACCEPT A
6	FRIENDLY AMENDMENT TO MOVE IT TO AUGUST.
7	MR. KLEIN: I WOULD AMEND MY MOTION TO
8	MOVE IT TO AUGUST IF MY SECOND WILL AGREE.
9	CHAIRMAN SHEEHY: YOU'RE THE SECOND.
10	MR. KLEIN: YOU ARE THE SECOND.
11	CHAIRMAN SHEEHY: I WAS MAKING THE
12	FRIENDLY AMENDMENT. AS LONG AS I HAVE A COMMITMENT
13	THAT IT WILL BE ON IN AUGUST, I'M COMFORTABLE WITH
14	THAT.
15	MR. KLEIN: THANK YOU.
16	CHAIRMAN SHEEHY: NOW, PUBLIC COMMENT. WE
17	HAVE DON REED IN SAN FRANCISCO.
18	MR. REED: YEAH. I'M STRUGGLING TO KEEP
19	TRACK OF THE VARIOUS AUDITS. WE'VE GOT AUDITS ON
20	AUDITS ON AUDITS.
21	MR. KLEIN: DON, ONE IS AN AUDIT, ONE IS A
22	SCIENTIFIC REVIEW MANDATED BY THE STRATEGIC PLAN.
23	THEY'RE TOTALLY TWO DIFFERENT THINGS.
24	MR. REED: RIGHT. THE IOM, IT SEEMS TO ME
25	TO BE EXTREMELY VALUABLE IN TERMS OF RENEWING THE

1	PROJECT OF RENEWING PROP 71. I THINK THAT'S A
2	WONDERFUL THING. AS TO WHEN IT IS DONE, I DON'T
3	KNOW WHAT THE BEST TIMING IS. MY ONLY CONCERN IS WE
4	DON'T WANT TO DO ANYTHING TO SEND A MESSAGE TO
5	SACRAMENTO THAT WE ARE IN ANY WAY VIOLATING THE
6	AGREEMENT ON 1064, IF THAT GOES FORWARD, WHICH SEEMS
7	TO BE IT'S POSSIBLE WE COULD END THE FRICTION WITH
8	SACRAMENTO IF WE REALLY MAKE SURE EVERYTHING IS
9	TAKEN CARE OF. SO THAT'S MY CONCERN.
10	CHAIRMAN SHEEHY: OKAY. ANY ADDITIONAL
11	PUBLIC COMMENT?
12	DR. CHIU: I RECALL THE PREVIOUS AUDIT
13	WHEN THE STATE BUREAU OF AUDITORS CAME FOR SUCH A
14	LONG PERIOD OF TIME. AND BECAUSE MOST OF THEM, IF
15	NOT ALL OF THEM, WERE NOT FAMILIAR WITH THE
16	SCIENTIFIC METHOD, IT TOOK A VERY LONG TIME TO
17	EXPLAIN OUR PROCESSES. AND THEY, OF COURSE, DID NOT
18	EVALUATE THE STRATEGIC PLAN OR ANYTHING THAT WAS
19	SCIENTIFIC CONTENT. I THINK THAT HAVING THE TWO
20	GROUPS PROPOSED WILL BE A GREAT IMPROVEMENT BECAUSE
21	AT LEAST YOU ARE GOING TO HAVE PEOPLE, CLINICIANS
22	AND SCIENTISTS, WHO UNDERSTAND WHAT THE MISSION IS
23	AND HOW DIFFICULT IT IS TO ACHIEVE THE MISSION. AND
24	WE WOULD GET A MUCH MORE COHERENT REVIEW OF WHAT
25	CIRM IS DOING NOW AND WHAT IT PLANS TO DO IN THE

1	FUTURE. THANK YOU.
2	DR. PRIETO: I'M VERY SUPPORTIVE OF THIS
3	CONCEPT, BUT I WOULD LIKE TO BE CERTAIN WHEN IT
4	COMES TO US AT THE BOARD THAT IT DOES MEET OUR
5	LEGISLATIVE REQUIREMENTS.
6	MR. KLEIN: THAT'S AN ABSOLUTE OBJECTIVE.
7	DR. PRIETO: AND THE OTHER THING I WOULD
8	LIKE TO SEE WHEN WE VOTE ON THIS IS WHAT
9	ALTERNATIVES WE HAVE TO MEET THOSE REQUIREMENTS,
10	WHAT OTHER OPTIONS MIGHT EXIST, IF ANY. I THINK
11	THIS IS PROBABLY THE BEST ONE CERTAINLY THAT I CAN
12	THINK OF, BUT I JUST WANT US TO MAKE AN INFORMED
13	DECISION.
14	MR. TORRES: MR. CHAIRMAN, IF I MAY, I
15	JUST RECEIVED A TELEPHONIC CALL AND A TEXT FROM
16	SENATOR ALQUIST THANKING THE BOARD FOR THEIR SUPPORT
17	OF HER LEGISLATION THIS MORNING THAT WE TOOK AN
18	ACTION. SO WE WANT TO SAY THANK YOU AGAIN TO
19	SENATOR ALQUIST FOR HER HELP THROUGHOUT THESE
20	NEGOTI ATI ONS.
21	DR. STEWARD: JEFF, I DO HAVE PUBLIC
22	COMMENT IN IRVINE.
23	CHAIRMAN SHEEHY: IRVINE, BUT I DO WANT TO
24	ECHO SENATOR TORRES' COMMENT AND OUR APPRECIATION
25	FOR SENATOR ALQUIST AND HAVING HER STAFF WORK WITH

	BARRISTERS' REPORTING SERVICE
1	US.
2	MS. LEVINE: I'M REPRESENTING THE PUBLIC
3	FROM IRVINE. MY NAME IS RENE LEVINE. AND I
4	UNDERSTAND THE VALIDATION THAT IS NEEDED FROM THE
5	IOM; HOWEVER, I SUPPORT JOAN'S COMMENT ON THE TIME
6	AND THE EVENTUAL RESULT FOR THE PEOPLE WHO ARE
7	AWAITING THE CURES. THANK YOU.
8	CHAIRMAN SHEEHY: THANK YOU. SO IF
9	THERE'S NO FURTHER PUBLIC COMMENT, WE'LL GO TO A
10	ROLL CALL.
11	MS. KING: JACOB LEVIN.
12	DR. LEVIN: YES.
13	MS. KING: BOB KLEIN.
14	MR. KLEIN: YES.
15	MS. KING: FRANCISCO PRIETO.
16	DR. PRI ETO AYE.
17	MS. KING: ED PENHOET.
18	DR. PENHOET: YES.
19	MS. KING: PHIL PIZZO.
20	DR. PI ZZO: YES.
21	MS. KING: JEANNIE FONTANA.
22	DR. FONTANA: YES.
23	MS. KING: DUANE ROTH.
24	MR. ROTH: YES.
25	MS. KING: JOAN SAMUELSON.
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1	MS. SAMUELSON: NO.
2	MS. KING: JEFF SHEEHY.
3	CHAIRMAN SHEEHY: YES.
4	MS. KING: OSWALD STEWARD.
5	DR. STEWARD: YES.
6	MS. KING: AND ART TORRES.
7	MR. TORRES: AYE.
8	MS. KING: AND THAT MOTION CARRIES.
9	DR. PIZZO: I'M GOING TO BE OFF THE CALL
10	FOR ABOUT TEN MINUTES AND I'LL BE BACK.
11	MS. KING: OKAY. VERY GOOD. THANK YOU,
12	DR. PIZZO. I WAS GOING TO SUGGEST WE TAKE A FEW
13	MINUTE BREAK ANYWAY SINCE IT'S A LONG MEETING IN
14	CASE.
15	CHAIRMAN SHEEHY: SHOULD WE TAKE A
16	TEN-MINUTE BREAK ALTOGETHER AND COME BACK IN TEN?
17	MR. KLEIN: JUST AS LONG AS SOMEONE STAYS
18	ON THE PHONE SO IF DR. PIZZO COMES BACK, HE DOESN'T
19	THINK WE'VE HUNG UP.
20	MS. KING: WE ARE NOT HANGING UP THE
21	PHONE. I WILL BE IN THE ROOM BY THE PHONE HERE IN
22	SAN FRANCISCO. AND IT PROBABLY I DON'T KNOW. I
23	THINK IT WOULD BE BEST IF PEOPLE DIDN'T ACTUALLY
24	HANG UP DURING THIS BREAK, MAYBE JUST MUTE YOUR
25	PHONE. BUT IF YOU NEEDED TO MAKE ANOTHER PHONE
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1	CALL, GET A DRINK OF WATER OR SOMETHING, WE THOUGHT
2	THIS BREAK WOULD BE APPROPRIATE.
3	(A RECESS WAS TAKEN.)
4	CHAIRMAN SHEEHY: WE'LL GIVE IT A COUPLE
5	MORE MINUTES. I THINK I'M GOING TO GO AHEAD AND GET
6	STARTED. SO ITEM NO. 5, SCOPE OF MATERIALS PROVIDED
7	TO GRANT WORKING GROUP MEMBERS IN ADVANCE OF
8	MEETINGS. SO WHAT THIS REFERENCES IS SOME OF THE
9	EXPERIENCES WE'VE HAD IN RECENT GRANTS WORKING GROUP
10	MEETINGS. FOR INSTANCE, I SAT DOWN NEXT TO THE
11	CHAIR AT DINNER AFTER THE FIRST DAY AND HE BASICALLY
12	SAID, "WHO ARE YOU?" AND THEN HE SAID, "AND WHO'S
13	KLEIN, WHO'S THIS GUY KLEIN?" AND SAID, "WHAT IS
14	PROGRAMMATIC REVIEW?"
15	AND SO WHAT IS HAPPENING, I THINK, IS
16	WHILE WE RETAIN A FAIR NUMBER OF WORKING GROUP
17	MEMBERS WHO COME OFTEN AND REGULARLY, SOME OF THE
18	HISTORY IS BEING LOST. AND WE END UP, IF THE CHAIR
19	OF THE WORKING GROUP DOESN'T KNOW WHAT PROGRAMMATIC
20	REVIEW IS, IT MAKES IT VERY DIFFICULT TO CONDUCT
21	PROGRAMMATIC REVIEW.
22	IF THEY DON'T KNOW WHO THE PATIENT
23	ADVOCATES ARE, WHY THEY'RE THERE, AND WHAT ROLE
24	THEY'RE SUPPOSED TO PLAY IN THIS PROCESS, IT MAKES
25	IT VERY AWKWARD AND DIFFICULT FOR US. AND SO THE
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1	THOUGHT WAS IS THAT CERTAIN MATERIALS BE PROVIDED
2	THAT ARE VERY EXPLICIT ABOUT THE ROLES, THE
3	MEMBERSHIP, PRIOR TO THE MEETING TO THE WORKING
4	GROUPS.
5	THE OTHER THING IS THE SCORE. OUR SCORING
6	HAS GOTTEN TO BE PRETTY, I THINK, CONCRETE. BUT
7	REVIEWERS SIT AT VARIOUS DIFFERENT REVIEW SETTINGS.
8	NIH REVIEWS IS A COMPLETELY DIFFERENT REVIEW
9	PROCESS, SCORING PROCESS. AND SO IT WOULD BE
10	HELPFUL THAT THEY GET VERY CLEAR INSTRUCTION. AND
11	FOR SPECIALIST REVIEWERS AS WELL WHO SOMETIMES
12	THERE'S ALWAYS THE COMMENT THAT'S MADE IN REVIEW, "I
13	DON'T KNOW THE SCALE, BUT THIS IS WHAT I GAVE IT. "
14	SO THAT THERE'S EXTREME CLARITY BEFORE PEOPLE
15	PRESENT THEIR INITIAL SCORES ON WHAT THE SCALE IS.
16	IT'S GENERALLY DIFFICULT FOR US TO
17	CONSIDER FOR FUNDING SCORES UNDER 75. GENERALLY IF
18	YOU GET 75 OR ABOVE, HISTORICALLY IF YOU GO BACK AND
19	LOOK AT WHAT THE ICOC HAS APPROVED, THAT HAS BEEN
20	THE FUNDABLE CATEGORY. I THINK THAT NEEDS TO BE
21	VERY EXPLICITLY MADE CLEAR, THAT WE USE THE ENTIRE
22	SCALE IN WRITING SO THAT THERE'S SOME DOCUMENTATION
23	THAT REVIEWERS, BECAUSE WE DO END UP, ESPECIALLY
24	WHEN WE HAVE SPECIALIZED REVIEWS, WITH NEW REVIEWERS
25	WHO HAVE NEVER PARTICIPATED IN OUR PROCESS WITH OUR

1	SPECIALISTS WHO MAY ONLY REVIEW A GRANT FOR US FOR
2	ONE REVIEW SESSION AND THAT'S THE ONLY TIME WE'LL
3	EVER SEE THEM, THAT THEY HAVE THIS INFORMATION SO
4	THAT THEY UNDERSTAND OUR PROCESS.
5	AND SO THE GOAL IS TO HAVE A MORE IS TO
6	HAVE MORE CLARITY WITH SCORES, TO HAVE A MORE ROBUST
7	PROGRAMMATIC REVIEW BECAUSE I THINK THAT WHAT'S
8	ACTUALLY TENDING TO HAPPEN IS THAT A LOT OF THE
9	FEATURES OF PROGRAMMATIC REVIEW IN SOME FASHION ARE
10	NOW COMING TO THE BOARD. AND IT WOULD BE GREAT IF
11	THE PROGRAMMATIC REVIEW AT THE WORKING GROUP WAS A
12	BIT MORE ROBUST. PARTIALLY IT IS BECAUSE OF THE
13	PREAP PROCESS WE END UP WITH FEWER APPLICATIONS.
14	WE'RE NOT CREATING A MIDDLE AREA. AND SO IT'S BEEN
15	PRETTY CUT AND DRIED, AND I THINK THAT IT'S NOT
16	CLEAR TO ME THAT WE'RE NOT LEAVING SOME SCIENCE
17	BEHIND. I THINK GIVEN OUR MISSION AND THE URGENCY
18	WITH WHICH WE NEED TO PROCEED, WE NEED TO MAKE
19	ABSOLUTELY SURE THAT WE DON'T LEAVE GOOD SCIENCE
20	BEHI ND.
21	SO THAT'S THE INTRODUCTION TO THE TOPIC.
22	BOB, DID YOU HAVE SOME COMMENTS YOU WANTED TO MAKE?
23	MR. KLEIN: THANKS, JEFF. THE SCIENTISTS
24	THEMSELVES WHO ARE LONG-STANDING MEMBERS OF THE PEER
25	REVIEW GROUP TALKED TO SEVERAL US. I WAS RECENTLY
	70

