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: AS INDICATED ON THE AGENDA
- DATE: THURSDAY, NOVEMBER 11, 2010 11 A.M.
- REPORTER: BETH C. DRAIN, CSR CSR. NO. 7152
- BRS FILE NO.: 88537

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2	12. PUBLIC COMMENT.	NONE	
	2		

	BARRISTERS' REPORTING SERVICE
1	THURSDAY, NOVEMBER 11, 2010
2	11:07 A.M.
3	
4	CHAIRMAN KLEIN: MELISSA, WITH THAT, COULD
5	YOU CALL THE ROLL.
6	MS. KING: ROBERT PRICE FOR ROBERT
7	BIRGENEAU.
8	DR. PRICE: HERE.
9	MS. KING: FLOYD BLOOM. DAVID BRENNER.
10	WILLIAM BRODY.
11	MS. KING: SUSAN BRYANT.
12	DR. BRYANT: HERE.
13	MS. KING: MARCY FEIT. MICHAEL FRIEDMAN.
14	LEEZA GIBBONS. MICHAEL GOLDBERG.
15	MR. GOLDBERG: HERE.
16	MS. KING: SAM HAWGOOD.
17	DR. HAWGOOD: HERE.
18	MS. KING: BOB KLEIN.
19	CHAIRMAN KLEIN: HERE.
20	MS. KING: SHERRY LANSING.
21	MS. LANSING: HERE.
22	MS. KING: TED LOVE.
23	DR. LOVE: HERE.
24	MS. KING: SHLOMO MELMED.
25	DR. MELMED: HERE.
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1	MS. KING: ED PENHOET. PHIL PIZZO.
2	CLAIRE POMEROY. FRANCISCO PRIETO.
3	DR. PRIETO: HERE.
4	MS. KING: ELIZABETH FINI FOR CARMEN
5	PULIAFITO. ROBERT QUINT. JOHN REED.
6	DR. REED: HERE.
7	MS. KING: I BELIEVE THAT WAS ELIZABETH
8	FINI IN ADDITION TO DR. REED, CORRECT?
9	DR. FONTANA: IT'S JEANNIE FONTANA.
10	MS. KING: DUANE ROTH.
11	MR. ROTH: HERE.
12	MS. KING: JOAN SAMUELSON.
13	MS. SAMUELSON: HERE.
14	MS. KING: DAVID SERRANO-SEWELL.
15	MR. SERRANO-SEWELL: HERE.
16	MS. KING: JEFF SHEEHY.
17	MR. SHEEHY: HERE.
18	MS. KING: JON SHESTACK.
19	MS. KING: OSWALD STEWARD. ART TORRES.
20	MR. TORRES: HERE.
21	MS. KING: JAMES ECONOMOU FOR EUGENE
22	WASHINGTON.
23	DR. ECONOMOU: HERE.
24	MS. GIBBONS: MELISSA, IT'S LEEZA GIBBONS.
25	I DISCONNECTED MYSELF MAKING SURE I WASN'T CAUSING
	4
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1 THAT STATIC. SO I'M BACK. 2 MS. KING: OKAY. GREAT. 3 DR. POMEROY: THIS IS CLAIRE POMEROY. YOU 4 RUSHED BY ME. JUST WANTED TO MAKE SURE YOU KNEW I 5 WAS HERE. 6 (PAUSE IN PROCEEDINGS.) 7 CHAIRMAN KLEIN: COULD YOU THEN LEAD US IN THE PLEDGE OF ALLEGIANCE. 8 9 (THE PLEDGE OF ALLEGIANCE.) 10 MS. KING: BOB, ONE MORE THING I'D LIKE TO 11 DO BEFORE WE GET STARTED IS JUST CIRCLE BACK WITH 12 THE PEOPLE THAT WERE NOT PRESENT THAT I WAS 13 EXPECTING TO BE PRESENT BECAUSE WE MAY HAVE JUST NOT HEARD THEM GIVEN THE STATIC. 14 15 DAVID BRENNER. CLAIRE POMEROY. 16 DR. POMEROY: HERE. 17 MS. KING: ROBERT QUINT. DR. QUINT, I THOUGHT I HEARD YOU, BUT I WASN'T SURE. ARE YOU 18 19 THERE? JON SHESTACK. OSWALD STEWARD. OKAY. 20 DR. FINI: MELISSA, YOU MISSED ME. 21 ELIZABETH FINI. 22 MS. KING: SO WE ACTUALLY NOW HAVE A QUORUM, WHICH IS GOOD NEWS. AND I'LL TURN IT OVER 23 24 TO YOU, CHAIRMAN KLEIN. 25 WITH ONE NOTE TO CHAIRMAN KLEIN, WE DID 5

1	SPEAK ABOUT THIS BRIEFLY, BUT I DID WANT TO REMIND
2	YOU THAT THERE IS A REQUEST THAT WE ALTER THE ORDER
3	ON THE AGENDA SLIGHTLY TO MAKE SURE THAT SOME OF THE
4	LATER ITEMS THAT ARE EITHER TIME SENSITIVE OR HAS
5	BEEN BUMPED A NUMBER OF TIMES GIVEN TIME AND QUORUM
6	CONSTRAINTS MOVE UP CLOSER TO THE BEGINNING.
7	CHAIRMAN KLEIN: I UNDERSTAND THAT, AND I
8	CERTAINLY AM GOING TO DO THAT. LET ME ASK A
9	QUESTION FOR INFORMATION WHICH WOULD BE HELPFUL TO
10	THE PROCESS AND TIMING. LET ME ASK. IS DUANE ROTH
11	ON?
12	MS. KING: YES.
13	CHAIRMAN KLEIN: DUANE, DO YOU HAVE ANY
14	ISSUES WITH EITHER ITEM 8 OR 9? DID DUANE HEAR ME?
15	MR. ROTH: THE ANSWER IS NO.
16	CHAIRMAN KLEIN: JEFF SHEEHY, DO YOU HAVE
17	ANY PROBLEMS WITH ITEMS 8 OR 9?
18	MS. KING: WHAT YOU ARE ASKING, BOB, IS
19	COULD WE MOVE THROUGH THOSE RELATIVELY QUICKLY, OR
20	ARE THERE GOING TO BE DISCUSSIONS AROUND THEM MORE,
21	RIGHT? WE'VE DISCUSSED ITEM 8 A NUMBER OF TIMES IN
22	FINANCE SUBCOMMITTEE MEETINGS. I DON'T WANT TO
23	SPEAK FOR THE BOARD, BUT I BELIEVE WE'RE AT A POINT
24	WHERE DISCUSSION COULD BE MINIMAL. AND ITEM 9 IS
25	ACTUALLY, SCOTT TOCHER IS SITTING TO MY LEFT, AND HE
	6
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1	CAN WALK US THROUGH THAT BRIEFLY, BUT I DON'T
2	BELIEVE THERE SHOULD BE ANY CONTROVERSY OR
3	DISCUSSION REALLY NECESSARY FOR THAT ONE. IT'S JUST
4	SOMETHING THAT WE NEED TO DO IN ACCORDANCE WITH THE
5	OAL PROCESS, IF I'M NOT MISTAKEN. IS THAT CORRECT,
6	MR. TOCHER?
7	MR. TOCHER: THAT'S RIGHT.
8	CHAIRMAN KLEIN: THAT'S RIGHT. I WANTED
9	TO MAKE CERTAIN THAT, JEFF, YOU HAD SOME PRIOR
10	QUESTIONS, I THINK, ON ITEMS. I THINK THEY WERE
11	ADDRESSED, BUT I JUST WANTED TO MAKE CERTAIN.
12	MS. KING: MR. SHEEHY.
13	MR. SHEEHY: YES. WHAT'S 8 AND 9?
14	MS. KING: ITEM NO. 8 IS CONSIDERATION OF
15	AMENDMENT AND AN ADOPTION OF THE LOAN ADMINISTRATION
16	POLICY. AND YOU WOULD BE FAMILIAR WITH THAT ALONG
17	WITH THE MEMBERS OF THE FINANCE SUBCOMMITTEE FROM
18	THE LAST
19	MR. SHEEHY: I KNOW THAT.
20	MS. KING: THE ONE FOLLOWING THAT IS ITEM
21	9, CONSIDERATION OF ADOPTION OF PROPOSED REGULATION
22	100801, INTELLECTUAL PROPERTY PROVISIONS APPLICABLE
23	TO LOAN RECIPIENTS.
24	MR. SHEEHY: I'M COMFORTABLE WITH BOTH OF
25	THOSE, BOB.
	-
	7

1	CHAIRMAN KLEIN: THANK YOU. MR. HARRISON,
2	COULD YOU LET US KNOW ON ITEM 8 OR 9, I BELIEVE THAT
3	THERE IS A TIMING ISSUE IN TERMS OF THE REGULATORY
4	PROCESS IN MAKING SURE WE GET THOSE DONE TODAY. IS
5	THAT A CORRECT STATEMENT?
6	MR. HARRISON: THAT'S CORRECT.
7	CHAIRMAN KLEIN: WOULD YOU EXPLAIN THAT TO
8	THE BOARD AND THE PUBLIC, PLEASE?
9	MR. HARRISON: I'LL DEFER TO SCOTT TOCHER
10	TO EXPLAIN THE OAL ASPECTS.
11	MR. TOCHER: THESE ARE REGULATIONS THAT
12	WERE NOTICED ONE YEAR AGO ON NOVEMBER 17TH. THAT
13	BEGAN THE PROCESS UNDER THE ADMINISTRATIVE PROCEDURE
14	ACT FOR PROMULGATING THESE REGULATIONS. SO THAT
15	ONE-YEAR TIME LIMIT EXPIRES ON NOVEMBER 17TH.
16	THEREFORE, THE ACTION OF THE BOARD TO FORMALLY ADOPT
17	THEM AND MOVE THE FILE ON TO OAL FOR ITS FINAL
18	CONSIDERATION MUST OCCUR BEFORE THE 17TH.
19	CHAIRMAN KLEIN: ALL RIGHT. AND IS THERE
20	ANY BOARD MEMBER THAT WISHES TO ADDRESS ANY ITEM IN
21	8 OR 9? BECAUSE WE'VE GONE THROUGH THOSE ON SEVERAL
22	OCCASIONS, I'M TRYING TO SEE HOW EFFICIENTLY WE CAN
23	ADDRESS THIS ITEM.
24	MS. KING: THE QUICKEST WAY BEING JUST TO
25	HAVE SOMEBODY MAKE A MOTION AND I CAN TAKE A ROLL
	8
	5

1	CALL.
2	CHAIRMAN KLEIN: I DON'T HEAR ANY COMMENT.
3	MR. ROTH: I'LL MAKE A MOTION.
4	CHAIRMAN KLEIN: IS THERE A MOTION TO
5	APPROVE ITEM 8, CONSIDERATION OF AMENDMENTS TO AND
6	ADOPTION OF THE LOAN ADMINISTRATION POLICY?
7	MR. ROTH: I'LL MAKE A MOTION THAT WE
8	APPROVE BOTH ITEMS 8 AND 9, IF I CAN DO THAT.
9	DR. HAWGOOD: SECOND.
10	CHAIRMAN KLEIN: ANY DISCUSSION BY THE
11	BOARD?
12	DR. PIZZO: NO, BUT PHIL PIZZO IS JUST
13	JOINING, AND I AGREE.
14	MS. KING: JUST FOR THE RECORD, MR.
15	HARRISON IS NODDING HIS HEAD TO MR. ROTH'S QUESTION
16	ABOUT WHETHER OR NOT WE CAN ALLOW A MOTION TO
17	CONSIDER BOTH ITEMS. SO THE ANSWER TO THAT IS YES.
18	CHAIRMAN KLEIN: OKAY. THANK YOU. AND IS
19	THERE A PUBLIC COMMENT FROM ANY SITE ON THESE TWO
20	ITEMS? NOT HEARING ANY, I WOULD LIKE TO CALL THE
21	QUESTION. AND, MELISSA, COULD YOU CALL THE ROLL.
22	MS. KING: I WILL. BEFORE I DO THAT, I
23	JUST WANT TO CONFIRM THAT WE ALL HAVE THE SAME
24	RECORD. WE HEARD DR. SAM HAWGOOD AS THE SECOND.
25	THE MAKER OF THE MOTION WAS DUANE ROTH.

9

	BARRISTERS' REPORTING SERVICE
1	ROBERT PRICE.
2	DR. PRICE: YES.
3	MS. KING: DAVID BRENNER, HAVE YOU JOINED
4	US? SUSAN BRYANT.
5	DR. BRYANT: YES.
6	MS. KING: LEEZA GIBBONS.
7	MS. GIBBONS: YES.
8	MS. KING: MICHAEL GOLDBERG.
9	MR. GOLDBERG: YES.
10	MS. KING: SAM HAWGOOD.
11	DR. HAWGOOD: YES.
12	MS. KING: BOB KLEIN.
13	CHAIRMAN KLEIN: YES.
14	MS. KING: SHERRY LANSING.
15	MS. LANSING: YES.
16	MS. KING: TED LOVE.
17	DR. LOVE: YES.
18	MS. KING: SHLOMO MELMED.
19	DR. MELMED: YES.
20	MS. KING: PHIL PIZZO.
21	DR. PIZZO: YES.
22	MS. KING: CLAIRE POMEROY.
23	DR. POMEROY: YES.
24	MS. KING: FRANCISCO PRIETO.
25	DR. PRIETO: YES.
	10

1	MS. KING: ELIZABETH FINI.
2	DR. FINI: YES.
3	MS. KING: ROBERT QUINT. JOHN REED.
4	DR. REED: YES.
5	MS. KING: DUANE ROTH.
6	MR. ROTH: YES.
7	MS. KING: JOAN SAMUELSON. DAVID
8	SERRANO-SEWELL.
9	MR. SERRANO-SEWELL: YES.
10	MS. KING: JEFF SHEEHY.
11	MR. SHEEHY: YES.
12	MS. KING: ART TORRES.
13	MR. TORRES: AYE.
14	MS. KING: JAMES ECONOMOU.
15	DR. ECONOMOU: YES.
16	MS. KING: I WILL CIRCLE BACK. JOAN
17	SAMUELSON, ARE YOU THERE? AND ROBERT QUINT. JON
18	SHESTACK, HAVE YOU JOINED US YET? OSWALD STEWARD.
19	CHAIRMAN KLEIN: SCOTT, DOES THE SUB VOCIA
20	COUNT MEAN THAT WE STILL HAVE A QUORUM WITHOUT THOSE
21	PEOPLE ANSWERING?
22	MR. HARRISON: WE HAVE 19 YES VOTES, BUT
23	YOU CAN LEAVE THE ROLL OPEN, CHAIR, IF YOU WOULD
24	LIKE TO DO SO.
25	CHAIRMAN KLEIN: I'M GOING TO LEAVE THE
	11

1	
1	WELL, IF WE HAVE 19 YES VOTES, WE ARE COVERED ON A
2	QUORUM.
3	MS. KING: THE MOTION CARRIES AND WE CAN
4	MOVE ON.
5	CHAIRMAN KLEIN: LET'S MOVE ON. LET ME
6	ASK ON ITEM 10, THAT'S BEEN BEFORE US BEFORE. ON
7	THAT ITEM WE RECEIVED A NUMBER OF LETTERS IN OUR
8	PACKET AT THE LAST BOARD MEETING ADDRESSING THE NEED
9	FOR A VENUE FOR THE PRESENTATION OF TRANSLATIONAL
10	MEDICINE INCLUDING CLINICAL WORK THAT WAS NOT
11	SUCCESSFUL, WHICH IS VERY DIFFICULT TO HAVE
12	PUBLISHED AT THIS POINT, BECAUSE THOSE LESSONS ARE
13	INVALUABLE AND INSTRUCTIVE TO ALL OF OUR WORK GOING
14	FORWARD.
15	I WOULD LIKE TO ASK, WE'RE GOING TO
16	DISCUSS THIS ITEM IF WE CAN DO IT AT THIS POINT
17	EFFICIENTLY, AND WE'LL HAVE A SHORT STAFF
18	PRESENTATION, BUT IS THERE BEFORE WE PRESENT IT,
19	IS THERE ANYONE THAT HAS AN ISSUE THAT I CAN
20	IDENTIFY EARLY THAT'S A MATERIAL ISSUE ON THIS ITEM?
21	NOT HEARING THAT, COULD I HAVE A SHORT STAFF
22	PRESENTATION ON THIS ITEM?
23	MR. SWEEDLER: THANK YOU, CHAIRMAN KLEIN.
24	THIS IS IAN SWEEDLER. DR. TROUNSON, AS YOU KNOW, IS
25	OUT OF TOWN, AND HE'S ASKED ME TO JUST MAKE A BRIEF
	12

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1	PRESENTATION ON HIS BEHALF.
2	GOAL HERE IS TO HAVE A TRANSLATIONAL
3	JOURNAL THAT'S FOCUSED ON STEM CELL RESEARCH THAT
4	WOULD FILL WHAT'S CURRENTLY CONSIDERED A GAP IN
5	SCIENTIFIC JOURNALS. THE GOAL HERE IS NOT TO HAVE
6	CIRM PUBLISH A JOURNAL. THE GOAL HERE IS TO HAVE
7	CIRM ENTER INTO A CONTRACT WITH A PUBLISHER WHEREBY
8	CIRM WOULD ASSIST WITH A SUBSIDY FOR UP THREE YEARS
9	UP TO \$200,000 A YEAR IN ORDER TO ACCELERATE THE
10	CREATION OF A JOURNAL, WHICH WOULD PROBABLY HAPPEN
11	WITHIN A FEW YEARS. BUT GIVEN THE URGENCY OF OUR
12	MISSION, WE WANT THAT TO HAPPEN SOONER.
13	IT WOULD BE AN INDEPENDENT JOURNAL. CIRM
14	WOULD NOT OPERATE IT OR HAVE EDITORIAL CONTROL.
15	CIRM'S ROLE WOULD PRIMARILY BE TO REACH AN AGREEMENT
16	ABOUT THE SCOPE OF THE KINDS OF RESEARCH WE HOPE THE
17	JOURNAL WILL INCLUDE AND TO SEE A BUSINESS PLAN THAT
18	WOULD HAVE SELF-SUFFICIENCY WITHIN THREE YEARS. AND
19	WE WOULD DO THAT THROUGH OUR NORMAL CONTRACTING
20	PROCESS.
21	IN YOUR PACKET THERE'S AN EXTENSIVE LIST
22	OF ENDORSEMENTS FROM LEADING STEM CELL SCIENTISTS
23	THROUGHOUT CALIFORNIA IN ACADEMIC AND INDUSTRY
24	ENVIRONMENTS. AND I'M HAPPY TO PROVIDE MORE DETAIL
25	IF ANYONE HAS QUESTIONS.

13

1	CHAIRMAN KLEIN: IAN, COULD YOU REPEAT FOR
2	THE RECORD, ALTHOUGH WE'VE DISCUSSED IT BEFORE, THE
3	PUBLICATIONS THAT ARE CURRENTLY IN THE BUSINESS WHO
4	AT THIS POINT EXPRESSED INTEREST IN DISCUSSING WITH
5	CIRM THE POTENTIAL OF COMPETING TO BE THE PRODUCER
6	OF THIS ONLINE JOURNAL?
7	MR. SWEEDLER: I'M AWARE OF THREE MAJOR
8	PUBLISHERS WHO HAVE CONTACTED US AND HAVE CONTINUED
9	TO CONTACT US. THEY'RE EAGERLY AWAITING THE RELEASE
10	OF THE RFP. THE ONES THAT I KNOW OF ARE THE
11	PUBLISHERS OF CELL STEM CELL, PUBLIC LIBRARY OF
12	SCIENCE, AND NATURE.
13	BUT WE DO EXPECT THERE TO BE OTHERS, AND
14	WE WILL MAKE AN AFFIRMATIVE EFFORT TO BRING THE RFP,
15	THE REQUEST FOR PROPOSALS, TO THE ATTENTION OF ANY
16	POTENTIAL PUBLISHER.
17	MS. KING: CHAIRMAN KLEIN, IF NOW IS THE
18	APPROPRIATE TIME, I WOULD LIKE TO READ INTO THE
19	RECORD A STATEMENT THAT I GOT ON THIS ITEM FROM
20	DR. BLOOM, WHO WHEN HE INFORMED ME HE COULD NOT BE
21	PRESENT AT THIS MEETING, BUT FELT VERY STRONGLY
22	ABOUT THIS ITEM, I SUGGESTED TO HIM THAT IF HE SENT
23	ME SOMETHING, I COULD READ IT INTO THE RECORD. IF
24	NOW IS THE TIME OR WHENEVER IS THE RIGHT TIME,
25	PLEASE LET ME KNOW.

