BEFORE THE

INDEPENDENT CITIZENS' OVERSIGHT COMMITTEE TO THE

CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE ORGANIZED PURSUANT TO THE CALIFORNIA STEM CELL RESEARCH AND CURES ACT

REGULAR MEETING

LOCATION: CROWNE PLAZA HOTEL

1177 AIRPORT BOULEVARD BURLINGAME, CALIFORNIA

SEPTEMBER 5 AND 6, 2012 4 P.M. AND 9 A.M. DATE:

BETH C. DRAIN, CSR REPORTER:

CSR. NO. 7152

BRS FILE NO.: 91120 & 91121

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1	BURLINGAME, CALIFORNIA; THURSDAY, SEPTEMBER 6, 2012
2	9 A.M.
3	
4	CHAIRMAN THOMAS: MEMBERS OF THE BOARD,
5	PLEASE TAKE THEIR SEATS. DO WE HAVE ANYBODY WHO'S
6	GOING TO BE ON BY PHONE STARTING AT 9 O'CLOCK?
7	I'D LIKE TO WELCOME EVERYBODY TO PHASE II
8	OF THE SEPTEMBER 5TH, 6TH, 2012, MEETING OF THE
9	INDEPENDENT CITIZENS OVERSIGHT COMMITTEE OF CIRM.
10	HAD A VERY PRODUCTIVE SESSION, LASTED TILL 10
11	O'CLOCK LAST NIGHT. I WANT TO THANK BOARD MEMBERS
12	AGAIN FOR STICKING WITH IT AND GETTING THROUGH A
13	SIGNIFICANT AMOUNT OF THE AGENDA. I THINK, AS YOU
14	WILL SEE, THAT WILL PAY DIVIDENDS IN OUR SESSION
15	TODAY. SO THANK YOU, BOARD MEMBERS, THANK YOU,
16	STAFF, THANK YOU, MEMBERS OF THE PUBLIC WHO SAT
17	THROUGH THE MEETING WITH US YESTERDAY EVENING.
18	WE'RE GOING TO TAKE UP A NUMBER OF ITEMS
19	TODAY. I WANT TO START WITH LET'S SEE. I
20	HAVEN'T GOTTEN TO THAT. OKAY. MARIA, PLEASE CALL
21	THE ROLL. DO WE NEED TO DO THE PLEDGE OF ALLEGIANCE
22	AS WELL, OR DOES THAT CARRY OVER, MR. HARRISON?
23	MR. HARRISON: THIS IS A CONTINUATION, SO
24	WE DON'T NEED TO DO IT AGAIN.
25	CHAIRMAN THOMAS: THANK YOU FOR THAT
	229

	DARKISIERS REPORTING SERVICE
1	CLARIFICATION.
2	MS. BONNEVILLE: ROBERT PRICE.
3	DR. PRICE: HERE.
4	MS. BONNEVILLE: DAVID BRENNER.
5	DR. BRENNER: HERE.
6	MS. BONNEVILLE: JACOB LEVIN. ANNE-MARIE
7	DULIEGE.
8	DR. DULIEGE: HERE.
9	MS. BONNEVILLE: MARCY FEIT. MICHAEL
10	FRIEDMAN.
11	DR. FRIEDMAN: HERE.
12	MS. BONNEVILLE: LEEZA GIBBONS.
13	MS. GIBBONS: HERE.
14	MS. BONNEVILLE: MICHAEL GOLDBERG. SAM
15	HAWGOOD.
16	DR. HAWGOOD: HERE.
17	MS. BONNEVILLE: STEPHEN JUELSGAARD.
18	DR. JUELSGAARD: HERE.
19	MS. BONNEVILLE: SHERRY LANSING. BERT
20	LUBIN.
21	DR. LUBIN: HERE.
22	MS. BONNEVILLE: MICHAEL MARLETTA. LEON
23	FINE.
24	DR. FINE: HERE.
25	MS. BONNEVILLE: PHIL PIZZO.
	230

1	DR. PIZZO: HERE.
2	MS. BONNEVILLE: CLAIRE POMEROY.
3	DR. POMEROY: HERE.
4	MS. BONNEVILLE: FRANCISCO PRIETO.
5	DR. PRIETO: HERE.
6	MS. BONNEVILLE: CARMEN PULIAFITO.
7	DR. PULIAFITO: PRESENT.
8	MS. BONNEVILLE: ROBERT QUINT.
9	DR. QUINT: HERE.
10	MS. BONNEVILLE: DUANE ROTH.
11	MR. ROTH: HERE.
12	MS. BONNEVILLE: JOAN SAMUELSON.
13	MS. SAMUELSON: PRESENT.
14	MS. BONNEVILLE: JEFF SHEEHY.
15	MR. SHEEHY: HERE.
16	MS. BONNEVILLE: JONATHAN SHESTACK.
17	MR. SHESTACK: HERE.
18	MS. BONNEVILLE: OSWALD STEWARD.
19	DR. STEWARD: HERE.
20	MS. BONNEVILLE: JONATHAN THOMAS.
21	CHAIRMAN THOMAS: HERE.
22	MS. BONNEVILLE: ART TORRES.
23	MR. TORRES: HERE.
24	MS. BONNEVILLE: KRISTINA VUORI.
25	DR. VUORI: HERE.
	231

1	MS. BONNEVILLE: JAMES ECONOMOU.
2	DR. ECONOMOU: HERE.
3	CHAIRMAN THOMAS: OKAY. WE'RE GOING TO
4	START WITH A NUMBER OF THE SHORTER ITEMS IF WE CAN
5	GET A COUPLE OF THOSE OUT FIRST. SO LET'S GO WITH
6	ITEM NO. 11, WHICH IS CONSIDERATION OF ITEMS FROM
7	THE SCIENCE SUBCOMMITTEE. DR. FEIGAL, YOU WILL BE
8	PRESENTING, PLEASE.
9	DR. FEIGAL: FIRST OF ALL, I JUST WANTED
10	TO SAY A FEW THANKS FOR THE DISCUSSION ON THE
11	ADDITIONAL ANALYSIS YESTERDAY. I JUST WANT TO GIVE
12	A SPECIAL THANKS TO THE SCIENTIFIC OFFICERS WHO
13	ACTUALLY SPENT AN ENORMOUS AMOUNT OF TIME TRYING TO
14	PUT TOGETHER A CREDIBLE PROCESS FOR HOW TO EVALUATE
15	INFORMATION AND THE AMOUNT OF WORK THAT THEY'VE DONE
16	TO TRY AND MAKE IT AS EVIDENCE BASED AS POSSIBLE.
17	SO I'D REALLY LIKE TO THANK THE SCIENTIFIC OFFICERS
18	FOR THAT.
19	I'D LIKE TO PARTICULARLY THANK DR. GILL
20	SAMBRANO FOR HIS EFFORTS TO REALLY PUT FORWARD A
21	VERY HIGH QUALITY, HIGH CALIBER-TYPE PROCESS. AND I
22	KNOW WE'RE GOING TO BE DISCUSSING PERHAPS SOME
23	CONSTRUCTIVE WAYS OF DOING THESE KIND OF DISCUSSIONS
24	IN THE FUTURE. BUT GIVEN THE EXPEDIENCY OF NEEDING
25	TO WORK VERY QUICKLY, I THINK THEY DO DESERVE A
	222
	232

1	SPECIAL ROUND OF THANKS. SO I DO WANT TO THANK
2	THEM, AND I WANT TO THANK THE BOARD FOR THE
3	DISCUSSION THAT TOOK PLACE.
4	WHAT I'D NOW LIKE TO TALK ABOUT IS
5	ACTUALLY THE EXTERNAL INNOVATION INITIATIVE. THIS
6	IS AN INITIATIVE APPROVED BY THE BOARD BACK IN
7	DECEMBER 8TH, AND THIS WAS REALLY A PROPOSAL TO
8	ALLOW CIRM FUNDING FOR CALIFORNIA SCIENTISTS WANTING
9	TO COLLABORATE ON EXISTING, ONGOING, EXTERNALLY
10	FUNDED PROJECTS WITH SCIENTISTS THAT ARE EXTERNAL TO
11	CALIFORNIA.
12	THERE ARE TWO AMENDMENTS THAT WE WANTED TO
13	MAKE TO THAT ALREADY APPROVED INITIATIVE, AND YOU
14	HAVE THAT IN YOUR PREREAD. THESE AMENDMENTS WERE
15	DISCUSSED AT THE JULY 25TH SCIENCE SUBCOMMITTEE
16	MEETING. THEY WERE APPROVED. AND SO WE ARE NOW
17	BRINGING THEM FORWARD AT THIS ICOC. SO THEY'VE
18	ALREADY BEEN DISCUSSED AND APPROVED AT THE
19	SCIENTIFIC SUBCOMMITTEE.
20	THE TWO AMENDMENTS ARE TO ALLOW CIRM
21	FUNDING FOR CALIFORNIA SCIENTISTS WANTING TO
22	COLLABORATE WITH SCIENTISTS EXTERNAL TO CALIFORNIA
23	ON AN EXISTING, EXTERNALLY FUNDED PROJECT. IN THE
24	PAST WHAT WE'VE REQUIRED IS, FOR PEOPLE TO
25	COLLABORATE, WE HAD TO BE THE INITIATOR OF THE RFA
	233

1	OF THE INITIATIVE. WHAT WE WOULD NOW BE ALLOWING IS
2	FOR AN ALREADY EXISTING PROJECT THAT'S ALREADY
3	EXTERNALLY FUNDED THE ABILITY TO ALLOW THOSE
4	CALIFORNIA SCIENTISTS TO BOLT ONTO THAT TYPE OF
5	PROJECT.
6	IT WOULD BE REVIEWED THROUGH OUR GRANT
7	REVIEW GROUP PROCESS, BUT WE WOULD ALLOW A MORE
8	FLEXIBLE MECHANISM TO ENABLE OUR CALIFORNIA
9	SCIENTISTS TO COLLABORATE EXTERNALLY OUTSIDE OF
10	CALIFORNIA. I KNOW CALIFORNIA HAS TREMENDOUS
11	SCIENTIFIC TALENT; BUT WE KNOW IN ORDER TO MOVE THE
12	SCIENCE FORWARD, IT TAKES REALLY A GLOBAL
13	COLLABORATION. AND WE WANT TO DO WHAT WE CAN TO
14	FACILITATE THAT.
15	THE SECOND AMENDMENT IS REALLY TO INCREASE
16	THE FLEXIBILITY OF THE AWARD DURATION AND THE
17	AMOUNT. WE ARE GOING TO STAY WITHIN THE SET-ASIDE
18	OF 15 MILLION; BUT WHAT WE WANT TO DO IS GO FROM A
19	REQUIREMENT THAT IT'S ONLY 500,000 AWARD FOR A
20	12-MONTH PERIOD, WE WANT INCREASE THAT UP TO A
21	CEILING OF \$1.5 MILLION AWARD UP TO A 36-MONTH
22	PERIOD.
23	SO THESE ARE REALLY THE ONLY TWO
24	AMENDMENTS THAT WE'RE MAKING TO AN ALREADY APPROVED
25	EXTERNAL INNOVATION INITIATIVE. SO LET ME STOP
	234

	DARRISIERS REPORTING SERVICE
1	THERE AND SEE IF THERE'S ANY QUESTION.
2	CHAIRMAN THOMAS: JEFF OR OS, IN YOUR
3	CAPACITIES AS CO-CHAIR OF THE SCIENCE SUBCOMMITTEE,
4	DO YOU WISH TO COMMENT ON EITHER OF THESE?
5	DR. STEWARD: I THINK THE MAIN THING IS
6	JUST TO INCREASE SOME FLEXIBILITY AND OPPORTUNITIES.
7	MR. SHEEHY: I WOULD SECOND THAT. I GIVE
8	STAFF TREMENDOUS CREDIT FOR INTRODUCING THESE
9	ELEMENTS THAT ALLOW US TO BE MORE NIMBLE. THIS IS
10	KIND OF THE GOAL OF THE FUND, TO BE ABLE TO SEIZE
11	OPPORTUNITIES. THERE'S GREAT SCIENCE GOING ON
12	OUTSIDE OF CALIFORNIA. THIS WILL GIVE OUR
13	RESEARCHERS A CHANCE TO TAKE PART IN IT. I THINK
14	IT'S A GREAT IDEA.
15	CHAIRMAN THOMAS: DO WE HEAR A MOTION TO
16	APPROVE THESE AMENDMENTS?
17	MS. SAMUELSON: I HAVE A QUESTION. DR.
18	FEIGAL, CAN YOU EXPLAIN THE RELATIONSHIP AND THE
19	INTERACTION BETWEEN THIS PROCESS AND THE GRANTS
20	WORKING GROUP?
21	DR. FEIGAL: SO WE WOULD HAVE THE SAME
22	PROCESS. THE PROPOSALS WILL COME IN. WE'LL PUT OUT
23	AN RFA OR PROGRAM ANNOUNCEMENT THAT WILL COVER THE
24	SCOPE OF WHAT WE WANT TO SEE COME IN IN TERMS OF
25	PROPOSALS. THE PROPOSALS WOULD HAVE TO BE CONNECTED
	235

1	TO SOME OTHER EXTERNALLY FUNDED PROJECT THAT'S GOING
2	ON, BUT THE CALIFORNIA COMPONENT AND THE CONTEXT IN
3	WHICH THEY'RE PLACED WITH THE BIGGER PROJECT WOULD
4	COME TO THE GRANTS REVIEW GROUP.
5	SO IT WOULD BE REVIEWED, RECOMMENDATIONS
6	WOULD BE MADE FROM THE GRANTS REVIEW GROUP, AND THEN
7	THE ICOC WOULD MAKE THE DECISIONS ABOUT FUNDING.
8	MS. SAMUELSON: AND WOULD THE GRANT
9	REVIEW WOULD THE GRANT THEY'RE REVIEWING COMPRISE
10	ALL THE FUNDS THAT ARE BEING SPENT FROM CIRM FUNDS?
11	DR. FEIGAL: THEY WOULD HAVE TO DESCRIBE
12	THE SCOPE OF WHAT IT IS THEY'RE GOING TO DO, THE
13	ACTIVITIES AND THE BUDGET THAT GO WITH IT. AND WHAT
14	WE WOULD ALSO WANT TO SEE IS THE CONTEXT IN WHICH
15	THEY'RE WORKING WITH THE EXTERNAL GROUP, BUT
16	REALIZING THAT'S EXTERNALLY FUNDED. IT WOULD
17	COME JUST TO BE CLEAR, IT'S THE SAME PROCESS WE
18	USE FOR ALL OF OUR OTHER INITIATIVES. THEY WOULD
19	COME TO THE GRANTS REVIEW GROUP FOR REVIEW AND
20	RECOMMENDATIONS, AND THE RECOMMENDATIONS WOULD BE
21	BROUGHT FORWARD TO THIS BODY FOR FINAL FUNDING
22	DECISION.
23	MS. SAMUELSON: HOW DOES THE EXTERNAL
24	GROUP OF SCIENTISTS, WHAT ROLE DO THEY PLAY THEN?
25	DR. FEIGAL: THEY ARE ALREADY EXTERNALLY
	226
	236

1	VETTED AND FUNDED BY SOME OTHER TYPE OF RESOURCE.
2	AND SO THE PROPOSAL THAT'S ACTUALLY COMING FORWARD
3	THAT USES CIRM FUNDING WOULD BE THE MAJOR FOCUS THAT
4	WE'RE WORKING ON, BUT THEY'D HAVE TO SHOW THEIR
5	COLLABORATION, THEY'D HAVE TO SHOW HOW THEY'RE
6	INTEGRATING WITH THE OTHER PROJECT, BUT WHAT WE
7	WOULD BE REVIEWING WOULD BE THE CALIFORNIA
8	COMPONENT.
9	MS. SAMUELSON: BUT IT'S THE SAME GRANT.
10	IT'S THE SAME PROJECT.
11	DR. FEIGAL: NO. WE WOULD HAVE TO GIVE A
12	CIRM GRANT FOR THE CALIFORNIA PROJECT.
13	MS. SAMUELSON: BUT IT'S ONE
14	COLLABORATIVE I'M NOT UNDERSTANDING. BUT IT'S
15	ONE GRANT, IT'S ONE PROJECT.
16	DR. FEIGAL: FOR THIS PARTICULAR ASPECT OF
17	IT, THEY'D HAVE TO SHOW HOW THE INTEGRATION IS TIED
18	INTO PLACE. THERE'D PROBABLY BE SOME LETTER OF
19	COLLABORATION TO SHOW THAT THE GROUPS ARE WORKING
20	TOGETHER, BUT IT WOULD BE A CIRM-ISSUED GRANT.
21	MS. SAMUELSON: BUT
22	DR. FEIGAL: FOR THE CALIFORNIA
23	COMPONENT.
24	MS. SAMUELSON: AND IS THAT BUT THE
25	COLLABORATION, THAT IS WHAT THE GRANT'S ALL ABOUT,
	237

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1	RIGHT?
2	DR. FEIGAL: WE ARE NOT THEY WOULD
3	DESCRIBE IT IN THEIR PROPOSAL IN TERMS OF WHAT
4	THEY'RE DOING THAT IS COLLABORATING WITH THE OTHER
5	GROUP. BUT PRIMARILY WHAT WOULD BE REVIEWED BY THE
6	GRANTS REVIEW GROUP WOULD BE THE SCOPE OF ACTIVITIES
7	THAT THE CALIFORNIA COMPONENT IS DOING. THEY COULD
8	DESCRIBE THAT IN THE CONTEXT OF THE LARGER PROJECT.
9	MS. SAMUELSON: BUT THEY WOULDN'T BE ABLE
10	TO INCLUDE IN THEIR ANALYSIS WHETHER THAT
11	COLLABORATION IS SOUND OR WORKING WELL OR DESIGNED
12	FOR
13	DR. FEIGAL: WELL, PRESUMABLY FOR A STRONG
14	PROPOSAL, THEY WOULD PROVIDE WHAT'S GOING ON WITH
15	THE TOTAL PROJECT AND WHY THEIR CONTRIBUTION TO IT
16	OR THEIR COMPONENT OF IT WOULD ADD STRENGTH OR VALUE
17	TO THAT PROJECT.
18	MS. SAMUELSON: AND THAT WOULD BE PART OF
19	SCORING AND GRANT RECOMMENDATIONS ON THE PART OF THE
20	GRANTS WORKING GROUP.
21	DR. FEIGAL: THAT WOULD BE PART OF WHAT
22	WE'D BE LOOKING AT, WHAT THE GRANT REVIEW GROUP
23	WOULD BE LOOKING AT.
24	MS. SAMUELSON: OKAY. OKAY. AND THAT
25	OTHER PROCESS WOULDN'T SLOW IT UP? IT'S IMPORTANT.
	220
	238

1	TE THESE ARE COLLARORATIVE PROJECTS. THAT'S WHAT WE
1	IF THESE ARE COLLABORATIVE PROJECTS, THAT'S WHAT WE
2	REALLY NEED, IT SEEMS TO ME, AND WE SHOULD HAVE OUR
3	EXPERTS WE'RE RELYING ON LOOKING AT THAT AS PART OF
4	THEIR REVIEW. AND IT SOUNDS LIKE THAT'S WHAT
5	THEY'RE DOING. OKAY. GOOD. THANK YOU.
6	DR. FEIGAL: THANK YOU.
7	MR. ROTH: MR. CHAIR, I'LL MAKE A MOTION
8	TO APPROVE.
9	CHAIRMAN THOMAS: IS THERE A SECOND?
10	DR. FRIEDMAN: SECOND.
11	CHAIRMAN THOMAS: SECONDED. I HEARD DR.
12	FRIEDMAN AMONGST OTHERS. WE'LL GIVE HIM THE SECOND
13	ON THIS ONE. ANY FURTHER DISCUSSION BY MEMBERS OF
14	THE BOARD?
15	DR. JUELSGAARD: SO, ELLEN, IN THESE
16	SITUATIONS, I'M JUST FOCUSED ON INTELLECTUAL
17	PROPERTY FOR A MOMENT, HOW DO WE ENVISION THE
18	OWNERSHIP OF ANY INVENTIONS THAT ARISE FROM THESE
19	COLLABORATIONS WITH SOMEBODY ON THE OUTSIDE?
20	DR. FEIGAL: THEY WOULD HAVE TO DISCUSS
21	THAT WITHIN THE SCOPE OF THEIR APPLICATION. SO
22	THEY'D HAVE TO PROACTIVELY TALK ABOUT HOW THAT WOULD
23	BE HANDLED, AND THAT WOULD BE PART OF OUR
24	ASSESSMENT.
25	DR. TROUNSON: IT WOULD BE NO DIFFERENT TO
	239

1	THE COLLABORATIONS WE CURRENTLY HAVE. WE DO
2	BOLT-ONS ALREADY WITH THE STATE OF MARYLAND,
3	GERMANY, AND OTHERS. AND SO WE WOULD USE EXACTLY
4	THE SAME PROCESS.
5	CHAIRMAN THOMAS: OTHER COMMENTS BY
6	MEMBERS OF THE BOARD?
7	MS. SAMUELSON: ANOTHER QUESTION. I TAKE
8	IT THERE ISN'T ANY PROBLEM WITH THE CALIFORNIA CURES
9	ACT'S LIMITATION OF FUNDING TO CALIFORNIA
10	SCIENTISTS.
11	DR. FEIGAL: WE WOULD FOLLOW THE LAW, AND
12	WE WOULD HAVE THE MONEY GO FOR
13	MS. SAMUELSON: YEAH.
14	DR. FEIGAL: WHAT WE'RE APPROVED TO DO.
15	MS. SAMUELSON: I ASK THAT FEELING THAT WE
16	WON'T SUCCEED IF OUR ACTIVITY ISN'T INTERNATIONAL ON
17	A DAILY BASIS. SO I THINK WE MUST HAVE THESE
18	COLLABORATIONS. I'M THRILLED THAT YOU'RE BRINGING
19	IT TO US. BUT ENOUGH SAID. THANK YOU.
20	CHAIRMAN THOMAS: ANY COMMENTS BY MEMBERS
21	OF THE PUBLIC ON THE MOTION? HEARING NONE, IS THIS
22	A VOICE VOTE, MR. HARRISON? ALL THOSE IN FAVOR OF
23	THE MOTION PLEASE SAY AYE. OPPOSED? ABSTENTIONS?
24	DO WE HAVE
25	MS. FEIT: I VOTED YES.
	240
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1	CHAIRMAN THOMAS: THANK YOU, MARCY. GOOD
2	MORNING, MARCY. OKAY. THE MOTION PASSES. THANK
3	YOU VERY MUCH.
4	DR. FEIGAL: THANK YOU VERY MUCH.
5	CHAIRMAN THOMAS: GEOFF LOMAX. WE'D LIKE
6	TO MOVE TO ITEM NO. 20 HERE.
7	MR. HARRISON: WE STILL HAVE ONE MORE ITEM
8	FROM THE SCIENCE SUBCOMMITTEE, THE MISSION
9	STATEMENT.
10	CHAIRMAN THOMAS: THANK YOU, MR. HARRISON.
11	WHO DO WE HAVE PRESENTING ON THAT?
12	MR. HARRISON: ALL OF THE BOARD'S
13	SUBCOMMITTEES HAVE MISSION STATEMENTS. THE SCIENCE
14	SUBCOMMITTEE WAS INITIALLY ESTABLISHED WITHOUT A
15	MISSION STATEMENT. WE BROUGHT A PROPOSED MISSION
16	STATEMENT TO THE SCIENCE SUBCOMMITTEE WITH THE
17	SUPPORT OF THE CO-CHAIRS, AND IT WAS RECOMMENDED FOR
18	YOUR APPROVAL.
19	AS YOU WILL SEE IN TAB 11 OF YOUR BINDER,
20	IT'S A FAIRLY STRAIGHTFORWARD MISSION STATEMENT. IT
21	DEFINES THE MEMBERSHIP AS WELL AS THE JURISDICTION
22	OF THE SUBCOMMITTEE, AND WE'D ASK FOR YOUR APPROVAL.
23	CHAIRMAN THOMAS: DO I HEAR A MOTION TO
24	THAT EFFECT?
25	DR. PIZZO: SO MOVED.
	241

1	CHAIRMAN THOMAS: DEAN PIZZO. THE SECOND?
2	DR. PRIETO: SECOND.
3	CHAIRMAN THOMAS: DR. PRIETO. ANY
4	DISCUSSION BY MEMBERS OF THE BOARD? ANY COMMENTS
5	FROM THE PUBLIC? HEARING NONE, PROCEED IMMEDIATELY
6	TO A VOICE VOTE. ALL THOSE IN FAVOR PLEASE SAY AYE.
7	OPPOSED? ABSTENTIONS? MARCY.
8	MS. FEIT: YES.
9	CHAIRMAN THOMAS: THANK YOU. MOTION
10	APPROVED. THANK YOU, MR. HARRISON.
11	DR. LOMAX, PLEASE, IF YOU COULD PROCEED
12	NOW TO ITEM 20, WHICH IS CONSIDERATION OF ADOPTION
13	OF AMENDMENTS TO THE MEDICAL AND ETHICAL STANDARDS
14	REGS X AND Y.
15	DR. LOMAX: THANK YOU, MR. CHAIRMAN,
16	MEMBERS OF THE BOARD. IN MAY OF THIS YEAR, YOU
17	AUTHORIZED US TO INITIATE PUBLIC COMMENTS ON A
18	SERIES OF AMENDMENTS TO THE MEDICAL AND ETHICAL
19	STANDARDS. THE AMENDMENTS INCLUDE SECTIONS 160, AND
20	THE AMENDMENTS TO THIS SECTION WOULD PROVIDE GREATER
21	FLEXIBILITY TO THE OVERSIGHT COMMITTEES THAT REVIEW
22	AND APPROVE TO THE PROCESS OF REVIEWING RESEARCH
23	THAT IS FUNDED BY CIRM. AND SPECIFICALLY IT ALLOWS
24	NONSCIENTISTS AND PUBLIC MEMBERS TO RECEIVE SOME
25	SORT OF STIPEND OR COMPENSATION FOR THEIR WORK. AND
	242

1	THAT RECOMMENDATION WAS ALSO ENDORSED BY THE
2	STANDARDS WORKING GROUP.
3	AND TO SECTION 170 WE OFFERED OUR GRANTEES
4	GREATER FLEXIBILITY IN TERMS OF AFFIRMING COMPLIANCE
5	WITH CIRM STANDARDS. SO A STEM CELL RESEARCH
6	OVERSIGHT COMMITTEE OR AN AUTHORIZED INSTITUTIONAL
7	OFFICIAL CAN DECLARE TO CIRM THAT THEIR PROTOCOLS
8	CONFORM TO OUR STANDARDS.
9	THESE AMENDMENTS WENT OUT FOR PUBLIC
10	COMMENT. WE RECEIVED NO PUBLIC COMMENT. AND TODAY
11	WE'RE REQUESTING THAT YOU AUTHORIZE US TO MOVE
12	FORWARD WITH THE PROCEDURES TO FINALIZE THESE
13	REGULATIONS.
14	CHAIRMAN THOMAS: THANK YOU, DR. LOMAX.
15	DO I HEAR A MOTION FROM A MEMBER OF THE BOARD TO SO
16	APPROVE?
17	MR. TORRES: SO MOVED.
18	CHAIRMAN THOMAS: MOVED BY SENATOR TORRES.
19	SECONDED BY DEAN HAWGOOD. FURTHER DISCUSSION FROM
20	MEMBERS OF THE BOARD? ANY COMMENTS FROM MEMBERS OF
21	THE PUBLIC? HEARING NONE, BEFORE WE VOTE, WOULD
22	LIKE TO THANK DR. LOMAX FOR HIS CONTINUED HARD WORK
23	KEEPING US IN LINE ETHICALLY AT ALL TIMES AND ALSO
24	TO MEMBERS OF THE COMMITTEE THAT HE CONVENES, WHICH
25	IS A VERY DEDICATED GROUP, AND WE THANK ALL FOR YOUR
	243

1	HARD WORK.
2	ALL THOSE IN FAVOR OF THE MOTION PLEASE
3	SAY AYE. OPPOSED? ABSTENTIONS? MARCY.
4	MS. FEIT: YES.
5	CHAIRMAN THOMAS: THANK YOU. MOTION
6	APPROVED. THANK YOU, DR. LOMAX.
7	DR. LOMAX: I'D JUST LIKE TO ADD THAT OUR
8	GRANTEE INSTITUTIONS HAVE MADE TREMENDOUS EFFORT TO
9	REALLY EMBRACE OUR REGULATIONS AND MOVE THIS PROCESS
10	ALONG AS WELL. SO I'D LIKE TO GIVE A SHOUT OUT TO
11	THEIR COMMITMENT TO THIS PROCESS AND OUR
12	REGULATIONS.
13	CHAIRMAN THOMAS: DULY NOTED. AND THANK
14	YOU AGAIN.
15	WE'RE GOING TO PROCEED NOW TO DISCUSSION
16	OF THE RESEARCH LEADERSHIP AWARD, WHICH IS ITEM NO.
17	10. DR. YAFFE.
18	DR. YAFFE: MR. CHAIRMAN, MEMBERS OF THE
19	BOARD, MEMBERS OF THE PUBLIC, I'M HERE TO PRESENT
20	THE CONTINUATION FOR YOUR CONSIDERATION OF
21	RECOMMENDATIONS FROM THE GRANTS WORKING GROUP OF THE
22	RESEARCH LEADERSHIP AWARD. AS THE CHAIR MENTIONED,
23	THIS IS ITEM NO. 10.
24	AND JUST TO BRIEFLY REVIEW THIS PROGRAM,
25	PARTICULARLY FOR THOSE WHO MAY BE NEW TO THE BOARD,
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1	THE GOALS OF THE RESEARCH LEADERSHIP AWARD ARE TO
2	FACILITATE THE RECRUITMENT TO CALIFORNIA OF THE MOST
3	PRODUCTIVE AND PROMISING EARLY TO MIDCAREER
4	SCIENTISTS IN STEM CELL BIOLOGY AND REGENERATIVE
5	MEDICINE. AND FOLLOWING THEIR RECRUITMENT, TO
6	SUPPORT THEIR ROBUST AND INNOVATIVE RESEARCH
7	PROGRAMS FOCUSED ON FUNDAMENTAL STUDIES OF
8	PLURIPOTENT AND PROGENITOR STEM CELL BIOLOGY AND/OR
9	THE TRANSLATIONAL STUDIES LEADING TO INNOVATIVE STEM
10	CELL-BASED THERAPIES FOR DISEASE AND INJURY.
11	THIS PROGRAM IS OPEN TO NON-PROFIT
12	CALIFORNIA INSTITUTIONS. IT HAS THE REQUIREMENT
13	THAT THE CANDIDATE OR PRINCIPAL INVESTIGATOR MUST
14	HOLD A POSITION OUTSIDE CALIFORNIA AT THE TIME OF
15	APPLICATION AND HAVE BEEN INDEPENDENT FOR AT LEAST
16	THREE YEARS.
17	THE INDIVIDUAL INSTITUTIONS THAT ARE
18	APPLYING FOR THESE AWARDS MAY RECEIVE ONLY ONE
19	AWARD. YOU, THE ICOC, AUTHORIZED UP TO EIGHT
20	AWARDS. FOUR AWARDS HAVE BEEN MADE TO DATE, ONE TO
21	ROBERT WECHSLER REYA AT SANFORD BURNHAM INSTITUTE,
22	ONE TO PETER COFFEY UC SANTA BARBARA, ONE TO ZHIGANG
23	HE AT UC BERKELEY, AND THE MOST RECENT TO ANDREW
24	MCMAHON AT USC.
25	THESE AWARD FEATURES RESEARCH SUPPORT FOR

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1	UP TO SIX YEARS, THE PROVISION THAT AWARDEES MUST
2	COMMIT AT LEAST 75 PERCENT OF THEIR TIME TO STEM
3	CELL AND REGENERATIVE MEDICINE RESEARCH, AND
4	ELIGIBLE COSTS THAT INCLUDE THE PI'S SALARY, LAB
5	OPERATIONS, FUNDS FOR LAB RELOCATION, FUNDS FOR
6	EQUIPMENT WHICH MUST BE MATCHED BY THE APPLICANT
7	INSTITUTION, AND APPROPRIATE FUNDS FOR FACILITIES
8	AND INDIRECT COSTS I SHOULD SAY APPROPRIATE
9	INDIRECT COSTS.
10	THE APPLICATIONS ARE REVIEWED AND WERE
11	REVIEWED BY THE GRANTS WORKING GROUP. THE CRITERIA
12	FOR THEIR REVIEW INCLUDES RESEARCH VISION AND PLANS.
13	HERE THEY'RE PARTICULARLY FOCUSED ON THE
14	SIGNIFICANCE AND THE INNOVATION OF THE PLAN.
15	THE PI'S ACCOMPLISHMENTS AND POTENTIAL.
16	HERE CONSIDERING PAST RESEARCH ACHIEVEMENT, THE
17	IMPACT OF THE APPLICANT'S WORK BOTH PAST AND
18	POTENTIAL, THE LEADERSHIP QUALITIES AND ABILITY OF
19	THE CANDIDATE, AND AN ASSESSMENT OF ACCOMPLISHMENTS
20	AND POTENTIAL BY LEADERS IN THE FIELD, AND THIS IS
21	ASSESSED VIA LETTERS OF RECOMMENDATION.
22	AND THE THIRD KEY REVIEW CRITERION IS
23	INSTITUTIONAL COMMITMENT AND ENVIRONMENT. HERE
24	WE'RE INTERESTED IN BOTH WHAT WILL THE INSTITUTION
25	PROVIDE FOR THE CANDIDATE, AND HOW WILL THE

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1	CANDIDATE'S RECRUITMENT AFFECT AND ENHANCE THE
2	INSTITUTION.
3	THIS RFA IS ON A RECURRING CYCLE WITH
4	DEADLINES APPROXIMATELY EVERY THREE MONTHS. THE
5	MOST RECENT DEADLINE, APPLICATION DEADLINE, WAS MAY
6	16TH. THE APPLICATIONS RECEIVED TWO APPLICATIONS
7	WERE RECEIVED. THEY WERE REVIEWED AT THE GRANTS
8	WORKING GROUP REVIEW, TELEPHONIC REVIEW, ON JUNE
9	20TH. AND THE RESULTS OF THAT REVIEW WERE THE
10	ASSESSMENT OF TWO APPLICATIONS, ONE YOU REVIEWED AT
11	THE JULY MEETING. IT WAS APPROVED. THAT WAS ANDREW
12	MCMAHON. AND THE ONE WE'RE BRINGING FOR YOUR
13	CONSIDERATION TODAY IS THE SECOND WITH A TITLE "STEM
14	CELL PATHOLOGIES IN PARKINSON'S DISEASE AS A KEY TO
15	REGENERATIVE STRATEGIES." THE REQUESTED FUNDS ARE
16	APPROXIMATELY 6.7 MILLION. THIS RECEIVED A SCORE OF
17	57, AND THE GRANTS WORKING GROUP RECOMMENDED IT FOR
18	FUNDING.
19	AT THIS POINT I'LL BE HAPPY TO ANSWER
20	QUESTIONS, OR PERHAPS MR. SHEEHY MAY HAVE COMMENTS.
21	CHAIRMAN THOMAS: MR. SHEEHY, DO YOU HAVE
22	COMMENTS?
23	MR. SHEEHY: HOW DO YOU WANT TO PROCEED
24	WITH THIS?
25	MS. SAMUELSON: I COULD GIVE A BRIEF
	247

1	SUMMARY IF WE THINK THAT MAKES SENSE.
2	THIS IS A WONDERFUL OPPORTUNITY FOR OUR
3	PORTFOLIO. WHEN THE EXTERNAL ADVISORY PANEL MADE
4	ITS RECOMMENDATIONS TO US ABOUT HOW WE SHOULD BE
5	PROCEEDING TO BE ACHIEVING OUR MISSION AS
6	AGGRESSIVELY AS POSSIBLE, THEY SAID THEY HOPED AND
7	RECOMMENDED THAT WE MAKE SURE THAT WE ARE ADVANCING
8	AS A GLOBAL LEADER ON STEM CELL RESEARCH BECAUSE
9	WE'RE THE ONLY PEOPLE IN THAT POSITION.
10	I AM CONFIDENT THAT WHEN DR. LANGSTON, THE
11	HEAD OF PARKINSON'S INSTITUTE, IS ABLE TO BEGIN
12	COLLABORATING WITH HIS LAB WITH DR. DENNIS STEINLER
13	AND HIS LAB, THEY WILL HAVE FORMED A GLOBAL
14	LEADERSHIP THAT WILL BE HELPING US IN SIGNIFICANT
15	DEGREE ACCOMPLISH THAT RECOMMENDATION.
16	LET ME JUST TELL YOU VERY BRIEFLY WHAT
17	THIS WILL ENTAIL. THE PARKINSON'S INSTITUTE HAS
18	MADE A BREAKTHROUGH, STARTLING BREAKTHROUGH
19	DISCOVERIES IN AREAS OF PARKINSON'S RESEARCH IN
20	PARTICULAR, BUT AFFECTING FAR BEYOND THAT, BEGINNING
21	WITH THE THING THAT DR. LANGSTON FOUNDED THE
22	INSTITUTE TO PROCEED FROM, WHICH WAS HIS DISCOVERY
23	OF MPTP, WHICH WAS A STREET DRUG THAT WAS MIXED
24	TOGETHER IN THE GARAGES OF HEROIN ADDICTS TO ATTEMPT
25	TO GET THAT SAME HIGH. AND INSTEAD, OVERNIGHT, IN
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1	ADDITION TO THE HIGH, THEY WOKE UP WITH ADVANCED
2	PARKINSON'S DISEASE. AND THAT DISCOVERY WAS FOUND
3	BY DR. LANGSTON IN A NEUROLOGICAL LAB IN THE SOUTH
4	BAY WHEN THE COMPANIONS OF THE PATIENT WHO WAS IN
5	THAT LAB WERE IN JAILS AND PSYCHIATRIC FACILITIES
6	BEING PROBED AND JAILED TO TRY TO FIGURE OUT WHAT
7	WAS GOING ON WITH THEIR STRANGE BEHAVIOR.
8	AND THEY WERE UNABLE TO EITHER SPEAK OR
9	MOVE SUFFICIENTLY TO COMMUNICATE WHAT WAS GOING ON.
10	DR. LANGSTON SAW PARKINSON'S, GAVE HIM L-DOPA, AND
11	HE SAID, "WHAT'S GOING ON HERE. PEOPLE HAVE BEEN
12	TREATING ME BADLY, AND I CAN'T MOVE OR SPEAK," HE
13	SAID AS HE MOVED AND SPOKE ON L-DOPA, AND THE REST
14	IS HISTORY.
15	THE INSTITUTE HAS BEEN A GLOBAL LEADER
16	ITSELF ON ISSUES OF THE NATURE OF PARKINSON'S
17	DISEASE AND EXTENDING FROM THAT THROUGH THE
18	ENVIRONMENTAL CONNECTIONS OF PESTICIDES AND
19	HERBICIDES AND OTHER TOXINS WITH PARKINSON'S DISEASE
20	AND OTHER NEURODEGENERATIVE DISORDERS. AND REALLY
21	THE PARKINSON'S INSTITUTE HAS BEEN ALONE IN MOVING
22	AHEAD AGGRESSIVELY IN THAT FIELD.
23	THEY WILL JOIN WITH DR. STEINLER ON WHAT
24	IS MAYBE THE HOT ISSUE IN PARKINSON'S RESEARCH, THE
25	ISSUE OF STEM CELL PATHOLOGIES. FOR SOME TIME
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1	THERE'S BEEN AN ATTEMPT TO MOVE AHEAD WITH CLINICAL
2	TRIALS ON PARKINSON'S. AND THERE HAVE BEEN SEVERAL
3	THAT HAVE BEEN CONDUCTED, BUT THEY HAVE BEEN
4	FOUNDERING. AND ONE REASON IS BELIEVED TO BE THAT
5	THERE'S SOME SORT OF AGENT THAT IS COMMUNICATED BY
6	THE STEM CELL WHEN IT'S GOING INTO THE DISEASE
7	ENVIRONMENT OR COMING OUT FROM THAT ENVIRONMENT TO
8	AFFECT A STEM CELL LINE.
9	AND THERE ARE LOTS OF THEORIES ABOUT IT AS
10	THERE HAVE BEEN WITH LOTS OF THE ISSUES IN THE
11	COMPLEX DISEASE THAT IS PARKINSON'S. BUT THERE
12	HASN'T BEEN A CONCERTED EFFORT WITH THE APPROPRIATE
13	EXPERTISE TO REALLY ATTACK IT. AND THAT'S WHAT'S
14	SUGGESTED HERE IN VERY BRIEF WORDS.
15	DR. LANGSTON IS HERE IN THE AUDIENCE AND
16	AVAILABLE TO ANSWER QUESTIONS, IF NECESSARY. HE'S
17	THE APPLICANT INSTITUTE REPRESENTING THE
18	APPLICANT INSTITUTION. DR. STEINLER IS READY TO BE
19	ON THE PHONE IF NEEDED TO ANSWER QUESTIONS.
20	I THINK THAT'S AN OVERVIEW. I AM, AS A
21	PATIENT, I AM THRILLED WITH THE OPPORTUNITY TO BE
22	ABLE TO WATCH THE MAGIC THAT WILL HAPPEN WHEN THESE
23	TWO MINDS ARE ABLE TO WORK TOGETHER AND DO IT WITH
24	THE FUNDS NECESSARY TO TACKLE THIS ENORMOUSLY
25	COMPLICATED ISSUE. SO WITH THAT, MAYBE WE SHOULD

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1	MOVE ON.
2	CHAIRMAN THOMAS: MR. SHEEHY.
3	MR. SHEEHY: JUST A COUPLE OF COMMENTS.
4	ONE, THE BREAK IN THE SCORES IS LARGELY DUE TO
5	REALLY A SIGNIFICANT DIFFERENCE OF OPINION BETWEEN
6	TWO OF THE WORLD'S LEADING EXPERTS IN PARKINSON'S.
7	SO IF YOU KNEW THE NAMES, THEY'RE FOLKS THAT WE
8	WOULD ALL KNOW. AND THEY JUST CAME DOWN ON THIS
9	REALLY STARKLY DIFFERENT IN HOW THEY THOUGHT THIS
10	APPLICATION WOULD WORK.
11	AND SO THAT REALLY DROVE IT. ONE OF THESE
12	EXPERTS SAID THEY THOUGHT THIS WAS A TREMENDOUS
13	APPLICATION, THAT IT WOULD PROVIDE SYNERGIES, THAT
14	THIS CANDIDATE WOULD PROVIDE TREMENDOUS SYNERGIES TO
15	THIS INSTITUTE AND TAKE IT TO A WHOLE NEW LEVEL.
16	THE OTHER PERSON DIDN'T LIKE IT. AND IT WAS REALLY
17	THAT STARK. WHEN YOU HAVE TWO KEY PEOPLE, YOU'RE
18	KIND OF LEFT WITH A FAIRLY BIG GAP BETWEEN WHAT THE
19	SCORES ARE AND SOME REAL DIFFICULTY IN COMING TO A
20	CLEAR CONSENSUS.
21	IN PROGRAMMATIC REVIEW THE GROUP DID
22	SUPPORT MOVING THIS FORWARD. AND I THINK PART OF
23	THE PROBLEM TOO WAS THAT FOR OUR EXPERTS, NOT A LOT
24	OF THEM KNEW MUCH ABOUT THE PARKINSON'S INSTITUTE.
25	I THINK THAT THAT IS A DILEMMA WE FACE GENERICALLY

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1	IN THIS RFA IS THAT SOME OF OUR PROGRAMS ARE
2	INTERNATIONALLY KNOWN. SOME OF THE INSTITUTIONS IN
3	CALIFORNIA ARE INTERNATIONALLY KNOWN AND SOME ARE
4	REALLY NOT WELL-KNOWN MUCH OUT OF CALIFORNIA. AND
5	SO PART OF WHAT THIS DOES LOOK AT IS WHAT THE IMPACT
6	OF WHAT THIS RECRUIT WILL BE ON THE INSTITUTION.
7	AND IF YOU DON'T HAVE A GOOD KNOWLEDGE BASE ABOUT
8	THE INSTITUTION WHEN YOU START OUT, THEN I THINK
9	YOU'RE AT SIGNIFICANT DISADVANTAGE STRUCTURALLY IN
10	THIS RFA.
11	AND IT GOES TO, IN MY MIND, ONE OF THE
12	DILEMMAS THAT WE'VE FACED ALL ALONG AS A BOARD, AS
13	AN AGENCY IS WHETHER OUR GOAL IS TO MAKE SURE THAT
14	THE INSTITUTIONS, OUR LEADING INSTITUTIONS, CONTINUE
15	TO FLOURISH AND DO WELL, OR WHETHER OUR GOAL IS TO
16	ALSO MAKE SURE THAT OTHER INSTITUTIONS IN CALIFORNIA
17	ALSO GET THE OPPORTUNITY TO ATTAIN THE HIGHEST RANK
18	THAT THEY CAN DO.
19	WE, I BELIEVE, HAVE BEEN SUCCESSFUL IN OUR
20	TRAINING GRANTS AND OUR FACILITIES GRANTS IN
21	EXPANDING THE CAPACITY OF CALIFORNIA TO ABSORB THE
22	RESEARCH FUNDS THAT WE'VE BEEN ALLOCATED BY THE
23	STATE, AND THAT IS PART WHAT WE EXIST TO DO, NOT
24	SIMPLY TO CONTINUE TO BUILD PROGRAMS THAT ARE
25	ALREADY WORLD-CLASS, BUT TO BUILD NEW PROGRAMS AND
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1	BRING THEM UP TO A WORLD-CLASS LEVEL. OTHERWISE
2	IT'S JUST NOT SIMPLY GOING TO BE FEASIBLE TO SPEND
3	THE FUNDS THAT WE HAVE.
4	SO THAT IS TO MY MIND THAT WAS LIKE THE
5	KEY PROGRAMMATIC CONSIDERATION. AND, AGAIN, WORKING
6	OFF THE RECOMMENDATION OF A WORLD EXPERT, A LEADING
7	EXPERT IN PARKINSON'S WHO FELT THAT THIS PARTICULAR
8	RECRUITMENT, THIS SCIENCE WOULD HAVE THE OPPORTUNITY
9	TO REALLY PROPEL THIS INSTITUTE TO A WHOLE NEW LEVEL
10	OF ACTIVITY, THAT IT FULFILLED A SIGNIFICANT GAP IN
11	THEIR SCIENTIFIC BENCH, SO TO SPEAK. THAT WAS KIND
12	OF HOW THIS ALL BROKE DOWN.
13	CHAIRMAN THOMAS: DEAN PIZZO, THEN DEAN
14	PULIAFITO, AND THEN DR. STEWARD.
15	DR. PIZZO: I THINK, JOAN, THANK YOU FOR
16	YOUR STATEMENTS, WHICH WERE EXCEPTIONALLY WELL PUT
17	WITH REGARD TO THE PROGRAMMATIC ISSUES AND
18	INITIATIVES IN PARKINSON'S DISEASE, WHICH I BOTH
19	UNDERSTAND AND SUPPORT FROM BOTH A SCIENTIFIC AND
20	MERITORIOUS PERSPECTIVE. I THINK JEFF HAS ADDED TO
21	THIS IN TERMS OF PROGRAMMATIC CONSIDERATIONS.
22	BUT I'D LIKE TO ALSO FRAME THIS IN A
23	SLIGHTLY DIFFERENT WAY JUST FOR DISCUSSION BECAUSE I
24	THINK THERE IS A BIG ISSUE AT STAKE. ON THE ONE
25	HAND, WHEN WE'RE TALKING ABOUT SUPPORTING A
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	<i>L 3 3</i>

PROGRAMMATIC INITIATIVE, A GRANT OR AN EFFORT IN A
DISEASE-SPECIFIC AREA, I THINK WE CAN BE REFINED AND
CONSIDERED IN THE SCOPE OF THE PROJECT AND ITS
LIMITATIONS.
I THINK THE CHALLENGE HERE, AT LEAST THE
CHALLENGE FOR ME, IS THAT WE'RE NOW TALKING ABOUT
CONSIDERABLE AMOUNT OF SUPPORT THAT IS NOT JUST
ABOUT A PROJECT, BUT ABOUT A NEW INVESTIGATOR TO
JOIN THIS COMMUNITY. AND I AGREE THAT THE SEED SOIL
ISSUE IS AN IMPORTANT ONE, THE BROAD ISSUE OF
MERITOCRACY VERSUS INSTITUTIONAL ENHANCEMENT OF HOW
AN INDIVIDUAL FLOURISHES. BUT WE'RE LOOKING AT NOT
JUST THE SHORT-TERM, IMMEDIATE INVESTMENT IN A
PROJECT, BUT IN MANY WAYS THE LONG-TERM INVESTMENT
IN AN INDIVIDUAL. AND THAT'S THE PART THAT I HAVE
MORE DIFFICULTY WITH ON THE BASIS OF THE INFORMATION
THAT WE HAVE AVAILABLE TO US RIGHT NOW.
WHAT I SEE IN THE READ IS NOT IN ANY WAY A
NEGATIVE COMMENTARY ON THE PROJECT AND THE
IMPORTANCE OF THE DISEASE AREA, BUT CONCERNS FAINT
PRAISE, AT LEAST LOOKING AT THE CODE WORDS THAT ARE
USED WITH REGARD TO THE INDIVIDUAL, WHICH ARE NOT AS
LAUDATORY AS ONE WOULD LIKE TO SEE. AND WHILE I
CERTAINLY WASN'T THERE, JEFF, AND CAN'T COMMENT, AND
I UNDERSTAND THE DYNAMICS OF HOW STRONG VOICES
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1	INFLUENCE CROWD DYNAMICS, THERE IS A, QUOTE, 35
2	PERCENT, NEARLY A THIRD OR JUST ABOVE A THIRD OF THE
3	GROUP, THAT OFFERED A MINORITY VIEW AND DID SO IN
4	REASONABLY STRONG WAYS.
5	SO I'M TROUBLED BY NOT THE PROGRAMMATIC
6	ISSUE, BUT BY THE INDIVIDUAL THAT WE'RE RECRUITING
7	AND WHETHER THIS IS WORTH THE INVESTMENT OR WILL
8	YIELD AN INVESTMENT OF SIGNIFICANCE, NOT JUST FOR
9	THIS PROJECT, BUT FOR MANY OTHERS OVER A LONG PERIOD
10	OF TIME TO COME.
11	MS. SAMUELSON: I'VE GOT A LOGISTICAL
12	QUESTION. I HAVE BEFORE ME THE THREE LETTERS OF
13	RECOMMENDATION WHICH I THINK ARE GOING TO BE A GREAT
14	STARTING POINT TO ADDRESS ONE OF THOSE TWO ISSUES.
15	IS OUR I.T. SPECIALIST AROUND HERE BECAUSE
16	THEY'RE HERE AND THEY COULD BE ON THE OTHER SCREENS?
17	DR. YAFFE: I BELIEVE THAT'S PROPRIETARY
18	AND CONFIDENTIAL INFORMATION. THOSE LETTERS WERE
19	SUBMITTED WITH THE UNDERSTANDING THAT THEY WERE NOT
20	GOING TO BECOME PUBLIC, ALTHOUGH WE COULD CERTAINLY
21	DISCUSS THEM IN CLOSED SESSION.
22	MS. SAMUELSON: I COULD CALL AND GET THE
23	PERMISSION. THIS IS ADDRESSING EXACTLY DR. PIZZO'S
24	QUESTION.
25	CHAIRMAN THOMAS: I THINK, JOAN, WE ARE
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,	COTNE TO HAVE A CLOSED SESSION ON THIS TORIS OF A
1	GOING TO HAVE A CLOSED SESSION ON THIS TOPIC. SO WE
2	CAN DISCUSS IT AT THAT POINT.
3	DR. PULIAFITO: WAS THAT CANDIDATE EVER
4	CONSIDERED FOR THIS AWARD PREVIOUSLY?
5	MS. SAMUELSON: YES. NOT IN THIS CONTEXT.
6	DR. PULIAFITO: MY QUESTION WAS WAS THIS
7	CANDIDATE WAS THIS PERSON PREVIOUSLY NOMINATED
8	FOR A RESEARCH LEADERSHIP AWARD AT CIRM?
9	CHAIRMAN THOMAS: MR. HARRISON.
10	MR. HARRISON: LET ME ANSWER CAREFULLY.
11	THIS APPLICANT HAS NEVER BEEN BEFORE THE BOARD WITH
12	AN APPLICATION FOR A RESEARCH LEADERSHIP AWARD.
13	DR. PULIAFITO: WHAT'S THE QUALIFICATION?
14	MR. SHEEHY: SHOULD WE GO INTO CLOSED
15	SESSION?
16	MS. SAMUELSON: MAYBE WE CAN JUST GO
17	THERE.
18	DR. STEWARD: ACTUALLY ALL I WANTED TO DO
19	WAS A MAKE A MOTION TO APPROVE JUST SO WE COULD PUT
20	THIS ON A FOOTING FOR SORT OF FORMAL DISCUSSION.
21	DR. PRIETO: I'LL SECOND.
22	CHAIRMAN THOMAS: BEEN MOVED AND SECONDED.
23	CONTINUED DISCUSSION.
24	DR. PRICE: CAN I ASK A QUESTION? IS IT
25	POSSIBLE FOR US TO BE TOLD THE ACTUAL SCORES OF THE
	356
	256