1	IN LONDON AND HAD A SEVERAL HOUR CONVERSATION WITH
2	DR. STEPHEN MINGER OF UNIVERSITY COLLEGE LONDON, NOW
3	WITH GENERAL ELECTRIC. HE INDICATED THAT WHILE HE
4	HAS BEEN WITH THE PEER REVIEW GROUP FOR SOME TIME,
5	THAT IN THE BEGINNING THERE'S SOME VERY DETAILED
6	SESSIONS OF EXPLAINING ALL OF THE ROLES OF THE
7	PARTIES AND PROGRAMMATIC REVIEW AND WHO THE MEMBERS
8	WERE. BUT AS WE GO FURTHER DOWNSTREAM AND HAVE MORE
9	SPECIALIZED REVIEWS, OUR ALTERNATE MEMBERS MAY NOT
10	HAVE BEEN THERE PREVIOUSLY. WE LACK THE CONTINUITY
11	OF KNOWLEDGE. AND THAT HE FELT VERY SPECIFICALLY IT
12	WOULD BE VALUABLE TO GET BIOS ON THE PEER REVIEW
13	MEMBERS AND AN EXPLANATION OF ROLES, OBVIOUSLY THE
14	EXPLANATION OF PEER REVIEW. BUT HE ALSO OF THE
15	PROGRAMMATIC REVIEW, BUT ALSO, AS JEFF SAYS, OF THE
16	SCORING. AS DR. TROUNSON HAS SAID, IT'S GOOD TO
17	HAVE THE SCORES THROUGH THE WHOLE RANGE. AS A
18	PHILOSOPHY WE'VE ASKED THEM TO DO THAT, AND THAT
19	CONTINUES TO BE CORRECT. BUT SPECIALISTS WILL COME
20	ON THE LINE WITHOUT THAT KNOWLEDGE.
21	THE ISSUE HERE IS WE HAVE A PHENOMENAL
22	SCIENTIFIC STAFF. DR. MINGER SAID THAT NEW PEOPLE
23	COMING INTO THE REVIEW, IT WOULD BE GOOD TO GIVE
24	THEM THE BIOS OF SCIENTIFIC STAFF AND EXPLAIN THE
25	FUNCTIONS OF THE VARIOUS SCIENTIFIC STAFF IN THE

1	MEETING AND THE LAWYERS THAT ARE THERE AND WHY
2	THEY'RE THERE SO THAT WHEN SOMEONE COMES IN, THEY
3	HAVE BINDERS THAT CAN GIVE THEM SOME COMFORT, THEY
4	UNDERSTAND THEIR ENVIRONMENT, THEY UNDERSTAND THE
5	PEOPLE THAT ARE THERE, AND THEY UNDERSTAND THE ROLES
6	TO HAVE THE MOST EFFECTIVE WORKING ENVIRONMENT.
7	SOMETIMES PEOPLE ARRIVE BY PLANE LATER THAN THE
8	BEGINNING OF THE SESSION SO THAT IT IS NOT POSSIBLE
9	TO THEN GO BACK THROUGH AN ENTIRE ORAL PRESENTATION,
10	AND THIS ALLOWS US TO CAPTURE THE BENEFIT OF A LOT
11	OF THAT KNOWLEDGE THROUGH A MORE FORMALIZED WRITTEN
12	PROCESS THAT I THINK WE'RE AT THE STAGE OF MATURITY
13	THAT AS BEST PRACTICE IT WOULD BE GOOD TO HAVE IN
14	ANY CASE.
15	CHAIRMAN SHEEHY: IF I MIGHT ADD, OTHER
16	ELEMENTS THAT I THINK ARE REALLY IMPORTANT IS THAT A
17	LOT OF THE PEOPLE COME IN BELIEVING THAT THIS IS A
18	SCIENTIFIC COMPETITION BETWEEN GRANTS. AND I THINK
19	WE NEED TO UP FRONT MAKE IT VERY CLEAR THAT EACH
20	GRANT IS TO BE SCORED AS TO WHETHER OR NOT IT'S
21	FUNDABLE, RECOMMENDED FOR FUNDING, NOT RELATIVE TO
22	THE OTHER GRANTS THAT THEY'RE REVIEWING. IS THIS
23	GRANT MERITORIOUS IN AND OF ITSELF? THERE'S SO
24	MUCH I THINK PEOPLE COME INTO THIS WHERE WE'RE
25	NOT GOING TO FUND EVERYTHING. IF EVERY SINGLE GRANT

1	THAT WAS UNDER REVIEW WAS WORTHY OF FUNDING, THEY
2	SHOULD BE RECOMMENDED TO THE BOARD FOR FUNDING. AND
3	PRESUMABLY, IF WE HAD THE RESOURCES, WE WOULD FUND
4	THEM.
5	THEY'RE NOT THE EVALUATION SHOULD BE
6	TAKEN IS THIS GRANT MERITORIOUS SOLELY IN AND OF
7	ITSELF, NOT RELATIVE TO THE OTHER GRANTS THAT ARE
8	BEING PRESENTED. AND I THINK THAT WE'RE UNIQUE THAT
9	THE UNIQUE FEATURE OF HOW WE ARE SET UP IS A UNIQUE
10	FEATURE OF OUR MISSION. WE HAVE A SHORT TIMELINE.
11	WE NEED TO GET THERE FAST. WE NEED TO FUND AS MUCH
12	SCIENCE AS WE CAN, AND I THINK THAT PEOPLE COME HERE
13	NOT, AND THIS IS NOT TO BE NEGATIVE ABOUT THE
14	SCIENTISTS WHO DO SUCH TREMENDOUS WORK FOR US, NOR
15	TOWARDS STAFF WHICH DOES AN INCREDIBLE JOB, BUT I
16	JUST THINK WE NEED TO BE MORE EXPLICIT ABOUT SOME OF
17	THESE FEATURES SO THAT WE DON'T END UP LEAVING
18	SCI ENCE BEHIND.
19	MR. KLEIN: JEFF, IS THE INTENT OF THIS
20	ITEM TO SEE IF THERE IS A MOTION FOR THE CHAIRS, THE
21	VICE CHAIRS OF THE GRANTS WORKING GROUP ALONG WITH
22	THE ADMINISTRATIVE CHAIRS OF THE GRANTS WORKING
23	GROUP AND THE EXECUTIVE COMMITTEE TO WORK WITH THE
24	SCIENTIFIC STAFF TO TRY AND BRING SOMETHING TO THE
25	BOARD THAT WOULD OUTLINE THE SCOPE OF MATERIALS THAT

1	WOULD BE PROVIDED AND WOULD PROVIDE EXAMPLES OF
2	DESCRIPTIONS OF THE ROLES AND THE SCORING APPROACH
3	THAT'S TAKEN IN GRANTS WORKING GROUP? IS THAT THERE
4	WHERE WE'RE
5	CHAIRMAN SHEEHY: WELL, I MEAN IT
6	REALLY I'D LIKE TO WORK WITH STAFF. I'D BE HAPPY
7	TO DO THIS ADMINISTRATIVELY MYSELF. I'D LIKE TO
8	HEAR FROM DR. SLADEK IF HE HAS OTHER THINGS THAT HE
9	THOUGHT MIGHT BE USEFUL TO ADD TO THIS. IT'S JUST
10	THERE'S A LEVEL OF PREPARATION ABOUT OUR PROCESSES
11	THAT THERE'S A LEVEL OF INFORMATION ABOUT OUR
12	PROCESSES THAT WE NEED TO MAKE SURE THAT THE WORKING
13	GROUP MEMBERS ARE AWARE OF BEFORE WE START OUR
14	PROCESSES.
15	DR. SLADEK: JEFF, SINCE YOU INVOKED MY
16	NAME, LET ME WEIGH IN. THIS IS JOHN SLADEK. I'M
17	CHAIR OF THE GRANTS WORKING GROUP, AT LEAST IN THE,
18	QUOTE, ADMINISTRATIVE SENSE. LET ME CALL UPON
19	I'VE BEEN IN ACADEMIA 42 YEARS NOW AND HAVE BEEN IN
20	THE PEER REVIEW SYSTEM SINCE THE LATE 1970S WHEN I
21	STARTED SERVING NIH. AND I THINK I'VE SEEN ALL
22	SHAPES AND FORMS OF COMMITTEES AT NSF, FOUNDATIONS,
23	ETC.
24	I THINK WHAT YOU'RE GETTING AT IS
25	ABSOLUTELY TRUE, AND I THINK IT'S AN INHERENT
	7.4

1	PROBLEM WHEN YOU HAVE ROTATING CHAIRS OF THE
2	REVIEWS. AND THAT IS NOT IN ANY WAY TO BE MEANT AS
3	A CRITICISM.
4	WHEN WE SIT, FOR EXAMPLE, ON NIH STUDY
5	SECTIONS, WE HAVE A CONSTANCY. THERE'S TWO
6	CONSTANCIES IN THOSE STUDY SECTIONS. ONE IS WHAT WE
7	USED TO CALL THE EXECUTIVE SECRETARY. I'LL CALL IT
8	A SCIENTIFIC REVIEW ADMINISTRATOR. THE OTHER IS THE
9	CHAIR OF THE STUDY SECTION. THE CHAIR OF THE STUDY
10	SECTION IS NOT AN EXPERT ON EVERY GRANT THAT GOES
11	THROUGH THAT PANEL AND MAY, IN FACT, NOT BE AN
12	EXPERT ON THE TOPIC OF THE SESSION. BUT HE OR SHE
13	IS AN EXPERT ON THE REVIEW PROCESS AND ALSO THE
14	MI SSI ON.
4 -	AND I HAVE FOUND MYSELF THE LAST COUPLE OF
15	
	ROUNDS, PERFECTLY HONEST WITH EVERYONE, I FOUND
16	ROUNDS, PERFECTLY HONEST WITH EVERYONE, I FOUND MYSELF SOMEWHAT FRUSTRATED THAT THE MISSION HASN'T
16 17	
16 17 18	MYSELF SOMEWHAT FRUSTRATED THAT THE MISSION HASN'T
16 17 18 19	MYSELF SOMEWHAT FRUSTRATED THAT THE MISSION HASN'T BEEN FULLY UNDERSTOOD, AS JEFF HAS POINTED OUT.
16 17 18 19 20	MYSELF SOMEWHAT FRUSTRATED THAT THE MISSION HASN'T BEEN FULLY UNDERSTOOD, AS JEFF HAS POINTED OUT. I'VE HEARD REVIEW CHAIRS MAKE COMMENTS THAT, "WELL,
16 17 18 19 20 21	MYSELF SOMEWHAT FRUSTRATED THAT THE MISSION HASN'T BEEN FULLY UNDERSTOOD, AS JEFF HAS POINTED OUT. I'VE HEARD REVIEW CHAIRS MAKE COMMENTS THAT, "WELL, TO GET THIS GRANT FUNDABLE, WE HAVE TO DO THIS."
16 17 18 19 20 21	MYSELF SOMEWHAT FRUSTRATED THAT THE MISSION HASN'T BEEN FULLY UNDERSTOOD, AS JEFF HAS POINTED OUT. I'VE HEARD REVIEW CHAIRS MAKE COMMENTS THAT, "WELL, TO GET THIS GRANT FUNDABLE, WE HAVE TO DO THIS." AND, AGAIN, THAT IS NOT THE PURPOSE OF THE REVIEWS,
15 16 17 18 19 20 21 22 23	MYSELF SOMEWHAT FRUSTRATED THAT THE MISSION HASN'T BEEN FULLY UNDERSTOOD, AS JEFF HAS POINTED OUT. I'VE HEARD REVIEW CHAIRS MAKE COMMENTS THAT, "WELL, TO GET THIS GRANT FUNDABLE, WE HAVE TO DO THIS." AND, AGAIN, THAT IS NOT THE PURPOSE OF THE REVIEWS, TO PASS SCIENTIFIC MERIT ON THE REVIEW. MORE THAN
16 17 18 19 20 21 22	MYSELF SOMEWHAT FRUSTRATED THAT THE MISSION HASN'T BEEN FULLY UNDERSTOOD, AS JEFF HAS POINTED OUT. I'VE HEARD REVIEW CHAIRS MAKE COMMENTS THAT, "WELL, TO GET THIS GRANT FUNDABLE, WE HAVE TO DO THIS." AND, AGAIN, THAT IS NOT THE PURPOSE OF THE REVIEWS, TO PASS SCIENTIFIC MERIT ON THE REVIEW. MORE THAN ONCE, AS, I'M SURE, JEFF AND JOAN MAY RECALL, I HAVE

1	AN NIH STUDY SECTION.
2	SO I THINK, JEFF, YOU'VE HIT EXACTLY ON
3	SOMETHING THAT NEEDS TO BE ADDRESSED. I THINK BOB'S
4	SUGGESTION THAT WE DO SO WITH THE ADMINISTRATIVE
5	CHAIR, MYSELF, AND THE CO-CHAIRS AND APPROPRIATE
6	OTHERS PARTICULARLY ON STAFF AND BRING IT BACK TO
7	THE ICOC IS A VERY FINE IDEA. I THINK WE NEED TO
8	GET BACK TO A MECHANISM OF CONSTANCY. AND, FRANKLY,
9	I WOULD BE HAPPY, FOR EXAMPLE, AND I'M NOT TRYING TO
10	MAKE MORE WORK FOR MYSELF, AND STAFF COULD DO THIS
11	ALSO, BUT AT THE BEGINNING OF THE SESSION, BEFORE WE
12	ACTUALLY START THE REVIEW, I THINK IT WOULD BE
13	EXTREMELY HELPFUL HAVING AN OVERVIEW FOR ALL THE
14	NEW, WONDERFUL REVIEWERS WE HAVE OF WHAT OUR PURPOSE
15	IS, OUR MISSION, AND OUR SCORING SYSTEM.
16	MR. KLEIN: DR. SLADEK, UNDERSTANDING THAT
17	THAT ORAL REVIEW, YOU'RE NOT INTENDING TO REPLACE
18	THE WRITTEN MATERIALS THAT WOULD GO OUT IN ADVANCE
19	SO THAT IF PEOPLE ARE NOT NECESSARILY PRESENT AT THE
20	OPENING OF THE SESSION, THEY DON'T MISS THE 20
21	MINUTES OF ORIENTATION.
22	DR. SLADEK: EXACTLY, BOB. I THINK FROM
23	TIME TO TIME THE CHAIR NEEDS OR SOMEONE NEEDS TO
24	REFRESH THAT HISTORY AND THAT MEMORY OF WHAT OUR
25	PURPOSE IS. SO THE WRITTEN MATERIALS WOULD BE

1	HELPFUL IF PEOPLE READ THEM. SOME WILL, SOME WON'T,
2	AND SOME WILL READ THEM IN A PERFUNCTORY MANNER
3	ONLY.
4	MR. KLEIN: IT'S VERY IMPORTANT THAT DR.
5	TROUNSON AND THE SCIENTIFIC LEADERS THAT ACCOMPANY
6	DR. TROUNSON WORK ON THESE MATERIALS SO THEY'RE
7	COMPLETELY COMFORTABLE. THEY PUT IN TREMENDOUS
8	EFFORT IN THESE SESSIONS, AND THEY SPEND A LOT OF
9	TIME ON THE ORIGINAL MEMBERS OF THE COMMITTEE
10	BRIEFING THEM, BUT THE ADDITION, AS WE BECOME MORE
11	SPECIALIZED, THE ADDITION OF SPECIAL ALTERNATIVES TO
12	THE BOARD WITH REVIEWS THAT MAKES THIS, I THINK, AN
13	IMMEDIATE NEED.
14	DR SLADEK: YOU'RE RIGHT, BOB. I THINK
15	ANOTHER THING WE MIGHT CONSIDER, IN MY RECENT MEMORY
16	THERE'S REALLY BEEN A MINORITY OF FULL-TIME OR
17	PERMANENT MEMBERS OF THE GRANTS WORKING GROUP, THAT
18	SMALLER GROUP OF 15, THERE HAVE BEEN VERY FEW OF US
19	ON THAT. I THINK IN THE LAST MEETING OR THE MEETING
20	BEFORE SUSAN BONNER-WIER AND MYSELF WERE THERE, AND
21	OF THE LARGER GROUP OF A HUNDRED OR MORE, MARK
22	FURTH, SHELLY HEIMFELD, STEVE MINGER, AND MAYBE ONE
23	OR TWO OTHERS WERE THERE. WHAT WE HAVE IS NOT A
24	STRONG COLLECTIVE HISTORY OF THE PAST REVIEWS AND
25	THE PROCESS AND THE MISSION. AND I, FRANKLY, WOULD