14

1 CHAIRMAN KLEIN: I THINK THAT WOULD BE 2 APPROPRIATE.

3 MS. KING: THANK YOU. SO, AGAIN, THIS IS 4 FROM ICOC MEMBER DR. FLOYD BLOOM. BECAUSE MY 5 COMMITMENTS AT THE ANNUAL SOCIETY FOR NEUROSCIENCE MEETING MAKE IT IMPOSSIBLE FOR ME TO BE ON THE 6 7 TELEPHONIC MEETING OF NOVEMBER 11, 2010, I THOUGHT IT MIGHT BE HELPFUL TO EXPRESS IN WRITING WHY I 8 9 SUPPORT PRESIDENT TROUNSON'S PROPOSAL THAT CIRM HELP 10 INITIATE A NEW ONLINE JOURNAL TO FACILITATE 11 SCIENTIFIC COMMUNICATION AMONG STEM CELL SCIENTISTS 12 DEVOTED TO THE TRANSLATIONAL ASPECTS OF STEM CELL 13 SCIENCE. 14 I JUST DID A SEARCH IN PUBMED FOR, QUOTE, 15 TRANSLATIONAL MEDICINE, CLOSE QUOTE, AND, QUOTE, 16 STEM CELLS, CLOSE QUOTE, AND GOT A LIST OF NEARLY 17 4500 ARTICLES. STANDING OF THE JOURNALS THAT THEY ARE IN SHOWS HOW VERY SCATTERED IS THE LITERATURE 18

15 INARSEATIONAL MEDICINE, CLOSE QUOTE, AND, QUOTE, 16 STEM CELLS, CLOSE QUOTE, AND GOT A LIST OF NEARLY 17 4500 ARTICLES. STANDING OF THE JOURNALS THAT THEY 18 ARE IN SHOWS HOW VERY SCATTERED IS THE LITERATURE 19 THESE ARTICLES CARRY. *PUBMED* ALSO LISTS NINE 20 JOURNALS WHOSE NAME CONTAINS SOME ASSOCIATION WITH 21 STEM CELLS, BUT EXCEPT FOR *NATURE REPORTS STEM* 22 *CELLS*, AND *CELL PRESSES CELL STEM CELLS* THAT DOES 23 NOT COME UP IN THE *PUBMED* LISTING, I HAVE NEVER 24 HEARD OF ANY OF THEM. AND NONE DEAL EXPLICITLY WITH 25 THE TRANSLATIONAL ISSUES OF APPLIED STEM CELL

15

1	RESEARCH.
2	AS ALAN NOTED IN HIS COVER NOTE TO THE
3	ICOC, SOME OF THESE ARE FINE JOURNALS, BUT THEY TEND
4	TO FOCUS ON BASIC RESEARCH. THERE ARE ALSO FOUR
5	JOURNALS THAT DEAL EXPLICITLY WITH TRANSLATIONAL
6	MEDICINE THAT INCLUDES SCIENCE'S TRANSLATIONAL
7	MEDICINE THAT IS ONLINE, BUT COVERS MUCH MORE THAN
8	STEM CELL RESEARCH TRANSLATION.
9	WHILE I WAS EDITOR-IN-CHIEF AT SCIENCE, WE
10	STARTED SEVERAL NEW ONLINE JOURNAL-LIKE ALL
11	ELECTRONIC PUBLICATIONS UNDER THE BANNER OF
12	KNOWLEDGE ENVIRONMENTS THAT INCLUDED ORIGINALLY ONLY
13	REVIEWS, NEWS OF MEETINGS, SEMINARS, AND LETTERS,
14	LATER BEGAN TO INCLUDE ORIGINAL RESEARCH AS WELL.
15	WHILE I WAS ABLE TO FINANCE THE FIRST OF THESE IN
16	SIGNAL TRANSDUCTION, THE ONE ON AGING RELIED ON A
17	FIVE-YEAR FUNDING COMMITMENT FROM THE ELLISON
18	FOUNDATION, BUT WAS EVENTUALLY TERMINATED BECAUSE IT
19	COULD NOT BECOME SELF-SUSTAINING.
20	THE SPECIFIC ELEMENTS THAT CONVINCE ME
21	THAT THE ICOC SHOULD PURSUE THIS NEW PUBLICATION ARE
22	DERIVED FROM THE RFP DRAFT THAT WE HAVE BEEN GIVEN.
23	THERE ARE FOUR POINTS. ONE, CIRM WILL SEEK A HIGHLY
24	QUALIFIED AND ESTABLISHED PUBLISHER TO OPERATE THE
25	NEW JOURNAL AND APPLY STRINGENT PEER REVIEW TO

1	SUBMITTALS. TWO, THE NEW JOURNAL WILL BE ONLINE
2	WITH OPEN ACCESS, FACILITATING DISSEMINATION OF ITS
3	CONTENTS BROADLY. THREE, THE NEW JOURNAL WILL BE
4	DEVOTED TO TRANSLATIONAL ASPECTS OF STEM CELL
5	RESEARCH. AND FOUR, THE NEW JOURNAL WILL HAVE THE
6	COMMITMENT TO PUBLISH NEGATIVE DATA QUICKLY.
7	IT IS POINT NO. 4 THAT TO ME WOULD PROVIDE
8	THE UNIQUE EFFECTS OF THIS FIELD OF EVOLVING BASIC
9	AND APPLIED RESEARCH. BY SHARING WHAT DIDN'T WORK
10	AND PERHAPS WITH SOME ATTENTION TO POSSIBLE TESTABLE
11	REASONS WHY IT DIDN'T WORK, THE NEW JOURNAL WOULD
12	STIMULATE BETTER REPLICATIONS AND GREATLY REDUCE THE
13	POSSIBILITIES OF WASTE IN TIME, RESOURCES, AND
14	EFFORTS. OFFERING AN ESTABLISHED, HIGHLY QUALIFIED
15	SCIENTIFIC PUBLISHER A SUBSIDY FOR A THREE-YEAR
16	PERIOD COULD INCENTIVIZE COMPETITION AND IMPROVE
17	CHANCES FOR SUCCESS.
18	A COLUMN DEVOTED TO CIRM'S WORK COULD ALSO
19	DESCRIBE THE AGENCY'S WORK EFFECTIVELY. THEREFORE,
20	I STRONGLY FAVOR MOVING FORWARD WITH AN RFP SUCH AS
21	THE DRAFT WE HAVE SEEN. I WOULD BE HAPPY TO
22	VOLUNTEER MY EFFORTS TO WORKING WITH ALAN AND STAFF
23	TO EVALUATE THE RESPONSES THE RFP DRAWS. WITH BEST
24	WISHES FOR A SUCCESSFUL MEETING, FLOYD BLOOM.
25	CHAIRMAN KLEIN: THANK YOU VERY MUCH. WE
	17

-	
1	SHALL CERTAINLY THANK FLOYD FOR THE EXTENSIVE AMOUNT
2	OF EFFORT HE PUT INTO THAT THOUGHTFUL COMMENT. IS
3	THERE ANY BOARD MEMBER WHO WOULD LIKE TO MAKE A
4	COMMENT OR A MAKE A MOTION THAT INCORPORATES THE
5	FOUR POINTS THAT FLOYD RAISED?
6	MS. LANSING: I WOULD LIKE TO SAY HOW MUCH
7	I SUPPORT THIS. I THINK OUR WHOLE MISSION WAS ABOUT
8	SHARING INFORMATION, AND THAT'S THE WAY WE CAN SPEED
9	THIS UP. SO I WOULD LIKE TO MAKE A MOTION TO MOVE
10	THIS AGENDA ITEM.
11	CHAIRMAN KLEIN: AND, SHERRY, IN THAT
12	MOTION WOULD YOU INCORPORATE FLOYD'S FOUR POINTS
13	FROM THE MEMO?
14	MS. LANSING: FINE WITH ME.
15	MR. SWEEDLER: CHAIRMAN KLEIN, IF I COULD
16	JUST CLARIFY. DR. BLOOM WASN'T, AS I UNDERSTOOD
17	THAT, SUGGESTING ANYTHING DIFFERENT. HE WAS MERELY
18	REFERRING TO ITEMS OF THE PROPOSAL AS IT EXISTS THAT
19	HE PARTICULARLY LIKED.
20	CHAIRMAN KLEIN: I UNDERSTAND. I'M JUST
21	TRYING TO CAPTURE THE ESSENCE OF THE PROPOSAL IN THE
22	MOTION.
23	MS. LANSING: I'M JUST MAKING THE MOTION
24	AS IS.
25	CHAIRMAN KLEIN: IS THERE A SECOND?
	18

1	MS. GIBBONS: SECOND.
2	MS. KING: SECOND IS LEEZA GIBBONS.
3	CHAIRMAN KLEIN: OKAY. ANY DISCUSSION? I
4	THINK WE'VE GONE THROUGH THIS BEFORE. THEREFORE,
5	HEARING NONE, I'D LIKE TO SEE IF THERE'S ANY PUBLIC
6	COMMENT.
7	MS. KING: WE DO HAVE ONE HERE IN SAN
8	FRANCISCO.
9	MR. REED: DON REED. THIS IS A REALLY
10	IMPORTANT AND SOLIDLY NEEDED ITEM. THE OPPOSITION
11	FREQUENTLY GATHERS UP THEIR PSEUDOINFORMATION IN A
12	VERY SYSTEMATIC WAY, AND WE NEED TO HAVE THE FACTUAL
13	INFORMATION GATHERED AND AVAILABLE. THANK YOU.
14	CHAIRMAN KLEIN: OKAY. ANY ADDITIONAL
15	PUBLIC AT ANY SITE? WITHOUT ANY ADDITIONAL PUBLIC,
16	MELISSA, COULD YOU CALL THE ROLL.
17	MS. KING: ROBERT PRICE.
18	DR. PRICE: YES.
19	MS. KING: SUE BRYANT.
20	DR. BRYANT: YES.
21	MS. KING: LEEZA GIBBONS.
22	MS. GIBBONS: YES.
23	MS. KING: MICHAEL GOLDBERG.
24	MR. GOLDBERG: YES.
25	MS. KING: SAM HAWGOOD.
	19

	BARRISTERS REFORTING SERVICE
1	DR. HAWGOOD: YES.
2	MS. KING: BOB KLEIN.
3	CHAIRMAN KLEIN: YES.
4	MS. KING: SHERRY LANSING.
5	MS. LANSING: YES.
6	MS. KING: TED LOVE. SHLOMO MELMED. PHIL
7	PIZZO.
8	DR. PIZZO: YES.
9	MS. KING: CLAIRE POMEROY.
10	DR. POMEROY: YES.
11	MS. KING: FRANCISCO PRIETO.
12	DR. PRIETO: AYE.
13	MS. KING: ELIZABETH FINI.
14	DR. FINI: YES.
15	MS. KING: ROBERT QUINT.
16	DR. QUINT: YES.
17	MS. KING: JOHN REED.
18	DR. REED: YES.
19	MS. KING: DUANE ROTH.
20	MR. ROTH: YES.
21	MS. KING: JOAN SAMUELSON. DAVID
22	SERRANO-SEWELL.
23	MR. SERRANO-SEWELL: YES.
24	MS. KING: JEFF SHEEHY.
25	MR. SHEEHY: YES.
	20

	BARRISTERS' REPORTING SERVICE
1	MS. KING: ART TORRES.
2	MR. TORRES: AYE.
3	MS. KING: JAMES ECONOMOU.
4	DR. ECONOMOU: YES.
5	MS. KING: IS THERE ANYONE ON THE LINE WHO
6	I DIDN'T CALL? AND I WILL CIRCLE BACK. DR. LOVE.
7	DR. LOVE: YES.
8	MS. KING: AND DR. MELMED.
9	CHAIRMAN KLEIN: DID YOU HEAR MY VOTE,
10	MELISSA?
11	MS. KING: I BELIEVE YOUR VOTE WAS YES.
12	CHAIRMAN KLEIN: THAT'S CORRECT.
13	MR. HARRISON: WE HAVE 19 YES VOTES.
14	CHAIRMAN KLEIN: LET'S MOVE ON TO THE NEXT
15	ITEM.
16	MR. HARRISON: BOB, BEFORE WE MOVE TO THE
17	NEXT ITEM, MELISSA POINTED OUT THAT WE HAD NOT ASKED
18	FOR PUBLIC COMMENT ON ITEMS 8 AND 9. I SUSPECT IS
19	THERE NOT ANY.
20	CHAIRMAN KLEIN: OKAY. I THOUGHT THAT I
21	HAD ASKED FOR PUBLIC COMMENT, BUT IT DOESN'T HURT TO
22	DO IT AGAIN.
23	MS. KING: I APOLOGIZE. I MISSED IT, BOB.
24	EVERYBODY ELSE HERE IS SAYING THAT YOU DID ASK FOR
25	IT.
	21
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1	CHAIRMAN KLEIN: IT NEVER HURTS TO BE
2	CONSERVATIVE ON THAT ITEM.
3	OKAY. SO WE THANK YOU FOR YOUR CAUTION.
4	SO ONE OTHER ITEM TO TRY AND GET QUICKLY
5	OUT OF THE WAY, IF WE CAN, ON ITEM 11, WE HAVE THE
6	POSTELECTION CYCLE COMING UP. THERE ARE TWO BILLS
7	PENDING ADDRESSING HUMAN EMBRYONIC STEM CELL
8	RESEARCH ON A BASIS CONSISTENT WITH THE ETHICAL
9	STANDARDS PUT OUT BY THE NIH UNDER THE OBAMA
10	ADMINISTRATION TERM. AND THE DEANS AND OTHER
11	ACADEMIC LEADERS IN THE COUNTRY HAVE SIGNED A VERY
12	SUPPORTIVE STATEMENT FOR THE FEDERAL GOVERNMENT
13	ENDORSING THE WHOLE SPECTRUM OF SCIENTIFIC RESEARCH,
14	INCLUDING HUMAN EMBRYONIC STEM CELL RESEARCH, THAT
15	IS EMBODIED IN THESE PIECES OF LEGISLATION.
16	SENATOR TORRES, COULD YOU PRESENT THE ITEM
17	THAT WENT TO THE LEGISLATIVE SUBCOMMITTEE?
18	MR. TORRES: THANK YOU VERY MUCH. WHAT
19	YOU HAVE BEFORE YOU IN ITEM 11 IS A RESOLUTION THAT
20	WE OWE A LOT OF CREDIT TO DR. FONTANA, JEFF SHEEHY,
21	DR. LOMAX, BOB, YOU, DUANE, ALAN, ELONA, AND IAN,
22	AND ALSO TO JAMES FOR TREMENDOUS INPUT IN PUTTING
23	TOGETHER WHAT I THINK IS A GOOD COMPROMISE THAT
24	TRANSCENDS NOT ONLY THIS LAME DUCK SESSION, IF
25	SOMETHING WERE TO COME UP WE ANTICIPATE THAT THAT

22

1	WILL BE NOT BE THE CASE BUT JUST IN CASE WE WOULD
2	ALREADY BE PREPARED WITH A RESOLUTION THAT COULD BE
3	VIEWED BY THE START OF THIS LAME DUCK SESSION
4	NOVEMBER 15TH.
5	BUT ALSO AND MORE IMPORTANTLY, AS DUANE
6	HAS MENTIONED, TO TRY AND DETERMINE OUR POSITION
7	EARLY ON AS THE CONGRESS EMERGES AND NOT TO LOSE
8	SIGHT OF THE FACT THAT THESE ISSUES COULD BE
9	EXTREMELY IMPORTANT TO THE NEW SPEAKER AND TO
10	WHOMEVER IS THE NEW CHAIR OF THE SCIENCE COMMITTEE
11	IN THE HOUSE, PRESENTLY CHAIRED BY HENRY WAXMAN.
12	SO WHAT YOU HAVE BEFORE YOU ARE A NUMBER
13	OF WHEREAS CLAUSES WHICH INCORPORATE MUCH OF THE
14	IDEAS PUT FORWARD BY ALL THE PARTICIPANTS THAT I
15	MENTIONED AND INCLUDING DON REED, WHO WAS VERY
16	HELPFUL IN ENSURING THAT WE INCLUDED THE FACT THAT
17	CIRM HAS BEEN CREATING JOBS IN CALIFORNIA, WHICH IS
18	VERY UNIQUE FOR A STATE AGENCY IN THESE TIMES.
19	THE RESOLVED CLAUSE SPEAKS FOR ITSELF, AND
20	I WOULD URGE AN AYE VOTE AND I SO MOVE.
21	MS. LANSING: CAN I ASK A QUESTION?
22	CHAIRMAN KLEIN: SURE, SHERRY. JUST ONE
23	MOMENT. COULD I SEE IF THERE'S A SECOND.
24	DR. PRIETO: I'LL SECOND.
25	CHAIRMAN KLEIN: SHERRY, YOU HAVE THE
	23

1	
1	FLOOR.
2	MS. LANSING: MY QUESTION IS MAYBE WE
3	SHOULD TAKE THE VOTE, AND THEN I HAVE A QUESTION
4	RELATED TO THIS.
5	CHAIRMAN KLEIN: THAT'S FINE. THIS IS BOB
6	KLEIN AGAIN. I WOULD LIKE TO AGAIN JUST EMPHASIZE
7	THE TREMENDOUS RESPECT I HAVE FOR THE SCIENTIFIC AND
8	CLINICAL LEADERS IN BIOMEDICAL RESEARCH STANDING UP
9	TO DEFEND THE RIGHT OF SCIENTISTS TO EXPLORE HUMAN
10	EMBRYONIC STEM CELLS ALONG WITH EVERY OTHER CELL
11	TYPE TO FIND THE BEST THERAPEUTIC APPROACH FOR EACH
12	DISEASE ON SCIENTIFIC MERIT. IT'S EXTREMELY
13	IMPORTANT TO PROTECT THE INTEGRITY OF THE SCIENTIFIC
14	PROCESS IN THIS COUNTRY, AND I REALLY WOULD LIKE TO
15	PERSONALLY APPLAUD THEIR COURAGE IN STANDING UP AND
16	TAKING A POSITION.
17	DR. PIZZO: CAN I JUST MAKE A COMMENT ON
18	THIS?
19	MS. LANSING: I WANT TO ASK MY QUESTION
20	THEN AS WELL.
21	DR. PIZZO: THE COMMENT IS FIRST TO THANK
22	YOU. AND I THINK, AS SAM HAWGOOD KNOWS, THIS WAS
23	NOT AN EASY THING TO DO BECAUSE THERE ARE MANY
24	PUBLIC UNIVERSITIES. THESE ARE DEANS OF SCHOOLS OF
25	MEDICINE THAT SIGNED THIS. IT WAS COORDINATED
	24

1	THROUGH THE COUNCIL OF DEANS. AND I THINK IT DOES
2	REPRESENT A VERY STRONG AFFIRMATION DESPITE ALL THE
3	ISSUES THAT EXIST AROUND THE COUNTRY THAT WOULD
4	OTHERWISE CONSPIRE AGAINST THIS KIND OF UNIFORMITY.
5	CHAIRMAN KLEIN: THANK YOU VERY MUCH.
6	SHERRY.
7	MS. LANSING: I JUST WANT TO BE SURE I
8	UNDERSTAND THIS BECAUSE WE'RE ASKING THEM TO SUPPORT
9	THE LEGISLATION THAT ARLEN SPECTER IS PUTTING
10	FORWARD, RIGHT?
11	CHAIRMAN KLEIN: AND DIANA DEGETTE. WE'RE
12	AGNOSTIC AS TO WHICH OF THE BILLS GO FORWARD, BUT WE
13	BELIEVE, AS THE SCIENTIFIC AND CLINICAL LEADERS DO,
14	THAT THIS IS AN OPPORTUNITY TO AFFIRM THE RIGHT TO
15	DO THIS RESEARCH.
16	MS. LANSING: WE'RE ASKING THEM TO REPEAL
17	DICKEY-WICKER.
18	CHAIRMAN KLEIN: WE'RE ASKING THEM TO
19	SPECIFICALLY CLARIFY THE UNDERSTANDING THAT
20	DICKEY-WICKER DOES NOT PREVENT DOING RESEARCH ON
21	HUMAN EMBRYONIC STEM CELL LINES.
22	MS. LANSING: SO MY QUESTION IS THIS
23	THING I'M ALL FOR THIS. AND MY QUESTION IS CAN
24	WE GET THIS TO HARRY REID ALSO BECAUSE I THINK HE'S
25	THE ONE THAT WOULD HAVE TO BRING THE SPECTER BILL OR
	25

1	
1	THE DEGETTE BILL FORWARD, ESPECIALLY THE SPECTER
2	BILL.
3	MR. TORRES: THAT'S MY INTENT, SHERRY.
4	MS. LANSING: THANK YOU. THAT WAS MY ONLY
5	QUESTION BECAUSE I HAD A CONVERSATION WITH ARLEN
6	SPECTER, WHO REALLY WANTS TO MOVE IT FORWARD, BUT HE
7	SAID THE PERSON THAT CONTROLS THAT IS HARRY REID.
8	MR. TORRES: THE OTHER VITAL PERSON IN
9	THIS WHOLE DEBATE IS, AS YOU WELL KNOW, SHERRY, IS
10	DIANE FEINSTEIN BECAUSE OF HER POSITION ON THE
11	APPROPRIATIONS COMMITTEE.
12	MS. LANSING: WE'LL GET IT TO BOTH OF
13	THEM. AND THEN ARE WE ALLOWED AS INDIVIDUAL
14	CITIZENS TO CALL THOSE PEOPLE?
15	CHAIRMAN KLEIN: WELL, WE'RE ALLOWED AS
16	INDIVIDUAL CITIZENS. AND WITH THE BOARD TAKING A
17	PUBLIC POSITION, WE'RE ALLOWED AS MEMBERS OF THE
18	BOARD, WITHIN THE CONSTRAINTS OF THE RESOLUTION, TO
19	SUPPORT THIS LEGISLATION AS FURTHERING THE
20	SCIENTIFIC MISSION OF THE INITIATIVE AND THE STATE.
21	MS. LANSING: THAT WAS MY QUESTION. THANK
22	YOU.
23	CHAIRMAN KLEIN: SO ADDITIONAL BOARD
24	COMMENT? ADDITIONAL PUBLIC COMMENT FROM ANY SITE?
25	OKAY. NOT HEARING ANY, MELISSA, UNLESS SENATOR
	26
	26

1	TORRES WOULD LIKE TO MAKE A CONCLUDING COMMENT.
2	MR. TORRES: NO. NO. BREVITY IS
3	IMPORTANT. CALL FOR THE VOTE.
4	MS. KING: ROBERT PRICE.
5	DR. PRICE: YES.
6	MS. KING: SUE BRYANT.
7	DR. BRYANT: YES.
8	MS. KING: LEEZA GIBBONS.
9	MS. GIBBONS: YES.
10	MS. KING: MICHAEL GOLDBERG.
11	MR. GOLDBERG: YES.
12	MS. KING: SAM HAWGOOD.
13	DR. HAWGOOD: YES.
14	MS. KING: BOB KLEIN.
15	CHAIRMAN KLEIN: YES.
16	MS. KING: SHERRY LANSING.
17	MS. LANSING: YES.
18	MS. KING: TED LOVE.
19	DR. LOVE: YES.
20	MS. KING: SHLOMO MELMED. PHIL PIZZO.
21	DR. PIZZO: YES.
22	MS. KING: CLAIRE POMEROY.
23	DR. POMEROY: YES.
24	MS. KING: FRANCISCO PRIETO.
25	DR. PRIETO: AYE.
	27