1	MEMBERS OF THE GRANTS WORKING GROUP, THE INDIVIDUAL
2	SCORES, RATHER THAN JUST STANDARD DEVIATION?
3	DR. SAMBRANO: SO I CAN'T GIVE YOU THE
4	INDIVIDUAL SCORES, BUT WHAT I CAN DO IS GIVE YOU THE
5	MEDIAN, WHICH IS A 58. THE RANGE WAS FROM 30 TO 75
6	WITH A STANDARD DEVIATION OF 14.
7	MS. SAMUELSON: THERE'S A DIFFERENCE OF
8	OPINION ABOUT THOSE NUMBERS. WE'RE GOING TO, I
9	SUPPOSE, HAVE TO DISCUSS THAT IN CLOSED SESSION AS
10	WELL.
11	CHAIRMAN THOMAS: THANK YOU, DR. SAMBRANO.
12	OTHER COMMENTS BY MEMBERS OF THE BOARD? MR. SHEEHY.
13	MR. SHEEHY: I REALLY THINK THAT MAYBE WE
14	SHOULD GO TO CLOSED SESSION. THAT'S MY SENSE ON
15	THIS ONE BEFORE WE DO ANYTHING ELSE.
16	CHAIRMAN THOMAS: OKAY. I THINK THAT'S
17	FAIR. MEMBERS, WHY DON'T WE DO SO WE HAVE A
18	BUNCH OF PEOPLE HERE OR SOME AT ANY RATE FOR PUBLIC
19	COMMENT. LET'S HEAR FROM THEM FIRST BEFORE WE GO TO
20	CLOSED SESSION.
21	ANYBODY WHO WOULD LIKE TO SPEAK, PLEASE
22	STATE YOUR NAME. YOU HAVE THREE MINUTES EACH, AND I
23	ASK THAT YOU RESPECT THAT TIME LIMITATION. THANK
24	YOU.
25	DR. LANGSTON: WELL, THIS IS VERY
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1	INTERESTING. I'M BILL LANGSTON, CEO AND MEDICAL
2	DIRECTOR OF THE PARKINSON'S INSTITUTE. I'M
3	INTERESTED YOU HAVE TWO WORLD AUTHORITIES ON
4	PARKINSON'S. I JUST WON THE PRITZKER AWARD FOR
5	LEADERSHIP IN PARKINSON'S DISEASE PRESENTED BY THE
6	FOX FOUNDATION, WHICH IS THE TOP AWARD IN THE FIELD.
7	SO I FEEL A LITTLE COMFORTABLE SPEAKING ON THIS
8	SUBJECT ALONG WITH WHOEVER YOUR EXPERTS ARE. I
9	WOULD LOVE TO KNOW.
10	WHAT I THINK I'M GOING TO DO IS THERE'S SO
11	MANY ISSUES THAT HAVE BEEN BROUGHT UP, AND I'VE GOT
12	THREE MINUTES. IT'S REALLY IMPOSSIBLE TO HIT THEM
13	ALL.
14	DENNIS, THE CANDIDATE, IS, I THINK, A
15	WORLD-CLASS SCIENTIST. I'M NOT SURE WHERE THIS
	CONCERNS ABOUT HIS CREDENTIALS COME FROM. HE'S ON
16	CONCERNS ABOUT HIS CREDENTIALS COME PROM. HE S ON
16 17	THE MICHAEL FOX BOARD AS THE STEM CELL
17	THE MICHAEL FOX BOARD AS THE STEM CELL
17 18	THE MICHAEL FOX BOARD AS THE STEM CELL REPRESENTATIVE. THAT'S A PRETTY HIGH HONOR IN OUR
17 18 19	THE MICHAEL FOX BOARD AS THE STEM CELL REPRESENTATIVE. THAT'S A PRETTY HIGH HONOR IN OUR FIELD.
17 18 19 20	THE MICHAEL FOX BOARD AS THE STEM CELL REPRESENTATIVE. THAT'S A PRETTY HIGH HONOR IN OUR FIELD. ONE OTHER COMMENT ABOUT THE INSTITUTE,
17 18 19 20 21	THE MICHAEL FOX BOARD AS THE STEM CELL REPRESENTATIVE. THAT'S A PRETTY HIGH HONOR IN OUR FIELD. ONE OTHER COMMENT ABOUT THE INSTITUTE, SOMEONE SAID THE INSTITUTE IS NEW TO CALIFORNIA, NOT
17 18 19 20 21	THE MICHAEL FOX BOARD AS THE STEM CELL REPRESENTATIVE. THAT'S A PRETTY HIGH HONOR IN OUR FIELD. ONE OTHER COMMENT ABOUT THE INSTITUTE, SOMEONE SAID THE INSTITUTE IS NEW TO CALIFORNIA, NOT OUTSIDE OF CALIFORNIA. ACTUALLY I THINK WE'RE MUCH
17 18 19 20 21 22	THE MICHAEL FOX BOARD AS THE STEM CELL REPRESENTATIVE. THAT'S A PRETTY HIGH HONOR IN OUR FIELD. ONE OTHER COMMENT ABOUT THE INSTITUTE, SOMEONE SAID THE INSTITUTE IS NEW TO CALIFORNIA, NOT OUTSIDE OF CALIFORNIA. ACTUALLY I THINK WE'RE MUCH BETTER KNOWN AROUND THE WORLD THAN WE ARE IN

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1	FACILE, WE CAN MOVE QUICKLY, WE HAVE GREAT
2	SCIENTISTS.
3	IN MY REMAINING TWO MINUTES, I WOULD LIKE
4	TO TELL YOU WHY WE'RE SO EXCITED ABOUT THIS SCIENCE.
5	I'VE BEEN IN THE TRANSPLANT FIELD FOR 20 YEARS. WE
6	ALWAYS ASSUMED THAT STEM CELLS WOULD TAKE OVER AFTER
7	WE WORKED WITH FETAL CELLS. KIND OF ON THE WAY TO
8	THE THEATER, SOMETHING FUNNY HAPPENED. AND THAT IS
9	FOR US SOMETHING TOTALLY UNEXPECTED HAPPENED. THESE
10	HEALTHY TRANSPLANTED NEURONS GOT PARKINSON'S
11	DISEASE. THEY DEVELOPED LEWY BODIES. SOMEHOW
12	PARKINSON'S DISEASE WAS TRANSMITTED FROM THE HOST
13	BRAIN WITH PARKINSON'S TO HEALTHY YOUNG NEURONS.
14	THIS WAS A STUNNER BOTH BECAUSE WE THOUGHT
15	THIS WAS GOING TO CURE PARKINSON'S AND, NO. 2, IT
16	WAS THE FIRST EVIDENCE WE'VE HAD IN THE HISTORY OF
17	MEDICINE THAT WHATEVER LURKS IN THE BRAIN AND CAUSES
18	THIS DISEASE IS STILL THERE AND IS CAPABLE OF BEING
19	TRANSMITTED.
20	THIS GRANT DIRECTLY ADDRESSES THAT MAJOR
21	BOTTLENECK IN TRANSPLANTATION. DENNIS HAS BEEN
22	WORKING IN THIS AREA A NUMBER OF YEARS. WE'VE BEEN
23	WORKING IN THIS AREA FOR A NUMBER OF YEARS. WE HAVE
24	A NEW THEORY WHICH WE JUST HAVE DATA AS RECENTLY AS
25	LAST WEEK WORKING WITH ZONDO BREAKFIELD AT HARVARD,
	259

1	THAT NEUROPROGENITOR CELLS ACTUALLY FORM LITTLE
2	BLOBS, LITTLE PACKETS THAT BREAK OFF THE CELL AND
3	CARRY THIS TOXIC PROTEIN WITH THEM. THAT'S THE
4	HYPOTHESIS OF THE GRANT, AND WE HAVE STRONG DATA
5	THIS ACTUALLY HAPPENS WITH STEM CELLS.
6	NOW, TACKLING THAT PROBLEM AND SOLVING THE
7	ISSUE OF WHY THIS HOW THIS DISEASE GETS
8	TRANSMITTED FROM CELL TO CELL WOULD BE A HUGE
9	BREAKTHROUGH IN THE FIELD. AND THIS IS WHAT I THINK
10	DENNIS AND OUR GROUP, THE RICHNESS OF THE
11	PARKINSON'S INSTITUTE AND PARKINSON'S AND THE
12	RICHNESS OF HIS BACKGROUND AND EXPERTISE, I THINK WE
13	CAN SOLVE THIS, PARTICULARLY WITH THIS NEW EXOSOMAL
14	HYPOTHESIS. AND EVEN IF IT'S THE SECOND ONE THAT'S
15	MORE IMPORTANT, WE CAN DO THAT.
16	LAST 30 SECONDS. THERE'S A TWO-FOR HERE.
17	IF WE CAN FIGURE OUT WHY THESE TOXIC PROTEINS GO
18	FROM CELL TO CELL, WE ACTUALLY MAY SOLVE A
19	FUNDAMENTAL PROBLEM IN PARKINSON'S. IF YOU READ THE
20	ARTICLE IN SCIENCE BY THE NOBEL PRIZE WINNER STANLEY
21	PRUSINER ABOUT THE TIME OUR GRANT WAS SUBMITTED, IT
22	TURNS OUT THAT MAYBE MOST NEURODEGENERATIVE DISEASES
23	INVOLVE THIS TYPE OF PREON-LIKE OR TOXIC PROTEIN
24	TRANSMISSION. IF WE CAN SOLVE THIS WITH STEM CELLS
25	FOR TRANSPLANTATION, WE ACTUALLY MIGHT ALSO SOLVE
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1	THE FUNDAMENTAL PROBLEM IN PARKINSON'S.
2	SO I JUST HOPE, WHEN YOU'RE TALKING ABOUT
3	ALL THESE ISSUES, YOU REALIZE AT LEAST IN OUR
4	COMMUNITY THERE'S SOME HUGE SCIENCE HERE THAT COULD
5	BE TRANSFORMATIVE FOR TRANSPLANTATION AND FOR
6	PARKINSON'S. THANK YOU.
7	CHAIRMAN THOMAS: THANK YOU, DOCTOR.
8	MS. KATSAROS: HELLO. MY NAME IS ROBIN
9	KATSAROS. MY HUSBAND IS JOHN KATSAROS. HE IS A
10	PARKINSON'S PATIENT, AND HE'S BEING SEEN BY THE
11	PARKINSON'S INSTITUTE. I DIDN'T KNOW I HAD ONLY
12	THREE MINUTES, SO MY NOTES HAVE SORT OF GONE BY THE
13	WAYSIDE. BUT AFTER SITTING IN THE BACK AS AN
14	OBSERVER AND LISTENING TO WHAT'S GOING ON, I'M A
15	LITTLE DISAPPOINTED BECAUSE I SEE THERE'S SOME
16	POLITICS GOING ON.
17	AND I THINK IT'S INTERESTING THAT SOMEBODY
18	MENTIONED THAT THE PARKINSON'S INSTITUTE IS NOT
19	KNOWN VERY WELL OUTSIDE OF CALIFORNIA. PROBABLY
20	BECAUSE THEY DON'T SPEND A LOT OF MONEY ON
21	MARKETING, AND THAT'S BECAUSE THEY SPEND THEIR MONEY
22	ON RESEARCH AND DEVELOPMENT. THEY HAVE DONE SOME
23	REMARKABLE, LIFE-CHANGING DEVELOPMENTS AT THE
24	PARKINSON'S INSTITUTE. BILL DR. LANGSTON JUST
25	MENTIONED THAT HE WAS AWARDED THE PRITZKER HONOR.

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1	IT'S PRESTIGIOUS. I DON'T KNOW THERE'S A LOT OF
2	OTHER PEOPLE IN THIS ROOM THAT CAN SAY THAT THEY'VE
3	BEEN HONORED SOMETHING WITH A \$500,000 AWARD.
4	\$100,000 OF IT WENT TO HIS OWN PERSONAL RESEARCH.
5	DR. CAROLYN TANNER, WHO IS THE DIRECTOR OF
6	CLINICAL RESEARCH, WAS RECENTLY AWARDED THE 2012
7	NEUROLOGIST OF THE YEAR AWARD BY ANA. THIS
8	ORGANIZATION IS KNOWN WORLDWIDE BY A LOT OF PEOPLE.
9	I'M SORRY IF SOME OF YOU HERE IN THIS ROOM AREN'T
10	QUITE FAMILIAR WITH THEIR REPUTATION, BUT THEY ARE
11	WORLD RENOWNED. THEY HAVE A NIMBLE, SMALL, FOCUSED
12	TEAM OF PEOPLE AND RESEARCHERS, AND THEY ARE THE
13	ONLY INSTITUTE IN THE ENTIRE UNITED STATES, I'D LIKE
14	TO REPEAT THAT, IN THE ENTIRE UNITED STATES THAT
15	COMBINES BASIC RESEARCH, CLINICAL RESEARCH, PATIENT
16	THERAPY, AND PATIENT TREATMENT. AND THAT'S A STORY
17	THAT WE NEED TO BE TELLING.
18	I AM PROUD OF THAT. I AM PROUD TO BE
19	ASSOCIATED WITH THIS ORGANIZATION, AND I THINK THAT
20	THE TEAM THAT HE HAS PUT TOGETHER IS ABSOLUTELY
21	AWESOME. I THINK CALIFORNIA WOULD BE WELL SERVED.
22	AND AS A TAXPAYER, I THINK IT'S IMPORTANT THAT WE
23	PUT OUR MONEY AND OUR RESEARCH INTO PLACES AND
24	PEOPLE AND THINGS THAT HAVE MADE A DIFFERENCE. THIS
25	ORGANIZATION HAS MADE A DIFFERENCE. AND I STRONGLY

1	URGE ALL OF YOU AND ANYBODY WHO IS QUESTIONING, AND
2	WHEN YOU GO INTO YOUR PRIVATE SESSION, THAT YOU
3	THINK ABOUT THAT AND YOU THINK ABOUT THE PEOPLE IN
4	THIS ROOM THAT HAVE PARKINSON'S, THE JOAN
5	SAMUELSONS, THE PEOPLE THAT ARE WORKING HARD, AND
6	YOU THINK ABOUT A SMALL ORGANIZATION THAT CAN MAKE A
7	DIFFERENCE IN FINDING A CURE FOR THIS HORRIBLE
8	DISEASE. THANK YOU.
9	MR. TORRES: AS A NEPHEW OF A PARKINSON'S
10	PATIENT WHO HAS PASSED ON, AND I KNOW MANY HERE IN
11	THIS ROOM SHARE THIS DISEASE, UNFORTUNATELY. BUT IF
12	ANYBODY IN THIS ROOM RECOGNIZES WHAT POLITICS IS, I
13	THINK I AM AN EXPERT. AND BELIEVE ME, MA'AM, THE
14	WORK THAT I'VE DONE FOR THE LAST THREE YEARS WITH
15	THIS BOARD HAS NEVER RESTED DECISIONS ON POLITICS.
16	IT HAS RESTED THEIR DECISIONS ON COMMITMENT, ON
17	PROGRAMMATIC REVIEW, AND ON THE SCIENCE. AND I HOPE
18	YOU GO AWAY FROM THIS MEETING WITH A LITTLE BIT MORE
19	COMFORT THAT WHATEVER DECISIONS ARE MADE ARE NOT
20	GOING TO BE POLITICAL ON THIS BOARD.
21	CHAIRMAN THOMAS: THANK YOU, SENATOR.
22	NEXT, PLEASE.
23	MR. WASSON: GOOD MORNING. MY NAME IS
24	GREG WASSON, AND HERE TODAY IS MY WIFE ANN. WE WERE
25	BOTH DIAGNOSED WITH PARKINSON'S DISEASE 17 YEARS

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1	AGO. WE'VE BEEN ACTIVE PARKINSON'S PATIENT
2	ADVOCATES FOR WELL OVER A DECADE.
3	BEGINNING IN 2001, WE REGULARLY TESTIFIED
4	BEFORE THE CALIFORNIA STATE SENATE IN SUPPORT OF THE
5	LEGISLATION THAT LEGALIZED EMBRYONIC STEM CELL
6	RESEARCH AND SOMATIC CELL NUCLEAR TRANSFER IN
7	CALIFORNIA. I'VE ALSO TESTIFIED BEFORE THE UNITED
8	STATES SENATE ON REGENERATIVE MEDICINE, AND I WAS A
9	MEMBER OF THE WORKING GROUP THAT HELPED PASS
10	PROPOSITION 71 AND CREATE THE CIRM.
11	IN THE TIME THAT WE'VE BEEN PARKINSON'S
12	PATIENT ADVOCATES, WE HAVE LEARNED THAT PARKINSON'S,
13	WHICH IS THE SECOND MOST PREVALENT NEUROLOGICAL
14	ILLNESS, ONE THING WE'VE LEARNED IS THAT PARKINSON'S
15	IS A FAR MORE COMPLEX DISEASE AND RESISTANT TO
16	SIGNIFICANT THERAPEUTIC INTERVENTION THAN WE HAD
17	THOUGHT A DECADE AGO. WE NOW KNOW THAT SOLVING THE
18	RIDDLE OF PARKINSON'S WILL REQUIRE MORE, MORE HARD
19	WORK BY OUR FINEST SCIENTIFIC MINDS, MORE HARD WORK
20	BY OUR BEST INSTITUTIONS, MORE FUNDING FROM AGENCIES
21	THAT HAVE BEEN CREATED TO SPEED THE TIME TO CURES
22	FOR CHRONIC DISEASES LIKE PARKINSON'S, AND ABOVE
23	ALL, WE NEED CREATIVITY, IMAGINATION, AND WISDOM.
24	DR. DENNIS STEINLER, THE PRINCIPAL
25	INVESTIGATOR UNDER THE PROPOSED GRANT, IS
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1	INTERNATIONALLY RENOWNED FOR HIS WORK IN STEM CELL
2	AND NEUROSCIENCE RESEARCH, INCLUDING PARKINSON'S
3	DISEASE. HIS PRESENT PROPOSAL, INCLUDING USE OF
4	DISEASE-IN-A DISH CLINICAL PROTOCOLS TO TEST THE
5	HYPOTHESIS OF CELL-TO-CELL TRANSMISSION THROUGH THE
6	MEDIUM OF EXOSOMES EXEMPLIFIES THE KIND OF CREATIVE
7	APPROACH BY RESEARCHERS THAT IS SORELY NEEDED IF WE
8	ARE TO MAKE REAL PROGRESS IN THE FIGHT AGAINST
9	PARKINSON'S.
10	DR. STEINLER WOULD BE TEAMING UP WITH THE
11	PARKINSON'S INSTITUTE, WHICH COMPLEMENTS THE
12	OBJECTIVES OF HIS RESEARCH PROPOSAL AS WELL AS THE
13	ENTREPRENEURIAL SPIRIT IT EMBODIES. THE PI IS KNOWN
14	THROUGHOUT THE PARKINSON'S COMMUNITY FOR INNOVATIVE
15	THINKING AND LANDMARK ACHIEVEMENTS. FROM THE USE OF
16	MPTP TO CREATE THE FIRST ANIMAL MODELS FOR TESTING
17	PREHUMAN CLINICAL TRIALS OF PARKINSON'S DISEASE
18	THERAPIES TO THE JUSTLY HERALDED TWIN STUDIES THAT
19	INVESTIGATED THE ROLE OF GENETICS IN PD, TO THE
20	LATEST THINKING ON THE NEXUS BETWEEN THE ENVIRONMENT
21	AND GENETICS AND THE DEVELOPMENT AND PROGRESSION OF
22	PARKINSON'S, THE INSTITUTE HAS CONSISTENTLY BEEN AT
23	THE FOREFRONT OF PARKINSON'S RESEARCH.
24	WE AS ADVOCATES HAVE WORKED WITH THE
25	INSTITUTION ON NUMEROUS PROJECTS INCLUDING THE
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	1 LUJ

1	IMPLEMENTATION AND CREATION OF THE CALIFORNIA
2	PARKINSON'S DISEASE REGISTRY. AS PATIENTS, WE ALSO
3	RECEIVE OUR OWN PERSONAL CARE AT THE PI AND HAVE
4	DONE SO FOR THE LAST FIVE YEARS. IN BOTH
5	CAPACITIES, WE HAVE OBSERVED THE DAILY INTERACTION
6	BETWEEN RESEARCHERS, PATIENTS, AND PHYSICIANS. THIS
7	CROSS POLLINATION, WHICH OCCURS BOTH BY DESIGN AND
8	THE COINCIDENCE OF EVERYBODY BEING IN THE SAME PLACE
9	AT THE SAME TIME, CREATES A REMARKABLY FERTILE
10	ATMOSPHERE FOR THE GENERATION OF NEW IDEAS AND
11	APPROACHES TO THE INVESTIGATION AND TREATMENT OF
12	THIS DISEASE.
13	WE ARE CONFIDENT THAT DR. STEINLER AND THE
14	INSTITUTE WILL BE STIMULATING A SUPPORTIVE
15	ENVIRONMENT IN WHICH TO CONDUCT THE PROPOSED
16	RESEARCH. WE STRONGLY URGE THE APPROVAL OF THIS
17	AWARD. THANK YOU.
18	MS. WASSON: AMEN TO THAT.
19	CHAIRMAN THOMAS: THANK YOU BOTH.
20	MR. GREENBERG: MY NAME IS JERRY
21	GREENBERG. I SERVED IN VIETNAM FROM '68 TO '69.
22	DURING THAT HORROR, I WAS EXPOSED TO AGENT ORANGE.
23	SERVICE FOR MY GOVERNMENT, I WAS ATTACKED BY
24	PARKINSON'S. THE PARKINSON'S INSTITUTE HAS BEEN A
25	GODSEND. TREATMENT, I'VE BEEN WORKING WITH SOME OF
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1	THE RESEARCHERS. I'VE BEEN WORKING WITH OTHERS AT
2	THE PARKINSON'S INSTITUTE AS AN ADVOCATE, A
3	VOLUNTEER. PEOPLE THERE ARE GREAT. THE ABILITY FOR
4	ME AS A PATIENT TO TALK DIRECTLY TO THE RESEARCHERS
5	IS UNIQUE.
6	WHAT IS IMPORTANT TO REALIZE, THAT WITH
7	THE AGING POPULATION AND THE GREATER PREVALENCE OF
8	CHEMICALS IN THE ENVIRONMENT, PARKINSON'S IS A
9	GROWING DISEASE. AND PARKINSON'S MODEL ALSO RELATES
10	TO ALS, PICK'S, ALZHEIMER'S, AND OTHERS OF THIS ILK.
11	SO THIS RESEARCH WHICH IS BEING PROPOSED
12	HERE MIGHT EXTEND WELL BEYOND PARKINSON'S, MIGHT
13	EXTEND GENERALLY TO DEGENERATIVE BRAIN DISORDERS.
14	I WATCHED MY MOTHER DEGENERATE AND DIE
15	FROM ALZHEIMER'S. I'VE SEEN PATIENTS THAT ARE MUCH
16	WORSE THAN I AM WITH PARKINSON'S. IT'S A TERRIBLE
17	DISORDER. FOR ME IT MEANT GIVING UP TWO OF MY
18	AVOCATIONAL PASSIONS. I LOVE COOKING. I WAS ONCE A
19	NATIONAL FINALIST IN A COOKING CONTEST; BUT WITH NO
20	SENSE OF SMELL, WHICH IMPACTS THE TASTE, I CAN'T
21	CREATE DISHES ANYMORE.
22	I WAS IN THE MIDDLE OF A WOODWORKING
23	PROJECT CARVING THE TEN COMMANDMENTS. AND I'VE GOT
24	A DRUG-RESISTANT TREMOR. COULD YOU IMAGINE TRYING
25	TO CARVE LIKE THIS? I WAS ALSO INVITED TO JOIN A

1	FENCING CLUB BECAUSE I FENCED IN COLLEGE. AGAIN,
2	WOULD YOU LIKE TO FENCE AGAINST ME WHEN I HAVE MY
3	HAND LIKE THAT?
4	AS NOTED, IT'S A TERRIBLE DISORDER. AND I
5	SEE THIS AS A WAY OF AT LEAST HALTING THE
6	PROGRESSION, IF NOT GENERATING THE CURE. SO I BEG
7	OF YOU TO APPROVE THIS.
8	IN SERVING MY GOVERNMENT, I ENDED UP WITH
9	THIS. I'M ASKING MY GOVERNMENT TO HELP ME END IT.
10	THANK YOU.
11	CHAIRMAN THOMAS: THANK YOU. NEXT PLEASE.
12	MR. LANE: HI. I'M BOB LANE FROM CHICO,
13	CALIFORNIA. I WAS HERE AT YOUR JULY MEETING. SINCE
14	THAT MEETING, I'VE TOURED THE PARKINSON'S INSTITUTE
15	RESEARCH FACILITY. I AM A PARKINSON'S ADVOCATE, I
16	AM A PARKINSON'S INSTITUTE PATIENT, AND I HAVE THIS
17	LITTLE SHAKING GOING ON.
18	I AM NOT A SCIENTIST. I SPENT A LOT OF MY
19	LIFE COLLECTING HEROES. IF YOU WILL PARDON ME,
20	ERNIE BANKS WAS ONE OF THEM, A SPLINTER OF A GUY
21	FROM THE CUBS WHO COULD HIT HOME RUNS.
22	A FEW WEEKS AGO I DISCOVERED A NOTE IN MY
23	FILE THAT MY GRANDFATHER, MY MATERNAL GRANDFATHER,
24	WROTE TO MY OTHER GRANDPA. HE WAS DESCRIBING THE
25	SYMPTOMS OF PARKINSON'S. THEY HAD NO IDEA THAT HE
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1	WAS DESCRIBING THE SYMPTOMS OF PARKINSON'S. THIS
2	WAS 69 YEARS AGO AND WAS WRITTEN AS PART OF A
3	TRANSMISSION BETWEEN TWO GRANDPAS ABOUT THEIR
4	GRANDSON'S BIRTH IN SAN ANTONIO, TEXAS.
5	ETHEL WAS SUBSEQUENTLY DIAGNOSED AS HAVING
6	PARKINSON'S. AND AS YOU KNOW, AT THAT TIME THERE
7	WAS NO MEDICINE FOR MY GRANDMOTHER.
8	IN 1959 MY GRANDFATHER DIED, AND MY
9	GRANDMOTHER WAS LEFT ALONE WITH PARKINSON'S. AND I
10	WAS SHUTTLED OFF TO CUBA, NEW YORK, A BOOMING
11	METROPOLIS OF A THOUSAND PEOPLE, TO HELP HER FOR THE
12	SUMMER. ETHEL LIKED A LITTLE HELP IN THE GARDEN.
13	SHE LIKED TO PLAY CARDS. SHE WASN'T HARD TO PLEASE.
14	AND I WATCHED HER STRUGGLE UP THE STAIRCASE IN A
15	TWO-STORY HOUSE WHERE SHE LIVED BY HERSELF FOR
16	ANOTHER TEN YEARS. THIS WILL GIVE ALL OF US HOPE.
17	SHE LIVED FOR 29 YEARS AFTER THAT DIAGNOSIS WITH
18	PARKINSON'S TO THE AGE OF 80.
19	I WAS RECENTLY MADE, AS I MENTIONED, A
20	PARKINSON'S ADVOCATE BY THE FOUNDATION. AND AT THAT
21	MEETING I MET JIM WONG, ANOTHER OF MY HEROES, A
22	BIOLOGIST. JIM CAN HARDLY WALK. HE DIDN'T COME
23	WITH A CHIP ON HIS SHOULDER. HE CAME TO HELP THE
24	OTHER ADVOCATES LEARN WHAT TO DO AS ADVOCATES TO
25	SUPPORT PEOPLE WITH PARKINSON'S WHO UNDERSTAND THIS
	269
	LUJ

1	DISEASE BECAUSE THEY HAVE IT.
2	I MET CARL AMES FROM PEORIA, ARIZONA. HE
3	WALKED FORWARD, HE'D STOP, AND HE'D HAVE TO WALK
4	BACKWARD TO GET GOING AGAIN, ANOTHER OF THE MALADIES
5	THAT COMES WITH THIS DISEASE. AND YOU KNOW THESE
6	STORIES. I KNOW YOU KNOW THEM. AND I'LL MOVE
7	ALONG.
8	MY SYMPTOMS, AS YOU CAN SEE, ARE
9	RELATIVELY MILD. I'M VERY FORTUNATE. WHAT YOU
10	DON'T SEE IS THE LOSS OF SENSE OF SMELL AND SO ON.
11	AS YOU KNOW, NOBODY KNOWS WHAT CAUSES THIS DISEASE,
12	LET ALONE THE CURE. AND THAT'S THE PROBLEM. MR.
13	CHAIRMAN AND MEMBERS OF THE BOARD, IT HAS BEEN 69
14	YEARS SINCE MY GRANDMOTHER CORRESPONDED WITH MY
15	GRANDFATHER CORRESPONDED WITH MY OTHER GRANDPA ABOUT
16	THE DISEASE.
17	JIMMY, CARL, AND ANOTHER GUY, CHRIS, THAT
18	i was going to mention are 40 years old and have the
19	DISEASE. IF THE STATISTICS ARE CORRECT, HALF A
20	MILLION PEOPLE, ALMOST THERE, HALF A MILLION PEOPLE
21	IN CALIFORNIA ALONE HAVE THE DISEASE. WE NEED YOUR
22	HELP. I ASK YOU PLEASE VOTE FOR THIS PROPOSAL.
23	THIS IS A TOUGH DISEASE. AND AS WE'VE SAID, MANY
24	PEOPLE MANY MORE PEOPLE ARE BECOMING AFFLICTED
25	WITH IT. THANK YOU FOR YOUR TIME AND CONSIDERATION.
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1	CHAIRMAN THOMAS: THANK YOU. NEXT PLEASE.
2	MS. NURIEGA: MY NAME IS JOANNE NURIEGA
3	(PHONETIC), AND I'VE BEEN DIAGNOSED WITH PARKINSON'S
4	FOR ALMOST TEN YEARS. I WAS NOT GOING TO SPEAK, BUT
5	SOMETHING PROPELLED ME OUT OF MY SEAT.
6	FIRST OF ALL, I APPRECIATE YOUR CONCERN
7	FOR THE MONEY AND WHERE IT GOES. WE'RE IN A
8	GOVERNMENT THAT SEEMS TO BE OUT OF CONTROL
9	FINANCIALLY. SO I'M GLAD YOU'RE NOT FOLLOWING SUIT
10	AND YOU'RE BEING VERY CAREFUL IN WHERE YOU PUT THE
11	\$6 MILLION.
12	WHEN I WAS DIAGNOSED, IN MY TERROR, I
13	SPENT MANY HOURS ON THE INTERNET LOOKING FOR HELP.
14	I FOUND THE PARKINSON'S INSTITUTE AND READ ABOUT IT,
15	AND I THOUGHT, WELL, THERE'S NO WAY THIS IS IN
16	CALIFORNIA. THIS IS PROBABLY IN NEW YORK, BUT I'M
17	GOING. WHEREVER THIS PLACE IS I'M GOING. WHEN I
18	SAW THE WORD "SUNNYVALE," I JUST BROKE DOWN IN TEARS
19	BECAUSE I KNEW THIS IS WHERE I SHOULD BE.
20	THE PARKINSON'S INSTITUTE IS NOT TUCKED IN
21	THE CORNER OF A MEDICAL FACILITY THAT DEALS WITH A
22	LOT OF OTHER DISEASES. THEY ARE PARKINSON'S
23	INSTITUTE, AND THEY'RE THE ADVOCATES FOR PEOPLE LIKE
24	ME. WHEN I WENT THERE, I GOT THE HELP I NEEDED.
25	BECAUSE OF THEM, I THINK I'M STANDING HERE IN GOOD
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1	CONDITION. I HAVE BAD MOMENTS AND I HAVE GOOD
2	MOMENTS, AND I'VE BEEN DETERMINED TO RISE ABOVE THIS
3	DISEASE.
4	SO IT SEEMS THE ISSUE HERE IS NOT MY
5	TREMOR AND NOT MY LOSS OF SMELL AND NOT MY SOFT
6	SPEECH TO YOU. THE ISSUE HERE IS YOU'RE TRYING TO
7	FIGURE OUT WHERE TO PUT YOUR MONEY. AND I AM ASKING
8	YOU TO PUT YOUR MONEY IN THE PARKINSON'S INSTITUTE.
9	IF YOU'RE CONCERNED ABOUT THE CALIBER OF THE DOCTOR
10	THEY'RE BRINGING, PERSONALLY I CAN'T IMAGINE THEM
11	GOING THROUGH ALL THIS, TAKING \$6 MILLION AND NOT
12	PICKING THE BEST DOCTOR IN THE WHOLE WORLD. WHY
13	WOULD THEY DO THAT? WHY WOULD THEY PICK SOMEBODY
14	INFERIOR AND WASTE THE MONEY?
15	THIS IS OUR CHANCE. THIS IS OUR CHANCE TO
16	GET SOME HELP. IN MY PURSE I HAVE A LITTLE
17	CONTAINER OF YELLOW PILLS. THAT'S ALL THAT KEEPS ME
18	MOVING. IT'S NOT GOING TO KEEP ME MOVING FOREVER.
19	PEOPLE TELL ME I'M FAIRLY YOUNG. I FEEL OLD
20	SOMETIMES, BUT MAYBE I HAVE 20, 30 YEARS AHEAD OF
21	ME. I DON'T KNOW. BUT THE YELLOW PILLS AREN'T
22	GOING TO GET ME THROUGH. THEY'RE GOING TO TURN ON
23	ME, AND THEY'RE GOING TO CAUSE DYSKINESIA PROBABLY.
24	THESE YELLOW PILLS AREN'T GOING TO KEEP ME WALKING
25	AND DOING THE THINGS I WANT TO DO.
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1	PLEASE, PLEASE WHEN YOU GO IN YOUR CLOSED
2	SESSION, CONSIDER US. I THANK YOU, THE PEOPLE THAT
3	DON'T HAVE PARKINSON'S, THAT YOU PUT YOUR TIME IN
4	THIS. WE REALLY APPRECIATE WHAT YOU'RE DOING.
5	PLEASE CONSIDER US AS YOU MAKE YOUR DECISION. THANK
6	YOU.
7	CHAIRMAN THOMAS: THANK YOU. THAT WOULD
8	APPEAR TO CONCLUDE PUBLIC COMMENT. I THINK WE CAN
9	NOW, MR. HARRISON
10	DR. JUELSGAARD: JUST ONE MORE THING, AND
11	I DON'T KNOW WHETHER THIS SHOULD BE ADDRESSED IN
12	OPEN SESSION OR CLOSED SESSION, BUT I'LL RAISE IT.
13	SO WHEN DR. SAMBRANO PRESENTED THE REVIEW CRITERIA
14	FOR THIS PARTICULAR AWARD, THE THIRD ONE WAS
15	INSTITUTIONAL COMMITMENT AND ENVIRONMENT. AND BEAR
16	WITH ME JUST A MINUTE. IN THE REVIEW DONE BY THE
17	GRANTS WORKING GROUP, THERE'S A SENTENCE AT THE END
18	OF A PARAGRAPH THAT SAID, "REVIEWERS FELT THAT THE
19	CANDIDATE WOULD BRING LEADERSHIP IN FUNDAMENTAL
20	STUDIES TO DISEASE MECHANISMS AND BASIC NSC
21	RESEARCH."
22	HERE'S THE IMPORTANT QUESTION FROM MY
23	POINT OF VIEW. THE QUESTION WHETHER THE INSTITUTION
24	COULD PROVIDE A CRITICAL MASS OF PERSONNEL,
25	ESSENTIAL RESOURCES, CORE FACILITIES, AND AN

1	APPROPRIATE ENVIRONMENT TO ENABLE ACHIEVEMENT OF THE
2	PROJECT GOALS.
3	SO IS THERE SOMEBODY WHO COULD SPEAK TO
4	THAT PARTICULAR PART OF THIS ISSUE SINCE IT IS ONE
5	OF OUR REVIEW CRITERIA?
6	CHAIRMAN THOMAS: MR. SHEEHY.
7	MR. SHEEHY: I WANT TO CLARIFY. I THINK
8	THAT SOME FOLKS MAY HAVE THOUGHT THAT I WAS BEING
9	CRITICAL OF THE PARKINSON'S INSTITUTE. I DO THINK
10	WE NEED TO HEAR FROM DR. LANGSTON. BUT I WAS
11	SPECIFICALLY TRYING TO ADDRESS WHAT I FELT WAS A
12	LIMITATION IN THE REVIEW IN PART BECAUSE OF THAT
13	SENTENCE AND BECAUSE THAT'S ONE OF THE MAJOR
14	CRITERIA FOR THIS GRANT.
15	PEOPLE WERE LOOKING UP THE INSTITUTE AND
16	DEBATING THIS, LOOKING IT UP ON THE WEBSITE AND
17	DEBATING THIS IN REAL-TIME. THAT IS NOT GOOD
18	EVIDENCE BASIS FOR DETERMINING WHETHER SUFFICIENT
19	CAPACITY EXISTS AT AN INSTITUTE TO ABSORB IT. AND I
20	FELT THAT THERE WERE SEVERAL PEOPLE IN THE ROOM WHO
21	DID NOT HAVE ENOUGH KNOWLEDGE ABOUT THE INSTITUTE TO
22	BE MAKING THOSE KINDS OF JUDGMENTS.
23	AND I PERSONALLY DID NOT KNOW ABOUT THE
24	PARKINSON'S INSTITUTE TILL I CAME ONTO THIS BOARD,
25	BUT I'VE BEEN IMPRESSED WITH THE WORK THAT THEY'VE
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1	DONE. WE HAVE GIVEN THEM GRANTS. AND I'VE BEEN			
2	PROUD TO VOTE FOR THOSE GRANTS. BUT I WAS			
3	EXPLAINING, TRYING TO EXPLAIN WHAT I FELT WAS A			
4	MAJOR SHORTCOMING IN THE REVIEW AMONGST SOME OF THE			
5	REVIEWERS.			
6	IF YOU PULL UP THE INSTITUTE ON THE			
7	WEBSITE, AND TWO OF YOU OR THREE OF YOU ARE			
8	DISCUSSING THE PERSONNEL AND YOU HAVEN'T DONE THAT			
9	BEFORE YOU GOT HERE, YOU HAVEN'T ACTUALLY TRIED TO			
10	FIGURE OUT WHAT GOES ON AT THAT INSTITUTE. I DON'T			
11	CONSIDER THAT A STRONG EVIDENCE BASIS FOR MAKING			
12	THOSE JUDGMENTS. SO I WOULD LOVE TO HEAR FROM			
13	DR. LANGSTON THOUGH.			
14	CHAIRMAN THOMAS: BEFORE DR. LANGSTON, WE			
15	HAVE DR. LUBIN.			
16	DR. LUBIN: SO IN THE DESCRIPTION OF THE			
17	FACILITY THAT'S PART OF THE APPLICATION, WASN'T			
18	THERE AN EXTENSIVE DESCRIPTION OF THE SCIENCE THAT'S			
19	TAKING PLACE AT THE PARKINSON'S INSTITUTE, THE			
20	NUMBER OF INVESTIGATORS, THE GRANTS THAT THEY HAVE,			
21	ETC., ETC.?			
22	MR. SHEEHY: COULD I RESPOND TO DR. LUBIN?			
23	I THINK YOU'VE BEEN ON THE OTHER SIDE OF THIS.			
24	MAYBE YOUR MEMORY IS SHORT, BUT YOU'VE BEEN ON THE			
25	OTHER SIDE OF I DON'T KNOW. I REMEMBER MAKING			
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THE SAME EXPERIENCE WITH PEOPLE WHO REALLY DIDN'T			
UNDERSTAND WHAT WAS GOING ON AT THE INSTITUTE AND			
LOSING ON THAT PARTICULAR DEBATE.			
DR. LUBIN: I KNOW WHAT HE'S TALKING			
ABOUT.			
MR. SHEEHY: IT'S THE SAME THING.			
EVERYBODY KNOWS HARVARD. EVERYBODY KNOWS JOHNS			
HOPKINS. AND IT'S JUST YOU GET TO THESE OTHER			
INSTITUTIONS AND SOMETIMES I DON'T KNOW. YOU GUYS			
KNOW THIS. THIS IS YOUR WORLD. I'M SHOCKED BY IT			
SOMETIMES.			
CHAIRMAN THOMAS: DR. YAFFE, THEN WE			
SHOULD HEAR FROM DR. LANGSTON.			
DR. YAFFE: JUST IN DIRECT ANSWER TO DR.			
LUBIN, YES, THERE IS A DESCRIPTION IN THE			
APPLICATION OF THE RESEARCH FACILITIES AND			
LABORATORY AVAILABLE FOR THE RESEARCH. AND WE COULD			
DISCUSS DETAILS OF THAT IN CLOSED SESSION, IF			
NECESSARY.			
CHAIRMAN THOMAS: DR. LANGSTON, PLEASE.			
DR. LANGSTON: FIRST OF ALL, BIGGER IS NOT			
NECESSARILY BETTER. WE ARE NOT ONE OF THE BIG			
INSTITUTIONS IN CALIFORNIA. I THINK WE WAY MAKE UP			
FOR THAT IN TERMS OF OUR FOCUS. WE HAVE A 60,000			
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1	SQUARE FOOT FACILITY. A QUARTER OF THAT IS WET
2	LABS. WE HAVE A FULL VIVARIUM. WE HAVE SOMETHING
3	LIKE TEN DIFFERENT TRANSGENIC MODELS. WE HAVE THE
4	FIRST TRANSGENIC EVER MADE IN OUR TRANSGENIC PEOPLE.
5	WE HAVE PROBABLY THE WORLD LEADER, CERTAINLY U.S. IN
6	LURK 2 BIOLOGY. WE HAVE A SUPERB SCIENTIST IN
7	GENETICS WHO HAS SUBMITTED WITH ME TWO CIRM GRANTS,
8	ONE OF WHICH WAS RATED NO. 1 IN 220, AND ONE OF
9	WHICH WAS NO. 2. SO WE'RE WORKING WITH ZINC FINGER
10	TECHNOLOGY NOW TO CORRECT GENETIC DEFECTS.
11	WE HAVE, AS I SAID, THE ONLY PRIMATE
12	FACILITY IN THE WORLD DEDICATED JUST FOR PARKINSON'S
13	RESEARCH. IT'S A VERY RICH COMMUNITY WITH A 25-YEAR
14	HISTORY.
15	WE ALSO HAVE THE CAPACITY TO TRANSLATE
16	STRAIGHT INTO THE CLINIC BECAUSE OUR CLINICAL
17	RESEARCH GROUP DOES CLINICAL TRIALS, AND WE'VE TWICE
10	RESEARCH GROOT BOES CELITERE TREATES, THE WE'VE TWICE
то	GONE FROM A BASIC DISCOVERY IN THE LABORATORY TO A
18 19 20	GONE FROM A BASIC DISCOVERY IN THE LABORATORY TO A
19	GONE FROM A BASIC DISCOVERY IN THE LABORATORY TO A PHASE I CLINICAL TRIAL WITHOUT EVER LEAVING THE
19 20 21	GONE FROM A BASIC DISCOVERY IN THE LABORATORY TO A PHASE I CLINICAL TRIAL WITHOUT EVER LEAVING THE BUILDING. ALL OF THIS, MIND YOUR, IS IN ONE ROOF,
19 20	GONE FROM A BASIC DISCOVERY IN THE LABORATORY TO A PHASE I CLINICAL TRIAL WITHOUT EVER LEAVING THE BUILDING. ALL OF THIS, MIND YOUR, IS IN ONE ROOF, DIFFERENT PEOPLE, SINGLE PURPOSE. SO FACILITIES HAS
19 20 21 22	GONE FROM A BASIC DISCOVERY IN THE LABORATORY TO A PHASE I CLINICAL TRIAL WITHOUT EVER LEAVING THE BUILDING. ALL OF THIS, MIND YOUR, IS IN ONE ROOF, DIFFERENT PEOPLE, SINGLE PURPOSE. SO FACILITIES HAS NEVER BEEN A PROBLEM FOR US. WE'VE GOT LOTS OF
19 20 21 22 23	GONE FROM A BASIC DISCOVERY IN THE LABORATORY TO A PHASE I CLINICAL TRIAL WITHOUT EVER LEAVING THE BUILDING. ALL OF THIS, MIND YOUR, IS IN ONE ROOF, DIFFERENT PEOPLE, SINGLE PURPOSE. SO FACILITIES HAS NEVER BEEN A PROBLEM FOR US. WE'VE GOT LOTS OF ROOM.