1	RECOMMEND WE ALSO TAKE A LOOK AT THE SCIENTIFIC
2	MEMBERSHIP AND SEE IF WE CAN'T GET MORE OF THE
3	FULL-TIME PERMANENT MEMBERS AT EACH REVIEW SESSION.
4	CHAIRMAN SHEEHY: SO, BOB, WOULD YOU LIKE
5	TO MAKE A MOTION?
6	MR. KLEIN: DR. TROUNSON. COULD WE HEAR
7	FROM DR. TROUNSON FIRST?
8	DR. TROUNSON: WELL, I THINK ALL THESE
9	POINTS ARE TAKEN WITH INTEREST. AND I KNOW THE
10	STAFF WORK REALLY HARD WITH EACH AND EVERY MEMBER
11	THAT THEY BRING FORWARD TO GIVE THEM AS MUCH
12	INFORMATION AS POSSIBLE.
13	THE LAST REVIEW WAS A VERY SPECIALIZED
14	REVIEW, AND WE WENT OUT OF THE WAY, WHICH WE HAVE
15	TO, TO GET THE BEST PEOPLE IN THE FIELD IN
16	IMMUNOLOGY BECAUSE WE REALLY DIDN'T HAVE MANY
17	IMMUNOLOGISTS AT ALL IN THE GROUP, IN THE ORIGINAL
18	GROUP OR IN THE BROADER GROUP. SO WHEN YOU DO A
19	SPECIALIZED SESSION LIKE THAT, YOU REALLY HAVE TO GO
20	OUTSIDE. AND WE FELT THAT IT WAS VERY IMPORTANT TO
21	HAVE A CHAIR WHO WAS A WORLD RENOWN EXPERT IN THIS
22	AREA. WE WENT INTERNATIONAL TO GET SOMEBODY WHO WAS
23	HIGHLY RECOMMENDED AS THE BEST PERSON IN THE WORLD
24	THAT WAS AVAILABLE.
25	SO THERE'S ALWAYS A BIT OF TENSION BETWEEN

1	GETTING THE BEST PEOPLE AND GETTING A CONSISTENT
2	CREW, IF YOU LIKE.
3	THE OTHER THING IS THAT THE CALL OF THE
4	ORIGINAL SCIENTISTS ARE BASICALLY NOT AVAILABLE AT
5	THE LEVEL THAT ARE NEEDED FOR ALL THE REVIEWS. THEY
6	ARE GIVING UP A LOT OF THEIR TIME TO DO THIS, AND SO
7	WE REALLY HAVE TO GO QUITE BROADLY TO GET THE RIGHT
8	PEOPLE AND GET THE BEST PEOPLE. SO I THINK THERE'S
9	A TENSION BETWEEN GETTING NEW PEOPLE OR PEOPLE WHO
10	HAVEN'T DONE A LOT OF THE WORK BEFORE AND GETTING
11	THE BEST PEOPLE.
12	I THINK WE WOULD BE HAPPY TO PROVIDE THEM
13	WITH ADDITIONAL INFORMATION, SPEND MORE TIME ON
14	INTRODUCTIONS. I THINK THEY DO THEY'RE ALL
15	PRETTY EXPERIENCED IN THIS REVIEW PROCESS, AND I
16	THINK THEY KNOW WHAT THE NUMBERS ARE. I THINK THEY
17	GO OUT OF THEIR WAY TO DO THE INDIVIDUAL PROJECTS
18	RATHER THAN MAKE ANY COMPARISONS. I THINK IT'S
19	BROUGHT TO THEIR ATTENTION IF THEY START TO THINK
20	THAT WAY PRETTY QUICKLY.
21	BUT THERE IS A PROGRAMMATIC ISSUE ABOUT
22	WHETHER WE SHOULD BE FUNDING A LOT OF EXACTLY THE
23	SAME PROJECTS. I THINK THAT'S SOMETHING THAT WE
24	NEED TO SORT OF CHEW AT SOME POINT IN TIME ANYWAY AS
25	A PROGRAMMATIC ISSUE THAT WE REALLY HAVEN'T SPENT

1	ANY TIME ON UP TILL NOW.
2	BUT I THINK IT WOULD BE VERY IMPORTANT TO
3	HAVE GIL SAMBRANO AND PAT OLSON INVOLVED IN THIS
4	PROCESS BECAUSE GIL HAS SO MUCH CONTACT OF
5	COURSE, HE HEADS UP THE REVIEW TEAMS SO MUCH
6	CONTACT WITH THE REVIEWERS, HE AND HIS STAFF, TO GET
7	ALL THE INFORMATION THAT'S NECESSARY. I THINK WE
8	HAD A POLICY OF TRYING TO GET THE BEST CHAIR FOR
9	BASIC, FOR TRANSLATIONAL, AND EARLY CLINICAL
10	STUDIES. THESE ARE VERY DIFFERENT AREAS AND
11	WOULDN'T NORMALLY BE IN THE SAME NIH AND MRC REVIEW
12	PROGRAM.
13	SO THERE WAS CERTAINLY ISSUES RAISED TO US
14	BY, FOR EXAMPLE, COMPANIES AND PEOPLE INVOLVED IN
15	THE TRANSLATION PRECLINICAL AREA THAT WE OUGHT TO
16	HAVE REVIEWERS THAT ARE MUCH MORE ACCUSTOMED TO THAT
17	TYPE OF THING RATHER THAN ASKING BASIC SCIENTISTS TO
18	DO THE REVIEWS OUT THERE. ALL OF THESE FACTORS NEED
19	TO BE RECOGNIZED AND THEN BROUGHT INTO THE OPTIMUM.
20	I'M SURE WE'D BE HAPPY, THE STAFF WOULD BE HAPPY TO
21	WORK TO OPTIMIZE THE REVIEW FOR EVERYBODY. AND SO
22	WE WELCOME THE INPUTS.
23	MR. KLEIN: DR. TROUNSON, I WOULD IN THAT
24	REGARD LIKE TO SAY THAT DR. OLSON, DR. SAMBRANO PUT
25	IN A HUGE AMOUNT OF EFFORT IN BRINGING THE WORLD'S

1	BEST PEOPLE TO THESE REVIEWS ALONG WITH YOUR EFFORTS
2	AND EVERYONE ELSE ON THE SCIENTIFIC STAFF. AND, DR.
3	SLADEK, THE PROBLEM IS THAT THE CHARTER MEMBERS OF
4	THE PEER REVIEW GROUP AS WELL ARE SOME OF THE
5	WORLD'S BEST IN THEIR FIELDS, AND IT'S JUST TOO MUCH
6	OF A DEMAND TO GET THEM TO ALL OF THESE SESSIONS.
7	AND BRINGING IN THESE PEOPLE WITH BACKGROUNDS THAT
8	HAVE SPECIAL RELEVANCE TO THE TOPIC HAS BROUGHT A
9	LOT OF VALUE AND KNOWLEDGE TO THESE PEER REVIEW
10	SESSI ONS.
11	BUT IN THIS CONTEXT, RECOGNIZING THAT WITH
12	OUR VOLUME AND THE SPREAD OF OUR SCOPE, I WOULD MAKE
13	THE MOTION THAT THE VICE CHAIRS OF THE WORKING
14	GROUPS ALONG WITH THE ADMINISTRATIVE CHAIR AND THE
15	EXECUTIVE COMMITTEE WORK WITH THE PRESIDENT AND DR.
16	SAMBRANO AND DR. OLSON AND THEIR SUPPORTING STAFF ON
17	DEVELOPING MATERIALS AS WELL AS PERHAPS A SHORT
18	POWERPOINT AT THE BEGINNING OF EACH SESSION TO WALK
19	PEOPLE THROUGH AND ANSWER A FEW QUESTIONS, GETTING
20	EVERYONE TO A COMMON LEVEL OF UNDERSTANDING,
21	OPTIMIZE THE VALUE OF THEIR INPUT AND THEIR
22	UNDERSTANDING OF THE CONTEXT OF THE INPUT FOR THESE
23	EXTRAORDINARY PEER REVIEW SESSIONS.
24	DR. STEWARD: COULD I MAKE A COMMENT? SO
25	I JUST WANTED TO HIGHLIGHT SOMETHING, AND REALLY

GOES BACK TO JOHN'S COMMENT. THERE'S THE ISSUE OF
THE CHAIR OF THE COMMITTEE AND THE REVIEWERS. OF
COURSE, WE NEED TO GET THE VERY BEST REVIEWERS FOR
WHATEVER AREA IS UNDER CONSIDERATION. THE CHAIR OF
THE COMMITTEE, AS JOHN SAID, DOES NOT NECESSARILY
NEED TO BE AN EXPERT IN THE AREA. IN FACT, WHAT THE
CHAIR NEEDS TO DO IS TO STORE, IF YOU WANT, THE
INSTITUTIONAL MEMORY OF PROCESS AND PROCEDURE AND
REALLY ENSURE FAIRNESS.
IN SOME RESPECTS, THE CHAIR REALLY MAYBE
IS ILL-ADVISED TO WEIGH IN STRONGLY ON ANYTHING
BECAUSE HE OR SHE IS THE CHAIR. I WOULD REALLY, I
THINK, REINFORCE THE IDEA OF TRYING TO THE EXTENT
POSSIBLE HAVE THE CHAIR BE SOMEONE WHO HAS
INSTITUTIONAL MEMORY, PREFERABLY THE CHAIR OF THE
SCIENTIFIC GROUP'S REGULAR CHAIR, RATHER THAN
BRINGING IN SOMEBODY WHO IS ENTIRELY NEW.
I WILL SAY WHILE I HAVE THE PODIUM HERE
I'M FULLY SUPPORTIVE OF THE IDEA OF PREPARING
MATERIALS FOR REVIEWERS IN ADVANCE. I THINK THAT'S
A GREAT IDEA. I WOULD RECOMMEND BREVITY. AS JOHN
SAID, SOME WILL READ IT, SOME WON'T. AND THE
SHORTER IT IS, THE MORE LIKELY IT IS THAT PEOPLE
WILL ACTUALLY SPEND THE TIME TO GO THROUGH IT.
THANK YOU.
82

1	MR. KLEIN: AND THE ITEM NO. 5 IN THIS
2	CASE IS WRITTEN FAIRLY NARROWLY, CONSIDERING THE
3	SCOPE OF MATERIALS. BUT THIS OTHER ITEM OF POLICY
4	IS A VERY IMPORTANT ITEM I THINK NEEDS TO BE
5	DISCUSSED. I'M GOING TO KEEP MY MOTION FOCUSED ON
6	THE ITEM THAT WE PROPERLY NOTICED.
7	CHAIRMAN SHEEHY: COULD WE GET A SECOND
8	FOR THAT?
9	MS. SAMUELSON: I'LL SECOND IT.
10	CHAIRMAN SHEEHY: AND MAYBE THE SOLUTION
11	TO THE QUESTION RAISED BY DR. STEWARD AND DR. SLADEK
12	IS MAYBE YOU CAN AGENDA AN ITEM INDEPENDENTLY FOR
13	THE BOARD, BOB, OR WOULD YOU CONSIDER THAT?
14	MR. KLEIN: YES. WOULD YOU WANT TO
15	CONSIDER THAT FIRST IN THE SCIENTIFIC COMMITTEE AND
16	THEN BRING IT TO THE BOARD, OR WOULD YOU WANT IT TO
17	GO DI RECTLY TO THE BOARD?
18	CHAIRMAN SHEEHY: I WOULD BE COMFORTABLE
19	WITH IT GOING DIRECTLY TO THE BOARD. I DO THINK
20	THAT IT DOES ENSURE THE CONTINUITY. I THINK OS'
21	POINTS WERE WELL TAKEN.
22	MR. KLEIN: OKAY. I UNDERSTAND.
23	MS. SAMUELSON: I ALSO THINK THAT THAT'S
24	SOMETHING WE CAN BE WORKING ON WITHIN THE WORKING
25	GROUP ON OUR OWN. WE ARE CHARGED UNDER THE
	83

1	PROPOSITION WITH THAT RESPONSIBILITY. AND I THINK
2	PART OF THE PROBLEM IS THAT WE HAVEN'T HAD ANYONE
3	OCCUPYING THE CHAIR ROLE. FOR A WHILE STU ORKIN WAS
4	STILL ON THE COMMITTEE, BUT NOT ACTIVE IN THAT ROLE.
5	MR. KLEIN: JOAN, JUST SO THE PUBLIC
6	UNDERSTANDS, THERE'S ALWAYS BEEN A CHAIR OF HIGH
7	QUALIFICATIONS, BUT THERE HASN'T BEEN A CHAIR THAT
8	IS THE PERMANENT CHAIR FOR A PERIOD OF TIME.
9	MS. SAMUELSON: WELL, I DON'T KNOW IF WE
10	HAD ANYONE OCCUPYING THE TITLE FOR A WHILE. STU IS
11	STILL ON THE WORKING GROUP. THIS ISN'T TO CRITICIZE
12	ANYONE. THEY'RE EXTREMELY BUSY PEOPLE.
13	MR. KLEIN: WE'VE HAD AN ACTING CHAIR FOR
14	EVERY PEER REVIEW GROUP.
15	MS. SAMUELSON: BUT THAT'S NOT WHAT I'M
16	TALKING ABOUT. I'M TALKING ABOUT WHAT OS WAS
17	TALKING ABOUT.
18	MR. KLEIN: I AGREE.
19	MS. SAMUELSON: AND JOHN. AND AT THE LAST
20	WORKING GROUP MEETING, I THINK THERE WAS THERE
21	WERE EXAMPLES OF THE PROBLEM. WE HAD SOMEONE WHO
22	WAS AN EXPERT IN THE FIELD, BUT NOT HAVING THAT
23	OVERARCHING VIEW IN MIND, AND HE DIDN'T KNOW WHAT A
24	PATIENT ADVOCATE WAS, HE DIDN'T UNDERSTAND OUR
25	MI SSI ON.
	9.4

1	MR. KLEIN: JOAN, DURING THE PROCESS OF
2	THE MEETING
3	MS. SAMUELSON: SO THAT WAS NOT SOMETHING
4	THAT HE WAS ASKED TO DO.
5	MR. KLEIN: WE ALL AGREE ON THE NEED FOR
6	THE CHAIR TO BE FULLY BRIEFED, BUT I WAS JUST, FOR
7	THE PUBLIC, TRYING TO MAKE IT CLEAR THAT WE ALWAYS
8	HAVE AN ACTING CHAIR. WHETHER OR NOT THE ACTING
9	CHAIR FULFILLS ALL THE RESPONSIBILITIES IS A
10	SEPARATE ISSUE.
11	MS. SAMUELSON: OF COURSE. OF COURSE.
12	THIS ISN'T A FUNDAMENTAL CRITICISM. IT'S JUST WE'RE
13	TRYING TO DO IT ALL BETTER. OF COURSE, THEY WANT US
14	TO DO. SO I WOULD JUST ECHO THE COMMENTS OF JOHN
15	SLADEK AND OF OS, AND WE SHOULD BE DOING THAT FROM
16	NOW THROUGH OUR NEXT GRANTS WORKING GROUP MEETING AS
17	WELL AS WE SHOULD BE DOING IT AT THE BOARD LEVEL AS
18	WELL.
19	CHAIRMAN SHEEHY: I JUST THINK THE POINT
20	ON HAVING A REGULAR CHAIR IS ONE THAT'S NOT AGENDAD
21	TODAY, JOAN. THAT WAS MY POINT. AND THAT IT WOULD
22	BE THERE'S NO REASON WHY CHAIRMAN KLEIN COULD NOT
23	PUT THAT ON THE AGENDA FOR THE JUNE MEETING, WHICH
24	WAS WHAT OS WAS TALKING ABOUT. WE CAN TAKE ACTION
25	ON THAT TODAY. AND THE QUESTION WAS WHETHER WE
	95