1	MS. KING: ELIZABETH FINI.
2	DR. FINI: YES.
3	MS. KING: ROBERT QUINT.
4	DR. QUINT: YES.
5	MS. KING: JOHN REED.
6	DR. REED: YES.
7	MS. KING: DUANE ROTH.
8	MR. ROTH: YES.
9	MS. KING: JOAN SAMUELSON. DAVID
10	SERRANO-SEWELL.
11	MR. SERRANO-SEWELL: YES.
12	MS. KING: JEFF SHEEHY.
13	MR. SHEEHY: YES.
14	MS. KING: ART TORRES.
15	MR. TORRES: AYE.
16	MS. KING: JAMES ECONOMOU.
17	DR. ECONOMOU: YES.
18	MS. KING: I'LL JUST CIRCLE BACK WITH
19	SHLOMO MELMED. JOAN SAMUELSON.
20	MS. SAMUELSON: I'M CALLING BACK IN ON MY
21	CELL PHONE. SOMETHING IS WRONG WITH THE OTHER
22	PHONE, AND I DIDN'T HEAR THE DISCUSSION, SO I SHOULD
23	PROBABLY ABSTAIN.
24	MS. KING: OKAY. THE VOTE FROM MS.
25	SAMUELSON, FOR THE RECORD, IS AN ABSTENTION. AND IS
	28
	20

1	THERE ANYBODY ELSE ON THE LINE THAT I DID NOT CALL?
2	OKAY. I WILL JUST CHECK WITH LEEZA JUST IN CASE.
3	LEEZA GIBBONS, ARE YOU THERE AND MAYBE HAD YOUR
4	PHONE MUTED?
5	MS. GIBBONS: YES, I'M HERE.
6	MS. KING: DID YOU HEAR THAT DISCUSSION,
7	LEEZA?
8	MS. GIBBONS: I DID AND I VOTED YES.
9	MS. KING: MAYBE WE JUST DIDN'T HEAR YOU.
10	ALL RIGHT. FOR THE RECORD THAT MOTION CARRIES.
11	CHAIRMAN KLEIN: THANK YOU VERY MUCH. AND
12	WE'LL NOW MOVE BACK TO THE TOP OF THE AGENDA TO ITEM
13	4. IS DR. OLSON THERE OR WHO, DR. OLSON, WOULD YOU
14	LIKE TO PRESENT THIS ITEM?
15	DR. OLSON: I AM HERE AND WILL SPEAK TO
16	THIS ITEM.
17	MS. KING: WE HAVE DR. OLSON.
18	DR. HAVTON: DR. HAVTON IS HERE.
19	MS. KING: THANK YOU SO MUCH, DR. HAVTON.
20	THAT'S WONDERFUL. I WAS HOPING YOU WERE ALREADY ON
21	THE LINE. SO WHAT WE'LL DO IS WE'LL START WITH A
22	PRESENTATION BY DR. OLSON. BUT CHAIRMAN KLEIN,
23	PLEASE BE ADVISED THAT THE APPLICANT, DR. HAVTON
24	FROM UCLA, IS ALSO ON THE LINE AND WOULD LIKE TO
25	MAKE A BRIEF STATEMENT AND IS ALSO AVAILABLE FOR
	20

29

1 QUESTIONS. 2 MR. HARRISON: CAN I JUST REMIND EVERYONE 3 THAT THIS APPLICATION WAS THE SUBJECT OF A MOTION BY 4 DR. PRIETO AND JEANNIE FONTANA TO FUND THE 5 APPLICATION. 6 DR. REED: CAN I HAVE A CLARIFICATION ON 7 HOW MUCH TIME THE PETITIONERS HAVE TO MAKE THE 8 **REMARKS?** 9 CHAIRMAN KLEIN: WHAT I'D LIKE TO DO IS, 10 SINCE WE HAVE ADDRESSED THIS PREVIOUSLY, HAVE THIS 11 BE FIVE MINUTES. BUT IF ANY BOARD MEMBER REQUESTS 12 ADDITIONAL INFORMATION FROM THE PETITIONER, I'M 13 GOING TO ASK THE PETITIONER TO STAY AT THE MIC AND 14 CONTINUE TO ANSWER THOSE QUESTIONS UNTIL THEY ARE 15 **RESOLVED**. 16 MS. KING: BEFORE DR. OLSON GETS STARTED, I'LL JUST REMIND THE BOARD THAT YOU HAVE IN FRONT OF 17 18 YOU THE PUBLIC SUMMARY OF THE APPLICATION, A 19 TRANSCRIPT EXCERPT FROM THE DISCUSSION OF THIS 20 APPLICATION AT THE BOARD MEETING IN L.A. ON OCTOBER 21 21ST, AND ALSO THE ORIGINAL EXTRAORDINARY PETITION 22 SENT IN BY DR. HAVTON. 23 AND THEN THE OTHER THING TO REMIND YOU OF 24 IS THAT YOU SHOULD HAVE A SHEET IN FRONT OF YOU THAT 25 AMY CHEUNG E-MAILED TO YOU LISTING WHETHER OR NOT 30

1	YOU HAVE A CONFLICT WITH THIS APPLICATION. AND IF
2	YOU DO, PLEASE REFRAIN FROM DISCUSSING OR VOTING ON
3	IT. THANK YOU.
4	CHAIRMAN KLEIN: SO COULD WE HAVE THE
5	SCIENTIFIC STAFF TO PROVIDE A SUMMARY, AND THEN I'M
6	GOING TO CALL ON DR. HAVTON AND THEN DISCUSSION.
7	BUT CERTAINLY IF A BOARD MEMBER HAS QUESTIONS AS TO
8	THE SCIENTIFIC STAFF'S PRESENTATION, WE'LL TAKE
9	THOSE AT THIS TIME, OR WE COULD ALSO TAKE THOSE
10	AFTER DR. HAVTON, WHICHEVER THE MEMBERS WOULD
11	PREFER.
12	DR. OLSON: I'M GOING TO GIVE THE REVIEW
13	SUMMARY. THIS IS AN APPLICATION FOR DEVELOPMENT
14	CANDIDATE FEASIBILITY AWARDS THAT PROPOSES TO USE
15	HUMAN EMBRYONIC STEM CELL-DERIVED MOTOR NEURONS AND
16	AUTONOMIC NEURONS TO TREAT INJURIES OF THE LOWER
17	SPINAL CORD. IN PARTICULAR, WHAT THE APPLICANT IS
18	FOCUSING ON IS A RAT MODEL OF BLADDER CONTROL.
19	SO THE IDEA WHAT THE APPLICANT PROPOSES
20	TO DO IS TO IN THIS RAT MODEL OF LOWER SPINAL CORD
21	INJURY TO ESSENTIALLY TRANSPLANT THE ESC-DERIVED
22	MOTOR AND AUTONOMIC NEURONS IN CONJUNCTION WITH A
23	SURGICAL TREATMENT TO PUT IN A NERVE ROOT AND LOOK
24	AT THOSE BOTH TO DO THIS TRANSPLANTATION IMMEDIATELY
25	AFTER THE INJURY AND A MONTH LATER.

31

SO BASICALLY IT IS A PRECLINICAL MODEL
FEASIBILITY STUDY. REVIEWERS BASICALLY WERE
SUPPORTIVE OF THE RATIONALE. THEY CONSIDERED THE
IMPACT HIGH. IT IS AN UNMET MEDICAL NEED. THEIR
BIG CONCERN HAD TO DO WITH FEASIBILITY OF DOING
THIS.
SO TO DO THIS STUDY, THERE WERE TWO MAIN
ISSUES. THEY NEEDED TO BE ABLE TO MAKE THE CELL
TYPES THAT THEY PROPOSE TO TRANSPLANT. THE
PRELIMINARY DATA PRESENTED BY THE APPLICANT AND, IN
FACT, IS ALSO IN A PUBLICATION BY THE APPLICANT, AS
TO THEIR ABILITY TO MAKE THE MOTOR NEURONS THEY WERE
GOING TO USE. I BELIEVE THE APPLICANT MENTIONED
THIS IN HIS EXTRAORDINARY PETITION. SO THE
PARTICULAR MOTOR NEURONS, THEY DID IT WITH A GREEN
FLUORESCENT PROTEIN RAT. SO A RAT INTO RAT, A RAT
THAT HAD BEEN LABELED WITH GREEN FLUORESCENT PROTEIN
FOR THIS PARTICULAR MOTOR NEURON SUBTYPE. THEY
SHOWED THAT YOU COULD GET THEY SHOWED THAT THE
NUMBER OF MOTOR NEURONS THAT THE SUBTYPE OF MOTOR
NEURON THAT HAD THAT PHENOTYPE WHEN THEY DID THE
DIFFERENTIATION WAS A VERY LOW PERCENTAGE.
THEY SHOWED NO DATA THAT THEY COULD GET
THE AUTONOMIC MOTOR NEURON. SO THE QUESTION TO THE
REVIEWERS WAS IF YOU'RE TALKING ABOUT TAKING
32

32

1	SOMETHING FORWARD INTO THE CLINIC AND YOU HAVEN'T
2	BEEN ABLE TO SHOW AT ALL THAT YOU CAN GET THE ONE
3	TYPE OF NEURON YOU'RE LOOKING FOR, YOU'VE BEEN ONLY
4	ABLE TO SHOW THAT YOU HAVE A VERY LOW PERCENTAGE OF
5	THE OTHER TYPE OF MOTOR NEURON, THEN, YOU KNOW, HOW
6	CAN YOU SAY WHAT IS DOING IT? HOW CAN YOU SAY
7	EVIDENCE YOU GET OF EFFICACY IS ATTRIBUTED TO THAT?
8	SO THAT WAS ONE THING, THE ABILITY TO PRODUCE THE
9	NEURONS THAT THEY CONSIDERED TO BE IMPORTANT FOR
10	THIS.
11	THE OTHER ONE HAD TO DO WITH THE ABILITY
12	TO SHOW ACCURATE REINNERVATION. I MISSPOKE MYSELF
13	BEFORE. THIS WAS ACTUALLY DONE IN THE RAT MODEL
14	WITH THE RAT CELLS. AND THIS IS CONSIDERED TO BE A
15	VERY CHALLENGING THING, AND THEY DID NOT CONSIDER
16	THAT THE DATA SUPPORTED THE ABILITY TO DO THIS AT
17	ALL. BUT, IN FACT, WHAT THE APPLICANT SHOWED WAS
18	THAT WHEN THE ROOT WAS REIMPLANTED, YOU GOT A LITTLE
19	BIT BETTER OUTCOME THAN WHEN IT WASN'T. SO THEY
20	ATTRIBUTED THAT TO TROPHIC SUPPORT RATHER THAN TO
21	ANY FUNCTION OF IN THE NEURONS. AND, IN FACT, THE
22	DATA THAT THEY SHOWED THAT HAD TO DO WITH THE
23	LABELED MOTOR NEURON IN THE INJURY, THE APPLICANT
24	THE REVIEWERS CONSIDERED TO BE DUE TO CELL DEATH AND
25	ABSOLUTELY NOT CONVINCING.

33

1	SO WHEN THE PREMISE OF THE PROPOSAL IS TO
2	DO THESE PRECLINICAL MODEL STUDIES, THE REVIEWERS
3	FELT THAT THE INABILITY TO SHOW THAT THEY WERE ABLE
4	TO GENERATE THE NEURONS NEEDED TO BE TESTED, THAT
5	THEY WERE UNABLE TO SHOW IN THE RAT MODEL WITH THE
6	RAT CELLS THAT THEY COULD GET ANY EVIDENCE THAT THIS
7	COULD HAPPEN, THAT THIS WAS WAY TOO EARLY, AND THAT
8	THERE NEEDED TO BE MORE EVIDENCE.
9	SO THEY DO NOT DISPUTE THE IMPORTANCE OF
10	THE IMPACT, BUT THEY DO DISPUTE WHETHER THEY CAN
11	CONDUCT THE STUDIES.
12	CHAIRMAN KLEIN: DR. OLSON, THIS IS BOB
13	KLEIN. DR. COLLINS AT THE LAST BOARD MEETING IN THE
14	TRANSCRIPT THAT WE HAVE SUMMARIZED A PORTION OF THE
15	DISCUSSION FROM THE PEER REVIEW MEETING THAT LOOKED
16	AT A DIFFERENT AIM THAN YOU'VE JUST DESCRIBED, AS I
17	UNDERSTAND IT. SHE SAID THAT THIS AS A DEVELOPMENT
18	CANDIDATE PROPOSAL IS TO GENERATE HUMAN EMBRYONIC
19	STEM CELL-DERIVED HEPATOCYTES TO SERVE AS A BRIDGE
20	TO REGENERATION FOR ACUTE LIVER FAILURE AND ALSO TO
21	SUPPORT PATIENTS WHO REQUIRE LARGE LIVER RESECTIONS
22	TO THE POINT WHERE THERE WOULD BE INADEQUATE LIVER
23	LEFT TO PROMOTE SURVIVAL UNTIL THE PATIENT'S OWN
24	LIVER COULD REGENERATE.
25	MS. KING: I'M SORRY TO INTERRUPT YOU, BUT
	34

1	I BELIEVE THE APPLICATION THAT YOU'RE DISCUSSING
2	THAT DR. COLLINS COMMENTED ON IS AGENDA ITEM NO. 5.
3	CHAIRMAN KLEIN: THANK YOU BECAUSE I WAS
4	HAVING A PROBLEM RECONCILING THIS ITEM, AND IT CAME
5	LABELED TO ME AS A PART OF THIS ITEM. SO THAT'S
6	VERY HELPFUL. I APPRECIATE THAT CLARIFICATION. IT
7	MAKES MY LIFE A LOT SIMPLER.
8	MS. KING: I KNOW THAT FOR THIS PARTICULAR
9	MEETING, THERE WERE LOTS AND LOTS OF DOCUMENTS. AND
10	SOME OF THEM CAME TO YOU AT DIFFERENT TIMES, AND I
11	APOLOGIZE FOR THAT. SO IF THERE ARE ANY QUESTIONS
12	ABOUT THE DOCUMENTS IN FRONT OF YOU AT ANY TIME,
13	PLEASE DON'T HESITATE TO ASK BECAUSE THIS MEETING
14	SEEMS TO HAVE MORE DOCUMENTS THAN MEETINGS WITH
15	AGENDAS THAT ARE FOUR TIMES AS LONG.
16	MS. SAMUELSON: I'D LIKE TO RAISE ONE
17	POINT FOR CLARIFICATION OR A QUESTION. CAN YOU HEAR
18	ME FIRST?
19	CHAIRMAN KLEIN: YES, JOAN.
20	MS. SAMUELSON: MY READING OF THE DOCUMENT
21	SHOWS A DIVERGENCE OF VIEWS ABOUT THE SUFFICIENCY OF
22	THE DATA, AND I WOULD JUST LIKE TO POINT THAT OUT.
23	THE PRIMARY REVIEWER THOUGHT THAT PRELIMINARY DATA
24	WAS SOLID WITH SOME NOTABLE EXCEPTIONS. AND I THINK
25	PROBABLY THE POINTS THAT DR. OLSON WAS TALKING
	25

35

ABOUT.

1

2 ONE OF THE OTHER THREE REVIEWERS, HOWEVER, 3 GAVE IT A VERY SOLID HIGH SCORE AND SAID THAT THE 4 PRELIMINARY DATA SUPPORT THE ABILITY OF THE PI AND 5 HIS COLLEAGUES TO CREATE THE SPINAL CORD LESION, SURGICALLY REPLANT INVOLVED ROOTS, AND CHARACTERIZE 6 7 NEWLY DIFFERENTIATED NEURONS, SO THE MOTOR NEURON AND AUTONOMIC MARKERS. THERE ALSO ARE SOME DATA IN 8 9 SUPPORT OF THE ABILITY OF IMPLANTED NEURAL PRECURSOR CELLS TO SPREAD THROUGHOUT THE LENGTH OF THE SPINAL 10 11 CORD FOLLOWING REPLANTATION. THERE ALSO IS 12 PROVOCATIVE DATA ON SENSORY CHANGES FOLLOWING 13 IMPLANTATION. ALL OF THESE ARE ENCOURAGING. 14 AND THERE ARE SEVERAL OTHER POINTS OF 15 SUPPORT FOR THE GRANT, NOT ON THIS POINT, BUT I 16 THOUGHT THAT WAS IMPORTANT TO PUT BEFORE THE BOARD. 17 DR. OLSON: AS MS. SAMUELSON IS WELL 18 AWARE, THAT THE INFORMATION THAT IS PRESENTED AT THE 19 MEETING ARE IN THE ACTUAL -- IS THE PART OF THE 20 DISCUSSION AND DOES NOT REPRESENT THE SUMMARY SCORE THAT IS REFLECTED. I CAN GO INTO THE PRELIMINARY 21 22 DATA, BUT THIS IS NOT A CLOSED SESSION. AND I AM 23 NOT TOTALLY COMFORTABLE WITH DISCLOSING INFORMATION 24 THAT, YOU KNOW, I WOULD CONSIDER CONFIDENTIAL. 25 CHAIRMAN KLEIN: AT THIS POINT IT MIGHT BE

36

1	HELPFUL FOR THE BOARD FOR DR. HAVTON TO SPEAK
2	BECAUSE HE CAN DECIDE WHICH INFORMATION HE FEELS IS
3	APPROPRIATE TO DISCLOSE AND WHICH HE THINKS HE'D
4	LIKE TO KEEP ON A PROPRIETARY BASIS.
5	DR. HAVTON: EVERYTHING IN THE APPLICATION
6	CAN BE DISCUSSED. THERE ARE NO SECRETS. WE HAVE AN
7	OPEN POLICY HERE, SO YOU ARE FREE TO SPEAK ABOUT ANY
8	ASPECT OF IT.
9	CHAIRMAN KLEIN: DR. HAVTON, WOULD YOU
10	MAKE YOUR PRESENTATION? AND THEN WE'LL SEE IF
11	THERE'S QUESTIONS THAT RELATE TO THAT.
12	DR. HAVTON: IS NOW A TIME FOR THAT? WHAT
13	I WOULD LIKE TO DO, THEN, IS FIRST MAKE A RESPONSE
14	AND COMMENT TO THE ASPECT OF THE TRANSPLANTED CELLS.
15	I THINK THERE IS A BIT OF A MISUNDERSTANDING WHAT
16	THE PURPOSE WAS FOR THE TRANSPLANTATION OF THE
17	RAT-TO-RAT CELLS.
18	OUR GOAL IN THAT PART OF THE PRELIMINARY
19	STUDIES WAS TO DEMONSTRATE THAT WE HAVE A METHOD OF
20	FINDING TRANSPLANTED CELLS IN THE RAT SPINAL CORD BY
21	USING THE GREEN FLUORESCENT PROTEIN AS A MARKER. WE
22	SHOW IN OUR PRELIMINARY DATA THAT WE CAN, IN FACT,
23	TRANSPLANT AND IDENTIFY CELLS THAT HAPPEN TO BE OF
24	RAT ORIGIN. I THINK THERE'S A BIT OF
25	MISUNDERSTANDING HERE THAT THE REVIEWERS MAY HAVE
	37

1	FELT THAT WE INJECTED CELLS THAT WERE TARGETED TO BE
2	MOTOR NEURONS, AND THAT IS NOT THE CASE. THE RAT
3	CELLS THAT WERE TRANSPLANTED WERE NOT
4	DIFFERENTIATED. WE WERE NOT AIMING OR TRANSPLANTING
5	MOTOR NEURONS THERE. IT WAS MORE AN EXPERIMENT TO
6	SHOW THAT WE CAN TRANSPLANT AND IDENTIFY THE
7	CRITICAL MARKER OF GSP. AND THAT'S WHY THERE IS A
8	LOW PERCENTAGE OF MOTOR NEURONS AS EXPECTED IN THE
9	POPULATION OF CELLS.