1	ANN AND SERGEY BRIN WERE GOING TO WRITE A LETTER IN
2	SUPPORT OF THIS PROPOSAL. SO WE HAVE SOME PRETTY
3	SOLID FINANCIAL BACKERS OUT THERE THAT WILL STEP
4	FORWARD IF THERE'S ANY SHORTAGE. BUT WE HAVE A
5	BOOMING LAB, AND I THINK WHAT'S EXCITING HERE IS THE
6	TECHNOLOGY OF PUTTING OUR RICHNESS OF THE BENCH
7	RESEARCH AND CLINICAL RESEARCH CAPABILITY WITH
8	DENNIS' EXPERTISE IN STEM CELL, THE SKY IS THE
9	LIMIT. I REALLY DO BELIEVE WE COULD WIND UP NOT
10	ONLY FIGURING OUT THIS ROADBLOCK FOR
11	TRANSPLANTATION, I BELIEVE WE COULD WIND UP SOLVING
12	THIS DISEASE WITH THAT TEAM.
13	I SAY THAT FROM MY HEART. I THINK THAT'S
14	REALLY A POSSIBILITY. AND FACILITIES WILL NOT BE A
15	LIMITATION.
16	CHAIRMAN THOMAS: THANK YOU, DR. LANGSTON.
17	DR. JUELSGAARD: IF I COULD ASK DR.
18	LANGSTON JUST A QUESTION, PLEASE. SO YOU SPOKE A
19	LOT ABOUT FACILITIES WHEREWITHAL, BUT I JUST WANT TO
20	ASK ABOUT FINANCIAL WHEREWITHAL. AND THE COMMENT
21	THAT YOU MADE IS THAT YOU HAVE STRONG BACKERS
22	INCLUDING THE BRINS.
23	THE ONLY FINANCIAL INFORMATION I COULD
24	FIND ON YOUR INSTITUTE SO FAR IS ON A WEBSITE CALLED
25	CHARITY NAVIGATOR, WHICH IS A COMMON WEBSITE USED TO
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1	RANK CHARITIES, AND THEY PROVIDE SOME FINANCIAL
2	INFORMATION. CAN YOU JUST DESCRIBE A LITTLE BIT
3	MORE ABOUT THE FINANCIAL HEALTH OF YOUR INSTITUTE?
4	DR. LANGSTON: THAT'S A WONDERFUL
5	QUESTION. SOMETHING I THINK ABOUT EVERY DAY. WE
6	ARE THE ONLY INSTITUTE OF OUR KIND THAT I KNOW OF
7	IF SOMEBODY CAN CORRECT ME ON THIS, I'D REALLY LOVE
8	IT THAT STARTED FROM SCRATCH. ALMOST ALL OF THE
9	BIG NONPROFITS, SCRIPPS, SALK, JONAS SALK STARTED
10	THAT WITH THE FUNDS FROM THE SALK VACCINE, THE BUCK
11	INSTITUTE, \$80 MILLION GRANT. WE STARTED FROM
12	SCRATCH. AND WE HAVE PULLED OURSELVES UP BY OUR
13	BOOTSTRAPS. WE LIVE ON GRANTS, PHILANTHROPY, WE'RE
14	DOING MORE AND MORE WORK WITH INDUSTRY NOW THAT
15	THERE'S SOME TARGETS OUT THERE FOR PARKINSON'S
16	DISEASE.
17	SO WE'RE KIND OF VERY SILICON VALLEY.
18	WE'RE VERY ENTREPRENEURIAL. IF IT LOOKS GOOD, WE GO
19	FOR IT. WE RAISE FUNDS FROM EVERY SOURCE WE CAN.
20	AND, IN ESSENCE, WE START EACH YEAR WITH GRANTS, NEW
21	GRANTS, NEW FUNDRAISING, ETC. I REALLY THINK WE'RE
22	QUITE UNIQUE THAT WAY. WE'RE VERY ENTREPRENEURIAL.
23	I GUESS THAT MAY SOUND NOT LIKE THE ANSWER YOU'D
24	LIKE TO HEAR, THAT WE HAVE A \$50 MILLION ENDOWMENT.
25	ON THE OTHER HAND, IT KEEPS EVERYBODY WORKING, AND
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1	WE'VE BEEN HERE FOR 25 YEARS. AND SO IT'S LIKE A				
2	BUSINESS. IT'S LIKE A BUSINESS.				
3	MS. SAMUELSON: I NEED TO ADD TO THAT.				
4	THAT TIME FRAME CORRESPONDS WITH THE TIME FRAME IN				
5	WHICH PARKINSON'S RESEARCH HAS BEEN FUNDED AT ALL BY				
6	THE FEDERAL GOVERNMENT. THAT'S NOT TRUE. 25 YEARS				
7	AGO ABOUT \$25 MILLION TOTAL WAS SPENT FROM THE NIH				
8	ON PARKINSON'S RESEARCH IN COMPARISON WITH HUNDREDS				
9	OF MILLIONS OF DOLLARS FOR ANY COMPARABLE DISORDER.				
10	AND IT'S BECAUSE NO ONE ASKED FOR IT, AND IT HAS				
11	BUILT FROM THERE. BUT THERE WEREN'T ANY FUNDS				
12	AVAILABLE FROM THE NIH BEFOREHAND, AND IT'S BEEN				
13	HARD WORK BY THE COMMUNITY GETTING COMPARABLE				
14	FUNDING THAT HAS BUILT IT FROM SCRATCH.				
15	AND NOW IT'S TIME FOR THE STEM CELL MONEY				
16	TO BE ADDED TO THAT FOR THESE TERRIBLY COMPLEX				
17	PROBLEMS THAT NEED TO BE ADDRESSED. AND I THINK				
18	THAT'S GOOD NEWS. I DON'T THINK IT'S AN INDICATOR				
19	OF LACK OF SOPHISTICATION OR CALIBER OF THE				
20	INSTITUTE. I THINK IT'S THE DEGREE OF DIFFICULTY OF				
21	THESE PROBLEMS THAT DEMAND NOW MORE FUNDS. AND IT'S				
22	GOOD NEWS THAT IT WILL BE SPENT SO WELL.				
23	AND I APPRECIATE COMPLETELY THAT YOU NEED				
24	TO BE CONVINCED OF THAT. I'M CONFIDENT YOU WILL				
25	BETWEEN THIS AND THE CLOSED SESSION.				
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1	CHAIRMAN THOMAS: YES, SIR.
2	MR. TAYLOR: I'M CLYDE TAYLOR FROM THE
3	PARKINSON'S INSTITUTE. MAY I ADDRESS PUBLIC
4	COMMENT?
5	CHAIRMAN THOMAS: YES. THREE MINUTES,
6	PLEASE.
7	MR. TAYLOR: THANK YOU FOR THE
8	OPPORTUNITY. AND THANKS TO THE GRANTS WORKING GROUP
9	FOR RECOMMENDING FUNDING OF THIS EXCEPTIONAL
10	PROJECT. I WAS ASKED TO SPEAK A BIT ABOUT THE SCALE
11	BECAUSE WE APPEAR SO SMALL IN TERMS OF OUR
12	COLLABORATIONS. WORLDWIDE WE COLLABORATE WITH MAX
13	PLANCK INSTITUTE IN GERMANY, WITH NUMEROUS
14	UNIVERSITIES ON THE EAST COAST, INCLUDING HARVARD,
15	WITH NUMEROUS PRIVATE PHARMACEUTICAL COMPANIES,
16	WHICH, AS ANYONE WHO'S FAMILIAR WITH PHARMACEUTICALS
17	OR DRUGS KNOW, THAT'S THE ONLY WAY BY WHICH WE WILL
18	OBTAIN ANY NEW THERAPIES FOR PARKINSON'S IS THROUGH
19	THE FUNDING AND THE EFFORTS OF DRUG COMPANIES,
20	INCLUDING GENENTECH, INCLUDING NOVARTIS, AND
21	NUMEROUS OTHERS. SO THE SCALE OF OUR SCIENTIFIC
22	REACH IS NOT LIMITED TO WHAT'S WITHIN THE DOORS OF
23	OUR BUILDING.
24	I DON'T KNOW IF IT HAS BEEN ADDRESSED IN
25	EARLIER COMMENTS, BUT THERE WAS ALSO IN THE MINORITY
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1	OPINION OF THE GRANTS WORKING GROUP SOME COMMENTS
2	ABOUT THE QUALIFICATIONS OF THE PRINCIPAL
3	INVESTIGATOR RELATIVE TO PARKINSON'S. SO I'M NOT
4	QUITE SURE WHERE THAT CAME FROM. I WOULD NOTE THAT
5	THE INVESTIGATOR HAS BEEN ON THE SCIENTIFIC ADVISORY
6	BOARD OF THE MICHAEL J. FOX FOUNDATION SINCE ITS
7	INCEPTION. THAT'S EXCLUSIVELY DEVOTED TO
8	PARKINSON'S. THE SECOND LARGEST FUNDER OF
9	PARKINSON'S RESEARCH AFTER THE U.S. GOVERNMENT, HAS
10	SOME 17 PUBLICATIONS SPECIFICALLY IN THIS FIELD, AND
11	HAS BEEN DEDICATED TO THIS PARTICULAR AREA, WHICH IS
12	BOTH INCLUSIVE OF PARKINSON'S AND CANCER, BUT THE
13	MECHANISMS ARE THE SAME, FOR SOME TIME. GOOD. IN
14	THE INTEREST OF TIME, I'LL THANK YOU.
15	CHAIRMAN THOMAS: THANK YOU. ANY COMMENTS
16	BY MEMBERS OF THE BOARD BEFORE WE GO INTO CLOSED
17	SESSION? DR. STEWARD.
18	DR. STEWARD: ANTICIPATING THE POSSIBLE
19	NEED FOR CLOSED SESSION FOR THE OTHER APPLICANT FOR
20	THIS, DO WE NEED TO MAKE SHALL WE DO THAT FIRST?
21	CHAIRMAN THOMAS: THE OTHER APPLICANT WE
22	FUNDED IN JULY.
23	DR. STEWARD: I'M SORRY.
24	CHAIRMAN THOMAS: OKAY. HEARING NO OTHER
25	BOARD DISCUSSION, WE NOW ADJOURN INTO CLOSED
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1	SESSION.			
2	MS. FEIT: COULD YOU PLEASE ASK MARIA TO			
3	CALL ME WHEN YOU'RE BACK IN SESSION?			
4	CHAIRMAN THOMAS: YES, WE SHALL, MARCY.			
5	MR. HARRISON: THE BOARD WILL BE CONVENING			
6	IN CLOSED SESSION TO CONSIDER CONFIDENTIAL AND			
7	PROPRIETARY INFORMATION RELATED TO THE RESEARCH			
8	LEADERSHIP AWARD APPLICATION PURSUANT TO HEALTH AND			
9	SAFETY CODE SECTION 125290.30(F)(3)(B) AND (C).			
10	CHAIRMAN THOMAS: THANK YOU, MR. HARRISON.			
11	(THE BOARD THEN CONVENED IN CLOSED			
12	SESSION, NOT REPORTED NOR HEREIN TRANSCRIBED. THE			
13	FOLLOWING WAS THEN HEARD IN OPEN SESSION:)			
14	CHAIRMAN THOMAS: MEMBERS PLEASE TAKE			
15	THEIR SEATS. WE'VE NOW FINISHED OUR CLOSED SESSION			
16	AND ARE BACK IN OPEN SESSION. IS MARCY BACK ON THE			
17	PHONE? LET'S GIVE JENNA, ARE YOU			
18	MS. PRYNE: WORKING ON IT.			
19	CHAIRMAN THOMAS: OKAY. SO MARCY WILL			
20	JOIN US IN A SECOND. SO THERE'S A MOTION ON THE			
21	TABLE THAT WE APPROVE THIS RESEARCH LEADERSHIP			
22	AWARD. ARE THERE ADDITIONAL COMMENTS BY MEMBERS OF			
23	THE BOARD?			
24	MR. TORRES: CALL FOR THE QUESTION.			
25	CHAIRMAN THOMAS: HEARING NONE, WE'VE			
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1	ALREADY HAD PUBLIC COMMENT. THERE'S MICHAEL RIGHT			
2	THERE. OKAY. SO, MR. HARRISON, I BELIEVE THIS IS A			
3	ROLL CALL VOTE ITEM.			
4	MR. HARRISON: CORRECT.			
5	CHAIRMAN THOMAS: THANK YOU. MARIA,			
6	PLEASE CALL THE ROLL.			
7	MS. BONNEVILLE: ROBERT PRICE.			
8	DR. PRICE: YES.			
9	MS. BONNEVILLE: DAVID BRENNER.			
10	DR. BRENNER: YES.			
11	MS. BONNEVILLE: JACOB LEVIN.			
12	DR. LEVIN: YES.			
13	MS. BONNEVILLE: ANNE-MARIE DULIEGE.			
14	DR. DULIEGE: YES.			
15	MS. BONNEVILLE: MARCY FEIT. MICHAEL			
16	FRIEDMAN.			
17	DR. FRIEDMAN: YES.			
18	MS. BONNEVILLE: LEEZA GIBBONS.			
19	MS. GIBBONS: YES.			
20	MS. BONNEVILLE: MICHAEL GOLDBERG. SAM			
21	HAWGOOD.			
22	DR. HAWGOOD: YES.			
23	MS. BONNEVILLE: STEPHEN JUELSGAARD.			
24	DR. JUELSGAARD: YES.			
25	MS. BONNEVILLE: SHERRY LANSING. BERT			
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1	LUBIN.	
2		DR. LUBIN: YES.
3		MS. BONNEVILLE: MICHAEL MARLETTA. LEON
4	FINE.	
5		DR. FINE: YES.
6		MS. BONNEVILLE: PHIL PIZZO.
7		DR. PIZZO: YES.
8		MS. BONNEVILLE: CLAIRE POMEROY.
9		DR. POMEROY: YES.
10		MS. BONNEVILLE: FRANCISCO PRIETO.
11		DR. PRIETO: AYE.
12		MS. BONNEVILLE: CARMEN PULIAFITO.
13		DR. PULIAFITO: YES.
14		MS. BONNEVILLE: ROBERT QUINT.
15		DR. QUINT: YES.
16		MS. BONNEVILLE: DUANE ROTH.
17		MR. ROTH: YES.
18		MS. BONNEVILLE: JOAN SAMUELSON.
19		MS. SAMUELSON: YES.
20		MS. BONNEVILLE: JEFF SHEEHY.
21		MR. SHEEHY: YES.
22		MS. BONNEVILLE: JONATHAN SHESTACK.
23		MR. SHESTACK: YES.
24		MS. BONNEVILLE: OSWALD STEWARD.
25		DR. STEWARD: YES.
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1	MS. BONNEVILLE: JONATHAN THOMAS.
2	CHAIRMAN THOMAS: YES.
3	MS. BONNEVILLE: ART TORRES.
4	MR. TORRES: AYE.
5	MS. BONNEVILLE: KRISTINA VUORI.
6	DR. VUORI: YES.
7	MS. BONNEVILLE: JAMES ECONOMOU.
8	DR. ECONOMOU: HERE.
9	MS. BONNEVILLE: MARCY, ARE YOU ON THE
10	LINE?
11	CHAIRMAN THOMAS: THANK YOU, MARIA. THE
12	MOTION PASSES.
13	(APPLAUSE.)
14	CHAIRMAN THOMAS: DR. LANGSTON,
15	CONGRATULATIONS. YOU CAN CONVEY THOSE TO DR.
16	STEINLER AS WELL. THANK YOU.
17	WE ARE NOW GOING TO MOVE ON TO THE
18	CONSIDERATION OF THE APPLICATIONS FOR BASIC BIOLOGY
19	IV. MR. HARRISON, DO YOU HAVE ANY OPENING COMMENTS
20	ON PROCESS HERE?
21	MR. HARRISON: AS USUAL, STAFF WILL MAKE
22	THE PRESENTATION REGARDING THE BASIC BIOLOGY
23	APPLICATIONS. AFTER THAT PRESENTATION, THE CHAIR
24	WILL ASK ANY OF YOU TO IDENTIFY APPLICATIONS ABOUT
25	WHICH YOU WOULD LIKE TO HEAR MORE, AND STAFF WILL
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1	MAKE A SPECIFIC PRESENTATION WITH RESPECT TO THOSE
2	APPLICATIONS. TO THE EXTENT THAT ANY OF THE
3	QUESTIONS WOULD REQUIRE CONFIDENTIAL INFORMATION TO
4	BE CONVEYED, WE'LL DEFER FURTHER CONSIDERATION UNTIL
5	CLOSED SESSION.
6	TYPICALLY WHAT WE DO IS TO START WITH
7	MOTIONS TO MOVE APPLICATIONS FROM TIER III TO TIER
8	I. AND THEN ONCE WE'VE EXHAUSTED THOSE, WE ASK FOR
9	ANY APPLICATIONS ANY MOTIONS TO MOVE AN
10	APPLICATION FROM TIER I TO TIER III BEFORE TAKING
11	FINAL VOTES ON THOSE APPLICATIONS IN BOTH TIER I AND
12	TIER III.
13	CHAIRMAN THOMAS: THANK YOU, MR. HARRISON.
14	DR. VESSAL: MR. CHAIRMAN, MEMBERS OF THE
15	BOARD, HERE TO PRESENT TO YOU RECOMMENDATIONS FROM
16	THE GRANTS WORKING GROUP FOR BASIC BIOLOGY ROUND IV
17	APPLICATIONS FOR YOUR CONSIDERATION.
18	BRIEFLY AS AN OVERVIEW FOR THIS RFA, THE
19	STUDIES WERE MEANT TO SUPPORT STUDIES FOR
20	TACKLING THE SIGNIFICANT AND UNRESOLVED ISSUES THAT
21	WERE IMPORTANT TO THE CONTROL OF THE STEM CELL FATE
22	AND ALSO TO FOSTER CUTTING-EDGE RESEARCH TO
23	UNDERSTAND THE MECHANISMS OF PLURIPOTENCY,
24	DIFFERENTIATION, CELLULAR REPROGRAMMING, AND DISEASE
25	MECHANISMS.

1	ALSO, THOSE STUDIES THAT WERE FOCUSED
2	PRIMARILY ON HUMAN CELLS WERE CALLED OUT FOR AND
3	WITH AN EXCEPTION FOR GROUNDBREAKING STUDIES THAT
4	WERE EITHER HIGHLY INNOVATIVE, THAT USED ANIMAL
5	MODEL SYSTEMS, THAT WERE NECESSARY TO USE ANIMAL
6	MODEL SYSTEMS.
7	THE PROJECT, IT'S A THREE-YEAR AWARD WITH
8	A DIRECT PROJECT COST OF UP TO \$300,000 PER YEAR AND
9	OVERALL OF ABOUT 25 GRANTS AND UP TO \$35 MILLION.
10	THE PROCESS FOR THE REVIEW, AS WITH THE
11	PREVIOUS ROUNDS, IT INVOLVED A PRELIMINARY
12	APPLICATION PROCESS WITH NO INSTITUTIONAL LIMITS ON
13	THE NUMBER OF PRE-APPS. THE PRE-APPS WERE REVIEWED
14	BY THE EXPERTS FROM OUTSIDE OF CALIFORNIA AS WELL AS
15	THE CIRM SCIENTISTS. AND THEN THE FULL APPLICATIONS
16	WERE REVIEWED BY THE GRANTS WORKING GROUP ON JUNE
17	27TH THROUGH 29TH IN BERKELEY.
18	WE RECEIVED 357 PRELIMINARY APPLICATIONS
19	FOR THIS RFA THIS YEAR, AND 64 WERE INVITED AND
20	REVIEWED FOR FULL REVIEW BY THE GRANTS WORKING GROUP
21	AND, OF COURSE, THE FINAL NUMBER TO BE DETERMINED
22	PENDING ON YOUR APPROVAL.
23	THE REVIEW CRITERIA THAT THE GRANTS
24	WORKING GROUP JUDGED THE APPLICATIONS WERE BASED ON
25	THE SIGNIFICANCE AND INNOVATION, FEASIBILITY AND
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1	EXPERIMENTAL DESIGN, PRINCIPAL INVESTIGATOR AND THE
2	RESEARCH TEAM INVOLVED, AND THE RESPONSIVENESS TO
3	THE RFA.
4	HERE'S A BASIC CHART FOR THE DISTRIBUTION
5	OF THE SCORES AND WHERE THE LINES WERE DRAWN FOR THE
6	FIRST TIER AND THIRD TIER. YOU CAN SEE, 74 WAS
7	WHERE IT WAS DRAWN FOR TIER I AND 66 WAS WHERE IT
8	WAS FOR TIER III.
9	AND BASICALLY IN TERMS OF NUMBERS, 25
10	APPLICATIONS WERE RECOMMENDED FOR FUNDING, FOR A
11	TOTAL OF \$33.9 MILLION, AND 39 FELL IN THE TIER III
12	THAT WERE NOT RECOMMENDED FOR FUNDING. AND, AGAIN,
13	AS A REMINDER, WE HAD A \$35 MILLION BUDGET APPROVED
14	BY YOU FOR THIS RFA. THANK YOU. IF YOU HAVE ANY
15	QUESTIONS, I'LL BE HAPPY TO ANSWER.
16	DR. STEWARD: WOULD IT BE POSSIBLE TO KEEP
17	THAT GRAPH UP THERE? IT'S JUST USEFUL TO HAVE A
18	VISUAL.
19	CHAIRMAN THOMAS: OKAY. MR. HARRISON, THE
20	APPROPRIATE MOVE NOW IS TO MOVE TO APPROVE THOSE
21	RECOMMENDED FOR FUNDING?
22	MR. HARRISON: I THINK THE STAFF WILL PUT
23	UP THE SPREADSHEET THAT IDENTIFIES THE SCORES AND
24	THE DISTRIBUTION OF APPLICATIONS IN TIER I AND TIER
25	III. AND IF MEMBERS HAVE QUESTIONS CONCERNING

1	SPECIFIC APPLICATIONS, NOW WOULD BE THE APPROPRIATE
2	TIME TO IDENTIFY THEM SO THAT STAFF CAN MAKE
3	ADDITIONAL PRESENTATION WE CAN ENTERTAIN FOR
4	DISCUSSION AND ANY MOTION WITH RESPECT TO SUCH
5	APPLICATIONS.
6	MR. SHESTACK: WHAT WAS THE CUTOFF NUMBER
7	FOR TIER I?
8	DR. SAMBRANO: 74 AND 66.
9	CHAIRMAN THOMAS: LET'S WAIT TILL WE GET
10	OUR GRAPHIC UP HERE.
11	MR. HARRISON: YOU CAN ALSO FIND A COPY OF
12	THE SLIDE DECK THAT STAFF JUST PRESENTED IN YOUR
13	BINDER.
14	CHAIRMAN THOMAS: I'M SORRY, MR. HARRISON.
15	REPEAT THAT PLEASE.
16	MR. HARRISON: COPY OF THE SLIDE DECK THAT
17	STAFF JUST PRESENTED IS IN YOUR BINDERS.
18	CHAIRMAN THOMAS: SO WE HAVE THOSE
19	PROJECTS HIGHLIGHTED THERE ON THE SCREEN THAT HAVE
20	BEEN RECOMMENDED FOR FUNDING. ARE YOU STILL ADDING
21	TO THAT, GIL?
22	DR. SAMBRANO: I'M SORRY. SOMEHOW THE
23	FILE DIDN'T CARRY OVER THE COLORS. BUT ON THIS
24	COLUMN HERE, AND THIS TABLE IS ALSO IN YOUR BOOKS,
25	IT SHOWS THE TIER AS TIER I OR TIER III. SO THAT'S
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1	ANOTHER WAY THAT YOU CAN LOOK AT THAT.
2	MR. HARRISON: SO THE QUESTION, CHAIR, FOR
3	MEMBERS OF THE BOARD IS WHETHER THERE ARE ANY
4	APPLICATIONS IN TIER III THAT THEY WOULD LIKE TO
5	HEAR MORE ABOUT.
6	CHAIRMAN THOMAS: YES. MR. SHESTACK.
7	MR. SHESTACK: I JUST WANTED TO UNDERSTAND
8	BECAUSE IT SEEMS LIKE IN TIER III THERE ARE SEVERAL
9	PROJECTS WITH A SCORE OF 70 OR 71, WHICH IS ABOVE
10	WHAT I THOUGHT THE CUTOFF WAS FOR TIER III. DID I
11	MISUNDERSTAND?
12	DR. SAMBRANO: SO THE INITIAL CUTOFF FOR
13	TIER I WAS AT 74. SO ANYTHING THAT WAS 74 OR ABOVE
14	WAS DEEMED TO BE TIER I, MERITORIOUS. ANYTHING
15	BELOW 66 WAS NOT. SO THAT WAS TIER III. THAT LEFT
16	IN BETWEEN, WHICH WAS A TEMPORARY TIER II. EACH OF
17	THOSE APPLICATIONS WERE DISCUSSED AND EITHER MOVED
18	UP INTO TIER I, AS INDICATED FOR SOME OF THOSE, AND
19	THE REST WERE MOVED INTO TIER III.
20	MR. SHESTACK: OKAY. I UNDERSTAND.
21	DR. PIZZO: DIFFERENT FROM OTHER TIMES IS
22	YOU'VE BIFURCATED THIS INTO TIER I AND TIER III, OR
23	RECOMMENDED FOR FUNDING OR NOT. MANY TIMES WE'VE
24	HAD A KIND OF TIER II THAT WE WOULD MOVE THINGS UP
25	OR DOWN.
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1	DR. SAMBRANO: SO THE PROCESS IS THE SAME
2	AS FAR AS THE GRANTS WORKING GROUP WHERE WE GO
3	THROUGH THIS PROCESS. THE FINAL RECOMMENDATIONS TO
4	THE BOARD IN MANY CASES ENDS UP BEING JUST TO
5	RECOMMEND OR NOT RECOMMEND. IT'S BEEN UNUSUAL TO
6	HAVE A TIER II THAT REMAINS.
7	DR. PIZZO: I GUESS THE OTHER THING, JUST
8	PROCEDURALLY, IS IF WE STAYED WITH THE RECOMMENDED
9	FUNDING FOR THIS PARTICULAR AWARD, IT WOULD BE A
10	ABOUT A MILLION POINT SIX OR SO MILLION DOLLARS, SO
11	THAT'S THE DELTA THAT REMAINS IN TERMS OF WHATEVER
12	DECISIONS WE MAKE.
13	DR. SAMBRANO: THAT'S CORRECT.
14	DR. PIZZO: UNLESS WE DECIDE TO ADD MORE
15	MONEY.
16	CHAIRMAN THOMAS: CORRECT. THANK YOU,
17	DEAN PIZZO.
18	MR. SHEEHY: I'D LIKE TO RAISE THE ISSUE
19	OF GRANT NO. 5764. AND I REALLY WANT TO
20	SPECIFICALLY ALLUDE TO THIS GRANT I REMEMBER THIS
21	GRANT FROM PROGRAMMATIC REVIEW, AND THEY MOVED TO
22	MOVE IT INTO TIER I. ONE OF THE PROGRAMMATIC
23	CONSIDERATIONS WAS THIS WAS A NEW INVESTIGATOR,
24	JUNIOR INVESTIGATOR. THEY THOUGHT IT WOULD REALLY
25	PROPEL THEIR CAREER. BUT IF YOU LOOK, AND IF YOU
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1	LOOK AT THE CRITERIA FOR THE GRANT, THE
2	QUALIFICATIONS OF THE PRINCIPAL INVESTIGATOR AND THE
3	RESEARCH TEAM WERE CRITICAL QUALIFICATIONS. AND
4	THIS INVESTIGATOR, AT THE TIME OF APPLICATION, HAD A
5	CO-APPOINTMENT WITH A DIFFERENT INSTITUTION. AND I
6	QUOTE, "REVIEWERS WERE PUZZLED BY THE DUAL
7	INSTITUTION APPOINTMENT AND EXPRESSED STRONG
8	CONCERNS THAT THIS COULD JEOPARDIZE THE PI'S ABILITY
9	TO LEAD THIS EFFORT."
10	NOW, WE HAVE A LETTER AND GENERALLY I
11	DON'T WANT TO DIG INTO THESE. THIS IS BASIC
12	SCIENCE. BUT SHE NOW HAS A FULL APPOINTMENT AT THE
13	INSTITUTION THAT SHE'S APPLYING FOR A GRANT FOR.
14	AND SO THAT ISSUE IS KIND OF MOOT. AND I FELT LIKE
15	IN PROGRAMMATIC REVIEW THAT HER I FELT LIKE
16	THAT I FEEL THAT THAT ISSUE BROUGHT HER BELOW THE
17	FUNDING LEVEL BECAUSE THAT WAS ONE OF THE THREE
18	MAJOR CRITERIA FOR THIS GRANT. AND I THINK THAT
19	THIS CLARIFICATION REALLY IN MY MIND I THINK IF
20	THE REVIEW GROUP HAD THIS INFORMATION, THEY WOULD
21	HAVE APPROVED THIS GRANT. 5764.
22	THIS SCORED A 68. SO THIS WAS RIGHT
23	UNDERNEATH THE MARGIN. AND I REMEMBER PEOPLE
24	TALKING SOMEBODY WAS VERY PASSIONATE, AND I DON'T
25	WANT TO SAY A SCIENTIFIC MEMBER OF THE REVIEW GROUP,

1	SO THIS WAS NOT A PATIENT ADVOCATE INSTIGATION.
2	WELL, YOU KNOW. I THINK THE MOTIVATION OF THE
3	REVIEWER WAS THIS IS A PROMISING NEW INVESTIGATOR
4	AND DOING INTERESTING SCIENCE. AND I REALLY FELT
5	LIKE THERE WAS A GREAT DEAL OF CONCERN OVER THE DUAL
6	APPOINTMENT. AND THE OTHER INSTITUTION WAS NOT IN
7	CALIFORNIA, SO THAT JUST GETS REALLY MESSY. AND IN
8	THIS LETTER IT'S CLEAR THAT THERE IS NOW A FULL
9	APPOINTMENT AT A CALIFORNIA INSTITUTION. SO I
10	PERSONALLY FEEL LIKE THAT ISSUE HAS BEEN ADDRESSED,
11	AND I PERSONALLY MAKE A MOTION TO MOVE THIS INTO THE
12	FUNDABLE CATEGORY.
13	CHAIRMAN THOMAS: IS THERE A SECOND?
14	MR. ROTH: I'LL SECOND.
15	CHAIRMAN THOMAS: SECONDED BY MR. ROTH.
16	FURTHER COMMENTS BY MEMBERS OF THE BOARD? IT WOULD
17	SEEM TO ME, BASED ON MR. SHEEHY'S DISCUSSION, THAT
18	IF THAT WERE THE OVERRIDING ISSUE AS TO WHY IT
19	WASN'T RECOMMENDED, THAT THIS SHOULD TAKE CARE OF
20	THAT.
21	DR. JUELSGAARD: CAN WE HEAR FROM STAFF
22	MORE FULLY ON THE REVIEW, PLEASE?
23	CHAIRMAN THOMAS: CERTAINLY.
24	DR. JUELSGAARD: AS OPPOSED TO JUST TRYING
25	TO SIT HERE AND READ THROUGH IT QUICKLY.
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1	CHAIRMAN THOMAS: NOW HEAR FROM THE GIANTS
2	FAN I'M SORRY, FROM BETTINA.
3	DR. STEFFEN: I'M DR. BETTINA STEFFEN IN
4	CASE DR. THOMAS DIDN'T MENTION THAT. I AM A GIANTS
5	FAN, AND I CAN GO ON IF YOU'D LIKE ME TO ELABORATE.
6	DR. FRIEDMAN: THREE MINUTES.
7	CHAIRMAN THOMAS: WHICH YOU HAVE IN GREAT
8	DEAL IN THE PAST, SO WE'LL STIPULATE TO YOUR STATUS.
9	THANK YOU.
10	DR. STEFFEN: ABOUT THE GRANT, I'M SORRY,
11	SO ALL THAT ASIDE, THIS PROPOSAL IS TO STUDY THE
12	DEVELOPMENT OF PACEMAKER CELLS FROM HUMAN-INDUCED
13	PLURIPOTENT STEM CELLS IN ORDER TO GENERATE
14	LONG-LASTING BIOLOGIC PACEMAKERS. AND THE PLAN
15	FOCUSES ON THE ROLE OF A PARTICULAR ION CHANNEL IN
16	THIS PROCESS, AND THE INVESTIGATOR WANTS TO STUDY
17	THE ROLE OF THIS PARTICULAR CHANNEL IN THE
18	DEVELOPMENT OF PACEMAKER CELLS. SO HOW DOES THIS
19	PROTEIN AFFECT THE DIFFERENTIATION PATHWAY? AND THE
20	INVESTIGATOR HAS IDENTIFIED A SMALL MOLECULE
21	ACTIVATOR.
22	SO THE GRANTS WORKING GROUP RECOGNIZED THE
23	SIGNIFICANCE OF THE PROPOSAL AND PRAISED THE CONCEPT
24	OF THE BIOLOGIC PACEMAKER AND HIGHLIGHTED THAT WHILE
25	THERE ARE DEVICES AVAILABLE, THEY EVENTUALLY HAVE TO

1	BE REPLACED AND ARE NOT APPROPRIATELY SIZED TO
2	PEDIATRIC PATIENTS. SO THAT WOULD BE AN IMPORTANT
3	ROLE FOR A BIOLOGIC PACEMAKER.
4	AND THE GRANTS WORKING GROUP THOUGHT THAT
5	THE PHARMACOLOGICAL INDUCTION, SO USING A SMALL
6	MOLECULE TO INDUCE DIFFERENTIATION TO THIS
7	PARTICULAR CELL TYPE, WAS AN INTERESTING AND
8	FEASIBLE APPROACH.
9	WITH RESPECT TO THE FEASIBILITY AND THE
10	EXPERIMENTAL DESIGN, THERE WERE A FEW CHALLENGES.
11	REVIEWERS EXPRESSED CONCERN THAT SOME OF THE
12	PROPOSED EXPERIMENTS RELY ON A SMALL MOLECULE WHERE
13	THE ASSUMPTION WAS THAT IT'S A SPECIFIC ACTIVATOR OF
14	THIS CHANNEL, AND THERE'S EVIDENCE THAT THE GRANTS
15	WORKING GROUP FELT THAT SOME OF THESE AGENTS THAT
16	WERE BEING EMPLOYED ARE NOT NECESSARILY SPECIFIC TO
17	THIS SINGLE CHANNEL.
18	REVIEWERS SUGGESTED THAT THE PROPOSAL
19	WOULD BE STRENGTHENED BY INCORPORATING SOME GENETIC
20	MANIPULATION, SO EITHER KNOCK DOWN OR UP REGULATION
21	OF THIS ION CHANNEL, TO CONFIRM ITS ROLE IN THE
22	PACEMAKER FORMATION.
23	THE PROPOSAL LACKED A CLEAR PLAN
24	DESCRIBING HOW TO ENSURE RETENTION OF THE PACEMAKER
25	CELL PHENOTYPE OVER TIME AND DID NOT ADDRESS
	296

1	CARDIOMYOCYTE MATURITY. WHAT THAT MEANS IS IS WHEN
2	YOU DRIVE THESE CELLS TO A PARTICULAR PHENOTYPE,
3	THEY REVERT TO OTHER CELL TYPES. SO YOU HAVE TO
4	FIGURE OUT HOW TO MAKE IT LONG LASTING IN CULTURE
5	AND ALSO ENSURE THAT IT HAS THE MATURITY, THE FULL
6	ELECTRICAL POTENTIAL OF AN ADULT-TYPE CELL IN ORDER
7	TO GET THE RIGHT ELECTRICAL ACTIVITY.
8	THEY THOUGHT THE PROPOSAL WAS WELL WRITTEN
9	AND HAD APPROPRIATE PRELIMINARY DATA. I THINK THE
10	PI AND THE TEAM, I THINK MR. SHEEHY SUMMARIZED SOME
11	OF THE CONCERNS, SO I WON'T GO OVER THOSE AGAIN, AND
12	THOUGHT THAT THE PI HAD ASSEMBLED A TEAM WITH
13	CO-INVESTIGATORS THAT DEMONSTRATE EXPERTISE IN STEM
14	CELL BIOLOGY, CARDIOVASCULAR BIOLOGY, AND THE
15	IMAGING REQUIRED TO EXECUTE THE PROGRAM. THE
16	PROPOSAL WAS FELT TO BE RESPONSIVE.
17	YOU HAVE ALREADY HEARD ABOUT THE
18	PROGRAMMATIC DISCUSSION, AND I WILL NOTE THAT AN
19	EXTRAORDINARY PETITION WAS SUBMITTED FOR THIS
20	APPLICATION.
21	MR. SHEEHY: JUST COULD I GET MORE DETAIL
22	ON THE PROGRAMMATIC DISCUSSION BECAUSE I'M KIND OF
23	PULLING THAT OUT OF MY MEMORY, AND YOU GUYS HAVE
24	NOTES. CAN YOU KIND OF TALK ABOUT WHY THE MOTION
25	WAS MADE AND WHAT THEY SAID? MAYBE GOING TO AND
	297

1	A LITTLE MORE DETAIL MAYBE ON THE SHORTCOMING FROM
2	THE DUAL INSTITUTIONAL APPOINTMENT. I'M READING OFF
3	THIS NOTE. I'M JUST TAKING IT ALL OUT OF MEMORY,
4	BUT IF YOU HAVE A LITTLE MORE GRANULARITY ON WHAT
5	IMPACT THAT MAY HAVE HAD ON THE REVIEW.
6	DR. STEFFEN: I THINK WHAT WAS REPRESENTED
7	HERE WAS THAT THE MOTION WAS MADE TO MOVE THE
8	APPLICATION TO TIER I, AND IT WAS NOTED THAT
9	WHAT'S WRITTEN UP HERE IS WHILE THERE WERE TECHNICAL
10	FLAWS IN THE PLAN, IT ADDRESSED AN IMPORTANT TOPIC,
11	SO SIGNIFICANCE. AND THAT IF GRANTED, THE AWARD
12	COULD HELP LAUNCH THE PI'S CAREER. AND THERE'S A
13	COMMENT HERE THAT THE PI'S TRACK RECORD REMAINED A
14	CONCERN, AND THE MOTION DID NOT PASS.
15	THERE WAS SOME DISCUSSION ABOUT
16	PUBLICATIONS, THERE WAS SOME DISCUSSION ABOUT THE
17	SPLIT INSTITUTION, AND THEN THE VOTE WAS TAKEN.
18	CHAIRMAN THOMAS: IS THERE AN INTEREST,
19	MR. SHEEHY, IN HEARING FROM THE EXTRAORDINARY
20	PETITIONER?
21	MR. SHEEHY: SURE.
22	DR. LIEU: THANK YOU FOR THIS OPPORTUNITY.
23	I AM DEBORAH LIEU. I AM THE PRINCIPAL INVESTIGATOR
24	OF THIS GRANT, AND I WOULD JUST LIKE TO ADDRESS ONE
25	OF THE MAJOR CONCERN FROM THE REVIEWER IN TERMS OF
	298
	230

1	MY EXPERIENCE AS AN INDEPENDENT INVESTIGATOR.
2	ACTUALLY I DON'T THINK MY EXPERIENCE CAME
3	THROUGH IN THE LIMITED TWO-PAGE BIOSKETCH. I
4	ACTUALLY HAVE 24 PUBLICATIONS. NOT ALL OF THEM WERE
5	LISTED BECAUSE THERE'S A SPACE CONSTRAINT. AND 12
6	OF THOSE WERE ON HUMAN PLURIPOTENT STEM CELLS AND
7	THEIR CARDIAC MUSCLE CELL DERIVATIVES. I'M THE
8	SENIOR AUTHOR ON THREE OF THESE PUBLICATIONS, AND I
9	ALSO HAVE THREE BIOLOGICAL PACEMAKER PUBLICATIONS AS
10	RELEVANT TO THE PROPOSAL.
11	I HAVE BEEN WORKING WITH HUMAN PLURIPOTENT
12	STEM CELLS AND THEIR CARDIAC DERIVATIVES FOR THE
13	LAST SIX YEARS AND HAVE BEEN ADVISING CIRM-FUNDED
14	LABS ON HOW TO CULTURE THESE HUMAN PLURIPOTENT STEM
15	CELLS AND DIFFERENTIATION OF THESE CELLS. AND I
16	WOULD JUST LIKE TO POINT OUT THIS IS NOT I'M NOT
17	IN THIS GRANT ALONE. I'M SUPPORTED BY A VERY STRONG
18	TEAM OF COLLABORATORS THAT ARE SENIOR AND
19	EXPERIENCED AND ESTABLISHED.
20	DR. NIPAVAN CHIAMVIMONVAT WITH ME HERE
21	TODAY, SHE IS THE LEADING EXPERT ON THE ION CHANNEL
22	THAT WE WANT TO PURSUE IN DIFFERENTIATING THESE
23	CELLS INTO PACEMAKER CELLS, AND SHE'S ACTUALLY THE
24	PERSON WHO DISCOVERED THE EXISTENCE OF THIS ION
25	CHANNEL IN CARDIAC MUSCLE CELL. AND OUR OTHER

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1	COLLABORATOR, DR. JAN NOLTA, SHE IS THE STEM CELL
2	PROGRAM DIRECTOR AT UC DAVIS, AND SHE HAS OVER 20
3	YEARS OF STEM CELL EXPERIENCE. AND LASTLY,
4	DR. DONALD BERS, HE'S THE WORLD RENOWNED SCIENTIST
5	ON CALCIUM SIGNALING, WHICH IS A VERY LARGE PART OF
6	THIS GRANT AS WELL.
7	AND YOU MENTIONED BEFORE, MY DUAL
8	INSTITUTIONAL APPOINTMENTS. I HAVE SINCE RESIGNED
9	FROM MY ASSISTANT PROFESSOR POSITION AT MT. SINAI TO
10	FOCUS MY RESEARCH A HUNDRED PERCENT AT UC DAVIS. SO
11	I HOPE YOU WILL TAKE ALL THESE INTO CONSIDERATION IN
12	REEVALUATING MY APPLICATION. THANK YOU.
13	DR. JUELSGAARD: SO IN LOOKING AT THE
14	SLIDES THAT WE SAW JUST BEFORE WE GOT TO THIS POINT,
15	SO WE HAVE RECOMMENDED FOR FUNDING 25 APPLICATIONS
16	AND A TOTAL DOLLAR AMOUNT OF \$33.9 MILLION. THE
17	BUDGET THAT WAS APPROVED BY THE ICOC IS 35 MILLION.
18	SO ASSUMING WE APPROVE ALL THE CURRENTLY RECOMMENDED
19	ONES, THAT LEAVES A DIFFERENCE OF 1.1 MILLION VERSUS
20	THE BUDGET. AND THIS PARTICULAR PROPOSAL IS FOR
21	1.33 MILLION.
22	SO IF WE DO PROCEED, I THINK WE SOMEHOW
23	HAVE TO SQUARE THE BUDGET ISSUE WITH THIS PROCESS.
24	CHAIRMAN THOMAS: THE BUDGET, MR.
25	JUELSGAARD, IS ALWAYS A TARGET. AND WE NEITHER NEED

300

1	TARGET AMOUNTS, HAVE WE DR. OLSON, ANTICIPATING
2	THE QUESTION.
3	DR. OLSON: I WAS JUST GOING TO COMMENT ON
4	THE FACT THAT OBVIOUSLY THIS BOARD HAS BEEN WORKING
5	IN THE PAST WITH \$3 BILLION TO ALLOCATE. AS YOU
6	WILL RECALL, IN MARCH AND THEN AGAIN IN MAY, WE WENT
7	THROUGH A STRATEGIC FINANCIAL PLAN WHERE WE SORT OF
8	PUT FORTH IN ORDER TO ACHIEVE GOALS, WE HAD AN
9	ALLOCATION OF MONEY TO DIFFERENT CATEGORIES. THE
10	POINT THAT MR. SHEEHY BROUGHT UP YESTERDAY WAS VALID
11	in asking, okay, if we introduce an additional 30
12	MILLION, WHERE DO WE GET IT? WE DID HAVE SAVINGS,
13	AS WAS NOTED, OF ROUGHLY 25 MILLION FROM EARLY
14	TRANSLATION. AND THIS BOARD SAID WE WILL TAKE
15	SO AT THE MOMENT YOU HAVE A SURPLUS OF
16	ONLY ABOUT \$20 MILLION UNLESS YOU PROPOSE TO ADDRESS
17	MONEY THAT HAS BEEN OTHERWISE ALLOCATED, WHICH IS
18	OBVIOUSLY A DECISION THAT THE BOARD CAN MAKE. BUT I
19	JUST WANT YOU TO RECOGNIZE THAT YOU ARE MAKING A
20	DECISION.
21	AS OUR PRESIDENT SHOWED YESTERDAY OR AS
22	CHILA SHOWED YESTERDAY, THE AMOUNT OF MONEY YOU HAVE
23	LEFT TO SPEND IS NOT WHAT YOU ONCE HAD. SO I THINK
24	THAT'S THE ONLY POINT THAT I BELIEVE MR. JUELSGAARD
25	IS MAKING AND MR. SHEEHY MADE YESTERDAY.
	302
	JUL

1	MR. SHEEHY: IF I COULD JUST CLARIFY MY
2	POSITION. I DO THINK THERE'S A DIFFERENCE BETWEEN A
3	PRIORI TRYING TO SAY WE'RE GOING TO MOVE \$30 MILLION
4	INTO A GRANT ROUND WITHOUT HAVING SEEN THE
5	APPLICATIONS AND NOT IDENTIFYING WHERE THAT \$30
6	MILLION IS COMING FROM WHEN, AS DR. OLSON HAS SAID,
7	WE DID A STRATEGIC PLAN THAT PRETTY MUCH ALLOCATED
8	OUT WHAT WE WERE INTENDING TO SPEND. AND TO GO OVER
9	BUDGET IN THIS PARTICULAR ROUND BY A COUPLE HUNDRED
10	THOUSAND, THIS WAS THE ONE GRANT THAT STOOD OUT TO
11	ME AS HAVING SOMETHING IN IT THAT I THOUGHT
12	PERSONALLY MIGHT HAVE MADE A DIFFERENCE IN THE
13	REVIEW.
14	AS A WHOLE, I WAS VERY COMFORTABLE WITH
15	WHAT THE REVIEW DID IN THIS SESSION, BUT I DID THINK
16	THAT THIS ISSUE OF A DUAL APPOINTMENT WAS
17	SIGNIFICANT. AND MAKING IT EASIER FOR BABIES TO GET
18	PACEMAKERS SEEMS LIKE IT MIGHT NOT BE A BAD IDEA.
19	BUT, AGAIN, I THINK THESE ARE ALL JUDGMENTS THAT WE
20	NEED TO MAKE INDIVIDUALLY. AND SO I DON'T THINK
21	IT'S NECESSARILY INCONSISTENT WITH A PIECE OF
22	SCIENCE FOR ME TO PICK OUT ONE THAT IS ROUGHLY WHERE
23	WE ALLOCATED THE FUNDS TO BEGIN WITH.
24	I DO NOTE IN MOST OF OUR BASIC BIOLOGY
25	ROUNDS, WE HAVE BEEN UNDER BUDGET. SO I'M JUST
	303

SUGGESTING MAYBE WE GO OVER A LITTLE BIT. BUT,
AGAIN, THIS IS ONE GRANT. OTHERS MAY HAVE OTHER
GRANTS. AND I DO AGREE FUNDAMENTALLY THAT WE NEED
TO BE PRUDENT AND WE SHOULD USE SOME DISCRETION.
THE REVIEW GROUP WORKED HARD ON THE RECOMMENDATIONS
THEY MADE.
DR. JUELSGAARD: YES. I WOULD NOTE THAT
THERE ARE SOME ADDITIONAL EXTRAORDINARY PETITIONS
THAT WE MAY WIND UP TALKING ABOUT SUBSEQUENTLY. AND
THE QUESTION, THEN, IS IF, LET'S SAY, WE VOTE ON
THIS AT THIS TIME AND APPROVE IT AND WE'RE SLIGHTLY
OVER THE BUDGET, WHAT ARE WE GOING TO THINK ABOUT
THE BUDGETARY ISSUE IF WE ALSO THINK THOSE ARE
WORTHY OF APPROVAL? SO WE NEED TO HAVE A LITTLE
FINANCIAL DISCIPLINE AS WE MOVE FORWARD ALA SOME OF
THE COMMENTS THAT WERE MADE EARLIER ABOUT SORT OF
OUR FINANCIAL WHEREWITHAL AS WE MOVE FORWARD IN THE
AGING OF THIS ORGANIZATION.
MR. SHEEHY: I AGREE TOTALLY. AND I READ
THE EXTRAORDINARY PETITIONS, AND THIS WAS THE ONLY
ONE THAT MOTIVATED ME TO MAKE THAT. AND I ACTUALLY
FUNDAMENTALLY AGREE WITH YOU. I PROBABLY WOULDN'T
MOVE UP MORE THAN ONE. AND IF OTHER FOLKS HAVE ONES
THAT THEY WANT TO MOVE UP, I THINK WE SHOULD TALK
ABOUT IT AND MAYBE PICK THE ONE THAT WE LIKE THE
304

1	BEST IF THAT'S INDEED WHAT WE'RE GOING TO DO OR DO
2	ZERO.
3	I AGREE WITH YOUR IMPULSE TO HAVE US SIT
4	HERE AND NOT SUDDENLY BLOW THE BUDGET TO BITS. BUT
5	I PERSONALLY LOOKED THROUGH ALL THESE EXTRAORDINARY
6	PETITIONS THAT CAME IN. I FELT THAT PEOPLE WERE
7	ARGUING BACK AND FORTH WITH THE REVIEW GROUP. I
8	THOUGHT THE REVIEW GROUP WORKED VERY HARD. THIS WAS
9	THE ONLY ISSUE THAT KIND OF STOOD OUT FOR ME AS
10	SOMETHING THAT MIGHT HAVE MADE A DIFFERENCE IN THE
11	REVIEW, AND IT WAS NOT A SCIENTIFIC ISSUE. IT WAS A
12	STRUCTURAL ISSUE. WHERE DOES THIS INDIVIDUAL WORK?
13	AND SO THAT'S WHY IT JUMPED OUT AS
14	SOMETHING I COULD EASILY COMPREHEND. AND WE WERE
15	ABOUT A GRANT UNDER BUDGET. THAT'S MY FRAMEWORK. I
16	PERSONALLY AM NOT INTENDING TO MOVE UP ANY MORE.
17	BUT I DO AGREE FUNDAMENTALLY WITH YOU THAT WE SHOULD
18	NOT MOVE UP ALL FIVE OR SIX OR HOWEVER MANY WE HAVE
19	WILLY-NILLY, AND WE SHOULD EXERT SOME DISCIPLINE
20	BECAUSE THE GROUP DID WORK HARD IN REVIEWING THESE
21	GRANTS.
22	CHAIRMAN THOMAS: CAN I JUST ASK A
23	QUESTION RAISED BY SOMETHING MR. SHEEHY SAID? HOW
24	UNDER BUDGET ARE WE ON PREVIOUS ROUNDS OF BASIC BIO?
25	DR. OLSON: I'M NOT SURE THAT'S REALLY THE
	305

1	POINT. THE REASON I SAY THAT IS BECAUSE YOU HAVE AN
2	EXPENDITURE YOU HAVE AWARDED ESSENTIALLY \$1.5
3	BILLION. YOU HAVE CONCEPTS APPROVED OF ROUGHLY, AND
4	NOT YET EITHER REVIEWED BY THE GRANTS WORKING GROUP
5	AND REVIEWED BY THIS BOARD, TOTALING ROUGHLY 300
6	LESS THAN THAT NOW, LET'S SAY 300 MILLION, AND YOU
7	HAVE ROUGHLY 860 MILLION IN SO-CALLED FUTURE
8	ALLOCATED MONEY THAT HAS BEEN BROADLY PLANNED TO
9	ADDRESS STRATEGIC PRIORITIES.
10	SO THE FACT WE HAVE MOST, MANY OF
11	OUR AWARDS, MOST OF OUR WELL, MAYBE NOT MOST AT
12	THIS POINT, BUT VERY MANY OF OUR AWARDS FALL IN THE
13	FUNDAMENTAL BIOLOGY CATEGORY BECAUSE OF THE FACT
14	THEY DO TEND TO BE SMALLER AWARDS. THEY'RE MORE
15	LIKE \$300,000 IN DIRECT PROJECT COST. SO \$900,000
16	OVER THREE YEARS IN CONTRAST TO SAY THE EARLY
17	TRANSLATION, THE SMALLEST OF WHICH IS 1.2 MILLION
18	IN DIRECT PROJECT COST OR UP TO 3.5 MILLION IN
19	CONTRAST TO DISEASE TEAMS, WHICH IS ROUGHLY, I'D
20	SAY, 10 TO 12 MILLION OR 10 TO 15 MILLION IN DIRECT
21	PROJECT COST. SO THAT WOULD BE MY RESPONSE.
22	CHAIRMAN THOMAS: I APPRECIATE THAT, DR.
23	OLSON. WE DID HAVE DISCUSSIONS ON THESE POINTS AND
24	THEY'RE ALL VERY IMPORTANT, BUT DID NOT ANSWER MY
25	QUESTION. IF YOU COULD ANSWER THE QUESTION, PLEASE.