1	WANTED TO BRING THAT BACK HERE OR PERHAPS ASK
2	CHAIRMAN KLEIN TO GO AHEAD AND AGENDA IT FOR THE
3	JUNE MEETING. AND IT SEEMED TO ME TO BE REASONABLE.
4	WHY PUT IN AN ADDITIONAL STEP? I THINK IT WOULD BE
5	HELPFUL FOR THE CONTINUITY. AND AS OS AND DR.
6	SLADEK SAID, IT'S NOT NECESSARY THAT EVERY CHAIR BE
7	AN EXPERT IN THE FIELD IN WHICH THEY'RE CONDUCTING
8	THE REVIEW.
9	SO DR. OLSON HAS BEEN WAITING TO COMMENT.
10	DR. OLSON: I HAVE TWO COMMENTS NOW.
11	WELL, THE FIRST COMMENT IS WITH RESPECT I MEAN
12	INSOFAR AS PROJECTS MOVE INTO DEVELOPMENT, SO I JUST
13	WANTED TO EMPHASIZE SOMETHING THAT DR. TROUNSON
14	SAID, THAT WHEN PROJECTS MOVE INTO DEVELOPMENT
15	INSOFAR AS MULTIDISCIPLINARY TEAMS ARE AN IMPORTANT
16	COMPONENT, THAT MEANS MULTIDISCIPLINARY EXPERTISE ON
17	THE GRANTS WORKING GROUP. AND SO WHAT IS A GROUP OF
18	PREDOMINANTLY BASIC BIOLOGISTS FOR A BASIC BIOLOGY
19	AWARD WITH, AGAIN, THE VARIATION OF EXPERTISE THAT'S
20	ENCOMPASSED BY STEM CELL RESEARCH, YOU CAN SEE THAT
21	THAT'S FURTHER EXACERBATED AND IMPORTANT THAT YOU
22	HAVE A VERY BROAD GROUP OF SCIENTISTS WHO
23	PARTICIPATE IN THE GRANTS WORKING GROUP.
24	AND THE SECOND COMMENT THAT I WOULD MAKE,
25	AND I WOULD RESPECTFULLY SUBMIT, THAT THE FUNCTION

1	OF THE WORKING GROUP, IT'S VERY MUCH AN OPERATIONAL
2	MATTER THAT'S PERTINENT TO CIRM AS WELL. I WOULD
3	SUGGEST THAT INCLUSION OF THE SINCE THE PRESIDENT
4	DOES HAVE RESPONSIBILITY FOR OPERATIONS OF THE
5	INSTITUTE, THAT, YOU KNOW, INCLUSION OF HIS INPUT
6	AND THAT OF THE SCIENTIFIC STAFF WOULD BE RELEVANT
7	TO A DISCUSSION OF THE OPERATIONS OF THE WORKING
8	GROUP. THANK YOU.
9	CHAIRMAN SHEEHY: I THINK THAT'S THE
10	INTENT OF THE RESOLUTION. I WOULD NOTE THE GRANTS
11	WORKING GROUP IS A SUBSET OF THE ICOC AND IS
12	RESPONSIBLE FOR MAKING RECOMMENDATIONS TO THE ICOC.
13	AND IT'S HARD AS A MEMBER OF THE ICOC STATUTORILY
14	EMPOWERED TO MAKE DECISIONS ON GRANTS TO PARTICIPATE
15	IN THE GRANTS WORKING GROUP, TO SIT THERE WITH
16	PEOPLE WHO LOOK AT ME LIKE WHO ARE YOU AND WHY ARE
17	YOU HERE. IT MAKES IT VERY DIFFICULT WHEN YOU START
18	PROGRAMMATIC REVIEW WHEN NO ONE IN THE ROOM KNOWS
19	WHAT YOU ARE DOING AND THEY'RE ALL PACKING THEIR
20	BAGS TO LEAVE. THEN THEY COME TO THE BOARD WITH
21	PROGRAMMATIC ISSUES THAT HAVEN'T BEEN RESOLVED AT
22	WORKING GROUP.
23	AS DUANE RIGHTLY MENTIONED, WE SHOULD
24	RESOLVE THOSE ISSUES AT THE WORKING GROUP WHERE WE
25	HAVE THE SCIENTISTS, BUT WE CAN'T RESOLVE THEM AT

1	THE WORKING GROUP BECAUSE NOBODY KNOWS WHAT THEY'RE
2	HANGING AROUND FOR.
3	DR. OLSON: I WOULD CERTAINLY NOT TAKE
4	ISSUE WITH THE FACT THAT IT'S TOTALLY APPROPRIATE TO
5	UNDERSTAND WHO THE PATIENT ADVOCATES ARE. AND I
6	TOTALLY SUPPORT THE NOTION OF BIOSKETCHES AT THE
7	START OF EVERY GRANTS WORKING GROUP MEETING. DR.
8	SAMBRANO GOES THROUGH THE PROCESS, INCLUDING
9	PROGRAMMATIC. I'M SURE THAT COULD BE MADE CLEARER.
10	THE POINT I WAS SIMPLY MAKING WAS WITH
11	RESPECT TO A DISCUSSION OF THE CHAIRMAN OF THE
12	WORKING GROUP AND MATTERS RELATING TO THAT, THAT I
13	DO THINK THAT IS AN OPERATIONAL MATTER THAT
14	SHOULD INCLUDE DISCUSSION WITH THE PRESIDENT AND
15	MEMBERS OF HIS STAFF AS WELL. THAT IS ALL I WAS
16	REQUESTI NG.
17	MR. KLEIN: DR. OLSON, I COMPLETELY AGREE
18	WITH THAT. AND IF I DIDN'T IF I DIDN'T MAKE MY
19	COMMENTS ABOUT THE SCIENTIFIC LEADERSHIP, THE
20	PRESIDENT, AND THE SCIENTIFIC LEADERSHIP BEING
21	INVOLVED IN THAT DISCUSSION CLEAR, I WILL CERTAINLY
22	REINFORCE THOSE COMMENTS. I COMPLETELY AGREE.
23	JEFF, JUST SO THAT THE PUBLIC UNDERSTAND,
24	IT WASN'T AS IF EVERYONE DIDN'T UNDERSTAND, BUT SOME
25	PEOPLE DIDN'T AND WERE THINKING THAT THEY DID NOT

1	HAVE A MATERIAL PART IN THE PROGRAMMATIC REVIEW.
2	CHAIRMAN SHEEHY: MOST OF THE WORKING
3	GROUP DID NOT KNOW WHAT THE PROGRAMMATIC REVIEW WAS
4	OR WHY THEY WERE THERE. WHEN THE CHAIR OF THE
5	WORKING GROUP DOES NOT KNOW WHAT THE PROGRAMMATIC
6	REVIEW IS AND WHAT THE FUNCTION OF IT IS, THEN
7	PROGRAMMATIC REVIEW IS MEANINGLESS.
8	MR. KLEIN: JEFF, I THINK THAT WE GOT
9	THROUGH A DISCUSSION AND THEN HAD A GOOD
10	PROGRAMMATIC REVIEW IN THAT SESSION, BUT WE
11	CERTAINLY NEED THE MATERIALS UP FRONT AND THE
12	EDUCATION UP FRONT SO WE DON'T HAVE TO DO IT AT THAT
13	TIME IN THAT SESSION.
14	CHAIRMAN SHEEHY: WE'LL SEE WHEN THOSE
15	GRANTS COME TO THE BOARD, BOB, AND WHAT KIND OF
16	DISCUSSION THAT WE END UP HAVING AT THE BOARD.
17	MR. KLEIN: I UNDERSTAND.
18	CHAIRMAN SHEEHY: I THINK IT'S GOING TO BE
19	ONE OF THE MORE COMPLICATED BOARD DISCUSSIONS, AND I
20	THINK THAT WE ACTUALLY COULD HAVE DONE A BETTER JOB
21	IN THE REVIEW.
22	IN ANY EVENT, WE HAVE A MOTION ON THE
23	FLOOR. DO WE HAVE FURTHER DISCUSSION ON THE MOTION?
24	JAMES, COULD YOU RESTATE THE MOTION?
25	MR. HARRISON: YES. AS I UNDERSTAND IT,
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1	THE MOTION IS TO REQUEST THAT STAFF WORK WITH THE
2	VICE CHAIRS OF THE GRANTS WORKING GROUP, THE
3	ADMINISTRATIVE CHAIR OF THE GRANTS WORKING GROUP,
4	AND THE EXECUTIVE COMMITTEE TO DEVELOP MATERIALS TO
5	PROVIDE TO MEMBERS OF THE GRANTS WORKING GROUP IN
6	ADVANCE OF THE MEETING AND AT THE MEETING.
7	MR. KLEIN: THE MOTION IS ALSO THOSE
8	PERSONS WORKING WITH THE SCIENTIFIC LEADERSHIP OF
9	THE AGENCY, SPECIFICALLY INCLUDING DR. TROUNSON,
10	DR. SAMBRANO, DR. OLSON, AND THEIR STAFF.
11	CHAIRMAN SHEEHY: THAT'S FINE. OKAY. DO
12	WE HAVE ANY FURTHER DISCUSSION?
13	MR. KLEIN: IS THERE A PUBLIC DISCUSSION?
14	CHAIRMAN SHEEHY: BOB, I THINK THAT WAS MY
15	CALL. I'M READY TO ASK FOR PUBLIC COMMENT UNLESS
16	YOU'D LIKE TO CHAIR THIS.
17	MR. KLEIN: I'M SORRY.
18	DR. CHIU: AND I MUST SAY THAT HAVING
19	SERVED ON MANY REVIEW PANELS, REVIEWERS HAVE A
20	MIND-SET OF WHAT THEY'RE USED TO. AND EVEN THOUGH
21	YOU SEND THE MATERIAL AND YOU REMIND THEM,
22	OFTENTIMES, ESPECIALLY IF THEY'RE NOT FAMILIAR WITH
23	THE SITUATION, THEY TEND TO FORGET. SO I APPLAUD
24	ALL THE SUGGESTIONS THAT HAVE BEEN BROUGHT UP TO
25	REMIND THEM AGAIN WITH CLARITY HOW CIRM IS DIFFERENT
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1	FROM OTHER REVIEW PANELS.
2	I KNOW THAT THE CIRM STAFF HAS A REALLY
3	HEAVY WORKLOAD TO IDENTIFY SCIENTISTS WHO ARE
4	COMPETENT TO REVIEW SO MANY SPECIALIZED ELEMENTS.
5	AND WHEN YOU BRING IN THESE NEW MEMBERS, THEY ARE
6	TOTALLY UNFAMILIAR AND THEY REALLY NEED TO BE
7	EDUCATED. AND I'M SURE YOU ARE GOING TO COME UP
8	WITH A PROCESS TO MAKE SURE THEY UNDERSTAND THE
9	PROCESS, THAT THEY'RE RANKING APPROPRIATELY EITHER
10	AT WHOLE OR CHANGING THEIR SCORES AT THE MEETING
11	WHEN THEY UNDERSTAND WHAT THEY'RE SUPPOSED TO DO.
12	BUT I THINK THAT YOU ARE IDENTIFYING A LOT OF ISSUES
13	THAT WILL HAVE TO BE PLAYED OUT, AND THEN YOU HAVE
14	TO REMIND THEM OVER AND OVER AGAIN OR THEY
15	TEND TO GO BACK TO THE NIH STANDARD UNFORTUNATELY
16	BECAUSE THEY'RE COMFORTABLE WITH THAT AND THEY THINK
17	THEY KNOW WHAT THEY'RE DOING. SO THAT'S ALL I HAVE
18	TO SAY.
19	CHAIRMAN SHEEHY: DO WE HAVE ADDITIONAL
20	PUBLIC COMMENT? CALL THE ROLL.
21	MS. KING: JACOB LEVIN.
22	DR. LEVIN: YES.
23	MS. KING: ROBERT KLEIN.
24	MR. KLEIN: YES.
25	MS. KING: FRANCISCO PRIETO.
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1	DR. PRI ETO AYE.
2	MS. KING: ED PENHOET.
3	DR. PENHOET: YES.
4	MS. KING: PHIL PIZZO.
5	DR. PI ZZO: YES.
6	MS. KING: JEANNIE FONTANA.
7	DR. FONTANA: YES.
8	MS. KING: DUANE ROTH. JOAN SAMUELSON.
9	MS. SAMUELSON: YES.
10	MS. KING: JEFF SHEEHY.
11	CHAIRMAN SHEEHY: YES.
12	MS. KING: OSWALD STEWARD.
13	DR. STEWARD: YES.
14	MS. KING: AND ART TORRES.
15	MR. TORRES: AYE.
16	MR. ROTH: I'M A YES ALSO.
17	MS. KING: FOR THE RECORD, THAT MOTION
18	CARRI ES.
19	CHAIRMAN SHEEHY: OKAY. SO AGENDA ITEM 6,
20	POLICY REGARDING UNUSED DISEASE RESEARCH TEAM AWARD
21	FUNDS FOR CLINICAL TRIALS. SO, BOB, WOULD YOU LIKE
22	TO PRESENT THIS ITEM? YOU'VE TALKED ABOUT IT AT TWO
23	PRIOR BOARD MEETINGS.
24	MR. KLEIN: ALL RIGHT. SO THIS IS AN ITEM
25	THAT HAS COME UP AT PRIOR BOARD MEETINGS. AND THE
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1	KEY HERE IS THAT WE HAVE A DISEASE TEAM AWARD CYCLE
2	THAT WE'VE PREVIOUSLY APPROVED WITH A 48-MONTH
3	TRAJECTORY TO GET TO A PHASE I IND APPROVAL AS A
4	CENTRAL DI SCUSSI ON.
5	THE CONTEXT IN WHICH THIS WAS RAISED
6	EARLIER, I THINK ACTUALLY IN THE CONCEPT DISCUSSION
7	OF THIS AWARD AND THEN LATER, WAS TO ASK THE
8	SCIENTIFIC TEAM TO COME BACK WITH A POLICY THAT
9	WOULD CREATE ESSENTIALLY AN INCENTIVE FOR TEAMS WHO
10	ARE MOVING FASTER WHO MAY GET TO AN IND,
11	THEORETICALLY AT LEAST, IN TWO YEARS, NOT TO HAVE AN
12	INTENT TO SPEND ALL OF THEIR MONEY TO GET TO THE
13	IND, BUT WHATEVER FUNDS THEY HAD SAVED TO BE ABLE TO
14	APPLY THOSE TO PHASE I TRIALS.
15	DR. OLSON HAS PREVIOUSLY INDICATED THAT
16	THIS SHOULD BE SUBJECT TO A REVIEW OF AN EXTERNAL
17	REVIEW COMMITTEE THAT IS SPECIALISTS IN CLINICAL
18	TRIALS, AND THAT SHE WANTED, IN PARTICULAR I THINK
19	DR. TROUNSON ALSO WANTED AND THE BOARD HAS
20	PREVIOUSLY EXPRESSED SUPPORT FOR HAVING A VICE
21	PRESIDENT WITH SUBSTANTIAL CLINICAL EXPERIENCE IN
22	PLACE AT THAT TIME TO ALSO REVIEW THE USE OF FUNDS
23	ALONG WITH THE STAFF IN TERMS OF THE BUDGET
24	APPLICATIONS AND THE EFFECTIVE DEPLOYMENT OF SUCH
25	STAFF AND SUCH FUNDS THAT MIGHT BE AVAILABLE FOR