10 WHAT OUR DATA SHOW THERE IS THAT WE ARE 11 CAPABLE OF FINDING TRANSPLANTED CELLS. WE'VE DONE 12 SIMILAR EXPERIMENTS WITH NONDIFFERENTIATED HUMAN 13 CELLS WITH SIMILAR RESULTS, BUT WITH OTHER MARKERS. WE'RE ALSO ABLE TO SHOW THAT OUR ROOT REPLANTATION 14 15 PROCEDURE, WHICH IS A SURGICAL PROCEDURE THAT WE DO 16 IN CONJUNCTION WITH THE CELL TRANSPLANTATION, AND 17 THEN THAT ROOT PROCEDURE IS PROTECTED, MEANING THAT IT INCREASES THE SURVIVAL OF THE TRANSPLANTED CELLS. 18 19 THIS IS ACTUALLY A GREAT AND UNEXPECTED FEATURE OF 20 OUR APPROACH BECAUSE IT ALLOWS US FOR USING SMALLER 21 VOLUMES IN THIS VERY SENSITIVE PART OF THE NERVOUS 22 SYSTEM. SO THAT IS ACTUALLY A FEATURE THAT WAS VERY 23 WELCOME AND IS NOT A PROBLEM AS THE REVIEWERS 24 INDICATED IN THEIR COMMENTS. 25 WHAT I WOULD LIKE TO SAY ALSO IS THAT,

38

1	JUST REEMPHASIZE THE FACT THAT THE RAT CELLS HAD A
2	DIFFERENT PURPOSE. THEY WERE NOT MOTOR NEURONS.
3	BUT WHAT WE HAVE, MY COLLEAGUES NOVITCH AND DR.
4	KORNBLUM HAVE EXTENSIVE EXPERIENCE IN MAKING MOTOR
5	NEURONS. SO THEY HAVE, IN FACT, PUBLISHED SUCH
6	PAPERS IN VERY PRESTIGIOUS JOURNALS AND SHOWN VERY
7	SOLID SCIENCE ON OUR ABILITY TO MAKE THOSE CELLS.
8	AND WHAT THE FEASIBILITY PROPOSAL IS ALL
9	ABOUT IS TO TAKE THOSE CELLS THAT HAVE BEEN WELL
10	PUBLISHED AND WELL CHARACTERIZED AND TEST THEM IN
11	THIS FEASIBILITY PROPOSAL TO USE THE DETECTION
12	METHODS THAT WE HAVE ALREADY DEVELOPED AND TO SEE
13	CAN WE ALSO MAKE THOSE PARTICULAR CELLS SURVIVE AND
14	GROW IN THE INJURED NERVOUS SYSTEM IN THIS MODEL.
15	AND THAT'S WHERE THE FEASIBILITY COMES IN, THAT OUR
16	NEXT STEP IS TO TEST THE HUMAN EMBRYONIC-DERIVED AND
17	MOTOR NEURONS IN THIS MODEL.
18	SO THAT'S THE RESPONSES TO THE ASPECT OF
19	THE CELL-TO-RAT TRANSPLANTATION. WHAT I WOULD ALSO
20	LIKE TO DO IS TO TAKE THIS OPPORTUNITY TO JUST VERY
21	BRIEFLY COMMENT UPON WHY WE BELIEVE THIS PROPOSAL IS
22	IMPORTANT.
23	FIRST OF ALL HERE, THERE IS NO PRESENT
24	CURE FOR SPINAL CORD INJURY, OF ANY TYPE OF SPINAL
25	CORD INJURY. WE ARE TARGETING A KIND OF SPINAL CORD
	39

1	INJURY THAT AFFECTS ABOUT 20 PERCENT OF ALL SPINAL
2	CORD INJURED PATIENTS THAT HISTORICALLY HAVE BEEN
3	EXCLUDED FROM ALL THE CURRENT AND PAST CLINICAL
4	TRIALS, AT LEAST MOST OF THE TRIALS. ALMOST ALL
5	TRIALS, THEY'RE NOT WELCOME IN THOSE TRIALS BECAUSE
6	THEY HAVE A DIFFERENT KIND OF INJURY THAT OFTEN
7	BECOMES A COMPOUNDING FACTOR IN MOST CLINICAL
8	STUDIES.
9	CURRENTLY THERE ARE NO TREATMENTS AND
10	THERE ARE NO CURES FOR THESE PATIENTS. WE ARE
11	TARGETING THE CHRONIC INJURIES WHICH ARE INJURIES
12	THAT WOULD INVOLVE ALL PATIENTS WITH THESE INJURIES.
13	ALL SPINAL CORD INJURED PATIENTS EVENTUALLY BECOME A
14	CHRONIC INJURED SPINAL CORD PATIENT. SO BY GOING
15	THAT APPROACH, WE'RE TARGETING A POPULATION THAT
16	ALSO HAVE NOT BEEN TARGETED BY THE SCIENTIFIC
17	COMMUNITY BECAUSE MOST OF THE RESEARCH ATTEMPTS AND
18	ALSO CLINICAL AMBITIONS HAS BEEN FOR THE ACUTE
19	INJURY.
20	WE'RE ALSO LOOKING AT THE BLADDER
21	DYSFUNCTION AS AN OUTCOME MEASURE AND AS A TARGET.
22	HERE WE HAVE TREMENDOUS SUPPORT FROM THE SPINAL CORD
23	INJURED COMMUNITY, INCLUDING PUBLISHED REPORTS WHERE
24	THE SPINAL CORD INJURED COMMUNITY HAS PRIORITIZED
25	THEIR MOST IMPORTANT FUNCTIONS. AND BLADDER

40

1 FUNCTION IS THE TOP OF THAT.

2 AND, AGAIN, OUR APPROACH HERE IS A CELL 3 REPLACEMENT STRATEGY, WHICH IS DIFFERENT FROM THE 4 STRATEGIES THAT OTHER OR I WOULD SAY MOST SPINAL 5 CORD INJURY PROPOSALS AND STUDIES ONGOING RIGHT NOW 6 ARE USING. MANY STUDIES RIGHT NOW ARE USING 7 REMYELINATION STRATEGIES OR ACUTE STRATEGIES, BUT CELL REPLACEMENT STRATEGY IS VERY DIFFERENT. THIS 8 9 IS ACTUALLY A STRATEGY THAT CAN ALSO BE OF INTEREST 10 FOR OTHER NEURODEGENERATIVE CONDITIONS SUCH AS ALS, SPINAL MUSCULAR ATROPHY, BUT ALSO MORE BROADLY 11 12 SPEAKING ALZHEIMER'S, PARKINSON'S, AND HUNTINGTON'S 13 WOULD ALSO HAVE AN INTEREST IN FINDING OUT IN OUR 14 MODEL HOW DO CELLS SURVIVE? WHAT ENVIRONMENTS DO 15 CELLS SURVIVE IN A CLINICALLY RELEVANT TRANSLATIONAL 16 **PROJECT**?

17 SO I THINK THAT HERE WE'VE TOUCHED ON A 18 NUMBER OF UNDERFUNDED AND UNDERSTUDIED AREAS IN 19 NEUROLOGICAL RESEARCH. AND AS A NEUROLOGIST WHO 20 TAKES CARE OF PATIENTS ON A REGULAR BASIS WITH THESE 21 INJURIES, I MUST SAY THAT THESE PATIENTS ARE VERY 22 FRUSTRATED. THEY FEEL VERY ISOLATED AND ALONE, AND 23 THEY ARE LOOKING FOR HELP. AND WE WOULD LIKE TO 24 GIVE THEM HOPE AND WOULD LIKE TO GIVE THEM A CHANCE 25 TO FOLLOW PROPOSALS AND STUDIES THAT CAN HOPEFULLY

41

 HELP THEM IN THE LONG TERM. CHAIRMAN KLEIN: OKAY. THANK YOU VERY MUCH. BOARD MEMBERS, QUESTIONS? MR. TORRES: DR. HAVTON, THANK YOU FOR JOINING US ON THIS CALL. AS A MEMBER OF THE GRANTS WORKING GROUP, I REMEMBER VERY CLEARLY THIS 	
 MUCH. BOARD MEMBERS, QUESTIONS? MR. TORRES: DR. HAVTON, THANK YOU FOR JOINING US ON THIS CALL. AS A MEMBER OF THE GRANTS 	
4 MR. TORRES: DR. HAVTON, THANK YOU FOR 5 JOINING US ON THIS CALL. AS A MEMBER OF THE GRANTS	
5 JOINING US ON THIS CALL. AS A MEMBER OF THE GRANTS	
6 WORKING GROUP I REMEMBER VERY CLEARLY THIS	
Worklind Groot, I Rehender Vert CLEARET THIS	
7 APPLICATION. AND ONE THING THAT STRUCK ME WAS PAGE	
8 1 WHERE WE FIND THAT THE EXPERIMENTAL GOALS MAY NOT	
9 BE ACHIEVABLE, AND THERE WAS CONSISTENT DISCUSSION	
10 ON THAT MATTER. COULD YOU GO OVER AS TO YOUR	
11 REBUTTAL ON THAT AGAIN FOR ME, PLEASE?	
12 DR. HAVTON: WHICH COMMENT WAS THAT?	
13 MR. TORRES: IT WAS PAGE 1.	
14 DR. HAVTON: IN WHICH DOCUMENT?	
15 MR. TORRES: REGARDING YOUR EXTRAORDINARY	
16 PETITION SUMMARY. THE LINE THAT STRUCK ME WHICH I	
17 REMEMBER FROM OUR DISCUSSION WAS THAT THE LAST	
18 COMMENT, NO. 3, HOWEVER, REVIEWERS DID NOT THINK THE	
19 PROPOSED EXPERIMENTAL GOALS WERE ACHIEVABLE. THAT	
20 WAS AN IMPORTANT ELEMENT IN OUR DISCUSSION. COULD	
21 YOU RESPOND TO THAT?	
22 DR. HAVTON: DEFINITELY. I JUST WANTED TO	
23 HAVE THE COMMENT IN FRONT OF ME. I HAVE THAT NOW.	
24 SO LET ME JUST SEE HERE. YES. THIS IS I KNOW	
25 WHAT YOU ARE REFERRING TO HERE. WHAT THE REVIEWERS	
42	

1	BROUGHT UP HERE IS THAT THEIR IMPRESSION, THAT ONE
2	MAY NEED ANATOMICALLY VERY ACCURATE AND TOPOGRAPHIC
3	OR VERY PRECISE REINNERVATION TO GET FUNCTIONAL
4	RECOVERY.
5	AND WE HAVE A DIFFERENT VIEW ON THIS. ONE
6	REASON FOR CHOOSING THE LOWER URINARY TRACT AND THE
7	BLADDER FOR REINNERVATION IS THAT IT'S A PROXIMAL
8	TARGET. NERVE CELLS NEED TO REGENERATE A MUCH
9	SHORTER DISTANCE COMPARED TO IF YOU ARE TRYING TO
10	REINNERVATE A LOWER EXTREMITY OR A HAND. AND FOR
11	THAT REASON, WE HAVE AN ADVANTAGE BECAUSE OF
12	DISTANCE THAT WE CAN REACH THE TARGET MORE QUICKLY.
13	ALSO, WHEN WE REINNERVATE A BLADDER, THE
14	FUNCTION THAT WE WANT IN THE END IS EITHER FOR THE
15	BLADDER TO CONTRACT OR TO BE QUIET. THERE ARE NO
16	INTERMEDIARY STAGES THAT REQUIRE MORE OF A
17	NEUROLOGICAL, SOPHISTICATED FINE-TUNING. IT'S YES
18	OR NO, ON OR OFF. AND WE BELIEVE THAT THAT IS MORE
19	EASILY ACHIEVED THAN A MORE DURATED FUNCTION SUCH AS
20	A FINE MOTOR TASK OR A COGNITIVE TASK OR ANYTHING
21	THAT WOULD REQUIRE MUCH MORE SOPHISTICATION.
22	SO I THINK THAT WHEN IT COMES TO THE
23	PRECISE ANATOMICAL PRECISION, THAT WE DON'T THINK
24	THAT IS AS BIG OF AN ISSUE. WE ALSO BELIEVE THAT
25	THERE IS A TREMENDOUS AMOUNT OF PLASTICITY IN THE
	12

43

1	SYSTEM. AS A NEUROLOGIST WORKING WITH PATIENTS WITH
2	NEUROLOGICAL INJURIES, WE WORK WITH THIS EVERY DAY
3	AND RETRAIN THE NERVOUS SYSTEM. AND WE THINK IF WE
4	CAN ACHIEVE A CONNECTION OF ANY TYPE, THAT THAT
5	CONNECTION IS NOT A FIXED CONNECTION. THAT'S A
6	CONNECTION THAT'S GOING TO BE TRAINABLE. AND, OF
7	COURSE, IN STEM CELL SCIENCE, THAT IS ONE OF OUR BIG
8	HOPES, THAT TRANSPLANTED STEM CELLS THAT BECOME
9	NEURONS CAN ALSO BE TRAINED.

10 AND SO IN OUR PROPOSAL WE PROVIDE THE 11 BIOLOGICAL TRANSLATIONAL ASPECT. BUT, OF COURSE, IN 12 CLINICAL PRACTICE, IN CLINICAL TRIALS IN THE FUTURE, 13 THERE WILL ALWAYS BE A COMPONENT OF TRAINING IN 14 NEUROLOGICAL REHABILITATION WITH PHYSICAL THERAPY 15 AND OTHER TASKS WHERE WE CAN HOPEFULLY ALSO TRAIN 16 EMBRYONIC STEM CELL-DERIVED NEURONS INTO DOING 17 SPECIFIC TASKS AND FINE-TUNING THE TASK. THERE ARE OTHER EXAMPLES IN MEDICINE WHERE WE TAKE ADVANTAGE 18 19 OF PLASTICITY IN REHABILITATION. SO I THINK THAT'S 20 A REASONABLE ASSUMPTION, THAT THIS IS NOT A FIXED, 21 HARDWIRED SYSTEM, BUT THERE'S A LOT OF OPPORTUNITY 22 TO WORK WITH THE SYSTEM. AND THAT WILL BE SOMETHING 23 THAT WILL BE TARGETED FOR FUTURE STUDIES, I'M SURE. 24 MR. TORRES: THANK YOU VERY MUCH. 25 CHAIRMAN KLEIN: SENATOR TORRES, THIS IS

44

 BOB KLEIN. I BELIEVE THAT, IN FACT, THERE WAS DISCUSSION IN THE PEER REVIEW THAT THE EXAMPLE FAILURES DID INVOLVE LONGER DISTANCES. AND A REVIEWER BROUGHT UP AS A STRATEGIC ADVANTAGE T THIS WAS A SHORTER DISTANCE THAT WAS CONTEMPLA AND, THEREFORE, THERE WAS A STRATEGIC ADVANTAGE 	ES OF
 FAILURES DID INVOLVE LONGER DISTANCES. AND A REVIEWER BROUGHT UP AS A STRATEGIC ADVANTAGE T THIS WAS A SHORTER DISTANCE THAT WAS CONTEMPLA AND, THEREFORE, THERE WAS A STRATEGIC ADVANTAGE 	
 4 REVIEWER BROUGHT UP AS A STRATEGIC ADVANTAGE T 5 THIS WAS A SHORTER DISTANCE THAT WAS CONTEMPLA 6 AND, THEREFORE, THERE WAS A STRATEGIC ADVANTAGE 	ГНАТ
5 THIS WAS A SHORTER DISTANCE THAT WAS CONTEMPLA 6 AND, THEREFORE, THERE WAS A STRATEGIC ADVANTAG	ГНАТ
6 AND, THEREFORE, THERE WAS A STRATEGIC ADVANTAG	
	ATED;
	GE IN
7 THIS APPROACH AT WHAT HE'S CALLING A PROXIMATE	Ξ
8 TARGET, BUT THERE WAS CERTAINLY DISAGREEMENT C	ON THIS
9 POINT	
10 MR. TORRES: RIGHT.	
11 CHAIRMAN KLEIN: IN THE DISCUSSIO	DN.
12 MR. TORRES: THANK YOU, BOB. YOU AR	۲E
13 CORRECT. AND THAT WAS THE DISCUSSION.	
14 MS. KING: DR. OLSON HAS A COMMENT.	
15 DR. OLSON: I JUST WANT TO RESPOND F	ROM
16 THE PERSPECTIVE OF THE REVIEWERS. AND THEN IF	- IT
17 WOULD BE HELPFUL TO THE BOARD, ALSO I WOULD BE	Ε ΗΑΡΡΥ
18 TO PROVIDE THE SCORE AND THE RANGE OF SCORES T	ГНАТ
19 EXPERT REVIEWERS DID GIVE TO THIS PROPOSAL.	
20 I JUST WANTED TO MAKE THE COMMENT TH	łΑT,
21 YOU KNOW, A SHORT DISTANCE IN A RAT IS NOT A S	SHORT
22 DISTANCE IN A HUMAN. SO ONE ALWAYS MUST KEEP	THAT
23 IN MIND.	
24 I ALSO JUST IN THE CONTEXT AND, A	AGAIN,
25 I'M TRYING TO HIGHLIGHT WHAT THE REVIEWERS' CO	DNCERNS
45	

1	WERE. AND I APPRECIATE THE POINT MADE BY THE
2	APPLICANT, THAT IT'S AN ON-OFF SYSTEM. I THINK THE
3	REVIEWER'S POINT WAS THAT, AS IN FACT THE APPLICANT
4	HAS JUST NOTED IN HIS EARLIER DISCUSSION WITH YOU,
5	THAT THE PRELIMINARY DATA THAT SHOWED THE STUDY IN
6	THE MOUSE OR PARDON ME IN THE RAT MODEL WITH
7	THE RAT CELLS SHOWED THAT THEY COULD LOOK AT IT. IN
8	FACT, DID NOT SHOW ANY EVIDENCE THAT THEY COULD DO
9	ANY KIND OF REINNERVATION. AND THAT'S WHAT THE
10	REVIEWERS ARE CONCERNED ABOUT.
11	I JUST WANT TO MAKE IT CLEAR THAT THE
12	REVIEWERS DO NOT DISPUTE THE IMPORTANCE OF THE FACT
13	THAT THERE ARE NO OPTIONS FOR SPINAL CORD INJURY
14	PATIENTS. THE REVIEWERS ARE JUST CONCERNED THAT,
15	GIVEN WHAT THE APPLICANT WANTS TO DO, THAT THERE IS
16	NOT ADEQUATE EVIDENCE TO SUGGEST THAT HE CAN DO IT
17	AT THIS POINT.
18	CHAIRMAN KLEIN: DR. OLSON, COULD YOU GIVE
19	US THE SCORE AND THE STANDARD DEVIATION AND THE HIGH
20	AND LOW?
21	DR. OLSON: SO THE AVERAGE SCORE ON THIS
22	APPLICATION WAS 56. THE MEDIAN SCORE WAS 53.
23	STANDARD DEVIATION WAS 11, BUT NO EXTRAORDINARY
24	NO MINORITY REPORT WAS REQUESTED TO BE FILED EVEN
25	WHEN THAT OPTION WAS MADE AVAILABLE, AND THE RANGE
	46

1	WAS 40 TO 75.
2	DR. REED: QUESTION FOR DR. OLSON IF I
3	MAY. JOHN REED HERE. THANK YOU. DR. OLSON, IS
4	IT WOULD YOU BE ABLE TO EXPRESS THE OPINION OF
5	YOURSELF AND THE STAFF IN TERMS OF WHETHER THE STAFF
6	BELIEVES THAT THE GRANT SHOULD BE FUNDED BY
7	EXCEPTION?
8	DR. OLSON: STAFF HAS NOT DOES NOT HAVE
9	AN OPINION.
10	DR. LOVE: PAT, COULD YOU GIVE US A LITTLE
11	BIT OF INSIGHT INTO WHY I HEARD ALL THE SCORES
12	THAT YOU GAVE AROUND THE MEDIANS, THE AVERAGE, AND
13	STANDARD DEVIATION. BUT THE SCORE OF 75 OBVIOUSLY
14	WASN'T A SUPER HIGH SCORE. WHY DO YOU THINK THAT
15	PERSON WAS GRAVITATING SO MUCH HIGHER THAN THE
16	PERSON SCORED AT 40?
17	DR. OLSON: I THINK YOU'RE GETTING MY
18	OPINION. I ACKNOWLEDGE WHAT YOU'RE HEARING. AND I
19	AM NO EXPERT IN SPINAL CORD INJURY AS WELL. WHAT I
20	WOULD SAY IS WHAT I THINK YOU'RE HEARING FROM THE
21	REVIEWERS, IF THE LIKELIHOOD OF ACHIEVING POSSIBLY
22	THE OBJECTIVES OF THE GRANT IS LOW, OKAY, BECAUSE
23	THEY HAVEN'T PROVIDED ADEQUATE DATA, WILL THE
24	APPLICANT TRY AND GENERATE MOTOR NEURONS? WILL THE
25	APPLICANT TRY AND GENERATE WILL THEY CONDUCT

47

1	RESEARCH THAT PERHAPS WILL LEAD TO MOTOR NEURONS OF
2	THE CELL MARKER STATUS THEY WANT? WILL THE
3	APPLICANT BE ABLE TO GENERATE AUTONOMIC NEURONS?
4	BECAUSE THAT'S SOMETHING THAT THEY'LL HAVE TO DO
5	PRESUMABLY AND GET THEM IN HIGHER THAN MAYBE A
6	COUPLE OF PERCENTAGES. THAT'S ALL I NOTE. SO
7	THEY'LL DO RESEARCH, I'M SURE, THAT IS ALONG THE
8	ΡΑΤΗ ΤΟ. ΟΚΑΥ.
9	WILL THEY COME ANYWHERES NEAR TO ACHIEVING
10	THE OBJECTIVES THEY LAID OUT IN THE APPLICATION IS
11	WHAT THE REVIEWERS ARE QUESTIONING BASED ON WHAT
12	THEY SAID. SO I THINK THAT IS MY OPINION.
13	DR. LOVE: THANK YOU, PAT.
14	MS. SAMUELSON: I CAN READ FROM THE
15	CRITIQUE BY THE REVIEWER WHO GAVE A PRELIMINARY
16	SCORE OF 80 AND, ACCORDING TO MY NOTES, WENT DOWN TO
17	70 AFTER THE COMPLETE DISCUSSION. SHALL I DO THAT?
18	DR. OLSON: I WOULD POINT OUT THAT THE
19	CRITIQUES ARE SUBMITTED BEFORE THE REVIEW. THEY DO
20	NOT NECESSARILY REFLECT THE OPINION AFTER THE
21	REVIEW, AFTER THE DISCUSSION. SO I WOULD STRONGLY
22	ENCOURAGE THAT I ACTUALLY THINK IT'S NOT APPROPRIATE
23	TO READ INDIVIDUAL REVIEWER CRITIQUES.
24	CHAIRMAN KLEIN: SO, JOAN, WITHOUT READING
25	IT, THE PERSON CAME DOWN TO 70, MAYBE YOU COULD JUST
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1	SUMMARIZE THEIR POINTS WITHOUT USING THEIR LANGUAGE.
2	WE WANT TO PROTECT ALWAYS THE INDIVIDUAL REVIEWER.
3	MS. SAMUELSON: RIGHT. SOMEHOW IT SEEMS
4	TO ME WE NEED TO COME UP WITH A PROCESS THAT SHARES
5	WITH THE BOARD THE SUM TOTAL OF VIEWS BECAUSE
6	THEY'RE NOT MONOLITHIC USUALLY IN MY EXPERIENCE OF
7	THIS PROCESS, BUT HAVING PARTICIPATED FOR A WHILE.
8	AND THERE'S A QUESTION REALLY ON THAT POINT. SO LET
9	ME DO THAT, BOB.
10	DR. PIZZO: IN ALL DUE RESPECT, BEFORE YOU
11	DO THAT, CAN I JUST OFFER A COMMENT ABOUT DOING IT,
12	AND OTHERS COULD REFLECT ON IT. I APPRECIATE ALL
13	THE THINGS YOU JUST SAID AND BOB'S REQUEST. MY
14	CONCERN IS THAT WE ARE, BY DOING THAT, ESTABLISHING
15	ANOTHER PRECEDENT, AND I WORRY ABOUT WHAT WE'RE
16	ABOUT TO EMBARK ON. IF WE START IN THESE SESSIONS
17	GETTING INTO INDIVIDUAL REVIEWS OR COMMENTS ABOUT
18	INDIVIDUAL REVIEWS, I THINK IT'S OPENING YET ANOTHER
19	DOOR THAT'S GOING TO ULTIMATELY CREATE MORE
20	CONFUSION.
21	I WOULD BEFORE YOU READ IT, JOAN, IF
22	I'M THE ONLY VOICE THAT HAS AN ANXIETY ABOUT THIS,
23	SO BE IT. BUT IF OTHERS
24	CHAIRMAN KLEIN: EXECUTIVE
25	DR. PIZZO: BOB, WOULD YOU WAIT A SECOND
	49