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1	DR. OLSON: I HAVE ALREADY ACCOUNTED I
2	GUESS THE OTHER COMMENT I CAN MAKE, I DON'T HAVE THE
3	EXACT NUMBERS, BUT THE SAVINGS IN ANY BASIC BIOLOGY
4	ROUND HAS BEEN ALREADY ACCOUNTED FOR IN THE PLAN.
5	CHAIRMAN THOMAS: THAT STILL DOES NOT
6	ANSWER.
7	DR. OLSON: THERE ARE NO SAVINGS REALLY.
8	THERE'S ONLY THE \$20 MILLION THAT YOU HAVEN'T YET
9	AWARDED UNDER THE DISEASE TEAM.
10	CHAIRMAN THOMAS: THE QUESTION PERTAINED
11	TO UNDERFUNDING AGAINST BUDGET ON BASIC BIOLOGY
12	ROUNDS.
13	DR. OLSON: IT WAS ONLY ONE ROUND WHERE WE
14	HAD, IF I REMEMBER, AND I'M SORRY I AM RELYING ON
15	MEMORY HERE, I BELIEVE IT WAS ONLY ONE ROUND WHERE
16	WE HAD THE BASIC BIOLOGY INITIATIVE THAT ACCOUNTED
17	FOR A ONE AND A TWO COMPONENTS TO IT, PART 1 AND
18	PART 2, WHERE ONE ROUND WAS SUBSTANTIALLY
19	UNDERFUNDED. IT WAS 17 MILLION VERSUS 30, BUT I
20	BELIEVE THE NEXT BILLION WAS CONSIDERABLY OVER THAT.
21	SO I THINK IF YOU ACTUALLY LOOK IN, AND
22	THIS IS IN THE DOCUMENT THAT WAS HANDED OUT TO YOU
23	IN MARCH, AND I WOULD NEED TO CONSULT THAT TO
24	SPECIFICALLY ADDRESS YOUR QUESTION, THAT PROBABLY
25	THE BASIC BIOLOGY GENERALLY COMES IN ROUGHLY AT WHAT
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160 S. OLD SPRINGS ROAD, SUITE 270, ANAHEIM, CALIFORNIA 92808

1	WAS ALLOCATED. WE'VE BEEN TRYING TO SIZE IT TO
2	ADDRESS WHAT WE GENERALLY FUND.
3	CHAIRMAN THOMAS: DR. TROUNSON.
4	DR. TROUNSON: I'M JUST MAKING I JUST
5	WANTED TO TAKE NOTE OF THE WAY THE DISCUSSION IS
6	GOING. IT MAY BE OF INTEREST TO YOU, AND IF IT IS,
7	I THINK, THEN, WE WOULD LIKE TO TALK A LITTLE BIT
8	ABOUT IT, THAT, IN FACT, STAFF HAVE A VIEW ABOUT ONE
9	OF THE PROJECTS. AND IT'S NOT ONE OF THE
10	EXTRAORDINARY PETITIONS ACTUALLY, AND WE THINK THAT
11	THE BOARD SHOULD HEAR ABOUT THAT. I WAS ACTUALLY
12	NOT AT THE GRANTS REVIEW, SO I WAS REALLY SURPRISED
13	THIS GRANT WASN'T FUNDED MYSELF.
14	BUT I DISCUSSED THIS WITH THE STAFF
15	EXTENSIVELY, AND IT'S NOT AN EXTRAORDINARY PETITION.
16	BUT BEFORE YOU COMPLETE THIS EXERCISE WHEN YOU'RE
17	TALKING ABOUT MAYBE JUST ONE OR OTHER OF THESE
18	PROJECTS, I WOULD ENCOURAGE YOU TO LISTEN TO ONE OF
19	THESE WHERE A PETITION ACTUALLY DIDN'T ARISE. AND I
20	THINK STAFF HAS A VERY STRONG VIEW ABOUT THIS
21	PARTICULAR STUDY AND WHY PERHAPS IT OUGHT TO BE
22	CONSIDERED.
23	CHAIRMAN THOMAS: PLEASE PROCEED.
24	DR. TROUNSON: MAYBE I CAN ASK THE SCIENCE
25	OFFICER. THIS IS PROJECT 6158. ONE OF THE REALLY
	200
	308

1	BIG PROBLEMS IN STEM CELL RESEARCH IS THE FAILURE TO
2	BE ABLE TO GET PLURIPOTENTIAL STEM CELLS ACROSS TO
3	BONE MARROW COLONIZING HEMATOPOIETIC STEM CELLS.
4	THIS IS A HUGE BARRIER. IT'S ONE OF THE MAJOR
5	BARRIERS SEEN IN STEM CELL BIOLOGY.
6	THIS PARTICULAR STUDY IS LOOKING AT A
7	NUMBER OF MODEL SYSTEMS, AND IT'S DEEP IN
8	DEVELOPMENTAL BIOLOGY BECAUSE IT WANTS TO STUDY
9	FISH, IT WANTS TO STUDY MICE, IT WANTS TO STUDY THE
10	HUMAN. IT WANTS TO LOOK AT THE RELATIONSHIP BETWEEN
11	THE DEVELOPING CELL AND THE NICHE. THE NICHE IS THE
12	SPACE IN WHICH THESE CELLS MATURE.
13	NOW, ONE OF OUR PROBLEMS IS WE CAN'T GET
14	THESE HEMATOPOIETIC BLOOD CELLS TO COLONIZE THE BONE
15	MARROW. WE HAVE BASICALLY LIVER-TYPE HEMATOPOIETIC
16	STEM CELLS. THAT'S NOT MUCH USE IF YOU'RE TRYING TO
17	HELP A PATIENT. AND OUR HEMATOPOIETIC SYSTEMS ARE
18	REALLY THE MOST ADVANCED IN THE WHOLE OF CELL
19	BIOLOGY, AND WE'VE GOT ONE OF THE BIGGEST PROBLEMS.
20	AND WE REALLY DON'T HAVE A LOT OF PROJECTS FOCUSED
21	ON GETTING ACROSS THIS SPACE.
22	I THINK STRONGLY THIS STUDY WILL COME UP
23	WITH INFORMATION THAT WILL HELP US UNDERSTAND WHAT'S
24	REQUIRED TO MATURE THESE CELLS INTO BONE MARROW
25	COLONIZING CELLS. SO I WANTED TO SORT OF AMPLIFY
	309
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1	THE PROBLEM AND SAY THIS IS A STUDY WHICH I THINK IS
2	VERY CLEVERLY DESIGNED TO HELP US UNDERSTAND WHAT
3	ARE THE FACTORS THAT ARE DRIVING THE MATURATION OF
4	THESE CELLS INTO THE BONE MARROW COLONIZING CELLS.
5	MAYBE KELLY CAN GIVE YOU A LITTLE BIT MORE
6	BACKGROUND ON THE SPECIFIC GRANT, BUT I WANTED TO
7	GIVE YOU THAT RISE IN INTAKE. IF I HAD BEEN AT THE
8	REVIEW, HOPEFULLY SOMEONE MIGHT HAVE ASKED ME SOME
9	QUESTION ABOUT IT, I WOULD HAVE FELT VERY STRONGLY
10	SUPPORTIVE MYSELF OF THIS STUDY. BUT I TALKED TO
11	ALL THE SCIENTISTS HERE AT CIRM, AND THEY FELT THAT
12	THIS WAS REMARKABLE IN ITS STANDOUT. AND IT'S 71,
13	SO IT'S VERY, VERY CLOSE TO THE BORDER, AND I THINK
14	IT DESERVES FURTHER CONSIDERATION.
15	DR. SHEPERD: ALAN ALREADY TOLD YOU A
16	LITTLE BIT ABOUT IT, BUT THIS PROPOSAL IS TAKING A
17	VERY BROAD AND COMPREHENSIVE APPROACH.
18	DR. STEWARD: COULD YOU JUST GIVE US A
19	NUMBER?
20	DR. SHEPERD: 6158. IF YOU LOOK AT THAT
21	SPREADSHEET UP THERE, THERE'S A LARGE BLOCK.
22	SO 6158. SO IF YOU LOOK AT THAT UPPER
23	BLOCK WHERE IT'S ALL IN GREEN DOWN TO THE 73, THEN
24	THERE'S A 71 THAT IS HIGHLIGHTED IN WHITE, THAT'S
25	6158. AND THEN THERE'S ANOTHER GREEN ONE BELOW IT.
	310
	310

1	SO THIS PROPOSAL IS TAKING A COMPREHENSIVE APPROACH
2	TO IDENTIFYING AND CHARACTERIZE THE MOLECULAR
3	FACTORS THAT CONTRIBUTE TO SPECIFICATION AND
4	AMPLIFICATION OF HEMATOPOIETIC STEM CELLS.
5	SO AS YOU'RE AWARE AND AS ALAN HAS ALLUDED
6	TO, ONE OF THE KEY BOTTLENECKS IN STEM CELL RESEARCH
7	IN GENERAL IS OUR CURRENT INABILITY TO DERIVE
8	ROBUSTLY EXPANDABLE AND FUNCTIONAL POPULATIONS OF
9	HUMAN HEMATOPOIETIC STEM CELLS IN QUANTITIES THAT
10	WOULD BE SUITABLE FOR MEDICAL PROCEDURES OR
11	THERAPIES SUCH AS THOSE THAT WOULD ENTAIL ALGOGENIC
12	OR AUTOLOGOUS BONE MARROW TRANSPLANT. AND ONE
13	REASON FOR THIS BOTTLENECK IS OUR FUNDAMENTAL LACK
14	OF KNOWLEDGE AS TO HOW TO RECREATE THE APPROPRIATE
15	CONDITIONS FOR SPECIFYING AND AMPLIFYING THESE CELL
16	TYPES IN THE HUMAN SYSTEM.
17	SO IN DEVELOPMENT THESE CELLS ARE ACTUALLY
18	SPECIFIED THROUGH A COORDINATED SET OF INTERACTIONS
19	BETWEEN THE DIFFERENTIATING CELLS AND THEIR STROMAL
20	MICROENVIRONMENT OR NICHE. SO THE FOCUS OF THIS
21	PROPOSAL IS TO DIRECTLY GO AFTER THOSE INTERACTIONS;
22	THAT IS, STUDY THE CROSSTALK BETWEEN HEMATOPOIETIC
23	STEM CELLS AND THEIR STROMAL NICHES, TO IDENTIFY
24	WHICH INTERACTIONS AND DETERMINANTS ARE THE KEY
25	ONES.
	311

1	THIS KNOWLEDGE COULD THEN BE APPLIED TO
2	CREATE A MORE AUTHENTIC CULTURE SYSTEM FOR DERIVING
3	AND EXPANDING OR MAINTAINING HUMAN HEMATOPOIETIC
4	STEM CELLS WITH THE GREATEST THERAPEUTIC POTENTIAL.
5	SO THE KEY STRENGTHS OF THIS PROPOSAL THAT
6	WERE RECOGNIZED BY THE REVIEWERS WERE THAT IT'S
7	OBVIOUSLY ADDRESSING A HUGE FUNDAMENTAL BOTTLENECK.
8	THEY'RE EMPLOYING A VERY POWERFUL COMPARATIVE
9	APPROACH WHERE THEY'RE LOOKING ACROSS MULTIPLE
10	SPECIES, SO MULTIPLE MODEL SYSTEMS WHERE YOU CAN
11	ACTUALLY DO THE EMBRYOLOGY AND LOOK AT THE IN VIVO
12	SITES WHERE THESE CELLS ARE BEING SPECIFIED AND
13	AMPLIFIED, SOMETHING THAT IS NOT PRACTICEABLE IN A
14	HUMAN SYSTEM.
15	BUT THEY'RE ALSO LOOKING IN HUMAN CELLS AS
16	WELL. SO THEY'RE LOOKING ACROSS MULTIPLE SPECIES
17	ACROSS DIFFERENT DEVELOPMENTAL SITES OF
18	HEMATOPOIESIS. AND THEY'RE LOOKING ACROSS ALSO
19	MULTIPLE TYPES OF IN VITRO SURROGATE NICHES. THE
20	REVIEWERS WERE IMPRESSED THAT IN ADDITION TO DOING
21	THIS MAJOR PROFILING APPROACH, THEY ALSO HAD GREAT
22	FUNCTIONAL READOUTS FOR TESTING THEIR HITS, BOTH IN
23	VIVO AND IN VITRO READOUTS. THEY'RE BRINGING
24	ENORMOUS RESOURCES TO THIS PROJECT.
25	THE PRINCIPAL INVESTIGATOR IS CONSIDERED
	312
	314

1	TO BE OUTSTANDING. THERE'S ALSO A PARTNER PRINCIPAL
2	INVESTIGATOR FROM FRANCE WHO IS ALSO VIEWED AS
3	EXTREMELY OUTSTANDING AND THE TEAM AS WELL.
4	SO WHY DID IT GET A 71? WELL, SOME
5	WEAKNESSES WERE ACKNOWLEDGED, TWO MAJOR ONES, WHICH
6	WERE BOTH HAD CAVEATS ASSOCIATED WITH THEM. SO ONE
7	IS THAT SOME OF THE REVIEWERS FELT THAT THERE WAS
8	LESS FOCUS ON HUMAN CELLS IN THIS PROPOSAL THAN IN
9	SOME OF THE OTHERS. HOWEVER, REVIEWERS DID AGREE
10	THAT SOME OF THE POWER AND UNIQUE ASPECTS OF THIS
11	PROPOSAL COME FROM THE FACT THAT THEY ARE COMPARING
12	ACROSS MULTIPLE SPECIES. IN FACT, SINCE YOU CANNOT
13	LOOK AT EMBRYONIC DEVELOPMENT OF HEMATOPOIESIS IN A
14	HUMAN SYSTEM, THEY FELT THAT THIS WAS A JUSTIFIED
15	USE OF A MODEL SYSTEM. AND THEY FELT THAT COMPARING
16	ACROSS MULTIPLE SPECIES AND INCORPORATING HUMAN
17	STUDIES ALONG THAT WILL HELP NARROW IN ON THOSE THAT
18	ARE RELEVANT TO THE HUMAN SYSTEM MORE QUICKLY.
19	THE OTHER WAS THERE WERE GOING TO BE SOME
20	COMPUTATIONAL APPROACHES AND ALGORITHMS THAT ARE
21	EMPLOYED TO BASICALLY INTEGRATE THE DATA THAT'S
22	GOING TO COME IN FROM ALL THESE DIFFERENT LINES OF
23	INVESTIGATION, WHICH WAS NOT WELL DESCRIBED, BUT
24	THERE WAS A LETTER OF COLLABORATION FROM SOME
25	MATHEMATICIANS. SO WHILE THIS APPROACH HAS NOT BEEN
	313
) 13

1	VALIDATED IN PRACTICE, THE REVIEWERS WERE
2	SUFFICIENTLY IMPRESSED BY THE PRELIMINARY DATA THAT
3	THEY STILL WERE VERY POSITIVE AND ENTHUSIASTIC ABOUT
4	THIS PROPOSAL IN GENERAL.
5	SO OVERALL THE REVIEWERS DIDN'T REALLY
6	FIND ANY TECHNICAL FLAWS OR WEAKNESSES OF
7	EXPERIMENTAL DESIGN. THE WEAKNESSES THEY DID
8	IDENTIFY RELATED TO A LACK OF INFORMATION PROVIDED
9	IN THE PROPOSAL. THEY GENERALLY THOUGHT IT WAS AN
10	INTERESTING AND POWERFUL APPROACH, AND THEY FELT
11	THAT IT WAS THE RIGHT PEOPLE FOR DOING THE JOB. AND
12	IF ANYBODY WOULD LIKE TO KNOW MORE DETAILS ABOUT THE
13	SPECIFIC EXPERIMENTAL APPROACH AND THE MODELS USED,
14	I'D BE HAPPY TO DISCUSS THAT IN CLOSED SESSION, BUT
15	MUCH OF IT IS UNPUBLISHED AND PROPRIETARY AND
16	CONFIDENTIAL.
17	DR. POMEROY: SO IN THE WRITTEN SUMMARY, I
18	BELIEVE I HAVE THE RIGHT ONE, IT TALKS ABOUT IT
19	BEING OVERLY AMBITIOUS, NOT ADDRESSING POTENTIAL
20	PITFALLS, NOT PROPOSING ALTERNATIVE STRATEGIES. AND
21	I DIDN'T REALLY HEAR THAT IN YOUR SUMMARY. COULD
22	YOU GO THROUGH THAT DISCUSSION?
23	DR. SHEPERD: WELL, THOSE WERE BROUGHT UP
24	DURING THE DISCUSSION, BUT PROBABLY THEY WEREN'T
25	MAJOR CONTRIBUTING FACTORS TO THE SCORE. AGREE,
	314

1	THEY DID AGREE AND DID COMMENT THAT THE SCOPE OF
2	THIS IS MASSIVE. THERE ARE FOUR AIMS. THEY'RE ALL
3	VERY AMBITIOUS. HOWEVER, SOME REVIEWERS DID COMMENT
4	THAT THEY FELT THAT EVEN IF A PORTION OF THE
5	PROPOSAL COULD BE SUCCESSFUL, IT WOULD STILL BE
6	WORTHWHILE. AND I REMIND THAT THERE ARE ACTUALLY
7	TWO TEAMS IN TWO DIFFERENT COUNTRIES WORKING ON
8	THIS, AND MUCH OF THE WORK WILL BE DONE BY THE
9	FRENCH INVESTIGATORS AS WELL. SO IT DID SEEM TO BE
10	VERY AMBITIOUS IN SCOPE.
11	BUT THAT WAS A MINOR CONCERN, BUT REALLY
12	WHAT THEY SAID WAS THE MAIN THING THAT CAUSED SOME
13	OF THE REVIEWERS TO GIVE A LOWER SCORE IS BECAUSE OF
14	THE SEEMINGLY MORE EMPHASIS ON SOME OF THE MODEL
15	SYSTEM STUDIES THAN ON THE HUMAN STUDIES. HOWEVER,
16	ALL THE INFORMATION WILL BE INTEGRATED, AND THE
17	OVERALL GOAL OF THE PROPOSAL WAS EVENTUALLY TO APPLY
18	THIS INFORMATION TO BE ABLE TO DERIVE EXPANDABLE AND
19	FUNCTIONAL HEMATOPOIETIC STEM CELLS FROM HUMAN
20	PLURIPOTENT STEM CELLS, WHICH ISN'T CURRENTLY
21	POSSIBLE.
22	DR. POMEROY: JUST TO MAKE SURE I
23	UNDERSTAND THIS, THE GRANTS WORKING GROUP FELT THAT
24	THERE WAS NO PROGRAMMATIC REASON TO FUND THE
25	APPLICATION IN THEIR DISCUSSIONS, BUT STAFF FELT

315

1	DIFFERENTLY. IS THAT AN ACCURATE SUMMARY?
2	DR. TROUNSON: WELL, I THINK IT'S
3	SCIENTIFICALLY THERE ARE TWO LABS, SO IT'S DOUBLE
4	THE SIZE.
5	DR. POMEROY: I'M JUST TALKING ABOUT
6	WHAT'S WRITTEN ON THIS PIECE OF PAPER. IT SAYS THAT
7	THE GRANTS WORKING GROUP DID NOT IDENTIFY A
8	PROGRAMMATIC REASON TO FUND IT. IS THAT A TRUE
9	STATEMENT OR NOT?
10	DR. SAMBRANO: YES. SO THE POINT IS THAT
11	THOSE THAT FELL INTO THAT INITIAL TIER II, THE
12	GRANTS WORKING GROUP HAD THE OPPORTUNITY TO RAISE
13	THEM UP IF THEY FOUND A PROGRAMMATIC REASON TO DO
14	SO. AND SO FOR THOSE FOR WHICH THEY DIDN'T, THAT
15	LANGUAGE IS PLACED IN THERE.
16	MR. ROTH: CLAIRE, MAYBE I CAN ADD A
17	LITTLE BIT. I'VE BEEN ASKING FOR STAFF THAT SITS
18	THROUGH THESE REVIEWS TO SPOT GRANTS THEY
19	COLLECTIVELY FEEL WE SHOULD TAKE A HARDER LOOK AT.
20	SO I WELCOME THIS KIND OF INPUT. WE DON'T HAVE THE
21	OPPORTUNITY TO HEAR THE DISCUSSION AND DIALOGUE AND
22	THINK THROUGH IT. BUT I THINK THIS IS SOMETHING
23	THAT CERTAINLY, AS A BOARD MEMBER, HELPS ME.
24	CHAIRMAN THOMAS: DR. LEVIN, THEN DR.
25	LUBIN.
	316
	310

1	DR. LEVIN: TWO THINGS. DON'T WE HAVE A
2	MOTION ON THE TABLE ON THE PREVIOUS GRANT STILL THAT
3	WE HAVE TO ADDRESS?
4	CHAIRMAN THOMAS: YES.
5	MR. SHEEHY: SHOULD I ADDRESS THAT BECAUSE
6	I HAVE A SOLUTION. SO I'M WILLING TO WITHDRAW MY
7	MOTION BECAUSE I AGREE WITH DUANE. I FELT LIKE
8	STAFF SEES A WINNER THAT SLIPS THROUGH, I'M
9	SUPPORTIVE OF THAT. I HAVE A LOT OF CONFIDENCE IN
10	DR. TROUNSON. SO I'M WILLING TO WITHDRAW MY MOTION,
11	AND THEN PERHAPS, IF WE CAN HAVE WHATEVER DISCUSSION
12	WE'RE GOING TO HAVE ON THIS GRANT, AND THEN I THINK
13	WE SHOULD GO BACK AND DEAL WITH MR. JUELSGAARD'S
14	POINT OF WHETHER WE'RE GOING TO BUST THIS BUDGET
15	WIDE OPEN OR NOT. AND AT THAT POINT, THEN, ONCE WE
16	MAKE THAT DECISION, THEN WHETHER OR NOT I MAKE MY
17	MOTION AGAIN, WE CAN COME BACK TO THAT. BUT I DON'T
18	WANT TO GET IN THE WAY OF SOMETHING THAT SEEMS TO
19	HAVE A VERY STRONG SCIENTIFIC RATIONALE.
20	DR. LEVIN: ONE MORE COMMENT. IN ANSWER
21	TO YOUR QUESTION, JON, IN BASIC BIOLOGY II, WE
22	AWARDED \$22 MILLION AND IN BASIC BIOLOGY III, WE
23	WARDED \$37 MILLION. SO IT SEEMS THAT WE STILL HAVE
24	ON THE ORDER OF 10 OR \$15 MILLION LESS THAN WE HAD
25	ORIGINALLY ANTICIPATED TO AWARD IN BASIC BIOLOGY
	317

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1	ROUNDS. AND I JUST WANTED TO SORT OF ENCOURAGE THE
2	BOARD TO CONSIDER THIS WAS A BOARD THAT STARTED
3	REALLY FUNDING THE BASIC BIOLOGY OF STEM CELLS AND
4	THE BASIC UNDERSTANDING. AND OBVIOUSLY AS WE
5	MATURED, WE'VE GONE FAR MORE INTO PUTTING ALL OUR
6	WEIGHT AND ALL OF OUR ATTENTION INTO TRANSLATIONAL
7	FOR REASONS WE ALL UNDERSTAND. AND I WORRY THAT
8	BASIC BIOLOGY AND THE BASIC UNDERSTANDING IS MAYBE
9	GETTING LEFT IN THE DUST A LITTLE, AND THAT IT'S
10	STILL THE SMALLER GRANTS AND IT'S WELL WORTH IT TO
11	EXTEND OURSELVES A LITTLE TO FULLY BRING NEW PEOPLE
12	INTO THE FIELD AND ADD TO OUR UNDERSTANDING OF THE
13	BASIC BIOLOGY OF STEM CELL SCIENCE.
14	I JUST WANTED IN THE CONTEXT OF THESE
15	DISCUSSIONS, I THINK IT'S WORTHY WHEN WE SEE ANY
16	GRANT THAT REALLY COULD MAKE A DIFFERENCE, CONSIDER
17	MOVING IT UP EVEN IF IT COSTS A FEW EXTRA HUNDRED
18	THOUSAND DOLLARS.
19	CHAIRMAN THOMAS: THANK YOU. I THINK
20	THOSE ARE VERY IMPORTANT POINTS. SO, MR. SHEEHY,
21	ARE YOU TABLING YOUR MOTION OR WHAT ARE YOU DOING
22	HERE?
23	MR. SHEEHY: I'M WITHDRAWING IT.
24	CHAIRMAN THOMAS: OKAY. AND THE SECOND?
25	DR. LUBIN: SO ALSO BEFORE I COMMENT ON
	318

1	THIS HEMATOPOIETIC ONE, DO WE HAVE EXTRAORDINARY
2	PETITIONS THAT WE'RE GOING TO HEAR THAT MIGHT ALSO
3	BE UPGRADED FROM ANOTHER RANK?
4	CHAIRMAN THOMAS: I THINK THE PROCEDURE IS
5	WE ASK IF THERE ARE MEMBERS OF THE BOARD WHO WANT TO
6	ELEVATE ANY OTHER PROPOSALS FROM TIER III TO TIER I.
7	IF THEY IDENTIFY A PROPOSAL THAT HAS AN
8	EXTRAORDINARY PETITION, THAT WILL BE DEALT WITH AT
9	THAT TIME. IF THOSE PROJECTS THAT HAVE
10	EXTRAORDINARY PETITIONS ARE NOT THE SUBJECT OF
11	RECOMMENDED PROJECTS, WE WILL THEN HEAR, IF THEY SO
12	CHOOSE, IN GENERAL PUBLIC COMMENT FROM THOSE
13	EXTRAORDINARY PETITIONERS.
14	DR. POMEROY: IS THERE A MOTION ABOUT THIS
15	ONE WE'VE BEEN DISCUSSING?
16	CHAIRMAN THOMAS: NOT YET.
17	DR. LUBIN: I STILL WANT TO TALK ABOUT
18	THIS ONE. SO I COMPLETELY AGREE WITH WHAT JACOB
19	SAID. I THINK THIS IS AN EXTREMELY EXCITING
20	APPLICATION THAT HAS ENORMOUS POTENTIAL TO BENEFIT
21	ANYONE THAT REQUIRES A TRANSPLANTATION OF A STEM
22	CELL, WHETHER CORD BLOOD, BONE MARROW, WHATEVER.
23	THE TRACKING AND THE NICHES THAT ARE THERE AND THE
24	BIOLOGY THAT IS VERY POORLY UNDERSTOOD, AND I
25	BELIEVE THIS COMPARATIVE APPROACH IS REALLY
	319

1	REMARKABLE AND OUTSTANDING. AND TO HAVE IT WITHIN
2	OUR PORTFOLIO OF WHAT CIRM SUPPORTS, I THINK, IS A
3	WISE INVESTMENT, AND IT'S A SMALL AMOUNT OF MONEY
4	COMPARED TO THE OTHER THINGS WE'RE INVESTING, WHICH
5	WILL HAVE AN ENORMOUS IMPACT, IN MY OPINION, ON THE
6	THERAPY OF ANYONE THAT REQUIRES A STEM CELL
7	TRANSPLANTATION.
8	CHAIRMAN THOMAS: THANK YOU.
9	DR. PIZZO: I WANT TO CERTAINLY UNDERSCORE
10	THE IMPORTANCE OF JACOB'S COMMENT ABOUT CONTINUING
11	TO FUND BASIC RESEARCH AND SMALL PROJECTS. I THINK
12	THIS IS CRITICAL.
13	I JUST HAVE SORT OF A PROCEDURAL QUESTION
14	THAT COMES BACK TO STAFF. RIGHT NOW WE'RE TALKING
15	ABOUT WHETHER WE SHOULD GO, QUOTE, ABOVE BUDGET.
16	THE QUESTION THAT I HAVE IS JUST PROCEDURAL. AS YOU
17	LOOKED AT THESE OTHER PROPOSALS THAT WENT FROM, IF
18	YOU WILL, TIER II TO TIER I, WERE THERE ANY THAT
19	WERE ON THE CUSP THAT MIGHT GO DOWN AS COMPARED TO
20	GO UP? SO COULD WE STILL KEEP THE OVERALL BUDGET,
21	AND IS THERE SOME FLEXIBILITY IN TERMS OF ONES THAT
22	ARE NOW ABOVE THE FUNDING LINE THAT MIGHT BE MOVED
23	DOWN? WAS THAT DISCUSSION PART OF YOUR DIALOGUE?
24	DR. JUELSGAARD: MR. CHAIRMAN, COULD I
25	JUST ADD TO DR. PIZZO'S QUESTION? BECAUSE THERE ARE

320

1	TWO PROJECTS THAT ARE NOW IN TIER I THAT STARTED IN
2	TIER III, AS I READ WHAT WAS GIVEN TO US PRIOR TO
3	THE BOARD MEETING. AND SO I'M JUST WONDERING HOW
4	THOSE MAKE THAT TRANSITION, MUCH LESS THE TIER II TO
5	TIER I.
6	DR. PIZZO: FAIR ENOUGH.
7	DR. TROUNSON: I'D ASK PATRICIA OLSON. I
8	WASN'T ACTUALLY AT THE REVIEW, SO IT'S NOT A GOOD
9	THING FOR ME TO COMMENT SPECIFICALLY ON THAT. PAT,
10	CAN YOU ADDRESS THESE ISSUES FOR THE BOARD?
11	DR. OLSON: LET ME MAKE SURE I UNDERSTAND
12	THE QUESTION. COULD YOU REPEAT THE QUESTION,
13	PLEASE?
14	DR. PIZZO: THE QUESTION THAT I WAS ASKING
15	IS REALLY IT'S A TEXTURE QUESTION OF THE DISCUSSION
16	OF THAT TOOK PLACE. AND THAT IS, OF THOSE THAT ARE
17	IN LET'S CALL IT JUST IN THE APPROVED CATEGORY NOW,
18	THE FUNDED CATEGORY, WERE THERE ANY THAT WERE AT THE
19	CUSP THAT IF WE HAD TO GROUP, LET'S SAY, THREE TO
20	FOUR PROPOSALS TOGETHER AND STILL ADHERE TO THE
21	BUDGET LIMIT, WOULD WE SHIFT WHERE THEY FELL?
22	DR. OLSON: OKAY. SO MY COMMENT WOULD BE
23	THEN ABOUT THE PROCESS IN PROGRAMMATIC. AS YOU
24	RECALL, WE START OUT BY JUST PUTTING UP A HISTOGRAM
25	OF ALL THE APPLICATIONS AS TO WHERE THEY FALL AS
	321

1	THEIR SCIENTIFIC SCORE. THE ENTIRE GRANTS WORKING
2	GROUP THEN MAKES A MOTION AS TO WHERE TO PLACE THE
3	GREEN LINE; I.E., THOSE APPLICATIONS ABOVE WHICH
4	THEY FEEL ARE SUFFICIENTLY MERITORIOUS THAT THEY
5	DON'T WARRANT FURTHER DISCUSSION.
6	THE GRANTS WORKING GROUP NEXT, THE ENTIRE
7	GRANTS WORKING GROUP, THEN MAKES A CALL AS TO WHERE
8	TO PLACE WHAT'S CALLED THE RED LINE. THOSE
9	APPLICATIONS WHO HAVE A SCORE BELOW WHICH IN THIS
10	ROUND ARE NOT SUFFICIENTLY MERITORIOUS, THAT THAT'S
11	THE STARTING POINT, THE SO-CALLED TIER III. IN
12	BETWEEN ARE THE SO-CALLED TIER II.
13	AT THIS POINT MR. SHEEHY, AS CHAIRMAN OF
14	THAT GROUP, BASICALLY ASKS ARE THERE DISCUSSIONS,
15	ARE THERE PROGRAMMATIC REASONS WHY A PARTICULAR
16	APPLICATION IN THAT SO-CALLED TIER II CATEGORY
17	SHOULD BE EITHER CONSIDERED FOR FUNDING, OR ARE
18	THERE REASONS WHY YOU DON'T WANT TO CONSIDER IT FOR
19	FUNDING AND REMOVE IT TO TIER III. SO IN SOME CASES
20	THERE ARE ACTIVE DISCUSSIONS BOTH WAYS. BUT THE
21	DEFAULT IS IF THERE IS NO DISCUSSION, THEN
22	PRESUMABLY IT AUTOMATICALLY MOVES TO TIER III.
23	SO IF YOU OBVIOUSLY I THINK YOU CAN
24	TELL BY LOOKING AT THAT, WHICH DISAPPEARED THE
25	INSTANT I MENTIONED IT. IT'S THERE NOW. IF YOU
	322

1	LOOK AT THIS, YOU CAN SEE THE APPLICATIONS THAT ARE
2	HIGHLIGHTED IN GREEN THAT FOR PROGRAMMATIC REASONS
3	WERE RAISED TO TIER I, WERE RECOMMENDED. AND I
4	BELIEVE YOU ALSO HAVE IN YOUR TAB, WHATEVER TAB THIS
5	IS, YOU HAVE A SUMMARY OF ALL THE PROGRAMMATIC
6	DISCUSSIONS FOR EACH OF THOSE APPLICATIONS. I
7	BELIEVE THAT SHOULD BE AT THE FRONT OF THE TAB, SORT
8	OF MAYBE RIGHT BEFORE OR AFTER THE SUMMARY.
9	MR. SHEEHY.
10	MR. SHEEHY: I WAS GOING TO SAY THE
11	SUMMARY OF THE PROGRAMMATIC SECTION IS RIGHT AFTER
12	THE GREEN THAT HAS THE SCORES. I THINK THEY'RE
13	FAIRLY DETAILED ON WHAT THE CONSIDERATIONS WERE THAT
14	CAUSED PEOPLE TO MOVE THOSE UP.
15	DR. OLSON: THERE WERE PROGRAMMATIC
16	REASONS IN SOME CASES WHY SPECIFIC APPLICATIONS THAT
17	WERE IN TIER II WERE FELT TO BE MERITORIOUS FOR
18	FUNDING AND WERE SUBSEQUENTLY RECOMMENDED BY THE
19	ENTIRE GRANTS WORKING GROUP.
20	MR. SHEEHY: COULD I JUST MAKE A POINT
21	ABOUT PROGRAMMATIC REVIEW? THE HISTOGRAM IS JUST A
22	BLIND SHOT JUST BY THE NUMBERS. LET'S BE CLEAR.
23	WHEN THINGS END UP IN THE LOWER TIERS, PEOPLE HAVE
24	NO IDEA WHAT THEY'RE PUTTING THERE. WE DO THIS FOR
25	THE SAME REASON WE GO THROUGH SUCH CONNIPTIONS ON

323

CONFLICTS. AND IN THIS PARTICULAR INSTANCE, PEOPLE
CANNOT BE IN THE ROOM WHEN THERE ARE CONFLICTS. SO
WE TRY TO GET THE CLEARLY MERITORIOUS GRANTS AND THE
CLEARLY NOT MERITORIOUS GRANTS ROUGHLY OFF THE
TABLE, WHICH IS THE POINT FOR THE HISTOGRAM, SO THAT
WE DON'T HAVE PEOPLE JUMPING AND RUNNING. WE'D BE
THREE DAYS DOING OUR FINAL RECOMMENDATIONS. SO
THOSE ARE JUST VERY BROAD BRUSHES.
AND I JUST WANT TO MAKE ONE MORE POINT
ABOUT THE FUNDING. I DID NOTICE IN HERE THAT A
COUPLE OF THE GRANTS THAT DID MAKE IT THROUGH
PROGRAMMATIC REVIEW, ONE OF THEM DID LOSE LOOKS
LIKE IT LOST AN AIM. SO WE MAY HAVE ENOUGH TO FUND
ONE MORE COMPLETE GRANT AT THE $1.2,\;1.3$ MILLION AND
STILL FIT OUR BUDGET. BEYOND THAT, I THINK WE STILL
HAVE THE PROBLEM MR. JUELSGAARD IDENTIFIED.
DR. JUELSGAARD: JUST ONE MORE QUESTION
FOR PAT. SO, PAT, IF I'M READING WHAT WAS GIVEN TO
US PRIOR TO THE BOARD MEETING CORRECTLY, THERE ARE
TWO, 6244 AND 5785, THAT HAD SCORES BELOW THE RED
LINE OF 66. 6244 HAD A SCORE OF 64, AND 5785 HAD A
SCORE OF 65. AND SOMEHOW THEY GOT ELEVATED FROM
TIER III TO TIER I.
I WOULD JUST LIKE TO UNDERSTAND THAT
PROCESS A LITTLE BIT BETTER BECAUSE I HAD UNDERSTOOD
324

1	THAT THE RED LINE WAS MORE A HARD AND FAST RED LINE,
2	BUT APPARENTLY IT ISN'T.
3	MR. SHEEHY: NO. JUST TO BE CLEAR, THAT'S
4	JUST A BALLPARK. WE JUST PUT THAT OUT THERE.
5	DR. OLSON: IT'S A STARTING POINT FOR
6	DISCUSSION.
7	MR. SHEEHY: RIGHT. AND I THINK THAT THEY
8	HAVE A REALLY GOOD DISCUSSION. REALLY, IF YOU LOOK
9	AT THIS PAGE, IT TELLS YOU WHY. THEY THOUGHT THAT
10	AIM 3 WAS NOT A GOOD AIM, DIDN'T HAVE THE MONEY TO
11	DO IT. SO THIS BECAME A MUCH BETTER GRANT ONCE YOU
12	CUT OUT AIM 3, AND THAT WAS THE RECOMMENDATION.
13	AGAIN, MORE SO PERHAPS THAN OTHER PROGRAMMATIC
14	REVIEWS, THIS WAS DRIVEN BY THE SCIENTISTS BECAUSE
15	HONESTLY I'M IN THE WEEDS A LITTLE BIT ON THIS
16	SOMETIMES. I THINK THIS IS REALLY SOME VERY
17	FUNDAMENTAL ISSUES, AS DR. TROUNSON HAD SAID. AND
18	THE PROGRAMMATIC CONSIDERATIONS THAT AROSE THAT LED
19	TO THESE KINDS OF CHANGES, I THOUGHT, WERE VERY
20	REASONABLE IN MY MIND. AND I THOUGHT THAT THE ONES
21	THAT MADE IT UP ALL SEEM TO HAVE FAIRLY CLEAR
22	JUSTIFICATIONS WITHIN THIS PROGRAMMATIC REVIEW
23	SUMMARY.
24	WE EXPLICITLY DON'T WANT TO BE DOMINATED
25	BY THE HEGEMONY OF THE SCORES THEMSELVES. AND THE
	325

1	RESEARCHERS SEEMED TO APPRECIATE THAT OPPORTUNITY.
2	STAFF HAS NOTED ONE THAT HAS SCIENTIFIC MERIT THAT
3	MAY HAVE ESCAPED THE PURVIEW OF THE COMMITTEE. SO,
4	AGAIN, WE NEED TO BE FLEXIBLE, NIMBLE. WE HAVE A
5	SHORT TIME FRAME.
6	CHAIRMAN THOMAS: ARE THERE ANY OTHER
7	COMMENTS BY MEMBERS OF THE BOARD ON THIS MOTION?
8	MR. HARRISON: WE ACTUALLY DON'T HAVE A
9	MOTION.
10	CHAIRMAN THOMAS: JUST CHECKING TO SEE IF
11	EVERYBODY WAS PAYING ATTENTION. DO WE HEAR A MOTION
12	ON THIS?
13	DR. PRICE: SO I MOVE THAT WE MOVE GRANT
14	APPLICATION 06158 INTO TIER I.
15	CHAIRMAN THOMAS: MOVED BY DR. PRICE.
16	DR. VUORI: I'LL SECOND IT.
17	CHAIRMAN THOMAS: ANY FURTHER DISCUSSION
18	BY MEMBERS OF THE BOARD ON THIS MOTION? MARIA,
19	YOU'RE SIGNALING SOMETHING.
20	MS. BONNEVILLE: WE HAVE OUR SPOTLIGHT
21	THAT'S COMING IN AT NOON. THEY'RE HERE ALREADY, SO
22	WE MAY HAVE TO STOP CONVERSATION AND RESTART AGAIN
23	AFTER.
24	CHAIRMAN THOMAS: LET'S SEE HOW CLOSE WE
25	ARE TO BEING IF NECESSARY, I ASSUME THEY CAN WAIT
	226
	326

FOR A COUPLE MINUTES.
DR. PIZZO: SO HERE'S THE STRUGGLE THAT
I'M HAVING. ON THE ONE HAND, I THINK THERE'S A
MERIT, WHICH I APPRECIATE AND UNDERSTAND, OF MOVING
OR RECONSIDERING A PROGRAM THAT STAFF THOUGHT WAS
MERITORIOUS THAT PERHAPS WASN'T CONSIDERED. THAT
MAKES A LOT OF SENSE TO ME, AND I APPLAUD DUANE'S
COMMENT ABOUT THAT. SO THAT'S ONE PIECE.
AND THE SECOND THAT I'M STRUGGLING WITH IS
YOU'VE RAISED A TECHNICALITY ABOUT WHY A YOUNG
INVESTIGATOR FOR A MERITORIOUS PROJECT MIGHT NOT BE
FUNDED, WHICH HAD TO DO WITH CHANGE OF INSTITUTIONS,
WHICH HAS BEEN RESOLVED. SO AS FAR AS I CAN SEE,
IT'S GOING TO BE A VERY HARD DECISION TO
DISCRIMINATE BETWEEN THESE TWO UNLESS WE RECONSIDER
THE AMOUNT OF FUNDING THAT WE'RE GOING TO APPLY FOR
THIS.
SO I WANT TO PUT ON THE TABLE THAT WE
DON'T MAKE WE'VE SPENT A LOT OF MONEY ON BIG
GRANTS, AND I WOULD LIKE US TO AT LEAST THINK ABOUT
TAKING AN EXTENSION ON THIS FOR PROJECTS THAT MAKE
SENSE EITHER SCIENTIFICALLY OR PROGRAMMATICALLY.
CHAIRMAN THOMAS: YES. THANK YOU. I
WOULD COMPLETELY AGREE WITH THAT, AND THAT'S IN
KEEPING WITH DR. LEVIN'S COMMENTS, WHICH I THOUGHT
327

1	WERE VERY PERCEPTIVE AND VERY IMPORTANT.
2	DR. PIZZO: I ALWAYS TRY TO DO THAT.
3	CHAIRMAN THOMAS: OKAY. SO IS THERE ANY
4	FURTHER DISCUSSION ON THIS MOTION? ANY COMMENTS BY
5	MEMBERS OF THE PUBLIC? HEARING NONE, WE NEED A ROLL
6	CALL ON THIS ONE. YES, WE DO. MARIA, PLEASE CALL
7	THE ROLL. EVERYBODY CHECK YOUR CONFLICTS CHART,
8	PLEASE.
9	MS. BONNEVILLE: ROBERT PRICE.
10	DR. PRICE: YES.
11	MS. BONNEVILLE: JACOB LEVIN.
12	DR. LEVIN: YES.
13	MS. BONNEVILLE: ANNE-MARIE DULIEGE.
14	DR. DULIEGE: YES.
15	MS. BONNEVILLE: MARCY FEIT.
16	MS. FEIT: YES.
17	MS. BONNEVILLE: LEEZA GIBBONS.
18	MS. GIBBONS: YES.
19	MS. BONNEVILLE: MICHAEL GOLDBERG. SAM
20	HAWGOOD.
21	DR. HAWGOOD: YES.
22	MS. BONNEVILLE: STEPHEN JUELSGAARD.
23	DR. JUELSGAARD: YES.
24	MS. BONNEVILLE: BERT LUBIN.
25	DR. LUBIN: YES.
	328
	320

1		MS. BONNEVILLE: MICHAEL MARLETTA. LEON
2	FINE.	
3		DR. FINE: YES.
4		MS. BONNEVILLE: PHIL PIZZO.
5		DR. PIZZO: YES.
6		MS. BONNEVILLE: CLAIRE POMEROY.
7		DR. POMEROY: YES.
8		MS. BONNEVILLE: FRANCISCO PRIETO.
9		DR. PRIETO: ABSTAIN.
10		MS. BONNEVILLE: CARMEN PULIAFITO.
11		DR. PULIAFITO: AYE.
12		MS. BONNEVILLE: ROBERT QUINT.
13		DR. QUINT: YES.
14		MS. BONNEVILLE: DUANE ROTH.
15		MR. ROTH: YES.
16		MS. BONNEVILLE: JOAN SAMUELSON.
17		MS. SAMUELSON: YES.
18		MS. BONNEVILLE: JEFF SHEEHY.
19		MR. SHEEHY: YES.
20		MS. BONNEVILLE: JONATHAN SHESTACK.
21		MR. SHESTACK: YES.
22		MS. BONNEVILLE: OSWALD STEWARD.
23		DR. STEWARD: YES.
24		MS. BONNEVILLE: JONATHAN THOMAS.
25		CHAIRMAN THOMAS: YES.
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	DOLINE T. L. D. TODDE C
1	MS. BONNEVILLE: ART TORRES.
2	MR. TORRES: AYE.
3	MS. BONNEVILLE: KRISTINA VUORI.
4	DR. VUORI: YES.
5	MS. BONNEVILLE: JAMES ECONOMOU.
6	DR. ECONOMOU: YES.
7	MS. BONNEVILLE: TED KRONTIRIS.
8	DR. KRONTIRIS: YES.
9	CHAIRMAN THOMAS: MOTION PASSES.
10	NOW, DEAN PIZZO.
11	DR. PIZZO: I WOULD LIKE TO PUT ANOTHER, I
12	GUESS IT WOULD HAVE TO BE A MOTION, ON THE TABLE
13	THAT WE INCREASE THE AMOUNT OF FUNDING FOR THE BASIC
14	SCIENCE GRANTS BY A NUMBER TO BE DETERMINED ABOVE
15	THE \$35 MILLION LEVEL TO SUPPORT CONSIDERATION OF
16	ANOTHER MERITORIOUS GRANT.
17	CHAIRMAN THOMAS: MR. HARRISON.
18	MR. HARRISON: COULD I MAKE A SUGGESTION
19	THAT WE TAKE A BREAK TO CONSIDER THE IMPLICATIONS OF
20	A MOTION LIKE THAT BEFORE WE PROCEED IN ORDER TO
21	ADDRESS POTENTIAL CONFLICT ISSUES? AND PERHAPS WE
22	COULD THEN BREAK FOR LUNCH AND THE SPOTLIGHT.
23	DR. PRICE: EXPLAIN THE COMPLICATION.
24	MR. HARRISON: THE COMPLICATION ARISES
25	FROM THE FACT THAT THERE ARE A SERIES OF
	330

1	APPLICATIONS THAT COULD BENEFIT FROM THIS ADDITIONAL
2	FUNDING. SO ALL OF THE MEMBERS THAT MIGHT HAVE AN
3	INTEREST IN THE INSTITUTION THAT HAS SUBMITTED SUCH
4	AN APPLICATION WOULD HAVE TO RECUSE THEMSELVES FROM
5	PARTICIPATING IN SUCH A MOTION OR MAKING IT. SO
6	THAT'S THE ISSUE, AND WE HAVE NOT IDENTIFIED THOSE
7	CONFLICTS.
8	CHAIRMAN THOMAS: CAN I ASK ANOTHER
9	QUESTION? WHILE I THINK THE MOTION IS A GREAT IDEA,
10	DO WE ACTUALLY NEED TO MOVE
11	DR. PIZZO: PROBABLY DON'T. COULD JUST
12	RECOMMEND.
13	CHAIRMAN THOMAS: OKAY. SO THAT TAKES
14	DR. PIZZO: I WITHDRAW MY MOTION. EVEN IF
15	IT WAS A GREAT IDEA, I STILL WITHDRAW IT.
16	CHAIRMAN THOMAS: PROBLEM SOLVED.
17	MR. SHEEHY: CAN I MAKE MY ORIGINAL MOTION
18	AGAIN? AND THEN WE CAN KIND OF WE'VE HAD THIS
19	DISCUSSION ABOUT THE BUDGET, KNOWING THAT THIS WILL
20	EXCEED OUR BUDGET. THE ISSUE, WE'VE HAD THE DEBATE
21	BACK AND FORTH. I DON'T THINK WE NEED TO
22	RECAPITULATE IT, AND MAYBE WE CAN GET THROUGH THIS
23	AND BE DONE. I MAKE MY ORIGINAL MOTION IF THERE'S A
24	SECOND.
25	DR. PIZZO: SECOND.
	221
	331

1	DR. HAWGOOD: JUST BEFORE WE DO THAT,
2	COULD WE CHECK WHETHER THERE ARE OTHER GRANTS, SO WE
3	DON'T ITERATE THIS?
4	CHAIRMAN THOMAS: YES. VERY GOOD. MR.
5	SHEEHY, CAN YOU HOLD OFF ON YOUR MOTION?
6	MR. SHEEHY: I WAS HOPING THAT WOULD BE
7	PART OF IT, SO I THANK DR. HAWGOOD FOR SUGGESTING
8	IT.
9	CHAIRMAN THOMAS: ARE THERE OTHER
10	PROPOSALS THAT ARE RECOMMENDED TO BE FUNDED IN TIER
11	III AND MOVED TO TIER I?
12	DR. LUBIN: CAN YOU MAKE THAT BY SAYING
13	YOU'D LIKE TO HEAR MORE ON THE SCIENTIFIC REVIEW, OR
14	DO YOU HAVE TO SAY YOU WANT TO MOVE IT TO TIER I?
15	CHAIRMAN THOMAS: YOU WOULD MOVE A
16	SPECIFIC ONE, AND THEN WE WOULD HAVE A SCIENTIFIC
17	DESCRIPTION OF THE PROJECT FOR WHATEVER WAS
18	RECOMMENDED.
19	DR. PULIAFITO: POINT OF INFORMATION.
20	WHERE DO THE EXTRAORDINARY PETITIONS COME IN IN THIS
21	THING?
22	CHAIRMAN THOMAS: NORMALLY THEY WOULD BE
23	GIVEN WITH ANY PROJECT THAT WAS RECOMMENDED TO BE
24	MOVED FROM TIER III TO TIER I. IF NONE ARE
25	RECOMMENDED THAT ARE THE SUBJECT OF EXTRAORDINARY
	332

1	PETITIONS, THEY WOULD BE PRESENTED, IF SO CHOSEN, IN
2	PUBLIC COMMENT.
3	MR. HARRISON: DR. PULIAFITO, THE BOARD'S
4	POLICY IS THAT IT DOES NOT AUTOMATICALLY ADDRESS
5	EXTRAORDINARY PETITIONS. THEY'RE ONLY DISCUSSED
6	UPON REQUEST BY A MEMBER OF THE BOARD.
7	CHAIRMAN THOMAS: BUT THEY ARE FREE TO BE
8	DISCUSSED BY THE PETITIONER IN PUBLIC COMMENT.
9	OKAY. SO
10	MR. SHESTACK: ARE THERE FOR THE TOP FOUR
11	OF THE GRANTS OF TIER II, ARE THERE ANY
12	EXTRAORDINARY PETITIONS? I THINK I SAW ONE, BUT I
13	HAVE SO MANY COME IN AT THE VERY END THAT I'M NOT
14	FAMILIAR WITH ALL. THERE ARE THREE. OF 6158, 6277,
15	6239, AND 5764, THERE ARE THREE EXTRAORDINARY
16	PETITIONS IN THAT GROUP OF FOUR?
17	MR. TORRES: YES.
18	MR. SHESTACK: WELL, I WOULD LIKE TO KNOW
19	MORE ABOUT 6239. DO I HAVE TO MAKE A PROPOSAL TO
20	GET THAT INFORMATION? I'M HAPPY TO MAKE THE MOTION.
21	CHAIRMAN THOMAS: NO. YOU CAN JUST ASK
22	FOR A STAFF PRESENTATION.
23	DR. STEWARD: JUST POINT OF ORDER
24	ACTUALLY. WE ARE AT A POINT WHERE WE'RE SUPPOSED TO
25	BREAK. WE DO HAVE A MOTION ON THE TABLE. WE COULD
	333

_	DARKISIERS REPORTING SERVICE
1	VOTE ON THAT MOTION, AND THEN CONSIDER THIS OTHER
2	AFTER THE NORMALLY I WOULD SAY LET'S GO AHEAD
3	BECAUSE OF THE TIMING ISSUE. IT'S SUPPOSED TO BE AT
4	NOON.
5	MR. SHESTACK: I APOLOGIZE.
6	DR. STEWARD: I WOULD LIKE TO JUST MOVE
7	THE QUESTION ON THE MOTION THAT IS ON THE FLOOR, AND
8	THEN WE CAN COME BACK AND CONSIDER THE REST.
9	MR. SHESTACK: THAT WOULD BE FINE.
10	CHAIRMAN THOMAS: OKAY. BEFORE WE VOTE ON
11	THAT, MARIA AND MR. HARRISON, SINCE WE'RE GETTING
12	FAIRLY CLOSE TO WRAPPING UP BASIC BIO, IS 12 O'CLOCK
13	LOCKED IN STONE?
14	MS. BONNEVILLE: WE COULD GO A LITTLE
15	LONGER.
16	CHAIRMAN THOMAS: I THINK WE'VE GOT SOME
17	MOMENTUM GOING HERE, AND I'D LIKE TO SEE IF WE CAN
18	COMPLETE THIS AGENDA ITEM. SO THERE'S A MOTION ON
19	THE TABLE, MR. SHEEHY, SECONDED BY MR. ROTH. ANY
20	FURTHER DISCUSSION ON THAT MOTION? COMMENTS FROM
21	MEMBERS OF THE PUBLIC. HEARING NONE, PLEASE TAKE
22	THE ROLL, MARIA.
23	DR. PULIAFITO: COULD I REQUEST READING
24	THE MOTION?
25	MR. HARRISON: THE MOTION IS TO MOVE
	334

1	APPLICATION RB 405764 TO TIER I.
2	MS. BONNEVILLE: ROBERT PRICE.
3	DR. PRICE: YES.
4	MS. BONNEVILLE: DAVID BRENNER.
5	DR. BRENNER: YES.
6	MS. BONNEVILLE: JACOB LEVIN.
7	DR. LEVIN: YES.
8	MS. BONNEVILLE: ANNE-MARIE DULIEGE.
9	DR. DULIEGE: YES.
10	MS. BONNEVILLE: TED KRONTIRIS.
11	DR. KRONTIRIS: YES.
12	MS. BONNEVILLE: LEEZA GIBBONS.
13	MS. GIBBONS: YES.
14	MS. BONNEVILLE: MICHAEL GOLDBERG. SAM
15	HAWGOOD.
16	DR. HAWGOOD: YES.
17	MS. BONNEVILLE: STEPHEN JUELSGAARD.
18	DR. JUELSGAARD: NO.
19	MS. BONNEVILLE: BERT LUBIN.
20	DR. LUBIN: YES.
21	MS. BONNEVILLE: LEON FINE.
22	DR. FINE: YES.
23	MS. BONNEVILLE: PHIL PIZZO.
24	DR. PIZZO: YES.
25	MS. BONNEVILLE: CARMEN PULIAFITO.
	335

1	DR. PULIAFITO: YES.
2	MS. BONNEVILLE: ROBERT QUINT.
3	DR. QUINT: YES.
4	MS. BONNEVILLE: DUANE ROTH.
5	MR. ROTH: YES.
6	MS. BONNEVILLE: JOAN SAMUELSON.
7	MS. SAMUELSON: YES.
8	MS. BONNEVILLE: JEFF SHEEHY.
9	MR. SHEEHY: YES.
10	MS. BONNEVILLE: JONATHAN SHESTACK.
11	MR. SHESTACK: YES.
12	MS. BONNEVILLE: OSWALD STEWARD.
13	DR. STEWARD: YES.
14	MS. BONNEVILLE: JONATHAN THOMAS.
15	CHAIRMAN THOMAS: YES.
16	MS. BONNEVILLE: ART TORRES.
17	MR. TORRES: AYE.
18	MS. BONNEVILLE: KRISTINA VUORI.
19	DR. VUORI: YES.
20	MS. BONNEVILLE: JAMES ECONOMOU.
21	DR. ECONOMOU: YES.
22	CHAIRMAN THOMAS: THANK YOU. CAN WE NOW
23	GET A BRIEF SCIENTIFIC PRESENTATION ON THE PROPOSAL
24	RAISED BY MR. SHESTACK.
25	DR. YAFFE: THIS IS 6239. THE TITLE IS
	336