1	THIS USE.
2	SO THE ISSUE HERE IS TO HAVE A SPECIFIC
3	MOTION TO RECOMMEND A POLICY THAT THE EXISTING
4	DISEASE TEAM AWARDS THAT ARE IN PROCESS, THAT THE
5	SCIENTIFIC STAFF BRING TO THE BOARD A PROGRAM TO
6	IMPLEMENT A POLICY TO PERMIT THE UTILIZATION OF
7	UNUSED FUNDS AT THE TIME OF A PHASE I APPROVAL TO BE
8	APPLIED TO A PHASE I WITH THE REQUIREMENT THAT STAFF
9	GET PROCESSING AND APPROVAL FROM AN EXTERNAL REVIEW
10	COMMITTEE AND THAT THERE BE A CLINICAL VP THAT
11	REVIEWS WITH DR. TROUNSON AND THE REST OF THE STAFF
12	THE BUDGET AND APPLICATIONS OF FUNDS AND THE PROCESS
13	THAT WOULD BE UTILIZED IN MOVING THIS FORWARD WITH
14	OUR FUNDING.
15	CHAIRMAN SHEEHY: DO I HAVE A SECOND FOR
16	THE MOTION?
17	DR. PRI ETO: SECOND.
18	MS. SAMUELSON: I HAVE A QUESTION ABOUT
19	THE MOTION. DO WE HAVE GRANTEES WHO HAVE EXPRESSED
20	THAT THIS IS SOMETHING THEY'RE PREPARED TO BENEFIT
21	FROM?
22	CHAIRMAN SHEEHY: YES.
23	MR. KLEIN: THERE ARE GRANTEES THAT APPEAR
24	AT THIS TIME, AND WE WILL NEVER KNOW UNTIL THEY GET
25	THERE, BUT THAT THEY MAY GET TO AN IND IN LESS THAN

ı	48 MUNTHS AND NOT HAVE USED ALL THEIR FUNDING.
2	HOWEVER, THE KEY HERE IS TO LOOK FORWARD AND BE
3	PREPARED FOR THAT EVENTUALITY AND PROVIDE AN EARLY
4	SIGNAL THAT SINCE THEY CAN CONSERVE FUNDS, THAT THEY
5	WILL NOT LOSE THOSE FUNDS, BUT THEY WOULD BE
6	RESPONSIBLY REVIEWED AS TO THE USE OF THOSE FUNDS ON
7	THE PHASE I TRIAL.
8	I HAD A DISCUSSION WITH DR. PENHOET ABOUT
9	THIS JUST YESTERDAY. AND, DR. PENHOET, DO YOU HAVE
10	ANY COMMENTS TO ADD?
11	DR. PENHOET: NO. ONLY THAT I'M STRONGLY
12	SUPPORTIVE OF REWARDING PEOPLE WHO MOVE THINGS
13	QUICKLY AND GET INTO THE CLINIC. AND SO I THINK WE
14	SHOULDN'T ENCOURAGE THEM TO JUST SPEND UP THE MONEY
15	DOING WHAT THEY'RE DOING IF THEY CAN USE IT
16	PRODUCTIVELY FOR THE CLINICAL STUDIES.
17	CHAIRMAN SHEEHY: I HAVE A QUESTION FOR
18	YOU, DR. PENHOET. ED, ARE THERE OUTSIDE CONTRACTORS
19	THAT WE MIGHT BE ABLE TO ENGAGE IN CASE BECAUSE
20	THERE WERE SOME PREDICATES, A VP BEING IN PLACE,
21	ETC., ETC. FOR SOME REASON THAT DIDN'T MOVE. I
22	KNOW THAT CLINICAL TRIALS IS A FAIRLY SPECIALIZED
23	AREA, ESPECIALLY IN CELL THERAPIES. WOULD WE BE
24	ABLE TO LOCATE A CONTRACTOR THAT COULD FILL THOSE
25	ROLES, DO YOU THINK?

1	DR. PENHOET: YES.
2	CHAIRMAN SHEEHY: BOB, WOULD YOU TAKE A
3	FRI ENDLY AMENDMENT?
4	MR. KLEIN: WELL, HOPEFULLY WE'RE GOING TO
5	HAVE A CLINICAL VICE PRESIDENT QUICKLY, SO THE
6	FRIENDLY AMENDMENT IS EITHER THE CLINICAL VICE
7	PRESIDENT NEEDS TO BE IN PLACE OR IF SOMETHING
8	HAPPENS VERY QUICKLY, YES, WE COULD HAVE A CONTRACT
9	SPECIALIST THAT THE SCIENTIFIC STAFF WOULD SELECT.
10	DR. TROUNSON: JUST ONE CLARIFICATION.
11	BOB, I THINK AS SOON AS WE HAVE SOMEONE APPOINTED,
12	WHICH WE HOPE WILL BE VERY SOON, IT WAS GOING TO BE
13	A CLINICAL ADVISORY GROUP THAT WAS TO BE INDEPENDENT
14	THAT WOULD BE ADVISING US ON THE PROGRESS OF THE
15	DISEASE TEAMS AND WHETHER THEY'RE MEETING THE
16	MILESTONES AND THE GO/NO-GO DECISIONS. SO THAT WE
17	INTEND TO PUT IN PLACE WITH SPECIALISTS,
18	SPECIALISTS, CLINICAL TRANSLATIONAL PEOPLE. AND I
19	UNDERSTAND THAT'S THE GROUP THAT WOULD BE ADVISING
20	ON THIS?
21	MR. KLEIN: MY UNDERSTANDING, AND PLEASE
22	CORRECT ME IF I'M WRONG, IS THAT THE EXTERNAL REVIEW
23	COMMITTEE THAT DR. OLSON HAS PREVIOUSLY REFERRED TO;
24	IS THAT CORRECT?
25	DR. TROUNSON: THAT'S CORRECT.
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	DARRISTERS REPORTING SERVICE
1	MR. KLEIN: THAT WAS A CONDITION THAT I
2	PUT INTO THE MOTION.
3	DR. TROUNSON: RI GHT.
4	CHAIRMAN SHEEHY: SO MAYBE WE COULD HAVE A
5	RESTATEMENT OF THE MOTION.
6	MR. HARRISON: AS I UNDERSTAND IT, THE
7	MOTION IS TO REQUEST THAT STAFF PREPARE A POLICY FOR
8	THE USE OF UNUSED DISEASE RESEARCH TEAM AWARDS FUNDS
9	AT THE TIME OF PHASE I APPROVAL FOR FURTHER CLINICAL
10	STUDIES, INCLUDING REVIEW BY AN EXTERNAL ADVISORY
11	COMMITTEE AND EITHER A VP FOR RESEARCH AND
12	DEVELOPMENT; OR IF SUCH INDIVIDUAL HAS NOT BEEN
13	APPOINTED AT THAT TIME, A CONTRACT SPECIALIST.
14	MR. KLEIN: AND THE SCIENTIFIC STAFF
15	APPROVAL OF THE BUDGETARY USES OF THOSE FUNDS.
16	CHAIRMAN SHEEHY: SO DO WE HAVE FURTHER
17	DISCUSSION? PUBLIC COMMENT? ROLL CALL, PLEASE.
18	MS. KING: JACOB LEVIN.
19	DR. LEVIN: YES.
20	MS. KING: ROBERT KLEIN.
21	MR. KLEIN: YES.
22	MS. KING: FRANCISCO PRIETO.
23	DR. PRI ETO AYE.
24	MS. KING: ED PENHOET.
25	DR. PENHOET: YES.
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1	MS. KING: PHIL PIZZO.
2	DR. PI ZZO: YES.
3	MS. KING: JEANNIE FONTANA.
4	DR. FONTANA: YES.
5	MS. KING: DUANE ROTH.
6	MR. ROTH: YES.
7	MS. KING: JOAN SAMUELSON.
8	MS. SAMUELSON: YES.
9	MS. KING: JEFF SHEEHY.
10	CHAIRMAN SHEEHY: YES.
11	MS. KING: OSWALD STEWARD.
12	DR. STEWARD: YES.
13	MS. KING: AND ART TORRES.
14	MR. TORRES: AYE.
15	MS. KING: AND THAT MOTION CARRIES AS
16	WELL.
17	CHAIRMAN SHEEHY: OKAY. THE NEXT ITEM ON
18	THE AGENDA ARE DISCUSSION ITEMS. WHAT WOULD BE
19	HELPFUL IS IN TALKING ABOUT THESE WOULD BE TO LAY
20	OUT THE ISSUES. WHAT WOULD BE REALLY USEFUL, I
21	THINK, FOR INSTANCE, IN PREAPPLICATION REVIEW AND IN
22	THE EXTRAORDINARY PETITION PROCESS TO REALLY MAKE
23	SURE THAT WE CAN GIVE A CLEAR CHARGE TO STAFF ON THE
24	TYPE OF INFORMATION THAT WE NEED TO HAVE AVAILABLE
25	TO US IN ORDER TO MAKE DECISIONS ABOUT WHAT WE DO
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1	WITH BOTH OF THESE PROCESSES.
2	SO THE FIRST ITEM IS THE PREAPPLICATION
3	REVIEW. SO IS THERE ANYONE THAT WOULD LIKE TO WE
4	DO HAVE A NICE PRESENTATION THAT THE STAFF HAS GIVEN
5	US.
6	MS. KING: WHAT WE HAVE IS A REPORT ON THE
7	PREAPPLICATION PROCESS THAT WAS PRESENTED PREVIOUSLY
8	TO THE BOARD BY DR. SAMBRANO. WE PROVIDED THAT TO
9	THIS SUBCOMMITTEE TO USE IN THE DISCUSSION.
10	CHAIRMAN SHEEHY: BUT, YOU KNOW, I'M HAPPY
11	TO WADE IN AND SAY SOME OF THE THINGS THAT I WOULD
12	FIND USEFUL TO KNOW ABOUT THE PREAP PROCESS IS HOW
13	THE SCORING IS DONE, WHERE THE CUTOFFS ARE. I THINK
14	IT WOULD BE USEFUL TOO TO HAVE A FRAMEWORK LAID OUT
15	BECAUSE WE REALLY WE CAN PUT THIS INTO CONTEXT IN
16	THAT EVERY CONCEPT WE APPROVE WE HAVE A RANGE OF
17	OPTIONS. WE CAN TAKE UNLIMITED GRANT APPLICATIONS,
18	WE CAN LIMIT THEM BY INSTITUTION, OR WE CAN USE A
19	PREAP PROCESS. AND SO BEING CLEAR ABOUT THAT WHEN A
20	CONCEPT COMES TO US. SOME OF THEM, FOR INSTANCE,
21	THE TRAINING GRANT, THE FACILITY GRANT ARE
22	NECESSARILY GOING TO BE LIMITED BY INSTITUTION.
23	SOME, LIKE BASIC BIOLOGY, CLEARLY ARE GOING TO NEED
24	SOME SORT OF PREAP PROCESS BECAUSE WE GET
25	OVERWHELMED BY THE NUMBER OF APPLICATIONS.
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1	BUT REALLY MAKING A COHERENT MENU OF WHAT
2	OUR CHOICES ARE AND WHAT EACH PARTICULAR CHOICE
3	LOOKS LIKE AND THE APPLICABILITY OF EACH TO EACH. I
4	ALSO DON'T THINK, AND, AGAIN, GOING BACK TO OUR LAST
5	ROUND, EVERY APPLICATION THE STEM CELL
6	TRANSPLANTATION IMMUNOLOGY ROUND DID NOT PRESENT US
7	WITH THE LEVEL OF APPLICATIONS THAT OVERWHELMED OUR
8	ABILITY TO REVIEW. SO THAT WAS ONE WHERE A PREAP
9	PROCESS WAS NOT NECESSARY. SO I THINK THAT KIND OF
10	FLEXIBILITY IS HELPFUL.
11	IN ADDITION, I WOULD LIKE US TO CONSIDER
12	FOR OUR DISEASE TEAMS, I REALLY THINK PERSONALLY I
13	WOULD LIKE US TO CONSIDER, AND, AGAIN, THIS IS GOING
14	FORWARD, NOT FOR THIS MEETING, BUT TO AT LEAST
15	CONSIDER A TWO-TIER PROCESS WITH THE WORKING GROUP
16	BECAUSE THE AMOUNT OF MONEY IS SO MUCH, I DON'T FEEL
17	COMFORTABLE TELLING AN APPLICANT THAT THEY DIDN'T
18	GET A FULL REVIEW, YOU KNOW, OF SOME SORT. WE DID
19	THIS IN THE FIRST DISEASE TEAM PROCESS EVEN THOUGH
20	WE DON'T ACKNOWLEDGE IT IN THAT WE DID MAKE DISEASE
21	TEAM PLANNING GRANTS. SO IN THAT WAY WE DID TAKE A
22	FIRST CUT AT THE DISEASE TEAMS.
23	NOW, WE DID GET ADDITIONAL DISEASE TEAM
24	GRANTS, BUT THOSE GRANTS ACTUALLY DID MANY OF
25	THOSE GRANTS, AT LEAST IN CONCEPT, DID RECEIVE A
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1	PREAPPLICATION REVIEW BY THE GRANTS WORKING GROUP.
2	THE OTHER THING THAT WOULD BE HELPFUL FOR
3	ME IS TO HAVE A CLEAR SENSE OF WHAT KIND OF FEEDBACK
4	WE GIVE TO THE GRANTEES OR THE APPLICANTS WHEN THEY
5	DO THE PREAP REVIEW. NOW, I KNOW STAFF HAS IMPROVED
6	THAT BASED ON SOME OF OUR OTHER DISCUSSIONS, BUT TO
7	HAVE SOME CLARITY ON THAT. CERTAINLY THE INITIAL
8	PROCESS WHERE IT WAS YES OR NO IS NOT HELPFUL, I
9	THINK, IN SOME WAYS IN THAT THE GRANTEES DON'T
10	REALLY UNDERSTAND WHY THEY DIDN'T GET THE
11	OPPORTUNITY TO SUBMIT A GRANT.
12	SO ANY OTHER CONSIDERATIONS PEOPLE HAVE
13	THAT THEY MAY WANT TO INTRODUCE, BUT THIS IS REALLY
14	JUST TO PROVIDE INFORMATION TO STAFF SO THAT WE CAN
15	HAVE A THOUGHTFUL DISCUSSION AND BRING THESE ISSUES
16	TO CLOSURE THE NEXT TIME WE MEET.
17	MR. KLEIN: JEFF, THIS IS BOB KLEIN. I
18	THINK TO POINT OUT THE VALUE OF THE PREAPPLICATION
19	PROCESS IN CASES WHERE IT'S REALLY NEEDED, I THINK
20	IT WOULD BE GOOD IF THE STAFF COULD TELL US ON THE
21	TOOLS AND TECHNOLOGIES ROUND HOW MANY APPLICATIONS
22	THEY RECEIVED.
23	DR. SAMBRANO: 225.
24	DR. OLSON: WE RECEIVED 225
25	PREAPPLI CATI ONS.