1 FOR ME TO FINISH? 2 CHAIRMAN KLEIN: I APOLOGIZE. I THOUGHT 3 YOU WERE FINISHED. 4 DR. PIZZO: NO, I'M NOT. IF OTHERS HAVE A 5 VIEW ABOUT BEGINNING TO REFER OR PARAPHRASE INDIVIDUAL COMMENTS FROM REVIEWERS, I THINK THEY 6 7 SHOULD BE REGISTERED. IF THERE ARE NONE, THEN I'LL 8 STAND QUIET. 9 MR. GOLDBERG: I SHARE YOUR CONCERN. 10 MR. ROTH: OBVIOUSLY I DON'T UNDERSTAND 11 THIS WHOLE PROCESS WE'RE GOING THROUGH. 12 DR. HAWGOOD: I'M VERY STRONGLY SUPPORTIVE 13 OF WHAT PHIL JUST SAID. I THINK THIS IS DANGEROUS 14 TERRITORY. MR. TORRES: I'D LIKE TO OFFER MY SUPPORT 15 16 TO PHIL'S COMMENT AS WELL. 17 DR. POMEROY: AGREED. MS. SAMUELSON: I DON'T DISAGREE WITH YOU. 18 19 WHAT CONCERNS ME IS HAVING SAT THROUGH THESE 20 DISCUSSIONS, AS WELL AS HAVING CAREFULLY READ THE 21 CRITIQUES, TO SAY THAT THE REVIEWERS FELT AND THEN 22 CONCLUDE THAT THERE WAS A SHARED VIEW OF A LACK OF 23 FEASIBILITY DOES NOT ACCURATELY REFLECT WHAT I 24 OBSERVED AND READ. 25 DR. PIZZO: I APPRECIATE THAT VERY MUCH, 50

1	AND I UNDERSTAND THE INTENT OF THE COMMENTS, AND I
2	ACCEPT THEM WITH ALL DUE RESPECT. BUT I KNOW FROM
3	PRIOR EXPERIENCE THAT THERE'S GOING TO ALWAYS BE A
4	RANGE OF REVIEWS. THAT'S WHY WE HAVE THE RANGE.
5	BUT THERE WILL BE SOME WHO HAVE A STRONG REACTION
6	EITHER POSITIVELY OR NEGATIVELY. AND SO IF WE START
7	GETTING INTO THE INDIVIDUAL REVIEWS, WE COULD
8	COUNTER BY SAYING LET'S HEAR THE MOST NEGATIVE ONE,
9	AND I THINK THAT'S GOING TO MOVE US IN A VERY MORE
10	DANGEROUS DISCUSSION ABOUT HOW WE RATE ANYTHING
11	GOING FORWARD.
12	DR. PRIETO: BOB, COULD I RESPOND TO THAT?
13	A COUPLE OF POINTS. I THINK I KNOW WHERE THIS
14	DECISION IS LIKELY TO LAND, BUT I'D LIKE TO JUST
15	ECHO SOME OF JOAN'S COMMENTS AND MAKE THE POINT AND
16	REMIND THE BOARD THAT IT IS ESSENTIAL THAT WE REMAIN
17	AS THE DECISION-MAKING BODY AND NOT THE REVIEWERS.
18	THERE ARE A NUMBER OF REASONS WHY THAT'S IMPORTANT
19	THAT I THINK BOB AND OTHERS HAVE DISCUSSED LONG
20	BEFORE TODAY.
21	BUT BEING THE DECISION-MAKING BODY MEANS
22	THAT WE CANNOT RUBBER STAMP THE ACTIONS OF THE
23	GRANTS WORKING GROUP. I THINK WE'RE ENTIRELY WITHIN
24	OUR APPROPRIATE ROLE IN DISCUSSING APPLICATIONS AND
25	DISCUSSING THE RANGE OF OPINION. I THINK THAT THOSE
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1	OF US WHO SIT ON THAT BODY AS PATIENT ADVOCATES ARE
2	ABLE TO SHARE, AND I THINK THAT'S WHAT JOAN IS DOING
3	NOW, THE FLAVOR OF THE DISCUSSION AND THE ISSUES
4	THAT WERE BROUGHT UP FOR PARTICULAR APPLICATIONS.
5	THIS HAPPENS TO BE ONE WHERE THERE WAS A
6	WIDE DISPARITY OF OPINIONS. I THINK THAT'S
7	REFLECTED IN THE VERY LARGE STANDARD DEVIATION. AND
8	THAT'S CENTERED ON IN LARGE PART A STRONG DIFFERENCE
9	OF OPINION, STRONGER THAN THERE IS FOR MOST
10	APPLICATIONS, ON WHETHER OR NOT THE GOALS OF THE
11	RESEARCHER WERE ACHIEVABLE OR NOT.
12	DR. PIZZO: SO I JUST WANT TO JUST FOR THE
13	RECORD MAKE CLEAR THAT I ABSOLUTELY AGREE WITH THE
14	LAST COMMENT AND UNDERSTAND THAT WE MUST BE AN
15	INDEPENDENT REVIEW BODY, THAT THE ICOC HAS TO
16	EXERCISE THAT ROLE. THAT SAID, I THINK IF WE START
17	GETTING INTO INDIVIDUAL REVIEWER COMMENTS, I THINK
18	IT OPENS A PATH THAT HAS LOTS OF LIABILITIES
19	ASSOCIATED WITH IT.
20	SO WITH ALL DUE RESPECT, I DO WANT US TO,
21	OF COURSE, BE INDEPENDENT. WE'VE ALL BEEN COUNSELED
22	ABOUT THAT. WE KNOW THAT THAT'S PART OF OUR
23	OBLIGATION. MY COMMENTS HAVE NOTHING TO DO WITH
24	THAT RESPONSIBILITY, BUT ONLY WITH REGARD TO HOW WE
25	PROCEED GOING FORWARD.

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1	DR. PRIETO: I AGREE WITH THAT.
2	MR. SHEEHY: COULD I MAKE A COMMENT? I
3	THINK I WANT TO SUPPORT WHAT DR. PRIETO HAS BEEN
4	SAYING. I THINK ONE OF THE THINGS THAT'S KIND OF
5	MISSING HERE IS THE BREADTH OF THE SCIENCE THAT WE
6	COVER IN A REVIEW AND THEN THE NARROWNESS. YOU HAVE
7	15 SCORES, BUT THERE ARE ONLY GOING TO BE ONE OR TWO
8	OF THOSE WHO ARE SPECIALISTS, IF EVEN ONE, THAT
9	REALLY KNOWS SPINAL CORD INJURY IN ANY REVIEW. I
10	KNOW THAT YOU GUYS AT NIH HAVE A STUDY SECTION
11	COMPOSED OF A WHOLE GROUP OF PEOPLE WHO ARE
12	SPECIALISTS IN THE PARTICULAR BRANCH OR AREA THAT
13	YOU ARE REVIEWING SO THAT WHEN YOU GET THIS SCORE,
14	IT REFLECTS A CONSENSUS OPINION AMONG EXPERTS, A
15	LARGE NUMBER OF EXPERTS.
16	WHEN YOU HAVE THREE REVIEWERS AND YOU HAVE
17	A SIGNIFICANT DEVIATION OF OPINION BETWEEN TWO OF
18	THE REVIEWERS AND THEN YOU ARE A REVIEW GROUP, WHICH
19	A LARGE NUMBER OF THEM REALLY ARE NOT SPECIALISTS IN
20	THAT FIELD, THEN A STRONG OPINION BY ONE REVIEWER
21	VERSUS A STRONG OPINION OF ANOTHER REVIEWER, I
22	THINK, HAS A LITTLE BIT MORE CONTEXT AND TEXTURE
23	THAN WHEN YOU HAVE 15 NEUROLOGISTS SITTING AROUND
24	AND TWO OF THEM DISAGREE AND THEN THAT GROUP OF
25	NEUROLOGISTS WHO HAVE GENERAL EXPERTISE IN THAT

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1	RANGE. I THINK THAT UNLESS WE'RE GOING TO WIND UP
2	HEARING EVERY REVIEW FOR EVERY GRANT, I THINK WE'RE
3	OPENING UP A VERY DANGEROUS DISCUSSION. I RESPECT
4	THE POINTS THAT ARE BEING MADE, BUT I JUST DISAGREE
5	WITH THEM.
6	AND SO I DON'T KNOW HOW TO HANDLE THIS,
7	BOB, BECAUSE YOU'RE THE PERSON WHO GAVE CONSENT TO
8	GO FORWARD, AND I'M OFFERING A COUNTER TO THAT. AND
9	I THINK BEFORE WE GO FORWARD, WE SHOULD AT LEAST BE
10	SURE THAT THAT'S THE VIEW OF THE MEMBERS OF THE
11	BOARD.
12	CHAIRMAN KLEIN: SO, DR. PRIETO I MEAN
13	DR. PIZZO, JEFF'S POINT AND DR. PRIETO'S POINT ARE
14	FUNDAMENTAL TO THE DISCUSSIONS WE'VE HAD ON 50, 60,
15	A HUNDRED GRANTS, WHICH IS THAT IN ORDER TO TALK
16	ABOUT THE CONTRASTING POSITIONS WHEN YOU HAVE SPLIT
17	OPINIONS, YOU REALLY HAVE TO PRESENT BOTH SIDES OF
18	THE ISSUE. CERTAINLY NOT WITH STATING THE LANGUAGE
19	OF ANY PARTICULAR REVIEWER, BUT ONE OF THE
20	FUNDAMENTAL REASONS FOR THE PATIENT ADVOCATES TO BE
21	ON THE PEER REVIEW IS TO BRIDGE OVER TO THE BOARD
22	AND COMMUNICATE WHAT THESE OPPOSING POSITIONS ARE.
23	SO
24	DR. PIZZO: I'M NEUTRALIZING THE
25	DISCUSSION ABOUT WHO'S BRINGING FORWARD THE CONCERN
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1	AND TRYING TO PLACE IT IN THE CONTEXT OF HOW WE GO
2	THROUGH THE PROCESS OF DOING REVIEWS AND SIMPLY
3	ARTICULATING THE POSITION THAT UNLESS WE'RE PREPARED
4	TO LOOK AT ALL THE REVIEWS AND TALK ABOUT ALL THE
5	REVIEWS FOR EVERY GRANT, I'M WORRIED THAT WHAT WE'RE
6	ABOUT TO NOW OR POTENTIALLY NOW DO OPENS UP A
7	DIFFERENT PATH FOR HOW WE'RE GOING TO FOLLOW
8	SUBSEQUENT BOTH UNIQUE POSITIONS AS WELL AS
9	INDIVIDUAL GRANT REVIEWS.

10 CHAIRMAN KLEIN: REALIZING YOUR CONCERN, 11 DR. PIZZO, AND THE OTHER CONCERNS THAT WERE STATED, I THINK IT'S IMPORTANT THAT WE HAVE THIS ISSUE GO TO 12 13 THE SCIENTIFIC COMMITTEE AND HAVE A THOUGHTFUL 14 DISCUSSION THERE. WE CAN TRY AND CREATE A FRAMEWORK 15 FOR UNDERSTANDING WHEN IT'S APPROPRIATE, WHAT THE 16 LIMITATIONS SHOULD BE, WHAT THE GUIDELINES SHOULD BE 17 THAT ARE INFORMATIVE AND IMPORTANT TO THE 18 DECISION-MAKING PROCESS, AND RETAIN THE INTEGRITY OF 19 EQUIVALENT REVIEWS FOR EQUIVALENT APPLICATIONS. 20 DR. ECONOMOU: CAN I MAKE A COMMENT? I'M

GLAD THAT SOMEONE BROUGHT UP -- I'M GLAD THAT JEFF BROUGHT UP THE MATTER OF STUDY SECTIONS. I THINK THAT THERE MIGHT BE A BIT OF A MISPERCEPTION. IN A STUDY SECTION, A STUDY SECTION HAS SCIENTISTS ALL OF WHOM ARE CAPABLE OF UNDERSTANDING THE SCIENCE AND

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1	THEN THREE OR FOUR REVIEWERS WHO ACTUALLY HAVE READ
2	THE APPLICATION FROM BEGINNING TO END AND THEN
3	PROVIDE A CRITIQUE. AND SO IN A STUDY SECTION, THE
4	PRIMARY AND SECONDARY, TERTIARY REVIEWERS WILL GO
5	OVER THEIR REVIEWS, THEN THEY CAN BE QUESTIONED BY
6	OTHER MEMBERS OF THE COMMITTEE THAT CAN UNDERSTAND
7	THE SCIENCE, AND THEN THEY TRY TO COME TO A
8	CONSENSUS VOTE.
9	THE THING THAT HAS CONCERNED ME ABOUT
10	THESE EXTRAORDINARY PETITIONS AND BY THE WAY, I
11	WANT MY COMMENTS TO BE NOT SPECIFIC TO THIS
12	APPLICATION BECAUSE I HAVE A CONFLICT HERE, BUT JUST
13	IN GENERAL TO THIS PROCESS IS THAT NO ONE ON THIS
14	COMMITTEE HAS ACTUALLY READ THIS APPLICATION.
15	CHAIRMAN KLEIN: DOCTOR, YOU KNOW, WHAT
16	I'M GOING TO NEED TO DO IS, BECAUSE WE ARE VERY
17	CAUTIOUS ON CONFLICTS, IS THAT I'M GOING TO RESERVE
18	YOUR COMMENTS TO THE SCIENTIFIC COMMITTEE BECAUSE
19	WE'VE GOT TO AVOID ANY COMMENTS THAT MAY SWAY
20	INDIVIDUALS ONE WAY OR THE OTHER RELATED TO THIS
21	APPLICATION.
22	DR. ECONOMOU: I UNDERSTAND.
23	MS. KING: FIRST OF ALL, YOUR COMMENTS MAY
24	BE APPROPRIATE TO ITEM NO. 7, WHICH WE HAVE NOT
25	GOTTEN TO YET. IT'S POSSIBLE. THEY MAY NOT BE, BUT
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1	ITEM NO. 7 IS WITH REGARD TO THE EXTRAORDINARY
2	PETITION PROCESS.
2	SECOND, ELONA BAUM HERE IN SAN FRANCISCO
4	HAS BEEN WAITING PATIENTLY TO MAKE A COMMENT, SO,
5	CHAIRMAN KLEIN, I SUGGEST WE HAVE MS. BAUM MAKE HER
6	COMMENTS.
7	DR. ECONOMOU: LET ME WITHDRAW MY COMMENT
8	AND I'LL MAKE IT AT A MORE APPROPRIATE TIME.
9	CHAIRMAN KLEIN: THANK YOU VERY MUCH.
10	WELCOME YOUR COMMENT AT A LATER TIME.
11	MS. BAUM: AND THANK YOU FOR GIVING ME AN
12	OPPORTUNITY TO REFLECT WHAT I THINK DR. TROUNSON
13	WOULD LIKE TO REFLECT ON THIS VERY TOPIC OF THE
14	PROCESS AND SCOPE OF DISCLOSURES. I THINK THAT HE
15	WOULD 100 PERCENT SUPPORT WHAT DR. PIZZO HAS JUST
16	SAID. I THINK THAT IT'S IMPERATIVE THAT WE HAVE A
17	PROCESS THAT WE STICK WITH. AND I'M SURE THAT DR.
18	TROUNSON WOULD FULLY ENDORSE EVERYTHING THAT WAS
19	ARTICULATED SO WELL BY DR. PIZZO. I DON'T NEED TO
20	REPEAT IT, BUT I JUST THOUGHT IT WAS IMPORTANT TO
21	HIGHLIGHT THAT FOR THE RECORD RIGHT NOW SINCE
22	UNFORTUNATELY DR. TROUNSON COULDN'T BE WITH US AT
23	THE MOMENT.
24	CHAIRMAN KLEIN: SO LET ME ASK THIS
25	QUESTION. JOAN, IN ORDER TO MOVE FORWARD ON THIS
	58

1	APPLICATION, COULD YOU MAKE JUST A GENERAL STATEMENT
2	OF WHAT YOU THOUGHT WAS THE GENERAL STRENGTH BROUGHT
3	UP DURING THE DISCUSSION OR DEFICIENCY. AND WE WILL
4	THEN SEE IF WE CAN MOVE FORWARD ON THIS APPLICATION.
5	YOU CAN TAKE THE OVERALL VIEW OF WHAT YOU HEARD FROM
6	DIFFERENT PEOPLE AND CONTRAST THE STRENGTH VERSUS
7	THE DEFICIENCY IF YOU'D LIKE, BUT THAT WILL HELP US
8	THROUGH THIS ITEM.
9	MS. SAMUELSON: OKAY. I'M NOT GOING TO
10	ATTEMPT TO SUMMARIZE THE FULL BREADTH OF THE
11	COMMENTS OF ALL OF THE PARTICIPANTS IN THAT REVIEW.
12	I THINK THAT'S I THINK THAT'S FRAUGHT WITH
13	DIFFICULTY, AND THAT WAS MY REASON FOR FIRST
14	SPEAKING. BUT I DO THINK THAT THE ISSUE OF THE FULL
15	BREADTH OF THE POINTS OF VIEW OF THE SCIENTIFIC
16	REVIEWERS NEEDS TO BE SOMEHOW COMMUNICATED TO THE
17	BOARD SO THAT THAT IS PART OF THEIR EDUCATION ABOUT
18	A GIVEN GRANT BEFORE MAKING A DECISION ABOUT ITS
19	FUNDABILITY
20	CHAIRMAN KLEIN: I THINK THAT'S
21	MS. SAMUELSON: OR WE LOSE OUR ABILITY
22	TO REALLY BE SUFFICIENTLY EDUCATED ABOUT IT TO MAKE
23	AN INFORMED JUDGMENT.
24	CHAIRMAN KLEIN: CONCEPTUALLY AND LEGALLY
25	I BELIEVE YOU'RE CORRECT, JOAN. IF YOU WILL IF
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1	YOU HAVE A STATEMENT TO MAKE ABOUT A POSITION HELD
2	BY SOME OF THE REVIEWERS, IN SUMMARY MAYBE YOU COULD
3	STATE WHAT THAT IS.
4	MS. SAMUELSON: OKAY. THERE WAS, IT
5	SEEMS, AND I DON'T THINK ANYBODY DISAGREES WITH
6	THIS, UNANIMOUS BELIEF THAT THERE'S A TREMENDOUS
7	NEED FOR THE THERAPIES THAT COULD COME FROM THIS
8	RESEARCH. AND WITH THAT AND THE FACT THERE WAS SOME
9	SUPPORT FOR THE EFFICACY, FEASIBILITY OF THE GRANT,
10	THAT THAT HAS BEEN DEMONSTRATED, SO WITH ADEQUATE
11	EVIDENCE OF THAT, THAT I THINK THE BOARD COULD VERY
12	COMFORTABLY CONCLUDE THAT, BECAUSE OF THE TREMENDOUS
13	NEED FOR THIS GRANT, IT'S ENTIRELY APPROPRIATE THAT
14	IT BE FUNDED. AND THAT IS ESPECIALLY TRUE BECAUSE
15	OF THE ABILITY TO IN PROGRAMMATIC REVIEW GIVE
16	SPECIAL ATTENTION TO THE NEED AS ANOTHER SORT OF
17	CRITERION. I THINK THAT'S IT.
18	CHAIRMAN KLEIN: OKAY. ARE THERE
19	ADDITIONAL BOARD COMMENTS?
20	DR. POMEROY: THOUGH THIS HAS BEEN
21	SOMEWHAT LONG, I THINK IT'S AN IMPORTANT DISCUSSION
22	FOR US TO HAVE. I WOULD LIKE TO JUST SAY THAT I
23	THINK AS A BOARD MEMBER, I'M DEPENDENT UPON THE
24	STAFF REPORTS ON THESE THINGS TO GIVE US AN
25	UNDERSTANDING OF THE FULL RANGE OF OPINIONS THAT
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WERE DISCUSSED WITHOUT IDENTIFYING INDIVIDUAL
REVIEWERS. AND I DON'T THINK IT SHOULD HAVE TO
BE I APPRECIATE JOAN DOING IT, BUT I DON'T THINK
IT SHOULD BE THE PATIENT ADVOCATES' ROLE TO DO THAT.
SO I JUST WANT TO EMPHASIZE THAT I WANT TO
BE COMFORTABLE THAT THE STAFF GIVE US THE FULL RANGE
OF THE DISCUSSION THAT TOOK PLACE SO THAT WE CAN
MAKE AN INFORMED DECISION.
CHAIRMAN KLEIN: SO THAT'S IMPORTANT AS
WELL TO DISCUSS IN THE SCIENTIFIC COMMITTEE BECAUSE
MY PERCEPTION THAT THE STAFF VIEWS THEIR FUNCTION AS
SUMMARIZING THE DOMINANT POSITION IF THERE'S NO
MINORITY REPORT FILED AND NOT GIVING YOU THE
CONTRAST, ALTHOUGH WE HAVE HEARD SOME REVIEWS FROM
THE STAFF THAT DOES VERY WELL PROVIDE US WITH THE
CONTRAST. SO I THINK THIS IS AN IMPORTANT
DISCUSSION WE NEED TO CONTINUE.
MS. KING: DR. OLSON WOULD LIKE TO MAKE A
COMMENT.
DR. OLSON: I DO JUST WANT TO COMMENT THAT
THE STAFF DOES CONSIDER IT ITS RESPONSIBILITY TO
ADEQUATELY CONVEY TO THE BOARD THE RANGE OF
DISCUSSION. I WOULD ALSO REMIND THE BOARD THAT AT
THE REVIEW WE PURPOSELY TELL THE REVIEWERS THAT THEY
CAN WEIGHT THE CRITERIA ANY WAY THEY CHOOSE, THE
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1	REVIEW CRITERIA. SO HIGH SCORES MAY IN SOME
2	REVIEWERS' MINDS JUST PUT MORE EMPHASIS ON IMPACT,
3	SO I THINK BUT THIS IS REALLY A GOAL OF STAFF, TO
4	TRY AND ADEQUATELY REFLECT TO THE BOARD WHAT THE
5	DISCUSSION IS AND WHAT IS PRESENTED AT THE MEETING.
6	CHAIRMAN KLEIN: OKAY. AND THEN ANY
7	ADDITIONAL BOARD COMMENT?
8	DR. REED: I HAVE ONE. I GUESS TO COME
9	BACK TO THE POINT PHIL WAS MAKING. I DO HAVE A LOT
10	OF CONCERNS ABOUT DELVING INTO THE INTRICACIES OF
11	SOME OF THESE REVIEWS FOR THE REASONS ALREADY
12	ARTICULATED. I THINK WHAT I WOULD PROPOSE AS AN
13	ALTERNATIVE IS THAT THE ROLE OF THIS BOARD IN
14	PARTICULAR SHOULD BE TO LOOK AT GRANTS THAT HAVE A
15	SPECIAL STRATEGIC VALUE TO THE OVERALL INITIATIVE
16	AND TO ASK OURSELVES WHETHER SOME THAT PERHAPS THE
17	STUDY SECTION DIDN'T FIND SUFFICIENTLY MERITORIOUS
18	TO MAKE THE PAYLINE SHOULD RISE TO THE LEVEL OF
19	FUNDABILITY BASED ON SPECIAL STRATEGIC MERIT OR
20	VALUE.
21	AND IF THE ARGUMENT THAT SOME WANT TO MAKE
22	FOR THIS PARTICULAR APPLICATION IS THAT THIS IS,
23	YES, IT'S HIGH RISK, IT'S CHALLENGING, TECHNICALLY
24	CHALLENGING WORK, BUT IT'S MERITORIOUS BECAUSE OF
25	THE IMPACT IT WOULD HAVE IF IT WORKED AND THAT,