1	"GENERATION OF MILS SYNDROME NEURONS TO EXPLORE
2	THERAPIES FOR MITOCHONDRIAL DNA DISEASE."
3	THE GOAL OF THE RESEARCH DESCRIBED BY THIS
4	PROPOSAL IS TO DEVELOP A DISEASE-IN-A-DISH MODEL FOR
5	AN INHERITED MITOCHONDRIAL DISEASE. MATERNALLY
6	INHERITED LEIGH'S SYNDROME, MILS, CAUSES SEVERE
7	NEUROLOGICAL DEFECTS IN CHILDREN AND, SIMILAR
8	MITOCHONDRIAL DISORDERS AFFECT ONE IN 2,000
9	INDIVIDUALS.
10	THE FIRST SPECIFIC AIM WILL BE TO GENERATE
11	ADDITIONAL INDUCED PLURIPOTENT STEM CELL LINES AND
12	APPROPRIATE CONTROLS FROM MILS PATIENTS. SECOND AIM
13	IS TO CHARACTERIZE BIOENERGETIC PROFILES OF NEURONS
14	UNDERGOING DIFFERENTIATION FROM PROGENITORS CARRYING
15	MILS MUTANT MITOCHONDRIA. THIRD SPECIFIC AIM WILL
16	BE TO TEST POTENTIAL THERAPEUTIC AGENTS AND DEVELOP
17	NEW APPROACHES FOR DRUG DISCOVERY USING IPS
18	CELL-DERIVED MILS NEURONS.
19	SO THIS PROJECT ADDRESSES ONE OF A LARGE
20	FAMILY OF DISEASES KNOWN AS MITOCHONDRIAL DISEASES.
21	THESE DISEASES AFFECT MITOCHONDRIA, THE POWER PLANTS
22	OF EVERY CELL, AND ARE PARTICULARLY FOCUSED IN USING
23	STEM CELLS AS A WAY TO GENERATE NEURONAL POPULATIONS
24	THAT PRESENT THIS DISEASE.
25	STRENGTHS IDENTIFIED BY THE REVIEWERS
	337

1	INCLUDE THE SIGNIFICANCE AND IMPORTANCE OF
2	DEVELOPING AN EXPERIMENTAL MODEL FOR MITOCHONDRIAL
3	DISEASE, WELL-REASONED STRATEGIES AND METHODS,
4	SUBSTANTIAL PRELIMINARY DATA, AND AN OUTSTANDING AND
5	PROLIFIC INVESTIGATOR.
6	WEAKNESSES INCLUDED SOME CONCERNS ABOUT
7	ASPECTS OF THE PROJECTS'S FEASIBILITY, CERTAIN
8	ASPECTS OF EXPERIMENTAL DESIGN, INADEQUATE
9	DEVELOPMENT OF PART OF THIS STUDY THAT PART
10	SPECIFICALLY RELATES TO AIM 3 AND LACK OF
11	EXPERIENCE OF THE PI AND OTHER KEY PERSONNEL IN
12	WORKING ON MITOCHONDRIAL DISEASE PARTICULARLY.
13	SO IN SUMMARY, THE REVIEWERS FELT THAT
14	THIS IS QUITE SOLID SCIENCE, BUT THE PROPOSAL DID
15	NOT GENERATE AS MUCH ENTHUSIASM AS SOME OF THE
16	HIGHER SCORING GRANTS, THOUGH THERE WERE NO CRITICAL
17	FLAWS IDENTIFIED. AN EXTRAORDINARY PETITION WAS
18	ALSO FILED.
19	MR. SHESTACK: THANK YOU VERY MUCH. DO WE
20	HAVE MUCH IN OUR PORTFOLIO IN THE BASIC BIO OR ANY
21	OF THE OTHER GRANTS MECHANISMS ON MITOCHONDRIAL
22	DISEASE?
23	DR. YAFFE: THERE ARE PERHAPS WELL,
24	ACTUALLY ONE OF THE GRANTS YOU APPROVE SHORTLY, I
25	EXPECT YOU WILL APPROVE, THAT'S IN TIER I, REFERS TO
	338

1	ENERGY METABOLISM AND MITOCHONDRIA AND AGING CELLS.
2	WE ALSO HAVE SEVERAL GRANTS DEALING WITH
3	MITOCHONDRIAL DISEASE THAT WERE IN EARLIER ROUNDS OF
4	BASIC BIOLOGY.
5	MR. SHESTACK: THANK YOU.
6	DR. VUORI: SO THE EXTRAORDINARY PETITION
7	APPEARS TO ADDRESS, ACCORDING TO THE COVER LETTER BY
8	THE APPLICANT, SOME OF THE MAJOR CRITICISM, AND IT'S
9	A NEW INFORMATION THAT IS PROVIDED HERE. COULD YOU
10	COMMENT ON THAT?
11	DR. YAFFE: THERE IS NEW INFORMATION.
12	THERE'S DATA. WE DON'T HAVE THE OPPORTUNITY TO
13	REVIEW THAT DATA. IT'S UNPUBLISHED, NONREVIEWED
14	DATA THAT ATTEMPTS TO ADDRESS A SPECIFIC CRITICISM
15	ABOUT THE LACK OF BIOENERGETIC ANALYSIS AND
16	DIFFERENCES BETWEEN THE MILS CELLS AND NORMAL CELLS.
17	THE APPLICANT ALSO ADDRESSES IN HIS OR HER
18	WAY THE OTHER CRITICISMS, MAYBE A DIFFERENCE IN
19	SCIENTIFIC OPINION REPRESENTED BY THE CRITICISMS OF
20	THE REVIEWERS.
21	CHAIRMAN THOMAS: DR. LUBIN.
22	DR. LUBIN: DO THEY COMMENT ON THE
23	FREQUENCY OR THE RARITY OF THESE CONDITIONS? AND DO
24	THEY HAVE A BANK OF CELLS NOW THAT THEY'VE ALREADY
25	OBTAINED FROM FAMILIES BECAUSE THESE ARE RARE?
	339

1	DR. YAFFE: THIS IS RARE. THEY HAVE SOME
2	COLLABORATORS WHO ARE WORKING AT A CENTER FOR
3	MITOCHONDRIAL DISEASE WHO HAVE INDICATED THE
4	AVAILABILITY OF CELLS FROM PATIENTS WITH THIS
5	DISORDER.
6	DR. TROUNSON: I DIDN'T NOTICE THIS
7	PARTICULARLY IN THE REVIEW, BUT THERE IS A BIT OF A
8	PROBLEM WITH THESE IPS STUDIES. WHAT HAPPENS A LOT
9	WITH MITOCHONDRIA, IT'S INHERITED IN A HETEROPLASMIC
10	WAY. SO UNLESS THE HETEROPLASMIA, WHICH IS THE
11	PROBLEM, IS ACTUALLY INHERITED, THEN IT'S NOT A
12	PROBLEM, IF YOU KNOW WHAT I MEAN. IT DOESN'T
13	CONTINUE. IT'S NOT LIKE A GENOMICS PROBLEM. SO
14	THERE'S LARGE NUMBERS OF MITOCHONDRIA. AND
15	FREQUENTLY IN MAKING IPS CELLS YOU LOSE ALL OF THE
16	ABNORMAL MITOCHONDRIA.
17	SO UNLESS THE STUDIES ACTUALLY PROVE THAT
18	IT CONTINUES ON WHEN YOU ACTUALLY MAKE THE IPS
19	CELLS, YOU HAVE A FLAWED STUDY. I ASKED THE
20	SCIENTIST WHETHER THIS FLAW REALLY HAD BEEN
21	ADDRESSED, AND IT HASN'T BEEN ADDRESSED. I THINK
22	IT'S A FATAL FLAW. IF IT DOESN'T GO ACROSS WHEN YOU
23	MAKE AN IPS CELL, YOU JUST HAVE A NORMAL CELL, NOT A
24	DISEASE CELL. AND IT'S A HUGE AND IMPORTANT ISSUE
25	TO ADDRESS. I DON'T THINK IT WAS REALLY PROPERLY
	340

1	ADDRESSED AS FAR AS I COULD TELL.
2	DR. PIZZO: THANKS FOR RAISING THAT, ALAN.
3	ISN'T IT TRUE, THOUGH, FOR EMBRYONIC STEM CELLS AS
4	WELL? THIS IS AN ISSUE OF MITOCHONDRIA PASSING.
5	DR. TROUNSON: LESS SO. LESS SO FROM THE
6	DATA THAT'S BEEN DERIVED. BASICALLY YOU'RE TAKING A
7	SOMATIC CELL AND THEN YOU'RE GOING TO REPROGRAM
8	THAT. YOU'RE SELECTING A VERY FEW CELLS THAT HAVE
9	ACTUALLY BEEN REPROGRAMMED. THE REPROGRAMMED CELLS
10	TEND TO CONTAIN A SET OF MITOCHONDRIA WHICH IS NOT
11	ABNORMAL, MUCH MORE SO THAN AN EMBRYONIC STEM CELL,
12	WHICH WOULD BE DERIVED FROM A MITOCHONDRIAL DISEASE
13	PATIENT.
14	DR. PIZZO: IT STILL IS AN ISSUE.
15	DR. TROUNSON: IT IS STILL AN ISSUE, BUT
16	THEY DO USE MITOCHONDRIAL TRANSPLANTS, OR THEY'RE
17	TRYING TO USE MITOCHONDRIAL TRANSPLANTS TO CORRECT
18	THIS IN EGGS AND EMBRYOS, BUT IT HASN'T WORKED AS
19	SUCH AT THE MOMENT IN THE HUMAN. I THINK THIS IS A
20	REAL PROBLEM IN IPS, A REAL PROBLEM. AND I THINK TO
21	A LESSER EXTENT IT REMAINS A PROBLEM IN EMBRYONIC
22	STEM CELLS.
23	CHAIRMAN THOMAS: HAVING HEARD THIS
24	DISCUSSION, DO I HEAR A MOTION TO APPROVE FUNDING
25	FOR THIS APPLICATION? HEARING NONE, THANK YOU, DR.
	341

1	YAFFE.
2	WE'LL MOVE ON. ARE THERE ANY OTHER
3	APPLICATIONS THAT MEMBERS OF THE BOARD WISH TO
4	ELEVATE FROM TIER III TO TIER I?
5	DR. VUORI: MR. CHAIRMAN, I WOULD LIKE TO
6	HEAR SCIENCE OFFICER PRESENTATION ON APPLICATION
7	6277.
8	DR. SCHEINER: I'M ZACH SCHEINER, SCIENCE
9	OFFICER AT CIRM. THIS IS APPLICATION 6277, ENTITLED
10	"MODELING ALEXANDER DISEASE USING PATIENT-SPECIFIC
11	INDUCED PLURIPOTENT STEM CELLS."
12	SO THIS APPLICATION PROPOSES TO GENERATE A
13	DISEASE-IN-A-DISH MODEL OF ALEXANDER'S DISEASE.
14	ALEXANDER'S DISEASE IS A RARE GENETIC DISORDER
15	CAUSED BY MUTATIONS IN A PROTEIN CALLED GFAP. GFAP
16	IS ONE OF THE MAJOR STRUCTURAL PROTEINS IN
17	ASTROCYTES, WHICH ARE ONE OF THE THREE MAJOR CELL
18	TYPES OF THE BRAIN. MUTATIONS IN GFAP CAUSE
19	ASTROCYTE DYSFUNCTION AND DEATH WHICH LEAD TO
20	NEURODEGENERATION IN PATIENTS WITH ALEXANDER'S
21	DISEASE.
22	THE APPLICANT PROPOSES TO GENERATE INDUCED
23	PLURIPOTENT STEM CELLS FROM ALEXANDER'S DISEASE AND
24	DIFFERENTIATE THESE CELLS INTO ASTROCYTES. THE
25	APPLICANT WOULD THEN USE THESE ASTROCYTES TO MODEL

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1	THE DISEASE, EXPLORE POTENTIAL MOLECULAR MECHANISMS,
2	AND TEST COMPOUNDS THAT MIGHT IMPROVE DISEASE
3	PATHOLOGY.
4	SO I'LL BRIEFLY SUMMARIZE THE STRENGTHS
5	AND WEAKNESSES OF THE PROPOSAL AS IDENTIFIED BY THE
6	GRANTS WORKING GROUP. THE MAIN STRENGTH IS NOVELTY
7	AND IMPORTANCE OF STUDYING ASTROCYTES. REVIEWERS
8	AGREED THAT ASTROCYTE BIOLOGY IS UNDERSTUDIED, AND
9	THIS PROJECT COULD CONTRIBUTE SIGNIFICANTLY TO THAT
10	FIELD IF SUCCESSFUL. THE PI WAS ALSO VIEWED AS A
11	STRENGTH OF THE PROPOSAL.
12	THERE WERE THREE MAIN WEAKNESSES
13	IDENTIFIED BY REVIEWERS, AND THESE ARE THE FIRST
14	THREE BULLETS UNDER FEASIBILITY AND EXPERIMENTAL
15	DESIGN IN THE REVIEW SUMMARY. THE FIRST IS THAT
16	REVIEWERS, "DID NOT FIND THE PRELIMINARY DATA
17	CONVINCING THAT ALL TECHNIQUES REQUIRED TO
18	SUCCESSFULLY EXECUTE THE PROGRAM ARE ESTABLISHED IN
19	THE PI'S LABORATORY." THE SECOND IS THAT THE
20	INDEPENDENCE OF THE SPECIFIC AIMS COULD JEOPARDIZE
21	THE SUCCESS OF THE PROGRAM. IN OTHER WORDS, IF AIM
22	1 AND 2 DON'T SUCCEED, THE CRITICAL AIM 3 WOULD NOT
23	EITHER. AND THE THIRD MAJOR WEAKNESS WAS THAT THE
24	NARROW PATHWAY FOCUS OF THE MECHANISTIC STUDIES WAS
25	JUDGED TO BE HIGH RISK. REVIEWERS WOULD HAVE LIKED
	343

1	TO SEE WORK PROPOSED ON OTHER SIGNALING PATHWAYS.
2	SO THE REVIEWERS WEIGHED THESE STRENGTHS
3	AND WEAKNESSES, ULTIMATELY VOTED TO PLACE THIS IN
4	TIER III, NOT RECOMMENDED FOR FUNDING. AN
5	EXTRAORDINARY PETITION WAS FILED BY THE APPLICANT ON
6	AUGUST 31ST. I'D BE HAPPY TO ANSWER QUESTIONS ABOUT
7	THAT OR THE REVIEW.
8	DR. POMEROY: COULD YOU BRIEFLY SUMMARIZE
9	THE EXTRAORDINARY PETITION FOR US?
10	DR. SCHEINER: SO THE OPINION OF CIRM
11	SO THE PETITION RESPONSE TO THE MAIN CRITICISMS OF
12	THE REVIEW, CIRM SCIENTIFIC STAFF OPINION IS THAT
13	THERE ARE NO FATAL FLAWS. THIS APPLICATION WAS
14	JUDGED TO BE OF A LOWER QUALITY THAN THE ONES ABOVE
15	IN SCIENTIFIC TERMS.
16	THE EXTRAORDINARY PETITION DOES NOT
17	CONTAIN NEW INFORMATION THAT WOULD MATERIALLY AFFECT
18	THE REVIEW, IN THE OPINION OF CIRM STAFF. THE
19	APPLICANT DOES INDICATE THAT THEY HAVE GENERATED NEW
20	DATA SINCE THE TIME OF THE GRANT SUBMISSION, BUT
21	IT'S JUST A DESCRIPTION OF THE DATA, AND IT DOESN'T
22	FULLY SATISFY THE REVIEWER CRITIQUES OF THE
23	PRELIMINARY DATA. I COULD GO INTO MORE DETAIL, BUT
24	THAT WOULD PROBABLY BE CONFIDENTIAL, PROPRIETARY.
25	CHAIRMAN THOMAS: DR. VUORI.
	344

3 1 1

DR. VUORI: I WAS STRUCK BY THE NOTION
THAT THERE IS NO REAL PORTFOLIO WITHIN CIRM FOCUSING
ON ASTROCYTES. COULD YOU COMMENT ON THAT A LITTLE
BIT?
DR. SCHEINER: SO TO DATE I DON'T THINK WE
HAVE ANY BASIC RESEARCH PROPOSALS IN ASTROCYTE
BIOLOGY. THERE IS ONE OTHER PROPOSAL IN THIS ROUND
THAT IS RECOMMENDED FOR FUNDING. SEE IF I CAN MOVE
DOWN THE I THINK I JUST MOVED TOO FAR DOWN. BUT
IT IS 6041 HERE, SCORE OF 68, RECOMMENDED FOR
FUNDING. SO THERE IS ONE RECOMMENDED IN THIS ROUND,
BUT BESIDES THAT ONE, WE DO NOT HAVE IT REPRESENTED
IN OUR PORTFOLIO.
THERE'S ALSO I'M SORRY ALSO A
TRANSLATIONAL GRANT THAT I WASN'T AWARE OF.
CHAIRMAN THOMAS: HAVING HEARD ALL THIS
DISCUSSION, IS THERE A MOTION TO ELEVATE FROM TIER
III TO TIER I? WE HAVE A MEMBER OF THE PUBLIC THAT
WOULD LIKE TO COMMENT? MR. HARRISON, IS THIS
APPROPRIATE FOR PUBLIC COMMENT AT THIS POINT? YES,
PLEASE. STATE YOUR NAME. THREE MINUTES, PLEASE.
DR. SHI: MR. CHAIRMAN, MEMBERS OF THE
BOARD, I AM YANHONG SHI, ASSOCIATE PROFESSOR FROM
CITY OF HOPE. I AM HERE TO ASK YOU TO CONSIDER
FUNDING MY APPLICATION RB 406277, MODELING ALEXANDER
345

1	DISEASE USING PATIENT-SPECIFIC INDUCED PLURIPOTENT
2	STEM CELLS, ALSO CALLED IPSC'S.
3	AS WE JUST HEARD, THIS PROPOSAL RECEIVED A
4	SCORE OF 70, ONLY ONE POINT BELOW THE 71 WHICH WAS
5	PROPOSED FOR FUNDING, AND SIX POINTS ABOVE THE
6	LOWEST SCORE RECOMMENDED FOR FUNDING.
7	I SPEAK HERE ON BEHALF OF CHILDREN WHO
8	SUFFER FROM ALEXANDER DISEASE, A NEUROLOGICAL
9	DISORDER THAT DESTROYS THEIR LIVES AND CAUSES A HUGE
10	TOLL BOTH ON THEIR FAMILIES AND ON SOCIETY. THIS
11	DISEASE OCCURS IN MANY ETHNIC AND RACIAL GROUPS WITH
12	ABOUT 12 PERCENT OF U.S. CASES HERE IN CALIFORNIA.
13	IT PRIMARILY AFFECTS ASTROCYTES, THE LONG NEURONAL
14	CELLS IN THE BRAIN THAT'S EXTREMELY UNDERSTUDIED.
15	THE MOST COMMON FORM OF THE DISEASE OCCURS
16	IN THE FIRST TWO YEARS OF LIFE. PATIENTS USUALLY
17	DIE BY THE AGE OF SIX. SYMPTOMS INCLUDE MENTAL
18	RETARDATION, SEIZURES, AND SPASTICITY. TODAY THERE
19	IS NO CURE OR EVEN A STANDARD TREATMENT FOR THESE
20	CHILDREN.
21	WE HAVE A PROPOSAL THAT A NEW STEM CELL
22	APPROACH CAN BE USED TO STUDY AND DEVELOP TREATMENTS
23	FOR THIS DISEASE. WE WILL MAKE IPSC'S FROM PATIENTS
24	TO ESTABLISH THE FIRST PATIENT-SPECIFIC CELLULAR
25	MODEL FOR THIS DISEASE THAT WILL BE USED FOR DRUG
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1	DISCOVERY AND THERAPY DEVELOPMENT. OUR FUNDING ON
2	ALEXANDER DISEASE WILL ALSO BENEFIT MANY OTHER
3	NEUROLOGICAL CONDITIONS THAT INVOLVE ASTROCYTE
4	DYSFUNCTION, INCLUDING ALZHEIMER'S, PARKINSON'S, AND
5	HUNTINGTON'S DISEASE, MS, AND ALS.
6	MY SCIENTIFIC REBUTTAL TO THE REVIEWERS'
7	COMMENTS IS DETAILED IN THE PETITION LETTER THAT'S
8	IN FRONT OF YOU. I JUST WANTED TO POINT OUT THAT WE
9	HAVE ESTABLISHED KEY TECHNIQUES REQUIRED FOR THIS
10	PROJECT, ASSEMBLED A TEAM OF INTERNATIONALLY
11	RENOWNED STEM CELL SCIENTIST, AND GENERATED
12	SUFFICIENT DATA TO WARRANT SUCCESS OF THIS PROJECT.
13	IN SUPPORT OF MY PETITION, THREE LETTERS
14	HAVE BEEN SENT TO YOU, TWO FROM PATIENT ADVOCACY
15	GROUPS AND A THIRD LETTER FROM A PHYSICIAN WHO TAKES
16	CARE OF THESE PATIENTS. THEY BELIEVE THAT OUR
17	PROPOSED STUDY IS THE ONLY PRACTICAL WAY TO
18	INVESTIGATE THE PATHOLOGY OF ALEXANDER DISEASE AND
19	BEST CHANCE TO TREAT IT. WE HOPE THAT THROUGH OUR
20	RESEARCH THESE CHILDREN CAN BE SAVED TO LIVE A
21	NORMAL AND FULFILLING LIFE. THANK YOU FOR YOUR
22	ATTENTION. ON BEHALF OF CHILDREN WITH ALEXANDER
23	DISEASE AND OTHER RELATED DISEASES, I HOPE YOU WILL
24	APPROVE OUR PROPOSAL FOR FUNDING.
25	CHAIRMAN THOMAS: THANK YOU, DOCTOR.
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1	MS. SAMUELSON: MR. CHAIRMAN, I'VE BEEN
2	LOOKING A LITTLE TOO LATE, I REALIZE, AT THE SUMMARY
3	AND SEEING THAT THERE ARE IMPLICATIONS FOR OTHER
4	DEGENERATIVE DISEASES, AS THE SPEAKER SAID, AND THAT
5	IT'S NOT ONLY HIGH RISK, IT'S HIGH RETURN, THAT THE
6	PROJECT COULD YIELD IMPORTANT RESULTS THAT WILL
7	CONTRIBUTE TO THE FIELD, AND THAT WAS AGREED TO BY
8	ALL REVIEWERS. SO IT SEEMS TO ME IT FALLS INTO THAT
9	CATEGORY OF BASIC BIOLOGY THAT REALLY COULD BE
10	FUELING THE TRANSLATIONAL EFFORTS AT THE SAME TIME.
11	SO I WOULD MOVE ITS FUNDING.
12	CHAIRMAN THOMAS: MOVED BY JOAN TO FUND
13	THIS. IS THERE A SECOND?
14	DR. VUORI: I'LL SECOND.
15	CHAIRMAN THOMAS: DR. VUORI. FURTHER
16	DISCUSSION BY MEMBERS OF THE BOARD? JOAN, EVERYBODY
17	DIDN'T HEAR, HER KEY POINT WAS THAT THIS IS
18	APPLICABLE TO A VARIETY OF CONDITIONS AND COULD
19	POTENTIALLY ADVANCE THE BALL ON MULTIPLE FRONTS, AND
20	IT IS HIGH RISK, HIGH REWARD, I THINK WHAT YOU WERE
21	SAYING.
22	MS. SAMUELSON: BASIC BIOLOGY IN A
23	TRANSLATIONAL CONTEXT. THAT'S IMPORTANT.
24	DR. PIZZO: I WONDER IS IT POSSIBLE TO
25	HAVE THE QUESTION THAT ALAN RAISED, WHICH IS WITH
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	DARRISIERS REPORTING SERVICE
1	REGARD TO THE WHOLE WELL, NO. I'LL WITHDRAW.
2	CHAIRMAN THOMAS: OTHER COMMENTS BY
3	MEMBERS OF THE BOARD?
4	DR. DULIEGE: AT THIS POINT ARE WE
5	CONSIDERING THIS MOTION PURELY ON THE SCIENTIFIC
6	MERIT AND IGNORING THE FINANCIAL IMPACT OF IT ON THE
7	BUDGET?
8	CHAIRMAN THOMAS: YES.
9	DR. DULIEGE: OKAY. THANK YOU.
10	CHAIRMAN THOMAS: ANY FURTHER DISCUSSION?
11	MARIA, WILL YOU PLEASE CALL THE ROLL.
12	MS. BONNEVILLE: ROBERT PRICE.
13	DR. PRICE: ABSTAIN.
14	MS. BONNEVILLE: DAVID BRENNER.
15	DR. BRENNER: NO.
16	MS. BONNEVILLE: JACOB LEVIN.
17	DR. LEVIN: YES.
18	MS. BONNEVILLE: ANNE-MARIE DULIEGE.
19	DR. DULIEGE: YES.
20	MS. BONNEVILLE: MARCY FEIT.
21	MS. FEIT: YES.
22	MS. BONNEVILLE: LEEZA GIBBONS.
23	MS. GIBBONS: YES.
24	MS. BONNEVILLE: SAM HAWGOOD.
25	DR. HAWGOOD: NO.
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1	MS. BONNEVILLE: STEPHEN JUELSGAARD.
2	SHERRY LANSING. BERT LUBIN.
3	DR. LUBIN: NO.
4	MS. BONNEVILLE: LEON FINE.
5	DR. FINE: NO.
6	MS. BONNEVILLE: PHIL PIZZO.
7	DR. PIZZO: YES.
8	MS. BONNEVILLE: CLAIRE POMEROY.
9	DR. POMEROY: ABSTAIN.
10	MS. BONNEVILLE: FRANCISCO PRIETO.
11	DR. PRIETO: YES.
12	MS. BONNEVILLE: CARMEN PULIAFITO.
13	DR. PULIAFITO: NO.
14	MS. BONNEVILLE: ROBERT QUINT.
15	DR. QUINT: ABSTAIN.
16	MS. BONNEVILLE: DUANE ROTH.
17	MR. ROTH: ABSTAIN.
18	MS. BONNEVILLE: JOAN SAMUELSON.
19	MS. SAMUELSON: YES.
20	MS. BONNEVILLE: JEFF SHEEHY.
21	MR. SHEEHY: YES.
22	MS. BONNEVILLE: JONATHAN SHESTACK.
23	MR. SHESTACK: YES.
24	MS. BONNEVILLE: OSWALD STEWARD.
25	DR. STEWARD: NO.
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1	MS. BONNEVILLE: JONATHAN THOMAS.
2	CHAIRMAN THOMAS: YES.
3	MS. BONNEVILLE: ART TORRES.
4	MR. TORRES: ABSTAIN.
5	MS. BONNEVILLE: KRISTINA VUORI.
6	DR. VUORI: YES.
7	MS. BONNEVILLE: JAMES ECONOMOU.
8	DR. ECONOMOU: NO.
9	CHAIRMAN THOMAS: IT WOULD APPEAR, MR.
10	HARRISON, THAT THE MOTION PASSES. COULD BE WRONG.
11	DR. PIZZO: YOU SOUND LIKE CNN.
12	MR. HARRISON: THE MOTION CARRIES BY A
13	VOTE OF 11 YES, SEVEN NO, AND FIVE ABSTENTIONS.
14	DR. PIZZO: NOW YOU'RE PBS.
15	CHAIRMAN THOMAS: THANK YOU. ARE THERE
16	ANY OTHER PROPOSALS THAT ANYBODY WOULD LIKE TO RAISE
17	FROM TIER III TO TIER I?
18	DR. LUBIN: SO I WOULD LIKE TO HEAR 06117
19	DISCUSSED, PLEASE, SCIENTIFICALLY.
20	DR. WHITTLESEA: THANK YOU, MR. CHAIRMAN,
21	MEMBERS OF THE BOARD. I'M KEVIN WHITTLESEA, SCIENCE
22	OFFICER AT CIRM. HAPPY TO PRESENT YOU WITH A REVIEW
23	OF APPLICATION 6117. THIS PROJECT IS ENTITLED "IN
24	VITRO 3D MODEL OF VASCULAR DISEASES." THIS PROJECT
25	PROPOSES TO DEVELOP A NEW MODEL OF VASCULAR DISEASES
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1	SUCH AS ATHEROSCLEROSIS. PROJECT BUILDS ON PREVIOUS
2	WORK BY THE APPLICANT WHICH A NOVEL TYPE OF
3	MULTIPOTENT VASCULAR STEM CELLS, WHICH ARE REFERRED
4	TO AS A VSC, WAS DISCOVERED USING AN ANIMAL MODEL.
5	THE WORK PROPOSED WILL USE A 3D CULTURE
6	SYSTEM TO MIMIC FORCES IN BLOOD CIRCULATION TO STUDY
7	VSC ROLES TO STUDY THE VSC'S BIOLOGY AND THE ROLE
8	THAT THEY MIGHT PLAY IN VASCULAR DISEASE.
9	COUPLE NOTES. BASICALLY THE KEY IT WAS
10	WELL SCORED. IT WAS SCORED AS A 67, NOT RECOMMENDED
11	FOR FUNDING. THE KEY CRITICISMS BY THE GRANTS
12	WORKING GROUP WERE IN THE AREA OF FEASIBILITY. I'LL
13	OUTLINE SOME OF THE POINTS IN EACH OF THE KEY
14	CATEGORIES.
15	SIGNIFICANCE AND INNOVATION WAS VIEWED AS
16	HIGHLY SIGNIFICANT IN THAT THEY HAVE THE POTENTIAL
17	TO CHANGE THE WAY WE UNDERSTAND VASCULAR REMODELING.
18	THE STUDIES WERE VIEWED AS INNOVATIVE SINCE THEY'RE
19	STUDYING A NOVEL CELL POPULATION THAT HAVE THE
20	POTENTIAL TO DIFFERENTIATE INTO MULTIPLE LINEAGES.
21	REGARDING FEASIBILITY AND EXPERIMENTAL
22	DESIGN, REVIEWERS WERE NOT CONVINCED BY PRELIMINARY
23	DATA PROVIDED TOWARD THE ABILITY TO ISOLATE THESE
24	VSC'S FROM HUMAN CELLS. I MENTIONED THEY WERE
25	DISCOVERED IN AN ANIMAL MODEL. IT'S WHETHER OR NOT
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1	THAT'S GOING TO TRANSLATE TO HUMAN TISSUE THAT WAS
2	AN OUTSTANDING QUESTION.
3	AND ADDITIONAL QUESTIONS LIKE THAT MIGHT
4	BROACH INTO CONFIDENTIAL INFORMATION, WHICH I'M
5	PREPARED TO DISCUSS EITHER HERE OR IN CONFIDENTIAL
6	SESSION.
7	THERE WAS NO EVIDENCE OF THE ABILITY TO
8	ISOLATE VASCULAR STEM CELLS FROM DISEASED HUMAN
9	TISSUE. THERE'S ONE OF THE QUESTIONS. PRELIMINARY
10	DATA WERE PROVIDED SHOWING THE ABILITY TO ISOLATE
11	FROM HUMAN TISSUE, BUT THERE WAS CONCERN EXPRESSED
12	THAT ABILITY TO ISOLATE FROM DISEASE TISSUE MIGHT
13	POSE ADDITIONAL CHALLENGES. AND THAT WAS THE
14	ABILITY TO COMPARE BOTH NORMAL AND DISEASED TISSUE.
15	THESE CELLS ISOLATED FROM NORMAL AND DISEASED TISSUE
16	WAS A PART OF THE APPLICATION. SO THAT WAS
17	CERTAINLY A CONSIDERATION.
18	AND THE PROPOSED STUDIES I MENTIONED
19	THEY WERE STUDYING FORCES APPLIED RELATED TO THE
20	VASCULAR SYSTEM AND HOW THOSE AFFECT REMODELING AND
21	THESE VSC'S. THERE WAS A CUSTOM 3D BIOREACTOR
22	DESCRIBED IN THE APPLICATION. THERE WAS NO EVIDENCE
23	PROVIDED THAT THAT BIOREACTOR WAS ACTUALLY
24	PHYSICALLY DEVELOPED AND IN PLACE, AND THERE WERE
25	SOME QUESTIONS ABOUT FEASIBILITY IN TERMS OF HOW

1	MUCH EFFORT MIGHT GO INTO THAT SYSTEM AND DEVELOPING
2	AND CHARACTERIZING THAT BIOREACTOR SYSTEM.
3	THE PI AND RESEARCH TEAM WERE VIEWED AS
4	HAVING ALL THE EXPERTISE REQUIRED TO CONDUCT THE
5	PROPOSED STUDIES. THIS WAS VIEWED AS RESPONSIVE TO
6	THE RFA, STUDYING A MULTIPOTENT HUMAN STEM CELL. AN
7	EXTRAORDINARY PETITION WAS SUBMITTED REGARDING THIS
8	APPLICATION. HAPPY TO ANSWER ANY QUESTIONS.
9	DR. LUBIN: CAN YOU COMMENT ON THE
10	EXTRAORDINARY PETITION?
11	DR. WHITTLESEA: THE EXTRAORDINARY
12	PETITION DIDN'T PROVIDE ANY NEW ADDITIONAL DATA.
13	THERE WERE COMMENTS PROVIDED THERE WERE SOME
14	PROGRAMMATIC ARGUMENTS MADE ABOUT A LACK OF
15	MECHANISTIC STUDIES IN THE CIRM PORTFOLIO RELATED TO
16	ATHEROSCLEROSIS AND RESTENOSIS. THERE WAS MENTION
17	MADE, THE CRITICISM I MENTIONED ABOUT WHETHER OR NOT
18	THE 3D BIOREACTOR HAD BEEN ESTABLISHED AND
19	DEVELOPED. A CLAIM WAS MADE IN THE EXTRAORDINARY
20	PETITION THAT IS THE CASE, THAT THE BIOREACTOR IS IN
21	PLACE. BUT, AGAIN, NO DATA WERE PROVIDED TO
22	DEMONSTRATE THAT.
23	AND THEN THERE WAS A POINT MADE REGARDING
24	THE ABILITY TO ISOLATE THESE CELLS FROM HUMAN
25	PATIENTS. THE EXTRAORDINARY PETITION CLAIMED THAT

1	VSC'S HAD BEEN ISOLATED FROM DISEASED TISSUE FROM
2	NORMAL AND DISEASED TISSUE FROM TEN PATIENTS, BUT WE
3	DIDN'T SEE ANY DATA THERE.
4	DR. LUBIN: WERE THERE COMMENTS ABOUT THE
5	PAPER IN NATURE DESCRIBING THIS AS A NEW STEM CELL
6	THAT'S NEVER BEEN IDENTIFIED BEFORE?
7	DR. WHITTLESEA: YES. THAT WAS MENTIONED
8	IN THE PAPER. THAT WAS REFLECTIVE OF THE ANIMAL
9	MODEL DATA THAT I DESCRIBED. THERE WAS A
10	PUBLICATION RECENTLY IN NATURE COMMUNICATION
11	DESCRIBING THESE OBSERVATIONS IN ANIMAL STUDIES.
12	CHAIRMAN THOMAS: THANK YOU, DR.
13	WHITTLESEA. HAVING HEARD THIS DISCUSSION, IS THERE
14	A MOTION BY A MEMBER OF THE BOARD TO ELEVATE THIS
15	FROM TIER III TO TIER I? HEARING NONE, WE HAVE ONE
16	COMMENT FROM A MEMBER OF THE PUBLIC.
17	DR. LI: HI, EVERYONE. I'M SONG LI,
18	PROFESSOR OF BIOENGINEERING AT UC BERKELEY, AND THE
19	PI OF THIS PROPOSAL. I REALLY APPRECIATE THIS
20	OPPORTUNITY TO SPEAK AND MAKE SOME POINTS.
21	SO, FIRST, I WANT TO SAY THIS PROJECT IS
22	UNIQUE. IT'S GROUNDBREAKING, NOVEL, AND WILL HAVE
23	HIGH IMPACT. WE IDENTIFIED THESE NOVEL STEM CELLS,
24	AS PUBLISHED IN THIS RECENT PAPER, AND THESE CELLS
25	ARE DORMANT CELLS IN THE BLOOD VESSEL WALL; AND THEN

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1	THEY'RE ACTIVATED, THEY CAN DIFFERENTIATE INTO BONE,
2	CARTILAGE, FAT CELLS, ETC., IN ATHEROSCLEROSIS AND
3	RESTENOSIS.
4	SO THIS COULD CAUSE HEART ATTACK AND
5	STROKE THAT WILL AFFECT EVERY ONE OF US IN THE
6	LIFETIME SOONER OR LATER. IN THE PAST 50 YEARS,
7	VASCULAR DISEASE IS CONSIDERED THE RESULT FROM
8	SMOOTH MUSCLE CELL OVERPROLIFERATION. BUT STUDY
9	REALLY SHOWED THAT STEM CELLS RATHER THAN SMOOTH
10	MUSCLE CELLS ACCOUNT FOR THIS DISEASE. SO THIS IS A
11	PARADIGM SHIFT. IN A NEWS ACTUALLY PEOPLE ALSO
12	NOTED THAT IT'S GROUNDBREAKING, AND IT WAS WIDELY
13	COVERED BY THE NEWS MEDIA, IT WAS HIGHLIGHTED IN
14	NATURE, AND IT WAS IN THE FRONT PAGE OF SAN
15	FRANCISCO CHRONICLE, FOX NEWS, NATIONAL RADIO
16	STATION, ETC.
17	SO IN ADDITION, WE HAVE THIS TRANSLATIONAL
18	COMPONENT IN THE SPECIFIC AIM. WHAT WE PROPOSE TO
19	DO IS DEVELOP HIGH THROUGHPUT SCREENING SYSTEM, THE
20	PLATFORM WITH A MICROARRAY OF THESE MICROTISSUES FOR
21	DRUG SCREENING. AND IT COULD LEAD TO THE
22	IDENTIFICATION OF NEW COMPOUNDS. SO THIS RESEARCH
23	WILL REALLY OPEN THE DOOR TO A LOT OF POSSIBILITIES
24	FOR NEW THERAPIES. FOR EXAMPLE, YOU CAN TARGET
25	THESE STEM CELLS, INSTEAD OF SMOOTH MUSCLE CELLS,
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1	FOR THERAPIES. THE DRUG CAN TARGET NOT
2	PROLIFERATION, BUT ALSO THE DIFFERENTIATION OF THE
3	CELLS INTO BONE OR CARTILAGE CELLS. THEN WE CAN
4	PREVENT THE PROGRESSION OF DISEASE, THE HARDENING OF
5	BLOOD VESSEL, ETC.
6	SO REGARDING THE TECHNICAL ISSUE, I WAS
7	NOT SURE WHETHER I SHOULD BE INCLUDING ALL THE DATA,
8	INCLUDING IN THIS PETITION, SO I DIDN'T. BUT
9	ACTUALLY, FOR THE STEM CELLS, WE HAVE ISOLATED ALL
10	THE CELLS FROM BOTH DISEASE VESSEL. IN A NORMAL
11	VESSEL THERE'S NO TECHNICAL ISSUE.
12	REGARDING THE BIOREACTOR, WE HAVE ALL THIS
13	BIOREACTOR THE PAST TEN YEARS IN THE LAB ALREADY.
14	WE USED THAT AND HAVE A LOT OF PUBLICATION WITH
15	THAT. WE PROPOSE TO INTEGRATE THIS INTO ARRAY
16	SYSTEM WITH HUNDREDS OR EVEN THOUSANDS OF ARRAYS OF
17	MICROTISSUES. THAT'S WHAT WE'RE GOING TO DO.
18	WE HAVE A WORLD CLASS COLLABORATOR, A
19	CO-PI, ON THE MICROTECHNOLOGY TO MAKE THIS HAPPEN.
20	FINALLY, I WANT TO ASK FOR THE
21	PROGRAMMATIC CONSIDERATION BECAUSE THIS IS A NEW
22	AREA, EMERGING AREA, IT HAS NOT BEEN COVERED BY CIRM
23	IN THE PAST, AND EVEN ATHEROSCLEROSIS, INCLUDING
24	THIS STEM CELL CONCEPT. IT'S A NEW, EMERGING TOPIC
25	AND SHOULD BE. HOPEFULLY YOU CAN INCLUDE THIS IN
	357
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1	THE CONSIDERATION. THANK YOU.
2	CHAIRMAN THOMAS: THANK YOU, DOCTOR.
3	HAVING HEARD PUBLIC COMMENT, IS THERE A MOTION BY
4	ANY MEMBER OF THE BOARD TO ELEVATE THIS FROM TIER
5	III TO TIER I? HEARING NONE, THAT CONCLUDES
6	DISCUSSION ON THAT TOPIC.
7	ARE THERE ANY OTHER? WE'RE RIGHT AROUND
8	THE CLUBHOUSE TURN, HOME STRETCH, JUST ABOUT TO
9	COMPLETE BASIC BIO. ANY OTHER TIER IIIS ANYBODY
10	WOULD LIKE TO ELEVATE TO TIER I?
11	MR. SHESTACK: I JUST HAVE TWO THINGS I
12	JUST WOULD ASK I'D ASK DR. LUBIN ONE MORE TIME.
13	I THINK THAT YOU FELT THIS WAS VERY NOVEL,
14	UNREPRESENTED BY CIRM, AND A CHANCE TO MAKE EXCITING
15	HEADWAY. SO I JUST WANT TO ASK WHEN I ASKED YOU
16	WHY YOU PULLED THIS OUT
17	DR. LUBIN: I DIDN'T GET A SENSE FROM
18	AROUND THIS TABLE THAT PEOPLE WERE GOING TO APPROVE
19	THIS, SO I DIDN'T SAY I RECOMMEND APPROVAL. I CAN
20	SAY THAT AND NO ONE CAN SECOND IT, AND THE SAME
21	EVENT COULD OCCUR. I THINK IT'S HIGHLY VALUABLE AND
22	IT'S VERY NOVEL, AND WE DON'T HAVE ANYTHING IN OUR
23	PORTFOLIO ABOUT CORONARY DISEASES OR BLOOD VESSEL
24	PATHOLOGY AND STEM CELLS. WE HAVE A LOT ABOUT
25	CARDIAC MUSCLE AND NOTHING ABOUT THIS PATHOLOGY AND
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1	NOTHING ABOUT THE OPPORTUNITY TO SCREEN FOR DRUGS
2	RELATED TO THIS. THAT'S WHY I ASKED TO HAVE THE
3	DISCUSSION.
4	CHAIRMAN THOMAS: REPEAT THAT.
5	DR. LUBIN: I DIDN'T DO IT BECAUSE I
6	DIDN'T GET A SENSE LOOKING AROUND MY FRIENDS HERE
7	THAT ANYONE ELSE WAS GOING TO SAY THEY WERE
8	INTERESTED, AND I DIDN'T WANT TO BE EMBARRASSED
9	BEING THE ONLY ONE SAYING LET'S CONSIDER IT. THE
10	REASON WHY I ASKED IT TO BE DISCUSSED IS I THINK
11	IT'S HIGHLY IMPORTANT, VERY NOVEL, A GREAT
12	PUBLICATION IN NATURE COMMUNICATION RELATED TO IT,
13	AND AN AREA WE'RE NOT DOING ANY RESEARCH IN. SO
14	WHEN WE TALK ABOUT IT AS PART OF OUR PORTFOLIO,
15	RATHER THAN THE RARE DISEASES, CARDIOVASCULAR
16	DISEASE IS NOT RARE. AND WE'RE LOOKING AT
17	REGENERATING CARDIAC MUSCLE, BUT WE'RE REALLY NOT
18	LOOKING AT THE BLOOD VESSELS THAT OCCLUDE
19	CIRCULATION AND FLOW AND DAMAGE THE CARDIAC MUSCLE.
20	THIS IS ONE THAT DOES. SO I WILL RECOMMEND
21	APPROVAL, MOVING FROM III TO I.
22	MR. SHESTACK: SECOND THAT.
23	DR. TROUNSON: SORRY, CHAIR. I DON'T
24	THINK THAT'S REALLY CORRECT, WHAT YOU'RE SAYING,
25	BECAUSE WE HAVE A NUMBER OF STUDIES IN TRANSLATION
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1	AT THE VERY LEAST THAT ARE ADDRESSING THESE.
2	DR. LUBIN: I DIDN'T KNOW THAT.
3	DR. TROUNSON: I DON'T THINK IT'S A RARITY
4	IN OUR PROGRAM AT ALL.
5	DR. LUBIN: THANK YOU FOR THE CORRECTION.
6	CHAIRMAN THOMAS: DID YOU STILL WANT TO
7	HAVE YOUR MOTION?
8	DR. LUBIN: I WILL MAKE THE MOTION.
9	CHAIRMAN THOMAS: SECONDED BY MR.
10	SHESTACK. DO YOU HAVE A COMMENT?
11	DR. FINE: HAVING HEARD THAT COMMENT, I
12	MUST SAY THAT I CONCUR WITH THAT. I THINK IT IS
13	WORTHY OF RECONSIDERATION.
14	CHAIRMAN THOMAS: OKAY. ANY OTHER
15	COMMENTS BY MEMBERS OF THE BOARD?
16	MS. FEIT: COULD WE REPEAT THE MOTION IN
17	FULL, PLEASE?
18	MR. HARRISON: THE MOTION IS TO MOVE
19	APPLICATION RB 46117 TO TIER I.
20	CHAIRMAN THOMAS: MARCY, DID YOU HAVE A
21	COMMENT?
22	MS. FEIT: NO. I JUST WANTED TO HAVE A
23	RESTATEMENT OF THE MOTION.
24	DR. STEWARD: JUST TO SAY THIS IS A REALLY
25	INTERESTING ROUND. I JUST SAY THAT THERE WERE 64
	360

1	APPLICATIONS REVIEWED, ACTUALLY 357 PREAPPLICATIONS.
2	THERE WERE A VERY LARGE NUMBER OF MERITORIOUS GRANTS
3	THAT WE SEE RIGHT AT THE BORDER AND NINE IN THE SAME
4	RANGE AS THIS ONE. I THINK THAT WHAT THE REVIEWERS
5	FACED HERE WAS TRYING TO SELECT A GROUP OF GRANTS
6	THAT WERE THE BEST OF THE BUNCH. AND THEY RANKED
7	THEM ACCORDINGLY. AND I'M GOING TO VOTE NO ON THIS
8	BECAUSE REALLY I'M JUST HAVING DIFFICULTY IN NOT
9	RESPECTING THE RANKINGS THAT THE REVIEWERS PROVIDED
10	OF THIS VERY EXCELLENT ROUND OF GRANTS.
11	CHAIRMAN THOMAS: THANK YOU, DR. STEWARD.
12	ANY OTHER COMMENTS BY MEMBERS OF THE BOARD?
13	DR. PIZZO: BUT I THINK, JUST AGAIN, TO
14	COME BACK TO IT, THAT POINT BEGS THE QUESTION AS TO
15	WHETHER THE THRESHOLD LEVEL THAT WE'VE SET FOR
16	FUNDING FOR THIS IS ONE WE WANT TO STAY WITH. THAT
17	IS ULTIMATELY WE'RE FITTING THIS INTO A
18	SELF-IMPOSED ALLOCATION. I UNDERSTAND HOW IT GOT
19	THERE, BUT THIS IS AN IMPORTANT AREA, AND WE ARE
20	GOING TO HAVE CONSEQUENCES FROM THAT.
21	CHAIRMAN THOMAS: ANY OTHER COMMENTS FROM
22	MEMBERS OF THE BOARD? OKAY. MARIA, PLEASE TAKE THE
23	ROLL.
24	MS. BONNEVILLE: DAVID BRENNER.
25	DR. BRENNER: NO.
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1		MS. BONNEVILLE: JACOB LEVIN.
2		DR. LEVIN: NO.
3		MS. BONNEVILLE: ANNE-MARIE DULIEGE.
4		DR. DULIEGE: NO.
5		MS. BONNEVILLE: MARCY FEIT.
6		MS. FEIT: NO.
7		MS. BONNEVILLE: TED KRONTIRIS.
8		DR. KRONTIRIS: NO.
9		MS. BONNEVILLE: LEEZA GIBBONS.
10		MS. GIBBONS: NO.
11		MS. BONNEVILLE: MICHAEL GOLDBERG. SAM
12	HAWGOOD.	
13		DR. HAWGOOD: NO.
14		MS. BONNEVILLE: STEPHEN JUELSGAARD. BERT
15	LUBIN.	
16		DR. LUBIN: YES.
17		MS. BONNEVILLE: MICHAEL MARLETTA. LEON
18	FINE.	
19		DR. FINE: YES.
20		MS. BONNEVILLE: PHIL PIZZO.
21		DR. PIZZO: NO.
22		MS. BONNEVILLE: CLAIRE POMEROY.
23		DR. POMEROY: NO.
24		MS. BONNEVILLE: FRANCISCO PRIETO.
25		DR. PRIETO: YES.
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1	MS. BONNEVILLE: CARMEN PULIAFITO.
2	DR. PULIAFITO: NO.
3	MS. BONNEVILLE: ROBERT QUINT.
4	DR. QUINT: YES.
5	MS. BONNEVILLE: DUANE ROTH.
6	MR. ROTH: NO.
7	MS. BONNEVILLE: JOAN SAMUELSON.
8	MS. SAMUELSON: YES.
9	MS. BONNEVILLE: JEFF SHEEHY.
10	MR. SHEEHY: YES.
11	MS. BONNEVILLE: JONATHAN SHESTACK.
12	MR. SHESTACK: YES.
13	MS. BONNEVILLE: OSWALD STEWARD.
14	DR. STEWARD: NO.
15	MS. BONNEVILLE: JONATHAN THOMAS.
16	CHAIRMAN THOMAS: NO.
17	MS. BONNEVILLE: ART TORRES.
18	MR. TORRES: AYE.
19	MS. BONNEVILLE: KRISTINA VUORI.
20	DR. VUORI: NO.
21	MS. BONNEVILLE: JAMES ECONOMOU.
22	DR. ECONOMOU: NO.
23	CHAIRMAN THOMAS: MR. HARRISON, I BELIEVE
24	THE MOTION FAILED.
25	MR. HARRISON: YES, THE MOTION FAILS BY A
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1	VOTE OF 8 TO 15.
2	CHAIRMAN THOMAS: THANK YOU. ANY OTHER
3	PROJECTS ANY MEMBER OF THE BOARD WOULD LIKE TO
4	ELEVATE FROM TIER III TO TIER I? HEARING NONE, DO
5	WE HAVE ANY REMAINING PUBLIC COMMENT? OKAY.
6	SO HERE'S MY QUESTION. WE HAVE THREE
7	PUBLIC COMMENTS BETWEEN FINISHING THE ROUND, BUT WE
8	HAVE THE SPOTLIGHT TO GO. WOULD THE BOARD LIKE TO
9	FINISH THE PUBLIC COMMENTS SO WE CAN ROUND OUT THIS
10	BEFORE WE GET YES. OKAY. PLEASE PROCEED IN SOME
11	ORDER OUT THERE. STATE YOUR NAME, THREE MINUTES,
12	PLEASE.
13	DR. LU: MY NAME IS WANGE LU. I'M
14	ASSOCIATE PROFESSOR AT THE BROAD CENTER FOR STEM
15	CELL RESEARCH AT USC, AND I'M A PRINCIPAL
16	INVESTIGATOR FOR BASIC BIOLOGY GRANT. THE GRANT
17	NUMBER IS RB 05816.
18	THIS GRANT PROPOSAL AIMED TO ADDRESS THE
19	ROLES OF A HIGHER ORDER NUCLEAR ARCHITECTURE IN
20	PLURIPOTENCY AND REPROGRAMMING. AND WE HAVE THE
21	REVIEWERS RAISE SEVERAL QUESTIONS, AND WE HAVE
22	RESPONSE TO THOSE CRITIQUES. AND IT IS IN THE
23	EXTRAORDINARY PETITION LETTER IN FRONT OF YOU.
24	I THINK ONE OF THE MAJOR CONCERN IS THE
25	REVIEWER FELT THAT THE STUDIES OF HIGH ORDER NUCLEAR
	364