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1	MR. KLEIN: SO IN THAT CASE WITH 225
2	APPLICATIONS, HOW MANY DO YOU THINK THAT YOU CAN
3	EFFECTIVELY REVIEW IN THE PEER REVIEW SESSION?
4	DR. OLSON: IN ONE REVIEW SESSION WE
5	BELIEVE WE COULD HANDLE ROUGHLY 60.
6	MR. TORRES: THAT'S ALL.
7	DR. OLSON: IN ONE REVIEW SESSION, IN A
8	FULL GRANTS WORKING GROUP SESSION.
9	MR. KLEIN: THAT'S THE REGULAR TWO-DAY
10	SESSI ON.
11	DR. OLSON: DAY AND A HALF TO TWO DAYS,
12	YES. AS YOU KNOW, THIS ONE'S TWO DAYS. THE
13	IMMUNOLOGY SESSION WE HAD 44.
14	DR. SAMBRANO: IT WAS AROUND THERE.
15	MS. SAMUELSON: WAS THERE ANY PREAP IN
16	THAT PROCESS?
17	DR. OLSON: NO, BECAUSE WE LIMITED IT BY
18	REQUIRING BOTH STEM CELL EXPERTISE AND IMMUNOLOGY
19	EXPERTISE. IF WE HAD REQUIRED ONLY IMMUNOLOGY
20	EXPERTISE, WE WOULD HAVE REQUIRED A PREAP.
21	MS. SAMUELSON: AND IN THE TOOLS AND
22	TECHNOLOGIES, WE DECLINED TO INVITE A FULL AP FROM
23	225 MINUS 60, WHATEVER THAT IS?
24	MR. KLEIN: THEY HAVEN'T YET GONE THROUGH
25	THE PREAP. THEY RECEIVED THE APPLICATIONS, JOAN,
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1	BUT THEY'RE ANTICIPATING THAT MAYBE THEY COULD
2	HANDLE 60. NOW, BASED UPON THE QUALITY THEY GET,
3	THEY COULD DECIDE TO HAVE MORE THAN ONE SESSION.
4	BUT AS YOU KNOW, DRAWING ON OUR REVIEWERS FROM
5	AROUND THE WORLD, WE HAVE TO LOOK TO THE QUALITY OF
6	THE SCIENCE. AND IF WE GET 65, MAYBE THEY CAN DO
7	THAT IN A DAY, BUT THERE'S A DECISION THERE ABOUT
8	REACHING ALL OF OUR OBJECTIVES AND OUR TRANSLATIONAL
9	GRANTS WHICH FOLLOW AND OUR DISEASE TEAM GRANTS
10	WHICH FOLLOW THAT AND NOT WANTING TO MOVE THOSE
11	SCHEDULES BACK.
12	DR. OLSON: SO THE 60 WAS A ROUGH TARGET
13	FIGURE FOR A TWO-DAY REVIEW.
14	CHAIRMAN SHEEHY: SO HAVE WE DONE EARLY
15	TRANSLATION II AS WELL?
16	DR. OLSON: YES.
17	CHAIRMAN SHEEHY: HOW MANY APPLICATIONS
18	WERE RECEIVED FOR THAT?
19	DR. OLSON: PREAPPLI CATIONS OR
20	APPLI CATI ONS?
21	CHAIRMAN SHEEHY: PREAPS.
22	DR. OLSON: 112.
23	CHAIRMAN SHEEHY: HAS THE CUT BEEN MADE ON
24	THOSE YET?
25	DR. OLSON: YES. WE HAVE INVITED 45.
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1	CHAIRMAN SHEEHY: SO HOW DO YOU DECIDE
2	WHERE TO MAKE THE CUT?
3	DR. OLSON: BASED ON EXTERNAL SCORES AND
4	INTERNAL ASSESSMENT OF RESPONSIVENESS PREDOMINANTLY.
5	MR. KLEIN: JEFF, MY UNDERSTANDING IS YOU
6	ARE GOING TO PUT THESE ITEMS FOR DISCUSSION. AND
7	THEN I THINK DO I UNDERSTAND CORRECTLY THAT YOU
8	ARE GOING TO MEET WITH THE SCIENTIFIC STAFF IN THE
9	INTERIM BEFORE THE NEXT SCIENTIFIC REVIEW COMMITTEE
10	SORT OF HELPING THEM DEVELOP THE MATERIALS?
11	CHAIRMAN SHEEHY: YEAH. A LOT OF THIS
12	IS MUCH AS I SAID ORIGINALLY, AND REALLY THIS WAS
13	THE GENESIS FOR THIS COMMITTEE, THE BOARD APPROVED
14	THIS PROCESS BY ONE VOTE. AND THEN WE REALLY
15	HAVEN'T HAD A CHANCE TO HAVE A DISCUSSION. AND TO
16	HAVE THIS DISCUSSION IS NOT MEANT AS CRITICISM OF
17	WHAT THE STAFF IS DOING, BUT SIMPLY TO HAVE AN
18	UNDERSTANDING OF WHAT'S GOING ON AND TO BE FULLY
19	INFORMED. I PERSONALLY AM AGNOSTIC ON THE ISSUE PER
20	SE.
21	DR. OLSON: I JUST WANT TO MAKE A
22	COUPLE
23	MR. ROTH: JEFF, I HAVE A COMMENT WHEN
24	YOU' RE READY.
25	DR. OLSON: I JUST WANTED TO MAKE A COUPLE
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1	OF COMMENTS REGARDING THIS. I THINK AS CHAIR SHEEHY
2	KNOWS, WE'VE CERTAINLY FOR THE EARLY TRANSLATION, I
3	THINK PROGRAMMATIC STARTS TO BE A VERY IMPORTANT
4	CONSIDERATION, AND I BELIEVE THIS COMMITTEE AND
5	MEMBERS OF THE BOARD KNOW THAT I WILL BE TALKING TO
6	YOU IN JUNE ABOUT OUR DEVELOPMENT PORTFOLIO PER SE
7	BECAUSE OUR PORTFOLIO AS A WHOLE, I THINK, STARTS
8	BECOMING IMPORTANT AS WE THINK ABOUT OUR EARLY
9	TRANSLATIONAL AND OUR DISEASE TEAM GRANTS GOING
10	FORWARD. I THINK THAT'S IMPORTANT INFORMATION THAT
11	ICOC MEMBERS, THAT THE WORKING GROUP, AND THAT THE
12	BOARD AS A WHOLE NEED TO BE AWARE OF IN ORDER TO
13	FULFILL THEIR RESPONSIBILITIES TO THE SCIENCE AND TO
14	THE PATIENTS IN MOVING THIS FORWARD.
15	SO THAT'S AN IMPORTANT CONSIDERATION. I
16	ALSO WANTED TO MAKE THE POINT THAT I THINK IN SOME
17	CASES WE'RE THINKING ALONG THE SAME LINES BECAUSE I
18	HAVE REQUESTED AND GIL AND HIS TEAM HAVE DONE THIS
19	IN THE PAST. I THINK BETTINA WAS THE DRIVER OR DR.
20	STEFFAN WAS THE DRIVER FOR THIS WITH THE DISEASE
21	TEAMS OF ACTUALLY HAVING CONFERENCE CALLS WITH ALL
22	THE REVIEWERS WHO WERE GOING TO PARTICIPATE IN THE
23	DISEASE TEAM AWARDS TO MAKE IT CLEAR WHAT THE GOALS
24	OF THAT RFA WERE AND WHAT WE ARE TRYING TO DO.
25	BECAUSE PARTICULARLY, I THINK, AS WE MOVE

1	INTO THESE MORE COMPLEX, THESE LARGER AWARDS, IT IS
2	VERY IMPORTANT BEFORE THE REVIEWERS START THEIR
3	REVIEW TO UNDERSTAND WHAT OUR OBJECTIVES ARE AND TO
4	TRY AND MAKE SURE, AS YOU HAVE INDICATED AND AS YOU
5	HAVE BROUGHT FORTH IN PART OF THE CONCERNS OF THIS
6	MEETING, THAT ALL PARTIES ARE ON THE SAME PAGE SO
7	THAT GOOD DECISIONS AND THE BEST DECISIONS CAN BE
8	MADE.
9	CHAIRMAN SHEEHY: DUANE.
10	MR. ROTH: MY COMMENT'S MORE GENERAL IN
11	THE FACT THAT I THINK THIS IS AN EXTREMELY IMPORTANT
12	ASPECT OF OUR REVIEW NOW THAT WE'RE BASICALLY GOING
13	TO BE USING IT ON A PRETTY ROUTINE BASIS, THAT IT BE
14	AS OBJECTIVE AND REALLY HANDLED VERY, VERY
15	CAREFULLY. I GET CONCERNED WHEN I HEAR THAT WE
16	START WITH A PRESUMPTION THAT WE CAN ONLY REVIEW SO
17	MANY GRANTS AND THAT WOULD BE AN ARTIFICIAL CUTOFF.
18	I'M GLAD BOB CLARIFIED THAT BECAUSE I THINK THOSE
19	ARE THE THINGS THAT WE HAVE TO BE VERY CAREFUL
20	ABOUT.
21	I KNOW WE'VE BEEN IN A TRIAL BASIS, BUT
22	YOU HAVE A SET OF EXPERIENCES. IT'S OBVIOUS IT'S
23	COMING THROUGH. AND I WOULD CHALLENGE PEOPLE
24	INVOLVED IN THE PROCESS TO SAY HOW CAN WE MAKE THIS
25	BETTER, MORE TRANSPARENT, AND GET THE RIGHT KIND OF
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1	RESULT THAT WE CAN STAND BEHIND UNDER SOME REAL
2	SCRUTI NY.
3	DR. SLADEK: I WEIGH IN ON BEHALF OF THE
4	GRANTS REVIEW GROUP. I THINK I HEAR GIL IN THE
5	BACKGROUND, SO MAYBE YOU COULD HELP ALSO. THERE ARE
6	SOME THINGS WE MIGHT CONSIDER. REALLY I SHARE
7	DUANE'S COMMENT ALSO ABOUT WORRYING ABOUT A
8	PREDETERMINED NUMBER THAT WE CAN REVIEW. IF I
9	RECALL, DURING THE EARLY DAYS OF OUR PROCESS, WE MAY
10	HAVE HAD SOME THREE-DAY MEETINGS. AND I, FOR ONE,
11	DON'T SEE WHY IT WOULDN'T BE POSSIBLE TO EXTEND
12	THESE OUT ANOTHER DAY TO BE ABLE TO HANDLE MORE OF A
13	VOLUME.
14	SECONDLY, ARE WE REQUIRED BY STATUTE TO
15	DISCUSS EVERY APPLICATION THAT COMES BEFORE THE
16	GRANTS REVIEW GROUP, OR COULD WE HAVE KIND OF A
17	TRIAGE SYSTEM WHERE, BASED ON THE SCORES AHEAD OF
18	TIME, WE DISCUSS ONLY THOSE WITHIN A CERTAIN
19	PERCENTI LE?
20	AND THE OTHER THOUGHT I HAD IS NIH, OF
21	COURSE, NOW, AND I DON'T WANT US TO BE LIKE NIH, AND
22	I'M PROBABLY THE ONE WHO'S SCREAMING THE LOUDEST NOT
23	TO BE, BUT WITH RESPECT TO THE REVIEW PROCESS, WE'RE
24	REVIEWING IN THE ORDER OF HIGHEST SCORE FIRST AND WE
25	GO DOWN THE LINE. WHILE THAT HAS SOME INHERENT
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1	PROBLEMS AND CAN PRODUCE SOME BLASES, IT DOES SPEED
2	UP THE PROCESS WHEN WE GET TO THE BOTTOM HALF.
3	SO I WONDER IF GIL COULD WEIGH IN ON SOME
4	OF THOSE.
5	DR. SAMBRANO: SURE. SO IN TERMS OF THE
6	OVERALL NUMBER THAT WE CAN REVIEW, THERE ARE SEVERAL
7	FACTORS THAT GO INTO IT. CERTAINLY ONE OF THEM IS
8	THE TIME OF REVIEW, SO WE CAN CERTAINLY SPEND AN
9	ADDITIONAL DAY OF REVIEW, BUT IT ALSO REQUIRES MORE
10	REVIEWERS TO FILL THAT NEED BECAUSE WHAT WE WANT TO
11	DO IS BE ABLE TO ASSIGN THREE REVIEWERS PER
12	APPLICATION TO ALLOW EACH TO ADEQUATELY REVIEW IT
13	AND PROVIDE DISCUSSION THAT'S GOING TO BE
14	SUBSTANTI VE.
15	AND AS YOU KNOW IN PARTICIPATING THROUGH
16	THESE REVIEWS, YOU WANT TO SPEND SUFFICIENT TIME
17	WITH THE APPLICATIONS TO ENSURE THAT THEY HAVE HAD
18	AN ADEQUATE REVIEW, THAT ALL THE POINTS IN TERMS OF
19	THE STRENGTHS AND WEAKNESSES HAVE BEEN CONSIDERED.
20	GIVEN THAT, A TWO-DAY MEETING WE CAN REASONABLY DO
21	ABOUT 60 APPLICATIONS. AND AT TIMES IT MIGHT EVEN
22	BE PUSHING IT. THREE DAYS, WE MIGHT BE ABLE TO GET
23	THROUGH 80 TO 90. BUT, AGAIN, THAT IS GOING TO BE
24	EXHAUSTIVE TO THE REVIEWERS WHO ARE PARTICIPATING IN
25	IT, AND IT MEANS THAT WE NEED TO FIND A WAY TO
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1	EITHER DO A BACK-TO-BACK REVIEW AS WE DID WITH TOOLS
2	AND TECHNOLOGIES AT ONE POINT. SO THERE ARE
3	MECHANISMS AROUND IT, BUT I THINK IT'S DIFFICULT TO
4	EXPAND MUCH BEYOND THAT.
5	SO WHEN WE GET 225 APPLICATIONS, THAT
6	CERTAINLY TRANSLATES TO MULTIPLE REVIEWS. THAT
7	CANNOT BE DONE IN THREE, FOUR DAYS.
8	MR. KLEIN: DR. SLADEK, THIS IS BOB KLEIN.
9	I SPECIFICALLY WANT TO EMPHASIZE THAT WHEN I HAD
10	PREVIOUSLY ASKED DR. OLSON, IF WE GOT QUALITY
11	CANDIDATE PROPOSALS, WHAT WOULD YOU RECOMMEND. AND
12	HER POSITION, WELL, IF WE HAD 80 HIGH QUALITY
13	PROPOSALS, WE'D DO A BACK-TO-BACK REVIEW. SO I
14	THINK IT IS IMPORTANT TO EMPHASIZE THAT SCIENTIFIC
15	STAFF IS NOT APPROACHING THIS WITH A HARD-LINE
16	CUTOFF. THEY HAVE AN ESTIMATED NUMBER; BUT IF THEY
17	GOT A GREATER NUMBER, THEY'VE ALWAYS BEEN VERY
18	RESPONSIVE. AND IN THE PRIOR TOOLS AND TECHNOLOGY
19	JUST REFERENCED, WE DID HAVE A BACK-TO-BACK REVIEW
20	BECAUSE OF ADDITIONAL CANDIDATE APPLICATIONS OF HIGH
21	QUALI TY.
22	DR. SLADEK: BOB, THAT'S VERY HELPFUL.
23	WHAT ABOUT THE OTHER TWO POINTS? CAN WE REVIEW IN
24	RANK ORDER BASED ON PRELIMINARY SCORES, AND DO WE
25	NEED TO DISCUSS EVERY PROPOSAL?
	100