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1	THEREFORE, IT DESERVES SPECIAL CONSIDERATION, I
2	THINK THAT WOULD BE A VERY SUITABLE WAY FOR THE
3	BOARD TO PROCEED AND TO DELIBERATE. BUT TO GET INTO
4	THE DETAILS OF THE LINE BY LINE OF THE CRITIQUES I
5	THINK IS NOT TERRIBLY USEFUL. SO I'D RATHER SEE IT
6	BROUGHT FORWARD BASED ON THE ARGUMENT THAT THIS IS
7	AN AREA THAT'S BEING OVERLOOKED BY OTHERS, IT'S
8	INCREDIBLY IMPORTANT CLINICALLY, AND, THEREFORE, WE
9	OUGHT TO GIVE THE GRANT A CHANCE ON THOSE GROUNDS
10	RATHER THAN QUESTIONING WHETHER THE REVIEW WAS DONE
11	AS PERFECTLY AS IT COULD HAVE BEEN.
12	CHAIRMAN KLEIN: LEGALLY, JOHN, WHILE THAT
13	COULD BE A STRUCTURE THAT WOULD WORK, WITHIN STATE
14	LAW THAT'S NOT GOING TO WORK BECAUSE THE PEER REVIEW
15	CANNOT BECOME DEFINITIVE DECISIONS EITHER ON
16	SCIENTIFIC GROUNDS OR ON STRATEGIC GROUNDS. SO WE
17	HAVE TO AND IN EXECUTIVE SESSION HAVE AN OPPORTUNITY
18	TO LOOK AT PROPRIETARY INFORMATION. AND WE HAVE IN
19	MANY CASES MADE DECISIONS THAT ARE DIFFERENT THAN
20	THE RECOMMENDATION OF THE PEER REVIEW GROUP BASED
21	UPON SCIENTIFIC DIFFERENCES, INCLUDING SOME WHERE
22	THERE WERE MISTAKES, SUCH AS THE KAREN ABOODY GRANT,
23	WHICH JUST GOT AN FDA APPROVAL FOR A PHASE AHEAD OF
24	THE PHASE THAT WE FUNDED, BUT NEVERTHELESS HAD SOME
25	OF THE SAME QUESTIONS ON.

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1	IN ANY CASE WE NEED TO DEAL WITH THIS AT A
2	SCIENTIFIC SUBCOMMITTEE BECAUSE OTHERWISE WE'RE NOT
3	GOING TO PROCEED THROUGH THIS AGENDA.
4	MS. KING: I JUST WANT TO REMIND YOU THAT
5	THERE'S NOT YET A MOTION ON THE TABLE WITH REGARD TO
6	THIS APPLICATION.
7	CHAIRMAN KLEIN: I UNDERSTAND THAT. I
8	HAVEN'T ASKED FOR A MOTION YET.
9	MR. HARRISON: TO CLARIFY, BOB, THERE WAS
10	A MOTION MADE AT THE LAST MEETING BY DR. PRIETO AND
11	JEANNIE FONTANA TO FUND THIS APPLICATION. WE LOST A
12	QUORUM, SO NO VOTE WAS TAKEN ON IT, BUT THERE IS A
13	PENDING MOTION.
14	CHAIRMAN KLEIN: SO INFORM ME, PLEASE,
15	BECAUSE I HAD TO LEAVE BEFORE THE END OF THE LAST
16	MEETING. SO THE BOARD MEETING WAS LEFT OPEN ON THIS
17	ISSUE, SO THIS IS CONSIDERED A PENDING MOTION; IS
18	THAT CORRECT?
19	MR. HARRISON: THAT'S CORRECT.
20	CHAIRMAN KLEIN: THANK YOU. SO THERE IS A
21	MOTION PENDING. IS THERE ANY ADDITIONAL BOARD
22	DISCUSSION?
23	MR. SHEEHY: I JUST I THOUGHT IT WAS
24	INTERESTING, NOTWITHSTANDING THE PROCESS QUESTION
25	THAT DR. REED RAISED, THAT HE PRETTY MUCH SUMMARIZED
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1	THE REASON WHY I THINK WE OUGHT TO APPROVE THIS
2	GRANT. I THINK WHAT JOAN WAS TRYING TO GET TO IS
3	THAT THERE IS SOME FUNDAMENTAL SCIENTIFIC MERIT
4	THERE, THAT THIS IS A HIGH RISK, HIGH REWARD GRANT
5	REALLY FROM A STRATEGIC AND PROGRAMMATIC POINT OF
6	VIEW, AN AREA THAT IS NOT BEING WELL THAT A LOT
7	OF PEOPLE AREN'T DOING WORK IN. THIS IS A SERIOUS
8	PROBLEM FOR PEOPLE, FOR PATIENTS. AND THAT I ALMOST
9	WANT TO SAY THAT DR. REED ACTUALLY OFFERED THE BEST
10	RATIONALE FOR GOING FORWARD. AND THIS IS PARTIALLY
11	WHY WE EXIST, TO KIND OF CATCH SOME OF THIS. WE
12	HAVE TO TAKE SOME RISK SOMETIMES, AND WE HAVE TO BE
13	THINKING ABOUT THE PATIENTS THAT ARE OUT THERE THAT
14	CAN BENEFIT FROM THIS.
15	IF SOME AREAS OF RESEARCH ARE
16	UNDERSTUDIED, ARE NOT WELL DEVELOPED, AND WE CAN
17	HELP MOVE THINGS ALONG, I THINK THAT'S WHY WE'RE
18	HERE. THIS IS CLEARLY AN AREA WHERE CELL THERAPY IS
19	ESSENTIAL FOR COMING UP WITH SOME SORT OF RELIEF FOR
20	THESE PATIENTS. SO I WOULD HOPE THAT WE WOULD GET
21	THIS THAT MEMBERS WILL LOOK AT THIS POSITIVELY
22	FROM A PROGRAMMATIC POINT OF VIEW NOTWITHSTANDING
23	THE VARIOUS DISCUSSIONS WE'VE HAD ABOUT SCIENCE.
24	AND I WOULD REMIND PEOPLE THAT THERE WAS A HIGH
25	STANDARD DEVIATION. THERE WERE SOME SCIENTISTS WHO

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1	DR. OLSON: THAT IS A CORRECT STATEMENT.
2	CHAIRMAN KLEIN: LET ME ASK DR. OLSON. IS
3	THERE AN ABILITY TO HAVE A MILESTONE IN THIS GRANT
4	TO ACHIEVE A PARTICULAR CRITICAL FACTOR THAT WOULD
5	DETERMINE WHETHER THE GRANT COULD SUCCESSFULLY
6	PROCEED TO ITS TARGET?
7	DR. OLSON: IF FUNDED BY THE BOARD, WE
8	WOULD WORK CLOSELY WITH THE APPLICANT TO ENSURE
9	APPROPRIATE MILESTONES.
10	CHAIRMAN KLEIN: ALL RIGHT. SO I WOULD
11	LIKE TO ACTUALLY SEE IF THE MAKERS OF THE MOTION
12	WOULD ACCEPT A FRIENDLY AMENDMENT THAT MILESTONES
13	SPECIFICALLY BE NEGOTIATED BY STAFF TO ENSURE THAT
14	FUNDS ARE ADVANCED WHEN CRITICAL POINTS ARE ACHIEVED
15	THAT ARE NECESSARY TO PROGRESS TOWARDS THE ULTIMATE
16	OBJECTIVE.
17	DR. PRIETO: AS THE MAKER OF THE MOTION, I
18	WOULD ACCEPT THAT AS A FRIENDLY AMENDMENT.
19	MS. KING: IF WE COULD ASK DR. REED
20	CHAIRMAN KLEIN: WHO WAS SECOND?
21	MS. KING: IT WAS JEANNIE FONTANA, WHO WAS
22	PRESENT FOR DR. REED. AND WE HAVE DR. REED PRESENT
23	ON THE PHONE TODAY. WE ALSO HAVE DR. FONTANA
24	JOINING US AS A SPECIAL GUEST, BUT I THINK IT'S MORE
25	APPROPRIATE TO HAVE DR. REED COMMENT IN THIS CASE
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SINCE HE'S PRESENT AND VOTING AT THE MEETING.
DR. REED: I'M A LITTLE CONFUSED. WHAT
EXACTLY DO YOU NEED ME TO COMMENT ABOUT?
CHAIRMAN KLEIN: JEANNIE FONTANA WAS ONE
OF THE CO-MAKERS OF THIS MOTION. AND I'VE ASKED IN
THE CONSIDERATION OF THE MOTION, SEPARATE FROM
WHETHER IT'S APPROVED OR DISAPPROVED, IF THE MAKER
OF THE MOTION WOULD ACCEPT AN AMENDMENT THAT THE
STAFF WILL INCORPORATE, IF IT'S APPROVED, MILESTONES
THAT ARE SET AT CRITICAL POINTS THAT ARE NECESSARY.
DR. REED: I SO ACCEPT.
CHAIRMAN KLEIN: OKAY.
DR. POMEROY: CAN STAFF CLARIFY HOW THIS
WOULD DIFFER FROM THEIR USUAL PROCESS?
DR. OLSON: IT WOULD NOT.
DR. POMEROY: THAT WAS MY UNDERSTANDING.
CHAIRMAN KLEIN: ON THE FEASIBILITY, ON
FEASIBILITY GRANTS AT A MILLION SIX, DO YOU HAVE
MULTIPLE MILESTONES GENERALLY?
DR. OLSON: WE WOULD ALSO HAVE MILESTONES
THERE DIRECTED TOWARDS THE AIMS PROPOSED BY THE
INVESTIGATOR.
CHAIRMAN KLEIN: OKAY. GENERALLY ON
FEASIBILITY GRANTS I HAVEN'T SEEN MILESTONES THAT
RIGOROUSLY UPHELD.
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1	DR. OLSON: WE'VE NEVER HAD A FEASIBILITY
2	AWARD BEFORE.
3	CHAIRMAN KLEIN: OKAY. SO I WASN'T
4	FAMILIAR WITH THE FACT THAT YOU HAD THIS LEVEL OF
5	CONTROL INTENDED FOR FEASIBILITY GRANTS.
6	DR. OLSON: I THINK THE IDEA WAS THAT
7	WE'RE LOOKING AT OUR EARLY TRANSLATIONAL AS PART OF
8	OUR PIPELINE PROGRAM, PART OF OUR APPLIED RESEARCH.
9	AND, THEREFORE, IT'S A LITTLE BIT MORE WE'RE MORE
10	CONCERNED. WE'RE MORE STRUCTURED.
11	CHAIRMAN KLEIN: GREAT. THAT'S VERY
12	WELCOME NEWS. THANK YOU VERY MUCH. IS THERE
13	ADDITIONAL BOARD COMMENT? IS THERE PUBLIC COMMENT?
14	MS. KING: THERE IS HERE IN SAN FRANCISCO.
15	WE ARE HONORED WITH THE PRESENCE OF ROMAN REED HERE
16	IN SAN FRANCISCO. HE'D LIKE TO MAKE A COMMENT.
17	MR. REED: THANK YOU VERY MUCH, MELISSA.
18	I APPRECIATE THE CHANCE. AS MOST OF YOU KNOW, THE
19	ROMAN REED SPINAL CORD INJURY RESEARCH ACT WAS
20	RECENTLY RENEWED, PASSED UNANIMOUSLY BY EVERY MEMBER
21	OF THE ASSEMBLY, THE SENATE, AND GOVERNOR
22	SCHWARZENEGGER. UNFORTUNATELY IT CAME WITH NO
23	MONEY.
24	THIS LOSS OF FUNDING WILL AFFECT PROMISING
25	SCIENCE AND SCIENTISTS LIKE DR. LEIF HAVTON. OVER
	69

1	THE LAST EIGHT YEARS, DR. HAVTON WAS FUNDED SEVEN
2	TIMES BY A CALIFORNIA AGENCY. EVERY ONE OF THOSE
3	GRANTS WAS APPROVED BY A PANEL OF SCIENTISTS FROM
4	OUT-OF-STATE IN A MANNER VERY SIMILAR TO THAT WHICH
5	YOU HAVE EMPLOYED HERE.
6	OUR GRANT'S RELATIVELY SMALL COMPARED TO
7	THE CIRM, BUT IT ADDED UP TO OVER HALF A MILLION
8	DOLLARS FOR ACCOMPLISHED AND SUCCESSFUL SCIENTISTS.
9	NOW THE FUNDING IS GONE, THIS IMPORTANT AREA OF
10	PROGRESS HAS BEEN CUT OFF. AND NOW WITH DR. HAVTON,
11	THE CIRM PROPOSAL INVOLVING EMBRYONIC STEM CELLS
12	COULD VERY WELL BE HELPFUL TO OUR OVERALL CAUSE IN
13	TURNING STEM CELLS INTO CURES, IF HIS RESEARCH IS
14	ALLOWED TO GO FORWARD, WITH VITAL FUNDING THE
15	CRUCIAL RESEARCH ENABLING GRANTS THAT CAN BE GIVEN
16	BY CIRM. BUT WHAT IS MOST IMPORTANT TO ME AND ALL
17	MY FRIENDS SITTING IN WHEELCHAIRS FOR TOO LONG IS
18	THIS NEW PROJECT ATTACKS CHRONIC SPINAL CORD INJURY.
19	THE MAJORITY OF SPINAL CORD INJURY
20	EXPERIMENTS INVOLVE THE NEW ACUTE STAGE ONLY TWO
21	WEEKS AFTER SPINAL CORD INJURY. THAT LEAVES OUT
22	NEARLY EVERYBODY, INCLUDING MYSELF SITTING HERE IN A
23	WHEELCHAIR TODAY. LOOK, WE ALL KNOW THAT SCIENCE IS
24	THE WAY TO CURES, BUT IT IS NOT THE REASON FOR
25	CURES. THE REASON FOR CURES IS TO HELP THE

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1	SUFFERING, TO HELP THE CHRONICALLY INJURED.
2	MY FATHER AND I ARE HERE TODAY TO GET ME
3	OUT OF THIS WHEELCHAIR AND STAND UP AND WALK AWAY
4	FROM WHEELCHAIRS FOREVER, AS CHRISTOPHER REEVE ONCE
5	TOLD ME, TO BEAT BACK CHRONIC SPINAL CORD INJURY
6	PARALYSIS. SO PLEASE THIS IS A VITAL NECESSITY FOR
7	HELPING OUR CHRONICALLY INJURED. THE URGENCY AND
8	THE NEED FOR BOWEL AND BLADDER TREATMENTS AND NEW
9	THERAPIES THAT WILL COME FROM HIS EXPERIMENT, IT
10	WILL BE APPLICABLE TO ALL OF SPINAL CORD RELATED
11	CONDITIONS. I URGE YOU TO APPROVE, TAKE A STAND FOR
12	THE CHRONICALLY INJURED. THANK YOU.
13	CHAIRMAN KLEIN: IS THERE ADDITIONAL
14	PUBLIC COMMENT?
15	MS. KING: WE HAVE ONE MORE HERE IN SAN
16	FRANCISCO.
17	MR. REED: THIS IS DON REED. I THINK THAT
18	THIS IS FIRST OF ALL, I'VE SEEN DR. HAVTON IN
19	ACTION FOR MANY YEARS, SINCE 2001, I BELIEVE. AND
20	HE ALWAYS SETS A TARGET AND SINGLEMINDEDLY GOES
21	FORWARD AND WORKS AND ACHIEVES IT. I THINK IF HE
22	SAYS THIS CAN BE DONE, PERSONALLY I BELIEVE HIM.
23	SINCE MY SON'S INJURY, DOCTORS HAVE TOLD
24	US THERE WAS NO HOPE. NOW THERE'S A POSSIBILITY OF
25	SOME HOPE. EVEN IF THIS IS ONLY A PIECE OF THE
	71

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1	PUZZLE, IT ADVANCES THE CAUSE OF CURES, AND I URGE
2	YOUR ACCEPTANCE. THANK YOU.
3	CHAIRMAN KLEIN: OKAY. IS THERE
4	ADDITIONAL PUBLIC COMMENT AT THE OTHER SITES?
5	HEARING NONE, MELISSA, COULD YOU CALL THE ROLL
6	UNLESS MR. HARRISON HAS A POINT TO MAKE.
7	MR. HARRISON: WE'RE READY FOR THE ROLL
8	CALL.
9	MS. KING: JUST BEFORE I DO THAT, VERY
10	QUICKLY I WANT TO CHECK AND SEE. HAS DR. DAVID
11	BRENNER JOINED THE CALL?
12	DR. BRENNER: YES, I HAVE.
13	MS. KING: HAS JON SHESTACK JOINED THE
14	CALL? OKAY. JUST AS A REMINDER, THERE ARE A NUMBER
15	OF MEMBERS WHO ARE IN CONFLICT ON THIS GRANT. YOU
16	HAVE YOUR LIST IN FRONT OF YOU TO TELL YOU WHETHER
17	OR NOT YOU ARE ONE OF THOSE INDIVIDUALS. AND I WILL
18	NOT CALL YOUR NAME IF YOU ARE IN CONFLICT. SO I'M
19	NOT FORGETTING YOU. I'M JUST NOT CALLING YOU ON
20	PURPOSE SINCE YOU'RE IN CONFLICT.
21	ROBERT PRICE.
22	DR. PRICE: YES.
23	MS. KING: DAVID BRENNER.
24	DR. BRENNER: NO.
25	MS. KING: LEEZA GIBBONS.
	72

1	MS. GIBBONS: YES.
2	MS. KING: MICHAEL GOLDBERG.
3	MR. GOLDBERG: NO.
4	MS. KING: SAM HAWGOOD.
5	DR. HAWGOOD: NO.
6	MS. KING: BOB KLEIN.
7	CHAIRMAN KLEIN: YES.
8	MS. KING: TED LOVE.
9	DR. LOVE: YES.
10	MS. KING: PHIL PIZZO.
11	DR. PIZZO: NO.
12	MS. KING: CLAIRE POMEROY.
13	DR. POMEROY: YES.
14	MS. KING: FRANCISCO PRIETO.
15	DR. PRIETO: AYE.
16	MS. KING: ELIZABETH FINI.
17	DR. FINI: NO.
18	MS. KING: ROBERT QUINT.
19	DR. QUINT: YES.
20	MS. KING: JOHN REED.
21	DR. REED: YES.
22	MS. KING: DUANE ROTH.
23	MR. ROTH: NO.
24	MS. KING: JOAN SAMUELSON.
25	MS. SAMUELSON: YES.
	73