1	ARCHITECTURE IS NOT SIGNIFICANT. AND WE BELIEVE
2	THAT THE REVIEWERS UNDERVALUE THE SIGNIFICANCE OF
3	THIS STUDIES BECAUSE THE NUCLEAR ARCHITECTURE IS
4	VERY IMPORTANT FOR PLURIPOTENT STEM CELLS.
5	SO EVEN THOUGH A LOT OF YOU ARE NOT
6	SCIENTISTS, BUT YOU PROBABLY HAVE HEARD A LOT OF
7	STUDIES ON EPIGENETICS BECAUSE EPIGENETICS IS VERY
8	IMPORTANT IN THE STEM CELL RESEARCH BETWEEN THE
9	MAJOR DIFFERENCES BETWEEN PLURIPOTENT STEM CELLS AND
10	SOMATIC CELLS LIES IN THE DIFFERENCES IN EPIGENOME.
11	AND YOU HAVE HEARD A LOT OF GRANT FUNDED DNA
12	METHYLATION OR HISTOMODIFICATION, BUT VERY LITTLE
13	HAS BEEN DONE TO STUDY THE NUCLEAR ARCHITECTURE.
14	AND THE NUCLEAR ARCHITECTURE HAS NOT BEEN STUDIED A
15	LOT BECAUSE OF THE TECHNICAL DIFFICULTY.
16	BUT NOW TECHNOLOGY CALLED CHROMOSOME
17	CONFIRMATION CAPTURE, IT MADE IT POSSIBLE TO STUDY
18	THE NUCLEAR ARCHITECTURE IN PLURIPOTENT STEM CELLS.
19	SO OUR PROPOSAL UTILIZE THE CUTTING-EDGE 3C, 4C
20	APPROACH TO ADDRESS THE ROLE OF NUCLEAR ARCHITECTURE
21	IN PLURIPOTENT STEM CELLS AS WELL AS SOMATIC CELL
22	REPROGRAMMING IPS CELL INDUCTION. SUCH STUDIES ARE
23	CREATIVE AND INNOVATIVE.
24	SO WE ALL KNOW THAT SOMATIC CELLS AND
25	PLURIPOTENT STEM CELLS, THEY ARE DIFFERENCE IN THE
	365

1	NUCLEAR ARCHITECTURE. STUDIES HAS BEEN DONE IN
2	SOMATIC AND NUCLEAR TRANSFER, SUGGESTING THAT THE
3	NUCLEAR ARCHITECTURE CHANGES SIGNIFICANTLY DURING
4	VERY SHORT PERIOD OF TIME OF SOMATIC CELL
5	REPROGRAMMING. SO IN THE PLURIPOTENT STEM CELL,
6	THERE MUST BE A PLURIPOTENCY-SPECIFIC HIGH ORDER
7	STRUCTURE, AND SUCH A STRUCTURE MUST BE IMPORTANT
8	FOR PLURIPOTENT GENE EXPRESSION.
9	SO I THINK IT'S EASY TO UNDERSTAND THAT
10	NOT ONLY THE 2D STRUCTURE, BUT ALSO 3D STRUCTURE IS
11	VERY IMPORTANT AS WELL. WHEN YOU FLY INTO SAN
12	FRANCISCO AND FROM THE AIRPLANE YOU CAN SEE THE
13	HIGHWAY CONNECT DIFFERENT ISLANDS; BUT IF YOU LOOK
14	CLOSER, YOU CAN SEE THE HIGHWAY INTERACT WITH THE
15	LOCAL STREETS AND THE BUILDINGS, TRAFFICS. AND
16	understanding of a 3d structure will be very
17	IMPORTANT FOR US TO DESIGN A BETTER HIGHWAY TO
18	IMPROVE THE TRAFFIC AND THE FUNCTION OF THE CITIES.
19	SO IN THE END, I WANT TO SAY THAT OUR
20	PROPOSAL STUDY IS A PIONEERING EFFORT AND REPRESENT
21	FUTURE DIRECTION OF STEM CELL BIOLOGY FIELD. AND
22	SUCH A STUDY WILL SIGNIFICANTLY IMPACT OUR
23	UNDERSTANDING OF PLURIPOTENT STEM CELLS AS WELL AS
24	APPLICATION IN THE CELL REPLACEMENT THERAPY.
25	THE CURRENT PORTFOLIO OF FUNDED CIRM
	366

1	GRANTS HAVE NOT COVERED THIS EMERGING RESEARCH AREA,
2	AND I HOPE THE BOARD WILL CONSIDER OUR APPEAL AND
3	AWARD FUNDING FOR OUR GRANT PROPOSAL. THANK YOU.
4	CHAIRMAN THOMAS: THANK YOU, DOCTOR.
5	NEXT, PLEASE.
6	DR. MIKKOLA: I AM HANNA MIKKOLA. I'M THE
7	PI OF THE GRANT, "MECHANISMS PROTECTING THE
8	SELF-RENEWAL OF HUMAN HEMATOPOIETIC STEM CELLS." I
9	BELIEVE THE NUMBER IS 6256.
10	SO MY LONG-STANDING GOAL SINCE MED SCHOOL
11	STUDENT IN FINLAND HAS BEEN TO IMPROVE THE TREATMENT
12	FOR LEUKEMIA. A MAJOR CLINICAL ROADBLOCK FOR THIS
13	IS THE LACK OF SUITABLE BONE MARROW DONORS AND THE
14	VERY LOW YIELD OF HSC'S IN CORD BLOOD. THE EFFORT
15	TO EXPAND HEMATOPOIETIC STEM CELLS OR GENERATE THEM
16	FROM PLURIPOTENT STEM CELLS HAVE ALL FAILED BECAUSE
17	WE LACK THE UNDERSTANDING OF THE CRITICAL
18	SELF-RENEWAL MECHANISMS IN HUMAN HEMATOPOIETIC STEM
19	CELLS.
20	CHALLENGING IT'S VERY CHALLENGING TO
21	STUDY SELF-RENEWAL IN HEMATOPOIETIC STEM CELLS
22	BECAUSE WE DON'T HAVE GOOD MARKERS FOR HUMAN HSC'S.
23	WE DON'T HAVE GOOD MODEL SYSTEMS. HOW DO YOU MAKE A
24	KNOCKOUT FOR HUMAN HEMATOPOIETIC STEM CELL? AND,
25	THEREFORE, THESE STUDIES HAVE REALLY BEEN LAGGING

BEHIND.
WITH THE HELP OF THE CIRM NEW FACULTY
AWARD THAT WE GOT FOUR AND A HALF YEARS AGO, WE'VE
BEEN ABLE TO EXTEND OUR PREVIOUS MOUSE HEMATOPOIETIC
STEM CELL STUDIES TO HUMAN. WE TOOK THIS TASK. WE
WANT TO WORK ON HUMAN EVEN IF IT'S CHALLENGING
BECAUSE WE BELIEVE THIS IS CRITICAL TO TAKE THIS
TOWARDS THERAPEUTIC APPLICATIONS. FOR EXAMPLE,
WE'VE NOW DEVELOPED A CULTURE SYSTEM WITH A
NICHE-BASED SYSTEM WHERE WE CAN MAINTAIN
HEMATOPOIETIC STEM CELLS IN THE UNDIFFERENTIATED
STATE FOR SEVERAL WEEKS. AND WE ARE ALREADY USING
THIS TECHNOLOGY IN A COLLABORATION IN A CIRM
LEUKEMIA DISEASE TEAM GRANT TO SCREEN FOR NOVEL
LEUKEMIA STEM CELL DRUGS AND THEIR TOXICITY.
MOREOVER, WE HAVE NOW IDENTIFIED NEW
SURFACE MARKER WHERE WE CAN VERY SPECIFICALLY
IDENTIFY THE HUMAN HEMATOPOIETIC STEM CELL
THROUGHOUT DEVELOPMENT, ALL NICHES, PLACENTA, FETAL
LIVER, BONE MARROW, SO WE IDENTIFY THE REAL
SELF-RENEWING HSC FROM THE VERY CLOSELY RELATED
DOWNSTREAM PROGENITORS THAT CAN'T SELF-RENEW.
MOREOVER, WE'VE SHOWN NOW THAT THIS
MARKER, GPI 80, IS ALSO FUNCTIONALLY REQUIRED FOR
HEMATOPOIETIC STEM CELL SELF-RENEWAL. WITH THESE
368

1	TOOLS WE ARE NOW PROPOSING OUR NEXT PROPOSAL TO
2	REALLY STUDY THE MECHANISMS, HOW HUMAN HEMATOPOIETIC
3	STEM CELLS SELF-RENEW. AND WE BELIEVE THAT WE CAN
4	DIRECTLY APPLY THIS RESEARCH, IT'S ON HUMAN CELLS,
5	TO TAKE THESE APPROACHES TO TRANSLATIONAL APPROACHES
6	THAT WE CAN USE TO EXPAND HEMATOPOIETIC STEM CELLS
7	OR GENERATE THEM FROM PATIENT-SPECIFIC PLURIPOTENT
8	STEM CELLS.
9	THE REVIEWERS PRAISED THE NOVELTY OF GMI
10	80 AS A MARKER AND A MOLECULE FOR SELF-RENEWAL, VERY
11	COMPELLING PRELIMINARY DATA, THE FEASIBLE
12	EXPERIMENTAL PLAN, AND THE EXPERTISE OF THE PI AND
13	TEAM. HOWEVER, THERE WERE CONCERNS RAISED. ONE
14	REVIEWER SUGGESTED THAT THE NEED FOR EXPANSION OF
15	AUTOLOGOUS HSC'S IS LIMITED, ALTHOUGH ANOTHER
16	REVIEWER CONSIDERED THIS HSC A KEY CLINICAL PROBLEM.
17	IF MAJORITY OF PATIENTS ARE STILL WAITING FOR
18	GRAFTS, HOW CAN THIS NOT BE IMPORTANT?
19	REVIEWERS ALSO EXPRESSED DOUBTS THAT THE
20	RESULTS OF FETAL LIVER ARE NOT APPLICABLE TO HSC'S.
21	WE SPECIFICALLY USED FETAL LIVER. THEY'RE THE MOST
22	HIGHLY SELF-RENEWING HSC'S. THEY EFFICIENTLY GRAFT
23	BONE MARROW. THEY ARE SUPPORTED BY BONE MARROW
24	STROMA, SO WE BELIEVE THAT THEY ARE, THEREFORE,
25	REALLY THE IDEAL CELL TO STUDY SELF-RENEWAL AND THE
	369

PROTOTYPE TO BE USED FOR REGENERATIVE MEDICINE
BECAUSE THIS IS THE CELL, THE DEVELOPMENTAL, VERY
CLOSELY RELATED CELL WE WOULD WANT TO GENERATE FROM
PLURIPOTENT STEM CELLS.
SO I THANK YOU VERY MUCH FOR YOUR
ATTENTION. SORRY TO KEEP YOU FROM LUNCH. AND I
REALLY HOPE THAT CIRM RECOGNIZE THE VALUE OF
SUPPORTING THE MOMENTUM THAT WE HAVE CREATED SO THAT
WE CAN TAKE THIS BASIC RESEARCH TOWARD CLINICAL
APPLICATION. THANK YOU VERY MUCH.
MR. TORRES: I WAS UNCLEAR. DOES THIS
APPLICANT HAVE ANOTHER GRANT IN THE PAST?
MS. GIBBONS: FOUR YEARS AGO.
DR. OLSON: IT HAS ABOUT SIX MORE MONTHS
TO GO WITHOUT A NO COST EXTENSION, BUT IT WOULD
SHE CURRENTLY HAS A NEW FACULTY AWARD, YES.
MR. TORRES: THANK YOU, DOCTOR.
DR. TEITELL: MR. CHAIRMAN, MEMBERS OF THE
BOARD, THANK YOU VERY MUCH FOR ALLOWING ME TO
ADDRESS YOU TODAY. MY NAME IS MIKE TEITELL. I'M A
PATHOLOGIST, A PHYSICIAN, AND A SCIENTIST AT UCLA,
AND THIS BOARD HAS FUNDED ME TWICE BEFORE, FOR WHICH
I THANK YOU.
MITOCHONDRIA ARE IMPLICATED IN
PATHOLOGICAL PROCESSES IN NEURODEGENERATIVE
370

1	DISEASES, INCLUDING PARKINSON'S DISEASE, ALZHEIMER'S
2	DISEASE, AND NEURODEFICIENCY SYNDROMES, MYOPATHIES,
3	CARDIAC TOXICITY, TO CHEMOTHERAPY. A PATH FORWARD
4	IN THESE DISEASES REQUIRES A DEEPER UNDERSTANDING OF
5	THE ROLE OF METABOLISM IN STEM CELL DIFFERENTIATION
6	AND FUNCTION.
7	WITH PRIOR CIRM FUNDING, BASIC BIOLOGY AND
8	SEED GRANT FUNDING, OUR LAB HELPED TO PIONEER
9	STUDIES OF METABOLISM IN PLURIPOTENT STEM CELLS,
10	ESPECIALLY FOCUSED ON APPLICABLE MITOCHONDRIA. WE
11	PUBLISHED THAT A SWITCH IN METABOLISM REGULATES THE
12	DIFFERENTIATION POTENTIAL OF PLURIPOTENT STEM CELLS.
13	OUR WORK WAS THE SUBJECT OF A COMMENTARY BY DR.
14	LEWIS CANTLEY OF HARVARD UNIVERSITY, A LEADER IN
15	METABOLISM IN STEM CELL FIELD. WE WERE INVITED BY
16	THE EDITOR AT CELL STEM CELL TO PROVIDE A REVIEW FOR
17	THE FIELD THAT IS CURRENTLY PENDING PROCESSING FOR
18	THE NOVEMBER ISSUE, AND A COMPANION ARTICLE FROM THE
19	LEADER OF A STEM CELL INSTITUTE IN THE MIDWEST AS A
20	PERSPECTIVE FOR AN UPCOMING MEETING SUPPORTED BY
21	CELL AT THE SALK INSTITUTE IN NOVEMBER OF THIS YEAR.
22	OUR CURRENT PROPOSAL IS TO EXPAND UPON
23	WHAT WE HAVE DONE SO FAR AND TO STUDY HOW
24	METABOLITES IMPACT THE EXPRESSION OF GENES THAT
25	CONTROL PLURIPOTENT STEM CELL DIFFERENTIATION.
	371
	3/1

1	CONCERNS RAISED IN THE REVIEW INCLUDED THE
2	IMPORTANCE OF THE STUDY, WHICH WE RESPECTFULLY
3	DISAGREE WITH THE REVIEWERS BECAUSE THESE
4	METABOLITES ARE CO-FACTORS, SUBSTRATES, AND
5	INHIBITORS FOR ENZYMES THAT REGULATE GENE STRUCTURE
6	AND EXPRESSION, WHICH CONTROLS DIFFERENTIATION AND
7	FUNCTION. MANY OF THOSE GRANTS WERE FUNDED BY THIS
8	BOARD. HOW CAN THIS NOT BE IMPORTANT?
9	IT'S ESPECIALLY IMPORTANT SINCE THERE ARE
10	DRUGS AND COMPOUNDS THAT EXIST AND THAT WE ARE
11	DEVELOPING THAT COULD HAVE IMPACT IN DISEASES SUCH
12	AS ALZHEIMER'S DISEASE AND PARKINSON'S SYNDROME.
13	THERE WAS A CONCERN FOR LACK OF PARALLELS
14	TO PRIOR STUDIES IN CANCER; BUT IF THERE WERE NO
15	PARALLELS, THEN THIS KIND OF BIOLOGY WOULD HAVE TO
16	EXIST UNIQUELY FOR STEM CELLS WITH DIFFERENT ENZYME
17	FUNCTIONS AND COFACTORS FOR WHICH THERE IS
18	ABSOLUTELY NO EVIDENCE IN THE LITERATURE AT ANY
19	LEVEL, AND WE WOULD CONSIDER IT EXTREMELY UNLIKELY.
20	THE CONCERN ALSO EXTENDED TO APPROACH AND
21	OFF-TARGET EFFECTS, BUT I WOULD COMMENT THAT WITH
22	CIRM FUNDING, WE HAVE MANAGED TO PUBLISH 18
23	MANUSCRIPTS, WE HAVE A TRACK RECORD OF CAREFUL
24	CONTROLS AND VALIDATION AND PROTOCOLS, AND OUR STUDY
25	DESIGNS DIRECTLY TARGET THE GENES THAT ARE AFFECTED
	272
	372

1	TO KNOW HOW METABOLISM CONTROLS THEM.
2	IN SUMMARY, I THANK YOU FOR ALLOWING ME TO
3	ADDRESS YOU AND ADDRESS THESE ISSUES. AGENTS
4	ALREADY EXIST AND ARE BEING DEVELOPED BY US AND BY
5	OTHERS IN CHEMICAL BIOLOGY APPROACHES. WE HAVE A
6	MANUSCRIPT THAT'S ALMOST ACCEPTED IN PRESS AT
7	DEVELOPMENTAL CELL TO CONTROL MITOCHONDRIA,
8	METABOLITES, AND THEIR METABOLISM TO IMPROVE STEM
9	CELL DIFFERENTIATION AND FUNCTION. TO MOVE AHEAD
10	AGAINST SIGNIFICANT DISEASES SUCH AS PARKINSON'S
11	DISEASE AND ALZHEIMER'S DISEASE, THE BASIC
12	UNDERSTANDING OF THE ROLE OF MITOCHONDRIA AND ITS
13	EFFECTS ON THE GENOME WHICH CONTROLS THE EXPRESSION
14	OF SURVIVAL GENES MUST BE INCREASED. METABOLITES
15	ARE DRUGABLE, AND THE WORK HAS CLINICAL SIGNIFICANCE
16	AND IMPLICATIONS. PLEASE ALLOW OUR WORK TO CONTINUE
17	TO MOVE AHEAD IN THIS CRITICAL AREA.
18	FINALLY, I'D LIKE TO SAY THAT THE CONCERNS
19	THAT WERE RAISED BY DR. TROUNSON IN THE OTHER
20	APPLICATION ARE NOT ISSUES RELATED TO OUR
21	APPLICATION SINCE WE DON'T LOOK AT HETEROPLASMIA IN
22	OUR SYSTEM. THANK YOU VERY MUCH.
23	CHAIRMAN THOMAS: WHAT NUMBER APPLICATION
24	WERE YOU?
25	DR. TITEL: 5746.
	373
	3, 3

CONCLUDES OUR PUBLIC COMMENT. HAVING HEARD THESE COMMENTS, DO ANY MEMBERS OF THE BOARD WISH TO MAKE A MOTION TO ELEVATE ANY OF THE DISCUSSED OR ANY OTHER PROPOSALS FROM TIER III TO TIER I? HEARING NO SUCH MOTION, THAT CONCLUDES OUR DISCUSSION ON BASIC BIOLOGY. MR. HARRISON, WHAT IS OUR PROCEDURE AT THIS POINT? MR. HARRISON: IF I COULD MAKE A SUGGESTION, GIVEN THE FACT THAT MOST OF THE MEMBERS WHO WOULD HAVE CONFLICTS WITH RESPECT TO	
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5 PROPOSALS FROM TIER III TO TIER I? HEARING NO SUCH 6 MOTION, THAT CONCLUDES OUR DISCUSSION ON BASIC 7 BIOLOGY. MR. HARRISON, WHAT IS OUR PROCEDURE AT 8 THIS POINT? 9 MR. HARRISON: IF I COULD MAKE A 10 SUGGESTION, GIVEN THE FACT THAT MOST OF THE MEMBERS 11 WHO WOULD HAVE CONFLICTS WITH RESPECT TO	
6 MOTION, THAT CONCLUDES OUR DISCUSSION ON BASIC 7 BIOLOGY. MR. HARRISON, WHAT IS OUR PROCEDURE AT 8 THIS POINT? 9 MR. HARRISON: IF I COULD MAKE A 10 SUGGESTION, GIVEN THE FACT THAT MOST OF THE MEMBERS 11 WHO WOULD HAVE CONFLICTS WITH RESPECT TO	
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8 THIS POINT? 9 MR. HARRISON: IF I COULD MAKE A 10 SUGGESTION, GIVEN THE FACT THAT MOST OF THE MEMBERS 11 WHO WOULD HAVE CONFLICTS WITH RESPECT TO	
9 MR. HARRISON: IF I COULD MAKE A 10 SUGGESTION, GIVEN THE FACT THAT MOST OF THE MEMBERS 11 WHO WOULD HAVE CONFLICTS WITH RESPECT TO	
SUGGESTION, GIVEN THE FACT THAT MOST OF THE MEMBERS WHO WOULD HAVE CONFLICTS WITH RESPECT TO	
WHO WOULD HAVE CONFLICTS WITH RESPECT TO	
12 APPLICATIONS IN TIER I ARE LIKELY ALSO TO HAVE THEM	
WITH RESPECT TO APPLICATIONS IN TIER III, IF WE	
14 COULD PROCEED WITH ONE OMNIBUS MOTION TO FUND THOSE	
APPLICATIONS IN TIER I AND TO CLOSE FUNDING FOR	
16 THOSE APPLICATIONS IN TIER III, THEN WE COULD HANDLE	
17 IT WITH A SIMPLE, SINGLE MOTION.	
MR. TORRES: SO MOVED.	
19 CHAIRMAN THOMAS: MOVED BY SENATOR TORRES.	
MS. GIBBONS: SECOND.	
CHAIRMAN THOMAS: SECONDED BY MS. GIBBONS.	
22 ANY DISCUSSION ON THE MOTION? PLEASE CALL THE ROLL.	
MR. HARRISON: JUST A REMINDER FOR MEMBERS	
TO INDICATE IF THEY HAVE A CONFLICT.	
MS. BONNEVILLE: ROBERT PRICE.	
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1	DR. PRICE: YES, EXCEPT FOR THOSE WITH
2	WHICH I HAVE A CONFLICT.
3	MS. BONNEVILLE: DAVID BRENNER.
4	DR. BRENNER: YES, EXCEPT FOR THOSE WITH
5	WHICH I HAVE A CONFLICT.
6	MS. BONNEVILLE: JACOB LEVIN.
7	DR. LEVIN: YES, EXCEPT FOR THOSE WITH
8	WHICH I HAVE A CONFLICT.
9	MS. BONNEVILLE: ANNE-MARIE DULIEGE.
10	DR. DULIEGE: YES.
11	MS. BONNEVILLE: MARCY FEIT.
12	MS. FEIT: YES, EXCEPT FOR THOSE WITH
13	WHICH I HAVE A CONFLICT.
14	MS. BONNEVILLE: TED KRONTIRIS.
15	DR. KRONTIRIS: YES, EXCEPT FOR THOSE WITH
16	WHICH I HAVE A CONFLICT.
17	MS. BONNEVILLE: LEEZA GIBBONS.
18	MS. GIBBONS: YES.
19	MS. BONNEVILLE: MICHAEL GOLDBERG. SAM
20	HAWGOOD.
21	DR. HAWGOOD: YES, EXCEPT FOR THOSE WITH
22	WHICH I HAVE A CONFLICT.
23	MS. BONNEVILLE: STEPHEN JUELSGAARD.
24	SHERRY LANSING. BERT LUBIN.
25	DR. LUBIN: YES.
	375
	JI J

1	MS. BONNEVILLE: MICHAEL MARLETTA. LEON
2	FINE.
3	DR. FINE: YES, EXCEPT FOR THOSE WITH
4	WHICH I HAVE A CONFLICT.
5	MS. BONNEVILLE: PHIL PIZZO.
6	DR. PIZZO: YES, EXCEPT FOR THOSE WITH
7	WHICH I HAVE A CONFLICT.
8	MS. BONNEVILLE: CLAIRE POMEROY.
9	DR. POMEROY: YES, EXCEPT FOR THOSE WITH
10	WHICH I HAVE A CONFLICT.
11	MS. BONNEVILLE: FRANCISCO PRIETO.
12	DR. PRIETO: YES, EXCEPT FOR THOSE WITH
13	WHICH I HAVE A CONFLICT.
14	MS. BONNEVILLE: CARMEN PULIAFITO.
15	DR. PULIAFITO: YES, EXCEPT FOR THOSE WITH
16	WHICH I HAVE A CONFLICT.
17	MS. BONNEVILLE: ROBERT QUINT.
18	DR. QUINT: YES.
19	MS. BONNEVILLE: DUANE ROTH.
20	MR. ROTH: YES, EXCEPT FOR THOSE WITH
21	WHICH I HAVE A CONFLICT.
22	MS. BONNEVILLE: JOAN SAMUELSON.
23	MS. SAMUELSON: YES.
24	MS. BONNEVILLE: JEFF SHEEHY.
25	MR. SHEEHY: YES, EXCEPT FOR THOSE WITH
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_	DARRISIERS REPORTING SERVICE
1	WHICH I HAVE A CONFLICT.
2	MS. BONNEVILLE: JONATHAN SHESTACK.
3	MR. SHESTACK: YES.
4	MS. BONNEVILLE: OSWALD STEWARD.
5	DR. STEWARD: YES, EXCEPT FOR THOSE WITH
6	WHICH I HAVE A CONFLICT.
7	MS. BONNEVILLE: JONATHAN THOMAS.
8	CHAIRMAN THOMAS: YES.
9	MS. BONNEVILLE: ART TORRES.
10	MR. TORRES: AYE.
11	MS. BONNEVILLE: KRISTINA VUORI.
12	DR. VUORI: YES, EXCEPT FOR THOSE WITH
13	WHICH I HAVE A CONFLICT.
14	MS. BONNEVILLE: JAMES ECONOMOU.
15	DR. ECONOMOU: YES, EXCEPT FOR THOSE WITH
16	WHICH I HAVE A CONFLICT.
17	CHAIRMAN THOMAS: OKAY. THE OMNIBUS
18	MOTION PASSES. THAT CONCLUDES OUR DISCUSSION OF
19	BASIC BIOLOGY. THANK YOU AGAIN TO DR. YAFFE AND ALL
20	THAT WERE SO INSTRUMENTAL IN WADING THROUGH AN
21	ENORMOUS NUMBER OF APPLICATIONS, WHITTLING DOWN.
22	WE'VE PRODUCED, I THINK, A VERY HIGH QUALITY ROUND
23	OF APPROVED PROJECTS HERE. AND SO TO ALL STAFF
24	THANK YOU VERY MUCH AGAIN.
25	(APPLAUSE.)
	377

1	DR. YAFFE: I'D LIKE TO DRAW PARTICULAR
2	ATTENTION TO DR. VESSAL WHO HEADED BASIC BIO IV
3	ASSISTED BY DR. KELLY SHEPERD.
4	CHAIRMAN THOMAS: THANK YOU.
5	(APPLAUSE.)
6	CHAIRMAN THOMAS: OKAY. HERE'S WHAT WE'RE
7	GOING TO DO. WE HAVE A SPOTLIGHT THAT HAS SAT HERE
8	PATIENTLY WAITING FOR US TO FINISH THIS ROUND. IF
9	EVERYBODY COULD PLEASE GO GRAB YOUR LUNCH AND/OR
10	VISIT THE RESTROOM. YOU HAVE A CHOICE. PLEASE COME
11	BACK. WE'D LIKE TO START THE SPOTLIGHT PROMPTLY.
12	THANK YOU.
13	(A RECESS WAS TAKEN.)
14	CHAIRMAN THOMAS: NOW PROCEEDING TO ITEM
15	16, CONSIDERATION OF MODIFICATION TO THE
16	EXTRAORDINARY PETITION POLICY AND ADOPTION OF AN
17	ADDITIONAL INFORMATION POLICY. MR. HARRISON.
18	MR. HARRISON: THIS IS AGENDA ITEM 16 IN
19	YOUR BINDERS. YOU HAVE A SUMMARY OF THE PROPOSED
20	AMENDMENTS TO THE EXTRAORDINARY PETITION POLICY AND
21	A PROPOSAL RELATING TO THE ADDITIONAL ANALYSIS
22	OPTION. THERE'S ALSO A FLOWCHART AT THE BACK OF THE
23	DOCUMENT THAT ATTEMPTS TO DEPICT DUANE ROTH'S
24	SUGGESTION, THE VARIOUS WAYS IN WHICH CIRM CONSIDERS
25	INFORMATION SUBMITTED BY APPLICANTS AFTER THE
	378
	370

1	APPLICATION HAS BEEN SUBMITTED.
2	THE BOARD OVER THE YEARS HAS ADOPTED
3	SEVERAL POLICIES TO ADDRESS CIRCUMSTANCES WHERE THE
4	APPLICANTS HAVE INFORMATION THAT THEY WISH TO BRING
5	TO CIRM'S ATTENTION AFTER THEY'VE SUBMITTED THEIR
6	APPLICATION. WE HAVE WHAT WE CALL A SUPPLEMENTAL
7	INFORMATION PROCESS WHICH OCCURS DURING THE PEER
8	REVIEW. WE HAVE OUR EXTRAORDINARY PETITION POLICY,
9	WHICH, OF COURSE, YOU'RE ALL FAMILIAR WITH, AND WE
10	HAVE AN ADDITIONAL ANALYSIS OPTION, WHICH WAS A
11	FORMER POLICY THAT EXPIRED AND WHICH WE'RE BRINGING
12	BACK TO YOU TODAY FOR PROPOSED ADOPTION.
13	THE PURPOSE OF THE DISCUSSION TODAY IS TO
14	TRY TO ENSURE THAT THESE THREE DIFFERENT MECHANISMS
15	ARE INTEGRATED AND EFFECTIVE AND ALSO TO PROVIDE
16	SOME GUIDELINES BOTH TO APPLICANTS AND TO YOU AS A
17	BOARD IN CONSIDERING INFORMATION THAT'S SUBMITTED BY
18	APPLICANTS AFTER THEIR APPLICATION IS SUBMITTED.
19	SO LET ME JUST BRIEFLY DESCRIBE THE
20	VARIOUS MECHANISMS. THE FIRST, AS I SAID, IS THE
21	SUPPLEMENTAL INFORMATION PROCESS. AND THIS PROCESS
22	PROVIDES FOR TWO MECHANISMS TO OBTAIN ADDITIONAL
23	INFORMATION FROM APPLICANTS BEFORE THE GRANTS
24	WORKING GROUP MEETS.
25	FIRST, CIRM STAFF AND GWG REVIEWERS ARE
	379

1	ASKED TO IDENTIFY QUESTIONS OR AMBIGUITIES IN
2	CONNECTION WITH AN APPLICATION PRIOR TO THE PEER
3	REVIEW MEETING. STAFF THEN SUBMITS THE QUESTIONS TO
4	THE APPLICANTS, AND THEY PROVIDE RESPONSES SO THAT
5	THE INFORMATION IS AVAILABLE TO THE PEER REVIEWERS
6	BEFORE THEY CONSIDER THE APPLICATIONS AT THE GRANTS
7	WORKING GROUP MEETING.
8	THE SECOND MECHANISM IS TO ADDRESS
9	QUESTIONS THAT ARISE DURING THE REVIEW. AND WHEN
10	QUESTIONS ARISE THAT ARE MATERIAL TO THE GRANTS
11	WORKING GROUP'S CONSIDERATION OF AN APPLICATION,
12	STAFF, BEFORE THE MEETING, ASKS APPLICANTS TO BE
13	AVAILABLE BY TELEPHONE IN ORDER TO RESPOND TO
14	IMPORTANT QUESTIONS. IF THOSE QUESTIONS ARISE,
15	STAFF CONTACTS THE APPLICANTS AND IN REAL-TIME GETS
16	A RESPONSE TO THE QUESTIONS THEY HAVE.
17	WHEN THERE IS A QUESTION THAT WOULD
18	REQUIRE THE SUBMISSION OF ADDITIONAL INFORMATION,
19	THE GRANTS WORKING GROUP DOES HAVE THE AUTHORITY TO
20	DEFER CONSIDERATION OF THAT APPLICATION UNTIL THE
21	APPLICANT HAS HAD AN OPPORTUNITY TO SUBMIT THE
22	INFORMATION AND THEY, THE GRANTS WORKING GROUP, HAVE
23	HAD AN OPPORTUNITY TO REVIEW IT.
24	WE ALSO EARLY ON ADOPTED WHAT WE'VE CALLED
25	AN EXTRAORDINARY PETITION POLICY. AS YOU ALL KNOW,
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1	YOU ARE A PUBLIC BOARD, AND ANY MEMBER OF THE
2	PUBLIC, INCLUDING APPLICANTS, IS FREE TO COMMUNICATE
3	WITH YOU EITHER ORALLY OR IN WRITING. TO TRY TO
4	PROVIDE SOME GUIDANCE TO APPLICANTS AND SOME
5	PARAMETERS TO MAKE THE PROCESS MORE EFFECTIVE, THE
6	BOARD ADOPTED A FORMAL POLICY ASKING APPLICANTS TO
7	SUBMIT ANY WRITTEN COMMENTS THEY HAVE WITH RESPECT
8	TO AN APPLICATION FIVE BUSINESS DAYS PRIOR TO THE
9	MEETING AT WHICH THE APPLICATION IS CONSIDERED AND
10	TO LIMIT THEIR WRITTEN COMMENTS TO THREE PAGES.
11	WHEN STAFF RECEIVES A TIMELY FILED
12	EXTRAORDINARY PETITION, IT GIVES THEM THE
13	OPPORTUNITY, THEN, TO REVIEW THE INFORMATION AND TO
14	BE PREPARED TO OFFER YOU A RECOMMENDATION AS TO
15	WHETHER THE EXTRAORDINARY PETITION RAISES QUESTIONS
16	THAT WOULD WARRANT ADDITIONAL CONSIDERATION OF THE
17	APPLICATION.
18	IT'S IMPORTANT TO NOTE, AS I SAID EARLIER,
19	THAT THE POLICY IS ONLY TO DISCUSS EXTRAORDINARY
20	PETITIONS IF A BOARD MEMBER WISHES TO RAISE IT. IN
21	OTHER WORDS, IT DOESN'T AUTOMATICALLY GUARANTEE AN
22	APPLICANT AN OPPORTUNITY TO HAVE SPECIAL
23	CONSIDERATION BY THE BOARD. OF COURSE, THE
24	APPLICANTS ARE FREE TO COME HERE AND MAKE PUBLIC
25	COMMENT, BUT THERE'S NO SPECIAL PREFERENCE GIVEN TO
	381

1	APPLICANTS WHO SUBMIT AN EXTRAORDINARY PETITION.
2	IT'S ALSO IMPORTANT TO BE CLEAR THAT
3	EXTRAORDINARY PETITIONS ARE DISTINCT FROM APPEALS.
4	CIRM HAS A FORMAL APPEALS PROCESS IN THE GRANTS
5	ADMINISTRATION POLICY, BUT THAT PROCESS IS LIMITED
6	TO APPEALS ALLEGING A CONFLICT OF INTEREST. SO
7	EXTRAORDINARY PETITIONS ARE SEPARATE AND DISTINCT
8	FROM THAT APPEALS PROCESS.
9	THE PROPOSED MODIFICATIONS TO THE
10	EXTRAORDINARY PETITION POLICY ARE RELATIVELY MODEST,
11	BUT WE FELT IT WAS IMPORTANT TO MAKE CLEAR BOTH TO
12	YOU AS A BOARD AS WELL AS TO THE APPLICANTS THAT IF
13	AN APPLICANT DOES NOT SUBMIT AN EXTRAORDINARY
14	PETITION WITHIN FIVE BUSINESS DAYS AS THE POLICY
15	REQUIRES, WE'RE NOT GOING TO LABEL IT AN
16	EXTRAORDINARY PETITION. WE WILL IDENTIFY IT AS
17	OTHER CORRESPONDENCE. WE WILL, OF COURSE, PROVIDE
18	IT TO YOU. AND YOU, OF COURSE, AS MEMBERS OF THE
19	BOARD, ARE FREE TO RAISE QUESTIONS ABOUT IT.
20	BUT THE IMPLICATION, THE MESSAGE WE HOPE
21	TO SEND IS THAT IF APPLICANTS DON'T SUBMIT THEIR
22	COMMENTS IN A TIMELY MANNER, THEN STAFF DOESN'T HAVE
23	THE OPPORTUNITY TO THOROUGHLY REVIEW THE INFORMATION
24	AND BE IN A POSITION TO ADVISE YOU AS A BOARD
25	WHETHER THE INFORMATION PRESENTED WARRANTS ANY
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1	SPECIAL CONSIDERATION.
2	SO WE WOULD PROPOSE TO LABEL ANY WRITTEN
3	COMMENT SUBMITTED BY APPLICANTS AFTER THE FIVE-DAY
4	DEADLINE AS OTHER CORRESPONDENCE.
5	THE OTHER THING WE WANTED TO MAKE CLEAR TO
6	APPLICANTS IS THAT THEY SHOULD REFRAIN FROM
7	PRESENTING NEW INFORMATION IN PUBLIC COMMENTS THAT
8	THEY HAVE NOT INCLUDED IN THE EXTRAORDINARY PETITION
9	BECAUSE THAT TOO DEPRIVES STAFF OF AN OPPORTUNITY TO
10	HAVE THE TIME TO IN ANY WAY ASSESS OR ANALYZE THOSE
11	COMMENTS.
12	I'D ALSO LIKE TO TALK BRIEFLY ABOUT THE
13	ADDITIONAL ANALYSIS OPTION. AS I MENTIONED EARLIER,
14	THE BOARD HAD ADOPTED AN ADDITIONAL ANALYSIS POLICY
15	ABOUT 24 MONTHS AGO. THE PURPOSE OF THE POLICY WAS
16	TO PROVIDE A MECHANISM BY WHICH THE BOARD COULD
17	DEFER CONSIDERATION OF AN APPLICATION WHERE THERE
18	WAS A MATERIAL DISPUTE OF FACT THAT COULD NOT BE
19	RESOLVED AT THE BOARD MEETING AT WHICH THE
20	APPLICATION WAS CONSIDERED. AND THIS AROSE OUT OF A
21	COUPLE OF INSTANCES IN WHICH THERE WAS A QUESTION
22	ABOUT THE USE OF A CELL LINE OR THE NUMBER OF CELL
23	LINES AVAILABLE WHERE THE ANSWER COULD BE OBTAINED,
24	BUT SIMPLY NOT IN THE TIME AVAILABLE TO THE BOARD.
25	SO RATHER THAN RUSHING TO A DECISION, THE
	383

1	BOARD DECIDED TO ADOPT THIS POLICY TO PROVIDE A
2	MECHANISM TO CONDITIONALLY DENY AN APPLICATION, BUT
3	TO REFER IT BACK TO THE CHAIR OF THE GRANTS WORKING
4	GROUP AND THE REVIEW CHAIR TO ASK THEM WHETHER THE
5	RESOLUTION OF THAT DISPUTE OF FACT WOULD CHANGE THE
6	RECOMMENDATION.
7	THAT POLICY EXPIRED BECAUSE THERE WAS A
8	SUNSET CLAUSE INSERTED IN IT. AT THE LAST MEETING,
9	AS YOU ALL KNOW, THE BOARD RELIED ON ITS INHERENT
10	AUTHORITY TO DEFER CONSIDERATION OF AN APPLICATION
11	AND TO OBTAIN ADDITIONAL ANALYSIS BY REFERRING FIVE
12	OF THE DISEASE TEAM II APPLICATIONS FOR ADDITIONAL
13	ANALYSIS.
14	WHAT WE'D LIKE TO DO TODAY IS TO OFFER YOU
15	A POLICY FOR CONSIDERATION THAT WE HOPE WOULD
16	PROVIDE GUIDELINES BOTH TO APPLICANTS AS WELL AS TO
17	YOU AS A BOARD WITH RESPECT TO THE CIRCUMSTANCES
18	UNDER WHICH IT WOULD BE APPROPRIATE TO UTILIZE THIS
19	MECHANISM.
20	SO THE PROPOSED POLICY WOULD BE AS
21	FOLLOWS: FIRST, THE ADDITIONAL ANALYSIS OPTION
22	SHOULD BE LIMITED TO TWO SETS OF CIRCUMSTANCES.
23	ONE, WHERE THERE IS A MATERIAL DISPUTE OF FACT OR,
24	TWO, WHERE THERE IS MATERIAL NEW INFORMATION. AND
25	WE WOULD SUGGEST THAT A MATERIAL DISPUTE OF FACT
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1	WOULD HAVE TO OR SHOULD MEET THE FOLLOWING CRITERIA.
2	THAT WOULD BE NO. 1, THAT THE APPLICANT DISPUTES THE
3	ACCURACY OF A STATEMENT IN THE REVIEW SUMMARY, THAT
4	THE DISPUTED FACT WAS SIGNIFICANT IN THE GRANTS
5	WORKING GROUP'S SCORING OR RECOMMENDATION; THIRD,
6	THAT THE DISPUTE RELATES TO AN OBJECTIVELY
7	VERIFIABLE FACT RATHER THAN A DIFFERENCE OF
8	SCIENTIFIC OPINION. FOURTH, THAT THE DISCREPANCY
9	WAS NOT RESOLVED THROUGH THE SUPPLEMENTAL
10	INFORMATION PROCESS. IN OTHER WORDS, IF THE GRANTS
11	WORKING GROUP HAD AN OPPORTUNITY TO WEIGH IN ON IT,
12	WE DON'T WANT THE APPLICANT TO COME BACK TO YOU AND
13	TAKE A SECOND BITE AT THE APPLE. AND THEN, FINALLY,
14	THAT THE RESOLUTION OF DISPUTE IS MATERIAL TO YOUR
15	DETERMINATION ABOUT WHETHER THE APPLICATION SHOULD
16	BE FUNDED.
17	SO THOSE ARE THE CRITERIA WE WOULD SUGGEST
18	FOR MATERIAL DISPUTE OF FACT.
19	WITH RESPECT TO MATERIAL NEW INFORMATION,
20	WE WOULD SUGGEST THE FOLLOWING GUIDELINES: ONE,
21	THAT THE INFORMATION BE VERIFIABLE THROUGH EXTERNAL
22	SOURCES; TWO, THAT THE NEW INFORMATION ACTUALLY CAME
23	ABOUT AFTER THE GRANTS WORKING GROUP'S CONSIDERATION
24	OF THE APPLICATION; THIRD, THAT THE INFORMATION
25	RESPONDS DIRECTLY TO A SPECIFIC CRITICISM OR
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FIVE, IN ORDER TO PROVIDE AN OPPORTUNITY FOR STAFF TO EVALUATE THE INFORMATION, THAT IT BE INCLUDED IN
TO EVALUATE THE INFORMATION, THAT IT BE INCLUDED IN
AN EXTRAORDINARY PETITION THAT'S TIMELY SUBMITTED.
THAT IS, THAT IS SUBMITTED FIVE DAYS BEFORE THE
DEADLINE.
SO WHAT DO WE MEAN BY EXTERNALLY
VERIFIABLE INFORMATION? SOME EXAMPLES MIGHT BE
APPROVAL BY THE FDA TO INITIATE A CLINICAL TRIAL, A
DOCUMENTED AND ENFORCEABLE AGREEMENT BETWEEN THE
APPLICANT AND A COMMERCIAL PARTNER, A FINAL COURT
DECISION OR ADMINISTRATIVE ACTION OR A DOCUMENTATION
CONFIRMING THAT A MANUSCRIPT HAS BEEN ACCEPTED FOR
PUBLICATION IN FINAL FORM. INFORMATION SUBMITTED AS
PART OF THE SUPPLEMENTAL INFORMATION PROCESS WOULD
NOT BE CONSIDERED NEW INFORMATION. AND FINALLY, NEW
SCIENTIFIC DATA WOULD NOT BE CONSIDERED NEW
INFORMATION UNLESS IT HAS BEEN PEER REVIEWED AND
PUBLISHED.
WITH RESPECT TO THE PROCESS FOR THE
ADDITIONAL ANALYSIS, SIMILAR TO THE WAY THE
ADDITIONAL ANALYSIS WAS HANDLED WITH RESPECT TO THE
DISEASE TEAM II APPLICATIONS, WE RECOMMEND THAT IT
BE CONDUCTED BY THE GRANTS WORKING GROUP REVIEW
CHAIR, A PATIENT ADVOCATE MEMBER OF THE GRANTS
386

1	WORKING GROUP, AND A SCIENTIFIC MEMBER OF THE PEER
2	REVIEW PANEL THAT EXAMINED THE APPLICATION. THE
3	REVIEW SHOULD BE LIMITED SPECIFICALLY TO THE
4	MATERIAL DISPUTE OF FACT OR THE MATERIAL NEW
5	INFORMATION IDENTIFIED BY THE BOARD. AND THE CHARGE
6	OF THIS SUBSET OF THE GRANTS WORKING GROUP WOULD BE
7	TO RECOMMEND WHETHER RESOLUTION OF THE FACTUAL
8	DISPUTE OR CONSIDERATION OF THE NEW INFORMATION IN
9	THEIR VIEW WARRANTS A CHANGE IN THE GRANTS WORKING
10	GROUP'S FUNDING RECOMMENDATION. WE WOULD NOT ASK
11	THEM TO RESCORE THE APPLICATION.
12	SO OUR REQUEST TODAY IS TO ASK FOR A
13	MOTION TO APPROVE THE MODIFICATIONS TO THE
14	EXTRAORDINARY PETITION POLICY AND TO ADOPT THE
15	ADDITIONAL ANALYSIS OPTION AS SET FORTH IN THE
16	DOCUMENTS WE SUBMITTED TO YOU.
17	DR. PULIAFITO: QUESTION. THE APPLICANTS,
18	AT WHAT TIME ARE THEY COMMUNICATED WITH ABOUT THE
19	RESULTS OF THE GRANTS WORKING GROUP REVIEW? AND ARE
20	THEY TOLD THAT THE GROUP OF RECOMMENDED FUNDING OR
21	NOT FUNDING?
22	MR. HARRISON: I'LL DEFER TO GIL SAMBRANO
23	TO ANSWER THAT.
24	DR. SAMBRANO: SO IT'S APPROXIMATELY TWO
25	WEEKS BEFORE THE SCHEDULED BOARD MEETING THAT
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	JO.

1	APPLICANTS RECEIVE BY E-MAIL THE REVIEW SUMMARY AND
2	THEN INSTRUCTIONS AND GUIDELINES ON HOW TO APPEAL OR
3	SUBMIT.
4	DR. PULIAFITO: BUT DOES THE REVIEW
5	SUMMARY SAY YOU'RE IN THE FIRST TIER. THE GRANTS
6	WORKING GROUP RECOMMENDED FUNDING, OR YOU'RE
7	DR. SAMBRANO: YES. IT PROVIDES THE SCORE
8	AND IT PROVIDES THE RECOMMENDATION.
9	MR. HARRISON: BY THE WAY, AS GIL
10	MENTIONED YESTERDAY, I BELIEVE, APPLICANTS ARE ALSO
11	ADVISED OF THE OPPORTUNITY TO FILE AN EXTRAORDINARY
12	PETITION AS WELL AS INFORMATION WITH RESPECT TO THE
13	APPEALS PROCESS IN THE GRANTS ADMINISTRATION POLICY.
14	SO ALL OF THAT INFORMATION IS PROVIDED TO APPLICANTS
15	WHEN THEY RECEIVE THE RECOMMENDATION FROM THE GRANTS
16	WORKING GROUP.
17	DR. PRICE: COULD YOU GO BACK TO THE
18	PREVIOUS SLIDE? SO I HAVE A QUESTION ABOUT BULLET
19	2. I DON'T SEE THE RELEVANCE TO THIS CONSIDERATION
20	OF THE NECESSITY THAT THE DATA BE PEER REVIEWED AND
21	PUBLISHED. IT SEEMS TO ME THE SIGNIFICANT THING IS
22	WHETHER THERE IS DATA WHICH SUPPORTS THE ARGUMENT
23	THAT THE GRANTS WORKING GROUP SAID DIDN'T EXIST. WE
24	HAVE SCIENTIFIC CAPABILITIES HERE. THE GRANTS
25	WORKING GROUP HAS THE ABILITY TO EVALUATE THE DATA.

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1	WHAT IS THE SIGNIFICANCE OF HAVING EXTERNAL PEER
2	REVIEW AND THE FACT THAT SOMETHING HAS ACTUALLY BEEN
3	PUBLISHED? THIS IS NOT A TENURE REVIEW. AND SO
4	WHAT'S IMPORTANT IS WHETHER OR NOT THE DATA EXISTS.
5	AND I THINK WE HAVE THE CAPABILITIES
6	IN-HOUSE TO MAKE OUR OWN EVALUATION, NOT IN THE
7	BOARD HERE NECESSARILY, BUT IN THE SCIENTIFIC STAFF
8	AND IN THE GRANTS WORKING GROUP.
9	MR. HARRISON: I'LL DEFER TO DR. STEWARD
10	TO ANSWER THAT ONE.
11	DR. STEWARD: FIRST OF ALL, THIS APPLIES
12	TO INFORMATION THAT COMES IN AFTER THE GRANTS
13	WORKING GROUP HAS SEEN THE DOCUMENT. SO THIS IS NEW
14	INFORMATION. AND THE REASON FOR THE PEER REVIEW
15	PART IS THAT WE GENERALLY DON'T HAVE THE TIME AS A
16	BOARD TO DRILL DOWN INTO THE SPECIFICS OF THE DATA
17	IN THE WAY THAT A REAL EXPERT PEER COULD DO. THE
18	SCIENTIFIC STAFF MAY NOT HAVE THE OPPORTUNITY TO DO
19	THAT EITHER. AND SO, REALLY, THIS IS JUST A WAY OF
20	SAYING, YES, THIS HAS BEEN PEER REVIEWED, AND IT IS
21	CONFIRMED TO BE REASONABLY SOLID SCIENTIFIC DATA.
22	DR. PRICE: BUT THESE EXTRAORDINARY
23	PETITIONS ARE BEING ANALYZED BY THE STAFF WHEN THEY
24	MAKE THEIR RECOMMENDATIONS TO US.
25	DR. STEWARD: YES, BUT JUST TO SAY, NOT
	389
	J 303

1	ALL OF THE SCIENCE THAT WE SUPPORT IS REPRESENTED BY
2	THE EXPERTISE OF SCIENTIFIC STAFF.
3	DR. TROUNSON: IT'S FREQUENTLY NOT
4	SUFFICIENT INFORMATION TO MAKE A JUDGMENT ON IT.
5	YOU REALLY DO NEED THE WHOLE SET OF SEQUENCES,
6	INCLUDING THE METHODOLOGIES AND THE CONTROLS AND
7	EVERYTHING ELSE. IT'S RARE THAT YOU DO GET THAT IN
8	UNPUBLISHED DATA. SO THE PROBLEM IS YOU CAN SAY
9	THAT PIECE OF DATA EXISTS, BUT IT'S INCREDIBLY
10	DIFFICULT TO MAKE A JUDGMENT ON THE VALIDITY OF THAT
11	DATA UNLESS YOU'VE GOT THE WHOLE SET, REALLY THE
12	WHOLE SET.
13	AND IT BECOMES REALLY A PROBLEM FOR US TO
14	GUESSTIMATE THE REAL VALUE OF IT; WHEREAS, IF IT'S
15	BEEN PUBLISHED AND HAS BEEN PEER REVIEWED, YOU MAY
16	NOT NECESSARILY AGREE WITH THE PEER REVIEW, BUT IT'S
17	BEEN REVIEWED. AND SO SOMEONE HAS BEEN THROUGH THE
18	WHOLE DATA SET. SO I THINK YOU COULD FEEL A LITTLE
19	BIT MORE CONFIDENCE ABOUT THAT DATA THAN IF YOU JUST
20	RECEIVED A TABLE OR A FIGURE, WHICH IS REALLY
21	FREQUENTLY WHAT YOU DO GET. AND PUTTING THAT IN
22	CONTEXT OF THAT IS THIS REAL INFORMATION, OR IS THIS
23	INFORMATION THAT YOU WOULD MAKE A JUDGMENT ON FOR A
24	10 OR \$20 MILLION PROJECT. I THINK YOU REALLY NEED
25	MORE INFORMATION THAN THAT.