1	DR. SAMBRANO: SO THAT'S THE NIH TRIAGE.
2	SO THE REASON WE DON'T DO THAT IS BECAUSE WE WANT TO
3	BE ABLE TO PROVIDE AN APPROPRIATE SUMMARY OF REVIEW
4	FOR EACH APPLICATION. AND THE FINAL DECISIONS ARE
5	MADE BY THE BOARD, BY THE LCOC, AND YOU WANT TO BE
6	ABLE TO BRING BACK ACROSS ALL APPLICATIONS THAT SAME
7	LEVEL OF REVIEW.
8	SO SOMETHING THAT THE GRANTS WORKING GROUP
9	MAY HAVE RANKED MORE HIGHLY OR MAY HAVE OMITTED IN
10	THEIR REVIEW BECAUSE OF THE TRIAGE MAY BE SOMETHING
11	THAT THE BOARD MAY WANT TO CONSIDER. SO WE WANT TO
12	PROVIDE ESSENTIALLY AN EVEN PLAYING FIELD AND ALLOW
13	EVERYBODY THE SAME REVIEW.
14	THE OTHER CHALLENGE, THOUGH, WITH THAT
15	TYPE OF TRIAGE IS THAT IT DOESN'T REALLY SAVE TIME
16	IN TERMS OF THE REVIEWERS REQUIRED TO DO THE REVIEW.
17	IT ONLY STREAMLINES THE ACTUAL MEETING. SO YOU CAN
18	REDUCE THE TIME SPENT DISCUSSING IN THE MEETING, BUT
19	YOU STILL NEED THE SAME NUMBER OF REVIEWERS TO
20	ADDRESS THOSE APPLICATIONS.
21	DR. SLADEK: ARE YOU HAVING DIFFICULTY
22	FINDING REVIEWERS?
23	DR. SAMBRANO: NO. THERE'S NOT A
24	DIFFICULTY IN FINDING REVIEWERS, BUT THERE ARE
25	ONLY THERE ARE 15 THAT CAN AT ANY ONE TIME BE
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1	PARTICIPATING IN THE GRANTS WORKING GROUP. SO WE
2	ADD EXPERTISE THROUGH SPECIALISTS. BUT THERE IS A
3	BENEFIT TO HAVING THE REVIEWERS WHO ARE PRESENT AT
4	THE MEETING ALL GET A SENSE OF THE OVERALL PORTFOLIO
5	OF APPLICATIONS THAT COME THROUGH SO THAT THEY CAN
6	HAVE A BETTER AND MORE PRODUCTIVE PROGRAMMATIC
7	DISCUSSION AFTERWARDS. IT ALSO GIVES THEM A BETTER
8	SENSE OF THE OBJECTIVES AND THOSE APPLICATIONS THAT
9	ARE LIKELY TO BE MOST RESPONSIVE AS A RESULT.
10	MS. SAMUELSON: THEY CAN DO THAT WITHOUT
11	HAVING TO NECESSARILY THEMSELVES DO THE FIRST READ
12	OF THE GRANT APPLICATION, RIGHT? WE CAN SEND OUT
13	THE RESPONSIBILITY FOR THE REVIEW, THE FIRST READ OF
14	THE APPLICATION, AND THE DRAFT OF THE ANALYSIS, THE
15	CRITIQUE AND PROPOSED SCORE, TO REVIEWERS BEYOND THE
16	REGULAR MEMBERS OF THE WORKING GROUP AS LONG AS THE
17	WORKING GROUP IS IN THE ROOM WHEN THOSE ARE
18	DI SCUSSED.
19	DR. SAMBRANO: THE APPLICATIONS BENEFIT
20	FROM HAVING, FOR EXAMPLE, EACH APPLICATION HAVING
21	THE PERSPECTIVE OF THREE DIFFERENT REVIEWERS. NOW,
22	EACH ONE LOOKS AT THE APPLICATION AND INDEPENDENTLY
23	MAKES A GENERAL ASSESSMENT, BUT THEN THEY COME TO
24	THE MEETING. AND THEN DURING THE DISCUSSION, THEIR
25	POINTS ARE ADDRESSED IN FRONT OF ALL THE OTHER

1	GRANTS WORKING GROUP MEMBERS, ALL THE OTHER
2	SCIENTISTS WHO THEN ADD THEIR EXPERTISE. USUALLY WE
3	FIND THAT THROUGH THAT DISCUSSION, THERE IS A BETTER
4	UNDERSTANDING OF CERTAIN CONCEPTS THAT MAY END UP
5	AFFECTING HOW THEY ACTUALLY FEEL ABOUT A PARTICULAR
6	APPLI CATI ON.
7	SO I THINK IT BENEFITS FROM CERTAINLY
8	NEEDING TO HAVE THAT INDIVIDUAL REVIEW BY THREE
9	INDEPENDENT REVIEWERS AND THEN HAVING THEM COME TO
10	THE MEETING AND HAVE A FULL DISCUSSION IN FRONT OF
11	THE OTHER SCIENTISTS.
12	MR. KLEIN: JEFF, WE ONLY HAVE ABOUT 15
13	MINUTES LEFT. I THOUGHT MAYBE YOU WOULD WANT TO
14	MOVE THROUGH THE OTHER ITEMS TO AT LEAST PUT THE
15	TEXTURE AND SKELETON TO THE ITEMS TO BE DISCUSSED IN
16	THE FUTURE.
17	CHAIRMAN SHEEHY: THAT'S A GOOD POINT.
18	YOU READ MY MIND. I JUST CHECKED MY CLOCK.
19	DR. LEVIN: CAN I MAKE ONE FINAL COMMENT,
20	THIS IS JACOB, BEFORE WE MOVE OFF THE TOPICS? I
21	THINK THAT IT'S IMPORTANT TO NOTE THAT IT'S BEEN
22	CLEAR FROM EVERYTHING THAT'S PRESENTED THAT FOR SOME
23	OF THESE COMPETITIONS, THE BURDEN OF REVIEW IS QUITE
24	LARGE, AND THERE NEEDS TO BE SOME SORT OF
25	PREAPPLICATION OR TRIAGE PROCESS. BUT IT'S VERY

1	IMPORTANT TO NOTE THAT WHAT WE'RE CURRENTLY DOING AT
2	CIRM IS NOT THE SAME AS THE PREAPPLICATION REVIEW
3	THAT GOES ON AT NSF OR NIH OR SOME OF THE
4	FOUNDATIONS IN ONE FUNDAMENTAL WAY, WHICH IS THAT ON
5	ALL OF THOSE PREAPPLICATIONS, THE SCORING OF THE
6	REVIEW IS ENTIRELY EXTERNAL TO THE AGENCY ITSELF.
7	IT'S BASED ON JUST BASICALLY THE GRANTS WORKING
8	GROUP MEMBERS IN OUR SITUATION. IT'S JUST THE
9	EXTERNAL PEER REVIEW, AND THERE ISN'T THAT INTERNAL
10	AGENCY PROGRAMMATIC REVIEW THAT WE DO AND THAT WE DO
11	IN CLOSED SESSION, SO NOT TRANSPARENTLY.
12	I THINK THAT IS SOMETHING THAT WE
13	SHOULD CONSIDER. THAT WASN'T DISCUSSED AS A
14	POTENTIAL OPTION, BUT IT IS. WE COULD ADD A FOURTH
15	POSSIBILITY TO DEAL WITH THIS, WHICH IS THAT
16	EVERYTHING IS DONE TRANSPARENTLY OR EVERYTHING IS
17	DONE PURELY BY EXTERNAL PEER REVIEW, INCLUDING THE
18	PROGRAMMATIC RANKING, RATHER THAN HAVING IT DONE BY
19	CIRM STAFF IN CLOSED SESSION.
20	DR. CHIU: MAY I MAKE A QUICK COMMENT? I
21	HAVE A NUMBER OF CONCERNS ABOUT THE PREAP, PRECISELY
22	ONE OF THE REASONS BEING WHAT WAS EXPRESSED. AND
23	THAT IS A COMPLETELY OPAQUE AS OPPOSED TO EVERY
24	OTHER PRACTICE THAT CIRM DOES IN SHOWING REVIEW IS
25	TAKING PLACE. IN FACT, IN ONE OF THE EARLIER AGENDA

1	ITEMS, YOU EVEN WANTED TO SHOW THE SPREAD OF THE
2	SCORE, ETC., IN MAKING YOUR FINAL DECISION. HERE
3	YOU HAVE TWO OR THREE EXTERNAL MEMBERS GIVING THE
4	SCORES.
5	I DON'T THINK, NO. 1, THAT THE GRANTEES
6	REALLY UNDERSTAND THE PROCESS OR WHAT THEY REALLY
7	NEED TO DO TO IN ORDER TO MAKE IT THROUGH THIS
8	PARTI CULAR BARRI ER.
9	SECOND, THERE IS NO DISCUSSION BETWEEN THE
10	REVIEWERS. SO THAT THEY GIVE A NUMBER OR ONE OR TWO
11	LINES OF COMMENTS, AND THEN A PREAP IS EITHER
12	DITCHED OR ACCEPTED.
13	THIRD, YOUR TRIAGE PERCENTILE IS
14	EXTRAORDINARILY HIGH. EVEN IF YOU ACCEPTED 80 OUT
15	OF 225, THAT'S 38 PERCENT OF APPLICATIONS THAT ARE
16	INVITED TO COME IN. MY CONCERN IS WHAT IF DURING
17	THIS PROCESS WE LOSE TWO OR THREE KEY, EXCELLENT
18	PROPOSALS JUST BECAUSE OF THE WAY THE SYSTEM IS
19	HANDLED AND NOBODY ELSE SEES THEM. AND THESE
20	APPLICANTS, THESE PREAPPLICANTS, DON'T EVEN HAVE A
21	CHANCE TO SUBMIT A FULL APPLICATION TO GET A SHOT AT
22	IT.
23	SO MY HOPE IS THAT WHILE THE VERY BAD ONES
24	YOU CAN ABSOLUTELY CLEAR WITH THE PREAP PROCESS,
25	THAT THE GRAY ZONE SHOULD BE BROADENED SO THAT THEY

1	HAVE A CHANCE. AND IF WITH THE FULL REVIEW, ONE OR
2	TWO OF THOSE THAT ACTUALLY DID NOT SCORE NECESSARILY
3	AMONGST THE TOP IN THE PREAP MIGHT TURN OUT TO BE
4	GOLD, AND THAT'S WHAT I'M HOPING FOR.
5	DR. TROUNSON: JUST ONE THING. I THINK IN
6	ALL THESE COMMENTS WE ALSO HAVE TO KEEP IN MIND THE
7	APPLICANTS. WE HAVE ACTUALLY BEEN TO THE HEADS OF
8	ALL THE STEM CELL GROUPS AND ALSO TO A BROAD RANGE
9	OF THE BIOTECH COMPANIES, AND WE'VE GOT VERY STRONG
10	SUPPORT FOR DOING THIS PREAPPLICATION PROCESS.
11	ONE OF THE MAIN DRIVERS IS FOR THEM TO
12	AVOID, PARTICULARLY WITH THESE BIG GRANTS, HAVING TO
13	PUT A LOT OF TIME INTO DRAFTING SUBSTANTIAL GRANTS
14	THAT REALLY HAVE NO CHANCE OF ACTUALLY MAKING IT.
15	AND THAT IS PARTICULARLY SOMETHING WHICH IS IRKSOME
16	FOR BOTH COMPANIES AND FOR INSTITUTES. SO IF THEY
17	CAN BE SUGGESTED TO GO BACK AND GET IMPROVED IN SOME
18	WAY TO GET TO BE MORE COMPETITIVE, THAT'S A BETTER
19	OUTCOME THAN SPENDING A LOT OF TIME DOING THIS.
20	SO THERE WAS A STRONG CONSENSUS,
21	ABSOLUTELY CONSENSUS, THAT THIS WAS A PREFERRED
22	SYSTEM TO ANYTHING ELSE THAT THEY'VE BEEN EXPOSED TO
23	OR HAD THOUGHT UP.
24	DR. CHIU: MAY I RESPOND TO THAT? I
25	TALKED WITH A LOT OF THE POTENTIAL GRANTEES, AND

1	MOST OF THEM ARE LOATHE TO SPEAK THEIR MINDS. THE
2	ONES WHO GOT THROUGH ARE VERY HAPPY WITH THE
3	PROCESS. THE ONES WHO DON'T GRIPE ABOUT IT ON THE
4	SIDE, BUT THEY DON'T WANT TO WRECK THEIR CHANCES IN
5	THE NEXT ROUND.
6	DR. TROUNSON: SO THESE WERE THE HEADS OF
7	THE STEM CELL GROUPS, GENERALLY THE REALLY SENIOR
8	SCIENTISTS. THEY HAVE NO COMPUNCTION IN TELLING US
9	EXACTLY WHAT THEY THINK, I CAN TELL YOU.
10	DR. CHIU: I UNDERSTAND, BUT THERE ARE A
11	LOT OF YOUNGER SCIENTISTS WHO ARE TRYING THEIR
12	INNOVATIVE PROJECTS, AND THEY DON'T QUITE KNOW
13	WHAT'S GOING ON. SO MY SUGGESTION, NO. 1, THAT THE
14	REVIEWERS SHOULD REALLY UNDERSTAND WHAT IS THE
15	PROCESS AND WHAT IS THE OBJECTIVE OF EACH RFA.
16	BECAUSE, AS I UNDERSTAND IT, THE PREAP PROCESS
17	TARGETS THOSE MOST RESPONSIVE TO THE OBJECTIVE OF
18	THE RFA AND NOT EVEN NECESSARILY GREAT SCIENCE AND
19	PROBABLY REASONABLY SO. BUT DO THE REVIEWERS
20	UNDERSTAND THAT? I'M SURE MANY OF THEM DO.
21	THE SECOND IS THAT THE GRANTEES
22	THEMSELVES, DO THEY UNDERSTAND THAT THAT'S WHAT
23	THEY' RE GOING TO BE JUDGED UPON? AND ONE
24	POSSIBILITY IS THAT THEY COULD GET DIRECT
25	BACK-AND-FORTH Q-AND-A SESSIONS WITH CIRM STAFF TO

1	EXPLAIN TO THEM HOW THEY SHOULD CRAFT THEIR
2	PREAPPLICATION SO THAT THEY CAN SHINE WHERE THERE IS
3	SOMETHING TO SHINE. AND THAT WAY CIRM COULD GET THE
4	BEST APPLICATIONS POSSIBLE.
5	DR. LEVIN: FOUNDATIONS AND NSF AND NIH DO
6	THIS, INTERACTIONS BEFORE THE PREAPS ARE EVEN GIVEN.
7	DR. CHIU: NIH DOES NOT DO ANY PREAP
8	EXCEPT FOR ONE. ONE OUT OF 4,000 STUDY SECTIONS DO
9	IT, AND I CALLED THEM TO FIND OUT, AND THEY HAD
10	SPECIAL DISPENSATION. OTHERWISE, AT THE NIH YOU'RE
11	NOT ALLOWED TO TRIAGE JUST BASED ON THE LETTER OF
12	INTENT OR PREAP. SO THIS IS A VERY SPECIALIZED
13	PROCESS, AND PRIVATE FOUNDATIONS OFTEN DO IT A LOT,
14	BUT THEY'RE ANSWERABLE ONLY TO THEIR PRIVATE DONORS.
15	CHAIRMAN SHEEHY: SO I THINK STAFF HAS
16	HEARD THESE COMMENTS. AND I WOULD RECOMMEND SENDING
17	ADDITIONAL COMMENTS THAT MIGHT BE USEFUL FOR STAFF
18	TO CONSIDER AND BRING THIS AGENDA ITEM BACK.
19	MR. TORRES: HE'S NEVER ALLOWED TO SPEAK.
20	CHAIRMAN SHEEHY: WE'RE NOT COMING TO
21	CLOSURE ON THIS ISSUE TODAY.
22	MR. TORRES: I THOUGHT IT WAS RELEVANT.
23	CHAIRMAN SHEEHY: WHAT WOULD BE HELPFUL IS
24	IF THERE'S ADDITIONAL FEEDBACK THAT'S GOING TO COME
25	IN, IF THERE'S ADDITIONAL FEEDBACK THAT COMES IN,