1	MS. KING: DAVID SERRANO-SEWELL.
2	MR. SERRANO-SEWELL: YES.
3	MS. KING: JEFF SHEEHY.
4	MR. SHEEHY: YES.
5	MS. KING: ART TORRES.
6	MR. TORRES: AYE.
7	MS. KING: AND I AM GOING TO DEFER TO
8	COUNSEL, JAMES HARRISON AND SCOTT TOCHER, FOR THE
9	VOTE TALLY. IF YOU COULD GIVE THEM JUST A MOMENT,
10	TALK AMONGST YOURSELVES.
11	CHAIRMAN KLEIN: LET IT NEVER BE SAID THAT
12	THIS GROUP RUBBER STAMPS ANYTHING.
13	DR. REED: CAN I MAKE A COMMENT WHILE
14	WE'RE WAITING FOR THE TALLY? I THINK IT WOULD BE
15	VERY USEFUL, GIVEN THE BOARD'S TENDENCY TO GET
16	INVOLVED IN THIS PROCESS, TO COMPARE OVER TIME SOME
17	MEASURES OF SUCCESS OF THE GRANTS THAT COME FORWARD
18	IN THE USUAL MANNER, MAKING THE PAYLINE, VERSUS
19	THOSE THAT WE AS A BOARD DECIDE TO FUND BY
20	EXCEPTION. IT WOULD BE VERY INTERESTING TO HAVE
21	DATA ON THAT A COUPLE YEARS FROM NOW AND KNOW
22	WHETHER OUR DECISIONS WERE WISE OR NOT.
23	CHAIRMAN KLEIN: I THINK THAT WOULD BE
24	VERY HELPFUL. AND I'M GOING TO REFER THAT TO THE
25	SCIENTIFIC STAFF AND ASK THEM COME UP WITH A
	_ <i>_</i>
	74

1	TIMETABLE WHEN THEY THINK IT WOULD BE APPROPRIATE TO
2	DO IT AND THEY HAVE A LARGE ENOUGH DISTRIBUTION AND
3	ENOUGH TIME TO FOLLOW THESE GRANTS TO STATISTICALLY
4	GIVE US FEEDBACK, BUT I THINK IT WOULD BE VERY
5	VALUABLE.
6	MS. KING: DR. OLSON HAS A COMMENT AS
7	WELL.
8	DR. OLSON: DR. REED, I WANT TO THANK YOU
9	FOR MAKING THAT SUGGESTION. I WAS THINKING THE SAME
10	THING DURING THE DISCUSSION, SPEAKING TO BOTH YOURS
11	AND CHAIRMAN KLEIN'S COMMENT. I WOULD NOTE THAT AS
12	I THINK, YOU KNOW, THE DATASET PROBABLY A FEW YEARS
13	DOWN THE ROAD WOULD BE A LOT MORE USEFUL THAN NOW
14	BECAUSE THERE ARE SO FEW AWARDS THAT WE HAVE CLOSED
15	OUT AT THIS POINT.
16	MR. HARRISON: THAT MOTION PASSES WITH 12
17	YES VOTES AND SIX NO VOTES.
18	CHAIRMAN KLEIN: THANK YOU VERY MUCH. WE
19	ARE GOING TO MOVE TO THE NEXT ITEM.
20	MS. KING: DR. HAVTON, THANK YOU VERY MUCH
21	FOR JOINING US. AS YOU JUST HEARD, YOUR APPLICATION
22	HAS BEEN APPROVED FOR FUNDING. I'M SURE STAFF WILL
23	BE IN TOUCH WITH YOU. AND I JUST WANTED TO THANK
24	YOU AND LET YOU KNOW THAT YOU ARE WELCOME TO STAY,
25	BUT YOU CAN ALSO GO AT THIS POINT.

75

1	DR. HAVTON: THANK YOU VERY MUCH. I WOULD
2	LIKE TO THANK THE BOARD FOR ALL THE INPUT AND FOR
3	YOUR SUPPORT. THANK YOU VERY MUCH.
4	CHAIRMAN KLEIN: THANK YOU. SO COULD WE
5	GO TO THE NEXT ITEM ON THE AGENDA, WHICH I BELIEVE
6	IS APPLICATION 1857.
7	MS. KING: CORRECT. AND IT'S ITEM NO. 5.
8	AND THE BOARD SHOULD HAVE TWO DOCUMENTS FOR THIS.
9	ONE IS A MEMO FROM DR. GILL SAMBRANO. IT'S ABOUT A
10	THREE-QUARTER PAGE MEMO. AND THE OTHER IS THE
11	PUBLIC SUMMARY FOR THE GRANT. AND SORRY I'M
12	CORRECTING MYSELF HERE. THERE'S ALSO A TRANSCRIPT
13	EXCERPT THAT WE SENT YOU FROM THE OCTOBER MEETING AS
14	WELL. BUT I WOULD SAY YOU DEFINITELY WANT TO HAVE
15	THE MEMO FROM STAFF IN FRONT OF YOU BECAUSE THAT IS
16	THE CRUX OF THE MATTER FOR THIS.
17	DR. PIZZO: MELISSA, JUST A PRACTICAL
18	QUESTION. DO WE HAVE, ASIDE FROM THIS, OTHER AREAS
19	WHERE VOTES ARE NEEDED?
20	MS. KING: WE DO. WE NEED TO VOTE ON THIS
21	ITEM AND ITEM NO. 6 AND THEN ALSO ITEM NO. 7.
22	DR. PIZZO: DO WE HAVE A QUORUM BECAUSE
23	I'M GOING TO BE IN A CONFLICT VERY SOON?
24	DR. PRIETO: I WILL ALSO HAVE TO LEAVE AT
25	ABOUT ONE O'CLOCK.
	76

76

1	MS. KING: WE HAVE ABOUT 15 MINUTES THEN
2	TO TRY AND GET THROUGH THE REMAINING ITEMS, I
3	BELIEVE. I BELIEVE BY LOSING BOTH OF YOU, UNLESS
4	I'M MISSING SOMETHING, WE WILL BE BELOW A QUORUM.
5	DR. PIZZO: I CAN STAY FOR JUST THAT
6	AMOUNT OF TIME UNFORTUNATELY UNLESS I CAN PICK UP A
7	CELL PHONE. I GUESS I CAN'T DO THAT.
8	MS. KING: NO. I'M SORRY THAT YOU HAVE TO
9	PARTICIPATE FROM A NOTICED LOCATION.
10	DR. PIZZO: THAT'S WHERE I'M AT NOW.
11	CHAIRMAN KLEIN: LET'S DO THIS, DR. PIZZO,
12	WITH YOUR COMMENT IN MIND AND DR. PRIETO'S COMMENT
13	IN MIND, WE HAVE A STAFF RECOMMENDATION ON THIS
14	ITEM, WHICH IS CERTAINLY A BENEFIT. COULD DR. OLSON
15	AND DR. SAMBRANO IS DR. SAMBRANO GOING TO MAKE
16	THE PRESENTATION?
17	MS. KING: DR. SAMBRANO IS NOT HERE, SO
18	DR. OLSON IS SIGNALING THAT SHE WILL MAKE THE
19	PRESENTATION.
20	CHAIRMAN KLEIN: THANK YOU. AND EVERYONE,
21	THIS IS A PUBLIC MEMO THAT'S AVAILABLE DATED
22	NOVEMBER 2D AS THE STAFF RECOMMENDATION.
23	MS. KING: CORRECT. IT'S POSTED ON OUR
24	WEB SITE.
25	CHAIRMAN KLEIN: DR. OLSON.
	77
	11

1	DR. OLSON: OKAY. SO I'M TALKING NOW
2	ABOUT AGENDA ITEM NO. 5. AND I WANT JUST TO REMIND
3	THE BOARD THAT THEY ESSENTIALLY APPROVED THIS
4	APPLICATION FOR FUNDING BASED ON THE GRANTS WORKING
5	GROUP RECOMMENDATION. AND WHAT THAT ENTAILED WAS
6	ELIMINATING CERTAIN ACTIVITIES. AND THE RELEVANT
7	ONE THAT WE WANT TO TALK TO YOU ABOUT IS CHANGING IT
8	FROM A DEVELOPMENT CANDIDATE AWARD TO A DEVELOPMENT
9	CANDIDATE FEASIBILITY AWARD.
10	WHAT WE WOULD LIKE TO REQUEST THE BOARD TO
11	DO IS GIVE STAFF THE FLEXIBILITY TO DETERMINE WHICH
12	IT IS BECAUSE THE DEVELOPMENT CANDIDATE AWARD
13	ALLOWED A CO-PI, AND THIS APPLICATION HAS A CO-PI,
14	MANY OF THE REMAINING ACTIVITIES WILL BE CONDUCTED
15	BY THE CO-PI. AND, THEREFORE, WE WANT THE
16	FLEXIBILITY TO ENSURE THAT THE PROJECT CAN BE RUN IN
17	THE BEST WAY POSSIBLE OBVIOUSLY WITH NOT THE FULL
18	FUNDING CONTEMPLATED BY THE DEVELOPMENT CANDIDATE
19	AWARD, BUT POSSIBLY FUNDING THAT ACTUALLY COULD GET
20	THE JOB DONE AND COULD ADDRESS, PERHAPS EVEN GET US
21	TO A DEVELOPMENT CANDIDATE BECAUSE MANY OF THE
22	ACTIVITIES THAT THE GRANTS WORKING GROUP RECOMMENDED
23	NOT BE INCLUDED WERE ONES THAT WOULD ACTUALLY
24	INCLUDE AFTER DEVELOPMENT CANDIDATE NOMINATION.
25	SO STAFF WOULD LIKE TO RECOMMEND WE HAVE
	78
	10

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1	THE FLEXIBILITY TO STILL CALL IT A DEVELOPMENT
2	CANDIDATE AWARD, BUT AGREE WITH YOUR APPROVAL AS THE
3	RECOMMENDATIONS OF THE BOARD OF THE GRANTS WORKING
4	GROUP AS TO THE ACTIVITIES THAT WOULD BE CUT OUT
5	YOU'VE ALREADY AGREED TO.
6	MS. KING: CHAIRMAN KLEIN, AS WE MOVE
7	SWIFTLY THROUGH THIS, I'D LIKE TO ASK JAMES HARRISON
8	TO READ THE MOTION THAT WOULD BE REQUIRED HERE GIVEN
9	THAT IT IS TWOFOLD AND RATHER COMPLICATED.
10	MR. HARRISON: BECAUSE THE BOARD
11	PREVIOUSLY ADOPTED A MOTION ON THE SUBJECT, THE
12	REQUIRED MOTION WILL HAVE TO AMEND THE PREVIOUS
13	MOTION. SO IF A MEMBER WOULD LIKE TO MAKE A MOTION,
14	I WOULD PROPOSE THE FOLLOWING: THAT THE MEMBER MOVE
15	TO AMEND THE BOARD'S MOTION ADOPTED AT THE BOARD'S
16	OCTOBER 21, 2010, MEETING REGARDING EARLY
17	TRANSLATION II APPLICATION 1857, TO APPROVE FUNDING
18	AT THE REQUESTED AMOUNT OF \$5,199,767 WITH THE
19	CONDITION THAT THE PRECLINICAL MODEL GMP CELL BANK
20	AND RELATED ACTIVITIES BE REMOVED, THAT THE BUDGET
21	BE ADJUSTED DOWNWARD TO REFLECT THESE CHANGES, AND
22	THE DESIGNATION OF DC OR DCF BE DELEGATED TO CIRM
23	STAFF.
24	MS. KING: THAT'S THE MOTION REQUIRED. WE
25	STILL NEED SOMEONE TO MAKE IT AND SOMEONE TO SECOND
	79

1	IT.
2	DR. PIZZO: I PROPOSE THAT MOTION.
3	CHAIRMAN KLEIN: DR. PIZZO IS MAKING THE
4	MOTION. IS THERE A SECOND?
5	DR. LOVE: SECOND.
6	CHAIRMAN KLEIN: OKAY. MOTION HAS BEEN
7	MADE AND SECONDED. IS THERE BOARD COMMENT? IS
8	THERE PUBLIC COMMENT?
9	DR. POMEROY: YES, THERE IS IN SACRAMENTO.
10	DR. MEYERS: THIS IS FRED MEYERS. I'M THE
11	EXECUTIVE ASSOCIATE DEAN AT THE UC DAVIS SCHOOL OF
12	MEDICINE. I'M NEEDING A LOT MORE DETAIL BEFORE I
13	COULD NOT OBJECT TO WHY THIS APPROVED PROPOSAL WOULD
14	BE SO SIGNIFICANTLY REDUCED. I DON'T UNDERSTAND WHY
15	PARTICULARLY THE ELEGANT GMP WORK WOULD BE DELETED
16	FROM AN ALREADY APPROVED GRANT.
17	MS. KING: BOB, I HAVE IAN SWEEDLER HERE
18	IN SAN FRANCISCO THAT WOULD LIKE TO MAKE A COMMENT
19	IN RESPONSE.
20	MR. SWEEDLER: THIS IS JUST A REMINDER OF
21	PROCESS. WHAT THE BOARD DID AT ITS LAST MEETING IS
22	MAKE ALL OF THOSE REDUCTIONS. IT'S BEEN REDUCED TO
23	A HALF-SIZE AWARD. SO THE STAFF REQUEST IS TO RAISE
24	THE AMOUNT OF THE AWARD.
25	THE REASONS FOR THE GRANTS WORKING GROUP'S
	80

1	RECOMMENDATION TO REMOVE CERTAIN ACTIVITIES WERE
2	PRESENTED AT THE LAST BOARD MEETING, AND THAT WAS IN
3	THE SUMMARY THAT I'M SURE DR. OLSON COULD ADDRESS
4	THAT. BUT THE MOTION RIGHT NOW IS TO INCREASE THE
5	SIZE OF THE AWARD.
6	DR. OLSON: IT'S TO GIVE STAFF THE
7	FLEXIBILITY TO INCREASE THE SIZE OF THE AWARD IN
8	DISCUSSION WITH THE PI, RESPECTING THE
9	RECOMMENDATIONS AND THE DECISION BY THE BOARD AT THE
10	OCTOBER MEETING.
11	CHAIRMAN KLEIN: SO SPECIFICALLY, DR.
12	OLSON, IT'S TO APPROVE THE WHOLE FIVE MILLION ONE
13	NINETY-NINE AND LET THE BOARD WORK OUT WITH THE
14	SCIENTIST WHAT SORT OF VALUE WILL BE DERIVED. THE
15	STAFF TO WORK OUT WITH THE SCIENTISTS WHERE THE
16	VALUE WILL BE DERIVED.
17	DR. OLSON: WELL, ACCEPTING THE
18	RECOMMENDATIONS OF THE GRANTS WORKING GROUP THAT
19	WERE PREVIOUSLY APPROVED BY THE BOARD. SO SOME
20	ACTIVITIES WILL BE LIMITED.
21	CHAIRMAN KLEIN: EXACTLY. BUT WITHIN THE
22	REMAINING ACTIVITIES, ALLOWING THE SCIENTIFIC STAFF
23	TO WORK OUT THE BUDGET WITH THE APPLICANT.
24	DR. OLSON: RIGHT. BECAUSE THE APPLICANT
25	ORGANIZATION WOULD HAVE BEEN LIMITED UNDER A DCF
	81
	01

1	AWARD TO 1.15 MILLION IN DIRECT PROJECT COSTS, AND
2	WE WANT A LITTLE BIT MORE FLEXIBILITY THAN THAT.
3	DR. MEYERS: THANK YOU SO MUCH. I DIDN'T
4	REALLY UNDERSTAND INITIALLY, AND YOU'VE REALLY DONE
5	A GREAT JOB OF CLARIFYING FOR ME. IF I CAN
6	PARTICIPATE IN THAT WITH THE PI AND HELP YOU WITH
7	THAT PROCESS, I'M HAPPY TO DO SO.
8	CHAIRMAN KLEIN: THANK YOU VERY MUCH.
9	APPRECIATE YOUR COMMENTS. ADDITIONAL PUBLIC
10	COMMENT?
11	MR. HARRISON, I THINK WE UNDERSTAND THE
12	MOTION. IS IT APPROPRIATE TO CALL THE ROLL?
13	MR. HARRISON: YES, IT IS.
14	CHAIRMAN KLEIN: MELISSA.
15	MS. KING: AGAIN, FOR THE BOARD MEMBERS,
16	YOU HAVE A SHEET IN FRONT OF YOU LETTING YOU KNOW
17	WHETHER OR NOT YOU HAVE A CONFLICT. I WILL NOT CALL
18	THOSE OF YOU IN CONFLICT. IF I MISS ANYONE
19	OTHERWISE, PLEASE DO SAY LET ME KNOW, BUT I WILL
20	NOT CALL YOU IF YOU HAVE A CONFLICT.
21	ROBERT PRICE.
22	DR. PRICE: YES.
23	MS. KING: DAVID BRENNER.
24	DR. BRENNER: YES.
25	MS. KING: SUSAN BRYANT.
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1	DR. BRYANT: YES.
2	MS. KING: LEEZA GIBBONS.
3	MS. GIBBONS: YES.
4	MS. KING: MICHAEL GOLDBERG.
5	MR. GOLDBERG: YES.
6	MS. KING: BOB KLEIN.
7	CHAIRMAN KLEIN: YES.
8	MS. KING: TED LOVE.
9	DR. LOVE: YES.
10	MS. KING: SHLOMO MELMED.
11	DR. MELMED: YOU SAID I HAVE A CONFLICT ON
12	THIS.
13	MS. KING: NO. YOU HAD A CONFLICT ON THE
14	PREVIOUS ONE, DR. MELMED. I'M SORRY. WE'RE ON
15	AGENDA ITEM NO. 5.
16	DR. MELMED: I KNOW WHAT YOU'RE ON, BUT
17	YOU E-MAILED ME AND SAID I HAVE A CONFLICT ON THIS.
18	CHAIRMAN KLEIN: HE COULD ABSTAIN IF
19	THERE'S A QUESTION.
20	MS. KING: THERE'S NO QUESTION. WE
21	APOLOGIZE. HE IS NOT ON THE LIST OF PEOPLE WITH
22	CONFLICTS. THERE WAS A MISCOMMUNICATION AMONG THE
23	STAFF, AND THE E-MAIL REFLECTED THAT HE DOES, BUT IN
24	FACT HE DOES NOT. SORRY, DR. MELMED.
25	DR. MELMED: THEN I VOTE YES.
	83

1	MS. KING: PHIL PIZZO.
2	DR. PIZZO: YES.
3	MS. KING: ELIZABETH FINI.
4	DR. FINI: YES.
5	MS. KING: ROBERT QUINT.
6	DR. QUINT: YES.
7	MS. KING: JOHN REED. DUANE ROTH.
8	MR. ROTH: YES.
9	MS. KING: JOAN SAMUELSON.
10	MS. SAMUELSON: YES.
11	MS. KING: DAVID SERRANO-SEWELL.
12	MR. SERRANO-SEWELL: YES.
13	MS. KING: ART TORRES.
14	MR. TORRES: AYE.
15	MS. KING: JAMES ECONOMOU.
16	DR. ECONOMOU: YES.
17	MS. KING: AND I'M GOING TO CIRCLE BACK
18	WITH LEEZA GIBBONS.
19	MS. GIBBONS: YES.
20	MS. KING: AGAIN, I AM DEFERRING TO
21	COUNSEL.
22	JUST TO CHECK, JOHN REED, ARE YOU PRESENT
23	AND DO YOU HAVE A VOTE ON THIS?
24	DR. REED: YES.
25	MS. KING: IS YOUR VOTE YES?
	84