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1	CHAIRMAN THOMAS: MR. SHESTACK. MR. ROTH.
2	MR. SHESTACK: I THINK OUR GRANT REVIEW
3	PROCESS IS NOT PERFECT, BUT IT IS ALWAYS GETTING
4	MORE PERFECT AND GETTING REFINED AND GETTING BETTER.
5	AND I THINK THAT EVEN THOUGH THE EXTRAORDINARY
6	PETITION PROCESS AND THE ADDITIONAL REVIEW AND
7	SUPPLEMENTAL DATA PROCESS MIGHT SEEM CHAOTIC, IT
8	ARRIVED AT A CLOSER, BETTER VERSION OF THE TRUTH
9	THAN WE HAD BEFORE WE DID IT. SO I APPLAUD
10	EVERYBODY FOR HAVING SOME FLEXIBILITY ON THAT.
11	I WOULD SUGGEST THAT THIS LANGUAGE WHERE
12	IT SAYS NEW INFORMATION SHOULD BE VERIFIABLE THROUGH
13	EXTERNAL SOURCES IS SUFFICIENT. AND I WOULD
14	CONSIDER STRIKING UNLESS IT HAS BEEN PEER REVIEWED
15	AND PUBLISHED BECAUSE, FOR INSTANCE, THE AMOUNT OF
16	TIME BETWEEN WHEN SOMEBODY PUTS IN A GRANT, THE
17	GRANT IS REVIEWED, AND THEN IT'S DECIDED ON IS OFTEN
18	STILL LESS THAN THE EIGHT-MONTH PERIOD IT MIGHT TAKE
19	FOR AN ARTICLE TO GET THROUGH PUBLICATION, TO GET
20	THROUGH THE PUBLICATION PROCESS.
21	IF YOU'RE DEALING WITH A COMPANY, FOR
22	INSTANCE, THAT'S DOING DISCOVERY SCIENCE ON A DRUG
23	OR A COMPOUND, THEY MAY NEVER PUT THAT STUFF THROUGH
24	A PEER REVIEW JOURNAL. THEY MAY SHARE THAT DATA
25	WITH YOU, BUT THEY MAY NOT PUT IT THROUGH. AS AN
	391

1	EXAMPLE, THE DECISION ON THE DMD GRANT, IF THIS
2	AND I UNDERSTAND PEOPLE HAD SOME OBJECTIONS, BUT
3	THAT WAS DATA THAT WAS REGULARLY SCHEDULED TO COME
4	OUT. THERE WAS GOING TO BE A MUSCLE BIOPSY 12
5	WEEKS, 36 WEEKS, 48 WEEKS, WHATEVER THE THING WAS,
6	AND NEW DATA WAS COMING OUT. WASN'T GOING TO BE
7	PEER REVIEWED AND PUBLISHED, BUT IT WAS, IT TURNS
8	OUT, GERMANE.
9	SO I THINK THAT WE WILL MISS THINGS. IT
10	IS NOT THAT MANY PEOPLE. I WOULD HOPE THAT PEOPLE,
11	AFTER THIS ROUND WEREN'T SO GRABBY ABOUT SAYING THEY
12	HAD REAL SUBSTANTIAL NEW INFORMATION, AND THEY MIGHT
13	NOT BE. BUT I THINK WE CAN TRUST THE DISCERNMENT OF
14	THE ADDITIONAL REVIEW GROUP TO FIGURE OUT IF THAT IS
15	REAL DATA. AND IF WE PUT THIS RESEARCH WERE PEER
16	REVIEWED AND PUBLISHED, YOU WILL BY DEFINITION MISS
17	SOME IMPORTANT NEW DATA ONCE IN A WHILE.
18	MR. ROTH: SO I AM THANKFUL TO HAVE THIS
19	CHART. SO I APPRECIATE THE WORK THAT WENT INTO IT
20	BECAUSE IT HELPS KEEP IN FRONT OF US OUR PROCESS,
21	AND IT'S SOMETIMES DIFFICULT TO REMEMBER ALL THE
22	LITTLE NUANCES WE PUT IN. I AGREE WITH THE LAST
23	STATEMENT THAT WE HAVE GOTTEN BETTER AND BETTER AT
24	IT. BUT I BELIEVE, BASED ON THE LAST TWO MEETINGS,
25	THERE'S A LONG WAY TO GO TO TRY TO BRING WHAT I

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1	BELIEVE SHOULD BE A FAIR, UNIVERSALLY FAIR PROCESS
2	AND A TRANSPARENCY AS MUCH AS WE CAN TO THIS REVIEW
3	PROCEDURE.
4	AND I'M TALKING ABOUT A COMPREHENSIVE
5	REVIEW OF WHAT WE'RE DOING AND SEE IF THERE ARE
6	OTHER WAYS WE COULD, IN FACT, IMPROVE THIS PROCESS
7	FOR THE BENEFIT OF ALL US, INCLUDING THE PATIENT
8	GROUPS THAT COME BEFORE US, INCLUDING THE SCIENTISTS
9	WHO COME BEFORE US, AND OUR DIFFICULT DECISIONS THAT
10	WE HAVE TO REACH OFTEN IN AN EMOTIONALLY CHARGED
11	SETTING ABOUT WHAT TO DO.
12	SO MY RECOMMENDATION WOULD BE THAT WE
13	APPROVE THIS WITH SOME MODIFICATIONS, IF YOU WANT TO
14	MAKE THOSE, BUT THAT WE ASSIGN A GROUP TO REALLY
15	TAKE A DEEP DIVE INTO THIS. AND I WOULD EVEN MAKE
16	SOME SUGGESTIONS OF WHAT THAT GROUP MIGHT LOOK LIKE.
17	AND COME BACK TO US ALONG WITH THE INSTITUTE OF
18	MEDICINE REVIEW, WHICH I THINK IS GOING TO BE DONE
19	BY THE END OF THE YEAR, SO THAT WE CAN THEN HAVE A
20	MEANINGFUL CONVERSATION ABOUT THIS.
21	SO IF I WERE LOOKING, I'D SAY IT'S TIME
22	THAT WE REALLY REEVALUATE EVERYTHING WE CAN. SO I'D
23	LOVE TO SEE SOME LEGAL REPRESENTATION SO WE MAKE
24	SURE WE'RE FULFILLING THE OBLIGATIONS, AND JAMES
25	DOES THAT, JEFF AND OS HAVE DONE A GREAT JOB AND
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HAVE SOME EXPERIENCE. I THINK PEOPLE LIKE
ANNE-MARIE WOULD BE GREAT WITH FRESH EYES, NEW EYES
TO COME ON. I THINK BERT AND KRISTINA AND SOME
PEOPLE WHO HAVE HAD SOME EXPERIENCE AND HAVE SOME
GOOD THOUGHTS ON THIS AND AREN'T NECESSARILY THE
PEOPLE THAT WROTE THE PROCESS OR DEVELOPED IT WOULD
BE GOOD TO GET THEM TOGETHER AND MAYBE ONE OR TWO
OUTSIDE PEOPLE, LIKE SOMEBODY FROM JDRF THAT REVIEWS
GRANTS, SO WE GET THEM INVOLVED, AND MAYBE A COMPANY
THAT HAS HAD SOME EXPERIENCE SUBMITTING GRANTS TO US
IN THE FEEDBACK.
BUT I THINK IF WE DID THAT AND BROUGHT
THAT BACK, THEN WE COULD HAVE A MEANINGFUL
CONVERSATION ABOUT WHAT PROCEDURES AND POLICIES WE
WANT TO ENACT.
DR. PULIAFITO: MY CONCERN IS ABOUT THE
INTEGRITY OF THE PROCESS IN GENERAL. AND I AGREE
WITH DUANE. I THINK THERE NEEDS TO BE REVIEW. I
UNDERSTAND THAT WE ARE THE FINAL AUTHORITY ON MAKING
THESE DECISIONS, BUT I AM QUITE CONCERNED TO SEE AN
INCONSISTENT APPROACH TO THE WAY WE HANDLE
RECOMMENDATIONS THAT DEVIATE FROM THE GRANTS WORKING
GROUP. AND MANY TIMES IT'S ON HOW TIRED THE BOARD
IS, THE ORDER IN WHICH THEY'RE PRESENTED, AND, QUITE
FRANKLY, CLEARLY IN SOME INSTANCES I WOULD AGREE
394

1	WITH SENATOR TORRES, YES, WE'RE NOT A POLITICAL
2	ORGANIZATION, BUT THERE WAS OBVIOUSLY LOTS OF
3	LOBBYING BEING DONE BY CERTAIN INDIVIDUALS LOBBYING
4	THE BOARD DIRECTLY ON THINGS. SO THAT'S NOT THE WAY
5	WE SHOULD BE DOING THINGS.
6	AND I'M CONCERNED THAT THERE'S GOING TO BE
7	AN ESCALATION. THERE IS NO REASON PEOPLE
8	THERE WILL BE MORE LOBBYING, MORE POLITICKING; AND
9	ON BIG MONEY GRANTS, VIRTUALLY EVERYBODY IS GOING TO
10	CALL UP THEIR FRIENDS AND TRY TO REOPEN THINGS. AND
11	WHEN WE REOPEN THINGS, FREQUENTLY WE'RE NOT MAKING
12	THE RIGHT DECISION. SO I HAVE CONCERNS, AND I SEE
13	THE OTHER DEANS SHAKING THEIR HEADS ABOUT THIS.
14	MR. SHEEHY: WELL, I ACTUALLY SUPPORT BOTH
15	WHAT DUANE ROTH HAS SAID AND DR. PULIAFITO. BUT I
16	REALLY THINK WHAT WE NEED TO DO IS GO BACK AND LOOK
17	AT THE PROCESS. I THINK THIS IS GOING TO BE AN
18	INEVITABLE OUTCOME OF OUR BIG MONEY GRANTS IF WE
19	DON'T I TALKED OFFLINE TO A COUPLE OF FOLKS DO
20	SOMETHING LIKE A REVERSE SITE VISIT. WE DON'T HAVE
21	MORE DIRECT CONTACT. THESE BIG GRANTS ARE TOO
22	COMPLEX. AND WHEN THE GRANTEES RAISE OBJECTIONS AND
23	THEY CAN'T GET A REAL-TIME ANSWER FROM THE
24	REVIEWERS, I THINK THAT SETS US UP FOR THE KINDS OF
25	MEETINGS WE'VE BEEN HAVING.
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1	I THINK IF THOSE CORE SCIENTIFIC ISSUES
2	THAT PEOPLE ARE DISPUTING CAN BE DEALT WITH IN
3	REAL-TIME AT THE REVIEW, I THINK THAT WOULD ADDRESS
4	A LOT OF THAT. I KNOW THAT THAT'S WHAT THE NIH USED
5	TO DO WITH THEIR BIG GRANTS, AND I THINK IF WE COULD
6	PERHAPS PULL TOGETHER THE GROUP THAT DUANE ROTH WAS
7	TALKING ABOUT AND REALLY FIGURE OUT HOW TO DO THIS,
8	THAT THIS WOULD TAKE CARE OF IT. I WOULD FEEL MORE
9	CONFIDENT SAYING NO EVEN TO A VERY EMOTIONAL APPEAL,
10	EVEN TO CERTAIN ARM TWISTING BY CERTAIN INDIVIDUALS,
11	IF I HAD SAT THERE AND HEARD THE VERY SAME ISSUE
12	ADDRESSED TO THE REVIEW GROUP AND THE REVIEW GROUP
13	EXPLAINED WHY THEY DON'T AGREE AND HAVE THE MATTER
14	SETTLED THERE DEFINITIVELY RATHER THAN HAVING THE
15	REVIEW GROUP MAKE THEIR ANALYSIS, YOU GET THE
16	REBUTTAL FROM THE GRANTEE, AND THEN WE'RE HERE WITH
17	BOTH THE REVIEWER AND THE REBUTTAL AND THE TWAIN
18	HAVEN'T MET IN A REALLY TRUE PEER REVIEW FASHION TO
19	REALLY GET TO THE BOTTOM OF IT.
20	AND I THINK THAT THESE BIG MONEY GRANTS,
21	YOU HAVE TO. THESE ARE INCREDIBLY COMPLEX GRANTS.
22	MR. TORRES: IT'S MY RECOLLECTION WE'VE
23	HAD GRANTEES ON THE PHONE, BUT THEY WERE NEVER ASKED
24	QUESTIONS IN THE WORKING GROUPS.
25	MR. SHEEHY: WE HAVEN'T HAD THEM ON THE
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1	PHONE, AND I THINK WE'VE HAD THE ABILITY, BUT I
2	THINK WE SHOULD FORMALIZE THE PROCESS.
3	MR. TORRES: THEN WE SHOULD BEGIN TO ASK
4	THE REVIEWERS TO CALL THE GRANTEES IF THEY HAVE
5	PROBLEMS.
6	MR. SHEEHY: I THINK WE SHOULD JUST
7	PLAN I THINK WE SHOULD SAVE THIS FOR THE PROCESS
8	THAT DUANE HAD RECOMMENDED, BUT I ACTUALLY THINK
9	THAT THEY SHOULD JUST EXPECT TO DO THIS. WE DO THIS
10	IN THE CDAP PROCESS. I THINK THAT PEOPLE COME OUT
11	OF THAT, MAYBE THEY DON'T AGREE, BUT THEY FEEL LIKE
12	THEY HAD THEIR SAY. I FEEL LIKE THE ISSUES ARE
13	REALLY PRETTY CHEWED UP BY THE TIME THEY GET THROUGH
14	HAVING GONE BACK AND FORTH WITH EACH OTHER.
15	DR. SAMBRANO: WELL, SORT OF. I WANT TO
16	JUST EXPLAIN THAT WE HAVE TO SOME EXTENT FORMALIZED
17	A PROCESS BY WHICH WE ALLOW REVIEWERS TO ASK
18	QUESTIONS OF THE APPLICANTS AND THEN PROVIDE AN
19	OPPORTUNITY FOR THE APPLICANT TO PROVIDE A RESPONSE
20	THAT WE FORWARD TO REVIEWERS. AND SO THIS HAPPENS A
21	COUPLE OF WEEKS BEFORE THE REVIEW. AND SO THAT
22	CERTAINLY ALLOWS TIME FOR ANY KEY ISSUES OR
23	UNADDRESSED QUESTIONS TO BE ADDRESSED.
24	AND THEN WE ALSO HAVE IMPLEMENTED A
25	MECHANISM BY WHICH IF A CRITICAL QUESTION ARISES
	397

1	DURING THE REVIEW, WE CONTACT THE APPLICANT. BUT,
2	YOU KNOW, IN ORDER TO DO THAT REAL-TIME QUESTION, IT
3	HAS TO BE OF A PARTICULAR TYPE. IT HAS TO BE
4	SOMETHING THAT CAN BE ANSWERED IMMEDIATELY,
5	BASICALLY A YES-OR-NO ANSWER. THEY CANNOT PROVIDE
6	DATA IN REAL-TIME TO A QUESTION FROM A REVIEWER THAT
7	IS ASKING FOR MORE DATA. SO I THINK THERE IS A
8	PARTICULAR TYPE OF QUESTION THAT CAN BE ADDRESSED
9	THERE.
10	I THINK THE OTHER THING THAT'S IMPORTANT
11	TO NOTE IS THAT THE RESPONSES FROM APPLICANTS IN
12	MOST CASES IN TERMS OF A PETITION IS BECAUSE THEIR
13	RECOMMENDATION IS NOT TO FUND. SO ONCE THEY GET
14	THAT RECOMMENDATION, THAT'S REALLY WHAT DRIVES THE
15	PETITION AND APPEALS. AND IN THE ABSENCE OF THAT,
16	THEY WON'T DO THAT. SO IF ALL OF THIS HAPPENS
17	BEFORE A RECOMMENDATION IS REACHED, I DON'T KNOW
18	THAT THAT'S NECESSARILY GOING TO SOLVE THE ISSUE.
19	DR. POMEROY: I'D FIRST LIKE TO
20	ACKNOWLEDGE THAT STAFF PUT A LOT OF THOUGHT INTO
21	THIS AND REACHED OUT TO A LOT OF PEOPLE IN TRYING TO
22	PERFECT THIS. AND I THINK THAT THE REAL ANXIETY
23	THAT WE'RE ALL EXPRESSING IS ALL THE WAYS THAT THE
24	PEER REVIEW PROCESS CAN BE CIRCUMVENTED. BUT I'D
25	ALSO LIKE TO POINT OUT THAT THE CONSTANTLY SHIFTING
	398

1	SET OF RULES IS ALSO VERY, VERY HARD AND UNFAIR TO
2	OUR INVESTIGATORS.
3	AND SO IT SEEMS LIKE WHAT WE DO IS WE
4	TWEAK THIS EACH TIME WE DISCOVER A NEW PROBLEM. AND
5	SO IF WE ARE GOING TO ASSEMBLE THIS GROUP, IT SHOULD
6	BE A DEFINITIVE THING THAT WE STICK TO. THERE
7	PROBABLY ISN'T A PERFECT SOLUTION. I THINK THE MAIN
8	MESSAGE I TOOK AWAY FROM THIS ONE IS THIS SHOULD NOT
9	BE USED TO HAVE A SCIENTIFIC DISCOURSE, A DIFFERENCE
10	OF SCIENTIFIC OPINION. AND THE MAIN MESSAGE OF THIS
11	WAS DO NOT USE THESE PROCESSES UNLESS YOU HAVE A
12	MATERIAL FACT THAT YOU CAN PROVE, NOT AN OPINION,
13	AND GENUINELY NEW DATA.
14	AND I PERSONALLY SUPPORT THAT EMPHASIS,
15	THAT TAKING TIME TO HAVE A BACK AND FORTH ABOUT
16	DIFFERENCES OF SCIENTIFIC OPINION IS NOT WE'RE
17	NEVER GOING TO RESOLVE THOSE. SO LET'S AT LEAST
18	LIMIT THE CONVERSATIONS.
19	CHAIRMAN THOMAS: VERY WELL SPOKEN.
20	DR. TROUNSON: I THINK ONE OF THE REALLY
21	CRITICAL THINGS IS ARE YOU ACTUALLY PUTTING MONEY
22	INTO THINGS WHICH ARE REALLY NOT GOING TO BE
23	EFFECTIVE? IS THAT BECAUSE IF YOU'RE PUTTING
24	MONEY INTO RESEARCH THAT ACTUALLY IS EFFECTIVE, THEN
25	IT WILL MAKE THEN IT'S A GOOD DECISION-MAKING.
	399

1	SO SOME OF THIS YOU CAN'T DECIDE, BUT WE'VE GOT
2	CAPABILITY OF ANALYZING SOME OF THE DECISIONS THAT
3	HAVE BEEN MADE, AND WE CAN SEE WHETHER IT FALLS IN
4	THE AREA THAT WE'D EXPECT.
5	BUT IT IS SOME CONCERN TO ME, AND I'M
6	EXPRESSING MY VIEW BECAUSE WHEN I HEAR THAT
7	SOMETIMES THE BOARD SAY THEY DON'T REALLY CARE TOO
8	MUCH ABOUT WHETHER THAT'S AN IMPORTANT FACT OR
9	THAT'S IMPORTANT INFORMATION OF SCIENTIFIC
10	INFORMATION, THAT IS A CONCERN BECAUSE I THINK YOU
11	MIGHT BE MAKING DECISIONS ON OTHER ASPECTS THAT
12	MIGHT BE EVEN EMOTIONAL.
13	SO I THINK REALLY PART OF THIS IS TO MAKE
14	SURE YOU FEEL CONFIDENT THAT WHAT YOU'RE MAKING A
15	DECISION ON IS REALLY IN THE BEST INTERESTS OF THE
16	AGENCY GOING FORWARD AND THE DELIVERY OF AN
17	EMPHATICALLY GOOD PROGRAM. I THINK ON BALANCE IT
18	PROBABLY IS. SO THERE WOULD BE POSSIBLY AREAS WHERE
19	IT BECOMES A LITTLE SHAKY. AND WE OUGHT TO HAVE
20	SOME IF YOU'RE GOING TO GO THROUGH THIS REVISION
21	OF A DISCUSSION OF IT, WE SHOULD HAVE SOME ANALYSIS
22	OF HOW THE DECISIONS ARE MADE AND WHETHER THE
23	DECISIONS WERE FORMULATED IN A DIFFERENT WAY, AND IS
24	THAT OUR EXPERIENCE THAT IT DIDN'T WORK VERY WELL
25	BECAUSE I THINK YOU NEED SOME FACTS AS WELL.
	400

1	IF YOU ARE GOING TO MAKE DECISIONS ABOUT
2	SETTING UP A BETTER REVIEW, DO IT ON FACTS OR AS
3	MANY FACTS AS WE CAN PUT TOGETHER FOR YOU. AND IF
4	YOU DO THAT, THEN I THINK YOU CAN FEEL, WELL, YOU'RE
5	PROBABLY DOING AS BEST YOU CAN.
6	I THINK THE PROBLEM ABOUT I'VE ACTUALLY
7	BEEN IN A SITUATION WHERE YOU GET CONFRONTED WITH
8	THE REVIEWERS AND THE RESEARCH TEAM. AND I'VE SEEN
9	THE GOOD AND THE BAD OF THAT AS WELL BECAUSE
10	SOMETIMES THAT DOESN'T WORK OUT VERY WELL AT ALL
11	EITHER. SO IT DEPENDS ON WHAT SET OF FACTS THAT
12	YOU'RE SEEKING OUT.
13	I WOULD JUST SAY IF YOU'RE GOING TO
14	FORMULATE A GROUP TO LOOK AT THIS, LET'S TRY AND
15	GATHER SOME FACTS FOR YOU THAT WOULD HELP YOU MAKE A
16	SET OF DECISIONS THAT ARE WORTHWHILE RATHER THAN
17	JUST GUESSING WHAT MIGHT BE BEST.
18	CHAIRMAN THOMAS: THANK YOU, DR. TROUNSON.
19	OTHER COMMENTS?
20	DR. STEWARD: SO JUST TO ADD HOPEFULLY ONE
21	LAST POINT BEFORE WE BRING THIS TO A VOTE. ONE OF
22	THE OTHER ISSUES, I THINK, THAT WE NEED TO BE
23	SENSITIVE TO IS THE AMOUNT OF TIME THAT THE
24	INVESTIGATORS ACTUALLY SPEND PUTTING THESE THINGS
25	TOGETHER. I THINK THAT MOST OF THE INVESTIGATORS
	401
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1	DON'T REALLY HAVE ANY CLUE ABOUT WHAT WE CONSIDER TO
2	BE USEFUL INFORMATION AND NOT. HAVING A BIT OF
3	GUIDANCE HERE WOULD, I THINK, BE EVEN MORE FAIR TO
4	THEM. IT WOULD HELP TO GUIDE WHATEVER THEY'RE GOING
5	TO PUT TOGETHER AND AT LEAST INDICATE THAT WE WOULD
6	BE WILLING OR NOT WILLING TO CONSIDER THAT
7	INFORMATION.
8	AT THE END OF THE DAY, THEY'RE STILL FREE
9	TO SEND IN WHATEVER THEY WANT AND STAND UP HERE AND
10	SAY WHATEVER THEY WANT AS LONG AS IT'S IN A
11	THREE-MINUTE AND THREE-PAGE TIME POINT, BUT
12	GUIDANCE, I THINK, WOULD HELP THEM AS WELL.
13	DR. LEVIN: I CERTAINLY WANT TO STRONGLY
14	SUPPORT DUANE'S AD HOC COMMITTEE TO LOOK AT THIS
15	BECAUSE I THINK THIS WHOLE PROCESS IS GETTING
16	UNWIELDY AND IT'S GROWING OUT OF CONTROL. EACH
17	ROUND WE HAVE MORE EXTRAORDINARY PETITIONS. AND AS
18	OS SAID, THE RULES OF THE GAME ARE NOT CLEAR. SOME
19	PEOPLE ARE EXPERTS AT WRITING EXTRAORDINARY
20	PETITIONS. SOME PEOPLE STATE THAT THEY DIDN'T EVEN
21	KNOW IT WAS POSSIBLE UNTIL AFTER HOWEVER LONG. SO
22	IT'S A VERY UNFAIR PLAYING FIELD IN THAT REGARD.
23	WHILE IT'S IMPORTANT TO GET A LOT OF INFORMATION,
24	YOU'RE NEVER GOING TO GET ALL THE INFORMATION THAT
25	YOU NEED TO MAKE A DECISION, AND WE NEED TO GO BY

402

WHAT'S A FAIR WAY TO MAKE DECISIONS.
WE'VE, AGAIN, STRAYED TO A PLACE WHERE NO
OTHER MAJOR GRANTING INSTITUTION THAT I KNOW OF
ACCEPTS SCIENTIFIC INFORMATION AFTER THE GRANT
SUBMISSION DEADLINE. SO THIS IS NEW JUST FOR US,
AND WE DO IT AS A MATTER OF COURSE NOW THAT THAT'S
OUT THERE. WE SHOULD PROBABLY REINVESTIGATE ALL OF
THESE ASPECTS OF WHAT WE CONSIDER, AND DO WE TAKE
NEW INFORMATION, HOW ARE WE SWAYED BY THINGS. BUT
UNTIL THAT POINT, I ALSO WOULD LIKE TO JUST SUGGEST
TWO VERY MINOR MODIFICATIONS TO THE WORDING FOR THE
EXTRAORDINARY PETITION.
ONE IS I THINK THAT IF WE'RE GOING TO
REQUIRE THAT YOU CAN ONLY HAVE AN EXTRAORDINARY
PETITION LABELED AS SO IF IT COMES IN WITHIN FIVE
DAYS. WE HAVE TO BE VERY CLEAR ABOUT HOW MUCH TIME
THEY'RE GOING TO HAVE TO GET THAT INFORMATION. SO
AT LEAST SAY YOU WILL GET YOUR RESULTS WITHIN FIVE
OR SEVEN BUSINESS DAYS FROM CIRM. YOU WILL GET
REVIEWERS' FEEDBACK AND YOUR FUNDING CATEGORY. I
DON'T THINK THAT THAT'S STATED ANYWHERE, WHEN
THEY'RE GOING TO BE INFORMED. I KNOW GIL SAID THAT
IT'S USUALLY TWO WEEKS BEFOREHAND, BUT WE SHOULD BE
VERY CLEAR ABOUT THAT. IF WE DON'T AT LEAST GIVE
THEM THAT BIG A WINDOW, IT'S NOT FAIR TO ASK THEM TO
403

1	TURN IT AROUND IN THAT MUCH TIME.
2	AND THE SECOND MODIFICATION I WOULD
3	SUGGEST IS THAT OTHER CORRESPONDENCE ALSO BE LIMITED
4	TO THREE PAGES. IT DIDN'T SAY THAT ANYWHERE, AND
5	THAT WILL SAVE EVERYBODY SOME HEARTACHE.
6	CHAIRMAN THOMAS: THANK YOU. THOSE ARE
7	BOTH GOOD SUGGESTIONS. I WILL SAY I BELIEVE WHEN
8	YOU SAY IT'S NOT A LEVEL PLAYING FIELD WITH RESPECT
9	TO EXTRAORDINARY PETITIONS, THAT AT THE TIME THEY'RE
10	NOTIFIED OF THE RESULTS OF THE REVIEW, ALL
11	APPLICANTS ARE GIVEN THE FULL MENU OF WAYS TO
12	APPEAL, WHICH INCLUDES THE EXTRAORDINARY PETITION
13	OPTION. AND THE FACT THAT SOME EXERCISE THAT AND
14	SOME DIDN'T ISN'T A MATTER OF UNFAIRNESS. IT'S JUST
15	THAT SOME CHOSE TO ACT AND SOME DIDN'T.
16	DR. LEVIN: I WAS MAINLY REFERRING TO THE
17	FACT THAT SOME PEOPLE ARE MORE AWARE OF WHAT THIS
18	BOARD GOING TO BE RESPONSIVE TO IN TERMS OF WHAT
19	GOES INTO AN EXTRAORDINARY PETITION OR WHETHER IT
20	WILL HAVE AN IMPACT OR WHAT IS ALLOWED AND OTHERS
21	AREN'T.
22	CHAIRMAN THOMAS: OKAY. SO FAIR POINT.
23	JOAN.
24	MS. SAMUELSON: QUICKLY. I THINK I'M
25	PROBABLY GOING TO VOTE AGAINST ANY CHANGES RIGHT
	404
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1	NOW, NOT THAT I THINK WE DON'T NEED THEM, BUT I
2	THINK THE CLOSER LOOK SHOULD HAPPEN FIRST. AND I
3	ALSO THINK THAT MOST LIKELY ALL OF THIS IS
4	SELF-POLICING TO SOME EXTENT. IF AN EXTRAORDINARY
5	PETITION COMES IN SOONER RATHER THAN LATER, IT'S
6	MORE LIKELY TO GET UP TO THE TOP OF THE STACK THAT I
7	CAN REVIEW BEFORE THE MEETING. SO IT BEHOOVES THEM
8	TO GET IN AT THE BEGINNING OF THOSE WINDOWS, AND
9	THEY'LL BE PREJUDICED IF THEY DON'T. SO THAT WILL
10	BE AN INCENTIVE.
11	AND I CRINGE TO THINK OF WHAT HAPPENS, WHO
12	DECIDES IF SOMETHING IS MATERIAL OR NOT OR PEER
13	REVIEWED OR NOT, AND THEN DOES THE INFORMATION NOT
14	COME TO US. AND I KNOW I DON'T WANT TO SIT HERE AND
15	HAVE TO COME UP WITH A BUNCH OF PROCEDURES ABOUT
16	THAT. SO, IN GENERAL, I THINK MORE INFORMATION THE
17	BETTER, AND THE MORE TRANSPARENT WE ARE THE BETTER.
18	AND THAT'S WHAT I'LL BE ENCOURAGING WHEN WE COME UP
19	WITH OUR NEXT LOOK AT HOW WE OPERATE.
20	CHAIRMAN THOMAS: THANK YOU. DEAN
21	PULIAFITO.
22	DR. PULIAFITO: I THINK THE RESOLUTION IS
23	A GREAT THING. BUT DO YOU ANTICIPATE RIGHT NOW
24	PEOPLE CAN BRING IN AN EXTRAORDINARY PETITION AND
25	THE BOARD MAY DECIDE, HEY, SOUNDS GOOD. WE'RE GOING
	405
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1	VOTE TO FUND YOU. DO YOU THINK UNDER THE NEW
2	SITUATION THAT WILL BE UNUSUAL? AND BEFORE ANYTHING
3	IS FUNDED BY BOARD VOTE, THEY WILL REFER IT FOR
4	REVIEW. IS THAT, YOU THINK, WHAT'S GOING TO HAPPEN
5	OR NOT?
6	MR. HARRISON: I THINK IT ULTIMATELY
7	DEPENDS UPON HOW THE BOARD RESPONDS TO THIS. BUT
8	THE NOTION IS TO GIVE YOU SOME TOOLS TO MAKE THOSE
9	DECISIONS. SO IN OTHER WORDS, IF SOMEONE SUBMITS
10	SOMETHING TWO DAYS BEFORE THE BOARD MEETING AND YOU
11	HAVEN'T HAD TIME TO ASSESS IT AND THEY HAD, TO DR.
12	LEVIN'S POINT, SUFFICIENT TIME TO SUBMIT, THEN YOU
13	CAN DECIDE NOT TO CONSIDER IT. AND THAT'S HOW
14	APPLICANTS, I THINK, WILL GET THE MESSAGE THAT THEY
15	EITHER HAVE TO ABIDE BY THESE RULES OR IT'S NOT
16	GOING TO WORK.
17	MR. ROTH: CAN I ASK A QUICK QUESTION?
18	WHEN DO WE HAVE OUR NEXT REVIEW OF GRANTS?
19	MR. HARRISON: NEXT WEEK.
20	MR. ROTH: NEXT WEEK IS THE GRANTS WORKING
21	GROUP. I'M TALKING ABOUT BOARD.
22	MR. HARRISON: OCTOBER.
23	MR. ROTH: SO THE REASON I ASK THE
24	QUESTION IS I WOULD LIKE REALLY TO APPROVE SOMETHING
25	TODAY, IF WE CAN, EVEN IF IT'S NOT PERFECT SO THAT
	406

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1	WE HAVE SOMETHING THAT WE CAN USE. AT LEAST THIS IS
2	A GUIDELINE. AND I'M WILLING ON THAT ONE ISSUE
3	ABOUT PEER REVIEW TO TRY TO FIND SOME WORDS THAT
4	WORK THERE, BUT I THINK WE SHOULD APPROVE SOMETHING
5	SO THAT THIS, AT LEAST, WOULD STAND AS A GUIDANCE
6	FOR US FOR THAT MEETING.
7	CHAIRMAN THOMAS: I THINK, DUANE, THAT'S A
8	VERY GOOD SUGGESTION, SPECIFICALLY WHY WE WANTED
9	THIS PARTICULAR TOPIC ON TODAY'S AGENDA SO IT COULD
10	ACT AS GUIDANCE FOR THE OCTOBER BOARD MEETING.
11	DR. KRONTIRIS: I PROBABLY WILL ABSTAIN ON
12	THIS. I'M NOT REALLY HAPPY WITH THIS EXTRA LEVEL OF
13	REVIEW. I WAS IN ON THE DISCUSSION OF THIS LAST
14	MEETING. I REALLY SUSPECT THIS IS GOING TO LEAD A
15	LOT OF INVESTIGATORS, CERTAINLY NOT ALL, TO MAKE
16	THESE EXTRAORDINARY PETITIONS THE NEXT PART OF THEIR
17	REVIEW. SO IF WE DO AGREE TO GO AHEAD WITH THIS, AS
18	I SUSPECT WE WILL FROM THE SOUNDS OF THE DISCUSSION,
19	I WONDER IF WE COULD AGREE THAT IF THIS REALLY
20	BEGINS TO PUT AN EXTRAORDINARY BURDEN ON THE STAFF
21	AS WE PROCEED TO THIS FURTHER COMPLICATION OF
22	REVIEW, THAT WE'RE OPEN TO RETHINKING HAVING DONE
23	THIS. THAT'S ALL.
24	CHAIRMAN THOMAS: THANKS, TED. DR.
25	TROUNSON.
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407

1	DR. TROUNSON: I'D MAKE ONE OBSERVATION TO
2	YOU, THAT IF YOU LOOK AT THIS MEETING, WE REALLY
3	CONCENTRATED ALL THE DISCUSSION ON THE EXTERNAL
4	PETITIONS. WE DIDN'T USED TO DO THAT BECAUSE WE
5	DIDN'T REALLY HAVE A LOT OF THEM. AND OFTEN IF THEY
6	CAME IN LATE, THE BOARD DIDN'T RAISE THEM. THEY
7	DIDN'T CONSIDER THEM IMPORTANT. NOW THE WHOLE FOCUS
8	IS ON THE EXTERNAL PETITIONS. SO WHY WOULDN'T ALL
9	THE SCIENTISTS PUT IN AN EXTERNAL PETITION? WE'RE
10	DRIVING THEM IN THAT DIRECTION.
11	DR. KRONTIRIS: EXACTLY.
12	DR. TROUNSON: WE DID BRING ONE TO YOU
13	THROUGH STAFF, WHICH WAS NOT ON THAT LIST AND I
14	THINK DESERVEDLY WORTHWHILE HAVING THAT DISCUSSION.
15	BUT YOU DO DISCUSS THE EXTERNAL PETITIONS AND NONE
16	OF THE OTHERS. SO WHY WOULDN'T YOU PUT IN ONE? YOU
17	HAVE TO BE NUTS. SO I THINK WE'VE GOT IT GOING THE
18	WRONG WAY, TO BE HONEST. UNLESS YOU REALLY WANT
19	THEM ALL TO DO IT, WHICH IS REALLY, I THINK, WHAT'S
20	GOING TO HAPPEN UNLESS YOU MAKE SOME CHANGE.
21	MS. GIBBONS: I JUST WANT TO BE CLEAR THAT
22	WHATEVER CHOICES AND DECISIONS WE MAKE ON THIS WHOLE
23	PROCESS, WHAT IS ACCEPTABLE AND ALLOWABLE UNDER OUR
24	STATUS AS A STATE AGENCY, AS A PUBLIC AGENCY? LIKE
25	IS IT ALWAYS APPROPRIATE AND ACCEPTABLE TO BE

408

1	COMMUNICATED WITH DIRECTLY FROM OUTSIDE FORCES? AND
2	CAN WE DO ANYTHING, SHOULD WE, I'M NOT SAYING ONE
3	WAY OR THE OTHER, NO MATTER WHAT WE VOTE ON, THAT'S
4	ALWAYS A PIPELINE THAT'S OPEN. AM I CORRECT?
5	MR. HARRISON: MEMBERS OF THE PUBLIC ARE
6	ALWAYS FREE TO CONTACT ANY OF YOU. BUT YOU AS A
7	BOARD COULD DETERMINE THAT IT'S NOT APPROPRIATE FOR
8	BOARD MEMBERS TO TAKE SUCH CALLS. THAT DOESN'T MEAN
9	THAT APPLICANTS AND INDIVIDUALS IN THE PUBLIC
10	COULDN'T MAKE THEM, BUT THAT WOULD BE A POLICY
11	CHOICE YOU COULD MAKE.
12	MS. GIBBONS: SO WE HAVE AUTONOMY OVER
13	THAT.
14	MR. HARRISON: CORRECT, OVER YOURSELVES.
15	MS. GIBBONS: WITH REGARD TO IF WE ARE
16	APPROACHED OR IF WE DO TAKE INFORMATION FROM A
17	MEMBER OF THE PUBLIC, WHAT GOVERNS OUR ABILITY TO
18	SPEAK WITH OTHER BOARD MEMBERS? IS IT SOMETHING TO
19	DO WITH NOTIFICATION? AND CAN YOU JUST REFRESH ME
20	ON THAT, PLEASE?
21	MR. HARRISON: YES. YOU ARE PROHIBITED AS
22	A GROUP, AT LEAST A MAJORITY OF YOU ARE PROHIBITED
23	EITHER ALL AT ONE TIME OR SERIALLY FROM DISCUSSING
24	AN ITEM THAT'S ON THE AGENDA, INCLUDING AN
25	APPLICATION.
	409

1	MS. GIBBONS: I'M LOOKING ON THE WEBSITE,
2	AND I KNOW THAT'S WHAT THIS GRAPH IS FOR. WE HAVE A
3	FANTASTIC WEBSITE. MAYBE I'M JUST NOT FINDING IT,
4	BUT WHERE IT TALKS ABOUT GRANTS. IS THE GOAL TO
5	HAVE A SPECIFIC SECTION FOR GRANTEES BECAUSE I'VE
6	HEARD SO MANY OF THEM SAY, AND MAYBE IT'S JUST A
7	DEFAULT POSITION THAT THEY GO TO, OF, WELL, I DIDN'T
8	KNOW I COULD DO AN EXTRAORDINARY PETITION. I DIDN'T
9	KNOW THIS. AND I DIDN'T KNOW THE TIMELINE. ARE WE
10	JUST GOING TO HAVE IT POSTED SOMEWHERE AND JUST SAY
11	LOOK AT THE WEBSITE. YES, YOU DID KNOW.
12	MR. HARRISON: WE HAVEN'T DISCUSSED THIS,
13	BUT MY GOAL WOULD BE TO TAKE ALL THESE THREE
14	POLICIES AND PUT ALL THE INFORMATION THAT PERTAINS
15	TO EACH OF THEM, SINCE THEY'RE RELATED, IN ONE PLACE
16	SO THAT IT IS CLEAR TO APPLICANTS WHAT MECHANISMS
17	CIRM HAS IN PLACE TO THE EXTENT THAT THEY WANT TO
18	COMMUNICATE WITH YOU OR TO PROVIDE SOME ADDITIONAL
19	INFORMATION.
20	MS. GIBBONS: I THINK THAT WOULD BE GREAT.
21	I THINK IT WOULD TAKE A LOT OFF OF US TOO JUST TO BE
22	ABLE TO REFER PEOPLE TO SOMETHING ON THE OFFICIAL
23	POSTING. THANK YOU.
24	DR. SAMBRANO: I JUST WANT TO REITERATE
25	THAT, AGAIN, EVERY APPLICANT RECEIVES AN E-MAIL FROM
	410
	410

1	ME THAT EXPLAINS THESE OPTIONS ALONG WITH THEIR
2	SCORE, RECOMMENDATION, AND SUMMARY.
3	MS. GIBBONS: I KNOW THEY KNOW. I'M JUST
4	SAYING THAT THEY NEED TO KNOW THAT WE KNOW THEY
5	KNOW. DO YOU KNOW WHAT I MEAN? THAT WE KNOW THEY
6	KNOW, AND WE ALL
7	CHAIRMAN THOMAS: I KNOW THAT DR. PRICE IS
8	NEXT.
9	DR. PRICE: JUST I'D LIKE TO SORT OF
10	RESPOND OR ASK SOME QUESTIONS OF ALAN IN REGARD TO
11	HIS LAST INTERVENTION. FIRST, EVEN IF WE ELIMINATED
12	WHAT WE'RE CALLING EXTRAORDINARY PETITIONS, WE HAVE
13	THE PUBLIC COMMENT PERIOD, AND WE END UP GETTING THE
14	EXTRAORDINARY PETITIONS IN ANOTHER FORM. AND THIS
15	TIME WE HAVE TO IN SOME WAY RESPOND, AND WE WOULDN'T
16	HAVE ANY INFORMATION WITH WHICH TO RESPOND. SO THE
17	VIRTUE AT LEAST ONE VIRTUE OF THE EXTRAORDINARY
18	PETITION PROCEDURE IS THAT WE HAVE SOMETHING TO GO
19	ON OTHER THAN THE EMOTIONAL STORIES THAT WE HEAR
20	FROM THE AUDIENCE.
21	THE SECOND QUESTION I HAVE IS IF THE BOARD
22	IS SERIOUS ABOUT ENFORCING THE TWO CRITERIA FOR
23	EXTRAORDINARY PETITIONS JAMES PUT UP THERE, WOULDN'T
24	THAT ELIMINATE, NOT ELIMINATE, OR LIMIT TO A GREAT
25	EXTENT THE NUMBER OF EXTRAORDINARY PETITIONS? AFTER
	411
	+ ++

1	ALL, HOW MANY PEOPLE CAN PRESENT GENUINELY NEW
2	INFORMATION TO US?
3	DR. TROUNSON: CAN I RESPOND TO THE FIRST
4	ONE? I THINK YOU GET ALL OF THIS DATA IN A BOOK,
5	AND YET NONE OF YOU ASK ANY QUESTIONS ABOUT THE
6	GRANTS THAT WERE NOT EXTRAORDINARY PETITIONS. NOW,
7	I THINK YOU'RE A LOT SMARTER THAN THAT. IF YOU
8	ACTUALLY DRILLED DOWN INTO THOSE, YOU WOULD HAVE
9	QUESTIONS ON THEM, BUT THEY WEREN'T RAISED.
10	I THINK KIND OF YOU MIGHT BE TAKING THE
11	EASY WAY OUT GOING TO THE EXTRAORDINARY PETITIONS.
12	I DON'T KNOW IF THAT'S A FAIR THING TO SAY, BUT IT'S
13	JUST GOT A FEEL ABOUT IT THAT BECAUSE THERE'S AN
14	EXTRAORDINARY PETITION IN THERE, YOU ARE GOING TO
15	THAT AND YOU'RE NOT GOING ANYWHERE ELSE. SO WHY
16	WOULDN'T EVERYBODY GO DOWN THAT TRACK?
17	IF YOU WERE ASKING MORE BROADLY, THERE MAY
18	NOT BE A PREFERENCE TO HAVE AN EXTRAORDINARY
19	PETITION. THEY MAY NOT. I'M NOT SUGGESTING IT
20	WOULDN'T HELP OR NOT HELP, BUT YOU'RE DRIVING ALL OF
21	THOSE PEOPLE INTO THAT DIRECTION. SO THEY WILL DO,
22	THEY CLEARLY WILL TO IT.
23	DR. PRICE: I DON'T WANT TO GET INTO A
24	DEBATE. I HAVE A RESPONSE. LET OTHERS TALK.
25	MS. FEIT: I'D LIKE TO MAKE A COMMENT. I
	412
	714

1	SIT ON A LOT OF THE GRANT REVIEWS, AND I THINK THE
2	DIFFICULT PART FOR THE MAJORITY OF THE BOARD IS MANY
3	OF YOU DON'T SIT IN ON THOSE REVIEWS. I CAN TELL
4	YOU THEY'RE EXTENSIVE, AND THERE'S A LOT OF THOUGHT
5	GONE INTO THE REVIEW OF EACH APPLICATION. AND IN
6	THE PAST WE REALLY TRUSTED THAT THERE WAS REALLY
7	NOTABLE SCIENTISTS IN THE ROOM DISCUSSING THE
8	SCIENCE. AND I CAN TELL YOU THEY TAKE IT VERY
9	SERIOUSLY.
10	I THINK THAT WE SHOULD NOT ENTERTAIN IT
11	SHOULD BE RARE THAT WE ENTERTAIN AN EXTRAORDINARY
12	PETITION, AND THAT IT SHOULD NOT COME FORWARD TO THE
13	BOARD UNLESS IT HAS HAD EXTRAORDINARY VETTING BY OUR
14	STAFF. AND I CAN TELL YOU OUR SCIENCE STAFF WORK
15	VERY HARD TO SURFACE ALL THE INFORMATION NECESSARY
16	BEFORE THE GRANT REVIEWS EVEN START AND DO A LOT OF
17	THE LEGWORK. AND SO THERE'S AN EXTENSIVE REVIEW TO
18	BEGIN WITH. I FEEL LIKE EVERYBODY ELSE, THAT WE'RE
19	STARTING TO PICK APART A REVIEW PROCESS THAT I
20	THOUGHT WAS WORKING VERY WELL.
21	AND I AGREE WITH ALAN, THAT WE'RE GOING TO
22	END UP SPENDING OUR ENTIRE BOARD MEETING
23	RE-REVIEWING PETITIONS AND GRANTS AND NOT REALLY
24	BEING SUPPORTIVE OF THE PROCESS WE ORIGINALLY PUT IN
25	PLACE. I THINK AN EXTRAORDINARY PETITION SHOULD BE
	413
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1	VERY RARE. IT WILL REQUIRE EXTRAORDINARY VETTING BY
2	OUR SCIENCE STAFF AGAIN AND BY OUR PRESIDENT, ALAN
3	TROUNSON, AND I THINK IT SHOULD NOT COME TO THE
4	BOARD UNLESS IT HAS GONE THROUGH THAT PROCESS AND
5	THERE'S ACTUAL FACT OR REASON TO RAISE IT TO THE
6	BOARD.
7	I THINK WHAT SHOULD COME TO THE BOARD IS
8	WHAT WE ORIGINALLY STARTED OUT WITH IS RECOMMENDED
9	FOR FUNDING, RECOMMENDED FOR FUNDING IN TIER II IF
10	FUNDING WAS AVAILABLE, AND NOT RECOMMENDED FOR
11	FUNDING. AND IT SHOULD BE VERY CLEAR AFTER ALL OF
12	THAT REVIEW AND ALL OF THAT WORK HAS BEEN DONE SO
13	THAT THE BOARD DOESN'T GET CAUGHT UP IN THE
14	POLITICKING OF A SPECIFIC DISEASE OR THE POLITICKING
15	OF A SPECIFIC GRANT.
16	CHAIRMAN THOMAS: I THINK JOAN WAS NEXT.
17	MS. SAMUELSON: I AGREE WITH EVERYTHING
18	MARCY JUST HAD TO SAY. ON THE OTHER HAND, AT THE
19	SAME TIME, I'VE BEEN SITTING HERE THINKING THAT
20	WE'VE DONE GREAT WORK AS A BOARD TODAY AND
21	YESTERDAY, THAT THERE'S BEEN REALLY EXTRAORDINARY
22	CONTRIBUTIONS FROM EVERYBODY ON THE BOARD PERTAINING
23	TO FAR BEYOND THE DECISION-MAKING THAT WAS RIGHT
24	IN FRONT OF OUR FACES BECAUSE IT GAVE US GOOD IDEAS
25	ABOUT FUTURE POLICIES AND ASSESSMENT OF OUR PROGRAM
	41.4

414

1	AND WHERE WE SHOULD GO FROM HERE AND ALL OF THAT,
2	WHICH IS OUR OBLIGATION.
3	SO THESE CONCRETE SITUATIONS HELP US TO DO
4	THE OTHER JOBS THAT WE HAVE AT THE SAME TIME. AND I
5	DON'T THINK WE WOULD DO AS QUALITY A JOB IF WE'RE
6	JUST LOOKING AT SHEETS OF POLICY.
7	MS. FEIT: I DON'T AGREE. I THINK THAT
8	THERE WERE IT SOUNDED TO ME LIKE THERE ARE BOARD
9	MEMBERS WHO HAVE BEEN UNCOMFORTABLE TODAY WITH WHAT
10	HAS GONE ON, AND THAT'S WHY WE'RE HAVING THIS
11	DISCUSSION. WELL, SOME OF YOU MAYBE FEEL VERY GOOD
12	ABOUT WHAT WENT ON. I DON'T THINK THAT EVERYBODY
13	FEELS THAT WAY.
14	DR. HAWGOOD: I THINK SEVERAL OF THE LAST
15	COMMENTS SUGGEST THAT WE'RE LOOKING FOR A POLICY
16	THAT WILL ALMOST PROTECT OURSELVES FROM OURSELVES.
17	I THINK THERE IS NO OPTION BUT TO HAVE AN APPEALS
18	PROCESS OF SOME SORT. THERE IS NOTHING STOPPING
19	ANYONE WRITING TO THE NIH COUNCIL AN APPEAL LETTER.
20	BUT WE HAVE TO HAVE THE SELF-DISCIPLINE TO FOCUS ON
21	THOSE THINGS THAT ARE TRULY APPEALABLE AND NOT GET
22	DRAWN INTO THINGS THAT SHOULD NOT BE CONSIDERED
23	APPEALABLE.
24	AND I THINK I AGREE WITH DUANE'S
25	RECOMMENDATION, BUT I WOULD HOPE THE GROUP CAN FOCUS
	415
	L J