1	EITHER GET IT TO MELISSA OR ME AND WE'LL FORWARD IT
2	ON TO STAFF IN ORDER TO INFORM THE DISCUSSION. THIS
3	JUST SHOWS THAT THIS AGAIN, THIS IS AN ISSUE WE
4	NEED TO ADDRESS DIRECTLY WITH A MORE THOROUGH
5	DISCUSSION. THIS WAS REALLY AN ATTEMPT TO GET THE
6	MAIN ISSUES OUT THERE. I HOPE WE HAVE SOME NOTES
7	THAT ARE BEING TAKEN AND THE STAFF IS AWARE OF THE
8	KINDS OF DISCUSSIONS WE NEED TO HAVE IN ORDER TO
9	MAKE POLICY IN THIS AREA.
10	THE NEXT ONE I'D LIKE TO TALK ABOUT IS THE
11	EXTRAORDINARY PETITION AND APPEALS PROCESS. WE HAVE
12	FIVE MINUTES, I THINK, LEFT IN THIS MEETING.
13	MS. SAMUELSON: JEFF, ARE WE GOING TO HAVE
14	AN OPPORTUNITY TO TALK AT ALL ABOUT THE SCOPE OF
15	THIS SUBCOMMITTEE?
16	CHAIRMAN SHEEHY: THAT'S NOT ON THIS
17	AGENDA.
18	MS. SAMUELSON: CAN WE AGENDIZE THAT FOR
19	THE FUTURE?
20	CHAIRMAN SHEEHY: ABSOLUTELY. SO JUST IN
21	TERMS OF THE EXTRAORDINARY PETITION AND APPEALS
22	PROCESS, I WANT TO MAKE A COMMENT, GET SOME OTHER
23	COMMENTS. ONE COMMENT I WOULD LIKE TO MAKE, ONE
24	THING THAT I WOULD LIKE TO SEE OPTIONED TO US IS A
25	REVIEW OPTION SO THAT THE BOARD IS NOT LEFT, LIKE WE

1	WERE AT THE LAST MEETING, WITH EITHER HAVING TO VOTE
2	A GRANT UP AND DOWN. AND IF THERE'S NEW INFORMATION
3	THAT COMES FORWARD THAT THE BOARD WISHES TO HAVE
4	CONSIDERED, WE SAW THIS IN THE DISEASE TEAMS, I
5	THINK IT'S A MUCH BETTER PROCESS WHEN WE DO GET
6	APPEALS, UNLESS THE BOARD FEELS STRONGLY THAT THE
7	MERIT HAS BEEN ACHIEVED, THE OPPORTUNITY TO GO BACK,
8	AND, AGAIN, THIS IS SOMETHING WE CAN WORK WITH
9	STAFF, TO AT LEAST CONSIDER AS AN OPTION THAT WE
10	MIGHT BRING FORWARD TO THE BOARD, BUT SOME SORT OF
11	REREVIEW EITHER BY THE PRIMARY REVIEWERS FROM THE
12	GRANT, BUT SOMETHING WHERE WE CAN GET A LITTLE MORE
13	INFORMATION ABOUT THE GRANT AND ALSO GIVE THE BOARD
14	ANOTHER OPTION BESIDES YES OR NO.
15	IF THERE ARE OTHER ANY OTHER
16	CONSI DERATI ONS?
17	MR. KLEIN: JEFF, MY UNDERSTANDING WAS
18	THAT JUST TO GET A CONSISTENT COMMUNICATION OUT TO
19	THE APPLICANTS OF WHAT THE EXTRAORDINARY PETITION
20	PERMITTED THEM TO DO.
21	CHAIRMAN SHEEHY: I THINK IT'S IMPORTANT
22	THAT WE MAKE I PERSONALLY, AGAIN, GOING INTO
23	PRESENTATION OF THIS ITEM FOR CONSIDERATION FOR
24	RESOLUTION, THINK THAT WE OUGHT TO STREAMLINE THE
25	PROCESS. WE HAVE TWO DIFFERENT PROCESSES. I REALLY

1	
1	THINK THEY SHOULD BE ONE. YOU CAN APPEAL FOR THIS
2	ISSUE OR FOR THAT ISSUE. ONE IS HANDLED
3	ADMINISTRATIVELY WHICH WE CURRENTLY CALL THE APPEALS
4	PROCESS AND IS ALMOST EXCLUSIVELY AN INTERNAL
5	PROCESS TO CIRM. AND THE SCIENTIFIC STAFF WITH
6	REREVIEW OF THE GRANT, IF IT'S ACCEPTED. THE OTHER
7	ONE, THE EXTRAORDINARY PETITION PROCESS, IS PART OF
8	THE ABILITY TO PETITION THE BOARD. BUT JUST, AGAIN,
9	THIS BECOMES A MENU ITEM, PUTTING THE OPTIONS OUT
10	THERE THAT AN APPLICANT HAS IF THEY'RE UNHAPPY AND
11	WHAT THEIR RECOURSE IS, AND THEN GIVING OPTIONS TO
12	THE BOARD WHEN THESE THINGS COME FORWARD. THIS IS A
13	BROKEN PROCESS. I THINK ALMOST EVERYBODY ON THE
14	BOARD WOULD AGREE THAT IT IS.
15	BUT IF THERE ARE OTHER ITEMS
16	DR. TROUNSON: IT'S GOT A LOT TO DO WITH
17	TIME AS WELL, JEFF. IF WE GET IT ONLY A DAY, OFTEN
18	WE ONLY GET IT A DAY OR EVEN WITHIN A DAY OF THE
19	BOARD MEETING, WHICH MAKES IT REALLY DIFFICULT FOR
20	EVEN US TO COMMENT ON. SO MAYBE WE HAVE TO TRY AND
21	FIGURE OUT HOW TO LENGTHEN THAT PROCESS, BUT IT WILL
22	LENGTHEN THE PROCESS TO DO SOME OF THESE THINGS
23	BECAUSE WE JUST DON'T SEEM TO GET THOSE RESPONSES IN
24	A REASONABLE TIME TO ALLOW US TO DO SOMETHING
25	FULLER. WE'RE ACTUALLY RESPONDING EVEN WITHIN A DAY

1	BECAUSE WE THINK THE BOARD REALLY NEEDS AS MUCH WE
2	CAN GIVE THEM, BUT IT MAKES IT PRETTY DIFFICULT.
3	AND THEN EVEN THE ONES, THERE IS NO
4	WRITTEN RESPONSE, BUT THE PEOPLE TURN UP AT THE
5	BOARD MEETING WHERE WE REALLY HAVEN'T HAD A CHANCE
6	BECAUSE WE WEREN'T AWARE THAT THAT WAS GOING TO
7	HAPPEN, AND IT MAKES IT VERY DIFFICULT ON THE SPOT
8	TO TRY AND PROVIDE THE BOARD WITH THE KIND OF
9	INFORMATION THAT THEY NEED. SO THERE'S A LOT OF
10	DIFFERENT ASPECTS I THINK WE NEED TO EXPLORE IN THIS
11	TO MAKE IT MORE FUNCTIONAL, MORE HELPFUL, AND MORE
12	SENSI BLE.
13	SO OTHERWISE, I THINK OTHERWISE I THINK
14	WE'LL KEEP GETTING STUCK WITH THE PROBLEMS OF THE
15	SHORT TERM OF WHAT WE CAN DO IN SUCH A SHORT TIME.
16	MR. ROTH: THIS IS ONE THAT I THINK REALLY
17	NEEDS TO BE RETHOUGHT COMPLETELY BECAUSE WHAT WE
18	HAVE RIGHT NOW DOESN'T SEEM TO BE WORKING. EVEN THE
19	EXTRAORDINARY PETITIONS, I THINK WITH THE EXCEPTION
20	POTENTIALLY OF ONE WHICH WE RESPONDED TO, WE AGREED
21	WITH THE REVIEWERS. AND THEN IN THE BOARD MEETINGS
22	TURNED AROUND AND DISAGREED WITH OUR OWN
23	DISAGREEMENT. AND I THINK WE JUST DON'T WANT TO DO
24	THAT.
25	SECOND, I THINK WE'RE INVITING VERY BAD
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1	PRECEDENT BEHAVIOR BY OPENING OURSELVES UP TO THE
2	KINDS OF THINGS THAT WE WENT THROUGH AT THE LAST
3	MEETING. WE JUST INVITE PEOPLE TO CONTINUE TO DO
4	THAT. I'D LIKE TO SEE US FIND A SOLUTION FOR
5	GRIEVANCES ON THE REVIEWS THAT EVERYBODY CAN GET
6	BEHIND AND ENDORSE AND EMBRACE. I THINK IT'S
7	IMPORTANT WE GET THERE.
8	JUST, ALAN, TO YOUR POINT, I'M A LITTLE
9	CONCERNED THAT WHEN WE GIVE THEM A FIVE-DAY DEADLINE
10	AND THEN WE GO AHEAD AND WITH ONE-DAY NOTICE WE TRY
11	TO RESPOND, THAT PUTS US IN A POSITION WHERE
12	SOMEBODY DOWN THE ROAD SAYS, WELL, YOU RESPONDED TO
13	THE OTHER GUY IN A DAY. WHY COULDN'T YOU DO ME? WE
14	EITHER HAVE TO HAVE RULES THAT WE ARE GOING SIT
15	BEHIND, STAND BEHIND, OR WE SHOULDN'T HAVE THE
16	RULES.
17	MR. TORRES: LET ME GIVE YOU AN EXAMPLE
18	BECAUSE I WANT TO SUPPORT ALAN AND DUANE ON THIS
19	BECAUSE I'VE EXPERIENCED IT THROUGH AT LEAST THE
20	SHORT TIME I'VE BEEN HERE. NO. 1, WE NEED TO
21	EXPLAIN THE PROCESS AS BEST WE CAN A LITTLE MORE
22	EXTENSIVELY TO THE GRANTEES. EVEN THE REVIEWERS
23	SITTING ON THE REVIEW GROUPS DON'T KNOW WHAT A
24	MINORITY REPORT IS ALL ABOUT. WE HAD TO EDUCATE
25	THEM. IF THEY WANTED TO FILE A MINORITY REPORT,
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THEY HAD AN OPTION TO DO AND WHAT DID IT ENTAIL,
WHAT DID IT MEAN. WE NEED TO DO MORE EDUCATION IN
THAT REGARD BECAUSE IT IS IMPOSSIBLE FOR, AS I HAVE
SEEN, FOR STAFF TO TURN AROUND AND REVIEW A PETITION
FOR GRIEVANCE AND DO IT REALLY SUBSTANTIVELY IN TIME
FOR ALL OF US TO REVIEW AT THE SAME TIME OR TO CALL
OTHER SOURCES TO SAY WHAT THEY THINK ABOUT THIS.
THIS IS THROWING IT OUT. MAYBE WE JUST
OUGHT TO HAVE ALL OF THE GRANTEES SIGN THAT I HAVE
READ THE EXTRAORDINARY PETITION GRIEVANCE PROCESS.
I AM AWARE OF IT BECAUSE THEY ALWAYS COME BACK AND
SAY I DIDN'T KNOW THAT THIS WAS POSSIBLE, OR I WOULD
HAVE FILED EARLIER HAD I KNOWN. WELL, THEY ALL KNOW
IT'S THERE. THEY ALL KNOW THE PROCESS IS THERE IF
THEY TOOK THE TIME TO READ IT. MAYBE WE NEED SOME
AFFIRMATION THAT THEY'VE READ IT SO THAT BOTH SIDES
KNOW THAT THEY'RE AWARE OF THEIR RIGHTS.
DR. LEVIN: THE PROCESS SHOULD BE
DISTRIBUTED WITH THE REVIEWS WHEN THE REVIEWS AND
THE SCORES ARE GIVEN BACK TO THE APPLICANTS.
DR. TROUNSON: IT IS.
DR. LEVIN: WE NEED TO BE SURE THAT THAT'S
DONE IN A TIMELY MANNER AND THAT THEY HAVE AT THE
END OF IT THE PROCEDURE FOR DOING EXTRAORDINARY
PETITIONS OR IF THEY HAVE SOME SORT
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1	DR. TROUNSON: BUT IT ACTUALLY IS. THEY
2	GET THE LETTER WITH THE REVIEW.
3	MR. TORRES: BUT IT IS, DUANE AND DR.
4	LEVIN. I'M SAYING TAKE IT A STEP FURTHER AND HAVE
5	THEM SIGN SOME KIND OF PAPER SAYING I'VE READ IT.
6	MR. KLEIN: SO PART OF THE PROBLEM IS IF
7	YOU READ THE PARAGRAPH RIGHT NOW, IT'S NOT REALLY
8	FULLY EXPLANATORY. AND I THINK ARLENE CHIU, DR.
9	CHIU POINTED OUT SOME ADDITIONAL EDUCATION OF THE
10	POTENTIAL GRANTEES IS IN ORDER. BUT WHEN THE STAFF
11	HAD ADEQUATE TIME TO RESPOND LIKE ON THE DISEASE
12	TEAMS, THEY DID AN EXTREMELY GOOD AND THOUGHTFUL AND
13	THOROUGH JOB OF RESPONDING. AND THERE WERE SOME
14	EXTRAORDINARY PETITIONS THAT WERE COMPLETELY ON THE
15	MERIT WITH CORRECTIONS TO SCIENTIFIC JUDGMENT THAT
16	WERE APPROVED, THANKFULLY RESCUING SOME HIGHLY
17	MERITORIOUS APPLICATIONS.
18	I THINK THE EXTRAORDINARY PETITION PROCESS
19	CAN WORK WITH THE RIGHT EDUCATION OF PEOPLE'S RIGHTS
20	PERHAPS BY GETTING THEM TO SIGN OFF UP FRONT SO
21	EVERYONE FOLLOWS THE RULES AND GIVES THE STAFF
22	ADEQUATE TIME TO DO A THOUGHTFUL JOB, WHICH IS SO
23	IMPORTANT, AS JEFF HAS EMPHASIZED, IN GIVING US
24	INFORMATION WE NEED TO MAKE THE RIGHT DECISIONS.
25	DR. FONTANA: I'M SORRY I HAVE TO GO, BUT
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1	I THINK THAT THIS IS SUCH A DESERVING AND WORTHY
2	PROCESS, THAT WE SHOULD SCHEDULE PERHAPS ANOTHER
3	PHONE CONVERSATION JUST TO FOCUS ON THIS ISSUE.
4	CHAIRMAN SHEEHY: THAT'S THE IDEA.
5	DR. PIZZO: I AGREE WITH JEANNIE.
6	UNFORTUNATELY I HAVE GO OFF FOR ANOTHER MEETING AS
7	WELL, BUT I TOTALLY AGREE.
8	CHAIRMAN SHEEHY: SO THEN I THINK IT WOULD
9	BE APPROPRIATE TO ADJOURN BECAUSE IT IS 2 0'CLOCK.
10	WE REACHED OUR TIME. AND I APPRECIATE EVERYBODY'S
11	PARTICIPATION TODAY.
12	(THE MEETING WAS THEN CONCLUDED AT 2:05
13	P. M.)
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REPORTER'S CERTIFICATE

I, BETH C. DRAIN, A CERTIFIED SHORTHAND REPORTER IN AND FOR THE STATE OF CALIFORNIA, HEREBY CERTIFY THAT THE FOREGOING TRANSCRIPT OF THE PROCEEDINGS BEFORE THE SCIENCE SUBCOMMITTEE OF THE INDEPENDENT CITIZEN'S OVERSIGHT COMMITTEE OF THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE IN THE MATTER OF ITS REGULAR MEETING HELD AT THE LOCATION INDICATED BELOW

210 KING STREET SAN FRANCISCO, CALIFORNIA ON TUESDAY, MAY 25, 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