1	DR. REED: YES.
2	MS. KING: THANK YOU.
3	MR. HARRISON: THAT MOTION CARRIES WITH 17
4	VOTES.
5	CHAIRMAN KLEIN: THANK YOU VERY MUCH. THE
6	NEXT ITEM IS ONLY TO CORRECT A CLERICAL ERROR THAT
7	WAS MADE IN THE APPLICATION. AND THE STAFF IS
8	RECOMMENDING THAT THIS AWARD BE INCREASED BY 73,484.
9	IS THERE A MOTION TO PUT THAT INTO DISCUSSION?
10	MR. TORRES: SO MOVED.
11	DR. PIZZO: SECOND.
12	CHAIRMAN KLEIN: PIZZO THE SECOND. BOARD
13	DISCUSSION? PUBLIC DISCUSSION? MR. HARRISON, ARE
14	WE IN A POSITION WE CAN CALL THE ROLL?
15	MR. HARRISON: YES, IF I COULD JUST
16	CLARIFY THE MOTION BECAUSE, AGAIN, THIS IS A
17	CIRCUMSTANCE WHERE THE BOARD IS AMENDING A
18	PREVIOUSLY ADOPTED MOTION. AS I UNDERSTAND IT, THE
19	MOTION IS TO AMEND THE MOTION ADOPTED AT THE BOARD'S
20	APRIL 29, 2010, MEETING REGARDING BASIC BIOLOGY
21	APPLICATION 1496 TO INCREASE THE AWARD BY \$73,484 TO
22	A TOTAL OF \$1,284,921 TO CORRECT A CLERICAL ERROR
23	EXCUSE ME TO INCREASE THE AMOUNT TO A TOTAL OF
24	\$1,358,405.
25	CHAIRMAN KLEIN: THANK YOU VERY MUCH, MR.
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1	HARRISON. WE ARE IN A POSITION TO CALL THE ROLL.
2	MS. KING: OKAY. ROBERT PRICE.
3	DR. PRICE: YES.
4	MS. KING: DAVID BRENNER.
5	DR. BRENNER: YES.
6	MS. KING: LEEZA GIBBONS.
7	MS. GIBBONS: YES.
8	MS. KING: MICHAEL GOLDBERG.
9	MR. GOLDBERG: YES.
10	MS. KING: SAM HAWGOOD.
11	DR. HAWGOOD: YES.
12	MS. KING: BOB KLEIN.
13	CHAIRMAN KLEIN: YES.
14	MS. KING: TED LOVE.
15	DR. LOVE: YES.
16	MS. KING: SHLOMO MELMED.
17	DR. MELMED: YES.
18	MS. KING: PHIL PIZZO.
19	DR. PIZZO: YES.
20	MS. KING: CLAIRE POMEROY.
21	DR. POMEROY: YES.
22	MS. KING: FRANCISCO PRIETO.
23	DR. PRIETO: YES.
24	MS. KING: ELIZABETH FINI.
25	DR. FINI: YES.
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1	MS. KING: ROBERT QUINT.
2	DR. QUINT: YES.
3	MS. KING: JOHN REED.
4	DR. REED: YES.
5	MS. KING: DUANE ROTH.
6	MR. ROTH: YES.
7	MS. KING: JOAN SAMUELSON.
8	MS. SAMUELSON: YES.
9	MS. KING: DAVID SERRANO-SEWELL.
10	MR. SERRANO-SEWELL: YES.
11	MS. KING: JEFF SHEEHY.
12	MR. SHEEHY: YES.
13	MS. KING: ART TORRES.
14	MR. TORRES: AYE.
15	MS. KING: JAMES ECONOMOU.
16	DR. ECONOMOU: YES.
17	MS. KING: I'M PRETTY SECURE IN SAYING
18	THAT MOTION CARRIES.
19	CHAIRMAN KLEIN: THE NEXT ITEM, BECAUSE WE
20	ONLY HAVE A COUPLE MINUTES, IS ITEM NO. 7. AND I
21	WILL DIRECT THE MEMBERS TO THEIR MATERIALS.
22	SPECIFICALLY TWO POINTS. ONE, THAT THIS IS A BOARD
23	OPTION TO REQUEST ADDITIONAL ANALYSIS AS REFLECTED
24	IN MATERIALS. THIS IS A PROPOSAL TO PERMIT THE
25	BOARD TO REQUEST WHEN AN APPLICATION BE REFERRED FOR
	07
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1	ADDITIONAL ANALYSIS UNDER LIMITED CIRCUMSTANCES.
2	ON SEPTEMBER 29TH, A DRAFT OF THIS
3	PROPOSAL PASSED THE SCIENTIFIC SUBCOMMITTEE BY A
4	VOTE OF NINE TO ZERO AND IT RECOMMENDED TO THE BOARD
5	FOR A TRIAL PERIOD OF 18 MONTHS. UPON EXPIRATION OF
6	THE TIME, THE POLICY WILL BE SUBJECT TO
7	RECONSIDERATION BY THE BOARD.
8	TO PUT IT INTO DISCUSSION, IS THERE A
9	MOTION THAT WE ADOPT?
10	DR. PIZZO: SO MOVED.
11	CHAIRMAN KLEIN: IS THERE A SECOND?
12	MR. TORRES: SECOND.
13	CHAIRMAN KLEIN: WE HAVE DISCUSSED THIS
14	MOTION BEFORE, BUT CERTAINLY IS THERE ANY BOARD
15	MEMBER WHO WOULD LIKE TO DISCUSS IT AGAIN?
16	MS. KING: I BELIEVE IT WAS DR. ECONOMOU
17	THAT HAD SOME COMMENTS THAT WERE RELATED TO THE
18	EXTRAORDINARY PETITION PROCESS.
19	CHAIRMAN KLEIN: WELL
20	MS. KING: MAYBE NOT RELATED TO THIS, SO
21	MAYBE WE WANT TO MOVE THROUGH THIS MORE QUICKLY.
22	CHAIRMAN KLEIN: WE'RE GOING TO BRING UP
23	DR. ECONOMOU'S COMMENT AFTER WE DON'T NEED A QUORUM.
24	MS. BAUM: BOB, I HATE TO DO THIS BECAUSE
25	I KNOW THAT THE TIME IS SHORT. I JUST WANT TO NOTE
	88

1	THAT THE 18-MONTH PROVISION MIGHT ACTUALLY UNDULY
2	RESTRICT ALL OF OUR OPERATIONS IN THE EVENT THAT
3	SOONER THAN THAT WE FIND THAT THE PROCESS IS
4	BURDENSOME OR NOT WORKING.
5	CHAIRMAN KLEIN: SO, ELONA, IF IT'S NOT
6	WORKING, IT CAN ALWAYS BE BROUGHT TO THE BOARD FOR
7	RECONSIDERATION. IF IT'S NOT WORKING IN SIX MONTHS,
8	WE CAN BRING IT UP AT THE BOARD.
9	MS. BAUM: OKAY. WITH THAT ON THE RECORD,
10	I THINK THAT'S VERY HELPFUL.
11	CHAIRMAN KLEIN: IS THERE ANY PUBLIC
12	COMMENT ON THIS? MR. HARRISON, ARE WE IN A POSITION
13	TO CALL THE ROLL?
14	MR. HARRISON: I BELIEVE WE ARE.
15	MS. KING: ROBERT PRICE.
16	DR. PRICE: YES.
17	MS. KING: DAVID BRENNER.
18	DR. BRENNER: YES.
19	MS. KING: SUSAN BRYANT.
20	DR. BRYANT: YES.
21	MS. KING: LEEZA GIBBONS.
22	MS. GIBBONS: YES.
23	MS. KING: MICHAEL GOLDBERG.
24	MR. GOLDBERG: YES.
25	MS. KING: SAM HAWGOOD.
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	BARRISTERS REFORTING SERVICE
1	DR. HAWGOOD: YES.
2	MS. KING: BOB KLEIN.
3	CHAIRMAN KLEIN: YES.
4	MS. KING: SHERRY LANSING. TED LOVE.
5	DR. LOVE: YES.
6	MS. KING: SHLOMO MELMED.
7	DR. MELMED: YES.
8	MS. KING: PHIL PIZZO.
9	DR. PIZZO: YES.
10	MS. KING: CLAIRE POMEROY.
11	DR. POMEROY: YES.
12	MS. KING: FRANCISCO PRIETO.
13	DR. PRIETO: AYE.
14	MS. KING: ELIZABETH FINI.
15	DR. FINI: YES.
16	MS. KING: ROBERT QUINT.
17	DR. QUINT: YES.
18	MS. KING: JOHN REED.
19	DR. REED: YES.
20	MS. KING: DUANE ROTH.
21	MR. ROTH: YES.
22	MS. KING: JOAN SAMUELSON.
23	MS. SAMUELSON: YES.
24	MS. KING: DAVID SERRANO-SEWELL.
25	MR. SERRANO-SEWELL: YES.
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1	MS. KING: JEFF SHEEHY.
2	MR. SHEEHY: YES.
3	MS. KING: ART TORRES.
4	MR. TORRES: AYE.
5	MS. KING: JAMES ECONOMOU.
6	DR. ECONOMOU: YES.
7	MS. KING: AND THAT MOTION CARRIES FOR THE
8	RECORD.
9	CHAIRMAN KLEIN: I BELIEVE, MR. HARRISON,
10	THAT THAT COMPLETES THE ITEMS IN WHICH WE NEED A
11	QUORUM.
12	MR. HARRISON: IT DOES INDEED.
13	CHAIRMAN KLEIN: DR. PIZZO, WE HAVE TWO
14	MINUTES TO SPARE.
15	DR. PIZZO: THANK YOU.
16	MS. KING: DR. PRIETO, IF YOU NEED TO GO
17	AT THIS TIME, YOU CAN GO AS WELL, THOUGH IT SOUNDS
18	LIKE THERE MAY BE SOMETHING ELSE TO DISCUSS.
19	CHAIRMAN KLEIN: I'D LIKE TO GET DR.
20	ECONOMOU'S COMMENT, PLEASE.
21	DR. ECONOMOU: I'LL KEEP MY COMMENTS VERY
22	SHORT. I THINK THE CONCERN THAT I HAVE ABOUT THESE
23	EXTRAORDINARY PETITIONS IS THAT THE OVERSIGHT
24	COMMITTEE IS BEING ASKED TO LOOK AT THESE PETITIONS
25	AND TO REVIEW ASPECTS OF THE SCIENCE WHEN THEY
	91
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1	HAVEN'T ACTUALLY READ THE APPLICATION, NOR WHEN MOST
2	OF US ARE REALLY EVEN COMPETENT TO JUDGE THE
3	SCIENCE.
4	SO I THINK THE ONLY COMMENT THAT I'D MAKE
5	IS IT WOULD BE NICE IF THERE WERE SOME MECHANISM BY
6	WHICH BY THE WAY, WE DON'T HAVE AN NIH STUDY
7	SECTION MECHANISM, WHICH YOU CAN REVISE AN
8	APPLICATION AND SEND IT BACK IN AND HAVE IT GO BACK
9	TO THE SAME STUDY SECTION AND THEN HAVE THEM LOOK AT
10	A REVISED APPLICATION WHERE THERE MIGHT HAVE BEEN
11	THINGS THAT THEY HAD OVERLOOKED. IT WOULD BE NICE
12	IF THERE WERE SOME SORT OF MECHANISM TO WHICH
13	SPECIFIC SCIENTIFIC ISSUES IN WHICH THERE MIGHT BE A
14	DISAGREEMENT BETWEEN THE APPLICANT AND THE REVIEWERS
15	COULD BE REREVIEWED BEFORE IT'S PRESENTED TO THIS
16	COMMITTEE. AND THAT WAY WE DON'T HAVE TO BE PUT
17	INTO AN UNCOMFORTABLE SITUATION OF EVALUATING THE
18	SCIENCE AS OPPOSED TO THE IMPORTANCE OF THE RESEARCH
19	THEME IN THE CONTEXT OF CIRM. THAT'S THE ONLY
20	COMMENT THAT I'D LIKE TO MAKE.
21	CHAIRMAN KLEIN: DR. ECONOMOU, TO GO
22	DIRECTLY TO THAT ISSUE, THIS LAST MOTION ON ITEM 7
23	YOU ADOPTED PROVIDES FOR A BOARD OPTION TO REQUEST
24	ADDITIONAL ANALYSIS AND FOR A PROCESS WHERE WE CAN
25	HAVE A LIMITED RECONSIDERATION OF INFORMATION. SO

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1	HOPEFULLY THAT IS DIRECTLY IN LINE WITH YOUR
2	THINKING, AT LEAST AS AN EXPERIMENT.
3	SECONDLY, I WOULD SAY THAT HOPEFULLY ON
4	THE BOARD AND THE BOARD'S DESIGN IS INTENDED TO
5	ACHIEVE A SITUATION WHERE SOME MEMBERS OF THE BOARD
6	WILL HAVE DIRECT EXPERIENCE RELATED TO EACH
7	APPLICATION DIRECTLY OR INDIRECTLY; BUT GIVEN THE
8	BROAD LEVEL OF EXPERTISE ON THE BOARD AND THE
9	PROGRAMMATIC ISSUES THAT ARE UNDER CONSIDERATION, AS
10	DR. REED SAYS, WE HAVE A VERY IMPORTANT ROLE IN
11	STRATEGIC DISCUSSIONS WHICH WE ARE HIGHLY QUALIFIED
12	TO PARTICIPATE IN. BUT IN EXECUTIVE SESSION, WITH
13	THE BENEFIT OF SCIENTIFIC STAFF WHICH PARTICULARLY
14	STUDIES THESE ISSUES, WE HAVE THE ABILITY TO GET A
15	GROUP OF BOARD MEMBERS WITHOUT CONFLICTS TO REALLY
16	GET INTO THE PROPRIETARY INFORMATION. AND
17	CONSTITUTIONALLY THAT'S VERY IMPORTANT TO US SO THAT
18	WE CAN PRESENT PROPERLY THE CASE THAT WHEN THERE IS
19	A DISCUSSION THAT'S GOING TO DELVE DOWN TO THOSE
20	LEVELS, THAT WE, WITH SCIENTIFIC STAFF SUPPORT, CAN
21	APPROPRIATELY JUDGE THE MERIT BECAUSE WE HAVE TO BE
22	CHARGED WITH THE FINAL DECISIONS ON BOTH SCIENTIFIC
23	AND STRATEGIC OR PROGRAMMATIC GROUNDS.
24	BUT IN THIS PARTICULAR CASE AS A
25	TELECONFERENCE, WE WERE NOT ABLE TO GO INTO
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1	PROPRIETARY SESSION, WHICH ENCUMBERED OUR ABILITY TO
2	GET DOWN TO THE LEVEL OF SOME PROPRIETARY ISSUES AND
3	CONFLICTS. IN ANY CASE, WE CONTINUALLY STRIVE TO
4	IMPROVE THIS PROCESS. AND HOPEFULLY ITEM 7 WE
5	ADOPTED TODAY, AS YOU QUITE PROPERLY OR MAYBE
6	INTUITIVELY POINTED IN THAT DIRECTION, WILL HELP US
7	GET ADDITIONAL FEEDBACK WHEN IT'S NECESSARY.
8	DR. ECONOMOU: I'M IN COMPLETE AGREEMENT.
9	I JUST WANTED TO SINCE I SPOKE OUT AT THE WRONG
10	TIME, I JUST WANTED TO GET MY FULL COMMENT ON THE
11	RECORD EVEN THOUGH IT WAS MALPOSITIONED IN THE
12	AGENDA. THANK YOU.
13	CHAIRMAN KLEIN: WE THANK YOU SO MUCH.
14	MR. ROTH: I'D LIKE TO MAKE A SIMILAR
15	COMMENT, BUT MUCH BROADER. I THINK WE'VE BEEN AT
16	THIS NOW FIVE YEARS PLUS. AND I THINK IT'S TIME
17	THAT WE STEP BACK AND HAVE A CAREFUL REVIEW OF HOW
18	WE FORMULATE OUR REVIEW PROCESS. I THINK WE SHOULD
19	BRING SOME OUTSIDE EXPERTS IN AND HAVE A COMMITTEE,
20	THE APPROPRIATE COMMITTEE, REALLY STAND BACK AND SAY
21	WHAT'S WORKING AND WHAT ISN'T BECAUSE I THINK
22	THERE'S SOME THINGS THAT I DON'T UNDERSTAND HOW
23	WE GET THEM TO THE BOARD AND HOW WE GO INTO, QUOTE,
24	PRESENTATIONS NOW FROM CERTAIN PEOPLE WHO, YOU KNOW,
25	WANT THEIR GRANT FUNDED. AND THOSE SORT OF THINGS,

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1	IN ADDITION TO THE POINTS THAT HAVE BEEN MADE BY THE
2	PATIENT ADVOCATES ABOUT HOW WE COMMUNICATE THAT, ALL
3	OF THOSE SHOULD BE RELOOKED. AND IT SHOULD BE DONE
4	IN A COMPREHENSIVE WAY SO THAT WE KEEP THE INTEGRITY
5	OF THIS PROCESS. IT IS CORE TO WHAT WE DO.
6	CHAIRMAN KLEIN: I HEARTILY AGREE WITH
7	YOU, DUANE. AND HOPEFULLY ON THE 8TH WHEN WE HAVE
8	THE STRATEGIC SCIENTIFIC PLAN REVIEW, WE'LL GET SOME
9	COMMENTS THAT WILL GO TO THE GENERAL SCOPE OF WHAT
10	IS WORKING, WHAT NEW CHANGES WE CAN MAKE TO IMPROVE
11	THE PROCESS. BUT I THINK THE SCIENTIFIC COMMITTEE
12	IS GOING TO HAVE TO HAVE SOME VIBRANT DISCUSSIONS ON
13	THIS TOPIC AS WE CONTINUE TO TRY AND IMPROVE. AND I
14	KNOW THAT YOU WILL BE A VERY ACTIVE PARTICIPANT IN
15	THAT PROCESS, SO I'M GOING TO LOOK FORWARD TO THAT
16	DISCUSSION.
17	UNFORTUNATELY I WON'T GET TO PARTICIPATE
18	IN ALL THOSE DISCUSSIONS, BUT I WANT TO SAY THAT THE
19	STATE LAW, OF COURSE, MAKES CERTAIN REQUIREMENTS OF
20	US IN TERMS OF WHAT OUR OPTIONS ARE AND EMPOWERS
21	THIS BOARD, BUT ALSO PUTS A GREAT DEAL OF
22	RESPONSIBILITY ON THIS BOARD TO MAKE DECISIONS
23	REPRESENTING THE SEVEN MILLION VOTERS AND EVERYONE
24	ELSE IN CALIFORNIA THAT WE HAVE A BOLD EXPERIMENT
25	HERE THAT HAS PRODUCED A LOT OF GREAT SCIENTIFIC

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1	DECISIONS, BUT WE PROBABLY IN THE COURSE OF THIS
2	PROCESS MAKE SOME THAT DON'T COME OUT AS WELL. AND
3	I APPLAUD YOUR DIRECTION TO US TO COMMIT OURSELVES
4	TO A FORMAL PROCESS HERE TO IMPROVE IT.
5	SO IS THERE ANY OTHER BOARD COMMENTS THAT
6	WOULD LIKE TO BE MADE?
7	MS. SAMUELSON: NOT TO BELABOR THAT ISSUE,
8	BUT I THINK IT'S MORE IMPORTANT THAT WE ADDRESS
9	THIS. I'M GLAD WE'RE GOING TO SEND SOME OF THESE
10	BACK TO THE SCIENTIFIC COMMITTEE. I THINK SOME SORT
11	OF EXTERNAL REVIEW, AS DUANE IS SAYING, IS
12	NECESSARY.
13	AND I AGREE. WE'VE BEEN HEARING
14	REPEATEDLY ABOUT IN THE EXTRAORDINARY PETITION
15	PROCESS THAT I DON'T DISAGREE WITH THAT. I AGREE
16	WITH A LOT OF IT.
17	CHAIRMAN KLEIN: SO I'D LIKE TO JUST
18	REMIND EVERYONE, AND MAYBE MR. HARRISON CAN ALSO
19	COMMENT, EVERY APPLICANT UNDER STATE LAW HAS THE
20	RIGHT TO COME TO THIS BOARD. WE'VE TRIED TO CREATE
21	A PROCESS THAT MAKES IT A MORE ORDERLY PROCESS WHERE
22	WE CAN GET ENOUGH LEAD-TIME TO HAVE A GOOD
23	SCIENTIFIC INPUT FROM OUR SCIENTIFIC STAFF. AND
24	THAT PROCESS HOPEFULLY COMMUNICATES VERY CLEARLY
25	THAT IF PEOPLE DON'T PERFORM WITHIN THE TIME LIMITS,

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1	THEY SIGNIFICANTLY REDUCE THEIR OPPORTUNITY FOR
2	APPROVAL. BUT IF WE DIDN'T HAVE AN EXTRAORDINARY
3	PETITION PROCESS, PEOPLE COULD STILL MAKE A
4	PRESENTATION.
5	SO WITHIN STATE LAW, WE'RE TRYING TO
6	CREATE A PROCESS THAT HAS INTEGRITY AND ADDRESSES
7	GIVING US AN OPPORTUNITY TO REVIEW THE SCIENCE WHERE
8	AN ISSUE CAN ARISE AND PROVIDES AN OPPORTUNITY FOR
9	AN APPLICANT TO SUBMIT ADDITIONAL INFORMATION, BUT
10	WE CERTAINLY NEED A VIGOROUS REVIEW OF THIS.
11	MR. HARRISON, IS THAT A CORRECT STATEMENT,
12	THAT THERE'S A LEGAL RIGHT UNDER CALIFORNIA LAW FOR
13	THESE APPLICANTS TO APPEAR AND MAKE A PUBLIC
14	COMMENT?
15	MR. HARRISON: YES, THAT'S RIGHT.
16	CHAIRMAN KLEIN: ALL RIGHT. SO ANY
17	ADDITIONAL BOARD COMMENT?
18	DR. PRIETO: WE'RE NOT VOTING ON ANYTHING
19	ELSE NOW, ARE WE?
20	CHAIRMAN KLEIN: MR. HARRISON, MY
21	UNDERSTANDING IS WE'VE COVERED EVERYTHING THAT NEEDS
22	A VOTE.
23	MR. HARRISON: THAT'S RIGHT. WE'VE
24	COMPLETED ALL OUR AGENDA ITEMS.
25	CHAIRMAN KLEIN: WHAT I WOULD LIKE TO DO
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0 7	01:08 P.M.)
5 6	THE MEETING AND THANK EVERYONE. (THE MEETING WAS THEN CONCLUDED AT
4	NO ADDITIONAL PUBLIC COMMENT, I'D LIKE TO ADJOURN THE MEETING AND THANK EVERYONE.
3	TO WELCOME ANY ADDITIONAL PUBLIC COMMENT. HEARING
2	AND, DR. PRIETO, WE RECOGNIZE THAT YOU ARE, I'D LIKE
1	FOR THOSE THAT CAN STAY AND ARE NOT BOUND BY TIME,
-	

1-800-622-6092 1-714-444-4100 EMAIL: DEPO@DEPO1.COM

REPORTER'S CERTIFICATE

I, BETH C. DRAIN, A CERTIFIED SHORTHAND REPORTER IN AND FOR THE STATE OF CALIFORNIA, HEREBY CERTIFY THAT THE FOREGOING TRANSCRIPT OF THE TELEPHONIC PROCEEDINGS BEFORE THE INDEPENDENT CITIZEN'S OVERSIGHT COMMITTEE OF THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE IN THE MATTER OF ITS REGULAR MEETING HELD ON THURSDAY, NOVEMBER 11, 2010, WAS HELD AS HEREIN APPEARS AND THAT THIS IS THE ORIGINAL TRANSCRIPT THEREOF AND THAT THE STATEMENTS THAT APPEAR IN THIS TRANSCRIPT WERE REPORTED STENOGRAPHICALLY BY ME AND TRANSCRIBED BY ME. I ALSO CERTIFY THAT THIS TRANSCRIPT IS A TRUE AND ACCURATE RECORD OF THE PROCEEDING.

BETH C. DRAIN, CSR 7152 BARRISTER'S REPORTING SERVICE 1072 BRISTOL STREET SUITE 100 COSTA MESA, CALIFORNIA (714) 444-4100