1	ON THAT ISSUE AND NOT TRY TO FIND A POLICY THAT WILL
2	PROTECT OURSELVES FROM OURSELVES BECAUSE I THINK
3	THAT POLICY IS NOT FINDABLE. AND WE HAVE TO JUST
4	EXERT GOOD BOARD DISCIPLINE AROUND WHAT'S APPEALABLE
5	AND WHAT'S NOT TO KEEP IT FAIR AND TRANSPARENT TO
6	EVERYONE.
7	CHAIRMAN THOMAS: THANK YOU. JUST WANT TO
8	MAKE A POINT ON THIS. THE SORT OF TENOR OF THIS
9	DISCUSSION IS THAT WE ENDED UP LAST COUPLE DAYS WITH
10	RESULTS THAT WEREN'T GOOD. IF YOU LISTEN TO THIS,
11	IT'S LIKE THINGS GOT WAY OUT OF HAND. SO I JUST
12	WANT TO REMIND EVERYBODY THAT WITH RESPECT TO THE
13	EXTRAORDINARY PETITIONS, STAFF ORIGINALLY CAME BACK
14	RECOMMENDING THAT TWO OF THOSE HAD MERIT. BOTH OF
15	THOSE ENDED UP GETTING FUNDED ALBEIT ONE MODIFIED.
16	A THIRD WHICH WAS NOT RECOMMENDED BY STAFF KEYED ON
17	A SPECIFIC FACT, AN ISSUE THAT WAS UP IN THE AIR
18	WHICH REGARDED MANUFACTURING ISSUES. THAT WAS TAKEN
19	BACK TO THE GRANTS WORKING GROUP WHICH VETTED IT IN
20	THE RE-REVIEW PROCESS, AND IT WAS APPROVED. AND
21	ONLY ONE THAT WAS NOT RECOMMENDED BY THE GRANTS
22	WORKING GROUP THROUGH THE RE-REVIEW PRACTICE WAS
23	APPROVED FOR FUNDING FOR OTHER REASONS, WHICH ISN'T
24	ATYPICAL FOR THIS BOARD, AND WITH SIGNIFICANT
25	CONDITIONS.
	416
	TTO

1	SO THE RESULT THAT WE REACHED WAS NOT ONE
2	THAT INVOLVED A RUNAWAY PROCESS. I WOULD ARGUE THAT
3	IF YOU HAVE A CHOICE BETWEEN HEARING SOMEBODY
4	SPEAKING HERE AND HAVING TO MAKE AN INSTANTANEOUS
5	DECISION THAT, IN MY OPINION, CANNOT BE WELL
6	INFORMED, PARTICULARLY WITH THE EMOTION OF THE
7	MOMENT, ETC., OR HAVING THE GRANTS WORKING GROUP IN
8	A DISTANT SETTING AWAY FROM THE EMOTION EVALUATING
9	THE SPECIFIC QUESTIONS THAT ARE PUT TO THEM TO
10	ARRIVE AT A MORE INFORMED, OBJECTIVE CONCLUSION, I
11	ARGUE THAT THAT WAS A GOOD THING TO DO.
12	NOW, PER FORCE THE RESULT OF THAT IS, IF
13	WE WERE TO CONTINUE ALONG AS IS, MORE PEOPLE WILL
14	PUT IN THE EXTRAORDINARY PETITIONS. THIS IS WHERE I
15	THINK DEAN HAWGOOD'S COMMENT IS PARTICULARLY ON
16	POINT, WHICH IS WE HAVE TO HAVE THE DISCIPLINE,
17	NOTWITHSTANDING THE TESTIMONY, TO DETERMINE WHAT
18	REALLY SHOULD, IF ANYTHING, GO FOR RE-REVIEW. I DO
19	THINK THE RE-REVIEW WAS VERY VALUABLE. I THINK
20	ANYBODY WHO SAT IN AND LISTENED TO THAT THOUGHT THAT
21	THAT WAS A GOOD THING.
22	SO THE DISCIPLINE DOES REST WITH US, BUT I
23	DON'T THINK WE SHOULD DISCOUNT THE PROCESS OR THINK
24	THAT IT DIDN'T WORK BECAUSE IN MY OPINION I THOUGHT
25	IT WORKED VERY WELL.
	417

1	I'M NOT SPEAKING TO THE BASIC BIO
2	EXTRAORDINARY PETITIONS HERE BECAUSE THEY DIDN'T
3	HAVE THE SAME PROCESS, JUST TO THE DISEASE TEAM.
4	OTHER COMMENTS?
5	DR. ECONOMOU: SO I THINK THE CONCERN THAT
6	MANY OF US HAVE HAD IS TO TRY TO GIVE AN OPINION
7	ABOUT SCIENTIFIC MERIT WHEN WE HAVEN'T READ THE
8	APPLICATION, WE'RE NOT FAMILIAR WITH THE SCIENCE,
9	AND A REAL CONCERN ABOUT SECOND-GUESSING A
10	DISTINGUISHED PEER REVIEWED COMMITTEE THAT REVIEWS
11	THE APPLICATION.
12	NOW, THE NIH HAS A SOLUTION FOR THAT.
13	THAT'S CALLED A REVISED APPLICATION. SO YOU GET
14	YOUR PINK SHEET, YOU LOOK THROUGH IT, YOU REWRITE
15	THE APPLICATION, YOU SEND A RESPONSE SAYING YOU GOT
16	THESE THINGS WRONG, YOU GOT THESE RIGHT, AND I FIXED
17	IT, AND THIS IS A BETTER APPLICATION. WE DON'T HAVE
18	THAT MULTIPLE CYCLE MECHANISM.
19	BUT WHAT I HAVE ARGUED IN FAVOR OF, WHICH
20	I THINK IS EMBEDDED IN THIS, IS A MECHANISM BY WHICH
21	APPLICANTS CAN LOOK AT THE REVIEW AND THEY CAN SAY I
22	THINK YOU GOT THESE THINGS WRONG. HERE'S SOME DATA
23	THAT JUST CAME OUT YESTERDAY, AND THEN HERE ARE SOME
24	FACTS THAT SOMEHOW SLIPPED PAST YOU. AND THEN IF
25	THIS COMES TO US AS AN EXTRAORDINARY PETITION, THAT
	410
	418

1	QUICK TURNAROUND RESPONSE ON MATTERS OF SCIENTIFIC
2	MERIT HAVE BEEN RE-REVIEWED BY THE SAME GROUP AND
3	THEY SAY THESE COMMENTS ARE VALID OR THESE COMMENTS
4	ARE NOT VALID.
5	AND THEN I HAVE A FEELING THAT THE TRIAGE
6	PROCESS OF BRINGING THIS UP FOR EXTRAORDINARY
7	PETITION WOULD NOT REST ON THESE UNCERTAIN ISSUES OF
8	SCIENTIFIC MERIT.
9	CHAIRMAN THOMAS: DR. PRICE.
10	DR. PRICE: I THINK WE HAVE A CERTAIN
11	PROBLEM WHICH IS DIFFERENT THAN, ALTHOUGH IT'S
12	SOMEWHAT RELATED TO, THE EXTRAORDINARY PETITION
13	PROCESS WE HAVE SORT OF BACKED INTO. AND IT RELATES
14	TO SOMETHING THAT MARCY FEIT SAID. AND I WOULD LIKE
15	TO REITERATE AND PUT ON THE TABLE SOMETHING THAT I
16	HOPE THIS COMMITTEE WILL CONSIDER.
17	AT ONE TIME A YEAR AGO, YEAR AND A HALF
18	AGO, I DON'T EXACTLY KNOW WHEN WE STOPPED DOING IT,
19	THE GRANTS WORKING GROUP PRESENTED US THE
20	APPLICATIONS IN THREE CATEGORIES: RECOMMENDED FOR
21	FUNDING, THE SECOND CATEGORY WAS RECOMMENDED FOR
22	FUNDING IF FUNDS ARE AVAILABLE, THE THIRD CATEGORY
23	WAS DO NOT FUND OR NOT RECOMMENDED FOR FUNDING.
24	SOMEHOW THAT MIDDLE CATEGORY DROPPED OUT.
25	AND LET ME DESCRIBE FOR THOSE OF YOU WHO
	419

CATEGORY, THE BOARD WOULD DISCUSS ALL OF
ORDER ALL OF THE APPLICATIONS IN THE
ED FOR FUNDING IF FUNDS WERE AVAILABLE.
T DISCUSSION, THEN MEMBERS COULD DECIDE,
E A MOTION TO PULL ONE OR ANOTHER OF THOSE
ON UP INTO TIER I. IN THAT WAY ALL OF THAT
TEGORY HAD AN EQUAL CHANCE OF BEING PULLED
THAN THE SITUATION WHERE IN AN AD HOC WAY
ONS ARE PULLED UP. AND IF YOU ARE LUCKY
BE IN THE EARLY ONE, YOU HAVE A MUCH
OT BECAUSE THE EARLY ONES USE UP OUR
EFORE WE EVER GET TO THE ONES THAT BY JUST
N'T BEEN DISCUSSED.
SO I WOULD HOPE THAT WHATEVER THIS
IS WOULD SERIOUSLY CONSIDER GOING BACK TO
RE WHICH I THINK WORKED SOMEWHAT BETTER
WE'RE DOING NOW.
DR. TROUNSON: WHAT HAPPENS, OF COURSE, WE
THREE CATEGORIES WHEN WE OVERSPENT THE
. WHEN WE HAD MORE WHEN YOU UNDERSPEND,
GORY DIDN'T EXIST BECAUSE THE GRANTS
ROUP HADN'T SPENT OUT THE WHOLE DOLLAR
BY THE BOARD. SO THAT WAS THE REASON WHY
OPPED BECAUSE THERE WAS NO REASON FOR THE
420

1	CATEGORY. SO IT WAS EITHER FUND OR NOT FUND, AND
2	THEY WERE CLEAR ON WHERE TO PUT THAT.
3	DR. PRICE: DOING THAT WE LOST SOMETHING.
4	DR. TROUNSON: WHAT YOU ARE ASKING FOR IS
5	THOSE GRAY CATS BACK IN, SO THOSE GRAY ONES BACK IN
6	THERE. AND TO SOME EXTENT THAT MIGHT HELP IF YOU
7	WERE PREPARED TO DISCUSS ALL OF THIS.
8	DR. PRICE: WE DID AT ONE TIME.
9	DR. TROUNSON: MAYBE THAT MIGHT HELP
10	BECAUSE THAT'S WHAT'S BEEN LOST BECAUSE YOU'RE NOT
11	DISCUSSING ANY OF THOSE GRAY CATS IN THAT.
12	DR. PRICE: UNLESS SOMEBODY IS HERE
13	SHOUTING AT US.
14	DR. TROUNSON: IT'S ONLY THE EXTRAORDINARY
15	PETITIONS.
16	CHAIRMAN THOMAS: LET'S HAVE A LITTLE
17	SEQUENCE HERE. MR. ROTH, MR. SHESTACK, DR. STEWARD,
18	AND THEN OTHERS.
19	MR. ROTH: SO IT'S TOUGH FIGHTING THE
20	MICROPHONE HERE WITH THE CHAIR. THE REASON I MADE
21	THE RECOMMENDATION I DID IS I BELIEVED THERE IS AN
22	AWFUL LOT TO BE DISCUSSED. AND I THINK A LOT OF
23	GOOD COMMENTS HAVE COME OUT, AND WE CAN PROBABLY
24	STAY HERE ANOTHER HOUR, BUT I THINK WE NEED TO MOVE
25	ON AND GET DOWN TO GETTING THE GROUP TOGETHER AND
	421

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1	TAKE THE TIME AFTER THEY COME BACK TO US AND REALLY
2	HAVE THIS WORKED OUT SO WE'RE ALL VERY COMFORTABLE
3	WITH IT.
4	WHILE I KNOW THERE'S MANY OTHER THINGS
5	THAT COULD BE SAID, I DON'T THINK WE'RE GOING TO GET
6	TO CONSENSUS ON WHAT WE'RE GOING TO DO TODAY FOR THE
7	OCTOBER MEETING. WE LIVE WITH THE PROCESS. IT'S
8	GENERALLY THIS PROCESS. SO LET'S TABLE IT. AND THE
9	RECOMMENDATION I'D MAKE IS TO FORM THE COMMITTEE AND
10	HAVE THEM COME BACK BY THE END OF THE YEAR.
11	CHAIRMAN THOMAS: DO WE HAVE A MOTION ON
12	THE TABLE? WE DON'T. DO YOU WANT
13	MR. ROTH: I WILL MAKE THAT AS A MOTION.
14	CHAIRMAN THOMAS: DOES THAT INCLUDE
15	ADOPTING THE RECOMMENDATIONS HERE?
16	MR. ROTH: THE ONES THAT ALREADY EXIST.
17	YOU WANT TO ADD THE OTHERS, JAMES?
18	MR. HARRISON: THE ADDITIONAL ANALYSIS
19	OPTION DOES NOT CURRENTLY EXIST, JUST TO BE CLEAR.
20	MR. ROTH: I WOULD ADD THAT BACK IN AND
21	MAKE A MOTION THAT WE ADOPT THIS WITH THE ADDITIONAL
22	ANALYSIS FOR THE NEXT MEETING, THAT WE FORM THE
23	COMMITTEE, AND THE COMMITTEE REPORT BACK BY THE END
24	OF THE CALENDAR YEAR.
25	MR. TORRES: SECOND.
	422
	422

1	CHAIRMAN THOMAS: SECONDED BY SENATOR
2	TORRES. DISCUSSION?
3	MR. SHESTACK: GOING BACK A POINT, I'D SAY
4	THAT SECOND THAT GRAY TIER, THE TIER II, IS, IN
5	FACT, WHAT HAPPENED ON THE LAST BOARD MEETING WITH
6	THE LAST TWO GRANTS, WITH THE ALS AND THE SCID
7	GRANT. PEOPLE SORT OF MAYBE IT WAS IN RESPONSE
8	TO AN EXTRAORDINARY PETITION, BUT IT SEEMED MORE
9	THAT THE SPIRIT OF THE GROUP SAID LET'S EXPAND OUR
10	PAYLINE. LET'S MAKE THE CUTOFF A LITTLE BIT
11	DIFFERENT. SO IT DOES DE FACTO EXIST. IT JUST WAS
12	NOT AS SYSTEMATIC.
13	BUT I WANTED TO POINT OUT THAT IT DID
14	EXIST. IF YOU'RE GOING TO DO THIS, I REALLY DO
15	URGE, EVEN FOR THE SAKE OF THE SHORT PERIOD OF TIME
16	UNTIL IT'S REEXAMINED, THAT YOU CHANGE SOME PART OF
17	THAT LANGUAGE AND LEAVE IT MORE AT THE DISCRETION OF
18	THE RE-REVIEW PANEL AND STAFF AS TO WHAT IS
19	VERIFIABLE NEW DATA RATHER THAN DEFINE IT AS
20	PUBLISHED AND PEER REVIEWED BECAUSE IT REALLY DOES
21	MAKE THE WHOLE POINT OF ADDITIONAL DATA MOOT. IT'S
22	REALLY JUST SAYING THAT IT'S A HURDLE THAT CAN NEVER
23	BE HURDLED, SO IT'S INSINCERE.
24	CHAIRMAN THOMAS: WOULD YOU ACCEPT THAT AS
25	A FRIENDLY?
	422
	423

1	MR. ROTH: I'LL ACCEPT THAT. THE ONE
2	ARGUMENT I WOULD GIVE BACK TO THAT IS IT CAN BE
3	THIRD-PARTY DATA THAT VALIDATES YOUR POINT, AND THAT
4	CAN BE PUBLISHED AND PEER REVIEWED. WE'RE ARGUING A
5	POINT, AND SOMEBODY ELSE PUBLISHES DATA THAT PROVES
6	THAT TRUE.
7	CHAIRMAN THOMAS: THAT WOULD BE A SUBSET
8	OF THE LARGER CATEGORY.
9	MR. SHESTACK: I ONLY USED THE EXAMPLE
10	THAT WE HAD.
11	MR. ROTH: I'LL ACCEPT THAT AMENDMENT.
12	CHAIRMAN THOMAS: SENATOR TORRES, DO YOU
13	TAKE THE FRIENDLY SECOND?
14	MR. TORRES: YES.
15	CHAIRMAN THOMAS: THANK YOU.
16	DR. STEWARD: NOT TO PROLONG, BUT I REALLY
17	DO ENCOURAGE US TO ADOPT SOMETHING GOING FORWARD
18	BECAUSE, FIRST OF ALL, THE HORSE IS OUT OF THE BARN
19	ON THIS. PEOPLE ARE JUST GOING TO INCREASE THE
20	NUMBER OF EXTRAORDINARY PETITIONS. I ABSOLUTELY
21	AGREE WITH DEAN HAWGOOD, THAT WE HAVE TO IMPOSE
22	DISCIPLINE ON OURSELVES. I THINK WE NEED A LITTLE
23	GUIDANCE ON THAT BECAUSE MEMBERS OF THE BOARD
24	CHANGE, NEW PEOPLE COME ON AND SAY, SHOULD I
25	CONSIDER THIS OR NOT?
	424
	12.1

160 S. OLD SPRINGS ROAD, SUITE 270, ANAHEIM, CALIFORNIA 92808

1	AND JUST ONE MORE POINT THAT IS MAYBE I
2	HOPE THIS ISN'T CUTTING THE PIPE TOO FINELY, BUT
3	JAMES AND OTHERS WORKED VERY HARD ON THIS DOCUMENT.
4	IT DOES NOT SAY HERE WHAT CAN BE INCLUDED IN THE
5	EXTRAORDINARY PETITION. IT SAYS WHAT WE DEFINE AS
6	NEW INFORMATION. THE INVESTIGATORS ARE STILL FREE
7	TO INCLUDE WHATEVER THEY WANT, ARGUE WITH THE
8	REVIEWERS, WHATEVER THEY WANT. IT'S JUST WHAT WE'RE
9	DEFINING AS NEW DATA.
10	MR. SHESTACK: WE HAVE GIVEN A CATEGORY
11	THAT IS WE HAVE CREATED A PROCESS WHERE GRANTS GO
12	BACK TO A WORK GROUP FOR ADDITIONAL REVIEW, AND THAT
13	ONLY HAPPENS IF THERE IS ADDITIONAL DATA.
14	MR. ROTH: CALL THE QUESTION.
15	CHAIRMAN THOMAS: QUESTION IS CALLED.
16	DR. LEVIN: I'M SORRY. I JUST WANTED TO
17	ADD AS AN AMENDMENT OR EVEN SMALLER AMENDMENT JUST
18	THE TWO POINTS I RAISED, THAT WE PROMISE TO PROVIDE
19	THEM THEIR FEEDBACK WITHIN SEVEN BUSINESS DAYS, AND
20	THAT WE LIMIT EVEN OTHER CORRESPONDENCE TO THREE
21	PAGES AS WELL IN THOSE DOCUMENTS. CAN WE ADD THAT?
22	MR. ROTH: THE THREE PAGES. WHAT ABOUT
23	THE SEVEN BUSINESS DAYS?
24	DR. PRICE: DON'T PUT MORE BURDEN ON OUR
25	STAFF THAN THEY ALREADY HAVE.
	425

1	MR. ROTH: I'M FINE WITH THREE PAGES, BUT
2	I DON'T KNOW IF YOU WANT TO PUT BURDEN ON THE STAFF
3	IN THAT SHORT WINDOW.
4	CHAIRMAN THOMAS: EVERYBODY, ONE AT A TIME
5	HERE.
6	DR. TROUNSON: WE ALREADY DO THAT. SO
7	THEY ALWAYS GET IT AT LEAST SEVEN DAYS, EIGHT DAYS,
8	NINE DAYS, TEN DAYS.
9	CHAIRMAN THOMAS: OKAY.
10	MR. ROTH: I ACCEPT.
11	CHAIRMAN THOMAS: OKAY. WE'RE FINE.
12	YOU'RE DOING IT CORRECTLY WITHIN THE SPIRIT OF DR.
13	LEVIN. SO, MR. HARRISON, WILL YOU PLEASE RESTATE
14	THE MOTION WITH VARIOUS AMENDMENTS?
15	MR. HARRISON: YES. THE MOTION IS TO
16	APPROVE THE PROPOSED AMENDMENTS TO THE EXTRAORDINARY
17	PETITION POLICY AND ADOPT THE ADDITIONAL ANALYSIS
18	OPTION WITH DIRECTION TO STAFF TO INCORPORATE THE
19	COMMENTS MADE BY DR. LEVIN AND MR. SHESTACK AND
20	LEEZA GIBBONS WITH RESPECT TO THE POSTING ON THE
21	WEBSITE, AND TO ESTABLISH A COMMITTEE TO REVIEW THE
22	PROCESS AND TO REPORT BACK TO THE BOARD.
23	CHAIRMAN THOMAS: VERY WELL SAID, MR.
24	HARRISON. OKAY. THIS IS A VOICE VOTE. ALL THOSE
25	IN FAVOR PLEASE SAY AYE. OPPOSED? ABSTENTIONS?
	426
	426

1	MARCY.
2	MS. FEIT: YES.
3	CHAIRMAN THOMAS: THANK YOU. VERY GOOD.
4	THANK YOU.
5	ALL RIGHT. I WAS HANDED A NOTE WHICH I
6	THINK PEOPLE, GETTING BACK TO OUR SPOTLIGHT, WHICH
7	WAS A VERY HEARTWARMING, ADDITIONAL NOTE WHICH IS
8	PEOPLE WITHOUT THE GENETIC DEFECT THAT VANESSA HAS
9	CAN ACCEPT A LIVER DONATED BY SOMEONE WITH HER
10	DISEASE. SO HER LIVER SAVED THE LIFE OF ANOTHER
11	CHILD THROUGH THE TRANSPLANT PROCESS.
12	SO WE NOW COME TO A BITTERSWEET PART OF
13	OUR AGENDA. WE HAVE TWO EXTREMELY SARTORIAL
14	GENTLEMEN SITTING IN THE AUDIENCE, WAITING FOR
15	HOURS, WHO HAVE COME TO BE RECOGNIZED FOR THEIR
16	EXCEPTIONAL SERVICE AS MEMBERS OF THE CIRM BOARD.
17	SO, TED AND DAVID, IF YOU WILL COME FORWARD, PLEASE,
18	TO THE PODIUM.
19	(APPLAUSE.)
20	CHAIRMAN THOMAS: HOLD ON. NOT YET. SO
21	I'M GOING TO SAY A FEW WORDS HERE ABOUT TED AS
22	REFERENCED IN THE RESOLUTION. SENATOR TORRES HAS
23	THE HONORS FOR MR. SERRANO-SEWELL. OKAY.
24	SO, TED, WHEREAS, TED LOVE IS AN
25	EXPERIENCED LIFE SCIENCES EXECUTIVE AND BOARD
	427

1	MEMBER, HAVING SERVED AS AN EXECUTIVE AT NUMEROUS
2	COMPANIES, INCLUDING ONYX PHARMACEUTICALS EXCUSE
3	ME. MARIA TOLD ME TO READ IT, BUT YOU'RE RIGHT.
	,
4	MS. BONNEVILLE: I SAID TALK ABOUT IT.
5	CHAIRMAN THOMAS: NO. YOU SAID TO READ
6	IT. OKAY. TED, THROUGHOUT HIS TENURE, BROUGHT
7	TREMENDOUS EXPERTISE FROM THE STANDPOINT OF THE
8	BIOTECH INDUSTRY. AS A MAJOR CONSTITUENT GROUP
9	REPRESENTED BY THE BOARD, TED SERVED IN A VARIETY OF
10	CAPACITIES, BOTH ACTING IN-HOUSE, BOTH AS A MEMBER
11	OF THE BOARD, AS A MEMBER OF MANY SUBCOMMITTEES, AND
12	ALWAYS PROVIDING SAGE COUNSEL THAT REFLECTED A
13	LONG-TIME TENURE IN THE BIOTECH INDUSTRY AND A
14	PERSPECTIVE FOR INDUSTRY THAT WAS GREATLY
15	APPRECIATED BY THE BOARD, WAS GREATLY NEEDED AS A
16	VOICE ON THE BOARD, AND WAS A LEADER TO THOSE IN THE
17	BIOTECH COMMUNITY THAT DEPENDED UPON HIM TO
18	REPRESENT THEM ON THE BOARD.
19	WE WERE VERY, VERY LUCKY TO HAVE HIM HERE.
20	WE ARE VERY SORRY TO SEE HIM GO, BUT THESE THINGS DO
21	HAPPEN. AND WE APPRECIATE NOT ONLY HIS MANY YEARS
22	OF DISTINGUISHED SERVICE; BUT IN THE CIRCLE OF LIFE
23	APPROACH, HE BROUGHT TO THE CONTROLLER'S ATTENTION
24	ANNE-MARIE WHO NOW SUCCEEDS HIM AS A MEMBER OF THE
25	BOARD AND WILL CARRY ON IN THE FINEST TRADITION OF
	428
	720

1	THE FIRST CLASS REPRESENTATIVE FROM THE BIOTECH
2	INDUSTRY.
3	SO, TED, THANK YOU SO MUCH FOR YOUR MANY
4	YEARS OF GREAT SERVICE, AND WE APPRECIATE AND NOTE
5	THAT BY THE RESOLUTION WHICH YOU HAVE, WHICH YOU CAN
6	PUT UP ON WHICHEVER OFFICE WALL YOU WOULD LIKE,
7	THANK YOU. AND IF YOU'D LIKE TO SAY A FEW WORDS,
8	PLEASE DO AT THIS TIME.
9	MR. TORRES: JUST A FEW.
10	DR. LOVE: THANK YOU, ART. I KNOW YOU
11	GUYS ARE VERY BUSY, BUT I DO WANT TO THANK THREE
12	CONSTITUENCIES. FIRST, STEVE WESTLEY AND JOHN
13	CHIANG, WHO GAVE ME THE HONOR OF SERVING ON THIS
14	BOARD SO I COULD DO SOMETHING FOR CALIFORNIA BESIDES
15	PAY SIZABLE QUARTERLY TAXES.
16	THE SECOND GROUP I'D LIKE TO THANK IS THE
17	BOARD ITSELF. IT HAS REALLY BEEN AN HONOR TO SERVE
18	WITH ALL OF YOU, A PLEASURE TO SERVE WITH ALL OF
19	YOU. I HAVE SO MUCH RESPECT FOR EACH OF YOU AS
20	INDIVIDUALS, AND I HAVE TREMENDOUS RESPECT FOR WHAT
21	WE WERE ABLE TO ACCOMPLISH COLLECTIVELY.
22	FINALLY, THE STAFF OF CIRM, BOTH THE
23	SCIENTIFIC STAFF AND THE ADMINISTRATIVE STAFF, DO
24	SUCH A WONDERFUL JOB. AND, AGAIN, I COUNT THESE
25	PEOPLE AS PEOPLE THAT I GREATLY ADMIRE, GREATLY
	429

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RESPECT, AND I'M HAPPY TO COUNT AMONG MY LIFELONG
FRIENDS. SO THANK YOU ALL AGAIN.
(APPLAUSE.)
CHAIRMAN THOMAS: ANY COMMENTS BY MEMBERS
OF THE BOARD? TOUGH ACT TO FOLLOW.
MS. SAMUELSON: I'D LIKE TO NOTE THAT HIS
SAGE COUNSEL ACCOMPANIES HIS SAGE JACKET.
CHAIRMAN THOMAS: YES, ALWAYS NATTILY
CLAD.
MR. SENATOR.
MR. TORRES: I CAN'T GO ON WITHOUT SAYING
SOMETHING ABOUT TED. YOU HAVE BEEN AN INCREDIBLE
FRIEND TO ME AND A WONDERFUL ADVISOR. AND GETTING
TO KNOW YOU AND JOYCE HAS BEEN A PLEASURE FOR ME.
BUT I MUST SAY EVEN THOUGH I LOVE YOU A LOT AND
JOYCE, I THINK I'M BEGINNING TO LOVE ANNE-MARIE A
LOT TOO. SO THANK YOU FOR BRINGING HER TO US AS
WELL. TED, THANK YOU FOR YOUR SERVICE, NOT ONLY IN
THE PUBLIC SECTOR, BUT CLEARLY WHEN YOU SERVED
WITHIN CIRM AS WELL AND BROUGHT A LOT OF GRAVITAS TO
THE OPERATION.
DAVID SERRANO-SEWELL'S FAMILY AND I HAVE
KNOWN EACH OTHER FOR 38 YEARS. AND I KNEW HIM WHEN
HE WAS A BABY BOY, AND I WAS HONORED TO OFFICIATE AT
HIS WEDDING. AND SO THE SERRANO-SEWELL FAMILY AND
430

1	TORRES FAMILIES GO BACK MANY YEARS.
2	AND I AM SO PROUD OF HIS SERVICE TO THE
3	CITY AS A DEPUTY CITY ATTORNEY FOR THE CITY AND
4	COUNTY OF SAN FRANCISCO, HIS SERVICE ON THIS BOARD,
5	HAVING CO-CHAIRED THE FACILITIES COMMITTEE, WHICH
6	REALLY BROUGHT FRUITION TO 12 FACILITIES ACROSS THE
7	STATE. IT TOOK DAVID'S LEADERSHIP TO DO THAT. AND
8	SECONDLY, ALONG WITH MARCY FEIT, ANOTHER GREAT BOARD
9	MEMBER, TO PUSH FOR THE BRIDGES PROGRAM. I DON'T
10	THINK THERE IS A PROGRAM, AND I KNOW WE HAVE FUNDED
11	SO MANY INCREDIBLE GRANTS, BUT THIS PROGRAM FUNDS
12	THE FUTURE STEM CELL SCIENTISTS.
13	AND I CAN GUARANTEE YOU THAT THE RESPONSE
14	FROM THE LEGISLATURE, FROM THE GOVERNOR, LIEUTENANT
15	GOVERNOR, THE CONTROLLER, THE TREASURER, THE
16	ATTORNEY GENERAL AS WELL ALL SPEAK HIGHLY OF THIS
17	PROGRAM BECAUSE THEY KNOW WHAT IT MEANS FOR
18	CALIFORNIA.
19	SO, DAVID, THANK YOU FOR THAT SERVICE.
20	THANK YOU FOR WORKING WITH MARCY TO MAKE SURE THAT
21	IT HAPPENED. AND I THINK THAT WE OWE YOU A DEBT OF
22	GRATITUDE FOR YOUR SACRIFICE, AND WE WISH YOU WELL
23	NOW AS THE NEWEST MEMBER OF THE CALIFORNIA MEDICAL
24	QUALITY ASSURANCE BOARD TO MAKE SURE THAT PATIENTS
25	ARE SAFE IN A DIFFERENT WAY IN THAT RESPECT. SO I

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1	APPLAUD YOUR EFFORTS AND YOUR EXPERIENCE AND YOUR
2	KNOWLEDGE AND YOUR SERVICE ON THIS BOARD. AND I
3	KNOW BOTH YOU AND TED, AFTER SITTING THROUGH HERE
4	FOR THE LAST HOUR, ARE GRATEFUL THAT YOU ARE LEAVING
5	THIS BOARD. CONGRATULATIONS, DAVID SERRANO-SEWELL.
6	(APPLAUSE.)
7	MR. SERRANO-SEWELL: I WAS TEASING TED I
8	WAS GOING TO VOLUNTEER HIM FOR THIS SPECIAL
9	COMMITTEE THAT MEMBER ROTH HAD SUGGESTED. AS TED
10	HAS SAID, FOR EACH ONE OF US IT'S SUCH A GREAT HONOR
11	AND A PRIVILEGE TO BE ON THIS BOARD. AND I
12	PARTICULARLY WANT TO RECOGNIZE AND EXPRESS MY DEEP
13	GRATITUDE TO MY COLLEAGUES, ESPECIALLY THE FOUNDING
14	MEMBERS, BUT ALL OF YOU. EIGHT YEARS IS A GOOD
15	CHUNK OF TIME BY ANY MEASURE. AND I HOPE YOU'VE
16	SEEN ME MATURE AND DEVELOP. BUT I WANT TO THANK YOU
17	FOR LETTING ME LEARN FROM YOU AND, MOST OF ALL,
18	BEING PATIENT WITH ME. THERE'S A LOT OF PASSIONATE,
19	PRODUCTIVE DISCUSSIONS THAT HAPPEN ON THIS BOARD,
20	AND I THINK THE RESULTS ARE WHAT WE'VE DONE.
21	I TOO WANT TO RECOGNIZE STAFF. IT'S BEEN
22	AN HONOR TO WORK WITH THEM, BOTH THE PRESIDENT'S
23	STAFF AND THE CHAIRMAN'S STAFF. AND ONE OTHER
24	MEMBER OF THE TEAM WHO'S SORT OF LIKE THE 30TH
25	MEMBER OF THE BOARD AND THAT IS JAMES. AS SOMEONE
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	T <i>JL</i>

1	WHO PRACTICES LAW EVERY DAY, AND I TRY TO GIVE
2	ADVICE, THE BEST ADVICE I POSSIBLY CAN TO MY CLIENT,
3	I'VE OFTEN LOOKED AT YOUR SORT OF LEADERSHIP AND
4	EXAMPLE, JAMES, BECAUSE WE'VE GIVEN A LOT OF
5	PROBLEMS TO OUR LEGAL TEAM, AND THEY'VE DONE A
6	FANTASTIC JOB.
7	I'M EXCITED ABOUT THIS NEW APPOINTMENT. I
8	THINK IT'S GOING TO BE A LOT OF FUN, BUT BEING A
9	PATIENT ADVOCATE IS PROBABLY THE GREATEST TITLE I'LL
10	EVER HAVE. SO THANKS.
11	(APPLAUSE.)
12	CHAIRMAN THOMAS: THANK YOU VERY MUCH,
13	BOTH OF YOU.
14	I'M GOING TO EXERCISE CHAIRMAN'S
15	PREROGATIVE HERE. THE MILKIN GROUP'S FASTER CURES
16	HAS A CONFERENCE STARTING FIRST THING IN THE MORNING
17	IN WASHINGTON, D.C., TO WHICH I'VE BEEN INVITED TO
18	REPRESENT CIRM AND STEM CELL INTERESTS. I NEED TO
19	GET TO THE AIRPORT. WE HAVE ONE REMAINING ITEM.
20	I'M GOING TO CEDE THE CHAIR. DEAN PULIAFITO IS
21	GOING THERE TOO. ARE YOU ON THE SAME PLANE? LITTLE
22	LATER. OKAY. SEE YOU THERE. CEDE THE MICROPHONE.
23	MS. BONNEVILLE: YOU NEED TO VOTE ON THE
24	RESOLUTIONS.
25	CHAIRMAN THOMAS: WE NEED TO VOTE ON THE
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1	RESOLUTION? YOU MEAN THERE'S A CHANCE IT'S NOT
2	UNANIMOUS? I AM LUMPING BOTH OF THESE TOGETHER.
3	MR. HARRISON: YOU ACTUALLY CAN'T. DAVID
4	SERRANO-SEWELL WILL APPRECIATE THIS. BUT BECAUSE
5	CHAIRMAN THOMAS: ALWAYS COUNT ON MR.
6	HARRISON. HE'S LIKE THE ACCOUNTANT.
7	MR. HARRISON: BECAUSE HIS NOMINATION AND
8	RESIGNATION OCCURRED AFTER THE BOARD AGENDA WAS
9	POSTED, WE HAD TO ADD THIS ITEM, WHICH REQUIRES A
10	SEPARATE VOTE AND A DETERMINATION BY YOU ALL THAT
11	THE MATTER CAME TO YOUR ATTENTION AFTER THE AGENDA
12	WAS POSTED, AND THAT IT'S NECESSARY TO TAKE ACTION
13	NOW. IF THERE WOULD BE A MOTION TO THAT EFFECT,
14	THAT WOULD BE GREAT.
15	DR. STEWARD: SO MOVED.
16	MS. GIBBONS: SECOND.
17	CHAIRMAN THOMAS: WE'RE VOTING SEPARATELY
18	OR ONLY ON ONE?
19	MR. HARRISON: JUST THIS MOTION FIRST,
20	THEN YOU CAN VOTE ON BOTH.
21	CHAIRMAN THOMAS: ALL THOSE IN FAVOR
22	PLEASE SAY AYE. OPPOSED? THANK YOU. MARCY, ON THE
23	PHONE.
24	MS. FEIT: YES.
25	CHAIRMAN THOMAS: THANK YOU, MARCY. ALL
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1	THOSE IN FAVOR OF THE TWO RESOLUTIONS BEING PASSED
2	TOGETHER PLEASE SAY AYE. OPPOSED? ABSTENTIONS?
3	MARCY.
4	MS. FEIT: YES.
5	CHAIRMAN THOMAS: GENTLEMEN,
6	CONGRATULATIONS.
7	(APPLAUSE.)
8	CHAIRMAN THOMAS: SENATOR TORRES, PLEASE,
9	WE HAVE ONE ITEM. IT'S KEVIN DOING A COMMUNICATIONS
10	UPDATE. I APOLOGIZE, BUT I DO NEED TO RUN OR I'M
11	GOING TO MISS THE SHUTTLE AND PLANE. THANK YOU,
12	EVERYBODY, FOR A TERRIFIC TWO-DAY MEETING, A LOT OF
13	HARD WORK, MANY HOURS. I THINK WE GOT GREAT
14	RESULTS. THANK YOU.
15	MR. TORRES: ELONA, YOU NEED TO GET ON THE
16	MIKE.
17	MS. BAUM: I THINK THERE'S ACTUALLY TWO
18	ITEMS BECAUSE WE HAVEN'T HEARD SCOTT PRESENT A
19	COUPLE MINOR CHANGES TO THE NEVER MIND. I STAND
20	CORRECTED.
21	MR. TORRES: MR. KEVIN MCCORMACK,
22	COMMUNICATIONS PLAN.
23	MR. MC CORMACK: MR. CHAIR, MEMBERS OF THE
24	BOARD, THANK YOU VERY MUCH. MY NAME IS KEVIN
25	MCCORMACK. I'M THE DIRECTOR OF COMMUNICATIONS AND
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1	PATIENT ADVOCATE OUTREACH. BECAUSE THIS IS MY FIRST
2	APPEARANCE BEFORE YOU, I THOUGHT I'D TAKE THE
3	OPPORTUNITY TO GO OVER A LITTLE BIT ABOUT THE KIND
4	OF COVERAGE WE'VE BEEN GETTING IN THE MEDIA, HOW
5	WE'RE TRYING TO GET MORE, BUT ALSO SOME OF THE
6	CHALLENGES WE FACE AS WE GO FORWARD.
7	I KNOW IT'S A HARD ACT TO FOLLOW EVEN IN
8	THAT JACKET. I KNOW A LOT OF PEOPLE HAVE TALKED
9	ABOUT THE STRUGGLES THAT TRADITIONAL MEDIA ARE
10	HAVING, AND THERE ARE CERTAINLY SOME, BUT THERE ARE
11	STILL, I THINK AS THIS SLIDE SHOWS, SOME ADVANTAGES
12	TO THE TRADITIONAL MEDIA. AS SOMEONE WHO'S FALLEN
13	ASLEEP MANY TIMES WITH AN IPAD, A NEWSPAPER IS A
14	MUCH SOFTER THING TO LAND ON YOU.
15	IN RECENT MONTHS WE'VE HAD SOME
16	CONSIDERABLE SUCCESS IN GETTING STORIES IN THE
17	MEDIA. THE SAN FRANCISCO CHRONICLE HAS RUN A NUMBER
18	OF STORIES SPECIFICALLY ABOUT FUNDING AND ALSO MORE
19	RECENTLY ABOUT OUR WORK WITH MACULAR DEGENERATION.
20	WE'VE HAD GOOD COVERAGE IN BOTH THE SACRAMENTO BEE,
21	SACRAMENTO BUSINESS JOURNAL, ON KQED AND NPR, AND ON
22	KIND OF LOCAL NEWSPAPERS SUCH AS KTSF, WHICH IS,
23	SORRY, A LOCAL CHINESE LANGUAGE NEWS CHANNEL. AND
24	EVEN WHEN OUR PRESIDENT, DR. TROUNSON, WENT TO
25	AUSTRALIA, HE PRODUCED A ONE-MAN MEDIA BLITZ.
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1	SO WE ARE HAVING SOME SUCCESS, BUT THERE
2	ARE A LOT OF PROBLEMS AS WELL BECAUSE THE MEDIA, AS
3	I'M SURE YOU'VE ALL NOTICED, IS SHRINKING, IT'S
4	CHANGING. YOU ONLY HAVE TO PICK UP A LOCAL
5	NEWSPAPER AND SEE HOW THIN IT IS THESE DAYS. ONCE
6	YOU GET PAST THE FIRST COUPLE OF NEWS PAGES, YOU'RE
7	INTO MOSTLY WIRE COPY AND STORIES FROM SYNDICATED
8	NEWSPAPERS.
9	AND THERE'S A REASON WHY. THIS IS
10	AFFECTING, NOT JUST THE QUALITY OF THE NEWS WE ALL
11	GET, BUT ALSO THE QUALITY OF HEALTH JOURNALISM AND
12	THE DIFFICULTY OF GETTING THE WORD OUT THERE. THE
13	NUMBER OF SPECIALIST HEALTH JOURNALISTS, FOR
14	INSTANCE, HAS DECLINED DRAMATICALLY IN THE LAST
15	DECADE. MANY NEWSPAPERS AND RADIO STATIONS AND TV
16	STATIONS HAVE NO HEALTH REPORTER, BUT IN FACT ASSIGN
17	STORIES TO A GENERAL ASSIGNMENT REPORTER. NOW, IT'S
18	HARD FOR A GENERAL ASSIGNMENT REPORTER TO BE ABLE TO
19	KIND OF DIG DEEPLY INTO THE NUANCES OF HEALTH
20	REPORTING. ONE DAY THEY'RE REPORTING ON A TRAFFIC
21	ACCIDENT, THE NEXT ON CITY HALL, AND THE NEXT ON A
22	NEW STUDY THAT'S COME OUT LOCALLY. IT'S VERY HARD
23	FOR THEM TO DO THAT. NEWSPAPERS ARE TYPICALLY OFTEN
24	KIND OF DELEGATING THAT TO SOMEONE ELSE, TAKING IT
25	FROM THE ASSOCIATED PRESS OR THE NEW YORK TIMES, FOR
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1	INSTANCE.
2	THE SAN JOSE MERCURY NEWS IS ONE OF THE
3	LARGEST LOCAL NEWSPAPERS THAT DOESN'T HAVE ITS OWN
4	HEALTH REPORTER. IN FACT, THE BAY AREA NEWS GROUP
5	WHICH COVERS MOST OF THE NEWSPAPERS IN THE BAY AREA
6	HAS ONE SPECIALIST HEALTHCARE REPORTER. SO THAT
7	MAKES IT DIFFICULT FOR US TO GET OUR MESSAGE OUT
8	LOCALLY, AND THOSE PATTERNS ARE BEING REPEATED
9	THROUGHOUT THE COUNTRY.
10	THAT HAS IMPACTS ON THE KINDS OF QUALITY
11	OF COVERAGE YOU GET AS WELL. THE KAISER FAMILY
12	FOUNDATION STUDY FOUND THAT 94 PERCENT OF HEALTH
13	JOURNALISTS FELT THAT BUDGET CUTS WERE SERIOUSLY
14	HURTING THE QUALITY OF HEALTHCARE NEWS COVERAGE.
15	AND THERE WAS ONE RECENT EXAMPLE. THE CBC NEWS
16	WEBSITE POSTED RESULTS FROM A STUDY SAYING THAT, AND
17	THIS IS THE OPENING LINE, THERE MAY BE HOPE FOR
18	PEOPLE WHO ARE UNABLE TO SMELL, BUT THE STUDY WAS
19	DONE IN MICE. AND NO PEOPLE WERE INTERVIEWED. THEY
20	JUST QUOTED A COUPLE OF PARAGRAPHS FROM THE NEWS
21	RELEASE ITSELF.
22	NOW, THAT DOESN'T NECESSARILY MEAN THAT
23	WHAT THEY REPORTED WAS WRONG, BUT IT SHOWS THAT THE
24	KIND OF DEPTH OF REPORTING THAT WE'RE LOOKING FOR,
25	THE KIND OF QUALITY OF REPORTING THAT WE'RE LOOKING

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1	FOR, AND TRADITIONALLY HAD COME TO EXPECT FROM THE
2	MEDIA JUST ISN'T THERE ANYMORE.
3	SO MORE AND MORE WE'RE TURNING ON ONLINE.
4	BUT EVEN THOUGH THERE'S A PROLIFERATION OF HEALTH
5	SITES ONLINE, MOST OF THOSE ARE BLOGS OR
6	INFORMATIONAL, NOT NEWS. EVEN ON THE SITES THAT ARE
7	NEWS, REPORTERS ARE UNDER PRESSURE TO TURN AROUND
8	STORIES FASTER AND TO POST STORIES MORE OFTEN. SO
9	THERE'S LESS OVERALL CONTENT AND LESS OVERALL
10	ORIGINAL CONTENT. IN FACT, IF YOU LOOK AT
11	NEWSPAPER, ABOUT 6 PERCENT OF THE CONTENT OF A
12	NEWSPAPER IS HEALTH COVERAGE. IF YOU GO TO THE
13	EQUIVALENT SITE OF A NEWSPAPER ONLINE, IT'S ONLY
14	ABOUT 2 PERCENT.
15	WHAT WE'RE DOING INCREASINGLY AND WHAT
16	EVERYONE IS DOING INCREASINGLY IS TURNING TO THE
17	SOCIAL MEDIA TO TRY AND GET THE MESSAGE OUT. THERE
18	ARE A NUMBER OF ADVANTAGES ABOUT THAT OBVIOUSLY. IT
19	ALLOWS YOU TO CREATE YOUR OWN MESSAGE, TO CONTROL
20	YOUR OWN MESSAGE, AND TO BYPASS THE MORE TRADITIONAL
21	MEDIA FILTERS. SO WE'RE USING BLOGS, FACEBOOK,
22	YOUTUBE, TWITTER. GIVES YOU AN OPPORTUNITY TO GET
23	YOUR MESSAGE OUT THERE AND TO BE VERY MUCH MORE
24	TARGETED IN TERMS OF THE GROUPS YOU SHARE.
25	FOR INSTANCE, AT CIRM WE'VE BEEN USING A
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1
     LOT OF -- WORKING WITH OUR PATIENT ADVOCATE FRIENDS.
 2
     AND LEEZA IS A PERFECT EXAMPLE OF SOMEONE WE'VE BEEN
 3
     USING TO TRY AND GET THE MESSAGE OUT TO VERY
 4
     SPECIFIC GROUPS. SO IT MEANS YOU CAN BE MORE
 5
     TARGETED IN THE AUDIENCE YOU GET THE MESSAGE OUT TO.
     OF COURSE, IT'S GOING TO BE A SMALLER AUDIENCE.
 6
 7
                SO HERE'S HOW THE STEM CELL AGENCY HAS
 8
     BEEN USING THE WEB. WE USE YOUTUBE, FACEBOOK,
     TWITTER, LINKED-IN, E-MAILS, THE PRESIDENT'S BLOG,
 9
10
     ALL SORTS OF DIFFERENT OPPORTUNITIES, ANYTHING THAT
11
     WE CAN THINK OF TO DIRECT PEOPLE MOSTLY BACK TO OUR
12
     WEBSITE BECAUSE THAT'S WHERE WE CAN GIVE THEM THE
13
     INFORMATION THAT WE REALLY CONTROL, THE INFORMATION
14
     WHERE THEY CAN GET KNOWLEDGE ABOUT NOT JUST WHAT WE
15
     DO, BUT HOW WE DO IT AND WHO WE DO IT WITH. SO FOR
     US IT'S THE MOST EFFECTIVE WAY OF KIND OF DRIVING
16
17
     PEOPLE TOWARDS OUR SITE. SO WE'RE USING THE SOCIAL
     MEDIA IN AS MANY DIFFERENT WAYS AS WE CAN.
18
19
                RIGHT NOW WE'RE GETTING ABOUT, WITH ALL
20
     OUR DIFFERENT SOCIAL MEDIA OUTLETS, WE'RE GETTING
21
     ABOUT 70,000 VIEWS TO OUR WEBSITE. OVER THE NEXT
22
     YEAR, WE HOPE TO INCREASE THAT TO ABOUT 100,000, AND
23
     THEN OVER THE NEXT FEW YEARS TO ABOUT 250,000.
24
     OBVIOUSLY THERE'S A NUMBER OF CHALLENGES IN THIS.
25
                I THINK ONE OF THE BIGGEST IS THAT NO ONE
                               440
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REALLY KNOWS HOW SOCIAL MEDIA IS GOING TO EVOLVE.
IT CHANGES FAIRLY RAPIDLY. ALL WE KNOW IS THAT WE
HAVE TO KEEP ON TOP OF IT, THAT IT'S VERY USEFUL.
IT'S A WAY OF GETTING YOUR MESSAGE OUT AND BEING
PART OF A CONVERSATION, A GENERAL CONVERSATION, THAT
YOU CAN'T DO WITH THE TRADITIONAL MEDIA.
TRADITIONAL MEDIA IS STILL VERY IMPORTANT. IT'S THE
BEST WAY OF REACHING A LARGE NUMBER OF PEOPLE WITH A
SINGLE MESSAGE. BUT WE HAVE TO KIND OF REPLICATE
THAT, THE PIECES WE GET IN THE TRADITIONAL MEDIA AND
TV AND RADIO, AND WORK WITH THOSE AND GET THEM OUT
ONLINE AS WELL SO THAT WE HIT AS MANY DIFFERENT
PEOPLE AS POSSIBLE.
WITH THAT.
MR. TORRES: WE ALSO WANT TO THANK DON
GIBBONS AND AMY AND TODD, OUR VIDEOGRAPHER, WHO
ALMOST WON AN AWARD UNTIL SOMEBODY SKEWED THE
RESULTS, I THINK, AN INCREDIBLE VIDEO ON DIABETES.
I WANT TO THANK YOU, KEVIN, FOR THE WORK YOU'VE BEEN
DOING TO BRING US INTO THE FUTURE AND TO MOVE OUR
AGENDA AND OUR MESSAGE OUT TO THE WORLD. AND,
AGAIN, TO THE TEAM THAT'S PART OF THE COMMUNICATION
TEAM AT CIRM, I PERSONALLY WANT TO THANK EACH AND
EVERY ONE OF YOU AS WELL.
MR. MC CORMACK: GREAT TEAM. I'D LIKE TO
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1	CONGRATULATE TODD IN ADVANCE WHO'S ACTUALLY WAITING.
2	HE CAME HERE TODAY LEAVING BEHIND HIS HEAVILY
3	PREGNANT WIFE, AND WE'RE EXPECTING GOOD NEWS FAIRLY
4	SOON, WE HOPE.
5	MR. TORRES: GOOD FOR YOU. A FUTURE
6	VOTER.
7	ANY OTHER COMMENTS?
8	MR. MC CORMACK: I'VE JUST BEEN ADVISED BY
9	LEGAL COUNSEL NOT TO CALL HER HEAVILY PREGNANT.
10	MR. TORRES: THANK YOU. LET THE RECORD
11	SHOW THAT WILL BE STRICKEN FROM THE RECORD. THANK
12	YOU.
13	ANY OTHER COMMENTS FROM MEMBERS OF THE
14	BOARD? WE WANT TO THANK YOU ALL VERY MUCH. MOTION
15	TO ADJOURN WILL BE ENTERTAINED.
16	(MULTIPLE MOTIONS AND MULTIPLE
17	SECONDS.)
18	MR. TORRES: ALL IN FAVOR SIGNIFY BY
19	SAYING AYE. OPPOSED? WE ARE ADJOURNED.
20	(THE MEETING WAS THEN CONCLUDED AT
21	03:14 P.M.)
22	
23	
24	
25	
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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 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

CROWNE PLAZA HOTEL 1177 AIRPORT BOULEVARD BURLINGAME, CALIFORNIA ON SEPTEMBER 6, 2012

WAS HELD AS HEREIN APPEARS AND THAT THIS IS THE ORIGINAL TRANSCRIPT THEREOF AND THAT THE STATEMENTS THAT APPEAR IN THIS TRANSCRIPT WERE REPORTED STENOGRAPHICALLY BY ME AND TRANSCRIBED BY ME. I ALSO CERTIFY THAT THIS TRANSCRIPT IS A TRUE AND ACCURATE RECORD OF THE PROCEEDING.

BETH C. DRAIN, CSR 7152 BARRISTER'S REPORTING SERVICE 160 S. OLD SPRINGS ROAD SUITE 270 ANAHEIM, CALIFORNIA (714) 444-4100

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